APPENDIX 3 – FULL PUBMED RETRIEVAL

Table 3A-1 – All Records in Pubmed Retrieval

(Note: Each row of the table contains a separate record, consisting of a Title and Abstract (if an Abstract exists). The title is separated from the Abstract by nine spaces).

Effects of a SARS-associated coronavirus vaccine in monkeys. The causative agent of severe acute respiratory syndrome (SARS) has been identified as a new type of coronavirus. Here, we have investigated the ability of adenoviral delivery of codon-optimised SARS-CoV strain Urbani structural antigens spike protein S1 fragment, membrane protein, and nucleocapsid protein to induce virus-specific broad immunity in rhesus macaques. We immunised rhesus macaques intramuscularly with a combination of the three Ad5-SARS-CoV vectors or a control vector and gave a booster vaccination on day 28. The vaccinated animals all had antibody responses against spike protein S1 fragment and T-cell responses against the nucleocapsid protein. All vaccinated animals showed strong neutralising antibody responses to SARS-CoV infection in vitro. These results show that an adenoviral-based vaccine can induce strong SARS-CoV-specific immune responses in the monkey, and hold promise for development of a protective vaccine against the SARS causal agent.
Vasculitis-Like Hemorrhagic Herpes Zoster and HIV Infections: An Intricate Association. Herein, we report the case of a 69-year-old patient who presented to our dermatology clinic for a skin eruption characterized by grouped hemorrhagic vesicles and erosions covered by hemorrhagic crusts on an erythematous background located on the lower right limb. The lesions were small, clustered, and variable in size (diameters between one and 10 mm) and located at the level of the L4-L5 dermatomes. The rash had started three to five days after the complete COVID-19 vaccination scheme with the BNT162b2 Pfizer BioNTech vaccine and had been accompanied by a flu-like syndrome. The histopathological examination established the diagnosis of leukocytoclastic vasculitis potentially in the context of a cytopathic zoster phenomenon. The atypical aspect of the zosterian eruption required additional laboratory work-up to identify possible causes of immunosuppression, i.e., screening for the presence of the human immunodeficiency virus (HIV) infection, solid cancers, as well as measurement of serum immunoglobulin concentrations, which revealed that the subject was HIV-positive. Antiviral treatment was started, with a favorable evolution of the lesions, and the patient was referred to an infectious diseases clinic for initiation of antiretroviral therapy (ART).
Pain associated with COVID-19 vaccination is unrelated to skin biopsy abnormalities. INTRODUCTION: Previous clinical observations raised the possibility that COVID-19 vaccination might trigger a small-fibre neuropathy. OBJECTIVES: In this uncontrolled observational study, we aimed to identify small fibre damage in patients complaining of generalized sensory symptoms and pain after COVID-19 vaccination. METHODS: We collected clinical data, including a questionnaire for assessing autonomic symptoms (Composite Autonomic Symptom Score-31), and investigated quantitative sensory testing (QST) and skin biopsy in 15 prospectively enrolled patients with generalized sensory symptoms and pain after COVID-19 vaccination. Nine patients complaining of orthostatic intolerance also underwent cardiovascular autonomic tests. RESULTS: We found that all patients experienced widespread pain, and most of them (11 of 15) had a fibromyalgia syndrome. All patients had normal skin biopsy findings, and in the 9 patients with orthostatic intolerance, cardiovascular autonomic tests showed normal findings. Nevertheless, 5 patients had cold and warm detection abnormalities at the QST investigation. CONCLUSIONS: In our study, most patients complaining of generalized sensory symptoms and pain after COVID-19 vaccination had clinical and diagnostic test findings compatible with a fibromyalgia syndrome. Although the abnormal QST findings we found in 5 patients might be compatible with a small-fibre neuropathy, they should be cautiously interpreted given the

psychophysical characteristics of this diagnostic test. Further larger controlled studies are needed to define precisely the association between small fibre damage and COVID-19 vaccination.

Pityriasis Rosea and Pityriasis Rosea-Like Eruption Following COVID-19 Vaccination: A Narrative Review. COVID-19 pandemic completely changed every aspect of human life. Several measures were adopted to limit the spreading of the infection. Among these, vaccination was the main one. Globally, vaccination campaign was a success, showing to be efficient in controlling and preventing the SARS-Cov2 infection, reducing the risk of disease progression, hospitalization, and mortality. However, with the increasing number of vaccines administered, several cutaneous reactions were described, making dermatologists key players in their recognition and treatment. Among these, also viral reactivations have been described. In particular, cases of Pityriasis Rosea (PR) and PR-like reactivations have been collected. An early diagnosis is mandatory to avoid mistreatments. In this context, we conducted a review of the current literature investigating cases of PR following COVID-19 vaccination with the aim of understanding the possible pathogenetic mechanisms and causal correlation as well as to investigate the risk of this cutaneous eruption, to offer clinicians a wide perspective on the linkage between PR and COVID-19 vaccines.

Spontaneous spinal epidural haematoma following COVID-19 vaccination: a case report. INTRODUCTION: COVID-19 vaccination side effects are rare but important medical situations. Spine-affecting side effects are amongst the rarest, but exceedingly important. Haemorrhagic spinal manifestations of COVID-19 and its vaccines are less reported with little knowledge about them. CASE PRESENTATION: An 80-year-old male who received his first shot of the COVID-19 vaccine had developed COVID-19 pneumonia, weakness, and sensory problems in his legs followed by sphincter incontinence within 5 days period. MRI showed a spontaneous epidural spinal epidural haematoma (SSEDH) in T10-L1. He underwent laminectomy and haematoma evacuation. One month follow-up showed no clinical improvement. DISCUSSION: To our knowledge, this was the first post-vaccination SSEDH and second in haemorrhagic spinal complications following COVID-19 vaccination. Considering the neuropathogenesis pathway of COVID-19 and its vaccines, there are common mechanisms of action that could potentially justify post-vaccination SSEDH such as seen in COVID-19 infection, itself. Early Neurosurgical intervention and better preoperative neurological status could be a beneficial modifier for favourable clinical outcomes. CONCLUSION: SSEDH and COVID-19 vaccine coincidence is a rare clinical event, still no solid association could be scientifically explained. Further studies are required for a reliable pathophysiologic association. Early diagnosis, interdisciplinary medical approach, and faster intervention are the cornerstone of the treatment paradigm.

Alarming Rise in Global Rabies Cases Calls for Urgent Attention: Current Vaccination Status and Suggested Key Countermeasures. In the wake of rising rabies cases worldwide, especially after the COVID-19 pandemic, it is time to understand the scenario better and suggest technically sound and plausible countermeasures. This article is an attempt at this perspective. Although a critical zoonotic viral disease, rabies is preventable. Medico-legally, the ailment is classified as furious rabies and paralytic rabies. The four world bodies, namely, the World Health Organisation (WHO), the Food and Agriculture Organisation (FAO), the World Organisation for Animal Health (OIE), and the Global Alliance for Rabies Control (GARC) endorsed framing a global support system to eradicate human death from dog-mediated rabies under the 'Zero by 30' framework. The framework calls for extending the vaccination of dogs to reduce the risk of human rabies. Stray dogs became aggressive primarily due to their food shortage during the pandemic lockdown. As many adopted stray dogs were disowned post-pandemic, decreased human-dog interactions increased the aggressiveness among dogs. As a result, 'dog-bite' cases rose, with a sudden spike in rabies cases and dog-bite-induced deaths in India and elsewhere. Jeopardising the 'Zero by 30' plan is certainly a public health concern. Stray dog sterilisation through the irreversible ductal occlusion technique and reversible

inhibition of sperm under guidance (RISUG) are other suggested interventions to control rabies. Importantly, wildlife like foxes, raccoons, skunks, and bats could also be rabid. Three out of the four WHO-pre-qualified human vaccines against rabies are intradermally administered as post-exposure prophylaxis, while the intramuscular one is more popular. Even though 'Zero by 30' may not be achieved within the set timeframe, it is time for a concerted and planned strategy by global agencies to curb the globally rising rabies cases and manage the disease better. The 'One Health' model seems to be a plausible guideline and the ultimate countermeasure to achieve this.

Autopsy findings in cases of fatal COVID-19 vaccine-induced myocarditis. COVID-19 vaccines have been linked to myocarditis, which, in some circumstances, can be fatal. This systematic review aims to investigate potential causal links between COVID-19 vaccines and death from myocarditis using post-mortem analysis. We performed a systematic review of all published autopsy reports involving COVID-19 vaccination-induced myocarditis through 3 July 2023. All autopsy studies that include COVID-19 vaccine-induced myocarditis as a possible cause of death were included. Causality in each case was assessed by three independent physicians with cardiac pathology experience and expertise. We initially identified 1691 studies and, after screening for our inclusion criteria, included 14 papers that contained 28 autopsy cases. The cardiovascular system was the only organ system affected in 26 cases. In two cases, myocarditis was characterized as a consequence from multisystem inflammatory syndrome. The mean age of death was 44.4Â years old. The mean and median number of days from last COVID-19 vaccination until death were 6.2 and 3Â days, respectively. We established that all 28 deaths were most likely causally linked to COVID-19 vaccination by independent review of the clinical information presented in each paper. The temporal relationship, internal and external consistency seen among cases in this review with known COVID-19 vaccine-induced myocarditis, its pathobiological mechanisms, and related excess death, complemented with autopsy confirmation, independent adjudication, and application of the Bradford Hill criteria to the overall epidemiology of vaccine myocarditis, suggests that there is a high likelihood of a causal link between COVID-19 vaccines and death from myocarditis.

Abnormal Uterine Bleeding Diagnoses and Care following COVID-19 Vaccination. BACKGROUND: There is evidence suggesting that COVID-19 vaccination may be associated with small, transitory effects on uterine bleeding, possibly including menstrual timing, flow, and duration, in some individuals. However, changes in health care seeking, diagnosis, and workup for abnormal uterine bleeding in the COVID-19 vaccine era are less clear. OBJECTIVES: To assess the impact of COVID-19 vaccination on incident abnormal uterine bleeding diagnosis and diagnostic evaluation in a large integrated health system. STUDY DESIGN: Using segmented regression, we assessed whether the availability of COVID-19 vaccines was associated with changes in monthly, population-based rates of incident abnormal uterine bleeding diagnoses compared to the pre-pandemic period in health system members ages 16-44 years who were not menopausal. We also compared clinical and demographic characteristics of patients diagnosed with incident abnormal uterine bleeding between December 2020 through October 13, 2021 by vaccination status (never vaccinated, vaccinated in the 60 days prior to diagnosis, vaccinated more than 60 days prior to diagnosis) and conducted detailed chart review of patients diagnosed with abnormal uterine bleeding within 1-60 days of COVID-19 vaccination in the same time period. RESULTS: In monthly populations ranging from 79,000 to 85,000 female health system members, incidence of abnormal uterine bleeding diagnosis per 100,000 person-days ranged from 8.97 to 19.19. There was no significant change in the level or trend in the incidence of abnormal uterine bleeding diagnoses between the pre-pandemic (January 2019-January 2020) and post-COVID-19 vaccine (December 2020-December 2021) periods. A comparison of clinical characteristics of 2,717 abnormal uterine bleeding cases by vaccination status suggested that abnormal bleeding among recently vaccinated patients was similar or less severe than abnormal

bleeding among patients who had never been vaccinated patients or those vaccinated more than 60 days prior. There were also significant differences in age and race of patients with incident abnormal uterine bleeding diagnoses by vaccination status: never vaccinated patients were the youngest and those vaccinated more than 60 days prior were the oldest; the proportion of patients who were Black/African American was highest among never vaccinated patients, and the proportion of Asian patients was higher among vaccinated patients. Chart review of 114 confirmed post-vaccination abnormal uterine bleeding cases diagnosed from December 2020 through October 13, 2021 found that the most common symptoms reported were changes in timing, duration, and volume of bleeding. Approximately one-third of cases received no diagnostic workup; 57% had no etiology for the bleeding documented in the electronic health record. In 12% of cases, the patient mentioned or asked about a possible link between their bleeding and their recent COVID-19 vaccine. CONCLUSIONS: The availability of COVID-19 vaccination was not associated with a change in incidence of medically attended abnormal uterine bleeding in our population of over 79,000 female patients of reproductive age. Additionally, among 2,717 patients with abnormal uterine bleeding diagnoses in the period following COVID-19 vaccine availability, receipt of the vaccine was not associated with greater bleeding severity.

Heterologous COVID-19 vaccines intervention effect on reactogenicity. To determine the change in the occurrence of short-term vaccine reactions on the use of heterologous Covid-19 booster, a single centre short-term study of two months duration was conducted. It was designed as an interventional study with registered clinical trial number # SLCTR/2022/008. It was conducted on medical students and faculty of a National university of medical sciences, Rawalpindi affiliated public sector medical college. A total of 348 individuals were administered with Ad5-nCoV vaccine and 101 with mRNA-1273 vaccine. They all had been previously vaccinated with two doses of BBIBP-CorV. BBIBP-CorV reactogenicity was considered a control group. Vaccine reactions, including pain and redness at the injection site, fever, no observed reactions at all, myalgia, feeling cold, dizziness, paraesthesia in the arm, lightheadedness, had a significant change in their frequencies in comparison to homologous vaccine (BBIBP-CorV) reactogenicity. It was concluded that mixing and matching of COVID-19 vaccines result in an increase in frequency of post-vaccine short-term reactions.

De novo pemphigus vulgaris and pemphigus foliaceus development following COVID-19 infection and vaccination: Matched case-control study.

Determination of the factors associated with antigen-specific CD4+ T-cell responses to BNT162b2 in patients with rheumatoid arthritis. OBJECTIVES: Understanding interpatient variation in CD4+T-cell responses is the bases for understanding the pathogenesis and management of rheumatoid arthritis (RA). We examined immune responses to SARS-CoV-2 vaccine in a cohort of patients with RA and determined factors associated with the responses. METHODS: Four hundred and thirty-one patients with RA having received two doses of BNT162b2, a messenger RNA-based vaccine for SARS-CoV-2, were included. Vaccine antigen-specific IgG was detected by ELISA, and antigen-specific CD4+T cells were detected by CD154 expression in response to antigenic stimulation. Expression of cytokines was concomitantly detected by intracellular staining. Associations among background variables, antigen-specific antibody production and the CD4+T-cell responses were analysed. Unsupervised hierarchical clustering was performed based on the profiles of antigen-specific cytokine production by CD4+T cells to stratify patients with RA. RESULTS: Multivariate analysis indicated that ageing negatively affects CD4+T-cell response as well as antibody production. No association was detected between the presence or the levels of rheumatoid factor/anti-cyclic citrullinated peptide antibody and anti-vaccine immune responses. Methotrexate and prednisolone reduced B cell but not T-cell responses. Conventional immunophenotyping by the expression of chemokine receptors was not associated with the actual CD4+T-cell response, except for T helper cells (Th1). Functional

immunophenotyping based on the profiles of antigen-specific cytokine production of CD4+T cells stratified patients with RA into three clusters, among which Th1-dominant type less frequently underwent joint surgery. CONCLUSIONS: Clinical and immunological variables that are associated with antigen-specific CD4 T-cell responses in patients with RA were determined by analysing immune responses against SARS-CoV-2 vaccine.

Sweet syndrome following the ChAdOx1-S vaccine. We report a case of vaccine-induced Sweet syndrome in a female patient in her 50s presenting with fevers and a scattered red patchy rash on the lower limbs. Seven days prior, she had received the first dose of AstraZeneca ChAdOx1-S vaccine. A skin biopsy confirmed Sweet syndrome. She did not respond to high doses of prednisolone and required methotrexate therapy to induce remission. This is one of the first reports of Sweet syndrome caused by the ChAdOx1-S vaccine and provides further evidence for vaccine-induced dermatosis. This case demonstrates that methotrexate can induce remission in cases of Sweet syndrome resistant to corticosteroids. This report also describes an approach to the differential diagnosis of patients presenting with a rash, fever and malaise.

Delivering COVID-19 vaccine trials at speed: the implementation of a phase IV UK multi-centre randomised controlled trial to determine safety and immunogenicity of COVID-19 vaccines co-administered with seasonal influenza vaccines (ComFluCOV). BACKGROUND: In February 2021, the UK Department of Health and Social Care sought evidence on the safety and immunogenicity of COVID-19 and influenza vaccine co-administration to inform the 2021/2022 influenza vaccine policy. Co-administration could support vaccine uptake and reduce healthcare appointments. ComFluCOV was a randomised controlled trial designed to provide this evidence. This report outlines the methods used to deliver the trial in 6 months to answer an urgent public health question as part of the COVID-19 pandemic response. METHODS: ComFluCOV was commissioned by the Department of Health and Social Care and was managed by the Bristol Trials Centre, a UK-registered clinical trials unit. It was classed as an Urgent Public Health trial which facilitated fast-track regulatory approvals. Trial materials and databases were developed using in-house templates and those used in other COVID-19 vaccine trials. Participants were recruited by advertising, and via a trial website. Electronic trial systems enabled daily review of participant data. Weekly virtual meetings were held with stakeholders and trial sites. RESULTS: ComFluCOV was delivered within 6 months from inception to reporting, and trial milestones to inform the Department of Health and Social Care policy were met. Set-up was achieved within 1 month. Regulators provided expedited reviews, with feedback ahead of submission. Recruitment took place at 12 sites. Over 380 site staff were trained. Overall, 679 participants were recruited in two months. The final report to the Department of Health and Social Care was submitted in September 2021, following a preliminary safety report in May 2021. Trial results have been published. CONCLUSION: The rapid delivery of ComFluCOV was resource intensive. It was made possible in part due to a unique set of circumstances created by the pandemic situation including measures put in place to support urgent public health research and public support for COVID-19 vaccine research. Elements of the trial could be adopted to increase efficiency in 'non-pandemic' situations including working with a clinical trials unit to enable immediate mobilisation of a team of experienced researchers, greater sharing of resources between clinical trials units, use of electronic trial systems and virtual meetings. TRIAL REGISTRATION: ISRCTN14391248, submitted on 17/03/2021. Registered on 30/03/2021.

Autoimmune disorders reported following COVID-19 vaccination: A disproportionality analysis using the WHO database. PURPOSE: Owing to adverse event following immunization (AEFI) related to autoimmune disorders and coronavirus disease 2019 (COVID-19) vaccines sharing common biological mechanisms, identifying the risk of AEFIs associated with COVID-19 vaccines remains a critical unmet need. We aimed to assess the potential safety signals for 16 AEFIs and explore co-reported adverse

events (AEs) and drugs using the global database of the World Health Organization, VigiBase. METHODS: We assessed the occurrence of 16 AEFIs following COVID-19 vaccination through the Standardized MedDRA Queries group "Immune-mediated/Autoimmune Disorders" from MedDRA and performed a disproportionality analysis using reporting odds ratio (ROR) and information component (IC) with 95% confidence intervals (CIs). RESULTS: We identified 25,219 events associated with COVID-19 vaccines in VigiBase. Although rare, we detected four potential safety signals related to autoimmune disorders following COVID-19 vaccination, including ankylosing spondylitis or psoriatic arthritis (ROR 1.86; 95% CI 1.53-2.27), inflammatory bowel disease (ROR 1.77; 95% CI 1.60-1.96), polymyalgia rheumatica (ROR 1.42; 95% CI 1.30-1.55), and thyroiditis (ROR 1.40; 95% CI 1.30-1.50), with positive IC(025) values. The top co-reported AEs were musculoskeletal disorders, and immunosuppressants were the most representative co-reported drugs. CONCLUSION: In addressing the imperative to comprehend AEFI related to autoimmune disorders following COVID-19 vaccination, our study identified four potential safety signals. Thus, our research underscores the importance of proactive safety monitoring for the identification of the four AEFIs following COVID-19 vaccination, considering the associated advantages.

Immune responses following BNT162b2 XBB.1.5 vaccination in patients on haemodialysis in Germany.

The association between COVID-19 vaccination and confirmed patients with hospitalization in Omicron era: A retrospective study. With the emergence of Omicron variant of severe acute respiratory syndrome coronavirus 2, Taiwan has encountered the greatest coronavirus disease 2019 (COVID-19) pandemic since 2022 spring. We analyzed the characteristics, vaccinations, and outcomes of hospitalized COVID-19 patients quarantined in a dedicated ward. This retrospective study enrolled hospitalized COVID-19 patients in the dedicated wards of a district hospital in southern Taiwan from May 2022 to July 2022. We assessed in-hospital mortality, hospital length of stay (LOS), and dedicated ward LOS. Among 209 COVID-19 patients, the in-hospital mortality rates were 20.7% and 29.7% (Pâ€…=â€….145) in patients with and without vaccination. A shorter dedicated ward LOS was noted in the vaccination group, with marginal statistical significance. Age, Charlson Comorbidity Index, and quick Sequential Organ Failure Assessment score were recognized as strong prognostic indicators for mortality in multivariable analysis. Vaccination demonstrated significant lower odds of death among relatively young populations in subgroup analysis. COVID-19 vaccination had significant efficacy in hospitalized COVID-19 patients in the relatively young group, and the effect may decline among individuals with advanced age and multiple comorbidities.

SCB-2019 protein vaccine as heterologous booster of neutralizing activity against SARS-CoV-2 Omicron variants after immunization with other COVID-19 vaccines. We assessed the non-inferiority of homologous boosting compared with heterologous boosting with the recombinant protein vaccine, SCB-2019, in adults previously immunized with different COVID-19 vaccines. Three equal cohorts (Nâ€‰~â€‰420) of Philippino adults (18-80â€‰years) previously immunized with Comirnaty, CoronaVac or Vaxzevria COVID-19 vaccines were randomized 1:1 to receive homologous or heterologous (SCB-2019) boosters. Neutralizing antibodies against prototype SARS-CoV-2 (Wuhan-Hu-1) were measured in all participants and against Delta variant and Omicron sub-lineages in subsets (30â€’50 per arm) 15â€‰days after boosting. Participants recorded solicited adverse events for 7â€‰days and unsolicited and serious adverse events until Day 60. Prototype SARS-CoV-2 neutralizing responses on Day 15 after SCB-2019 were statistically non-inferior to homologous Vaxzevria boosters, superior to CoronaVac, but lower than homologous Comirnaty. Neutralizing responses against Delta and Omicron BA.1, BA.2, BA.4 and BA.5 variants after heterologous SCB-2019 were higher than homologous CoronaVac or Vaxzevria, but lower than homologous Comirnaty. Responses against Omicron BF.7, BQ.1.1.3, and XBB1.5 following heterologous SCB-2019 were lower than after homologous Comirnaty booster but significantly higher than after Vaxzevria booster. SCB-

2019 reactogenicity was similar to CoronaVac or Vaxzevria, but lower than Comirnaty; most frequent events were mild/moderate injection site pain, headache and fatigue. No vaccine-related serious adverse events were reported. Heterologous SCB-2019 boosting was well tolerated and elicited neutralizing responses against all tested SARS-COV-2 viruses including Omicron BA.1, BA.2, BA.4, BA.5, BF.7, BQ.1.1.3, and XBB1.5 sub-lineages that were non-inferior to homologous boosting with CoronaVac or Vaxzevria, but not homologous Comirnaty booster.

Association of respiratory infections and the impact of vaccinations on cardiovascular diseases. Influenza, pneumococcal, SARS-CoV2 and RSV infections are important causes of high morbidity and mortality in the elderly. Beyond the burden of infectious diseases, they are also associated with several non-infectious complications like cardiovascular events. A growing body of evidence in prospective studies and meta-analyses has shown the impact of influenza and pneumococcal vaccines on types of cardiovascular outcomes in the general population. Influenza vaccination showed a potential benefit for primary and secondary prevention of cardiovascular diseases across all ages. A reduced risk of cardiovascular events for individuals aged 65 years and older was associated with pneumococcal vaccination. Despite scientific evidence on the effectiveness, safety, and benefits of the vaccines and recommendations to vaccinate elderly patients and those with risk factors, vaccination rates remain sub-optimal in this population. Doubts about vaccine necessity or efficacy and concerns about possible adverse events in patients and physicians refers to delayed acceptance. Vaccination campaigns targeting increasing professional recommendations and public perceptions should be implemented in the coming years. The aim of this review paper is to summarize the effect of vaccination in the field of cardiovascular disease to achieve a higher vaccination rate in this patient population.

A Systematic Review of COVID-19 Vaccine-Induced Takotsubo Cardiomyopathy: A 2023 Update. Takotsubo cardiomyopathy (TCM) is a life-threatening transient left ventricular dysfunction triggered by either physical or emotional stressors. Concerns have been raised on reports of TCM after the coronavirus disease 2019 (COVID-19) vaccine. Our study provides comprehensive detail on COVID-19 vaccine-induced TCM. We conducted a systemic literature search using major databases, including PubMed, EMBASE, and Google Scholar up to November 2023, to identify cases of COVID-19 vaccine-induced TCM using the MeSH terms and keywordsÂ "covid-19 vaccines" and "takotsubo cardiomyopathy". We identified 15 case reports, including 16 patients with COVID-19 vaccine-induced TCM. The mean age was 55.81 Â± 19.13 years, and 75% of the patients were female. The most common presentation was chest pain (62.5%), and the average time to first symptom onset was 3.12 Â± 2.24 days. COVID-19 vaccine-induced TCM was reported in 43.75% of patients receiving the first and second dose each, and 87% of patients had messenger ribonucleic acid (mRNA) COVID-19 vaccine (Pfizer, Moderna). The elevated level of cardiac troponins was found in all the patients with a left ventricular ejection fraction (LVEF) of <50% in 15 patients, and T-wave inversion (50%) was the most common electrocardiographic finding. The mean length of the hospital stay was 7.27 Â± 3.95 days, and 87% of patients were discharged. COVID-19 vaccine-induced TCM is a rare but life-threatening complication. TCM should be included in the differential diagnosis of chest pain or dyspnea in patients recently receiving the COVID-19 vaccine.

Ventricular fibrillation and ventricular tachycardia post-SARS-CoV-2-targeted mRNA/viral vector vaccination.

Superior mesenteric vein thrombosis due to COVID-19 vaccination: a case report. BACKGROUND: The worldwide vaccination response to COVID-19 has been associated with rare thrombotic complications, including the case of postvaccination splanchnic venous thrombosis we report here. CASE PRESENTATION: An 80-year-old Japanese male with abdominal pain presented to our hospital six days after receiving a dose of the COVID-19 messenger ribonucleic acid vaccine. Abdominal

computed tomography showed localized edema of the small intestine, increased density of the surrounding adipose tissue, and a thrombus in the superior mesenteric vein. Conservative inpatient treatment with unfractionated heparin relieved the thrombosis, and the patient is currently receiving oral apixaban as an outpatient. CONCLUSION: Reported cases of thrombosis after COVID-19 vaccination typically have been associated with viral vector vaccines, with few reports of thrombosis induced by mRNA vaccines. The potential for venous thrombosis should be explored when patients present with abdominal pain soon after COVID-19 vaccination.

Prospective monitoring of adverse events following vaccination with Modified vaccinia Ankara - Bavarian Nordic (MVA-BN) administered to a Canadian population at risk of Mpox: A Canadian Immunization Research Network study. MVA-BN is an orthopoxvirus vaccine that provides protection against both smallpox and mpox. In June 2022, Canada launched a publicly-funded vaccination campaign to offer MVA-BN to at-risk populations including men who have sex with men (MSM) and sex workers. The safety of MVA-BN has not been assessed in this context. To address this, the Canadian National Vaccine Safety Network (CANVAS) conducted prospective safety surveillance during public health vaccination campaigns in Toronto, Ontario and in Vancouver, British Columbia. Vaccinated participants received a survey 7 and 30Â days after each MVA-BN dose to elicit adverse health events. Unvaccinated individuals from a concurrent vaccine safety project evaluating COVID-19 vaccine safety were used as controls. Vaccinated and unvaccinated participants that reported a medically attended visit on their 7-day survey were interviewed. Vaccinated participants and unvaccinated controls were matched 1:1 based on age group, gender, sex and provincial study site. Overall, 1,173 vaccinated participants completed a 7-day survey, of whom 75Â % (nÂ =Â 878) also completed a 30-day survey. Mild to moderate injection site pain was reported by 60Â % of vaccinated participants. Among vaccinated participants 8.4Â % were HIV positive and when compared to HIV negative vaccinated individuals, local injection sites were less frequent in those with HIV (48Â % vs 61Â %, pÂ =Â 0.021), but health events preventing work/school or requiring medical assessment were more frequent (7.1Â % vs 3.1Â %, pÂ =Â 0.040). Health events interfering with work/school, or requiring medical assessment were less common in the vaccinated group than controls (3.3Â % vs. 7.1Â %, pÂ <Â 0.010). No participants were hospitalized within 7 or 30Â days of vaccination. No cases of severe neurological disease, skin disease, or myocarditis were identified. Our results demonstrate that the MVA-BN vaccine appears safe when used for mpox prevention, with a low frequency of severe adverse events and no hospitalizations observed.

Immunomodulators and risk for breakthrough COVID-19 after third SARS-CoV-2 mRNA vaccine among patients with rheumatoid arthritis: a cohort study.

Prenatal Exposure to COVID-19 mRNA Vaccine BNT162b2 Induces Autism-Like Behaviors in Male Neonatal Rats: Insights into WNT and BDNF Signaling Perturbations. The COVID-19 pandemic catalyzed the swift development and distribution of mRNA vaccines, including BNT162b2, to address the disease. Concerns have arisen about the potential neurodevelopmental implications of these vaccines, especially in susceptible groups such as pregnant women and their offspring. This study aimed to investigate the gene expression of WNT, brain-derived neurotrophic factor (BDNF) levels, specific cytokines, m-TOR expression, neuropathology, and autism-related neurobehavioral outcomes in a rat model. Pregnant rats received the COVID-19 mRNA BNT162b2 vaccine during gestation. Subsequent evaluations on male and female offspring included autism-like behaviors, neuronal counts, and motor performance. Molecular techniques were applied to quantify WNT and m-TOR gene expressions, BDNF levels, and specific cytokines in brain tissue samples. The findings were then contextualized within the extant literature to identify potential mechanisms. Our findings reveal that the mRNA BNT162b2 vaccine significantly alters WNT gene expression and BDNF levels in both male and female rats, suggesting a profound impact on key neurodevelopmental pathways. Notably, male

rats exhibited pronounced autism-like behaviors, characterized by a marked reduction in social interaction and repetitive patterns of behavior. Furthermore, there was a substantial decrease in neuronal counts in critical brain regions, indicating potential neurodegeneration or altered neurodevelopment. Male rats also demonstrated impaired motor performance, evidenced by reduced coordination and agility. Our research provides insights into the effects of the COVID-19 mRNA BNT162b2 vaccine on WNT gene expression, BDNF levels, and certain neurodevelopmental markers in a rat model. More extensive studies are needed to confirm these observations in humans and to explore the exact mechanisms. A comprehensive understanding of the risks and rewards of COVID-19 vaccination, especially during pregnancy, remains essential.

Ipsilateral immunization after a prior SARS-CoV-2 mRNA vaccination elicits superior B cell responses compared to contralateral immunization. mRNA vaccines have proven to be pivotal in the fight against COVID-19. A recommended booster, given 3 to 4Â weeks post the initial vaccination, can substantially amplify protective antibody levels. Here, we show that, compared to contralateral boost, ipsilateral boost of the SARS-CoV-2 mRNA vaccine induces more germinal center B cells (GCBCs) specific to the receptor binding domain (RBD) and generates more bone marrow plasma cells. Ipsilateral boost can more rapidly generate high-affinity RBD-specific antibodies with improved cross-reactivity to the Omicron variant. Mechanistically, the ipsilateral boost promotes the positive selection and plasma cell differentiation of pre-existing GCBCs from the prior vaccination, associated with the expansion of T follicular helper cells. Furthermore, we show that ipsilateral immunization with an unrelated antigen after a prior mRNA vaccination enhances the germinal center and antibody responses to the new antigen compared to contralateral immunization. These findings propose feasible approaches to optimize vaccine effectiveness.

Association between COVID-19 vaccines and development of chronic morbidities: a cross-sectional study in the Jordanian population. BACKGROUND: In Jordan, individuals recently diagnosed with chronic illnesses have expressed concerns with regard to COVID-19 vaccines. This study aims to investigate potential associations between COVID-19 vaccination and the likelihood of recipients developing chronic conditions such as autoimmune diseases, rheumatoid arthritis, diabetes, asthma, and hypertension. METHODOLOGY: Through a cross-sectional survey-based descriptive approach, this research was conducted to gather data within the Jordanian context. A web-based survey was utilized to collect demographic information, record vaccine-related side effects, and document the chronic disease status subsequent to COVID-19 vaccination. Statistical analysis was employed to reveal any potential associations between the vaccine, its side effects, and the emergence of chronic morbidities. RESULTS: The study involved 414 participants, among whom 10.4% exhibited pre-existing chronic diseases before vaccination. Remarkably, post-vaccination, 23.7% of participants were newly diagnosed with chronic illnesses. Statistical analysis indicated a significant correlation between COVID-19 vaccination and the subsequent development of chronic diseases (p-value Ë, 0.01). the investigation found no significant association between vaccination and the emergence of diabetes, hypertension, or asthma (p-value â‰¥0.01) However, an association was found between COVID-19 vaccination and the development of autoimmune diseases and rheumatoid arthritis (p-value Ë, 0.01). CONCLUSIONS: This study highlights an association between the occurrence of autoimmune diseases and COVID-19 vaccination, while findings related to diabetes, asthma, and hypertension did not display significant associations. The results emphasize the necessity for further research to ascertain potential causal relationship.

 COVID-19 vaccine was the rescue management offered during after the pandemic times, however many patients complained from post-COVID vaccine side effects. Those side effects were either of a short term or long term ones. People in Jordan are worried about the association of COVID-19 vaccine and the occurrence of chronic morbidities just after vaccination. Therefore our study aimed to investigate any possible association of COVID-19 vaccines

and increased tendency of chronic morbidities. In our research we chose most common encountered post COVID-19 vaccine chronic diseases in clinical practice in Jordan; Diabetes, hypertension, asthma, rheumatoid arthritis and autoimmune diseases. The study participants (Nâ€‰=â€‰414) were people in Jordan more than 18 years old and got vaccinated during the past three year 2020-2023.From our study we found that vaccinated participants suffered from many short term side effects, of which the most common were general fatigue and insomnia followed by headache and fever. As for the long term side effects of the COVID-19 vaccine we figured out an increase in the incidence of chronic morbidities in general post COVID-19 vaccine and an association between the occurrence of autoimmune diseases and rheumatoid arthritis and COVID-19 vaccine. Therefore we concluded an important association between COVID-19 vaccine and autoimmune diseases that should be taken into consideration in clinical practice or for future investigations.

Safety of COVID-19 Vaccination During Pregnancy and Lactation: A VigiBase Analysis. BACKGROUND: There is limited evidence on the safety of coronavirus disease 2019 (COVID-19) vaccination during pregnancy and lactation. Thus, we aimed to evaluate the association between COVID-19 vaccination during pregnancy and lactation and reporting risk of adverse pregnancy or lactation outcomes. METHODS: Using VigiBase, we performed a disproportionality analysis with case/non case design. Cases were defined based on the Standardized MedDRA Queries (SMQs) of "pregnancy and neonatal topics" and non-cases were defined as all other adverse events. We included all reports with COVID-19 vaccines as the suspected cause. Using the full database as the comparators, reporting odds ratios (RORs) with 95% confidence intervals (CIs) were estimated by logistic regression while adjusting for maternal age. Infants' age and sex were additionally adjusted in analyzing the risk of COVID-19 vaccination during lactation. RESULTS: We identified 10,266 and 6,474 reports with the SMQ of "pregnancy and neonatal topics" associated with COVID-19 vaccines during pregnancy and lactation, respectively. No significant RORs of adverse pregnancy outcomes associated with COVID-19 vaccines during pregnancy were observed; however, "functional lactation disorders" showed significant disproportionality during lactation with adjusted ROR of 1.48 (95% CI, 1.21-1.79). Further analysis that analyzed "functional lactation disorders" at a preferred term level, showed higher ROR in mastitis (2.76 [95% CI, 1.45-5.27]). CONCLUSION: Overall, we did not observe a positive association between COVID-19 vaccination during pregnancy and risk of reporting adverse pregnancy outcomes. However, we found a significant disproportionate reporting association between COVID-19 vaccination during lactation and "functional lactation disorders", specifically mastitis. Continuous surveillance is warranted to confirm the safety of COVID-19 vaccine during pregnancy and lactation.

Pediatric humoral immune responses and infection risk after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and two-dose vaccination during SARS-CoV-2 omicron BA.5 and BN.1 variants predominance in South Korea. BACKGROUND: Humoral immune responses and infection risk after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and coronavirus disease 2019 (COVID-19) vaccination during the Omicron BA.5 and BN.1 variants predominant period remains unexplored in pediatric population. METHODS: We examined anti-spike (anti-S) immunoglobulin G (IgG) responses in a total of 986 children aged 4-18 years who visited outpatient clinics between June 2022 and January 2023, with a history of SARS-CoV-2 infection alone, completed two doses of COVID-19 vaccination alone, vaccine-breakthrough infection (i.e., infection after the single dose of vaccination), and no antigenic exposure. Furthermore, to determine SARS-CoV-2 infection risk, the incidence of newly developed SARS-CoV-2 infection was investigated up to March 2023. RESULTS: The anti-S IgG levels in the 'vaccine-breakthrough infection' group exceeded those in the 'infection alone' and 'vaccination alone' groups (both P <0.01). Furthermore, the 'vaccination alone' group experienced more rapid anti-S IgG waning than the 'infection alone' and 'vaccine-breakthrough infection' groups (both P <0.01). We could not identify newly developed SARS-

CoV-2 infection in the 'vaccine-breakthrough infection' group. CONCLUSION: Our findings suggest that hybrid immunity, acquired from SARS-CoV-2 infection and COVID-19 vaccination, was a potentially higher and longer-lasting humoral immune response and protected against SARS-CoV-2 infection in pediatric population during Omicron BA.5 and BN.1 variants predominant.

Vaccine-induced immune thrombotic thrombocytopenia post COVID-19 booster vaccination in Brazil: a case series. BACKGROUND: The emergence of new variants of SARS-CoV-2 has led to the administration of different booster vaccines to mitigate COVID-19. Vaccines with adenoviral vectors have been rarely associated with vaccine-induced immune thrombotic thrombocytopenia (VITT). OBJECTIVES: This study aimed to describe 15 cases of VITT after the third and fourth doses of the COVID-19 vaccine in Brazil. METHODS: Cases were reported after all kinds of anti-SARS-CoV-2 booster vaccinations between October 17, 2021, and September 4,Â 2022. RESULTS: Of the 26 suspected cases, 15 cases of VITT were analyzed. Of these, 10 were classified as definite VITT, 2 as probable, 1 as possible, and 2 as unlikely. The estimated frequency of definite, probable, or possible VITT was 0.33 cases per million. Cases were assigned to ChAdOx1 (13 cases), Ad26.COV2.S (1 case), and BNT162b2 (1 case). None of the patients received an adenoviral vaccine as a primary vaccination. The average age of participants was 34 years, and symptoms usually appeared 8 days after vaccination. Headache was the most common symptom, and cerebral veins were the most affected thrombotic site. The overall mortality risk was 53%. Anti-plateletÂ factor 4 enzyme-linked immunosorbent assay serology was positive in 11 out of 15 patients (73.3%), negative in 2 (13.3%), and missing in 2 (13.3%). CONCLUSION: The study confirms that VITT is linked to the first exposure to adenoviral vector vaccines. Since January 2023, Brazil has recommended preferably COVID-19 messenger RNA vaccines for individuals aged 18 to 39 years. We suggest that, in the current disease scenario, COVID-19 adenovirus vaccines should not be the first choice for individuals aged <50 years who have not received a previous dose of this type of vaccine.

Breakthrough infections after COVID-19 vaccinations do not elicit platelet hyperactivation and are associated with high platelet-lymphocyte and low platelet-neutrophil aggregates. BACKGROUND: Severe COVID-19 is associated with an excessive immunothrombotic response and thromboinflammatory complications. Vaccinations effectively reduce the risk of severe clinical outcomes in patients with COVID-19, but their impact on platelet activation and immunothrombosis during breakthrough infections is not known. OBJECTIVES: To investigate how preemptive vaccinations modify the platelet-immune crosstalk during COVID-19 infections. METHODS: Cross-sectional flow cytometry study of the phenotype and interactions of platelets circulating in vaccinated (nÂ = 21) and unvaccinated patients with COVID-19, either admitted to the intensive care unit (ICU, nÂ = 36) or not (non-ICU, nÂ = 38), in comparison to matched SARS-CoV-2-negative patients (nÂ = 48), was performed. RESULTS: In the circulation of unvaccinated non-ICU patients with COVID-19, we detected hyperactive and hyperresponsive platelets and platelet aggregates with adaptive and innate immune cells. In unvaccinated ICU patients with COVID-19, most of whom had severe acute respiratory distress syndrome, platelets had high P-selectin and phosphatidylserine exposure but low capacity to activate integrin Î±IIbÎ²3, dysfunctional mitochondria, and reduced surface glycoproteins. In addition, in the circulation of ICU patients, we detected microthrombi and platelet aggregates with innate, but not with adaptive, immune cells. In vaccinated patients with COVID-19, who had no acute respiratory distress syndrome, platelets had surface receptor levels comparable to those in controls and did not form microthrombi or platelet-granulocyte aggregates but aggregated avidly with adaptive immune cells. CONCLUSION: Our study provides evidence that vaccinated patients with COVID-19 are not associated with platelet hyperactivation and are characterized by platelet-leukocyte aggregates that foster immune protection but not excessive immunothrombosis. These findings advocate for the importance of vaccination in preventing severe COVID-19.

COVID-19 Vaccination and Abnormal Blood Glucose Level.

Association of clinical characteristics and vaccines with risk of persistently viral clearance in patients infected with SARS-CoV-2 Omicron variant in Shanghai, China. IMPORTANCE: The global COVID-19 pandemic does not appear to end in the near future. Currently, limited data are available on the risk factors for delayed viral clearance in patients with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron variant infection. OBJECTIVE: This study aimed to investigate the association of clinical characteristics and vaccination with prolonged viral clearance. METHODS: This retrospective cohort included 16,985 patients who had contracted the SARS-CoV-2 Omicron variant between April 5 and May 30, 2022, in Shanghai, China, and had mild or no symptoms. The patients were admitted to the quarantine venue at the Shanghai New International Expo Center. RESULTS: Of the 16,985 participants, the occurrence of viral clearance was â‰¤8 andÂ >Â 8 days in 11,009 (64.8Â %) and 5976 (35.2Â %) participants, respectively. Risk factors related to patients who remained persistently polymerase chain reaction (PCR)-positive were sex (Male, odds ratio [OR] 1.221, pÂ <Â 0.001), older age (35-49, OR 1.389, pÂ <Â 0.001; 50-64, OR 1.659, pÂ <Â 0.001; â‰¥65, OR 2.139, pÂ <Â 0.001), presence of symptoms (OR 1.093, pÂ =Â 0.030), number of vaccinations (two doses, OR 0.753, pÂ <Â 0.001; three doses, OR 0.797, pÂ <Â 0.001; four doses, OR 0.543, pÂ <Â 0.001), and cycle threshold (Ct) value for ORF1ab gene at diagnosis (25-35, OR 0.235, pÂ <Â 0.001; >35, OR 0.079, pÂ <Â 0.001). The lower rates of increase in Ct values were observed in the later viral shedding group than in the early viral shedding group for ORF1ab (Î²Â =Â -0.791, pÂ <Â 0.001) and N genes (Î²Â =Â -0.825, pÂ <Â 0.001). CONCLUSION: Prolonged SARS-CoV-2 RNA detection and higher viral concentrations were associated with factors such as male sex, older age, symptomatic status, and fewer doses of vaccination in patients admitted to Shanghai Makeshift Hospital between April 5 and May 30, 2022.

Adverse reactions to cosmetic implants after COVID-19 vaccination: Correspondence.

Characteristics of long COVID and the impact of COVID-19 vaccination on long COVID 2 years following COVID-19 infection: prospective cohort study. This prospective cohort study aimed to identify characteristics of long COVID and any potential mitigating effects of COVID-19 vaccinations in patients 24Â months following COVID-19 infection. Adult patients diagnosed with COVID-19 between February 17, 2020, and March 24, 2020, were scheduled to visit the study hospital four times (6, 12, 18, and 24Â months after infection) to assess their symptoms, quality of life, and mental health. Among the 235 patients, 121 (51.5%) completed the study visits. Of these, 59.5% were female, with a median age of 52Â years. Mild to moderate disease severity were identified in 101 (83.4%)Â patients. A total of 75 participants (62.0%) were still experiencing long COVID symptoms 24Â months after acute infection. Fatigue, amnesia, difficulty concentrating, and insomnia were the most common symptoms. The frequency of neuropsychiatric symptoms did not differ based on vaccination status or the number of doses received. Quality of life improved over time for the participants, but 32.2% of respondents still reported anxiety/depression at the end of the study. Overall, our cohort demonstrates that long COVID can persist up to 24Â months after COVID-19 infection, affecting mental health and quality of life.

Risk of disease flares after SARS-CoV-2 mRNA vaccination in patients with systemic lupus erythematosus. This study aims to elucidate the effectiveness and safety of SARS-CoV-2 mRNA vaccination in patients with systemic lupus erythematosus (SLE). We enrolled uninfected SLE patients who received two vaccine doses (BNT162b2 or mRNA-1273) and historical unvaccinated patients. Neutralizing antibodies, adverse reactions, and disease flares were evaluated 4â€‰weeks after the second vaccination. Ninety patients were enrolled in each group. Among the vaccinated patients, SLE Disease Activity Index (SLEDAI), and prednisolone doses before vaccination were 2, and 5â€‰mg/d, respectively. After the second vaccination, 19 (21.1%) had no neutralizing antibodies. Adverse

reactions occurred in 88.9% within 3â€‰d. Negative antibodies were associated with anemia and mycophenolate mofetil administration. SLEDAI increased modestly but significantly after vaccination, with 13 (14.4%) experiencing flares and 4 (4.4%) severe flares (nephritis in three and vasculitis in one). The flare rate was higher in vaccinated patients than unvaccinated controls. The mean duration between the second vaccination and flares was 35â€‰d, and flares occurred at least 8â€‰days after vaccination. Multivariable analysis showed that high SLEDAI and anti-dsDNA antibodies were associated with flares. The vaccine type, neutralizing antibody titer, and adverse reaction frequency did not affect flares. Therefore, residual disease activity before vaccination increases flare risk.

Recurrent SARS-CoV-2 mutations at Spike D796 evade antibodies from pre-Omicron convalescent and vaccinated subjects. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has evolved substantially through the coronavirus disease 2019 (COVID-19) pandemic: understanding the drivers and consequences of this evolution is essential for projecting the course of the pandemic and developing new countermeasures. Here, we study the immunological effects of a particular mutation present in the Spike protein of all Omicron strains and find that it prevents the efficient binding of a class of antibodies raised by pre-Omicron vaccination and infection. These findings reveal a novel consequence of a poorly understood Omicron mutation and shed light on the drivers and effects of SARS-CoV-2 evolution.

Herpes Zoster after COVID-19 Infection or Vaccination: A Prospective Cohort Study in a Tertiary Dermatology Clinic. BACKGROUND: Herpes zoster (HZ) has been observed to occur after COVID-19 infection and vaccination; however, knowledge regarding the demographic data, clinical presentations, and treatment outcomes of HZ is limited. OBJECTIVE: To compare the demographic data, clinical manifestations, treatments, and outcomes of patients with and without HZ within 14â€‰days of COVID-19 infection or vaccination. METHODS: This prospective cohort study involving patients diagnosed with cutaneous HZ was conducted at a dermatology clinic from October 2021 to January 2023. RESULTS: Among a total of 232 patients with HZ, the median age was 62.0â€‰years and 59.1% were female. HZ developed in 23 (9.9%) and four (1.7%) patients after COVID-19 vaccination and infection, respectively. The mean duration from vaccination and the median duration from infection to HZ onset were 5.7 and 8.5â€‰days, respectively. The proportion of female patients was significantly higher in the group of patients with COVID-19 vaccination or infection than in those without such a history (Pâ€‰=â€‰0.035). Patients who developed HZ following the recent COVID-19 infection had a median age of 42.5â€‰years, which was lower than that of the other groups. Dissemination occurred in 8.7% of the patients after COVID-19 vaccination. HZ recurrence was reported in five cases, of which 80% had been vaccinated or infected with COVID-19 during the previous 21â€‰days. All patients had similar durations of antiviral treatment, crust-off time, and duration of neuralgia. CONCLUSIONS: HZ after COVID-19 vaccination is more frequently observed in females, while HZ after COVID-19 infection tends to occur in younger patients. Disseminated HZ is more common in patients recently vaccinated against COVID-19. COVID-19 vaccination or infection may trigger recurrent HZ infection.

Insufficient anti-spike RBD IgA responses after triple vaccination with intramuscular mRNA BNT162b2 vaccine against SARS-CoV-2. OBJECTIVES: This study aims to examine whether the parenterally administered mRNA-based COVID-19 vaccines can induce sufficient mucosal-type IgA responses to prevent SARS-CoV-2 transmission. METHODS: We examined the longitudinal kinetics of SARS-CoV-2 spike RBD-specific IgA and IgG responses in sera of Japanese healthcare workers (HCWs) after receiving two doses and the third dose of BNT162b2 mRNA vaccines. During the prospective cohort study, Omicron breakthrough infections occurred in 62 participants among 370 HCWs who had received triple doses of the vaccine. Pre-breakthrough sera of infected HCWs and non-infected HCWs were examined for the levels of anti-RBD IgA and IgG titers. RESULTS: The seropositivity of anti-RBD

IgA at 1Â M after the second vaccine (2D-1M) and after the third dose (3D-1M) was 65.4% and 87.4%, respectively, and wanes quickly. The boosting effect on anti-RBD Ab titers following breakthrough infections was more notable for anti-RBD IgA than for IgG. There were partial cause-relationships between the lower anti-RBD IgA or IgG at pre-breakthrough sera and the breakthrough infection. CONCLUSIONS: Parenterally administered COVID-19 vaccines do not generate sufficient mucosal-type IgA responses despite strong systemic IgG responses to SARS-CoV-2. These results demonstrate the necessity and importance of reevaluating vaccine design and scheduling to efficiently increase oral or respiratory mucosal immunity against SARS-CoV-2.

Lipid nanoparticle-encapsulated DNA vaccine robustly induce superior immune responses to the mRNA vaccine in Syrian hamsters. DNA vaccines for infectious diseases and cancer have been explored for years. To date, only one DNA vaccine (ZyCoV-D) has been authorized for emergency use in India. DNA vaccines are inexpensive and long-term thermostable, however, limited by the low efficiency of intracellular delivery. The recent success of mRNA/lipid nanoparticle (LNP) technology in the coronavirus disease 2019 (COVID-19) pandemic has opened a new application for nucleic acid-based vaccines. Here, we report that plasmid encoding a trimeric spike protein with LNP delivery (pTS/LNP), similar to those in Moderna's COVID-19 vaccine, induced more effective humoral responses than naked pTS or pTS delivered via electroporation. Compared with TSmRNA/LNP, pTS/LNP immunization induced a comparable level of neutralizing antibody titers and significant T helper 1-biased immunity in mice; it also prolonged the maintenance of higher antigen-specific IgG and neutralizing antibody titers in hamsters. Importantly, pTS/LNP immunization exhibits enhanced cross-neutralizing activity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants and protects hamsters from the challenge of SARS-CoV-2 (Wuhan strain and the Omicron BA.1 variant). This study indicates that pDNA/LNPs as a promising platform could be a next-generation vaccine technology.

Radial nerve motor palsy after COVID vaccination: A case report. Vaccinations are one of the most effective ways in primary prevention of infectious diseases. Due to the SARS-CoV-2 vaccination, an extensive public discussion considering possible side effects has been started. In this report, we present a patient with a radial nerve motor palsy after a vaccination with tozinameran (ComirnatyÂ®).

Prevalence and determinants of adverse events following ChAdOx1 nCoV-19 vaccination (COVISHIELD) - A retrospective cohort study among healthcare workers in central Karnataka, India. BACKGROUND: India has launched COVID vaccination program on January 16, 2021 and precautionary dose (third dose) on January 10, 2022. Our study evaluated adverse events following immunization (AEFI) among healthcare workers (HCWs) following first, second, and precautionary dose of ChAdOx1 nCoV-19 (COVISHIELD) vaccine. We also evaluated the association of AEFI with the study participants' characteristics. OBJECTIVES: (1) To assess the adverse events among HCWs following first, second, and precautionary dose of COVISHIELD vaccine. (2) To determine the factors associated with adverse events of COVISHIELD vaccine. MATERIALS AND METHODS: A retrospective cohort study was conducted among HCWs of a tertiary care teaching hospital in central Karnataka from January 2021 to June 2022. A semi-structured, pretested questionnaire was used to interview the HCW of tertiary care teaching hospital regarding adverse events following first, second, and precautionary dose of COVISHIELD vaccine; data collected was entered in MS Excel 2019 and analyzed using SPSS v24.0. RESULTS: Among 454 participants majority of them were females (231, 50.88%) and in the age group 18-27 years (151, 33.25%), and the majority were nursing staff (147, 32.37%). Adverse events were reported among 204 (44.93%) following the first dose, 149 (32.81%) after the second dose, and 230 (50.66%) participants following the precautionary dose. Generalized weakness and fever were the common adverse effects reported by participants. CONCLUSION: Majority of the study population did not report any adverse events following vaccination. Among the study

participants who reported adverse events, most events were reported on the same day. Symptoms were mild in severity and short-lived.

Assessing Menstrual Changes Among Young Indian Females Post-SARS-CoV-2 Vaccination. Background The rollout of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines has significantly enhanced immunity against coronavirus disease 2019 (COVID-19), leading to a reduction in the severity of illness, hospitalizations, and deaths. While various side effects of the vaccine have been reported, its impact on the menstrual cycle remains unclear. Methods We conducted a cross-sectional study involving university students who had received either partial or full vaccination against SARS-CoV-2. Data was gathered through a questionnaire designed to assess the relationship between menstrual changes and the SARS-CoV-2 vaccination. Results A total of 773 participants, with a mean age of 20.6 Â± 1.7 years, were included in this study. The participants reported a significant increase in the irregularity of the menstrual cycle. We observed a slight increase in the length of the menstrual cycle, from 30.0 Â± 4.0 days (pre-vaccination) to 30.5 Â± 5.6 days (post-vaccination), which was statistically significant ($p<0.001$). The duration of menstruation also increased, from 4.9 Â± 1.7 days (pre-vaccination) to 5.0 Â± 1.7 days (post-vaccination). However, this increase in menstrual length due to vaccination was not statistically significant ($p = 0.898$). Notably, there was a significant increase in pain reported by the participants after receiving the SARS-CoV-2 vaccine ($p = 0.004$). Conclusion The SARS-CoV-2 vaccination significantly impacted the regularity of the menstrual cycle, length of the menstrual cycle, and pain during menstruation, though temporarily. Our study found no significant differences in menstrual changes or the type of vaccine administered (Covishield and Covaxin).

Durability of humoral and cellular immunity six months after the BNT162b2 bivalent booster. Studies about the duration of the humoral and cellular response following the bivalent booster administration are still scarce. We aimed at assessing the humoral and cellular response in a cohort of healthcare workers that received this booster. Blood samples were collected before the administration of the bivalent booster from Pfizer-BioNTech and after 14, 28, 90, and 180 days. Neutralizing antibodies against either the D614G strain, the delta variant, the BA.5 variant, or the XBB.1.5 subvariant were measured. The cellular response was assessed by measurement of the release of interferon gamma from T cells in response to an in vitro SARS-CoV-2 stimulation. A substantial waning of neutralizing antibodies was observed after 6 months (23.1-fold decrease), especially considering the XBB.1.5 subvariant. The estimated T(1/2) of neutralizing antibodies was 16.1 days (95% Clâ€‰=â€‰10.2-38.4 days). Although most participants still present a robust cellular response after 6 months (i.e., 95%), a significant decrease was also observed compared to the peak response (0.95 vs. 0.41 UI/L, pâ€‰=â€‰0.0083). A significant waning of the humoral and cellular response was observed after 6 months. These data can also help competent national authorities in their recommendation regarding the administration of an additional booster.

Drug- or Vaccine-Induced/Aggravated Psoriatic Arthritis: A Systematic Review. INTRODUCTION: Drugs and vaccines have been less studied as inducing or aggravating factors for psoriatic arthritis (PsA) compared with psoriasis. Thus, the present study collected and summarized the publications to date about this issue. METHODS: We conducted a systematic literature search through the PubMed, Embase, and Cochrane databases to identify all reports on potential drug- and vaccine-related PsA events until 28 February 2023. RESULTS: In total, 179 cases from 79 studies were eligible for study. Drugs commonly reported include coronavirus disease 2019 (COVID-19) mRNA vaccines (6 cases), bacillus Calmette-Guerin (BCG) vaccine (3 cases), interferon (18 cases), immune-checkpoint inhibitors (ICI) (19 cases), and biologic disease-modifying antirheumatic drugs (bDMARDs) (127 cases). Drugs causing psoriasis may also induce or aggravate PsA (6 cases). BDMARD-related PsA mostly occurred in a "paradoxical" setting, in which the bDMARDs approved for the treatment of psoriasis induce or

aggravate PsA. The reported latency may be delayed up to 2Â years. Peripheral arthritis (82.3%) was the most common manifestation of drug- and vaccine-related PsA, followed by dactylitis (29.1%), enthesitis (23.4%), and spondyloarthritis (17.7%). CONCLUSIONS: Drugs and vaccines may be implicated in the aggravation of PsA. Possible mechanisms include cytokine imbalance, immune dysregulation, or inadequate PsA treatment response compared with psoriasis. Most reports are case based without controls, so more studies are needed to further prove the causality. However, early recognition of factors causing or aggravating PsA is important to prevent the irreversible joint damage.

Severity of COVID-19 Pneumonia in Kidney Transplant Recipients According to SARS-CoV-2 Vaccination. We reviewed 24 kidney transplantat recipients (KTRs) who had radiologically confirmed coronavirus disease 2019 (COVID-19) pneumonia. Enrolled KTRs were divided into a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-vaccination (+) group (n = 18) and a vaccination (-) group (n = 6). Clinical outcomes of the two groups including death, pulmonary outcome, and renal outcome were compared. COVID-19 pneumonia was worse in vaccination (-) KTRs. Two out of six vaccination (-) KTRs needed continuous renal replacement therapy (CRRT) and mechanical ventilator (MV) and expired. In contrast, only one KTR expired and required CRRT and MV out of 18 vaccination (+) KTRs. Our results suggest that SARS-CoV-2 vaccination attenuates severity of COVID-19 pneumonia in KTRs.

Public's perspective on COVID-19 adenovirus vector vaccines after thrombosis with thrombocytopenia syndrome (TTS) reports and associated regulatory actions - A cross-sectional study in six EU member states. OBJECTIVE: In 2021, thrombosis with thrombocytopenia syndrome (TTS) was confirmed by the European Medicines Agency (EMA) as a rare side effect of the COVID-19 adenovirus vector vaccines VaxzevriaÂ® and JcovdenÂ®. This study aimed to describe the public's knowledge of TTS and how it affected the willingness to be vaccinated with COVID-19 vaccines and other vaccines in six European countries. METHODS: From June to October of 2022, a multi-country cross-sectional online survey was conducted in Denmark, Greece, Latvia, Netherlands, Portugal, and Slovenia. The minimum target of participants to be recruited was based on the size of the country's population. The results were analysed descriptively. RESULTS: In total, 3794 respondents were included in the analysis; across the six countries, 33.3Â %-68.3Â % reported being familiar with signs and symptoms of TTS, although 3.1-61.4Â % of those were able to identify the symptoms correctly. The reported changes in willingness to be vaccinated against COVID-19 and with other vaccines varied per country. The largest reported change in the willingness to be vaccinated with VaxzevriaÂ® and JcovdenÂ® was observed in Denmark (61.2Â %), while the willingness to be vaccinated with other COVID-19 vaccines changed most in Slovenia (30.4Â %). The smallest decrease in willingness towards future vaccination against COVID-19 was reported in the Netherlands (20.9Â %) contrasting with the largest decrease observed in Latvia (69.1Â %). CONCLUSION: Knowledge about TTS seemed to have influenced the public's opinion in Europe resulting in less willingness to be vaccinated with VaxzevriaÂ® and JcovdenÂ®. Willingness for vaccination against COVID-19 with other vaccines and widespread use of vaccines to prevent other diseases also differed and seemed to be determined by the approaches taken by national health authorities when reacting to and communicating about COVID-19 vaccination risks. Further investigation of optimal risk communication strategies is warranted.

Reported side-effects following Oxford/AstraZeneca COVID-19 vaccine in the north-west province, Iran: A cross-sectional study. While the vaccination was introduced as a promising tool to control the Coronavirus disease 2019 (COVID-19) pandemic, concerns about vaccine-related side effects had grown. Due to the widespread administration of the COVID-19 vaccine worldwide for the first time, it was necessary to evaluate the safety and potential side effects in recipients. This study aims to assess,

the incidence of adverse effects following Oxford-AstraZeneca vaccination and identify their related factors. In this cross-sectional survey-based study, 453 volunteers participated, including 235 men and 218 women. The reported adverse reactions from recipients of the ChAdOx1 nCoV-19 (Oxford-AstraZeneca) vaccine were collected by using a questionnaire. The findings showed that the incidence of adverse reactions, such as neurological, systematic, gastrointestinal, respiratory, and local symptoms were significantly higher after the first dose compared to the second dose. Systematic symptoms were the most prevalent reported side effects after the first and second dose injection. The demographical study of participants showed that individuals aged 18-34 and females were more prone to present adverse events following vaccination. However, no significant relationship was found between the occurrence of side effects and the recipients' body mass index. Despite the life-saving role of vaccination against SARS-CoV-2, it may have some adverse reactions in recipients. The severity and frequency of side effects were different. So, they were dependent on several factors, including gender and age. Altogether, post-vaccination adverse reactions were mild and tolerable.

Acute exacerbation of idiopathic pulmonary fibrosis after bivalent {tozinameran and famtozinameran} mRNA COVID-19 vaccination. An 82-year-old man diagnosed with interstitial lung disease through computed tomography (CT) 1 year prior received a bivalent (tozinameran and famtozinameran) mRNA COVID-19 vaccine. He developed respiratory symptoms 1.5 months later, and chest high-resolution CT revealed new ground-glass opacities showing traction bronchiectasis. Transbronchial lung cryobiopsy revealed organizing acute lung injury and fibrosis with architectural destruction. The patient was diagnosed with an acute exacerbation of idiopathic pulmonary fibrosis (AE-IPF). The bivalent mRNA COVID-19 vaccination was determined as the cause of the AE-IPF based on detailed medical history and examination findings. High-dose corticosteroid therapy improved the patient's symptoms and radiological findings.

A patient safety knowledge graph supporting vaccine product development. BACKGROUND: Knowledge graphs are well-suited for modeling complex, unstructured, and multi-source data and facilitating their analysis. During the COVID-19 pandemic, adverse event data were integrated into a knowledge graph to support vaccine safety surveillance and nimbly respond to urgent health authority questions. Here, we provide details of this post-marketing safety system using public data sources. In addition to challenges with varied data representations, adverse event reporting on the COVID-19 vaccines generated an unprecedented volume of data; an order of magnitude larger than adverse events for all previous vaccines. The Patient Safety Knowledge Graph (PSKG) is a robust data store to accommodate the volume of adverse event data and harmonize primary surveillance data sources. METHODS: We designed a semantic model to represent key safety concepts. We built an extract-transform-load (ETL) data pipeline to parse and import primary public data sources; align key elements such as vaccine names; integrated the Medical Dictionary for Regulatory Activities (MedDRA); and applied quality metrics. PSKG is deployed in a Neo4J graph database, and made available via a web interface and Application Programming Interfaces (APIs). RESULTS: We import and align adverse event data and vaccine exposure data from 250 countries on a weekly basis, producing a graph with 4,340,980 nodes and 30,544,475 edges as of July 1, 2022. PSKG is used for ad-hoc analyses and periodic reporting for several widely available COVID-19 vaccines. Analysis code using the knowledge graph is 80% shorter than an equivalent implementation written entirely in Python, and runs over 200 times faster. CONCLUSIONS: Organizing safety data into a concise model of nodes, properties, and edge relationships has greatly simplified analysis code by removing complex parsing and transformation algorithms from individual analyses and instead managing these centrally. The adoption of the knowledge graph transformed how the team answers key scientific and medical questions. Whereas previously an analysis would involve aggregating and transforming primary datasets from scratch to answer a specific question, the team can now iterate easily and respond as

quickly as requests evolve (e.g., "Produce vaccine-X safety profile for adverse event-Y by country instead of age-range").

mRNA vaccines against SARS-CoV-2 induce divergent antigen-specific T-cell responses in patients with lung cancer. BACKGROUND: The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron variant is highly transmissible and evades pre-established immunity. Messenger RNA (mRNA) vaccination against ancestral strain spike protein can induce intact T-cell immunity against the Omicron variant, but efficacy of booster vaccination in patients with late-stage lung cancer on immune-modulating agents including anti-programmed cell death protein 1(PD-1)/programmed death-ligand 1 (PD-L1) has not yet been elucidated. METHODS: We assessed T-cell responses using a modified activation-induced marker assay, coupled with high-dimension flow cytometry analyses. Peripheral blood mononuclear cells (PBMCs) were stimulated with various viral peptides and antigen-specific T-cell responses were evaluated using flow cytometry. RESULTS: Booster vaccines induced CD8(+) T-cell response against the ancestral SARS-CoV-2 strain and Omicron variant in both non-cancer subjects and patients with lung cancer, but only a marginal induction was detected for CD4(+) T cells. Importantly, antigen-specific T cells from patients with lung cancer showed distinct subpopulation dynamics with varying degrees of differentiation compared with non-cancer subjects, with evidence of dysfunction. Notably, female-biased T-cell responses were observed. CONCLUSION: We conclude that patients with lung cancer on immunotherapy show a substantial qualitative deviation from non-cancer subjects in their T-cell response to mRNA vaccines, highlighting the need for heightened protective measures for patients with cancer to minimize the risk of breakthrough infection with the Omicron and other future variants.

Postural orthostatic tachycardia syndrome after COVID-19 vaccination. BACKGROUND: There is an association between coronavirus disease 2019 (COVID-19) mRNA vaccination and the incidence or exacerbation of postural orthostatic tachycardia syndrome (POTS). OBJECTIVE: The purpose of this study was to characterize patients reporting new or exacerbated POTS after receiving the mRNA COVID-19 vaccine. METHODS: We prospectively collected data from sequential patients in a POTS clinic between July 2021 and June 2022 reporting new or exacerbated POTS symptoms after COVID-19 vaccination. Heart rate variability (HRV) and skin sympathetic nerve activity (SKNA) were compared against those of 24 healthy controls. RESULTS: Ten patients (6 women and 4 men; age 41.5 Â± 7.9 years) met inclusion criteria. Four patients had standing norepinephrine levels > 600 pg/mL. All patients had conditions that could raise POTS risk, including previous COVID-19 infection (N = 4), hypermobile Ehlers-Danlos syndrome (N = 6), mast cell activation syndrome (N = 6), and autoimmune (N = 7), cardiac (N = 7), neurological (N = 6), or gastrointestinal conditions (N = 4). HRV analysis indicated a lower ambulatory root mean square of successive differences (46.19 Â±24 ms; P = .042) vs control (72.49 Â± 40.8 ms). SKNA showed a reduced mean amplitude (0.97 Â± 0.052 Î¼V; P = .011) vs control (1.2 Â± 0.31 Î¼V) and burst amplitude (1.67 Â± 0.16 Î¼V; P = .018) vs control (4. 3 Â± 4.3 Î¼V). After 417.2 Â± 131.4 days of follow-up, all patients reported improvement with the usual POTS care, although 2 with COVID-19 reinfection and 1 with small fiber neuropathy did have relapses of POTS symptoms. CONCLUSION: All patients with postvaccination POTS had pre-existing conditions. There was no evidence of myocardial injuries or echocardiographic abnormalities. The decreased HRV suggests a sympathetic dominant state. Although all patients improved with guideline-directed care, there is a risk of relapse.

Increased breadth and neutralization of antibodies against SARS-CoV-2 variants after infection and vaccination: A serosurveillance study in pediatric patients of Southern Switzerland. Little information is available about the nature of the immune response in children after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection or vaccination. The aim of this study is to define the seroprevalence and the features of the antibody response in children of Southern

Switzerland during the different waves of Coronavirus Disease 2019 (COVID-19) pandemic.Â By analyzing 756 sera collected from children aged 0 to 16Â years admitted to the Institute of Pediatrics of Southern Switzerland during the prepandemic period (before March 2020) and the first four pandemic waves (between March 2020 and June 2022), we investigated binding titers, cross-reactivity, and neutralizing properties of the serum antibodies against SARS-CoV-2 variants.Â Seroprevalence varied from 6% during the first wave to 14% and 17% during the second and third waves, respectively, peaking at 39% during the fourth wave. The 96 seropositive cases were mostly asymptomatic (42.7%) or showed mild (20.8%) to moderate (32.3%) symptoms. Moderate symptoms and close contact with COVID-19-positive individuals were associated with a higher infection risk (Pâ€‰<â€‰0.001). The antibody response was mainly driven by IgG directed to the receptor-binding domain (RBD) of Wuhan-1 SARS-CoV-2 Spike (S). Children infected in the first three waves produced antibodies with up to 11-fold and 5.5-fold reduction in binding and neutralizing titers, respectively, against different SARS-CoV-2 variants, including Beta, Delta, and Omicron BA.1, BA.2, and BA.5. Such reductions were less pronounced in children infected during the fourth wave, who showed the highest frequency and titers of neutralizing antibodies against the same variants. Compared to infection, vaccination with a Wuhan-1-based messenger RNA (mRNA) vaccine induced higher and heterogenous levels of antibodies cross-reacting to the different SARS-CoV-2 variants analyzed. Â Conclusions: Despite the high burden of COVID-19 in Southern Switzerland, we observed an initial low seroprevalence of SARS-CoV-2 in children, which increased in the later waves. The antibody response was poor in the first three waves and improved in the fourth wave, when children produced higher levels of neutralizing antibodies after vaccination or infection with Delta and/or Omicron variants. What is Known: â€¢ Children were marginally affected by the initial SARS-CoV-2 variants. â€¢ The number of infected and hospitalized children increased after the appearance of the Omicron variants. What is New: â€¢ Seroprevalence of SARS-CoV-2 in children of Southern Switzerland increased overtime. â€¢ Children produced higher levels of neutralizing antibodies after vaccination or infection with Delta and/or Omicron variants in the fourth wave compared to children infected in the first three waves.

Hypophysitis after COVID-19 vaccination in a patient with Rathke's cleft cyst: A case report. With the widespread vaccination of COVID-19 vaccine, a few cases have been reported that COVID-19 vaccine may cause endocrine disorders. A 59-y-old man presented with a loss of appetite after the first COVID-19 vaccination, which resolved spontaneously after 3â€‰d. After the second COVID-19 vaccination, the symptoms including the loss of appetite, nausea, and vomiting reappeared and worsened along with loss of vision. He was found to have severe hyponatremia, and further investigations revealed secondary adrenal insufficiency, secondary hypothyroidism and Rathke's cleft cyst. The patient responded well to glucocorticoid and levothyroxine supplementation, and at 1-y follow-up the patient developed hypogonadism. We hypothesize that hypophysitis is probably induced by COVID-19 vaccine and report the rare but serious adverse reactions for early recognition and intervention.

A Successfully Treated COVID-19 Vaccine Induced Immune Thrombocytopenic Purpura. Immune Thrombocytopenic Purpura (ITP) is a life-threatening condition where an accurate initial assessment is essential to be able to offer the proper therapy in a timely matter to improve the outcome of the patient. Here, we present a case of ITP secondary to the coronavirus disease 2019 (COVID-19) vaccine (BioNTech, Pfizer vaccine). A 61-year-old obese African American female presented to the emergency room (ER) from a clinic with a platelet count of 11k/ul 21 days afterÂ she received the second dose of the BioNTech, Pfizer vaccine. The patient was immediately started on intravenous immunoglobulin (IVIG) 1g/kg twice daily (bid) and dexamethasone 20 mg IV every 12 hrs (q12h). The next day, the plateletÂ count increased to 63 k/ul, and after the second dose of IVIG, the platelet count improved

to 122 k/ul and trended up.Â The early detection of ITP induced by the mRNA COVID-19 vaccine is determinant to guide the early and proper therapy with immunoglobulins and steroids to improve the outcome of our patients.

Case report: A case of fulminant type 1 diabetes mellitus after COVID-19 vaccination during treatment of advanced gastric cancer: pitfall in managing immune-related adverse events. The occurrence of fulminant type 1 diabetes mellitus as an adverse event during cancer immunotherapy has been previously reported. However, little is known about the causal relationship between the coronavirus disease 2019 (COVID-19) vaccination and fulminant type 1 diabetes mellitus. A 60-year-old man with advanced gastric cancer, receiving S-1 + oxaliplatin and nivolumab therapy, followed by nab-paclitaxel + ramucirumab as a second-line treatment, with steroid supplementation for complications of hypopituitarism-induced hypoadrenocorticism, was administered a COVID-19 vaccine after three cycles of nab-paclitaxel + ramucirumab. Two days later, he developed severe malaise and anorexia, which required emergency admission to our hospital for suspected adrenal insufficiency. Despite increasing steroids, his general condition changed suddenly after 12 hours leading to his death. Histopathological analysis of autopsy samples revealed loss of the islets of Langerhans, indicating fulminant type 1 diabetes mellitus. We failed to recognize the onset of fulminant type 1 diabetes mellitus because its symptoms were similar to those of adrenal insufficiency. The number of reports on the onset of fulminant type 1 diabetes mellitus after COVID-19 vaccination has been increasing, and in this case, the onset occurred on the second day after COVID-19 vaccination, suggesting an association between vaccination and fulminant type 1 diabetes mellitus. Clinicians should be aware of the risk of fulminant type 1 diabetes mellitus, although rare, after COVID-19 vaccination.

Appearance of tolerance-induction and non-inflammatory SARS-CoV-2 spike-specific IgG4 antibodies after COVID-19 booster vaccinations. BACKGROUND: Understanding the characteristics of the humoral immune responses following COVID-19 vaccinations is crucial for refining vaccination strategies and predicting immune responses to emerging SARS-CoV-2 variants. METHODS: A longitudinal analysis of SARS-CoV-2 spike receptor binding domain (RBD) specific IgG antibody responses, encompassing IgG subclasses IgG1, IgG2, IgG3, and IgG4 was performed. Participants received four mRNA vaccine doses (group 1; n=10) or two ChAdOx1 nCoV-19 and two mRNA booster doses (group 2; n=19) in Bangladesh over two years. RESULTS: Findings demonstrate robust IgG responses after primary Covishield or mRNA doses; declining to baseline within six months. First mRNA booster restored and surpassed primary IgG responses but waned after six months. Surprisingly, a second mRNA booster did not increase IgG levels further. Comprehensive IgG subclass analysis showed primary Covishield/mRNA vaccination generated predominantly IgG1 responses with limited IgG2/IgG3, Remarkably, IgG4 responses exhibited a distinct pattern. IgG4 remained undetectable initially but increased extensively six months after the second mRNA dose, eventually replacing IgG1 after the 3rd/4th mRNA doses. Conversely, initial Covishield recipients lack IgG4, surged post-second mRNA booster. Notably, mRNA-vaccinated individuals displayed earlier, robust IgG4 levels post first mRNA booster versus Covishield counterparts. IgG1 to IgG4 ratios decreased with increasing doses, most pronounced with four mRNA doses. This study highlights IgG response kinetics, influenced by vaccine type and doses, impacting immunological tolerance and IgG4 induction, shaping future vaccination strategies. CONCLUSIONS: This study highlights the dynamics of IgG responses dependent on vaccine type and number of doses, leading to immunological tolerance and IgG4 induction, and shaping future vaccination strategies.

An Elderly Patient Developed Ulcerative Colitis after SARS-CoV-2 mRNA Vaccination: A Case Report and Review of the Literature. An 86-year-old man presented to our hospital with symptoms of diarrhea and bloody stool, which had manifested two weeks after receiving his third SARS-CoV-2 mRNA vaccination. Colonoscopy revealed diffuse, rough-surfaced mucosa extending from the

ascending colon to the rectum. Despite attempting probiotic treatment, the patient's condition did not improve, leading to admission. Endoscopic findings at admission worsened. Based on endoscopic and histopathological findings, the patient was diagnosed with ulcerative colitis. Corticosteroids and 5-aminosalicylic acid were administered, and the clinical symptoms improved. Subsequently, the disease worsened during steroid tapering, and filgotinib was added, leading to steroid-free remission.

Relapse of Ulcerative Colitis with Immune Thrombocytopenia and Pyoderma Gangrenosum Subsequent to Receiving COVID-19 Vaccination. This case illustrates the complex interactions of the immune responses after vaccination and highlights their potential connections to various autoimmune conditions. A 22-year-old man with quiescent ulcerative colitis (UC) presented with abdominal pain, rectal bleeding, and thrombocytopenia 7 days after receiving the third COVID-19 mRNA vaccination. Laboratory data confirmed the diagnosis of immune thrombocytopenia. High-dose intravenous immunoglobulin administration boosted the patient's platelet count. Simultaneously, colonoscopy revealed that his UC had relapsed. Although salazosulfapyridine briefly improved his symptoms, his stool frequency worsened one week later. The patient also developed pyoderma gangrenosum. Subsequent treatment with infliximab notably improved both pyoderma gangrenosum and UC.

Reactivation of previously controlled Vogt-Koyanagi-Harada disease more than 46 years following COVID-19 vaccination: a case study. We report a case of Vogt-Koyanagi-Harada (VKH) disease that recurred 46 years after initial treatment. A 59-year-old woman presented with a 2-month history of bilateral vision blurring. She had received her third dose of coronavirus disease 2019 (COVID-19) vaccination 4 months before the onset of blurring. The best-corrected visual acuity (BCVA) was 1.0 in the right eye and 0.15 in the left eye at the initial visit. Iritis and synechia were observed between the lens and iris bilaterally. A sunset glow fundus was found in both eyes with no serous retinal detachments or disc hyperemia. The patient had a history of VKH disease and had been treated with whole-body corticosteroid administration at another hospital when she was 13 years old. The patient was diagnosed with VKH disease recurrence, and oral corticosteroid therapy and corticosteroid eyedrop treatment were initiated. The treatment response was good. At the time of this writing, recurrence had not been observed for 14 months, and the BCVA was 1.0 in both eyes. To our knowledge, this case represents the longest recorded interval of VKH disease recurrence in the literature to date. COVID-19 vaccination might be the cause of long-term well-controlled disease recurrence.

Acute liver injury after SARS-CoV-2 vaccination and luspatercept administration in a patient with Î²-thalassemia.

Benign fasciculation syndrome and migraine aura without headache as possible adverse events after BNT162b2 mRNA vaccination: a web-based survey. AIM: To determine the characteristics of patients who experienced muscle fasciculations and migraine auras without headache after BNT162b2 immunization. METHODS: In January 2022, we published a case report that described a 48-year-old female patient who experienced muscle twitching and migraine auras without headache following BNT162b2 immunization. A self-administered online survey was sent to people who had written to us and complained of similar symptoms described in the case report (N=20). RESULTS: The survey was completed by 11 participants, of whom 10 reported muscle twitching following BNT162b2 immunization lasting a median of 14 (4-36.5) days. Five of these participants (50%) reported migraine auras without headache. Participants further reported on self-identified triggers that altered the intensity of their symptoms, such as anxiety or caffeine. Fifty percent of participants who got an acute SARS-CoV-2 infection (3/6) experienced increased muscle symptom intensity during the acute phase of the disease. CONCLUSION: To the best of our knowledge, our survey is the first to summarize

patients' experiences of these phenomena occurring after BNT162b2 immunization. It is important to note that no causal relationship between vaccination and these phenomena can be inferred.

Analysis of influencing factors on long COVID in COVID-19 patients infected with omicron variant three months after discharge: a cross-sectional study. BACKGROUND: The purpose of this study is to analyze the influencing factors associated with Long-COVID in patients infected with Omicron variant of COVID-19 in Changchun City, Jilin Province, China three months after discharge in March 2022. METHODS: In this study, we conducted a telephone follow-up based on the real-world data collected from the Affiliated Hospital to Changchun University of Chinese Medicine, Changchun Tongyuan Shelter Hospital and Changchun Infectious Disease Hospital during the COVID-19 epidemic in Changchun in March 2022. We used the Global COVID-19 Clinical Platform Case Report Form for Post COVID condition as a follow-up questionnaire to collect the general information, past medical history, clinical symptoms, COVID-19 vaccine inoculation doses, and other relevant information to analyze the symptom characteristics of COVID-19 patients three months after discharge from the hospital and related factors affecting Long COVID. RESULTS: A total of 1,806 patients with COVID-19 were included in this study, 977 males and 829 females, with a mean age of 38.5 [30.0, 49.4] years, and the number of female patients suffering from Long COVID (50.87%) was greater than male patients (pâ€‰=â€‰0.023). The binary logistic regression analysis of factors influencing Long COVID showed that smoking history (OR (95%CI)â€‰=â€‰0.551(0.425-0.714), pâ€‰<â€‰0.001, taking never smoking as a reference), allergy history (OR (95%CI)â€‰=â€‰1.618 (1.086-2.413), p-value 0.018, taking no allergy as a reference), first symptoms (OR (95%CI)â€‰=â€‰0.636 (0.501-0.807), pâ€‰<â€‰0.001, with no first symptoms as reference) and COVID-19 vaccine inoculation doses (OR (95%CI)â€‰=â€‰1.517 (1.190-1.933), p-value 0.001, with â‰¤â€‰2 doses of COVID-19 vaccine inoculation doses as reference) constituted its influencing factors. The first symptoms of patients on admission mainly included fever (512 cases, 71.81%), cough (279 cases, 39.13%) and dry or itchy throat (211 cases, 29.59%). The most common symptoms of Long COVID were persistent fatigue (68 cases), amnesia (61 cases), insomnia (50 cases) and excessive sweating (50 cases). CONCLUSION: The first symptoms on admission were predominantly fever, cough and dry or itchy throat. The most common symptoms of Long COVID were persistent fatigue, amnesia, insomnia and excessive sweating, and female patients were at a higher risk of Long COVID.

Political orientation of online media sources and reporting of Covid-19 vaccine myocarditis. BACKGROUND: Political orientation may play a formative role in perceptions of risk associated with COVID-19 vaccination including vaccine myocarditis (CVM). Whether political alignment of news sources plays a role in perception of this risk is unknown. OBJECTIVE: We examined the relationship between political orientation of online media sites and aspects of reporting of CVM. METHODS: Media sites were classified as "left" or "right" biased using the Allsides media bias rating report. For each site "COVID vaccine myocarditis" was searched in articles posted May 2021 to December 2022. Each search return was reviewed for the following: 1) Did it contain numerical data regarding CVM risk? 2) Did it report benefits of covid vaccination? 3) Did it mention covid infection-related myocarditis? Monthly reports of vaccine-related adverse events were obtained from the Vaccine Adverse Events Reporting System (VAERS). RESULTS: A total of 487 online reports regarding CVM were reviewed. Comparison of monthly report volumes from left vs. right biased media sources demonstrated significant correlation (r = 0.546, p = 0.013). Additionally monthly reporting of CVM was temporally related to monthly volume of VAERS reporting (r = 0.519, p = 0.023). These data suggest that monthly reporting volumes were driven by availability of information regarding CVM rather than media political alignment. Left biased media sources were significantly more likely to include numerical CVM data vs. right biased sources (76.6% vs. 24.3%, p<0.001) and likewise were more likely to include data supporting benefits of covid vaccination (85.1% vs. 21.7%. p<0.001). In

contrast, there was no difference regarding mention of COVID-19 infection-related myocarditis (24.5% vs. 24.3%, p = 0.957). CONCLUSION: Political orientation of online news sites was not associated with frequency of CVM reports but was related to report content, most notably whether reports included numerical data regarding CVM risk. These differential reporting characteristics may contribute to the relationship between political orientation and patient conceptualization of risk of CVM.

The Relationship Between Menstrual Cycle Irregularities and COVID-19 Vaccination. Background After COVID-19 vaccination, females reported irregularities and changes in their menstrual cycle. We aimed to explore the menstrual irregularities following COVID-19 vaccination in Saudi women of childbearing age. Methodology The study was a cross-sectional study conducted among women in Riyadh, Saudi Arabia, who had no history of menstrual irregularities before receiving the first dose of the COVID-19 vaccine. The participants filled out an online self-administered questionnaire via Google Form about any menstrual irregularities they experienced after receiving the COVID-19 vaccine. Results A total of 535 participants completed the survey. The study found that 41.7% (223) of women experienced menstrual changes after the first dose of the COVID-19 vaccine, increasing to 44.1% (236) after the second dose. The incidence of these changes varied between the first and second doses. For example, the incidence of changes in period duration decreased from 51.6% to 48.3% after the first and second doses, respectively. Similarly, the incidence of delayed periods decreased from 48.4% to 47.9%, while dysmenorrhea increased slightly from 30.9% to 32.2% after the two doses. The incidence of heavier menstrual flow increased from 26.9% to 30.5%, while the incidence of lighter menstrual flow decreased from 26.9% to 24.6% after the first and second doses, respectively. Conclusions There is an increased incidence of changes in menstrual cycle after COVID-19 vaccination, particularly in menstrual cycle length, menstrual pain, and the flow of menstruation. Future studies are needed to investigate the potential underlying biological mechanisms.

Graves' disease post-COVID-19 m-RNA vaccine in pediatric age group. The surge of the COVID-19 pandemic (December / 2019 - May/2023) and its catastrophic effect worldwide have necessitated emergent intervention to reduce its influence on people's health and life. To eliminate and reduce the impact of COVID-19 infection, COVID-19 vaccination was emergently authorized in December 2020 which has established good safety and efficacy. Having said that, some adverse effects merged in a few individuals. We are reporting an adolescent patient a 17-year-old female who has been diagnosed with Graves' disease after post-COVID-19 vaccinations. In addition, she was a confirmed case of COVID-19 infection three months earlier. The patient presented with typical features of hyperthyroidism 30 days post receiving the first dose of the vaccination. Based on the patient's presentation relative to the administration of the vaccine and prior infection of the virus. We proposed the synergistic effect of both factors to induce Graves' disease in this young healthy female with no family history of autoimmune disease. We are reporting this case for pediatric endocrinologists to be aware of the interaction and possible impact of the COVID-19 vaccine on thyroid function.

Association between Pfizer-BioNTech mRNA vaccine and myocardial infarction: clinical and angiographic insights. OBJECTIVE: With the widespread administration of the BioNTech mRNA-based COVID-19 vaccine, there is a need to evaluate its potential effects on cardiovascular health, particularly its association with myocardial infarction (MI). This study aimed to investigate the relationship between BioNTech vaccination and MI, as well as its impact on clinical and angiographic parameters. METHODS: A retrospective analysis was conducted at the Eskisehir Osmangazi University, Eskisehir City Hospital, between April 2020 and May 2023 on a cohort of 1 151 patients hospitalised with MI. The patients were stratified into a BioNTech+ (vaccinated) and a BioNTech- (unvaccinated) groups. Medical records were reviewed for demographic information, clinical data and

angiographic findings. Statistical analyses were performed, including logistic regression models adjusting for potential confounders. RESULTS: The BioNTech- group had a higher mean number of percutaneous transluminal coronary angioplasty procedures and stents compared to the BioNTech+ group. Haematological parameters and lipid profiles showed some discrepancies between the two groups. The BioNTech- group had higher white blood cell and platelet counts, while also exhibiting a higher mean low-density lipoprotein cholesterol level. The prevalence of co-morbidities and cardiovascular risk factors differed between the groups. CONCLUSION: This study found associations between the BioNTech vaccination and clinical and angiographic parameters in patients with MI.

Increased risk of functional neurological disorders following SARS-CoV-2 vaccination. BACKGROUND AND PURPOSE: The purpose of this study was to evaluate the possible correlation between SARS-CoV-2 vaccines and the onset of neurological syndromes. The aim was to challenge the association between SARS-CoV-2 vaccinations and the onset of acute functional neurological disorders (FNDs) compared to other neurological syndromes in hospitalized patients. METHODS: In this prospective cohort study, all adult inpatients consecutively admitted to a tertiary neurological centre were included. The prevalence and characteristics of neurological syndromes were compared between unvaccinated and vaccinated cases stratified according to the onset from vaccination. The study involved 843 subjects, namely 411 unvaccinated (UVC) and 432 vaccinated cases; these groups were comparable for demographics and clinical diagnosis distribution. RESULTS: Compared to UVC, subjects hospitalized within the first 30â€‰days from vaccine exhibited higher prevalence of FNDs (12.3% vs. 3.6%; odds ratio 4.2, 95% confidence interval 1.6-11.1) and headache (10.8% vs. 5%; odds ratio 4.1, 95% confidence interval 1.9-8.8) but no other neurological syndromes. The FND cases following vaccinations showed similar premorbid conditions and severity but a higher percentage of sensory symptoms and pain compared to UVC FND cases. CONCLUSIONS: SARS-CoV-2 vaccination is associated with a significant short-term increased risk of FND and headache requiring hospitalization in an acute neurological setting.

COVID vaccine-induced lupus nephritis: Case report and review of the literature. Vaccines offer an effective strategy to prevent infectious diseases with minimal adverse effects. On rare occasions, vaccination can disrupt the immune response leading to induction of autoimmune diseases. We describe a case of new-onset lupus nephritis following COVID-19 vaccination with the first dose of the Pfizer vaccine. Her symptoms and lab values improved with steroids, hydroxychloroquine, and mycophenolate mofetil.

Vaccinations in patients diagnosed with an autoimmune disorder receiving an immunosuppressive agent: a best practice implementation project. INTRODUCTION: Immunosuppressed patients face increased health risks due to infections such as influenza or COVID-19. Scientific evidence supports improved health-related outcomes in this patient population, such as reduced hospitalizations, with up-to-date vaccinations. The project setting, a community-based rheumatology clinic, did not have a vaccination record specific to the needs of immunosuppressed patients, which may lead to a suboptimal immunization status in these patients. OBJECTIVE: This project aimed to promote evidence-based practices regarding the use of vaccinations in patients diagnosed with autoimmune disorders receiving immunosuppressive agents. METHODS: This project used the JBI evidence implementation framework to promote best practices regarding vaccination. Two audit criteria were identified using a JBI Evidence Summary. Baseline audits identified gaps between the evidence and current practice. Barriers to best practice were then identified, and strategies implemented. Post-implementation audits measured changes in compliance. RESULTS: Baseline audits revealed 67% compliance with the two best practices. Barriers included a lack of provider awareness of the current vaccination recommendations for immunosuppressed patients and a lack of customizable vaccine records. Strategies to address these barriers included educating providers about current national

vaccination recommendations and implementing a new patient vaccination history intake form. Post-implementation audits revealed 83% compliance, with a 16% increase from baseline. CONCLUSIONS: This evidence-based implementation project enhanced best practices by educating providers and implementing an updated patient vaccination history form. Recommendations include the improved compliance with the use of the new form and to assess the effectiveness and usability of a customizable electronic form that interfaces with the clinic's electronic medical records.

Association of COVID-19 Vaccinations with Flares of Systemic Rheumatic Disease: A Case-Crossover Study. OBJECTIVES: To determine the association of COVID-19 vaccination with flares of systemic rheumatic disease (SRD). METHODS: Adults with autoimmune or autoinflammatory conditions ("systemic rheumatic disease") in a single-center COVID-19 Rheumatology Registry were invited to enroll in a study of flares. COVID-19 vaccine information from 3/5/21-9/6/22 was obtained from chart review and self-report. Participants self-reported periods of SRD flare and periods without SRD flare. "Hazard periods" were defined as time before self-report of flare, and "control periods" as time before self-report of no flare. The association between flare and COVID-19 vaccination was evaluated during hazard and control periods through univariate conditional logistic regression stratified by participant, using lookback windows of 2, 7 and 14â€‰days. RESULTS: 434 subjects (mean age 59â€‰years [Â±13], 84.1% female, 81.8% White, 64.5% inflammatory arthritis, 27.0% connective tissue diseases) contributed both hazard and control periods and were included in analysis. A total of 1316 COVID-19 vaccinations were identified (58.5% Pfizer-BioNTech, 39.5% Moderna, 1.4% Johnson & Johnson); 96.1% of participants received â‰¥1 dose and 93.1% â‰¥2 doses. There was no association between COVID-19 vaccination and flares in the subsequent 2, 7 or 14â€‰days (OR 1.46 [95% CI, 0.86-2.46], OR 1.09 [95% CI, 0.76-1.55], OR 0.85 [95% CI, 0.64-1.13] respectively). Analyses stratified on sex, age, SRD subtype and vaccine manufacturer similarly showed no association between vaccination and flare. CONCLUSION: COVID-19 vaccination was not associated with flares in this cohort of participants with SRD. These data are reassuring and can inform shared decision-making on COVID-19 immunization.

The association between frailty, long-term care home characteristics and COVID-19 mortality before and after SARS-CoV-2 vaccination: a retrospective cohort study. BACKGROUND: The relative contributions of long-term care (LTC) resident frailty and home-level characteristics on COVID-19 mortality has not been well studied. We examined the association between resident frailty and home-level characteristics with 30-day COVID-19 mortality before and after the availability of SARS-CoV-2 vaccination in LTC. METHODS: We conducted a population-based retrospective cohort study of LTC residents with confirmed SARS-CoV-2 infection in Ontario, Canada. We used multi-level multivariable logistic regression to examine associations between 30-day COVID-19 mortality, the Hubbard Frailty Index (FI), and resident and home-level characteristics. We compared explanatory models before and after vaccine availability. RESULTS: There were 11,179 and 3,655 COVID-19 cases in the pre- and post-vaccine period, respectively. The 30-day COVID-19 mortality was 25.9 and 20.0% during the same periods. The median odds ratios for 30-day COVID-19 mortality between LTC homes were 1.50 (95% credible interval [CrI]: 1.41-1.65) and 1.62 (95% CrI: 1.46-1.96), respectively. In the pre-vaccine period, 30-day COVID-19 mortality was higher for males and those of greater age. For every 0.1 increase in the Hubbard FI, the odds of death were 1.49 (95% CI: 1.42-1.56) times higher. The association between frailty and mortality remained consistent in the post-vaccine period, but sex and age were partly attenuated. Despite the substantial home-level variation, no home-level characteristic examined was significantly associated with 30-day COVID-19 mortality during either period. INTERPRETATION: Frailty is consistently associated with COVID-19 mortality before and after the availability of SARS-CoV-2 vaccination. Home-level characteristics previously attributed to COVID-19 outcomes do not explain significant home-to-home variation in COVID-19 mortality.

COVID-19 vaccination and corneal allograft rejection- a review. AIM: To provide a comprehensive literature review on the perceived correlation between COVID-19 vaccination and corneal allograft rejection, and to characterize risk factors, time course, graft outcomes and proposed immunological basis. METHODS: A literature review was conducted in August 2023 using 4 electronic databases: PubMed, EMBASE, MEDLINE and Scopus. Articles were sourced using key words associated with COVID-19 vaccination and corneal graft. All articles were screened for relevance by abstract review. Duplicates and articles related to COVID-19 infection were excluded. No time limits were set. Additional literature searches regarding cause of corneal graft rejection, rates of graft rejection associated with other vaccines and the cellular mechanism of rejection were also performed. RESULTS: 262 articles were identified from the literature search. 37 papers were included in the analysis based on defined inclusion criteria. This consisted of systematic reviews (n=6), review articles (n=5), retrospective studies (n=3), case series (n=8), letter to the editor (n=1) and case reports (n= 14). The majority of reported allograft rejections were in penetrating keratoplasties. Risk factors for COVID-19 vaccination associated rejection were previous allograft rejection episodes, repeat grafts and penetrating keratoplasty. Most reported rejection episodes were mild and resolved with treatment. Notably, several studies reported nil increase in corneal allograft rejection episodes over the COVID-19 vaccination period. Rejection episodes are associated with a broad spectrum of other vaccines and the complete pathophysiology is undetermined. CONCLUSION: Corneal allograft rejection appears to be a rare complication of COVID-19 vaccination most frequently observed in high-risk corneal transplants. The true extent of this correlation remains controversial; however, clinician awareness of this risk is essential to its mitigation. Patient counselling around symptom monitoring following vaccination and discussion around topical steroid prophylaxis may be prudent.

Risk of severe COVID-19 outcomes after autumn 2022 COVID-19 booster vaccinations: a pooled analysis of national prospective cohort studies involving 7.4 million adults in England, Northern Ireland, Scotland and Wales. BACKGROUND: UK COVID-19 vaccination policy has evolved to offering COVID-19 booster doses to individuals at increased risk of severe Illness from COVID-19. Building on our analyses of vaccine effectiveness of first, second and initial booster doses, we aimed to identify individuals at increased risk of severe outcomes (i.e., COVID-19 related hospitalisation or death) post the autumn 2022 booster dose. METHODS: We undertook a national population-based cohort analysis across all four UK nations through linked primary care, vaccination, hospitalisation and mortality data. We included individuals who received autumn 2022 booster doses of BNT162b2 (Comirnaty) or mRNA-1273 (Spikevax) during the period September 1, 2022 to December 31, 2022 to investigate the risk of severe COVID-19 outcomes. Cox proportional hazard models were used to estimate adjusted hazard ratios (aHR) and 95% confidence intervals (CIs) for the association between demographic and clinical factors and severe COVID-19 outcomes after the autumn booster dose. Analyses were adjusted for age, sex, body mass index (BMI), deprivation, urban/rural areas and comorbidities. Stratified analyses were conducted by vaccine type. We then conducted a fixed-effect meta-analysis to combine results across the four UK nations. FINDINGS: Between September 1, 2022 and December 31, 2022, 7,451,890 individuals â‰¥18 years received an autumn booster dose. 3500 had severe COVID-19 outcomes (2.9 events per 1000 person-years). Being male (male vs female, aHR 1.41 (1.32-1.51)), older adults (â‰¥80 years vs 18-49 years; 10.43 (8.06-13.50)), underweight (BMI <18.5 vs BMI 25.0-29.9; 2.94 (2.51-3.44)), those with comorbidities (â‰¥5 comorbidities vs none; 9.45 (8.15-10.96)) had a higher risk of COVID-19 hospitalisation or death after the autumn booster dose. Those with a larger household size (â‰¥11 people within household vs 2 people; 1.56 (1.23-1.98)) and from more deprived areas (most deprived vs least deprived quintile; 1.35 (1.21-1.51)) had modestly higher risks. We also observed at least a two-fold increase in risk for those with various chronic neurological conditions, including Down's syndrome, immunodeficiency, chronic kidney

disease, cancer, chronic respiratory disease, or cardiovascular disease. INTERPRETATION: Males, older individuals, underweight individuals, those with an increasing number of comorbidities, from a larger household or more deprived areas, and those with specific underlying health conditions remained at increased risk of COVID-19 hospitalisation and death after the autumn 2022 vaccine booster dose. There is now a need to focus on these risk groups for investigating immunogenicity and efficacy of further booster doses or therapeutics. FUNDING: National Core Studies-Immunity, UK Research and Innovation (Medical Research Council and Economic and Social Research Council), Health Data Research UK, the Scottish Government, and the University of Edinburgh.

Unraveling the association between vaccine attitude, vaccine conspiracies and self-reported side effects following COVID-19 vaccination among nurses and physicians in Jordan. BACKGROUND: The negative impact of vaccine conspiracies is linked with negative health behavior. The aim of the current study was to examine the association between attitudes toward booster COVID-19, influenza, and monkeypox (mpox) vaccinations with post-COVID-19 vaccine side effects, vaccine conspiracies, and attitude towards mandatory vaccination among nurses and physicians in Jordan. METHODS: A structured closed-ended questionnaire was used to collect data on demographics, COVID-19 history, COVID-19 vaccine type and doses received, self-reported side effects post-COVID-19 vaccination, acceptance of booster COVID-19, seasonal influenza, and mpox vaccinations, attitudes towards mandatory vaccination, and beliefs in vaccine conspiracies. RESULTS: The study sample comprised a total of 341 participants. Acceptance of yearly booster COVID-19 vaccination was expressed by 46.6% of the sample, while 73.3% accepted seasonal influenza vaccination, and only 37.0% accepted mpox vaccination. A higher frequency of self-reported side effects following the first COVID-19 vaccine dose was associated with embrace of vaccine conspiracies and vaccine type. For the second vaccine dose, a higher frequency of self-reported side effects was associated with the embrace of vaccine conspiracies, older age, and affiliation to private sector. In multinomial logistic regression analyses, the lower embrace of vaccine conspiracies was associated with lower odds of reporting side effects post-COVID-19 vaccination. The lower embrace of vaccine conspiracies and favorable attitude towards mandatory vaccination were associated with the willingness to get COVID-19, influenza, and mpox vaccinations. CONCLUSION: The study findings highlighted the negative impact of embracing vaccine conspiracies on health-seeking behavior among nurses and physicians. The findings indicated that the willingness to get vaccinated was associated with lower endorsement of vaccine conspiracies. Additionally, the lower embrace of vaccine conspiracies was associated with a lower frequency of self-reported side effects following COVID-19 vaccination. These results emphasize the importance of addressing vaccine misinformation and promoting accurate information to ensure optimal vaccine uptake and public health outcomes.

Antibody responses after BNT162b2 vaccination in Japanese geriatric intermediate care facilities. BACKGROUND: To evaluate antibody responses against the primary series of vaccination of severe acute respiratory syndrome coronavirus-2 [SARS-CoV-2] vaccines in the staff and residents of Japanese geriatric intermediate care facilities. METHODS: All subjects (159 staff and 96 residents) received two doses of the BNT162b2 mRNA vaccine 3Â weeks apart. Baseline data of subject were collected using a structured form. Serum samples were collected three times: before vaccination, 3Â weeks after the first dose, and 4Â weeks after the second dose, and anti-receptor binding domain of the spike protein of SARS-CoV-2 [anti-RBD] IgG was measured using two immunoassays. RESULTS: After the second dose, geometric mean titers [GMT] of anti-RBD with both the Abbott and Roche assay were significantly lower in residents than staff (2282 AU/mL vs. 8505 AU/mL, and 258 U/mL vs. 948 U/mL, respectively). Multivariate analysis of characteristics affecting antibody responses (â‰¥1280 AU/mL for Abbott andÂ >Â 210 U/mL for Roche) showed lower odds ratios [ORs] for older age (adjusted OR per 10Â year increase [aOR]Â =Â 0.62, 95Â % confidence interval [95Â %CI]; 0.38-

1.02), steroid usage (aORÂ =Â 0.09, 95Â %CI; 0.01-0.60) and regular nonsteroidal anti-inflammatory drugs [NSAIDs] usage (aORÂ =Â 0.16, 95Â %CI; 0.03-0.88). CONCLUSIONS: Elderly people and steroid and NSAID users had lower antibody responses following the second vaccine dose.

Uveal effusion syndrome following COVID-19 vaccination. PURPOSE: To report a rare case of uveal effusion syndrome following COVID-19 vaccination. OBSERVATION: A 71-year-old Asian man presented to his ophthalmologist with blurred vision and noticing distorted lines in his left eye two weeks after the first dose of COVID-19 vaccination. Examination revealed choroidal detachment and he was advised systemic corticosteroids. The symptoms were ignored and the second vaccine dose was taken. After five months, he presented to our clinic with persistent visual complaints. He also had a history of COVID-19 infection three months prior to vaccination. Ocular examination revealed a quiet anterior chamber with annular choroidal detachment consistent with the diagnosis of Type 3 uveal effusion syndrome. B-scan ultrasonography revealed increased choroidal thickness with detachment. Optical coherence tomography showed subretinal fluid with retinal pigment epithelium and choroidal folds. Ultrasound biomicroscopy revealed all around supraciliary effusion in the left eye. The patient was treated with oral prednisolone and mycophenolate mofetil which resulted in complete resolution of uveal effusion and improvement in visual acuity. CONCLUSIONS AND IMPORTANCE: Uveal effusion syndrome is a rare ocular disease, however it may manifest following COVID-19 vaccination. Our case highlights the importance of a complete ophthalmic examination in patients with ocular symptoms after vaccination.

Autoimmune response after SARS-CoV-2 infection and SARS-CoV-2 vaccines. The complicated relationships between autoimmunity, COVID-19, and COVID-19 vaccinations are described, giving insight into their intricacies. Antinuclear antibodies (ANA), anti-Ro/SSA, rheumatoid factor, lupus anticoagulant, and antibodies against interferon (IFN)-I have all been consistently found in COVID-19 patients, indicating a high prevalence of autoimmune reactions following viral exposure. Furthermore, the discovery of human proteins with structural similarities to SARS-CoV-2 peptides as possible autoantigens highlights the complex interplay between the virus and the immune system in initiating autoimmunity. An updated summary of the current status of COVID-19 vaccines is presented. We present probable pathways underpinning the genesis of COVID-19 autoimmunity, such as bystander activation caused by hyperinflammatory conditions, viral persistence, and the creation of neutrophil extracellular traps. These pathways provide important insights into the development of autoimmune-related symptoms ranging from organ-specific to systemic autoimmune and inflammatory illnesses, demonstrating the wide influence of COVID-19 on the immune system.

Healthcare Workers' Adherence and Attitudes Toward the Adherence to COVID-19 Precautionary Guidelines Post-Vaccination: A Cross-Sectional Pilot Study. BACKGROUND: Healthcare workers (HCWs) have shown increased adherence to infection control practices during the COVID-19 pandemic. However, there is a need to assess their adherence to and attitude toward COVID-19 guidelines after being vaccinated. The purpose of this pilot study is to assess the adherence to and attitudes toward the adherence to COVID-19 guidelines among HCWs who have been vaccinated. METHODS: A retrospective cross-sectional design was employed. One hundred and eight participants were recruited via email from a medical center in the Midwest United States. The participants completed online surveys measuring the level of adherence to and attitudes toward the adherence to COVID-19 guidelines. The response rate was 5.4%. FINDINGS: Most participants were female (73.1%) and white (82.4%). The participants adhered to COVID-19 guidelines 79.7% of the time. The most frequently followed guidelines were performing hand hygiene, wearing a respirator or well-fitting mask in areas where patients may be present, and wearing eye protection when entering the room for a patient with suspected or confirmed COVID-19 infection. The least performed precautions were performing COVID-19 testing after exposure to a suspected or confirmed COVID-19 case and

maintaining social distancing. There was a significant decrease in the perceived importance of adherence to COVID-19 precautions post-vaccination (p <.001, 95% CI [-0.78, -0.35]). CONCLUSIONS: The increased perception of safety after receiving COVID-19 vaccination may negatively influence HCWs' adherence to COVID-19 precautionary guidelines. Continuous education and monitoring of HCWs' safety practices are important to influence HCWs' attitudes to adhere to COVID-19 precautions, particularly after vaccination.

Autoimmune and auto-inflammatory adverse events after COVID-19 vaccination in the United States. We identified 3620 autoimmune-related adverse events among 223.2 million US residents using Vaccine Adverse Events Reporting System and the COVID-19 Data Tracker. This study is the first to quantify the cumulative incidence of autoimmune and auto-inflammatory adverse events after COVID-19 vaccination. We reported autoimmune and auto-inflammatory adverse events across 6 major classes of medical conditions and stratified by age, sex, and manufacturer.

Identification of key genes associated with persistent immune changes and secondary immune activation responses induced by influenza vaccination after COVID-19 recovery by machine learning methods. COVID-19 is hypothesized to exert enduring effects on the immune systems of patients, leading to alterations in immune-related gene expression. This study aimed to scrutinize the persistent implications of SARS-CoV-2 infection on gene expression and its influence on subsequent immune activation responses. We designed a machine learning-based approach to analyze transcriptomic data from both healthy individuals and patients who had recovered from COVID-19. Patients were categorized based on their influenza vaccination status and then compared with healthy controls. The initial sample set encompassed 86 blood samples from healthy controls and 72 blood samples from recuperated COVID-19 patients prior to influenza vaccination. The second sample set included 123 blood samples from healthy controls and 106 blood samples from recovered COVID-19 patients who had been vaccinated against influenza. For each sample, the dataset captured expression levels of 17,060 genes. Above two sample sets were first analyzed by seven feature ranking algorithms, yielding seven feature lists for each dataset. Then, each list was fed into the incremental feature selection method, incorporating three classic classification algorithms, to extract essential genes, classification rules and build efficient classifiers. The genes and rules were analyzed in this study. The main findings included that NEXN and ZNF354A were highly expressed in recovered COVID-19 patients, whereas MKI67 and GZMB were highly expressed in patients with secondary immune activation post-COVID-19 recovery. These pivotal genes could provide valuable insights for future health monitoring of COVID-19 patients and guide the creation of continued treatment regimens.

Immune-mediated diseases after vaccinations with AZD1222, BNT-162b2, &/or mRNA-1273: An observational investigation of 78 patients. BACKGROUND: Immune-mediated diseases (IMDs) after nucleic acid-based vaccines have been sporadically reported since their introduction during the worldwide COVID-19 crisis. Confirming their cause-effect association remains challenging. We analysed the effects of AZD1222 (ChAdOx1 nCoV-19), BNT-162b2, and/or mRNA-1273 on the development &/or deterioration of IMDs in terms of the time of clinical onsets of IMDs after exposure to these vaccines. METHODS: We retrospectively reviewed 78 in-patients in Taipei Veterans General Hospital, who presented with IMDs within 120Â days after receiving AZD1222, BNT-162b2, &/or mRNA-1273 vaccinations in Taiwan from May 2021 to April 2022. The duration from inoculation to development of IMD was analysed by two-tailed Kolmogorov-Smirnov (K-S) test for goodness of fit. RESULTS: The average time to new IMDs or flare-up of the diseases following vaccinations was 36Â Â±Â 26Â days for all 91 events in these 78 patients. The onset time of IMDs after vaccinations was not haphazard as analysed by two-tailed K-S test for overall 91 events (40 new and 51 deteriorating episodes, pÂ <Â 0.001). The IMDs presenting as non-connective tissue diseases (non-

CTDs) have a shorter duration of incubation after vaccinations than those of CTDs (<14.7Â days, 95Â % confidence interval [CI], 3.0 to 26.4, pÂ =Â 0.014). Furthermore, systemic vasculitis and type 2 inflammatory diseases were observed exclusively in those receiving AZD1222. CONCLUSION: AZD1222, BNT-162b2, or mRNA-1273 influence the activities of IMDs in ways yet to be explored. High index of suspicion to IMDs after nucleic acid-based vaccine inoculation against COVID-19 may be important for primary care physicians.

Morphological and Metabolic Criteria of COVID-19 Vaccine Associated Axillary Nodes on 18-Fluorodeouxyglucose PET/CT Imaging in Breast Cancer Patients. BACKGROUND: Â In the current era vaccine-associated lymphadenopathy (VAL) is not an uncommon presentation on 18F-FDG PET/CT examinations in patients inoculated with Coronavirus disease 2019 (COVID-19) vaccination. In this study, we are presenting data of VAL on 18F-FDG PET/CT regarding its prevalence, temporal response to vaccination and imaging characteristics of VAL. METHODS: Seventy-eight (78) consecutive vaccinated breast cancer (BC) patients who had 18FDG PET/CT were retrospectively analyzed. All patients had COVID-19 vaccine shots in contralateral arms and none in breast cancer site axilla (BSA). Â In 35 patients 18FDG avid nodes were found in vaccine site axilla (VSA). In 25 patients 18FDG avid nodes were found in BSA. Morphological criteria on CT images like size, presence of fatty hila and fat stranding of axillary nodes were analyzed. Metabolic criteria on PET images like SUVmax of nodes and liver as reference were also measured. RESULTS: Out of 78 patients, 35 had Â positive nodes in VSA (45% prevalence) and 25/78 had BSA (33% prevalence). Mean duration of COVID-19 vaccination in each group was 8 Â±04 week (non-significant p-value). On CT images, 18FDG avid nodes in VSA were significantly smaller (10 Â± 03 mm) and with intact fatty hila without fat stranding than nodes in BSA with loss of fatty hila (25 Â±10 mm; p <0.0001). Mean SUVmax of nodes in VSA was significantly lower (2.4 Â±1.1) than nodes in BSA (10.2 Â±5.5 - p-value <0.0001). Nodes in VSA showed a significant positive linear correlation between size and SUVmax (p-value 0.00001). Â Similarly, nodes in VSA showed a significant negative linear correlation between duration and SUVmax (p-value 0.00003). Â In VSA group, 03 patients having SUVmax >2 SD of Hepatic SUVmax were subjected to ultrasound guided fine needle aspiration (FNA) and turned out to be metastatic in nature. CONCLUSION: In COVID-19 vaccinated patients with BC, 18FDG avid nodes in VSA may pose diagnostic challenge. However, morphological (size < 10 mm short axis, intact fatty hila without fat stranding) and metabolic criteria (SUVmax <2.4 with negative correlation with time of inoculation) have higher diagnostic accuracy in resolving the dilemma. Nodes in VSA having SUVmax > 2 SD of hepatic SUVmax should be considered for FNA to rule out possible metastasis.

Long term follow up and outcomes of Covid-19 vaccine associated myocarditis in Victoria, Australia: A clinical surveillance study. BACKGROUND: Myocarditis and myopericarditis are well described adverse events of special interest (AESI) following COVID-19 vaccinations. Although reports are reassuring regarding initial clinical outcomes, information about longer term outcomes remains limited. We aimed to further this knowledge and report outcomes to 6Â months post diagnosis from a single population cohort. METHODS: Reports of myocarditis following COVID-19 vaccination were followed up by SAEFVIC (Surveillance of Adverse Events Following Vaccination in the Community), the state-wide vaccine safety service for Victoria, Australia. Confirmed myocarditis cases (Brighton Collaboration Criteria levels 1-3) were followed up via surveys at 1, 3 and 6Â months post symptom onset. Responses received between 22 February 2021 and 30 September 2022 were analysed. RESULTS: 87.5Â % (NÂ =Â 182) of eligible participants completed at least 1 survey report. 377 reports were analysed. 76.9Â % of completed reports were from male patients. The median age of patients was 21Â years [IQR: 16 to 32]. 54.8Â % (nÂ =Â 74) of survey reports at 6Â months, reported ongoing symptoms. At all follow-up time points, females were significantly more likely to have ongoing symptoms. At 6Â months, 51.9Â % of male respondents reported symptom resolution compared to

22.6Â % of female patients (pÂ =Â 0.002). Females were also more likely to continue medication and have ongoing exercise restrictions. However, males were significantly more likely to have higher initial peak troponin results and abnormal initial cardiac imaging investigations. CONCLUSIONS: There appears to be a significant proportion of patients who experience ongoing symptoms to 6Â months post onset amongst patients that experience these AESI. Male patients were more likely to report earlier and more complete symptom recovery, despite significantly higher average initial peak troponin. This difference in phenotypic presentation in females compared to males warrants further investigation and there is a need for longer term follow up data.

An 82-year-old man with new skin lesions after COVID-19 vaccination. Background: During the height of the SARS CoV-2 (severe acutre respiratory syndrome coronavirus disease 2019 [COVID 19]) pandemic, there have been numerous case reports of cutaneous reactions shortly after COVID-19 vaccine administration. Most reported cases are local injection-site reactions, whereas persistent or delayed cutaneous reactions have not been as common. Methods: We present the case of an 82-year-old man with persistent rash after the second COVID-19 vaccination. Results: A specific diagnosis was confirmed after the third skin biopsy. Conclusion: Patients are frequently referred to an allergist for various cutaneous reactions that occurred after vaccination, concerned about a possible drug allergy. This case emphasizes the importance of keeping a broad differential diagnosis when encountering a persistent skin rash not resolved by oral antihistamines or steroids.

The application of cardiac MRI in Myocarditis after COVID-19 vaccines: Case series from single medical center in Taiwan. During the coronavirus disease 2019 (COVID-19) pandemic, reports of vaccine-induced myocarditis, particularly messenger ribonucleic acid (mRNA)-based myocarditis, were widely spread. This case series describes various cases of COVID-19 vaccine-induced myocarditis confirmed by cardiac magnetic resonance imaging (MRI), including those who were administered rare protein-based vaccines. Eleven patients comprising eight males and 3 females with suspected myocarditis underwent cardiac MRI at Taichung Veterans General Hospital between October 2021 and May 2022. The median age of the patients was 33.5 years old (range: 22-57 years). The onset of myocarditis was mainly observed following mRNA vaccine inoculation. One patient received the MVC COV1901 vaccine, a unique protein-based COVID-19 vaccine in Taiwan, and met the 2018 Lake Louise Criteria for the diagnosis of myocarditis, confirmed by cardiac MRI. Most patients reported chest discomfort after receiving various vaccine types. Among four patients with reduced left ventricular ejection fraction (LVEF), two showed LVEF restoration during the follow-up period, and the other two were lost to follow-up. Cardiac MRI characterizes myocardial features such as edema, inflammation, and fibrosis, and has been proven to diagnose myocarditis accurately with a sensitivity of 87.5% and a specificity of 96.2% according to the 2018 Lake Louise criteria. This diagnosis was achieved without invasive procedures such as endomyocardial biopsy or coronary angiography.

Hematology in the post-COVID era: spotlight on vaccine-induced immune thrombotic thrombocytopenia and a conceptual framework (the 4P's) for anti-PF4 diseases. INTRODUCTION: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a life-threatening prothrombotic disorder first identified following the introduction of adenoviral vector vaccines for COVID-19. The condition is characterized by anti-PF4 antibodies and clinically presents with thrombocytopenia and thrombosis often in unusual anatomical sites. AREAS COVERED: In this review, we discuss the clinical presentation, diagnostic testing, and treatment of VITT. We also review VITT-like syndromes that have been described in patients without previous vaccination. We propose a conceptual framework for the mechanism of anti-PF4 diseases that includes sufficiently high levels of PF4, the presence of a Polyanion that can form immune complexes with PF4, a Pro-inflammatory milieu, and an immunological Predisposition - the 4Ps. EXPERT OPINION: Significant progress has been made in understanding the characteristics of the VITT antibody and in testing methods that can confirm that

diagnosis. Future work should be directed at understanding long-term outcomes, mechanisms of thrombosis, and individual risk factors for this rare but dangerous immune-thrombotic disease.

Association between sleep duration and antibody acquisition after mRNA vaccination against SARS-CoV-2. INTRODUCTION: Sleep enhances the antibody response to vaccination, but the relationship between sleep and mRNA vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is not fully understood. METHODS: In this prospective observational study, we investigated the influence of sleep habits on immune acquisition induced by mRNA vaccines against SARS-CoV-2 in 48 healthy adults (BNT-162b2, n=34; mRNA-1273, n=14; female, n=30, 62.5%; male, n=18, 37.5%; median age, 39.5 years; interquartile range, 33.0-44.0 years) from June 2021 to January 2022. The study measured sleep duration using actigraphy and sleep diaries, which covered the periods of the initial and booster vaccinations. RESULTS: Multivariable linear regression analysis showed that actigraphy-measured objective sleep duration 3 and 7 days after the booster vaccination was independently and significantly correlated with higher antibody titers (B=0.003; 95% confidence interval, 0.000-0.005; Beta=0.337; p=0.02), even after controlling for covariates, including age, sex, the type of vaccine, and reactogenicity to the vaccination. Associations between acquired antibody titer and average objective sleep duration before vaccination, and any period of subjective sleep duration measured by sleep diary were negligible. DISCUSSION: Longer objective, but not subjective, sleep duration after booster vaccination enhances antibody response. Hence, encouraging citizens to sleep longer after mRNA vaccination, especially after a booster dose, may increase protection against SARS-CoV-2. STUDY REGISTRATION: This study is registered at the University Hospital Medical Information Network Center (UMIN: https://www.umin.ac.jp) on July 30, 2021, #UMIN000045009.

Sutimlimab suppresses SARS-CoV-2 mRNA vaccine-induced hemolytic crisis in a patient with cold agglutinin disease. Cold agglutinin disease (CAD) is a rare form of acquired autoimmune hemolytic anemia driven mainly by antibodies that activate the classical complement pathway. Several patients with CAD experience its development or exacerbation of hemolysis after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection or after receiving the SARS-CoV-2 mRNA vaccine. Therefore, these patients cannot receive an additional SARS-CoV-2 mRNA vaccination and have a higher risk of severe SARS-CoV-2 infection. Sutimlimab is a monoclonal antibody that inhibits the classical complement pathway of the C1s protein and shows rapid and sustained inhibition of hemolysis in patients with CAD. However, whether sutimlimab could also inhibit hemolysis caused by SARS-CoV-2 mRNA vaccination is uncertain. Here, we present the case of a 70-year-old man with CAD who repeatedly experienced a hemolytic crisis after receiving SARS-CoV-2 mRNA vaccines. The patient eventually underwent SARS-CoV-2 mRNA vaccination safely, without hemolytic attack, under classical pathway inhibition therapy with sutimlimab. This report suggests that appropriate sutimlimab administration can suppress SARS-CoV-2 mRNA vaccination-induced CAD exacerbation, and that it could be a preventive strategy to minimize hemolytic attacks in susceptible populations.

[Neurological complications after covid-19 vaccination]. The aim of our work was to study the relevance and incidence of neurological post-vaccination complications during the COVID-19 pandemic. Based on the results of a systematic literature search of several databases, the current review describes the diagnosed complications, including neurological, that occurred after the administration of the COVID-19 vaccine during the pandemic period. To fully establish the pathophysiological mechanisms of the development of a causal relationship of neurological complications with vaccines against COVID-19, it becomes necessary to continue long-term studies. This will make it possible to carry out a pharmacological correction of the quality of vaccine safety.

Review of a Series of Surveys on Adverse Reactions to the COVID-19 mRNA-1273 Vaccine at Okayama University. This paper presents the results of a series of surveys conducted from July 2021 to March 2023 to investigate the post-vaccination adverse reactions to the mRNA-1273 (Moderna) vaccine among faculty, staff, and students at Okayama University. These studies complement the official surveys conducted by the Ministry of Health, Labour and Welfare (MHLW) and provide a more representative picture of adverse reactions in the general population including large numbers of healthy young people. Pain, swelling, redness at the injection site, fever, headache, and malaise were the main adverse reactions reported. The proportion of adverse reactions was generally higher after the second vaccination and decreased with each additional vaccination. No statistically significant differences in the adverse reactions were found for males and females and those with/without a history of allergy, but a lower proportion of fever was observed in older participants and those with underlying medical conditions. We also evaluated the association between adverse reactions and antibody titers after the third vaccination and found no significant differences in antibody levels one month after vaccination. This series of studies highlights the importance of conducting surveys in diverse populations to provide a more representative picture of post-vaccination adverse reactions during a pandemic.

Airway and Systemic Immune Responses Following the Third COVID-19 Vaccination in COPD Patients. INTRODUCTION: Booster vaccinations are required to maintain protection against COVID-19. COPD patients are at higher risk of developing severe illness following SARS-CoV-2 infection. Previous cross-sectional analysis after the second COVID-19 booster showed similar immune responses in COPD patients and controls, but pre-vaccination samples were not available. This longitudinal study evaluated systemic and airway immune responses in COPD patients using samples obtained pre- and post-third COVID-19 vaccination. METHODS: Twelve COPD patients were recruited, with plasma, nasal and sputum (n = 10) samples collected pre-vaccination and 4- and 14-weeks post vaccination. Samples were analyzed for anti-spike IgA and IgG and cellular immunity. The ability of plasma and nasal samples to block ACE2-spike protein interaction was assessed for Wild type, Delta, and Omicron spike variants. RESULTS: Vaccinations increased anti-spike IgG in plasma ($p < 0.001$), nasal (IgG $p < 0.001$) and sputum ($p = 0.002$) samples, IgA in plasma ($p < 0.001$) and blood cellular immunity ($p = 0.001$). Plasma and nasal anti-spike IgA levels correlated (rho: 0.6, $p = 0.02$), with similar results for IgG (rho: 0.79, $p = 0.003$). Post-vaccination nasal ($p = 0.002$) and plasma ($p < 0.001$) samples were less effective at blocking Omicron spike binding to ACE2 compared to the Wild type spike variant. DISCUSSION: Airway and systemic immune responses against SARS-CoV-2 increased in COPD patients following a third COVID-19 vaccination. Nasal and systemic responses in COPD patients were less effective against Omicron variant compared to previous variants.

COVID-19 vaccine-associated myocarditis: Analysis of the suspected cases reported to the EudraVigilance and a systematic review of the published literature. BACKGROUND: Myocarditis secondary to Coronavirus Disease 2019 (COVID-19) vaccination has been reported in the literature. OBJECTIVE: This study aimed to characterize the reported cases of myocarditis after COVID-19 vaccination based on age, gender, doses, and vaccine type from published literature and the EudraVigilance database. METHODS: We performed an analysis in the EudraVigilance database (until December 18, 2021) and a systematic review of published literature for reported cases of suspected myocarditis and pericarditis (until 30th June 2022) after the COVID-19 vaccination. RESULTS: EudraVigilance database analysis revealed 16,514 reported cases of myocarditis or pericarditis due to the vaccination with COVID-19 vaccines. The cases of myo- or pericarditis were reported predominantly in the age group of 18-64 (nâ€¯=â€¯12,214), and in males with a male-to-female (M: F) ratio of 1.7:1. The mortality among myocarditis patients was low, with 128 deaths (2 cases per 10.000.000 administered doses) being reported. For the systematic review, 72 studies with 1026

cases of myocarditis due to the vaccination with COVID-19 vaccines were included. The analysis of published cases has revealed that the male gender was primarily affected with myocarditis post-COVID-vaccination. The median (IQR) age of the myocarditis cases was 24.6 [19.5-34.6] years, according to the systematic review of the literature. Myocarditis cases were most frequently published after the vaccination with m-RNA vaccines and after the second vaccination dose. The overall mortality of published cases was low (nâ€¯=â€¯5). CONCLUSION: Myocarditis is a rare serious adverse event associated with a COVID-19 vaccination. With early recognition and management, the prognosis of COVID-19 vaccine-induced myocarditis is favorable.

COVID-19 Vaccines and Axillary Nerve Dysfunction: A Case Report. COVID-19 resulted in a worldwide pandemic and the rapid introduction of vaccines in an attempt to mitigate it. Neuritis and neuropathy after intramuscular injection had been previously seen with influenza vaccines and appear to be a side effect of the COVID-19 vaccine as well. In the following report, we present the case of a 43-year-old female who developed axillary nerve symptoms after administration of the COVID-19 vaccine and her subsequent recovery.

Immunogenicity and safety of inactivated SARS-CoV-2 vaccines in people living with HIV: A longitudinal cohort study. To clarify the characteristics in immunogenicity and safety of inactivated SARS-Cov-2 vaccines among HIV-infected individuals, a longitudinal cohort study was performed on HIV-infected and HIV-uninfected participants with no history of COVID-19 infection and COVID-19 vaccine inoculation. Participants information and adverse events were collected. Blood samples were collected on the same day before vaccination, 21 days after the first shot, 28 days after the second shot, 6 months after the second vaccination and 14 days after the third dose to test anti-receptor-binding domainÂ IgG antibody, viral load, CD4+, CD8+â€‰T cell count. Our result showed that although HIV-infected adults with low nadir CD4+â€‰T cell countâ€‰â‰¤â€‰350 cells/mm(3) generate significantly lower immune response after three shots of vaccine compared with HIV-negative controls, 100% of all the HIV-infected and healthy controls were seroconverted after the third shot. Seroconversion ratio and antibody level of 190 days after two shots of vaccination for HIV-infected with nadir CD4+â€‰T cell countâ€‰â‰¤â€‰350 were significantly lower than that of healthy controls. No significant difference was found in viral load among blood samples collected at each time points. CD4 and CD4/CD8 ratio value were found increased greatly after each shot of inoculation in HIV-infected individuals with nadir CD4+â€‰T cell countâ€‰â‰¤â€‰350. Multiple logistic regression analysis showed that among HIV-infected individuals, PLWH with CD4+â€‰T cell count â‰¤ 350 were less likely experience seroconversion 21 days after the first shot, and less likely maintained antibody immunity 6 months post 2nd dose. Adverse events after each inoculation were not serious and recovered within 1 week. In conclusion, inactivated COVID-19 vaccine was safe and effective in people living with HIV after three shots of vaccination. HIV-infected individuals with low nadir CD4+â€‰T cell countâ€‰â‰¤â€‰350 was associated with a nonoptimal antibody response. Further vaccination strategies could be developed for those with low CD4+â€‰T cell counts.

Development of an Oral IgA Response against SARS-CoV-2 Following Immunization with Different COVID-19 Vaccines. The mucosal immune response is recognized to be important in the early control of infection sustained by viruses with mucosal tissues as the primary site of entry and replication, such as SARS-CoV-2. Mucosal IgA has been consistently reported in the mouth and eye of SARS-CoV-2 infected subjects, where it correlated inversely with COVID-19 symptom severity. Yet, there is still scarce information on the comparative ability of the diverse SARS-CoV-2 vaccines to induce local IgA responses at the virus entry site. Thus, the aim of this study was to assess the presence of anti-SARS-CoV-2 IgA in the saliva of 95 subjects vaccinated with a booster dose and different combinations of vaccines, including mRNA-1273 (Moderna), BNT162b2 (Pfizer-BioNTech), and Vaxzevria (AstraZeneca). The results showed the presence of a mucosal response in 93.7% of

vaccinated subjects, with a mean IgA titer of 351.5 Â± 31.77 U/mL, strongly correlating with the serum anti-SARS-CoV-2 IgG titer ($p < 0.0001$). No statistically significant differences emerged between the vaccine types, although the salivary IgA titer appeared slightly higher after receiving a booster dose of the mRNA-1273 vaccine (Moderna) following two doses of BNT162b2 (Pfizer-BioNTech), compared to the other vaccine combinations. These data confirm what was previously reported at the eye level and suggest that monitoring salivary IgA may be a useful tool for driving forward vaccine design and surveillance strategies, potentially leading to novel routes of vaccine administration and boosting.

Occurrence and Risk Factors of Relapse Activity after Vaccination against COVID-19 in People with Multiple Sclerosis: 1-Year Follow-Up Results from a Nationwide Longitudinal Observational Study. Several studies reported post-SARS-CoV-2-vaccination (PV) symptoms. Even people with multiple sclerosis (PwMS) have concerns about disease activity following the SARS-CoV-2 vaccination. We aimed to determine the proportion of PwMS with PV relapses, the PV annualized relapse rate (ARR), the time from vaccination to subsequent relapses, and identify sociodemographic/clinical risk factors for PV relapses. PwMS were surveyed several times at baseline and four follow-ups as part of a longitudinal observational study regarding the safety and tolerability of the SARS-CoV-2 vaccination. The inclusion criteria for this analysis were age â‰¥18 years, â‰¥1 SARS-CoV-2 vaccination, and â‰¥1-year observation period since initial vaccination. Of 2466 PwMS, 13.8% reported PV relapses (mostly after second [N = 147] or booster vaccination [N = 145]) at a median of 8.0 (first/third quantile: 3.55/18.1) weeks PV, with the shortest period following initial vaccination (3.95 weeks). The ARR was 0.153 (95% confidence interval: 0.138-0.168), with a median observation period since initial vaccination of 1.2 years. Risk factors for PV relapses were younger age, female gender, moderate-severe disability levels, concurrent autoimmune diseases, relapsing-remitting MS courses, no DMT, and relapses within the year prior to the first vaccination. Patients' health conditions before/during initial vaccination may play a more important role in PV relapse occurrence than vaccination per se.

Do Not Leave Your Patients in the Dark-Using American College of Rheumatology and European Alliance of Associations for Rheumatology Recommendations for Vaccination in Polish Adult Patients with Autoimmune Inflammatory Rheumatic Diseases. (1) Introduction: Patients with autoimmune inflammatory rheumatic diseases (AIIRD) face a higher infectious risk compared to the general population. As per the ACR and EULAR recommendations, vaccinations against influenza, COVID-19, pneumococci, and tetanus are recommended for most patients with AIIRD. (2) Objectives: This study aimed to assess vaccination coverage among Polish AIIRD patients and identify factors influencing it. (3) Patients and Methods: This study was conducted at the reference rheumatological center in Poland between May 2023 and October 2023. The study participants completed a questionnaire covering their knowledge of vaccination recommendations, actual vaccination status, factors affecting their decision to vaccinate, and their perspectives on immunization. (4) Results: This study involved 300 AIIRD patients and 60 controls. Both groups exhibited comparably low vaccination rates for all diseases (the highest for COVID-19-52% in both groups and the lowest for pneumococci-7.7% and 10%, respectively). Knowledge about recommended vaccinations was limited among patients in both groups. AIIRD patients were also not aware that they should avoid live vaccines. The primary motivators for vaccination among AIIRD patients were fear of infection (up to 75%) and medical advice (up to 74.6%). Conversely, the predominant reasons for non-vaccination were a lack of knowledge that vaccination is recommended (up to 74.7%) and concerns about potential adverse effects (up to 48.6%). Many patients reported not receiving vaccination recommendations from either primary care physicians or rheumatologists. (5) Conclusions: To enhance vaccination coverage among AIIRD patients in Poland, it is essential to educate them about vaccinations during routine

medical consultations, emphasizing the increased risk of infection, informing them about recommended vaccinations, and clarifying doubts about adverse effects.
Long-Term Analyses of SARS-CoV-2 Humoral and T Cell Responses and Breakthrough SARS-CoV-2 Infections after Two Doses of BNT162b2 Followed by mRNA-1273 and Bivalent Omicron-Adapted BNT162b2 Vaccines: A Prospective Study over 2 Years in Non-Immunocompromised Individuals. Long-term analyses of the immune response following SARS-CoV-2 mRNA vaccines are essential to determining its characteristics and providing the basis for vaccination strategies. We conducted a prospective study in a cohort of 268 healthy adults followed for >2 years after two doses of BNT162b2. Antibodies targeting the receptor-binding domain of the S1 subunit of the spike of SARS-CoV-2 (anti-RBD) were measured at eight time points; T cell response was analyzed using an interferon-Î³ release assay. A total of 248 (93%) subjects received mRNA-1273 on month 9; 93 (35%) received the bivalent Omicron-adapted BNT162b2 vaccine between months 19 and 26. Breakthrough infections occurred in 215 (80%) participants, with frequencies unaffected by the additional vaccines. Anti-RBD declined over the initial 9 months, increased after mRNA-1273, and declined gradually thereafter. In 50 (17%) previously infected subjects, anti-RBD levels were significantly higher up to month 9 ($p < 0.05$) but subsequently declined below those of uninfected individuals. Anti-RBD titers protective against SARS-CoV-2 could not be defined. Most subjects developed a positive T cell response that remained after 26 months. Waning of protection against SARS-CoV-2 infection occurred over time, resulting in non-severe breakthrough infections in most participants. The evolution of anti-RBD suggests modulation of the immune response through immune imprinting.
Hearing Loss after COVID-19 and Non-COVID-19 Vaccination: A Systematic Review. (1) Background: Vaccine safety is an important topic with public health implications on a global scale. The purpose of this study was to systematically review available literature assessing sensorineural hearing loss (SNHL) incidence and severity following both coronavirus disease 2019 (COVID-19) and non-COVID-19 vaccinations, as well as prognosis and outcomes. (2) Methods: This systematic review was performed according to the Preferred Reporting Items for Systematic Review and Meta-Analysis guidelines. Relevant publications evaluating post-vaccination SNHL were selected from PubMed and Embase, searching from inception to July 2023. (3) Results: From 11 observational studies, the incidence of post-vaccination SNHL was low for both COVID-19 and non-COVID-19 vaccines, ranging from 0.6 to 60.77 per 100,000 person-years, comparable to all-cause SNHL. (4) Conclusions: The incidence rates of SNHL following COVID-19 and non-COVID-19 vaccinations remained reassuringly low. Most patients experienced improved hearing function in the weeks to months following vaccination. This study underscores the importance and safety of vaccinations and encourages ongoing surveillance and detailed reporting of hearing loss cases post-vaccination.
Intravenous Administration of Ad26.COV2.S Does Not Induce Thrombocytopenia or Thrombotic Events or Affect SARS-CoV-2 Spike Protein Bioavailability in Blood Compared with Intramuscular Vaccination in Rabbits. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a very rare but serious adverse reaction that can occur after Ad26.COV2.S vaccination in humans, leading to thrombosis at unusual anatomic sites. One hypothesis is that accidental intravenous (IV) administration of Ad26.COV2.S or drainage of the vaccine from the muscle into the circulatory system may result in interaction of the vaccine with blood factors associated with platelet activation, leading to VITT. Here, we demonstrate that, similar to intramuscular (IM) administration of Ad26.COV2.S in rabbits, IV dosing was well tolerated, with no significant differences between dosing routes for the assessed hematologic, coagulation time, innate immune, or clinical chemistry parameters and no histopathologic indication of thrombotic events. For both routes, all other non-adverse findings observed were consistent with a normal vaccine response and comparable to those observed for unrelated or other Ad26-based control vaccines. However, Ad26.COV2.S induced significantly higher

levels of C-reactive protein on day 1 after IM vaccination compared with an Ad26-based control vaccine encoding a different transgene, suggesting an inflammatory effect of the vaccine-encoded spike protein. Although based on a limited number of animals, these data indicate that an accidental IV injection of Ad26.COV2.S may not represent an increased risk for VITT.

Sex Differences in Serious Adverse Events Reported Following Booster Doses of COVID-19 Vaccination in Thailand: A Countrywide Nested Unmatched Case-Control Study. A booster dose of a COVID-19 vaccine has been proven effective in restoring vaccine effectiveness and is currently recommended for use in some populations at risk of severe COVID-19 infection. Since sex differences in adverse events are significant in response to the vaccines, the safety of booster selection must be studied to avoid serious adverse events (SAE), such as life-threatening diseases. First, this study aimed to identify sex differences in SAE incidences using a prospective cohort design. Second, a nested unmatched case-control study was used to identify factors associated with reported SAE within 30 days after the booster shot. Multivariable logistic regression indicated the adjusted odds ratio by accounting for host and vaccine variables, thus, policy effects. The findings confirmed that SAE was rare and that age-sex-dominated disease classifications differed. Specific to SAE following the booster dose, we found that females aged 12-40 had a higher risk of being reported with SAE than males of the same age, while males over 50 had a higher risk than females. Other risk factors identified were the presence of metabolic syndrome and the use of certain vaccine brands. Mechanisms could be explained by individual host responses rather than the vaccines' direct effect. Therefore, SAE could be preventable by age-sex-specific vaccine selection, post-vaccination precautions, and early symptom detection. Future vaccine development should aim to limit host-specific reactogenicity for safety concerns.

The Impact of Vaccination against SARS-CoV-2 on Health Outcomes and Hospital Visits after Omicron Infection in Children and Adolescents Aged 5-18 Years: A Danish Nation-Wide Cohort Study. This study investigates the impact of vaccination against SARS-CoV-2 on health outcomes and hospital contacts in children and adolescents aged 5-18 years infected with the SARS-CoV-2 Omicron variant, comparing previously vaccinated with unvaccinated. Using national register data, vaccinated and unvaccinated Danish children and adolescents with a positive SARS-CoV-2 test between 1 January and 31 March 2022 (Omicron dominance period) were included. The Prior Event Rate Ratio (PERR) was used to explore differences in hospital contacts (hospitalizations and emergency room (ER) visits), while Inverse Treatment Probability Weighted (IPW) risk ratios were used to explore the risk of severe health outcomes within six weeks following SARS-CoV-2 infection. Vaccinated 5-11-year-old girls had fewer visits to the ER compared to unvaccinated ones, PERR 0.92 (95% CI 0.84-1.00). Vaccinated 5-11-year-old boys had fewer hospitalizations (PERR 0.79 (0.64-0.99)) and more ER visits (PERR 1.13 (1.04-1.22)) compared to unvaccinated ones. An unadjusted and significant lower risk of febrile seizure among vaccinated 5-11-year-olds compared to unvaccinated ones was found (risk ratio 0.12 (0.04-0.39), p â‰¤ 0.01. No significant differences were found for severe conditions or for croup or pneumonia in either age group. The results indicate a modest protective effect of the vaccine in terms of hospital contacts, but no protective effect on health outcomes after SARS-CoV-2 Omicron infection in this population of Danish children and adolescents.

Dose Intervals and Time since Final Dose on Changes in Metabolic Indices after COVID-19 Vaccination. The rapid development and implementation of COVID-19 vaccines merit understanding its effects on metabolic indices. This retrospective longitudinal study investigated the influence of first-to-second-dose intervals and time since the final dose on the metabolic indices of individuals receiving COVID-19 vaccinations. A total of 318 Saudi subjects (59.7% females) aged 12-60 years received COVID-19 vaccines via the national vaccination program. We collected the anthropometric data and fasting blood samples at specific time points before vaccination and after the final vaccination dose, and

biochemical metabolic indices, including glucose and lipid profile, were measured. We also collected the dates of vaccination and COVID-19 history during the study period. The participants were stratified into groups based on first-to-second-dose intervals and time since the final dose to compare pre-and post-vaccination changes in metabolic indices between the groups. Logistic regression analysis revealed no differences in pre- to post-vaccination metabolic status between groups based on first-to-second-dose intervals in either adolescents or adults. However, shorter intervals (â‰¤6 months) between the final dose and follow-up were associated with a decrease in total cardiometabolic components, especially triglyceride levels (OR = 0.39, 95% CI: (0.22-0.68), p < 0.001) than longer intervals (>6 months) in adults. In conclusion, time duration since final dose was associated with pre- to post-vaccination changes in metabolic indices, especially triglyceride levels, indicating that post-vaccination improvements wane over time. Further research is needed to validate the observed relationship, as it may contribute to optimizing vaccine effectiveness and safety in the future.

Association between COVID-19 Infection or Vaccination Outcomes and Methylenetetrahydrofolate Reductase Gene Polymorphism: A Systematic Review of the Literature. BACKGROUND: Thrombosis is a detrimental sequala of COVID-19 infection; thus, prophylactic anti-coagulant therapy has been deemed mandatory in treatment unless serious contraindications are present. Susceptibility to thromboembolic events in COVID-19, or following COVID-19 vaccination, is likely attributable to an interplay of factors, including a patient's baseline clinical status and comorbidities, alongside genetic risk factors. In Europe, 8-20% of the population are homozygous for the MTHFR (methylene tetrahydrofolate reductase) variant, which compromises folate metabolism and elevates homocysteine levels. While heightened homocysteine levels are considered a risk factor for thromboembolic events, the precise clinical significance remains a contentious issue. However, recent research suggests elevated homocysteine levels may predict the course and severity of COVID-19 infection. Given the lack of reliable biomarkers predictive of COVID-19 thrombotic risk existing in practice, and the accessibility of MTHFR screening, we established two main outcomes for this study: (1) to determine the association between hereditary MTHFR mutations and COVID-19 severity and thromboembolic events and (2) to determine the link between MTHFR variants and adverse thrombotic events following COVID-19 vaccination. METHODS: The review was conducted in accordance with PRISMA guidelines. Medline, Scopus, and Web of Science databases were searched from pandemic inception (11 March 2020) to 30 October 2023. Eligibility criteria were applied, and data extraction performed. RESULTS: From 63 citations identified, a total of 14 articles met the full inclusion criteria (8 of which were cross-sectional or observational studies, and 6 were case studies or reports). Among the eight observational and cross-sectional studies evaluating the relationship between MTHFR variants (C667T; A1298C) and thromboembolic events in COVID-19 infection, four studies established a connection (n = 2200), while the remaining four studies failed to demonstrate any significant association (n = 38). CONCLUSIONS: This systematic review demonstrated a possible association between the MTHFR gene variants and COVID-19 severity, thromboembolic events, and adverse events following vaccination. However, the paucity of robust data precluded any firm conclusions being drawn. Further prospective trials are required to determine the connection between the MTHFR gene variant and COVID-19 infection and vaccination outcomes.

Giant Cell Arteritis after COVID-19 Vaccination with Long-Term Follow-Up: A Case Report and Review of the Literature. Giant cell arteritis (GCA) is a chronic vasculitis that primarily affects the elderly, and can cause visual impairment, requiring prompt diagnosis and treatment. The global impact of the coronavirus disease 2019 (COVID-19) pandemic has been substantial. Although vaccination programs have been a key defense strategy, concerns have arisen regarding post-vaccination immune-mediated disorders and related risks. We present a case of GCA after COVID-19 vaccination with 2

years of follow-up. A 69-year-old woman experienced fever, headaches, and local muscle pain two days after receiving the COVID-19 vaccine. Elevated inflammatory markers were observed, and positron emission tomography (PET) revealed abnormal uptake in the major arteries, including the aorta and subclavian and iliac arteries. Temporal artery biopsy confirmed the diagnosis of GCA. Treatment consisted of pulse therapy with methylprednisolone, followed by prednisolone (PSL) and tocilizumab. Immediately after the initiation of treatment, the fever and headaches disappeared, and the inflammation markers normalized. The PSL dosage was gradually reduced, and one year later, a PET scan showed that the inflammation had resolved. After two years, the PSL dosage was reduced to 3 mg. Fourteen reported cases of GCA after COVID-19 vaccination was reviewed to reveal a diverse clinical picture and treatment response. The time from onset of symptoms to GCA diagnosis varied from two weeks to four months, highlighting the challenge of early detection. The effectiveness of treatment varied, but was generally effective similarly to that of conventional GCA. This report emphasizes the need for clinical vigilance and encourages further data collection in post-vaccination GCA cases.

Post-COVID-19 and Post-COVID-19 Vaccine Arthritis, Polymyalgia Rheumatica and Horton's Arteritis: A Single-Center Assessment of Clinical, Serological, Genetic, and Ultrasonographic Biomarkers. The potential role of the COVID-19 vaccine and infection to induce autoimmunity is currently underestimated despite the literature emphasizing arthralgia as a common adverse event. We aimed to study the impact of rheumatological complications post-COVID-19 (PC) and post-COVID-19 vaccine (PCV), comparing undifferentiated arthritis (UA) to Polymyalgia Rheumatica, Horton's Arteritis (PMR-HA) and isolated arthritis to UA with "connective-like" accompanying symptoms. We retrospectively included 109 patients with at least 6 months of follow-up, analyzing serum biomarkers, joint ultrasound (US), lung HRCT, DLCO, and HLA haplotypes. There were 87 UA patients showing increased gastrointestinal and lung involvement ($p = 0.021$ and $p = 0.012$), higher anti-spike protein IgG levels ($p = 0.003$), and anti-SARS-CoV-2 IgG positivity ($p = 0.003$). Among them, 66 cases progressed to ACR-EULAR 2010 early arthritis after 3 months, whereas PMR-HA patients were more commonly PCV (81.8%, $p = 0.008$), demonstrating higher CRP ($p = 0.007$) and ESR ($p = 0.006$) levels, a lower rate of ANA positivity ($p = 0.005$), and a higher remission rate after six months ($p = 0.050$). In UA patients, the prevalent HLA was DRB1*11 and C*07 (36.8% and 42.1%). Serum calprotectin, interleukin-6, and C*07 ($p = 0.021$, 0.041, 0.018) seemed more specific for isolated UA. Conversely, "connective-like" arthritis showed poorer DLCO ($p = 0.041$) and more frequent US synovitis ($p = 0.041$). In conclusion, UA is a frequent common PC and PCV complication and may persist over time when compared to PMR-HA.

COVID-19 Vaccination-Related Delayed Adverse Events among Patients with Systemic Lupus Erythematosus. BACKGROUND: The safety profile of COVID-19 vaccination is well documented, but hesitancy among people with immune-mediated inflammatory diseases, often immunocompromised, remains high, partially due to a scarcity of data on safety over a longer term. We herein aimed to assess delayed adverse events (DAEs) occurring >7 days after COVID-19 vaccination in systemic lupus erythematosus (SLE) versus other rheumatic autoimmune diseases (rAIDs), non-rheumatic AIDs (nrAIDs), and healthy controls (HCs). METHODS: Self-reported data were captured within the COVID-19 Vaccination in Autoimmune Diseases (COVAD)-2 online survey, which comprised >150 centres and responses from 106 countries, between February and June 2022. Logistic regression analysis adjusting for important confounders (age, sex, ethnicity) was used to compare groups. RESULTS: Of 7203 eligible individuals, 882 (12.2%) patients had SLE, 3161 (43.9%) patients had rAIDs, 426 (5.9%) patients had nrAIDs, and 2734 (38.0%) were HCs. SLE patients had a median age of 39 years (IQR: 31-50); 93.7% were women. SLE patients reported, more frequently, major DAEs (OR: 1.6; 95% CI: 1.2-2.0; $p = 0.001$) and hospitalisation (OR: 2.2; 95% CI: 1.4-3.4; $p < 0.001$) compared

to HCs, severe rashes (OR: 2.4; 95% CI: 1.3-4.2; p = 0.004) compared to people with rAIDS, and hospitalisation (OR: 2.3; 95% CI: 1.1-4.9; p = 0.029) as well as several minor DAEs compared to people with nrAIDs. Differences were observed between vaccines in terms of frequency of major DAEs and hospitalisations, with the latter seen more frequently in patients receiving the Moderna vaccine. People with SLE with no autoimmune multimorbidity less frequently reported overall minor DAEs compared to SLE patients with comorbid nrAIDs (OR: 0.5; 95% CI: 0.3-1.0; p = 0.036). CONCLUSION: Hospitalisations post-vaccination were more frequent in SLE patients than in HCs. Monitoring of SLE patients following COVID-19 vaccination can help in identifying DAEs early, informing patients about expected DAEs, and supporting patients, especially those with autoimmune multimorbidity.

The Serum ACE2, CTSL, AngII, and TNFÎ± Levels after COVID-19 and mRNA Vaccines: The Molecular Basis. BACKGROUND: The SARS-CoV-2 virus as well as the COVID-19 mRNA vaccines cause an increased production of proinflammatory cytokines. AIM: We investigated the relationship between ACE2, CTSL, AngII, TNFÎ± and the serum levels of IL-6, IL-10, IL-33, IL-28A, CD40L, total IgM, IgG, IgA and absolute count of T- and B-lymphocytes in COVID-19 patients, vaccinees and healthy individuals. METHODS: We measured the serum levels ACE2, AngII, CTSL, TNFÎ± and humoral biomarkers (CD40L, IL-28A, IL-10, IL-33) by the ELISA method. Immunophenotyping of lymphocyte subpopulations was performed by flow cytometry. Total serum immunoglobulins were analyzed by the turbidimetry method. RESULTS: The results established an increase in the total serum levels for ACE2, CTSL, AngII and TNFÎ± by severely ill patients and vaccinated persons. The correlation analysis described a positive relationship between ACE2 and proinflammatory cytokines IL-33 (r = 0.539) and CD40L (r = 0.520), a positive relationship between AngII and CD40L (r = 0.504), as well as between AngII and IL-33 (r = 0.416), and a positive relationship between CTSL, total IgA (r = 0.437) and IL-28A (r = 0.592). Correlation analysis confirmed only two of the positive relationships between TNFÎ± and IL-28A (r = 0.491) and CD40L (r = 0.458). CONCLUSIONS: In summary, the findings presented in this study unveil a complex web of interactions within the immune system in response to SARS-CoV-2 infection and vaccination.

"Multisystem Inflammatory Syndrome in Children"-Like Disease after COVID-19 Vaccination (MIS-V) with Potential Significance of Functional Active Autoantibodies Targeting G-Protein-Coupled Receptors (GPCR-fAAb) for Pathophysiology and Therapy. BACKGROUND: An infection with SARS-CoV-2 can trigger a systemic disorder by pathological autoimmune processes. A certain type of this dysregulation is known as Multisystemic inflammatory syndrome in children (MIS-C). However, similar symptoms may occur and have been described as Multisystemic inflammatory syndrome after SARS-CoV-2 Vaccination (MIS-V) following vaccination against SARS-CoV-2. We report the case of a 12-year-old boy who was identified with MIS-C symptoms without previous SARS-CoV-2 infection after receiving two doses of the Pfizer-BioNTech COVID-19 vaccine approximately one month prior to the onset of symptoms. He showed polyserositis, severe gastrointestinal symptoms and, consequently, a manifestation of a multiorgan failure. IgG antibodies against spike proteins of SARS-CoV-2 were detected, indicating a successful vaccination, while SARS-CoV-2 Nucleocapsid protein antibodies and SARS-CoV-2 PCR were not detected. Several functional, active autoantibodies against G-protein-coupled receptors (GPCR-fAAb), previously associated with Long COVID disease, were detected in a cardiomyocyte bioassay. Immunosuppression with steroids was initiated. Due to side effects, treatment with steroids and later interleukin 1 receptor antagonists had to be terminated. Instead, immunoadsorption was performed and continued with tacrolimus and mycophenolic acid therapy, leading to improvement and discharge after 79 days. GPCR-fAAb decreased during therapy and remained negative after clinical curing and under continued immunosuppressive therapy with tacrolimus and mycophenolic acid. Follow-up of the patient showed him in good condition after one year. CONCLUSIONS: Infection with SARS-CoV-2 shows a broad and severe variety of symptoms,

partly due to autoimmune dysregulation, which, in some instances, can lead to multiorgan failure. Despite its rarity, post-vaccine MIS-C-like disease may develop into a serious condition triggered by autoimmune dysregulation. The evidence of circulating GPCR-fAAb and their disappearance after therapy suggests a link of GPCR-fAAb to the clinical manifestations. Thus, we hypothesize a potential role of GPCR-fAAb in pathophysiology and their potential importance for the therapy of MIS-C or MIS-V. However, this observation needs further investigation to prove a causative correlation.

Acceptance of COVID-19 vaccine and associated factors among healthcare workers in Katsina state: a cross-sectional study in Northwest Nigeria. OBJECTIVES: Healthcare workers were prioritised to receive the COVID-19 vaccine in Nigeria. Administration of COVID-19 vaccination in Nigeria was challenging because of a lack of trust in vaccine safety and vaccine effectiveness among healthcare workers, who are expected to provide reliable information about vaccines and vaccine-preventable diseases in the communities. Hence, their acceptance and attitudes towards COVID-19 preventive practices could influence the acceptance of the vaccine by the local population. This cross-sectional study assessed the acceptance of the COVID-19 vaccine among healthcare workers in Katsina State. We predicted the variables that increased the vaccine acceptance using logistic regression analysis. SETTING: This hospital-based study was conducted at primary, secondary and tertiary healthcare facilities in Nigeria. PARTICIPANTS: A total of 793 healthcare workers were included in this study. Of these, 65.4% (n=519) were male. OUTCOME MEASURES: To assess acceptance of COVID-19 vaccine measures, and factors increasing acceptance among healthcare workers. RESULTS: Of the healthcare workers, 80% (638) were tested for the SARS-CoV-2, of whom 10.8% (n=65) tested positive. Approximately 97% (n=765) of them believed that the COVID-19 vaccine was safe, and 90% (n=714) received the first dose of the vaccine. Healthcare workers between 30 and 39 years were more likely to accept the vaccine (aOR: 7.06; 95%â€‰CI 2.36 to 21.07; p<0.001). Those who had been tested for COVID-19 were more likely (aOR:7.64; 95%â€‰CI 3.62 to 16.16; p<0.001) to accept the vaccine. CONCLUSIONS: Our findings showed that the age and prior COVID-19 testing were the main factors influencing the acceptance of the COVID-19 vaccine. There was high acceptance of the COVID-19 vaccine among healthcare workers in Katsina State, Nigeria. Future studies should focus on the completion of doses and serological testing for immunity.

No association between SARS-CoV-2 vaccination and ischaemic stroke or high-risk transient ischaemic attack. BACKGROUND: Initiation of SARS-CoV-2 (Severe acute respiratory syndrome coronavirus type 2) vaccinations aroused scepticism within the general-public about risks including stroke. Our aim was to explore temporal associations between vaccination and cerebrovascular events through an analysis of a prospective large-scale cohort of consecutive stroke and high-risk TIA (transitory ischaemic attack) patients. METHODS: We prospectively recruited a cohort of consecutive ischaemic stroke and high-risk TIA (ABCD2-ScoreÂ â‰¥Â 4) patients treated at the Innsbruck University Hospital (STROKE-CARD Registry Study, NCT04582825) from December 2020 until February 2022. SARS-CoV-2 vaccination status and the time of administration was ascertained by electronic health-data. A Cox model with vaccination status as time-dependent co-variable was employed to examine its association with ischaemic events. RESULTS: Data on 572 participants were available with 355 (62.1%) vaccinated against SARS-CoV-2 before suffering cerebral ischaemia. In our cohort, no temporal association between vaccination and cerebrovascular event was detected (HR 1.06 [0.85-1.34; pÂ =Â 0.60]) and this also applies to TIA (HR [0.82 0.37-1.85; pÂ =Â 0.64]) or minor stroke (HR 1.18 [0.89-1.56; pÂ =Â 0.26]) and subgroups defined by sex and age. Neither vector-based (HR 1.11 [0.79-1.56; pÂ =Â 0.55]) nor mRNA-based (HR 1.06 [0.84-1.34; pÂ =Â 0.61]) vaccinations were associated with the occurrence of cerebral ischaemia. CONCLUSION: Among patients with stroke or high-risk TIA, SARS-CoV-2 vaccination was not associated with cerebral ischaemia.

Seroprevalence Of SARS-COV-2 infection in asymptomatic indigenous from the largest Brazilian periurban area. This study assessed the seroprevalence of SARS-CoV-2 in 496 asymptomatic individuals from Mato Grosso do Sul, located in Dourados, the largest periurban indigenous area in Brazil, from January 25 to February 4, 2021. The volunteers participated before receiving their first dose of the CoronaVac inactivated vaccine. For screening, blood samples were collected and analyzed using SARS-CoV-2 rapid tests and the enzyme-linked immunosorbent assay (ELISA). We observed varying trends in total anti-SARS-CoV-2 antibodies across different variables. Seropositivity among the participants tested was 63.70% (316/496) using the rapid test and 52.82% (262/496) were positive using the ELISA method. The majority of participants identified with the Guarani-KaiowÃ¡ ethnic group, with 66.15% (217/328), and other ethnic groups with 58.84% (193/328). The median age of the subjects was 30.5 years, with 79.57% (261/328) being femaleThis research showed the elevated seroprevalence of SARS-CoV-2 antibodies in asymptomatic Brazilians. The findings indicate a high seropositivity rate among the asymptomatic indigenous population of Midwest Brazil. This underscores the overlooked status of these communities and underscores the need for targeted national initiatives that emphasize the protection of vulnerable ethnic groups in the fight against COVID-19.

Factors Associated with COVID-19 Vaccination among Racial/Ethnic Minority Groups with HIV in South Florida. BACKGROUND: Racial/ethnic minority groups with HIV in the United States are particularly vulnerable to COVID-19 consequences and can significantly benefit from increased uptake of COVID-19 vaccines. This study identified factors associated with full COVID-19 vaccination among people with HIV. SETTING: Ryan White HIV/AIDS Program (RWP) in Miami-Dade County, Florida. METHODS: Data were collected from 299 RWP adult clients during January-March 2022 using a cross-sectional phone survey. Multivariable logistic regression was used to estimate adjusted odds ratios (aORs) with 95% confidence intervals (CIs). All analyses were weighted to be representative of the race/ethnicity and sex distribution of clients in the RWP. RESULTS: Eighty-four percent of participants were fully vaccinated with a primary vaccine series; stratified by race/ethnicity, the percentages were 88.9% of Hispanic, 72.0% of Black/African American, and 67.5% of Haitian participants. Fully vaccinated participants were less likely to be Black/African American than Hispanic (aOR=0.18; 95% CI=0.05-0.67) and more likely to not endorse any misconceptions about COVID-19 vaccines (aOR=8.26; 95% CI=1.38-49.64), to report encouragement to get vaccinated from sources of information (aOR=20.82; 95% CI=5.84-74.14), and to perceive that more than 50% of their social network was vaccinated (aOR=3.35; 95% CI=1.04-10.71). Experiences of healthcare discrimination, structural barriers to access vaccines, and recommendations from HIV providers were not associated with full vaccination. CONCLUSIONS: These findings highlight the importance of delivering accurate and positive messages about vaccines and engaging social networks to promote COVID-19 vaccination among PWH. This information can be leveraged to promote uptake of subsequent boosters and other recommended vaccines.

Trends in the COVID-19 Pandemic in Italy during the Summers of 2020 (before Mass Vaccination), 2021 (after Primary Mass Vaccination) and 2022 (after Booster Mass Vaccination): A Real-World Nationwide Study Based on a Population of 58.85 Million People. Like all RNA viruses, SARS-CoV-2 shows a high mutation rate, which has led to the emergence of new variants. Among them, Gamma and Delta developed at the turn of 2020-2021 in Amazonas and India, two ecoregions characterized by hot-humid weather, very similar to that of the summer season in Italy due to climate change, the first Western country to be hit hard by COVID-19 and to experience lockdown restrictions in a democratic framework of 58.85 million people. The aim of our research has been to evaluate the impact of climate on the COVID-19 pandemic in Italy during the summers of 2020 (before mass vaccination), 2021 (after primary mass vaccination) and 2022 (after booster mass vaccination), also

taking into account the emergence of these two variants. METHODS: During the state of national health emergency and the Draghi government, the Civil Defense Department released the aggregate data coming from the Ministry of Health, the Higher Institute of Health, the Independent Provinces and the Italian Regions daily, in order to inform about the pandemic situation in Italy. Among these data there were the number of deaths, hospitalizations in intensive care units (ICU), non-ICU patients, contagions and performed swabs. By means of a team effort, we have collected and elaborated all these data, comparing the COVID-19 pandemic in Italy during the summers of 2020 (following the nationwide lockdown), 2021 and 2022. RESULTS: from the summer of 2020 to the summers of 2021 and 2022 all pandemic trend indicators have shown a sharp worsening in Italy. COVID-19 deaths increased by â‰ˆ298% and â‰ˆ834%, ICU hospitalizations by â‰ˆ386% and â‰ˆ310%, non-ICU hospitalizations by â‰ˆ224% and â‰ˆ600%, contagions by â‰ˆ627% and â‰ˆ6850% (i.e., â‰ˆ68.50 times), swabs by â‰ˆ354% and â‰ˆ370%, and the mean positivity rate passed from â‰ˆ1% to â‰ˆ2% and â‰ˆ20%, respectively. CONCLUSIONS: SARS-CoV-2 can be transmitted in any climate, including areas with hot and humid weather, and the emergence of variants adapted to hot-humid climates may result in summer COVID-19 outbreaks, even in neither tropical nor subtropical countries. Although COVID-19 vaccines can confer cross-protection against newly emerging variants, this cross-immunity is naturally not absolute but limited, considering that vaccine protection wanes significantly after 6 months. It follows that a subject vaccinated at the beginning of the winter will not be completely covered in the height of the summer, and we should not forget the unvaccinated. As a final remark, the long and strict nationwide lockdown made it possible to flatten SARS-CoV-2 circulation and, therefore, its negative impact on Italy during the summer of 2020.

Patient Presentations in a Community Pain Clinic after COVID-19 Infection or Vaccination: A Case-Series Approach. OBJECTIVES: Early case report studies and anecdotes from patients, medical colleagues, and social media suggest that patients may present to chronic pain clinics with a number of complaints post COVID-19 infection or vaccination. The aim of this study is to systematically report on a consecutive series of chronic pain patients seen in a community-based pain clinic, who acquired symptoms after COVID-19 infection or vaccination. METHODS: This retrospective cross-sectional descriptive study identified all patients seen at the clinic over a 4-month period (January-April 2022) with persistent symptoms after COVID-19 infection, vaccination, or both. Information was collected on sex, gender, age, details of vaccination, new pains, or exacerbation of old pain plus the development of novel symptoms. RESULTS: The study identified 21 community dwellers (17 females and 4 males; F/M 4.25/1; age range 22-79 years; mean age 46.3 years), with symptoms attributed to COVID-19 infection or vaccination. Several patients suffered exacerbation of previous pains or developed novel pains, as well as high levels of anxiety and mood disorders. A review of the existing literature provides support for the spectrum of symptoms displayed by the study group. CONCLUSIONS: Information collected in this study will add to the body of COVID-19-related literature and assist particularly community practitioners in recognizing and managing these conditions.

Decreased Self-reported Physical Fitness Following SARS-CoV-2 Infection and the Impact of Vaccine Boosters in a Cohort Study. BACKGROUND: The long-term effects of coronavirus disease 2019 (COVID-19) on physical fitness are unclear, and the impact of vaccination on that relationship is uncertain. METHODS: We compared survey responses in a 1-year study of US military service members with (n = 1923) and without (n = 1591) a history of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. We fit Poisson regression models to estimate the association between history of SARS-CoV-2 infection and fitness impairment, adjusting for time since infection, demographics, and baseline health. RESULTS: The participants in this analysis were primarily young adults aged 18-39 years (75%), and 71.5% were male. Participants with a history of SARS-CoV-2 infection were more likely to report difficulty exercising (38.7% vs 18.4%; P < .01), difficulty

performing daily activities (30.4% vs 12.7%; P < .01), and decreased fitness test (FT) scores (42.7% vs 26.2%; P < .01) than those without a history of infection. SARS-CoV-2-infected participants were at higher risk of these outcomes after adjusting for other factors (unvaccinated: exercising: adjusted risk ratio [aRR], 3.99; 95% CI, 3.36-4.73; activities: aRR, 5.02; 95% CI, 4.09-6.16; FT affected: aRR, 2.55; 95% CI, 2.19-2.98). Among SARS-CoV-2-positive participants, full vaccination before infection was associated with a lower risk of post-COVID-19 fitness impairment (fully vaccinated: exercise: aRR, 0.81; 95% CI, 0.70-0.95; activities: aRR, 0.76; 95% CI, 0.64-0.91; FT: aRR, 0.87; 95% CI, 0.76-1.00; boosted: exercise: aRR, 0.62; 95% CI, 0.51-0.74; activities: aRR, 0.52; 95% CI, 0.41-0.65; FT: aRR, 0.59; 95% CI, 0.49-0.70). CONCLUSIONS: In this study of generally young, healthy military service members, SARS-CoV-2 infection was associated with lower self-reported fitness and exercise capacity; vaccination and boosting were associated with lower risk of self-reported fitness loss.

Chest pain attendances to a Paediatric Emergency Department pre- and post-COVID-19 vaccination. BACKGROUND: Introduction of the mRNA vaccination for coronavirus disease 2019 (COVID-19) has been associated with an increase in cases of peri/myocarditis. In our retrospective cross-sectional study, we aim to (I) describe paediatric chest pain attendance, and (II) study resource utilisation in the Emergency Department (ED) of KK Women's and Children's Hospital (KKH), stratified by pre-pandemic, during the pandemic pre- and post-COVID vaccination introduction in adolescents. METHODS: We reviewed records of adolescents aged 12 to 18 years old who presented to our ED with the triage complaint of chest pain between 1 January 2019 to 31 January 2022, and determined the attendance rates, aetiologies and resource utilisation during the above time periods. RESULTS: There were 2,418 ED attendances for chest pain in our study population. Among 887 inpatient admissions for chest pain, 1.8% were attributed to a cardiac cause. Comparing the pre-pandemic period to the period after the mRNA COVID-19 vaccination was introduced, ED chest pain rates increased from a median of 0.5% of ED attendances [interquartile range (IQR), 0.3-0.5%] to 0.9% (IQR, 0.7-2.0%) (P<0.001), while admission rates increased from a median of 26.2% of ED attendances (IQR, 24.1-29.1%) to 40.9% (IQR, 37.6-56.6%) (P<0.001). Cardiac enzyme orders among ED visits for chest pain increased from a pre-pandemic median of 0% (IQR, 0.0-2.6%) to a post-vaccination median of 26.1% (IQR, 17.2-56.2%) (P<0.001) and were due to concerns for vaccine-related myocarditis. Seven cases of probable vaccine-related myocarditis presented with chest pain to our ED. CONCLUSIONS: Paediatric chest pain is largely non-cardiac in origin. ED chest pain attendance rates and resource utilisation increased after the introduction of mRNA COVID-19 vaccination in adolescents.

A Case of Diabetic Chorea Secondary to Appetite Loss Due to COVID-19 Vaccination. A 76-year-old woman with type 2 diabetes mellitus was admitted to our hospital with a complaint of involuntary movements of the limbs and face. Brain MRI demonstrated a bilateral high signal of putamen on the T1 weighted image, and she was diagnosed with diabetic chorea. She took a second dose of the COVID-19 vaccine 28 days before admission and lost her appetite. Consequently, her HbA1c level on admission decreased from 13.5% to 10.0% in 28 days. This case suggests that diabetic chorea could be induced by the rapid amelioration of a hyperglycemic state due to appetite loss after COVID-19 mRNA vaccination.

Comment on "SARS-CoV-2 vaccine safety and COVID-19 risk perception in hematopoietic stem cell transplant recipients".

Strategies for the development and approval of COVID-19 vaccines and therapeutics in the post-pandemic period. The spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has resulted in significant casualties and put immense strain on public health systems worldwide, leading to economic recession and social unrest. In response, various prevention and control strategies have been implemented globally, including vaccine and drug development and the promotion of preventive measures. Implementing these strategies has effectively curbed the

transmission of the virus, reduced infection rates, and gradually restored normal social and economic activities. However, the mutations of SARS-CoV-2 have led to inevitable infections and reinfections, and the number of deaths continues to rise. Therefore, there is still a need to improve existing prevention and control strategies, mainly focusing on developing novel vaccines and drugs, expediting medical authorization processes, and keeping epidemic surveillance. These measures are crucial to combat the Coronavirus disease (COVID-19) pandemic and achieve sustained, long-term prevention, management, and disease control. Here, we summarized the characteristics of existing COVID-19 vaccines and drugs and suggested potential future directions for their development. Furthermore, we discussed the COVID-19-related policies implemented over the past years and presented some strategies for the future.

Axillary Lymphadenopathy Can Be Long Lasting Finding on MRI After COVID-19 Booster Vaccination.

Case Study of Autopsy Findings in a Population of Post-COVID-19 Vaccination in Thailand.
Thailand began offering the coronavirus disease 2019 (COVID-19) vaccine nationwide in February 2021, with 1,885 deaths reported by the end of the year. Therefore, it is essential to assess the correlation between vaccination and cause of death from autopsy. This study included 34 autopsies of a deceased within 30 days after COVID-19 vaccination performed in Bangkok under the postmortem inquest service area of Bhumibol Adulyadej Hospital. The autopsies were performed by forensic pathologists. Moreover, detailed information about the deceased was collected, including age, sex, medical records, vaccination history, scene investigation reports, autopsy reports, cause of death, and a probable causal relationship between vaccination and cause of death. There were 24 males (70.59%), and the average age of the deceased was 52.76 years. Of all individuals, 28 (82.36%), 4 (11.76%), and 2 (5.88%) were vaccinated with AstraZeneca, Sinopharm, and SinoVac, respectively. The most common cause of death was ischemic heart disease (n = 17). None of the deceased patients had a causal relationship to the vaccine. Deaths were due to natural causes, as no definitive link between vaccination and cause of death was established in the study.

Clinical-epidemiological characteristics and survival of cases of severe acute respiratory syndrome (SARS) due to COVID-19, according to the COVID-19 vaccination schedule in Brazil, 2021-2022: a prospective study. OBJECTIVE: To analyze the clinical and sociodemographic characteristics and survival of individuals with severe acute respiratory syndrome due to COVID-19 according to the COVID-19 vaccination schedule, Brazil, 2021-2022. METHODS: This was a cohort study based on data from the Influenza Epidemiological Surveillance Information System; the Kaplan-Meier and Survival Tree methods were used to analyze survival. RESULTS: Among the 559,866 hospitalized cases, a higher proportion of vaccinated individuals was found among female (15.0%), elderly people aged â‰¥ 80 (34.5%), people from the Southeast region (15.7%), those who did not undergo respiratory support (21.2%) and those who did progress to death (15.2%); the survival curve showed that risk of death for unvaccinated individuals was higher in all age groups (p-value < 0.001); elderly people aged â‰¥ 80, who did not undergo mechanical ventilation and who had a booster dose had lower risk when compared to their peers who had two doses or were unvaccinated (hazard ratio = 0.64; 95%CI 0.62;0.67). CONCLUSION: Lowest risk of death was found in vaccinated individuals, especially those who had two doses or a booster dose as well. MAIN RESULTS: Prevalence was found to be high among unvaccinated individuals. Risk of death was lower among those vaccinated with a booster dose, compared to those not vaccinated, in all age groups analyzed. IMPLICATIONS FOR SERVICES: The number of hospitalizations of unvaccinated individuals with severe acute respiratory syndrome was high, which increases the demand for health services to care for these individuals. PERSPECTIVES: It is necessary to promote widespread vaccination of the entire population of Brazil, in addition to the regular provision of booster doses for the different population groups.

Cutaneous manifestations of the COVID-19 pandemic in schoolchildren and adolescents. This review article focuses on cutaneous manifestations in schoolchildren and adolescents 6 to 18 years old connected with various aspects of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, including personal protective equipment (PPE), SARS-CoV-2 infection, and the SARS-CoV-2 vaccine. The use of PPE has been associated with mask-related acne due to microbiome dysbiosis and disruption of skin homeostasis, leading to the emergence of new acne or exacerbation of preexisting acne. Chilblain-like lesions, erythema multiforme-like eruptions, and cutaneous manifestations of multisystem inflammatory syndrome related to SARS-CoV-2 are the most commonly described skin manifestations of SARS-CoV-2 infection. The proposed mechanisms involve either the direct interaction of the virus with the skin through cutaneous receptor angiotensin-converting enzyme 2 in the epidermal basal layer or hyperactive immune responses. The impact of SARS-CoV-2 infection has also been described on adnexa, including hair changes such as alopecia areata and telogen effluvium, as well as nail changes presenting as onychomadesis and periungual desquamation. Cutaneous adverse effects of the SARS-CoV-2 vaccine have been described in case reports and differ from those in adults. Therefore, there is a need for increased awareness regarding the most prevalent cutaneous manifestations associated with COVID-19 in children because they tend to be mild or nonspecific in nature.

Corrigendum: FcÎ³RIIa-dependent platelet activation identified in COVID-19 vaccine-induced immune thrombotic thrombocytopenia-, heparininduced thrombocytopenia, streptokinase- and anisoylated plasminogen-streptokinase activator complex-induced platelet activation. [This corrects the article DOI: 10.3389/fcvm.2023.1282637.].

The value of serum neutralizing antibody in evaluating predictability of COVID-19 after recovery and the validation of vaccine. BACKGROUND: This work aimed to study natural humoral immune response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. METHODS: Chemiluminescent immunoassay (CLIA) was used to detect the neutralizing antibody (Nabs) and IgG. RESULTS: Nabs peaked on days 57-96 after symptom onset and remained detected on days 97-132. The Nabs in the 32 patients who were dynamically monitored showed four changing patterns. The titers of Nabs and IgG were correlated, and three modes of relationship were found between them. CONCLUSIONS: Nabs showed a regular change in the course of coronavirus disease 2019 (COVID-19). The detection of Nabs is very important for monitoring the course of COVID-19 and predicting the strength of antibody protection.

Humoral immune response in people living with HIV after administration of SARS-CoV-2 vaccine CoronaVac or BNT162b2 or CoronaVac/BNT162b2 booster sequence: A cross-sectional study. BACKGROUND: The evidence of SARS-CoV-2 vaccine effectiveness in people living with HIV (PLWH) is limited. This study evaluated the humoral immune response to CoronaVacâ„¢ (virus inactivated) and BNT162b2 (mRNA- based) vaccines in PLWH and HIV-negative controls, with and without a booster sequence. METHODS: We conducted a cross-sectional study on PLWH and HIV-negative controls who received CoronaVac or BNT162b2, with a subgroup receiving a CoronaVac/BNT162b2 booster. Blood samples were collected 4-6Â months after primary vaccination and tested for anti-SARS-CoV-2 protein S (aSAb) and neutralizing antibodies (NtAb) using validated assays. Immune response was evaluated by age, sex, previous COVID-19 history, and CD4Â +Â cell count. FINDINGS: One hundred and eighty nine participants were enrolled with 161 (85%) being PLWH. Among participants without previous known COVID-19, median aSAb levels were significantly lower in PLWH who received CoronaVac compared to BNT162b2 (32 U/mL vs. 587 U/mL, pÂ <Â 0.001), with similar results in HIV-negative controls. NtAb presence was also significantly lower after CoronaVac compared to BNT162b2 (30% vs. 93%, pÂ <Â 0.001). The booster sequence group showed a significant increase in aSAb titers in both PLWH and HIV-negative controls (from 33 U/ml to 2500 U/ml, pÂ <Â 0.001), and

NtAb positivity increased from 20% to 95 % in PLWH, and 27% to 100% in HIV-negative controls. Prior COVID-19 led to significantly higher post-vaccine antibody titers particularly in the BNT162b2 group. PLWH with CD4Â +Â countÂ <Â 200 cells/mL showed a weaker immune response to both vaccines. INTERPRETATION: CoronaVac resulted in a weaker immune response in both PLWH and HIV-negative controls compared to BNT162b2, particularly in immunosuppressed PLWH without prior COVID-19. Hybrid immunity and heterologous booster vaccination increased antibody levels. FUNDING: Local funding.

The spectrum of side effects associated with COVID-19 vaccines in patients with inborn errors of immunity. OBJECTIVE: COVID-19 immunization was implemented with emergency-use authorization. We had concerns/lack of information on mRNA vaccine side effects in different inborn errors of immunity (IEI) types. METHODS: We enrolled 141 patients (IEIP) and 151 healthy controls(HC) who received SARS-CoV-2 vaccine/s(Sinovac and/or Pfizer-BioNTech(mRNA vaccine), one to five doses), questioned them for side-effects, evaluated in three groups according to the vaccine/s they received; only Sinovac, only Pfizer-BioNTech, and both vaccines. RESULTS: Arm pain, generalized weakness, myalgia, and fever were common side effects in IEI-P and HC groups. Generalized weakness/fatigue, fever, and palpitation were significantly frequent in IEI-P who experienced COVID-19 compared to those who did not (pâ€¯=â€¯0.021, pâ€¯=â€¯0.047, and pâ€¯=â€¯0.024, respectively). Severe symptoms after vaccination, new-onset splenomegaly and pancytopenia, urticaria, herpes simplex virus (HSV), and varicella zoster virus (VZV) reactivation were seen in four IEI-P (2.8%). CONCLUSION: IEI-P mRNA vaccination is relatively safe compared to the conventional vaccine. Individuals who experience uncommon side effects should undergo immunological screening.

Stakeholders' perspectives on barriers to and facilitators of school-based HPV vaccination in the context of COVID-19 pandemic-related disruption: a qualitative mixed methods study. Despite successfully implementing the Human Papilloma Virus Vaccine (HPVV) program, Saskatchewan (SK) struggled to improve HPVV uptake rates. This suboptimal uptake of HPVV with a status quo of HPV-linked cervical cancer incidence rate is mainly because HPVV's impact on cancer prevention has not been realized adequately by vaccine providers and receivers. Further exploration of determinants of HPVV uptake is required to uncover high-resolution quality improvement targets for investment and situate contextually appropriate policies to improve its uptake. The study undertook a qualitative inquiry into understanding stakeholders' perspectives on HPVV experience through school-based programmes. It collected data through semi-structured initial interviews (Nâ€‰=â€‰16) and follow-up interviews (Nâ€‰=â€‰10) from across Saskatchewan's four Integrated Service Areas. Document analysis was conducted on all publicly available documents that included information on HPVV from January 2015 to July 2023. Thematic analysis of the data identified that inadequate information, awareness and education about HPV infection and HPVV among several groups, especially, parents, youth and school staff, was the main barrier to optimal HPVV uptake. Vaccine-related logistics, including the technical and text-heavy vaccine information sheet, understaffing, and time constraints, were other important factors that impeded HPVV uptake. A person-centred approach could educate parents in multiple dimensions.

Update on coronavirus disease 2019: Ophthalmic Manifestations and Adverse Reactions to Vaccination. The coronavirus disease 2019 (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 was one of the most devastating public health issues in recent decades. The ophthalmology community is as concerned about the COVID-19 pandemic as the global public health community is, as COVID-19 was recognized to affect multiple organs in the human body, including the eyes, early in the course of the outbreak. Ophthalmic manifestations of COVID-19 are highly variable and could range from mild ocular surface abnormalities to potentially sight and life-threatening orbital and neuro-ophthalmic diseases. Furthermore, ophthalmic manifestations may

also be the presenting or the only findings in COVID-19 infections. Meanwhile, global vaccination campaigns to attain herd immunity in different populations are the major strategy to mitigate the pandemic. As novel vaccinations against COVID-19 emerged, so were reports on adverse ophthalmic reactions potentially related to such. As the world enters a post-pandemic state where COVID-19 continues to exist and evolve as an endemic globally, the ophthalmology community ought to be aware of and keep abreast of the latest knowledge of ophthalmic associations with COVID-19 and its vaccinations. This review is a summary of the latest literature on the ophthalmic manifestations of COVID-19 and the adverse ophthalmic reactions related to its vaccinations.

The first autopsy case of Epstein-Barr virus-positive marginal zone lymphoma that deteriorated after COVID-19 vaccination. This is the first autopsy case of Epstein-Barr virus-positive marginal zone lymphoma (EBVâ€‰+â€‰MZL) with an other iatrogenic immunodeficiency-associated lymphoproliferative disorders (LPD) (methotrexate [MTX]-associated LPD) that deteriorated after the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. This case had a unique immunophenotype. A 71-year-old female patient with rheumatoid arthritis receiving MTX presented with fatigue 1 week after the SARS-CoV-2 vaccination. She was hospitalized due to hepatorenal dysfunction and pancytopenia. Computed tomography revealed systemic lymphadenopathy. Her physical condition deteriorated, and the patient died. The autopsy revealed systemic lymphadenopathy comprising medium-sized atypical lymphocytes and scattered Hodgkin/Reed-Sternberg (H/RS)-like cells. An immunohistochemical examination showed that atypical lymphocytes were positive for CD79a and MUM-1 and some were positive for CD20 and IRTA-1. H/RS-like cells were immunoreactive for CD30 and CD15 and ringed by T cells. Both cell types were positive for EBV-encoded small RNA. The majority of H/RS-like cells were positive for CD20, whereas a small number of CD3-positive cells were admixed. We herein presented the first autopsy case of EBVâ€‰+â€‰MZL that deteriorated after the SARS-CoV-2 vaccination.

A rare adverse effects of COVID-19 vaccine in a patient with a latent tumor: A case report and literature review. The 2019 novel coronavirus infection has done significant damage to the world. The effectiveness and safety of the vaccine, the most critical measure to control the epidemic, has attracted attention. In this case, we report the diagnosis and treatment of a rare patient with adverse effects of the COVID-19 vaccine who had G6PD deficiency by genetic tests. We discuss the possible impact of G6PD deficiency on COVID-19 infection and potential vaccine adverse effects. Patients with severe G6PD deficiency should be monitored for vaccine safety. This article may complement a rare mechanism of vaccine side effects and chemotherapy-related side effects.

End stage renal disease in patient with microscopic polyangiitis and atypical hemolytic-uremic syndrome arose 3 weeks after the third dose of anti-SARS-CoV2 vaccine mRNA-1273: A case report with literature revision. RATIONALE: Immune system deregulation, including AAV, is a key event that may potentially evolve into ESRD. Abnormal activation of the cAP is also a cardinal feature of TMA, particularly aHUS. The kidney is the most frequently involved organ, and renal-limited forms of TMA are often encountered in clinical practice. Isolated case reports described the occurrence of renal TMA in AAV patients. Some cases of both de novo and relapses of AAV and/or TMAs after anti-SARS-CoV2 vaccination have been reported. We reported, for the 1st time, a case of patients with new-onset MPA and aHUS occurring 3 weeks after the third dose of mRNA-1273 vaccine anti-SARS-CoV2. PATIENT CONCERNS: We present a 67-year-old man, affected by arterial hypertension, reported, after mRNA-1273 vaccine anti-SARS-CoV2, anuria, fatigue, anorexia and nausea. Laboratory data revealed acute renal failure. DIAGNOSIS: Positivity of MPO-ANCA was observed. 7 days after admission, we observed a worsening of anemia and thrombocytopenia with haptoglobin reduction, LDH increase and presence of schistocytes. Plasma levels of ADAMTS-13 were normal. A renal biopsy was performed, and findings were consistent with microscopic polyangiitis, with features of micro-

thrombotic glomerulopathy. Genetic tests revealed absence of hybrid genes associated with the increased risk of aHUS. INTERVENTIONS AND OUTCOMES: We started renal replacement treatment, including hemodialysis, and pulsed methylprednisolone, with no improvement of laboratory parameters. Then, plasma exchange was performed leading to partial haematological response. Only with Eculizumab, a human C5 inhibitor, we observed a normalization of haptoglobin levels and platelets' count. However, three months after discharge, the patient still required hemodialysis. LESSONS: To our knowledge we observed the first case aHUS, without genetic predisposition, associated with MPA occurring after the third dose of anti-SARS-CoV2 vaccine. This case report highlights the potential link between anti-SARS-CoV2 vaccine as a trigger of MPA and aHUS. This systematic review offers additional perspectives. It is plausible to hypothesize that the vaccine was the trigger for the development of these 2 diseases.Solid evidence on the mechanisms of interaction between vaccine and immune system, the role of genetic predisposition, and other variables, will shed additional light on the controversial link between anti-SARS-CoV2 vaccine and autoimmunity.

Correction: Endovascular treatment for vaccine-induced cerebral venous sinus thrombosis and thrombocytopenia following ChAdOx1 nCoV-19 vaccination: a report of three cases.

Absence of Myocardial Involvement After SARS-CoV-2 Vaccination in Asymptomatic Adolescents. This study aimed to evaluate the presence of subclinical myocardial damage in adolescents who were vaccinated against SARS-CoV-2. One hundred twenty asymptomatic adolescents with a mean age of 16.0 Â± 0.4 years (51% girls) underwent cardiac magnetic resonanceÂ (CMR) imaging. SARS-CoV-2 IgG/IgM antibody testing was performed, and self-reportedÂ dates of confirmed SARS-CoV-2 infection and/or vaccination were collected. ParticipantsÂ were classified according to SARS-CoV-2 status as naÃ¯ve (non-infected and unvaccinated, nÂ = 74), infected (unvaccinated, n = 23), and vaccinated (independently of past infection status,Â n = 23).Â Biventricular volumes and ejection fraction and myocardial T2 relaxation time wereÂ similar in the three groups. T1 relaxation time was slightly higher in vaccinated adolescentsÂ (1249 Â± 35 ms) than in naÃ¯ve and infected participants (1231 Â± 30 ms and 1227 Â± 29 ms,Â respectively; p = 0.035), although this difference was considered clinically irrelevant. ThisÂ observational study found no evidence of relevant subclinical myocardial involvement afterÂ SARS-CoV-2 vaccination in asymptomatic adolescents.

Association Between Electronic Device Use at Bedtime and COVID-19 Vaccine-Related Adverse Events During the COVID-19 Pandemic in Korean Adults: A Nationwide Cross-Sectional Population-Based Study. BACKGROUND: The coronavirus disease 2019 (COVID-19) pandemic has led to heightened mood disturbances linked to increased electronic device use at bedtime (EUB). General anxiety may contribute to an increased likelihood of experiencing nocebo responses, which have been reported to be associated with COVID-19 vaccine-related adverse events (CAEs). However, no related studies have been conducted to examine this association to date. METHODS: We executed a nationwide cross-sectional study to explore these correlations during the pandemic. Using data from the 2022 National Sleep Survey of South Korea, we analyzed the sleep health of 4,000 adults aged 20-69 years between January and February 2022. Shift workers and those with severe sleep disorders were excluded. Participants with EUB more than four days a week were labeled as high frequency EUB, and those reporting CAEs after both vaccine doses were marked as having a presence of CAEs. The survey also included details about anthropometric data, socioeconomic status, and sleep status. RESULTS: Of the 3,702 participants, 92.6% had received two or more vaccine doses, with 41.2% experiencing CAEs. Furthermore, 73.7% had a high EUB frequency. Factors associated with CAE reporting included younger age, female sex, and high EUB frequency, while heavy alcohol use was found to be less likely to be associated with CAE reporting. Notably, a high EUB frequency was significantly associated with reported CAEs (odds ratio, 1.223; 95% confidence interval, 1.028-1.455; P = 0.023). CONCLUSION: A nationwide online survey conducted in South Korea during the pandemic found that individuals who

engaged in the relatively frequent use of electronic devices during bedtime had worse sleep quality and increased COVID-19-related adverse events compared with those using these devices less frequently. These findings have the potential to enhance our understanding of the impact of the use of electronic devices at bedtime on health.

Safety and immunogenicity of primary vaccination with a SARS-CoV-2 mRNA vaccine (SYS6006) in Chinese participants aged 18 years or more: Two randomized, observer-blinded, placebo-controlled and dose-escalation phase 1 clinical trials. Vaccination plays a key role in preventing morbidity and mortality caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). We aimed to evaluate the safety and immunogenicity of a SARS-CoV-2 messenger ribonucleic acid (mRNA) vaccine SYS6006. In the two randomized, observer-blinded, placebo-controlled phase 1 trials, 40 adult participants aged 18-59â€‰years and 40 elderly participants aged 60â€‰years or more were randomized to receive two doses of SYS6006 or placebo (saline). Adverse events (AEs) were collected through 30â€‰days post the second vaccination. Immunogenicity was assessed by live-virus neutralizing antibody (Nab), spike protein (S1) binding antibody (S1-IgG), and cellular immunity. The result showed that 7/15, 9/15 and 4/10 adult participants, and 9/15, 8/15 and 4/10 elderly participants reported at least one AE in the 20-Âµg, 30-Âµg and placebo groups, respectively. Most AEs were grade 1. Injection-site pain was the most common AE. Two adults and one elder reported fever. No vaccination-related serious AE was reported. SYS6006 elicited wild-type Nab response with a peak geometric mean titer of 232.1 and 130.6 (adults), and 48.7 and 66.7 (elders), in the 20-Âµg and 30-Âµg groups, respectively. SYS6006 induced moderate-to-robust Nab response against Delta, and slight Nab response against Omicron BA.2 and BA.5. Robust IgG response against wild type and BA.2 was observed. Cellular immune response was induced. In conclusion, two-dose primary vaccination with SYS6006 demonstrated good safety and immunogenicity during a follow-up period of 51â€‰days in immunologically naive population aged 18â€‰years or more. (Trial registry: Chictr.org.cn ChiCTR2200059103 and ChiCTR2200059104).

Thrombosis and Bleeding in Patients with Vaccine-Induced Immune Thrombotic Thrombocytopenia: A Systematic Review of Published Cases. INTRODUCTION: â€ƒVaccine-induced immune thrombotic thrombocytopenia (VITT) is a highly prothrombotic reaction to COVID-19 (coronavirus disease 2019) adenoviral vector vaccines. Its distinct bleeding and thrombotic patterns compared with other platelet consumptive disorders remain unclear. METHODS: â€ƒWe performed a systematic review of the literature (PubMed and Embase) up to July 31, 2022, including case reports and case series providing nonaggregate data of VITT patients. Accurate VITT diagnosis required fulfillment of the following criteria: (1) endorsement by the authors, (2) consistent vaccine type and timing, (3) presence of thrombocytopenia and thrombosis, (4) detection of anti-platelet factor 4 antibodies. Data are presented as frequencies with 95% confidence intervals (CIs) calculated with the exact binomial method. RESULTS: â€ƒWe retrieved 143 eligible studies, describing 366 patients. Of 647 thrombotic events, 53% (95% CI: 49-56) were venous thromboses at unusual sites and 30% (95% CI: 27-34) were cerebral venous sinus thromboses (CVSTs). The ratio of venous-to-arterial events was 4.1. Thromboses in most sites were associated with at least another thrombotic event, with the exception of CVST and CNS arterial thrombosis (isolated in 49 and 39% of cases, respectively). Bleeding occurred in 36% (95% CI: 31-41) of patients; 68% (95% CI: 59-75) of bleeding events were intracranial hemorrhages (ICHs). Overall mortality was 24% (95% CI: 19-29), and 77% (95% CI: 58-90) in patients with isolated CVST complicated by ICH. CONCLUSION: â€ƒVITT displays a venous-to-arterial thrombosis ratio comparable to heparin-induced thrombocytopenia. However, VITT is characterized by a higher prevalence of CVST and ICH, which contribute to the increased bleeding frequency and mortality.

Special focus on the association between COVID-19 vaccination and Raynaud's phenomenon in autoimmune disease.
Rate and Cause of Sudden Cardiac Death in the Young During the COVID-19 Pandemic and Vaccination.
[After the COVID-19 pandemic-Which new vaccinations for adults are available or coming soon?]. The accumulation of respiratory infections in the winter months repeatedly highlights the relevance of prevention through vaccination, even beyond aÂ pandemic. Current developments in this field are therefore highly relevant, particularly for older people who are more susceptible to infections due to immune senescence and comorbidities. The Standing Committee on Vaccination (STIKO) has responded accordingly by recommending the 20-valent pneumococcal conjugate vaccine PCV20 for standard and indication vaccination of adults. Furthermore, new vaccines against respiratory syncytial virus (RSV) infections are available for which the STIKO has not yet issued aÂ recommendation. The development of other more effective and more immunogenic vac2cines is being driven in particular by new technologies, such as mRNA or vector vaccines. Various higher valent pneumococcal vaccine candidates and, for example, universal influenza vaccines are also already in development.
Acute Myocarditis Following COVID-19 Vaccination in a Young Adult. The mRNA vaccines for coronavirus disease-2019 (COVID-19) have been implemented across the globe for both emergent and non-emergent applications. We present a rare case of myocarditis following the second dosage of COVID-19 vaccine. In this case, myocarditis was suspected by troponin and erythrocyte sedimentation rate (ESR) levels prior to echocardiography, whichÂ demonstrated mild pericardial effusion, mild tricuspid regurgitation, and mild asymmetric left ventricular hypertrophy.Â Mild to moderate symptoms of myocardial inflammation persisted throughout the patient's admission, which attributed to the clinical presentation of chest pain and palpitations. As the patient had no relevant history to account for cardiac pathologies prior to vaccination, this case report serves to further investigate the association between mRNA-derived vaccination and subsequent acute myocarditis development.
Wrist Extensor Tenosynovitis After COVID-19 Vaccination. We present the case of a 54-year-old right-handed woman with no medical history of rheumatic disease or trauma to the upper extremities who developed painful nodules along her left upper extremity and torso immediately after receiving the mRNA-1273 SARS-CoV-2 vaccine booster for COVID-19 in her left upper extremity. Most of the nodules subsided within several days, but several persisted over the dorsum of the left wrist with physical examination and imaging findings consistent with second and fourth extensor compartment tenosynovitis. She ultimately underwent excision of the left wrist extensor tenosynovitis, followed by a repeat excision for recurrence of symptoms.
Bendamustine impairs humoral but not cellular immunity to SARS-CoV-2 vaccination in rituximab-treated B-cell lymphoma-affected patients. BACKGROUND: Patients with B-cell lymphoma are a fragile category of subjects, particularly exposed to infections and characterized by an impaired vaccination response due to the disease itself and, even more, to the chemotherapy regimen. For this reason, extensive knowledge of the immune response status of these subjects is of fundamental importance to obtain possible indications for a tailored immunization strategy. METHODS: We enrolled two cohorts of patients with B-cell lymphoma under rituximab treatment or 3-24 months after treatment. In all patients, we evaluated both humoral and cellular immunological memory toward SARS-CoV-2, after standard vaccination and upon one booster dose. RESULTS: We observed no Spike-specific IgG production in patients (n = 25) under anti-CD20 treatment, whereas patients (n = 16) vaccinated after the completion of chemotherapy showed a higher humoral response. Evaluating SARS-CoV-2-specific T-cell response, we found that patients in both cohorts had developed robust cellular immunity after vaccination. Of the 21 patients (51%) that experienced a breakthrough

SARS-CoV-2 infection, only six patients developed severe disease. Interestingly, these six patients had all been treated with rituximab plus bendamustine. Notably, we observed that Spike-specific IgG levels in patients treated with rituximab plus bendamustine were absent or lower compared with those in patients treated with rituximab plus other chemotherapy, whereas Spike-specific T-cell response was not different based on chemotherapy regiment. DISCUSSION: Our results show that, in patients with B-cell lymphoma under rituximab therapy, anti-SARS-CoV-2 mRNA vaccination induces a weak or absent humoral response but a consistent T-cell response. In addition, chemotherapy regimens with bendamustine further reduce patients' ability to mount a Spike-specific humoral response even after a long time period from chemotherapy discontinuation. These results provide evidence that different chemotherapeutics display different immunosuppressive properties that could be taken in to account in the choice of the right drug regimen for the right patient. Moreover, they question whether immunocompromised patients, particularly those treated with bendamustine, need interventions to improve vaccine-induced immune response.

Characterization of SARS-CoV-2-specific humoral immunity and associated factors in the healthy population post-vaccination. OBJECTIVES: To investigate factors that may influence humoral immunity post-vaccination with a COVID-19-inactivated vaccine (SC2IV). METHODS: A total of 1596 healthy individualsÂ from the Seventh Affiliated Hospital, Sun Yat-sen University (1217) and Shenzhen Baotian Hospital (379) were enrolled in this study among which 694 and 218 participants were vaccinated with two-dose SC2IV, respectively. Physical examination indices were recorded. The levels of neutralizing antibody (NA), Spike IgG, receptor-binding domain (RBD) IgG, RBD IgGÂ +Â IgMÂ +Â IgA, and nucleocapsid IgG of SARS-CoV-2 were measured by a non-virus ELISA kit. Multiple statistical analyses were carried out to identify factors that influence humoral immunity post-vaccination. RESULTS: The two-dosage vaccination could induce NA in more than 90Â % of recipients. The NA has the strongest correlation with anti-RBD IgG. Age is the most important independent index that affects the NA level, while basophil count, creatine kinase-MB, mean corpuscular hemoglobin, the ratio of albumin to urine creatinine, and thyroglobulin antibody have relatively minor contributions. Indices that affect the NA level were different between males and females. Antibodies targeting other epitopes of SARS-CoV-2 were detected in recipients without anti-RBD. CONCLUSIONS: The factors identified in association with the NA level post-vaccination may help to evaluate the protective effect, risk of re-infection, the severity of symptoms, and prognosis for vaccine recipients in clinical.

Damage-associated cellular markers in the clinical and pathogenic profile of vaccine-induced immune thrombotic thrombocytopenia. BACKGROUND: Adenoviral vector-based COVID-19 vaccine-induced immune thrombotic thrombocytopenia (VITT) is rare but carries significant risks of mortality and long-term morbidity. The underlying pathophysiology of severe disease is still not fully understood. The objectives were to explore the pathophysiological profile and examine for clinically informative biomarkers in patients with severe VITT. METHODS: Twenty-two hospitalized patients with VITT, 9 pre- and 21 post-ChAdOx1 vaccine controls, were recruited across England, United Kingdom. Admission blood samples were analyzed for cytokine profiles, cell death markers (lactate dehydrogenase and circulating histones), neutrophil extracellular traps, and coagulation parameters. Tissue specimens from deceased patients were analyzed. RESULTS: There were strong immune responses characterized by significant elevations in proinflammatory cytokines and T helper 1 and 2 cell activation in patients with VITT. Markers of systemic endothelial activation and coagulation activation in both circulation and organ sections were also significantly elevated. About 70% (nÂ = 15/22) of patients met the International Society for Thrombosis and Haemostasis criteria for disseminated intravascular coagulation despite negligible changes in the prothrombin time. The increased neutrophil extracellular trap formation, in conjunction with marked lymphopenia, elevated

lactate dehydrogenase, and circulating histone levels, indicates systemic immune cell injury or death. Both lymphopenia and circulating histone levels independently predicted 28-day mortality in patients with VITT. CONCLUSION: The coupling of systemic cell damage and death with strong immune-inflammatory and coagulant responses are pathophysiologically dominant and clinically relevant in severe VITT.

Pulmonary function assessment after COVID-19 in vaccinated healthcare workers. COVID-19 typically presents with flu-like symptoms due to the viral infection itself. The most severe cases are characterised by lung damage, an important factor in fatal outcome due to alveolar damage. In some cases, patients develop a long COVID with persistent symptoms of chest pain and fatigue. Causes, including organ damage or inflammation, are being investigated. Clinical outcomes are variable and permanent lung damage is not fully understood, while vaccination is effective against severe infection but its effect on respiratory function in mild cases remains uncertain. This retrospective study aims to analyse changes in lung function in HCWs who had COVID-19 between 2020 and 2022, comparing their spirometric test results before and after the pandemic and taking into account their vaccination status. 321 HCWs were included in the study. The study examined spirometric parameters both before and after the pandemic, and all measured outcomes except the FEV1/FVC ratio showed a significant decrease during the study period. We then assessed the association between SARS-CoV-2 infection and changes in lung function parameters, analysing infections in 2020, 2021 and 2022 separately. We found a statistically significant difference in Forced vital capacity (FVC) between infected and non-infected subjects in 2020 and 2021, but not in 2022. To evaluate the protective effect of SARS-CoV-2 vaccination on respiratory function, a linear regression analysis was performed using changes in FVC, Forced expiratory volume in 1Â s (FEV1), FVC/FEV1 ratio and Peak expiratory flow (PEF) as dependent variables. The analysis showed that the decline in FVC was significantly lower in subjects who had been vaccinated prior to infection. The study concludes that subclinical SARS-CoV-2 infections in 2020 and 2021 worsened respiratory parameters (FVC and FEV1), but vaccination protected against these effects. Even healthy individuals with previous infections showed respiratory changes, with vaccination providing protection, especially for FVC decline. This highlights the importance of vaccinating healthcare workers against COVID-19.

Factors associated with COVID-19 autumn 2022 booster uptake in the Netherlands among older adults agedÂ â‰¥Â 60Â years and younger adults with chronic conditions. BACKGROUND: A booster with bivalent COVID-19 vaccine was offered in the Netherlands in autumn, 2022. We aimed to investigate vaccine uptake during the autumn 2022 booster round among the population subgroups at risk for severe COVID-19 that were specifically targeted by this campaign: the medical risk group aged 18-59Â years and individualsÂ â‰¥Â 60Â years. We calculated booster uptake in both populations and analyzed determinants of booster uptake among those who had received at least one prior COVID-19 vaccination. METHODS: Having had an autumn 2022 booster dose was defined as having received a COVID-19 vaccination between 19 September 2022 and 7 March 2023. The study population included individuals who received at least one previous COVID-19 vaccination. National registries of sociodemographic determinants and COVID-19 vaccination were linked by a unique person identifier. Voting proportions for political parties were included at neighborhood level. Determinants of COVID-19 vaccine autumn booster uptake were ranked by importance by random forest analyses. RESULTS: Booster uptake was 68Â % among those agedÂ â‰¥Â 60 and 30Â % among those aged 18-59Â years with a medical risk factor for severe disease. For both target groups the most important determinant for booster uptake was age (15Â % in 18-29Â years to 72Â % in 80Â +Â years). Voting proportions for progressive liberal political parties ranked second in the random forest analysis in both groups, with an increasing proportion of votes associated with higher uptake. In the 60Â +Â group, household type ranked third, with highest vaccine uptake among

married couples without children (72Â %) and the lowest uptake among unmarried couples with children (47Â %). In the medical risk group, migration status ranked third. Migrants with two parents born abroad had the lowest uptake (18Â %), whereas migrants with both parents born in the Netherlands had the highest uptake (35Â %). CONCLUSION: The target group of people agedÂ â‰¥Â 60Â years was much better reached than the target group of people with a medical risk aged 18-59Â years. Uptake varied considerably among subgroups in both target groups. The findings of this study can be used in future vaccination strategies as well as for further research to better understand the drivers and barriers of vaccine uptake among the subgroups with notably low uptake.

Autoantibodies against angiotensin-converting enzyme 2 (ACE2) after COVID-19 infection or vaccination. Autoantibodies against angiotensin-converting enzyme 2 (ACE2) are frequently reported in patients during coronavirus disease 2019 (COVID-19) with evidence for a pathogenic role in severe infection. However, little is known of the prevalence or clinical significance of ACE2 autoantibodies in late convalescence or following COVID-19 vaccination. In this study, we measured ACE2 autoantibodies in a cohort of 182 COVID-19 convalescent patients, 186 COVID-19 vaccine recipients, and 43 adolescents with post-mRNA vaccine myopericarditis using two ACE2 enzymatic immunoassays (EIAs). ACE2 IgM autoantibody EIA median optical densities (ODs) were lower in convalescent patients than pre-COVID-19 control samples with only 2/182 (1.1%) convalescents testing positive. Similarly, only 3/182 (1.6%) convalescent patients tested positive for ACE2 IgG, but patients with history of moderate-severe COVID-19 tended to have significantly higher median ODs than controls and mild COVID-19 patients. In contrast, ACE2 IgG antibodies were detected in 10/186 (5.4%) COVID-19 vaccine recipients after two doses of vaccination. Median ACE2 IgG EIA ODs of vaccine recipients were higher than controls irrespective of the vaccine platform used (inactivated or mRNA). ACE2 IgG ODs were not correlated with surrogate neutralizing antibody levels in vaccine recipients. ACE2 IgG levels peaked at day 56 post-first dose and declined within 12 months to baseline levels in vaccine recipients. Presence of ACE2 antibodies was not associated with adverse events following immunization including myopericarditis. One convalescent patient with ACE2 IgG developed Guillain-Barre syndrome, but causality was not established. ACE2 autoantibodies are observed in COVID-19 vaccine recipients and convalescent patients, but are likely innocuous.

The Persistence of Specific Immunoglobulin A Against SARS-CoV-2 in Human Milk After Maternal COVID-19 Vaccination. Objectives: To investigate SARS-CoV-2 specific immunoglobulin A (sIgA) in breast milk of Thai mothers post COVID-19 vaccination and/or SARS-CoV-2 infection, and to compare the sIgA among lactating mothers with varying COVID-19 vaccination regimes. Materials and Methods: A longitudinal study was conducted in lactating mothers receiving â‰¥2 doses of COVID-19 vaccine or confirming SARS-CoV-2-positive test as a part of an infant feeding survey. Vaccination and infection details were collected through questionnaires and interviews. Self-collected breast milk samples (30â€‰mL) at 1, 3, and 6 months postvaccination or infection were analyzed for sIgA through enzyme-linked immunosorbent assay (ELISA). Results: Eighty-eight lactating mothers (152 milk samples), average age of 30.7â€‰Â±â€‰6.2 years, were recruited. Fifty-five percent of milk samples were from lactating mothers with both SARS-CoV-2 infection and vaccination (hybrid immunity); 40% were from those with vaccination alone (COVID naÃ¯ve). Sixty percent of lactating mothers received mixed types of vaccines. Median sIgA ratio in breast milk was 2.67 (0.82-7.85). Breast milk sIgA at 1, 3, and 6 months were higher in mothers with hybrid immunity than in COVID naÃ¯ve (geometric mean [95% confidence interval]: 3.30 [2.06-5.29] versus 1.04 [0.52-2.04], 3.39 [2.24-5.13] versus 1.26 [0.77-2.06], 4.29 [3.04-6.06] versus 1.33 [0.74-2.42], respectively). No significant differences were observed among various vaccination regimes. Conclusion: sIgA against SARS-CoV-2 was detected in breast milk for up to 6 months after immunization together with infection at a greater level than after immunization or infection alone. This immunity could be

transferred and protective against SARS-CoV-2 infection. Discontinuation of breastfeeding among mothers who received COVID vaccination or experienced infection should be discouraged. Clinical Trial Registration number: TCTR20220215012.

RE: Incidence of SARS-CoV-2 Breakthrough Infections After Vaccination in Adults: A Population-Based Survey Through 1 March 2023.

COVID-19 Vaccine-Triggered Bullous Pemphigoid: Two New Cases from Saudi Arabia.

Mycobacterium Indicus Pranii Vaccination-Induced Cutaneous Granuloma in COVID-19 Patients.

A Study to Describe the Pattern of Cutaneous Adverse Effects of COVID-19 Vaccines (Covishield and Covaxin). BACKGROUND: Vigorous administration of COVID-19 vaccines to tackle the ongoing pandemic has led to increasing research on adverse effects including both systemic and cutaneous. OBJECTIVE: A prospective observational study to delineate the cutaneous adverse effects of two vaccines, namely Covishield and Covaxin, administered in two doses in northern India. MATERIALS AND METHODS: The study was conducted in a tertiary hospital in northern India wherein patients were asked to report voluntarily any cutaneous adverse effects after COVID-19 vaccination to the dermatology department. The data were collected using excel sheets and later analyzed taking into consideration the age, vaccine types, and duration of onset of adverse effects. RESULTS: Of the 19,672 vaccination jabs, 296 (1.5%) developed cutaneous adverse effects of which the incidence was higher in Covishield vaccine group compared to Covaxin vaccine group. The incidence of side effects was more with the first dose of either vaccine compared to the second dose. All the side effects were benign and were managed symptomatically or were self-limiting. LIMITATIONS: The number of vaccine recipients was limited and there was a considerable overlap of adverse effects with both vaccines. Voluntary reporting of cases is not an accurate representation of the scale of patients with adverse effects. CONCLUSION: Rampant administration of vaccines along with widespread advertisement of vaccine-induced side effects via social media has created apprehension in the general population. This warrants studies improving awareness about the most vital preventive measure available to halt and eventually end the COVID-19 pandemic.

Mycobacterium Indicus Pranii (MIP) Vaccine: Pharmacology, Indication, Dosing Schedules, Administration, and Side Effects in Clinical Practice. Mycobacterium indicus pranii (MIP), previously called Mw vaccine, is a one-of-a-kind immunomodulatory vaccine. It was indigenously developed in India for use in leprosy. MIP is heat-killed Mycobacterium w, which is a non-pathogenic atypical mycobacterium belonging to Class IV of Runyon classification. It shares epitopes with Mycobacterium leprae and Mycobacterium tuberculosis, which forms the rationale behind its use in leprosy and tuberculosis. MIP activates both innate and acquired immunity. It induces a Th1 and Th17 immune response along with downregulation of Th2 pathway and activates macrophages and dendritic cells. MIP vaccine is safe with adverse effects such as local site erythema, swelling, and rarely fever and other systemic reactions. Apart from leprosy, MIP has been used in dermatological diseases such as warts and psoriasis. Clinical trials have evaluated the efficacy of MIP in a plenitude of non-dermatological conditions such as category II tuberculosis, Gram-negative sepsis, non-small cell lung cancer, human immunodeficiency virus (HIV), muscle-invasive bladder cancer, and very recently, coronavirus 2019 (COVID-19). In vitro and animal studies have also demonstrated its utility in leishmaniasis, melanoma, and as a vaccine for the prevention of pregnancy. The PubMed database was searched using "Mycobacterium indicus pranii, MIP, Mycobacterium w" as the keyword in title. This comprehensive review provides useful information for healthcare professionals about immunotherapeutic potential of MIP vaccine, its composition, dosing schedule, administration, and side effects besides its efficacy in various indications other than leprosy.

Acute disseminated encephalomyelitis following the COVID-19 Vaccine Sinopharm in low- and middle-income country: a case report. INTRODUCTION AND IMPORTANCE: Coronavirus disease

2019 (COVID-19) is a disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and various vaccines against it have been developed. Acute disseminated encephalomyelitis (ADEM) is a disease of the central nervous system that cause inflammation and demyelination and manifests as a multi-symptom acute neurological condition. Although infections are usually the cause of ADEM, vaccines may cause 5-10% of cases. CASE PRESENTATION: A 40-year-old woman had received a second dose of the Sinopharm COVID-19 vaccine 4 months before her visit and experienced sudden gait imbalance and vertigo a day after her vaccination, which lasted for more than a month. On examination, no signs of skin bruising or bleeding were observed, and her vital signs were within the normal range. On neurological assessment, the patient had a Glasgow Coma Scale score of 14/15 (E4V5M5), had normal pupil size and light reaction, normal fundus, normal deep tendon reflexes and bilateral extensor plantar response. Meningeal symptoms were absent, and SARS-CoV-2 RNA tests using NAAT (Nucleic Acid Amplification Test) were negative. Development of central nervous system (CNS) manifestations during the recovery phase of fever, along with typical MRI findings; the diagnosis of para-infectious ADEM with COVID-19 vaccination was made. After the treatment with methylprednisolone sodium succinate injection, the patient showed improvement. CLINICAL DISCUSSION: ADEM associated with post-vaccinations is a rare condition. There has been growing evidence that shared epitopes between neuronal proteins and SARS-CoV-2 antigens may trigger autoimmune reactions against the CNS through molecular mimicry as its pathogenesis. CONCLUSION: We suggest the need for a strict vaccine safety monitoring system and post-vaccine monitoring and surveillance.

Sustained spike-specific IgG antibodies following CoronaVac (Sinovac) vaccination in sub-Saharan Africa, but increased breakthrough infections in baseline spike-naive individuals. INTRODUCTION: This study investigated the antibody responses to the inactivated COVID-19 vaccine, CoronaVac (Sinovac Biotech) in the African population to provide valuable insights into long-term immunity and breakthrough infections against SARS-CoV-2 in individuals with varying prior IgG seropositivity. METHODS: Real-life cohorts were used to longitudinally track antibody levels against the SARS-CoV-2 spike and nucleoprotein in 60 participants over 12 months to examine the levels of multiple antibody isotypes (S-IgG, S-IgM, S-IgA, N-IgG, and N-IgM). RESULTS: Throughout the 12 months, we observed consistently high and stable seropositivity rates for spike-IgG antibodies, spike-IgM antibodies showed a decline in frequencies over time, and spike-IgA levels remained moderate and stable. Vaccinated individuals previously positive for spike-IgG antibodies demonstrated strong and persistent seropositivity, while those initially negative experienced a gradual and delayed increase in seropositivity rates. The fold change analysis of S- and N- antibody responses demonstrated a consistently stable and comparable profile over time, indicating that vaccine-induced antibody responses remain constant and lack significant fluctuations beyond the initial boost. The study emphasized that individuals lacking previous IgG positivity showed reduced vaccine-induced spike-IgG antibodies and were more susceptible to breakthrough infections, highlighting their higher vulnerability. All cases of breakthrough infections were asymptomatic, indicating the conferred protection to the vaccinated individuals. DISCUSSION: The findings corroborated earlier studies on the effectiveness of the CoronaVac vaccine and emphasized the significance of accounting for pre-existing seropositivity in vaccine assessments. This study effectively demonstrated durable antibody responses against SARS-CoV-2 in the African population following the CoronaVac vaccination, providing crucial insights for informing vaccination strategies and safeguarding vulnerable populations. Continuous surveillance is imperative for tracking breakthrough infections and monitoring waning immunity. The insights gained offer crucial direction for public health strategies and enhance comprehension of vaccine effectiveness in sub-Saharan Africa. Further research should

explore functional outcomes, cellular immune responses, and the vaccine's effectiveness against different variants to enhance our understanding and optimize vaccine strategies.

Effectiveness of a Fourth COVID-19 mRNA Vaccine Dose Against the Omicron Variant in Solid Organ Transplant Recipients. BACKGROUND: The effectiveness of booster doses of COVID-19 vaccines in solid organ transplant recipients is unclear. We conducted a population-based matched cohort study using linked administrative healthcare databases from Ontario, Canada to estimate the marginal vaccine effectiveness of a fourth versus third dose of the BNT162b2 and mRNA-1273 vaccines against clinically important outcomes (ie, hospitalization or death) and infection during the era of the Omicron variant. METHODS: We matched 3120 solid organ transplant recipients with a third COVID-19 vaccine dose (reference) to 3120 recipients with a fourth dose. Recipients were matched on the third dose date (Â±7 d). We used a multivariable Cox proportional hazards model to estimate the marginal vaccine effectiveness with outcomes occurring between December 21, 2021 and April 30, 2022. RESULTS: The cumulative incidence of COVID-19-related hospitalization or death was 2.8% (95% confidence interval [CI], 2.0-3.7) in the third dose group compared with 1.1% (95% CI, 0.59-1.8) in the fourth dose group after 84 d of follow-up ($P < 0.001$). The adjusted marginal vaccine effectiveness was 70% (95% CI, 47-83) against clinically important outcomes and 39% (95% CI, 21-52) against SARS-CoV-2 infection. CONCLUSIONS: Compared with a third dose, a fourth dose of the COVID-19 vaccine was associated with improved protection against hospitalization, death, and SARS-CoV-2 infection during the Omicron era. Results highlight the importance of a booster COVID-19 vaccine dose in solid organ transplant recipients.

COVISHIELD vaccine-induced thyroiditis: a case report. BACKGROUND: The rapid development of coronavirus disease 2019 vaccines during the pandemic has left their long-term effects largely unknown. Instances of autoimmune and subacute thyroiditis showing features of autoimmune/inflammatory syndrome induced by adjuvants have been reported post-vaccination. This case report aims to highlight the autoimmune/inflammatory syndrome induced by adjuvants syndrome after coronavirus disease 2019 vaccination, drawing attention to a possible connection with thyroid dysfunction and urging for further thorough research. CASE PRESENTATION: We present a case of thyroiditis induced by the COVISHIELD vaccine in a 37-year-old Indian woman. An apparently normal and healthy adult woman developed neck pain and easy fatigability 2Â weeks after the second dose of COVISHIELD, which gradually increased and was associated with irritability, decreased sleep, excessive sweating, tremor, palpitation, and weight loss. She presented to the outpatient department after 1Â week of symptoms and was evaluated with laboratory tests and imaging. She was diagnosed with thyroiditis due to the coronavirus disease 2019 vaccine and was treated with propranolol. CONCLUSION: This case report adds to the growing evidence of coronavirus disease 2019 vaccine-related thyroid issues. The development of thyroiditis is rare and underreported post-coronavirus disease 2019 vaccination; hence, research to evaluate the association of coronavirus disease 2019 vaccines with thyroid dysfunction needs to be done in the future.

New daily persistent headache after SARS-CoV-2 infection in Latin America: a cross-sectional study. BACKGROUND: Persistent headache is a frequent symptom after coronavirus disease 2019 (COVID-19) and there is currently limited knowledge about its clinical spectrum and predisposing factors. A subset of patients may be experiencing new daily persistent headache (NDPH) after COVID-19, which is among the most treatment-refractory primary headache syndromes. METHODS: We conducted a cross-sectional study in Latin America to characterize individuals with persistent headache after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and to identify factors associated with NDPH. Participants over 18 years old who tested positive for SARS-CoV-2 infection and reported persistent headache among their symptoms completed an online survey that included demographics, past medical history, persistent headache clinical characteristics, and COVID-19

vaccination status. Based on participants' responses, NDPH diagnostic criteria were used to group participants into NDPH and non-NDPH groups. Participant data was summarized by descriptive statistics. Student's t and Mann-Whitney U tests were used according to the distribution of quantitative variables. For categorical variables, Pearson's chi-square and Fisher's exact tests were used according to the size of expected frequencies. Binomial logistic regression using the backward stepwise selection method was performed to identify factors associated with NDPH. RESULTS: Four hundred and twenty-one participants from 11 Latin American countries met the inclusion criteria. One in four participants met the NDPH diagnostic criteria. The mean age was 40 years, with most participants being female (82%). Over 90% of the participants reported having had mild/moderate COVID-19. Most participants had a history of headache before developing COVID-19 (58%), mainly migraine type (32%). The most predominant clinical characteristics in the NDPH group were occipital location, severe/unbearable intensity, burning character, and radiating pain (pâ€‰<â€‰0.05). A higher proportion of anxiety symptoms, sleep problems, myalgia, mental fog, paresthesia, nausea, sweating of the face or forehead, and ageusia or hypogeusia as concomitant symptoms were reported in participants with NDPH (pâ€‰<â€‰0.05). Palpebral edema as a concomitant symptom during the acute phase of COVID-19, occipital location, and burning character of the headache were risk factors associated with NDPH. CONCLUSION: This is the first study in Latin America that explored the clinical spectrum of NDPH after SARS-CoV-2 infection and its associated factors. Clinical evaluation of COVID-19 patients presenting with persistent headache should take into consideration NDPH.

Humoral Response to SARS-COV-2 Vaccination in Patients with Multiple Sclerosis and Neuromyelitis Optica Spectrum Disorder: A Real-World Study. INTRODUCTION: The risk of SARS-CoV-2 infection or severe coronavirus disease 2019 (COVID-19) has been shown to increase in patients with multiple sclerosis (MS). Vaccination is recommended in this patient population, and the effect of disease-modifying treatments (DMTs) on response to vaccination should be considered. METHODS: This prospective, observational, cross-sectional study investigated humoral response after COVID-19 vaccination as well as possible predictors for response in patients with MS and other neuroinflammatory diseases who received DMTs in routine clinical practice in Spain. Responses were compared versus those seen in healthy controls. RESULTS: After vaccination against COVID-19, most patients with MS developed an immune response comparable to that of healthy individuals. However, approximately half of patients receiving a sphingosine-1-phosphate modulator (SP1-M, fingolimod or siponimod) or a B-cell-depleting agent (aCD20, ocrelizumab or rituximab) did not develop protective antibodies, although patients receiving other DMTs had humoral immune responses comparable to healthy controls. Lymphocyte count was not associated with reduced humoral response in patients receiving an SP1-M or aCD20, whereas, in patients receiving an aCD20 or SP1-M, older age was associated with lower anti-SARS-CoV-2 spike protein immunoglobulin G antibody levels. CONCLUSIONS: Treatment with aCD20 or SP1-M therapies appears to be associated with a lower humoral response to vaccines against SARS-CoV-2. Vaccination prior to initiation of these DMTs should be recommended whenever possible.

Temporal changes to adult case fatality risk of COVID-19 after vaccination in England between May 2020 and February 2022: a national surveillance study. OBJECTIVES: Risk of death after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection has fallen during the pandemic, largely due to immunity from vaccination. In England, the timing and extent of this reduction varied due to staggered eligibility during the primary vaccination campaign, based on age and clinical risk group. Duration of protection is less well understood. Our objective was to estimate the case fatality risk (CFR) by vaccination status and time since last dose during a period of widespread community testing, to better understand the impact of coronavirus disease 2019 (COVID-19) vaccination and

duration of protection. DESIGN: SARS-CoV-2 cases diagnosed between May 2020 and February 2022 were linked to vaccine records from the National Immunisation Management System. CFR was calculated as the proportion of cases that died of COVID-19 per the death certificate, aggregated by week of specimen and stratified by 10-year age band and vaccination status. SETTING: England, UK. PARTICIPANTS: A total of 10,616,148 SARS-CoV-2 cases, aged â‰¥18 years, recorded by England's laboratory reporting system. MAIN OUTCOME MEASURES: Case fatality risk of COVID-19, stratified by age band and vaccination status. RESULTS: Overall, a reduction in CFR was observed for all age bands, with a clear temporal link to when the age group became eligible for primary vaccination and then the first booster. CFR increased with age (0.3% 50-59 years; 1.2% 60-69; 4.7% 70-79; 16.3% 80+) and was highest in the unvaccinated - albeit a reduction was observed over time. The highest CFR was seen in the unvaccinated 80+ group prior to vaccination rollout (30.6%). CFR was consistently lowest in vaccinated populations within 6 months of last dose, yet increased after over 6 months elapsed since last dose, across all age bands. CONCLUSIONS: COVID-19 CFR reduced after vaccination, with the lowest CFR seen across all age bands when vaccinated up to 6 months prior to specimen date. This provides some evidence for continued booster doses in older age groups.

Inactivated vaccines reduce the risk of liver function abnormality in NAFLD patients with COVID-19: a multi-center retrospective study. BACKGROUND: Abnormal liver function was frequently observed in nonalcoholic fatty liver disease (NAFLD) patients infected with SARS-CoV-2. Our aim was to explore the effect of SARS-CoV-2 inactivated vaccines on liver function abnormality among NAFLD patients with COVID-19. METHODS: The multi-center retrospective cohort included 517 NAFLD patients with COVID-19 from 1 April to 30 June 2022. Participants who received 2 doses of the vaccine (nÂ =Â 274) were propensity score matched (PSM) with 243 unvaccinated controls. The primary outcome was liver function abnormality and the secondary outcome was viral shedding duration. Logistic and Cox regression models were used to calculate the odds ratio (OR) and hazard ratio (HR) for the outcomes. Sensitivity analysis was conducted to assess robustness. FINDINGS: PSM identified 171 pairs of vaccinated and unvaccinated patients. Liver function abnormality was less frequent in the vaccinated group (adjusted OR, 0.556 [95% CI (confidence interval), 0.356-0.869], pÂ =Â 0.010). Additionally, the vaccinated group demonstrated a lower incidence of abnormal bilirubin levels (total bilirubin: adjusted OR, 0.223 [95% CI, 0.072-0.690], pÂ =Â 0.009; direct bilirubin: adjusted OR, 0.175 [95% CI, 0.080-0.384], pÂ <Â 0.001) and shorter viral shedding duration (adjusted HR, 0.798 [95% CI, 0.641-0.994], pÂ =Â 0.044) than the unvaccinated group. Further subgroup analysis revealed similar results, while the sensitivity analyses indicated consistent findings. INTERPRETATION: SARS-CoV-2 vaccination in patients with NAFLD may reduce the risk of liver dysfunction during COVID-19. Furthermore, vaccination demonstrated beneficial effects on viral shedding in the NAFLD population. FUNDING: 23XD1422700, Tszb2023-01, Zdzk2020-10, Zdxk2020-01, 2308085J27 and JLY20180124.

Menstrual changes after COVID-19 vaccine administration: a systematic review. OBJECTIVE: During the mass vaccination campaign for COVID-19, cases of menstrual cycle changes in women emerged, so it was thought that the COVID-19 vaccine could affect the menstrual cycle. Over time, these observations have become more frequent, which strengthens the idea. This systematic review aims to show changes in the menstrual cycle after COVID-19 vaccination. MATERIALS AND METHODS: This study was carried out following the guidelines of the Cochrane Collaboration and the Meta-analysis of Observational Studies in Epidemiology and the Preferred Reporting Items for Systematic Reviews and Meta-Analyzes. RESULTS: A suitable bibliography on PubMed/Medline and Scopus was searched by combining text, words, and titles of medical topics. After completing the search, a total of 42 articles were included in this systematic review. CONCLUSIONS: The COVID-19 vaccines may have an impact on the quality of life of women. The changes in the menstrual cycle tend to resolve

within 2-3 months of vaccination and the symptoms are mild to moderate and tend to self-limit over time.

Erythema nodosum after COVID-19 vaccine associated with varicella-zoster virus reactivation.

Correction to: Vaccines and variants: an update on cardiopulmonary assessment prior to return to high-hazard occupations following COVID-19.

Risk of cardiac arrhythmia and cardiac arrest after primary and booster COVID-19 vaccination in England: A self-controlled case series analysis. BACKGROUND: Various cardiac arrhythmias have been reported after COVID-19 infection and vaccination. We assessed the risk after primary immunisation with the ChAdOx1 adenovirus vectored vaccine, and primary and booster immunisation with an mRNA vaccine in 40 million vaccinated adults with 121 million doses (33.9% ChAdOx1 and 66.1% mRNA) in England. METHODS: Hospital admissions for a cardiac arrhythmia and emergency care attendance for a cardiac arrest in individuals aged 18Â years and older on the 31st March 2021 were linked to the national COVID-19 immunisation register. The incidence of events 1-14 and 15-28Â days after vaccination relative to a post-vaccination control period was estimated using the self-controlled case series method modified for fatal events. Outcomes were stratified by arrhythmia type, vaccine type, age group and dose number (up to five). Elevated relative incidence (RI) estimates with pÂ <Â 0.001 were considered strong evidence of an association. FINDINGS: There was an increased risk of admission for arrhythmia events that were largely palpitations without myocarditis within 14Â days of a second priming dose of an mRNA vaccine in 18-49Â year olds with an RI of 1.66 (95Â % confidence interval 1.47,1.86) for BNT162b2 and 3.75 (2.52,5.57) for mRNA-1273 (pÂ <Â 0.001) and also after a first booster dose, 1.34 (1.17,1.53) and 1.75 (1.43,2.15) respectively (pÂ <Â 0.001). No other cardiac arrhythmia, including cardiac arrest, showed an elevated incidence within 28Â days of vaccination for any dose, age group or vaccine type. In contrast the risk of a cardiac arrhythmia of all types, including a cardiac arrest, was consistently elevated in those testing positive for SARS-CoV-2 infection. INTERPRETATION: Our study provides reassuring evidence of the safety of the ChAdOx1 and mRNA COVID-19 vaccines with respect to serious cardiac arrhythmias and of the favourable risk benefit of mRNA booster vaccination.

Rapid transient and longer-lasting innate cytokine changes associated with adaptive immunity after repeated SARS-CoV-2 BNT162b2 mRNA vaccinations. INTRODUCTION: Cytokines and chemokines play an important role in shaping innate and adaptive immunity in response to infection and vaccination. Systems serology identified immunological parameters predictive of beneficial response to the BNT162b2 mRNA vaccine in COVID-19 infection-naÃ¯ve volunteers, COVID-19 convalescent patients and transplant patients with hematological malignancies. Here, we examined the dynamics of the serum cytokine/chemokine responses after the 3(rd) BNT162b2 mRNA vaccination in a cohort of COVID-19 infection-naÃ¯ve volunteers. METHODS: We measured serum cytokine and chemokine responses after the 3(rd) dose of the BNT162b2 mRNA (Pfizer/BioNtech) vaccine in COVID-19 infection-naÃ¯ve individuals by a chemiluminescent assay and ELISA. Anti-Spike binding antibodies were measured by ELISA. Anti-Spike neutralizing antibodies were measured by a pseudotype assay. RESULTS: Comparison to responses found after the 1(st) and 2(nd) vaccinations showed persistence of the coordinated responses of several cytokine/chemokines including the previously identified rapid and transient IL-15, IFN-Î³, CXCL10/IP-10, TNF-Î±, IL-6 signature. In contrast to the transient (24hrs) effect of the IL-15 signature, an inflammatory/anti-inflammatory cytokine signature (CCL2/MCP-1, CCL3/MIP-1Î±, CCL4/MIP-1Î², CXCL8/IL-8, IL-1Ra) remained at higher levels up to one month after the 2(nd) and 3(rd) booster vaccinations, indicative of a state of longer-lasting innate immune change. We also identified a systemic transient increase of CXCL13 only after the 3(rd) vaccination, supporting stronger germinal center activity and the higher anti-Spike antibody responses. Changes of the IL-15 signature, and the inflammatory/anti-inflammatory cytokine profile correlated with neutralizing

antibody levels also after the 3(rd) vaccination supporting their role as immune biomarkers for effective development of vaccine-induced humoral responses. CONCLUSION: These data revealed that repeated SARS-Cov-2 BNT162b2 mRNA vaccination induces both rapid transient as well as longer-lasting systemic serum cytokine changes associated with innate and adaptive immune responses. CLINICAL TRIAL REGISTRATION: Clinicaltrials.gov, identifier NCT04743388.

Humoral antibody response following mRNA vaccines against SARS-CoV-2 in solid organ transplant recipients; a status after a fifth and bivalent vaccine dose. BACKGROUND: In solid organ transplant (SOT) recipients, the humoral response following COVID-19 vaccination is reduced, as a result of their immunosuppressed treatment. In this study, we investigated antibody concentrations after booster vaccinations until the fifth dose, the latter by monovalent or bivalent BA1 or BA4/5 vaccines. In addition, we evaluated the efficacy of vaccination by recording breakthrough infections, hospitalizations, and deaths. METHOD: This prospective cohort study included 438 SOT recipients (>18 years) vaccinated with mRNA vaccines against COVID-19 from January 2021 until March 2023. Blood samples were drawn before and after each vaccination and tested for SARS-CoV-2 spike RBD IgG antibodies with the lowest and highest cut-off at 7.1 and 5,680 BAU/mL, respectively. Vaccine information, breakthrough infections, and hospitalizations were collected from the medical records. RESULTS: Most participants received BNT162b2 and 61.4% received five vaccine doses. The response proportion in SOT recipients increased from 86.7% after the fourth dose to 93.0% following the fifth dose. Antibody concentration decreased with 142.7 BAU/mL between the third and fourth dose (median 132 days, Quartile 1: 123, Quartile 3: 148) and 234.3 BAU/mL between the fourth and fifth (median 250 days, Quartile 1: 241, Quartile 3: 262) dose among those without breakthrough infection (p=0.34). When comparing the Omicron BA.1 or Omicron BA.4/BA.5 adapted vaccines, no significant differences in antibody concentration were found, but 20.0% of SOT recipients receiving a monovalent fifth vaccine dose had a breakthrough infection compared to 4.0% and 7.9% among those who received BA.1 and BA.4/BA.5 adapted vaccines, respectively (p=0.04). Since January 2021, 240 (54.8%) participants had a breakthrough infection, and 22 were hospitalized, but no deaths were observed. CONCLUSIONS: The fifth COVID-19 vaccine dose raised antibody response to 93.0% of the study population. Additional booster doses, as well as bivalent vaccines, led to higher levels of antibody concentration in SOT recipients. We found a lower incidence of breakthrough infections among SOT recipients after receiving a bivalent vaccine as a fifth dose compared to those receiving a monovalent dose. Antibody concentrations did not wane when the time between doses was prolonged from four to eight months.

Sonographic Assessment of Axillary Lymph Nodes Post COVID-19 Vaccine. Background The development of axillary lymphadenopathy post COVID-19 vaccine became an area of concern. This needs to be addressed and investigated to provide updated data that could contribute to its management and imaging guidelines. Objectives This study aims to detect possible changes in lymph nodes (LNs) after COVID-19 vaccination, decrease the rate of over-investigation and medical costs, and identify possible predisposing factors that could trigger the development of lymphadenopathy. Methods This was a retrospective cohort study conducted in King Fahad University Hospital, a secondary hospital in Al Khobar, Kingdom ofÂ Saudi Arabia (KSA), on a total of 1,257 vaccinated patients who underwent axillary ultrasonography (US) from December 2020 till the second of October 2022. All required data were collected using an Excel sheet and analyzed using Statistical Product and Service Solutions (SPSS, version 21) (IBM SPSS Statistics for Windows, Armonk, NY). Results Out of the 1183 cases, 460 (38.9%) cases had abnormal LNs post COVID-19 vaccine based on US, while LNs were normal in 723 (61.1%) cases. The prevalence of axillary lymphadenopathy was significantly more common in females than males (39.1% of cases in female patients versus 22.2% of cases in male patients (P = 0.049)). In addition, lymphadenopathy was more prevalent among

patients who received the COVID-19 vaccine less than four weeks ago, compared to others who received the vaccine four to eight weeks ago, 8-12 weeks ago, and more than 12 weeks ago (100% vs 73.3% vs 34.2% vs 72% (P = 0.001)). Conclusion In conclusion, a significant number of patients were found to have lymphadenopathy after receiving the COVID-19 vaccine. The only predisposing factors identified to be associated with the development of lymphadenopathy were gender (females more than males) and duration since receiving the vaccine (four weeks).

A Case of TAFRO Syndrome Developed after COVID-19 Vaccination. TAFRO syndrome is a systemic inflammatory disorder, which is characterized by thrombocytopenia, anasarca, fever, reticulin myelofibrosis, renal dysfunction, and organomegaly. It often presents with progressive clinical symptoms and can be fatal. COVID-19 vaccination is important to reduce the number of COVID-19-infected populations and lower the risk of becoming severe. However, serious adverse events have been reported. TAFRO syndrome that progresses after the COVID-19 mRNA vaccination has not yet been reported. A 45-year-old man developed fever, gross hematuria, renal dysfunction, pleural effusions, and ascites immediately after vaccination. This case fulfilled three major categories (thrombocytopenia, anasarca, and systemic inflammation) and two minor categories (renal insufficiency and myelofibrosis) and was diagnosed with TAFRO syndrome. High-dose steroid treatment was initiated, followed by prednisolone administration. After treatment, renal dysfunction and fluid retention were resolved. Universal vaccination against COVID-19 is important for lowering the risk of spreading COVID-19 infection. Several complications, such as renal, hematological, and heart diseases, have been reported; however, its pathogenesis is unclear. The possibility of various complications after the COVID-19 vaccination, including TAFRO syndrome, should be considered.

Establishing clinically meaningful ranges of metal hypersensitivity in orthopaedic patients using COVID-19 vaccine-induced adaptive immune responses from fully vaccinated adults. BACKGROUND: This study aimed to assess metal sensitization ranges among orthopaedic patients by comparing adaptive immune responses in all-comer pre- and post-operative orthopaedic adults who were COVID-19 unvaccinated or vaccinated vs patients with a painful aseptic implant by lymphocyte transformation test (LTT) to SARS-CoV-2-Spike-Protein (SP) and implant metal(s), respectively. METHODS: Data were retrospectively reviewed from three independent groups: unvaccinated COVID-19 adults (nÂ =Â 23); fully COVID-19 vaccinated adults (nÂ =Â 35); unvaccinated, painful aseptic implant patients with history of metal allergy (nÂ =Â 98). Standard in vitro LTT for SP and implant metal(s) (nickel, cobalt) were performed and rated as negative (stimulation index [SI]<2), mild (SIÂ â‰¥Â 2), positive (SIÂ â‰¥Â 4-15), and high sensitization (SIÂ >Â 15) adaptive immune responses to tested antigen. RESULTS: Overall, 17/23 (74%) of unvaccinated adults showed negative to mild LTT ranges, and 35/35 (100%) of vaccinated showed mild to positive LTT ranges to SP. Vaccinated individuals showed significantly higher median SI (16.1) to SP than unvaccinated (median SI, 1.7; PÂ <Â 0.0001). Most vaccinated adults (94%) showed a lymphocyte SIÂ >Â 4 to SP, establishing LTT SIÂ â‰¥Â 4 with >90% sensitivity for diagnosing effective COVID-19 adaptive immune responses. Significantly fewer painful orthopaedic patients (41%) showed comparable elevated levels of lymphocyte metal sensitivity at SIÂ â‰¥Â 4 compared to vaccinated group (PÂ <Â 0.0001). CONCLUSIONS: Vaccinated adults showed significantly higher lymphocyte SI to SP than unvaccinated indicating that SI ranges â‰¥4 should be set as unequivocally diagnostic of LTT-positive adaptive immune responses to tested antigen. This analysis supports using higher LTT SI ranges (SIÂ â‰¥Â 4) in diagnosing clinical orthopaedic-related Type IV metal-hypersensitivity responses among orthopaedic patients.

Humoral immune response after Ad26.COV2.S vaccination in patients with multiple sclerosis treated with natalizumab. The immunomodulatory effects of disease-modifying therapies for multiple sclerosis might affect the immune response to vaccines for severe acute respiratory syndrome

coronavirus 2. We analyzed the severe acute respiratory syndrome coronavirus 2-specific antibody response and lymphocyte profile before and after Ad26.COV2.S (Johnson & Johnson) vaccination in natalizumab-treated patients with multiple sclerosis. There was a 72-fold increase in mean anti-severe acute respiratory syndrome coronavirus 2 spike immunoglobulin G levels 4 weeks after vaccination and a 137-fold increase after 6 months. Other immune signals were within normal ranges. Natalizumab-treated patients with multiple sclerosis had a robust immune response to Ad26.COV2.S vaccine, and other immune signals were not significantly affected.

The assessment and interpretation of published data on Guillain-Barre syndrome after SARS-CoV-2 vaccination requires care.

From mass vaccination to personalized vaccinology? The COVID-19 case. Commentary. In recent times, especially as a result of the experience gained worldwide with the COVID19 pandemic vaccination campaigns, the personalization of vaccination strategies is becoming increasingly important. This does not yet mean bringing precision medicine and genomics approaches into immunization campaigns, but where there is more than one vaccine against the same disease, there is a need to identify criteria for personalizing vaccination.Vaccination strategies based on prescription appropriateness - whenever is possible - can lead to more effective immune response, reduced rates of adverse events, increased public confidence in vaccination and higher vaccination coverage, contributing to a decrease of morbidity and mortality related to preventable diseases.

A penile edema induced by mRNA SARS-CoV-2 vaccine.

Association of a coronavirus disease 2019 (COVID-19) vaccine booster with control of a COVID-19 outbreak in a long-term care facility in Switzerland, November to December 2021. Coronavirus disease 2019 (COVID-19) outbreaks in long-term care facilities are often correlated with high case fatality rates. We describe the association of administration of an mRNA booster with the control of an outbreak. Our findings highlight the possibility of vaccine booster early in an outbreak as a promising method to mitigate the spread of infection.

ABO blood group associated with cerebral venous thrombosis after Oxford-AstraZeneca COVID-19 vaccination: a case-control study. OBJECTIVES: To determine whether blood group influences development of cerebral venous thrombosis (CVT) after administration of the coronavirus disease 2019 (COVID-19) AstraZeneca ChAdOx1-S vaccine. DESIGN: A case-control study. Univariate and multivariate logistic regression was used to determine the association between blood type and COVID-19 vaccination status. SETTING: Vaccinated and unvaccinated patients recruited from the international Bio-Repository to Establish the Aetiology of Sinovenous Thrombosis study and the Cerebral Venous Sinus Thrombosis With Thrombocytopenia Syndrome Study Group. PARTICIPANTS: All patients were of European descent and age and sex matched. Cases (nâ€‰=â€‰82) were patients â‰¥18 years old who suffered a CVT within 28 days of a first dose of ChAdOx1-S vaccine. Controls (nâ€‰=â€‰441) were unvaccinated CVT patients â‰¥18 years old. All patients were of European descent. MAIN OUTCOME MEASURES: Frequency of blood type and ABO allele distribution by vaccination status. RESULTS: Blood group O was found to be more prevalent among CVT patients with vaccine-induced thrombotic thrombocytopenia (VITT-CVT) after ChAdOx1-S vaccination compared with unvaccinated CVT cases (43% vs. 17%, respectively, pâ€‰<â€‰0.001). Blood group A was less prevalent, though still high, in the vaccinated group compared with the unvaccinated group (47% vs. 71%, respectively, pâ€‰<â€‰0.001). No significant differences were observed in the VITT-CVT non-ChAdOx1-S vaccine group and unvaccinated pre-COVID-19 CVT group for blood group. CONCLUSIONS: Blood group O is more prevalent among patients with VITT-CVT after ChAdOx1-S vaccination compared with unvaccinated cases, independent of well-established CVT risk factors. A larger dataset may be able to determine whether those of blood groups B and/or AB may be safely

vaccinated with the low cost, readily available and easily transported ChAdOx1-S rather than adopting a complete ban.

No Evidence That Analgesic Use after COVID-19 Vaccination Negatively Impacts Antibody Responses. Uptake of mRNA vaccines, especially booster immunizations, against COVID-19 has been lower than hoped, perhaps in part due to their reactogenicity. Analgesics might alleviate symptoms associated with vaccination, but they might also impact immune responses. We semiquantitatively measured Ab responses following COVID-19 vaccination in 2354 human participants surveyed about analgesic use after vaccination. Participants who used nonsteroidal anti-inflammatory drugs or acetaminophen after vaccination showed elevated Ab levels against the receptor-binding domain of Spike protein relative to those who did not use analgesics. This pattern was observed for both mRNA-1273 and BNT162b2 and across age groups. Participants who used analgesics more frequently reported fatigue, muscle aches, and headaches than did those who did not use painkillers. Among participants who reported these symptoms, we observed no statistically significant differences in Ab levels irrespective of analgesic use. These data suggest that elevated Ab levels are associated with symptoms and inflammatory processes rather than painkiller use per se. Taken together, we find no evidence that analgesic use reduces Ab responses after COVID-19 vaccination. Recommendation of their use to alleviate symptoms might improve uptake of booster immunizations.

Risk of anaphylaxis after COVID-19 vaccination in South Korea: A nationwide self-controlled case series analysis.

Eosinophilic Granulomatosis With Polyangiitis Following COVID-19 Vaccination: A Case Report. The current emergence of the coronavirus disease 2019 (COVID-19) pandemic and the possible side effects of COVID-19 mRNA vaccination remain worrisome. Few cases of vaccination-related side effects, such as vasculitis, have been reported. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome, is a type of vasculitis characterized by the histological richness of eosinophils, asthma, polyneuropathy, sinusitis, and skin or lung involvement. Here, we report the first case of new onset EGPA following COVID-19 vaccination in Korea. A 71-year old woman developed a skin rash and presented with progressive weakness of the upper and lower extremities after the BNT162b2 vaccination (Pfizer-BioNTech). She was diagnosed with EGPA and her symptoms improved after systemic steroid and immunosuppressant therapy. Although it is very rare, clinicians should be aware that EGPA may occur after COVID-19 vaccination.

Stacking Ensemble of Disproportionality Indicators for Adverse Vaccine Reactions Detection-An Empirical Study on Predicting Adverse Reactions of COVID-19 Vaccines. Vaccine safety is a critical issue for public health, which has recently become more crucial than ever since COVID-19 started to spread worldwide in 2020. Many COVID-19 vaccines have been developed and used without following the traditional three clinical trial stages. Instead, most COVID-19 vaccines were approved through emergency use approval (EUA) within one year, significantly raising the risk of rare and severe adverse events. Reporting systems like the Vaccine Adverse Event Reporting System (VAERS) have been established worldwide to detect unknown and severe adverse reactions as early as possible. Although experts and researchers have been working hard to find ways to detect adverse vaccine event (AVE) signals from VAERS data, most of the contemporary methods are statistical methods based on measuring the disproportionality between vaccine-induced events and non-vaccine-induced events. This paper proposes a novel ensemble AVE detection method, which adopts a stacking ensemble of various disproportionality indicators, fusing dual-scale contingency values measured in single and cumulative yearly duration, and embraces the concept of feature concatenation. Experiments conducted on US VAERS data to predict AVE caused by COVID-19 vaccines show that our proposed method is effective. We observed that: (1) Stacking ensemble of various disproportionality indicators is superior to any single disproportionality indicator and voting

ensemble method; (2) Fusing dual-scale contingency values and feature concatenation brings synergy to our proposed stacking ensemble AVE detection. Compared to the best disproportionality metric in this study, our top-performing ensemble version exhibited a 34% improvement in accuracy, 71% in precision, 29% in recall, and 77% in F-measure, with a slight decrease (8%) in specificity.

Live-virus serum neutralization after bivalent SARS-CoV-2 mRNA vaccination in hemodialysis patients. The development of bivalent booster vaccines addresses the ongoing evolution of the emerging B.1.1.529 (omicron) variant subtypes that are known to escape vaccine-induced neutralizing antibody response. Little is known about the immunogenicity and reactogenicity of bivalent mRNA vaccines in hemodialysis patients with impaired vaccine response. In this prospective, observational cohort study, we analyzed SARS-CoV-2 anti-S1 IgG, surrogate neutralizing antibodies (SNA), and live-virus neutralization against the SARS-CoV-2 wildtype and the BA.5 variant in 42 hemodialysis patients with and without prior SARS-CoV-2 infection before and after an additional fifth bivalent vaccine dose. Anti-S1 IgG and SNA were significantly higher in hemodialysis patients with prior infection than in patients without infection (pâ€‰<â€‰0.001 and pâ€‰<â€‰0.01, respectively). In patients without prior infection, both antibody levels increased, and live-virus neutralizing antibodies against the wildtype and the BA.5 variant were correspondingly significantly higher after bivalent booster vaccination (pâ€‰<â€‰0.001 for both). Conversely, in patients with prior infection, anti-S1 IgG and SNA did not alter significantly, and bivalent booster vaccination did not induce additional humoral immune response against the SARS-CoV-2 wildtype and the BA.5 variant. Thus, bivalent mRNA vaccines might increase humoral responses in hemodialysis patients without prior infection. Larger clinical trials are needed to help guide vaccination strategies in these immunocompromised individuals.

Neuromuscular diseases associated with COVID-19 vaccines: a systematic review and pooled analysis of 258 patients. BACKGROUND: Neuromuscular diseases (NMD) emerged as one of the main side effects of the COVID-19 vaccination. We pooled and summarized the evidence on the clinical features and outcomes of NMD associated with COVID-19 vaccination. METHODS: We comprehensively searched three databases, Medline, Embase, and Scopus, using the key terms covering "Neuromuscular disease" AND "COVID-19 vaccine", and pooled the individual patient data extracted from the included studies. RESULTS: A total of 258 NMD cases following COVID-19 have been reported globally, of which 171 cases were Guillain-BarrÃ© syndrome (GBS), 40 Parsonage-Turner syndrome (PTS), 22 Myasthenia Gravis (MG), 19 facial nerve palsy (FNP), 5 single fiber neuropathy, and 1 Tolosa-Hunt syndrome. All (100%) SFN patients and 58% of FNP patients were female; in the remaining NMDs, patients were predominantly male, including MG (82%), GBS (63%), and PTS (62.5%). The median time from vaccine to symptom was less than 2â€‰weeks in all groups. Symptoms mainly appeared following the first dose of vector vaccine, but there was no specific pattern for mRNA-based. CONCLUSION: COVID-19 vaccines might induce some NMDs, mainly in adults. The age distribution and gender characteristics of affected patients may differ based on the NMD type. About two-thirds of the cases probably occur less than 2 weeks after vaccination.

Interstitial lung disease following COVID-19 vaccination: a disproportionality analysis using the Global Scale Pharmacovigilance Database (VigiBase). BACKGROUND AND OBJECTIVE: Despite several case reports, population-based studies on interstitial lung disease (ILD) following COVID-19 vaccination are lacking. Given the unprecedented safety issue of COVID-19 vaccination, it is important to assess the worldwide patterns of ILD following COVID-19 vaccination. This study aimed to investigate the signals of COVID-19 vaccine-associated ILD compared with other vaccinations using disproportionality analysis. METHODS: We analysed the VigiBase database during the period between 13 December 2020 and 26 January 2023. We adopted the case/non-case approach to assess the disproportionality signal of ILD for COVID-19 vaccines via 1:10 matching by age and sex. We

compared COVID-19 vaccines with all other vaccines as the reference group. RESULTS: Among 1 233 969 vaccine-related reports, 679 were reported for ILD. The majority of ILD cases were related to tozinameran (376 reports, 55.4%), Vaxzevria (129 reports, 19.0%) and elasomeran (78 reports, 11.5%). The reporting OR of ILD following COVID-19 vaccination was 0.86 (95% CI 0.64 to 1.15) compared with all other vaccines. CONCLUSION: No significant signal of disproportionate reporting of ILD was observed for COVID-19 vaccines compared with all other vaccines. Moreover, when compared with the influenza vaccines that are known to cause ILD, no signal was observed. This study results might help decision-making on the subsequent COVID-19 vaccination strategy of ILD. Further large and prospective studies are required for more conclusive evidence.

Glucose control during breakthrough SARS-CoV-2 infections in vaccinated patients with type 1 diabetes. AIMS: This study aims at evaluating the trend of glycemic control metrics during the infection of SARS-CoV-2 in individuals with Type 1 Diabetes (T1D) using a Continuous Glucose Monitoring (CGM) system and vaccinated against COVID-19. MATERIALS AND METHODS: This is a retrospective study of T1D subjects who got a breakthrough SARS-CoV-2 infection between November 2021 and February 2022. Data of glycemic control of CGM-derived metrics were compared 14Â days before COVID-19 (Time 1), 14Â days during COVID-19 (Time 2) and 14Â days after COVID-19 (Time 3). RESULTS: A total of 106 patients with T1D and breakthrough SARS-CoV-2 infection was included in the analysis. A significant reduction of GMI [%, 7.41Â Â±Â 1.60 vs 7.52Â Â±Â 1.63, PÂ =Â 0.006)] and increase of TIR [%, 54.6Â Â±Â 20.4 vs 52.1Â Â±Â 19.7, PÂ =Â 0.026] were observed at Time 3 as compared with Time 2. There was a significant reduction of SD (PÂ <Â 0.001) and CV (PÂ <Â 0.001) at Time 3 and Time 2 as compared with Time 1, associated with significant changes of mean glucose levels, TBR level 1 and total daily insulin doses. CONCLUSIONS: Breakthrough SARS-CoV-2 infection did not worsen glycemic control in vaccinated people with T1D.

Circular RNA vaccines with long-term lymph node-targeting delivery stability after lyophilization induce potent and persistent immune responses. messenger RNA (mRNA) vaccines are a key technology in combating existing and emerging infectious diseases. However, the inherent instability of mRNA and the nonspecificity of lipid nanoparticle-encapsulated (LNP) delivery systems result in the need for cold storage and a relatively short-duration immune response to mRNA vaccines. Herein, we develop a novel vaccine in the form of circRNAs encapsulated in LNPs, and the circular structure of the circRNAs enhances their stability. Lyophilization is considered the most effective method for the long-term preservation of RNA vaccines. However, this process may result in irreversible damage to the nanoparticles, particularly the potential disruption of targeting modifications on LNPs. During the selection of lymph node-targeting ligands, we found that LNPs modified with mannose maintained their physical properties almost unchanged after lyophilization. Additionally, the targeting specificity and immunogenicity remained unaffected. In contrast, even with the addition of cryoprotectants such as sucrose, the physical properties of LNPs were impaired, leading to an obvious decrease in immunogenicity. This may be attributed to the protective role of mannose on the surface of LNPs during lyophilization. Freshly prepared and lyophilized mLNP-circRNA vaccines elicited comparable immune responses in both the rabies virus model and the SARS-CoV-2 model. Our data demonstrated that mLNP-circRNA vaccines elicit robust immune responses while improving stability after lyophilization, with no compromise in tissue targeting specificity. Therefore, mannose-modified LNP-circRNA vaccines represent a promising vaccine design strategy.

Evaluation of Seroconversion Rate Following SARS COV 2 Vaccination in Health Care Workers at Shahid Beheshti University of Medical Sciences. BACKGROUND: Vaccines are the most effective way to prevent Coronavirus 2 severe acute respiratory syndrome (SARS-CoV-2). This study examines and compares the efficiency of AstraZeneca, Sinopharm, and Sputnik vaccines and the correlation of antibody response with age, sex, and history of corona disease in employees of Shahid Beheshti

University of Medical Sciences. METHODS: 202 participants were included, of which 82 were administered the Astra-Zeneca, 59 were given the Sinopharm, and 61 were given the Sputnik vaccine. SARSCoV-2 IgM and IgG antibody levels were checked four weeks after passing the second dose of all three vaccines using the enzyme-linked immunosorbent assay (ELISA) technique. RESULTS: There was no significant difference between the amount of IgM and IgG antibodies among three vaccines ($p=0.056$). For all three vaccines, gender and age did not significantly affect the amount of IgM and IgG antibodies. The history of infection with COVID-19 increased the antibody response ($p>0.5$). CONCLUSION: The titer of IgM and IgG antibodies were not statistically significantly different. The IgM and IgG antibodies produced by vector-based vaccines are higher than the Sinopharm vaccine. Gender did not affect the produced antibody titer. No significant linear relationship was found between age and antibody titer. In people from this study who received two doses of the AstraZeneca vaccine and had a corona history, the average amount of both IgM and IgG antibodies was measured more than the other participants.

Analysis of SARS-CoV-2 Variant-Specific Serum Antibody Post-Vaccination Utilizing Immortalized Human Hepatocyte-Like Cells (HLC) to Assess Development of Immunity. BACKGROUND: Our previous studies demonstrated that SARS-CoV-2 spike protein could bind to primary hepatocytes and immortalized Hepatocyte-like cells (HLC) via the asialoglycoprotein receptor-1 (ASGR-1). The binding of biotinylated spike protein could be inhibited by Spike-neutralizing monoclonal antibodies, anti-ASGR-1 antibodies and unlabeled spike protein. The cells were unable to bind Spike S1 and Spike S1 was incapable of blocking labeled Spike protein, suggesting that the Receptor Binding Domain (RBD) was not involved in the binding event. This study was done to investigate the utility of these cells and immortalized alveolar type 2-like (AT-2) cells in studying the development of variant-specific antibodies post-vaccination. METHODS: Serum was collected from 10 individuals pre- and post-vaccination with the J&J, Moderna or Pfizer vaccines. The serum samples were quantified for variant-specific antibodies in a flow cytometry-based immunofluorescent assay utilizing beads coated with biotinylated variant spike proteins. Inhibition of spike protein binding to HLC and AT-2 cells by donor serum was analyzed by immunofluorescent confocal analysis. RESULTS: All variant spike proteins bound to HLC and AT-2 cells. Post-vaccination serum samples demonstrated increases of SARS-CoV-2 antibody levels from 2 weeks to 2.5 months post-vaccination with associated increased spike-blocking capacity. It was also demonstrated that vaccination with all the available vaccines stimulated antibodies that inhibited binding of all the available variant spike proteins to both HLC and AT-2 cells. CONCLUSION: HLC, along with AT-2 cells, provides a useful platform to study the development of neutralizing antibodies post-vaccination. Vaccination with the 3 available vaccines all elicited neutralizing serum antibodies that inhibited binding of each of the variant spike proteins to both AT-2 and HLC cells. This study suggests that inhibition of spike binding to target cells may be a more useful technique to assess immunity than gross quantitation of antibody.

Ocular Flutter-Myoclonus-Ataxia Syndrome After mRNA BNT162b2 COVID-19 Vaccine: A Case Report. Ocular flutter (OF) is a rare oculomotor syndrome. The most common etiologies are paraneoplastic, postinfectious and toxic-metabolic. However post-vaccinal etiology was rarely reported in OF. Here, we reported a post-vaccinal clinical syndrome characterized by OF-myoclonus and ataxia associated with oligoclonal bands (OCBs). A 60-year-old male who presented with dizziness, unsteady gait, involuntary movements, involuntary conjugate eye oscillations and extremity jerks that started 3 days after the second dose of mRNA BNT162b2 Covid-19 vaccine. Routine biochemical and serological analysis were within normal limits. No pathological finding was detected in brain MRI. Paraneoplastic and autoimmune encephalitis tests were unremarkable in cerebrospinal fluid (CSF). Oligoclonal bands were positive in CSF. This is the first description of the relationship between vaccines against SARS-CoV-2 and the clinical syndrome of OF, Myoclonus and Ataxia (OFMAS). Humoral immune

mechanisms seem to play an important role in OFMAS. Presence of OCBs in CSF may also be associated with this condition.

Analysis of the Association Between BNT162b2 mRNA COVID-19 Vaccination and Deaths Within 10 Days After Vaccination Using the Sex Ratio in Japan. INTRODUCTION: The association between coronavirus disease 2019 (COVID-19) vaccinations and deaths after vaccination has been investigated primarily through cohort and self-controlled case series studies. In the present study, the sex ratios of reported deaths were compared by period. METHODS: Descriptive analysis was conducted using data on deaths reported after vaccination with the BNT162b2 mRNA vaccine. The data used were published by the Ministry of Health, Labour and Welfare in Japan. The risk period was defined as within 10 days of vaccination, and the control period was defined as 11 to 180 days after vaccination. Sex ratios were calculated for all-cause deaths and each outcome by dividing the number of males by that of females and multiplying by 100. Fisher's exact test was performed to analyze the results. Graphs were created to show the number of days from vaccination to death and that of reported deaths. RESULTS: For all-cause deaths among individuals aged â‰¥65 years, the sex ratio during the risk period was 92, significantly lower than that during the control period (130) (p=0.0050). Conversely, for all-cause deaths among those aged â‰¤64 years, the sex ratio during the risk period was 204, significantly higher than that during the control period (111) (p=0.044). Reported deaths were concentrated during the risk period in both groups. Sex ratios by period for each outcome were also examined. However, the differences were not significant across any of the outcomes. CONCLUSION: The results indicate that the BNT162b2 mRNA vaccination may influence the occurrence of death during the risk period. In a cohort study in Japan, there was no significant increase in all-cause mortality owing to vaccination. This does not contradict the results of the present study. The results of a cohort study provide support for vaccine safety. However, this does not indicate that vaccine-related deaths are nonexistent; it only indicates that their number is not large enough to make a significant difference. Japan has relief services for adverse health effects that provide financial support to patients. On this occasion, it is difficult to determine whether a postvaccination death is incidental or vaccine-related. A self-controlled risk interval design and a comparison of sex ratios by period may be useful in examining the association between vaccination and deaths after vaccination when a cohort study does not detect a significant difference due to a low mortality rate. The latter approach may be particularly useful for analyzing data with reporting bias. The author believes that this approach may not provide conclusive evidence, but it can offer valuable insights into assessing vaccine safety.

Persistent immune imprinting after XBB.1.5 COVID vaccination in humans. Immune imprinting - also known as 'original antigenic sin' - describes how the first exposure to a virus shapes the immunological outcome of subsequent exposures to antigenically related strains. SARS-CoV-2 Omicron breakthrough infections and bivalent COVID-19 vaccination were shown to primarily recall cross-reactive memory B cells and antibodies induced by prior mRNA vaccination with the Wuhan-Hu-1 spike rather than priming naive B cells that recognize Omicron-specific epitopes. These findings underscored a strong immune imprinting resulting from repeated Wuhan-Hu-1 spike exposures. To understand if immune imprinting can be overcome, we investigated memory and plasma antibody responses after administration of the updated XBB.1.5 COVID mRNA vaccine booster. Our data show that the XBB.1.5 booster elicits neutralizing antibody responses against current variants that are dominated by recall of pre-existing memory B cells previously induced by the Wuhan-Hu-1 spike. These results indicate that immune imprinting persists even after multiple exposures to Omicron spikes through vaccination and infection, including post XBB.1.5 spike booster mRNA vaccination, which will need to be considered to guide the design of future vaccine boosters.

Occurrence of adult-onset Still's disease after coronavirus disease 2019 BNT162B2 vaccination in a patient with ulcerative colitis: A case report and review of literature. KEY CLINICAL MESSAGE: We report an extremely rare occurrence of adult-onset Still's disease (AOSD) in a patient with ulcerative colitis. The possibility of autoinflammatory conditions such as AOSD should be considered when evaluating or treating symptoms suspected as side effects of the severe acute respiratory syndrome coronavirus 2 vaccination, regardless of the associated comorbidities. SUMMARY: A woman in her 50s with a history of stable ulcerative colitis (UC) for 20â€‰years, managed using salazosulfapyridine, presented with migratory rashes, spiking fever, edema, and joint pain that started 1â€‰week after receiving the BNT162B2 mRNA vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Laboratory tests revealed extremely high serum ferritin levels. The patient was diagnosed with adult-onset Still's disease (AOSD) based on the relevant classification criteria after ruling out other diseases. Detection of high levels of interleukin-18, an inflammatory cytokine related to AOSD, supported the diagnosis. Nonsteroidal anti-inflammatory drug monotherapy alone resulted in significant improvements in both the abovementioned symptoms and the elevated inflammatory marker levels. AOSD in a patient with UC is extremely rare. Only one case of AOSD with UC was reported before the coronavirus disease 2019 era. This case indicates that SARS-CoV-2 vaccination can trigger a hyperinflammatory response, classified as AOSD, in a patient with UC, which is extremely rare.

Alleviation of shoulder injury related to vaccine administration (SIRVA) pain and disability following COVID-19 vaccine with chiropractic biophysics(Â®) (CBP(Â®)) methods: a case report and long-term follow-up with global implications. [Purpose] To present the dramatic improvement in posture, radiographic parameters and the alleviation of neck and severe shoulder pain related to shoulder injury associated with vaccine administration (SIRVA) after a COVID-19 injection with a shoulder mobility and posture rehabilitation program. [Participant and Methods] A middle-aged male presented complaining of severe left shoulder pain evolving since receiving a COVID-19 vaccination. The pain was severe and throbbed into the neck. Posture analysis showed a chronic stooped posture with forward head posture and thoracic hyperkyphosis. Treatment included 42 sessions of Chiropractic Biophysics(Â®) technique and a shoulder rehabilitation program using three-dimensional vibration. [Results] At 4-months, the patient reported no neck or shoulder pain. There was a 60% decrease in neck disability. The forward head decreased 34 mm, thoracic hyperkyphosis decreased 13Â°, and T1-T12 forward lean decreased 73 mm, among other radiographic parameters. Re-assessment after 26-months showed maintenance of the treatment induced posture/x-ray corrections and shoulder pain relief. [Conclusion] This case demonstrates immediate and long-term improvement in a patient suffering from COVID-19 vaccine SIRVA, concomitant with neck pain and disability as well as significant radiographic postural/spinal deformity. These conditions all improved and were maintained at a 2â€…year follow-up without further treatment.

Distinctions between survivors and non-survivors with SARS-CoV-2 vaccine-induced thrombotic thrombocytopenia: A systematic review and meta-analysis. Vaccine-inducing immune thrombocytopenia, thrombosis, and bleeding emerge as infrequent and potential complications with mortality risk in healthy subjects. However, differences between survivors and non-survivors with SARS-CoV-2 vaccine-induced thrombotic thrombocytopenia (VITT) are unclear. METHODS: According to the PRISMA statement, we conducted a systematic review and meta-analysis, and the protocol was registered in PROSPERO. The main objective is to identify differences among survivors and non-survivors of SARS-CoV-2 VITT patients. We systematically searched through PubMed, Scopus, and Web of Science. We included cohorts, case series, and case reports. We classified bleeding complications according to the ISTH definition. Statistics: unpaired Student's t-test or one-way ANOVA, Wilcoxon, and Kruskal-Wallis. RESULTS: We systematically searched from January 2021 to

June 2021 and identified 51 studies that included 191 patients. Non-survivors had the most severe thrombocytopenia (p 0.02) and lower fibrinogen measurements (p 0.01). Subjects vaccinated with mRNA vaccines (BNT162b2 and mRNA-1273) had an earlier onset of adverse events following immunization (p 0.001). We identified a higher trend of overall thrombotic events (p 0.001) in recipients of viral mechanism-dependent vaccines (Table 2). Non-survivors with cerebral venous sinus thrombosis (CVST) had more severe thrombocytopenia (p 0.01) than survivors with CVST. Finally, 61Â % of survivors and 50Â % with thrombosis received heparin. CONCLUSION: We identified more severe thrombocytopenia, lower fibrinogen measurements, and a higher trend of overall thrombotic events, including CVST and thrombotic storm, particularly with viral mechanisms-dependent vaccines in non-survivors VITT patients.

Longitudinal study of antibody response following SARS-CoV-2 vaccination with Pfizer-BioNTech BNT162b2. OBJECTIVES: To assess the immunity of healthcare and non-healthcare workers in the Alcoy health area (Spain) after completing three doses of the Pfizer-BioNTech vaccine and how it relates with individual factors. METHODS: We conducted a prospective, observational, longitudinal, analytical study to observe immunogenicity in healthcare and non-healthcare workers at Virgen de los Lirios Hospital following administration of three doses of the Pfizer-BioNTech vaccine. Anti-SARS-CoV-2 spike protein IgG antibody concentrations were determined, while COVID-19 infections were identified by qualitative detection of IgG against the nucleocapsid protein. Samples from volunteers were analyzed 15 days, 3 months, and 6 months after receiving the second vaccine dose, and 12 months after receiving the third (booster) dose. A questionnaire was used to collect demographic data, risk factors, and use of immunosuppressive drugs. Statistical analyses were performed with SPSS software, and mean antibody levels over time were compared using ANOVA. RESULTS: Participation was 99.5â€¯% (199/200). The IgG concentration was higher in men and in obese individuals. No significant changes were noted in factors such as smoking. CONCLUSIONS: All participants developed humoral immunity, except for three subjects who were receiving immunosuppressive treatment. Participants with previous COVID-19 infection had higher antibody levels.

Successful treatment of new-onset diabetes mellitus and IgA nephropathy after COVID-19 vaccination: a case report. De novo glomerular injuries or relapse of nephropathy following COVID-19 vaccine has been reported. Here we present the first case of successful treatment of new-onset diabetes mellitus and biopsy-proven IgA nephropathy after COVID-19 vaccination. A 56-year-old man with no known medical history of renal dysfunction or diabetes mellitus developed both within 3 months after receiving a third dose of inactivated COVID-19 vaccine (Vero cells). His symptoms were characterized by brown urine, severe dry mouth, and excessive thirst. Randomly acquired blood glucose levels exceeded 33.3 mmol/L. A kidney biopsy showed IgA nephropathy. He was started on insulin for glycemic control. After glucocorticoid and cyclophosphamide treatment, oral tablets of repaglinide, combined with acarbose, controlled blood glucose and stabilized kidney function. This case is unique because the kidneys and pancreas were simultaneously affected by the vaccine. Successful treatment of the disease proved that cyclophosphamide combined with glucocorticoids were effective and that blood glucose was successfully controlled. This treatment option could be useful in similar cases in the future.

Breakthrough infection among healthcare personnel following exposure to COVID-19: Experience after one year of the world's largest vaccination drive. CONTEXT: The COVID-19 vaccination drive globally was supposedly a game-changing event. However, the emerging variants of the virus and waning immunity over time posed new challenges for breakthrough infections. Standing at the frontline of defense against COVID-19, healthcare personnel (HCP) were vulnerable to such infections. AIMS: This study estimates i) the vaccine breakthrough infections (VBI) among HCP

following exposure to COVID-19 cases, and ii) the mean interval between the second dose of vaccine and laboratory-confirmed SARS-CoV-2 infection. MATERIALS AND METHODS: A cross-sectional study was conducted including 385 HCP with a history of exposure to COVID-19 cases during January and February 2022. Demographic details and clinical and vaccination history were collected from the test forms and the Web-based hospital management system. Laboratory testing of COVID-19 was carried out by real-time RT-PCR test. RESULTS: The majority of the HCP were males (262; 68.05%) and nurses (180; 46.75%) by occupation. Two doses of vaccines were received by 278 (87.7%) HCP. VBI was confirmed in 185 (66.55%) HCP. No significant difference in VBI between the COVAXIN and COVISHIELD recipients (P = 0.69) was observed. The interval between the second dose and confirmed SARS-CoV-2 infection was significantly higher (P < 0.00001) in COVAXIN recipients (median 228 days) than in COVISHIELD recipients (median 95 days). CONCLUSIONS: The incidence of VBI was very high among the HCP, but not statistically different among the COVAXIN and COVISHIELD-recipients. Waning immunity over time suggests boosting immunity with a third dose because of emerging variants.

Eleven-month SARS-CoV-2 binding antibody decay, and associated factors, among mRNA vaccinees: implications for booster vaccination. BACKGROUND: We examined the 11â€‰month longitudinal antibody decay among two-dose mRNA vaccinees, and identified factors associated with faster decay. METHODS: The study included samples from the COVID-19 Occupational Risk, Seroprevalence and Immunity among Paramedics (CORSIP) longitudinal observational study of paramedics in Canada. Participants were included if they had received two mRNA vaccines without prior SARS-CoV-2 infection and provided two blood samples post-vaccination. The outcomes of interest were quantitative SARS-CoV-2 antibody concentrations. We employed spaghetti and scatter plots (with kernel-weighted local polynomial smoothing curve) to describe the trend of the antibody decay over 11â€‰months post-vaccine and fit a mixed effect exponential decay model to examine the loss of immunogenicity and factors associated with antibody waning over time. RESULTS: This analysis included 652 blood samples from 326 adult paramedics. Total anti-spike antibody levels peaked on the twenty-first day (antibody level 9042â€‰Uâ€‰ml(-1)) after the second mRNA vaccine dose. Total anti-spike antibody levels declined thereafter, with a half-life of 94 [95â€Š% CI: 70, 143] days, with levels plateauing at 295â€‰days (antibody level 1021â€‰Uâ€‰ml(-1)). Older age, vaccine dosing interval <35â€‰days, and the BNT162b2 vaccine (compared to mRNA-1273 vaccine) were associated with faster antibody decay. CONCLUSION: Antibody levels declined after the initial mRNA series with a half-life of 94â€‰days, plateauing at 295â€‰days. These findings may inform the timing of booster vaccine doses and identifying individuals with faster antibody decay.

The relationship between the number of COVID-19 vaccines and infection with Omicron ACE2 inhibition at 18-months post initial vaccination in an adult cohort of Canadian paramedics. The coronavirus disease 2019 (COVID-19) pandemic, caused by the SARS-CoV-2 virus, has rapidly evolved since late 2019, due to highly transmissible Omicron variants. While most Canadian paramedics have received COVID-19 vaccination, the optimal ongoing vaccination strategy is unclear. We investigated neutralizing antibody (NtAb) response against wild-type (WT) Wuhan Hu-1 and Omicron BA.4/5 lineages based on the number of doses and past SARS-CoV-2 infection, at 18â€‰months post-initial vaccination (with a Wuhan Hu-1 platform mRNA vaccine [BNT162b2 or mRNA-1273]). Demographic information, previous COVID-19 vaccination, infection history, and blood samples were collected from paramedics 18â€‰months post-initial mRNA COVID-19 vaccine dose. Outcome measures were ACE2 percent inhibition against Omicron BA.4/5 and WT antigens. We compared outcomes based on number of vaccine doses (two vs. three) and previous SARS-CoV-2 infection status, using the Mann-Whitney U test. Of 657 participants, the median age was 40â€‰years (IQR 33-50) and 251 (42â€Š%) were females. Overall, median percent inhibition to BA.4/5 and WT was 71.61â€Š% (IQR 39.44-92.82)

and 98.60â€Š% (IQR 83.07-99.73), respectively. Those with a past SARS-CoV-2 infection had a higher median percent inhibition to BA.4/5 and WT, when compared to uninfected individuals overall and when stratified by two or three vaccine doses. When comparing two vs. three WT vaccine doses among SARS-CoV-2 negative participants, we did not detect a difference in BA.4/5 percent inhibition, but there was a difference in WT percent inhibition. Among those with previous SARS-CoV-2 infection(s), when comparing two vs. three WT vaccine doses, there was no observed difference between groups. These findings demonstrate that additional Whttps://www.covid19immunitytaskforce.ca/citf-databank/#accessing https://www.covid19immunitytaskforce.ca/citf-databank/#accessinguhan Hu-1 platform mRNA vaccines did not improve NtAb response to BA.4/5, but prior SARS-CoV-2 infection enhances NtAb response.

Errors and issues in risk of all-cause and cardiac-related mortality after vaccination against COVID-19: A meta-analysis of self-controlled case series studies.

Assessing the risk of COVID-19 reinfection and severe outcomes among individuals with substance use disorders: a retrospective study using real-world electronic health records. OBJECTIVE: Despite advancement in vaccines and treatments for COVID-19 over the past 2â€‰years, many concerns remain about reinfection and waning immunity against COVID-19 and its variants, especially among people with substance use disorder (SUD). The study assessed the risk of COVID-19 reinfection and severe illness among adults with SUD and their vaccination status to inform management in this vulnerable population as the pandemic continues. DESIGN: Retrospective cohort study. SETTING: Nationwide electronic health records (TriNetX database) in the USA among adults with COVID-19 infection from January 2020 to June 2022. PARTICIPANTS: Adults (age â‰¥18 years) who were infected by COVID-19, excluding those who had cancer or lived in nursing homes or palliative care facilities. OUTCOME MEASURES: COVID-19 reinfection was defined as a new diagnosis after 45 days of the initial infection. Logistic regression was applied to assess the OR of COVID-19 reinfection and severe outcomes within 30 day of reinfection for adults with alcohol (AUD), opioid (OUD), cocaine (CUD), stimulant (STUD), cannabis (CAUD) and other use disorders, controlled for demographic and comorbid conditions. RESULTS: The SUD cohort was 13%-29%â€‰more likely to be reinfected by COVID-19 and had significantly higher 30-day mortality. Adults with AUD, STUD and OUD were at greater risks (adjusted ORs, AORs=1.69-1.86) of emergency department, hospital and intensive care admissions after 30 days of reinfection. Individuals with SUD and multiple vaccines doses were associated with decreased risks of worse COVID-19 outcomes. Lower COVID-19 reinfection rates (AORs=0.67-0.84) were only found among individuals with AUD, CUD or CAUD who had COVID-19 vaccination. CONCLUSIONS: Individuals with SUD had greater risks of COVID-19 reinfection and poor outcomes, especially those with OUD, STUD and AUD. Multiple vaccinations are recommended to reduce severe illness after COVID-19 reinfection in the SUD population.

[Multiple microthromboses with autoimmune hemolytic anemia after BNT162b2 mRNA vaccination]. A 68-year-old man was referred to our hospital with dizziness and mild fever one week after receiving the second dose of the COVID-19 mRNA vaccine (BNT162b2). Laboratory tests showed hemolytic anemia and a positive direct Coombs test, and he was diagnosed with autoimmune hemolytic anemia (AIHA). On admission, the patient had impaired consciousness with auditory hallucinations, and a head MRI scan showed multiple high-signal areas on diffusion-weighted imaging, suggesting multiple recent infarctions. Echocardiography also showed decreased wall motion in the inferior and posterior walls. A skin biopsy to investigate the cause revealed many platelets and fibrin thrombi in the capillaries and small veins, which was considered the cause of the organ damage. After starting prednisolone (1 mg/kg) for AIHA, hemolytic anemia as well as impaired consciousness, and decreased

wall motion rapidly improved. Microthrombosis after BNT162b2 mRNA vaccination is rare, and autoimmune abnormalities appeared to contribute to onset in this case.

Global burden of vaccine-associated anaphylaxis and their related vaccines, 1967-2023: A comprehensive analysis of the international pharmacovigilance database. BACKGROUND: Vaccine-associated anaphylaxis is a rare but life-threatening reaction that occurs within minutes to hours of exposure to allergens. As studies utilizing large-scale data to investigate this topic are limited, further research is needed to assess its burden, long-term trends, and associated risk factors so as to gain a comprehensive understanding of vaccine-associated anaphylaxis globally. Therefore, this study aimed to investigate the global burden of vaccine-associated anaphylaxis and related vaccines. METHOD: This study utilized the World Health Organization International Pharmacovigilance Database, in which reports of vaccine-associated anaphylaxis between 1967 and 2023 were obtained (total reportsâ€‰=â€‰131,255,418). We estimated the global reporting counts, reported odds ratio (ROR), and information component (IC) to identify the relationship between 19 vaccines and associated anaphylaxis in 156 countries and territories. RESULTS: We identified 31,676 reports of vaccine-associated anaphylaxis among 363,290 reports of all-cause anaphylaxis. The cumulative number of reports on vaccine-associated anaphylaxis has gradually increased over time, with a dramatic increase after 2020, owing to reports of COVID-19 mRNA vaccine-associated anaphylaxis. The typhoid vaccines were associated with the most anaphylactic reports (ROR: 4.35; IC(0.25) : 1.86), followed by encephalitis (3.27; 1.45), hepatitis B (2.69; 1.30), cholera (2.65; 0.54), hepatitis A (2.44; 1.12), influenza (2.36; 1.16), inactivated whole-virus COVID-19 (2.21; 1.02), and COVID-19 mRNA vaccines (1.89; 0.79). In terms of age- and sex-specific risks, vaccine-associated anaphylaxis reports develop more frequently in females and at young ages. The Ad5-vectored COVID-19 vaccine anaphylaxis reports were associated with the highest fatality rate (15.0%). CONCLUSIONS: Although multiple vaccines are associated with various spectra and risks of anaphylaxis, clinicians should recognize the possibility of anaphylaxis occurring with all vaccines, particularly the COVID-19 mRNA and inactivated whole-virus COVID-19 vaccines, and consider the risk factors associated with vaccine anaphylaxis reports. Further studies are warranted to identify better ways of preventing vaccine-associated anaphylaxis.

HLA binding-groove motifs are associated with myocarditis induction after Pfizer-BioNTech BNT162b2 vaccination. BACKGROUND AND AIMS: We found a higher incidence of myocarditis in young males who had received at least two Pfizer-BioNTech BNT162b2 vaccinations. The human leukocyte antigens (HLA) are known to play an important role in infectious and autoinflammatory diseases. We hypothesized that certain HLA alleles might be associated with vaccination-induced myocarditis. METHODS: HLA typing was performed using next-generation sequencing technology with the Illumina Iseq100 platform. HLA class I and II loci were genotyped in 29 patients with post-vaccination myocarditis and compared with HLA data from 300 healthy controls. RESULTS: We demonstrate that the DRB1*14:01, DRB1*15:03 alleles and the motifs in HLA-Aâ€‰-â€‰Leu62 and Gln63, which are part of binding pocket B and HLA-DR Tyr47, His60, Arg70 and Glu74, which are part of binding pockets P4, P7 and P9, were significantly associated with disease susceptibility. CONCLUSIONS: Our findings suggest that immunogenetic fingerprints in HLA peptide-binding grooves may affect the presentation of peptides derived from the Pfizer-BioNTech BNT162b2 vaccination to T cells and induce an inflammatory process that results in myocarditis.

Employment of a high throughput functional assay to define the critical factors that influence vaccine induced cross-variant neutralizing antibodies for SARS-CoV-2. The scale and duration of neutralizing antibody responses targeting SARS-CoV-2 viral variants represents a critically important serological parameter that predicts protective immunity for COVID-19. In this study, we describe the development and employment of a new functional assay that measures neutralizing antibodies for

SARS-CoV-2 and present longitudinal data illustrating the impact of age, sex and comorbidities on the kinetics and strength of vaccine-induced antibody responses for key variants in an Asian volunteer cohort. We also present an accurate quantitation of serological responses for SARS-CoV-2 that exploits a unique set of in-house, recombinant human monoclonal antibodies targeting the viral Spike and nucleocapsid proteins and demonstrate a reduction in neutralizing antibody titres across all groups 6 months post-vaccination. We also observe a marked reduction in the serological binding activity and neutralizing responses targeting recently newly emerged Omicron variants including XBB 1.5 and highlight a significant increase in cross-protective neutralizing antibody responses following a third dose (boost) of vaccine. These data illustrate how key virological factors such as immune escape mutations combined with host demographic factors such as age and sex of the vaccinated individual influence the strength and duration of cross-protective serological immunity for COVID-19.

Reply to 'New onset of systemic lupus erythematosus following COVID-19 mRNA vaccination'.

Dual Effects of 3-epi-betulin from Daphniphyllum glaucescens in Suppressing SARS-CoV-2-Induced Inflammation and Inhibiting Virus Entry. The continuous emergence of SARS-CoV-2 variants has led to a protracted global COVID-19 pandemic with significant impacts on public health and global economy. While there are currently available SARS-CoV-2 vaccines and therapeutics, most of the FDA-approved antiviral agents directly target viral proteins. However, inflammation is the initial immune pathogenesis induced by SARS-CoV-2 infection, there is still a need to find additional agents that can control the virus in the early stages of infection to alleviate disease progression for the next pandemic. Here, we find that both the spike protein and its receptor CD147 are crucial for inducing inflammation by SARS-CoV-2 in THP-1 monocytic cells. Moreover, we find that 3-epi-betulin, isolated from Daphniphyllum glaucescens, reduces the level of proinflammatory cytokines induced by SARS-CoV-2, consequently resulting in a decreased viral RNA accumulation and plaque formation. In addition, 3-epi-betulin displays a broad-spectrum inhibition of entry of SARS-CoV-2 pseudoviruses, including Alpha (B.1.1.7), Eplison (B.1.429), Gamma (P1), Delta (B.1.617.2) and Omicron (BA.1). Moreover, 3-epi-betulin potently inhibits SARS-CoV-2 infection with an EC(50) of <20 Î¼M in Calu-3 lung epithelial cells. Bioinformatic analysis reveals the chemical interaction between the 3-epi-betulin and the spike protein, along with the critical amino acid residues in the spike protein that contribute to the inhibitory activity of 3-epi-betulin against virus entry. Taken together, our results suggest that 3-epi-betulin exhibits dual effect: it reduces SARS-CoV-2-induced inflammation and inhibits virus entry, positioning it as a potential antiviral agent against SARS-CoV-2.

Thrombotic anti-PF4 immune disorders: HIT, VITT, and beyond. Antibodies against the chemokine platelet factor 4 (PF4) occur often, but only those that activate platelets induce severe prothrombotic disorders with associated thrombocytopenia. Heparin-induced thrombocytopenia (HIT) is the prototypic anti-PF4 disorder, mediated by strong activation of platelets through their FcÎ³IIa (immunoglobulin G [IgG]) receptors (FcÎ³RIIa). Concomitant pancellular activation (monocytes, neutrophils, endothelium) triggers thromboinflammation with a high risk for venous and arterial thrombosis. The classic concept of HIT is that anti-PF4/heparin IgG, recognizing antigen sites on (cationic) PF4 that form in the presence of (anionic) heparin, constitute the heparin-dependent antibodies that cause HIT. Accordingly, HIT is managed by anticoagulation with a nonheparin anticoagulant. In 2021, adenovirus vector COVID-19 vaccines triggered the rare adverse effect "vaccine-induced immune thrombotic thrombocytopenia" (VITT), also caused by anti-PF4 IgG. VITT is a predominantly heparin-independent platelet-activating disorder that requires both therapeutic-dose anticoagulation and inhibition of FcÎ³RIIa-mediated platelet activation by high-dose intravenous immunoglobulin (IVIG). HIT and VITT antibodies bind to different epitopes on PF4; new immunoassays can differentiate between these distinct HIT-like and VITT-like antibodies. These studies indicate that (1) severe, atypical presentations of HIT ("autoimmune HIT") are associated with both HIT-like

(heparin-dependent) and VITT-like (heparin-independent) anti-PF4 antibodies; (2) in some patients with severe acute (and sometimes chronic, recurrent) thrombosis, VITT-like antibodies can be identified independent of proximate heparin exposure or vaccination. We propose to classify anti-PF4 antibodies as type 1 (nonpathogenic, non- platelet activating), type 2 (heparin dependent, platelet activating), and type 3 (heparin independent, platelet activating). A key concept is that type 3 antibodies (autoimmune HIT, VITT) require anticoagulation plus an adjunct treatment, namely high-dose IVIG, to deescalate the severe anti-PF4 IgG-mediated hypercoagulability state.

The intention to get COVID-19 booster vaccination and its association with cognitive and emotional factors: A survey of Chinese COVID-19 infected people in Hong Kong. BACKGROUND: Although the pandemic has ended officially, COVID-19 remains impactful. Booster COVID-19 vaccination is still needed to protect individuals against COVID-19 and the disease's harmful consequences. This study investigated the prevalence of the intention to get booster COVID-19 vaccination after receiving the COVID-19 diagnosis and its associated factors among people reporting prior COVID-19. METHODS: A population-based anonymous telephone survey was conducted in Hong Kong, China from June to August 2022 among Chinese people reporting prior COVID-1 between February and August 2022 and having taken up â‰¥2 doses of COVID-19 vaccines prior to COVID-19 diagnosis. RESULTS: The prevalence of the intention to get booster vaccination was 59.2Â %. Older age (>60Â years), being currently married, not employed full-time, and having chronic diseases were positively associated with the intention to get booster vaccination. Adjusted for the background factors, higher levels of the cognitive factors of perceived susceptibility to COVID-19, perceived acquired moderate-to-strong immunity against COVID-19, and perceived adequate knowledge of COVID-19 were positively associated with the intention to get booster vaccination; stronger perceived severity of prior infection despite vaccination was negatively associated with the intention outcome. In contrast, stronger mental distress due to COVID-19, illness concern, and emotional representation were positively associated with the intention. Self-perceived long COVID status was not a significant factor. DISCUSSION: The prevalence of the intention to get booster COVID-19 vaccination was limited, especially among younger people reporting prior COVID-19. Health promotion is still required among people reporting prior COVID-19 and may emphasize the significant cognitive factors positively associated with the intention. Future studies are needed to confirm the findings, clarify the role of emotional factors on booster vaccination, and explore other factors of the intention to get booster vaccination among people reporting prior COVID-19.

SARS-CoV-2 vaccination enhances the effector qualities of spike-specific T cells induced by COVID-19. T cells are critical for immune protection against severe COVID-19, but it has remained unclear whether repeated exposure to SARS-CoV-2 antigens delivered in the context of vaccination fuels T cell exhaustion or reshapes T cell functionality. Here, we sampled convalescent donors with a history of mild or severe COVID-19 before and after SARS-CoV-2 vaccination to profile the functional spectrum of hybrid T cell immunity. Using combined single-cell technologies and high-dimensional flow cytometry, we found that the frequencies and functional capabilities of spike-specific CD4(+) and CD8(+) T cells in previously infected individuals were enhanced by vaccination, despite concomitant increases in the expression of inhibitory receptors such as PD-1 and TIM3. In contrast, CD4(+) and CD8(+) T cells targeting non-spike proteins remained functionally static and waned over time, and only minimal effects were observed in healthy vaccinated donors experiencing breakthrough infections with SARS-CoV-2. Moreover, hybrid immunity was characterized by elevated expression of IFN-Î³, which was linked with clonotype specificity in the CD8(+) T cell lineage. Collectively, these findings identify a molecular hallmark of hybrid immunity and suggest that vaccination after infection is associated with cumulative immunological benefits over time, potentially conferring enhanced protection against subsequent episodes of COVID-19.

RBD-specific antibody response after two doses of different SARS-CoV-2 vaccines during the mass vaccination campaign in Mongolia. The SARS-CoV-2 vaccination campaign began in February 2021 and achieved a high rate of 62.7% of the total population fully vaccinated by August 16, 2021, in Mongolia. We aimed to assess the initial protective antibody production after two doses of a variety of types of SARS-CoV-2 vaccines in the Mongolian pre-vaccine antibody-naÃ¯ve adult population. This prospective study was conducted from March-April to July-August of 2021. All participants received one of the four government-proposed COVID-19 vaccines including Pfizer/BioNTech (BNT162b2), AstraZeneca (ChAdOx1-S), Sinopharm (BBIBP-CorV), and Sputnik V (Gam-COVID-Vac). Before receiving the first shot, anti-SARS-CoV-2 S-RBD human IgG titers were measured in all participants (n = 1833), and titers were measured 21-28 days after the second shot in a subset of participants (n = 831). We found an overall average protective antibody response of 84.8% (705 of 831 vaccinated) in 21-28 days after two doses of the four types of COVID-19 vaccines. Seropositivity and titer of protective antibodies produced after two shots of vaccine were associated with the vaccine types, age, and residence of vaccinees. Seropositivity rate varied significantly between vaccine types, 80.0% (28 of 35) for AstraZeneca ChAdOx1-S; 97.0% (193 of 199) for Pfizer BNT162b2; 80.7% (474 of 587) for Sinopharm BBIBP-CorV, and 100.0% (10 of 10) for Sputnik V Gam-COVID-Vac, respectively. Immunocompromised vaccinees with increased risk for developing severe COVID-19 disease had received the Pfizer vaccine and demonstrated a high rate of seropositivity. A high geometric mean titer (GMT) was found in vaccinees who received BNT162b2, while vaccinees who received ChAdOx1-S, Sputnik V, and BBIBP-CorV showed a lower GMT. In summary, we observed first stages of the immunization campaign against COVID-19 in Mongolia have been completed successfully, with a high immunogenicity level achieved among the population with an increased risk for developing severe illness.

Safety of Janssen Ad26.COV.S and Astra Zeneca AZD1222 COVID-19 Vaccines among Mobile Phone Users in Malawi: Findings from a National Mobile-Based Syndromic Surveillance Survey, July 2021 to December 2021. The safety profiles of the Ad26.COV2.S and AZD1222 COVID-19 vaccines have not been described in the general population in Malawi. We present self-reported adverse events (AE) following the receipt of these vaccines in Malawi as part of a national syndromic surveillance survey. We conducted phone-based syndromic surveillance surveys among adults (â‰¥18 years) with verbal consent. We used secure tablets through random digit dialing to select mobile phone numbers and collected data electronically. Survey questions included whether the respondent had received the COVID-19 vaccines, whether they had experienced any AE following vaccination, and the severity of the AE. We used multivariable analysis to identify factors associated with self-reported AE post-COVID-19 vaccination. A total of 11,924 (36.0%) out of 33,150 respondents reported receiving at least one dose of either Ad26.COV2.S or AZD1222 between July-December 2021; of those, 65.1% were female. About 49.2% of the vaccine recipients reported at least one AE, 90.6% of which were mild, and 2.6% were severe. Higher education level and concern about the safety of COVID-19 vaccines were associated with AE self-report (Adjusted Odds Ratio [AOR] 2.63 [95% CI 1.96-3.53] and 1.44, [95% CI 1.30-1.61], respectively), while male gender and older age were associated with reduced likelihood of AE self-report (AORs 0.81, [95% CI 0.75-0.88], 0.62 [95% CI 0.50-0.77], respectively). Ad26.COV2.S and AZD1222 vaccines are well-tolerated, with primarily mild and few severe AE among adults living in Malawi. Self-reporting of AE following COVID-19 vaccination is associated with gender, age, education, and concern about the safety of the vaccines. Recognizing these associations is key when designing and implementing COVID-19 vaccination communication messages to increase vaccination coverage.

Unpacking adverse events and associations post COVID-19 vaccination: a deep dive into vaccine adverse event reporting system data. INTRODUCTION: The rapid development of COVID-19

vaccines has provided crucial tools for pandemic control, but the occurrence of vaccine-related adverse events (AEs) underscores the need for comprehensive monitoring. METHODS: This study analyzed the Vaccine Adverse Event Reporting System (VAERS) data from 2020-2022 using statistical methods such as zero-truncated Poisson regression and logistic regression to assess associations with age, gender groups, and vaccine manufacturers. RESULTS: Logistic regression identified 26 System Organ Classes (SOCs) significantly associated with age and gender. Females displayed especially higher odds in SOC 19 (Pregnancy, puerperium and perinatal conditions), while males had higher odds in SOC 25 (Surgical and medical procedures). Older adults (>65) were more prone to symptoms like Cardiac disorders, whereas those aged 18-65 showed susceptibility to AEs like Skin and subcutaneous tissue disorders. Moderna and Pfizer vaccines induced fewer SOC symptoms compared to Janssen and Novavax. The zero-truncated Poisson regression model estimated an average of 4.243 symptoms per individual. CONCLUSION: These findings offer vital insights into vaccine safety, guiding evidence-based vaccination strategies and monitoring programs for precise and effective outcomes.

Factors associated with parental intention to vaccinate their child against influenza, Finland, February to March, 2022: a web-based survey. BackgroundInfluenza vaccination for children aged 6 months to 6 years is included in the national vaccination programme in Finland. Although all vaccines in the programme are free of charge, national coverage of influenza vaccination among children under 3 years and 3-6 years during 2020/21 was 43% and 35% respectively, with regional differences.AimTo assess factors underlying parental vaccination intention in order to increase influenza vaccine uptake among children.MethodsWe conducted a web-based survey among parents (nâ€‰=â€‰17,844) of randomly selected eligible children (aged 6 months-6 years) in February-March 2022 in five Finnish municipalities from regions of high and low coverage. Logistic regressions were used to determine associations between vaccination intention and e.g. sociodemographic factors, attitudes and knowledge. Linkage to the national vaccination register was used to confirm realisation of vaccination intention after the study.ResultsParticipation rate was 13% (nâ€‰=â€‰2,322 parents). Influenza knowledge, trust in official information, responding parent's education level, adherence to the vaccination programme, number of children and changes in attitudes towards vaccination since COVID-19 were all associated with intention to vaccinate. Vaccination intention for children was 64%, and realised vaccination 51%.ConclusionDespite the low participation rate, both vaccinated and unvaccinated children were represented. Influenza vaccine uptake is not dependent on a single factor. Our results identified the need for open dialogue between parents and healthcare professionals, as the lack of vaccine being offered by healthcare professionals was the most reported reason for not vaccinating.

Behavioral Predictors Associated with COVID-19 Vaccination and Infection Among Men Who Have Sex with Men in the Republic of Korea. OBJECTIVES: This study investigated the impact of socioeconomic factors and sexual orientation-related attributes on the rates of coronavirus disease 2019 (COVID-19) vaccination and infection among men who have sex with men (MSM). METHODS: A web-based survey, supported by the National Research Foundation of Korea, was conducted among paying members of the leading online portal for the LGBTQ+ community in Korea. The study participants were MSM living in Korea (N=942). COVID-19 vaccination and infection were considered dependent variables, while sexual orientation-related characteristics and adherence to non-pharmacological intervention (NPI) practices served as primary independent variables. To ensure analytical precision, nested logistic regression analyses were employed. These were further refined by dividing respondents into 4 categories based on sexual orientation and disclosure (or "coming-out") status. RESULTS: Among MSM, no definitive association was found between COVID-19 vaccination status and factors such as socioeconomic or sexual orientation-related attributes (with the latter including HIV status, sexual orientation, and disclosure experience). However, key determinants

influencing COVID-19 infection were identified. Notably, people living with HIV (PLWH) exhibited a statistically significant predisposition towards COVID-19 infection. Furthermore, greater adherence to NPI practices among MSM corresponded to a lower likelihood of COVID-19 infection. CONCLUSIONS: This study underscores the high susceptibility to COVID-19 among PLWH within the LGBTQ+ community relative to their healthy MSM counterparts. Consequently, it is crucial to advocate for tailored preventive strategies, including robust NPIs, to protect these at-risk groups. Such measures are essential in reducing the disparities that may emerge in a post-COVID-19 environment.
Optimizing Signal Management in a Vaccine Adverse Event Reporting System: A Proof-of-Concept with COVID-19 Vaccines Using Signs, Symptoms, and Natural Language Processing. INTRODUCTION: The Vaccine Adverse Event Reporting System (VAERS) has already been challenged by an extreme increase in the number of individual case safety reports (ICSRs) after the market introduction of coronavirus disease 2019 (COVID-19) vaccines. Evidence from scientific literature suggests that when there is an extreme increase in the number of ICSRs recorded in spontaneous reporting databases (such as the VAERS), an accompanying increase in the number of disproportionality signals (sometimes referred to as 'statistical alerts') generated is expected. OBJECTIVES: The objective of this study was to develop a natural language processing (NLP)-based approach to optimize signal management by excluding disproportionality signals related to listed adverse events following immunization (AEFIs). COVID-19 vaccines were used as a proof-of-concept. METHODS: The VAERS was used as a data source, and the Finding Associated Concepts with Text Analysis (FACTA+) was used to extract signs and symptoms of listed AEFIs from MEDLINE for COVID-19 vaccines. Disproportionality analyses were conducted according to guidelines and recommendations provided by the US Centers for Disease Control and Prevention. By using signs and symptoms of listed AEFIs, we computed the proportion of disproportionality signals dismissed for COVID-19 vaccines using this approach. Nine NLP techniques, including Generative Pre-Trained Transformer 3.5 (GPT-3.5), were used to automatically retrieve Medical Dictionary for Regulatory Activities Preferred Terms (MedDRA PTs) from signs and symptoms extracted from FACTA+. RESULTS: Overall, 17% of disproportionality signals for COVID-19 vaccines were dismissed as they reported signs and symptoms of listed AEFIs. Eight of nine NLP techniques used to automatically retrieve MedDRA PTs from signs and symptoms extracted from FACTA+ showed suboptimal performance. GPT-3.5 achieved an accuracy of 78% in correctly assigning MedDRA PTs. CONCLUSION: Our approach reduced the need for manual exclusion of disproportionality signals related to listed AEFIs and may lead to better optimization of time and resources in signal management.
Two Cases of Delayed Bullous Local Reactions to the ChAdOx1 Adenovirus Vector Vaccine against SARS-CoV-2.
Leukocytoclastic Vasculitis with Ischemic Colitis Following COVID-19 AstraZeneca Vaccine.
Cases of Pernio-Like Lesions after mRNA-1273 Vaccination with Clinical and Pathological Features: A Single-Center Experience. The currently available coronavirus disease 2019 (COVID-19) vaccines in South Korea include mRNA (Moderna(Â®) and Pfizer(Â®)) and adenoviral vector (AstraZeneca(Â®) and Janssen(Â®)) vaccines. Dermatologic side effects of COVID-19 vaccines range from local injection site reactions to systemic eruptions, including morbilliform rashes or erythema multiforme. Pernio-like lesions, one of the most common cutaneous manifestations of COVID-19, have been rarely reported post-vaccination. Herein, we report four cases of pernio-like lesions, which were detected in a single tertiary hospital within 2 months, after the first dose of mRNA-1273 (Moderna(Â®)) vaccination was administered. In this study, we discuss the clinical and pathological features of our cases and compare them with those of previously reported cases of pernio-like lesions after COVID-19 vaccination. It is pivotal to realize that perniolike lesions can be a possible side effect of COVID-19

vaccination and that the number of patients experiencing this side effect is bound to be quite high in real-world clinical settings.

A Generalized Lichen Planus Following COVID-19 Vaccination: A Case Report. As part of the efforts to overcome the ongoing coronavirus disease 2019 (COVID-19) pandemic, mass vaccination programs against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been initiated. Since then, an increasing number of cutaneous adverse events associated with the COVID-19 vaccines have been reported. Lichen planus (LP) is a rare inflammatory mucocutaneous disease with various clinical presentations, although uncommon, occurring following vaccination. There have been several cases of LP reported following COVID-19 vaccination. However, there has been no report of generalized LP following the COVID-19 vaccine to our knowledge. Herein, we report a case of generalized LP following the Oxford/AstraZeneca (AZD1222) vaccine. A 68-year-old female presented with widespread, erythematous pruritic papules and plaques on the trunk and both limbs, which developed 2 to 3 days after administration of the AZD1222 vaccine. Histopathological examinations revealed cellular interface dermatitis. The patient was diagnosed with generalized LP and was successfully treated with systemic corticosteroid and cyclosporine. As the vaccination campaign against COVID-19 is ongoing and early recognition and treatment are essential to reduce the morbidity of this condition, clinicians should be aware that LP could follow COVID-19 vaccination regardless of the type of vaccine administered.

Prolongation of the Menstrual Cycle After Receipt of the Primary Series and Booster Doses of mRNA Coronavirus Disease 2019 (COVID-19) Vaccination. OBJECTIVE: To quantitatively evaluate the effect of a booster vaccination dose against coronavirus disease 2019 (COVID-19) on menstrual cycle in a large-scale retrospective cohort study using a menstrual cycle tracking smartphone application (app). METHODS: Prospectively or retrospectively recorded data, including the start and finish dates of menstrual cycles, were collected with the app. Detailed data on vaccinations, side effects, and participants' characteristics were retrospectively collected from a questionnaire on the app. For each COVID-19 vaccination shot (first, second, and third), within-individual changes in menstrual cycle length up to the fourth postvaccination cycle were evaluated. RESULTS: Among the 7,376 and 6,873 participants who had the first and second COVID-19 vaccine doses in different menstrual cycles, respectively, menstrual cycles immediately after the vaccination (first postvaccination cycles) were an average of 0.22 days (95% CI, 0.06-0.39) and 0.37 days (95% CI, 0.20-0.54) longer than the prevaccination cycle. In contrast, among the 1,672 participants who received the first and second doses in the same cycle, the first postvaccination cycle was an average of 4.21 days (95% CI, 3.69-4.72) longer. The second to fourth postvaccination cycles returned to the level of the prevaccination cycle. However, among the 4,768 participants who had the third COVID-19 vaccine dose, the menstrual cycle immediately after the vaccination was an average of 1.20 days (95% CI, 1.00-1.40) longer, with prolongation of cycles of 0.27 days (95% CI, 0.10-0.44) to 0.41 days (95% CI, 0.22-0.59) persisting from the second to the fourth postvaccination cycle. CONCLUSION: The booster shot against COVID-19 may have a greater and longer-lasting effect on menstrual cycles than the primary-series shots. Although the effect size was small, evidence on the side effects of immunization on menstruation should be accumulated.

HIV viral load and CD4+ count are not associated with experiencing Covid-19 vaccine adverse events: case-control study.

Safety of COVID-19 Vaccination in Patients With Breast Cancer: Cross-Sectional Study in China. BACKGROUND: The widespread use of vaccines against the novel coronavirus disease (COVID-19) has become one of the most effective means to establish a population immune barrier. Patients with cancer are vulnerable to COVID-19 infection, adverse events, and high mortality, and should be the focus of epidemic prevention and treatment. However, real-world data on the safety of vaccines for

patients with breast cancer are still scarce. OBJECTIVE: This study aims to compare the safety of COVID-19 vaccines between patients vaccinated before or after being diagnosed with breast cancer. METHODS: Patients with breast cancer who sought medical advice from October 2021 to December 2021 were screened. Those who received COVID-19 vaccines were enrolled in this study to analyze the safety of the vaccines. The primary outcome was patient-reported adverse events (AEs). All events after vaccine injection were retrospectively documented from the patients. RESULTS: A total of 15,455 patients with breast cancer from 41 hospitals in 20 provinces in China were screened, and 5766 patients who received COVID-19 vaccines were enrolled. Of those enrolled, 45.1% (n=2599) of patients received vaccines before breast cancer diagnosis, 41.3% (n=2379) were vaccinated after diagnosis, and 13.6% (n=784) did not known the accurate date of vaccination or cancer diagnosis. Among the patients vaccinated after diagnosis, 85.4% (n=2032) were vaccinated 1 year after cancer diagnosis and 95.4% (n=2270) were vaccinated during early-stage cancer. Of all 5766 vaccinated patients, 93.9% (n=5415) received an inactivated vaccine, 3.7% (n=213) received a recombinant subunit vaccine, and 2.4% (n=138) received other vaccines, including adenovirus and mRNA vaccines. In the first injection of vaccines, 24.4% (n=10, 95% CI 11.2-37.5) of patients who received an adenovirus vaccine reported AEs, compared to only 12.5% (n=677, 95% CI 11.6-13.4) of those who received an inactivated vaccine. Patients with metastatic breast cancer reported the highest incidence of AEs (n=18, 16.5%, 95% CI 9.5-23.5). Following the second injection, patients who received an inactivated vaccine (n=464, 8.7%, 95% CI 8.0-9.5) and those who received a recombinant vaccine (n=25, 8.7%, 95% CI 5.5-12.0) reported the same incidence of AEs. No significant differences in patient-reported AEs were found between the healthy population and patients with breast cancer (16.4% vs 16.9%, respectively); the most common AEs were local pain (11.1% vs 9.1%, respectively), fatigue (5.5% vs 6.3%, respectively), and muscle soreness (2.3% vs 3.6%, respectively). The type of vaccine and time window of vaccination had little impact on patient-reported AEs. CONCLUSIONS: Compared with patients vaccinated before breast cancer diagnosis, there were no significant differences in patient-reported AEs in the patients vaccinated after diagnosis. Thus, it is safe for patients with breast cancer, especially for those in the early stage, to receive COVID-19 vaccines. TRIAL REGISTRATION: Chinese Clinical Trial Registry ChiCTR2200055509; https://tinyurl.com/33zzj882.

COVID-19 Vaccination: Safeguarding Against Post-COVID Cardiovascular Complications.

Clozapine Serum Concentrations Are Disrupted by SARS-CoV-2 Vaccinations. This paper reports the case of a 27-year-old man with paranoid schizophrenia who was finally stabilized on clozapine medication. After vaccination against severe acute respiratory syndrome coronavirus 2, serum levels of clozapine increased. It is well established that immune responses can trigger cytokine cascades affecting drug metabolism, which, in the case of clozapine treatment, can lead to severe intoxication.

Post-COVID-19 vaccination myocarditis: a prospective cohort study pre and post vaccination using cardiovascular magnetic resonance. BACKGROUND: Concerns about COVID-19 vaccination induced myocarditis or subclinical myocarditis persists in some populations. Cardiac magnetic resonance imaging (CMR) has been used to detect signs of COVID-19 vaccination induced myocarditis. This study aims to: (i) characterise myocardial tissue, function, size before and after COVID-19 vaccination, (ii) determine if there is imaging evidence of subclinical myocardial inflammation or injury after vaccination using CMR. METHODS: Subjects agedâ€‰â‰¥â€‰12yrs old without prior COVID-19 or COVID-19 vaccination underwent two CMR examinations: first,â€‰â‰¤â€‰14Â days before the first COVID-19 vaccination and a second timeâ€‰â‰¤â€‰14Â days after the second COVID-19 vaccination. Biventricular indices, ejection fraction (EF), global longitudinal strain (GLS), late gadolinium enhancement (LGE), left ventricular (LV) myocardial native T1, T2, extracellular volume (ECV) quantification, lactate dehydrogenase (LDH), white cell count (WCC), C-reactive protein (CRP),

NT-proBNP, troponin-T, electrocardiogram (ECG), and 6-min walk test were assessed in a blinded fashion. RESULTS: 67 subjects were included. First and secondÂ CMR examinations were performed a median of 4Â days before the first vaccination (interquartile range 1-8Â days) and 5Â days (interquartile range 3-6Â days) after the secondÂ vaccination respectively. No significant change in global native T1, T2, ECV, LV EF, right ventricular EF, LV GLS, LGE, ECG, LDH, troponin-T and 6-min walk test was demonstrated after COVID-19 vaccination. There was a significant WCC decrease (6.51â€‰Â±â€‰1.49 vs 5.98â€‰Â±â€‰1.65, pâ€‰=â€‰0.003) and CRP increase (0.40â€‰Â±â€‰0.22 vs 0.50â€‰Â±â€‰0.29, pâ€‰=â€‰0.004). CONCLUSION: This study found no imaging, biochemical or ECG evidence of myocardial injury or inflammation post COVID-19 vaccination, thus providing some reassurance that COVID-19 vaccinations do not typically cause subclinical myocarditis.

Progressive shingles in a toddler due to reactivation of Varicella Zoster vaccine virus four days after infection with SARS-CoV-2; a case report. BACKGROUND: Herpes zoster (HZ) is the clinical syndrome associated with reactivation of latent varicella-zoster virus (VZV). Several factors have been implicated to promote VZV reactivation; these include immunosuppression, older age, mechanical trauma, physiologic stress, lymphopenia, and more recently, infection with severe acute respiratory syndrome coronavirus-2 (SARS- CoV-2). Recent reports suggest an increase in the number of HZ cases in the general population during the global COVID-19 pandemic. However, it is unknown what proportion of HZ during the pandemic is due to reactivation of wild-type or vaccine-strain VZV. CASE: Here we report the first known case of HZ concomitant with SARS-CoV2 infection in a 20-month-old female who was treated with a single dose of dexamethasone, due to reactivation of the vaccine-type strain of VZV after presenting with a worsening vesicular rash. CONCLUSION: In this case, we were able to show vaccine-strain VZV reactivation in the context of a mild acute symptomatic COVID-19 infection in a toddler. Being able to recognize HZ quickly and effectively in a pediatric patient can help stave off the significant morbidity and mortality associated with disease process.

N(1)-methylpseudouridylation of mRNA causes +1 ribosomal frameshifting. In vitro-transcribedÂ (IVT) mRNAs are modalities that can combat human disease, exemplified by their use as vaccines for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). IVTÂ mRNAs are transfected into target cells, where they are translated into recombinant protein, and the biological activity or immunogenicity of the encoded protein exerts an intended therapeutic effect(1,2). Modified ribonucleotides are commonly incorporated into therapeutic IVTÂ mRNAs to decrease their innate immunogenicity(3-5), but their effects on mRNA translation fidelity have not been fully explored. Here we demonstrate that incorporation of N(1)-methylpseudouridine into mRNA results in +1 ribosomal frameshifting in vitro and that cellular immunity in mice and humans to +1 frameshifted products from BNT162b2Â vaccine mRNA translation occurs after vaccination. The +1 ribosome frameshifting observed is probably a consequence of N(1)-methylpseudouridine-induced ribosome stalling during IVTÂ mRNA translation, with frameshifting occurring at ribosome slippery sequences. However, we demonstrate that synonymous targeting of such slippery sequences provides an effective strategy to reduce the production of frameshifted products. Overall, these data increase our understanding of how modified ribonucleotides affect the fidelity of mRNA translation, and although there are no adverse outcomes reported from mistranslation of mRNA-based SARS-CoV-2 vaccines in humans, these data highlight potential off-target effects for future mRNA-based therapeutics and demonstrate the requirement for sequence optimization.

A case of vitiligo after COVID-19 vaccination: a possible role of thymic dysfunction. During the coronavirus disease 2019 (COVID-19) pandemic, vaccines help control the spread of infection. To date, 47 vaccines have been approved, with another 227 candidates in various stages of development. In the short period of time since the beginning of their use, evidence has begun to

emerge of complications following vaccination in the form of the development or exacerbation of a number of pathological conditions (Block et al., 2022; Haseeb et al., 2022). For example, a population-based study in France identified 1612 cases of myocarditis and 1613 cases of pericarditis requiring hospital treatment within five months of vaccination (le Vu et al., 2022).
Systematic review exploring the clinical features of optic neuritis after SARS-CoV infection and vaccination. BACKGROUND: This study aims to characterise the symptoms and clinical features of optic neuritis (ON) following SARS-CoV-2 infection and vaccination. METHOD: A literature search was conducted in four databases (PubMed, Medline, Embase and Google Scholar) to identify relevant case reports and case series. The records were screened and articles adhering to the inclusion criteria were critically appraised. RESULTS: Sixty-eight studies were found to be eligible for inclusion, including 34 reporting ON following SARS-CoV-2 infection and an equal number reporting cases postvaccination. In total 93 patients and 125 eyes were included. The infection cohort included 42 patients and 56 eyes, 51.2% were female and 33.3% experienced bilateral ON. The mean visual acuity was 1.64 log of minimum angle of resolution (LogMAR), while pain was present in 77.8%. Oligoclonal bands were present in 3 patients, myelin oligodendrocyte glycoprotein (MOG) antibodies in 18 patients and AQP-4 antibodies in 4 patients. The vaccination cohort included 51 patients and 69 eyes. 60.8% were female and 35.3% had a bilateral ON. The mean visual acuity was 0.93 LogMAR. Oligoclonal bands were present in 46.7%, MOG antibodies in nine patients and AQP-4 antibodies in three patients. CONCLUSION: Patients with ON post-SARS-CoV infection were more likely to experience severe visual impairment than in cases following vaccination. Further research is required to outline the clinical features of ON after COVID-19 infection and vaccination, and establish causality.
Rapid increase in salivary IgA and broad recognition of spike protein following SARS-CoV-2 vaccination. Saliva is a key component of mucosal immunity, which protects the oral cavity from viral infections. However, salivary immune response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), in terms of immunoglobulin dynamics and recognition, have not been investigated sufficiently. In this study, saliva samples were collected from individuals that received SARS-CoV-2 vaccine, and immunoglobulin G (IgG), IgM, and IgA against whole spike protein and S1 protein were measured. IgA against whole spike protein increased significantly following vaccination, while IgA against S1 protein did not. Of note, the IgA response was evident two weeks after the first vaccine dose and continued to rise thereafter. On the contrary, IgG antibodies against S1 increased significantly at four weeks after vaccination. These results reveal the dynamics and recognition antigens of immunoglobulins in saliva, indicating the function of IgA in the mucosal immune system. These findings may pave the way for further studies on mucosal immune response induced by vaccination.
Serological assays for differentiating natural COVID-19 infection from vaccine induced immunity. BACKGROUND: Natural SARS-CoV-2 infection may elicit antibodies to a range of viral proteins including non-structural protein ORF8. RNA, adenovirus vectored and sub-unit vaccines expressing SARS-CoV-2 spike would be only expected to elicit S-antibodies and antibodies to distinct domains of nucleocapsid (N) protein may reliably differentiate infection from vaccine-elicited antibody. However, inactivated whole virus vaccines may potentially elicit antibody to wider range of viral proteins, including N protein. We hypothesized that antibody to ORF8 protein will discriminate natural infection from vaccination irrespective of vaccine type. METHODS: We optimized and validated the anti-ORF8 and anti-N C-terminal domain (NCTD) ELISA assays using sera from pre-pandemic, RT-PCR confirmed natural infection sera and BNT162b2 (BNT) or CoronaVac vaccinees. We then applied these optimized assays to a cohort of blood donor sera collected in April-July 2022 with known vaccination and self-reported infection status. RESULTS: We optimized cut-off values for the anti-ORF8 and anti-N-CTD IgG ELISA assays using receiver-operating-characteristic (ROC) curves. The sensitivity of the

anti-ORF8 and anti-N-CTD ELISA for detecting past infection was 83.2% and 99.3%, respectively. Specificity of anti-ORF8 ELISA was 96.8Â % vs. the pre-pandemic cohort or 93% considering the pre-pandemic and vaccine cohorts together. The anti-N-CTD ELISA specificity of 98.9% in the pre-pandemic cohort, 93% in BNT vaccinated and only 4Â % in CoronaVac vaccinated cohorts. Anti-N-CTD antibody was longer-lived than anti-ORF8 antibody after natural infection. CONCLUSIONS: Anti-N-CTD antibody assays provide good discrimination between natural infection and vaccination in BNT162b2 vaccinated individuals. Anti-ORF8 antibody can help discriminate infection from vaccination in either type of vaccine and help estimate infection attack rates (IAR) in communities.

Development of Pilomatrixoma at the Vaccination Site: A Rare Complication of COVID-19 Vaccination - A Case Report. BACKGROUND Pilomatrixoma, pilomatricoma, or calcifying epithelioma of Malherbe, is a common benign tumor that arises from the base of the hair follicle. Pilomatrixoma has previously been reported at vaccination sites. This report is of a 65-year-old man with an 18-month history of an enlarging pilomatrixoma of the left upper arm at the vaccination site, following a first COVID-19 vaccination. CASE REPORT The case involves a 65-year-old man who developed a left shoulder mass 1.5 years ago. The mass appeared at his COVID-19 vaccine site 3 months after receiving the first dose. The mass measures 3 cm in diameter, was mobile, and exhibited no signs of infection in the physical examination. Surgical excision was performed, and pathology confirmed the mass as a pilomatrixoma, characterized by basaloid cells and keratinization. Three months after surgery, no recurrence was observed. CONCLUSIONS This report has presented an association between vaccination injection sites and pilomatrixoma aligning with previous findings. Enhanced awareness about this condition can substantially improve pilomatrixoma diagnosis accuracy and reduce unnecessary examinations and treatments. Furthermore, we recommend that, along with clinical symptoms, ultrasound imaging be considered a valuable diagnostic tool for pilomatrixoma, with histopathological results to confirm the diagnosis.

Monitoring of antibody levels in healthcare workers after inactivated coronavirus disease 19 vaccination. OBJECTIVE: Because of the coronavirus disease 19 pandemic, studies on vaccination are being conducted in our country as well as across the world. In this study, the antibody levels in healthcare workers vaccinated with two doses of inactivated vaccine and the factors affecting these levels were investigated. METHODS: Randomly selected volunteers from healthcare workers, who had been vaccinated with two doses of inactivated vaccine in January to February 2021, were included in the study. Blood samples were drawn twice, 1 month and 6 months after the second dose vaccine (CoronaVac:Sinovac Life Science Co, Ltd, Beijing, China). The antibody levels were determined by the chemiluminescence microparticle immunoassay method using kits for quantitative detection of immunoglobulin class G antibodies to severe acute respiratory syndrome coronavirus 2. RESULTS: The mean antibody levels of 129 volunteers were 1232.5 (min: 103 to max: 7151) AU/mL in the first month and 403.5 (min: 23 to max: 4963) AU/mL in the sixth month. According to the survey results, 91 (71%) volunteers had not been diagnosed with coronavirus disease 19 before vaccination. The antibody levels 1 month and 6 months after the second dose of vaccination were significantly higher in those who had been diagnosed with coronavirus disease 19 before vaccination than in those who had not. It was found that age, gender, fast food, or healthy nutrition had no effect on antibody levels. CONCLUSION: Vaccines are very important both to protect against coronavirus disease 19 and to experience only a mild form of the disease. Immunoglobulin class G levels formed after vaccination may be affected by many factors and may decrease over time.

Infection image: reoccurrence of Kaposi`s sarcoma after SARS-CoV-2 mRNA vaccination in an HIV-infected patient.

IgA Vasculitis following AstraZeneca/Oxford COVID-19, case report. Immunoglobulin A (IgA) vasculitis, also known as Henoch-SchÃ¶nlein purpura, is an immune-mediated vasculitis that affects

small vessels. IgA vasculitis could be triggered by numerous conditions including infectious and non-infectious conditions. So far, few reported cases of Covid-19 vaccines related vasculitis. We report a case of IgA vasculitis after AstraZeneca/Oxford COVID-19 vaccine. A 29-year-old healthy man who developed purpuric skin lesions one week after his second AstraZeneca/Oxford COVID-19 vaccine which complicated by glomerulonephritis and gastrointestinal involvement. Skin biopsy revealed fibrinoid necrosis and leukocytoclasia consistent with small vessel vasculitis. Due to the temporal association, AstraZeneca/Oxford COVID-19 vaccine-related IgA vasculitis would be the most likely explanation.

Clinical outcomes in hospitalized plasma and platelet transfusion recipients prior to and following widespread blood donor SARS-CoV-2 infection and vaccination. BACKGROUND: The safety of transfusion of SARS-CoV-2 antibodies in high plasma volume blood components to recipients without COVID-19 is not established. We assessed whether transfusion of plasma or platelet products during periods of increasing prevalence of blood donor SARS-CoV-2 infection and vaccination was associated with changesÂ in outcomes in hospitalized patients without COVID-19. METHODS: We conducted a retrospective cohort study of hospitalized adults who received plasma or platelet transfusions at 21 hospitals during pre-COVID-19 (3/1/2018-2/29/2020), COVID-19 pre-vaccine (3/1/2020-2/28/2021), and COVID-19 post-vaccine (3/1/2021-8/31/2022) study periods. We used multivariable logistic regression with generalized estimating equations to adjust for demographics and comorbidities to calculate odds ratios (ORs) and 95% confidence intervals (CIs). RESULTS: Among 21,750 hospitalizations of 18,584 transfusion recipients without COVID-19, there were 697 post-transfusion thrombotic events, and oxygen requirements were increased in 1751 hospitalizations. Intensive care unit length of stay (nâ€‰=â€‰11,683) was 3â€‰days (interquartile range 1-5), hospital mortality occurred in 3223 (14.8%), and 30-day rehospitalization in 4144 (23.7%). Comparing the pre-COVID, pre-vaccine and post-vaccine study periods, there were no trends in thromboses (OR 0.9 [95% CI 0.8, 1.1]; pâ€‰=â€‰.22) or oxygen requirements (OR 1.0 [95% CI 0.9, 1.1]; pâ€‰=â€‰.41). In parallel, there were no trends across study periods for ICU length of stay (pâ€‰=â€‰.83), adjusted hospital mortality (OR 1.0 [95% CI 0.9-1.0]; pâ€‰=â€‰.36), or 30-day rehospitalization (pâ€‰=â€‰.29). DISCUSSION: Transfusion of plasma and platelet blood components collected during the pre-vaccine and post-vaccine periods of the COVID-19 pandemic was not associated with increased adverse outcomes in transfusion recipients without COVID-19.

Schwannoma and Post-vaccine Changes: A Case Report. Schwannomas are benign sheaths of Schwann cells that can present with degenerative and morphological changes; necrosis or hemorrhage are rare findings in these tumors. We present the case of a 28-year-old man with a C2-C4 cervical Schwannoma who experienced upper limb paresthesia in 2020 while presenting with COVID-19 symptoms. The patient later recovered and came to our institution, where surgery was scheduled one year after the initial diagnosis. One week before surgery, the patient received the first dose of the Moderna vaccine. Despite being asymptomatic, the patient underwent successful total resection of the schwannoma, which was confirmed histologically. However, extensive necrosis with abundant foamy macrophages was observed, suggesting a possible link to post-vaccine effects.

Association Between Pfizer COVID-19 Vaccine Adverse Effects and Diabetes Mellitus: A Prospective Multicenter Study. Introduction The epidemic of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) triggered the contagion of coronavirus disease 2019 (COVID-19), which killed many individuals globally. The Pfizer BioNTech vaccine was the first messenger ribonucleic acid (mRNA)-based vaccine that boosted immunity against various adverse reactions. The objective of this study was to evaluate the frequency of Pfizer vaccine side effects among participants with and without diabetes mellitus (DM). Methods This multicenter study was cross-sectional and was performed using a non-probability consecutive sampling technique. The study duration was six months, from October

1, 2022, to March 31, 2023. A total of 750 participants who received both doses of the Pfizer vaccine were included in the study. Demographic details such as gender, age, comorbidities,Â preceding COVID-19 infection, and the occurrence of any local and systemic side effects of the first and second doses of vaccine were recorded. The association between local and general side effects and the presence of DM was assessed using the chi-square test. Results Of the 750 participants included in the study, 289 (77.1%) were males with diabetes mellitus (DM), and 217 (57.9%) were non-diabetic participants; however, 86 (22.9%) females had DM, and 158 (42.1%) were non-diabetic; their mean ages were 48.23 Â± 16.22 and 37.56 Â± 12.15 years, respectively. The most commonly occurring side effects after receiving the first dose of the Pfizer vaccine were: injection site burning in 251 (66.9%) diabetic and 254 (67.7%) non-diabetic participants. Likewise, the frequency of side effects of the second dose of the Pfizer vaccine showed that the most commonly reported side effects were: muscle pain, found in 240 (64.0%) diabetic patients and 194 (51.7%) non-diabetics, with a statistically significant association (p =0.001). Conclusion This study concluded that participants with DM had local and generalÂ adverse effects considerably more frequently than those without DM. The most frequently observed adverse effects in both diabetic and non-diabetic participants were injection site burning, rashes, muscle pain, and fever after receiving both doses of the Pfizer vaccine. Moreover, most of the side effects were minor.

Comparison of Venous Thromboembolism Outcomes after COVID-19 and Influenza Vaccinations. Background â€ƒPublished data on the risk of venous thromboembolism (VTE) with coronavirus disease 2019 (COVID-19) vaccines are scarce and inconclusive, leading to an unmet need for further studies. Methods â€ƒA retrospective, multicentered study of adult patients vaccinated for one of the three approved COVID-19 vaccines in the United States of America and a pre-COVID-19 cohort of patients vaccinated for influenza at two institutions: Mayo Clinic Enterprise sites and the Medical College of Wisconsin, looking at rate of VTE over 90 days. VTE was identified by applying validated natural language processing algorithms to relevant imaging studies. Kaplan-Meier curves were used to evaluate rate of VTE and Cox proportional hazard models for incident VTE after vaccinations. Sensitivity analyses were performed for age, sex, outpatient versus inpatient status, and type of COVID-19 vaccine. Results â€ƒA total of 911,381 study subjects received COVID-19 vaccine (mean age: 56.8 [standard deviation, SD: 18.3] years, 55.3% females) and 442,612 received influenza vaccine (mean age: 56.5 [SD: 18.3] years, 58.7% females). VTE occurred within 90 days in 1,498 (0.11%) of the total 1,353,993 vaccinations: 882 (0.10%) in the COVID-19 and 616 (0.14%) in the influenza vaccination cohort. After adjusting for confounding variables, there was no difference in VTE event rate after COVID-19 vaccination compared with influenza vaccination (adjusted hazard ratio: 0.95 [95% confidence interval: 0.85-1.05]). No significant difference in VTE rates was observed between the two cohorts on sensitivity analyses. Conclusion â€ƒIn this large cohort of COVID-19-vaccinated patients, risk of VTE at 90 days was low and no different than a pre-COVID-19 cohort of influenza-vaccinated patients.

Effective measures to improve influenza vaccination coverage among healthcare workers during and after COVID-19. The influenza vaccine is the most effective measure to prevent influenza. The aim of this study was to evaluate the impact of measures taken by the hospital on the influenza vaccination coverage of medical staff after implementation. We collected and compared the influenza vaccination of staff in key departments from 2018 to 2022. As the results, in 2018 and 2019, the influenza vaccination rates of staff in key departments in our hospital were generally as low as 10.3% and 11.6%, respectively. After the policy of free vaccination for staff in key departments was adopted in 2020 and other incentive measures, the overall influenza vaccination rates of key departments from 2020 to 2022 were 77.2%, 71.4%, and 81.3%, respectively, which were significantly higher than the pre-2020 vaccination rates in our hospital and healthcare workers in most regions of China. In

conclusion, with the implementation of several measures to promote influenza vaccination, the rate of influenza vaccination among medical staff has significantly increased.

Characterization of COVID-19 vaccine clinical trial discussions on the social question-and-answer site Quora. INTRODUCTION: Throughout the COVID-19 pandemic, underserved populations, such as racial and ethnic minorities, were disproportionately impacted by illness, hospitalization, and death. Equity in clinical trials means that the participants in clinical trials represent the people who are most likely to have the health condition and need the treatment that the trial is testing. Infodemiology approaches examining user conversations on social media platforms have the potential to elucidate specific barriers and challenges related to clinical trial participation, including among racial and ethnic minority populations. MATERIALS AND METHODS: The study retrospectively collected and analyzed user question and answer posts from Quora in October 2021 using an inductive content coding approach. We also examined user's publicly available profile metadata to identify racial and ethnic minority users to capture their experiences, attitudes, topics, and discussions of barriers to COVID-19 vaccine trials. RESULTS: A total of 1073 questions and 7479 answers were collected. A total of 763 questions and 2548 answers were identified as related to COVID-19 vaccine clinical trials. The majority of these online interactions focused on asking questions and sharing knowledge and opinions about COVID-19 vaccine trials, including major topics related to: (a) interpreting whether clinical trial results could be trusted; (b) questions about vaccine efficacy and safety; (c) understanding trial design, regulatory considerations, and vaccine platforms; and (d) questions about trial enrollment, length, and adequate representation. Additionally, four major barriers discussed included: (i) disagreement from users regarding whether clinical trials require representation from different racial and ethnic minorities; (ii) concerns regarding the safety of trials when participating; (iii) lack of knowledge on how to participate in a trial; and (iv) questions ofÂ whether participants could withdraw from a trial to access an approved COVID-19 vaccine. CONCLUSIONS: Our study found active user discussions related to COVID-19 vaccine clinical trials on Quora, including those specific to minority health topics and thoseÂ posted by a smaller group of self-identified racial and ethnic minority online users. Results from this study can help identify barriers to participation among the general public and underrepresented groups while also supporting the design of future outreach strategies to help with recruitment and inclusive trialÂ participation.

Case series of patients with acute and chronic urticaria after COVID-19 vaccination.

Clinical characteristics of motor functional neurological disorder manifesting as limb weakness after vaccination against coronavirus disease 2019: A case series. BACKGROUND: The characteristics of functional limb weakness (FLW) as one of the manifestations of functional neurological disorder after vaccination against coronavirus disease 2019 (COVID-19) remain controversial. METHODS: In this descriptive case series, we aimed to elucidate the characteristics of Japanese patients with FLW who claimed muscle weakness after COVID-19 vaccination among patients who visited our outpatient clinic between 1 June 2021 and 31 December 2022. RESULTS: Nine patients were diagnosed with FLW (mean age: 30.8Â years), including two men and seven women. Seven patients were vaccinated with the BioNTech/Pfizer vaccine and two with the mRNA-1273 Moderna vaccine. All patients demonstrated various positive signs for FLW. Magnetic resonance imaging or computed tomography indicated no abnormality that could explain their symptoms. At the time of the clinic visit, five patients were treated for psychiatric disorders, including depression, insomnia, attention-deficit hyperactivity disorder, and Asperger's syndrome. Muscle weakness spread to the limbs beyond the vaccinated arm in seven patients. CONCLUSIONS: We describe the basic characteristics of FLW in Japanese patients after COVID-19 vaccination. Further recognition of these characteristics could aid the diagnosis of FLW by physicians allowing them to support these patients effectively.

Longitudinal SARS-CoV-2 neutralization of Omicron BA.1, BA.5 and BQ.1.1 after four vaccinations and the impact of breakthrough infections in haemodialysis patients. BACKGROUND: Individuals on haemodialysis (HD) are more vulnerable to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection than the general population due to end-stage kidney disease-induced immunosuppression. METHODS: A total of 26 HD patients experiencing SARS-CoV-2 infection after a third vaccination were matched 1:1 with 26 of 92 SARS-CoV-2-naÃ¯ve patients by age, sex, dialysis vintage and immunosuppressive drugs receiving a fourth vaccination with a messenger RNA-based vaccine. A competitive surrogate neutralization assay was used to monitor vaccination success. To determine infection neutralization titres, Vero-E6 cells were infected with SARS-CoV-2 variants of concern (VoCs), Omicron sublineage BA.1, BA.5 and BQ.1.1. The 50% inhibitory concentration (IC50, serum dilution factor 1:x) was determined before, 4Â weeks after and 6Â months after the fourth vaccination. RESULTS: A total of 52 HD patients received four coronavirus disease 2019 (COVID-19) vaccinations and were followed up for a median of 6.3Â months. Patient characteristics did not differ between the matched cohorts. Patients without a SARS-CoV-2 infection had a significant reduction of real virus neutralization capacity for all Omicron sublineages after 6Â months (PÂ <Â .001 each). Those patients with a virus infection did not experience a reduction in real virus neutralization capacity after 6Â months. Compared with the other Omicron VoC, the BQ.1.1 sublineage had the lowest virus neutralization capacity. CONCLUSIONS: SARS-CoV-2-naÃ¯ve HD patients had significantly decreased virus neutralization capacity 6Â months after the fourth vaccination, whereas patients with a SARS-CoV-2 infection had no change in neutralization capacity. This was independent of age, sex, dialysis vintage and immunosuppression. Therefore, in infection-naÃ¯ve HD patients a fifth COVID-19 vaccination might be reasonable 6Â months after the fourth vaccination.

Impact of coronavirus disease 2019 vaccination on live birth rates after inÂ vitro fertilization. OBJECTIVE: To investigate coronavirus disease 2019 (COVID-19) vaccination on the live birth rates in patients who underwent inÂ vitro fertilization. DESIGN: Retrospective cohort study. SETTING: Academic fertility practice. PATIENT(S): Patients who underwent fresh or frozen embryo transfer cycles at an academic center between January 1, 2020, and December 31,Â 2021. INTERVENTION(S): Coronavirus disease 2019 vaccination, defined as completing a 2-dose regimen (Pfizer or Moderna) or 1-dose regimen (Johnson & Johnson/Janssen) before cycle initiation. MAIN OUTCOME MEASURE(S): The primary outcome was the live birth rate per embryo transfer. The secondary outcomes included positive human chorionic gonadotropin (hCG) and clinical pregnancy rates per embryo transfer. The outcomes from cycles among vaccinated and unvaccinated patients were compared. Descriptive statistics were used to analyze demographic and cycle characteristics using the Student t test and Wilcoxon rank sum, Pearson chi-square, and Fisher exact tests as appropriate for univariate analysis. Generalized estimating equation models were used to examine the strength of the relationship between vaccination status and pregnancy outcomes. RESULT(S): Among 709 unvaccinated and 648 vaccinated fresh cycles, no statistically significant differences were observed between the number of oocytes retrieved, oocyte maturity, fertilization, and blastocyst utilization rates. In the adjusted multivariate analysis, no statistically significant differences were noted between fresh cycles among vaccinated patients compared with those among unvaccinated patients with the rates of positive hCG (adjusted odds ratio [aOR], 1.37; 95% confidence interval [CI], 0.84-2.25), clinical pregnancy (aOR, 1.22; 95% CI, 0.73-2.03), or live birth (aOR, 1.37; 95% CI, 0.79-2.25) per embryo transfer. Among 264 unvaccinated and 423 vaccinated frozen embryo transfer (FET) cycles, vaccinated patients had higher odds of positive hCG (aOR, 1.54; 95% CI, 1.08-2.20), clinical pregnancy (aOR, 1.80; 95% CI, 1.27-2.56), and live birth (aOR, 2.31; 95% CI, 1.60-3.32) per embryo transfer than unvaccinated patients. CONCLUSION(S): Patients who were COVID-19 vaccinated before FET had higher rates of biochemical pregnancy, clinical pregnancy, and live birth. Vaccination was not associated with the pregnancy or

live birth rates after fresh cycles. This study contributes to evidence supporting COVID-19 vaccination for patients attempting pregnancy.
The frequency of SARS-CoV-2 infection/vaccination-related chorea depends on the inclusion/exclusion criteria.
The frequency of SARS-CoV-2 infection/vaccination-related chorea depends on the inclusion/exclusion criteria - author's reply.
Association of COVID-19 Vaccination Rates and Facility Characteristics on COVID-19 Cases, Hospitalizations, and Deaths in US Nursing Homes. OBJECTIVES: Nursing home residents have been disproportionately affected by the COVID-19 pandemic. Despite recognition as a priority group for receipt of the COVID-19 vaccine, vaccine uptake and COVID-19 cases, hospitalizations, and deaths in nursing home facilities were variable across nursing homes. This study has 2 objectives: (1) to describe nursing facility characteristics associated with higher vs lower vaccination rates and (2) to estimate facility characteristics associated with COVID-19 cases, hospitalizations, and deaths, stratified by vaccination rate. DESIGN: Cross-sectional study. SETTING AND PARTICIPANTS: Facility-level data from 12,811 US nursing home facilities. METHODS: Using the CMS's Nursing Home COVID-19 Public File, we analyzed nursing home COVID-19 vaccination rates and outcomes from June 13, 2021, to September 19, 2021. We performed multivariable logistic regressions and identified facility characteristics associated with increased vaccination uptake and COVID-19 outcomes. RESULTS: Nursing homes with average vaccination rates â‰¤80% experienced higher total average COVID-19 cases, hospitalizations, and deaths compared to facilities with >80% average vaccination rates during the Delta surge. Moreover, facility factors, such as higher average age of residents, proportion of non-white residents, nurse staffing hours, and occupancy rates, were variably associated with increased risk of COVID-19 outcomes. CONCLUSIONS AND IMPLICATIONS: Facilities with higher resident vaccination rates experienced lower average COVID-19 cases, hospitalizations, and deaths in US nursing homes. Access to vaccines may play a role in mitigating harm associated with infectious diseases. Additionally, facility factors associated with increased adverse outcomes were variably associated with increased odds of COVID-19 outcomes, often, irrespective of vaccination level. As the COVID-19 pandemic continues to evolve and as the possibility of other infectious disease variants emerge, this research provides insight into facility factors, including vaccine uptake, that may mitigate adverse outcomes.
Ocular inflammatory events following COVID-19 vaccination: reporting of suspected adverse drug reactions to regulatory authorities in the UK. BACKGROUND/AIMS: The UK Medicines and Healthcare products Regulatory Agency (MHRA) has published suspected adverse drug reactions to vaccines against COVID-19. Ocular inflammatory events following COVID-19 vaccination have been reported worldwide. METHODS: We analysed MHRA data on spontaneous reports of suspected ocular inflammatory events following COVID-19 vaccination between January 2021 and September 2022. RESULTS: The MHRA received 300 UK spontaneous suspected reports of ocular inflammatory events following COVID-19 vaccination, with a calculated prevalence of 6.6 events per 1â€‰000â€‰000 vaccinated individuals. Anterior uveitis was the most common phenotype (58.3%), followed by optic neuritis in 39.3%. Median number of days between vaccination and onset was 8â€‰days. Resolution of the event was seen in 52.3%. CONCLUSION: Ocular inflammatory events following COVID-19 vaccination have a very rare prevalence in the UK. There is no increase in the reporting rate of uveitis, optic neuritis and scleritis following COVID-19 vaccination when compared with the range of incidence in the UK population. The Yellow Card System represents a vital instrument within the domain of pharmacovigilance, empowering patients and healthcare professionals to contribute to the ongoing monitoring of medication safety.
COVID-19 vaccination and autoimmunity: Causality, precipitation or chance association?

Neutralization of SARS-CoV-2 Omicron BQ.1, BQ.1.1 and XBB.1 variants following SARS-CoV-2 infection or vaccination in children. Emergence of highly transmissible Omicron subvariants led to increased SARS-CoV-2 infection and disease in children. However, minimal knowledge exists regarding the neutralization capacity against circulating Omicron BA.4/BA.5, BA.2.75, BQ.1, BQ.1.1 and XBB.1 subvariants following SARS-CoV-2 vaccination in children versus during acute or convalescent COVID-19, or versus multisystem inflammatory syndrome (MIS-C). Here, we evaluate virus-neutralizing capacity against SARS-CoV-2 variants in 151 age-stratified children (â€‰<5, 5-11, 12-21 years old) hospitalized with acute severe COVID-19 or MIS-C or convalescent mild (outpatient) infection compared with 62 age-stratified vaccinated children. An age-associated effect on neutralizing antibodies is observed against SARS-CoV-2 following acute COVID-19 or vaccination. The primary series BNT162b2 mRNA vaccinated adolescents show higher vaccine-homologous WA-1 neutralizing titers compared with <12 years vaccinated children. Post-infection antibodies did not neutralize BQ.1, BQ.1.1 and XBB.1 subvariants. In contrast, monovalent mRNA vaccination induces more cross-neutralizing antibodies in young children <5 years against BQ.1, BQ.1.1 and XBB.1 variants compared with â‰¥5 years old children. Our study demonstrates that in children, infection and monovalent vaccination-induced neutralization activity is low against BQ.1, BQ.1.1 and XBB.1 variants. These findings suggest a need for improved SARS-CoV-2 vaccines to induce durable, more cross-reactive neutralizing antibodies to provide effective protection against emerging variants in children.

Analysis of clinical factors and ultrasound features associated with COVID-19 vaccine-related axillary lymphadenopathy: A large group study. PURPOSE: To investigate factors that distinguish COVID-19 vaccine-related axillary lymphadenopathy from malignancy or other etiologies. METHODS: From June 2021 to April 2022, 3859 consecutive female patients had breast and axillary ultrasound (US) at our institution. After exclusions, 592 patients were included in the study. We retrospectively reviewed clinical history and US features of enlarged axillary lymph nodes. Assessed clinical factors included age, vaccination type, dose and vaccination date, and ultrasound features included cortical thickness, shape, marginal irregularity, focal cortical thickening, fatty hilum, and number and anatomic location of enlarged lymph nodes. The seven US features were used to score the severity of lymphadenopathy. Binary logistic models and independent two-sample t-tests were used for statistical analysis. RESULTS: Among 592 patients (mean age 49.3Â Â±Â 10.3Â years), 406(68.6%), 90(15.2%), 42(7.1), 4(0.7%) and 50(8.4%) patients received Pfizer, AstraZeneca, Moderna, Janssen and cross inoculation of more than one type, respectively. 185(31.3%), 376(63.5%) and 31(5.2%) patients received a first, second and third dose, respectively. The interval between vaccination and US was 30.9Â Â±Â 21.5Â days. US showed axillary lymphadenopathy (LAP) in 113 patients (19.1%). Clinical factors associated with LAP were age younger than 50Â years, mRNA vaccine, first dose and shorter interval(PÂ <Â 0.05). US features associated with LAP were mean cortical thickness of 4.6Â Â±Â 1.63Â mm, oval shape (70.8%), smooth margin (53.1%), focal cortical thickening (62.8%) and preserved fatty hilum (84.1%). Using our scoring method, the mean overall score for vaccine-related LAP was 2.45Â Â±Â 1.51 points. CONCLUSION: Awareness of influencing factors and sonographic features can help differentiate COVID-19 vaccine-related adenopathy from other etiologies.

Clinical Assessment of SARS-CoV-2 Antibodies in Oral Fluids Following Infection and Vaccination. BACKGROUND: SARS-CoV-2 variants continue to circulate globally, even within highly vaccinated populations. The first-generation SARS-CoV-2 vaccines elicit neutralizing immunoglobin G (IgG) antibodies that prevent severe COVID-19 but induce only weak antibody responses in mucosal tissues. There is increasing recognition that secretory immunoglobin A (SIgA) antibodies in the upper respiratory tract and oral cavity are critical in interrupting virus shedding, transmission, and progression of disease. To fully understand the immune-related factors that influence SARS-CoV-2

dynamics at the population level, it will be necessary to monitor virus-specific IgG and SIgA in systemic and mucosal compartments. CONTENT: Oral fluids and saliva, with appropriate standardized collection methods, constitute a readily accessible biospecimen type from which both systemic and mucosal antibodies can be measured. Serum-derived IgG and immunoglobin A (IgA) are found in gingival crevicular fluids and saliva as the result of transudation, while SIgA, which is produced in response to mucosal infection and vaccination, is actively transported across salivary gland epithelia and present in saliva and passive drool. In this mini-review, we summarize the need for the implementation of standards, highly qualified reagents, and best practices to ensure that clinical science is both rigorous and comparable across laboratories and institutions. We discuss the need for a better understanding of sample stability, collection methods, and other factors that affect measurement outcomes and interlaboratory variability. SUMMARY: The establishment of best practices and clinical laboratory standards for the assessment of SARS-CoV-2 serum and mucosal antibodies in oral fluids is integral to understanding immune-related factors that influence COVID-19 transmission and persistence within populations.

Acute exacerbation of pulmonary arterial hypertension after COVID-19 vaccination.

Can a microbiota-derived health supplement mitigate adverse events after COVID-19 vaccination in children?

SARS-CoV-2 mRNA vaccines induce greater complement activation and decreased viremia and Nef antibodies in men with HIV-1. BACKGROUND: Immune dysregulation in people with HIV-1 (PWH) persists despite potent antiretroviral therapy (ART) and, consequently, PWH tend to have lower immune responses to licensed vaccines. However, limited information is available about the impact of mRNA vaccines in PWH. This study details the immunologic responses to SARS-CoV-2 mRNA vaccines in PWH and their impact on HIV-1. METHODS: We quantified anti-S IgG binding and neutralization of three SARS-CoV-2 variants of concern and complement activation in blood from virally suppressed men with HIV-1 (MWH) and men without HIV-1 (MWOH), and the characteristics that may impact the vaccine immune responses. We also studied antibody levels against HIV-1 proteins and HIV-1 plasma RNA. RESULTS: MWH had lower anti-S IgG binding and neutralizing antibodies against the three variants compared to MWOH. MWH also produced anti-S1 antibodies with a ten-fold greater ability to activate complement and exhibited higher C3a blood levels than MWOH. MWH had decreased residual HIV-1 plasma viremia and anti-Nef IgG approximately 100 days after immunization. CONCLUSIONS: MWH respond to SARS-CoV-2 mRNA vaccines with lower antibody titers and with greater activation of complement, while exhibiting a decrease in HIV-1 viremia and anti-Nef antibodies. These results suggest an important role of complement activation mediating protection in MWH.

Dynamics of T-cell Responses Following COVID-19 mRNA Vaccination and Breakthrough Infection in Older Adults. INTRODUCTION: While older adults generally mount weaker antibody responses to a primary COVID-19 vaccine series, T-cell responses remain less well characterized in this population. We compared SARS-CoV-2 spike-specific T-cell responses after 2- and 3-dose COVID-19 mRNA vaccination and subsequent breakthrough infection in older and younger adults. METHODS: We quantified CD4+ and CD8+ T-cells reactive to overlapping peptides spanning the ancestral SARS-CoV-2 spike protein in 40 older adults (median age 79) and 50 younger health care workers (median age 39), all COVID-19 naive, using an activation-induced marker assay. T-cell responses were further assessed in 24 participants, including 8 older adults, who subsequently experienced their first SARS-CoV-2 breakthrough infection. RESULTS: A third COVID-19 mRNA vaccine dose significantly boosted spike-specific CD4+ and CD8+ T-cell frequencies to above 2-dose levels in older and younger adults. T-cell frequencies did not significantly differ between older and younger adults after either dose. Multivariable analyses adjusting for sociodemographic, health, and vaccine-related variables

confirmed that older age was not associated with impaired cellular responses. Instead, the strongest predictors of CD4+ and CD8+ T-cell frequencies post-third-dose were their corresponding post-second-dose frequencies. Breakthrough infection significantly increased both CD4+ and CD8+ T-cell frequencies, to comparable levels in older and younger adults. Exploratory analyses revealed an association between HLA-A*02:03 and higher post-vaccination CD8+ T-cell frequencies, which may be attributable to numerous strong-binding HLA-A*02:03-specific CD8+ T-cell epitopes in the spike protein. CONCLUSION: Older adults mount robust T-cell responses to 2- and 3-dose COVID-19 mRNA vaccination, which are further boosted following breakthrough infection.

Vaccine development against tuberculosis before and after Covid-19. Coronavirus disease (Covid-19) has not only shaped awareness of the impact of infectious diseases on global health. It has also provided instructive lessons for better prevention strategies against new and current infectious diseases of major importance. Tuberculosis (TB) is a major current health threat caused by Mycobacterium tuberculosis (Mtb) which has claimed more lives than any other pathogen over the last few centuries. Hence, better intervention measures, notably novel vaccines, are urgently needed to accomplish the goal of the World Health Organization to end TB by 2030. This article describes how the research and development of TB vaccines can benefit from recent developments in the Covid-19 vaccine pipeline from research to clinical development and outlines how the field of TB research can pursue its own approaches. It begins with a brief discussion of major vaccine platforms in general terms followed by a short description of the most widely applied Covid-19 vaccines. Next, different vaccination regimes and particular hurdles for TB vaccine research and development are described. This specifically considers the complex immune mechanisms underlying protection and pathology in TB which involve innate as well as acquired immune mechanisms and strongly depend on fine tuning the response. A brief description of the TB vaccine candidates that have entered clinical trials follows. Finally, it discusses how experiences from Covid-19 vaccine research, development, and rollout can and have been applied to the TB vaccine pipeline, emphasizing similarities and dissimilarities.

Case Report: Gene expression profiling of COVID-19 vaccination-related lymphadenopathies reveals evidence of a dominantly extrafollicular immune response. mRNA-based vaccines against SARS-CoV-2 have been proven to be very efficient in preventing severe COVID-19. Temporary lymphadenopathy (LA) has been observed as a common adverse event following immunization. Here we describe a case series of three female patients with prominent local to generalized LA after SARS-CoV-2 mRNA-1273 vaccination, which led to lymph node biopsy due to the suspicion of lymphoma or metastasis. All three patients morphologically showed similar patterns of follicular hyperplasia and especially extrafollicular blast activation. Two of the three patients only had short-lasting humoral immune responses to the vaccination. Gene expression profiling (GEP) using the HTG Immune response panel revealed that all three patients clustered together and clearly differed from the GEP-patterns of COVID-19, infectious mononucleosis and non-specific follicular hyperplasia. The closest similarities were seen with lymph nodes showing extrafollicular activation of B-blasts as well as hemophagocytosis. The GEP of the vaccination-induced LA was reminiscent of an immune response with little potential of immunologic memory. mRNA-1273 vaccination-induced LA may to a certain extend reflect disordered immune response with potentially poor immunologic memory in affected individuals.

Humoral immune response to an mRNA-1273 booster after chAdOx1-nCoV-19-priming among patients undergoing hemodialysis. OBJECTIVES: Patients who are undergoing dialysis due to end-stage kidney disease are susceptible to greater coronavirus disease 2019 (COVID-19) complications. While vaccination is seen as the most effective tactic against COVID-19, the dialysis population usually has impaired immune responses to vaccination. Owing to the global vaccine supply shortage in the early phase of the COVID-19 pandemic, hemodialysis patients in Taiwan were administered

homologous ChAdOx1 nCoV-19/ChAdOx1 nCoV-19 at 12-week intervals, with a third booster shot of mRNA-1273 given 12 weeks after the second dose. We assessed the antibody responses of these patients to this extended-interval dosing protocol. MATERIALS AND METHODS: A total of 168 hemodialysis patients (mean age: 67 Â± 13 years) without prior COVID-19 infection were vaccinated between June 16, 2021, and January 5, 2022, and followed until February 10, 2022. The primary outcome was seroconversion with an antispike immunoglobulin G (IgG) antibody level â‰¥50 arbitrary units (AU)/mL at 4 weeks after the administration of an mRNA-1273 booster shot. The secondary outcome was the level of antispike IgG antibodies. Multivariable linear regression models were used to evaluate the associations between the baseline characteristics and the antispike IgG level. RESULTS: A total of 163 (97.0%) patients reached the primary endpoint, with antibody levels after the third booster dose of mRNA-1273 being significantly higher than those after the second dose of ChAdOx1 nCoV-19 (median IgG titer 12,007 [4394-23,860] vs. 846 [interquartile range 295-2114] AU/mL; P < 0.001). Patients who were male, older, had a higher body mass index, had a lower total lymphocyte count, and used immunosuppressants had lower antibody levels. CONCLUSION: A third booster dose of mRNA-1273 after two consecutive priming doses of ChAdOx1 nCoV-19 with extended intervals resulted in adequate humoral immune responses among hemodialysis patients.

FcÎ³RIIa - dependent platelet activation identified in COVID-19 vaccine-induced immune thrombotic thrombocytopenia-, heparin-induced thrombocytopenia, streptokinase- and anisoylated plasminogen-streptokinase activator complex-induced platelet activation. Coronavirus disease 2019 (COVID-19), which was caused by the coronavirus - severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was globally responsible for remarkable morbidity and mortality. Several highly effective vaccines for COVID-19 were developed and disseminated worldwide within an unprecedented timescale. Rare but dangerous clotting and thrombocytopenia events, and subsequent coagulation abnormalities, have been reported after massive vaccination against SARS-CoV-2. Soon after their global rollout, reports of a morbid clinical syndrome following vaccination with adenovirus-DNA-based vaccines appeared. In the spring of 2021, reports of a novel, rare and morbid clinical syndrome, with clinically devastating and fatal complication after vaccination with adenovirus-based coronavirus vaccines (Janssen/Johnson & Johnson and Astra-Zeneca vaccines) led to a brief suspension of their use by several countries. Those complications were associated with unusual cerebral and splanchnic venous thrombosis, and circulating autoantibodies directed against anti-platelet factor 4 (PF4), a protein secreted from platelets, leading to the designation: Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). The reported VITT incidence remains very low and does not affect the overall benefit of immunization, however, if left untreated, VITT can be debilitating or even fatal. VITT resembled specific adverse drugs' reactions that also involved the production of autoantibodies and subsequent abnormal platelet activation through platelet FcÎ³RIIa. These unusual but well-documented drug reactions were heparin-induced thrombocytopenia (HIT), streptokinase- (SK), and anisoylated plasminogen-streptokinase activator complex- (APSAC) associated with platelet-activating antibodies. There was considerable overlapping of clinical features between VITT, COVID-19 and these adverse drugs' reactions. We review the phenomenon of VITT against the backdrop of shared and common mechanisms that underlie HIT-, SK-, and APSAC-platelet FcÎ³RIIa-dependent platelet activation. An understanding of VITT's pathogenesis may be achieved by comparing and contrasting VITT-, HIT-, SK- and APSAC-induced platelet activation mechanisms, their respective physiopathology and similarities. Discussing these conditions in parallel provides insight into complex immunological disorders and diseases associated with abnormal hemostasis and thrombosis in particular.

Effects of Antibodies in the Serum After the Administration of COVID Vaccines and Their Hematological and Cardiovascular Complications. The outbreak of COVID-19 was seen first in

Wuhan, China, on December 31, 2019. Following this, the virus has emerged, mutated, and spread to all parts of the world, taking many lives. Scientists and healthcare workers all over the world have been involved in developing vaccines and drugs to prevent the deadly virus from spreading. In this review article, we focus on how the human body responds to immune responses by producing antibodies against our immune system and serum levels in different age groups. Few studies are being considered, which include data collected from adults in the UK community, health workers from Oxfordshire, studies from the UK, healthcare workers at a university healthcare center in Turkey, and lastly, non-seropositive and seronegative healthcare workers in the USA children's hospital, respectively, and their responses to the goal. In addition to focusing on this study and its results, we also discuss the role of different vaccines and their development and antibody responses in the body due to natural and post-vaccine infections that include both doses in humans. We focus mainly on immunoglobulin M (IgM) and immunoglobulin G (IgG) levels in the serum produced by plasma cells, as they are involved in the first line of defense against the disease. With the development of effective vaccines and their production, trial, and market distribution to needy people, there are certain prospects for slowing down the progression of the virus, reducing mortality, and preventing re-infection in humans. However impactful and beneficial these vaccines have proven, they also carry a certain amount of danger to the people taking them. We also discuss in this article certain infrequent hematological and cardiovascular complications of the vaccine and their effect on the population.

Evaluation of local and systemic side effects of Turkovac vaccine in adults. BACKGROUND: COVID-19 is a respiratory disease that caused a pandemic after reportedly emerging from Wuhan, China, in December 2019. Different types of COVID-19 vaccines such as viral vectors, mRNA, and inactivated vaccines have been produced since the beginning of the pandemic. Turkovac is an inactive COVID-19 vaccine developed and produced in TÃ¼rkiye. We conducted our study to investigate the local and systemic side effects of the Turkovac vaccine. METHODS: A cross-sectional survey-based study was conducted to collect data on the postvaccine side effects in people aged over 18 who were vaccinated with Turkovac, between March and June 2022, in the Malatya Turgut Ã–zal University Research and Training Hospital. A 54 question, multiple-choice questionnaire was used to collect demographic data from the participants and identify the possible local and systemic side effects after Turkovac vaccine administration. RESULTS: Of the 403 participants included in the study, 134 (33.3%) were female and 269 (66.7%) were male with a mean age of 47.7 Â± 13.7. The most common local side effects observed after vaccination were pain at the injection site (22.8%) and local swelling and redness (0.5%). Systemic side effects included weakness or fatigue (4.2%), muscle or joint pain (2%), headache (1.7%), fever (1%), cough (0.25%), lymphadenopathy (0.25%), and urticaria (0.25%). Side effects were most commonly observed within the first 24 h. We found that for participants under 47 years of age, female sex, chronic diseases, and regular medication use were associated with the risk of suffering side effects. DISCUSSION: Our study revealed that Turkovac is a generally well-tolerated vaccine and had no side effects. More studies are required to evaluate Turkovac's side effects in other populations.

Association of Cardiovascular Events with COVID-19 Vaccines using Vaccine Adverse Event Reporting System (VAERS): A Retrospective Study. BACKGROUND: COVID-19 vaccines have played a crucial role in reducing the burden of the global pandemic. However, recent case reports have indicated the association of the COVID- 19 vaccines with cardiovascular events but the exact association is unclear so far. OBJECTIVE: Therefore, the objective of the current study is to find out the association of cardiovascular events with COVID-19 vaccines. METHODS: The COVID-19 Vaccine Knowledge Base (Cov19VaxKB) tool was used to query the Vaccine Adverse Event Reporting System (VAERS) database. The proportional reporting ratio [PRR (â‰¥2)] with associated chi-squared value (>4), and the

number of cases > 0.2% of total reports, was used to assess the association of COVID-19 vaccines with cardiovascular events. RESULTS: A total of 33,754 cases of cardiovascular events associated with COVID-19 vaccines were found in the Cov19VaxKB tool. The cases were observed in different age groups (18-64, and 65 years and above) and gender. The disproportionality measures indicate a statistically significant association between cardiovascular events and COVID-19 vaccines. CONCLUSION: The current study identified a signal of various cardiovascular events with the COVID-19 vaccines. However, further causality assessment is required to confirm the association.

COVID-19 vaccine safety and side effects in children aged 5-11 years: a cross-sectional study. INTRODUCTION: The COVID-19 pandemic has prompted a global drive for vaccination, including children. Despite the urgency, understanding the safety and side effects remains crucial. Our study aimed to evaluate the safety of the Pfizer- BioNTech (BNT162b2) vaccine in children by determining the proportion of vaccinated children who experienced side effects and identifying factors associated with postvaccination side effects. MATERIALS AND METHODS: A cross-sectional study was conducted among children who received the COVID-19 vaccine between 3 February and 8 May 2022. Data were collected using a self-administered questionnaire filled out by the parent or legal guardian. RESULTS: The mean age of the study participants was 9 years old and 43.1% were males. Out of the 195 participants in the study, 62 (31.8%) reported side effects after vaccination. The most frequently reported side effects were pain at the injection site (29.7%, n=58), fever (15.9%, n=31), localised inflammation (10.8%, n=21) and arthralgia/myalgia (9.2%, n=18). There were no reported severe adverse events such as anaphylaxis or myocarditis. Most side effects occurred within the first two days post-vaccination. There was a higher proportion of side effects among children with underlying co-morbidities. No significant differences were observed based on age, weight, ethnicity and the presence of allergies, or the use of premedication. CONCLUSION: The BNT162b2 vaccine was generally welltolerated in children, with most side effects being mild and self-limiting. These findings support the safety of the COVID-19 vaccine and would guide healthcare professionals, parents and policy-makers in making informed decisions about COVID-19 vaccination, especially among high-risk groups.

COVID-19 vaccine-induced immune thrombotic thrombocytopenia: pathophysiology and diagnosis. Coronavirus disease-19 (COVID-19) vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare but serious clinical condition with high mortality rate in apparently healthy individuals without noticeable risk factors. VITT typically arises due to the administration of vaccines that possess recombinant adenoviral vectors, including ChAdOx1 nCov-19 (AstraZeneca) and Ad26 COV2.S (Johnson & Johnson/Janssen). Thrombosis frequently occurs at atypical sites, such as the cerebral or splanchnic circulations, in this particular pathological state. Similar to heparin-induced thrombotic thrombocytopenia (HITT), it seems that the cause of VITT is the misdirection of anti-platelet factor 4 antibodies (anti-PF4 Abs), an ancient antimicrobial mechanism. Anti-PF4 Abs in patients with VITT activates the coagulation system, leading to thrombosis. This process occurs through the stimulation of platelets (Plts) and neutrophils and subsequently release of neutrophil extracellular traps (NETs). Due to the potentially fatal consequences of VITT, early diagnosis is mandatory. In addition to thrombocytopenia, thrombosis, and the presence of anti-PF4 Abs, the day of symptoms onset and the elevation of D-dimer are also required for definitive diagnosis of VITT. The absence of one or more criteria can result in the exclusion of definitive VITT and lead to the diagnosis of probable, possible, or unlikely VITT.

COVID-19 Vaccine in Immunosuppressed Adults with Autoimmune rheumatic Diseases (COVIAAD): safety, immunogenicity and antibody persistence at 12 months following Moderna Spikevax primary series. OBJECTIVE: To assess the safety, immunogenicity and cellular responses following the Moderna Spikevax primary series in rheumatic disease. METHODS: We conducted a 12-month,

prospective, non-randomised, open-label, comparative trial of adults with either rheumatoid arthritis (RA, n=131) on stable treatment; systemic lupus erythematosus (SLE, n=23) on mycophenolate mofetil (MMF); other rheumatic diseases on prednisone â‰¥10â€‰mg/day (n=8) or age-matched/sex-matched controls (healthy control, HC, n=58). Adverse events (AEs), humoral immune responses (immunogenicity: IgG positivity for anti-SARS-CoV-2 spike protein and its receptor binding domain, neutralising antibodies (NAbs)), cellular responses (ELISpot) and COVID-19 infection rates were assessed. RESULTS: Frequency of solicited self-reported AEs following vaccination was similar across groups (HC 90%, RA 86%, SLE 90%); among them, musculoskeletal AEs were more frequent in RA (HC 48% vs RA 66% (Î”95% CI CI 3 to 32.6)). Disease activity scores did not increase postvaccination. No vaccine-related serious AEs were reported. Postvaccination immunogenicity was reduced in RA and SLE (RA 90.2%, SLE 86.4%; for both, Î”CIs compared with HC excluded the null). Similarly, NAbs were reduced among patients (RA 82.6%, SLE 81.8%). In RA, age >65 (OR 0.3, 95%â€‰CI 0.1 to 0.8) and rituximab treatment (OR 0.003, 95% CI 0.001 to 0.02) were negative predictors of immunogenicity. ELISpot was positive in 16/52 tested RA and 17/26 HC (Î”CI 11.2-53.3). During the study, 11 HC, 19 RA and 3 SLE patients self-reported COVID-infection. CONCLUSION: In COVID-19 Vaccine in Immunosuppressed Adults with Autoimmune Diseases, the Moderna Spikevax primary series was safe. MMF, RA age >65 and rituximab were associated with reduced vaccine-induced protection.

The appearance of anti-spike receptor binding domain immunoglobulin G4 responses after repetitive immunization with messenger RNA-based COVID-19 vaccines. OBJECTIVES: It is crucial to analyze the consequences of repeated messenger RNA (mRNA)-based COVID-19 vaccinations on SARS-CoV-2 spike receptor binding domain (RBD)-specific immunoglobulin (Ig)G subclass and the possible causal relationship with breakthrough infection. METHODS: We examined the longitudinal kinetics of RBD-specific IgG subclass antibodies in sera after receiving the second, third, and fourth doses of mRNA-based COVID-19 vaccines in Japanese healthcare workers. Anti-RBD IgG subclass in sera of patients with COVID-19-infected who had not received the COVID-19 vaccine were also examined. We compared anti-RBD IgG subclass antibody titers in the serum of pre-breakthrough-infected vaccinees and non-infected vaccinees. RESULTS: The seropositivity of anti-RBD IgG4 after the vaccination was 6.76% at 1 month after the second dose, gradually increased to 50.5% at 6 months after the second dose, and reached 97.2% at 1 month after the third dose. The seropositivity and titers of anti-RBD IgG1/IgG3 quickly reached the maximum at 1 month after the second dose and declined afterward. The elevated anti-RBD IgG4 Ab levels observed after repeated vaccinations were unlikely to increase the risk of breakthrough infection. CONCLUSIONS: Repeated vaccinations induce delayed but drastic increases in anti-RBD IgG4 responses. Further functional investigations are needed to reveal the magnitude of the high contribution of spike-specific IgG4 subclasses after repeated mRNA-based COVID-19 vaccinations.

Increasing Levels of Serum Anti-Spike S1-RBD IgG after 120 Days of the Pfizer-BioNTech-mRNA Second Dose Vaccination. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccines, such as Pfizer-BioNTech, have demonstrated high efficacy; however, there is limited data on the duration of immune responses besides their relationships with age, gender, body mass index (BMI), and the presence of previous coronavirus disease-2019 (COVID-19) infection. This study aimed to evaluate SARS-COVID-19 Anti-Spike IgG levels after 30 days (one month) and 120 days (four months) of the 2(nd) dose of Pfizer-BioNTech vaccine given to medical students at Al-Iraqi University, Baghdad, Iraq. This study was performed after the obtainment of the acceptance and approval of the Medical College of Al-Iraqi University and the Iraqi Ministry of Health. Two groups of students were randomly picked up from the Medical College of Al-Iraqi University. They were completely vaccinated by administering two doses of Pfizer-BioNTech/0.5 ml for each dose. After taking their permission, 5

ml of their blood (one group after one month and the second group after four months of vaccination) was drawn in the Higher Education lab inside the Medical College of Al-Iraqi University. It took approximately four months to collect the samples (from October 2021 until February 2022). Following that, serological analysis was done for measuring the SARS-CoV-2 spike protein IgG by using Elabscience/SARS-CoV-2 spike protein IgG ELISA Kit (USA) (+ve <0.06) that was performed in the Higher Education lab of Medical College of Al-Iraqi University. Demographic data were also collected from participants, including age, gender, BMI, blood group, and the presence of previous COVID-19 infection. For statistical analysis, SPSS (version 26) and STATISTICA (version 12) were used to input, check, and analyze data. Standard approaches of frequencies and percentages were used for qualitative variables, while for quantitative variables, meanÂ±standard deviation was used. A P-value of <0.05 was considered a significant plasma level of the SARS-COVID-19 Anti-Spike IgG. The study results showed that in group 1 (after one month of the 2(nd) dose), the male-female ratio was 62.2: 37.8, the mean age of the vaccinated students was 28.2000 years old, and the BMI was 25.5454 kg/m2 with 33.3% previously COVID-19 infected individuals. In group 2 (after four months of the 2(nd) dose), the male-female ratio was 44.4: 55.6, the mean age of the vaccinated students was 25.8444 years old , and the BMI was 24.7584 kg/m2 with 24.4% previously COVID-19 infected individuals. The plasma levels of SARS-COVID-19 Anti-Spike IgG after the 2(nd) dose of the Pfizer-BioNTech vaccine in group 1 (one month) and group 2 (four months) were statistically non-parametric. Once the independent two samples Mann-Whitney test was used, a significant difference (P<0.05) was observed in SARS-COVID-19 Anti-Spike IgG plasma levels after 30 days of the 2(nd) dose of the Pfizer-BioNTech vaccine administration, compared to the 120 days of administration. In conclusion, SARS-COVID-19 Anti-Spike IgG levels significantly increased in group 2 (four months after the 2(nd) dose of the Pfizer-BioNTech vaccine), compared to group 1 (one month after the 2(nd) dose of the Pfizer-BioNTech vaccine).

The usability of testing skin reaction applying skin prick tests with Comirnaty (Pfizer, USA) vaccine in detecting the risk of developing post-vaccination immediate hypersensitivity response (anaphylaxis) after administration of this vaccine. INTRODUCTION: COVID-19 vaccines became a relevant element of prevention during COVID-19 pandemic. It is worth highlighting the importance of severe allergic post-vaccination reactions. AIM: To evaluate the usability of skin reaction tests using skin prick tests with Comirnaty (Pfizer, USA) vaccine in risk detection of the post-vaccine immediate hypersensitivity reaction (anaphylaxis) after administration of this vaccine [PvIHR(A)]. MATERIAL AND METHODS: The analysis embraces 102 people, 85 women and 17 men with a history of immediate hypersensitivity (anaphylaxis) [IHR(A)]. Detailed medical history was collected and skin prick tests were made among participants. The positive and negative test results were illustrated in Figure 1. RESULTS: As it stands in Table 1, considering all participants of the study, a positive result of the skin prick tests was obtained only in 2 cases, a negative result in 99 and 1 result was questionable. The two positive results were found in participants from a group with a previous PvIHR(A) in their past medical history and they decided not to get vaccinated. The one questionable result was of a person that had PvIHR(A) after administration of the first dose of Comirnaty vaccine (Pfizer, USA). This person decided to get vaccinated again and there was no PvIHR(A) observed. CONCLUSIONS: COVID-19 vaccination involves a low risk of anaphylaxis. Purposefulness of providing the skin prick tests using the mRNA vaccine is questionable, due to their low sensitivity and low specificity.

Long-term follow-up of a young male who developed acute macular neuroretinopathy following COVID-19 vaccination. This report presents the clinical findings and prognosis of a healthy male patient who developed acute macular neuroretinopathy after COVID-19 vaccination. Abnormal findings improved about 1â€‰month after the onset and disappeared 3â€‰months later. The subjective symptoms disappeared in 3â€‰months, and no recurrence was observed for 1â€‰year.

Optic neuritis after mRNA COVID-19 vaccination: a case report. Our case reported a 22-year-old male presented with headache, and sudden vision loss, 10â€‰days after receiving the first dose of COVID-19 vaccination. Counting fingers in both eyes was his visual acuity on examination and bilateral optic disc edema on fundoscopy was found. Brain MRI was normal. After methylprednisolone pulse therapy, plasmapheresis, and IV cyclophosphamide courses, the optic disc edema disappeared, and his visual function did not improve. Reported cases of optic neuritis develop after mRNA COVID-19 vaccination are limited.

T cell immune memory after covid-19 and vaccination. The T cell memory response is a crucial component of adaptive immunity responsible for limiting or preventing viral reinfection. T cell memory after infection with the SARS-CoV-2 virus or vaccination is broad, and spans multiple viral proteins and epitopes, about 20 in each individual. So far the T cell memory response is long lasting and provides a high level of cross reactivity and hence resistance to viral escape by variants of the SARS-CoV-2 virus, such as the omicron variant. All current vaccine regimens tested produce robust T cell memory responses, and heterologous regimens will probably enhance protective responses through increased breadth. T cell memory could have a major role in protecting against severe covid-19 disease through rapid viral clearance and early presentation of epitopes, and the presence of cross reactive T cells might enhance this protection. T cell memory is likely to provide ongoing protection against admission to hospital and death, and the development of a pan-coronovirus vaccine might future proof against new pandemic strains.

Adverse reactions following COVID-19 vaccine among healthcare professionals working in Ethiopia: a facility-based cross-sectional study. BACKGROUND OF THE STUDY: One of the best medical approaches for halting the spread of infectious diseases is vaccination. During the COVID-19 pandemic, healthcare workers (HCWs) were a high-risk population. Due to their susceptibility in terms of their working environment, front-line healthcare personnel should receive vaccinations before others. OBJECTIVE: The purpose of this study was to assess the adverse reactions to COVID-19 vaccines among Ethiopian healthcare professionals in 2022. METHODS: A facility-based cross-sectional study design was conducted in Addis Ababa Health Facilities, Ethiopia. A total of 290 health professionals who were vaccinated during the study period were involved. Data entry was done by Epidata (version 3.1) and analyzed using SPSS software version 26. Bivariable analysis was conducted and a p value of less than 0.25 was selected for further multivariable analysis. A p value of 0.05 was considered statistically significant at a 95% confidence level. RESULTS: A total of 277 study participants were successfully involved in the study, yielding a response rate of 95.5%. The study participants comprised 123 (44.4%) women and 154 (55.6%) men. The majority of them (202, 72.9%) had received the Oxford AstraZeneca vaccine. Among the 277 study participants, 142 (51.3%) had developed adverse reactions associated with vaccination. Of these, 81 (29.2%) had moderate adverse reactions. Only 2 (0.7%) had developed adverse reactions that led to hospitalization. The most reported short-term adverse reactions were injection site pain (151, 54.5%), headache (114, 41.2%), fever (104, 37.5%), fatigability and tiredness (94, 33.9%), chills (92, 33.2%), muscle pain (79, 28.5%), and decreased sleep quality (34, 12.3%). The multivariable logistic regression showed that the odds of having an adverse reaction were 1.501 times higher among women than men (AORâ€‰=â€‰1.501, 95% CI [1.08, 2.754]). CONCLUSION AND RECOMMENDATIONS: This study revealed that adverse effects following the COVID-19 vaccine were moderate in magnitude and minimal in severity. This study showed that adverse reactions that led to hospitalization were rare. Based on the findings of this study, it is recommended that national, multicenter, prospective, and randomized studies be conducted to assess the independent association of each vaccine.

Incidence of SARS-CoV-2 infection in children shortly after ending zero-COVID-19 policy in China on December 7, 2022: a cross-sectional, multicenter, seroepidemiological study. BACKGROUND:

China discontinued the zero-COVID-19 policy on December 7, 2022, and then COVID-19 surged mid-December 2022 through mid-January 2023. However, the actual incidence was unknown. This study aimed to estimate the incidence of SARS-CoV-2 infection in children shortly after ending the zero-COVID-19 policy. METHODS: This multicenter cross-sectional study included 1,065 children aged 8â€‰months to 12â€‰years from seven hospitals at six regions across Jiangsu province, based on the convenience sampling, from February 10 to March 10, 2023. Group I comprised 324 children aged 8â€‰months-2â€‰years without COVID-19 vaccination, group II consisted of 338 preschool children aged 3-5â€‰years with varied vaccination history, and group III contained 403 primary school children aged 6-12â€‰years with mostly vaccinated. The COVID-19 vaccines were composed of inactivated SARS-CoV-2. In addition, 96 children's sera collected in 2014 were included as negative controls. IgG and IgM antibodies against nucleocapsid (N) and subunit 1 of spike (S1) of SARS-CoV-2 (anti-N/S1) were measured with commercial kits (YHLO Biotech, Shenzhen, China). RESULTS: None of the 96 children (5.1â€‰Â±â€‰3.5â€‰years; 58.3% boys) in 2014 was positive for anti-N/S1 IgG or IgM. Of the 1,065 children (5.0â€‰Â±â€‰3.5â€‰years; 56.0% boys), 988 (92.8%) were anti-N/S1 IgG positive but none was anti-N/S1 IgM positive. The positive rate of anti-N/S1 IgG in Group I, II, and III was 90.4, 88.5, and 98.3%, respectively, with significantly higher in group III than in groups I and II (pâ€‰<â€‰0.0001). The median antibody titers in group III (381.61â€‰AU/ml) were much higher than that in group I (38.34â€‰AU/ml) and II (51.88â€‰AU/ml; pâ€‰<â€‰0.0001). CONCLUSION: More than 90% children experienced SARS-CoV-2 infection shortly after ending zero-COVID-19 policy in China, much higher than estimated infections by other studies. The widespread SARS-CoV-2 infection in unvaccinated children should be influential on the policy of COVID-19 vaccination in children in the future.

Disturbance of Adaptive Immunity System Was Accompanied by a Decrease in Plasma Short-Chain Fatty Acid for Patients Hospitalized During SARS-CoV-2 Infection After COVID-19 Vaccination. INTRODUCTION: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection can lead to disorders of immune function and a decrease in the diversity of intestinal flora. We aimed to explore the changes of circulating immune cell subsets and the plasma level of intestinal short-chain fatty acids (SCFAs) in patients with Coronavirus disease 2019 (COVID-19), further understanding the pathogenesis of COVID-19. METHODS: The study included 83 newly diagnosed COVID-19 patients and 39 non-COVID-19 controls. All have completed a full course of vaccination against SARS-CoV-2. The levels of peripheral lymphocyte subsets and plasma cytokines were detected by flow cytometry. Targeted metabolomics was used to explore the level of SCFAs in plasma. RESULTS: Compared with the non-COVID-19 group, COVID-19 patients showed a decrease in CD19(+)B cells, CD4(+)T cells, CD8(+)T cells, NK cells, CD4(+)CD8(+)T cells and CD4(-)CD8(-)T cells (all $p<0.001$) and concomitantly an increase in sIL-2R, IL-6 and IL-10 (all $p<0.005$). These alterations were more pronounced in those critical patients. In addition, COVID-19 patients had lower levels of propanoic acid (PA), butyric acid (BA), isobutyric acid (IBA) and isohexanoic acid (ICA) (all $p<0.01$). Among them, the level of ICA is positively correlated with the absolute number of immune cells. CONCLUSION: Our study suggests the immune cell subsets in COVID-19 patients who had completed vaccination were still severely disturbed and concomitantly lower SCFAs, especially in severe patients with poor prognosis. Lower levels of plasma SCFAs may contribute to lymphopenia in COVID-19. The potential relationship between plasma SCFAs and immune cell reduction provides a new direction for the treatment of COVID-19.

Small fiber neuropathy with normal intra-epidermal nerve fiber density but reduced sweat gland density after third BNT162b2 shot. Small fiber neuropathy (SFN) has not been reported after the third dose of BNT162b2 in a previously healthy vaccinee. A 44-year-old previously healthy female developed pain and sensory disturbances in varying locations after the third BNT162b2 dose.

Additionally, she developed recurrent tinnitus, headaches, arthralgia, neck stiffness, and motor dysfunction. A skin biopsy five months after symptom onset revealed normal intra-epidermal nerve fiber density (IENFD) but reduced sweat gland nerve fiber density. She is intended for a first series of intravenous immunoglobulins. SARS-CoV-2 vaccinations may be complicated by SFN; the diagnosis SARS-CoV-2 vaccination SFN may be delayed; IENFD may be normal, but sweat gland nerve fiber density may document SFN; and full recovery after SFN cannot always be achieved quickly.

Serological response 5 months after the BNT162b2 COVID-19 vaccination in patients with various hematological disorders in Japan. PURPOSE: Patients with hematological malignancies are at an increased risk of severe infection with coronavirus disease 2019 (COVID-19). However, developing an adequate immune response after vaccination is difficult, especially in patients with lymphoid neoplasms. Since the long-term effects of the BNT162b2 vaccine are unclear, the humoral immune response 5 months after the two vaccinations in patients with hematological disorders was analyzed. MATERIALS AND METHODS: Samples were collected from 96 patients vaccinated twice with BNT162b2 and treated with at least one line of an antitumor or immunosuppressive drug in our hospital from November 2021 to February 2022. Serum anti-severe acute respiratory syndrome coronavirus 2 (anti-SARS-CoV-2) spike (S) antibody titers were analyzed. Patients were age- and sex-matched using propensity matching and compared with a healthy control group. Patients with serum anti-SARS-CoV-2 S antibodies were defined as 'responder' if >50 U/mL. The patients had B-cell non-Hodgkin lymphoma (B-NHL), multiple myeloma, chronic myeloid leukemia, etc. RESULTS: Patients had significantly low antibody levels (median, 55.3 U/mL vs. 809.8 U/mL; $p<0.001$) and a significantly low response rate ($p<0.001$). Multivariate analysis showed that patients with B-NHL, aged >72 years, were associated with a low response to vaccination. There were no significant differences between patients with chronic myeloid leukemia and healthy controls. CONCLUSION: Our study shows that patients with hematological disorders are at risk of developing severe COVID-19 infections because of low responsiveness to vaccination. Moreover, the rate of antibody positivity differed between the disease groups. Further studies are warranted to determine an appropriate preventive method for these patients, especially those with B-NHL.

COVID-19 vaccine-induced immune thrombotic thrombocytopenia: a review. Rare but serious thrombotic incidents in relation to thrombocytopenia, termed vaccine-induced immune thrombotic thrombocytopenia (VITT), have been observed since the vaccine rollout, particularly among replication-defective adenoviral vector-based severe acute respiratory syndrome coronavirus 2 vaccine recipients. Herein, we comprehensively reviewed and summarized reported studies of VITT following the coronavirus disease 2019 (COVID-19) vaccination to determine its prevalence, clinical characteristics, as well as its management. A literature search up to October 1, 2021 using PubMed and SCOPUS identified a combined total of 720 articles. Following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guideline, after screening the titles and abstracts based on the eligibility criteria, the remaining 47 full-text articles were assessed for eligibility and 29 studies were included. Findings revealed that VITT cases are strongly related to viral vector-based vaccines, which are the AstraZeneca COVID-19 vaccine (95%) and the Janssen COVID-19 vaccine (4%), with much rarer reports involving messenger RNA-based vaccines such as the Moderna COVID-19 vaccine (0.2%) and the Pfizer COVID-19 vaccine (0.2%). The most severe manifestation of VITT is cerebral venous sinus thrombosis with 317 cases (70.4%) and the earliest primary symptom in the majority of cases is headache. Intravenous immunoglobulin and non-heparin anticoagulant are the main therapeutic options for managing immune responses and thrombosis, respectively. As there is emerging knowledge on and refinement of the published guidelines regarding VITT, this review may assist the medical communities in early VITT recognition, understanding the clinical presentations,

diagnostic criteria as well as its management, offering a window of opportunity to VITT patients. Further larger sample size trials could further elucidate the link and safety profile.

A case report of constrictive pericarditis following COVID-19 vaccination. BACKGROUND: COVID-19 infection and the COVID-19 vaccines have been associated with rare cases of pericarditis. We present a case of constrictive pericarditis (CP) following the vaccine. CASE SUMMARY: A 19-year-old healthy male started having progressive abdominal pain, emesis, dyspnoea, and pleuritic chest pain 2 weeks after the second dose of Pfizer vaccine. Computed tomography angiography chest revealed bilateral pleural effusions and pericardial thickening with effusion. Cardiac catheterization showed ventricular interdependence. Cardiac magnetic resonance (CMR) showed septal bounce and left ventricular tethering suggestive of CP. A total pericardiectomy was performed with significant symptom improvement. Pathology showed chronic fibrosis without amyloid, iron deposits, or opportunistic infections. Patient had Epstein-Barr Virus (EBV) viraemia 825â€…IU/mL and histoplasmosis complement-fixation positive with negative serum and urine antigen. Hypercoagulable panel and infectious workup were otherwise negative. The patient had resolution of cardiac symptoms at 3 months of follow-up. DISCUSSION: The patient developed progressive symptoms within 2 weeks of his second Pfizer vaccine. Echocardiogram and CMR had classic signs of CP, and pericardial pathology confirmed fibrotic pericardium. The patient had no prior surgery, thoracic radiation, or bacterial infection. Epstein-Barr Virus viraemia was thought to be reactionary, and histoplasmosis complement likely represented chronic exposure. The timing of symptoms and negative multidisciplinary workup raises the suspicion for COVID vaccine-induced CP. The COVID vaccines benefits far exceed the risks, but complications still can occur. Practitioners should have a high index of suspicion to allow prompt diagnosis of CP.

Adverse reactions after Covid-19 vaccination in persons affected by leprosy: A scoping review. BACKGROUND: Leprosy reactions are the main pathway leading to severe nerve damage and disability. These reactions can occur at any time. The coronavirus disease 2019 (Covid-19) pandemic led to a catastrophic loss of human life and has had a devastating impact on persons affected by leprosy. OBJECTIVE: To achieve deep insight into the subject of adverse reactions acquired after Covid vaccinations in persons affected by leprosy through a literature review. MATERIALS AND METHODS: A scoping review was conducted in the studies published between July 2021 and June 2022 using the Preferred Reporting Items for Systematic Review and Meta-Analysis Extension for Scoping Reviews (PRISMA-ScR) checklist. RESULTS: Using the search strategy, a total of 130 articles were found, of which five were relevant to the study. The adverse reactions were acquired mostly in males [9 (81.8%)]; the majority of them belong to borderline tuberculoid [4 (36.4%)], and most of them were released from treatment (multi-drug therapy) [7 (63.6%)]. CONCLUSION: Surveillance and management of adverse events following immunization (AEFI) are essential; even minor AEFI should be reported and documented in a line list.

Clinical Approach to Post-acute Sequelae After COVID-19 Infection and Vaccination. The spike protein of SARS-CoV-2 has been found to exhibit pathogenic characteristics and be a possible cause of post-acute sequelae after SARS-CoV-2 infection or COVID-19 vaccination. COVID-19 vaccines utilize a modified, stabilized prefusion spike protein that may share similar toxic effects with its viral counterpart. The aim of this study is to investigate possible mechanisms of harm to biological systems from SARS-CoV-2 spike protein and vaccine-encoded spike protein and to propose possible mitigation strategies. We searched PubMed, Google Scholar, and 'grey literature' to find studies that (1) investigated the effects of the spike protein on biological systems, (2) helped differentiate between viral and vaccine-generated spike proteins, and (3) identified possible spike protein detoxification protocols and compounds that had signals of benefit and acceptable safety profiles.Â We found abundant evidence that SARS-CoV-2 spike protein may cause damage in the cardiovascular,

hematological, neurological, respiratory, gastrointestinal, and immunological systems. Viral and vaccine-encoded spike proteins have been shown toÂ play a direct role in cardiovascular and thrombotic injuries from both SARS-CoV-2 and vaccination. Detection of spike protein for at least 6-15 months after vaccination and infection in those with post-acute sequelae indicatesÂ spike protein as a possible primary contributing factor to long COVID. We rationalized that these findings give support to the potential benefit of spike protein detoxification protocols in those with long-term post-infection and/or vaccine-induced complications. We propose a base spike detoxification protocol, composed of oral nattokinase, bromelain, and curcumin. This approach holds immense promise as a base of clinical care, upon which additional therapeutic agents are applied with the goal of aiding in the resolution of post-acute sequelae after SARS-CoV-2 infection and COVID-19 vaccination. Large-scale, prospective, randomized, double-blind, placebo-controlled trials are warranted in order to determine the relative risks and benefits of the base spike detoxification protocol.

Antibody Response After the Third SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients and People Living With HIV (COVERALL-2). BACKGROUND: After basic immunization with 2 mRNA SARS-CoV-2 vaccine doses, only a small proportion of patients who are severely immunocompromised generate a sufficient antibody response. Hence, we assessed the additional benefit of a third SARS-CoV-2 vaccine in patients with different levels of immunosuppression. METHODS: In this observational extension of the COVERALL trial (Corona Vaccine Trial Platform), we recruited patients from the Swiss HIV Cohort Study and the Swiss Transplant Cohort Study (ie, lung and kidney transplant recipients). We collected blood samples before and 8 weeks after the third SARS-CoV-2 vaccination with either mRNA-1273 (Moderna) or BNT162b2 (Pfizer-BioNTech). The primary outcome was the proportion of participants showing an antibody response (Elecsys Anti-SARS-CoV-2 S test; threshold â‰¥100 U/mL) 8 weeks after the third SARS-CoV-2 vaccination. We also compared the proportion of patients who reached the primary outcome from basic immunization (the first and second vaccines) to the third vaccination. RESULTS: Nearly all participants (97.2% [95% CI, 95.9%-98.6%], 564/580) had an antibody response. This response was comparable between mRNA-1273 (96.1% [95% CI, 93.7%-98.6%], 245/255) and BNT162b2 (98.2% [95% CI, 96.7%-99.6%], 319/325). Stratification by cohort showed that 99.8% (502/503) of people living with HIV and 80.5% (62/77) of recipients of solid organ transplants achieved the primary endpoint. The proportion of patients with an antibody response in solid organ transplant recipients improved from the second vaccination (22.7%, 15/66) to the third (80.5%, 62/77). CONCLUSIONS: People living with HIV had a high antibody response. The third vaccine increased the proportion of solid organ transplant recipients with an antibody response. Clinical Trials Registration.â€ƒNCT04805125 (ClinicalTrials.gov).

Evolution of Humoral and Cellular Immunity Post-Breakthrough Coronavirus Disease 2019 in Vaccinated Patients With Hematologic Malignancy Receiving Tixagevimab-Cilgavimab. BACKGROUND: In-depth immunogenicity studies of tixagevimab-cilgavimab (T-C) are lacking, including following breakthrough coronavirus disease 2019 (COVID-19) in vaccinated patients with hematologic malignancy (HM) receiving T-C as pre-exposure prophylaxis. METHODS: We performed a prospective, observational cohort study and detailed immunological analyses of 93 patients with HM who received T-C from May 2022, with and without breakthrough infection, during a follow-up period of 6 months and dominant Omicron BA.5 variant. RESULTS: In 93 patients who received T-C, there was an increase in Omicron BA.4/5 receptor-binding domain (RBD) immunoglobulin G (IgG) antibody titers that persisted for 6 months and was equivalent to 3-dose-vaccinated uninfected healthy controls at 1 month postinjection. Omicron BA.4/5 neutralizing antibody was lower in patients receiving B-cell-depleting therapy within 12 months despite receipt of T-C. COVID-19 vaccination during T-C treatment did not incrementally improve RBD or neutralizing antibody levels. In 16

patients with predominantly mild breakthrough infection, no change in serum neutralization of Omicron BA.4/5 postinfection was detected. Activation-induced marker assay revealed an increase in CD4(+) (but not CD8(+)) T cells post infection, comparable to previously infected healthy controls. CONCLUSIONS: Our study provides proof-of-principle for a pre-exposure prophylaxis strategy and highlights the importance of humoral and cellular immunity post-breakthrough COVID-19 in vaccinated patients with HM.

Immune responses and clinical outcomes following the third dose of SARS-CoV-2 mRNA-BNT162b2 vaccine in advanced breast cancer patients receiving targeted therapies: a prospective study. PURPOSE: Metastatic breast cancer patients are the most prevalent oncology population with advanced disease facing COVID-19 pandemic. Immune responses after mRNA-based vaccination during treatment with CDK4/6 inhibitors or HER2-directed agents remain unclear. We conducted a prospective analysis to elucidate changes in antibody titers and lymphocyte counts following full course of mRNA-BNT162b2 (tozinameran) vaccination in recipients undergoing these targeted therapies. METHODS: Patients who had received a booster dosing and had been treated for at least 6 months were eligible. Antibody titers against SARS-CoV-2 spike protein were measured at four subsequent time points. Immunophenotyping of circulating lymphocytes was performed before the third dose of tozinameran and four weeks later to quantify the absolute counts of CD3(+)CD4(+) T-helper cells, CD3(+)CD8(+) T-cytotoxic cells, CD19(+) B cells, and CD56(+)CD16(+) NK cells. We also assessed the incidence of breakthrough infections and investigated whether immune changes affect time-to-treatment failure (TTF) after booster vaccination. RESULTS: The current analysis included 69 patients, of whom 38 (55%) and 31 (45%) were being treated with CDK4/6 inhibitors and HER2-targeted therapies, respectively. All participants received a third dose of tozinameran between September 23 and October 7, 2021. Multivariate analysis revealed that CDK4/6 inhibition predicted a significantly impaired humoral response after the booster dose. This detrimental effect was also evident for T-helper cell counts before the third immunization, but it disappeared in the subsequent evaluation. After a median follow-up of 22.3 months, we observed 19 (26%) cases of COVID-19 outbreaks, all experiencing favorable clinical outcomes. Univariate analysis showed a significant association between the onset of SARS-CoV-2 infections and the use of CDK4/6 inhibitors, as well as with an impaired antibody and T-helper cell response. Only the last two covariates remained independent predictors after multivariate testing. Dynamic variations in antibody titers and T-helper cell counts did not affect TTF in multivariate regression analysis. CONCLUSIONS: Our results confirm that the immune response to tozinameran is impaired by CDK4/6 inhibitors, increasing the odds of breakthrough infections despite the third vaccine dose. Current evidence recommends maintaining efforts to provide booster immunizations to the most vulnerable cancer patients, including those with advanced breast cancer undergoing CDK4/6 inhibition.

Analysis of vaccine responses after anti-CD20 maintenance in B-cell lymphoma in the Balearic Islands. A single reference center experience. INTRODUCTION: The use of maintenance approaches with anti-CD20 monoclonal antibodies has improved the outcomes of B-cell indolent lymphomas but may lead to significant peripheral B-cell depletion. This depletion can potentially hinder the serological response to neoantigens. METHODS: Our objective was to analyze the effect of anti-CD20 maintenance therapy in a reliable model of response to neoantigens: SARS-CoV-2 vaccine responses and the incidence/severity ofCOVID-19 in a reference hospital. RESULTS: In our series (n=118), the rate of vaccination failures was 31%. Through ROC curve analysis, we determined a cutoff for SARS-CoV-2 vaccine serologic response at 24 months from the last anti-CD20 dose. The risk of severe COVID-19 was notably higher within the first 24months following the last anti-CD20 dose (52%) compared to after this period (just 18%) (p=0.007). In our survival analysis, neither vaccine response nor hypogammaglobulinemia significantly affected OS. While COVID-19 led to a modest mortality rate

of 2.5%, this figure was comparable to the OS reported in the general immunocompetent population. However, most patients with hypogammaglobulinemia received intravenous immunoglobulin therapy and all were vaccinated. In conclusion, anti-CD20 maintenance therapy impairs serological responses to SARS-CoV-2 vaccines. DISCUSSION: We report for the first time that patients during maintenance therapy and up to 24 months after the last anti-CD20 dose are at a higher risk of vaccine failure and more severe cases of COVID-19. Nevertheless, with close monitoring, intravenous immunoglobulin supplementation or proper vaccination, the impact on survival due to the lack of serological response in this high-risk population can be mitigated, allowing for the benefits of anti-CD20 maintenance therapy, even in the presence of hypogammaglobulinemia.

Three doses of COVID-19 mRNA vaccine induce class-switched antibody responses in inflammatory arthritis patients on immunomodulatory therapies. Patients with inflammatory arthritis (IA) are at increased risk of severe COVID-19 due to medication-induced immunosuppression that impairs host defenses. The aim of this study was to assess antibody and B cell responses to COVID-19 mRNA vaccination in IA patients receiving immunomodulatory therapies. Adults with IA were enrolled through the Johns Hopkins Arthritis Center and compared with healthy controls (HC). Paired plasma and peripheral blood mononuclear cell (PBMC) samples were collected prior to and 30 days or 6 months following the first two doses of mRNA vaccines (D2; HC=77 and IA=31 patients), or 30 days following a third dose of mRNA vaccines (D3; HC=11 and IA=96 patients). Neutralizing antibody titers, total binding antibody titers, and B cell responses to vaccine and Omicron variants were analyzed. Anti-Spike (S) IgG and S-specific B cells developed appropriately in most IA patients following D3, with reduced responses to Omicron variants, and negligible effects of medication type or drug withholding. Neutralizing antibody responses were lower compared to healthy controls after both D2 and D3, with a small number of individuals demonstrating persistently undetectable neutralizing antibody levels. Most IA patients respond as well to mRNA COVID-19 vaccines as immunocompetent individuals by the third dose, with no evidence of improved responses following medication withholding. These data suggest that IA-associated immune impairment may not hinder immunity to COVID-19 mRNA vaccines in most individuals.

Side effects of COVID-19 vaccines in the middle eastern population. The COVID-19 pandemic has caused severe worldwide health concerns since its first description as the SARS-COV-2 virus in December 2019. The wide dissemination of this virus, together with the lack of treatment, prompted vaccine development within a short period of time to elicit a protective immunity against COVID-19. Due to their rapid development, potential subsequent side effects of COVID-19 vaccines were overlooked, which might lead to many health concerns. This is especially true for patients at a greater risk of harm from COVID-19, such as pregnant women, children, and patients with pre-existing chronic diseases. In this review, we provide a summary of common to rare side effects of administrated COVID-19 vaccines in a Middle Eastern population. We have found that the distinction between side effects from COVID-19 vaccines in terms of frequency and severity is attributed to the differences in study populations, gender, and age. Pain at the injection site, fever, headache, fatigue, and muscle pain were the most common reported side effects. Vaccinated subjects with previous COVID-19 infection exhibited an equivalent neutralizing response after just one dose compared to two doses of vaccine. Consequently, individuals who experienced more side effects had significantly higher antibody levels. This indicates that having better immunity correlates with higher antibody levels, leading to a higher frequency of vaccine side effects. Individuals with underlying comorbidities, particularly having known allergies and with illnesses such as diabetes and cancer, might be more prone to post-vaccination side effects. Studies of a high-risk population in Middle Eastern countries are limited. Future studies should be considered to determine long-term side effects, side effects after booster doses, and side effect differences in cases of heterologous and homologous vaccination

for better understanding and proper handling of high-risk populations and patients who experience these side effects.

COVID-19 Vaccination and Its Relation to New-Onset Diabetes: A NarrativeÂ Review. The COVID-19 vaccination has been effective in preventing a lot of complications caused by SARS-CoV-2 and its variants. Meanwhile, diabetes mellitus, one of the root causes of many co-morbidities, exhibited itself during the COVID-19 pandemic and after COVID-19 vaccination. Diabetes mellitus introduced itself in a new perspective, leading to a variety of presentations and causing a significant number ofÂ emergency admissions. Many of the pre-diabetes patients with no prior history of diabetes developed fulminant type 1 diabetes mellitus (T1DM) after the COVID-19 vaccination. Some cases of conversion of type 2 diabetes mellitus (T2DM) into T1DM were reported. Some prediabetes/diabetes patientsÂ presented with the development of diabetic ketoacidosis after COVID-19 vaccination, whereas some previously healthy people with no relation to diabetes also developed acute exacerbations of new-onset T1DM or T2DM along with lethal ketoacidosis. The purpose of writing this review was to explore what kind of people are more prone to develop new-onset diabetes or diabetic complications, including diabetic ketoacidosis, the typical presentation of these patients, possible mechanisms that lead to these complications occurring after the COVID-19 vaccination, how they can be managed, and whether there is a good prognosis after management or not.

A Case of Leg Pain After the Initial Dose of the COVID-19 Vaccine, Followed by Deep Vein Thrombosis and Pulmonary Embolism After the Second Dose. COVID-19 has been spreading worldwide. Therefore, the COVID-19 vaccine is recommended for prevention. However, adverse events after COVID-19 vaccination remain an issue, and we should monitor patients for adverse events and determine their association with COVID-19 vaccination. Here, we report a case involving a 48-year-old Japanese woman who experienced dull left leg pain that resolved spontaneously after the first vaccine dose, followed by deep vein thrombosis (DVT) and pulmonary embolism (PE) after the second dose. The findings from this case suggest that the COVID-19 vaccine could cause severe adverse events, such as DVT. Therefore, patients should understand their subjective symptoms and report any side effects experienced after the first dose before they take the second dose. Furthermore, medical providers should enquire about all possible symptoms experienced after the initial dose before they administer the second dose.

CanSino COVID-19 Vaccine: Comparison of Vaccine Adverse Effects Among Diabetic and Non-diabetic Recipients. Introduction The emergence of potent vaccines is crucial in the fight against the coronavirus disease 2019 (COVID-19) pandemic. Two of the many factors influencing the acceptance of the vaccine are perceptions about its efficacy, effectiveness, safety, and side effects. Thus, this study compared patients with and without diabetes mellitus (DM) who received the CanSino (CanSinoBIO,Â Tianjin, China) COVID-19 vaccination to identify the prevalence of local and general side effects. Methods This was a multicenter, cross-sectional study performed using a non-probability sampling method. The study period was six months, from August 1, 2022, to January 31, 2023. The study included 600 participants who provided informed consent and had received the CanSino vaccine in a single dose. Demographic characteristics of the participants, including gender, age, weight, and height; comorbidities such as hypertension and diabetes; previous infection with COVID-19; and the prevalence of any local and systemic side effects following vaccination, were documented. Between diabetic and non-diabetic participants, the relationship between local and general side effects and satisfaction levels was assessed using the chi-square test. Results The study findings showed that out of 600 participants, 287 (95.7%) were males and 13 (4.3%) were females who had DM, whereas 229 (76.3%) males and 71 (23.7%) females did not. There was a statistically significant association between the two groups ($p < 0.001$). After receiving a single dose of the CanSino vaccine, the most frequently noticeable side effect was fever, which was noticed in 260

(86.75%) diabetic patients and 279 (93.0%) non-diabetic participants, with a significant association noted among them (p=0.010). Among the non-diabetic participants, 164 (54.7%) were satisfied, and 155 (51.7%) diabetics and 65 (21.7%) non-diabetic participants were extremely pleased with their vaccinations. Conclusion This study concluded that participants with comorbid diseases such as DM had both general and local side effects far more frequently than those without DM. The most noticeable side effects after a single dose of CanSino were fever, injection site pain, and burning. The CanSino vaccine did not require hospitalization and had a relatively low frequency of local and systemic side effects.

Immediate and Long-Term Adverse Events of COVID-19 Vaccines: A One-Year Follow-Up Study From the Kurdistan Region of Iraq. Background The administration of COVID-19 vaccines has been critical in controlling the spread of the virus. However, understanding the potential adverse events (AEs) associated with these vaccines is crucial for public health. While most previous studies observed only short-term AEs, this study aimed to investigate the immediate and long-term AEs following the first and second doses of Pfizer, AstraZeneca, and Sinopharm vaccines, providing valuable long-term insights. Methodology A prospective, one-year, follow-up study was conducted by tracking 922 vaccinated individuals to assess short-term and long-term AEs. Demographics, clinical characteristics, vaccine types, and dose effects were taken into consideration. AEs were classified based on severity and duration. Statistical analyses were performed to compare differences among the vaccine groups, with p-values <0.05 considered significant.Â Bowker's and chi-square tests were performed using JMP Pro 14.3.0. Results Of the 922 participants, 55.53% (n = 512) were vaccinated with Pfizer, and 23.32% (n = 215) and 21.15% (n = 195) were vaccinated with Sinopharm and AstraZeneca, respectively. Overall, 72.34% of participants (n = 667) were sufferingÂ from AEs after the first dose, with a lower prevalence of AEs after the second dose (52.71%, n = 486). Pfizer exhibited the highest percentage and severity of AEs, followed by AstraZeneca and Sinopharm.Â Most AEsÂ reported in this study were mild and resolved within 72 hours, with females experiencing more frequent AEs. The common short-term AEs observed were fever, injection-site pain, myalgia, fatigue, and headache.Â Notably, there were no chronic AEs, and only one case of myocarditis was associated with AstraZeneca. Conclusions Despite the variation in the prevalence of AEs among the three vaccines, the vaccination process proved to be safe with no serious short-term AEs.Â However, the long-term AEs associated with AstraZeneca and the decrease in the prevalence of AEs after the second dose of the COVID-19 vaccines warrant further investigations and priority for future research.

Sensorineural Hearing Loss as a Complication of COVID-19 and the COVID-19 Vaccine. The relationship between COVID-19 and sensorineural hearing loss (SNHL) continues to solidify in light of a growing body of evidence.Â In addition to the well-established COVID-19 symptoms and sequelae, otolaryngologists have observed an increased incidence of SNHL in patients with COVID-19 and following COVID-19 immunizations. Although the precise mechanisms behind this association remain unclear, various hypotheses are discussed within the scientific literature. This case report expands on the relationship between COVID-19 and SNHLÂ by discussing a unique case of bilateral tinnitus and subsequent SNHL shortly following COVID-19 immunization. It contributes to the growing body of evidence associating COVID-19 with SNHL, underlining the importance of further research to understand potential causal mechanisms. It underscores the clinical importance of monitoring hearing in COVID-19 patients and those receiving immunizations, advocating for increased awareness among clinicians to facilitate early identification and appropriate intervention in cases of COVID-19-related hearing loss.

Adverse Events Following mRNA COVID-19 Vaccine in 2021 and 2022: A Retrospective Analysis in Costa Rica and Italy. Introduction Pharmacovigilance plays a crucial role in evaluating and monitoring the safety of medicines, which is essential for preventing harm to patients and improving

public health. This study aims to compare the pharmacovigilance systems of Costa Rica and Italy and assess the safety profile of coronavirus disease 2019 (COVID-19) vaccines in both countries. Methods Data were collected from the official pharmacovigilance platforms in Costa Rica and Italy. Adverse events following immunization (AEFIs) were categorized by system organ class. Reports of suspected AEFIs associated with COVID-19 vaccines were analyzed for the period from January 1, 2021, to December 31, 2022. Results Both countries achieved high vaccination rates, with 84.9% in Italy and 92.9% in Costa Rica. A higher proportion of AEFIs occurred in females in both countries, with 53% and 65% in Naples and Costa Rica, respectively. Most AEFIs were observed in individuals aged 18-64 years. The rate of serious adverse reactions was lower in both countries than the international average. However, Naples reported a higher incidence of serious events per 100,000 inhabitants. Discussion The study sheds light on the importance of vaccine safety profiling and the significance of a comprehensive understanding of vaccine safety and effectiveness, specific population data, and collaborative strategies to mitigate and improve safety. Additionally, the study highlighted the significance of considering sex and gender when evaluating vaccine safety and efficacy, as sex-specific differences may impact vaccine outcomes. Conclusion Continuous pharmacovigilance efforts, collaborative approaches, and comprehensive data analysis are critical in ensuring vaccine safety and efficacy and safeguarding global public health. Lessons learned from the COVID-19 pandemic highlight the importance of proactive measures in addressing emerging challenges in vaccine safety and rollout programs worldwide.

Post-COVID-19 Vaccination Infection Among Adults in Saudi Arabia: A Cross-Sectional Study. BACKGROUND: While vaccines were one of the most effective tools to combat the COVID-19 pandemic, breakthrough infections have been reported. AIM OF THE WORK: We aimÂ to evaluate the effectiveness of Pfizer and AstraZeneca vaccines in preventing breakthrough infection, as well as to determine the possible risk factors and outcomes of post-vaccination infection. METHODS: This is a cross-sectional study using self-reported data of adult SaudiÂ residents, including Saudi and non-Saudi people who received at least two doses of either Pfizer or AstraZeneca vaccines. Based on the presence of COVID-19 symptoms that were confirmed by PCR, the participants were classified into three groups: (1) those withÂ evidence of infection before vaccination, (2) those who had infection after vaccination, and (3) those who had infection before and after vaccination. For further evaluation, we compared the severity and outcomes in the participants who were infected before and after vaccination. RESULTS: The study included 694 participants: 69.1% received three doses of the vaccine, and 71.1% of them were vaccinated with the Pfizer vaccine. COVID-19 infection was reported in 48.3% of the total subjects, with a higher infection rate (17.8%) after vaccination compared to 12.5% before vaccination. Additionally, 18.32% of participants experienced infection both before and after vaccination. Out of the total 694 participants, 137 (19.7%) had breakthrough infections. Pfizer vaccine was more prevalent among the non-infected group (74.25% vs. 65.5%), while AstraZeneca vaccine was more prevalent among the infected group (6.4% vs. 5.9% ($p<0.039$). Diabetes was significantly higher among the infected group (16.9% vs. 8.1%, $p=0.001$, OR=2.29, 95% CI=1.42-3.68). Among those who were infected before and after vaccination, 71.9% reported less severe symptoms after vaccination. CONCLUSION: Breakthrough infections may occur after vaccination; however, vaccines are overall effective in preventing severe symptoms. Pfizer vaccine appeared to be more effective in preventing COVID-19 infection. The presence of comorbidities, including diabetes, may increase the risk of infection.

Comparison of Time to Report the Side Effects after AstraZeneca and Sinopharm Vaccinations in Users of the COVID-19 Symptom Study App: A Survey in South Iran. BACKGROUND: Concerns about the side effects of SARS-CoV-2 vaccines have been raised nationwide. We aimed to compare the time to report the side effects of the Oxford-AstraZeneca and Sinopharm COVID-19 vaccines.

METHODS: Information on side effects of AstraZeneca and Sinopharm COVID-19 vaccines was obtained from the COVID-19 Symptom Study App affiliated with Shiraz University of Medical Science during 2021. A COX regression model with an adjusted Hazard Ratio and 95% Confidence Interval; HR (95% C.I) was reported at the significance level of < 0.05. RESULTS: 4478 and 5555 participants received the AstraZeneca and Sinopharm vaccines, respectively; more age, history of SARS-CoV-2 infection, first vaccine dose, hypertension, and hypertension with cardiovascular disease were seen in the AstraZeneca group (P < 0.05 for all). However, the AstraZeneca group had lower immune deficiency and time to report the side effects (P < 0.05 for both). There was significantly less time to pain HR(95% C.I.); 0.50 (0.47-0.52), vertigo 0.65 (0.61-0.69), weakness 0.41 (0.38-0.44), headache 0.43 (0.39-0.74), anorexia 0.31 (0.28-0.34), nausea 0.56 (0.51-0.62), severer allergy 0.71 (0.63-0.81), general inflammation 0.27 (0.23-0.31), fever > 38oC 0.12 (0.1-0.15), eye inflammation 0.45 (0.39-0.52), diarrhea 0.85 (0.73-0.99), blurred vision 0.73 (0.61-0.86), injection site redness 0.32 (0.26-0.39), fatigue/paleness 0.53 (0.50-0.57), joint pain 0.55 (0.41-0.73), auxiliary gland inflation 0.59 (0.43-0.80), convulsions 0.30 (0.17-0.52), and severe side effects 0.3 (0.27-0.33) in the AstraZeneca group; However, skin rash 0.77 (0.57-1.05) and hospitalization 0.72 (0.21-2.55) were the same. CONCLUSION: Sinopharm COVID-19 vaccine recipients reported longer times to report vaccine-related side effects than AstraZeneca; due to the lack of adverse effects like hospitalization, vaccination should continue to control the pandemic; more real-population studies are needed on the long-term effects of vaccination against COVID-19.

Toxic Epidermal Necrolysis after COVID-19 mRNA-1237 Vaccination. This letter illustrates a case of toxic epidermal necrolysis (TEN) after COVID-19 mRNA-1273 vaccination, which corresponds with the existing published data and contributes detailed knowledge of TEN reaction after vaccination. Interestingly, the reaction started at the site of vaccination and the patient went on to tolerate a major excipient of the vaccine suggesting the reaction may be associated with the mRNA itself or is triggered by the immunostimulatory action of the vaccine.

Monitoring SARS CoV-2 antibodies positivity in healthcare workers after inactivated CoronaVac(Â®) vaccine. INTRODUCTION: In this study, we aimed to monitor anti-spike and anti-nucleocapsid antibodies positivity in healthcare workers (HCWs) vaccinated with two doses of inactivated CoronaVac(Â®) (Sinovac, China) vaccine. METHODS: Overall, 242 volunteer HCWs were included. Of the participants, 193 were HCWs without history of prior documented COVID-19 (Group 1), while 49 had history of prior documented COVID-19 before vaccination (Group 2). The participants were followed up for SARS-CoV-2 antibodies positivity at four different blood sampling time points (immediately before the second vaccine dose and at the 1(st), 3(rd) months and 141-150 days after the second dose). We investigated the serum IgG class antibodies against SARS-CoV-2 RBD region and IgG class antibodies against SARS-CoV-2 nucleocapsid antigen by chemiluminescent microparticle immunoassay (CMIA) method using commercial kits. RESULTS: We found positive serum anti-RBD IgG antibody in 76.4% of the participants (71% in Group 1; 98% in Group 2) 28 days after the first dose. When the antibody levels of the groups were compared at the four blood sampling time points, Group 2 anti-RBD IgG levels were found to be significantly higher than those in Group 1 at all follow-up time points. Although anti-RBD IgG positivity persisted in 95.6% of all participants in the last blood sampling time point, a significant decrease was observed in antibody levels compared to the previous blood sampling time point. Anti-nucleocapsid IgG antibody was positive in 12 (6.2%) of participants in Group 1 and 32 (65.3%) in Group 2 at day 28 after the first dose. At the fourth blood sampling time point, anti-nucleocapsid antibodies were found to be positive in a total of 20 (9.7%) subjects, 10 (6.1%) in Group 1 and 10 (23.8%) in Group 2. CONCLUSIONS: In this study, it was determined that serum antibody levels decreased in both groups after the third month after the second dose in HCWs vaccinated with CoronaVac(Â®) vaccine.

Durable natural killer cell response after three doses of SARS-CoV-2 inactivated vaccine in HIV-infected individuals. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine can induce a potent cellular and humoral immune response to protect against SARS-CoV-2 infection. However, it was unknown whether SARS-CoV-2 vaccination can induce effective natural killer (NK) cell response in people living with human immunodeficiency virus (PLWH) and healthy individuals. METHODS: Forty-seven PLWH and thirty healthy controls (HCs) inoculated with SARS-CoV-2 inactivated vaccine were enrolled from Beijing Youan Hospital in this study. The effect of SARS-CoV-2 vaccine on NK cell frequency, phenotype, and function in PLWH and HCs was evaluated by flow cytometry, and the response of NK cells to SARS-CoV-2 Omicron Spike (SARS-2-OS) protein stimulation was also evaluated. RESULTS: SARS-CoV-2 vaccine inoculation elicited activation and degranulation of NK cells in PLWH, which peaked at 2 weeks and then decreased to a minimum at 12 weeks after the third dose of vaccine. However, in vitro stimulation of the corresponding peripheral blood monocular cells from PLWH with SARS-2-OS protein did not upregulate the expression of the aforementioned markers. Additionally, the frequencies of NK cells expressing the activation markers CD25 and CD69 in PLWH were significantly lower than those in HCs at 0, 4 and 12Â weeks, but the percentage of CD16 + NK cells in PLWH was significantly higher than that in HCs at 2, 4 and 12Â weeks after the third dose of vaccine. Interestingly, the frequency of CD16 + NK cells was significantly negatively correlated with the proportion of CD107a + NK cells in PLWH at each time point after the third dose. Similarly, this phenomenon was also observed in HCs at 0, 2, and 4 weeks after the third dose. Finally, regardless of whether NK cells were stimulated with SARS-2-OS or not, we did not observe any differences in the expression of NK cell degranulation markers between PLWH and HCs. CONCLUSION: s:SARS-CoV-2 vaccine elicited activation and degranulation of NK cells, indicating that the inoculation of SARS-CoV-2 vaccine enhances NK cell immune response.

Primary cutaneous marginal zone lymphoproliferative disorder following COVID-19 vaccination. During the coronavirus disease 2019 (COVID-19) pandemic, COVID-19 vaccines were administered worldwide. A number of skin reactions, including primary cutaneous T-cell lymphoproliferative disorders (LPDs) were reported following COVID-19 vaccination. We report a case of primary cutaneous marginal zone lymphoproliferative disorder (PCMZLPD) secondary to COVID-19 vaccination. A 57-year-old man presented with an erythematous nodule on his left arm at the site of vaccine inoculation following his first dose of the Moderna (mRNA-1273) vaccine a few weeks prior. The nodule continued to progress in size after the second dose. A skin biopsy specimen of the nodule showed a diffuse dermal infiltrate of small to medium-sized lymphocytes with plasma cells and histiocytes. The infiltrate was composed of CD3(+) T cells with CD20(+) and CD79a(+) B cells. The neoplastic B cells reacted with BCL-2 and were negative for BCL-6 and CD10. Kappa light chain restriction was identified by in situ hybridization. Gene rearrangement studies revealed kappa light chain monoclonality, confirming the diagnosis of PCMZLPD. The temporal association with the Moderna vaccination and the occurrence of the lesion at the inoculation site indicate a COVID-19 vaccination-induced PCMZLPD. This is one of the rare cases of PCMZLPD following COVID-19 vaccination.

Serological response and immune-related adverse events following COVID-19 vaccination in cancer patients treated with immune checkpoint inhibitors: A systematic review and meta-analysis. With the popularity of Coronavirus disease 2019 (COVID-19) vaccine and the development of vaccination strategies, the impact of COVID-19 vaccine on cancer patients receiving immune checkpoint inhibitors (ICIs) is still unclear. In the systematic review and meta-analysis of patients with ICIs, we assessed the serological response of cancer patients receiving COVID-19 vaccine, and explored the risk of immune related adverse events (irAEs). We searched PubMed, EMBASE and Cochrane Library as of 10 June 2023, and included cancer patients who received ICIs and COVID-19 vaccine. The systematic review

and meta-analysis include cohort study, cross-sectional study and case report. The outcome included the serological response, Spike-specific T-cell response, irAEs and rare adverse events. When possible, the data were analysed by random effect analysis, and the statistical heterogeneity was assessed by Q-test and I(2) statistics. We explored the sources of heterogeneity through L'Abbe plots, Galbraith radial plots, and sensitivity analysis. The publication bias was evaluated by Egger's, Begg's linear regression test and funnel plot, and the impact of publication bias was further analysed by trim and fill method. 27 studies were eligible (19 cohort studies, 1 cross-sectional study and 7 case reports), involving 8331 patients (with 4724 receiving ICIs). Most studies used mRNA vaccine (BNT162b2 or mRNA-1273). Compared with cancer patients receiving chemotherapy, cancer patients receiving ICIs were significantly more likely to have seroconversion (RRÂ =Â 1.05, 95%CI 1.01-1.10, PÂ =Â 0.02). There were no statistically significant differences in seroconversion rates when comparing cancer patients receiving ICIs with controls without cancer (RRÂ =Â 0.95, 95%â€‰CI 0.89-1.01, PÂ =Â 0.09) or with cancer patients receiving targeted therapy (RRÂ =Â 1.05, 95% CI 0.79-1.39, PÂ =Â 0.75). The incidence of irAEs in patients receiving ICIs before and after COVID-19 vaccination was (21.96%, 95%CI 16.66%-28.94%) and (14.88%, 95%CI 8.65%-25.57%), respectively. The most common irAEs were endocrine abnormalities, skin disorders, etc. The certainty of evidence was low in cancer patients with ICIs, compared with those receiving chemotherapy, and very low versus controls without cancer. Cancer patients treated with ICIs seem to be able to receive COVID-19 vaccine safely without increasing the incidence of irAEs.

Interim results from a phase I randomized, placebo-controlled trial of novel SARS-CoV-2 beta variant receptor-binding domain recombinant protein and mRNA vaccines as a 4th dose booster. BACKGROUND: SARS-CoV-2 booster vaccination should ideally enhance protection against variants and minimise immune imprinting. This Phase I trial evaluated two vaccines targeting SARS-CoV-2 beta-variant receptor-binding domain (RBD): a recombinant dimeric RBD-human IgG(1) F(c)-fusion protein, and an mRNA encoding a membrane-anchored RBD. METHODS: 76 healthy adults aged 18-64Â y, previously triple vaccinated with licensed SARS-CoV-2 vaccines, were randomised to receive a 4th dose of either an adjuvanted (MF59Â®, CSL Seqirus) protein vaccine (5, 15 or 45Â Î¼g, NÂ =Â 32), mRNA vaccine (10, 20, or 50Â Î¼g, NÂ =Â 32), or placebo (saline, NÂ =Â 12) at least 90 days after a 3rd boost vaccination or SARS-CoV-2 infection. Bleeds occurred on days 1 (prior to vaccination), 8, and 29. CLINICALTRIALS: govNCT05272605. FINDINGS: No vaccine-related serious or medically-attended adverse events occurred. The protein vaccine reactogenicity was mild, whereas the mRNA vaccine was moderately reactogenic at higher dose levels. Best anti-RBD antibody responses resulted from the higher doses of each vaccine. A similar pattern was seen with live virus neutralisation and surrogate, and pseudovirus neutralisation assays. Breadth of immune response was demonstrated against BA.5 and more recent omicron subvariants (XBB, XBB.1.5 and BQ.1.1). Binding antibody titres for both vaccines were comparable to those of a licensed bivalent mRNA vaccine. Both vaccines enhanced CD4(+) and CD8(+) T cell activation. INTERPRETATION: There were no safety concerns and the reactogenicity profile was mild and similar to licensed SARS-CoV-2 vaccines. Both vaccines showed strong immune boosting against beta, ancestral and omicron strains. FUNDING: Australian Government Medical Research Future Fund, and philanthropies Jack Ma Foundation and IFM investors.

Solitary Eruptive Keratoacanthoma Developing at Site of COVID-19 Vaccine Injection.

COVID-19 vaccination and relapse activity: A nationwide cohort study of patients with multiple sclerosis in Denmark. BACKGROUND AND PURPOSE: We evaluated whether there was a difference in the occurrence of relapses pre- and post-COVID-19 vaccination in a nationwide cohort of Danish patients with relapsing multiple sclerosis. METHODS: We conducted a population-based, nationwide cohort study with a cutoff date of 1 October 2022. We used McNemar tests to assess

changes in the proportion of patients with recorded relapses within 90â€‰days and 180â€‰days before and after first vaccine dose, and a negative binomial regression model to compare the 90 and 180â€‰days postvaccination annualized relapse rate (ARR) to the 360â€‰days prevaccination ARR. Multivariate Cox regression was used to estimate relapse risk factors. RESULTS: We identified 8169 vaccinated (87.3% Comirnaty) patients without a recorded history of a positive COVID-19 test. We did not find statistically significant changes in the proportion of patients with relapses in the 90â€‰days (1.3% vs. 1.4% of patients, pâ€‰=â€‰0.627) and 180â€‰days (2.7% vs. 2.6% of patients, pâ€‰=â€‰0.918) pre- and postvaccination. Also, a comparison of the ARR 360â€‰days before (0.064, 95% confidence interval [CI]â€‰=â€‰0.058-0.070) with the ARR 90 (0.057, 95% CIâ€‰=â€‰0.047-0.069, pâ€‰=â€‰0.285) and 180 (0.055, 95% CIâ€‰=â€‰0.048-0.063, pâ€‰=â€‰0.060) days after vaccination did not show statistically significant differences. Lower age, higher Expanded Disability Status Scale score, and relapse within 360â€‰days before vaccination were associated with a higher risk of relapse. CONCLUSIONS: We did not find evidence of increased relapse activity following the administration of the first dose of the COVID-19 vaccine.

Magnitude and Duration of Serum Neutralizing Antibody Titers Induced by a Third mRNA COVID-19 Vaccination against Omicron BA.1 in Older Individuals. BACKGROUND: The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron variant (B.1.1.529) is dominating coronavirus disease 2019 (COVID-19) worldwide. The waning protective effect of available vaccines against the Omicron variant is a critical public health issue. This study aimed to assess the impact of the third COVID-19 vaccination on immunity against the SARS-CoV-2 Omicron BA.1 strain in older individuals. MATERIALS AND METHODS: Adults aged â‰¥60 years who had completed two doses of the homologous COVID-19 vaccine with either BNT162b2 (Pfizer/BioNTech, New York, NY, USA, BNT) or ChAdOx1 nCoV (SK bioscience, Andong-si, Gyeongsangbuk-do, Korea, ChAd) were registered to receive the third vaccination. Participants chose either BNT or mRNA-1273 (Moderna, Norwood, MA, USA, m1273) mRNA vaccine for the third dose and were categorized into four groups: ChAd/ChAd/BNT, ChAd/ChAd/m1273, BNT/BNT/BNT, and BNT/BNT/m1273. Four serum specimens were obtained from each participant at 0, 4, 12, and 24 weeks after the third dose (V1, V2, V3, and V4, respectively). Serum-neutralizing antibody (NAb) activity against BetaCoV/Korea/KCDC03/2020 (NCCP43326, ancestral strain) and B.1.1.529 (NCCP43411, Omicron BA.1 variant) was measured using plaque reduction neutralization tests. A 50% neutralizing dilution (ND(50)) >10 was considered indicative of protective NAb titers. RESULTS: In total, 186 participants were enrolled between November 24, 2021, and June 30, 2022. The respective groups received the third dose at a median (interquartile range [IQR]) of 132 (125 - 191), 123 (122 - 126), 186 (166 - 193), and 182 (175 - 198) days after the second dose. Overall, ND(50) was lower at V1 against Omicron BA.1 than against the ancestral strain. NAb titers against the ancestral strain and Omicron BA.1 variant at V2 were increased at least 30-fold (median [IQR], 1235.35 [1021.45 - 2374.65)] and 129.8 [65.3 - 250.7], respectively). ND(50) titers against the ancestral strain and Omicron variant did not differ significantly among the four groups (P = 0.57). NAb titers were significantly lower against the Omicron variant than against the ancestral strain at V3 (median [IQR], 36.4 (17.55 - 75.09) vs. 325.9 [276.07 - 686.97]; P = 0.012). NAb titers against Omicron at V4 were 16 times lower than that at V3. Most sera exhibited a protective level (ND(50) >10) at V4 (75.0% [24/32], 73.0% [27/37], 73.3% [22/30], and 70.6% [12/17] in the ChAd/ChAd/BNT, ChAd/ChAd/m1273, BNT/BNT/BNT, and BNT/BNT/m1273 groups, respectively), with no significant differences among groups (P = 0.99). CONCLUSION: A third COVID-19 mRNA vaccine dose restored waning NAb titers against Omicron BA.1. Our findings support a third-dose vaccination program to prevent the waning of humoral immunity to SARS-CoV-2.

Durability of immune response against omicron BA.2 and BA.4/5 and T cell responses after boosting with mRNA and adenoviral vector-based vaccines following heterologous CoronaVac/ChAdOx-1nCov-

19 vaccination. Heterologous vaccination with inactivated vaccine followed by adenoviral vector-based vaccine has shown superiority in enhancing immune response compared to homologous primary series. However, data comparing immunity decline after a third booster following heterologous CoronaVac/ChAdOx-1nCov-19 has been limited. Here, we assessed neutralizing activity against omicron variant and T cell response at 3 months monitoring in 96 individuals who received ChAdOx-1nCov-19, BNT162b2, or mRNA-1273 as a third dose following heterologous CoronaVac/ChAdOx-1nCov-19. Comparing the antibody levels at 3 and 1 month(s) after the third booster, the results showed a persistence of anti-RBD IgG in all vaccine regimens, with the IgG level waning slower in the ChAdOx-1nCov-19 boosted group (geometric mean ratio (GMR): 0.64 (95%CI: 0.59-0.70)) compared to the BNT162b2 (0.34 (95%CI:0.31-0.38)) and mRNA-1273 boosted groups (0.32 (95%CI: 0.29-0.36)). Neutralizing activity against omicron BA.2 and BA.4/5 dropped by 1.2 to 1.5-fold but remained detectable, with the highest level observed in the mRNA-1273 group, followed by BNT162b2 and ChAdOx-1nCov-19 groups, respectively. Furthermore, the number of individuals with T cell reactivity decreased in BNT162b2 and mRNA-1273 groups, while it increased in ChAdOx-1nCov-19 group at 3-month post-boost compared to 1 month. Data on the durability of immune response could help comprehensively optimize the booster vaccine strategy.

COVID-19 vaccines should be evaluated from the societal perspective. The COVID-19 pandemic demonstrates the importance of valuing vaccines from a broad societal perspective (SP), as opposed to a narrower health-payer perspective (HPP). COVID-19's catastrophic global impacts extend not only to its health-related effects, but also to the profound macroeconomic losses caused by lockdowns required for disease control, leading to the worst global economic crisis in a century. COVID-19 vaccination (CV) has been the central policy tool for resolving this economic crisis, and it has been hypothesized that this macroeconomic benefit alone justifies the cost of CV many times over. Yet HPP-based vaccine valuations are wholly insensitive to this enormous benefit, not allowing it to influence the allocation of given health budgets nor the determination of the magnitudes of such budgets, thereby risking inadequate societal spending on CV. HPP allocates given health budgets to maximize only health, giving no weight to macroeconomic outcomes, causing allocative inefficiency by not allowing welfare-improving trade-offs of health for wealth. HPP assumes health budgets are optimal, not scrutinizing whether their scale adequately reflects the macroeconomic benefits of health spending, thereby risking productive inefficiency by foregoing health spending increases such as on CV that could raise both population-level health and wealth. These allocative and productive inefficiencies in turn distort for-profit R&D incentives, risking dynamic inefficiency. And since the socio-economic and health burdens of COVID-19 are disproportionately borne by the worse off, HPP's failure to promote optimal levels of societal investment in CV may disproportionately burden the worse off as well, exacerbating inequality. Vaccine valuations from the societal perspective allow the allocation and determination of health budgets to reflect macroeconomic and distributional values, thereby promoting allocative, productive, and dynamic efficiency, as well as equity. These considerations of efficiency and equity support evaluating CV, and to ensure a level playing field, all vaccines, from a societal perspective.

Analysis of humoral and cellular immunity after SARS-CoV-2 vaccination in patients with multiple sclerosis treated with immunomodulatory drugs. We analyzed immune response to SARS-CoV-2 vaccination by measuring specific IgG titers and T-cell reactivity to different SARS-CoV-2 peptides in multiple sclerosis patients taking different disease-modifying treatments. Of the 88 patients included, 72 developed any kind of immune response after vaccination. Although DMTs such as fingolimod and anti-CD20+ treatments prevented patients from developing a robust humoral response to the vaccine, most of them were still able to develop a cellular response, which could be crucial for long-

term immunity. It is probably advisable that all MS patients take additional/booster doses to increase their humoral and/or cellular immune response to SARS-CoV-2.

Partial recovery of SARS-CoV-2 immunity after booster vaccination in renal transplant recipients. The pandemic caused by the SARS-CoV-2 coronavirus has been especially detrimental to patients with end-stage renal disease. History with other vaccines suggests that patients with renal disease may not respond adequately to the SARS-CoV-2 vaccine. The aim of this study is to evaluate the immunity to SARS-CoV-2 mRNA vaccines in renal patients. Post SARS-CoV-2 vaccination first, and after the booster dose, antibodies and cellular immunity were studied in patients on hemodialysis (NÂ =Â 20), peritoneal dialysis (NÂ =Â 10) and renal transplantation (NÂ =Â 10). After the two doses of vaccine, there was an effective immunity in dialysis patients, with 100% seroconversion and 87% detection of cellular immunity (85% in hemodialysis and 90% in peritoneal dialysis). In contrast, in renal transplant recipients there was only 50% seroconversion and cellular immunity was detected in 30% of patients. After the booster dose, all dialysis patients achieved a cellular and antibody immunity, whereas in transplant patients, despite improvement, 20% did not produce antibodies and in 37.5% cellular immunity could not be detected. The mRNA vaccine plus booster performs excellently in dialysis patients, whereas in kidney transplant recipients, despite the booster, complete immunization is not achieved.

Memory T cell responses in seronegative older adults following SARS-CoV-2 vaccination. Generating memory T cell responses besides humoral immune responses is essential when it comes to the efficacy of a vaccine. In this study, the presence of memory T cell responses after aluminum-adjuvanted inactivated whole-virion SARS-CoV-2 vaccine (CoronaVac) in seronegative and seropositive elderly individuals were examined. CD4(+) and CD8(+) memory T cell proliferation and IFN-Î³ production capacities were evaluated. Additionally, clinical frailty scale (CFS) and FRAIL scales of the individuals were scored. CD4(+) memory T cell responses more prominent than CD8(+) memory T cells. In seronegative individuals, 80% of them had memory CD4(+) and IFN-Î³, whereas 50% of them had memory CD4(+) and all of them had IFN-Î³ responses. Additionally, 40% of seronegative patients and 50% of seropositive patients had memory CD8(+) responses. To sum up, humoral immune responses are not associated with memory T cell responses, and in seronegative individuals, memory T cell responses can be detected.

Myocarditis following Coronavirus vaccination. INTRODUCTION: Myocarditis is an adverse reaction discovered after the marketing of SARS-CoV-2 mRNA vaccines. Nevertheless, this effect is not mentioned as an adverse reaction in the summary of product characteristics of other types of vaccines against this disease. OBJECTIVE: In this work, we aim to present the cases of myocarditis after vaccination against COVID-19 reported to the national Tunisian centre of pharmacovigilance. METHOD: We present the cases of myocarditis reported after the COVID-19 vaccination. All cases are diagnosed according to Brighton's case definition of myocarditis. The vaccines causality assessment was estimated by the French imputability updated method of BÃ©gaud etÂ al. RESULTS: We included five patients. The sex ratio (M/F) was 4. The mean age was 30 years. All patients had no notable cardiovascular history and did not report any significant past medical history. The onset of symptoms was two days post-vaccination in three patients. The predominant reported symptoms are chest pain and dyspnea in the five cases. Cardiac magnetic resonance imaging (MRI) confirmed the myocarditis diagnosis in four patients (not performed for one patient).All cases were classified as definitive cases according to the Brighton case definition of myocarditis. No patient required hospitalization in a cardiac intensive care unit. All the patients recovered from acute myocarditis within a few days. CONCLUSION: Reported cases of myocarditis post-COVID-19 vaccination in our population are rare, not severe, and have a quick favorable outcome.

Differential peripheral blood mononuclear cell reactivity against SARS-CoV-2 proteins in naÃ¯ve and previously infected subjects following COVID-19 vaccination. The decline in vaccine efficacy and the risk of reinfection by SARS-CoV-2 make new studies important to better characterize the immune response against the virus and its components. Here, we investigated the pattern of activation of T-cells and the expression of inflammatory factors by PBMCs obtained from naÃ¯ve and previously infected subjects following COVID-19 vaccination, after PBMCs stimulation with S1, RBD, and N-RBD SARS-CoV-2 proteins. PBMCs showed low levels of ACE2 and TMPRSS2 transcripts, which were not modulated by the exposure of these cells to SARS-CoV-2 proteins. Compared to S1 and RBD, N-RBD stimulation showed a greater ability to stimulate T-cell reactivity, according to CD25 and CD69 markers. Interestingly, T-cell reactivity was more pronounced in vaccinated subjects with prior SARS-CoV-2 infection than in vaccinated donors who never had been diagnosed with COVID-19. Finally, N-RBD stimulation promoted greater expression of IL-6 and IFN-Î³ in PBMCs, which reinforces the greater immunogenic potential of this protein in the vaccinated subjects. These data suggest that PBMCs from previously infected and vaccinated subjects are more reactive than those derived from just vaccinated donors. Moreover, the N-RBD together viral proteins showed a greater stimulatory capacity than S1 and RBD viral proteins.

The risk factors of SARS-CoV-2 antibody level differences in healthcare workers post vaccination in Siloam hospitals: A nationwide multicenter study. BACKGROUND: Several vaccines have been approved against COVID-19, and 5 have been used in Indonesia. Due to the decrease in antibody levels 3 to 6 months after the second dose of CoronaVac, healthcare workers received the third booster of mRNA vaccine (mRNA-1273) to increase the antibody level. This study aimed to evaluate the risk factors of anti-S-RBD IgG levels differences in healthcare workers. METHODS: This study is a retrospective cohort study of 576 healthcare workers without previous SARS-CoV-2 infection who received 2 doses of CoronaVac and the third dose of mRNA-1273 6 months after the second dose. Blood samples were obtained 2nd, 6th, 12th, and 24th weeks after the second dose of CoronaVac vaccine administration, with mRNA-1273 booster on week 20. Quantitative measurements of IgG antibodies were performed with Elecsys Anti-SARS-CoV-2 S immunoassay. We identify the baseline factors predicting post-vaccination antibody titers using univariate and multivariate linear regression analysis. RESULTS: This study comprised 576 participants aged 32 years old, 72.05% female, and 45.84% from high-risk occupation subgroups. The median antibodies titer level on the 2nd, 6th, 12th, and 24th weeks after the second vaccine dose administration were 40.99 u/mL, 42.01 u/mL, 54.78 u/mL, and 23,225 u/mL. Antibody levels trended highest in female and younger age group (20-29 years old). CONCLUSIONS: The third dose of vaccine increased the quantitative SARS-CoV-2 spike IgG antibody titers and eliminated differences in antibodies titer by gender.

Safety and efficacy of SARS-CoV-2 vaccination in patients with immune thrombocytopenia: A two-centre review. Multiple studies have reported immune thrombocytopenia (ITP) relapse following SARS-CoV-2 vaccination, however baseline ITP relapse rate and antibody response to vaccination are not known. Patients with ITP who received at least one of the first three SARS-CoV-2 vaccination doses were included in the study. One hundred and twenty-four patients met the inclusion criteria. Relapse rate was 4.2% following a first vaccine dose, 9.1% after a second and 2.9% after a third; baseline relapse rate was 7.6%. Ninety-four per cent of patients who received three vaccine doses developed a clinical antibody response. SARS-CoV-2 vaccination appears to be safe and effective in patients with ITP.

Outcomes Among Patients Hospitalized for COVID-19 Treated with Remdesivir in an Urban Center Pre-COVID-19 Vaccination. OBJECTIVE: Data on treatment outcomes among minority populations treated with remdesivir are limited. We sought to evaluate outcomes among patients hospitalized with COVID-19 and treated with remdesivir among a predominantly Black and LatinX population.

METHODS: This was a retrospective cohort study of adult patients hospitalized with COVID-19 and treated with remdesivir at an urban hospital in Newark, NJ, between May 1, 2020, and April 30, 2021, prior to widespread COVID-19 vaccination uptake. We describe 28-day mortality by demographic, socio-economic, and clinical factors, including clinical status by World Health Organization's (WHO) 8-point Ordinal Scale for Clinical Improvement. RESULTS: A total of 206 patients met study inclusion criteria (52% were male, 41% non-Hispanic Black and 42% Hispanic). Overall mortality at 28Â days was 11%. Eighty-one percent of patients with baseline WHO status of 4 or greater recovered by day 14. Mortality was higher among those who were older (pâ€‰=â€‰0.01), those with underlying diabetes mellitus (pâ€‰=â€‰0.047), those with more severe illness on admission by WHO Ordinal Scale (WHO statusâ€‰â‰¥â€‰4), and those on concomitant tociluzimab or convalescent plasma use. CONCLUSIONS: We found that remdesivir was effective in treating most COVID-19 patients in our study. Traditional risk factors, such as advanced age and underlying co-morbidities, were associated with worse clinical outcomes and deaths.

A web-based genome-wide association study reveals the susceptibility loci of common adverse events following COVID-19 vaccination in the Japanese population. The coronavirus disease 2019 (COVID-19) pandemic has spread rapidly worldwide. To prevent its spread, mRNA-based vaccines made by Pfizer/BioNTech (BNT162b1) and Moderna (mRNA-1273) have been widely used, including in Japan. Various adverse events have been reported following the COVID-19 mRNA vaccination, with differences observed among individuals. However, analyses of the genetic background associated with the susceptibility to side effects have been limited. In the present study, we performed genome-wide association studies (GWAS) for self-reported adverse events of the COVID-19 mRNA vaccination in 4545 Japanese individuals and identified 14 associated loci. Among these, 6p21 was associated with 37.5Â Â°C or higher fever, 38Â Â°C or higher fever, and muscle pain. HLA allele association analysis revealed that various HLA alleles were associated with the adverse effects; HLA-DQA1*03:01 and HLA-A*11:01 were more reliably associated with the adverse effects. Our results may enable the preparation and management of adverse effects by identifying the susceptibility to these adverse events. Furthermore, we obtained valuable data that may lead to a better understanding of the mechanisms of action of the COVID-19 mRNA vaccines.

Delineation of DNA and mRNA COVID-19 vaccine-induced immune responses in preclinical animal models. Nucleic acid vaccines are designed based on genetic sequences (DNA or mRNA) of a target antigen to be expressed in vivo to drive a host immune response. In response to the COVID-19 pandemic, mRNA and DNA vaccines based on the SARS-CoV-2 Spike antigen were developed. Surprisingly, head-to-head characterizations of the immune responses elicited by each vaccine type has not been performed to date. Here, we have employed a range of preclinical animal models including the hamster, guinea pig, rabbit, and mouse to compare and delineate the immune response raised by DNA, administered intradermally (ID) with electroporation (EP) and mRNA vaccines (BNT162b2 or mRNA-1273), administered intramuscularly (IM), expressing the SARS-CoV-2â€‰WT spike antigen. The results revealed clear differences in the quality and magnitude of the immune response between the two vaccine platforms. The DNA vaccine immune response was characterized by strong T cell responses, while the mRNA vaccine elicited robust humoral responses. The results may assist in guiding the disease target each vaccine type may be best matched against and suggest mechanisms to further enhance the breadth of each platform's immune response.

[Adverse effect incidence of Pfizer/BioNTech COVID-19 vaccine: Retrospective cohort study]. BACKGROUND: Coronavirus SARS-CoV-2 has been the cause of multiple hospitalizations due to respiratory distress, pneumonia, multi-organic failure and death in all the world. The BioNTech/Pfizer lab was the first to get the approval from the Food and Drug Administration (FDA) for vaccine application, beginning with health workers. However, there are a few studies about adverse effects

after applying the COVID-19 vaccine. OBJECTIVE: To assess the presence and time of onset of adverse effects produced by the COVID-19 vaccine. MATERIAL AND METHODS: A retrospective cohort study was carried out, including medical residents from the Hospital de Especialidades No. 1 (Specialties Hospital No. 1) from the BajÃ-o National Medical Center, who received two doses of Pfizer-BioNTech vaccine and decided to participate voluntarily. We obtained the information by a self-assessment tool sent via email. All adverse effects were collected emphasizing those described in the literature. RESULTS: A total of 101 medical residents were included. It was observed that 55.54% presented adverse effects after the first dose, which appeared in the first 24 hours after the vaccine was administered. After the second dose, 54.5% presented symptomatology, 41.6% during first 24 hours after the vaccine was administered. CONCLUSIONS: It was observed symptomatology after applying the complete series (two doses) of BioNTech/Pfizer; however, there were mild and of short duration.

Comparison of side effects of the dose-1 of AstraZeneca and Sinopharm vaccines in patients with multiple sclerosis in Kermanshah, Iran (2021). Background: Coronavirus 2019 (COVID-19) vaccination is recommended for people with multiple sclerosis (MS). This study evaluated the side effects of Sinopharm and AstraZeneca vaccines in MS patients. Methods: In this cross-sectional study among MS patients in Kermanshah province, Iran, who received Sinopharm or AstraZeneca vaccine, sampling was performed through convenience sampling according to the nationwide MS registry of Iran (NMSRI). Demographic and clinical information of the participants and data on the side effects of vaccines were collected by telephone after the first dose. The data were analyzed in SPSS software. Results: 264 vaccinated MS patients (217 with Sinopharm and 47 with AstraZeneca) were studied. In the Sinopharm and AstraZeneca groups, respectively, 58.5% and 73.3% of patients had side effects that were not significantly different between the 2 groups ($P = 0.064$). In the AstraZeneca group, the severity of side effects and prevalence of taking painkillers were significantly higher ($P < 0.050$) and the interval between vaccination and side effects onset was significantly shorter ($P = 0.013$). The most commonly experienced side effects in the Sinopharm group were fatigue (29.0%), myalgia (24.9%), fever (24.0%), and headache (21.7%), and in the AstraZeneca group were fever (59.6%), chills (51.1%), myalgia (40.4%), and fatigue (34.0%). Logistic regression by controlling for confounding variables showed that considering some factors as confounding factors did not show a significant difference between the 2 vaccines in the experience of side effects ($P = 0.104$). Conclusion: The AstraZeneca vaccine caused more severe side effects in MS patients than the Sinopharm vaccine. Most of the side effects were moderate in severity and transient.

A retrospective cohort study: vaccination status and safety analysis of SARS-CoV-2 vaccine in patients with Wilson's disease. BACKGROUND: Wilson's disease (WD) is a rare hepatic and neurological disorder, which can dramatically worsen by traumatic injuries, surgeries, and infections. No studies have reported safety data of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination in WD patients. We aimed to investigate the SARS-CoV-2 vaccination status and post-vaccination adverse events in WD patients. METHODS: This is a multicenter, retrospective, observational study. We investigated the vaccination rates, the type of vaccine, subjective reasons for non-vaccination, and the adverse events following vaccination. Logistic regression analysis was used to assess the correlation between vaccination status and increased Unified Wilson's Disease Rating Scale (UWDRS) scores. RESULTS: A total of 554 WD patients with a mean (SD) age of 25.3 (10.85) years were included in this study, of whom 336 (60.6%) were males and 218 (39.4%) were females. 368 (66.4%) patients received at least one dose of the SARS-CoV-2 vaccine.186 (33.6%) patients were unvaccinated. Logistic regression analysis showed that vaccination against SARS-CoV-2 was not significantly associated with increased UWDRS scores. The safety analysis demonstrated that 21.2% had post-vaccination adverse events. CONCLUSIONS: In this study, vaccination against SARS-CoV-2 was safe in WD patients, providing evidence for the safety of vaccination in WD patients.

Neuro-Ophthalmic Adverse Events of COVID-19 Infection and Vaccines: A Nationwide Cohort Study. PURPOSE: To evaluate the association of COVID-19 infection and vaccination with neuro-ophthalmic adverse events. METHODS: In this nationwide population-based retrospective cohort study, 8,498,353 patients were classified into three groups: control, COVID-19 infection, and COVID-19 vaccination. We conducted separate analyses for the early phase (within 60 days) and late phases (61-180 days) to estimate the incidence rates and hazard ratio (HR) for each neuro-ophthalmic adverse event. The adverse events included in this analysis were optic neuritis, papilledema, ischemic optic neuropathy, third nerve palsy, fourth nerve palsy, sixth nerve palsy, facial palsy, nystagmus, ptosis, blepharospasm, anomalies of pupillary function, and Guillain-BarrÃ© syndrome/Miller Fisher syndrome (GBS/MFS). RESULTS: Neuro-ophthalmic adverse events other than ptosis and GBS/MFS exhibited no significant increase after COVID-19, and their incidence was extremely low. The incidence rate of ptosis in both phases was significantly higher in patients administered COVID-19 vaccination (HR = 1.65 in the early phase and HR = 2.02 in the late phase) than in the control group. Additionally, BNT162b2 conferred a lower ptosis risk than ChAdOx1. GBS/MFS had a significantly higher incidence rate in the early phase (HR = 5.97) in patients with COVID-19 infection than in the control group. CONCLUSIONS: Ptosis was associated with COVID-19 vaccination, particularly with the ChAdOx1 vaccine, while GBS/MFS was associated with COVID-19 infection. In contrast, no association was found between other neuro-ophthalmic adverse events and COVID-19 infection or vaccination. These results may provide helpful insights for diagnosing and treating the neuro-ophthalmological adverse events after COVID-19.

Severe COVID-19 in solid organ transplant recipients in the post-vaccination era: Persistence in the burden of disease and in disparities of care.

Development and validation of prediction models for poor sleep quality among older adults in the post-COVID-19 pandemic era. BACKGROUND: Corona Virus Disease 2019 (COVID-19) has a significant impact on sleep quality. However, the effects on sleep quality in the post-COVID-19 pandemic era remain unclear, and there is a lack of a screening tool for Chinese older adults. This study aimed to understand the prevalence of poor sleep quality and determine sensitive variables to develop an effective prediction model for screening sleep problems during infectious diseases outbreaks. MATERIALS AND METHODS: The Peking University Health Cohort included 10,156 participants enrolled from April to May 2023. The Pittsburgh Sleep Quality Index (PSQI) scale was used to assess sleep quality. The data were randomly divided into a training-testing cohort (nâ€‰=â€‰7109, 70%) and an independent validation cohort (nâ€‰=â€‰3027, 30%). Five prediction models with 10-fold cross validation including the Least Absolute Shrinkage and Selection Operator (LASSO), Stochastic Volatility Model (SVM), Random Forest (RF), Artificial Neural Network (ANN), and XGBoost model based on the area under curve (AUC) were used to develop and validate predictors. RESULTS: The prevalence of poor sleep quality (PSQI >7) was 30.69% (3117/10,156). Among the generated models, the LASSO model outperformed SVM (AUC 0.579), RF (AUC 0.626), ANN (AUC 0.615) and XGBoost (AUC 0.606), with an AUC of 0.7. Finally, a total of 12 variables related to sleep quality were used as parameters in the prediction models. These variables included age, gender, ethnicity, educational level, residence, marital status, history of chronic diseases, SARS-CoV-2 infection, COVID-19 vaccination, social support, depressive symptoms, and cognitive impairment among older adults during the post-COVID-19 pandemic. The nomogram illustrated that depressive symptoms contributed the most to the prediction of poor sleep quality, followed by age and residence. CONCLUSIONS: This nomogram, based on twelve-variable, could potentially serve as a practical and reliable tool for early identification of poor sleep quality among older adults during the post-pandemic period.

 The poor sleep quality (PSQI >7) was still prevalent among older adults during the post-COVID-19 pandemic.The LASSO model was the best model to predict poor

sleep quality among older adults, compared with SVM, RF, ANN and XGBoost.This prediction model, based on twelve variables, may potentially serve as a practical and reliable tool for the early identification of poor sleep quality among older adults during the post-pandemic period.

A landscape on disorders following different COVID-19 vaccination: a systematic review of Iranian case reports. There have been massive studies to develop an effective vaccine against SARS-CoV-2 which fortunately led to manage the recent pandemic, COVID-19. According to the quite rapidly developed vaccines in a fast window time, large investigations to assess the probable vaccine-related adverse events are crucially required. COVID-19 vaccines are available of different platforms and the primary clinical trials results presented acceptable safety profile of the approved vaccines. Nevertheless, the long-term assessment of the adverse events or rare conditions need to be investigated. The present systematic review, aimed at classification of probable vaccine-related unsolicited adverse events in Iranian population through the data collection of the published case report studies.The related published case reports were explored via PubMed, Web of Science and Google scholar according to the available published data up to 14(th) Dec, 2022 using PRISMA guideline. Out of 437 explored studies, the relevant data were fully investigated which totally led to 40 studies, including 64 case reports with a new onset of a problem post-vaccination. The cases were then classified according to the various items, such as the type of adverse event and COVID-19 vaccines.The reported COVID-19 vaccines in the studied cases included BBIBP-CorV, ChAdOx1-S, Sputnik V and COVAXIN. The results showed that the adverse events presented in 8 different categories, including cutaneous involvements in 43.7% (nâ€‰=â€‰28), neurologic problems (nâ€‰=â€‰16), blood/vessel involvement (nâ€‰=â€‰6), cardiovascular involvement (nâ€‰=â€‰5), ocular disorders (nâ€‰=â€‰4), liver disorder/failure (nâ€‰=â€‰2), graft rejection (nâ€‰=â€‰2) and one metabolic disorder. Notably, almost 60% of the cases had no comorbidities. Moreover, the obtained data revealed nearly half of the incidences occurred after the first dose of injection and the median duration of improvement after the symptom was 10 days (range: 2-120). In addition, 73% of all the cases were either significantly improved or fully recovered. Liver failure following ChAdOx1-S vaccination was the most serious vaccine adverse event which led to death in two individuals with no related medical history.Although the advantages of COVID-19 vaccination is undoubtedly significant, individuals including with a history of serious disease, comorbidities and immunodeficiency conditions should be vaccinated with the utmost caution. This study provides a comprehensive overview and clinical implications of possible vaccine-related adverse events which should be considered in further vaccination strategies. Nevertheless, there might be a bias regarding potential under-reporting and missing data of the case reports included in the present study. Although the reported data are not proven to be the direct vaccination outcomes and could be a possible immune response over stimulation, the people the population with a medium/high risk should be monitored after getting vaccinated against COVID-19 of any platforms. This could be achieved by a carefull attention to the subjects ' medical history and also through consulting with healthcare providers before vaccination.

Association between levels of receptor binding domain antibodies of SARS-CoV-2, receipt of booster and risk of breakthrough infections: LA pandemic surveillance cohort study. Prevention of COVID-19 with vaccine requires multiple doses and updated boosters to maintain protection; however currently there are no tests that can measure immunity and guide clinical decisions about timing of booster doses. This study examined the association between the risk of COVID-19 breakthrough infections and receptor binding domain (RBD) antibody levels and receipt of booster of COVID-19 vaccines. A community sample of Los Angeles County adults were surveyed between 2021 and 2022 to determine if they had a self-reported breakthrough infection. Predictors included RBD antibody levels, measured by binding antibody responses to the ancestral strain at baseline and self-reported

booster shot during the study period. Of the 859 participants, 182 (21%) reported a breakthrough infection. Irrespective of the level of antibodies, the risk of breakthrough infection was similar, ranging from 19 to 23% (Pâ€‰=â€‰0.78). The risk of breakthrough infections was lower among participants who had a booster shot (Pâ€‰=â€‰0.004). The protective effect of a booster shot did not vary by antibody levels prior to receiving the booster. This study found no association between RBD antibody levels and risk of breakthrough infections, while the receipt of booster was associated with lower risk of breakthrough infections, which was independent of pre-booster antibody levels. Therefore, antibody levels might not be a useful guide for clinical decisions about timing of booster doses.

Associations of myeloid cells with cellular and humoral responses following vaccinations in patients with neuroimmunological diseases. Disease-modifying therapies (DMTs) are widely used in neuroimmunological diseases such as multiple sclerosis (MS) and neuromyelitis optica spectrum disorder (NMOSD). Although these treatments are known to predispose patients to infections and affect their responses to vaccination, little is known about the impact of DMTs on the myeloid cell compartment. In this study, we use mass cytometry to examine DMT-associated changes in the innate immune system in untreated and treated patients with MS (nâ€‰=â€‰39) or NMOSD (nâ€‰=â€‰23). We also investigated the association between changes in myeloid cell phenotypes and longitudinal responsiveness to homologous primary, secondary, and tertiary SARS-CoV-2 mRNA vaccinations. Multiple DMT-associated myeloid cell clusters, in particular CD64(+)HLADR(low) granulocytes, showed significant correlations with B and T cell responses induced by vaccination. Our findings suggest the potential role of myeloid cells in cellular and humoral responses following vaccination in DMT-treated patients with neuroimmunological diseases.

Platelet dropping, bleeding and new treatment requirements in ITP patients after inactivated COVID-19 vaccination. Significant decreases in platelet counts and ITP relapses have been documented in ITP patients receiving COVID-19 mRNA vaccines; however, the effect of the inactivated COVID-19 vaccine on ITP patients remains unclear. The present study aimed to investigate the impact of inactivated COVID-19 vaccines on ITP patients, with a focus on platelet dropping events, bleeding events/scores, and the requirement of a new round of treatment. A total of 118 ITP patients, with 97 chronic ITP and 21 persistent ITP, who received inactivated COVID-19 immunization were investigated retrospectively. Following vaccination (within 1 month), ITP patients reported platelet dropping (31.36Â %), new bleeding events (22.88Â %), increases in bleeding scores (23.73Â %), and new treatment requirements (22.03Â %). Among them, persistent ITP patients with disease duration of 3-12 months had higher ratios of the above adverse events (71.43Â %, 57.14Â %, 61.90Â % and 71.43Â %, respectively) than chronic ITP patients with duration > 1 year (22.68Â %, 15.46Â %, 15.46Â % and 11.34Â %, respectively); patients' disease duration was negatively correlated with platelet dropping events and new treatment requirements. Furthermore, logistic regression analysis also supported the above findings, revealing that persistent ITP patients had 9.40-9.70, 7.24-10.08, and 27.17-28.51 times incidence of having platelet dropping events, new bleeding events, and new treatment requirements after vaccination, respectively, when compared to chronic ITP patients. In conclusion, the present study demonstrates that after receiving inactivated COVID-19 vaccines, ITP patients may experience platelet dropping, which may lead to new bleeding events and the requirement of a new round of treatment for ITP recurrence. As a result, platelet level monitoring is crucial for ITP patients during the vaccination, especially those with persistent ITP.

The Promotion of Humoral Immune Responses in Humans via SOCS1-Mediated Th2-Bias Following SARS-CoV-2 Vaccination. The effectiveness of SARS-CoV-2 vaccines varies among individuals. During the COVID-19 global pandemic, SARS-CoV-2 infection showed significant Th1 characteristics, suggesting that the immune disorder and production of SARS-CoV-2 antibodies may be related to

Th1/Th2 bias. However, the molecular mechanisms underlying Th1/Th2 bias effects on host immune responses to viruses remain unclear. In this study, the top three subjects with the highest and lowest changes in anti-SARS-CoV-2 antibodies after receiving three doses of SARS-CoV-2 vaccination were selected and defined as the elevated group (E) and the control group (C), respectively. Peripheral blood was collected, single-cell sequencing was performed before and after the third dose of the SARS-CoV-2 vaccine, and the changes in T cell clusters were analyzed. Compared with the C group, the Treg pre-vaccination proportion was lower in E, while the post-vaccination proportion was higher, suggesting that Tregs may be crucial in this process. Differential analysis results of Tregs between the two groups revealed that differentially expressed genes (DEGs) were significantly enriched in the IL4 pathway. Correlation analysis between DEGs and serum antibody showed that the expression of NR4A2, SOCS1, and SOCS3 in Tregs was significantly correlated with serum antibodies, suggesting that the immune response in E group changed to Th2 bias, thereby promoting host humoral immune responses. On the other hand, antibody-related genes SOCS1 and NR4A2, as well as lnc-RNA MALAT1 and NEAT1, were highly expressed in the CD4-MALAT1 subclusters. In summary, our study revealed that Th2 bias promotes humoral immune responses in humans by increasing SOCS1 in T cells after SARS-CoV-2 vaccination. Moreover, NR4A2, SOCS1, MALAT1, and NEAT1 were identified as the potential key biomarkers or treatment targets for enhanced SARS-CoV-2 antibody production by influencing the Th1/Th2 balance in T cells. Our findings have important implications for population stratification and tailored therapeutics for more effective SARS-CoV-2 vaccines.

Factors Associated with Early Versus Late Uptake of the COVID-19 Vaccine during Pregnancy over Time in Australia: A Population-Based Cohort Study. BACKGROUND: Pregnant women are at an increased risk of hospitalisation, admission to the intensive care unit, mechanical ventilation, and death from SARS-CoV-2 infection. The aim of this study is to determine the predictive factors associated with COVID-19 vaccine uptake during pregnancy over time in a population with a high background uptake of maternal influenza and pertussis vaccination. METHODS: This is a population-based, cohort study of all pregnant women who gave birth in Victoria, Australia between 1 July 2021 and 30 June 2022. Data from the Victorian Perinatal Data Collection were analysed using univariable and multivariable logistic regression. RESULTS: This study reports on 77,719 women who gave birth over a 12 month period, of whom 49,281 (63.4%) received a COVID-19 vaccine, 54,887 (70.6%) received an influenza vaccination and 63,594 (81.8%) received a pertussis vaccine by the time of delivery. Pregnant women aged >30 years (aOR 1.31 CI 1.27, 1.36), who had >=8 antenatal visits (aOR 1.08 CI 1.04, 1.12), and those who received influenza vaccine (aOR 1.23 CI 1.19, 1.28) were more likely to have received a COVID-19 vaccine. Those who smoked (aOR 0.7 CI 0.66, 0.74), were First Nations (aOR 0.83 CI 0.74, 0.93) and those who gave birth in public hospitals (aOR 0.65 CI 0.63, 0.68) were less likely to receive COVID-19 vaccine in the first 12 months of the rollout. CONCLUSION: Maternal age, smoking, parity and Indigenous status were factors associated with delayed and sustained lower coverage, even in a population with background maternal influenza and pertussis coverage of 70.6% and 81.8%, respectively.

Age and Comorbidities as Risk Factors for Severe COVID-19 in Mexico, before, during and after Massive Vaccination. During 2020-2023, Mexico had a large COVID-19 emergency with >331,000 adult deaths and one of the highest excess mortalities worldwide. Age at COVID-19 death has been lower in Mexico than in high-income countries, presumably because of the young demographics and high prevalence of chronic metabolic diseases in young and middle-aged adults. SARS-CoV-2 vaccination covered 85% of adults with at least one dose and 50% with booster(s) up to April 2022. No new vaccination efforts or updated boosters were introduced until October 2023; thus, we explored the public health impact of massive SARS-CoV-2 vaccination against ancestral strains and asked whether their real-world protection has persisted through time. We compared three periods

with respect to vaccine roll-outs: before, during and after vaccine introduction in a national retrospective cohort of >7.5 million COVID-19 cases. The main findings were that after vaccination, COVID-19 mortality decreased, age at COVID-19 death increased by 5-10 years, both in populations with and without comorbidities; obesity stopped being a significant risk factor for COVID-19 death and protection against severe disease persisted for a year after boosters, including at ages 60-79 and 80+. Middle-aged adults had the highest protection from vaccines/hybrid immunity and they more than halved their proportions in COVID-19 deaths.

Humoral and Cellular Immunity Are Significantly Affected in Renal Transplant Recipients, following Vaccination with BNT162b2. BACKGROUND: Renal transplant recipients (RTRs) tend to mount weaker immune responses to vaccinations, including vaccines against the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). METHODS: Humoral immunity was assessed using anti-receptor binding domain (RBD) and neutralizing antibodies (NAb) serum levels measured by ELISA, and cellular immunity was assessed using T-, B-, NK, natural killer-like T (NKT)-cell subpopulations, and monocytes measured by flow cytometry, and also specific T-cell immunity, at predefined time points after BNT162b2 vaccination, in 57 adult RTRs. RESULTS: Administration of three booster doses was necessary to achieve anti-RBD and NAb protective levels in almost all patients (92.98%). Ab production, at several time points, was positively correlated with the corresponding renal function and inversely correlated with hemodialysis vintage (HDV) and treatment with mycophenolic acid (MPA). A gradual rise in several cell subpopulations, including total lymphocytes ($p = 0.026$), memory B cells ($p = 0.028$), activated CD4 ($p = 0.005$), and CD8 cells ($p = 0.001$), was observed even after the third vaccination dose, while a significant reduction in CD3+PD1+ ($p = 0.002$), NKT ($p = 0.011$), and activated NKT cells ($p = 0.034$) was noted during the same time interval. Moreover, SARS-CoV-2-specific T-cells were present in 41% of the patients who were unable to develop Nabs, and their positivity rates four months after the second dose were in inverse correlation with monocytes ($p = 0.045$) and NKT cells ($p = 0.01$). CONCLUSIONS: SARS-CoV-2-specific T-cell responses preceded the humoral ones, while two booster doses were needed for this group of immunocompromised patients to mount a protective immune response.

Vaccination with an HIV T-Cell Immunogen (HTI) Using DNA Primes Followed by a ChAdOx1-MVA Boost Is Immunogenic in Gut Microbiota-Depleted Mice despite Low IL-22 Serum Levels. Despite the important role of gut microbiota in the maturation of the immune system, little is known about its impact on the development of T-cell responses to vaccination. Here, we immunized C57BL/6 mice with a prime-boost regimen using DNA plasmid, the Chimpanzee Adenovirus, and the modified Vaccinia Ankara virus expressing a candidate HIV T-cell immunogen and compared the T-cell responses between individuals with an intact or antibiotic-depleted microbiota. Overall, the depletion of the gut microbiota did not result in significant differences in the magnitude or breadth of the immunogen-specific IFNÎ³ T-cell response after vaccination. However, we observed marked changes in the serum levels of four cytokines after vaccinating microbiota-depleted animals, particularly a significant reduction in IL-22 levels. Interestingly, the level of IL-22 in serum correlated with the abundance of Roseburia in the large intestine of mice in the mock and vaccinated groups with intact microbiota. This short-chain fatty acid (SCFA)-producing bacterium was significantly reduced in the vaccinated, microbiota-depleted group. Therefore, our results indicate that, although microbiota depletion reduces serum levels of IL-22, the powerful vaccine regime used could have overcome the impact of microbiota depletion on IFNÎ³-producing T-cell responses.

Characteristics of Persistent Symptoms Manifested after SARS-CoV-2 Vaccination: An Observational Retrospective Study in a Specialized Clinic for Vaccination-Related Adverse Events. Background: Although many adverse reactions after SARS-CoV-2 vaccination have been reported, there have been few comprehensive studies on persistent symptoms after SARS-CoV-2 vaccination. The aim of this

study was to determine the clinical characteristics of patients with various persistent symptoms after SARS-CoV-2 vaccination. Methods: A retrospective descriptive study was performed for patients who visited a specialized clinic established at Okayama University Hospital to evaluate adverse events after SARS-CoV-2 vaccination during the period from April 2021 to March 2023. Results: Descriptive analysis was performed for 121 of 127 patients who visited the clinic during the study period, and separate analysis was performed for the other 6 patients who had serious complications, who required treatment with prednisolone, and who had persistent symptoms. The median [interquartile range] age of the patients was 48 years [31-64 years], and the patients included 44 males (36.4%) and 77 females (63.6%). The most frequent symptoms were sensory impairment (34 patients, 28.1%), general fatigue (30 patients, 24.8%), fever/low-grade fever (21 patients, 17.4%), and headache (21 patients, 17.4%). Serious complications included myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), sarcoidosis, aseptic meningitis, neuromyelitis optica spectrum disorders (NMOSDs), tendon adhesions, and idiopathic thrombocytopenia. Conclusions: Although causal relationships were not determined, 15 persistent symptoms after SARS-CoV-2 vaccination were characterized. All of the symptoms had onset from 12 hours to one week after vaccination, with 10 symptoms persisting for 6 months or longer. The most frequent symptom was sensory impairment.

SARS-CoV-2 Antibody Profiles in Maternal Serum and Breast Milk Following mRNA COVID-19 Vaccination: A Longitudinal Prospective Observational Cohort Study. COVID-19 vaccination during pregnancy protects infants against symptomatic COVID-19. Vaccination of lactating mothers may offer additional protection, but our understanding of immune responses in breast milk is limited. We, therefore, performed a single-center prospective cohort study of lactating mothers who received a COVID-19 mRNA primary vaccine series to evaluate the durability, breadth, and neutralizing capacity of the antibody responses in breast milk. Spike IgG- and IgA-binding antibodies of ancestral SARS-CoV-2 in serum and breast milk were quantified over 9 months using Meso Scale Discovery (MSD) V-PLEX assays, and ancestral titers were compared to four variants of concern (Alpha, Beta, Delta, Gamma) at a single time point. Neutralizing antibodies against ancestral SARS-CoV-2 and Omicron BA.4/5 were compared before and after vaccination using a pseudovirus-neutralization assay. Eleven lactating mothers received either Pfizer BNT162b2 (7/11) or Moderna mRNA-1273 (4/11) vaccine primary series. IgG and IgA titers increased in serum and breast milk following each dose, peaking 1-4 weeks after series completion. Titers remained significantly elevated for 7-9 months, except for in breast milk IgA which returned to baseline within 1 month. Furthermore, binding antibodies against all included variants were detected in breast milk collected 1-3 weeks after series completion. However, while vaccination induced a strong neutralizing response against ancestral SARS-CoV-2 in serum and more modest response in breast milk, it did not induce neutralizing antibodies against Omicron BA.4/5 in either specimen type. This study demonstrates that maternal COVID-19 mRNA vaccination may enhance immune protection for infants through breast milk via increased IgG- and IgA-binding-and-neutralizing antibodies; although, variant-specific boosters may be required to optimize immune protection.

Chronic Fatigue and Dysautonomia following COVID-19 Vaccination Is Distinguished from Normal Vaccination Response by Altered Blood Markers. SARS-CoV-2 mRNA vaccination can entail chronic fatigue/dysautonomia tentatively termed post-acute COVID-19 vaccination syndrome (PACVS). We explored receptor autoantibodies and interleukin-6 (IL-6) as somatic correlates of PACVS. Blood markers determined before and six months after first-time SARS-CoV-2 vaccination of healthy controls (N = 89; 71 females; mean/median age: 39/49 years) were compared with corresponding values of PACVS-affected persons (N = 191; 159 females; mean/median age: 40/39 years) exhibiting chronic fatigue/dysautonomia (â‰¥three symptoms for â‰¥five months after the last SARS-CoV-2 mRNA vaccination) not due to SARS-CoV-2 infection and/or confounding

diseases/medications. Normal vaccination response encompassed decreases in 11 receptor antibodies (by 25-50%, $p < 0.0001$), increases in two receptor antibodies (by 15-25%, $p < 0.0001$) and normal IL-6. In PACVS, serological vaccination-response appeared significantly ($p < 0.0001$) altered, allowing discrimination from normal post-vaccination state (sensitivity = 90%, $p < 0.0001$) by increased Angiotensin II type 1 receptor antibodies (cut-off â‰¤ 10.7 U/mL, ROC-AUC = 0.824 Â± 0.027), decreased alpha-2B adrenergic receptor antibodies (cut-off â‰¥ 25.2 U/mL, ROC-AUC = 0.828 Â± 0.025) and increased IL-6 (cut-off â‰¤ 2.3 pg/mL, ROC-AUC = 0.850 Â± 0.022). PACVS is thus indicated as a somatic syndrome delineated/detectable by diagnostic blood markers.

Comparative Immune Response after Vaccination with SOBERANA(Â®) 02 and SOBERANA(Â®) plus Heterologous Scheme and Natural Infection in Young Children. (1) Background: In children, SARS-CoV-2 infection is mostly accompanied by mild COVID-19 symptoms. However, multisystem inflammatory syndrome (MIS-C) and long-term sequelae are often severe complications. Therefore, the protection of the pediatric population against SARS-CoV-2 with effective vaccines is particularly important. Here, we compare the humoral and cellular immune responses elicited in children (n = 15, aged 5-11 years) vaccinated with the RBD-based vaccines SOBERANA(Â®) 02 and SOBERANA(Â®) Plus combined in a heterologous scheme with those from children (n = 10, aged 4-11 years) who recovered from mild symptomatic COVID-19. (2) Methods: Blood samples were taken 14 days after the last dose for vaccinated children and 45-60 days after the infection diagnosis for COVID-19 recovered children. Anti-RBD IgG and ACE2-RBD inhibition were assessed by ELISA; IgA, cytokines, and cytotoxic-related proteins were determined by multiplex assays. Total B and T cell subpopulations and IFN-Î³ release were measured by multiparametric flow cytometry using a large panel of antibodies after in vitro stimulation with S1 peptides. (3) Results: Significant higher levels of specific anti-RBD IgG and IgA and ACE2-RBD inhibition capacity were found in vaccinated children in comparison to COVID-19 recovered children. Th1-like and Th2-like CD4(+) T cells were also significantly higher in vaccinated subjects. IFN-Î³ secretion was higher in central memory CD4(+) T cells of COVID-19 recovered children, but no differences between both groups were found in the CD4(+) and CD8(+) T cell effector, terminal effector, and naÃ¯ve T cell subpopulations. In contrast to low levels of IL-4, high levels of IL-2, IL-6, IFN-Î³, and IL-10 suggest a predominant Th1 cell polarization. Cytotoxic-related proteins granzyme A and B, perforin, and granulin were also found in the supernatant after S1 stimulation in both vaccinated and recovered children. (4) Conclusions: Vaccination with the heterologous scheme of SOBERANA(Â®) 02/SOBERANA(Â®) Plus induces a stronger antibody and cellular immune response compared to natural infections in young children.

The Time-Dependent Association of Torque Teno Virus Load with the Level of SARS-CoV-2 S1 IgG Antibodies Following COVID-19 Vaccination in Kidney Transplant Recipients. Kidney transplant recipients (KTR) show an impaired humoral immune response to COVID-19 vaccination due to their immunocompromised status. Torque teno virus (TTV) is a possible marker of immune function. This marker may be helpful in predicting the immune response after COVID-19 vaccination in order to decide which vaccination strategy should be applied. We therefore investigated whether TTV load is associated with the humoral response after COVID-19 vaccination. Of the KTR who participated in two prospective vaccination studies and received two to four doses of the mRNA-1273 COVID-19 vaccine, 122 were included. TTV load was measured prior to vaccination, and S1 IgG antibody levels were measured 28 days after vaccination. TTV load was independently inversely associated with S1 IgG antibodies after COVID-19 vaccination (B: -2.19 (95% CI: -3.6--0.8), $p = 0.002$). Interestingly, we found a significant interaction between TTV load and time after transplantation ($p = 0.005$). When patients were longer after transplantation, TTV load was less predictive for S1 IgG antibody response after vaccination compared to patients that were shorter after transplantation. Our data suggest that TTV load is a good marker in predicting COVID-19 vaccination antibody response and may be helpful

in selecting a strategy shortly after transplantation. However, this marker should be handled with caution longer after transplantation.
Clinical Syndromes Related to SARS-CoV-2 Infection and Vaccination in Pediatric Age: A Narrative Review. This narrative review aims to report the main clinical manifestations, therapeutic strategies, outcomes, and complications of acute SARS-CoV-2 infection in childhood and to summarize the data relating the SARS-CoV-2 vaccination efficacy and safety in pediatric age. SARS-CoV-2 infection mostly occurs asymptomatically in the pediatric population, while multisystem inflammatory syndrome in children (MIS-C) represents the most severe coronavirus disease 2019 (COVID-19)-related illness, a life-threatening event with a high morbidity rate. After the development of SARS-CoV-2 vaccines and their subsequent approval in children, the rate of infection as well as the number of its related complications have shown a drastic decrease. Fully vaccinated children are protected from the risk of developing a severe disease and a similar protective role has been observed in the reduction of complications, in particular MIS-C. However, long-lasting immunity has not been demonstrated, booster doses have been required, and reinfection has been observed. With regards to vaccine safety, adverse events were generally mild to moderate in all age groups: local adverse events were the most commonly reported. Nevertheless, a potential association between SARS-CoV-2 vaccine and the subsequent development of inflammatory manifestations has been suggested. Myocarditis has rarely been observed following vaccination; it appeared to be more frequent among adolescent males with a mild clinical course leading to a complete recovery. SARS-CoV-2 vaccine-related MIS-C cases have been described, although a univocal definition and an exact time interval with respect to vaccination has not been reported, thus not establishing a direct causal link. Current evidence about COVID-19 vaccination in children and adolescents suggest that benefits outweigh potential risks. Long-term data collection of the post-authorization safety surveillance programs will better define the real incidence of SARS-CoV-2 vaccine-related complications in the pediatric population.
Effect of SARS-CoV-2 Infection and BNT162b2 Vaccination on the mRNA Expression of Genes Associated with Angiogenesis. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), discovered in December 2019 in Wuhan, China, caused the coronavirus disease 2019 (COVID-19). Due to the rate of spread of this virus, the World Health Organization, in March 2020, recognised COVID-19 as a worldwide pandemic. The disease is multisystemic with varying degrees of severity. Unfortunately, despite intensive research, the molecular changes caused by SARS-CoV-2 remain unclear. Mechanisms affected by the virus infection include endothelial dysfunction and angiogenesis. Similarly, the vaccines developed so far affect the process of angiogenesis, contributing to the development of undesirable effects on part of the cardiovascular system. The presented research aimed to investigate the impact of the SARS-CoV-2 infection and the Pfizer Comirnaty vaccine (BNT162b2) on the molecular aspect of angiogenesis. We found that convalescents vaccinated with one dose of BNT162b2 were characterised by higher MMP-7 (metalloproteinases 7) expression than non-vaccinated convalescents and healthy volunteers vaccinated with one dose of BNT162b2. Moreover, non-vaccinated convalescents showed increased mRNA expression of ADAMTS1 (ADAM metallopeptidase with thrombospondin type 1 motif 1) compared to healthy volunteers vaccinated with one dose of BNT162b2. In addition, we showed significant sex differences in the expression of MMP-7. In conclusion, the results of our study suggest a significant impact of SARS-CoV-2 infection and vaccination on the course of angiogenesis at the molecular level.
Impact of COVID-19 and Vaccination During Pregnancy on Placenta-Mediated Complications (COVIGRO Study). OBJECTIVES: COVID-19 has been associated with preterm birth (PTB) and placental-mediated complications, including fetal growth restriction and preeclampsia (PE). This study aimed to estimate the impact of COVID-19 and vaccination on adverse pregnancy outcomes and

markers of placental function. METHODS: We performed a study on a prospective cohort of women recruited in the first trimester of pregnancy during the early COVID-19 pandemic period (December 2020 to December 2021). At each trimester of pregnancy, the assessment included a questionnaire on COVID-19 and vaccination status; serological tests for COVID-19 (for asymptomatic infection); measurement of placental growth factor (PlGF) and soluble fms-like tyrosine kinase 1 (sFlt-1) in maternal blood; measurement of mean uterine artery pulsatility index (UtA-PI); and pregnancy outcomes (PTB, PE, birth weight below the fifth and the tenth percentile). RESULTS: Among 788 patients with complete data, we observed 101 (13%) cases of symptomatic infection and 74 (9%) cases of asymptomatic infection with SARS-CoV-2. Most cases (73%) of infection were among women with previous vaccination or COVID-19 infection before pregnancy. COVID-19 infection was not associated with adverse pregnancy outcomes, abnormal fetal growth, sFlt-1/PlGF ratio, or mean UtA-PI. Vaccination during pregnancy did not influence these outcomes either. We observed no case of severe COVID-19 infection requiring respiratory support. CONCLUSION: Mild symptomatic or asymptomatic COVID-19 during pregnancy did not influence the risk of adverse pregnancy outcomes and the markers of placental function in predominantly vaccinated women. Fetal growth monitoring is unlikely to be mandatory in women with mild symptoms of COVID-19.

SARS-CoV-2 breakthrough infections following inactivated vaccine vaccination induce few neutralizing antibodies against the currently emerging Omicron XBB variants.

Different immunological responses following immunization with two mRNA vaccines. INTRODUCTION: Immunological responses were investigated following immunization with two mRNA vaccines: BNT162b2 and mRNA-1273. METHODS: Neutralizing antibody (NAb) was assayed before, 2-4 weeks after, and 3 and 6 months after the primary immunization, and the same time-points after booster dose with 6- or 8-months interval. Whole-blood culture was stimulated with spike antigen, and cytokine production was assayed. RESULTS: NAb was detected after primary immunization, NAb titers began to decrease three months after primary immunization with BNT162b2, lower than those after mRNA-1273, and elevated after booster immunization. The NAb level was 1/2 lower against Î´ variant, and 1/16 lower against omicron variant in comparison with that against Î± variant. Cytokine production following immunization with mRNA-1273 was maintained within three months at higher levels of Th1 (TNF-Î±), Th2 (IL-4 and IL-5), and inflammatory cytokines (IL-6 and IL-17) than that following immunization with BNT162b2, reflecting prominent levels of NAb following immunization with mRNA-1273. Cytokine production decreased six months after primary immunization in both vaccine recipients and was enhanced following booster doses. During the omicron outbreak, medical staff members in the outpatient office experienced asymptomatic infection, with a greater than 4-fold increase in NAb titers against omicron variant even after booster immunization. Asymptomatic infection enhanced the production of Th2 and inflammatory cytokines. CONCLUSION: mRNA-1273 induced stronger NAb responses with wide-range cross-reactive antibodies against Î´ and omicron variants. mRNA-1273 induced higher levels of Th1, Th2, and inflammatory cytokines than BNT162b2 did, reflecting higher levels of NAb against variant strains.

Pooled rates and demographics of POTS following SARS-CoV-2 infection versus COVID-19 vaccination: Systematic review and meta-analysis. PURPOSE: To address recent concerns of postural orthostatic tachycardia syndrome (POTS) occurring after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and coronavirus disease 2019 (COVID-19) vaccination. METHODS: We searched PubMed, Web of Science, and Scopus as of 1st June 2023. We performed a systematic review and meta-analysis of pooled POTS rate in SARS-CoV-2-infected and COVID-19-vaccinated groups from epidemiological studies, followed by subgroup analyses by characteristic. Meta-analysis of risk ratio was conducted to compare POTS rate in infected versus uninfected groups. Meta-analysis of demographics was also performed to compare cases of post-infection and post-

vaccination POTS from case reports and series. RESULTS: We estimated the pooled POTS rate of 107.75 (95Â % CI: 9.73 to 273.52) and 3.94 (95Â % CI: 0 to 16.39) cases per 10,000 (i.e., 1.08Â % and 0.039Â %) in infected and vaccinated individuals based on 5 and 2 studies, respectively. Meta-regression revealed age as a significant variable influencing 86.2Â % variance of the pooled POTS rate in infected population (PÂ <Â 0.05). Moreover, POTS was 2.12-fold more likely to occur in infected than uninfected individuals (RRÂ =Â 2.12, 95Â % CI: 1.71 to 2.62, PÂ <Â 0.001). Meta-analyzed demographics for cases of post-infection (nÂ =Â 43) and post-vaccination (nÂ =Â 17) POTS found no significant differences in several variables between groups, except that the time from exposure to symptom onset was shorter for cases of post-vaccination POTS (PÂ <Â 0.05). CONCLUSION: Although evidence is limited for post-vaccination POTS, our study showed that POTS occur more frequently following SARS-CoV-2 infection than COVID-19 vaccination.

Possible association between vaccination against SARS-CoV-2 and recurrence of macular edema due to branch retinal vein occlusion: a case report. We herein describe a patient who developed recurrence of macular edema (ME) due to branch retinal vein occlusion (BRVO) 3 days after administration of the BNT162b2 vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). A man in his early 50s visited our hospital because of vision loss in his right eye. His logarithmic best-corrected visual acuity (BCVA) was -0.79 in both eyes. ME due to superior temporal BRVO was observed in his right eye, and the central foveal thickness (CFT) was 486â€‰Âµm. The patient was treated with an intravitreal aflibercept injection with logarithmic BCVA of -0.79, leading to resolution of the ME with a CFT of 299â€‰Âµm. Three months after the initial visit, he received a fourth dose of an mRNA vaccine. Three days later, he developed vision loss in his right eye. Although the logarithmic BCVA was maintained at -0.79, ME recurred with a CFT of 507â€‰Âµm. The patient was treated with an additional dose of intravitreal aflibercept injection. The ME resolved and the logarithmic BCVA in the right eye was maintained at -0.79. This case indicates a possible association between vaccination against SARS-CoV-2 and recurrence of ME due to BRVO.

Post-acute midterm follow-up cardiac MRI findings and clinical outcomes in patients with COVID-19 vaccine-associated myocarditis: a comprehensive systematic review and meta-analysis.
PURPOSE: Although previous investigations revealed favourable in-hospital outcomes of COVID-19 vaccine-related myocarditis, the mid-term prognosis is still unclear. Hence, we aim to summarise existing evidence on the follow-up imaging and clinical findings in patients with COVID-19 vaccine-related myocarditis. METHODS: We performed a systematic search in online databases using relevant key terms covering COVID-19 vaccine, myocarditis, follow-up, and cardiac MRI. We included all observational studies that reported cardiac MRI findings of patients with myocarditis following COVID-19 vaccination in both acute and follow-up phases. Data on clinical outcomes and cardiac MRI findings were extracted and pooled using a random-effect model. RESULTS: A total of 27 studies (126 patients) met our eligibility criteria. At the time of follow-up, myocarditis symptoms were resolved in all patients, but abnormal electrocardiography and elevated troponin levels were detected in 18.7% and 3.8% of them, respectively. Median imaging follow-up times varied from 3 to 6.3â€‰months. On follow-up cardiac MRI, the persistence of LGE was observed in 76% (95%CI: 62 to 85%), but its extension declined compared to the baseline in almost all patients. Persistent LGE was accompanied by myocardial edoema in six patients, and it was consistent with myocardial fibrosis (LGE without edoema) in the remaining cases. Mean changes (95%CI) of cardiac MRI left ventricular ejection fraction (LVEF) (%) was +2.97 (+1.59 to +4.34) from baseline. CONCLUSION: In conclusion, although most patients likely experience favourable clinical outcomes without serious complications, cardiac MRI abnormalities, mainly LGE, may persist in a notable proportion of them beyond the acute phase.

Antibody Response to SARS-CoV-2 Vaccination in Heart Failure Patients: Retrospective Single-Center Cohort Study. We sought to investigate the impact of heart failure on anti-spike antibody

positivity following SARS-CoV-2 vaccination. Our study included 103 heart failure (HF) patients, including those with and without left ventricular assist devices (LVAD) selected from our institutional transplant waiting list as well as 104 non-heart failure (NHF) patients who underwent open heart surgery at our institution from 2021 to 2022. All the patients received either heterologous or homologous doses of BNT162b2 and CoronaVac. The median age of the HF group was 56.0 (interquartile range (IQR): 48.0-62.5) and the NHF group was 63.0 (IQR: 56.0-70.2) years, and the majority were males in both groups (n = 78; 75.7% and n = 80; 76.9%, respectively). The majority of the patients in both the HF and NHF groups received heterologous vaccinations (n = 43; 41.7% and n = 52; 50.3%, respectively; p = 0.002). There was no difference in the anti-spike antibody positivity between the patients with and without heart failure (p = 0.725). Vaccination with BNT162b2 led to significantly higher antibody levels compared to CoronaVac alone (OR: 11.0; 95% CI: 3.8-31.5). With each passing day after the last vaccine dose, there was a significant decrease in anti-spike antibody positivity, with an OR of 0.9 (95% CI: 0.9-0.9). Furthermore, hyperlipidemia was associated with increased antibody positivity (p = 0.004).

A Machine Learning Approach Unveils the Relationships between Sickness Behavior and Interoception after Vaccination: Suggestions for Psychometric Indices of Higher Vulnerability. OBJECTIVE: Prior research has suggested a possible connection between vaccination and manifestations of Sickness Behavior; however, a need remains to first delve deeper into this association and second examine how Interoceptive Awareness and emotional factors may modulate individuals' perceptions of their health status post vaccination. METHOD: An online retrospective cross-sectional survey of 647 individuals who received a COVID-19 vaccination was conducted. Together with vaccination side effects, socio-demographic characteristics, health status, level of concern about vaccination, and Interoceptive Awareness were collected at the baseline level. Mood, sleep, and Sickness Behavior were assessed at baseline and after vaccination. Data were analyzed using inferential statistics and machine learning techniques. RESULTS: After vaccination, there was a significant increase in Sickness Behavior levels (mean (Â±SD) SicknessQ T0 = 1.57 (Â±2.72), mean (Â±SD) SicknessQ T1 = 5.54 (Â±5.51); p-value = 0.001; ES = 0.77). A Machine Learning analysis revealed specific patterns of individual dispositions (sex and age), baseline emotional characteristics (levels of depression, anxiety, stress, and concern about adverse reactions), as well as some components of Interoceptive Awareness (Noticing, Body Listening, and Attention Regulation), as predictors of high levels of Sickness Behavior, both in terms of overall scores (JRIP: 72.65% accuracy, AUC = 0.692, d = 0.709; F1 = 0.726) and individual items (JRIP: 75.77% accuracy, AUC = 0.694; d = 0.717; F1 = 0.754). CONCLUSIONS: Our results provide new insight into post-immune reactions by highlighting the contribution of Interoceptive Awareness in modulating the severity of Sickness Behavior. This sheds light on the role of awareness of bodily sensations in modulating perceptions of health status, helping to identify the characteristics that make individuals more prone to feeling sick.

Frailty and Humoral Immune Responses Following COVID-19 Vaccination among Patients Undergoing Hemodialysis. BACKGROUND: Patients with end-stage kidney disease who are undergoing dialysis have reduced immune responses to COVID-19 vaccination. Frailty is extremely common among dialysis patients and may contribute to the impaired immunogenicity. This study aimed to determine the association between frailty and humoral immune responses following COVID-19 vaccination in hemodialysis patients. DESIGN, SETTING, PARTICIPANTS: Adult hemodialysis patients without prior SARS-CoV-2 infection who received a priming dose of ChAdOx1 nCoV-19, an adenovirus-vectored vaccine, were assessed for eligibility. Participants were categorized as robust, pre-frail, or frail using the Fried frailty criteria. Humoral responses were assessed 28 days after vaccination by measuring titers of anti-spike IgG antibodies. The primary outcome was anti-spike antibody seroconversion, defined as antibody levels â‰¥50 AU/mL. Multivariable-adjusted logistic regression models were

used to assess the association between frailty status and the primary outcome. RESULTS: A total of 206 participants (mean age 67 Â± 13 years, 50% women) were included in the study, of whom 50 (24%) were characterized as frail, 86 (42%) were characterized as pre-frail, and 70 (34%) were characterized as robust. Anti-spike antibody levels were progressively lower with more advanced stages of frailty (P <0.001). Compared with robust patients, a significantly smaller proportion of pre-frail and frail patients developed anti-spike antibody seroconversion (87%, 66%, and 40%, respectively; P <0.001). Frailty was associated with the absence of humoral responses after adjustment for age, sex, body mass index, diabetes, coronary artery disease, serum albumin, and lymphocyte count (OR=0.25; 95% CI, 0.08-0.80). CONCLUSIONS: Frailty is independently associated with impaired humoral responses following COVID-19 vaccination among hemodialysis patients. Strategies aimed at preventing or attenuating frailty in the dialysis population are warranted.

Ischemic stroke after COVID-19 bivalent vaccine administration in patients aged 65 years and older in the United States. The Centers for Disease Control and Prevention announced in January 2023 a potential connection between administration of the Pfizer novel coronavirus disease-2019 (COVID-19) bivalent vaccine booster and ischemic stroke (IS). A retrospective cohort study was conducted to compare the hazard of IS in patients aged 65 years and over administered the Pfizer bivalent booster versus those administered the Pfizer/Moderna monovalent or Moderna bivalent boosters. De-identified patient electronic health data were collected from TriNetX, a cloud-based analytics platform that includes data from over 90 million unique patients in the United States. Patients aged 65 years and over at the time of administration of a Pfizer bivalent, Moderna bivalent, or Pfizer/Moderna monovalent booster were included for analysis. Cohorts were propensity-score matched. The hazard ratios (HR) and 95% confidence intervals (CI) for IS between matched cohorts at 1-21 and 22-42 days after booster administration were calculated. There was reduced hazard of IS in the Pfizer bivalent cohort compared to the monovalent cohort at both timepoints: 1-21 days after vaccination (HR: 0.54, 95% CI: 0.47-0.62), and 22-42 days after vaccination (HR: 0.62, 95% CI: 0.54-0.72) (nâ€‰=â€‰79,036 patients per cohort). There was reduced hazard of IS in the Pfizer bivalent cohort compared to the Moderna bivalent cohort at 1-21 days after vaccination (HR: 0.75, 95% CI: 0.58-0.96) (nâ€‰=â€‰26,962 patients per cohort). This analysis provides no evidence that the Pfizer bivalent vaccine is associated with increased hazard of IS compared to the monovalent or Moderna bivalent vaccines.

Excess mortality in Cyprus during the COVID-19 vaccination campaign.

Cellular mechanisms associated with sub-optimal immune responses to SARS-CoV-2 bivalent booster vaccination in patients with Multiple Myeloma. BACKGROUND: The real-world impact of bivalent vaccines for wild type (WA.1) and Omicron variant (BA.5) is largely unknown in immunocompromised patients with Multiple Myeloma (MM). We characterize the humoral and cellular immune responses in patients with MM before and after receiving the bivalent booster, including neutralizing assays to identify patterns associated with continuing vulnerability to current variants (XBB1.16, EG5) in the current post-pandemic era. METHODS: We studied the humoral and cellular immune responses before and after bivalent booster immunization in 48Â MM patients. Spike binding IgG antibody levels were measured by SARS-CoV-2 spike binding ELISA and neutralization capacity was assessed by a SARS-CoV-2 multi-cycle microneutralization assays to assess inhibition of live virus. We measured spike specific T-cell function using the QuantiFERON SARS-CoV-2 (Qiagen) assay as well as flow-cytometry based T-cell. In a subset of 38 patients, high-dimensional flow cytometry was performed to identify immune cell subsets associated with lack of humoral antibodies. FINDINGS: We find that bivalent vaccination provides significant boost in protection to the omicron variant in our MM patients, in a treatment specific manner. MM patients remain vulnerable to newer variants with mutations in the spike portion. Anti-CD38 and anti-BCMA therapies affect the immune machinery

needed to produce antibodies. INTERPRETATION: Our study highlights varying immune responses observed in MM patients after receiving bivalent COVID-19 vaccination. Specifically, a subgroup of MM patients undergoing anti-CD38 and anti-BCMA therapy experience impairment in immune cells such DCs, B cells, NK cells and TFH cells, leading to an inability to generate adequate humoral and cellular responses to vaccination. FUNDING: National Cancer Institute (National Institutes of Health), National Institute of Allergy and Infectious Diseases (National Institutes of Health), NCI Serological Sciences Network for COVID-19 (SeroNet) and The Icahn School of Medicine at Mount Sinai.

Disruption of gender-affirming health care, and COVID-19 illness, testing, and vaccination among trans Australians during the pandemic: a cross-sectional survey. OBJECTIVES: To assess rates of disruption of gender-affirming health care, of coronavirus disease 2019 (COVID-19) illness, testing, and vaccination, and of discrimination in health care among Australian trans people during the COVID-19 pandemic. DESIGN, SETTING: Online cross-sectional survey (1-31 May 2022); respondents were participants recruited by snowball sampling for TRANSform, an Australian longitudinal survey-based trans health study, 1 May - 30 June 2020. PARTICIPANTS: People aged 16 years or older, currently living in Australia, and with a gender different to their sex recorded at birth. MAIN OUTCOME MEASURES: Proportions of respondents who reported disruptions to gender-affirming health care, COVID-19 illness, testing, and vaccination, and positive and negative experiences during health care. RESULTS: Of 875 people invited, 516 provided valid survey responses (59%). Their median age was 33 years (interquartile range, 26-45 years); 193 identified as women or trans women (37%), 185 as men or trans men (36%), and 138 as non-binary (27%). Of 448 respondents receiving gender-affirming hormone therapy, 230 (49%) reported disruptions to treatment during the pandemic; booked gender-affirming surgery had been cancelled or postponed for 37 of 85 respondents (44%). Trans-related discrimination during health care was reported by a larger proportion of participants than in a pre-pandemic survey (56% v 26%). COVID-19 was reported by 132 respondents (26%), of whom 49 reported health consequences three months or more after the acute illness (37%; estimated Australian rate: 5-10%). Three or more COVID-19 vaccine doses were reported by 448 participants (87%; Australian adult rate: 70%). CONCLUSIONS: High rates of COVID-19 vaccination among the trans people we surveyed may reflect the effectiveness of LGBTIQA+ community-controlled organisation vaccination programs and targeted health promotion. Training health care professionals in inclusive services for trans people could improve access to appropriate health care and reduce discrimination.

Thrombocytopenia and venous thromboembolic events after BNT162b2, CoronaVac, ChAdOx1 vaccines and SARS-CoV-2 infection: a self-controlled case series study. This study assessed the association between COVID-19 vaccines, SARS-CoV-2 infection and the risk of thrombocytopenia and venous thromboembolism (VTE). This self-controlled case series study used hospital records between 1st February 2021 and 28th February 2022 linked to the national immunisation registry and COVID-19 surveillance data in Malaysia. Conditional Poisson regression was used to estimate incidence rate ratios (IRR) of events in the risk period (day 1-21 post-exposure) relative to control period with the corresponding 95% confidence interval (CI) adjusted for calendar period. We found no significant increased risk of thrombocytopenia in 1-21Â days following BNT162b2, CoronaVac and ChAdOx1 vaccines while the risk was increased following SARS-CoV-2 infection (IRR 15.52, 95% CI 13.38-18.00). Similarly, vaccination with BNT162b2, CoronaVac, or ChAdOx1 was not associated with an increased risk of VTE during the 1-21Â days risk period. SARS-CoV-2 infection was associated with increased risk of VTE (IRR 39.84, 95% CI 27.45-32.44). Our findings showed low event rates of thrombocytopenia and VTE following booster vaccination with comparable safety profiles between those who received homologous and heterologous booster combinations. Our findings showed the risk of

thrombocytopenia and VTE was not increased after COVID-19 vaccination while the risks were substantially higher after SARS-CoV-2 infection.
Progression of hemolysis in a patient with hereditary spherocytosis after the second dose of COVID-19 mRNA vaccine: Correspondence.
Association between long COVID and vaccination: A 12-month follow-up study in a low- to middle-income country. OBJECTIVE: There is a lack of estimates regarding the at-risk population associated with long COVID in Pakistan due to the absence of prospective longitudinal studies. This study aimed to determine the prevalence of long COVID and its association with disease severity and vaccination status of the patient. DESIGN AND DATA SOURCES: This prospective cohort study was conducted at the Aga Khan University Hospital and recruited patients aged > 18 years who were admitted between February 1 and June 7, 2021. During this time, 901 individuals were admitted, after excluding patients with missing data, a total of 481 confirmed cases were enrolled. RESULTS: The mean age of the study population was 56.9Â±14.3 years. Among patients with known vaccination status (n = 474), 19%(n = 90) and 19.2%(n = 91) were fully and partially vaccinated, respectively. Severe/critical disease was present in 64%(n = 312). The mortality rate following discharge was 4.58%(n = 22). Around 18.9%(n = 91) of the population required readmission to the hospital, with respiratory failure (31.8%, n = 29) as the leading cause. Long COVID symptoms were present in 29.9%(n = 144), and these symptoms were more prevalent in the severe/critical (35.5%, n = 111) and unvaccinated (37.9%, n = 105) cohort. The most prominent symptoms were fatigue (26.2%, n = 126) and shortness of breath (24.1%, n = 116), followed by cough (15.2%, n = 73). Vaccinated as compared to unvaccinated patients had lower readmissions (13.8% vs. 21.51%) and post-COVID pulmonary complications (15.4% vs. 24.2%). On multivariable analysis, after adjusting for age, gender, co-morbidity, and disease severity, lack of vaccination was found to be an independent predictor of long COVID with an Odds ratio of 2.42(95% CI 1.52-3.84). Fully and partially vaccinated patients had 62% and 56% reduced risk of developing long COVID respectively. CONCLUSIONS: This study reports that the patients continued to have debilitating symptoms related to long COVID, one year after discharge, and most of its effects were observed in patients with severe/critical disease and unvaccinated patients.
COVID and COVID vaccine-related corneal morbidity: A review. Systemic coronavirus disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus has had several ocular consequences. Many vaccines have been developed against the disease, with adverse events being reported as well. Various ocular adverse events secondary to coronavirus disease 2019 (COVID-19) vaccines have also featured in literature in recent times. This review features the reported corneal-related effects of COVID infection and vaccination. These include direct effects on corneal grafts and unilateral or bilateral corneal melts. The compilation of reported experiences from across the world in this systematic review will help clinicians recognize the possible presentations, pathogenesis, and management of the same.
Endocrine diseases associated with COVID-19 vaccination: case report. SARS-CoV-2 vaccination is not free of adverse effects. We present two cases of endocrine involvement associated with COVID-19 vaccination. A 46-year-old woman who, after receiving the first COVID-19 vaccination dose, presented persistent fever and signs of thyrotoxicosis after being diagnosed with subacute thyroiditis associated with COVID-19 vaccination; the condition remitted with the use of corticoids. A 71-year-old male, who after COVID-19 vaccination, presented hyperinsulinemic hypoglycemia, testing positive for anti-insulin antibodies; he was diagnosed with autoimmune hypoglycemia associated with COVID-19 vaccination and received treatment with prednisone, controlling the episodes of hypoglycemia. In conclusion, endocrine diseases associated with COVID-19 vaccination are extremely rare and their timely detection allows adequate treatment.

Factors associated with unexplained sudden deaths among adults aged 18-45 years in India - A multicentric matched case-control study. BACKGROUND OBJECTIVES: In view of anecdotal reports of sudden unexplained deaths in India's apparently healthy young adults, linking to coronavirus disease 2019 (COVID-19) infection or vaccination, we determined the factors associated with such deaths in individuals aged 18-45 years through a multicentric matched case-control study. METHODS: This study was conducted through participation of 47 tertiary care hospitals across India. Cases were apparently healthy individuals aged 18-45 years without any known co-morbidity, who suddenly (<24 h of hospitalization or seen apparently healthy 24 h before death) died of unexplained causes during 1 st October 2021-31 st March 2023. Four controls were included per case matched for age, gender and neighborhood. We interviewed/perused records to collect data on COVID-19 vaccination/infection and post-COVID-19 conditions, family history of sudden death, smoking, recreational drug use, alcohol frequency and binge drinking and vigorous-intensity physical activity two days before death/interviews. We developed regression models considering COVID-19 vaccination â‰¤42 days before outcome, any vaccine received anytime and vaccine doses to compute an adjusted matched odds ratio (aOR) with 95 per cent confidence interval (CI). RESULTS: Seven hundred twenty nine cases and 2916 controls were included in the analysis. Receipt of at least one dose of COVID-19 vaccine lowered the odds [aOR (95% CI)] for unexplained sudden death [0.58 (0.37, 0.92)], whereas past COVID-19 hospitalization [3.8 (1.36, 10.61)], family history of sudden death [2.53 (1.52, 4.21)], binge drinking 48 h before death/interview [5.29 (2.57, 10.89)], use of recreational drug/substance [2.92 (1.1, 7.71)] and performing vigorous-intensity physical activity 48 h before death/interview [3.7 (1.36, 10.05)] were positively associated. Two doses lowered the odds of unexplained sudden death [0.51 (0.28, 0.91)], whereas single dose did not. INTERPRETATION CONCLUSIONS: COVID-19 vaccination did not increase the risk of unexplained sudden death among young adults in India. Past COVID-19 hospitalization, family history of sudden death and certain lifestyle behaviors increased the likelihood of unexplained sudden death.

Post-Vaccination Syndrome: A Descriptive Analysis of Reported Symptoms and Patient Experiences After Covid-19 Immunization. INTRODUCTION: A chronic post-vaccination syndrome (PVS) after covid-19 vaccination has been reported but has yet to be well characterized. METHODS: We included 241 individuals aged 18 and older who self-reported PVS after covid-19 vaccination and who joined the online Yale Listen to Immune, Symptom and Treatment Experiences Now (LISTEN) Study from May 2022 to July 2023. We summarized their demographics, health status, symptoms, treatments tried, and overall experience. RESULTS: The median age of participants was 46 years (interquartile range [IQR]: 38 to 56), with 192 (80%) identifying as female, 209 (87%) as non-Hispanic White, and 211 (88%) from the United States. Among these participants with PVS, 127 (55%) had received the BNT162b2 [Pfizer-BioNTech] vaccine, and 86 (37%) received the mRNA-1273 [Moderna] vaccine. The median time from the day of index vaccination to symptom onset was three days (IQR: 1 day to 8 days). The time from vaccination to symptom survey completion was 595 days (IQR: 417 to 661 days). The median Euro-QoL visual analogue scale score was 50 (IQR: 39 to 70). The five most common symptoms were exercise intolerance (71%), excessive fatigue (69%), numbness (63%), brain fog (63%), and neuropathy (63%). In the week before survey completion, participants reported feeling unease (93%), fearfulness (82%), and overwhelmed by worries (81%), as well as feelings of helplessness (80%), anxiety (76%), depression (76%), hopelessness (72%), and worthlessness (49%) at least once. Participants reported a median of 20 (IQR: 13 to 30) interventions to treat their condition. CONCLUSIONS: In this study, individuals who reported PVS after covid-19 vaccination had low health status, high symptom burden, and high psychosocial stress despite trying many treatments. There is a need for continued investigation to understand and treat this condition.

Acute exacerbation of immunoglobulin A nephropathy complicated by alveolar hemorrhage after coronavirus disease 2019 vaccination: A case report. RATIONALE: Reports have suggested a relationship between coronavirus disease 2019 (COVID-19) vaccination and new-onset or recurring renal diseases, of which immunoglobulin A (IgA) nephropathy is a representative disease. Alveolar hemorrhage in patients with IgA nephropathy is rare but reportedly has a high mortality and morbidity. To our knowledge, there have been no reports regarding the development of IgA nephropathy with alveolar hemorrhage following COVID-19 vaccination. PATIENTS CONCERN: A 23-year-old Japanese man presented with hemoptysis and peripheral edema a few days after receiving a second dose of a COVID-19 mRNA vaccine. Severe renal failure and alveolar hemorrhage were noted thereafter, and renal biopsy showed crescentic glomerulonephritis with mesangial proliferation accompanied by mesangial electron-dense deposits containing IgA. Renal biopsy tissue also showed chronic histological changes suggestive of acute exacerbation of preexisting IgA nephropathy. DIAGNOSIS: The diagnosis of IgA nephropathy complicated by alveolar hemorrhage was made. INTERVENTIONS AND OUTCOMES: Renal function did not recover despite treatment with high-dose steroids; the patient was maintained on hemodialysis and eventually underwent successful renal transplantation. LESSONS: The present case suggested that although extremely rare, severe renal failure requiring renal replacement therapy could occur in patients with IgA nephropathy after COVID-19 vaccination. Future accumulation of similar cases is needed to predict the risk of renal injury following vaccination.

Patterns and outcomes of late onset thyroid disturbances after COVID-19 vaccination: A report of 75 cases. Isolated cases of subacute thyroiditis exist in the early period of COVID-19 vaccination, largely after mRNA vaccines. Here we report late onset thyroid disturbances and persistent health issues in patients of thyroid disorders after COVID-19 vaccination. Seventy-five patients with post COVID-19 vaccination thyroid disturbances were identified. Among these, 41 had flare of underlying thyroid illness, majority occurring at a median time lag of 28.4â€‰weeks since 2nd dose. Thirty-one cases of new onset hypothyroidism and three of new onset hyperthyroidism were reported, with a median time lag respectively of 17.2 and 22.6â€‰weeks since 2nd dose. Most cases occurred after ChAdOx1-nCoV-19, which was the commonest vaccine employed in mass roll out in India. Significant improvement was observed in majority, after a median follow up of 22-26â€‰weeks. New onset health issues persisting for â‰¥4â€‰weeks were reported in 37.3% and were common in individuals with history of COVID-19 before vaccine. New onset metabolic, musculoskeletal, and reproductive disorders were the common health complaints. Active monitoring is warranted for late onset adverse events after COVID-19 vaccines of all types. Larger studies with involvement of unvaccinated individuals are required to understand the incidence and causality of late onset thyroid disturbances after COVID-19 vaccines.

Case of Exacerbation of Psoriasis Following COVID-19 Vaccination During Treatment with Brodalumab, Which Resulted in Secondary Failure. A 43-year-old Japanese man who had suffered psoriasis vulgaris for eight years visited our hospital. His comorbidities were dyslipidemia, hyperuricemia, and obesity. He received phototherapy for six months, which did not result in improvement. Following treatment with brodalumab, his skin symptoms improved. However, seven months after brodalumab treatment, he received two doses of the mRNA-1273 COVID-19 vaccine, with a one-month interval between doses. One month following the second vaccination, his skin symptoms were exacerbated. He received additional NB-UVB therapy, but his skin symptoms did not improve. Nine months after the addition of NB-UVB therapy, treatment was switched to bimekizumab, and his skin became almost clear. Psoriasis is often associated with comorbidities like metabolic syndrome. Currently, additional COVID-19 vaccination is recommended for high-risk cases such as those with metabolic syndrome. Therefore, it is essential to remain vigilant regarding the

potential exacerbation of psoriasis following COVID-19 vaccination even during treatment with highly effective biologic therapy.
Kikuchi Disease After SARS-CoV-2 Vaccination: A Case Report With Immunohistochemical Analyses. SARS-CoV-2 vaccines have been administered in many countries after the COVID-19 pandemic. Lymphadenopathy is a side effect of SARS-CoV-2 vaccine. We report a rare example of Kikuchi disease in the cervical lymph nodes after SARS-CoV-2 vaccination. A 41-year-old man complained of a swollen neck and fever 9 days after the first dose of SARS-CoV-2 mRNA-1273 vaccine. Computed tomography revealed enlarged cervical lymph nodes. Fine needle aspiration and resection were performed, and the clinicopathological diagnosis was consistent with Kikuchi disease. Histologically, the resected lymph nodes lost their polarity, and many histiocytes were aggregated with karyorrhectic nuclear debris and apoptosis. SARS-CoV-2 positive cells were small lymphocytes detected by immunohistochemistry. This is the first report that demonstrated SARS-CoV-2 expression in Kikuchi disease post-SARS-CoV-2 vaccination.
Hematuria in patients with IgA nephropathy after vaccine for SARS-CoV-2.
Safety and efficacy of the intranasal spray SARS-CoV-2 vaccine dNS1-RBD: a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. BACKGROUND: The live-attenuated influenza virus vector-based intranasal SARS-CoV-2 vaccine (dNS1-RBD, Pneucolin; Beijing Wantai Biological Pharmacy Enterprise, Beijing, China) confers long-lasting and broad protection in animal models and is, to our knowledge, the first COVID-19 mucosal vaccine to enter into human trials, but its efficacy is still unknown. We aimed to assess the safety and efficacy (but not the immunogenicity) of dNS1-RBD against COVID-19. METHODS: We did a multicentre, randomised, double-blind, placebo-controlled, adaptive design, phase 3 trial at 33 centres (private or public hospitals, clinical research centres, or Centre for Disease Control and Prevention) in four countries (Colombia, Philippines, South Africa, and Viet Nam). Men and non-pregnant women (aged â‰¥18 years) were eligible if they had never been infected with SARS-CoV-2, and if they did not have a SARS-CoV-2 vaccination history at screening or if they had received at least one dose of other SARS-CoV-2 vaccines 6 months or longer before enrolment. Eligible adults were randomly assigned (1:1) to receive two intranasal doses of dNS1-RBD or placebo administered 14 days apart (0Â·2 mL per dose; 0Â·1 mL per nasal cavity), with block randomisation via an interactive web-response system, stratified by centre, age group (18-59 years or â‰¥60 years), and SARS-CoV-2 vaccination history. All participants, investigators, and laboratory staff were masked to treatment allocation. The primary outcomes were safety of dNS1-RBD in the safety population (ie, those who had received at least one dose of dNS1-RBD or placebo) and efficacy against symptomatic SARS-CoV-2 infection confirmed by RT-PCR occurring 15 days or longer after the second dose in the per-protocol population (ie, those who received two doses, were followed up for 15 days or longer after the second dose, and had no major protocol deviations). The success criterion was predefined as vaccine efficacy of more than 30%. This trial is registered with the Chinese Clinical Trial Registry (ChiCTR2100051391) and is completed. FINDINGS: Between Dec 16, 2021, and May 31, 2022, 41â€‰620 participants were screened for eligibility and 31â€‰038 participants were enrolled and randomly assigned (15â€‰517 in the vaccine group and 15â€‰521 in the placebo group). 30â€‰990 participants who received at least one dose (15â€‰496 vaccine and 15â€‰494 placebo) were included in the safety analysis. The results showed a favourable safety profile, with the most common local adverse reaction being rhinorrhoea (578 [3Â·7%] of 15â€‰500 vaccine recipients and 546 [3Â·5%] of 15â€‰490 placebo recipients) and the most common systemic reaction being headache (829 [5Â·3%] vaccine recipients and 797 [5Â·1%] placebo recipients). We found no differences in the incidences of adverse reactions between participants in the vaccine and placebo groups. No vaccination-related serious adverse events or deaths were observed. Among 30â€‰290 participants who received two doses, 25â€‰742 were included in the per-protocol efficacy analysis

(12â€‰840 vaccine and 12â€‰902 placebo). The incidence of confirmed symptomatic SARS-CoV-2 infection caused by omicron variants regardless of immunisation history was 1Â·6% in the vaccine group and 2Â·3% in the placebo group, resulting in an overall vaccine efficacy of 28Â·2% (95% CI 3Â·4-46Â·6), with a median follow-up duration of 161 days. INTERPRETATION: Although this trial did not meet the predefined efficacy criteria for success, dNS1-RBD was well tolerated and protective against omicron variants, both as a primary immunisation and as a heterologous booster. FUNDING: Beijing Wantai Biological Pharmacy Enterprise, National Science and Technology Major Project, National Natural Science Foundation of China, Fujian Provincial Science and Technology Plan Project, Natural Science Foundation of Fujian Province, Xiamen Science and Technology Plan Special Project, Bill & Melinda Gates Foundation, the Ministry of Education of China, Xiamen University, and Fieldwork Funds of Xiamen University.

COVID-19 inpatient mortality in Brazil from 2020 to 2022: a cross-sectional overview study based on secondary data. BACKGROUND: In Brazil, the COVID-19 pandemic found the universal and public Unified Health System (SUS) with problems accumulated over time, due, among other reasons, to low investments, and disparities in resource distribution. The preparedness and response of the healthcare system, involving the SUS and a private sector, was affected by large socioeconomic and healthcare access inequities. This work was aimed at offering an overview of COVID-19 inpatient mortality during the pandemic in Brazil, exploring factors associated with its variations and, specifically, differences across public, private (for-profit) and philanthropic (private non-profit) inpatient healthcare units, providers, and non-providers of services to the SUS. METHODS: This cross-sectional study used public secondary data. The main data source was the SIVEP-Gripe, which comprises data on severe acute respiratory illness records prospectively collected. We also employed the National Record of Health Establishments, the SUS' Hospitalization Information System and municipalities' data from IBGE. We considered adult COVID-19 hospitalizations registered in SIVEP-Gripe from February 2020 to December 2022 in inpatient healthcare units with a minimum of 100 cases in the period. Data analyses explored the occurrence of inpatient mortality, employing general linear mixed models to identify the effects of patients', health care processes', healthcare units' and municipalities' characteristics on it. RESULTS: About 70% of the COVID-19 hospitalizations in Brazil were covered by the SUS, which attended the more vulnerable population groups and had worse inpatient mortality. In general, non-SUS private and philanthropic hospitals, mostly reimbursed by healthcare insurance plans accessible for more privileged socioeconomic classes, presented the best outcomes. Southern Brazil had the best performance among the macro-regions. Black and indigenous individuals, residents of lower HDI municipalities, and those hospitalized out of their residence city presented higher odds of inpatient mortality. Moreover, adjusted inpatient mortality rates were higher in the pandemic peak moments and were significantly reduced after COVID-19 vaccination reaching a reasonable coverage, from July 2021. CONCLUSIONS: COVID-19 exposed socioeconomic and healthcare inequalities and the importance and weaknesses of SUS in Brazil. This work indicates the need to revert the disinvestment in the universal public system, a fundamental policy for reduction of inequities in the country.

The humoral and cellular immune responses following booster vaccination with SARS-CoV-2 mRNA in people living with human immunodeficiency virus. INTRODUCTION: People living with human immunodeficiency virus (PLWH) have higher mortality rates from COVID-19 than those without HIV. Additionally, the seroconversion rate of antibodies following a second dose of SARS-CoV-2 vaccine is lower in PLWH than non-infected individuals, indicating the need for booster vaccination. Here, we evaluated the humoral and cellular immune responses to booster SARS-CoV-2 vaccination in PLWH. METHODS: The dynamics of anti-spike IgG titers and antigen-specific interferon (IFN)-Î³ levels to SARS-CoV-2 vaccination were assessed over a 6-month period following a third vaccination of 34

PLWH. RESULTS: Antibody titers for humoral immunity were 50Â % lower at 24 weeks post-vaccination than those at 12 weeks. However, those at 24 weeks after the booster vaccination were approximately eight times higher than before. Regarding cellular immunity, IFN-Î³ levels at 24 weeks after the third vaccination were lower than those at 12 weeks, but nearly 90Â % of participants maintained a cut-off value of â‰¥0.15 IU/mL. A comparison between two groups with CD4(+) T lymphocytes counts of <500/Î¼L or â‰¥500/Î¼L exhibited no statistically significant differences in antibody or IFN-Î³ levels. However, in the group with CD4(+) T lymphocyte counts of <500/Î¼L, the rate of IFN-Î³ above the cut-off value at 24 weeks after the booster vaccination was lower than that of â‰¥500/Î¼L. CONCLUSION: An immune response is expected in PLWH given successful antiretroviral therapy with booster SARS-CoV-2 vaccination. However, caution should be exercised for cases with low CD4(+) T-lymphocyte counts. (240/250 words).

Effect of SARS-CoV-2 infection and vaccine on ovarian reserve: A systematic review. OBJECTIVE: To evaluate the effect of SARS-CoV-2 infection and vaccination on ovarian reserve. METHODS: Relevant articles were identified in the EMBASE, PubMed, and Web of Science databases from January 2020 to May 2023. Available clinical indicators of ovarian reserve, such as anti-MÃ¼llerian hormone (AMH), antral follicle count (AFC), follicle-stimulating hormone (FSH), and estradiol (E2), as well as the time interval from infection or vaccination to measurements, were assessed. RESULTS: Only 2 studies provided evidence that SARS-CoV-2 infection could damage ovarian function. In a comparison of the vaccinated and unvaccinated groups, although 1 prospective cohort study observed the transient statistically significant decrease on serum AMH levels at 3 or 6Â months of follow-up, serum AMH levels remained within the normal reserve range (>1.1Â ng/dl) throughout the study period. CONCLUSION: Overall, whether ovarian reserve may be affected by SARS-CoV-2 infection remains controversial and further investigations are warranted to clarify this issue. Based on the current evidence, it is safe to assume that COVID-19 vaccination does not exert any adverse effect on ovarian reserve parameters such as AMH, AFC, FSH, and E2, which will provide reassurance for women attempting to fall pregnant.

Effects of SARS-CoV-2 Vaccines on Sperm Quality: Systematic Review. BACKGROUND: The COVID-19 pandemic, caused by SARS-CoV-2, has triggered a global public health crisis of unprecedented proportions. SARS-CoV-2 vaccination is a highly effective strategy for preventing infections and severe COVID-19 outcomes. Although several studies have concluded that COVID-19 vaccines are unlikely to affect fertility, concerns have arisen regarding adverse events, including the potential impact on fertility; these concerns are plagued by limited and inconsistent evidence. OBJECTIVE: This review aims to provide a recent assessment of the literature on the impact of COVID-19 vaccines on male sperm quality. The possible impact of COVID-19 vaccines on fertility potential was also examined to draw a clearer picture and to evaluate the effects of COVID-19 on male reproductive health. METHODS: PubMed, Scopus, Web of Science, Embase, and Cochrane databases were searched from their inception to October 2023. Eligible studies included articles reporting SARS-CoV-2 vaccination and human semen quality and fertility, as well as the impact of vaccination on assisted reproductive technology treatment outcomes. The quality of cohort studies was assessed using the Newcastle-Ottawa Scale, and the quality of cross-sectional studies was assessed using the quality evaluation criteria recommended by the Agency for Healthcare Research and Quality. The systematic review followed PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. RESULTS: The initial literature search yielded 4691 records by searching 5 peer-reviewed databases (PubMed, Scopus, Web of Science, Embase, and Cochrane). Finally, 24 relevant studies were selected for our study. There were evident research inequalities at the regional level, with the United States and Western European countries contributing 38% (9/24) of the studies, Middle Eastern countries contributing 38% (9/24), China accounting for 21% (5/24), and Africa and South America accounting

for none. Nonetheless, the overall quality of the included studies was generally good. Our results demonstrated that serious side effects of the COVID-19 vaccine are extremely rare, and men experience few problems with sperm parameters or reproductive potential after vaccination. CONCLUSIONS: On the basis of the studies published so far, the COVID-19 vaccine is safe for male reproductive health. Obviously, vaccination is a wise option rather than experience serious adverse symptoms of viral infections. These instances of evidence may help reduce vaccine hesitancy and increase vaccination coverage, particularly among reproductive-age couples. As new controlled trials and prospective cohort studies with larger sample sizes emerge, the possibility of a negative effect of the COVID-19 vaccine on sperm quality must be further clarified.

Symptoms and steroid dose adjustments following the Covid-19 vaccine in patients with adrenal insufficiency. BACKGROUND: A proportion of patients with adrenal insufficiency (AI) require increases in their maintenance glucocorticoids following the Covid-19 vaccine as a result of vaccine-related symptoms or development of incipient or frank adrenal crisis. In a large cohort of AI patients, we aim to characterise symptoms, changes in glucocorticoid dosage, occurrence of adrenal crises and whether there are differences between the mRNA and adenovirus vector vaccines. PATIENTS AND METHODS: Patients with AI of any aetiology were invited to complete a short, structured questionnaire of their experience of the Covid-19 vaccination. RESULTS: 279 of the 290 patients enrolled to this study fully completed the questionnaires. 176, 100 and 3 received the Astra Zeneca (AZ), Pfizer-BioNTech (PB) and Moderna (MD) as initial vaccine respectively; and for the second vaccine, 170, 99 and 10 received AZ, PB and MD respectively. Moderate to severe symptoms occurred in 44.8 and 39.7% after the first and second vaccines respectively, were of early onset (6.0Â h, IQR 2-12 &. 6.0Â h, IQR 2-24Â h) and short duration (24Â h, IQR 12-72Â h & 26Â h, IQR 12-72Â h). 34.4 and 29.7% increased their maintenance glucocorticoid dose. DISCUSSION: The Covid-19 vaccines appear well-tolerated in patients with AI, with similar frequency of symptoms to that reported in the background population. The AZ vaccine leads to slightly greater post-vaccination symptom burden and need to increase glucocorticoid dosage, but this does not translate to greater adverse outcomes.

Miscarriage after SARS-CoV-2 vaccination: A population-based cohort study. OBJECTIVE: To evaluate the risk of miscarriage following SARS-CoV-2 vaccination, while accounting for the competing risk of induced abortion. DESIGN: Population-based cohort study. SETTING: Ontario, Canada. PARTICIPANTS: Women aged 15-50â€‰years with a confirmed pregnancy at â‰¤19 completed weeks' gestation. METHODS: Exposure to first SARS-CoV-2 vaccination, handled in a time-varying manner, was defined as (i) unvaccinated, (ii) remotely vaccinated >28â€‰days before the estimated conception date or (iii) recently vaccinated â‰¤28â€‰days before conception and up to 120â€‰days after conception. MAIN OUTCOME MEASURES: The outcome was miscarriage, occurring between the estimated date of conception and up to 19 completed weeks of pregnancy. Fine-Grey hazard models, accounting for the competing risk of induced abortion, generated hazard ratios (aHR), adjusted for socio-demographic factors, comorbidities, and biweekly periods. RESULTS: Included were 246â€‰259 pregnant women, of whom 34% received a first SARS-CoV-2 vaccination. Miscarriage occurred at a rate of 3.6 per 10â€‰000 person-days among remotely vaccinated women and 3.2 per 10â€‰000 person-days among those recently vaccinated, in contrast to a rate of 1.9 per 10â€‰000 person-days among unvaccinated women, with corresponding aHR of 0.98 (95% confidence interval [CI] 0.91-1.07) and 1.00 (95% CI 0.93-1.08). CONCLUSIONS: SARS-CoV-2 vaccination was not associated with miscarriage while accounting for the competing risk of induced abortion. This study reiterates the importance of including pregnant women in new vaccine clinical trials and registries, and the rapid dissemination of vaccine safety data.

Anti-NMDA Autoimmune Encephalitis Post-COVID-19 Vaccination in a Pediatric Patient: A Case Report. Post-coronavirus disease 2019 (COVID-19) vaccination encephalitis is rarely reported

particularly in the pediatric population. Herein, we report the first case of postvaccination anti-N-methyl-d-aspartate (NMDA) encephalitis in close temporal association with receiving COVID-19 vaccine in a pediatric patient. The patient is a 13-year-old female who received the first dose of the Pfizer-BioNTech COVID-19 vaccine and presented with subacute neurological and psychiatric symptoms and eventually confirmed the diagnosis of anti-NMDA autoimmune encephalitis. The patient recovered after receiving intravenous immunoglobulins and steroids.

Assessment of COVID-19 vaccine acceptance and its associated factors in Debre Berhan City, Ethiopia, 2022. BACKGROUND: The COVID-19 pandemic has spread over the world. The ability to achieve sufficient immunization coverage to end the global pandemic depends on the acceptance of the COVID-19 vaccine, but it has faced a major challenge around the world. In low-income and developing countries, 22.7% of the population has received at least one dose of the Covid-19 vaccine, which means that a large percentage of the population are unvaccinated, even though they have access to the Covid-19 vaccine so many countries do not accept the vaccine. The aim of this study was to assess COVID-19 vaccine acceptance and its associated factors in Debre Berhan City, Ethiopia, 2022. METHODS: A mixed-methods approach comprising both qualitative interviews and a quantitative survey was used among participants in Debre Berhan City. A multi-stage sampling technique was used to recruit the study participants. An in-depth interview was used for the qualitative data. Data was collected by a face-to-face interview questionnaire from June 08 to July 08, 2022. The collected data was entered using Epi Data version 4.6 and analyzed using SPSS version 25. Variables with a p-value less than 0.25 at Bivariable logistic regression analysis were entered into multivariable logistic regression analysis. Logistics regression was employed, and a p-value <0.05 was considered statistically significant. RESULT: A total of 765 participants were included in the study, with a response rate of 97.08%. More than half (52.9%) of the respondents had the willingness to accept the COVID-19 vaccine. Participants who had Contact with COVID-19 patient (AOR = 3.98; 95% CI: (1.30-12.14), having good knowledge of COVID-19 vaccine (AOR = 4.63; 95% CI: (1.84-11.63), and positive attitude toward the COVID-19 vaccine (AOR = 3.41; 95% CI: (1.34-8.69) were statistically significantly associated variables with COVID-19 vaccine acceptance. CONCLUSION AND RECOMMENDATION: The present study revealed that the acceptance COVID-19 vaccine was 52.9, and a significant proportion of participants were hesitant to receive the vaccine and refused to get vaccinated. Significantly associated Variables for COVID-19 vaccine acceptance were Contact with COVID-19 patient, having good knowledge of the COVID-19 vaccine, and having a positive attitude towards the COVID-19 vaccine. Various stakeholders to apprise the public about the cause of the disease and the scientific development of vaccine in order to enhance acceptance of the vaccine.

Understanding the implications of under-reporting, vaccine efficiency and social behavior on the post-pandemic spread using physics informed neural networks: A case study of China. In late 2019, the emergence of COVID-19 in Wuhan, China, led to the implementation of stringent measures forming the zero-COVID policy aimed at eliminating transmission. Zero-COVID policy basically aimed at completely eliminating the transmission of COVID-19. However, the relaxation of this policy in late 2022 reportedly resulted in a rapid surge of COVID-19 cases. The aim of this work is to investigate the factors contributing to this outbreak using a new SEIR-type epidemic model with time-dependent level of immunity. Our model incorporates a time-dependent level of immunity considering vaccine doses administered and time-post-vaccination dependent vaccine efficacy. We find that vaccine efficacy plays a significant role in determining the outbreak size and maximum number of daily infected. Additionally, our model considers under-reporting in daily cases and deaths, revealing their combined effects on the outbreak magnitude. We also introduce a novel Physics Informed Neural Networks (PINNs) approach which is extremely useful in estimating critical parameters and helps in evaluating the predictive capability of our model.

Superior neutralizing response after first versus second SARS-CoV-2 infection in fully vaccinated individuals. Currently, the majority of the population has been vaccinated against COVID-19 and/or has experienced SARS-CoV-2 infection either before or after vaccination. The immunological response to repeated episodes of infections is not completely clear. We measured SARS-CoV-2 specific neutralization titers by a pseudovirus assay after BA.1 infection and RBD-specific immunoglobulin G (IgG), immunoglobulin A (IgA), and immunoglobulin M (IgM) in a cohort of COVID-19 uninfected and triple vaccinated individuals (breakthrough infection group, BTI) as compared with those previously infected by SARS-CoV-2 (reinfection group, REI) who underwent identical vaccination schedule. SARS-CoV-2 specific neutralizing response after BA.1 infection was significantly higher in the BTI group as compared with the REI. Furthermore, neutralization titers in REI were not significant different from convalescent non reinfected controls. RBD-specific IgG and IgA, but not IgM, were also significantly higher in BTI as compared with REI. Our results show that the first episode of SARS-CoV-2 infection induces a significant increase in neutralizing titers in triple vaccinated individuals and that previous SARS-CoV-2 infection compromise significantly the neutralization response induced by reinfection, even by divergent SARS-CoV-2 variants and at least up to 2 years postinfection, suggesting a fundamental limitation in inducing effective booster through the intranasal route in previously infected individuals.

COVID-19 vaccine triggers autoimmune disease? Possible mechanism and current evidence.

Factors associated with the permission for child vaccination in the context of the COVID-19 pandemic. OBJECTIVE: To identify factors associated with permission for child vaccination in the context of the COVID-19 pandemic. METHOD: Cross-sectional study, with parents/guardians of children aged up to 1 year, 11 months and 29 days, aged 18 years or older, with internet access and residents of the state of Alagoas. The collection was conducted between June 2021 and April 2022, using a structured instrument via Google formsÂ®. Fisher's Exact and Pearson's chi-square statistical tests were used. RESULTS: A total of 94 parents/guardians participated. There was an association between permission for child vaccination during the COVID-19 pandemic and higher education level of parents/guardians, with the lack of an educational bond with the child, and between parents/guardians who would allow the application of the COVID-19 vaccine. CONCLUSION: Permission for child vaccination in the context of the COVID-19 pandemic was associated with higher education level of parents/guardians and the absence of educational bond of the child.

[Experiencia en la vacunaciÃ³n frente a la COVID-19 en personas con antecedentes de alergia.]. OBJECTIVE: A common consultation since the beginning of the vaccination campaign against COVID-19 was related to people with a history of allergy to drugs or other vaccines. The objective of the study was to describe what happened after the administration of the vaccine against COVID-19 in people with a history of moderate and severe allergy, vaccinated against COVID-19 in a Primary Care Emergency Center (PCEC). METHODS: Observational descriptive study with sixty-four people with a history of moderate and severe allergy was carried out, vaccinated in PCEP, between May and October 2021, in the BarcelonÃ©s Nord and Maresme (Barcelona province), after assessment by primary care pharmacologists and pharmacists. The percentage of people with adverse events that occurred after vaccination during their stay in the PCEP, the types detected and severity were calculated. Subsequently, a telephone survey was conducted to determine patient satisfaction. A descriptive analysis (calculation of proportions) was performed. RESULTS: The mean age of 49.7 years (from twelve to ninety-four years) and 90.6% were women. 87.5% of the administered vaccines were ComirnatyÂ®. Adverse events occurring after vaccination were detected in fifteen patients (23.4%), of whom four (6.25%) were manifestations of hypersensitivity, all classified as mild. The reasons for vaccination were a history of allergy to NSAIDs (45.3%), antibiotics (32.8%), analgesics (17.2%), vaccines (28.1%), other substances (40.6%) and anaphylaxis (26.6%). The degree of general

satisfaction was 9.11 (out of 10). CONCLUSIONS: The percentage of patients with a history of anaphylaxis and allergic drug reactions who present hypersensitivity reactions to COVID-19 vaccines is 6.25% and all are mild.

Hemophagocytic lymphohistiocytosis (HLH) after COVID-19 vaccination.

The Effect of Vit-D Supplementation on the Side Effect of BioNTech, Pfizer Vaccination and Immunoglobulin G Response Against SARS-CoV-2 in the Individuals Tested Positive for COVID-19: A Randomized Control Trial. BACKGROUND: Vitamin D participates in the biological function of the innate and adaptive immune system and inflammation. We aim to specify the effectiveness of the vitamin D supplementation on the side effects BioNTech, Pfizer vaccination, and immunoglobulin G response against severe acute respiratory syndrome coronavirus 2 in subjects tested positive for coronavirus disease 2019 (COVID-19). METHODS: In this multi-center randomized clinical trial, 498 people tested positive for COVID-19 were divided into 2 groups, receiving vitamin D capsules or a placebo (1 capsule daily, each containing 600 IU of vitamin D) over 14-16 weeks. Anthropometric indices and biochemical parameters were measured before and after the second dose of vaccination. RESULT: Fourteen to 16 weeks after supplementation, the intervention group had an immunoglobulin G (IgG) increase of 10.89 Â± 1.2 g/L, while the control group had 8.89 Â± 1.3 g/L, and the difference was significant between both groups (p = 0.001). After the second dose of vaccination, the supplement group significantly increased their 25-hydroxy vitamin D from initially 28.73 Â± 15.6 ng/mL and increased to 46.48 Â± 27.2 ng/mL, and the difference between them was significant. Those with a higher body mass index (BMI) had the most of symptoms, and the difference of side effects according to BMI level was significantly different. In 8 weeks after supplementation obese participants had the lowest IgG levels than overweight or normal subjects. The proportion of all types of side effects on the second dose was significantly diminished compared with the first dose in the intervention group. CONCLUSION: Supplementation of 600 IU of vitamin D3 can reduce post-vaccination side effects and increase IgG levels in participants who received BioNTech, Pfizer vaccine. TRIAL REGISTRATION: ClinicalTrials.gov Identifier: NCT05851313.

Adverse reactions in young children receiving the coronavirus disease 2019 vaccine. BACKGROUND: We sought to investigate the occurrence of adverse reactions in Japanese children aged 6â€‰months to 4â€‰years who received the BNT162b2 coronavirus disease 2019 (COVID-19) vaccine, to examine parental considerations, and to evaluate potential risk factors associated with post-vaccination fever. METHODS: This cross-sectional survey study targeted 1617 children aged 6â€‰months to 4â€‰years who received their primary doses of BNT162b2 from November 10, 2022, to April 30, 2023, in Okayama Prefecture. We surveyed the occurrence of local and systemic reactions within 1â€‰week after vaccination, and described the incidence proportions of adverse reactions for 515 participants overall and by age group. The study also examined the impact of previous COVID-19 infection and co-administration of the seasonal influenza vaccine on post-vaccination fever. A survey also assessed parents' reasons for vaccinating their children and the sources of information they used. RESULTS: Adverse reactions were infrequent (5.2%, with fever â‰¥37.5Â°C; no cases exceeded 39Â°C) and did not increase with vaccine doses administered. The risk of post-vaccination fever was not statistically associated with a history of COVID-19-the adjusted risk ratio (aRR) was 0.99, and the 95% confidence interval (CI) was 0.41-2.39-but was associated with co-administration of the seasonal influenza vaccine (aRR 3.24, 95% CI 1.14-9.18). Parental decisions regarding vaccination were influenced by official government guidelines and primary care physicians' opinion. CONCLUSION: This study provides valuable insight into the safety profile of the BNT162b2 vaccine in Japanese children aged 6â€‰months to 4â€‰years. Further research involving larger cohorts and appropriate control groups is needed.

Sudden Death Is More Likely to Result From SARS-COV-2 Infection Than Multiple Sclerosis.

Immune thrombocytopenic purpura in an elderly patient with cerebral hemorrhage after the fourth mRNA-1273 COVID-19 vaccination.

Immunogenicity and Safety of a SARS-CoV-2 Inactivated Vaccine KCONVAC in Chinese Children: Randomized, Double-blind, Placebo-controlled Phase 1 and 2 Trials. BACKGROUND: It is important to extend the indication of severe acute respiratory syndrome coronavirus 2 vaccine to children to improve the vaccine intake rate and reduce infection in this population. METHODS: In 2 phase 1 and phase 2 randomized, double-blind and placebo-controlled trials, 84 and 480 Chinese healthy children 3 to 17 years old were enrolled, respectively, and randomized in 3:1 ratio to receive 2 doses of a severe acute respiratory syndrome coronavirus 2 inactivated vaccine, KCONVAC or placebo. The 2 doses were given 28 days apart. Adverse events (AEs) were recorded through Day 28 after each dosing. Live virus neutralizing antibody and receptor binding domain antibody (RBD-IgG) were tested before vaccination and after the second dose. RESULTS: Two doses of the vaccine, KCONVAC, elicited geometric mean titers of 142-150 for neutralizing antibody and 4154-4253 for RBD-IgG 28 days after the second dose. Seroconversion rates were 100% after 2 doses for both antibodies in both trials. The predominant AEs were injection-site pain, cough and fever. Most AEs were grade 1 or 2 in intensity. Five participants reported 6 vaccination-unrelated serious AEs in the phase 2 trial. CONCLUSIONS: Two doses of this study vaccine, KCONVAC, were well tolerated and immunogenic in children 3 to 17 years of age.

Comparison of anti-nucleocapsid antibody assays for the detection of SARS-CoV-2 Omicron vaccine breakthroughs after various intervals since the infection. Antibody assays with the nucleocapsid (NC) protein as the target antigen can identify severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections when polymerase chain reaction (PCR) analyses are unavailable. Regarding the kinetics of NC-specific antibodies, vaccine breakthroughs with Omicron subvariants may differ from infections with the ancestral wild-type virus. Therefore, we evaluated which assays have the highest sensitivity for detecting NC-specific antibodies after various intervals since breakthrough infections with an Omicron subvariant. The study included 279 samples from vaccinated subjects who experienced PCR-confirmed Omicron breakthrough infections between 21 and 266 days before sampling. The samples were comparatively assessed with the ElecsysÂ® Anti-SARS-CoV-2 N (Roche), the Anti-SARS-CoV-2-NCP-ELISA (Euroimmun), the recomLine SARS-CoV-2 IgG (Mikrogen), and the SARS-CoV-2 ViraChip IgG assays (Viramed). In the whole cohort, the ElecsysÂ® Anti-SARS-CoV-2 N assay displayed the highest sensitivity (93%, pâ€‰<â€‰0.0001), followed by the recomLine SARS-CoV-2 IgG assay (70%), the SARS-CoV-2 ViraChip IgG assay (41%) and the Anti-SARS-CoV-2-NCP-ELISA (35%). Although measured antibody levels and time-dependent sensitivities differed, the extent of the antibody decrease was similar among all assays. As demonstrated by this study, manufacturer-dependent differences in the sensitivities of NC-specific antibody assays should be considered when serology is applied to link previous SARS-CoV-2 infections with potential post-COVID sequelae.

Dysmenorrhea, intermenstrual bleeding, menstrual flow volume changes, and irregularities following COVID-19 vaccination and the association with vaccine skepticism: A retrospective observational study. BACKGROUND: COVID-19 vaccines have provided fertile ground for research, especially with the unprecedented spread of misinformation about this disease and its vaccines. Among women, one of the most frequently reported side effects of the vaccine has been menstrual disturbance. OBJECTIVE: To investigate the perceived impact of COVID-19 vaccines on the menstrual cycle. In addition, the research seeks to identify factors that could predispose certain individuals to experience these effects, thereby contributing to a deeper understanding of the interplay between vaccines and menstrual health. DESIGN: We conducted a retrospective observational cross-sectional study. METHODS: Any woman of menstruating age who received at least one dose of the COVID-19 vaccine and currently resides in Saudi Arabia was invited to complete an online questionnaire. The

questionnaire compared menstruation characteristics-regularity, volume, intermenstrual bleeding, and dysmenorrhea-before and after receiving the COVID-19 vaccine, taking into consideration possible predisposing factors such as polycystic ovarian syndrome, contraceptives, or period-blocking pills. RESULTS: Women without polycystic ovarian syndrome experienced less change in dysmenorrhea post-vaccine compared to those with polycystic ovarian syndrome (23.88% versus 37.78%, pâ€‰=â€‰0.045). Women using hormonal contraceptives were about two times more likely to experience changes in volume compared to those not using contraceptives (odds ratioâ€‰=â€‰2.09, 95% confidence interval = 1.23-3.57, pâ€‰=â€‰0.006). COVID-19 vaccine skeptics were about three times more likely to perceive changes in regularity post-vaccine compared to non-skeptics (odds ratioâ€‰=â€‰2.96, 95% confidence interval = 1.79-4.90, pâ€‰<â€‰0.001). They were also three times more likely to perceive changes in volume post-vaccine (odds ratioâ€‰=â€‰3.04, 95% confidence intervalâ€‰=â€‰1.95-4.74, pâ€‰<â€‰0.001). CONCLUSION: Our data suggest significant associations between COVID-19 skepticism, the use of hormonal contraceptives, and the reported post-vaccine menstrual disturbances. This underscores the importance of public education efforts aimed at dispelling misinformation and addressing controversies related to these vaccines.

Analysis of a comprehensive dataset: Influence of vaccination profile, types, and severe acute respiratory syndrome coronavirus 2 re-infections on changes in sports-related physical activity one month after infection. This dataset was created with the primary objective of elucidating the intricate relationship between the incidence of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) re-infections and the pre-illness vaccination profile and types concerning alterations in sports-related physical activity (PA) after SARS-CoV-2 infection among adults. A secondary objective encompassed a comprehensive statistical analysis to explore the influence of three key factors-namely, Vaccination profile, Vaccination types, and Incidence of SARS-CoV-2 re-infections-on changes in PA related to exercise and sports, recorded at two distinct time points: one to two weeks prior to infection and one month after the last SARS-CoV-2 infection. The sample population (n = 5829), drawn from Hellenic territory, adhered to self-inclusion and exclusion criteria. Data collection spanned from February to March 2023 (a two-month period), involving the utilization of the Active-Q (an online, interactive questionnaire) to automatically assess weekly habitual sports-related PA among adults both before and after their last SARS-CoV-2 infection. The questionnaire also captured participant characteristics, pre-illness vaccination statuses (i.e., unvaccinated, partially vaccinated, fully vaccinated, and vaccine types), and occurrences of SARS-CoV-2 re-infections. The dataset sheds light on two noteworthy phenomena: (i) the intricate interplay between post-acute SARS-CoV-2 infection and a decline in sports-related physical activity (-27.6 Â± 0.6%, 95%CI: -26.1 - -29.1), influenced by the pre-illness vaccination profile factor (p = 0.040); and (ii) the divergence in sports-related physical activity decline between partially vaccinated (-38.2 Â± 0.7%, 95%CI: -35.3 - -41.1, p = 0.031) and fully vaccinated respondents (-19.2 Â± 0.5%, 95%CI: -17.2 - -21.2). These phenomena underscore the imperative for tailored interventions and further investigation to promote the resumption of physical activity and mitigate long-term repercussions. Furthermore, this dataset enriches our understanding of the dynamics of sports-related physical activity and provides valuable insights for public health initiatives aiming to address the consequences of COVID-19 on sports-related physical activity levels. Consequently, this cross-sectional dataset is amenable to a diverse array of analytical methodologies, including univariate and multivariate analyses, and holds potential relevance for researchers, leaders in the sports and medical sectors, and policymakers, all of whom share a vested interest in fostering initiatives directed at reinstating physical activity and mitigating the enduring ramifications of post-acute SARS-CoV-2 infection.

Adhesive capsulitis following COVID-19 vaccination: a case report and review of literature. Shoulder injury related to vaccine administration (SIRVA) has been frequently reported adverse event following COVID-19 vaccination. Multiple studies have reported various injuries including subacromial bursitis, rotator cuff tears, nerve injury, and most commonly, adhesive capsulitis. Adhesive capsulitis is defined as an inflammatory disease of the joint capsule characterized by pain and stiffness. Herein, we present a case of a 38-year-old female, known to have uncontrolled diabetes mellites and asthma, presented to upper extremity orthopedic clinic complaining of 6Â months history of left shoulder pain and limited range of motion following COVID-19 vaccination administration. Clinical examination and radiological studies were consistent with adhesive capsulitis, the patient was then referred for intensive rehabilitation program that provided adequate response. In conclusion, the main etiology of SIRVA has been attributed to suboptimal injection technique, a standardized definition, implementation of safe vaccines injection protocols, and further education and awareness of SIRVA is needed to healthcare practitioners to allow better understanding and prevention.

Vaccine-induced SARS-CoV-2 antibody response: the comparability of S1-specific binding assays depends on epitope and isotype discrimination. BACKGROUND: Quantification of the SARS-CoV-2-specific immune response by serological immunoassays is critical for the management of the COVID-19 pandemic. In particular, neutralizing antibody titers to the viral spike (S) protein have been proposed as a correlate of protection (CoP). The WHO established the First International Standard (WHO IS) for anti-SARS-CoV-2 immunoglobulin (Ig) (NIBSC 20/136) to harmonize binding assays with the same antigen specificity by assigning the same unitage in binding antibody units (BAU)/ml. METHOD: In this study, we analyzed the S1-specific antibody response in a cohort of healthcare workers in Germany (n = 76) during a three-dose vaccination course over 8.5 months. Subjects received either heterologous or homologous prime-boost vaccination with ChAdOx1 nCoV-19 (AstraZeneca) and BNT162b2 (Pfizer-BioNTech) or three doses of BNT162b2. Antibodies were quantified using three anti-S1 binding assays (ELISA, ECLIA, and PETIA) harmonized to the WHO IS. Serum levels of neutralizing antibodies were determined using a surrogate virus neutralization test (sVNT). Binding assays were compared using Spearman's rank correlation and Passing-Bablok regression. FINDINGS: All assays showed good correlation and similar antibody kinetics correlating with neutralizing potential. However, the assays show large proportional differences in BAU/ml. ECLIA and PETIA, which detect total antibodies against the receptor- binding domain (RBD) within the S1 subunit, interact similarly with the convalescent plasma-derived WHO IS but differently with vaccine serum, indicating a high sensitivity to the IgG/IgM/IgA ratio. CONCLUSION: All three binding assays allow monitoring of the antibody response in COVID-19-vaccinated individuals. However, the assay-specific differences hinder the definition of a common protective threshold in BAU/ml. Our results highlight the need for the thoughtful use of conversion factors and consideration of method-specific differences. To improve the management of future pandemics and harmonize total antibody assays, we should strive for reference material with a well-characterized Ig isotype composition.

Sequential cellular and humoral responses after repetitive COVID-19 vaccination in patients treated with anti-CD20 antibodies. Patients treated with anti-CD20 antibodies for haematological disorders have insufficient immune responses to mRNA COVID-19 vaccines; however, relevant sequential data are lacking. We sequentially evaluated the humoral and cellular immune responses in 22 patients who had received anti-CD20 antibodies within 12â€‰months before the first vaccination, before and after the third and fourth vaccinations. Humoral responses improved gradually, along with the resolution of B-cell depletion. A steady increase was noted in cellular responses, regardless of the B-cell status. Our findings suggest the potential benefit of repeated vaccinations in these patients until B-cell recovery is confirmed while enhancing cellular responses.

Comparison of post-COVID-19 vaccination hypermetabolic lymphadenopathy on (18)F-fluorodeoxyglucose PET/CT between virus-vector vaccine and mRNA vaccine. PURPOSE: We compared hypermetabolic lymphadenopathy (HLN) on (18)F-fluorodeoxyglucose (FDG) positron emission tomography (PET)/computed tomography (CT) after virus-vector and mRNA vaccines for coronavirus disease 2019 (COVID-19). METHODS: This retrospective study included 573 participants who underwent FDG PET/CT after receiving a virus-vector vaccine (ChAdOx1, AstraZeneca [AZ] group) or an mRNA vaccine (mRNA-1273, Moderna [M] group) from July 2021 to October 2021. The incidence and avidity of HLN were evaluated and correlated with clinical features and vaccine type. The final analysis was conducted with 263 participants in the AZ group and 310 participants in the M group. RESULTS: The HLN incidence was significantly lower in the AZ group than in the M group (38/263 [14%] vs. 74/310 [24%], pâ€‰=â€‰0.006). The FDG avidity of HLN was comparable between the two groups. The HLN incidence in both groups was significantly higher within 4Â weeks after the vaccination compared with more than 4Â weeks. The HLN incidence within 4Â weeks of the vaccination was significantly higher in the M group than in the AZ group (pâ€‰=â€‰0.008), whereas a difference in HLN incidence between the two groups was not observed after the same duration (pâ€‰=â€‰0.11). CONCLUSIONS: The mRNA mRNA-1273 COVID-19 vaccine was found to be associated with higher glucose hypermetabolism in regional lymph nodes within the first 4Â weeks compared with the virus-vector vaccine, as indicated by the presence of HLN on FDG PET/CT. The degree of glucose hypermetabolism was comparable between the two vaccines.

Weak SARS-CoV-2-specific responses of TIGIT-expressing CD8 + T cells in people living with HIV after a third dose of a SARS-CoV-2 inactivated vaccine. BACKGROUND: T-cell immunoreceptor with immunoglobulin and immunoreceptor tyrosine-based inhibition motif domains (TIGIT), an inhibitory receptor expressed on T cells, plays a dysfunctional role in antiviral infection and antitumor activity. However, it is unknown whether TIGIT expression on T cells influences the immunological effects of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) inactivated vaccines. METHODS: Forty-five people living with HIV (PLWH) on antiretroviral therapy (ART) for more than two years and 31 healthy controls (HCs), all received a third dose of a SARS-CoV-2 inactivated vaccine, were enrolled in this study. The amounts, activation, proportion of cell subsets, and magnitude of the SARS-CoV-2-specific immune response of TIGIT + CD4 + and TIGIT + CD8 + T cells were investigated before the third dose but 6 months after the second vaccine dose (0W), 4 weeks (4W) and 12 weeks (12W) after the third dose. RESULTS: Compared to that in HCs, the frequency of TIGIT + CD8 + T cells in the peripheral blood of PLWH increased at 12W after the third dose of the inactivated vaccine, and the immune activation of TIGIT + CD8 + T cells also increased. A decrease in the ratio of both T naÃ¯ve (T N) and central memory (T CM) cells among TIGIT + CD8 + T cells and an increase in the ratio of the effector memory (T EM) subpopulation were observed at 12W in PLWH. Interestingly, particularly at 12W, a higher proportion of TIGIT + CD8 + T cells expressing CD137 and CD69 simultaneously was observed in HCs than in PLWH based on the activation-induced marker assay. Compared with 0W, SARS-CoV-2-specific TIGIT + CD8 + T-cell responses in PLWH were not enhanced at 12W but were enhanced in HCs. Additionally, at all time points, the SARS-CoV-2-specific responses of TIGIT + CD8 + T cells in PLWH were significantly weaker than those of TIGIT - CD8 + T cells. However, in HCs, the difference in the SARS-CoV-2-specific responses induced between TIGIT + CD8 + T cells and TIGIT - CD8 + T cells was insignificant at 4W and 12W, except at 0W. CONCLUSIONS: TIGIT expression on CD8 + T cells may hinder the T-cell immune response to a booster dose of an inactivated SARS-CoV-2 vaccine, suggesting weakened resistance to SARS-CoV-2 infection, especially in PLWH. Furthermore, TIGIT may be used as a potential target to increase the production of SARS-CoV-2-specific CD8 + T cells, thereby enhancing the effectiveness of vaccination.

Axillary lymph nodes enlargement after Sars-CoV-2 vaccine in patients undergoing breast examination: comment.

Differences and similarities between COVID-19 related-headache and COVID-19 vaccine related-headache. A case-control study. INTRODUCTION: Headache is a frequent symptom at the acute phase of coronavirus disease 2019 (COVID-19) and also one of the most frequent adverse effects following vaccination. In both cases, headache pathophysiology seems linked to the host immune response and could have similarities. We aimed to compare the clinical phenotype and the frequency and associated onset symptoms in patients with COVID-19 related-headache and COVID-19 vaccine related-headache. SUBJECTS AND METHODS: A case-control study was conducted. Patients with confirmed COVID-19 infection and COVID-19-vaccine recipients who experienced new-onset headache were included. A standardised questionnaire was administered, including demographic variables, prior history of headaches, associated symptoms and headache-related variables. Both groups were matched for age, sex, and prior history of headache. A multivariate regression analysis was performed. RESULTS: A total of 238 patients fulfilled eligibility criteria (143 patients with COVID-19 related-headache and 95 subjects experiencing COVID-19 vaccine related-headache). Patients with COVID-19 related-headache exhibited a higher frequency of arthralgia, diarrhoea, dyspnoea, chest pain, expectoration, anosmia, myalgia, odynophagia, rhinorrhoea, cough, and dysgeusia. Further, patients with COVID-19 related-headache had a more prolonged daily duration of headache and described the headache as the worst headache ever experienced. Patients with COVID-19 vaccine-related headache, experienced more frequently pain in the parietal region, phonophobia, and worsening of the headache by head movements or eye movements. CONCLUSION: Headache caused by SARS-CoV-2 infection and COVID-19 vaccination related-headache have more similarities than differences, supporting a shared pathophysiology, and the activation of the innate immune response. The main differences were related to associated symptoms.

SARS-CoV-2 Vaccination can Only Be Held Responsible for Small Fiber Neuropathy if all Differential Diagnoses Are Excluded.

Association between sex hormones and anti-S/RBD antibody responses to COVID-19 vaccines in healthcare workers. Healthcare workers (HCWs) are the target population for vaccination against coronavirus disease (COVID-19) as they are at a high risk of exposure and transmission of pathogens to patients. Neutralizing antibodies developed after COVID-19 vaccination decline within few months of vaccination. Several factors, including age and sex, can affect the intensity, efficacy, and duration of immune response to vaccines. However, sex-specific analyses of humoral responses to COVID-19 vaccines are lacking. This study aimed to evaluate sex-based differences in anti-S/RBD (Receptor Binding Domain) responses at three different time points after the second dose of mRNA COVID-19 vaccine in HCWs in relation to age, and to investigate the role of sex hormones as potential markers of response. Anti-S/RBD levels after two doses of the mRNA vaccine were collected from 521 HCWs naÃ¯ve to COVID-19, working at two Italian Clinical Centers. Multiple regression analysis was applied to evaluate the association between anti-S levels and sex, age, and plasma levels of sex hormones. Significantly higher anti-S/RBD response to the COVID-19 vaccination was found in female HCWs, and a significant and more abrupt decline in response with time was observed in women than that in men. A novel, positive association of testosterone plasma levels and higher anti-S levels in male HCWs was found, suggesting its potential role as sex specific marker in males. In conclusion, understanding the sex-based differences in humoral immune responses to vaccines may potentially improve vaccination strategies and optimize surveillance programs for HCWs.

Erythrodermic pityriasis rubra pilaris following SARS-CoV-2 vaccination treated with bimekizumab.

Evaluation of Humoral Response following SARS-CoV-2 mRNA-Based Vaccination in Liver Transplant Recipients Receiving Tailored Immunosuppressive Therapy. Background: The role of tailored

immunosuppression (IS) in the development of the humoral response (HR) to SARS-CoV-2 mRNA-based vaccination in liver transplant (LT) recipients is unknown. Methods: This is a single-centre prospective study of patients who underwent LT between January 2015 and December 2021 and who have received three doses of mRNA-based SARS-CoV-2 vaccination. Patients undergoing Tacrolimus-based immunosuppression (TAC-IS) were compared with those undergoing Everolimus-based immunosuppression (EVR-IS). Patients receiving the TAC-EVR combination were divided into two groups based on trough TAC concentrations, i.e., above or below 5 ng/mL. HR (analysed with ECLIA) was assessed at 30 to 135 days after vaccination. The primary outcome was the presence of a positive antibody titre (â‰¥0.8 U/mL). Secondary outcomes were the presence of a highly protective antibody titre (â‰¥142 U/mL), median antibody titre, and incidence of COVID-19. Results: Sixty-one participants were included. Twenty-four (40%) were receiving TAC-IS and thirty-seven (60%) were receiving EVR-IS. At the median follow-up of 116 (range: 89-154) days, there were no significant differences in positive antibody titre (95.8% vs. 94.6%; p = 0.8269), highly-protective antibody titre (83.3% vs. 81.1%; p = 0.8231), median antibody titre (2410 [IQ range 350-2500] vs. 1670 [IQ range 380-2500]; p = 0.9450), and COVID-19 incidence (0% vs. 5.4%; p = 0.5148). High serum creatinine and low estimated glomerular filtration rate were risk factors for a weak or absent HR. Conclusions: Three doses of mRNA-based SARS-CoV-2 vaccination yielded a highly protective HR in LT recipients. The use of TAC or EVR-based IS does not appear to influence HR or antibody titre, while renal disease is a risk factor for a weak or null HR.

Safety and immunogenicity of the third and fourth doses of vaccine against SARS-CoV-2 following a 2-dose regimen of inactivated whole-virion SARS-CoV-2 vaccine. This study followed healthcare personnel (HCP) who had completed a primary series of CoronaVac and then received the third and fourth doses of COVID-19 vaccine. The primary objective was to determine the seroconversion rate of neutralizing antibodies against wild-type SARS-CoV-2 and VOCs at day 28 after the third dose of vaccine and day 28 after the fourth dose of vaccine. This prospective cohort study was conducted at Maharaj Nakorn Chiang Mai Hospital, a tertiary care hospital affiliated to Chiang Mai University from July 2021 to February 2022. Two hundred and eighty-three participants were assessed for eligibility; 142 had received AZD1222 and 141 BNT162b2 as the third dose. Seroconversion rates using a 30% inhibition cutoff value against wild-type SARS-CoV-2 were 57.2%, 98.6%, 97.8%, and 98.9% at points before and after the third dose, before and after the fourth dose, respectively among those receiving AZD1222 as the third dose. Frequencies were 31.9%, 99.3%, 98.9%, and 100% among those receiving BNT162b2 as the third dose, respectively. The seroconversion rates against B.1.1.529 [Omicron] were 76.1% and 90.2% (p-value 0.010) at 4Â weeks after the third dose in those receiving AZD1222 and BNT162b2 as the third dose, respectively. After a booster with the mRNA vaccine, the seroconversion rates increased from 21.7 to 91.3% and from 30.4 to 91.3% in those receiving AZD1222 and BNT162b2 as the third dose, respectively. No serious safety concerns were found in this study. In conclusion, antibody responses waned over time regardless of the vaccine regimen. The booster dose of the vaccine elicited a humoral immune response against SARS-CoV-2 including SARS-CoV-2 variants of concern, including B.1.1.529 [Omicron], which was circulating during the study period. However, the results might not be extrapolated to other Omicron sublineages.

Clinical course and follow-up of pediatric patients with COVID-19 vaccine-associated myocarditis compared to non-vaccine-associated myocarditis within the prospective multicenter registry-"MYKKE". BACKGROUND: Since the onset of widespread COVID-19 vaccination, increased incidence of COVID-19 vaccine-associated myocarditis (VA-myocarditis) has been noted, particularly in male adolescents. METHODS: Patients <18 years with suspected myocarditis following COVID-19 vaccination within 21 days were enrolled in the PedMYCVAC cohort, a substudy within the prospective multicenter registry for pediatric myocarditis "MYKKE." Clinical data at initial admission,

3- and 9-months follow-up were monitored and compared to pediatric patients with confirmed non-vaccine-associated myocarditis (NVA-myocarditis) adjusting for various baseline characteristics. RESULTS: From July 2021 to December 2022, 56 patients with VA-myocarditis across 15 centers were enrolled (median age 16.3 years, 91% male). Initially, 11 patients (20%) had mildly reduced left ventricular ejection fraction (LVEF; 45%-54%). No incidents of severe heart failure, transplantation or death were observed. Of 49 patients at 3-months follow-up (median (IQR) 94 (63-118) days), residual symptoms were registered in 14 patients (29%), most commonly atypical intermittent chest pain and fatigue. Diagnostic abnormalities remained in 23 patients (47%). Of 21 patients at 9-months follow-up (259 (218-319) days), all were free of symptoms and diagnostic abnormalities remained in 9 patients (43%). These residuals were mostly residual late gadolinium enhancement in magnetic resonance imaging. Patients with NVA-myocarditis (n=108) more often had symptoms of heart failure (PÂ =Â .003), arrhythmias (PÂ =Â .031), left ventricular dilatation (PÂ =Â .045), lower LVEF (P < .001) and major cardiac adverse events (PÂ =Â .102). CONCLUSIONS: Course of COVID-19 vaccine-associated myocarditis in pediatric patients seems to be mild and differs from non-vaccine-associated myocarditis. Due to a considerable number of residual symptoms and diagnostic abnormalities at follow-up, further studies are needed to define its long-term implications.
SARS-CoV-2 vaccination complicated by small fiber neuropathy, mast cell activation syndrome, and pericarditis.
COVID-19 Vaccination-related Complex Regional Pain Syndrome Masquerading as Erythromelalgia: A Case Report.
Thrombotic Thrombocytopenic Purpura Following Pfizer-BioNTech COVID-19 Vaccination in a Patient With Multiple Myeloma: Case Report and Literature Review. The vaccines developed to prevent infection and mitigate morbidity and mortality in patients with COVID-19 demonstrated high efficacy in clinical trials but were associated with adverse events, most of which were mild and transient. However, some adverse events were rather serious, with grave prognoses. Of note, a few cases of autoimmune hematological conditions such as thrombotic thrombocytopenic purpura (TTP), immune thrombocytopenic purpura (ITP), and vaccine-induced immune thrombotic thrombocytopenia (VITT) were reported. TTP following Pfizer-BioNTech mRNA vaccination is exceptionally rare, with very scant literature. This case report describesÂ an interesting case of a 61-year-old woman who presented 22 days after receiving the third dose of the Pfizer-BioNTech mRNA COVID-19 vaccine with malaise, bloody stools, and jaundice. Her medical history was significant forÂ multiple myeloma previously treated with autologous bone marrow transplant andÂ in remission with chemotherapy. She also had a history of chronic heart failure with preserved ejection fraction (HFpEF) and neuropathy treated with daily vitamins.Â The diagnosis was predicted by her classic presentation and was clinched by low ADAMTS13 activity. She was treated with plasmapheresis, steroids, and monoclonal antibodies. Intriguingly, her hospital stay was further complicated by an episode of generalized tonic-clonic seizure requiring intubation and mechanical ventilation for airway protection. Albeit infrequent, COVID-19 vaccine-associated TTP is associated with substantial morbidity and mortality. Hence, early diagnosis and treatment are essential in patients presenting with thrombocytopenia after COVID-19 vaccination.
Mondor's disease following the third dose of BNT162b2 m-RNA COVID-19 vaccine.
Longevity of the humoral and cellular responses after SARS-CoV-2 booster vaccinations in immunocompromised patients. We assessed the humoral and cellular immune responses after two booster mRNA vaccine administrations [BNT162b2 (Pfizer-BioNTech vaccine)] in cohorts of immunocompromised patients (nâ€‰=â€‰199) and healthy controls (HC) (nâ€‰=â€‰54). All patients living with HIV (PLWH) and chronic kidney disease (CKD) patients and almost all (98.2%) of the primary immunodeficiency (PID) patients had measurable antibodies 3 and 6Â months after

administration of the third and fourth vaccine dose, comparable to the HCs. In contrast, only 53.3% and 83.3% of the multiple sclerosis (MS) and rheumatologic patients, respectively, developed a humoral immune response. Cellular immune response was observed in all PLWH after administration of four vaccine doses. In addition, cellular immune response was positive in 89.6%, 97.8%, 73.3% and 96.9% of the PID, MS, rheumatologic and CKD patients, respectively. Unlike the other groups, only the MS patients had a significantly higher cellular immune response compared to the HC group. Administration of additional vaccine doses results in retained or increased humoral and cellular immune response in patients with acquired or inherited immune disorders.

Factors associated with uptake of bivalent mRNA COVID-19 vaccines in a large US health care system. BACKGROUND: Bivalent mRNA COVID-19 vaccines were developed to provide protection against the original SARS-CoV-2 strain and Omicron BA.4/BA.5 variants, but uptake in the United States has been low. Sociodemographic disparities in COVID-19 vaccine uptake have been documented, but it is unclear if similar disparities persist among individuals who previously completed a primary series of monovalent COVID-19 vaccine. METHODS: We conducted a retrospective cohort study at Kaiser Permanente Southern California (KPSC) including youth aged 5-17Â years and adults agedÂ â‰¥18Â years who were KPSC members and had completed a primary series of monovalent COVID-19 vaccine. Individuals were followed from index date (date of eligibility for bivalent vaccine) to 03/31/2023 to ascertain receipt of any dose of bivalent mRNA COVID-19 vaccine or until disenrollment from KPSC or death. Multivariable robust Poisson regression was conducted to assess the adjusted relative risk and 95Â % confidence intervals of factors associated with receipt of bivalent vaccine. RESULTS: The final cohorts included 305,339 youth and 2,534,619 adults, of whom 19.5Â % and 30.7Â %, respectively, had received bivalent COVID-19 vaccine. Factors associated with being more likely to receive bivalent COVID-19 vaccine included older age, Asian race, more prior year outpatient and virtual visits, Charlson scoreÂ â‰¥1, and immunocompromised status. Factors associated with being less likely to receive a bivalent COVID-19 vaccine included age 12-17 vs 5-11Â years, Hispanic and non-Hispanic Black race/ethnicity, â‰¥1 prior year inpatient or emergency department visits, prior history of SARS-CoV-2 infection (adults only), Medicaid insurance, and higher neighborhood deprivation index. CONCLUSION: Even among youth and adults who had previously received a primary series of monovalent COVID-19 vaccine, sociodemographic and clinical disparities were observed in receipt of bivalent COVID-19 vaccine. These findings are critical to inform equitable strategies for the implementation of the updated monovalent COVID-19 vaccine targeting the Omicron XBB strain.

Willingness to receive and recommend hypothetical mpox vaccination and associated factors in Chinese adults: a community-based survey in Shenzhen, China. OBJECTIVES: China may face new threats to public health due to the increased risk of imported mpox (monkeypox) cases. However, research gaps exist in the acceptance of mpox vaccination and potential associated factors in the Chinese population. STUDY DESIGN: We conducted a cross-sectional study targeting community residents in Shenzhen, China, from August 5 to September 7 2022. METHODS: A self-administered questionnaire was used to collect information about demographic and health characteristics, mpox-related perceptions, and attitudes towards mpox vaccination. Multivariable logistic regression models were applied to detect the factors associated with willingness to receive and recommend mpox vaccination. RESULTS: A total of 2293 community residents were included in the analyses (average age: 34.03, female: 72.6%). Among the participants, 76.9% were aware of mpox, 62.1% were aware of the global mpox outbreak, but only 53.6% had a high knowledge level of mpox. Males had a higher proportion of high knowledge (56.9% vs 52.3%, Pï¼œ0.05) and a lower proportion of high worry (30.2% vs 45.4%, Pï¼œ0.05) than females. Approximately 69.1% of the participants were willing to vaccinate against mpox, and 69.6% were willing to recommend mpox vaccination to people around

them, in which no gender difference was found. The obstacle reported most among people hesitant to receive vaccination was concerning the safety and side-effects, whereas it changed to be concerning the suitability due to individual health differences among people hesitant to recommend mpox vaccines. Factors associated with the willingness to receive and recommend mpox vaccination included having a history of influenza vaccination, having a history of COVID-19 vaccination, being aware of the global mpox outbreak, having a high knowledge level of mpox, and having a high level of mpox-related worry. CONCLUSIONS: This study identified a moderate willingness to receive and recommend mpox vaccination among Chinese adults. Without gender differences, willingness to receive and recommend mpox vaccination was significantly associated with mpox-related perceptions, such as awareness, knowledge, and worry. Authoritative and up-to-date information is needed to help the general population improve public confidence in mpox vaccines in China.

COVID-19 vaccination attitudes, values, intentions: US parents for their children, September 2021. OBJECTIVES: To compare vaccine-related attitudes and values of parents of children 2-17Â years old to other adults, examine intentions to vaccinate their children, and identify factors associated with intending to vaccinate children. METHODS: A nationally representative survey was conducted in September 2021 (just before the EUA for children 5-11Â years old) using Ipsos KnowledgePanel, a probability-based web panel. The survey measured COVID-19 vaccination status, intentions, attitudes, values, and trust in public health authorities among US adults. Scale response options to survey items were dichotomized, and cross-tabulations and logistic regressions were performed. RESULTS: Parents had lower odds of reporting being vaccinated against COVID-19 than other adults even after adjusting for associated sociodemographic characteristics such as age (aOR: 0.66; 95Â %CI: 0.50-0.87). The most prevalent parental concerns about COVID-19 vaccines included the speed of their development (88Â %), potential side effects (78Â %), suspicion of government (77Â %), and suspicion of pharmaceutical companies (72Â %). Fewer than half (42Â %) of parents intended to vaccinate their children 5-11Â years old, while 38Â % were uncertain and 20Â % were unlikely to ever vaccinate their children. Vaccinated parents had higher odds than unvaccinated parents of intending to vaccinate their children (OR: 675.51; 95Â %CI: 106.46-4286.12). Discussions with healthcare providers who encouraged COVID-19 vaccination were positively associated with intent to vaccinate children (OR: 11.29; 95Â %CI: 2.60-49.02). CONCLUSIONS: We found parental vaccination and conversations with providers were positively associated with intent to vaccinate children. Decisions about childhood vaccination need to be supported by healthcare providers and a public health system that makes vaccine access and related information equitable and accessible. Vaccination-related decision making should be guided by healthcare providers and provide information about safety and risk to children.

Review of short-term and long-term adverse effects of covid-19 vaccination during pregnancy. BACKGROUND: The covid-19 pandemic sparked a debate about the safety of vaccines during pregnancy. However, pregnant women were excluded from the Pfizer-BioNTech vaccine phase 3 trials. As two years have passed since the first Covid-19 vaccine and more studies have been conducted, we want to evaluate the scientific literature to determine any actual risks in taking the vaccine during pregnancy. METHODS: We conducted literature research using PubMed and Google Scholar databases from January to April 2023. As the review considers short- and long-term adverse effects it was divided into two parts. The first part was conducted as a systematic review. The second concerning long-term negative effects due to lack of research is a literature review. The inclusion criteria for the systematic review part were singleton pregnancies, women vaccinated during pregnancy, and studies from 2020 and later. The most common short-term pregnancy adverse effects were included in the search: preterm delivery, small gestation age, intrauterine death, congenital defects, stillborn, fetal growth retardation, spontaneous abortion. Maternal immune activation was

the primary concern for the long-term adverse effects and whether vaccination could cause it. The search terms included maternal immune activation, fetal neurodevelopment, neuropsychiatric disorders and the studies used were from 2019. RESULTS: Most studies showed no significant difference in short-term adverse effects between vaccinated and non-vaccinated women and their fetuses. However, the literature is insufficient to evaluate possible long-term adverse effects. CONCLUSION: Available evidence supports the safety of administering SARS-CoV-2 vaccines to pregnant women, but further systematic reviews and meta-analyses are essential. Maternal immune activation caused by vaccination may impact a child's neurodevelopment and should be a concern for future studies.

Reverse Engineering of a Pathogenic Antibody Reveals the Molecular Mechanism of Vaccine-Induced Immune Thrombotic Thrombocytopenia. The massive COVID-19 vaccine roll-out campaign illuminated a range of rare side effects, the most dangerous of whichâ”€vaccine-induced immune thrombotic thrombocytopenia (VITT)â”€is caused by adenoviral (Ad)-vectored vaccines. VITT occurrence had been linked to the production of pathogenic antibodies that recognize an endogenous chemokine, platelet factor 4 (PF4). Mass spectrometry (MS)-based evaluation of the ensemble of anti-PF4 antibodies obtained from a VITT patient's blood indicates that the major component is a monoclonal antibody. Structural characterization of this antibody reveals several unusual characteristics, such as the presence of an N-glycan in the Fab segment and high density of acidic amino acid residues in the complementarity-determining regions. A recombinant version of this antibody (RVT1) was generated by transient expression in mammalian cells based on the newly determined sequence. It captures the key properties of VITT antibodies such as their ability to activate platelets in a PF4 concentration-dependent fashion. Homology modeling of the Fab segment reveals a well-defined polyanionic paratope, and the docking studies indicate that the polycationic segment of PF4 readily accommodates two Fab segments, cross-linking the antibodies to yield polymerized immune complexes. Their existence was verified with native MS by detecting assemblies as large as (RVT1)(3)(PF4)(2), pointing out at FcÎ³RIIa-mediated platelet activation as the molecular mechanism underlying VITT clinical manifestations. In addition to the high PF4 affinity, RVT1 readily binds other polycationic targets, indicating a polyreactive nature of this antibody. This surprising promiscuity not only sheds light on VITT etiology but also opens up a range of opportunities to manage this pathology.

Inactivated COVID-19 vaccines in peri-pregnancy period: Evaluation of safety for both pregnant women and neonates. BACKGROUND: Pregnant women have been excluded from vaccination of COVID-19 due to the lack of strong clinical evidence, which may place pregnant women at greater risk of contracting COVID-19. We conducted this study in China to investigate the maternal and neonatal safety of inactivated COVID-19 vaccination administered during the peri-pregnancy period. METHODS: This prospective observational cohort study enrolled pregnant women who received pregnancy care between January 1, 2021, and December 31, 2021. Pregnant women were categorized into vaccine group (nÂ =Â 60) and control group (nÂ =Â 60) based on whether they had received an inactivated COVID-19 vaccine within peri-pregnancy period. The primary outcomes were the incidence of maternal premature rupture of membranes (PROM) and neonatal adverse events, including induced labor/death, premature birth, low birth weight, and neonatal intensive care unit (NICU) admission and several secondary outcomes related to pregnant women and neonates. Inverse probability treatment weighting (IPTW) was employed to adjust for baseline covariates. Linear and logistic regression models were established after IPTW for continuous and binary outcomes, respectively. In sensitivity analysis, E-values were calculated and propensity score matching analysis and multivariate regression analysis used to demonstrate the robustness of IPTW results. Moreover, vaccination time subgroup analysis and medication subgroup analysis were conducted. RESULTS: Out

of 120 neonates delivered, there was no significant difference in PROM (25.42Â % vs. 19.67Â %, pÂ =Â 0.438) or neonatal adverse events (11.86Â % vs. 4.92Â %, pÂ =Â 0.148) between the vaccine and control groups. Moreover, among the secondary outcomes only serum alanine transaminase (ALT) at first trimester had a statistically significant difference between the groups, ALT levels were significantly higher in the vaccine group during the first trimester (20.67Â Â±Â 20.34 vs. 13.05Â Â±Â 9.43; RR: 5.38; pÂ =Â 0.04). In sensitivity analysis, the E-values calculated for the primary outcomes PROM and neonatal adverse events are 2.04 and 5.00 respectively. PSM analysis and multivariate regression analysis reached the same conclusion. The results of primary outcomes are both consistent across the vaccination time subgroup and medication subgroup. CONCLUSION: The sensitivity analysis illustrates the robustness of our results, so we can conclude that the vaccination of inactivated COVID-19 vaccine during the peri-pregnancy period is safe for both the pregnant woman and neonates no matter what time of vaccination and the use of medication. In addition, it is recommended to monitor ALT levels throughout the first trimester of pregnancy.

CLINICAL PROFILES AND CHARACTERISTICS OF MENSTRUAL DYSFUNCTION IN WOMEN AFTER SUFFERING FROM COVID-19 OR VACCINATION. OBJECTIVE: The aim: To investigate changes in the characteristics of menstrual function in women after suffering from Covid-19 or vaccination against SARS-CoV-2. PATIENTS AND METHODS: Materials and methods: After the retrospective analysis of 378 medical records patients were divided into: Group 1 (177 women) with menstrual function disorders (MFD) after COVID-19, Group 2 (121 women) with MFD after SARS-CoV-2 vaccination, Group C (80 women) without MFD after COVID-19 or vaccination (controls). The study focused on the clinical and hormonal menstrual cycle characteristics and factors influencing MFD. RESULTS: Results: Dyshormonal thyroid disorders were observed in 63.0% of Group 1 and 45.7% of Group 2 patients; hyperprolactinemia - in 31.0% and 39.4%, hyperÂ¬estrogenia - in 50% and 21%, and hyperandrogenism - in 39% and 20%. MFD was associated with hyperandrogenism with concurrent hyperprolactinemia, in the context of thyroid dysfunction; and with changes of gonadotropin production, along with normal and elevated estrogen concentrations and worsening of mental health that suggest disruption of central regulatory and feedback mechanisms in the pituitary-thyroid-ovarian system under the stressors influence. CONCLUSION: Conclusions: There are changes in the menstrual cycle associated with disruption of the hypothalamus-pituitary-ovary system and thyroid function in women after suffering from Covid-19 or vaccination. To reestablish reproductive homeostasis, employing a personalized diagnostic strategy is recommended, encompassing the evaluation of thyroid gland status, hormonal profiling, and the consideration of psychosocial facets.

Langerhans Cell Hyperplasia Mimicking Langerhans Cell Histiocytosis: A Rare Complication of COVID-19 Vaccination. Langerhans cell histiocytosis (LCH) is a rare disorder characterized by the abnormal proliferation of Langerhans cells, a type of immune cell that is normally present in the skin and various other tissues. LCH can affect people of any age but is most commonly diagnosed in children. We report a case of a patient with LCH who developed ipsilateral axillary lymphadenopathology post-COVID-19 vaccination. Lymph node biopsy showed diffuse Langerhans cell hyperplasia which mimicked LCH. Clinically and radiologically, it looked to be a reactive lymph node. The patient was kept on follow up only and after 1 year of follow up the size of lymph nodes regressed confirming to be reactive in nature rather than neoplastic. To the best of our knowledge, this is the second case of Langerhans cell hyperplasia post-COVID-19 vaccination being reported in the literature.

The association between antipyretic analgesics use and SARS-CoV-2 antibody titers following the second dose of the BNT162b2 mRNA vaccine: An observational study. Antipyretic analgesics are used to manage and control symptoms occurring after vaccination, but may hamper immunogenicity or vaccine efficacy. We examined the association between prophylactic or therapeutic use of

antipyretic analgesics and SARS-CoV-2 antibody titers for vaccine recipients. Data were obtained from 1,498 staff members of a medical and research institution in Tokyo, Japan, who had received the second dose of the BNT162b2 vaccine. We quantitatively measured anti-SARS-CoV-2 spike protein IgG titers in the participants three months after vaccination. The prophylactic and therapeutic use of antipyretic analgesics was ascertained via a questionnaire. A linear regression model was used to examine the association between antipyretic analgesic use and log-transformed anti-SARS-CoV-2 spike protein IgG titers. Based on model parameters, we estimated geometric mean titers (GMT) and the corresponding 95Â % confidence intervals (CI). The results showed that IgG titers in vaccine recipients who used antipyretic analgesics therapeutically was higher than the titers in those who did not (geometric mean ratio [GMR]Â =Â 1.26, 95Â % CIÂ =Â 1.17-1.34) with GMTs being 6,147 (95Â % CIÂ =Â 5,833-6,460) and 4,895 (95Â % CIÂ =Â 4,676-5,115) for those who used antipyretic analgesics therapeutically and those who did not, respectively. The association was attenuated, but remained statistically significant after adjusting for symptoms (GMRÂ =Â 1.14, 95Â % CIÂ =Â 1.06-1.23). We did not find any evidence of significant association in relation to the prophylactic use of antipyretic analgesics (GMRÂ =Â 0.96, 95Â % CIÂ =Â 0.84-1.10), with GMTs being 5,245 (95Â % CIÂ =Â 4,577-5,913) and 5,452 (95Â % CIÂ =Â 5,258-5,645) for those who used antipyretic analgesics prophylactically and those who did not, respectively. In conclusion, we did not find any evidence of suppression of the humoral response after the second dose of SARS-CoV-2 vaccination by prophylactic or therapeutic use of antipyretic analgesics.

Plasma from patients with vaccine-induced immune thrombotic thrombocytopenia displays increased fibrinolytic potential and enhances tissue-type plasminogen activator but not urokinase-mediated plasminogen activation. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare complication of adenovirus vector-based COVID-19 vaccines. VITT is associated with markedly raised levels of D-dimer; yet, how VITT modulates the fibrinolytic system is unknown. OBJECTIVES: We aimed to compare changes in fibrinolytic activity in plasma from patients with VITT, patients diagnosed with venous thromboembolism (VTE) after vaccination but without VITT (VTE-no VITT), and healthy vaccinated controls. METHODS: Plasma levels of plasmin-antiplasmin (PAP) complexes, plasminogen, and alpha-2-antiplasmin (Î±2AP) from 10 patients with VITT, 10 patients with VTE-no VITT, and 14 healthy vaccinated controls were evaluated by enzyme-linked immunosorbent assay and/or Western blotting. Fibrinolytic capacity was evaluated by quantitating PAP levels at baseline and after exÂ vivo plasma stimulation with 50-nM tissue-type plasminogen activator (tPA) or urokinase for 5 minutes. RESULTS: Baseline PAP complex levels in control and VTE-no VITT individuals were similar but were âˆ¼7-fold higher in plasma from patients with VITT (PÂ < .0001). VITT samples also revealed consumption of Î±2AP and fibrinogenolysis consistent with a hyperfibrinolytic state. Of interest, VITT plasma produced significantly higher PAP levels after exÂ vivo treatment with tPA, but not urokinase, compared to the other groups, indicative of increased fibrinolytic potential. This was not due to D-dimer as addition of D-dimer to VTE-no VITT plasma failed to potentiate tPA-induced PAP levels. CONCLUSION: A marked hyperfibrinolytic state occurs in patients with VITT, evidenced by marked elevations in PAP, Î±2AP consumption, and fibrinogenolysis. An unidentified plasma cofactor that selectively potentiates tPA-mediated plasminogen activation also appears to exist in the plasma of patients with VITT.

One-year antibody durability induced by EuCorVac-19, a liposome-displayed COVID-19 receptor binding domain subunit vaccine, in healthy Korean subjects. OBJECTIVE: EuCorVac-19 (ECV-19), an adjuvanted liposome-displayed receptor binding domain (RBD) COVID-19 vaccine, previously reported interim Phase 2 trial results showing induction of neutralizing antibodies 3 weeks after prime-boost immunization. The objective of this study was to determine the longer-term antibody response of the vaccine. METHODS: To assess immunogenicity 6 and 12 months after vaccination,

participants in the Phase 2 trial (NCT04783311) were excluded if they: 1) withdrew, 2) reported COVID-19 infection or additional vaccination, or 3) exhibited increasing Spike (S) antibodies (representing possible non-reported infection). Following exclusions, of the 197 initial subjects, anti-S IgG antibodies and neutralizing antibodies were further assessed in 124 subjects at the 6-month timepoint, and 36 subjects at the 12-month timepoint. RESULTS: Median anti-S antibody half-life was 52 days (interquartile range [IQR]:42-70), in the "early" period from 3 weeks to 6 months, and 130 days (IQR:97-169) in the "late" period from 6 to 12 months. There was a negative correlation between initial antibody titer and half-life. Anti-S and neutralizing antibody responses were correlated. Neutralizing antibody responses showed longer half-lives; the early period had a median half-life of 120 days (IQR:81-207), and the late period had a median half-life of 214 days (IQR:140-550). CONCLUSION: These data establish antibody durability of ECV-19, using a framework to analyze COVID-19 vaccine-induced antibodies during periods of high infection.
The anti-SARS-CoV-2 BNT162b2 vaccine suppresses mithramycin-induced erythroid differentiation and expression of embryo-fetal globin genes in human erythroleukemia K562Â cells. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is causative of the ongoing coronavirus disease 2019 (COVID-19) pandemic. The SARS-CoV-2 Spike protein (S-protein) plays an important role in the early phase of SARS-CoV-2 infection through efficient interaction with ACE2. The S-protein is produced by RNA-based COVID-19 vaccines, that were fundamental for the reduction of the viral spread within the population and the clinical severity of COVID-19. However, the S-protein has been hypothesized to be responsible for damaging cells of several tissues and for some important side effects of RNA-based COVID-19 vaccines. Considering the impact of COVID-19 and SARS-CoV-2 infection on the hematopoietic system, the aim of this study was to verify the effect of the BNT162b2 vaccine on erythroid differentiation of the human K562Â cell line, that has been in the past intensively studied as a model system mimicking some steps of erythropoiesis. In this context, we focused on hemoglobin production and induced expression of embryo-fetal globin genes, that are among the most important features of K562 erythroid differentiation. We found that the BNT162b2 vaccine suppresses mithramycin-induced erythroid differentiation of K562Â cells. Reverse-transcription-qPCR and Western blotting assays demonstrated that suppression of erythroid differentiation was associated with sharp inhibition of the expression of Î±-globin and Î³-globin mRNA accumulation. Inhibition of accumulation of Î¶-globin and Îµ-globin mRNAs was also observed. In addition, we provide in silico studies suggesting a direct interaction between SARS-CoV-2 Spike protein and Hb Portland, that is the major hemoglobin produced by K562Â cells. This study thus provides information suggesting the need of great attention on possible alteration of hematopoietic parameters following SARS-CoV-2 infection and/or COVID-19 vaccination.
Risk of New Retinal Vascular Occlusion After Messenger RNA COVID-19 Vaccination Within Aggregated Electronic Health Record Data.
Risk of New Retinal Vascular Occlusion After Messenger RNA COVID-19 Vaccination Within Aggregated Electronic Health Record Data-Reply.
Susac syndrome in a patient with migraine shortly after COVID-19 booster vaccination: more than a temporal relation?
Leukopenia associated with lamotrigine initiation after COVID-19 vaccine booster: A case report and literature review. Adverse lamotrigine effects are more likely with concomitant use of antiepileptic drugs, rapid dose titration, and multiple drug use, highlighting the importance of measuring its concentration. Here, lamotrigine was administered the day after the third mRNA vaccination to a 20-year-old bipolar woman with these risk factors. Leukopenia occurred on day 12 without rapid concentration increase, but leukocytes gradually recovered after 22 weeks without discontinuation of lamotrigine. The second mRNA vaccination did not induce leukopenia. Possibly, a

synergetic immune response to simultaneous vaccination and lamotrigine caused leukopenia, which recovered as the response weakened. Lamotrigine initiation immediately after mRNA vaccination may be a leukopenia risk factor.

Longitudinal increase of humoral responses after four SARS-CoV-2 vaccinations and infection in MS patients on fingolimod. BACKGROUND: Humoral responses after SARS-CoV-2 vaccination are greatly impaired in multiple sclerosis (MS) patients on fingolimod. Effects of repeated vaccination and infections on long-term responses are unclear. METHODS: Prospective study in 60 MS patients on fingolimod measuring humoral responses after up to four vaccinations and 8 months after fourth vaccination. RESULTS: Anti-WH1 antibody titers increased with each additional vaccination. At long-term follow-up titers increased further and most patients developed new humoral responses against the BA.1 omicron variant. CONCLUSION: Repeated SARS-CoV-2 vaccinations boost humoral immunity and, probably together with SARS-CoV-2 infections, induce humoral responses on the long-term in almost all patients.

Severity of AdverseÂ Effects of Sinovac COVID-19 Vaccine in Postmenopausal Women: A Multicenter Experience From Pakistan. Introduction The most significant element in halting the coronavirus disease 2019 (COVID-19) epidemic was the availability of reliable and efficient vaccines. Vaccine acceptability is influenced by many factors, including perceptions of the vaccine's safety and side effects. Adverse reactions to vaccines can vary with regard to the type, although they are frequently mild, localized, temporary, and self-limiting. Therefore, this study aimed to assess the prevalence of side effects experienced by postmenopausal women after receiving the Sinovac vaccine. Methods This multicenter, prospective cross-sectional study was carried out at multiple centers in Karachi, Pakistan. In this study, the non-probability sampling method was used. The studyÂ continued from August 1, 2022, to January 31, 2023, forÂ six months. The study comprised 600 postmenopausal women over the age of 50 years who received two doses of Sinovac COVID-19 vaccination. Demographic parameters such as gender, the existence of comorbidities, and local and systemic side effects in postmenopausal women were documented asÂ frequencies and percentages. Age, weight, and duration of comorbidities are expressed as means and standard deviations. Results The study findings showed that the mean age of study participants was 63.93 Â± 8.24 years. There were related comorbidities with hypertension and diabetes mellitus in 181Â (30.2%) and 40Â (6.7%) women, respectively. Fever was the most often reported sideÂ effect, with 349Â (58.2%) participantsÂ reporting it and 198Â (56.7%) participantsÂ reporting it as mild. After the second dose, 234 (39.5%) participants reported fever as their most frequent adverse effect, and 158 (67.5%) of them reported it was mild. Conclusion This study concluded that the most commonly reported side effects among postmenopausal women were fever, pain, and swelling at the injection site after getting either dose of Sinovac vaccine. These overall side effects were generally mild to moderate in intensity, not life-threatening, and did not require hospitalization, although fever was reported in severe intensity in some cases, particularly after the first dose.

Low switched memory B cells are associated with no humoral response after SARS-CoV-2 vaccine boosters in kidney transplant recipients. INTRODUCTION: The humoral response after SARS-CoV-2 vaccination and boosters in kidney transplant recipients (KTRs) is heterogeneous and depends on immunosuppression status. There is no validated immune measurement associated with serological response in clinical practice. Multicolor flow cytometric immunophenotyping could be useful for measuring immune response. This study aimed to study B- and T-cell compartments through Standardized EuroFlow PID Orientation after SARS-CoV-2 vaccination and their association with IgG SARS-CoV-2 seropositivity status after two doses or boosters. METHODS: We conducted a multicenter prospective study to evaluate humoral response after SARS-CoV-2 vaccination in KTRs. Heterologous regimen: two doses of inactivated SARS-CoV-2 and two boosters of BNT162b2 mRNA (n=75).

Homologous vaccination: two doses of BNT162b2 mRNA and one BNT162b2 mRNA booster (n=13). Booster doses were administrated to KTRs without taking into account their IgG SARS-CoV-2 seropositivity status. Peripheral blood samples were collected 30 days after the second dose and after the last heterologous or homologous booster. A standardized EuroFlow PID Orientation Tube (PIDOT) and a supervised automated analysis were used for immune monitoring cellular subsets after boosters. RESULTS: A total of 88 KTRs were included and divided into three groups according to the time of the first detected IgG SARS-CoV-2 seropositivity: non-responders (NRs, n=23), booster responders (BRs, n=41), and two-dose responders (2DRs, n=24). The NR group was more frequent on mycophenolate than the responder groups (NRs, 96%; BRs, 80%; 2DRs, 42%; p=0.000). Switched memory B cells in the 2DR group were higher than those in the BR and NR groups (medians of 30, 17, and 10 cells/ul, respectively; p=0.017). Additionally, the absolute count of central memory/terminal memory CD8 T cells was higher in the 2DR group than in the BR and NR groups. (166, 98, and 93 cells/ul, respectively; p=0.041). The rest of the T-cell populations studied did not show a statistical difference. CONCLUSION: switched memory B cells and memory CD8 T-cell populations in peripheral blood were associated with the magnitude of the humoral response after SARS-CoV-2 vaccination. Boosters increased IgG anti-SARS-CoV-2 levels, CM/TM CD8 T cells, and switched MBCs in patients with seropositivity after two doses. Interestingly, no seropositivity after boosters was associated with the use of mycophenolate and a lower number of switched MBCs and CM/TM CD8 T cells in peripheral blood.

Association between History of Vaccination and Symptoms at Diagnosis of Coronavirus Disease 2019. INTRODUCTION: We investigated the association between history of vaccination for coronavirus disease 2019 (COVID-19) and symptoms at its diagnosis. METHODS: We retrospectively analyzed 2566 consecutive individuals suspected of having COVID-19 and visited a designated clinic between January and September 2022 (1733 were diagnosed with COVID-19, and 816 tested negative for COVID-19) in Japan. The individuals were divided by vaccination history for COVID-19. RESULTS: In the COVID-19-free individuals, the vaccination was not significantly associated with any symptoms. Contrarily, those with COVID-19 demonstrated an inverse relationship between the vaccination and body temperature; the adjusted mean value was higher by 0.01Â°C, 0.04Â°C, 0.09Â°C, 0.27Â°C, and 0.34Â°C and 0.48Â°C in individuals vaccinated 2-4, 4-6, 6-8, 8-10, and >10 months before and those unvaccinated, respectively, than in those vaccinated within 2 months (P = 0.96, 0.41, 0.081, 0.006, 0.004, and <0.001). Furthermore, among the affected population, individuals vaccinated long before or never vaccinated more frequently complained of fatigue and headache; the adjusted odds ratios of those vaccinated >10 months before and those unvaccinated compared with those vaccinated within 2 months were 2.53 and 2.45 for fatigue and 2.53 and 2.17 for headache (all P < 0.05). Contrarily, the prevalence of rhinorrhea, sore throat, and cough was higher in recently vaccinated individuals (adjusted odds ratios of those vaccinated within 2 months versus those unvaccinated, 2.40, 2.46, and 2.46; all P < 0.05). CONCLUSIONS: Symptoms at the COVID-19 diagnosis differed with the vaccination history. Information on vaccination history would be worth using when suspecting COVID-19 based on symptoms.

Vaccine conspiracy association with higher COVID-19 vaccination side effects and negative attitude towards booster COVID-19, influenza and monkeypox vaccines: A pilot study in Saudi Universities. Conspiracies regarding vaccines are widely prevalent, with negative consequences on health-seeking behaviors. The current study aimed to investigate the possible association between the embrace of vaccine conspiracies and the attitude to booster COVID-19, seasonal influenza, and monkeypox (mpox) vaccinations as well as the perceived side effects following COVID-19 vaccination. The target population involved academic staff and university students in health colleges in the Kingdom of Saudi Arabia. A self-administered questionnaire was distributed in January 2023 to collect data on

participants' demographics, self-reported side effects following each dose, willingness to get booster COVID-19, seasonal influenza, and mpox vaccinations, as well as an evaluation of vaccine conspiracies and attitude to mandatory vaccination. Among the 273 participants, the willingness to receive yearly booster COVID-19 vaccination was observed among 26.0% of the participants, while it was 46.9% and 34.1% for seasonal influenza and mpox vaccinations, respectively. Multinomial logistic regression analyses demonstrated a significant correlation between endorsing vaccine conspiracies and higher frequency of self-reported side effects following uptake of the second and third doses of COVID-19 vaccines. Vaccine conspiracies were also correlated with attitude toward booster COVID-19, influenza, mpox, and mandatory vaccination. The findings of this pilot study highlighted the potential adverse impact of the preexisting notions and negative attitudes toward vaccines, which could have contributed to heightened perceived side effects following COVID-19 vaccination. The study also highlighted the ongoing divisions concerning mandatory vaccination policies, emphasizing the need for cautious implementation of this strategy as a last resort for public health benefit.

Branch retinal artery occlusion with unruptured retinal arterial macroaneurysm post-SARS-CoV-2 vaccination: A case report. INTRODUCTION: Many adverse occurrences in the eye have been reported after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. This is the first report of a patient with an unruptured retinal arterial macroaneurysm (RAM) who developed branch retinal artery occlusion (BRAO) one day after SARS-CoV-2 vaccination (BNT162b2 by Pfizer-BioNTech). PATIENT REPORT: A 75-year-old man with a pertinent history of type-2 diabetes mellitus visited the hospital complaining of sudden visual loss in his right eye 1 day after receiving the fourth dose of the SARS-CoV-2 mRNA vaccine; his best-corrected visual acuity (BCVA) decreased from 1.0 to 0.7 (Snellen decimal). The patient had previously been diagnosed with an unruptured RAM and superior paracentral acute middle maculopathy in the same eye. Fundus examination showed increased sheathing of blood vessels. Indocyanine green showed a hyperfluorescent area suggestive of RAM on the right eye disc. Fluorescein angiography and optical coherence tomography angiography revealed arterial obstruction findings in the upper retinal area. DIAGNOSIS AND INTERVENTION: The patient was diagnosed with BRAO with RAM and was followed up without any additional treatment. Follow-up examination after 4 months did not show any improvement in BCVA value. CONCLUSION: This case suggested that BRAO could develop after SARS-CoV-2 vaccination in patients with unruptured RAM; however, more research is required to investigate the causes.

Exacerbation of Minimal Change Disease Following mRNA COVID-19 Vaccination. BACKGROUND Minimal change disease is a common cause of nephrotic syndrome in adults. There are few reported cases of vaccine-related podocytopathy with nephrotic-range proteinuria in the setting of a minimal change disease history. There have been rare reports of acute renal damage following vaccination to prevent COVID-19 and some cases of exacerbation of ongoing nephropathy. This report is a 33-year-old man with a 22-year history of nephrotic syndrome due to minimal change disease which exacerbated following a third dose of an mRNA SARS-CoV-2 vaccine for COVID-19. CASE REPORT We report a case of nephrotic syndrome after the third dose of the BNT162b2 mRNA COVID-19 vaccine. The patient presented with mild edema in the bilateral lower extremities and sacrum. Laboratory investigations confirmed nephrotic-range proteinuria and hypoalbuminemia. A kidney sonogram demonstrated mild renal parenchymal disease and a small non-obstructing right renal calculus. Renal biopsy revealed diffuse podocyte foot process effacement, punctuate IgG podocyte cytoplasmic staining, and minimal global glomerulosclerosis, consistent with a diagnosis of a diffuse podocytopathy with a minimal change disease phenotype. The patient was started on oral prednisone treatment, which led to remission of his symptoms and normalization of lab test results with normal BUN and Cr and resolution of proteinuria. Treatment was tapered off over the course of 28 weeks. CONCLUSIONS We presents a case of longstanding minimal change disease that showed

exacerbation following a third dose of an mRNA vaccine for SARS-CoV-2. Although this may be a rare association, this case supports that patients with chronic glomerulonephritis need to be monitored.

The association between influenza vaccination and the perception of COVID-19 as well as COVID-19 vaccination behavior among community residents in Anhui province, China. Influenza is a significant public health threat associated with high morbidity and mortality globally. This study investigated the influenza vaccination rate (IVR) among community residents in Anhui province, China, and explored the association between participants' influenza vaccination and their key sociodemographic characteristics, perception of COVID-19 as well as COVID-19 vaccination behavior. We found that the IVR among respondents in Anhui province was 27.85% in 2020. Regression analyses revealed that males (ORâ€‰=â€‰1.41, 95% CI: 1.01â€‰~â€‰1.96), residents with above middle school education (ORâ€‰=â€‰1.88, 95% CI: 1.04â€‰~â€‰3.39), considered themselves likely to be infected with COVID-19 (ORâ€‰=â€‰1.53, 95% CI: 1.04â€‰~â€‰2.24), had received the COVID-19 vaccine (ORâ€‰=â€‰9.85, 95% CI: 3.49â€‰~â€‰27.78), did not plan to receive COVID-19 vaccine in the future (ORâ€‰=â€‰1.70, 95% CI: 1.17â€‰~â€‰2.47), and had no adverse reactions after COVID-19 vaccination (ORâ€‰=â€‰1.54, 95% CI: 1.04â€‰~â€‰2.27) were associated with a higher IVR. The acceptance of influenza vaccination was mainly associated with respondents' gender, education, perception of COVID-19, history of COVID-19 vaccination in city and countryside community residents in Anhui province.

Assessment of multiple domains of pain following BNT162b2 mRNA COVID-19 vaccination. Pain at the injection site is the most frequent reaction among COVID-19 vaccine recipients, but its characteristics were not fully described yet. The purpose of this study was to investigate multiple domains of pain following BNT162b2 mRNA vaccination. We included 107 subjects undergoing primary shot of the vaccination twice into deltoid muscle with a 3-week interval. They completed 6 sessions of pain assessments, one before the first and second dose (1-0, 2-0), and 1st/7th day after the first and second dose (1-1/1-7, 2-1/2-7). Pain visual analog scale (VAS), pain distribution, and pressure pain threshold (PPT) on deltoid muscle were evaluated in each session. The mean VAS (at rest/shoulder motion) was 6.0/27.6 mm at 1-1, and 12.8/34.0 mm at 2-1. Approximately, 90% of recipients showed localized pain within the upper arm. Percentage change of PPTs at 1-1 and 2-1 was bilaterally (ipsilateral/contralateral) decreased to 87.4/89.4% and 80.6/91.0%, which was recovered to the baseline level at 1-7 and 2-7. Temporary, mild-to-moderate intensity, localized distribution, concomitant with bilateral mechanical hyperalgesia on the deltoid muscle, were typical pain characteristics following this vaccination. These findings provide a rationale that will be informative for future recipients. J. Med. Invest. 70 : 355-360, August, 2023.

Inhibitory effects of SARS-CoV-2 spike protein and BNT162b2 vaccine on erythropoietin-induced globin gene expression in erythroid precursor cells from patients with Î²-thalassemia. During the recent coronavirus disease 2019 (COVID-19) pandemic several patients with Î²-thalassemia have been infected by severe acute respiratory syndrome coronavirus (SARS-CoV-2), and most patients were vaccinated against SARS-CoV-2. Recent studies demonstrate an impact of SARS-CoV-2 infection on the hematopoietic system. The main objective of this study was to verify the effects of exposure of erythroid precursor cells (ErPCs) from patients with Î²-thalassemia to SARS-CoV-2 spike protein (S-protein) and the BNT162b2 vaccine. Erythropoietin (EPO)-cultured ErPCs have been either untreated or treated with S-protein or BNT162b2 vaccine. The employed ErPCs were from a Î²-thalassemia cellular Biobank developed before the COVID-19 pandemic. The genotypes wereÂ Î²(+)-IVSI-110/Î²(+)-IVSI-110 (one patient), Â Î²(0)39/Î²(+)-IVSI-110 (3 patients), and Î²(0)39/Â Î²(0)39 (2 patients). After treatment with S-protein or BNT162b2 for 5 days, lysates were analyzed by high performance liquid chromatography (HPLC), for hemoglobin production, and isolated RNA was assayed by RT-qPCR, for detection of globin gene expression. The main conclusions of the results obtained are that SARS-CoV-

2 S-protein and BNT162b2 vaccine (a) inhibit fetal hemoglobin (HbF) production by Î²-thalassemic ErPCs and (b) inhibit Î³-globin mRNA accumulation. In addition, we have performed in silico studies suggesting a high affinity of S-protein to HbF. Remarkably, the binding interaction energy of fetal hemoglobin to S-protein was comparable with that of angiotensin-converting enzyme 2 (ACE2). Our results are consistent with the hypothesis of a relevant impact of SARS-CoV-2 infection and COVID-19 vaccination on the hematopoietic system.

Immunothrombosis and Complement Activation Contribute to Disease Severity and Adverse Outcome in COVID-19. Severe COVID-19 is characterized by systemic inflammation and multiple organ dysfunction syndrome (MODS). Arterial and venous thrombosis are involved in the pathogenesis of MODS and fatality in COVID-19. There is evidence that complement and neutrophil activation in the form of neutrophil extracellular traps are main drivers for development of microvascular complications in COVID-19. Plasma and serum samples were collected from 83 patients infected by SARS-CoV-2 during the two first waves of COVID-19, before the availability of SARS-CoV-2 vaccination. Samples were collected at enrollment, day 11, and day 28; and patients had differing severity of disease. In this comprehensive study, we measured cell-free DNA, neutrophil activation, deoxyribonuclease I activity, complement activation, and D-dimers in longitudinal samples of COVID-19 patients. We show that all the above markers, except deoxyribonuclease I activity, increased with disease severity. Moreover, we provide evidence that in severe disease there is continued neutrophil and complement activation, as well as D-dimer formation and nucleosome release, whereas in mild and moderate disease all these markers decrease over time. These findings suggest that neutrophil and complement activation are important drivers of microvascular complications and that they reflect immunothrombosis in these patients. Neutrophil activation, complement activation, cell-free DNA, and D-dimer levels have the potential to serve as reliable biomarkers for disease severity and fatality in COVID-19. They might also serve as suitable markers with which to monitor the efficacy of therapeutic interventions in COVID-19.

Incidence of Omicron Variant Reinfection and Reduction of Reinfection Risk After Coronavirus Disease 2019 Vaccination in Children. Data are limited on the incidence of coronavirus disease 2019 (COVID-19) reinfection in children. This population-based cohort study in Niigata, Japan from January to November 2022 demonstrated the incidence of reinfection was 1337/48 099 (2.8%), and the hazard ratio for reinfection in vaccinated children was 0.29 (95% confidence interval, 0.20-0.40).

Impact of sex and age on vaccine-related side effects and their progression after booster mRNA COVID-19 vaccine. In mRNA COVID-19 vaccination, side effects after the first and second dose have been well reported. However, studies about side effects after booster vaccine are sparse. 272 healthcare workers who received the third mRNA COVID-19 vaccine were recruited, and impact of sex, age, and symptoms on the side effect progression was statistically analyzed. Females and younger adults had a higher frequencies of general fatigue, headache, joint pain, chills and axillary pain compared to males and elderly adults, respectively. In longitudinal analysis, prolonged time to recovery from side effects was found among females and younger adults. Finally, between the third and second dose vaccinations, 52% of subjects had a longer duration of side effects following the third vaccine compared to the second, and joint pain was the culprit symptom related to the prolonged duration of side effects. Following the second vaccine dose, 25% of subjects had a longer duration of side effects and asthma and ear fullness, which exacerbated the underlying allergic condition, and COVID arm symptom were the culprit symptoms. These highlight the impact of sex, age, and culprit symptoms on the progress of side effects following the booster mRNA COVID-19 vaccine.

Neurological complications following mRNA COVID-19 vaccination: Oral and lower limb paresthesia. A case discussion and literature review. Vaccines used in the coronavirus pandemic have reported

some minor side effects such as pain at the injection site, headache, myalgia and fever. Also major neurological side effects have been experienced by some patients. We present the clinical case of a healthy woman who two weeks after being vaccinated with the third dose of Moderna COVID-19 Vaccine, began to feel numbness in mouth, both feet, legs, interscapular space, and hands. She was diagnosed with distal sensory polyneuropathy caused by the vaccine. Progressive improvement was seen. The patient did not require corticosteroid medication. We reviewed the literature to assess the frequency of this type of complication. Key words:COVID-19, SARS-CoV-2, vaccine, vaccination, peripheral axonal neuropathy, transverse myelitis, oral manifestations.

Safety and immunogenicity of heterologous boosting with orally administered aerosolized bivalent adenovirus type-5 vectored COVID-19 vaccine and B.1.1.529 variant adenovirus type-5 vectored COVID-19 vaccine in adults 18 years and older: a randomized, double blinded, parallel controlled trial. Vaccination strategies that can induce a broad spectrum immune response are important to enhance protection against SARS-CoV-2 variants. We conducted a randomized, double-blind and parallel controlled trial to evaluate the safety and immunogenicity of the bivalent (5Ã—10(10)viral particles) and B.1.1.529 variant (5Ã—10(10)viral particles) adenovirus type-5 (Ad5) vectored COVID-19 vaccines administrated via inhalation. 451 eligible subjects aged 18 years and older who had been vaccinated with three doses inactivated COVID-19 vaccines were randomly assigned to inhale one dose of either B.1.1.529 variant Ad5 vectored COVID-19 vaccine (Ad5-nCoVO-IH group, N=150), bivalent Ad5 vectored COVID-19 vaccine (Ad5-nCoV/O-IH group, N=151), or Ad5 vectored COVID-19 vaccine (5Ã—10(10)viral particles; Ad5-nCoV-IH group, N=150). Adverse reactions reported by 37 (24.67%) participants in the Ad5-nCoVO-IH group, 28 (18.54%) in the Ad5-nCoV/O-IH group, and 26 (17.33%) in the Ad5-nCoV-IH group with mainly mild to moderate dry mouth, oropharyngeal pain, headache, myalgia, cough, fever and fatigue. No serious adverse events related to the vaccine were reported. Investigational vaccines were immunogenic, with significant difference in the GMTs of neutralizing antibodies against Omicron BA.1 between Ad5-nCoV/O-IH (43.70) and Ad5-nCoV-IH (29.25) at 28 days after vaccination (P=0.0238). The seroconversion rates of neutralizing antibodies against BA.1 in Ad5-nCoVO-IH, Ad5-nCoV/O-IH, and Ad5-nCoV-IH groups were 56.00%, 59.60% and 48.67% with no significant difference among the groups. Overall, the investigational vaccines were demonstrated to be safe and well tolerated in adults, and was highly effective in inducing mucosal immunities in addition to humoral and cellular immune responses defending against SARS-CoV-2 variants.Trial registration: Chictr.org identifier: ChiCTR2200063996.

Seroprevalence and factors associated with SARS-CoV-2 infection among healthcare workers: cross-sectional study. BACKGROUND: Healthcare workers (HCWs) are at a higher risk of contracting COVID-19 due to their close contact with infected patients. However, the true burden of COVID-19 among HCWs in Yemen is unknown due to the inadequate availability of healthcare and the subclinical nature of the disease. This study aims to estimate the seroprevalence of SARS-CoV-2 infection among HCWs in two Yemeni governorates and identify associated factors using a cross-sectional design. METHOD: A total of 404 HCWs were surveyed from June 2022 to September 2022 in Lahj and AL-Dhalea hospitals. A self-administered questionnaire collected demographic data, COVID-19 infection history, and vaccination status. A total of 404 human sera were tested using a specific electrochemiluminescence immunoassay assay. Association analysis was conducted to identify associations between antibody prevalence and demographic and vaccine-related variables. RESULT: The median age of the HCWs was 31 (Range 20-64) years, with 65.0% being male and 35.0% female. Of all HCWs, 94% were SARS-CoV-2 seropositive and 77.0% had no confirmed test of COVID-19-related symptoms. There was no significant association between seropositivity and demographic factors such as age, gender, occupation, or COVID-19 vaccination (Pâ€‰>â€‰0.05). CONCLUSION: The seroprevalence of SARS-CoV-2 was high among HCWs in Yemen, primarily due to natural

infection rather than vaccination. Compliance with infection prevention and control measures did not significantly affect seropositivity. This study highlights the need for improved healthcare systems and resources to reduce the burden of COVID-19 and promote infection prevention and control (IPC) measures among HCWs in Yemen.

Investigation of the SARS-CoV-2 post-vaccination antibody response in Canadian farmed mink. Currently, SARS-CoV-2 have been detected in farmed mink in 13 different countries. Due to the high susceptibility and transmissibility among mink, great concerns of mink serving as a reservoir to generate novel variants with unknown virulence and antigenic properties arose. These concerns have consequently resulted in entire mink productions being culled and banned. This study investigates the post-vaccination antibody response in the Canadian farmed mink vaccinated with a commercial Index spike protein-based vaccine, approved for use in cats, and compares the antibody response to that observed post infection in Danish farmed mink. Blood samples were obtained from 50 mink at the Canadian Centre for Fur Animal Research (CCFAR), Dalhousie University (Truro, Canada). The sera were initially analyzed for antibodies by enzyme-linked immunosorbent assay (ELISA), and selected sera was subsequently tested in a virus neutralization tests. The levels of neutralizing antibodies were evaluated for an ancestral D614G strain and a recent circulating SARS-CoV-2 variant of concern (Omicron BA.4). The results revealed that the vaccine induced a strong antibody response in mink by reaching antibody titer levels of up to 1:12800 in the ELISA. Moreover, high levels of neutralizing antibodies were obtained, and despite the great level of genetic differences between the ancestral and Omicron BA.4 strains, the vaccinated mink showed high levels of cross-reacting neutralizing antibodies. Interestingly, the antibody levels towards SARS-CoV-2 in the Canadian vaccinated mink were significantly higher than observed in recently SARS-CoV-2 infected Danish mink and equal to anamnestic responses following re-infection. In conclusion, the vaccine used in the Canadian farmed mink was able to induce a strong and broad-reacting antibody response in mink, which could limit the spread of SARS-CoV-2 in farmed mink and thereby reduce the risk of mink serving as a SARS-CoV-2 reservoir for human infections.

A case of subacute thyroiditis after influenza vaccination. SUMMARY: A 40-year-old Japanese woman presented to the outpatient clinic with fever and palpitations 2 days after receiving the influenza vaccine (Influenza HA Vaccine 'KMB'Â®) following the second dose of coronavirus disease 2019 (COVID-19) vaccine (COVID-19 vaccine Moderna intramuscular injectionÂ®). At the first visit, the patient presented with a swollen thyroid gland with mild tenderness, and she was diagnosed with subacute thyroiditis (SAT) based on the presence of thyrotoxicosis (free T3: 5.42 pg/mL; free T4: 2.34 ng/dL; and thyroid-stimulating hormone (TSH): <0.01 Î¼IU/mL), a high C-reactive protein level (5.77 mg/dL), a negative TSH receptor antibody, and characteristic ultrasound findings. The patient's human leukocyte antigen types were A2, A11, B35, B51, DR4, and DR1403. Prednisolone (15 mg/day) was given as an initial dose, after which the fever subsided, and the dose was tapered and discontinued after 6 weeks. The patient was thought to have developed SAT due to influenza vaccination. SAT after influenza vaccination may be overlooked. For patients with SAT, it is necessary to obtain information regarding their vaccination history. LEARNING POINTS: After influenza vaccination, subacute thyroiditis (SAT) may develop. If persistent fever, anterior neck pain, swelling, tenderness of the thyroid gland, and symptoms of thyrotoxicosis are observed immediately after vaccination for several viruses, including influenza, an examination to rule out the onset of SAT is recommended. Human leukocyte antigen type A2 (HLA-A2) and HLA-B35 may be linked to the development of SAT following influenza vaccination. The two doses of the coronavirus disease 2019 (COVID-19) vaccine given before the influenza vaccine may affect the onset of SAT.

Deep Learning Analysis of COVID-19 Vaccine Hesitancy and Confidence Expressed on Twitter in 6 High-Income Countries: Longitudinal Observational Study. BACKGROUND: An ongoing monitoring

of national and subnational trajectory of COVID-19 vaccine hesitancy could offer support in designing tailored policies on improving vaccine uptake. OBJECTIVE: We aim to track the temporal and spatial distribution of COVID-19 vaccine hesitancy and confidence expressed on Twitter during the entire pandemic period in major English-speaking countries. METHODS: We collected 5,257,385 English-language tweets regarding COVID-19 vaccination between January 1, 2020, and June 30, 2022, in 6 countries-the United States, the United Kingdom, Australia, New Zealand, Canada, and Ireland. Transformer-based deep learning models were developed to classify each tweet as intent to accept or reject COVID-19 vaccination and the belief that COVID-19 vaccine is effective or unsafe. Sociodemographic factors associated with COVID-19 vaccine hesitancy and confidence in the United States were analyzed using bivariate and multivariable linear regressions. RESULTS: The 6 countries experienced similar evolving trends of COVID-19 vaccine hesitancy and confidence. On average, the prevalence of intent to accept COVID-19 vaccination decreased from 71.38% of 44,944 tweets in March 2020 to 34.85% of 48,167 tweets in June 2022 with fluctuations. The prevalence of believing COVID-19 vaccines to be unsafe continuously rose by 7.49 times from March 2020 (2.84% of 44,944 tweets) to June 2022 (21.27% of 48,167 tweets). COVID-19 vaccine hesitancy and confidence varied by country, vaccine manufacturer, and states within a country. The democrat party and higher vaccine confidence were significantly associated with lower vaccine hesitancy across US states. CONCLUSIONS: COVID-19 vaccine hesitancy and confidence evolved and were influenced by the development of vaccines and viruses during the pandemic. Large-scale self-generated discourses on social media and deep learning models provide a cost-efficient approach to monitoring routine vaccine hesitancy.
The association of post-COVID-related symptoms and preceding SARS-CoV-2 infection among fully vaccinated paramedics in Canada. This study investigated the association between previous SARS-CoV-2 infection and risk of symptoms associated with post COVID conditions among fully vaccinated paramedics in Canada. We included vaccinated paramedics who provided blood sample and questionnaire data on the same date during the study period. We examined the presence of symptoms associated with post-COVID conditions, depression severity against prior SARS-CoV-2 infection categories. Compared to "no previous SARS-CoV-2 infection" group, there was no detected association between "known prior SARS-CoV-2 infection" (OR: 1.42, 95% CI:0.96-2.09), nor "unknown prior SARS-Cov-2 infection" (OR: 0.54, 95% CI:0.29-1.00), and "the presence of symptoms associated with post-COVID conditions".
COVID-19 Vaccine, Safety in a Case with Underlying Pituitary Adenoma.
Longitudinally Extensive Myelitis Onset in Subacute Combined Degeneration Combined with a Novel Coronavirus Vaccine Injection.
Psychological factors associated with vaccination hesitancy: an observational study of patients hospitalized for COVID-19 in a later phase of the pandemic in Italy. INTRODUCTION: Vaccination against SARS-CoV-2 has been used to reduce the severity of COVID-19 disease and the incidence of new cases. However, a significant proportion of people have shown vaccination hesitancy. METHODS: This study explored psychological factors related to vaccination hesitancy in a sample of Italian COVID-19 patients (N = 54), hospitalized during 2021, after vaccines had been made available and while the vaccination campaign was on-going. Consecutive patients, aged 18 or older, admitted to the hospital with a diagnosis of COVID-19 were assessed with a set of standardized measures. RESULTS: In our sample, 48.1% was not vaccinated and 7.4% died within 6months after hospitalization, with a preponderance of deaths among non-vaccinated patients. Non-vaccinated participants had higher resilience scores at the CD-RISC-10 scale than vaccinated ones (33.6 Â± 5.50 vs 28.6 Â± 6.61; t40.2=+ 2.94, p = 0.005). No statistically significant differences were found between the two groups for any other measures. DISCUSSION: Higher levels of resilience among non-vaccinated patients may reflect

greater identity worth and self-esteem, in turn resulting in a decrease in vaccination likelihood. This finding may have important public health implications, as it indicates that specific psychological aspects, such as resilience, may result in vaccination hesitancy, with implications for hospitalization rates, and thus healthcare costs, as well as loss of lives.

Oral Chronic Graft-versus-Host Disease in Post-Hematopoietic Stem Cell Transplant Patients Following SARS-CoV-2 Vaccination: Case Reports. Patients receiving allogeneic hematopoietic stem cell transplant may experience graft-versus-host disease (GVHD) in which donor immune cells cause an immune reaction in host tissues. Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccines are highly effective in prevention of severe coronavirus-2019 (COVID-19) disease, but the vaccine can result in immune activation and GVHD. Herein, we report 4 cases of oral manifestations that may have been stimulated by COVID-19 or vaccination with Pfizer or Moderna vaccines. We believe this study is the first to report oral changes driven by an inflammatory/immune mechanism leading to oral symptomatic cGVHD. The clinical impact of this study is early recognition and appropriate management of oral symptomatic cGVHD following COVID-19 disease or SARS-CoV-2 vaccination.

Presence of MDSC associates with impaired antigen-specific T cell reactivity following COVID-19 vaccination in cirrhotic patients. BACKGROUND AND AIMS: Cirrhosis entails high risk of serious infections and abated efficiency of vaccination, but the underlying mechanisms are only partially understood. This study aimed at characterizing innate and adaptive immune functions, including antigen-specific T cell responses to COVID-19 vaccination, in patients with compensated and decompensated cirrhosis. METHODS: Immune phenotype and function in peripheral blood from 42 cirrhotic patients and 44 age-matched healthy controls were analysed after two doses of the mRNA-based COVID-19 vaccines [BNT162b2 (Pfizer BioNTech) or mRNA-1273 (Moderna)]. RESULTS: Cirrhotic patients showed significantly reduced blood counts of antigen-presenting dendritic cells (DC) and high counts of monocytic myeloid-derived suppressor cells (M-MDSC) as compared to healthy controls. In addition, monocytic cells recovered from cirrhotic patients showed impaired expression of the antigen-presenting molecule HLA-DR and the co-stimulatory molecule CD86 upon Toll-like receptor (TLR) stimulation. These features were more prominent in patients with decompensated cirrhosis (Child-Pugh classes B & C). Interestingly, while patients with compensated cirrhosis (Child-Pugh class A) showed an inflammatory profile with myeloid cells producing the proinflammatory cytokines IL-6 and TNF, decompensated patients produced reduced levels of these cytokines. Cirrhotic patients, in particular those with more advanced end-stage liver disease, mounted reduced antigen-specific T cell reactivity to COVID-19 vaccination. Vaccine efficiency inversely correlated with levels of M-MDSC. CONCLUSION: These results implicate MDSC as mediators of immunosuppression, with ensuing deficiency of vaccine-specific T cell responses, in cirrhosis.

Prevalence of Side Effects of the AstraZeneca COVID-19 Vaccine: A Multicenter Experience From Pakistan. Introduction The most efficient method of combating theÂ coronavirus disease 2019Â (COVID-19)Â pandemic would be to use effective, safe, and proven vaccines; however, their widespread use has been hampered partly by concerns over possible adverse effects. Therefore, this study aimed to assess the prevalence of Oxford/AstraZeneca vaccine side effects among participants. Methods This was a multicenter, cross-sectional study conducted using a non-probability sampling technique. The duration of the study was nine months, from February 1, 2022, to October 31, 2022. The study included 900 participants who provided informed consent and had received two doses of the AstraZeneca vaccine. Demographic characteristics of participants, such as gender, age, comorbidities, AstraZenecaÂ vaccine with both doses along with booster dose, previous exposure to COVID-19 infection, and the prevalence of any local and systemic side effects following the firstÂ and secondÂ doses of vaccine, were documented. Results The study findings showed that of the 900

participants, 414Â (46.0%) were males and 486Â (54.0%) were females; their mean age was 40.72Â Â±Â 13.47 years. Among them, 198Â (22.0%) had hypertension and 144Â (16.0%) had diabetesÂ mellitus. Following the first dose of the AstraZenecaÂ vaccine, pain at the injection site was the most commonly reported side effect in 594Â (66.0%) participants. Moreover, swelling at the injection site was the most commonly reported side effect in 522Â (58.0%) participants after receiving the secondÂ dose of the vaccine. The level of satisfaction showed that the majority of the 648 participantsÂ (72.0%) were satisfied with their vaccination. Conclusion This study concluded that painÂ at the injection site was the most commonly reported side effect, followed by swelling and fever after the first dose of the vaccine. Following the second dose of the vaccine, adverse effects included headache, swelling, and burning at the injection site.

Bell's palsy or an aggressive infiltrating basaloid carcinoma post-mRNA vaccination for COVID-19? A case report and review of the literature. We report on an aggressive, infiltrating, metastatic, and ultimately lethal basaloid type of carcinoma arising shortly after an mRNA vaccination for COVID-19. The wife of the patient, since deceased, gave the consent for publishing the case. The malignancy was of cutaneous origin and the case showed symptoms consistent with Bell's palsy and trigeminal neuralgia beginning four days post-vaccination (right side head temporal pain). The temporal pain was suggestive for inflammation and impairment of T cell immune activation. Magnetic Resonance Imaging (MRI) showed a vascular loop on the left lateral aspect of the 5(th) cranial root exit of cerebellopontine angle constituting presumably a normal variant and was considered as an unrelated factor to the right-sided palsy and pain symptoms that corresponded to cranial nerves V (trigeminal nerve) and VII (facial nerve). In this study we describe all aspects of this case and discuss possible causal links between the rapid emergence of this metastatic cancer and mRNA vaccination. We place this within the context of multiple immune impairments potentially related to the mRNA injections that would be expected to potentiate more aggressive presentation and progression of cancer. The type of malignancy we describe suggests a population risk for occurrence of a large variety of relatively common basaloid phenotype cancer cells, which may have the potential for metastatic disease. This can be avoidable with early diagnosis and adequate treatment. Since facial paralysis/pain is one of the more common adverse neurological events following mRNA injection, careful inspection of cutaneous/soft tissue should be conducted to rule out malignancy. An extensive literature review is carried out, in order to elucidate the toxicity of mRNA vaccination that may have led to the death of this patient. Preventive and precise routine clinical investigations can potentially avoid future mortalities. See also Figure 1(Fig. 1).

Impact of Covid-19 Vaccination on Spontaneous Pharmacovigilance Reporting in France. INTRODUCTION: In 2021, the massive Covid-19 vaccination campaign in France was accompanied by an intensified pharmacovigilance monitoring of their potential adverse drug reactions. The importance of this reporting might have led to an important selective reporting and overloading of Pharmacovigilance Centres, delaying the recording of some reports in the national pharmacovigilance database. In this context, we aimed to evaluate the impact of the Covid-19 vaccination campaign in France and related reports on spontaneous reporting of adverse drug reactions that were not related to the Covid-19 vaccine. METHODS: We performed time-series analyses considering the monthly number of adverse drug reactions reported between January 1, 2018 and April 30, 2022 using the French Pharmacovigilance database. The impact of the Covid-19 vaccination campaign on the monthly reporting not Covid-19 vaccine related was estimated using interrupted time-series. January 2021, marking the start of the campaign, was the intervention date in the models. Analyses were run globally first considering all adverse drug reaction reports, and second according to notifier type and to case seriousness. RESULTS: We included 170,294 reports registered in the French Pharmacovigilance database between January 1, 2018 and April 30, 2022 that were not Covid-19

vaccine-related. Among these, 77,067 (45.3%) were serious and 146,683 (86.1%) had been reported by health care professionals. The campaign start was associated with a nearly 35.0% decrease in average monthly reporting that was not Covid-19 vaccine-related, with a significant level decrease in the monthly number of reports of -658.0 ($p < 10(-3)$) immediately after the vaccination campaign start and a subsequent slope decrease of -50.0 ($p < 10(-3)$). This decrease was mainly due to a significant level and slope decrease (level: -739.2 $p < 10(-3)$; slope: -39 [$p < 10(-2)$]) for health care professional reports. A similar level decrease was found for the monthly number of both serious and non-serious reports (-402.3, $p < 10(-3)$; and -311.9, $p = 10(-2)$, respectively). According to the ATC 1 level, the decrease in the monthly number of reports showed similar patterns for all drugs. However, a potential increase in the number of serious reports suspecting antineoplastic and immunomodulating drugs (ATC L) or drugs targeting blood was observed (ATC B). CONCLUSION: Our study showed a significant impact of the Covid-19 campaign vaccination in the reporting of adverse drug reactions that were not Covid-19 vaccine-related, of roughly 35%. This leads to a loss of information regarding the monitoring of drug safety that could have impacted the system capacity to detect safety signals for drugs other than Covid-19 vaccines.
Does COVID-19 or COVID-19 vaccination worsen migraines?
Breast erythema following COVID-19 infection and vaccination in implant-based breast reconstruction: An underestimated complication?
Accruing real-world data confirm that SARS-CoV-2 vaccination is not associated with stroke.
Multisystem Inflammatory Syndrome (MIS) following SARS-CoV-2 vaccinations; a systematic review. BACKGROUND: Although SARS-CoV-2 vaccines are generally safe, there are growing concerns about their link to a potentially life-threatening multi-system inflammatory syndrome following vaccination (MIS-V). We conducted this systematic review to elucidate the prevalence of MIS, severity, treatment, and outcomes following SARS-CoV-2 vaccination. METHODS: We searched PubMed, Scopus, ScienceDirect, Google Scholar, Virtual Health Library (VHL), Cochrane Library, and Web of Science databases for articles and case reports about MIS-V. We performed a qualitative analysis of individual cases from the included studies. RESULTS: Of the 1366 studies identified by database search, we retrieved twenty-six case reports and two cohort studies. We analyzed the data of 37 individual cases extracted from 27 articles. The average age of the cases included in this review was 18 (1-67) years, with the most being male (M: F 3.1:1). Of the 37 included cases, the cardiovascular system was the most affected system by MIS (36, 97.3%), followed by the gastrointestinal tract (32, 86.5%). CONCLUSION: MIS after SARS-CoV-2 vaccinations can be fatal, but the incidence is low. Prompt recognition of MIS and ruling out the mimickers are critical in the patient's early recovery.
Clinician Prompts for Human Papillomavirus Vaccination: A Cluster Randomized Trial. OBJECTIVE: We assessed the impact of an online intervention using clinician prompts for human papillomavirus (HPV) vaccination with a cluster randomized controlled trial. METHODS: The randomized trial occurred July 2021-January 2022 in 48 primary care pediatric practices (24 intervention, 24 control) across the US. We trained clinicians via two online learning modules, plus weekly ''quick tips'' delivered via text or email. The training taught practices to implement a staff prompt to the clinician (e.g., printed reminders placed on the keyboard) plus electronic health record (EHR) prompts (if not already done) at well and acute/chronic visits for initial and subsequent HPV vaccination. We assessed missed opportunities for HPV vaccination using logistic regression models accounting for clustering by practice on an intent to treat basis. Surveys assessed facilitators and barriers to using prompts. RESULTS: During the 6-month intervention, missed opportunities for HPV vaccination increased (worsened) in both intervention and control groups. However, at well child care visits, missed opportunities for the initial HPV vaccine increased by 4.5 (95% CI:Â -9.0%, -0.1%) percentage points less in intervention versus control practices. Change in missed opportunities for subsequent

doses at well child care and non-well child care visits did not differ between trial groups. An end-of trial survey found understaffing as a common challenge. CONCLUSIONS: Clinician prompts reduced missed opportunities for HPV vaccination at well child care visits. Understaffing related to the COVID-19 pandemic may have led to worsening missed opportunities for both groups and likely impeded practices in fully implementing changes.

COVID-19 Vaccine Hesitancy Among US Adults: Safety and Effectiveness Perceptions and Messaging to Increase Vaccine Confidence and Intent to Vaccinate. OBJECTIVE: Public health agencies have a critical role in providing effective messaging about mitigation strategies during a public health emergency. The objectives of this study were (1) to understand perceptions of COVID-19 vaccines, including concerns about side effects, safety, and effectiveness and how these perceptions influence vaccine decision-making among US adults and (2) to learn what messages might motivate vaccine uptake. METHODS: In April and May 2021, we conducted 14 online focus groups with non-Hispanic English-speaking and English- and Spanish-speaking Hispanic adults (Nâ€‰=â€‰99) not vaccinated against COVID-19. We oversampled adults aged 18-39 years and rural residents and systematically assessed 10 test messages. Researchers used a standardized guide and an a priori codebook for focus group discussions, coding transcripts, and thematic analysis. RESULTS: Vaccine hesitancy factors included fear of the unknown; long-term side effects, including infertility; and beliefs that the vaccines were developed too quickly and were not sufficiently effective. Motivating factors for receiving vaccination included the ability to safely socialize and travel. Health care providers were considered important trusted messengers. Participants were critical of most messages tested. Messages that came across as "honest" about what is not yet known about COVID-19 vaccines were perceived more positively than other messages tested. Messages were seen as ineffective if perceived as vague or lacking in data and specificity. CONCLUSIONS: Messages that were simple and transparent about what is unknown about vaccines relative to emerging science were viewed most favorably. Health care providers, friends, and family were considered influential in vaccination decision-making. Findings underscore the benefits of research-informed strategies for developing and disseminating effective messages addressing critical issues in a public health emergency.

Post-acute sequelae of COVID-19 in solid organ transplant recipients. BACKGROUND: Post-acute sequelae of coronavirus disease 2019 (COVID-19) (PASC), defined as prolonged symptoms following an episode of COVID-19, is not well-characterized in solid organ transplant recipients (SOTR). In this study, we aimed to assess the prevalence of PASC in SOTR, its descriptive characteristics, and associated risk factors. METHODS: We retrospectively identified SOTRs with acute COVID-19 between June 1, 2020 and April 15, 2022, and abstracted demographic and medical history, characteristics of acute COVID-19 illness, and COVID-19 vaccination status. We defined PASC as ongoing/new symptoms present at 6Â weeks or longer following acute COVID-19 diagnosis. RESULTS: Among 208 SOTRs with acute COVID-19, 72 (35%) developed PASC. Common symptoms were respiratory symptoms (67%), headache (40%), and difficulty concentrating (10%). Severe acute COVID-19 disease and presence of respiratory symptoms were associated with higher odds of PASC in multivariable analyses, while receipt of at least one COVID-19 vaccination prior to transplantation was protective. CONCLUSION: We found that PASC occurs in about a third of SOTRs with acute COVID-19 and has similar symptoms as described previously in immunocompetent hosts. Pre-transplant vaccination may be protective. Further prospective multicenter studies are needed.

SARS-CoV-2 vaccination and multiple sclerosis: a large multicentric study on relapse risk after the third booster dose. BACKGROUND: COVID-19 vaccines have been recommended to people with multiple sclerosis (pwMS) and, to ensure durable immunity, a third booster dose has been administered in several countries. Data about potential risks associated with the third booster dose in pwMS, such as vaccine-triggered disease exacerbations, are still scarce. OBJECTIVE: To investigate

whether the administration of a third booster dose of mRNA COVID-19 vaccines was associated with an increased risk of short-term disease reactivation in a large cohort of pwMS. METHODS: We retrospectively selected 1265 pwMS who received a third booster dose of an mRNA COVID-19 vaccine. Demographic and clinical data were collected, including the presence, number and characteristics of relapses in the 60Â days prior to and after the third booster dose. RESULTS: In the selected cohort, the relapse rate in the two months after administration of the third booster dose of mRNA COVID-19 vaccines did not increase when compared with the prior two months. Indeed, the percentage of pwMS experiencing relapses in the 60Â days following the administration of the third booster dose was 2.1%, similar to the percentage recorded in 60Â days prior to vaccination, which was 1.9%. CONCLUSIONS: The third booster dose of mRNA COVID-19 vaccines appeared to be safe for pwMS.

Adverse events after first and second doses of COVID-19 vaccination in England: a national vaccine surveillance platform self-controlled case series study. OBJECTIVES: To estimate the incidence of adverse events of interest (AEIs) after receiving their first and second doses of coronavirus disease 2019 (COVID-19) vaccinations, and to report the safety profile differences between the different COVID-19 vaccines. DESIGN: We used a self-controlled case series design to estimate the relative incidence (RI) of AEIs reported to the Oxford-Royal College of General Practitioners national sentinel network. We compared the AEIs that occurred seven days before and after receiving the COVID-19 vaccinations to background levels between 1 October 2020 and 12 September 2021. SETTING: England, UK. PARTICIPANTS: Individuals experiencing AEIs after receiving first and second doses of COVID-19 vaccines. MAIN OUTCOME MEASURES: AEIs determined based on events reported in clinical trials and in primary care during post-license surveillance. RESULTS: A total of 7,952,861 individuals were vaccinated with COVID-19 vaccines within the study period. Among them, 781,200 individuals (9.82%) presented to general practice with 1,482,273 AEIs. Within the first seven days post-vaccination, 4.85% of all the AEIs were reported. There was a 3-7% decrease in the overall RI of AEIs in the seven days after receiving both doses of Pfizer-BioNTech BNT162b2 (RIâ€‰=â€‰0.93; 95% CI: 0.91-0.94) and 0.96; 95% CI: 0.94-0.98), respectively) and Oxford-AstraZeneca ChAdOx1 (RIâ€‰=â€‰0.97; 95% CI: 0.95-0.98) for both doses), but a 20% increase after receiving the first dose of Moderna mRNA-1273 (RIâ€‰=â€‰1.20; 95% CI: 1.00-1.44)). CONCLUSIONS: COVID-19 vaccines are associated with a small decrease in the incidence of medically attended AEIs. Sentinel networks could routinely report common AEI rates, which could contribute to reporting vaccine safety.

Specific immune responses after BNT162b2 mRNA vaccination and COVID-19 infection. Although vaccines against COVID-19 are effective tools in preventing severe disease, recent studies have shown enhanced protection after vaccine boosters. The aim of our study was to examine the dynamics and duration of both humoral and cellular immune responses following a three-dose regimen of the BNT162b2 mRNA vaccine. In a longitudinal prospective study we enrolled 86 adults who received the BNT162b2 vaccine, 35 unvaccinated individuals with a history of mild COVID-19 and a control group of 30 healthy SARS-CoV-2 seronegative persons. We assessed the SARS-CoV-2-specific T cell responses and IgG production up to 12 months post the third BNT162b2 dose in 24 subjects. The vaccinated group had significantly higher IgG antibody levels after two doses compared to the convalescent group ($p<0.001$). After the third dose, IgG levels surged beyond those detected after the second dose ($p<0.001$). Notably, these elevated IgG levels were maintained 12 months post the third dose. After two doses, specific T cell responses were detected in 87.5% of the vaccinated group. Additionally, there was a significant decrease before the third dose. However, post the third dose, specific T cell responses surged and remained stable up to the 12-month period. Our findings indicate that the BNT162b2 vaccine induces potent and enduring humoral and cellular responses, which are

notably enhanced by the third dose and remain persistant without a significant decline a year after the booster. Further research is essential to understand the potential need for subsequent boosters.

Spontaneous Intracranial Hypotension Complicated by a Cerebral Venous Thrombosis Following an mRNA Covid-19 Vaccination: Coincidence vs Cause? Spontaneous intracranial hypotension (SIH) is a rare cause of persistent headache, particularly among young and middle-aged people. A potentially life-threatening complication of SIH is a cerebral venous thrombosis (CVT). The authors present a case in which a patient presented with SIH complicated by CVT one week after receiving a booster dose of mRNA COVID-19 vaccine. According to our literature review, this is the first such case report. LEARNING POINTS: Spontaneous intracranial hypotension is rarely complicated by cerebral venous thrombosis (CVT).The majority of cerebral venous thrombosis cases post-COVID-19 vaccination occurred in patients administered with adenoviral vaccines. CVT following administration of mRNA COVID-19 vaccines is rare.Clinicians should consider COVID-19 vaccine-induced CVT in recently vaccinated patients; MRI plays an important role in accurate diagnosis.

Aortic Thrombosis Associated with Three Types of COVID-19 Vaccine. Aortic thrombosis has been studied little in patients with COVID-19 and an association has recently been reported with the vaccine for this disease. The aim of the present study is to report five cases of aortic thrombosis at our institution within a three-month period associated with the COVID-19 vaccine. Five cases of aortic thrombosis were evaluated-three women and two men aged 29, 49, 51, 60, and 79 years. Four thrombi involved the thoracic aortic and one involved the abdominal aorta, with embolisms found in the kidneys, spleen, liver, upper limbs, and lower limbs. Embolectomy was performed on the limbs, and anticoagulant therapy was performed for the abdominal arteries. The patients recovered well and anticoagulant therapy was maintained. Aortic thrombosis is uncommon but was associated with the AstraZeneca vaccine in this case series.

A novel SARS-CoV-2 Beta RBD DNA vaccine directly targeted to antigen-presenting cells induces strong humoral and T cell responses. Throughout the COVID-19 pandemic, several variants of concern (VoC) of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have evolved, affecting the efficacy of the approved COVID-19 vaccines. To address the need for vaccines that induce strong and persistent cross-reactive neutralizing antibodies and T cell responses, we developed a prophylactic SARS-CoV-2 vaccine candidate based on our easily and rapidly adaptable plasmid DNA vaccine platform. The vaccine candidate, referred to here as VB2129, encodes a protein homodimer consisting of the receptor binding domain (RBD) from lineage B.1.351 (Beta) of SARS-CoV-2, a VoC with a severe immune profile, linked to a targeting unit (human LD78Î²/CCL3L1) that binds chemokine receptors on antigen-presenting cells (APCs) and a dimerization unit (derived from the hinge and C(H)3 exons of human IgG3). Immunogenicity studies in mice demonstrated that the APC-targeted vaccine induced strong antibody responses to both homologous Beta RBD and heterologous RBDs derived from Wuhan, Alpha, Gamma, Delta, and Omicron BA.1 variants, as well as cross-neutralizing antibodies against these VoC. Overall, preclinical data justify the exploration of VB2129 as a potential booster vaccine that induces broader antibody- and T cell-based protection against current and future SARS-CoV-2 VoC.

Using a Bayesian hierarchical approach to study the association between non-pharmaceutical interventions and the spread of Covid-19 in Germany. Non-Pharmaceutical Interventions (NPIs) are community mitigation strategies, aimed at reducing the spread of illnesses like the coronavirus pandemic, without relying on pharmaceutical drug treatments. This study aims to evaluate the effectiveness of different NPIs across sixteen states of Germany, for a time period of 21 months of the pandemic. We used a Bayesian hierarchical approach that combines different sub-models and merges information from complementary sources, to estimate the true and unknown number of infections. In this framework, we used data on reported cases, hospitalizations, intensive care unit occupancy,

and deaths to estimate the effect of NPIs. The list of NPIs includes: "contact restriction (up to 5 people)", "strict contact restriction", "curfew", "events permitted up to 100 people", "mask requirement in shopping malls", "restaurant closure", "restaurants permitted only with test", "school closure" and "general behavioral changes". We found a considerable reduction in the instantaneous reproduction number by "general behavioral changes", "strict contact restriction", "restaurants permitted only with test", "contact restriction (up to 5 people)", "restaurant closure" and "curfew". No association with school closures could be found. This study suggests that some public health measures, including general behavioral changes, strict contact restrictions, and restaurants permitted only with tests are associated with containing the Covid-19 pandemic. Future research is needed to better understand the effectiveness of NPIs in the context of Covid-19 vaccination.

Polyethylene glycol (PEG)-associated immune responses triggered by clinically relevant lipid nanoparticles in rats. With the large-scale vaccination of lipid nanoparticles (LNP)-based COVID-19 mRNA vaccines, elucidating the potential polyethylene glycol (PEG)-associated immune responses triggered by clinically relevant LNP has become imminent. However, inconsistent findings were observed across very limited population-based studies. Herein we initiated a study using LNP carrier of Comirnaty(Â®) as a representative, and simulated real-world clinical practice covering a series of time points and various doses correlated with approved LNP-delivered drugs in a rat model. We demonstrated the time- and dose-dependency of LNP-induced anti-PEG antibodies in rats. As a thymus-independent antigen, LNP unexpectedly induced isotype switch and immune memory, leading to rapid enhancement and longer lasting time of anti-PEG IgM and IgG upon re-injection in rats. Importantly, initial LNP injection accelerated the blood clearance of subsequent dosing in rats. These findings refine our understandings on LNP and possibly other PEG derivatives, and may promote optimization of related premarket guidelines and clinical protocols.

Immunogenicity and reactogenicity of a first booster with BNT162b2 or full-dose mRNA-1273: A randomised VACCELERATE trial in adults â‰¥75Â years (EU-COVAT-1). BACKGROUND: Vaccination remains crucial for protection against severe SARS-CoV-2 infection, especially for people of advanced age, however, optimal dosing regimens are as yet lacking. METHODS: EU-COVAT-1-AGED Part A is a randomised controlled, adaptive, multicentre phase II trial evaluating safety and immunogenicity of a 3rd vaccination (1st booster) in individuals â‰¥75Â years. Fifty-three participants were randomised to full-doses of either mRNA-1273 (SpikevaxÂ®, 100Â Âµg) or BNT162b2 (ComirnatyÂ®, 30Â Âµg). The primary endpoint was the rate of 2-fold circulating antibody titre increase 14Â days post-vaccination measured by quantitative electrochemiluminescence (ECL) immunoassay, targeting RBD region of Wuhan wild-type SARS-CoV-2. Secondary endpoints included the changes in neutralising capacity against wild-type and 25 variants of concern at 14Â days and up to 12Â months. Safety was assessed by monitoring of solicited adverse events (AEs) for seven days after on-study vaccination. Unsolicited AEs were collected until the end of follow-up at 12Â months, SAEs were pursued for a further 30Â days. RESULTS: Between 08th of November 2021 and 04th of January 2022, 53 participants â‰¥75Â years received a COVID-19 vaccine as 1st booster. Fifty subjects (BNT162b2 nÂ =Â 25/mRNA-1273 nÂ =Â 25) were included in the analyses for immunogenicity at day 14. The primary endpoint of a 2-fold anti-RBD IgG titre increase 14Â days after vaccination was reached for all subjects. A 3rd vaccination of full-dose mRNA-1273 provided higher anti-RBD IgG titres (Geometric mean titre) D14 mRNA-127310711Â IU/mL (95Â %-CI: 8003;14336) vs. BNT162b2: 7090Â IU/mL (95Â %-CI: 5688;8837). We detected a pattern showing higher neutralising capacity of full-dose mRNA-1273 against wild-type as well as for 23 out of 25 tested variants. INTERPRETATION: Third doses of either BNT162b2 or mRNA-1273 provide substantial circulating antibody increase 14Â days after vaccination. Full-dose mRNA-1273 provides higher antibody levels

with an overall similar safety profile for people â‰¥75Â years. FUNDING: This trial was funded by the European Commission (Framework Program HORIZON 2020).

Response to Letter to the Editor, Comment on "Effect of COVID vaccinations on monthly migraine days".

Citrobacter freundii-associated osteomyelitis and thromboembolic events following Moderna COVID-19 vaccination: a rare case report from Nepal. INTRODUCTION: Vaccination against coronavirus disease 2019 (COVID-19) is essential for controlling the ongoing cases of this disease. Citrobacter infections of the bones and joints are extremely uncommon. Thromboembolism and deep vein thrombosis (DVT) are very rare complications. CASE PRESENTATION: The authors present a rare case of osteomyelitis, septic arthritis, deep venous thrombosis, and pulmonary embolism in a 15-year-old previously healthy boy occurring shortly after receiving the second dose of the Moderna COVID-19 vaccine. He experienced pain, swelling in the right leg, shortness of breath, and fever, followed by chest pain and leg edema. Treatment included anticoagulation, ketorolac for pain management, antipyretics, and intravenous antibiotics (Tazobactam/Piperacillin, Linezolid, Clindamycin) for osteomyelitis. DISCUSSION: The risk of COVID-19 vaccine-related thrombotic events is minimal. Thrombotic events reported among mRNA is very rare. Citrobacter freundii bone and joint infections are very rare, accounting for a small percentage of cases. Some documented cases include cefotaxime-resistant strains causing necrotizing fascitis and osteomyelitis, including postarthroplasty infections. Due to the diverse range of susceptibility patterns and the widespread occurrence of drug resistance, personalized treatment based on culture and sensitivity testing is recommended. However, in rare cases, severe complications like DVT and joint infections associated with Citrobacter infection may occur and should be reported to the vaccine adverse events reporting system. CONCLUSION: Administering the COVID-19 vaccine to enhance natural antibodies is crucial, despite the low risk of infection, thromboembolism, and DVT. Healthcare providers should stay vigilant about adverse effects postvaccination and promptly report those cases.

COVID-19 vaccination of patients with chronic immune-mediated inflammatory disease. OBJECTIVE: This study aimed to analyze the safety and efficacy of COVID-19 vaccines among patients with chronic immune-mediated inflammatory disease (IMID) in China. METHODS: Participants who were diagnosed with a chronic IMID were eligible for inclusion in this study. Age- and sex-matched healthy vaccinated individuals were set as the control group. All participants received two doses of the inactivated CoronaVac vaccine or three doses of the recombinant protein subunit vaccine ZF2001. Adverse events, IMID activity after vaccination, and the rate of COVID-19 in the two groups were compared. RESULTS: There were 158 patients in the IMID group, with an average age of 40â€‰Â±â€‰14Â years old, and 98 female subjects. In the IMID group, 123 patients received the inactivated CoronaVac vaccine, and 35 patients received the recombinant protein subunit vaccine ZF2001. There were 153 individuals in the control group, including 122 who received the CoronaVac vaccine and 31 who received the recombinant protein subunit vaccine ZF2001. The frequency of vaccine-related adverse events in the IMID group was less than that in the control group, all of which were mild local effects, and no serious events occurred. Of note, no disease flares occurred in the IMID group. No participants in either group subsequently got COVID-19, so the incidence rate was 0% in both groups. CONCLUSION: COVID-19 vaccination was found to be safe for IMID subjects, any adverse events were mild, and vaccination did not increase the risk of disease activity. Meanwhile, vaccination could effectively reduce the incidence of COVID-19 in IMID patients. In the future, studies with a larger sample size and a longer duration are needed.

Reinfection rates, change in antibody titers and adverse events after COVID-19 vaccination among patients previously infected with COVID-19 in Metro Manila, Philippines: a secondary analysis of a completed cohort study. BACKGROUND: Variation in immune response to COVID-19 vaccines is

observed among different ethnicities. We aimed to describe the reinfection rates, change in antibody titers, and adverse events among Filipinos. METHODS: This is a secondary analysis of a cohort study of 307 participants within one year of having COVID-19 infection. We measured COVID-19 antibody levels at pre-determined timepoints (Days 21, 90, 180, 270, and 360 from initial infection). We monitored for COVID-19 symptoms and obtained details on COVID-19 vaccination. An adjudication committee classified the participants as probable, possible, or unlikely COVID-19 reinfection. We determined the probable reinfection rate, adverse events, and the geometric mean titer (GMT) ratio of pre- and post-vaccination antibody levels according to type and brand of COVID-19 vaccine. RESULTS: At the end of the follow-up period, 287 (93.5%) out of 307 study participants were fully vaccinated, 1 was partially vaccinated (0.3%), and 19 were unvaccinated (6.2%). Among the fully vaccinated participants, those given mRNA vaccines had the lowest reinfection rate (19.2 cases/100 person-years, 95% CI 9.6, 38.4), followed by viral vector vaccines (29.8 cases/100 person-years, 95% CI 16.9, 52.4). We observed the highest reinfection rate among those given inactivated virus vaccines (32.7 cases/100 person-years, 95% CI 23.6, 45.3). The reinfection rate was 8.6 cases/100 person-years (95% CI 4.1, 17.9) for unvaccinated participants and 3.6 cases/100 person-years (95% CI 0.5, 25.3) for partially vaccinated participants. We observed the largest rise in antibody titers among those given mRNA vaccines (GMT ratio 288.5), and the smallest rise among those given inactivated virus vaccines (GMT ratio 16.7). We observed the highest percentage of adverse events following immunization with viral vector vaccines (63.8%), followed by mRNA vaccines (62.7%), and the lowest for inactivated virus vaccines (34.7%). No serious adverse events were reported. CONCLUSION: Vaccinees given the mRNA vaccines had the lowest reinfection rate and the highest rise in antibody titers. Vaccinees given inactivated virus vaccines had the highest reinfection rate, smallest rise in antibody titers, and lowest percentage of adverse events. The small sample size and imbalanced distribution of the type of vaccines received limits the external generalizability of our results. STUDY REGISTRATION: The cohort study was registered at the Philippine Health Research Registry on December 14, 2020 (PHRR201214-003199).

Impact of the COVID-19 pandemic on the spontaneous reporting and signal detection of adverse drug events. External factors severely affecting in a short period of time the spontaneous reporting of adverse events (AEs) can significantly impact drug safety signal detection. Coronavirus disease 2019 (COVID-19) represented an enormous challenge for health systems, with over 767 million cases and massive vaccination campaigns involving over 70% of the worldwide population. This study investigates the potential masking effect on certain AEs caused by the substantial increase in reports solely related to COVID-19 vaccines within various spontaneous reporting systems (SRSs). Three SRSs were used to monitor AEs reporting before and during the pandemic, namely, the World Health Organisation (WHO) global individual case safety reports database (VigiBaseÂ®), the United States Food and Drug Administration Adverse Event Reporting System (FAERS) and the Japanese Adverse Drug Event Report database (JADER). Findings revealed a sudden over-reporting of 35 AEs (â‰¥ 200%) during the pandemic, with an increment of the RRF value in 2021 of at least double the RRF reported in 2020. This translates into a substantial reduction in signals of disproportionate reporting (SDR) due to the massive inclusion of COVID-19 vaccine reports. To mitigate the masking effect of COVID-19 vaccines in post-marketing SRS analyses, we recommend utilizing COVID-19-corrected versions for a more accurate assessment.

Seroprevalence of anti-SARS-CoV-2 antibodies before and after implementation of anti-COVID-19 vaccination among hospital staff in Bangui, Central African Republic. Healthcare workers (HCWs) are at high to very high risk for SARS-CoV-2 infection. The persistence of this pandemic worldwide has instigated the need for an investigation of the level of prevention through immunization and vaccination against SARS-CoV-2 among HCWs. The objective of our study was to evaluate any changes

in anti-COVID-19 serological status before and after the vaccination campaign of health personnel in the Central African Republic. We carried out a repeated cross-sectional serological study on HCWs at the university hospital centers of Bangui. Blood samples were collected and tested for anti-SARS-CoV-2 IgM and IgG using the ELISA technique on blood samples. A total of 179 and 141 HCWs were included in the first and second surveys, respectively. Of these staff, 31.8% of HCWs were positive for anti-SARS-CoV-2 IgG in the first survey, whereas 95.7% were positive for anti-SARS-CoV-2 IgG in the second survey. However, the proportion of HCWs positive for SARS-CoV-2 IgM antibodies was low (9.7% in the first survey and 3.6% in the second survey). These findings showed a sharp increase in seroprevalence over a one-year period. This increase is primarily due to the synergistic effect of the infection and the implementation of vaccines against COVID-19. Further studies to assess the persistence of anti-SARS-CoV-2 antibodies are needed.

[Case Report: MPO-ANCA Associated Vasculitis After Pfizer-BioNTech COVID-19 mRNA Vaccination]. We report a case of MPO-anti-neutrophil cytoplasmic antibody ANCA-associated vasculitis, with pulmonary-renal syndrome, after the mRNA booster third dose vaccine Pfizer BioNTech against COVID-19 in 71-year-old Caucasian man with no specific past medical history. A kidney biopsy diagnosed ANCA-associated pauci-immune crescentic glomerulonephritis. Renal function and constitutional symptoms have been partially improved with treatment with dialysis, intravenous rituximab and steroid pulse therapy. No disease following either infection or vaccination with fourth dose against COVID-19.

Deep immunological imprinting due to the ancestral spike in the current bivalent COVID-19 vaccine. To combat the evolving SARS-CoV-2 Omicron variants, bivalent COVID-19 mRNA vaccines, encoding both ancestral and Omicron BA.5 spikes, have replaced monovalent vaccines in numerous countries. However, fourth doses of either vaccine result in similar neutralizing antibody titers against Omicron subvariants, raising the possibility of immunological imprinting. To address this, we investigate antibody responses in 72 participants given three doses of a monovalent mRNA vaccine, followed by a bivalent or monovalent booster, or those with breakthrough infections with BA.5 or BQ. Bivalent boosters do not show notably higher binding or virus-neutralizing titers against various SARS-CoV-2 variants compared to monovalent ones. However, breakthrough infections lead to significantly better neutralization of Omicron subvariants. Multiple analyses, including antigenic mapping, suggest that the ancestral spike in bivalent vaccines is causing deep immunological imprinting, preventing broadening of antibodies to the BA.5 component, thereby defeating its intended goal. Its removal from future vaccine compositions is therefore strongly recommended.

Adrenal Crisis Associated With COVID-19 Vaccination in Patients With Adrenal Insufficiency. Vaccination is generally recommended for patients with adrenal insufficiency receiving glucocorticoid replacement therapy because they are at risk of experiencing adrenal crisis during infections. Conventional vaccinations, such as those for influenza virus, have rarely been associated with adrenal crisis in patients with adrenal insufficiency; therefore, increasing the glucocorticoid dose during vaccination is not necessarily recommended. The COVID-19 mRNA vaccines exhibit a higher degree of adverse reactions, including fever and general fatigue, than those of conventional vaccines. Here, we present 3 cases of adrenal crisis associated with mRNA COVID-19 (BNT162b2) vaccination in patients with secondary adrenal insufficiency. Two patients presented with adrenal crisis after the second dose, whereas 1 presented with adrenal crisis after the first dose. Within 24â€…hours of vaccination, all patients presented with fatigue and appetite loss, and 2 patients were febrile. None of them increased their glucocorticoid dosage at the time of vaccination, leading to an adrenal crisis. To date, 9 cases of adrenal crisis, including ours, associated with COVID-19 vaccination have been reported. Considering the high degree of adverse reactions to COVID-19 vaccination, administration of

prophylactic stress dose of glucocorticoids is strongly recommended, particularly in patients with symptomatic adverse reactions, to protect them from adrenal crisis.

Two Cases of Thyroiditis in Adolescents Following COVID-19 Vaccinations. With the onset of the COVID-19 pandemic and the development of widespread vaccination strategies, there have been case reports in the adult literature suggesting an increase in thyroiditis after COVID-19 vaccination. We herein describe 2 children who presented with thyroiditis after COVID-19 vaccination. Two children who received Pfizer-BioNTech COVID-19 messenger RNA vaccines later developed symptoms of thyroid hyperactivity, had positive thyroid-stimulating immunoglobulin (TSI) levels and received treatment directed toward Graves disease. Our case series is the first to demonstrate Graves disease after COVID-19 vaccination in the pediatric population. Given this possibility, it is important for pediatricians to be watchful for symptoms of thyroiditis post vaccination to prevent treatment delays.

The impact of COVID-19 on Japanese patients with eosinophilic gastrointestinal disorders during the vaccination era. BACKGROUND: Eosinophilic gastrointestinal disorders (EGIDs) are chronic allergic diseases categorized as eosinophilic esophagitis (EoE) and non-EoE EGIDs. Few studies regarding the association between EGIDs and coronavirus disease 2019 (COVID-19) have been reported. Although most Japanese individuals received the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine, the incidence of COVID-19 remained high in 2022. This study examines the incidence of COVID-19 in patients with EGIDs during the vaccination era. METHODS: Patients with EGIDs who visited our department between October and December 2022 were enrolled in the study. The incidence and severity of COVID-19 prior to October 1, 2022 were determined. Patients who reported having COVID-19 also reported their hospitalization history, intensive care unit admissions, and EGID flares. The number of SARS-CoV-2 vaccinations received and treatment for EGIDs were obtained from the patients' medical records. RESULTS: Of 111 patients with EGIDs (65 with EoE and 46 with non-EoE EGIDs) included in this study, 31 (28%) patients reported having COVID-19, including 14 (22%) with EoE and 17 (37%) with non-EoE EGIDs. Fifty-nine (84%) patients received two or more vaccinations, and 11 (16%) patients received no vaccinations. COVID-19 was mild in all but one patient who had moderate symptoms. COVID-19 was not associated with EGID flares. EGID treatments and an unvaccinated status were not associated with an increased risk of COVID-19. CONCLUSION: COVID-19 was mild in patients with EGIDs and not associated with EGIDs flares during the vaccination era. There was a relatively high incidence of COVID-19 among patients with non-EoE EGIDs.

Reply to comment to "axillary lymph nodes enlargement after Sars-CoV-2 vaccine in patients undergoing breast examination: a single-centre experience in 285 women".

Factors associated with COVID-19 vaccination coverage in hypertensive patients with Omicron infection in Shanghai, China. The potential future burden of COVID-19 is determined by the level of susceptibility of the population to infection. The protective effect provided by those previously infected diminishes over several months, while individuals with mixed immunity have the highest degree and persistence of protection. This study aimed to clarify the vaccination status of COVID-19 patients with hypertension and to analyze the characteristics and risk factors of non-vaccinated patients to protect this vulnerable population in the future. The study ultimately enrolled 4576 hypertensive patients with Omicron infection from April 6, 2022, to May 15, 2022. Among them, 3556 patients (77.7%) had received at least one dose of vaccine, and 2058 patients (45.0%) received a booster dose. In the multivariate logistic analysis, male (OR 1.328, 95% CI 1.138-1.550, pâ€‰<â€‰.001), age (60-69â€‰years vs.18-49â€‰years) (OR 0.348, 95% CI 0.270-0.448, pâ€‰<â€‰.001), age (â‰¥70â€‰years vs.18-49â€‰years) (OR 0.130, 95% CI 0.100-0.169, pâ€‰<â€‰.001), diabetes mellitus (OR 0.553, 95% CI 0.463-0.661, pâ€‰<â€‰.001), chronic pulmonary diseases (OR 0.474, 95% CI 0.260-0.863, pâ€‰=â€‰.015), chronic kidney disease (OR 0.177, 95% CI 0.076-0.410, pâ€‰<â€‰.001), and cancer (OR 0.225, 95% CI 0.094-0.535,

pâ€‰=â€‰.001) were associated with vaccinated status. The vaccine coverage rate, especially the booster vaccine, was low for hypertensive patients with Omicron infection. Females, increasing age, and coexisting chronic diseases were associated with more inadequate vaccine coverage in hypertensive COVID-19 patients. Targeted interventions are required to address the under-vaccination of diverse hypertensive populations.

The Burden of COVID-19 in Adult Patients With Hematological Malignancies: A Single-center Experience After the Implementation of Mass-vaccination Programs Against SARS-CoV-2. BACKGROUND/AIM: Despite the widespread mass-vaccination programs worldwide and the continuing evolution of COVID-19 therapeutics, the burden of SARS-CoV-2 infection in patients with hematological malignancies (HM) remains elusive. The aim of the present study was to assess the clinical characteristics, outcomes and therapeutic strategies applied in HM patients hospitalized during the post-vaccine period in Greece. PATIENTS AND METHODS: From June 2021 to October 2022, 60 HM patients with COVID-19 were retrospectively analyzed. Exploratory end-points included the incidence of intubation, probability of recovery, mortality, and duration of remdesivir (RDV) administration. RESULTS: Overall, mechanical ventilation (MV) was required for five patients and crude mortality was 8.3%. HM of lymphocytic origin (p=0.035) and obesity (p=0.03) were the main determinants of the risk of intubation and among several laboratory markers, only LDH>520 IU/l was proven to be an independent MV predictor (p=0.038). The number of co-existing comorbidities (p=0.05) and disease severity on admission (p<0.001) were found to rule the probability of recovery, and dexamethasone was associated with worse prognosis, particularly in patients with mild/moderate COVID-19. RDV was administered to the entire cohort, of whom 38 were managed with an extended course. In the multivariate analysis, patients with HM of lymphocytic origin were more likely to receive RDV for more than five days (p=0.002). CONCLUSION: Our study emphasizes the frailty of HM patients, even in the era of Omicron-variant predominance, and underlines the need to optimize therapy.

Th2 and Th17-Associated Immunopathology Following SARS-CoV-2 Breakthrough Infection in Spike-Vaccinated ACE2-humanized Mice. Vaccines have demonstrated remarkable effectiveness in protecting against COVID-19; however, concerns regarding vaccine-associated enhanced respiratory diseases (VAERD) following breakthrough infections have emerged. Spike protein subunit vaccines for SARS-CoV-2 induce VAERD in hamsters, where aluminum adjuvants promote a Th2-biased immune response, leading to increased type 2 pulmonary inflammation in animals with breakthrough infections. To gain a deeper understanding of the potential risks and the underlying mechanisms of VAERD, we immunized ACE2-humanized mice with SARS-CoV-2 Spike protein adjuvanted with aluminum and CpG-ODN. Subsequently, we exposed them to increasing doses of SARS-CoV-2 to establish a breakthrough infection. The vaccine elicited robust neutralizing antibody responses, reduced viral titers, and enhanced host survival. However, following a breakthrough infection, vaccinated animals exhibited severe pulmonary immunopathology, characterized by a significant perivascular infiltration of eosinophils and CD4(+) T cells, along with increased expression of Th2/Th17 cytokines. Intracellular flow cytometric analysis revealed a systemic Th17 inflammatory response, particularly pronounced in the lungs. Our data demonstrate that aluminum/CpG adjuvants induce strong antibody and Th1-associated immunity against COVID-19 but also prime a robust Th2/Th17 inflammatory response, which may contribute to the rapid onset of T cell-mediated pulmonary immunopathology following a breakthrough infection. These findings underscore the necessity for further research to unravel the complexities of VAERD in COVID-19 and to enhance vaccine formulations for broad protection and maximum safety.

A single blinded, phase IV, adaptive randomised control trial to evaluate the safety of coadministration of seasonal influenza and COVID-19 vaccines (The FluVID study). OBJECTIVES:

We evaluated the frequency of moderate and severe adverse events following coadministration of seasonal influenza vaccine (SIV) versus placebo with COVID-19 vaccines among adults to support practice guidelines. METHODS: FluVID is a participant-blinded, phase IV, randomised control trial. On the same day as the participant's scheduled COVID-19 vaccine, participants were randomised to receive SIV or saline placebo; those assigned placebo at visit one then received SIV a week later, and vice versa. Self-reported adverse events were collected daily for seven days following each visit. The primary endpoint was any solicited adverse event of at least moderate severity occurring up to seven days following receipt of SIV or placebo. This was modelled using a Bayesian logistic regression model. Analyses were performed by COVID-19 vaccine type and dose number. RESULTS: Overall, 248 participants were enrolled; of these, 195 had received BNT162b2 and 53 had received mRNA1273 COVID-19 vaccines according to national guidelines. After randomisation, 119 were assigned to receive SIV and 129 were assigned to receive placebo at visit one. Adverse events were most frequently reported as mild (grade 1) in nature. Among 142 BNT162b2 booster dose one and 43 BNT162b2 booster dose two recipients, the posterior median risk difference for moderate/severe adverse events following SIV versus placebo was 13% (95% credible interval [CrI] -0.03 to 0.27) and 13% (95%CrI -0.37 to 0.12), respectively. Among 18 mRNA1273 booster dose one and 35 mRNA1273 booster dose two recipients, the posterior median risk difference of moderate/severe adverse events following influenza vaccine versus placebo was 6% (95%CrI -0.29 to 0.41) and -4% (95%CrI -0.30 to 0.23), respectively. CONCLUSION: Adverse events following SIV and COVID-19 co-administration were generally mild and occurred with similar frequency to events following COVID-19 vaccine alone. We found no evidence to justify routine separation of SIV and COVID-19 vaccine doses. CLINICAL TRIAL REGISTRATION: ACTRN12621001063808.

Optic Neuritis following Second Administration of COVID-19 Vaccine: A Case Report. A 28-year-old woman presented to eye casualty with signs and symptoms suggestive of optic neuritis following a recent COVID-19 vaccination (the Moderna mRNA-1273 vaccine). The best corrected visual acuity was 6/15 in the right eye and 6/6 in the left eye with a relative afferent pupillary defect in the right eye. Following examination and investigation, she was found to fit the McDonald criteria for multiple sclerosis and was commenced on disease-modifying therapy. Demyelinating events have been identified to occur following COVID-19 vaccinations. In this case, we have found that the Moderna mRNA-1273 vaccine could have contributed to the development of optic neuritis following a second dose of the vaccine.

Deficient Immune Response following SARS-CoV-2 Vaccination in Patients with Hepatobiliary Carcinoma: A Forgotten, Vulnerable Group of Patients. INTRODUCTION: Data on immune response rates following vaccination for severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) in patients with hepatobiliary carcinoma (HBC) are rare. However, impaired immunogenicity must be expected due to the combination of chronic liver diseases (CLDs) with malignancy and anticancer treatment. METHODS: In this prospective, longitudinal study, 101 patients were included, of whom 59 were patients with HBC under anticancer treatment. A cohort of patients with a past medical history of gastrointestinal cancer, of whom 28.6% had HBC without detectable active tumor disease having been off therapy for at least 12 months, served as control. Levels of SARS-CoV-2 anti-spike IgG, surrogate neutralization antibodies (sNABs), and cellular immune responses were compared. In uni- and multivariable subgroup analyses, risk factors for impaired immunogenicity were regarded. Data on rates and clinical courses of SARS-CoV-2 infections were documented. RESULTS: In patients with HBC under active treatment, levels of SARS-CoV-2 anti-spike IgG were significantly lower (2.55 log(10) BAU/mL; 95% CI: 2.33-2.76; $p < 0.01$) than in patients in follow-up care (3.02 log(10) BAU/mL; 95% CI: 2.80-3.25) 4 weeks after two vaccinations. Antibody levels decreased over time, and differences between the groups diminished. However, titers of SARS-CoV-2 sNAB were for a longer time

significantly lower in patients with HBC under treatment (64.19%; 95% CI: 55.90-72.48; $p < 0.01$) than in patients in follow-up care (84.13%; 95% CI: 76.95-91.31). Underlying CLD and/or liver cirrhosis Child-Pugh A or B (less than 8 points) did not seem to further impair immunogenicity. Conversely, chemotherapy and additional immunosuppression were found to significantly reduce antibody levels. After a third booster vaccination for SARS-CoV-2, levels of total and neutralization antibodies were equalized between the groups. Moreover, cellular response rates were balanced. Clinically, infection rates with SARS-CoV-2 were low, and no severe courses were observed. CONCLUSION: Patients with active HBC showed significantly impaired immune response rates to basic vaccinations for SARS-CoV-2, especially under chemotherapy, independent of underlying cirrhotic or non-cirrhotic CLD. Although booster vaccinations balanced differences, waning immunity was observed over time and should be monitored for further recommendations. Our data help clinicians decide on individual additional booster vaccinations and/or passive immunization or antiviral treatment in patients with HBC getting infected with SARS-CoV-2.

Lung Adenocarcinoma Size Decrease after SARS-CoV-2 Vaccination during Long-Term Pembrolizumab Treatment: A Case Report. A man in his late 40s was diagnosed with clinical stage 4B lung adenocarcinoma with a PD-L1 tumor proportion score of 100% and high tumor mutational burden. A partial response was achieved after administration of pembrolizumab. The patient received two doses of a SARS-CoV-2 vaccine (BNT162b2) after 59 courses, and a chest computed tomography revealed consolidation in the peri-tumoral area, which subsequently disappeared, and the tumor continued to shrink in the next 4 months. This case provides indirect evidence for the persistence of cancer immunity during long-term treatment with immune checkpoint inhibitors and the potential for further activation.

Kikuchi Fujimoto Lymphadenitis: A Rare Association With COVID-19 Vaccination. Kikuchi-Fujimoto disease (KFD), also known as histiocytic necrotizing lymphadenitis, is an uncommon cause of protracted cervical lymphadenopathy in both children and adults. Although the majority of cases have been documented in Asia, this disease has been characterized globally since it was first identified in Japan in 1972. KFD's etiology is not entirely understood, although various theories have been postulated. Usually benign, Kikuchi-Fujimoto disease resolves within six months. KFD must be distinguished from other causes of chronic lymphadenopathy, such as lymphoma, inflammatory illnesses, autoimmune conditions, viral lymphadenopathy, and also from tuberculosis, especially in India, where it is still endemic. Here, we present the case report of a healthcare worker with a known case of hypothyroidism and autoimmune skin disorder who presented with prolonged fever, joint pain, and generalized lymphadenopathy post-COVID vaccination and was diagnosed as having KFD on biopsy, which can be associated with a very unusual presentation of this disease.

Pemphigus Foliaceus after COVID-19 Vaccination: A Report of Two Cases. Autoimmune bullous diseases (AIBDs) following coronavirus disease (COVID-19) vaccination have been previously documented in medical literature, given the comparable nature of the RNA antigen in these vaccines to that of the cellular nuclear matter. However, pemphigus foliaceus has been reported less frequently than other postimmunization AIBDs worldwide. Two women were admitted to our hospital with skin erosion over their faces, trunks, and extremities after receiving COVID-19 vaccination. Upon examination and consultation with pathologists, the diagnosis of pemphigus foliaceus was confirmed for both patients. In an effort to contribute to the knowledge on this intriguing topic, we present these two aforementioned cases of pemphigus foliaceus following COVID-19 vaccination, which may initially appear as a typical occurrence but exhibit some noteworthy characteristics.

Clinicopathological characteristics of cutaneous complications following COVID-19 vaccination: A case series. INTRODUCTION: Several vaccine-related cutaneous adverse events occurred following the

widespread use of vaccines to prevent coronavirus disease 2019 (COVID-19). This case series reports 25 patients with de novo or accentuated dermatologic conditions after receiving the Sinopharm, Sputnik V, AstraZeneca, or BIV1-CovIran vaccine in Iran. METHODS AND RESULTS: Twenty-five eligible patients with a mean age of 46.80â€‰years were investigated. The cutaneous adverse events included pityriasis rosea, zoster, viral exanthema, urticaria, bullous pemphigoid, pemphigus vulgaris, and acute generalized exanthematous pustulosis. The manifestations appeared 14.45â€‰Â±â€‰6.98 and 20.79â€‰Â±â€‰22.18â€‰days following injection of the first and second doses of COVID-19 vaccines, respectively. All patients experienced new cases of cutaneous disease other than two who developed flare-ups of lichen planus and psoriasis. CONCLUSION: Several cutaneous reactions, ranging from allergic events to skin diseases, have been reported following the injection of COVID-19 vaccines. Focal injection-site reactions are the most common cutaneous adverse events; however, de-novo skin diseases and a flare-up of preexisting cutaneous disorders have also been described. Although many cases of COVID-19 vaccine-related cutaneous diseases have been published, our zoster/lichen planus and AGEP cases after vaccination are interesting. A more detailed understanding of cutaneous adverse events following COVID-19 vaccination will facilitate better diagnosis and management.

NEURO-COVAX: An Italian Population-Based Study of Neurological Complications after COVID-19 Vaccinations. OBJECTIVE: In this Italian population-based study, we aimed to evaluate the neurological complications after the first and/or second dose of COVID-19 vaccines and factors potentially associated with these adverse effects. METHODS: Our study included adults aged 18 years and older who received two vaccine doses in the vaccination hub of Novegro (Milan, Lombardy) between 7 and 16 July 2021. The NEURO-COVAX questionnaire was able to capture the neurological events, onset and duration. That data that were digitized centrally by the Lombardy region were used to match the demographic/clinical characteristics and identify a vulnerability profile. Associations between vaccine lines and the development of complications were assessed. Digital healthcare system matching was also performed to evaluate severe neurological complications (Guillain-BarrÃ¨ syndrome, Bell's palsy, transverse myelitis, encephalitis) and the incidence of hospital admissions and/or the mortality rate after two doses of the vaccines. RESULTS: The NEURO-COVAX-cohort included 19.108 vaccinated people: 15.368 with BNT162b2, 2077 with mRNA-1273, 1651 with ChAdOx1nCov-19, and 12 with Ad26.COV2.S who were subsequently excluded. Approximately 31.2% of our sample developed post-vaccination neurological complications, particularly with ChAdOx1nCov-19. A vulnerable clinical profile emerged, where over 40% of the symptomatic people showed comorbidities in their clinical histories. Defining the neurological risk profile, we found an increased risk for ChAdOx1nCov-19 of tremors (vs. BNT162b2, OR: 5.12, 95% CI: 3.51-7.48); insomnia (vs. mRNA-1273, OR: 1.87, 95% CI: 1.02-3.39); muscle spasms (vs. BNT162b2, OR: 1.62, 95% CI: 1.08-2.46); and headaches (vs. BNT162b2, OR: 1.49, 95% CI: 0.96-1.57). For mRNA-1273, there were increased risks of parethesia (vs. ChAdOx1nCov-19, OR: 2.37, 95% CI: 1.48-3.79); vertigo (vs. ChAdOx1nCov-19, OR: 1.68, 95% CI: 1.20-2.35); diplopia (vs. ChAdOx1nCov-19, OR: 1.55, 95% CI: 0.67-3.57); and sleepiness (vs. ChAdOx1nCov-19, OR: 1.28, 95% CI: 0.98-1.67). In the period that ranged from March to August 2021, no one was hospitalized and/or died of severe complications related to COVID-19 vaccinations. DISCUSSION: This study estimates the prevalence and risk for neurological complications potentially associated with COVID-19 vaccines, thus improving the vaccination guidelines and loading in future personalized preventive medicine.

Factors Affecting SARS-CoV-2 IgG Production after Vaccination and/or Disease: A Large-Scale Seroprevalence Study. This study aimed at identifying factors influencing SARS-CoV-2-specific IgG antibody levels after vaccination and/or infection. Between January 2022 and March 2023, 2000 adults (â‰¥18 years, Salzburg, Austria) participated in this population-based seroprevalence study by

providing 3 mL of blood to detect SARS-CoV-2-specific IgG antibodies using an anti-SARS-CoV-2 IgG quantitative assay and by completing a self-designed questionnaire including anthropometric factors, vaccination information, and medical history. For 77 of the participants, a time-course study up to 24 weeks post vaccination or quarantine end was performed. Convalescent-only subjects had the lowest median antibody titer (65.6 BAU/mL) compared to vaccinated and hybrid immunized subjects (p-value < 0.0001) The type of vaccine as well as vaccine combinations significantly influenced the levels of SARS-CoV-2 spike-protein-specific IgG, ranging from a median antibody level of 770.5 BAU/mL in subjects who were vaccinated only to 3020.0 BAU/mL in hybrid immunized subjects (p-value < 0.0001). Over time, a significant decline in the levels of neutralizing antibodies was found. Depending on the subpopulation analyzed, further significant influencing factors included sex assigned at birth, disease severity, chronic diseases, and medication. A hybrid immunization resulted in more robust immune responses. Nevertheless, there were multiple other factors impacting these responses. This knowledge should be included in future vaccination strategies and serve as a guide in the development of personalized medicine.

Longitudinal Analysis of SARS-CoV-2-Specific Cellular and Humoral Immune Responses and Breakthrough Infection following BNT162b2/BNT162b2/BNT162b2 and ChAdOx1/ChAdOx1/BNT162b2 Vaccination: A Prospective Cohort in Naive Healthcare Workers. Assessing immune responses post-SARS-CoV-2 vaccination is crucial for optimizing vaccine strategies. This prospective study aims to evaluate immune responses and breakthrough infection in 235 infection-naÃ¯ve healthcare workers up to 13-15 months after initial vaccination in two vaccine groups (108 BNT/BNT/BNT and 127 ChAd/ChAd/BNT). Immune responses were assessed using the interferon-gamma enzyme-linked immunospot (ELISPOT) assay, total immunoglobulin, and neutralizing activity through surrogate virus neutralization test at nine different time points. Both groups exhibited peak responses one to two months after the second or third dose, followed by gradual declines over six months. Notably, the ChAd group exhibited a gradual increase in ELISPOT results, but their antibody levels declined more rapidly after reaching peak response compared to the BNT group. Six months after the third dose, both groups had substantial cellular responses, with superior humoral responses in the BNT group ($p < 0.05$). As many as 55 breakthrough infection participants displayed higher neutralization activities against Omicron variants, but similar cellular responses compared to 127 infection-naÃ¯ve individuals, suggesting cross-immunity. Distinct neutralization classifications (<30%, >80% inhibition) correlated with different ELISPOT results. Our study reveals diverse immune response patterns based on vaccine strategies and breakthrough infections, emphasizing the importance of understanding these dynamics for optimized vaccination decisions.

Factors Associated with COVID-19 Vaccine Uptake among Schoolgoing Adolescent Girls and Young Women in South Africa. (1) Background: By October 2022, vaccination rates with at least one dose of a COVID-19 vaccine were low among adolescent girls aged 12-17 (38%) and young women aged 18-34 (45%) in South Africa. This study aimed to measure and identify barriers to and facilitators of motivation to take up, access to, and uptake of COVID-19 vaccines among schoolgoing adolescent girls and young women in two districts in South Africa. (2) Methods: Using the theory of the HIV prevention cascade, we conceptualised the relationship between motivation, access, and uptake of COVID-19 vaccines, and associated barriers. Potential barriers and facilitators were identified using bivariate and multivariable Poisson regression. (3) Results: Among all 2375 participants, access was high (69%), but motivation (49%) and vaccination with at least one COVID-19 vaccine (45%) were lower. Fear of injections was a barrier to vaccine uptake (aRR 0.85 95% CI 0.82-0.88), while being tested for COVID-19 (aRR 2.10 95% CI 1.85-2.38) and believing that the COVID-19 vaccine was safe (aRR 1.31 95% CI 1.18-1.44) and would prevent you from getting very sick (aRR 1.11 95% CI 1.04-1.19)

were facilitators. (4) Conclusions: The controversy about the value of vaccinating adolescents and the delay in vaccine rollout for adolescents and young adults may have contributed to fears about the safety and efficacy of COVID-19 vaccines, as well as a lack of motivation to get vaccinated.

Twenty-Month Monitoring of Humoral Immune Response to BNT162b2 Vaccine: Antibody Kinetics, Breakthrough Infections, and Adverse Effects. BACKGROUND: Vaccination is one of the most effective life-saving medical interventions, and the introduction of SARS-CoV-2 vaccines was intended to prevent the serious implications of COVID-19. The objectives of the study were (i) to observe the humoral immune response to the BNT162b2 vaccine and SARS-CoV-2 infection (mainly breakthrough infections), (ii) to demonstrate the persistence of anti-SARS-CoV-2 antibodies over time in relation to the number of received vaccine doses and the course of infection, and (iii) to determine the adverse effects after primary vaccine doses. METHODS: To assess the humoral response, IgG and IgA anti-S1 antibodies were quantified by ELISA assays. In total, the tests were carried out seven times in almost two years. RESULTS: We demonstrated strong immunogenicity (compared to levels before primary vaccination, 150- and 20-fold increases in IgG and IgA, respectively) of the BNT162b2 vaccine. Over time, we observed a systematic decline in antibody levels, which may have contributed to breakthrough infections. Although they caused seroconversion similar to the booster, antibody levels in such patients fell more rapidly than after re-vaccination. On the other hand, in individuals who did not receive booster(s) and who did not present breakthrough infection, anti-SARS-CoV-2 antibodies returned to pre-vaccination levels after 20 months. The most commonly recognized adverse effects were injection site redness and swelling. CONCLUSION: Vaccination is highly effective in preventing the most severe outcomes of COVID-19 and should be performed regardless of prior infection. Booster doses significantly enhance anti-SARS-CoV-2 antibody levels and, in contrast to those obtained by breakthrough infection, they remain longer.

Thyroid Eye Disease as Initial Manifestation of Graves' Disease Following Viral Vector SARS-CoV-2 Vaccine: Report of a Case and Review of the Literature. COVID-19, a contagious disease caused by the novel coronavirus SARS-CoV-2, emerged in 2019 and quickly became a pandemic, infecting more than 700 million people worldwide. The disease incidence, morbidity and mortality rates have started to decline since the development of effective vaccines against the virus and the widespread immunization of the population. SARS-CoV-2 vaccines are associated with minor local or systemic adverse reactions, while serious adverse effects are rare. Thyroid-related disorders have been reported after vaccination for COVID-19, and Graves' disease (GD) is the second most common amongst them. Thyroid eye disease (TED), an extrathyroidal manifestation of GD, is rarely observed post-COVID-19 vaccination. All TED cases followed mRNA-based vaccinations, but two new onset mild TED cases post-viral vector vaccine (ChAdox1nCoV-19) have also been reported. We report the case of a 63-year-old woman who presented with new onset hyperthyroidism and moderate-to-severe and active TED 10 days after she received the first dose of a viral vector vaccine against SARS-CoV-2. This is the first case of moderate-to-severe TED after such a vaccine. Our patient was initially treated with intravenous glucocorticoids, and subsequently with intravenous rituximab, due to no response. The disease was rendered inactive after rituximab, but constant diplopia persisted, and the patient was referred for rehabilitative surgery.

New-Onset Rheumatic Immune-Mediated Inflammatory Diseases Following SARS-CoV-2 Vaccinations until May 2023: A Systematic Review. A comprehensive, up-to-date systematic review (SR) of the new-onset rheumatic immune-mediated inflammatory diseases (R-IMIDs) following COVID-19 vaccinations is lacking. Therefore, we investigated the demographics, management, and prognosis of new R-IMIDs in adults following SARS-CoV-2 vaccinations. A systematic literature search of Medline, Embase, Google Scholar, LitCovid, and Cochrane was conducted. We included any English-language study that reported new-onset R-IMID in adults following the post-COVID-19 vaccination. A total of

271 cases were reported from 39 countries between January 2021 and May 2023. The mean age of patients was 56 (range 18-90), and most were females (170, 62.5%). Most (153, 56.5%) received the Pfizer BioNTech COVID-19 vaccine. Nearly 50% of patients developed R-IMID after the second dose of the vaccine. Vasculitis was the most prevalent clinical presentation (86, 31.7%), followed by connective tissue disease (66, 24.3%). The mean duration between the vaccine's 'trigger' dose and R-IMID was 11 days. Most (220, 81.2%) received corticosteroids; however, 42% (115) received DMARDs such as methotrexate, cyclophosphamide, tocilizumab, anakinra, IV immunoglobulins, plasma exchange, or rituximab. Complete remission was achieved in 75 patients (27.7%), and 137 (50.6%) improved following the treatment. Two patients died due to myositis. This SR highlights that SARS-CoV-2 vaccines may trigger R-IMID; however, further epidemiology studies are required.

Metabolic Syndrome Is Associated with Poor Omicron Infection Prognosis While Inactivated Vaccine Improves the Outcome of Coronavirus Disease 2019 among Chinese Inhabitants: A Retrospective Observational Study from a Chinese Municipality. Coronavirus disease 2019 (COVID-19) and metabolic syndrome (MetS) are currently highly prevalent diseases worldwide. Studies on clinical outcomes of patients with Omicron and MetS, especially after vaccination with an inactivated vaccine are limited. Herein, we explored the relationship between MetS and the outcome of Omicron infection. STUDY DESIGN: This was a retrospective observational study. METHODS: This study recruited 316 individuals with Omicron infection. The inpatient data from between 8 January and 7 February 2022 were obtained from designated isolation hospitals in Tianjin, China. Hierarchical and multivariable analysis was conducted on age, gender, number of complications, and vaccination status. RESULTS: Among the 316 study participants, 35.1% were diagnosed with MetS. The results showed that MetS was strongly associated with Intensive Unit Care (ICU) admission, Polymerase Chain Reaction (PCR) re-positivity, and severe COVID-19. The ICU admission rates of the unvaccinated individuals, those who received two-dose and full vaccination (3 doses), were 66.7%, 19.2%, and 0, respectively ($p < 0.01$). Two-dose and three-dose vaccinations significantly reduced PCR re-positivity. CONCLUSIONS: In summary, MetS increases the risk of ICU admission, PCR re-positivity, and severe COVID-19. MetS is a composite predictor of poor outcomes of Omicron infection. Two shots of inactivated vaccine, specifically three doses, effectively protect against Omicron even in the high-risk group.

Healthcare Worker Characteristics Associated with SARS-CoV-2 Vaccine Uptake in Ireland; a Multicentre Cross-Sectional Study. The prevention of SARS-CoV-2 acquisition and transmission among healthcare workers is an ongoing challenge. Vaccination has been introduced to mitigate these risks. Vaccine uptake varies among healthcare workers in the absence of vaccine mandates. We investigated engagement with SARS-CoV-2 vaccination among healthcare workers and identified characteristics associated with lower vaccine uptake. This multi-site cross-sectional study recruited n = 1260 healthcare workers in both clinical and non-clinical roles over a three-month period from November 2022. Participants reported their engagement with the primary SARS-CoV-2 vaccination programme and subsequent booster programmes, as well as providing demographic, occupational and personal medical history information. Multivariable linear regression identified characteristics associated with vaccine uptake. Engagement with vaccination programmes was high, with 88% of participants receiving at least one booster dose after primary vaccination course. Younger age and female sex were associated with reduced vaccine uptake. Healthcare workers in non-clinical roles also had reduced vaccine uptake. These findings should inform vaccination strategies across healthcare settings and target populations with reduced vaccine uptake directly, in particular young, female, and non-clinical healthcare workers, both for SARS-CoV-2 and other healthcare-associated vaccine-preventable infections.

Changes in Students' Perceptions Regarding Adolescent Vaccinations through a Before-After Study Conducted during the COVID-19 Pandemic: GIRASOLE Project Study. The COVID-19 pandemic caused a reduction in vaccination coverage for all age groups, especially in non-infant age. The main objective of the present study is to evaluate the effectiveness of an online intervention conducted among adolescents during the COVID-19 pandemic in increasing knowledge and positive attitudes toward vaccinations. The study, which took place online from March to May 2021, involved 267 students from six lower secondary schools in Palermo city (Italy); they filled out the questionnaire before and after the intervention. The questionnaire was based on the protection motivation theory (PMT), which estimates the improvement in vaccination-related knowledge and attitudes. The pre- and post-intervention comparison showed a significant increase in the perception of the disease severity: strongly agree pre-intervention n = 150 (58.6%) and post-intervention n = 173 (67.6%, $p < 0.001$), rated on a five-point Likert scale. In a multivariate analysis, the factor associated with the improvement in the score after the intervention was the school dropout index (low vs. very high dropout index OR 4.5; $p < 0.03$). The educational intervention was more effective in schools with lower early school leaving rates, an indirect index of socio-economic status. The topic of vaccination has caught the adolescents' attention, it is, therefore, important that interventions tackling teenagers are tailored to reduce their emotional tension about the perception of adverse effects and improve vaccination coverage.

Multivariate Analysis of Adverse Reactions and Recipient Profiles in COVID-19 Booster Vaccinations: A Prospective Cohort Study. BACKGROUND: This study investigated the impact of vaccinated population profiles, vaccine type/interval, and the number of vaccine doses on adverse reactions to receiving a coronavirus disease 2019 (COVID-19) booster vaccination. METHODS: A survey of adverse reactions was conducted from January 2022 to December 2022 among Osaka University Dental Hospital employees who received their third or fourth doses. The study included 194 third-dose recipients and 131 fourth-dose recipients. Comparisons of the occurrence of adverse reactions between the third- and fourth-dose groups were analyzed via a chi-squared test. The relationships between each adverse reaction occurrence and recipient profiles, vaccine type/interval, and the number of vaccine doses were analyzed via a logistic regression analysis. RESULTS: No significant differences were found in the occurrence of adverse reactions between the third and fourth doses. Younger recipients often developed injection site reaction, fatigue, chills, fever, arthralgia, headache, diarrhea, and any adverse reactions more often. Females had higher frequencies of fatigue, chills, headache, and nausea compared to males. Recipients without underlying diseases had higher frequencies of fever and nausea than those with underlying diseases. CONCLUSIONS: Younger recipients and females were at higher risk for adverse reactions to a COVID-19 booster vaccination, while the number of vaccinations, vaccination interval, vaccine type, and cross-vaccination showed no significant associations.

Association between Vaccination Status for COVID-19 and the Risk of Severe Symptoms during the Endemic Phase of the Disease. The global health emergency caused by COVID-19 concluded in May 2023, marking the beginning of an endemic phase. This study aimed to evaluate the association between vaccination status and other patient characteristics and the risk of severe disease during this new endemic period. A nationwide cohort study was conducted in Mexico, where we analyzed data from 646 adults who had received positive confirmation of COVID-19 through PCR testing from May to August 2023. The overall risk of severe symptoms in the study sample was 5.3%. The average time elapsed from the last vaccine shot to symptom onset was over six months in all the immunized groups (1, 2 or 3 vaccine doses). Compared to unvaccinated patients, those with three vaccine doses showed an elevated risk of severe symptoms. Advancing age and various chronic comorbidities (specifically cardiovascular, kidney, and obstructive pulmonary conditions) were associated with a

heightened risk of severe COVID-19 manifestations. These findings underscore the ongoing seriousness of COVID-19, even in an endemic phase, underscoring the urgent need for tailored interventions aimed at high-risk patients.

Risks of Adverse Outcomes for Hospitalized COVID-19 Patients during the Four Waves in Brazil According to SARS-CoV-2 Variants, Age Group, and Vaccine Status. Brazil was hit with four consecutive waves of COVID-19 until 2022 due to the ancestral SARS-CoV-2 (B.1 lineage), followed by the emergence of variants/subvariants. Relative risks of adverse outcomes for COVID-19 patients hospitalized during the four waves were evaluated. Data were extracted from the largest Brazilian database (SIVEP-Gripe), and COVID-19 patients who were hospitalized during the peak of each of the four waves (15-week intervals) were included in this study. The outcomes of in-hospital death, invasive (IMV) and non-invasive (NIV) ventilation requirements, and intensive care unit (ICU) admission were analyzed to estimate the relative risks. A higher risk of in-hospital death was found during the second wave for all age groups, but a significant reduction was observed in the risk of death for the elderly during the third and fourth waves compared to patients in the first wave. There was an increased risk of IMV requirement and ICU admissions during the second wave for patients aged 18-59 years old compared to the first wave. Relative risk analysis showed that booster-vaccinated individuals have lower risks of in-hospital death and IMV requirement in all age groups compared to unvaccinated/partially vaccinated patients, demonstrating the relevance of full/booster vaccination in reducing adverse outcomes for patients who were hospitalized during the variant prevalence.

Hybrid Immunity Results in Enhanced and More Sustained Antibody Responses after the Second Sinovac-CoronaVac Dose in a Brazilian Cohort: DETECTCoV-19 Cohort. We measured anti-SARS-CoV-2 antibody responses before and after CoronaVac (inactivated) vaccination in a case-control study performed in CoronaVac-immunized individuals participating in a longitudinal prospective study of adults in Manaus (DETECTCoV-19). Antibody responses were measured by standard serological immunoassays. Peak anti-S-RBD and neutralizing RBD-ACE2 blocking antibody responses after two doses of CoronaVac vaccine were similar in vaccine breakthrough cases (n = 9) and matched controls (n = 45). Individuals with hybrid immunity resulting from prior SARS-CoV-2 infection followed by vaccination (n = 22) had elevated levels of anti-N, anti-S-RBD and RBD-ACE2 blocking antibodies after the second vaccine dose compared to infection-naÃ¯ve individuals (n = 48). Post-vaccination SARS-CoV-2-specific antibody responses rapidly waned in infection-naÃ¯ve individuals. Antibody responses wane after vaccination, making individuals susceptible to infection by SARS-CoV-2 variants. These findings support the need for booster doses after primary vaccination. Population antibody serosurveys provide critical information toward implementing optimal timing of booster doses.

Investigating Acute Hepatitis after SARS-CoV-2 Vaccination or Infection: A Genetic Case Series. (1) Background: Despite the advantages of COVID-19 vaccination, rare cases of acute hepatitis developing after the administration of the COVID-19 vaccine or the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection have been reported. The aim of the study is to describe a case series of patients who experienced the onset of acute hepatitis, with or without autoimmune features, following SARS-CoV-2 vaccination or infection and to hypothesize a genetic susceptibility in the pathogenesis. (2) Methods: A group of patients with acute onset hepatitis following SARS-CoV-2 vaccination or infection were evaluated in our hepatology outpatient clinic, where they underwent biochemical and autoimmune tests. Hepatitis A (HAV), B (HBV), and C virus (HCV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), and human immunodeficiency virus (HIV) infections were excluded. Patients with a diagnosis of autoimmune hepatitis (AIH) or drug-induced liver injury (DILI) underwent HLA typing and histological testing. (3) Results: Five patients experienced new-onset AIH after COVID-19 vaccination, one of which developed mild symptoms after vaccination

that strongly worsened during subsequent SARS-CoV-2 infection. One patient had AIH relapse after COVID-19 vaccination while on maintenance immunosuppressive treatment. All of them had HLA DRB1 alleles known to confer susceptibility to AIH (HLA DRB1*03,*07,*13,*14), and in three of them, HLA DRB1*11 was also detected. Two patients developed acute hepatitis without autoimmune hallmarks which resolved spontaneously, both positive for HLA DRB1*11. (4) Conclusions: An association between AIH and COVID-19 vaccine or infection can be hypothesized in individuals with a genetic predisposition. In patients without autoimmune features and spontaneous improvement of hypertransaminasemia, the diagnosis of drug-induced liver injury (DILI) is probable. Further studies are needed to determine the presence of an actual association and identify a possible role of HLA DRB1*11 in the pathogenesis of acute liver injury after SARS-CoV2 vaccination or infection.

Blood Coagulation and Thrombotic Disorders following SARS-CoV-2 Infection and COVID-19 Vaccination. Although abundant data confirm the efficacy and safety profile of the developed vaccines against COVID-19, there are still some concerns regarding vaccination in high-risk populations. This is especially valid for patients susceptible to thrombotic or bleeding events and hesitant people due to the fear of thrombotic incidents following vaccination. This narrative review focuses on various inherited and acquired thrombotic and coagulation disorders and the possible pathophysiologic mechanisms interacting with the coagulation system during immunization in view of the currently available safety data regarding COVID-19 vaccines. Inherited blood coagulation disorders and inherited thrombotic disorders in the light of COVID-19, as well as blood coagulation and thrombotic disorders and bleeding complications following COVID-19 vaccines, along with the possible pathogenesis hypotheses, therapeutic interventions, and imaging for diagnosing are discussed in detail. Lastly, the lack of causality between the bleeding and thrombotic events and COVID-19 vaccines is debated, but still emphasizes the importance of vaccination against COVID-19, outweighing the minimal risk of potential rare adverse events associated with coagulation.

Kinetics of adaptive immune responses after administering mRNA-Based COVID-19 vaccination in individuals with and without prior SARS-CoV-2 infections. OBJECTIVE: We aimed to compare the adaptive immune response in individuals with or without prior SARS-CoV-2 infections following the administration of mRNA-based COVID-19 vaccines. METHODS: A total of 54 participants with ages ranging from 37 to 56 years old, consisting of 23 individuals without a history of SARS-CoV-2 infection (uninfected group) and 31 individuals with prior infection of SARS-CoV-2 (infected group) who have received two doses of mRNA SARS-CoV-2 vaccines were enrolled in this study. We measured the IFN-Î³ level upon administration of BNT162b2 (PF) or mRNA-1273 (MO) by QuantiFERON SARS-CoV-2. The production of neutralizing antibodies was evaluated by a surrogate virus neutralization assay, and the neutralizing capacity was assessed by a plaque reduction neutralization test (PRNT(50)). The immune response was compared between the two groups. RESULTS: A significantly higher level of IFN-Î³ (pâ€‰<â€‰0.001) and neutralization antibodies (pâ€‰<â€‰0.001) were observed in the infected group than those in the uninfected group following the first administration of vaccines. The infected group demonstrated a significantly higher PRNT(50) titer than the uninfected group against the Wuhan strain (pâ€‰<â€‰0.0001). Still, the two groups were not significantly different against Delta (pâ€‰=â€‰0.07) and Omicron (pâ€‰=â€‰0.14) variants. Following the second vaccine dose, T- and B-cell levels were not significantly increased in the infected group. CONCLUSION: A single dose of mRNA-based COVID-19 vaccines would boost immune responses in individuals who had previously contracted SARS-CoV-2.

Background rates for severe cutaneous reactions in the US: Contextual support for safety assessment of COVID-19 vaccines and novel biologics. The global COVID-19 public health crisis has resulted in extraordinary collaboration to expeditiously develop vaccines and therapeutics. The safety of these biologics is closely monitored by the US Food and Drug Administration (FDA) and the Centers for

Disease Control and Prevention (CDC). Novel products may have limited safety data, and although serious medical outcomes associated with vaccination are rare, knowledge of background incidence rates of medical conditions in the US population puts reported adverse events (AEs) in perspective for further study. Although relatively minor vaccination skin reactions are common, rare instances of severe delayed hypersensitivity reactions such as erythema multiforme (EM), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and SJS/TEN overlap syndrome may occur. To aid in the assessment of these events, we performed a literature search in PubMed and Web of Science on the background incidence of EM, SJS, SJS/TEN, and TEN in the US population and on published reports of these conditions occurring post-vaccination. The US background annual incidence rates per million individuals of all ages ranged from 5.3 to 63.0 for SJS, from 0.4 to 5.0 for TEN, and from 0.8 to 1.6 for SJS/TEN. Since these conditions may overlap, some studies reported rates for EM/SJS/TEN combined, however we did not find studies with exclusive EM incidence rates. The published literature, including studies of reports submitted to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS), describes post-vaccination EM, SJS, SJS/TEN and/or TEN as rare occurrences. The vaccines most frequently associated with these conditions were measles, mumps, and rubella; diphtheria, tetanus, and pertussis; and varicella. The majority of VAERS reports of EM, SJS, SJS/TEN, or TEN occurred in children within 30Â days of vaccination. This review summarizes background rates of these disorders in the general population and published AEs among vaccine recipients, to support safety surveillance of COVID-19 vaccines and other biologics.

Adverse events of acute nephrotoxicity reported to EudraVigilance and VAERS after COVID-19 vaccination. OBJECTIVES: The present study aimed to estimate the reporting rates (RRs) of acute kidney injury (AKI) and renal failure (RF) after COVID-19 vaccination in the European Economic Area (EEA) and the United States. METHODS: We retrieved and analyzed pharmacovigilance data on suspected AKI and RF cases and fatalities post COVID-19 vaccination with licensed vaccines reported to EudraVigilance and VAERS between week 52/2020 and week 52/2022 or week 1/2023, respectively. Reporting rates with 95% confidence intervals were estimated per million administered vaccine doses. RESULTS: In total, 4,244 AKI and 1,557 RF suspected cases were notified to EudraVigilance (1,692 AKI/971 RF) and VAERS (2,552 AKI/586 RF) during the study period following the administration of >1.6 billion COVID-19 vaccine doses (EEA: 970,934,453/US: 666,511,603). The overall RRs were 3.03 (95Â % CI: 2.94-3.12) for AKI and 1.11 (95Â % CI: 1.06-1.17) for RF per million administered vaccine doses. Indices for statistically significant increased risks were found in subjects, especially males, â‰¥65Â years compared to 18-64Â years old (AKI: ORÂ =Â 7.23, 95Â % CI: 6.63-7.88, pÂ =Â 0.000, and RF: ORÂ =Â 4.74, 95Â % CI: 3.99-5.63, pÂ <Â 0.001). AKI reporting rates were higher in the US, while RF reporting rates were higher in Europe. Both potential side effects were elevated following vectored rather than mRNA vaccines, with the highest reporting rates post AD26.COV2.S vaccination in the US (AKI: RRÂ =Â 12.24, 95Â % CI: 10.66-13.81; RF: RRÂ =Â 3.17, 95Â % CI: 2.36-3.97). There were 1,312 deaths possibly associated with AKI (RRÂ =Â 0.94, 95Â % CI: 0.89-0.99) and 460 deaths possibly associated with RF (RRÂ =Â 0.33, 95Â % CI: 0.30-0.36) per million vaccine doses. Fatalities were lower in Europe than in the US (AKI: ORÂ =Â 0.25, 95Â % CI: 0.22-0.28, pÂ <Â 0.001; RF: ORÂ =Â 0.82, 95Â % CI: 0.69-0.99, pÂ =Â 0.036). CONCLUSIONS: AKI and RF may be observed rarely following vaccination against COVID-19. Further studies are warranted to confirm these findings and uncover the underlying pathophysiological mechanism.

Immunity Induced by Inactivated SARS-CoV-2 Vaccine: Breadth, Durability, Potency, and Specificity in a Healthcare Worker Cohort. Vaccination has proven to be highly effective against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), but the long-term immunogenicity and the functional preserved immune responses of vaccines are needed to inform evolving evidence-based guidelines for boosting schedules. We enrolled 205 healthcare workers into a cohort study; all had

received three doses of BBIBP-CorV (China Sinopharm Bio-Beijing Company, Beijing, China) inactivated vaccine. We assessed SARS-CoV-2 specific binding antibodies, neutralizing antibodies, and peripheral T and B cell responses. We demonstrated that more robust antibody responses to SARS-CoV-2 were elicited by booster immunization compared with primary vaccination. Neutralizing antibody titers to SARS-CoV-2 Omicron BA.1 were also efficiently elevated post-homologous vaccine booster despite being in a lower titer compared with the prototype stain. In addition to S-specific humoral and cellular immunity, BBIBP-CorV also induced N-specific antibody and effector T cell responses. The third-dose vaccination led to further expansion of critical polyfunctional T cell responses, likely an essential element for vaccine protection. In particular, a functional role for Tfh cell subsets in immunity was suggested by the correlation between both CD4(+) Tfh and CD8(+) Tfh with total antibody, IgG, B cell responses, and neutralizing antibodies. Our study details the humoral and cellular responses generated by the BBIBP-CorV booster vaccination in a seven-month follow-up study. There is a clear immunologic boosting value of homologous inactivated SARS-CoV-2 vaccine boosters, a consideration for future vaccine strategies.

Combined copper and zinc deficiency is associated with reduced SARS-CoV-2 immunization response to BNT162b2 vaccination. The essential trace elements copper, selenium and zinc are of relevance for immunity and immune response to vaccination. In this longitudinal study, adult healthcare workers (nÂ =Â 126) received two doses of an mRNA vaccine (BNT162b2), and longitudinal serum samples were prepared. Vaccine-induced antibodies and their neutralizing activity were analyzed, and the trace elements copper, zinc, and selenium along with the copper transporter ceruloplasmin were measured. Subjects with combined deficiency of copper and zinc, i.e. both in the lowest tertiles at baseline, displayed particularly low antibody titers at three (Double Q1: 13 AU/mL vs. not double Q1: 29 AU/mL) and six (Double Q1: 200 AU/mL vs. not double Q1: 425 AU/mL) weeks after vaccination (pÂ <Â 0.05). The results indicate the potential importance of an adequate trace element status of copper and zinc for raising a strong vaccine-induced SARS-CoV-2 antibody response, and highlights the importance of considering combined micronutrient insufficiencies, as single deficiencies may synergize.

Pregnancy outcomes following natural conception and assisted reproduction treatment in women who received COVID-19 vaccination prior to conception: a population-based cohort study in China. INTRODUCTION: The coronavirus disease-2019 (COVID-19) pandemic has swept across the world and continues to exert serious adverse effects on vulnerable populations, including pregnant women and neonates. The vaccines available at present were designed to prevent infection from COVID-19 strains and control viral spread. Although the incidence of pregnancy cycle outcomes are not likely to increase patients vaccinated prior to pregnancy compared with unvaccinated patients based on our knowledge of vaccination safety, there is no specific evidence to support this hypothesis. Therefore, the current study aimed to investigate the association between maternal vaccination prior to conception and pregnancy outcomes. METHODS: We retrospectively analyzed 2,614 women who received prenatal care and delivered in the Obstetrical Department of The First Affiliated Hospital of Anhui Medical University between February 2022 and November 2022. Of the 1,380 eligible pregnant women, 899 women who had received preconception vaccination were assigned to a vaccine group and 481 women who were not vaccinated were control group. Of the enrolled patients, 291 women received fertility treatment (141 vaccinated women, 150 unvaccinated women). The primary outcomes were pregnancy complications (hypothyroidism, gestational diabetes mellitus, pregnancy-induced hypertension, polyhydramnios, oligohydramnios, premature rupture of membranes and postpartum hemorrhage), obstetric outcomes (preterm birth rate, cesarean section rate) and neonatal outcomes (birth-weight, body length, low-birth-weight rate, rate of congenital defects, neonatal mortality and admission to the neonatal intensive care unit). RESULTS: There was no

significant difference in the incidence of complications during pregnancy and delivery when compared between the vaccine group and control group in either univariate- or multivariate-models. The type of vaccine was not associated with the odds of adverse pregnancy outcome. Among the women with infertility treatment, the vaccinated group and the unvaccinated group had similar pregnancy outcomes. CONCLUSION: Women who received COVID-19 vaccination prior to conception had similar maternal and neonatal outcomes as women who were unvaccinated. Our findings indicate that COVID-19 vaccinations can be safely administered prior to pregnancy in women who are planning pregnancy or assisted reproductive treatment. During new waves of COVID-19 infection, women who are planning pregnancy should be vaccinated as soon as possible to avoid subsequent infections.

Bibliometric analysis of scientific papers on adverse reactions to COVID-19 vaccines published between 2019 and 2023. The Coronavirus Disease 2019 (COVID-19) pandemic has now persisted globally for four years, resulting in a staggering death toll of over 4 million individuals. The COVID-19 vaccine has emerged as a highly effective tool in controlling the spread of this virus. However, as the number of individuals receiving COVID-19. In this context, the investigation of adverse reactions related to COVID-19 vaccines holds paramount importance in relevant research. The purpose is to evaluate the current research status regarding adverse reactions associated with COVID-19 vaccines, offering insights for future research. A total of 3,746 articles were included in this analysis, and there has been a notable upward trajectory in the volume of published articles. The CiteSpace v6.1.R6, VOSviewer, SCImago Graphica, and Excel 2019 were employed to analyze and visualize the results. The institutions, countries, journals, authors, co-cited references, and keywords of these articles were analyzed. Furthermore, this study delves into the characteristics of articles on adverse reactions associated with COVID-19 vaccines. It was observed that the number of studies on COVID-19 vaccines has increased year by year since 2019 and witnessed a surge in output in 2021. The vast majority of studies have affirmed the overall safety of COVID-19 vaccines, with adverse reactions tending to be more concentrated in specific diseases. These findings provide valuable ideas for future research in this field and suggest the importance of strengthening international cooperation on adverse reactions to COVID-19 vaccines.

Characterization of hypermetabolic lymph nodes after SARS-CoV-2 vaccination using PET-CT derived node-RADS, in patients with melanoma. This study aimed to evaluate the diagnostic accuracy of Node Reporting and Data System (Node-RADS) in discriminating between normal, reactive, and metastatic axillary LNs in patients with melanoma who underwent SARS-CoV-2 vaccination. Patients with proven melanoma who underwent a 2-[(18)F]-fluoro-2-deoxy-D-glucose positron emission tomography/computed tomography (2-[(18)F]-FDG PET/CT) between February and April 2021 were included in this retrospective study. Primary melanoma site, vaccination status, injection site, and 2-[(18)F]-FDG PET/CT were used to classify axillary LNs into normal, inflammatory, and metastatic (combined classification). An adapted Node-RADS classification (A-Node-RADS) was generated based on LN anatomical characteristics on low-dose CT images and compared to the combined classification. 108 patients were included in the study (54 vaccinated). HALNs were detected in 42 patients (32.8%), of whom 97.6% were vaccinated. 172 LNs were classified as normal, 30 as inflammatory, and 14 as metastatic using the combined classification. 152, 22, 29, 12, and 1 LNs were classified A-Node-RADS 1, 2, 3, 4, andÂ 5, respectively. Hence, 174, 29, and 13 LNs were deemed benign, equivocal, and metastatic. The concordance between the classifications was very good (Cohen's k: 0.91, CI 0.86-0.95; p-valueâ€‰<â€‰0.0001). A-Node-RADS can assist the classification of axillary LNs in melanoma patients who underwent 2-[(18)F]-FDG PET/CT and SARS-CoV-2 vaccination.

Increased Metabolic Activity of the Thymus and Lymph Nodes in Pediatric Oncology Patients After Coronavirus Disease 2019 Vaccination. We hypothesized that (18)F-FDG PET/MRI would reveal

thymus activation in children after coronavirus disease 2019 (COVID-19) vaccination. Methods: We retrospectively analyzed the (18)F-FDG PET/MRI scans of 6 children with extrathoracic cancer before and after COVID-19 vaccination. We compared pre- and postvaccination SUV(max), mean apparent diffusion coefficient, and size of the thymus and axillary lymph nodes using a paired t test. Results: All 6 patients showed increased (18)F-FDG uptake in the axillary lymph nodes after vaccination (P = 0.03). In addition, these patients demonstrated increased (18)F-FDG uptake in the thymus. When compared with baseline, the postvaccination scans of these patients demonstrated an increased mean thymic SUV (P = 0.02), increased thymic size (P = 0.13), and decreased thymic mean apparent diffusion coefficient (P = 0.08). Conclusion: (18)F-FDG PET/MRI can reveal thymus activation in addition to local lymph node reactions in children after COVID-19 vaccination.

Echocardiographic function evaluation in adolescents following BNT162b2 Pfizer-BioNTech mRNA vaccination: A preliminary prospective study. BACKGROUND: Vaccination against coronavirus disease 2019 (COVID-19) is crucial for preventing and minimizing illness. Myocarditis and pericarditis after messenger RNA (mRNA) COVID-19 vaccination in adolescents and young adult males have been reported. Most of the studies in this area rely on retrospective symptom reporting, especially for adolescents experiencing myocarditis as a potential side effect. However, prospective postvaccination echocardiographic evaluation is rare. METHODS: The study enrolled adolescents aged 12 to 15 years who received the second dose of the BNT162b2 Pfizer-BioNTech mRNA (BNT) vaccine. Serial echocardiographic examinations were conducted at baseline before vaccination, followed by subsequent assessments on days 2, 7, 14, and 28 to identify any notable differences or abnormal changes in cardiac function. Clinical symptom assessments were also recorded during each follow-up. RESULTS: The study included 25 adolescents, comprising 14 males and 11 females, who completed the four follow-ups. Their mean age was 14â€‰Â±â€‰1 years. The average interval between the first and second BNT vaccine doses was 90â€‰Â±â€‰7 days. Ejection fraction values were 73.8% Â± 5.2% at baseline, followed by 75.7% Â± 5.3%, 75.5% Â± 4.6%, 75.7% Â± 4.5%, and 77.8% Â± 5.8% at day 2, 7, 14, and 28, respectively. The cardiac function remained stable across all time points, with no significant differences observed between male and female participants. Within postvaccination 48 hours, 18 (72%) of the enrolled adolescents experienced temporary discomfort symptoms, which completely resolved by the final follow-up on the 28th day after vaccination. CONCLUSION: Although adolescents vaccinated with the second dose of BNT vaccine commonly experienced transient postvaccination discomfort, the serial echocardiographic examinations did not reveal any significant deterioration of cardiac function within 28 days. Further studies are required to investigate the incidence of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) mRNA vaccination-associated myocarditis in adolescents and the related mechanisms.

Safety, tolerability, and immunogenicity of a CpG/Alum adjuvanted SARS-CoV-2 recombinant protein vaccine (ZR202-CoV) in healthy adults: Preliminary report of a phase 1, randomized, double-blind, placebo-controlled, dose-escalation trial. This was a phase 1 dose-escalation study of ZR202-CoV, a recombinant protein vaccine candidate containing a pre-fusion format of the spike (S)-protein (S-trimer) combined with the dual-adjuvant system of Alum/CpG. A total of 230 participants were screened and 72 healthy adults aged 18-59â€‰years were enrolled and randomized to receive two doses at a 28-day interval of three different ZR202-CoV formulations or normal saline. We assessed the safety for 28â€‰days after each vaccination and collected blood samples for immunogenicity evaluation. All formulations of ZR202-CoV were well-tolerated, with no observed solicited adverse events â‰¥ Grade 3 within 7â€‰days after vaccination. No unsolicited adverse events â‰¥ Grade 3, or serious adverse events related to vaccination occurred as determined by the investigator. After the first dose, detectable immune responses were observed in all subjects. All subjects that received ZR202-CoV seroconverted at 14â€‰days after the second dose by S-binding IgG antibody,

pseudovirus and live-virus based neutralizing antibody assays. S-binding response (GMCs: 2708.7â€‰~â€‰4050.0 BAU/mL) and neutralizing activity by pseudovirus (GMCs: 363.1â€‰~â€‰627.0 IU/mL) and live virus SARS-CoV-2 (GMT: 101.7â€‰~â€‰175.0) peaked at 14â€‰days after the second dose of ZR202-CoV. The magnitudes of immune responses compared favorably with COVID-19 vaccines with reported protective efficacy.

Identifying Predominant Causes of Death Among Hospitalized COVID-19 Patients During Poland's Second and Third Waves. BACKGROUND Number of confirmed COVID-19 deaths per million population in Poland between November 2020 and May 2021 was one of the largest in Europe. This retrospective study was conducted at a single center in Poland between November 2020 and May 2021to evaluate the morbidity and mortality rates in 581 patients hospitalized with COVID-19. MATERIAL AND METHODS A retrospective single-center study was conducted in a dedicated COVID-19 hospital from November, 2020 to May, 2021. The data of 581 hospitalized patients were analyzed. Multimorbidity was assessed using the Charlson Comorbidity Index, including chronic kidney, respiratory, cardiovascular diseases, diabetes mellitus, cancer, and dementia. The observation period covered admission to the hospital for severe COVID-19 until discharge or death. Diagnosis of COVID-19 was confirmed by quantitative reverse transcription polymerase chain reaction test. Statistical analysis was carried out in the IBM SPSS Statistics program. RESULTS The mortality rate was 35% of all admitted patients. Lung damage was the cause of death in 60%, bacterial superinfection in 26%, arterial thrombosis or thromboembolism in 9%, and heart failure in 5% of patients. The chi-square test showed a significant relationship between sex and the cause of death related to COVID-19 pneumonia and bacterial ventilator-associated pneumonia (VAP). CONCLUSIONS The findings from this study supports findings from other countries that between November 2020 and May 2021, before SARS-CoV-2 vaccination programs were fully implemented and before effective medications and antiviral agents were developed, patients with severe COVID-19 had high rates of morbidity and mortality.

Acute Necrotizing Myelitis Associated with COVID-19. Acute ascending hemorrhagic longitudinally extensive transverse myelitis is a rare inflammatory demyelinating disorder, which invades several vertebral segments and progresses rapidly and manifests severe symptoms. We present a case of acute necrotizing myelitis associated with COVID-19 infection. A 10-year-old female, with no previous medical history and no prior administration of COVID-19 vaccination, contracted COVID-19 in early April 2022. Two weeks later, she suffered from severe posterior neck pain and also presented with motor weakness and numbness in both lower extremities, making it difficult to walk independently and spontaneously void urine. Initial spinal cord MR showed longitudinally segmental extensive T2 hyperintensities. Cerebrospinal fluid (CSF) analysis revealed elevated red blood cell, normal white blood cell, and elevated protein levels and absence of oligoclonal bands. CSF culture and viral polymerase chain reaction were negative. Autoimmune work-up was negative. She was started on intravenous methylprednisolone 1g/day for 5 days and immunoglobulin (Ig) 2 g/kg for 5 days. She was also treated with six courses of therapeutic plasma exchange. Nevertheless, her pain and motor weakness persisted. She eventually developed respiratory failure. Follow-up MR presented a newly noted small hemorrhagic component. She was consequently treated with two additional courses of methylprednisolone and Ig. At 6-months follow-up, neurological examination showed improvement with normal sensory function and motor grade IV function in both upper extremities. We present the case of acute necrotizing myelitis associated with COVID-19 infection. Multiple courses of methylprednisolone and Ig showed mild improvement in motor and sensory function. However, poor prognosis was unavoidable due to rapid progression of the disease.

Potential determinants of antibody responses after vaccination against SARS-CoV-2 in older persons: the Doetinchem Cohort Study. BACKGROUND: Immune responses to vaccination vary widely

between individuals. The aim of this study was to identify health-related variables potentially underlying the antibody responses to SARS-CoV-2 vaccination in older persons. We recruited participants in the long-running Doetinchem Cohort Study (DCS) who underwent vaccination as part of the national COVID-19 program, and measured antibody concentrations to SARS-CoV-2 Spike protein (S1) and Nucleoprotein (N) at baseline (T0), and a month after both the first vaccination (T1), and the second vaccination (T2). Associations between the antibody concentrations and demographic variables, including age, sex, socio-economic status (SES), comorbidities (cardiovascular diseases and immune mediated diseases), various health parameters (cardiometabolic markers, inflammation markers, kidney- and lung function) and a composite measure of frailty ('frailty index', ranging from 0 to 1) were tested using multivariate models. RESULTS: We included 1457 persons aged 50 to 92 years old. Of these persons 1257 were infection naÃ¯ve after their primary vaccination series. The majority (Nâ€‰=â€‰954) of these individuals were vaccinated with two doses of BNT162b2 (Pfizer) and their data were used for further analysis. A higher frailty index was associated with lower anti-S1 antibody responses at T1 and T2 for both men (R(T1)â€‰=â€‰-0.095, P(T1)â€‰=â€‰0.05; R(T2)â€‰=â€‰-0.11, P(T2)â€‰=â€‰0.02) and women (R(T1)â€‰=â€‰-0.24, P(T1)â€‰<â€‰0.01; R(T2)â€‰=â€‰-0.15, P(T2)â€‰<â€‰0.01). After correcting for age and sex the frailty index was also associated with the relative increase in anti-S1 IgG concentrations between the two vaccinations (Î²â€‰=â€‰1.6, Pâ€‰<â€‰0.01). Within the construct of frailty, history of a cardiac catheterization, diabetes, gastrointestinal disease, a cognitive speed in the lowest decile of the population distribution, and impaired lung function were associated with lower antibody responses after both vaccinations. CONCLUSIONS: Components of frailty play a key role in the primary vaccination response to the BNT162b2 vaccine within an ageing population. Older persons with various comorbidities have a lowered immune response after their first vaccination, and while frail and sick older persons see a stronger increase after their second vaccination compared to healthy people, they still have a lower antibody response after their second vaccination.

Safety of BNT162b2 mRNA COVID-19 vaccine in children with chronic kidney disease: a national population study from South Korea. BACKGROUND: In South Korea, COVID-19 vaccination has been recommended to adolescents aged 12â€‰-â€‰17 since October, 2021. We aimed to assess the rate of adverse events following COVID-19 vaccination in adolescents with chronic kidney disease (CKD) in South Korea, using national cohort data. METHODS: We retrieved the clinical information of adolescents 12â€‰-â€‰17Â years old from the Korea Disease Control and Prevention Agency-COVID19-National Health Insurance Service (K-COV-N) database, to calculate incidence rates of purpura and other hemorrhagic conditions, Guillain-BarrÃ© syndrome (GBS), Kawasaki disease/multisystem inflammatory syndrome in children (MIS-C), myocarditis and/or pericarditis, and anaphylaxis in adolescents with CKD, after BNT162b2 vaccination. RESULTS: Among the 2306 adolescents with CKD, 62.7% (nâ€‰=â€‰1446) had received the BNT-162b2 vaccine. GBS, Kawasaki disease/MIS-C, and anaphylaxis or anaphylactic shock did not occur during the observation period. Purpura and hemorrhagic conditions were more frequent in the unvaccinated group (7/860 vs. 1/1446), while myocarditis/pericarditis was observed only in the vaccinated group (0/860 vs. 1/1446). Adjusted odds ratio for any of the two adverse events was lower in vaccinated adolescents than in the unvaccinated group which did not reach statistical significance (adjusted odds ratioâ€‰=â€‰0.14, 95% confidence interval: 0.02, 1.16, Pâ€‰=â€‰0.068). CONCLUSIONS: In this national cohort study of adolescents with CKD in South Korea, we observed no evidence of increased risk of adverse events following BNT162b2 vaccination. Our finding offers insights into the safety of COVID-19 vaccines, empowering adolescent patients with CKD and their caregivers to make informed decisions.

Safety, immunogenicity and immune-persistence of heterologous prime-boost immunization with BBIBP-CorV and ZF2001 against SARS-CoV-2 in healthy adults aged 18 years or older. BACKGROUND: Because SARS-CoV-2 mutations and immunity wane over time, a third dose of heterologous COVID-19 vaccine is proposed for individuals primed with inactivated COVID-19 vaccine. RESEARCH DESIGN AND METHODS: We conducted a single-center, open-label trial to assess the safety, immunogenicity, and immune-persistence of a heterologous BBIBP-CorV/ZF2001 prime-boost vaccination in Chinese adults. 480 participants who had been primed with two doses of BBIBP-CorV, received a third dose of ZF2001 after an interval of 3-4, 5-6, or 7-9â€‰months. RESULTS: The overall incidence of adverse reactions within 30â€‰days after vaccination was 5.83%. No serious adverse reactions were reported. The respective geometric mean titers (GMTs) of neutralizing antibodies for 3-4, 5-6, and 7-9â€‰months groups at baseline were 2.06, 2.02, and 2.10; which increased to 55.42, 63.45, and 62.06 on day 14; then decreased to 17.53, 23.79, and 26.73 on day 30; before finally waning to 8.29, 9.24, and 9.51 on day 180. After the booster, the three groups showed no significant differences in GMTs. GMTs were lower in older participants than younger participants. CONCLUSIONS: A heterologous BBIBP-CorV/ZF2001 prime-boost vaccination was safe and immunogenic. Prime-boost intervals did not affect the immune response. The immune response was weaker in older adults than younger adults. CLINICAL TRIAL IDENTIFIER: NCT05205083.

Pfizer BNT 162b2 COVID-19 vaccine-induced fulminant myopericarditis: A case study. The use of mRNA COVID-19 vaccine can on rare occasions cause life-threatening, fulminant myopericarditis. This case report demonstrates previously reported benefit of early use of venoarterial extracorporeal membrane oxygenation mechanical assistance and supports the use of intravenous highly purified immunoglobulin pharmacotherapy to help achieve a good clinical outcome.

Incidence and Transmission of SARS-CoV-2 in US Child Care Centers After COVID-19 Vaccines. IMPORTANCE: SARS-CoV-2 surveillance studies in US child care centers (CCCs) in the post-COVID-19 vaccine era are needed to provide information on incidence and transmission in this setting. OBJECTIVE: To characterize SARS-CoV-2 incidence and transmission in children attending CCCs (students) and their child care providers (CCPs) and household contacts. DESIGN, SETTING, AND PARTICIPANTS: This prospective surveillance cohort study was conducted from April 22, 2021, through March 31, 2022, and included 11 CCCs in 2 cities. A subset (surveillance group) of CCPs and students participated in active surveillance (weekly reverse transcription-polymerase chain reaction [RT-PCR] swabs, symptom diaries, and optional baseline and end-of-study SARS-CoV-2 serologic testing), as well as all household contacts of surveillance students. Child care center directors reported weekly deidentified self-reported COVID-19 cases from all CCPs and students (self-report group). EXPOSURE: SARS-CoV-2 infection in CCC students. MAIN OUTCOMES AND MEASURES: SARS-CoV-2 incidence, secondary attack rates, and transmission patterns were determined from diary entries, self-reports to CCC directors, and case logs. Incidence rate ratios were measured using Poisson regression clustering on centers with a random intercept and unstructured matrix. RESULTS: From a total population of 1154 students and 402 CCPs who self-reported cases to center directors, 83 students (7.2%; mean [SD] age, 3.86 [1.64] years; 55 male [66%]), their 134 household contacts (118 adults [mean (SD) age, 38.39 (5.07) years; 62 female (53%)], 16 children [mean (SD) age, 4.73 (3.37) years; 8 female (50%)]), and 21 CCPs (5.2%; mean [SD] age, 38.5 [12.9] years; 18 female [86%]) participated in weekly active surveillance. There were 154 student cases (13%) and 87 CCP cases (22%), as defined by positive SARS-CoV-2 RT-PCR or home antigen results. Surveillance students had a higher incidence rate than self-report students (incidence rate ratio, 1.9; 95% CI, 1.1-3.3; Pâ€‰=â€‰.01). Students were more likely than CCPs to have asymptomatic infection (34% vs 8%, Pâ€‰<â€‰.001). The CCC secondary attack rate was 2.7% to 3.0%, with the upper range representing possible but not definite secondary cases. Whether the index case was a student or CCP,

transmission within the CCC was not significantly different. Household cumulative incidence was 20.5%, with no significant difference in incidence rate ratio between adults and children. Household secondary attack rates were 50% for children and 67% for adults. Of 30 household cases, only 5 (17%) represented secondary infections caused by 3 students who acquired SARS-CoV-2 from their CCC. Pre- and poststudy seroprevalence rates were 3% and 22%, respectively, with 90% concordance with antigen or RT-PCR results. CONCLUSIONS AND RELEVANCE: In this study of SARS-CoV-2 incidence and transmission in CCCs and students' households, transmission within CCCs and from children infected at CCCs into households was low. These findings suggest that current testing and exclusion recommendations for SARS-CoV-2 in CCCs should be aligned with those for other respiratory viruses with similar morbidity and greater transmission to households.

Global COVID-19 Vaccination in Infants and Children: Effectiveness, Safety, and Challenges. COVID-19 Vaccines, which include mRNA and inactivated vaccines, have been proven effective and safe for infants and children aged more than six months in reducing the severity of the disease, hospitalization, multisystem inflammatory syndrome in children, and death. Nonetheless, the real-world effectiveness of these vaccines in preventing infection is generally lower than in clinical trials due to the emergence of variants of concern, especially the Omicron strains. Despite the availability of vaccines for children, their uptake remains low globally, particularly among parents who are hesitant to vaccinate their children. This review article aims to provide a comprehensive overview of COVID-19 vaccine safety and efficacy from clinical trials and the current COVID-19 vaccine recommendations for infants and children aged 6 months to < 12 years for 2023-2024, discuss the progress made in vaccine implementation and real-world effectiveness, and address the knowledge gap and future directions.

De Novo ANCA-Negative Pauci-Immune Crescentic Glomerulonephritis After COVID-19 mRNA Vaccination: A Case Report. To prevent the spread of the coronavirus disease 2019 (COVID-19) pandemic, vaccines have been authorized for emergency use and implemented worldwide. We present a case of de novo glomerulonephritis (GN) after use of the COVID-19 mRNA vaccine BNT162b2. A 48-year-old man with no relevant medical history was referred for sudden and persistent worsening of renal insufficiency 1.5 months after the second vaccine dose. He had arthralgia and skin rash a week after vaccination. Abdominal pain and diarrhea started 2 weeks later, and he was admitted to the hospital for enteritis treatment. Colonoscopy showed multiple ulcerations and petechiae suggestive of vasculitis in the terminal ileum. After prednisolone therapy, his gastrointestinal symptoms improved, but his renal function continued to deteriorate. Based on kidney biopsy findings and nephrotic-range proteinuria (5,306 mg/24 hours), he was diagnosed with anti-neutrophil cytoplasmic autoantibody (ANCA)-negative pauci-immune crescentic GN (CrGN). He received high-dose steroid pulse therapy and oral cyclophosphamide, and then, gradually underwent steroid tapering, with improvement in proteinuria and renal function over several weeks. Several cases of GN suspected to be related to COVID-19 vaccines have been reported. To our knowledge, this is the first case report of ANCA-negative pauci-immune crescentic CrGN with extrarenal involvement after COVID-19 mRNA vaccination. Our finding expands the spectrum of COVID-19 vaccine-associated GN.

Effectiveness and Safety of COVID-19 Vaccination During Preconceptional and Preclinical Pregnancy Period: A National Population Study. BACKGROUND: We aimed to assess the risk of maternal severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and early abortive outcomes after the association between coronavirus disease 2019 (COVID-19) vaccination during the preconceptional period and preclinical pregnancy, which are likely to be inadvertent vaccination. METHODS: We used data from the Korea Disease Control and Prevention Agency-COVID19-National Health Insurance Service cohort from December 2020 to December 2021. The vaccinated pregnant

women were matched to unvaccinated pregnant controls at a 1:4 ratio. The risks of SARS-CoV-2 infection and intensive care unit (ICU) admission within 14 days of infection were analyzed to assess its effectiveness. For safety measures, the adjusted relative risks (aRRs) of early abortive outcomes for the first COVID-19 vaccination during the preconceptional and preclinical periods were calculated considering covariates. We compared the risk of early abortion between mRNA and viral vector vaccines. RESULTS: The overall COVID-19 vaccination rates during the preconceptional period and preclinical pregnancy were 3.1% (6,662/215,211) and 2.6% (5,702/215,211), respectively. The cumulative incidence of ICU admission within 14 days of SARS-CoV-2 infection was 6/100,000 in the unvaccinated group, whereas there were no ICU admissions in the vaccinated groups. The risks of early abortive outcomes were not significantly different between the preconceptional vaccination group and the unvaccinated group (aRR, 1.04; 95% confidence interval [CI],0.99-1.10) or between preclinical pregnancy vaccination and their matched controls (1.02; 95% CI, 0.96-1.08). mRNA and viral vector vaccines have shown similar risks for early abortive outcomes and miscarriages. CONCLUSION: Our findings have provided compelling evidence regarding the effectiveness and safety of COVID-19 vaccination prior to and during early pregnancy. Further research is required to extend the safety and efficacy profiles of COVID-19 vaccines to pregnant women and their babies.

Immunomodulators and risk for breakthrough infection after third COVID-19 mRNA vaccine among patients with rheumatoid arthritis: A cohort study. OBJECTIVES: To investigate COVID-19 breakthrough infection after third mRNA vaccine dose among patients with RA by immunomodulator drug class, and we hypothesized that CD20 inhibitors (CD20i) would have higher risk for breakthrough COVID-19 vs. TNF inhibitors (TNFi). METHODS: We performed a retrospective cohort study investigating breakthrough COVID-19 among RA patients at Mass General Brigham in Boston, MA, USA. Patients were followed from the date of 3rd vaccine dose until breakthrough COVID-19, death, or end of follow-up (18/Jan/2023). Covariates included demographics, lifestyle, comorbidities, and prior COVID-19. We used Cox proportional hazards models to estimate breakthrough COVID-19 risk by immunomodulator drug class. We used propensity score (PS) overlap-weighting to compare users of CD20i vs. TNFi. RESULTS: We analyzed 5781 patients with RA that received 3 mRNA vaccine doses (78.8% female, mean age 64.2 years). During mean follow-up of 12.8 months, 1173 (20.2%) had breakthrough COVID_19. Use of CD20i (adjusted HR 1.74, 95%CI 1.30-2.33) and glucocorticoid monotherapy (adjusted HR 1.47, 95%CI 1.09-1.98) were each associated with breakthrough COVID-19 compared to TNFi use. In the PS overlap-weighted analysis, CD20i users also had higher breakthrough COVID-19 risk than TNFi users (HR 1.62, 95%CI 1.02-2.56). A sensitivity analysis excluding patients with cancer or interstitial lung disease yielded similar findings. CONCLUSIONS: We identified CD20i and glucocorticoid monotherapy as risk factors for breakthrough COVID-19 among patients with RA after a 3rd vaccine dose. This contemporary study highlights the real-world impact of blunted immune responses in these subgroups and the need for effective risk mitigation strategies.

Emergency department presentations for chest complaints after mRNA COVID-19 vaccinations in children and adolescents. OBJECTIVE: To investigate characteristics and management of children presenting with chest complaints to a tertiary paediatric ED post-mRNA COVID-19 vaccine. METHODS: This was a retrospective medical record review with data linkage to the Australian Immunisation Register. The study setting was the Royal Children's Hospital, Melbourne, Australia. Children <18â€‰years who had a troponin blood test performed in hospital within 14â€‰days of receiving mRNA COVID-19 vaccination were included. Elevated troponin and myocarditis or pericarditis as per Brighton criteria was the primary outcome. Vaccination status, length of stay, investigations and clinical management were secondary outcomes. RESULTS: Six hundred and ten patients had a troponin test in 13â€‰months. After exclusion of trauma-related tests (nâ€‰=â€‰31), known cardiac patients (nâ€‰=â€‰75) and others (nâ€‰=â€‰145), 359 troponins were obtained due to

chest complaints and related symptoms, with 283 troponins assessed to be mRNA vaccination-related. There was a temporal peak in presentations with a 30-fold monthly increase in troponin post-commencement of mRNA COVID-19 vaccines. In those with chest complaints following mRNA vaccination, mean age was 14â€‰years and 50.4% were female. Fourteen out of 283 (5%) vaccine-related troponins were abnormal with 14 patients assessed to have vaccine-associated myocarditis. No patients had pericarditis. CONCLUSIONS: There was a large number of possible mRNA COVID-19 vaccine-related chest complaints presenting to the ED. Few patients had abnormal troponins or myocarditis.

Activation of coagulation and proinflammatory pathways in thrombosis with thrombocytopenia syndrome and following COVID-19 vaccination. Thrombosis with thrombocytopenia syndrome (TTS) is a rare but potentially severe adverse event following immunization with adenovirus vector-based COVID-19 vaccines such as Ad26.COV2.S (Janssen) and ChAdOx1 (AstraZeneca). However, no case of TTS has been reported in over 1.5 million individuals who received a second immunization with Ad26.COV2.S in the United States. Here we utilize transcriptomic and proteomic profiling to compare individuals who receive two doses of Ad26.COV2.S with those vaccinated with BNT162b2 or mRNA-1273. Initial Ad26.COV2.S vaccination induces transient activation of platelet and coagulation and innate immune pathways that resolve by day 7; by contrast, patients with TTS show robust upregulation of these pathways on days 15-19 following initial Ad26.COV2.S vaccination. Meanwhile, a second immunization or a reduced initial dose of Ad26.COV2.S induces lower activation of these pathways than does the full initial dose. Our data suggest a role of coagulation and proinflammatory pathways in TTS pathogenesis, which may help optimize vaccination regimens to reduce TTS risk.

Antibody levels following vaccination against SARS-CoV-2 during an 11-month follow-up. AIMS: The primary aim of our monitoring was to determine the duration of persistence of antibody levels following administration of the Comirnaty (Pfizer/BioNTech) mRNA vaccine. The second aim was to analyse the effect of selected factors on the level of antibodies. METHODS: The study cohort consisted of 250 employees of the Medirex JSC laboratories. For the quantitative determination of specific IgG anti-S1 and anti-S2 antibodies to SARS-CoV-2, chemiluminescence immunoassay was used. Twenty-nine subjects were excluded from the analysis due to extreme values of antibody levels in individual measurements. The effect of gender, age, BMI, comorbidity, and adverse reactions after vaccination with the Comirnaty (Pfizer/BioNTech) mRNA vaccine on antibody levels was analysed. Comparisons were made for five samples collected from two weeks after the 1st dose to 36 weeks after the 2nd dose of the mRNA vaccine. After the fifth sampling, the cohort was divided into two groups. Group 1 received the 3rd dose, and Group 2 were controls. We performed the last (sixth) sample collection two weeks after booster administration in Group 1and 11 months after the 2nd dose of the vaccine in controls. Between months 8 and 10 after the 2nd dose, we performed a cellular immunity test. RESULTS: Altogether 99.6% of the participants had a positive antibody level at week 36. Antibodies were still present in controls at month 11 after the 2nd dose. Significantly higher antibody levels were found in females, younger subjects, and those with selected adverse reactions. Reactive specific T lymphocytes were present in 65.6% of the subjects between weeks 36 and 44. CONSLUSION: The antibody response decreased with the time since the 2nd dose but was still present in the control group at week 48. The effect of booster on antibody levels was clearly demonstrated. We have not confirmed an association of cellular immunity with the level of antibodies or with the antibodies present.

Blistering Disease After COVID-19 Vaccination.

Humoral Response After 5 Successive Doses of COVID-19 Vaccine in Kidney Transplant Patients: Comment.

Newborn and Early Infant Outcomes Following Maternal COVID-19 Vaccination During Pregnancy. IMPORTANCE: The study team previously showed that maternal mRNA COVID-19 vaccination during pregnancy confers protection against SARS-CoV-2 infection and COVID-19-related hospital admission in newborns and young infants. In this study, the study team evaluated newborn and early infant safety outcomes following maternal messenger RNA (mRNA) COVID-19 vaccination during pregnancy, for which there is limited comparative epidemiological evidence. OBJECTIVE: To determine if maternal mRNA COVID-19 vaccination during pregnancy is associated with adverse newborn and early infant outcomes. DESIGN, SETTING, AND PARTICIPANTS: This population-based retrospective cohort study took place in Ontario, Canada, using multiple linked health administrative databases. Singleton live births with an expected delivery date between May 1, 2021, and September 2, 2022, were included. Data were analyzed from January 2023 through March 2023. EXPOSURE: Maternal mRNA COVID-19 vaccination (1 or more doses) during pregnancy. MAIN OUTCOMES AND MEASURES: Severe neonatal morbidity (SNM), neonatal death, neonatal intensive care unit (NICU) admission, neonatal readmission, and hospital admission up to 6 months of age. The study team calculated inverse probability of treatment weighted risk ratios (RRs) and fit weighted Cox proportional hazards regression models comparing outcomes in infants of mothers who received COVID-19 vaccination during pregnancy with those who received no COVID-19 vaccine doses before delivery. RESULTS: In total, 142â€¯006 infants (72â€¯595 male [51%]; mean [SD] gestational age at birth, 38.7 [1.7] weeks) were included; 85â€¯670 were exposed to 1 or more COVID-19 vaccine doses in utero (60%). Infants of vaccinated mothers had lower risks of SNM (vaccine exposed 7.3% vs vaccine unexposed 8.3%; adjusted RR [aRR], 0.86; 95% CI, 0.83-0.90), neonatal death (0.09% vs 0.16%; aRR, 0.47; 95% CI, 0.33-0.65), and NICU admission (11.4% vs 13.1%; aRR, 0.86; 95% CI, 0.83-0.89). There was no association between maternal vaccination during pregnancy and neonatal readmission (5.5% vs 5.1%; adjusted hazard ratio, 1.03; 95% CI, 0.98-1.09) or 6-month hospital admission (8.4% vs 8.1%; adjusted hazard ratio, 1.01; 95% CI, 0.96-1.05). CONCLUSIONS AND RELEVANCE: In this population-based cohort study in Ontario, Canada, maternal mRNA COVID-19 vaccination during pregnancy was associated with lower risks of SNM, neonatal death, and NICU admission. In addition, neonatal and 6-month readmissions were not increased in infants of mothers vaccinated during pregnancy.

Safety and Benefits of COVID-19 Vaccination in Pregnancy-Implications for the Maternal Vaccination Platform.

New-Onset Acute Interstitial Nephritis Post-SARS-CoV-2 Infection and COVID-19 Vaccination: A Panoramic Review. The 2019 coronavirus disease (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) has posed a considerable challenge to global healthcare. Acute interstitial nephritis (AIN) post SARS-CoV-2 infection and vaccination has been reported, but its clinical features and pathogenesis remained unclear. We reviewed so far the largest 22 cases of AIN post SARS-CoV-2 infection and 36 cases of AIN following COVID-19 vaccination. The onset of AIN was mainly related to messenger RNA vaccines (52.8%). Apart from fever, proteinuria (45.5%) was the main manifestation of AIN post SARS-CoV-2 infection, left acute kidney injury (AKI, 63.9%) in patients post COVID-19 vaccination. The potential mechanism of vaccination induced AIN was conjugating vaccines with proteins to form a hapten, which activated dendritic cells and promoted a cascade immunological reaction leading to AIN.

Covid- 19 Vaccine-induced Myocarditis. Myocarditis and pericarditis are rare adverse reactions, more commonly seen in young males after receiving the second dose of an mRNA vaccine. However, the benefits of vaccination heavily outweigh the risk of these side effects. In addition, vaccination boosters are effective against the newest, more infective variants. Therefore we expect more vaccines to be administered in the following years. The objective of this study is to review the current understanding of the mechanism, diagnosis, and treatment of myocarditis and pericarditis. Proposed

mechanisms include molecular mimicry against the S protein and hypersensitivity reactions with mRNA vaccines and platelet aggregation and thrombus formation in cardiac blood vessels with adenoviral vaccines. Diagnosis of myocarditis is based on clinical findings, cardiac enzymes, ECG, MRI, and echocardiographic findings. Management includes NSAIDs and cardiovascular support in selected cases with ventricular dysfunction. Most patients have a mild presentation with preservation of cardiac function and recover entirely within seven days; the average hospital stay is three days. Long-term complications are infrequent.

Multisystem Inflammatory Syndrome Due to COVID-19 Infection in Vaccinated Versus Unvaccinated Adolescents: A Case Report. Symptoms of COVID-19 infection are usually mild in the healthy pediatric population. In some pediatric patients, COVID-19 infection can lead to multisystem inflammatory syndrome in children (MIS-C). We report two cases. Case 1 is a rare case of MIS-C symptoms, presenting withÂ myalgia, chest pain, and fever three days after the second dose of the Pfizer-BioNTech COVID-19 vaccine, which is compared with Case 2, which is a case of MIS-C in an unvaccinated patient with COVID-19 infection who was noted to have acute kidney injury and fluid refractory hypotension. Although MIS-C was reported as a vaccine side effect, we conclude that COVID-19 infection led to the development of MIS-C in our case, not the COVID-19 vaccine. MIS-C symptoms were also noted to be less severe after the COVID-19 vaccine than in the unvaccinated patients.

Vitiligo Following COVID-19 Vaccination and Primary Infection: A Case Report and Systematic Review. Vitiligo is an acquired pigmentation disorder with different theorized etiologies, although the exact pathogenesis is still largely unknown. It presents as well-demarcated white plaques throughout the body that result from the loss of melanocytes within the epidermis. Commonly, this condition presents alongside other autoimmune conditions, and it is associated with both genetic and non-genetic factors. We present a patient with no history of autoimmune disease who developed vitiligo after receiving her vaccines against COVID-19. This first occurred within 24 hours of receiving her first vaccine and then worsened after receiving her second vaccine. The depigmented rash was localized to the face, arms, and chest. She was treated with both oral and topical steroids, as well as topical tacrolimus cream. Despite adherence to treatment, the patient only reported subjective improvement in her skin lesions overall. While vitiligo arises sporadically, the temporal relationship between vaccinations and depigmentation makes a stronger case for the vaccine as the inciting factor for this patient, though coincidence is possible. A systematic review of the literature regarding the onset of vitiligo following both infection with and vaccination against COVID-19, this case offers a unique presentation that had a sudden onset and creates a learning opportunity for clinicians to investigate the potential relationship between the receipt of the vaccine and the onset of this skin condition. The goal of this report is to help clinicians be cognizant of the possibility of developing or worsening skin diseases after infection or vaccination so that they can be addressed and treated appropriately.

THE EFFECT OF COVID-19 VACCINES ON PNEUMOTHORAX IN GERIATRIC PATIENTS HOSPÄ°TALIZED IN INTENSIVE CARE UNIT DUE TO COVID-19. In our study, we examined the effect of COVID-19 vaccination on the incidence of pneumothorax in intensive care patients over age 65. COVID-19 intensive care patients that presented to our department between April 2020 and May 2021 during the COVID-19 pandemic were evaluated retrospectively. Patients were divided into two main groups, i.e., before and after the vaccination period. Patients were evaluated retrospectively for the following parameters: gender, age, side of pneumothorax, mortality, discharge, comorbidity, and additional pleural complications. The total number of patients was 87, i.e., 66 patients before vaccination and 21 patients after vaccination. When patients in the pre- and post-vaccination period were compared, there was a significant difference in the incidence of pneumothorax between the two groups

(p<0.05). Pneumothorax was less common after vaccination. When patients with pneumothorax and tube thoracostomy were evaluated according to pre- and post-vaccination mortality, mortality was significantly higher (89%) in the pre-vaccination period (p<0.05). We consider that COVID-19 vaccines used in patients aged over 65 reduced the incidence of pleural complications, especially pneumothorax. We think that mortality due to pneumothorax in patients over 65 years of age was lower during the vaccination period. In addition, we think that bilateral pneumothorax was more common in the non-vaccinated period. As a result, we think that life-threatening pneumothorax and similar complications could be reduced by increasing the number of vaccines made in the COVID-19 pandemic and spreading it around the world.

Guillain-BarrÃ© Syndrome Post COVID-19 Vaccination with ChAdOx1 nCoV-19 Vaccine: A Colombian Case Report. BACKGROUND: Adverse events after vaccination against COVID-19 include rare events, such as Guillain-BarrÃ© syndrome. Study Aims. Documentation of clinical and temporary characteristics of the Guillain-BarrÃ© syndrome after using anti-COVID-19 ChAdOx1 nCoV-19 vaccine. Case Presentation. An adult, 29-year-old male, without relevant medical history, who developed neuromuscular symptoms nine days after administration of the first dose of anti-COVID-19 ChAdOx1 nCoV-19 vaccine. RESULTS: Symptoms appeared nine days after vaccination, with lower limbs paresthesia. Three days later, paresthesia of upper limbs occurred. The following day, distal weakness of limbs, with standing and gripping difficulties, occurred. The clinical evaluation demonstrated dysarthria, incomplete palpebral closure, bilateral facial, and tongue paresis. The electromyography was compatible with a motor demyelinating polyneuropathy, confirming the diagnosis of the Guillain-BarrÃ© syndrome. Management with five sessions of plasma exchange was prescribed, with favorable clinical results. CONCLUSIONS: Clinical and laboratory tests confirmed the Guillain-BarrÃ© syndrome and the time elapsed from the date of the vaccine administration to the appearance of initial symptoms, added to the absence of other causes, and allowed to establish that the disease was caused by the vaccination.

Concurrent pretibial myxedema and thyroid eye disease following mRNA COVID-19 vaccine in a patient with history of Graves' disease. A 70-year-old female had a history of thyroid surgery for benign nodules and Graves' disease. Following mRNA COVID-19 vaccination, she presented Graves' orbitopathy and pretibial myxedema. Symptoms of thyroid eye disease and thyroid dermopathy improved after 500-mg methylprednisolone infusions.

Antibody Production after COVID-19 Vaccination in Patients with Inborn Errors of Immunity. BACKGROUND: Few studies have evaluated COVID-19 vaccine efficacy in patients with inborn errors of immunity (IEI). OBJECTIVE: To evaluate the levels of antibody (Ab) production and function after COVID-19 vaccination in IEI patients with phagocytic, complement, and Ab deficiencies and their comparison with healthy controls. METHODS: Serum samples were collected from 41 patients and 32 healthy controls at least one month after the second dose of vaccination, while clinical evaluations continued until the end of the third dose. Levels of specific anti-receptor-binding domain (RBD) IgG and anti-RBD neutralizing antibodies were measured using EUROIMMUN and ChemoBind kits, respectively. Conventional SARS-CoV-2 neutralization test (cVNT) was also performed. Cutoff values of â‰¤20, 20-80, and â‰¥80 (for cVNT and Chemobined) and 0.8-4.2, 4.2-8.5, and â‰¥8.5 (for EUROIMMUN) were defined as negative/weak, positive/moderate, and positive/significant, respectively. RESULTS: A considerable distinction was observed between the Ab-deficient patients and the controls for Ab concentration (EUROIMMUN, p<0.01) and neutralization (ChemoBind, p<0.001). However, there was no significant difference compared with the other patient groups. A near-zero cVNT in Ab-deficient patients was found compared to the controls (p<0.01). A significant correlation between the two kits was found using the whole data (R2=0.82, p<0.0001). CONCLUSION: Despite varying degrees of Ab production, all Ab deficient patients, as well as almost half of those

with complement and phagocytic defects, did not effectively neutralize the virus (cVNT). In light of the decreased production and efficiency of the vaccine, a revised immunization plan may be needed in IEI.

Reactogenicity, pregnancy outcomes, and SARS-CoV-2 infection following COVID-19 vaccination during pregnancy in Canada: A national prospective cohort study. OBJECTIVE: To describe self-reported reactogenicity, pregnancy outcomes, and SARS-CoV-2 infection following COVID-19 vaccination during pregnancy. DESIGN: National, prospective cohort study. SETTING: Participants across Canada were enrolled from July 2021 until June 2022. POPULATION: Individuals pregnant during the COVID-19 pandemic, regardless of vaccination status, were included. METHODS: The Canadian COVID-19 Vaccine Registry for Pregnant and Lactating Individuals (COVERED) was advertised through traditional and social media. Surveys were administered at baseline, following each vaccine dose if vaccinated, pregnancy conclusion, and every two months for 14Â months. Changes to pregnancy or vaccination status, SARS-CoV-2 infections, or significant health events were recorded. MAIN OUTCOME MEASURES: Reactogenicity (local and systemic adverse events, and serious adverse events) within 1Â week post-vaccination, pregnancy and neonatal outcomes, and subsequent SARS-CoV-2 infection. RESULTS: Among 2868 participants who received 1-2 doses of a COVID-19 vaccine during pregnancy, adverse events described included: headache (19.5-33.9%), nausea (4.8-13.8%), fever (2.7-10.2%), and myalgia (33.4-42.2%). Reactogenicity was highest after the 2nd dose of vaccine in pregnancy. Compared to 1660 unvaccinated participants, there were no statistically significant differences in adverse pregnancy or infant outcomes, aside from an increased risk of NICU admissionÂ â‰¥Â 24Â h among the unvaccinated group. During follow-up, there was a higher rate of participant-reported SARS-CoV-2 infection in the unvaccinated compared to the vaccinated group (18[47.4%] vs. 786[27.3%]). CONCLUSIONS: Participant-reported reactogenicity was similar to reports from non-pregnant adults. There was no increase in adverse pregnancy and birth outcomes among vaccinated vs. unvaccinated participants and lower rates of SARS-CoV-2 infection were reported in vaccinated participants. TWEETABLE ABSTRACT: No significant increase in adverse pregnancy or infant outcomes among vaccinated versus unvaccinated pregnant women in Canada.

Association between acceptance of routine pregnancy vaccinations and COVID-19 vaccine uptake in pregnant patients. OBJECTIVE: COVID-19 vaccination is a key approach to reduce morbidity and mortality in pregnant patients and their newborns. Anti-vaccine sentiment has recently increased with unclear impact on pregnant patients. We examined the association between acceptance of tetanus-diphtheria-acellular pertussis (Tdap) and influenza vaccines, considered to be routine pregnancy vaccines, and COVID-19 vaccine acceptance. Secondarily, we identified other predictors of COVID-19 vaccine uptake and described pregnancy outcomes in patients who were and were not vaccinated during pregnancy. METHODS: A retrospective cohort study of all patients who delivered at a single site from December 2020 - March 2022. Demographic, pregnancy, neonatal, and vaccination data were abstracted from the electronic medical record, which imports vaccine history from the California Immunization Registry. The relationship between influenza and Tdap vaccine acceptance, other baseline characteristics, and COVID-19 vaccine uptake was assessed using univariable and multivariable regression analysis. RESULTS: Of the 7857 patients who delivered during the study period, 4410 (56.1%) accepted the COVID-19 vaccine. Of those who received the COVID-19 vaccine, 3363 (97.6%) and 3049 (88.5%) received influenza and Tdap vaccines, respectively. Patients were more likely to receive the COVID-19 vaccine if they had advanced maternal age, obesity, Asian race, and private insurance. After adjustment for baseline differences, COVID vaccine acceptance was associated with receipt of Tdap (aOR 2.10, 95% CI 1.90-2.33) and influenza vaccines (aOR 2.83, 95% CI 2.55-3.14). There were no differences in preterm birth, low birthweight, and NICU admission between patients who received and did not receive the COVID-19 vaccine. CONCLUSION: Patients

were more likely to accept COVID-19 vaccination if they received Tdap or influenza vaccinations. Older age, obesity, Asian race, and private insurance were independent predictors of vaccine uptake. Disparities in COVID-19 vaccination uptake bear further exploration to guide efforts in equitable and widespread vaccine distribution.

Long-term safety and immunogenicity of an MF59-adjuvanted spike glycoprotein-clamp vaccine for SARS-CoV-2 in adults aged 18-55 years or â‰¥56 years: 12-month results from a randomised, double-blind, placebo-controlled, phase 1 trial. BACKGROUND: We previously demonstrated the safety and immunogenicity of an MF59-adjuvanted COVID-19 vaccine based on the SARS-CoV-2 spike glycoprotein stabilised in a pre-fusion conformation by a molecular clamp using HIV-1 glycoprotein 41 sequences. Here, we describe 12-month results in adults aged 18-55 years and â‰¥56 years. METHODS: Phase 1, double-blind, placebo-controlled trial conducted in Australia (July 2020-December 2021; ClinicalTrials.govNCT04495933; active, not recruiting). Healthy adults (Part 1: 18-55 years; Part 2: â‰¥56 years) received two doses of placebo, 5Â Î¼g, 15Â Î¼g, or 45Â Î¼g vaccine, or one 45Â Î¼g dose of vaccine followed by placebo (Part 1 only), 28 days apart (nÂ =Â 216; 24 per group). Safety, humoral immunogenicity (including against virus variants), and cellular immunogenicity were assessed to day 394 (12 months after second dose). Effects of subsequent COVID-19 vaccination on humoral responses were examined. FINDINGS: All two-dose vaccine regimens were well tolerated and elicited strong antigen-specific and neutralising humoral responses, and CD4(+) T-cell responses, by day 43 in younger and older adults, although cellular responses were lower in older adults. Humoral responses waned by day 209 but were boosted in those receiving authorised vaccines. Neutralising activity against Delta and Omicron variants was present but lower than against the Wuhan strain. Cross-reactivity in HIV diagnostic tests declined over time but remained detectable in most participants. INTERPRETATION: The SARS-CoV-2 molecular clamp vaccine is well tolerated and evokes robust immune responses in adults of all ages. Although the HIV glycoprotein 41-based molecular clamp is not being progressed, the clamp concept represents a viable platform for vaccine development. FUNDING: This study was funded by the Coalition for Epidemic Preparedness Innovations, the National Health and Medical Research Council of Australia, and the Queensland Government.

A prospective cohort study of preconception COVID-19 vaccination and miscarriage. STUDY QUESTION: To what extent is preconception maternal or paternal coronavirus disease 2019 (COVID-19) vaccination associated with miscarriage incidence? SUMMARY ANSWER: COVID-19 vaccination in either partner at any time before conception is not associated with an increased rate of miscarriage. WHAT IS KNOWN ALREADY: Several observational studies have evaluated the safety of COVID-19 vaccination during pregnancy and found no association with miscarriage, though no study prospectively evaluated the risk of early miscarriage (gestational weeks [GW] <8) in relation to COVID-19 vaccination. Moreover, no study has evaluated the role of preconception vaccination in both male and female partners. STUDY DESIGN, SIZE, DURATION: An Internet-based, prospective preconception cohort study of couples residing in the USA and Canada. We analyzed data from 1815 female participants who conceived during December 2020-November 2022, including 1570 couples with data on male partner vaccination. PARTICIPANTS/MATERIALS, SETTING, METHODS: Eligible female participants were aged 21-45â€‰years and were trying to conceive without use of fertility treatment at enrollment. Female participants completed questionnaires at baseline, every 8â€‰weeks until pregnancy, and during early and late pregnancy; they could also invite their male partners to complete a baseline questionnaire. We collected data on COVID-19 vaccination (brand and date of doses), history of SARS-CoV-2 infection (yes/no and date of positive test), potential confounders (demographic, reproductive, and lifestyle characteristics), and pregnancy status on all questionnaires. Vaccination status was categorized as never (0 doses before conception), ever (â‰¥1

dose before conception), having a full primary sequence before conception, and completing the full primary sequence â‰¤3â€‰months before conception. These categories were not mutually exclusive. Participants were followed up from their first positive pregnancy test until miscarriage or a censoring event (induced abortion, ectopic pregnancy, loss to follow-up, 20 weeks' gestation), whichever occurred first. We estimated incidence rate ratios (IRRs) for miscarriage and corresponding 95% CIs using Cox proportional hazards models with GW as the time scale. We used propensity score fine stratification weights to adjust for confounding. MAIN RESULTS AND THE ROLE OF CHANCE: Among 1815 eligible female participants, 75% had received at least one dose of a COVID-19 vaccine by the time of conception. Almost one-quarter of pregnancies resulted in miscarriage, and 75% of miscarriages occurred <8 weeks' gestation. The propensity score-weighted IRR comparing female participants who received at least one dose any time before conception versus those who had not been vaccinated was 0.85 (95% CI: 0.63, 1.14). COVID-19 vaccination was not associated with increased risk of either early miscarriage (GW: <8) or late miscarriage (GW: 8-19). There was no indication of an increased risk of miscarriage associated with male partner vaccination (IRRâ€‰=â€‰0.90; 95% CI: 0.56, 1.44). LIMITATIONS, REASONS FOR CAUTION: The present study relied on self-reported vaccination status and infection history. Thus, there may be some non-differential misclassification of exposure status. While misclassification of miscarriage is also possible, the preconception cohort design and high prevalence of home pregnancy testing in this cohort reduced the potential for under-ascertainment of miscarriage. As in all observational studies, residual or unmeasured confounding is possible. WIDER IMPLICATIONS OF THE FINDINGS: This is the first study to evaluate prospectively the relation between preconception COVID-19 vaccination in both partners and miscarriage, with more complete ascertainment of early miscarriages than earlier studies of vaccination. The findings are informative for individuals planning a pregnancy and their healthcare providers. STUDY FUNDING/COMPETING INTEREST(S): This work was supported by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Institute of Health [R01-HD086742 (PI: L.A.W.); R01-HD105863S1 (PI: L.A.W. and M.L.E.)], the National Institute of Allergy and Infectious Diseases (R03-AI154544; PI: A.K.R.), and the National Science Foundation (NSF-1914792; PI: L.A.W.). The funders had no role in the study design, data collection, analysis and interpretation of data, writing of the report, or the decision to submit the paper for publication. L.A.W. is a fibroid consultant for AbbVie, Inc. She also receives in-kind donations from Swiss Precision Diagnostics (Clearblue home pregnancy tests) and Kindara.com (fertility apps). M.L.E. received consulting fees from Ro, Hannah, Dadi, VSeat, and Underdog, holds stock in Ro, Hannah, Dadi, and Underdog, is a past president of SSMR, and is a board member of SMRU. K.F.H. reports being an investigator on grants to her institution from UCB and Takeda, unrelated to this study. S.H.-D. reports being an investigator on grants to her institution from Takeda, unrelated to this study, and a methods consultant for UCB and Roche for unrelated drugs. The authors report no other relationships or activities that could appear to have influenced the submitted work. TRIAL REGISTRATION NUMBER: N/A.

Systematic review and meta-analysis of the factors affecting waning of post-vaccination neutralizing antibody responses against SARS-CoV-2. Mass COVID-19 vaccination and continued introduction of new SARS-CoV-2 variants increased prevalence of hybrid immunity at various stages of waning protection. We systematically reviewed waning of post-vaccination neutralizing antibody titers in different immunological settings to investigate differences. We searched published and pre-print studies providing post-vaccination neutralizing antibody responses against the Index strain or Omicron BA.1. We used random effects meta-regression to estimate fold-reduction from months 1 to 6 post last dose by primary vs booster regimen and infection-naÃ¯ve vs hybrid-immune cohorts. Among 26 eligible studies, 65 cohorts (range 3-21 per stratum) were identified. Month-1 titers varied

widely across studies within each cohort and by vaccine platform, number of doses and number of prior infections. In infection-naÃ¯ve cohorts, the Index strain waned 5.1-fold (95%CI: 3.4-7.8; nâ€‰=â€‰19 cohorts) post-primary regimen and 3.8-fold (95%CI: 2.4-5.9; nâ€‰=â€‰21) post-booster from months 1 to 6, and against Omicron BA.1 waned 5.9-fold (95%CI: 3.8-9.0; nâ€‰=â€‰16) post-booster; Omicron BA.1 titers post-primary were too low to assess. In hybrid-immune, post-primary cohorts, titers waned 3.7-fold (95%CI: 1.7-7.9; nâ€‰=â€‰8) against the Index strain and 5.0-fold (95%CI: 1.1-21.8; nâ€‰=â€‰6) against Omicron BA.1; post-booster studies of hybrid-immune cohorts were too few (nâ€‰=â€‰3 cohorts each strain) to assess. Waning was similar across vaccination regimen and prior-infection status strata but was faster for Omicron BA.1 than Index strains, therefore, more recent sub-variants should be monitored. Wide differences in peak titers by vaccine platform and prior infection status mean titers drop to non-protective levels sooner in some instances, which may affect policy.

Evaluation of immune response to SARS-CoV-2 Omicron sublineages six months after different vaccination regimens in Italy. The Omicron variant is the most divergent, displaying more mutations than previous SARS-CoV-2 variants, particularly in the gene that encodes the spike protein. This study aimed to assess the persistence of neutralizing antibodies towards the SARS-CoV-2 Omicron sublineages (BA.2, BA.5, BQ.1, XBB and XBB1.5) six months after the third dose in different vaccination regimens. Subjects who received 3 doses of mRNA vaccine retained their neutralization activity against BA.2 and BA.5, even though 56.3% and 66.7% showed aÂ â‰¥Â 2-fold reduction in the neutralizing antibody titre, respectively. Subjects who had received the adenovirus-based vaccine plus a booster dose of mRNA vaccine retained their neutralization activity especially against BA.2. With regard to BQ.1, XBB and XBB.1.5, the majority of the subjects showed aÂ â‰¥Â 2-fold reduction in neutralizing antibody titre, with the greatest evasion being observed in the case of XBB. Overall, our results provide further evidence that triple homologous/heterologous vaccination and hybrid immunity result in detectable neutralizing antibodies against the ancestral virus; however, emerging Omicron sublineages, such as XBB and XBB.1.5, show a great evasive capacity, which compromises the effectiveness of current COVID-19 vaccines.

Immune responses and clinical outcomes after COVID-19 vaccination in patients with liver disease and liver transplant recipients. BACKGROUND & AIMS: Comparative assessments of immunogenicity following different COVID-19 vaccines in patients with distinct liver diseases are lacking. SARS-CoV-2-specific T-cell and antibody responses were evaluated longitudinally after one to three vaccine doses, with long-term follow-up for COVID-19-related clinical outcomes. METHODS: A total of 849 participants (355 with cirrhosis, 74 with autoimmune hepatitis [AIH], 36 with vascular liver disease [VLD], 257 liver transplant recipients [LTRs] and 127 healthy controls [HCs]) were recruited from four countries. Standardised immune assays were performed pre and post three vaccine doses (V1-3). RESULTS: In the total cohort, there were incremental increases in antibody titres after each vaccine dose ($p < 0.0001$). Factors associated with reduced antibody responses were age and LT, whereas heterologous vaccination, prior COVID-19 and mRNA platforms were associated with greater responses. Although antibody titres decreased between post-V2 and pre-V3 (pÂ = 0.012), patients with AIH, VLD, and cirrhosis had equivalent antibody responses to HCs post-V3. LTRs had lower and more heterogenous antibody titres than other groups, including post-V3 where 9% had no detectable antibodies; this was heavily influenced by intensity of immunosuppression. Vaccination increased T-cell IFNÎ³ responses in all groups except LTRs. Patients with liver disease had lower functional antibody responses against nine Omicron subvariants and reduced T-cell responses to Omicron BA.1-specific peptides compared to wild-type. 122 cases of breakthrough COVID-19 were reported of which 5/122 (4%) were severe. Of the severe cases, 4/5 (80%) occurred in LTRs and 2/5 (40%) had no serological response post-V2. CONCLUSION: After three COVID-19 vaccines, patients

with liver disease generally develop robust antibody and T-cell responses to vaccination and have mild COVID-19. However, LTRs have sustained no/low antibody titres and appear most vulnerable to severe disease. IMPACT AND IMPLICATIONS: Standardised assessments of the immune response to different COVID-19 vaccines in patients with liver disease are lacking. We performed antibody and T-cell assays at multiple timepoints following up to three vaccine doses in a large cohort of patients with a range of liver conditions. Overall, the three most widely available vaccine platforms were immunogenic and appeared to protect against severe breakthrough COVID-19. This will provide reassurance to patients with chronic liver disease who were deemed at high risk of severe COVID-19 during the pre-vaccination era, however, liver transplant recipients had the lowest antibody titres and remained vulnerable to severe breakthrough infection. We also characterise the immune response to multiple SARS-CoV-2 variants and describe the interaction between disease type, severity, and vaccine platform. These insights may prove useful in the event of future viral infections which also require rapid vaccine development and delivery to patients with liver disease.

52-year-old man â€¢ intermittent fevers â€¢ recently received second dose of COVID-19 vaccine â€¢ tremors in all 4 extremities â€¢ Dx? â–º intermittent fevers â–º recently received second dose of COVID-19 vaccine â–º tremors in all 4 extremities.

Socioeconomic impact of the COVID-19 crisis and early perceptions of COVID-19 vaccines among immigrant and nonimmigrant people living with HIV followed up in public hospitals in Seine-Saint-Denis, France. The burden of the first year of the coronavirus disease 2019 (COVID-19) pandemic was greater for vulnerable populations, such as immigrants, people living in disadvantaged urban areas, and people with chronic illnesses whose usual follow-up may have been disrupted. Immigrants receiving care for HIV in Seine-Saint-Denis' hospitals have a combination of such vulnerabilities, while nonimmigrant people living with HIV (PLWHIV) have more heterogeneous vulnerability profiles. The ICOVIH study aimed to compare the socioeconomic effects of the COVID-19 crisis as well as attitudes toward COVID-19 vaccination among immigrant and nonimmigrant PLWHIV. A questionnaire assessed vulnerabilities prior to the COVID-19 epidemic and the impact of the early epidemic on administrative, residential, professional, and financial fields. We surveyed 296 adults living with HIV at four hospitals in Seine-Saint-Denis, the poorest metropolitan French department, between January and May 2021. Administrative barriers affected 9% of French-born versus 26.3% of immigrant participants. Immigrants experienced financial insecurity and hunger more often than nonimmigrant participants (21.8% versus 7.1% and 6.6% versus 3%, respectively). Spontaneous acceptance of vaccination was higher among nonimmigrant than among immigrant participants (56.7% versus 32.1%), while immigrants were more likely to wait for their doctor's recommendation or for their doctor to convince them than their French-born counterparts (34.2% versus 19.6%). The trust-based doctorâ€'patient relationship established through HIV follow-up appeared to be a determining factor in the high acceptance of the COVID-19 vaccine among immigrant participants.

Subacute thyroiditis following COVID-19 vaccination: Case presentation. Background: Subacute thyroiditis (SAT) is an organ-specific disease that various drugs, including COVID-19 vaccines, can trigger. COVID-19 infection has been associated with thyroid gland damage and disease SARS-CoV-2 direct action, euthyroid sick syndrome, and immune-mediated mechanisms are all potential mechanisms of thyroid damage. It denotes thyroid gland inflammation, most commonly of viral origin, and belongs to the transitory, self-limiting thyroid gland diseases group, causing complications in approximately 15% of patients in the form of permanent hypothyroidism. Some authors say SAT is the most common thyroid disease associated with COVID-19.Purpose: The occurrence of SAT many weeks after administering the second COVID-19 vaccine is rare and has limited documentation in academic literature. This study aims to present the occurrence of SAT after administering the COVID-19 vaccine. We present the case of a 37-year-old man who developed SAT 23 days after receiving the

second dose of Pfizer BioNTech's COVID-19 mRNA vaccine.Research design and study sample: Due to neck pain and an elevated body temperature (up to 38.2Â°C), a 37-year-old male subject presented for examination 23 days after receiving the second Pfizer BioNTech mRNA vaccine against SARS-CoV-2 viral infection. The patient denied ever having an autoimmune disease or any other disease. Painful neck palpation and a firm, slightly enlarged thyroid gland with no surrounding lymphadenopathy were identified during the exam. The heart rate was 104 beats per minute. All of the remaining physical findings were normal.Data collection and/or Analysis: Data collected during the disease are integral to the medical record.Results: Hematology and biochemistry analyses at the initial and follow-up visits revealed minor leukocytosis, normocytic anaemia, and thrombocytosis, followed by a mild increase in lactate dehydrogenase and decreased iron levels. The patient's thyroid function and morphology had recovered entirely from post-vaccine SAT.Conclusions: Results from this study emphasise the need for healthcare professionals to promptly report any case of SAT related to COVID-19 vaccination. Further investigation is warranted to understand the immunopathogenesis of COVID-19-associated thyroiditis and the impact of COVID-19 immunization on this condition.

Adverse Effects Reported and Insights Following Sinopharm COVID-19 Vaccination. Vaccines are promising strategies for controlling COVID-19; however, COVID-19 vaccine side effects play a central role in public confidence in the vaccine and its uptake process. This study aimed to provide evidence on the post-vaccination early side effects of the BBIBP-CorV (Sinopharm) vaccine. This cross-sectional survey-based study was conducted between November 2021 and January 2022 among recipients of the BBIBP-CorV vaccine, using a questionnaire-based survey. Our final sample consisted of 657 participants, including 392 women. Among the study cases, only 103 (15.7%) participants received one dose of vaccine, and the rest received both doses (Nâ€‰=â€‰554, 84.3%). Systemic symptoms (first dose: Nâ€‰=â€‰187, both doses: Nâ€‰=â€‰128) were the most commonly reported events after vaccination, and among them, injection site pain (first dose: 19.3%, both doses: 12.9%) was the most prevalent adverse effect. All reporting events were mild and resolved in less than 3Â days without hospitalization. Among the participants, females and young people aged 35-65 were more prone to manifest side effects (Nâ€‰=â€‰169, 53.3%) after the vaccine injection. Furthermore, our results revealed that the recipients who were suffering from underlying diseases, including diabetes, renal disorder, and respiratory illness, reported fewer adverse responses after vaccination in comparison with healthy individuals. Vaccination against SARS-CoV-2 may lead to some adverse reactions in recipients. However, the frequency of post-vaccination early side effects differed in people, but all responses were slight and temporary.

Cutaneous lymphoproliferative disorders after COVID-19 vaccination: clinical presentation, histopathology, and outcomes. Individual reports described lymphoproliferative disorders (LPDs) after COVID-19 vaccination; however, the relationship between cases is unexamined. We aim to determine if there are cases of cutaneous LPDs associated with COVID-19 vaccination and their outcomes. We present a review of world literature, vaccine registries, and two unreported cases of LPDs after COVID-19 vaccination. Review of the medical literature, VAERS, and our two cases reveal predominance of Pfizer-BioNTech vaccine, younger patients, and males. All cases resulted in favorable outcomes. Approximately 84% of cases demonstrated CD30+ positivity in their skin biopsies, suggesting that an antigenic trigger may lead to a type IV adaptive immune response, with clonal expansion of CD30+ T-cells and subsequent oncogenic mutational hits eventuating in transient LPDs. LPDs after COVID-19 vaccination appear in the context of the same vaccines (proportionally to their global market shares), share clinical and pathological findings, and have indolent, self-limited character.

Retrospective analysis of epidemiologic features and clinical course of COVID-19 patients and comparison between vaccinated and unvaccinated patients. At our Pneumology Department, we

dealt with three waves of COVID-19 pandemics. The purpose of this study is to compare patients' epidemiological and clinical characteristics across waves and to assess the effect of vaccination on clinical presentation, course, and prognosis. From March 2020 to March 2022, a retrospective cohort study was conducted to compare patient characteristics. Based on the time of hospital admission, data from 456 patients were collected and divided into three groups (IW, IIW, and IIIW). In addition, we looked at the link between vaccination and clinical presentation and hospitalization outcome. The average age and comorbidities of patients increased, as did the worsening of respiratory conditions at admission (PaO2/FiO2 median 207 in IW, 95.5 in IIW, and 99 in IIIW). Continuous positive airway pressure (CPAP) was the primary respiratory support during the first wave, but an increase in the use of high flow nasal cannula and noninvasive ventilation was later observed, resulting in a higher hospital discharge rate and a lower intubation rate. Vaccinated patients had less severe COVID-19-related respiratory failure, a better clinical course, and a higher hospital discharge rate (71.4% in V-group vs 44.7% in NV-group, p<0.001). Patients' characteristics changed over the three waves, possibly due to virus mutations. The advancement of clinical and therapeutic management knowledge has contributed to a reduction in the severity of respiratory failure. The vaccination campaign improved the clinical course and reduced mortality.

Recurrent giant cellulitis-like Sweet syndrome induced by SARS-CoV-2 Pfizer-BioNTech mRNA vaccine. Primary and booster vaccines for SARS-CoV-2 are the most effective methods of preventing infection and are generally considered safe. However, many cutaneous adverse events have been reported following vaccination. To date, there have been seven reported cases of Sweet syndrome occurring after the first dose of the SARS-CoV-2 vaccine. We describe a rare case of atypical giant-cellulitis like Sweet syndrome reemerging after receiving the SARS-CoV-2 booster vaccine.

The impact of Bacillus Calmette-GuÃ©rin vaccination on antibody response after COVID-19 vaccination. Earlier studies showed that BCG vaccination improves antibody responses of subsequent vaccinations. Similarly, in older volunteers we found an increased IgG receptor-binding domain (RBD) concentration after SARS-CoV-2 infection if they were recently vaccinated with BCG. This study aims to assess the effect of BCG on the serum antibody concentrations induced by COVID-19 vaccination in a population of adults older than 60 years. Serum was collected from 1,555 participants of the BCG-CORONA-ELDERLY trial a year after BCG or placebo, and we analyzed the anti-SARS-CoV-2 antibody concentrations using a fluorescent-microsphere-based multiplex immunoassay. Individuals who received the full primary COVID-19 vaccination series before serum collection and did not test positive for SARS-CoV-2 between inclusion and serum collection were included in analyses (nÂ = 945). We found that BCG vaccination before first COVID-19 vaccine (median 347Â days [IQR 329-359]) did not significantly impact the IgG RBD concentration after COVID-19 vaccination in an older European population.

Health Care Costs Following COVID-19 Hospitalization Prior to Vaccine Availability. BACKGROUND: Postacute sequelae of coronavirus (PASC) disease of 2019 (COVID-19) include morbidity and mortality, but little is known of the impact on medical expenditures. This study measures patients' health care costs after COVID hospitalization before vaccinations. METHODS: The Merative MarketScan database is used to track trends in medical expenditures for commercially insured patients hospitalized for COVID-19 (case subjects) compared with COVID-19 patients not hospitalized (control subjects) using a propensity score matching model. Medical expenditures were estimated from 30-, 60-, and 120-day clean periods after an initial COVID-19 encounter through the end of 2020. RESULTS: Average total medical expenditures were 96% higher for individuals hospitalized for COVID-19 starting 30â€‰days after initial COVID-19 encounter and almost 70% higher 120â€‰days after based on the propensity score matching. The average spending differential was $11,242 30â€‰days after and $4959 120â€‰days after. This effect is highest for inpatient

admissions and services 60â€‰days after at $56,862 and lowest among pharmaceuticals 120â€‰days after at $329. The magnitude of the difference is greater for those with hypertension or diabetes where total expenditures is $14,958 30â€‰days after, and $5962 120â€‰days after compared with those without these chronic conditions. DISCUSSION: The results suggest both health and economic implications for COVID-19 hospitalization and supports the use of vaccinations to help mitigate these implications. PASC includes increased health care costs for hospitalized patients, particularly for those with chronic conditions. Preventing COVID-19 hospitalization has economic value in terms of reduced medical spending in addition to health benefits associated with reduced morbidity and mortality.

Risk of lymphadenopathy from SARS-CoV-2 vaccination in Korea: a self-controlled case series analysis. OBJECTIVES: To assess the risk of lymphadenopathy following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. METHODS: A self-controlled case series design was used to determine whether the risk of lymphadenopathy was higher in the 1-day to 42-day risk interval after coronavirus disease 2019 (COVID-19) vaccination compared to the control period. In addition, subgroup analyses were conducted according to baseline characteristics, time since vaccination, and sensitivity analyses adjusted for the length of the risk interval. RESULTS: The risk of developing lymphadenopathy in the risk interval (1-42 days) after COVID-19 vaccination compared to the control period was significantly increased, with a relative incidence (RI) of 1.17 (95% confidence interval [CI], 1.17 to 1.18) when the first, second, and third doses were combined. The RI was greater on the day of vaccination (1.47; 95% CI, 1.44 to 1.50). In subgroup analyses by baseline characteristics, a significantly increased risk or trend toward increased risk was observed in most subgroups except for those aged 70 years and older, with a significant increase in risk in younger individuals, those with a Charlson's comorbidity index <5, and those who received mRNA vaccines (mRNA-1273>BNT162b2). Within the 1-day to 42-day post-dose risk period, the relative risk was highest during the 1-day to 7-day post-dose period (1.59; 95% CI, 1.57 to 1.60) compared to the control period, and then the risk declined. In the sensitivity analysis, we found that the longer the risk window, the smaller the RI. CONCLUSIONS: SARS-CoV-2 vaccination is associated with a statistically significant increase in the risk of lymphadenopathy, and this risk was observed only with mRNA vaccines.

Assessing associations and predictors of COVID-19 vaccine uptake among college students in a university setting. Objectives: This study assessed the uptake of the COVID-19 vaccine and factors related to vaccination coverage among college students in a university setting. Methods: A cross-sectional study design included undergraduate and graduate students in a university community as study participants. Survey questions assessed the uptake of the COVID-19 vaccine and various predictor variables related to vaccination decision-making. Data analysis included descriptive statistics, correlation statistics, and binary logistic regression. Results: Of the 385 participants, most were undergraduate students. Participants who received the influenza vaccine in the past flu season were more likely to receive the COVID-19 vaccine. Participants with perceived susceptibility to COVID-19 were five times more likely to receive the COVID-19 vaccine. Conclusions: Influenza vaccination coverage and perceived susceptibility were associated with the uptake of the COVID-19 vaccine. Study findings may serve to inform behavior change interventions and educational programs for students in university communities.

Immune response and safety of inactivated SARS-CoV-2 vaccines during pregnancy: a real-world observational study. BACKGROUND: As pregnant women are excluded from clinical trials of inactivated SARS-CoV-2 vaccines, it is important to assess the immune response in women receiving the vaccination while unknowingly pregnant. METHODS: In a multicenter cross-sectional study, we enrolled 873 pregnant women aged 18-45â€‰years. Serum antibody levels induced by inactivated vaccines were determined. Adverse events were collected by self-reported survey after vaccination.

Logistic regression model and restricted cubic spline model were used to investigate the association of factors with antibody positivity. RESULTS: As the doses of the vaccine increase, neutralizing antibody (NAb) positivity was 98.3%, 39.5%, and 9.5% in pregnant women, respectively. The dose of vaccine and duration since vaccination were associated with NAb positivity. The OR of two and three doses of vaccines were 7.20 and 458.33 (Pâ€‰<â€‰0.05). NAb levels and duration since vaccination showed a linear relationship in pregnant women vaccinated two doses, with a decrease to a near seropositivity threshold at 22â€‰weeks. Adverse events were mainly mild or moderate after vaccinated during pregnancy, with no increase in incidence compared with whom vaccinated during pre-pregnancy. CONCLUSIONS: The use of inactivated vaccines during pregnancy induced favorable immune persistence, and the incidence of adverse events did not increase.

Association between COVID-19 and vaccination on menstrual cycle. OBJECTIVE: To evaluate changes in the menstrual pattern of women of reproductive age infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or vaccinated against coronavirus disease 2019 (COVID-19). METHODS: A cross-sectional study at the University of Campinas, Brazil using Google questionnaire applied from December 2021 through February 2022, disseminated through snowball technique. Participants responded about characteristics of their menstrual cycle before the pandemic and before COVID-19 vaccination, and then about characteristics of their cycle 3â€‰months after infection with SARS-CoV-2 and 3â€‰months after vaccination. Our primary outcome was a binary indicator of changes in the menstrual cycle. We used multivariate regression analysis to identify factors associated with menstrual changes. RESULTS: We received 1012 completed questionnaires and 735 (72.7%) were from women aged between 20 and 39â€‰years, 745 (73.6%) were White and 491 (48.6%) lived with a partner. A total of 419 (41.6%) of the women reported SARS-CoV-2 infection; however, only two of them were hospitalized, and 995 (98.8%) of women had at least one dose of COVID-19 vaccine. About menstrual characteristics, 170 (41.3%) reported changes after having COVID-19 and 294 (29.9%) after COVID-19 vaccination, respectively. Few years of schooling, lower income, and non-white ethnicity were related to higher reports of menstrual changes after COVID-19. Menstrual changes after COVID-19 vaccination were associated with not using contraception. Higher body mass index was associated with irregularities in cyclicity and bleeding days, after COVID-19 and COVID-19 vaccination, respectively. CONCLUSION: Our results corroborated the stability of the menstrual cycle after having COVID-19 or COVID-19 vaccination; however, there is a potential relationship between menstrual changes and socioeconomic factors as well as contraceptive use.

Cancerous Patient, COVID-19 Vaccination, Blood Viscosity and Stroke-Like Complication.

COVID-19, Vaccination, Multisystem Inflammatory Syndrome, Aneurysm, Screening and Post Vaccination Death.

Analyzing COVID-19 Vaccination Side Effects Among the Adult Population in Jeddah, Saudi Arabia. The COVID-19 pandemic has brought vaccination to the forefront of global attention. The Pfizer-BioNTech vaccine, an mRNA vaccine that encodes the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) glycoprotein spike, has emerged as a significant player in global vaccination efforts. It is generated from lipid nanoparticles and has been subject to various regulatory approvals and authorizations. The United Kingdom became the first country to approve the Pfizer vaccine on December 2, 2020. The World Health Organization (WHO) authorized the emergency use of the Pfizer vaccine on December 31, 2020, facilitating its production and distribution worldwide. In Saudi Arabia, as well as globally, concerns about the safety and effectiveness of vaccines have been raised. Several studies have reported side effects of the Pfizer vaccine, including rare conditions such as myocarditis. In our study, we aimed to systematically investigate the symptoms experienced after vaccination, considering the administration of three doses. We also explored the duration of these symptoms and whether they necessitated hospital visits, primary healthcare interventions, or resolved on their own.

Our study employed an online cross-sectional design conducted in Jeddah, Saudi Arabia, utilizing an online self-reported survey. A total of 332 participants who met the predefined criteria were recruited for the study. The rate of COVID-19 infection after 1st and 2nd doses of Pfizer and AstraZeneca vaccines was significantly lower in middle-age subgroups (31-45 years), in comparison to young (18-30 years) and upper middle-age subgroups (46-60 years). For the AstraZeneca vaccine, the infection rate in the middle-aged group was higher after 2nd dose as compared to its 1st dose. Overall, greater infection rates were observed in upper-middle-aged subgroups with all doses of Pfizer and AstraZeneca vaccines. Fatigue and fever were the most common generalized side effects while redness/swelling/pain at the injection site, muscle pain, and joint pain were the most important local side-effects. Fatigue, fever, muscle pain, and joint pain were significantly common after 1st dose of Pfizer and fever was a significant side effectÂ after 2nd dose of Pfizer in comparison to AstraZeneca doses. Understanding the spectrum of side effects associated with the vaccine is crucial for healthcare professionals and individuals receiving the vaccine, as it enables informed decision-making and appropriate management of potential adverse reactions.

Impact of COVID-19 and vaccination campaign on 1,755 systemic sclerosis patients during first three years of pandemic. Possible risks for individuals with impaired immunoreactivity to vaccine, ongoing immunomodulating treatments, and disease-related lung involvement during the next pandemic phase. INTRODUCTION: The impact of COVID-19 pandemic represents a serious challenge for 'frail' patients' populations with inflammatory autoimmune systemic diseases such as systemic sclerosis (SSc). We investigated the prevalence and severity of COVID-19, as well the effects of COVID-19 vaccination campaign in a large series of SSc patients followed for the entire period (first 38 months) of pandemic. PATIENTS AND METHOD: This prospective survey study included 1755 unselected SSc patients (186Â M, 1,569F; mean age 58.7Â Â±Â 13.4SD years, mean disease duration 8.8Â Â±Â 7.3SD years) recruited in part by telephone survey at 37 referral centers from February 2020 to April 2023. The following parameters were carefully evaluated: i. demographic, clinical, serological, and therapeutical features; ii. prevalence and severity of COVID-19; and iii. safety, immunogenicity, and efficacy of COVID-19 vaccines. RESULTS: The prevalence of COVID-19 recorded during the whole pandemic was significantly higher compared to Italian general population (47.3Â % vs 43.3Â %, pÂ <Â 0.000), as well the COVID-19-related mortality (1.91Â % vs 0.72 %, pÂ <Â 0.001). As regards the putative prognostic factors of worse outcome, COVID-19 positive patients with SSc-related interstitial lung involvement showed significantly higher percentage of COVID-19-related hospitalization compared to those without (5.85Â % vs 1.73Â %; pÂ <Â 0.0001), as well as of mortality rate (2.01Â % vs 0.4Â %; pÂ =Â 0.002). Over half of patients (56.3Â %) received the first two plus one booster dose of vaccine; while a fourth dose was administered to 35.6Â %, and only few of them (1.99Â %) had five or more doses of vaccine. Of note, an impaired seroconversion was recorded in 25.6Â % of individuals after the first 2 doses of vaccine, and in 8.4Â % of patients also after the booster dose. Furthermore, the absence of T-cell immunoreactivity was observed in 3/7 patients tested by QuantiFERONÂ® SARSCoV-2 Starter Set (Qiagen). The efficacy of vaccines, evaluated by comparing the COVID-19-related death rate recorded during pre- and post-vaccination pandemic periods, revealed a quite stable outcome in SSc patients (death rate from 2.54Â % to 1.76Â %; pÂ =Â ns), despite the significant drop of mortality observed in the Italian general population (from 2.95Â % to 0.29Â %; pÂ <Â 0.0001). CONCLUSIONS: An increased COVID-19 prevalence and mortality rate was recorded in SSc patients; moreover, the efficacy of vaccines in term of improved outcomes was less evident in SSc compared to Italian general population. This discrepancy might be explained by concomitant adverse prognostic factors: increased rate of non-responders to vaccine in SSc series, low percentage of individuals with four or more doses of vaccine, ongoing immunomodulating treatments, disease-related interstitial lung disease, and/or reduced preventive measures in the

second half of pandemic. A careful monitoring of response to COVID-19 vaccines together with adequate preventive/therapeutical strategies are highly recommendable in the near course of pandemic in this frail patients' population.

Safety and immunogenicity of a heterologous booster with an RBD virus-like particle vaccine following two- or three-dose inactivated COVID-19 vaccine. LYB001 is an innovative recombinant SARS-CoV-2 vaccine that displays a repetitive array of the spike glycoprotein's receptor-binding domain (RBD) on a virus-like particle (VLP) vector to boost the immune system, produced using Covalink plug-and-display protein binding technology. LYB001's safety and immunogenicity were assessed in 119 participants receiving a booster with (1) 30â€‰Î¼g LYB001 (I-I-30â€‰L) or CoronaVac (I-I-C), (2) 60â€‰Î¼g LYB001 (I-I-60â€‰L) or CoronaVac in a ratio of 2:1 after two-dose primary series of inactivated COVID-19 vaccine, and (3) 30â€‰Î¼g LYB001 (I-I-I-30â€‰L) after three-dose inactivated COVID-19 vaccine. A well-tolerated reactogenicity profile was observed for LYB001 as a heterologous booster, with adverse reactions being predominantly mild in severity and transient. LYB001 elicited a substantial increase in terms of the neutralizing antibody response against prototype SARS-CoV-2 28â€‰days after booster, with GMT (95%CI) of 1237.8 (747.2, 2050.6), 554.3 (374.6, 820.2), 181.9 (107.6, 307.6), and 1200.2 (831.5, 1732.3) in the I-I-30â€‰L, I-I-60â€‰L, I-I-C, and I-I-I-30â€‰L groups, respectively. LYB001 also elicited a cross-neutralizing antibody response against the BA.4/5 strain, dominant during the study period, with GMT of 201.1 (102.7, 393.7), 63.0 (35.1, 113.1), 29.2 (16.9, 50.3), and 115.3 (63.9, 208.1) in the I-I-30â€‰L, I-I-60â€‰L, I-I-C, and I-I-I-30â€‰L groups, respectively, at 28â€‰days after booster. Additionally, RBD-specific IFN-Î³, IL-2, IL-4 secreting T cells dramatically increased at 14â€‰days after a single LYB001 booster. Our data confirmed the favorable safety and immunogenicity profile of LYB001 and supported the continued clinical development of this promising candidate that utilizes the VLP platform to provide protection against COVID-19.

Immunoglobulin A Vasculitis Following ChadOx1 nCoV-19/AZD1222 (AstraZeneca COVID-19 Vaccine) Vaccination.

What Are the Risks of Guillain-BarrÃ© Syndrome After SARS-CoV-2 Infection and COVID-19 Vaccination?

Association Between Guillain-BarrÃ© Syndrome and COVID-19 Infection and Vaccination: A Population-Based Nested Case-Control Study. BACKGROUND AND OBJECTIVES: Existing data regarding occurrence of Guillain-BarrÃ© syndrome (GBS) after coronavirus disease 2019 (COVID-19) infection and vaccination are inconclusive. We aimed to assess the association between GBS and both severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and COVID-19 vaccine. METHODS: We conducted a nested case-control study in a cohort of 3,193,951 patients aged 16 years or older, without a diagnosis of prior GBS, from the largest health care provider in Israel. Participants were followed from January 1, 2021, until June 30, 2022, for the occurrence of GBS. Ten randomly selected controls were matched to each case of GBS on age and sex. We assessed both SARS-CoV-2 infection and COVID-19 vaccine administration in the prior 6 weeks in cases and controls. RESULTS: Overall, 76 patients were diagnosed with GBS during follow-up and were matched to 760 controls. A positive test for SARS-CoV-2 was detected in 9 (11.8%) cases and 18 (2.4%) controls. An administration of COVID-19 vaccine was detected in 8 (10.5%) cases (all Pfizer-BioNTech [BNT162b2] vaccine) and 136 (17.9%) controls (134 Pfizer-BioNTech vaccine). Multivariable conditional logistic regression models showed that the odds ratio for GBS associated with SARS-CoV-2 infection and COVID-19 vaccine administration was 6.30 (95% CI 2.55-15.56) and 0.41 (95% CI 0.17-0.96), respectively. The results were similar when exposure to SARS-CoV-2 infection or COVID-19 vaccine administration was ascertained in the prior 4 and 8 weeks, although did not reach statistical significance for COVID-19 vaccine at 4 weeks. DISCUSSION: Our study suggests that SARS-CoV-2

infection is associated with increased risk of GBS, whereas Pfizer-BioNTech COVID-19 vaccine is associated with decreased risk of GBS.

The impact of Gam-COVID-Vac, an Adv5/Adv26 COVID-19 vaccine, on the biomarkers of endothelial function, coagulation and platelet activation. COVID-19 vaccines have played a critical role in controlling the COVID-19 pandemic. Although overall considered safe, COVID-19 vaccination has been associated with rare but severe thrombotic events, occurring mainly in the context of adenoviral vectored vaccines. A better understanding of mechanisms underlying vaccine-induced hypercoagulability and prothrombotic state is needed to improve vaccine safety profile. We assessed changes to the biomarkers of endothelial function (endothelin, ET-1), coagulation (thrombomodulin, THBD and plasminogen activator inhibitor, PAI) and platelet activation (platelet activating factor, PAF, and platelet factor 4 IgG antibody, PF4 IgG) within a three-week period after the first (prime) and second (boost) doses of Gam-Covid-Vac, an AdV5/AdV26-vectored COVID-19 vaccine. Blood plasma collected from vaccinees (n = 58) was assayed using ELISA assays. Participants were stratified by prior COVID-19 exposure based on their baseline SARS-CoV-2-specific serology results. We observed a significant post-prime increase in circulating ET-1, with levels sustained after the boost dose compared to baseline. ET-1 elevation following dose 2 was most pronounced in vaccinees without prior COVID-19 exposure. Prior COVID-19 was also associated with a mild increase in post-dose 1 PAI. Vaccination was associated with elevated ET-1 up to day 21 after the second vaccine dose, while no marked alterations to other biomarkers, including PF4 IgG, were seen. A role of persistent endothelial activation following COVID-19 vaccination warrants further investigation.

Prolonged headache with vaccine- and dose-specific headache pattern associated with vaccine against SARS-CoV-2 in patients with migraine. OBJECTIVE: To examine SARS-CoV-2 vaccine-related headache characteristics and risk factors in migraine patients. METHODS: This retrospective cohort study included 732 migraine patients who had AstraZeneca Vaxzevria, Pfizer-BioNTech Comirnaty, or Moderna Spikevax vaccines. Participants provided information through questionnaires and headache diaries. Headache frequency before and after vaccination and factors associated with headache risk were examined. RESULTS: Approximately a third of patients reported increased headache the day after having primary and booster doses, with mean increaseâ€‰Â±â€‰SD of 1.9â€‰Â±â€‰1.2 and 1.8â€‰Â±â€‰1.1 days/week, respectively. Proportions of migraine patients with headache (after vaccination vs. before vaccination) increased after having primary-dose Vaxzevria (35.3% vs. 22.8%, pâ€‰<â€‰0.001) but not Spikevax (23.8% vs. 26.7%, pâ€‰=â€‰0.700) or Comirnaty (33.2% vs. 25.8%, pâ€‰=â€‰0.058). Headache proportion increased after having all three boosters (Vaxzevria 27.1% vs. 17.9% pâ€‰=â€‰0.003; Comirnaty 34.1% vs. 24.5% pâ€‰=â€‰0.009; Spikevax 35.2% vs. 24.8% pâ€‰=â€‰0.031). For primary dose with Vaxzevria and Comirnaty, headache risk increased on the vaccination day, peaked on the day after vaccination, and subsided within a week, while for Spikevax headache risk rose gradually after vaccination, peaked on the seventh post-vaccination day and subsided subsequently. For booster dose, headache risk generally increased on the vaccination day, peaked on the day after vaccination, and subsided gradually with fluctuating pattern within a month. Our study also showed that headache increased on the day before primary dose but not booster dose vaccination and it may be attributable to stress associated with having to undertake new vaccines. Multivariable analyses showed that depression was associated with headache. CONCLUSION: Prolonged headache with vaccine- and dose-specific headache pattern was found. Patients with higher risks of vaccine-related headache must be informed of the potential worsening headache.

Acute cerebellitis following COVID-19 vaccination: A case report. A plethora of neurological symptoms have been reported as the side effects of COVID-19 vaccines. Vaccine-associated acute cerebellitis is quite rare. Here, we report a 45-year-old female with acute onset cerebellitis, beginning

10â€‰days after administration of Sinopharm vaccine. The patient's CSF COVID-19 PCR was found to be positive, with no pulmonary symptoms.

Association between COVID-19 vaccination and critical outcomes among older adults with dementia: a comparative cohort study. BACKGROUND: As COVID-19 vaccines became available, understanding their potential benefits in vulnerable populations has gained significance. This study explored the advantages of COVID-19 vaccination in individuals with cognitive disorders by analyzing health-related variables and outcomes. METHODS: A prospective cohort study analyzed electronic medical records of 25,733 older adults with cognitive disorders and 65,544 older adults without cognitive disorders from March 2020 to February 2022. COVID-19 vaccination status was the primary exposure variable, categorized as fully vaccinated or unvaccinated. The primary outcomes measured were all-cause mortality and hospitalization rates within 14 and 400â€‰days post-vaccination. Data on vaccination status, demographics, comorbidities, testing history, and clinical outcomes were collected from electronic health records. The study was ethically approved by the relevant medical facility's Institutional Review Board (0075-22-MHS). RESULTS: Vaccinated individuals had significantly lower mortality rates in both groups. In the research group, the mortality rate was 52% (nâ€‰=â€‰1852) for unvaccinated individuals and 7% (nâ€‰=â€‰1,241) for vaccinated individuals (pâ€‰<â€‰0.001). Similarly, in the control group, the mortality rate was 13.58% (nâ€‰=â€‰1,508) for unvaccinated individuals and 1.85% (nâ€‰=â€‰936) for vaccinated individuals (pâ€‰<â€‰0.001), despite higher COVID-19 positivity rates. In the research group, 30.26% (nâ€‰=â€‰1,072) of unvaccinated individuals tested positive for COVID-19, compared to 37.16% (nâ€‰=â€‰6,492) of vaccinated individuals (pâ€‰<â€‰0.001). In the control group, 17.31% (nâ€‰=â€‰1922) of unvaccinated individuals were COVID-19 positive, while 37.25% (nâ€‰=â€‰18,873) of vaccinated individuals tested positive (pâ€‰<â€‰0.001). Vaccination also showed potential benefits in mental health support. The usage of antipsychotic drugs was lower in vaccinated individuals (28.43%, nâ€‰=â€‰4,967) compared to unvaccinated individuals (37.48%, nâ€‰=â€‰1,328; 95% CI [0.92-1.28], pâ€‰<â€‰0.001). Moreover, vaccinated individuals had lower antipsychotic drug prescription rates (23.88%, nâ€‰=â€‰4,171) compared to unvaccinated individuals (27.83%, nâ€‰=â€‰968; 95% CI [-1.02 to -0.63], pâ€‰<â€‰0.001). Vaccination appeared to have a positive impact on managing conditions like diabetes, with 38.63% (nâ€‰=â€‰6,748) of vaccinated individuals having diabetes compared to 41.55% (nâ€‰=â€‰1,472) of unvaccinated individuals (95% CI [0.24, 0.48], pâ€‰<â€‰0.001). DISCUSSION: The findings highlight the importance of vaccination in safeguarding vulnerable populations during the pandemic and call for further research to optimize healthcare strategies for individuals with cognitive disorders.

Exploring hematic crasis variations in cancer patients following SARS-CoV-2 vaccination: a real-practice study. SARS-CoV-2 vaccination is strongly recommended, particularly for fragile patients such as those undergoing active oncological treatments. It is crucial to conduct post-marketing surveillance in this patient population. In our study, we conducted a retrospective analysis of real-world data, including 136 patients who received SARS-CoV-2 vaccines and were undergoing anticancer treatments between March 1st and June 30th, 2021. All patients received mRNA vaccines, namely Pfizer-BioNTech's COMIRNATY (BNT162b2 mRNA) and Moderna's mRNA-1273 COVID-19 vaccines. We collected blood samples from the patients one week to 10 days before and after vaccine administration to assess full blood count with white cell differentials. Additionally, we monitored serology titers to detect any previous SARS-CoV-2 infection before hospital admission and tracked changes over time. Our findings revealed a significant occurrence of leukopenia following both the first and second vaccine doses among patients receiving chemotherapy and chemo-immunotherapy. Importantly, this effect was independent of demographic factors such as sex, age, and Body Mass

Index. In the chemo-immunotherapy treated group, we observed that concomitant immune-mediated diseases were significantly associated with leukopenia following the second vaccine dose. Notably, in healthy subjects, transient neutropenia was recognized as an adverse event following vaccination. The observed lymphocytopenia during SARS-CoV-2 infection, combined with the impact on leukocyte counts observed in our study, underscores the need for larger post-marketing surveillance studies. Despite a treatment delay occurring in 6.6% of patients, the administration of mRNA vaccines did not have a significant impact on the treatment schedule in our series. These findings from a real-world setting provide valuable insights and suggest avenues for further prospective studies to explore potential complex interactions specific to this patient population.

Association between breakthrough infection with COVID-19 and Toxoplasma gondii: a cross-sectionalÂ study. The breakthrough infection following COVID-19 vaccination has been a subject of concern recently. Evidence suggestsÂ that COVID-19 vaccine efficacy diminishes over time due to multiple factors related to the host, and vaccine. Coinfection with other pathogens was claimed earlier as a contributing cause for this phenomenon. Hence, we aimed to stratify the association of post-COVID-19 vaccination breakthrough coinfection withÂ Toxoplasma gondiiÂ (T. gondii) and its impact on disease severity. This cross-sectional study included 330 COVID-19-vaccinated patients confirmed by RT-PCR. They were also screened for anti-Â T. gondiiÂ antibodies using ELISA. Toxoplasma seropositive cases' whole blood was screened for DNA using PCR to correlate results with COVID-19 severity. Out of 330 COVID-19 vaccinated patients with breakthrough infection, 34.5% (114 patients) showed positivity forÂ Toxoplasma IgG by ELISA, and none of the cases was IgM positive. Eleven patients (9.6%) of the IgG-positive cases were positive by PCR. Positive PCR cases correlated positively with theÂ Toxoplasma IgG titer (Pâ€‰<â€‰0.001), and the Cutoff point was 191.5. Molecular analysis ofÂ Toxoplasma and COVID-19 severity showed that 8 (72.7%), 1 (9.1%), and 2 cases (18.2%) had mild, moderate, and severe courses of the disease, respectively, with no significant correlation. Our study reported a heightened prevalence of latent toxoplasmosis among mild cases of COVID-19 breakthrough infection. Nevertheless, a discernible correlation between latent toxoplasmosis and COVID-19 severity is lacking. Hence, implementing studies on a larger scale could provide a more comprehensive comprehension of this association.

Fulminant Vaccine-Induced Immune Thrombotic Thrombocytopenia After ChAdOx1 nCoV-19 (AZD1222) Vaccine Administration in a Woman With Obesity: A Case Report. Vaccine-induced immune thrombotic thrombocytopenia (VITT), also known as thrombosis with thrombocytopenia syndrome, is a rare complication of ChAdOx1 nCoV-19 (AZD1222) vaccine administration. The overall incidence of VITT worldwide is one case per 100 000 exposures. Because of the high mortality rate from VITT, thorough monitoring is crucial to predict the risk of occurrence. The underlying risk factors for VITT are not fully understood. Potential risk factors include sex (female) and young age (less than 50 years), but further research must be conducted to confirm these assumptions. We report the case of a woman with obesity, which is a risk factor for deep vein thrombosis in the legs and for pulmonary embolism, who experienced fulminant VITT after AZD1222 vaccine administration. Keywords: Vaccine-induced immune thrombotic thrombocytopenia, AZ vaccine, Obesity, Risk factor.

Cytotoxic lesion of corpus callosum after COVID-19 vaccination: case report. PURPOSE: Cytotoxic lesions of corpus callosum (CLOCCs) are associated with many disease entities. Serious neurological complications after coronavirus disease 2019 (COVID-19) vaccination are rare. CASE REPORT: A 20-year-old man presented with severe headache for 2 days. He had received the first dose of ChAdOx1nCoV-19 COVID-19 vaccine 5 days ago. Persistent dull headache occurred on the third day after vaccination and intensified gradually to awaken him from sleep at night. No neck stiffness was observed. Brain magnetic resonance angiography (MRA) 9 days after vaccination revealed an oval-shaped diffusion-weighted restriction lesion at the splenium of corpus callosum with a mildly high

signal intensity on T2-weighted images (T2WI) and low signal intensity on apparent diffusion coefficient (ADC) imaging but without enhancement after contrast injection. A COVID-19 polymerase chain reaction test was negative. A blood test revealed slight leukocytopenia, thrombocytopenia, and hyponatremia. Further autoimmune and hematological studies were normal. A cerebrospinal fluid study revealed normal intracranial pressure. The patient's headache improved gradually. Follow-up brain MRA 5 weeks after vaccination revealed complete disappearance of the diffusion-weighted restriction lesion of the splenium. CONCLUSION: CLOCCs are rare transient adverse effect of COVID-19 vaccination possibly related to a cytokine storm. The splenic lesion might disappear spontaneously with a good prognosis.

Arthritis after vaccination against SARS-CoV-2 infection: Reactive arthritis or post-vaccination arthritis?

Letter to the Editor from Lui et al: 'Increased risk of Thyroid Eye Disease following Covid-19 Vaccination'.

Response to Letter to the Editor from Lui et al: 'Increased risk of Thyroid Eye Disease following Covid-19 Vaccination'.

High Caregiver Adverse Childhood Experiences Are Associated With Pediatric Influenza and COVID-19 Vaccination Uptake. BACKGROUND: Factors surrounding vaccine uptake are complex. Although anxiety, which could influence vaccination decisions, has been associated with adverse childhood experiences (ACEs), little is known about links between caregiver ACEs and pediatric vaccine uptake. We evaluated associations between caregivers' ACEs and decisions to vaccinate their children with influenza and coronavirus disease (COVID-19) vaccines. METHODS: A cross-sectional study of caregivers of patients â‰¥6 months at one pediatric primary care center (PPCC) was performed. Caregivers completed a 19-question survey examining caregiver ACEs, influenza vaccine acceptance and beliefs, and intention to vaccinate their child with the COVID-19 vaccine. Demographic characteristics, social risks (eg, housing and food insecurity), and vaccination data for children present with each caregiver were extracted from the electronic health record (EHR). Statistical analyses included Ï‡2 tests for categorical variables and t-tests for continuous variables. RESULTS: A total of 240 caregivers participated, representing 283 children (mean age of 5.9 years, 47% male). Twenty-four percent (nâ€…=â€…58) had high ACEs (â‰¥4). Of those with high ACEs, 55% accepted pediatric influenza vaccination compared with 38% with low ACEs (Pâ€…=â€….02). Those with high ACEs had more positive attitudes toward influenza vaccine safety and efficacy (Pâ€…â‰¤â€….02). Those with high, compared with low, ACEs were also more likely to accept COVID-19 vaccination (38% vs 24%; Pâ€…=â€….04). CONCLUSIONS: Pediatric influenza vaccination rates and intention to vaccinate children against COVID-19 differed between caregivers with high and low ACEs: those with more ACEs were more likely to vaccinate. Further studies assessing the role of caregiver ACEs on vaccine decision-making are warranted.

Monovalent Omicron COVID-19 vaccine triggers superior neutralizing antibody responses against Omicron subvariants than Delta and Omicron bivalent vaccine. The continuous evolution of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants poses a challenge to determine the optimal updated composition of the coronavirus disease 2019 (COVID-19) vaccine. The present study aimed to investigate the immunogenicity of the Delta monovalent vaccine, the Omicron monovalent vaccine, and the Delta and Omicron BA.1 bivalent vaccine. Three COVID-19 vaccines were designed using the heterologous DNA prime-protein boost strategy, with each vaccine containing either Delta receptor-binding domain (RBD) of the spike protein, Omicron RBD, or both Delta and Omicron antigens. Temporal serum antibody binding titers and neutralizing antibody titers induced by the three vaccines in New Zealand White rabbits were analyzed. To further dissect the vaccine elicited antibodies (mAb) responses at the molecular level, a panel of rabbit monoclonal

antibodies (RmAbs) was generated by a high-throughput single B cell sorting and discovery pipeline and further comprehensively characterized. The Omicron monovalent vaccine induced higher antibody binding titers and neutralization activities than the Delta and Omicron bivalent vaccine. Four RmAbs with robust neutralization capacity were isolated from rabbits immunized with the Omicron or Delta monovalent vaccine. Notably, 9E11 isolated from the Omicron monovalent vaccine group neutralized all the Omicron subvariants with an IC(50) value ranging from 1.5 to 503.6â€‰ng/mL; thus, this vaccine could serve as a prophylactic and therapeutic intervention. Given the increasing incidence of COVID-19 cases due to the Omicron variant, RBD from the Omicron strain could serve as a candidate immunogen that can induce higher neutralization activities against the SARS-CoV-2 Omicron sublineages.

Chronic shoulder injury related to vaccine administration following coronavirus disease 2019 vaccination: a case report. BACKGROUND: Shoulder injury related to vaccine administration, defined as shoulder pain and limited range of motion occurring after administration in the upper arm, has been previously reported. The symptom resolved completely after treatment with oral nonsteroidal anti-inflammatory drugs or an intraarticular steroid injection, however there have been few reports of long-term symptoms following coronavirus disease 2019 vaccination. This case report describes a healthy, middle-aged, healthcare worker who developed post-vaccination subacromial-subdeltoid bursitis that lasted for more than 6 months after Pfizer-BioNTech coronavirus disease 2019 vaccination. CASE PRESENTATION: A 55-year-old Japanese woman with no significant medical history was vaccinated in the standard site, with the needle direction perpendicular to the skin. Within a few hours after the second vaccination, severe shoulder pain and limited range of motion appeared. Although shoulder range of motion improved, her shoulder pain did not improved for several months, and she consulted an orthopedic doctor 5 months later. Radiographs of her left shoulder did not provide helpful diagnostic information. High intensity in the subacromial-subdeltoid space was seen on short TI inversion recovery of magnetic resonance imaging, showing subacromial-subdeltoid bursitis. She was diagnosed with a shoulder injury related to vaccine administration. The patient was started on an oral anti-inflammatory drug, and the left subacromial space was injected with 2.5Â mg of betamethasone with 3Â ml of 1% lidocaine without epinephrine every 2 weeks. One month after starting this treatment, since her shoulder pain had not improved, the oral anti-inflammatory drug was switched to tramadol hydrochloride acetaminophen. However, 3 months after switching medication, the shoulder pain continued, and she worked so as to have minimal impact on her shoulder. CONCLUSION: A case of subacromial-subdeltoid bursitis following a second dose of the Pfizer-BioNTech coronavirus disease 2019 vaccine that lasted many months is reported. Injection technique is a modifiable risk factor, the adverse effects of which could potentially be mitigated with appropriate and relevant training of healthcare providers. To prevent this type of case, the appropriate landmark, needle length, and direction should be confirmed.

Comparative Analysis of IgG Antibody Titers Induced by Three Different SARS-COV-2 Vaccines in Healthy Adults of Pakistan. Covid-19 is a contagious disease caused by severe acute respiratory syndrome corona virus 2 (SARS-CoV-2). In order to control this disease, different effective vaccines have been developed. This study is an attempt to determine the strength and duration of immunogenicity of various established vaccines. This cross-sectional, observational study was conducted to compare the efficacy of three different vaccines; Pfizer BNT 162b2, Sinovac, and CanSino, respectively, after a duration of 3Â months, in the healthy adult population of Pakistan. In this study 371 healthy participants (aged 12-25Â years) of both genders (male and females) were enrolled. The blood sample was drawn 90Â days after the complete vaccination process. The humoral response (IgG) was analyzed by electrochemiluminescence immunoassay (ECLIA) method with Roche Anti-SARS-CoV-2 S analyzer kit. Descriptive statistical analysis was performed using IBM SPSS statistics

version 22 and Pâ€‰<â€‰0.05 was considered significant. The mean antibody titer in Pfizer-group was 12,536.35Â U/mL, followed by 5168.68Â U/mL in the Sinovac group and 4284.32Â U/mL in the CanSino group. The Pfizer-group showed gender-specific significant differences, with higher antibody levels in males (Pâ€‰=â€‰0.006) as compared to Sinovac and Cansino groups. The Mean IgG antibody levels of the Pfizer-vaccinated group were significantly higher than the Sinovac-vaccinated group and the CanSino-vaccinated group (Pâ€‰=â€‰0.000, each). However, the mean difference between the Sinovac-vaccinated group and the CanSino-vaccinated group was not significant. Vaccine-induced seropositivity was found in the whole cohort. The mRNA-based vaccine produced the highest immune response, and thus, it is recommended for future application.

Autoimmune hepatitis collapsed after the COVID-19 vaccination.

Case Report: Branch Retinal Vein Occlusion Post-mRNA SARS-CoV-2 (COVID-19) Vaccination. SIGNIFICANCE: Systemic thromboembolic complications are well documented to be associated with coronavirus disease 2019 (COVID-19); however, there have been a growing number of reports regarding ocular complications stemming from COVID-19 vaccinations. This case illustrates a clear temporal and possible causal relationship of COVID-19 vaccination with an ocular microvascular disorder, namely, retinal vein occlusion. PURPOSE: This study aimed to report a case of inferotemporal branch retinal vein occlusion after messenger RNA Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. CASE REPORT: A middle-aged woman developed right eye central scotoma 2 days after COVID-19 vaccination. She had transient hypertension during the first 2 days post-vaccination. A decrease in visual acuity (6/18) was documented. Initial retinal findings included flame-shaped hemorrhages and cotton-wool spots along inferotemporal branch retinal vessels. Optical coherence tomography revealed right eye cystoid macular edema. Laboratory investigation revealed mildly raised erythrocyte sedimentation rate and C-reactive protein. Other systemic examinations were unremarkable. She was treated for right eye inferotemporal branch retinal vein occlusion with cystoid macular edema and was given intravitreal anti-vascular endothelial growth factor monthly in three doses. Her visual acuity improved to 6/6 with resolved cystoid macular edema. CONCLUSIONS: This case illustrates a clear temporal and possible causal relationship between COVID-19 vaccination and retinal vein occlusion. Post-vaccination transient hypertension or the immunological and inflammatory response to the vaccine may have contributed to the venous occlusive event in this case. Eye care providers should remain aware of this possibility. The effectiveness of intravitreal anti-vascular endothelial growth factor for the treatment of macular edema secondary to branch retinal vein occlusion was demonstrated in this patient.

No observable influence of COVID-19 inactivated vaccines on pregnancy and birth outcomes in the first trimester of gestation. BACKGROUND: While studies have demonstrated that certain COVID-19 vaccines administered during pregnancy did not affect neonatal or maternal outcomes significantly, the safety of inactivated SARS-CoV-2 vaccines in China, given during the first trimester, remains to be fully elucidated. METHOD: A retrospective cohort study was conducted involving female participants who gave birth from January to October 2021. The study compared pregnancy, delivery, and neonatal outcomes between subjects who received one or two doses of the inactivated COVID-19 vaccines during their first trimester and unvaccinated control subjects. RESULTS: A total of 2658 pregnant women was recruited. Among them, 2358 (88.7%) reported ongoing pregnancies; 326 (13.8%) of these were vaccinated. Additionally, 277 (10.4%) experienced spontaneous miscarriages between 6 to 20 gestational weeks; 40 (14.4%) of these were vaccinated, yielding an odds ratio of 0.67-1.36 (95% confidence interval) for COVID-19 vaccination. The comparison of neonatal complications, including an Apgar score less than 7, preterm birth, low birth weight, and newborn respiratory complications, between unvaccinated and vaccinated participants revealed no statistical significance. CONCLUSION: The administration of COVID-19 inactivated vaccines during the first

trimester of pregnancy is not associated with adverse pregnancy or neonatal outcomes, providing a substantial ground for pertinent health education.

Determinants of compliance to influenza and COVID-19 vaccination in a cohort of solid organ transplant patients in Puglia, Southern Italy (2017-2022). Influenza and Coronavirus Disease 2019 (COVID-19) vaccination are recommended in both solid organ transplant (SOT) candidates and recipients. In Puglia, Southern Italy, an active vaccination offer program has been activated targeting these patients. This study aims at investigating vaccination coverage (VC) for both vaccines in a SOT patients' cohort, as well as at identifying the vaccination compliance determinant. This is a retrospective, population-based study. The study population consists of the SOT patients who accessed Bari's "Policlinico" General Hospital during 2017-2022. Patients were contacted and, after providing their consent, asked their immunization status regarding influenza and COVID-19 and whether they had already undergone transplant or were waiting to do so. Regression models were fitted to investigate the determinants of VCs for influenza vaccination (2021/22 and 2022/23 seasons) and for COVID-19 vaccination (three-dose base cycle, first and second booster doses). Three-hundred and ten SOT patients were identified; 85.2% (264/310) had already undergone SOT. VCs were suboptimal, especially for constant yearly influenza vaccination (17.7%) and COVID-19 vaccination's second booster (1.94%). Logistic regression highlighted that influenza VCs are higher for SOT recipients than SOT candidates, as well as for older patients, although when considering both vaccination seasons only age significantly impact the vaccination uptake. Older age was the only influential variable for COVID-19 VC. VCs for SOT patients seem to be unsatisfying. Stronger interventions are required.

Cardiovascular Events After Coronavirus Disease 2019 Vaccinations Versus Long Coronavirus Disease.

Neutralising antibody responses against SARS-CoV-2 Omicron BA.4/5 and wild-type virus in patients with inflammatory bowel disease following three doses of COVID-19 vaccine (VIP): a prospective, multicentre, cohort study. BACKGROUND: Patients with inflammatory bowel disease (IBD) receiving anti-TNF and JAK-inhibitor therapy have attenuated responses to COVID-19 vaccination. We aimed to determine how IBD treatments affect neutralising antibody responses against the Omicron BA.4/5 variant. METHODS: In this multicentre cohort study, we prospectively recruited 340 adults (69 healthy controls and 271 IBD) at nine UK hospitals between May 28, 2021 and March 29, 2022. The IBD study population was established (>12 weeks therapy) on either thiopurine (nÂ =Â 63), infliximab (nÂ =Â 45), thiopurine and infliximab combination therapy (nÂ =Â 48), ustekinumab (nÂ =Â 45), vedolizumab (nÂ =Â 46) or tofacitinib (nÂ =Â 24). Patients were excluded if they were being treated with any other immunosuppressive therapies. Participants had two doses of either ChAdOx1 nCoV-19 or BNT162b2 vaccines, followed by a third dose of either BNT162b2 or mRNA1273. Pseudo-neutralisation assays against SARS-CoV-2 wild-type and BA.4/5 were performed. The half maximal inhibitory concentration (NT50) of participant sera was calculated. The primary outcome was anti-SARS-CoV-2 neutralising response against wild-type virus and Omicron BA.4/5 variant after the second and third doses of anti-SARS-CoV-2 vaccine, stratified by immunosuppressive therapy, adjusting for prior infection, vaccine type, age, and interval between vaccination and blood collection. This study is registered with ISRCTN (No. 13495664). FINDINGS: Both heterologous (first two doses adenovirus vaccine, third dose mRNA vaccine) and homologous (three doses mRNA vaccine) vaccination strategies significantly increased neutralising titres against both wild-type SARS-CoV-2 virus and the Omicron BA.4/5 variant in healthy participants and patients with IBD. Antibody titres against BA.4/5 were significantly lower than antibodies against wild-type virus in both healthy participants and patients with IBD (pÂ <Â 0.0001). Multivariable models demonstrated that neutralising antibodies against BA.4/5 after three doses of vaccine were significantly lower in patients with IBD on infliximab (Geometric Mean Ratio (GMR) 0.19 [0.10, 0.36], pÂ <Â 0.0001), infliximab and

thiopurine combination (GMR 0.25 [0.13, 0.49], pÂ <Â 0.0001) or tofacitinib (GMR 0.43 [0.20, 0.91], pÂ =Â 0.028), but not in patients on thiopurine monotherapy, ustekinumab, or vedolizumab. Breakthrough infection was associated with lower neutralising antibodies against wild-type (pÂ =Â 0.037) and BA.4/5 (pÂ =Â 0.045). INTERPRETATION: A third dose of a COVID-19 mRNA vaccine based on the wild-type spike glycoprotein significantly boosts neutralising antibody titres in patients with IBD. However, responses are lower against the Omicron variant BA.4/5, particularly in patients taking anti-TNF and JAK-inhibitor therapy. Breakthrough infections are associated with lower neutralising antibodies and immunosuppressed patients with IBD may receive additional benefit from bivalent vaccine boosters which target Omicron variants. FUNDING: Pfizer.

Administration of an excessive dosage of covid-19 pfizer vaccine in an infant: Case report of clinical and immune responses. INTRODUCTION/CASE REPORT: We describe the case of a 6-month-old female infant who received the equivalent of 6 adult doses of the COVID-19 Pfizer vaccine due to an immunization error. The patient underwent clinical and laboratory evaluations from the time of vaccination error (January 2022) until November 2022. In the first three days after immunization, she presented with low-grade fever (38Â Â°C) and mild pain and induration at the injection site. She showed no other symptoms afterwards. Laboratory tests were within normal limits for age, except for an elevated D-dimer (3.71 ug/mL; normal: up to 0.5 ug/mL) and as the echocardiogram and electrocardiogram were within normal limits as well, no interventions were instituted at that moment. On the tenth day, immune response evaluation showed a strong expression of cytokines related to the Th2 profile and a well-controlled inflammatory state. Forty-three days after the vaccine administration inflammation status remained, with a predominance of cellular immune response, IFN-Î³ expression increased compared to the previous evaluation, and a robust antiviral state was in place. After 90Â days, immune response evaluation showed a significant reduction in the inflammatory state, still with a predominance of the cellular immune response. Clinically, the patient remained well, with no other noteworthy intercurrences, until the last appointment in November 2022. This child has had no evidence of a severe adverse effect associated to the vaccine overdose. CONCLUSION: The close follow-up of this case of vaccination error demonstrated that the COVID-19 Pfizer was safe and immunogenic in this individual, noting careful monitoring and followup of these vaccine administration errors is crucial.

Risk of Coronavirus Disease 2019 Messenger RNA Vaccination-Associated Myocarditis and Pericarditis - A Systematic Review of Population-Based Data. PURPOSE: Early studies showed that the risks of mRNA vaccine-associated myocarditis and pericarditis are low but with substantial variation across studies. Study characteristics, ethnicity, vaccine types, dose intervals, and SARS-CoV-2 infection prevalence may influence the rates of myocarditis and pericarditis after mRNA vaccination in population-based studies. METHODS: We comprehensively searched MEDLINE for relevant articles published before November 30, 2022. We also searched the websites of health authorities in several countries for unpublished surveillance data on myocarditis and pericarditis after mRNA vaccination. The outcome of interest was the incidence of myocarditis and pericarditis developed after mRNA vaccination for COVID-19. RESULTS: A total of 17 studies form 10 countries were included for review. We noted that considerable heterogeneity in study characteristics, including surveillance method, case definition, and observation period, may partially be responsible for the widely varied reported rates. Studies from countries that adopted active surveillance reported higher rates than those using passive surveillance. Compared to BNT162b2 vaccine, mRNA-1273 may have a higher risk of myocarditis only in young men after the second dose. Our comparison of sex-, age-, vaccine type-, and dose-specific rates of myocarditis across countries did not support the hypothesis that individuals with recent SARS-CoV-2 infection and young Asian males were at higher risk. We also could not find sufficient evidence to conclude whether extending the between-dose interval could reduce

myocarditis incidence following mRNA vaccination. CONCLUSION: Differences in the study characteristics must be fully considered when comparing the risks of mRNA vaccine-related myocarditis and pericarditis in different countries.

New-onset Immune-mediated Necrotizing Myopathy and Trigeminal Neuropathy after SARS-CoV-2 mRNA Vaccination in a Patient with Rheumatoid Arthritis and SjÃ¶gren's Syndrome. We present the case of a 42-year-old woman with rheumatoid arthritis and SjÃ¶gren's syndrome treated with adalimumab who developed immune-mediated necrotizing myopathy (IMNM) and trigeminal neuropathy after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccination. Trigeminal neuralgia and elevated serum creatine kinase levels emerged 12 days post-vaccination, followed by myalgia in the femoral muscles. IMNM was histologically diagnosed. The pathogenesis may involve molecular mimicry between the SARS-CoV-2 spike glycoprotein and autologous tissues triggered by vaccination. This case emphasizes the association between SARS-CoV-2 vaccination, tumor necrosis factor inhibitor, IMNM, and trigeminal neuropathy, as well as the importance of monitoring immune-mediated adverse events following SARS-CoV-2 vaccination in patients with autoimmune disease.

Safety of COVID-19 mRNA vaccination and effects of SARS-CoV-2 infection in children and adults with mast cell disorders. Mastocytosis is characterized by abnormal clonal mast cell proliferation. Given the paucity of data in patients with mastocytosis, it is crucial to assess the safety of COVID-19 vaccines in this population. We aimed to assess the risk of allergic reactions and the effect of COVID-19 infection among patients with mastocytosis. Participants were recruited from Canada and Israel between December 2021 and May 2022. Consenting participants were administered standardized questionnaires querying whether they were infected with COVID-19, if they received the first and second dose vaccines, and post-vaccination side effects including allergic reactions (urticaria/angioedema, current rash flaring, need for updosing medications, or respiratory symptoms) and common side effects including injection site reaction (ISR) and flu-like symptoms. Forty participants with mastocytosis were administered a standardized questionnaire (median ageâ€‰=â€‰9, 59% male). Amongst all participants, 16 (39%) reported COVID-19 infection and most (75%) reported flu-like symptoms, 3 (19%) were asymptomatic, 1 suffered from shortness of breath/chest pain and 1 from facial flushing. Of the 25 participants who were eligible for vaccination (â‰¥â€‰5Â years old), 80% received a first-dose vaccine and 68% received a second-dose vaccine. Of those who received the first-dose vaccine, most (60%) remained asymptomatic, 20% developed flu-like symptoms, 20% had an ISR, and 1 patient had an allergic reaction (urticaria and swelling). Of those who received the second-dose vaccine, most (53%) were asymptomatic, and 1 had an allergic reaction. No significant difference was found between side effects of both vaccine doses. No reactions fulfilled the criteria for anaphylaxis in either dose. This study reveals that among patients with mastocytosis, COVID-19 vaccine and infection were well-tolerated in the majority of cases.

Vaccine-Induced Immune Thrombocytopenia and Thrombosis (VITT)-Insights from Clinical Cases, In Vitro Studies and Murine Models. An effective worldwide vaccination campaign started and is still being carried out in the face of the coronavirus disease 2019 (COVID-19) pandemic. While vaccines are great tools to confront the pandemic, predominantly adenoviral vector-based vaccines can cause a rare severe adverse effect, termed vaccine-induced immune thrombocytopenia and thrombosis (VITT), in about 1 in 100,000 vaccinated individuals. VITT is diagnosed 5-30 days post-vaccination and clinically characterized by thrombocytopenia, strongly elevated D-dimer levels, platelet-activating anti-platelet factor 4 (PF4) antibodies and thrombosis, especially at atypical sites such as the cerebral venous sinus and/or splanchnic veins. There are striking similarities between heparin-induced thrombocytopenia (HIT) and VITT. Both are caused by anti-PF4 antibodies, causing platelet and leukocyte activation which results in massive thrombo-inflammation. However, it is still

to be determined why PF4 becomes immunogenic in VITT and which constituent of the vaccine triggers the immune response. As VITT-like syndromes are increasingly reported in patients shortly after viral infections, direct virus-PF4 interactions might be most relevant. Here we summarize the current information and hypotheses on the pathogenesis of VITT and address in vivo models, especially murine models for further studies on VITT.

Batch-dependent safety of the BNT162b2 mRNA COVID-19 vaccine.

Neutralization against Omicron sublineages (BA.2/BA.5/BQ.1.1/XBB/XBB.1.5) in bivalent BNT162b2-vaccinated HCWs with or without risk factors, or following BT infection with Omicron. SARS-CoV-2-BA.4/5-adapted-bivalent-BNT162b2-vaccine ((bv)BNT), developed in response to the recent emergence of immune-evasive Omicron-variants, has been given to individuals who completed at least 2-doses of the monovalent-BNT162b2-vaccine ((mv)BNT). In the present cohort study, we evaluated neutralization-titers (NT(50)s) against Wuhan-strain (SCoV2(Wuhan)) and Omicron-sublineages including BA.2/BA.5/BQ.1.1/XBB/XBB.1.5, and vaccine-elicited S1-binding-IgG in sera from participants-vaccinated with 5th-(bv)BNT following 4th-(mv)BNT. The 5th-(bv)BNT-dose elicited good protective-activity against SCoV2(Wuhan) with geometric-mean (gMean)-NT(50) of 1966-2091, higher than the peak-values post-4th-(mv)BNT with no statistical significance, and favorable neutralization-activity against not only BA.5 but also BA.2, with ~â€‰3.2-/~â€‰2.2-fold greater gMean-NT(50) compared to the peak-values post-4th-(mv)BNT-dose, in participants with or without risk factors. However, neutralization-activity of sera post-5th-(bv)BNT-dose was low against BQ.1.1/XBB/XBB.1.5. Interestingly, participants receiving (bv)BNT following breakthrough (BT) infection during Omicron-wave had significantly enhanced neutralization-activity against SCoV2(Wuhan)/BA.2/BA.5 with ~â€‰4.6-/~â€‰6.3-/~â€‰8.1-fold greater gMean-NT(50), respectively, compared to uninfected participants receiving (bv)BNT. Sera from BT-infected-participants receiving (bv)BNT had enhanced neutralization-activity against BQ.1.1/XBB/XBB.1.5 by ~â€‰3.8-fold compared to those from the same participants post-4th-(mv)BNT-dose, and had enhanced gMean-NT(50) ~â€‰5.4-fold greater compared to those of uninfected-participants' sera post-(bv)BNT. These results suggest that repeated stimulation brought about by exposure to BA.5's-Spike elicit favorable cross-neutralization-activity against various SARS-CoV-2-variants.

Phase II, Safety and Immunogenicity of RAZI Cov Pars (RCP) SARS Cov-2 Vaccine in Adults Aged 18-70 Years; A Randomized, Double-Blind Clinical Trial. BACKGROUND: This study explores the safety and immunogenicity of the Razi-Cov-Pars (RCP) SARS Cov-2 recombinant spike protein vaccine. METHOD: In a randomized, double-blind, placebo-controlled trial, adults aged 18-70 were randomly allocated to receive selected 10Â Âµg/200Â Âµl vaccine strengths or placebo (adjuvant). It included two intramuscular injections at days 0 and 21, followed by an intranasal dose at day 51. Immediate and delayed solicited local and systemic adverse reactions after each dose up to a week, and specific IgG antibodies against SARS Cov-2 spike antigens two weeks after the 2nd dose were assessed as primary outcomes. Secondary safety outcomes were abnormal laboratory findings and medically attended adverse events (MAAE) over six months follow up. Secondary immunogenicity outcomes were neutralizing antibody activity and cell-mediated immune response. RESULT: Between May 27th and July 15th, 2021, 500 participants were enrolled. Participants' mean (SD) age was 37.8 (9.0), and 67.0 % were male. No immediate adverse reaction was observed following the intervention. All solicited local and systemic adverse events were moderate (Grade I-II). Specific IgG antibody response against S antigen in the vaccine group was 5.28 times (95Â %CI: 4.02-6.94) the placebo group with a 75Â % seroconversion rate. During six months of follow-up, 8 SAEs were reported, unrelated to the study intervention. The participants sustained their acquired humoral responses at the end of the sixth month. The vaccine predominantly resulted in T-helper 1 cell-mediated immunity, CD8(+) cytotoxic T-cell increase, and no increase in inflammatory IL-6 cytokine. CONCLUSION: RCP vaccine is

safe and creates strong and durable humoral and cellular immunity. TRIAL REGISTRATION: (IRCT20201214049709N2).

Clinical manifestations and outcomes of coronavirus disease 2019 among pediatric liver transplant recipients in the delta and omicron variant pandemic: A retrospective study. To determine the clinical manifestations and outcomes of the coronavirus disease 2019 (COVID-19) in children who underwent liver transplantation (LT). A retrospective study was conducted at a transplant center in Thailand to include LT recipients aged < 18 years who had been infected with COVID-19. Out of a total of 54 children, there were 31 probable cases (57.4%) diagnosed using an antigen test kit and 23 confirmed cases (42.6%) diagnosed using polymerase chain reaction (14 children) or severe acute respiratory syndrome coronavirus 2 antigen (9 children). Approximately half of the children (25, 46.3%) received the BNT162b2 vaccine before the infection, with 3 and 2 doses in 5 and 18 children, respectively. While some had COVID-19 during the delta pandemic, most (46 children, 85.2%) were infected during the omicron pandemic, of which manifestations included fever (67.4%), cough (50%), and rhinorrhea (47.8%), and symptoms lasted approximately 3 days. None had severe diseases. All patients with mild-to-moderate disease were advised to continue the same immunosuppressive therapy as before the infection. Compared to unvaccinated children or children with one dose of the vaccine, fever was less common in those who received â‰¥ 2 doses (OR: 0.08; 95%CI: 0.01-0.57, adjusted for age and immunosuppressive types). Favipiravir was prescribed in most patients (90.7%). Only a few children had long COVID-19 or abnormal liver function tests lasting > 1 month (4 children, 7.4%, both). Pediatric LT recipients with COVID-19 during the delta and omicron variant pandemic reported mild symptoms despite undergoing immunosuppressive therapy.

A modelled analysis of the impact of COVID-19-related disruptions to HPV vaccination. COVID-19 disrupted school attendance in many countries, delaying routine adolescent vaccination against human papillomavirus (HPV) in some settings. We used Policy1-Cervix, a dynamic model simulating HPV transmission, natural history, vaccination, cervical screening, and diagnosis of HPV-related cancers, to estimate the impact on HPV-related cancers from disruptions to HPV vaccination in a high-income setting. A baseline scenario of no disruption to HPV vaccination was modelled, which assumed uptake of the nonavalent vaccine at the age of 12 by 82.4% of females and 75.5% of males, as is the coverage in Australia. Additional lifetime HPV-related cancer cases were calculated for three disruption scenarios affecting one birth cohort (2008; aged 12 in 2020) compared to the baseline scenario: (1) 1-year delay (no doses missed); (2) 1- to 7-year delay (slow catch-up); (3) no catch-up (herd effects only). A fourth scenario assumed no catch-up HPV vaccination for two birth cohorts, that is all individuals born in 2008 and in 2009 missed vaccination (worst-case scenario). Compared to 1532 HPV-related cancer cases estimated for the baseline no disruption scenario, we found a 1-year delay could result in â‰¤0.3% more HPV-related cancers (n = 4) but the increase would be greater if catch-up was slower (5%; n = 70), and especially if there was no catch-up (49%; n = 750). Additional cancers for a single missed cohort were most commonly cervical (23% of the additional cases) and anal cancers (16%) in females and oropharyngeal cancers in males (20%). In the worst-case scenario of two birth cohorts missing vaccination, â‰¤62% more HPV-related cancers would be diagnosed (n = 1892). In conclusion, providing catch-up of missed HPV vaccines is conducted, short-term delays in vaccinating adolescents are unlikely to have substantial long-term effects on cancer.

Unraveling the debate: Can the skin manifestations of SARS-CoV-2 infection and vaccination be explained by the reactivation of herpes virus? Since the COVID-19 outbreak, there have been numerous reports concerning COVID-19 skin manifestations. Debate has ensued as to whether these lesions are unique or represent a form of viral reactivation. The aim of this research was to compare the incidence of herpetic skin lesions between a COVID-19 group, a Sars-CoV-2 mRNA vaccination group, and their respective controls, taking into account their Herpesviridae carrier status. To achieve

this goal, the Maccabi Healthcare Services' database was scanned and cohorts of both verified COVID-19 and mRNA vaccinated patients were extracted and matched to random control groups. Patients with a documented occurrence of any Herpesviridae infection that occurred prior to the studied 'event' (i.e., COVID-19 or mRNA vaccination) were regarded as carriers of Herpesviridae. A COVID-19-related or vaccination-related lesion was defined as a clinically diagnosed herpetic lesion appearing 1â€‰month after the index date. In the COVID-19 cohort, there was an insignificant difference in herpetic lesion incidence between the groups. However, logistic regression demonstrated that the interaction of COVID-19 with the Herpesviridae carrier status was statistically significant. For the vaccination cohort, the data showed statistically significant differences between groups in herpetic frequencies, which manifested as an almost 2-fold odds of developing a herpetic lesion. In conclusion, following the analysis of two large cohorts, there is evidence to support the contribution of both COVID-19 and the mRNA vaccine to the reactivation of Herpesviridae. Our results diminish the idea that COVID-19 has unique, herpetic-like lesions.

Dynamics of immunity over time: decline of anti-SARS-CoV-2 IgG antibodies and T-cell responses after mRNA vaccination in residents and health care workers in nursing homes and homes with assisted living support. BACKGROUND: In the present study, we investigated the dynamics of immunity over time by measuring anti SARS-CoV-2 IgG antibodies and SARS-CoV-2 specific T-cell responses (interferon-gamma release assay) after two doses of vaccines in residents and health care workers (HCW). Mostly, 224 (98%) residents and 244 (89%) HCW received two doses of mRNA vaccine (BNT162b2, Pfizer-BioNTech); the rest of the participants received heterologous vaccinations with mRNA and vector vaccines. The study was conducted at the time when the Delta variant of SARS-CoV-2 prevailed. METHODS: We analyzed blood samples of 228 residents (median age 83.8 years) and of 273 HCW (median age 49.7 years) from five nursing homes and one home for the elderly with assisted living support at one specific time point. Participants received two vaccinations. The blood samples were analyzed for SARS-CoV-2 specific IgG antibody and T-cell responses. RESULTS: The initial immune responses in the younger participants were about 30% higher than in the older age group. Over time the estimated mean of the parameters (estimated from the study sample for the total population) decreased in all groups within the maximum observation period of 232 days. Comorbidities such as coronary heart disease or diabetes mellitus reduced the initial immune responses regardless of age. With regard to measured IgG antibody levels, absolute values decreased over time, whereas the interferon-gamma response remained at a constant level between day 120 and 180 and seemed to be less dependent on the time elapsed after vaccination. CONCLUSIONS: Based on our data, it does not seem possible to determine a reliable threshold of robust immunity, but we suggest that high titres of neutralizing capacity and interferon-gamma response might be an indicator of protection against severe COVID-19 courses.

Brachial Neuritis After a COVID-19 Booster Vaccination: A Case Report and Literature Review. Idiopathic brachial neuritis also known as Parsonage-Turner syndrome is a rare neurological disorder characterised by pain and paraesthesia involving the shoulder girdle and upper limb, followed by weakness of the affected area. The cause is not very well understood and is often misdiagnosed leading to delayed treatment and long-term disability. There are many risk factors for the condition, with immunisations being accountable for as many as 15% of cases. In response to the coronavirus disease 2019 (COVID-19) pandemic, many companies have been producing and distributing COVID-19 vaccinations. To our knowledge, there have been 42 cases of brachial neuritis reported following COVID-19 vaccination to date. Here, we report a case of brachial neuritis following a patient's fourth COVID-19 vaccination and present a review of the literature.

Menstrual irregularities associated with COVID-19 vaccines among women in Saudi Arabia: A survey during 2022. Some changes appeared in women's menstrual cycle after receiving the coronavirus

disease 2019 (COVID-19) vaccine, but the information about the pattern and characteristics of these symptoms was unclear. This study was conducted to estimate the prevalence of menstruation change and evaluate the association between COVID-19 vaccination and the occurrence of such disturbance. An online web-based survey was conducted during March-April 2022 that targeted 729 COVID-19 vaccinated women aged between 18 and 45 years in the Jazan region of Kingdom of Saudi Arabia. The tool collected demographic information, psychological data, and COVID-19 post-vaccination side effects. The overall prevalence of menstrual change among the women was 60.9% (95% CI 57.3-64.4). 66.3% and 64.1% of women, respectively, in the age group of 25-34 and 35-45 years were more affected. Most of the detected abnormalities were related to delayed menstruation and changes in pain intensity. Menstrual disturbances that occur after immunization are transient and have no long-term implications. Menstrual disorders are prevalent before vaccination, but there is a considerable increase following vaccination. Because there is no apparent cause for these post-vaccine disturbances, and their effects are difficult to anticipate, it is preferable to warn those concerned and encourage them to learn more about the biological changes causing these problems.

Evaluation of Covid-19 anti-spike IgG antibody five months after the second Covid-19 vaccination. BACKGROUND: Studies in different communities have shown significant differences in IgG antibody titers in the time period after the first and second doses of the vaccines. This study aimed to serologically evaluate the IgG anti-spike antibody titer five months after injection of the second COVID-19 vaccine in healthcare workers. MATERIALS AND METHOD: This study was performed in healthcare personnel for whom five months had passed since their second anti-Covid-19 vaccination. The level of IgG antibody against SARS-CoV-2 spike protein was measured by ELISA. Healthcare workers in Mofid Children's hospital received three brands of vaccines: Sputnik V, Sinopharm, and AstraZeneca. RESULTS: The mean titer of anti-spike IgG was 4.3Â±2.29 units. The percentage of positive cases of the antibody was estimated to be 96.4%. The titer of anti-spike IgG antibody was dependent on both the occupational area and a positive history of Covid-19 disease. CONCLUSION: About 96.4% of the staff vaccinated against Covid-19 had a high titer of anti-spike IgG antibody even five months after inoculation of the second dose. The field of occupational can affect the level of antibody present.

SARS-CoV-2 S-RBD IgG & Neutralizing antibodies among different categories of health care workers post third dose BNT162b2 mRNA COVID-19 vaccine. Neutralizing antibodies (NTAb) play a significant role in preventing and protecting against SARS-CoV-2 virus infection. Identifying NTAb is undoubtedly imperative in understanding the immunity toward COVID-19 better. However, it is interesting to note that the production of NTAb varies among individuals, especially among healthcare workers (HCWs), as they are exposed to the virus daily. Hence, we would like to investigate factors affecting the production of S-RBD IgG and NTAb among different categories of HCWs, particularly after receiving the third dose of the BNT162b2 mRNA COVID-19 Vaccine. A total of 361 HCWs from our hospital were prospectively enrolled and had their S-RBD IgG and NTAb titers measured. They were studied in relation to the degree of exposure to COVID-19, breakthrough infections, gender, age, race, household income, housing type, household number, and education levels. HCWs with the highest risk of exposure to COVID-19, breakthrough infections, and male gender displayed the highest median titers of both S-RBD IgG and NTAb, and the differences were statistically significant (pâ€‰<â€‰.05). Age, race, household income, housing type, household number, and education levels were revealed to be insignificant. We concluded that the degree of exposure to COVID-19, breakthrough infections, and male gender are significant factors in NTAb production among HCWs.

Cardiac side effects of RNA-based SARS-CoV-2 vaccines: Hidden cardiotoxic effects of mRNA-1273 and BNT162b2 on ventricular myocyte function and structure. BACKGROUND AND PURPOSE: To

protect against SARS-CoV-2 infection, the first mRNA-based vaccines, Spikevax (mRNA-1273, Moderna) and Comirnaty (BNT162b2, Pfizer/Biontech), were approved in 2020. The structure and assembly of the immunogen-in both cases, the SARS-CoV-2 spike (S) glycoprotein-are determined by a messenger RNA sequence that is translated by endogenous ribosomes. Cardiac side-effects, which for the most part can be classified by their clinical symptoms as myo- and/or pericarditis, can be caused by both mRNA-1273 and BNT162b2. EXPERIMENTAL APPROACH: As persuasive theories for the underlying pathomechanisms have yet to be developed, this study investigated the effect of mRNA-1273 and BNT162b2 on the function, structure, and viability of isolated adult rat cardiomyocytes over a 72â€‰h period. KEY RESULTS: In the first 24â€‰h after application, both mRNA-1273 and BNT162b2 caused neither functional disturbances nor morphological abnormalities. After 48â€‰h, expression of the encoded spike protein was detected in ventricular cardiomyocytes for both mRNAs. At this point in time, mRNA-1273 induced arrhythmic as well as completely irregular contractions associated with irregular as well as localized calcium transients, which provide indications of significant dysfunction of the cardiac ryanodine receptor (RyR2). In contrast, BNT162b2 increased cardiomyocyte contraction via significantly increased protein kinase A (PKA) activity at the cellular level. CONCLUSION AND IMPLICATIONS: Here, we demonstrated for the first time, that in isolated cardiomyocytes, both mRNA-1273 and BNT162b2 induce specific dysfunctions that correlate pathophysiologically to cardiomyopathy. Both RyR2 impairment and sustained PKA activation may significantly increase the risk of acute cardiac events.

Safety profile of inactivated COVID-19 in healthy adults aged â‰¥ 18 years: A passive surveillance in Indonesia. Coronavirus Disease 2019 (COVID-19) vaccination in Indonesia has shown effectiveness in reducing the morbidity and mortality of Covid-19. The study aims to evaluate the incidence rate and severity of Adverse Events Following Immunization (AEFI) of inactivated SARS-CoV-2 vaccine during the first quarter of 2021 until the second quarter of 2022 in Indonesia. More than two hundred million Sinovac/CoronaVac were given from January 13th, 2021, until June 30th, 2022. Data for this study were collected manually and electronically from the national vaccine safety website managed by the National Committee (NC) of AEFI Indonesia and the Ministry of Health Indonesia. The total number of injections observed in the study was 264,311,992 doses consisting of 142,449,795 (first dose), 121,613,324 (second dose), and 248,873 (booster dose). Of the injections given, 301 subjects with Serious AEFIs (SAE) and 10.261 subjects with non-serious AEFIs (AE) reported, with a majority of SAE and AEs found in the first dose. Most of the SAEs were classified as coincidental events by the NC AEFI (IR 0.8/1 million doses on first dose injection; 0.31 on second dose injection). ISRR (immunization stress-related response) is in the second rank of SAEs reported (0.59 IR/1 million doses on the first dose; 0.14 on the second dose). The incidence rate of SAEs and AEs, both in the variable of age, sex, and symptoms per 1 million dose injections in Indonesia, was very rare according to WHO guidelines. Most SAEs were classified as coincidences or unrelated to the vaccine. The result showed that the Sinovac/CoronaVac in Indonesia is safe.

Reply: Increased risk of fetal loss after COVID-19 vaccination.

Increased risk of fetal loss after COVID-19 vaccination.

Association Between Pandemic Fatigue and Disease Knowledge, Attitudes, Concerns, and Vaccination Intention at Two Key Moments of the COVID-19 Pandemic. Objective: This study aimed to describe the change in knowledge, attitudes, concerns, perceptions, preventive practices, and vaccination intention at two key time points of the COVID-19 pandemic and to assess whether these changes varied by level of pandemic fatigue. Methods: Data included in this study came from the third and the ninth round of the COSMO-Spain cross-sectional study. A general linear model was used to investigate the interaction terms between rounds and levels of pandemic fatigue. Results: Changes between rounds were observed in knowledge, attitudes, concerns, perceptions, behaviours, and

vaccination intention. Significant interactions between rounds indicated that those with low levels of pandemic fatigue had a greater increase in knowledge, lower decrease in concerns, greater decrease in agreement with the decisions made, and lower increase in vaccination intention compared with those with high pandemic fatigue. Conclusion: As a pandemic evolves, it becomes necessary to consider the level of pandemic fatigue of the population and how this affects knowledge, concerns, and agreement with the measures adopted, as they influence the population's adherence to public health recommendations aimed at controlling infections and protecting the most vulnerable.

Early humoral and cellular responses after bivalent SARS-CoV-2 mRNA-1273.214 vaccination in long-term care and retirement home residents in Ontario, Canada: An observational cohort study. Immunogenicity of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) bivalent mRNA-1273.214 vaccine (Original/Omicron B.1.1.529 [BA.1]) is underreported in vulnerable older adults in congregate care settings. In residents of 26 long-term care and retirement homes in Ontario, Canada, humoral (i.e., serum anti-spike and anti-receptor binding domain [anti-RBD]) IgG and IgA antibodies and live SARS-CoV-2 neutralization) and cellular (i.e., CD4(+) and CD8(+) activation-induced marker spike-specific T cell memory) responses were assessed 7-120 days postvaccination with four monovalent mRNA vaccines (nâ€‰=â€‰494) or subsequent bivalent mRNA-1273.214 vaccination (fifth vaccine) (nâ€‰=â€‰557). Within 4 months, anti-spike and anti-RBD antibody levels were similar after monovalent and bivalent vaccination in infection-naÃ¯ve individuals. Hybrid immunity (i.e., vaccination and natural infection) generally increased humoral responses. After bivalent vaccination, compared to monovalent vaccination, residents with hybrid immunity had elevated anti-spike and anti-RBD IgG and IgA antibodies. Omicron BA.1 antibody-mediated neutralization, and CD8(+) T cell memory responses to the Omicron BA.1 spike protein, were also higher after bivalent vaccination. Humoral and cellular responses were, therefore, noninferior within 4 months of bivalent mRNA-1273.214 vaccination compared to monovalent mRNA vaccination. Waning of humoral but not cellular immunity was particularly evident in individuals without hybrid immunity. Continued monitoring of vaccine-associated and hybrid immunity against emerging Omicron variants of concern is necessary to assess longevity of protection.

SARS-CoV-2 mRNA vaccine requires signal peptide to induce antibody responses. New SARS-CoV-2 variants continue to prevail worldwide, and effective vaccines are needed to prevent an epidemic. mRNA vaccines are gradually being applied to the prevention and control of infectious diseases with significant safety and effectiveness. The spike (S) protein of SARS-CoV-2 is the main target of mRNA vaccine design, but the impact of the signal peptide (SP), transmembrane region (TM), and cytoplasmic tail (CT) on mRNA vaccine remains unclear. In this study, we constructed three forms of mRNA vaccines related to the S protein: full-length, deletion of the TM and CT, and simultaneous deletion of the SP, TM and CT, and compared their immunogenicity. Our experimental data show that full-length S protein and deletion of the TM and CT could effectively induce neutralizing antibody production in mice, while S protein without the SP and TM could not. This indicates that the S protein SP is necessary for the design of mRNA vaccine.

Pericardial effusion and systemic capillary leak syndrome late post-SARS-CoV-2 vaccination. We report an interesting case of pericardial effusion associated with idiopathic systemic capillary leak syndrome (ISCLS) following administration of SARS-CoV-2 vaccine. This patient initially presented with dyspnoea and chest pain, with non-pitting oedema and clear lung fields. The diagnosis of ISCLS was made based on the clinical syndrome and laboratory evidence of polycythaemia and hypoalbuminaemia. An enlarging pericardial effusion was diagnosed on transthoracic echocardiogram. Daily point-of-care ultrasound (POCUS)-guided volume management and serial transthoracic echocardiograms contributed to avoidance of refractory shock, cardiac tamponade and critical care admission.

A single immunization with core-shell structured lipopolyplex mRNA vaccine against rabies induces potent humoral immunity in mice and dogs. The persistence and clinical consequences of rabies virus (RABV) infection have prompted global efforts to develop a safe and effective vaccines against rabies. mRNA vaccines represent a promising option against emerging and re-emerging infectious diseases, gaining particular interest since the outbreak of COVID-19. Herein, we report the development of a highly efficacious rabies mRNA vaccine composed of sequence-modified mRNA encoding RABV glycoprotein (RABV-G) packaged in core-shell structured lipopolyplex (LPP) nanoparticles, named LPP-mRNA-G. The bilayer structure of LPP improves protection and delivery of RABV-G mRNA and allows gradual release of mRNA molecules as the polymer degrades. The unique core-shell structured nanoparticle of LPP-mRNA-G facilitates vaccine uptake and demonstrates a desirable biodistribution pattern with low liver targeting upon intramuscular immunization. Single administration of low-dose LPP-mRNA-G in mice elicited potent humoral immune response and provided complete protection against intracerebral challenge with lethal RABV. Similarly, single immunization of low-dose LPP-mRNA-G induced high levels of virus-neutralizing antibody titers in dogs. Collectively, our data demonstrate the potential of LPP-mRNA-G as a promising next-generation rabies vaccine used in human and companion animals.

Intraneural ganglion cyst of the peroneal nerve occurring after coronavirus disease-19 vaccination: A case report. Ganglion cysts are relatively common, but intraneural ganglion cysts (INGCs) within peripheral nerves are rare and poorly understood. We present the case of a 58-year-old woman who presented with acute right-foot drop. She experienced acute knee pain radiating from the lateral leg to the dorsal foot two days after the first coronavirus disease-19 (COVID-19) vaccination (BNT162b2, Pfizer-BioNTech). She had no history of trauma or medication use. Two weeks after the onset of symptoms, she developed a dorsiflexor weakness of the right foot (Medical Research Council grade, poor). The weakness worsened to a "trace" grade despite providing conservative management for one month. Ultrasonography revealed a fusiform echolucent structure within the course of the right common peroneal nerve around the fibular head. Magnetic resonance imaging revealed multiple intraneural cysts within the right common peroneal nerve. Nerve conduction and electromyographic studies revealed multiphasic motor unit action potentials accompanied by abnormal spontaneous activities in the innervated muscles, along with axonal degeneration of the deep peroneal nerves. Surgical removal of the cyst was performed, and the patient's symptoms gradually improved. Pathological examination revealed a cystic structure containing mucinous or gelatinous fluid and lined with flattened or cuboidal cells. The clinical course and sequential electromyographic findings relevant to this symptomatic cyst were temporally related to the vaccination date. The present case suggests that INGC-induced peroneal palsy is a possible complication after COVID-19 vaccination.

Pernicious Anemia Following COVID-19 Vaccination: A Report of Two Cases. Since December 2019 and the global epidemic of COVID-19 different countries have focused on vaccines, and one of the inactivated produced vaccines was the Sinopharm COVID-19 vaccine. Some side effects of this vaccine were reported previously, including pain at the vaccination site, fatigue, lethargy, headache, and tenderness, which were more prevalent among individuals <49 years old. Herein, we reported two patients aged 45 and 51 years old. Both patients have different signs and symptoms after receiving the second dose of the vaccine. None had a history of chronic disease. On examination and following labs and other diagnostic investigations, we found megaloblastic anemia due to atrophic gastritis and low intrinsic factor. These cases showed an autoimmune side effect of the Sinopharm COVID-19 vaccine that was previously reported with an exact mechanism but other features called Covid Arm, Guillain-BarrÃ© syndrome, and thrombocytopenia. The mechanism of this reaction is unclear yet.

Deranged Liver Function Test After COVID 19 Vaccination: A Rare Presentation With Review Of Literature. Word Health Organization declared COVID 19 infection as pandemic in 2020. Since then different countries had started working on vaccination. After multiple trials different vaccinations got approved. The first vaccine to be received in Pakistan was Sinopharm and was provided to nearly all health care professionals on priority basis. The safety profile of different vaccines were satisfactory and there were very few side effects reported till date. We are reporting the first case in Pakistan where a female health care professional developed vaccination induced deranged liver function test with delayed but complete recovery. Extensive workup was done to rule out all other differentials of deranged liver function test.

Latent Mastocytosis Triggered by COVID-19 Vaccination: A Case Report. BACKGROUND: Hereby, we describe the first case of latent mastocytosis triggered by mRNA-based vaccine to prevent COVID-19 infection. CASE PRESENTATION: In a 42-year-old Arabian man affected by slight, undiagnosed mastocytosis, the second dose of the COVID-19 vaccine made more blatant his latent disease. The postvaccination diagnostic iter is illustrated and the potential reasons causing the onset of the cutaneous mastocytosis are discussed. CONCLUSION: In certain patients, clinicians should keep a longer follow-up of their patients, following the COVID-19 vaccination, not related to a few hours for the risk of immediate-type adverse events only.

Serum per- and polyfluoroalkyl substance concentrations and longitudinal change in post-infection and post-vaccination SARS-CoV-2 antibodies. Per- and polyfluoroalkyl substances (PFAS) are ubiquitous throughout the United States. Previous studies have shown PFAS exposure to be associated with a reduced immune response. However, the relationship between serum PFAS and antibody levels following SARS-CoV-2 infection or COVID-19 vaccination has not been examined. We examined differences in peak immune response and the longitudinal decline of antibodies following SARS-CoV-2 infection and COVID-19 vaccination by serum PFAS levels in a cohort of essential workers in the United States. We measured serum antibodies using an in-house semi-quantitative enzyme-linked immunosorbent assay (ELISA). Two cohorts contributed blood samples following SARS-CoV-2 infection or COVID-19 vaccination. We used linear mixed regression models, adjusting for age, race/ethnicity, gender, presence of chronic conditions, location, and occupation, to estimate differences in immune response with respect to serum PFAS levels. Our study populations included 153 unvaccinated participants that contributed 316 blood draws over a 14-month period following infection, and 860 participants and 2451 blood draws over a 12-month period following vaccination. Higher perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), and perfluorononanoic acid (PFNA) concentrations were associated with a lower peak antibody response after infection (pÂ =Â 0.009, 0.031, 0.015). Higher PFOS, perfluorooctanoic acid (PFOA), PFHxS, and PFNA concentrations were associated with slower declines in antibodies over time after infection (pÂ =Â 0.003, 0.014, 0.026, 0.025). PFOA, PFOS, PFHxS, and PFNA serum concentrations prior to vaccination were not associated with differences in peak antibody response after vaccination or with differences in decline of antibodies over time after vaccination. These results suggest that elevated PFAS may impede potential immune response to SARS-CoV-2 infection by blunting peak antibody levels following infection; the same finding was not observed for immune response to vaccination.

SARS-CoV-2 mRNA vaccination-induced immunological memory in human nonlymphoid and lymphoid tissues. Tissue-resident lymphocytes provide organ-adapted protection against invading pathogens. Whereas their biology has been examined in great detail in various infection models, their generation and functionality in response to vaccination have not been comprehensively analyzed in humans. We therefore studied SARS-CoV-2 mRNA vaccine-specific T cells in surgery specimens of kidney, liver, lung, bone marrow, and spleen compared with paired blood samples from largely virus-naive individuals. As opposed to lymphoid tissues, nonlymphoid organs harbored significantly

elevated frequencies of spike-specific CD4+ T cells compared with blood showing hallmarks of tissue residency and an expanded memory pool. Organ-derived CD4+ T cells further exhibited increased polyfunctionality over those detected in blood. Single-cell RNA-Seq together with T cell receptor repertoire analysis indicated that the clonotype rather than organ origin is a major determinant of transcriptomic state in vaccine-specific CD4+ T cells. In summary, our data demonstrate that SARS-CoV-2 vaccination entails acquisition of tissue memory and residency features in organs distant from the inoculation site, thereby contributing to our understanding of how local tissue protection might be accomplished.

Graves' disease following COVID-19 vaccination: a population-based, matched case-control study. OBJECTIVE: Multiple cases and case series reported Graves' disease (GD) following coronavirus disease 2019 (COVID-19) vaccination. We aimed to determine whether COVID-19 vaccination was associated with the incidence of GD. METHODS: We analyzed data from Clalit Health Services, the largest healthcare organization in Israel, which insures 4.7 million patients. A population-based, matched, case-control study was performed. Cases were defined as adult patients diagnosed with GD between December 2020 and November 2022. Each case was matched with controls in a 1:2 ratio. Each control was assigned an index date which was identical to that of their matched case, defined as the date of GD diagnosis. Time between vaccination date and the diagnosis of Graves' disease or index date was assessed. RESULTS: A total of 726 patients with Graves' disease were matched with 1452 controls. The study patients and controls have received similar proportions of the COVID-19 vaccine (at least one dose: 80% (581/726) vs. 77.8% (1129/1452), P=0.22, respectively). In a univariate analysis, at least one dose of the COVID-19 vaccine was not associated with the incidence of GD [odds ratio 95% confidence interval: 1.15 (0.92-1.43)]. The mean time between first COVID-19 vaccination and the diagnosis of GD for cases or index date for controls was not significantly different [275.69 days (standard deviation 144.37) for cases compared to 275.45 days (standard deviation 145.76) for controls]. CONCLUSIONS: Our study found no association between COVID-19 vaccination and the incidence of GD.

Comprehensive evaluation of the effect of inactivated SARS-CoV-2 vaccination on female fertility: A retrospective cohort study. Fear of possible negative effects of coronavirus disease 2019 (COVID-19) vaccine on fertility is the main reason for vaccine hesitancy among the public especially women of childbearing age. Despite the high coverage of COVID-19 vaccination in China, more scientific evidence is still needed to address their concerns and guide fertility counseling and management in the future. Herein, we performed a retrospective cohort study at a single large center for reproductive medicine in China between August 2020 and May 2023. Patients aged 20-42 years with no history of laboratory-confirmed COVID-19 were included and categorized into different groups according to their vaccination status. The serum sex hormone levels, anti-MÃ¼llerian hormone concentrations, embryo quality, and pregnancy outcomes were evaluated and compared among them. We found there were no significant differences in the concentrations of follicle-stimulating hormone, luteinizing hormone and progesterone between the unvaccinated, first-dose, second-dose, and booster vaccinated groups. However, the estradiol showed a highly significant increase in the one-dose vaccinated group compared with its levels in other groups. Among unvaccinated and either vaccinated patients, anti-MÃ¼llerian hormone levels were comparable (pâ€‰=â€‰0.139). The number of oocytes retrieved, fertilization rate and good-quality embryo rate were all similar between each group of in vitro fertilization and intracytoplasmic sperm injection. No significant differences were observed regarding other laboratory parameters. Moreover, the vaccination status of infertile couples did not exert any adverse effect on the pregnancy outcomes in all assisted reproductive technologies cycles. In short, we comprehensively evaluated the reproductive safety of inactivated severe acute respiratory syndrome coronavirus 2 vaccine and found any dose of vaccination wouldn't

negatively affect female fertility parameters such as sex hormone levels and ovarian reserve. Moreover, this is the first study to complete the live birth follow-up of the cohort after receiving inactivated severe acute respiratory syndrome coronavirus 2 vaccine, further dispelling the misconception and providing reassurance for decision-making by clinicians.
Before blaming SARS-CoV-2 infection or vaccination for acute peripheral artery occlusion, rule out differential causes.
Characterization and predictive risk scoring of long COVID in a south indian cohort after breakthrough COVID infection; a prospective single centre study. BACKGROUND: With the World Health Organization (WHO) declaring an end to the COVID-19 pandemic, the focus has shifted to understanding and managing long-term post-infectious complications. "Long COVID," characterized by persistent or new onset symptoms extending beyond the initial phase of infection, is one such complication. This study aims to describe the incidence, clinical features and risk profile of long COVID among individuals in a South Indian cohort who experienced post-ChAdOx1 n-Cov-2 vaccine breakthrough infections. METHODS: A single-centre hospital-based prospective observational study was conducted from October to December 2021. The study population comprised adult patients (>â€‰18 years) with a confirmed COVID-19 diagnosis who had received at least a single dose of vaccination. Data was collected using a specially tailored questionnaire at week 2, week 6, and week 12 post-negative COVID-19 test. A propensity score based predictive scoring system was developed to assess the risk of long COVID. RESULTS: Among the 414 patients followed up in the study, 164 (39.6%) reported long COVID symptoms persisting beyond 6 week's post-infection. The presence of long COVID was significantly higher among patients above 65 years of age, and those with comorbidities such as Type II Diabetes Mellitus, hypertension, dyslipidemia, coronary artery disease, asthma, and cancer. Using backwards selection, a reduced model was developed, identifying age (OR 1.053, 95% CI 0.097-1.07, pâ€‰<â€‰0.001), hypertension (OR 2.59, 95% CI 1.46-4.59, pâ€‰=â€‰0.001), and bronchial asthma (OR 3.7176, 95% CI 1.24-11.12, pâ€‰=â€‰0.018) as significant predictors of long COVID incidence. A significant positive correlation was observed between the symptomatic burden and the number of individual comorbidities. CONCLUSIONS: The significant presence of long COVID at 12 weeks among non-hospitalised patients underscores the importance of post-recovery follow-up to assess for the presence of long COVID. The predictive risk score proposed in this study may help identify individuals at risk of developing long COVID. Further research is needed to understand the impact of long COVID on patients' quality of life and the potential role of tailored rehabilitation programs in improving patient outcomes.
Humoral and T-cell immune response following three doses of SARS-CoV-2 mRNA vaccine in giant cell arteritis: analysis of a prospective cohort.
Venous Thromboembolism After COVID-19 Infection Among People With and Without Immune-Mediated Inflammatory Diseases. IMPORTANCE: Immune-mediated inflammatory diseases (IMIDs) and COVID-19 are independently associated with venous thromboembolisms (VTEs). OBJECTIVE: To determine if individuals with IMIDs are at higher risk of VTE following COVID-19 infection compared with individuals without IMIDs. DESIGN, SETTING, AND PARTICIPANTS: Population-based matched cohort study using multiple deterministically linked health administrative databases from Ontario, Canada, and including patients testing positive for COVID-19 between January 1, 2020, and December 30, 2021, and followed up until March 31, 2022. Individuals with IMIDs (nâ€‰=â€‰28â€¯440) who tested positive for COVID-19 were matched with up to 5 individuals without an IMID (nâ€‰=â€‰126â€¯437) who tested positive for COVID-19. Matching was based on year of birth, sex, neighborhood income, and rural/urban residence. Data analysis was performed from August 6, 2022, to August 21, 2023. EXPOSURE: Diagnosis of an IMID, identified using algorithms based on diagnostic codes, procedures, and specialist visits. MAIN OUTCOME AND

MEASURE: The main outcome was estimated age- and sex-standardized incidence of VTE. Proportional cause-specific hazard models compared the risk of VTE in people with and without IMIDs. Death was a competing risk. Models adjusted for history of VTE, 2 or more doses of a COVID-19 vaccine 14 or more days prior to COVID-19 diagnosis, and the Charlson Comorbidity Index. Routinely collected health data were used, so the hypothesis tested was formulated after data collection but prior to being granted access to data. RESULTS: The study included 28â€¯440 individuals (16â€¯741 [58.9%] female; 11â€¯699 [41.1%] male) with an IMID diagnosed prior to first COVID-19 diagnosis, with a mean (SD) age of 52.1 (18.8) years at COVID-19 diagnosis. These individuals were matched to 126â€¯437 controls without IMIDs. The incidence of VTE within 6 months of COVID-19 diagnosis among 28â€¯440 individuals with an IMID was 2.64 (95% CI, 2.23-3.10) per 100â€¯000 person-days compared with 2.18 (95% CI, 1.99-2.38) per 100â€¯000 person-days among 126â€¯437 matched individuals without IMIDs. The VTE risk was not statistically significantly different among those with vs without IMIDs (adjusted hazard ratio, 1.12; 95% CI, 0.95-1.32). CONCLUSIONS AND RELEVANCE: In this retrospective population-based cohort study of individuals with IMIDs following COVID-19, individuals with IMIDs did not have a higher risk of VTE compared with individuals without an IMID. These data provide reassurance to clinicians caring for individuals with IMIDs and COVID-19.

An analysis of reported cases of hemophagocytic lymphohistiocytosis (HLH) after COVID-19 vaccination. Although COVID-19 vaccines are an effective public health tool to combat the global pandemic, serious adverse events, such as hemophagocytic lymphohistiocytosis (HLH), caused by them are a concern. In this systematic review, cases of HLH reported after COVID-19 vaccination have been examined to understand the relationship between the two and propose effective therapeutic strategies. Furthermore, ruxolitinib's potential as a cytokine inhibitor and its affinity for CD25 were initially assessed through molecular docking, aiming to aid targeted HLH therapy. PubMed and Web of Science databases were searched for published individual case reports on the occurrence of HLH after the administration of any COVID-19 vaccine. A total of 17 articles (25 patients) were included in this qualitative analysis. Furthermore, molecular docking was employed to investigate the therapeutic potential of ruxolitinib for HLH after COVID-19 vaccination. The mean age of patients who developed HLH after COVID-19 vaccination was 48.1â€‰years. Most HLH episodes occurred after the BNT162b2 mRNA COVID-19 vaccination (14/25 cases) and to an extent after the ChAdOx1 nCov-19 vaccination (5/25 cases). Almost all affected patients received steroid and antibiotic therapy. Three patients died despite treatment because of esophagus rupture, neutropenic fever, bacteroides bacteremia, refractory shock, and encephalopathy and shock. Visual docking results of IL-2â€‰RÎ± and ruxolitinib using the Discovery Studio 2019 Client software yielded a model score of 119.879. The findings highlight the importance of considering and identifying the adverse effects of vaccination and the possibility of using ruxolitinib for treating HLH after COVID-19 vaccination.

Baricitinib treatment of extragenital lichen sclerosus caused by COVID-19 vaccine.

Arthroscopic debridement for acute hemorrhagic subacromial bursitis following COVID-19 vaccine administration: A case report. The rapid rollout of vaccinations in response to the COVID-19 pandemic has led to their widespread distribution and administration throughout the world. The benefit of these vaccinations in preventing the spread of the disease and diminishing symptoms in patients who contract COVID-19 has been fervently studied and reported. While vaccinations remain an effective and generally safe method of limiting disease transmission and virus-related mortality, vaccine administration is not completely without risk. Shoulder injuries related to vaccine administration (SIRVA) have been described with previously available vaccines but have yet to be widely reported in the COVID-19 vaccination population. We present a case report of a young, high-functioning patient who presented with acute subacromial bursitis after COVID-19 vaccine

administration due to improper vaccination technique. The patient was treated with arthroscopic shoulder surgery and had near immediate relief of shoulder symptoms.
Herpetic anterior uveitis following COVID-19 vaccines: a case series. PURPOSE: To report a case series of herpetic uveitis following COVID-19 vaccinations. METHODS: Demographic, clinical and treatment-related data of herpetic anterior uveitis cases was collected at five tertiary eye hospitals between January 2021 and June 2022. A retrospective database review at one of the centers comparing the number of cases of herpetic eye disease before and after the introduction of COVID-19 vaccination was performed as well. RESULTS: Twenty-four patients (9 female, 15 male) with a mean age of 54â€‰years (range 28-83â€‰years) were diagnosed with herpetic uveitis, reporting an onset of symptoms 3-42â€‰days after the first, second or third dose of COVID-19 vaccination. Median time between vaccination and onset of herpetic eye disease was 10â€‰days (mean 12.7â€‰Â±â€‰10.15â€‰days) days. The administered vaccines were BNT162b2, mRNA-1273, BBIBP-CorV and Ad26.COV2.S. The cases included 11 HSV, 10 VZV and 1 CMV anterior uveitis, 2 were not further specified. There was an equal number of first episodes (nâ€‰=â€‰12, 50%) and recurrent episodes (nâ€‰=â€‰12, 50%). Response to established regimens was generally good. The retrospective database review revealed the exact same incidence of herpetic uveitis during the pandemic and ongoing vaccination compared to prior SARS-CoV-2. CONCLUSION: This report includes 24 cases of herpetic anterior uveitis in a temporal relationship to various COVID-19 vaccines. This study supports the potential risk of herpetic eye disease following COVID-19 vaccines, but proof of a direct, causal relationship is missing.
The more symptoms the better? Covid-19 vaccine side effects and long-term neutralizing antibody response. Protection against SARS-CoV-2 wanes over time, and booster uptake has been low, in part because of concern about side effects. We examined the relationships between local and systemic symptoms, biometric changes, and neutralizing antibodies (nAB) after mRNA vaccination. Data were collected from adults (n = 364) who received two doses of either BNT162b2 or mRNA-1273. Serum nAB concentration was measured at 1 and 6 months post-vaccination. Daily symptom surveys were completed for six days starting on the day of each dose. Concurrently, objective biometric measurements, including skin temperature, heart rate, heart rate variability, and respiratory rate, were collected. We found that certain symptoms (chills, tiredness, feeling unwell, and headache) after the second dose were associated with increases in nAB at 1 and 6 months post-vaccination, to roughly 140-160% the level of individuals without each symptom. Each additional symptom predicted a 1.1-fold nAB increase. Greater increases in skin temperature and heart rate after the second dose predicted higher nAB levels at both time points, but skin temperature change was more predictive of durable (6 month) nAB response than of short-term (1 month) nAB response. In the context of low ongoing vaccine uptake, our convergent symptom and biometric findings suggest that public health messaging could seek to reframe systemic symptoms after vaccination as desirable.
Electroencephalographic findings post-COVID-19 vaccination: A systematic review of case reports and case series. A number of different neurological complications have been reported following vaccination against the coronavirus disease 2019 (COVID-19). Electroencephalogram (EEG) is one of the modalities used to evaluate the neurological complications of diseases. The aim of the present study was to identify the EEG changes in participants vaccinated against COVID-19. PubMed, Scopus, Web of Science, medRxiv, and Google Scholar were searched up to 1 September 2022, with terms related to COVID-19 vaccines, EEG, neurological signs/symptoms, or neurological disorders. All case reports and case series were included if the participants had received at least one dose of a COVID-19 vaccine and a post vaccination EEG report was also reported. We used the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for case reports and case series to appraise the methodological

quality of the included studies. Thirty-one studies were included, which were comprised of 24 case reports and seven case series and a total of 36 participants. Generalised slowing and non-convulsive focal status epilepticus were the most common EEG findings post-COVID-19 vaccination. The most frequent symptoms were headache, fatigue, generalised weakness, and vomiting. In addition, the most common signs were encephalopathy, post-ictal phases, and confusion. Encephalitis, acute disseminated encephalomyelitis, and post-vaccinal encephalopathy were the most commonly diagnosed adverse events. Furthermore, most of the imaging studies appeared normal. The EEG reports mainly showed background slowing and epileptiform discharges, encephalitis, encephalopathies, and demyelinating disorders. Future studies with larger samples and more vaccine types may help to further unravel the potential neurological effects of COVID-19 vaccinations on recipients.

High-resolution MR neurography follow-up of SARS-CoV-2 vaccination-associated neuralgic amyotrophy. Little is known about the value of high-resolution follow-up imaging in patients with neuralgic amyotrophy (NA) and the question of the best treatment algorithm remains unclear. Three patients (one female, two male) with the clinical presentation of SARS-CoV-2-vaccination-associated NA underwent initial magnetic resonance neurography (MRN) imaging and follow-up examinations. All patients showed a marked clinical improvement, independent of treatment, including an almost full recovery of motor function over the course of 8-12â€‰months which was accurately mirrored by imaging findings on MRN. MRN imaging is a valuable tool for monitoring the further clinical course of patients suffering from vaccination-associated NA.

Thrombosis with thrombocytopenia syndrome (TTS) following adenovirus vector COVID-19 vaccination in Canada. INTRODUCTION: Identifying and monitoring adverse events following vaccination contributed to the safety and effectiveness of COVID-19 mass vaccination campaigns. In March 2021, international reports emerged of an adverse event following vaccination with adenovirus vector COVID-19 vaccines (ChAdOx1-S [recombinant] and Ad26.COV2.S) of thrombosis with low platelet counts, referred to as thrombosis with thrombocytopenia syndrome (TTS). We described TTS reports in Canada following adenovirus vector COVID-19 vaccines and investigated whether the observed number of events were higher than expected. METHODS: Reports of TTS following receipt of ChAdOx1-S [recombinant] or Ad26.COV2.S meeting the Canadian case definition for TTS and diagnostic certainty levels 1-3 of the Brighton Collaboration case definition, submitted to the Canadian Adverse Events Following Immunization Surveillance System and Canada Vigilance Database between February 26, 2021 and October 31, 2022 were included. Demographics and characteristics of the TTS reports are described along with an analysis comparing the observed number of reports to the expected number. RESULTS: As of October 31, 2022, 56 reports of TTS following administration of ChAdOx1-S [recombinant] and no reports following Ad26.COV2.S vaccines were reported in Canada, of which 37 had functionally positive anti-PF4 antibodies. The median age was 56Â years; males accounted for 54Â % of reports. Five deaths were reported. The observed number of reports exceeded the expected for all ages and sexes combined, as well as for males aged 30-49 and 60-69Â years, and females aged 40-59Â years. CONCLUSION: Based on international surveillance data, Canada evaluated a statistical signal of TTS following adenovirus vector vaccines. The investigation of this signal demonstrated how post-market vaccine safety surveillance systems were successful in investigating rare adverse events during the rollout of COVID-19 vaccines in Canada. As adenovirus vector vaccines continue to be administered, characterization of the association between the vaccine and TTS informs immunization programs and policies.

Health-care Worker Engagement in Federally Qualified Health Centers and Associations with Confidence in Making Health-care Recommendations: Evidence from the Louisiana Community Engagement Alliance. Throughout the coronavirus disease 2019 (COVID-19) pandemic, there

have been numerous demands on primary care practices and providers affecting work engagement and burnout, which can affect health-care delivery and patient outcomes. We determined potentially modifiable factors associated with work engagement among employees of federally qualified health centers (FQHCs) throughout Louisiana. Resilient coping, spirituality, and social support were associated with being engaged at work. FQHC employees perceiving a more chaotic work environment and those with depressive or anxiety symptoms were less likely to be engaged at work. Being engaged was associated with confidence in COVID-19 vaccine recommendation for adults.

Response to Dr. Somovilla del Saz's letter to the editor regarding "Risk of all-cause and cardiac-related mortality after vaccination against COVID-19: A meta-analysis of self-controlled case series studies". This is a response to Dr. Somovilla del Saz's letter to the editor regarding Marchand et al.'s article, "Risk of all-cause and cardiac-related mortality after vaccination against COVID-19: A meta-analysis of self-controlled case series studies." The response is on behalf of all authors clarifying misconceptions about the work.

Reduced neutralization and Fc effector function to Omicron subvariants in sera from SARS-CoV-1 survivors after two doses of CoronaVac plus one dose subunit vaccine. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron harbors more than 30 mutations of the spike protein and exhibits substantial immune evasion. Although previous study indicated that BNT162b2 messenger RNA vaccine induces potent cross-clade pan-sarbecovirus neutralizing antibodies in survivors of the infection by SARS-CoV-1, the neutralization activity and Fc-mediated effector functions of these cross-reactive antibodies elicited in SARS-CoV-1 survivors to Omicron subvariants still remain largely unknown. In this study, the neutralization activity and Fc-mediated effector functions of antibodies boosted by a third dose vaccination were characterized in SARS-CoV-1 convalescents and healthy individuals. Potent cross-clade broadly neutralizing antibodies were observed in SARS-CoV-1 survivors who received a three-dose vaccination regimen consisting of two priming doses of CoronaVac followed by one booster dose of the protein subunit vaccine ZF2001. However, the induced antibodies exhibited both reduced neutralization and impaired Fc effector functions targeting multiple Omicron subvariants. Importantly, the data also support the notion that immune imprints resulted from SARS-CoV-1 infection may exacerbate the impairment of neutralization activity and Fc-mediated effector functions to Omicron subvariants and provided invaluable information to vaccination strategy in future.

Acupuncture as a therapeutic intervention for post-COVID-19 vaccination urticaria: a systematic review and meta-analysis protocol. INTRODUCTION: The COVID-19 pandemic persisted for over 3â€‰years since its onset in December 2019, posing an ongoing global threat to human health. In the absence of specific antiviral medications for COVID-19, vaccination has emerged as a popular preventive measure adopted by the general public. However, an undesirable consequence of COVID-19 vaccination has been the frequent incidence of urticaria, a type of adverse skin manifestations. Despite the prevalence of this issue, there is currently a lack of clinical evidence exploring the potential utility of acupuncture as a therapeutic approach to managing urticaria arising after COVID-19 vaccination. To address this knowledge gap, this study aims to comprehensively evaluate the effectiveness and safety of acupuncture as a therapeutic intervention for treating urticaria in the general population following COVID-19 vaccination. METHODS AND ANALYSIS: The retrieval strategies employed in this study involve obtaining all relevant articles published from December 2019 to October 2023. These articles will be obtained from databases including PubMed, EMBASE, Cochrane Library, Web of Science, Chinese National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (SinoMed), VIP database and the WanFang database. Subsequently, the collected articles will undergo a thorough screening process based on predefined inclusion and exclusion criteria. Additionally, study quality will be evaluated using the Cochrane risk bias assessment tool. To

conduct the meta-analysis, we will employ the Review Manager software (RevMan V.5.3). Finally, the study findings will be evaluated for their level of evidence. ETHICS AND DISSEMINATION: As this is a secondary review of published clinical data, this study does not involve direct contact with human subjects, and therefore, ethical approval and consent are not required. The findings of the study will be disseminated through a peer-reviewed journal, ensuring that the results undergo rigorous evaluation by experts in the field. PROSPERO REGISTRATION NUMBER: CRD42022377343.

COVID-19 booster vaccine acceptance following allergy evaluation in individuals with allergies.

Immunity induced by vaccination with recombinant influenza B virus neuraminidase protein breaks viral transmission chains in guinea pigs in an exposure intensity-dependent manner. Vaccines that can slow respiratory virus transmission in the population are urgently needed for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and influenza virus. Here, we describe how a recombinant neuraminidase-based influenza virus vaccine reduces transmission in vaccinated guinea pigs in an exposure intensity-based manner.

Clinical features and outcomes of Myasthenia Gravis associated with COVID-19 vaccines: A systematic review and pooled analysis. BACKGROUNDS: Myasthenia Gravis (MG), a chronic neuromuscular junction disorder, emerged as one of the serious side effects of the Coronavirus Disease 2019 (COVID-19) vaccination. We aimed to summarize the findings of studies on the clinical features and outcomes of COVID-19 vaccination-associated MG. METHODS: We performed a systematic search on 3 databases, Medline, Embase, and Scopus, using the query "COVID-19 vaccine" and "Myasthenia Gravis." Patients' data, including clinical data, MG subtype, vaccine type, and vaccine dose number, were extracted from the eligible studies. RESULTS: A total of 20 COVID-19 vaccination-related MGs have been reported worldwide. The median (interquartile range) age was 64 (51, 75) years; 85% (17/20) of them were male, and 70% (14/20) of patients had received messenger RNA-based vaccines. The most common symptoms, in order of frequency, were binocular diplopia (8/11) and ptosis (4/11); the median (interquartile range) time from vaccine to MG symptoms was 6 (2, 7.5) days. Repetitive nerve stimulation showed abnormal decrement in 85% (11/13) of patients, and all 4 patients getting single-fiber electromyography showed an abnormal finding. Nine out of twelve patients with data on clinical outcomes experienced partial/complete improvement of symptoms within 1 month. CONCLUSION: MG cases after the COVID-19 vaccine are more likely to occur among males and adults older than 50 years. Our pooled cohort data suggest MG symptoms appear within 2 weeks after receiving the vaccine. The presenting symptoms in MG cases associated with COVID-19 vaccine are possibly similar to non-vaccination related MGs. Most patients are expected to experience partial/complete improvement within 1 month.

A Silent Outbreak of Hepatitis E Virus (HEV) Infection or False-Positive Reaction of Anti-HEV IgM after COVID-19 Vaccination? Epidemiological Investigation of an Outbreak in a Korean Factory Complex in 2022. BACKGROUND/AIMS: To investigate a reported outbreak of presumed hepatitis E virus (HEV) infection in a Korean food manufacturing facility and to explore the association between anti-HEV immunoglobulin M (IgM) positivity and coronavirus disease 2019 (COVID-19) infection or vaccination. METHODS: Twenty-four cases of anti-HEV IgM positivity were reported among 646 workers at the facility in 2022. An epidemiological investigation was conducted, comprising HEV-RNA testing of blood and environmental samples, analysis of group meal records, and an association between anti-HEV IgM positivity and confirmed COVID-19 infection or vaccination. RESULTS: All 24 patients were asymptomatic, with cases spread sporadically across the facility. HEV RNA was not detected in the serum or environmental samples. Four out of 340 meals (1.2%) showed a significantly higher proportion of anti-HEV positivity in each meal intake group than in the non-intake group on certain days. Although the cumulative rate of COVID-19 infection showed no difference, the anti-HEV IgM positive group showed significantly higher proportions of >2 doses of COVID-19 vaccination

(83.3% vs 48.7%, p=0.021), vaccination within 90 days (45.8% vs 19.7%, p=0.008), and having the Moderna vaccine administered as the last vaccine (75.0% vs 14.5%, p<0.001) than those of the anti-HEV negative group. In four multivariable models, three or more COVID-19 vaccinations and the Moderna vaccine as the last vaccine were consistently associated with anti-HEV IgM positivity, while the specific day group meal intake was also a significant factor. CONCLUSIONS: This epidemiological investigation showed that anti-HEV IgM positivity may occur as a false-positive result related to COVID-vaccination over three times and use of the Moderna vaccine, although a portion of true HEV infection may not be excluded.

Occurrence of proliferative myositis after COVID-19 vaccination: A case report. Proliferative myositis (PM) is a benign intramuscular tumor that might mimic a malignant one due to its unusual pseudosarcomatous inflammatory nature. In this report, we describe a patient who developed PM after vaccination with Sinopharm coronavirus disease (COVID-19) vaccine. A 73 years old man was admitted due to rapidly-growing painful mass in his left thigh from a few days ago, curtailing his walking. He received a recent COVID-19 vaccination (Sinopharm COVID-19 vaccine) about 5 days before the beginning of symptoms. No history of trauma was present. On physical exam, a round firm mass was found in lateral side of mid portion of left thigh within the muscle with tenderness on palpation. An oval-shaped well-defined intramuscular mass measured 15Â Ã—Â 41 mm was noted in vastus lateralis muscle in ultrasonography. Left thigh magnetic resonance imaging (MRI) showed a well-defined intramuscular mass with a definite margin of 19Â Ã—Â 39 mm. Finally, ultrasound (US)-guided core needle biopsy showed muscular tissue with a loose mass composed of plump fibroblasts and myofibroblasts and large ganglion-like cell with abundant amphophilic to basophilic cytoplasm, vesicular nuclei and prominent nucleoli. Pathology report showed a very rare case identified as proliferative myositis. It should be noted that we cannot make a direct link between these 2 events. PM is an extremely rare entity; however, its relation with COVID-19 vaccination might be a coincidence.

Safety and immunogenicity of a modified Omicron-adapted inactivated vaccine in healthy adults: a randomized, double-blind, active-controlled Phase III clinical trial. BACKGROUND: Updated vaccine strategies are needed to protect against new SARS-CoV-2 variants with increased immune escape. Here, information on the safety and immunogenicity of an inactivated Omicron-adapted vaccine is presented, as compared with CoronaVac. METHODS: A randomized, double-blind, active-controlled, phase III clinical trial was conducted to compare a modified Omicron-adapted vaccine (Omicron vaccine) with the authorized prototype vaccine (CoronaVacÂ®) as a booster dose. Healthy adults aged â‰¥18 years, who have previously received 2 or 3 doses of CoronaVac (2C or 3C cohort) at least 6 months before, were enrolled to get a booster dose of Omicron vaccine or CoronaVac in a ratio of 2:1 (2C/3C+1O/1C). Back-up serums after two initial doses of CoronaVac (2C+0) for adults aged 26-45 years were collected from a previous study. Immunogenicity and safety data at 28 days after vaccination were collected and analyzed. One of the primary objectives was to evaluate the superiority of immunogenicity of Omicron vaccine booster against Omicron BA.1, compared with CoronaVac booster against BA.1. Another objective was to evaluate the non-inferiority of immunogenicity of Omicron vaccine booster against BA.1, compared with two initial doses of CoronaVac against ancestral strain. RESULTS: Between June 1(st) and July 21(st), 2022, a total of 1,500 healthy adults were enrolled. Results show that all pre-specified superiority criteria for BA.1 neutralizing antibody were met. Specifically, within the 3C cohort (3C+1O vs. 3C+1C), the geometric mean titers' (GMT) ratio and 95% confidence interval (CI) was 1.64 (1.42, 1.89), with the lower 95%CI â‰¥1; a GMT ratio of 1.84 (1.57, 2.16) was observed for 2C+1O versus 3C+1C. For seroconversion rate, the lower 95%CIs of differences between immuno-comparative groups (2/3C+1O vs. 3C+1C) were all above the superiority criterion 0%. However, the non-inferiority criterion of the lower 95%CI

of GMT ratio â‰¥2/3 was unfulfilled for 2C/3C+1O against BA.1 versus 2C+0 against ancestral strain. Safety profiles were similar between groups, with no safety concerns identified. CONCLUSION: The Omicron-adapted vaccine was well-tolerated and could elicit superior immune responses as compared with CoronaVac against Omicron, while it appeared inferior to CoronaVac against ancestral strain. CLINICAL TRIAL REGISTRATION: https://classic.clinicaltrials.gov/ct2/show/NCT05381350?term=NCT05381350&draw=2&rank=1, identifier NCT05381350.

ChatGPT and safety of COVID-19 vaccines.

Questionable robustness in the findings of a meta-analysis. Marchand and colleagues conducted a meta-analysis examining COVID vaccine effects on all-cause and cardiac-related mortality. Findings aligned with previous research, showing no association with all-cause mortality. However, cardiac-related mortality exhibited a 6% increase post-vaccination. Concerns arise from reliance on a non-peer-reviewed study (Ladapo, 2022) influencing results significantly. Sensitivity analyses were lacking, undermining result robustness, particularly in gender-specific outcomes. Adherence to PRISMA guidelines for transparency and thoroughness could strengthen conclusions. This study underscores vaccine safety scrutiny, yet the influence of biased sources and absence of sensitivity testing warrant careful consideration.

Outcomes of patients with acute coronary syndrome according to COVID-19 vaccination status. BACKGROUND: COVID-19 vaccination has been associated with reduced risk of acute coronary syndrome (ACS); however, several studies have reported cardiovascular complications following vaccination. We aimed to investigate the effect of COVID-19 vaccination status on the treatment and outcome of ACS patients. METHODS: The study was based on the 2021 Acute Coronary Syndrome Israeli Survey. Patients were stratified into two groups according to COVID-19 vaccination status, vaccinated compared to unvaccinated. Patients who had received at least 2 vaccination doses up to 1 week prior to ACS hospitalization were considered vaccinated. The primary endpoint was 1-year all-cause mortality. RESULTS: A total of 1261 patients with ACS were included, of whom 990 (78.5%) were vaccinated. Vaccinated patients were older and less frequently smokers. There were no significant differences in coronary reperfusion rates and treatment with guideline-based medical therapy during hospital stay and at discharge. The primary endpoint of 1-year all-cause mortality occurred in 38 (3.8%) and 14 (5.2%) patients in the vaccinated and unvaccinated groups respectively (Pâ€…=â€…0.42). 30-day MACE occurred in 94 (9.5%) in the vaccinated patients compared to 31 (11.5%) in the unvaccinated group (Pâ€…=â€…0.39). These results remained similar following adjustment for confounders. CONCLUSION: There was no association between COVID-19 vaccination status and the outcomes of patients with ACS. Our findings provide support for the cardiovascular safety of COVID-19 mRNA vaccines in patients at high cardiovascular risk.

A Dynamic Model for Estimating the Retention Duration of Neutralizing Antibody Titers after Vaccination in a COVID-19 Convalescent Population. We measured neutralizing antibodies (nAbs) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in a cohort of 235 convalescent patients (representing 384 analytic samples). They were followed for up to 588 days after the first report of onset in Taiwan. A proposed Bayesian approach was used to estimate nAb dynamics in patients postvaccination. This model revealed that the titer reached its peak (1819.70 IU/mL) by 161 days postvaccination and decreased to 154.18 IU/mL by day 360. Thus, the nAb titers declined one-half year after vaccination. Protection, against variant B.1.1.529 (i.e., Omicron) may only occur during the peak period.

COVID-19 vaccination and myasthenia gravis.

The role of co-morbidities in the development of an AEFI after COVID-19 vaccination in a large prospective cohort with patient-reported outcomes in the Netherlands. BACKGROUND: The

effect of a preexisting comorbidity on the occurrence of adverse events after immunization (AEFIs) has been studied poorly. In this longitudinal cohort study, we assess the association between co-morbidities and the occurrence of AEFIs after COVID-19 vaccination. Also, we described the occurrence of flare-ups and their manifestation after COVID-19 vaccination in people with rheumatic diseases. RESEARCH DESIGN AND METHODS: We performed multivariable logistic regression to investigate the association between the occurrence of AEFIs and 10 common comorbidities using patient-reported data from people vaccinated with the AstraZeneca, Johnson&Johnson, Moderna, or Pfizer vaccine. RESULTS: Occurrence of any AEFI, injection site reactions, headache, fatigue, and/or malaise was significantly associated with presence of comorbidities, including psychological disorders, musculoskeletal disorders, and endocrine disorders after the first and second doses (OR ranges 1.23-1.77). One participant with rheumatoid arthritis experienced a flare-up after receiving the first dose of the AstraZeneca vaccine. DISCUSSION/CONCLUSION: The results showed that the odds of reporting an AEFI after COVID-19 vaccination is significantly higher in the presence of some comorbidities whilst flare-ups are uncommon after receiving COVID-19 vaccination in people with rheumatic disease. In-depth research is needed to validate our results and unravel the observed associations from a mechanistic perspective.

Airway surveillance and lung viral control by memory T cells induced by COVID-19 mRNA vaccine. Although SARS-CoV-2 evolution seeds a continuous stream of antibody-evasive viral variants, COVID-19 mRNA vaccines provide robust protection against severe disease and hospitalization. Here, we asked whether mRNA vaccine-induced memory T cells limit lung SARS-CoV-2 replication and severe disease. We show that mice and humans receiving booster BioNTech mRNA vaccine developed potent CD8 T cell responses and showed similar kinetics of expansion and contraction of granzyme B/perforin-expressing effector CD8 T cells. Both monovalent and bivalent mRNA vaccines elicited strong expansion of a heterogeneous pool of terminal effectors and memory precursor effector CD8 T cells in spleen, inguinal and mediastinal lymph nodes, pulmonary vasculature, and most surprisingly in the airways, suggestive of systemic and regional surveillance. Furthermore, we document that: (a) CD8 T cell memory persists in multiple tissues for > 200 days; (b) following challenge with pathogenic SARS-CoV-2, circulating memory CD8 T cells rapidly extravasate to the lungs and promote expeditious viral clearance, by mechanisms that require CD4 T cell help; and (c) adoptively transferred splenic memory CD8 T cells traffic to the airways and promote lung SARS-CoV-2 clearance. These findings provide insights into the critical role of memory T cells in preventing severe lung disease following breakthrough infections with antibody-evasive SARS-CoV-2 variants.

Safety of COVID-19 Vaccines among Patients with Type 2 Diabetes Mellitus: Real-World Data Analysis (Diabetes Metab J 2023;47:356-65).

Frequency And Factors Associated With Adverse Reactions After Administration of Inactivated COVID-19 Vaccine Among Health Workers. BACKGROUND: The 2019 coronavirus (COVID-19) has precipitated a significant public health crisis. Our study aimed to evaluate the prevalence and risk factors associated with adverse reactions to the inactivated CoronaVac vaccine. METHODS: The study involved voluntary health workers who received CoronaVac vaccine. We documented the sociodemographic information of 2,019 participants who volunteered for our study. Of these, 1,964 and 1,702 participants were interviewed by phone 1 month after the first and second dose, respectively, during which they were queried about any adverse reactions. RESULTS: Within the first week after the first dose, adverse reactions were observed in 856 (43.3%) participants, with 133 (6.7%) experiencing them during the second week, and 96 (4.9%) people at the end of the first month. For the second dose, 276 individuals (16.2%) reported adverse reactions. The prevalence of both local and systemic adverse events ranged from 9.5-11.2% overall. Fatigue was the most common adverse reaction overall, while pain at the injection site was the most frequent local adverse reaction.

CONCLUSIONS: The evaluation of both systemic and local side effects revealed no significant adverse reactions to the inactivated CoronaVac vaccine (Sinovac Life Sciences, Beijing, China). Our study found that the incidence of systemic and local adverse responses to the CoronaVac vaccination was lower than the rates reported in studies involving the recombinant adenovirus type-5, BNT162b1, and ChAdOx1nCoV-19 COVID-19 vaccines, all of which underwent the World Health Organization LULUC/PQ evaluation process.

Risk Factors for Not Completing a 2-Dose Primary Series of Messenger RNA COVID-19 Vaccination in a Large Health Care System in Southern California: Retrospective Cohort Study. BACKGROUND: COVID-19 vaccination is crucial in combating the COVID-19 pandemic. Messenger RNA COVID-19 vaccines were initially authorized as a 2-dose primary series and have been widely used in the United States; completing the 2-dose primary series offers protection against infection, severe illness, and death. Understanding the risk factors for not completing the 2-dose primary series is critical to evaluate COVID-19 vaccination programs and promote completion of the 2-dose primary series. OBJECTIVE: This study examined potential risk factors for not completing a 2-dose primary series of mRNA COVID-19 vaccination. METHODS: We conducted a retrospective cohort study among members aged â‰¥18 years from a large integrated health care system, Kaiser Permanente Southern California, from December 14, 2020, to June 30, 2022. Noncompletion of the 2-dose primary series was defined as not completing the second dose within 6 months after receipt of the first dose. Crude noncompletion rates were estimated overall and by demographic characteristics, health care use patterns, comorbidity, and community-level socioeconomic factors. A Poisson regression model was fit to examine associations of individual-level and community-level risk factors with noncompletion of the 2-dose primary series. RESULTS: Among 2.5 million recipients of â‰¥1 dose of mRNA COVID-19 vaccines, 3.3% (n=81,202) did not complete the second dose within 6 months. Members aged 25-44 years, 65-74 years, and â‰¥75 years were less likely to not complete the 2-dose primary series than those aged 18-24 years, while members aged 45-64 years were more likely to not complete the 2-dose primary series (adjusted risk ratio [aRR] 1.13, 95% CI 1.10-1.15). Male sex was associated with a higher risk of noncompletion (aRR 1.17, 95% CI 1.15-1.19). Hispanic and non-Hispanic Black race/ethnicity were associated with a lower risk of noncompletion (range aRR 0.78-0.91). Having Medicaid and prior influenza vaccination were associated with a higher risk of noncompletion. Having SARS-CoV-2 infection, experiencing an adverse event, or having an inpatient and emergency department visit during the minimum recommended dose intervals were associated with a higher risk of not completing the 2-dose primary series (aRR 1.98, 95% CI 1.85-2.12; 1.99, 95% CI 1.43-2.76; and 1.85, 95% CI 1.77-1.93, respectively). Those who received the first dose after June 30, 2021, were more likely to not complete the 2-dose primary series within 6 months of receipt of the first dose. CONCLUSIONS: Despite limitations such as being a single-site study and the inability to consider social factors such as employment and vaccine attitudes, our study identified several risk factors for not completing a 2-dose primary series of mRNA vaccination, including being male; having Medicaid coverage; and experiencing SARS-CoV-2 infection, adverse events, or inpatient and emergency department visits during the minimum recommended dose intervals. These findings can inform future efforts in developing effective strategies to enhance vaccination coverage and improve the completion rate of necessary doses.

Acute and Chronic Demyelinating Polyneuropathy post AstraZeneca Covid-19 Vaccine.

Migraine worsening after COVID-19 and COVID-19 vaccination: Are we facing a nocebo effect? BACKGROUND AND PURPOSE: In clinical practice patients may report migraine worsening as a consequence of COVID-19 (either infection or vaccines), however, data in this area are lacking. We aimed to investigate the link between COVID-19 and COVID-19 vaccination with migraine worsening and its associated factors. METHODS: An online survey was sent to migraine patients followed up in a

Spanish Headache Clinic, collecting demographic data, and information regarding SARS-CoV-2 infection and vaccination. We asked patients if they had noticed worsening of their migraine after these events and assessed concerns about infection, vaccination and migraine worsening. We also extracted data from participants' own electronic diaries (e-diaries), including 1-month data before and after their reported infection and/or vaccination. We compared participants who self-reported migraine worsening since infection or vaccination with those who did not. RESULTS: Of 550 participants, 44.9% (247/550) reported having had COVID-19 at least once and 83.3% (458/550) had been vaccinated. Sixty-one patients reported migraine worsening since COVID-19 and 52 since the vaccination. Among the risk factors for perceived migraine worsening in the two settings (infection and vaccination) was concern about migraine worsening itself (infection: odds ratio [OR] 2.498 [95% CI: 1.02-6.273], pâ€‰=â€‰0.046; vaccination: OR 17.3 [95% CI: confidence interval 5.3-68], pâ€‰<â€‰0.001). e-diary information was available for 136 of the 550 patients, 38.2% (52/136) for COVID-19 and 39.7% (54/136) for vaccination. We observed no significant difference in headache frequency 1â€‰month before and after infection or vaccination, even when comparing patients with and without self-reported migraine worsening. CONCLUSIONS: Our preliminary data point to a negligible role of the infection and vaccination on migraine worsening and to the possible presence of a nocebo effect in these settings, as a remarkable proportion of patients had a clear perception of migraine worsening.

Case Report: Spectrum of interesting ocular manifestations following COVID-19 vaccination: a case series of real-world presentations. PURPOSE: We report the ocular findings that patients experienced after receiving the coronavirus disease 2019 (COVID-19) vaccination in three different eye centers in Malaysia. OBSERVATIONS: A total of four cases were reported. Three patients received the Pfizer-BioNTech vaccine, while the other received the Oxford AstraZeneca type. Ocular symptoms occurred after the first vaccine dose in two patients and after the second vaccine dose in the other two. Three out of four patients required active treatment for their vision complications postvaccination. The first patient had acute-onset retinal pigment epitheliitis within 3Â h of vaccination and was treated conservatively. The second patient developed unilateral choroidal neovascularization 3 days after vaccination and required intravitreal antivascular endothelial growth factor injection. The third patient presented with bilateral acute multifocal placoid pigment epitheliopathy a week after vaccination and responded to intravenous methylprednisolone. The fourth patient presented with herpes zoster infection and unilateral anterior nongranulomatous uveitis 2 weeks after vaccination and was treated with oral acyclovir and topical corticosteroids. All patients reported some amount of visual recovery. CONCLUSIONS AND IMPORTANCE: Visual symptoms and various ocular adverse events can occur following COVID-19 vaccination, which warrants further investigation and urgent intervention if necessary. We would suggest patients receiving the COVID-19 vaccination be aware of possible ocular complications and report any symptoms, regardless of severity.

Sequence of COVID-19 Vaccination and COVID-19 Infection and Their Association With the Development of Active Tuberculosis: A Case-Control Study. Introduction Information regarding the cross-risk of coronavirus disease 2019 (COVID-19) and tuberculosis (TB) is still sparse. This study aimed to identify the patterns of sequence of COVID-19 vaccination and COVID-19 infection and to explore the association between COVID-19 vaccination, COVID-19 infection, and the development of active TB. Methods It was a case-control study conducted in RSUD Dr. Iskak Hospital, Tulungagung, between October 2022 and April 2023. Active cases of TB patients were compared with non-TB controls in the same hospital, with the same age and sex. Their pattern of sequence of COVID-19 vaccination and infection was investigated. Logistic regression was used to assess the association between these key variables. Results Of 296 case-control sets, 64.2% were female. The mean Â±

standard deviation of age was 46 Â± 15.6 years. 5.7% of the cases and 6.4% of the controls had a history of COVID-19 infection, whereas 58.8% and 68.4% had been vaccinated (mostly after infection). The adjusted odds ratio (95% confidence interval) of COVID-19 infection on risk to the development of active TB was 1.45 (0.58, 3.65). Those of COVID-19 vaccination of one to four doses were 0.42 (0.17, 1), 0.98 (0.58, 1.66), 0.48 (0.25, 0.93), and 0.09 (0.01, 0.81), respectively. Conclusion It was found that there were five patterns of sequence of COVID-19 infection and COVID-19 vaccination, with the most frequent being having COVID-19 infection before COVID-19 vaccination. Our data did not support the association between COVID-19 infection and the subsequent development of active TB. On the other hand, COVID-19 vaccination has been demonstrated to increase some protection against the development of active TB.

Antigen-specific CD4(+) T cells exhibit distinct transcriptional phenotypes in the lymph node and blood following vaccination in humans. SARS-CoV-2 infection and mRNA vaccination induce robust CD4(+) T cell responses that are critical for the development of protective immunity. Here, we evaluated spike-specific CD4(+) T cells in the blood and draining lymph node (dLN) of human subjects following BNT162b2 mRNA vaccination using single-cell transcriptomics. We analyze multiple spike-specific CD4(+) T cell clonotypes, including novel clonotypes we define here using Trex, a new deep learning-based reverse epitope mapping method integrating single-cell T cell receptor (TCR) sequencing and transcriptomics to predict antigen-specificity. Human dLN spike-specific T follicular helper cells (T(FH)) exhibited distinct phenotypes, including germinal center (GC)-T(FH) and IL-10(+) T(FH), that varied over time during the GC response. Paired TCR clonotype analysis revealed tissue-specific segregation of circulating and dLN clonotypes, despite numerous spike-specific clonotypes in each compartment. Analysis of a separate SARS-CoV-2 infection cohort revealed circulating spike-specific CD4(+) T cell profiles distinct from those found following BNT162b2 vaccination. Our findings provide an atlas of human antigen-specific CD4(+) T cell transcriptional phenotypes in the dLN and blood following vaccination or infection.

Risk of Guillain-BarrÃ© Syndrome Following COVID-19 Vaccines: A Nationwide Self-Controlled Case Series Study. BACKGROUND AND OBJECTIVES: Guillain-BarrÃ© syndrome (GBS) has been inconsistently associated with some coronavirus disease 2019 (COVID-19) vaccines. We aimed to quantify the risk of GBS according to the type of COVID-19 vaccine in a large population. METHODS: Using the French National Health Data System linked to the COVID-19 vaccine database, we analyzed all individuals aged 12 years or older admitted for GBS from December 27, 2020, to May 20, 2022. We estimated the relative incidence (RI) of GBS within 1-42 days after vaccination up to the first booster dose compared with baseline periods using a self-controlled case series design. We then derived the number of cases attributable to the vaccination. Analyses were adjusted for the period and stratified by age group, sex, and for the presence of severe acute respiratory syndrome coronavirus 2 or common acute infections. RESULTS: Of 58,530,770 people aged 12 years or older, 88.8% received at least 1 COVID-19 vaccine dose and 2,229 were hospitalized for GBS during the study period. Patients had a median age of 57 years, and 60% were male patients. The RI of GBS between 1-42 days was 2.5 (95% CI 1.8-3.6) for the first dose of ChAdOx1-S and 2.4 (95% CI 1.2-5.0) for the unique dose of Ad26.COV2.S vaccine. We estimated 6.5 attributable GBS cases per million persons having received a first dose of ChAdOx1-S and 5.7 cases per million for the Ad26.COV2.S vaccine. Except for the age group of 12-49 years after the second dose of the messenger RNA (mRNA)-1273 vaccine (RI 2.6, 95% CI 1.2-5.5), none of the RI estimates were found significantly increased for the mRNA vaccines. DISCUSSION: In summary, we found increased risks of GBS after the first administration of ChAdOx1-S and Ad26.COV2.S vaccines. In this comprehensive assessment at the French population level, there was no statistically significant increase in the risk of GBS after the administration of mRNA vaccines. This is reassuring in the context of the ongoing and future use of mRNA-based booster vaccination.

COVID-19 anti immunoglobulin G antibodies serum levels among health care workers post COVID -19 vaccination: A single center study. Coronavirus disease 2019 (COVID-19) pandemic has urged the scientific community internationally to find answers in terms of therapeutics and vaccines to control the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The post vaccination immune response differs between individuals especially health care workers who are the first line of defense to combat this disease. Our aim was to measure levels of anti-IgG antibodies titer post COVID-19 vaccination among health care workers in Suez Canal University Hospital. The study included 141 healthcare workers. Of these, 54 were physicians, 80 nurses, 6 health service workers, and one security guard. We used the Roche Elecsys Anti-SARS-CoV-2 assay for serological detection of IgG. Seropositive was found in 96.5% of the participants, and 43.3% of them had evidence of the prior history of COVID-19 infection. The highest titers of IgG in sera were found in the youngest age groups (20 - <35) years with a mean of 335.1 U/ ml. Participants who received the Sinovac vaccine had the highest mean IgG titer, 354.6U/ml; followed by Sinopharm (mean 352.15 U/ml) then Pfizer and Moderna (311.7U/ml) and AstraZeneca vaccine had the least mean level (267.31U/ml). Fatigue was the most significant short side effect occurring with 34% of the participants. In conclusion, there was a significant rising in serum IgG titer post-vaccine, and better antibody response in those previously infected with COVID-19. The post-COVID-19 vaccine serum IgG titers were affected by age, prior history of COVID-19 infection, and type of vaccine while short side effects post-vaccination may be affected by age and type of the vaccine.

ST-Segment Elevation Acute Myocardial Infarction Associated to Covid-19 Vaccination in A Healthy Young Adult with Normal Coronary Arteries. Despite the beneficial effects of anti-COVID-19 vaccination, monitoring its safety has identified potential cardiac adverse events, mainly myocarditis and pericarditis. The case of a healthy 32-year-old male patient who developed acute myocardial infarction (AMI) 48 hours after the second dose of anti-COVID-19 mRNA vaccine (BNT162b2) is reported. This is the first reported case in the literature of an AMI associated to post-COVID-19 vaccination with mRNA vaccine (BNT162b2) in a healthy young adult without coronary risk factors and normal coronary arteries. Despite this adverse event, the continuation of the anti-COVID-19 vaccination campaign is encouraged due to the benefits it brings.

Immunogenicity and safety of AZD2816, a beta (B.1.351) variant COVID-19 vaccine, and AZD1222 (ChAdOx1 nCoV-19) as third-dose boosters for previously vaccinated adults: a multicentre, randomised, partly double-blinded, phase 2/3 non-inferiority immunobridging study in the UK and Poland. BACKGROUND: This study aimed to evaluate AZD2816, a variant-updated COVID-19 vaccine expressing the full-length SARS-CoV-2 beta (B.1.351) variant spike protein that is otherwise similar to AZD1222 (ChAdOx1 nCoV-19), and AZD1222 as third-dose boosters. METHODS: This phase 2/3, partly double-blinded, randomised, active-controlled study was done at 19 sites in the UK and four in Poland. Adult participants who had received a two-dose AZD1222 or mRNA vaccine primary series were randomly assigned by means of an Interactive Response Technology-Randomisation and Trial Supply Management system (1:1 within each primary-series cohort, stratified by age, sex, and comorbidities) to receive AZD1222 or AZD2816 (intramuscular injection; 5â€ˆÃ—â€ˆ10(10) viral particles). Participants, investigators, and all sponsor staff members involved in study conduct were masked to randomisation. AZD1222 and AZD2816 doses were prepared by unmasked study staff members. The primary objectives were to evaluate safety and humoral immunogenicity (non-inferiority of day-29 pseudovirus neutralising antibody geometric mean titre [GMT] against ancestral SARS-CoV-2: AZD1222 booster vs AZD1222 primary series [historical controls]; margin 0Â·67; SARS-CoV-2-seronegative participants). This study is registered with ClinicalTrials.gov, NCT04973449, and is completed. FINDINGS: Between June 27 and Sept 30, 2021, 1394 participants of the 1741 screened were randomly assigned to AZD1222 or AZD2816 following an AZD1222 (n=373, n=377) or mRNA

vaccine (n=322, n=322) primary series. In SARS-CoV-2-seronegative participants receiving AZD1222 or AZD2816, 78% and 80% (AZD1222 primary series) and 90% and 93%, respectively (mRNA vaccine primary series) reported solicited adverse events to the end of day 8; 2%, 2%, 1%, and 1% had serious adverse events and 12%, 12%, 10%, and 11% had adverse events of special interest, respectively, to the end of day 180. The primary immunogenicity non-inferiority endpoint was met: day-29 neutralising antibody GMT ratios (ancestral SARS-CoV-2) were 1Â·02 (95% CI 0Â·90-1Â·14) and 3Â·47 (3Â·09-3Â·89) with AZD1222 booster versus historical controls (AZD1222 and mRNA vaccine primary series, respectively). Responses against beta were greater with AZD2816 versus AZD1222 (GMT ratios, AZD1222, mRNA vaccine primary series 1Â·84 [1Â·63-2Â·08], 2Â·22 [1Â·99-2Â·47]). INTERPRETATION: Both boosters were well tolerated, with immunogenicity against ancestral SARS-CoV-2 similar to AZD1222 primary-series vaccination. AZD2816 gave greater immune responses against beta versus AZD1222. FUNDING: AstraZeneca.

Nirmatrelvir-Ritonavir and COVID-19 Mortality and Hospitalization Among Patients With Vulnerability to COVID-19 Complications. IMPORTANCE: Postmarket analysis of individuals who receive nirmatrelvir and ritonavir (Paxlovid [Pfizer]) is essential because they differ substantially from individuals included in published clinical trials. OBJECTIVE: To examine the association of nirmatrelvir and ritonavir with prevention of death or admission to hospital in individuals with different risks of complications from COVID-19 infection. DESIGN, SETTING, AND PARTICIPANTS: This is a cohort study of adult patients in British Columbia, Canada, between February 1, 2022, and February 3, 2023. Patients were eligible if they belonged to 1 of 4 higher-risk groups of individuals who received priority for COVID-19 vaccination. Two groups included clinically extremely vulnerable (CEV) people who were severely (CEV1) or moderately immunocompromised (CEV2). CEV3 individuals were not immunocompromised but had medical conditions associated with a high risk for complications from COVID-19. A fourth expanded eligibility (EXEL) group was added to allow wider access to nirmatrelvir and ritonavir for certain other higher-risk individuals who were not in a CEV group, such as those older than 70 years who were unvaccinated. EXPOSURES: Patients with COVID-19 who received nirmatrelvir and ritonavir were matched to patients in the same vulnerability group; who were of the same sex, age, and propensity score for nirmatrelvir and ritonavir treatment; and who were also infected within 1 month of the individual treated with nirmatrelvir and ritonavir. MAIN OUTCOMES AND MEASURES: The primary outcome was death from any cause or emergency hospitalization with COVID-19 within 28 days. RESULTS: There were 6866 individuals included in the study, of whom 3888 (56.6%) were female and whose median (IQR) age was 70 (57-80) years. Compared with unexposed controls, treatment with nirmatrelvir and ritonavir was associated with statistically significant relative reductions in the primary outcome in the CEV1 group (560 patients; risk difference [RD], -2.5%, 95% CI, -4.8% to -0.2%) and the CEV2 group (2628 patients; RD, -1.7%; 95% CI, -2.9% to -0.5%). In the CEV3 group, the RD was -1.3%, but the findings were not statistically significant (2100 patients; 95% CI, -2.8% to 0.1%). In the EXEL group, treatment was associated with higher risk of the outcome (RD, 1.0%), but the findings were not statistically significant (1578 patients; 95% CI, -0.9% to 2.9%). CONCLUSIONS AND RELEVANCE: In this cohort study of 6866 individuals in British Columbia, nirmatrelvir and ritonavir treatment was associated with reduced risk of COVID-19 hospitalization or death in CEV individuals, with the greatest benefit observed in severely immunocompromised individuals. No reduction in the primary outcome was observed in lower-risk individuals, including those aged 70 years or older without serious comorbidities.

Clinical outcome of breakthrough COVID-19 in multiple myeloma patients after three or more anti-SARS-CoV-2 vaccine doses: a single center analysis of 64 cases.

National prevalence and socioeconomic factors associated with the acceptance of COVID-19 vaccines in South Korea: a large-scale representative study in 2021. OBJECTIVE: Among the global efforts

toward preventing the COVID-19 pandemic, vaccines are a pivotal factor in ending the pandemic. Thus, through a large-scale population-based study, we investigated the individual-, social-, and family-associated factors affecting the acceptance of COVID-19 vaccines in South Korea. PATIENTS AND METHODS: Data were obtained from a nationwide representative study (Korea Community Health) conducted in 2021. To determine the individual-, social-, and family-associated variables for COVID-19 vaccination acceptance, we investigated data from 225,319 individuals. RESULTS: In the total sample (n=225,319), 184,529 COVID-19-vaccinated people and 40,790 non-vaccinated people were evaluated. The factors related to the acceptance of COVID-19 vaccination were significantly associated with the demographic factors, namely, older age group, female sex, and a history of influenza vaccination, as well as medical conditions such as diabetes, hypertension, and depression. Socioeconomic conditions influencing the acceptance of COVID-19 vaccination were significantly associated with low-income families and blue-collar workers. Health-related risk factors were high in the obese group. However, a noteworthy negative association was found between the acceptance of vaccination and smoking habits and alcohol consumption. Conversely, a positive association was observed between academic level and vaccination acceptance. CONCLUSIONS: Our findings suggest that old age, female sex, a history of influenza vaccination, medical conditions, such as diabetes, hypertension, and depression, low-income families, blue-collar workers, and health-related risk factors, such as obesity, were associated with the acceptance of COVID-19 vaccination. Additionally, a high academic level, absence of smoking habits, and non-current alcohol use were positively associated with vaccine acceptance.

Guillain-BarrÃ© Syndrome Following the mRNA COVID-19 Vaccination: Comment. Dear Editor, we would like to share ideas on the publication "Guillain-BarrÃ© Syndrome Following the BNT162b2 mRNA COVID-19 Vaccine [1]." In order to advance our understanding of this consequence, Algahtani et al. describe a case of Guillain-BarrÃ© syndrome following the first dose of the BNT162b2 mRNA COVID-19 vaccination [1]. Guillain-BarrÃ© syndrome following COVID-19 vaccination is treatable, according to Algahtani et al. [1]. The advantages of providing the vaccination exceed the dangers, according to Algahtani et al. [1]. Algahtani and co. mentioned Given the detrimental effects of COVID-19, it is crucial to be aware of the emergence of any potential neurological side effects after immunization, such as Guillain-BarrÃ© syndrome [1]. We can all agree that COVID-19 prevention is essential and that additional research is required to address the underlying clinical problem. The outcome of a vaccination test and the development of a clinical condition may be related. Prior to treating the clinical issues caused by COVID-19 vaccination, a few crucial aspects need to be taken into account Comorbidities should be taken into account first. For instance, when the sickness and the clinical state co-occur, dengue vaccinations may be employed. Early detection of asymptomatic COVID-19 individuals is crucial [2]. It's likely that prior COVID-19 epidemics affected the effectiveness and outcomes of the immunization. Infection with COVID-19 may have an impact on clinical outcomes. Without the necessary laboratory testing, it can be difficult to completely rule out an illness that was previously asymptomatic. A significant auxiliary influence is genetics [3]. The immune system's reaction to specific hereditary features may have an impact on how it reacts to the negative side effects of vaccination. Understanding how underlying genetic variables affect vaccine efficacy in clinical settings would be highly beneficial. In fact, more research is required to find a solution to this problem. The volume of clinical information needed will aid in researchers' knowledge.

SARS-CoV-2 mRNA vaccination induces an intranasal mucosal response characterized by neutralizing antibodies. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine-induced systemic antibody profiles are well characterized; however, little is known about whether intranasal mucosal antibodies are induced or can neutralize virus in response to mRNA vaccination. OBJECTIVE: We sought to evaluate intranasal mucosal antibody production with SARS-

CoV-2 mRNA vaccination. METHODS: SARS-CoV-2-specific IgG and IgA concentrations and neutralization activity from sera and nasal mucosa via nasal epithelial lining fluid (NELF) collection were measured in SARS-CoV-2 mRNA-vaccinated healthy volunteers (NÂ = 29) by using multiplex immunoassays. Data were compared before and after vaccination, between mRNA vaccine brands, and by sex. RESULTS: SARS-CoV-2 mRNA vaccination induced an intranasal immune response characterized by neutralizing mucosal antibodies. IgG antibodies displayed greater Spike 1 (S1) binding specificity than did IgA in serum and nasal mucosa. Nasal antibodies displayed greater neutralization activity against the receptor-binding domain than serum. Spikevax (Moderna)-vaccinated individuals displayed greater SARS-CoV-2-specific IgG and IgA antibody concentrations than did Comirnaty (BioNTech/Pfizer)-vaccinated individuals in their serum and nasal epithelial lining fluid. Sex-dependent differences in antibody response were not observed. CONCLUSION: SARS-CoV-2 mRNA vaccination induces a robust systemic and intranasal antibody production with neutralizing capacity. Spikevax vaccinations elicit a greater antibody response than does Comirnaty vaccination systemically and intranasally.

New-onset chronic spontaneous urticaria post-COVID-19 vaccination-South African case series. BACKGROUND: Chronic spontaneous urticaria (CSU) is defined as the spontaneous occurrence of hives, angioedema, or both for more than 6 weeks; several inciting triggers including vaccines have been implicated. Coronavirus disease 2019 (COVID-19) vaccinations have been well tolerated by patients with CSU. However, reports have emerged of CSU triggered by COVID-19 vaccination and this study describes a South African case series. OBJECTIVE: To provide details of the first case series of new-onset CSU post-COVID-19 vaccination in Africa and summarize the global literature of reported cases to date. METHODS: All patients referred to our Urticaria Center of Excellence in Cape Town from the initiation of the COVID-19 vaccine rollout in South Africa (from February 2021 to August 2022) were reviewed to identify patients who developed new-onset CSU within 12 weeks of receiving a COVID-19 vaccine. Medical history, physical examinations, and laboratory investigations were reviewed. RESULTS: More than 20 million adults received COVID-19 vaccinations in South Africa during the study period. Eight patients had new-onset chronic urticaria post-COVID-19 vaccination; 6 of the 8 patients were female, the median age was 41 years (interquartile range [IQR], 38-44), and all had a history of atopy. Only 1 reported COVID-19 infection post vaccination. Chronic urticaria occurred following Pfizer-BioNTech, AstraZeneca, and Janssen Ad26.COV2.S vaccination in 6, 1, and 1 patient, respectively, with a median of 12 days (IQR, 3-38) from vaccination to symptoms onset. The baseline median score for Urticarial Activity Score 7 was 34 (IQR, 29-40), and 5 of the 8 patients (63%) had a total IgE level of more than 43 IU/L. All patients received high-dose antihistamines, with only 3 patients controlled. CONCLUSIONS: New-onset CSU can rarely be triggered by COVID-19 vaccinations, most commonly mRNA vaccines. COVID-19 vaccine-triggered CSU appears to have a phenotype similar to that triggered by other inciting agents and across populations.

Development of Peptic Ulcer following Second Shot of Sputnik V Vaccine: A Case Report and Literature Review of Rare Side Effects of Sputnik V Vaccine. Considering the global spread of the coronavirus disease 2019 (COVID-19), it is expected that vaccination against its causative agent, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), will reduce the related morbidity and mortality. However, the safety of the COVID-19 vaccines and their potential and unknown side effects are a matter of concern. With the ongoing development and implementation of COVID-19 vaccination programs around the world, the side effects, safety, and effectiveness of these vaccines are gradually being reported, providing researchers with valuable information that can affect the production and utilization of the COVID-19 vaccines. The present study intended to report a case of peptic ulcer disease (PUD) development following vaccination with Gam-COVID-Vac, a vector-based COVID-19 vaccine containing two recombinant human adenoviruses (rAd26 and rAd5).

Nephrotic Syndrome with Acute Kidney Injury after Covaxin (BBV152) COVID-19 Vaccination: A Case from India.

Anti-GAD antibody-positive fulminant type 1 diabetes developed following SARS-CoV-2 vaccination. Vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been used worldwide since the 2020 coronavirus pandemic. However, several negative side-effects of these vaccines have been reported. Herein, we present a case of a patient with fulminant type 1 diabetes that developed shortly after administration of the SARS-CoV-2 vaccine. A 47-year-old man with no medical history presented with hyperglycemia-related symptoms shortly after receiving the third messenger ribonucleic acid SARS-CoV-2 vaccine. Based on hyperglycemia, diabetic ketoacidosis at onset, relatively low hemoglobin A1c levels, and complete depletion of endogenous insulin secretion, the patient was diagnosed with fulminant type 1 diabetes and insulin therapy was initiated. Through human leukocyte antigen genotyping, the disease-susceptible alleles for type 1 diabetes, DRB1*04:05 and DQB1*04:01, were identified. The patient tested positive for serum anti-glutamic acid decarboxylase antibodies, which are normally negative for fulminant type 1 diabetes, implying that immunomodulation triggered by SARS-CoV-2 vaccination influenced the onset of type 1 diabetes.

15-month post-COVID syndrome in outpatients: Attributes, risk factors, outcomes, and vaccination status - longitudinal, observational, case-control study. BACKGROUND: While the short-term symptoms of post-COVID syndromes (PCS) are well-known, the long-term clinical characteristics, risk factors and outcomes of PCS remain unclear. Moreover, there is ongoing discussion about the effectiveness of post-infection vaccination against severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) to aid in PCS recovery. METHODS: In this longitudinal and observational case-control study we aimed at identifying long-term PCS courses and evaluating the effects of post-infection vaccinations on PCS recovery. Individuals with initial mild COVID-19 were followed for a period of 15 months after primary infection. We assessed PCS outcomes, distinct symptom clusters (SC), and SARS-CoV-2 immunoglobulin G (IgG) levels in patients who received SARS-CoV-2 vaccination, as well as those who did not. To identify potential associating factors with PCS, we used binomial regression models and reported the results as odds ratios (OR) with 95% confidence intervals (95%CI). RESULTS: Out of 958 patients, follow-up data at 15 month after infection was obtained for 222 (23.2%) outpatients. Of those individuals, 36.5% (81/222) and 31.1% (69/222) were identified to have PCS at month 10 and 15, respectively. Fatigue and dyspnea (SC2) rather than anosmia and ageusia (SC1) constituted PCS at month 15. SARS-CoV-2 IgG levels were equally distributed over time among age groups, sex, and absence/presence of PCS. Of the 222 patients, 77.0% (171/222) were vaccinated between 10- and 15-months post-infection, but vaccination did not affect PCS recovery at month 15. 26.3% of unvaccinated and 25.8% of vaccinated outpatients improved from PCS (p= .9646). Baseline headache (SC4) and diarrhoea (SC5) were risk factors for PCS at months 10 and 15 (SC4: OR 1.85 (95%CI 1.04-3.26), p=.0390; SC5: OR 3.27(95%CI 1.54-6.64), p=.0009). CONCLUSION: Based on the specific symptoms of PCS our findings show a shift in the pattern of recovery. We found no effect of SARS-CoV-2 vaccination on PCS recovery and recommend further studies to identify predicting biomarkers and targeted PCS therapeutics.

Comparison of Antibody Responses After CoronaVac and BNT162b2 Vaccines in Healthcare Workers. Since the initial outbreak in late December 2019, the coronavirus disease 2019 (COVID-19) pandemic has become a significant healthcare issue worldwide. Despite patients getting the total recommended doses of the COVID-19 vaccine, it is still unable to stop the spread of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Our study aimed to evaluate the antibody response in the 3rd month after two doses of the CoronaVac vaccine and after a single dose of the BNT162b2 vaccine. One hundred thirty-five people from Tarsus State Hospital health workers were included in the study. We collected serum samples from healthcare workers 3Â months post-

vaccination, and the Anti-SARS-CoV-2 Quanti-Vac ELISA IgG kit coated with recombinant S1 antigen was used to test for SARS-CoV-2 antibodies. Antibody levels of BNT162b2 (last vaccine) patients are significantly higher than CoronaVac ones (pâ€‰<â€‰0.05). It was determined that those who do not have a concomitant disease and those who do not smoke have higher antibody levels after CoronaVac than the others (pâ€‰<â€‰0.05). It was determined that 53.1% of 32 patients with pain, swelling, redness at the vaccination site after CoronaVac did not have pain/swelling/redness at the vaccination site after BNT162b2 (pâ€‰<â€‰0.05). Headache was also more common after CoronaVac compared to the BNT162b2 vaccine (pâ€‰<â€‰0.05). In conclusion, IgG seropositivity was lower after CoronaVac than BNT162b2, and the antibody level for CoronaVac recipients has decreased over time since vaccination, but not for BNT162b2 recipients.

Dermatomyositis Flare-Up Following the SARS-CoV-2 Vaccine: A Case Report and Literature Review. Dermatomyositis is a rare auto-immune inflammatory myopathy of unknown etiology. Several environmental factors, including vaccines, have been identified as potential triggers in genetically susceptible individuals. Since the beginning of the coronavirus disease 2019 (COVID-19) pandemic, the development of vaccines (mRNA and vector-based) has been the most effective tool in reducing the incidence, hospitalization rates, and mortality of COVID-19. However, among individuals with immune dysregulation and auto-immune conditions, unique challenges may arise with immune stimulation. We present a case of a dermatomyositis flare-up following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. A 40-year-old Hispanic female presented to the emergency department with shortness of breath, muscle pain and weakness, and skin rash for two days. She had been recently diagnosed with dermatomyositis six months prior based on clinical presentation, laboratory investigations, and characteristic muscle biopsy findings. She had been on treatment with mycophenolate mofetil, prednisone, and hydroxychloroquine since. She reported receiving the second dose of the BNT162b2 COVID-19 vaccine one day prior to the onset of symptoms. Physical examination revealed erythematous plaques over her cheeks, upper chest, and arms, in addition to GottronÂ papules on her hands. She had reduced proximal muscle strength and scattered dry crackles bilaterally on lung auscultation. Her laboratory investigations were remarkable for elevated erythrocyte sedimentation rate, C-reactive peptide, creatinine kinase, and troponin T. The SARS- CoV-2 PCR test was negative. CT scan of the chest showed evidence of pneumonitis. A diagnosis of the dermatomyositis flare-up potentially secondary to the SARS-CoV-2 BNT162b2 vaccine was established. The patient was admitted and treated with pulse steroids and intravenous immunoglobulin. She responded well to therapy and was discharged home four days later. There have been several reports of a new onset of dermatomyositis following the SARS-CoV-2 vaccine which highlights the need for further large-scale studies to estimate the prevalence of such adverse effects. The benefits of the SARS-CoV-2 vaccine outweigh the risks even among patients with auto-immune and rheumatologic conditions; however, it is important for clinicians to recognize the possibility of occurrence of such events in order to manage patients appropriately.

Comparison of the Serial Humoral Immune Response according to the Immunosuppressive Treatment after SARS-CoV-2 mRNA Vaccination. Objective The objective of this study was to estimate the humoral immune response evaluated by immunoglobulin G (IgG) against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike receptor-binding domain (RBD-IgG) following the third mRNA coronavirus disease 2019 (COVID-19) vaccination in patients with kidney disease who received immunosuppressive treatment. Methods The primary outcome was RBD-IgG levels after the third SARS-CoV-2 vaccination. The primary comparison was the RBD-IgG levels between patients with kidney disease who received immunosuppressive treatment (n=124) and those who did not (n=33). Results The RBD-IgG levels were significantly lower in the patients with kidney disease who received immunosuppressive treatment than in those who did not receive immunosuppressive treatment. The

RBD-IgG levels were lower in patients treated with glucocorticoid monotherapy than in those who did not receive immunosuppressive treatment. Even in patients who received â‰¤5 mg prednisolone, the RBD-IgG levels were significantly lower. Nine of the 10 patients who received rituximab within one year before the first vaccination did not experience seroconversion after the third vaccination. Meanwhile, all nine patients who received rituximab only after the second vaccination experienced seroconversion, even if B cell recovery was insufficient. Patients treated with mycophenolate mofetil plus glucocorticoid plus belimumab had significantly lower RBD-IgG levels than those treated with mycophenolate mofetil plus glucocorticoid. Conclusion The RBD-IgG levels were lower in patients with kidney disease who received immunosuppressive treatment than in those who did not receive immunosuppressive treatment. Low-dose glucocorticoid monotherapy affected the humoral immune response following the third mRNA COVID-19 vaccination.

Disease Flares Following COVID-19 Vaccination in Patients with Inflammatory Bowel Disease. Objective Flares of inflammatory bowel disease (IBD) can occur infrequently after vaccination for coronavirus disease 2019 (COVID-19), although the details of this phenomenon are poorly understood. To clarify the possibility of an unfavorable response in patients with IBD, we investigated IBD-related symptoms during the COVID-19 vaccination. Methods Between October 2021 and February 2022, we obtained the COVID-19 vaccination status of 411 IBD patients who were being treated at our institution. The disease course of IBD after vaccination was investigated in 188 patients with ulcerative colitis (UC) and 119 patients with Crohn's disease (CD) who had received at least one dose of the vaccine during the clinical remission phase. The baseline characteristics before vaccination were compared between the patients with UC with or without disease flares. Results During the 30-day follow-up period, eight patients with UC (4.3%) and one patient with CD (0.8%) experienced disease flares following vaccination. Disease flares occurred after the first vaccination in six patients and after the second vaccination in three patients. As for the timing of onset of disease flares, eight events (88.9%) occurred within one week of vaccination. Two patients required hospitalization, and one patient with CD required surgery for an intra-abdominal abscess. The baseline characteristics did not significantly differ between patients with UC who experienced flares and those who did not. Conclusion IBD flares following COVID-19 vaccination are rare and vaccination should therefore be recommended for patients with IBD. However, the possibility of disease flares should be considered for approximately one week after each vaccination, especially in patients with UC.

What do children aged 12-18 think about COVID-19 vaccines? OBJECTIVES: Vaccines are crucial for preventing the spread of the coronavirus pandemic and controlling its effects. We aimed to determine the desire of children aged 12-18 to be vaccinated with the current vaccines, the reasons for wanting or not wanting to be vaccinated, where they had learned about the vaccine, how many of the children with a history of chronic disease want to be vaccinated, and which factors affect them. METHODS: A questionnaire form was completed for children aged 12-18 years who applied to Gazi University Pediatric Emergency Department and the Child Health and Diseases Polyclinic between April 1, 2022, and September 30, 2022. RESULTS: A total of 924 children participated in the study. The mean age of the participants was 14.64Â±1.77 years. The willingness to be vaccinated was 83.1%. Being older, living in the city, having a mother, father, or sibling who was vaccinated, information about vaccines obtained from health personnel, a completed national vaccination program, and the presence of a first-degree relative in the healthcare field significantly increased the probability of the child being vaccinated. The most important factors affecting the desire to be vaccinated in children were the vaccination status of the mother, father, or sibling and the completed national vaccination program. CONCLUSION: We found that the immunization status of the parents is the most important

factor guiding the child's desire to be vaccinated and that the most common reason for vaccine hesitancy is the side effects of the vaccine.

SARS-CoV-2 infection following booster vaccination: Illness and symptom profile in a prospective, observational community-based case-control study. BACKGROUND: Booster COVID-19 vaccines have shown efficacy in clinical trials and effectiveness in real-world data against symptomatic and severe illness. However, some people still become infected with SARS-CoV-2 following a third (booster) vaccination. This study describes the characteristics of SARS-CoV-2 illness following a third vaccination and assesses the risk of progression to symptomatic disease in SARS-CoV-2 infected individuals with time since vaccination. METHODS: This prospective, community-based, case-control study used data from UK-based, adult (â‰¥18 years) users of the COVID Symptom Study mobile application, self-reporting a first positive COVID-19 test between June 1, 2021 and April 1, 2022. To describe the characteristics of SARS-CoV-2 illness following a third vaccination, we selected cases and controls who had received a third and second dose of monovalent vaccination against COVID-19, respectively, and reported a first positive SARS-CoV-2 test at least 7 days after most recent vaccination. Cases and controls were matched (1:1) based on age, sex, BMI, time between first vaccination and infection, and week of testing. We used logistic regression models (adjusted for age, sex, BMI, level of social deprivation and frailty) to analyse associations of disease severity, overall disease duration, and individual symptoms with booster vaccination status. To assess for potential waning of vaccine effectiveness, we compared disease severity, duration, and symptom profiles of individuals testing positive within 3 months of most recent vaccination (reference group) to profiles of individuals infected between 3 and 4, 4-5, and 5-6 months, for both third and second dose. All analyses were stratified by time period, based on the predominant SARS-CoV-2 variant at time of infection (Delta: June 1, 2021-27 Nov, 2021; Omicron: 20 Dec, 2021-Apr 1, 2022). FINDINGS: During the study period, 50,162 (Delta period) and 162,041 (Omicron) participants reported a positive SARS-CoV-2 test. During the Delta period, infection following three vaccination doses was associated with lower odds of long COVID (symptomsâ‰¥ 4 weeks) (OR=0.83, CI[0.50-1.36], pÂ <Â 0.0001), hospitalisation (OR=0.55, CI[0.39-0.75], pÂ <Â 0.0001) and severe symptoms (OR=0.36, CI[0.27-0.49], pÂ <Â 0.0001), and higher odds of asymptomatic infection (OR=3.45, CI[2.86-4.16], pÂ <Â 0.0001), compared to infection following only two vaccination doses. During the Omicron period, infection following three vaccination doses was associated with lower odds of severe symptoms (OR=0.48, CI[0.42-0.55], pÂ <Â 0.0001). During the Delta period, infected individuals were less likely to report almost all individual symptoms after a third vaccination. During the Omicron period, individuals were less likely to report most symptoms after a third vaccination, except for upper respiratory symptoms e.g. sneezing (OR=1.40, CI[1.18-1.35], pÂ <Â 0.0001), runny nose (OR=1.26, CI[1.18-1.35], pÂ <Â 0.0001), sore throat (OR=1.17, CI[1.10-1.25], pÂ <Â 0.0001), and hoarse voice (OR=1.13, CI[1.06-1.21], pÂ <Â 0.0001), which were more likely to be reported. There was evidence of reduced vaccine effectiveness during both Delta and Omicron periods in those infected more than 3 months after their most recent vaccination, with increased reporting of severe symptoms, long duration illness, and most individual symptoms. INTERPRETATION: This study suggests that a third dose of monovalent vaccine may reduce symptoms, severity and duration of SARS-CoV-2 infection following vaccination. For Omicron variants, the third vaccination appears to reduce overall symptom burden but may increase upper respiratory symptoms, potentially due to immunological priming. There is evidence of waning vaccine effectiveness against progression to symptomatic and severe disease and long COVID after three months. Our findings support ongoing booster vaccination promotion amongst individuals at high risk from COVID-19, to reduce severe symptoms and duration of illness, and health system burden. Disseminating knowledge on expected symptoms following booster vaccination may encourage vaccine uptake.

Evaluating the role of COVID-19 vaccines in the landscape of medication-induced alopecia areata.
25-Hydroxyvitamin D concentrations do not affect the humoral or cellular immune response following SARS-CoV-2 mRNA vaccinations. BACKGROUND: To improve effectiveness of vaccination against SARS-CoV-2, it is important to identify factors that influence the immune response induced by vaccination. Evidence for the role of vitamin D in immune response against SARS-CoV-2 is contradictory. It is therefore of interest whether 25-hydroxyvitamin D (25[OH]D) concentrations affect the humoral and/or cellular response following SARS-CoV-2 vaccination. METHODS: In this prospective cohort study, blood samples were collected from 98 SARS-CoV-2 naive health care workers (HCW) receiving the first two doses of either BNT162b2 or mRNA-1273 in 2021. Wild-type spike (S) protein binding and neutralizing antibodies were determined approximately three weeks after the first dose and four to five weeks after the second dose. Antigen specific T-cells and functionality (proliferative response and interferon gamma [IFN-Î³] release) were determined in 18 participants four weeks after the second dose of BNT162b2. We studied the association between 25(OH)D concentrations, which were determined prior to vaccination, and humoral and cellular immune responses following vaccination. RESULTS: We found no association between 25(OH)D concentrations (median 55.9Â nmol/L [IQR 40.5-69.8]) and binding or neutralizing antibody titers after complete vaccination (fold change of antibody titers per 10Â nmol/L 25(OH)D increase: 0.98 [95% CI 0.93-1.04] and 1.03 [95% CI: 0.96-1.11], respectively), adjusted for age, sex and type of mRNA vaccine. Subsequently, continuous 25(OH)D concentrations were divided into commonly used clinical categories (<25Â nmol/L [nÂ =Â 6, 6%], 25-49Â nmol/L [nÂ =Â 33, 34%], 50-75Â nmol/L [nÂ =Â 37, 38%] andÂ â‰¥75Â nmol/L [nÂ =Â 22, 22%]), but no association with the humoral immune response following vaccination was found. Also, 25(OH)D concentrations were not associated with the SARS-CoV-2 specific T cell response. CONCLUSION: No association was found between 25(OH)D concentrations and the humoral or cellular immune response following mRNA vaccination against SARS-CoV-2. Based on our findings there is no rationale to advise vitamin D optimization preceding SARS-CoV-2 vaccination in HCW with moderate vitamin D status.
SARS-CoV-2 vaccines and myocarditis. The development of safe and effective vaccines against severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) was a major turning point in the fight against the Coronavirus 2019 (COVID-19) pandemic. However, pharmacovigilance has revealed a small but significant incidence of cardiac inflammation manifesting clinically as myocarditis or pericarditis, particularly in younger vaccine recipients. The incidence is the highest among men under age 40 within a week of receiving the second dose of the mRNA vaccine. In this review, we summarise the evidence for, and guidelines in relation to, SARS-CoV2 vaccine-related myocarditis.
Overview of SARS-CoV-2 infection and vaccine associated myocarditis compared to non-COVID-19-associated myocarditis: A systematic review and meta-analysis. BACKGROUND: Previous literature suggests that both SARS-CoV-2 infection and COVID-19 mRNA vaccine are associated with myocarditis, in which the incidence is higher in the infection group. COVID-19 mRNA vaccine-related myocarditis is noted to have a more benign course. Despite these findings, there is a need for a larger population systematic review that compares the outcomes to pre-pandemic acute myocarditis to better understand the extent of the current post-COVID state. METHODS: We performed a literature search with PubMed and EMBASE and identified studies investigating COVID-19 and its vaccinated population, and the population prior to the pandemic (control group) who had myocarditis. We performed a one-group meta-analysis of the incidence, baseline demographics, and outcomes of myocarditis for each group. RESULTS: The incidence in the SARS-CoV-2 infection group was 2.76 per thousand (95% CI, 0.85-8.92), 19.7 per million (95% CI, 12.3-31.6) in the vaccine group, and 0.861 per million (95% CI, 0.04-16.7) in the control group. The majority of patients were male, with the highest proportion in the vaccine group. The mean age was the youngest in the vaccine group (24.8, 95% CI,

19.1-30.6). The vaccine group had the lowest mortality (2.0%, 95% CI, 1.3-2.7) followed by the control and the SARS-CoV-2 infection group. The vaccine group had the lowest proportion of immunoglobulin and glucocorticoid use, mechanical circulatory support, and cardiogenic shock. CONCLUSION: Our study showed favorable outcomes of myocarditis in patients with COVID-19 mRNA vaccination, despite a higher incidence than pre-COVID controls. Further studies with standardized myocarditis diagnostic criteria assessing long-term outcomes are necessary.

Increased Risk of New-Onset Asthma After COVID-19: A Nationwide Population-Based Cohort Study. BACKGROUND: Previous studies have suggested that respiratory virus infections may be associated with new-onset asthma. However, whether coronavirus disease 2019 (COVID-19) is associated with an increased risk of new-onset asthma remains unclear. OBJECTIVE: We aimed to evaluate whether recent COVID-19 increases the risk of new-onset asthma and whether COVID-19 vaccination could mitigate this risk. METHODS: We constructed 3 different study designs using the Korean National Health Insurance claim-based database: study 1: COVID-19-diagnosed subjects (COVID-19 cohort) and their matched controls; study 2: COVID-19-vaccinated subjects (vaccination cohort) and their matched controls; and study 3: vaccination cohort and their matched controls, excluding subjects diagnosed with COVID-19. RESULTS: In study 1, 1.6% of the COVID-19 cohort and 0.7% of the matched cohort developed new-onset asthma, with incidences of 31.28 and 14.55 per 1,000 person-years, respectively ($P < .001$). The COVID-19 cohort had a higher risk of new-onset asthma (adjusted hazard ratio [aHR] 2.14; 95% CI 1.88-2.45) than matched controls. In study 2, the vaccination cohort had a lower risk of new-onset asthma than the matched controls (aHR 0.82; 95% CI 0.76-0.89). However, among subjects without a COVID-19 diagnosis, COVID-19 vaccination was not associated with a reduced risk of new-onset asthma in study 3 (aHR 0.95; 95% CI 0.87-1.04). In subgroup analysis, the risk of new-onset asthma was significantly lower in fully vaccinated subjects and higher in older subjects and in those with diabetes mellitus than in their counterparts. CONCLUSIONS: The COVID-19 was associated with a higher incidence of new-onset asthma, which might be preventable by COVID-19 vaccination.

Comparison of Anti-SARS-CoV-2-Specific Antibody Signatures in Maternal and Infant Blood after COVID-19 Infection versus COVID-19 Vaccination during Pregnancy. OBJECTIVE: â€ƒThe Advisory Committee on Immunization Practices and The American College of Obstetricians and Gynecologists recommend coronavirus disease 2019 (COVID-19) vaccine for pregnant persons to prevent severe illness and death. The objective was to examine levels of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG, IgM, and IgA against spike protein receptor binding domain (RBD) and nucleocapsid protein (NCP) in maternal and infant/cord blood at delivery after COVID 19 vaccination compared with SARS-CoV-2 infection at in mother-infant dyads at specified time points. STUDY DESIGN: â€ƒMothers with SARS-CoV-2 infection (nâ€‰=â€‰31) or COVID-19 vaccination (nâ€‰=â€‰25) during pregnancy were enrolled between July 2020 and November 2021. Samples were collected at delivery and IgG, IgM, and IgA to RBD of spike and NCPs compared in the infected and vaccinated groups. Timing of infection/vaccination prior to delivery and correlation with antibody levels was performed. RESULTS: â€ƒThe majority of participants received vaccination within 90 days of delivery and over half received the Pfizer BioNTech vaccine. There were no significant correlations between antibody levels and timing of infection or vaccination. Infant IgG levels to the RBD domain of spike protein were higher in the vaccinated group (nâ€‰=â€‰25) as compared with the infants born to mothers with infection (nâ€‰=â€‰31). Vaccination against COVID-19 during pregnancy was associated with detectable maternal and infant anti-RBD IgG levels at delivery irrespective of the timing of vaccination. CONCLUSION: â€ƒTiming of vaccination had no correlation to the antibody levels suggesting that the timing of maternal vaccination in the cohort did not matter. There was no IgM detected in infants from vaccinated mothers. Infants from vaccinated mothers had robust IgG

titers to RBD, which have a lasting protective effect in infants. KEY POINTS: Â· COVID-19 vaccination during pregnancy had detectable antibody.. Â· No correlation between antibody levels and timing of vaccination.. Â· Infants from vaccinated mothers had robust IgG titers to RBD..

Postvaccination Symptoms After a Fourth Dose of mRNA SARS-CoV-2 Vaccination in Patients With Inflammatory Bowel Disease.

Antibody response in patients undergoing chronic hemodialysis post-severe acute respiratory syndrome coronavirus 2 vaccination: A prospective observational study. Vaccination is important for patients undergoing hemodialysis (HD) to prevent coronavirus disease 2019 (COVID-19) infection since they are more vulnerable. However, they exhibit a weak response to vaccines, underscoring the importance of understanding whether antibodies are sufficiently produced and their durability post-COVID-19 vaccination. This prospective observational study assessed the antibody response of Korean patients undergoing HD for 1 year. We compared the antibody responses of patients undergoing HD to the COVID-19 vaccine with those of healthy volunteers from 2021 to 2022. The patient and control groups received 2 doses of ChAdOx1 nCoV-19 and mRNA-1273, respectively. Immunoglobulin G (IgG) and neutralizing antibody levels were measured weeks or months apart after 2 doses for 1 year using enzyme-linked immunosorbent and fluorescence-based competitive severe acute respiratory syndrome coronavirus 2 neutralizing assays, respectively. We analyzed the third dose's effect on the patient group by categorizing the group into patients who received the third dose and those who did not since it was initiated midway through the study. In the control group, we enrolled participants who had completed 3 doses of mRNA-1273 since almost all participants received the third dose. Thirty-two patients undergoing HD and 15 healthy participants who received 2 doses of ChAdOx1 nCoV-19 and 3 of mRNA-1273, respectively, were enrolled. Although antibody production was weaker in the patient group than in the control group ($P < .001$), patients showed an increase in IgG levels (0.408â€‰Â±â€‰0.517 optical density (OD) pre-vaccination, 2.175â€‰Â±â€‰1.241 OD in patients with 2 doses, and 2.134â€‰Â±â€‰1.157 OD in patients with 3 doses 1 year after the second dose) and neutralizing antibodies (23â€‰Â±â€‰8% pre-vaccination, 87â€‰Â±â€‰23% in patients with 2 doses, and 89â€‰Â±â€‰18% in patients with 3 doses 1 year after the second dose) post-vaccination ($P < .001$). In the patient group, 19 patients received a third dose (BNT162b2 or mRNA-1273); however, it did not increase the antibody levels ($P = 1.000$). Furthermore, the antibodies produced by the vaccination did not wane until 1 year. Two doses of vaccination resulted in a significant antibody response in patients undergoing HD, and antibody levels did not wane until 1 year.

Between mandatory vaccination and the COVID-19 pandemic: effects on the vaccination coverage trend inÂ aÂ province of Southern Italy. BACKGROUND AND AIM: Although vaccination is considered an extraordinarily effective and safe tool for the prevention of infectious diseases, from 2013 to 2016 CVs at national level showed a downward trend, falling well below the 95% threshold recommended by the WHO to limit the circulation of viruses and bacteria in the community and to obtain the so-called herd effect in addition to the protection of individual vaccinated individuals. The aim of the study was to assess vaccination coverage data following the introduction of Law 119/2017 and in like to COVID-19 pandemic the impact on vaccination coverage. METHODS: The study was conducted from 1 October 2019 to 1 October 2022, using the OnVac programme. RESULTS: The analysis of the coverage rates of hexavalent vaccination during the entire study period shows that there was an increase in vaccinations during the two-year period 2020-2021, followed by a drastic decrease down to values below 95%. where variable coverage was noted between the two genders with higher percentages in the female sex. Contrary to expectations, 2021 did not allow the recovery of the defaulting cohorts, with a drop in coverage much higher than in previous years (with values approaching the values of 2008), not only for polio, diphtheria and tetanus, but also for measles,

mumps, rubella, chicken pox and HPV, effectively getting worse over the previous decade. CONCLUSIONS: immunization challenges need to be addressed to ensure that every child, adolescent or patient at risk is immunized, especially but not only for COVID-19.

COVID-19 vaccination-related headache showed two different clusters in the long-term course: a prospective multicenter follow-up study (COVA-Head Study). BACKGROUND: Although acute headache following COVID-19 vaccination is widely acknowledged, the long-term progression of these headaches remains poorly understood. Our objective was to identify various phenotypes of prolonged or worsened headaches associated with COVID-19 vaccination and document any changes in these phenotypes over an extended period. Additionally, we aimed to document the diverse headache presentations among patients with pre-existing primary headaches. METHODS: A multinational, prospective observational study was conducted to investigate prolonged or worsened headaches associated with COVID-19 vaccination. Questionnaires assessing COVID-19 vaccination-related headaches at three time points (initial visit, 3(rd) month follow-up, and 6th month follow-up) were developed for the study. Headache specialists/clinicians evaluated patients using these questionnaires in a prospective manner. Repeated K-means cluster analysis was performed to identify patient profiles with prolonged or worsened headaches related to COVID-19 vaccination. RESULTS: Among the 174 patients included in the study, there was a female-to-male ratio of 128 (73.6%) to 46 (26.4%). The mean age of the patient group was 45.2â€‰Â±â€‰13.3Â years, and 107 patients (61.5%) had a pre-existing history of primary headaches. Through the analysis, two major clusters were identified based on headache characteristics at each visit. During the first visit (nâ€‰=â€‰174), Cluster 1 primarily comprised patients with a history of primary headaches, frontal localization of pain, throbbing pain type, more severe headaches accompanied by symptoms such as nausea, phonophobia, photophobia, and osmophobia, and worsened by physical activity. In contrast, Cluster 2 consisted of patients with longer headache durations (over one month) and a stabbing/pressing quality of pain. Patients in Cluster 1 had a higher prevalence of migraine as the pre-existing primary headache disorder compared to Cluster 2 (90.48% vs. 68.18%, respectively; pâ€‰=â€‰0.005). CONCLUSION: The identification of two distinct phenotypes of prolonged or worsened headaches related to COVID-19 vaccination can provide valuable clinical insights. Having an awareness of the potential worsening of headaches following COVID-19 vaccination, particularly in patients with a primary headache disorder such as migraine, can help clinicians and headache experts anticipate and adjust their treatment strategies accordingly. This knowledge can aid in preplanning treatment modifications and optimize patient care.

Childhood primary angiitis of the central nervous system following COVID-19 vaccination (BNT162b2/Pfizer-BioNtech): A case report. Childhood primary angiitis of the central nervous system (cPACNS) is a vasculitis of unknown etiology that is confined to the central nervous system (CNS) and can lead to repeated cerebral infarctions if left untreated. Several cases of cPACNS after COVID-19 have been reported. Herein, we present a case of post-vaccination cPACNS. A 9-year-old healthy boy presented with persistent headache and fever after receiving the second COVID-19 vaccine (BNT162b2/Pfizer-BioNtech) dose. Brain magnetic resonance angiography (MRA) performed on the sixth day of symptom onset after vaccination revealed stenosis of the left middle cerebral artery; the patient was referred to our department on the 12th day of symptom onset. Blood tests indicated only minimal evidence of inflammation, whereas cerebrospinal fluid examination indicated pleocytosis. Brain magnetic resonance imaging (MRI) revealed vascular wall thickening and contrast enhancement of the artery with worsened stenosis. We diagnosed the patient as having cPACNS and treated him with three courses of methylprednisolone pulse therapy. The headaches and fever disappeared with improvement of vascular stenosis. The patient has been in remission for more than 1â€‰year since cPACNS onset. This is the first report of a case of cPACNS after mRNA vaccination for

COVID-19. Most previous cases of COVID-19-associated cPACNS presented with ischemic stroke. However, the present case could be treated for vasculitis prior to stroke and thus had a favorable prognosis. The mRNA vaccine for COVID-19 differs from other existing vaccines, and further accumulation of data of cases is required to determine adverse CNS reactions.

Incessant myopericarditis after mRNA vaccination requiring IL-1 receptor antagonist therapy and pericardiectomy: case report. BACKGROUND: During the COVID-19 pandemic, there has been global administration of novel mRNA vaccines that are effective in reducing the burden of COVID-19. In tandem with this administration, mRNA vaccine-associated complications have been identified. One such complication is mRNA vaccine-associated pericarditis. CASE SUMMARY: This is a case of a 40-year old male who developed clinical pericarditis 3 days after his first dose of the Pfizer-BioNtech mRNA COVID-19 vaccination. The diagnosis of mRNA vaccine-induced pericarditis was confirmed on cardiac magnetic imaging and was resistant to numerous lines of medical therapy. These included substantial simple and opioid-based analgaesia, colchicine, prednisolone, interleukin-1 receptor antagonist therapy (anakinra), and a ketamine infusion that were all titrated over the course of eight hospital admissions. Ultimately, surgical pericardiectomy was performed that resulted in a favourable outcome. DISCUSSION: This case depicts an example of incessant mRNA vaccine-associated pericarditis, a known complication of the Pfizer-BioNtech mRNA COVID-19 vaccination. There is limited evidence guiding the therapy of mRNA-induced pericarditis especially when recurrent and resistant to simple analgaesia, colchicine, and steroids. Thus, this case represents a potential framework to help future cases of incessant mRNA vaccine-induced pericarditis.

Is there an association between peri-diagnostic vaccination and clinical outcomes in COVID-19 patients? BACKGROUND: Peri-diagnostic vaccination contemporaneous with SARS-CoV-2 infection might boost antiviral immunity and improve patient outcomes. We investigated, among previously unvaccinated patients, whether vaccination (with the Pfizer, Moderna, or J&J vaccines) during the week before or after a positive COVID-19 test was associated with altered 30-day patient outcomes. METHODS: Using a deidentified longitudinal EHR repository, we selected all previously unvaccinated adults who initially tested positive for SARS-CoV-2 between December 11, 2020 (the date of vaccine emergency use approval) and December 19, 2021. We assessed whether vaccination between days -7 and +7 of a positive test affected outcomes. The primary measure was progression to a more severe disease outcome within 30 days of diagnosis using the following hierarchy: hospitalization, intensive care, or death. RESULTS: Among 60,031 hospitalized patients, 543 (0.91%) were initially vaccinated at the time of diagnosis and 59,488 (99.09%) remained unvaccinated during the period of interest. Among 316,337 nonhospitalized patients, 2,844 (0.90%) were initially vaccinated and 313,493 (99.1%) remained unvaccinated. In both analyses, individuals receiving vaccines were older, more often located in the northeast, more commonly insured by Medicare, and more burdened by comorbidities. Among previously unvaccinated patients, there was no association between receiving an initial vaccine dose between days -7 and +7 of diagnosis and progression to more severe disease within 30 days compared to patients who did not receive vaccines. CONCLUSIONS: Immunization during acute SARS-CoV-2 infection does not appear associated with clinical progression during the acute infectious period.

Polyarteritis nodosa in a patient with chronic hepatitis B following COVID-19 vaccination: a case report. Different types of vasculitis have been reported after various vaccine administrations. Recently, the coronavirus disease 2019 (COVID-19) vaccine was one of the most common vaccine-induced vasculitis. Herein, we describe a 56-year-old male patient with chronic hepatitis B who presented with abdominal pain for 2 days, which was associated with vomiting and bloody diarrhea. He had a history of petechial rash for 25Â days, multiple joint pain and lower limb weakness after the second dose of the COVID-19 vaccine. A skin biopsy showed medium-sized vessel vasculitis.

Polyarteritis nodosa (PAN) was diagnosed depending on the American College of Rheumatology criteria. He was treated with steroids, plasmapheresis and antiviral medication with a good prognosis. In patients with a past medical history of chronic hepatitis B, the covid vaccine may be associated with an increased risk of developing a PAN, so clinicians should suspect the occurrence of this disease after COVID-19 vaccination.

Endovascular treatment of cerebral sinus thrombosis due to vaccine-induced immune thrombotic thrombocytopenia. INTRODUCTION: There is little data on the role of endovascular treatment (EVT) of cerebral venous sinus thrombosis (CVST) due to vaccine-induced immune thrombotic thrombocytopenia (VITT). Here, we describe clinical characteristics and outcomes of CVST-VITT patients who were treated with EVT. PATIENTS AND METHODS: We report data from an international registry of patients who developed CVST within 28â€‰days of SARS-CoV-2 vaccination, reported between 29 March 2021 and 6 March 2023. VITT was defined according to the Pavord criteria. RESULTS: EVT was performed in 18/136 (13%) patients with CVST-VITT (92% aspiration and/or stent retrieval, 8% local thrombolysis). Most common indications were extensive thrombosis and clinical or radiological deterioration. Compared to non-EVT patients, those receiving EVT had a higher median thrombus load (4.5 vs 3). Following EVT, local blood flow was improved in 83% (10/12, 95% confidence interval [CI] 54-96). One (6%) asymptomatic sinus perforation occurred. Eight (44%) patients treated with EVT also underwent decompressive surgery. Mortality was 50% (9/18, 95% CI 29-71) and 88% (8/9, 95% CI 25-66) of surviving EVT patients achieved functional independence with a modified Rankin Scale score of 0-2 at follow-up. In multivariable analysis, EVT was not associated with increased mortality (adjusted odds ratio, 0.66, 95% CI 0.16-2.58). DISCUSSION AND CONCLUSION: We describe the largest cohort of CVST-VITT patients receiving EVT. Half of the patients receiving EVT died during hospital admission, but most survivors achieved functional independence.

Scleroderma after COVID-19 Infection and Vaccination. Scleroderma is a rare autoimmune connective tissue disorder characterized by fibrotic hardening and tightening of the skin. Scleroderma develops as a drug-induced and paraneoplastic phenomenon; however, scleroderma associated with COVID-19 has been rarely discussed. We present an updated review of scleroderma after the COVID-19 infection and vaccination. Literature searches were conducted on MEDLINE (PubMed), Embase, Scopus, and Google Scholar from 2019 to January 2023. In all, 13 studies were selected based on the subject relevance, with screening of references contained in the selected papers. As of January 2023, we had four patients with scleroderma after the COVID-19 infection (M(age) = 54.50 years; R(age) = 47-61 years; man-woman ratio = 1:3) and 10 patients with scleroderma after the COVID-19 vaccination (M(age) = 62.8 years; R(age) = 45-73 years; man-woman ratio = 1:9). Moderna's Spikevax accounted for two patients, Pfizer-BioNTech's Tozinameran accounted for seven patients, and Oxford-Astra Zeneca's Vaxzevria accounted for one patient. Hypotheses for the pathogenesis of scleroderma after the COVID-19 infection and vaccination included molecular mimicry, cytokine activation, and endothelial injury. Although the benefits of the COVID-19 vaccines still outweigh the risks, we advise clinicians to monitor for this rare potential complication.

Sequential heterologous immunization with COVID-19 vaccines induces broader neutralizing responses against SARS-CoV-2 variants in comparison with homologous boosters. The recently prevalent variants of concerns (VOCs) of SARS-CoV-2 belong to Omicron variants which display increased transmissibility and evade from immune protection generated by vaccines and/or natural infections. Better immunization strategies should be explored to induce broader immune responses against evolving SARS-CoV-2 variants. Here, we used inactivated vaccines derived from ancestral (Wu), Delta (Del) and Omicron (Omi) strains to immunize mice with homologous booster (3Â Ã—Â Wu, 3Â Ã—Â Del and 3Â Ã—Â Omi) or heterologous sequential booster (Wu/Del/Omi and Omi/Wu/Del) to evaluate their responses against two pre-Omicron (Wu and Del) and four Omicron

variants. Even though neutralization responses against Wu and Del variants were similar in heterologous and homologous immunization groups, heterologous immunization groups induced significantly stronger neutralizing antibody against BA.1 (4.1-11 folds higher) and BA.2 (4.7-14.2 folds higher) than those of homologous immunization groups. While homologous immunization only induced strong neutralizing responses to either pre-Omicron variants (Wu and Del) in 3Â Ã—Â Wu and 3Â Ã—Â Del groups or to Omicron variants (BA.1 and BA.2) in 3Â Ã—Â Omi group, heterologous immunization groups induced strong and broader neutralizing responses to both pre-Omicron (Wu, Del) and Omicron variants (BA.1 and BA.2). Homologous and heterologous immunization groups elicited similar antigen-specific T cell (IFN-Î³(+)) and B cell responses. Compared with homologous immunization, heterologous immunization could induce stronger plasma cell responses, which have the potential to generate broader and stronger neutralizing antibodies. However, neither heterologous nor homologous immunization groups induced strong neutralizing antibody against variants with bigger genetic deviation, such as BA.4/5 or BF.7, only weak neutralizing responses were induced. Surveillance on SARS-CoV2 variants evolution and immunization strategy are needed to explore better vaccines with broader and stronger neutralizing antibodies against post pandemic COVID-19.

Association between use of antipyretics and antibody titers after two doses of the BNT162b2 SARS-CoV-2 vaccine in adolescents and young adults with underlying diseases. There are few reports on the association between antipyretic use and antibody titers in adolescents and young adults following SARS-CoV-2 vaccination. Multivariable linear regression analyses were performed to examine the association between antipyretic use and antibody titers. The use of antipyretics was not associated with antibody titers (Î² coefficient [95% CI]Â =Â -0.107 [-0.438 to 0.224]).

Humoral immune response to COVID-19 mRNA vaccines in patients with relapsing multiple sclerosis treated with ofatumumab. BACKGROUND: There are limited data available regarding the impact of ofatumumab, an anti-CD20Â B-cell-depleting monoclonal antibody for relapsing multiple sclerosis (RMS), on vaccination response. The study objective was to assess humoral immune response (HIR) to non-live coronavirus disease 2019 (COVID-19) messenger RNA (mRNA) vaccination in patients with RMS treated with ofatumumab. METHODS: This was an open-label, single-arm, multicenter, prospective pilot study of patients with RMS aged 18-55 years who received 2 or 3 doses of a COVID-19 mRNA vaccine after â‰¥1 month of subcutaneous ofatumumab (20Â mg/month) treatment. The primary endpoint was the proportion of patients achieving HIR, as defined by local laboratory severe acute respiratory syndrome coronavirus-2 qualitative immunoglobulin G assays. Assay No. 1 was â‰¥14 days after the second or third vaccine dose. Assay No. 2 was 90 days thereafter. RESULTS: Of the 26 patients enrolled (median [range] age: 42 [27-54] years; median [range] ofatumumab treatment duration: 237 [50-364] days), HIR was achieved by 53.9%Â (14/26; 95% CI: 33.4Â -Â 73.4%) at Assay No. 1 and 50.0%Â (13/26; 95% CI: 29.9Â -Â 70.1%) at Assay No. 2. Patients who received 3 vaccine doses had higher HIR rates (Assay No. 1: 70.0%Â [7/10]; Assay No. 2: 77.8%Â [7/9]) than those who received 2 doses (Assay No. 1: 46.7%Â [7/15]; Assay No. 2: 42.9%Â [6/14]). Of patients aged <40 years without previous anti-CD20 therapy, HIR was achieved by 90.0%Â (9/10) at Assay No. 1 and 75.0%Â (6/8) at Assay No. 2. No serious adverse events were reported. CONCLUSION: Patients with RMS treated with ofatumumab can mount HIRs following COVID-19 vaccination. A plain language summary, infographic and a short video summarizing the key results are provided in supplementary material. CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov: NCT04847596 (https://clinicaltrials.gov/ct2/show/NCT04847596).

New-onset aplastic anemia after SARS-CoV-2 vaccination. Aplastic anemia (AA) is a rare autoimmune disease. Drugs, viruses, and radiation are among the most common etiologic factors, and most cases have immune pathophysiology. SARS-CoV-2 vaccines have been linked with rare side

effects, including cases of acquired aplastic anemia. Here we review all the reported cases of new-onset AA after SARS-CoV-2 vaccination, and discuss their clinical characteristics and management. 18 patients in these case reports had a median age of 58Â years. The time from vaccination to onset of aplastic anemia ranged from 1Â day to 7Â months, with a median of 2.5Â weeks. Seventeen patients were diagnosed with severe or very severe aplastic anemia post-vaccination and all patients received standard treatments for acquired aplastic anemia. Seventeen patients achieved a complete or partial response and only 1 patient died. Aplastic anemia can be considered a very rare SARS-CoV-2 vaccine-related adverse event, although a causative relationship has not been proven. Reporting cases of such uncommon post-vaccination events could help clinicians to consider aplastic anemia when pancytopenia is observed after vaccination. The benefits of SARS-Cov-2 vaccination are established, and reports of rare events serve only to increase awareness in daily clinical practice.

Quadriparesis with different diagnoses after COVID-19 vaccination: Case series and literature review. Following vaccination with adenoviral vector-based ChAdOx1 nCoV-19, serious neurological adverse events have been reported. Here we report two cases who presented with quadriparesis following the adenoviral vector-based ChAdOx1 nCoV-19 vaccine. A 55-year-old male patient presented with quadriparesis after 8 days of the second dose of ChAdOx1 nCoV-19 vaccination. Imaging showed features of stroke with right basilar artery thrombosis; he was started on anticoagulation following which the patient's neurological status improved and he was discharged during the 7(th) week of hospital stay. A 19-year-old male patient presented with quadriparesis after 16 days of the first dose of ChAdOx1 nCoV-19 vaccination. Cerebral spinal fluid and nerve conduction study was suggestive of Guillain-Barre syndrome (GBS). Two doses of intravenous immunoglobulin were given, following which the patient's neurological status improved and he was discharged in the 11(th) week of his hospital stay. Awareness of neurological adverse effects and emphasis on the underlying mechanism of vaccine-induced thrombotic thrombocytopenia (VITT) and molecular mimicry in patients presenting with quadriparesis following ChAdOx1 nCoV-19 vaccination is important.

Safety and Immunogenicity of Inactivated Whole Virion COVID-19 Vaccine CoviVac in Clinical Trials in 18-60 and 60+ Age Cohorts. We present the results of a randomized, double-blind, placebo-controlled, multi-center clinical trial phase I/II of the tolerability, safety, and immunogenicity of the inactivated whole virion concentrated purified coronavirus vaccine CoviVac in volunteers aged 18-60 and open multi-center comparative phase IIb clinical trial in volunteers aged 60 years and older. The safety of the vaccine was assessed in 400 volunteers in the 18-60 age cohort who received two doses of the vaccine (n = 300) or placebo (n = 100) and in 200 volunteers in 60+ age cohort all of whom received three doses of the vaccine. The studied vaccine has shown good tolerability and safety. No deaths, serious adverse events (AEs), or other significant AEs related to vaccination have been detected. The most common AE in vaccinated participants was pain at the injection site ($p < 0.05$). Immunogenicity assessment in stage 3 of Phase II was performed on 167 volunteers (122 vaccinated and 45 in Placebo Group) separately for the participants who were anti-SARS-CoV-2 nAB negative (69/122 in Vaccine Group and 28/45 in Placebo Group) or positive (53/122 in Vaccine Group and 17/45 in Placebo Group) at screening. On Day 42 after the 1st vaccination, the seroconversion rate in participants who were seronegative at screening was 86.9%, with the average geometric mean neutralizing antibody (nAB) titer of 1:20. A statistically significant ($p < 0.05$) increase in IFN-Î³ production by peptide-stimulated T-cells was observed at Days 14 and 21 after the 1st vaccination. In participants who were seropositive at screening but had nAB titers below 1:256, the rate of fourfold increase in nAB levels was 85.2%, while in the participants with nAB titers > 1:256, the rate of fourfold increase in nAB levels was below 45%; the participants who were seropositive at screening of the 2nd vaccination did not lead to a significant increase in nAB titers. In conclusion, inactivated vaccine CoviVac has shown good tolerability and safety, with over 85% NT seroconversion rates after

complete vaccination course in participants who were seronegative at screening in both age groups: 18-60 and 60+. In participants who were seropositive at screening and had nAB titers below 1:256, a single vaccination led to a fourfold increase in nAB levels in 85.2% of cases. These findings indicate that CoviVac can be successfully used both for primary vaccination in a two-dose regimen and for booster vaccination as a single dose in individuals with reduced neutralizing antibody levels.

COVID-19 Vaccines over Three Years after the Outbreak of the COVID-19 Epidemic. The outbreak of COVID-19 started in December 2019 and spread rapidly all over the world. It became clear that the development of an effective vaccine was the only way to stop the pandemic. It was the first time in the history of infectious diseases that the process of the development of a new vaccine was conducted on such a large scale and accelerated so rapidly. At the end of 2020, the first COVID-19 vaccines were approved for marketing. At the end of March 2023, over three years after the outbreak of the COVID-19 pandemic, 199 vaccines were in pre-clinical development and 183 in clinical development. The candidate vaccines in the clinical phase are based on the following platforms: protein subunit, DNA, RNA, non-replication viral vector, replicating viral vector, inactivated virus, virus-like particles, live attenuated virus, replicating viral vector combined with an antigen-presenting cell, non-replication viral vector combined with an antigen-presenting cell, and bacterial antigen-spore expression vector. Some of the new vaccine platforms have been approved for the first time for human application. This review presents COVID-19 vaccines currently available in the world, procedures for assurance of the quality and safety of the vaccines, the vaccinated population, as well as future perspectives for the new vaccine platforms in drug and therapy development for infectious and non-infectious diseases.

Stimulation of Potent Humoral and Cellular Immunity via Synthetic Dual-Antigen MVA-Based COVID-19 Vaccine COH04S1 in Cancer Patients Post Hematopoietic Cell Transplantation and Cellular Therapy. Hematopoietic cell transplantation (HCT) and chimeric antigen receptor (CAR)-T cell patients are immunocompromised, remain at high risk following SARS-CoV-2 infection, and are less likely than immunocompetent individuals to respond to vaccination. As part of the safety lead-in portion of a phase 2 clinical trial in patients post HCT/CAR-T for hematological malignancies (HM), we tested the immunogenicity of the synthetic modified vaccinia Ankara-based COVID-19 vaccine COH04S1 co-expressing spike (S) and nucleocapsid (N) antigens. Thirteen patients were vaccinated 3-12 months post HCT/CAR-T with two to four doses of COH04S1. SARS-CoV-2 antigen-specific humoral and cellular immune responses, including neutralizing antibodies to ancestral virus and variants of concern (VOC), were measured up to six months post vaccination and compared to immune responses in historical cohorts of naÃ¯ve healthy volunteers (HV) vaccinated with COH04S1 and naÃ¯ve healthcare workers (HCW) vaccinated with the FDA-approved mRNA vaccine Comirnaty(Â®) (Pfizer, New York, NY, USA). After one or two COH04S1 vaccine doses, HCT/CAR-T recipients showed a significant increase in S- and N-specific binding antibody titers and neutralizing antibodies with potent activity against SARS-CoV-2 ancestral virus and VOC, including the highly immune evasive Omicron XBB.1.5 variant. Furthermore, vaccination with COH04S1 resulted in a significant increase in S- and N-specific T cells, predominantly CD4(+) T lymphocytes. Elevated S- and N-specific immune responses continued to persist at six months post vaccination. Furthermore, both humoral and cellular immune responses in COH04S1-vaccinated HCT/CAR-T patients were superior or comparable to those measured in COH04S1-vaccinated HV or Comirnaty(Â®)-vaccinated HCW. These results demonstrate robust stimulation of SARS-CoV-2 S- and N-specific immune responses including cross-reactive neutralizing antibodies by COH04S1 in HM patients post HCT/CAR-T, supporting further testing of COH04S1 in immunocompromised populations.

Characteristics of Vaccine- and Infection-Induced Systemic IgA Anti-SARS-CoV-2 Spike Responses. Mucosal IgA is widely accepted as providing protection against respiratory infections, but stimulation

of mucosal immunity, collection of mucosal samples and measurement of mucosal IgA can be problematic. The relationship between mucosal and circulating IgA responses is unclear, however, whole blood is readily collected and circulating antigen-specific IgA easily measured. We measured circulating IgA against SARS-CoV-2 spike (S) to investigate vaccine- and infection-induced production and correlation with protection. Circulating IgA against ancestral (Wuhan-Hu-1) and Omicron (BA.1) S proteins was measured at different time points in a total of 143 subjects with varied backgrounds of vaccination and infection. Intramuscular vaccination induced circulating anti-SARS-CoV-2 S IgA. Subjects with higher levels of vaccine-induced IgA against SARS-CoV-2 S ($p = 0.0333$) or receptor binding domain (RBD) ($p = 0.0266$) were less likely to experience an Omicron breakthrough infection. The same associations did not hold for circulating IgG anti-SARS-CoV-2 S levels. Breakthrough infection following two vaccinations generated stronger IgA anti-SARS-CoV-2 S responses ($p = 0.0002$) than third vaccinations but did not selectively increase circulating IgA against Omicron over ancestral S, indicating immune imprinting of circulating IgA responses. Circulating IgA against SARS-CoV-2 S following breakthrough infection remained higher than vaccine-induced levels for over 150 days. In conclusion, intramuscular mRNA vaccination induces circulating IgA against SARS-CoV-2 S, and higher levels are associated with protection from breakthrough infection. Vaccination with ancestral S enacts imprinting within circulating IgA responses that become apparent after breakthrough infection with Omicron. Breakthrough infection generates stronger and more durable circulating IgA responses against SARS-CoV-2 S than vaccination alone.

A Candidate DNA Vaccine Encoding the Native SARS-CoV-2 Spike Protein Induces Anti-Subdomain 1 Antibodies. The ideal vaccine against viral infections should elicit antibody responses that protect against divergent strains. Designing broadly protective vaccines against SARS-CoV-2 and other divergent viruses requires insight into the specific targets of cross-protective antibodies on the viral surface protein(s). However, unlike therapeutic monoclonal antibodies, the B-cell epitopes of vaccine-induced polyclonal antibody responses remain poorly defined. Here we show that, through the combination of neutralizing antibody functional responses with B-cell epitope mapping, it is possible to identify unique antibody targets associated with neutralization breadth. The polyclonal antibody profiles of SARS-CoV-2 index-strain-vaccinated rabbits that demonstrated a low, intermediate, or high neutralization efficiency of different SARS-CoV-2 variants of concern (VOCs) were distinctly different. Animals with an intermediate and high cross-neutralization of VOCs targeted fewer antigenic sites on the spike protein and targeted one particular epitope, subdomain 1 (SD1), situated outside the receptor binding domain (RBD). Our results indicate that a targeted functional antibody response and an additional focus on non-RBD epitopes could be effective for broad protection against different SARS-CoV-2 variants. We anticipate that the approach taken in this study can be applied to other viral vaccines for identifying future epitopes that confer cross-neutralizing antibody responses, and that our findings will inform a rational vaccine design for SARS-CoV-2.

SARS-CoV-2-Specific CD8(+) T-Cells in Blood but Not in the Lungs of Vaccinated K18-hACE2 Mice after Infection. Severe acute respiratory syndrome coronavirus (SARS-CoV)-2 enters the host by infecting nasal ciliated cells. Then, the virus can spread towards the oropharyngeal cavity and the pulmonary tissues. The antiviral adaptive immunity is promptly induced in response to the virus's detection, with virus-specific T-lymphocytes appearing before antiviral antibodies. Both the breadth and potency of antiviral CD8(+) T-cell immunity have a key role in containing viral spread and disease severity. Current anti-SARS-CoV-2 vaccines do not impede the virus's replication in the upper respiratory tract, and there is consensus on the fact that the best potency of the antiviral immune response in both blood and the upper respiratory tract can be reached upon infection in vaccinees (i.e., breakthrough infection). However, whether the antiviral CD8(+) T-cells developing in response to the breakthrough infection in the upper respiratory tract diffuse to the lungs is also still largely

unknown. To fill the gap, we checked the CD8(+) T-cell immunity elicited after infection of K18-hACE2 transgenic mice both at 3 weeks and 3 months after anti-spike vaccination. Virus-specific CD8(+) T-cell immunity was monitored in both blood and the lungs before and after infection. By investigating the de novo generation of the CD8(+) T-cells specific for SARS-CoV-2 viral proteins, we found that both membrane (M) and/or nucleocapsid (N)-specific CD8(+) T-cells were induced at comparable levels in the blood of both unvaccinated and vaccinated mice. Conversely, N-specific CD8(+) T-cells were readily found in the lungs of the control mice but were either rare or absent in those of vaccinated mice. These results support the idea that the hybrid cell immunity developing after asymptomatic/mild breakthrough infection strengthens the antiviral cell immunity in the lungs only marginally, implying that the direct exposition of viral antigens is required for the induction of an efficient antiviral cell immunity in the lungs.

Exploring the Impact of COVID-19 on Physical Activity One Month after Infection and Its Potential Determinants: Re-Infections, Pre-Illness Vaccination Profiles/Types, and Beyond. This study investigated changes in physical activity (PA) after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection while considering age, PA level, underlying medical conditions (UMCs), vaccination profiles/types, re-infections, disease severity, and treatment. Data were collected from 5829 respondents by using a validated web-based questionnaire. The findings showed that there was a significant overall decrease in PA (-16.2%), including in daily occupation (-11.9%), transportation (-13.5%), leisure-time (-16.4%), and sporting (-27.6%) activities. Age, PA level, UMCs, vaccination profiles/types, disease severity, and treatment played a role in determining PA in individuals' post-acute SARS-CoV-2 infections. Re-infections did not impact the decline in PA. Unvaccinated individuals experienced a significant decline in PA (-13.7%). Younger (-22.4%) and older adults (-22.5%), those with higher PA levels (-20.6%), those with 2-5 UMCs (-23.1%), those who were vaccinated (-16.9%) or partially vaccinated (-19.1%), those with mRNA-type vaccines only (-17.1%), those with recurrent (-19.4%)-to-persistent (-54.2%) symptoms, and those that required hospital (-51.8%) or intensive care unit (-67.0%) admission during their infections had more pronounced declines in PA. These findings emphasize the complex relationship between post-acute SARS-CoV-2 infection and PA and highlight the need for targeted interventions, further research, and multidisciplinary care to promote PA resumption and mitigate long-term effects on global public health.

Riding the Omicron BA.5 Wave: Improved Humoral Response after Vaccination with Bivalent Omicron BA.4-5-Adapted mRNA SARS-CoV-2 Vaccine in Chronic Hemodialysis Patients. Hemodialysis patients faced an excess morbidity and mortality during the COVID-19 pandemic. We evaluated the effect of second-generation mRNA vaccines against Omicron BA.4 and BA.5 variants of SARS-CoV-2 on humoral immunity. The study population comprised 66 adult hemodialysis patients who have encountered four SARS-CoV-2 antigen contacts through vaccination or infection. We assessed their humoral response using an anti-SARS-CoV-2 spike receptor binding domain IgG antibody assay (S-RBD-ab), measuring neutralizing antibodies against ancestral strain of SARS-CoV-2, Delta, and Omicron in a surrogate virus neutralization test (SVNT), and specifically against BA.5 in a plaque reduction neutralization test (PRNT) before and four weeks after vaccination with Comirnaty Original/Omicron BA.4-5. During the following six months, SARS-CoV-2 infections and symptom severity were documented. The bivalent mRNA vaccine led to a 7.6-fold increase in S-RBD-ab levels and an augmented inhibition of the Omicron variant in SVNT by 35% (median). Seroconversion in the Omicron BA.5-specific PRNT was attained by in 78.4% of previously negative patients (29/37). Levels of S-RBD-ab correlated with inhibition in the Omicron-specific SVNT and neutralization titers in the BA.5-PRNT. Eleven SARS-CoV-2 infections occurred in the six-month follow-up, none of which took a life-threatening course. The bivalent mRNA vaccine improved the SARS-CoV-2 virus variant-specific

humoral immunity in chronic hemodialysis patients. Measurement of S-RBD-ab can be used in hemodialysis patients to estimate their humoral immunity status against Omicron BA.5.

Anti-SARS-CoV-2 Antibody Level Is Associated with a History of COVID-19 Infection and mRNA Vaccination in Patients with Diabetes. Type 2 diabetes mellitus (T2DM) is associated with higher severity and mortality in SARS-CoV-2 infections. Vaccination has been encouraged to boost immunity and prevent these unfortunate outcomes. Few studies have evaluated antibody levels after COVID-19 vaccination in patients with T2DM. Therefore, we examined the vaccination status and anti-SARS-CoV-2 antibody levels to identify the factors that affect the antibody levels in patients with T2DM. This cross-sectional study was conducted at the Dr. Hasan Sadikin Hospital and Bandung Kiwari Hospital, Bandung, West Java, Indonesia, between October and November 2022. Adult participants with and without T2DM were tested for SARS-CoV-2 antibodies using a point-of-care quantitative immunochromatographic assay. We enrolled 289 participants: 201 participants with T2DM and 88 participants without T2DM. The T2DM participants had a lower vaccination rate compared with the non-T2DM participants. However, no significant differences in antibody levels were observed between the two groups. Higher antibody levels among the T2DM participants were associated with mRNA vaccination and a history of COVID-19 illness. The lower antibody response observed among the T2DM participants with chronic obstructive pulmonary disease suggests that such patients may need antibody level measurement and an additional booster vaccine.

Humoral Immunity in Immunosuppressed IBD Patients after the Third SARS-CoV-2 Vaccination: A Comparison with Healthy Control Subjects. INTRODUCTION: The COVID-19 pandemic is a result of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Vaccination against COVID-19 is crucial for preventing severe illness and controlling the pandemic. This study aimed to examine how immunosuppressed patients with inflammatory bowel disease (IBD) responded to the third mRNA vaccination against SARS-CoV-2. The patients were undergoing treatments such as anti-TNF (infliximab, adalimumab), anti-Î±4ÃŸ7 integrin (vedolizumab), anti-IL12/23 (ustekinumab) and azathioprine (purine analog). Their responses were compared to those of healthy individuals. METHODS: In this prospective study, 81 IBD patients and 15 healthy controls were enrolled 2-4 months after receiving the third mRNA vaccination. This study measured IgG antibody levels against the SARS-CoV-2 spike protein's receptor binding domain (RBD) and assessed potential neutralization capacity using a surrogate virus neutralization test (sVNT). RESULTS: Overall, immunosuppressed IBD patients (without SARS-CoV-2 infection) exhibited significantly lower levels of anti-S-IgG (anti-RBD-IgG) and binding inhibition in the sVNT after the third vaccination compared to healthy controls. Patients under anti-TNF therapy showed notably reduced anti-S-IgG levels after the booster vaccination, in contrast to those receiving ustekinumab and azathioprine ($p = 0.030$, $p = 0.031$). IBD patients on anti-TNF therapy demonstrated significantly increased anti-S-IgG levels following prior SARS-CoV-2 infection ($p = 0.020$). CONCLUSION: Even after the third vaccination, immunosuppressed IBD patients exhibited diminished humoral immunity compared to healthy controls, especially those on anti-TNF therapy. Cases of penetrating infections led to considerably higher antibody levels in IBD patients under anti-TNF therapy compared to uninfected patients. Further investigation through prospective studies in immunosuppressed IBD patients is needed to determine whether this effectively safeguards against future infections or severe disease.

Multisystem Inflammatory Syndrome in Children Following COVID-19 Vaccination: A Sex-Stratified Analysis of the VAERS Database Using Brighton Collaboration Criteria. Multisystem inflammatory syndrome in children (MIS-c) is an uncommon, but serious, inflammatory response that occurs after SARS-CoV-2 infection. As time went by, MIS-c was also reported as a potential adverse event following COVID-19 vaccination. A descriptive analysis was performed of Individual Case Safety Reports (ICSRs) associated with anti COVID-19 vaccines and related to the pediatric population from

2020 to 2022. The present pharmacovigilance study aimed to describe cases of MIS-c following COVID-19 vaccination, stratified by sex, reported in the Vaccine Adverse Events Reporting System (VAERS) and meeting the Brighton Collaboration criteria for case definition. We assessed all suspected cases through the case definition and classification of the Brighton Collaboration Group, and only definitive, probable, and possible cases were included in the analysis. The Reporting Odds Ratio (ROR) with 95% Confidence Interval (CI) was computed to assess if males have a lower/higher probability of reporting ICSRs with MIS-c compared with females. Overall, we found 79 cases of potentially reported MIS-c following vaccination. This study demonstrated that MIS-c following vaccination was more commonly reported for male subjects with a median age of 10 years (IQR 10.0-11.4), especially after the first dose of anti COVID-19 vaccines with a median time to onset of 27 days. Even so, the rate of occurrence of MIS-c following anti COVID-19 vaccines is lower (0.12/100,000 vaccinated subjects; 95% CI, 0.12-0.13). Overall, all ICSRs were serious and caused or prolonged hospitalization. Finally, disproportionality analysis showed that males had a higher reporting probability of MIS-c compared with females following immunization with mRNA COVID-19 vaccines. Since only a few years of marketing are available, further data from real-life contexts are needed.

Latent TB Infection, Vitamin D Status and COVID-19 Severity in Mongolian Patients. We aimed to determine potential risk factors for COVID-19 severity including serum vitamin D levels and latent TB infection among Mongolian inpatients diagnosed with COVID-19, and to study the effects of disease complications and treatment outcomes. This study included patients admitted to the Mongolian National Center for Communicable Disease, a main referral center for infectious disease in Mongolia, with COVID-19 ascertained by a positive PCR test. Patients' demographic, clinical, and laboratory data were analyzed. Of the 270 patients enrolled, 125 (46%) had mild-to-moderate illness, 86 (32%) had severe illness, and 59 (22%) had critical illness. Ten (91%) of the 11 patients who had active TB were hospitalized with severe or critical COVID-19, suggesting that they had a higher risk of falling into the severe category (OR = 10.6 [1.2; 92.0] 95% CI). Severe vitamin D deficiency (25(OH)D < 10 ng/mL) was present in 32% of the patients, but was not significantly associated with the severity of illness (p = 0.65). Older age, being male, having active TB and/or COPD were associated with greater COVID-19 severity, whereas a history of COVID-19 vaccination and the presence of a BCG vaccination scar were protective in terms of disease severity.

Therapeutic Effects of Treating COVID-19 Vaccine-Induced Anti-TIF1-Î³-Positive Dermatomyositis. An increase in skin-related autoimmune disorders has been reported as an adverse effect of coronavirus disease 2019 (COVID-19) vaccines. We present the case of a 90-year-old Taiwanese female who was newly diagnosed with anti-transcription intermediary factor 1-gamma (anti-TIF1-Î³)-positive dermatomyositis (DM) after receiving a second dose of the AstraZeneca COVID-19 vaccine. Under treatment with prednisolone and monoclonal antibody therapy of abatacept, her skin lesions improved, and her muscle power increased. The serum creatinine phosphokinase level decreased from 4858 to 220 U/L, and the anti-TIF1-Î³ antibody titer decreased from 202 to 99. Flow cytometry data showed an increase in T cells, while NK cells, B cells (CD19), and plasma blasts all decreased. These findings suggest that standard DM treatment might be beneficial to patients with COVID-19 vaccine-induced DM.

Disseminated Herpes Zoster Following Protein Subunit and mRNA COVID-19 Vaccination in Immunocompetent Patients: Report of Two Cases and Literature Review. Disseminated herpes zoster (DHZ), resulting from the reactivation of the varicella-zoster virus (VZV), typically occurs in immunocompromised persons. To date, only four cases of DHZ following mRNA, viral vector, or inactivated COVID-19 vaccinations have been reported in immunocompetent patients. Herein, we present the first case of DHZ following the protein subunit COVID-19 vaccination (case 1, 64 years old) and a case of DHZ following mRNA COVID-19 vaccination (case 2, 67 years old) in elderly,

immunocompetent male patients. Both cases were generally healthy, without a remarkable underlying disease and without a history of immunosuppressant use. Case 1 developed DHZ (left C3-5 predominant) 1 month after receiving the third dose of the SARS-CoV-2 spike protein vaccine (MVC-COV1901). Case 2 developed DHZ (right V1-3 predominant) 7 days after receiving the second dose of the mRNA-1273 SARS-CoV-2 vaccine. Through skin examination, Tzanck smears, and dermoscopy, the diagnosis of COVID-19 vaccination-related DHZ was established in both cases. Oral famciclovir (250 mg, three times/day for 7 days) was administered, and both cases achieved total remission of skin lesions without visceral involvement or severe post-herpetic neuralgia. Our cases demonstrate that DHZ, as a rare cutaneous adverse event in immunocompetent patients, can be secondary not only to mRNA COVID-19 vaccination but also to the protein subunit COVID-19 vaccination. It is speculated that the spike protein of SARS-CoV-2 could be the common trigger for the reactivation of VZV among different types of vaccinations.

Specific Cellular and Humoral Response after the Third Dose of Anti-SARS-CoV-2 RNA Vaccine in Patients with Immune-Mediated Rheumatic Diseases on Immunosuppressive Therapy.
OBJECTIVE: Data on cellular and humoral immunogenicity after the third dose of anti-SARS-CoV-2 vaccines in patients with immune-mediated rheumatic diseases (IMRDs) are scarce. Herein, we evaluated the adaptive immune response in IMRD patients treated with different immunosuppressive therapies (conventional synthetic disease-modifying antirheumatic drugs [csDMARDs], biological disease-modifying antirheumatic drugs [bDMARDs], and targeted synthetic disease-modifying antirheumatic drugs [tsDMARDs]) after the booster of the anti-SARS-CoV-2 vaccine to determine whether any drug reduced the vaccine's response. METHODS: A single-center prospective study was conducted, including patients presenting with IMRD and healthy controls (HC). Specific anti-SARS-CoV-2 interferon-gamma (IFN-Î³) production was evaluated between 8-12 weeks after the third dose of the SARS-CoV-2 vaccine. In addition, anti-Spike IgG antibody titers were also measured. RESULTS: Samples were obtained from 79 IMRD patients (51 women, 28 men; mean age 57 Â± 11.3 years old): 43 rheumatoid arthritis, 10 psoriatic arthritis, 14 ankylosing spondylitis, 10 undifferentiated spondyloarthritis, and 2 inflammatory bowel disease-associated spondyloarthritis (IBD-SpA). In total, 31 HC (mean age 50.9 Â± 13.1 years old, 67.7% women) were included in the study. Post-vaccine results displayed positive T-cell immune responses in 68 out of 79 (86.1%) IMRD patients (82.3% of those without prior COVID-19). All HC and IMRDs patients had an antibody response against the SARS-CoV-2 receptor-binding domain; however, the HC response was significantly higher (median of 18,048 AU/mL) than in IMRDs patients (median of 6590.3 AU/mL, $p < 0.001$). MTX and leflunomide were associated with lower titers of IgG and IFN-Î³ responses. Among bDMARDs, adalimumab, etanercept, and guselkumab are associated with reduced cellular responses. CONCLUSION: Our preliminary data show that the majority of our IMRD patients develop cellular and humoral responses after the SARS-CoV-2 booster vaccination, emphasizing the relevance of vaccination in this group. However, the magnitude of specific responses was dependent on the immunosuppressive therapy administered. Specific vaccination protocols and personalized decisions about boosters are essential for these patients.

Correction to: Acceptance of COVID-19 vaccination among parents of children with autism and other neurodevelopmental disorders in Saudi Arabia: a cross-sectional study.

Public health factors help explain cross country heterogeneity in excess death during the COVID19 pandemic. The COVID-19 pandemic has taken a devastating toll around the world. Since January 2020, the World Health Organization estimates 14.9 million excess deaths have occurred globally. Despite this grim number quantifying the deadly impact, the underlying factors contributing to COVID-19 deaths at the population level remain unclear. Prior studies indicate that demographic factors like proportion of population older than 65 and population health explain the cross-country

difference in COVID-19 deaths. However, there has not been a comprehensive analysis including variables describing government policies and COVID-19 vaccination rate. Furthermore, prior studies focus on COVID-19 death rather than excess death to assess the impact of the pandemic. Through a robust statistical modeling framework, we analyze 80 countries and show that actionable public health efforts beyond just the factors intrinsic to each country are important for explaining the cross-country heterogeneity in excess death.

Duration of SARS-CoV-2 mRNA vaccine persistence and factors associated with cardiac involvement in recently vaccinated patients. At the start of the COVID-19 pandemic, the BNT162b2 (BioNTech-Pfizer) and mRNA-1273 (Moderna) mRNA vaccines were expediently designed and mass produced. Both vaccines produce the full-length SARS-CoV-2 spike protein for gain of immunity and have greatly reduced mortality and morbidity from SARS-CoV-2 infection. The distribution and duration of SARS-CoV-2 mRNA vaccine persistence in human tissues is unclear. Here, we developed specific RT-qPCR-based assays to detect each mRNA vaccine and screened lymph nodes, liver, spleen, and myocardium from recently vaccinated deceased patients. Vaccine was detected in the axillary lymph nodes in the majority of patients dying within 30 days of vaccination, but not in patients dying more than 30 days from vaccination. Vaccine was not detected in the mediastinal lymph nodes, spleen, or liver. Vaccine was detected in the myocardium in a subset of patients vaccinated within 30 days of death. Cardiac ventricles in which vaccine was detected had healing myocardial injury at the time of vaccination and had more myocardial macrophages than the cardiac ventricles in which vaccine was not detected. These results suggest that SARS-CoV-2 mRNA vaccines routinely persist up to 30 days from vaccination and can be detected in the heart.

Omicron variant neutralizing antibodies following BNT162b2 BA.4/5 versus mRNA-1273 BA.1 bivalent vaccination in patients with end-stage kidney disease. Neutralization of Omicron subvariants by different bivalent vaccines has not been well evaluated. This study characterizes neutralization against Omicron subvariants in 98 individuals on dialysis or with a kidney transplant receiving the BNT162b2 (BA.4/BA.5) or mRNA-1273 (BA.1) bivalent COVID-19 vaccine. Neutralization against Omicron BA.1, BA.5, BQ.1.1, and XBB.1.5 increased by 8-fold one month following bivalent vaccination. In comparison to wild-type (D614G), neutralizing antibodies against Omicron-specific variants were 7.3-fold lower against BA.1, 8.3-fold lower against BA.5, 45.8-fold lower against BQ.1.1, and 48.2-fold lower against XBB.1.5. Viral neutralization was not significantly different by bivalent vaccine type for wild-type (D614G) (Pâ€‰=â€‰0.48), BA.1 (Pâ€‰=â€‰0.21), BA.5 (Pâ€‰=â€‰0.07), BQ.1.1 (Pâ€‰=â€‰0.10), nor XBB.1.5 (Pâ€‰=â€‰0.10). Hybrid immunity conferred higher neutralizing antibodies against all Omicron subvariants. This study provides evidence that BNT162b2 (BA.4/BA.5) and mRNA-1273 (BA.1) induce similar neutralization against Omicron subvariants, even when antigenically divergent from the circulating variant.

Effects of COVID-19 vaccination on human fertility: a post-pandemic literature review. Although vaccination with the Coronavirus disease 2019 vaccine is important and effective in the prevention of SARS-CoV-2 infection, the public expressed concerns regarding the adverse effects of vaccine on fertility. Some reviews have focused on it, they have been unable to collect sufficient research data because of the earlier publication period. As relevant evidence has gradually increased, we reviewed these studies from the perspectives of males, females with or without pregnancy, and different vaccine types. The results suggest that although males may experience fluctuations in semen parameters within their physiological ranges after receiving the vaccine, it has not yet reached a level of influence on the partner's pregnancy probability. As to female without pregnancy, it is believed that vaccination will not affect fertility; however, more research is needed to explore the short-term impact. Vaccination during any trimester is considered safe in pregnant women.

Case Report: Two Case Reports of Pulmonary Hypertension after mRNA COVID-19 Vaccination. BACKGROUND: We herein report two cases of sudden onset symptomatic pulmonary hypertension after coronavirus disease 2019 (COVID-19) vaccination. CASE SUMMARY: Pulmonary hypertension in previously healthy adult males occurred within three weeks of receiving the second dose of the Pfizer (BNT162b2) mRNA COVID-19 vaccine from different lots. Both patients experienced a sudden onset of severe fatigue and dyspnea on exertion with negative severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) polymerase chain reaction (PCR) testing. The diagnosis was made by serial transthoracic echocardiography in the first case and by both transthoracic echocardiography and right heart catheterization in the second. Both cases resulted in functional limitations and likely permanent organ damage. No evidence of pulmonary emboli was detected in either case. DISCUSSION: Pulmonary hypertension is a serious disease characterized by damage to lung vasculature and restricted blood flow through narrowed arteries from the right to left heart. The onset of symptoms is typically insidious, progressive and incurable, leading to right heart failure and premature death. The World Health Organization (WHO) classifies pulmonary hypertension into five categories and recently re-defined it as a resting mean pulmonary artery pressure greater than 20 mmHg. Sudden onset pulmonary hypertension would only be expected in the settings of surgical pneumonectomy or massive pulmonary emboli with compromise of at least 50% of the lung vasculature. We present here two novel cases of sudden onset pulmonary hypertension without evidence of pulmonary emboli, both of which occurred after receiving a COVID-19 mRNA vaccine.

The Impact of COVID-19 Vaccines on the Development of Acute Complications in Type 1 and 2 Diabetes Patients: A Cross-Sectional Study in the Eastern Province of Saudi Arabia. BACKGROUND: COVID-19 vaccines were developed to control the pandemic spread as they have been proven to be efficient and safe. However, the likelihood of such postvaccination effects as poor glycemic control and adverse events has been noted in several studies. OBJECTIVE: To determine the effect of COVID-19 vaccines on the glycemic control and the development of hyperglycemic emergencies among type 1 and 2 diabetes patients. METHODS: A cross-sectional study was conducted on 409 participants aged 18 years and above with type 1 or 2 diabetes who had received at least a single dose of COVID-19 vaccine. RESULTS: Among the 409 diabetes patients, a majority reported general mild postvaccination symptoms regardless of diabetes duration or type. After vaccination, severe diabetic emergencies were mostly reported in long-standing diabetes patients. Diabetes-related complications and emergencies were more profound among those who had received the Pfizer vaccine. Nonetheless, occurrence of adverse events could possibly be due to various factors, including the duration of diabetes and COVID-19 infection status. CONCLUSION: COVID-19 vaccinations have the potential to influence diabetic patients in regard to acute glycemic complications. However, vaccine efficiency and benefits are superior to the side effects of COVID-19 vaccines, as these adverse events only affect a small number of individuals. A need for postvaccination monitoring of diabetes patients is suggested.

Association of vaccination status with the clinicobiochemical profile, hospital stay, and mortality in COVID-19: A case-control study. BACKGROUND AND AIMS: The effectiveness of coronavirus disease 2019 (COVID-19) vaccines in reducing symptoms, disease advancement, complications, and mortality in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection has been well-established. This case-control study aimed to compare different blood parameters, and prognostic and survival outcomes of COVID-19 patients based on vaccination status. METHODS: We performed a case-control study that included hospitalized patients with COVID-19 at Tribhuvan University Teaching Hospital, Kathmandu, Nepal. Individuals who received vaccination were designated as cases and unvaccinated individuals as controls. Demographics, co-morbidity, clinical data, laboratory data, and disease outcomes were recorded for both groups. Multivariate, Cox, and linear regression were

used for analysing blood parameters, hospital admission, survival, and hospital stay, respectively, between cases and controls. RESULTS: Out of 100 participants enrolled, 46 were vaccinated, and 54 weren't. At admission, ferritin and erythrocyte sedimentation rate (ESR) were significantly lower in cases. At discharge, cases showed a higher monocyte than controls. Ferritin, ESR, and d-imer showed excellent performance in determining the severity of symptoms. Significant correlation and regression of ferritin and ESR with the length of hospital stay was observed. Length of hospital stay was significantly lower in cases than in controls. No significant differences between cases and controls were observed in mortality. CONCLUSION: COVID-19 vaccines effectively reduced hospitalization duration. Ferritin and ESR were significantly lower in vaccinated individuals and showed the best utility in monitoring the disease.

Chronic bilateral dacryoadenitis with concurrent tattoo inflammation following COVID-19 vaccination and infection.

Correction to: Higher risk of short term COVID-19 vaccine adverse events in myositis patients with autoimmune comorbidities: results from the COVAD study.

How Should Doctors Frame the Risk of a Vaccine's Adverse Side Effects? It Depends on How Trustworthy They Are. BACKGROUND: How health workers frame their communication about vaccines' probability of adverse side effects could play an important role in people's intentions to be vaccinated (e.g., positive frame: side effects are unlikely v. negative frame: there is a chance of side effects). Based on the pragmatic account of framing as implicit advice, we expected that participants would report greater vaccination intentions when a trustworthy physician framed the risks positively (v. negatively), but we expected this effect would be reduced or reversed when the physician was untrustworthy. DESIGN: In 4 online experiments (nâ€‰=â€‰191, snowball sampling and nâ€‰=â€‰453, 451, and 464 UK residents via Prolific; M(age)â‰ˆ 34 y, 70% women, 84% White British), we manipulated the trustworthiness of a physician and how they framed the risk of adverse side effects in a scenario (i.e., a chance v. unlikely adverse side effects). Participants reported their vaccination intention, their level of distrust in health care systems, and COVID-19 conspiracy beliefs. RESULTS: Physicians who were trustworthy (v. untrustworthy) consistently led to an increase in vaccination intention, but the way they described adverse side effects mattered too. A positive framing of the risks given by a trustworthy physician consistently led to increased vaccination intention relative to a negative framing, but framing had no effect or the opposite effect when given by an untrustworthy physician. The exception to this trend occurred in unvaccinated individuals in experiment 3, following serious concerns about one of the COVID vaccines. In that study, unvaccinated participants responded more favorably to the negative framing of the trustworthy physician. CONCLUSIONS: Trusted sources should use positive framing to foster vaccination acceptance. However, in a situation of heightened fears, a negative framing-attracting more attention to the risks-might be more effective. HIGHLIGHTS: How health workers frame their communication about a vaccine's probability of adverse side effects plays an important role in people's intentions to be vaccinated.In 4 experiments, we manipulated the trustworthiness of a physician and how the physician framed the risk of adverse side effects of a COVID vaccine.Positive framing given by a trustworthy physician promoted vaccination intention but had null effect or did backfire when given by an untrustworthy physician.The effect occurred over and above participants' attitude toward the health care system, risk perceptions, and beliefs in COVID misinformation.

Management and Characteristics of Embolism and Thrombosis After COVID-19 Vaccination: Scoping Review. This scoping review aims to 1) identify characteristics of participants who developed embolism and/or thrombotic event(s) after COVID-19 vaccination and 2) review the management during the new vaccine development of the unexpected event(s).Â This review was conducted following PRISMA for scoping review guidelines. Peer-reviewed articles were searched for studies

involving participants with embolism and/or thrombotic event(s) after COVID-19 vaccination with the management described during the early phase after the approval of vaccines. The 12 studies involving 63 participants were included in this review. The majority of participants' ages ranged from 22 to 49 years. The embolism and/or thrombotic event(s) often occur within 30 days post-vaccination. Five of the included studies reported the event after receiving viral vector vaccines and suggested a vaccine-induced immune thrombotic thrombocytopenia as a plausible mechanism. Cerebral venous sinus thrombosis was the most frequently reported post-vaccination thrombosis complication. In summary, the most frequently reported characteristics and management from this review were consistent with international guidelines. Future studies are recommended to further investigate the incidence and additional potential complications to warrant the benefit and safety after receiving COVID-19 vaccine and other newly developed vaccines.

COVID-19 Vaccine Uptake, Hesitancy, and Flare in a Large Rheumatology Practice Network. OBJECTIVE: The goal of this study was to ascertain COVID-19 vaccine uptake, reasons for hesitancy, and self-reported flare in a large rheumatology practice-based network. METHODS: A tablet-based survey was deployed by 108 rheumatology practices from December 2021 to December 2022. Patients were asked about COVID-19 vaccine status and why they might not receive a vaccine or booster. We used descriptive statistics to explore the differences between vaccination status and vaccine and booster hesitancy, comparing patients with and without autoimmune and inflammatory rheumatic diseases (AIIRDs). We used multivariable logistic regression to examine the association between vaccine uptake and AIIRD status and self-reported flare and AIIRD status. We reported adjusted odds ratios (aORs). RESULTS: Of the 61,158 patients, 89% reported at least one dose of vaccine; of the vaccinated, 68% reported at least one booster. Vaccinated patients were less likely to have AIIRDs (44% vs 56%). A greater proportion of patients with AIIRDs were vaccine hesitant (14% vs 10%) and booster hesitant (21% vs 16%) compared to patients without AIIRDs. Safety concerns (28%) and side effects (23%) were the main reasons for vaccine hesitancy, whereas a lack of recommendation from the physician was the primary factor for booster hesitancy (23%). Patients with AIIRD did not have increased odds of self-reported flare or worsening disease compared to patients without with AIIRD (aOR 0.99, 95% confidence interval [CI] 0.94-1.05). Among the patients who were vaccine hesitant and booster hesitant, 12% and 39% later reported receiving a respective dose. Patients with AIIRD were 32% less likely to receive a vaccine (aOR 0.68, 95% CI 0.65-0.72) versus patients without AIIRD. CONCLUSION: Some patients who are vaccine and booster hesitant eventually receive a vaccine dose, and future interventions tailored to patients with AIIRD may be fruitful.

Nosocomial outbreak in a respiratory ward caused by the SARS-CoV-2 Omicron BA 5.2.1 subvariant associated with non-severe illness in vaccinated patients. In this short report, we describe an outbreak of COVID-19 caused by Omicron subvariant BA.5.2.1 in highly vaccinated patients in a respiratory ward in a large acute general hospital in North West London, United Kingdom. The attack rate was high (14/33 (42%)) but the clinical impact was relatively non-severe including in patients who were at high risk of severe COVID-19. Twelve of fourteen patients had COVID-19 vaccinations. There was only one death due to COVID-19 pneumonitis. The findings of this outbreak investigation suggest that while the transmissibility of Omicron BA.5.2.1 subvariant is high, infections caused by this strain are non-severe in vaccinated patients, even if they are at high risk of severe COVID-19 infection.

Autoimmune bullous disorder flares following severe acute respiratory syndrome coronavirus 2 vaccination: a case series. BACKGROUND: Autoimmune bullous disorders develop due to autoantibodies targeting intercellular adhesion proteins of hemidesmosomes and desmosomes and may be triggered by viral infections and vaccines. Recent reports suggest that the coronavirus disease 2019 vaccination may trigger flares or exacerbations of preexisting autoimmune diseases, including

new onset autoimmune bullous disorders. There are less data on whether vaccination against severe acute respiratory syndrome coronavirus 2 may also exacerbate preexisting autoimmune bullous disorders. CASE PRESENTATION: Here we present three cases, two white males (ages 69Â years and 88Â years) with bullous pemphigoid and one white 50-year-old female with pemphigus foliaceus, wherein all individuals developed minor, tractable flares of their preexisting autoimmune bullous disorders after receiving the coronavirus disease 2019 vaccination, which were readily treatable with topical or low-dose systemic corticosteroids. CONCLUSIONS: Dermatologists managing patients with autoimmune bullous disorders should be cognizant of the uncommon potential for flares of the disorder following vaccination for severe acute respiratory syndrome coronavirus 2. Flares of bullous pemphigoid and pemphigus foliaceus following vaccination for severe acute respiratory syndrome coronavirus 2 in these cases were mild and tractable.

Pretransplantation coronavirus disease 2019 vaccination requirements: A matched case-control study of factors associated with waitlist inactivation. Numerous United States transplant centers require solid organ transplantation candidates to be vaccinated against the coronavirus disease of 2019 to be active on the United Network for Organ Sharing waiting list. This study examined characteristics of adult patients on one center's kidney transplantation waiting list whose status was inactivated due to a lack of coronavirus disease 2019 vaccination by July 1, 2022, and who did not subsequently provide proof of vaccination by August 31, 2022 (cases). Patients in the control group were retrospectively matched to patients in the case group in a 4-to-1 fashion according to age, sex, and "active" status on the waiting list. Multivariable logistic regression was performed, with race/ethnicity, primary language, health insurance, education, and Vaccine Equity Metric (VEM, a measure of health equity at the zip code level) quartile as covariates. Results revealed that patients from zip codes in the lowest VEM quartile (odds ratio [OR] 1.89; P = .02) and those insured by governmental payors (Medicare: OR, 2.00; P < .01 and Medicaid: OR, 2.89; P < .01) had higher odds of being inactivated than those from zip codes that make up the highest VEM quartile and those insured by commercial payors, respectively. These findings serve as a cautionary tale regarding universal pretransplantation vaccination requirements, which may raise equity concerns that should be considered upon policy implementation.

Accelerated and intensified manufacturing of an adenovirus-vectored vaccine to enable rapid outbreak response. The Coalition for Epidemic Preparedness Innovations' "100-day moonshot" aspires to launch a new vaccine within 100â€‰days of pathogen identification, followed by large-scale vaccine availability within the "second hundred days." Here, we describe work to optimize adenoviral vector manufacturing for rapid response, by minimizing time to clinical trial and first large-scale supply, and maximizing output from the available manufacturing footprint. We describe a rapid virus seed expansion workflow that allows vaccine release to clinical trials within 60â€‰days of antigen sequence identification, followed by vaccine release from globally distributed sites within a further 40â€‰days. We also describe a perfusion-based upstream production process, designed to maximize output while retaining simplicity and suitability for existing manufacturing facilities. This improves upstream volumetric productivity of ChAdOx1 nCoV-19 by approximately fourfold and remains compatible with the existing downstream process, yielding drug substance sufficient for 10,000 doses from each liter of bioreactor capacity. This accelerated manufacturing process, along with other advantages such as thermal stability, supports the ongoing value of adenovirus-vectored vaccines as a rapidly adaptable and deployable platform for emergency response.

Thyroid FNA cytology: Impact of the COVID-19 pandemic and vaccination in a Brazilian series. BACKGROUND: The coronavirus disease 2019 pandemic prompted changes in medical practice, with a reduction in cytopathology volumes and a relative increase in the malignancy rate during lockdown and the initial postlockdown period. To date, no study has evaluated the impact of these changes on

the volume of rapid on-site evaluation (ROSE) or on the frequency of cases according to The Bethesda System for Reporting Thyroid Cytopathology (TBSRTC) categories after vaccination. METHODS: Ultrasound-guided thyroid fine-needle aspiration (FNA) and ROSE assessments performed from January 2019 to May 2022 were evaluated retrospectively according to TBSRTC categories for three periods: prepandemic (period 1), from transmission to expansion (period 2), and after vaccination (period 3). RESULTS: There were 7531 nodules from 5815 patients. FNA cases increased throughout the pandemic despite a drop during lockdown. The frequency of TBSRTC categories changed. Nondiagnostic cases had an increase of 18.1% in period 2 and 76.2% after vaccination compared with prepandemic levels. Malignant cases increased from 2.3% to 4.2% in period 2 and to 5.1% in period 3, representing increases of 83.1% and 121.2%, respectively, compared with period 1. Data corrected by time showed increases in categories IV, V, and VI and a decrease in benign nodules during the two pandemic periods. ROSE was performed in 787 cases during the prepandemic period, and there were decreases of 29.4% and 22.8% in periods 2 and 3, respectively. The ROSE-to-category I ratio was reduced significantly after vaccination. CONCLUSIONS: Increased volume with sustained lower benign rates and higher malignant rates before and after vaccination indicate better selection of patients for FNA. A worse adequacy rate was correlated with a decrease in the number of ROSE assessments.

Broad and potent neutralizing antibodies are elicited in vaccinated individuals following Delta/BA.1 breakthrough infection. With the emergence of SARS-CoV-2 viral variants, there has been an increase in infections in vaccinated individuals. Here, we isolated monoclonal antibodies (mAbs) from individuals experiencing a breakthrough infection (Delta or BA.1) to determine how exposure to a heterologous Spike broadens the neutralizing antibody response at the monoclonal level. All mAbs isolated had reactivity to the Spike of the vaccine and infection variant. While many mAbs showed reduced neutralization of current circulating variants, we identified mAbs with broad and potent neutralization of BA.2.75.2, XBB, XBB.1.5, and BQ.1.1 indicating the presence of conserved epitopes on Spike. These results indicate that variant-based vaccine boosters have the potential to broaden the vaccine response.

Determinants of de novo B cell responses to drifted epitopes in post-vaccination SARS-CoV-2 infections. Vaccine-induced immunity may impact subsequent de novo responses to drifted epitopes in SARS-CoV-2 variants, but this has been difficult to quantify due to the challenges in recruiting unvaccinated control groups whose first exposure to SARS-CoV-2 is a primary infection. Through local, statewide, and national SARS-CoV-2 testing programs, we were able to recruit cohorts of individuals who had recovered from either primary or post-vaccination infections by either the Delta or Omicron BA.1 variants. Regardless of variant, we observed greater Spike-specific and neutralizing antibody responses in post-vaccination infections than in those who were infected without prior vaccination. Through analysis of variant-specific memory B cells as markers of de novo responses, we observed that Delta and Omicron BA.1 infections led to a marked shift in immunodominance in which some drifted epitopes elicited minimal responses, even in primary infections. Prior immunity through vaccination had a small negative impact on these de novo responses, but this did not correlate with cross-reactive memory B cells, arguing against competitive inhibition of naÃ¯ve B cells. We conclude that dampened de novo B cell responses against drifted epitopes are mostly a function of altered immunodominance hierarchies that are apparent even in primary infections, with a more modest contribution from pre-existing immunity, perhaps due to accelerated antigen clearance.

Aseptic Meningitis after BNT-162b2 COVID-19 Vaccination: Case Report and Literature Review. We encountered a-27-year-old female patient who developed refractory severe headache and photophobia after the first dose of COVID-19 vaccine. Despite her prior history of migraine, we diagnosed COVID-19 vaccine-induced aseptic meningitis. Symptoms were significantly resolved after

methylprednisolone therapy. On reviewing the literature, we could find only nine similar cases, with over half of them affecting women aged 20-40 years. Although uncommon, aseptic meningitis should be suspected in patients with persistent or delayed onset of headache following COVID-19 vaccination.
Association of Myelin Oligodendrocyte Glycoprotein Antibody-associated Disease with Coronavirus Disease 2019 Vaccination and Infection: A Case Report of Cortical Encephalitis and Transverse Myelitis Relapse. We herein report a case of myelin oligodendrocyte glycoprotein (MOG) antibody-associated disease (MOGAD) that occurred following coronavirus disease 2019 (COVID-19) vaccination and its subsequent relapse after COVID-19 infection. A 34-year-old woman developed cortical encephalitis in the right temporoparietal lobe one week after receiving the mRNA-1273 vaccine. The cerebrospinal fluid was positive for anti-MOG antibody. Her symptoms gradually improved after three courses of intravenous methylprednisolone therapy. Six months later, she experienced a relapse of transverse myelitis following COVID-19 infection. Despite treatment with plasma exchange, the patient remained paralyzed in both lower limbs. We herein review the relationship between MOGAD and COVID-19 vaccination/infection.
Intranasal administration with recombinant vaccine PRVXJ-delgE/gI/TK-S induces strong intestinal mucosal immune responses against PDCoV. Porcine deltacoronavirus (PDCoV) is a novel coronavirus that causes enteric diseases in pigs leading to substantial financial losses within the industry. The absence of commercial vaccines and limited research on PDCoV vaccines presents significant challenges. Therefore, we evaluated the safety and immunogenicity of recombinant pseudorabies virus (PRV) rPRVXJ-delgE/gI/TK-S through intranasal mucosal immunization in weaned piglets and SPF mice. Results indicated that rPRVXJ-delgE/gI/TK-S safely induced PDCoV S-specific and PRV gB-specific antibodies in piglets, with levels increasing 7 days after immunization. Virus challenge tests demonstrated that rPRVXJ-delgE/gI/TK-S effectively improved piglet survival rates, reduced virus shedding, and alleviated clinical symptoms and pathological damage. Notably, the recombinant virus reduced anti-inflammatory and pro-inflammatory responses by regulating IFN-Î³, TNF-Î±, and IL-1Î² secretion after infection. Additionally, rPRVXJ-delgE/gI/TK-S colonized target intestinal segments infected with PDCoV, stimulated the secretion of cytokines by MLVS in mice, stimulated sIgA secretion in different intestinal segments of mice, and improved mucosal immune function. HE and AB/PAS staining confirmed a more complete intestinal mucosal barrier and a significant increase in goblet cell numbers after immunization. In conclusion, rPRVXJ-delgE/gI/TK-S exhibits good immunogenicity and safety in mice and piglets, making it a promising candidate vaccine for PDCoV.
Discretion in decision to receive COVID-19 vaccines and associated socio-economic inequalities in rates of uptake: a whole-of-population data linkage study from Australia. OBJECTIVE: In Australia, first and second compared to third dose of a COVID-19 vaccine were implemented under different policies and contexts, resulting in greater discretion in decisions to receive a third compared to first and second dose. We quantified socio-economic inequalities in first and third dose to understand how discretion is associated with differences in uptake. STUDY DESIGN: Whole-of-population cohort study. METHODS: Linked immunisation, census, death and migration data were used to estimate weekly proportions who received first and third doses of a COVID-19 vaccine until 31 August 2022 for those with low (no formal qualification) compared to high (university degree) education, stratified by 10-year age group (from 30 to 89 years). We estimated relative rates using Cox regression, including adjustment for sociodemographic factors. RESULTS: Among 13.1 million people in our study population, 94% had received a first and 80% a third dose by 31 August 2022. Rates of uptake of first and third dose were around 50% lower for people with low compared to high education. Gaps were small in absolute terms for first dose, and at the end of the study period ranged from 1 to 11 percentage points across age groups. However, gaps were substantial for third dose, particularly at

younger ages where the socio-economic gap was as wide as 32 percentage-points. CONCLUSION: Education-related inequalities in uptake were larger where discretion in decisions was larger. Policies that limited discretion in decisions to receive vaccines may have contributed to achieving the dual aims of maximising uptake and minimising inequalities.

Clinical and immunological outcomes of SARS-CoV-2 infection in patients with inborn errors of immunity receiving different brands and doses of COVID-19 vaccines. INTRODUCTION: Vaccines against severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) provide successful control of the coronavirus-2019 (COVID-19) pandemic. The safety and immunogenicity studies are encouraging in patients with inborn errors of immunity (IEI); however, data about mortality outcomes and severe disease after vaccination still need to be fully addressed. Therefore, we aimed to determine the clinical and immunological outcomes of SARS-CoV-2 infection in patients with IEI who have received vaccination. MATERIALS AND METHODS: Eighty-eight patients with a broad range of molecular etiologies were studied; 45 experienced SARS-CoV-2 infection. Infection outcomes were analyzed in terms of genetic etiology, background clinical characteristics, and immunization history, including the type and number of doses received and the time elapsed since vaccination. In addition, anti-SARS-CoV-2 antibodies were quantified using electrochemiluminescent immunoassay. RESULTS: Patients were immunized using one of the three regimens: inactivated (Sinovac, CoronavacÂ®), mRNA (BNT162b2, ComirnatyÂ®, Pfizer-Biontech), and a combination. All three regimens induced comparable anti-SARS-CoV-2 IgG levels, with no differences in the adverse events. Among 45 patients with COVID-19, 26 received a full course of vaccination, while 19 were vaccine-naive or received incomplete dosing. No patients died due to COVID-19 infection. The fully immunized group had a lower hospitalization rate (23% vs. 31.5%) and a shorter symptomatic phase than the others. Among the fully vaccinated patients, serum IgM and E levels were significantly lower in hospitalized patients than non-hospitalized patients. CONCLUSION: COVID-19 vaccines were well-tolerated by the IEI patients, and a full course of immunization was associated with lower hospitalization rates and a shorter duration of COVID-19 symptoms.

Mortality and clinical outcomes following SARS-CoV-2 infection among individuals with haematological malignancies: A Danish population-based cohort study. OBJECTIVES: We aimed to quantify the risk of death following a positive test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) among individuals with haematological malignancies, stratified by virus variants and type of malignancy. METHODS: Using the Danish nationwide registries, we conducted a population-based cohort study among individuals who received a discharge diagnosis of haematological malignancies during the 5â€‰years prior to testing positive for SARS-CoV-2 (February 2020-April 2023). All individuals were followed for 30â€‰days after a positive test, and overall and time-stratified case fatality risks (CFR) were estimated. RESULTS: We identified 7154 individuals with a history of haematological malignancies who tested positive for SARS-CoV-2. Among these, we observed 223 deaths, yielding a CFR of 3.1%. The CFR was highest at the beginning of the pandemic (10%) and gradually declined to 1.9% during the period of Omicron BA1/BA2 predominance. The highest CFR was observed among individuals with acute leukaemia (CFR 6.2%, adjusted relative risk 1.95, 95% confidence interval 1.33-2.88) compared to individuals with lymphoma (CFR 3%). CONCLUSIONS: We observed a reduction in the CFR over time, which may be attributed to new treatments, COVID-19 vaccination and the emergence of less aggressive variants.

Ocular manifestations following COVID-19 vaccination. BACKGROUND: Immunologic and inflammatory adverse effects following vaccination against COVID-19 are being reported. While some reactions may develop denovo others concern its immunogenic effect in patients with pre-existing inflammatory conditions. METHODS: Retrospective consecutive patients diagnosed with ocular inflammatory manifestations within 8 weeks of receiving COVID-19 vaccination who presented to a

tertiary eye care centre in South India. RESULTS: Ninety-eight eyes of 67 patients presenting with ocular inflammatory manifestations within 8 weeks following COVID-19 vaccination were studied. The mean age was 43 years (+/- 14.82; range 19-80 years). The most common presentations were anterior uveitis (nâ€‰=â€‰31, 31.7%), followed by panuveitis (nâ€‰=â€‰24, 24.5%). The mean time to onset of symptoms was 25 days (+/- 15.48; range 2-55 days) following a dose of vaccine. Among all patients, 39 (58.2%) had a previous history of ocular inflammation. Mean presenting visual acuity was 0.4 (0-4) logMAR units and mean final visual acuity was 0.2 (0-4) logMAR units. The causes for reduced vision included of cystoid macular edema (n=2, 2%), chorioretinal atrophy (n=2.2%), optic atrophy (n=1.1%), retinal vascular occlusion (n=1.1%) and acute retinal necrosis (n=1.1%). CONCLUSION: Infective and immunogenic adverse events should be watched out for after COVID-19 vaccination. It is difficult to establish causality for such manifestations, nevertheless, most of them were mild and had good final visual outcomes.

A Brighton Collaboration standardized template with key considerations for a benefit/risk assessment for the Novavax COVID-19 Vaccine (NVX-CoV2373), a recombinant spike protein vaccine with Matrix-M adjuvant to prevent disease caused by SARS-CoV-2 viruses. Novavax, a global vaccine company, began evaluating NVX-CoV2373 in human studies in May 2020 and the pivotal placebo-controlled phase 3 studies started in November 2020; five clinical studies provided adult and adolescent clinical data for over 31,000 participants who were administered NVX-CoV2373. This extensive data has demonstrated a well-tolerated response to NVX-CoV2373 and high vaccine efficacy against mild, moderate, or severe COVID-19 using a two-dose series (Dunkle et al., 2022) [1], (Heath et al., 2021) [2], (Keech et al., 2020) [3], (Mallory et al., 2022) [4]. The most common adverse events seen after administration with NVX-CoV2373 were injection site tenderness, injection site pain, fatigue, myalgia, headache, malaise, arthralgia, nausea, or vomiting. In addition, immunogenicity against variants of interest (VOI) and variants of concern (VOC) was established with high titers of ACE2 receptor-inhibiting and neutralizing antibodies in these studies (EMA, 2022) [5], (FDA, 2023) [6]. Further studies on correlates of protection determined that titers of anti-Spike IgG and neutralizing antibodies correlated with efficacy against symptomatic COVID-19 established in clinical trials (pÂ <Â 0.001 for recombinant protein vaccine and pÂ =Â 0.005 for mRNA vaccines for IgG levels) (Fong et al., 2022) [7]. Administration of a booster dose of the recombinant protein vaccine approximately 6Â months following the primary two-dose series resulted in substantial increases in humoral antibodies against both the prototype strain and all evaluated variants, similar to or higher than the antibody levels observed in phase 3 studies that were associated with high vaccine efficacy (Dunkle et al., 2022) [1], (Mallory et al., 2022) [4]. These findings, together with the well tolerated safety profile, support use of the recombinant protein vaccine as primary series and booster regimens.

Retinal Artery and Vein Occlusion Risks after Coronavirus Disease 2019 or Coronavirus Disease 2019 Vaccination. PURPOSE: To evaluate the incidence of new retinal artery occlusion (RAO) and retinal vein occlusion (RVO) after the diagnosis of coronavirus disease 2019 (COVID-19) or vaccination against COVID-19 and compare the incidences with the population with neither. DESIGN: Nationwide population-based cohort study. PARTICIPANTS: From a nationwide population-based cohort, 8 418 590 patients were categorized into control (group 1), COVID-19 infection (group 2), and COVID-19 vaccination (group 3) groups. METHODS: The cumulative incidence of RAO and RVO was calculated in groups 1, 2, and 3 using the Kaplan-Meier method. We calculated hazard ratios (HRs) and 95% confidence intervals (CIs) based on the Poisson distribution for RAO and RVO according to each group and subgroup using Cox proportional hazards models, with group 1 as the reference. We conducted univariable and multivariable analyses for the risk factors of RAO and RVO according to each subgroup. MAIN OUTCOME MEASURES: Cumulative incidence and risks of incidence of RAO and RVO

from the index date to dayÂ 60. RESULTS: In multivariable analysis, no significant increase in RAO and RVO risks after COVID-19 or COVID-19 vaccination were observed in either men or women. These results were observed consistently across various conditions in sensitivity analyses. In subgroup analysis, individuals who were vaccinated before infection showed no significant increase in RAO or RVO risks in both sexes compared with the control group. In the subgroup analysis of vaccinated patients, the HRs of RAO and RVO for different vaccine types did not show an increase compared with the control group; however, an exception was observed in women who received mRNA-1273 vaccines, who showed a higher RAO HR (4.65; 95% CI, 1.27-17.03; PÂ = 0.021). CONCLUSIONS: Within 60 days of COVID-19 diagnosis or vaccination, RAO and RVO occurred rarely. We observed no increase in the HR of RVO and RAO relative to COVID-19 or COVID-19 vaccination except for a possible increase in the RAO HR in women who received mRNA-1273, for which the raw incidence was extremely low. Further investigation is required to validate this result. FINANCIAL DISCLOSURE(S): The author(s) have no proprietary or commercial interest in any materials discussed in this article.

A multi-country analysis of COVID-19 hospitalizations by vaccination status. BACKGROUND: Individuals vaccinated against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), when infected, can still develop diseaseÂ that requires hospitalization. It remains unclear whether these patients differ from hospitalized unvaccinated patients with regard to presentation, coexisting comorbidities, and outcomes. METHODS: Here, we use data from an international consortium to study thisÂ question and assess whether differences between these groups areÂ context specific. Data from 83,163 hospitalized COVID-19 patients (34,843 vaccinated, 48,320 unvaccinated) from 38 countries were analyzed. FINDINGS: While typical symptoms were more often reported in unvaccinated patients, comorbidities, including some associated with worse prognosis in previous studies, were more common in vaccinated patients. Considerable between-country variation in both in-hospital fatality risk and vaccinated-versus-unvaccinated difference in this outcome was observed. CONCLUSIONS: These findings will inform allocation of healthcare resources in future surges as well as design of longer-term international studies to characterize changes in clinical profile of hospitalized COVID-19 patients related to vaccination history. FUNDING: This work was made possible by the UK Foreign, Commonwealth and Development Office and Wellcome (215091/Z/18/Z, 222410/Z/21/Z, 225288/Z/22/Z, and 220757/Z/20/Z); the BillÂ & Melinda GatesÂ Foundation (OPP1209135); and the philanthropic support of the donorsÂ to the University of Oxford's COVID-19 Research Response Fund (0009109). Additional funders are listed in the "acknowledgments" section.

Risk of COVID-19 after natural infection or vaccination. BACKGROUND: While vaccines have established utility against COVID-19, phase 3 efficacy studies have generally not comprehensively evaluated protection provided by previous infection or hybrid immunity (previous infection plus vaccination). Individual patient data from US government-supported harmonized vaccine trials provide an unprecedented sample population to address this issue. We characterized the protective efficacy of previous SARS-CoV-2 infection and hybrid immunity against COVID-19 early in the pandemic over three-to six-month follow-up and compared with vaccine-associated protection. METHODS: In this post-hoc cross-protocol analysis of the Moderna, AstraZeneca, Janssen, and Novavax COVID-19 vaccine clinical trials, we allocated participants into four groups based on previous-infection status at enrolment and treatment: no previous infection/placebo; previous infection/placebo; no previous infection/vaccine; and previous infection/vaccine. The main outcome was RT-PCR-confirmed COVID-19 >7-15 days (per original protocols) after final study injection. We calculated crude and adjusted efficacy measures. FINDINGS: Previous infection/placebo participants had a 92% decreased risk of future COVID-19 compared to no previous infection/placebo participants (overall hazard ratio [HR] ratio: 0.08; 95% CI: 0.05-0.13). Among single-dose Janssen participants, hybrid immunity conferred greater protection than vaccine alone (HR: 0.03; 95% CI: 0.01-0.10). Too

few infections were observed to draw statistical inferences comparing hybrid immunity to vaccine alone for other trials. Vaccination, previous infection, and hybrid immunity all provided near-complete protection against severe disease. INTERPRETATION: Previous infection, any hybrid immunity, and two-dose vaccination all provided substantial protection against symptomatic and severe COVID-19 through the early Delta period. Thus, as a surrogate for natural infection, vaccination remains the safest approach to protection. FUNDING: National Institutes of Health.

Flu vaccination coverage in Italy in the COVID-19 era: A fuzzy functional k-means (FFKM) approach. BACKGROUND: In Europe, flu vaccination coverage has decreased, and there are complex barriers to overcome to vaccinate against flu. Many studies have been conducted to estimate vaccination coverage. The COVID-19 pandemic threatens to disrupt immunization programs in many countries, including Italy, where vaccination against the flu is recommended but not mandatory. This paper aims to understand changes in flu vaccine uptake in Italian regions. METHODS: Using functional data analysis and fuzzy functional k-means clustering, we investigated changes in flu vaccine coverage in Italian regions before (2010-2019) and after (2020-2022) the COVID-19 vaccination period. RESULTS: The period of COVID-19 pandemic brought an increase in vaccine coverage globally. Elbow's method determined that the optimal number of clusters in vaccination uptake is 2. Apulia, Basilicata, Emilia Romagna, Liguria, Molise, Tuscany, and Umbria in 2019 belong less to the group with low flu vaccination uptake (G1) but increase their tendency to belong to this group over time: they decrease their propensity to be vaccinated for flu. For others, it seems that COVID-19 served as a push to increase flu vaccination coverage rates. Sicily appears to be the region that has responded best to the pandemic, changing its membership value from 2019 to 2022. CONCLUSION: The present study highlights that the COVID-19 era has resulted in a higher flu vaccination coverage rate. Moreover, the regional level's improvement or worsening in flu vaccination coverage rate is not affected by the historical gap and socio-cultural and economic differences prevailing among Italian regions.

Distinguishing SARS-CoV-2 infection and vaccine responses up to 18 months post-infection using nucleocapsid protein and receptor-binding domain antibodies. The prediction of the durability of immunity against COVID-19 is relevant, and longitudinal studies are essential for unraveling the details regarding protective SARS-CoV-2 antibody responses. It has become challenging to discriminate between COVID-19 vaccine- and infection-induced immune responses since all approved vaccines in Europe and the USA are based on the viral spike (S) protein, which is also the most commonly used antigen in immunoassays measuring immunoglobulins (Igs) against SARS-CoV-2. We have developed a nucleocapsid (N) protein-based sandwich ELISA for detecting pan anti-SARS-CoV-2 Ig with a sensitivity and specificity of 97%. Generalized mixed models were used to determine the degree of long-term humoral immunity against the N protein and the receptor-binding domain (RBD) of the S protein in a cohort of infected individuals to distinguish between COVID-19 vaccine- and infection-induced immunity. N-specific waning could be observed in individuals who did not experience reinfection, while individuals who experienced reinfection had a new significant increase in N-specific Ig levels. In individuals that seroconverted without a reinfection, 70.1% remained anti-N seropositive after 550 days. The anti-RBD Ig dynamics were unaffected by reinfection but exhibited a clear increase in RBD-specific Ig when vaccination was initiated. In conclusion, a clear difference in the dynamics of the antibody response against N protein and RBD was observed over time. Anti-N protein-specific Igs can be detected up to 18 months after SARS-CoV-2 infection allowing long-term discrimination of infectious and vaccine antibody responses.IMPORTANCELongitudinal studies are essential to unravel details regarding the protective antibody responses after COVID-19 infection and vaccination. It has become challenging to distinguish long-term immune responses to SARS-CoV-2 infection and vaccination since most approved vaccines are based on the viral spike (S) protein, which is also mostly used in immunoassays measuring immunoglobulins (Igs) against SARS-CoV-2. We have

developed a novel nucleocapsid (N) protein-based sandwich ELISA for detecting pan-anti-SARS-CoV-2 Ig, exhibiting high sensitivity and specificity. Generalized mixed models were used to determine long-term humoral immunity in a cohort of infected individuals from the Faroe Islands, distinguishing between COVID-19 vaccine- and infection-induced immunity. A clear difference in the dynamics of the antibody response against N protein and S protein was observed over time, and the anti-N protein-specific Igs could be detected up to 18 months after SARS-CoV-2 infection. This enables long-term discrimination between natural infection and vaccine-dependent antibody responses.

Unexpected vaginal bleeding and COVID-19 vaccination in nonmenstruating women. The association between coronavirus disease 2019 (COVID-19) vaccination and vaginal bleeding among nonmenstruating women is not well studied. The Norwegian Institute of Public Health followed several cohorts throughout the pandemic and early performed a systematic data collection of self-reported unexpected vaginal bleeding in nonmenstruating women. Among 7725 postmenopausal women, 7148 perimenopausal women, and 7052 premenopausal women, 3.3, 14.1, and 13.1% experienced unexpected vaginal bleeding during a period of 8 to 9 months, respectively. In postmenopausal women, the risk of unexpected vaginal bleeding (i.e., postmenopausal bleeding) in the 4 weeks after COVID-19 vaccination was increased two- to threefold, compared to a prevaccination period. The corresponding risk of unexpected vaginal bleeding after vaccination was increased three- to fivefold in both nonmenstruating peri- and premenopausal women. In the premenopausal women, Spikevax was associated with at 32% increased risk as compared to Comirnaty. Our results must be confirmed in future studies.

Maternal first trimester COVID-19 vaccination and risk of major non-genetic congenital anomalies. BACKGROUND: Information regarding the risk of early pregnancy COVID-19 vaccination on the development of major congenital anomalies in the offspring is still limited. Here, we study the association between any COVID-19 vaccination during the 1st trimester and at least one major non-genetic congenital anomaly in the offspring. METHODS: We used data from the Dutch Pregnancy Drug Register, an ongoing cohort study. We selected participants with a pregnancy that ended after at least 20â€‰weeks gestation. Pregnant participants self-reported their COVID-19 vaccination status and the presence of congenital anomalies in the offspring. We used logistic regression analyses to study the association between 1st trimester COVID-19 vaccination (gestational week 2â€‰+â€‰0 to 12â€‰+â€‰6) and the risk of at least one major non-genetic congenital anomaly in the offspring. Clustering of anomalies on the ICD10 level by 1st trimester COVID-19 vaccination status was explored using Fisher exact tests. RESULTS: We included 3721 participants of whom 795 (21.4%) were COVID-19 vaccinated during the 1st trimester. The percentage of participants who gave birth to a child with at least one major non-genetic congenital anomaly was comparable between participants who were 1st trimester vaccinated (1.1%) and participants who were not (1.2%) (adjusted odd ratio 0.78 [95% confidence interval 0.35-1.71]). We found no clustering of major non-genetic congenital anomalies by 1st trimester COVID-19 vaccination status (pâ€‰>â€‰.05). CONCLUSIONS: There were no indications of an increased risk of major non-genetic congenital anomalies in the offspring after maternal 1st trimester COVID-19 vaccination. Our findings suggest COVID-19 vaccines are safe during early pregnancy.

Association between BNT162b2 vaccination and health-related quality of life up to 18Â months post-SARS-CoV-2 infection in Israel. We determined whether COVID-19 vaccination was associated with Quality of Life (QoL) changes among individuals previously infected with SARS-CoV-2 in Israel. Using a validated questionnaire, we collected information about socio-demographics, SARS-CoV-2 infection, COVID-19 vaccination and QoL (using the EQ-5D-5L tool) 3-18Â months post-infection among adults tested for SARS-CoV-2 by polymerase chain reaction in Northern Israel between March 2020-June 2022. We compared post-COVID QoL between those vaccinated against COVID-19 at the

time of infection and those not, using an adjusted linear regression model, stratified by time elapsed since infection. Of 951 participants, mean EQ-5D Utility Index (EQ-5D UI) was 0.82 (SDâ€‰=â€‰0.26) and 0.83 (SDâ€‰=â€‰0.25) among the 227 double and 250 triple vaccinated respectively, compared to 0.76 (SDâ€‰=â€‰0.33) among those who received 0 dose (nâ€‰=â€‰243). The size of the effect of vaccination was small (Cohen's dâ€‰=â€‰0.2). In the adjusted model, previously infected individuals vaccinated with two or more doses reported a QoL score post- infection 0.05 points higher (CIâ€‰=â€‰0.01-0.10, pâ€‰=â€‰0.02) compared with those unvaccinated when infected. No association between vaccination and QoL was detected beyond 12Â months post-infection. Vaccination with two or more doses of COVID19 vaccine, or at least the BNT162b2 vaccine, may modestly mitigate QoL losses associated with post-acute COVID-19 symptoms, at least in the first 12Â months post-infection.

Reply to "The nature and severity of SARS-CoV-2 vaccines side effects are highly dependent on study design" and "Self-reported side effects following COVID-19 vaccination in athletes: Correspondence".

Life-threatening severe acute respiratory syndrome coronavirus-2 mRNA vaccine-associated myocarditis after COVID-19 myocarditis.

Relapsing TIPIC Syndrome after Administration of an mRNA-Based COVID-19 Vaccine. Reported vascular complications following mRNA-based COVID-19 vaccines are consisting of myocarditis, cerebral venous thrombosis, cerebral vascular thrombosis, and vaccine-induced thrombocytopenia. Here, we describe a case of a 49-year-old woman with left-sided pain above the middle common carotid artery (carotidynia) starting a few days after her second vaccination with an mRNA-based COVID-19 vaccine (Spikevax). Imaging was indicative of transient perivascular inflammation of the carotid artery (TIPIC) syndrome. The diagnostic workup for other immunologically mediated diseases was negative. The inflammation subsided after a course of prednisone and aspirin, and clinical symptoms vanished, but later mildly relapsed in the context of a viral upper respiratory tract infection other than SARS-CoV-2. Carotidynia because of TIPIC syndrome may present as an immunogenic side effect of the newly developed mRNA-based vaccinations against COVID-19. TIPIC syndrome should be considered in new-onset neck pain after vaccination.

Clinical characteristics and prognosis of temporary miller fisher syndrome following COVID-19 vaccination: a systematic review of case studies. BACKGROUND: Miller Fisher syndrome (MFS) is a subtype of Guillain-BarrÃ© syndrome (GBS) which is characterized by the three components of ophthalmoplegia, ataxia, and areflexia. Some studies reported MFS as an adverse effect of the COVID-19 vaccination. We aimed to have a detailed evaluation on demographic, clinical, and para-clinical characteristics of subjects with MFS after receiving COVID-19 vaccines. MATERIALS AND METHODS: A thorough search strategy was designed, and PubMed, Web of Science, and Embase were searched to find relevant articles. Each screening step was done by twice, and in case of disagreement, another author was consulted. Data on different characteristics of the patients and types of the vaccines were extracted. The risk of bias of the studies was assessed using Joanna Briggs Institute (JBI) tools. RESULTS: In this study, 15 patients were identified from 15 case studies. The median age of the patients was 64, ranging from 24 to 84 years. Ten patients (66.6%) were men and Pfizer made up 46.7% of the injected vaccines. The median time from vaccination to symptoms onset was 14 days and varied from 7 to 35 days. Furthermore,14 patients had ocular signs, and 78.3% (11/14) of ocular manifestations were bilateral. Among neurological conditions, other than MFS triad, facial weakness or facial nerve palsy was the most frequently reported side effect that was in seven (46.7%) subjects. Intravenous immunoglobulin (IVIg) was the most frequently used treatment (13/15, 86.7%). Six patients received 0.4 g/kg and the four had 2 g/kg. Patients stayed at the hospital from five to 51 days. No fatal outcomes were reported. Finally, 40.0% (4/15) of patients completely recovered, and the rest experienced improvement. CONCLUSION: MFS after COVID-19 immunization has favorable

outcomes and good prognosis. However, long interval from disease presentation to treatment in some studies indicates that more attention should be paid to MFS as the adverse effect of the vaccination. Due to the challenging diagnosis, MFS must be considered in list of the differential diagnosis in patients with a history of recent COVID-19 vaccination and any of the ocular complaints, ataxia, or loss of reflexes, specially for male patients in their 60s and 70s.

Major cardiovascular events after COVID-19, event rates post-vaccination, antiviral or anti-inflammatory therapy, and temporal trends: Rationale and methodology of the CORONA-VTE-Network study.

Association between ethnic background and COVID-19 morbidity, mortality and vaccination in England: a multistate cohort analysis using the UK Biobank. OBJECTIVES: Despite growing evidence suggesting increased COVID-19 mortality among people from ethnic minorities, little is known about milder forms of SARS-CoV-2 infection. We sought to explore the association between ethnic background and the probability of testing, testing positive, hospitalisation, COVID-19 mortality and vaccination uptake. DESIGN: A multistate cohort analysis. Participants were followed between 8 April 2020 and 30 September 2021. SETTING: The UK Biobank, which stores medical data on around half a million people who were recruited between 2006 and 2010. PARTICIPANTS: 405â€‰541 subjects were eligible for analysis, limited to UK Biobank participants living in England. 23â€‰891 (6%) of participants were non-white. PRIMARY AND SECONDARY OUTCOME MEASURES: The associations between ethnic background and testing, testing positive, hospitalisation and COVID-19 mortality were studied using multistate survival analyses. The association with single and double-dose vaccination was also modelled. Multistate models adjusted for age, sex and socioeconomic deprivation were fitted to estimate adjusted HRs (aHR) for each of the multistate transitions. RESULTS: 18â€‰172 (4.5%) individuals tested positive, 3285 (0.8%) tested negative and then positive, 1490 (6.9% of those tested positive) were hospitalised, and 129 (0.6%) tested positive at the moment of hospital admission (ie, direct hospitalisation). Finally, 662 (17.4%) died after admission. Compared with white participants, Asian participants had an increased risk of negative to positive transition (aHR 1.24 (95% CI 1.02 to 1.52)), testing positive (95% CI 1.44 (1.33 to 1.55)) and direct hospitalisation (1.61 (95% CI 1.28 to 2.03)). Black participants had an increased risk of hospitalisation following a positive test (1.71 (95% CI 1.29 to 2.27)) and direct hospitalisation (1.90 (95% CI 1.51 to 2.39)). Although not the case for Asians (aHR 1.00 (95% CI 0.98 to 1.02)), black participants had a reduced vaccination probability (0.63 (95% CI 0.62 to 0.65)). In contrast, Chinese participants had a reduced risk of testing negative (aHR 0.64 (95% CI 0.57 to 0.73)), of testing positive (0.40 (95% CI 0.28 to 0.57)) and of vaccination (0.78 (95% CI 0.74 to 0.83)). CONCLUSIONS: We identified inequities in testing, vaccination and COVID-19 outcomes according to ethnicity in England. Compared with whites, Asian participants had increased risks of infection and admission, and black participants had almost double hospitalisation risk, and a 40% lower vaccine uptake.

Efficacy and safety of an inactivated virus-particle vaccine for SARS-CoV-2, BIV1-CovIran: randomised, placebo controlled, double blind, multicentre, phase 3 clinical trial. OBJECTIVE: To report the efficacy, safety, and exploratory immunogenicity findings of two 5 Âµg doses of the BIV1-CovIran vaccine. DESIGN: Randomised, placebo controlled, double blind, multicentre, phase 3 clinical trial. SETTING: In six cities of Iran, including Bushehr, Isfahan, Karaj, Mashhad, Shiraz, and Tehran. The first vaccine or placebo injection of the first participant was on 16 May 2021 in Tehran. The last vaccine or placebo injection of the last participant occurred on 15 July 2021 in Isfahan. PARTICIPANTS: 20â€‰000 participants aged 18-75 years were randomly assigned to the intervention or placebo groups with a ratio of 2:1. INTERVENTION: 5 Âµg vaccine or placebo with the interval of 28 days. MAIN OUTCOME MEASURES: Vaccine efficacy for a 90 day follow-up period, safety and explanatory immunogenicity assessment, and variant detection during the trial. RESULTS: 20â€‰000 participants

were recruited and randomly assigned to receive BIV1-CovIran (n=13â€‰335 (66.7%)) or placebo (n=6665 (33.3%)). Participants' mean age was 38.3 (standard deviation 11.2) years, and 6913 (34.6%) were female. Among vaccinated participants that had covid-19 reported during the follow-up (median 83 days), 758 (5.9%) had symptoms, 144 (1.1%) had severe infection, and seven (0.1%) were critical. Among participants who received placebo during the follow-up, 688 (10.7%) had symptoms, 221 (3.4%) had severe infection, and 19 (0.3%) were critical. Overall efficacy was 50.2% (95% confidence interval 44.7% to 55.0%) against symptomatic covid-19, 70.5% (63.7% to 76.1%) against severe disease, and 83.1% (61.2% to 93.5%) against critical cases. Two deaths were reported in the efficacy population in the placebo group, no deaths were from the intervention group. During follow-up, 41â€‰922 adverse events were reported: 28â€‰782 (68.7%) were adverse reactions, of which 19â€‰363 (67.3%) were in the intervention group. Most adverse reactions were mild or moderate in severity (grade 1 or 2) and self-limiting. No serious adverse events were related to the injections. For variant investigation, of 119 participants positive for the SARS-CoV-2 variant, 106 (89.1%) were positive for the delta variant. CONCLUSIONS: A two dose regimen of the BIV1-CovIran vaccine conferred efficacy of 50.2% against symptomatic covid-19, 70.5% against severe disease, and 83.1% against critical disease. Vaccination was well tolerated, with no safety concerns raised. TRIAL REGISTRATION: Iranian Registry of Clinical Trials, IRCT20201202049567N3. FUNDING: Shifa-Pharmed Industrial Group.

Fibrinogenolysis and fibrinolysis in vaccine-induced immune thrombocytopenia and thrombosis. BACKGROUND: Vaccine-induced immune thrombocytopenia and thrombosis (VITT) is a rare syndrome associated with adenoviral vector vaccines for COVID-19. The syndrome is characterized by thrombosis, anti-platelet factor 4 (PF4) antibodies, thrombocytopenia, high D-dimer, and hypofibrinogenemia. OBJECTIVES: To investigate abnormalities in fibrinolysis that contribute to the clinical features of VITT. METHODS: Plasma samples from 18 suspected VITT cases were tested for anti-PF4 by ELISA and characterized as meeting criteria for VITT (11/18) or deemed unlikely (7/18; non-VITT). Antigen levels of PAI-1, factor XIII (FXIII), plasmin-Î±(2)antiplasmin (PAP), and inflammatory markers were quantified. Plasmin generation was quantified by chromogenic substrate. Western blotting was performed with antibodies to fibrinogen, FXIII-A, and plasminogen. RESULTS: VITT patients 10/11 had scores indicative of overt disseminated intravascular coagulation, while 0/7 non-VITT patients met the criteria. VITT patients had significantly higher levels of inflammatory markers, IL-1Î², IL-6, IL-8, TNFÎ±, and C-reactive protein. In VITT patients, both fibrinogen and FXIII levels were significantly lower, while PAP and tPA-mediated plasmin generation were higher compared to non-VITT patients. Evidence of fibrinogenolysis was observed in 9/11 VITT patients but not in non-VITT patients or healthy controls. Fibrinogen degradation products were apparent, with obvious cleavage of the fibrinogen Î±-chain. PAP complex was evident in those VITT patients with fibrinogenolysis, but not in non-VITT patients or healthy donors. CONCLUSION: VITT patients show evidence of overt disseminated intravascular coagulation and fibrinogenolysis, mediated by dysregulated plasmin generation, as evidenced by increased PAP and plasmin generation. These observations are consistent with the clinical presentation of both thrombosis and bleeding in VITT.

Oral adverse events following COVID-19 and influenza vaccination in Australia. Vaccine hesitancy, spurred by misinterpretation of Adverse Events (AEs), threatens public health. Despite sporadic reports of oral AEs post-COVID-19 vaccination, systematic analysis is scarce. This study evaluates these AEs using the Australian Database of Adverse Event Notifications (DAEN). A secondary analysis of DAEN data was conducted, with the analysis period commencing from the start of the COVID-19 vaccination rollout in February 2021 and the inception of the influenza vaccine database in 1971, both through until December 2022. The focus of the analysis was on oral AEs related to COVID-19 and influenza vaccines. Reports were extracted according to a predefined schema and then stratified by

vaccine type, sex, and age. Oral paresthesia was the most common oral AE after COVID-19 vaccination (75.28 per 10,000 reports), followed by dysgeusia (73.96), swollen tongue (51.55), lip swelling (49.43), taste disorder (27.32), ageusia (25.85), dry mouth (24.75), mouth ulceration (18.97), oral hypoaesthesia (15.60), and oral herpes (12.74). While COVID-19 and influenza vaccines shared most oral AEs, taste-related AEs, dry mouth, and oral herpes were significantly more common after COVID-19 vaccination. mRNA vaccines yielded more oral AEs than other types. Females had higher oral AE incidence. Most oral AEs did not differ significantly between COVID-19 and influenza vaccination. However, specific oral AEs, particularly taste-related, dry mouth, and oral herpes, were more prevalent after COVID-19 vaccination compared with seasonal influenza, especially in females and mRNA vaccine recipients.

Oral Steroid Responsive Allergic Eruption Following COVID-19 Vaccination. Cutaneous reactions following immunization, while rare, are a known adverse effect of many vaccinations. The precise etiology of such dermatologic manifestations and their long-term effects are largely unknown. This case study describes a 37-year-old female patient who initially presented with an edematous, pruritic facial rash that developed one day after vaccination against COVID-19, progressively worsened, and proved resistant to various forms of treatment. Following extensive workup, patch testing revealed a previously non-existent allergy to gold sodium thiosulfate. The use of metals, such as gold, in vaccine manufacturing and biotechnology may suggest the possibility of a relationship between injections and immunologic sensitization. Patch testing may be a useful adjunct in evaluating persistent cutaneous reactions following vaccination.

Association of seizure with COVID-19 vaccines in persons with epilepsy: A systematic review and meta-analysis. Seizure aggravation following coronavirus disease 2019 (COVID-19) vaccines is a major cause behind vaccine hesitancy among persons with epilepsy (PwE), resulting in lower immunization rates. We systematically reviewed seizure-activity-related events in PwE following COVID-19 vaccination. We systematically searched PubMed, Web of Science, Scopus, and Cochrane Library, until January 31, 2023, and included articles reporting seizure activity-related events in PwE receiving COVID-19 vaccination. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses were followed. The protocol was registered with PROSPERO (CRD42022312475). Outcomes included pooled incidence proportions of (a) increased seizure frequency, (b) status epilepticus (SE), and (c) change in seizure type. Of the 2207 studies, 16 entered the meta-analysis. The pooled incidence proportion of increased seizure frequency (16 studies-3245 PwE) was 5% (95% CI: 3%-7%, I(2) â€‰=â€‰52%). Regarding increased seizure frequency, no significant difference was observed between mRNA and viral vector (OR: 1.11, 95% CI: 0.49-2.52, I(2) â€‰=â€‰0%), and between mRNA and inactivated virus (OR: 1.60, 95% CI: 0.27-9.37; I(2) â€‰=â€‰0%). The pooled incidence proportion of SE (15 studies-2387 PwE) was 0.08% (95% CI: 0.02%-0.33%, I(2) â€‰=â€‰0%). Ultimately, the pooled incidence proportion of change in seizure type (7 studies-1172 PwE) was 1% (95% CI: 1%-2%, I(2) â€‰=â€‰0%). The meta-analysis revealed post-COVID-19-vaccination increased seizure frequency in 5% of PwE, with no difference between mRNA and viral vector or inactivated virus vaccines. Furthermore, we found 0.08% and 1% incidence proportions for postvaccination SE and change in seizure type, respectively. While noteworthy, these values are far less than reports for COVID-19 infection, emphasizing vaccination importance in preventing COVID-19 consequences in PwE.

Review of adverse events associated with COVID-19 vaccines, highlighting their frequencies and reported cases. This review examines the immunological and autoimmune adverse events associated with COVID-19 vaccines, highlighting their frequencies, reported cases, and associations with specific vaccine classes. The concept of vaccine-induced immune thrombotic thrombocytopenia is crucial in addressing vaccine skepticism. Understanding this concept helps healthcare professionals

identify and manage potential adverse events after vaccination. Despite their rarity, immunological and autoimmune adverse events cause concern and anxiety among the public. To maintain public trust in vaccination programs, healthcare professionals and public health agencies must actively monitor and address these adverse events, promptly disclose suspicious incidents, take measures to mitigate dangers, and inform the public with transparency and accurate information. Continuing research and surveillance are essential for understanding the underlying mechanisms of these adverse events and developing strategies to minimize their occurrence.

Myocarditis Following Inactivated SARS-CoV-2 Vaccine (Vero Cell) in an Adult Female in Vietnam: A Case Report. During the Coronavirus disease 2019 (COVID-19) pandemic, vaccination against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) has proven to be an important measure to help control disease spread and improve patient outcome. There are four distinct vaccine categories: inactivated viral vaccines, messenger RNA (mRNA) vaccines, adenovirus vector-based vaccines, and adjuvanted protein vaccines. In 2021, increased cases of myocarditis and pericarditis were reported after mRNA and adenovirus vector-based COVID-19 vaccination. A similar reporting pattern has not been observed after receipt of inactivated virus vaccines. Here, we present a case of clinically suspected acute myocarditis in a 26-year-old female, occurring 11 days after the administration of Sinopharm Vero Cell, an inactivated virus COVID-19 vaccine. This event led to acute heart failure, with marked clinical resolution observed within 34 days.

Dynamic Antibody Response and Hybrid Immunity Following Multiple COVID-19 Vaccine Doses and Infection: A Case Study. This case study highlights the dynamic nature of the antibody response to SARS-CoV-2 in a vulnerable subject aged 70 years between 2021 and 2023. This individual had been vaccinated with six doses of the ancestral (Wuhan-Hu-1) COVID-19 vaccine and had a breakthrough infection 126 days after receiving Covovaxâ„¢ (CO) as the sixth dose. The serostatus for total immunoglobulin specific to the receptor binding domain (total RBD Ig) changed from negative to positive following a two-dose CoronaVac (CV) vaccination, indicating a successful immune response. Booster doses, including AZD1222 (AZ), half-dose BNT162b2 (PF), and CO, increased the total RBD Ig levels, except for CV. The individual experienced a breakthrough infection by the Omicron BA.5 variant, leading to a substantial surge in total RBD Ig to over 10(5) U/mL. This generated sustained and extended antibody persistence, with the half-life of total RBD Ig lasting approximately 103.6 days. Furthermore, it has been observed that this breakthrough infection generated the highest neutralizing antibodies against BA.5, followed by XBB.1.5, BQ.1.1, and BA.2.75, respectively.

Longitudinal long COVID symptoms in Japanese patients after COVID-19 vaccinations. We conducted a subgroup analysis of a study on the long-term effects of COVID-19 (long COVID) in Japan to assess the effect of vaccination on long COVID symptoms. We assessed the clinical course of 111 patients with long COVID at the time of vaccination. The follow-up period was one year from the onset of COVID-19 or until the administration of the third vaccine dose. Of the 111 patients, 15 (13.5%) reported improvement, four (3.6%) reported deterioration, and 92 (82.9%) reported no change in their long COVID symptoms after vaccination. The most common long COVID symptoms before vaccination were alopecia, dyspnea, muscle weakness, fatigue, and headache among participants whose symptoms improved. Reduced dyspnea and alopecia were the most frequently reported improvements in symptoms after vaccination. Some symptoms persisted, including sleep disturbance, myalgia, and hypersensitivity. Vaccination did not appear to have a clinically important effect on patients with long COVID symptoms.

Factors influencing immunogenicity and safety of SARS-CoV-2 vaccine in liver transplantation recipients: a systematic review and meta-analysis. BACKGROUND: This review summarizes the factors influencing the efficacy and safety of the COVID-19 vaccine in LTR through meta-analysis,

hoping to provide strategies for vaccine use. METHODS: Electronic databases were screened for studies on mRNA vaccines in LTR. The primary outcome was the pooled seroconversion rate, and the secondary outcome was the incidence of adverse events+breakthrough infections. Subgroup analyses were made based on BMI, associated comorbidities, presence of baseline leukopenia, time since transplant, and drugs used. RESULT: In total, 31 articles got included. The pooled seroconversion rate after at least two doses of SARS-CoV-2 vaccination was 72% (95% CI [0.52-0.91). With significant heterogeneity among studies I(2)Â =Â 99.9%, the seroconversion rate was about 72% (95%CI [0.66-0.75]), from the studies reporting two doses of vaccine slightly higher around 75%(95%CI [0.29-1.22]) from studies reporting three doses. The pooled seroconversion rate within the lower to normal BMI group was 74% (95% CI [0.22-1.27], Pi=0.005) against 67% (95% CI [0.52-0.81], Pi=0.000) in the high BMI group. The pooled seroconversion rate in the ''positive leukopenia'' group was the lowest, 59%. Leukopenia could influence the vaccine seroconversion rate in LTR. From the time since transplant analysis after setting seven years as cut off point, the pooled seroconversion rate after at least two doses of COVID-19 vaccination was 53% (95% CI [0.18-0.83], P=0.003, I(2)Â =Â 99.6%) in <7years group and 83% (95% CI [0.76-0.90], P=0.000 I(2)Â =Â 95.7%) in > 7years group. The only time since transplantation had reached statistical significance to be considered a risk factor predictor of poor serological response (OR=1.27 95%CI [1.03-1.55], P=0.024). The breakthrough infection rate after vaccination was very low2% (95% CI 0.01-0.03, I(2)Â =Â 63.0%), and the overall incidence of adverse events, which included mainly pain at the injection site and fatigue, was 18% (95%CI [0.11-0.25], I(2)Â =Â 98.6%, Pi=0.000). CONCLUSION: The seroconversion rate in LTR vaccinated with at least two doses of mRNA COVID-19 vaccine could be significantly affected by the vaccine type, immunosuppressant used, BMI, leukopenia, associated comorbidities, and time since transplantation. Nevertheless, booster doses are still recommended for LTR.

The seven-fold rise in incidence of Stevens-Johnson syndrome & toxic epidermal necrolysis: Associations with COVID-19 and the vaccine. Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) is a rare, potentially life threatening mucocutaneous hypersensitivity reaction resulting in desquamation of the skin and mucosa. These patients are managed on burns units due to the widespread desquamation. We report the largest case series of participants developing SJS/TEN in the setting of recent COVID infection or vaccination. We found a seven-fold increase in SJS/TEN since the COVID pandemic. This increase correlates with an increase in COVID infections and vaccination rates. We explore the immunopathological relationships between COVID and SJS/TEN and propose theories for possible associations.

[Autoimmune hemolytic anemia following the third dose of the COVID-19 vaccine]. The development and exacerbation of autoimmune diseases following coronavirus disease 2019 (COVID-19) vaccination have been reported; however, there are few reports of autoimmune hemolytic anemia (AIHA). A 75-year-old woman was admitted to the emergency department 46 days after receiving her third dose of the mRNA-1273 COVID-19 vaccine because of fatigue and general weakness. Initial laboratory analyses revealed severe hemolytic anemia with positive direct and indirect Coombs test and elevation of serum indirect bilirubin and lactate dehydrogenase. The patient had no underlying disease after a close examination and was diagnosed with warm AIHA, which was thought to be associated with COVID-19 vaccination. The anemia improved daily after the administration of prednisolone. Clinicians should be aware of the possibility of AIHA being caused by COVID-19 vaccination, and monotherapy with prednisolone should be considered in cases of severe anemia.

COVID-19 vaccine uptake and associated factors among adolescents and youths: Findings and implications for future vaccination programmes. Adolescents and youths are a key part of the population that needs to be protected against the coronavirus disease 2019 (COVID-19). This is

because they are more likely to spread the virus to vulnerable individuals. In view of these concerns, this study investigated the uptake of COVID-19 vaccines and associated factors among adolescents and youths attending secondary schools in Zambia. This cross-sectional study was conducted among 1500 school-going adolescents in Lusaka from September 2022 to November 2022. Overall, 1409 participants took part giving a response rate of 94%. Only 29.2% (n = 411) of the participants were vaccinated against COVID-19 at the time of the study. Compared to their unvaccinated counterparts, vaccinated adolescents and youths scored higher for knowledge (66.2% vs 57.8%) and attitudes (76.7% vs 39.4%) regarding COVID-19 vaccines. Healthcare workers, family/friends and social media were key sources of information regarding the vaccine. Factors associated with increased vaccine uptake were positive attitudes (AOR = 33.62, 95% CI: 19.92-56.73), indicating it was stressful to follow COVID-19 preventive measures (AOR = 1.47, 95% CI: 1.09-1.99), participants in Grade 12 (AOR = 3.39, 95% CI: 1.94-5.91), Grade 11 (AOR = 2.59, 95% CI: 1.94-5.91), Grade 10 (AOR = 3.48, 95% CI: 1.98-6.11) and Grade 9 (AOR = 3.04, 95% CI: 1.74-5.32) compared to Grade 8. This study found a relatively low uptake of COVID-19 vaccines among adolescents and youths in Zambia. There is a need to provide adequate strategies to address knowledge and attitude gaps regarding COVID-19 vaccines to improve uptake and reduce future morbidity and mortality.

Prevalence and risk factors of COVID-19 infection, mortality, and post-infection lung fibrosis in patients with type 2 diabetes: a cross-sectional study. OBJECTIVES: The clinical course of coronavirus disease 2019 (COVID-19) infection is often aggressive, with unfavorable outcomes for those with comorbidities such as type 2 diabetes mellitus (T2DM). We aimed to assess the prevalence and risk factors of COVID-19 infection, mortality, and post-infection lung fibrosis in patients with COVID-19 infection who had T2DM. METHODS: In this cross-sectional study, we included adult patients with T2DM who attended an endocrinology clinic and underwent testing for COVID-19 infection. RESULTS: Among 1039 included patients, the mean age was 59.5â€‰Â±â€‰11.0 years and 429 (41.3%) were men. Overall, 87.1% of patients had received COVID-19 vaccination and 32.3% had confirmed COVID-19 infection. The COVID-19-related mortality was 3.0% and rate of post-COVID-19 lung fibrosis was 19.1%. Vaccination was associated with lower COVID-19-related mortality (odds ratio [OR]: 0.03, 95% confidence interval [CI]: 0.0-0.3) and post-COVID-19 lung fibrosis risk (OR: 0.3, 95% CI: 0.1-0.9). CONCLUSION: Patients with T2DM exhibited a high prevalence of COVID-19 infection and associated mortality. However, COVID-19 vaccines were beneficial in reducing the risks of COVID-19-related mortality and post-infection lung fibrosis in these patients. COVID-19 vaccines and boosters are recommended for patients with T2DM. Further studies involving larger study populations are necessary to validate these findings.

Dermatomyositis in Association With SARS-CoV-2 Infection or COVID-19 Vaccine. OBJECTIVE: New-onset and relapsed dermatomyositis (DM) has been reported following SARS-CoV-2 infection or COVID-19 vaccination. This study aims to show the characteristics of a DM cohort after COVID-19 infection and vaccination. METHODS: A retrospective review was performed on patients treated for DM between March 1, 2020, and October 31, 2022. Charts were evaluated for the presence of new-onset DM or relapse of preexisting DM following either SARS-CoV-2 infection or COVID-19 vaccination. Data on symptom onset, timing of vaccination, type of vaccination, and disease characteristics were collected. RESULTS: Ninety-eight patients treated for DM at our institution in the Division of Rheumatology were included. In total, 12 of 98 patients (12.2%) experienced DM symptoms (either incident or relapse) following either infection or vaccination. Of the 12 patients who developed incident disease or relapse, 7 (58.3%) developed postinfection symptoms, and 8 (66.7%) developed symptoms after vaccination (3 patients had symptoms following both infection and vaccination). The mean onset of symptoms following COVID-19 infection was 3.2â€‰days (median 0.5â€‰days), and mean onset following COVID-19 vaccination was 5.75â€‰days (median

3.5â€‰days). Nine of 12 patients (75%) had a positive myositis-specific antibody, and the remaining 3 (25%) had myositis-associated antibodies. There was no predominant vaccine associated with the development of postvaccination DM symptoms. CONCLUSION: This retrospective review revealed a strong temporal relationship between DM symptoms and COVID-19 infection or vaccination in 12.2% of all patients with DM evaluated in our clinic during the pandemic. Additional studies are required to understand the possible pathophysiology behind this association.

Olfactory Hallucinations Following COVID-19 Vaccination. BACKGROUND: Vaccine-induced phantosmia is a rare adverse effect of vaccination and has not been previously reported related to the Johnson & Johnson (J&J) COVID-19 vaccine. CASE PRESENTATION: Three weeks after receiving the J&J COVID-19 vaccine, a 39-year-old veteran started smelling a burning odor in the absence of an identifiable source. At presentation to the clinic, his general and neurological examinations, brain magnetic resonance imaging, and electroencephalogram were all unremarkable. The episodes persisted for nearly 2 years (21 months postvaccination). CONCLUSIONS: This is the only case of phantosmia reported after the use of the J&J COVID-19 vaccine and aligns with the literature that reports 1 case of phantosmia and 2 cases of hyposmia following the Pfizer-BioNTech COVID-19 mRNA vaccine. This information will help health care professionals understand the possible adverse effects of COVID-19 vaccination and be better equipped to counsel patients about the benign but potentially long-lasting adverse effects of the J&J COVID-19 vaccine.

Three Cases of Arteritic Anterior Optic Neuropathy Several Months after COVID-19 Vaccination. BACKGROUND: Vaccines have been approved worldwide to control the coronavirus disease-19 (COVID-19). However, the postvaccination side effects remain controversial. Here, we describe three Japanese cases of arteritic anterior ischaemic optic neuropathy (AAION) following COVID-19 vaccination. Case presentation. The first case involved an 87-year-old woman who presented with vision loss in the right eye 2 months after her second COVID-19 vaccine and in the left eye 2 days later. The second case involved an 88-year-old woman who presented with vision loss in both eyes 3 months after receiving a second vaccine. The third case involved an 80-year-old man who presented with vision loss in the right eye 5 months after receiving a second vaccine. The C-reactive protein level and erythrocyte sedimentation rate were elevated in all patients. Biopsy of the temporal artery or auricular cartilage showed arteritic occlusion in case 2 and polychondritis in case 3. These patients were referred to a local Japanese hospital in 2021 over a period of no longer than 3 months. CONCLUSION: We observed three cases of AAION after the affected individuals received their second COVID-19 vaccine. Further long-term investigations of ophthalmological events after COVID-19 vaccination are warranted.

Patient-reported reactogenicity and safety of COVID-19 vaccinations vs. comparator vaccinations: a comparative observational cohort study. BACKGROUND: In the course of the SARS-CoV-2 pandemic, multiple vaccines were developed. Little was known about reactogenicity and safety in comparison to established vaccines, e.g. influenza, pneumococcus, or herpes zoster. Therefore, the present study aimed to compare self-reported side effects in persons vaccinated against SARS-CoV-2 with the incidence of side effects in persons receiving one of the established vaccines. METHODS: A longitudinal observational study was conducted over a total of 124Â days using web-based surveys. Persons receiving either a vaccination against SARS-CoV-2 or one of the established vaccines (comparator group) were included. In the first questionnaire (short-term survey), 2Â weeks after vaccination, mainly local and systemic complaints were evaluated. The long-term survey (42Â days after vaccination) and follow-up survey (124Â weeks after vaccination) focused on medical consultations for any reason. Multivariate analyses were conducted to determine the influence of the vaccine type (SARS-CoV-2 vs. comparator) and demographic factors. RESULTS: In total, data from 16,636 participants were included. Self-reported reactogenicity was lowest in the comparator group

(53.2%) and highest in the ChAdOx1 group (85.3%). Local reactions were reported most frequently after mRNA-1273 (73.9%) and systemic reactions mainly after vector-based vaccines (79.8%). Almost all SARS-CoV-2 vaccines showed increased odds of reporting local or systemic reactions. Approximately equal proportions of participants reported medical consultations. None in the comparator group suspected a link to vaccination, while this was true for just over one in 10 in the mRNA-1273 group. The multivariate analysis showed that people with SARS-CoV-2 vaccination were not more likely to report medical consultations; patients who had received a regimen with at least one ChAdOx1 were even less likely to report medical consultations. Younger age, female gender and higher comorbidity were mostly associated with higher odds of medical consultations. CONCLUSION: The rate of adverse reactions after established vaccinations was roughly comparable to previous studies. Two weeks after vaccination, participants in the SARS-CoV-2 vaccination group reported more local and systemic local reactions than participants in the comparator group. In the further course, however, there were no higher odds of medical consultations in either of the two groups. Thus, altogether, we assume comparable safety. TRIAL REGISTRATION: DRKS-ID DRKS00025881 and DRKS-ID DRKS00025373.

CMR findings after COVID-19 and after COVID-19-vaccination-same but different? Cardiac involvement has been described in varying proportions of patients recovered from COVID-19 and proposed as a potential cause of prolonged symptoms, often described as post-COVID or long COVID syndrome. Recently, cardiac complications have been reported from COVID-19 vaccines as well. We aimed to compare CMR-findings in patients with clinical cardiac symptoms after COVID-19 and after vaccination. From May 2020 to May 2021, we included 104 patients with suspected cardiac involvement after COVID-19 who received a clinically indicated cardiac magnetic resonance (CMR) examination at a high-volume center. The mean time from first positive PCR to CMR was 112â€‰ Â± 76Â days. During their COVID-19 disease, 21% of patients required hospitalization, 17% supplemental oxygen and 7% mechanical ventilation. In 34 (32.7%) of patients, CMR provided a clinically relevant diagnosis: Isolated pericarditis in 10 (9.6%), %), acute myocarditis (both LLC) in 7 (6.7%), possible myocarditis (one LLC) in 5 (4.8%), ischemia in 4 (3.8%), recent infarction in 2 (1.9%), old infarction in 4 (3.8%), dilated cardiomyopathy in 3 (2.9%), hypertrophic cardiomyopathy in 2 (1.9%), aortic stenosis, pleural tumor and mitral valve prolapse each in 1 (1.0%). Between May 2021 and August 2021, we examined an additional 27 patients with suspected cardiac disease after COVID-19 vaccination. Of these, CMR provided at least one diagnosis in 22 (81.5%): Isolated pericarditis in 4 (14.8%), acute myocarditis in 9 (33.3%), possible myocarditis (acute or subsided) in 6 (22.2%), ischemia in 3 (37.5% out of 8 patients with stress test), isolated pericardial effusion (>â€‰10Â mm) and non-compaction-cardiomyopathy each in 1 (3.7%). The number of myocarditis diagnoses after COVID-19 was highly dependent on the stringency of the myocarditis criteria applied. When including only cases of matching edema and LGE and excluding findings in the right ventricular insertion site, the number of cases dropped from 7 to 2 while the number of cases after COVID-19 vaccination remained unchanged at 9. While myocarditis is an overall rare side effect after COVID-19 vaccination, it is currently the leading cause of myocarditis in our institution due to the large number of vaccinations applied over the last months. Contrary to myocarditis after vaccination, LGE and edema in myocarditis after COVID-19 often did not match or were confined to the RV-insertion site. Whether these cases truly represent myocarditis or a different pathological entity is to be determined in further studies.

Monitoring the evolution of myocarditis following COVID-19 mRNA vaccination with serial cardiac magnetic resonance imaging.

A large survey on COVID-19 vaccination in patients with Parkinson's disease and healthy population. BACKGROUND: A full rollout of COVID-19 vaccination offers the most promising prospect of bringing

the pandemic to an end. This study aimed to compare the coverage, safety, and confidence of COVID-19 vaccination between patients with Parkinson's disease (PD) and healthy individuals so as to give suggestions for future immunization programs. METHODS: A web-based, nationwide, multicenter survey was carried out in China from 2021 to 2022. The age and sex-standardized vaccination rate was calculated. Multivariate stepwise logistic regression models were used to estimate the influencing factors of vaccination status. We also investigated vaccination safety, willingness, confidence, and reasons for hesitancy with some ad hoc questions. RESULTS: A total of 962 PD patients and 1208 healthy individuals participated in this survey with a vaccination rate of 71.1% vs 94.4% respectively. PD patients living in first-tier cities, with comorbidities, experiencing unstable PD with a longer course and levodopa use were less likely to get vaccinated, while healthy individuals living in first-tier cities and feeling physically poor exhibited a lower vaccination rate. For PD patients, concern about the adverse impact on existing illness and disagreement from doctors were the most common reasons for vaccination hesitancy. Whereas, no evidence was present that they experienced any local or systematic adverse events more frequently or seriously than healthy individuals, or their state of PD and comorbidities was seriously exacerbated after vaccination. A prominent transition from a little concerned to unconcerned about the security and efficacy of vaccines was evident among both two populations from pre-vaccination to post-vaccination. CONCLUSIONS: The COVID-19 vaccination rate was remarkably lower in PD patients than healthy individuals in China. The approved vaccines have shown an acceptable safety profile. Our findings would offer a reference to guide future clinical decision-making of COVID-19 vaccination and improve the immunization management of PD patients.

Postmenopausal bleeding after COVID-19 vaccination. BACKGROUND: There is a growing literature base regarding menstrual changes following COVID-19 vaccination among premenopausal people. However, relatively little is known about uterine bleeding in postmenopausal people following COVID-19 vaccination. OBJECTIVE: This study aimed to examine trends in incident postmenopausal bleeding diagnoses over time before and after COVID-19 vaccine introduction, and to describe cases of new-onset postmenopausal bleeding after COVID-19 vaccination. STUDY DESIGN: For postmenopausal bleeding incidence calculations, monthly population-level cohorts consisted of female Kaiser Permanente Northwest members aged â‰¥45 years. Those diagnosed with incident postmenopausal bleeding in the electronic medical record were included in monthly numerators. Members with preexisting postmenopausal bleeding or abnormal uterine bleeding, or who were at increased risk of bleeding due to other health conditions, were excluded from monthly calculations. We used segmented regression analysis to estimate changes in the incidence of postmenopausal bleeding diagnoses from 2018 through 2021 in Kaiser Permanente Northwest members meeting the inclusion criteria, stratified by COVID-19 vaccination status in 2021. In addition, we identified all members with â‰¥1 COVID-19 vaccination between December 14, 2020 and August 14, 2021, who had an incident postmenopausal bleeding diagnosis within 60 days of vaccination. COVID-19 vaccination, diagnostic procedures, and presumed bleeding etiology were assessed through chart review and described. A temporal scan statistic was run on all cases without clear bleeding etiology. RESULTS: In a population of 75,530 to 82,693 individuals per month, there was no statistically significant difference in the rate of incident postmenopausal bleeding diagnoses before and after COVID-19 vaccine introduction (P=.59). A total of 104 individuals had incident postmenopausal bleeding diagnosed within 60 days following COVID-19 vaccination; 76% of cases (79/104) were confirmed as postvaccination postmenopausal bleeding after chart review. Median time from vaccination to bleeding onset was 21 days (range: 2-54 days). Among the 56 postmenopausal bleeding cases with a provider-attributed etiology, the common causes of bleeding were uterine or cervical lesions (50% [28/56]), hormone replacement therapy (13% [7/56]), and proliferative

endometrium (13% [7/56]). Among the 23 cases without a clear etiology, there was no statistically significant clustering of postmenopausal bleeding onset following vaccination. CONCLUSION: Within this integrated health system, introduction of COVID-19 vaccines was not associated with an increase in incident postmenopausal bleeding diagnoses. Diagnosis of postmenopausal bleeding in the 60 days following receipt of a COVID-19 vaccination was rare.

Assessment of antibody dynamics and neutralizing activity using serological assay after SARS-CoV-2 infection and vaccination. The COVID-19 antibody test was developed to investigate the humoral immune response to SARS-CoV-2 infection. In this study, we examined whether S antibody titers measured using the anti-SARS-CoV-2 IgG II Quant assay (S-IgG), a high-throughput test method, reflects the neutralizing capacity acquired after SARS-CoV-2 infection or vaccination. To assess the antibody dynamics and neutralizing potency, we utilized a total of 457 serum samples from 253 individuals: 325 samples from 128 COVID-19 patients including 136 samples from 29 severe/critical cases (Group S), 155 samples from 71 mild/moderate cases (Group M), and 132 samples from 132 health care workers (HCWs) who have received 2 doses of the BNT162b2 vaccinations. The authentic virus neutralization assay, the surrogate virus neutralizing antibody test (sVNT), and the Anti-N SARS-CoV-2 IgG assay (N-IgG) have been performed along with the S-IgG. The S-IgG correlated well with the neutralizing activity detected by the authentic virus neutralization assay (0.8904. of Spearman's rho value, $p < 0.0001$) and sVNT (0.9206. of Spearman's rho value, $p < 0.0001$). However, 4 samples (2.3%) of S-IgG and 8 samples (4.5%) of sVNT were inconsistent with negative results for neutralizing activity of the authentic virus neutralization assay. The kinetics of the SARS-CoV-2 neutralizing antibodies and anti-S IgG in severe cases were faster than the mild cases. All the HCWs elicited anti-S IgG titer after the second vaccination. However, the HCWs with history of COVID-19 or positive N-IgG elicited higher anti-S IgG titers than those who did not have it previously. Furthermore, it is difficult to predict the risk of breakthrough infection from anti-S IgG or sVNT antibody titers in HCWs after the second vaccination. Our data shows that the use of anti-S IgG titers as direct quantitative markers of neutralizing capacity is limited. Thus, antibody tests should be carefully interpreted when used as serological markers for diagnosis, treatment, and prophylaxis of COVID-19.

Prevalence of Antibodies to COVID-19 Due to Infection or Vaccination in US Adults. OBJECTIVE: -Determine the seroprevalence of SARS-CoV-2 infection and vaccination in a population applying for life insurance. SETTING: -This is a cross-sectional study of 2584 US life insurance applicants, to determine the seroprevalence of antibodies to COVID-19. This convenience sample was selected on two consecutive days April 25-26, 2022. RESULTS: -For COVID-19, 97.3% are seropositive, and 63.9% have antibodies to nucleocapsid protein, a marker of prior infection. An additional, 33.7% have been vaccinated with no serologic evidence of infection. METHODOLOGY: -Serum and urine samples from a nationwide group of insurance applicants for routine risk assessment were collected. The examination of applicants typically occurs, in their homes, their place of employment, or a clinic. The paramedic exam occurs 7-14 days after the insurance application. Before the exam, an office assistant calls the applicant and inquires if they have been in contact with a person with SARS-CoV-2, been ill within the last 2 weeks, felt sick, or recently had a fever. If the applicant answers yes, the exam is rescheduled. Before sample collection, the applicant reads and signs a consent form to release medical information and testing. Next, the examiner records the applicant's blood pressure, height, and weight. Then, a blood and a urine sample are collected and sent with the consent form to our laboratory via Federal Express. On April 25-26, 2022, we tested 2584 convenience samples from adult insurance applicants for the presence of antibodies to nucleocapsid and spike proteins from SARS-CoV-2. As a standard practice, we reported the client-specified test profile results to our life insurance carriers. In contrast, the COVID-19 test results were only available to the authors. Patient and Public Involvement.-There was no patient involvement in study design, reporting of results, or journal

publication selection. There was patient consent to publish de-identified study results. No public involvement occurred in the creation or completion of the study. The authors thank the participants in this study for approving the use of their blood samples to further society's understanding of the SARS-CoV-19 pandemic. Ethics Review.-Western Institutional Review Board reviewed the study design and determined it to be exempt under the Common Rule and applicable guidance. Therefore, it is exempt under 45 CFR Â§ 46.104(d)(4) from using de-identified study samples for epidemiologic investigation, WIRB Work Order #1-1324846-1. In addition, all test subjects had signed a consent allowing research of their blood and urine samples with the removal of personally identifiable information. RESULTS: -The combined seroprevalence for antibodies to nucleocapsid, a marker of prior infection, and antibodies to spike protein, an indicator of either previous infection or vaccination, was 97.3%. Higher infection rates occur in younger vs older age groups, with a non-statistical difference for vaccinated and acquired natural immunity. For the age group 16-84, the total estimated seroprevalence of COVID-19 in the US is 249 million cases. CONCLUSIONS: -The US population has widespread immune resistance to current variants of COVID-19 due to prior infection or vaccination. The infectivity of new variants and silent disease, independent of previous infection or vaccination, are the driving force behind the sporadic increase in clinical SARS-CoV-2 cases.

Clinical characteristics, outcomes and risk factors for mortality in hospitalized diabetes and chronic kidney disease patients after COVID-19 infection following widespread vaccination. BACKGROUND: COVID-19 poses a significant threat to patients with comorbidities, such as diabetes and chronic kidney disease (CKD). China experienced a nationwide COVID-19 endemic from December 2022 to January 2023, which is the first occurrence of such an outbreak following China's widespread administration of COVID-19 vaccinations. METHODS: A total of 338 patients with diabetes and CKD combined with COVID-19 infection between December 7, 2022 and January 31, 2023 were included in this study. The end follow-up date was February 10, 2023. Univariate analysis and multivariate Cox analysis were used to analyze risk factors for death. RESULTS: During the 50-day median follow-up period, 90 patients in the study cohort died, for a mortality rate of 26.63%. The median age of the study cohort was 74Â years, with a male predominance of 74%. During hospitalization, 21% of patients had incident AKI, 17% of patients experienced stroke, and 40% of patients experienced respiratory failure. Cox proportional hazard regression showed that older age, a diagnosis of severe or critically severe COVID-19 infection, incident AKI and respiratory failure, higher level of average values of fasting glucose during hospitalization, UA, and total bilirubin were independent risk factors for death in our multivariate model. CONCLUSIONS: These findings highlight the critical importance of identifying and managing comorbid risk factors for COVID-19, especially among the elderly, in order to optimize clinical outcomes, even after COVID-19 vaccination.

Chronic Spontaneous Urticaria Following mRNA COVID-19 Booster Vaccination at a Military Academy. Several adverse cutaneous reactions have been reported in the literature after SARS-CoV-2 vaccination with emerging reports on chronic spontaneous urticaria (CSU). However, there is little literature of chronic urticaria after COVID-19 boosters in a military population and the impact on operational readiness. We present a retrospective case series of CSU following Moderna COVID-19 booster vaccinations at the US Naval Academy (USNA). Demographics, clinical features, and impact on readiness were evaluated. Forty-nine students from the USNA were evaluated for urticaria after their third COVID-19 booster vaccination. Seventeen individuals were diagnosed with CSU. The median age was 20â€‰years and predominantly male; the median time interval between vaccination and the onset of urticaria was 11â€‰days. Out of 13 referred to Allergy, 7 patients had CU index performed and 2 were positive. Four patients received a second booster vaccination subsequently and did not have any exacerbation of symptoms. Symptoms were controlled with antihistamines, and none required immunomodulator or immunosuppressive therapies. All students were able to

complete their commissioning, and none were referred for a medical board. In this series, USNA students who developed CSU after the mRNA COVID-19 Moderna booster vaccine did not have limitations from commissioning, duty status, or issues with subsequent COVID-19 vaccinations.

Assessment of Myocardial (18)F-FDG Uptake at PET/CT in Asymptomatic SARS-CoV-2-vaccinated and Nonvaccinated Patients. Background Patients who developed myocarditis following SARS-CoV-2 vaccination show abnormalities on cardiac MRI. However, whether myocardial changes occur in asymptomatic individuals following vaccination is not well established. Purpose To assess myocardial (18)Fluorine-fluorodeoxyglucose ((18)F-FDG) uptake on PET/CT in asymptomatic SARS-CoV-2 vaccinated patients compared to nonvaccinated patients. Materials and Methods This retrospective study included patients who underwent (18)F-FDG PET/CT for indications unrelated to myocarditis during the period before (11/1/2020 - 2/16/2021) and after (2/17/20121 - 3/31/2022) SARS-CoV-2 vaccines were available. Myocardial and axillary FDG uptake were quantitatively assessed using maximum standardized uptake value (SUVmax). SUVmax values in all patients and in patients stratified by sex (male/female), age (<40, 41-60, >60 years), and time interval between vaccination and PET/CT were compared using Mann-Whitney U test or Kruskal-Wallis test with post ad -hoc Dwass, Steel, Critchlow-Fligner multiple comparison analysis. Results The study included 303 nonvaccinated patients (mean age, 52.9 years Â± 14.9 [SD]; 157 females) and 700 vaccinated patients (mean age, 56.8 years Â± 13.7 [SD]; 344 females). Vaccinated patients had overall higher myocardial FDG uptake compared to nonvaccinated patients (median SUVmax, 4.8 [IQR: 3.0-8.5] vs median SUVmax, 3.3 [IQR: 2.5-6.2]; P < .0001). Myocardial SUVmax was higher in vaccinated patients regardless of sex (median range, 4.7-4.9 [IQR: 2.9-8.6]) or patient age (median range, 4.7-5.6 [IQR: 2.9-8.6]) compared to corresponding nonvaccinated groups (sex median range, 3.2-3.9 [IQR: 2.4-7.2]; age median range, 3.3-3.3 [IQR: 2.3-6.1]; P range, <.001-.015). Furthermore, increased myocardial FDG uptake was observed in patients imaged 1-30, 31-60, 61-120, and 121-180 days after their second vaccination (median SUVmax range, 4.6-5.1 [IQR: 2.9-8.6]) and increased ipsilateral axillary uptake was observed in patients imaged 1-30, 31-60, 61-120 days after their 2nd vaccination (median SUVmax range, 1.5-2.0 [IQR: 1.2-3.4]) compared to the nonvaccinated patients (P range, <.001-<.001). Conclusion Compared to nonvaccinated patients, asymptomatic patients who received their 2nd vaccination 1-180 days prior to imaging showed increased myocardial FDG uptake on PET/CT. See also the editorial by Bluemke in this issue.

COVID-19 Vaccines and Myocardial Injury.

Safety and efficacy of one and two booster doses of SARS-CoV-2 mRNA vaccines in kidney transplant recipients: A randomized clinical trial. BACKGROUND: Kidney transplant recipients are at risk for a severe course of COVID-19 with a high mortality rate. A considerable number of patients remains without a satisfactory serological response after the baseline and adjuvant SARS-CoV-2 vaccination schedule. METHODS: In this prospective, randomized study, we evaluated the efficacy and safety of one and two booster doses of mRNA vaccines (either mRNA-1273 or BNT162b2) in 125 COVID-19 naive, adult kidney transplant recipients who showed an insufficient humoral response (SARS-CoV-2 IgG <10 AU/ml) to the previous 2-dose vaccination schedule. The primary outcome was the difference in the rate of a positive antibody response (SARS-CoV-2 IgG â‰¥10 AU/ml) between one and two booster doses at 1 month after the final booster dose. RESULTS: A positive humoral response was observed in 36 (62%) patients receiving two booster doses and in 28 (44%) patients receiving one booster dose (odds ratio [OR], 2.10, 95% confidence interval [CI], 1.02-4.34, p = .043). Moreover, median SARS-CoV-2 IgG levels were higher with two booster doses (p = .009). The number of patients with positive virus neutralizing antibody (VNA) levels was numerically higher with two booster doses compared to one booster dose, but without statistical significance (66%Â vs. 50%, p = .084). There was no significant difference in positive seroconversions rate and antibody levels between mRNA-

1273 and BNT162b2. CONCLUSION: A higher number of kidney transplant recipients achieved a positive antibody response after two booster doses compared to one booster dose.

The Clinical Course of New-Onset Ocular Myasthenia Gravis Caused by Pfizer-BioNTech COVID-19 Vaccine. PURPOSE: Myasthenia gravis (MG) caused by COVID-19 vaccine had been reported, but the clinical course of new-onset ocular MG had never been described. We would like to document the clinical course of a patient with new-onset ocular MG which was caused by Pfizer-BioNTech COVID-19 vaccine. CASE REPORT: A 39-year-old woman noticed diplopia one week after she accepted the first dose of Pfizer- BioNTech COVID-19 vaccine. Diagnosis of ocular MG was made after investigation. Despite intravenous immunoglobulins, pyridostigmine and prednisolone therapy, she had no improvement until 10 days after treatment. She then rapidly improved, and almost fully recovered in the following 10 days. We had observed this patient for 8 months. After tapering off steroid, she remained stable to date, though she still suffered from transient diplopia on awakening. CONCLUSION: No matter the symptoms at onset, the clinical course or the response to steroid therapy was identical to ocular MG that we had ever known. Ocular MG caused by COVID-19 vaccine could probably be an iatrogenic life-long disease.

A Case Report of Guillain-BarrÃ© Syndrome In Association with SARS-CoV-2 Vaccination in Malaysia. PURPOSE: Guillain-BarrÃ© Syndrome (GBS) associated with SARS-CoV-2 vaccine administration is very rare. Early recognition of GBS at early stage could prevent extensive nerve damage with potential respiratory and autonomic failure. CASE REPORT: We report a case of paraparetic spectrum of GBS in a 53-year-old lady who presented with rapidly progressive acute flaccid paralysis involving both lower extremities with areflexia eight days after the first dose of Sinovac vaccine for SARS-CoV-2 in Malaysia. Cerebrospinal fluid (CSF) albuminocytological dissociation was seen and nerve conduction study (NCS) revealed sensory neuropathy. The diagnosis of GBS was made based on the Brighton criteria. Patient responded well to intravenous immunoglobulin (IVIG). CONCLUSION: Though there is currently no convincing evidence of any causation between GBS and SARS- CoV-2 vaccination, clinicians should remain vigilant and consider GBS in the differential diagnosis for patient who presents with weakness with reduced or absent deep tendon reflex after vaccination against SARS-CoV-2.

Updated beliefs and shaken confidence: evidence from vaccine hesitancy caused by experiencing "COVID arm". BACKGROUND: Public health depends largely on people's knowledge, beliefs, or behaviors regarding their health and medical treatments. Although works based on the health belief model have shown that public beliefs about medical treatments affect willingness to take the treatments, little is known about the effects of changes in beliefs on attitudes toward treatment. How one's past experiences relate to one's beliefs about a given medical treatment is worth considering. METHODS: We implemented an online panel survey in February 2021 and March 2022 in Japan before and after COVID-19 vaccines were administered to the public within the country. We exploited delayed localized hypersensitivity reactions to COVID-19 vaccines, namely, "COVID arm", as an exogenous shock to investigate the relationship between past negative experiences and current beliefs about medical treatments or science. "COVID arm" was an unexpected side effect and thus likely caused updated beliefs about the vaccine. Out of the nonprobability sample of 15,000 respondents in the first wave in February 2021, 9,668 respondents also responded to the second wave conducted in March 2022. Outcome variables were whether experiencing "COVID arm" affected the respondents' 1) confidence in vaccine safety, 2) willingness to take the next dose of COVID-19 vaccines, 3) acknowledgment of the importance of vaccination, and 4) confidence in science. We measured the impact of experience with "COVID arm" on changes in the probability that survey respondents would respond affirmatively to questions posed about the issues listed above. RESULTS: Experiencing "COVID arm" significantly lowered confidence in the safety of vaccination by 4.3

percentage points, which was approximately 6% of the sample mean for the first wave, and lowered the probability of taking a second dose of the COVID-19 vaccine by 1.5 percentage points. These adverse impacts were observed after conditioning background characteristics and prior confidence in vaccination. Experiencing "COVID arm" affected neither the acknowledged importance of vaccination nor confidence in science in a statistically significant way. CONCLUSIONS: An unexpected and uncomfortable shock regarding beliefs about a treatment decreases willingness to take the treatment. An appropriate public health policy should account for this effect. TRIAL REGISTRATION: The survey was preregistered with the American Economic Association's RCT Registry (Fukai et al., 2022).
Analysis of the adverse events following the mRNA-1273 COVID-19 vaccine. OBJECTIVE: This study aims to characterize the adverse events (AEs) following the administration of the mRNA-1273 COVID-19 vaccine from the Vaccine Adverse Event Reporting System (VAERS) data. METHODS: In this case/non-case analysis, reports between 1 January 2021, and 27 October 2022, were extracted from VAERS. AEs were defined as preferred terms (PTs) by Medical Dictionary for Regulatory Activities (MedDRA) terminology. Disproportionality analyses were conducted to calculate the reporting odds and proportional reporting ratios. The Bayesian approach was used to calculate information component (IC) values and Empirical Bayesian Geometric Mean scores for all the AEs detected. RESULTS: 186 MedDRA PTs compromising 702,495 AEs associated with the mRNA-1273 vaccine were identified. Three statistically significant signals were identified for general and systemic AEs, administration site conditions, and product issues. Cardiac disorders were rarely reported, the most common being; 489 reports for 'myocarditis' (19.44%), 475 for 'acute myocardial infarction' (18.88%), 457 for 'myocardial infarction' (18.16%), 290 for 'bradycardia' (11.53%) and 281 for 'pericarditis' (11.17%). CONCLUSIONS: The most frequently identified AEs following mRNA-1273 vaccination agree with those listed within the Summary of Product Characteristics. In addition, disproportionality analysis did not find any statistically significant signals for myocarditis or pericarditis.
A panty rosea-like eruption following the second Pfizer-BioNTech COVID-19 vaccine administration dose in a pediatric patient.
Vaccination Status and Outcome of Hospitalized Patients with Coronavirus Disease 2019 Before and After the Spread of Omicron Variant: An Observational Study from Ä°zmir, Turkey. OBJECTIVE: Despite the efforts in vaccination against coronavirus disease 2019 (COVID-19), breakthrough infections occur and the need for hospitalization continues. We aimed to determine the relationship between severe acute respiratory syndrome coronavirus 2 vaccination and the severity of COVID-19 and mortality among hospitalized patients with COVID-19. MATERIAL AND METHODS: This cross-sectional study was conducted between September 2021 and February 2022 in a university hos- pital in Turkey. Hospitalized patients with COVID-19 (both in clinics and in intensive care units), â‰¥18 years old, and who had no previous COVID-19 were included in the study. The demographic characteristics, clinical data, vaccination status, and outcome of the patients were analyzed retrospectively and the relationship between vaccination status and mortality was determined statistically. RESULTS: Of the 674 patients, 180 (26.7%) had no vaccination, 282 (41.8%) had incomplete vaccination, and 212 (31.5%) were fully vaccinated according to the updated vaccination recommendations. While 44.0% of the patients were fully vaccinated before the occur- rence of omicron variant, 15.9% of the patients were fully vaccinated during the wave of the omicron variant. The patients with no vaccination were younger and had fewer comorbidities. The overall mortality was 31.8%. Under 50 years old, all the patients with fully vaccination survived and the patients with no vaccination or incomplete vaccination had higher (10.1%) mortality. During the omicron period, mortality was lower in fully vaccinated pateints. CONCLUSION: Immunization with and booster doses of BNT162b2 should be encouraged to protect both healthy and vulnerable populations.

Myositis after SARS-CoV-2 vaccination occurs more frequently than assumed and is probably causally related. We read with interest the article by Camargo-Coronel et al. reporting on a systematic review of patients with idiopathic, inflammatory myopathy developing after anti-SARS-CoV-2 vaccinations.

Case report on meningoenceplapathy in an Indian patient post CoViD vaccination. The SARS-COV-2 infection-related severe illness is prevented by vaccinations. Therefore, it is relevant to report a case of post vaccine meningoencephalitis in a 30 year old male Indian patient, who presented with weakness in all the extremities, episodes of loose stool, fever, vomiting, tachypnea and loss of consciousness immediately following the 2nd dose of the COVID vaccination (COVAXIN).

Small Fiber Neuropathy After SARS-CoV-2 Infection and Vaccination: A Case-Based Comparison. COVID-19-associated neuropathies, whether post-infection or post-vaccination, have not been fully described. A variety of theories exist to explain these phenomena, manyÂ of them centering onÂ immune dysregulation.Â We aim to contribute to the discussion on the similarities and differences behind the two conditions and to bolster the call for further research to be done in this area. We will discuss two different case presentations, one patient experiencing a post-COVID-19 infection neuropathy and the other experiencing a post-COVID-19 vaccination neuropathy.

Vaccination after developing long COVID: Impact on clinical presentation, viral persistence, and immune responses. BACKGROUND: Vaccination protects against severe COVID-19 manifestations. For those with post-COVID-19 conditions (PCC) or long COVID, the impact of COVID-19 vaccination on the evolution of symptoms, immune responses, and viral persistence is unclear. METHODS: In this prospective observational cohort study, we evaluated the number of PCC symptoms, affected organ systems, and psychological well-being scores before and after patients with PCC received COVID-19 vaccination. We simultaneously evaluated biomarkers of systemic inflammation and levels of plasma cytokines/chemokines. We measured plasma and intracellular levels of SARS-CoV-2 antigens, and immunoreactivity to SARS-CoV-2 antigens in blood. RESULTS: COVID-19 vaccination was associated with decreases in number of PCC symptoms (pre-vaccination: 6.56 Â± 3.1 vs post-vaccination: 3.92 Â± 4.02; PÂ <0.001) and affected organ systems (pre-vaccination: 3.19 Â± 1.04 vs post-vaccination: 1.89 Â± 1.12; PÂ <0.001), and increases in World Health Organization (WHO)-5 Well-Being Index Scores (pre-vaccination: 42.67 Â± 22.76 vs post-vaccination: 56.15 Â± 22.83; PÂ <0.001). Patients with PCC also had significantly decreased levels of several pro-inflammatory plasma cytokines/chemokines after COVID-19 vaccination including sCD40L, GRO-â•º, macrophage inflammatory protein (MIP)-1â•º, interleukin (IL)-12p40, G-colony stimulating factor (CSF), M-CSF, IL-1Î², and stem cell factor (SCF). PCC participants presented a certain level of immunoreactivity toward SARS-CoV-2, that was boosted with vaccination. SARS-CoV-2 S1 antigen persisted in the blood of PCC participants, mostly in non-classical monocytes, regardless of participants receiving vaccination. CONCLUSIONS: Our study shows higher pro-inflammatory responses associated with PCC symptoms and brings forward a possible role for vaccination in mitigating PCC symptoms by decreasing systemic inflammation. We also observed persistence of viral products independent of vaccination that could be involved in perpetuating inflammation through non-classical monocytes.

Baseline immune states (BIS) associated with vaccine responsiveness and factors that shape the BIS. Vaccines are among the greatest inventions in medicine, leading to the elimination or control of numerous diseases, including smallpox, polio, measles, rubella, and, most recently, COVID-19. Yet, the effectiveness of vaccines varies among individuals. In fact, while some recipients mount a robust response to vaccination that protects them from the disease, others fail to respond. Multiple clinical and epidemiological factors contribute to this heterogeneity in responsiveness. Systems immunology studies fueled by advances in single-cell biology have been instrumental in uncovering pre-

vaccination immune cell types and genomic features (i.e., the baseline immune state, BIS) that have been associated with vaccine responsiveness. Here, we review clinical factors that shape the BIS, and the characteristics of the BIS associated with responsiveness to frequently studied vaccines (i.e., influenza, COVID-19, bacterial pneumonia, malaria). Finally, we discuss potential strategies to enhance vaccine responsiveness in high-risk groups, focusing specifically on older adults.

Association between BNT162b2 and CoronaVac vaccination and risk of CVD and mortality after COVID-19 infection: A population-based cohort study. It is unknown if vaccination affects the risk of post-COVID-19 cardiovascular diseases (CVDs). Therefore, this retrospective cohort study examines the short-term and long-term risks of post-infection CVD among COVID-19 patients with different vaccination status utilizing data from electronic health databases in Hong Kong. Cox proportional hazards regression adjusted with inverse probability of treatment weighting is used to evaluate the risks of incident CVD (coronary heart disease, stroke, heart failure) and all-cause mortality in COVID-19 patients. Compared with unvaccinated patients, vaccinated patients have a lower risk of CVD and all-cause mortality, and the lowest risk is observed in those who completed three doses of vaccine. Similar patterns in the subgroups of different vaccine platforms, age, gender, Charlson comorbidity index, and disease severity are observed. These findings highlight a positive dose-response relationship between overall CVD risk reduction and the number of vaccine doses received.

Transient Adrenal Insufficiency Following Pfizer/BioNTech Coronavirus Disease-2019 Vaccine Overdose.

Altered liver function test after Covid-19 vaccines: A retrospective control group study. BACKGROUND AND PURPOSE: Liver injury after Covid-19 vaccine has been described, although the incidence was not well established. We aimed to compare cumulative incidence of new onset liver test alteration after Covid-19 vaccination, and to compare with an historical control of influenza vaccination. METHODS: We conducted a retrospective cohort study which included adults who received at least one dose of Covid-19 vaccine from January 1 to May 30, 2021 and a control group who received a single dose of influenza vaccine during 2019, in a tertiary medical center from Argentina. RESULTS: We included 29â€‰798 patients in Covid-19 vaccine group and 24â€‰605 in influenza vaccine group. Liver function tests were performed in 7833 (26.9%) in Covid-19 vaccine group and 8459 (34.37%) in influenza vaccine group. Cumulative incidence at 90â€‰days of new onset liver enzyme test alteration was 4.7 per 1000 (95% 4.0-5.5) for Covid-19 group, and 5.1 per 1000 (95% 4.3-6.1) for the influenza vaccine group (p valueâ€‰=â€‰0.489). Two patients in the Covid-19 vaccine group developed immune mediated liver injury. CONCLUSIONS: We found no difference in liver test alteration between groups. These findings support the safety of Covid-19 vaccines. While we have identified two cases that are consistent with immune mediated liver injury following COVID-19 vaccination, we believe that the available data is insufficient to attribute them solely to the vaccination.

Mechanistic modeling projections of antibody persistence after homologous booster regimens of COVID-19 vaccine Ad26.COV2.S in humans. Mechanistic model-based simulations can be deployed to project the persistence of humoral immune response following vaccination. We used this approach to project the antibody persistence through 24â€‰months from the data pooled across five clinical trials in severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2)-seronegative participants following vaccination with Ad26.COV2.S (5â€‰Ã—â€‰10(10) viral particles), given either as a single-dose or a homologous booster regimen at an interval of 2, 3, or 6â€‰months. Antibody persistence was quantified as the percentage of participants with detectable anti-spike binding and wild-type virus neutralizing antibodies. The projected overall 24-month persistence after single-dose Ad26.COV2.S was 70.5% for binding antibodies and 55.2% for neutralizing antibodies, and increased after any homologous booster regimen to greater than or equal to 89.9% for binding and

greater than or equal to 80.0% for neutralizing antibodies. The estimated model parameters quantifying the rates of antibody production attributed to short-lived and long-lived plasma cells decreased with increasing age, whereas the rate of antibody production mediated by long-lived plasma cells was higher in women relative to men. Accordingly, a more pronounced waning of antibody responses was predicted in men aged greater than or equal to 60â€‰years and was markedly attenuated following any homologous boosting regimen. The findings suggest that homologous boosting might be a viable strategy for maintaining protective effects of Ad26.COV2.S for up to 24â€‰months following prime vaccination. The estimation of mechanistic modeling parameters identified the long-lived plasma cell pathway as a key contributor mediating antibody persistence following single-dose and homologous booster vaccination with Ad26.COV2.S in different subgroups of recipients stratified by age and sex.
A double-blind, randomised, placebo-controlled parallel study to investigate the effect of sex and dietary nitrate on COVID-19 vaccine-induced vascular dysfunction in healthy men and women: protocol of the DiNOVasc-COVID-19 study. BACKGROUND: Cardiovascular events, driven by endothelial dysfunction, are a recognised complication of COVID-19. SARS-CoV-2 infections remain a persistent concern globally, and an understanding of the mechanisms causing endothelial dysfunction, particularly the role of inflammation, nitric oxide, and whether sex differences exist in this response, is lacking. We have previously demonstrated important sex differences in the inflammatory response and its impact on endothelial function and separately that the ingestion of inorganic nitrate can protect the endothelium against this dysfunction. In this study, we will investigate whether sex or a dietary inorganic nitrate intervention modulates endothelial function and inflammatory responses after the COVID-19 vaccine. METHODS: DiNOVasc-COVID-19 is a double-blind, randomised, single-centre, placebo-controlled clinical trial. A total of 98 healthy volunteers (49 males and 49 females) will be recruited. Participants will be randomised into 1 of 2 sub-studies: part A or part B. Part A will investigate the effects of sex on vascular and inflammatory responses to the COVID-19 vaccine. Part B will investigate the effects of sex and dietary inorganic nitrate on vascular and inflammatory responses to the COVID-19 vaccine. In part B, participants will be randomised to receive 3 days of either nitrate-containing beetroot juice (intervention) or nitrate-deplete beetroot juice (placebo). The primary outcome for both sub-studies is a comparison of the change in flow-mediated dilatation (FMD) from baseline after COVID-19 vaccination. The study has a power of > 80% to assess the primary endpoint. Secondary endpoints include change from baseline in inflammatory and leukocyte counts and in pulse wave analysis (PWA) and pulse wave velocity (PWV) following the COVID-19 vaccination. DISCUSSION: This study aims to evaluate whether sex or dietary influences endothelial function and inflammatory responses in healthy volunteers after receiving the COVID-19 vaccine. TRIAL REGISTRATION: ClinicalTrials.gov NCT04889274.Â Registered on 5 May 2023. The study was approved by the South Central - Oxford C Research Ethics Committee (21/SC/0154).
Comment on self-reported symptoms after COVID-19 vaccination.
New-onset minimal change disease following the Moderna COVID-19 vaccine. We report the case of nephrotic syndrome after COVID-19 vaccination. The patient was a man in his 30s with no comorbidities other than atopic dermatitis. Over the course of 2â€‰weeks after the first COVID-19 vaccination, systemic oedema gradually appeared. He was referred to the nephrology department for investigation of the systemic oedema. On admission, he presented with pitting oedema in his lower extremities. Initial examinations revealed massive urinary protein and decreased serum albumin, at 13.9â€‰g/g Cr and 1.5â€‰g/dL, respectively. Renal biopsy was performed, and minimal change disease was diagnosed. Prednisolone 60â€‰mg/day was promptly started on the 5th day of hospitalisation, and complete remission was achieved on the 12th day. Prednisolone was once

tapered off in 1.5 years successfully though minimal change disease was relapsed in 1â€‰month after the steroid withdrawal.

Explaining the U.S. rural disadvantage in COVID-19 case and death rates during the Delta-Omicron surge: The role of politics, vaccinations, population health, and social determinants. The Delta-Omicron wave of the COVID-19 pandemic (Wave 4) in the United States occurred in Fall of 2021 through Spring of 2022. Although vaccinations were widely available, this was the deadliest period to date in the U.S., and the toll was especially high in rural areas, exacerbating an existing rural mortality penalty. This paper uses county-level multilevel regression models and publicly available data for 47 U.S. states and the District of Columbia. We describe differences in COVID-19 case and mortality rates across the rural-urban continuum during Wave 4 of the COVID-19 pandemic. Using a progressive modeling approach, we evaluate the relative contribution of a range of explanatory factors for the rural disadvantage we observe, including: pre-pandemic population health composition, vaccination rates, political partisanship, socioeconomic composition, access to broadband internet rate, and primary care physicians per capita. Results show that rural counties had higher observed burdens of cases and deaths in Wave 4 compared to more urban counties. The most remote rural counties had Wave 4 COVID-19 mortality rates 52% higher than the most urban counties. Older age composition, worse pre-pandemic population health, lower vaccination rates, higher share of votes cast for Donald Trump in the 2020 Presidential election, and lower socioeconomic composition completely explained the rural disadvantage in reported COVID-19 case rates in Wave 4, and accounting for these factors reversed the observed rural disadvantage in COVID-19 mortality. In models of mortality rate, Trump vote share had the largest effect size, followed by the percentage of the population age 50 or older, the poverty rate, the pre-pandemic mortality rate, the share of residents with a 4-year college degree, and the vaccination rate. These findings add to a growing literature describing the disproportionate toll of the COVID-19 pandemic on rural America, highlighting the combined effect of multiple sources of rural disadvantage.

Fatal Myocarditis After COVID-19 Vaccination: Fourteen Autopsy-Confirmed Cases: Erratum.

Renal outcomes in IgA nephropathy following inactivated SARS-CoV-2 vaccination. INTRODUCTION: There are increasing case reports on de novo or relapsing IgA nephropathy (IgAN) following SARS-CoV-2 vaccines, although the follow-up information on renal outcomes in IgAN patients post-SARS-CoV-2 vaccination is limited. In this study, we evaluated the renal outcomes of IgAN patients following inactivated vaccines. METHODS: We investigated the change in eGFR, proteinuria and hematuria in 113 primary IgAN patients post-vaccination. Worsening proteinuria was defined as an increase in proteinuria by more than 0.5 times and proteinuriaâ€‰>â€‰1Â g/d. Univariate and multivariable logistic regression analysis were used to evaluate possible predictors of worsening proteinuria. We then compared the renal outcomes of vaccinated patients after 6Â months with 101 unvaccinated patients who were followed during the same period. RESULTS: A 2.54% (0.64, 8.61) decrease in renal function was observed in post-vaccination patients. Subgroup analysis revealed a significant decrease in eGFR in patients with 30â€‰â‰¤â€‰eGFRâ€‰<â€‰60 (mL/min/1.73Â m(2)) post second SARS-CoV-2 dose (nâ€‰=â€‰18, pâ€‰=â€‰0.01). In addition, 10 individuals displayed worsening proteinuria post-vaccination, with the proteinuria subsequently ameliorating significantly after 6-month. Multivariate analysis showed that higher eGFR levels was an independent protective factor for worsening proteinuria. The renal outcome tended towards a decrease in eGFR in vaccinated patients after 6Â months follow-up, although the difference was not significant (pâ€‰=â€‰0.06). CONCLUSION: Kidney function in IgAN patients tended to worsen after SARS-CoV-2 vaccination, particularly those with initial poor kidney function. This pattern of disease flare appears to be clinically mild, and further research is needed to determine whether the impact on kidney function is long-term.

Delayed adverse events following COVID-19 vaccination in patients with systemic sclerosis and other autoimmune diseases: a substudy of the COVAD-2 cohort. Data on short-term safety of COVID-19 vaccination in patients with systemic sclerosis (SSc) were explored previously in the first COVID-19 vaccination in autoimmune diseases (COVAD) survey conducted in 2021. However, delayed adverse events (ADEs) (occurringâ€‰>â€‰7Â days post-vaccination) are poorly characterized in these patients with SSc. In this study, we analysed delayed COVID-19 vaccine-related ADEs among patients with SSc, other systemic autoimmune and inflammatory disorders (SAIDs) and healthy controls (HCs) using data from the second COVAD study conducted in 2022. The COVAD-2 study was a cross-sectional, patient self-reported global e-survey conducted from February to June 2022. Data on demographics, SSc/SAID disease characteristics, COVID-19 infection history, and vaccination details including delayed ADEs as defined by the Centre for Disease Control were captured and analysed. Among 17,612 respondents, 10,041 participants fully vaccinated against COVID-19 were included for analysis. Of these, 2.6% (nâ€‰=â€‰258) had SSc, 63.7% other SAIDs, and 33.7% were HCs. BNT162b2 Pfizer (69.4%) was the most administered vaccine, followed by MRNA-1273 Moderna (32.25%) and ChadOx1 nCOV-19 Oxford/AstraZeneca (12.4%) vaccines. Among patients with SSc, 18.9% reported minor, while 8.5% experienced major delayed ADEs, and 4.6% reported hospitalization. These frequencies were comparable to those of the ADEs reported by other patients with SAIDs and HCs. However, patients with SSc reported a higher frequency of difficulty in breathing than HCs [OR 2.3 (1.0-5.1), pâ€‰=â€‰0.042]. Patients with diffuse cutaneous SSc experienced minor ADEs [OR 2.1 (1.1-4.4), pâ€‰=â€‰0.036] and specifically fatigue more frequently [OR 3.9 (1.3-11.7), pâ€‰=â€‰0.015] than those with limited cutaneous SSc. Systemic sclerosis patients with concomitant myositis reported myalgia more frequently [OR 3.4 (1.1-10.7), pâ€‰=â€‰0.035], while those with thyroid disorders were more prone to report a higher frequency of joint pain [OR 5.5 (1.5-20.2), pâ€‰=â€‰0.009] and dizziness [OR 5.9 (1.3-27.6), pâ€‰=â€‰0.024] than patients with SSc alone. A diagnosis of SSc did not confer a higher risk of delayed post-COVID-19 vaccine-related ADEs overall compared with other SAIDs and HCs. However, the diffuse cutaneous phenotype and coexisting autoimmune conditions including myositis and thyroid disease may increase the risk of minor ADEs. These patients may benefit from pre-vaccination counselling, close monitoring, and early initiation of appropriate care in the post-COVID-19 vaccination period.

Menstrual cycle alterations in reproductive age women after anti COVID-19 vaccination. A survey in 419 Italian women and quality of life and sexual function evaluation. BACKGROUND: Pharmacovigilance agencies did not collect data regarding menstrual changes after COVID-19 vaccination even if many women experienced it. Our aim was to evaluate whether COVID-19 vaccination is associated with secondary changes in menstrual cycle and to assess both quality of life (QoL) and sexual function (SF). METHODS: This study is a retrospective analysis referred to our Department from January 2021 to December 2021. The study cohort responded to same questionnaires before the second dose of vaccination (referring to previous 3 months) and 3 months after that (referring to three menstrual cycles after full-dose vaccination). The surveys administered were FSFI, FSDS, SF-36, MEDI-Q and the VAS-scale for dysmenorrhea. RESULTS: Four-hundred-nineteen vaccinated women were included in the study. The survey did not show a significant change in menstrual cycle length before and after COVID-19 vaccine (5.88Â±3.67 vs. 4.97Â±2.89, P=0.21); the interval between periods was significantly higher after a full-cycle vaccination (28.32Â±7.34 vs. 32.38Â±7.45, P<0.02); 32 patients (7.6%) developed amenorrhea after the second dose; VAS Scale did not change significantly (median range 3 (3-5) vs. 4 (3-6), P=0.20). MEDI-Q did not show significant variations before and after the vaccination (43.21Â±11.65 vs. 40.28Â±9.88, P=0.35). QoL and SF did not change significantly (FSFI median 27 [24-29] vs. 28 [25-30], P=0.12, FSDS median 9 [5-11] vs. 8 [4-12], P=0.22), SF-36 median 81 [70-85] vs. 82 [72-86], P=0.43). CONCLUSIONS: COVID-19 vaccination is

associated with a significant change in intervals between menstrual cycles without other alterations in menstrual characteristics, in QoL or SF.
Livedoid skin reaction and mRNA Covid-19 vaccine: correspondence.
Autoimmune inflammatory reactions triggered by the COVID-19 genetic vaccines in terminally differentiated tissues. As a result of the spread of SARS-CoV-2, a global pandemic was declared. Indiscriminate COVID-19 vaccination has been extended to include age groups and naturally immune people with minimal danger of suffering serious complications due to COVID-19. Solid immuno-histopathological evidence demonstrates that the COVID-19 genetic vaccines can display a wide distribution within the body, affecting tissues that are terminally differentiated and far away from the injection site. These include the heart and brain, which may incur in situ production of spike protein eliciting a strong autoimmunological inflammatory response. Due to the fact that every human cell which synthesises non-self antigens, inevitably becomes the target of the immune system, and since the human body is not a strictly compartmentalised system, accurate pharmacokinetic and pharmacodynamic studies are needed in order to determine precisely which tissues can be harmed. Therefore, our article aims to draw the attention of the scientific and regulatory communities to the critical need for biodistribution studies for the genetic vaccines against COVID-19, as well as for rational harm-benefit assessments by age group.
New onset of systemic lupus erythematosus following COVID-19 mRNA vaccination.
Factors associated with IgG titers against SARS-CoV-2 spike protein after second vaccination in people living with HIV controlled with anti-retroviral therapy. OBJECTIVE: This study aimed to identify factors associated with the response to the SARS-CoV-2 vaccine in people living with HIV (PLWH). METHODS: This study was conducted at the Jikei University School of Medicine, Tokyo, Japan. IgG antibodies against spike and nucleocapsid proteins were detected using Abbott SARS-CoV-2 IgG II Quant assays. RESULTS: During the investigation period, 371 PLWH were enrolled in this study. PLWH with previous COVID-19 infection, untreated or poorly controlled HIV infection, and those whose blood samples were obtained within less than seven days after the second vaccination were excluded. A total of 310 PLWH controlled with anti-retroviral therapy were included in the final analysis. Multivariate analysis demonstrated that chronic kidney disease (CKD) (Î²Â =Â -0.353, pÂ =Â 0.049) and the duration between the second vaccination and blood sampling (Î²Â =Â -0.005, pÂ <Â 0.001) were associated with low spike protein IgG titers. CONCLUSION: Even without hemodialysis or kidney transplant, CKD was associated with vaccine response in PLWH.
Keigai-rengyo-to as post-exposure prophylaxis for severe acute respiratory syndrome coronavirus 2 infection. BACKGROUND: Effective prevention against COVID-19 is urgently required to control vaccine breakthrough infection. Laboratory and clinical data suggested that Keigai-rengyo-to (KRT) performs biological activity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). We investigated whether KRT could prevent SARS-CoV-2 in medical personnel exposed to patients with COVID-19. METHODS: We conducted an open-label controlled clinical trial of medical personnel after COVID-19 vaccination at our hospital (ClinicalTrials.gov: UMIN000048389). Participants were close contacts recently exposed (<72Â h) to patients with COVID-19. We provided the participants with KRT (7.5Â g/day for 5 days) or no drug as a control. The primary endpoint was nicking endonuclease amplification reaction or polymerase chain reaction confirming incident SARS-CoV-2 infection. Safety was assessed in all treated participants. RESULTS: Between January and September 2022, 38 close contacts were assigned: 20 to the KRT group and 18 to the control group. During 2 weeks of follow-up, 10/38 (26%) participants had new-onset COVID-19. The incidence of COVID-19 was significantly lower in the KRT group (2/20; 10%) than in the control group (8/18; 44%), with a medium effect size (pÂ <Â 0.05; phi coefficientÂ =Â -0.391; total absolute risk reduction: 34.4% points). The number needed to treat to prevent the occurrence of a COVID-19 case was 2.9. The

overall relative risk was 0.23 (95% confidence interval: 0.06-0.78). No serious safety problems were detected. CONCLUSION: Post-exposure prophylaxis with KRT can prevent the onset of COVID-19 in close contacts after vaccination. More randomized clinical trials with larger samples are required to better evaluate KRT as a post-exposure prophylaxis of SARS-CoV-2.

An Exploratory Study of the Impact of COVID-19 Vaccine Spontaneous Reporting on Masking Signal Detection in EudraVigilance. INTRODUCTION: During the signal detection process, statistical methods are used to identify drug-event combinations (DECs) which are disproportionately reported when compared with other drugs and events in the entire database. We hypothesise that the high volume of COVID-19 vaccine adverse drug reaction (ADR) reports transmitted to EudraVigilance may have affected the performance of disproportionality statistics used in routine signal detection, potentially resulting in signals either being masked, or false associations being flagged as potential signals. OBJECTIVE: Our aim was to study the impact of COVID-19 vaccine spontaneous reporting on statistical signal detection in EudraVigilance. METHODS: We recalculated the reporting odds ratio (ROR) for signals that were previously discussed at the level of the Pharmacovigilance Risk Assessment Committee, or signals that were retrieved from EudraVigilance, by omitting COVID-19 vaccine reports from the standard ROR calculation and then comparing the lower confidence interval (LCI) of the recalculated ROR to the LCI of the actual ROR in EudraVigilance. RESULTS: In total, 52 signals for 38 active substances were reviewed. For 35 signals, the LCI of the recalculated ROR value was lower than the LCI of the actual ROR (suggesting that COVID-19 vaccine ADR reporting had a positive effect on the strength of the signal) while for 15 signals the LCI of the recalculated ROR value was higher than the LCI of the actual ROR (suggesting that COVID-19 vaccine ADR reporting had an attenuating effect on the strength of the signal). For two signals, no change in the ROR was observed. In our analysis, six significant results were found. Five DECs were found to be masked: bleomycin and immune thrombocytopenia (actual ROR LCI = 0.94, recalculated ROR LCI = 1.02), vortioxetine and heavy menstrual bleeding (actual ROR LCI = 0.3, recalculated ROR LCI = 1.06), caplacizumab and heavy menstrual bleeding (actual ROR LCI = 0.98, recalculated ROR LCI = 3.47), ziprasidone and amenorrhoea (actual ROR LCI = 0.84, recalculated ROR LCI = 1.67), and azacitidine and pericarditis (actual ROR LCI = 0.81, recalculated ROR LCI = 2.01). For the DEC of adalimumab and immune reconstitution inflammatory syndrome, the LCI of the actual ROR value was 1.14 and removing COVID-19 vaccine reporting resulted in an LCI of the recalculated ROR value of 0.94 (below threshold). CONCLUSIONS: We demonstrated five cases of masking and one case of false-positive association due to the influence of COVID-19 vaccine spontaneous reporting on the ROR. This suggests that the high number of adverse drug reaction reports for COVID-19 vaccines in EudraVigilance has the potential to affect routine statistical signal detection activities. The impact of COVID-19 vaccine ADR reports on current signal detection practices requires further evaluation and solutions to tackle masking issues in EudraVigilance may need to be developed.

Immune response, phenotyping and molecular graft surveillance in kidney transplant recipients following severe acute respiratory syndrome coronavirus 2 vaccination. BACKGROUND: Understanding immunogenicity and alloimmune risk following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination in kidney transplant recipients is imperative to understanding the correlates of protection and to inform clinical guidelines. METHODS: We studied 50 kidney transplant recipients following SARS-CoV-2 vaccination and quantified their anti-spike protein antibody, donor-derived cell-free DNA (dd-cfDNA), gene expression profiling (GEP), and alloantibody formation. RESULTS: Participants were stratified using nucleocapsid testing as either SARS-CoV-2-naÃ¯ve or experienced prior to vaccination. One of 34 (3%) SARS-CoV-2 naÃ¯ve participants developed anti-spike protein antibodies. In contrast, the odds ratio for the association of a prior history of SARS-CoV-2 infection with vaccine response was 18.3 (95% confidence interval 3.2, 105.0, p

< 0.01). Pre- and post-vaccination levels did not change for median dd-cfDNA (0.23%Â vs. 0.21% respectively, p = 0.13), GEP scores (9.85Â vs. 10.4 respectively, p = 0.45), calculated panel reactive antibody, de-novo donor specific antibody status, or estimated glomerular filtration rate. CONCLUSIONS: SARS-CoV-2 vaccines do not appear to trigger alloimmunity in kidney transplant recipients. The degree of vaccine immunogenicity was associated most strongly with a prior history of SARS-CoV-2 infection.

Broad-spectrum vaccine via combined immunization routes triggers potent immunity to SARS-CoV-2 and its variants. The development of broad-spectrum SARS-CoV-2 vaccines will reduce the global economic and public health stress from the COVID-19 pandemic. The use of conserved T-cell epitopes in combination with spike antigen that induce humoral and cellular immune responses simultaneously may be a promising strategy to further enhance the broad spectrum of COVID-19 vaccine candidates. Moreover, this research suggests that the combined vaccination strategies have the ability to induce both effective systemic and mucosal immunity, which may represent promising strategies for maximizing the protective efficacy of respiratory virus vaccines.

Association between levels of IgG antibodies from vaccines and Omicron symptomatic infection among children and adolescents in China. BACKGROUND: Measurements of IgG antibodies to wild-type SARS-CoV-2 antigens can assess vaccine efficacy, but the absolute risk of Omicron symptomatic infection at different IgG levels for children and adolescents remains uncertain, as well as the minimum effective antibody level. We sought to determine the relationship between the tertiles of IgG antibodies to wild-type SARS-CoV-2 antigens and children with symptomatic infection of the pandemic and duration to negative conversion in China for the first time. METHODS: A retrospective study was conducted, including 168 participants under 18â€‰years old from the No.2 People's Hospital of Lanzhou, China, diagnosed with Omicron variant BA.2.38 between July 8, 2022, and August 2, 2022. We calculated odds ratios (OR) in univariate and multivariate regression to assess the association of symptomatic infection with the tertiles of IgG, respectively. Kaplan-Meier curves and Cox proportional hazards regression were used to evaluate the relationship between IgG level and negative conversion time. RESULTS: The average age of the 168 children included in this study was 7.2 (4.7) years old, 133 (79.2%) were symptomatic patients, and the average negative conversion time was 12.2 (3.5) days. The participants with high IgG levels were less likely to become symptomatic, had a shorter turnaround time, and had higher values of IgM and nucleic acid CT. Compared to those with the lowest tertile of IgG, patients with the highest tertile had a 91% lower risk of developing a symptomatic infection after fully adjusting for confounders (ORâ€‰=â€‰0.09, 95% CI, 0.02-0.36, pâ€‰=â€‰0.001). There's no robust relationship between IgG level and negative conversion time in multivariate Cox regression. CONCLUSION: The risk of developing a symptomatic infection can be predicted independently by tertiles of IgG antibodies to wild-type SARS-CoV-2 antigens. High IgG levels can inhibit viral replication, vastly reduce the risk of symptomatic infections and promote a virus-negative conversion, especially when IgG quantitative detection was â‰¥3.44â€‰S/CO, a potential threshold for protection and booster strategy in the future. More data and research are needed in the future to validate the predictive models.

Immunocytometric analysis of patients with thymic epithelial tumors revealed that COVID-19 vaccine booster strongly enhanced the immune response. BACKGROUND: Thymic epithelial tumors (TETs) are rare malignancies with heterogeneous clinical manifestations. The high frequency of autoimmune paraneoplastic disorders observed in such patients requires caution when using COVID-19 vaccines. Furthermore, TETs are often associated with severe immunodeficiency, making it difficult to predict vaccine immunization. Therefore, we aimed to evaluate immune response to COVID-19 vaccine in patients with TETs. METHODS: We conducted a prospective study enrolling patients who underwent the SARS-Cov-2 mRNA full vaccine cycle (two doses plus a booster after 6 months of

BNT162b2). All patients were enrolled before receiving 1(st) vaccine dose and were followed over the vaccination cycle for up to 6 months after the booster dose to i) assess humoral and cellular responses, ii) define biomarkers predictive of effective immunization, and iii) evaluate the safety of the vaccine. RESULTS: At the end of the full vaccine cycle, 27 (61.4%) patients developed humoral and 38 (86.4%) cellular responses (IFN Î³ release by stimulated cells) and showed an increase in activated TH1 and TH17 cells, particularly significant after the booster dose. The number of B and T lymphocytes at baseline was predictive of humoral and cellular responses, respectively. Patients with no evidence of tumor lesions had a higher probability of achieving a humoral response than those with evidence of the disease. Furthermore, the percentage of patients with immune-related disorders (75%), particularly Good's syndrome (47.7%) and myasthenia gravis (29.5%), did not change over the entire vaccine cycle. Overall, 19 of the 44 enrolled patients (43.2%) had COVID-19 during the observation period; none required hospitalization or oxygen support, and no fatalities were observed. CONCLUSION: SARS-Cov-2 mRNA vaccine determines the immune responses in patients with TET, particularly after the booster dose, and in patients with no evidence of tumor lesions. Preliminary analysis of B and T lymphocytes may help identify patients who have a lower probability of achieving effective humoral and cellular responses and thus may need passive immunization. The vaccine prevented severe COVID-19 infection and is safe.

Long-Term Neutralizing Antibody Titers After BNT162b2 Vaccination in Hemodialysis Patients.

Autoimmune hepatitis following mRNA COVID-19 vaccine.

Immunogenicity and safety of COVID-19 vaccines among people living with HIV: A systematic review and meta-analysis. Available data suggest that the immunogenicity of COVID-19 vaccines might decrease in the immunocompromised population, but data on vaccine immunogenicity and safety among people living with HIV (PLWH) are still lacking. The purpose of this meta-analysis is to compare the immunogenicity and safety of COVID-19 vaccines in PLWH with healthy controls. We comprehensively searched the following databases: PubMed, Cochrane Library, and EMBASE. The risk ratio (RR) of seroconversion after the first and second doses of a COVID-19 vaccine was separately pooled using random-effects meta-analysis. Seroconversion rate was lower among PLWH compared with healthy individuals after the first (RR = 0.77, 95% conï¬•dent interval (CI) 0.64-0.92) and second doses (RR = 0.97, 95%CI 0.95-0.99). The risk of total adverse reactions among PLWH is similar to the risk in the healthy group, after the first (RR = 0.87, 95%CI 0.70-1.10) and second (RR = 0.83, 95%CI 0.65-1.07) doses. This study demonstrates that the immunogenicity and safety of SARS-CoV-2 vaccine in fully vaccinated HIV-infected patients were generally satisfactory. A second dose was related to seroconversion enhancement. Therefore, we considered that a booster dose may provide better seroprotection for PLWH. On the basis of a conventional two-dose regimen for COVID-19 vaccines, the booster dose is very necessary.

Randomized open-label controlled study of cancer vaccine OSE2101 versus chemotherapy in HLA-A2-positive patients with advanced non-small-cell lung cancer with resistance to immunotherapy: ATALANTE-1. BACKGROUND: Patients with advanced non-small-cell lung cancer (NSCLC) treated with immune checkpoint blockers (ICBs) ultimately progress either rapidly (primary resistance) or after durable benefit (secondary resistance). The cancer vaccine OSE2101 may invigorate antitumor-specific immune responses after ICB failure. The objective of ATALANTE-1 was to evaluate its efficacy and safety in these patients. PATIENTS AND METHODS: ATALANTE-1 was a two-step open-label study to evaluate the efficacy and safety of OSE2101 compared to standard-of-care (SoC) chemotherapy (CT). Patients with human leukocyte antigen (HLA)-A2-positive advanced NSCLC without actionable alterations, failing sequential or concurrent CT and ICB were randomized (2 : 1) to OSE2101 or SoC (docetaxel or pemetrexed). Primary endpoint was overall survival (OS). Interim OS futility analysis was planned as per Fleming design. In April 2020 at the time of interim analysis, a decision was taken to

prematurely stop the accrual due to coronavirus disease 2019 (COVID-19). Final analysis was carried out in all patients and in the subgroup of patients with ICB secondary resistance defined as failure after ICB monotherapy second line â‰¥12 weeks. RESULTS: Two hundred and nineteen patients were randomized (139 OSE2101, 80 SoC); 118 had secondary resistance to sequential ICB. Overall, median OS non-significantly favored OSE2101 over SoC {hazard ratio (HR) [95% confidence interval (CI)] 0.86 [0.62-1.19], PÂ = 0.36}. In the secondary resistance subgroup, OSE2101 significantly improved median OS versus SoC [11.1 versus 7.5 months; HR (95% CI) 0.59 (0.38-0.91), PÂ = 0.017], and significantly improved post-progression survival (HR 0.46, PÂ = 0.004), time to Eastern Cooperative Oncology Group (ECOG) performance status deterioration (HR 0.43, PÂ = 0.006) and Quality of Life Questionnaire Core 30 (QLQ-C30) global health status compared to SoC (PÂ = 0.045). Six-month disease control rates and progression-free survival were similar between groups. Grade â‰¥3 adverse effects occurred in 11.4% of patients with OSE2101 and 35.1% in SoC (PÂ = 0.002). CONCLUSIONS: In HLA-A2-positive patients with advanced NSCLC and secondary resistance to immunotherapy, OSE2101 increased survival with better safety compared to CT. Further evaluation in this population is warranted.

Oculomotor Nerve Palsy in a 10-Year-Old Boy After Vaccination With BioNTech (Pfizer) Against Coronavirus Disease 2019: A Case Report.

Outcome findings of COVID-19 vaccine among 31â€‰977 pregnant women in Indonesia. OBJECTIVE: We provide an overview of the safety of messenger RNA and inactivated coronavirus disease 2019 (COVID-19) vaccine and monitoring of pregnant women after COVID-19 vaccination. The vaccine safety outcome profile is beneficial for further recommendations of COVID-19 vaccination in pregnancy. METHODS: This research was conducted as descriptive research. Sampling was performed using an online questionnaire to be filled out voluntarily and distributed to all pregnant women in Indonesia who received the COVID-19 vaccination. Data collection was performed and descriptive statistics were obtained. RESULTS: Among 31â€‰977 pregnant women, 24â€‰212 (75.7%) received the first dose, 7619 (23.8%) received the second dose, and 146 (4.5%) received the third dose of the COVID-19 vaccine. Sinovac vaccine is the most administered vaccine to pregnant women (27â€‰122 [84%]). Most pregnant women (78.7%) who were vaccinated had no adverse effects after immunization, while the most reported adverse effects were mild symptoms. CONCLUSION: The current study contributed evidence that COVID-19 vaccination during pregnancy has minimal adverse effects. These findings may help pregnant women and healthcare providers to make informed decisions regarding vaccination.

The clinicopathological features of thrombosis with thrombocytopenia syndrome following ChAdOx1-S (AZD1222) vaccination and case outcomes in Australia: a population-based study. BACKGROUND: Thrombosis with thrombocytopenia syndrome (TTS) associated with viral vector COVID-19 vaccines, including ChAdOx1-S (AstraZeneca AZD1222) vaccine, can result in significant morbidity and mortality. We report the clinicopathological features of TTS following ChAdOx1-S vaccination and summarise the case outcomes in Australia. METHODS: In this cohort study, patients diagnosed with TTS in Australia between 23 March and 31 December 2021 were identified according to predefined criteria. Cases were included if they met the Therapeutic Goods Administration (TGA) probable and confirmed case definitions and were reclassified using Centres for Disease Control and Prevention (CDC) definition for analysis. Data were collected on patient baseline characteristics, clinicopathological features, risk factors, treatment and outcomes. FINDINGS: A total of 170 TTS cases were identified, with most occurring after the first dose (87%) of ChAdOx1-S. The median time to symptom onset after vaccination and symptom onset to admission was 11 and 2 days respectively. The median age of cases was 66 years (interquartile range 55-74). All except two patients received therapeutic anticoagulation and 66% received intravenous immunoglobulin. Overall, 85.3% of cases

were discharged home after a median hospitalisation of 6 days, 9.4% required ongoing rehabilitation and 5.3% died. Eight deaths were related to TTS, with another dying from an unrelated condition while receiving treatment for TTS. Deaths occurred more commonly in those classified as Tier 1 according to the CDC definition and were associated with more severe thrombocytopenia and disease-related haemorrhage. INTERPRETATION: TTS, while rare, can be severe and have catastrophic outcomes in some individuals. In Australia, the mortality rate was low compared to that reported in other high-income countries. Almost all received therapeutic anticoagulation with no bleeding complications and were successfully discharged. This emphasises the importance of community education and an established pathway for early recognition, diagnosis and treatment of TTS. FUNDING: Australian Commonwealth Department of Health and Aged Care. H.A Tran, N. Wood, J. Buttery, N.W. Crawford, S.D. Chunilal, V.M. Chen are supported by Medical Research Future Funds (MRFF) grant ID 2015305.

Guillain-Barre syndrome before and during the COVID-19 pandemic in a referral center of Mexico. BACKGROUND: During the COVID-19 pandemic, an increase in the number of Guillain-Barre syndrome (GBS) cases has been reported. OBJECTIVE: To describe the clinical characteristics and prognosis of patients with GBS before and during the COVID-19 pandemic. MATERIAL AND METHODS: Prospective cohort of GBS patients divided in two subgroups: before (2018-2019) and during (2020-2021) the COVID-19 pandemic. Clinical and paraclinical characteristics, as well as deaths, were recorded. A good prognosis was defined as independent ambulation recovery at three months. RESULTS: Two-hundred and one patients were included (123 during and 78 before the pandemic), out of whom 69% were males; age was 45 Â± 16 years, and there was 2.5% of in-hospital deaths. During the pandemic, a higher frequency of the demyelinating variant (50%), bulbar cranial nerves involvement (44% vs. 28%), prior history of vaccination (16% vs. 0%), and a lower MRC score (30 Â± 16.7 vs. 34.3 Â± 17.7) were documented. An increase in the number of cases was observed from July to September (38 vs. 13). There were no significant differences in independent ambulation recovery or in the number of deaths. CONCLUSIONS: During the COVID-19 pandemic, a higher number of GBS cases were treated, out of which 16% were associated with the SARS-CoV-2 vaccine; patients treated during the pandemic did not have a worse prognosis.

Bullous pemphigoid associated with prodromal-phase by repeated COVID-19 vaccinations.

Distinct intrathecal inflammatory signatures following relapse and anti-COVID-19 mRNA vaccination in multiple sclerosis. BACKGROUND: The role of vaccine-mediated inflammation in exacerbating multiple sclerosis (MS) is a matter of debate. OBJECTIVE: In this cross-sectional study, we compared the cerebrospinal fluid (CSF) inflammation associated with MS relapses or anti-COVID-19 mRNA vaccinations in relapsing-remitting multiple sclerosis (RRMS). METHODS: We dosed CSF cytokines in 97 unvaccinated RRMS patients with clinical relapse within the last 100 days. In addition, we enrolled 29 stable RRMS and 24 control patients receiving COVID-19 vaccine within the last 100 days. RESULTS: In RRMS patients, a negative association was found between relapse distance and the CSF concentrations of the pro-inflammatory cytokines interleukin (IL)-2 (beta = -0.265, p = 0.016), IL-6 (beta = -0.284, p = 0.01), and IL-17 (beta = -0.224, p = 0.044). Conversely, vaccine distance positively correlated with a different set of cytokines including IL-12 (beta = 0.576, p = 0.002), IL-13 (beta = 0.432, p = 0.027), and IL-1ra (beta = 0.387, p = 0.05). These associations were significant also considering other clinical characteristics. No significant associations emerged between vaccine distance and CSF molecules in the control group. CONCLUSION: Vaccine for COVID-19 induces a central inflammatory response in RRMS patients that is qualitatively different from that associated with disease relapse.

Typeâ€‰1 diabetes, COVID-19 vaccines and short-term safety: Subgroup analysis from the global COVAD study. AIMS/INTRODUCTION: Coronavirus disease 2019 (COVID-19) vaccinations have

been proven to be generally safe in healthy populations. However, the data on vaccine safety in patients with typeâ€‰1 diabetes are scarce. This study aimed to evaluate the frequency and severity of short-term (<7-day) adverse vaccination events (AEs) and their risk factors among typeâ€‰1 diabetes patients. MATERIALS AND METHODS: This study analyzed data from the COVID-19 vaccination in Autoimmune Diseases (COVAD) survey database (May to December 2021; 110 collaborators, 94 countries), comparing <7-day COVID-19 vaccine AE among typeâ€‰1 diabetes patients and healthy controls (HCs). Descriptive statistics; propensity score matching (1:4) using the variables age, sex and ethnicity; and multivariate analyses were carried out. RESULTS: This study analyzed 5,480 completed survey responses. Of all responses, 5,408 were HCs, 72 were typeâ€‰1 diabetes patients (43 females, 48.0% white European ancestry) and Pfizer was the most administered vaccine (39%). A total of 4,052 (73.9%) respondents had received two vaccine doses. Patients with typeâ€‰1 diabetes had a comparable risk of injection site pain, minor and major vaccine AEs, as well as associated hospitalizations to HCs. However, typeâ€‰1 diabetes patients had a higher risk of severe rashes (3% vs 0.4%, OR 8.0, 95% confidence interval 1.7-36), Pâ€‰=â€‰0.007), although reassuringly, these were rare (nâ€‰=â€‰2 among type 1 diabetes patients). CONCLUSIONS: COVID-19 vaccination was safe and well tolerated in patients with typeâ€‰1 diabetes with similar AE profiles compared with HCs, although severe rashes were more common in typeâ€‰1 diabetes patients.
Short Term Side Effects Of Inactivated COVID-19 Vaccines Among Pakistani Population: A Survey-Based Cross-Sectional Study. OBJECTIVES: To assess the short-term adverse effects of two inactivated coronavirus disease-2019 vaccines, and the demographic factors associated with such events. METHODS: The cross-sectional study was conducted in Karachi from August to October 2021 after approval from the ethics review board of Dow University of Health Sciences, Karachi, and comprised adults of either gender who had received at least one dose of either Sinopharm or CoronaVac vaccine. Data was collected using online and printed survey forms. The questionnaire investigated the symptoms experienced by the participants after the administration of the vaccine dose. Data was analysed using SPSS 22. RESULTS: Of the 1000 survey forms filled, 896 were analysed; 505(56.4%) women and 391(43.6%) men were included in the study. Most of the participants were aged 18-30 years 644(71.9%). Overall, 581(64.8%) subjects had received Sinopharm vaccine, and 315(35.2%) received CoronaVac. The incidence of side effects after the first and second dose respectively was 63.3% (368 out of 581) and 55.2% (239 out of 433) for Sinopharm and 65.4% (206 out of 315) and 61.4% (89 out of 145) for CoronaVac. The factors associated with a higher risk of side effects were female gender and young age (p<0.05). CONCLUSIONS: Most of the reported symptoms were minor in nature, like pain at the injection site, and women and those of young age reported such symptoms more than men and the elderly.
Letter by Cosentino and Marino Regarding Article, "Circulating Spike Protein Detected in Post-COVID-19 mRNA Vaccine Myocarditis".
Letter by Schwartz and Prasad Regarding Article, "Circulating Spike Protein Detected in Post-COVID-19 mRNA Vaccine Myocarditis".
Response by Yonker et al to Letter Regarding Article, "Circulating Spike Protein Detected in Post-COVID-19 mRNA Vaccine Myocarditis".
Herpes zoster in a patient with first onset of childhood nephrotic syndrome following the second SARS-CoV-2 vaccination.
Risk of Thrombosis Following the First Dose of ChAdOx1 nCoV-19 Vaccine in Patients Undergoing Maintenance Hemodialysis: A Self-Controlled Case Series Study. BACKGROUND: The ChAdOx1 nCoV-19 vaccine is associated with vaccine-induced thrombosis and thrombocytopenia (VITT). Patients with end-stage renal disease (ESRD) under hemodialysis are at elevated risk of heparin-

induced thrombocytopenia, which shares similar mechanisms with VITT. We aimed to examine the risk of VITT after the first dose of ChAdOx1 nCoV-19 vaccine using a self-controlled case series analysis (SCCS) in the hemodialyzed ESRD population. METHODS: Drawing from the largest multi-center electronic medical records database in Taiwan, we identified adult patients, with or without hemodialysis, between 1st December, 2020, and 31st December, 2021, who received a first dose of ChAdOx1 nCoV-19 vaccine and had an outcome of thrombocytopenia, venous thrombosis, or arterial thrombosis. We calculated the incident rate ratios (IRRs) of outcomes in different periods at risk, compared to periods not at risk. RESULTS: Â We identified 59 hemodialysis patients and 41 non-dialysis patients with an outcome. The SCCS analyses showed, for the hemodialysis group, a significantly increased risk of outcomes during the period 31 to 60 days post-exposure to ChAdOx1 nCoV-19 vaccine (IRR: 2.823; 95% CI: 1.423-5.600). However, in non-dialysis patients there was no increase in risks during any of the post-exposure risk periods. CONCLUSION: For ESRD patients under hemodialysis, the first dose of ChAdOx1 nCoV-19 vaccine was associated with a 2.8-fold increase in risk of thrombosis.

Investigating the impact of prior COVID-19 on IgG antibody and interferon Î³ responses after BBIBP-CorV vaccination in a disease endemic population: A prospective observational study. BACKGROUND AND AIMS: COVID-19 vaccinations have reduced morbidity and mortality from the disease. Antibodies againstÂ severe acute respiratory syndrome coronavirus 2 (SARSâ€‘CoVâ€‘2) have been associated with immune protection. Seroprevalence studies revealed high immunoglobulin G (IgG) antibody levels to SARS-CoV-2 in the Pakistani population before vaccinations. We investigated the effect of BBIBP-CorV vaccination on circulating IgG antibodies and interferon (IFN)-Î³ from T cells measured in a cohort of healthy individuals, with respect to age, gender, and history of COVID-19. METHODS: The study was conducted between April and October 2021. BBIBP-CorV vaccinated participants were followed up to 24 weeks. Antibodies to SARS-CoV-2 Spike protein and its receptor-binding domain (RBD) were measured. IFNÎ³ secreted by whole blood stimulation of Spike protein and extended genome antigens was determined. RESULTS: Study participants with a history of prior COVID-19 displayed a higher magnitude of IgG antibodies to Spike and RBD. IgG seropositivity was greater in those with prior COVID-19, aged 50 years or younger and in females. At 24 weeks after vaccination, 37.4% of participants showed IFN-Î³ responses to SARS-CoV-2 antigens. T cell IFN-Î³ release was higher in those with prior COVID-19 and those aged 50 years or less. Highest IFN-Î³ release was observed to extended genome antigens in individuals both with and without prior COVID-19. CONCLUSION: We found that IgG seropositivity to both Spike and RBD was affected by prior COVID-19, age and gender. Importantly, seropositive responses persisted up to 24 weeks after vaccination. Persistence of vaccine induced IgG antibodies may be linked to the high seroprevalence observed earlier in unvaccinated individuals. Increased T cell reactivity to Spike and extended genome antigens reflects cellular activation induced by BBIBP-CorV. COVID-19 vaccination may have longer lasting immune responses in populations with a higher seroprevalence. These data inform on vaccination booster policies for high-risk groups.

Good Outcome With Respect to Acute Necrotizing Encephalitis in Children Associated With Post-infectious SARS-CoV-2. This case report demonstrates an excellent outcome in a child with acute necrotizing encephalitis that was likely associated with the post-infectious SARS-CoV-2. The aim of this report is to emphasize that early diagnosis and initiation of immunotherapy treatment may yield good outcome, particularly with the use of tocilizumab and high-dose methylprednisolone. Post immunotherapy, significant neurological improvement was seen through the gradual improvement of Glasgow Coma Scale (GCS) score of 6 to GCS score of 12 within three weeks and subsequently acquired almost full neurological function with minimally dependent activity of daily living (ADL) at eight weeks in the post-treatment follow-up. It is interesting to identify that the possible causative

factor could be the natural infection in a vaccinated patient. This was evidenced by the persistently high SARS-CoV-2 immunoglobulin G (IgG)-Spike antibodies titre in a patient vaccinated with two doses of BNT162b2, 11 months before presentation.

Takotsubo Cardiomyopathy Following COVID-19 Vaccine Booster Dose: A Case Report. Although the efficacy and safety of the coronavirus disease 2019 (COVID-19) vaccine have been established, side effects and adverse events related to the COVID-19 vaccine are still coming out. COVID-19 vaccine also has the potential to cause acute and long-term cardiovascular effects, which include myocarditis, pericarditis, myopericarditis, myocardial infarction, pulmonary embolism, thrombotic thrombocytopenia, and pulmonary hemorrhage. Although uncommon, takotsubo cardiomyopathy (TCM) has also been reported following COVID-19 vaccination. We report a case of TCM following the COVID-19 vaccine in a 59-year-old female who presented with intermittent chest pain and dyspnea following the COVID-19 vaccine booster dose. She had no identifiable triggers for TCM, no risk factors for cardiovascular disease, and normal cardiac enzyme levels, ruling out other causes of cardiac dysfunction. The diagnosis of TCM was supported by imaging findings and the absence of obstructive or thrombotic lesions on angiography.

Reverse Takotsubo Cardiomyopathy Following COVISHIELD Vaccination: A Rare Case of an Anaphylactic Reaction. This case report describes a 47-year-old female healthcare worker who developed reverse takotsubo cardiomyopathy (TTC) following the administration of the COVISHIELD COVID-19 vaccine. Within minutes of receiving the vaccine, she experienced acute shortness of breath, nausea, and restlessness, along with a significant drop in blood pressure. She was diagnosed with an anaphylactic reaction and promptly treated with adrenaline and fluids. In the intensive cardiac care unit, she exhibited hypotension, had vision loss, and developed pulmonary edema. Further evaluation revealed abnormal ECG findings, elevated troponin levels, and reduced left ventricular ejection fraction (LVEF). Coronary angiography ruled out obstructive coronary artery disease. The patient gradually improved over several days and was discharged with a recovered left ventricular function. This case highlights the occurrence of TTC triggered by anaphylaxis to the COVID-19 vaccine and emphasizes the need for preparedness to manage such emergencies in vaccination centers.

Impact of SARS-CoV-2 mRNA vaccine on arthritis condition in rheumatoid arthritis.
BACKGROUND: The SARS-CoV-2 mRNA vaccine has been reported to cause various adverse reactions, including the development or exacerbation of autoimmune diseases, but the adverse reactions and the effects of the vaccines on disease activity in patients with rheumatoid arthritis (RA) remain unknown. We therefore investigated the arthritis condition in RA patients after SARS-CoV-2 vaccination. METHODS: RA patients who visited our hospital from January to April 2022 completed a questionnaire regarding adverse reactions to the SARS-CoV-2 vaccine. We compared the frequency and duration of post-vaccination arthralgia between RA patients and health care workers in our hospital. For the RA patients who reported post-vaccination arthralgia, we collected medical records for the 6 months after vaccination. RESULTS: Of the 1198 vaccinated RA patients, 256 (21.4%) had systemic inflammatory symptoms, 18 (1.5%) had allergies including urticaria and asthma, and 37 (3.1%) had arthralgia. A few patients had extra-articular manifestations such as acute exacerbation of interstitial lung disease. Compared with health care workers, RA patients more frequently developed arthralgia, and the arthralgia was longer lasting than that in controls: only 9 (0.8%) of the 1117 health care workers reported arthralgia, and all cases resolved within 3 days. Data from 31 of the 37 RA patients with post-vaccination arthralgia were further analyzed; in these patients, disease activity was highest after 2 months, and 10 patients required additional DMARDs within 6 months. The proportion of concomitant use of PSL at vaccination was higher in these patients. No patients on biological DMARDs or targeted synthetic DMARDs prior to vaccination needed additional DMARDs or a change

of regimen. CONCLUSION: RA patients had more frequent and longer-lasting arthralgia after vaccination than healthy subjects, and one-third of patients with post-vaccination arthralgia required additional DMARDs. Although the SARS-CoV-2 mRNA vaccine was administered safely in most RA patients, in some patients RA symptoms may worsen after vaccination.

Assessment of vaccinations and breakthrough infections after adjustment of the dynamic zero-COVID-19 strategy in China: an online survey. Coronavirus disease 2019 (COVID-19) cases in China has grown rapidly after adjustment of the dynamic zero-COVID-19 strategy. However, how different vaccination states affect symptoms, severity and post COVID conditions was unclear. Here, we used an online questionnaire to investigate the infection status of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) among 11,897 participants, with 55.55% positive and 28.42% negative. The common COVID-19 symptoms were fatigue (73.31%), cough (70.02%), fever (65.25%) and overall soreness (58.64%); self-reported asymptomatic infection accounted for 0.7% of participants. The persistent symptoms at 1 month after infection included fatigue (48.7%), drowsiness (34.3%), cough (30.1%), decreased exercise ability (23.1%) and pharyngeal discomfort (19.4%), which was reduced by more than 200% at 2 months. Participants with complications such as chronic obstructive pulmonary disease, respiratory diseases, diabetes, hypertension, etc. have a higher proportion of hospitalization and longer recovery time (pâ€‰<â€‰=â€‰0.01). Multiple vaccination statuses reduced the infection (pâ€‰<â€‰0.001) and severity rates (pâ€‰=â€‰0.022) by varying degrees as well as reduced the risk of high fever (>39.1â€‰Â°C), chills, diarrhea and ageusia/anosmia, respectively (pâ€‰<â€‰0.05). Vaccination may enhance some upper respiratory symptoms, including sore throat, nasal congestion and runny nose, respectively (pâ€‰<â€‰0.05). Participants who had been vaccinated within 3 months were better protected by helping reduce their risk of overall soreness, chills and ageusia/anosmia, respectively (pâ€‰<â€‰0.05). In conclusion, our work has updated the epidemic characteristics of the breakthrough infection (BTI) wave after the dynamic zero-COVID-19 strategy, providing data and insights on how different vaccination statuses affect COVID-19 symptoms and disease prognosis.

A case of COVID-19 mRNA vaccine-related erythema nodosum and interstitial granulomatous drug reaction.

Safety of BNT162b2 and CoronaVac during pregnancy on birth outcomes and neonatal mortality: a cohort study from Brazil. BACKGROUND: COVID-19 vaccines have been shown to protect pregnant individuals against mild and severe COVID-19 outcomes. However, limited safety data are available for inactivated (CoronaVac) and mRNA (BNT162b2) vaccines during pregnancy regarding their effect on birth outcomes and neonatal mortality, especially in low- and middle-income countries. METHODS: We conducted a retrospective population-based cohort study in Rio de Janeiro, Brazil, with 17â€Š513 singleton live births conceived between 15 May 2021 and 23 October 2021. The primary exposure was maternal vaccination with CoronaVac or mRNA BNT162b2 vaccines and sub-analyses were performed by the gestational trimester of the first dose and the number of doses given during pregnancy. The outcomes were pre-term birth (PTB), small for gestational age (SGA), low birthweight (LBW), low Apgar 5 and neonatal death. We used the Cox model to estimate the hazard ratio (HR) with a 95% CI and applied the inverse probability of treatment weights to generate adjusted HRs. RESULTS: We found no significant increase in the risk of PTB (HR: 0.98; 95% CI 0.88, 1.10), SGA (HR: 1.09; 95% CI 0.96, 1.27), LBW (HR: 1.00; 95% CI 0.88, 1.14), low Apgar 5 (HR: 0.81; 95% CI 0.55, 1.22) or neonatal death (HR: 0.88; 95% CI 0.56, 1.48) in women vaccinated with CoronaVac or BNT162b2 vaccines. These findings were consistent across sub-analyses stratified by the gestational trimester of the first dose and the number of doses given during pregnancy. We found mild yet consistent protection against PTB in women who received different vaccine platforms during the third trimester of pregnancy (any vaccines, HR: 0.78; 95% CI 0.63, 0.98; BNT162b2, HR: 0.75; 95%

CI 0.59, 0.99). CONCLUSIONS: This study provides evidence that COVID-19 vaccination in all trimesters of pregnancy, irrespective of the vaccine type, is safe and does not increase the risk of adverse birth outcomes or neonatal deaths.

Clinical Application of In Vitro Tests for COVID-19 Vaccine Delayed Hypersensitivity Diagnostics. Drug hypersensitivity reactions can be classified as immediate or delayed. While diagnostic options for immediate reactions are well developed and standardized, delayed reactions (in many cases type IV according to Gell and Coombs) are a challenge for allergy work-up. In recent years, some in vitro markers have been proposed and used for delayed reactions, such as contact dermatitis. Primary strategy: Avoidance is difficult to achieve, especially for COVID-19 vaccinations, when immunity against infection is extremely important. The aim of our study was to evaluate the application of in vitro delayed hypersensitivity tests in COVID-19 vaccines. Seven patients with a positive history of severe delayed drug allergy were enrolled. Vein blood was collected to stimulate cells with the tested vaccines (Comirnaty, Janssen, Spikevax) and excipients with the assessment of CD40L, CD69, IL-2, IL-4, IL-6, IL-10, IFNgamma, TNFalfa, and intracellular markers: granulysin and INFgamma. In addition, basophile activation tests, patch tests, skin prick tests, and intradermal tests were performed with the tested vaccine. Finally, the decision was made to either administer a vaccine or resign. Two out of seven patients were considered positive for drug hypersensitivity in the in vitro test according to the high vaccine stimulation index measured with CD69 (6.91 and 12.18) and CD40L (5.38 and 15.91). All patch tests, BATs, and skin tests were negative. Serum interleukin measurements were inconclusive as the impact of the vaccine itself on the immunity system was high. Intracellular markers gave uncertain results due to the lack of stimulation on the positive control. CD69 and CD40L could be reliable in vitro markers for delayed hypersensitivity to COVID-19 vaccines. Patch tests, skin tests, BATs, and serum interleukins did not confirm their usefulness in our study.

COVID-19 Vaccination and Disease Course in People with Multiple Sclerosis in Greece. Over the past three years, humanity faced the abrupt spread of COVID-19, responsible for a worldwide health crisis. Initially, it was believed that individuals with chronic disorders, including multiple sclerosis, were more likely to be infected and suffer a worse degree of COVID-19 disease. Therefore, data with regard to COVID-19 disease outcomes in these populations may provide additional insight with regard to the management of chronic diseases during viral pandemics. The objective of this study is to evaluate COVID-19 disease course in people with multiple sclerosis (PwMS) during the COVID-19 pandemic in Greece and explore the impact of vaccination in the outcome of SARS-CoV-2 infection in this population. Anonymized data, extracted from nationwide administrative records between February 2020 and December 2021, were retrospectively analyzed in order to identify PwMS with SARS-CoV-2 infection. Demographic data, as well as data regarding COVID-19 infection and vaccination, were additionally collected. The study sample included 2351 PwMS (65.1% females, 51.2% unvaccinated at the time of infection). A total of 260 PwMS were hospitalized, while 25 PwMS died from COVID-19 disease and its complications. Older age, male sex and the presence of comorbidities were independently associated with a higher probability of hospitalization. The risk of hospitalization was decreased in PwMS receiving some disease-modifying treatments. Anti-CD20s demonstrated high odds ratios without reaching statistical significance. Regarding fatal outcome, only age reached statistical significance. Vaccination provided a significant protective effect against hospitalization but did not exhibit a statistically significant effect on mortality.

First tonic-clonic seizure five hours after Ad26.COV2.S vaccination without acute brain lesion but long-term chorea.

Immunogenicity and Reactogenicity of Coadministration of COVID-19 and Influenza Vaccines. IMPORTANCE: COVID-19 and seasonal influenza vaccines were previously given separately, although their coadministration is warranted for vaccination adherence. Limited data on their coadministration

have been published. OBJECTIVE: To compare the reactogenicity and immunogenicity of COVID-19 and influenza vaccinations administered together with those of COVID-19 vaccination alone. DESIGN, SETTING, AND PARTICIPANTS: This prospective cohort study included health care workers at a large tertiary medical center in Israel who received the Influvac Tetra (Abbott) influenza vaccine (2022/2023), the Omicron BA.4/BA.5-adapted bivalent (Pfizer/BioNTech) vaccine, or both. Vaccination began in September 2022, and data were collected until January 2023. Vaccines were offered to all employees and were coadministered or given separately. Adverse reaction questionnaires were sent, and serologic samples were also collected. EXPOSURES: Receiving COVID-19 vaccine, influenza vaccine, or both. MAIN OUTCOMES AND MEASURES: The main outcomes for the reactogenicity analysis were symptoms following vaccine receipt, assessed by a digital questionnaire: any local symptoms; fever; weakness or fatigue; any systemic symptoms; and their duration. The immunogenicity analysis' outcome was postvaccination anti-spike IgG titer. RESULTS: This study included 2 cohorts for 2 separate analyses. The reactogenicity analysis included 588 participants (of 649 questionnaire responders): 85 in the COVID-19 vaccine-alone group (median [IQR] age, 71 [58-74] years; 56 [66%] female); 357 in the influenza vaccine-alone group (median [IQR] age, 55 [40-65] years; 282 [79%] female); and 146 in the coadministration group (median [IQR] age, 61 [50-71] years; 81 [55%] female). The immunogenicity analysis included 151 participants: 74 participants in the COVID-19 vaccine group (median [IQR] age, 67 [56-73] years; 45 [61%] female) and 77 participants in the coadministration group (median [IQR] age, 60 [49-73] years; 42 [55%] female). Compared with COVID-19 vaccination alone, the risk of systemic symptoms was similar in the coadministration group (odds ratio, 0.82; 95% CI, 0.43-1.56). Geometric mean titers in the coadministration group were estimated to be 0.84 (95% CI, 0.69-1.04) times lower than in the COVID-19 vaccine-alone group. CONCLUSIONS AND RELEVANCE: In this cohort study of health care workers who received a COVID-19 vaccine, an influenza vaccine, or both, coadministration was not associated with substantially inferior immune response or to more frequent adverse events compared with COVID-19 vaccine administration alone, supporting the coadministration of these vaccines.

Association of Guillain-BarrÃ© syndrome following COVID-19 vaccination. Background: Among the various side-effects of COVID-19 vaccinations, Guillain-BarrÃ© syndrome (GBS) has been found to have some interesting association with the vaccinations. This paper mainly focuses on exploring different associations between COVID-19 vaccination and GBS.Method: A systematic search was conducted on electronic databases including PubMed, Google Scholar, Cochrane, and Embase for case reports published until July 2022. A total of 42 case reports involving 67 individuals from 16 different countries were documented. Reports were analyzed to identify presenting symptoms, diagnosis, treatment, and pathophysiological mechanisms related to the relevant issues.Results: The studies included a diverse range of individuals with ages ranging from 13 to 87Â years, with an average age of 51.66Â years and a male predominance. The average time between vaccination and symptom onset was 12.67Â days. Prominent clinical features observed in the case reports included back pain, facial diplegia, weakness, and paresthesia. Diagnostic studies primarily involved cerebrospinal fluid (CSF) analysis and electromagnetic studies. A key diagnostic clue was the presence of albuminocytological dissociation in CSF. Available treatment options consisted of intravenous immunoglobulin (IVIG), plasmapheresis, and steroids.Conclusion: This review highlights the diverse and clinically relevant associations between COVID-19 vaccination and GBS. The findings underscore the importance of conducting further studies to explore the causative links in this correlation and gain a better understanding of the relationship.

Author reply to "Response to 'A case of acquired idiopathic generalized anhidrosis following severe acute respiratory syndrome coronavirus 2 vaccination'".

Sinopharm (HB02)-associated vaccine-induced immune thrombotic thrombocytopenia: a case report. BACKGROUND: Vaccine-induced thrombotic thrombocytopenia is associated with the coronavirus disease 2019 vaccines. It has been reported by vector-based vaccines. To the best of our knowledge, there is no report about vaccine-induced thrombotic thrombocytopenia in whole-virus vaccines. We are presenting the first case of vaccine-induced thrombotic thrombocytopenia with this type of vaccine. CASE PRESENTATION: An 18-year-old male CaucasianÂ patient with complaints of severe abdominal, low back, and lower extremity pain presented to the medical center. He received the first dose of the Sinopharm (HB02) vaccine against coronavirus disease 2019 10Â days before hospital attendance. In the laboratory examination, decreased platelet count and increased D-dimer were observed. During hospital admission, the diagnosis of pulmonary embolism was reached. He received vaccine-induced thrombotic thrombocytopenia therapy consisting of intravenous immune globulin and direct oral anticoagulant. Platelet count increased and he was discharged after 1Â month. CONCLUSION: This case highlights the possibility of vaccine-induced thrombotic thrombocytopenia occurrence by whole-virus coronavirus disease 2019 vaccines. Compared with vector-based vaccines, this phenomenon is rare for whole-virus vaccines. More studies on this type of vaccine regarding thrombotic thrombocytopenia should be considered.

Vaccination in post-tuberculosis lung disease management: A review of the evidence. INTRODUCTION AND OBJECTIVES: Post-tuberculosis lung disease (PTLD), as other chronic respiratory disorders, may have infectious complications; some of them can be prevented with vaccinations. So far, no document has discussed the potential role of vaccination in PTLD. Therefore, the objective of this review was to describe vaccination recommendations to prevent infections potentially capable of complicating PTLD. MATERIALS AND METHODS: A non-systematic review of the literature was conducted. The following keywords were used: tuberculosis, vaccination, vaccines and PTLD. PubMed/MEDLINE and Embase were used as the search engine, focusing on English-language literature only. RESULTS: We identified 9 vaccines potentially useful in PTLD. Influenza, pneumococcal and anti-COVID-19 vaccinations should be recommended. Patients with PTLD can also benefit from vaccination against shingles. Vaccination against pertussis is mainly relevant during childhood. Diphtheria, tetanus and measles vaccination are recommended for general population and should be considered in patients with PTLD not previously vaccinated. Tdap (Tetanus, diphtheria, and pertussis) booster should be repeated in every adult every ten years. Vaccination against BCG retains its importance during early childhood in countries where TB is endemic. CONCLUSIONS: Vaccination deserves to be considered among the strategies to prevent and/or mitigate PTLD complications. Further evidence is necessary to better understand which vaccines have the greatest impact and cost-benefit.

mRNA COVID-19 Vaccination Does Not Exacerbate Symptoms or Trigger Neural Antibody Responses in Multiple Sclerosis. BACKGROUND AND OBJECTIVE: In people with multiple sclerosis (pwMS), concern for potential disease exacerbation or triggering of other autoimmune disorders contributes to vaccine hesitancy. We assessed the humoral and T-cell responses to SARS-CoV-2 after mRNA vaccination, changes in disease activity, and development of antibodies against central or peripheral nervous system antigens. METHODS: This was a prospective 1-year longitudinal observational study of pwMS and a control group of patients with other inflammatory neurologic disorders (OIND) who received an mRNA vaccine. Blood samples were obtained before the first dose (T1), 1 month after the first dose (T2), 1 month after the second dose (T3), and 6 (T4), 9 (T5), and 12 (T6) months after the first dose. Patients were assessed for the immune-specific response, annualized relapse rate (ARR), and antibodies to onconeuronal, neural surface, glial, ganglioside, and nodo-paranodal antigens. RESULTS: Among 454 patients studied, 390 had MS (22 adolescents) and 64 OIND; the mean (SD) age was 44 (14) years; 315 (69%) were female; and 392 (87%) were on disease-modifying therapies.

Antibodies to the receptor-binding domain were detected in 367 (86%) patients at T3 and 276 (83%) at T4. After a third dose, only 13 (22%) of 60 seronegative patients seroconverted, and 255 (92%) remained seropositive at T6. Cellular responses were present in 381 (93%) patients at T3 and in 235 (91%) patients at T6 including all those receiving anti-CD20 therapies and in 79% of patients receiving fingolimod. At T3 (429 patients) or T6 (395 patients), none of the patients had developed CNS autoantibodies. Seven patients had neural antibodies that were already present before immunization (3 adult patients with MS had MOG-IgG, 2 with MG and 1 with MS had neuronal cell surface antibodies [unknown antigen], and 1 with MS had myelin antibody reactivity [unknown antigen]. Similarly, no antibodies against PNS antigens were identified at T3 (427 patients). ARR was lower in MS and not significantly different in patients with OIND. Although 182 (40%) patients developed SARS-CoV-2 infection, no cases of severe COVID-19 or serious adverse events occurred. DISCUSSION: In this study, mRNA COVID-19 vaccination was safe and did not exacerbate the autoimmune disease nor triggered neural autoantibodies or immune-mediated neurologic disorders. The outcome of patients who developed SARS-CoV-2 infection was favorable.

Effects of the COVID-19 booster vaccine on glycemia and insulin resistance in people with type 1 diabetes: A prospective pilot study. AIMS: Inflammation can trigger hyperglycemia in people with type 1 diabetes (T1D). Vaccines purposefully intend to cause an acute immunogenic response, and booster vaccines may cause even more potent immunologic responses. However, the effects of vaccines on glycemic control and insulin requirements in the days immediately post-vaccination remains poorly understood. The aim of this study was to examine the changes in glycemic control and insulin usage immediately preceding and following a COVID-19 booster vaccine among adults with T1D. METHODS: In this prospective cohort study of adults with T1D, participants wore blinded Dexcom G6 Pro continuous glucose monitors for 10Â days. After a baseline period, participants received a COVID-19 booster vaccine, and subsequent changes in glycemic indices were evaluated. RESULTS: Among the 21 enrolled participants, 38% received a Moderna and 62% Pfizer-BioNTech booster. Compared to baseline (162.9Â Â±Â 44.1Â mg/dL), mean glucose was significantly increased at Day 2 (172.8Â Â±Â 47.0Â mg/dL; pÂ =Â 0.04) and Day 3 (173.1Â Â±Â 45.0Â mg/dL; pÂ =Â 0.02) post-vaccination. Insulin resistance was also increased on Day 2 (pÂ =Â 0.03). There were no differences in outcome metrics between booster vaccine manufacturers. CONCLUSIONS: These results suggest that adults with type 1 diabetes may experience transient mild glycemic elevations after receiving a COVID-19 booster vaccination. Studies examining the effects of other vaccines are warranted.

Aplastic anemia after SARS-CoV-2 infection or vaccines: case series and literature review.

DNase analysed by a novel competitive assay in patients with complications after ChAdOx1 nCoV-19 vaccination and in normal unvaccinated blood donors. Increased levels of neutrophil extracellular traps (NETs) have been detected in individuals with vaccine complications after the ChAdOx1 nCov vaccine with a correlation between the severity of vaccine side effects and the level of NETosis. DNases may disrupt NETs by degrading their content of DNA, and a balance has been reported between NETs and DNases. Because of this and since the inflammatory marker NETs may be used as a confirmatory test in diagnosing VITT, it is of interest to monitor levels of DNase in patients with increased NETs levels. The current novel rapid DNase ELISA was tested in blood samples of patients with known increased levels of NETs with or without VITT after ChAdOx1 nCoV-19 vaccination. DNase levels in VITT patients were significantly increased compared with normal unvaccinated blood donors and compared with patients with post-vaccination symptoms but not VITT. However, since EDTA was found to inhibit DNase, serum and not EDTA-plasma samples should be applied for DNase testing. The novel DNase assay may serve as a supplementary test to the NETs test when analysing samples from patients with suspected increased NETs levels.

Relapse of immune thrombocytopenia after receiving AstraZeneca coronavirus disease-2019 vaccine: A case report. Immune thrombocytopenic purpura (ITP) is an autoimmune disease characterized by a low platelets count. In this paper, we present a case of ITP relapse in a 31-year-old Iranian woman as a potential complication of the AstraZeneca vaccine.

Management of coronavirus disease 2019 vaccine-induced cutaneous complications: A comprehensive literature review. Despite the numerous reports of cutaneous manifestations associated with vaccines for coronavirus disease 2019 (COVID-19), the relationship between COVID-19 vaccines and cutaneous side effects remains unevaluated. In this review, we examine these manifestations and their management. Reported dermatoses included injection-site reaction (early and delayed), type I allergic reaction, morbilliform eruption, pityriasis rosea, Sweet syndrome, lichen planus, psoriasis, herpes zoster reactivation, erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis (TEN). The most common COVID-19 vaccination-related cutaneous manifestations are delayed local reactions, approximately 66% of which are associated with the Moderna vaccine, and 33% with the Pfizer vaccine. Aside from mild injection-site reactions, severe reactions include anaphylaxis and TEN. Most reactions, except for Stevens-Johnson syndrome and anaphylaxis, though unpredictable and unpreventable are mild and can be treated symptomatically. Findings from this review should allow primary care physicians and dermatologists to reach faster diagnosis and initiate prompt intervention.

Stigma Experienced by Patients Who Recovered from COVID-19 in Post-Vaccination Period in Thailand; Prevalence and Associated Factors. PURPOSE: Social stigma related to coronavirus disease-2019 (COVID-19) has been a public concern since its emergence, especially in the patients who are reintegrating into their society. However, the insights into COVID-19 stigmatization after vaccine availability are limited. This study aimed to estimate the prevalence, severity and associated factors of stigma experienced by patients who recovered from COVID-19 and reintegrated into their communities. The insights gained from this study are not only beneficial to COVID-19 but can also be used as a background information in future epidemics. PATIENTS AND METHODS: This study consisted of two phases. The first phase involved the translation and validation of the COVID-19-related stigma questionnaire. The second phase was a questionnaire-based cross-sectional survey conducted between January and February 2022, at the Vajira Hospital, Bangkok, Thailand. A series of questionnaires regarding stigma, negative emotions (Depression Anxiety Stress Scale-21), and personal information were administered to COVID-19 patients who were already discharged and returned to their communities from June 2021 to February 28, 2022 (N = 354). RESULTS: The prevalence of stigma among the patients who recovered from COVID-19 was 57.9%. These were classified as mild (28.2%), moderate (21.5%), and severe (8.2%). Pearson's correlation analysis revealed that longer admissions ($r = -0.151$, $p = 0.001$) and longer duration from discharge ($r = -0.222$, $p = 0.001$) were related to lower stigma. Higher stigma was associated with higher levels of depression ($r = 0.528$, $p < 0.001$), anxiety ($r = 0.506$, $p < 0.001$) and stress ($r = 0.583$, $p < 0.001$). CONCLUSION: Social stigma related to COVID-19 in Thailand declined during the post-vaccination period. However, this issue did not disappear, and still took a toll on mental health. Our findings suggested that providing appropriate assessment and help to the patients who recovered from COVID-19 is essential, even in the post-vaccination period.

Cranial nerve Palsy following COVID-19 Vaccination Responsive to Plasma Exchange. BACKGROUND: Globally, mass COVID-19 vaccine administration has revealed various adverse effects of the vaccine, such as various neurological symptoms, which are currently identified as a result of an excessive immune response. CASE REPORT: A 70-year-old woman presented with progressive unilateral oculomotor nerve palsy and decreased visual acuity 12 days after receiving the Moderna COVID-19 vaccine. In adults, such palsy is typically caused by microvascular disease (ischemia) or

compressive tumors. Given the temporal relationship between vaccination and symptoms and the exclusion of other possible causative factors, the patient's oculomotor nerve palsy and optic nerve involvement was considered to be related to the vaccination. Cranial nerve palsy following COVID-19 vaccination was diagnosed, and after pulse steroid and plasma exchange, the patient showed steady recovery. CONCLUSION: Our patient with cranial nerve palsy following COVID-19 vaccination responded well to plasma exchange after limited improved toward steroid. This case highlights the importance of early identification and treatment of the immunological effects of COVID-19 vaccines on cranial nerves.

Acute Asymmetric Sensorimotor Variant of Chronic Inflammatory Demyelinating Polyneuropathy Triggered by mRNA-1273 COVID-19 Vaccination. PURPOSE: Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) developing in the postvaccination period was distinctly unusual and its course was rarely well described. We aimed to clearly depict the clinical features of acute-onset multifocal acquired demyelinating sensory and motor neuropathy (MADSAM) caused by mRNA-1273 COVID-19 vaccination. CASE REPORT: A 74-year-old man noticed weakness of hands 2-3 days after he accepted the second dose of mRNA-1273 COVID-19 vaccine. He soon became unable to walk within one week. Initially, muscle power of bilateral hand grasping was most severely affected. He had stayed on at the nadir for 3.5 months until the diagnosis of CIDP was made. Nerve conduction studies showed typical evidences of acquired demyelinating, but no sural spare pattern. He was treated with intermittent pulse steroid therapy. Two weeks after treatment, INCAT disability score improved from 10 to 4, but remained at 4 thereafter: arm disability score was 3 and that of leg was 1, which suggested muscles of upper limbs were more severely affected. CONCLUSION: Diagnosis of acute-onset MADSAM was challenging at the beginning of this disease. For vaccine-triggered CIDP, time to symptom onset could be as short as 2-3 days. Delay in recognition may influence the remission of this disease. Muscles of upper limbs were more affected than those of lower limbs. Intermittent steroid pulse therapy would be an alternative to daily oral steroid therapy. Keyword: chronic inflammatory demyelinating polyradiculoneuropathy, COVID-19 vaccination.

Incidence of anti-platelet factor4/polyanionic antibodies, thrombocytopenia, and thrombosis after COVID-19 vaccination with ChAdOx1 nCoV-19 in Thais. BACKGROUND: The prevalence of anti-platelet factor 4 (PF4)/polyanionic antibodies occurring after vaccination with ChAdOx1 nCoV-19 is low. Most of these antibodies are not associated with vaccine-induced thrombotic thrombocytopenia. It remains unknown whether these antibodies are preexisting or occur as a result of vaccination. In this study, we demonstrated the incidence of anti-PF4/polyanionic antibodies, thrombocytopenia, and thrombosis after vaccination with ChAdOx1 nCoV-19 in a large cohort of Thais. METHODS: We conducted a prospective study in a cohort of health care workers and members of the general population who received COVID-19 vaccination with ChAdOx1 nCoV-19. Blood collection for complete blood count, D-dimer, and anti-PF4/polyanionic antibodies was performed before vaccination (day 0), day 10, and day 28 after vaccination. Anti-PF4/polyanionic antibodies were detected using enzyme-link immunosorbent assay (ELISA). Functional assay was performed for all positive ELISA tests. RESULTS: A total of 720 participants were included in the study. 214 participants received both the first and second doses, 91 participants received only the first, 51 received only the second, and 364 received the third booster dose of ChAdOx1 nCoV-19. Median age was 42 years (IQR, 34-53). 67% of participants were female. Three participants developed seroconversion, yielding an incidence of vaccination-induced anti-PF4/polyanionic antibodies of 0.42% (95% confidence interval 0.08, 1.23). Fourteen (1.9%) participants had preexisting anti-PF4/polyanionic antibodies before the vaccination but their optical density of anti-PF4/polyanionic antibodies did not significantly increase over time. None of the anti-PF4/polyanionic positive sera induced platelet aggregation. Abnormal D-dimer levels following vaccination were not different

among the positive and negative anti-PF4/polyanionic groups (11.8% vs. 13.2%, pâ€‰=â€‰0.86). Thrombocytopenia occurred in one person with negative anti-PF4/polyanionic antibodies. No clinical thrombosis or bleeding occurred. CONCLUSION: We found a low incidence of seroconversion of anti-PF4/polyanionic antibodies after vaccination with ChAdOx1 nCoV-19 in Thais. Most of the anti-PF4/polyanionic antibodies were preexisting and did not significantly increase after vaccination with ChAdOx1 nCoV-19. Following vaccination, some participants with anti-PF4/polyanionic antibodies had elevated D-dimer levels, while only one developed thrombocytopenia and no thrombotic events were observed.

Socio-demographic factors associated with COVID-19 vaccine uptake and refusal among Ugandan women. BACKGROUND: This paper analyzes associations of socio-demographic factors with the uptake of COVID-19 vaccines, the refusal to get vaccinated against COVID-19, and various reasons stated for refusing vaccination against COVID-19 among a representative sample of Ugandan women. METHODS: This paper utilizes a representative cross-sectional survey collected among women aged 15-49 years in Uganda between September and November 2021. Regression analyses are used to study the associations of a broad range of socio-demographic characteristics with COVID-19 vaccine uptake, refusal of vaccination, and reasons for refusal among the respondents. RESULTS: 4211 women were included in the analysis. 11% of them were vaccinated against COVID-19, 76% were willing to get vaccinated, 13% were unwilling to get vaccinated. Fear of side effects was the most commonly stated reason for refusing vaccination (69%). Factors significantly and positively associated with being vaccinated against COVID-19 were age, higher education, urban residency, having savings, partial instead of complete income loss during the pandemic, and usage of modern contraceptives. Factors significantly and positively associated with refusing vaccination against COVID-19 were urban residency and current pregnancy, while age, having savings, and using modern contraceptives were factors associated with a lower likelihood of refusing vaccination, albeit with varying statistical significance. Few factors were strongly related to the stated reasons for refusing the vaccines; the fear of side effects significantly increased with age, while having received negative information on the vaccines was significantly less common among women with higher education. CONCLUSIONS: This study documents a low COVID-19 vaccination rate and a high willingness to get vaccinated among Ugandan women. Positive age and education gradients in vaccine uptake point to inequity in access to vaccination, potentially resulting from prioritizations of groups at particularly high risk. Refusal to be vaccinated was relatively low and systematic factors behind vaccine refusal were hardly to be found, even less so for particular reasons given for refusal.

Background rates of adverse events of special interest for COVID-19 vaccines: A multinational Global Vaccine Data Network (GVDN) analysis. BACKGROUND: The Global COVID Vaccine Safety (GCoVS) project was established in 2021 under the multinational Global Vaccine Data Network (GVDN) consortium to facilitate the rapid assessment of the safety of newly introduced vaccines. This study analyzed data from GVDN member sites on the background incidence rates of conditions designated as adverse events of special interest (AESI) for COVID-19 vaccine safety monitoring. METHODS: Eleven GVDN global sites obtained data from national or regional healthcare databases using standardized methods. Incident events of 13 pre-defined AESI were included for a pre-pandemic period (2015-19) and the first pandemic year (2020). Background incidence rates (IR) and 95% confidence intervals (CI) were calculated for inpatient and emergency department encounters, stratified by age and sex, and compared between pre-pandemic and pandemic periods using incidence rate ratios. RESULTS: An estimated 197 million people contributed 1,189,652,926 person-years of follow-up time. Among inpatients in the pre-pandemic period (2015-19), generalized seizures were the most common neurological AESI (IR ranged from 22.15 [95% CI 19.01-25.65] to 278.82 [278.20-279.44] per 100,000 person-years); acute disseminated encephalomyelitis was the least common (<0.5 per 100,000

person-years at most sites). Pulmonary embolism was the most common thrombotic event (IR 45.34 [95% CI 44.85-45.84] to 93.77 [95% CI 93.46-94.08] per 100,000 person-years). The IR of myocarditis ranged from 1.60 [(95% CI 1.45-1.76) to 7.76 (95% CI 7.46-8.08) per 100,000 person-years. The IR of several AESI varied by site, healthcare setting, age and sex. The IR of some AESI were notably different in 2020 compared to 2015-19. CONCLUSION: Background incidence of AESIs exhibited some variability across study sites and between pre-pandemic and pandemic periods. These findings will contribute to global vaccine safety surveillance and research.

The role of vaccination in COPD: influenza, SARS-CoV-2, pneumococcus, pertussis, RSV and varicella zoster virus. Exacerbations of COPD are associated with worsening of the airflow obstruction, hospitalisation, reduced quality of life, disease progression and death. At least 70% of COPD exacerbations are infectious in origin, with respiratory viruses identified in approximately 30% of cases. Despite long-standing recommendations to vaccinate patients with COPD, vaccination rates remain suboptimal in this population.Streptococcus pneumoniae is one of the leading morbidity and mortality causes of lower respiratory tract infections. The Food and Drug Administration recently approved pneumococcal conjugate vaccines that showed strong immunogenicity against all 20 included serotypes. Influenza is the second most common virus linked to severe acute exacerbations of COPD. The variable vaccine efficacy across virus subtypes and the impaired immune response are significant drawbacks in the influenza vaccination strategy. High-dose and adjuvant vaccines are new approaches to tackle these problems. Respiratory syncytial virus is another virus known to cause acute exacerbations of COPD. The vaccine candidate RSVPreF3 is the first authorised for the prevention of RSV in adults â‰¥60â€…years and might help to reduce acute exacerbations of COPD. The 2023 Global Initiative for Chronic Lung Disease report recommends zoster vaccination to protect against shingles for people with COPD over 50â€…years.

Lower magnitude and faster waning of antibody responses to SARS-CoV-2 vaccination in anti-TNF-Î±-treated IBD patients are linked to lack of activation and expansion of cTfh1 cells and impaired B memory cell formation. BACKGROUND: Patients with inflammatory bowel disease (IBD) and healthy controls received primary SARS-CoV-2-mRNA vaccination and a booster after six months. Anti-TNF-Î±-treated patients showed significantly lower antibody (Ab) levels and faster waning than Î±4Î²7-integrin-antagonist recipients and controls. This prospective cohort study aimed to elucidate the underlying mechanisms on the basis of circulating T-follicular helper cells (cTfh) and B memory cells. METHODS: We measured SARS-CoV-2- Wuhan and Omicron specific Abs, B- and T-cell subsets at baseline and kinetics of Spike (S)-specific B memory cells along with distributions of activated cTfh subsets before and after primary and booster vaccination. FINDINGS: Lower and faster waning of Ab levels in anti-TNF-Î± treated IBD patients was associated with low numbers of total and naÃ¯ve B cells vs. expanded plasmablasts prior to vaccination. Along with their low Ab levels against Wuhan and Omicron VOCs, reduced S-specific B memory cells were identified after the 2nd dose which declined to non-detectable after 6 months. In contrast, IBD patients with Î±4Î²7-integrin-antagonists and controls mounted and retained high Ab levels after the 2nd dose, which was associated with a pronounced increase in S-specific B memory cells that were maintained or expanded up to 6 months. Booster vaccination led to a strong increase of Abs with neutralizing capacity and S-specific B memory cells in these groups, which was not the case in anti-TNF-Î± treated IBD patients. Of note, Ab levels and S-specific B memory cells in particular post-booster correlated with the activation of cTfh1 cells after primary vaccination. INTERPRETATIONS: The reduced magnitude, persistence and neutralization capacity of SARS-CoV-2 specific Abs after vaccination in anti-TNF-Î±-treated IBD patients were associated with impaired formation and maintenance of S-specific B memory cells, likely due to absent cTfh1 activation leading to extra-follicular immune responses and diminished B memory cell diversification. These observations have implications for patient-tailored vaccination

schedules/vaccines in anti-TNF-Î±-treated patients, irrespective of their underlying disease. FUNDING: The study was funded by third party funding of the Institute of Specific Prophylaxis and Tropical Medicine at the Medical University Vienna. The funders had no role in study design, data collection, data analyses, interpretation, or writing of report.

Thrombocytopenic, thromboembolic and haemorrhagic events following second dose with BNT162b2 and ChAdOx1: self-controlled case series analysis of the English national sentinel cohort. BACKGROUND: Thrombosis associated with thrombocytopenia was a matter of concern post first and second doses of BNT162b2 and ChAdOx1 COVID-19 vaccines. Therefore, it is important to investigate the risk of thrombocytopenic, thromboembolic and haemorrhagic events following a second dose of BNT162b2 and ChAdOx1 COVID-19 vaccines. METHODS: We conducted a large-scale self-controlled case series analysis, using routine primary care data linked to hospital data, among 12.3 million individuals (16 years old and above) in England. We used the nationally representative Oxford-Royal College of General Practitioners (RCGP) sentinel network database with baseline and risk periods between 8th December 2020 and 11th June 2022. We included individuals who received two vaccine (primary) doses of the BNT162b2 mRNA (Pfizer-BioNTech) and two vaccine doses of ChAdOx1 nCoV-19 (Oxford-AstraZeneca) vaccines in our analyses. We carried out a self-controlled case series (SCCS) analysis for each outcome using a conditional Poisson regression model with an offset for the length of risk period. We reported the incidence rate ratios (IRRs) and 95% confidence intervals (CI) of thrombocytopenic, thromboembolic (including arterial and venous events) and haemorrhagic events, in the period of 0-27 days after receiving a second dose of BNT162b2 or ChAdOx1 vaccines compared to the baseline period (14 or more days prior to first dose, 28 or more days after the second dose and the time between 28 or more days after the first and 14 or more days prior to the second dose). We adjusted for a range of potential confounders, including age, sex, comorbidities and deprivation. FINDINGS: Between December 8, 2020 and February 11, 2022, 6,306,306 individuals were vaccinated with two doses of BNT162b2 and 6,046,785 individuals were vaccinated with two doses of ChAdOx1. Compared to the baseline, our analysis show no increased risk of venous thromboembolic events (VTE) for both BNT162b2 (IRR 0.71, 95% CI: 0.65-0.770) and ChAdOx1 (IRR 0.91, 95% CI: 0.84-0.98); and similarly there was no increased risk for cerebral venous sinus thrombosis (CVST) for both BNT162b2 (IRR 0.87, 95% CI: 0.41-1.85) and ChAdOx1 (IRR 1.73, 95% CI: 0.82-3.68). We additionally report no difference in IRR for pulmonary embolus, and deep vein thrombosis, thrombocytopenia, including idiopathic thrombocytopenic purpura (ITP), and haemorrhagic events post second dose for both BNT162b2. INTERPRETATION: Reassuringly, we found no associations between increased risk of thrombocytopenic, thromboembolic and haemorrhagic events post vaccination with second dose for either of these vaccines. FUNDING: Data and Connectivity: COVID-19 Vaccines Pharmacovigilance study.

Reassurance on bleeding and thrombotic events following second dose BNT162b2 and ChAdOx1 COVID-19 vaccines.

Barriers and Intention to Get Vaccinated for COVID-19 and Associated Factors Among Adults in Southwest Ethiopia: A Theory of Planned Behavior Approach. BACKGROUND: Different vaccines have been approved for use against coronavirus disease and distributed globally in different regions. Efforts should be made on the vaccination to control the spread and impacts of the coronavirus pandemic. However, the general population's attitudes and intention to uptake coronavirus disease 2019 (COVID-19) vaccinations were poor. OBJECTIVE: This study aimed to assess the barriers to and intention to be vaccinated against COVID-19 and the associated factors among adults in the Jimma zone, Ethiopia. METHODS: A community-based cross-sectional study with multistage sampling was conducted with 621 participants from 16 April to 17 May 2022. Multivariable logistic regression was used to identify factors associated with the outcome of interest. Statistical p-value â‰¤0.05 was set

at p â‰¤ 0.05. Qualitative data were supplemented with quantitative results. RESULTS: The majority of the study participants (382 [61.5%]) intended to uptake the COVID-19 vaccine. In this study, travel history (Adjusted Odds Ratio (AOR) = 2.18, 95% CI 1.23-3.87), vaccination history (AOR = 2.64, 95% CI 1.69-4.12), perceptions of infection prevention for COVID-19 (AOR = 1.97, 95% CI 1.28-3.03), subjective norm (AOR = 2.27, 95% CI 1.52-3.39), and perceived behavioral control (PBC) (AOR = 2.30, 95% CI 1.55-3.41) were significantly associated with the intention to be vaccinated against COVID-19. CONCLUSION: More than half of the adult participants intended to be vaccinated against COVID-19. The study participant's traveling history, vaccination history, perception of infection prevention for COVID-19, subjective norms, and Perceived Behavioral Control were significantly associated with the intention to be vaccinated.

Mucosal antibody responses following Vaxzevria vaccination. Mucosal antibodies play a key role in protection against breakthrough COVID-19 infections and emerging viral variants. Intramuscular adenovirus-based vaccination (Vaxzevria) only weakly induces nasal IgG and IgA responses, unless vaccinees have been previously infected. However, little is known about how Vaxzevria vaccination impacts the ability of mucosal antibodies to induce Fc responses, particularly against SARS-CoV-2 variants of concern (VoCs). Here, we profiled paired mucosal (saliva, tears) and plasma antibodies from COVID-19 vaccinated only vaccinees (uninfected, vaccinated) and COVID-19 recovered vaccinees (COVID-19 recovered, vaccinated) who both received Vaxzevria vaccines. SARS-CoV-2 ancestral-specific IgG antibodies capable of engaging FcÎ³R3a were significantly higher in the mucosal samples of COVID-19 recovered Vaxzevria vaccinees in comparison with vaccinated only vaccinees. However, when IgG and FcÎ³R3a engaging antibodies were tested against a panel of SARS-CoV-2 VoCs, the responses were ancestral-centric with weaker recognition of Omicron strains observed. In contrast, salivary IgA, but not plasma IgA, from Vaxzevria vaccinees displayed broad cross-reactivity across all SARS-CoV-2 VoCs tested. Our data highlight that while intramuscular Vaxzevria vaccination can enhance mucosal antibodies responses in COVID-19 recovered vaccinees, restrictions by ancestral-centric bias may have implications for COVID-19 protection. However, highly cross-reactive mucosal IgA could be key in addressing these gaps in mucosal immunity and may be an important focus of future SARS-CoV-2 vaccine development.

Re: COVID-19 as a factor associated with early dental implant failures: A retrospective analysis-There is a need for research on the effect of COVID-19 vaccination on dental implant failure: Implications for policymaking and insurance.

Uptake of human papillomavirus vaccination and its associated factors among adolescents in Gambella town, Southwest, Ethiopia: a community-based cross-sectional study. OBJECTIVE: To assess the uptake of human papillomavirus (HPV) vaccination and its associated factors among adolescents in Gambella town, Southwest Ethiopia. DESIGN: A community-based cross-sectional study. SETTING: Gambella town, Southwest Ethiopia. PARTICIPANTS: A total of 882 adolescents were included between May and July 2022. OUTCOME: Uptake of HPV vaccination. METHODS: A cluster sampling technique was used to select study participants. An interviewer-administered and pretested questionnaire was used to collect the data. The collected data were entered into Epi-data V.4.6 and exported to STATA V.16 for cleaning, coding and analysis. A binary logistic regression model was used to test the association between independent and dependent variables. Variables with a p<0.05 in the multivariable logistic regression were considered statistically significant factors for the uptake of HPV vaccination. RESULTS: A total of 825 adolescents participated in this study. Among participants, 48% (95% CI 44.6% to 51.4%) have been vaccinated for HPV. Ever heard of the HPV vaccine (AOR 2.5, 95%â€‰CI 1.23 to 5.08), good knowledge of HPV infection (AOR 3.62, 95%â€‰CI 2.17 to 6.02), good knowledge of the HPV vaccine (AOR 5.54, 95%â€‰CI 3.28 to 9.36) and attitude towards the HPV vaccine (AOR 2.74, 95%â€‰CI 1.88 to 3.98) were significantly associated HPV vaccination.

CONCLUSION: In the current study, the uptake of HPV vaccination was found to be low. The finding highlights the importance of promoting community health education about HPV infection and vaccines and providing behaviour change education, which plays a substantial role in promoting the uptake of HPV vaccination.

The booster dose of BNT162b2 mRNA vaccine in patients after hematopoietic stem cell transplantation: humoral and clinical response and serological conversion predictors.

Spectrum of various CNS inflammatory demyelination diseases following COVID-19 vaccinations. BACKGROUND AND PURPOSE: Although rare, neurological adverse events have been reported post-COVID-19 vaccination. This study reports 16 patients diagnosed with CNS inflammatory demyelinating diseases (CNS-IDD) within 6Â weeks of COVID-19 vaccine administration. METHODOLOGY: A prospective observational study was conducted from June 2021 to May 2022. All patients were diagnosed according to the latest international guidelines with CNS-IDD within 6Â weeks of COVID-19 vaccine exposure. Data regarding the demographic profile, clinical features, type of COVID-19 vaccination, radiological findings and occurrence of symptoms were noted and further analysed using descriptive statistics. RESULTS: We reported 16 cases (median age 40Â years) of CNS demyelination: fourteen occurred in temporal association with ChAdOx1-S vaccine and two in association with BBV152 vaccine. Median time duration of presenting symptoms after vaccination was 19Â days (3-40Â days). The most common presentation was myelitis (7/16 patients), followed by optic neuritis (6/16 patients). Demyelination events were reported after first and second dose in thirteen and five patients respectively, although two patients reported such events after both vaccine dosages. Myelin oligodendrocyte glycoprotein (MOG) IgG antibodies were positive in eight patients. Tumefactive demyelination was seen in four patients. Management included high-dose methylprednisolone, PLEX, IVIG or a combination of those, with a favourable outcome in the majority of cases. CONCLUSION: Although a rare event, awareness regarding potential demyelinating episodes post-COVID-19 vaccination can help in early diagnosis. The presence of increased MOG-IgG antibodies with temporal association in post-COVID vaccine patients raises a possibility of an immunogenic phenomenon leading to demyelinating disorders.

Neutralization against Omicron subvariants after BA.5/BF.7 breakthrough infection weakened as virus evolution and aging despite repeated prototype-based vaccination(1). BACKGROUND: Omicron had swept the mainland China between December 2022 and January 2023, while SARS-CoV-2 still continued to evolve. To fully prepare for the next wave, it's urgent to evaluate the humoral immune response post BA.5/BF.7 breakthrough infection against predominant sub-lineages among existing vaccination strategies and the elders. METHOD: This study enrolled a longitudinal young-adult cohort from 2/3-dose vaccination to 1 month after breakthrough infection, and an elder cohort at 1 month after breakthrough infection. Seral samples were collected and tested for humoral immune response to SARS-CoV-2 subvariants including WT, BA.2, BA.5, BF.7, BQ.1.1, CH.1.1, XBB.1.5. RESULTS: BA.5/BF.7 breakthrough infection induced higher neutralization activity than solely vaccination in all SARS-CoV-2 strains, while the latest Omicron subvariants, BQ.1.1, CH.1.1, XBB.1.5, exhibited the strongest neutralization evasion ability. There was a negative correlation between age and humoral immune response in WT, BA.5, BQ.1.1, and XBB.1.5. Compared to non-vaccination groups, breakthrough infection in two-dose vaccination groups had significantly higher neutralizing antibody against WT, BA.2, BA.5, BF.7 but not to BQ.1.1, CH.1.1, XBB.1.5 while booster dose against the prototype prior-breakthrough would not further significantly enhance individual's humoral responses against the latest Omicron subvariants. CONCLUSIONS: Newer variants manifest increasing immune evasion from neutralization and repeated prototype-based booster vaccines may not further enhance neutralizing antibody against emerging new variants. Older adults have lower levels of neutralizing

antibody. Future vaccination strategies should aim to enhance effective neutralization to contemporary variants.

SARS-CoV-2 mRNA vaccination induces an antigen-specific T cell response correlating with plasma interferon-gamma in B cell depleted patients. Emerging evidence is encouraging and suggests that a substantial proportion of patients without antibody responses (due to anti-CD20 therapy or other etiologies) to severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccines develop T cell responses. However, antigen-specific T cellular responses are notoriously difficult to assess clinically, given the lack of such assays under satisfactory CAP/CLIA regulation, and the laborious nature of the flow cytometric assessment. To evaluate the ability to apply a clinically feasible assay to measure T cellular responses to SARS-CoV-2 mRNA vaccination, we compared flow cytometric and enzyme-linked immunosorbent assay (ELISA) based assays in 24 participants treated with anti-CD20 therapy. T cellular activation (CD69Â +Â CD137+ surface expression, i.e., activation induced markers [AIM]) and intracellular interferon gamma (INFÎ³) production via flow cytometry was compared to plasma Interferon Gamma Release Assay (IGRA) via ELISA. Plasma INFÎ³ production measured by IGRA correlated with the percent of INFÎ³-producing AIM positive T cells, supporting the use of IGRA assay as a robust assessment of T cellular response to the SARS-CoV-2 vaccine for B-cell depleted patients that is clinically feasible, time efficient, and cost effective.

Post COVID-19 Symptoms Among Infected Vaccinated Individuals: A Cross-Sectional Study in Saudi Arabia. INTRODUCTION: Multiple studies investigated the endurance and occurrence of symptoms three monthsÂ after SARS-CoV-2 infection. This study examines the possibleÂ effects of COVID-19 vaccination on the persistence of post-recovery symptoms. PATIENTS AND METHODS: A cross-sectional survey was conducted in Saudi Arabia to evaluate 14 prevalent long COVID-19 symptoms among vaccinated individuals. Patients self-reported their acute COVID-19 experience, demographic information, chronic conditions, vaccine history, and persistent symptoms. RESULTS: Of the 484 patients, four respondents were excluded from the study as they had not received the vaccine, and 111 (23.1%) were vaccinated but did not get infected and were also excluded. The remaining 369 (76.9%) reported COVID-19 and a vaccination and thus they were included in the study. The occurrence of post-COVID-19 symptoms was reportedÂ in 59 (16.1%) forâ€‰â‰¤â€‰3Â months, 202 (54.8%) experienced persistent symptoms 3-6Â months, and 108 (29.1%) reported symptoms lastingâ€‰>â€‰6Â months. In relation to age group, persistent symptoms 3-6Â months after recovery was more common in thoseâ€‰>â€‰50Â years and symptoms lastingâ€‰>â€‰6Â months were more common in 30-50Â years of age (pâ€‰<â€‰0.001). Persistence of symptoms forâ€‰â€‰3-6Â months was more common in those who were infected prior to vaccination compared to those who were infected after vaccination (Pâ€‰<â€‰0.001). Of the included patients, 323 (87.5%) rated their health as good, 41 (11.1%) considered it fair, and 5 (1.4%) described their well-being as poor or terrible. CONCLUSION: The study provides informationÂ of persistent symptoms in vaccinated individuals who had recovered from COVID-19 and highlights the need for targeted interventions to alleviate post-COVID-19 symptoms. The study is limited by its reliance on self-reported data and potential selection bias. Future research is needed to understand the mechanisms underlying persistent symptoms in vaccinated individuals and to identify effective interventions for long COVID.

Association Between Low Anti-spike Antibody Levels After the Third Dose of SARS-CoV-2 Vaccination and Hospitalization due to Symptomatic Breakthrough Infection in Kidney Transplant Recipients. BACKGROUND: Whether anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody levels post-third coronavirus disease (COVID-19) vaccination correlate with worse outcomes due to breakthrough infection is unclear. We evaluated the association between anti-SARS-CoV-2 antibody levels and symptomatic breakthrough infection or hospitalization during the Omicron surge

in kidney transplant recipients. METHODS: In total, 287 kidney transplant recipients expected to receive a third vaccination were enrolled between November 2021 and February 2022. The Abbott SARS-CoV-2 IgG II Quant test (Abbott, Chicago, IL, USA) was performed within three weeks before and four weeks after the third vaccination. The incidence of symptomatic breakthrough infection and hospitalization from two weeks to four months post-third vaccination was recorded. RESULTS: After the third vaccination, the seropositive rate and median antibody titer of the 287 patients increased from 57.1% to 82.2% and from 71.7 (interquartile range [IQR] 7.2-402.8) to 1,612.1 (IQR 153.9-5,489.1) AU/mL, respectively. Sixty-four (22.3%) patients had symptomatic breakthrough infections, of whom 12 required hospitalization. Lower anti-receptor-binding domain (RBD) IgG levels (<400 AU/mL) post-third vaccination were a risk factor for symptomatic breakthrough infection (hazard ratio [HR]=3.46, P<0.001). Anti-RBD IgG levels <200 AU/mL were a critical risk factor for hospitalization (HR=36.4, P=0.007). CONCLUSIONS: Low anti-spike IgG levels after third vaccination in kidney transplant recipients were associated with symptomatic breakthrough infection and, particularly, with hospitalization during the Omicron surge. These data can be used to identify patients requiring additional protective measures, such as passive immunization using monoclonal antibodies.

New Insights Into SARS-CoV-2-specific Antibody Levels in Kidney Transplantation Recipients After Three Vaccination Doses.

Response to "a case of acquired idiopathic generalized anhidrosis following severe acute respiratory syndrome coronavirus 2 vaccination".

Delayed Recurrent Erythema Nodosum Following COVID-19 Vaccine: A Case Report. Erythema nodosum (EN) is a skin lesion that presents due to an inflammation of the subcutaneous fat, which is manifested clinically as a sudden onset of tender erythematous lesions. These lesions are typically localized to the pretibial surface. The cause of EN is mainly idiopathic, other causes are drugs, infections, autoimmune diseases, and inflammatory bowel disease. As vaccines are rarely known to cause EN, we are reporting a case of a 19-year-old female with a delayed recurrent reaction following the second dose of the COVID-19 vaccine.

Antibody titer after administration of mRNA-based vaccine against severe acute respiratory syndrome coronavirus 2 in liver transplant recipients. INTRODUCTION: The mRNA-based vaccine was released as a COVID-19 prophylactic; however, its efficacy in organ transplant recipients is unknown. This study aimed to clarify this in liver transplant recipients. METHODS: Herein, liver transplant recipients from two hospitals who received vaccines were included. Immunoglobulin-G antibodies against the spike and nucleocapsid proteins were measured chronologically after the second, third, and fourth vaccine doses. RESULTS: Antibody levels in 125 liver transplant recipients and 20 healthy volunteers were analyzed. The median age at transplant was 35 (interquartile range 1, 53) years, and the period between transplant and the first dose was 15.2â€‰Â±â€‰7.7â€‰years. After the second and third doses, 89.1% and 100% of recipients displayed a positive humoral response, respectively. Anti-spike antibodies after the second dose were significantly reduced at 3 and 6â€‰months, compared to that at 1â€‰month (26.0 [5.4, 59.5], 14.7 [6.5, 31.4] vs. 59.7 [18.3, 164.0] AU/mL, respectively, pâ€‰<â€‰0.0001). However, a booster vaccine significantly elevated anti-spike antibodies in LT recipients (pâ€‰<â€‰0.0001) as well as in healthy controls (pâ€‰<â€‰0.0001). Additionally, the decay rate was comparable between the transplant recipients and controls (2.1 [0.8, 4.5] vs. 2.7 [1.1, 4.1] AU/mL/day, pâ€‰=â€‰0.9359). Only 4.0% of vaccinated transplant recipients were positive for anti-nucleocapsid antibodies. CONCLUSION: Liver transplant recipients can acquire immunity similar to that of healthy people through vaccination against SARS-CoV-2. The antibody decay rate is the same, and booster vaccinations should be administered similarly to that in healthy individuals.

SARS-CoV-2 Antibody Response Following COVID-19 Vaccination, a Longitudinal Study. BACKGROUND: The objective was studying the antibody response following immunization with COVID-19 vaccines. MATERIAL AND METHODS: It was a longitudinal study of healthcare workers (HCWs). Two groups were taken, Group 1 had taken first dose of the COVID-19 vaccine, at least 3 weeks have passed. Group 2 had taken two doses of COVID-19 vaccine and at least 2 weeks have passed. A quantitative test for antibodies to SARS-CoV-2 spike protein was done. Follow-up of both groups was done after 3 months of collection of the first sample. RESULTS: The antibody titre of the 57 HCWs in Group 1, decreased significantly 125 days after the first dose [median = 2,013 U/ml] as compared to the titre 30 days after the first dose of Covishield vaccine[median = 9,965.26 U/ml]. The median interval between two doses of vaccine was 34 days. In Group 2, the antibody titre of the 60 HCWs in Group 2, decreased significantly 114 days after second dose[median = 1,411 U/ml] as compared to the titre 19.5 days after second dose of Covishield vaccine [median = 2,377.5]. There was no significant difference in the antibody titre in follow-up samples of HCWs with and without side effects. CONCLUSION: The antibody titre decreases after 13 to 17 weeks post the second dose of Covishield vaccination. The decision of the Government of India to increase the interval between two doses of Covishield is justified. Low antibody titre can be the reason for breakthrough infections. The antibody titre was not related to side effects post-vaccination.

Confirmed cases of COVID-19 after vaccination against COVID in health personnel in BogotÃ¡, Colombia. OBJECTIVE: The present study aims to estimate the frequency of COVID 19 infections in vaccinated health personnel at a Los CObos Medical Center in BogotÃ¡, Colombia. The percentage of people positive to the PCR test and their clinical characteristics were analyzed. METHODS: We performed a cross-sectional study. The primary study variable was the COVID vaccination registry. We analyzed sex, age, signs, and symptoms. Multivariable logistic regression was applied to assess changes over time and to identify variables associated with vaccination in target groups. RESULTS: A cohort of 999 people working at Los Cobos Medical Center and followed from March to August 2021. The average age of this cohort was 37.0Â years (devestÂ =Â 10.5Â years), 67.7Â % were women. Two hundred eleven physicians, 287 nurses, 305 assistants, and 196 clerks follows. In addition, 8.4Â % to be PCR positive after vaccination. The average age was 36.0 (devestÂ =Â 23.4Â years), 59 women and 25 men. Of these, 15 were administrative, 14 were doctors, 29 nurses, and 26 nursing assistants. The vaccination status found that 21.4Â % do not vaccinates, 7.1Â % were partially vaccinated, and 71.4Â % with a complete schedule. When questioned about symptoms in these patients, 4.0Â % were symptomatic, and 5.9Â % were asymptomatic. CONCLUSIONS: A recent epidemiological study involving 12,364 health workers with a mean age of 38Â years quantifies the protection in six months from the vaccine. The presence of antibodies was associated with 83Â % protection against active SARS-CoV-2 infection (PCR positivity during the study period), which confirms the existence of protective Immunity at levels comparable to those obtained by the approved vaccines; our study found effectiveness of 92.6Â %. Higher than that found in this study, possibly explained by the characteristics of the individuals included.

Soluble factors in COVID-19 mRNA vaccine-induced myocarditis causes cardiomyoblast hypertrophy and cell injury: a case report. BACKGROUND: Inflammation affecting the heart and surrounding tissues is a clinical condition recently reported following COVID-19 mRNA vaccination. Assessing trends of these events related to immunization will improve vaccine safety surveillance and best practices for forthcoming vaccine campaigns. However, the causality is unknown, and the mechanisms associated with cardiac myocarditis are not understood. CASE PRESENTATION: After the first dose, we reported an mRNA vaccine-induced perimyocarditis in a young patient with a history of recurrent myocardial inflammation episodes and progressive loss of cardiac performance. We tested this possible inflammatory cytokine-mediated cardiotoxicity after vaccination in the acute phase (ten

days), and we found a significant elevation of MCP-1, IL-18, and IL-8 inflammatory mediators. Still, these cytokines decreased considerably at the recovery phase (42 days later). We used the cardiomyoblasts cell line to test the effect of serum on cell viability, observing that serum from the acute phase reduced the cell viability to 75%. We did not detect this toxicity in cells when we tested serum from the patient in the recovery phase. We also tested serum-induced hypertrophy, a phenomenon in myocarditis and heart failure. We found that acute phase-serum has hypertrophy effects, increasing 25% of the treated cardiac cells' surface and significantly increasing B-type natriuretic peptide. However, we did not observe the hypertrophic effect in the recovery phase or sera from healthy controls. CONCLUSION: Our results opened the possibility of the inflammatory cytokines or serum soluble mediators as key factors for vaccine-associated myocarditis. In this regard, identifying anti-inflammatory molecules that reduce inflammatory cytokines could help avoid vaccine-induced myocardial inflammation.

Common characteristics of shoulder injury related to vaccine administration following COVID-19 vaccination: a comprehensive systematic review. BACKGROUND: The pathogenesis of shoulder injury related to vaccine administration (SIRVA) is incompletely understood, but it is postulated to be an immune-mediated inflammatory response to a vaccine antigen, leading to shoulder pain and dysfunction. The purpose of this investigation is to systematically review the literature related to SIRVA specifically after the COVID-19 vaccination by describing the diagnostic and clinical characteristics, diagnoses associated with SIRVA, and incidence between vaccine types. METHODS: A systematic review was performed to identify level I to IV studies and case descriptions of shoulder pain occurring after COVID-19 vaccination. To confirm that no studies were missing from the systematic review, references of studies from the initial search were scanned for additional relevant studies. RESULTS: A total of 22 studies, comprised of 81 patients, were identified meeting the inclusion/exclusion criteria. Reports were most commonly published from countries in Asia (53.1%; nÂ =Â 43/81). The most commonly described vaccines were Oxford-AstraZeneca at 37.0% (nÂ =Â 30/81) and Pfizer-BioNTech at 33.3% (nÂ =Â 27/81). Symptoms occurred most commonly after at least 72Â hours of administration (30.9%, nÂ =Â 25/81). One hundred percent of patients (nÂ =Â 81/81) described pain as an associated symptom and 90.1% of patients (nÂ =Â 73/81) described multiple symptoms. The diagnostic modalities utilized to identify a specific pathology consisted of magnetic resonance imaging (55.6%; nÂ =Â 45/81), ultrasound (28.4; nÂ =Â 23/81), radiograph (25.9%; nÂ =Â 21/81), and computed tomography (4.9%; 4/81). Nearly a third of patients (32.1%; nÂ =Â 26/81) were diagnosed with bursitis, while 22 (27.2%) were diagnosed with adhesive capsulitis, 17 (21.0%) with either rotator cuff tear or tendinopathy, and 14 (17.3%) with polymyalgia rheumatica or polymyalgia rheumatica-like syndrome. The 2 most common treatment options were physical therapy (34.6%; nÂ =Â 28/81) and nonsteroidal anti-inflammatory medications (33.3%; 27/81). The majority of SIRVA cases (52.1%; nÂ =Â 38/73) completely resolved within a few weeks to months. CONCLUSION: Despite the limited quality and lack of large-scale studies, it is important for providers to recognize SIRVA as a potential risk factor as the number of patients receiving COVID-19 vaccinations and boosters continues to rise.

Similarities and differences between myocarditis following COVID-19 mRNA vaccine and multiple inflammatory syndrome with cardiac involvement in children. Despite the multiple benefits of vaccination, cardiac adverse Events Following COVID-19 Immunization (c-AEFI) have been reported. These events as well as the severe cardiac involvement reported in Multisystem inflammatory syndrome in children (MIS-C) appear more frequent in young adult males. Herein, we firstly report on the inflammatory profiles of patients experiencing c-AEFI in comparison with age, pubertal age and gender matched MIS-C with cardiac involvement. Proteins related to systemic inflammation were found higher in MIS-C compared to c-AEFI, whereas a higher level in proteins related to myocardial

injury was found in c-AEFI. In addition, higher levels of DHEAS, DHEA, and cortisone were found in c-AEFI which persisted at follow-up. No anti-heart muscle and anti-endothelial cell antibodies have been detected. Overall current comparative data showed a distinct inflammatory and androgens profile in c-AEFI patients which results to be well restricted on heart and to persist months after the acute event.

Chatting with ChatGPT to learn about safety of COVID-19 vaccines - A perspective. Vaccine hesitancy is among the top 10 threats to global health, according to the World Health Organization (WHO). In this exploration, we delve into ChatGPT capacity to generate opinions on vaccine hesitancy by interrogating this AI chatbot for the 50 most prevalent counterfait messages, false and true contraindications, and myths circulating on the internet regarding vaccine safety. Our results indicate that, while the present version of ChatGPT's default responses may be incomplete, they are generally satisfactory. Although ChatGPT cannot substitute an expert or the scientific evidence itself, this form of AI has the potential to guide users toward information that aligns well with scientific evidence.

Operational strategies to deal with the COVID-19 emergency: recommendations from the Italian national society SIAGASCOT following the introduction of vaccines against the SARS-CoV-2 infection. BACKGROUND: This article aims to present the operational recommendations adopted by the Italian national society for orthopaedic surgery, arthroscopy, and sports medicine (SIAGASCOT) in managing patients eligible to undergo elective orthopaedic surgery during the COVID-19 pandemic after the beginning of a national vaccination campaign. MATERIALS AND METHODS: An extensive literature search, analysing medical databases and scientific societies protocols, was performed to support this document. A four-step approach was used: 1-definition of priorities; 2-definition of significant clusters of interventions; 3-extraction of recommendations from international literature; and 4-adaptation of the recommendations to the specific features of the Italian healthcare system. RESULTS: Three operational priorities were defined ("continuity of care and containment of the virus spread", "examination of waiting lists", and "definition of the role of vaccines"),Â six significant clusters of intervention were identified, and recommendations regarding the risk management for healthcare staff and hospital facility as well as the preoperative, in-hospital, and postoperative management were produced. Patient selection, preoperative screening, and pre-hospitalization procedures, which are regarded as pivotal roles in the safe management of patients eligible to undergo elective orthopaedic surgery, were analysed extensively. CONCLUSIONS: This document presents national-wide recommendations for managing patients eligible to undergo elective orthopaedic surgery with the beginning of the vaccination campaign. This paper could be the basis for similar documents adapted to the local healthcare systems in other countries. LEVEL OF EVIDENCE: Level IV.

Differences in the efficacy and safety of the COVID-19 vaccination campaign in males and females. Does only sex matter?

A prospective longitudinal cohort study on risk factors for COVID-19 vaccination failure (RisCoin): methods, procedures and characterization of the cohort. The primary objective of the RisCoin study was to investigate the interplay of genetic, metabolic, and lifestyle factors as well as stress levels on influencing the humoral immune response after at least two COVID-19 vaccinations, primarily with mRNAs, and the risk of SARS-CoV-2 breakthrough infections during follow-up. Here, we describe the study design, procedures, and study population. RisCoin is a prospective, monocentric, longitudinal, observational cohort study. Between October and December 2021, 4515 participants with at least two COVID-19 vaccinations, primarily BNT162b2 and mRNA-1273, were enrolled at the LMU University Hospital of Munich, thereof >â€‰4000 healthcare workers (HCW), 180 patients with inflammatory bowel disease under immunosuppression, and 119 patients with mental disorders. At enrollment, blood and saliva samples were collected to measure anti-SARS-CoV-2 antibodies, their

neutralizing capacity against Omicron-BA.1, stress markers, metabolomics, and genetics. To ensure the confidential handling of sensitive data of study participants, we developed a data protection concept and a mobile application for two-way communication. The application allowed continuous data reporting, including breakthrough infections by the participants, despite irreversible anonymization. Up to 1500 participants attended follow-up visits every two to six months after enrollment. The study gathered comprehensive data and bio-samples of a large representative HCW cohort and two patient groups allowing analyses of complex interactions. Our data protection concept combined with the mobile application proves the feasibility of longitudinal assessment of anonymized participants. Our concept may serve as a blueprint for other studies handling sensitive data on HCW.

Rheumatoid arthritis and older age are associated with lower humoral and cellular immune response to primary series COVID-19 mRNA vaccine. OBJECTIVE: People with autoimmune disease have worse COVID-19 infection-related outcomes, lower antibody responses to COVID-19 vaccine, and higher rates of breakthrough infection. Immunosuppressive medications used to treat rheumatoid arthritis (RA) are associated with lower COVID-19 vaccine responses, though independent contributions of comorbidities, T-cell immunity, and age are less clear. We sought to test the hypothesis that RA, immunosuppressive medications used to treat RA, and older age, contribute to reduced B and T cell response to COVID-19 vaccine. METHODS: We evaluated serum samples, taken the day of 1st vaccine dose, the day of 2nd dose, 2-6Â weeks after 2nd dose, 7-12Â weeks after 2nd dose, 13-24Â weeks after 2nd dose, and 2-6Â weeks after the 3rd dose, for anti-spike IgG and neutralizing antibody levels to Wuhan and Omicron BA.1 and peripheral blood mononuclear cells (PBMC) for spike-specific IFN-Î³ and IL-2 production by ELISPOT assay in 46 RA and 101 non-autoimmune control participants before and after the primary series COVID-19 mRNA vaccination. RESULTS: RA participants had lower spike-specific IgG and Wuhan-strain neutralizing antibody levels 2-6Â weeks compared to controls after the second dose of primary vaccine series. Neutralizing antibody levels against Omicron BA.1 were low in both groups. IFN-Î³ production correlated with Wuhan neutralizing antibody levels, while older age negatively correlated with spike-specific IL-2, IFN-Î³ and IgG. Lower antibody levels were associated with older age, RA status, and medication usage, while lower T cell responses were associated primarily with older age. CONCLUSIONS: These data indicate lower COVID-19 mRNA vaccine-induced antibody levels in persons with RA compared to individuals without RA, likely partially attributable to immune suppressive medications. At the same time, older age is associated with lower antibody and cellular immune response to COVID-19 vaccines.

Association between rubella vaccination response and long-term immune response to severe acute respiratory syndrome coronavirus 2 after BNT162b2 vaccination. In a previous study, we demonstrated an association between a low response to rubella vaccination and a decreased acquisition of anti-severe acute respiratory syndrome coronavirus 2 spike immunoglobulin G (anti-S IgG) shortly after the second dose of the BNT162b2 vaccine. The present study aimed to explore whether this association persists in terms of long-term antibody retention following the second dose of BNT162b2. Through multivariable analysis, we found a significant association between a low response to rubella vaccination and reduced anti-S IgG titers approximately eight months after the second dose of BNT162b2.

Viral kinetics of SARS-CoV-2 following onset of COVID-19 in symptomatic patients infected with the ancestral strain and omicron BA.2 in Hong Kong: a retrospective observational study. BACKGROUND: Assessment of viral kinetics of SARS-CoV-2 can inform on host immune responses to the virus and on the viral transmission potential. We aimed to characterise viral shedding kinetics by age, virus type, and clinical outcome, and to examine the potential effect of vaccination on viral

shedding. METHODS: In this retrospective observational study, we analysed longitudinal data on cycle threshold (Ct) values of reverse-transcription quantitative PCR (RT-qPCR) assays of upper respiratory tract samples from symptomatic patients with COVID-19. Patients who were confirmed with COVID-19 with at least one Ct value of the RT-qPCR test available within 28 days after symptom onset, and discharged or died at the time of the analysis, were included in the study. Patients were isolated in hospitals in Hong Kong during three major epidemic waves dominated by the ancestral strain or omicron BA.2. We modelled the temporal trajectories of viral burden in these patients. Electronic medical records of the patients with COVID-19 were retrieved and linked to the patients' epidemiological information obtained from contact tracing. Patients who were infected outside Hong Kong, infected with variants other than the ancestral strain or omicron BA.2, not reporting any COVID-19 related symptoms, still hospitalised at the time of analysis, missing information on age, time of symptom onset, infection severity, vaccination or clinical outcome, infected more than once, or treated with nirmatrelvir-ritonavir or molnupiravir were excluded from analysis. The main outcome of this study is the temporal change of SARS-CoV-2 viral burden measured by Ct values of RT-qPCR tests in symptomatic patients with COVID-19. FINDINGS: Among 22â€ˆ461 symptomatic patients with COVID-19 confirmed from July 1, 2020, to May 22, 2022, the estimated viral burden from a random-effects model indicated a longer duration of viral shedding in patients with more severe outcomes of infection (mean difference 13Â·1 days, 95% CI 12Â·9-13Â·3, for fatal vs mild-to-moderate) and in older patients (5Â·2, 5Â·0-5Â·5, for age â‰¥80 years vs 0-18 years). Vaccinated individuals with a breakthrough infection with the omicron BA.2 variant had a generally lower viral burden and shorter durations of viral shedding (mean difference of 2-4 days) over 4 weeks after onset than unvaccinated individuals infected with omicron BA.2, particularly in patients whose last dose of COVID-19 vaccine was received â‰¤90 days before symptom onset. Marginal differences in viral burden following symptom onset and the duration of viral shedding were observed between unvaccinated individuals infected with the ancestral strain and omicron BA.2. INTERPRETATION: The viral kinetics since symptom onset characterised for symptomatic patients with COVID-19 in our study show that previously vaccinated or younger individuals, or those with a milder infection, shed fewer viruses in a shorter period, implying possible transmission dynamics of SARS-CoV-2 and protective mechanisms of vaccination against infection and severe outcomes. FUNDING: Hong Kong Health and Medical Research Fund and Hong Kong Collaborative Research Fund.

Dynamics of inflammatory responses after SARS-CoV-2 infection by vaccination status in the USA: a prospective cohort study. BACKGROUND: Cytokines and chemokines play a critical role in the response to infection and vaccination. We aimed to assess the longitudinal association of COVID-19 vaccination with cytokine and chemokine concentrations and trajectories among people with SARS-CoV-2 infection. METHODS: In this longitudinal, prospective cohort study, blood samples were used from participants enrolled in a multi-centre randomised trial assessing the efficacy of convalescent plasma therapy for ambulatory COVID-19. The trial was conducted in 23 outpatient sites in the USA. In this study, participants (aged â‰¥18 years) were restricted to those with COVID-19 before vaccination or with breakthrough infections who had blood samples and symptom data collected at screening (pre-transfusion), day 14, and day 90 visits. Associations between COVID-19 vaccination status and concentrations of 21 cytokines and chemokines (measured using multiplexed sandwich immunoassays) were examined using multivariate linear mixed-effects regression models, adjusted for age, sex, BMI, hypertension, diabetes, trial group, and COVID-19 waves (pre-alpha or alpha and delta). FINDINGS: Between June 29, 2020, and Sept 30, 2021, 882 participants recently infected with SARS-CoV-2 were enrolled, of whom 506 (57%) were female and 376 (43%) were male. 688 (78%) of 882 participants were unvaccinated, 55 (6%) were partly vaccinated, and 139 (16%) were fully vaccinated at baseline. After adjusting for confounders, geometric mean concentrations of interleukin

(IL)-2RA, IL-7, IL-8, IL-15, IL-29 (interferon-Î»), inducible protein-10, monocyte chemoattractant protein-1, and tumour necrosis factor-Î± were significantly lower among the fully vaccinated group than in the unvaccinated group at screening. On day 90, fully vaccinated participants had approximately 20% lower geometric mean concentrations of IL-7, IL-8, and vascular endothelial growth factor-A than unvaccinated participants. Cytokine and chemokine concentrations decreased over time in the fully and partly vaccinated groups and unvaccinated group. Log(10) cytokine and chemokine concentrations decreased faster among participants in the unvaccinated group than in other groups, but their geometric mean concentrations were generally higher than fully vaccinated participants at 90 days. Days since full vaccination and type of vaccine received were not correlated with cytokine and chemokine concentrations. INTERPRETATION: Initially and during recovery from symptomatic COVID-19, fully vaccinated participants had lower concentrations of inflammatory markers than unvaccinated participants suggesting vaccination is associated with short-term and long-term reduction in inflammation, which could in part explain the reduced disease severity and mortality in vaccinated individuals. FUNDING: US Department of Defense, National Institutes of Health, Bloomberg Philanthropies, State of Maryland, Mental Wellness Foundation, Moriah Fund, Octapharma, HealthNetwork Foundation, and the Shear Family Foundation.

Identifying a causal link between prolactin signaling pathways and COVID-19 vaccine-induced menstrual changes. COVID-19 vaccines have been instrumental tools in the fight against SARS-CoV-2 helping to reduce disease severity and mortality. At the same time, just like any other therapeutic, COVID-19 vaccines were associated with adverse events. Women have reported menstrual cycle irregularity after receiving COVID-19 vaccines, and this led to renewed fears concerning COVID-19 vaccines and their effects on fertility. Herein we devised an informatics workflow to explore the causal drivers of menstrual cycle irregularity in response to vaccination with mRNA COVID-19 vaccine BNT162b2. Our methods relied on gene expression analysis in response to vaccination, followed by network biology analysis to derive testable hypotheses regarding the causal links between BNT162b2 and menstrual cycle irregularity. Five high-confidence transcription factors were identified as causal drivers of BNT162b2-induced menstrual irregularity, namely: IRF1, STAT1, RelA (p65 NF-kB subunit), STAT2 and IRF3. Furthermore, some biomarkers of menstrual irregularity, including TNF, IL6R, IL6ST, LIF, BIRC3, FGF2, ARHGDIB, RPS3, RHOU, MIF, were identified as topological genes and predicted as causal drivers of menstrual irregularity. Our network-based mechanism reconstruction results indicated that BNT162b2 exerted biological effects similar to those resulting from prolactin signaling. However, these effects were short-lived and didn't raise concerns about long-term infertility issues. This approach can be applied to interrogate the functional links between drugs/vaccines and other side effects.

Association of COVID-19 Versus COVID-19 Vaccination With Kidney Function and Disease Activity in Primary Glomerular Disease: A Report of the Cure Glomerulonephropathy Study. RATIONALE & OBJECTIVE: Patients with glomerular disease (GN) may be at increased risk of severe COVID-19, yet concerns over vaccines causing disease relapse may lead to vaccine hesitancy. We examined the associations of COVID-19 with longitudinal kidney function and proteinuria and compared these with similar associations with COVID-19 vaccination. STUDY DESIGN: Observational cohort study from July 1, 2021, to January 1,Â 2023. SETTING & PARTICIPANTS: A prospective observational study network of 71 centers from North America and Europe (CureGN) with children and adults with primary minimal change disease, focal segmental glomerulosclerosis, membranous nephropathy, or IgA nephropathy. EXPOSURE: COVID-19 and COVID-19 vaccination. OUTCOME: Repeated measure of estimated glomerular filtration rate (eGFR); recurrent time-to-event outcome of GN disease worsening as defined by doubling of the urinary protein-creatinine ratio (UPCR) to at least 1.5g/g or increase in dipstick urine protein by 2 ordinal levels to 3+(300mg/dL) or above. ANALYTICAL APPROACH:

Interrupted time series analysis for eGFR. Prognostic matched sequential stratification recurrent event analysis for GN disease worsening. RESULTS: Among 2,055 participants, 722 (35%) reported COVID-19 infection; of these, 92 (13%) were hospitalized, and 3 died (<1%). The eGFR slope before COVID-19 infection was-1.40mL/min/1.73m(2) (Â± 0.29 SD); within 6 months after COVID-19 infection, the eGFR slope was-4.26mL/min/1.73m(2) (Â± 3.02 SD), which was not significantly different (P=0.34). COVID-19 was associated with increased risk of worsening GN disease activity (HR, 1.35 [95% CI, 1.01-1.80]). Vaccination was not associated with a change in eGFR (-1.34mL/min/1.73m(2)Â±0.15 SD vs-2.16mL/min/1.73m(2)Â±1.74 SD; P=0.6) or subsequent GN disease worsening (HR 1.02 [95% CI, 0.79-1.33]) in this cohort. LIMITATIONS: Infrequent or short follow-up. CONCLUSIONS: Among patients with primary GN, COVID-19 infection was severe for 1 in 8 cases and was associated with subsequent worsening of GN disease activity, as defined by proteinuria. By contrast, vaccination against COVID-19 was not associated with change in disease activity or kidney function decline. These results support COVID-19 vaccination for patients with GN. PLAIN-LANGUAGE SUMMARY: In this cohort study of 2,055 patients with minimal change disease, focal segmental glomerulosclerosis, membranous nephropathy, or IgA nephropathy, COVID-19 resulted in hospitalization or death for 1 in 8 cases and was associated with a 35% increase in risk for worsening proteinuria. By contrast, vaccination did not appear to adversely affect kidney function or proteinuria. Our data support vaccination for COVID-19 in patients with glomerular disease.

Pediatric hemophagocytic lymphohistiocytosis after concomitant administration of SARS-CoV-2 vaccine and influenza vaccine. Hemophagocytic lymphohistiocytosis (HLH) is a highly lethal disease characterized by fever, cytopenia, splenomegaly, and hemophagocytosis. Whereas infectious diseases, malignant tumors, and autoimmune diseases are often triggers for HLH, reports of HLH associated with vaccination are limited. In this report, we describe a case of HLH in a 12-year-old female patient after simultaneous administration of the bivalent messenger RNA severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine and quadrivalent inactivated influenza vaccine. The patient presented to our hospital with fever on the day after vaccination. Considering the splenomegaly, cytopenia, hemophagocytosis in the bone marrow, and high ferritin level, HLH was diagnosed 12 days after vaccination. Various tests ruled out any infectious disease, malignant tumor, or autoimmune disease. The patient was treated only with 2 mg/kg/day of oral prednisolone, fever improved 13 days after vaccination, and blood test findings rapidly improved. Although HLH after SARS-CoV-2 vaccination or concomitant administration with influenza vaccination is still rare, we emphasize the importance of early HLH diagnosis when persistent fever is observed following vaccination.

Post-vaccination SARS-Cov-2 T-cell receptor repertoires in patients with multiple sclerosis and related disorders. BACKGROUND: Attenuation in post-vaccination SARS-CoV-2 humoral responses has been demonstrated in people treated with either anti-CD20 therapies or sphingosine-1-phosphate (S1P) receptor modulators. In the setting of disease modifying therapy (DMT) use, humoral response may not correlate with effective immunity, and analysis of vaccine-mediated SARS-CoV-2-specific memory T-cell responses is crucial. While vaccination in patients treated with anti-CD20 agents leads to deficient antibody production, emerging data from live cell assays suggests intact T-cell responses to vaccination. We evaluated post-vaccination SARS-CoV-2 T-cell receptor (TCR) repertoires in DMT-treated patients using the ImmunoSeq(R) assay, an assay that does not require live cells. METHODS: Adults 18-80 years old without prior COVID-19, with neuroimmune conditions, who had been vaccinated with two doses of Pfizer-BioNTech or Moderna mRNA vaccines at least 3 weeks and up to 6 months prior, were recruited. Whole blood was obtained for immunosequencing, and matched serum was obtained for humoral analysis. Immunosequencing of the CDR3 regions of human TCRÎ² chains was completed using the immunoSEQR Assay (Adaptive Biotechnologies). TCR sequences were

mapped across a set of TCR sequences reactive to SARS-CoV-2. Clonal diversity (breadth) and frequency (depth) of TCRs specific to SARS-CoV-2 spike protein were calculated and relationships with clinical variables were assessed. RESULTS: Forty patients were recruited into the study, aged 25-77, and 27 female. 37 had MS, 2 had neuromyelitis optica spectrum disorder (NMOSD), and 1 had hypophysitis. Subjects treated with anti-CD20 agents and S1P receptor modulators had severely attenuated humoral responses, but SARS-CoV-2-spike-specific TCR clonal depth and breadth were robust across all treatment classes except S1P modulators. No spike-specific or non-spike-specific SARS-CoV-2-associated TCRs were found in those treated with S1P modulators (pÂ =Â 0.002 for both breadth and depth). Subjects treated with fumarates exhibited somewhat lower spike TCR breadth than subjects treated with other or no DMTs (median 2.27Â Ã—Â 10^-5 for fumarates and 4.96Â Ã—Â 10^-5 for all others, pÂ =Â 0.008), but no statistically significant difference was demonstrated with spike TCR depth. No other significant associations with DMT type were found. We found no significant correlations between depth or breadth and age, duration of treatment, type of vaccination, or time interval since vaccination. CONCLUSION: This is the first study to characterize post-vaccination SARS-CoV-2 TCR repertoires in DMT-treated individuals. We demonstrated a dichotomous response to SARS-CoV-2 vaccination in anti-CD20-treated patients, with severely attenuated humoral response but intact TCR depth and breadth. It is unclear to what degree each arm of the adaptive immune system impacts post-vaccine immunity, both from the standpoint of incidence of post-vaccine infections and that of infection severity, and further clinical studies are necessary. S1P modulator-treated subjects exhibited both severely attenuated humoral responses and absent spike-specific TCR depth and breadth, information which is crucial for counseling of patients on these agents. Our methodology can be used in larger studies to determine the benefit of repeated vaccination doses, including those that are modified to better target modern or seasonal variants, without the use of live cell assays.

Impact of COVID-19 vaccination on mortality after acute myocardial infarction. BACKGROUND: COVID-19 vaccines are highly immunogenic but cardiovascular effects of these vaccines have not been properly elucidated. OBJECTIVES: To determine impact of COVID-19 vaccination on mortality following acute myocardial infarction (AMI). METHODS: This was a single center retrospective observation study among patients with AMI enrolled in the the North India ST-Elevation Myocardial Infarction (NORIN-STEMI) registry. In all the enrolled patients, data regarding patient's vaccination status including details on type of vaccine, date of vaccination and adverse effects were obtained. All enrolled subjects were followed up for a period of six months. The primary outcome of the study was all-cause mortality both at one month and at six months of follow-up. Propensity-weighted score logistic regression model using inverse probability of treatment weighting was used to determine the impact of vaccination status on all-cause mortality. RESULTS: A total of 1578 subjects were enrolled in the study of whom 1086(68.8%) were vaccinated against COVID-19 while 492(31.2%) were unvaccinated. Analysis of the temporal trends of occurrence of AMI post vaccination did not show a specific clustering of AMI at any particular time. On 30-day follow-up, all-cause mortality occurred in 201(12.7%) patients with adjusted odds of mortality being significantly lower in vaccinated group (adjusted odds ratio[aOR]: 0.58, 95% CI: 0.47-0.71). Similarly, at six months of follow-up, vaccinated AMI group had lower odds of mortality(aOR: 0.54, 95% CI: 0.44 to 0.65) as compared to non-vaccinated group. CONCLUSIONS: COVID-19 vaccines have shown to decrease all-cause mortality at 30 days and six months following AMI.

Vaccination effects on reducing COVID-19 complications in pregnancy: A large-scale report from Iran. OBJECTIVE: The objective of this study was to evaluate the effects of maternal coronavirus disease 2019 (COVID-19) vaccination on preventing severe complications of COVID-19 in pregnant women. METHODS: A retrospective study was conducted in pregnant women infected with severe acute

respiratory syndrome coronavirus 2 (SARS-CoV-2) during pregnancy and/or for up to 6â€‰weeks postpartum between September 1, 2021, to January 30, 2022. The data was retrieved from a national database. The pregnant women were divided into two groups of vaccinated and unvaccinated. The proposed outcomes (the need for hospitalization, intensive care unit admission, and mechanical ventilation and products of conception complications) were compared between the two groups. RESULTS: Approximately 90â€‰000 pregnant women infected with COVID-19 were included in the study. The data of the vaccinated (19â€‰922) and unvaccinated (70â€‰147) groups were analyzed and compared. Pregnant patients in the vaccinated group had a significantly lower rate of hospitalization (21.2% vs 29.4%) (odds ratio [OR], 0.648 [95% confidence interval (CI), 0.625-0.673], Pâ€‰=â€‰0.0001) and intensive care unit admission (3.7% vs 7.8%) (OR, 0.453 [95% CI, 0.382-0.535], Pâ€‰=â€‰0.0001). The need for mechanical ventilation was also lower, although not statistically significant, in the vaccinated group than in the unvaccinated group (30 of 155 [19.4%] vs 418 of 1597 [26.2%]) (OR, 0.677 [95% CI, 0.448-1.024], Pâ€‰=â€‰0.063). Cesarean section (54.3% vs 58.1%) (OR, 0.856 [95% CI, 0.751-0.977], Pâ€‰=â€‰0.021) and stillbirth (0.4% vs 3.6%) (OR, 0.097 [95% CI, 0.026-0.252], Pâ€‰=â€‰0.0001) were also significantly lower in the vaccinated patients. Most pregnant women in the vaccinated group (18â€‰484-96.14%) received Sinopharm BIBP COVID-19 inactivated vaccine. No significant differences were seen in the effect of different types of COVID-19 vaccines on reducing COVID-19 complications in infected pregnant patients. CONCLUSION: Maternal COVID-19 immunization is effective in reducing COVID-19 complications in infected pregnant women.

Thromboembolism after Astra Zeneca COVID-19 vaccine: Not always PF4- antibody mediated. Cases of thromboembolic events in 2021 flared up the discussion about the safety of Astra Zeneca's AZD1222 vaccine. We hereby report three cases of pulmonary embolism (PE), one case of extended portal vein thrombosis, and one case of combined portal vein thrombosis and PE within 2â€‰weeks after vaccination with the Astra Zeneca AZD1222 vaccine in a 60-year-old, a 50-year old, a 33-year-old, a 30-year old, and a 40-year-old male in that year. All patients were healthy before. In three patients, we observed thrombocytopenia and to some extent unusually low antibody levels for the Spike Protein (S-protein), while the other two had normal thrombocyte counts. Only one patient had anti-platelet factor 4 (PF4)-antibodies detectable as it has been described in the "heparin-induced thrombocytopenia (HIT)-like" disease of "vaccine-induced prothrombotic immune thrombocytopenia" (VIPIT) and we therefore assume that heterogeneous mechanisms led to PE. Therefore, we advise to collect and report more cases, in order to determine the age-related risks of vaccination balanced against the benefits of immunity to SARS-COV-2 for the AZD1222 vaccine in order to gain knowledge for the next pandemic.

Knowledge and training of Italian students in Healthcare Settings on COVID-19 vaccines and vaccination strategies, one year after the immunization campaign. INTRODUCTION: COVID-19 vaccines represent an important opportunity for defeating the disease, as long as high vaccination acceptance rates are achieved. Healthcare workers (HCWs) have a relevant role in the promotion of immunization among the population and since students in healthcare area will be HCWs it is crucial to provide more in-depth knowledge on vaccinations. Therefore, the aim of the study is to assess the knowledge of medical and pharmaceutical area students regarding COVID-19 vaccination and the impact of a specific Elective Teaching Activity (ETA) on the increase of students' knowledge. The ETA was held one year after the immunization campaign in Italy. METHODS: Students' knowledge was tested with a questionnaire before and after attending the course. Descriptive statistical methods were used to analyse the results obtained. Student's t-tests for paired data were used. RESULTS: Overall, 387 students at the University of Florence attended the course and took the same test before and after the ETA on COVID-19 vaccines. Despite achieving satisfactory average scores in the pre-

course test (26/32 Â± 4.0), all students were able to significantly enhance their final score (+17.1%; p < 0.001), indicating that the ETA was highly effective in improving their knowledge of COVID-19 vaccination. Medical students demonstrated a better comprehension of the role of the medical specialist in public health in the COVID-19 vaccination campaign, while some uncertainties were revealed regarding the role of pharmacists. CONCLUSIONS: The results of this study confirm that specific training activities on vaccination are effective for implementing the knowledge of future health professionals.

Acute cholangitis following mRNA COVID-19 vaccine booster in a patient receiving an anti-amyloid antibody for Alzheimer's disease: A case report. A 77-year-old woman had 2 weeks of fever and flu-like symptoms starting several hours after receiving an mRNA booster for SARS-CoV-2 and the influenza vaccine, in separate shots. Laboratory tests showed cholangitis. Medical history included APOE-Îµ4 carrier genotype, mild Alzheimer's disease, participation in a clinical trial of aducanumab, and resolving polymyalgia rheumatica. The patient recovered with at-home supportive care. She had aducanumab-associated amyloid-related imaging abnormalities-edema (ARIA-E) both before and after the acute cholangitis. Two months following the vaccinations polymyalgia rheumatica recurred. This case raises questions about interactions among immune-mediated disease, complications of anti-amyloid monoclonal antibodies, and adverse events following SARS-CoV-2 mRNA vaccination.

Upregulated CD8(+) MAIT cell differentiation and KLRD1 gene expression after inactivated SARS-CoV-2 vaccination identified by single-cell sequencing. BACKGROUND: The primary strategy for reducing the incidence of COVID-19 is SARS-CoV-2 vaccination. Few studies have explored T cell subset differentiation and gene expressions induced by SARS-CoV-2 vaccines. Our study aimed to analyze T cell dynamics and transcriptome gene expression after inoculation with an inactivated SARS-CoV-2 vaccine by using single-cell sequencing. METHODS: Single-cell sequencing was performed after peripheral blood mononuclear cells were extracted from three participants at four time points during the inactivated SARS-CoV-2 vaccination process. After library preparation, raw read data analysis, quality control, dimension reduction and clustering, single-cell T cell receptor (TCR) sequencing, TCR V(D)J sequencing, cell differentiation trajectory inference, differentially expressed genes, and pathway enrichment were analyzed to explore the characteristics and mechanisms of postvaccination immunodynamics. RESULTS: Inactivated SARS-CoV-2 vaccination promoted T cell proliferation, TCR clone amplification, and TCR diversity. The proliferation and differentiation of CD8(+) mucosal-associated invariant T (MAIT) cells were significantly upregulated, as were KLRD1 gene expression and the two pathways of nuclear-transcribed mRNA catabolic process, nonsense-mediated decay, and translational initiation. CONCLUSION: Upregulation of CD8(+) MAIT cell differentiation and KLRD1 expression after inactivated SARS-CoV-2 vaccination was demonstrated by single-cell sequencing. We conclude that the inactivated SARS-CoV-2 vaccine elicits adaptive T cell immunity to enhance early immunity and rapid response to the targeted virus.

Postural orthostatic tachycardia syndrome and other related dysautonomic disorders after SARS-CoV-2 infection and after COVID-19 messenger RNA vaccination. The COVID-19 pandemic has caused a challenge for our society due to the post-acute sequelae of the disease. Persistent symptoms and long-term multiorgan complications, known as post-acute COVID-19 syndrome, can occur beyond 4 weeks from the onset of the COVID-19 infection. Postural orthostatic tachycardia syndrome (POTS) is considered a variety of dysautonomia, which is characterized by chronic symptoms that occur with standing and a sustained increase in heart rate, without orthostatic hypotension. POTS can lead to debilitating symptoms, significant disability, and impaired quality of life. In this narrative review, the etiopathogenic basis, epidemiology, clinical manifestations, diagnosis, treatment, prognosis, and socioeconomic impact of POTS, as well as other related dysautonomic disorders, after COVID-19 infection and SARS-CoV-2 postvaccination, were discussed. After a search conducted in March 2023, a

total of 89 relevant articles were selected from the PubMed, Google Scholar, and Web of Science databases. The review highlights the importance of recognizing and managing POTS after COVID-19 infection and vaccination, and the approach to autonomic disorders should be known by all specialists in different medical areas. The diagnosis of POTS requires a comprehensive clinical assessment, including a detailed medical history, physical examination, orthostatic vital signs, and autonomic function tests. The treatment of POTS after COVID-19 infection or vaccination is mainly focused on lifestyle modifications, such as increased fluid and salt intake, exercise, and graduated compression stockings. Pharmacotherapy, such as beta-blockers, fludrocortisone, midodrine, and ivabradine, may also be used in selected cases. Further research is needed to understand the underlying mechanisms, risk factors, and optimal treatment strategies for this complication.

Original SARS-CoV-2 monovalent and Omicron BA.4/BA.5 bivalent COVID-19 mRNA vaccines: phase 2/3 trial interim results. This ongoing, open-label, phase 2/3 trial compared the safety and immunogenicity of the Omicron BA.4/BA.5-containing bivalent mRNA-1273.222 vaccine with the ancestral Wuhan-Hu-1 mRNA-1273 as booster doses. Two groups of adults who previously received mRNA-1273 as primary vaccination series and booster doses were enrolled in a sequential, nonrandomized manner and received single-second boosters of mRNA-1273 (nâ€‰=â€‰376) or bivalent mRNA-1273.222 (nâ€‰=â€‰511). Primary objectives were safety and the noninferiority or superiority of neutralizing antibody (nAb) responses against Omicron BA.4/BA.5 and ancestral SARS-CoV-2 with the D614G mutation (ancestral SARS-CoV-2 (D614G)), 28â€‰days post boost. Superiority and noninferiority were based on prespecified success criteria (lower bounds of 95% CIâ€‰>â€‰1 and <â€‰0.677, respectively) of the mRNA-1273.222:mRNA-1273 geometric mean ratios. Bivalent Omicron BA.4/BA.5-containing mRNA-1273.222 elicited superior nAb responses against BA.4/BA.5 versus mRNA-1273 and noninferior responses against ancestral SARS-CoV-2 (D614G) at day 29 post boost in participants without detectable prior SARS-CoV-2 infection. Day 29 seroresponses against Omicron BA.4/BA.5 were higher for mRNA-1273.222 than for mRNA-1273 and similar against ancestral SARS-CoV-2 (D614G), both meeting noninferiority criterion. The safety profile of mRNA-1273.222 was similar to that previously reported for mRNA-1273 with no new safety concerns identified. Continued monitoring of neutralization and real-world vaccine effectiveness are needed as additional divergent-virus variants emerge. ClinicalTrials.gov registration: NCT04927065.

Long-term multiple metabolic abnormalities among healthy and high-risk people following nonsevere COVID-19. Few studies have identified the metabolic consequences of the post-acute phase of nonsevere COVID-19. This prospective study examined metabolic outcomes and associated factors in nonsevere, RT-PCR-confirmed COVID-19. The participants' metabolic parameters, the prevalence of long-term multiple metabolic abnormalities (â‰¥â€‰2 components), and factors influencing the prevalence were assessed at 1, 3, and 6Â months post-onset. Six hundred individuals (mean age 45.5â€‰Â±â€‰14.5Â years, 61.7% female, 38% high-risk individuals) with nonsevere COVID-19 attended at least one follow-up visit. The prevalence of worsening metabolic abnormalities was 26.0% for BMI, 43.2% for glucose, 40.5% for LDL-c, 19.1% for liver, and 14.8% for C-reactive protein. Except for lipids, metabolic-component abnormalities were more prevalent in high-risk hosts than in healthy individuals. The prevalence of multiple metabolic abnormalities at the 6-month follow-up was 41.3% and significantly higher in high-risk than healthy hosts (49.2% vs 36.5%; Pâ€‰=â€‰0.007). Factors independently associated with a lower risk of these abnormalities were being female, having dyslipidemia, and receiving at least 3 doses of the COVID-19 vaccine. These findings suggest that multiple metabolic abnormalities are the long-term consequences of COVID-19. For both high-risk and healthy individuals with nonsevere COVID-19, healthcare providers should monitor metabolic profiles, encourage healthy behaviors, and ensure complete vaccination.

Immunogenicity and safety of NVX-CoV2373 as a booster: A phase 3 randomized clinical trial in adults. BACKGROUND: To combat the SARS-CoV-2 pandemic, multiple vaccines using different manufacturing platforms have been developed, including NVX-CoV2373 (an adjuvanted recombinant protein vaccine). As SARS-CoV-2 variants have emerged, some of which evade vaccine-induced immunity, introduction of vaccine booster doses has become critical. Employing different vaccine types for primary series vaccination and boosting could expand vaccine coverage and access. This study assessed whether NVX-CoV2373 would induce robust responses when used as a booster. METHODS: The 2019nCoV-307 study was a phase 3, randomized, observer-blinded trial evaluating immunogenicity and safety of NVX-CoV2373 in previously vaccinated adults aged 18-49Â years in the United States (NCT05463068). Participants were randomized 1:1:1 to receive one intramuscular injection of NVX-CoV2373 from one of three different manufacturing lots. Immunogenicity was assessed by immunoglobulin G (IgG) and neutralizing antibodies (NAb). These responses were compared for the three lots, and for participants with primary series with or without a prior booster dose of the mRNA-1273, BNT162b2, Ad26.COV2.S, or NVX-CoV2373 COVID-19 vaccines. RESULTS: A total of 911 participants were randomized between July 11 and 13, 2022, with 905 being assessed for safety and 848 for immunogenicity. Immunogenicity of NVX-CoV2373 met prespecified equivalence criteria between lots, and the booster dose was well-tolerated. NVX-CoV2373 induced robust IgG and NAb responses when used as a first or later booster dose, regardless of primary series vaccine type. Seroconversion rates were also similar across previous vaccine types. Induced antibodies were strongly reactive, even to the immune-evasive Omicron BA.1 and BA.5 variants. CONCLUSIONS: NVX-CoV2373 showed consistent immunogenicity between lots, with no new safety signals identified. Use of NVX-CoV2373 as a booster dose (first or later) is supported.

Impact of different classes of immune-modulating treatments on B cell-related and T cell-related immune response before and after COVID-19 booster vaccination in patients with immune-mediated diseases and primary immunodeficiency: a cohort study. OBJECTIVES: To evaluate the potential of immunosuppressed patients to mount B-cell and T-cell responses to COVID-19 booster vaccination (third vaccination). METHODS: Patients with primary immunodeficiency (PID), immune-mediated inflammatory diseases (IMIDs) on CD20-depleting treatment with rituximab (RTX), or IMIDs treated with conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) or biological disease-modifying antirheumatic drug (bDMARDs) were included and assessed before (baseline visit (BL)) and 2, 4 and 8 weeks after COVID-19 booster vaccination. Serum B-cell responses were assessed by antibody levels against SARS-CoV-2 spike protein (anti-spike IgG antibody (S-AB)) and a surrogate virus neutralisation test (sVNT). T-cell responses were assessed by an interferon gamma release assay (IGRA). RESULTS: Fifty patients with PID (n=6), treated with RTX therapy (n=13), or treated with csDMARDs/bDMARDs (n=31) were included. At BL, anti-S-AB titres in PID and csDMARD/bDMARD-treated patients were low (although significantly higher than RTX patients); measures of B-cell-mediated response increased significantly after booster vaccination. In the RTX cohort, low BL anti-S-AB and sVNT values did not improve after booster vaccination, but patients had significantly elevated IGRA responses post booster vaccination compared with the other groups. csDMARD/bDMARD-treated patients showed the highest BL values in all three assays with greater increases in all parameters after booster vaccination compared with patients with PID. CONCLUSION: Patients with IMID on therapeutic B-cell depletion have low anti-S-AB and sVNT values before and after booster vaccination but show significantly higher levels of IGRA compared with other immunosuppressed patients, suggesting an underlying mechanism attempting to compensate compromised humoral immunity by upregulating T-cell responsiveness. PID appears to have a stronger impact on antiviral immune response than csDMARD/bDMARD treatment.

Nonketotic hyperglycemic-induced hemichorea-hemiballismus following COVID-19 (BNT162b2) vaccination.

Low incidence of de novo HLA antibodies after COVID-19 vaccination: A cohort study of patients awaiting kidney transplantation. BACKGROUND: Antibodies against human leukocyte antigen (anti-HLA Abs) are associated with an increased risk of allograft loss. Herein, we report the prospective follow-up for anti-HLA Abs formation in 103 patients with end-stage kidney disease on the waiting list for transplantation who underwent COVID-19 vaccination. PATIENTS AND METHODS: Sera were tested before and after vaccination using Luminex technology. The cohort comprised of 62 males and 41 females with a mean age of 56 Â± 14 years. The patients received BNT162b2 (80.4%), mRNA-1273 (18.5%), AZD1222 (0.40%), or ChAdOx1-S (0.80%) vaccine. Patients were tested before and within 119 Â± 50, 95 Â± 46 and 25 Â± 26 days after the first, second, and third dose of the vaccine, respectively. RESULTS: No significant change in calculated panel reactive antibody (cPRA) after vaccination was seen. Although 98.1% of patients had no change in anti-HLA Abs profile or cPRA after vaccination, two patients (1.9%) developed de novo anti-HLA Abs against class I or II HLA antigens. In those two patients, the cPRA changed from 0% and 63% at baseline to 9% and 90% after vaccination, respectively. Both patients received the BNT162b2 mRNA-based vaccine. The earliest detected anti-HLA Abs was 18 days after the first dose. CONCLUSION: In rare cases, new anti-HLA antibodies were observed after COVID-19 vaccination, with potential implications for transplantation. The low incidence of this phenomenon is outweighed by the clinical benefits of vaccination.

Case report of long-term postural tachycardia syndrome in a patient after messenger RNA coronavirus disease-19 vaccination with mRNA-1273. BACKGROUND: Postural tachycardia syndrome (POTS) is characterized by orthostatic intolerance and heart rate increase in an upright position without orthostatic hypotension. It has been described after coronavirus disease-19 (COVID-19) as well as after COVID-19 vaccination. CASE SUMMARY: A 54-year-old female patient presented with a 9-months history of severe orthostatic intolerance since COVID-19 vaccination with messenger RNA (mRNA)-1273 (Spikevax, Moderna). Except for diet-controlled coeliac disease, the patient was healthy, had no allergies, and did not take regular medication. Tilt table testing revealed a significant heart rate increase to 168 bpm without orthostatic hypotension accompanied by light-headedness, nausea, and syncope, findings consistent with POTS. Potential underlying causes including anaemia, thyroid dysfunction, adrenal insufficiency, pheochromocytoma, (auto)-immune disease, chronic inflammation as well as neurological causes were ruled out. Echocardiography and cardiac stress magnetic resonance imaging (MRI) did not detect structural or functional heart disease or myocardial ischaemia. Forty-eight-hour-electrocardiogram (ECG) showed no tachycardias other than sinus tachycardia. Finally, genomic analysis did not detect an inherited arrhythmia syndrome. Serologic analysis revealed adequate immune response to mRNA-1273 vaccination without signs of previous severe acute respiratory syndrome-coronavirus-2 infection. While ivabradine was not tolerated and metoprolol extended release only slightly improved symptoms, physical exercise reduced orthostatic intolerance moderately. At a 5-months follow-up, the patient remained dependant on assistance for activities of daily living. DISCUSSION: The temporal association of POTS with the COVID-19 vaccination in a previously healthy patient and the lack of evidence of an alternative aetiology suggests COVID-19 vaccination is the potential cause of POTS in this patient. To our knowledge, this is the first case reporting severe, long-term, and treatment-refractory POTS following COVID-19 vaccination with mRNA1273.

Even after SARS-CoV-2 booster, there is increased COVID-19 breakthrough infection in patients with plasma cell disorders.

Achievement of sufficient antibody response after a fourth dose of wild-type SARS-CoV-2 mRNA vaccine in nursing home residents. BACKGROUND: Infection control during COVID-19 outbreaks

in nursing facilities is a critical public health issue. Antibody responses before and after the fourth (second booster) dose of wild-type severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine in nursing home residents have not been fully characterized. METHODS: This study included 112 individuals: 54 nursing home residents (mean age: 84.4 years; 35 SARS-CoV-2-naive and 19 previously infected) and 58 healthcare workers (mean age: 47.7 years; 25 SARS-CoV-2-naive and 33 previously infected). Antispike and antinucleocapsid antibody responses to messenger RNA vaccination were evaluated using serum samples collected shortly and 5 months after the third dose, and shortly after the fourth dose. RESULTS: The median immunoglobulin G (IgG) level in SARS-CoV-2-naive residents was similar to that in SARS-CoV-2-naive healthcare workers after the fourth dose (24,026.3 vs. 30,328.6â€‰AU/mL, pâ€‰=â€‰.79), whereas after the third dose the IgG level of SARS-CoV-2-naive residents was approximately twofold lower than that in SARS-CoV-2-naive healthcare workers. In residents with previous SARS-CoV-2 infection, timing of infection in relation to vaccination affected the kinetics of antibody responses. Residents infected after the third dose showed the highest IgG levels after the fourth dose among all groups (median: 64,328.8â€‰AU/mL), in contrast to residents infected before initiating vaccination with antibody levels similar to those of SARS-CoV-2-naive residents. CONCLUSIONS: Advanced aged nursing home residents, poor responders in the initial SARS-CoV-2 vaccine series, could achieve sufficient antibody responses after the fourth (second booster) vaccination, comparable to those of younger adults.

The nature and severity of SARS-CoV-2 vaccine side effects in athletes are highly dependent on study design.

Compulsory Vaccination Coverage in 12 Sub-Saharan African Countries Two Years Following the COVID-19 Pandemic. The coronavirus disease 2019 (COVID-19) pandemic is a global threat, challenging health services' provision and utilization. This study aimed to assess compulsory vaccination coverage in 12 Sub-Saharan African countries two years following the COVID-19 pandemic using the Health Belief Model. A cross-sectional survey was conducted from November 1 to December 15, 2022. Multivariate logistic regression was conducted to identify the determinants of vaccination coverage. Among the 5032 respondents, 73.1% reported that their children received compulsory vaccination. The lowest coverage was observed in Ghana (36.5%), while the highest was in Burkina Faso and Congo (92.0%). Factors associated with non-vaccination included older mothers (adjusted odds ratio (AOR)â€‰=â€‰1.04, 95%CI: 1.03-1.05), lower mothers' education, older children (AORâ€‰=â€‰0.76, 95%CI: 0.60-0.96), children with chronic illnesses (AORâ€‰=â€‰0.55, 95%CI: 0.45-0.66), and difficult accessibility to healthcare facilities (AORâ€‰=â€‰11.27, 95%CI: 9.48-13.44). Low perceived risk, in which non-vaccinated children were believed to be at no higher risk for infectious diseases and the disease severity would not worsen among non-vaccinated children, increased the likelihood of non-vaccination (AORâ€‰=â€‰2.29, 95%CI: 1.75-2.99 and AORâ€‰=â€‰2.12, 95%CI: 1.64-2.73, respectively). Perceiving vaccines as unnecessary, and needless for breastfed babies increased the probability of non-vaccination (AORâ€‰=â€‰1.38, 95%CI: 1.10-1.73 and AORâ€‰=â€‰1.69, 95%CI: 1.31-2.19, respectively). Higher odds of non-vaccination were found when the provision of vaccine information did not motivate parents to vaccinate their children (AORâ€‰=â€‰4.29, 95%CI: 3.15-5.85). Conversely, believing that vaccines were safe for children decreased the odds of non-vaccination (AORâ€‰=â€‰0.72, 95%CI: 0.58-0.88). Parental perceptions and concerns should be considered in interventions aiming to increase compulsory vaccine acceptance and coverage.

Anti-GAD Encephalitis Following COVID-19 Vaccination: A Case Report. Since December 2020, a significantly higher number of people worldwide have been vaccinated for coronavirus disease 2019 (COVID-19). Neurological complications have been reported after these vaccines, although a definitive causal relationship has not been proven in the available literature. We describe a 51-year-

old man presenting with anti-glutamic acid decarboxylase (anti-GAD) antibody positive autoimmune encephalitis with progressive cognitive impairment and behavioral abnormalities, presenting shortly after the second dose of mRNA COVID-19 vaccine, possibly representing a serious vaccine-related adverse event. Response to high-dose steroid and intravenous immunoglobulin treatment was positive. As many people around the world have been vaccinated against COVID-19, this case shows that autoimmune encephalitis and even anti-GAD antibody positive autoimmune encephalitis can develop as a side effect after this new vaccine, but with early diagnosis and appropriate treatment, the clinic can have a good prognosis. Observational studies with large numbers of patients are needed to explain causality.

SARS-CoV-2 vaccine-triggered autoimmunity: Molecular mimicry and/or bystander activation of the immune system. Induced autoimmunity or autoinflammatory-like conditions as a rare vaccine-related adverse event have been reported following COVID-19 vaccination. Such inadvertent adverse reactions have raised somewhat concerns about the long-term safety of the developed vaccines. Such multifactorial phenomena may be related to the cross-reactivity between the viral-specific antigens with the host self-proteins through molecular mimicry mechanism and/or nonspecific bystander activation of the non-target antigen-independent immunity by the entities of the vaccine products. However, due to the low incidence of the reported/identified individuals and insufficient evidence, autoimmunity following the COVID-19 vaccination has not been approved. Thereby, it seems that further designated studies might warrant post-monitoring of the inevitable adverse immunologic reactions in the vaccinated individuals, especially among hypersensitive cases, to address possible immunological mechanisms induced by the viral vaccines, incorporated adjuvants, and even vaccine delivery systems.

Self-reported side effects following COVID-19 vaccination in athletes: Correspondence.

The intersection of biological sex and gender in adverse events following seasonal influenza vaccination in older adults. BACKGROUND: Women/females report more adverse events (AE) following immunization than men/males for many vaccines, including the influenza and COVID-19 vaccines. This discrepancy is often dismissed as a reporting bias, yet the relative contributions of biological sex and gender are poorly understood. We investigated the roles of sex and gender in the rate of AE following administration of the high-dose seasonal influenza vaccine to older adults (â‰¥â€‰75 years) using an AE questionnaire administered 5-8 days post-vaccination. Participant sex (male or female) was determined by self-report and a gender score questionnaire was used to assign participants to one of four gender categories (feminine, masculine, androgynous, or undifferentiated). Sex steroid hormones and inflammatory cytokines were measured in plasma samples collected prior to vaccination to generate hypotheses as to the biological mechanism underpinning the AE reported. RESULTS: A total of 423 vaccines were administered to 173 participants over four influenza seasons (2019-22) and gender data were available for 339 of these vaccinations (2020-22). At least one AE was reported following 105 vaccinations (25%), by 23 males and 82 females. The majority of AE occurred at the site of injection, were mild, and transient. The odds of experiencing an AE were 3-fold greater in females than males and decreased with age to a greater extent in females than males. The effects of gender, however, were not statistically significant, supporting a central role of biological sex in the occurrence of AE. In males, estradiol was significantly associated with IL-6 and with the probability of experiencing an AE. Both associations were absent in females, suggesting a sex-specific effect of estradiol on the occurrence of AE that supports the finding of a biological sex difference. CONCLUSIONS: These data support a larger role for biological sex than for gender in the occurrence of AE following influenza vaccination in older adults and provide an initial investigation of hormonal mechanisms that may mediate this sex difference. This study highlights the complexities of measuring gender and the importance of assessing AE

separately for males and females to better understand how vaccination strategies can be tailored to different subsets of the population.

Neonatal and maternal outcomes following SARS-CoV-2 infection and COVID-19 vaccination: a population-based matched cohort study. Understanding the impact of SARS-CoV-2 infection and COVID-19 vaccination in pregnancy on neonatal and maternal outcomes informs clinical decision-making. Here we report a national, population-based, matched cohort study to investigate associations between SARS-CoV-2 infection and, separately, COVID-19 vaccination just before or during pregnancy and the risk of adverse neonatal and maternal outcomes among women in Scotland with a singleton pregnancy ending at â‰¥20 weeks gestation. Neonatal outcomes are stillbirth, neonatal death, extended perinatal mortality, preterm birth (overall, spontaneous, and provider-initiated), small-for-gestational age, and low Apgar score. Maternal outcomes are admission to critical care or death, venous thromboembolism, hypertensive disorders of pregnancy, and pregnancy-related bleeding. We use conditional logistic regression to derive odds ratios adjusted for socio-demographic and clinical characteristics (aORs). We find that infection is associated with an increased risk of preterm (aOR=1.36, 95% Confidence Interval [CI]â€‰=â€‰1.16-1.59) and very preterm birth (aOR = 1.90, 95% CI 1.20-3.02), maternal admission to critical care or death (aOR=1.72, 95% CIâ€‰=â€‰1.39-2.12), and venous thromboembolism (aOR = 2.53, 95% CIâ€‰=â€‰1.47-4.35). We find no evidence of increased risk for any of our outcomes following vaccination. These data suggest SARS-CoV-2 infection during pregnancy is associated with adverse neonatal and maternal outcomes, and COVID-19 vaccination remains a safe way for pregnant women to protect themselves and their babies against infection.

Associations of Mental Health and Experience of the COVID-19 Pandemic with United States Adults' Intentions to Be Vaccinated. COVID-19 vaccine uptake in the United States has proved challenging. A deeper characterization extending beyond demographics and political ideologies of those hesitating or resisting is needed to guide ongoing conversations. This study examined associations between US adults' vaccination intentions and mental health history, experience of the COVID-19 pandemic, and mental health outcomes. An online population-based cross-sectional survey was administered nationwide during January 4-7, 2021. Participants were questioned about past and current mental health, and completed the Patient Health Questionnaire 8 (PHQ-8), Generalized Anxiety Disorder 7-item (GAD-7), and Posttraumatic Diagnostic Scale (PDS)-5 (to capture symptoms of depression, anxiety, and traumatic stress, respectively). Experience of the pandemic included cumulative county-level COVID case and death rates, self-reported COVID-19 testing/exposure/diagnosis, and self-reported impact on routines, resources, and relationships. Of 936 respondents, 66% intended to be vaccinated, 14.7% responded "maybe," and 19.6% "no." Past diagnosis of obsessive compulsive disorder, less impact on routines or social supports, not having been screened or tested for COVID-19, not knowing someone who tested positive, and not self-isolating were associated with less intention to vaccinate. After controlling for demographic and pandemic experience factors, symptoms of traumatic stress, but not other mental health outcomes, were associated with less intention to vaccinate. The apparent contradiction between less negative impact of the pandemic and symptoms of traumatic stress being associated with less intention to be vaccinated indicates the complex nature of barriers to vaccine uptake. Results from this study contribute to the evidence base needed to improve ongoing and future communications about, and strategies to increase uptake of, vaccination.

Correlation of a commercial platform's results with post-vaccination SARS-CoV-2 neutralizing antibody response and clinical host factors. INTRODUCTION: The objective of this study was to describe the correlation between the commercially available assay for anti-S1/RBD IgG and protective serum neutralizing antibodies (nAb) against SARS-CoV-2 in an adult population after SARS-CoV-2

vaccination, and determine if clinical variables impact this correlation. METHODS: We measured IgG anti-S1/RBD using the IgG-II CMIA assay and nAb IC50 values against SARS-CoV-2 WA-1 in sera serially collected post-mRNA vaccination in veterans and healthcare workers of the Veterans Affairs Connecticut Healthcare System (VACHS) between December 2020 and January 2022. The correlation between IgG and IC50 was measured using Pearson correlation. Clinical variables (age, sex, race, ethnicity, prior COVID infection defined by RT-PCR, history of malignancy, estimated glomerular filtration rate (GFR calculated using CKD-EPI equation) were collected by manual chart review. The impact of these clinical variables on the IgG-nAb correlation was analyzed first with univariable regression. Variables with a significance of $p < 0.15$ were analyzed with forward stepwise regression analysis. RESULTS: From 127 sera samples in 100 unique subjects (age 20-93 years; mean 63.83; SD 15.63; 29% female; 67% White), we found a robust correlation between IgG anti-S1/RBD and nAb IC50 ($R2 = 0.83$, $R2adj = 0.70$, $p < 0.0001$). Race, ethnicity, and a history of malignancy were not significant on univariable analysis. GFR ($p < 0.05$) and prior COVID infection ($p < 0.001$) had a significant impact on the correlation between IgG anti-S1/RBD and nAb IC50. Age ($p = 0.06$) and sex ($p = 0.07$) trended towards significance on univariable analysis, but were not significant on multivariable regression. CONCLUSIONS: There was a strong correlation between IgG anti-S1/RBD and nAb IC50 after SARS-CoV-2 vaccination. Clinical comorbidities, such as prior COVID infection and renal function, impacted this correlation. These results may assist the prediction of post-vaccination immune protection in clinical settings using cost-effective commercial platforms.

PRESUMED PANUVEITIS FOLLOWING COVID-19 VACCINATION IN A PATIENT WITH GRANULOMATOUS TATTOO INFLAMMATION. PURPOSE: To report a case of panuveitis that developed following COVID-19 vaccination in a patient with a recent history of granulomatous tattoo inflammation. METHODS: Case report. RESULTS: A 25-year-old woman with a recent history of biopsy-proven granulomatous tattoo inflammation developed bilateral eye pain and blurred vision 1 week following her second mRNA-1273 COVID-19 vaccination (Moderna, Inc, Cambridge, MA). Examination revealed bilateral panuveitis. Workup for infectious etiologies and sarcoidosis was negative. The intraocular inflammation initially resolved with systemic prednisone therapy but then recurred following tapering, requiring the initiation of mycophenolate mofetil. CONCLUSION: A case of panuveitis that developed following a COVID-19 vaccination in a patient with a recent history of tattoo inflammation is reported. The temporal relationship between the vaccine and the development of uveitis in this patient may be coincidental and should be interpreted with caution, but multiple vaccines have been associated with uveitis, presumably as a result of their generalized stimulation of the immune system. It is believed that this case of tattoo-associated uveitis may have been exacerbated by the generalized inflammatory effect of COVID-19 vaccination.

Myocardial injury related to SARS-CoV-2 mRNA vaccination: The plot thickens.

Post-Vaccine SARS-CoV-2 Reinfection and Associated Factors Among Health Care Providers in Addis Ababa Public Hospitals, Addis Ababa, 2022: A Cross-Sectional Study. BACKGROUND OF THE STUDY: The protection against Coronavirus variants 2019 by pre-existing antibodies due to the current vaccination or natural infection is a global concern. In Ethiopia, case reports show that a significant number of health professionals are reported to get re-infected after vaccination. There are also more studies that revealed the symptomatic SARS-COV-2 re-infection, in particular, among healthcare providers actively engaged in Addis Ababa public health facilities. OBJECTIVE: This study has aimed at assessing the magnitude of post-vaccine reinfection of SARS-COV-2 and associated factors among health care providers in Addis Ababa public hospitals, Addis Ababa, 2022 G.C. METHODS: A facility-based cross-sectional study was conducted from July 11 to July 30, 2022. A total of 422 health professionals were included. A simple random sampling method was employed to select 40% of the total hospitals. Then the total sample size was equally allocated to each selected

hospital, and then each individual was selected purposefully. The data was collected using a structured, self-administered questionnaire. The analysis was done using SPSS version 26.0, and for data entry, EPi Info version 7.1 was used. Both bivariable and multivariable logistic regression analyses were used to determine the p-value. RESULTS: Overall, 418 healthcare providers were enrolled in this study, making the response rate 99.05%. The magnitude of SARS-COV-2 reinfection was 60 (14.4%) (95% CI 10.8-17.9). Healthcare professionals who took infection prevention (IP) training on COVID-19 (AORâ€‰=â€‰7.177: CIâ€‰=â€‰4.761-9.698) were associated with SARS-COV-2 reinfection; those with a history of chronic respiratory diseases (AORâ€‰=â€‰3.029: CIâ€‰=â€‰2.406-9.133) were associated with SARS-COV-2 reinfection; health professionals who took the third dose of SARS-COV-2 vaccine (AORâ€‰=â€‰1.75: CIâ€‰=â€‰1.14-2.68) and being a midwife were statistically significant. CONCLUSION AND RECOMMENDATION: This study showed the prevalence of SARS-COV-2 reinfection among vaccinated healthcare providers with a pre-vaccination infection history was high; IP training on COVID-19 was needed; educational status, profession, type of vaccine taken in the first dose, chronic respiratory diseases, and number of vaccinations were significantly associated with SARS-COV-2 reinfection after vaccination. Giving IP training, encouraging taking the vaccine as protocol, and using proper personal protective equipment are recommended.

Active surveillance of adverse events following COVID-19 vaccines in a tertiary care hospital. BACKGROUND: Vaccination is a safe and effective way to prevent disease and save lives, but it may also produce some undesirable adverse events (AEs)which may affect healthy individuals. Therefore, the monitoring of AE following immunization (AEFIs) is necessary. The objective of this study was to assess the AEs following COVID-19 vaccinations in a tertiary care hospital. METHODOLOGY: The study was conducted as active vaccine safety surveillance for a period of 6â€‰months among the COVID-19 vaccine beneficiaries of the study site. Active surveillance was conducted via initiating two telephone contacts. The first surveillance was conducted in 8â€‰days and the second surveillance after 28â€‰days of post-vaccination. All identified AEs following immunizations (AEFIs) were reported and analysed by the AEFI investigation team at the study site. The causality assessment of each identified AEFI was performed using the World Health Organization's causality assessment algorithm. RESULTS: A total of 2927 enrolled study population completed the study with a response rate of 80.85%. The study identified 902 AEFIs from 614 study populations with an incidence rate of 20.97%. Of which 794 and 79 AEFIs were associated with COVISHIELDâ„¢ and COVAXIN(Â®), respectively. The majority of the events were reported among the age group of 18-29â€‰years. Overall, only three events were serious and no deaths were reported among the study population. A total of 75.59% of events had a consistent causal association with vaccination and were categorized as vaccine product-related reactions. The study identified various factors such as gender (pâ€‰=â€‰0.019), age (pâ€‰<â€‰0.05), co-morbid status (pâ€‰=â€‰0.032) and dose number (pâ€‰=â€‰0.001) as potential predictors for development of AEFI. CONCLUSION: The study identified only 0.33% of events as serious, and 99.67% of the study population recovered from the AEFIs, which reveals that COVISHIELDâ„¢ and COVAXIN(Â®) have a generally favourable safety profile. However, close monitoring is required to identify the potential signals, as the safety data from the clinical trials are limited.

Antibody response following the fourth SARS-CoV-2 vaccine dose during the Omicron wave in Brazil. We investigated the impact of the fourth dose with ChAdOx1 nCoV-19 (AstraZeneca) in the humoral immune response to SARS-CoV-2 during a 9-month follow-up period in which Omicron was the predominant variant in Brazil. IgG for the SARS-CoV-2 spike protein (S) and nucleocapsid (N) proteins were analyzed in samples collected before and after the fourth dose. All participants were tested monthly for SARS-CoV-2 infection by RT-qPCR. The antibody response induced by the fourth dose of the coronavirus disease 2019 vaccine was evaluated and compared with the response induced by the

second and third doses. The additional antibody response to the viral S protein after the fourth dose was smaller than those after the third vaccine dose. In contrast, an increase in the N IgG levels could be observed after the fourth dose compared to other vaccine doses. In the comparison of the antibody response before and after the fourth dose, an increase in both S-and-N IgG was noted, mainly in the positive qPCR group. We did not observe a significant decline in IgG levels after the fourth dose, as observed after the second and third doses, therefore, a sustained humoral response to both S and N proteins seems to be achieved.

Symptom flares after COVID-19 infection versus vaccination among youth with PANS/PANDAS. Background: Flares of autoimmune conditions can happen after coronavirus disease 2019 (COVID-19) infection and after COVID-19 vaccines. Patients and clinicians confront difficult decisions about vaccine safety when considering efforts to balance the risks of disease exacerbation after vaccines versus the protection that vaccines offer to potential serious life-threatening complications of COVID-19 infection. Objective: To examine symptom flares after COVID-19 infection and vaccines in the case of a form of autoimmune encephalitis that primarily affects children and young adults (pediatric acute-onset neuropsychiatric syndrome [PANS] / pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections [PANDAS]). Method: A cross-sectional study that used a survey distributed through PANS/PANDAS groups, organizations, and clinics. Results: Surveys were completed by 496 parents and/or caregivers of children with PANS/PANDAS. Among the children reported to have had a COVID-19 infection (n = 178), 43% reported severe flares of PANS/PANDAS symptoms, 23% reported mild flares, and 30% reported no symptom flares. Among those who had received COVID-19 vaccines (n = 181), 65% observed no changes in PANS/PANDAS symptoms after the vaccine, 19% reported mild flares, and 15% reported severe flares. Paired sample t-tests showed that, after COVID-19 infections, children with PANS/PANDAS were significantly more likely to experience a severe symptom flare than a mild flare or no change in symptoms. In contrast, after receiving COVID-19 vaccines, children were significantly more likely to experience no change in PANS/PANDAS symptoms than to endure a mild or severe symptom flare. In addition, children who recovered from PANS/PANDAS were significantly more likely to have no symptom change versus children who were managing the condition, both after COVID-19 infection (92% versus 25%) and vaccine receipt (100% versus 66%). Conclusion: These results support COVID-19 vaccination for most individuals with PANS/PANDAS given that the frequencies of symptom flares and setbacks after COVID-19 infection were significantly higher than after the COVID-19 vaccine. Nonetheless, further studies are needed to fully assess the risk-benefit balance and to provide a more individualized approach to disease prevention in people with immune vulnerabilities.

Comparison of bivalent and monovalent SARS-CoV-2 variant vaccines: the phase 2 randomized open-label COVAIL trial. Vaccine protection against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection wanes over time, requiring updated boosters. In a phase 2, open-label, randomized clinical trial with sequentially enrolled stages at 22 US sites, we assessed safety and immunogenicity of a second boost with monovalent or bivalent variant vaccines from mRNA and protein-based platforms targeting wild-type, Beta, Delta and Omicron BA.1 spike antigens. The primary outcome was pseudovirus neutralization titers at 50% inhibitory dilution (ID(50) titers) with 95% confidence intervals against different SARS-CoV-2 strains. The secondary outcome assessed safety by solicited local and systemic adverse events (AEs), unsolicited AEs, serious AEs and AEs of special interest. Boosting with prototype/wild-type vaccines produced numerically lower ID(50) titers than any variant-containing vaccine against all variants. Conversely, boosting with a variant vaccine excluding prototype was not associated with decreased neutralization against D614G. Omicron BA.1 or Beta monovalent vaccines were nearly equivalent to Omicron BA.1â€‰+â€‰prototype or Betaâ€‰+â€‰prototype bivalent vaccines for neutralization of Beta, Omicron BA.1 and Omicron

BA.4/5, although they were lower for contemporaneous Omicron subvariants. Safety was similar across arms and stages and comparable to previous reports. Our study shows that updated vaccines targeting Beta or Omicron BA.1 provide broadly crossprotective neutralizing antibody responses against diverse SARS-CoV-2 variants without sacrificing immunity to the ancestral strain. ClinicalTrials.gov registration: NCT05289037 .

Immunogenicity of COVID-19 vaccines in lung cancer patients. OBJECTIVE: Patients with lung cancer are at increased risk of SARS-CoV-2 infection and severe complications from COVID-19, but information on the efficacy of anti-SARS-CoV-2 vaccine in these patients is scarce. We aimed at evaluating the safety and immunogenicity of COVID-19 vaccines in this population. PATIENTS AND METHODS: The prospective, nationwide SOLID substudy, enrolled adults with lung cancer who were fully vaccinated against COVID-19. Serum anti-SARS-CoV-2 IgG antibody levels were quantitatively assessed two weeks and six months after receipt of the last dose using a chemiluminescent microparticle immunoassay. Multivariate odds ratios for the association between demographic and clinical factors and seronegativity after vaccination were estimated. RESULTS: 1973 lung cancer patients were enrolled. Most patients had stage IV disease (66%) and were receiving active cancer treatment (82.7%). No significant differences were found in the probability of being seronegative for anti-SARS-CoV-2 IgG antibodies after full vaccination between patients who were receiving active cancer treatment and those who were not (pÂ =Â 0.396). The administration of immunotherapy or oral targeted therapy and immunization with mRNA-1273 COVID-19 vaccine were factors independently associated with increased odds of being seropositive after vaccination. From all patients, 1405 received the second dose of vaccine and high levels of antibody titers were observed in 93.6% of patients two weeks after second dose. At six months, multivariate logistic regression analysis showed that performance statusÂ â‰¥Â 2 was independently associated with a higher probability of being seronegative after full vaccination with an OR 4.15. On the other hand, received chemotherapy or oral target therapy and vaccination with mRNA-1273 were a factor independently associated with lower odds of being seronegative after full vaccination with an OR 0.52, 0.37 and 0.34, respectively. CONCLUSIONS: Lung cancer patients can safely achieve a strong immune response against SARS-CoV-2 after full vaccination, regardless of the cancer treatment received. TRIAL REGISTRATION: NCT04407143.

Dermatological manifestations associated with COVID-19 and COVID-19 vaccination: results from the Lebanese COVID registry. BACKGROUND: A number of cutaneous manifestations and adverse cutaneous reactions have been associated with COVID-19 infection and vaccine. OBJECTIVES: A Lebanese national registry was established to characterize the dermatologic manifestations and adverse cutaneous reactions associated with COVID-19 infection and vaccination in a sample of the Lebanese population. METHODS: An observational cross-sectional study was conducted via a web-based clinical form distributed to physicians wishing to report their cases from May 2021 till May 2022. RESULTS: In total, 142 patients were entered in the registry, of which 133 were adults and nine were pediatric patients. The main dermatological manifestations reported with COVID-19 infection in the adult group were urticaria (32.9%), telogen effluvium (21.4%), morbilliform (10%), and papulosquamous (8.6%) eruptions. Urticaria was the most common adverse cutaneous reaction to the vaccine (33%). Interestingly, herpes zoster was triggered in 12 patients post vaccination in our series with this finding more frequently seen in patients above the age of 41 (Pâ€‰=â€‰0.013). In the pediatric group, the most reported dermatological findings associated with COVID-19 infection were malar erythema (25%) and telogen effluvium (25%). One 16-year-old patient developed lichen planus after one dose of a COVID-19 vaccine. No deaths were reported in both age groups. CONCLUSION: This Lebanese registry adds more robust evidence that clinical manifestations of the

COVID-19 virus and vaccine are diverse. More studies are necessary to establish the pathophysiology of these dermatological findings in the context of COVID-19 infection and vaccination.

Impact of inactivated COVID-19 vaccination on female ovarian reserve: a propensity score-matched retrospective cohort study. PURPOSE: To explore the impact of inactivated COVID-19 vaccination on ovarian reserve as assessed by serum anti-MÃ¼llerian hormone (AMH) concentration. METHODS: A total of 3160 women were included in this single-center retrospective cohort study between June 2021 and October 2022. Vaccination information were collected from official immunization records available in personal mobile apps. Serum AMH was qualified by electrochemiluminescence immunoassay and compared with previous measurement data within three years. Women were categorized to the vaccinated group if they received two doses of inactivated COVID-19 vaccines (Sinopharm or Sinovac) between AMH tests (n = 488), and to the control group if not vaccinated (n = 2672). Propensity score matching and multivariate linear regression were performed to control for potential confounders. The main outcome measures were the numeric AMH change and percentage AMH change between the two tests. RESULTS: There were 474 women left in each group after matching all baseline characteristics. The mean interval from the first to second AMH measurement was 508.0 Â± 250.2 and 507.5 Â± 253.6 days for vaccinated and unvaccinated women, respectively (P = 0.680). Both groups had a significant AMH decrease in the second test compared with the first test (P = 0.001). However, the second AMH level remained comparable between groups (3.26 Â± 2.80 vs. 3.24 Â± 2.61 ng/mL, P = 0.757). Similarly, no significant differences were observed in numerical (-0.14 Â± 1.32 vs. -0.20 Â± 1.56 ng/mL, P = 0.945) and percentage (2.33 Â± 58.65 vs. 0.35 Â± 48.42%, P = 0.777) AMH changes. The results were consistent in sub-analyses for women aged <35 and â‰¥35 years. There were also no significant differences when vaccinated women were divided according to the time interval after vaccination: â‰¤30, 31-60, 61-90, and â‰¥91 days. CONCLUSION: Our study provides the first evidence that inactivated COVID-19 vaccination has no measurable detrimental effect on ovarian reserve, regardless of female age and vaccination interval. This reassuring finding adds to the safety evidence of COVID-19 vaccine in fertility, and should be useful to promote vaccine acceptance. Multicenter prospective cohort studies are needed to validate our conclusion.

COVID-19 Vaccine Associated with Cutaneous Involvement: Correspondence. How to cite this article: Mungmunpuntipantip R, Wiwanitkit V. COVID-19 Vaccine Associated with Cutaneous Involvement: Correspondence. Indian J Crit Care Med 2023;27(8):599.

The Number of Neurological Side Effects of SARS-CoV-2 Vaccinations is Increasing.

Knowledge, attitudes, concern, behaviors, and barriers associated with the readiness to receive seasonal influenza vaccine among healthcare workers in oncology setting during the COVID-19 pandemic. This study examines the knowledge, attitudes, concerns, behaviors, and barriers related to seasonal influenza vaccination among healthcare workers (HCWs) in the oncology setting during the COVID-19 pandemic. The objective is to assess the readiness of HCWs to receive the influenza vaccine. A cross-sectional study was conducted at the King Hussein Cancer Center (KHCC) in Amman, Jordan. HCWs were surveyed using a self-administered web-based questionnaire between October 2021 and November 2021. Among 223 participants, the coverage rates for seasonal influenza vaccination ranged from 65% to 81% during the autumns of 2019 and 2020, respectively. These vaccination rates showed a significant increase despite the challenges posed by the COVID-19 pandemic. Furthermore, 89.1% of the participants expressed their intention to receive the vaccine in the autumn of 2021. The analysis revealed a significant association between receiving the influenza vaccine in 2020 and the participants' work experience (Pâ€‰<â€‰.001, respectively). Additionally, receiving the influenza vaccination was significantly associated with higher knowledge levels (Pâ€‰=â€‰.036, 0.015). Although knowledge about the influenza vaccine was generally high, concerns and barriers were identified. This study demonstrates a high rate of influenza vaccination

among HCWs during the COVID-19 pandemic. The participants also expressed a strong willingness to receive the vaccine in the post-pandemic season and exhibited good knowledge about it. However, concerns and barriers related to vaccination remain. These findings emphasize the importance of addressing these concerns and barriers to further enhance influenza vaccination rates among HCWs.

The prevalence and clinical course of shoulder injury related to vaccine administration (SIRVA) after COVID-19 vaccines in Dutch hospital workers. INTRODUCTION: Shoulder Injury Related to Vaccine Administration (SIRVA) is a rare disorder characterized by persistent shoulder pain and limited range of motion presenting within 48Â h after vaccine administration. With the widespread distribution of the COVID-19 vaccine, the incidence of SIRVA is expected to rise. This sudden rise in vaccine administration presents an ideal opportunity to estimate the prevalence of SIRVA and to better characterize SIRVA. OBJECTIVE: This study aims to investigate the prevalence of SIRVA following COVID-19 vaccine administration among hospital workers in the Netherlands. METHODS: A questionnaire was sent to all hospital workers from a single non-academic hospital in the Netherlands. Respondents who had active SIRVA complaints were invited for an outpatient orthopaedic clinic assessment. Data was collected on participant characteristics and physical examination including assessment of active and passive range of motion (ROM). An ultrasound was performed to identify potential abnormalities. RESULTS: 32 out of 981 (3.3%) respondents reported shoulder pain with limited ROM occurring within 48Â h after vaccine administration lasting for at least 7Â days. Of these 32 respondents with SIRVA, 18 (56.2%) still reported active symptoms at the time of the survey. Clinical examination of 13 (72.2%) respondents with active SIRVA complaints showed limited glenohumeral ROM, limitations in activities of daily living and injection site pain. Twelve out of thirteen (92.3%) respondents with active SIRVA complaints showed abnormalities of the soft-tissue of the shoulder on ultrasound. Physiotherapy was the most common treatment modality for persistent SIRVA complaints (38.9%). CONCLUSIONS: The prevalence of SIRVA is estimated at 3% in the adult working population. Signs and symptoms of SIRVA are variable in severity, localization and timing. Soft-tissue abnormalities is the most common clinical sign. This study contributes to clinician's knowledge on SIRVA, aiding in early recognition and treatment, which are imperative for prevention of persistent and severe shoulder pathology.

Immune responses and safety of COVID-19 vaccination in atypical hemolytic uremic syndrome patients in Taiwan. Atypical hemolytic uremic syndrome is a rare, life-threatening disorder which can be triggered by COVID 19 infection and COVID 19 vaccination then induce multiple organ failure. Our study is the first to evaluate immune responses to COVID-19 vaccination and safety in a cohort of patients in a local single-center study in Taiwan.. Results indicate that vaccines effectively shield aHUS patients from severe COVID-19 complications without significant safety concerns. A double booster dose for the third vaccine is essential for optimal efficacy. Anti-complement therapy did not influence vaccination effectiveness. Transplant aHUS patients had the lowest immune response titers, indicating a need for additional vaccine doses. Compared to healthcare workers, aHUS patients had poor T-cell responses. We noted a superior trend with mixed-type COVID-19 vaccinations in aHUS patients, while fixed-type mRNA demonstrated better results in healthcare workers. Our findings endorse COVID-19 vaccination as a potent strategy to safeguard aHUS patients from severe complications, emphasizing the importance of vigilant monitoring pre- and post-vaccination.

Optic Neuritis and Cranial Neuropathies Diagnosis Rates before Coronavirus Disease 2019, in the Initial Pandemic Phase, and Post-Vaccine Introduction. PURPOSE: To compare rates of diagnosis of neuro-ophthalmic conditions across the Coronavirus Disease 2019 (COVID-19) pandemic with pre-pandemic levels. DESIGN: Multicenter, retrospective, observational study. PARTICIPANTS: Patients seen for eye care between March 11, 2019, and December 31,Â 2021. METHODS: A multicenter electronic health record database, Sight Outcomes Research Collaborative (SOURCE), was queried for

new diagnoses of neuro-ophthalmic conditions (cranial nerve [CN] III, IV, VI, and VII palsy; diplopia; and optic neuritis) and new diagnoses of other ophthalmic conditions from January 1, 2016, to December 31, 2021. Data were divided into 3 periods (pre-COVID, pre-COVID vaccine, and after introduction of COVID vaccine), with a 3-year look-back period. Logistic regressions were used to compare diagnosis rates across periods. Two-sample z-test was used to compare the log odds ratio (OR) of the diagnosis in each period with emergent ocular conditions: retinal detachment (RD) and acute angle-closure glaucoma (AACG). MAIN OUTCOME MEASURES: Diagnosis rate of neuro-ophthalmic conditions in each study period. RESULTS: A total of 323 261 unique patients (median age 59 years [interquartile range, 43-70], 58% female, 68% White) across 5 academic centers were included, with 180 009 patients seen in the pre-COVID period, 149Â 835 patients seen in the pre-COVID vaccine period, and 164 778 patients seen in the COVID vaccine period. Diagnosis rates of CN VII palsy, diplopia, glaucoma, and cataract decreased from the pre-COVID period to the pre-vaccine period. However, the optic neuritis diagnoses increased, in contrast to a decrease in RD diagnoses (PÂ = 0.021). By comparing the diagnosis rates before and after widespread vaccination, all eye conditions evaluated were diagnosed at higher rates in the COVID vaccination period compared with pre-COVID and pre-vaccine periods. The log OR of neuro-ophthalmic diagnosis rates across every period comparison were largely similar to emergency conditions (RD and AACG, $P > 0.05$). However, the log OR of cataract and glaucoma diagnoses were different to RD or AACG ($P < 0.05$) in each period comparison. CONCLUSIONS: Neuro-ophthalmic diagnoses had a similar reduction in diagnosis rates as emergent eye conditions in the first part of the pandemic, except optic neuritis. After widespread COVID-19 vaccination, all ophthalmic diagnosis rates increased compared with pre-pandemic rates, and the increase in neuro-ophthalmic diagnosis rates did not exceed the increase in RD and AACG diagnosis rates. FINANCIAL DISCLOSURE(S): Proprietary or commercial disclosure may be found in the Footnotes and Disclosures at the end of this article.

Association between virus variants, vaccination, previous infections, and post-COVID-19 risk. OBJECTIVES: The SARS-CoV-2 Omicron variant has spread rapidly and has been the dominant variant since 2022. The course of acute infection, in a vaccinated population, with Omicron is milder compared with earlier variants. However, little is known about how the occurrence of long-term symptoms after Omicron infection compared with other variants is modulated by previous infections and/or vaccinations. METHODS: Participants of the DigiHero study provided information about their SARS-CoV-2 infections, vaccinations, and symptoms 12 or more weeks after infection (post-COVID-19 condition - PCC). RESULTS: Participants infected with wildtype SARS-CoV-2 had the highest PCC risk (adjusted odds ratio [aOR] 6.44, 95% confidence interval (CI): 5.49; 7.56), followed by participants infected with Alpha and Delta compared with the reference group (individuals infected with Omicron having received three or more vaccinations). Among those infected with a specific variant, the number of preceding vaccinations was not associated with a risk reduction for PCC, whereas previous infection was strongly associated with a lower PCC risk (aOR 0.14, 95% CI 0.07; 0.25). CONCLUSIONS: While infection with Omicron is less likely to result in PCC compared with previous variants, lack of protection by vaccination suggests a substantial challenge for the healthcare system during the early endemic period. In the midterm, the protective effects of previous infections can reduce the burden of PCC.

Vitiligo following the COVID-19 Vaccination and Infection.

Bullous Pemphigoid Developed after the COVID-19 Vaccine. A 91-year-old man presented with pruriginous tense blisters and erosions on the upper and lower extremities (Figures 1A and 1B). Mucous membranes were unaffected and Nikolsky's sign was negative. These lesions appeared 48 hours after the administration of the second dose of the Pfizer-BioNTech COVID-19 vaccine. The

patient had received the first dose of the same vaccine 23 days prior to the onset of lesions. He did not suffer from any other post-vaccination adverse effects.

Erythema Nodosum Induced by the Pfizer- BioNTech Vaccine. A 42-year-old man presented with a painful nodular dermatitis with 38.5Â°C fever and joint pain, which started overnight. The patient had taken the first dose of Pfizer-BioNTech (Comirnaty, INN-COVID-19 mRNA) vaccine 8 days ago. He denied any kind of recent infections, inflammatory conditions, malignancies, or drugs administration.

Use of adrenaline to manage suspected anaphylaxis following COVID-19 vaccination: An Australian retrospective cohort study. BACKGROUND: The rate of anaphylaxis following COVID-19 vaccinations is estimated to be 2-11 cases per million doses administered. However, adrenaline is occasionally used in individuals who are later diagnosed with immunisation stress-related responses, as their initial presenting signs and symptoms can appear similar to that of anaphylaxis. This study aims to describe the clinical profile of individuals who had received adrenaline following a COVID-19 vaccine and their subsequent revaccination outcomes. METHODS: We examined notifications of cases who had received adrenaline following a COVID-19 vaccine in New South Wales, Australia. The cases were classified into Brighton Collaboration Case Definition (BCCD) for anaphylaxis, their clinical presentation, management and subsequent revaccination outcomes were compared. RESULTS: From 22 February 2021 to 30 September 2021, there were 222 cases where adrenaline was administered. Of these, 32 (14 %) fulfilled Level 1 BCCD, 59 (27%) Level 2, 2 (1%) Level 3, 97 (44%) Level 4 and 32 (14 %) Level 5. The most commonly reported symptoms were sensation of throat closure (nÂ =Â 116, 52%), difficulty breathing (nÂ =Â 82, 37%) and nausea (nÂ =Â 55, 25 %). Of the 176 (79%) individuals who proceeded to further vaccination, 89 (51%) received the same vaccine formulation and only 14 (8%) experienced another allergic adverse event with 9 (5%) receiving adrenaline. CONCLUSION: Less than one in five individuals who received adrenaline met Level 1 BCCD criteria for anaphylaxis. Many reactions that were treated with adrenaline had little to no diagnostic certainty of anaphylaxis and in such cases repeat vaccination had a high likelihood of being tolerated. Increased awareness and education on objective signs and symptoms of anaphylaxis is required to ensure appropriate use of adrenaline.

Report from an ICT 2022 workshop on toxicology for Covid19 vaccines: Industry, regulatory and CRO perspectives. The Covid pandemic took the world by surprise in late 2019 and the need for rapid development of vaccines became paramount. The challenge was how to accelerate standard vaccine development times as much as possible. With knowledge of the genetic code of SARsCOV2, vaccine manufacturers throughout the world have risen to the challenge and several new vaccines were rapidly developed for emergency use. In March 2020, global Regulatory Authorities met to consider how to start early clinical trials and accept rolling submissions. Before use in clinical trials or any mass vaccination campaigns, the safety of the candidate vaccine needs to be evaluated. Non-clinical toxicology studies are required as an important part of vaccine safety evaluation. The extent of the toxicology evaluation prior to the start of clinical trials depended on several factors, including: the type of the candidate vaccine as well as already available supportive information with the candidate vaccine or similar vaccine types. For vaccine candidates with pre-existing data, this would save valuable time whilst a full toxicology evaluation was completed in parallel. For vaccines with more limited data, toxicology data was required before clinical development could start. This workshop examined the nonclinical toxicology studies for new Covid vaccines from the perspectives of: Vaccine manufacturers with different vaccine technologies, managing global regulatory submissions/responses; CROs, managing the urgency of conducting and reporting studies and supporting new players in the vaccine world; and Regulatory Authorities, in supporting the review process, juggling the need for safety and quality with mounting pressure to approve vaccines.

BA.1/BA.5 Immunogenicity, Reactogenicity, and Disease Activity after COVID-19 Vaccination in Patients with ANCA-Associated Vasculitis: A Prospective Observational Cohort Study. Emerging omicron subtypes with immune escape lead to inadequate vaccine response with breakthrough infections in immunocompromised individuals such as Anti-neutrophil Cytoplasmic Antibody (ANCA)-associated vasculitis (AAV) patients. As AAV is considered an orphan disease, there are still limited data on SARS-CoV-2 vaccination and prospective studies that have focused exclusively on AAV patients are lacking. In addition, there are safety concerns regarding the use of highly immunogenic mRNA vaccines in autoimmune diseases, and further studies investigating reactogenicity are urgently needed. In this prospective observational cohort study, we performed a detailed characterization of neutralizing antibody responses against omicron subtypes and provided a longitudinal assessment of vaccine reactogenicity and AAV disease activity. Different vaccine doses were generally well tolerated and no AAV relapses occurred during follow-up. AAV patients had significantly lower anti-S1 IgG and surrogate-neutralizing antibodies after first, second, and third vaccine doses as compared to healthy controls, respectively. Live-virus neutralization assays against omicron subtypes BA.1 and BA.5 revealed that previous SARS-CoV-2 vaccines result in an inadequate neutralizing immune response in immunocompromised AAV patients. These data demonstrate that new vaccination strategies including adapted mRNA vaccines against epitopes of emerging variants are needed to help protect highly vulnerable individuals such as AAV patients.

COPD-Related Mortality before and after Mass COVID-19 Vaccination in Northern Italy. BACKGROUND/OBJECTIVE: Little is known about the impact of the COVID-19 pandemic on mortality from COPD at the population level. The objective was to investigate COPD-related mortality throughout different epidemic waves in Italy before and after the vaccination campaign, which started in late December 2020 and initially targeted the population aged â‰¥80 years. METHODS: Death certificates of residents in Veneto (Northeastern Italy) aged â‰¥40 years between 2008 and 2021 were analyzed. Age-standardized morality rates were computed for death certificates with any mention of COPD. Generalized estimating equation (GEE) models were fitted to estimate the expected mortality during the pandemic. The results were stratified by age groups of 40-79 and â‰¥80 years, main comorbidities, and place of death. RESULTS: COPD was mentioned in 3478 death certificates in 2020 (+14% compared to the 2018-2019 average) and in 3133 in 2021 (+3%). Age-standardized mortality rates increased in all age and sex groups in 2020; in 2021, mortality returned to pre-pandemic levels among the elderly but not in the population aged 40-79 years (+6%). GEE models confirmed this differential trend by age. COPD-related mortality peaks were observed, especially in the first pandemic waves, with COVID-19 identified as the underlying cause of death in a relevant proportion (up to 35% in November 2020-January 2021). Mortality with comorbid diabetes and hypertensive diseases slightly increased during the pandemic. CONCLUSION: COPD-related mortality increased at the beginning of the pandemic, due to deaths from COVID-19. The start of the vaccination campaign was associated with an important decline in COPD-related mortality, especially among the elderly, who first benefited from COVID-19 vaccines. The study findings show the role of mass vaccination in reducing COPD-related deaths during the later phases of the pandemic.

Impact of a COVID-19 Outbreak in an Elderly Care Home after Primary Vaccination. Elderly care home residents are particularly vulnerable to COVID-19 due to immune-senescence, pre-existing medical conditions, and the risk of transmission from staff and visitors. This study aimed to describe the outcomes of a COVID-19 outbreak in a long-term care facility for elderly persons following the initial vaccination. A single-center, retrospective, observational design was used to analyze the variables associated with hospitalization and death rate by logistic regression. Adjusted odds ratios (aOR) and their 95% confidence intervals (CI) were calculated. Sixty-eight residents received the first dose of the COVID-19 vaccine. Despite being negative six days after vaccination, the performance of a

second test 4 days later revealed 51 positives (75.0%) among residents and 18 among workers (56.3%). A total of 65 of the 68 residents (95.58%) had positive results with symptoms, whereas 34.9% required hospitalization, and 25.8% died. The best-fitting model to explain the distribution of cases reflects three points at the time of infection.. The time from vaccination to symptom onset explains the hospitalization and mortality rates since a day elapsed halves the risk of hospitalization (aOR = 0.57; CI = 0.38-0.75) and the risk of death by a quarter (aOR = 0.74; CI = 0.63-0.88). Nursing homes present an elevated risk of transmission and severity of SARS-CoV-2 infection. Although vaccination reduces the risk of hospitalization and death, extreme prevention and control measures are essential in these institutions despite the high vaccination coverage.

COVID-19 Vaccination Actual Uptake and Potential Inequalities Due to Socio-Demographic Characteristics: A Population-Based Study in the Umbria Region, Italy. Socio-demographic factors are responsible for health inequalities also in vaccination. The aim of this study was to evaluate their role at the population level through a population-based study performed on the whole population entitled to receive COVID-19 vaccines in the Umbria Region, Italy, and registered to the Regional Healthcare Service as of 28 February 2021. Socio-demographic characteristics and vaccination status in terms of uptake of at least one dose of any available vaccine, completion of the primary vaccination cycle and uptake of the booster doses as of 28 February 2022 were collected from the Umbria regional database. The percentage of eligible population who did not initiate the COVID-19 vaccination, complete the full vaccination cycle and get the booster dose was 11.8%, 1.2% and 21.5%, respectively. A younger age, being a non-Italian citizen, and not holding an exemption for chronic disease/disability and a GP/FP were associated with all the endpoints. Females, as compared to males, were more likely to not initiate the vaccination but less likely to not receive the booster dose. On the contrary, the findings did not show a significant association between the deprivation index and the vaccine uptake. The findings, beyond confirming current knowledge at the population level, provide new inputs for better tailoring vaccination campaigns.

No Significant Association between 25-OH Vitamin D Status and SARS-CoV-2 Antibody Response after COVID-19 Vaccination in Nursing Home Residents and Staff. Vitamin D is an essential nutrient for various physiological functions, including immunity. While it has been suggested that higher vitamin D levels/supplementation are associated with a better immune response to COVID-19 vaccination, conflicting data exist. Therefore, we aimed to investigate the association between vitamin D (25-hydroxyvitamin D) deficiency/supplementation, and SARS-CoV-2 antibody responses post-vaccination in nursing home residents (NHRs) and staff (NHS). Blood samples were collected from 115 NHRs and 254 NHS at baseline and 14 days after primary course BNT162b2 vaccination. Baseline samples were assessed for serum 25-hydroxyvitamin D levels, while follow-up samples were analyzed for spike protein S1 receptor-binding domain (S1RBD) IgG antibody concentrations and 50% pseudoneutralization titers. Vitamin D supplementation status was obtained from NHRs medical records. We compared immune responses between (severe) vitamin D-deficient and -sufficient NHRs/NHS and between supplemented and non-supplemented NHRs, stratified for history of SARS-CoV-2 infection and participant type. No significant differences in either binding or neutralizing COVID-19 vaccine antibody response were found between groups. The prevalence of vitamin D deficiency (<20 ng/mL) was 45% (95% CI: 36-54%) among NHRs and 60% (95% CI: 54-66%) among NHS. Although we showed that vitamin D status may not be related to a better COVID-19 vaccine antibody response, addressing the high prevalence of vitamin D deficiency in the nursing home population remains important.

Factors Associated with Pneumonia in Patients Hospitalized with COVID-19 and the Role of Vaccination. Patients with COVID-19 can develop different forms of the illness with more or less severe symptoms. A 2-year retrospective cohort study was conducted to evaluate the factors

associated with the development of pneumonia in patients hospitalized with COVID-19 from March 2020 to February 2022. A total of 385 patients (59.0% males) with a mean age of 69.0 Â± 16.0 years were included. At hospital admission, 318 patients (82.6%) reported one or more comorbidities, namely 201 (52.2%) subjects were affected by hypertension, 98 (25.5%) type 2 diabetes, 84 (21.8%) obesity, 36 (9.4%) cancer, and 14 (3.6%) suffered from kidney disease and were being treated with dialysis, and 76 (19.7%) resulted in being vaccinated with a higher prevalence of BNT162b2 vaccine (15.0%). Pneumonia was diagnosed in 276 (71.7%) patients. Multivariate regression analysis showed that pneumonia in COVID-19 patients was positively associated with type 2 diabetes (OR 1.81; 95% CI 1.00-3.27), obesity (OR 2.52; 95% CI 1.27-4.98), and negatively with hypertension (OR 0.58; 95% CI 0.35-0.96). Vaccination against SARS-CoV-2 resulted in a strongly protective factor against the development of pneumonia in COVID-19 patients (OR 0.49; 95% CI 0.28-0.85).

Antibiotic Use Prior to COVID-19 Vaccine Is Associated with Higher Risk of COVID-19 and Adverse Outcomes: A Propensity-Scored Matched Territory-Wide Cohort. Background: Antibiotics may increase the risk of COVID-19 among non-vaccinated subjects via probable gut dysbiosis. We aimed to investigate whether antibiotics also affect the clinical outcomes of COVID-19 vaccine recipients. Methods: This was a territory-wide cohort study of 3,821,302 COVID-19 vaccine recipients (aged â‰¥ 18 years) with â‰¥2 doses of either BNT162b2 or CoronaVac. Exclusion criteria included prior COVID-19, prior gastrointestinal surgery, and immunocompromised status. The primary outcome was COVID-19 infection and secondary outcomes included COVID-19-related hospitalization and severe infection (composite of intensive care unit admission, ventilatory support, and/or death). Exposure was pre-vaccination antibiotic use (within 180 days of first vaccine dose). Covariates included age, sex, Charlson Comorbidity Index, and concomitant medication use. Subjects were followed from the index date (first dose vaccination) until outcome occurrence, death, an additional dose of vaccination, or 15 November 2022. Propensity score (PS) matching and a Poisson regression model were used to estimate the adjusted incidence rate ratio (aIRR) of outcomes with antibiotic use. Results: Among 342,338 PS matched three-dose vaccine recipients (mean age: 57.4 years; male: 45.1%) with a median follow-up of 13.6 months (IQR: 9.2-16.3), antibiotics were associated with a higher risk of COVID-19 infection (aIRR: 1.16;95% CI: 1.14-1.19), hospitalization (aIRR: 1.75;95% CI: 1.65-1.86), and severe infection (aIRR: 1.60; 95% CI: 1.21-2.11). Notably, antibiotic use was associated with a higher risk of severe infection and death among CoronaVac recipients (aIRR: 1.62 95% CI: 1.18-2.22 and aIRR: 2.70, 95% CI: 1.54-4.73 for the two secondary outcomes, respectively), but not BNT162b2 recipients. Conclusions: Pre-vaccination use of antibiotics was associated with a higher risk of COVID-19 infection, hospitalization, and severe disease outcomes.

Multimorbidity and Serological Response to SARS-CoV-2 Nine Months after 1st Vaccine Dose: European Cohort of Healthcare Workers-Orchestra Project. Understanding antibody persistence concerning multimorbidity is crucial for vaccination policies. Our goal is to assess the link between multimorbidity and serological response to SARS-CoV-2 nine months post-first vaccine. We analyzed Healthcare Workers (HCWs) from three cohorts from Italy, and one each from Germany, Romania, Slovakia, and Spain. Seven groups of chronic diseases were analyzed. We included 2941 HCWs (78.5% female, 73.4% â‰¥ 40 years old). Multimorbidity was present in 6.9% of HCWs. The prevalence of each chronic condition ranged between 1.9% (cancer) to 10.3% (allergies). Two regression models were fitted, one considering the chronic conditions groups and the other considering whether HCWs had diseases from â‰¥2 groups. Multimorbidity was present in 6.9% of HCWs, and higher 9-months post-vaccine anti-S levels were significantly associated with having received three doses of the vaccine (RR = 2.45, CI = 1.92-3.13) and with having a prior COVID-19 infection (RR = 2.30, CI = 2.15-2.46). Conversely, lower levels were associated with higher age (RR = 0.94, CI = 0.91-0.96), more time since the last vaccine dose (RR = 0.95, CI = 0.94-0.96), and multimorbidity (RR = 0.89, CI = 0.80-1.00).

Hypertension is significantly associated with lower anti-S levels (RR = 0.87, CI = 0.80-0.95). The serological response to vaccines is more inadequate in individuals with multimorbidity.

Eosinophilic Granulomatosis with Polyangiitis after mRNA-1273 SARS-CoV-2 Vaccine. During one of the worst global health crises, millions of people were vaccinated against SARS-CoV-2. In rare cases, new onset systemic inflammatory diseases were reported with temporal coincidence to the vaccination. We describe a case of severe Eosinophilic Granulomatosis with Polyangiitis (EGPA) in a young asthmatic woman, occurring after a second dose of the mRNA-1273 vaccine. She presented with multisystem EGPA with cardiac and central nervous system involvement, complicated by secondary immune thrombocytopenia (ITP). We review the reported cases of EGPA coinciding with SARS-CoV-2 mRNA vaccination. All potentially vaccine-related EGPA cases reported so far occurred within 14 days from immunization. EGPA is very rare with an incidence of 1:1,000,000 inhabitants, and the number of reported post-vaccination EGPA cases lies within the expected incidence rate for the period. While we cannot prove a causal relationship between the vaccine and EGPA onset, the temporal relationship with the vaccine immune stimulation is intriguing, in a disease occurring almost always in adults with asthma and/or chronic rhinosinusitis and driven by an aberrant Th2 lymphocyte activation with hypereosinophilia; nevertheless, cases of inflammatory diseases (IMIDs) emerging in the context of vaccination remain rare and the benefits of preventing severe COVID presentations with SARS-CoV-2 mRNA vaccines remain unquestionable.

The Effects of Vaccines on the Sequelae Rates of Recurrent Infections and the Severity of Pulmonary COVID-19 Infection by Imaging. Although vaccines have been shown to reduce the number of COVID-19 infection cases significantly, vaccine-related reactions, long COVID-19 syndrome, and COVID-19 infection following vaccination continue to be a burden on healthcare services and warrant further scientific research. The purpose of this study was to research the severity of pulmonary COVID-19 infection following vaccination and the sequelae rates of recurrent infections in vaccinated cases by imaging. Patients who underwent follow-up CTs at 1 month, 3 months, and 6 months in our hospital with a diagnosis of COVID-19 were scanned retrospectively. Furthermore, all essential information was gathered from patients' immunization records. The major findings of our study were: (1) sequelae were frequently observed in unvaccinated cases; (2) the correlation between vaccination status and the severity of sequelae was significant; (3) there was not any significant relationship between the vaccine type and the severity of sequelae; and (4) hematocrit, hemoglobin, and lymphocyte parameters may be used as predictors of sequelae rates. COVID-19 infection, although reduced in prevalence following the development of vaccines, still remains a public health concern because of reinfection. Vaccination not only appears to protect against primary infection, but also seems to reduce reinfection and sequalae rates following reinfection.

Pustular Eruption following COVID-19 Vaccination: A Narrative Case-Based Review. From the beginning of public vaccinations until the relaxation of COVID-19 measures, many case reports, case series and case-control studies have been published indicating cutaneous side effects of COVID-19 vaccination. Post-vaccination pustular eruption was reported as well, with a challenging differential diagnosis between pustular psoriasis, AGEP (acute generalized exanthematous pustulosis) and neutrophil pustular eruptions. We report a case of 56-year-old woman presented with acute generalized pustular flare up culminated 5 days after the second dose of BNT162b2(Pfizer) vaccination. She was diagnosed with pustular psoriasis flare and due to the regulating role of IL-1 in pustular psoriasis and in the cytokine storm observed in cases of COVID-19 postvaccination inflammation; we decided to treat the patient with an IL-1 antagonist, subcutaneous anakinra (100 mg daily) along with acitretin. One week later, after anakinra withdrawal, she presented a pustular psoriasis flare and a 7-day anakinra re-administration led to a satisfactory improvement in the skin lesions. We also reviewed the medical literature and found 28 case reports with pustular eruption

after the COVID-19 vaccination. We compared the patients reported, regarding sex, age, number of doses, post-vaccination period and vaccine brand, and compared those results with our patient. Finally, as indicated by our case and other cases with similarly treated pustular eruptions. targeted therapy to this cytokine imbalance such as anakinra (IL-1) antagonist can improve the clinical course of the patient.

Assessing the Influence of COVID-19 Vaccination Coverage on Excess Mortality across 178 Countries: A Cross-Sectional Study. The COVID-19 pandemic has had a devastating impact on global health, necessitating urgent and effective strategies to mitigate its consequences. Vaccination programs have been implemented worldwide to combat virus transmission and reduce the disease burden. This study aimed to investigate the relationship between COVID-19 vaccination coverage and all-cause excess mortality in 178 nations during the first two years of the pandemic. Multiple regression analysis, after adjusting for life expectancy at birth, confirmed a significant association between higher vaccination coverage and lower all-cause mortality rates ($\hat{I}^2$ = -106.8, 95% CI -175.4 to -38.2, p = 0.002). These findings underscore the importance of vaccination campaigns in reducing overall mortality during the COVID-19 pandemic. Evidence-based decision making and resource allocation can benefit from this information, facilitating the optimization of vaccination strategies for maximal impact on mortality reduction. Further research and continuous monitoring are crucial to understanding the long-term effects of vaccination coverage on population health in the ongoing pandemic.

Retinal Vein Occlusion after COVID-19 Vaccination-A Review. Background Retinal vein occlusion (RVO) occurring after COVID-19 vaccination has been reported worldwide. Such a sight-threatening condition occurring after COVID-19 vaccination is a menace to ophthalmic health. This article reviews current evidence related to post-COVID-19 vaccination RVO. Method A total of 29 relevant articles identified on PubMed in January 2023 were selected for review. Observation All cases presented to ophthalmologists with visual loss shortly after COVID-19 vaccination. Mean and median age were both 58. No sex predominance was observed. RVO was diagnosed from findings on dilated fundal examination and ophthalmic imaging. AstraZeneca and BNT vaccines accounted for most cases. Vascular risk factors, e.g., diabetes mellitus and hypertension, were common. Most laboratory tests requested came back unremarkable. Most patients responded well to standard treatment, except those with ophthalmic comorbidities. Visual prognosis was excellent on short-term follow-up. Discussion The causality between RVO and COVID-19 vaccination is undeterminable because of the nature of articles, heterogenous reporting styles, contradicting laboratory findings and co-existing vascular risk factors. Vaccine-induced immune thrombotic thrombocytopenia, retinal vasculitis and homocysteinaemia were proposed to explain post-vaccination RVO. Large-scale studies have demonstrated that the incidence of RVO following COVID vaccination is very low. Nevertheless, the effects of boosters on retinal vasculature and ophthalmic health are still unclear. Conclusions The benefits of COVID-19 vaccination are believed to outweigh its ophthalmic risks. To ensure safe vaccination, the prior optimisation of comorbidities and post-vaccination monitoring are important. COVID-19 vaccines (including boosters) should be offered with reasonable confidence. Further studies are warranted to elucidate the ophthalmic impact of vaccines.

Kinetics of SARS-CoV-2 Spike Antibodies after the Second and Third Dose of the BNT162b2 COVID-19 Vaccine and Association with Epidemiological Characteristics and Breakthrough Infection in a Cohort Study of Healthcare Workers. To prospectively study the kinetics of immune responses after immunization with the BNT162b2 mRNA COVID-19 vaccine and their association with epidemiological parameters and breakthrough infection (BI), we measured total (TAbs-WT) and neutralizing antibodies against wild-type (NAbs-WT) and Omicron (NAbs-O) SARS-CoV-2 spike proteins in healthcare workers (HCWs) after the second (4 and 8 months) and third dose (1 and 8 months).

Vaccinated HCWs (n = 486), with a median age (IQR) of 49 years (38-56), were included in this prospective cohort study. BI was observed 4 and 8 months after the second dose in 8/486 (1.6%) and 15/486 (3.1%) HCWs, respectively, and 1 and 8 months after the third dose in 17/486 (3.5%) and 152/486 (31.3%) HCWs, respectively. A comparison of immune responses 1 month after the third dose in vaccinated HCWs without a BI or with a BI in the next 7 months did not detect any statistically significant differences in the TAbs-WT (median (IQR): 16,611.0 (13,011.0) U/mL vs. 17,572.5 (14,501.0) U/mL, p = 0.529) and NAbs-WT (median (IQR): 96.5% (1.7) vs. 96.7% (1.9), p = 0.555). After infection, HCWs with a BI had significantly increased TAbs-WT levels at all time points compared to healthy HCWs. The findings of the present study indicate that antibody levels after three doses of the BNT162b2 vaccine are not directly associated with the possibility of a BI.

Antibody Kinetics after Three Doses of SARS-CoV-2 mRNA Vaccination in Patients with Inflammatory Bowel Disease. Background: The emergence of new SARS-CoV-2 variants calls for more data on SARS-CoV-2 mRNA vaccine response. Aims: We aimed to assess the response to a third mRNA vaccine dose against SARS-CoV-2 in inflammatory bowel disease (IBD) patients. Methods: This was a single-center, observational prospective study of IBD patients who received a third mRNA vaccine dose against SARS-CoV-2. Antibody titers were taken post-third-dose at one and three months using the Roche Elecsys anti-SARS-CoV-2-S enzyme immunoassay. Titers less than 0.8 units/mL were considered negative according to the manufactures. Titers between 0.8 units/mL and 250 units/mL were considered non-neutralizing. Titers greater than 250 units/mL were considered neutralizing. Results: Eighty-three patients were included, all of whom had detectable antibodies at 3 months post-third dose. A total of 89% showed neutralizing and 11% non-neutralizing titers. Participants with non-neutralizing titers were more likely to be on systemic corticosteroids (p = 0.04). Two participants seroconverted from negative to positive, whereas 86% with non-neutralizing titers boosted to neutralizing levels. Only one participant with neutralizing titers after a third dose had a decrease to a non-neutralizing level within 3 months. Conclusions: Our findings support the ongoing recommendations for additional doses in immunocompromised individuals. However, longitudinal studies with a greater-sized patient population are needed.

What Remains up to 7 Months after Severe and Moderate Pneumonia in Non-Vaccinated Patients with Long COVID? Results of a CT Study. BACKGROUND: There is a growing evidence of long-lasting lung changes after COVID-19. Our aim was to assess the degree of lung injury and evaluate the recovery process of 4-7-month-non-vaccinated convalescent patients discharged from hospital after moderate and severe COVID-19 pneumonia, who presented with symptoms of long-COVID. METHODS: On control lung CT after mean 5-month recovery period, we classified and determined the prevalence of residual radiological abnormalities in 39 symptomatic patients. To assess the advancement of the persisting changes we used the total severity score (TSS) and the chest CT score and then correlated the results with clinical data. RESULTS AND CONCLUSIONS: On follow-up CT images, 94.9% of patients showed persistent radiological abnormalities. The most frequent changes were ground-glass opacities (74.4%), reticular pattern (64.1%), fibrotic changes (53.8%), nodules (33.3%), bronchiectasis (15.4%), vascular enlargement (10.3%), and cavitation (5.1%). The median TSS score was 4.1 points (interquartile range 3), whereas the median of the chest CT score 5.4 points (interquartile range of 4.5). No significant differences were observed between sex subgroups and between the severe and moderate course groups. There were no association between both CT scores and the severity of the initial disease, indicating that, mean 5 months after the disease, pulmonary abnormalities reduced to a similar stage in both subgroups of severity.

Fetal Cardiac Hemodynamic and Sonographic Anomalies in Maternal COVID-19 Infection Depending on Vaccination Status-Polish Multicenter Cohort Study. Most obstetrical studies have focused on maternal response to the SARS-CoV-2 virus but much less is known about the effect of COVID-19 on

fetal physiology. We aimed to evaluate the effect of the maternal SARS-CoV-2 infection on the fetal homeostasis with the use of detailed ultrasonography and echocardiography and consideration of the effect of vaccination. This was a multi-center study of fetuses who had prenatal detailed ultrasound and echocardiographic examinations performed by fetal cardiology specialists. The subjects were divided based on the COVID vaccination status (vaccinated women who did not have COVID-group V, unvaccinated women who had COVID-group UV, and unvaccinated women who did not have COVID-control group). We evaluated the ultrasound and echocardiography results obtained. The study group included 237 gravidas from four prenatal cardiology centers. In the group of fetuses with normal heart anatomy, normal cardiovascular function had 147 (81%) fetuses and functional cardiovascular anomalies were present in 35 (19%) cases. Functional cardiovascular anomalies were present in 11 (16%) fetuses in the V group, 19 (47%) fetuses in the UV group and 5 (8%) fetuses in the control group ($p < 0.01$). There were 56 (24%) fetuses with extracardiac anomalies. Extracardiac anomalies were present in 20 (22%) fetuses in the V group, 22 (45%) fetuses of the UV group and in 14 (14%) fetuses in the control group ($p < 0.01$). Our study has proved that maternal COVID-19 infection can affect the fetal physiology and mild cardiac and extracardiac markers detected by fetal ultrasonography and echocardiography. Moreover, maternal vaccination results in lower occurrence of these findings in fetuses.

Association of Obesity with SARS-CoV-2 and Its Relationship with the Humoral Response Prior to Vaccination in the State of Mexico: A Cross-Sectional Study. Obesity is associated with an increased risk of contracting infections. This study aimed to estimate the risk of COVID-19 infection associated with obesity and to assess its role in the specific antibody response against SARS-CoV-2 in 2021. This study included 980 participants from the State of Mexico who participated in a serological survey where they were tested for SARS-CoV-2 IgG anti-S1/S2 and anti-RBD antibodies and asked for height, weight, and previous infection data via a questionnaire. Of the cohort of 980 participants, 451 (46.02%) were seropositive at the time of recruitment (45.2% symptomatic and 54.8% asymptomatic). The risk of SARS-CoV-2 infection with obesity was 2.18 (95% CI: 1.51-3.16), 2.58 (95% CI: 1.63-4.09), and 1.88 (95% CI: 1.18-2.98) for seropositive, asymptomatic, and symptomatic individuals, respectively, compared to those with normal weight. Anti-S1/S2 and anti-RBD IgG antibodies tended to be higher in overweight and obese participants in the seropositive group and stratified by different obesity classes. Additionally, there was a positive correlation between anti-S1/S2 and anti-RBD IgG antibodies and BMI in both men and women in the seropositive group. Obesity is an independent risk factor for SARS-CoV-2 infection when adjusted for confounding variables; however, the relationship between BMI and anti-S1/S2 and anti-RBD IgG antibody levels differed markedly in the presence or absence of symptoms.

Antibody response to SARS-CoV-2 vaccines in patients with relapsing multiple sclerosis treated with evobrutinib: A Bruton's tyrosine kinase inhibitor. BACKGROUND: Evobrutinib is an oral, central nervous system (CNS)-penetrant and highly selective covalent Bruton's tyrosine kinase inhibitor under clinical development for patients with relapsing multiple sclerosis (RMS). OBJECTIVE: To investigate the effect of evobrutinib on immune responses in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccinated patients with RMS from a Phase II trial (NCT02975349). METHODS: A post hoc analysis of patients with RMS who received evobrutinib 75 mg twice daily and SARS-CoV-2 vaccines during the open-label extension (n = 45) was conducted. Immunoglobulin (Ig)G anti-S1/S2-specific SARS-CoV-2 antibodies were measured using an indirect chemiluminescence immunoassay. RESULTS: In the vaccinated subgroup, mean/minimum evobrutinib exposure pre-vaccination was 105.2/88.7 weeks. In total, 43 of 45 patients developed/increased S1/S2 IgG antibody levels post-vaccination; one patient's antibody response remained negative post-vaccination and the other had antibody levels above the upper limit of detection, both pre- and post-vaccination. Most patients (n =

36/45), regardless of pre-vaccination serostatus, had a 10-100-fold increase of antibody levels pre- to post-vaccination. Antibody levels post-booster were higher versus post-vaccination. CONCLUSION: These results suggest evobrutinib, an investigational drug with therapeutic potential for patients with RMS, acts as an immunomodulator, that is, it inhibits aberrant immune cell responses in patients with RMS, while responsiveness to foreign de novo and recall antigens is maintained.

Axillary lymph nodes enlargement after Sars-CoV-2 vaccine in patients undergoing breast examination: a single-centre experience in 285 women. PURPOSE: To assess the incidence of axillary lymphadenopathy over established time ranges after COVID-19 vaccination and lymph node pathologic features (i.e. size increase and qualitative characteristics) in subjects undergoing axillary evaluation during a breast imaging examination. METHODS AND MATERIALS: The institutional review board approved this prospective study. INCLUSION CRITERIA: women undergoing mammography and breast ultrasound between July and October 2021; information about the COVID-19 vaccine and infection, if any. EXCLUSION CRITERIA: known metastatic lymphadenopathy. Participants were divided into 5 subgroups according to time between vaccine and imaging:â€‰<â€‰6Â weeks; 7-8Â weeks; 9-10Â weeks; 11-12Â weeks;â€‰>â€‰12Â weeks. Evaluation of axillary lymph nodes was performed with ultrasound. Descriptive statistical analysis was performed. pâ€‰<â€‰0.05 was considered significant. RESULTS: A total of 285 women were included. Most of the patients underwent Moderna vaccine (nâ€‰=â€‰175, 61.4%). 63/285 patients had a previous history of breast cancer (22.1%). 13/17 (76.5%) patients with previous COVID-19 infection had no previous history of cancer, whereas 4/17 had a previous history of cancer (pâ€‰<â€‰.001). 41/285 (14.4%) women showed lymphadenopathy, and they were significantly younger (46.9â€‰Â±â€‰11.6Â years) than women with borderline (54.0â€‰Â±â€‰11.9Â years) or no lymphadenopathy (57.3â€‰Â±â€‰11.9Â years) (pâ€‰<â€‰.001). Lymphadenopathy and borderline lymphadenopathy were more frequently observed in the Moderna-vaccinated women and in the subgroup of patients evaluatedâ€‰<â€‰6Â weeks after vaccination (pâ€‰<â€‰0.001). The most common pathologic feature was cortical thickening, followed by complete or partial effacement of fatty hilum. CONCLUSION: A lymphadenopathy within 12Â weeks after vaccination is a common finding particularly in younger women and after Moderna vaccine and no further assessment should be required.

Eruptive Pruritic Maculopapular Rash After Pfizer-BioNTech COVID-19 Vaccination: Challenge.

COVID-19 vaccination for patients with epilepsy: A Chinese expert consensus. Coronavirus disease-2019 (COVID-19) first emerged in late 2019 and has since spread worldwide. More than 600 million people have been diagnosed with COVID-19, and over 6 million have died. Vaccination against COVID-19 is one of the best ways to protect humans. Epilepsy is a common disease, and there are approximately 10 million patients with epilepsy (PWE) in China. However, China has listed "uncontrolled epilepsy" as a contraindication for COVID-19 vaccination, which makes many PWE reluctant to get COVID-19 vaccination, greatly affecting the health of these patients in the COVID-19 epidemic. However, recent clinical practice has shown that although a small percentage of PWE may experience an increased frequency of seizures after COVID-19 vaccination, the benefits of COVID-19 vaccination for PWE far outweigh the risks, suggesting that COVID-19 vaccination is safe and recommended for PWE. Nonetheless, vaccination strategies vary for different PWE, and this consensus provides specific recommendations for PWE to be vaccinated against COVID-19.

Rectal Administration of Leishmania Cells Elicits a Specific, Th1-Associated IgG2a Response in Mice: New Perspectives for Mucosal Vaccination against Leishmaniasis, after the Repurposing of a Study on an Anti-Viral Vaccine Candidate. The mucosal immune system plays a pivotal role in the control of infections, as it represents the first line of defense against most pathogens, from respiratory viruses to intestinal parasites. Mucosal vaccination is thus regarded as a promising strategy to protect

animals, including humans, from infections that are acquired by ingestion, inhalation or through the urogenital system. In addition, antigens delivered at the mucosal level can also elicit systemic immune responses. Therefore, mucosal vaccination is potentially effective also against systemic infections acquired through non-mucosal routes, for example, through the bite of hematophagous insects, as in the case of leishmaniasis, a widespread disease that affects humans and dogs. Here, we explored the potential of antigen rectal administration for the generation of anti-Leishmania immunity. Mice were immunized through rectal administration of whole cells of the model parasite Leishmania tarentolae (using a clone engineered to express the spike protein of the SARS-CoV-2 virus generated in a previous study). A specific anti-Leishmania IgG antibody response was detected. In addition, the recorded IgG2a/IgG1 ratio was higher than that of animals injected subcutaneously; therefore, suggesting a shift to a Th1-biased immune response. Considering the importance of a Th1 polarization as a protective response against Leishmania infections, we suggest that further investigation should be focused on the development of novel types of vaccines against these parasites based on rectal immunization.

Increased risk of Thyroid Eye Disease following Covid-19 Vaccination. CONTEXT: SARS-CoV-2 infection and Covid-19 vaccines have been associated with thyroid disorders. OBJECTIVE: We analyzed the risk of Thyroid Eye Disease (TED) following Covid-19 vaccination. DESIGN: Self-controlled case series study. SETTING: Tertiary referral center for TED. PARTICIPANTS: A total of 98 consecutive patients with newly-developed (Nâ€‰=â€‰92) or reactivated (Nâ€‰=â€‰6) TED occurring between January 1, 2021, and August 31, 2022. INTERVENTION: Assessment of TED in patients undergoing Covid-19 vaccination. MAIN OUTCOME MEASURES: Person-days were defined as exposed if TED occurred 1-28 days after vaccination, and unexposed if occurring outside such time-window. Conditional Poisson regression models were fitted to calculate incidence-rate-ratio (IRR), and 95% confidence-intervals (95%CI) of exposed vs unexposed. Sensitivity analyses were conducted considering different exposed periods and effect modification by potential TED risk factors. RESULTS: Covid-19 vaccines were administered in 81 subjects, 25 (31%) of whom developed TED in exposed, and 56 (69%) in unexposed periods. The IRR for TED was 3.24 (95%CI 2.01-5.20), and 4.70 (95%CI 2.39-9.23) in patients below 50 years of age. Sex, smoking, and radioiodine treatment did not modify the association between TED and vaccination. TED risk was unrelated to the number of vaccine doses, and progressively decreased over time following vaccination (P-trendâ€‰=â€‰0.03). CONCLUSIONS: The risk of TED was significantly increased after Covid-19 vaccination, especially in subjects below 50 years of age. Possible mechanisms include spike protein interaction with ACE-II receptor, cross-reactivity with thyroid self-proteins, and immune reactions induced by adjuvants. We suggest monitoring of individuals undergoing Covid-19 vaccination, especially if young and at risk for autoimmunity.

A case of hyperacute postvaccinal encephalopathy after BNT162b2 nCoV-19 vaccine. The global severe acute respiratory syndrome coronavirus 2 pandemic contributed to the development of a large variety of vaccines, of which postvaccinal hyperacute encephalopathy is a very rare complication. Despite its rarity, if diagnosed properly, appropriate treatment can be rapidly applied. A healthy 53-year-old woman was admitted for a seizure on the day she received the second dose of the BNT 162b2 nCoV-19 vaccine. She subsequently developed irritability, which gradually worsened over several days. Cerebrospinal fluid analysis revealed mild pleocytosis and normal protein levels. Brain magnetic resonance imaging (MRI) revealed diffuse sulcal hyperintensity on the entire brain surface on fluid-attenuated inversion recovery images with meningeal enhancement. The patient was diagnosed with hyperacute postvaccinal encephalopathy and received immunosuppressive therapy with corticosteroids and therapeutic plasmapheresis. Fortunately, the patient responded to therapy, achieving almost complete recovery from the neurological symptoms, with only mild memory

impairment remaining after 3 weeks. Based on the clinical presentation, electroencephalogram findings, and MRI, our patient developed hyperacute encephalopathy within 24 hours of vaccine administration, which we surmised from the temporal course of symptoms and brain imaging findings. Further studies are required to elucidate the pathogenesis of coronavirus disease 2019 vaccination-related encephalopathy.

Association of inactivated COVID-19 vaccination with maternal coagulation function in early pregnancy. Reports of rare but severe thrombotic events after receiving some COVID-19 vaccines brought concerns for the possibility of vaccine-induced coagulation abnormality. However, no study has reported the impacts of COVID-19 vaccination on coagulation function in pregnant women. We aimed to explore whether vaccination with inactivated COVID-19 vaccines before pregnancy was associated with coagulation changes in pregnant women. We conducted a retrospective cohort study in a tertiary-care hospital in Shanghai, China. A total of 5166 pregnant women were included, of whom 2721 (52.7%) completed vaccination before conception. Compared with unvaccinated women, the mean serum levels of prothrombin time (PT) and fibrinogen (FIB) were lower in vaccinated women by 0.09 (Î²â€‰=â€‰-0.09, 95% confidence interval [CI], -0.13, -0.05) mg/L and 0.11 (Î²â€‰=â€‰-0.11, 95% CI, -0.15, -0.07) mg/L, and the mean D-DimerÂ (D-D) levels were higher by 0.12 (Î²â€‰=â€‰0.12, 95% CI, 0.09, 0.15) mg/L. However, no significant association was observed between COVID-19 vaccination and serum levels of activated partial thromboplastin time (APTT), fibrinogen degradation product (FDP) or thrombin time (TT). Our findings suggested that inactivated COVID-19 vaccination before conception resulted in a small change in maternal coagulation function, but this might not have clinical significance.

Imaging Acute and Chronic Cardiac Complications of COVID-19 and after COVID-19 Vaccination. COVID-19 is associated with acute and longer-term cardiovascular manifestations including myocardial injury, myopericarditis, stress-induced cardiomyopathy, myocardial infarction, and thromboembolic disease. Although the morbidity and mortality related to acute COVID-19 have decreased substantially, there is growing concern about the longer-term cardiovascular effects of the disease and postacute sequelae. Myocarditis has also been reported after messenger ribonucleic acid (mRNA)-based COVID-19 vaccination, with the highest risk among adolescent boys and young adult men. Noninvasive imaging including cardiac MRI has a key role in identifying the presence of cardiovascular disease, evaluating for potential mechanisms of injury, stratifying risk of future adverse cardiovascular events, and potentially guiding treatment in patients with suspected cardiovascular injury after COVID-19 and vaccination. Patterns of injury identified at cardiac MRI after COVID-19 include myocarditis and pericarditis, myocardial ischemia, and infarction. Myocardial edema and late gadolinium enhancement have been described months after the initial infection in a minority of patients with persistent cardiac symptoms after COVID-19. In patients with myocarditis after receiving a COVID-19 vaccination, the most common pattern of late gadolinium enhancement is subepicardial at the basal inferolateral wall, and patients tend to have milder imaging abnormalities compared with those from other causes of myocarditis. This article describes the role of multimodality cardiac imaging and imaging findings in patients with acute and longer-term cardiovascular manifestations of COVID-19 and in patients with myocarditis after receiving an mRNA-based COVID-19 vaccination. (Â©)RSNA, 2023 Online supplemental material is available for this article. Quiz questions for this article are available through the Online Learning Center.

Lightning can strike twice: recurrent multiple evanescent white dot syndrome (MEWDS) following both COVID-19 vaccination and subsequent COVID-19 infection. Multiple evanescent white dot syndrome has been reported to occur following COVID-19 vaccination and also secondary to COVID-19 infection. Increasingly, patients are querying their risk from further vaccination against COVID-19, vaccination for other diseases (such as influenza) and the risk of disease with COVID-19 infection

itself. Here we report an interesting case in which the patient developed MEWDS following COVID vaccination, then, one year later, developed MEWDS in the fellow eye associated with COVID-19 infection.

Sustained and Boosted Antibody Responses in Breast Milk After Maternal SARS-CoV-2 Vaccination. Background: Pregnant and lactating women were not included in the initial large vaccine clinical trials for SARS-CoV-2 (COVID) infection. Delineating the antibody titers in serum and breast milk of lactating women is important to determine the safety and benefits of vaccination in this special population. Objective: To investigate COVID vaccinations in breastfeeding dyads and effects on lactation, the Antibody Detection of Vaccine-Induced Secretory Effects trial (ADVISE) prospectively evaluated anti-COVID antibodies in serum and breast milk after initial paired and booster vaccines. Methods: This is a prospective longitudinal surveillance cohort study of lactating women. Eligibility criteria included â‰¥18 years of age, currently lactating, and at enrollment either received COVID vaccination within the past 60 days or planning vaccination within 60 days. Results: Among 63 lactating mothers, COVID vaccination led to breast milk secretory IgA (sIgA) and IgG antibodies with consistent viral neutralizing activity. Milk sIgA titers increased further after second vaccination and were prolonged after a third booster dose, including women with extended breastfeeding beyond 12 months. Milk IgG antibody titers were higher and more sustained than sIgA. Antibody titers were not associated with individual dyad characteristics or vaccine manufacturer. Vaccine-induced antibodies from milk were not detected in infant circulation. Conclusions and Relevance: Maternal COVID vaccination during lactation is well tolerated and generates sustained and boosted antibody responses in breast milk. COVID-specific sIgA and IgG antibodies with neutralizing activity are found in breast milk, including boosted mothers who continue breastfeeding beyond 12 months. These data support universal COVID vaccinations for all lactating mothers, including booster immunizations during extended breastfeeding (NCT04895475).

Guillain-BarrÃ© Syndrome Following the Administration of Adenovirus Vector-Based COVID-19 Vaccine. As countries worldwide deployed their respective coronavirus disease 2019 (COVID-19) vaccination programs to mitigate the risk of COVID-19 to their citizens, several side effects and complications from the use of the various types of COVID-19 vaccines were documented and are continued to be monitored to further study the safety and efficacy of these vaccines. One such complication, the Guillain-BarrÃ© syndrome (GBS), was reported in some individuals who received a COVID-19 adenovirus vector-based vaccine. In this particular report, we describe one such case. The patient had diarrhea and fever one day after vaccination, which was a triggering event. Seven days post vaccination, the patient had bilateral symmetrical weakness with absent deep tendon reflexes. However, causality between the vaccine administered and the suspected adverse reaction cannot be readily assumed. The benefits and risk profiles of each available vaccine should be assessed continuously for it to be improved and truly useful in this pandemic. Thorough post-vaccination surveillance, along with national reporting mechanisms are needed to help establish and confirm possible links between GBS and adenovirus vector-based COVID-19 vaccines. This link needs to be probed further in prospective studies and clinical trials.

Single cell characteristics of patients with vaccine-related adverse reactions following inactivated COVID-19 vaccination. A good safety and immunogenicity profile was reported in Phase I and II clinical trials of inactivated SARS-CoV-2 vaccines. Here, we report two cases associated with vaccine-associated adverse events, including one patient with fever and another with anaphylactic shock resulting from inactivated SARS-CoV-2 vaccination. Cell sub-types and the importance of genetic characteristics were assessed using single-cell mRNA sequencing and machine learning. Overall, the patient with fever showed a significant increase in the numbers of cytotoxic CD8 T cells and MKI67(high) CD8 T cells. A potential concurrent infection with the Epstein-Barr virus enhanced

interferon type I responses to vaccination against the virus. STAT1, E2F1, YBX1, and E2F7 played a key role in the transcription regulation of MKI67(high) CD8 T cells. In contrast, the patient with allergic shock displayed predominant increases in the numbers of S100A9(high) monocytes, activated CD4 T cells, and PPBP(high) megakaryocytes. The decision tree showed that LYZ and S100A8 in S100A9(high) monocytes contributed to the degranulation of neutrophils and activation of neutrophils involved in allergic shock. PPBP and PF4 were major contributors to platelet degranulation. These findings highlight the diversity of adverse reactions following inactivated SARS-CoV-2 vaccination and show the emerging role of cellular subtypes and central genes in vaccine-associated adverse reactions.

 The identification of cell sub-types may help in the diagnosis of COVID-19 vaccine-related adverse events.COVID-19 vaccination-related acute pulmonary edema may induce a higher risk of thrombosis.The long-term fever after vaccination may attribute to the excessive type I interferon responses.

Lessons Learnt from Case Series of Out-of-hospital Cardiac Arrest and Unexpected Death after COVID-19 Vaccination. Vaccination against COVID-19 has raised concerns about myocarditis in young men, as out-of-hospital cardiac arrest (OHCA) or sudden death after vaccination has been reported sporadically. Common features of these cases are occurrence in young men, within a few weeks after vaccination, in patients with no structural heart diseases. Cases of unexplained nocturnal death showed fibrotic or hypertrophied myocardium, and one case of OHCA presented ventricular fibrillation (VF) triggered by a prominent J wave on an automated external defibrillator and histopathologic findings compatible with myocarditis. Both myocarditis and J waves are prevalent in young men, and these cases imply that myocarditis augments J waves, which trigger VFs, and primary electrical disorders are a leading cause of death. To prevent such issues, artificial intelligence (AI)-assisted interpretation of historical electrocardiogram findings may help predict future J wave formation leading to VF, as digital electrocardiogram (ECG) findings are well suited for AI interpretation.

Risk of Bell's palsy following SARS-CoV-2 infection: a nationwide cohort study. OBJECTIVES: Despite some evidence of an increased risk of neurologic symptoms following viral vector COVID-19 vaccine administration, it is unclear whether SARS-CoV-2 infection is associated with Bell's palsy (BP), especially over a long enough follow-up period. METHODS: The study population of this nationwide population-based study was derived from the South Korean population, including 11Â 593Â 365 and 36Â 565Â 099 participants with and without COVID-19, respectively. The Fine and Gray's regression model was utilized to calculate the adjusted subdistribution hazard ratio (aSHR), considering death as a competing risk, to assess the association between SARS-CoV-2 infection and the risk of BP. All participants were followed up from 1 December 2021, until the incident BP, SARS-CoV-2 infection, death, or 31 March 2022. Subgroup analyses were conducted based on participants' vaccination status (completion of the primary series vs. unvaccinated). RESULTS: COVID-19 was associated with an increased risk of BP in all participants (aSHR, 1.24; CI, 1.19-1.29). However, the size of the COVID-19-related BP risk was significantly lower among those who completed the primary series of the COVID-19 vaccine (aSHR, 1.20; 95% CI, 1.15-1.25) compared to those who were unvaccinated (aSHR, 1.84; 95% CI, 1.59-2.12; p for interaction: <0.001). The severity of COVID-19 exhibited a gradual escalation in BP risk for both vaccinated and unvaccinated individuals. DISCUSSION: While both unvaccinated individuals and those who completed the primary series of the COVID-19 vaccine may be at an increased risk of developing BP due to COVID-19, the risk appears to be lower among those who completed the vaccination.

Increased Incidence of Pediatric Uveitis Associated with the COVID-19 Pandemic Occurring Before COVID-19 Vaccine Implementation: A Time-Series Analysis. OBJECTIVE: To examine whether the COVID-19 pandemic was associated with an increased incidence of uveitis in children. STUDY DESIGN:

We performed a time-series analysis of patient records from a national, hospital-based, French surveillance system. All children hospitalized for uveitis in France between January 2012 and March 2022 were included. The incidence of newly diagnosed uveitis per 100â€ˆ000 children per trimester in France was analyzed by a quasi-Poisson regression. A cohort of children diagnosed with uveitis at Robert-DebrÃ© Hospital was used to compare the characteristics of uveitis after and before the onset of the pandemic. RESULTS: During the study period, 2492 children were hospitalized for uveitis in France. The COVID-19 pandemic, which started in March 2020, was associated with a significant increase in the occurrence of uveitis (estimated cumulative change, 44.9%; 95% CI 11.4-78.4; PÂ <Â .001). The increase in the incidence of pediatric uveitis started in October 2020, while the national immunization program targeting children aged less than 18Â years began in June 2021. This increase involved all forms of uveitis, regardless of location, and clincial characteristics were similar to those diagnosed before the pandemic. CONCLUSIONS: Our study evidenced a significant increase in the incidence of pediatric uveitis following the COVID-19 pandemic. This increase occurred 6Â months before the implementation of the national COVID-19 vaccination program for children, suggesting that the resurgence of this rare disease is independent of COVID-19 vaccination.

Guillain-BarrÃ© Syndrome and COVID-19 Vaccine: A Multicenter Retrospective Study of 46 Cases. In the context of the global vaccination campaign against COVID-19, several cases of postvaccinal Guillain-BarrÃ© syndrome (GBS) were reported. Whether a causal relationship exists between these events has yet to be established. We investigated the clinical and electromyographic characteristics of patients who developed GBS after COVID-19 vaccination and compare these with findings in patients with GBS, without a history of recent vaccination. We included 91 cases between March 2020 and March 2022, treated at 10 referral hospitals of Buenos Aires, Argentina. Of these, 46 had received vaccination against COVID-19 within the previous month. Although Medical Research Council sum-scores were similar in both groups (median 52 vs. 50; P = 0.4), cranial nerve involvement was significantly more frequent in the postvaccination group (59% vs. 38%; P = 0.02), as was bilateral facial paralysis (57% vs. 24%; P = 0.002). No differences were found in clinical or neurophysiological phenotypes, although 17 subjects presented the variant of bilateral facial palsy with paresthesias (11 vs. 6; P = 0.1); nor were significant differences observed in length of hospital stay or mortality rates. Future vaccine safety monitoring and epidemiology studies are essential to demonstrate any potential causal relationship between these events.

Pediatric asthma exacerbation and COVID-19 pandemic: Impacts, challenges, and future considerations. OBJECTIVE: Asthma, a common disease among children and adolescents, poses a great health risk when ignored; therefore, a thorough follow-up to prevent exacerbations is emphasized. The aim of the present study is to investigate asthma exacerbation in children during the Coronavirus disease 2019 (COVID-19) era. DATA SOURCES: This narrative review has been done by searching the PubMed and Embase databases using Asthma, COVID-19, Pandemic, and Symptom flare up as keywords. STUDY SELECTIONS: Studies related to asthma exacerbation in COVID-19 pandemic were included. RESULTS: Based on studies, controlled or mild to moderate asthma has not been considered a risk factor for COVID-19 severity and has not affected hospitalization, intensive care unit (ICU) admission, and mortality. Surprisingly, emergent and non-emergent visits and asthmatic attacks decreased during the pandemic. The three main reasons for decreased incidence and exacerbation of asthma episodes in the COVID-19 era included reduced exposure to environmental allergens, increasing the acceptance of treatment by pediatrics and caregivers, and decreased risk of other respiratory viral infections. Based on the available studies, COVID-19 vaccination had no serious side effects, except in cases of uncontrolled severe asthma, and can be injected in these children. Also, there was no conclusive evidence of asthma exacerbation after the injection of COVID-19 vaccines. CONCLUSION: Further studies are recommended to follow the

pattern of asthma in the post-pandemic situation and to become prepared for similar future conditions.
A review of China's compensation program for adverse reactions following immunization. Vaccination is a compelling measure to battle infectious diseases and protect public health. However, because of the constraints on human cognition, it is difficult to ensure that vaccines are safe. Adverse reactions to immunization can cause individual injury. In numerous countries, no-fault programs have been established to compensate individuals for vaccine-related injuries. China also established a vaccine injury compensation system with its own unique characteristics. The Vaccine Administration Law was promulgated in 2019 to establish a compensation system for those who experience adverse reactions following immunization; nevertheless, the compensation system is imperfect. Even when the applicable terms are applied to deal with vaccine-related injuries, some issues remain, such as unreasonable diagnosis and evaluation procedures for adverse reactions, excessively strict standards regarding proof and inconsistent compensation standards across the country. Therefore, to provide effective compensation for vaccine recipients, it is important to clarify the standards of proof and establish a sensible vaccine injury compensation system that includes Corona Virus Disease 2019 vaccine-injury compensation.
COVID-19 vaccine confidence in the post-vaccination era: Perceptions among adults with immune-mediated inflammatory diseases. OBJECTIVE: Assess the perceived protection afforded by a range of COVID-19 vaccines in immune-mediated inflammatory diseases patients previously vaccinated against SARS-CoV-2. STUDY DESIGN: Survey. METHODS: On-line cross-sectional survey aimed at evaluating the perceived protection (and its determinants) afforded by a range of COVID-19 vaccines among immune-mediated inflammatory diseases previously vaccinated for COVID-19. RESULTS: Out of 493 eligible respondents who lived in Brazil, 397 (80.5%) were confident that their primary vaccination series would protect them against severe COVID-19. In multivariate analysis, only overlapping immune-mediated inflammatory diseases remained (negatively) associated with the perception of protection. CONCLUSIONS: No influence was found between COVID-19 vaccine types and the perception of protection after initial vaccinations.
Graves' disease after COVID mRNA vaccination for the first time diagnosed in adolescence-case report. Cause and effect relationship or simple coincidence? OBJECTIVES: Over the past 3 years, coronavirus disease 2019 with its worldwide spread has profoundly marked public health, therefore anti-COVID-19 vaccinations have been developed to prevent the dissemination of the disease. To date, 71 cases of Graves' disease (GD) after vaccination against SARS-Cov-2 were described in the adult population. Our goal is to present the first case in the paediatric population. CASE PRESENTATION: We present the first case of a 16-year-old adolescent girl who developed GD 6-7 weeks after the second dose anti-COVID-19 mRNA vaccine. Therapy with methimazole and propranolol was started, achieving normal thyroid function and negativity of thyroid autoantibodies at the time of therapy discontinuation after 8 months. CONCLUSIONS: This case shows that the development of GD after COVID-19 mRNA vaccination can occur also in the adolescent population. Nevertheless, the small number of cases of GD described so far, after many millions of vaccinations, makes it impossible to determine whether this is simple a coincidence or a cause. Further epidemiological data on the incidence of GD in the vaccination period compared to the previous period will be able to clearly define this question.
A rare encounter: Kikuchi-Fujimoto disease presenting atypically after BNT162b2 COVID-19 vaccination: a case report.
Three is better than two: humoral response in allogeneic HSCT after the third BNT162b2 SARS-CoV-2 mRNA vaccine.

Prior cycles of anti-CD20 antibodies affect antibody responses after repeated SARS-CoV-2 mRNA vaccination. BACKGROUNDWhile B cell depletion is associated with attenuated antibody responses to SARS-CoV-2 mRNA vaccination, responses vary among individuals. Thus, elucidating the factors that affect immune responses after repeated vaccination is an important clinical need.METHODSWe evaluated the quality and magnitude of the T cell, B cell, antibody, and cytokine responses to a third dose of BNT162b2 or mRNA-1273 mRNA vaccine in patients with B cell depletion.RESULTSIn contrast with control individuals (n = 10), most patients on anti-CD20 therapy (n = 48) did not demonstrate an increase in spike-specific B cells or antibodies after a third dose of vaccine. A third vaccine elicited significantly increased frequencies of spike-specific non-naive T cells. A small subset of B cell-depleted individuals effectively produced spike-specific antibodies, and logistic regression models identified time since last anti-CD20 treatment and lower cumulative exposure to anti-CD20 mAbs as predictors of those having a serologic response. B cell-depleted patients who mounted an antibody response to 3 vaccine doses had persistent humoral immunity 6 months later.CONCLUSIONThese results demonstrate that serial vaccination strategies can be effective for a subset of B cell-depleted patients.FUNDINGThe NIH (R25 NS079193, P01 AI073748, U24 AI11867, R01 AI22220, UM 1HG009390, P01 AI039671, P50 CA121974, R01 CA227473, U01CA260507, 75N93019C00065, K24 AG042489), NIH HIPC Consortium (U19 AI089992), the National Multiple Sclerosis Society (CA 1061-A-18, RG-1802-30153), the Nancy Taylor Foundation for Chronic Diseases, Erase MS, and the Claude D. Pepper Older Americans Independence Center at Yale (P30 AG21342).

Measuring income-associated inequalities in COVID-19 vaccination on a global scale: a modeling study. Inequalities in the accessibility and utilization of quality, safe, and effective coronavirus disease 2019 (COVID-19) vaccines across and within countries limited their value in protecting health during the COVID-19 pandemic. We quantified cross-country, income-associated inequality in COVID-19 vaccination using statistical models based on the data for 79 countries through December 2021. We found notable inequality in vaccinations per capita. At least 11.9% of doses administered in high-income countries could be redistributed to low-income countries to substantially reduce income-associated inequality in vaccinations. The results of this modeling study indicate that reliance on multiple doses of vaccine to attain optimal protection from COVID-19 is a significant contributor to inequality in vaccinations per capita. Dose-sharing mechanisms should account for and include efforts to optimize the capabilities of health systems to deliver vaccines.

Omicron infection following vaccination enhances a broad spectrum of immune responses dependent on infection history. Pronounced immune escape by the SARS-CoV-2 Omicron variant has resulted in many individuals possessing hybrid immunity, generated through a combination of vaccination and infection. Concerns have been raised that omicron breakthrough infections in triple-vaccinated individuals result in poor induction of omicron-specific immunity, and that prior SARS-CoV-2 infection is associated with immune dampening. Taking a broad and comprehensive approach, we characterize mucosal and blood immunity to spike and non-spike antigens following BA.1/BA.2 infections in triple mRNA-vaccinated individuals, with and without prior SARS-CoV-2 infection. We find that most individuals increase BA.1/BA.2/BA.5-specific neutralizing antibodies following infection, but confirm that the magnitude of increase and post-omicron titres are higher in the infection-naive. In contrast, significant increases in nasal responses, including neutralizing activity against BA.5 spike, are seen regardless of infection history. Spike-specific T cells increase only in infection-naive vaccinees; however, post-omicron T cell responses are significantly higher in the previously-infected, who display a maximally induced response with a highly cytotoxic CD8+ phenotype following their 3(rd) mRNA vaccine dose. Responses to non-spike antigens increase significantly regardless of prior infection status. These findings suggest that hybrid immunity induced

by omicron breakthrough infections is characterized by significant immune enhancement that can help protect against future omicron variants.

Predictors of immune persistence induced by two-dose BBIBP-CorV vaccine in high-risk occupational population. BACKGROUND: The immune protection from infection may wane over time as neutralizing antibody levels decline. We aimed to develop a nomogram to predict long-term immune persistence induced by two-dose BBIBP-CorV vaccine and calculate the neutralizing antibody decline probability of individuals. METHODS: In the initial study, a total of 809 participants were recruited and randomly allocated (1:1:1) to vaccination group with three two-dose schedules on days 0 and 14, 0 and 21, or 0 and 28. The participants with neutralizing antibody titers of 16 or above on day 28 after the second dose were followed up at month 3, 6 and 10. Multivariable Cox proportional hazards regression model and nomogram model were used to identify predictors associated with maintaining of neutralizing antibody levels during 10Â months after the second dose. RESULTS: A total of 744 participants followed up at day 28 after the second dose. The participants with ageÂ â‰¥Â 50 (aHRÂ =Â 3.556, 95Â %CI: 1.141-4.884, PÂ =Â 0.028) were associated with a high risk of response loss (titersÂ <Â 16). The participants who were in 0-28Â d group (aHRÂ =Â 0.403, 95Â %CI: 0.177-0.919, PÂ =Â 0.031), had an influenza vaccination history (aHRÂ =Â 0.468, 95Â %CI: 0.267-0.921, PÂ =Â 0.033) or were female (aHRÂ =Â 0.542, 95Â %CI: 0.269-0.935, PÂ =Â 0.035) tended to maintain immune persistence during 10Â months after the second dose. The nomogram was constructed and showed moderate discrimination[C-index:0.711 (95Â %CI: 0.652-0.770); AUC: 0.731 (95Â %CI: 0.663-0.792)] and good calibration. CONCLUSIONS: From 28Â days to 10Â months after receipt of the second dose of the BBIBP-CorV vaccine, neutralizing antibody levels were substantially decreased, especially among men, among persons 50Â years of age or older, among persons with the 0-14Â d group, and among persons without history of influenza vaccination. TRIAL REGISTRATION: Chinese Clinical Trial Registry, ChiCTR2100041705, ChiCTR2100041706.

Neuro-ophthalmic complications of varicella-zoster virus. PURPOSE OF REVIEW: This review broadly describes recent neuro-ophthalmic manifestations of varicella-zoster virus (VZV) reported in literature. RECENT FINDINGS: Despite varicella vaccination, the incidence of herpes zoster continues to rise, potentially leading to devastating consequences when ocular complications occur.A small but growing literature documents cases of retinal disease because of varicella reactivation after SARS-CoV-2 vaccination, ischemic optic neuropathy occurring during herpes zoster ophthalmicus, VZV-induced orbital apex syndrome, and immune-mediated ocular complications in patients with prior neuro-ophthalmic manifestations of VZV. SUMMARY: It is important for clinicians to keep abreast of the diverse neuro-ophthalmic manifestations of VZV as early diagnosis and treatment often lead to better visual outcomes.

Ibuprofen, other NSAIDs and COVID-19: a narrative review. At the start of the coronavirus disease 2019 (COVID-19) pandemic (March 2020), there was speculation that non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, used to manage some of the symptoms of COVID-19, could increase the susceptibility to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and negatively impact clinical outcomes. In the absence of any robust mechanistic and clinical evidence, this speculation led to confusion about the safety of ibuprofen, contributing to the so-called 'infodemic' surrounding COVID-19. A wealth of evidence has been generated in subsequent years, and this narrative review aims to consider the body of in vitro and in vivo research, observational studies, systematic reviews and meta-analyses on the use of NSAIDs, including ibuprofen, in COVID-19. Overall, the direction of evidence supports that NSAIDs do not increase susceptibility to infection, nor worsen disease outcomes in patients with COVID-19. Neither do they impact the immune response to COVID-19 vaccines. There is no basis to limit the use of NSAIDs, and doing so may deprive patients of effective self-care measures to control symptoms.

Characteristics of headaches attributed to SARS-CoV-2 vaccination and factors associated with its frequency and prolongation: a cross-sectional cohort study. BACKGROUND: Headache is the most frequent neurological adverse event following SARS-CoV-2 vaccines. We investigated the frequency, characteristics, and factors associated with post-vaccination headaches, including their occurrence and prolongation (â‰¥ 48â€‰h). METHODS: In this observational cross-sectional cohort study, retrospective data collected between April 2021-March 2022 were analyzed. Univariate and multivariate logistic regressions were used to evaluate the effect of clinicodemographic factors on the odds of post-vaccination headache occurrence and prolongation. RESULTS: Of 2,500 people who were randomly sent the questionnaire, 1822 (mean age: 34.49â€‰Â±â€‰11.09, female: 71.5%) were included. Headache prevalence following the first (V(1)), second (V(2)), and third (V(3)) dose was 36.5, 23.3, and 21.7%, respectively (pâ€‰<â€‰0.001). Post-vaccination headaches were mainly tension-type (46.5%), followed by migraine-like (36.1%). Headaches were mainly bilateral (69.7%), pressing (54.3%), moderate (51.0%), and analgesic-responsive (63.0%). They mainly initiated 10â€‰h [4.0, 24.0] after vaccination and lasted 24â€‰h [4.0, 48.0]. After adjusting for age and sex, primary headaches (V(1): aOR: 1.32 [95%CI: 1.08, 1.62], V(2): 1.64 [1.15, 2.35]), post-COVID-19 headaches (V(2): 2.02 [1.26, 3.31], V(3): 2.83 [1.17, 7.47]), headaches following the previous dose (V(1) for V(2): 30.52 [19.29, 50.15], V(1) for V(3): 3.78 [1.80, 7.96], V(2) for V(3): 12.41 [4.73, 35.88]), vector vaccines (V(1): 3.88 [3.07, 4.92], V(2): 2.44 [1.70, 3.52], V(3): 4.34 [1.78, 12.29]), and post-vaccination fever (V(1): 4.72 [3.79, 5.90], V(2): 6.85 [4.68, 10.10], V(3): 9.74 [4.56, 22.10]) increased the odds of post-vaccination headaches. Furthermore, while primary headaches (V(1): 0.63 [0.44, 0.90]) and post-COVID-19 headaches (V(1): 0.01 [0.00, 0.05]) reduced the odds of prolonged post-vaccination headaches, psychiatric disorders (V(1): 2.58 [1.05, 6.45]), headaches lasting â‰¥48â€‰h following the previous dose (V(1) for V(2): 3.10 [1.08, 10.31]), and migraine-like headaches at the same dose (V(3): 5.39 [1.15, 32.47]) increased this odds. CONCLUSION: Patients with primary headaches, post-COVID-19 headaches, or headaches following the previous dose, as well as vector-vaccine receivers and those with post-vaccination fever, were at increased risk of post-SARS-CoV-2-vaccination headaches. Primary headaches and post-COVID-19 headaches reduced the odds of prolonged post-vaccination headaches. However, longer-lasting headaches following the previous dose, migraine-like headaches at the same dose, and psychiatric disorders increased this odd.

Despite delayed kinetics, people living with HIV achieve equivalent antibody function after SARS-CoV-2 infection or vaccination. The kinetics of Fc-mediated functions following SARS-CoV-2 infection or vaccination in people living with HIV (PLWH) are not known. We compared SARS-CoV-2 spike-specific Fc functions, binding, and neutralization in PLWH and people without HIV (PWOH) during acute infection (without prior vaccination) with either the D614G or Beta variants of SARS-CoV-2, or vaccination with ChAdOx1 nCoV-19. Antiretroviral treatment (ART)-naÃ¯ve PLWH had significantly lower levels of IgG binding, neutralization, and antibody-dependent cellular phagocytosis (ADCP) compared with PLWH on ART. The magnitude of antibody-dependent cellular cytotoxicity (ADCC), complement deposition (ADCD), and cellular trogocytosis (ADCT) was differentially triggered by D614G and Beta. The kinetics of spike IgG-binding antibodies, ADCC, and ADCD were similar, irrespective of the infecting variant between PWOH and PLWH overall. However, compared with PWOH, PLWH infected with D614G had delayed neutralization and ADCP. Furthermore, Beta infection resulted in delayed ADCT, regardless of HIV status. Despite these delays, we observed improved coordination between binding and neutralizing responses and Fc functions in PLWH. In contrast to D614G infection, binding responses in PLWH following ChAdOx-1 nCoV-19 vaccination were delayed, while neutralization and ADCP had similar timing of onset, but lower magnitude, and ADCC was significantly higher than in PWOH. Overall, despite delayed and differential kinetics, PLWH on ART

develop comparable responses to PWOH, supporting the prioritization of ART rollout and SARS-CoV-2 vaccination in PLWH.

Safety and immunogenicity of rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine against SARS-CoV-2 in healthy adolescents: an open-label, non-randomized, multicenter, phase 1/2, dose-escalation study. To protect young individuals against SARS-CoV-2 infection, we conducted an open-label, prospective, non-randomised dose-escalation Phase 1/2 clinical trial to evaluate the immunogenicity and safety of the prime-boost "Sputnik V" vaccine administered at 1/10 and 1/5 doses to adolescents aged 12-17 years. The study began with the vaccination of the older cohort (15-to-17-year-old participants) with the lower (1/10) dose of vaccine and then expanded to the whole group (12-to-17-year-old participants). Next, 1/5 dose was used according to the same scheme. Both doses were well tolerated by all age groups. No serious or severe adverse events were detected. Most of the solicited adverse reactions were mild. No significant differences in total frequencies of adverse events were registered between low and high doses in age-pooled groups (69.6% versus 66.7%). In contrast, the 1/5 dose induced significantly higher humoral and T cell-mediated immune responses than the 1/10 dose. The 1/5 vaccine dose elicited higher antigen-binding (both S and RBD-specific) as well as virus-neutralising antibody titres at the maximum of response (day 42), also resulting in a statistically significant difference at a distanced timepoint (day 180) compared to the 1/10 vaccine dose. Higher dose resulted in increased cross-neutralization of Delta and Omicron variants. CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, NCT04954092, LP-007632.

Factors associated with parental intention to vaccinate their preschool children against COVID-19: a cross-sectional survey in urban area of Jakarta, Indonesia. PURPOSE: We reported a survey-based study assessing the parental intention to vaccinate children of 5 to 7 years old against coronavirus disease 2019 (COVID-19). The aim of this study is to assess factors influencing the parental intention to vaccinate their children against COVID-19. MATERIALS AND METHODS: This study adopted a cross-sectional design, held at the public health center of Senen district, Jakarta, Indonesia from November 1-30, 2022. The off-line questionnaires were distributed via the school administrator to all eligible parents. Factors associated with intention to vaccinate were analyzed with the regression logistic models. RESULTS: Of the 435 parents in this study, 215 had already vaccinated their children against COVID-19 (49.4%), and the overall intention of the participants to vaccinate was 69.7%. Factors associated with intention to vaccinate the children against COVID-19 were parental employment status, parental COVID-19 vaccine status and concern of contracting COVID-19. Parents who are employed, had completed vaccines with COVID-19 booster vaccine, and had concern of their children contracting COVID-19 were more likely to vaccinate their children (odds ratio [OR], 2.10; 95% confidence interval [CI], 1.22-3.69; p=0.011; OR, 2.15; 95% CI, 1.21-3.83; p=0.013; OR, 2.40; 95% CI, 1.34-4.30; p=0.004, respectively). Concern on the vaccine's side effects was negatively associated with the willingness to vaccinate. CONCLUSION: This study showed that childhood COVID-19 vaccine only covered half of the population, with parental intentions for childhood COVID-19 vaccination being high, reaching almost two-thirds of the study participants. Factors influencing parental intentions were employment status, parental COVID-19 vaccine status, concerns about COVID-19 and concerns about vaccine side effects.

Is SARS-CoV-2 vaccination related Guillain-BarrÃ© syndrome really different from that due to other causes?

Anti-SARS-CoV-2 receptor binding domain antibodies after the second dose of Sinovac and AstraZeneca vaccination. PURPOSE: The Sinovac and AstraZeneca vaccines are the primary coronavirus disease 2019 vaccines in Indonesia. Antibody levels in vaccine-injected individuals will decline substantially over time, but data supporting the duration of such responses are limited.

Therefore, this study aims to quantitatively evaluate antibody responses resulting from the completion of Sinovac and AstraZeneca administration in Indonesian adults. MATERIALS AND METHODS: Participants were divided into two groups based on their vaccine type. Both groups were then assessed on the anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) receptor binding domain (anti-SRBD) concentrations. The anti-SRBD level was measured using Elecsys anti-SARS-CoV-2 S assay and analyzed every month until 3 months after the second vaccination. RESULTS: The results presented significant differences (p=0.000) in immunoglobulin G (IgG) titers among the vaccines' measurement duration, where all samples observed a decrease in IgG titers over time. The mean titer levels of anti-SRBD IgG in the group given Sinovac were high in the first month after vaccination and decreased by 55.7% in 3 months. AstraZeneca showed lesser immune response with a slower decline rate. Adverse effects following immunization (AEFI) showed that systemic reactions are the most reported in both vaccines, with a higher percentage in the second dose of AstraZeneca type vaccines. CONCLUSION: Sinovac induced more significant titers of anti-SRBD IgG 1 month after the second dose but generated fewer AEFIs. In contrast, AstraZeneca generated more AEFIs, in mild to moderate severity, but provided lower levels of anti-SRBD IgG.

Simultaneous administration of mRNA COVID-19 bivalent booster and influenza vaccines. The U.S. Food and Drug Administration authorized use of mRNA COVID-19 bivalent booster vaccines on August 31, 2022. Currently, CDC's clinical guidance states that COVID-19 and other vaccines may be administered simultaneously. At time of authorization and recommendations, limited data existed describing simultaneous administration of COVID-19 bivalent booster and other vaccines. We describe simultaneous influenza and mRNA COVID-19 bivalent booster vaccine administration between August 31-December 31, 2022, among persons aged â‰¥6Â months in the Vaccine Safety Datalink (VSD) by COVID-19 bivalent booster vaccine type, influenza vaccine type, age group, sex, and race and ethnicity. Of 2,301,876 persons who received a COVID-19 bivalent booster vaccine, 737,992 (32.1%) received simultaneous influenza vaccine, majority were female (53.1%), aged â‰¥18Â years (91.4%), and non-Hispanic White (55.7%). These findings can inform future VSD studies on simultaneous influenza and COVID-19 bivalent booster vaccine safety and coverage, which may have implications for immunization service delivery.

Immune response after SARS-CoV-2 vaccination in patients with inflammatory immune-mediated diseases receiving immunosuppressive treatment. BACKGROUND: Real world data on the response to the SARS-CoV-2 vaccine in patients with immunomediated diseases (IMIDs) treated with immunesuppressants is of great interest because vaccine response may be impaired. The main aim was to study the humoral and cellular immune response after SARS-CoV-2 vaccination in patients with IMIDs treated with immunosuppressants. The secondary aim was to describe the frequency of SARS-CoV-2 infections after vaccination in these patients. MATERIAL AND METHODS: This is an observational study including 86 patients with IMIDs. All patients were treated with biologic or targeted synthetic disease-modifying antirheumatic drugs [b/tsDMARDs: TNF inhibitors (TNFi), rituximab, anti-interleukin 6 receptor (anti-IL6R) or JAK inhibitors (JAKi)]. Demographic and clinical information were collected. After 4-6Â weeks of 2nd and 3rd vaccine doses, humoral response was assessed using the Thermo Scientific ELiA SARS-CoV-2-Sp1 IgG Test. Also, in patients with serum SARS-CoV-2 antibody levels under 100UI/ml, cellular response was analyzed using the QuantiFERON SARS-CoV-2 Starter Pack. RESULTS: A total of 86 patients under b/tsDMARDs and 38 healthy controls were included. Most patients received TNFi (45 with TNFi, 31 with rituximab, 5 with anti-IL6R and 5 with JAKi). SARS-CoV-2 antibodies (Ab) were present in an 86% of patients with IMIDs and in 100% healthy controls (pâ€‰=â€‰0.017). However, 12 (14%) patients had undetectable SARS-CoV-2 Ab levels, all treated with rituximab. In addition, SARS-CoV-2 Ab (IU/ml) were statistically lower in patients (Mdn (IQR): 59.5 (17-163) in patients vs 625 (405-932) in controls, pâ€‰<â€‰0.001).

Patients treated with rituximab had lower Ab levels than those treated with TNFi and controls (pâ€‰<â€‰0.001). The cellular response to SARS-CoV-2 vaccine was evaluated in 30 patients. Eleven patients had a positive cellular response, being more frequent in patients treated with rituximab (pâ€‰=â€‰0.03). SARS-CoV-2 infection was reported in 43% of patients and 34% of controls after vaccination. Only 6 (7%) patients required hospitalization, most of whom treated with rituximab (67%). CONCLUSION: SARS-CoV-2 antibody levels were lower in patients than in controls, especially in patients treated with rituximab. A cellular response can be detected despite having a poor humoral response. Severe infections in vaccinated patients with IMIDs are rare, and are observed mainly in patients treated with rituximab.

Post-COVID-19 vaccine uveitis: A case series. OBJECTIVE: With the recent emergence and worldwide distribution of COVID-19 vaccines, many side effects may be underreported and possibly unknown. Cases of vaccine-associated uveitis have been linked to almost all vaccines administered in the past; however, there is scarcity of literature providing insight into post-COVID-19 vaccine-associated uveitis. This case series documents patients presenting with uveitis after administration of the Pfizer and Moderna mRNA vaccines, in hope of advancing our current understanding of potential ocular complications of COVID-19 vaccines. METHODS: Patients with ocular symptoms consistent with uveitis within 14 days after administration of the Pfizer or Moderna COVID-19 vaccines were included in this case series. RESULTS: Eight patients with a mean age of 44.4 years (range, 19-83) were included. Six patients received a Pfizer, and 2 received a Moderna vaccine. Four patients presented after their first dose, 3 after their second dose, and 1 after both doses. The mean onset of ocular symptoms after the vaccine was 5.19 days (range, 1-14), and the mean BCVA was 0.678. Patients were diagnosed with bilateral anterior granulomatous uveitis (case 1), unilateral non-granulomatous anterior uveitis (case 2, 5-8), and bilateral non-granulomatous anterior uveitis (case 3-4). CONCLUSIONS: The pathogenesis of vaccine-induced uveitis is not properly understood; however, the outcomes of this case series will aid in establishing a temporal association between the Pfizer and Moderna COVID-19 vaccines and the onset of uveitis. As the rate of COVID-19 vaccinations increases globally, it is imperative for physicians to be aware of the possible association and presentation of these ocular findings and diagnoses in order to treat patients effectively.

Increased incidence of rheumatoid arthritis after COVID-19. An increase in the incidence of inflammatory arthritis after COVID-19 has been reported. Since many diseases exhibit population-specific causal effect sizes, we aimed to evaluate the incidence trends of inflammatory arthritis, including rheumatoid arthritis (RA), after COVID-19 in a large admixed Colombian population. Data analysis for this retrospective, population-based cohort study was carried out using the COOSALUD EPS registry. The following codes were selected for analyses: M059, seropositive RA, M069, unspecified RA, M060 seronegative RA, and other RA-related diagnoses: M064, M139, M068, M058, M130 and M053. The study period was limited to January 01, 2018, through December 31, 2022. Incidence rates (IRs) and incidence rate ratios (IRRs) were assessed. A Cox survival model was built to evaluate the influence of age, gender, and COVID-19 vaccination status on the development of inflammatory arthritis. A bioinformatic analysis was performed to evaluate the homology between SARS-CoV-2 and autoantigen peptides related to RA. The entire population study comprised 3,335,084 individuals. During the pandemic period (2020-2022) the total IIR for seropositive and unspecified RA were 1.60 (95% CI, 1.16-2.22) and 2.93 (95% CI, 2.04-4.19), respectively, and the IIR for overall RA-related diagnosis was 2.01 (95% CI 1.59-2.53). The age groups hazard ratios (HRs) were increased until the age group of 51-60Â years (HR: 9.16; 95% CI, 7.24-11.59) and then decreased slightly in the age group 61Â years or older (HR: 5.364; 95% CI, 4.24-6.78) compared to those within 18-30Â years. Men were less at risk than women to develop inflammatory arthritis (HR: 0.21; 95% CI, 0.18-0.24). The greater time since COVID-19 diagnosis was associated with a lower likelihood of

developing inflammatory arthritis (HR: 0.99; 95% CI:0.998-0.999). Vaccination (all types of COVID-19 vaccines included) did not prevent the development of inflammatory arthritis after COVID-19. Low identity was found between the SARS-CoV-2 ORF1ab antigen and the human antigens Poly ADP-ribose polymerase 14 and Protein mono-ADP-ribosyltransferase PARP9 isoform D (39% and 29%, respectively). In conclusion, our study confirms increased incidence of inflammatory arthritis, including RA, after COVID-19, with the greatest increase occurring before the first year post-covid. Women in their fifties were more susceptible. Further research is required to examine the effectiveness of vaccination in preventing post-COVID inflammatory arthritis and the mechanisms implicated in the development of RA after COVID-19.

The rates and symptoms of natural and breakthrough infection pre- and post- Covid-19 non-mRNA vaccination at various peaks amongst Iranian healthcare workers. BACKGROUND/AIMS: The aim of this study was to determine the rate of natural and breakthrough infection and related symptoms of Covid-19 amongst Iranian healthcare workers (HCWs) who were vaccinated by different non-mRNA-based vaccines at peak points. METHODS: In this cross-sectional study, the RT-PCR test was performed for a total of 10,581 HCWs suspicious of Covid-19 infection. For each HCW, the frequency of SARS-CoV-2 infection and the time of transmission based on vaccination administration time and schedule were examined during different waves of the pandemic. Based on these findings, the study patients were divided into three groups: natural, natural/breakthrough, and breakthrough. RESULTS: In total, 53% of the HCWs were exposed to SARS-CoV-2 infection between 1 and 5 times within two years after the current pandemic, while 20.7% and 32.3% experienced natural and breakthrough SARS-CoV-2 infection, respectively. Only 6% of the breakthrough-infected HCWs had naturally contracted SARS-CoV-2 infection during the initial waves. The highest natural peaks of infection occurred during the interval administration of the first and second dose of the first vaccination series, while the single highest peak of breakthrough infection belonged to the Omicron wave. It occurred simultaneously with the administration of the third vaccination dose. On the other hand, the highest rate of reinfection was observed amongst people who had received the Sinopharm and Bharat vaccines full-doses. CONCLUSION: This study compared the clinical differences between the two peaks of Omicron and Delta. This study indicates the rates of natural and breakthrough SARS-CoV-2 infections according to vaccination schedules and different waves of the pandemic.

Acute exacerbation of ocular graft-versus-host disease and anterior uveitis after COVID-19 vaccination. BACKGROUND: To report a case of simultaneous occurrence of acute exacerbation of ocular graft-versus-host disease (GVHD) and anterior uveitis following coronavirus disease 2019 (COVID-19) vaccination. CASE PRESENTATION: A 60-year-old man with primary myelofibrosis and GVHD after receiving allogeneic hematopoietic stem cell transplantation (HSCT), developed acute exacerbation of ocular GVHD and anterior uveitis after receiving first dose of COVID-19 vaccine. The patient developed erythema of the eyelids, conjunctival hyperemia, superficial punctate keratopathy, and prominent anterior chamber inflammation in both eyes. The ocular GVHD and anterior uveitis were managed with mainly topical corticosteroids, antibiotics, lubricants, and systemic corticosteroids, but were difficult to control. Intravitreal injection of dexamethasone was administered, and the inflammation gradually subsided 6 months after the onset of initial symptoms. CONCLUSIONS: Clinicians should be aware of rare refractory anterior uveitis and acute exacerbation of ocular GVHD after COVID-19 vaccination in patients undergoing HSCT. Early diagnosis and aggressive treatment should be considered to reduce the likelihood of severe complications.

SARS CoV-2 IgG seropositivity post-vaccination among dental professionals: a prospective study. BACKGROUND: The COVID-19 pandemic has spread very rapidly around the world. Various regional and national lockdowns were imposed to control the spread. Meanwhile, vaccine development and population vaccination were the next steps for pandemic control. Workers in the dental field, both

dentists and dental assistants, however, were close to the sources of aerosol generated during dental procedures and thus were the group of workers the most exposed to COVID-19 infection. The aim of our study was to monitor the immune response before and after the vaccine in a high-risk population, composed by dental professionals. METHODS: A clinical prospective study was carried out among dental professionals at the Academic Dental Polyclinic, Wroclaw Medical University (WrocÅ‚aw, Lower Silesia region, Poland). Blood samples were collected at an interval of one year - March/April 2020, before the vaccination against COVID-19, and April 2021, after the vaccination. The analysis was performed on serum with four different methods: qualitative, semi-quantitative, and quantitative IgG count for SARS-CoV-2, and SARS-CoV-2 neutralizing antibodies. RESULTS: A total of 42 healthy adult volunteers participated in the study. The results showed a statistically significant difference (pâ€‰<â€‰0.05) in antibody levels before and after vaccination (1st and 2nd measurement) for each test method. The tests that were used affected the results and the test that showed the strongest relationship with the result was the Qualitative test. CONCLUSIONS: Dental professionals are the adult working population most at risk for COVID-19. Monitoring SARS-CoV-2-status-related seropositivity can provide useful information occupational risk factors for dental professionals.

Characteristics of sudden hearing loss after different COVID-19 vaccinations: a systematic review and meta-analysis. INTRODUCTION: COVID-19 vaccines are essential to prevent complications and reduce the burden of SARS-CoV-2. However, these vaccines showed side effects such as fatigue, pain, fever, and rarely hearing loss. In this review, we aim to summarize studies investigating hearing loss following COVID-19 vaccination and try to find the possible association and risk factors for this hazardous complication. METHODS: We performed a comprehensive search of five electronic databases (PubMed, Scopus, Web of Science, google scholar, Cochrane) from inception until 9 October 2022. We finally included 16 studies after the first and second scans. We used SPSS to analyze the extracted data. RESULTS: A total of 630 patients were identified, with a mean age of 57.3. Of the patients, 328 out of 609 vaccinated patients took the Pfizer-BioNTech BNT162b2 vaccine, while 242 (40%) took the Moderna COVID-19 vaccine. The mean time from vaccination to hearing impairment was 6.2, ranging from a few hours to one month after the last dose. The results found a significant difference between vaccine types in terms of incidence and prognosis of the condition, while they showed that the number of doses prior to the onset had no significance. CONCLUSION: SNHL has been reported in a small number of people who have received the COVID-19 vaccine, but it is unclear at this time whether the vaccine is directly causing this condition. However, the COVID-19 vaccine has been demonstrated to be safe and effective in preventing illness, and the benefits of vaccination are significant compared to any potential risks. PROTOCOL REGISTRATION: The protocol of this study was registered on Prospero CRD42022367180.

Unilateral lymphoedema after a second dose of BNT162b2 COVID-19 mRNA vaccine.

Erratum: Predictors of Gross Hematuria After SARS-CoV-2 mRNA Vaccination in Patients with IgA Nephropathy.

A systematic review of the evidence on the associations and safety of COVID-19 vaccination and post COVID-19 condition. Post COVID-19 condition (PCC) refers to persistent or recurring symptoms (>8 weeks) occurring â‰¤12 weeks following acute COVID-19. The objective of this systematic review was to assess the evidence on the risk of PCC with vaccination before or after COVID-19 or after developing PCC, and the safety of vaccination among those already experiencing PCC. A search was conducted up to 13 December 2022 and standard systematic review methodology was followed. Thirty-one observational studies were included. There is moderate confidence that two doses of vaccine given pre-infection reduced the odds of PCC (pooled OR (pOR) 0.67, 95% CI 0.60-0.74, I2 = 59.9%), but low confidence that one dose may not reduce the odds (pOR 0.64, 95% CI

0.31#x2013;1.31, I2 = 99.2%), and the evidence is very uncertain about the effect of three doses (pOR 0.45, 95% CI 0.10#x2013;1.99, I2 = 30.9%). One of three studies suggested vaccination shortly after COVID-19 may offer additional protection from developing PCC compared to unvaccinated individuals, but this evidence was very uncertain. For those with PCC, vaccination was not associated with worsening PCC symptoms (10 studies) and appears safe (3 studies), but it is unclear if vaccination may change established PCC symptoms.

Homologous versus Heterologous prime-boost COVID-19 Vaccination in autologous hematopoietic stem cell transplantation recipients: a blinded randomized controlled trial.
BACKGROUND/PURPOSE: Optimizing vaccine efficacy is of particular concern in patients undergoing hematopoietic stem cell transplantation (HSCT), which mainly have an inadequate immune response to primary SARS-CoV-2 vaccination. This investigation aimed to explore the potential prime-boost COVID-19 vaccination strategies following autologous (auto-) HSCT. METHODS: In a randomized clinical trial, patients who had already received two primary doses of receptor-binding domain (RBD) tetanus toxoid (TT) conjugated SARS-CoV-2 vaccine during three to nine months after auto-HSCT were randomized to receive either a homologous RBD-TT conjugated or heterologous inactivated booster dose four weeks after the primary vaccination course. The primary outcome was comparing the anti-S IgG Immune status ratio (ISR) four weeks after the heterologous versus homologous booster dose. The assessment of safety and reactogenicity adverse events was considered as the secondary outcome. RESULTS: Sixty-one auto-HSCT recipients were recruited and randomly assigned to receive either homologous or heterologous booster doses four weeks after the primary vaccination course. The mean ISR was 3.40 (95% CI: 2.63- 4.16) before the booster dose with a 90.0% seropositive rate. The ISR raised to 5.12 (95% CI: 4.15- 6.08) with a 100% seropositive rate after heterologous (P= 0.0064) and to 3.42 (95% CI: 2.67- 4.17) with a 93.0% seropositivity after the homologous booster doses (P= 0.96). In addition, the heterologous group suffered more AEs following the booster dosage than the homologous group, but this difference was not statistically significant (p = 0.955). In multivariable analysis, the prime-boost vaccination strategy (heterologous versus homologous), the level of ISR before the booster dose, and the length of time between auto-HSCT and booster dose were the positive predictors of serologic response to a booster dose. No serious adverse event is attributed to booster vaccination. CONCLUSION: In patients who were primed with two SARS-CoV-2 vaccine doses during the first year after auto-HSCT, heterologous prime-boost COVID-19 vaccination with inactivated platform resulted in considerably enhanced serologic response and non-significantly higher reactogenicity adverse events than homologous RBD-TT conjugated prime-boost COVID-19 vaccination strategy.

Characteristics and factors associated with severity of COVID-19 infections in primary care.
INTRODUCTION: Primary care service plays a vital role in early clinical assessment of patients with COVID-19 in Malaysia. This study aimed to evaluate the potential risk factors of COVID-19 severity at presentation to primary care facilities in the post-vaccination period. METHOD: Clinical records from the Selangkah system of all patients with COVID-19 aged above 18 years seen at COVID-19 assessment centres located in 10 government health clinics in Gombak district, Selangor, from 1 October to 31 December 2021 with complete documentation and outcomes were retrieved. Demographics, comorbidities, clinical features and vaccination statuses and types were retrospectively evaluated. The variables were compared between mild and severe diseases. Univariate and multivariable logistic regressions were used to identify the factors affecting disease severity. RESULTS: A total of 4406 patients (median age=37 years, men=51.2%) were analysed. Approximately 97.1% of the cases were mild, while 2.9% were severe. Fever, difficulty breathing, lethargy, throat irritation/runny nose, oxygen saturation of <95%, respiratory rate of >20 breaths per minute, CoronaVac vaccination and hypertension were the determinants of severity (P<0.05).

CONCLUSION: The high proportion (97.1%) of mild cases in this study compared with an earlier report (81.8%) during the pre-vaccination period may suggest the impact of vaccine, as 84.9% of this cohort was fully vaccinated. Our study also demonstrated a significant difference in COVID-19 severity between the vaccine types. The identified clinical features and comorbidities could assist primary care doctors in stratifying patients with COVID-19 judiciously in terms of hospital referral or home quarantine.

Adverse reactions to cosmetic implants after COVID-19 vaccination: A literature review. BACKGROUND: As the world's population of people vaccinated with the COVID-19 vaccine increases, adverse reactions are increasingly being reported. There have been progressive reports of the effects of COVID-19 vaccination on cosmetic fillers or prostheses, but they have not been reviewed based on their clinical morphologic patterns. This article reviewed the progress of research on adverse reactions to cosmetic implants after COVID-19 vaccination. METHODS: We researched the English-language literature up to October 15, 2022, using predefined keywords to identify relevant studies about adverse reactions to cosmetic implants after the COVID-19 vaccination, collecting patient characteristics, implant type, the time interval between vaccination and implantation or injection, time of onset, symptoms, treatments, and outcomes. RESULTS: Among the adverse reactions to implants associated with COVID-19 vaccination, we distinguished between (1) injectable fillers and (2) surgical prosthetic implants. The most common adverse reactions were at the site of hyaluronic acid injection and breast prosthesis after Pfizer vaccination, mainly DIRs, and mainly manifested as edema, rash, fever, and capsular contracture. This paper also reported the possible causes, treatments of DIRs, and limitations of current studies. CONCLUSIONS: In this article, we attempted to investigate and discuss all the adverse reactions of cosmetic implants related to COVID-19 vaccination in the current literature, to unmask these reactions and make a more accurate assessment of vaccine safety.

Impacts of the COVID-19 pandemic on Chinese assisted reproductive technology institutions and human sperm banks: reflections in the post-pandemic era. OBJECTIVE: The COVID-19 pandemic has been the most serious public health emergency encountered in modern assisted reproductive technology (ART) development. In order to identify lessons learned, this study reviews the effect of the pandemic on ART institutions and human sperm banks in China, and summarizes the experiences and reflections of Chinese scholars post-pandemic era. METHODS: This review is based on multiple consensus statements on the COVID-19 pandemic issued by Chinese experts as well as current national regulations and principles in ART institutions and human sperm banks to document the current situation of ART services in China, describe the impact of the pandemic on these services, and offer Chinese reflections on worrying issues in the post-pandemic era. RESULTS: China reached one million ART cycles in 2016, and there are currently 540 ART medical institutions and 27 human sperm banks, with 540 licensed for AIH, 91 for AID, 415 for conventional IVF and ICSI and 85 for PGT. Of these, only 4 institutions carry out 10,000 cycles or more annually, and the proportion of institutions with less than 1,000 cycles has reached 66%, which means that a considerable number of ART institutions are still not saturated. As a consequence of the COVID-19 pandemic, 63.6% of ART providers and 95.5% of human sperm banks suspended operations. By the end of May 2020, China, as an early country affected by the pandemic achieved a national resumption rate of ART medical services of 99.2% and that of human sperm banks of 100.0%. Reports from the first and largest human sperm bank in China showed that qualification, semen concentration and sperm viability rates measured at primary screening have significantly decreased post-pandemic. Much like in other countries, Chinese experts developed a consensus on prevention and control measures during the pandemic. In principle, all ART activities should be suspended during acute phases of infection spread. Chinese scholars highlight that attention should be paid to young patients with fertility requirements

during and after COVID-19, and emphasize the importance of fertility evaluation and clinical intervention. In addition, couples should be reminded that during ART treatment, disinfectants should not be used excessively to minimize risks of damaging the reproductive system, gametes and zygotes. At the same time, timely and reasonable guidance for tackling negative emotions from stress response is needed to provide reassurance and to avoid irrational fear and excessive stress. Seminal parameters should be re-examined 2Â months after SARS-CoV-2 vaccination, and ART treatments recommenced if no abnormalities are detected. CONCLUSIONS: Given the growing frequency of outbreaks of global infectious diseases in recent years, ART institutions and human sperm banks should pay attention to improving their prevention and control capabilities. To a certain extent, decisions and measures adopted in China during COVID-19 pandemic are worthy of recognition and acceptance. Chinese scholars have discussed, proactively responded to and understand the key issues surrounding ART development during the pandemic with the aim of contributing to the substantial progress and healthy development of ART services in the world.

Kinetics of COVID-19 mRNA primary and booster vaccine-associated neutralizing activity against SARS-CoV-2 variants of concern in long-term care facility residents: a prospective longitudinal study in Japan. BACKGROUND: Coronavirus disease 2019 (COVID-19) remains a threat to vulnerable populations such as long-term care facility (LTCF) residents, who are often older, severely frail, and have multiple comorbidities. Although associations have been investigated between COVID-19 mRNA vaccine immunogenicity, durability, and response to booster vaccination and chronological age, data on the association of clinical factors such as performance status, nutritional status, and underlying comorbidities other than chronological age are limited. Here, we evaluated the anti-spike IgG level and neutralizing activity against the wild-type virus and Delta and Omicron variants in the sera of LTCF residents, outpatients, and healthcare workers before the primary vaccination; at 8, 12, and 24Â weeks after the primary vaccination; and approximately 3Â months after the booster vaccination. This 48-week prospective longitudinal study was registered in the UMIN Clinical Trials Registry (Trial ID: UMIN000043558). RESULTS: Of 114 infection-naÃ¯ve participants (64 LTCF residents, 29 outpatients, and 21 healthcare workers), LTCF residents had substantially lower anti-spike IgG levels and neutralizing activity against the wild-type virus and Delta variant than outpatients and healthcare workers over 24Â weeks after the primary vaccination. In LTCF residents, booster vaccination elicited neutralizing activity against the wild-type virus and Delta variant comparable to that in outpatients, whereas neutralizing activity against the Omicron variant was comparable to that in outpatients and healthcare workers. Multiple regression analyses showed that age was negatively correlated with anti-spike IgG levels and neutralizing activity against the wild-type virus and Delta variant after the primary vaccination. However, multivariate regression analysis revealed that poor performance status and hypoalbuminemia were more strongly associated with a lower humoral immune response than age, number of comorbidities, or sex after primary vaccination. Booster vaccination counteracted the negative effects of poor performance status and hypoalbuminemia on the humoral immune response. CONCLUSIONS: LTCF residents exhibited suboptimal immune responses following primary vaccination. Although older age is significantly associated with a lower humoral immune response, poor performance status and hypoalbuminemia are more strongly associated with a lower humoral immune response after primary vaccination. Thus, booster vaccination is beneficial for older adults, especially those with a poor performance status and hypoalbuminemia.

Lack of vitamin D predicts impaired long-term immune response to COVID-19 vaccination. PURPOSE: Low vitamin D levels were reported to negatively influence the outcome of acute COVID-19, as well as to be linked to Long-COVID. However, few studies have investigated, so far, its effects on humoral-response to anti-SARS-CoV-2 vaccination, reporting conflicting results. We aimed to evaluate the impact of baseline 25(OH)vitamin D (25(OH)D) levels on humoral-response to a two-

dose cycle of Pfizer-BioNTech-vaccine up to 9-10 months after immunization. METHODS: We retrospectively included 119 consecutive healthcare-workers (median age 53 years) without a previous history of acute COVID-19 or anti-SARS-CoV-2 immunoglobulins presence immunized with two doses of Comirnaty-vaccine from January to February 2021. 25(OH)D was measured at time of first-immunization. Immune response was evaluated at: time 0 (T0), before the first-dose; T1, time of second-dose (21 days after T0); T2, T3, T4 at 1, 5 and 9 months after T1, respectively. RESULTS: Median 25(OH)D levels were 25.6â€‰ng/mL, and vitamin D deficiency (25(OH)D <20 ng/mL) was observed in 29 subjects (24.8%). In those with vitamin D deficiency, we found a non-significant trend towards lower antibody-titers at T3, and significantly lower titers at T4 as compared to those not vitamin D-deficient, also observing a more pronounced antibody-titers negative drop from peak-T2 and T4 in those with vitamin D deficiency. A positive correlation between 25(OH)D levels and antibody-titers at T4 (pâ€‰=â€‰0.043) was found. In multiple linear-regression analysis, 25(OH)D deficiency and older-age resulted as negative independent factors associated with antibody titer at T4 (pâ€‰=â€‰0.026, pâ€‰=â€‰0.004; respectively). CONCLUSION: In our relatively young cohort presenting low prevalence of hypovitaminosis D, the long-term humoral response to anti-SARS-CoV-2 vaccination was negatively influenced by low baseline 25(OH)D. Vitamin D supplementation could be tested as a strategy to optimize the vaccination campaigns to prevent severe COVID-19.

COVID-19 vaccine triggered autoimmune hepatitis: case report.

Risk of breakthrough COVID-19 after vaccination among people with multiple sclerosis on disease-modifying therapies. BACKGROUND: Disease-modifying therapies (DMTs) for people with multiple sclerosis (pwMS) may decrease vaccine effectiveness. We aimed to explore the association between various DMTs and the risk for breakthrough COVID-19. METHODS: Population-based data from Clalit Health Services, Israel's largest healthcare organization, were used. PwMS treated with DMTs without prior COVID-19 were followed from the commencement of the mass vaccination campaign in December 2020. The end of follow-up was at the time of COVID-19 infection, the receipt of a third vaccine dose or until the end of August 2021. Time-dependent multivariate Cox proportional hazard models were used to estimate hazard ratios for COVID-19 according to vaccination, DMT, age, gender, disability and comorbidities. RESULTS: 2511 PwMS treated with DMTs were included (Age: 46.2â€‰Â±â€‰14.6, 70% Female, EDSS: 3.0â€‰Â±â€‰2.1). Of whom, 2123 (84.5%) received 2 vaccine doses. On multivariate models that included all pwMS, vaccination was protective (HRâ€‰=â€‰0.41, Pâ€‰<â€‰0.001). On multivariate models that included only fully vaccinated pwMS cladribine, ocrelizumab, S1P receptor modulators and natalizumab were associated with breakthrough COVID-19 (HRâ€‰=â€‰6.1, 4.7, 3.7 and 3.3; Pâ€‰=â€‰0.004, 0.008, 0.02 and 0.05, respectively). On multivariate models that included unvaccinated and fully vaccinated pwMS on each DMT separately, a protective trend was noted for vaccination on all DMTs (0.09â€‰<â€‰HRâ€‰<â€‰0.65), except for cladribine (HRâ€‰=â€‰1.1). This protective trend was not statistically significant on ocrelizumab, S1P receptor modulators and natalizumab. COVID-19 among pwMS was generally mild. Only 2 vaccinated pwMS had a severe infection with eventual recovery. CONCLUSIONS: Vaccination effectively protects pwMS from COVID-19. An increased risk of breakthrough infection was noted on high-efficacy DMTs, however COVID-19 after vaccination was usually mild.

Effect of Cardiopulmonary Bypass on SARS-CoV-2 Vaccination Antibody Levels. Background Adults undergoing heart surgery are particularly vulnerable to respiratory complications, including COVID-19. Immunization can significantly reduce this risk; however, the effect of cardiopulmonary bypass (CPB) on immunization status is unknown. We sought to evaluate the effect of CPB on COVID-19 vaccination antibody concentration after cardiac surgery. Methods and Results This prospective observational clinical trial evaluated adult participants undergoing cardiac surgery requiring CPB at a

single institution. All participants received a full primary COVID-19 vaccination series before CPB. SARS-CoV-2 spike protein-specific antibody concentrations were measured before CPB (pre-CPB measurement), 24â€‰hours following CPB (postoperative day 1 measurement), and approximately 1â€‰month following their procedure. Relationships between demographic or surgical variables and change in antibody concentration were assessed via linear regression. A total of 77 participants were enrolled in the study and underwent surgery. Among all participants, mean antibody concentration was significantly decreased on postoperative day 1, relative to pre-CPB levels (-2091â€‰AU/mL, P<0.001). Antibody concentration increased between postoperative day 1and 1 month post CPB measurement (2465â€‰AU/mL, P=0.015). Importantly, no significant difference was observed between pre-CPB and 1 month post CPB concentrations (P=0.983). Two participants (2.63%) developed symptomatic COVID-19 pneumonia postoperatively; 1 case of postoperative COVID-19 pneumonia resulted in mortality (1.3%). Conclusions COVID-19 vaccine antibody concentrations were significantly reduced in the short-term following CPB but returned to pre-CPB levels within 1â€‰month. One case of postoperative COVID 19 pneumonia-specific mortality was observed. These findings suggest the need for heightened precautions in the perioperative period for cardiac surgery patients.

SARS-CoV-2 vaccination in children and adolescents with and without type 1 diabetes mellitus. Adults with Diabetes Mellitus (DM) have increased risk of severe clinical presentation during COVID-19 infection, while children and adolescents with type 1 diabetes (T1D) have the same mild clinical course as their healthy peers, especially those with optimal glycemic control. The present review focuses on the necessity of COVID-19 vaccination among children and adolescents with T1D, and also in their non-diabetic peers. The efficacy and safety of COVID-19 vaccines are also discussed, as well as their various side-effects, ranging from common mild to very rare and serious ones. Furthermore, the results of COVID-19 vaccination of adolescents with and without T1D are reported, as well as the efficacy and concerns about childhood vaccination. It is concluded that patients with DM of all age groups should maintain optimal diabetic control in order to avoid glycemic deterioration during COVID-19 infection. Furthermore, despite the very rare and serious complications of COVID-19 vaccines, vaccination against COVID-19 is recommended for children and adolescents with T1D to prevent glycemic deterioration and rare but serious complications of COVID-19 infection.

Distal Chronic Inflammatory Demyelinating Polyneuropathy Following COVID-19 Vaccination in a Patient with Solitary Plasmacytoma: A Case Report and Literature Review. We herein report a rare case of distal chronic inflammatory demyelinating polyneuropathy (CIDP) following coronavirus disease 2019 (COVID-19) vaccination. A 39-year-old woman with a solitary plasmacytoma developed general weakness 7 days after receiving the second dose of the Pfizer-BioNTech COVID-19 vaccine, which had progressed for 3 months. A neurological examination revealed limb weakness with areflexia. Serological tests identified the presence of IgG antibodies against anti-GM1 and anti-GM2 gangliosides. Comprehensive evaluations met the criteria of distal CIDP. Intravenous immunoglobulin, intravenous methylprednisolone, oral prednisolone, and plasma exchange were administered, and she gradually improved. Physicians should be aware of CIDP as a rare complication of COVID-19 vaccination.

Acute Interstitial Nephritis with Glomerular Capillary IgA Deposition Following SARS-CoV-2 mRNA Vaccination. We herein report a case of acute kidney injury (AKI) presenting as acute interstitial nephritis (AIN) after the first dose of the BNT162b2 mRNA vaccine against coronavirus disease 2019 (COVID-19). A 69-year-old man with a history of diabetes and hypertension presented with AKI 4 days after receiving the vaccine. Despite the administration of methylprednisolone pulse treatment, his renal function worsened, which prompted us to initiate temporal hemodialysis. His renal function subsequently improved, and a renal biopsy confirmed AIN and glomerular capillary IgA deposition

without apparent crescents. The clinical history and histological findings suggest a relationship between severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination and AIN as a rare side effect.

Immunogenicity and reactogenicity of fractional, heterologous primary COVID-19 vaccination schedules with BNT162b2 boosters in 5-11-year-old Thai children: A multicenter, prospective, double-blind, randomized control trial. OBJECTIVE: To evaluate immunogenicity and safety of heterologous COVID-19 primary vaccination regimens of CoronaVac with fractional and standard BNT162b2 dosages in 5-11-year-old Thai children. METHODS: This prospective, multicenter, double-blind, randomized control trial divided participants 1:1:1:1 to receive a second dose of either standard (10-Î¼g) or half-dose (5-Î¼g) BNT162b2 vaccines as follows: CoronaVac/10-Î¼g-BNT162b2 (Group 1), CoronaVac/5-Î¼g-BNT162b2 (Group 2), 10-Î¼g-BNT162b2/10-Î¼g-BNT162b2 (Group 3), or 10-Î¼g-BNT162b2/5-Î¼g-BNT162b2 (Group 4). A subset of participants from each arm received 10-Î¼g-BNT162b2 booster (third) doses 16Â weeks after their second vaccination. Humoral and cellular immunogenicity were assessed and adverse events (AEs) digitally self-reported. RESULTS: Of 553 enrolled participants, 50 % were male, the median (interquartile range) age was 8.65 (7.00, 10.00) years, and a majority (91Â %) had normal weight-for-height. All participants exhibited similarly robust neutralizing antibodies (NAb) against the ancestral Wuhan strain two weeks after the second vaccination, with titers highest in Group 1 (737.60, 95% CI [654.80, 830.88]), followed by Groups 3 (630.42, 95% CI [555.50, 715.45]), 2 (593.98, 95% CI [506.02, 697.23]), and 4 (451.79, 95% CI [388.62, 525.23]), as well as 56.01Â % and 49.68Â % seroconversion for BA.1 and BA.5, respectively. Half-dose BNT162b2 as a second dose induced significantly lower NAb titers compared to their respective full-dose regimens (pÂ =Â 0.03 for Groups 1 vs 2 and pÂ <Â 0.001 for Groups 3 vs 4). 77.71Â % of participants developed SARS-CoV-2 ancestral spike protein-specific T-cell responses two weeks after the second vaccination. This was similar across arms. Booster doses generated NAb titers 5.69-11.51-folds higher than the second vaccination against BA.1. AEs were similar across arms, all mild or moderate, and fully resolved 2-3Â days thereafter. CONCLUSION: Standard and fractional heterologous regimens of CoronaVac-BNT162b2 induced similar or higher humoral immunity than homologous BNT162b2 and represent alternative vaccine regimens for children. These findings are highly relevant in settings concurrently using both vaccines.

Clinical characteristics and immune profiles of patients with immune-mediated alopecia associated with COVID-19 vaccinations. BACKGROUND: The clinical characteristics and pathomechanism for immune-mediated alopecia following COVID-19 vaccinations are not clearly characterized. OBJECTIVE: We investigated the causality and immune mechanism of COVID-19 vaccines-related alopecia areata (AA). STUDY DESIGN: 27 new-onset of AA patients after COVID-19 vaccinations and 106 vaccines-tolerant individuals were enrolled from multiple medical centers for analysis. RESULTS: The antinuclear antibody, total IgE, granulysin, and PARC/CCL18 as well as peripheral eosinophil count were significantly elevated in the patients with COVID-19 vaccines-related AA compared with those in the tolerant individuals (PÂ =Â 2.03Â Ã—Â 10(-5)-0.039). In vitro lymphocyte activation test revealed that granulysin, granzyme B, and IFN-Î³ released from the T cells of COVID-19 vaccines-related AA patients could be significantly increased by COVID-19 vaccine excipients (polyethylene glycol 2000 and polysorbate 80) or spike protein (PÂ =Â 0.002-0.04). CONCLUSIONS: Spike protein and excipients of COVID-19 vaccines could trigger T cell-mediated cytotoxicity, which contributes to the pathogenesis of immune-mediated alopecia associated with COVID-19 vaccines.

Safety and immunogenicity of SARS-CoV-2 self-amplifying RNA vaccine expressing an anchored RBD: A randomized, observer-blind phase 1 study. VLPCOV-01 is a lipid nanoparticle-encapsulated self-amplifying RNA (saRNA) vaccine that expresses a membrane-anchored receptor-binding domain (RBD) derived from the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein.

A phase 1 study of VLPCOV-01 is conducted (jRCT2051210164). Participants who completed two doses of the BNT162b2 mRNA vaccine previously are randomized to receive one intramuscular vaccination of 0.3, 1.0, or 3.0Â Î¼g VLPCOV-01, 30Â Î¼g BNT162b2, or placebo. No serious adverse events have been reported. VLPCOV-01 induces robust immunoglobulin G (IgG) titers against the RBD protein that are maintained up to 26Â weeks in non-elderly participants, with geometric means ranging from 5,037 (95% confidence interval [CI] 1,272-19,940) at 0.3Â Î¼g to 12,873 (95% CI 937-17,686) at 3Â Î¼g compared with 3,166 (95% CI 1,619-6,191) with 30Â Î¼g BNT162b2. Neutralizing antibody titers against all variants of SARS-CoV-2 tested are induced. VLPCOV-01 is immunogenic following low-dose administration. These findings support the potential for saRNA as a vaccine platform.

PAD4-Induced NETosis Via Cathepsin G-Mediated Platelet-Neutrophil Interaction in ChAdOx1 Vaccine-Induced Thrombosis-Brief Report. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare syndrome characterized by platelet anti-PF4 (platelet-activating antiplatelet factor 4)-related thrombosis. Platelet-neutrophil interaction has been suggested to play a role, but the underlying mechanism has not been fully elucidated. METHODS: The study included 10 patients with VITT after ChAdOx1 (chimpanzee adenovirus Oxford 1) nCoV-19 (Oxford-AstraZeneca) vaccine administration, 10 patients with ischemic stroke (IS), 10 patients with acute deep vein thrombosis, and 10 control subjects in whom blood levels of neutrophil extracellular traps (NETs), soluble TF (tissue factor), and thrombin generation were examined. Furthermore, we performed in vitro studies comparing the effect of serum from patients and controls on NETs formation. Finally, immunohistochemistry was performed in cerebral thrombi retrieved from a patients with VITT and 3 patients with IS. RESULTS: Compared with patients with IS, patients with deep vein thrombosis, controls, and patients with VITT had significantly higher blood values of CitH3 (citrullinated histone H3), soluble TF, D-dimer, and prothrombin fragment 1+2 (P<0.0001). Blood CitH3 significantly correlated with blood soluble TF (Spearman rank correlation coefficient=0.7295; P=0.0206) and prothrombin fragment 1+2 (Spearman rank correlation coefficient=0.6809; P<0.0350) in patients with VITT. Platelet-neutrophil mixture added with VITT plasma resulted in higher NETs formation, soluble TF and thrombin generation, and platelet-dependent thrombus growth under laminar flow compared with IS and deep vein thrombosis plasma; these effects were blunted by PAD4 (protein arginine deiminase 4) and cathepsin G inhibitors, anti-FcÎ³RIIa (Fc receptor for IgG class IIa), and high doses of heparin. Immunohistochemistry analysis showed a more marked expression of PAD4 along with more diffuse neutrophil infiltration and NETs formation as well as TF and cathepsin expression in VITT thrombus compared with thrombi from patients with IS. CONCLUSIONS: Patients with VITT display enhanced thrombogenesis by PAD4-mediated NETs formation via cathepsin G-mediated platelet/neutrophil interaction.

Vaccine-elicited B- and T-cell immunity to SARS-CoV-2 is impaired in chronic lung disease patients. BACKGROUND: While vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) provides significant protection from coronavirus disease 2019, the protection afforded to individuals with chronic lung disease is less well established. This study seeks to understand how chronic lung disease impacts SARS-CoV-2 vaccine-elicited immunity. METHODS: Deep immune phenotyping of humoral and cell-mediated responses to the SARS-CoV-2 vaccine was performed in patients with asthma, COPD and interstitial lung disease (ILD) compared to healthy controls. RESULTS: 48% of vaccinated patients with chronic lung diseases had reduced antibody titres to the SARS-CoV-2 vaccine antigen relative to healthy controls. Vaccine antibody titres were significantly reduced among asthma (p<0.035), COPD (p<0.022) and a subset of ILD patients as early as 3-4â€…months after vaccination, correlating with decreased vaccine-specific memory B-cells in circulation. Vaccine-specific memory T-cells were significantly reduced in patients with asthma (CD8(+) p<0.004; CD4(+)

p<0.023) and COPD (CD8(+) p<0.008) compared to healthy controls. Impaired T-cell responsiveness was also observed in a subset of ILD patients (CD8(+) 21.4%; CD4(+) 42.9%). Additional heterogeneity between healthy and disease cohorts was observed among bulk and vaccine-specific follicular T-helper cells. CONCLUSIONS: Deep immune phenotyping of the SARS-CoV-2 vaccine response revealed the complex nature of vaccine-elicited immunity and highlights the need for more personalised vaccination schemes in patients with underlying lung conditions.

Immune responses and disease biomarker long-term changes following COVID-19 mRNA vaccination in a cohort of rheumatic disease patients. INTRODUCTION: The longitudinal responses towards multiple doses of COVID-19 mRNA vaccines in patients with systemic autoimmune diseases remain incompletely understood. While observational studies suggested the safety of COVID-19 mRNA vaccines in rheumatic disease patients, laboratory evidence is lacking. METHODS: Here we evaluated seroreactivity, clinical manifestions, and multiple disease biomarkers after 2 or 3 doses of COVID-19 mRNA vaccines in a cohort of patients with rheumatic diseases. RESULTS: Most patients generated high SARS-CoV-2 spike-specific neutralizing antibodies comparable to those in healthy controls after 2 doses of mRNA vaccines. The antibody level declined over time but recovered after the third dose of the vaccine. Patients with systemic lupus erythematosus (SLE) or psoriatic arthritis (PsA) remained without significant flares post-vaccination. The changes in anti-dsDNA antibody concentration and expression of type I interferon (IFN) signature genes were highly variable but did not show consistent or significant increases. Frequency of double negative 2 (DN2) B cells remained largely stable. DISCUSSION: Our data provide experimental evidences indicating the efficacy and safety of repeated COVID-19 mRNA vaccination in rheumatic disease patients.

Effects of COVID-19 and Influenza Vaccination on Rheumatic Diseases: Results From a Survey of Patient-Reported Outcomes After Vaccination. BACKGROUND: This study aimed to compare the occurrence of adverse events (AEs) and disease flares after vaccination against coronavirus disease 2019 (COVID-19) and influenza in patients with autoimmune rheumatic diseases (ARDs). METHODS: Between November 2021 and March 2022, a survey was conducted among patients with ARD who received COVID-19 and influenza vaccinations. The questionnaire included 11 mandatory and closed-ended questions, and the following items were collected: medical history, immunization history, type of vaccine, patient-reported AEs, flare-up of the underlying disease after vaccination, and a confirmed diagnosis of COVID-19 or influenza. We compared the occurrence of vaccine-related adverse reactions to the COVID-19 and influenza vaccines based on the survey results. Multivariate logistic regression analysis was used to identify the factors affecting AEs or disease flares and to compare the post-vaccine response to mixed and matched vaccines. RESULTS: We analyzed 601 adults with ARD who received the COVID-19 vaccine, with a mean age of 49.6 years (80.5% female). A total of 255 participants (42.4%) received a complete course of primary vaccination, 342 (56.9%) completed the booster dose, and 132 (38.6%) received a mixed vaccine. The frequencies of AEs (188 [52.2%] vs. 21 [5.8%]; P < 0.001) and disease flares (58 [16.2%] vs. 5 [1.4%]; P < 0.001) after COVID-19 vaccination were significantly higher than those after influenza vaccination. In the risk factor analysis, previous allergic reaction to other vaccines (odds ratio, 1.95; confidence interval, 1.07-3.70; P = 0.034) was the only factor associated with the occurrence of AEs. There was no difference in the post-vaccine responses between the mixed and matched vaccines. CONCLUSION: The results of the survey of patients with ARD revealed that patient-reported AEs and underlying disease flares after receiving the COVID-19 vaccine were significantly higher than those after the influenza vaccine.

Immunogenicity and Safety of Booster SARS-CoV-2 mRNA Vaccine Dose in Allogeneic Hematopoietic Stem Cell Transplantation Recipients. Allogeneic hematopoietic stem cell transplantation (HSCT) recipients are susceptible to severe outcomes of Coronavirus disease 2019 (COVID-19). Most guidelines recommend a fourth dose (ie, booster) of COVID-19 vaccine to reduce the infection risk,

and observational studies are needed to determine the immunogenicity and safety of the booster dose in this population. The primary outcome was to determine the quantitative anti-receptor-binding domain (RBD) antibody titers after the fourth dose of the COVID-19 vaccine. The secondary outcomes included adverse effects and all-cause mortality. This single-group prospective cohort included allogeneic HSCT recipients age â‰¥18 years who received their fourth dose of COVID-19 mRNA vaccine between December 15, 2021, and August 2, 2022. We excluded patients with a history of COVID-19 diagnosis and those who received i.v. Ig within 21 days of antibody testing or rituximab within 6 months before study entry. We used regression models to determine the contributing factors significantly associated with post-fourth dose anti-RBD titer. Sixty-seven patients (median age, 59.5 years; IQR, 53.5 to 65.5 years; 33 males [61%]) received the fourth dose of vaccine, and 54 were included in the anti-RBD titer analysis. The median anti-RBD titers at 4 to 6 weeks after the third and fourth doses differed significantly (13,350 U/mL [IQR, 2618 to 34,740 U/mL] and 44,500 U/mL [IQR, 11,163 to 84,330 U/mL], respectively; P < .0001). In univariate analysis, the post-third dose anti-RBD titer (Î²Â =Â .70; 95% CI, .54 to .87; P < .001) and treatment with mycophenolate compounds (Î²Â =Â -1.05; 95% CI, -1.97 to -1.12; PÂ =Â .03) significantly predicted the antibody response to the fourth dose. In multivariate analysis, the inverse association between treatment with mycophenolate compounds and the post-fourth dose anti-RBD antibody titer was not significant (Î²Â =Â -.57; 95% CI, -1.32 to .19; PÂ =Â .14), whereas the significant association between the anti-RBD titers following the third and fourth doses did not change considerably (Î²Â =Â .66; 95% CI, .47 to .86; P < .001). The most frequent adverse event was vaccination site soreness (44%), followed by fatigue (16%), myalgia (4%), and headache (2%). No recipient experienced new or worsened preexisting graft-versus-host disease within 40 days of vaccination, and no patient died. Six patients (11%) developed breakthrough severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection not associated with hospitalization or severe outcomes. The fourth dose of the COVID-19 vaccine appears to be highly immunogenic and safe in allogeneic HSCT recipients. Further studies are needed to determine the neutralizing antibody titers against SARS-CoV-2 subvariants and the effectiveness and immunogenicity of bivalent vaccines in allogeneic HSCT recipients.

Keratosis pilaris-like eruptions in a child following COVID-19 vaccination.

Dermoscopy-assisted prevalence of hair loss after COVID-19 vaccination among an Egyptian population: a cross-sectional study. ABSTACT: BACKGROUND: Coronavirus disease (COVID-19) currently named SARS-CoV-2 is a contagious disease caused by a coronavirus; incompatible data are present on the possible relationship among COVID-19 vaccines and hair loss. AIMS: The objective of the current study was to assess dermoscopically the prevalence of hair loss among an Egyptian population following COVID-19 vaccination. METHODS: A total of 2000 participants were enrolled in this cross-sectional study. Adult males and females who received one of recognized COVID-19 vaccine were included, irrespective of the status of previous COVID-19 infection. Those who were aged less than 18Â years or above 60Â years were excluded. Furthermore, subjects self-reporting hair loss were assessed by dermoscopy. RESULTS: Among the studied cases, nâ€‰=â€‰478 (23.9%) complained of hair loss following vaccination. The majority of cases noticed their hair loss during the first 2Â months post-vaccination (nâ€‰=â€‰215 after the first month and nâ€‰=â€‰158 after the 2nd month respectively). CONCLUSION: We reported prevalence of post-vaccination hair fall that was confirmed by trichoscopy and which affected approximately one quarter of participants who received COVID-19 vaccines. Other factors, such as stress and infection, cannot be excluded and remain to be further investigated by larger multicenter studies.

Lower Eyelid Complication After Blepharoplasty and COVID-19 Vaccination. BACKGROUND: Following COVID-19 mass vaccination campaign, new- and unknown-related reactions haveÂ emerged. CASE REPORT: FourÂ months after transcutaneous lower blepharoplasty andÂ few

days after the second dose of SARS-CoV-2 Pfizer mRNA vaccination,Â a 57-year-old manÂ developed a bilateral palpebral ecchymosis. While the lesion healed spontaneously on the left side, the ecchymosis on the right lower lid did not regress. It presented swelling and hard consistency, clinically involving only skin layer. No alterations were revealed uponÂ blood tests and instrumental evaluations. Histological examination showedÂ lymphovascularÂ hyperplasia on a probable reactive basis. The lesion was resistant to medical and surgical therapies. After 15 months, it regressed spontaneously. CONCLUSIONS: In the reported case, an evident chronological relationship exists between surgical site and vaccine reaction, while other etiopathogenetic factors were excluded. This case represents a previously undescribed condition linking postvaccination reaction and long-term surgical outcome. LEVEL OF EVIDENCE V: This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266 .

Viral burden is associated with age, vaccination, and viral variant in a population-representative study of SARS-CoV-2 that accounts for time-since-infection-related sampling bias. In this study, we evaluated the impact of viral variant, in addition to other variables, on within-host viral burden, by analysing cycle threshold (Ct) values derived from nose and throat swabs, collected as part of the UK COVID-19 Infection Survey. Because viral burden distributions determined from community survey data can be biased due to the impact of variant epidemiology on the time-since-infection of samples, we developed a method to explicitly adjust observed Ct value distributions to account for the expected bias. By analysing the adjusted Ct values using partial least squares regression, we found that among unvaccinated individuals with no known prior exposure, viral burden was 44% lower among Alpha variant infections, compared to those with the predecessor strain, B.1.177. Vaccination reduced viral burden by 67%, and among vaccinated individuals, viral burden was 286% higher among Delta variant, compared to Alpha variant, infections. In addition, viral burden increased by 17% for every 10-year age increment of the infected individual. In summary, within-host viral burden increases with age, is reduced by vaccination, and is influenced by the interplay of vaccination status and viral variant.

Trends in occurrence of takotsubo syndrome and association with SARS-CoV-2 infection and COVID-19 vaccination. AIMS: Takotsubo syndrome (TTS) is a serious heart disease associated with significant morbidity and mortality. TTS has been related to SARS-CoV-2 infection and COVID-19 vaccine; however, the current data are scarce. We aimed to examine the associations between SARS-CoV-2 infection and its vaccine with TTS. METHODS: We conducted a nested case-control study in a cohort of 3â€Š237â€Š909 adults from the largest healthcare provider in Israel. Patients were followed from 1 March 2020 until 31 December 2021 for the occurrence of TTS. Ten randomly selected controls were matched to each case of TTS on age, sex, and duration of follow-up. Exposure to SARS-CoV-2 infection and COVID-19 vaccine in the prior 30â€Šdays was assessed in cases and controls. RESULTS: During the follow-up 144 patients developed TTS and were matched to 1440 controls. The mean age of cases and their matched controls was 71.4â€ŠÂ±â€Š12â€Šyears, and 136 (94.4%) of them were women. Conditional logistic regression analysis showed that SARS-CoV-2 infection and COVID-19 vaccine were not associated with an increased risk of TTS; odds ratio (OR)â€Š=â€Š2.04 [95% confidence interval (CI), 0.50-8.2] and 0.87 (0.49-1.54), respectively. The absolute number of TTS cases in the prepandemic period (March-December 2018-2019) was 82 in 2018 and 80 in 2019. The number of TTS cases decreased to 56 during the corresponding period of 2020 (first pandemic year) and increased back to 81 in 2022. CONCLUSION: No significant association was found between SARS-CoV-2 infection or COVID-19 vaccination and TTS occurrence.

Acute Liver Failure Caused by Secondary Hemophagocytic Lymphohistiocytosis After COVID-19 Vaccination - Case Report and Literature Review. Hemophagocytic lymphohistiocytosis (HLH) is a

congenital or acquired hyperinflammatory syndrome, in some cases accompanied by acute liver failure. We present a case report of acute liver failure associated with HLH after COVID-19 vaccination and bring a literature review of the connection between HLH and COVID-19 vaccination. HLH has significant mortality rate, and liver transplantation is not a therapeutic option. Therefore, early recognition and timely conservative treatment are corner stones in reducing HLH-related morbidity and mortality.

Case report: Giant pituitary neuroendocrine tumor presented along with acute visual loss due to pituitary apoplexy after receiving COVID-19 vaccination. OBJECTIVE: A case of giant pituitary neuroendocrine tumor presented along with acute visual loss due to pituitary apoplexy after receiving a COVID-19 vaccination is reported. CASE PRESENTATION: A 45-year-old man was referred for a giant pituitary tumor with bitemporal hemianopsia. A surgical procedure was planned and then delayed due to the COVID-19 outbreak in Japan, with a Pfizer/BioNTech vaccine administered while awaiting surgery. Three days after the second COVID-19 vaccination the patient noted a progressively worsening headache that caused pituitary apoplexy and then a decrease in vision. Emergency surgery was thus performed. CONCLUSION: Pituitary apoplexy is a rare and life-threatening complication that may occur after undergoing a COVID-19 vaccination.

Evaluation of the Most Visible Symptoms Associated with COVID-19 Vaccines Among the Residents of Makkah, Saudi Arabia: An Observational, Cross-Sectional Study. BACKGROUND: This research evaluated the most visible symptoms associated with coronavirus (COVID-19) vaccines among residents in Makkah of Saudi Arabia. METHODS: A cross-sectional study was conducted in 2021 among a representative sample of residents receiving COVID-19 vaccination at King Abdullah Medical City, â€•Al Ukayshiyyah, and Umm Al-Qura University vaccination centers. A total of 805 participants selected by a census sampling method were included. Data regarding characteristics, medical history, and post-vaccination symptoms were obtained with an interview-based questionnaire. RESULTS: The participants' mean age was 25.20 Â± 15.5 years. Of them, 61.7% and 38.3% received one and two doses of the COVID-19 vaccine, respectively. 2.2% have an allergic reaction to the COVID-19 vaccine. 25.3% were infected with COVID-19, 23% were infected before the first dose, and only 1.6% were infected after the first dose. Significant statistical associations were found between males and females in smoking status, age, body mass index, history of diabetes mellitus, and types of COVID-19 vaccines (P-value < 0.05). After adjustment for confounding variables, male participants had lower odds of having swelling, redness, or pain at the injection site, muscle or joint pain, headache, dizziness, and nausea compared to female participants [OR = 0.596, 95% CI = (0.388-0.916)], [OR = 0.272, 95% CI = (0.149-0.495)], [OR = 0.529, 95% CI = (0.338-0.828)], [OR = 0.263, 95% CI = (0.125-0.554)], and [OR = 0.145, 95% CI = (0.31-0.679), P < 0.05 for all], respectively. CONCLUSION: The female participants may have a higher risk of post-COVID-19 vaccination symptoms than males among Makkah residents of Saudi Arabia.

Sudden sensorineural hearing loss after receiving an inactivated viral vaccine, Sinopharm: Two-case report. The prevalence of Coronavirus Disease 2019 is a global threat. Due to the high mortality rate caused by this disease, the vaccination is mandatory to protect patients against it and reduce the mortality. Rapid development and widespread use of vaccines have raised the possibility of adverse side effects over the course of administration and follow-up. In this study, we investigated an adverse event of sudden sensorineural hearing loss in two patients receiving first dose of Sinopharm, an inactivated viral vaccine. Both patients experienced sudden hearing loss in their left ear some days after receiving the first dose of the Sinopharm and had normal otoscopic examinations in both ears and mild to severe sensorineural hearing loss was reported in the left ear. After imaging evaluation with magnetic resonance imaging which showed no pathologic points. Two patients were treated with prednisolone and valacyclovir. Both patients experienced response and had good prognosis in

their follow-up. Our study showed that there is no direct evidence of an association between Coronavirus Disease 2019 vaccination. A viral infection can cause sudden sensorineural hearing loss and should be considered as a possible side effect after vaccination. Although the number of side effects reported in clinical trials has been very low, long-term follow-up of patients is needed to assess the vaccine's safety, given the incidence of these cases.

Syncope following Pfizer BioNTech (bnt162b2) vaccination unmasking Brugada syndrome. The Brugada syndrome is an uncommon inherited condition associated with increased risk of ventricular tachyarrhythmias and sudden cardiac death. Different triggers including fever are well known to precipitate the Brugada pattern on electrocardiogram. We report a patient who presents with syncope, two days after the first dose of the BNT162b2 vaccine due to fever-related unmasking of Brugada syndrome.

Retinal artery occlusion following CoronaVac injection in a 45-year-old Filipino. BACKGROUND: While complex public health challenges and the emergence of variants have impeded responses to the COVID pandemic, vaccines continue to represent a crucial tool in mitigating the risk of morbidity and mortality. Safety issues weigh heavily upon both the utility and acceptability of every vaccine. Reports of sight-threatening events are scarce. CASE DESCRIPTION: We report the case of a hypertensive 45-year-old Filipino who noted unilateral (right eye) blurring of vision within 48 hours of his first dose of CoronaVac (Sinovac, China), an inactivated SARS-CoV-2/COVID-19 vaccine, with macular retinal arterial occlusion noted on day 21 post-inoculation. Further work-up revealed abnormal glycemic, metabolic, inflammatory, and bleeding parameters. Vision improved from counting fingers to 20/100 at week 6 with no interventions. CONCLUSION: A potential association between retinal vasoocclusion and inoculation with CoronaVac in our patient is supported by the temporal sequence of events, multiple mechanisms put forward in other cases, and reports of vascular adverse reactions in large country-level trials. It is mitigated by the profound infrequency of such events and the potentially substantial risk for ocular ischemic events imparted by the patient's baseline clinical background. Continued understanding of vaccine adverse reactions, however rare, is important not only for individual patient safety. This is helpful in ensuring the utility of current vaccines and in preserving the acceptability of vaccines through and beyond the current pandemic.

Waning Humoral Response 6 Month after Double Vaccination with the mRNA-BNT162b2 Vaccine in Hemodialysis Patients. INTRODUCTION: Although most hemodialysis patients (HDP) exhibit an initial seroresponse to vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), studies have shown this response to be lower compared to healthy subjects. This fact raised concerns regarding the durability of the immune response and effective protection against severe Coronavirus disease 2019 (COVID-19) in this vulnerable population. The aim of our study was to evaluate the change in antibody levels over time in HDP population. MATERIALS AND METHODS: We performed a prospective multicenter study, evaluating antibody response among HDP at 2 and at 6 months after complete two-dose vaccination course with the mRNA-BNT162b2 (Pfizer-BioNTech) vaccine. The study was performed in 14 hemodialysis units of a private dialysis provider in Lithuania. The serum samples of 189 HDP were tested for SARS-CoV-2 IgG against the Spike glycoprotein. RESULTS: 189 HDP participated in the study. Patients were 64.3Â±15.7 years of age, 116 (61.4%) were males and 73 (38.6%) were females. Among them, 183 (96.8%) were seropositive for anti-S IgG at 2 months after the second immunization dose. Six months after the second dose only 145 (76.7%) of study participants had positive anti-S IgG titers. The median level of anti-S IgG titers after 2 months was 383.1 BAU/mL (166.2-995.6) and after 6 months this level significantly decreased to 51.4 BAU/mL (22.0-104.0) ($p<0.001$). Seroresponses at both time points inversely correlated with increasing patient's age. Risk factor for absent response after 2 months included oncologic disease. Systemic autoimmune disease and a history of myocardial infarction increased risk to be seronegative 6

months after the second vaccine dose. CONCLUSIONS: The majority of hemodialysis patients seroresponded after BNT162b2/Pfizer vaccination, but vaccine-induced humoral immunity wanes over time.

Immune response to SARS-CoV-2 mRNA vaccination in multiple sclerosis patients after rituximab treatment interruption. Peripheral B cell depletion via anti-CD20 treatment is a highly effective disease-modifying treatment for reducing new relapses in multiple sclerosis (MS) patients. A drawback of rituximab (RTX) and other anti-CD20 antibodies is a poor immune response to vaccination. While this can be mitigated by treatment interruption of at least six months prior to vaccination, the timing to resume treatment while maintaining subsequent vaccine responses remains undetermined. Here, we characterized SARS-CoV-2 S-directed antibody and B cell responses throughout three BNT162b2 mRNA vaccine doses in RTX-treated MS patients, with the first two doses given during treatment interruption. We examined B-cell mediated immune responses in blood samples from patients with RTX-treated MS throughout three BNT162b2 vaccine doses, compared to an age- and sex-matched healthy control group. The first vaccine dose was given 1.3 years (median) after the last RTX infusion, the second dose one month after the first, and the third dose four weeks after treatment re-initiation. We analyzed SARS-CoV-2 S-directed antibody levels using enzyme-linked immunosorbent assay (ELISA), and the neutralization capacity of patient serum against SARS-CoV-2 S-pseudotyped lentivirus using luciferase reporter assay. In addition, we assessed switched memory (CD19(+)CD20(+)CD27(+)IgD(-)), unswitched memory (CD19(+)CD20(+)CD27(+)IgD(+)), naÃ¯ve (CD19(+)CD20(+)CD27(-)IgD(+)), and double negative (DN, CD19(+)CD20(+)CD27(-)IgD(-)) B cell frequencies, as well as their SARS-CoV-2 S-specific (CoV(+)) and Decay Accelerating Factor-negative (DAF(-)) subpopulations, using flow cytometry. After two vaccine doses, S-binding antibody levels and neutralization capacity in SARS-CoV-2-naÃ¯ve MS patients were comparable to vaccinated healthy controls, albeit with greater variation. Higher antibody response levels and CoV(+)-DN B cell frequencies after the second vaccine dose were predictive of a boost effect after the third dose, even after re-initiation of rituximab treatment. MS patients also exhibited lower frequencies of DAF(-) memory B cells, a suggested proxy for germinal centre activity, than control individuals. S-binding antibody levels in RTX-treated MS patients after two vaccine doses could help determine which individuals would need to move up their next vaccine booster dose or postpone their next RTX infusion. Our findings also offer first indications on the potential importance of antigenic stimulation of DN B cells and long-term impairment of germinal centre activity in rituximab-treated MS patients.

Class switch towards spike protein-specific IgG4 antibodies after SARS-CoV-2 mRNA vaccination depends on prior infection history. Vaccinations against SARS-CoV-2 reduce the risk of developing serious COVID-19 disease. Monitoring spike-specific IgG subclass levels after vaccinations may provide additional information on SARS-CoV-2 specific humoral immune response. Here, we examined the presence and levels of spike-specific IgG antibody subclasses in health-care coworkers vaccinated with vector- (Sputnik, AstraZeneca) or mRNA-based (Pfizer-BioNTech, Moderna) vaccines against SARS-CoV-2 and in unvaccinated COVID-19 patients. We found that vector-based vaccines elicited lower total spike-specific IgG levels than mRNA vaccines. The pattern of spike-specific IgG subclasses in individuals infected before mRNA vaccinations resembled that of vector-vaccinated subjects or unvaccinated COVID-19 patients. However, the pattern of mRNA-vaccinated individuals without SARS-CoV-2 preinfection showed a markedly different pattern. In addition to IgG1 and IgG3 subclasses presented in all groups, a switch towards distal IgG subclasses (spike-specific IgG4 and IgG2) appeared almost exclusively in individuals who received only mRNA vaccines or were infected after mRNA vaccinations. In these subjects, the magnitude of the spike-specific IgG4 response was comparable to that of the spike-specific IgG1 response. These data suggest that the priming of the

immune system either by natural SARS-CoV-2 infection or by vector- or mRNA-based vaccinations has an important impact on the characteristics of the developed specific humoral immunity.

Differences in SARS-CoV-2 specific humoral and cellular immune responses after contralateral and ipsilateral COVID-19 vaccination. BACKGROUND: Individual doses of dual-dose vaccine-regimens are sequentially administered into the deltoid muscle, but little attention has so far been paid to the immunological effects of choosing the ipsilateral or the contralateral side for the second dose. METHODS: In an observational study, 303 previously naive individuals were recruited, who received the second dose of the COVID-19 vaccine BNT162b2 on either the ipsilateral (nÂ =Â 147) or the contralateral side (nÂ =Â 156). Spike-specific IgG, IgG-avidity, and neutralizing antibodies were quantified using ELISA and a surrogate assay 2 weeks after dose 2. A subgroup of 143 individuals (64 ipsilateral, 79 contralateral) was analysed for spike-specific CD4 and CD8 T-cells using flow-cytometry. FINDINGS: Median spike-specific IgG-levels did not differ after ipsilateral (4590 (IQR 3438) BAU/ml) or contralateral vaccination (4002 (IQR 3524) BAU/ml, pÂ =Â 0.106). IgG-avidity was also similar (pÂ =Â 0.056). However, neutralizing activity was significantly lower after contralateral vaccination (pÂ =Â 0.024). Likewise, median spike-specific CD8 T-cell levels were significantly lower (pÂ =Â 0.004). Consequently, the percentage of individuals with detectable CD8 T-cells was significantly lower after contralateral than after ipsilateral vaccination (43.0% versus 67.2%, pÂ =Â 0.004). Spike specific CD4 T-cell levels were similar in both groups, but showed significantly higher CTLA-4 expression after contralateral vaccination (pÂ =Â 0.011). These effects were vaccine-specific, as polyclonally stimulated T-cell levels did not differ. INTERPRETATION: Both ipsilateral and contralateral vaccination induce a strong immune response, but secondary boosting is more pronounced when choosing vaccine administration-routes that allows for drainage by the same lymph nodes used for priming. Higher neutralizing antibody activity and higher levels of spike-specific CD8 T-cells may have implications for protection from infection and severe disease and support general preference for ipsilateral vaccination. FUNDING: Financial support was provided in part by the State chancellery of the Saarland to M.S.

Urticaria exacerbations and adverse reactions in patients with chronic urticaria receiving COVID-19 vaccination: Results of the UCARE COVAC-CU study. BACKGROUND: Concern about disease exacerbations and fear of reactions after coronavirus disease 2019 (COVID-19) vaccinations are common in chronic urticaria (CU) patients and may lead to vaccine hesitancy. OBJECTIVE: We assessed the frequency and risk factors of CU exacerbation and adverse reactions in CU patients after COVID-19 vaccination. METHODS: COVAC-CU is an international multicenter study of Urticaria Centers of Reference and Excellence (UCAREs) that retrospectively evaluated the effects of COVID-19 vaccination in CU patients aged â‰¥18 years and vaccinated with â‰¥1 dose of any COVID-19 vaccine. We evaluated CU exacerbations and severe allergic reactions as well as other adverse events associated with COVID-19 vaccinations and their association with various CU parameters. RESULTS: Across 2769 COVID-19-vaccinated CU patients, most (90%) received at least 2 COVID-19 vaccine doses, and most patients received CU treatment and had well-controlled disease. The rate of COVID-19 vaccination-induced CU exacerbation was 9%. Of 223 patients with CU exacerbation after the first dose, 53.4% experienced recurrence of CU exacerbation after the second dose. CU exacerbation most often started <48 hours after vaccination (59.2%), lasted for a few weeks or less (70%), and was treated mainly with antihistamines (70.3%). Factors that increased the risk for COVID-19 vaccination-induced CU exacerbation included female sex, disease duration shorter than 24 months, having chronic spontaneous versus inducible urticaria, receipt of adenovirus viral vector vaccine, having nonsteroidal anti-inflammatory drug/aspirin intolerance, and having concerns about getting vaccinated; receiving omalizumab treatment and Latino/Hispanic ethnicity lowered the risk. First-dose vaccine-related adverse effects, most commonly local reactions, fever, fatigue, and muscle pain,

were reported by 43.5% of CU patients. Seven patients reported severe allergic reactions. CONCLUSIONS: COVID-19 vaccination leads to disease exacerbation in only a small number of CU patients and is generally well tolerated.

Membranous nephropathy following SARS-CoV-2 mRNA-1273 vaccination.

Vaccine-induced and hybrid immunity to SARS-CoV-2 after three or four doses of BNT162b2 - results from 22 months follow-up of a healthcare workers cohort, Israel, 2020-2022. OBJECTIVES: SARS-CoV-2 remains a global health concern 3 years after its emergence. Safe and effective vaccines mitigate the pandemic impact, but the optimal schedule remains unclear, especially in a context where a high proportion of the population is infected. METHODS: We periodically measured anti-spike SARS-CoV-2 immunoglobulin (Ig)G titers using a quantitative assay in an Israeli healthcare worker cohort who all received at least two BNT162b2 doses and either received further doses and/or were subsequently infected up to 22 months after dose two, and compared geometric mean concentrations according to number of doses received and infection status using analysis of variance. RESULTS: Among the 993 included participants, infection after dose two led to higher geometric mean concentration IgG titers than a third dose (4285 vs 2845 arbitrary unit/ml 1-2 months after infection/vaccination, PÂ =Â 0.03). In 16-18 months after dose two, those infected and those who received three or four vaccine doses all had IgG geometric mean concentration levels above 500 arbitrary unit/ml with no significant differences among groups (PÂ =Â 0.6). IgG levels plateaued 16-22 months after dose two. CONCLUSION: Three BNT162b2 doses provide long-term immunogenicity comparable to breakthrough infection after dose two. Dose four transiently increases IgG levels and may be especially important for providing additional protection to vulnerable individuals during periods of increased transmission risk.

Myocarditis and Pericarditis Post-mRNA COVID-19 Vaccination: Insights from a Pharmacovigilance Perspective. Concerns remain regarding the rare cardiovascular adverse events, myocarditis and pericarditis (myo/pericarditis), particularly in younger individuals following mRNA COVID-19 vaccination. Our study aimed to comprehensively assess potential safety signals related to these cardiac events following the primary and booster doses, with a specific focus on younger populations, including children as young as 6 months of age. Using the Vaccine Adverse Events Reporting System (VAERS), the United States national passive surveillance system, we conducted a retrospective pharmacovigilance study analyzing spontaneous reports of myo/pericarditis. We employed both frequentist and Bayesian methods and conducted subgroup analyses by age, sex, and vaccine dose. We observed a higher reporting rate of myo/pericarditis following the primary vaccine series, particularly in males and mainly after the second dose. However, booster doses demonstrated a lower number of reported cases, with no significant signals detected after the fourth or fifth doses. In children and young adults, we observed notable age and sex differences in the reporting of myo/pericarditis cases. Males in the 12-17 and 18-24-year-old age groups had the highest number of cases, with significant signals for both males and females after the second dose. We also identified an increased reporting for a spectrum of cardiovascular symptoms such as chest pain and dyspnea, which increased with age, and were reported more frequently than myo/pericarditis. The present study identified signals of myo/pericarditis and related cardiovascular symptoms after mRNA COVID-19 vaccination, especially among children and adolescents. These findings underline the importance for continued vaccine surveillance and the need for further studies to confirm these results and to determine their clinical implications in public health decision-making, especially for younger populations.

Fever and dyspnea after anti-Covid-19 vaccination: a challenging diagnosis. There is still little information regarding the long-term safety of the vaccines. We report a case of new-onset adult-onset Still's disease (AOSD) that occurred following Covid-19Â vaccination. This patient went to the

emergency room with dyspnea from the last two weeks and bilateral swellings that occurred several weeks after the first vaccination. Based on the symptoms and laboratory results, we suspected AOSD. Considering the time relationship between Covid-19Â vaccination and AOSD onset in our patient, and possible mechanisms linking vaccination with the onset of autoimmune disorders, physicians should consider adverse events from Covid-19 vaccination and assess the benefits and risks of vaccination for each patient.

Factors Associated with COVID-19 Testing, Vaccination, and Use of Digital Contact Tracing Apps among Black and Latinx MSM (BLMSM) in Los Angeles. This study examines the factors associated with COVID-19 testing, vaccination intent (both individually and jointly), and willingness to use contact tracing digital apps among a cohort of Black and Latinx men who have sex with men (BLMSM) living in Los Angeles during the initial peak (July 2020) of the COVID-19 pandemic. A questionnaire detailing participants COVID-19 experiences was sent to 300 primarily BLMSM after the first state-wide COVID-19 lockdown. Logistic regression models with random cluster effects were used for analyses. Forty-two percent (42%) tested for COVID-19, 27% were willing to get vaccinated, and about 45% reported willingness to use contact tracing digital apps. Controlling for intervention participation, age, education, marital status, employment, health, tobacco, binge drinking, and self-reported anxiety, those who were depressed had 33% (95% CI: 0.13 to 0.82) odds of using a prevention strategy (either test for COVID-19 or vaccination intent) as the group who were not depressed. Those who had high school diploma or less had 23% (95% CI: 0.11 to 0.48) odds to use digital contact tracing apps as the group with education level of at least Associate's or Bachelor's degree. Without considering the format of the test kits, vaccine side effects, and ease of use for digital contact tracing apps, participants appeared to still be hesitant in using COVID-19 prevention strategies at the initial height of the pandemic. Our findings suggest the need for further investigation into this hesitancy to better inform and prepare for future epidemics.

Assessment of humoral immune response to different COVID-19 vaccines in patients undergoing maintenance hemodialysis. INTRODUCTION: The immune response to different Coronavirus Disease 2019 (COVID-19) vaccines is under-investigated in end-stage kidney disease (ESKD) patients, especially in the Middle East and North Africa. We carried out this research to estimate the effectiveness of COVID-19 immunization in ESKD patients on regular hemodialysis (HD). METHODS: In this prospective observational study, we enrolled 60 ESKD patients on regular HD who had completed COVID-19 vaccination and 30 vaccinated healthy participants. Serum levels of severe acute respiratory syndrome coronavirus 2 immunoglobulin G (SARS-COV2 IgG) were quantified 1 month after completing the vaccination schedule, and all participants were followed up from October 2021 to March 2022. The vaccines used in the study were from Pfizer-BioNTech, AstraZeneca, and Sinopharm. RESULTS: The median level of SARS-COV2 IgG was lower in HD patients than in healthy participants ($p < 0.001$). Regarding the type of COVID-19 vaccination, there was no statistical difference in SARS-COV2 IgG levels among HD patients. During the observation period, none of the HD patients had COVID-19. CONCLUSION: COVID-19 vaccination appeared to be protective in HD patients for 6 months and the side effects of vaccines were tolerable.

Ancestral SARS-CoV-2 and Omicron BA.5-specific neutralizing antibody and T-cell responses after Omicron bivalent booster vaccination in previously infected and infection-naive individuals. Coronavirus disease-2019 (COVID-19) bivalent ancestral/Omicron messenger RNA (mRNA) booster vaccinations became available to boost and expand the immunity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron infections. In a prospective cohort study including 59 healthcare workers, we assessed SARS-CoV-2 ancestral and Omicron BA.5-specific neutralizing antibody and T-cell responses in previously infected and infection-naive individuals. Also, we assessed the effect of an ancestral/Omicron BA.1 bivalent mRNA booster vaccination on these immune

responses. 10 months after previous monovalent mRNA vaccinations, ancestral SARS-CoV-2 S1-specific T-cell and anti-RBD IgG responses remained detectable in most individuals and a previous SARS-CoV-2 infection was associated with increased T-cell responses. T-cell responses, anti-RBD IgG, and Omicron BA.5 neutralization activity increased after receiving an ancestral/Omicron BA.1 bivalent booster mRNA vaccination. An Omicron BA.5 infection in addition to bivalent vaccination, led to a higher ratio of Omicron BA.5 to ancestral strain neutralization activity compared to no bivalent vaccination and no recent SARS-CoV-2 infection. In conclusion, SARS-CoV-2 T-cell and antibody responses persist for up to 10 months after a monovalent booster mRNA vaccination. An ancestral/Omicron BA.1 bivalent booster mRNA vaccination increases these immune responses and also induces Omicron BA.5 cross-neutralization antibody activity. Finally, our data indicate that hybrid immunity is associated with improved preservation of T-cell immunity.

Transcriptomic profile of TNF(high) MAIT cells is linked to B cell response following SARS-CoV-2 vaccination. INTRODUCTION: Higher frequencies of mucosal-associated invariant T (MAIT) cells were associated with an increased adaptive response to mRNA BNT162b2 SARS-CoV-2 vaccine, however, the mechanistic insights into this relationship are unknown. In the present study, we hypothesized that the TNF response of MAIT cells supports B cell activation following SARS-CoV-2 immunization. METHODS: To investigate the effects of repeated SARS-CoV-2 vaccinations on the peripheral blood mononuclear cells (PBMCs), we performed a longitudinal single cell (sc)RNA-seq and scTCR-seq analysis of SARS-CoV-2 vaccinated healthy adults with two doses of the Pfizer-BioNTech BNT162b2 mRNA vaccine. Collection of PBMCs was performed 1 day before, 3 and 17 days after prime vaccination, and 3 days and 3 months following vaccine boost. Based on scRNA/TCR-seq data related to regulatory signals induced by the vaccine, we used computational approaches for the functional pathway enrichment analysis (Reactome), dynamics of the effector cell-polarization (RNA Velocity and CellRank), and cell-cell communication (NicheNet). RESULTS: We identified MAIT cells as an important source of TNF across circulating lymphocytes in response to repeated SARS-CoV-2 BNT162b2 vaccination. The TNF(high) signature of MAIT cells was induced by the second administration of the vaccine. Notably, the increased TNF expression was associated with MAIT cell proliferation and efficient anti-SARS-CoV-2 antibody production. Finally, by decoding the ligand-receptor interactions and incorporating intracellular signaling, we predicted TNF(high) MAIT cell interplay with different B cell subsets. In specific, predicted TNF-mediated activation was selectively directed to conventional switched memory B cells, which are deputed to high-affinity long-term memory. DISCUSSION: Overall, our results indicate that SARS-CoV-2 BNT162b2 vaccination influences MAIT cell frequencies and their transcriptional effector profile with the potential to promote B cell activation. This research also provides a blueprint for the promising use of MAIT cells as cellular adjuvants in mRNA-based vaccines.

Multi-phasic gene profiling using candidate gene approach predict the capacity of specific antibody production and maintenance following COVID-19 vaccination in Japanese population. BACKGROUND: Vaccination against severe acute respiratory syndrome coronavirus type 2 is highly effective in preventing infection and reducing the severity of coronavirus disease (COVID-19). However, acquired humoral immunity wanes within six months. Focusing on the different tempo of acquisition and attenuation of specific antibody titers in individuals, we investigated the impact of genetic polymorphisms on antibody production after COVID-19 vaccination. METHODS: In total 236 healthcare workers from a Japanese municipal hospital, who received two doses of the vaccine were recruited. We employed a candidate gene approach to identify the target genetic polymorphisms affecting antibody production after vaccination. DNA samples from the study populations were genotyped for 33 polymorphisms in 15 distinct candidate genes encoding proteins involved in antigen-presenting cell activation, T cell activation, T-B interaction, and B cell survival. We measured

total anti-SARS-Cov2 spike IgG antibody titers and analyzed the association with genetic polymorphisms at several time points after vaccination using an unbiased statistical method, and stepwise logistic regression following multivariate regression. RESULTS: Significant associations were observed between seven SNPs in NLRP3, OAS1, IL12B, CTLA4, and IL4, and antibody titers at 3 weeks after the first vaccination as an initial response. Six SNPs in NLRP3, TNF, OAS1, IL12B, and CTLA4 were associated with high responders with serum antibody titer > 4000 BAU/ml as boosting effect at 3 weeks after the second vaccination. Analysis of long-term maintenance showed the significance of the three SNPs in IL12B, IL7R, and MIF for the maintenance of antibody titers and that in BAFF for attenuation of neutralizing antibodies. Finally, we proposed a predictive model composed of gene profiles to identify the individuals with rapid antibody attenuation by receiver operating characteristic (ROC) analysis (area under the curve (AUC)= 0.76, sensitivity = 82.5%, specificity=67.8%). CONCLUSIONS: The candidate gene approach successfully showed shifting responsible gene profiles and initial and boosting effect mainly related to the priming phase into antibody maintenance including B cell survival, which traces the phase of immune reactions. These gene profiles provide valuable information for further investigation of humoral immunity against COVID-19 and for building a strategy for personalized vaccine schedules.

A qualitative assessment of the adverse effects associated with COVID-19 vaccines: a study from Jordan. OBJECTIVES: The current study aimed to qualitatively explore the side effects reported by participants who received the COVID-19 vaccine among the Jordanian population. METHODS: Between April 18th and May 12th, 2022, an in-depth interview was conducted with a purposive sample of vaccinated individuals to assess the side effects of the COVID-19 vaccine in this study. Thematic analysis was used to identify themes and sub-themes within the current qualitative data. RESULTS: A total of 20 participants were interviewed. They had a mean age of 41.3 (SDâ€‰=â€‰14.3) years. Half of the participants were females (nâ€‰=â€‰10, 50.0%). The study revealed six main themes: first, most of the respondents believed that COVID-19 vaccines were safe. Second, the vaccines are not equivalent in their safety. The third there showed that participants follow preventive measures to decrease the possibility of experiencing side effects. The fourth theme showed that reporting of side effects by the participants is dependent on the experienced side effects. Moreover, the next theme revealed that participants showed hesitancy to take more than one type of vaccine. Finally, participants were willing to take the vaccine annually, because they believed that the vaccine is better than the disease itself and decreases the aggressive effects of the disease. CONCLUSIONS: This study found that the majority of participants believed in the safety of the COVID-19 vaccines and emphasized the responsibility of the healthcare providers in increasing awareness among the population about the importance of the vaccines. Enhancing such awareness is essential to improve the acceptance of receiving different types of vaccines.

Socio-demographic characteristics associated with COVID-19 vaccination uptake in Switzerland: longitudinal analysis of the CoMix study. BACKGROUND: Vaccination is an effective strategy to reduce morbidity and mortality from coronavirus disease 2019 (COVID-19). However, the uptake of COVID-19 vaccination has varied across and within countries. Switzerland has had lower levels of COVID-19 vaccination uptake in the general population than many other high-income countries. Understanding the socio-demographic factors associated with vaccination uptake can help to inform future vaccination strategies to increase uptake. METHODS: We conducted a longitudinal online survey in the Swiss population, consisting of six survey waves from June to September 2021. Participants provided information on socio-demographic characteristics, history of testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), social contacts, willingness to be vaccinated, and vaccination status. We used a multivariable Poisson regression model to estimate the adjusted rate ratio (aRR) and 95% confidence intervals (CI) of COVID-19 vaccine uptake. RESULTS: We recorded

6,758 observations from 1,884 adults. For the regression analysis, we included 3,513 observations from 1,883 participants. By September 2021, 600 (75%) of 806 study participants had received at least one vaccine dose. Participants who were older, male, and students, had a higher educational level, household income, and number of social contacts, and lived in a household with a medically vulnerable person were more likely to have received at least one vaccine dose. Female participants, those who lived in rural areas and smaller households, and people who perceived COVID-19 measures as being too strict were less likely to be vaccinated. We found no significant association between previous SARS-CoV-2 infections and vaccination uptake. CONCLUSIONS: Our results suggest that socio-demographic factors as well as individual behaviours and attitudes played an important role in COVID-19 vaccination uptake in Switzerland. Therefore, appropriate communication with the public is needed to ensure that public health interventions are accepted and implemented by the population. Tailored COVID-19 vaccination strategies in Switzerland that aim to improve uptake should target specific subgroups such as women, people from rural areas or people with lower socio-demographic status.

Cardiac sequelae in athletes following COVID-19 vaccination: evidence and misinformation. The recognition of myocarditis as a rare side effect of SARS-CoV-2 mRNA vaccination has sparked a global debate on vaccine safety, especially in the realm of sports. The main proposed mechanisms in the pathogenesis of COVID-19 mRNA vaccination-associated myocarditis (C-VAM) are based on the activation of the innate- and adaptive immune system against a susceptible immune-genetic background, including the recognition of mRNA as an antigen by the immune system, molecular mimicry between SARS-CoV-2 spike glycoprotein and cardiac tissue antigens and inflammatory sex-hormone signalling. The relatively younger age of the athlete population hypothetically constellates an increased risk of C-VAM. A subgroup analysis in individuals under 40 years revealed a low incidence of myocarditis following COVID-19 mRNA vaccination when compared to positive SARS-CoV-2 tests. No confirmed cases of athletes experiencing cardiac complications after mRNA vaccination have been reported. Most athletes only reported mild side effects after COVID-19 vaccination. A small but statistically significant decrease in maximal oxygen consumption in recreational athletes occurred after BNT162b2 mRNA booster vaccine administration. The clinical relevance and temporality of which remain to be determined. Many speculative social media reports attribute sudden cardiac arrest/death (SCA/D) in athletes to mRNA vaccination. Large media outlets have thoroughly debunked these claims. There is currently no evidence to support the claim that COVID-19 mRNA vaccination increases the risk of myocardial sequelae or SCA/D in athletes. However, specific vaccine regimen selection and timing may be appropriate to prevent detrimental performance effects.

Homologous or heterologous COVID-19 vaccine schemes: comparison of immune responses and side effects. Real-life data are needed regarding the appropriate time and selection of vaccination strategies, homologous or heterologous. We aimed to compare neutralizing antibody levels and side effects in different vaccination schemes. The study included 310 Health Care Workers (HCWs) vaccinated with 5 different schemes. Antispike/RBD IgG levels were measured between 28 and 60 days after the last dose. Side effects in participants were recorded, and pharmacovigilance records were reviewed from the outpatient vaccine clinic. Mean age of the participants was 38 Â± 11 years of whom 226 (72.9%) were female, and 84 (27.1%) were male. After booster doses, increasing antibody levels were detected in all groups. Mean antibody levels were detected to be statistically lower in 3 doses of inactivated vaccines group. The side effects were no significant difference between groups. Booster dose administration with mRNA vaccines stands out as the most accurate strategy for those at risk of contracting severe COVID-19 and HCWs caring for this population.

Inability to work following COVID-19 vaccination-a relevant aspect for future booster vaccinations. OBJECTIVES: COVID-19 vaccination is a key prevention strategy to reduce the spread and severity of SARS-CoV-2 infections. However, vaccine-related inability to work among healthcare workers (HCWs) could overstrain healthcare systems. STUDY DESIGN: The study presented was conducted as part of the prospective CoVacSer cohort study. METHODS: This study examined sick leave and intake of pro re nata medication after the first, second, and third COVID-19 vaccination in HCWs. Data were collected by using an electronic questionnaire. RESULTS: Among 1704 HCWs enrolled, 595 (34.9%) HCWs were on sick leave following at least one COVID-19 vaccination, leading to a total number of 1550 sick days. Both the absolute sick days and the rate of HCWs on sick leave significantly increased with each subsequent vaccination. Comparing BNT162b2mRNA and mRNA-1273, the difference in sick leave was not significant after the second dose, but mRNA-1273 induced a significantly longer and more frequent sick leave after the third. CONCLUSION: In the light of further COVID-19 infection waves and booster vaccinations, there is a risk of additional staff shortages due to postvaccination inability to work, which could negatively impact the already strained healthcare system and jeopardise patient care. These findings will aid further vaccination campaigns to minimise the impact of staff absences on the healthcare system.

Heterologous vaccination (ChAdOx1 and BNT162b2) induces a better immune response against the omicron variant than homologous vaccination. BACKGROUND: The ongoing COVID-19 pandemic has seen the emergence of numerous novel variants of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. In this study, we compared the efficacy of three different forms of immunization against the wild-type, delta, and omicron variants of the virus: two doses of the BNT or AZ vaccine (BNT/BNT or AZ/AZ) as homologous vaccination, three doses of AZ/AZ/BNT as heterologous vaccination, and naturally occurring immunization in severe COVID-19 cases. METHODS: We collected serum samples from vaccine recipients (67 receiving BNT/BNT, 111 receiving AZ/AZ, and 18 receiving AZ/AZ/BNT) and 46 patients who were admitted to the hospital with severe COVID-19. Blood samples were taken one month after the last injection and the efficacy of the vaccination was determined using the surrogate virus neutralization test (sVNT), with a positive result defined as an inhibition rate of over 30%. Serum samples from COVID-19 patients were taken at various points during their hospitalization and tested for inhibition rates. RESULTS: Our results indicated that there was no notable difference in the levels of neutralizing antibodies (nAb) in vaccine recipients and patients against the wild-type and delta variants. However, when it came to the omicron variant, the vaccine recipients had significantly lower nAb titers. Among the vaccine recipients, those who received a booster dose of BNT after their first two doses of AZ (AZ/AZ/BNT) demonstrated the highest level of protection against the omicron variant at 44.4%, followed closely by the COVID-19 patients. In analyzing the serial samples taken from hospitalized COVID-19 patients, we observed that their inhibition rates against the wild-type and delta variants improved over time, while the inhibition rate against the omicron variant decreased. CONCLUSION: In conclusion, our findings suggest that heterologous booster vaccination after primary vaccination produces higher nAb titers and provides a higher level of protection against the omicron variant compared to primary vaccination alone. This protective effect was similar to that observed in patients with severe COVID-19.

Associations Among Menstrual Cycle Length, Coronavirus Disease 2019 (COVID-19), and Vaccination. OBJECTIVE: To assess whether coronavirus disease 2019 (COVID-19) is associated with menstrual cycle length changes and, if so, how that compares with those undergoing vaccination or no event (control). METHODS: We conducted a retrospective cohort analysis in which we analyzed prospectively tracked cycle-length data from users of a period tracker application who also responded to a survey regarding COVID-19 symptoms and vaccination. We restricted our sample to users aged 16-45 years, with normal cycle lengths (24-38 days) and regular tracking behavior during the five

cycles around COVID-19 symptoms or vaccination or a similar time period for those experiencing no event (control group). We calculated the within-user change in cycle length (days) from the three consecutive cycles preevent average (either vaccination, disease, or neither; cycles 1-3) to the event (cycle 4) and postevent (cycle 5) cycles. We used mixed-effects models to estimate the age- and country-adjusted difference in change in cycle length across the groups. RESULTS: We included 6,514 users from 110 countries representing 32,570 cycles (COVID-19 symptoms: 1,450; COVID-19 vaccination: 4,643; control: 421). The COVID-19 cohort experienced a 1.45-day adjusted increase in cycle length during cycle 4 (COVID-19) compared with their three preevent cycles (95% CI 0.86-2.04). The vaccinated group experienced a 1.14-day adjusted increase in cycle length during cycle 4 (COVID-19 vaccine) compared with their preevent average (95% CI 0.60-1.69). The control group (neither vaccine nor disease) experienced a 0.68-day decrease (95% CI -1.18 to -0.19) in a similar time period. Post hoc tests showed no significant differences in the magnitude of changes between the COVID-19 and vaccination cohorts. In both cohorts, cycle length changes disappeared in the postevent cycle. CONCLUSION: Experiencing COVID-19 is associated with a small change in cycle length similar to COVID-19 vaccination. These changes resolve quickly within the next cycle.
A severe relapse of pemphigus vulgaris after SARS-CoV-2 vaccination.
A case of generalized pustular psoriasis complicated by acute respiratory distress syndrome after COVID-19 vaccination.
Antibody response after third dose of COVID-19 mRNA vaccination in allogeneic hematopoietic stem cell transplant recipients is comparable to that in healthy counterparts. To determine the efficacy of SARS-CoV-2 mRNA vaccination for allogeneic hematopoietic stem cell transplantation (allo-HSCT) recipients, we measured antibody titer serially in 92 allo-HSCT patients. Among the evaluable 87Â patients, median age at vaccination was 53Â years (range,Â 18-75). The average time between allo-HSCT and vaccination was 3.3Â years (range,Â 0.5-15.7). One month after the second dose, 70 patients (80.5%) had a positive response, whereas 17 patients (19.5%) had a negative response (<â€‰20Â U/mL). Only patients older than 44 years hadÂ a negative response. Low IgM level was the only significant predictor of vaccine failure in elderly patients. When antibody response before and after the third vaccination was examined in 47 patients, antibodies increased significantly from a median of 18.3 U/mL to 312.6 U/mL (Pâ€‰<â€‰0.01). The median antibody titer after the third vaccination of healthy individuals (nâ€‰=â€‰203) was 426.4 U/mL, which was comparable to that of patients (Pâ€‰=â€‰0.2). The antibody titer after the third mRNA vaccination increased even in patients whose first two mRNA vaccinationsÂ failed. These findings suggest that allo-HSCT recipients should receive the mRNA vaccine regularly.
Comment on urological complications after COVID 19 vaccine.
[Relationship of patients with multiple sclerosis to vaccination against COVID-19]. OBJECTIVE: To study the attitude of patients with multiple sclerosis (MS) to vaccination as a method of preventing infectious diseases, in particular, COVID-19. MATERIAL AND METHODS: The data of a survey of 408 patients with MS in the Sverdlovsk region in relation to vaccination against COVID-19, conducted using the original questionnaire, were analyzed. RESULTS: According to the survey data, 266 (65.2%) patients with MS are positive about vaccination. 222 (54.4%) patients with MS refused vaccination. The most common reasons for refusal were - fear that the vaccine could worsen the state of health - 44.1%, coronavirus infection in the last 6 months - 14.85%, Â«I was always told that I should not be vaccinatedÂ» - 14.4%, a combination of the above answers - 16.65%. The accumulated world experience and our observations demonstrate the important role of vaccination of patients with MS from COVID-19. CONCLUSIONS: It is necessary to rise the awareness of vaccination among patients with MS, since until recently this has been given insufficient attention.

MRI Features of Multiple Cranial Neuropathies in Guillain-BarrÃ© Syndrome Occurring after COVID-19 Vaccination: A Case Report. Guillain-BarrÃ© syndrome (GBS) is an immune-mediated demyelinating polyneuropathy characterized by progressive, ascending, and symmetrical paralysis. It is known to be triggered by an antecedent infection or vaccination. Recently, GBS development following coronavirus disease 2019 (COVID-19) vaccination has been reported. Cranial neuropathies in typical GBS patients usually involve the facial and the lower cranial nerves (from IX to XII). We report a rare case of multiple cranial neuropathies involving trigeminal, abducens, and facial nerves in a patient who developed GBS following COVID-19 vaccination on the basis of obvious MRI features.

Acute pulmonary hypertension due to microthrombus formation following COVID-19 vaccination: a case report. BACKGROUND: Several side effects have been reported after mRNA COVID-19 vaccinations. Nonetheless, the risk of pulmonary hypertension (PH) is rarely reported. Most cases with acute PH following vaccination were due to macropulmonary embolism secondary to deep vein thrombosis. However, acute PH due to microthrombus formation after COVID-19 vaccination has not been reported before, although a microthrombus has been considered to lead to the dysfunction of multiple organs, particularly in patients infected with COVID-19. CASE SUMMARY: A 63-year-old woman without any past medical history presented to our hospital with facial and bilateral pedal oedema and progressive dyspnoea on exertion. Her symptoms began the day after her second COVID-19 vaccination and developed gradually, which prompted her to seek consultation in our hospital 6 weeks later. An echocardiogram revealed substantially elevated right heart pressure, and cardiac catheterization revealed high pulmonary artery pressure (mean PAP, 30â€…mmHg). Contrast-enhanced computed tomography and venous echography revealed no apparent thrombus, and ventilation/perfusion (V/Q) scintigraphy revealed no V/Q mismatch. However, elevated D-dimer indicated the presence of a coagulation-fibrinolysis system in her body; thus, heparin therapy was initiated intravenously on Day 3 for 4 days, followed by direct oral anticoagulants ended on Day 16. Her symptoms substantially improved as her D-dimer level decreased, and a follow-up cardiac catheterization on Day 14 revealed a decline in mean PAP (15â€…mmHg). DISCUSSION: Our case suggests that the presence of acute PH is likely due to microangiopathy. Further studies are required to reveal the relationship between immune responses and microthrombus formation after COVID-19 vaccination.

Immunogenicity and reactogenicity of inactivated SARS-CoV-2 vaccines in healthy adults. INTRODUCTION: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is highly pathogenic to humans and has caused the ongoing coronavirus disease 2019 (COVID-19) pandemic. Vaccines are one of the efficient ways to prevent the viral infection. After COVID-19 vaccination, the monitoring of the dynamic change in neutralizing antibodies is necessary to determine booster requirements. METHODS: We estimated the effectiveness of the inactivated vaccines by monitoring dynamic SARS-CoV-2 neutralizing antibodies for over 2 years. Additionally, we also investigated the activation of T lymphocytes (CD3+ T cells) after three doses of the inactivated vaccine. RESULT: The results showed that the rate of reduction of SARS-CoV-2 neutralizing antibody levels gradually showed after each booster dose. The IgG/IgM level at 9 months after the third vaccination were significantly higher than those at 6 months after the second dose ($p<0.0001$). The expression of CD25+T cell in 18-35 age group was significantly higher than that in the other groups. Nine months after the third dose (the time of last blood sample collection), the expression of CD25+T cell in the 18-35 age group was significantly higher than that at 6 months after the second dose. CD25+T cell in the 18-35 years old group was significantly higher than 6 months after the second vaccination. CONCLUSION: CD25, a late activation marker of lymphocytes and high-activity memory T cell subgroup, exhibited higher levels at the later stages after vaccination. COVID-19 booster vaccination in older adults and regular testing of

SARS-CoV-2 neutralizing antibodies are recommended. Booster doses should be administered if the antibody level falls below the 30% inhibition rate.

Herpesviruses reactivation following COVID-19 vaccination: a systematic review and meta-analysis. BACKGROUND: The reactivation of herpesviruses (HHV) in COVID-19 patients is evident in the literature. Several reports have been published regarding the reactivation of these viruses (HSV, VZV, EBV, and CMV) among those who got COVID-19 vaccines. In this study, we aimed to review the current evidence to assess whether HHVs reactivation has any association with the prior administration of COVID-19 vaccines. METHODS: A systematic search was conducted on 25 September 2022 in PubMed/MEDLINE, Web of Science, and EMBASE. We included all observational studies, case reports, and case series which reported the reactivation of human herpesviruses following administration of COVID-19 vaccines. RESULTS: Our systematic search showed 80 articles that meet the eligibility criteria. Among the evaluated COVID-19 vaccines, most of the vaccines were mRNA based. Evidence from observational studies showed the possible relation between COVID-19 vaccine administration and VZV and HSV reactivation. The results of our proportion meta-analysis showed that the rate of VZV reactivation among those who received the COVID-19 vaccine was 14 persons per 1000 vaccinations (95% CI 2.97-32.80). Moreover, our meta-analysis for HSV reactivation showed the rate of 16 persons per 1000 vaccinations (95% CI 1.06-46.4). Furthermore, the evidence from case reports/series showed 149 cases of HHV reactivation. There were several vaccines that caused reactivation including BNT162b2 mRNA or Pfizer-BioNTech (nâ€‰=â€‰76), Oxford-AstraZeneca (nâ€‰=â€‰22), mRNA-1273 or Moderna (nâ€‰=â€‰17), Sinovac (nâ€‰=â€‰4), BBIBP-CorV or Sinopharm (nâ€‰=â€‰3), Covaxin (nâ€‰=â€‰3), Covishield (nâ€‰=â€‰3), and Johnson and Johnson (nâ€‰=â€‰1). Reactivated HHVs included varicella-zoster virus (VZV) (nâ€‰=â€‰114), cytomegalovirus (CMV) (nâ€‰=â€‰15), herpes simplex virus (HSV) (nâ€‰=â€‰14), Epstein-Barr virus (EBV) (nâ€‰=â€‰6), and HHV-6 (nâ€‰=â€‰2). Most cases reported their disease after the first dose of the vaccine. Many patients reported having comorbidities, of which hypertension, diabetes mellitus, dyslipidemia, chicken pox, and atrial fibrillation were common. CONCLUSION: In conclusion, our study showed the possible association between COVID-19 vaccination and herpesvirus reactivation. The evidence for VZV and HSV was supported by observational studies. However, regarding other herpesviruses (EBV and CMV), further research especially from observational studies and clinical trials is required to elucidate the interaction between COVID-19 vaccination and their reactivation.

Adverse Events Following the BNT162b2 mRNA COVID-19 Vaccine (Pfizer-BioNTech) in Aotearoa New Zealand. INTRODUCTION: In February 2021, New Zealand began its largest ever immunisation programme with the BNT162b2 mRNA coronavirus disease 2019 (COVID-19) vaccine. OBJECTIVE: We aimed to understand the association between 12 adverse events of special interest (AESIs) and a primary dose of BNT162b2 in the New Zealand population aged â‰¥5 years from 19 February 2021 through 10 February 2022. METHODS: Using national electronic health records, the observed rates of AESIs within a risk period (1-21 days) following vaccination were compared with the expected rates based on background data (2014-2019). Standardised incidence ratios (SIRs) were estimated for each AESI with 95% confidence intervals (CIs) using age group-specific background rates. The risk difference was calculated to estimate the excess or reduced number of events per 100,000 persons vaccinated in the risk period. RESULTS: As of 10 February 2022, 4,277,163 first doses and 4,114,364 second doses of BNT162b2 had been administered to the eligible New Zealand population aged â‰¥5 years. The SIRs for 11 of the 12 selected AESIs were not statistically significantly increased post vaccination. The SIR (95% CI) for myo/pericarditis following the first dose was 2.3 (1.8-2.7), with a risk difference (95% CI) of 1.3 (0.9-1.8), per 100,000 persons vaccinated, and 4.0 (3.4-4.6), with a risk difference of 3.1 (2.5-3.7), per 100,000 persons vaccinated following the second dose. The highest SIR

was 25.6 (15.5-37.5) in the 5-19 years age group, following the second dose of the vaccine, with an estimated five additional myo/pericarditis cases per 100,000 persons vaccinated. A statistically significant increased SIR of single organ cutaneous vasculitis (SOCV) was also observed following the first dose of BNT162b2 in the 20-39Â years age group only. CONCLUSIONS: A statistically significant association between BNT162b2 vaccination and myo/pericarditis was observed. This association has been confirmed internationally. BNT162b2 was not found to be associated with the other AESIs investigated, except for SOCV following the first dose of BNT162b2 in the 20-39Â years age group only, providing reassurances around the safety of the vaccine.
Efficacy of COVID-19 vaccination in adult patients with sickle cell disease: Comment.
Response to "Efficacy of COVID-19 vaccination in adult patients with sickle cell disease: Comment".
Response to Letter to the Editor From Kleebayoon and Wiuwanikit: "Subacute THYROiditis Related to SARS-CoV-2 Vaccine and COVID-19 (THYROVAC Study): A Multicenter Nationwide Study".
COVID-19 Vaccination and Gout Flare Risk in Patients With Infrequent or Frequent Flares: A Prospective Cohort Study. OBJECTIVE: To assess post-COVID-19 vaccination gout flare risk with differing baseline flare burden. METHODS: We prospectively studied gout patients with infrequent or frequent flares, defined as â‰¤1 flare/year or â‰¥2 flares/year, respectively. COVID-19 vaccine-naive patients managed with urate-lowering therapy between February and June 2021 were included and voluntarily decided on vaccination. Participants were followed for 12â€‰weeks after enrollment or first vaccine dose. Gout flares and risk factors were compared between groups. RESULTS: Of 530 participants, 308 (58.1%) had infrequent flares and 222 (41.9%) had frequent flares at baseline, with 248 (142 infrequent and 106 frequent) receiving two-dose COVID-19 vaccination. Vaccination increased cumulative flare incidence at 12â€‰weeks in the infrequent but not the frequent flare group (26.1% vs 10.8%, P =â€‰0.001, compared with 60.4% vs 65.5%, P =â€‰0.428). Flare incidence in the final 4â€‰weeks of observation decreased significantly only in the vaccinated infrequent flare group (4.3% vs 12.0%, P =â€‰0.017). Multivariable analyses showed that vaccination (odds ratio [OR] 2.82, 95% confidence interval [95% CI] 1.50-5.30, P =â€‰0.001), flare in the preceding year (OR 1.95, 95% CI 1.03-3.71, P =â€‰0.04), and body mass index (OR 1.09, 95% CI 1.01-1.19, P =â€‰0.03) were independently associated with increased flare risk in the infrequent flare group. Baseline serum urate (mg/dl) was an independent risk factor in the frequent flare group (OR 1.23, 95% CI 1.05-1.45, P =â€‰0.012). CONCLUSION: COVID-19 vaccination was associated with increased early gout flares only in patients with previously infrequent flares.
Secondary immunoglobulin A nephropathy with gross hematuria leading to rapidly progressive glomerulonephritis following severe acute respiratory syndrome coronavirus 2 vaccination: a case report. BACKGROUND: The outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection has been followed by many reports of the development and relapse of autoimmune diseases associated with SARS-CoV-2 vaccination. Some of these reports have involved relapse or onset of immunoglobulin A (IgA) nephropathy following SARS-CoV-2 vaccination. Here, we report on a patient with IgA nephropathy who presented with gross hematuria and rapidly progressive glomerulonephritis following SARS-CoV-2 vaccination. CASE PRESENTATION: A 63-year-old male patient with a history of habitual tonsillitis underwent bilateral tonsillectomy. He had a history of alcoholic cirrhosis of the liver and microscopic hematuria and proteinuria were indicated during a health checkup 2 years before hospital admission. He developed hematuria after the SARS-CoV-2 vaccination, which led to rapidly progressive glomerulonephritis, for which he was hospitalized. A renal biopsy led to the diagnosis of IgA nephropathy. Although pulse steroid therapy during his condition resulted in hepatic encephalopathy, three courses combined with mizoribine improved his renal function. CONCLUSION: SARS-CoV-2 mRNA vaccines activate T cells, which are involved in the

pathophysiology of IgA nephropathy. Therefore, this case suggests that the exacerbation of IgA nephropathy by the vaccine favors the vasculitis aspect of the disease.

Acute myocarditis after administration of COVID-19 vaccine: comment.

Bilateral Relentless Placoid Chorioretinitis Following Pfizer-BioNTech COVID-19 Vaccination: Specific Antigenic Trigger or Nonspecific Immune Activation? PURPOSE: To report bilateral relentless placoid chorioretinitis following Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine administration. CASE REPORT: A 55-year-old Caucasian New Zealand-born woman presented with progressive left eye vision loss and bilateral photopsias and floaters occurring 10â€‰days after receiving the Pfizer-BioNTech COVID-19 vaccination. She had a similar self-limiting episode of photopsias and floaters without vision loss 1 year prior after receiving the influenza vaccine. Snellen visual acuity (VA) was 20/25 in the right eye, and count fingers at 2 m in the left eye. Bilateral, active, creamy, plaque-like lesions were present at the level of the retinal pigment epithelium and choroid, suggestive of relentless placoid chorioretinitis. Commencement of 100â€‰mg oral prednisolone and 3â€‰g mycophenolate daily resulted in recovery of the foveal ellipsoid layer with VA of 20/25 in each eye after 8â€‰weeks. Subsequent activations occurred following COVID-19 infection and respiratory infection. CONCLUSION: This is the first reported case of relentless placoid chorioretinitis occurring as a potential side-effect of the Pfizer-BioNTech COVID-19 vaccine. Vaccination, and not infection, could be assumed to be the likely trigger. Subsequent flares following COVID-19 and a nonspecific respiratory infection during periods of inadequate immunosuppression suggest that a COVID-19 antigen or general immune activation could also be the trigger.

Association between COVID-19 vaccination and myasthenia gravis: A population-based, nested case-control study. BACKGROUND: Existing data regarding the link between COVID-19 vaccine and myasthenia gravis (MG) are scarce. We aimed to assess the association between Pfizer-BioNTech vaccine with both new-onset MG and MG exacerbation. METHODS: For the first aim, we conducted a nested case-control study in a cohort of 3,052,467 adults, without a diagnosis of MG, from the largest healthcare provider in Israel. Subjects were followed from January 1, 2021 until June 30, 2022 for the occurrence of MG. Ten randomly selected controls were matched to each case of new-onset MG on age and sex. For the second aim, a nested case-control study was conducted in a cohort of 1446 MG patients. Four randomly selected MG patients (controls) were matched to each case of MG exacerbation. Exposure to COVID-19 vaccine in the prior 4â€‰weeks was assessed in cases and controls. RESULTS: Overall, 332 patients had new-onset MG and were matched with 3320 controls. Multivariable conditional logistic regression models showed that the odds ratio (OR) for new-onset MG, associated with COVID-19 vaccine, was 1.14 (95% CI 0.73-1.78). The results were consistent in sensitivity analysis that used more stringent criteria to define MG. Overall, 62 patients with MG exacerbation were matched to 248 MG controls. The multivariable OR for MG exacerbation, associated with COVID-19 vaccine, was 1.35 (95% CI 0.37-4.89). All results were similar when the prior exposure to COVID-19 vaccine was extended to 8â€‰weeks. CONCLUSION: This study suggests that Pfizer-BioNTech vaccine is not associated with increased risk of new-onset nor exacerbation of MG.

SARS-CoV-2 vaccination and infection in ozanimod-treated participants with relapsing multiple sclerosis. OBJECTIVE: To investigate the serologic response, predictors of response, and clinical outcomes associated with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination and infection in ozanimod-treated participants with relapsing multiple sclerosis (RMS) from DAYBREAK. METHODS: DAYBREAK (ClinicalTrials.gov-NCT02576717), an open-label extension study of oral ozanimod 0.92â€‰mg, enrolled participants aged 18-55â€‰years with RMS who completed phase 1-3 ozanimod trials. Participants who were fully vaccinated against SARS-CoV-2 with mRNA or non-mRNA vaccines, were unvaccinated, and/or had COVID-19-related adverse events (AEs, with or without vaccination) and postvaccination serum samples were included (nâ€‰=â€‰288). Spike

receptor binding domain (RBD) antibody levels (seroconversion: â‰¥0.8â€‰U/mL) and serologic evidence of SARS-CoV-2 infection (nucleocapsid IgG: â‰¥1â€‰U/mL) were assessed (Roche Elecsys/Cobas e411 platform). RESULTS: In fully vaccinated participants (nâ€‰=â€‰148), spike RBD antibody seroconversion occurred in 90% (nâ€‰=â€‰98/109) of those without serologic evidence of prior SARS-CoV-2 exposure (100% [nâ€‰=â€‰80/80] seroconversion after mRNA vaccination) and in 100% (nâ€‰=â€‰39/39) of participants with serologic evidence of viral exposure. mRNA vaccination predicted higher spike RBD antibody levels, whereas absolute lymphocyte count (ALC), age, body mass index, and sex did not. COVID-19-related AEs were reported in 10% (nâ€‰=â€‰15/148) of fully vaccinated participants-all were nonserious and not severe; all participants recovered. INTERPRETATION: Most ozanimod-treated participants with RMS mounted a serologic response to SARS-CoV-2 vaccination and infection, regardless of participant characteristics or ALC levels. In this analysis, all COVID-19-related AEs post-full vaccination in participants taking ozanimod were nonserious and not severe.

The protective effect of COVID-19 vaccines on developing multisystem inflammatory syndrome in children (MIS-C): a systematic literature review and meta-analysis. OBJECTIVE: To review whether the current COVID-19 vaccines can prevent the occurrence of multisystem inflammatory syndrome in children (MIS-C) and adolescents. METHODS: A systematic literature review and meta-analysis were performed. The data were abstracted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Primary outcome was the efficacy of COVID-19 vaccination in preventing MIS-C development. The search was performed in PubMed and Embase. RESULTS: The review yielded 13 studies, which were included for critical appraisal and data extraction. The available studies showed a reduced incidence of MIS-C after mRNA COVID-19 vaccination in children aged 12-18 years. Four studies were eligible for meta-analysis and the pooled odds ratio for MIS-C in vaccinated children compared to unvaccinated children was 0.04 (95% confidence interval: 0.03-0.06). Additionally, the risk of MIS-C as an adverse effect of vaccination was much lower compared to the risk of MIS-C post-infection. CONCLUSIONS: Our systematic review highlights the current available evidence on the efficacy of COVID-19 vaccination in preventing MIS-C. The published studies so far - mainly conducted during the Delta wave - indicate that (original strain) COVID-19 mRNA vaccines in children are safe and associated with significantly less development of MIS-C. These findings further reinforce the recommendation for COVID-19 vaccination in children, which should be promoted and largely supported.

Political quarrel overshadows vaccination advocacy: How the vaccine debate on Brazilian Twitter was framed by anti-vaxxers during Bolsonaro administration. Despite Brazil's tradition of successful mass immunization programs, the country has been experiencing alarming declines in vaccination coverage, especially among children. That is aggravated by the growth of anti-vaccine movements and the spread of health misinformation in social media in the last decade, which have worsened during the COVID-19 outbreak. Several reports link populism and far-right politicians to anti-vaccination support worldwide, which was also the case in Brazil during president Jair Bolsonaro's administration. This project aimed to identify the circulating pro and anti-vaccine narratives in Portuguese on Twitter, during a crucial decision-making period regarding childhood vaccination in Brazil, from December 9, 2021, until February 9, 2022. From the over one million tweets and four million retweets collected, we identified two well-defined groups, one in favor and another against vaccination. Within the sample, we selected 1500 influencer tweets with the highest impact (>500 retweets) and conducted content analysis. Although the pro-vaccine influencers were more retweeted than anti-vaxxer ones, we observed that anti-vaccine movements were more succesful in framing discussions on Twitter. The subject of COVID-19 was the target of political polarization embedded in populist, anti-science and anti-traditional media discourses promoted by anti-vaxxers.

As a counterpart, the pro-vaccine influencers reacted inarticulately, focusing on criticizing the anti-vaccination actors, attitudes, and policies instead of promoting vaccines. Based on reults, we claim that a well-coordinated network of health communicators from science centers and health institutions, in partnership with properly briefed social media influencers and fact-checking sources, would more efectively pre-tempt the public about vaccine misinformation.

SARS-CoV-2 serology in pediatrics: Seroprevalence studies in unvaccinated children and humoral antibody response post vaccination. BACKGROUND: Humoral response against SARS-CoV-2 is increasingly accepted as the central correlate of immune protection. Recent pediatric seroprevalence data are extremely limited. Significant knowledge gaps also exist in immune response to mRNA SARS-CoV-2 vaccination in children. As children demonstrate distinct response to naÃ¯ve infection relative to adults, it is essential to investigate age-specific differences in seroprevalence and antibody response to SARS-CoV-2 vaccination. METHODS: Seroprevalence was assessed through two cross-sectional serosurveys prior to COVID-19 vaccination approval in children <5Â years using residual patient specimens (nÂ =Â 2902). To assess antibody response post-vaccination, 842 participants (580 children, 262 adults) were prospectively recruited with informed consent. Participation required completion of a health questionnaire and blood donation. Samples were collected at varying times post-vaccination and assayed using the Abbott AdviseDx SARS-CoV-2 IgG II and DiaSorin LIAISON SARS-CoV-2 TrimericS IgG assays. RESULTS: Significant increases in seroprevalence were observed between the first and second serosurveys in unvaccinated children <6Â months to 5Â years (38-75%). In the prospective vaccination cohort, serokinetic response decreased with time post-dose of an mRNA vaccine. Measured IgG titres were significantly higher in children relative to adults across all time points. CONCLUSIONS: This is the largest evaluation of quantitative SARS-CoV-2 antibody assays in a cohort of Canadian children, adolescents, and adults. Findings suggest high rates of SARS-CoV-2 exposure among unvaccinated young children in the Toronto community. Additional data supports children have higher antibody titres relative to adults post-vaccination.

Comparative antibody and cell-mediated immune responses, reactogenicity, and efficacy of homologous and heterologous boosting with CoronaVac and BNT162b2 (Cobovax): an open-label, randomised trial. BACKGROUND: Few trials have compared homologous and heterologous third doses of COVID-19 vaccination with inactivated vaccines and mRNA vaccines. The aim of this study was to assess immune responses, safety, and efficacy against SARS-CoV-2 infection following homologous or heterologous third-dose COVID-19 vaccination with either one dose of CoronaVac (Sinovac Biotech; inactivated vaccine) or BNT162b2 (Fosun Pharma-BioNTech; mRNA vaccine). METHODS: This is an ongoing, randomised, allocation-concealed, open-label, comparator-controlled trial in adults aged 18 years or older enrolled from the community in Hong Kong, who had received two doses of CoronaVac or BNT162b2 at least 6 months earlier. Participants were randomly assigned, using a computer-generated sequence, in a 1:1 ratio with allocation concealment to receive a (third) dose of CoronaVac or BNT162b2 (ancestral virus strain), stratified by types of previous COVID-19 vaccination (homologous two doses of CoronaVac or BNT162b2). Participants were unmasked to group allocation after vaccination. The primary endpoint was serum neutralising antibodies against the ancestral virus at day 28 after vaccination in each group, measured as plaque reduction neutralisation test (PRNT(50)) geometric mean titre (GMT). Surrogate virus neutralisation test (sVNT) mean inhibition percentage and PRNT(50) titres against omicron BA.1 and BA.2 subvariants were also measured. Secondary endpoints included geometric mean fold rise (GMFR) in antibody titres; incidence of solicited local and systemic adverse events; IFNÎ³(+) CD4(+) and IFNÎ³(+) CD8(+) T-cell responses at days 7 and 28; and incidence of COVID-19. Within-group comparisons of boost in immunogenicity from baseline and between-group comparisons were done according to intervention received (ie, per protocol) by paired and unpaired t test, respectively, and cumulative incidence of

infection was compared using Kaplan-Meier curves and a proportional hazards model to estimate hazard ratio. The trial is registered with ClinicalTrials.gov, NCT05057169. FINDINGS: We enrolled participants from Nov 12, 2021, to Jan 27, 2022. We vaccinated 219 participants who previously received two doses of CoronaVac, including 101 randomly assigned to receive CoronaVac (CC-C) and 118 randomly assigned to receive BNT162b2 (CC-B) as their third dose; and 232 participants who previously received two doses of BNT162b2, including 118 randomly assigned to receive CoronaVac (BB-C) and 114 randomly assigned to receive BNT162b2 (BB-B) as their third dose. The PRNT(50) GMTs on day 28 against ancestral virus were 109, 905, 92, and 816; against omicron BA.1 were 9, 75, 8, and 86; and against omicron BA.2 were 6, 80, 6, and 67 in the CC-C, CC-B, BB-C, and BB-B groups, respectively. Mean sVNT inhibition percentages on day 28 against ancestral virus were 83%, 96%, 87%, and 96%; against omicron BA.1 were 15%, 58%, 19%, and 69%; and against omicron BA.2 were 43%, 85%, 50%, and 90%, in the CC-C, CC-B, BB-C, and BB-B groups, respectively. Participants who had previously received two doses of CoronaVac and a BNT162b2 third dose had a GMFR of 12 (p<0Â·0001) compared with those who received a CoronaVac third dose; similarly, those who had received two doses of BNT162b2 and a BNT162b2 third dose had a GMFR of 8 (p<0Â·0001). No differences in CD4(+) and CD8(+) T-cell responses were observed between groups. We did not identify any vaccination-related hospitalisation within 1 month after vaccination. We identified 58 infections when omicron BA.2 was predominantly circulating, with cumulative incidence of 15Â·3% and 15Â·4% in the CC-C and CC-B groups, respectively (p=0Â·93), and 16Â·7% and 14Â·0% in the BB-C and BB-B groups, respectively (p=0Â·56). INTERPRETATION: Similar levels of incidence of, presumably, omicron BA.2 infections were observed in each group despite very weak antibody responses to BA.2 in the recipients of a CoronaVac third dose. Further research is warranted to identify appropriate correlates of protection for inactivated COVID-19 vaccines. FUNDING: Health and Medical Research Fund, Hong Kong. TRANSLATION: For the Chinese translation of the abstract see Supplementary Materials section.

Impact of the COVID-19 pandemic on hospital admissions due to viral hepatitis in Spain. BACKGROUND: Before the advent of COVID-19 vaccines, hospitalizations due to SARS-CoV-2 infection during 2020 collapsed most medical centers worldwide. Disruptions in health care for clinical conditions other than COVID-19 were not uniform. Herein, we report the impact of COVID-19 on hospitalizations due to viral hepatitis in Spain. METHODS: Retrospective study of all hospitalizations in Spain during 10 months before (pre-pandemic period) and after (pandemic period) March 1st 2020. Admissions with a diagnosis of hepatitis B, C and/or delta were retrieved and compared using the Spanish National Registry of Hospital Discharges. RESULTS: Nationwide hospitalizations declined 14.6% during the pandemic period, from 3,144,164 to 2,684,845. This reduction was significantly more pronounced for admissions due to viral hepatitis (18.1% drop), falling from 46,521 to 38,115. During the pandemic period, patients admitted with viral hepatitis died significantly more frequently than during the pre-pandemic period (7.2% vs 6.1%; pÂ <Â 0.001). Liver transplants significantly declined during the pandemic period. COVID-19 was diagnosed in 10.3% of patients hospitalized with viral hepatitis during the pandemic period. This subset of patients was older and died 2.4-fold more frequently than the rest, despite having advanced liver disease less frequently. CONCLUSION: Hospitalizations due to viral hepatitis significantly declined in Spain during the COVID-19 pandemic. Patients admitted with viral hepatitis experienced a greater mortality during the pandemic period. Deaths were more pronounced when coinfected with SARS-CoV-2 despite having advanced liver disease less frequently.

Association of vaccination, international travel, public health and social measures with lineage dynamics of SARS-CoV-2. Continually emerging SARS-CoV-2 variants of concern that can evade immune defenses are driving recurrent epidemic waves of COVID-19 globally. However, the impact of

measures to contain the virus and their effect on lineage diversity dynamics are poorly understood. Here, we jointly analyzed international travel, public health and social measures (PHSM), COVID-19 vaccine rollout, SARS-CoV-2 lineage diversity, and the case growth rate (GR) from March 2020 to September 2022 across 63 countries. We showed that despite worldwide vaccine rollout, PHSM are effective in mitigating epidemic waves and lineage diversity. An increase of 10,000 monthly travelers in a single country-to-country route between endemic countries corresponds to a 5.5% (95% CI: 2.9 to 8.2%) rise in local lineage diversity. After accounting for PHSM, natural immunity from previous infections, and waning immunity, we discovered a negative association between the GR of cases and adjusted vaccine coverage (AVC). We also observed a complex relationship between lineage diversity and vaccine rollout. Specifically, we found a significant negative association between lineage diversity and AVC at both low and high levels but not significant at the medium level. Our study deepens the understanding of population immunity and lineage dynamics for future pandemic preparedness and responsiveness.

Herpes Zoster Reactivation After mRNA and Adenovirus-Vectored Coronavirus Disease 2019 Vaccination: Analysis of National Health Insurance Database. BACKGROUND: Our study aimed to determine the risk of herpes zoster reactivation and coronavirus disease 2019 (COVID-19) vaccination (mRNA vaccine [BNT162b2] and adenovirus-vectored vaccine [ChAdOx1 nCoV-19]). METHODS: This retrospective study analyzed herpes zoster cases diagnosed between 26 February 2021 and 30 June 2021 and registered in the National Health Insurance Service database. A matched case-control study with a 1:3 matching ratio and a propensity score matching (PSM) study with a 1:1 ratio of vaccinated and unvaccinated individuals were performed. RESULTS: In the matched case control analysis, BNT162b2 was associated with an increased risk of herpes zoster reactivation (first dose adjusted odds ratio [aOR], 1.11; 95% confidence interval [CI], 1.06-1.15; second dose aOR, 1.17; 95% CI, 1.12-1.23). PSM analysis revealed a statistically significant increase in risk within 18 days following any vaccination (adjusted hazard ratio [aHR], 1.09; 95% CI, 1.02-1.16). BNT162b2 was associated with an increased risk at 18 days postvaccination (aHR, 1.65; 95% CI, 1.35-2.02) and second dose (aHR, 1.10; 95% CI, 1.02-1.19). However, the risk did not increase in both analyses of ChAdOx1 vaccination. CONCLUSIONS: mRNA COVID-19 vaccination possibly increases the risk of herpes zoster reactivation, and thus close follow-up for herpes zoster reactivation is required.

Methodological and statistical considerations: Batch-dependent adverse effects of COVID-19 vaccines.

Thrombosis Development After mRNA COVID-19 Vaccine Administration: A Case Series. The coronavirus disease 2019 (COVID-19) pandemic remains one of the largest global health crises of the last century. Fortunately, COVID-19 vaccines have proven to be one of the most promising options in halting the progression of the pandemic. As more and more people receive COVID-19 vaccines, the medical community has learned a great deal about their efficacy and the occurrence of very rare adverse effects. While the number of thromboembolic events post-adenoviral vaccines has been well-documented in the medical literature, there has been limited information regarding thrombosis development after receiving a messenger RNA (mRNA)-based vaccine. This case series highlights four different patients who received an mRNA-based COVID-19 vaccine and subsequently developed venous thromboembolism. Therefore, we hope that after reviewing this article, physicians will be more aware of thrombosis-related developments following mRNA vaccine administration for COVID-19. Fortunately, with early diagnosis and prompt treatment, patients can still expect full recovery from any vaccine thrombosis-associated complications, and the benefits of receiving an mRNA-based COVID-19 vaccine still outweigh the risks of post-vaccination complications.

Biventricular Takotsubo Cardiomyopathy as an Unusual Presentation of SARS-CoV-2 mRNA Vaccine-Associated Multisystemic Inflammatory Syndrome. Biventricular takotsubo cardiomyopathy

(BiTCM) is a rare entity, seldom reported. We describe a case of a female presenting with multisystemic inflammatory syndrome associated with the administration of a vaccine against coronavirus disease 2019 (COVID-19). In this particular case, the patient experienced the onset of symptoms shortly after receiving a COVID-19 vaccine. Early recognition of biventricular takotsubo cardiomyopathy and timely initiation of appropriate treatment are crucial. Prompt management includes stabilizing the patient's hemodynamic status, alleviating symptoms, and addressing any underlying causes, such as inflammation or immune-related responses. Close clinical surveillance is necessary to monitor the patient's cardiac function, assess response to treatment, and prevent potential complications.

Comment: Post COVID-19 Vaccination Encephalitis as a Cause of Subacute Progressive Dementia: A Case Report and Literature Review.

Research landscape on COVID-19 and liver dysfunction: A bibliometric analysis. BACKGROUND: The global spread of severe acute respiratory syndrome coronavirus 2, responsible for coronavirus disease 2019 (COVID-19), poses a significant risk to public health. Beyond the respiratory issues initially associated with the condition, severe cases of COVID-19 can also lead to complications in other organs, including the liver. Patients with severe COVID-19 may exhibit various clinical signs of liver dysfunction, ranging from minor elevations in liver enzymes without symptoms to more serious cases of impaired liver function. Liver damage is more commonly observed in patients with severe or critical forms of the disease. AIM: To present the research landscape on COVID-19 and liver dysfunction while also offering valuable insights into the prominent areas of interest within this particular domain. METHODS: On 18 February 2023, Scopus was utilised to conduct a comprehensive exploration of the relationship between COVID-19 and the liver dysfunction. The investigation encompassed the period from 1 January 2020 to 31 December 2022. Primary sources were meticulously examined and organised in a Microsoft Excel 2013 spreadsheet, categorised by journal, institution, funding agency, country and citation type. VOSviewer version 1.6.18 was employed to explore the prominent topics and knowledge network related to the subject. RESULTS: There were 2336 publications on COVID-19 and liver dysfunction analysed in this study, of which 558 were published in 2020, 891 in 2021 and 887 in 2022. Researchers from 111 different countries participated in the retrieved documents. The United States contributed the most studies, with 497 documents, representing 21.28% of the total, followed by China with 393 documents (16.82%) and Italy with 255 documents (10.92%). In the context of research related to COVID-19 and the liver, co-occurrence analysis identified three distinct clusters of topics: (1) 'COVID-19 vaccines in liver transplant recipients'; (2) 'liver function tests as a predictor of the severity and clinical outcomes in hospitalised patients'; and (3) 'care of patients with liver disease during the COVID-19 pandemic'. CONCLUSION: This bibliometric study provides a comprehensive overview of liver-related publications in COVID-19 research over the past 3 years. This study highlights the significant contributions of high-income nations, particularly the United States, China, and Italy, to the production of liver-related scholarly literature in this field. Most of the articles focused on liver dysfunction in patients with COVID-19 and the implications of the virus for gastroenterologists and hepatologists.

SARS-CoV-2 infection risk is higher in vaccinated patients with inflammatory autoimmune diseases or liver transplantation treated with mycophenolate due to an impaired antiviral immune response: results of the extended follow up of the RIVALSA prospective cohort. BACKGROUND: A relevant proportion of immunocompromised patients did not reach a detectable seroconversion after a full primary vaccination cycle against SARS-CoV-2. The effect of different immunosuppressants and the potential risks for SARS-CoV-2 infection in these subjects is largely unknown. METHODS: Patients from the Rivalsa prospective, observational cohort study with planned anti SARS-CoV-2 third dose

mRNA vaccination between October and December 2021 were asked to participate to this follow-up study. Patients were asked about eventual confirmed positivity to SARS-CoV-2 infection within 6 months from the third dose and to undergo a blood draw to evaluate seroconversion status after the additional vaccine shot. RESULTS: 19 out of 114 patients taking part in the survey developed a confirmed SARS-CoV-2 infection; we identified mycophenolate treatment as an independent predictor of an increased risk of infection even after the third vaccine dose (OR: 5.20, 95% CI: 1.70-20.00, p=0.0053). This result is in agreement with the in vitro evidence that MMF impairs both B and T lymphocytes driven immune responses (reduction both in memory B cells producing anti-spike antibodies and in proliferating CD4+ and CD8+ T cells). CONCLUSIONS: Immunocompromised patients need an additional vaccine administration to reach a detectable seroconversion, thus fostering a more personalized approach to their clinical management. Moreover, patients undergoing mycophenolate treatment show a specific increased infection risk, with respect to other immunosuppressants thus supporting a closer monitoring of their health status.

NVX-CoV2373-induced T- and B-cellular immunity in immunosuppressed people with multiple sclerosis that failed to respond to mRNA and viral vector SARS-CoV-2 vaccines. IMPORTANCE: Immunological response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination is important, especially in people with multiple sclerosis (pwMS) on immunosuppressive therapies. OBJECTIVE: This study aims to determine whether adjuvanted protein-based vaccine NVX-CoV2373 is able to induce an immune response to SARS-CoV-2 in pwMS with inadequate responses to prior triple mRNA/viral vector vaccination. DESIGN SETTING AND PARTICIPANTS: We conducted a single-center, prospective longitudinal cohort study at the MS Center in Dresden, Germany. In total, 65 participants were included in the study in accordance with the following eligibility criteria: age > 18 years, immunomodulatory treatment, and insufficient T-cellular and humoral response to prior vaccination with at least two doses of SARS-CoV-2 mRNA (BNT162b2, mRNA-1273) or viral vector vaccines (AZD1222, Ad26.COV2.S). INTERVENTIONS: Intramuscular vaccination with two doses of NVX-CoV2373 at baseline and 3 weeks of follow-up. MAIN OUTCOMES AND MEASURES: The development of SARS-CoV-2-specific antibodies and T-cell responses was evaluated. RESULTS: For the final analysis, data from 47 patients on stable treatment with sphingosine-1-phosphate receptor (S1PR) modulators and 17 on ocrelizumab were available. The tolerability of the NVX-CoV2373 vaccination was overall good and comparable to the one reported for the general population. After the second NVX-CoV2373 vaccination, 59% of S1PR-modulated patients developed antispike IgG antibodies above the predefined cutoff of 200 binding antibody units (BAU)/ml (mean, 1,204.37 [95% CI, 693.15, 2,092.65] BAU/ml), whereas no clinically significant T-cell response was found. In the subgroup of the patients on ocrelizumab treatment, 23.5% developed antispike IgG > 200 BAU/ml (mean, 116.3 [95% CI, 47.04, 287.51] BAU/ml) and 53% showed positive spike-specific T-cellular responses (IFN-gamma release to antigen 1: mean, 0.2 [95% CI, 0.11, 0.31] IU/ml; antigen 2: mean, 0.24 [95% CI, 0.14, 0.37]) after the second vaccination. CONCLUSIONS: Vaccination with two doses of NVX-CoV2373 was able to elicit a SARS-CoV-2-specific immune response in pwMS lacking adequate immune responses to previous mRNA/viral vector vaccination. For patients receiving S1PR modulators, an increase in anti-SARS-CoV-2 IgG antibodies was detected after NVX-CoV2373 vaccination, whereas in ocrelizumab-treated patients, the increase of antiviral T-cell responses was more pronounced. Our data may impact clinical decision-making by influencing the preference for NVX-CoV2373 vaccination in pwMS receiving treatment with S1PR modulation or anti-CD20 treatment.

Application of spatial transcriptomics analysis using the Visium system for the mouse nasal cavity after intranasal vaccination. Intranasal vaccines that elicit mucosal immunity are deemed effective against respiratory tract infections such as severe acute respiratory syndrome coronavirus 2

(SARS-CoV-2), but their ability to induce humoral immunity characterized by immunoglobulin A (IgA) and IgG production is low. It has been reported that vaccination with a mixture of a viscous base carboxyvinyl polymer (CVP) and viral antigens induced robust systemic and mucosal immune responses. In this study, we analyzed the behavior of immunocompetent cells in the nasal cavity over time by spatial transcriptome profiling induced immediately after antigen vaccination using CVP. We established a method for performing spatial transcriptomics using the Visium system in the mouse nasal cavity and analyzed gene expression profiles within the nasal cavity after intranasal vaccination. Glycoprotein 2 (Gp2)-, SRY-box transcription factor 8 (Sox8)-, or Spi-B transcription factor (Spib)-expressing cells were increased in the nasal passage (NP) region at 3-6 hr after SARS-CoV-2 spike protein and CVP (S-CVP) vaccination. The results suggested that microfold (M) cells are activated within a short period of time (3-6 hr). Subsequent cluster analysis of cells in the nasal cavity showed an increase in Cluster 9 at 3-6 hr after intranasal vaccination with the S-CVP. We found that Il6 in Cluster 9 had the highest log2 fold values within the NP at 3-6 hr. A search for gene expression patterns similar to that of Il6 revealed that the log2 fold values of Edn2, Ccl20, and Hk2 also increased in the nasal cavity after 3-6 hr. The results showed that the early response of immune cells occurred immediately after intranasal vaccination. In this study, we identified changes in gene expression that contribute to the activation of M cells and immunocompetent cells after intranasal vaccination of mice with antigen-CVP using a time-series analysis of spatial transcriptomics data. The results facilitated the identification of the cell types that are activated during the initial induction of nasal mucosal immunity.

Retained avidity despite reduced cross-binding and cross-neutralizing antibody levels to Omicron after SARS-COV-2 wild-type infection or mRNA double vaccination. INTRODUCTION: The rapid evolution of SARS-CoV-2 has posed a challenge to long-lasting immunity against the novel virus. Apart from neutralizing function, binding antibodies induced by vaccination or infection play an important role in containing the infection. METHODS: To determine the proportion of wild-type (WT)-generated antibodies recognizant of more recent variants, plasma samples from either SARS-CoV-2 WT-infected (n = 336) or double-mRNA (Comirnaty)-vaccinated individuals (n = 354, age and sex matched to the convalescent group) were analyzed for binding antibody capacity against the S1 protein of the BA.1 omicron variant. RESULTS: Overall, 38.59% (95% CI, 37.01- 40.20) of WT-generated antibodies recognized Omicron BA.1 S1 protein [28.83% (95% CI, 26.73-30.91) after infection and 43.46% (95% CI, 41.61-45.31) after vaccination; $p < 0.001$]. Although the proportion of WT-generated binding and neutralizing antibodies also binding to BA.1 is substantially reduced, the avidity of the remaining antibodies against the Omicron variant was non-inferior to that of the ancestral virus: Omicron: 39.7% (95% CI: 38.1-41.3) as compared to the avidity to WT: 27.0% (95% CI, 25.5-28.4), respectively ($p < 0.001$). Furthermore, we noticed a modestly yet statistically significant higher avidity toward the Omicron epitopes among the vaccinated group (42.2%; 95% CI, 40.51-43.94) as compared to the convalescent counterparts (36.4%; 95% CI, 33.42-38.76) ($p = 0.003$), even after adjusting for antibody concentration. DISCUSSION: Our results suggest that an aspect of functional immunity against the novel strain was considerably retained after WT contact, speculatively counteracting the impact of immune evasion toward neutralization of the strain. Higher antibody levels and cross-binding capacity among vaccinated individuals suggest an advantage of repeated exposure in generating robust immunity.

Safety profile and SARS-CoV-2 breakthrough infections among HCWs receiving anti-SARS-CoV-2 and influenza vaccines simultaneously: an Italian observational study. In October/December 2021, World Health Organization and other international agencies recommended the offer of the third dose of anti-SARS-CoV-2 vaccine. In this period, the routine offer of seasonal influenza vaccination was also guaranteed and simultaneous administration of the two vaccines was encouraged. This study aims to

evaluate the safety profile and to estimate the incidence of SARS-CoV-2 breakthrough infections in subjects receiving the anti-SARS-CoV-2 and influenza vaccines simultaneously. The study population was represented by healthcare workers (HCWs) of Bari Policlinico General Hospital who received the influenza (Flucelvax TetraÂ®) and/or anti-SARS-CoV-2 vaccination (BNT162b2 mRNA COVID-19 vaccine, ComirnatyÂ®) either in coadministration or separately in October 2021. Reports of adverse events following immunization (AEFIs) were investigated to study the safety of both vaccines in coadministration and in separate-instance administration. Post-vaccination SARS-CoV-2 breakthrough infection was also studied. 942 HCWs accepted to join our study. 610/942 received both vaccines simultaneously. 25.26Â % subjects (238/942) were only vaccinated against SARS-CoV-2, while the remaining 94 HCWs received the influenza vaccination first and subsequently received the anti-SARS-CoV2 booster dose. 717 HCWs reported AEFIs (Reporting Rate 76.1 per 100 subjects). Simultaneous administration of the two vaccines was not related with an increase of the rate of AEFIs compared to the single administration of SARS-CoV-2 vaccine, but the AEFIs' rate was lower among subjects who received only influenza vaccine. Post-vaccination SARS-CoV-2 infections were notified for 41.5Â % of enrolled subjects (391/942). Incidence of breakthrough infection and symptomatic disease was not significantly different between the simultaneous administration group and other subjects. Our data suggests that simultaneous administration of a quadrivalent influenza vaccine and an mRNA anti-SARS-CoV-2 vaccine neither affected the safety of said products nor was associated with a higher risk of SARS-CoV-2 breakthrough infection.

Impact of prior COVID-19 infection on perceptions about the benefit and safety of COVID-19 vaccines. In this online survey of 1,733 US adults in December 2021, respondents believed COVID-19 vaccines are less beneficial and less safe for someone who had already had COVID-19. Those who experienced COVID-19 after being vaccinated believed that the vaccines are less beneficial and less safe than those who had not. Findings highlight the need to better communicate evolving evidence of COVID-19 vaccine benefit and safety and to tailor communications to peoples' COVID-19 history and vaccination status.

Estimation of antibody levels after COVID-19 vaccinations: Preliminary evidence for immune interoception. To date, 72 % of the world's population has received at least one COVID-19 vaccination. The number of antibodies produced by some individuals is exponentially higher than in others, for various mostly unknown reasons. This variation causes great diversity in the future susceptibility to infection by the original or variants of the SARS-CoV-2 virus. The following study investigated whether individuals were able to estimate the strength of their antibody response after their COVID-19 vaccinations. 166 recently vaccinated participants provided a blood sample for determination of antibody titers. Participants were asked to estimate how many antibodies they thought they had produced, and were further asked how protected they felt from COVID-19 due to vaccination. Both self-rated antibody levels, and feelings of protection against COVID-19 were significantly related to their actual IgG spike antibody titers, after controlling for age, days since vaccination, BMI and cross vaccination. These results suggest that individuals may have a form of "immune interoception" which relates to their response to their COVID-19 vaccination.

Covid-19 vaccination reported side effects and hesitancy among the Syrian population: a cross-sectional study. INTRODUCTION: Studying post-vaccination side effects and identifying the reasons behind low vaccine uptake are pivotal for overcoming the pandemic. METHODS: This cross-sectional study was distributed through social media platforms and face-to-face interviews. Data from vaccinated and unvaccinated participants were collected and analyzed using the chi-square test, multivariable logistic regression to detect factors associated with side effects and severe side effects. RESULTS: Of the 3509 participants included, 1672(47.6%) were vaccinated. The most common reason for not taking the vaccine was concerns about the vaccine's side effects 815(44.4). The majority of

symptoms were mild 788(47.1%), followed by moderate 374(22.3%), and severe 144(8.6%). The most common symptoms were tiredness 1028(61.5%), pain at the injection site 933(55.8%), and low-grade fever 684(40.9%). Multivariable logistic regression analysis revealed that <40â€‰years (vs. â‰¥40; OR: 2.113, p-value = 0.008), females (vs. males; OR: 2.245, p-value< .001), did not receive influenza shot last year (vs. did receive Influenza shot last year OR: 1.697, p-value = 0.041), AstraZeneca (vs. other vaccine brands; OR: 2.799, p-value< .001), co-morbidities (vs. no co-morbidities; OR: 1.993, p-value = 0.008), and diabetes mellitus (vs. no diabetes mellitus; OR: 2.788, p-value = 0.007) were associated with severe post-vaccine side effects. Serious side effects reported were blood clots 5(0.3%), thrombocytopenia 2(0.1%), anaphylaxis 1(0.1%), seizures 1(0.1%), and cardiac infarction 1(0.1%). CONCLUSION: Our study revealed that most side effects reported were mild in severity and self-limiting. Increasing the public's awareness of the nature of the vaccine's side effects would reduce the misinformation and improve the public's trust in vaccines. Larger studies to evaluate rare and serious adverse events and long-term side effects are needed, so people can have sufficient information and understanding before making an informed consent which is essential for vaccination.

 Age < 40 years, females, not receiving influenza shot, AstraZeneca vaccine, co-morbidities, and diabetes mellitus were factors significantly associated with severe post-vaccination side effects.Although most of the reported vaccine side effects were mild in severity and well-tolerated, larger prospective studies to understand the causes of rare serious adverse events and long-term side effects are needed to overcome vaccine hesitancy among people and enable them to have sufficient information and understanding before making an informed consent which is essential for vaccination.

[The most common gastrointestinal alterations in patients with post-COVID syndrome]. INTRODUCTION: Post-COVID syndrome may affect the gastrointestinal tract. However, risk factors of post-COVID syndrome are still unknown. OBJECTIVE: We aimed to identify the most common gastrointestinal symptoms, abnormal laboratory findings and risk factors relevant to post-COVID syndrome. METHOD: In this retrospective study, we included 79 patients admitted to Semmelweis University Department of Surgery, Transplantation and Gastroenterology between October 2020 and September 2022. We investigated clinical data, laboratory findings and determined the major risk factors. RESULTS: Most of the patients were women (46/79), their mean age was 47.6 years and patients were overweight (BMI: 26.3 kg/m2). The most common comorbidities were cardiovascular diseases (21/79), hypertension (20/79), diabetes (11/79) and malignant diseases (9/79). Typical indications for gastroscopy were dyspepsia (16/79) and epigastric pain (10/79). The most common indications for colonoscopy were diarrhea (29/79) and weight loss (28/79). Among abnormal laboratory findings, liver enzymes levels (GOT: 83.5 U/L, GPT: 85 U/L, GGT: 70 U/L) and ferritin (351.5 ng/mL) were higher in post-COVID patients. Typical conditions diagnosed by gastroscopy, colonoscopy and abdominal ultrasound were gastroesophageal reflux disease (11/26), irritable bowel syndrome (2/19) and diffuse hepatic lesions, respectively. The number of unvaccinated patients was higher compared to those receiving any COVID-19 vaccines (58% vs. 29%). Of the vaccinated patients, 12 patients received mRNA vaccines (10 Pfizer-BioNTech, 2 Moderna) and 6 patients received viral vector vaccines (2 AstraZeneca, 4 Sputnik V). CONCLUSION: We identified female gender, obesity, cardiovascular diseases, cancer, hypertension and diabetes as major risk factors of post-COVID syndrome. Vaccinated status may prevent post-COVID gastrointestinal symptoms. Orv Hetil. 2023; 164(31): 1206-1212.

Autoimmune diabetes mellitus after COVID-19 vaccination in adult population: a systematic review of case reports. BACKGROUND: Autoimmune/type 1 diabetes mellitus (T1DM) is a recently described rare occurrence following the administration of adjuvants such as coronavirus disease 2019 (COVID-19) vaccines. This systematic review aimed to review all available literature on the potential association between COVID-19 vaccines and T1DM. METHODS: The Directory of Open Access

Journals, MEDLINE, Google Scholar, and Scopus were systematically searched for all published studies from inception to July 2022. Articles reporting T1DM development within 8 weeks of administration of COVID-19 vaccine were included. Two reviewers independently performed the risk of bias assessment following the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Case Reports. RESULTS: Eight eligible studies were retrieved, comprising 12 patients diagnosed with T1DM after being vaccinated with a COVID-19 vaccine. Six patients (50%) reported T1DM after receiving the second dose. Five patients (41.7%) presented with diabetic ketoacidosis, of which four presented within the first eight days after vaccination. Five patients (41.7%) had genetic susceptibility, with RNA binding motif protein 45 (RBM45/DRB1) and major histocompatibility complex, class II, DQ beta 1 (HLA-DQB1) mutations being prominent. INTERPRETATION: In this review, we have shown a small number of new-onset diabetes cases coincidently occurring soon after the COVID-19 vaccine, especially in those with genetic susceptibility. Despite being older, these patients had a similar phenotype to T1DM. While there might be a causal relationship between COVID-19 vaccines and T1DM development, this should not influence decisions regarding vaccination since the overall benefit outweighs the risk. Further larger prospective trials are needed to assess causal relationship and to clarify the potential roles of COVID-19 vaccine-derived antigens in autoimmune disease development. PROTOCOL REGISTRATION: PROSPERO-CRD42022342093.

COVID-19 vaccination and leprosy-A UK hospital-based retrospective cohort study. BACKGROUND: Individuals with leprosy are at risk of leprosy reactions, T-cell mediated immunological complications, which lead to nerve function impairment. Leprosy reactions require systemic immunosuppression which is a risk factor for severe COVID-19. Vaccination for SARS-CoV-2 infection is recommended in the UK and became widely available in 2021 with individuals at increased risk of severe disease, including the immunosuppressed, prioritised. Vaccines for SARS-CoV-2 may provoke a T cell response. The latter poses a theoretical risk of provoking an immunological response to latent Mycobacterium leprae infection leading to clinical disease or in those with clinical disease triggering a leprosy reaction. BCG vaccination is associated with the development of leprosy in a small proportion of healthy contacts of people with leprosy within twelve weeks of administration. BCG causes a Th1 immune response. METHODOLOGY/PRINCIPAL FINDINGS: We performed a retrospective cohort study to determine the SARS-CoV-2 vaccination status of individuals diagnosed with leprosy attending the Leprosy Clinic in 2021 and whether any had developed leprosy or experienced a new leprosy reaction within twelve weeks of receiving a dose of a SARS-CoV-2 vaccine. The electronic patient records were used to retrieve data. Fifty-two individuals with leprosy attended the clinic in 2021 of which five people were newly diagnosed with leprosy. Thirty-seven (71%) were male and the median age was 48.5 years old (Range 27-85 years). Eight (15.4%) individuals were taking multi-drug therapy (MDT) and eight (15.4%) had completed MDT within three years of the study. Twenty-two (41.5%) individuals were prescribed a systemic immunosuppressant drug during 2021. Ten (18.9%) individuals have one or more risk factors for severe COVID-19. The SARS-CoV-2 vaccination status of fifty (96%) were recorded of which forty-nine were vaccinated (98%). One individual had declined vaccination. One individual was diagnosed with borderline tuberculoid (BT) leprosy having developed red skin lesions with reduced sensation (which increased in size and number) and thickened peripheral nerves one week after a second dose of BNT162b2 vaccine. Another individual who had completed MDT more than three years earlier developed red plaques and tender thickened nerves consistent with a leprosy Type 1 reaction eight weeks after a single dose of BNT162b2 vaccine (having received two doses of CoronaVac vaccine three months earlier). CONCLUSIONS/SIGNIFICANCE: The development of BT leprosy and a Type 1 reaction in another individual shortly after a dose of BNT162b2 vaccine may be associated with vaccine mediated T cell responses. The benefits of vaccination to reduce the risk of severe COVID-19 outweigh these

unwanted events but data from leprosy endemic countries may provide further information about potential adverse effects of augmented T cell responses in individuals with leprosy or latent M. leprae infection.
Comparison of SARS-CoV-2 Hyperimmune Immunoglobulins Following Infection Plus Vaccination vs Infection. This cross-sectional study compares the neutralizing titers of convalescent plasma and hyperimmune antiâ€“SARS-CoV-2 intravenous immunoglobulins against circulating Omicron subvariants.
Otolaryngologic Side Effects After COVID-19 Vaccination. OBJECTIVES: With widespread vaccination against COVID-19, concerns regarding side effects have been raised. We aim to assess the frequency of otolaryngologic adverse events (AEs) following COVID-19 vaccination as compared with other vaccines in a national database. STUDY DESIGN: Retrospective analysis of national registry. METHODS: The Food and Drug Administration's Vaccine Adverse Event Reporting System (VAERS) database was queried from December 2020 to May 2021 for all COVID-19 vaccination AEs. Complaints were categorized as otolaryngologic and sub stratified into different anatomic components. Reporting odds ratios (ROR) and proportional reporting ratios (PRR) were determined for AEs of clinical significance. RESULTS: The total number of AEs reported from vaccination with the Moderna, Pfizer-BioNTech, and Janssen vaccines equaled 1,280,950. Of these, 62,660 (4.9%) were otolaryngologic in nature, with 32.6% associated with the oropharynx/larynx, 18.3% with the nasal cavity/sinuses, 17.1% with the ears/vestibular system, 10.0% with the oral cavity, and 21.9% miscellaneous. Signal ratios reached significance levels for dysgeusia (nâ€‰=â€‰2124, PRR: 17.33, ROR: 16.36), ageusia (nâ€‰=â€‰1376, PRR: 2.81, ROR: 2.81), anosmia (nâ€‰=â€‰983, PRR: 4.01, ROR: 4.01), rhinorrhea (nâ€‰=â€‰2203, PRR: 2.99, ROR: 3.00), throat tightness (nâ€‰=â€‰3666, PRR: 4.99, ROR: 5.00), throat irritation (nâ€‰=â€‰3313, PRR: 4.51, ROR: 4.52), dysphagia (nâ€‰=â€‰2538, PRR: 2.07, ROR: 2.07), tinnitus (nâ€‰=â€‰4377, PRR: 3.97, ROR: 3.98), and vertigo (nâ€‰=â€‰2887, PRR: 3.93, ROR: 3.93). Signal ratios were not significant for facial paralysis, Bell's palsy, anaphylaxis, sinusitis, hearing disability, and ear pain. CONCLUSIONS: Although several otolaryngologic symptoms were reported, few were found to be clinically significant. Of note, facial paralysis, Bell's palsy, and anaphylaxis did not meet signal thresholds to be determined significant. LEVEL OF EVIDENCE: 4 Laryngoscope, 2023.
Susceptibility to SARS-CoV-2 Infection and Immune Responses to COVID-19 Vaccination Among Recipients of Solid Organ Transplants. Solid organ transplant recipients (SOTRs) are at high risk for infections including SARS-CoV-2, primarily due to use of immunosuppressive therapies that prevent organ rejection. Furthermore, these immunosuppressants are typically associated with suboptimal responses to vaccination. While COVID-19 vaccines have reduced the risk of COVID-19-related morbidity and mortality in SOTRs, breakthrough infection rates and death remain higher in this population compared with immunocompetent individuals. Approaches to enhancing response in SOTRs, such as through administration of additional doses and heterologous vaccination, have resulted in increased seroresponse and antibody levels. In this article, safety and immunogenicity of mRNA COVID-19 vaccines in SOTRs are explored by dose. Key considerations for clinical practice and the current vaccine recommendations for SOTRs are discussed within the context of the dynamic COVID-19 vaccination guideline landscape. A thorough understanding of these topics is essential for determining public health and vaccination strategies to help protect immunocompromised populations, including SOTRs.
Wells' Syndrome associated with COVID-19 vaccination.
Pseudomonas aeruginosa infection following COVID-19 vaccination.
Herpes zoster infection following SARS-CoV-2 vaccine BNT162b2.

Delayed inflammatory reaction to hyaluronic acid lip filler after the Pfizer-BioNTech COVID-19 vaccine: A case report. Hypersensitivity reactions can be a side effect to any vaccine, but they are usually rare. The COVID-19 vaccination may cause hypersensitivity, and several cases of delayed hypersensitivity (DH) to hyaluronic acid (HA) dermal filler have been documented. The current report presents a case of a 36-year-old female patient with DH to HA dermal filler after receiving the Pfizer-BioNTech COVID-19 vaccine. Symptoms, including dryness, swelling, and a painless nodule, appeared after the first and second doses of the vaccine. The patient was treated with intralesional hyaluronidase and triamcinolone in the outpatient clinic. Although HA is relatively safe and routinely used in aesthetic medicine, DH reactions must be considered. Therefore, an appropriate patient history should be obtained, and physicians should provide counselling on the potential reactions to avoid these adverse effects.

Associations between laboratory variables and clinical features in patients hospitalized with COVID-19 after non-mRNA vaccination in China: A cross-sectional study. OBJECTIVES: Based on the data during the outbreak of COVID-19 in Wuxi city in China, we explored the relationship between laboratory variables and clinical features in patients hospitalized with COVID-19 after non-mRNA vaccination, and attempted to identify the significant impact of vaccination and COVID-19 infection on humans. METHODS: A retrospective observational cohort study was carried out. Patients who received non-mRNA COVID-19 vaccines and were hospitalized with COVID-19 between June 28, 2022, and July 24, 2022 were included. The correlation between different vaccine statuses, the time to negative PCR test, and biochemical parameters were investigated. RESULTS: All patients had a mild COVID-19 disease. The number of vaccine doses exerted no effects on the time to negative PCR test (PÂ =Â 0.559). No differences were evident among inactivated, adenoviral-vectored, and recombinant subunit vaccines in the time to negative PCR test.Patients who just received one dose had significantly lower blood glucose levels than those who received three doses (PÂ =Â 0.024), whereas two doses had no effect on blood glucose levels (one dose vs. two doses, PÂ =Â 0.223; two doses vs. three doses, PÂ =Â 0.457).Body temperature (Î²Â =Â 0.168, PÂ =Â 0.011) and the percentage of lymphocytes (Î²Â =Â -0.219, PÂ =Â 0.001) were substantially correlated with the time to COVID-19 negative PCR test. The prolonged stay was linked to a rise in GOT that fell within the usual range (PÂ =Â 0.025).The percentage of lymphocytes (PÂ =Â 0.007) and serum potassium (PÂ =Â 0.004) were concordant with the marked change in body temperature. CONCLUSIONS: The dose and type of vaccination had no effect on the time to COVID-19 negative PCR test in patients with mild COVID-19. Comparing the first dose with the booster dose, the blood glucose levels increased within the normal range. The period at which the COVID-19 nucleic acid turned negative correlated with body temperature, the proportion of lymphocytes, GOT, and serum potassium.

Humoral and Cellular Immune Responses of People Living With Human Immunodeficiency Virus After 3 Doses of Messenger RNA BNT162b2 Severe Acute Respiratory Syndrome Coronavirus 2 Vaccine: A Prospective Cohort Study. BACKGROUND: Recent studies have shown good serological and cellular immune responses in people living with human immunodeficiency virus (PLWH) after receipt of 2 doses of messenger RNAA (mRNA) severe acute respiratory syndrome coronavirus 2 vaccine. Data are missing regarding the response after 3 vaccine doses. METHODS: We followed up a group of PLWH who received 3 doses of the mRNA BNT162b2 vaccine and for whom data of humoral immune response after 2 vaccine doses were available. Patients provided a blood sample 4-6 months after the booster dose. The aim of the study was to measure the serological and cellular response after the third dose and to evaluate factors associated with the vaccine response. RESULTS: Fifty patients have provided a serum sample for serological evaluation after the booster. The anti-receptor-binding domain (RBD) immunoglobulin (Ig) G titers were higher after the booster with a median delta of 3240â€…arbitrary units/mL. The median CD4(+) T-cell count was 660/Î¼L (interquartile range, 515-

958/Î¼L) and had no influence on the antibody level. Factors associated with lower delta included higher CD8(+) T-cell count (P = .02) and longer time between the third dose and the blood test (P = .01). Higher anti-RBD IgG titer after the second vaccine (P = .03), as well as a longer interval between second and third doses (P = .031) were associated with higher delta. There was no increase in the median number of activated interferon Î³(+) and tumor necrosis factor Î±(+) CD4(+) T cells after the booster (n = 8). CONCLUSIONS: The anti-RBD IgG level after 3 doses of mRNA BNT162b2 vaccine was higher than the level after 2 doses, suggesting additional value of the booster. Cellular response did not further increase after a booster.

Guillain-Barre Syndrome Followed by Covid-19 Infection, Vaccination and Other Precipitating Factors during the Pandemic. BACKGROUND AND AIMS: Guillain-BarrÃ© syndrome (GBS) is usually triggered by an infection. Vaccination is mentioned as a possible trigger in a small number of GBS cases. The aim of this study was to notice GBS distinctness provoked by various triggers during the COVID-19 pandemic. MATERIAL AND METHODS: A total of 109 GBS patients were divided into three groups, respectively: COVID-19 infection associated (19 patients), COVID-19 vaccination associated (16 patients) and precipitated by some other factors (74 patients). We compared the clinical, neurophysiological and laboratory characteristics of these three groups. RESULTS: Neither were differences recorded in the age of the patients of these three groups at the time of illness, nor in the number of days from the precipitating factor to the onset of symptoms. There were no clinical differences between groups related to severity of the disease or patients' recovery. The only clinical difference was observed in relation to facial nerve bilateral affection because it was significantly higher in the post-vaccination group. According to neurophysiological findings, demyelinating form dominated in all three groups. CONCLUSION: Clinical characteristics, electrophysiological findings and laboratory characteristics did not differ significantly in Guillain-Barre syndrome followed by COVID-19 infection, vaccination and other precipitating factors during the pandemic. The bilateral involvement of facial nerves was significantly higher in the post-vaccination group. Most of these cases had a mild form of the disorder-distal paresthesias GBS variant.

COVID-19, Vaccine, and Guillain-BarrÃ© Syndrome: Association or Causation.

Syndrome of Transient Headache and Neurological Deficits with Cerebrospinal Fluid Lymphocytosis (HaNDL): A Case Report - Is there an Association with the COVID-19 Vaccine?

Sickness absence due to mandatory COVID-19 certificates in the workplace. BACKGROUND: As vaccines for COVID-19 became available, many countries introduced an obligation in 2021 for employees to prove their COVID-19 status at work, known in Germany as the 3G rule (vaccinated, recovered, tested). In view of the controversial debate, there was concern that employees might try to avoid providing mandatory COVID-19 certificates by taking sick leave. The aim of this study was to investigate whether mandatory COVID-19 tests in the workplace led to such an evasive response. METHOD: For an empirical panel analysis, we collected data from official sources and combined aggregated health insurance data on sick leave, epidemiological data on laboratory-confirmed COVID-19 infections, and vaccination rates for the German states from September 2021 to January 2022. We used a regional panel data analysis to estimate the impact of the mandatory COVID-19 certificates at the workplace on workers' sick leave. The regional vaccination rate reflected differences in treatment intensity. RESULTS: This study contributes to the limited evidence on the potential impact of introducing mandatory COVID-19 certificates at the workplace on sickness absence rates. In fact, our results showed that after controlling for infection rates, a one percentage point lower vaccination rate led to a 0.021 percentage point increase in the sickness absence rate when the 3G rule came into effect. This effect was measured with high statistical precision. In addition, in robustness checks, we controlled for a number of other possible influencing factors that may have affected sickness behaviours, such as time-varying labour market situations. However, the results remained robust.

CONCLUSIONS: The results of our empirical panel analysis implied that mandatory COVID-19 certificates in the workplace led to evasive responses and to additional days of sick leave of a relevant magnitude. Testing obligations were meant to help contain the epidemic. However, when introducing controversial obligations, it is important to consider evasive responses and to design the rules appropriately and communicate them convincingly.

Mechanistic Model Describing the Time Course of Humoral Immunity Following Ad26.COV2.S Vaccination in Non-Human Primates. Mechanistic modeling can be used to describe the time course of vaccine-induced humoral immunity and to identify key biologic drivers in antibody production. We used a six-compartment mechanistic model to describe a 20-week time course of humoral immune responses in 56 non-human primates (NHPs) elicited by vaccination with Ad26.COV2.S according to either a single-dose regimen (1 Ã— 10(11) or 5 Ã— 10(10) viral particles [vp]) or a two-dose homologous regimen (5 Ã— 10(10) vp) given in an interval of 4 or 8 weeks. Humoral immune responses were quantified by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike-specific binding antibody concentrations as determined by spike protein-enzyme-linked immunosorbent assay. The mechanistic model adequately described the central tendency and variability of binding antibody concentrations through 20 weeks in all vaccination arms. The estimation of mechanistic modeling parameters revealed greater contribution of the antibody production mediated by short-lived cells as compared with long-lived cells in driving the peak response, especially post second dose when a more rapid peak response was observed. The antibody production mediated by long-lived cells was identified as relevant for generating the first peak and for contributing to the long-term time course of sustained antibody concentrations in all vaccination arms. The findings contribute evidence on the key biologic components responsible for the observed time course of vaccine-induced humoral immunity in NHPs and constitute a step toward defining immune biomarkers of protection against SARS-CoV-2 that might translate across species. SIGNIFICANCE STATEMENT: We demonstrate the adequacy of a mechanistic modeling approach describing the time course of binding antibody concentrations in non-human primates (NHPs) elicited by different dose levels and regimens of Ad26.COV2.S. The findings are relevant for informing the mechanism-based accounts of vaccine-induced humoral immunity in NHPs and translational research efforts aimed at identifying immune biomarkers of protection against SARS-CoV-2 infection.

Prolonged febrile illness following first dose of ChAdOx1. A woman in her 40s, with a known history of fibromyalgia, presented with high-grade fever and constitutional symptoms occurring 5â€‰days following vaccination with Oxford-AstraZeneca COVID-19 vaccine (ChAdOx1). Her inflammatory markers and neutrophil count were found to be elevated and as such, she was started on antibiotics. Despite treatment, markers remained elevated and temperature spikes persisted for another 4 weeks before these symptoms subsided, and her blood tests normalised. All investigations taken in the interim were negative, with no source being identified for the fever. As a result, a positron emission tomography scan was performed to attempt to localise the source of these symptoms. This revealed low-to-moderate grade lymph node tracer uptake above and below the diaphragm most pervasive in the right axilla, with uptake in the right arm corresponding with the site of vaccination.

Stroke Following Coronavirus Disease 2019 Vaccination: Evidence Based on Different Designs of Real-World Studies. BACKGROUND: We aimed to evaluate whether coronavirus disease 2019 (COVID-19) vaccination was associated with stroke. METHODS: We conducted a systematic meta-analysis of studies using cohort, self-controlled case series (SCCS), and case-crossover study (CCOS) designs to evaluate incidence risk ratios (IRRs) and 95% confidence intervals (CIs) of ischemic stroke (IS), hemorrhagic stroke (HS), and cerebral venous sinus thrombosis (CVST) following COVID-19 vaccination. Risks of stroke were pooled among subpopulations categorized by vaccine type, dose,

age, and sex. Sensitivity analysis was performed by different defined risk periods. RESULTS: Fourteen studies involving 79 918 904 individuals were included. Cohort studies showed decreased risks of IS (IRR, 0.82 [95% CI, .75-.90]) and HS (IRR, 0.75 [95% CI, .67-.85]) postvaccination, but not CVST (IRR, 1.18 [95% CI, .70-1.98]). SCCS identified increased risks 1-21 days postvaccination (IRRIS, 1.05 [95% CI, 1.00-1.10]; IRRHS, 1.16 [95% CI, 1.06-1.26]) or 1-28 days postvaccination (IRRIS, 1.04 [95% CI, 1.00-1.08]; IRRHS, 1.37 [95% CI, 1.15-1.64]), similar to CVST (IRR, 1.58 [95% CI, 1.08-2.32]). CCOS reported an increased risk of CVST after ChAdOx1 vaccination (IRR, 2.9 [95% CI, 1.1-7.2]). CONCLUSIONS: Although different study designs yielded inconsistent findings, considering the relatively low background incidence of stroke and benefits of vaccination, even a potentially increased risk of stroke postvaccination should not justify vaccine hesitancy.

Association between bisphosphonate use and COVID-19 related outcomes. BACKGROUND: Although there are several efficacious vaccines against COVID-19, vaccination rates in many regions around the world remain insufficient to prevent continued high disease burden and emergence of viral variants. Repurposing of existing therapeutics that prevent or mitigate severe COVID-19 could help to address these challenges. The objective of this study was to determine whether prior use of bisphosphonates is associated with reduced incidence and/or severity of COVID-19. METHODS: A retrospective cohort study utilizing payer-complete health insurance claims data from 8,239,790 patients with continuous medical and prescription insurance January 1, 2019 to June 30, 2020 was performed. The primary exposure of interest was use of any bisphosphonate from January 1, 2019 to February 29, 2020. Bisphosphonate users were identified as patients having at least one bisphosphonate claim during this period, who were then 1:1 propensity score-matched to bisphosphonate non-users by age, gender, insurance type, primary-care-provider visit in 2019, and comorbidity burden. Main outcomes of interest included: (a) any testing for SARS-CoV-2 infection; (b) COVID-19 diagnosis; and (c) hospitalization with a COVID-19 diagnosis between March 1, 2020 and June 30, 2020. Multiple sensitivity analyses were also performed to assess core study outcomes amongst more restrictive matches between BP users/non-users, as well as assessing the relationship between BP-use and other respiratory infections (pneumonia, acute bronchitis) both during the same study period as well as before the COVID outbreak. RESULTS: A total of 7,906,603 patients for whom continuous medical and prescription insurance information was available were selected. A total of 450,366 bisphosphonate users were identified and 1:1 propensity score-matched to bisphosphonate non-users. Bisphosphonate users had lower odds ratios (OR) of testing for SARS-CoV-2 infection (OR = 0.22; 95%CI:0.21-0.23; p<0.001), COVID-19 diagnosis (OR = 0.23; 95%CI:0.22-0.24; p<0.001), and COVID-19-related hospitalization (OR = 0.26; 95%CI:0.24-0.29; p<0.001). Sensitivity analyses yielded results consistent with the primary analysis. Bisphosphonate-use was also associated with decreased odds of acute bronchitis (OR = 0.23; 95%CI:0.22-0.23; p<0.001) or pneumonia (OR = 0.32; 95%CI:0.31-0.34; p<0.001) in 2019, suggesting that bisphosphonates may protect against respiratory infections by a variety of pathogens, including but not limited to SARS-CoV-2. CONCLUSIONS: Prior bisphosphonate-use was associated with dramatically reduced odds of SARS-CoV-2 testing, COVID-19 diagnosis, and COVID-19-related hospitalizations. Prospective clinical trials will be required to establish a causal role for bisphosphonate-use in COVID-19-related outcomes. FUNDING: This study was supported by NIH grants, AR068383 and AI155865, a grant from MassCPR (to UHvA) and a CRI Irvington postdoctoral fellowship, CRI2453 (to PH).

 The COVID-19 pandemic challenged the world to rapidly develop strategies to combat the virus responsible for the disease. While several effective vaccines and new drugs have since become available, these therapies are not always easy to access and take time to generate and distribute. To address these challenges, researchers have tried to find ways to repurpose existing medications that are already commonly used and known to be safe. One potential candidate are bisphosphonates, a family of drugs used to reduce bone loss in

patients with osteoporosis. Bisphosphonates have been shown to boost the immune response to viral infections, and it has been observed that patients prescribed these drugs are less likely to develop or die from pneumonia. But whether bisphosphonates are effective against COVID-19 had not been fully explored. To investigate, Thompson, Wang et al. analyzed insurance claims data from about 8 million patients between January 2019 and June 2020, including around 450,000 individuals that had filled a prescription for bisphosphonates. Patients prescribed bisphosphonates were then compared to non-users that were similar in terms of their gender, age, the type of health insurance they had, their access to healthcare, and other health comorbidities. The study revealed that bisphosphonate users were around three to five times less likely to be tested for, diagnosed with, or hospitalized for COVID-19 during the first four months of the pandemic. They were also less commonly diagnosed with other respiratory infections in 2019, like bronchitis or pneumonia. Although the results suggest that bisphosphonates provide some protection against COVID-19, they cannot directly prove it. Verifying that bisphosphonates can treat or prevent COVID-19 and/or other respiratory infections requires more studies that follow patients in real-time rather than studying previously collected data. If such studies confirm the link, bisphosphonates could be a helpful tool to protect against COVID-19 or other virus outbreaks. The drugs are widely available, safe, and affordable, and therefore may provide an alternative for patients who cannot access other medications or vaccines.

Risk of all-cause and cardiac-related mortality after vaccination against COVID-19: A meta-analysis of self-controlled case series studies. Self-controlled case series (SCCS) is a novel study design uniquely equipped to ethically quantify the safety of vaccination. We sought out to perform a meta-analysis on all SCCS assessing mortality associated with COVID-19 vaccination in the immediate post-vaccination period. We included SCCS investigating the safety of COVID-19 vaccination and reporting all-cause and cardiac-related mortality. Three SCCS were located, totaling approximately 750,000 patients. The pooled hazard ratio (HR) revealed no significant association of COVID-19 vaccination with all-cause mortality (HRâ€‰=â€‰0.89, 95% CI [0.71, 1.10], pâ€‰=â€‰.28). Regarding cardiac-related mortality, the pooled HR suggests that COVID-19 vaccination is associated with an increased risk of cardiac-related mortality (HRâ€‰=â€‰1.06, 95% CI [1.02, 1.11], pâ€‰=â€‰.007). Subgroup analysis showed that the male gender is significantly associated with an increased incidence of cardiac-related deaths (HRâ€‰=â€‰1.09, 95% CI [1.02, 1.15], pâ€‰=â€‰.006). In conclusion, COVID-19 vaccination may be associated with a small increase in cardiac-related mortality, especially among males. Prospero Prospective Registration Number: CRD42022372256.

Antibody neutralization capacity after coronavirus disease 2019 vaccination in people with HIV in Canada. OBJECTIVES: Many vaccines require higher/additional doses or adjuvants to provide adequate protection for people with HIV (PWH). Here, we compare coronavirus disease 2019 (COVID-19) vaccine-induced antibody neutralization capacity in PWH vs. HIV-negative individuals following two vaccine doses. DESIGN: In Canadian prospective observational cohorts, including a multicentre study of PWH receiving at least two COVID-19 vaccinations (mRNA or ChAdOx1-S), and a parallel study of HIV-negative controls (Stop the Spread Ottawa Cohort), we measured vaccine-induced neutralization capacity 3â€Šmonths post dose 2 (Â±1â€Šmonth). METHODS: COVID-19 neutralization efficiency was measured by calculating the half maximal inhibitory dilution (ID50) using a high-throughput protein-based neutralization assay for Ancestral (Wuhan), Delta and Omicron (BA.1) spike variants. Univariable and multivariable quantile regression were used to compare COVID-19-specific antibody neutralization capacity by HIV status. RESULTS: Neutralization assays were performed on 256 PWH and 256 controls based on specimen availability at the timepoint of interest, having received two vaccines and known date of vaccination. There was a significant interaction between HIV status and previous COVID-19 infection status in median ID50. There were no differences in median ID50 for HIV+ vs. HIV-negative persons without past COVID-19 infection. For participants with

past COVID-19 infection, median ICD50 was significantly higher in controls than in PWH for ancestral SARS-CoV-2 and Omicron variants, with a trend for the Delta variant in the same direction. CONCLUSION: Vaccine-induced SARS-CoV-2 neutralization capacity was similar between PWH vs. HIV-negative persons without past COVID-19 infection, demonstrating favourable humoral-mediated immunogenicity. Both HIV+ and HIV-negative persons demonstrated hybrid immunity. TRIAL REGISTRATION: clinicaltrials.gov NCT04894448.
Impaired T-cell response to mRNA vaccination heralds risk of COVID-19 in long-term allogeneic hematopoietic stem cell transplantation survivors.
Correspondence on 'Vocal fold paralysis following first dose of Oxford-AstraZeneca coronavirus disease 2019 vaccine'.
Neutralizing Antibody Responses against Five SARS-CoV-2 Variants and T Lymphocyte Change after Vaccine Breakthrough Infections from the SARS-CoV-2 Omicron BA.1 Variant in Tianjin, China: A Prospective Study. OBJECTIVE: To investigate whether Omicron BA.1 breakthrough infection after receiving the SARS-CoV-2 vaccine could create a strong immunity barrier. METHODS: Blood samples were collected at two different time points from 124 Omicron BA.1 breakthrough infected patients and 124 controls matched for age, gender, and vaccination profile. Live virus-neutralizing antibodies against five SARS-CoV-2 variants, including WT, Gamma, Beta, Delta, and Omicron BA.1, and T-lymphocyte lymphocyte counts in both groups were measured and statistically analyzed. RESULTS: The neutralizing antibody titers against five different variants of SARS-CoV-2 were significantly increased in the vaccinated population infected with the Omicron BA.1 variant at 3 months after infection, but mainly increased the antibody level against the WT strain, and the antibody against the Omicron strain was the lowest. The neutralizing antibody level decreased rapidly 6 months after infection. The T-lymphocyte cell counts of patients with mild and moderate disease recovered at 3 months and completely returned to the normal state at 6 months. CONCLUSION: Omicron BA.1 breakthrough infection mainly evoked humoral immune memory in the original strain after vaccination and hardly produced neutralizing antibodies specific to Omicron BA.1. Neutralizing antibodies against the different strains declined rapidly and showed features similar to those of influenza. Thus, T-lymphocytes may play an important role in recovery.
Early-onset Cervical Myelitis after COVID-19 Vaccination. A 33-year-old woman developed paresthesia in her right thumb approximately 30 minutes after receiving the BNT162b2 (Pfizer-BioNTech) severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. The paresthesia gradually spread to her right-side limbs and trunk, and cervical magnetic resonance imaging (MRI) revealed a localized lesion in the right dorsal column. After glucocorticoid therapy, her symptoms and MRI findings improved. Although disease developing less than 24 hours after vaccination is considered an unlikely cause of immuno-associated adverse events following vaccination, we discuss the possible mechanisms involved in early-onset central nervous system inflammation after vaccination in view of preexisting immunopathological susceptibility.
Comparative Risks of Potential Adverse Events Following COVID-19 mRNA Vaccination Among Older US Adults. IMPORTANCE: Head-to-head safety comparisons of the mRNA vaccines for SARS-CoV-2 are needed for decision making; however, current evidence generalizes poorly to older adults, lacks sufficient adjustment, and inadequately captures events shortly after vaccination. Additionally, no studies to date have explored potential variation in comparative vaccine safety across subgroups with frailty or an increased risk of adverse events, information that would be useful for tailoring clinical decisions. OBJECTIVE: To compare the risk of adverse events between mRNA vaccines for COVID-19 (mRNA-1273 and BNT162b2) overall, by frailty level, and by prior history of the adverse events of interest. DESIGN, SETTING, AND PARTICIPANTS: This retrospective cohort study was conducted between December 11, 2020, and July 11, 2021, with 28 days of follow-up following the week of

vaccination. A novel linked database of community pharmacy and Medicare claims data was used, representing more than 50% of the US Medicare population. Community-dwelling, fee-for-service beneficiaries aged 66 years or older who received mRNA-1273 vs BNT162b2 as their first COVID-19 vaccine were identified. Data analysis began on October 18, 2022. EXPOSURE: Dose 1 of mRNA-1273 vs BNT162b2 vaccine. MAIN OUTCOMES AND MEASURES: Twelve potential adverse events (eg, pulmonary embolism, thrombocytopenia purpura, and myocarditis) were assessed individually. Frailty was measured using a claims-based frailty index, with beneficiaries being categorized as nonfrail, prefrail, and frail. The risk of diagnosed COVID-19 was assessed as a secondary outcome. Generalized linear models estimated covariate-adjusted risk ratios (RRs) and risk differences (RDs) with 95% CIs. RESULTS: This study included 6â€¯388â€¯196 eligible individuals who received the mRNA-1273 or BNT162b2 vaccine. Their mean (SD) age was 76.3 (7.5) years, 59.4% were women, and 86.5% were White. A total of 38.1% of individuals were categorized as prefrail and 6.0% as frail. The risk of all outcomes was low in both vaccine groups. In adjusted models, the mRNA-1273 vaccine was associated with a lower risk of pulmonary embolism (RR, 0.96 [95% CI, 0.93-1.00]; RD, 9 [95% CI, 1-16] events per 100â€¯000 persons) and other adverse events in subgroup analyses (eg, 11.0% lower risk of thrombocytopenia purpura among individuals categorized as nonfrail). The mRNA-1273 vaccine was also associated with a lower risk of diagnosed COVID-19 (RR, 0.86 [95% CI, 0.83-0.87]), a benefit that was attenuated by frailty level (frail: RR, 0.94 [95% CI, 0.89-0.99]). CONCLUSIONS AND RELEVANCE: In this cohort study of older US adults, the mRNA-1273 vaccine was associated with a slightly lower risk of several adverse events compared with BNT162b2, possibly due to greater protection against COVID-19. Future research should seek to formally disentangle differences in vaccine safety and effectiveness and consider the role of frailty in assessments of COVID-19 vaccine performance.

COVID-19 Vaccination and Cardiac Arrhythmias: A Review. PURPOSE OF REVIEW: In this review, we aim to delve into the existing literature, seeking to uncover the mechanisms, investigate the electrocardiographic changes, and examine the treatment methods of various cardiac arrhythmias that occur after administration of the COVID-19 vaccine. RECENT FINDINGS: A global survey has exposed an incidence of arrhythmia in 18.27% of hospitalized COVID-19 patients. Furthermore, any type of COVID-19 vaccine - be it mRNA, adenovirus vector, whole inactivated, or protein subunit - appears to instigate cardiac arrhythmias. Among the cardiac adverse events reported post-COVID-19 vaccination, myocarditis emerges as the most common and is thought to be a potential cause of bradyarrhythmia. When a patient post-COVID-19 vaccination presents a suspicion of cardiac involvement, clinicians should perform a comprehensive history and physical examination, measure electrolyte levels, conduct ECG, and carry out necessary imaging studies. In our extensive literature search, we uncovered various potential mechanisms that might lead to cardiac conduction abnormalities and autonomic dysfunction in patients who have received the COVID-19 vaccine. These mechanisms encompass direct viral invasion through molecular mimicry/spike (S) protein production, an escalated inflammatory response, hypoxia, myocardial cell death, and the eventual scar/fibrosis. They correspond to a range of conditions including atrial tachyarrhythmias, bradyarrhythmia, ventricular arrhythmias, sudden cardiac death, and the frequently occurring myocarditis. For treating these COVID-19 vaccination-induced arrhythmias, we should incorporate general treatment strategies, similar to those applied to arrhythmias from other causes.

Cardiac inflammation associated with COVID-19 mRNA vaccination and previous myocarditis.

The Global Network COVID-19 studies: a review. With the paucity of data available regarding COVID-19 in pregnancy in low- and middle-income countries (LMICs), near the start of the pandemic, the Global Network for Women's and Children's Health Research, funded by the National Institute of Child Health and Human Development (NICHD), initiated four separate studies to better understand

the impact of the COVID-19 pandemic in eight LMIC sites. These sites included: four in Asia, in Bangladesh, India (two sites) and Pakistan; three in Africa, in the Democratic Republic of the Congo (DRC), Kenya and Zambia; and one in Central America, in Guatemala. The first study evaluated changes in health service utilisation; the second study evaluated knowledge, attitudes and practices of pregnant women in relationship to COVID-19 in pregnancy; the third study evaluated knowledge, attitude and practices related to COVID-19 vaccination in pregnancy; and the fourth study, using antibody status at delivery, evaluated changes in antibody status over time in each of the sites and the relationship of antibody positivity with various pregnancy outcomes. Across the Global Network, in the first year of the study there was little reduction in health care utilisation and no apparent change in pregnancy outcomes. Knowledge related to COVID-19 was highly variable across the sites but was generally poor. Vaccination rates among pregnant women in the Global Network were very low, and were considerably lower than the vaccination rates reported for the countries as a whole. Knowledge regarding vaccines was generally poor and varied widely. Most women did not believe the vaccines were safe or effective, but slightly more than half would accept the vaccine if offered. Based on antibody positivity, the rates of COVID-19 infection increased substantially in each of the sites over the course of the pandemic. Most pregnancy outcomes were not worse in women who were infected with COVID-19 during their pregnancies. We interpret the absence of an increase in adverse outcomes in women infected with COVID-19 to the fact that in the populations studied, most COVID-19 infections were either asymptomatic or were relatively mild.
Severe Graves' disease in a child following a single dose of Pfizer-BioNTech SARS-CoV-2 vaccine.
Assessment of psychological distress & COVID-19 vaccination: Comment.
Dacryoadenitis post COVID-19 infection and immunization. Dacryoadenitis can be a rare presentation following COVID-19 infection or can be an immunological response post COVID-19 vaccination. Herein we report two cases of lacrimal gland involvement, one post COVID-19 infection, and the other post COVID-19 vaccination. A definitive causal relationship, however, remains uncertain.
Regional Myopericarditis Mimicking Inferior Myocardial Infarction Following COVID-19 Vaccination: A Rare Adverse Event. We present the case of a 41-year-old man who developed myopericarditis after receiving the Pfizer COVID-19 vaccine. The patient experienced a sudden onset of chest and abdominal pain 16 days after vaccination. Electrocardiogram findings revealed deep T-wave inversion and minimal ST-segment elevation. Further investigation through coronary artery angiography and computed tomography identified an anomalous left main coronary artery. Magnetic resonance imaging confirmed the diagnosis of myopericarditis. This case highlights the importance of considering myopericarditis as a potential cause of chest pain and elevated cardiac biomarkers following COVID-19 vaccination, particularly in young individuals. Clinicians should be aware of this adverse event and include it in the differential diagnosis for patients presenting with similar symptoms after vaccination.
Bacillus Calmette-Guerin (BCG) Site Reaction after Coronavirus Disease 2019 (COVID-19) mRNA Vaccination.
Comparison of humoral and cellular immune responses in hematologic diseases following completed vaccination protocol with BBIBP-CorV, or AZD1222, or BNT162b2 vaccines against SARS-CoV-2. BACKGROUND: Vaccination has proven the potential to control the COVID-19 pandemic worldwide. Although recent evidence suggests a poor humoral response against SARS-CoV-2 in vaccinated hematological disease (HD) patients, data on vaccination in these patients is limited with the comparison of mRNA-based, vector-based or inactivated virus-based vaccines. METHODS: Forty-nine HD patients and 46 healthy controls (HCs) were enrolled who received two-doses complete vaccination with BNT162b2, or AZD1222, or BBIBP-CorV, respectively. The antibodies reactive to the

receptor binding domain of spike protein of SARS-CoV-2 were assayed by Siemens ADVIA Centaur assay. The reactive cellular immunity was assayed by flow cytometry. The PBMCs were reactivated with SARS-CoV-2 antigens and the production of activation-induced markers (TNF-Î±, IFN-Î³, CD40L) was measured in CD4(+) or CD8(+) T-cells ex vivo. RESULTS: The anti-RBD IgG level was the highest upon BNT162b2 vaccination in HDs (1264 BAU/mL) vs. HCs (1325 BAU/mL) among the studied groups. The BBIBP-CorV vaccination in HDs (339.8 BAU/mL (***)pâ€‰<â€‰0.001) and AZD1222 in HDs (669.9 BAU/mL *pâ€‰<â€‰0.05) resulted in weaker antibody response vs. BNT162b2 in HCs. The response rate of IgG production of HC vs. HD patients above the diagnostic cut-off value was 100% vs. 72% for the mRNA-based BNT162b2 vaccine; 93% vs. 56% for the vector-based AZD1222, or 69% vs. 33% for the inactivated vaccine BBIBP-CorV, respectively. Cases that underwent the anti-CD20 therapy resulted in significantly weaker ((**)pâ€‰<â€‰0.01) anti-RBD IgG level (302 BAU/mL) than without CD20 blocking in the HD group (928 BAU/mL). The response rates of CD4(+) TNF-Î±(+), CD4(+) IFN-Î³(+), or CD4(+) CD40L(+) cases were lower in HDs vs. HCs in all vaccine groups. However, the BBIBP-CorV vaccine resulted the highest CD4(+) TNF-Î± and CD4(+) IFN-Î³(+) T-cell mediated immunity in the HD group. CONCLUSION: We have demonstrated a significant weaker overall response to vaccines in the immunologically impaired HD population vs. HCs regardless of vaccine type. Although, the humoral immune activity against SARS-CoV-2 can be highly evoked by mRNA-based BNT162b2 vaccination compared to vector-based AZD1222 vaccine, or inactivated virus vaccine BBIBP-CorV, whereas the CD4(+) T-cell mediated cellular activity was highest in HDs vaccinated with BBIBP-CorV.

Combined intranasal and intramuscular parainfluenza 5-, simian adenovirus ChAdOx1- and poxvirus MVA-vectored vaccines induce synergistically HIV-1-specific T cells in the mucosa.
INTRODUCTION: The primary goal of this work is to broaden and enhance the options for induction of protective CD8(+) T cells against HIV-1 and respiratory pathogens. METHODS: We explored the advantages of the parainfluenza virus 5 (PIV5) vector for delivery of pathogen-derived transgenes alone and in combination with the in-human potent regimen of simian adenovirus ChAdOx1 prime-poxvirus MVA boost delivering bi-valent mosaic of HIV-1 conserved regions designated HIVconsvX. RESULTS: We showed in BALB/c mice that the PIV5 vector expressing the HIVconsvX immunogens could be readily incorporated with the other two vaccine modalities into a single regimen and that for specific vector combinations, mucosal CD8(+) T-cell induction was enhanced synergistically by a combination of the intranasal and intramuscular routes of administration. DISCUSSION: Encouraging safety and immunogenicity data from phase 1 human trials of ChAdOx1- and MVA-vectored vaccines for HIV-1, and PIV5-vectored vaccines for SARS-CoV-2 and respiratory syncytial virus pave the way for combining these vectors for HIV-1 and other indications in humans.

Prevalence and factors associated with flares following COVID-19 mRNA vaccination in patients with rheumatoid arthritis, psoriatic arthritis and spondyloarthritis: a national cohort study. OBJECTIVE: To determine prevalence and factors associated with flares post Coronavirus disease 2019 (COVID-19) mRNA vaccination in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) and spondyloarthritis (SpA). METHODS: A retrospective multi-centre study was conducted (January 2021 to February 2022). Data were collected during index visit, defined as first post-vaccine visit in which the patient had a physician-defined flare, or if at least 3 months had elapsed since first vaccine dose, whichever came first. Factors associated with flares were identified using mixed effects Cox regression and expressed as hazard ratio (HR) and 95% confidence interval (CI). RESULTS: Total of 2377 patients were included (1563 RA, 415 PsA and 399 SpA). Among patients with RA, PsA and SpA, 21.3%, 24.1% and 21.8% experienced a flare respectively. Of those who experienced a flare, only 10.2%, 11.0% and 14.9% were severe in patients with RA, PsA and SpA respectively. Patients with low or moderate/high disease were more likely to flare compared to those in remission in patients with RA only (HR: 1.68, 95% CI 1.22-2.31; HR: 2.28, 95% CI 1.50-3.48, respectively). Receiving the Moderna

vaccine was associated with a higher HR of flare compared to the Pfizer vaccine in patients with PsA only (HR: 2.21, 95% CI 1.20-4.08). Patients who had two vaccine doses were found to be less likely to flare (HR: 0.08, 95% CI 0.06-0.10). HRs of flares were not significantly different among RA, PsA and SpA. CONCLUSION: About one-fifth of patients experienced a disease flare post COVID-19 mRNA vaccination, but most flares were non-severe. Patients with active disease prior to vaccination should be monitored closely for disease flares, especially in patients with RA.

Psychological and Personality Characteristics Associated With COVID-19 Vaccination Behavior in Korean General Population. BACKGROUND: This study characterized coronavirus disease 2019 (COVID-19) vaccination behavior in the Korean general population using cluster analysis and explored related psychological factors. METHODS: We categorized 1,500 individuals based on their attitudes toward COVID-19 vaccination using hierarchical clustering and identified their level of vaccine acceptance. We examined the associations between vaccine acceptance and behavioral and psychological characteristics. RESULTS: Clustering revealed three groups according to vaccine acceptance: 'totally accepting' (n = 354, 23.6%), 'somewhat accepting' (n = 523, 34.9%), and 'reluctant' (n = 623, 41.5%). Approximately 60% of all participants who belonged to the 'totally accepting' and 'somewhat accepting' groups were willing to receive a COVID-19 vaccine despite concerns about its side effects. High vaccine acceptance was associated with older age, regular influenza vaccination, and trust in formal sources of information. Participants with high vaccine acceptance had higher levels of gratitude, extraversion, agreeableness, and conscientiousness, and lower levels of depression, anxiety, and neuroticism. CONCLUSIONS: People weighed the benefits of COVID-19 vaccination against the risk of side effects when deciding to receive the COVID-19 vaccine. Our findings also indicate that this vaccination behavior may be affected by coping mechanisms and psychological factors.

Kikuchi-Fujimoto Disease Following COVID-19 Vaccination: Experience at a Population-Based Referral Center. OBJECTIVES: Multiple case reports describe Kikuchi-Fujimoto disease (KFD) following COVID-19 vaccination, but the true nature of this phenomenon is unknown. The purpose of this study was to further assess the relationship between KFD and COVID-19 vaccination at the population level. METHODS: Confirmed KFD cases from January 2018 to April 2022 were identified from provincial pathology archives and analyzed in the context of vaccination statistics from public health resources. RESULTS: Our statistical models provide evidence of a temporal association between KFD and both antecedent COVID-19 vaccine administration as well as age-stratified vaccination rates. Eight new cases of plausible COVID-19 vaccine-associated KFD are presented, collectively exhibiting clinical and pathologic features that overlap substantially with those of idiopathic KFD. CONCLUSIONS: Our findings indicate that KFD is observed in association with COVID-19 vaccination and suggest that mechanistic studies are warranted.

Overt Hypothyroidism Status Post Pfizer-BioNTech Vaccination: A Case Study. Coronavirus disease (COVID-19) is among the most contagious viral illnesses, affecting millions worldwide. Although precautions such as social distancing, hand sanitizing, and the use of masks decreased the transmission of the virus, the situation went uncontrolled until vaccination came to light. Vaccination was vital in limiting the incidence, prevalence, and severity caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Based on the mechanism, several types of vaccines, such as Pfizer-BioNTech, Moderna, AstraZeneca, Johnson & Johnson, and Covaxin, were approved by the US Food and Drug Administration (FDA). A booster dose was implemented as the vaccine's effectiveness decreased with time. Several side effects, such as fever, soreness around the injection site, fatigue, chills, muscle weakness, and headache, have been reported after vaccination with Pfizer-BioNTech, but thyroid dysfunction is relatively rare. Several case reports and even case series describing links between COVID-19 vaccination and various types of thyroid dysfunction have appeared in the

literature. However, the exact reasons have yet to be explained. This report presents the case of a healthy 50-year-old woman diagnosed with overt hypothyroidism three weeks after the administration of the Pfizer-BioNTech vaccine.

New-onset severe eosinophilic granulomatosis with polyangiitis following the third dose ofÂ mRNA COVID-19 vaccine: A case report. Eosinophilic granulomatosis with polyangiitis (EGPA) is a complex multifactorial disease that results in multisystemic inflammation of the small- and medium-sized arteries. The exact pathogenesis of this syndrome is poorly understood, but it is postulated to result from a combination of eosinophilic dysfunction, genetic predisposition, and the development of autoantibodies after exposure to an unknown stimulus. We describe a case of new-onset EGPA following the third dose of the Pfizer-BioNTech mRNA vaccine in an infection-naive middle-aged man with a background history of allergic respiratory symptoms. The patient developed acute onset of mononeuritis multiplex, pauci-immune glomerulonephritis, and leucocytoclastic vasculitis 10â€‰days after receiving the booster dose. His laboratory markers including eosinophil count, antineutrophil cytoplasmic antibodies, and renal function tests improved markedly after the initiation of pulse steroid therapy and rituximab infusion. However, his peripheral muscle weakness and neuropathic pain did not respond to the initial therapy but improved later with intravenous cyclophosphamide and intravenous immunoglobulin. To the best of our knowledge, this is the fourth case report of post-coronavirus disease 2019 vaccination precipitation of EGPA. All reported cases including our report were in patients with previous allergic manifestations who received mRNA-based coronavirus disease 2019 vaccines, and all the patients developed mononeuritis multiplex at presentation. Despite the few reported cases of post-vaccination autoimmune phenomena, the temporal association between vaccination administration and disease onset does not indicate causality, given the mass vaccination programmes employed. However, the novel use of the mRNA platform in vaccine delivery necessitates vigilant monitoring by the scientific committee.

Cardiovascular Assessment up to One Year After COVID-19 Vaccine-Associated Myocarditis.

Association of Parsonage-Turner syndrome with COVID-19 infection and vaccination: a systematic review. OBJECTIVES: The exact etiology of Parsonage-Turner syndrome is unknown, but it is known to be preceded by infection, vaccination, or surgical intervention. In this review, we describe associations of Parsonage-Turner syndrome with COVID-19 infection and vaccination. METHODS: A systematic literature search was conducted using PubMed/MEDLINE, ScienceDirect, and Google Scholar. Microsoft Excel was used for data extraction and statistical analysis. The quality of case reports and case series was assessed using the Joanna Briggs Institute Critical Appraisal Tool. RESULTS: We selected 44 case reports and 10 case series, including 68 patients (32 post-vaccination and 36 with post-COVID-19 infection Parsonage-Turner syndrome). Middle-aged males were predominantly affected in both groups. The most frequently administered vaccine was Comirnaty (Pfizer) (53%). The mean latency was 11.7 days in the post-vaccination group and 20.3 days in the post-infection group. The most affected nerves in both groups were the axillary, suprascapular, and musculocutaneous nerves; and 78.1% and 38.9% of patients showed partial amelioration of their symptoms in the post-vaccination and post-infection groups, respectively. CONCLUSION: Post-vaccination Parsonage-Turner syndrome presents earlier than post-infection disease. Pain and sensorimotor deficits of the upper limb are common in both situations. Complete or partial recovery occurs in most cases.

Causation or Association: Important Considerations for mRNA Vaccines in Patients With Ophthalmic Disease: The COVID-19 Pandemic and Beyond.

Association of Prior COVID-19 Vaccination With SARS-CoV-2 Infection and Death in Children and Young Persons During the Omicron Variant Period in Brazil. This case-control study evaluates

nationwide information surveillance systems in Brazil to estimate vaccine effectiveness against outcomes of COVID-19 in children and young persons.
The impact of hybrid immunity on immune responses after SARS-CoV-2 vaccination in persons with multiple sclerosis treated with disease-modifying therapies. BACKGROUND AND PURPOSE: Hybrid immunity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) develops from a combination of natural infection and vaccine-generated immunity. Multiple sclerosis (MS) disease-modifying therapies (DMTs) have the potential to impact humoral and cellular immunity induced by SARS-CoV-2 vaccination and infection. The aims were to compare antibody and T-cell responses after SARS-CoV-2 mRNA vaccination in persons with MS (pwMS) treated with different DMTs and to assess differences between naÃ¯vely vaccinated pwMS and pwMS with hybrid immunity vaccinated following a previous SARS-CoV-2 infection. METHODS: Antibody and T-cell responses were determined in pwMS at baseline and 4 and 12â€‰weeks after the second dose of SARS-CoV-2 vaccination in 143 pwMS with or without previous SARS-CoV-2 infection and 40 healthy controls (HCs). The MS cohort comprised natalizumab (nâ€‰=â€‰22), dimethylfumarate (nâ€‰=â€‰23), fingolimod (nâ€‰=â€‰38), cladribine (nâ€‰=â€‰30), alemtuzumab (nâ€‰=â€‰17) and teriflunomide (nâ€‰=â€‰13) treated pwMS. Immunoglobulin G antibody responses to SARS-CoV-2 antigens were measured using a multiplex bead assay and FluoroSpot was used to assess T-cell responses (interferon Î³ and interleukin 13). RESULTS: Humoral and T-cell responses to vaccination were comparable between naÃ¯vely vaccinated HCs and pwMS treated with natalizumab, dimethylfumarate, cladribine, alemtuzumab and teriflunomide, but were suppressed in fingolimod-treated pwMS. Both fingolimod-treated pwMS and HCs vaccinated following a previous SARS-CoV-2 infection had higher antibody levels 4â€‰weeks after vaccination compared to naÃ¯vely vaccinated individuals. Antibody and interferon Î³ levels 12â€‰weeks after vaccination were positively correlated with time from last treatment course of cladribine. CONCLUSION: These findings are of relevance for infection risk mitigation and for vaccination strategies amongst pwMS undergoing DMT.
Market Failure, State Failure: The Political Economy of Supply Chain Strengthening to Ensure Equitable Access to Vaccines and Medicines in Low- and Middle-Income Countries. CONTEXT: Much of the existing work on the political economy of vaccine access has focused on how intellectual property rights agreements contribute to inequitable COVID-19 vaccine access between high-income and low- and middle-income countries (LMICs). The two solutions that emerged to scale up access in LMICs involved either voluntary arrangements under COVAX or a waiver of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) to allow immediate access to intellectual property. However, an additional constraint on access is weak and ineffective supply chains within LMICs that have eroded over several decades of health-sector reform. METHODS: This article reviews the literature on the political economy of supply chain strengthening in LMICs and identifies key challenges to equitable access to emergent vaccines and other medicines emanating from market and state failures in internal supply chains. FINDINGS: Over the past century, supply chain policies in LMICs have alternated among an emphasis on addressing market failures contributing to unaffordability of vaccines/medicines, an emphasis on state failures contributing to unavailability of vaccines/medicines, and a more recent move toward public-private hybrid arrangements to strengthen supply chains. CONCLUSIONS: In addition to reshoring production capacity through a TRIPs waiver, the international community must address chronic weakness in internal supply chains in LMICs to ensure access to novel vaccines/medicines.
Acute motor axonal neuropathy associated with the Pfizer SARS-CoV-2 vaccine.
Severity and Outcome of Post-Vaccine COVID-19 among Healthcare Workers in a University Hospital in India. Healthcare workers (HCWs) are at high risk of COVID-19 infection despite vaccination. Limited data exist on COVID-19 cases among vaccinated HCWs. This study aimed to describe the

clinical characteristics and outcomes of RT PCR-confirmed COVID-19 cases in vaccinated HCWs, at a COVID clinic in a medical college hospital. This single-center, prospective cohort study included HCWs who received at least one dose of the COVID-19 vaccine and tested positive for COVID-19 within 6 months. Data on demographics, symptoms, work category, COVID-19 vaccination interval, and infection severity were collected. Of 2381 vaccinated HCWs, 105 tested positive and were categorized as mild, moderate, or severe cases. Among vaccinated HCWs, 4.41% had post-vaccine COVID-19 infections. All 105 cases received the first dose, and 79 received the second dose. Of the cases, 47.6% were partially vaccinated, and 53.3% were breakthrough cases. The mean age was 30.90Â±8.69 years, with 63.8% male and 36.2% female cases. Most cases (85.7%) acquired infection in the hospital, and 47.6% had direct contact with COVID-19 patients. Common symptoms included fatigue (85.7%), fever (82.9%), and cough (64.8%). Among cases, 93.3% were mild, 5.7% were moderate, and 0.9% were severe. Hospital admission and supplemental oxygen therapy were required for moderate and severe cases. No mortality was reported. Certain variables were associated with age, preventive measures, workplace type, symptoms, and comorbidities. Breakthrough infections can occur among fully vaccinated HCWs but with reduced severity and mortality. Monitoring and infection control measures remain crucial even in vaccinated individuals. This study provides insights into clinical presentations, oxygen therapy requirements, and outcomes of post-vaccine COVID-19 cases among HCWs. The data will inform strategies for booster doses to prevent COVID-19.

COVID-19 inactivated and non-replicating viral vector vaccines induce regulatory training phenotype in human monocytes under epigenetic control. BACKGROUND: Trained immunity is the enhanced innate immune response resulting from exposure to pathogens or vaccines against an unrelated pathogen stimulus. Certain vaccines induce a memory like response in monocytes and NK cells, leading to modulation in cytokine production, metabolic changes, and modifications in histone patterns. Here, we hypothesized that vaccination against SARS-CoV-2 could induce the training of monocytes in addition to stimulating the adaptive immune response. METHODS: Therefore, we aimed to investigate the immunophenotyping, cytokine and metabolic profile of monocytes from individuals who were completely immunized with two doses of inactivated COVID-19 vaccine or non-replicating viral vector vaccine. Subsequently, we investigated the epigenetic mechanisms underlying monocyte immune training. As a model of inflammatorychallenge, to understand if the monocytes were trained by vaccination and how they were trained, cells were stimulated in vitro with the endotoxin LPS, an unrelated stimulus that would provoke the effects of training. RESULTS: When challenged in vitro, monocytes from vaccinated individuals produced less TNF-Î± and those who received inactivated vaccine produced less IL-6, whereas vaccination with non-replicating viral vector vaccine induced more IL-10. Inactivated vaccine increased classical monocyte frequency, and both groups showed higher CD163 expression, a hallmark of trained immunity. We observed increased expression of genes involved in glycolysis and reduced IRG1 expression in vaccinated subjects, a gene associated with the tolerance phenotype in monocytes. We observed that both vaccines reduced the chromatin accessibility of genes associated with the inflammatory response, the inactivated COVID-19 vaccine trained monocytes to a regulatory phenotype mediated by histone modifications in the IL6 and IL10 genes, while the non-replicating viral vector COVID-19 vaccine trained monocytes to a regulatory phenotype, mediated by histone modifications in the IL6, IL10, TNF, and CCL2 genes. CONCLUSIONS: Our findings support the recognized importance of adopting vaccination against SARS CoV-2, which has been shown to be effective in enhancing the adaptive immune response against the virus and reducing mortality and morbidity rates. Here, we provide evidence that vaccination also modulates the innate immune response by controlling the detrimental inflammatory response to unrelated pathogen stimulation.

Immune Response Kinetics Following a Third Heterologous BNT162b2 Booster Dose After Primary 2-Dose ChAdOx1 Vaccination in Relation to Omicron Breakthrough Infection: A Prospective Nationwide Cohort Study in South Korea. BACKGROUND: Immune responses to each vaccine must be investigated to establish effective vaccination strategies for the ongoing coronavirus disease (COVID-19) pandemic. We investigated the long-term kinetics of immune responses after heterologous booster vaccination in relation to Omicron breakthrough infection (BI). METHODS: Our study included 373 healthcare workers who received primary ChAdOx1 vaccine doses and a third BNT162b2 vaccine dose. BIs that occurred after the third vaccine were investigated. Blood specimens were collected before and 3 months after the booster dose from participants without BI and 1, 4, and 6 months after BI from participants who experienced BI. Spike-specific binding and neutralizing antibody levels against the wild-type virus, Omicron BA.1, and Omicron BA.5, as well as cellular responses, were analyzed. RESULTS: A total of 346 participants (82 in the no BI group; 192 in the BI group during the BA.1/BA.2 period; 72 in the BI group during the BA.5 period) were included in the analysis. Participants without BI exhibited the highest binding and neutralizing antibody concentrations and greatest cellular response 1 month after the third vaccination, which reached a nadir by the ninth month. Antibody and cellular responses in participants who experienced BI substantially increased postinfection. Neutralizing antibody titers in individuals who experienced BI during the BA.1/BA.2 period showed more robust increase against wild-type virus than against BA.1 and BA.5. CONCLUSIONS: Our findings provide evidence of antigenic imprinting in participants who received a heterologous booster vaccination, thereby serving as a foundation for further studies on the impact of BIs on immune responses.

Post-COVID-19 Syndrome 2 Years After the First Wave: The Role of Humoral Response, Vaccination and Reinfection. BACKGROUND: The aim of this study was to describe the long-term evolution of post-COVID-19 syndrome over 2 years after the onset of severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) in survivors of the first wave. METHODS: This prospective study was based on interviews and investigated post-COVID-19 syndrome 6, 12, and 24 months after the disease onset in all adult in- and outpatients with COVID-19 followed at Udine Hospital (Italy) during the first wave (March-May 2020). Humoral response, vaccination status, and reinfection were assessed. RESULTS: Overall, 230 patients (53.5% female; mean age 54.7 years) were interviewed 2.3 years (standard deviation = 0.11) after acute onset. Post-COVID-19 syndrome was observed in 36.1% of patients (n = 83) at 2 years. The most common persistent symptoms were fatigue (14.4%), rheumatological (14.4%), and psychiatric symptoms (9.6%). Overall, 55.4% (46 of 83) of long haulers searched for healthcare system support and 21 (45.7%) were visited by a specialist. Female gender (odds ratio [OR] = 2.50, P = .005), a proportional increase in the number of symptoms during acute COVID-19 (OR = 1.40, P = .001), and the presence of comorbidities (OR = 1.57, P = .004) were all independent risk factors for post-COVID-19 syndrome. Vaccination and reinfection had no impact on post-COVID-19 syndrome dynamics. The presence of receptor-binding domain (RBD) SARS-CoV-2 immunoglobulin G (IgG) and non-RBD SARS-CoV-2 IgG titers were not associated with the occurrence of post-COVID-19 syndrome. CONCLUSIONS: Two years after COVID-19, the burden of persistent symptoms remains high among in- and outpatients' population infected during the first wave. Post-COVID-19 dynamic does not seem to be influenced by SARS-CoV-2 immunization status and reinfection.

SARS-CoV-2 Vaccine-Induced Immune Responses Among Hematopoietic Stem Cell Transplant Recipients. BACKGROUND: Although severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination reduces the risk and severity of coronavirus disease 2019 (COVID-19), several variables may impact the humoral response among patients undergoing hematopoietic stem cell transplantation (HSCT). METHODS: A retrospective chart review was conducted among SARS-CoV-2-

vaccinated HSCT recipients between 2020 and 2022 at a single center in Boston, Massachusetts. Patients age â‰¥18 years who received doses of Pfizer, Moderna, or J&J vaccines were included. Anti-spike (S) immunoglobulin G (IgG) titer levels were measured using the Roche assay. Responders (â‰¥0.8â€…U/mL) and nonresponders (<0.8â€…U/mL) were categorized and analyzed. Multivariable linear and logistic regression were used to estimate the correlation coefficient and odds ratio of response magnitude and status. RESULTS: Of 152 HSCT recipients, 141 (92.8%) were responders, with a median (interquartile range [IQR]) anti-S IgG titer of 2500 (107.9-2500) U/mL at a median (IQR) of 80.5 (36-153.5) days from last dose, regardless of the number of doses received. Higher quantitative titers were associated with receipt of more vaccine doses (coeff, 205.79; 95% CI, 30.10 to 381.47; P = .022), being female (coeff, 343.5; 95% CI, -682.6 to -4.4; P = .047), being younger (<65 years; coeff, 365.2; 95% CI, -711.3 to 19.1; P = .039), and not being on anti-CD20 therapy (coeff, -1163.7; 95% CI, -1717.7 to -609.7; P = .001). Being male (odds ratio [OR], 0.11; 95% CI, 0.01 to 0.93; P = .04) and being on anti-CD20 therapy (OR, 0.16; 95% CI, 0.03 to 0.70; P = .016) were associated with nonresponse. CONCLUSIONS: Overall, most HSCT recipients had high SARS-CoV-2 antibody responses. More vaccine doses improved the magnitude of immune responses. Anti-S IgG monitoring may be useful for identifying attenuated vaccine-induced responses.

A Probable Association of Aseptic Meningoencephalitis, Complicated With Cerebral Salt Wasting Syndrome Following COVID-19 Vaccination: A Case Report. Coronavirus disease-19 (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) occurred worldwide, and it affected millions of people around the world and killed millions of lives without a definitive treatment. During this challenging time, vaccine production has been hugely carried outÂ leading to the invention of many vaccines against COVID-19. As any vaccineÂ can have some side effects, COVID-19 vaccines also need surveillance and reporting side effects worldwide. Currently, more than 10 vaccines are available against SARS-CoV-2 infection globally. There are many neurological complicationsÂ reported by SARS-CoV-2 vaccines. There are some reported neurological complications, such as ischemic stroke, Guillain-BarrÃ© syndrome, transverse myelitis, Bell's palsy, cerebral venous sinus thrombosis, optic neuritis, meningoencephalitis, small fiberÂ neuropathy, and Tolosa-Hunt syndrome. We present a case of an elderly man whoÂ presented with fever, fits, hyponatremia, and polyuria following COVID-19 vaccination and was found to have cerebral salt wastingÂ (CSW) with the exclusion of other causes.

Cytotoxic Lesions of the Corpus Callosum (CLOCC) Suggesting Exacerbation by Heterogeneous COVID-19 Booster Vaccination. Cytotoxic lesions of the corpus callosum (CLOCC) is a disease entity associated with reversible lesions of the corpus callosum on magnetic resonance imaging (MRI). CLOCC is caused by a variety of etiologies, but CLOCC after vaccination is extremely rare. Four prior cases of CLOCC after the first dose of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine have been reported; these were localized to the splenium and showed early clinical and neuroradiological recovery. We experienced an unusual case in which a heterogeneous COVID-19 booster vaccination caused rather severe CLOCC damage. A 74-year-old Japanese woman presented with ataxia, high fever, and hearing loss several days after her third vaccination against COVID-19. This booster was an mRNA-1273 while her first and second vaccinations were both BNT162b2 type. SARS-CoV-2 real-time reverse transcriptase polymerase chain reaction (RT-PCR) analysis was negative, but serum SARS-CoV-2 S-IgG antibodies were elevated. Her cerebrospinal fluid (CSF) showed an elevated cell countÂ and high levels of protein and interleukin-6 (IL-6). Brain MRI showed CLOCC spreading throughout the body of the corpus callosum. After the exclusion of other potential causes, the diagnosis of vaccination-related CLOCC was made. Six months later, recovery of clinical and MRI findings remained incomplete. It was suggested that the patient's CLOCC might have been

caused by the increase in CSF IL-6 due to an enhanced immune response from the heterogeneous vaccination, resulting in more severe damage to the corpus callosum than usual.

Onset of Guillain-Barre Syndrome and Transverse Myelitis Following COVID-19 Vaccination. Guillain-Barre syndrome (GBS) and transverse myelitis (TM) are both neuro-inflammatory disorders that are attributed to dysfunctions of the peripheral nervous system and spinal cord, respectively. The two conditions involve immune-mediated destruction and inflammation of the nervous system and may present clinically as a weakness in the muscles, loss of normal sensations, and even paralysis of the body or extremities. Although the incidence of GBS and TM is quite rare, there have been reports of the two diseases developing in patients, either independently or concurrently, following COVID-19 vaccinations. In this case report, we present a patient (male) who lost functions and sensations in his lower extremities 60 days after he received the COVID-19 booster vaccine. The patient's blood work was unremarkable. Magnetic resonance imaging (MRI) of his thoracic spine and an electromyography study revealed evidence of nerve demyelination, which supports the diagnosis of GBS/TM overlap syndrome. He was ultimately treated with intravenous immunoglobulins (IVIGs) and gained back functions in his lower extremities.

Retinal Changes After COVID-19 Infection and COVID-19 Vaccination. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) disease was first reported in 2019 and was initially associated with respiratory pathology. With the improvement of knowledge about this disease, it was noticed that, among other symptoms, some patients presented visual acuity changes associated with retinal vascular changes, mainly associated with thrombotic phenomena. Later, with the development of vaccines against SARS-CoV-2 disease, cases of visual acuity alterations secondary to thrombotic phenomena were also reported. CASE PRESENTATION: In this article, a series of clinical cases with retinal vascular alterations after COVID-19 infection and vaccination are described. CONCLUSION: COVID-19 infection and vaccination increase the risk of retinal vascular events. The purpose of this article is to present a set of clinical cases with various manifestations of vascular changes in the retina associated with COVID-19 infection and COVID-19 vaccination observed in the Department of Ophthalmology of Centro Hospitalar UniversitÃ¡rio de Santo AntÃ³nio, in Porto, Portugal.

Antibody response to inactivated COVID-19 vaccine in patients with type 2 diabetes mellitus after the booster immunization. BACKGROUND: The immunogenicity of booster inactivated COVID-19 vaccines in patients with type 2 diabetes mellitus (T2DM) has remained unclear. Our study aims to investigate the antibody response to inactivated COVID-19 vaccine following booster vaccination in patients with T2DM. METHODS: A total of 201 patients with T2DM and 102 healthy controls (HCs) were enrolled. The levels of anti-SARS-CoV-2 total antibodies, anti-receptor-binding domain (RBD)-specific IgG, neutralizing antibody (NAb) toward SARS-CoV-2 wild type (WT), and NAb toward SARS-CoV-2 Omicron BA.4/5 subvariant were measured to evaluate the vaccine-induced immunological responses. RESULTS: The titers of anti-RBD-specific IgG (pâ€‰=â€‰0.018) and inhibition rates of NAb toward WT (pâ€‰=â€‰0.007) were significantly decreased in patients with T2DM compared to HCs after booster vaccination for more than 6â€‰months. Both HCs and patients with T2DM showed poor resistance against BA.4/5 due to the detected inhibition rates being lower than the positive threshold. The levels of anti-RBD-specific IgG were positively associated with the proportions of CD3(+) CD4(-) CD8(-) T cells (pâ€‰=â€‰0.045), and patients with T2DM who had anti-RBD-specific IgG positivity showed higher proportions of CD3(+) CD4(-) CD8(-) T cells compared to those negative (pâ€‰=â€‰0.005). CONCLUSIONS: Patients with T2DM showed impaired antibody responses after booster vaccination for more than 6â€‰months. Decreased anti-BA.4/5 responses give rise to the possibility of breakthrough infections for both patients with T2DM and HCs.

Thrombosis with thrombocytopenia syndrome: A database review of clinical trial and post-marketing experience with Ad26.COV2.S. BACKGROUND: Thrombosis with thrombocytopenia syndrome (TTS) is a very rare disorder described after vaccination with adenoviral vector-based COVID-19 vaccines. Co-occurring thrombosis with thrombocytopenia reported after vaccination can be a proxy for identification of TTS. METHODS: Descriptive database review of all cases of co-occurring (within 42Â days) thrombosis with thrombocytopenia in participants in Ad26.COV2.S clinical trials or recipients of Ad26.COV2.S in real-world clinical practice. Cases were retrieved from Janssens' clinical trial and Global Medical Safety databases. RESULTS: There were 34 cases of co-occurring thrombosis with thrombocytopenia in Ad26.COV2.S recipients (46 per 100,000 person-years) and 15 after placebo (75 per 100,000 person-years) in clinical trials. Among Ad26.COV2.S recipients, mean age at the time of the event was 63Â years (range 25-85), 82 % were male, mean time-to-onset 112Â days (range 8-339) post-last Ad26.COV2.S dose, 26 events occurred post-dose-1, and 7 within a 28-day risk window post-vaccination. Diagnostic certainty was evaluated using Brighton Collaboration, US Centers for Disease Control and Prevention, and European Medicines Agency Pharmacovigilance Risk Assessment Committee case definitions. One case met the highest level of diagnostic certainty for all 3 definitions. There were 355 spontaneous reports of co-occurring thrombosis with thrombocytopenia in the Global Medical Safety database, 47 % males, 85 % within 28-days after vaccination. Twenty-seven cases met the highest level of diagnostic certainty for all definitions, 21 female, 19 with cerebral venous sinus thrombosis, age-range 18-68Â years. Time-to-onset was 7-14Â days post-vaccination in 20 cases. There were 8 fatalities. CONCLUSION: TTS induced by Ad26.COV2.S is very rare. Most co-occurring thrombosis with thrombocytopenia does not constitute TTS.

Prevalence of Post COVID-19 Vaccination Side Effects amongst Corp Members in an NYSC Orientation Camp in North Central Nigeria. BACKGROUND: Covid-19 vaccination is recommended for the prevention of Covid-19 infection. However, there is paucity of studies assessing post-vaccination side effects, especially in Africa, and thus, the need for this study. OBJECTIVES: To determine the prevalence of post-covid-19 vaccination side effects; the frequency of occurrence of each side effect and the willingness to receive the second dose of the vaccine. METHODS: A descriptive cross-sectional study was conducted among Corp members undergoing the three-week compulsory orientation course in a National Youth Service Corps (NYSC) orientation camp in Keffi, North-Central Nigeria. A total of 552 Corp members received the Covid-19 vaccine (AstraZeneca), 268 consented and were enrolled in the study. Data were obtained through online Google forms and were analyzed using SPSS version 26. RESULTS: The mean age of the respondents was 25 years (SD = 2.5). The prevalence of post-covid-19 vaccination side effects was 90.7%, 95% CI (86.8 - 93.8). The most common side effects were weakness (53.5%), pain at the injection site (52.7%), and headache (52.7%). There was a weak association between the duration of symptoms and intake of medications (Cramer's V = 0.148) which was not statistically significant. About a quarter, 62 (24.0%), of the respondents who received the first dose of the vaccine, were unwilling to accept the second dose, mainly due to their fear of the side effects - 53 (85.5%). CONCLUSION: Our study population had a high prevalence of post-covid-19 vaccination side effects. Thus, the need to educate recipients on possible side effects and remedies.

Neurological symptoms after COVID-19 vaccination: a report on the clinical presentation of the first 50 patients. OBJECTIVES: Neurological symptoms associated with Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) vaccination were discovered in the context of billions of administered vaccine doses. The clinical manifestations often resemble post Coronavirus Disease 2019 (post-COVID-19) syndrome (PCS) features and may be considered as post-COVID-19 vaccine syndrome (PVS). Data regarding frequency, severity and pathophysiological mechanisms are scarce.

METHODS: We assessed routine clinical examinations in 50 patients reporting new-onset neurological symptoms after SARS-CoV-2 vaccination, including neurological examination, laboratory and electrophysiology tests, as well as self-report questionnaires measuring fatigue, depressive symptoms, anxiety, risk of somatic symptom disorder, and health-related quality of life. Patients were included when symptoms occurred after confirmed COVID-19 vaccination and without prior SARS-CoV-2 infection, and if no alternative diagnosis was found to explain the symptoms. RESULTS: The most frequently reported symptoms were paraesthesia (56%), fatigue (46%) and cognitive impairment (36%). Neurological, routine laboratory, and electrophysiological examinations did not yield distinct pathological findings. Neuropsychological testing of a subgroup revealed deficits in attention, executive function and memory. DISCUSSION: The spectrum of clinical manifestations post-vaccination poses a substantial overlap with PCS symptoms. As no pathological findings were obtained in routine diagnostics, uncertainty remains about the underlying pathophysiological mechanisms and requires further investigation beyond routine work-up.

Unveiling the interplay between evidence, valuesÂ and cognitive biases. The case of the failure of the AstraZeneca COVID-19 vaccine. This paper depicts a Covid science case, that of the AstraZeneca Vaxzevria vaccine, with specific focus on what happened in Italy. Given that we believe acknowledging the role of non-evidential factors in medicine is an important insight into the recent philosophy of science, we illustrate how in the case of Vaxzevria, the interplay between facts, values (both epistemic and non-epistemic) and cognitive biases may have possibly led to different institutional decisions based on the same evidence. The structure of the paper is as follows. First, we provide a glossary of the relevant terms involved, that is to say, epistemic values, non-epistemic valuesÂ and cognitive biases. Second, we sketch a timeline of Vaxzevria's approvals and suspensions by relevant institutional healthcare authorities with special focus on Italy and the Italian Medicines Agency. Then we show the interplay between the evidence base, epistemic as well as non-epistemic values and cognitive biases using a narrative review of political decisions along with newspaper and social media content pertaining to Vaxzevria. We briefly compare Italy with other European countries to show that different political decisions were made on the basis of the same evidence.

How Infection and Vaccination Are Linked to Acute and Chronic Urticaria: A Special Focus on COVID-19. Since more than a century ago, there has been awareness of the connection between viral infections and the onset and exacerbation of urticaria. Our knowledge about the role of viral infection and vaccination in acute and chronic urticaria improved as a result of the COVID-19 pandemic but it has also highlighted knowledge gaps. Viral infections, especially respiratory tract infections like COVID-19, can trigger the onset of acute urticaria (AU) and the exacerbation of chronic urticaria (CU). Less frequently, vaccination against viruses including SARS-CoV-2 can also lead to new onset urticaria as well as worsening of CU in minority. Here, with a particular focus on COVID-19, we review what is known about the role of viral infections and vaccinations as triggers and causes of acute and chronic urticaria. We also discuss possible mechanistic pathways and outline the unmet needs in our knowledge. Although the underlying mechanisms are not clearly understood, it is believed that viral signals, medications, and stress can activate skin mast cells (MCs). Further studies are needed to fully understand the relevance of viral infections and vaccinations in acute and chronic urticaria and to better clarify causal pathways.

The Prospective COVID-19 Post-Immunization Serological Cohort in Munich (KoCo-Impf): Risk Factors and Determinants of Immune Response in Healthcare Workers. Antibody studies analyze immune responses to SARS-CoV-2 vaccination and infection, which is crucial for selecting vaccination strategies. In the KoCo-Impf study, conducted between 16 June and 16 December 2021, 6088 participants aged 18 and above from Munich were recruited to monitor antibodies, particularly in healthcare workers (HCWs) at higher risk of infection. Roche Elecsys(Â®) Anti-SARS-CoV-2 assays on

dried blood spots were used to detect prior infections (anti-Nucleocapsid antibodies) and to indicate combinations of vaccinations/infections (anti-Spike antibodies). The anti-Spike seroprevalence was 94.7%, whereas, for anti-Nucleocapsid, it was only 6.9%. HCW status and contact with SARS-CoV-2-positive individuals were identified as infection risk factors, while vaccination and current smoking were associated with reduced risk. Older age correlated with higher anti-Nucleocapsid antibody levels, while vaccination and current smoking decreased the response. Vaccination alone or combined with infection led to higher anti-Spike antibody levels. Increasing time since the second vaccination, advancing age, and current smoking reduced the anti-Spike response. The cumulative number of cases in Munich affected the anti-Spike response over time but had no impact on anti-Nucleocapsid antibody development/seropositivity. Due to the significantly higher infection risk faced by HCWs and the limited number of significant risk factors, it is suggested that all HCWs require protection regardless of individual traits.

The Potential Role of SARS-CoV-2 Infection and Vaccines in Multiple Sclerosis Onset and Reactivation: A Case Series and Literature Review. The recent SARS-CoV-2 pandemic and related vaccines have raised several issues. Among them, the potential role of the viral infection (COVID-19) or anti-SARS-CoV-2 vaccines as causal factors of dysimmune CNS disorders, as well as the safety and efficacy of vaccines in patients affected by such diseases and on immune-active treatments have been analyzed. The aim is to better understand the relationship between SARS-CoV-2 infection/vaccines with dysimmune CNS diseases by describing 12 cases of multiple sclerosis/myelitis onset or reactivation after exposure to SARS-CoV-2 infection/vaccines and reviewing all published case reports or case series in which MS onset or reactivation was temporally associated with either COVID-19 (8 case reports, 3 case series) or anti-SARS-CoV-2 vaccines (13 case reports, 6 case series). All the cases share a temporal association between viral/vaccine exposure and symptoms onset. This finding, together with direct or immune-based mechanisms described both during COVID-19 and MS, claims in favor of a role for SARS-CoV-2 infection/vaccines in unmasking dysimmune CNS disorders. The most common clinical presentations involve the optic nerve, brainstem and spinal cord. The preferential tropism of the virus together with the presence of some host-related genetic/immune factors might predispose to the involvement of specific CNS districts.

Cluster Analysis Identifies Distinct Patterns of T-Cell and Humoral Immune Responses Evolution Following a Third Dose of SARS-CoV-2 Vaccine in People Living with HIV. (1) Background: Many vaccines require higher, additional doses or adjuvants to provide adequate protection for people living with HIV (PLWH). Despite their potential risk of severe coronavirus disease 2019, immunological data remain sparse, and a clear consensus for the best booster strategy is lacking. (2) Methods: Using the data obtained from our previous study assessing prospective T-cell and humoral immune responses before and after administration of a third dose of SARS-CoV-2 vaccine, we assessed the correlations between immune parameters reflecting humoral and cellular immune responses. We further aimed at identifying distinct clusters of patients with similar patterns of immune response evolution to determine how these relate to demographic and clinical factors. (3) Results: Among 80 PLWH and 51 healthcare workers (HCWs) enrolled in the study, cluster analysis identified four distinct patterns of evolution characterised by specific immune patterns and clinical factors. We observed that immune responses appeared to be less robust in cluster A, whose individuals were mostly PLWH who had never been infected with SARS-CoV-2. Cluster C, whose individuals showed a particularly drastic increase in markers of humoral immune response following the third dose of vaccine, was mainly composed of female participants who experienced SARS-CoV-2. Regarding the correlation study, although we observed a strong positive correlation between markers mirroring humoral immune response, markers of T-cell response following vaccination correlated only in a lesser extent with markers of humoral immunity. This suggests that neutralising antibody titers alone are not

always a reliable reflection of the magnitude of the whole immune response. (4) Conclusions: Our findings show heterogeneity in immune responses among SARS-CoV-2 vaccinated PLWH. Specific subgroups could therefore benefit from distinct immunization strategies. Prior or breakthrough natural infection enhances the activity of vaccines and must be taken into account for informing global vaccine strategies among PLWH, even those with a viro-immunologically controlled infection.

The Impact of COVID-19 Vaccination on Inflammatory Skin Disorders and Other Cutaneous Diseases: A Review of the Published Literature. Background: Four vaccines have been authorized by the European Medicines Agency (EMA): viral vector-based vaccines (AstraZeneca; AZD1222 and Johnson & Johnson; Ad26.COV2. and 2 mRNA-based vaccines (Pfizer/BioNTech; BNT162b2 and Moderna; mRNA-1273). Adverse events (AEs) related to vaccination have been described in the literature. The main aim of the dermatological practice was to avoid the diffusion of COVID-19, allowing the continuity of care for patients. Objective: The aim of this review article is to investigate current literature regarding cutaneous reactions following COVID-19 vaccination, mainly inflammatory dermatological diseases. Materials and methods: Investigated manuscripts included metanalyses, reviews, letters to the editor, real-life studies, case series, and reports. Results: We selected a total of 234 articles involving more than 550 patients. We have divided the results section into various sub-sections to ensure greater understanding for readers. Conclusions: Clinicians should keep in mind the possibility of new onsets or the worsening of several dermatoses following vaccination in order to promptly recognize and treat these AEs. Certainly, vaccination should not be discouraged.

Assessment of Risk Perception of COVID-19 Post Vaccination amongst the General Population of Riyadh Region. COVID-19 is a highly contagious disease caused by SARS-CoV-2. Vaccination against the virus was first approved in Saudi Arabia in December 2020. Vaccinated individuals are still at risk of getting infected with the virus and can transmit the disease. Therefore, the perception of vaccinated individuals regarding the disease can help limit the spread of the virus. OBJECTIVES: To measure the risk perception of COVID-19 following vaccination and factors that have an effect on risk perception; to identify the health protective behaviours of the vaccinated individuals. METHODOLOGY: This is a quantitative analytical cross-sectional, questionnaire-based study. The target population includes individuals aged 18 and above who live in the Riyadh region and have been vaccinated, during the period of June 2021 to December 2021. RESULTS: The perception of 30.2% of participants did not change after vaccination, with many participants continuing to "always" take precautions even after vaccination. Numerous factors, such as age, gender, marital status, occupational status, employment status, and total household income, have shown significant effects towards risk perception. CONCLUSION: Many vaccinated individuals have continued to take precautionary steps and their risk perception has not changed.

Influence of the Single Nucleotide Polymorphisms rs12252 and rs34481144 in IFITM3 on the Antibody Response after Vaccination against COVID-19. The COVID-19 mRNA vaccine is the first mRNA vaccine approved for human administration by both the U.S. Food and Drug Administration and the European Medicines Agency. Studies have shown that the immune response and the decay of immunity after vaccination with the COVID-19 vaccines are variable within a population. Host genetic factors probably contribute to this variability. In this study, we investigated the effect of the single-nucleotide polymorphisms rs12252 and rs34481144 in the interferon-induced transmembrane protein (IFITM) 3 gene on the humoral immune response after vaccination against COVID-19 with mRNA vaccines. Blood samples were collected from 1893 healthcare workers and medical students at multiple time points post-vaccination and antibody titers against the SARS-CoV-2 S1 protein receptor binding domain were determined at all time points. All participants were genotyped for the rs34481144 and rs12252 polymorphisms in the IFITM3 gene. After the second and third vaccinations, antibody titer levels increased at one month and decreased at six months ($p < 0.0001$) and were

higher after the booster vaccination than after the basic immunization ($p < 0.0001$). Participants vaccinated with mRNA-1273 had a higher humoral immune response than participants vaccinated with BNT162b2. rs12252 had no effect on the antibody response. In contrast, carriers of the GG genotype in rs34481144 vaccinated with BNT162b2 had a lower humoral immune response compared to A allele carriers, which reached statistical significance on the day of the second vaccination ($p = 0.03$) and one month after the second vaccination ($p = 0.04$). Further studies on the influence of rs12252 and rs34481144 on the humoral immune response after vaccination against COVID-19 are needed.

A Case of Acquired Aplastic Anemia after Severe Hepatitis- Probably Induced by the Pfizer/BioNTech Vaccine: A Case Report and Review of Literature. INTRODUCTION: An important but rare adverse effect of vaccines is their association with autoimmune events, including hepatitis and aplastic anemia (AA). In this paper, we report a case of hepatitis followed by AA that occurred after the COVID-19 vaccine was administered. CASE REPORT: This paper focuses on a 30-year-old female who presented with acute hepatitis three weeks after receiving the second dose of the coronavirus Pfizer/BioNTech vaccine. After an extensive diagnostic evaluation was conducted that did not discover a specific cause, the Pfizer/BioNTech vaccine was suspected and the patient was treated with corticosteroids. One week after the onset of a liver disorder, the patient presented with gum bleeding and pancytopenia, and the diagnosis of AA was established via laboratory testing and bone marrow biopsy. After the diagnosis, the patient received immunosuppressive therapy using anti-lymphocyte serum (ATGAM) and CYCLOSPORINE A with progressive improvements in cytopenia. The important issue is whether AA is related to acute hepatitis or the coronavirus vaccine. CONCLUSION: Clinicians should be aware of the risk of both the possibility of acute hepatitis, AA, or both after receiving the COVID-19 vaccination. It is very hard to distinguish the cause of AA between vaccine- and hepatitis-related AA. Predicting who develops hepatic or myelo-complications after vaccination is difficult.

Associations between COVID-19 Vaccination and Behavioural Intention to Receive Seasonal Influenza Vaccination among Chinese Older Adults: A Population-Based Random Telephone Survey. During the Coronavirus Disease 2019 (COVID-19) pandemic, seasonal influenza remained a significant health threat for older adults. Seasonal influenza vaccination (SIV) is highly effective and safe for older adults. This study investigated the associations of COVID-19 vaccination, perceptions related to COVID-19 and SIV, with the behavioural intention to receive SIV among older adults in Hong Kong, China. A random telephone survey was conducted among 440 community-dwelling Hong Kong residents aged 65 years or above, between November 2021 and January 2022. Among the participants, 55.7% intended to receive SIV in the next year. After adjustment for significant background characteristics, concern about whether SIV and COVID-19 vaccination would negatively affect each other was associated with a lower intention to receive SIV, while a perceived higher risk of co-infection with COVID-19 and seasonal influenza was positively associated with the dependent variable. In addition, the perceived severe consequences of seasonal influenza, perceived benefits of SIV, received cues to action from doctors and participants' family members or friends, and the perception that more older people would receive SIV was associated with a higher behavioural intention. Future programmes promoting SIV among older adults should modify perceptions related to COVID-19 vaccination and SIV at the same time.

SARS-CoV-2 Antibody Dynamics after COVID-19 Vaccination and Infection: A Real-World Cross-Sectional Analysis. The Coronavirus disease 2019 (COVID-19) pandemic, caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), continues to surge despite the widespread use of vaccination. In Thailand, more than 77% and 39% of the population received two doses and three doses of COVID-19 vaccines as of December 2022, respectively. In addition, during the Omicron

predominant period in 2022, more than 70% of Thai individuals have been infected. To gain comprehensive insight into SARS-CoV-2 antibody dynamics following vaccination or following vaccination and infection (hybrid immunity), we performed a cross-sectional analysis of sera samples from individuals who received COVID-19 vaccination and/or have been infected with COVID-19 in Thailand between January 2021 and December 2022. A total of 4126 samples were collected. Humoral immunity was evaluated by quantifying the immunoglobulin (including IgG, IgM, and IgA isotypes) specific to the SARS-CoV-2 receptor-binding domain (RBD) or Ig anti-RBD. The results showed that individuals who received two-dose vaccination alone had lower levels of Ig anti-RBD, which rapidly waned over time. To restore the waning antibody, a third dose vaccination is recommended for uninfected individuals who have only received 2 doses.

Heterologous Booster with BNT162b2 Induced High Specific Antibody Levels in CoronaVac Vaccinees. Immune responses after COVID-19 vaccination should be evaluated in different populations around the world. This study compared antibody responses induced by ChAdOx1 nCoV-19, CoronaVac, and BNT162b2 vaccines. Blood samples from vaccinees were collected pre- and post-vaccinations with the second and third doses. The study enrolled 78 vaccinees, of whom 62.8% were women, with the following median ages: 26 years-ChAdOx1 nCoV-19; 40 years-CoronaVac; 30 years-BNT162b2. Serum samples were quantified for anti-RBD IgG and anti-RBD IgA and anti-spike IgG by ELISA. After two vaccine doses, BNT162b2 vaccinees produced higher levels of anti-RBD IgA and IgG, and anti-spike IgG compared to ChAdOx1 nCoV-19 and CoronaVac vaccinees. The third dose booster with BNT162b2 induced higher levels of anti-RBD IgA and IgG, and anti-spike IgG in CoronaVac vaccinees. Individuals who reported a SARS-CoV-2 infection before or during the study had higher anti-RBD IgA and IgG production. In conclusion, two doses of the studied vaccines induced detectable levels of anti-RBD IgA and IgG and anti-spike IgG in vaccinees. The heterologous booster with BNT162b2 increased anti-RBD IgA and IgG and anti-spike IgG levels in CoronaVac vaccinees and anti-RBD IgA levels in ChAdOx1 nCoV-19 vaccinees. Furthermore, SARS-CoV-2 infection induced higher anti-RBD IgA and IgG levels in CoronaVac vaccinees.

Humoral and Cellular Immunity following Five Doses of COVID-19 Vaccines in Solid Organ Transplant Recipients: A Systematic Review and Meta-Analysis. Solid organ transplant (SOT) recipients are at increased risk of COVID-19 infection because of their suppressed immunity. The available data show that COVID-19 vaccines are less effective in SOT recipients. We aimed to assess the cellular and humoral immunogenicity with an increasing the number of doses of COVID-19 vaccines in SOT recipients and to identify factors affecting vaccine response in this population. A systematic review and meta-analysis were conducted to identify ongoing and completed studies of humoral and cellular immunity following COVID-19 vaccines in SOT recipients. The search retrieved 278 results with 45 duplicates, and 43 records did not match the inclusion criteria. After title and abstract screening, we retained 189 records, and 135 records were excluded. The reasons for exclusion involved studies with immunocompromised patients (non-transplant recipients), dialysis patients, and individuals who had already recovered from SARS-CoV-2 infection. After full-text reading, 55 observational studies and randomized clinical trials (RCTs) were included. The proportion of responders appeared higher after the third, fourth, and fifth doses. The risk factors for non-response included older age and the use of mycophenolate mofetil, corticosteroids, and other immunosuppressants. This systematic review and meta-analysis demonstrates the immunogenicity following different doses of COVID-19 vaccines among SOT patients. Due to the low immunogenicity of vaccines, additional strategies to improve vaccine response may be necessary.

Evaluation of Antibody Response and Adverse Effects following Heterologous COVID-19 Vaccine Booster with mRNA Vaccine among Healthcare Workers in Indonesia. Background: The administration of the third (or booster) dose of COVID-19 vaccine is important in maintaining

protection against SARS-CoV-2 infection or the severity of the disease. In Indonesia, health care workers (HCWs) are among the first to receive a booster dose of the COVID-19 vaccine. In this study, we evaluated the antibody response and adverse events following heterologous booster vaccine using mRNA-1273 among HCWs that were fully vaccinated with inactivated viral vaccine as the priming doses. Methods: 75 HCWs at Dr. Soetomo General Hospital in Surabaya, Indonesia, participated in this study. The level of antibody against the SARS-CoV-2 receptor binding domain was analyzed at 1, 3, and 5 months following the second priming dose and at 1, 3, and 5 months after the booster dose. Results: We found a significantly higher level of antibody response in subjects receiving a booster dose of the mRNA-1273 vaccine compared to those receiving an inactivated viral vaccine as a booster. Interestingly, participants with hypertension and a history of diabetes mellitus showed a lower antibody response following the booster dose. There was a higher frequency of adverse events following injection with the mRNA-1273 vaccine compared to the inactivated viral vaccine, although the overall adverse events were considered minor. Conclusions: A heterologous booster dose using mRNA vaccine resulted in a high antibody response; however, participants with hypertension and diabetes mellitus displayed a lower antibody response.

Fatigue Potentially Reduces the Effect of Transcranial Magnetic Stimulation on Depression Following COVID-19 and Its Vaccination. COVID-19's long-term effects, known as Long-COVID, present psychiatric and physical challenges in recovered patients. Similarly, rare long-term post-vaccination side effects, resembling Long-COVID, are emerging (called Post-Vaccine). However, effective treatments for both conditions are scarce. Our clinical experience suggests that transcranial magnetic stimulation (TMS) often aids recovery in Long-COVID and Post-Vaccine patients. However, its effectiveness is reduced in patients with severe fatigue. Therefore, we retrospectively analysed Tokyo TMS Clinic's outpatient records (60 in total; mean age, 38 years) to compare Long-COVID and post-vaccine patients' characteristics and symptoms, assess the impact of TMS on their symptoms, and investigate the role of fatigue in depression recovery with TMS. The primary outcome was the regression coefficient of the initial fatigue score on depression score improvement using TMS. Secondary outcomes included psychiatric/physical scores before and after TMS and their improvement rates. We found no differences in the initial symptoms and background factors between Long-COVID and Post-Vaccine patients. After ten TMS sessions, all psychiatric and physical symptom scores improved significantly. TMS improves depression, insomnia, anxiety, and related neuropsychiatric symptoms, which were the primary complaints in this study. Thus, we conclude that TMS improves depression and anxiety. The effectiveness of TMS in treating depression in Long-COVID and Post-Vaccine patients decreased as fatigue severity increased. In conclusion, TMS relieved depressive symptoms following COVID-19 and vaccination; however, fatigue may hinder its effectiveness.

Serological Responses after a Fourth Dose of SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients: A Systematic Review and Meta-Analysis. The humoral immune response and safety of the fourth dose of the coronavirus disease 2019 (COVID-19) vaccine in solid organ transplant (SOT) recipients need to be fully elucidated. We conducted a systematic review and meta-analysis to assess the efficacy and safety associated with this additional dose of the COVID-19 vaccine in the SOT recipients. A comprehensive search was conducted to identify studies on SOT patients without prior natural SARS-CoV-2 infection who received the fourth dose of the COVID-19 vaccine. Serological antibody responses following vaccination were synthesized by a meta-analysis of proportions. The proportions for each outcome were integrated by using a random-effects model. Approximately 56-92% of the SOT patients developed a humoral immune response, and the pooled seroprevalence rate was 75% (95% confidence interval [CI], 62-82%) after administering the third vaccine dose. Following the fourth dose of vaccination, approximately 76-95% of the patients developed a humoral immune

response. The pooled seroprevalence rate after the fourth dose was 85% (95% CI, 79-91%). Of the patients who initially tested seronegative after the second dose, approximately 22-76% of patients subsequently became seropositive after the third dose. The pooled seroconversion rate for the third dose was 47% (95% CI, 31-64%). Among the patients who were seronegative after the third dose, approximately 25-76% turned seropositive after the fourth dose. The pooled seroconversion rate after the fourth dose was 51% (95% CI, 40-63%). Safety data were reported in three studies, demonstrating that adverse effects following the fourth dose were generally mild, and patients with these adverse effects did not require hospitalization. No transplant rejection or serious adverse events were observed. A fourth dose of the COVID-19 vaccine in SOT recipients was associated with an improved humoral immune response, and the vaccine was considered relatively safe.

New Onset Autoimmune Diseases after the Sputnik Vaccine. The vertiginous advance for identifying the genomic sequence of SARS-CoV-2 allowed the development of a vaccine including mRNA-based vaccines, inactivated viruses, protein subunits, and adenoviral vaccines such as Sputnik. This study aims to report on autoimmune disease manifestations that occurred following COVID-19 Sputnik vaccination. Patients and Methods: A retrospective study was conducted on patients with new-onset autoimmune diseases induced by a post-COVID-19 vaccine between March 2021 and December 2022, in two referral hospitals in Mexico City and Argentina. The study evaluated patients who received the Sputnik vaccine and developed recent-onset autoimmune diseases. Results: Twenty-eight patients developed recent-onset autoimmune diseases after Sputnik vaccine. The median age was 56.9 Â± 21.7 years, with 14 females and 14 males. The autoimmune diseases observed were neurological in 13 patients (46%), hematological autoimmune manifestations occurred in 12 patients (42%), with thrombotic disease observed in 10 patients (28%), and autoimmune hemolytic anemia in two patients (7.1%). Rheumatological disorders were present in two patients (7.1%), and endocrine disorders in one patient (3.5%). Principio del formulario Conclusion: Although the COVID-19 Sputnik vaccine is generally safe, it can lead to adverse effects. Thrombosis and Guillain-Barre were the most frequent manifestations observed in our group of patients.

Changes in Peripheral Immune Cells after the Third Dose of SARS-CoV-2 mRNA-BNT162b2 Vaccine and Disease Outcomes in Cancer Patients Receiving Immune Checkpoint Inhibitors: A Prospective Analysis of the Vax-on-Third-Profile Study. BACKGROUND: Anti-SARS-CoV-2 mRNA vaccines can deeply affect cell-mediated immune responses in immunocompromised recipients, including cancer patients receiving active treatments. The clinical implications of changes in peripheral blood lymphocyte subsets following the third dose of mRNA-BNT162b2 vaccination (tozinameran) in patients on immune checkpoint blockade are not fully understood. We conducted a prospective analysis of the Vax-On-Third-Profile study to evaluate the impact of circulating lymphocyte dynamics on disease outcomes in this subgroup of patients. METHODS: Recipients of booster dosing who had received before vaccination at least one course of an anti-PD-1/PD-L1 treatment for an advanced solid tumor were eligible. Immunophenotyping of peripheral blood was performed before the third dose of tozinameran (timepoint-1) and four weeks later (timepoint-2) to quantify the absolute counts of lymphocyte subpopulations, including CD3(+)CD4(+) T cells, CD3(+)CD8(+) T cells, B cells, and NK cells. Logistic regression was used to analyze the relationship between lymphocyte subsets and durable clinical benefit (DCB). The log-rank test and Cox regression model were applied to evaluate the relationship between lymphocyte subpopulations and both vaccine-related time-to-treatment failure (V-TTF) and overall survival (OS). RESULTS: We included a total of 56 patients with metastatic disease who were given a third dose of tozinameran between 23 September and 7 October 2021 (median age: 66 years; male: 71%). Most recipients had a diagnosis of lung cancer and were being treated with pembrolizumab or nivolumab. Compared to baseline, the third immunization resulted in

an incremental change in the median counts of all lymphocyte subpopulations, which was statistically significant only for NK cells ($p < 0.001$). A significant correlation was found between NK cell counts and DCB at timepoint-2 ($p < 0.001$). Multivariate logistic regression analysis of DCB confirmed the predictive significance of high-level NK cell counts ($p = 0.020$). In multivariate Cox regression analysis, high-level NK cell counts independently predicted longer V-TTF [HR 0.34 (95% CI 0.14-0.80), $p = 0.014$] and OS [HR 0.36 (95% CI 0.15-0.89), $p = 0.027$]. CONCLUSIONS: Our data suggest expansion of NK cell counts as the most noteworthy change in circulating lymphocytes after the third dose of tozinameran in cancer patients receiving PD-1/PD-L1-targeted agents. This change correlated with enhanced therapeutic efficacy, improving the rate of disease control, and prolonging survival outcomes. Similar findings have not been previously reported, implying that they have proof-of-concept value and warrant further confirmation.

Safety and immunogenicity of a SARS-CoV-2 Gamma variant RBD-based protein adjuvanted vaccine used as booster in healthy adults. A Gamma Variant RBD-based aluminum hydroxide adjuvanted vaccine called ARVAC CG was selected for a first in human clinical trial. Healthy male and female participantsÂ (18-55 years old) with a complete COVID-19-primary vaccine scheme were assigned to receive two intramuscular doses of either a low-dose or a high-dose of ARVAC CG. The primary endpoint was safety. The secondary objective was humoral immunogenicity. Cellular immune responses were studied as an exploratory objective. The trial was prospectively registered in PRIISA.BA (Registration Code 6564) and ANMAT and retrospectively registered in ClinicalTrials.gov (NCT05656508). Samples from participants of a surveillance strategy implemented by the Ministry of Health of the Province of Buenos AiresÂ that were boosted with BNT162b2 were also analyzed to compare with the booster effect of ARVACÂ CG. ARVAC CG exhibits a satisfactory safety profile, a robust and broad booster response of neutralizing antibodies against the Ancestral strain of SARS-CoV-2 and the Gamma, Delta, Omicron BA.1 and Omicron BA.5 variants of concern and a booster effect on T cell immunity in individuals previously immunized with different COVID-19 vaccine platforms.

Dosing interval regimen shapes potency and breadth of antibody repertoire after vaccination of SARS-CoV-2 RBD protein subunit vaccine. Vaccination with different vaccines has been implemented globally to counter the continuous COVID-19 pandemic. However, the vaccine-elicited antibodies have reduced efficiency against the highly mutated Omicron sub-variants. Previously, we developed a protein subunit COVID-19 vaccine called ZF2001, based on the dimeric receptor-binding domain (RBD). This vaccine has been administered using different dosing intervals in real-world setting. Some individuals received three doses of ZF2001, with a one-month interval between each dose, due to urgent clinical requirements. Others had an extended dosing interval of up to five months between the second and third dose, a standard vaccination regimen for the protein subunit vaccine against hepatitis B. In this study, we profile B cell responses in individuals who received three doses of ZF2001, and compared those with long or short dosing intervals. We observed that the long-interval group exhibited higher and broader serologic antibody responses. These responses were associated with the increased size and evolution of vaccine-elicited B-cell receptor repertoires, characterized by the elevation of expanded clonotypes and somatic hypermutations. Both groups of individuals generated substantial amounts of broadly neutralizing antibodies (bnAbs) against various SARS-CoV-2 variants, including Omicron sub-variants such as XBB. These bnAbs target four antigenic sites within the RBD. To determine the vulnerable site of SARS-CoV-2, we employed cryo-electron microscopy to identify the epitopes of highly potent bnAbs that targeted two major sites. Our findings provide immunological insights into the B cell responses elicited by RBD-based vaccine, and suggest that a vaccination regimen of prolonging time interval should be used in practice.

BNT162b2 mRNA COVID-19 against symptomatic Omicron infection following a mass vaccination campaign in southern Brazil: A prospective test-negative design study. BACKGROUND: Evidence regarding effectiveness of BNT162b2 mRNA COVID-19 vaccine against Omicron in Latin America is limited. We estimated BNT162b2 effectiveness against symptomatic COVID-19 in Brazil when Omicron was predominant. METHODS: This prospective test-negative, case-control study was conducted in Toledo, Brazil, following a mass COVID-19 vaccination with BNT162b2. Patients were included if they were aged â‰¥12Â years, sought care for acute respiratory symptoms in the public health system between November 3, 2021 and June 20, 2022, and were tested for SARS-CoV-2 using RT-PCR. In the primary analysis, we determined the effectiveness of two doses of BNT162b2 against symptomatic COVID-19. RESULTS: A total of 4,574 were enrolled; of these, 1,758 patients (586 cases and 1,172 controls) were included in the primary analysis. Mean age was 27.7Â years, 53.8Â % were women, and 90.1Â % had a Charlson comorbidity index of zero. Omicron accounted for >97Â % of all identified SARS-CoV-2 variants, with BA.1 and BA.2 accounting for 84.3Â % and 12.6Â %, respectively. Overall adjusted estimate of two-dose vaccine effectiveness against symptomatic COVID-19 was 46.7Â % (95Â %CI, 19.9Â %-64.6Â %) after a median time between the second dose and the beginning of COVID-19 symptoms of 94Â days (IQR, 60-139Â days). Effectiveness waned from 77.7Â % at 7-29Â days after receipt of a second dose to <30Â % (non-significant) after â‰¥120Â days. CONCLUSION: In a relatively young and healthy Brazilian population, two doses of BNT162b2 provided protection against symptomatic Omicron infection. However, this protection waned significantly over time, underscoring the need for boosting with variant-adapted vaccines in this population prior to waves of disease activity. TRIAL REGISTRATION NUMBER: ClinicalTrials.gov number, NCT05052307 (https://clinicaltrials.gov/ct2/show/NCT05052307).

Temporally Associated Invasive Pneumococcal Disease and SARS-CoV-2 Infection, Alaska, USA, 2020-2021. Streptococcus pneumoniae can co-infect persons who have viral respiratory tract infections. However, research on S. pneumoniae infections that are temporally associated with SARS-CoV-2 infections is limited. We described the epidemiology and clinical course of patients who had invasive pneumococcal disease (IPD) and temporally associated SARS-CoV-2 infections in Alaska, USA, during January 1, 2020-December 23, 2021. Of 271 patients who had laboratory-confirmed IPD, 55 (20%) had a positive SARS-CoV-2 test result. We observed no major differences in age, race, sex, or underlying medical conditions among IPD patients with and without SARS-CoV-2. However, a larger proportion of IPD patients with SARS-CoV-2 died (16%, n = 9) than for those with IPD alone (4%, n = 9) (p<0.01). IPD patients with SARS-CoV-2 were also more likely to be experiencing homelessness (adjusted OR 3.5; 95% CI 1.7-7.5). Our study highlights the risk for dual infection and ongoing benefits of pneumococcal and COVID-19 vaccination, especially among vulnerable populations.

A study of the efficacy and safety of plaque psoriasis treatment by TNF-Î± and IL-17A inhibitor biologics in patients who received the inactivated SARS-CoV-2 vaccine. BACKGROUND: Vaccination is an important method for the prevention of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission. There is currently a lack of real-world clinical data regarding the safety and efficacy of coronavirus disease 2019 (COVID-19) vaccines with respect to plaque psoriasis treatment involving tumor necrosis factor-Î± (TNF-Î±) and interleukin-17A (IL-17A) inhibitors. METHODS: We longitudinally analyzed 152 patients with plaque psoriasis, 86 of whom received two doses of inactivated COVID-19 vaccine (either BBIBP-CorV or CoronaVac). Comparisons were made between patients undergoing treatment with biologics (TNF- Î± inhibitors or IL-17A inhibitors) or acitretin. Routine blood tests were used to assess safety; the psoriasis area and severity index (PASI) and dermatology life quality index (DLQI) were used to assess efficacy. RESULTS: After inactivated COVID-19 vaccination, biologics retained considerable advantages in terms of improving skin lesions (measured by PASI) and quality of life (measured by DLQI), compared with conventional treatment

(pâ€‰<â€‰0.05 and pâ€‰<â€‰0.01, respectively). Routine blood tests and hepatorenal function analyses suggested that inactivated SARS-CoV-2 vaccines did not alter the safety of biologics treatment (pâ€‰>â€‰0.05). CONCLUSIONS: Inactivated SARS-CoV-2 vaccines do not have significant impacts on the safety and efficacy of biologics (TNF-Î± inhibitors or IL-17A inhibitors) in patients with moderate to severe plaque psoriasis.

Nephrotic syndrome following COVID-19 vaccination: a systematic review. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 infection has caused significant morbidity and mortality. Vaccines produced against this virus have proven highly effective. However, adverse events following vaccination have also been reported. One of them is nephrotic syndrome, that can be associated with different pathologic pictures. This review aims to provide a wider understanding of incidence, etiopathogenesis, and management of nephrotic syndrome following vaccinationÂ against SARS-CoV-2. METHODS AND RESULTS: A literature search was undertaken using appropriate keywords in various databases like PubMed, Google Scholar, Europe PMC, and Science Direct. Twenty-one articles were included following qualitative assessment. Data of 74 patients from these articles were included. DISCUSSION: The pathogenesis of nephrotic syndrome following COVID vaccination has been widely attributed to the activation of angiotensin-converting enzyme-2 receptors, leading to podocyte effacement. Relapses haveÂ also been reported in patients with prior history of nephrotic syndrome following COVID-19 vaccination. A renal biopsy is necessary to identify the histopathological picture. Management of COVID-19 vaccine-induced nephrotic syndrome was mainly reported as successfully attainableÂ with corticosteroids and supportive management. CONCLUSION: Further investigations will help in establishing an early diagnosis and salvaging kidney function.

Differences in Coronavirus disease - 19 vaccination related side effects in patients with ulcerative colitis and Crohn's disease in Japan. BACKGROUND/PURPOSE OF THIS STUDY: It has been recommended that individuals with inflammatory bowel disease (IBD) be vaccinated against Coronavirus disease -Â 19 (COVID-19). Recently, we documented the incidence of side effects (SEs) after COVID-19 immunization among individuals with IBD in Japan. However, the study did not show differences between the types of IBD or the patients' clinical backgrounds. In this survey, we aimed at investigating whether the frequency of SEs differed among patients with IBD. METHODS: A cross-sectional survey was conducted among adult patients with IBD at Kobe University between March 2022 and September 2022. RESULTS: Total 195 patients, including 134 with ulcerative colitis (UC) and 61 with Crohn's disease (CD), completed the questionnaire and were included in the analysis. Of these, 92.3%, 91.3% and 44.1% received the initial, second and third dose of the COVID-19 vaccine, respectively. The frequency of local symptoms following the initial, second and third dose of theÂ vaccine was comparable between patients with UC and CD (69.6% vs. 72.7%, 64.2% vs. 69.1% and 63.5% vs. 73.9%, respectively). Muscle pain after the initial and second doses of the COVID-19 vaccine was more common among patients treated with corticosteroids (58.1% vs. 37.6% and 60.0% vs. 31.8%, pâ€‰<â€‰0.05). Female sex, younger age and current or former smoking were associated with an increased incidence of fever or chills after the initial dose of theÂ vaccine (pâ€‰<â€‰0.05). In contrast, corticosteroid use was identified as a factor associated with an increased incidence of muscle pain after the initial dose of vaccine (pâ€‰<â€‰0.05). CONCLUSION: The use of corticosteroids could increase the risk of muscle pain following COVID-19 vaccination. Additionally, factors such as female sex, younger age and current or former smoking can affect the incidence of fever or chills. This information should encourage patients with IBD to get vaccinated against COVID-19.

Risk of Worsening Heart Failure and All-Cause Mortality Following COVID-19 Vaccination in Patients With Heart Failure: A Nationwide Real-World Safety Study. BACKGROUND: Patients with heart failure are vulnerable to the SARS-CoV-2 infection. However, limited evidence exists on the safety of

the SARS-CoV-2 mRNA vaccines in this patient population. The objective of this study was to investigate the risk of all-cause mortality, worsening heart failure, venous thromboembolism, and myocarditis associated with the mRNA vaccines in patients with heart failure. METHODS: Using Danish nationwide registries, 2 cohorts were constructed: (1) all prevalent heart failure patients in 2019 aged 40 to 95 years and (2) all prevalent heart failure patients in 2021 aged 40 to 95 years, who were vaccinated with either of the 2 mRNA vaccines (BNT162B2 or mRNA-1273). The patients in the 2 cohorts were matched 1:1 using exact exposure matching on age, sex, and duration of heart failure. To estimate standardized absolute risks, outcome-specific Cox regression analyses were performed. RESULTS: The total study population comprised 101â€‰786 patients. The median age of the study population was 74 years (interquartile range, 66-81). The standardized risk of all-cause mortality within 90 days was 2.23% (95% CI, 2.10%-2.36%) in the vaccinated cohort and 2.56% (95% CI, 2.43%-2.70%) in the unvaccinated cohort (90-day risk difference, -0.33% [95% CI, -0.52% to -0.15%]). The standardized risk of worsening heart failure within 90 days was 1.10% (95% CI, -1.01% to 1.19%) in the 2021 (vaccinated) cohort and 1.08% (95% CI, 0.99%-1.17%) in the 2019 (unvaccinated) cohort (risk difference, 0.02% [95% CI, -0.11% to 0.15%]). No significant differences were found regarding venous thromboembolism or myocarditis. CONCLUSIONS: Receiving an mRNA vaccine was not associated with an increased risk of worsening heart failure, myocarditis, venous thromboembolism, or all-cause mortality.

Coronavirus Disease 2019 Frequency After CoronaVac Vaccine: Ascovid Study. OBJECTIVE: It is accepted that the only way to end severe acute respiratory syndrome coronavirus 2 epidemic is through community vaccination. The frequency and clinical features of infection after vaccination are not known clearly. The aim of this study is to determine the frequency and clinical features of coronavirus disease 2019 seen after either the first or second dose of CoronaVac vaccination in healthcare workers and their relatives. MATERIAL AND METHODS: This is a cross-sectional retrospective survey study. The study was carried out in 2013 volunteers, including 1903 (94.5%) healthcare workers and 110 (5.5%) relatives of healthcare workers. The frequency and clinical features of coronavirus disease 2019 before and after the first or second dose of CoronaVac vaccination were retrospectively evaluated using an online questionnaire conducted in July 2021. RESULTS: A total of 2013 people, 1312 women and 701 men, participated in the study. Of these individuals, 245 (12.1%) were polymerase chain reaction positive for coronavirus disease 2019 before vaccination. Of this group, 185 (75.5% of polymerase chain reaction positives and 9.1% of the whole population) received home-based therapy, while 38 (15.5%) received hospital admission. Asymptomatic polymerase chain reaction positivity before vaccination was seen in 22 (9%) individuals. There were 177 (8.8%) participants who developed polymerase chain reaction positivity at any time after vaccination. In 129 (72.8%) of these participants, polymerase chain reaction positivity occurred 21 days after the second dose of vaccine. While the number of patients hospitalized before vaccination was 38 (15.5% of the polymerase chain reaction positivity group and 1.89% of the general population), the number of patients hospitalized after the vaccination was 17 (10.1% of the polymerase chain reaction positivity group and 0.80% of the general population). The decrease in hospitalization proportion was statistically significant (P = .002). CONCLUSION: The frequency of coronavirus disease 2019, severe illness, and hospitalization rates were found to be lower in postvaccination period. The vaccine is effective in preventing coronavirus disease 2019 and severe disease.

Generalised Tonic-Clonic Seizure in Adolescents Following COVID-19 Vaccination: A Case Report on a Mere Co-incidence. Coronavirus disease 2019 (COVID-19) is a novel infectious disease caused by the severe acute respiratory syndrome (SARS) coronavirus 2 (SARS-CoV-2). This disease caused one of the largest pandemics in human history. During the second COVID-19Â surge, the Indian government

faced the threat posed by the growing COVID-19 pandemic by informing citizens and encouraging the use of preventive measures such as face masks, hand sanitization, personal protective equipment, quarantines, and vaccination. Vaccination is an effective prophylactic intervention in public health, and COVID-19 vaccines have been developed to achieve immunity against viruses and stop the transmission of infection. However, vaccines have side effects, and by early 2021, many doubts arose regarding COVID-19 vaccinations. Few people were not taking immunization because post-immunization adverse events were reported. We are reporting a case of seizures after immunization with Covaxin.

HPV16 E6/E7 -based mRNA vaccine is therapeutic in mice bearing aggressive HPV-positive lesions. HPV (Human papillomavirus) affects 600,000 people worldwide each year. Almost all cervical cancers are associated with a past HPV infection. In particular, the positivity to the high-risk type HPV16 is detected in most of the invasive cervical cancers. FDA has approved prophylactic vaccines that protect against new HPV16 infections, but do not induce immunity in those patients with established infections or neoplasms. To date, no therapeutic vaccine targeting HPV16-associated lesions has been authorized. We have developed an mRNA-based vaccine against the HPV16 late oncoproteins E6 and E7, which are abundantly and exclusively expressed in high-grade squamous intraepithelial lesions (HSILs), a stage of the cervical disease that precedes the progression to carcinoma. Our in vitro and in vivo studies demonstrated that the translated mRNA is functional and elicits an antigen-specific adaptive immune response. Upon immunization with the vaccine, mice with HPV16+ lesions exhibited tumor growth inhibition, extension of lifespan, and development of a protective immune memory. In light of these results and the remarkable clinical success of mRNA vaccines against SARS-CoV2, we believe that our mRNA-based therapeutic vaccine has the potential to offer a non-invasive treatment alternative to the current standard of care for HPV16+ HSILs.

Erratum: Breakthrough infections with the omicron and delta variants of SARS-CoV-2 result in similar re-activation of vaccine-induced immunity. [This corrects the article DOI: 10.3389/fimmu.2022.964525.].

SARS CoV-2 IgG positivity among the people in Dhaka city: An observation from the post vaccine period. Immunity status after mass vaccination program against SARS CoV-2 has not been evaluated in Bangladesh. This study aims to assess the IgG response against SARS-CoV-2 among the vaccine receivers in Bangladesh. After signed consent, blood samples were tested for SARS CoV-2 IgG from volunteers between March, 21 and April, 22 using ELISA where IgG index â‰¥0.9 was considered as positive Among 3034 participants, IgG positivity was calculated approximately 82% for vaccine recipients; lowest (58%) during March-April, 21 which increased to 85-95% later. IgG positivity and mean index was 82% and 3.04 in vaccinated whereas 56% and 1.5 in unvaccinated cases. IgG positivity and mean index reduced with age: 90% and 2.56, 79% and 2.23, 73% and 2.13 in 18-40Â y, 41-60Â y, >60Â y group respectively. Vaccinated with COVID-19 history showed highest IgG positivity and index (94% and 3.1) compared to vaccinated without COVID-19 history (76% and 1.6), unvaccinated with COVID-19 history (75% and 1.5) and unvaccinated without COVID-19 history (51% and 0.9). IgG positivity and index reduced as interval between IgG testing and vaccination increases. Our findings suggest a robust IgG response among the vaccine recipients. Negative correlation of IgG positivity and index with age and time necessitates continuous monitoring of immunity status.

A China-developed adenovirus vector-based COVID-19 vaccine: review of the development and application of Ad5-nCov. INTRODUCTION: The global spread of COVID-19 has prompted the development of vaccines. A recombinant adenovirus type-5 vectored COVID-19 vaccine (Ad5-nCoV) developed by Chinese scientists has been authorized for use as a prime and booster dose in China and several other countries. AREAS COVERED: We searched published articles as of 4 May 2023, on PubMed using keywords related to Adenovirus vector, vaccine, and SARS-CoV-2. We reported the

progress and outcomes of Ad5-nCov, including vaccine efficacy, safety, immunogenicity based on pre-clinical trials, clinical trials, and real-world studies for primary and booster doses. EXPERT OPINION: Ad5-nCoV is a significant advancement in Chinese vaccine development technology. Evidence from clinical trials and real-world studies has demonstrated well-tolerated, highly immunogenic, and efficacy of Ad5-nCoV in preventing severe/critical COVID-19. Aerosolized Ad5-nCoV, given via a novel route, could elicit mucosal immunity and improve the vaccine efficacy, enhance the production capacity and availability, and reduce the potential negative impact of preexisting antibodies. However, additional research is necessary to evaluate the long-term safety and immunogenicity of Ad5-nCoV, its efficacy against emerging variants, its effectiveness in a real-world context of hybrid immunity, and its cost-effectiveness, particularly with respect to aerosolized Ad5-nCoV.

Henoch-schonlein purpura following exposure to SARS-CoV2 vaccine or infection: a systematic review and a case report. BACKGROUND: Henoch-Schonlein purpura (HSP) is an IgA-mediated systemic small-vessel vasculitis (IgAV) that typically presents with a variable tetrad of symptoms. HSP if often preceded by respiratory tract infections, vaccinations, drugs or malignancies. During the recent COVID-19 pandemic multiples cases of HSP have been described after both infection and vaccination for SARS-CoV2. This study aims to perform a systematic review of literature and describe an additional complicated case of de-novo HSP appeared after the administration of the third dose of a mRNA-SARS-CoV2 vaccination. METHODS: Electronic bibliographic research was performed to identify all the original reports describing cases of de-novo HSP or IgAV appeared after respiratory infection or vaccine administration for SARS-CoV2. We included all case series or case reports of patients who respected our inclusion and exclusion criteria. RESULTS: Thirty-eight publications met our pre-defined inclusion criteria, for an overall number of 44 patients. All patients presented with palpable purpura variable associated with arthralgia, abdominal pain or renal involvement. Increased levels of inflammation markers, mild leukocytosis and elevated D-dimer were the most common laboratory findings. Up to 50% of patients presented proteinuria and/or hematuria. Almost all skin biopsies showed leukocytoclastic vasculitis, with IgA deposits at direct immunofluorescence in more than 50% of cases. CONCLUSIONS: Our results suggest that the immune response elicited by SARS-CoV2 vaccine or infection could play a role in the development of HSP. Current research suggests a possible role of IgA in immune hyperactivation, highlighted by early seroconversion to IgA found in some COVID-19 patients who develop IgA vasculitis.

Factors associated with perceived fear of future pandemics and/or epidemics: a cross-sectional study in Cyprus. This study aims to understand the levels of fear experienced by individuals regarding future pandemics and/or epidemics among the general population of Cyprus and comprehensively examine the diverse factors that influence this perceived fear. The cross-sectional study was conducted from October 1st, 2022, to February 19th, 2023. A proportionate quota sampling method was used for the recruitment, by recruiting a fixed number of participants from each age group, sex, and place of residence. The study collected information on sociodemographic and health-related characteristics, health literacy, trust, COVID-19 vaccination information, and perceived fear of future epidemics and/or pandemics using a self-administered questionnaire. The survey included 1075 participants, with 53.7% of them reporting fear of future pandemics. Logistic regression analysis revealed that women (ORâ€‰=â€‰2.37, 95% CI 1.78, 3.16) and individuals vaccinated against COVID-19 (ORâ€‰=â€‰1.57, 95% CI 1.02, 2.43) were significantly more likely to experience fear of future pandemics. Moreover, higher levels of trust (ORâ€‰=â€‰1.04, 95% CI 1.02, 1.06) and higher health literacy (ORâ€‰=â€‰1.05, 95% CI 1.03, 1.08) were associated with an increased likelihood of fearing future pandemics. Conversely, unemployment (ORâ€‰=â€‰0.30, 95% CI 0.13, 0.65) and having a postgraduate education decreased the likelihood of fearing future pandemics (ORâ€‰=â€‰0.56, 95% CI 0.34, 0.90). The linear regression model revealed that older age

(Î²â€‰=â€‰-Â 0.10, 95% CI -Â 0.14, -Â 0.05) was negatively associated with a higher score of fear regarding future pandemics. Conversely, being in a vulnerable group (Î²â€‰=â€‰2.02, 95% CI 0.75, 3.28) and having at least one chronic disease (Î²â€‰=â€‰1.76, 95% CI 0.68, 2.84) showed positive associations with increased fear of future epidemics and/or pandemics. The findings emphasize the need for relevant authorities to prioritize mental health and disseminate information in a manner that avoids spreading fear and panic, particularly among vulnerable population groups.

Adverse effect of VEGFR-2 (rs1870377) polymorphism on the clinical course of COVID-19 in females and males in an age-dependent manner. The COVID-19 pandemic has affected people worldwide with varying clinical presentations ranging from mild to severe or fatal, and studies have found that age, gender, and some comorbidities can influence the severity of the disease. It would be valuable to have genetic markers that might help predict the likely outcome of infection. For this objective, genes encoding VEGFR-2 (rs1870377), CCR5Î”32 (rs333), and TLR3 (rs5743313) were analyzed for polymorphisms in the peripheral blood of 160 COVID-19 patients before COVID-19 vaccine was available in TÃ¼rkiye. We observed that possession of the VEGFR-2 rs1870377 mutant allele increased the risk of severe/moderate disease in females and subjects â‰¥65 years of age, but was protective in males <65 years of age. Other significant results were that the CCR5Î”32 allele was protective against severe disease in subjects â‰¥65 years of age, while TLR3 rs5743313 polymorphism was found to be protective against severe/moderate illness in males <65 years of age. The VEGFR-2 rs1870377 mutant allele was a risk factor for severe/moderate disease, particularly in females over the age of 65. These findings suggest that genetic polymorphisms have an age- and sex-dependent influence on the severity of COVID-19, and the VEGFR-2 rs1870377 mutant allele could be a potential predictor of disease severity.

Outcomes After Decompressive Surgery for Severe Cerebral Venous Sinus Thrombosis Associated or Not Associated with Vaccine-Induced Immune Thrombosis with Thrombocytopenia: A Multicenter Cohort Study. BACKGROUND: Clinical observations indicated that vaccine-induced immune thrombosis with thrombocytopenia (VITT)-associated cerebral venous sinus thrombosis (CVST) often has a space-occupying effect and thus necessitates decompressive surgery (DS). While comparing with non-VITT CVST, this study explored whether VITT-associated CVST exhibits a more fulminant clinical course, different perioperative and intensive care unit management, and worse long-term outcome. METHODS: This multicenter, retrospective cohort study collected patient data from 12 tertiary centers to address priorly formulated hypotheses concerning the clinical course, the perioperative management with related complications, extracerebral complications, and the functional outcome (modified Rankin Scale) in patients with VITT-associated and non-VITT CVST, both with DS. RESULTS: Both groups, each with 16 patients, were balanced regarding demographics, kind of clinical symptoms, and radiological findings at hospital admission. Severity of neurological symptoms, assessed with the National Institute of Health Stroke Scale, was similar between groups at admission and before surgery, whereas more patients with VITT-associated CVST showed a relevant midline shift (â‰¥â€‰4Â mm) before surgery (100% vs. 68.8%, pâ€‰=â€‰0.043). Patients with VITT-associated CVST tended to undergo DS early, i.e., â‰¤Â 24Â h after hospitalÂ admission (pâ€‰=â€‰0.077). Patients with VITT-associated CVST more frequently received platelet transfusion, tranexamic acid, and fibrinogen perioperatively. The postoperative management was comparable, and complications were evenly distributed. More patients with VITT-associated CVST achieved a favorable outcome (modified Rankin Scaleâ€‰â‰¤â€‰3) at 3Â months (pâ€‰=â€‰0.043). CONCLUSIONS: Although the prediction of individual courses remains challenging, DS should be considered early in VITT-associated CVST because an overall favorable outcome appears achievable in these patients.

Potential reduction of post-acute sequelae of SARS-CoV-2 symptoms via vaccination. The objective of this observational study is to determine whether vaccination for SARS-CoV-2 alters the clinical presentation of post-COVID conditions (PCC). Self-reported data provided by patients requesting care for PCC at the Mayo Clinic were analyzed to assess for a relationship between vaccination status prior to COVID infection and PCC symptoms. In all, 477 subjects were included in this study. In total, 245 (51.4%) were vaccinated. Vaccinated subjects with PCC reported less abdominal pain, anosmia, parosmia, chest pain/tightness, dizziness, numbness/tingling, dyspnea, spells/tremors, and weakness. For hospitalized patients who developed PCC, vaccinated patients reported less chest pain, cough, dizziness, and dyspnea. After applying Bonferroni correction for multiple comparisons, decreased abdominal pain remained significant. We conclude that vaccination against SARS-CoV-2 may reduce the symptoms of PCC, leading to improved morbidity and function. Further studies on the impact of vaccination on PCC and recovery are needed.

Association Between Coronavirus Disease 2019 Vaccination and Mortality After Major Operations. OBJECTIVE: The objective of this study was to compare postoperative 90-day mortality between (1) fully vaccinated patients with COVID-19-positive and negative diagnosis, and (2) vaccinated and unvaccinated patients with COVID-19 positive diagnosis. BACKGROUND: Societal guidelines recommend postponing elective operations for at least 7 weeks in unvaccinated patients with preoperative coronavirus disease 2019 (COVID-19) infection. The role of vaccination in this infection-operation time risk is unclear. METHODS: We conducted a national US multicenter retrospective, matched cohort study spanning July 2021 to October 2022. Participants were included if they underwent a high-risk general, vascular, orthopedic, neurosurgery, or genitourinary surgery. All-cause mortality occurring within 90 days of the index operation was the primary outcome. Inverse probability treatment weighted propensity scores were used to adjust logistic regression models examining the independent and interactive associations between mortality, exposure status, and infection proximity. RESULTS: Of 3401 fully vaccinated patients in the 8-week preoperative period, 437 (12.9%) were COVID-19-positive. Unadjusted mortality rates were not significantly different between vaccinated patients with COVID-19 (22, 5.0%) and vaccinated patients without COVID-19 (99, 3.3%; P = 0.07). After inverse probability treatment weighted adjustment, mortality risk was not significantly different between vaccinated COVID-19-positive patients compared to vaccinated patients without COVID-19 (adjusted odds ratio = 1.38, 95% CI: 0.70, 2.72). The proximity of COVID-19 diagnosis to the index operation did not confer added mortality risk in either comparison cohort. CONCLUSIONS: Contrary to risks observed among unvaccinated patients, postoperative mortality does not differ between patients with and without COVID-19 when vaccinated against the severe acute respiratory syndrome coronavirus 2 virus and receiving a high-risk operation within 8 weeks of the diagnosis, regardless of operation timing relative to diagnosis.

Pemphigus vulgaris after the second dose of COVID-19 vaccination: a case report. BACKGROUND: As many people worldwide have been vaccinated, more triggered autoimmune bullous diseases have been noticed. We reported a case of new-onset pemphigus Vulgaris after COVID-19 vaccinations. CASE PRESENTATION: A 50Â years old Syrian female presented with multiple erosions on her extremities, in addition to oral erosions and genital ulcers, after the 2nd dose of the mRNA COVID-19 vaccine. The lesions were multiple tenders and well-defined, reddish erythematous oral ulcers. At the same time the Skin examination showed hyper-pigmented patches over the extremities, a sequel of ruptured bullae. Pemphigus Vulgaris was diagnosed by histology. She continued on 35Â mg/day of prednisone for another 2Â weeks. CONCLUSIONS: Pemphigus is not a contraindication to vaccination, although it may be worse or present as a first onset.

Re-evaluation of the risk of venous thromboembolism after COVID-19 vaccination using haematological criteria. An elevated risk of venous thromboembolism (VTE) following a first dose

of the ChAdOx1 adenovirus-vectored vaccine was found in a national epidemiological study in England using routine discharge diagnosis codes. Separately, the syndrome of vaccine-induced immune thrombotic thrombocytopenia (VITT) was identified using haematological criteria based on presence of thrombocytopenia, significantly elevated D-dimers and development of anti-PF4 antibodies. To re-evaluate risk estimates using haematological criteria, we obtained the haematology results for hospital admitted patients aged 18-64Â years in 43 National Health Service trusts in England who were included in the national epidemiological study. Diagnoses were confirmed and haematological parameters obtained from local records without knowledge of vaccination status. The haematological parameters in patients admitted for a confirmed VTE following ChAdOx1 or BNT162b2 mRNA vaccination were then compared with those in a randomly selected 40% sample of unvaccinated patients with VTE. Overall, 12 (14%) of the 84 vaccinated cases had a diagnosis compatible with VITT, 11 after a first dose of ChAdOx1 and one after a first dose of BNT162b2. Thrombocytopenia (platelet count <150 Ã— 10(9)/L) occurred in 17 vaccinated (20%) and 4 (4%) of 108 unvaccinated patients, with all 6 cases of severe thrombocytopenia (<50 Ã— 10(9)/L) occurring within 42Â days of a first dose of ChAdOx1. The attributable risk estimates for a cerebral venous thrombosis (CVT) or other VTE with thrombocytopenia after a first dose of ChAdOx1 vaccine were 2.82 and 9.62 per million doses respectively. However, elevated risks were also found after a first dose of ChAdOx1 for VTE without thrombocytopenia with relative incidences for CVT and other VTE of 2.67 (1.77-3.77) and 1.93 (1.57-2.35) respectively. While we identified a distinct population with features of VITT within 42Â days of receiving ChAdOx1 vaccination, confirming current diagnostic criteria, we also found evidence of an increased risk of a VTE without thrombocytopenia after ChAdOx1 vaccine.

Immunologic response and seroconversion following third-dose COVID-19 vaccination in solid organ transplant recipients: A meta-analysis. INTRODUCTION: The immunogenicity and efficacy of COVID-19 vaccination varied by demographic, including solid organ transplant recipients on immunosuppressive therapy. AIM: This purpose of this study is to assess seropositivity and seroconversion in solid-organ transplant recipients before and after third-dose COVID-19 vaccination. METHODS: This study is a systematic review and meta-analysis performed using PRISMA guidelines. To analyze clinical and cohort studies reporting immunologic response and seroconversion third-dose vaccination, a systematic search was performed using electronic databases (PubMed, Scopus, Cochrane, Directory of Open Access Journal (DOAJ), and Clinicaltrials.gov). RESULT: There were 18 full-text papers that could be analyzed qualitatively and quantitatively. After the third vaccination, the pooled rate seropositivity was 67.00% (95% CI 59.511; 74.047, I2Â =Â 93.82%), and the pooled rate seroconversion was 52.51% (95% CI 44.03; 60.91, I2Â =Â 92.15%). The pooled rate of seroconversion after the mRNA-based booster was 52.380% (95% CI 40.988; 63.649, I2Â =Â 94.35%), and after the viral-vector-based booster was 42.478% (95% CI 35.222; 49.900, I2Â =Â 0.00%). CONCLUSION: Based on the analysis of immunologic responses and seroconversion findings, the third-dose vaccination of solid organ transplant recipients is an effective method in establishing better immunity against COVID-19.

Common Side Effects of Pfizer COVID-19 Vaccine: An Experience From Pakistan. Introduction The severe acute respiratory syndrome coronavirus 2 (SARSâ€‘CoVâ€‘2) epidemic spread quickly. Vaccines are now being distributed to stop the infectious spread and halt fatalities. The Pfizer-BioNTech vaccine was the first mRNA-based vaccine introduced to boostÂ immunity against COVID-19; however, it could lead to various adverse reactions. Therefore, the aim of this study was to assess the prevalence of Pfizer vaccine side effects among participants. Methods This was a multicenter cross-sectional study that was performed using a non-probability sampling method. The study period was about six months from March 1, 2022, to August 31, 2022. A total of 1000 participants who received

two doses of the Pfizer vaccine met the inclusion criteria. Demographic details of participants, for example, gender, age, comorbidities, Pfizer vaccine with both doses along with booster dose, previous exposure to coronavirus disease 2019 (COVID-19) infection, and the incidence of any local and systemic side effects following the first and second doses of vaccine, were reported.Â Results The study findings showed that out of 1000 participants, 644 (64.4%) were males and 356 (35.6%) were females; their mean age was 43.06Â±14.98 years. Among them, 280 (28.0%) had hypertension and 356 (35.6%) had diabetes. Following the first dose of the Pfizer vaccine, burning at the injection site and fever were the most commonly reported side effects in 704 (70.4%) and 700 (70.0%) participants, respectively. Following the second dose of the Pfizer vaccine, muscle pain was the most commonly reported side effect in 628 (62.8%) participants. Conclusion This study concluded that the most frequent adverse effects of the Pfizer vaccine were burning at the injection site, fever, pain at the injection site, muscle pain, swelling at the injection site, and joint pain. Moreover, the first dose was associated with more side effects than the second dose.

A 20-Year-Old Man with IgA Vasculitis following COVID-19 Vaccination. IgA vasculitis is a common type of vasculitis that is generally triggered by infectious causes. Vaccines have been reported as a trigger as well. Herein, we report a case of a young man who is previously healthy and who developed IgA vasculitis after the first dose of the COVID-19 mRNA vaccine Pfizer-BioNTech. The patient's symptoms were mainly skin and joint without renal or other system involvement. The patient had an excellent outcome with complete resolution after treatment with steroid tapering and azathioprine as a steroid-sparing agent over 6â€‰months.

Responding to COVID-19 vaccine-related safety events: WHO Western Pacific regional experience and lessons learned. PROBLEM: Novel vaccines were developed in an unprecedentedly short time in response to the global coronavirus disease (COVID-19) pandemic, which triggered concerns about the safety profiles of the new vaccines. This paper describes the actions and outcomes of three major adverse events of special interest (AESIs) reported in the World Health Organization's (WHO's) Western Pacific Region: anaphylaxis, thrombosis with thrombocytopenia syndrome (TTS) and post-vaccination death. CONTEXT: During the large-scale introduction of various novel COVID-19 vaccines, robust monitoring of and response to COVID-19 vaccine safety events were critical. ACTION: We developed and disseminated information sheets about anaphylaxis and TTS; provided tailor-made training for anaphylaxis monitoring and response, webinars about TTS and AESIs, and an algorithm to support decision-making about AESIs following immunization; as well as provided country-specific technical support for causality assessments, including for possible vaccination-related deaths. OUTCOME: Each major vaccine event and situation of high concern was responded to appropriately and in a timely manner with comprehensive technical support from WHO. Our support activities have not only strengthened countries' capacities for vaccine safety surveillance and response, but also enabled countries to decrease the negative impact of these events on their immunization programmes and maintain the confidence of health-care professionals and the general population through proactive delivery of risk communications. DISCUSSION: This paper summarizes selected, major AESIs following COVID-19 vaccination and responses made by WHO's Regional Office for the Western Pacific to support countries. The examples of responses to vaccine safety events during the pandemic and unprecedented mass vaccination campaigns could be useful for countries to adopt, where applicable, to enhance their preparation for activities related to monitoring vaccine safety.

COVID-19 vaccine-related adverse events following immunization in the WHO Western Pacific Region, 2021-2022. The speed at which new vaccines against coronavirus disease (COVID-19) were developed and rolled out as part of the global response to the pandemic was unprecedented. This report summarizes COVID-19 vaccine-related safety data in the World Health Organization Western Pacific Region. Data for 1 March 2021 to 31 March 2022 from 36 out of 37 countries and areas in the

Western Pacific Region are presented. More than 732 million doses of eight COVID-19 vaccines were administered; reporting rates of adverse events following immunization (AEFIs) and serious AEFIs were 130.1 and 5.6 per 100 000 doses administered, respectively. Anaphylaxis, thrombosis with thrombocytopenia syndrome, and myocarditis/pericarditis were the most frequent COVID-19 adverse events of special interest (AESIs) reported. The reported rates of AESIs in the Western Pacific Region were within the range of expected or background rates. Vaccine benefits far outweigh the risk of reported serious adverse reactions and serious outcomes of COVID-19. Continued AEFI surveillance is recommended to better understand and ensure the safety profiles of novel COVID-19 vaccines.

A Case of Painful Diplopia after COVID-19 Vaccination: Could It Be Tolosa-Hunt Syndrome? Herein, we report a rare case of Tolosa-Hunt syndrome (THS) following coronavirus disease 2019 (COVID-19) vaccine administration. A 64-year-old patient presented with recurrent horizontal diplopia and ipsilateral orbital pain, 2 weeks after being administered the COVID-19 vaccination. A diagnosis of THS was based on the relevant criteria after ruling out the differential diagnoses. The clinical presentation improved with corticosteroid administration. THS must be recognized as a complication of COVID-19 vaccination. This association can be explained by an autoimmune response.

An electronic medical record reminder is independently associated with improved opportunistic influenza vaccination rates for older inpatients. BACKGROUND: Influenza vaccination will have added importance this winter given the possibility of further waves of the COVID-19 pandemic. This study examines the impact of an electronic medical record (EMR) reminder on influenza vaccine uptake among eligible hospital inpatients. METHODS: We included a convenience sample of 750 adults (median age 77â€‰years) who are eligible for influenza vaccination (â©¾65â€‰years and/or length of stay >30â€‰days). A live electronic dashboard identified patients eligible for vaccination, prompting reminders sent to the clinical teams via the EMR. RESULTS: The EMR reminder was associated with almost a 50% higher likelihood of vaccination after adjusting for other covariates (odds ratio 1.48 (95% confidence interval 1.00-2.20); pâ€‰=â€‰0.048). DISCUSSION: Reminders sent to the clinical team via the EMR appear to be an effective means of increasing vaccine uptake and should be considered as part of this year's drive to vaccinate eligible patients in hospital.

Preclinical evaluation of general toxicity and safety pharmacology of a receptor-binding domain-based COVID-19 subunit vaccine in various animal models. The coronavirus disease 2019 pandemic has resulted in the introduction of several naÃ¯ve methods of vaccine development, which have been used to prepare novel viral vectors and mRNA-based vaccines. However, reluctance to receive vaccines owing to the uncertainty regarding their safety is prevalent. Therefore, rigorous safety evaluation of vaccines through preclinical toxicity studies is critical to determine the safety profiles of vaccine candidates. This study aimed to evaluate the toxicity profile of HuVac-19, a subunit vaccine of SARS-CoV-2 utilizing the receptor-binding domain as an antigen, in rats, rabbits, and dogs using single- and repeat-dose study designs. Repeat-dose toxicity studies in rats and rabbits showed transient changes in hematological and serum biochemical parameters in the adjuvant and/or vaccine groups; however, these changes were reversed or potentially reversible after the recovery period. Moreover, temporary reversible changes in absolute and relative organ weights were observed in the prostate of rats and the thymus of rabbits. Gross examination of the injection sites in rats and rabbits treated with the adjuvant- and HuVac-19 showed discoloration and foci, whereas histopathological examination showed granulomatous inflammation, inflammatory cell infiltration, and myofiber degeneration/necrosis. This inflammatory response was local, unassociated with other toxicological changes, and resolved. In a pharmacological safety study, no toxicological or physiological changes associated with HuVac-19 administration were observed. In conclusion, HuVac-19 was not associated with any major systemic adverse effects in the general toxicity and safety pharmacology evaluation,

demonstrating that HuVac-19 is a vaccine candidate with sufficient capacity to be used in human clinical trials.

Safety of BA.4-5 or BA.1 bivalent mRNA booster vaccines: nationwide cohort study. OBJECTIVE: To examine the association between the omicron adapted bivalent mRNA covid-19 booster vaccines received as a fourth dose and risk of adverse events. DESIGN: Nationwide cohort study. SETTING: Denmark. PARTICIPANTS: 2â€‰225â€‰567 adults aged â‰¥50 years who received three covid-19 vaccine doses during the study period, 1 January 2021 to 10 December 2022. MAIN OUTCOME MEASURES: The main outcome measure was rates of hospital visits for 27 different adverse events in a 28 day main risk period after vaccination with a bivalent omicron adapted mRNA booster vaccine as a fourth dose compared with reference period rates from day 29 after the third or fourth vaccine dose and onward. RESULTS: 1â€‰740â€‰417 adults (mean age 67.8 years, standard deviation 10.7 years) received a bivalent mRNA vaccine as a fourth dose. Fourth dose vaccination with a bivalent mRNA vaccine was not associated with a statistically significant increased rate of any of the 27 adverse outcomes within 28 days (eg, incidence rate ratio of 0.95, 95% confidence interval of 0.87 to 1.04 for ischaemic cardiac events based on 672 v 9992 events during the compared 28 day risk and reference period, respectively), nor when analysed according to age, sex, or vaccine type, or when using alternative analytical approaches. However, post hoc analysis detected signals for myocarditis (statistically significant in female participants), although the outcome was rare and findings were based on few cases. No risk of cerebrovascular infarction was found (incidence rate ratio 0.95, 95% confidence interval 0.87 to 1.05; 644 v 9687 events). CONCLUSIONS: The use of bivalent mRNA vaccines as a fourth vaccine dose against covid-19 was not associated with an increased risk of 27 different adverse events in adults aged â‰¥50 years.

Erythema multiforme reactions following Pfizer/BioNTech (tozinameran) vaccination: two case-reports with positive rechallenge and review of the literature. AIM: Pfizer/BioNTech (BNT162b2) is a COVID-19 vaccine with a reassuring safety profile. The main adverse reactions are mild local reactions. Cutaneous reactions are generally minor. The most common cutaneous reaction reported was a local injection-site reaction. CASE STUDY: Here we present 2 cases of erythema multiform (EM) following BNT162b2 vaccination with positive rechallenge. The 1st case was about a 51-year-old woman who developed 5 days after the 1st dose of the mRNA Pfizer/BioNTech (BNT162b2) a macular, erythematous, round-shaped lesions on the hands, knees and soles. She experienced a positive rechallenge one month later. In the 2nd case, a 55-year-old man presented 6 days following the 2nd shot of the mRNA Pfizer/BioNTech (BNT162b2), targetoid eruption on the upper and lower members. The patient reported that he had the same skin lesions in ankles and soles few days following the 1st shot of the same vaccine. CONCLUSION: Few cases of EM following COVID-19 vaccination were reported in the literature and positive rechallenge in only one case. Rechallenge was not performed in most cases. Our two cases are particular because of the positive rechallenge in both patients. This is the gold standard to confirm that the vaccine was the culprit agent in inducing EM.

Guillain Barre Syndrome after vaccination against Corona Virus Disease19: Managed in limited resource setting. A 16-year-old boy who classically featured Guillain Barre Syndrome (GBS) after Corona Virus Disease-19 vaccination was timely treated successfully in limited resource setting in far western province. After Moderna (mRNA COVID 19 Vaccine) vaccination, he rapidly developed ascending paralysis of limbs without autonomic and sensory or cranial nerve involvement. He has been treated with Intravenous Immuno-Globulin (IVIG). Over six-weeks long observation and supportive care and he was discharged with full recovery. Many GBS cases after vaccination have been reported but yet to know the association of vaccine. It is very important to address the complication for successful vaccination programme. Keywords: Complication; COVID-19; guillain barre syndrome; vaccine.

A prospective cohort study protocol: monitoring and surveillance of adverse events following heterologous booster doses of Oxford AstraZeneca COVID-19 vaccine in previous recipients of two doses of Sinopharm or Sputnik V vaccines in Iran. BACKGROUND: Regarding the paucity of evidence on the side effects of the booster dose of Oxford AstraZeneca vaccine in vaccinated people with Sinopharm or Sputnik V, we aimed to set up a cohort event monitoring (CEM) study to capture adverse events occurring in individuals who will receive the booster doses of AstraZeneca (either the first or second booster dose) following being vaccinated with Sinopharm or sputnik V vaccines in Iran. METHODS: The present study is an active COVID-19 vaccine safety surveillance through an observational prospective cohort study that will be conducted in vaccination centers in Iran. The study will be conducted in twelve provinces of Iran. Study sites are vaccination centers where the AstraZeneca vaccine is administered to the cohort population. The study population includes all individuals who have received two doses of Sinopharm or Sputnik V vaccines and either the first or second booster dose of AstraZeneca according to the national guidelines for immunization in Iran in 2023. We are planning to include 30,000 eligible people in this study. Each individual will be followed up for 13 weeks after either the first or second booster dose of the AstraZeneca vaccine. Furthermore, convenience sampling is used to include participants in the present study. Participation in the study will be strictly voluntary. DISCUSSION: With the planned study we will provide a valid epidemiological evidence to improve the understanding of the safety of the booster dose of the AstraZeneca and to better evaluate the effectiveness of public health interventions. This could help policy makers in managing the COVID-19 pandemic according to scientific evidence.

Thyroid disturbances after COVID-19 and the effect of vaccination in children: a prospective tri-center registry analysis. Rapidly evolving clinical data suggest that the novel coronavirus (SARS-CoV-2) and vaccination against COVID-19 might be associated with thyroid disturbances. However, studies remain limited among the pediatric population. Our aim was to assess the prevalence and permanence of thyroid autoimmunity (TA) and dysfunction in children after an acute infection and its potential association with vaccination.Â A prospective, multicenter registry analysis was performed among 458 children (mean age: 12.4â€‰Â±â€‰3,8Â years, 45.4% male) with preceding COVID-19. Patient inclusion lasted from 24(th) March, 2021 to 23(rd) March, 2022 at three pediatric outpatient facilities at Semmelweis University, Budapest. Primary outcomes were the rate of thyroid disturbances assessed by laboratory parameters (thyroid function tests, antithyroglobulin [ATG] and anti-thyroid peroxidase [ATPO] antibodies) and thyroid ultrasound. TA rate among vaccinated and unvaccinated children was determined. Children with newly diagnosed thyroid alterations were followed up for 12.7â€‰Â±â€‰4.3Â months.Â Six children had previous thyroid disease. Out of 452 children, 30 cases (6.6%) of newly diagnosed TA (six of them had abnormal thyroid-stimulating hormone [TSH] levels) and eight cases (1.8%) of isolated TSH elevation were observed. Ultrasound-proven autoimmune thyroiditis (AIT) was 4.0%. No association was found between COVID-19 vaccination and thyroid autoimmunity (Ï‡(2)(1,Nâ€‰=â€‰452)â€‰=â€‰0.138, pâ€‰=â€‰0.815). Among children with TA, 73.3% had long-lasting alterations.Â Conclusion: Vaccination had no effect on the prevalence of TA. Until further controlled studies state otherwise, children with preceding COVID-19 might benefit from thyroid screening. What is Known: â€¢ Numerous case reports implicate that coronavirus disease-2019 (COVID-19) and vaccination against SARS-CoV-2 can be responsible for thyroid disturbances. â€¢ Thyroid alterations discovered during acute COVID-19 tend to cease by time and only incidental thyroid autoimmunity (TA) is diagnosed after COVID-19.Â In adults, no increase in vaccine-related hyper- or hypothyroidism was found. What is New: â€¢ TA rate after COVID-19 vaccination among children was not increased.Â TA had no role in long COVID syndrome. â€¢ We discovered a considerable rate of TA (6.6%) and ultrasound-proven autoimmune

thyroiditis (AIT) (4.0%) after SARS-CoV-2 infection, and the majority of these alterations remained positive after 6Â months.

Incidence of diabetes following COVID-19 vaccination and SARS-CoV-2 infection in Hong Kong: A population-based cohort study. BACKGROUND: The risk of incident diabetes following Coronavirus Disease 2019 (COVID-19) vaccination remains to be elucidated. Also, it is unclear whether the risk of incident diabetes after Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection is modified by vaccination status or differs by SARS-CoV-2 variants. We evaluated the incidence of diabetes following mRNA (BNT162b2), inactivated (CoronaVac) COVID-19 vaccines, and after SARS-CoV-2 infection. METHODS AND FINDINGS: In this population-based cohort study, individuals without known diabetes were identified from an electronic health database in Hong Kong. The first cohort included people who received â‰¥1 dose of COVID-19 vaccine and those who did not receive any COVID-19 vaccines up to September 2021. The second cohort consisted of confirmed COVID-19 patients and people who were never infected up to March 2022. Both cohorts were followed until August 15, 2022. A total of 325,715 COVID-19 vaccine recipients (CoronaVac: 167,337; BNT162b2: 158,378) and 145,199 COVID-19 patients were 1:1 matched to their respective controls using propensity score for various baseline characteristics. We also adjusted for previous SARS-CoV-2 infection when estimating the conditional probability of receiving vaccinations, and vaccination status when estimating the conditional probability of contracting SARS-CoV-2 infection. Hazard ratios (HRs) and 95% confidence intervals (CIs) for incident diabetes were estimated using Cox regression models. In the first cohort, we identified 5,760 and 4,411 diabetes cases after receiving CoronaVac and BNT162b2 vaccines, respectively. Upon a median follow-up of 384 to 386 days, there was no evidence of increased risks of incident diabetes following CoronaVac or BNT162b2 vaccination (CoronaVac: 9.08 versus 9.10 per 100,000 person-days, HR = 0.998 [95% CI 0.962 to 1.035]; BNT162b2: 7.41 versus 8.58, HR = 0.862 [0.828 to 0.897]), regardless of diabetes type. In the second cohort, we observed 2,109 cases of diabetes following SARS-CoV-2 infection. Upon a median follow-up of 164 days, SARS-CoV-2 infection was associated with significantly higher risk of incident diabetes (9.04 versus 7.38, HR = 1.225 [1.150 to 1.305])-mainly type 2 diabetes-regardless of predominant circulating variants, albeit lower with Omicron variants (p for interaction = 0.009). The number needed to harm at 6 months was 406 for 1 additional diabetes case. Subgroup analysis revealed no evidence of increased risk of incident diabetes among fully vaccinated COVID-19 survivors. Main limitations of our study included possible misclassification bias as type 1 diabetes was identified through diagnostic coding and possible residual confounders due to its observational nature. CONCLUSIONS: There was no evidence of increased risks of incident diabetes following COVID-19 vaccination. The risk of incident diabetes increased following SARS-CoV-2 infection, mainly type 2 diabetes. The excess risk was lower, but still statistically significant, for Omicron variants. Fully vaccinated individuals might be protected from risks of incident diabetes following SARS-CoV-2 infection.

Excess Death Rates for Republican and Democratic Registered Voters in Florida and Ohio During the COVID-19 Pandemic. IMPORTANCE: There is evidence that Republican-leaning counties have had higher COVID-19 death rates than Democratic-leaning counties and similar evidence of an association between political party affiliation and attitudes regarding COVID-19 vaccination; further data on these rates may be useful. OBJECTIVE: To assess political party affiliation and mortality rates for individuals during the initial 22 months of the COVID-19 pandemic. DESIGN, SETTING, AND PARTICIPANTS: A cross-sectional comparison of excess mortality between registered Republican and Democratic voters between March 2020 and December 2021 adjusted for age and state of voter registration was conducted. Voter and mortality data from Florida and Ohio in 2017 linked to mortality records for January 1, 2018, to December 31, 2021, were used in data analysis. EXPOSURES: Political party affiliation. MAIN OUTCOMES AND MEASURES: Excess weekly deaths during the COVID-

19 pandemic adjusted for age, county, party affiliation, and seasonality. RESULTS: Between January 1, 2018, and December 31, 2021, there were 538â€¯159 individuals in Ohio and Florida who died at age 25 years or older in the study sample. The median age at death was 78 years (IQR, 71-89 years). Overall, the excess death rate for Republican voters was 2.8 percentage points, or 15%, higher than the excess death rate for Democratic voters (95% prediction interval [PI], 1.6-3.7 percentage points). After May 1, 2021, when vaccines were available to all adults, the excess death rate gap between Republican and Democratic voters widened from -0.9 percentage point (95% PI, -2.5 to 0.3 percentage points) to 7.7 percentage points (95% PI, 6.0-9.3 percentage points) in the adjusted analysis; the excess death rate among Republican voters was 43% higher than the excess death rate among Democratic voters. The gap in excess death rates between Republican and Democratic voters was larger in counties with lower vaccination rates and was primarily noted in voters residing in Ohio. CONCLUSIONS AND RELEVANCE: In this cross-sectional study, an association was observed between political party affiliation and excess deaths in Ohio and Florida after COVID-19 vaccines were available to all adults. These findings suggest that differences in vaccination attitudes and reported uptake between Republican and Democratic voters may have been factors in the severity and trajectory of the pandemic in the US.

Impact of COVID-19 and effects of booster vaccination with BNT162b2 on six-month long COVID symptoms, quality of life, work productivity and activity impairment during Omicron. BACKGROUND: Longitudinal estimates of long COVID burden during Omicron remain limited. This study characterized long-term impacts of COVID-19 and booster vaccination on symptoms, Health-Related Quality of Life (HRQoL), and Work Productivity Activity Impairment (WPAI). METHODS: Outpatients withâ€‰â‰¥â€‰1 self-reported symptom and positive SARS-CoV-2 test at CVS Health United States test sites were recruited between 01/31 and 04/30/2022. Symptoms, EQ-5D and WPAI were collected via online surveys until 6Â months following infection. Both observed and model-based estimates were analyzed. Effect sizes based on Cohen's d quantified the magnitude of outcome changes over time, within and between vaccination groups. Mixed models for repeated measures were conducted for multivariable analyses, adjusting for covariates. Logistic regression assessed odds ratio (OR) of long COVID between vaccination groups. RESULTS: At long COVID start (Week 4), 328 participants included 87 (27%) Boosted with BNT162b2, 86 (26%) with a BNT162b2 primary series (Primed), and 155 (47%) Unvaccinated. Mean age was 42.0Â years, 73.8% were female, 26.5% hadâ€‰â‰¥â€‰1 comorbidity, 36.9% prior infection, and 39.6% reportedâ€‰â‰¥â€‰3 symptoms (mean: 3.1 symptoms). At Month 6, among 260 participants, Boosted reported a mean of 1.1 symptoms versus 3.4 and 2.8 in Unvaccinated and Primed, respectively (pâ€‰<â€‰0.001). Boosted had reduced risks ofâ€‰â‰¥â€‰3 symptoms versus Unvaccinated (observed: OR 0.22, 95% CI 0.10-0.47, pâ€‰<â€‰0.001; model-based: OR 0.36, 95% CI 0.15-0.87, pâ€‰=â€‰0.019) and Primed (observed: OR 0.29, 95% CI 0.13-0.67, pâ€‰=â€‰0.003; model-based: OR 0.59, 95% CI 0.21-1.65, pâ€‰=â€‰0.459). Results were consistent usingâ€‰â‰¥â€‰2 symptoms. Regarding HRQoL, among those with long COVID, Boosted had higher EQ-5D Utility Index (UI) than Unvaccinated (observed: 0.922 vs. 0.731, pâ€‰=â€‰0.014; model-based: 0.910 vs. 0.758, p-valueâ€‰=â€‰0.038) and Primed (0.922 vs. 0.648, pâ€‰=â€‰0.014; model-based: 0.910 vs. 0.708, p-valueâ€‰=â€‰0.008). Observed and model-based estimates for EQ-VAS and UI among Boosted were comparable with pre-COVID since Month 3. Subjects vaccinated generally reported better WPAI scores. CONCLUSIONS: Long COVID negatively impacted HRQoL and WPAI. The BNT162b2 booster could have a beneficial effect in reducing the risk and burden of long COVID. Boosted participants reported fewer and less durable symptoms, which contributed to improve HRQoL and maintain WPAI levels. Limitations included self-reported data and small sample size for WPAI.

Solid-Organ Transplant Recipient Attitudes Regarding COVID-19 Vaccines: Comment.

Comment on "Reactogenicity Study of mRNA COVID-19 Vaccine". Dear Editor, we would like to share ideas on the publication "Reactogenicity Study of mRNA Vaccines Against COVID-19." InglÃ©s Torruella et al. compare the reactogenicity of two types of mRNA vaccines against COVID-19, CommirnatyÂ® (Pfizer) and SpikevaxÂ® (Moderna), in a healthcare population. According to InglÃ©s Torruella et al., the greater reactogenicity and its consequences for the first and second doses of the SpikevaxÂ® vaccine compared to ComirnatyÂ®, and for the second dose compared to the first dose of both vaccines, provides useful knowledge for planning COVID-19 vaccination campaigns in healthcare settings. A variety of factors need to be looked at in order to fully understand the results. It is impossible to draw a relationship between asymptomatic COVID-19 and the lack of symptoms without the required laboratory investigations. Without extensive laboratory testing, asymptomatic COVID-19 and the lack of clinical symptoms could be incorrectly diagnosed. A silent COVID-19 must be ruled out if neither the most recent clinical signals nor the most recent clinical markers are present. Additionally, genetic variations appear to affect how certain individuals' immune systems react to COVID-19. Before the findings can be verified, more clinical study will be needed.

[Response to the letter to the editor of "Commentary on the COVID-19 mRNA vaccine reactogenicity study"]. Dear Editor, Our study aims to compare the short-term adverse effects and their consequences between the RNAm vaccines CommirnatyÂ® (Pfizer) and SpikevaxÂ® (Moderna), as well as these short-term adverse effects and their consequences between the first and second doses of these vaccines with each other. Possible long-term adverse effects were not the subject of our studyâ€¦.

Thrombotic microangiopathy concurrent with disseminated intravascular coagulation after SARS-CoV-2 vaccination.

A case of anti-MDA5 antibody-positive dermatomyositis with severe necrosis on limbs after COVID-19 vaccination.

New-onset Glaucoma Following Moderna COVID-19 Vaccination. AIM: To report a case of new-onset glaucoma following administration of the Moderna (mRNA-1273) vaccine. BACKGROUND: Previous studies have reported a low incidence of ocular adverse events induced by the coronavirus disease 2019 (COVID-19) vaccine. The literature on open-angle glaucoma associated with COVID-19 vaccination is limited. CASE DESCRIPTION: The patient complained of blurred vision 2 days following the administration of the second dose of the Moderna vaccine in July 2021. At presentation, the ophthalmic examination showed elevated intraocular pressure (IOP) of 30 mm Hg in her right eye (OD) and 18 mm Hg in her left eye (OS). There were no signs of intraocular inflammation or glaucomatous optic neuropathy at the initial presentation. She was treated with a topical Î²-blocker first. In addition, 1 month later, her IOPs were 28 mm Hg OD and 26 mm Hg OS. Although treated with multiple antiglaucoma medications, her optic cup-to-disc ratios were increased in both eyes (OU) compared to May 2019. She developed a glaucomatous visual field (VF) defect OD in October 2021. Optical coherence tomography (OCT) revealed progressive retinal nerve fiber layer (RNFL) thinning in OU. CONCLUSION: Glaucoma may be a rare but severe ocular adverse event of the Moderna vaccines. The ophthalmologist should pay attention to the risk of increased IOP following COVID-19 vaccination. CLINICAL SIGNIFICANCE: We reported a case of new-onset open-angle glaucoma presumably associated with COVID-19 vaccination. HOW TO CITE THIS ARTICLE: Su Y, Yeh S, Chen M. New-onset Glaucoma Following Moderna COVID-19 Vaccination. J Curr Glaucoma Pract 2023;17(2):106-109.

A Young Adult With Multisystem Inflammatory Syndrome Following Weeks of Initial COVID-19 Respiratory Infection, With No Prior COVID-19 Vaccination: A Case Report. Multisystem inflammatory syndrome (MIS) following COVID-19, a condition primarily diagnosed in children, has also been observed less frequently in adults. It usually presents with a multitude of symptoms,

mimicking a shock-like state characterized by multiple organ failure. Diagnosis often involves ruling out other conditions and timely management to mitigate morbidity and mortality. In this case, a 39-year-old unvaccinated Caucasian male patient reported symptoms of fever, chills, night sweats, diarrhea, headache, nasal congestion, and facial pain. Despite treatment with antipyretics, the fever persisted. The patient had tested positive for COVID-19 via polymerase chain reaction (PCR) six weeks prior. Clinical findings included low oxygen saturation, sinus tachycardia, abnormal liver function, elevated inflammatory markers, a negative respiratory viral panel, a negative immunologic workup, and a positive Clostridium difficile (C. difficile) PCR. Following complaints of chest pain which quickly escalated to cardiac arrest, he was diagnosed with myopericarditis. These manifestations met the multisystem inflammatory syndrome in adults (MIS-A) diagnostic criteria as stipulated by the Centers for Disease Control and Prevention. The diagnosis of MIS-A was reached through exclusion. Notably, the patient responded well to symptomatic management. Given the infrequent occurrence of MIS-A cases, even in 2023, it remains a challenging diagnosis. Despite existing guidelines for management, the recovery of this patient solely through symptomatic treatment prior to the consideration of conventional treatment is striking. The patient had concurrent infections, including a C. difficile infection, but these did not account for the overall clinical presentation, particularly the myopericarditis and positive laboratory findings.

Eculizumab discontinuation in a patient with atypical hemolytic uremic syndrome after ChAdOx1 nCoV-19 vaccination. Eculizumab has proven to be effective in patients with atypical hemolytic uremic syndrome (aHUS) in clinical trials and in the real world, but the optimal duration of therapy remains unknown. Standard maintenance treatment is often life-long, but the possibility of discontinuation has not yet been systematically tested. We describe a case of aHUS after ChAdOx1 nCoV-19 vaccination in a patient with homozygous CFHR3/CFHR1 gene deletion who discontinued eculizumab maintenance therapy 24 weeks after achieving disease remission. We report the safety of discontinuing eculizumab treatment with the aim of minimizing the risk of adverse reactions, reducing the risk of meningitis, improving quality of life, and reducing the considerable treatment costs.

Effectiveness and Safety of COVID-19 Vaccinations: An Umbrella Meta-Analysis. Objectives: This umbrella meta-analysis aims to provide comprehensive and synthesized evidence regarding the effectiveness and safety of COVID-19 vaccinations based on current studies. Methods: Studies from the Cochrane Library, PubMed, and EMBASE, published before 10 December 2021, were included in the analysis. The pooled results of effectiveness and safety were estimated and shown in forest plots. Results: We included nineteen studies (fifteen studies regarding safety and nine regarding effectiveness) in the analysis. The mRNA vaccines, adenovirus vector vaccines, subunit vaccines, and inactivated vaccines were found to be effective; however, mRNA vaccines, adenovirus vector vaccines and subunit vaccines were associated with local adverse events and systemic events when compared with inactivated vaccines. Conclusion: Our study suggested that till date, COVID-19 vaccination is still a preferred pharmaceutical way to control the widespread pandemic. However, all reported adverse events should be revisited to provide further evidence for mass vaccinations.

Myocarditis following COVID-19 mRNA vaccinations: Twin and sibling case series. ImportanceMyocarditis and myopericarditis are well described adverse events of special interest (AESI) following COVID-19 vaccinations. Whilst the aetiology is still being investigated; there is evidence that genetic predisposition may be a risk factor for the development of myocarditis. Furthermore, hormones are thought to contribute to sex-specific differences in myocarditis, skewed toward a larger risk in adolescent males. OBJECTIVE: This unique sibling case series may help highlight potential mechanisms and prognostic factors in the development of myocarditis following COVID-19 vaccination in adolescent males. In this context, twin and familial studies provide a unique

epidemiological perspective to investigate the interplay between genetic predisposition and other factors. PARTICIPANTS: Observational case series of all siblings reported to SAEFVIC with chest pain following COVID-19 vaccinations in Victoria, Australia. EXPOSURE: mRNA vaccination (Comirnaty BNT162b2 COVID-19 (Pfizer-BioNTech) and Spikevax mRNA-1273 (Moderna). FINDINGS: Our case series comprises 6 young males; two sets of monozygotic twins and one set of fraternal brothers following reports of chest pain associated with COVID-19 mRNA vaccination. Five patients were diagnosed with myocarditis as per Brighton Collaboration Criteria (Level 2). The remaining sibling, who did not have myocarditis, was subsequently diagnosed with pubertal delay. CONCLUSIONS: Understanding the genetic and hormonal risk factors and aetiology for myocarditis associated with COVID-19 vaccines is paramount. Further evaluation of specific genetic targets or biomarkers is required to understand the implications of population vaccine policy, particularly for adolescent and young adult males at highest risk for this AESI.

Post-vaccine COVID-19 acute myocarditis: case reports and literature review. COVID-19 vaccines have reduced both lethality and hospitalization rates of the novel coronavirus disease. Nevertheless, multiple side effects have been reported in the literature, most often are harmless. We report two cases of acute myocarditis, hospitalized in the emergency department for chest pain occurring after the second dose of mRNA vaccine AstraZeneca. The SARS-Cov-2 infection was ruled out in both patients with a negative PCR obtained by nasal swabs and normal thoracic CT scans. Both patients had high levels of high-sensitive cardiac troponin I. Acute coronary syndromes were excluded with cardiac catheterization. Cardiac Magnetic resonance imaging (MRI) showed signs in favor of acute myocarditis. The evolution was favorable for both patients after being put on anti-inflammatory treatment. The universality and accumulation of reports concerning acute myocarditis following COVID vaccination, in the absence of any other diagnostic element that could explain the myocardial injury, establish a strong causal link, although the etiopathogenesis of such injury remains poorly elucidated.

Echocardiographic Assessment Of Left Ventricular Function After COVID-19 Vaccination In Adults. OBJECTIVES: To assess left ventricular function by conventional and speckle tracking echocardiography in subjects having received coronavirus disease-2019 vaccine. METHOD: The cohortstudy was conducted from April 2021 to April 2022 at the Department of Cardiology, Kafrelsheikh University Hospital, Egypt, and comprised adults of either gender who had received coronavirus disease-2019 vaccine. Detailed history was noted before clinical assessment, electrocardiogram and echocardiography, which were done at baseline and after two weeks of the last vaccine dose. Apical 4, apical 3 and apical 2 strains were obtained to get the global longitudinal strain. Data was analysed using SPSS 20. RESULTS: Of the 100 subjects, 50(50%) each were males and females. The overall mean age was 39.20Â±14.57 years. There were 16(16%) subjects with diabetes mellitus and 21(21%) with hypertension. Regarding vaccine distribution, 34(34%) had received AstraZeneca AZD1222, 31(31%) had BioNTech Pfizer vaccine BNT162B2 and 35(35%) had Sinopharm Beijing Institute of Biological Products BBIBP-CorV. The global longitudinal strain before and after vaccination did not show a significant difference ($p<0.063$). There was no significant variation in global longitudinal strain between the various vaccination types ($p=0.584$). CONCLUSIONS: The studied vaccines had similarly acceptable safety profiles regarding left ventricular functions.

Elevated serum levels of T-cell immunoglobulin and mucin-domain containing molecule 3 in patients with systemic inflammation following COVID-19 vaccination. BACKGROUND: ChAdOx1 nCoV-19 vaccine has been widely used. Some unexpected adverse effects such as the development of systemic hyper inflammation with multiorgan involvement after vaccination, in rare cases, have been reported. However, its pathogenesis remains unclear. METHODS: This study recruited two cases who suffered from systemic inflammation following ChAdOx1 nCoV-19 vaccine and two 30-year-old male

volunteers without underlying disease who have received ChAdOx1 nCoV-19 vaccine as control group. Blood samples were collected from our patients and healthy subjects before and after treatment with anti-inflammatory agent such as glucocorticoid and tocilizumab. The immune profile from our patients and healthy controls were measured using a human XL cytokine Proteome Profiler array (ARY022b, R&D Systems). RESULTS: Biochemical parameters revealed leukocytosis with segmented neutrophil dominance and elevated serum levels of C-reactive protein (CRP), erythrocyte sedimentation rate, and ferritin in these two patients. The cytokine array revealed that mean levels of T cell immunoglobulin and mucin-domain containing-3 (TIM-3) (3640.3 vs 1580.5 pixels per inch [ppi]), B-cell activating factor (BAFF) (3036.8 vs 1471.0 ppi), urokinase plasminogen activator surface receptor (uPAR) (1043.1 vs 516.8 ppi), Resistin (1783.7 vs 711.3 ppi), platelet-derived growth factor (PDGF)-AB/BB (1980.7 vs 939.7 ppi), macrophage inflammatory protein-3-beta (MIP-3Î²) (911.9 vs 346.2 ppi), and interferon-inducible T-cell alpha chemoattractant (I-TAC) (1026.3 vs 419.7 ppi) were 2-fold higher in the patients than in normal subjects who received ChAdOx1 nCoV-19 vaccine. CONCLUSION: We demonstrated that systemic inflammation may occur in subjects who have received the ChAdOx1 nCoV-19 vaccination. Moreover, we proposed immune markers, which may be implicated in the pathogenesis of systemic inflammation following COVID-19 vaccination as potential diagnostic biomarkers.

Risk of Noninfectious Uveitis after Coronavirus Disease 2019 Vaccination in a United States Claims Database. PURPOSE: To assess noninfectious uveitis (NIU) risk after coronavirus disease 2019 (COVID-19) vaccination in patients without a history of uveitis. DESIGN: A retrospective matched cohort study and self-controlled case series (SCCS) analysis using a longitudinal data asset with claims data from the OptumLabs Data Warehouse from December 11, 2020, through November 30,Â 2021. PARTICIPANTS: The matched cohort analysis included patients continuously enrolled for 730 days before December 11, 2020, who received a COVID-19 vaccination during the study period. This COVID-19-vaccinated group was matched to a COVID-19-unvaccinated historical cohort enrolled in 2018 and 2019. The SCCS design included individuals from the vaccinated cohort who experienced an NIU event during the study period. Enrollees with a history of uveitis were excluded. METHODS: Hazard ratios (HRs) were calculated using Cox proportional hazards models in the matched cohort design. Incidence rate ratios (IRRs) comparing NIU incidence in exposed risk periods after vaccination and unexposed control periods within individuals were calculated using conditional Poisson regression models in the SCCS design. Models were adjusted for age, recent receipt of non-COVID-19 vaccinations, corticosteroid or immunosuppressive use, and smoking history. Subgroup analyses were conducted by vaccination type and age group. MAIN OUTCOME MEASURES: Rates of NIU identified with International Classification of Diseases, Tenth Revision, codes. RESULTS: The matched cohort analysis included 4 611 378 patients, with 2 305 689 per cohort. The adjusted HR comparing NIU incidence in the COVID-19-vaccinated and unvaccinated cohort was 0.91 (95% confidence interval [CI], 0.75-1.10; PÂ = 0.33). The SCCS analysis included 686 patients. The IRR comparing NIU risk after vaccination with risk during control intervals was 1.05 (95% CI, 0.89-1.23; PÂ = 0.57). An increased risk was found in the subgroup aged 5 to 44 years (IRR, 1.40; 95% CI, 1.04-1.87; PÂ = 0.024). CONCLUSIONS: The matched cohort and SCCS analyses did not detect increased NIU risk after COVID-19 vaccination overall in individuals without history of uveitis, providing reassurance about the vaccine's safety. The finding of increased risk in the youngest subgroup suggests heightened immune responses in younger individuals, warranting further investigation. FINANCIAL DISCLOSURE(S): Proprietary or commercial disclosure may be found in the Footnotes and Disclosures at the end of this article.

Incidence and Determinants of Symptomatic and Asymptomatic SARS-CoV-2 Breakthrough Infections After Booster Dose in a Large European Multicentric Cohort of Health Workers-ORCHESTRA Project.

BACKGROUND: SARS-CoV-2 breakthrough infections (BI) after vaccine booster dose are a relevant public health issue. METHODS: Multicentric longitudinal cohort study within the ORCHESTRA project, involving 63,516 health workers (HW) from 14 European settings. The study investigated the cumulative incidence of SARS-CoV-2 BI after booster dose and its correlation with age, sex, job title, previous infection, and time since third dose. RESULTS: 13,093 (20.6%) BI were observed. The cumulative incidence of BI was higher in women and in HW agedâ€‰<â€‰50Â years, but nearly halved after 60Â years. Nurses experienced the highest BI incidence, and administrative staff experienced the lowest. The BI incidence was higher in immunosuppressed HW (28.6%) vs others (24.9%). When controlling for gender, age, job title and infection before booster, heterologous vaccination reduced BI incidence with respect to the BNT162b2 mRNA vaccine [Odds Ratio (OR) 0.69, 95% CI 0.63-0.76]. Previous infection protected against asymptomatic infection [Relative Risk Ratio (RRR) of recent infection vs no infection 0.53, 95% CI 0.23-1.20] and even more against symptomatic infections [RRR 0.11, 95% CI 0.05-0.25]. Symptomatic infections increased from 70.5% in HW receiving the booster dose sinceâ€‰<â€‰64Â days to 86.2% when time elapsed wasâ€‰>â€‰130Â days. CONCLUSIONS: The risk of BI after booster is significantly reduced by previous infection, heterologous vaccination, and older ages. Immunosuppression is relevant for increased BI incidence. Time elapsed from booster affects BI severity, confirming the public health usefulness of booster. Further research should focus on BI trend after 4th dose and its relationship with time variables across the epidemics.

Association Between Duration of SARS-CoV-2 Positivity and Long COVID. In an observational study, we analyzed 1293 healthcare workers previously infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), of which 34.1% developed postacute sequelae of SARS-CoV-2 infection (also known as long COVID). Using a multivariate logistic regression model, we demonstrate that the likelihood of developing long COVID in infected individuals rises with the increasing of duration of infection and that 3 doses of the BNT162b2 vaccine are protective, even during the Omicron wave.

Evaluation of disease control after SARS-CoV-2 infection or vaccination in patients with NSAID-exacerbated airway disease. Background: There are insufficient data on changes in disease control after severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection or vaccination in patients with nonsteroidal anti-inflammatory drug exacerbated respiratory disease (N-ERD). Objective: This study aimed to investigate the history of coronavirus disease 2019 (COVID-19) in patients with N-ERD, determine whether they experienced exacerbations of asthma or rhinitis after COVID-19, and evaluate their postvaccination asthma and rhinitis control data. Methods: The demographic characteristics of patients with N-ERD and whether they had had symptoms of asthma, changes in nasal symptom scores Sino-nasal outcome test (SNOT-22), Asthma Control Test (ACT) within 1 month after SARS-CoV-2 vaccination or infection were recorded. The prevalence of COVID-19 in patients with N-ERD and in healthy controls was estimated. Results: A total of 103 patients with N-ERD and 100 healthy controls were included in the study. Thirty seven of the patients (35.9%) and 65 of the controls (65%) had a history of COVID-19. There were no significant differences in changes in the ACT and SNOT-22 scores after SARS-CoV-2 vaccination ($p = 0.999$). Although, the change in ACT score after infection was significant ($p = 0.017$; $r = 0.39$), there was no significant change in level of asthma control ($p < 0.001$). Conclusion: The history of COVID-19 was less frequent in the N-ERD group. There was no deterioration in asthma and rhinitis controls after SARS-CoV-2 vaccination. Although a significant decrease was observed in the ACT scores after COVID-19, there was no deterioration in the level of asthma control.

Cholera and COVID-19 pandemic prevention in multiple hotspot districts of Uganda: vaccine coverage, adverse events following immunization and WASH conditions survey. BACKGROUND:

Between March,Â 2020 and December, 2021 due to cholera andÂ coronavirus disease 2019 (COVID-19) pandemics, there were 1,534 cholera cases with 14 deaths and 136,065 COVID-19 cases with 3,285 deaths reported respectively in Uganda. This study investigated mass vaccination campaigns for the prevention of the two pandemics namely: oral cholera vaccine (OCV) and COVID-19 vaccine coverage; adverse events following immunization (AEFI); barriers and enablers for the vaccine uptake and assessed water, sanitation and hygiene (WASH) conditions in the six cholera and COVID-19 hotspot districts of Uganda. METHODS: A household survey was conducted between January and February, 2022 in the six cholera hotspot districts of Uganda which had recently conducted OCV mass vaccination campaigns and had ongoing COVID-19 mass vaccination campaigns. The survey randomly enrolled 900 households with 4,315 persons of whom 2,085 were above 18Â years. Data were collected using a data entry application designed in KoBoToolbox and analysed using STATA version 14. Frequencies, percentages, odds ratios, means, confidence intervals and maps were generated and interpreted. RESULTS: The OCV coverage for dose one and two were 85% (95% CI: 84.2-86.4) and 67% (95% CI: 65.6-68.4) respectively. Among the 4,315 OCV recipients, 2% reported mild AEFI, 0.16% reported moderate AEFI and none reported severe AEFI. The COVID-19 vaccination coverage for dose one and two were 69.8% (95% CI: 67.8-71.8) and 18.8% (95% CI: 17.1-20.5) respectively. Approximately, 23% (478/2,085) of COVID-19 vaccine recipient reported AEFI; most 94% were mild, 0.6% were moderate and 2 cases were severe. The commonest reason for missing COVID-19 vaccine was fear of the side effects. For most districts (5/6), sanitation (latrine/toilet) coverage were low at 7.4%-37.4%. CONCLUSION: There is high OCV coverage but low COVID-19 vaccine and sanitation coverage with high number of moderate cases of AEFI recorded due to COVID-19 vaccines. The low COVID-19 vaccine coverage could indicate vaccine hesitancy for COVID-19 vaccines. Furthermore, incorporation of WASH conditions assessment in the OCV coverage surveys is recommended for similar settings to generate data for better planning. However, more studies are required on COVID-19 vaccine hesitancy.

Dynamics of anti-RBD (anti-receptor binding domain) levels in diabetes patients following the ChAdOx1 nCoV-19 vaccine (AZD1222) in the Thai population. The ChAdOx1 nCoV-19 vaccine (AZD1222) was used in Thailand during the early outbreak of coronavirus disease 2019 (COVID-19). A previous study showed a low immune response in diabetes patients after the first dose of the AZD1222 vaccine. Furthermore, humoral immune responses after the second vaccination were inconsistent. This study evaluated the immunogenicity following the first and second doses of the AZD1222 vaccine in people with type 2 diabetes (T2D) compared with the general population of Thailand. This was a prospective, single-center cohort study. 59 adults with T2D and 118 age- and sex-matched healthcare personnel were eligible. The participants received two doses of AZD1222 12Â weeks apart. Antibodies against the receptor-binding domain (anti-RBD) of the SARS-CoV-2 spike protein, using an automated electrochemiluminesence immunoassay (ECLIA), were measured at baseline, 8 and 12Â weeks after the first dose of vaccine, and 4Â weeks after the second dose of vaccine. The anti-RBD levels were reported as the geometric mean concentration (GMC) and compared between groups using the geometric mean ratio (GMR). A total of 177 participants were included: The average age of 59 T2D patients was 60.1Â years (SD: 11.4), and 31 (52.5%) of them were female. The GMC of anti-RBD 8 and 12Â weeks after the first vaccination were significantly lower in T2D (week 8 60; 17.05 BAU/mL, 95% confidence interval [CI]â€‰ â€‰11.1-26.19, Pâ€‰=â€‰0.035, week 12; 24.68 BAU/mL, 95% CIâ€‰â€‰16.4-37.0, Pâ€‰=â€‰0.002) than in those without diabetes (week 8; 29.79 BAU/mL, 95% CIâ€‰â€‰22.07-40.42, week 12; 50.67 BAU/mL, 95% CIâ€‰â€‰40.62-63.20). However, there was no difference in the GMC of anti-RBD 4Â weeks after the second vaccination among groups (T2D; 687.95 BAU/mL, 95% CIâ€‰â€‰462.7-1022.7, Normal; 697.95 BAU/mL, 95% CIâ€‰583.7-834.5, Pâ€‰=â€‰0.947). In both groups, the

GMC of anti-RBD was persistently high without decline 12Â weeks after the first vaccination. Albuminuria was a major factor related to low humoral immune responses in T2D patients after the second dose of AZD122 vaccine (the GMR was 0.29, 95% Clâ€‰0.08-0.98, Pâ€‰=â€‰0.047) whereas the HbA1C level and age were not. Immunogenicity in T2D cases was lower than in the normal population after the first dose of the AZD1222 vaccine. The two doses of AZD122 vaccine induced immunity in T2D equal to that of normal individuals in Thailand. People with diabetes should be boosted as soon as possible to induce adequate immunity to prevent COVID-19 infection.

Safety signal identification for COVID-19 bivalent booster vaccination using tree-based scan statistics in the Vaccine Safety Datalink. BACKGROUND: Traditional active vaccine safety monitoring involves pre-specifying health outcomes and biologically plausible outcome-specific time windows of concern, limiting the adverse events that can be evaluated. In this study, we used tree-based scan statistics to look broadly for >60,000 possible adverse events after bivalent COVID-19 vaccination. METHODS: Vaccine Safety Datalink enrollees aged â‰¥5Â years receiving Moderna or Pfizer-BioNTech bivalent COVID-19 vaccine through November 2022 were followed for 56Â days post-vaccination. Incident diagnoses in inpatient or emergency department settings were analyzed for clustering within the hierarchical ICD-10-CM diagnosis code "tree" and temporally within post-vaccination follow-up. The conditional self-controlled tree-temporal scan statistic was used, conditioning on total number of cases of each diagnosis and total number of cases of any diagnosis occurring during the scanning risk window across the entire tree. PÂ =Â 0.01 was the pre-specified cut-off for statistical significance. RESULTS: Analysis included 352,509 doses of Moderna and 979,189 doses of Pfizer-BioNTech bivalent vaccines. After Moderna vaccination, no statistically significant clusters were found. After Pfizer-BioNTech, there were clusters of unspecified adverse events (Days 1-3, pÂ =Â 0.0001-0.0007), influenza (Days 35-56, pÂ =Â 0.0001), cough (Days 44-55, pÂ =Â 0.0002), and COVID-19 (Days 52-56, pÂ =Â 0.0004). CONCLUSIONS: For Pfizer-BioNTech only, we detected clusters of: (1) unspecified adverse effects, as have been observed in other vaccine studies using this method, and (2) respiratory disease toward the end of follow-up. The respiratory clusters were likely due to overlap of follow-up with the spread of respiratory syncytial virus, influenza, and COVID-19, i.e., confounding by seasonality. The untargeted nature of the method and its inherent adjustment for the many diagnoses and risk intervals evaluated are unique advantages. Limitations include susceptibility to time-varying confounding, lower statistical power for assessing risks of specific outcomes than in traditional studies targeting fewer outcomes, and the possibility of missing adverse events not strongly clustered in time or within the "tree."

Is vaccine response to SARS-CoV-2 preserved after switching to anti-CD20 therapies in patients with multiple sclerosis or related disorders? BACKGROUND: Although vaccination against SARS-CoV-2 is recommended prior to introducing anti-CD20 therapies, limited data are available regarding the evolution of post-vaccinal immunity. METHODS: This retrospective study compared anti-Spike antibody titres at 6 and 12 months from SARS-CoV-2 vaccination between patients vaccinated before switching to anti-CD20 ('Switch') and two control groups: (1) patients vaccinated under disease-modifying therapies (DMTs) other than fingolimod and anti-CD20 ('Other DMTs'); (2) patients vaccinated on anti-CD20 ('Anti-CD20'). Anti-Spike-specific T-cell responses were compared between 'Switch' and 'Anti-CD20' groups. RESULTS: Fifty-three patients were included in the 'Switch' group, 54 in the 'Other DMTs' group and 141 in the 'Anti-CD20' group. At 6 months, in the subset of patients who received a booster dose, the 'Switch' group had lower anti-Spike titres compared with the 'Other DMTs' group (median 241.0 IQR (88.0; 504.0) BAU/mL vs 2034 (1155; 4634) BAU/mL, p<0.001), and less patients in the 'Switch' group reached the protective threshold of 264 BAU/mL. The 'Switch' group had higher anti-Spike titres than the 'Anti-CD20' group (7.5 (0.0; 62.1) BAU/mL, p=0.001). Anti-Spike titres were not different between the 'Switch' and 'Other DMTs' groups before booster

administration. These results were similar at 12 months. Spike-specific T-cell positivity was similar between the 'Switch' and 'Anti-CD20' groups at 6 and 12 months (60.4% vs 61.0%, p=0.53, and 79.4% vs 87.5%, p=0.31, respectively). CONCLUSIONS: Despite a primary vaccination performed before the first anti-CD20 cycle, our results suggest weaker immune responses at 6 and 12 months and decreased booster efficacy after introducing anti-CD20. Patients vaccinated prior to anti-CD20 introduction might falsely be considered as fully protected by vaccination.

SARS-CoV-2 mRNA vaccine-induced immune responses in rheumatoid arthritis. Our objective was to characterize T and B cell responses to vaccination with SARS-CoV-2 antigens in immunocompromised rheumatoid arthritis (RA) patients. In 22 RA patients, clinical and biological variables were analyzed before and 4 weeks after each of 3 messenger RNA (mRNA) vaccine doses and compared with unmatched healthy individuals. Sequentially sampled peripheral blood mononuclear cells and sera were collected to determine immune profiles and to analyze the T cell response to a spike peptide pool and B cell specificity to the receptor-binding domain (RBD). Anti-spike antibodies were detectable in 6 of 22 RA patients after 1 dose of vaccine with increasing titers after each booster dose, although the overall response was lower compared with that in healthy control individuals. Responding patients after the first dose were more likely to have RA antibodies and a higher baseline proportion of circulating follicular B cells. In RA patients, the mRNA vaccine elicited a robust CD4+ T response to a spike peptide pool following the first and second doses. Consistent with the serologies, RBD-specific B cells exhibited a modest increase after the first dose and the second dose resulted in marked increases only in a fraction of the RA patients to both ancestral and omicron RBD. Our results highlight the importance of multidose COVID-19 vaccination in RA patients to develop a protective humoral response. However, these patients rapidly develop specific T CD4+ responses, despite delayed B cell responses.

Systemic Lupus Erythematosus and COVID-19. PURPOSE OF REVIEW: To describe the current state of knowledge regarding COVID-19 in patients with systemic lupus erythematosus (SLE). We focus on (i) SARS-CoV-2 vaccination uptake, immunogenicity and safety, and (ii) outcomes of COVID-19 in patients with SLE and pertinent risk factors for adverse sequelae. RECENT FINDINGS: Notwithstanding the potential concern of patients about possible post-vaccination side-effects, the safety of anti-SARS-CoV-2 vaccines in patients with SLE has been undisputedly confirmed in numerous studies. Humoral immunogenicity is generally attained in SLE, although affected by the use of background immunosuppressive drugs, especially rituximab. The latter has also clearly been implicated with adverse COVID-19 outcomes in SLE, including need for hospitalization, mechanical ventilation and death. Although the wide adoption of vaccination has significantly improved COVID-19 outcomes, patients with SLE continue to pose challenges during the pandemic, mainly owing to administered immunosuppressive medications.

Factors associated with 60-day readmission among inpatients with COVID-19 at 21 United States health systems. Identifying patients at risk for readmission after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection could facilitate care planning and prevention. This retrospective cohort study of 60-day readmission included 105â€‰543 COVID-19 patients at 21 US healthcare systems who were discharged alive between February 2020 and November 2021. Generalized linear mixed regression analyses tested predictors of 60-day readmission and severity. The all-cause readmission rate was 15% (95% confidence interval [CI]â€‰=â€‰10%-21%), with 22% (95% CIâ€‰=â€‰18%-26%) of readmitted patients needing intensive care, and 6% (95% CIâ€‰=â€‰05%-07%) dying. Factors associated with readmission included male sex, government insurance, positive smoking history, co-morbidity burden, longer index admissions, and diagnoses at index admission (e.g., cancer, chronic kidney disease, and liver disease). Death and intensive care rates at readmission declined postvaccine availability. Receiving at least two COVID-19 vaccine doses,

which were more common among older patients and those with comorbid conditions, was not independently associated with readmission but predicted a reduced risk of death at readmission. This retrospective cohort study identified factors associated with all-cause readmission for patients re-admitted to the same health system after hospitalization with SARS-CoV-2 infection. Patients who are male, who smoke, who have a higher comorbidity burden, and have government insurance may benefit from additional postacute care planning.

Establishing immunogenicity and safety of needle-free intradermal delivery by nanoporous ceramic skin patch of mRNA SARS-CoV-2 vaccine as a revaccination strategy in healthy volunteers. INTRODUCTION: Nanoporous microneedle arrays (npMNA) are being developed as skin patches for vaccine delivery. As alternative for needle-based immunisation, they may potentially result in higher vaccine acceptance, which is important for future mass vaccination campaigns to control outbreaks, such as COVID-19, and for public vaccination in general. In this study we investigated the safety and immunogenicity of needle-free intradermal delivery of a fractional third or fourth dose of mRNA-1273 vaccine by npMNA. METHODS: This study was an open-label, randomised-controlled, proof-of-concept study. Healthy adults were eligible if they had received a primary immunisation series against SARS-CoV-2 with two doses of mRNA-1273 (Moderna) or BNT162b2 (Pfizer-BioNTech) mRNA vaccine. A history of a COVID-19 infection or booster vaccination with mRNA-1273 or BNT162b2 was allowed if it occurred at least three months before inclusion. Participants were randomised in a 1:1 ratio to receive 20Â Âµg mRNA-1273 vaccine, either through npMNA patch applied on the skin (ID-patch group), or through intramuscular (IM) injection (IM-control group). Primary outcomes were reactogenicity up to two weeks after vaccination, and fold-increase of SARS-CoV-2 spike S1-specific IgG antibodies 14 days post-vaccination. RESULTS: In April 2022, 20 participants were enroled. The geometric mean concentration (GMC) did not increase in the ID-patch group after vaccination, in contrast to the IM-control group (GMC was 1,006 BAU/mL (95% CI 599-1,689), 3,855 (2,800-5,306), and 3,513 (2,554-4,833) at day 1, 15 and 29, respectively). In addition, SARS-CoV-2-specific T cell responses were lower after ID vaccination through npMNA. CONCLUSION: Needle-free delivery of 20Â Âµg mRNA-1273 vaccine by npMNA failed to induce antibody and T cell responses. As this is a potentially very useful vaccination method, it is important to determine which adjustments are needed to make this npMNA successful. CLINICAL TRIAL REGISTRY (ON CLINICALTRIAL.GOV): NCT05315362.

No evidence of durable trained immunity after two doses of adenovirus-vectored or mRNA COVID-19 vaccines.

Expected usefulness of the third dose COVID-19 vaccine for cancerous patient.

Self-reported side effects following COVID-19 vaccination in athletes: A retrospective study. Billions of coronavirus disease 19 (COVID-19) vaccines have been administered worldwide. However, limited data on side effects have been reported in athletes. This study aimed to describe the incidence of side effects following COVID-19 vaccination in athletes and to identify the factors associated with the main side effects in this population. Information on COVID-19 vaccination, side effects, and overall symptom duration was retrospectively collected from recreational and competitive athletes. A total of 460 participants were included in this study. Fever and arm pain were more frequently reported after the first-dose vaccination, 9.6% vs 4.6%, pâ€‰=â€‰.007 and 81.3% vs 24.9%, pâ€‰â‰¤â€‰.001. Myalgia was more common after the second-dose vaccination, 0.65% vs. 7.1% pâ€‰â‰¤â€‰.001. Males were more likely to present with arm pain after the first and second vaccinations. Those with SARS-CoV-2 infection before vaccination were less likely to present with arm pain after the first dose of vaccination (OR: 0.162, pâ€‰â‰¤â€‰.001) and more likely to present with fever after the second dose of vaccination (OR: 3.442, pâ€‰=â€‰.046). First-dose vaccination with the BNT162b2 vaccine compared to other brands was characterized by lower odds of

fever (OR: 0.394, pâ€‰=â€‰.017). Our results indicated mild adverse effects and a short duration of symptoms in athletes following COVID-19 vaccination.

Sex-specific differences in myocardial injury incidence after COVID-19 mRNA-1273 booster vaccination. AIMS: To explore the incidence and potential mechanisms of oligosymptomatic myocardial injury following COVID-19 mRNA booster vaccination. METHODS AND RESULTS: Hospital employees scheduled to undergo mRNA-1273 booster vaccination were assessed for mRNA-1273 vaccination-associated myocardial injury, defined as acute dynamic increase in high-sensitivity cardiac troponin T (hs-cTnT) concentration above the sex-specific upper limit of normal on day 3 (48-96â€‰h) after vaccination without evidence of an alternative cause. To explore possible mechanisms, antibodies against interleukin-1 receptor antagonist (IL-1RA), the SARS-CoV-2-nucleoprotein (NP) and -spike (S1) proteins and an array of 14 inflammatory cytokines were quantified. Among 777 participants (median age 37â€‰years, 69.5% women), 40 participants (5.1%; 95% confidence interval [CI] 3.7-7.0%) had elevated hs-cTnT concentration on day 3 and mRNA-1273 vaccine-associated myocardial injury was adjudicated in 22 participants (2.8% [95% CI 1.7-4.3%]). Twenty cases occurred in women (3.7% [95% CI 2.3-5.7%]), two in men (0.8% [95% CI 0.1-3.0%]). Hs-cTnT elevations were mild and only temporary. No patient had electrocardiographic changes, and none developed major adverse cardiac events within 30â€‰days (0% [95% CI 0-0.4%]). In the overall booster cohort, hs-cTnT concentrations (day 3; median 5, interquartile range [IQR] 4-6 ng/L) were significantly higher compared to matched controls (nâ€‰=â€‰777, median 3 [IQR 3-5] ng/L, pâ€‰<â€‰0.001). Cases had comparable systemic reactogenicity, concentrations of anti-IL-1RA, anti-NP, anti-S1, and markers quantifying systemic inflammation, but lower concentrations of interferon (IFN)-Î»1 (IL-29) and granulocyte-macrophage colony-stimulating factor (GM-CSF) versus persons without vaccine-associated myocardial injury. CONCLUSION: mRNA-1273 vaccine-associated myocardial injury was more common than previously thought, being mild and transient, and more frequent in women versus men. The possible protective role of IFN-Î»1 (IL-29) and GM-CSF warrant further studies.

Adverse Events among Beneficiaries who Received a Dose of Sputnik V Vaccine at a Tertiary Care Hospital in Coastal Karnataka, India. INTRODUCTION: Vaccination has played a vital role in containing the COVID-19 pandemic. Sputnik V was the third vaccine approved for emergency use in India. The objectives of the present study were to document the adverse events following Sputnik V vaccination and the factors associated with adverse events. METHODOLOGY: This cross-sectional study was conducted during September and October 2021 in a teaching hospital of Karnataka. Ethics approval and CTRI registration were obtained before collecting the data. All persons receiving at least one dose of vaccine were invited to participate and baseline information was collected after written informed consent. They were contacted telephonically to enquire about the adverse events. Data were entered in Microsoft Excel and analyzed using SPSS Version 23 to describe percentages and proportions. RESULTS: The median age of 2532 participants was 31 (IQR 25-39) years and 60.4% were males. Minor adverse events were seen among 29.4% participants. Most common symptoms with first dose were fever, vaccination site tenderness, myalgia and headache, and with second dose were fever, myalgia, headache, and vaccination site tenderness. No severe adverse events were reported in our study. The adverse events were seen more among females ($P < 0.05$) and with the first dose ($P < 0.05$). CONCLUSION: Most common adverse events were similar to symptoms suggested by the vaccine manufacturers with fever being the most common one. A follow-up after a longer lag time may be recommended to enquire whether the vaccinees developed serious adverse events.

Genome-wide association studies of response and side effects to the BNT162b2 vaccine in Italian healthcare workers: Increased antibody levels and side effects in carriers of the HLA-A*03:01 allele. The remarkable variability of response to vaccines against SARS-CoV-2 is apparent. The present study

aims to estimate the extent to which the host genetic background contributes to this variability in terms of immune response and side effects following the administration of the BNT162b2 vaccine. We carried out a genome wide association study (GWAS) by genotyping 873 Italian healthcare workers who underwent anti-SARS-CoV-2 vaccination with the BNT162b2 vaccine and for whom information about anti-SARS-CoV-2 spike antibodies titers and vaccine side effects were available. The GWAS revealed a significant association between the HLA locus and the anti-SARS-CoV-2 Spike antibodies level at 2â€‰months following the first dose of vaccine (SNP: rs1737060; pâ€‰=â€‰9.80â€‰Ã—â€‰10(-11)). In particular, we observed a positive association between the antibody levels and the presence of the HLA-A*03:01 allele. The same allele was found associated with a 2-2.4-fold increased risk of experiencing specific side effects such as fever, chills and myalgia and a 1.5-1.8-fold increased risk of joint pain, nausea, fatigue, headache and asthenia, independently of age and sex. This study confirms that the heterogeneity in the immune response to the BNT162b2 vaccine and in its side effects are at least partially influenced by genetic variants. This information, integrated with individual biological and lifestyle-related correlates, could be of use in the definition of algorithms aimed at the identification of subjects in which the administration of additional vaccine doses would be particularly beneficial to maintain immunity against the virus.

Comparison of anti-spike IgG, anti-spike IgA levels and neutralizing antibody activity induced by CoronaVac and BNT162b2 vaccines in patients with inflammatory rheumatic diseases receiving immunosuppressive therapy. BACKGROUND: The importance of COVID-19 vaccination for patients on immunosuppressive (IS) medication has increased due to the high risk of severe disease or mortality. Different vaccines have varying efficacy rates against symptomatic COVID-19, ranging from 46.8% to 95%. The objective of this study was to examine the differences in anti-Spike IgG, anti-Spike IgA, and neutralizing antibody (NAb) activity between the inactive CoronaVac vaccine and the mRNA-based BNT162b2 vaccine in IS patients. METHOD: A total of 441 volunteers, including 104 IS patients, 263 healthy controls (HC), who received two doses of CoronaVac or BNT162b2, and 74 unvaccinated patients with a history of SARS-CoV-2 infection, were included in the study. Anti-spike IgG, IgA, and NAb activity were investigated. RESULTS: Immunogenicity with BNT162b2 was higher than with CoronaVac, but in IS groups, it was lower than HC (CoronaVac-IS: 79.3%, CoronaVac-HC: 96.5%, pâ€‰<â€‰0.001; BNT162b2-IS: 91.3%, BNT162b2-HC: 100%, pâ€‰=â€‰0.005). With CoronaVac, anti-Spike IgG levels were significantly lower than BNT162b2 (CoronaVac-IS: 234.5AU/mL, CoronaVac-HC: 457.85AU/mL; BNT162b2-IS: 5311.2AU/mL, BNT162b2-HC: 8842.8AU/mL). NAb activity in the BNT162b2 group was significantly higher. NAb and anti-Spike IgG levels were found to be correlated. Among the IS group, a significantly lower response to the vaccines was observed when using rituximab. IgA levels were found to be lower with CoronaVac. CONCLUSIONS: Although immunogenicity was lower in IS patients, an acceptable response was obtained with both vaccines, and significantly higher anti-Spike IgG, anti-Spike IgA, and NAb activity levels were obtained with BNT162b2.

Miller Fischer syndrome after COVID-19 infection and vaccine: a systematic review. BACKGROUND: COVID-19 (CoranaVirus disease 2019) is an ongoing infectious disease caused by the RNA SARS-CoV-2 virus (Severe Acute Respiratory Syndrome CoronaVirus-2). The virus mainly causes respiratory symptoms, but neurological symptoms have also been reported to be part of the clinical manifestations of the disease. The aim of this study was to systematically review Miller fisher syndrome (MFS) published cases, in the context of COVID-19 infection or vaccination. METHODS: A systematic literature review on Medline was performed. A total of 21 papers were included in the present review. RESULTS: Twenty-two MFS cases (77% males) were identified, 14 related to COVID-19 infection and 8 to vaccination against COVID-19. The median age of the adult patients was 50Â years (interquartile range 36-63Â years). Sixteen patients (73%) had the classic triad of MFS

(ophthalmoplegia, ataxia, areflexia), four (18%) had acute ophthalmoplegia and one other characteristic symptom and two patients (9%) had only one other characteristic symptom, but they tested positive for GQ1b antibodies. Nine (41%) patients had positive GQ1b antibodies and were classified as "definite" MFS. Albuminocytologic dissociation was found in half of the cases. The outcome was favourable in the majority of cases (86%) whereas one patient, despite the initial improvement, died because of a cardiac arrest, after cardiac arrythmia. CONCLUSIONS: MFS after COVID-19 infection/vaccination was found to have the typical epidemiological characteristics of classic MFS; being rare, occurring more often after infection than vaccination, affecting mainly middle-aged males usually within 3Â weeks after the event and having an excellent prognosis after treatment with IVIG or even with no treatment at all. We found no evidence that MFS after COVID-19 infection was different from MFS after COVID-19 vaccination, although the former tended to occur earlier.

The use of prescription drugs and health care services during the 6-month post-COVID-19 period. COVID-19 and other acute respiratory viruses can have a long-term impact on health. We aimed to assess the common features and differences in the post-acute phase of COVID-19 compared with other non-chronic respiratory infections (RESP) using population-based electronic health data. We applied the self-controlled case series method where prescription drugs and health care utilisation were used as indicators of health outcomes during the six-month-long post-acute period. The incidence rate ratios of COVID-19 and RESP groups were compared. The analysis included 146 314 individuals. Out of 5452 drugs analysed, 14 had increased administration after COVID-19 with drugs for cardiovascular diseases (trimetazidine, metoprolol, rosuvastatin) and psychotropic drugs (alprazolam, zolpidem, melatonin) being most prevalent. The health impact of COVID-19 was more apparent among females and individuals with non-severe COVID-19. The increased risk of exacerbating pre-existing conditions was observed for the COVID-19 group. COVID-19 vaccination did not have effect on drug prescriptions but lowered the health care utilisation during post-acute period. Compared with RESP, COVID-19 increased the use of outpatient services during the post-infection period. The long-term negative impact of COVID-19 on life quality must be acknowledged, and supportive health care and public health services provided.

Complications after administration of mRNA vaccine against COVID-19 - case report and short review. The pandemic of the disease COVID-19 (COronaVIrus Disease 2019) caused by the SARS-CoV-2 coronavirus (severe acute respiratory syndrome coronavirus 2) resulted in millions of deaths and many patients have chronic consequences after overcoming the acute condition. Several vaccines have been developed in an effort to stop the spread of the virus, but they have potentially serious adverse effects. We present a case report of a patient with acute (myocarditis, exacerbation of bronchial asthma) and long-term (postural orthostatic tachycardia syndrome - POTS) complications after vaccination with the second dose of mRNA vaccine BNT162b2 (ComirnatyÂ®). Treatment consists of regimen measures, numerous pharmacotherapy (metoprolol, ivabradine, corticosteroids, antihistamines, antiphlogistics, bronchodilators) and several nutraceuticals (maritime pine bark extract, quercetin, vitamins, magnesium, phosphatidylcholine). In the discussion, we analyze post-vaccination injury and present a short review of the current literature.

Nonepisodic Angioedema with Eosinophilia Following Receipt of the BNT162b2 mRNA COVID-19 Vaccine. Angioedema with eosinophilia (AE) is a rare disease of unknown etiology characterized by episodic (EAE) or nonepisodic AE (NEAE). Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA-based vaccines function as immunogens and intrinsic adjuvants and have been shown to be safe in large-scale trials. However, the long-term adverse reactions, especially those related to eosinophilic complications, have not been fully clarified. We herein report a case of self-limited but severe NEAE that developed in a young woman one week after receiving the second BNT162b2 mRNA

vaccine. The symptoms that impaired her activities of daily living, such as edema, gradually resolved with supportive care over 10 weeks without corticosteroid treatment.

Comparing the recurrence of audio-vestibular disorders following breakthrough infection of COVID-19 vs. those following vaccine administration. PURPOSE: The term "breakthrough infection" of COVID-19 indicates that subjects who previously received COVID-19 vaccination became infected with COVID-19. This study compared the recurrence of audio-vestibular disorders following breakthrough infection of COVID-19 vs. those following vaccine administration. PATIENTS AND METHODS: Fifty patients with previous known audio-vestibular disorders visited our clinic due to recurrence of inner ear symptoms following breakthrough infection of COVID-19 and were assigned to Group A. Another 50 patients who had recurrent inner ear symptoms following COVID-19 vaccination were assigned to Group B for comparison. The post-breakthrough infection interval is defined from date of breakthrough infection to the onset of inner ear symptoms, while the post-vaccination interval means the time from date of vaccination to the onset of inner ear symptoms. These two intervals were calculated and then compared. RESULTS: The time from latest vaccination to the breakthrough infection of COVID-19 was 4Â m (median), likely due to waning of IgG response. To the onset of inner ear symptoms, the post-breakthrough infection interval was 40d (median) for Group A, which was significantly longer than 10d (median) of the post-vaccination interval for Group B. CONCLUSION: The post-breakthrough infection interval (median, 40d) is significantly longer than the post-vaccination interval (median, 10d) to exacerbate pre-existing audio-vestibular disorders. The reason is probably because an interval of 40d is related to IgG peak response following COVID-19 breakthrough infection, while that of 10d is responsible for IgG production after COVID-19 vaccination.

Recurrent Varicella After SARS-CoV-2 Vaccination in a Healthy Female.

Differential impacts of vaccine scandal by ethnic and socioeconomic factors: Evidence from China. Widespread vaccination against important diseases plays a key role for global health security, particularly in the context of the COVID-19 pandemic. However, building and maintaining trust in immunization services remains challenging because of doubts about quality and safety of vaccines. China has periodically faced mounting pressure and even public outrage triggered by incidents of poor-quality vaccines. We aimed to evaluate the impact of the diphtheria, pertussis, and tetanus (DPT) vaccine scandal of 2018 in China and the ensuing misinformation on vaccination, and investigate differential responses to the scandal by ethnic and socioeconomic factors. With data from January 2017 to December 2018 in Sichuan province, China, we used a difference-in-differences (DID) method to compare the changes in the county-level monthly DPT vaccinations against the hepatitis B vaccinations, both before and after the DPT vaccine scandal. We found that the number of DPT vaccinations decreased by 14.0 percent in response to the vaccine scandal and ensuing misinformation. The number of vaccinations in minority regions, under-developed regions, and regions with poor medical resources decreased more than in non-minority regions, developed regions, and regions with good medical resources (24.5 versus 10.1 percent, 17.3 versus 8.3 percent, and 17.0 versus 8.7 percent, respectively). People did more online searching for "Substandard vaccine" and "DPT vaccine" after the scandal, with the socioeconomically advantaged group searching more compared with the socioeconomically disadvantaged group. The results suggest the urgent need to make true information about the vaccine easily accessible over the internet, especially for the socioeconomically disadvantaged groups. Our findings for China can also have implications for immunization service planning for better safeguarding public health in other countries, particularly developing ones.

European Society of Breast Imaging (EUSOBI) guidelines on the management of axillary lymphadenopathy after COVID-19 vaccination: 2023 revision. Axillary lymphadenopathy is a

common side effect of COVID-19 vaccination, leading to increased imaging-detected asymptomatic and symptomatic unilateral axillary lymphadenopathy. This has threatened to negatively impact the workflow of breast imaging services, leading to the release of ten recommendations by the European Society of Breast Imaging (EUSOBI) in August 2021. Considering the rapidly changing scenario and data scarcity, these initial recommendations kept a highly conservative approach. As of 2023, according to newly acquired evidence, EUSOBI proposes the following updates, in order to reduce unnecessary examinations and avoid delaying necessary examinations. First, recommendation n. 3 has been revised to state that breast examinations should not be delayed or rescheduled because of COVID-19 vaccination, as evidence from the first pandemic waves highlights how delayed or missed screening tests have a negative effect on breast cancer morbidity and mortality, and that there is a near-zero risk of subsequent malignant findings in asymptomatic patients who have unilateral lymphadenopathy and no suspicious breast findings. Second, recommendation n. 7 has been revised to simplify follow-up strategies: in patients without breast cancer history and no imaging findings suspicious for cancer, symptomatic and asymptomatic imaging-detected unilateral lymphadenopathy on the same side of recent COVID-19 vaccination (within 12Â weeks) should be classified as a benign finding (BI-RADS 2) and no further work-up should be pursued. All other recommendations issued by EUSOBI in 2021 remain valid.

Acute Recurrent Pancreatitis in a Pediatric Patient in the Setting of Viral Infection and COVID-19 Vaccination. Acute pancreatitis within pediatric populations is predominately caused by mechanical obstruction, trauma, medications, and infections. We present a case of an adolescent female without any known anatomic or metabolic pre-disposition, developing recurrent acute pancreatitis that is seemingly related to acute viral infection and COVID-19 vaccination.

Serological Evaluation of Antibody Titers After Vaccination Against COVID-19 in 18-44-Year-Old Individuals at a Tertiary Care Center. Background The evaluation of the effectiveness of the vaccines (ChAdOx1-nCOV; Covishield and BBV-152; Covaxin) against coronavirus disease 2019 (COVID-19) is necessary to assess their efficacy. Because most antibodies that neutralize the coronavirus are directed against the receptor binding domain within the spike protein of the virus, these antibodies serve as markers for viral neutralizers and, in turn, for vaccine response. The present study aimed to evaluate the anti-neutralizing antibodyÂ (receptor binding domain (RBD)) and immunoglobulin G2 (IgG2) titers following the completion of the vaccination schedule (both vaccines) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Methodology In this longitudinal prospective study, conducted in a tertiary care center, 30 sequentially (two doses) vaccinated study participants between the ages of 18 and 44 years were sampled for estimation of anti-RBD antibody titer and IgG2. All statistical analysis was done using SPSS version 20 (IBM Corp., Armonk, NY, USA). P-values less than 0.05 were considered significant. Results There was a statistically significant increase in the neutralizing antibody titer after one month of the second dose ($z = -4.597$, $p < 0.001$), while a significant decrease was seen in the IgG2 levels ($z = -3.075$, $p = 0.002$). The results showed a significant neutralizing effect of the vaccines being used, with Covishield being more effective than Covaxin. The levels of neutralizing antibodies were independent of all demographic variables such as age, sex, and body mass index. Conclusions This study evaluating the efficacy of the two vaccines, namely, Covishield and Covaxin, is the first of its kind in the state of Chhattisgarh. The results of this study are similar to previous studies conducted in India and outside India, concluding that Covishield is a more effective vaccine.

COVID-19 vaccine induced poor neutralization titers for SARS-CoV-2 omicron variants in maternal and cord blood. INTRODUCTION: Maternally derived antibodies are crucial for neonatal immunity. Understanding the binding and cross-neutralization capacity of maternal and cord antibody responses to SARS-CoV-2 variants following COVID-19 vaccination in pregnancy can inform neonatal immunity.

METHODS: Here we characterized the binding and neutralizing antibody profile at delivery in 24 pregnant individuals following two doses of Moderna mRNA-1273 or Pfizer BNT162b2 vaccination. We analyzed for SARS-CoV-2 multivariant cross-neutralizing antibody levels for wildtype Wuhan, Delta, Omicron BA1, BA2, and BA4/BA5 variants. In addition, we evaluated the transplacental antibody transfer by profiling maternal and umbilical cord blood. RESULTS: Our results reveal that the current COVID-19 vaccination induced significantly higher RBD-specific binding IgG titers in cord blood compared to maternal blood for both the Wuhan and Omicron BA1 strain. Interestingly, the binding IgG antibody levels for the Omicron BA1 strain were significantly lower when compared to the Wuhan strain in both maternal and cord blood. In contrast to the binding, the Omicron BA1, BA2, and BA4/5 specific neutralizing antibody levels were significantly lower compared to the Wuhan and Delta variants. It is interesting to note that the BA4/5 neutralizing capacity was not detected in either maternal or cord blood. DISCUSSION: Our data suggest that the initial series of COVID-19 mRNA vaccines were immunogenic in pregnant women, and vaccine-elicited binding antibodies were detectable in cord blood at significantly higher levels for the Wuhan and Delta variants but not for the Omicron variants. Interestingly, the vaccination did not induce neutralizing antibodies for Omicron variants. These results provide novel insight into the impact of vaccination on maternal humoral immune response and transplacental antibody transfer for SARS-CoV-2 variants and support the need for bivalent boosters as new variants emerge.

A Case of Bilateral Frosted Branch Angiitis after mRNA COVID-19 Vaccination. We report a case of bilateral frosted branch angiitis (FBA) following mRNA-1273 COVID-19 vaccination. A 79-year-old male was referred to our hospital with a sudden onset of blurred vision in the right eye, which occurred during his return home after receiving the third dose of a messenger RNA (mRNA) COVID-19 vaccine. Fundoscopy revealed severe retinal vasculitis with sheathing of the artery and vein in the right eye more so than in the left eye, suggestive of bilateral FBA. Optical coherence tomography showed significant macular edema and serous retinal detachment in the right eye. Polymerase chain reaction assay detected Epstein-Barr virus (EBV) in the aqueous humor, and antibody against the EBV viral capsid antigen was positive for IgM. The next day, best-corrected visual acuity (BCVA) worsened to 0.08 due to macular edema in the left eye. After 2 courses of pulse steroid therapy and intravenous infusion of acyclovir, macular edema had disappeared and sheathing of retinal vessels was improving. At 5 months after the mRNA COVID-19 vaccination, BCVA was maintained 0.15 in the right eye and 0.7 in the left eye. Severe uveitis, such as FBA, can occur after mRNA COVID-19 vaccination.

Immunogenicity and safety of inactivated SARS-CoV-2 vaccine in haemodialysis patients: a prospective cohort study. End-stage renal disease patients on haemodialysis (HD) have been largely excluded from SARS-CoV-2 vaccine trials due to safety reasons and shown to mount lower responses to vaccination. This study aims to evaluate the immunogenicity and safety of inactivated COVID-19 vaccine among HD patients compared to healthy controls. All subjects who received the primary inactivated COVID-19 vaccination had their blood samples tested 21Â days after the second dose. We report the immunogenicity based on anti-RBD IgG titre (IU/mL), the inhibition rate of neutralizing antibodies (NAbs) (%) to RBD, and seroconversion rates. Adverse events were assessed within 30Â min and on the 7th day after each dose. Among 75 HD patients and 71 healthy controls, we observed no significant difference in all immunogenicity measures: anti-RBD IgG GMT (277.91â€‰Â±â€‰7.13Â IU/mL vs. 315.50â€‰Â±â€‰3.50Â IU/mL, pâ€‰=â€‰0.645), NAbs inhibition rate (82% [53-96] vs. 84% [39-98], pâ€‰=â€‰0.654), and seroconversion rates (anti-RBD IgG: 86.7% vs. 85.9%, pâ€‰=â€‰0.895; NAbs: 45.3% vs. 60.6%, pâ€‰=â€‰0.065). The number of adverse events is not significantly different between the two groups. The primary inactivated SARS-

CoV-2 vaccination elicits an adequate antibody response and can be safely administered in haemodialysis patients.
Letter to the Editor From Kleebayoon and Wiuwanikit: "Subacute THYROiditis Related to SARS-CoV-2 VAccine and Covid-19 (THYROVAC Study): A Multicenter Nationwide Study".
Podocytopathies related to either COVID-19 infection or its vaccination, our experience and literature review. Coronavirus disease 2019 (COVID-19) affects several organs including the kidney resulting in acute kidney injury (AKI) and variants of podocytopathies. From the beginning to the middle period of the COVID-19 pandemic, we have collected eight renal biopsies with various renal diseases including 4 podocytopathies. In addition, from the middle period to the near end of the COVID-19 pandemic, we have seen two of the patients who developed nephrotic syndrome following COVID-19 vaccination. Three of 4 podocytopathies were collapsing glomerulopathy (also called collapsing focal segmental glomerulosclerosis) and the fourth was a minimal change disease (MCD). Two of three collapsing glomerulopathy were found in African American patients, one of who was tested positive for having the high-risk allele APOL-1 G1. In addition, the two renal biopsies showed either MCD or replaced MCD following COVID-19 vaccination. MCD can be a rare complication following COVID-19 infection and COVID-19 vaccination, raising the question if there are similar antigens induced by the infection or by the vaccination that trigger the MCD. This article reports our experience of diagnosing podocytopathies related to either COVID-19 infection or its vaccination and provides a literature review regarding the incidence and potential pathophysiology in the field.
Safety evaluation of COVID-19 vaccination during early pregnancy: A single-center prospective cohort study of Chinese pregnant women. This prospective cohort study aimed to evaluate the safety of an inactivated coronavirus disease 2019 (COVID-19) vaccine in pregnant women at a tertiary hospital in Hubei, China. Pregnancy outcomes were compared between pregnant vaccinated and unvaccinated women. Composite adverse pregnancy outcomes were defined as one or more of maternal adverse outcomes (prenatal pyrexia, postpartum hemorrhage, maternal intensive care unit admission, and a prethrombotic state) and adverse neonatal outcomes (premature delivery, intrauterine fetal death or induction of labor, fetal macrosomia, fetal growth restriction, small-for-gestational age, fetal abnormalities, neonatal admission to the neonatal intensive care unit, and birth asphyxia). Of a total of 845 participants in the delivery cohort, 41.2% (348/845) received at least one dose of the COVID-19 vaccination, and 33.6% (284/845) received two doses. In total, 25.3% (88/348) of the vaccinated group were vaccinated at 0-4â€‰weeks of pregnancy. No significant difference was found in the composite adverse outcomes between the vaccinated and unvaccinated participants, regardless of whether vaccination occurred before (44/243 [18.1%] vs. 71/497 [14.3%]; Pâ€‰=â€‰.17) or during early pregnancy (14/105 [13.3%] vs. 71/497[14.3%]; Pâ€‰=â€‰.79). These findings indicate that the pregnancy outcomes of women who received the COVID-19 vaccination, even if they were vaccinated early in pregnancy, were comparable to those of unvaccinated women. This study was registered with the Chinese Clinical Trial Center (ChiCTR2100051756).
Reduced prophylactic effect of tixagevimab-cilgavimab in patients with hematological malignancies and without antibody response after SARS-COV-2 vaccination.
SARS-CoV-2 breakthrough infections after COVID-19 vaccination in patients with inflammatory bowel disease: a systematic review and meta-analysis. BACKGROUND: Patients with inflammatory bowel disease (IBD) have an attenuated serologic response to COVID-19 vaccination. It is unclear whether an impaired immune response in vaccinated IBD patients impacts the susceptibility to SARS-CoV-2 infection and occurrence of severe COVID-19. OBJECTIVES: To evaluate SARS-CoV-2 breakthrough infection rates and the disease course of COVID-19 in vaccinated IBD patients. DESIGN: A systematic literature search and meta-analysis was performed. DATA SOURCES AND METHODS: The

search was performed in Embase, Medline, Web of Science Core Collection, Cochrane Central Register of Controlled Trials and CINAHIL. The articles were independently screened and selected by two reviewers. A random-effects model was used to calculate the pooled relative risk for breakthrough infections in vaccinated IBD patients and controls. RESULTS: A total of 16 studies were included, with study periods ranging from January 2020 to October 2021 and follow-up time from 3â€‰weeks to 6â€‰months. The breakthrough infection rates range from 0 to 37.4% in vaccinated IBD patients. The disease course of COVID-19 was generally mild, with low hospitalization and mortality rates (0-8.7% and 0-4.3%, respectively). Vaccinated IBD patients had a significantly lower relative risk of breakthrough infection rate compared to unvaccinated controls (risk ratio: 0.07, 95% CI: 0.03-0.18). No difference was observed between IBD patients and non-IBD controls, and between partially and fully vaccinated IBD patients. The impact of immunosuppressive therapy on breakthrough infection rates differs between studies. Most studies showed no impact from immunosuppressive treatment, anti-tumour necrosis factor alpha or corticosteroids and other biologics; one study reported higher rates for patients treated with infliximab versus vedolizumab. CONCLUSION: Vaccination is effective to prevent COVID-19 infections in patients with IBD. Breakthrough infections do occur, but the disease course is generally mild. Available data seem to suggest a declining trend of breakthrough infections during calendar time. REGISTRATION: The protocol was published in the PROSPERO database (CRD42021292853).

Nationwide experiences with trough levels, durability, and disease activity among inflammatory bowel disease patients following COVID-19 vaccination. BACKGROUND: The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has complicated the management of inflammatory bowel diseases (IBD). OBJECTIVES: This study aimed to assess the efficacy of different anti-SARS-CoV-2 vaccines under different treatments in IBD patients and identify predictive factors associated with lower serological response, including anti-tumor necrosis factor (anti-TNF) drug levels. DESIGN: A prospective, double-center study of IBD patients was conducted following messenger ribonucleotide acid (mRNA) and non-mRNA anti-SARS-CoV-2 vaccination. METHODS: Healthy control (HC) patients were enrolled to reduce bias. Baseline and control samples were obtained 14â€‰days after the second dose to assess the impact of conventional and biological treatments. Clinical and biochemical activity, serological response level, and anti-TNF drug levels were measured. RESULTS: This study included 199 IBD (mean age, 40.9â€‰Â±â€‰12.72â€‰years) and 77 HC participants (mean age, 50.3â€‰Â±â€‰12.36â€‰years). Most patients (76.9%) and all HCs received mRNA vaccines. Half of the IBD patients were on biological treatment (anti-TNF 68.7%). Biological and thiopurine combined immunomodulation and biological treatment were associated with lower serological response (pâ€‰<â€‰0.001), and mRNA vaccination promoted better antibody levels (pâ€‰<â€‰0.001). Higher adalimumab levels caused lower serological response (pâ€‰=â€‰0.006). W8â€‰persistence of anti-SARS-CoV-2 level was equal in IBD and HC groups. Vaccination did not aggravate clinical disease activity (pâ€‰=â€‰0.65). CONCLUSION: Anti-SARS-CoV-2 vaccination is considerably efficacious in IBD patients, with mRNA vaccines promoting better antibody levels. The negative impact of combined biological treatment, especially with high adalimumab drug levels, on serological response to vaccination should be considered. Although midterm durability of vaccination is encouraging, more data are needed to expand the existing understanding on this issue.

 Adjustment of COVID-19 vaccination to adalimumab trough level is considerable due to the reduced serological response. mRNA vaccination should be preferred in case of IBD patients with an equal durability of anti-SARS-CoV-2 level of subjects and healthy control participants.

Immunogenicity and safety in pigs of PHH-1V, a SARS-CoV-2 RBD fusion heterodimer vaccine candidate. The continuing high global incidence of COVID-19 and the undervaccinated status of

billions of persons strongly motivate the development of a new generation of efficacious vaccines. We have developed an adjuvanted vaccine candidate, PHH-1V, based on a protein comprising the receptor binding domain (RBD) of the Beta variant of SARS-CoV-2 fused in tandem with the equivalent domain of the Alpha variant, with its immunogenicity, safety and efficacy previously demonstrated in mouse models. In the present study, we immunized pigs with different doses of PHH-1V in a prime-and-boost scheme showing PHH-1V to exhibit an excellent safety profile in pigs and to produce a solid RBD-specific humoral response with neutralising antibodies to 7 distinct SARS-CoV-2 variants of concern, with the induction of a significant IFNÎ³(+) T-cell response. We conclude that PHH-1V is safe and elicits a robust immune response to SARS-CoV-2 in pigs, a large animal preclinical model.

Predictors and prevalence of COVID-19 vaccination in patients with focal epilepsy following resection surgery. BACKGROUND AND PURPOSE: In light of the ongoing COVID-19 pandemic, vaccination has emerged as the primary and most effective solution. The aim of this study was to examine compliance rates of vaccination and explore the factors that predict vaccine uptake among patients with epilepsy (PWE) who have undergone resection surgery. METHOD: To examine the variations in vaccination coverage, safety concerns, and factors influencing vaccination hesitancy among PWE who have undergone resection surgery, this study recruited patients with at least one-year follow-up. We utilized questionnaires to gather clinical characteristics and obtain information regarding COVID-19 vaccines. RESULTS: Among the 303 patients included in the study, a majority of 229 (75.58%) achieved a seizure-free outcome (Engel Ia). Of these patients, 178 (58.75%) received at least one dose of COVID-19 vaccine, and the vaccination rate has remained relatively consistent over the past six months. Nearly 94.95% of those who received the vaccine completed the full vaccination regimen, with the majority (nÂ =Â 174, 97.75%) opting for an inactivated vaccine. Only three patients reported side effects unrelated to epilepsy, and one patient experienced a worsening of typical aura seizures within one month after vaccination. Notably, significant positive associations were observed between COVID-19 vaccine acceptance and adulthood (age 18Â years or older) (ORÂ =Â 1.820, 95% CIÂ =Â 1.018-3.252, pÂ =Â 0.043) as well as achieving a seizure-free outcome (ORÂ =Â 2.823, 95% CIÂ =Â 1.619-4.921, pÂ <Â 0.001). Regarding the unvaccinated patients, approximately one-fifth expressed willingness to receive a future COVID-19 vaccine, while the remainder were hesitant (41.60%) or unsure (39.20%) about vaccination. These reservations mainly stemmed from concerns about the potential worsening of seizures and vaccine safety. CONCLUSIONS: Inactivated vaccines can be considered safe for individuals with epilepsy who have undergone resection surgery. The likelihood of being vaccinated was found to be comparatively higher among the cohort with seizure-free status or adults. To promote COVID-19 vaccination among children, it is crucial to implement comprehensive education and public awareness campaigns that emphasize the safety of vaccines. These efforts will help encourage widespread acceptance of vaccination and ensure the well-being of individuals with epilepsy.

Incidence of breakthrough infections after COVID-19 vaccination among the COVID-19 vaccine recipients at a Tertiary Care Hospital in Srinagar. COVID-19 infections despite complete vaccination are called breakthrough infections. Breakthrough infections may decrease the vaccination confidence among people. This study was conducted soon after the Covishield vaccine was approved for use in J and K to find out the incidence of breakthrough infections among the recipients of the Covishield vaccine at SKIMS and to find out the associated factors. List of beneficiaries (between February 14, and May 15, 2021) was obtained from the records. Information was gathered telephonically. Incidence of breakthrough infections 6-month postvaccination was determined. Among 919 participants, the incidence of breakthrough infections was 2.7% (25 cases). The medical profession was associated with a higher frequency of breakthrough infections. Most infections were

mild to moderate (96%). One (4%) person required hospitalization. Thus, COVID-19 infections can occur despite complete vaccination. Increased exposure places an individual at higher risk of breakthrough infections. Therefore, where exposure is high, COVID-appropriate behavior should be followed despite being vaccinated.

Kinetics of humoral immune response and severity of infection after three doses of SARS-CoV-2 mRNA vaccine in a large cohort of kidney transplant recipients. BACKGROUND: COVID-19 in kidney transplant recipients is associated with high morbidity and mortality. In this study we aimed to evaluate: (i) the seroconversion rate after BNT162b2 (Pfizer-BioNTech) SARS-CoV-2 vaccine, (ii) factors associated with humoral response, (iii) clinical outcome of COVID-19 in kidney transplanted patients. METHODS: We enrolled a cohort of 743 kidney transplant recipients followed up from March 2020 until April 2022. A subset of 336 patients, who received three-doses of SARS-CoV-2 vaccine, was analyzed in terms of kinetics of humoral immune response and compared to a control group of 94 healthcare workers. Antibody response was tested before vaccination (T(0)), 15 and 90Â days after the second dose (T(1) and T(2)), on the day of the third dose (T(3)) and one month after the third dose (T(4)). RESULTS: We observed that 66 out of 743 subjects had COVID-19 infection pre-vaccination: 65.2% had severe symptoms, 27.3% were hospitalized (9 deaths), none were asymptomatic. After three doses, 51 patients had COVID-19 infection, 60.8% were asymptomatic, 27.5% reported mild symptoms, 3.9% showed severe symptoms, 7.8% were hospitalized (2 deaths). In the subset of 336 vaccinated patients, an antibody levelâ€‰>â€‰0.8 U/ml was detected at T(1), that increased at T(2) and T(3,) peaking at T(4). Independent factors associated with a negative antibody titer at T(4) were decreasing estimated glomerular filtration rate, time from transplantation, and antimetabolites (all pâ€‰<â€‰0.001) and age (pâ€‰=â€‰0.007). CONCLUSIONS: The kinetics of humoral response after threeÂ doses of vaccine in kidney transplant patients is characterized by a late but effective immune response against SARS-CoV-2, reducing morbidity and mortality.

Severe hyponatremia with consciousness disturbance after receiving SARS-CoV-2 mRNA vaccination. SUMMARY: There are very few reports of syndrome of inappropriate antidiuresis hormone secretion (SIADH) after receiving severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine. Herein, we present the case of an 84-year-old woman who developed severe hyponatremia following the second administration of the SARS-CoV-2 mRNA vaccine. The patient presented with nausea, vomiting, and headache. Laboratory tests showed a plasma sodium level of 119 mmol/L. After receiving 500 mL of intravenous saline over a 2-h period, her plasma sodium level raised to 121 mmol/L, but her symptoms persisted. Considering that rapid plasma sodium correction was necessary, we started 3% saline solution overnight. Her plasma sodium level raised to 132 mmol/L and her symptoms completely resolved. Clinical and laboratory findings were consistent with a diagnosis of SIADH. In the absence of any other triggering factors, we concluded that the condition was likely associated with the vaccination. Clinicians should be aware of the potential for hyponatremia, particularly SIADH, associated with SARS-CoV-2 mRNA vaccination. LEARNING POINTS: Reports of syndrome of inappropriate antidiuresis hormone secretion after receiving severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination are limited. If nausea, headache, and confusion are observed immediately after SARS-CoV-2 vaccination, clinicians should consider the presence of hyponatremia. As similar case reports to date have presented with severe hyponatremia, prompt treatment may be required.

Uptake of the COVID-19 Vaccination and Associated Factors Among Health Care Providers in Addis Ababa, Ethiopia. BACKGROUND: The COVID-19 vaccine is intended to provide acquired immunity against severe acute respiratory syndrome coronavirus 2Â (SARS-CoV-2). As a result, 12 billion doses of the COVID-19 vaccination have been given globally as of August 1, 2022. Due to occupational exposure, health professionals obtained priority for COVID-19 vaccination. However, despite the

availability of COVID-19 vaccines in countries, there is a discrepancy in the uptake of vaccine among different populations including Health-Care Providers. OBJECTIVE: Assessments of the factors associated with uptake of COVID-19 vaccination among health-care providers in Addis Ababa, Ethiopia in 2022. METHODS: From June 10 to July 10, 2022, a facility-based cross-sectional study was carried out in Addis Ababa, Ethiopia, involving 473 health-care professionals, used descriptive statistics to summarize the participant's characteristics, and multivariable logistic regression to analyze factors affecting COVID-19 vaccination uptake. P-value <0.05 was used to determine the level of significance. RESULTS: The response rate of the participants was 94.2%. The uptake rate of COVID-19 vaccine among health-care providers was 359 (75.8%). Vaccine uptake was positively associated with higher perceived concerns regarding COVID-19 [AOR = 7.45, (4.041-13.754)], higher monthly income, [AOR: 2.623 (1.398 -4.923)] compared those who earned lower, being married [AOR: 2.114, (1.068-4.181)] and being advanced age (36-45) years old [AOR =0.486 (0.258-0.916)] compared to 18-26 years old. However, being female professional reduced the odds of vaccine uptake [AOR = 0.486 (CI; 0.258-0.916)] in contrast of their counterpart. CONCLUSION: The uptake of COVID-19 vaccine among health professionals is relatively higher than in earlier reports. However, this was not yet sufficient for the level required to achieve herd immunity. Hence, the Ministry of health should work in collaboration to address concerns about the safety and effectiveness of COVI D-19 vaccine to increase COVID-19 vaccine uptake. Moreover, Health professionals, social media, regular media outlet should strengthen health education on concerns of covid-19 infection.

Generalized Eosinophilia Following Moderna COVID-19 Vaccine Administration: Comment.

Evaluation of Side Effects Associated with COVID-19 Vaccines in Pregnant Women. BACKGROUND: A variety of vaccinations have been developed to fight the coronavirus disease 2019 (Covid-19) 2 years after the coronavirus epidemic spread globally. During clinical studies, these vaccinations were linked to mild to severe side effects. This study aimed to evaluate the short-term side effects of Covid-19 vaccination in pregnant women in Zabol (Iran). METHODS: This cross-sectional study was conducted between August and October 2021 to collect data on the adverse side effects of Covid-19 vaccinations among 117 pregnant women in Zabol (Iran). A questionnaire was used to collect demographic data, vaccination information, and vaccine complications. SPSS software Version 22 was used to analyze the data at 2 levels descriptive and inferential statistics. RESULTS: A total of 117 pregnant women aged 27.67 Â± 5.14 years were included. After the first and second doses of Covid-19 vaccinations, 91 (86.7%) and 84 (71.8%) pregnant women, respectively, suffered adverse effects. Moreover, after the first dose, 55(51.4%) and 60 (56.1%) of pregnant women reported fatigue and headache, and after the second dose, 39 (33.3%) and 37 (31.6%) reported fatigue and headache, respectively. CONCLUSION: The side effects reported in our study after receiving Covid-19 vaccinations in pregnant women were similar to those described in clinical studies of vaccines and were mild to moderate, showing that injectable vaccines had safe profiles. More research is needed, however, to assess the long-term side effects of existing vaccines.

COVID-19 mRNA vaccination is associated with IgA nephropathy: an analysis of the Japanese adverse drug event report database. Purpose: Coronavirus disease 2019 (COVID-19) mRNA vaccines are used worldwide to prevent severe symptoms of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. IgA nephropathy (IgAN) is the most common form of glomerular injury after COVID-19 vaccination; however, because of the low frequency of such events, only a few reports have been published. A large pharmacovigilance database of real-world spontaneous adverse event (AE) reports is essential for evaluating the drug-associated safety signals regarding rare AEs. Herein, we aimed to investigate the frequency of IgAN after the COVID-19 vaccination, using the Japanese Adverse Drug Event Report (JADER) database. Methods: Data on drug-associated AEs reported between April 2004 and May 2022 were obtained from the JADER database on the Pharmaceuticals

and Medical Devices Agency website. To evaluate the safety signals for the targeted AEs, reporting odds ratios (RORs), information components (ICs), and their 95% confidence intervals (CIs) were calculated using two-by-two contingency tables. Results: A total of 697,885 cases were included in the analysis. Safety signals were detected for IgAN (ROR: 6.49, 95% CI: 4.38-9.61; IC: 2.27, 95% CI: 1.70-2.83). Of 30 cases for IgAN associated with COVID-19 mRNA vaccines, 16 had information available on time to onset. Of the 16 cases, 11 occurred â‰¤2Â days after vaccination, and two occurred >28Â days after vaccination. Conclusion: These results suggest that, compared with other drugs, COVID-19 vaccination is associated with a higher frequency of IgAN. Monitoring of gross hematuria following COVID-19 vaccination should be needed.

Pregnancy, fetal, and neonatal outcomes after a first booster dose of covid-19 vaccine during pregnancy in Ontario, Canada: population based, retrospective cohort study. OBJECTIVE: To assess risk of adverse pregnancy, fetal, and neonatal outcomes after a third dose (first booster dose) of covid-19 vaccine during pregnancy among individuals who had completed both doses of primary covid-19 vaccine series before pregnancy. DESIGN: Population based, retrospective cohort study. SETTING: Ontario, Canada, from 20 December 2021 to 31 August 2022. PARTICIPANTS: Individuals were included if they were pregnant with an expected date of delivery from 20 December 2021 (start date of third dose eligibility for everyone â‰¥18 years) to 31 August 2022, who had completed the two doses of primary covid-19 messenger RNA vaccine series before pregnancy, and became eligible for a third dose (â‰¥six months since dose two) before the end of pregnancy. MAIN OUTCOME MEASURES: Pregnancy outcomes included hypertensive disorders of pregnancy, placental abruption, caesarean delivery, chorioamnionitis, and postpartum hemorrhage. Fetal and neonatal outcomes included stillbirth, preterm birth, admission to neonatal intensive care unit for >24 h, newborn 5 min Apgar score <7, and small-for-gestational age infant (<10th percentile). We estimated hazard ratios and 95% confidence intervals for study outcomes, treating dose three as a time varying exposure and adjusting for confounding using inverse probability weighting. RESULTS: Among 32 689 births, 18 491 (56.6%) were born to individuals who received a third covid-19 dose during pregnancy. Compared with eligible individuals who did not receive a third dose during pregnancy, no increased risks were associated with receiving a third covid-19 vaccine dose during pregnancy for placental abruption (adjusted hazard ratio 0.84 (95% confidence interval 0.70 to 1.02)), chorioamnionitis (0.67 (0.49 to 0.90)), postpartum haemorrhage (1.01 (0.89 to 1.16)), caesarean delivery (0.90 (0.87 to 0.94)), stillbirth (0.56 (0.39 to 0.81)), preterm birth (0.91 (0.84 to 0.99)), neonatal intensive care unit admission (0.96 (0.90 to 1.03)), 5 min Apgar score<7 (0.96 (0.82 to 1.14)), or small-for-gestational age infant (0.86 (0.79 to 0.93)). CONCLUSION: Receipt of a third covid-19 vaccine dose during pregnancy was not associated with an increased risk of adverse pregnancy, fetal, or neonatal outcomes. These findings can help to inform evidence based decision making about the risks and benefits of covid-19 booster doses during pregnancy.

Prevalence and Factors Associated with Depression Among Older Adults During the COVID-19 Pandemic: A Cross-Sectional Study in Urban Areas in Thailand. PURPOSE: This study examined the prevalence of and factors associated with depression symptoms among Thai older adults during the COVID-19 pandemic. PATIENTS AND METHODS: A cross-sectional survey was conducted among older adults in urban areas in Bangkok, Thailand, between July and October 2021. The 15-item Thai Geriatric Depression Scale (TGDS-15) was used to determine the prevalence of depression symptoms, and multiple logistic regression was conducted to identify the associated factors. RESULTS: A total 156 older adults survey responses were received. The largest group of participants (80.8%) was aged below 70, women (50.6%), married (67.9%), retired (41%), having sufficient income (67.9%), living with their families (89.1%). More than half (71.8%) had an underlying disease, with hypertension being the most common (39.1%). In addition, 17.3% of the participants had received compulsory

COVID-19 vaccination. Only 0.6% had a history of COVID-19 infection. The prevalence of depression among Thai older adults was 20.5%. Univariate analysis demonstrated occupation and income sufficiency was associated with depression symptoms. The results of the multivariate analysis found that the "non-worker" group was 3.54 times more likely to experience depression symptoms than the reference group (OR = 3.54, 95% CI = 1.25-10.02, p = 0.018) when controlling for the confounding factors. CONCLUSION: This study highlights the importance of addressing depression symptoms among Thai older adults, in which occupation and income sufficiency were the main variable factors for depression. Our study further suggested that the importance of interventions such as increasing job availability and establishing financial aid policies may ameliorate depression symptoms among older adults, especially in high-risk groups during the pandemic situation such as the COVID-19.

Safety and adverse effects of the coronavirus disease 2019 vaccine among the general Japanese adult population. OBJECTIVES: We aimed to identify and explore the association between the characteristics of coronavirus disease 2019 (COVID-19) vaccine recipients and the types of vaccine-related adverse effects in the general Japanese adult population. METHODS: An anonymous self-report questionnaire was distributed to 4393 students and 1657 white and blue-collar workers (NÂ =Â 6050). Data on vaccine-related adverse effects were collected twice, once after each vaccination. The data collection was performed daily from the day of injection (D0) until the sixth day after injection (D6). The list of adverse effects comprised local reactions at the injection site (pain, redness, and swelling) and systemic symptoms (fever, fatigue, headache, myalgia, joint pain, chills, and nausea or vomiting). The Student's t-test and Mann-Whitney U test were used to analyze parametric and non-parametric data, respectively. RESULTS: The incidence of adverse reactions to the COVID-19 vaccination was higher after the second dose (e.g., redness: 47.1%; swelling: 60.6%; fever: 80.6%) of vaccination than after the first dose (e.g., redness: 16.4%; swelling: 37.2%; fever: 11.9%). Women reported adverse reactions to the vaccination more frequently. Some adverse reactions included more symptoms in younger participants, and participants with a lower body mass index were more at risk for these symptoms. CONCLUSIONS: Some adverse reactions to the COVID-19 vaccination are a greater risk of symptoms in the younger group, women, and participants with lower BMI. Care should be taken to monitor women, younger people, and individuals with a low body mass index for adverse effects after receiving the COVID-19 vaccination.

Stroke after SARS-CoV-2 vaccination: Comment.

SARS-CoV-2 vaccination can only be held responsible for tinnitus after alternative pathophysiology has been ruled out.

Persistently raised blood pressure following coronavirus disease 2019 vaccines: Implication for future systematic research and monitoring.

Heavy bleeding and other menstrual disturbances in young women after COVID-19 vaccination. BACKGROUND: Many signals of menstrual disturbances as possible side effects of vaccination against COVID-19 have been reported. Our objective was to compare the risk of menstrual disturbances before and after vaccination among women aged 18-30Â years in Oslo, Norway. METHODS: We used electronic questionnaires to collect reports of menstrual disturbances from 3972 women aged 18-30Â years, participating in the population-based Norwegian Young Adult Cohort. We examined the occurrence of menstrual disturbances (heavier bleeding than usual, prolonged bleeding, shorter interval between menstruations, longer interval between menstruations, spot bleedings, stronger pain during menstruation, period pain without bleeding) before and after the first and second dose of COVID-19 vaccine. Relative risks (RR) according to vaccination were estimated using a self-controlled case-series design. We performed additional analyses stratified by vaccine brand, contraception/hormone use, and presence of gynecological condition(s). RESULTS: The prevalence of any menstrual disturbance was 36.7Â % in the last menstrual cycle prior the first vaccine dose. The RR

for heavier bleeding than usual was 1.90 (95Â % CI: 1.69-2.13) after the first vaccine dose and 1.84 (95Â % CI 1.66-2.03) after the second dose. Increased risks of prolonged bleeding, shorter interval between menstruations, and stronger pain during menstruation were also observed after both doses. The RRs did not differ with vaccine brand, contraception/hormone use, or presence of gynecological condition(s) for any of the menstrual disturbances. CONCLUSION: Menstrual disturbances were common regardless of vaccination. We found increased risk of menstrual disturbances after vaccination, particularly for heavier bleeding than usual, prolonged bleeding, shorter interval between menstruations, and stronger period pain. In the future, menstrual characteristics should be included in vaccine trials.

Is the COVID-19 vaccine really protective in pregnancy against low birthweight?

Outcomes of hematologic malignancy patients with SARS-CoV-2 breakthrough infections after tixagevimab-cilgavimab during community transmission of monoclonal antibody resistant variants.

Detection of axillary lymphadenopathy after Covid-19 vaccination during breast examination: Case series and review of the literature after one year. OBJECTIVES: The aim of this study is to evaluate accidental findings of axillary lymphadenopathy during breast examination. Postvaccination axillary lymphadenopathy is a possible cause of adenopathies but these findings used to be exceedingly rare. Nowadays, after Covid-19 vaccination it is found more often. Covid-19 vaccination started at the end of December 2020 with two types of vaccine, Moderna and Pfizer-BioNTech in the Czech Republic. The aim of this article is to present a single centre experience with Covid-19 lymphadenopathy during the general vaccination in the Czech population and summarization of recommendations. METHODS: In January to February 2021 ultrasound revealed axillary lymphadenopathy in several patients during breast examination in our certified centre. In four of them it was concluded as lymphadenopathy after Covid-19 vaccination. A search (using databases PubMed and Google Scholar) of the available literature for the years 2020 and 2021 was performed. RESULTS: These four patients were examined during the first two months of 2021. In all of them pathological lymph nodes with typical sonographic signs were seen in the ipsilateral axilla. We searched the literature for follow-up recommendations and summarized them in our article. CONCLUSION: Accidental findings of axillary lymphadenopathy during ultrasound breast examination will be more often. There will be more cases of lymphadenopathy with an increasing number of people being vaccinated against Covid-19.

Assessment of Adverse Reactions, Antibody Patterns, and 12-month Outcomes in the Mother-Infant Dyad After COVID-19 mRNA Vaccination in Pregnancy. IMPORTANCE: Longitudinal data on COVID-19 messenger RNA (mRNA) vaccine reactogenicity and immunogenicity in pregnancy and for the mother-infant dyad are needed. OBJECTIVE: To examine COVID-19 mRNA vaccine reactogenicity and immunogenicity in pregnancy and observe longitudinal maternal and infant outcomes. DESIGN, SETTING, AND PARTICIPANTS: This prospective cohort study of pregnant individuals enrolled in the COVID-19 Vaccination in Pregnancy and Lactation study from December 1, 2020, through December 31, 2021, with follow-up through March 31, 2022, was conducted at a large academic medical center in an urban metropolitan area in California. Pregnant individuals receiving COVID-19 mRNA vaccines (mRNA-1273 [Moderna] and BNT162b2 [Pfizer-BioNTech]) were eligible. Of 81 participants enrolled, 5 were excluded after enrollment: 1 terminated pregnancy, 1 received the third vaccine dose prior to delivery, and 3 delivered prior to completing the initial vaccine series. EXPOSURE: COVID-19 mRNA vaccination at any time during pregnancy. MAIN OUTCOMES AND MEASURES: The primary outcomes were vaccine response as measured by blood Immunoglobulin G (IgG) titers after each vaccine dose and self-reported postvaccination symptoms. Patients' IgG titers were measured in cord blood and in infant blood at intervals up to 1 year of life; IgG and IgA titers were measured in maternal milk. Clinical outcomes were collected from medical records. RESULTS: Of 76 pregnant individuals included

in final analyses (median [IQR] maternal age, 35 [29-41] years; 51 [67.1%] White; 28 [36.8%] primigravid; 37 [48.7%] nulliparous), 42 (55.3%) received BNT162b2 and 34 (44.7%) received mRNA-1237. There were no significant differences in maternal characteristics between the 2 vaccine groups. Systemic symptoms were more common after receipt of the second vaccine dose than after the first dose (42 of 59 [71.2%] vs 26 of 59 [44.1%]; Pâ€‰=â€‰.007) and after mRNA-1237 than after BNT162b2 (25 of 27 [92.6%] vs 17 of 32 53.1%; Pâ€‰=â€‰.001). Systemic symptoms were associated with 65.6% higher median IgG titers than no symptoms after the second vaccine dose (median [IQR], 2596 [1840-4455] vs 1568 [1114-4518] RFU; Pâ€‰=â€‰.007); mean cord titers in individuals with local or systemic symptoms were 6.3-fold higher than in individuals without symptoms. Vaccination in all trimesters elicited a robust maternal IgG response. The IgG transfer ratio was highest among individuals vaccinated in the second trimester. Anti-SARS-CoV-2 IgG was detectable in cord blood regardless of vaccination trimester. In milk, IgG and IgA titers remained above the positive cutoff for at least 5-6 months after birth, and infants of mothers vaccinated in the second and third trimesters had positive IgG titers for at least 5 to 6 months of life. There were no vaccine-attributable adverse perinatal outcomes. CONCLUSIONS AND RELEVANCE: The findings of this cohort study suggest that mRNA COVID-19 vaccination in pregnancy provokes a robust IgG response for the mother-infant dyad for approximately 6 months after birth. Postvaccination symptoms may indicate a more robust immune response, without adverse maternal, fetal, or neonatal outcomes.

Diabetes incidence before and after COVID-19 vaccination - Results from the German Disease Analyzer database. OBJECTIVE: We investigated whether COVID-19 vaccination had an impact on diabetes risk. METHODS: We used data of 6,198 patients (mean age 64.3Â years) from the nationwide Disease Analyzer database, a representative panel of physicians' practices in Germany. Patients received their first COVID-19 vaccination between 1 April 2021 and 31 March 2022, and all were newly diagnosed with diabetes within 183Â days before or after this vaccination. Incident rates of diabetes after vaccination were compared to incident rates before vaccination. RESULTS: The incidence rate of diabetes was lower after vaccination than before vaccination (incidence rate ratioÂ =Â 0.79, 95% confidence interval: 0.75-0.83). The number of incident cases of diabetes was not greater in 2021 than in 2019. CONCLUSION: Our study did not confirm an increased risk of diabetes after COVID-19 vaccination. Further studies are needed to show whether the vaccination may be associated with a reduced diabetes risk.

COVID-19 infection following influenza vaccine injection and its complications among nurses working in educational-medical hospitals of Ardabil in 2020. OBJECTIVES: Health care workers are one of the groups at risk of influenza. Currently, influenza vaccination is very important more than ever before. Influenza is evolutionarily similar to SARS-CoV-2, and they have some common epitopes and mechanisms. Thus reducing the severity of COVID-19 disease by influenza vaccination seems possible. Therefore, the aim of this study is to investigate the relationship between influenza vaccination and COVID-19 infection among clinical nurses. METHODOLOGY: The present study is a prospective analysis of nurses working in educational-medical hospitals of Ardabil. In this study, two groups of nurses were considered as case and control groups. The collected data were analyzed using SPSS software and descriptive (mean, standard deviation and frequency) and analytical (Chi-square) tests. RESULTS: A total of 279 individuals were included in the study according to the research criteria. The maximum duration of the disease was one week in the control group and four weeks in the case group. Chi-square test showed that there was a significant difference in terms of disease duration between the two groups (P = 0.000). Chi-square test showed that there was a statistically significant difference in terms of disease treatment between the two groups (P = 0.000). CONCLUSION: Influenza vaccine reduces the incidence of COVID-19 and reduces the need for hospitalization in patients with

this disease. However, due to the positive effects of influenza vaccine on COVID-19 and its low cost, it is recommended to inject influenza vaccine more than before.

NOTTO Guidelines for Vaccine Induced Thrombotic Thrombocytopenia in Organ Donation and Transplantation. From the context of organ donation, COVID-19 vaccine-induced thrombotic thrombocytopenia (VITT) is important as there is an ethical dilemma in utilizing versus discarding organs from potential donors succumbing to VITT. This consensus statement is an attempt by the National Organ and Tissue Transplant Organization (NOTTO) apex technical committees India to formulate the guidelines for deceased organ donation and transplantation in relation to VITT to help in appropriate decision making. VITT is a rare entity, but a meticulous approach should be taken by the Organ Procurement Organization's (OPO) team in screening such cases. All such cases must be strictly notified to the national authorities like NOTTO, as a resource for data collection and ensuring compliance withprotocols in the management of adverse events following immunization. Organs from any patient who developed thrombotic events up to 4 weeks after adenoviral vector-based vaccination should be linked to VITT and investigated appropriately. The viability of the organs must be thoroughly checked by the OPO, and the final decision in relation to organ use should be decided by the expert committee of the OPO team consisting of a virologist, a hematologist, and atreating team. Considering the organ shortage, in case of suspected/confirmed VITT, both clinicians and patients should consider the risk-benefit equationbased on available experience, and an appropriate written informed consent of potential recipients and family members should be obtained before transplantation of organs from suspected or proven VITT donors.

Factors associated with stroke after COVID-19 vaccination: a statewide analysis. BACKGROUND: The objective of our study was to evaluate vaccine type, COVID-19 infection, and their association with stroke soon after COVID-19 vaccination. METHODS: In a retrospective cohort study, we estimated the 21-day post-vaccination incidence of stroke among the recipients of the first dose of a COVID-19 vaccine. We linked the Georgia Immunization Registry with the Georgia Coverdell Acute Stroke Registry and the Georgia State Electronic Notifiable Disease Surveillance System data to assess the relative risk of stroke by the vaccine type. RESULTS: Approximately 5 million adult Georgians received at least one COVID-19 vaccine between 1 December 2020 and 28 February 2022: 54% received BNT162b2, 41% received mRNA-1273, and 5% received Ad26.COV2.S. Those with concurrent COVID-19 infection within 21 days post-vaccination had an increased risk of ischemic (OR = 8.00, 95% CI: 4.18, 15.31) and hemorrhagic stroke (OR = 5.23, 95% CI: 1.11, 24.64) with no evidence for interaction between the vaccine type and concurrent COVID-19 infection. The 21-day post-vaccination incidence of ischemic stroke was 8.14, 11.14, and 10.48 per 100,000 for BNT162b2, mRNA-1273, and Ad26.COV2.S recipients, respectively. After adjusting for age, race, gender, and COVID-19 infection status, there was a 57% higher risk (OR = 1.57, 95% CI: 1.02, 2.42) for ischemic stroke within 21 days of vaccination associated with the Ad26.COV2.S vaccine compared to BNT162b2; there was no difference in stroke risk between mRNA-1273 and BNT162b2. CONCLUSION: Concurrent COVID-19 infection had the strongest association with early ischemic and hemorrhagic stroke after the first dose of COVID-19 vaccination. Although not all determinants of stroke, particularly comorbidities, were considered in this analysis, the Ad26.COV2.S vaccine was associated with a higher risk of early post-vaccination ischemic stroke than BNT162b2.

Ethical and legal race-responsive vaccine allocation. In many countries, the COVID-19 pandemic varied starkly between different racial and ethnic groups. Before vaccines were approved, some considered assigning priority access to worse-hit racial groups. That debate can inform rationing in future pandemics and in some of the many areas outside COVID-19 that admit of racial health disparities. However, concerns were raised that "race-responsive" prioritizations would be ruled unlawful for allegedly constituting wrongful discrimination. This legal argument relies on an

understanding of discrimination law as demanding color-blindness. We argue that a, color-blind understanding of discrimination would be hostile only to one of two rationales for prioritizing the relevant racial minorities in settings of racial health disparities. We also propose a method for incorporating appropriate race-responsive concerns that is in many ways ethically and legally superior to ones suggested thus far. That method turns artificial intelligence, thanks precisely to its artificial and "black box" nature (features that underlie recent concerns about artificial intelligence's discriminatory potential), into an instrument of social justice.

mRNA: Vaccine or Gene Therapy? The Safety Regulatory Issues. COVID-19 vaccines were developed and approved rapidly in response to the urgency created by the pandemic. No specific regulations existed at the time they were marketed. The regulatory agencies therefore adapted them as a matter of urgency. Now that the pandemic emergency has passed, it is time to consider the safety issues associated with this rapid approval. The mode of action of COVID-19 mRNA vaccines should classify them as gene therapy products (GTPs), but they have been excluded by regulatory agencies. Some of the tests they have undergone as vaccines have produced non-compliant results in terms of purity, quality and batch homogeneity. The wide and persistent biodistribution of mRNAs and their protein products, incompletely studied due to their classification as vaccines, raises safety issues. Post-marketing studies have shown that mRNA passes into breast milk and could have adverse effects on breast-fed babies. Long-term expression, integration into the genome, transmission to the germline, passage into sperm, embryo/fetal and perinatal toxicity, genotoxicity and tumorigenicity should be studied in light of the adverse events reported in pharmacovigilance databases. The potential horizontal transmission (i.e., shedding) should also have been assessed. In-depth vaccinovigilance should be carried out. We would expect these controls to be required for future mRNA vaccines developed outside the context of a pandemic.

Characteristics of Teenagers Presenting with Chest Pain after COVID-19 mRNA Vaccination. In this study, we evaluated the clinical and radiological manifestations of teenagers presenting with chest pain after coronavirus disease 2019 (COVID-19) messenger RNA (mRNA) vaccination. We retrospectively enrolled 61 teenage patients, aged 13 to 19 years, who underwent echocardiography and cardiac magnetic resonance imaging (CMR) for chest pain after COVID-19 mRNA vaccination, from November 2021 to April 2022. Medical records, laboratory results, echocardiographic, and CMR findings were analyzed. The mean age of the participants was 14.4 Â± 1.9 years, with a male:female ratio of 28:33. Among the sixty-one patients with chest pain after COVID-19 vaccination, only two (3.3%) were diagnosed as confirmed myocarditis, and almost all of them recovered with conservative treatments. However, on CMR, 24 (39.3%) presented with mild myocardial abnormalities; 22 (36.1%) showed myocardial edema, and 19 (31.1%) were found to have a myocardial injury. Multivariate logistic analyses revealed that older age and female sex were significantly associated with myocardial abnormalities. In teenagers who present with chest pain after COVID-19 mRNA vaccination, confirmed myocarditis is uncommon. However, myocardial abnormalities on CMR might occur frequently, and females in their late teens might be more vulnerable to myocardial abnormalities.

The Effect of COVID-19 Severity, Associated Serum Autoantibodies and Time Interval after the Disease on the Outcomes of Fresh Oocyte ART Cycles in Non-Vaccinated Patients. It is assumed that SARS-CoV-2- and COVID-19-associated autoimmune processes may affect the outcomes of assisted reproductive technology (ART) cycles. This observational prospective study included 240 infertile patients: 105 patients had no history of COVID-19 (group 1) and 135 patients had experienced COVID-19 (group 2) in a mild (n = 85) or moderate (n = 50) form less than 12 months prior to oocyte retrieval. Using ELISAs, the profiles of their serum autoantibodies were determined, including antiphospholipid antibodies and antibodies to nuclear and thyroid antigens. The parameters of oogenesis and embryogenesis, as well as the pregnancy and childbirth rates, did not differ

between groups 1 and 2, and also between the subgroups with different severities of COVID-19. However, when oocyte retrieval was performed less than 180 days after COVID-19, a higher proportion of poor-quality blastocysts was obtained (p = 0.006). A high risk of early miscarriage was found in the patients with moderate COVID-19. In group 2, IgG antibodies to annexin V, phosphatidylethanolamine (PE), and TSHr were detected more often than in group 1 (p = 0.035; p = 0.028; and p = 0.033, respectively), and a weak inverse correlation was revealed between anti-PE IgG and the number of oocytes and zygotes obtained. The results of the study suggest a possible adverse effect of COVID-19 and its associated autoantibodies on the outcomes of fresh oocyte ART cycles and early pregnancy, which depends on the severity of COVID-19 and the time interval after the disease.

New-onset and relapsed Graves' disease following COVID-19 vaccination: aÂ comprehensive review of reported cases. Global Coronavir us disease 2019 (COVID-19) vaccination efforts are being intensified to combat the pandemic. As the frequency of immunization against COVID-19 has increased, some adverse effects related to vaccination have emerged. Within this context, this article reviewed 62 Graves' disease (GD) cases following COVID-19 vaccination, to probe the potential association between the vaccination and the onset of GD. A comprehensive search of the PubMed, Web of Science, and Scopus databases was conducted to collect GD cases following COVID-19 vaccination up to June 7, 2023. Among the 62 GD cases included in this review, there were 33 (53.2%) new-onset GD and 10 (16.1%) relapsed GD patients following mRNA vaccination, 14 (22.6%) new-onset GD and 4 (6.5%) relapsed GD patients following viral vector vaccination, and 1 (1.6%) relapsed GD patients following inactivated vaccination. Median durations to symptoms onset for new-onset and relapsed GD were 12 (range: 1-60) and 21 (range: 5-30) days following mRNA vaccination, while 7 (range: 1-28) and 14 (range: 10-14) days following viral vector vaccination, respectively. While the definitive pathogenesis of GD following COVID-19 vaccination remains unclear, it might be associated with cross-immune responses triggered by molecular mimicry, and an adjuvant-induced autoimmune/inflammatory syndrome. However, due to the limited number of observed GD cases following COVID-19 vaccination and the lack of systematic experimental studies, a causal relationship between COVID-19 vaccination and the onset of GD has not been definitively confirmed. It should be highlighted that most of GD patients following COVID-19 vaccination experienced positive outcomes after treatment. In the broader context of ending the COVID-19 pandemic and reducing mortality rates, the benefits of COVID-19 vaccination significantly outweigh mild risks such as treatable GD. Adherence to the COVID-19 vaccination schedule is therefore imperative in effectively managing the pandemic.

Alopecia universalis after injection of messenger RNA COVID-19 vaccine. A case report. Messenger RNA vaccines against SARS-CoV-2 infection, or COVID-19 dramatically changed the landscape of the fight against COVID-19 pandemic. However, they might be associated with various side effects, such as myocarditis. Herein we report a case of alopecia universalis occurring after injection of an mRNA COVID-19 vaccine in a Japanese patient. Healthcare workers should be aware of this rather rare complication after vaccinations.

COVID-19 Severity and Waning Immunity After up to 4 mRNA Vaccine Doses in 73â€¯608 Patients With Cancer and 621â€¯475 Matched Controls in Singapore: A Nationwide Cohort Study. IMPORTANCE: Despite patients with cancer being at risk of poor outcomes from COVID-19, there are few published studies for vaccine efficacy in this group, with suboptimal immunogenicity and waning vaccine efficacy described in small studies being a concern. OBJECTIVE: To assess the incidence rate of severe COVID-19 disease outcomes associated with the number of vaccine doses received and the waning of protection over time. DESIGN, SETTING, AND PARTICIPANTS: A prospective multicenter observational cohort study was carried out over 2 time periods (September 15, 2021, to December 20, 2021 [delta wave], and January 20, 2022, to November 11, 2022 [omicron wave]) predominated

by SARS-CoV-2 delta and omicron variants, respectively. Overall, 73â€¯608 patients with cancer (23â€¯217 active treatment, 50â€¯391 cancer survivors) and 621â€¯475 controls matched by age, sex, race and ethnicity, and socioeconomic status were included. EXPOSURE: Vaccine doses received, from zero to 4 doses, and time elapsed since last vaccine dose. OUTCOMES: Competing-risk regression analyses were employed to account for competing risks of death in patients with cancer. Main outcomes were incidence rate ratios (IRRs) of COVID-19 infection, hospitalization, and severe disease (defined as requirement for supplemental oxygen, intensive care, or death). The IRRs stratified by time from last vaccine dose served as indicators of waning of vaccine effectiveness over time. RESULTS: The mean (SD) age of actively treated patients with cancer, cancer survivors, and controls were 62.7 (14.7), 62.9 (12.6), and 61.8 (14.7) years, respectively. Of 73â€¯608 patients with cancer, 27â€¯170 (36.9%) were men; 60â€¯100 (81.6%) were Chinese, 7432 (10.1%) Malay, 4597 (6.2%) Indian, and 1479 (2.0%) were of other races and ethnicities. The IRRs for the 3-dose and 4-dose vs the 2-dose group (reference) for COVID-19 hospitalization and severe disease were significantly lower during both the delta and omicron waves in cancer and control populations. The IRRs for severe disease in the 3-dose group for active treatment, cancer survivors, and controls were 0.14, 0.13, and 0.07 during the delta wave and 0.29, 0.19, and 0.21 during omicron wave, respectively. The IRRs for severe disease in the 4-dose group during the omicron wave were even lower at 0.13, 0.10 and 0.10, respectively. No waning of vaccine effectiveness against hospitalization and severe disease was seen beyond 5 months after a third dose, nor up to 5 months (the end of this study's follow-up) after a fourth dose. CONCLUSION: This cohort study provides evidence of the clinical effectiveness of mRNA-based vaccines against COVID-19 in patients with cancer. Longevity of immunity in preventing severe COVID-19 outcomes in actively treated patients with cancer, cancer survivors, and matched controls was observed at least 5 months after the third or fourth dose.

Clinical and Demographic Factors Associated With COVID-19, Severe COVID-19, and SARS-CoV-2 Infection in Adults: A Secondary Cross-Protocol Analysis of 4 Randomized Clinical Trials. IMPORTANCE: Current data identifying COVID-19 risk factors lack standardized outcomes and insufficiently control for confounders. OBJECTIVE: To identify risk factors associated with COVID-19, severe COVID-19, and SARS-CoV-2 infection. DESIGN, SETTING, AND PARTICIPANTS: This secondary cross-protocol analysis included 4 multicenter, international, randomized, blinded, placebo-controlled, COVID-19 vaccine efficacy trials with harmonized protocols established by the COVID-19 Prevention Network. Individual-level data from participants randomized to receive placebo within each trial were combined and analyzed. Enrollment began July 2020 and the last data cutoff was in July 2021. Participants included adults in stable health, at risk for SARS-CoV-2, and assigned to the placebo group within each vaccine trial. Data were analyzed from April 2022 to February 2023. EXPOSURES: Comorbid conditions, demographic factors, and SARS-CoV-2 exposure risk at the time of enrollment. MAIN OUTCOMES AND MEASURES: Coprimary outcomes were COVID-19 and severe COVID-19. Multivariate Cox proportional regression models estimated adjusted hazard ratios (aHRs) and 95% CIs for baseline covariates, accounting for trial, region, and calendar time. Secondary outcomes included severe COVID-19 among people with COVID-19, subclinical SARS-CoV-2 infection, and SARS-CoV-2 infection. RESULTS: A total of 57â€¯692 participants (median [range] age, 51 [18-95] years; 11â€¯720 participants [20.3%] aged â‰¥65 years; 31â€¯058 participants [53.8%] assigned male at birth) were included. The analysis population included 3270 American Indian or Alaska Native participants (5.7%), 7849 Black or African American participants (13.6%), 17â€¯678 Hispanic or Latino participants (30.6%), and 40â€¯745 White participants (70.6%). Annualized incidence was 13.9% (95% CI, 13.3%-14.4%) for COVID-19 and 2.0% (95% CI, 1.8%-2.2%) for severe COVID-19. Factors associated with increased rates of COVID-19 included workplace exposure (high vs low: aHR, 1.35 [95% CI, 1.16-1.58]; medium vs low: aHR, 1.41 [95% CI, 1.21-1.65]; Pâ€‰<â€‰.001) and living condition risk (very

high vs low risk: aHR, 1.41 [95% CI, 1.21-1.66]; medium vs low risk: aHR, 1.19 [95% CI, 1.08-1.32]; Pâ€‰<â€‰.001). Factors associated with decreased rates of COVID-19 included previous SARS-CoV-2 infection (aHR, 0.13 [95% CI, 0.09-0.19]; Pâ€‰<â€‰.001), age 65 years or older (aHR vs age <65 years, 0.57 [95% CI, 0.50-0.64]; Pâ€‰<â€‰.001) and Black or African American race (aHR vs White race, 0.78 [95% CI, 0.67-0.91]; Pâ€‰=â€‰.002). Factors associated with increased rates of severe COVID-19 included race (American Indian or Alaska Native vs White: aHR, 2.61 [95% CI, 1.85-3.69]; multiracial vs White: aHR, 2.19 [95% CI, 1.50-3.20]; Pâ€‰<â€‰.001), diabetes (aHR, 1.54 [95% CI, 1.14-2.08]; Pâ€‰=â€‰.005) and at least 2 comorbidities (aHR vs none, 1.39 [95% CI, 1.09-1.76]; Pâ€‰=â€‰.008). In analyses restricted to participants who contracted COVID-19, increased severe COVID-19 rates were associated with age 65 years or older (aHR vs <65 years, 1.75 [95% CI, 1.32-2.31]; Pâ€‰<â€‰.001), race (American Indian or Alaska Native vs White: aHR, 1.98 [95% CI, 1.38-2.83]; Black or African American vs White: aHR, 1.49 [95% CI, 1.03-2.14]; multiracial: aHR, 1.81 [95% CI, 1.21-2.69]; overall Pâ€‰=â€‰.001), body mass index (aHR per 1-unit increase, 1.03 [95% CI, 1.01-1.04]; Pâ€‰=â€‰.001), and diabetes (aHR, 1.85 [95% CI, 1.37-2.49]; Pâ€‰<â€‰.001). Previous SARS-CoV-2 infection was associated with decreased severe COVID-19 rates (aHR, 0.04 [95% CI, 0.01-0.14]; Pâ€‰<â€‰.001). CONCLUSIONS AND RELEVANCE: In this secondary cross-protocol analysis of 4 randomized clinical trials, exposure and demographic factors had the strongest associations with outcomes; results could inform mitigation strategies for SARS-CoV-2 and viruses with comparable epidemiological characteristics.

Immunogenicity and reactogenicity of heterologous COVID-19 vaccination in pregnant women. This open-labeled non-inferiority trial evaluated immunogenicity and reactogenicity of heterologous and homologous COVID-19 vaccination schedules in pregnant Thai women. 18-45-year-old pregnant women with no history of COVID-19 infection or vaccination and a gestational age of â‰¥12â€‰weeks were randomized 1:1:1 into three two-dose primary series scheduled 4â€‰weeks apart: BNT162b2-BNT162b2 (Group 1), ChAdOx1-BNT162b2 (Group 2), and CoronaVac-BNT162b2 (Group 3). Serum antibody responses, maternal and cord blood antibody levels at delivery, and adverse events (AEs) following vaccination until delivery were assessed. The 124 enrolled participants had a median age of 31 (interquartile range [IQR] 26.0-35.5) years and gestational age of 23.5 (IQR 18.0-30.0) weeks. No significant difference in anti-receptor binding domain (RBD) IgG were observed across arms at 2â€‰weeks after the second dose. Neutralizing antibody geometric mean titers against the ancestral Wuhan strain were highest in Group 3 (258.22, 95% CI [187.53, 355.56]), followed by Groups 1 (187.47, 95% CI [135.15, 260.03]) and 2 (166.63, 95% CI [124.60, 222.84]). Cord blood anti-RBD IgG was correlated with, and equal to or higher than, maternal levels at delivery (râ€‰=â€‰0.719, Pâ€‰<â€‰.001) and inversely correlated with elapsed time after the second vaccination (râ€‰=â€‰-0.366, Pâ€‰<â€‰.001). No significant difference in cord blood antibody levels between groups were observed. Local and systemic AEs were mild-to-moderate and more frequent in Group 2. Heterologous schedules of CoronaVac-BNT162b2 or ChAdOx1-BNT162b2 induced immunogenicity on-par with BNT162b2-BNT162b2 and may be considered as alternative schedules for primary series in pregnant women in mRNA-limited vaccine settings.

Vaccination against coronavirus disease 2019 in patients with pulmonary hypertension: a national prospective cohort study. BACKGROUND: Coronavirus disease 2019 (COVID-19) has potential risks for both clinically worsening pulmonary hypertension (PH) and increasing mortality. However, the data regarding the protective role of vaccination in this population are still lacking. This study aimed to assess the safety of approved vaccination for patients with PH. METHODS: In this national prospective cohort study, patients diagnosed with PH (World Health Organization [WHO] groups 1 and 4) were enrolled from October 2021 to April 2022. The primary outcome was the composite of PH-related major adverse events. We used an inverse probability weighting (IPW) approach to control

for possible confounding factors in the baseline characteristics of patients. RESULTS: In total, 706 patients with PH participated in this study (mean age, 40.3 years; mean duration after diagnosis of PH, 8.2 years). All patients received standardized treatment for PH in accordance with guidelines for the diagnosis and treatment of PH in China. Among them, 278 patients did not receive vaccination, whereas 428 patients completed the vaccination series. None of the participants were infected with COVID-19 during our study period. Overall, 398 patients received inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine, whereas 30 received recombinant protein subunit vaccine. After adjusting for baseline covariates using the IPW approach, the odds of any adverse events due to PH in the vaccinated group did not statistically significantly increase (27/428 [6.3%] vs. 24/278 [8.6%], odds ratio = 0.72, P = 0.302). Approximately half of the vaccinated patients reported at least one post-vaccination side effects, most of which were mild, including pain at the injection site (159/428, 37.1%), fever (11/428, 2.6%), and fatigue (26/428, 6.1%). CONCLUSIONS: COVID-19 vaccination did not significantly augment the PH-related major adverse events for patients with WHO groups 1 and 4 PH, although there were some tolerable side effects. A large-scale randomized controlled trial is warranted to confirm this finding. The final approval of the COVID-19 vaccination for patients with PH as a public health strategy is promising.

Immunogenicity, safety and reactogenicity of heterologous (third dose) booster vaccination with a full or fractional dose of two different COVID-19 vaccines: A phase 4, single-blind, randomized controlled trial in adults. In this phase 4 study we assessed boosting with fractional doses of heterologous COVID-19 vaccines in Brazilian adults primed with two doses of CoronaVac (Sinovac/Butantan, SÃ£o Paulo, Brazil) at least 4 months previously. Participants received either full-dose of ChAdOx1-S (Group 1, nâ€‰=â€‰232), a half dose of ChAdOx1-S (Group 2, nâ€‰=â€‰236), or a half dose of BNT162b2 (Group 3, nâ€‰=â€‰234). The primary objective was to show 80% seroresponse rates (SRR) 28â€‰d after vaccination measured as IgG antibodies against a prototype SARS-CoV-2 spike-protein. Safety was assessed as solicited and unsolicited adverse events. At baseline all participants were seropositive, with high IgG titers overall. SRR at Day 28 were 34.3%, 27.1% and 71.2%, respectively, not meeting the primary objective of 80%, despite robust immune responses in all three groups with geometric mean-fold rise (GMFR) in IgG titers of 3.39, 2.99 and 7.42, respectively. IgG immune responses with similar GMFR were also observed against SARS-CoV-2 variants, Alpha, Beta, Delta, Gamma and D614G. In subsets (nâ€‰=â€‰35) of participants GMFR of neutralizing immune responses against live prototype SARS-CoV-2 virus and Omicron BA.2 were similar to the IgG responses as were pseudo-neutralizing responses against SARS-CoV-2 prototype and Omicron BA.4/5 variants. All vaccinations were well tolerated with no vaccine-related serious adverse events and mainly transient mild-to-moderate local and systemic reactogenicity. Heterologous boosting with full or half doses of ChAdOx1-S or a half dose of BNT162b2 was safe and immunogenic in CoronaVac-primed adults, but seroresponse rates were limited by high baseline immunity.

Randomised controlled trials of behavioural nudges delivered through text messages to increase influenza and COVID-19 vaccines among pregnant women (the EPIC study): study protocol. BACKGROUND: Influenza and COVID-19 infections during pregnancy may have serious adverse consequences for women as well as their infants. However, uptake of influenza and COVID-19 vaccines during pregnancy remains suboptimal. This study aims to assess the effectiveness of a multi-component nudge intervention to improve influenza and COVID-19 vaccine uptake among pregnant women. METHODS: Pregnant women who receive antenatal care at five tertiary hospitals in South Australia, Western Australia and Victoria will be recruited to two separate randomised controlled trials (RCTs). Women will be eligible for the COVID-19 RCT is they have received two or less doses of a COVID-19 vaccine. Women will be eligible for the influenza RCT if they have not received the 2023 seasonal influenza vaccine. Vaccination status at all stages of the trial will be confirmed by the

Australian Immunisation Register (AIR). Participants will be randomised (1:1) to standard care or intervention group (nâ€‰=â€‰1038 for each RCT). The nudge intervention in each RCT will comprise three SMS text message reminders with links to short educational videos from obstetricians, pregnant women and midwives and vaccine safety information. The primary outcome is at least one dose of a COVID-19 or influenza vaccine during pregnancy, as applicable. Logistic regression will compare the proportion vaccinated between groups. The effect of treatment will be described using odds ratio with a 95% CI. DISCUSSION: Behavioural nudges that facilitate individual choices within a complex context have been successfully used in other disciplines to stir preferred behaviour towards better health choices. If our text-based nudges prove to be successful in improving influenza and COVID-19 vaccine uptake among pregnant women, they can easily be implemented at a national level. TRIAL REGISTRATION: ClinicalTrials.gov Identifier NCT05613751. Registered on November 14, 2022.

Prevalence of and risk factors for self-reported menstrual changes following COVID-19 vaccination: a Danish cohort study. STUDY QUESTION: Are there some characteristics that render individuals more susceptible to report menstrual changes following the Coronavirus disease 2019 (COVID-19) vaccination? SUMMARY ANSWER: We found that 30% of menstruating women reported menstrual changes following COVID-19 vaccination and several potential risk factors including stress, vaccine concerns, severe COVID-19 infection, and immediate vaccine symptoms were associated with these reports. WHAT IS KNOWN ALREADY: Studies suggest that COVID-19 vaccination might temporarily prolong menstrual cycle length by less than 1Â day. Specific characteristics may trigger menstrual changes in temporal relation to the vaccination simply by chance or render women more vigilant to potential menstrual changes after being vaccinated. However, research investigating potential risk factors for reporting menstrual changes following COVID-19 vaccination is limited. STUDY DESIGN, SIZE, DURATION: A population-based Danish cohort study. Data were collected from May 2021 to December 2021 as a part of the BiCoVac Cohort with the aim of examining non-specific effects following COVID-19 vaccination. The main study population included 13Â 648 menstruating women aged 16-65Â years who completed all surveys, received their first dose of a COVID-19 vaccine during the data collection period, and completed questions related to their menstrual cycle. PARTICIPANTS/MATERIALS, SETTING, METHODS: Potential risk factors included 14 biological, physical, or psychological measures. Information on most potential risk factors was self-reported and collected before the participants' first COVID-19 vaccination. Information about any menstrual change following COVID-19 vaccination was self-reported at the end of the data collection period. Logistic regression analyses were used to estimate crude and adjusted odds ratios (ORs) with 95% CIs for the association between each potential risk factor and reporting menstrual changes following COVID-19 vaccination. MAIN RESULTS AND THE ROLE OF CHANCE: Any menstrual change following COVID-19 vaccination was reported by 30% of menstruating women. Most of the potential risk factors were associated with reports of menstrual changes following COVID-19 vaccination. In particular, higher odds were found among women who reported â‰¥5 immediate vaccine symptoms; OR 1.67 [1.50-1.86], had had a prior severe COVID-19 infection; OR 2.17 [1.40-3.35], had a high-stress level at baseline; OR 1.67 [1.32-2.10], or were concerned about COVID-19 vaccines prior to vaccination; OR 1.92 [1.50-2.45]. Lower odds were found among women with regular menstrual cycles using hormonal contraception; OR 0.71 [0.65-0.78]. LIMITATIONS, REASONS FOR CAUTION: We were unable to address the causal effect of COVID-19 vaccination on the reported menstrual changes, as information about menstrual changes was not available among non-vaccinated women. WIDER IMPLICATIONS OF THE FINDINGS: The study identified several potential risk factors for reporting menstrual changes following COVID-19 vaccination. Further studies are needed to establish causal associations and the clinical impact of self-reported menstrual changes. STUDY

FUNDING/COMPETING INTEREST(S): The BiCoVac data collection was funded by TrygFonden (id-number: 153678). No competing interests are declared. TRIAL REGISTRATION NUMBER: N/A.

Kinetics of specific anti-SARS-CoV-2 IgM, IgA, and IgG responses during the first 12 months after SARS-CoV-2 infection: A prospective longitudinal study. Coronavirus 2019 (COVID-19) is a global health threat. The kinetics of antibodies against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) need to be assessed, as the long-term duration of these immunoglobulins remains largely controversial. The aim of this study was to assess the longitudinal dynamics of anti-SARS-CoV-2 antibodies against the nucleocapsid (N) protein and the receptor-binding domain (RBD) of the spike protein up to one year in a cohort of 190 COVID-19 patients. Between March and September 2021, we enrolled patients from two regional hospitals in Casablanca, Morocco. Blood samples were collected and analyzed for antibody levels. We used the commercial Euroimmun ELISA for the determination of anti-N IgM, the Abbott Architectâ„¢ SARS-CoV-2 IgG test for the detection of anti-RBD IgG, and an in-house kit for the assay of anti-N IgG and anti-N IgA. IgM and IgA antibodies were assessed 2-5, 9-12, 17-20 and 32-37 days after symptom onset. IgG antibodies were also assessed 60, 90, 120 and 360 days after symptom onset. One-third of patients developed IgM (32%), while two-thirds developed IgA (61%). One month of symptom onset, most patients developed IgG, with 97% and 93% positivity for anti-RBD IgG and anti-N IgG, respectively. The anti-RBD IgG positivity rate remained high up to one year of follow-up. However, the anti-N IgG positivity rate decreased over time, with only 41% of patients testing positive after one year's follow-up. IgG levels were significantly higher in older people (over 50 years) than in other study participants. We also found that patients who had received two doses of ChAdOx1 nCoV-19 vaccine prior to infection had a lower IgM response than unvaccinated patients. This difference was statistically significant two weeks after the onset of symptoms. We present the first study in Africa to measure the kinetics of antibody response (IgA, IgM and IgG) to SARS-CoV-2 over one year. Most participants remained seropositive for anti-RBD IgG after one year but showed a significant decline in antibody titers.

New-onset and relapsed thrombotic microangiopathy post-COVID-19 vaccination. Thrombotic microangiopathy (TMA) associated with coronavirus disease 2019 (COVID-19) vaccination has been reported, however, the clinical characteristics and pathogenesis remained mysterious. We reviewed 84 TMA cases post-COVID-19 vaccination, including 64 patients diagnosed with thrombotic thrombocytopenic purpura (TTP), 17 cases presented as atypical hemolytic uremic syndrome (aHUS), and threeÂ cases manifested as unclassified TMA. TMA episodes were mostly associated with messenger RNA vaccines. For TTP, 67.6% of females developed symptoms after the first dose of the vaccine, and 63.0% of males were secondary to the second dose (pâ€‰=â€‰0.015). Compared with TTP, aHUS generally appeared within 7â€‰days (pâ€‰=â€‰0.002) and showed higher levels of serum creatinine (pâ€‰<â€‰0.001). 87.5% of TTP received plasma exchange (PEX)-based treatment, and 52.9% of aHUS adopted non-PEX-based therapies (pâ€‰<â€‰0.001). Mechanistically, complement dysfunction, neutrophil activation, and the generation of pathogenic autoantibodies resulting from molecular mimicry contribute to explaining the pathogenesis of TMA post-COVID-19 vaccination.

[Development and preservation of specific T-cell immunity after COVID-19 or vaccination against this infection]. Aim evaluation of specific T-cell immunity against SARS-CoV-2 in primary and secondary response to virus antigens by screening method. MATERIALS AND METHODS: Patients were tested 11.5 months after COVID-19 and 610 months before and after vaccination. Healthy volunteers were screened before, 26 times during the vaccination course, and 68 months after revaccination with the Sputnik V vaccine. IgG and IgM antibodies to SARS-CoV-2 were detected by ELISA using commercially available kits (Vector-Best, Russia). Antigenic (AG) activation of T cells in the fraction of bloods mononuclear cells was assessed by IFN- production after AG stimulation in the

wells of plates from ELISA kits intended for detection of antibodies against SARS-CoV-2. Data were processed by MS Excel and Statistica 10.0 software. RESULTS: AG-specific T cells were detected in 88.5% of vaccinated healthy volunteers, half of whom were found to have T cells appearing earlier than antibodies to AG. After 6-8 months, the level of AG activation decreases. Following the revaccination, the level of AG activation of memory T cells in vitro increases within six months in 76.9100.0% of vaccinated subjects. On the contrary, after COVID-19, 86.7% of individuals had in their blood the AG-specific T cells with high activity at the time of vaccination. The activity of T cells recognizing the RBD domain of the SARS-CoV-2 S protein and the proportion of individuals who had these cells in their blood increased after the vaccination of reconvalescents. CONCLUSION: T-cell immunity against SARS-CoV-2 antigens has been shown to persist for 6 months after illness. In vaccinated individuals without history of COVID-19, such duration of the preservation of AG-specific T cells in blood was only achieved after the revaccination.

Myasthenia Gravis Exacerbation Following Immunization With the BNT162b2 mRNA COVID-19 Vaccine: Report of a Case and Review of the Literature. Acute exacerbations of Myasthenia Gravis (MG) may be triggered by infections and certain drugs. No consensus has been reached on vaccines and the risk for developing myasthenic crisis. During the COVID-19 pandemic, MG patients are considered at high risk for severe illness, and vaccination is strongly recommended. We report the case of a 70-year-old woman with MG, diagnosed 2Â years earlier, that developed myasthenic crisis 10Â days after the second dose of the BNT162b2 mRNA COVID-19 vaccine (Pfizer-BioNTech). The patient had no previous MG exacerbations in her history. Following increase of oral pyridostigmine and prednisone treatment, the patient underwent immunoglobulin and plasma exchange therapy. Due to persisting symptoms, immunotherapy was switched to rituximab, under which a clinical remission was achieved. MG patients infected with SARS-CoV-2 may develop severe acute respiratory distress syndrome and have a higher mortality compared to the general population. In addition, reports of new-onset MG following COVID-19 infection accumulate. By contrast, since the beginning of the vaccination program, only 3 cases of new-onset MG after COVID-19 vaccinations have been published and 2 cases of severe MG exacerbation. Vaccinations in MG patients have always been debated, but most studies confirm their safety. In the era of COVID-19 pandemic, vaccination protects against infection and severe illness, especially in vulnerable populations. The rare occurrence of side effects should not discourage clinicians from recommending COVID-19 vaccination, but close follow-up of MG patients is recommended during the post-vaccination period.

COVID-19 Vaccine Seroresponse Based on The Timing of The Primary Series; Pre- versus Post-Renal Transplantation. BACKGROUND: Coronavirus disease 2019 (COVID-19) poses a serious risk to patients with chronic kidney disease (CKD) and renal transplant. While COVID-19 vaccination is recommended before transplant, there are limited data comparing vaccine timing. Our aim is to evaluate serological responses to COVID-19 vaccines pre- and post-renal transplant and the durability of antibody levels. METHODS: We retrospectively evaluated the antibody response of adult renal transplant recipients who had received at least a primary series of the COVID-19 vaccine. The patients were divided into two groups based on the timing; pre- or post-transplant. Antibody titer levels were evaluated at least 4Â weeks after vaccination for each group. Titer durability was assessed by calculating the median titer level of individuals. RESULTS: A total of 139 patients were identified between January 2019 and April 2022. Twenty-nine patients were excluded because of previous COVID-19 infection, and 15 patients were excluded each for insufficient vaccine doses and lack of titer data. Forty patients were included for the pre-transplant group and 40 for post-transplant. The number of pre-transplant patients who developed antibodies (39 patients, 97.5%) was significantly greater than the number of post-transplant patients (21 patients, 52.5%) with pÂ <Â .01. The median post-vaccination titer levels were significantly greater in the pre-transplant group up to 5Â months

after vaccination (pÂ <Â .05). The pre-transplant group's titers seemed sustained even after renal transplantation. CONCLUSION: Vaccinating renal transplant patients before transplant results in increased achievement of seroresponse, higher levels of antibody titers, and sustained titers following transplant. Larger and prospective studies are warranted to confirm the findings.

Sex differences in cerebral venous sinus thrombosis after adenoviral vaccination against COVID-19. INTRODUCTION: Cerebral venous sinus thrombosis associated with vaccine-induced immune thrombotic thrombocytopenia (CVST-VITT) is a severe disease with high mortality. There are few data on sex differences in CVST-VITT. The aim of our study was to investigate the differences in presentation, treatment, clinical course, complications, and outcome of CVST-VITT between women and men. PATIENTS AND METHODS: We used data from an ongoing international registry on CVST-VITT. VITT was diagnosed according to the Pavord criteria. We compared the characteristics of CVST-VITT in women and men. RESULTS: Of 133 patients with possible, probable, or definite CVST-VITT, 102 (77%) were women. Women were slightly younger [median age 42 (IQR 28-54) vs 45 (28-56)], presented more often with coma (26% vs 10%) and had a lower platelet count at presentation [median (IQR) 50x10(9)/L (28-79) vs 68 (30-125)] than men. The nadir platelet count was lower in women [median (IQR) 34 (19-62) vs 53 (20-92)]. More women received endovascular treatment than men (15% vs 6%). Rates of treatment with intravenous immunoglobulins were similar (63% vs 66%), as were new venous thromboembolic events (14% vs 14%) and major bleeding complications (30% vs 20%). Rates of good functional outcome (modified Rankin Scale 0-2, 42% vs 45%) and in-hospital death (39% vs 41%) did not differ. DISCUSSION AND CONCLUSIONS: Three quarters of CVST-VITT patients in this study were women. Women were more severely affected at presentation, but clinical course and outcome did not differ between women and men. VITT-specific treatments were overall similar, but more women received endovascular treatment.

Long COVID prevalence and impact on quality of life 2Â years after acute COVID-19. There has been an increasing interest in the long-term impact of long COVID. However, only a few studies have investigated the clinical manifestations of long COVID after 24Â months of acute infection. In this study, prospective online surveys were conducted in adults previously diagnosed with coronavirus disease 2019 (COVID-19) in South Korea between February 13 and March 13, 2020, at 6, 12, and 24Â months after COVID-19. We investigated self-reported symptoms and the EuroQol-5-dimension index. Among 900 individuals enrolled initially, 150 completed all 3 surveys. After excluding the cases of COVID-19 reinfection, 132 individuals were included in the final analysis. Among the 132 participants, 94 (71.2%) experienced symptoms of long COVID. The most frequently reported symptoms were fatigue (34.8%), amnesia (30.3%), concentration difficulties (24.2%), insomnia (20.5%), and depression (19.7%). Notably, no significant differences were noted in the incidence of long COVID at 24Â months in terms of the number of vaccinations received. Although the neuropsychiatric quality of life improved over time, it continued to affect 32.7% of participants. Symptoms of long COVID, particularly neuropsychiatric symptoms, tend to persist over time, and COVID-19 vaccination or the number of vaccinations received may not significantly affect the incidence of long COVID.

Results of the first nationwide cohort study of outcomes in dialysis and kidney transplant patients before and after vaccination for COVID-19. BACKGROUND: Patients on kidney replacement therapy (KRT) have been identified as a vulnerable group during the coronavirus disease 2019 (COVID-19) pandemic. This study reports the outcomes of COVID-19 in KRT patients in Sweden, a country where patients on KRT were prioritized early in the vaccination campaign. METHODS: Patients on KRT between January 2019 and December 2021 in the Swedish Renal Registry were included. Data were linked to national healthcare registries. The primary outcome was monthly all-cause mortality over 3Â years of follow-up. The secondary outcomes were monthly COVID-19-related

deaths and hospitalizations. The results were compared with the general population using standardized mortality ratios. The difference in risk for COVID-19-related outcomes between dialysis and kidney transplant recipients (KTRs) was assessed in multivariable logistic regression models before and after vaccinations started. RESULTS: On 1 January 2020, there were 4097 patients on dialysis (median age 70Â years) and 5905 KTRs (median age 58Â years). Between March 2020 and February 2021, mean all-cause mortality rates increased by 10% (from 720 to 804 deaths) and 22% (from 158 to 206 deaths) in dialysis and KTRs, respectively, compared with the same period in 2019. After vaccinations started, all-cause mortality rates during the third wave (April 2021) returned to pre-COVID-19 mortality rates among dialysis patients, while mortality rates remained increased among transplant recipients. Dialysis patients had a higher risk for COVID-19 hospitalizations and death before vaccinations started {adjusted odds ratio [aOR] 2.1 [95% confidence interval (CI) 1.7-2.5]} but a lower risk after vaccination [aOR 0.5 (95% CI 0.4-0.7)] compared with KTRs. CONCLUSIONS: The COVID-19 pandemic in Sweden resulted in increased mortality and hospitalization rates among KRT patients. After vaccinations started, a distinct reduction in hospitalization and mortality rates was observed among dialysis patients, but not in KTRs. Early and prioritized vaccinations of KRT patients in Sweden probably saved many lives.

Incidence of Bell's palsy after coronavirus disease (COVID-19) vaccination: a systematic review and meta-analysis. OBJECTIVE: To estimate the pooled incidence of Bell's palsy after COVID-19 vaccination. METHODS: PubMed, Scopus, EMBASE, Web of Science, and Google Scholar were searched by 2 independent researchers. We also searched the grey literature including references of the references and conference abstracts. We extracted data regarding the total number of participants, first author, publication year, the country of origin, sex, type of vaccines, and the number of patients who developed Bell's palsy after COVID-19 vaccination. RESULTS: The literature search revealed 370 articles, subsequently deleting duplicates 227 remained. After careful evaluation of the full texts, 20 articles remained for meta-analysis. The most commonly administered vaccines were Pfizer followed by Moderna. In total, 4.54e+07 individuals received vaccines against COVID-19, and 1739 cases developed Bell's palsy. In nine studies, controls (individuals without vaccination) were enrolled. The total number of controls was 1 809 069, of whom 203 developed Bell's palsy. The incidence of Bell's palsy after COVID-19 vaccines was ignorable. The odds of developing Bell's palsy after COVID-19 vaccines was 1.02 (95% CI: 0.79-1.32) (I^2 = 74.8%, $P < .001$). CONCLUSION: The results of this systematic review and meta-analysis show that the incidence of peripheral facial palsy after COVID-19 vaccination is ignorable and vaccination does not increase the risk of developing Bell's palsy. Maybe, Bell's palsy is a presenting symptom of a more severe form of COVID-19, so clinicians must be aware of this.

Ocular posterior segment complications following COVID-19 vaccination. BACKGROUND: The SARS-CoV-2 pandemic has had a significant impact on healthcare, including eye care, worldwide. Effective and safe vaccines have been developed using both conventional and novel technologies to combat SARS-CoV-2 infection. While vaccination has been shown to be remarkably effective in reducing the spread and associated morbidity and mortality of COVID-19 disease, there have been reports of complications to theÂ posterior segmentÂ of the eye. METHODS: We present a case-based analysis of reported complications of COVID-19 vaccination to the posterior segment of the eye. The study aims to highlight the diversity of possible complications and discuss the plausible involved pathophysiologic mechanisms. RESULTS: The most significant complications reported were retinal macro orÂ microvascular occlusions, uveitis, and central serous chorioretinopathy. These complications are rare but require prompt diagnosis and management to prevent serious visual morbidity. CONCLUSIONS: Our study highlights the need for ophthalmologists to be aware of possible complications related to COVID-19 vaccination and the importance of prompt diagnosis and

management. The findings of this study may help ophthalmologists to better understand and manage these rare complications.

IgM nephropathy in a patient with dermatomyositis following COVID-19 vaccination: A case report. BACKGROUND: Dermatomyositis (DM) is a systemic autoimmune disease characterized by distinct skin lesions and a clinically heterogeneous constellation of systemic manifestations. This disease poses a challenge to clinicians because of its rarity, diverse clinical presentations, and variable organ involvement, resulting from an autoimmune attack on affected organs, which could be triggered by environmental factors in genetically susceptible individuals. Renal involvement is rare, with immunoglobulin M (IgM) nephropathy yet to be reported in patients with DM. CASE PRESENTATION: A 38-year-old man was admitted to Shariati Hospital, affiliated with Tehran University of Medical Sciences, with proximal weakness of the upper and lower extremities that had developed in the preceding month after receiving the Sinopharm COVID-19 vaccine. The patient was diagnosed with DM based on the heliotrope rash, Gottron's papules, progressive proximal muscle weakness, and paraclinical findings. IgM nephropathy developed subsequently, diagnosed by light and immunofluorescence microscopy. CONCLUSION: We describe the first case of IgM nephropathy in a DM patient following COVID-19 vaccination. This phenomenon requires further investigation into the possible crosslinks between the pathogenesis of IgM nephropathy with DM and the COVID-19 vaccine. Diagnosing renal complications in DM patients promptly and accurately can help to achieve the best outcomes.

Bilateral Optic Neuritis and Hypophysitis With Diabetes Insipidus 1 Month After COVID-19 mRNA Vaccine: Case Report and Literature Review. Either optic neuritis (neuropathy) or hypopituitarism has been known to occur separately after COVID-19 vaccination. In this report, we describe the rare combination of hypophysitis and optic neuritis which occurred after COVID-19 vaccination. A 74-year-old woman began to have thirst, polydipsia, and polyuria, and was diagnosed as central diabetes insipidus 1 month after the fourth COVID-19 mRNA vaccine. Head magnetic resonance imaging (MRI) disclosed the thickened pituitary stalk and enlarged pituitary gland with high contrast enhancement as well as the absence of high-intensity signals in the posterior pituitary lobe on the T1-weighted image, leading to the diagnosis of lymphocytic hypophysitis. She was well with desmopressin nasal spray until further 2 months later, when she developed bilateral optic neuritis, together with gait disturbance, intention tremor of the upper extremities, urinary retention, constipation, abnormal sensation in the distal part of the lower extremities, and moderate hemiplegia on the left side. Autoantibodies, including anti-aquaporin 4 (AQP4) and anti-myelin oligodendrocyte glycoprotein (MOG), were all negative. She showed multifocal spinal cord lesions on MRI and oligoclonal bands in the cerebrospinal fluid obtained by spinal tap, and so underwent steroid pulse therapy with methylprednisolone in the tentative diagnosis of multiple sclerosis, resulting in visual acuity recovery and alleviation of neurological symptoms. In the literature review, the combination of optic neuritis and hypophysitis, mostly with diabetes insipidus, was reported in 15 patients as case reports before the years of COVID-19 pandemic. The COVID-19 vaccination would trigger the onset of hypophysitis and optic neuritis in this patient.

Breakthrough COVID-19 infection in people with MS after SARS-CoV-2 vaccination: Should we still be concerned?

Risk of COVID-19 in people with multiple sclerosis who are seronegative following vaccination. BACKGROUND: People with multiple sclerosis (pwMS) treated with certain disease-modifying therapies (DMTs) have attenuated IgG response following COVID-19 vaccination; however, the clinical consequences remain unclear. OBJECTIVE: To report COVID-19 rates in pwMS according to vaccine serology. METHODS: PwMS with available (1) serology 2-12â€‰weeks following COVID-19 vaccine 2 and/or vaccine 3 and (2) clinical data on COVID-19 infection/hospitalisation were included. Logistic

regression was performed to examine whether seroconversion following vaccination predicted risk of subsequent COVID-19 infection after adjusting for potential confounders. Rates of severe COVID-19 (requiring hospitalisation) were also calculated. RESULTS: A total of 647 pwMS were included (mean age 48â€‰years, 500 (77%) female, median Expanded Disability Status Scale (EDSS) 3.5% and 524 (81%) exposed to DMT at the time of vaccine 1). Overall, 472 out of 588 (73%) were seropositive after vaccines 1 and 2 and 222 out of 305 (73%) after vaccine 3. Seronegative status after vaccine 2 was associated with significantly higher odds of subsequent COVID-19 infection (odds ratio (OR): 2.35, 95% confidence interval (CI): 1.34-4.12, pâ€‰=â€‰0.0029), whereas seronegative status after vaccine 3 was not (OR: 1.05, 95% CI: 0.57-1.91). Five people (0.8%) experienced severe COVID-19, all of whom were seronegative after most recent vaccination. CONCLUSION: Attenuated humoral response to initial COVID-19 vaccination predicts increased risk of COVID-19 in pwMS, but overall low rates of severe COVID-19 were seen.

Immune-related adverse events and disease outcomes after the third dose of SARS-CoV-2 mRNA-BNT162b2 vaccine in cancer patients receiving immune checkpoint inhibitors. BACKGROUND: The clinical implications of the third dose of coronavirus disease 2019 (COVID-19) vaccines in patients receiving immune checkpoint inhibitors are currently unknown. We performed a prospective analysis of the Vax-On-Third study to investigate the effects of antibody response on immune-related adverse events (irAEs) and disease outcomes. METHODS: Recipients of the booster dose of SARS-CoV-2 mRNA-BNT162b2 vaccine who had received at least one course of an anti-PD-1/PD-L1 treatment before vaccination for an advanced solid malignancy were eligible. RESULTS: The current analysis included 56 patients with metastatic disease (median age: 66Â years; male: 71%), most of whom had a lung cancer diagnosis and were being treated with pembrolizumab- or nivolumab-based regimens. The optimal cut-point antibody titer of 486 BAU/mL allowed a dichotomization of recipients into low-responders (Low-R,â€‰<â€‰486 BAU/mL) or high-responders (High-R,â€‰â‰¥â€‰486 BAU/mL). After a median follow-up time of 226Â days, 21.4% of patients experienced moderate to severe irAEs without any recrudescence of immune toxicities preceding the booster dose. The frequencies of irAE before and after the third dose did not differ, but an increase in the cumulative incidence of immuno-related thyroiditis was observed within the High-R subgroup. On multivariate analysis, an enhanced humoral response correlated with a better outcome in terms of durable clinical benefit, which resulted in a significant reduction in the risk of disease control loss but not mortality. CONCLUSIONS: Our findings would strengthen the recommendation not to change anti-PD-1/PD-L1 treatment plans based on current or future immunization schedules, implying that all these patients should be closely monitored.

[SARS-CoV-2 mRNA-based vaccine in hemodialysis patients: a single center-experience]. Hemodialysis patients have an increased risk of severe complications when infected with SARS-CoV-2. The introduction of the SARS-CoV-2 vaccine represented an important progress in limiting severe forms of the disease. The focus of our study is the detection of the antibody titer in chronic hemodialysis patients vaccinated with the mRNA vaccine BNT162b2 (Comirnaty, Pfizer-BioNTech). The antibody titers were measured in 57 hemodialysis patients, vaccinated with 3 doses according to ministerial criteria, by ElectroChemiLuminescence ImmunoAssay (ECLIA). The response was defined as an antibody titer above the dosable level > 0,8 UI/ml. A good antibody response was defined as titer > 250 UI/ml. Infections with SARS-CoV-2 and adverse effects to the vaccine were recorded. Our study showed in 93% of the hemodialysis patients a dosable antibody response after the second dose of the vaccine. After the third dose of the vaccine, 100% of the hemodialysis patients reached a dosable antibody titer. The vaccine proved to be safe, no serious adverse events were observed. After the third dose, SARS-CoV-2 infections were still observed, but with reduced severity. A vaccination

course against SARS-CoV-2 infection with three doses of BNT162b2 in the dialysis patient is associated with a good immune response and protects against severe infections.

Acute Thrombotic Thrombocytopenic Purpura: Rare and Life-Threatening Side Effect of Recent BNT-162b2 COVID-19 Vaccination. Description Thrombotic thrombocytopenic purpura (TTP) is a rare, potentially life-threatening disorder characterized by uncontrolled and spontaneous clot formation throughout the body. Known secondary causes of TTP include malignancy, bone marrow transplantation, pregnancy, various medications, and HIV infection. TTP in the setting of COVID-19 vaccination is rare and not well reported. Reported cases have been confined primarily to the AstraZeneca and Johnson and Johnson COVID-19 Vaccines. TTP in the setting of Pfizer BNT-162b2 vaccination has only recently been reported. We present a patient with no obvious risk factors for TTP who presented with acute altered mental status and was found to have objective evidence of TTP. To our knowledge, there are very few reported cases of TTP in the setting of a recent Pfizer COVID-19 vaccination.

Suspected Anaphylactic Reaction Following Second Dose of the Pfizer-BioNTech (BNT162b2) Coronavirus Vaccine in a Geriatric Female. Description Anaphylaxis is a rare but serious adverse reaction that can occur following mRNA-based vaccination against coronavirus (COVID-19). This is a case of a geriatric patient presenting with hypotension and an urticarial rash with bullous lesions following a syncopal episode with incontinence. She received the second dose of the Pfizer-BioNTech (BNT162b2) COVID-19 vaccine three days prior, and first developed the skin abnormalities the morning after receiving the vaccine. She had no past history of anaphylaxis or allergies to vaccinations. Her presentation met the diagnostic criteria for anaphylaxis, according to the World Allergy Organization: she had acute onset illness involving the skin and was hypotensive with symptoms suggestive of end-organ dysfunction. The latest literature published on anaphylaxis to mRNA-based COVID-19 vaccination indicates that this is an extremely rare complication. From December 14, 2020, to January 18, 2021, 9 943 247 doses of the Pfizer-BioNTech vaccine and 7 581 429 doses of the Moderna vaccine were administered in the United States. Sixty-six of these patients met anaphylaxis criteria. Of these cases, 47 received the Pfizer vaccine and 19 received the Moderna vaccine. Unfortunately, the mechanisms of these adverse reactions remain poorly understood, although it is postulated that particular vaccine components such as polyethylene glycol or polysorbate 80 may be the underlying triggers. This case demonstrates the importance of recognizing anaphylactic signs and symptoms, as well as proper patient education about the benefits and potential, albeit rare, adverse effects, of vaccination.

Post-COVID-19 Vaccination CNS Magnetic Resonance Imaging Findings: A Systematic Review. OBJECTIVE: This systematic review aims to synthesize and analyze the available literature on central nervous system (CNS) magnetic resonance imaging (MRI) findings in individuals who have received COVID-19 vaccinations. Our objective is to enhance understanding of potential neurological side effects, inform clinical practice, and guide future research on the neurological implications of COVID-19 vaccination. METHODS: In this systematic review, we conducted a comprehensive search in PubMed, Scopus, and Web of Science from January 2020 to April 2023, using terms related to COVID-19 vaccination and CNS MRI findings. We evaluated the quality of the study, extracted relevant data, and included 89 eligible studies that covered various vaccines, demographics of patients, symptoms, and MRI findings to provide a thorough understanding of SARS-CoV-2 vaccination-related CNS problems. RESULTS: We investigated CNS MRI findings following COVID-19 vaccination across various vaccine types. Common diseases associated with post-vaccination CNS MRI findings included cerebral venous sinus thrombosis (CVST), vaccine-induced immune thrombotic thrombocytopenia (VITT), acute disseminated encephalomyelitis (ADEM), acute myelitis, autoimmune encephalitis (AE), and others. Patients presented with diverse onset symptoms and neurological manifestations.

Abnormalities identified in CNS MRI findings included white matter (WM) hyperintensity. Our analysis offers a comprehensive overview of the current literature on post-vaccination CNS MRI findings. Discussion. We highlight a range of post-COVID-19 vaccination CNS MRI findings, including CVST, with a higher incidence in individuals receiving the ChAdOx1 (AstraZeneca) vaccine. Other notable observations include cases of ADEM, myelitis or transverse myelitis (TM), Guillain-BarrÃ© syndrome (GBS), and acute encephalopathy following COVID-19 vaccination. The incidence of these neurological complications is extremely rare, and the benefits of vaccination outweigh the risks. The reviewed studies were primarily case reports or case series, and thus large-scale epidemiological studies and controlled clinical trials are needed to better understand the underlying mechanisms and risk factors associated with these neurological complications following COVID-19 vaccination.

New onset or relapsing neuromyelitis optica temporally associated with SARS-CoV-2 infection and COVID-19 vaccination: a systematic review. BACKGROUND: Neuromyelitis optica spectrum disorder (NMOSD) is a rare chronic neuroinflammatory autoimmune condition. Since the onset of the COVID-19 pandemic, there have been reports of NMOSD clinical manifestations following both SARS-CoV-2 infections and COVID-19 vaccinations. OBJECTIVE: This study aims to systematically review the published literature of NMOSD clinical manifestations associated with SARS-CoV-2 infections and COVID-19 vaccinations. METHODS: A Boolean search of the medical literature was conducted between December 1, 2019 to September 1, 2022, utilizing Medline, Cochrane Library, Embase, Trip Database, Clinicaltrials.gov, Scopus, and Web of Science databases. Articles were collated and managed on Covidence(Â®) software. The authors independently appraised the articles for meeting study criteria and followed PRISMA guidelines. The literature search included all case reports and case series that met study criteria and involved NMOSD following either the SARS-CoV-2 infection or the COVID-19 vaccination. RESULTS: A total of 702 articles were imported for screening. After removing 352 duplicates and 313 articles based on exclusion criteria, 34 articles were analyzed. A total of 41 cases were selected, including 15 patients that developed new onset NMOSD following a SARS-CoV-2 infection, 21 patients that developed de novo NMOSD following COVID-19 vaccination, 3 patients with known NMOSD that experienced a relapse following vaccination, and 2 patients with presumed Multiple Sclerosis (MS) that was unmasked as NMOSD post-vaccination. There was a female preponderance of 76% among all NMOSD cases. The median time interval between the initial SARS-CoV-2 infection symptoms and NMOSD symptom onset was 14â€‰ days (range 3-120â€‰ days) and the median interval between COVID-19 vaccination and onset of NMO symptoms was 10 â€‰days (range 1 to 97â€‰ days). Transverse myelitis was the most common neurological manifestation in all patient groups (27/41). Management encompassed acute treatments such as high dose intravenous methylprednisolone, plasmapheresis, and intravenous immunoglobulin (IVIG) and maintenance immunotherapies. The majority of patients experienced a favorable outcome with complete or partial recovery, but 3 patients died. CONCLUSION: This systematic review suggests that there is an association between NMOSD and SARS-CoV-2 infections and COVID-19 vaccinations. This association requires further study using quantitative epidemiological assessments in a large population to better quantify the risk.

Mucocutaneous presentations of consultant critical and non-critical cases of admitted COVID-19 patients, outpatients, and vaccine-associated dermatoses: a clinical atlas and a large original study of two general COVID-19 centers from Iran. Rapid and proper diagnosis of mucocutaneous presentations of COVID-19 which in many cases are representing internal organ damage is a key way to better approach these patients, and it could be even lifesaving. In this original study, we reported consultant critical and non-critical cases of admitted COVID-19 patients and some interesting outpatient cases for 14 months, and some newly encountered vaccine-associated dermatoses. We presented 121 cases divided into 12 categories; all had full multi-aspects photographs attached as an

atlas to a Supplementary File. These categories were:1- Generalized papulopustular eruptions (3 patients), 2- Erythroderma (4 patients), 3- Maculopapular lesions(16 patients), 4- Mucosal lesions (8 patients), 5- Urticarial lesions and angioedema (16 patients), 6- Vascular injuries (22 patients), 7- Vesiculobullous lesions (12 patients), 8- The specific new onset of mucocutaneous presentations or aggravation of any especial previous dermatoses (9 patients), 9- Nail changes (3 patients), 10- Hair loss (2 patients), 11- Non-specific mucocutaneous problems (16 patients) and 12-Vaccine-associated dermatoses (10 patients).In the pandemic, if we countered with extensive mucocutaneous lesions with vascular components or vesiculobullous erosive lesions in association with any cutaneous rash that could be an alarming sign of a probable life-threatening systemic event, we would need to approach them as soon as possible.

Appropriate sampling and long follow-up are required to rigorously evaluate longevity of humoral memory after Vaccination. One of the goals of vaccination is to induce long-term immunity against the infection and/or disease. However, evaluating the duration of protection following vaccination often requires long-term follow-ups that can conflict with the desire to rapidly publish results. Arunachalam et al. JCI 2023 followed individuals receiving third or fourth dose of mRNA COVID19 vaccines for up to 6 months and in finding that the levels of SARS-CoV2-specific antibodies (Abs) declined with similar rates for the two groups came to the conclusion that additional boosting is unnecessary to prolong immunity to SARS-CoV-2. However, this may be premature conclusion to make. Accordingly, we demonstrate that measuring Ab levels at 3 time points and only for a short (up to 6 month) duration does not allow to accurately and rigorously evaluate the long-term half-life of vaccine-induced Abs. By using the data from a cohort of blood donors followed for several years, we show that after re-vaccination with vaccinia virus (VV), VV-specific Abs decay bi-phasically and even the late decay rate exceeds the true slow loss rate of humoral memory observed years prior to the boosting. We argue that mathematical modeling should be used to better optimize sampling schedules to provide more reliable advice about the duration of humoral immunity after repeated vaccinations.

Heart Rate Variability in Normotensive and Hypertensive Adults After a Year of Receiving Oxford/AstraZeneca COVID-19 Vaccine: A Cross-Sectional Observational Study. Background and aim Heart rate variability (HRV) helps in assessing the autonomic nervous system's function, which has been implicated in cardiovascular disease risk. HRV has been found to be deranged in hypertension. In addition, studies have shown that COVID-19 infection and vaccination can affect HRV. However, the long-term effect of HRV on hypertension has not been explored after COVID-19 vaccination. The objective of this study was to observe the HRV in hypertensive adults after one year of receiving the Oxford/AstraZeneca COVID-19 vaccine and to compare it with normotensive adults. Methods The study included 105 normotensives (blood pressure below 120/80 mmHg) and 75 hypertensive participants who had received the Oxford/AstraZeneca COVID-19 vaccine one year prior. HRV was measured using the PowerLab system (ADInstruments) with the participants in a sitting posture. The HRV parameters assessed included the time domain, frequency domain, and nonlinear measures. Data were presented in descriptive and inferential statistical terms, and the parameters of two groups of individuals were compared by either an unpaired t-test or the Mann-Whitney U test. Results A total of 105 normotensive participants with a mean age of 42.51 Â± 9.28 years and 75 hypertensive participants with a mean age of 44.24 Â± 10.19 years comprised the sample (p=0.24). Normotensive individuals had a higher standard deviation of RR intervals, a higher coefficient of variation of RR intervals, a higher standard deviation of heart rate, and a higher percentage of successive differences in RR intervals in the time domain. They also had higher values of very low-frequency power, low-frequency (LF) power, and high-frequency (HF) power in the frequency domain. The LF/HF ratio was not significantly different between the two groups. In

nonlinear analysis, SD2, a measure of long-term heart rate variability, was higher in normotensive individuals. Conclusion The Oxford/AstraZeneca COVID-19 vaccine did not have a significant effect on HRV parameters in normotensive and hypertensive adults one year after vaccination. However, changes in HRV parameters were observed between supine and standing positions, suggesting the importance of postural changes in HRV assessment.

The Effect of COVID-19 Vaccine on Women's Reproductive Health: A Cross-Sectional Study. INTRODUCTION: The coronavirus disease 2019 (COVID-19) vaccine was developed to stimulate acquired immunity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Symptoms of reproductive health abnormalities have been reported following the administration of the adenovirus and mRNA-containing vaccine. Such complaints included irregular menstrual cycles, miscarriages, changes in sexual interest, vaginal bleeding, and decreased milk supply in breastfeeding mothers. This study aimed to explore the effect of the COVID-19 vaccine on the reproductive health of women attending five primary healthcare centers in the western region of Saudi Arabia. METHODS: A cross-sectional study was conducted with 300 women between 15 and 50 years. Five primary healthcare centers were included from May to September 2022. Non-probability convenient sampling technique was used; data were collected via a self-administered questionnaire from women who received any number or type ofÂ COVID-19 vaccine. Data were analyzed using Statistical Package for the Social Sciences (SPSS) version 22 (IBM SPSS Statistics, Armonk, NY, USA). RESULTS: Of those who responded to the questionnaire (297 participants), 74% were married, and 52% had 1-3 children. Of the pregnant women, only 4% lost their pregnancy. In addition, of the breastfeeding mothers, 10% noticed a decrease in milk production after the vaccination. The effect of the vaccination status on decreased libido was 11%. A small proportion (18%) of the participants reported worsening dietary habits after the vaccine. Less than half of the participants (44%) reported a change in the length and amount of the menstrual cycle, and 29%Â worsened premenstrual syndrome (PMS). There was no significant association between the type and the number of doses on the rate of miscarriage (p=0.47), breastmilk production (p=0.47), libido (p=0.11), health diet habits (p=0.15), monthly cycle (p=0.570), heavy menses (p=0.999), and PMS symptoms in the study participants. CONCLUSION: COVID-19 vaccination remains necessary to prevent severe infection and is safe for females of reproductive age, whether trying to get pregnant or lactating, and has no significant effect on the menstrual cycle. This research can be used as a basis when deciding on vaccines in case of future pandemics and remove misinformation and doubts regarding the vaccines that should be adequately addressed.

Differential cellular and humoral immune responses in immunocompromised individuals following multiple SARS-CoV-2 vaccinations. INTRODUCTION: The heterogeneity of the immunocompromised population means some individuals may exhibit variable, weak or reduced vaccine-induced immune responses, leaving them poorly protected from COVID-19 disease despite receiving multiple SARS-CoV-2 vaccinations. There is conflicting data on the immunogenicity elicited by multiple vaccinations in immunocompromised groups. The aim of this study was to measure both humoral and cellular vaccine-induced immunity in several immunocompromised cohorts and to compare them to immunocompetent controls. METHODS: Cytokine release in peptide-stimulated whole blood, and neutralising antibody and baseline SARS-CoV-2 spike-specific IgG levels in plasma were measured in rheumatology patients (n=29), renal transplant recipients (n=46), people living with HIV (PLWH) (n=27) and immunocompetent participants (n=64) post third or fourth vaccination from just one blood sample. Cytokines were measured by ELISA and multiplex array. Neutralising antibody levels in plasma were determined by a 50% neutralising antibody titre assay and SARS-CoV-2 spike specific IgG levels were quantified by ELISA. RESULTS: In infection negative donors, IFN-Î³, IL-2 and neutralising antibody levels were significantly reduced in rheumatology patients (p=0.0014, p=0.0415, p=0.0319, respectively) and renal transplant recipients (p<0.0001, p=0.0005, p<0.0001, respectively)

compared to immunocompetent controls, with IgG antibody responses similarly affected. Conversely, cellular and humoral immune responses were not impaired in PLWH, or between individuals from all groups with previous SARS-CoV-2 infections. DISCUSSION: These results suggest that specific subgroups within immunocompromised cohorts could benefit from distinct, personalised immunisation or treatment strategies. Identification of vaccine non-responders could be critical to protect those most at risk.

Health inequalities in post-COVID-19 outcomes among adults aged 50+ in Europe: has COVID-19 exposed divide between postcommunist countries and Western Europe? BACKGROUND: COVID-19 affected people and countries disproportionately and continues to impact the health of people. The aim is to investigate protective health and socio-geographical factors for post-COVID-19 conditions in adults aged 50 years and older in Europe. METHODS: Using longitudinal data from the Survey of Health, Ageing and Retirement in Europe, collected from June to August 2021, protective factors against post-COVID-19 condition among 1909 respondents who self-reported a positive COVID-19 test result were investigated using multiple logistic regression models. RESULTS: Male adults living outside of Czechia, Poland, Hungary and Slovakia (Visegrad group, V4), who received the COVID-19 vaccination, tertiary or higher education, had a healthy weight (body mass index, BMI 18.5-24.9â€‰kg/m(2)) and no underlying health condition/s, showed protective effects against post-COVID-19 condition. Health inequalities associated with BMI were observed in education attainment and comorbidities, with higher BMI having lower education attainment and higher comorbidities. Health inequality was particularly evident in individuals in V4 with higher obesity prevalence and lower attainment of higher education than those living in other regions in the study. CONCLUSION: Our study suggests that healthy weight and higher education attainment are predictors associated with a lower incidence of post-COVID-19 condition. Health inequality associated with education attainment was particularly relevant in V4. Our results highlight health inequality in which BMI was associated with comorbidities and educational attainment. To reduce obesity prevalence among older people with lower education, raising awareness about the risks of obesity and providing assistance in maintaining a healthy weight are needed.

Living with vaccine-induced immune thrombocytopenia and thrombosis: a qualitative study. OBJECTIVES: To explore the experiences of people up to 18 months after being diagnosed with vaccine-induced immune thrombocytopenia and thrombosis (VITT). DESIGN: A semistructured qualitative study, conducted via Zoom, of a cohort of people with VITT. SETTING: Participants discussed their experiences of hospitalisation and following discharge. PARTICIPANTS: 14 individuals diagnosed with VITT, recruited via a Facebook support group and advertising on Twitter. RESULTS: Thematic analysis identified challenges of obtaining medical care and diagnosis; fear of the severity of symptoms and unclear prognosis; and lack of family support due to isolation imposed by the COVID-19 pandemic. Once home, participants experienced continued significant symptoms; fear of recurrence; inadequate medical knowledge of their condition; and difficulties coping with residual physical disabilities and psychosocial losses. Also reported were feelings of isolation and abandonment due to lack of government support. CONCLUSIONS: This is a significantly challenged group of people, with multiple health, financial, social and psychological losses. These losses have been compounded by experiences of limited governmental and societal recognition of the problems they face.

Chorea following SARS-CoV-2 infection and vaccination: a systematic review of reported cases. OBJECTIVES: Chorea following SARS-CoV-2 infection and vaccination, has been increasingly recognized. We aimed to synthesize clinical and paraclinical characteristics, treatment responses, and outcomes of this neurologic complication. METHODS: We systematically reviewed LitCOVID, the World Health Organization database on COVID-19, and MedRxiv up to March 2023, following a

published protocol. RESULTS: We included 14 chorea cases in patients with SARS-CoV-2 infection and eight following COVID-19 vaccination. Acute or subacute chorea preceded COVID-19 symptoms within 1-3 days or developed up to 3 months after infection. Frequently it was generalized (85.7%), with associated neurological manifestations (encephalopathy 35.7%; other movement disorders 7.1%). After vaccination, chorea had a sudden onset (87.5%) within 2 weeks (75%); 87.5% of cases presented hemichorea, with hemiballismus (37.5%) or other movement disorders; 12.5% presented additional neurological findings. Cerebrospinal fluid was normal in 50% of infected individuals but abnormal in all vaccinated cases. Brain magnetic resonance imaging detected normal basal ganglia in 51.7% of infection cases and 87.5% following vaccination. CONCLUSION: In SARS-CoV-2 infection, chorea may present several pathogenic mechanisms: autoimmune response to infection, direct infection-related injury, or an infection-related complication (i.e., acute disseminated encephalomyelitis, cerebral venous sinus thrombosis, hyperglycemia); also, previous Sydenham chorea may relapse. After COVID-19 vaccination, chorea could be due to an autoimmune reaction or other mechanisms (vaccine-induced hyperglycemia, stroke).

Risk of Herpes Zoster Ophthalmicus After COVID-19 Vaccination in a Large US Health Care Claims Database. PURPOSE: Herpes zoster ophthalmicus (HZO) after COVID-19 vaccination has been reported in numerous case studies. However, no large-scale epidemiologic studies have been conducted to date. The purpose of this study was to determine whether COVID-19 vaccination is associated with an increased risk of HZO. DESIGN: Retrospective before-and-after risk interval analysis. METHODS: RESULTS: In total, 1,959,157 patients received a dose of a COVID-19 vaccine during the study period and met eligibility criteria. A total of 80 individuals without a prior history of HZO were included in the analysis because they developed HZO in the risk or control period. Patients had a mean age of 54.0 years (SDÂ =Â 12.3 years). There were 45 cases of HZO in the risk interval after COVID-19 vaccination. There was not an increased risk of HZO after vaccination with BNT162b2 (IRRÂ =Â 0.90, 95% CI: 0.49-1.69, PÂ =Â .74), mRNA-1273 (IRRÂ =Â 0.74, 95% CI: 0.36-1.54, PÂ =Â .42), or Ad26.COV2.S (IRRÂ =Â 0.50, 95% CI: 0.07-2.56, PÂ =Â .42). CONCLUSIONS: This study found no evidence of increased risk of HZO after COVID-19 vaccination, providing reassurance for patients and providers who may be concerned about the safety profile of the COVID-19 vaccines.

New-onset systemic vasculitis following SARS-CoV-2 infection and vaccination: the trigger, phenotype, and outcome. The global health crisis caused by the COVID-19 pandemic overwhelmed the capacity of healthcare systems to cope with the rapidly spreading infection and its associated complications. Among these complications, autoimmune phenomena such as systemic vasculitis emerged as a significant challenge. Both the SARS-CoV-2 virus and the vaccines developed to combat it appeared to induce clinical manifestations resembling various types of systemic vasculitis, affecting large, medium, and small vessels. These virus- or vaccine-induced vasculitides exhibited a distinct natural history and course from de novo vasculitis, as they were more responsive to steroid therapy and some mild cases even resolved spontaneously. Notably, there have been no confirmed cases of SARS-CoV-2 infection or vaccination triggering variable vessel vasculitis like Behcet's disease or Kawasaki disease. IgA vasculitis, which is predominantly a pediatric condition, was more prevalent in adults after COVID-19 infection and they had a favorable outcome with glucocorticoid treatment. The impact of immunosuppression, especially B-cell-depleting agents, on the immunogenicity of the vaccine was evident, but there was no significant increase in the incidence of SARS-CoV-2 infection in these patients compared to the general population. Considering their relatively benign course, these post-COVID or post-vaccine vasculitides seem to be amenable to 0.8 to 1Â mg/kg prednisolone or equivalent, which could be gradually tapered. The need for immunosuppression and the duration of steroid therapy should be determined on an individual basis. While the world still reels from the perils of a deadly pandemic, the aftermath continues to haunt.

Our narrative review aims to explore the effects of COVID and the vaccine on systemic vasculitis, as well as the effect of disease and immunosuppression on the immunogenicity of the COVID vaccine.

Posterior scleritis following COVID-19 vaccination or infection simulating uveal melanoma in 8 consecutive patients. OBJECTIVES: To determine clinical features and outcomes of posterior scleritis masquerading as uveal melanoma following vaccination against COVID-19 and/or COVID-19 infection. SUBJECTS/METHODS: All patients with posterior scleritis referred to our service to rule out intraocular tumour between February 2021 and June 2022, who previously had COVID-19 vaccination and/or infection (nâ€‰=â€‰8). A retrospective detailed review of patient charts and imaging was carried out. RESULTS: Previous COVID-19 vaccination was documented in 6 patients (75%) and previous COVID-19 infection and vaccination in 2 patients (25%). Demographic features included mean age of 59 years (median 68, range 5-86 years), white race (nâ€‰=â€‰7, 87%), and male sex (nâ€‰=â€‰5, 63%). Mean visual acuity at presentation was 0.24 LogMAR (median 0.18, range 0.0-0.70). The main presenting symptom was blurred vision with pain (nâ€‰=â€‰5, 63%). Features that suggested scleritis and not uveal melanoma included pain (nâ€‰=â€‰6, 75%), anterior scleritis (nâ€‰=â€‰3, 38%), disc oedema (nâ€‰=â€‰1, 13%), choroidal detachment (nâ€‰=â€‰3, 38%), choroidal folds (nâ€‰=â€‰3, 38%), diffusely thickened scleral wall on ultrasonography (nâ€‰=â€‰2, 25%), Tenon's oedema (nâ€‰=â€‰5, 63%), and scleral nodule with medium/high internal reflectivity on ultrasonography (nâ€‰=â€‰4, 50%). Follow-up information at mean of 2 months (range 0.25-7 months) revealed visual acuity at date last seen was mean 0.30 LogMAR (median 0.29, range 0.0-0.54). By 2 months, resolution of "tumour" was noted in 5/6 (83%) patients with follow-up. CONCLUSIONS: Posterior scleritis following COVID-19 vaccination and/or infection can masquerade as choroidal melanoma. At 2 months duration, partial or complete resolution of features with minimal visual consequence was noted.

Safety surveillance of the NVX-CoV2373 COVID-19 vaccine among Koreans aged 18Â years and over. BACKGROUND: In the Republic of Korea (Korea), the NVX-CoV2373 (Novavax) coronavirus disease 2019 (COVID-19) vaccination was administered to 18-year-olds and over from February 14, 2022. This study sought to assess the frequency and severity of reported adverse events following the Novavax COVID-19 vaccination in Korea. METHODS: Adverse events based on two national vaccine safety data were analyzed; the COVID-19 vaccination management system (CVMS) and the text-message survey (TMS). RESULTS: CVMS identified that the reporting rate of adverse events per 100,000 doses were lower after booster doses (84.0) than after dose 1 (254.6) or dose 2 (272.9); and in 65-year-olds and over (83.4) than in 18- to 64-year-olds (168.1). The TMS found that local and systemic adverse events were lower in 65-year-olds and over than in 18- to 64-year-olds (pÂ <Â 0.001). CONCLUSIONS: Overall, we identified no major safety issues and fewer adverse events following the Novavax COVID-19 vaccination among 65-year-olds and over in Korea.

ANCA-associated vasculitis after Pfizer-BioNTech COVID-19 vaccination: two case reports.

Incidence of multiple sclerosis relapses and pseudo-relapses following COVID-19 vaccination. BACKGROUND: The coronavirus disease 2019 (COVID-19) pandemic created an urgency for an effective vaccine. The FDA approved vaccines offered by Pfizer-BioNTech (BNT162b2), ModernaTX (mRNA-1273) and Janssen/Johnson & Johnson (Ad26.COV2.S) have shown minimal side effects (SE) in general population studies. Multiple sclerosis (MS) patients were not specifically represented in the above studies. The MS community is interested in how these vaccines behave in people with MS. In this study, we compare the SE experienced by MS to that of the general population after SARS-CoV-2 vaccination and evaluate their risk of relapses or pseudo-relapses. METHODS: A retrospective, single-site, cohort study of 250 MS patients who received the initial cycle of FDA approved SARS-CoV-2 vaccines with 151 of whom also received an additional booster dose. SE resulting immediately after COVID-19 vaccination were collected as part of the standard clinical care during patient visits.

RESULTS: Out of the studied 250 MS patients, 135 received the first and second doses of BNT162b2 with less than 1% and 4% pseudo-relapses respectively and 79 received the third BNT162b2 dose with a pseudo-relapse rate of 3%. 88 received the mRNA-1273 vaccine with a pseudo-relapse frequency of 2% and 5% after the first and second doses respectively. 70 patients had the mRNA-1273 vaccine booster with a 3% pseudo-relapse rate. 27 received the Ad26.COV2.S first dose, 2 of whom received a second Ad26.COV2.S booster dose, with no reports of MS worsening. No acute relapses were reported in our patient population. All patients experiencing pseudo-relapse symptoms returned to baseline within 96Â h. CONCLUSION: COVID-19 vaccine is safe in patients with MS. Cases of temporary worsening of MS symptoms following SARS-CoV-2 are rare. Our findings support those reported by other recent studies and the CDC recommendation for MS patients to receive the FDA-approved COVID-19 vaccines, including the boosters.

T-Cell Immunity Against Severe Acute Respiratory Syndrome Coronavirus 2 Measured by an Interferon-Î³ Release Assay Is Strongly Associated With Patient Outcomes in Vaccinated Persons Hospitalized With Delta or Omicron Variants. BACKGROUND: We measured T-cell and antibody responses to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in vaccinated patients hospitalized for coronavirus disease 2019 (COVID-19) and explored their potential value to predict outcomes. METHODS: This was a prospective, longitudinal study including vaccinated patients hospitalized with Delta and Omicron SARS-CoV-2 variants. TrimericS-IgG antibodies and SARS-CoV-2 T-cell response were measured using a specific quantitative interferon-Î³ release assay (IGRA). Primary outcome was all-cause 28-day mortality or need for intensive care unit (ICU) admission. Cox models were used to assess associations with outcomes. RESULTS: Of 181 individuals, 158 (87.3%) had detectable SARS-CoV-2 antibodies, 92 (50.8%) showed SARS-CoV-2-specific T-cell responses, and 87 (48.1%) had both responses. Patients who died within 28 days or were admitted to ICU were less likely to have both unspecific and specific T-cell responses in IGRA. In adjusted analyses (adjusted hazard ratio [95% confidence interval]), for the entire cohort, having both T-cell and antibody responses at admission (0.16 [.05-.58]) and Omicron variant (0.38 [.17-.87]) reduced the hazard of 28-day mortality or ICU admission, whereas higher Charlson comorbidity index score (1.27 [1.07-1.51]) and lower oxygen saturation to fraction of inspired oxygen ratio (2.36 [1.51-3.67]) increased the risk. CONCLUSIONS: Preexisting immunity against SARS-CoV-2 is strongly associated with patient outcomes in vaccinated individuals requiring hospital admission for COVID-19. Persons showing both T-cell and antibody responses have the lowest risk of severe outcomes.

COVID-19 Vaccine Adverse Event Detection Based on Multi-Label Classification With Various Label Selection Strategies. Analyzing massive VAERS reports without medical context may lead to incorrect conclusions about vaccine adverse events (VAE). Facilitating VAE detection promotes continual safety improvement for new vaccines. This study proposes a multi-label classification method with various term-and topic-based label selection strategies to improve the accuracy and efficiency of VAE detection. Topic modeling methods are first used to generate rule-based label dependencies from Medical Dictionary for Regulatory Activities terms in VAE reports with two hyper-parameters. Multiple label selection strategies, namely one-vs-rest (OvsR), problem transformation (PT), algorithm adaption (AA), and deep learning (DL) methods, are used in multi-label classification to examine the model performance, respectively. Experimental results indicated that the topic-based PT methods improve the accuracy by up to 33.69% using a COVID-19 VAE reporting data set, which improves the robustness and interpretability of our models. In addition, the topic-based OvsR methods achieve an optimal accuracy of up to 98.88%. The accuracy of the AA methods with topic-based labels increased by up to 87.36%. By contrast, the state-of-art LSTM- and BERT-based DL methods have relatively poor performance with accuracy rates of 71.89% and 64.63%, respectively. Our findings reveal that the proposed method effectively improves the model accuracy and

strengthens VAE interpretability by using different label selection strategies and domain knowledge in multi-label classification for VAE detection.

Risk of herpes zoster following mRNA COVID-19 vaccine administration. BACKGROUND: Adverse events following mRNA COVID-19 vaccines, including herpes zoster (HZ), have been reported. We conducted a cohort study to evaluate the association between mRNA COVID-19 vaccination and subsequent HZ at Kaiser Permanente Southern California (KPSC). RESEARCH DESIGN AND METHODS: The vaccinated cohort consisted of KPSC members who received their first dose of mRNA COVID-19 vaccine (mRNA-1273 and BNT162b2) during 12/2020-05/2021 and were matched to unvaccinated individuals on age and sex. Incident HZ cases occurring within 90â€‰days of follow-up were identified by diagnosis codes and antiviral medications. Cox proportional hazards models estimated adjusted hazard ratios (aHR), comparing HZ incidence between the vaccinated and unvaccinated cohorts. RESULTS: Cohort included 1,052,362 mRNA-1273 recipients, 1,055,461 BNT162b2 recipients, and 1,020,334 comparators. Compared to unvaccinated individuals, aHR for HZ up to 90â€‰days after the second dose of mRNA-1273 and BNT162b2 was 1.14 (1.05-1.24) and 1.12 (1.03-1.22), respectively. In those aged â‰¥50â€‰years not vaccinated with zoster vaccine, aHR was also increased after the second dose of mRNA-1273 (1.18 [1.06-1.33]) and BNT162b2 (1.15 [1.02-1.29]) vaccine vs. unvaccinated individuals. CONCLUSIONS: Our findings suggest a potential increased risk of HZ after a second dose of mRNA vaccines, potentially driven by the increased risk in individuals aged â‰¥50â€‰years without history of zoster vaccination.

Predictors of persistent symptoms after mRNA SARS-CoV-2 vaccine-related myocarditis (myovacc registry). AIMS: Epidemiological surveillance has raised safety concerns for mRNA SARS-CoV-2-vaccination-related myocarditis. We aimed to analyze epidemiological, clinical and imaging findings associated with clinical outcomes in these patients in an international multi-center registry (NCT05268458). METHODS AND RESULTS: Patients with clinical and CMR diagnosis of acute myocarditis within 30 days after mRNA SARS-CoV-2-vaccination were included from five centers in Canada and Germany between 05/21 and 01/22. Clinical follow-up on persistent symptoms was collected. We enrolled 59 patients (80% males, mean age 29 years) with CMR-derived mild myocarditis (hs-Troponin-T 552 [249-1,193] ng/L, CRP 28 [13-51] mg/L; LVEF 57â€‰Â±â€‰7%, LGE 3 [2-5] segments). Most common symptoms at baseline were chest pain (92%) and dyspnea (37%). Follow-up data from 50 patients showed overall symptomatic burden improvement. However, 12/50 patients (24%, 75% females, mean age 37 years) reported persisting symptoms (median interval 228 days) of chest pain (nâ€‰=â€‰8/12, 67%), dyspnea (nâ€‰=â€‰7/12, 58%), with increasing occurrence of fatigue (nâ€‰=â€‰5/12, 42%) and palpitations (nâ€‰=â€‰2/12, 17%). These patients had initial lower CRP, lower cardiac involvement in CMR, and fewer ECG changes. Significant predictors of persisting symptoms were female sex and dyspnea at initial presentation. Initial severity of myocarditis was not associated with persisting complaints. CONCLUSION: A relevant proportion of patients with mRNA SARS-CoV-2-vaccination-related myocarditis report persisting complaints. While young males are usually affected, patients with persisting symptoms were predominantly females and older. The severity of the initial cardiac involvement not predicting these symptoms may suggest an extracardiac origin.

Temporal association between the age-specific incidence of Guillain-BarrÃ© syndrome and SARS-CoV-2 vaccination in Republic of Korea: a nationwide time-series correlation study. BACKGROUND: The incidence of Guillain-BarrÃ© syndrome (GBS) changed significantly during the coronavirus disease 2019 (COVID-19) pandemic. Emerging reports suggest that viral vector-based vaccines may be associated with an elevated risk of GBS. METHODS: In this nationwide time-series correlation study, we examined the age-specific incidence of GBS from January 2011 to August 2022, as well as data on severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccinations and

infections from February 2021 to August 2022. We compared the forecasted estimates of age-specific GBS incidence, using the pre-SARS-CoV-2 period as a benchmark, with the actual incidence observed during the post-vaccination period of the pandemic. Furthermore, we assessed the temporal association between GBS, SARS-CoV-2 vaccinations, and COVID-19 for different age groups. RESULTS: In the age group of 60 and older, the rate ratio was significantly elevated during June-August and November 2021. A significant, strong positive association was observed between viral vector-based vaccines and GBS incidence trends in this age group (r=0.52, p=0.022). For the 30 to 59 years age group, the rate ratio was notably high in September 2021. A statistically significant, strong positive association was found between mRNA-based vaccines and GBS incidence in this age group (r=0.61, p=0.006). CONCLUSION: Viral vector-based SARS-CoV-2 vaccines were found to be temporally associated with an increased risk of GBS, particularly in older adults. To minimize age-specific and biological mechanism-specific adverse events, future vaccination campaigns should adopt a more personalized approach, such as recommending homologous mRNA-based SARS-CoV-2 vaccines for older adults to reduce the heightened risk of GBS.

Schnitzler syndrome associated with recurrent subacute thyroiditis and SARS-CoV-2 vaccine-A case review.

SARS-CoV-2-specific immune responses and clinical outcomes after COVID-19 vaccination in patients with immune-suppressive disease. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) immune responses and infection outcomes were evaluated in 2,686 patients with varying immune-suppressive disease states after administration of two Coronavirus Disease 2019 (COVID-19) vaccines. Overall, 255 of 2,204 (12%) patients failed to develop anti-spike antibodies, with an additional 600 of 2,204 (27%) patients generating low levels (<380â€‰AUâ€‰ml(-1)). Vaccine failure rates were highest in ANCA-associated vasculitis on rituximab (21/29, 72%), hemodialysis on immunosuppressive therapy (6/30, 20%) and solid organ transplant recipients (20/81, 25% and 141/458, 31%). SARS-CoV-2-specific T cell responses were detected in 513 of 580 (88%) patients, with lower T cell magnitude or proportion in hemodialysis, allogeneic hematopoietic stem cell transplantation and liver transplant recipients (versus healthy controls). Humoral responses against Omicron (BA.1) were reduced, although cross-reactive T cell responses were sustained in all participants for whom these data were available. BNT162b2 was associated with higher antibody but lower cellular responses compared to ChAdOx1 nCoV-19 vaccination. We report 474 SARS-CoV-2 infection episodes, including 48 individuals with hospitalization or death from COVID-19. Decreased magnitude of both the serological and the T cell response was associated with severe COVID-19. Overall, we identified clinical phenotypes that may benefit from targeted COVID-19 therapeutic strategies.

Perceptions of COVID-19 vaccine side effects by political affiliation. BACKGROUND: We sought to assess the extent to which subjective experiences of COVID-19 vaccine side effects among US adults are associated with political party identification. METHODS: An online survey was conducted of a national sample of US adults (NÂ =Â 1259) identifying as either Republican or Democrat. RESULTS: There was no significant difference by party identification in the perceived severity of vaccination side effects; however, Republicans were significantly less likely to recommend the vaccine to others in light of their experience (ORÂ =Â 0.40; 95% CI, 0.31-0.51; PÂ <Â 0.001). Republicans also reported having a larger share of COVID-19-vaccinated friends and family who experienced notable side effects (ORÂ =Â 1.31; 95% CI, 1.02-1.68; PÂ <Â 0.05). There was a positive association between respondents' perceived side-effect severity and the proportion of peers who also reported notable side effects (rÂ =Â 0.43; PÂ <Â 0.001). CONCLUSION: Subjective appraisals of the vaccinated may affect broader vaccine acceptability.

Outcomes following SARS-CoV-2 infection in individuals with and without inflammatory rheumatic diseases: a Danish nationwide cohort study. OBJECTIVE: In a setting with an extensive SARS-CoV-

2 test strategy and availability of effective vaccines, we aimed to investigate if patients with inflammatory rheumatic diseases (IRD) face greater risk of contracting SARS-CoV-2 and have a worse prognosis of increased risk of hospitalisation, assisted ventilation and death compared with the general population. METHODS: This was a nationwide, population-based register study that compared outcomes of SARS-CoV-2 infection in Danish patients with IRD (n=66 840) with matched population controls (n=668 400). The study period was from March 2020 to January 2023. Cox regression analyses were used to calculate incidence rate ratios (IRRs) for SARS-CoV-2-related outcomes. RESULTS: We observed a difference in time to first and second positive SARS-CoV-2 test in patients with IRD compared with the general population (IRR 1.06, 95% CI 1.05 to 1.07) and (IRR 1.21, 95% CI 1.15 to 1.27). The risks of hospital contact with COVID-19 and severe COVID-19 were increased in patients with IRD compared with population controls (IRR 2.11, 95% CI 1.99 to 2.23) and (IRR 2.18, 95% CI 1.94 to 2.45). The risks of assisted ventilation (IRR 2.33, 95% CI 1.89 to 2.87) and COVID-19 leading to death were increased (IRR 1.98, 95% CI 1.69 to 2.33). Patients with IRD had more comorbidities compared with the general population. A third SARS-CoV-2 vaccination was associated with a reduced need for hospitalisation with COVID-19 and reduced the risk of death. CONCLUSION: Patients with IRD have a risk of SARS-CoV-2, which nearly corresponds to the general population but had a substantial increased risk of hospitalisation with COVID-19, severe COVID-19, requiring assisted ventilation and COVID-19 leading to death, especially in patients with comorbidities.

An Update in COVID-19 Vaccine Reactions in 2023: Progress and Understanding. It has been 3 years since the coronavirus disease 2019 (COVID-19) pandemic was initially declared, and 2 years have passed since the first COVID-19 vaccines were introduced. Since then, 13.2 billion COVID-19 vaccine doses have been administered worldwide, largely with multiple doses of messenger RNA vaccines. Although mild local and systemic adverse effects after COVID-19 vaccination are common, serious adverse effects following immunization are rare, particularly when compared with the large number of vaccine doses administered. Immediate and delayed reactions are relatively common and present similarly to allergic and hypersensitivity reactions. Despite this, reactions generally do not commonly recur, cause sequelae, or contraindicate revaccination. In this Clinical Management Review, we provide an updated perspective of COVID-19 vaccine reactions, their spectrum and epidemiology, and recommended approaches to evaluation and management.

SARS-CoV-2-specific T cell responses wane profoundly in convalescent individuals 10 months after primary infection. A key question in the coronavirus disease 2019 (COVID-19) pandemic is the duration of specific T cell responses against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) post primary infection, which is difficult to address due to the large-scale COVID-19 vaccination and re-exposure to the virus. Here, we conducted an analysis of the long-term SARS-CoV-2-specific T cell responses in a unique cohort of convalescent individuals (CIs) that were among the first to be infected worldwide and without any possible antigen re-exposure since then. The magnitude and breadth of SARS-CoV-2-specific T cell responses correlated inversely with the time that had elapsed from disease onset and the age of those CIs. The mean magnitude of SARS-CoV-2-specific CD4 and CD8 T cell responses decreased about 82% and 76%, respectively, over the time period of ten months after infection. Accordingly, the longitudinal analysis also demonstrated that SARS-CoV-2-specific T cell responses waned significantly in 75% of CIs during the follow-up. Collectively, we provide a comprehensive characterization of the long-term memory T cell response in CIs, suggesting that robust SARS-CoV-2-specific T cell immunity post primary infection may be less durable than previously expected.

Evaluation of autoantibody profile in healthy subjects after mRNA vaccination against COVID-19. BACKGROUND: SARS-CoV-2 severe acute respiratory syndrome has rapidly spread worldwide since 2019. All scientific and technological forces have concentrated towards the formulation of vaccines to

contain the disease. In less than one year (December 2020) a first messenger RNA vaccine (Comirnaty, BioNTech/Pfizer) was authorized. However, the research community has wondered about possible side effects on the immune system, given the vaccines administration in phase 4. AIM: This study aims to evaluate the mRNA vaccine impact on the development of possible positive autoantibody profile in healthcare workers without any previous underlying pathology, after first, second and booster dose of Pfizer vaccine, by determining: circulating immune complexes concentrations (CIC); anti-myeloperoxidase (MPO) and anti-proteinase 3 (PR3) autoantibodies, the presence of antinuclear antibodies (ANA) and subsequent second level tests (extractable nuclear antigen (ENA) screen, double-strand DNA, extractable nuclear antigen (ANA) profile). METHODS: The subjects were divided according to anti-SARS-CoV-2 IgG RBD antibodies increasing concentrations in: Group IÂ <Â 10 BAU/ml (NÂ =Â 114); Group IIÂ >Â 1000 BAU/ml (NÂ =Â 112); Group IIIÂ >Â 2500 BAU/ml (NÂ =Â 78). RESULTS: Our data show no autoreactive response changes over time in healthy subjects after vaccination. In fact, evaluation of ANA, CIC, anti-MPO, anti-PR3 and the detection of specific autoantigens, did not display significant variations. CONCLUSIONS: The results suggest the exclusion of a correlation between the administration of the vaccine and the possible onset of autoimmune disorders. Nevertheless, further investigations will be needed to test for any long-term side effects on an ever-growing population.

Humoral immune responses associated with control of SARS-CoV-2 breakthrough infections in a vaccinated US military population. BACKGROUND: COVID-19 vaccines have been critical for protection against severe disease following infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) but gaps remain in our understanding of the immune responses that contribute to controlling subclinical and mild infections. METHODS: Vaccinated, active-duty US military service members were enrolled in a non-interventional, minimal-risk, observational study starting in May, 2021. Clinical data, serum, and saliva samples were collected from study participants and were used to characterise the humoral immune responses to vaccination and to assess its impact on clinical and subclinical infections, as well as virologic outcomes of breakthrough infections (BTI) including viral load and infection duration. FINDINGS: The majority of VIRAMP participants had received the Pfizer COVID-19 vaccine and by January, 2022, NÂ =Â 149 had a BTI. The median BTI duration (PCR+ days) was 4 days and the interquartile range was 1-8 days. Participants that were nucleocapsid seropositive prior to their BTI had significantly higher levels of binding and functional antibodies to the spike protein, shorter median duration of infections, and lower median peak viral loads compared to seronegative participants. Furthermore, levels of neutralising antibody, ACE2 blocking activity, and spike-specific IgA measured prior to BTI also correlated with the duration of infection. INTERPRETATION: We extended previous findings and demonstrate that a subset of vaccine-induced humoral immune responses, along with nucleocapsid serostatus are associated with control of SARS-CoV-2 breakthrough infections in the upper airways. FUNDING: This work was funded by the DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) in collaboration with the Defense Health Agency (DHA) COVID-19 funding initiative for the VIRAMP study.

Humoral and cellular BNT162b2 mRNA-based booster vaccine-induced immunity in patients with multiple myeloma and persistence of neutralising antibodies: results of a prospective single-centre cohort study. BACKGROUND: Currently available messenger ribonucleic acid (mRNA)-based vaccines against coronavirus disease (COVID-19) have been shown to be effective even in highly immunocompromised hosts, including patients with multiple myeloma. However, vaccination failure can be observed in all patient groups. METHODS: This prospective study longitudinally assessed the humoral and cellular responses to a third booster dose of BNT162b2 mRNA-based vaccine in patients with myeloma (n = 59) and healthy controls (n = 22) by measuring the levels of anti-spike (S)

antibodies (electro-chemiluminescence immunoassay) including neutralising antibodies and specific T-cells (enzyme-linked immunospot assay) following booster administration. RESULTS: The third booster dose showed a high immunogenicity on the serological level among the patients with multiple myeloma (median anti-S level = 41 binding antibody units [BAUs]/ml pre-booster vs 3902 BAU/ml post-booster, p <0.001; increase in the median neutralising antibody level from 19.8% to 97%, p <0.0001). Four of five (80%) patients with a complete lack of any serological response (anti-S immunoglobulin level <0.8 BAU/ml) after two vaccine doses developed detectable anti-S antibodies after booster vaccination (median anti-S level = 88 BAU/ml post-booster). T-cell responses were largely preserved among the patients with multiple myeloma with no difference from the healthy controls following baseline vaccination (median spot-forming units [SFU]/106Â of peripheral blood mononuclear cells = 193 vs 175, p = 0.711); these responses were augmented significantly after booster administration among the patients with multiple myeloma (median SFU/106Â of peripheral blood mononuclear cells = 235 vs 443, p <0.001). However, the vaccination responses remained highly heterogeneous and diminished over time, with insufficient serological responses occurring even after booster vaccination in a few patients irrespective of the treatment intensity. CONCLUSIONS: Our data demonstrate improvements in humoral and cellular immunity following booster vaccination and support the assessment of the humoral vaccine response in patients with multiple myeloma until a threshold for protection against severe COVID-19 is validated. This strategy can allow the identification of patients who might benefit from additional protective measures (e.g. pre-exposure prophylaxis via passive immunisation).

Studies probe COVID-19 shots' link to rare symptoms. Details emerge for uncommon cases of neurologic complications, blood pressure swings, and other side effects.

Bivalent vaccination against COVID-19 can trigger a humoral response in immunocompromised patients who receive monoclonal antibody prophylaxis.

Effects of Covid-19 Vaccination during Pregnancy on the Obstetric and Neonatal Outcomes in a Tertiary Health Care Center. BACKGROUND: Pregnancy is an immuno-compromised state, and pregnant women with COVID-19 are at an increased risk for adverse pregnancy outcomes. Thus, the Center for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization (ACIP) have advocated for COVID-19 vaccination in pregnant women. COVAXIN and COVISHIELD were the vaccines being used in India in the first phase of vaccination, but limited data exist on pregnancy outcomes regarding SARS-CoV-2 vaccines and pregnancy and lactation. MATERIAL AND METHODS: A retrospective study was conducted which included only women who delivered after 24 weeks gestation. Women with an unknown vaccination status or with past or active COVID-19 infection were excluded. Demographic characteristics, maternal and obstetric outcomes, and fetal and neonatal outcomes were compared between the unvaccinated and vaccinated groups. Statistical analysis was done with Chi-square testing and the Fisher exact test using SPSS-26 software. RESULTS: Deliveries before a gestation of 37 weeks were significantly higher in the unvaccinated group compared to the vaccinated group. Rates of vaginal deliveries and preterm deliveries were found to be higher in the unvaccinated population. Women who had taken COVAXIN had a higher rate of adverse events compared to those who had taken COVISHIELD. CONCLUSION: There were no significant differences in adverse obstetric outcomes attributed to vaccine administration between the vaccinated and unvaccinated pregnant women. The beneficial effects of the vaccines in protecting against COVID-19 infection, particularly in pregnancy, outweigh the minor adverse events associated with vaccine administration.

Case report: Sudden onset optic neuritis shortly after SARS-CoV-2 vaccination in an allogeneic hematopoietic stem cell transplant recipient with chronic graft-vs.-host disease. Hematopoietic stem cell transplantation (HSCT) recipients affected by severe acute respiratory syndrome

coronavirus 2 (SARS-CoV-2) have a high mortality rate. The American Society of Transplantation and Cellular Therapy (ASTCT) and the European Society for Blood and Marrow Transplantation (EBMT) recommend vaccination for these vulnerable populations. However, emerging data suggested that vaccination might elicit immunological adverse events, including an exacerbation of graft-vs.-host disease (GVHD). Herein, we report a case of severe optic neuritis developed shortly after AstraZeneca COVID-19 vaccination in an allogeneic HSCT recipient with underlying chronic GVHD. The patient had a headache 5 days after vaccination, and the disease progressed rapidly to complete blindness 17 days after the vaccination. The diagnosis of optic neuritis was well-confirmed by the presence of an anti-myelin oligodendrocyte glycoprotein antibody and the typical features of MRI image and Ophthalmoscopy. Other differential diagnoses, such as infection or leukemia relapse in the central nervous system (CNS), were carefully excluded. A timely high-dose corticosteroid was administered, and her visual acuity improved rapidly. She returned to her baseline status 1 month later. With more than 1 year of follow-up, no optic neuritis or leukemia relapse was observed. In summary, allogeneic transplant recipients can develop severe optic neuritis after vaccination. Optic neuritis can be an exacerbation of GVHD or rarely a sporadic adverse event of vaccination. Furthermore, our experience indicates that a prompt diagnosis and early steroid treatment are vital for a good recovery.

Long-lasting neutralizing antibodies and T cell response after the third dose of mRNA anti-SARS-CoV-2 vaccine in multiple sclerosis. BACKGROUND AND OBJECTIVES: Long lasting immune response to anti-SARS-CoV-2 vaccination in people with Multiple Sclerosis (pwMS) is still largely unexplored. Our study aimed at evaluating the persistence of the elicited amount of neutralizing antibodies (Ab), their activity and T cell response after three doses of anti-SARS-CoV-2 vaccine in pwMS. METHODS: We performed a prospective observational study in pwMS undergoing SARS-CoV-2 mRNA vaccinations. Anti-Region Binding Domain (anti-RBD) of the spike (S) protein immunoglobulin G (IgG) titers were measured by ELISA. The neutralization efficacy of collected sera was measured by SARS-CoV-2 pseudovirion-based neutralization assay. The frequency of Spike-specific IFNÎ³-producing CD4+ and CD8+ T cells was measured by stimulating Peripheral Blood Mononuclear Cells (PBMCs) with a pool of peptides covering the complete protein coding sequence of the SARS-CoV-2 S. RESULTS: Blood samples from 70 pwMS (11 untreated pwMS, 11 under dimethyl fumarate, 9 under interferon-Î³, 6 under alemtuzumab, 8 under cladribine, 12 under fingolimod and 13 under ocrelizumab) and 24 healthy donors were collected before and up to six months after three vaccine doses. Overall, anti-SARS-CoV-2 mRNA vaccine elicited comparable levels of anti-RBD IgGs, neutralizing activity and anti-S T cell response both in untreated, treated pwMS and HD that last six months after vaccination. An exception was represented by ocrelizumab-treated pwMS that showed reduced levels of IgGs ($p<0.0001$) and a neutralizing activity under the limit of detection ($p<0.001$) compared to untreated pwMS. Considering the occurrence of a SARS-CoV-2 infection after vaccination, the Ab neutralizing efficacy ($p=0.04$), as well as CD4+ ($p=0.016$) and CD8+ ($p=0.04$) S-specific T cells, increased in treated COVID+ pwMS compared to uninfected treated pwMS at 6 months after vaccination. DISCUSSION: Our follow-up provides a detailed evaluation of Ab, especially in terms of neutralizing activity, and T cell responses after anti-SARS-CoV-2 vaccination in MS context, over time, considering a wide number of therapies, and eventually breakthrough infection. Altogether, our observations highlight the vaccine response data to current protocols in pwMS and underline the necessity to carefully follow-up anti-CD20- treated patients for higher risk of breakthrough infections. Our study may provide useful information to refine future vaccination strategies in pwMS.

Longitudinal Association Between Social Isolation and COVID-19 Vaccine Uptake in Japanese Older Citizen: an Observational Study. BACKGROUND: Social isolation is associated with decreased intent to receive vaccination against coronavirus disease 2019 (COVID-19); however, its association with COVID-19 vaccine uptake is unknown. OBJECTIVE: The present study aimed to determine the

association between social isolation and subsequent COVID-19 vaccination using the data from a representative Japanese sample. DESIGN: Longitudinal observational study. PARTICIPANTS: Japanese citizens aged â€‰â‰¥â€‰65Â years who participated in the Quality of Life in COVID-19 Era (QoLCoVE) study which began in March 2020. MAIN MEASURES: Social isolation was assessed in March 2020 using the abbreviated Lubben Social Network Scale, with a score of â€‰â‰¤â€‰11 indicating social isolation. To evaluate the relationship between social isolation at the baseline and COVID-19 vaccine uptake (including reservation for vaccine administration) between August and September 2021, we estimated adjusted risk ratios with 95% CIs using modified Poisson regression with adjustment for potential confounders. KEY RESULTS: A total of 921 participants met the inclusion criteria in the initial survey, of whom 720 (78.2%) completed the follow-up survey. Median age was 70Â years (interquartile range: 66-72), and 329 (45.7%) participants were male. Twenty-one (16.5%) of 127 socially isolated participants, and 48 (8.1%) of 593 non-socially isolated participants did not receive the COVID-19 vaccine. Socially isolated participants were less likely to take COVID-19 vaccine than non-socially isolated participants (adjusted risk ratio 1.98, 95% CI: 1.18-3.32). CONCLUSIONS: Social isolation is associated with reduced COVID-19 vaccine uptake among older adults. To further promote COVID-19 vaccination in the older population, support for social isolation might be necessary.

[Severe aplastic anemia after BTN162b2 mRNA COVID-19 vaccination in a patient undergoing hemodialysis]. Although vaccination against coronavirus infection 2019 (COVID-19) has been found to be effective, reports of adverse reactions continue to appear. We report the development of severe aplastic anemia post BTN162b2 mRNA COVID-19 vaccination in patient undergoing dialysis. The pathogenesis and risk factors for post-vaccination aplastic anemia remain unclear. We must remain vigilant to aplastic anemia following COVID-19 vaccination. The risk of aplastic anemia should be identified, and management methods should be established.

A cohort study reveals different dynamics of SARS-CoV-2-specific antibody formation after Comirnaty and Vaxzevria vaccination. The Coronavirus (COVID-19) Disease Pandemic, caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), has affected millions of people worldwide, prompting a collective effort from the global scientific community to develop a vaccine against it. This study purports to investigate the influence of factors such as sex, age, type of vaccination (Comirnaty, BNT162b2, Pfizer Inc. or Vaxzevria, ChAdOx1-S, Oxford/AstraZeneca), and time since vaccine administration on the process of antibody production. Both of them are based on the introduction of SARS-CoV-2 spike protein (S protein) to the body using different mechanisms (mRNA and recombinant adenovirus, respectively). S protein is responsible for host cell attachment and penetration via its receptor-binding domain (RBD domain). The level of anti-RBD IgG antibodies was tested with an ELISA-based immunodiagnostic assay in serum samples from a total of 1395 patients at 3 time points: before vaccination, after the first dose, and after the second dose. Our novel statistical model, the Generalized Additive Model, revealed variability in antibody production dynamics for both vaccines. Interestingly, no discernible variation in antibody levels between men and women was found. A nonlinear relationship between age and antibody production was observed, characterized by decreased antibody levels for people up to 30 and over 60Â years of age, with a lack of correlation in the middle age range. Collectively, our findings further the understanding of the mechanism driving vaccine-induced immunity. Additionally, we propose the Generalized Additive Model as a standardized way of presenting data in similar research.

Safety and immunogenicity against ancestral, Delta and Omicron virus variants following a booster dose of an inactivated whole-virus COVID-19 vaccine (VLA2001): Interim analysis of an open-label extension of the randomized, controlled, phase 3 COV-COMPARE trial. OBJECTIVES: Booster doses for COVID-19 vaccinations have been shown to amplify the waning immune response after

primary vaccination and to enhance protection against emerging variants of concern (VoCs). Here, we aimed to assess the immunogenicity and safety of a booster dose of an inactivated whole-virus COVID-19 vaccine (VLA2001) after primary vaccination with 2 doses of either VLA2001 or ChAdOx1-S (Oxford-Astra Zeneca), including the cross-neutralization capacity against the Delta and Omicron VoCs. METHODS: This interim analysis of an open-label extension of a randomized, controlled phase 3 trial assessed a single booster dose of an inactivated whole-virus COVID-19 vaccine (VLA2001) in healthy or medically stable adults aged 18 years and above, recruited in 21 clinical sites in the UK, who had previously received two doses of either VLA2001 or ChAdOx1-S. Safety outcomes were frequency and severity of solicited injection site and systemic reactions within 7 days after booster vaccination as well as frequency and severity of any unsolicited adverse events (AE) after up to 6 months. Immunogenicity outcomes were the immune response to ancestral SARS-CoV-2 assessed 14 days post booster expressed as geometric mean titres (GMT), GMT fold ratios and seroconversion of specific neutralizing antibodies and S-protein binding IgG antibodies. Immunogenicity against the Delta and Omicron VoCs was assessed as a post-hoc outcome with a pseudovirus neutralization antibody assay. This study is registered with ClinicalTrials.gov, NCT04864561, and is ongoing. RESULTS: A booster dose of VLA2001 was administered to 958 participants, of whom 712 had been primed with VLA2001, and 246 with ChAdOx1-S. Within 7 days following these booster doses, 607 (63.4%) participants reported solicited injection site reactions, and 487 (50.8%) reported solicited systemic reactions. Up to 14 days post booster, 751 (78.4%) participants reported at least one adverse event. The tolerability profile of a booster dose of VLA2001 was similar in VLA2001-primed and ChAdOx1-S-primed participants. In VLA2001-primed participants, the GMT (95% CI) of neutralizing antibodies increased from 32.5 (22.8, 46.3) immediately before to 521.5 (413.0, 658.6) 2 weeks after administration of the booster dose, this corresponds to a geometric mean fold rise (GMFR) of 27.7 (20.0, 38.5). Compared to 2 weeks after the second priming dose, the GMFR was 3.6 (2.8, 4.7). In the ChAdOx1-S primed group, the GMT (95% CI) of neutralizing antibodies increased from 65.8 (43.9, 98.4) immediately before to 188.3 (140.3, 252.8) 2 weeks after administration of the booster dose, a geometric mean fold rise (GMFR) of 3.0 (2.2, 4.0). Compared to 2 weeks after the second priming dose, the GMFR was 1.6 (1.1, 2.2). For S-protein binding IgG antibodies, the pre- versus post-booster GMT fold ratio (95% CI) was 34.6 (25.0, 48.0) in the VLA2001-primed group and 4.0 (3.0, 5.2) in the ChAdOx1-S-primed group. Compared to 2 weeks after the second priming dose, the GMT fold rise of IgG antibodies was 3.8 (3.2, 4.6) in the VLA2001-primed group and 1.2 (0.9, 1.6) in the ChAdOx1-S-primed group. The GMT against Delta (B.1.617.2) and Omicron (BA.4/5) increased from 4.2 to 260, and from 2.7 to 56.7, respectively, when boosting subjects previously primed with VLA2001. Following the boost, 97% of subjects primed with VLA2001 had detectable Delta- and 94% Omicron-neutralizing antibodies. In subjects primed with ChAdOx1-S, the GMT against Delta and Omicron titres increased from 9.1 to 92.5, and from 3.6 to 12.3, respectively. After boosting, 99% of subjects primed with ChAdOx1-S had detectable Delta- and 70% Omicron-neutralizing antibodies. In both VLA2001 and ChAdOx1-S primed subjects, the additional VLA2001 dose boosted T cell responses against SARS-CoV-2 antigens to levels above those observed before the booster dose. CONCLUSION: A booster dose of VLA2001 was safe and well tolerated after primary immunization with VLA2001 and ChAdOx1-S. The tolerability of a booster dose of VLA2001 was similar to the favourable profile observed after the first and second priming doses. Both in a homologous and a heterologous setting, boosting resulted in higher neutralizing antibody titres than after primary immunization and significant increases in cross-neutralization titres against Delta and Omicron were observed after the booster dose. These data support the use of VLA2001 in booster programmes in ChadOx1-S primed groups.

Effect of SARS-CoV-2 infection on seizure, anxiety, and depression in 107 patients with epilepsy. OBJECTIVE: To study the effects of severe acute respiratory syndrome coronavirus 2(SARS-CoV-2) on epileptic seizures, anxiety, and depression in patients with epilepsy. METHODS: Based on the inclusion and exclusion criteria, an ambispective cohort study was hereby conducted on patients with epilepsy infected with SARS-CoV-2 who visited the outpatient and ward of the Department of Neurology of Xinyang Central Hospital from December 2022 (when the domestic epidemic prevention and control policy was lifted) to February 2023. A face-to-face questionnaire survey involving factors including basic information, vaccination with inactivated COVID-19 vaccines, number of seizures within 2Â months before and after SARS-CoV-2 infection, and scores of anxiety and depression was carried out. RESULTS: A total of 107 patients with epilepsy satisfying the inclusion and exclusion criteria completed the follow-up after 2Â months. It was found that enrolled patients maintained the original dose of antiepileptic drugs, but the frequency of seizures after COVID-19 infection could not be controlled. After infection with SARS-CoV-2, the frequency of seizures in patients with epilepsy in 2Â months increased compared with that before infection (PÂ <Â 0.05). Meanwhile, compared with the vaccinated group, the high-frequency seizure rate of epilepsy in the unvaccinated group was higher. (PÂ <Â 0.05), and the anxiety and depression scores of patients with epilepsy were worse than those before they were infected (PÂ <Â 0.05). CONCLUSION: Being infected with SARS-CoV-2 can increase the number of seizures and aggravate the degree of anxiety and depression in patients with epilepsy. The inactivated vaccine is protective, and the inactivated SARS-CoV-2 vaccine can reduce the rate of high-frequency seizures.

New-Onset Pemphigoid Gestationis Following COVID-19 Vaccination.

Relapse of Evans syndrome following BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine: case report and literature review. INTRODUCTION: Coronavirus disease 2019 (COVID-19) vaccines are considered to be safe. Only few cases of vaccine-induced immune thrombocytopenia or immune hemolysis have been reported so far. Evans syndrome (ES) is a very rare syndrome characterized mainly by warm autoimmune hemolytic anemia (wAIHA) and immune thrombocytopenia (ITP). CASE PRESENTATION: We present a case of a 47-year-old male with a history of wAIHA, diagnosed in 1995 and successfully treated with glucocorticoids, with sustained remission. ITP was diagnosed in May 2016. Due to refractoriness to glucocorticoids, intravenous immunoglobulins (IVIGs), azathioprine and vinblastine, he was splenectomised in April 2017, resulting in complete remission. In May 2021, eight days after the second dose of BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine, he experienced mucocutaneous bleeding. Blood tests showed platelet count (PC) of 8Ã—109/L, while his hemoglobin (Hb) was normal (153 g/L). He was treated with prednisone and azathioprine, without response. On day 28 after vaccine administration, weakness, jaundice and dark brown urine occurred. His laboratory tests: PC 27Ã—109/L, Hb 45 g/L, reticulocytes 10.4%, total bilirubin 106.6 Î¼mol/L, direct bilirubin 19.8 Î¼mol/L, lactate dehydrogenase 633 U/L, haptoglobin Ë,0.08 g/L, and positive Coombs test were consistent with ES relapse. After treatment with glucocorticoids, azathioprine and IVIGs, his blood count finally improved (PC 490Ã—109/L, Hb 109 g/L) and remained stable on day 40 of hospitalization. CONCLUSIONS: Although it is unclear whether the relationship between COVID-19 vaccination and relapse of ES in our patient is coincidental or causal, it highlights the need for monitoring of serious outcomes following vaccination.

Multiregional Population-Based Cohort Study for Evaluation of the Association Between Herpes Zoster and mRNA Vaccinations for Severe Acute Respiratory Syndrome Coronavirus-2: The VENUS Study. BACKGROUND: This study was performed to assess the increased risk of herpes zoster (HZ) associated with mRNA vaccines for coronavirus disease 2019. METHODS: This population-based cohort study was conducted in 4 municipalities in Japan. Individuals covered under public health insurance systems without a history of HZ were followed from October 1, 2020 to November 30,

2021. Incidence rates of HZ within 28 days of BNT162b2 or mRNA-1273 vaccination were compared. Adjusted incidence rate ratios (IRR) and 95% confidence intervals (CI) were estimated using a Poisson regression model, including vaccination status as a time-dependent covariate. Subgroup analyses by sex, age, and municipality were also conducted. RESULTS: A total of 339 548 individuals (median age, 74 years) were identified. During follow up, 296 242 individuals (87.2%) completed the primary series, among whom 289 213 and 7019 individuals received homologous BNT162b2 and mRNA-1273 vaccines, respectively. The adjusted IRRs of the first and second BNT162b2 vaccinations were 1.05 (95% CI, 0.84-1.32) and 1.09 (95% CI, 0.90-1.32), respectively. No cases of HZ were observed after mRNA-1273 vaccination. In subgroup analysis, the adjusted IRR of the second BNT162b2 vaccination was 2.94 (95% CI, 1.41-6.13) in individuals aged <50 years old. CONCLUSIONS: No increased risk of HZ was found after BNT162b2 vaccination in the overall study population. However, an increased risk was observed in the younger subgroup.

Safety and efficacy of dendritic cell vaccine for COVID-19 prevention after 1-Year follow-up: phase I and II clinical trial final result. INTRODUCTION: Interim analysis of phase I and phase II clinical trials of personalized vaccines made from autologous monocyte-derived dendritic cells (DCs) incubated with S-protein of SARS-CoV-2 show that this vaccine is safe and well tolerated. Our previous report also indicates that this vaccine can induce specific T-cell and B cell responses against SARS-CoV-2. Herein, we report the final analysis after 1 year of follow-up regarding its safety and efficacy in subjects of phase I and phase II clinical trials. METHODS: Adult subjects (>18 years old) were given autologous DCs derived from peripheral blood monocytes, which were incubated with the S-protein of SARS-CoV-2. The primary outcome is safety in phase I clinical trials. Meanwhile, optimal antigen dosage is determined in phase II clinical trials. Corona Virus Disease 2019 (COVID-19) and Non-COVID-19 adverse events (AEs) were observed for 1 year. RESULTS: A total of 28 subjects in the phase I clinical trial were randomly assigned to nine groups based on antigen and Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) dosage. In the phase II clinical trial, 145 subjects were randomly grouped into three groups based on antigen dosage. During the 1-year follow-up period, 35.71% of subjects in phase I and 16.54% in phase II had non-COVID AEs. No subjects in phase I experienced moderate-severe COVID-19. Meanwhile, 4.31% of subjects in phase II had moderate-severe COVID-19. There is no difference in both COVID and non-COVID-19 AEs between groups. CONCLUSIONS: After 1 year of follow-up, this vaccine is proven safe and effective for preventing COVID-19. A phase III clinical trial involving more subjects should be conducted to establish its efficacy and see other possible side effects.

Clinical characteristics of unvaccinated or incompletely vaccinated children with neurological manifestations due to SARS-CoV-2 Omicron infection. Omicron generally causes milder disease than previous strains of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), especially in fully vaccinated individuals. However, incompletely vaccinated children may develop Omicron-related complications such as those affecting the central nervous system. To characterize the spectrum of clinical manifestations of neuro-COVID and to identify potential biomarkers associated with clinical outcomes, we recruited 15 children hospitalized for Omicron-related neurological manifestations in three hospitals in Hong Kong (9 boys and 6 girls aged 1-13 years). All were unvaccinated or incompletely vaccinated. Fourteen (93.3%) were admitted for convulsion, including benign febrile seizure (nâ€‰=â€‰7), complex febrile seizure (nâ€‰=â€‰2), seizure with fever (nâ€‰=â€‰3), and recurrent breakthrough seizure (nâ€‰=â€‰2), and the remaining nonconvulsive patient developed encephalopathic state with impaired consciousness. None of the seven children with benign febrile seizure and six of eight children with other neurological manifestations had residual deficits at 9-month follow-up. SARS-CoV-2 RNA was undetectable in the cerebrospinal fluid (CSF) specimens of seven patients who underwent lumbar puncture. Spike-and-wave/sharp waves affecting

the frontal lobes were detected in four of seven (57.1%) patients who underwent electroencephalogram. Children with Omicron-related neurological manifestations had significantly higher blood levels of IL-6 (pâ€‰<â€‰0.001) and CHI3L1 (pâ€‰=â€‰0.022) than healthy controls, and higher CSF levels of IL-6 (pâ€‰=â€‰0.002) than children with non-COVID-19-related febrile illnesses. Higher CSF-to-blood ratios of IL-8 and CHI3L1 were associated with longer length of stay, whereas higher ratios of IL-6 and IL-8 were associated with higher blood tau level. The role of CSF:blood ratio of IL-6, IL-8, and CHI3L1 as prognostic markers for neuro-COVID should be further evaluated.

Does COVID-19 vaccine exacerbate rotator cuff symptoms? A prospective study. BACKGROUND: Shoulder injury related to vaccine administration (SIRVA) is a rare but increasing complication after vaccination. The aim of this study was to increase awareness of post-vaccination shoulder pain and to investigate the effect of the clinical condition of the shoulder before vaccination on the loss of function that may occur after vaccination. METHODS: This prospective study included 65 patients agedâ€‰>â€‰18Â years who were diagnosed with unilateral shoulder impingement and/or bursitis. The first vaccination was performed on the shoulders with rotator cuff symptoms, then the second vaccination was performed on healthy shoulders of same patients as soon as the health system allowed. Pre-vaccination MRI of the symptomatic shoulders of the patients was performed and VAS, ASES and Constant scores were evaluated. At 2Â weeks after vaccination of the symptomatic shoulder,Â scores were reassessed. For the patients with changes in the scores, MRI was performed again and the treatment of all patients was started. A second vaccination was given to asymptomatic shouldersÂ and the patients were recalled two weeks later and theirÂ scores were evaluated. RESULTS: After vaccination, the symptomatic shoulder of 14 patients was affected. No clinical changes were observed in the asymptomatic shouldersÂ after vaccination. The VAS scores of the symptomatic shoulders evaluated after vaccination were significantly higher than theÂ scores evaluated before vaccination (pâ€‰=â€‰0.001). The ASES and Constant scores of symptomatic shoulders evaluated after vaccination were significantly decreased compared to theÂ scores evaluated before vaccination (pâ€‰=â€‰0.001). CONCLUSIONS: Exacerbation of symptoms may occur if symptomatic shoulders are vaccinated.Â Before vaccination, a detailed anamnesis should be taken from the patients and vaccination should be performedÂ to the asymptomatic side.

New Insights into Kidney Disease after COVID-19 Infection and Vaccination: Histopathological and Clinical Findings. In addition to its pulmonary effects, COVID-19 has also been found to cause acute kidney injury (AKI), which has been linked to high mortality rates. In this review, we collected data from 20 clinical studies on post-COVID-19-related AKI and 97 cases of AKI associated with COVID-19 vaccination. Acute tubular injury was by far the most common finding in the kidneys of patients with COVID-19-related AKI. Among patients hospitalized for COVID-19, 34.0% developed AKI, of which 59.0%, 19.1%, and 21.9% were stage 1, 2, and 3, respectively. Though kidney disease and other adverse effects after COVID-19 vaccination overall appear rare, case reports have accumulated suggesting that COVID-19 vaccination may be associated with a risk of subsequent kidney disease. Among the patients with post-vaccination AKI, the most common pathologic findings include crescentic glomerulonephritis (29.9%), acute tubular injury (23.7%), IgA nephropathy (18.6%), ANCA-associated vasculitis (17.5%), minimal change disease (17.5%), and thrombotic microangiopathy (10.3%). It is important to note that crescentic glomerulonephritis appears to be more prevalent in patients who have newly diagnosed renal involvement. The proportions of patients with AKI stages 1, 2, and 3 after COVID-19 vaccination in case reports were 30.9%, 22.7%, and 46.4%, respectively. In general, clinical cases of new-onset and recurrent nephropathy with AKI after COVID-19 vaccination have a positive prognosis. In this article, we also explore the underlying pathophysiological

mechanisms of AKI associated with COVID-19 infection and its vaccination by describing key renal morphological and clinical features and prognostic findings.

The Presence of Lung Cancer Affects SARS-CoV-2 Vaccine Uptake and Attitude in Chinese Patients: A Clinical Cross-Sectional Investigation. With the SARS-CoV-2 mutations evolving and prompt of SARS-CoV-2 vaccines, no information is available on SARS-CoV-2 vaccination status in Chinese patients with lung cancer. An electronic questionnaire including sociodemographic characteristics, vaccine status, side effect post-vaccination, and attitude towards a fourth dose of vaccine was conducted within 1018 Chinese patients with lung cancer from October 18th, 2022, to November 25th, 2022. Among 1018 patients, a total of 75 (13.7%) patients reported acceptable systemic adverse events in those had received the SARS-CoV-2 vaccine (549, 54%), the most common of which was fever (39, 7%). Factors including females (OR, 1.512; 95% CI, 1.076-2.124), residents in the municipality (OR, 2.048; 95% CI, 1.238-3.389), undergoing therapy (OR, 2.897; 95% CI, 1.348-6.226), disagree to vaccines is safe for patients with lung cancer (OR, 3.816; 95% CI, 2.198-6.626) contributed to hesitancy. Among 373 patients had received three doses, half respondents (206, 55.2%) were hesitant to receive a fourth dose due to the safety concern and efficacy towards the variants. In conclusion, low vaccine uptake rates in patients with lung cancer could be improved by increasing confidence in vaccine safety, particularly for those with negative beliefs. Appropriate guidance and individualized vaccination plans that meet the healthcare needs of patients with lung cancer were needed during the constantly evolving pandemic.

Neutralizing antibody levels associated with injectable and aerosolized Ad5-nCoV boosters and BA.2 infection. BACKGROUND: Several COVID-19 vaccines are in widespread use in China. Few data exist on comparative immunogenicity of different COVID-19 vaccines given as booster doses. We aimed to assess neutralizing antibody levels raised by injectable and inhaled aerosolized recombinant adenovirus type 5 (Ad5)-vectored COVID-19 vaccine as a heterologous booster after an inactivated COVID-19 vaccine two-dose primary series. METHODS: Using an open-label prospective cohort design, we recruited 136 individuals who had received inactivated vaccine primary series followed by either injectable or inhaled Ad5-vectored vaccine and measured neutralizing antibody titers against ancestral SARS-CoV-2 virus and Omicron BA.1 and BA.5 variants. We also measured neutralizing antibody levels in convalescent sera from 39 patients who recovered from Omicron BA.2 infection. RESULTS: Six months after primary series vaccination, neutralizing immunity against ancestral SARS-CoV-2 was low and neutralizing immunity against Omicron (B.1.1.529) was lower. Boosting with Ad5-vectored vaccines induced a high immune response against ancestral SARS-CoV-2. Neutralizing responses against Omicron BA.5 were â‰¥Â 80% lower than against ancestral SARS-CoV-2 in sera from prime-boost subjects and in convalescent sera from survivors of Omicron BA.2 infection. Inhaled aerosolized Ad5-vectored vaccine was associated with greater neutralizing titers than injectable Ad5-vectored vaccine against ancestral and Omicron SARS-CoV-2 variants. CONCLUSIONS: These findings support the current strategy of heterologous boosting with injectable or inhaled Ad5-vectored SARS-CoV-2 vaccination of individuals primed with inactivated COVID-19 vaccine.

Urological complications after COVID 19 vaccine according to age, sex and manufacturer. OBJECTIVES: To examine the effects of age, sex, and type of COVID-19 vaccine on urological complications after vaccination with COVID-19. MATERIALS AND METHODS: We used the Vaccine Adverse Event Reporting System (VAERS) data from December 2020 to August 2022 to analyze urological symptoms post-vaccination adverse events (AEs) associated with COVID-19 vaccines authorized for the U.S. POPULATION: We collected AEs after 1-2 dose vaccination in VAERS, but not those after an additional booster shot. Age was divided into three groups (<â€‰18Â years, 18-64Â years, andâ€‰>â€‰64Â years), and compared incidence of AEs after vaccination with either mRNA vaccine (mRNA-1273, Moderna; and BNT162b2, Pfizer-BioNTech) or a viral vector vaccine (JNJ-

78436735, Janssen/Johnson and Johnson) as reported in VAERS data. RESULTS: Cumulative incidence rates (CIRs) of LUTS, voiding symptom, storage symptom, infection, and hematuria were 0.057, 0.282, 0.223, 1.245, and 0.214, respectively. By gender, CIRs OF LUTS, storage symptom, and infection were statistically significantly higher in women, whereas CIRs of voiding symptom and hematuria were statistically significantly higher in men. CIRs of AEs per 100,000 in age groups ofâ€‰<â€‰18Â years, 18-64Â years, andâ€‰>â€‰64Â years were 0.353, 1.403, and 4.067, respectively. All AE types except for voiding symptom displayed the highest CIRs in the Moderna vaccine group. CONCLUSIONS: Based on an updated analysis of available data, the prevalence of urologic complications following administration of COVID-19 vaccines is low. However, specific urologic complications such as gross hematuria are not low in incidence.

PD-1/PD-L1 blockade restores tumor-induced COVID-19 vaccine bluntness. The COVID-19 vaccinations are crucial in protecting against the global pandemic. However, accumulating studies revealed the severely blunted COVID-19 vaccine effectiveness in cancer patients. The PD-1/PD-L1 immune checkpoint blockade (ICB) therapy leads to durable therapeutic responses in a subset of cancer patients and has been approved to treat a wide spectrum of cancers in the clinic. In this regard, it is pivotal to explore the potential impact of PD-1/PD-L1 ICB therapy on COVID-19 vaccine effectiveness during ongoing malignancy. In this study, using preclinical models, we found that the tumor-suppressed COVID-19 vaccine responses are largely reverted in the setting of PD-1/PD-L1 ICB therapy. We also identified that the PD-1/PD-L1 blockade-directed restoration of COVID-19 vaccine effectiveness is irrelevant to anti-tumor therapeutic outcomes. Mechanistically, the restored COVID-19 vaccine effectiveness is entwined with the PD-1/PD-L1 blockade-driven preponderance of follicular helper T cell and germinal center responses during ongoing malignancy. Thus, our findings indicate that PD-1/PD-L1 blockade will greatly normalize the responses of cancer patients to COVID-19 vaccination, while regardless of its anti-tumor efficacies on these patients.

Author Response: SARS-CoV-2 Vaccination Safety in Guillain-BarrÃ© Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy, and Multifocal Motor Neuropathy.

Reader Response: SARS-CoV-2 Vaccination Safety in Guillain-BarrÃ© Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy, and Multifocal Motor Neuropathy.

The vaccine-response in patients with cirrhosis after COVID-19 vaccination: A systematic analysis of 168,245 patients with cirrhosis.

Do COVID-19 viral infection and its mRNA vaccine carry an equivalent risk of myocarditis? Review of the current evidence, insights, and future directions. According to recent epidemiological analysis, the percentage of world population infected with COVID-19 by end of December 2020 is approximately 12.56%(1). COVID induced acute care and ICU hospitalization rates are around 9.22 (95% CI: 18.73-19.51), and 4.14 (95% CI: 4.10-4.18) per 1000 population(1). Although therapeutic strategies such as antivirals, intravenous immunoglobulins and corticosteroids have shown modest efficacy in reducing the disease progression, they are not disease specific and only temper the immune mediated attack on the systemic tissues. Therefore, clinicians started to rely on mRNA COVID-19 vaccines, which are clinically efficacious in reducing the incidence, disease severity and systemic complications of COVID-19 infections. Nevertheless, usage of COVID-19 mRNA vaccines is also associated with cardiovascular complications such as myocarditis and pericarditis. On the other hand, COVID-19 infections itself are associated with cardiovascular complications such as myocarditis. The underlying signaling pathways for occurrence of COVID-19 and mRNA COVID-19 vaccine induced myocarditis are quite different although there is some overlap in autoimmunity and cross reactivity mechanisms. With media reports highlighting the cardiovascular complications of COVID-19 vaccines such as myocarditis, general population have become more hesitant and uncertain regarding the safety and efficacy of these mRNA vaccines. We plan to review the current literature and provide

insights into their pathophysiological mechanisms for myocarditis and offer recommendations for further research studies in this regard. This will hopefully dispel some doubts and encourage more people to be vaccinated for preventing the risk of COVID-19 induced myocarditis and other associated cardiovascular complications.

Rare Case of Thygeson Superficial Punctate Keratitis After COVID-19 Vaccination. PURPOSE: The aim of this study was to elucidate a rare corneal association of the coronavirus disease 2019 (COVID-19) vaccine. Although cases of corneal involvement after vaccination have been reported, we present the first case of Thygeson superficial punctate keratitis (TSPK) linked to the COVID-19 vaccine. METHODS: This study is a case report. RESULTS: A 25-year-old woman was assessed in the ophthalmology clinic for recurrent ocular surface symptoms after receiving the COVID-19 vaccine. She was followed in clinic and was found to have a remitting and recurring pattern of bilateral intraepithelial corneal opacities with associated subepithelial haze primarily overlying the pupillary area. These corneal lesions responded well to topical corticosteroid ophthalmic drops. Based on the clinical appearance, the response to treatment, negative herpes simplex virus serology, and the temporal relationship between vaccination and ocular findings, a diagnosis of COVID-19 vaccine-induced TSPK was suspected. CONCLUSIONS: Although the COVID-19 vaccine remains overwhelmingly safe, clinicians should be aware of possible corneal side effects, including TSPK. Prompt ophthalmic assessment in those presenting with ocular symptoms after vaccination is encouraged.

Incidence of Graft Rejection in Descemet Membrane Endothelial Keratoplasty After COVID-19 mRNA Vaccination. PURPOSE: The aim of this study was to investigate the Descemet membrane endothelial keratoplasty (DMEK) rejection rate after COVID-19 vaccination with an mRNA vaccine. METHODS: This was a multicenter, retrospective cohort study. A total of 198 patients who underwent DMEK between January 2006 and December 2020 were divided into 2 cohorts: consecutive patients who received at least 1 COVID-19 vaccination in 2021 (vaccination started from February 2021 in Japan) and nonvaccinated patients (control cohort). Patients who had a postoperative observation period of less than 90 days were excluded. The main outcome measurement was the incidence of graft rejection. A Cox proportional hazards regression model was used for comparisons with the nonvaccinated group. RESULTS: Six rejection episodes were observed in 198 patients (124 nonvaccinated and 74 vaccinated patients), with 1 occurring in the nonvaccinated group and 5 in the vaccinated group. In the univariate model, vaccination had a significant effect on rejection episodes (P = 0.003). The effect of vaccination was also significant (P = 0.004) after adjusting for covariates. CONCLUSIONS: This study suggests that there may be a higher rejection rate after COVID-19 vaccination in patients who underwent DMEK. Patients should be warned of the rejection risk and its typical symptoms before receiving an mRNA COVID-19 vaccine, although further larger studies are needed to confirm the involvement of vaccination.

Patent Foramen Ovale-associated Stroke and COVID-19 Vaccination. Background: COVID-19 infection has been associated with paradoxical thromboembolism through a patent foramen ovale (PFO) and ischaemic stroke. Such events have not been reported after COVID-19 vaccination. The aim of the present study was to investigate PFO-associated stroke during the mass COVID-19 vaccination in Slovenia. Methods: This prospective study, conducted between 26 December 2020 and 31 March 2022, enrolled consecutive patients (â‰¥18 years) with PFO-associated stroke referred for a percutaneous closure to a single interventional facility in Slovenia. Results: A total of 953,546 people aged between 18 and 70 years received at least one dose of a COVID-19 vaccine approved by the European Medicines Agency. Of the 28 patients presenting with PFO-associated stroke, 12 patients (42.9%) were vaccinated prior to the event, of whom nine were women and three were men, aged between 21 and 70 years. Stroke occurred within 35 days after vaccination in six patients (50%).

Clinical presentation included motor dysphasia, paresis, vertigo, ataxia, paraesthesia, headache, diplopia and hemianopia. At hospital discharge, 11 patients (91.6%) had at least one residual ischaemic lesion. Conclusion: A temporal coincidence of COVID-19 vaccination and PFO-associated stroke has been described. A potential cause-effect relationship may only be hypothesised.

The Incidence and Severity of COVID-19 Infection Post Vaccination in Saudi Arabia. Background Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the causative agent of coronavirus disease 2019 (COVID-19). Presently, there is ongoing continuous research for more therapeutic options with a wide variety of vaccine availability. However, many people have worried about the vaccine's side effects. Hence, the current study was conducted to determine the prevalence of vaccinated individuals, side effects, and the rate of infectivity post vaccination including the three doses of vaccinations. Methods A cross-sectional questionnaire-based survey was conducted using Google Forms (Google, Inc., Mountain View, CA). Five hundred forty-three individuals participated and reported their status of COVID-19 infection, vaccination, and side effects. All the participants from Saudi Arabia received all the vaccine shots including the booster dose. Results Most of the Saudi nationals were fully vaccinated, and most received Pfizer vaccines for their first and second shots. Pain at the injection site was reported as the most common adverse effect followed by fever, headache, fatigue, and joint pain. Conclusion From the findings, it is concluded that most of the population of Saudi Arabia was vaccinated effectively. Pain at the injection site is identified as the primary adverse effect of vaccination. Most of the population is vaccinated with the Pfizer vaccine. Long-term side effect monitoring is recommended with large population studies to confirm the status of vaccines and adverse effects.

Acute Vaccine-Related Encephalopathy and Acute Disseminated Encephalomyelitis (ADEM) After COVID-19 Vaccination: A Case Series From Bangladesh. There are several reported cases of various neurological adverse effects following the COVID-19 vaccination globally. Acute vaccine-related encephalopathy and acute disseminated encephalomyelitis (ADEM) are included among them. Here we are reporting three cases of ADEM and one case of acute vaccine-related encephalopathy from Bangladesh, which have a possible association with COVID-19 vaccines. All three ADEM cases were elderly; two cases developed symptoms after receiving the second dose of the Sinopharm vaccine, and another case after receiving the second dose of the Sinovac vaccine. We have treated another case of acute vaccine-related encephalopathy following receiving the Moderna vaccine. The patients had features of encephalopathy, including altered consciousness and convulsions. The ADEM cases had MRI (magnetic resonance imaging) brain findings suggestive of ADEM. The other case had normal MRI findings. All the cases were treated with intravenous corticosteroids with full recovery, except for one ADEM patient, who developed aspiration pneumonia and died. Though it is not possible to conclude that COVID-19 vaccination is the causative agent behind these cases, this case series will help to increase awareness regarding the early detection and treatment of these serious adverse effects.

Serological Response to COVID-19 and Its Association With Measles-Rubella (MR)-Containing Vaccines. BACKGROUND AND OBJECTIVES: Â Epidemiological studies suggest that coronavirus disease 2019 (COVID-19) has a less severe disease course and a more favorable prognosis among children. Childhood vaccines and heterologous immunity have been suggested as reasons for this. Additionally, the structural similarity between the measles, rubella, and severe acute respiratory syndrome coronavirusÂ 2 (SARS-CoV-2) virus particles may affect immune responses. The objective of this study was to compare COVID-19 antibody titers and disease severity between measles-rubella (MR) vaccinated and unvaccinated children. Additionally, we aimed to evaluate and compare the antibody response in recipients of a single dose and two doses of the MR vaccine. METHODS: Â The study was prospective and comparative and included 90 COVID-19-positive children aged nine

months to 12 years. The study was registered under the clinical trials registry of India (CTRI/2021/01/030363). COVID-19 antibody titers were measured at two weeks, six weeks, and 12 weeks, along with the assessment of MR antibody titers. COVID-19 antibody titers and disease severity were compared between MR-vaccinated and MR-unvaccinated children. The comparison of COVID-19 antibody titers between recipients of a single dose and two doses of MR vaccine was also conducted. RESULTS: The results showed significantly higher median COVID-19 antibody titers at all time points during follow-up in the MR-vaccinated group ($P<0.05$). However, the two groups had no significant difference in the disease severity. Moreover, there was no difference in the antibody titers of MR one dose and two dose recipients. CONCLUSION: Exposure to even a single dose of MR-containing vaccine enhances the antibody response against COVID-19. However, randomized trials are necessary to further explore this subject.

De novo immune complex-mediated membranoproliferative glomerulonephritis after COVID-19 vaccination.

SARS-CoV-2 Infection-and mRNA Vaccine-induced Humoral Immunity among Schoolchildren in Hawassa, Ethiopia. BACKGROUND: With the persisting low vaccination intake, particularly in children of low-and middle-income countries (LMICs), seroepidemiological studies are urgently needed to guide and tailor COVID-19 pandemic response efforts in schools and to put mitigation strategies in place for a future post-pandemic resurgence. However, there is limited data on SARS-CoV-2 infection-induced and vaccine-induced humoral immunity in schoolchildren in LMICs, including Ethiopia. METHODS: As the spike receptor binding domain (RBD) is the major target for neutralization antibodies and useful to predict the correlates of protection, we used an in-house anti-RBD IgG ELISA to assess and compare infection-induced antibody response at two-time points and BNT162b2 (BNT) vaccine-induced antibody response at a one-time point in schoolchildren in Hawassa, Ethiopia. In addition, we measured and compared the levels of binding IgA antibodies to spike RBD of SARS-CoV-2 Wild type, Delta, and Omicron variants in a small subset of unvaccinated and BNT-vaccinated schoolchildren. RESULTS: When we compare SARS-CoV-2 infection-induced seroprevalences among unvaccinated school children (7-19 years) at the two blood sampling points with a 5-month interval, we observed an over 10% increase, from 51.8% (219/419) in the first week of December 2021 (post-Delta wave) to 67.4% (60/89) by the end of May 2022 (post-Omicron wave). Additionally, we found a significant correlation ($p = 0.001$) between anti-RBD IgG seropositivity and a history of having COVID-19-like symptoms. Compared to the levels of SARS-CoV-2 infection-induced anti-RBD IgG antibodies before vaccination, higher levels of BNT vaccine-induced anti-RBD IgG antibodies were observed even in SARS-CoV-2 infection-naÃ¯ve schoolchildren of all age groups ($p = 0.0001$). Importantly, one dose of the BNT vaccine was shown to be adequate to elicit a strong antibody response in schoolchildren with pre-existing anti-RBD IgG antibodies comparable to that of SARS-CoV-2 infection-naive schoolchildren receiving two doses of BNT vaccine, suggesting a single dose administration of the BNT vaccine could be considered for schoolchildren who had prior SARS-CoV-2 infection when a shortage of vaccine supply is a limiting factor to administer two doses irrespective of their serostatus. Despite the small sample size of study participants, the BNT vaccine is shown to be immunogenic and safe for schoolchildren. Irrespective of schoolchildren's vaccination status, we observed a similar pattern of significantly higher levels of IgA antibodies to Delta-RBD than to Omicron-RBD ($p < 0.001$) in a randomly selected subset of schoolchildren, yet comparable to Wuhan-RBD, suggesting these schoolchildren were more likely to have had SARS-CoV-2 infection with Delta variant. Additionally, we noted a broader IgA antibody reactivity to SARS-CoV-2 variants in vaccinated schoolchildren with prior SARS-CoV-2 infection, supporting the superiority of hybrid immunity. CONCLUSION: Our serological data indicate a significant increase in SARS-CoV-2 seroprevalence in children at a post-Omicron five-month follow-up compared to a post-Delta enrolment. Despite the small sample size of

study participants, the BNT vaccine is shown to be immunogenic and safe for schoolchildren. Hybrid immunity would likely provide a broader humoral immunity against Wuhan strain, Delta, and Omicron variants than natural infection or vaccination alone does. However, future longitudinal cohort studies in SARS-CoV-2-naÃ¯ve and COVID-19-recovered schoolchildren receiving the BNT vaccine are needed for a better understanding of the kinetics, breadth, and durability of BNT vaccine-induced multivariant-cross reactive immunity.

Durability of immune response after SARS-CoV-2 vaccination in patients with chronic liver disease. AIM: The present study aimed to evaluate the durability of immune response after basic and booster immunization with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines in patients with chronic liver disease (CLD). METHODS: Patients with CLD and complete basic or booster immunization with SARS-CoV-2 vaccines were included in this study. Based on the vaccination situation, they were divided into the basic immunity group (Basic) and the booster immunity group (Booster), which were then subdivided into four groups according to the time interval from completion of basic immunization or booster immunization to serological specimen collection. The positive rates and antibody titers of novel coronavirus neutralizing antibody (nCoV NTAb) and novel coronavirus spike receptor-binding domain antibody (nCoV S-RBD) were analyzed. RESULTS: A total of 313 patients with CLD were enrolled in this study, including 201 in Basic and 112 in Booster. The positive rates of nCoV NTAb and nCoV S-RBD within 30 days of completing basic immunization were 80.4% and 84.8%, respectively, but decreased rapidly with the extension of vaccination time, and only 29% and 48.4% of patients with CLD remained positive for nCoV NTAb and nCoV S-RBD, respectively, after 120 days of completing basic immunization. Within 30 days of booster immunization, the positive rates of nCoV NTAb and nCoV S-RBD in patients with CLD rapidly increased from 29.0% and 48.4% at the end of basic immunization to 95.2% and 90.5%, and maintained a high level (defined as the positive rate >50%) until 120 days when the positive rates of nCoV NTAb and nCoV S-RBD were still high at 79.5% and 87.2%, respectively. After basic immunization, the time for nCoV NTAb and nCoV S-RBD to turn negative was 120 and 169 days, respectively, and the negative time of nCoV NTAb and nCoV S-RBD was significantly prolonged to 266 days and 329 days, respectively. CONCLUSION: It is safe and effective for patients with CLD to complete basic and booster immunization with SARS-CoV-2 vaccines. After booster immunization, the immune response of patients with CLD was further improved and the durability of the SARS-CoV-2 antibody was significantly prolonged.

Immunity following SARS-CoV-2 vaccination in autoimmune neurological disorders treated with rituximab or ocrelizumab. BACKGROUND: Rituximab (RTX) and ocrelizumab (OCR), B cell-depleting therapy targeting CD20 molecules, affect the humoral immune response after vaccination. How these therapies influence T-cell-mediated immune response against SARS-CoV-2 after immunization remains unclear. We aimed to evaluate the humoral and cellular immune response to the COVID-19 vaccine in a cohort of patients with multiple sclerosis (MS), neuromyelitis optica spectrum disorders (NMOSD), and myasthenia gravis (MG). METHODS: Patients with MS (83), NMOSD (19), or MG (7) undergoing RTX (n=47) or OCR (n=62) treatment were vaccinated twice with the mRNA BNT162b2 vaccine. Antibodies were quantified using the SARS-CoV-2 IgG chemiluminescence immunoassay, targeting the spike protein. SARS-CoV-2-specific T cell responses were quantified by interferon Î³ release assays (IGRA). The responses were evaluated at two different time points (4-8 weeks and 16-20 weeks following the 2nd dose of the vaccine). Immunocompetent vaccinated individuals (n=41) were included as controls. RESULTS: Almost all immunocompetent controls developed antibodies against the SARS-CoV-2 trimeric spike protein, but only 34.09% of the patients, without a COVID-19 history and undergoing anti-CD20 treatment (via RTX or OCR), seroconverted. This antibody response was higher in patients with intervals of longer than 3 weeks between vaccinations. The duration of therapy was significantly shorter in seroconverted patients (median 24

months), than in the non-seroconverted group. There was no correlation between circulating B cells and the levels of antibodies. Even patients with a low proportion of circulating CD19(+) B cells (<1%, 71 patients) had detectable SARS-CoV-2 specific antibody responses. SARS-CoV-2 specific T cell response measured by released interferon Î³ was detected in 94.39% of the patients, independently of a humoral immune response. CONCLUSION: The majority of MS, MG, and NMOSD patients developed a SARS-CoV-2-specific T cell response. The data suggest that vaccination can induce SARS-CoV-2-specific antibodies in a portion of anti-CD20 treated patients. The seroconversion rate was higher in OCR-treated patients compared to those on RTX. The response represented by levels of antibodies was better in individuals, with intervals of longer than 3 weeks between vaccinations.

Structural characterization of a pathogenic antibody underlying vaccine-induced immune thrombotic thrombocytopenia (VITT). Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare but extremely dangerous side effect that has been reported for several adenoviral (Ad)-vectored COVID-19 vaccines. VITT pathology had been linked to production of antibodies that recognize platelet factor 4 (PF4), an endogenous chemokine. In this work we characterize anti-PF4 antibodies obtained from a VITT patient's blood. Intact-mass MS measurements indicate that a significant fraction of this ensemble is comprised of antibodies representing a limited number of clones. MS analysis of large antibody fragments (the light chain, as well as the Fc/2 and Fd fragments of the heavy chain) confirms the monoclonal nature of this component of the anti-PF4 antibodies repertoire, and reveals the presence of a fully mature complex biantennary N-glycan within its Fd segment. Peptide mapping using two complementary proteases and LC-MS/MS analysis were used to determine the amino acid sequence of the entire light chain and over 98% of the heavy chain (excluding a short N-terminal segment). The sequence analysis allows the monoclonal antibody to be assigned to IgG2 subclass and verify that the light chain belongs to the Î»-type. Incorporation of enzymatic de- N -glycosylation into the peptide mapping routine allows the N -glycan in the Fab region of the antibody to be localized to the framework 3 region of the V (H) domain. This novel N -glycosylation site (absent in the germline sequence) is a result of a single mutation giving rise to an NDT motif in the antibody sequence. Peptide mapping also provides a wealth of information on lower-abundance proteolytic fragments derived from the polyclonal component of the anti-PF4 antibody ensemble, revealing the presence of all four subclasses (IgG1 through IgG4) and both types of the light chain (Î» and Îº). The structural information reported in this work will be indispensable for understanding the molecular mechanism of VITT pathogenesis.

Acute Lymphocytic Myocarditis in a Young Male Post-COVID-19. BACKGROUND: Lymphocytic myocarditis is a rare form of myocarditis, associated with a high mortality rate due to a high risk of sudden cardiac death. Lymphocytic myocarditis might present as a relevant extrapulmonary manifestation after coronavirus disease 2019 (COVID-19) infection. Case presentation. We report a case of a 26-year-old male with lymphocytic myocarditis, presenting with a 1-month history of increasing fatigue, palpitations, and shortness of breath. Eight weeks before, he was tested positive for SARS-CoV-2. He had received 2-dose schedule of the COVID-19 mRNA vaccine ComirnatyÂ® (BioNTech/Pfizer) 6 months prior to his admission. Diagnostic work-up by echocardiography and cardiac magnetic resonance (CMR) imaging demonstrated a severely reduced left ventricular function and a strong midmyocardial late gadolinium enhancement (LGE). Histology and immunohistology of the endomyocardial biopsies revealed an acute lymphocytic myocarditis. Immunosuppressive therapy with a steroid taper in combination with azathioprine 300â€‰mg/day was initiated. The patient was equipped with a LifeVestÂ®. On day 17, a non-sustained ventricular tachycardia was documented. Follow-up CMR imaging after 3 months showed a slightly improved systolic left ventricular function, and a strong LGE was still detectable. CONCLUSIONS: The case highlights the significance of recognizing lymphocytic myocarditis correlated to COVID-19. It is important to be vigilant also of a

later presentation of cardiomyopathy in patients diagnosed with COVID-19 due to high mortality without immediate support.

The impact of immunotherapies on COVID-19 case fatality rates during the US vaccination campaign: a multidisciplinary open data analysis using FDA Adverse Event Reporting System and Our World in Data. Introduction: Patients under immunotherapies were excluded from the pivotal trials of vaccinations against the severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2), and no population-level data on disease outcomes such as case fatality rates in relation to vaccination coverage exist. Our study aims to fill this gap by investigating whether CFRs in patients with immunotherapies decrease with increasing vaccination coverage in the total population. Methods: We combined aggregated open source data on COVID-19 vaccination coverage from "Our World in Data" with publicly available anonymized COVID-19 case reports from the FDA Adverse Event Reporting System to compute COVID-19 CFRs for patients under immunotherapy at different vaccination coverage levels in the total population. CFRs at different vaccination coverage levels were then compared to CFRs before vaccination campaign start. Results: While we found an overall decrease in CFRs on population level with increasing vaccination coverage, we found no decrease in people using anti-CD20 or glucocorticoids. Discussion: Risk-mitigation strategies on an individual- and population-level are thus still needed to lower the probability of fatal SARS-CoV2 infection for these vulnerable populations.

Generalized morphea induced by the COVID-19 vaccine in a patient with chronic urticaria. Adverse events following vaccinations have been noted for centuries, but as of recently, discussions concerning these adverse effects have increased due to the COVID-19 pandemic and the consequent delivery of vaccinations. Through presenting new cases of such adverse events and reviewing the literature, we aim to facilitate the recognition of COVID-19 vaccine-induced autoimmune diseases that may occur in the years after the pandemic has been contained. We report on a case of biopsy-proven morphea after the COVID-19 vaccine, in which case the patient developed diffuse skin lesions all over her body. The patient was known to have chronic urticaria and received two doses of the Pfizer-BioNTech COVID-19 vaccines (BioNTech, Fosun Pharma, Pfizer, New York City, USA). The patient started to notice itchy lesions on her arms two months after taking her second dose of the vaccine. This is the first case reported of generalized morphea following COVID-19 vaccination with another autoimmune disease and represents the first case of generalized morphea reported in the Middle East.

Chronic inflammatory demyelinating polyneuropathy after SARS-CoV2 vaccination: update of the literature and patient characterization. Since the beginning of worldwide vaccination against COVID-19 disease, some reports have revealed a possible relationship between SARS CoV2 vaccination and chronic inflammatory demyelinating polyneuropathy (CIDP). We reviewed the available evidences regarding this topic, adding three new cases to those reported so far, with the purpose to outline the characteristics of these post-vaccinal CIDP. Seventeen subjects were studied. A total of 70.6% of CIDP cases were related to viral vector vaccines, most occurring after the administration of the first dose. CIDPs that occurred after the second dose (17%) were temporally associated with mRNA vaccines. The clinical course and electrophysiology of all patients met the criteria for acute-subacute CIDP (A-CIDP). Administration of the viral vector vaccine was significantly correlated with a higher probability of having cranial nerve impairment (pâ€‰=â€‰0.004). The electrophysiological phenotype, laboratory and imaging data, and first-line therapies were substantially similar to those of the classical CIDP. The take-home message of the present paper is that the SARS CoV2 vaccine, especially the AstraZeneca vaccine, may be associated with inflammatory neuropathies with acute onset, often indistinguishable from Guillain-BarrÃ© syndrome (GBS). Hence, the importance of tracked prospectively patients with GBS occurred post-SARS-CoV2 vaccine.

Distinguishing GBS from A-CIDP is crucial because treatment strategies and long-term prognosis are different.

The attitude and knowledge of pediatricians and family physicians toward COVID-19 vaccination in children: A cross-sectional study. COVID-19 vaccines to children are expected to reduce the transmission of the disease to high-risk groups and achieve herd immunity in younger populations. A positive attitude toward COVID-19 vaccination in children among healthcare workers (HCWs) is predicted to reduce parents' hesitancy to vaccinate their children. This study aimed to assess the knowledge and attitude of pediatricians and family physicians toward COVID-19 vaccination in children. A total of 112 pediatricians and 96 family physicians (specialists and residents) were interviewed to assess the level of knowledge, attitude, and perceived safety of COVID-19 vaccines for children. Physicians willing to receive regular COVID-19 vaccination (analogous to the influenza vaccine) had significantly higher knowledge and attitude scores (Pâ€‰<â€‰.05). Multivariate analysis indicated that a higher knowledge score and having at least five years of experience as a specialist were significantly associated with a positive attitude among pediatricians or family physicians (Pâ€‰<â€‰.05). Pfizer/BioNTech was the preferred COVID-19 vaccine in children among physicians of both groups (>67%). Around 71% of physicians believed COVID-19 vaccines for children do not cause or worsen any health condition. Educational and training programs that increase the knowledge of physicians about COVID-19 vaccines and their safety in children are recommended to inform a more positive attitude.

Symptom profiles and vaccination status for COVID-19 after the adjustment of the dynamic zero-COVID policy in China: An observational study. There has been a substantial rise in coronavirus disease 2019 (COVID-19) cases after adjusting the dynamic zero-COVID policy in China. We conducted a survey to investigate the self-perceived symptom profile and its association with vaccination status during this outbreak. There were 552 individuals in this survey. The infected individuals displayed various symptoms associated with different factors. The three most common symptoms were fatigue (92.21%), phlegm (91.49%), and cough (89.31%). Two typical clusters of COVID-19 symptoms were identified through hierarchical clustering: one was the symptoms with a high probability of co-occurrence that primarily involved the upper respiratory tract, and the other was the symptoms with a high prevalence of severe cases that affected multiple systems. Symptoms exhibited distinct across regions. Hebei Province reported the most severe respiratory symptoms, and Chongqing City reported the worst neurological and digestive symptoms. Cough and fatigue occurred together in most regions. Nevertheless, the cough severity of Zhejiang, Liaoning, and Yunnan provinces was lower than in other areas (t-test pâ€‰<â€‰0.001). Regression analysis suggested a potential protective effect of recent vaccination on some symptoms. Compared with people who had been vaccinated within half a year, those for more than 1 year had a higher risk of developing phlegm, cough, vertigo, and nausea (all pâ€‰<â€‰0.05). Our study illustrated the characteristics and symptom profiles of COVID-19 during this wave and provided data supporting its relationship with multiple factors. These findings offered new insights into the recent COVID-19 pandemic in China.

Antibodies against platelet factor 4 and the risk of cerebral venous sinus thrombosis in patients with vaccine-induced immune thrombotic thrombocytopenia. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare complication of adenoviral vector-based vaccines against SARS-CoV-2. This syndrome is caused by antibodies against platelet factor 4 (PF4; CXCL4) that lead to platelet activation and is characterized by thrombocytopenia and thrombosis in unusual locations, including cerebral venous sinus thrombosis (CVST). VITT can be classified based on anti-PF4 antibodies properties inÂ vitro: those that require PF4 to activate platelets (PF4-dependent) and those that can activate platelets without additional PF4 (PF4-independent) in the serotonin release assay. OBJECTIVES: We aim to characterize the relationship of VITT platelet-activating profiles

with CVST. METHODS: We conducted a retrospective cohort study involving patients with confirmed VITT who were tested between March and June 2021. Data were collected with an anonymized form and cases were identified as VITT with high clinical suspicion according to platelet activation assays. Anti-PF4 antibody binding regions on PF4 were further characterized with alanine scanning mutagenesis. RESULTS: Of the patients with confirmed VITT (nÂ = 39), 17 (43.6%) had PF4-dependent antibodies and 22 (56.4%) had PF4-independent antibodies. CVST occurred almost exclusively in PF4-independent patients (11 of 22 vs 1 of 17; PÂ < .05). Additionally, PF4-independent antibodies bound to 2 distinct epitopes on PF4, the heparin-binding region and a site typical for heparin-induced thrombocytopenia antibodies, whereas PF4-dependent antibodies bound to only the heparin-binding region. CONCLUSION: These findings suggest that VITT antibodies that cause PF4-independent platelet activation represent a unique subset of patients more likely to be associated with CVST, possibly due to the 2 different types of anti-PF4 antibodies.

Long-term outcome in vaccine-induced immune thrombocytopenia and thrombosis. BACKGROUND: Rapid diagnosis and treatment has improved outcome of patients with vaccine-induced immune thrombocytopenia and thrombosis (VITT). However, after the acute episode, many questions on long-term management of VITT remained unanswered. OBJECTIVES: To analyze, in patients with VITT, the long-term course of anti-platelet factor 4 (PF4) antibodies; clinical outcomes, including risk of recurrent thrombosis and/or thrombocytopenia; and the effects of new vaccinations. METHODS: 71 patients with serologically confirmed VITT in Germany were enrolled into a prospective longitudinal study and followed for a mean of 79 weeks from March 2021 to January 2023. The course of anti-PF4 antibodies was analyzed by consecutive anti-PF4/heparin immunoglobulin G enzyme-linked immunosorbent assay and PF4-enhanced platelet activation assay. RESULTS: Platelet-activating anti-PF4 antibodies became undetectable in 62 of 71 patients (87.3%; 95% CI, 77.6%-93.2%). In 6 patients (8.5%), platelet-activating anti-PF4 antibodies persisted for >18 months. Five of 71 patients (7.0%) showed recurrent episodes of thrombocytopenia and/or thrombosis; in 4 of them (80.0%), alternative explanations beside VITT were present. After further COVID-19 vaccination with a messenger RNA vaccine, no reactivation of platelet-activating anti-PF4 antibodies or new thrombosis was observed. No adverse events occurred in our patients subsequently vaccinated against influenza, tick-borne encephalitis, varicella, tetanus, diphtheria, pertussis, and polio. No new thrombosis occurred in the 24 patients (33.8%) who developed symptomatic SARS-CoV-2 infection following recovery from acute VITT. CONCLUSION: Once the acute episode of VITT has passed, patients appear to be at low risk for recurrent thrombosis and/or thrombocytopenia.

Association of Self-Reported COVID-19 Vaccination Status with COVID-19 Infection among Adult Long-Term Hematopoietic Cell Transplantation Survivors. Hematopoietic cell transplantation (HCT) recipients experience significant morbidity and mortality from coronavirus disease 19 (COVID-19) infection. Data are limited regarding long-term HCT survivors' uptake of and experiences with COVID-19 vaccination and infection. This study aimed to characterize COVID-19 vaccination uptake, use of other prevention measures, and COVID-19 infection outcomes in adult HCT recipients at our institution. Between July 1, 2021, and June 30, 2022, long-term adult HCT survivors were surveyed regarding overall health, chronic graft-versus-host (cGVHD) status, and experiences with COVID-19 vaccinations, prevention measures, and infections. Patients reported COVID-19 vaccination status, vaccine-related adverse effects, use of nonpharmaceutical prevention measures, and infections. Comparisons by response and vaccination status were performed using the chi-square test and Fisher exact test for categorical variables and the Kruskal-Wallis test for continuous variables. Of 4758 adult HCT survivors who underwent HCT between 1971 and 2021 and consented to participate in annual surveys, 1719 (36%) completed the COVID-19 module, and 1598 of 1705 (94%) reported receiving â‰¥1 dose of COVID-19 vaccine. Severe vaccine-related adverse effects were infrequent (5%).

Among respondents receiving an mRNA vaccine, completion of doses according to the Centers for Disease Control and Prevention's vaccine recommendations at the time of survey return was 2 doses in 675 of 759 (89%), 3 doses in 610 of 778 (78%), and 4 doses in 26 of 55 (47%). Two hundred fifty respondents (15%) reported COVID-19 infection; 25 (10%) required hospitalization. Vaccinated respondents reported significantly higher uptake of household vaccination (1284 of 1404 [91%] versus 18 of 88 [20%]; P < .001) and the use of nonpharmaceutical interventions (P < .001). Vaccinated respondents were significantly less likely to have contracted COVID-19 (85 of 1480 [6%] versus 130 of 190 [68%]; P < .001), as were their household members (149 of 1451 [10%] versus 85 of 185 [46%]; P < .001). Receipt of additional COVID-19 vaccine doses beyond the first dose was associated with a reduced risk of COVID-19 infection (odds ratio, .63; 95% confidence interval, .47 to .85; PÂ =Â .002). Vaccination was well tolerated and associated with a lower risk of COVID-19 infection among HCT survivors and their household contacts. Vaccination and booster doses should be encouraged as part of a multifaceted approach in this high-risk population.

Major cardiovascular events after COVID-19, event rates post-vaccination, antiviral or anti-inflammatory therapy, and temporal trends: Correspondence.

Might chronic spontaneous urticaria develop after SARS-CoV-2 vaccinations?

Omicron Variant-Specific Serological Imprinting Following BA.1 or BA.4/5 Bivalent Vaccination and Previous SARS-CoV-2 Infection: A Cohort Study. BACKGROUND: Continuous evolution of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) outpaces monovalent vaccine cross-protection to new viral variants. Consequently, bivalent coronavirus disease 2019 (COVID-19) vaccines including Omicron antigens were developed. The contrasting immunogenicity of the bivalent vaccines and the impact of prior antigenic exposure on new immune imprinting remains to be clarified. METHODS: In the large prospective ENFORCE cohort, we quantified spike-specific antibodies to 5 Omicron variants (BA.1 to BA.5) before and after BA.1 or BA.4/5 bivalent booster vaccination to compare Omicron variant-specific antibody inductions. We evaluated the impact of previous infection and characterized the dominant antibody responses. RESULTS: Prior to the bivalent fourth vaccine, all participants (N = 1697) had high levels of Omicron-specific antibodies. Antibody levels were significantly higher in individuals with a previous polymerase chain reaction positive (PCR+) infection, particularly for BA.2-specific antibodies (geometric mean ratio [GMR] 6.79, 95% confidence interval [CI] 6.05-7.62). Antibody levels were further significantly boosted in all individuals by receiving either of the bivalent vaccines, but greater fold inductions to all Omicron variants were observed in individuals with no prior infection. The BA.1 bivalent vaccine generated a dominant response toward BA.1 (adjusted GMR 1.31, 95% CI 1.09-1.57) and BA.3 (1.32, 1.09-1.59) antigens in individuals with no prior infection, whereas the BA.4/5 bivalent vaccine generated a dominant response toward BA.2 (0.87, 0.76-0.98), BA.4 (0.85, 0.75-0.97), and BA.5 (0.87, 0.76-0.99) antigens in individuals with a prior infection. CONCLUSIONS: Vaccination and previous infection leave a clear serological imprint that is focused on the variant-specific antigen. Importantly, both bivalent vaccines induce high levels of Omicron variant-specific antibodies, suggesting broad cross-protection of Omicron variants.

SARS-CoV-2 infection and COVID-19 vaccination in cancer patients undergoing immune checkpoint inhibitors. Cancer patients are susceptible to severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). Different antitumor treatments have attracted wide attention in the context of coronavirus disease 2019 (COVID-19), especially immune checkpoint inhibitors (ICIs) that have revolutionized oncology changes. It may also have protective and therapeutic roles in viral infections. In this article, we collected 26 cases of SARS-CoV-2 infection during ICIs therapy and 13 related to COVID-19 vaccination from Pubmed, EMBASE, and Wed of Science. Of these 26 cases, 19 (73.1%) presented mild cases and 7 (26.9%) were severe cases. Melanoma (47.4%) was a common cancer type in mild cases and lung cancer (71.4%) in severe cases (Pâ€‰=â€‰0.016). The results showed

that their clinical outcomes varied widely. Although there are similarities between the immune checkpoint pathway and COVID-19 immunogenicity, ICIs therapy overactivated T cells, which often leads to immune-related adverse events. In fact, the COVID-19 vaccine has been shown to be safe and effective in patients treated with ICIs. In this review, we report the vital clinical observations of SARS-CoV-2 infection or vaccination in cancer patients treated with ICIs and explore the potential interaction between them.

Immediate adverse reactions following COVID-19 vaccination among 16-65-year-old Danish citizens. INTRODUCTION: There is sparse knowledge of immediate adverse reactions following COVID-19 vaccination. OBJECTIVE: This study aimed to estimate the frequency and number of immediate adverse reactions following COVID-19 vaccination in a Danish population. METHODS: The study used data from the Danish population-based cohort study BiCoVac. The frequencies of 20 self-reported adverse reactions were estimated for each vaccine dose stratified by sex, age, and vaccine type. Also, the distributions of number of adverse reactions following each dose were estimated stratified by sex, age, vaccine type, and prior COVID-19 infection. RESULTS: A total of 889,503 citizens were invited and 171,008 (19 %) vaccinated individuals were included in the analysis. The most frequently reported adverse reaction following the first dose of COVID-19 vaccine was redness and/or pain at the injection site (20 %) while following the second and third dose, tiredness was the most frequently reported adverse reaction (22 % and 14 %, respectively). Individuals aged 26-35Â years, females, and those with a prior COVID-19 infection were more likely to report adverse reactions compared with older individuals, males, and those with no prior COVID-19 infection, respectively. Following the first dose, individuals vaccinated with ChAdOx1-2 (AstraZeneca) reported more adverse reactions compared with individuals vaccinated with other vaccine types. Individuals vaccinated with mRNA-1273 (Moderna) reported more adverse reactions following the second and third dose compared with individuals vaccinated with BNT162b2 (Pfizer-BioNTech). CONCLUSION: The frequency of immediate adverse reactions was highest among females and younger persons, however, most of the Danish citizens did not experience immediate adverse reactions following COVID-19 vaccination.

The Incidence of Graves' Hyperthyroidism Before and After COVID-19 Messenger RNA Vaccination. OBJECTIVE: Case reports of postvaccine early-onset Graves' hyperthyroidism (PVGD) after the administration of COVID-19 vaccination have emerged. Our aim was to investigate whether the incidence of Graves' hyperthyroidism (GD) has increased after the introduction of COVID-19 vaccination. METHODS: We compared the incidence of new-onset GD at a single academic center during 2 periods: December 2017 to October 2019 and December 2020 to October 2022, ie, before and after the implementation of COVID-19 vaccinations. We defined PVGD as laboratory-confirmed hyperthyroidism and GD within 4 weeks after the vaccination or clear onset of symptoms of thyrotoxicosis within 4 weeks of vaccination with evidence of hyperthyroidism and GD within 3 months. RESULTS: During the prevaccination period, 803 patients carried diagnoses of GD, and of these, 131 were new. During the postvaccination period, 901 patients carried diagnoses of GD, and of these, 138 were new. There was no statistically significant difference in the incidence of GD (PÂ = .52), age at onset, gender, or race between the 2 groups. Twenty-four of 138 newly diagnosed patients in the post-COVID-19 group met the criteria for PVGD. The median free T4 was higher, but this was not statistically significant (3.9 vs 2.5 ng/dL, PÂ = .05). There were no differences in age, gender, race, antibody titers, or type of vaccination between PVGD and controls. CONCLUSION: There was no increase in new-onset GD after COVID-19 vaccination. Median free T4 was higher in patients with PVGD, but this was not statistically significant.

Impaired Seroconversion After Severe Acute Respiratory Syndrome Coronavirus 2 mRNA Vaccine in Patients With Thymic Epithelial Tumors. INTRODUCTION: Thymic epithelial tumors (TETs) are rare malignancies associated with dysregulation of the immune system and humoral- and cell-mediated

immunity abnormalities. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine is effective in preventing coronavirus disease 2019 morbidity and mortality. The aim of this study was to evaluate the seroconversion in patients with TET after two doses of mRNA vaccine. METHODS: This is a prospective study in which consecutive patients with TET were enrolled before receiving the first dose of SARS-CoV-2 mRNA vaccine (BNT162b2 by Pfizer-BioNTech). SARS-CoV-2 spike-binding immunoglobulin (Ig)G antibody serologic levels were analyzed at different time points, including before first vaccine dose (T0), 1 month after the second dose (T2), and 3 months after the second dose (T3). RESULTS: Overall, 39 patients were included in the analysis. All patients had negative antibody titer results at T0. There were 19 patients (48.7%) in the follow-up with no residual tumor lesion/s (referred as no evidence of disease), and 20 (51.3%) had evidence of disease (ED) and were receiving systemic treatment. Dysregulations of the immune system were diagnosed in 29 patients (74.4%) with Good syndrome (GS) being the most frequent immune disorder (48.7%). At univariate analysis, lack of seroconversion at T2 was significantly associated with ED ($p < 0.001$) and with GS (pÂ = 0.043). A significant association with impaired seroconversion was confirmed at multivariate analysis for ED (pÂ = 0.00101) but not for GS (pÂ = 0.625). CONCLUSIONS: Our data revealed that patients with TET with ED had substantially higher probability of impaired seroconversion after SARS-CoV-2 mRNA vaccine as compared with patients with no evidence of disease.
Lack of Seroconversion Following COVID-19 Vaccination Is an Independent Risk Factor for SARS-CoV-2 Infection in Patients With Inflammatory Bowel Disease: Data from ESCAPE-IBD, an IG-IBD Study.
Value of vaccine and vaccine excipient skin testing to COVID-19 vaccines.
Skin reaction following SARS-CoV-2 vaccine BNT162b2.
Pivoting to protein: the immunogenicity and safety of protein-based NVX-CoV2373 as a heterologous booster for inactivated and viral vector COVID-19 vaccines. INTRODUCTION: Approximately half of the 13.4 billion COVID-19 vaccine doses administered globally were inactivated or viral vector platforms. The harmonization and optimization of vaccine regimens has become a key focus of policymakers and health-care providers and presents an opportunity to reassess the continued use of pandemic-era vaccines. AREAS COVERED: Immunological evidence from studies of various homologous and heterologous regimens has been rapidly published; however, interpretation of these data is complicated by the many vaccine types and highly variable participant viral exposure and vaccination histories. Recent studies demonstrate that after primary series doses of inactivated (i.e. BBV152, and BBIBP-CorV), and viral vector (ChAdOx1 nCov-2019) vaccines, a heterologous boost with protein-based NVX-CoV2373 elicits more potent ancestral strain and omicron-specific antibody responses compared to homologous and heterologous inactivated and viral vector boosts. EXPERT OPINION: While mRNA vaccines likely yield similar performance to protein-based heterologous booster doses, the latter offers notable advantages to countries with high uptake of inactivated and viral vector vaccines in terms of transportation and storage logistics and can potentially appeal to vaccine hesitant individuals. Moving forward, vaccine-mediated protection in inactivated and viral vector recipients may be optimized with the use of a heterologous protein-based booster such as NVX-CoV2373. PIVOTING TO PROTEIN: The Immunogenicity and Safety of Protein-based NVX-CoV2373 as a Heterologous Booster for Inactivated and Viral Vector COVID-19 Vaccines. Inactivated or viral vector primary series following a booster dose with homologous or heterologous inactivated vaccines (i.e., BBV152, BBIBP-CorV), and homologous or heterologous viral vector vaccines (i.e., ChAd-Ox1 nCov-19) induces suboptimal immunogenicity compared to the enhanced immunogenicity of heterologous protein-based vaccine NVX-CoV2373.
COVID-19 Vaccination Acceptability: A Cross-Sectional Study Among Lebanese Residents. OBJECTIVE: Concerns about the side effects of available coronavirus disease (COVID-19) vaccines have

posed a significant barrier to vaccination in several countries. Accordingly, the current study aimed to assess the acceptability of COVID-19 vaccination and its predictors among the Lebanese population. METHODS: A cross-sectional study was conducted in February 2021 among Lebanese adults from the 5 main Lebanese districts. The questionnaire included demographic data, questions about COVID-19 experience, COVID-19 anxiety syndrome scale, and attitudes regarding the COVID-19 vaccine. Data were analyzed on SPSS, version 23. Statistical significance was considered at a P value â‰¤ 0.05 with a 95% CI. RESULTS: Of 811 participants, 45.4% (95% CI: 41.9-48.9) accepted taking the COVID-19 vaccine. Choices were negatively affected by concerns about the side effects of the vaccine and positively affected by anxiety and seeking COVID-19 news very closely. Moreover, if the COVID-19 vaccination was a requirement for traveling, participants would be more willing to get the vaccine. CONCLUSIONS: Since 54.7% of the studied Lebanese adults were either unwilling or undecided to get the vaccine and COVID-19 news was retrieved mainly from the Ministry of Public Health online site and the local news, the existing targeted campaign should be enforced toward encouraging vaccination to reach herd immunity against COVID-19 and revealing the safety of the vaccines.

Gaining perspective on messenger RNA coronavirus disease 2019 vaccination risk.

Exposure of progressive immune dysfunction by SARS-CoV-2 mRNA vaccination in patients with chronic lymphocytic leukemia: A prospective cohort study. BACKGROUND: Patients with chronic lymphocytic leukemia (CLL) have reduced seroconversion rates and lower binding antibody (Ab) and neutralizing antibody (NAb) titers than healthy individuals following Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) mRNA vaccination. Here, we dissected vaccine-mediated humoral and cellular responses to understand the mechanisms underlying CLL-induced immune dysfunction. METHODS AND FINDINGS: We performed a prospective observational study in SARS-CoV-2 infection-naÃ¯ve CLL patients (n = 95) and healthy controls (n = 30) who were vaccinated between December 2020 and June 2021. Sixty-one CLL patients and 27 healthy controls received 2 doses of the Pfizer-BioNTech BNT162b2 vaccine, while 34 CLL patients and 3 healthy controls received 2 doses of the Moderna mRNA-1273 vaccine. The median time to analysis was 38 days (IQR, 27 to 83) for CLL patients and 36 days (IQR, 28 to 57) for healthy controls. Testing plasma samples for SARS-CoV-2 anti-spike and receptor-binding domain Abs by enzyme-linked immunosorbent assay (ELISA), we found that all healthy controls seroconverted to both antigens, while CLL patients had lower response rates (68% and 54%) as well as lower median titers (23-fold and 30-fold; both $p < 0.001$). Similarly, NAb responses against the then prevalent D614G and Delta SARS-CoV-2 variants were detected in 97% and 93% of controls, respectively, but in only 42% and 38% of CLL patients, who also exhibited >23-fold and >17-fold lower median NAb titers (both $p < 0.001$). Interestingly, 26% of CLL patients failed to develop NAbs but had high-titer binding Abs that preferentially reacted with the S2 subunit of the SARS-CoV-2 spike. Since these patients were also seropositive for endemic human coronaviruses (HCoVs), these responses likely reflect cross-reactive HCoV Abs rather than vaccine-induced de novo responses. CLL disease status, advanced Rai stage (III-IV), elevated serum beta-2 microglobulin levels (Î²2m >2.4 mg/L), prior therapy, anti-CD20 immunotherapy (<12 months), and intravenous immunoglobulin (IVIg) prophylaxis were all predictive of an inability to mount SARS-CoV-2 NAbs (all p â‰¤ 0.03). T cell response rates determined for a subset of participants were 2.8-fold lower for CLL patients compared to healthy controls (0.05, 95% CI 0.01 to 0.27, $p < 0.001$), with reduced intracellular IFNÎ³ staining ($p = 0.03$) and effector polyfunctionality ($p < 0.001$) observed in CD4+ but not in CD8+ T cells. Surprisingly, in treatment-naÃ¯ve CLL patients, BNT162b2 vaccination was identified as an independent negative risk factor for NAb generation (5.8, 95% CI 1.6 to 27, $p = 0.006$). CLL patients who received mRNA-1273 had 12-fold higher ($p < 0.001$) NAb titers and 1.7-fold higher (6.5, 95% CI 1.3 to 32, $p = 0.02$) response rates than BNT162b2 vaccinees despite similar disease characteristics. The absence of detectable NAbs in CLL patients was associated with reduced

naÃ¯ve CD4+ T cells (p = 0.03) and increased CD8+ effector memory T cells (p = 0.006). Limitations of the study were that not all participants were subjected to the same immune analyses and that pre-vaccination samples were not available. CONCLUSIONS: CLL pathogenesis is characterized by a progressive loss of adaptive immune functions, including in most treatment-naÃ¯ve patients, with preexisting memory being preserved longer than the capacity to mount responses to new antigens. In addition, higher NAb titers and response rates identify mRNA-1273 as a superior vaccine for CLL patients.

Longitudinal analysis of memory Tfh cells and antibody response following CoronaVac vaccination. The inactivated vaccine CoronaVac is one of the most widely used COVID-19 vaccines globally. However, the longitudinal evolution of the immune response induced by CoronaVac remains elusive compared with other vaccine platforms. Here, we recruited 88 healthy individuals who received 3 doses of CoronaVac vaccine. We longitudinally evaluated their polyclonal and antigen-specific CD4+ T cells and neutralizing antibody response after receiving each dose of vaccine for over 300 days. Both the second and third doses of vaccine induced robust spike-specific neutralizing antibodies, with a third vaccine further increasing the overall magnitude of antibody response and neutralization against Omicron sublineages B.1.1.529, BA.2, BA.4/BA.5, and BA.2.75.2. Spike-specific CD4+ T cells and circulating T follicular helper (cTfh) cells were markedly increased by the second and third dose of CoronaVac vaccine, accompanied by altered composition of functional cTfh cell subsets with distinct effector and memory potential. Additionally, cTfh cells were positively correlated with neutralizing antibody titers. Our results suggest that CoronaVac vaccine-induced spike-specific T cells are capable of supporting humoral immunity for long-term immune protection.

Two Cases of Venous Thromboembolism Shortly After Adenovirus-Based COVID-19 Vaccination. As the coronavirus disease 2019 (COVID-19) global pandemic continues, multiple vaccines have been developed to decrease infection rate and number of deaths. Vaccine administration is especially important as new COVID-19 variants emerge. While the number of severe thromboembolic events reported after adenovirus-based vaccination has gained attention, there is little information regarding the presentation and management of post-vaccination venous thromboembolism (VTE). Here, we present two cases of VTE after the Janssen vaccine administration. In the first case, a 98-year-old African American female with hypertension developed bilateral lower extremity edema that evolved into unilateral lower extremity edema 20-35 days following the Janssen vaccine administration. She was found to have an extensive unilateral proximal femoral deep vein thrombosis (DVT) 35 days after the vaccination. In the second case, a 64-year-old African American female developed ecchymosis and unilateral edema six days after the Janssen vaccine administration. She was found to have proximal superficial vein thrombosis two days later. In both cases, laboratory data, including platelets and anti-heparin antibodies were within normal limits.Â Thus, VTE may be an adverse effect of the Janssen vaccine or any adenovirus-based vaccine, but further surveillance and investigation to elucidate this association are necessary. We advise practitioners to have a high index of suspicion for thrombosis after Janssen vaccine administration, regardless of the presence of thrombocytopenia, and avoidance of heparin products until heparin antibody results return.

Atypical progress of frozen shoulder after COVID-19 vaccination: A case report. BACKGROUND: After vaccination was mandated worldwide, various adverse effects associated with the coronavirus disease 2019 (COVID-19) vaccination, including shoulder pain, have been reported. Here, we report a case of new-onset shoulder pain after BNT162b2 (Comirnaty, Pfizer-BioNTech) mRNA vaccination. CASE SUMMARY: A 50-year-old man visited our rehabilitation center with left shoulder range of motion (ROM) limitation that had persisted for more than 5 mo. The history included no specific noteworthy events, except vaccination. The pain in the patient's left deltoid muscle appeared 1 day after the second BNT162b2 vaccination and intensified to severe pain. The patient self-administered

aspirin, with which the pain subsided immediately, whereas ROM limitation persisted. At the first visit, the patient complained of dull pain and ROM restriction of the left shoulder (flexion 130Â°, abduction 110Â°, and external rotation 40Â°). Among the diagnostic studies conducted for the evaluation of the shoulder, magnetic resonance imaging showed a thickened coracohumeral ligament. Nerve conduction studies and needle electromyography showed no electrodiagnostic abnormalities. The patient received comprehensive rehabilitation for 7 mo and had an overall improvement in pain and ROM of the left shoulder. CONCLUSION: In this case of severe shoulder pain after COVID-19 vaccination that subsided immediately with aspirin treatment, the exact cause and mechanism of pain are unclear. However, the clinical symptoms and diagnostic workups in our report suggest the possibility that the COVID-19 vaccination triggered an immunochemical response that resulted in shoulder pathology.

Correlation between COVID-19 vaccination and diabetes mellitus: A systematic review. BACKGROUND: Coronavirus disease 2019 (COVID-19) is one of the current global public health threats and vaccination is the most effective tool to reduce the spread and decrease the severity of COVID-19. Diabetes is one of the important chronic diseases threatening human health and is a common comorbidity of COVID-19. What is the impact of diabetes on the immunization effect of COVID-19 vaccination? Conversely, does vaccination against COVID-19 exacerbate the severity of pre-existing diseases in patients with diabetes? There are limited and conflicting data on the interrelationship between diabetes and COVID-19 vaccination. AIM: To explore the clinical factors and possible mechanisms underlying the interaction between COVID-19 vaccination and diabetes. METHODS: We conducted a comprehensive search of PubMed, MEDLINE, EMBASE, and Reference Citation Analysis (https://www.referencecitationanalysis.com) online databases, and medRxiv and bioRxiv gray literature using the keywords "SARS-CoV-2", "COVID-19", "vaccine", "vaccination", "antibody", and "diabetes" individually or in combination, with a cut-off date of December 2, 2022. We followed inclusion and exclusion criteria and after excluding duplicate publications, studies with quantifiable evidence were included in the full-text review, plus three manually searched publications, resulting in 54 studies being included in this review. RESULTS: A total of 54 studies were included, from 17 countries. There were no randomized controlled studies. The largest sample size was 350963. The youngest of the included samples was 5 years old and the oldest was 98 years old. The included population included the general population and also some special populations with pediatric diabetes, hemodialysis, solid organ transplantation, and autoimmune diseases. The earliest study began in November 2020. Thirty studies discussed the effect of diabetes on vaccination, with the majority indicating that diabetes reduces the response to COVID-19 vaccination. The other 24 studies were on the effect of vaccination on diabetes, which included 18 case reports/series. Most of the studies concluded that COVID-19 vaccination had a risk of causing elevated blood glucose. A total of 12 of the 54 included studies indicated a "no effect" relationship between diabetes and vaccination. CONCLUSION: There is a complex relationship between vaccination and diabetes with a bidirectional effect. Vaccination may contribute to the risk of worsening blood glucose in diabetic patients and diabetic patients may have a lower antibody response after vaccination than the general population.

Spontaneous reporting of adverse reactions associated with the COVID-19 vaccine in health care professionals: A descriptive observational study conducted in a Portuguese hospital. BACKGROUND: The coronavirus disease 2019 (COVID-19) was classified as a pandemic in March 2020 by the World Health Organization. The Pfizer-BioNTech COVID-19 vaccine was the first to be authorized in the European Union, based on data from phase 1, 2, and 3 clinical trials of limited duration. Concerns have been raised regarding the vaccine's safety profile. Some of the adverse drug reactions (ADRs) associated with vaccines may not have been identified during clinical trials. This study aimed to identify ADRs associated with the Pfizer-BioNTech vaccine in health care professionals

at a Portuguese tertiary university hospital. METHODS: The data used in this analysis consist of ADRs reported through a spontaneous notification system from vaccines administered between December 27, 2020, and January 31, 2021. ADRs were categorized according to the MedDRA terminology. RESULTS: A total of 8,605 Pfizer-BioNTech vaccines were administered to 4568 health care professionals. ADRs were reported among 520 of the vaccines, with an incidence of 13.56% in women and 5.31% in men. The mean age of the population reporting ADRs was 41.52 years, with a standard deviation of 9.83 years. The most frequent ADRs were myalgia (n = 274), headache (n = 199), pyrexia (n = 164), injection site pain (n = 160), fatigue (n = 84), nausea (n = 81), chills (n = 65), lymphadenopathy (n = 64), and arthralgia (n = 53). Hypersensitivity reactions occurred in 15 health care professionals, with no anaphylactic reactions observed. A total of four Important Medical Events were observed, which consisted of two cases of syncope, one case of sudden hearing loss, and one case of transverse myelitis. CONCLUSION: The vaccine was well-tolerated among the study participants. Reactogenicity was greater after the second dose. The incidence of ADRs was higher in women and individuals aged between 40 to 49 years. Systemic adverse reactions were most frequently reported. Systematic monitoring of ADRs of COVID-19 vaccines in real-life context is essential for a more robust establishment of its safety profile.

Central Retinal Vein Occlusion after mRNA COVID-19 Vaccination. A 47-year-old man presented with visual loss in the right eye 8 h after the first dose of a coronavirus disease 2019 (COVID-19) vaccine developed by Pfizer/BioNTech (BNT162b2). The best corrected visual acuity (BCVA) was 20/200. Fundus examination showed dilated and tortuous retinal veins at the posterior pole, retinal hemorrhages throughout the fundus, and macular edema. Fluorescein angiography showed multiple hypofluorescent spots that appeared to be fluorescent block due to retinal hemorrhages and hyperfluorescent leakage from the retinal veins. The eye was diagnosed with central retinal vein occlusion (CRVO). For the treatment of macular edema, intravitreal injection of aflibercept (IVA) was administered and treated with one plus pro re nata regimen. Five IVAs were performed over a 10-month follow-up period, with resolution of macular edema, and the BCVA recovered to 20/20. The patient was young and had no history of diabetes mellitus, hypertension, or atherosclerotic diseases, and his blood tests showed no abnormal findings. Both antigen test and polymerase chain reaction test for COVID-19 were negative, and the antibody test was positive due to vaccination. The development of CRVO in this patient may have been related to COVID-19 vaccination, and the appropriate IVA treatment resulted in a good visual prognosis.

Symmetric DWI hyperintensities in CMT1X patients after SARS-CoV-2 vaccination should not be classified as stroke-like lesions. The interesting case report by Zhang et al on a 39 years-old male with Charcot-Marie-Tooth disease type 1X has several limitations. The causal relation between the two episodes of asyndesis, dysphagia, and dyspnea 37 d after the second dose of the inactivated severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) vaccine (Beijing Institute of Biological Products Co., Ltd., Beijing, China) remains unproven. SARS-CoV-2 vaccination cannot trigger a genetic disorder. It also remains unsupported that the patient had a stroke-like episode (SLE). SLEs occur in mitochondrial disorders but not in hereditary neuropathies. Because of the episodic nature of the neurological symptoms, it is critical to rule out seizures. Overall, the causal relation between vaccination and the neurological complications remains unsupported and the interpretation of symmetric diffusion-weighted imaging lesions on cerebral magnetic resonance imaging should be carefully revised.

Acute macular neuroretinopathy following Moderna COVID-19 vaccination. PURPOSE: To describe the occurrence of an acute macular neuroretinopathy (AMN) after administration of a Moderna COVID-19 Vaccine. METHODS: Case report. RESULTS: A 23-year-old female presented bilateral visual loss one week after the first dose of COVID-19 vaccine. Fundus examination revealed

the classic wedge-shaped lesions with petaloid configuration around both foveas. Hypo-reflective macular lesions are evident in the near-infrared reflectance image. The spectral-domain optical coherence tomography reveled hyperreflectivity of the outer nuclear and plexiform layers, attenuation of the ellipsoid zone and disruption of interdigitation zone corresponding to the lesions. CONCLUSIONS: Despite the large number of doses of COVID-19 vaccines administered worldwide, there are not many reported cases of AMN. Most of them occurred after viral vector vaccines. Described here is one of the few cases that observed a time period of several days after receiving the Moderna messenger RNA vaccine. It is not possible to establish causality although this suggests an inflammatory or autoimmune response to the vaccine.
Cord blood antibodies following BBIBP-CorV (Sinopharm) vaccination during pregnancy. OBJECTIVE: This study aimed to evaluate the maternal and umbilical cord blood antibody levels, after COVID vaccination during pregnancy. METHOD: The women who received the COVID-19 vaccine (Sinopharm) during pregnancy were included. Maternal and cord blood samples were tested to detect the severe acute respiratory syndrome coronavirus 2 receptor binding domain (RBD) specific antibodies. In addition, obstetric information and side effects after vaccination were gathered. RESULT: A total of 23 women were included. Eleven pregnant women took two doses and 12 cases received a single dose of the vaccine. No IgM antibody was detected in any maternal blood or cord blood samples. The RBD-specific Immunoglobulin G (IgG) antibody was positive in mothers receiving 2 doses of the vaccine and their infants. But the antibody titers were under the positive cut-off threshold for the other 12 women who were vaccinated with a single dose. Women who received both doses of vaccine had significantly higher IgG levels than a single dose of Sinopharm (pâ€‰=â€‰.025). The same result was demonstrated in infants born to these mothers (pâ€‰=â€‰.019). CONCLUSION: There was a significant correlation between maternal and neonatal IgG concentrations. Although, receiving both doses of the BBIBP-CorV vaccine (not 1 dose) during pregnancy is highly beneficial for increasing humoral immunity for the mother and fetus.
Vaccination in kidney disease: what did we learn from COVID-19 pandemic. PURPOSE OF REVIEW: Patients with kidney disease were prioritized during COVID-19 vaccination efforts. Initial data on vaccine seroconversion and efficacy were confounded by heterogeneous vaccination regimens as well as response assessments. Recent data have addressed responses to evolving vaccine regimens, and addressed concerns in this high-risk population. RECENT FINDINGS: mRNA vaccines BNT162b2 (Pfizer/BioNTech), mRNA1273 (Moderna) were the predominant vaccines used in two and three-dose regimens. Although population-based studies show reduced rates of seroconversion in kidney disease cohorts, there continues to be evolving efficacy largely due to emerging variants, and utilization of ongoing vaccine development. Recommendations on vaccination regimens now exclude use of monovalent mRNA vaccines, with bivalent vaccines are now the preferred effective vaccination. Individualization and adjustment of immunosuppressive drugs is recommended for maximal serological response in transplant recipients and patient with autoimmune kidney diseases. SUMMARY: Waning responses to initial vaccination regimen, as well as emerging variants of concern have resulted in multiple dose regimens being investigated in patient with kidney disease. Use of bivalent mRNA vaccine is now recommended for initial as well as subsequent vaccine doses.
Reply to the letter "skin manifestations following anti-COVID-19 vaccination: A multicentric study from Turkey: Correspondence".
Maculopapular eruptions following COVID-19 vaccination: Pityriasis rosea or pityriasis rosea-like eruptions?
Prospective interpretation of Covid vaccines. A cross sectional study, Ordu province experience. During the pandemic period, many regulations were made to reduce the spread of the epidemic throughout the country and restrictions were applied. We aimed to interpret the effects of

vaccination status, total number of vaccination doses and preferred vaccine type on the prognostic process of the patients we treated inpatients with the diagnosis of Covid-19 in our pandemic service. The present descriptive cross-sectional study was conducted in Ordu, Turkey. One hundred and fifty-two people participated. 80.9% (nâ€‰=â€‰123) of whom were vaccinated against SARS-Cov-2, and 19.1% (nâ€‰=â€‰29) were unvaccinated. When the treatment processes of the participants were analyzed in general, it was observed that the clinical condition of the individuals who received at least one dose of BNT162b2 vaccine did not worsen (Ï‡(2)â€‰=â€‰40.080; pâ€‰=â€‰.011). It was determined that BNT162b2 vaccine was not among the vaccine preferences of the cases who needed to be transferred to the intensive care unit in this process and whose clinical processes resulted in death during follow-up in intensive care or service after intensive care referral (Ï‡(2)â€‰=â€‰64.417; pâ€‰=â€‰.024). According to these results, our study proves once again the protective role of vaccines against epidemic diseases and their progression.

The onset of de novo autoantibodies in healthcare workers after mRNA based anti-SARS-CoV-2 vaccines: a single centre prospective follow-up study. Nowadays, data concerning the risk of autoimmune disease after SARS-CoV-2 (COVID-19) vaccination is controversial. The aim of this single centre prospective follow-up study was to evaluate whether healthcare workers (HCWs) vaccinated with BNT162b2 mRNA and mRNA-1273 will show a development and/or a persistence of autoantibodies, focussing on the detection of antibodies against nuclear antigens (antinuclear antibodies, ANA). We enrolled 155 HCWs, however only 108 of them received the third dose and were considered for further analysis. Blood samples were collected before vaccine inoculation (T0), at 3 (T1) and 12â€‰months (T2) after the first dose. All samples were analysed for the presence of a) ANA using indirect Immunofluorescence [IIF] (dilutions of 1:80, 1:160. 1:320 and 1:640), and anti-smooth muscle antibodies (ASMA); b) anti-myeloperoxidase (anti-MPO), anti-proteinase 3 (anti-PR3) and anti-citrullinated peptide antibodies (aCCP) [FEIA]; c) anti-phospholipid antibodies (anticardiolipin [aCL], anti-beta-2- glycoprotein I [anti-ÃŸ-2GPI] (Chemiluminescence). Line-blot technology was performed using the following kit: EUROLINE ANA profile 3 plus DFS70 (IgG). Our research suggests that mRNA based anti-SARSCoV-2 vaccines can induce the production of de novo ANA in 22/77(28,57%) of subjects and that the percentage of positivity seems to be directly correlated to the number of vaccine expositions: 6/77 (7,79%) after 2 doses; 16/77 (20,78%) after 3 doses. Since it is known that hyperstimulation of the immune system could lead to autoimmunity, these preliminary results seem to further sustain the idea that the hyperstimulation of the immune system might lead to an autoinflammatory mechanism and eventually to autoimmune disorders. However, the link between SARS-CoV-2 vaccination and the development of autoimmune diseases needs to be further investigated.

[COVID-19 vaccination status among nurses and associated factors in long-term care facilities : Results of aÂ cross-sectional survey within the Covid-Heim project]. BACKGROUND: Nurses working in long-term care facilities were vaccinated first before residents as aÂ matter of priority to protect the latter. Although the vaccination rate of nursing staff eventually rose due to aÂ facility-based vaccination requirement, studies on associated factors of vaccination status are currently not available for the long-term care setting in Germany. OBJECTIVE: Associated factors of COVID-19 vaccination status among nursing staff in long-term care facilities were explored. METHODS: An online survey was conducted between October 26th 2021 and January 31st 2022. AÂ total of 1546 nurses working in long-term care in Germany responded to questions concerning the Covid-19 vaccination campaign. Logistic regression analyses were performed. RESULTS: In this study 8 out of 10 nurses were vaccinated against COVID-19 (80.6%). Approximately 7 out of 10 nurses thought at least aÂ few times about quitting their job since the pandemic began (71.4%). A positive COVID-19 vaccination status was associated with older age, full-time employment, COVID-19 deaths at the

facility and working in northern or western Germany. Frequent thoughts of quitting their job were associated with negative COVID-19 vaccination status. CONCLUSION: The present findings provide evidence on factors associated with the COVID-19 vaccination status of nurses in long-term care facilities in Germany for the first time. Further quantitative as well as qualitative studies are necessary for aÂ more comprehensive understanding of the COVID-19 vaccination decision-making among nurses in long-term care, in order to implement target-oriented future vaccination campaigns in this care setting.

Adverse events following immunisation (AEFI) of COVISHIELD vaccination among healthcare workers in Ghana. OBJECTIVE: To describe the incidence of adverse events following immunisation (AEFI) and determine the factors that affect the onset and duration of AEFI after COVISHIELD vaccination among healthcare workers. DESIGN: Prospective cohort study. SETTING: Tertiary healthcare, Korle-Bu, Ghana. PARTICIPANT: Three thousand and twenty-two healthcare workers at least 18 years of age were followed up for 2â€‰months after receiving two doses of the COVISHIELD vaccine. PRIMARY OUTCOME: The occurrence of the AEFI was identified by self-reporting to the AEFI team members. RESULTS: A total of 3022 healthcare workers had at least one AEFI (incidence rate of 706.0 (95% CI 676.8 to 736.1) per 1000 doses) with an incidence rate of 703.0 (95% CI 673.0 to 732.0) per 1000 doses for non-serious AEFI and an incidence rate of 3.3 (95% CI 1.6 to 6.1) per 1000 doses for serious AEFI. The most commonly reported systemic adverse events were headache (48.6%), fever (28.5%), weakness (18.4%) and body pains (17.9%). The estimated median time to onset of the AEFI following the first-dose vaccination was 19 hours and the median AEFI duration was 40 hours or 2â€‰days. Delayed-onset AEFI occurred in 0.3% after first dose and 0.1% after second dose. Age, sex, previous SARS-CoV-2 infection, history of allergies and comorbidity were not significantly associated with the onset and duration of AEFI. However, participants who used paracetamol seemed to be significantly protected (HR 0.15; 95% CI 0.14, 0.17) from having a long duration of AEFI. CONCLUSION: The results of our study indicate a high incidence of non-serious AEFI and the rare occurrence of serious AEFI after COVISHIELD vaccination in healthcare workers. The rate of AEFI was higher after the first dose than after the second dose. Sex, age, previous SARS-CoV-2 infection, allergies and comorbidity were not significantly associated with the onset and duration of AEFI.

The Relationship Between Psoriasis, COVID-19 Infection and Vaccination During Treatment of Patients. Since the outbreak of the COVID-19 pandemic in December 2019, scientists worldwide have been looking for a way to control this global threat. One of the most successful and practical solutions has been the development and worldwide distribution of the COVID-19 vaccines. However, in a small percentage of cases, vaccination can lead to de novo development or exacerbation of immune or inflammatory conditions such as psoriasis. Due to the immunomodulatory nature of this disease, people affected by psoriasis and other related skin conditions have been encouraged to receive COVID-19 vaccines, which are immunomodulatory by nature. As such, dermatological reactions are possible in these patients, and cases of onset, exacerbation or change in the type of psoriasis have been observed in patients administered with COVID-19 vaccines. Considering the rarity and minor nature of some of these cutaneous reactions to COVID-19 vaccination, there is a general consensus that the benefits of vaccination outweigh the potential risks of experiencing such side effects. Nevertheless, healthcare workers who administer vaccines should be made aware of the potential risks and advise recipients accordingly. Furthermore, we suggest careful monitoring for potentially deleterious autoimmune and hyperinflammatory responses using point-of-care biomarker monitoring.

Evaluation of severe acute respiratory syndrome coronavirus 2 monoclonal antibodies in high-risk solid organ transplant recipients across three major coronavirus disease 2019 variant waves. BACKGROUND: Coronavirus disease 2019 (COVID-19) continues to impact immunocompromised

populations including solid organ transplant recipients (SOTRs). Monoclonal antibodies (mAbs) have shown effectiveness in reducing COVID-19-related hospitalizations and emergency department (ED) visits in SOTRs at different time frames in the COVID-19 pandemic; however, less data exist on the impact of mAbs for SOTRs across variant waves and with the advent of available COVID-19 vaccines. METHODS: This retrospective study included SOTR outpatients who tested positive for SARS-CoV-2 and received mAbs from December 2020 to February 2022 (n = 233); using in-house sequencing of clinical samples, we monitored the emergence of Alpha, Delta, and Omicron variants. The primary outcome was a composite of 29-day COVID-19-related hospitalizations and ED visits. Prespecified secondary outcomes included individual components of the primary endpoint; for patients requiring hospitalization post-mAb administration, we describe their inpatient treatment. RESULTS: A low percentage of SOTRs treated with mAb required hospitalization or an ED visit (14.6% overall); this did not differ across COVID-19 variants (p = .152). Hospitalization and ED visits did not significantly differ between abdominal and cardiothoracic SOTRs. For hospitalized patients, the majority received treatment with corticosteroids and few required intensive care unit (ICU) care. CONCLUSION: Among SOTR outpatients with mild or moderate COVID-19 symptoms, early administration of mAb minimizes the need for hospital care. For patients requiring hospitalization, corticosteroids were common but patients experienced low rates of oxygen supplementation and ICU care. Use of mAbs in SOTRs should be considered early in the disease when therapy is available.

Immune response of heterologous versus homologous prime-boost regimens with adenoviral vectored and mRNA COVID-19 vaccines in immunocompromised patients. Due to rare but major adverse reactions to the AstraZeneca adenoviral ChAdOx1-S-nCoV-19 vaccine (ChAd), German health authorities recommended adults under 60 who received one dose of ChAd, to receive a second dose of the BioNTech mRNA BNT162b2 vaccine (BNT) as a booster. Studies in the general population suggest an enhanced efficacy of the heterologous (ChAd-BNT) compared to the homologous (BNT-BNT) vaccination regimen. However, an analysis of the efficacy in patient populations with a high risk of severe COVID-19 due to acquired immunodeficiency is still missing. We therefore compared both vaccination regimens in healthy controls, patients with gynecological tumors after chemotherapy, patients on dialysis and patients with rheumatic diseases concerning the humoral and cellular immune response. The humoral and cellular immune response differed substantially in healthy controls compared to patients with acquired immunodeficiency. Overall, the most significant differences between the two immunization regimens were found in neutralizing antibodies. These were always higher after a heterologous immunization. Healthy controls responded well to both vaccination regimens. However, the formation of neutralizing antibodies was more pronounced after a heterologous immunization. Dialysis patients, on the other hand, only developed an adequate humoral and particularly cellular immune response after a heterologous immunization. Tumor and rheumatic patients also - to a weaker extent compared to dialysis patients - benefited from a heterologous immunization. In conclusion, the heterologous COVID-19 vaccination regimens (ChAd-BNT) seem to have an advantage over the homologous vaccination regimens, especially in immunocompromised patients such as patients with end-stage kidney disease treated with hemodialysis.

Pre- and post-vaccination characteristics and risk factors for COVID-19 outcomes in a Swedish population-based cohort of COPD patients. RATIONALE: Evidence on risk factors for Coronavirus disease 2019 (COVID-19) outcomes among patients with COPD in relation to COVID-19 vaccination remains limited. The objectives of the present study were to characterise determinants of COVID-19 infection, hospitalisation, intensive care unit (ICU) admission and death in COPD patients in their unvaccinated state compared to when vaccinated. METHODS: We included all COPD patients in the Swedish National Airway Register (SNAR). Events of COVID-19 infection (test and/or healthcare

encounter), hospitalisation, ICU admission and death were identified from 1 January 2020 to 30 November 2021. Using adjusted Cox regression, associations between baseline sociodemographics, comorbidities, treatments, clinical measurements and COVID-19 outcomes, during unvaccinated and vaccinated follow-up time, were analysed. RESULTS: The population-based COPD cohort included 87â€‰472 patients, among whom 6771 (7.7%) COVID-19 infections, 2897 (3.3%) hospitalisations, 233 (0.3%) ICU admissions and 882 (1.0%) COVID-19 deaths occurred. During unvaccinated follow-up, risk of COVID-19 hospitalisation and death increased with age, male sex, lower education, non-married status and being foreign-born. Comorbidities increased risk of several outcomes, e.g. respiratory failure for infection and hospitalisation (adjusted hazard ratios (HR) 1.78, 95% CI 1.58-2.02 and 2.51, 2.16-2.91, respectively), obesity for ICU admission (3.52, 2.29-5.40) and cardiovascular disease for mortality (2.80, 2.16-3.64). Inhaled COPD therapy was associated with infection, hospitalisation and death. COPD severity was also associated with COVID-19, especially hospitalisation and death. Although the risk factor panorama was similar, COVID-19 vaccination attenuated HRs for some risk factors. CONCLUSION: This study provides population-based evidence on predictive risk factors for COVID-19 outcomes and highlights the positive implications of COVID-19 vaccination for COPD patients.

A comparative analysis on serious adverse events reported for COVID-19 vaccines in adolescents and young adults. This study aims to assess the safety profile of COVID-19 vaccines (mRNA and viral vector vaccines) in teenagers and young adults, as compared to Influenza and HPV vaccines, and to early data from Monkeypox vaccination in United States. METHODS: We downloaded data from the Vaccine Adverse Event Reporting System (VAERS) and collected the following Serious Adverse Events (SAEs) reported for COVID-19, Influenza, HPV and Monkeypox vaccines: deaths, life-threatening illnesses, disabilities, hospitalizations. We restricted our analysis to the age groups 12-17 and 18-49, and to the periods December 2020 to July 2022 for COVID-19 vaccines, 2010-2019 for Influenza vaccines, 2006-2019 for HPV vaccines, June 1, 2022 to November 15, 2022 for Monkeypox vaccine. Rates were calculated in each age and sex group, based on an estimation of the number of administered doses. RESULTS: Among adolescents the total number of reported SAEs per million doses for, respectively, COVID-19, Influenza and HPV vaccines were 60.73, 2.96, 14.62. Among young adults the reported SAEs rates for, respectively, COVID-19, Influenza, Monkeypox vaccines were 101.91, 5.35, 11.14. Overall, the rates of reported SAEs were significantly higher for COVID-19, resulting in a rate 19.60-fold higher than Influenza vaccines (95% C.I. 18.80-20.44), 4.15-fold higher than HPV vaccines (95% C.I. 3.91-4.41) and 7.89-fold higher than Monkeypox vaccine (95% C.I. 3.95-15.78). Similar trends were observed in teenagers and young adults with higher Relative Risks for male adolescents. CONCLUSION: The study identified a risk of SAEs following COVID-19 vaccination which was markedly higher compared to Influenza vaccination and substantially higher compared to HPV vaccination, both for teenagers and young adults, with an increased risk for the male adolescents group. Initial, early data for Monkeypox vaccination point to significantly lower rates of reported SAEs compared to those for COVID-19 vaccines. In conclusion these results stress the need of further studies to explore the bases for the above differences and the importance of accurate harm-benefit analyses, especially for adolescent males, to inform the COVID-19 vaccination campaign.

Do COVID-19 Vaccinations Affect the Most Common Post-COVID Symptoms? Initial Data from the STOP-COVID Register-12-Month Follow-Up. Around the world, various vaccines have been developed to prevent the SARS-CoV-2 virus infection and consequently the COVID-19 disease. However, many patients continue to report persistent symptoms after the acute phase. Since gathering scientific information on long COVID and post-COVID syndrome has become an urgent issue, we decided to investigate them in relation to the vaccination status of patients from the STOP-COVID registry. In this retrospective study, we analyzed data from the medical visit after contraction

of COVID-19 and follow-up visits in the 3rd and 12th month after the disease. In total, 801 patients were included in the analysis. The most frequent complaints after 12 months included deterioration of exercise tolerance (37.5%), fatigue (36.3%), and memory/concentration difficulties (36.3%). In total, 119 patients declared that they had been diagnosed with at least one new chronic disease since the end of isolation, and 10.6% required hospitalization. The analysis of individual symptoms revealed that headache ($p = 0.001$), arthralgia ($p = 0.032$), and dysregulation of hypertension ($p = 0.030$) were more common in unvaccinated patients. Considering headache and muscle pain, people vaccinated after the disease manifested these symptoms less frequently. Subsequent research is needed to consider vaccines as a preventive factor for post-COVID syndrome.

A Recent SARS-CoV-2 Infection Enhances Antibody-Dependent Cellular Cytotoxicity against Several Omicron Subvariants following a Fourth mRNA Vaccine Dose. Since the beginning of the SARS-CoV-2 pandemic, several variants of concern (VOCs), such as the Alpha, Beta, Gamma, Delta and Omicron variants, have arisen and spread worldwide. Today, the predominant circulating subvariants are sublineages of the Omicron variant, which have more than 30 mutations in their Spike glycoprotein compared to the ancestral strain. The Omicron subvariants were significantly less recognized and neutralized by antibodies from vaccinated individuals. This resulted in a surge in the number of infections, and booster shots were recommended to improve responses against these variants. While most studies mainly measured the neutralizing activity against variants, we and others previously reported that Fc-effector functions, including antibody-dependent cellular cytotoxicity (ADCC), play an important role in humoral responses against SARS-CoV-2. In this study, we analyzed Spike recognition and ADCC activity against several Omicron subvariants by generating cell lines expressing different Omicron subvariant Spikes. We tested these responses in a cohort of donors, who were recently infected or not, before and after a fourth dose of mRNA vaccine. We showed that ADCC activity is less affected than neutralization by the antigenic shift of the tested Omicron subvariant Spikes. Moreover, we found that individuals with a history of recent infection have higher antibody binding and ADCC activity against all Omicron subvariants than people who were not recently infected. With an increase in the number of reinfections, this study helps better understand Fc-effector responses in the context of hybrid immunity.

Durable Anti-SARS-CoV-2 Antibody Response after mRNA-1273 Booster in Peritoneal Dialysis Patients during the Omicron Wave. Anti-SARS-CoV-2 vaccination of dialysis patients has been proven to be safe and effective to reduce COVID-19-related morbidity and mortality. However, data on the durability of anti-SARS-CoV-2 antibodies post-vaccination in peritoneal dialysis (PD) patients are scarce. In this prospective single-center cohort study we measured anti-SARS-CoV-2 RBD antibodies 3 and 6 months after the 3rd dose of the mRNA-1273 vaccine in 27 adult PD patients and recorded breakthrough infections. Furthermore, in a mixed model analysis, we analyzed potential factors influencing the humoral response following vaccination. Anti-SARS-CoV-2 RBD antibody levels declined from 21,424 BAU/mL at 1 month to 8397 BAU/mL at 3 months and to 5120 BAU/mL at 6 months after the 3rd dose, but remained higher than pre-3rd dose levels (212 BAU/mL). Eight patients (29.6%) were infected with SARS-CoV-2 within six months from the 3rd dose during the Omicron wave. Previous high antibody levels, high glomerular filtration rate (GFR) and low Davies Comorbidity Score were associated with higher anti-SARS-CoV-2 antibody levels after the booster. In conclusion, PD patients exhibited a robust and durable humoral response after a third dose of the mRNA-1273 vaccine. A high GFR and low comorbidity as well as previous high antibody levels predicted a better humoral response to vaccination.

Vaccine-Induced Immune Thrombotic Thrombocytopenia following BNT162b2 mRNA COVID-19 Booster: A Case Report. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a life-threatening complication caused by platelet activation via platelet factor 4 (PF4) antibodies. We

report a healthy 28-year-old man who developed hemoptysis, bilateral leg pain, and headaches three weeks after his third dose of the COVID-19 vaccine with the first BNT162b2 (from Pfizer-BioNTech) injection. He had previously had the first and second doses with ChAdOx1 nCov-19 without any discomfort. Serial investigations demonstrated pulmonary embolisms, cerebral sinus, and deep iliac venous thrombosis. Positive PF4 antibody assay (ELISA) confirmed the diagnosis of VITT. He had a prompt response to intravenous immunoglobulins (IVIGs) at a total dose of 2 g/kg and his symptoms are now in remission with anticoagulant. Although the definite mechanism is unknown, the VITT was most likely triggered by his COVID-19 vaccine. We report this case of VITT following BNT162b2, a mRNA-based vaccine, and suggest that VITT could still happen without the adenoviral vector vaccines.

Neurological Disorders following COVID-19 Vaccination. Nowadays, people all over the world have been receiving different types of coronavirus disease 2019 (COVID-19) vaccines. While their effectiveness has been well recognized, various post-vaccination disorders are not fully understood. In this review, we discuss neurological disorders related to vascular, immune, infectious, and functional factors following COVID-19 vaccination, and attempt to provide neuroscientists, psychiatrists, and vaccination staff with a reference for the diagnosis and treatment of these diseases. These disorders may present as a recurrence of previous neurological disorders or new-onset diseases. Their incidence rate, host and vaccine characteristics, clinical manifestations, treatment, and prognosis differ significantly. The pathogenesis of many of them remains unclear, and further studies are needed to provide more evidence. The incidence rate of severe neurological disorders is relatively low, most of which are reversible or treatable. Therefore, the benefits of vaccination outweigh the risk of COVID-19 infection, especially among fragile populations.

Assessment of COVID-19 Vaccine Acceptance and Its Associated Factors during the Crisis: A Community-Based Cross-Sectional Study in Benin. BACKGROUND: Having a maximum number of people vaccinated was the objective to control the COVID-19 pandemic. We report in this manuscript the factors associated with the willingness to be vaccinated against COVID-19 during the pandemic period. METHODS: From April to May 2022, a community-based cross-sectional survey was performed. Participants were randomly selected from four districts in Benin (taking into account the COVID-19 prevalence). Mixed-effect logistic regression models were used to identify the variables associated with COVID-19 vaccine acceptance. RESULTS: A total of 2069 participants were included. The proportion of vaccine acceptance was 43.3%. A total of 24.2% were vaccinated and showed proof of vaccination. The population's request for vaccination was higher after the third epidemic wave. The district of residence, the education level, a fear of being infected, the channel of information, poor medical conditions, a good knowledge of the transmission mode and symptoms, and good behaviors were significantly associated with vaccine acceptance. CONCLUSION: The overall acceptance of the COVID-19 vaccine in the Beninese population was relatively high. However, vaccine campaigns in areas with a low acceptance as well as the disclosure of information, particularly on our knowledge of the disease and the safety, side effects, and effectiveness of the COVID-19 vaccines, should be strengthened with adapted and consistent messages.

Common Adverse Events from Mixing COVID-19 Vaccine Booster in Hanoi, Vietnam. BACKGROUND: Mixing vaccines was proposed as a solution to tackle supply chain interruptions during the crisis of the COVID-19 pandemic. This study aimed to investigate the safety of mixing COVID-19 vaccines for a booster dose in Hanoi, Vietnam. METHOD: A cross-sectional study was conducted via a telephone-based interview to identify the adverse events following COVID-19 vaccination among 719 participants in Hanoi, Vietnam. RESULTS: In total, 45.76% of participants experienced at least one adverse event following two doses of the COVID-19 vaccine. Most of the adverse events were local effects with mild symptoms such as fever, headache, muscle pain, and/or pain at the site. In general, matching two doses in the same vaccines was not associated with the

adverse events as compared to mixing vaccines (OR = 1.43, 96%CI: 0.93-2.2), except matching two doses of Pfizer (OR = 2.25, 95%CI: 1.33-3.82). CONCLUSION: The findings of this study suggest the overall safety of mixed vaccination. In light of the vaccine shortage, mixing vaccinations for COVID-19 prevention is a good solution. Further studies with larger cohorts and investigating immunity following mixing vaccines are needed to elucidate the mechanism.

COVID-19 Vaccination Status as Well as Factors Associated with COVID-19 Vaccine Acceptance and Hesitancy among Prisoners and the Implications. Prisoners form a population who are highly vulnerable to COVID-19 due to overcrowding, limited movement, and a poor living environment. Consequently, there is a need to ascertain the status of COVID-19 vaccination and factors associated with hesitancy among prisoners. A cross-sectional questionnaire-based study was undertaken among prisoners at three district jails in Punjab Province, Pakistan. A total of 381 prisoners participated and none of the study participants had received an influenza vaccine this year. In total, 53% received at least one dose of a COVID-19 vaccine, with the majority having two doses. The top three reasons of vaccine acceptance were "fear of contracting SARS-CoV-2 infection" (56.9%), "desire to return to a pre-pandemic routine as soon as possible" (56.4%), and "having no doubts on the safety of COVID-19 vaccines" (39.6%). There was no statistically significant difference ($p > 0.05$) in any demographic variables between vaccinated and unvaccinated prisoners except for age, which was strongly association with COVID-19 vaccine uptake (Ï‡(2)(3) = 76.645, $p < 0.001$, Cramer's V = 0.457). Among the unvaccinated prisoners (N = 179), only 16 subsequently showed willingness to receive a COVID-19 vaccine. The top three reasons for hesitancy were: COVID-19 is not a real problem/disease (60.1%), safety concerns (51.1%), and COVID-19 vaccine is a conspiracy (50.3%). Efforts are needed to address their concerns given this population's risks and high hesitancy rates, especially among younger prisoners.

Anti-SARS-CoV-2 IgG Antibody Response in Individuals Infected Post Complete Vaccination: A 6-Month Longitudinal Study in Healthcare Professionals. Serological assays have been used to evaluate the magnitude of naturally acquired and BNT162b2 vaccine-induced immunity. In order to assess the extent to which the antibody response correlates with infection-mediated protection after vaccination, we investigated the kinetics of anti-SARS-CoV-2-S1 IgG in fully vaccinated healthy individuals who did or did not develop COVID-19 within 8 months after the booster dose. The anti-SARS-CoV-2-S1 receptor-binding, domain-specific IgG titer was assessed in serum samples collected at various intervals from 4 months after the second and 6 months after the third dose. The IgG level decreased 33% within 6 months after the second dose and, one month after the third dose, increased dramatically (>300%) compared with the pre-booster time point. COVID-19 infection within two months after the third dose did not cause significant IgG variation, but later viral infections elicited an IgG response similar to the initial response to the booster. The probability of developing COVID-19 and the severity of symptoms were not related to the antibody titer. Our data indicate that repeated exposure to viral antigens by either vaccination or infection at short-term intervals elicits limited boosting effects and that an IgG titer alone is not associated with the prediction of future infections and their symptomatology.

Pulmonary Embolism after Vaccination with the COVID-19 Vaccine (Pfizer, BNT162b2): A Case Report. Pulmonary embolism causes pulmonary vascular obstruction and damages circulation, leading to death in serious cases. Various cases of thrombosis have been reported as adverse reactions after vaccination with COVID-19 vaccines, and reliable studies on thrombosis with thrombocytopenia syndrome (TTS) have been confirmed, especially for viral vector vaccines. However, the association with mRNA vaccines has not been proven. We report a case of pulmonary embolism and deep vein thrombosis that occurred after using mRNA COVID-19 vaccines (BNT162b2).

Anaphylatoxin Complement 5a in Pfizer BNT162b2-Induced Immediate-Type Vaccine Hypersensitivity Reactions. The underlying immunological mechanisms of immediate-type hypersensitivity reactions (HSR) to COVID-19 vaccines are poorly understood. We investigate the mechanisms of immediate-type hypersensitivity reactions to the Pfizer BNT162b2 vaccine and the response of antibodies to the polyethylene glycol (PEG)ylated lipid nanoparticle after two doses of vaccination. Sixty-seven participants, median age 35 and 77.3% females who tolerated two doses of the BNT162b2 vaccine (non-reactors), were subjected to various blood-sampling time points. A separate group of vaccine reactors (10 anaphylaxis and 37 anonymised tryptase samples) were recruited for blood sampling. Immunoglobulin (Ig)G, IgM and IgE antibodies to the BNT162b2 vaccine, biomarkers associated with allergic reaction, including tryptase for anaphylaxis, complement 5a(C5a), intercellular adhesion molecule 1 (ICAM-1) for endothelial activation and Interleukin (IL)-4, IL-10, IL-33, tumour necrosis factor (TNF) and monocyte chemoattractant protein (MCP-1), were measured. Basophil activation test (BAT) was performed in BNT162b2-induced anaphylaxis patients by flow cytometry. The majority of patients with immediate-type BNT162b2 vaccine HSR demonstrated raised C5a and Th2-related cytokines but normal tryptase levels during the acute reaction, together with significantly higher levels of IgM antibodies to the BNT162b2 vaccine (IgM 67.2 (median) vs. 23.9 AU/mL, $p < 0.001$) and ICAM-1 when compared to non-reactor controls. No detectable IgE antibodies to the BNT162b2 vaccine were found in these patients. The basophil activation tests by flow cytometry to the Pfizer vaccine, 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol (DMG-PEG) and PEG-2000 were negative in four anaphylaxis patients. Acute hypersensitivity reactions post BNT162b2 vaccination suggest pseudo-allergic reactions via the activation of anaphylatoxins C5a and are independent of IgE-mechanisms. Vaccine reactors have significantly higher levels of anti-BNT162b2 IgM although its precise role remains unclear.

Assessment of mRNA Vaccine Immunogenicity in Solid Organ Transplant Recipients. Background and Objectives: Solid organ transplant (SOT) recipients have a higher risk of suffering from severe Coronavirus (COVID-19) compared to the general population. Studies have shown impaired immunogenicity of mRNA vaccines in this high-risk population; thus, SOT recipients have been prioritized globally for primary and booster doses. Materials and Methods: We analyzed 144 SOT recipients who had previously received two doses of BNT162b2 or mRNA1273 vaccine, and who were subsequently vaccinated with a booster dose of the mRNA1273 vaccine. Humoral and cellular immune responses were measured 1 and 3 months after the second dose, and 1 month after the third dose. Results: One month after the second dose, 33.6% (45/134) of patients displayed a positive antibody response with a median (25th, 75th) antibody titer of 9 (7, 161) AU/mL. Three months after the second dose, 41.8% (56/134) tested positive with a median (25th, 75th) antibody titer of 18 (7, 251) AU/mL. After the booster dose, the seropositivity rate increased to 69.4% (93/134), with a median (25th, 75th) titer of 966 (10, 8027) AU/mL. The specific SARS-CoV-2 T-cell response was assessed in 44 randomly selected recipients 3 months after the second dose, and 11.4% (5/44) of them had a positive response. Following the third dose, 42% (21/50) tested positive. Side effects after the third dose were mild, with pain at the injection site being the most frequent adverse effect, reported by 73.4% of the recipients. Conclusion: Our study shows a mild delayed increase in antibody titer, three months after primary vaccination compared to one month after. It also shows a robust augmentation of humoral and specific T-cell responses after the booster dose, as well as the safety and tolerability of the mRNA vaccines in SOT recipients.

Evaluation of Antibody Kinetics Following COVID-19 Vaccination in Greek SARS-CoV-2 Infected and NaÃ¯ve Healthcare Workers. We investigated the antibody kinetics after vaccination against COVID-19 in healthcare workers of a Greek tertiary hospital. Eight hundred and three subjects were included, of whom 758 (94.4%) received the BNT162b2 vaccine (Pfizer-BioNTech), eight (1%) mRNA-

1273 (Moderna), 14 (1.7%) ChAdOx1 (Oxford-AstraZeneca) and 23 (2.9%) Ad26.COV2.S (Janssen). Before the second dose, at 2, 6 and 9 months after the second dose and at 2 and 6 months after the third dose, anti-spike IgG were quantified by the chemiluminescence microparticle immunoassay method. One hundred subjects were infected before vaccination (group A), 335 were infected after receiving at least one vaccine dose (group B), while 368 had never been infected (group C). Group A presented a greater number of hospitalizations and reinfections compared to group B ($p < 0.05$). By multivariate analysis, younger age was associated with an increased risk of reinfection (odds ratio: 0.956, $p = 0.004$). All subjects showed the highest antibody titers at 2 months after the second and third dose. Group A showed higher antibody titers pre-second dose, which remained elevated 6 months post-second dose compared to groups B and C ($p < 0.05$). Pre-vaccine infection leads to rapid development of high antibody titer and a slower decline. Vaccination is associated with fewer hospitalizations and fewer reinfections.

Arrhythmias after COVID-19 Vaccination: Have We Left All Stones Unturned? SARS-CoV-2 vaccination offered the opportunity to emerge from the pandemic and, thereby, worldwide health, social, and economic disasters. However, in addition to efficacy, safety is an important issue for any vaccine. The mRNA-based vaccine platform is considered to be safe, but side effects are being reported more frequently as more and more people around the world become treated. Myopericarditis is the major, but not the only cardiovascular complication of this vaccine; hence it is important not to underestimate other side effects. We report a case series of patients affected by cardiac arrhythmias post-mRNA vaccine from our clinical practice and the literature. Reviewing the official vigilance database, we found that heart rhythm disorders after COVID vaccination are not uncommon and deserve more clinical and scientific attention. Since the COVID vaccine is the only vaccination related to this side effect, questions arose about whether these vaccines could affect heart conduction. Although the risk-benefit ratio is clearly in favor of vaccination, heart rhythm disorders are not a negligible issue, and there are red flags in the literature about the risk of post-vaccination malignant arrhythmias in some predisposed patients. In light of these findings, we reviewed the potential molecular pathways for the COVID vaccine to impact cardiac electrophysiology and cause heart rhythm disorders.

COVID-19 Vaccines and Atrial Fibrillation: Analysis of the Post-Marketing Pharmacovigilance European Database. Atrial fibrillation (AF) has been described in COVID-19 patients. Recently, some case reports and US pharmacovigilance analyses described AF onset as a rare adverse event following COVID-19 vaccination. The possible correlation is unclear. We systematically analyzed the reports of AF related to COVID-19 vaccines collected in the European pharmacovigilance database, EudraVigilance (EV), from 2020 to November 2022. We carried out descriptive and disproportionality analyses. Moreover, we performed a sensitivity analysis, excluding the reports describing other possible alternative AF causes (pericarditis, myocarditis, COVID-19, or other drugs that may cause/exacerbate AF). Overall, we retrieved 6226 reports, which represented only 0.3% of all those related to COVID-19 vaccines collected in EV during our study period. AF reports mainly referred to adults (in particular, >65 years old), with an equal distribution in sex. Reports were mainly related to tozinameran (54.04%), elasomeran (28.3%), and ChAdOx1-S (14.32%). The reported AF required patient hospitalization in 35% of cases and resulted in a life-threatening condition in 10% of cases. The AF duration (when reported) was highly variable, but the majority of the events had a short duration (moda = 24 h). Although an increased frequency of AF reporting with mRNA vaccines emerges from our study, other investigations are required to investigate the possible correlation between COVID-19 vaccination and the rare AF occurrence.

Kounis syndrome in a patient following AstraZeneca coronavirus disease 2019 vaccination: a case report. INTRODUCTION AND IMPORTANCE: Kounis syndrome, also known as allergic angina

syndrome, is defined as the occurrence of an acute coronary syndrome concomitantly with a hypersensitivity reaction. It is a very important diagnosis and missing it may be fatal to the patient. This is a medical emergency, and immediate treatment should be initiated. The treatment of Kounis syndrome is challenging because treatment of either acute coronary syndrome and hypersensitivity reaction can lead to the worsening of the other injury. This case is the first reported case of Kounis syndrome following coronavirus disease 2019 vaccination in Sri Lanka according to our knowledge. CASE PRESENTATION: We discuss a 54-year-old female Sri Lankan patient who developed Kounis syndrome following Oxford AstraZeneca COVID-19 vaccination. The patient initially developed anaphylaxis following the AstraZeneca COVID-19 vaccine and subsequently developed acute coronary syndrome secondary to anaphylaxis. The patient was treated appropriately and eventually recovered from her condition. CONCLUSION: This syndrome should be suspected when there is a concurrent acute coronary syndrome with allergic reactions. This is an often under- or misdiagnosed condition, and physicians should be educated about it. Caregivers should be aware of its pathophysiology, as treatment of either of the two may worsen the other injury.

Age-associated B cells predict impaired humoral immunity after COVID-19 vaccination in patients receiving immune checkpoint blockade. Age-associated B cells (ABC) accumulate with age and in individuals with different immunological disorders, including cancer patients treated with immune checkpoint blockade and those with inborn errors of immunity. Here, we investigate whether ABCs from different conditions are similar and how they impact the longitudinal level of the COVID-19 vaccine response. Single-cell RNA sequencing indicates that ABCs with distinct aetiologies have common transcriptional profiles and can be categorised according to their expression of immune genes, such as the autoimmune regulator (AIRE). Furthermore, higher baseline ABC frequency correlates with decreased levels of antigen-specific memory B cells and reduced neutralising capacity against SARS-CoV-2. ABCs express high levels of the inhibitory FcÎ³RIIB receptor and are distinctive in their ability to bind immune complexes, which could contribute to diminish vaccine responses either directly, or indirectly via enhanced clearance of immune complexed-antigen. Expansion of ABCs may, therefore, serve as a biomarker identifying individuals at risk of suboptimal responses to vaccination.

Papuloerythroderma of Ofuji following COVID-19 vaccination.

Correction: Belimumab is not associated with COVID-19 mRNA vaccination failure in systemic lupus erythematosus.

Impact of Imprinted Immunity Induced by mRNA Vaccination in an Experimental Animal Model. The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron variants has led to concerns that ancestral SARS-CoV-2-based vaccines may not be effective against newly emerging Omicron subvariants. The concept of "imprinted immunity" suggests that individuals vaccinated with ancestral virus-based vaccines may not develop effective immunity against newly emerging Omicron subvariants, such as BQ.1.1 and XBB.1. In this study, we investigated this possibility using hamsters. Although natural infection induced effective antiviral immunity, breakthrough infections in hamsters with BQ.1.1 and XBB.1 Omicron subvariants after receiving the 3-dose mRNA-lipid nanoparticle vaccine resulted in only faintly induced humoral immunity, supporting the possibility of imprinted immunity.

Vaccine-carditis study: Spanish multicenter registry of inflammatory heart disease after COVID-19 vaccination. INTRODUCTION AND OBJECTIVES: Vaccines against SARS-CoV-2 have been a major scientific and medical achievement in the control of the COVID-19 pandemic. However, very infrequent cases of inflammatory heart disease have been described as adverse events, leading to uncertainty in the scientific community and in the general population. METHODS: The Vaccine-Carditis Registry has included all cases of myocarditis and pericarditis diagnosed within 30Â days after COVID-19 vaccination since August 1, 2021 in 29 centers throughout the Spanish territory. The

definitions of myocarditis (probable or confirmed) and pericarditis followed the consensus of the Centers for Disease Control and the Clinical Practice Guidelines of the European Society of Cardiology. A comprehensive analysis of clinical characteristics and 3-month evolution is presented. RESULTS: From August 1, 2021, to March 10, 2022, 139 cases of myocarditis or pericarditis were recorded (81.3% male, median age 28 years). Most cases were detected in the 1st week after administration of an mRNA vaccine, the majority after the second dose. The most common presentation was mixed inflammatory disease (myocarditis and pericarditis). 11% had left ventricular systolic dysfunction, 4% had right ventricular systolic dysfunction, and 21% had pericardial effusion. In cardiac magnetic resonance studies, left ventricular inferolateral involvement was the most frequent pattern (58%). More than 90% of cases had a benign clinical course. After a 3-month follow-up, the incidence of adverse events was 12.78% (1.44% mortality). CONCLUSIONS: In our setting, inflammatory heart disease after vaccination against SARS-CoV-2 predominantly affects young men in the 1st week after the second dose of RNA-m vaccine and presents a favorable clinical course in most cases.

Clinical Features of COVID-19 Vaccine-Associated Autoimmune Hepatitis: A Systematic Review. Autoimmune hepatitis (AIH) is an inflammatory liver disease wherein the body's immune system instigates an attack on the liver, causing inflammation and hepatic impairment. This disease usually manifests in genetically predisposed individuals and is triggered by stimuli or environments such as viral infections, environmental toxins, and drugs. The causal role of COVID-19 vaccination in AIH remains uncertain. This review of 39 cases of vaccine-related AIH indicates that female patients above the age of 50 years or those with potential AIH risk factors may be susceptible to vaccine-related AIH, and the clinical features of vaccine-associated AIH are similar to those of idiopathic AIH. These features commonly manifest in patients after the first dose of vaccination, with symptom onset typically delayed by 10-14 days. The incidence of underlying liver disease in patients with potential health conditions associated to liver disease is similar to that of patients without preexisting illnesses. Steroid administration is effective in treating vaccine-related AIH-susceptible patients, with most patients experiencing improvement in their clinical symptoms. However, care should be taken to prevent bacterial infections during drug administration. Furthermore, the possible pathogenic mechanisms of vaccine-associated AIH are discussed to offer potential ideas for vaccine development and enhancement. Although the incidence of vaccine-related AIH is rare, individuals should not be deterred from receiving the COVID-19 vaccine, as the benefits of vaccination significantly outweigh the risks.

Serological Response to SARS-CoV-2 Vaccine in Hemodialyzed Patients and the Association with Later COVID-19 Positivity. BACKGROUND: The effectiveness of the COVID-19 vaccine may differ in hemodialysis patients. The aim of this prospective multicenter study was to determine the degree of serological response to the SARS-CoV-2 vaccine in the population of dialysis patients and its association with later SARS-CoV-2 infections. METHODS: A blood sample was taken for the determination of COVID-19 serological status (IgG antibodies) in 706 dialysis patients 16 weeks after vaccination with the second dose (Pfizer-BioNTech). RESULTS: Only 314 (44.5%) hemodialyzed patients had a satisfactory response to the COVID-19 vaccine. Eighty-two patients (11.6%) had a borderline response, while 310 patients (43.9%) had an unsatisfactory (negative) post-vaccinal antibody titer. A longer dialysis vintage had an increased odds ratio (OR) of 1.01 for the occurrence of COVID-19 positivity after vaccination. In the group of subsequently positive patients, 28 patients (13.6%) died from complications of COVID-19. We have found differences in mean survival time between patients with and without appropriate responses to vaccination in favor of patients with a satisfactory serological response. CONCLUSIONS: The results showed that the dialysis population will not have the same serological response to the vaccine as the general population. The majority of dialysis patients did not develop a severe clinical picture or die at the time of positivity for COVID-19.

Transient dermatomyositis-like reaction following COVID-19 messenger RNA vaccination.

SARS-CoV-2 vaccination for unexpected death from atrial myocarditis: Comment.

Answer to the letter to the editor by J. Finsterer concerning "A case of fatal multi-organ inflammation following COVID-19 vaccination" by H. Nushida et al. (https://doi.org/10.1016/j.legalmed.2023.102244.).

ACUTE MACULAR NEURORETINOPATHY FOLLOWING SARS-CoV-2 VACCINATION. PURPOSE: To report a case of acute macular neuroretinopathy (AMN) following SARS-CoV-2 vaccination. METHODS: Case report. RESULTS: An otherwise healthy 28-year-old white woman presented to an ophthalmology department with complaints of black paracentral vision scotomata on both eyes that appeared 2 days after receiving the first dose of Vaxzevria vaccine. Fundus examination revealed bilateral red brown petaloid lesions around the fovea. On spectral domain optical coherence tomography, a hyperreflective plaque between the outer plexiform and outer nuclear layers along with disruption of ellipsoid zone/interdigitation zone was observed. A diagnosis of AMN was made. CONCLUSION: AMN may be an extremely rare adverse event of SARS-COV-2 vaccination, especially in patients with other risk factors. SYNOPSIS: An otherwise healthy 28-year-old white woman was diagnosed with AMN 2 days after SARS-CoV-2 vaccination.

Response to: Low incidence of neurological recurrence after two-dose COVID-19 vaccination.

Hyperglycemia Associated With Raynaud Phenomenon and Liver Dysfunction After COVID-19 Vaccination in Type 1 Diabetes Mellitus. BACKGROUND/OBJECTIVE: The association of COVID-19 vaccinations and the changes in glycemic control remains debatable. We report a case of a patient with type 1 diabetes mellitus (DM) with previously well-controlled glucose on a hybrid closed-loop insulin pump who developed significant glucose variation, new onset Raynaud phenomenon, and liver dysfunction after the vaccination. CASE REPORT: A 33-year-old man with type 1 DM since the age of 5 years was on an insulin pump for 17 years. He had a reasonable controlled glucose level with a hemoglobin A1c level of 6.8% (51 mmol/mol). Three days after he received the COVID-19 vaccination, his glucose level started to fluctuate in the range of 46 to 378 mg/dL with 3.5 times higher total daily insulin requirement. The patient developed white-pale cold hands, weight gain, fatigue, and liver dysfunction. Computed tomography of the abdomen revealed mild hepatomegaly, and laboratory workup was negative for hepatitis. One month later, his glucose level became better controlled, and his liver function improved. Continuous glucose monitoring revealed that his glucose profile returned to baseline after 6 weeks. DISCUSSION: COVID-19 vaccination resulted in significant glucose variation and fluctuations in this patient. It could be explained by the vaccine-induced immune response causing an increase in insulin resistance, such as in adipose tissue and muscle cells. Immune stimulation could have also caused the abnormal liver function and explain his new onset Raynaud phenomenon. CONCLUSION: We described, for the first time, the long-term continuous glucose monitoring glucose profile with a hybrid closed-loop system in type 1 DM after COVID-19 vaccination. Clinicians need to keep alert to glycemic excursion and side effects after immunization in type 1 DM.

COVID-19 Immune Response In Adults Post Measles-Rubella Vaccination. Objective: This study aimed to see how measles, mumps, and rubella vaccination affected the increase in SARS-CoV-2 immunoglobulin levels in individuals who had received the second dose of the SARS-CoV-2 vaccine. Material and Method: This research is a quasi-experimental type with a pre-post test design. The population studied were adults who had received the second dose of the SARS-CoV-2 vaccine, consisting of 30 people. Results: The results of this study were that most (60%) research subjects experienced an increase in IgM and some subjects (46.6%) experienced an increase in anti-SARS-CoV-2 IgG levels. The administration of the MR vaccination had no effect on increasing anti-SARS-CoV-2 IgG and IgM levels. This happened because the increase in IgM and IgG levels in the pre and post-tests in most research subjects was relatively low. Conclusion: The administration of the MR vaccine

to adults who had received a second dose of the SARS-CoV-2 vaccine elicited a response with low levels of IgG and IgM SARS-CoV-2.

Adverse events following COVID-19 vaccination among pregnant women attending primary health centers: An active-surveillance study. INTRODUCTION: Vaccine safety is a major barrier to the uptake of the COVID-19 vaccine by pregnant women. To bring confidence among pregnant women towards vaccine intake, there is a need to synthesize evidence on safety profile of vaccination. OBJECTIVE: To assess adverse events (AEs) following COVID-19 vaccination among pregnant women. MATERIALS AND METHODS: A vaccine safety surveillance was conducted at 2 rural primary health centers (PHC) located in Anantapur District, India. A total of 420 pregnant women were monitored for AEs following COVID-19 vaccination for a period of 30â€¯min and followed for 1 month for late reactions through telephonic interviews. All AEs were subjected to causality and severity assessment. Descriptive statistics were used to represent adverse events. RESULTS: The COVID-19 vaccine acceptance rate among pregnant women was 64.4%. A total of 420 pregnant women received 670 vaccine doses (Covishieldâ€¯=â€¯372, Covaxinâ€¯=â€¯298) against COVID-19. Majority of vaccine intake was observed during the second trimester. The incidence rate of AEs following the COVID-19 vaccine among pregnant women was 93.8%, and the majority include injection site pain (28.4%, 29.6%), fever (25.5%, 19.0%), myalgia (8.21%, 12.3%), and malaise (13.6%, 8.4%). Most AEs notified are probable and mild in nature. CONCLUSION: The COVID-19 vaccine acceptance rate among pregnant women was 64.4%. A 30â€¯days incidence rate of AEs following COVID-19 vaccination among pregnant women was 93.8%, with the most common mild events like injection site pain, and fever. A further follow-up cohort study by taking an adequate sample size was recommended to capture fetal-maternal outcomes.

The polymorphisms of TNF-Î± related-gene and antibody production following third dose of COVID-19 vaccination: A pilot study. INTRODUCTION: Vaccination is one of the most pertinent prevention strategies for the Coronavirus Disease 2019 (COVID-19) pandemic. Several factors, both intrinsic (particularly genetic) and extrinsic, can influence vaccine efficacy. However, very little research has been conducted into the genetic component's impact on immunogenicity following COVID-19 vaccination. Therefore, we present the antibody formation in thirteen people who received a third vaccination (booster) dose of the Moderna mRNA-1273 vaccine and the differences in the polymorphism Tumor Necrosis Factor-Alpha (TNF-Î±) related genes in this population. METHODS: Our study included 13 participants with no comorbidities or a history of COVID-19 infection. The Chemiluminescent Microparticle Immunoassay (CMIA) was used to measure antibody production in serum. Polymorphism was recognized using the polymerase chain reaction (PCR) amplification technique. RESULTS: In this study, TNF-Î± related gene (GG) significantly influenced the formation of the antiSARS-CoV-2 spike protein IgG antibody level (pâ€¯=â€¯0.005) in our sample. CONCLUSION: Although the polymorphism of the cytokine gene, particularly TNF-Î±, seems to influence antibody levels in our study population, a more comprehensive analysis is required for better generalization due to the nature of our pilot study.

Autoimmune diseases related to post-SARS-CoV-2 vaccination; a rheumatology perspective.

A Case of Takotsubo Cardiomyopathy Triggered by Asthma Exacerbation After mRNA-based Vaccination for COVID-19. It is recommended to get the multiple coronavirus disease 2019 (COVID-19) vaccinationsÂ for almost all people including asthma patients. A 70-year-old Japanese woman with asthmaÂ experienced worsening of respiratory symptoms after the second dose of the mRNA-based COVID-19 vaccine BNT162b2. The patient had hypercapnic respiratory failure and cardiac-apex ballooning and was diagnosed with takotsubo cardiomyopathy induced by asthma exacerbation. Therapies for asthma exacerbation resulted in prompt improvement of respiratory failure and cardiac-apex ballooning.Â Our findings suggest that asthma patients are prone to

exacerbations after receiving the COVID-19 vaccination; therefore, stratification of the patients at risk is required.

Retinal vascular occlusion following SARS-CoV-2 vaccination: A VAERS database analysis. PURPOSE: To evaluate the cases of retinal vessel occlusion following COVID-19 vaccination and evaluate the onset interval and clinical presentations in patients diagnosed with vaccine associated retinal artery occlusion (RAO) and retinal vein occlusion (RVO). DESIGN: Retrospective study of the cases reported to the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Events Reporting System (VAERS) between December 11, 2020 and July 1, 2022. PARTICIPANTS: Patients diagnosed with retinal vessel occlusion following vaccination with BNT162b2, mRNA-1273, and Ad26.COV2.S globally. METHODS: We performed a descriptive analysis of the patient demographics and clinical presentation in patients with retinal vessel occlusion. The correlation between the vaccines and continuous and categorical variables were assessed. We performed the post-hoc analysis to evaluated the association between RAO and RVO onset post-vaccination, and vaccine and dosage. Finally, a 30-day reverse analysis for RAO and RVO onset following administration of vaccine. A major limitation in the methods of this study is the lack of control group for assessing the risk of retinal vessel occlusive disease in patients who received the vaccine compared to the patients who were unvaccinated. MAIN OUTCOME MEASURES: The crude reporting rate of retinal vessel occlusion following SARS-CoV-2 vaccine. The ocular and systemic presentations, onset duration and short term risk of RAO and RVO following vaccination. RESULTS: During the study period, 1351 retinal vessel occlusion cases were reported globally. The crude reporting rates of retinal vessel occlusion for BNT162b2, mRNA-1273, and Ad26.COV2.S were 0.36, 0.41, and 0.69, respectively. The majority of the retinal vessel occlusion cases were reported following BNT162b2 (n=606, 74.17%). The mean age of patients with RVO and RAO was 58.54 Â± 16.06 years and 64.63 Â± 16.16 years, respectively. In the cohort, 817 and 433 patients were diagnosed with RVO and RAO, respectively. Most cases of RVO (41.12%) and RAO (48.27%) were reported within the first week post-vaccination. We observed that the mean onset interval for RVO was significantly longer in patients who received Ad26.Cov2.S (54.07 Â± 88.98 days) compared to BNT162b2 (18.07 Â± 28.66 days) and mRNA-1273 (22.85 Â± 38.13 days) vaccines ($p<0.0001$). This was further confirmed by post-hoc analysis, which revealed a significantly longer onset duration for the Ad26.Cov2.S compared to BNT162b2 and mRNA 1273 vaccines ($p<0.0001$). The reverse Kaplan Meier 30-day risk analysis showed a significant a higher risk of RVO onset following BNT162b2 compared to other vaccines($p<0.0001$). CONCLUSIONS: The low crude reporting rate highlights a low safety concern for retinal vessel occlusion following SARS-CoV-2 vaccination. This study provides insights into possible temporal association between reported retinal vessel occlusion events with SARS-CoV-2 vaccines, however further insights are needed to understand the underlying immunopathological mechanisms that promote thrombosis of retinal vasculature on vaccine administration.

Prevertebral Inflammatory Myofibroblastic Tumor Following COVID Vaccine Booster Dose. We report a case of a 30-year-old previously higid female presenting with dorsal pain and persistent fever after COVID-19 vaccine booster dose. CT and MR revealed a prevertebral heterogeneous and infiltrating mass, with spontaneous regression in control imaging which biopsy confirmed an inflammatory myofibroblastic tumor.

Henoch-SchÃ¶nlein purpura in a 6-year-old boy after initial COVID-19 vaccination. The COVID-19 pandemic has significantly impacted global health, and the widespread immunization of adults against SARS-CoV-2 has played a pivotal role in altering the course of the disease. While COVID-19 vaccine adverse events are generally uncommon and mild, the recent vaccination of the pediatric population has emphasized the need for vigilance and reporting of potential side effects. In this case report, we present a 6-year-old boy who developed Henoch-SchÃ¶nlein purpura following the

administration of the first dose of Pfizer-BioNTech BNT16B2b2 mRNA COVID-19 vaccine, making it the earliest reported case of such an adverse event. Our report highlights the importance of continued monitoring and reporting of adverse events in pediatric patients receiving the COVID-19 vaccine, as well as the need for prompt diagnosis and management of potential vaccine-related complications.
Axillary Lymph Nodes in Breast Cancer Patients After COVID-19 Vaccine. One of the side effects of vaccines used to end the COVID-19 epidemic is non-specifically enlarged axillary lymph nodes. Such lymphadenopathy detected during clinical examination of breast cancer patients may require additional imaging or interventional procedures that should not normally be performed. This study has been designed to estimate the incidence of palpable enlarged axillary lymph node in breast cancer patients who had received COVID-19 vaccination in the past 3Â months in the same arm as compared to those without vaccination. Breast cancer patients admitted to M.U. Medical Faculty Breast polyclinic between January 2021 and March 2022 were screened, and clinical staging was performed after thorough clinical examination. Among these patients with suspected enlarged axillary lymph node and those undergoing sentinel lymph node biopsy (SLNB), they were divided into two groups as vaccinated and unvaccinated. Age, menopausal status, tumor size, tumor location, surgery, pathology results, hormonal receptor status, and SLNB results were statistically compared with groups. There was no significant difference between groups in terms of age, menopause, tumor size, tumor location, surgery, pathological results, and hormone receptor status. The SLNB being reported as reactive only was 89.1% in the vaccinated group and 73.2% in the non-vaccinated group which was statistically significant different. Reactive lymph nodes were commonly found with an excess of 16% in patients who had received COVID-19 vaccination in the past 3Â months. This required caution and additional examination of the axillary lymph nodes in this period.
Antibody level dynamics until after the third dose of COVID-19 vaccination. The antibody titers of volunteers, including elderly people, were investigated after the second dose of the BNT162b2 vaccine (Pfizer-BioNTech) as an mRNA vaccine against the coronavirus disease 2019 (COVID-19). Serum samples were collected from 105 volunteers (44 healthcare workers and 61 elderly people) 7-14 days after the second vaccine dose, and antibody titers were measured. The antibody titers of study participants in their 20s were significantly higher than those of other age groups. Furthermore, the antibody titers of participants aged <60 years were significantly higher than those of participants aged â‰¥60 years. Serum samples were repeatedly collected from 44 healthcare workers until after the third vaccine dose. Eight months after the second round of vaccination, the antibody titer levels decreased to the same level as that before the second vaccine dose. After the third booster vaccination, the antibody titer recovered to the same level as that after the second dose. Neutralizing activities were also investigated at four time points before and after the second vaccine dose. The antibody titers and neutralizing activity were positively correlated. Therefore, neutralizing activity can be predicted by measuring the antibody titer. In conclusion, the antibody titers in the elderly population were significantly lower than those in the younger population. Although the antibody titers increased following vaccination, their levels showed a decline after several months, returning to the same level as that after a single dose of mRNA vaccination. The antibody titer levels recovered after the third dose of vaccination, which had already been administered in Japan. Routine administration of vaccine should be considered in the future.
An unusual case of acquired aplastic anemia following SARS-CoV-2 vaccination: A case report. Aplastic Anemia (AA) is a condition where the body's immune system attacks and destroys the hematopoietic stem cells, leading to pancytopenia and an empty bone marrow. AA can be effectively treated using immunosuppressive therapy or hematopoietic stem-cell transplantation. The damage to stem cells in the bone marrow can be due to several causes, such as autoimmune diseases, medication like cytotoxic drugs and antibiotics, and exposure to toxins or chemicals in the

environment. In this case report, we present the diagnosis and treatment of a 61-year-old man who was diagnosed with Acquired Aplastic Anemia, which could have developed following his serial immunizations with the SARS-CoV-2 COVISHIELD viral vector vaccine. The patient received immunosuppressive therapy consisting of cyclosporine, anti-thymocyte globulin, and prednisone, resulting in a significant improvement in his condition.

Carditis following COVID-19 vaccination: balancing the risks and benefits.

Risk of carditis after three doses of vaccination with mRNA (BNT162b2) or inactivated (CoronaVac) covid-19 vaccination: a self-controlled cases series and a case-control study. BACKGROUND: Large-scale comparative research exploring the risk after the third dose and after inactivated covid-19 vaccination is limited. This study aimed to assess the risk of carditis following three doses of BNT162b2 or CoronaVac. METHODS: We conducted a self-controlled case series (SCCS) and a case-control study using electronic health and vaccination records in Hong Kong. Carditis incidents within 28 days of covid-19 vaccination were included as cases. In the case-control study, up to 10 hospitalized controls were selected with stratified probability sampling by age, sex, and hospital admission (Â±1 day). The incidence rate ratios (IRRs) were reported from conditional Poisson regressions for SCCS, and adjusted odds ratios (ORs) were reported from multivariable logistic regressions. FINDINGS: A total of 8,924,614 doses of BNT162b2 and 6,129,852 doses of CoronaVac were administered from February 2021 to March 2022. The SCCS detected increased carditis risks after BNT162b2: 4.48 (95%confidence interval [CI]:2.99-6.70] in 1-14 days and 2.50 (95%CI:1.43-4.38) in 15-28 days after first dose; 10.81 (95%CI:7.63-15.32) in 1-14 days and 2.95 (95%CI:1.82-4.78) in 15-28 days after second dose; 4.72 (95%CI:1.40-15.97) in 1-14 days after third dose. Consistent results were observed from the case-control study. Risks were specifically found in people aged below 30 years and males. No significant risk increase was observed after CoronaVac in all primary analyses. INTERPRETATIONS: We detected increased carditis risks within 28 days after all three doses of BNT162b2 but the risk after the third doses were not higher than that of the second dose when compared with baseline period. Continuous monitoring of carditis after both mRNA and inactivated covid-19 vaccines is needed. FUNDING: : This study was funded by Hong Kong Health Bureau (COVID19F01).

Vaccination in liver diseases and liver Transplantation: Recommendations, implications and opportunities in the post-covid era. The interest in vaccination efficacy and toxicity has surged following the Covid-19 pandemic. Immune responses to several vaccines have been shown to be suboptimal in patients with chronic liver disease (CLD) or post-liver transplant (LT), as a consequence of cirrhosis-associated immune dysfunction (CAID) or post-LT immunosuppression respectively. Accordingly, vaccine-preventable infections may be more common or severe than in the general population. The Covid-19 pandemic has greatly accelerated research and development into vaccination technology and platforms, which will have spillover benefits for liver patients. The aims of this review are: (i) to discuss the impact of vaccine-preventable infections on CLD and post-LT patients, (ii) to appraise current evidence supporting vaccination strategies, and (iii) to provide some insight into recent developments relevant for liver patients.

Outcomes in children with rheumatic diseases following COVID-19 vaccination and infection: data from a large two-center cohort study in Thailand. INTRODUCTION: Vaccination against coronavirus disease 2019 (COVID-19) is effective in protecting patients from severe COVID-19 infection. Disease flare-up following immunization in children with rheumatic disorders may result in patient reluctance to receive the vaccine. Underlying rheumatic diseases or the use of immunosuppressive drugs may influence the outcomes of COVID-19 vaccination and infection. We aimed to describe outcomes in children with rheumatic diseases following COVID-19 immunization and infection. METHODS: This retrospective study was performed at two large academic centers in

Thailand. During the COVID-19 pandemic, all patients were routinely queried about COVID-19-related conditions. We included patients with rheumatic diseases aged <18 years who received at least one dose of a COVID-19 vaccine or had a history of COVID-19 infection with more than 6 months of recorded follow-up after the last vaccine dose or COVID-19 illness. Demographic information and data on clinical symptoms, disease activity, treatment, outcomes, and COVID-19 vaccination and infection were collected. RESULTS: A total of 479 patients were included. Most (229; 47.81%) patients had juvenile idiopathic arthritis, followed by connective tissue diseases (189; 39.46%), vasculitis syndromes (42; 8.76%), and other rheumatic diseases (19; 3.97%). Approximately 90% of patients received at least one dose of COVID-19 vaccination, and half of the patients had COVID-19 infection. Among patients, 10.72% and 3.27% developed a flare after COVID-19 vaccination and COVID-19 illness, respectively. Flare severity after COVID immunization and infection was mainly mild to moderate. The predictor of flare after COVID-19 vaccination was the use of prednisolone â‰¥10â€…mg/day before vaccination (hazard ratio: 2.04, 95% confidence interval: 1.05-3.97, pâ€‰=â€‰0.037). Inactive disease before receiving the COVID-19 vaccination was a predictor of inactive status after a flare (hazard ratio: 2.95, 95% confidence interval: 1.04-8.40; pâ€‰=â€‰0.043). Overall, 3.36% and 1.61% of patients experienced a new onset of rheumatic disease after receiving the COVID-19 vaccine and after COVID-19 infection, respectively. CONCLUSION: The COVID-19 vaccine is recommended for children with rheumatic disease, particularly those who are in stable condition. After COVID-19 vaccination, patients-especially those with active disease before vaccination or those receiving concurrent prednisolone doses of â‰¥10â€…mg/day-should be closely monitored.

Acute interstitial nephritis following COVID-19 vaccination.

COVID-19, Coronavirus Vaccines, and Possible Association with LipschÃ¼tz Vulvar Ulcer: A Systematic Review. LipschÃ¼tz genital ulcer is a self-limited, non-sexually acquired disorder characterized by the sudden onset of a few ulcers. A primary Epstein-Barr virusÂ infection is currently considered the most recognized cause. Recent reports document cases temporally related with coronavirus disease 2019 (COVID-19) or immunization against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). We carried out a review of the literature to investigate the possible association between COVID-19 or the immunization against SARS-CoV-2 and genital ulcer. The pre-registered study (CRD42023376260) was undertaken following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses methodology. Excerpta Medica, the National Library of Medicine, and Web of Sciences were searched. Inclusion criteria encompassed instances of acute LipschÃ¼tz ulcer episodes that were temporally linked to either COVID-19 or a vaccination against SARS-CoV-2. Eighteen articles were retained. They provided information on 33 patients 15 (14-24) years of age (median and interquartile range), who experienced a total of 39 episodes of LipschÃ¼tz ulcer temporally associated with COVID-19 (Nâ€‰=â€‰18) or an immunization against SARS-CoV-2 (Nâ€‰=â€‰21). The possible concomitant existence of an acute Epstein-Barr virusÂ infection was excluded in 30 of the 39 episodes. The clinical presentation and the disease duration were similar in episodes temporally associated with COVID-19 and in those associated with an immunization against SARS-CoV-2. In conclusion, COVID-19 and immunization against SARS-CoV-2 add to Epstein-Barr virus as plausible triggers of LipschÃ¼tz genital ulcer.

Comparison of self-reported symptoms in COVID-19 patients who had or had not previously received COVID-19 mRNA vaccination. Although mRNA coronavirus disease 2019 (COVID-19) vaccines have been reported for high effectiveness against symptoms, it remains unclear whether post-vaccination infections are less symptomatic than infections in vaccine-naive individuals. We included patients with COVID-19 diagnosed by polymerase chain reaction tests during Japan's alpha and delta variant epidemics. COVID-19 symptoms at approximately 4â€‰weeks were compared based on

COVID-19 vaccination status. In total, 398 cases (372 symptomatic and 26 asymptomatic; 286 unvaccinated, 66 vaccinated with one dose, and 46 with two doses) were analyzed. The most common symptoms were fever (78.4%), fatigue (78.4%), cough (74.4%), loss of taste or smell (62.8%), and headache (59.8%). Post-vaccination infections were significantly less likely to be symptomatic. Possible confounder-adjusted odds ratios of two vaccine doses against fatigue, dry eyes and mouth, insomnia, fever, shortness of breath, unusual muscle pains, and loss of taste or smell were 0.18 (95% confidence interval [CI]: 0.09-0.38), 0.22 (95% CI: 0.08-0.59), 0.33 (95% CI: 0.14-0.80), 0.31 (95% CI: 0.15-0.63), 0.36 (95% CI: 0.16-0.76), 0.40 (95% CI: 0.19-0.82), and 0.44 (95% CI: 0.22-0.87), respectively. Post-vaccination infections after two mRNA COVID-19 vaccine doses show milder and fewer symptoms than infections in unvaccinated patients, highlighting the effectiveness of vaccination.

Effect of COVID-19 and its vaccines on surgical and postsurgical mortality, ICU admission and 90-day readmission for elective surgical procedures in a United States veteran population. BACKGROUND: We investigated how COVID-19 infection and vaccination impact elective surgical outcomes. METHODS: We retrospectively compared pre-pandemic (P) veterans to those with COVID (C) more than three weeks preoperatively or no COVID (NC) history after carotid endarterectomy, CABG, hip replacement, or colectomy. Subgroup analysis considered vaccination. Age and sex propensity matching, and conditional logistic regression analyzed one-year-mortality, 90-day-readmission, and ICU requirements among 519Â â€‹C, 1038 NC, and 2076Â â€‹P, culled from 61,641 veterans. RESULTS: NC, C, and P had similar ICU requirements and mortality, although NC required fewer readmissions. However, NC immunized at least once were readmitted and died less commonly than C who received at least one immunization. CONCLUSIONS: SARS-CoV-2 history increased readmission without affecting ICU requirement or mortality. Further studies should evaluate whether the worse outcomes in postoperative patients with histories of both COVID infection and one vaccination reflect the effects of incomplete vaccination or dataset limitations.

Evaluation of T and B cell immunophenotyping and antibody response post Covid-19 vaccination. PURPOSE: To evaluate T and B cell subsets and IgG antibodies in response to SARS-CoV-2 post COVID-19 vaccination. METHODS: A total of 50 healthy adults (18-60 years) receiving anti-SARS-CoV-2 vaccination (COVISHIELD) were recruited for the study. Blood samples were collected from participants at 3 time points; just before vaccination (Visit 0, V(0)), just before booster dose (Visit 1, V(1)) and 6th month after 1st dose (Visit 2, V(2)). Peripheral blood mononuclear cell isolation was done and evaluated for T and B cell subsets by Flow cytometry. Quantitative determination of IgG antibodies to SARS-CoV-2 was done by Chemiluminescence immunoassay in all samples. Final data for all three visits was available for 37 participants who remained healthy. Ethics approval was obtained from Medanta Institution of Ethics Committee vide MICR No. 1290/2021 dated 24th May 2021. RESULTS: Mean age of the participants was 34.6Â â€‹Â±Â â€‹5.7 years (Range: 24-45 years). Highly significant improvement in SARS-CoV-2 IgG levels was observed after each visit {Mean IgG: (V(0) v/s. V(1): 133.8Â â€‹Â±Â â€‹339.2AU/ml v/s. 434.5Â â€‹Â±Â â€‹519.2AU/ml; p-valueÂ â€‹=Â â€‹0.003) and V(0) v/s. V(2): 133.8Â â€‹Â±Â â€‹339.2AU/ml v/s. 420.9Â â€‹Â±Â â€‹394.2AU/ml; p-valueÂ â€‹=Â â€‹0.002) Between visits 0 and 1, the mean value for CD4 NaÃ¯ve T cells showed significant increase, while CD4 central memory (CM) T cells showed significant decrease. Between visits 0 and 2 the mean values for CD4 NaÃ¯ve T cells, CD8 NaÃ¯ve T cells and Pre germinal centre (Pre GC) B cells showed significant increase. During the same period the mean values for CD4CM, CD8 effector memory (EM) and CD8 CM T cells showed significant decrease. CONCLUSION: It is concluded that both, humoral and cellular immunity, play an important role in maintaining immunity against COVID-19 infection, following COVISHIELD vaccination. Moreover, in subjects with normalisation of antibody levels post vaccination, persistence of T cell subsets may still offer some immunity.

Evaluation of non-clinical toxicity studies of COVID-19 vaccines. In this study we evaluated the outcomes of non-clinical toxicity studies of various SARS-CoV-2 vaccines produced with different manufacturing technologies, with focus on Repeated Dose Toxicity (RDT) and Developmental and Reproductive Toxicity (DART) studies. We found that RDT and DART studies at doses relevant for human treatment showed no adverse effects while remaining observations were expected findings including local reactogenicity, immune response and macroscopic findings at the injection site. We have also reviewed the European Medicines Agency (EMA) nonclinical assessment reports for market authorization. Regardless of utilized vaccine manufacturing technology EMA assessment of the non-clinical studies consisted most frequently of comments related to study design, species selection and missing data. Sponsors have often submitted platform studies (vaccine studies with the same technology/construct but using other antigens) as supplementary data. Animal model-based toxicity testing has shown rather small effects, which have been never serious adverse effects. The translational value to support clinical development is mainly to inflammatory effects, indicative of the primary action of the vaccines. From a 3R perspective supportive platform technology data consisting of previously executed RDT and DART studies from the same platform technology are encouraged to be implemented in the vaccine assessment process.

Post-COVID Vaccine Thrombocytopenia.

Characterization of stability, safety and immunogenicity of the mRNA lipid nanoparticle vaccine IribovaxÂ® against COVID-19 in nonhuman primates. mRNA-lipid nanoparticle (mRNA-LNP) vaccines have proved their efficacy, versatility and unprecedented manufacturing speed during the COVID-19 pandemic. Here we report on the physicochemical properties, thermostability, immunogenicity, and protective efficacy of the nucleoside-modified mRNA-LNP vaccine candidate IribovaxÂ® (also called SNEG2c). Injection of BALB/c mice, rabbits and nonhuman primates with two doses of SNEG2c induced production of high-titers of SARS-CoV-2 spike-specific and receptor-binding domain (RBD)-neutralizing antibodies in immunized animals. In addition to the strong humoral response, SNEG2c elicited substantial Th1-biased T-cell response. Sera from rhesus macaques immunized with a low dose of the vaccine showed robust spike-specific antibody titers 3-24Ã— as high as those in convalescent sera from a panel of COVID-19 patients and 50% virus neutralization geometric mean titer of 1024 against SARS-CoV-2. Strikingly, immunization with SNEG2c completely cleared infectious SARS-CoV-2 from the upper and lower respiratory tracts of challenged macaques and protected them from viral-induced lung and trachea lesions. In contrast, the non-vaccinated macaques developed moderate to severe pulmonary pathology after the viral challenge. We present the results of repeat-dose and local tolerance toxicity and thermostability studies showing how the physicochemical properties of the mRNA-LNPs change over time and demonstrating that SNEG2 is safe, well tolerated and stable for long-term. These results support the planned human trials of SNEG2c.

Anti-PEG IgM production induced by PEGylated liposomes as a function of administration route. Modifying the surface of nanoparticles with polyethylene glycol (PEG) is a commonly used approach for improving the in vitro stability of nanoparticles such as liposomes and increasing their circulation half-lives. We have demonstrated that, in certain conditions, an intravenous (i.v.) injection of PEGylated liposomes (PEG-Lip) induced anti-PEG IgM antibodies, which led to rapid clearance of second doses in mice. SARS-CoV-2 vaccines, composed of mRNA-containing PEGylated lipid nanoparticles, have been widely administered as intramuscular (i.m.) injections, so it is important to determine if PEGylated formulations can induce anti-PEG antibodies. If the favorable properties that PEGylation imparts to therapeutic nanoparticles are to be widely applicable this should apply to various routes of administration. However, there are few reports on the effect of different administration routes on the in vivo production of anti-PEG IgM. In this study, we investigated anti-

PEG IgM production in mice following i.m., intraperitoneal (i.p.) and subcutaneous (s.c.) administration of PEG-Lip. PEG-Lip appeared to induce anti-PEG IgM by all the tested routes of administration, although the lipid dose causing maximum responses varied. Splenectomy attenuated the anti-PEG IgM production for all routes of administration, suggesting that splenic immune cells may have contributed to anti-PEG IgM production. Interestingly, in vitro experiments indicated that not only splenic cells but also cells in the peritoneal cavity induced anti-PEG IgM following incubation with PEG-Lip. These observations confirm previous experiments that have shown that measurable amounts of PEG-Lip administered i.p., i.m. or s.c. are absorbed to some extent into the blood circulation, where they can be distributed to the spleen and/or peritoneal cavity, and are recognized by B cells, triggering anti-PEG IgM production. The results obtained in this study have important implications for developing efficient PEGylated nanoparticular delivery system.

Immune response after two doses of the BNT162b2 COVID-19 vaccine and risk of SARS-CoV-2 breakthrough infection in Tyrol, Austria: an open-label, observational phase 4 trial. BACKGROUND: Correlates of protection could help to assess the extent to which a person is protected from SARS-CoV-2 infection after vaccination (so-called breakthrough infection). We aimed to clarify associations of antibody and T-cell responses after vaccination against COVID-19 with risk of a SARS-CoV-2 breakthrough infection and whether measurement of these responses enhances risk prediction. METHODS: We did an open-label, phase 4 trial in two community centres in the Schwaz district of the Federal State of Tyrol, Austria, before the emergence of the omicron (B.1.1.529) variant of SARS-CoV-2. We included individuals (aged â‰¥16 years) a mean of 35 days (range 27-43) after they had received a second dose of the BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine. We quantified associations between immunological parameters and breakthrough infection and assessed whether information on these parameters improves risk discrimination. The study is registered with the European Union Drug Regulating Authorities Clinical Trials Database, 2021-002030-16. FINDINGS: 2760 individuals (1682 [60Â·9%] female, 1078 [39Â·1%] male, mean age 47Â·4 years [SD 14Â·5]) were enrolled into this study between May 15 and May 21, 2021, 712 (25Â·8%) of whom had a previous SARS-CoV-2 infection. Over a median follow-up of 5Â·9 months, 68 (2Â·5%) participants had a breakthrough infection. In models adjusted for age, sex, and previous infection, hazard ratios for breakthrough infection for having twice the immunological parameter level at baseline were 0Â·72 (95% CI 0Â·60-0Â·86) for anti-spike IgG, 0Â·80 (0Â·70-0Â·92) for neutralising antibodies in a surrogate virus neutralisation assay, 0Â·84 (0Â·58-1Â·21) for T-cell response after stimulation with a CD4 peptide pool, and 0Â·77 (0Â·54-1Â·08) for T-cell response after stimulation with a combined CD4 and CD8 peptide pool. For neutralising antibodies measured in a nested case-control sample using a pseudotyped virus neutralisation assay, the corresponding odds ratio was 0Â·78 (0Â·62-1Â·00). Among participants with previous infection, the corresponding hazard ratio was 0Â·73 (0Â·61-0Â·88) for anti-nucleocapsid Ig. Addition of anti-spike IgG information to a model containing information on age and sex improved the C-index by 0Â·085 (0Â·027-0Â·143). INTERPRETATION: In contrast to T-cell response, higher levels of binding and neutralising antibodies were associated with a reduced risk of breakthrough SARS-CoV-2 infection. The assessment of anti-spike IgG enhances the prediction of incident breakthrough SARS-CoV-2 infection and could therefore be a suitable correlate of protection in practice. Our phase 4 trial measured both humoral and cellular immunity and had a 6-month follow-up period; however, the longer-term protection against emerging variants of SARS-CoV-2 remains unclear. FUNDING: None.

Chest CT features of COVID-19 in vaccinated versus unvaccinated patients: use of CT severity score and outcome analysis. OBJECTIVES: To evaluate the impact of vaccination on severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and moreover on coronavirus disease 2019 (COVID-19) pneumonia, by assessing the extent of lung disease using the CT severity score

(CTSS). METHODS: Between September 2021 and February 2022, SARS-CoV-2 positive patients who underwent chest CT were retrospectively enrolled. Anamnestic and clinical data, including vaccination status, were obtained. All CT scans were evaluated by two readers using the CTSS, based on a 25-point scale. Univariate and multivariate logistic regression analyses were performed to evaluate the associations between CTSS and clinical or demographic variables. An outcome analysis was used to differentiate clinical outcome between vaccinated and unvaccinated patients. RESULTS: Of the 1040 patients (537 males, 503 females; median age 58Â years), 678 (65.2%) were vaccinated and 362 (34.8%) unvaccinated. Vaccinated patients showed significantly lower CTSS compared to unvaccinated patients (pâ€‰<â€‰0.001), also when patients without lung involvement (CTSSâ€‰=â€‰0) were excluded (pâ€‰<â€‰0.001). Older age, male gender and lower number of doses administered were associated with higher CTSS, however, in the multivariate analysis, vaccination status resulted to be the variable with the strongest association with CTSS. Clinical outcomes were significantly worse in unvaccinated patients, including higher number of ICU admissions and higher mortality rates. CONCLUSIONS: Lung involvement during COVID-19 was significantly less severe in vaccinated patients compared with unvaccinated patients, who also showed worse clinical outcomes. Vaccination status was the strongest variable associated to the severity of COVID-related, more than age, gender, and number of doses administered.

Safety, immunogenicity and protection of heterologous boost with an aerosolised Ad5-nCoV after two-dose inactivated COVID-19 vaccines in adults: a multicentre, open-label phase 3 trial. BACKGROUND: Aerosolised Ad5-nCoV is one of the first licensed mucosal respiratory vaccine against SARS-CoV-2 in the world; however, the safety profile of this vaccine has not been reported in a large population yet. METHODS: This multicentre, open-label phase 3 trial, done in 15 centres in six provinces (Jiangsu, Hunan, Anhui, Chongqing, Yunnan, Shandong) in China, aimed to evaluate the safety and immunogenicity of aerosolised Ad5-nCoV in healthy adults (members of the general population with no acute febrile disorders, infectious disease, serious cardiovascular diseases, serious chronic diseases or progressive diseases that cannot be controlled) at least 18 years old, who had received two doses of inactivated COVID-19 vaccine as their primary regimen. This study contained a non-randomly assigned safety cohort and a centrally randomly assigned (1:1) immunogenicity subcohort. The patients in the immunogenicity subcohort received aerosolised Ad5-nCov (aerosolised Ad5-nCoV group) or inactivated vaccine (inactivated COVID-19 group) The primary endpoints were the incidence of adverse reactions within 28 days following the booster vaccination with aerosolised Ad5-nCoV in the safety population (collected through a daily record of any solicited or unsolicited adverse events filled by each participant) and the geometric mean titre of neutralising antibodies at day 28 after the booster dose in the immunogenicity subcohort (measured with a pseudovirus neutralisation test). This study was registered with ClinicalTrials.gov, NCT05204589. FINDINGS: Between Jan 22, 2022, and March 12, 2022, we recruited 11â€‰410 participants who were screened for eligibility, of whom 10â€‰267 (99Â·8%) participants (5738 [55Â·9%] men, 4529 [44Â·1%] women; median age 53 years [18-92]) received the study drugs: 9847 (95Â·9%) participants in the open-label cohort to receive aerosolised Ad5-nCoV, and 420 (4Â·1%) in the immunogenicity subcohort (212 in the aerosolised Ad5-nCoV group and 208 in the inactivated vaccine group). Adverse reactions were reported by 1299 (13%) of 10â€‰059 participants within 28 days after receiving the booster vaccination with aerosolised Ad5-nCoV, but most of the adverse reactions reported were mild to moderate in severity. Participants in the aerosolised Ad5-nCoV group had a significantly higher level of the neutralising antibodies against omicron BA.4/5 (GMT 107Â·7 [95% CI 88Â·8-130Â·7]) than did those in the inactivated vaccine group (17Â·2 [16Â·3-18Â·2]) at day 28. INTERPRETATION: The heterologous booster regimen with aerosolised Ad5-nCoV is safe and highly immunogenic, boosting both systemic and mucosal immunity against omicron subvariants. FUNDING: National Natural

Science Foundation of China, Jiangsu Provincial Science Fund for Distinguished Young Scholars, and Jiangsu Provincial Key Project of Science and Technology Plan. TRANSLATION: For the Chinese translation of the abstract see Supplementary Materials section.

Safety of monovalent and bivalent BNT162b2 mRNA COVID-19 vaccine boosters in at-risk populations in Israel: a large-scale, retrospective, self-controlled case series study. BACKGROUND: COVID-19 continues to be a major health threat, particularly among at-risk groups, including individuals aged 60 years or older and people with particular medical conditions. Nevertheless, the absence of sufficient vaccine safety information is one of the key contributors to vaccine refusal. We aimed to assess the short-term safety profile of the BNT162b2 mRNA COVID-19 vaccine booster doses. METHODS: In this self-controlled case series study, we used a database of members of the largest health-care organisation in Israel. We analysed the medical records of individuals at risk of COVID-19 complications who had received two doses of the monovalent BNT162b2 mRNA COVID-19 vaccine (tozinameran, Pfizer-BioNTech) as their primary course of vaccination and then also received BNT162b2 mRNA COVID-19 vaccine boosters between July 30, 2021, and Nov 28, 2022, as a monovalent first or second booster, or as a bivalent first, second, or third booster, or a combination of these. We included individuals who had active membership of the health-care organisation and who were alive (excluding COVID-19 deaths) throughout the entire study period. We excluded individuals who, during the study period, were either not active Clalit Health Services members or died of non-COVID-19 causes, and those who were infected with COVID-19 during the 7-day period after vaccination. Individuals' at-risk status was assessed on the day before the baseline period started. The primary outcome was non-COVID-19 hospitalisation for 29 adverse events that might be associated with vaccination. For each adverse event, we compared the risk difference of hospitalisation during a 28-day pre-vaccination baseline period versus during a 28-day post-vaccination period, using a non-parametric percentile bootstrap method. FINDINGS: Of the 3â€‰574â€‰243 members of the health-care organisation, 1â€‰073â€‰110 received a first monovalent booster, 394â€‰251 received a second monovalent booster, and 123â€‰084 received a bivalent first, second, or third booster. Overall, we found no indication of an elevated risk of non-COVID-19 hospitalisation following administration of any of the booster vaccines (risk difference in events per 100â€‰000 individuals: first monovalent booster -37Â·1 [95% CI -49Â·8 to -24Â·2]; second monovalent booster -37Â·8 [-62Â·2 to -13Â·2]; and bivalent booster -18Â·7 [-53Â·6 to 15Â·4]). Except for extremely rare elevated risks after the first monovalent booster-of myocarditis (risk difference 0Â·7 events per 100â€‰000 individuals [95% CI 0Â·3-1Â·3]), seizures (2Â·2 [0Â·4-4Â·1]), and thrombocytopenia (2Â·6 [0Â·7-4Â·7])-we found no safety signals in other adverse events, including ischaemic stroke. INTERPRETATION: This study provides the necessary vaccine safety assurances for at-risk populations to receive timed roll-out booster vaccinations. These assurances could reduce vaccine hesitancy and increase the number of at-risk individuals who opt to become vaccinated, and thereby prevent the severe outcomes associated with COVID-19. FUNDING: Israel Science Foundation and Israel Precision Medicine Partnership programme.

Association Between Anti-CD20 Therapies and COVID-19 Severity Among Patients With Relapsing-Remitting and Progressive Multiple Sclerosis. IMPORTANCE: In patients with multiple sclerosis (MS), factors associated with severe COVID-19 include anti-CD20 therapies and neurologic disability, but it is still unclear whether these 2 variables are independently associated with severe COVID-19 or whether the association depends on MS clinical course. OBJECTIVE: To assess the association between anti-CD20 therapies and COVID-19 severity in patients with relapsing-remitting MS (RRMS) and progressive MS (PMS). DESIGN, SETTING, AND PARTICIPANTS: This multicenter, retrospective cohort study used data from the COVISEP study, which included patients with MS and COVID-19 from February 1, 2020, to June 30, 2022, at 46 French MS expert centers, general hospitals, and private

neurology practices. Eligible patients with RRMS were those treated with high-efficacy MS therapy (ie, anti-CD20, fingolimod, or natalizumab), and eligible patients with PMS were those younger than 70 years with an Expanded Disability Status Scale (EDSS) score of 8 or lower. Patients were monitored from COVID-19 symptom onset until recovery or death. EXPOSURES: Current anti-CD20 therapy (ocrelizumab or rituximab). MAIN OUTCOMES AND MEASURES: The main outcome was severe COVID-19 (ie, hospitalization with any mode of oxygenation or death). All analyses were conducted separately in patients with RRMS and PMS using propensity score-weighted logistic regression. Subgroup analyses were performed according to COVID-19 vaccine status, sex, EDSS score, and age. RESULTS: A total of 1400 patients, 971 with RRMS (median age, 39.14 years [IQR, 31.38-46.80 years]; 737 [76.1%] female) and 429 with PMS (median age, 54.21 years [IQR, 48.42-60.14 years]; 250 [58.3%] female) were included in the study. A total of 418 patients with RRMS (43.0%) and 226 with PMS (52.7%) were treated with anti-CD20 therapies. In weighted analysis, 13.4% and 2.9% of patients with RRMS treated and not treated with anti-CD20 had severe COVID-19, respectively, and anti-CD20 treatment was associated with increased risk of severe COVID-19 (odds ratio [OR], 5.20; 95% CI, 2.78-9.71); this association persisted among vaccinated patients (7.0% vs 0.9%; OR, 8.85; 95% CI, 1.26-62.12). Among patients with PMS, 19.0% and 15.5% of patients treated and not treated with anti-CD20 had severe COVID-19, respectively, and there was no association between anti-CD20 treatment and severe COVID-19 (OR, 1.28; 95% CI, 0.76-2.16). In PMS subgroup analysis, anti-CD20 exposure interacted negatively with EDSS score (Pâ€‰=â€‰.009 for interaction) and age (Pâ€‰=â€‰.03 for interaction); anti-CD20 therapies were associated with risk of severe COVID-19 only in patients with less neurologic disability and younger patients with PMS. CONCLUSIONS AND RELEVANCE: In this cohort study, risk of severe COVID-19 was higher in patients with PMS than in those with RRMS. Use of anti-CD20 therapies was associated with an increased risk of severe COVID-19 among patients with RRMS. In patients with PMS, there was no association between anti-CD20 therapies and risk of severe COVID-19.

Long-term safety of COVID vaccination in individuals with idiopathic inflammatory myopathies: results from the COVAD study. Limited evidence on long-term COVID-19 vaccine safety in patients with idiopathic inflammatory myopathies (IIMs) continues to contribute to vaccine hesitancy. We studied delayed-onset vaccine adverse events (AEs) in patients with IIMs, other systemic autoimmune and inflammatory disorders (SAIDs), and healthy controls (HCs), using data from the second COVID-19 Vaccination in Autoimmune Diseases (COVAD) study. A validated self-reporting e-survey was circulated by the COVAD study group (157 collaborators, 106 countries) from Feb-June 2022. We collected data on demographics, comorbidities, IIM/SAID details, COVID-19 history, and vaccination details. Delayed-onset (>â€‰7Â day) AEs were analyzed using regression models. A total of 15165 respondents undertook the survey, of whom 8759 responses from vaccinated individuals [median age 46 (35-58) years, 74.4% females, 45.4% Caucasians] were analyzed. Of these, 1390 (15.9%) had IIMs, 50.6% other SAIDs, and 33.5% HCs. Among IIMs, 16.3% and 10.2% patients reported minor and major AEs, respectively, and 0.72% (nâ€‰=â€‰10) required hospitalization. Notably patients with IIMs experienced fewer minor AEs than other SAIDs, though rashes were expectedly more than HCs [OR 4.0; 95% CI 2.2-7.0, pâ€‰<â€‰0.001]. IIM patients with active disease, overlap myositis, autoimmune comorbidities, and ChadOx1 nCOV-19 (Oxford/AstraZeneca) recipients reported AEs more often, while those with inclusion body myositis, and BNT162b2 (Pfizer) recipients reported fewer AEs. Vaccination is reassuringly safe in individuals with IIMs, with AEs, hospitalizations comparable to SAIDs, and largely limited to those with autoimmune multimorbidity and active disease. These observations may inform guidelines to identify high-risk patients warranting close monitoring in the post-vaccination period.

Impact of peripheral mitochondrial DNA level on immune response after COVID-19 vaccination. The efficacy of vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the elderly is partially hindered by immunosenescence, resulting from decreased mtDNA levels. This study evaluated the correlation between mtDNA levels in peripheral leukocytes and immune response to the SARS-CoV-2 vaccine. Two hundred ten participants (median age 79.5 years), including 83 frail residents/inpatients and 70 robust outpatients, were analyzed. Anti-spike IgG antibody (IgG(S)) titers were serially measured from before the first vaccination to after the third vaccination. The mtDNA levels and cell-mediated immunity were measured in 45 elderly and 22 elderly individuals two months after the third vaccination. The robust group had consistently higher IgG(S) titers than the frail group. The mtDNA levels positively correlated with IgG(S) titers, as well as with cell-mediated immunity. These findings suggest that mtDNA levels positively impact vaccine-induced immunity. Further studies into maintaining mtDNA levels may provide insights into immunosenescence in the elderly.

A case report of vaccine-induced immune thrombotic thrombocytopenia (VITT) with genetic analysis. The emergence of the rare syndrome called vaccine-induced immune thrombocytopenia and thrombosis (VITT) after adenoviral vector vaccines, including ChAdOx1 nCov-19, raises concern about one's predisposing risk factors. Here we report the case of a 56-year-old white man who developed VITT leading to death within 9 days of symptom onset. He presented with superior sagittal sinus thrombosis, right frontal intraparenchymal hematoma, frontoparietal subarachnoid and massive ventricular hemorrhage, and right lower extremity arterial and venous thrombosis. His laboratory results showed elevated D-dimer, C-reactive protein, tissue factor, P-selectin (CD62p), and positive anti-platelet factor 4. The patient's plasma promoted higher CD62p expression in healthy donors' platelets than the controls. Genetic investigation on coagulation, thrombophilia, inflammation, and type I interferon-related genes was performed. From rare variants in European or African genomic databases, 68 single-nucleotide polymorphisms (SNPs) in one allele and 11 in two alleles from common SNPs were found in the patient genome. This report highlights the possible relationship between VITT and genetic variants. Additional investigations regarding the genetic predisposition of VITT are needed.

Delayed presentation of biopsy-proven eosinophilic myocarditis following COVID-19 mRNA vaccine. Myopericarditis associated with COVID-19 mRNA vaccines has been recognized as an uncommon adverse reaction, especially among young, healthy adult males. Eosinophilic myocarditis is a rare form of inflammation reflecting a hypersensitivity reaction following an inciting event commonly caused by drugs including vaccines. Eosinophilic myocarditis, a subtype of myocarditis, is characterized by eosinophilic myocardial infiltrates. It is usually accompanied by systemic eosinophilia in the form of a drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome and is rarely associated with myocyte fibrosis and/or necrosis. In this report, we present a case of biopsy-proven eosinophilic myocarditis in a 24-year-old male patient, likely secondary to COVID-19 mRNA vaccination. To our knowledge, this is the first report to describe delayed eosinophilic myocarditis following the COVID-19 mRNA vaccine. Clinicians should be aware of possible delayed presentation to avoid associated morbidity.

Neuro-Ophthalmic Complications of COVID-19 Infection and Vaccination. The COVID-19 pandemic has led to the identification of new disease phenotypes associated with infection by the SARS-CoV-2 virus. This includes multiple neuro-ophthalmological sequelae, which have been associated with COVID-19 infection and administration of COVID-19 vaccines. Some of these associations have a plausible pathophysiological link to the infection or vaccination but true causation has yet to be established. We review the literature for associations reported between COVID-19

infection or vaccination and neuro-ophthalmic sequelae and review the potential pathophysiological processes that may underlie these associations.

Response to mRNA SARS-CoV-2 vaccination evaluated by B-cell receptor repertoire after tixagevimab/cilgavimab administration. The use of anti-SARS-CoV-2 antibody products like tixagevimab/cilgavimab represents an important strategy to protect immunocompromised patients with haematological malignancies from COVID-19. Although patients who receive these agents should still be vaccinated, the use of tixagevimab/cilgavimab can mask the production of anti-spike antibody after vaccination, making it hard to assess vaccine response. We have newly established a quantification method to assess the response to SARS-CoV-2 vaccination at the mRNA level using B-cell receptor (BCR) repertoire assay and the Coronavirus Antibody Database (CoV-AbDab). Repeated blood samples before and after vaccination were analysed for the BCR repertoire, and BCR sequences were searched in the database. We analysed the number and percentage frequency of matched sequences. We found that the number of matched sequences increased 2â€‰weeks after the first vaccination and quickly decreased. Meanwhile, the number of matched sequences more rapidly increased after the second vaccination. These results show that the postvaccine immune response can be assessed at the mRNA level by analysing the fluctuation in matching sequences. Finally, BCR repertoire analysis with CoV-AbDab clearly demonstrated the response to mRNA SARS-CoV-2 vaccination even after tixagevimab/cilgavimab administration in haematological malignancy patients who underwent allogeneic haematopoietic stem cell transplantation.

Hypersensitivity reactions to anti-SARS-CoV-2 vaccines: Basophil reactivity to excipients. Basophil activation test (BAT) can tackle multiple mechanisms underlying acute and delayed hypersensitivity to drugs and vaccines and might complement conventional allergy diagnostics but its role in anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine-related hypersensitivity is ill-defined. Therefore, 89 patients with possible hypersensitivity (56â€¯% with delayed mucocutaneous manifestations) to anti-SARS-CoV-2 vaccines were tested with BAT for Macrogol 3350, DMG-PEG 2000, PEG 20000, polysorbate-80 and trometamol and compared to 156 subjects undergoing pre-vaccine BAT. A positive BAT was associated with delayed reaction onset (pÂ =Â 0.010) and resolution (pÂ =Â 0.011). BAT was more frequently positive to DMG-PEG 2000 than to other excipients in both groups (pÂ <Â 0.001). DMG-PEG 2000 reactivity was less frequent in vaccine-naÃ¯ve (6â€¯%) than vaccinated subjects (35â€¯%, pÂ <Â 0.001) and associated with mRNA-1273 vaccination. DMG-PEG 2000 BAT might therefore have a diagnostic role in subjects with delayed hypersensitivity reactions. Natural immunity might be a key player in basophil activation.

Herbal medicine use in Republic of Korea to alleviate side effects of COVID-19 vaccines: A cross-sectional study. OBJECTIVE: Coronavirus disease 2019 (COVID-19) has spread worldwide, and several virus variants have emerged. Vaccines are administered to help prevent the infection. In Republic of Korea, most people take herbal medicine. This study investigated the use of herbal medicine to counter the side effects of COVID-19 vaccines. METHODS: This cross-sectional study was conducted using an online survey. Chi-square tests were used to determine differences in the use of herbal medication according to sociodemographic characteristics. Independent two-sample and paired t-tests were performed to examine the effect and satisfaction of herbal medicine use for countering the side effects of COVID-19 vaccines. One-way analysis of variance was used to determine vaccine-related differences. RESULTS: A total of 233 and 181 participants received the first and second doses of COVID-19 vaccines, respectively. The majority of herbal medicine users were in their thirties, had a bachelor's degree, suffered from side effects of vaccination, and received Vaxzevria for their first COVID-19 vaccine dose and Comirnaty for their second dose. The herbal medicine group had a higher satisfaction level of post-vaccination side effects than the non-herbal medicine group (PÂ <Â 0.0001). The numeric rating scale scores for vaccination side effects were

lower among participants who took herbal medication to alleviate those symptoms (PÂ <Â 0.0001). The most commonly used herbal formula was Shuanghetang. CONCLUSION: A third of participants receiving COVID-19 vaccines used herbal medication to counter the side effects of vaccination. The use of herbal medicine was associated with age, education level, vaccine brand, and whether side effects of vaccination occurred. Herbal medication use was associated with greater satisfaction compared to vaccine recipients not using herbal medication. Please cite this article as: Yoon HC. Herbal medicine use in Republic of Korea to alleviate side effects of COVID-19 vaccines: A cross-sectional study. J Integr Med. 2023; 21(4):361-368.

Hepatitis B reactivation: A possible cause of coronavirus disease 2019 vaccine induced hepatitis. BACKGROUND AND AIMS: Coronavirus disease 2019 (COVID-19) vaccines were rapidly implemented globally and vaccine-associated immune-related hepatitis was recently reported. We aim to investigate its impact in regions endemic of chronic hepatitis B (CHB). METHODS: We retrospectively collected patients who developed hepatitis within 90 days after COVID-19 vaccination in Taiwan. The mechanisms of hepatitis included vaccine induced liver injury (VILI) and immune-related hepatitis, which are direct liver injuries defined as aspartate or alanine aminotransferase (AST or ALT) increased â‰¥ 5-fold upper limit of normal (ULN) and/or AST or ALT â‰¥ 3-fold of ULN with concurrent total bilirubin â‰¥ 2-fold of ULN. Indirect liver injury due to HBV reactivation was defined as HBsAg reverse seroconversion or significant rise in HBV DNA level. The demographics, clinical data, and course of hepatitis were compared statistically. RESULTS: Twenty-five patients were included with a median age of 54. The culprit vaccines were ChAdOx1 nCoV-19 (nÂ =Â 9), mRNA-1273 (nÂ =Â 12), and BNT162b2 (nÂ =Â 4). The characteristics of hepatitis were comparable regardless of vaccine subtypes. The median onset of hepatitis was 25 days post vaccination, with a peak of 10-fold ALT-increase. The etiologies included HBV reactivation (nÂ =Â 10), VILI (nÂ =Â 10), and immune-related hepatitis (nÂ =Â 5). HBV reactivation accounts for 90% of vaccine-induced hepatitis in patients of CHB (nÂ =Â 10), and two patients died. Patients with initial AST levels >500 U/L increased 27-fold risks of liver injury greater than moderate severity compared with those without. CONCLUSIONS: COVID-19 vaccine induced hepatitis is a clinical significant complication, and HBV reactivation may account for a possible mechanism.

Clinical features ofÂ newly diagnosed systemic lupus erythematosus after SARS-CoV-2 vaccination. Systemic lupus erythematosus (SLE) is an autoimmune disease that causes damage to multiple organs. Various factors, including vaccination, have been associated with SLE development. Vaccination for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) began in 2020, and there are a few reports on the exacerbation of SLE after SARS-CoV-2 vaccination. The influence of SARS-CoV-2 vaccination on SLE development remains unclear. We present the case of a 53-year-old man who developed peritonitis and was subsequently diagnosed with SLE on Day 9 after receiving a third dose of the messenger ribonucleic acid-1273 SARS-CoV-2 vaccine. This case and previous reports have shown that patients who developed SLE after SARS-CoV-2 vaccination are more likely to develop it within 2â€‰weeks of vaccination, especially when they have a higher rate of immunological abnormalities or a family history of autoimmune diseases. Furthermore, these features suggest that type I interferon is involved in the pathogenesis of SLE after SARS-CoV-2 vaccination.

Trends in Laboratory-Confirmed SARS-CoV-2 Reinfections and Associated Hospitalizations and Deaths Among Adults Aged â‰¥18 Years - 18 U.S. Jurisdictions, September 2021-December 2022. Although reinfections with SARS-CoV-2 have occurred in the United States with increasing frequency, U.S. epidemiologic trends in reinfections and associated severe outcomes have not been characterized. Weekly counts of SARS-CoV-2 reinfections, total infections, and associated hospitalizations and deaths reported by 18 U.S. jurisdictions during September 5, 2021-December 31, 2022, were analyzed overall, by age group, and by five periods of SARS-CoV-2 variant predominance

(Delta and Omicron [BA.1, BA.2, BA.4/BA.5, and BQ.1/BQ.1.1]). Among reported reinfections, weekly trends in the median intervals between infections and frequencies of predominant variants during previous infections were calculated. As a percentage of all infections, reinfections increased substantially from the Delta (2.7%) to the Omicron BQ.1/BQ.1.1 (28.8%) periods; during the same periods, increases in the percentages of reinfections among COVID-19-associated hospitalizations (from 1.9% [Delta] to 17.0% [Omicron BQ.1/BQ.1.1]) and deaths (from 1.2% [Delta] to 12.3% [Omicron BQ.1/BQ.1.1]) were also substantial. Percentages of all COVID-19 cases, hospitalizations, and deaths that were reinfections were consistently higher across variant periods among adults aged 18-49 years compared with those among adults aged â‰¥50 years. The median interval between infections ranged from 269 to 411 days by week, with a steep decline at the start of the BA.4/BA.5 period, when >50% of reinfections occurred among persons previously infected during the Alpha variant period or later. To prevent severe COVID-19 outcomes, including those following reinfection, CDC recommends staying up to date with COVID-19 vaccination and receiving timely antiviral treatments, when eligible.

Left Ventricular Function in Patients with Myopericarditis After mRNA COVID-19 Vaccination: Comment.

Manifestations of adverse events post Sinovac vaccine immunization at Wirasakti Hospital, Kupang. BACKGROUND: Since it was first discovered, COVID-19 has spread worldwide and has been declared a pandemic by the World Health Organization. One of the various efforts made to prevent the spread of COVID-19 is the development of the COVID-19 vaccine. One of the vaccines developed and used by the Indonesian government is the Sinovac vaccine. However, like vaccines in general, there are always vaccine safety problems which are better known as adverse events following immunization (AEFI). OBJECTIVE: The purpose of this study is to determine the AEFI manifestations that occurred in Sinovac vaccination participants at Wirasakti Hospital, Kupang. METHODS: The sample included 51 people, who later became known as research subjects. The criteria for vaccine recipients and instructions for recording AEFI refer to the technical guidelines issued by the Ministry of Health, namely the Decree of the Director General of Disease Prevention and Control number HK.02.02/4/1/2021 regarding technical instructions for implementation of vaccination in the context of combating pandemic COVID-19. RESULTS: The results showed that out of 198 vaccination participants, 15 of them had AEFI and those who had AEFI were women. The AEFI manifestations that occur are dizziness, palpitations, shortness of breath, cramps in the hands, and trembling hands. All AEFI that occurred are non-serious in nature. CONCLUSION: Sinovac vaccine is relatively safe to use because only a small proportion of respondents (29.4%) have AEFI.

[Vaccination approach in patients with an allergic reaction to COVID-19 vaccines or at risk of developing allergic reactions]. INTRODUCTION: There is consensus that patients at risk of developing an allergic reaction to COVID-19 vaccines should be evaluated by an immunologist-allergist to determine whether vaccination should be recommended. We wanted to share our experiences in the management of these high-risk patients, from diagnostic tests in allergological evaluation to the vaccination process. MATERIALS AND METHODS: Our retrospective cross-sectional study included patients who had previously developed an allergic reaction to COVID-19 vaccines or drugs and therefore were referred to our allergy and immunology clinic. Prick and intradermal tests were performed on all patients with methylprednisolone acetate (Depo-MedrolÂ®, Pfizer) 40 mg/mL containing polyethylene Glycol (PEG) and triamcinolone acetonide (KenacortÂ®, Deva) 40 mg/mL containing polysorbate 80. While vaccination with desensitization was recommended for all patients with positive skin tests, split-dose vaccination was recommended for patients with negative skin tests. After explaining the risks and benefits, the choice of the vaccine (Pfizer/BioNTech or Sinovac/ CoronoVac) was left to the patients' discretion. RESULT: A total of 41 patients, 10 males, and 31

females, with a mean age of 42.37 Â± 14.177 years were included. Eighteen patients with a history of allergy after COVID-19 vaccines were analyzed according to the type of reaction and type of vaccine administered (Pfizer/BioNTech/Coronovac; Anaphylaxis: 4/1, Urticaria: 11/2). Moreover, there was a history of drug allergy in 23 patients who had not been vaccinated before. Skin tests with PEG were positive in a total of seven patients while skin tests with polysorbate 80 were negative in all patients. No allergic reaction developed in seven patients who underwent desensitization and in 34 patients who received a split dose. CONCLUSIONS: Considering the potentially life-saving benefits of vaccination in a global pandemic environment, it is a safe and effective method to administer vaccines to at-risk patients using desensitization or split dosing techniques, based on their sensitivity status determined through a PEG skin test. This approach allows for the avoidance of preventing access to vaccines, while still ensuring the safety of patients.

A Case of Concurrent Acute Macular Neuroretinopathy and Paracentral Acute Middle Maculopathy Following Pfizer-BioNTech COVID-19 Vaccination. We present a 65-year-old woman who developed sudden and severe vision loss in her left eye one day after the administration of the second dose of COVID vaccine. The best corrected visual acuity in this eye was 1/10. Diffuse paracentral acute middle maculopathy was detected on spectral domain optical coherence tomography (OCT). OCT angiography images revealed concurrent vascular flow defects consistent with acute macular neuroretinopathy in the deep retinal capillary plexus and choriocapillaris layers. At the end of the six-month follow-up, there was no improvement in visual acuity, and atrophy and thinning developed in all layers of the retina.

Insights into SARS-CoV-2-associated subacute thyroiditis: from infection to vaccine. Since the COVID-19 emergence as a global pandemic in March 2020, more than 5 million SARS-CoV-2-related deaths have been globally documented. As the pandemic progressed, it became clear that, although the infection is mainly characterized as a respiratory disease, it also affects other organs and systems, including the thyroid gland. Indeed, emerging evidence suggests that SARS-CoV-2 can act as a trigger for various thyroid disorders, for example, subacute thyroiditis (SAT), Grave's disease, and non-thyroidal illness syndrome. The entry of SARS-CoV-2 into the host cells is mainly mediated by the ACE2-receptor, making organs and systems with high expression of this receptor, such as the thyroid gland, highly vulnerable to COVID-19. Accumulating data propose that SAT may be an underestimated manifestation of COVID-19 infection. Importantly, if SAT remains unrecognized, it may trigger or aggravate potential other complications of the disease, for example, respiratory insufficiency and cardiovascular complications, and thus negatively influence prognosis. Moreover, recent case reports, case series, and systematic reviews highlight SAT as a potential side effect of the vaccination against SARS-CoV-2. The present review aims to raise awareness of SARS-CoV-2-associated- and post-vaccination subacute thyroiditis, to discuss recent evidence regarding its pathophysiology, and to present useful information for this special form of SAT related to daily clinical practice.

Single Ad26.COV2.S booster dose following two doses of BBIBP-CorV vaccine against SARS-CoV-2 infection in adults: Day 28 results of a phase 1/2 open-label trial. BACKGROUND: The inactivated COVID-19 whole-virus vaccine BBIBP-CorV has been extensively used worldwide. Heterologous boosting after primary vaccination can induce higher immune responses against SARS-CoV-2 than homologous boosting. The safety and immunogenicity after 28Â days of a single Ad26.COV2.S booster dose given at different intervals after 2 doses of BBIBP-CorV are presented. METHODS: This open-label phase 1/2 trial was conducted in healthy adults in Thailand who had completed 2-dose primary vaccination with BBIBP-CorV. Participants received a single booster dose of Ad26.COV2.S (5Â Ã— Â 10(10) virus particles) 90-240Â days (Group A1; nÂ =Â 360) or 45-75Â days (Group A2; nÂ =Â 66) after the second BBIBP-CorV dose. Safety and immunogenicity were assessed over 28Â days. Binding IgG antibodies to the full-length pre-fusion Spike and anti-nucleocapsid proteins of SARS-CoV-2 were

measured by enzyme-linked immunosorbent assay. The SARS-CoV-2 pseudovirus neutralization assay and live virus microneutralization assay were used to quantify the neutralizing activity of antibodies against ancestral SARS-CoV-2 (Wuhan-Hu-1) and the delta (B.1.617.2) and omicron (B.1.1.529/BA.1 and BA.2) variants. The cell-mediated immune response was measured using a quantitative interferon (IFN)-Î³ release assay in whole blood. RESULTS: Solicited local and systemic adverse events (AEs) on days 0-7 were mostly mild, as were unsolicited vaccine-related AEs during days 0-28, with no serious AEs. On day 28, anti-Spike binding antibodies increased from baseline by 487- and 146-fold in Groups A1 and A2, and neutralizing antibodies against ancestral SARS-CoV-2 by 55- and 37-fold, respectively. Humoral responses were strongest against ancestral SARS-CoV-2, followed by the delta, then the omicron BA.2 and BA.1 variants. T-cell-produced interferon-Î³ increased approximately 10-fold in both groups. CONCLUSIONS: A single heterologous Ad26.COV2.S booster dose after two BBIBP-CorV doses was well tolerated and induced robust humoral and cell-mediated immune responses measured at day 28 in both interval groups. CLINICAL TRIALS REGISTRATION: NCT05109559.

Safety of simultaneous vaccination with COVID-19 vaccines in the Vaccine Safety Datalink. INTRODUCTION: Safety data on simultaneous vaccination (SV) with primary series monovalent COVID-19 vaccines and other vaccines are limited. We describe SV with primary series COVID-19 vaccines and assess 23 pre-specified health outcomes following SV among persons agedÂ â‰¥5Â years in the Vaccine Safety Datalink (VSD). METHODS: We utilized VSD's COVID-19 vaccine surveillance data from December 11, 2020-May 21, 2022. Analyses assessed frequency of SV. Rate ratios (RRs) were estimated by Poisson regression when the number of outcomes wasÂ â‰¥5 across both doses, comparing outcome rates between COVID-19 vaccinees receiving SV and COVID-19 vaccinees receiving no SV in the 1-21Â days following COVID-19 vaccine dose 1 and 1-42Â days following dose 2 by SV type received ("All SV", "Influenza SV", "Non-influenza SV"). RESULTS: SV with COVID-19 vaccines was not common practice (dose 1: 0.7 % of 8,455,037 persons, dose 2: 0.3 % of 7,787,013 persons). The most frequent simultaneous vaccines were influenza, HPV, Tdap, and meningococcal. Outcomes following SV with COVID-19 vaccines were rare (total of 56 outcomes observed after dose 1 and dose 2). Overall rate of outcomes among COVID-19 vaccinees who received SV was not statistically significantly different than the rate among those who did not receive SV (6.5 vs. 6.8 per 10,000 persons). Statistically significant elevated RRs were observed for appendicitis (2.09; 95 % CI, 1.06-4.13) and convulsions/seizures (2.78; 95 % CI, 1.10-7.06) in the "All SV" group following dose 1, and for Bell's palsy (2.82; 95 % CI, 1.14-6.97) in the "Influenza SV" group following dose 2. CONCLUSION: Combined pre-specified health outcomes observed among persons who received SV with COVID-19 vaccine were rare and not statistically significantly different compared to persons who did not receive SV with COVID-19 vaccine. Statistically significant adjusted rate ratios were observed for some individual outcomes, but the number of outcomes was small and there was no adjustment for multiple testing.

Evaluation of potential adverse events following COVID-19 mRNA vaccination among adults aged 65 years and older: Two self-controlled studies in the U.S. BACKGROUND: Our near-real-time safety monitoring of 16 adverse events (AEs) following COVID-19 mRNA vaccination identified potential elevation in risk for six AEs following primary series and monovalent booster dose administration. The crude association with AEs does not imply causality. Accordingly, we conducted robust evaluation of potential associations. METHODS: We conducted two self-controlled case series studies of COVID-19 mRNA vaccines (BNT162b2 and mRNA-1273) in U.S. Medicare beneficiaries agedÂ â‰¥Â 65Â years. Adjusted incidence rate ratio (IRRs) and 95 % confidence intervals (CIs) were estimated following primary series doses for acute myocardial infarction (AMI), pulmonary embolism (PE), immune thrombocytopenia (ITP), disseminated intravascular coagulation (DIC); and following monovalent

booster doses for AMI, PE, ITP, Bell's Palsy (BP) and Myocarditis/Pericarditis (Myo/Peri). RESULTS: The primary series study included 3,360,981 individuals who received 6,388,542 primary series doses; the booster study included 6,156,100 individuals with one monovalent booster dose. The AMI IRR following BNT162b2 primary series and booster was 1.04 (95 % CI: 0.91 to 1.18) and 1.06 (95 % CI: 1.003 to 1.12), respectively; for mRNA-1273 primary series and booster, 1.01 (95 % CI: 0.82 to 1.26) and 1.05 (95 % CI: 0.998 to 1.11), respectively. The hospital inpatient PE IRR following BNT162b2 primary series and booster was 1.19 (95 % CI: 1.03 to 1.38) and 0.86 (95 % CI: 0.78 to 0.95), respectively; for mRNA-1273 primary series and booster, 1.15 (95 % CI: 0.94 to 1.41) and 0.87 (95 % CI: 0.79 to 0.96), respectively. The studies' results do not support that exposure to COVID-19 mRNA vaccines elevate the risk of ITP, DIC, Myo/Peri, and BP. CONCLUSION: We did not find an increased risk for AMI, ITP, DIC, BP, and Myo/Peri and there was not consistent evidence for PE after exposure to COVID-19 mRNA primary series or monovalent booster vaccines. These results support the favorable safety profile of COVID-19 mRNA vaccines administered in the U.S. elderly population.

Vaccination status of COVID-19 patients followed up in the ICU in a country with heterologous vaccination policy: A multicenter national study in Turkey. OBJECTIVE: Vaccination against severe acute respiratory syndrome coronavirus-2 (SARS-2) prevents the development of serious diseases has been shown in many studies. However, the effect of vaccination on outcomes in COVID-19 patients requiring intensive care is not clear. METHODS: This is a retrospective multicenter study conducted in 17 intensive care unit (ICU) in Turkey between January 1, 2021, and December 31, 2021. Patients aged 18 years and older who were diagnosed with COVID-19 and followed in ICU were included in the study. Patients who have never been vaccinated and patients who have been vaccinated with a single dose were considered unvaccinated. Logistic regression models were fit for the two outcomes (28-day mortality and in-hospital mortality). RESULTS: A total of 2968 patients were included final analysis. The most of patients followed in the ICU during the study period were unvaccinated (58.5%). Vaccinated patients were older, had higher Charlson comorbidity index (CCI), and had higher APACHE-2 scores than unvaccinated patients. Risk for 28-day mortality and in-hospital mortality was similar in across the year both vaccinated and unvaccinated patients. However, risk for in-hospital mortality and 28-day mortality was higher in the unvaccinated patients in quarter 4 adjusted for gender and CCI (OR: 1.45, 95% CI: 1.06-1.99 and OR: 1.42, 95% CI: 1.03-1.96, respectively) compared to the vaccinated group. CONCLUSION: Despite effective vaccination, fully vaccinated patients may be admitted to ICU because of disease severity. Unvaccinated patients were younger and had fewer comorbid conditions. Unvaccinated patients have an increased risk of 28-day mortality when adjusted for gender and CCI.

Neutralizing activity and T-cell response after bivalent fifth dose of messenger RNA vaccine in people living with HIV. OBJECTIVES: To investigate immunogenicity of SARS-CoV-2 vaccine third booster dose (3BD; fifth dose) with bivalent vaccine original/BA4/5 vaccine in people living with HIV (PLWH). METHODS: This is an observational cohort study to evaluate the outcomes of SARS-CoV-2 vaccination (HIV-VAC study). We analyzed microneutralization assay and interferon-Î³ production in 48 PLWH on antiretroviral therapy with clusters of differentiation (CD4) count <200 cell/mm(3) and/or previous AIDS according to immunization status: vaccinated PLWH who had a previous SARS-CoV-2 infection (hybrid immunization, HI) vs those only vaccinated (non-hybrid immunization, nHI) and current CD4 count. RESULTS: After 15 days from its administration (T1), the 3BD bivalent messenger RNA vaccine elicited a statistically significant increase of neutralizing antibodies (nAbs) geometric mean titers from T0 to T1 against W-D614G (fold increase 4.8; P <0.0001), BA.5 (8.6 P <0.0001), BQ.1.1 (6.4, P <0.0001) and XBB.1 (6.5, P <0.0001). When compared to BA.5, nAbs geometric mean titers against BQ.1.1 and XBB.1 decreased by 3.5 and 4.1-fold, respectively. After controlling for age, years from AIDS diagnosis, CD4 count at administration and CD4 count nadir, the fold change reduction in nAbs response to

other variants of concerns as compared to BA.1, was larger in participants with HI vs those nHI: 0.59 lower (95% confidence interval 0.36-0.97, PÂ =Â 0.04) for BQ.1.1 and 0.67 lower (95% confidence interval: 0.47-0.96, PÂ =Â 0.03) for XBB.1. In contrast, the analysis carried little evidence for an association between current CD4 count and response to the fifth dose of bivalent vaccine. Furthermore, cell-mediated immunity remained stable. CONCLUSION: Our data support the current recommendation of offering bivalent mRNA vaccine booster doses to PLWH with low CD4 count or previous AIDS at first vaccination, especially in those who never previously acquired SARS-CoV-2 and regardless of current CD4 count.

Risk of congenital malformation after first trimester mRNA COVID-19 vaccine exposure in pregnancy: the COVI-PREG prospective cohort. OBJECTIVES: This study aimed to evaluate the risk of congenital malformation among pregnant women exposed to the mRNA COVID-19 vaccines during the first trimester of pregnancy, which is a developmental period where the foetus is at risk of teratogenicity. METHODS: Pregnant women were prospectively enrolled from March 2021 to March 2022, at the time of COVID-19 vaccination. Pregnant women exposed to at least one dose of mRNA COVID-19 vaccine from conception to 11Â weeks of gestations and 6Â days were compared with pregnant women exposed to the vaccine from 12Â weeks to the end of pregnancy. The primary outcome was a confirmed congenital malformation at birth. RESULTS: A total of 1450 pregnant women were enrolled including 124 in the first trimester and 1326 in the second and third trimester. The overall proportion of congenital malformation was 0.81% (nÂ =Â 1/124; 95% CI: 0.02-4.41) and 0.83% (nÂ =Â 11/1326; 95% CI: 0.41-1.48) among pregnant exposed to the COVID-19 vaccine during the first and second/third trimester, respectively. First trimester exposure was not associated with a higher risk of congenital malformation with a relative risk of 0.89 (95% CI: 0.12-6.80) with no significant changes after adjustment through exploratory analysis. CONCLUSIONS: Pregnant women exposed to mRNA COVID-19 vaccine before 12Â weeks of gestation did not have an increased risk of congenital malformation compared with women exposed outside the teratogenic window. Because vaccination is safe and effective, emphasis must be placed on promoting vaccination during pregnancy.

Ayurvedic management of neurological deficits post COVID-19 vaccination - A report of two cases. The world witnessed much research fund allocation on the COVID-19 outbreak's epidemiology, pathology, impact on lifestyles, social behaviours and treatment possibilities. The highly contagious nature of the disease compelled scientific communities and related organisations to hasten vaccine development and supplies. Well-timed international collaborations resulted in quicker development of varied forms of vaccines against COVID-19. Prospective observational studies and systematic reviews on vaccine trials reported their safety and efficacies. Nevertheless, post-marketing surveillance is quintessential to ascertain such safety and efficacy claims. There have been scattered reports lately of several adverse temporal events, such as haematological, immunological and neurological untoward occurrences following COVID-19 inoculation. There is a growing piece of evidence of the impact of COVID vaccination on patients with neurological-neuroimmunological disorders. Here two unrelated cases of neurological deficits post-COVID vaccination are reported. One was an incidence of Acute Disseminated Encephalomyelitis, while the other was an acute exacerbation of Multiple Sclerosis following vaccination. Ayurvedic treatments were effective in either of these conditions. Case series and case reports shall judiciously add information to vaccine safety data and acknowledge the necessity of clinician approval, based on detailed individualised assessments before mass vaccination.

A case of severe oral mucosal GVHD induced by heterologous SARS-CoV-2 vaccination after cord blood transplantation. Patients who have undergone hematopoietic cell transplantation (HCT) are at a higher risk of severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) infection than

the general population. Therefore, early vaccination is recommended for post-transplant patients. Although exacerbation of chronic graft-versus-host disease (cGVHD) after the initial vaccination has been reported, it is unknown whether severe cGVHD occurs when different RNA vaccines are combined. We treated a patient who developed severe oral mucosal cGVHD after receiving two different RNA vaccines. Visual inspection showed that the patient presented with typical mucocutaneous cGVHD, and cGVHD in this case responded well to low-dose steroids compared to common oral GVHD exacerbations. Histopathological findings revealed T cell, B cell, and conspicuous neutrophil infiltration. Multiple doses of SARS-Cov2 vaccination are required in post-transplant recipients. In conclusion, it is essential to obtain the vaccination history of allo-HSCT recipients with cGVHD exacerbation. Furthermore, reviewing the pathological findings may help treat patients with lower doses of steroids.

Analyzing the effect of the COVID-19 vaccine on Parkinson's disease symptoms. BACKGROUND: Parkinson's Disease (PD) is one of the most common neurodegenerative diseases. PD has recently received more attention by researchers in the midst of the COVID-19 pandemic. OBJECTIVE: Yet to be researched is the effect of the COVID-19 vaccines on PD patients. Several PD patients are still hesitant to the vaccine due to this unaddressed fear. The purpose of this study is to address this gap. METHODS: Surveys were administered to PD patients 50 years and older at UF Fixel Institute who received at least one dose of the COVID-19 vaccine. Survey questions included patients' severity of PD symptoms before and after the vaccine and extent of worsening PD symptoms post-vaccination. After three weeks of collecting responses, the data was analyzed. RESULTS: 34 respondents were eligible for data consideration because they fell within the age range being studied. A total of 14 respondents out of 34 (41%, p=0. 0001) reported that their PD symptoms worsened after the COVID-19 vaccine to some extent. CONCLUSION: There was strong evidence of worsening of PD symptoms post COVID-19 vaccination, however it was mostly mild and limited to a couple of days. The worsening had statistically significant moderate positive correlation with vaccine hesitancy and post-vaccine general side effects. A possible causative mechanism of PD symptom worsening using existing scientific knowledge would be stress and anxiety associated with vaccine hesitancy and the extent of post-vaccine general side effects (fever, chills, pain), likely via simulating a mild systemic infection/inflammation the latter already established causes of PD symptom worsening.

SARS-CoV-2 infection: a possible trigger for the recurrence of IgA nephropathy after kidney transplantation? Immunoglobulin A nephropathy, the most common primary glomerulonephritis worldwide, is a leading cause of chronic kidney disease and end-stage kidney failure. Several cases of immunoglobulin A nephropathy relapse in native kidneys have been described after COVID-19 vaccination or SARS-CoV-2 infection. Here, we report the case of a 52-year-old kidney transplant recipient who had aÂ stable transplant function for more than 14Â years, with a glomerular filtration rate above 30Â ml/min/1.73 m(2). The patient had been vaccinated against COVID-19 four times with the Pfizer-BioNTech vaccine, most recently in March 2022. Eight weeks after a symptomatic SARS-CoV-2 infection in June 2022, his glomerular filtration rate had decreased by more than 50%, and his proteinuria increased to 17.5Â g per day. A renal biopsy indicated highly active immunoglobulin A nephritis. Despite steroid therapy, the function of the transplanted kidney deteriorated, and long-term dialysis became necessary because of recurrence of his underlying renal disease. This case report provides what is, to our knowledge, the first description of recurrent immunoglobulin A nephropathy in a kidney transplant recipient after SARS-CoV-2 infection leading to severe transplant failure and finally graft loss.

Neurologic Complications of COVID-19. OBJECTIVE: This article describes the spectrum of neurologic complications occurring in acute or postacute infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as well as the neurologic risks and benefits of vaccination

against SARS-CoV-2. LATEST DEVELOPMENTS: Early in the COVID-19 pandemic, reports of neurologic complications of COVID-19 began to surface. A variety of neurologic conditions have since been reported in association with COVID-19. Understanding of the underlying mechanism of COVID-19 neurologic involvement continues to evolve; however, the evidence seems to suggest that aberrant inflammatory responses may play a role. In addition to neurologic symptoms in acute COVID-19, neurologic post-COVID-19 conditions are increasingly recognized. The development of COVID-19 vaccines has been essential in preventing the spread of COVID-19. With increasing numbers of vaccine doses administered, various neurologic adverse events have been reported. ESSENTIAL POINTS: Neurologists must be aware of the potential acute, postacute, and vaccine-associated neurologic complications associated with COVID-19 and be poised to serve as integral members of multidisciplinary care teams for patients with COVID-19-related conditions.

Kikuchi-Fujimoto Disease in the Axilla after COVID-19 Vaccination: A Case Report. BACKGROUND: Kikuchi-Fujimoto disease (KFD) is a rare, self-limiting inflammatory condition of unknown etiology that is characterized by fever and painful lymphadenopathy. KFD commonly involves the posterior cervical region and very rarely occurs in the axilla. CASE PRESENTATION: We report on a case of KFD that presented 3 weeks after receiving the messenger ribonucleic acid-based coronavirus disease 2019 (COVID-19) vaccine. In this case, we suspected the lesions as COVID-19 vaccination-related lymphadenopathy on the initial ultrasonographic examination. CONCLUSION: Through this case report, we highlight that KFD should be considered in the differential diagnosis of patients with axillary lymphadenopathy who have undergone COVID-19 vaccination, as unusual side effects of COVID-19 vaccination have been increasingly reported in the literature owing to the rapid development of various COVID-19 vaccines during the pandemic period. In addition, we emphasize the importance of clinical suspicion in diagnosing KFD due to the fact that axillary involvement of KFD is extremely rare.

Reactogenicity and safety of COVID-19 primary immunisation and booster vaccination regimens: a comparative observational cohort study. BACKGROUND: Since the beginning of the COVID-19 vaccination campaigns, recommendations regarding the vaccination have been very dynamic. Although the safety and efficacy of different vaccines have been analysed, data were scarce for vaccine regimens combining different vaccines. We therefore aimed to evaluate and compare the perceived reactogenicity and need for medical consultation after the most frequently applied homologous and heterologous COVID-19 vaccination regimens. METHODS: In an observational cohort study, reactogenicity and safety were assessed within a maximum follow-up time of 124Â days using web-based surveys. Reactogenicity was assessed for different vaccination regimens 2Â weeks after a vaccination (short-term survey). The following surveys, long-term and follow-up surveys, focused on the utilisation of medical services, including those that were not suspected to be vaccine-related. RESULTS: Data of 17,269 participants were analysed. The least local reactions were seen after a ChAdOx1â€‰-â€‰ChAdOx1 regimen (32.6%, 95% CI [28.2, 37.2]) and the most after the first dose with mRNA-1273 (73.9%, 95% CI [70.5, 77.2]). Systemic reactions were least frequent in participants with a BNT162b2 booster after a homologous primary immunisation with ChAdOx1 (42.9%, 95% CI [32.1, 54.1]) and most frequent after a ChAdOx1â€‰-â€‰mRNA-1273 (85.5%, 95% CI [82.9, 87.8]) and mRNA-1273/mRNA-1273 regimen (85.1%, 95% CI [83.2, 87.0]). In the short-term survey, the most common consequences were medication intake and sick leave (after local reactions 0% to 9.9%; after systemic reactions 4.5% to 37.9%). In the long-term and follow-up surveys, between 8.2 and 30.9% of participants reported consulting a doctor and between 0% and 5.4% seeking hospital care. The regression analyses 124Â days after the first and after the third dose showed that the odds for reporting medical consultation were comparable between the vaccination regimens. CONCLUSIONS: Our analysis revealed differences in reactogenicity between the COVID-19 vaccines and vaccination

regimens in Germany. The lowest reactogenicity as reported by participants was seen with BNT162b2, especially in homologous vaccination regimens. However, in all vaccination regimens reactogenicity rarely led to medical consultations. Small differences in seeking any medical consultation after 6Â weeks diminished during the follow-up period. In the end, none of the vaccination regimens was associated with a higher risk for medical consultation. TRIAL REGISTRATION: DRKS DRKS00025881Â (https://drks.de/search/de/trial/DRKS00025373). Registered on 14 October 2021. DRKS DRKS00025373Â (https://drks.de/search/de/trial/DRKS00025881). Registered on 21 May 2021. Registered retrospectively.

Aspect-based classification of vaccine misinformation: a spatiotemporal analysis using Twitter chatter. BACKGROUND: The spread of misinformation of all types threatens people's safety and interrupts resolutions. COVID-19 vaccination has been a widely discussed topic on social media platforms with numerous misleading and fallacious information. This false information has a critical impact on the safety of society as it prevents many people from taking the vaccine, decelerating the world's ability to go back to normal. Therefore, it is vital to analyze the content shared on social media platforms, detect misinformation, identify aspects of misinformation, and efficiently represent related statistics to combat the spread of misleading information about the vaccine. This paper aims to support stakeholders in decision-making by providing solid and current insights into the spatiotemporal progression of the common misinformation aspects of the various available vaccines. METHODS: Approximately 3800 tweets were annotated into four expert-verified aspects of vaccine misinformation obtained from reliable medical resources. Next, an Aspect-based Misinformation Analysis Framework was designed using the Light Gradient Boosting Machine (LightGBM) model, which is one of the most advanced, fast, and efficient machine learning models to date. Based on this dataset, spatiotemporal statistical analysis was performed to infer insights into the progression of aspects of vaccine misinformation among the public.Â Finally, the Pearson correlation coefficient and p-values are calculated for the global misinformation count against the vaccination counts of 43 countries from December 2020 until July 2021. RESULTS: The optimized classification per class (i.e., per an aspect of misinformation) accuracy was 87.4%, 92.7%, 80.1%, and 82.5% for the "Vaccine Constituent," "Adverse Effects," "Agenda," "Efficacy and Clinical Trials" aspects, respectively. The model achieved an Area Under the ROC Curve (AUC) of 90.3% and 89.6% for validation and testing, respectively, which indicates the reliability of the proposed framework in detecting aspects of vaccine misinformation on Twitter.Â The correlation analysis shows that 37% of the countries addressed in this studyÂ were negatively affected by the spread of misinformation on Twitter resulting in reduced number of administered vaccines during the same timeframe. CONCLUSIONS: Twitter is a rich source of insight on the progression of vaccine misinformation among the public. Machine Learning models, such as LightGBM, are efficient for multi-class classification and proved reliable in classifying vaccine misinformation aspects even with limited samples in social media datasets.

Safety of SARS-CoV-2 mRNA vaccines and effects of immunosuppressive drugs on adverse reactions in patients with rheumatic diseases.

[Incidence and prognosis of olfactory and gustatory dysfunctions related to infection of SARS-CoV-2 Omicron strain: a national multi-center survey of 35 566 population]. Objective: This cross-sectional investigation aimed to determine the incidence, clinical characteristics, prognosis, and related risk factors of olfactory and gustatory dysfunctions related to infection with the SARS-CoV-2 Omicron strain in mainland China. Methods: Data of patients with SARS-CoV-2 from December 28, 2022, to February 21, 2023, were collected through online and offline questionnaires from 45 tertiary hospitals and one center for disease control and prevention in mainland China. The questionnaire included demographic information, previous health history, smoking and alcohol drinking, SARS-CoV-2 vaccination, olfactory and gustatory function before and after infection, other symptoms after

infection, as well as the duration and improvement of olfactory and gustatory dysfunction. The self-reported olfactory and gustatory functions of patients were evaluated using the Olfactory VAS scale and Gustatory VAS scale. Results: A total of 35 566 valid questionnaires were obtained, revealing a high incidence of olfactory and taste dysfunctions related to infection with the SARS-CoV-2 Omicron strain (67.75%). Females(Ï‡2=367.013, P<0.001) and young people(Ï‡2=120.210, P<0.001) were more likely to develop these dysfunctions. Gender(OR=1.564, 95%CI: 1.487-1.645), SARS-CoV-2 vaccination status (OR=1.334, 95%CI: 1.164-1.530), oral health status (OR=0.881, 95%CI: 0.839-0.926), smoking history (OR=1.152, 95%CI=1.080-1.229), and drinking history (OR=0.854, 95%CI: 0.785-0.928) were correlated with the occurrence of olfactory and taste dysfunctions related to SARS-CoV-2(above P<0.001). 44.62% (4 391/9 840) of the patients who had not recovered their sense of smell and taste also suffered from nasal congestion, runny nose, and 32.62% (3 210/9 840) suffered from dry mouth and sore throat. The improvement of olfactory and taste functions was correlated with the persistence of accompanying symptoms(Ï‡2=10.873, P=0.001). The average score of olfactory and taste VAS scale was 8.41 and 8.51 respectively before SARS-CoV-2 infection, but decreased to3.69 and 4.29 respectively after SARS-CoV-2 infection, and recovered to 5.83and 6.55 respectively at the time of the survey. The median duration of olfactory and gustatory dysfunctions was 15 days and 12 days, respectively, with 0.5% (121/24 096) of patients experiencing these dysfunctions for more than 28 days. The overall self-reported improvement rate of smell and taste dysfunctions was 59.16% (14 256/24 096). Gender(OR=0.893, 95%CI: 0.839-0.951), SARS-CoV-2 vaccination status (OR=1.334, 95%CI: 1.164-1.530), history of head and facial trauma(OR=1.180, 95%CI: 1.036-1.344, P=0.013), nose (OR=1.104, 95%CI: 1.042-1.171, P=0.001) and oral (OR=1.162, 95%CI: 1.096-1.233) health status, smoking history(OR=0.765, 95%CI: 0.709-0.825), and the persistence of accompanying symptoms (OR=0.359, 95%CI: 0.332-0.388) were correlated with the recovery of olfactory and taste dysfunctions related to SARS-CoV-2 (above P<0.001 except for the indicated values). Conclusion: The incidence of olfactory and taste dysfunctions related to infection with the SARS-CoV-2 Omicron strain is high in mainland China, with females and young people more likely to develop these dysfunctions. Active and effective intervention measures may be required for cases that persist for a long time. The recovery of olfactory and taste functions is influenced by several factors, including gender, SARS-CoV-2 vaccination status, history of head and facial trauma, nasal and oral health status, smoking history, and persistence of accompanying symptoms.

Risk of myocarditis and pericarditis in mRNA COVID-19-vaccinated and unvaccinated populations: a systematic review and meta-analysis. OBJECTIVE: To summarise the available evidence on the risk of myocarditis and/or pericarditis following mRNA COVID-19 vaccination, compared with the risk among unvaccinated individuals in the absence of COVID-19 infection. DESIGN: Systematic review and meta-analysis. DATA SOURCES: Electronic databases (Medline, Embase, Web of Science and WHO Global Literature on Coronavirus Disease), preprint repositories (medRxiv and bioRxiv), reference lists and grey literature were searched from 1 December 2020 until 31 October 2022. STUDY SELECTION: Epidemiological studies of individuals of any age who received at least one dose of an mRNA COVID-19 vaccine, reported a risk of myo/pericarditis and compared the risk of myo/pericarditis to individuals who did not receive any dose of an mRNA COVID-19 vaccine. DATA EXTRACTION AND SYNTHESIS: Two reviewers independently conducted screening and data extraction. The rate of myo/pericarditis among vaccinated and unvaccinated groups was recorded, and the rate ratios were calculated. Additionally, the total number of individuals, case ascertainment criteria, percentage of males and history of SARS-CoV-2 infection were extracted for each study. Meta-analysis was done using a random-effects model. RESULTS: Seven studies met the inclusion criteria, of which six were included in the quantitative synthesis. Our meta-analysis indicates that within 30-day follow-up period, vaccinated individuals were twice as likely to develop myo/pericarditis in the absence of

SARS-CoV-2 infection compared to unvaccinated individuals, with a rate ratio of 2.05 (95% CI 1.49-2.82). CONCLUSION: Although the absolute number of observed myo/pericarditis cases remains quite low, a higher risk was detected in those who received mRNA COVID-19 vaccinations compared with unvaccinated individuals in the absence of SARS-CoV-2 infection. Given the effectiveness of mRNA COVID-19 vaccines in preventing severe illnesses, hospitalisations and deaths, future research should focus on accurately determining the rates of myo/pericarditis linked to mRNA COVID-19 vaccines, understanding the biological mechanisms behind these rare cardiac events and identifying those most at risk.

Correction to: Heightened COVID-19 Mortality in People With Severe Mental Illness Persists After Vaccination: A Cohort Study of Greater Manchester Residents. BACKGROUND AND HYPOTHESIS: Previous studies show that people with severe mental illness (SMI) are at higher risk of COVID-19 mortality, however limited evidence exists regarding risk post-vaccination. We investigated COVID-19 mortality among people with schizophrenia and other SMIs before, during and after the UK vaccine roll-out. STUDY DESIGN: Using the Greater Manchester (GM) Care Record to access routinely collected health data linked with death records, we plotted COVID-19 mortality rates over time in GM residents with schizophrenia/psychosis, bipolar disorder (BD) and/or recurrent major depressive disorder (MDD) from February 2020 to September 2021. Multivariable logistic regression was used to compare mortality risk (risk ratios; RRs) between people with SMI (N=190,188) and age-sex matched controls (N=760,752), adjusted for sociodemographic factors, pre-existing comorbidities and vaccination status. STUDY RESULTS: Mortality risks were significantly higher among people with SMI compared with matched controls, particularly among people with schizophrenia/psychosis (RR 3.14, CI 2.66-3.71) and/or BD (RR 3.17, CI 2.15-4.67). In adjusted models, the relative risk of COVID-19 mortality decreased, though remained significantly higher than matched controls for people with schizophrenia (RR 1.53, CI 1.24-1.88) and BD (RR 2.28, CI 1.49-3.49), but not recurrent MDD (RR 0.92, CI 0.78-1.09). People with SMI continued to show higher mortality rate ratios relative to controls throughout 2021, during vaccination roll-out. CONCLUSIONS: People with SMI, notably schizophrenia and bipolar disorder, were at greater risk of COVID-19 mortality compared to matched controls. Despite population vaccination efforts that have prioritised people with SMI, disparities still remain in COVID-19 mortality for people with SMI.

COVID-19 pandemic and adrenals: deep insights and implications in patients with glucocorticoid disorders. PURPOSE: Coronavirus disease-19 (COVID-19) has spread throughout the world. It was initially defined as a potentially severe syndrome affecting the respiratory tract, but it has since been shown to be a systemic disease with relevant extrapulmonary manifestations that increase mortality. The endocrine system has been found to be vulnerable to COVID-19 infection. The current review aims to evaluate the available data on the impact of COVID-19 infection and treatment, as well as COVID-19 vaccines, on adrenal gland function, particularly in patients with GC disorders. METHODS: A thorough search of published peer-reviewed studies in PubMed was performed using proper keywords. RESULTS: Adrenal viral tropism and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) replication in the adrenal glands have been demonstrated, and adrenal insufficiency (AI) is a rare, but potentially severe complication in COVID-19 disease, whose recognition can be difficult if only for the empirical treatments administered in the early stages. Glucocorticoid (GC) treatment have had a pivotal role in preventing clinical deterioration in patients with COVID-19, but long-term GC use may increase COVID-19-related mortality and the development of iatrogenic AI. Patients with GC disorders, especially AI and Cushing's syndrome, have been identified as being at high risk of COVID-19 infection and complications. Published evidence suggests that AI patient awareness and proper education may help adjust GC replacement therapy appropriately when necessary, thereby reducing COVID-19 severity. The COVID-19 pandemic has had an impact on AI management,

particularly in terms of adherence to patients' care plans and self-perceived challenges. On the other hand, published evidence suggests that the clinical course of COVID-19 may be affected by the severity of hypercortisolism in patients with CS. Therefore, to ameliorate the risk profile in these patients, cortisol levels should be adequately controlled, along with careful monitoring of metabolic and cardiovascular comorbidities. To date, the COVID-19 vaccine remains the only available tool to face SARS-CoV-2, and it should not be treated differently in patients with AI and CS. CONCLUSION: SARS-CoV-2 infection has been linked to adrenal damage and AI is a rare complication in COVID-19 disease, requiring prompt recognition. Educational efforts and patient awareness may reduce COVID-19 severity in patients with AI. Control of cortisol levels and monitoring of complications may improve the clinical course of COVID-19 in patients with CS.

A case of recurrence of pyoderma gangrenosum after COVID-19 vaccine.

A mutation in the coronavirus nsp13-helicase impairs enzymatic activity and confers partial remdesivir resistance. Coronaviruses (CoVs) encode nonstructural proteins 1-16 (nsps 1-16) which form replicase complexes that mediate viral RNA synthesis. Remdesivir (RDV) is an adenosine nucleoside analog antiviral that inhibits CoV RNA synthesis. RDV resistance mutations have been reported only in the nonstructural protein 12 RNA-dependent RNA polymerase (nsp12-RdRp). We here show that a substitution mutation in the nsp13-helicase (nsp13-HEL A335V) of the betacoronavirus murine hepatitis virus (MHV) that was selected during passage with the RDV parent compound confers partial RDV resistance independently and additively when expressed with co-selected RDV resistance mutations in the nsp12-RdRp. The MHV A335V substitution did not enhance replication or competitive fitness compared to WT MHV and remained sensitive to the active form of the cytidine nucleoside analog antiviral molnupiravir (MOV). Biochemical analysis of the SARS-CoV-2 helicase encoding the homologous substitution (A336V) demonstrates that the mutant protein retained the ability to associate with the core replication proteins nsps 7, 8, and 12 but had impaired helicase unwinding and ATPase activity. Together, these data identify a novel determinant of nsp13-HEL enzymatic activity, define a new genetic pathway for RDV resistance, and demonstrate the importance of surveillance for and testing of helicase mutations that arise in SARS-CoV-2 genomes. IMPORTANCE Despite the development of effective vaccines against COVID-19, the continued circulation and emergence of new variants support the need for antivirals such as RDV. Understanding pathways of antiviral resistance is essential for surveillance of emerging variants, development of combination therapies, and for identifying potential new targets for viral inhibition. We here show a novel RDV resistance mutation in the CoV helicase also impairs helicase functions, supporting the importance of studying the individual and cooperative functions of the replicase nonstructural proteins 7-16 during CoV RNA synthesis. The homologous nsp13-HEL mutation (A336V) has been reported in the GISAID database of SARS-CoV-2 genomes, highlighting the importance of surveillance of and genetic testing for nucleoside analog resistance in the helicase.

Hypermetabolic Axillary Lymph Nodes Associated with COVID-19 Vaccination in Breast Cancer Management. A 42-year-old female patient diagnosed with invasive ductal breast ca underwent (18)F-fluorodeoxyglucose (FDG) positron emission tomography/ computed tomography (PET/CT) scan for staging, 1.5 cm diameter hypermetabolic lesion was observed in the lower inner quadrant of the right breast that was compatible with primary tumor [maximum standardized uptake value (SUV(max)): 10.5]. No pathological (18)F-FDG uptake was observed in lymph nodes whose fatty hilum was seen in the right axilla. However, in the left axilla and left deep axilla, hypermetabolic lymph nodes with a maksimum diameter of 19 mm and fatty hilum were observed (SUV(max): 8.0). In a detailed CT evaluation, these lymph nodes have thicker walls than the ones in the right axilla. The patient was questioned again and coronavirus disease-2019 (COVID-19) vaccination history (with BNT162b2, COVID-19 mRNA vaccine) was determined that was administrated to the left arm 5 days

ago. Tru-cut biopsy was performed from the left aksillary lymph nodes and proved to be reactive lymphoid tissue and there was no primary or metastatic tumor in these axillary lymph node tissues. The patient was given neoadjuvant chemotherapy 4.5 months after the first (18)F-FDG PET/CT, and the second was performed for the treatment response evaluation. Significant regression was determined from the findings. The patient underwent right total mastechtomy. She was being followed up with adjuvant chemotherapy and radiotherapy. In conclusion, hypermetabolic lymph nodes in the axillas should be interrogated for vaccination in patients with breast cancer. Hypermetabolic lymph nodes observed on the same side of the vaccinated arm in the (18)F-FDG PET/CT scan may be related to vaccine-induced reactive lymph node enlargement. Lymph node metastasis may be excluded, especially if there are hypermetabolic lymph nodes with preserved fatty hilum in the contralateral axilla on the same side as the vaccinated arm. Active lymph nodes reactive to the vaccine become inactive after a while.

New-Onset Fulminant Type 1 Diabetes Following SARS-CoV-2 Protein Subunit Vaccine: A Case Report and Literature Review. The ravages of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) worldwide have sped up the development of relevant vaccines, which is accompanied by public concerns over possible adverse effects. We report a rare case of a 39-year-old woman who suffered from severe hyperglycemia and ketoacidosis with normal hemoglobin A1c four days after SARS-CoV-2 protein subunit vaccine, which is consistent with the diagnosis of fulminant type 1 diabetes (FT1D). She received insulin therapy and recovered after 24 days from onset of the symptoms. This is the first case of new-onset FT1D after SARS-CoV-2 protein subunit vaccination and one of only six that developed after any form of SARS-CoV-2 vaccination. We hope to raise awareness of this potential adverse consequence and recommend careful monitoring after vaccination in patients even without a medical history of diabetes.

Serological response following COVID-19 vaccines in patients living with HIV: a dose-response meta-analysis. To quantify the pooled rate and risk ratio of seroconversion following the uncomplete, complete, or booster dose of COVID-19 vaccines in patients living with HIV. PubMed, Embase and Cochrane library were searched for eligible studies to perform a systematic review and meta-analysis based on PRIMSA guidelines. The pooled rate and risk ratio of seroconversion were assessed using the Freeman-Tukey double arcsine method and Mantel-Haenszel approach, respectively. Random-effects model was preferentially used as the primary approach to pool results across studies. A total of 50 studies involving 7160 patients living with HIV were analyzed. We demonstrated that only 75.0% (56.4% to 89.9%) patients living with HIV achieved a seroconversion after uncomplete vaccination, which improved to 89.3% (84.2% to 93.5%) after complete vaccination, and 98.4% (94.8% to 100%) after booster vaccination. The seroconversion rates were significantly lower compared to controls at all the stages, while the risk ratios for uncomplete, complete, and booster vaccination were 0.87 (0.77 to 0.99), 0.95 (0.92 to 0.98), and 0.97 (0.94 to 0.99), respectively. We concluded that vaccine doses were associated with consistently improved rates and risk ratios of seroconversion in patients living with HIV, highlighting the significance of booster vaccination for patients living with HIV.

No Immunological Interference or Safety Concerns When Adjuvanted Recombinant Zoster Vaccine Is Coadministered With a Coronavirus Disease 2019 mRNA-1273 Booster Vaccine in Adults Aged 50 Years and Older: A Randomized Trial. BACKGROUND: There is growing consensus that coronavirus disease 2019 booster vaccines may be coadministered with other age-appropriate vaccines. Adding to the limited available data supporting coadministration, especially with adjuvanted vaccines, could enhance vaccine coverage in adults. METHODS: In this phase 3, randomized, open-label study, eligible adults aged â‰¥50 years were randomly assigned (1:1) to receive mRNA-1273 (50 Âµg) booster vaccination and a first dose of recombinant zoster vaccine (RZV1) 2 weeks apart

(Seq group) or concomitantly (Coad group). The second RZV dose (RZV2) was administered 2 months post-RZV1 in both groups. Primary objectives were noninferiority of anti-glycoprotein E (gE) and anti-spike protein antibody responses in the Coad group compared to the Seq group. Safety and further immunogenicity assessments were secondary objectives. RESULTS: In total, 273 participants were randomized to the Seq group and 272 to the Coad group. Protocol-specified noninferiority criteria were met. The adjusted geometric mean concentration ratio (Seq/Coad) was 1.01 (95% confidence interval [CI], .89-1.13) for anti-gE antibodies 1 month post-RZV2, and 1.09 (95% CI, .90-1.32) for anti-spike antibodies 1 month post-mRNA-1273 booster. No clinically relevant differences were observed in overall frequency, intensity, or duration of adverse events between the 2 study groups. Most solicited adverse events were mild/moderate in intensity, each with median duration â‰¤2.5 days. Administration site pain and myalgia were the most frequently reported in both groups. CONCLUSIONS: Coadministration of mRNA-1273 booster vaccine with RZV in adults aged â‰¥50 years was immunologically noninferior to sequential administration and had a safety and reactogenicity profile consistent with both vaccines administered sequentially. Clinical Trials Registration.â€ƒNCT05047770.

Acantholytic Dyskeratosis Post-COVID-19 Vaccination: Another Case With Rapid Response to Isotretinoin.

Does the SARS-CoV-2 mRNA vaccine damage the ovarian reserve? To search whether or not the severe acute respiratory syndrome corona virus-2 (SARS-CoV-2) messenger ribonucleic acid (mRNA) vaccine affects the fertility of women at the 6th months by using AMH, which is an ovarian reserve test. Our study, designed as a prospective case-control study, included 104 women who presented to the GOP EAH obstetrics and gynecology outpatient clinic in January and February 2022. The study group included 74 women who presented to the outpatient clinic and planned to be vaccinated and 30 women who refused to be vaccinated as the control group. Anti-COVID-19 antibody levels in all participants were checked before participation in the study, and participants who were positive were excluded from the study. Blood was taken from the participants in both control and study groups to evaluate their AMH levels before the 2 doses of vaccination. After 2 doses of the vaccine, they were called for follow-up, and serological tests were performed to check whether they were positive for anti-COVID-19 antibodies. Participants in both groups were referred for follow-up after 6 months, samples were taken again for AMH, and the data were recorded. The mean age of the study group was 27.6â€…Â±â€…5.3 years, and the mean age of the control group was 28.65â€…Â±â€…5.25 years (Pâ€…=â€….298). There was no statistically significant difference between the vaccinated and nonvaccinated groups in terms of AMH levels measured at the 6th month (Pâ€…=â€….970). When the vaccinated group was compared in terms of AMH values at the first visit before vaccination and at the 6th month after vaccination, no statistically significant difference was found between them (p:0.127) mRNA vaccination to protect against SARS-CoV-2 does not adversely affect ovarian reserve, which is an indirect indicator of fertility. mRNA vaccines continue to be the most important method of protection against epidemics. Carefully and accurately informing women who are hesitant to get vaccinated is of great importance for the success of the fight against the epidemic.

Myocarditis post-COVID-19 vaccination. There has been much interest in the possible adverse events associated with available anti-coronavirus disease of 2019 (COVID-19) vaccines, given the rapid pace at which they had to be developed during the pandemic. One such adverse event is myocarditis post-COVID-19 vaccination. Several pathophysiological mechanisms have been proposed that might help us understand the relationship between the messenger ribonucleic acid (mRNA) vaccine and the occurrence of myocarditis, though we are yet to ascertain the causal link between them. Although the actual absolute incidence of myocarditis post-COVID-19 vaccination remains low among the large, general population that has been vaccinated, there has been a high relative

incidence of this adverse event. We aim to review the existing literature and bring to light what we have so far understood with respect to the association between COVID-19 vaccination and myocarditis. This will help in better understanding the burden of the pathology along with alleviating apprehensions associated with it.

Prevalence and risk factors of long COVID 6-12 months after infection with the Omicron variant among nonhospitalized patients in Hong Kong. Long COVID has been reported among patients with COVID-19, but little is known about the prevalence and risk factors associated with long COVID 6-12 months after infection with the Omicron variant. This is a large-scale retrospective study. A total of 6242 out of 12â€‰950 nonhospitalized subjects of all ages with SARS-CoV-2 infection (confirmed by polymerase chain reaction/rapid antigen test) during the Omicron dominant outbreak (December 31, 2021-May 6, 2022) in Hong Kong were included. Prevalence of long COVID, frequencies of symptoms, and risk factors were analyzed. Three thousand four hundred and thirty (55.0%) subjects reported at least one long COVID symptom. The most reported symptom was fatigue (1241, 36.2%). Female gender, middle age, obesity, comorbidities, vaccination after infection, having more symptoms, and presenting fatigue/chest tightness/headache/diarrhea in the acute stage of illness were identified as associated risk factors for long COVID. Patients who had received three or more doses of vaccine were not associated with a lower risk of long COVID (adjusted odds ratio 1.105, 95% confidence interval 0.985-1.239, pâ€‰=â€‰0.088). Among patients with at least three doses of vaccine, there was no significant difference in the risk of long COVID between the CoronaVac vaccine and BNT162b2 vaccine (pâ€‰>â€‰0.05). Omicron infection can lead to long COVID in a significant proportion of nonhospitalized patients 6-12 months after infection. Further investigation is needed to uncover the mechanisms underlying the development of long COVID and determine the impact of various risk factors such as vaccines.

The presence of senescent peripheral T-cells is negatively correlated to COVID-19 vaccine-induced immunity in cancer patients under 70 years of age. PURPOSE: Cancer patients are at risk of severe COVID-19 infection, and vaccination is recommended. Nevertheless, we observe a failure of COVID-19 vaccines in this vulnerable population. We hypothesize that senescent peripheral T-cells alter COVID-19 vaccine-induced immunity. METHODS: We performed a monocentric prospective study and enrolled cancer patients and healthy donors before the COVID-19 vaccination. The primary objective was to assess the association of peripheral senescent T-cells (CD28(-)CD57(+)KLRG1(+)) with COVID-19 vaccine-induced immunity. RESULTS: Eighty cancer patients have been included, with serological and specific T-cell responses evaluated before and at 3 months post-vaccination. Age â‰¥ 70 years was the principal clinical factor negatively influencing the serological (p=0.035) and specific SARS-CoV-2 T-cell responses (p=0.047). The presence of senescent T-cells was correlated to lower serological (p=0.049) and specific T-cell responses (p=0.009). Our results sustained the definition of a specific cut-off for senescence immune phenotype (SIP) (â‰¥ 5% of CD4 and â‰¥ 39.5% of CD8 T-cells), which was correlated to a lower serological response induced by COVID-19 vaccination for CD4 and CD8 SIP(high) (p=0.039 and p=0.049 respectively). While CD4 SIP level had no impact on COVID-19 vaccine efficacy in elderly patients, our results unraveled a possible predictive role for CD4 SIP(high) T-cell levels in younger cancer patients. CONCLUSIONS: Elderly cancer patients have a poor serological response to vaccination; specific strategies are needed in this population. Also, the presence of a CD4 SIP(high) affects the serological response in younger patients and seems to be a potential biomarker of no vaccinal response.

COVID-19 vaccine coverage, safety, and perceptions among patients with diabetes mellitus in China: a cross-sectional study. AIMS: Diabetes mellitus (DM), one of the most common chronic diseases in China, is a risk factor for SARS-COV-2 infection and poor prognosis of COVID-19. The COVID-19 vaccine is one of the key measures to control the pandemic. However, the actual coverage of COVID-

19 vaccination and associated factors remain unclear among DM patients in China. We conducted this study to investigate the COVID-19 vaccine coverage, safety, and perceptions among patients with DM in China. METHODS: A cross-sectional study of a sample of 2200 DM patients from 180 tertiary hospitals in China was performed using a questionnaire developed through the Wen Juan Xing survey platform to collect information regarding their coverage, safety, and perceptions of COVID-19 vaccination. A multinomial logistic regression analysis model was performed to determine any independent relationships with COVID-19 vaccination behavior among DM patients. RESULTS: In total, 1929 (87.7%) DM patients have received at least one dose COVID-19 vaccine, and 271 (12.3%) DM patients were unvaccinated. In addition, 65.2% (n = 1434) were booster vaccinated against COVID-19, while 16.2% (n = 357) were only fully vaccinated and 6.3% (n = 138) were only partially vaccinated. The prevalence of adverse effects after the first dose of vaccine, the second dose of vaccine, and the third dose of vaccine were 6.0%, 6.0%, and 4.3% respectively. Multinomial logistic regression analysis showed that DM patients complicated with immune and inflammatory diseases (partially vaccinated: OR = 0.12; fully vaccinated: OR = 0.11; booster vaccinated: OR = 0.28), diabetic nephropathy (partially vaccinated: OR = 0.23; fully vaccinated: OR = 0.50; booster vaccinated: OR = 0.30), and perceptions on the safety of COVID-19 vaccine (partially vaccinated: OR = 0.44; fully vaccinated: OR = 0.48; booster vaccinated: OR = 0.45) were all associated with the three of vaccination status. CONCLUSION: This study showed that higher proportion of COVID-19 vaccine coverage among patients with DM in China. The concern about the safety of the COVID-19 vaccine affected the vaccine behavior in patients with DM. The COVID-19 vaccine was relatively safe for DM patients due to all side effects were self-limiting.

Comparative B cell and antibody responses induced by adenoviral vectored and mRNA vaccines against COVID-19. Both vector and mRNA vaccines were an important part of the response to the COVID-19 pandemic and may be required in future outbreaks and pandemics. However, adenoviral vectored (AdV) vaccines may be less immunogenic than mRNA vaccines against SARS-CoV-2. We assessed anti-spike and anti-vector immunity among infection-naÃ¯ve Health Care Workers (HCW) following two doses of AdV (AZD1222) versus mRNA (BNT162b2) vaccine. 183 AdV and 274 mRNA vaccinees enrolled between April and October 2021. Median ages were 42 and 39 years, respectively. Blood was collected at least once, 10-48 days after vaccine dose 2. Surrogate virus neutralization test (sVNT) and spike binding antibody titres were a median of 4.2 and 2.2 times lower, respectively, for AdV compared to mRNA vaccinees ($p<0.001$). Median percentages of memory B cells that recognized fluorescent-tagged spike and RBD were 2.9 and 8.3 times lower, respectively for AdV compared to mRNA vaccinees. Titres of IgG reactive with human Adenovirus type 5 hexon protein rose a median of 2.2-fold after AdV vaccination but were not correlated with anti-spike antibody titres. Together the results show that mRNA induced substantially more sVNT antibody than AdV vaccine due to greater B cell expansion and targeting of the RBD. Pre-existing AdV vector cross-reactive antibodies were boosted following AdV vaccination but had no detectable effect on immunogenicity.

Effect of vaccine dosing intervals on Omicron surrogate neutralization after three doses of BNT162b2. BACKGROUND: Increasing the interval between the first and second SARS-CoV-2 vaccine doses enhances vaccine immunogenicity, however the optimal timing of the third vaccine is unknown. In this study, we investigated how the time interval between the first and second (V1-V2), or second and third (V2-V3) doses affects immunogenicity after three doses of the BNT162b2 (Comirnaty, Pfizer-BioNTech) vaccine. METHODS: This is an observational cohort consisting of 360 participants enrolled in the COVID-19 Occupational Risks, Seroprevalence, and Immunity among Paramedics in Canada (CORSIP) study. Immune responses to BA.1 and other variants were measured from serum using an ACE2 competitive binding assay for surrogate SARS-CoV-2 neutralization. We fit a multiple linear regression model to estimate the independent association between both the V1-V2 and V2-V3

intervals and serum SARS-CoV-2 neutralization, while adjusting for age, sex, and the V3-to-blood collection interval. We examined vaccine dosing intervals as continuous variables and categorized them into quartiles. RESULTS: The mean age was 40 years, 45% were female sex (at birth), and the median BA.1 surrogate neutralization was 61% (IQR 38-77%). The multivariate analysis indicated that longer V1-V2 (Î²Â =Â 0.1292, 95% CI: 0.04807-0.2104) and V2-V3 (Î²Â =Â 0.2653, 95% CI: 0.2291-0.3015) intervals were associated with increased surrogate neutralization of BA.1. These results were consistent when examining responses against Spike from other SARS-CoV-2 strains. When categorized into V2-V3 quartiles, the first (56-231 days), and second (231-266 days) quartiles demonstrated decreased BA.1 surrogate neutralization compared to the longest V2-V3 quartile (282-329 days). There was no significant difference in surrogate neutralization between the long (266-282 days) and longest (282-329 days) V2-V3 intervals. CONCLUSION: Longer intervals between first, second and third doses are independently associated with increased immunogenicity for all tested SARS-CoV-2 strains. Increasing the intervals between the second and third vaccine doses up to 8.9 months provided additive benefits increasing the immunogenicity of BNT162b2 vaccine schedules.

IgA nephropathy after COVID-19 vaccination and analysis of reported cases. BACKGROUND: Immunoglobin A nephropathy (IgAN) is one of the most common forms of chronic glomerulonephritis and has been shown to occur in association with vaccinations. While various vaccines against COVID-19 have become widely used, their side effects, especially on IgAN following COVID-19 vaccines are still unclear. In this report, we describe the clinical courses and histopathologic findings of a newly diagnosed case of IgAN after receiving the mRNA-1273 (Moderna) COVID-19 vaccination. METHODS: This study presents a case of new-onset IgAN following mRNA-1273 COVID-19 (Moderna) vaccination. In addition, we review and analyze similar cases previously reported in the literature up to October 2022. RESULTS: Of the 52 cases reviewed, including our own, the majority of patients were female, and 64% of patients had initial onset IgAN. The most common manifestation was gross hematuria (87%), other associated symptoms were fever (44%), myalgia (8%), arthralgia (4%), and edema (4%). Many of these cases occurred after receiving Pfizer products as the second vaccination. Oral corticosteroids were used to 16 cases, and steroid pulse therapy was used to treat 7 cases. CONCLUSION: While this is not a controlled study, it is important for physicians to consider the possibility that COVID-19 vaccines may provoke a flare of IgAN. Several therapeutic agents may be useful for treating COVID-19 vaccine-induced IgAN, although a specific mechanism or pathophysiological association cannot be confirmed without further research.

A Possible Association Between COVID-19 Vaccine and Complicated Pleural Effusion: A Case Report. As COVID-19 vaccines gain more prevalence, previously unrecognized side effects continue to be reported. We report a case of 78 male with no significant past medical history who was found to have a unilateral pleural effusion with symptoms that started two days after the administration of a COVID-19 vaccine. The initial presumption was bacterial pneumonia with parapneumonic effusion. However, the lack of clinical response prompted surgical intervention, and a diagnosis of empyema was established. No evidence of infectious etiology was found. This case helps to support the previously limited evidence in the recent medical literature that suggests a possible association between COVID-19 vaccines and pleurisy/effusion.

Humoral SARS-CoV-2 Vaccine Responses in Patients With Giant Cell Arteritis and Polymyalgia Rheumatica: Decay After Primary Vaccination and Effects of the Booster. OBJECTIVE: Vaccination remains essential in preventing morbidity of SARS-CoV-2 infections. We previously showed that >10 mg/day of prednisolone and methotrexate was associated with reduced antibody concentrations after primary vaccination in patients with giant cell arteritis (GCA) and polymyalgia rheumatica (PMR). This follow-up study was undertaken to measure the decay of antibody concentrations and the immunogenicity of SARS-CoV-2 booster vaccination. METHODS: Patients with GCA/PMR included in

the primary vaccination (BNT162b2 [Pfizer-BioNTech] or ChAdOx1 [Oxford/AstraZeneca]) study were asked again to donate blood samples 6 months after primary vaccination (nÂ =Â 24) and 1 month after booster vaccination (nÂ =Â 46, BNT162b2 or mRNA1273). Data were compared to those of age-, sex-, and vaccine-matched controls (nÂ =Â 58 and nÂ =Â 42, respectively). Multiple linear regression was performed with post-booster antibody concentrations as dependent variable and post-primary vaccination antibodies, prednisolone >10mg/day, and methotrexate use as predicting variables. RESULTS: Antibody concentrations decreased faster over time in GCA/PMR patients than in controls, which was associated with prednisolone treatment during primary vaccination. Post-booster antibody concentrations were comparable between patients and controls. Antibody concentrations post primary vaccination, but not treatment during booster vaccination, were predictive for antibody concentrations post booster vaccination. CONCLUSION: These results indicate that the decay of humoral immunity after primary vaccination is associated with prednisolone treatment, whereas the subsequent increase after booster vaccination, was not. Patients with low antibody concentrations following primary vaccination remained at an immunogenic disadvantage after a single booster vaccination. This longitudinal study in GCA/PMR patients stresses the importance of repeated booster vaccination for patients with poor responses to primary vaccination.

Autoimmune hepatitis following COVID-19 vaccination: Clinical characteristics of 35 reported cases. The coronavirus disease 2019 (COVID-19) vaccines have been shown to be effective in protecting people from severe disease progression, hospitalisation and death. However, a wide range of side effects have been reported worldwide. New onset or flare-up of autoimmune hepatitis (AIH) is an extremely rare adverse event following COVID-19 vaccination, with the majority of cases presenting with mild symptoms. Unfortunately, there have been cases of fatal complications. In this mini-review, we have summarised the clinical characteristics of a total of 35 currently reported cases of AIH after COVID-19 vaccination and suggest that patients with autoimmune diseases may be at higher risk of developing AIH after vaccination.

Reactogenicity, immunogenicity and breakthrough infections following heterologous or fractional second dose COVID-19 vaccination in adolescents (Com-COV3): A randomised controlled trial. BACKGROUND: This was the first study to investigate the reactogenicity and immunogenicity of heterologous or fractional second dose COVID-19 vaccine regimens in adolescents. METHODS: A phase II, single-blind, multi-centre, randomised-controlled trial recruited across seven UK sites from September to November 2021, with follow-up visits to August 2022. Healthy 12-to-16 years olds were randomised (1:1:1) to either 30Â Âµg BNT162b2 (BNT-30), 10Â Âµg BNT162b2 (BNT-10), or NVX-CoV2373 (NVX), 8 weeks after a first 30Â Âµg dose of BNT162b2. The primary outcome was solicited systemic reactions in the week following vaccination. Secondary outcomes included immunogenicity and safety. 'Breakthrough infection' analyses were exploratory. FINDINGS: 148 participants were recruited (median age 14 years old, 62% female, 26% anti-nucleocapsid IgG seropositive pre-second dose); 132 participants received a second dose. Reactions were mostly mild-to-moderate, with lower rates in BNT-10 recipients. No vaccine-related serious adverse events occurred. Compared to BNT-30, at 28 days post-second dose anti-spike antibody responses were similar for NVX (adjusted geometric mean ratio [aGMR]) 1.09 95% confidence interval (CI): 0.84, 1.42] and lower for BNT-10 (aGMR 0.78 [95% CI: 0.61, 0.99]). For Omicron BA.1 and BA.2, the neutralising antibody titres for BNT-30 at day 28 were similar for BNT-10 (aGMR 1.0 [95% CI: 0.65, 1.54] and 1.02 [95% CI: 0.71, 1.48], respectively), but higher for NVX (aGMR 1.7 [95% CI: 1.07, 2.69] and 1.43 [95% CI: 0.96, 2.12], respectively). Compared to BNT-30, cellular immune responses were greatest for NVX (aGMR 1.73 [95% CI: 0.94, 3.18]), and lowest for BNT-10 (aGMR 0.65 [95% CI: 0.37, 1.15]) at 14 days post-second dose. Cellular responses were similar across the study arms by day 236 post-second dose. Amongst SARS-CoV-2 infection naÃ¯ve participants, NVX participants had an 89% reduction in risk of self-reported

'breakthrough infection' compared to BNT-30 (adjusted hazard ratio [aHR] 0.11 [95% CI: 0.01, 0.86]) up until day 132 after second dose. BNT-10 recipients were more likely to have a 'breakthrough infection' compared to BNT-30 (aHR 2.14 [95% CI: 1.02, 4.51]) up to day 132 and day 236 post-second dose. Antibody responses at 132 and 236 days after second dose were similar for all vaccine schedules. INTERPRETATION: Heterologous and fractional dose COVID-19 vaccine schedules in adolescents are safe, well-tolerated and immunogenic. The enhanced performance of the heterologous schedule using NVX-CoV2373 against the Omicron SARS-CoV-2 variant suggests this mRNA prime and protein-subunit boost schedule may provide a greater breadth of protection than the licensed homologous schedule. FUNDING: National Institute for Health Research and Vaccine Task Force. TRIAL REGISTRATION: International Standard Randomised Controlled Trial Number registry: 12348322.

Adverse Effects of COVID-19 Vaccination in Patients with Transfusion-Dependent Thalassemia: An Observational Study from a Tertiary Care Center in Punjab, India. Vaccination against SARS-CoV-2 is the most important weapon in the arsenal in the battle against COVID-19. There is concern about an increased risk of adverse effects in patients with transfusion-dependent thalassemia (TDT), which affects vaccine acceptance. A predesigned questionnaire was used to evaluate adverse effects (local/systemic within 90 days after vaccination) in participants >18 years of age with TDT. A total of 100 patients received 129 vaccine doses. The mean age of the patients was 24.3 Â± 5.7 years, and M:F ratio of 1.6:1. Covishield (Serum Institute of India) was administered to 89% of the participants, and Covaxin (Bharat Biotech Limited) to 11% of the participants. Adverse effects were documented in 62% of the respondents and were more pronounced after the first dose (52%) compared to the second dose (9%). The most frequent adverse effects were pain at the injection site (43%) and fever (37%). All adverse effects were mild and none of the participants required hospitalization. There were no differences in adverse effects among different vaccines, in the presence or absence of comorbidities, blood groups, or ferritin levels. The SARS-CoV-2 vaccine appears to be safe for patients with TDT.

Humoral and cellular immune responses eleven months after the third dose of BNT162b2 an mRNA-based COVID-19 vaccine in people with HIV - a prospective observational cohort study. BACKGROUND: We investigated long-term durability of humoral and cellular immune responses to third dose of BNT162b2 in people with HIV (PWH) and controls. METHODS: In 378 PWH with undetectable viral replication and 224 matched controls vaccinated with three doses of BNT162b2, we measured IgG-antibodies against the receptor binding domain of SARS-CoV-2 spike protein three months before third dose of BNT162b2, and four and eleven months after. In 178 PWH and 135 controls, the cellular response was assessed by interferon-Î³ (IFN-Î³) release in whole blood four months after third dose. Differences in antibody or IFN-Î³ concentrations were assessed by uni- and multivariable linear regressions. FINDINGS: Before the third dose the concentration of SARS-CoV-2 antibodies was lower in PWH than in controls (unadjusted geometric mean ratio (GMR): 0.68 (95% CI: 0.54-0.86, pÂ =Â 0.002). We observed no differences in antibody concentrations between PWH and controls after four (0.90 (95% CI: 0.75-1.09), pÂ =Â 0.285) or eleven months (0.89 (95% CI: 0.69-1.14), pÂ =Â 0.346) after the third dose. We found no difference in IFN-Î³ concentrations four months after the third dose between PWH and controls (1.06 (95% CI: 0.71-1.60), pÂ =Â 0.767). INTERPRETATION: We found no differences in antibody concentrations or cellular response between PWH and controls up to eleven months after third dose of BNT162b2. Our findings indicate that PWH with undetectable viral replication and controls have comparable immune responses to three doses of the BNT162b2 vaccine. FUNDING: This work was funded by the Novo Nordisk Foundation (NFF205A0063505, NNF20SA0064201), the Carlsberg Foundation (CF20-476 0045), the Svend Andersen Research Foundation (SARF2021), and Bio- and Genome Bank Denmark.

Role of anti-polyethylene glycol (PEG) antibodies in the allergic reactions to PEG-containing Covid-19 vaccines: Evidence for immunogenicity of PEG. A small fraction of recipients who receive polyethylene-glycol (PEG)-containing COVID-19 mRNA-LNP vaccines (Comirnaty and Spikevax) develop hypersensitivity reactions (HSRs) or anaphylaxis. A causal role of anti-PEG antibodies (Abs) has been proposed, but not yet been proven in humans.We used ELISA for serial measurements of SARS-CoV-2 neutralizing Ab (anti-S) and anti-PEG IgG/IgM Ab levels before and after the first and subsequent booster vaccinations with mRNA-LNP vaccines in a total of 291 blood donors. The HSRs in 15 subjects were graded and correlated with anti-PEG IgG/IgM, just as the anti-S and anti-PEG Ab levels with each other. The impacts of gender, allergy, mastocytosis and use of cosmetics were also analyzed. Serial testing of two or more plasma samples showed substantial individual variation of anti-S Ab levels after repeated vaccinations, just as the levels of anti-PEG IgG and IgM, which were over baseline in 98-99 % of unvaccinated individuals. About 3-4 % of subjects in the strongly left-skewed distribution had 15-45-fold higher values than the median, referred to as anti-PEG Ab supercarriers. Both vaccines caused significant rises of anti-PEG IgG/IgM withÂ >10-fold rises in aboutÂ âˆ¼10 % of Comirnaty, and all Spikevax recipients. The anti-PEG IgG and/or IgM levels in the 15 vaccine reactors (3 anaphylaxis) were significantly higher compared to nonreactors. Serial testing of plasma showed significant correlation between the booster injection-induced rises of anti-S and anti-PEG IgGs, suggesting coupled anti-S and anti-PEG immunogenicity.Conclusions: The small percentage of people who have extremelevels of anti-PEG Ab in their blood may be at increased risk for HSRs/anaphylaxis to PEGylated vaccines and other PEGylated injectables. This risk might be further increased by the anti-PEG immunogenicity of these vaccines. Screening for anti-PEG Ab "supercarriers" may help predicting reactors and thus preventing these adverse phenomena.

Changes in haemostasis and inflammatory markers after mRNA BNT162b2 and vector Ad26.CoV2.S SARS-CoV-2 vaccination. INTRODUCTION: Reported thromboembolic events after SARS-CoV-2 vaccinations are still raising concerns, predominantly in non-scientific population. The aim of our study was to investigate the differences between haemostasis and inflammatory markers in the subjects vaccinated with mRNA BNT162b2 and vector Ad26.CoV2.S vaccine. MATERIALS AND METHODS: The study included 87 subjects vaccinated with mRNA BNT162b2 and 84 with Ad26.CoV2.S vaccine. All the laboratory parameters (TAT, F 1Â +Â 2, IL-6, CRP, big endothelin-1, platelets, fibrinogen, D-dimers, VWF activity) were investigated for the mRNA vaccine at five (before the first dose, 7 and 14Â days after the first and second vaccine dose), and three time points (before the first dose, 7 and 14Â days after) for the vector vaccine, respectively. All the markers were measured by well-established laboratory methods. RESULTS: Our results have shown statistically higher CRP levels in the vector group 7Â days after vaccination (PÂ =Â 0.014). Furthermore, study has revealed statistically significant rise in D-dimers (PÂ =Â 0.004) between tested time points in both vaccine groups but without clinical repercussions. CONCLUSION: Although statistically significant changes in haemostasis markers have been obtained, they remained clinically irrelevant. Thus, our study implicates that there is no plausible scientific evidence of a significant disruption in the coagulation and inflammatory processes after vaccination with BNT162b2 mRNA and Ad26.CoV2.S vector SARS-CoV-2 vaccines.

Letter to the editor: "hook" (prozone) effect in sars-cov-2 anti-spike binding antibody levels following vaccination, infection, or monoclonal antibody in solid organ transplant recipients. Anti-spike binding antibody (Ab) levels are used by some providers to inform COVID-19 risk assessment for solid organ transplant recipients (SOTRs). As has been observed with other Ab assays, in the setting of high binding Ab, quantitative results may demonstrate artifactually low values (i.e., â€œhookâ€• or prozone effect). Within two studies of SARS-CoV-2 vaccination of SOTRs (an observational cohort and a single-center trial), Ab levels were assessed using the semiquantitative Roche Elecsys anti-SARS-

CoV-2 S assay. In the observational cohort, we flagged 9 samples with either a paradoxical decrease or weak (<10x) rise after Tixagevimab/Cilgavimab (T/C) administration. This prompted retesting with up-front 1:50 dilution, with serial dilution performed until returning two results within expected assay variation. Subsequently, all post-vaccination clinical trial samples were retested. Hook effect was suspected if retest level was both â‰¥15% and â‰¥200U/mL higher than original level. From the observational cohort, all 9 flagged samples demonstrated a hook effect. Of 377 clinical trial samples (all rerun), 34/377 (9%) demonstrated a hook effect. Among the hook effect samples (n=43), the original median (IQR) titer was 1950 (650 â€“ 4390) U/mL, and upon retesting this increased to 5685 (2981 â€“ 9853) U/mL representing a 1.6 (1.3â€“6.0)-fold increase (p=0.03). Marked hook effect (>700x increase) was observed in two participants with recent vaccination plus breakthrough infection. Hook effect was observed in SOTRs tested using a SARS-CoV-2 clinical Ab assay in the setting of high analyte. Laboratories and clinicians should be aware of this artifact and consider serial dilution to confirm accurate quantitative results.

New-onset pemphigus vulgaris and pemphigus foliaceus following COVID-19 infection and vaccination, systematic review of case reports and a causal hypothesis.

Hybrid immunity in older adults is associated with reduced SARS-CoV-2 infections following BNT162b2 COVID-19 immunisation. BACKGROUND: Older adults, particularly in long-term care facilities (LTCF), remain at considerable risk from SARS-CoV-2. Data on the protective effect and mechanisms of hybrid immunity are skewed towards young adults precluding targeted vaccination strategies. METHODS: A single-centre longitudinal seroprevalence vaccine response study was conducted with 280 LCTF participants (median 82â€‰yrs, IQR 76-88â€‰yrs; 95.4% male). Screening by SARS-CoV-2 polymerase chain reaction with weekly asymptomatic/symptomatic testing (March 2020-October 2021) and serology pre-/post-two-dose Pfizer-BioNTech BNT162b2 vaccination for (i) anti-nucleocapsid, (ii) quantified anti-receptor binding domain (RBD) antibodies at three time-intervals, (iii) pseudovirus neutralisation, and (iv) inhibition by anti-RBD competitive ELISA were conducted. Neutralisation activity: antibody titre relationship was assessed via beta linear-log regression and RBD antibody-binding inhibition: post-vaccine infection relationship by Wilcoxon rank sum test. RESULTS: Here we show neutralising antibody titres are 9.2-fold (95% CI 5.8-14.5) higher associated with hybrid immunity (pâ€‰<â€‰0.00001); +7.5-fold (95% CI 4.6-12.1) with asymptomatic infection; +20.3-fold, 95% (CI 9.7-42.5) with symptomatic infection. A strong association is observed between antibody titre: neutralising activity (pâ€‰<â€‰0.00001) and rising anti-RBD antibody titre: RBD antibody-binding inhibition (pâ€‰<â€‰0.001), although 18/169 (10.7%) participants with high anti-RBD titre (>100BAU/ml), show inhibition <75%. Higher RBD antibody-binding inhibition values are associated with hybrid immunity and reduced likelihood of infection (pâ€‰=â€‰0.003). CONCLUSIONS: Hybrid immunity in older adults was associated with considerably higher antibody titres, neutralisation and inhibition capacity. Instances of high anti-RBD titre with lower inhibition suggests antibody quantity and quality as independent potential correlates of protection, highlighting added value of measuring inhibition over antibody titre alone to inform vaccine strategy.

 Older adults continue to be at risk of COVID-19, particularly in residential care home settings. We investigated the effect of infection and vaccination on antibody development and subsequent SARS-CoV-2 infection in older adults. Antibodies are proteins that the immune system produces on infection or vaccination that can help respond to subsequent infection with SARS-CoV-2. We found that older adults produce antibodies to SARS-CoV-2 after 2-doses of Pfizer BioNTech BNT162b2 vaccine. The strongest immune responses were seen among those older adults who also had prior history of infection. The results highlight the importance of both antibody quality and quantity when considering possible indicators of protection against COVID-19 and supports the need for a third, booster, vaccination in this age group..

Effect of COVID-19 vaccination on mortality by COVID-19 and on mortality by other causes, the Netherlands, January 2021-January 2022. BACKGROUND: We aimed to estimate vaccine effectiveness (VE) against COVID-19 mortality, and to explore whether an increased risk of non-COVID-19 mortality exists in the weeks following a COVID-19 vaccine dose. METHODS: National registries of causes of death, COVID-19 vaccination, specialized health care and long-term care reimbursements were linked by a unique person identifier using data from 1 January 2021 to 31 January 2022. We used Cox regression with calendar time as underlying time scale to, firstly, estimate VE against COVID-19 mortality after primary and first booster vaccination, per month since vaccination and, secondly, estimate risk of non-COVID-19 mortality in the 5 or 8Â weeks following a first, second or first booster dose, adjusting for birth year, sex, medical risk group and country of origin. RESULTS: VE against COVID-19 mortality wasÂ >Â 90Â % for all age groups two months after completion of the primary series. VE gradually decreased thereafter, to around 80Â % at 7-8Â months post-primary series for most groups, and around 60Â % for elderly receiving a high level of long-term care and for people aged 90+ years. Following a first booster dose, the VE increased toÂ >Â 85Â % in all groups. The risk of non-COVID-19 mortality was lower or similar in the 5 or 8Â weeks following a first dose compared to no vaccination, as well as following a second dose compared to one dose and a booster compared to two doses, for all age and long-term care groups. CONCLUSION: At the population level, COVID-19 vaccination greatly reduced the risk of COVID-19 mortality and no increased risk of death from other causes was observed.

Cellular and humoral immune responses after a third dose of SARS-CoV-2 mRNA vaccine in lung transplant recipients in Japan. BACKGROUND: Lung transplant (LTx) recipients are at higher risk of infection with severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2). There is an increasing demand for additional analysis regarding the efficacy and safety of after the initial series of mRNA SARS-CoV-2 vaccines in Japanese transplant recipients. METHOD: In this open-label, nonrandomized prospective study carried out at Tohoku University Hospital, Sendai, Japan, LTx recipients and controls received third doses of either the BNT162b2 or the mRNA-1273 vaccine, and the cellular and humoral immune responses were analyzed. RESULTS: A cohort of 39 LTx recipients and 38 controls participated in the study. The third dose of SARS-CoV-2 vaccine promoted much greater humoral responses at 53.9 % of LTx recipients than after the initial series at 28.2 % of patients without increasing the risk of adverse events. However, still fewer LTx recipients responded to the SARS-CoV-2 spike protein with the median IgG titer of 129.8 AU/mL and with the median IFN-Î³ level of 0.01Â IU/mL when compared to controls with those of 7394 AU/mL and 0.70Â IU/mL, respectively. CONCLUSION: Although the third dose of mRNA vaccine in LTx recipients was effective and safe, impaired cellular and humoral responses to SARS-CoV-2 spike protein were noted. Given lower antibody production and establishing vaccine safety, repeating the administration of mRNA vaccine will lead to robust protection in such a high-risk population (jRCT1021210009).

Inflammatory rheumatic diseases with onset after SARS-CoV-2 infection or COVID-19 vaccination: a report of 267 cases from the COVID-19 and ASD group. OBJECTIVES: To better define the spectrum of new-onset post-COVID-19 and post-COVID-19 vaccine inflammatory rheumatic diseases (IRD) from a large multicentric observational study. METHODS: Consecutive cases of IRD encountered during a 12-month period and satisfying one of the following inclusion criteria: (a) onset of the rheumatic manifestations within 4â€‰weeks from SARS-CoV-2 infection or (b) onset of the rheumatic manifestations within 4â€‰weeks from the administration of one of the COVID-19 vaccines ws recruited. RESULTS: The final analysis cohort comprised 267 patients, of which 122 (45.2%) in the post-COVID-19 and 145 (54.8%) in the postvaccine cohort. Distribution of IRD categories differed between the two cohorts: the post-COVID-19 cohort had a higher percentage of patients classified as having inflammatory joint diseases (IJD, 52.5% vs 37.2%, p=0.013) while the

post-vaccine cohort had a higher prevalence of patients classified as polymyalgia rheumatica (PMR, 33.1% vs 21.3%, p=0.032). No differences were detected in the percentage of patients diagnosed with connective tissue diseases (CTD 19.7% vs 20.7%, p=0.837) or vasculitis (6.6% vs 9.0%, p=0.467). Despite the short follow-up period, IJD and PMR patients' response to first-line therapy was favourable, with both groups achieving a drop in baseline disease activity scores of ~30%â€‰and ~70% respectively. CONCLUSION: Our article reports the largest cohort published to date of new-onset IRD following SARS-CoV-2 infection or COVID-19 vaccines. Although causality cannot be ascertained, the spectrum of possible clinical manifestations is broad and includes IJD, PMR, CTD and vasculitis.

Comparison of Female Ovarian Reserve Before vs After COVID-19 Vaccination. This cohort study examines the association of COVID-19 vaccination with levels of anti-Mullerian hormone and antral follicle count in women seeking fertility treatment.

Clinical efficacy of the fourth dose of the BNT162b2 vaccine in maintenance dialysis patients. BACKGROUND AND OBJECTIVES: Highly effective vaccines against severe acute respiratory syndrome virus 2 have been developed and administered worldwide. However, protection from coronavirus disease 2019 is not absolute and an optimal vaccination regimen needs to be established. This study assessed the clinical efficacy of the coronavirus disease 2019 vaccine among dialysis patients receiving 3 or 4 doses of vaccine. DESIGN, SETTING, PARTICIPANTS, AND MEASUREMENTS: This retrospective study was conducted using the electronic database of Clalit Health Maintenance Organization in Israel. Chronic dialysis patients treated with either hemodialysis or peritoneal dialysis during the coronavirus disease 2019 pandemic were included. We compared clinical outcomes of patients who had received three or four doses of the severe acute respiratory syndrome virus 2 vaccine. RESULTS: This study included 1,030 patients on chronic dialysis,Â with a mean age of 68â€‰Â±â€‰13Â years. Among them, 502 patients had received 3 doses of the vaccine and 528 received 4 doses. Severe acute respiratory syndrome virus 2 infection rates, severe COVID-19 that resulted in hospitalizations, COVID-19-related mortality and all-cause mortality rates were lower among chronic dialysis patients who received a fourth dose of vaccine as compared to those who received only 3 doses (after controlling for age, sex and comorbidities). Despite lower mortality rates observed with the Omicron variant, the fourth dose was significantly associated with reduced COVID-19-related mortality (1.7% vs. 3.8%, pâ€‰=â€‰0.04). Odds ratio for COVID-19-related mortality was 0.44 with 95% CI 0.2-0.98. CONCLUSIONS: As seen in the general population and with previous vaccine boosters, the fourth dose of the BNT162b2 vaccine reduced rates of severe COVID-19-related hospitalization and mortality among chronic dialysis patients. Further studies are needed to establish the optimal regimens of vaccination for patients on chronic dialysis.

Comment on: 'Clinical characteristics of patients with pityriasis rubra pilaris following SARS-CoV-2 vaccination' by Gambichler.

Effect of an inactivated coronavirus disease 2019 vaccine, CoronaVac, on blood coagulation and glucose: a randomized, controlled, open-label phase IV clinical trial. BACKGROUND: Billions of doses of coronavirus disease 2019 (COVID-19) vaccines have been administered and several cases of thrombocytopenia with thrombosis syndrome (TTS) have been reported after the administration of adenoviral vector vaccines. However, the effects of an inactivated COVID-19 vaccine, CoronaVac, on coagulation are not well understood. METHODS: In this randomized, controlled, open-label phase IV clinical trial, 270 participants including 135 adults aged 18-59 years and 135 adults aged 60 years or older, were enrolled and randomized to the CoronaVac group or to the control group in a 2:1 ratio and received two doses of CoronaVac or one dose of the 23-valent pneumococcal polysaccharide vaccine and one dose of inactivated hepatitis A vaccine on days 0 and 28, respectively. Adverse events were collected for 28 days after each dose. Blood samples were taken on days 0, 4, 14, 28, 32,

42, and 56 after the first dose to evaluate neutralizing antibody titers and laboratory parameters of coagulation function and blood glucose. RESULTS: Fourteen days after the second dose of CoronaVac, the seroconversion rates of neutralizing antibodies against the prototype strain and beta, gamma, and delta variants of concern (VOC) of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) reached peak values of 89.31%, 23.3%, 45.3%, and 53.5%, respectively. The incidence of adverse reactions was 43.6% and 52.2% in the CoronaVac group and in the control group, respectively. All were mild or moderate in severity. For the laboratory parameters, there was no difference in the means of any parameter between the two groups at any time point, except for the D-dimer on day 14. However, the D-dimer in the CoronaVac group decreased on day 14 compared to the value at baseline, while a higher D-dimer value, instead of a decreased D-dimer value, was a risk factor for TTS. CONCLUSION: CoronaVac showed a good safety profile and could induce a humoral response against the prototype and VOCs of SARS-CoV-2 in adults 18 years or older, with no abnormal effects on laboratory parameters of blood glucose and coagulation function.

Evaluation of a commercial interferon-Î³ release assay for the detection of SARS-CoV-2 T-cell response after vaccination. OBJECTIVE: Evidence regarding the role of cellular immunity in protecting against COVID-19 is emerging. To better assess immune status, simple and robust assays measuring specific T-cell responses associated with humoral responses are needed. We aimed to evaluate the Quan-T-Cell SARS-CoV-2 test for measuring cellular immune responses in vaccinated healthy and immunosuppressed subjects. METHODS: T-cell responses were assessed in healthy vaccinated and unvaccinated and unexposed healthcare workers to determine the sensitivity and specificity of the EUROIMMUN SARS-CoV-2 Quan-T-Cell IGRA test performed on vaccinated kidney transplant recipients (KTRs). RESULTS: The EUROIMMUN SARS-CoV-2 Quan-T-Cell IGRA test showed good sensitivity (87.2%) and specificity (92.3%) at the calculated 147 mIU/mL cutoff, with an 88.33% accuracy. In KTRs, specific cellular immunity was lower than the antibody response; however, those with a positive IGRA result produced as much IFN-Î³ as healthy individuals. CONCLUSIONS: The EUROIMMUN SARS-CoV-2 Quan-T-Cell IGRA test showed good sensitivity and specificity for the detection of specific T-cell responses against the SARS-CoV-2 spike protein. These results present an additional tool for better management of COVID-19, especially in vulnerable populations.

A Rare Case of COVID-19 Vaccination-Induced Cholangiopathic Liver Injury. Drug-induced liver injury is a serious adverse drug reaction that can result in acute liver injury or cholestatic injury affecting the bile ducts, known as cholangiopathic liver injury (CLI). Although CLI is not as familiar as the hepatocellular pattern, emerging evidence suggests that it may occur after coronavirus disease 2019 (COVID-19) vaccination. This case report focuses on an 89-year-old woman who developed CLI after receiving the tozinameran COVID-19 vaccine. The main aim of this report was to raise awareness of the possibility of developing CLI after COVID-19 vaccination and to underscore the critical significance of promptly identifying and managing this infrequent but severe side effect.

Acute myocardial infarction after inactivated COVID-19 vaccination: a case report and literature review. A number of vaccines have been developed and deployed globally to restrain the spreading of the coronavirus disease 2019 (COVID-19). The adverse effect following vaccination is an important consideration. Acute myocardial infarction (AMI) is a kind of rare adverse event after COVID-19 vaccination. Herein, we present a case of an 83-year-old male who suffered cold sweat ten minutes after the first inactivated COVID-19 vaccination and AMI one day later. The emergency coronary angiography showed coronary thrombosis and underlying stenosis in his coronary artery. Type II Kounis syndrome might be a potential mechanism, which is manifested as coronary thrombosis secondary to allergic reactions in patients with underlying asymptomatic coronary heart disease. We also summarize the reported AMI cases post COVID-19 vaccination, as well as overview and discuss the proposed mechanisms of AMI after COVID-19 vaccination, thus providing insights for

clinicians to be aware of the possibility of AMI following COVID-19 vaccination and potential underlying mechanisms.

Fear of fertility side effects is a major cause for COVID-19 vaccine hesitance in infertile patients. INTRODUCTION: This study aims to investigate the acceptance, hesitance and attitudes of infertile female patients toward the COVID-19 vaccination. METHODS: An anonymous cross-sectional online survey was conducted between 28th of January to 10th of August 2022. The questionnaire consisted of 35 questions on demographics, COVID-19 vaccination status, prior concerns of the vaccinated participants and reasons for not vaccinating among unvaccinated participants, and factors influencing the decision not to vaccinate. RESULTS: Of 406 participants who answered all questions, 92.1% reported having received at least one dose of COVID-19 vaccine, 7.9% were unvaccinated. Factors associated with the decision for vaccination were full time or part time employment (p =â€‰0.05), high trust in the principle of vaccination (p <â€‰0.001), high willingness for other vaccination during fertility treatment (pâ€‰<â€‰0.001) and risk factors for severe COVID-19 (p =â€‰0.007). Concerns about directly occurring adverse effects after vaccination (42.0%), about impact on own fertility (21.9%) or on the fertility treatment (27.5%) were the main concerns beforehand of vaccinated participants. Correlations between fertility concerns and mistrust in the general principle of vaccination were found. Beside general health concerns, unvaccinated participants reported fears about fertility impairment as the most important arguments against a COVID-19 vaccination (median of 5.0 on a five-point-Likert scale). CONCLUSION: Both vaccinated and unvaccinated participants stated having concerns and fears about side effects of the COVID-19 vaccination on their fertility. To increase patients' trust in medical recommendations, such as vaccination, to avoid mistrust in the medical system and to maintain patient's compliance, there should be additional educational services that address infertile patients and their needs.

Case report: A case of epidermolysis bullosa acquisita with IgG and IgM anti-basement membrane zone antibodies relapsed after COVID-19 mRNA vaccination. We report a case of autoimmune bullous disease (AIBD) with IgG and IgM autoantibodies against epidermal basement membrane zone (BMZ), which showed recurrence of mucocutaneous lesions after coronavirus disease 2019 (COVID-19) mRNA vaccination. A 20-year-old Japanese woman with a 4-year history of epidermolysis bullosa acquisita (EBA) presented to our clinic. She noticed fever and rash on the same day and visited at our hospital 2 days later. Physical examination revealed blisters, erosions and erythema on the face, shoulder, back, upper arms, and lower lip. A skin biopsy from the forehead showed subepidermal blister. Direct immunofluorescence showed linear depositions of IgG, IgM, and C3c in the epidermal BMZ. By indirect immunofluorescence of 1M NaCl-split normal human skin, circulating IgG autoantibodies were bound to the dermal side of the split at 1:40 serum dilution, and circulating IgM antibodies were bound to the epidermal side of the spilt. After the increase of prednisolone dose to 15 mg/day, the mucocutaneous lesions resolved in a week. The present case is the first case of possible EBA with IgG and IgM anti-BMZ antibodies, in which the mucocutaneous lesions were recurred after COVID-19 mRNA vaccination. Clinicians should be aware that bullous pemphigoid-like AIBDs, including EBA and IgM pemphigoid, might be developed after COVID-19 mRNA vaccination.

Renal Complications Following COVID-19 Vaccination: A Narrative Literature Review. BACKGROUND: Renal complications have previously been reported with various vaccinations, including those for influenza and hepatitis. On a similar note, a spectrum of nephrological complications, both de novo, and flare-ups, were reported after immunization with various coronavirus disease 2019 (COVID-19) vaccines, causing concerns among patients as well as physicians. MATERIALS AND METHODS: A systematic search of the literature published on renal complications seen post-COVID-19 vaccination was performed up to April 2022 using electronic databases such as PubMed and Google Scholar. RESULT: Immunoglobulin A (IgA) nephropathy, minimal change disease,

glomerulonephritis, acute kidney injury, nephrotic syndrome, and anti-neutrophil cytoplasmic antibody-associated vasculitis were some of the renal complications reported upon administration of COVID-19 vaccines. The causality and underlying pathogenic mechanisms linking these complications and COVID-19 vaccination remain unclear. Nonetheless, a temporal relationship has been established with dysregulated T-cell response, transient systemic pro-inflammatory cytokine response, molecular mimicry, delayed hypersensitivity reaction to the vaccine, and other mechanisms such as hyperresponsive IgA, dysregulation of neutrophil extracellular traps were hypothesized as the possible mechanisms linking renal complications and COVID-19 vaccination. CONCLUSION: This review emphasizes the need for rigorous surveillance and reporting of the adverse events following COVID-19 vaccination and explores the underlying mechanisms instigating these renal complications in individuals vaccinated against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Assessment of Post-Vaccination Immunologic Responses in Inactivated Virus COVID-19 Respondents. INTRODUCTION: The Indonesian Government's plan to contain the COVID-19 pandemic, aside from implementing health protocols, also involves vaccinating everyone with the inactivated SARS CoV2 vaccine until herd immunity is reached. The aim of this study was to assess the post-vaccination immune response to inactivated SARS CoV2 vaccine, namely Sinovac/Sinopharm, by measuring the antibodies (IgM and IgG) in subjects after their second dose of vaccination. MATERIALS AND METHODS: The design of the study was a cohort study using simple random sampling with 51 respondents aged 18-56 years who had received two doses of inactivated SARS-CoV-2 vaccine. All respondents were screened for SARS-CoV-2 infection prior to inclusion. Serum IgM and IgG antibodies were detected using a specific and sensitive automated chemiluminescent immunoassay (CLIA). CLIA uses the Cut Off Point (COI) value of >1 AU/ml for IgM and the Reactive Value of >10 AU/ml for IgG. RESULTS: This study showed that the IgM levels using a reactive Cut Off Point (COI) >1 were 18% in the first month, 14% in the third month, and 10% in the sixth month. There was a constant decline in the third comparison. Meanwhile, compared to the first month, 59% of respondents had IgG levels with reactive values over 10 AU/ml, which after decreasing by 35% in the third month, the number increased by 47% in the sixth month. CONCLUSION: It has been evident that IgG and IgM antibody response could be induced by inactivated SARS-CoV-2 vaccine which can be influenced by age and detection time after the second dose of vaccination. Boosters, however, must be given after six months of the second dose, since antibody levels were seen to decrease after this period.

Recurring nodular scleritis following inactivated vaccination for COVID-19. KEY CLINICAL MESSAGE: Though COVID-19 vaccination saved many lives all around the world, it has had many adverse effects including ophthalmologic side effects. It is important to report such adverse effects to provide timely diagnosis and management. ABSTRACT: Since the COVID-19 global outbreak, many types of vaccines have been introduced. These vaccines have been associated with some adverse effects including ocular manifestations. Herein, we report a case of a patient who developed nodular scleritis shortly after receiving the first and second doses of the inactivated COVID-19 vaccine, Sinopharm.

Upper extremity deep vein thrombosis following BBIBP-CorV COVID-19 vaccine (Sinopharm vaccine): A case report. KEY CLINICAL MESSAGE: In patients with acute symptoms such as pain, swelling, and erythema of the upper extremities shortly after receiving COVID-19 vaccines, even inactivated virus vaccines, these symptoms may indicate thrombosis, which may be due to the vaccination. ABSTRACT: BBIBP-CorV COVID-19 vaccine (Sinopharm vaccine) is an inactivated whole virus vaccine to control the COVID-19 pandemic. Studies concluded that inactivated COVID-19 vaccines do not increase the risk of thrombosis. This report presents a 23-year-old man with the chief complaint of severe pain, swelling, and erythema of the right upper extremity following his second dose of the Sinopharm vaccine. Duplex ultrasound of the right upper extremity revealed upper extremity deep

vein thrombosis, and treatment started with oral anticoagulation. It is probably the first upper extremity deep vein thrombosis case following inactivated COVID-19 vaccines.

Comment on: Retinal venous occlusion in a child following Corbevax COVID-19 vaccination.

Comment on: A rare case of cortical blindness following vaccination against SARS-CoV-2.

A COVID-19 perspective of Vogt-Koyanagi-Harada disease. Vogt-Koyanagi-Harada (VKH) disease, a bilateral granulomatous panuveitis associated with multisystem involvement, is a T-cell-mediated autoimmune disorder in which cytotoxic T-cell target melanocytes in genetically susceptible individuals. Recently, there has been an increase in literature on the new onset of uveitis and reactivation of previously diagnosed cases of uveitis following Covid-19 vaccinations. It has been postulated that Covid-19 vaccines can lead to an immunomodulatory change resulting in an autoimmune phenomenon in the recipients. VKH following COVID-19 infection was reported in four patients and a total of 46 patients developing VKH or VKH-like disease following COVID-19 vaccinations. There are reports of four patients who had been recovering or recovered from VKH after receiving the first dosage of the vaccine and developed worsening of ocular inflammation after receiving the second dose of the vaccine.

Trends of humoral immune responses to heterologous antigenic exposure due to vaccination & omicron SARS-CoV-2 infection: Implications for boosting. BACKGROUND & OBJECTIVES: Vaccination and natural infection can both augment the immune responses against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), but how omicron infection has affected the vaccine-induced and hybrid immunity is not well studied in Indian population. The present study was aimed to assess the durability and change in responses of humoral immunity with age, prior natural infection, vaccine type and duration with a minimum gap of six months post-two doses with either ChAdOx1 nCov-19 or BBV152 prior- and post-emergence of the omicron variant. METHODS: A total of 1300 participants were included in this observational study between November 2021 and May 2022. Participants had completed at least six months after vaccination (2 doses) with either ChAdOx1 nCoV-19 or an inactivated whole virus vaccine BBV152. They were grouped according to their age (â‰¤ or â‰¥60 yr) and prior exposure of SARS-CoV-2 infection. Five hundred and sixteen of these participants were followed up after emergence of the Omicron variant. The main outcome was durability and augmentation of the humoral immune response as determined by anti-receptor-binding domain (RBD) immunoglobulin G (IgG) concentrations, anti-nucleocapsid antibodies and anti-omicron RBD antibodies. Live virus neutralization assay was conducted for neutralizing antibodies against four variants - ancestral, delta and omicron and omicron sublineage BA.5. RESULTS: Before the omicron surge, serum anti-RBD IgG antibodies were detected in 87 per cent participants after a median gap of eight months from the second vaccine dose, with a median titre of 114 [interquartile range (IQR) 32, 302] BAU/ml. The levels increased to 594 (252, 1230) BAU/ml post-omicron surge ($P<0.001$) with 97 per cent participants having detectable antibodies, although only 40 had symptomatic infection during the omicron surge irrespective of vaccine type and previous history of infection. Those with prior natural infection and vaccination had higher anti-RBD IgG titre at baseline, which increased further [352 (IQR 131, 869) to 816 (IQR 383, 2001) BAU/ml] ($P<0.001$). The antibody levels remained elevated after a mean time gap of 10 months, although there was a decline of 41 per cent. The geometric mean titre was 452.54, 172.80, 83.1 and 76.99 against the ancestral, delta, omicron and omicron BA.5 variants in the live virus neutralization assay. INTERPRETATION & CONCLUSIONS: Anti-RBD IgG antibodies were detected in 85 per cent of participants after a median gap of eight months following the second vaccine dose. Omicron infection probably resulted in a substantial proportion of asymptomatic infection in the first four months in our study population and boosted the vaccine-induced humoral immune response, which declined but still remained durable over 10 months.

Self-reported symptoms after COVID-19 vaccination. Distinct sex, age, and geographical outcomes in Lebanese and Italian cohorts. Following the COVID-19 discovery in December 2019, different vaccines were authorized in 2021 in Italy and Lebanon, but side effects and the impact of sex and age remained partly explored. We designed a web-based "Google Form" questionnaire to record self-reported systemic and local side effects up to 7Â days after 1st and 2nd dose of the vaccine in two distinct Italian and Lebanese cohorts. Twenty-one questions in Italian and Arabic languages explored the prevalence and severity of 13 symptoms. Results were compared with respect to living country, timing, sex, and age classes. A total of 1,975 Italian subjects (age 42.9â€‰Â±â€‰SD16.8Â years; 64.5% females) and 822 Lebanese subjects (age 32.5â€‰Â±â€‰SD15.9Â years; 48.8% females) joined the study. The most common symptoms in both groups were injection site pain, weakness, and headache after the 1st and 2nd doses. The rate of post-vaccinal symptoms and the severity score were significantly higher in females than in males and progressively decreased with increasing age following both doses. We find that among two populations from the Mediterranean basin, the anti-COVID-19 vaccine generates mild age and sex-dependent adverse effects, with ethnic differences and prevalent symptoms rate and severity in females.

ChAdOx1 nCoV-19 (AZD1222) vaccine-induced Fc receptor binding tracks with differential susceptibility to COVID-19. Despite the success of COVID-19 vaccines, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants of concern have emerged that can cause breakthrough infections. Although protection against severe disease has been largely preserved, the immunological mediators of protection in humans remain undefined. We performed a substudy on the ChAdOx1 nCoV-19 (AZD1222) vaccinees enrolled in a South African clinical trial. At peak immunogenicity, before infection, no differences were observed in immunoglobulin (Ig)G1-binding antibody titers; however, the vaccine induced different Fc-receptor-binding antibodies across groups. Vaccinees who resisted COVID-19 exclusively mounted FcÎ³R3B-binding antibodies. In contrast, enhanced IgA and IgG3, linked to enriched FcÎ³R2B binding, was observed in individuals who experienced breakthrough. Antibodies unable to bind to FcÎ³R3B led to immune complex clearance and resulted in inflammatory cascades. Differential antibody binding to FcÎ³R3B was linked to Fc-glycosylation differences in SARS-CoV-2-specific antibodies. These data potentially point to specific FcÎ³R3B-mediated antibody functional profiles as critical markers of immunity against COVID-19.

Acute angle closure glaucoma following COVID-19 vaccination.

Post-authorization safety surveillance of Ad.26.COV2.S vaccine: Reports to the Vaccine Adverse Event Reporting System and v-safe, February 2021-February 2022. BACKGROUND: On 2/27/2021, FDA authorized Janssen COVID-19 Vaccine (Ad.26.COV2.S) for use in individuals 18Â years of age and older. Vaccine safety was monitored using the Vaccine Adverse Event Reporting System (VAERS), a national passive surveillance system, and v-safe, a smartphone-based surveillance system. METHODS: VAERS and v-safe data from 2/27/2021 to 2/28/2022 were analyzed. Descriptive analyses included sex, age, race/ethnicity, seriousness, AEs of special interest (AESIs), and cause of death. For prespecified AESIs, reporting rates were calculated using the total number of doses of Ad26.COV2.S administered. For myopericarditis, observed-to-expected (O/E) analysis was performed based on the number verified cases, vaccine administration data, and published background rates. Proportions of v-safe participants reporting local and systemic reactions, as well as health impacts, were calculated. RESULTS: During the analytic period, 17,018,042 doses of Ad26.COV2.S were administered in the United States, and VAERS received 67,995 reports of AEs after Ad26.COV2.S vaccination. Most AEs (59,750; 87.9 %) were non-serious and were similar to those observed during clinical trials. Serious AEs included COVID-19 disease, coagulopathy (including thrombosis with thrombocytopenia syndrome; TTS), myocardial infarction, Bell's Palsy, and Guillain-BarrÃ© syndrome (GBS). Among AESIs, reporting rates per million doses of Ad26.COV2.S administered ranged from 0.06 for

multisystem inflammatory syndrome in children to 263.43 for COVID-19 disease. O/E analysis revealed elevated reporting rate ratios (RRs) for myopericarditis; among adults ages 18-64Â years, the RR was 3.19 (95 % CI 2.00, 4.83) within 7Â days and 1.79 (95 % CI 1.26, 2.46) within 21Â days of vaccination. Of 416,384 Ad26.COV2.S recipients enrolled into v-safe, 60.9 % reported local symptoms (e.g. injection site pain) and 75.9 % reported systemic symptoms (e.g., fatigue, headache). One-third of participants (141,334; 33.9 %) reported a health impact, but only 1.4 % sought medical care. CONCLUSION: Our review confirmed previously established safety risks for TTS and GBS and identified a potential safety concern for myocarditis.

The effect of COVID-19 vaccination on anticoagulation stability in adolescents and young adults using vitamin K antagonists. INTRODUCTION: The European Medicine Agency has authorized COVID-19 vaccination in adolescents and young adults (AYAs) from 12Â years onwards. In elderly vitamin K antagonist (VKA) users, COVID-19 vaccination has been associated with an increased risk of supra- and subtherapeutic INRs. Whether this association is also observed in AYAs using VKA is unknown. Our aim was to describe the stability of anticoagulation after COVID-19 vaccination in AYA VKA users. MATERIALS AND METHODS: A case-crossover study was performed in a cohort of AYAs (12-30Â years) using VKAs. The most recent INR results before vaccination, the reference period, were compared with the most recent INR after the first and, if applicable, second vaccination. Several sensitivity analyses were performed in which we restricted our analysis to stable patients and patients without interacting events. RESULTS: 101 AYAs were included, with a median age [IQR] of 25 [7] years, of whom 51.5Â % were male and 68.3Â % used acenocoumarol. We observed a decrease of 20.8Â % in INRs within range after the first vaccination, due to an increase of 16.8Â % in supratherapeutic INRs. These results were verified in our sensitivity analyses. No differences were observed after the second vaccination compared to before and after the first vaccination. Complications after vaccination occurred less often than before vaccination (9.0 vs 3.0 bleedings) and were non-severe. CONCLUSIONS: the stability of anticoagulation after COVID-19 vaccination was decreased in AYA VKA users. However, the decrease might not be clinically relevant as no increase of complications nor significant dose adjustments were observed.

Polyarteritis nodosa diagnosed inÂ a young male after COVID-19 vaccine: A case report. In response to the coronavirus disease 2019 pandemic, the coronavirus disease 2019 vaccine was rapidly developed and the effectiveness of the vaccine has been established. However, various adverse effects have been reported, including the development of autoimmune diseases. We report a case of new-onset polyarteritis nodosa in a 32-year-old male following the coronavirus disease 2019 vaccination. The patient developed limb pain, fever, pulmonary embolism, multiple subcutaneous nodules, and haematomas. Skin biopsy revealed necrotising inflammation accompanied by fibrinoid necrosis and high inflammatory cell infiltration in the walls of medium to small arteries. The symptoms resolved following corticosteroid treatment. Although it is difficult to prove a relationship between the vaccine and polyarteritis nodosa, similar cases have been reported and further reports and analyses are therefore necessary.

BA.1 Bivalent COVID-19 Vaccine Use and Stroke in England. This study investigates the association between bivalent COVID-19 vaccines and ischemic stroke, as well as the effect of simultaneous influenza vaccination on the association.

Rare cases of Guillain-BarrÃ© syndrome after COVID-19 vaccination, Germany, December 2020 to August 2021. BackgroundGuillain-BarrÃ© syndrome (GBS) has been associated with vaccination against COVID-19.AimWe aimed to compare clinical characteristics and analyse excess GBS cases following administration of different COVID-19 and influenza vaccines in Germany versus the expected numbers estimated from pre-pandemic background incidence rates.MethodsWe analysed safety surveillance data reported to the German national competent authority between 27 December

2020 and 31 August 2021. GBS cases were validated according to Brighton Collaboration (BC) criteria. We conducted observed vs expected (OvE) analyses on cases fulfilling BC criteria levels 1 to 4 for all four European Medicines Agency-approved COVID-19 vaccines and for influenza vaccines.ResultsA total of 214 GBS cases after COVID-19 vaccination had been reported, of whom 156 were eligible for further analysis. Standardised morbidity ratio estimates 3-42 days after vaccination were 0.34 (95% confidence interval (CI): 0.25-0.44) for Comirnaty, 0.38 (95%â€¯CI: 0.15-0.79) for Spikevax, 3.10 (95%â€¯CI: 2.44-3.88) for Vaxzevria, 4.16 (95%â€¯CI: 2.64-6.24) for COVID-19 Vaccine Janssen and 0.60 (95%â€¯CI: 0.35-0.94) for influenza vaccines. Bilateral facial paresis was reported in 19.7% and 26.1% of the 156 GBS cases following vaccination with Vaxzevria and COVID-19 Vaccine Janssen, respectively, and only in 6% of cases exposed to Comirnaty.ConclusionThree and four times more GBS cases than expected were reported after vaccination with Vaxzevria and COVID-19 Vaccine Janssen, respectively, therefore GBS might be an adverse event of vector-based vaccines. Bifacial paresis was more common in cases with GBS following vaccination with vector-based than mRNA COVID-19 vaccines.

Adolescent COVID-19 Cases During the SARS-CoV-2 Delta and Omicron Variant Surges in Kentucky: Association With Vaccination and Prior Infection. PURPOSE: Effectiveness of COVID-19 mRNA vaccines is influenced by SARS-CoV-2 variant and history of prior infection. Data regarding protection against SARS-CoV-2 infection among adolescents, accounting for prior infection and time since vaccination, are limited. METHODS: SARS-CoV-2 testing and immunization data from the Kentucky Electronic Disease Surveillance System and the Kentucky Immunization Registry, August-September 2021 (Delta predominance) and January 2022 (Omicron Predominance) among adolescents aged 12-17Â years, were used to assess association of SARS-CoV-2 infection with mRNA vaccination and prior SARS-CoV-2 infection. Estimated protection was derived from prevalence ratios ([1-PR]Â Ã— 100%). RESULTS: During Delta predominance, 89,736 tested adolescents were evaluated. Completion of primary series (second dose of mRNA vaccine â‰¥ 14Â days prior to testing) and history of prior infection (> 90Â days prior to testing) were both protective against SARS-CoV-2 infection (primary series: 81%, 95% confidence interval [CI] 79.7-82.3; prior infection: 66%, 95% CI 62.0-69.6). Prior infection plus primary series provided the greatest protection (92.3%, 95% CI 88.0-95.1). During Omicron predominance, 67,331 tested adolescents were evaluated. Primary series alone provided no benefit against SARS-CoV-2 infection after 90Â days; prior infection was protective for up to one year (24.2%, 95% CI 17.2-30.7). Prior infection plus booster vaccination provided the greatest protection against infection (82.4%, 95% CI 62.1-91.8). DISCUSSION: Strength and duration of protection against infection provided by COVID-19 vaccination and prior SARS-CoV-2 infection differed by variant. Vaccination provided additional benefit to the protection offered by prior infection alone. Remaining up to date with vaccination is recommended for all adolescents regardless of infection history.

Development of Dermatomyositis after Pfizer BioNTeh COVID-19 Vaccine: A Case Report. INTRODUCTION: The Coronavirus Disease 2019 (COVID-19) pandemic led to the fast development of vaccines, which is considered a medical advance in healthcare. With the extensive vaccination campaign performed worldwide, many adverse events following immunization (AEFI) were reported. Most of them were flu-like symptoms, mild and self-limiting. However, serious adverse events, such as dermatomyositis (DM), an idiopathic autoimmune connective tissue disease, have also been reported. CASE PRESENTATION: In this report, we describe a case of skin erythema, edema, and diffuse myalgia attributed at first to Pfizer BioNTeh, COVID-19 vaccination, given the temporal relationship and the absence of significant medical history. The causality assessment score was I1B2. However, after completing the etiological assessment, an invasive breast carcinoma was identified, and we retained the diagnosis of paraneoplastic DM. CONCLUSION: This study underlines the

importance of completing the etiological assessment before attributing any adverse reaction to vaccination to maintain optimal patient care.
Age, Sex and BMI Relations with Anti-SARS-CoV-2-Spike IgG Antibodies after BNT162b2 COVID-19 Vaccine in Health Care Workers in Northern Greece. The aim of this work was to study age, sex, and BMI (Body Mass Index)-related differences in the development of anti-SARS-CoV-2-Spike IgG antibodies, after vaccination with the BNT162b2 COVID-19 vaccine, in health care workers of a General Hospital in a city in Northern Greece. Blood sampling was drawn two to four weeks following the second dose of the vaccine, and six months after the first blood sample collection. Measurement of serum IgG antibodies against the spike domain of SARS-CoV-2 was performed using the SARS-CoV-2 IgG II Quant assay. All participants had sufficient serum IgG titers in the first measurement. Women developed higher IgG titers than men. The IgG titers were inversely related to age in both sexes; there was also a small, insignificant tendency to be inversely related to BMI. Six months after the first measurement, the IgG titers decreased dramatically to values less than 5% of the initial. This decrease was observed in both men and women and was inversely related to age. Multivariate regression analysis showed that age and sex explained with statistical significance 9% of the variance in SARS-CoV-2 IgG titers in our study population; the role of BMI was limited and insignificant.
Evaluation of the Diagnostic Performance of Two Automated SARS-CoV-2 Neutralization Immunoassays following Two Doses of mRNA, Adenoviral Vector, and Inactivated Whole-Virus Vaccinations in COVID-19 NaÃ¯ve Subjects. BACKGROUND: Limited data are available on humoral responses determined by automated neutralization tests following the administration of the three different types of COVID-19 vaccinations. Thus, we here evaluated anti-SARS-CoV-2 neutralizing antibody titers via two different neutralization assays in comparison to total spike antibody levels. METHODS: Healthy participants (n = 150) were enrolled into three subgroups who were tested 41 (22-65) days after their second dose of mRNA (BNT162b2/mRNA-1273), adenoviral vector (ChAdOx1/Gam-COVID-Vac) and inactivated whole-virus (BBIBP-CorV) vaccines, with no history or serologic evidence of prior SARS-CoV-2 infection. Neutralizing antibody (N-Ab) titers were analyzed on a Snibe Maglumi(Â®) 800 instrument and a Medcaptain Immu F6(Â®) Analyzer in parallel to anti-SARS-CoV-2 S total antibody (S-Ab) levels (Roche Elecsys(Â®) e602). RESULTS: Subjects who were administered mRNA vaccines demonstrated significantly higher SARS-CoV-2 N-Ab and S-Ab levels compared to those who received adenoviral vector and inactivated whole-virus vaccinations ($p < 0.0001$). N-Ab titers determined by the two methods correlated with each other ($r = 0.9608$; $p < 0.0001$) and S-Ab levels ($r = 0.9432$ and $r = 0.9324$; $p < 0.0001$, respectively). Based on N-Ab values, a new optimal threshold of Roche S-Ab was calculated (166 BAU/mL) for discrimination of seropositivity showing an AUC value of 0.975 ($p < 0.0001$). Low post-vaccination N-Ab levels (median value of 0.25 Î¼g/mL or 7.28 AU/mL) were measured in those participants (n = 8) who were infected by SARS-CoV-2 within 6 months after immunizations. CONCLUSION: Both SARS-CoV-2 N-Ab automated assays are effective to evaluate humoral responses after various COVID-19 vaccines.
A Pharmacoepidemiological Study of Myocarditis and Pericarditis Following the First Dose of mRNA COVID-19 Vaccine in Europe. This study assessed the myocarditis and pericarditis reporting rate of the first dose of mRNA COVID-19 vaccines in Europe. Myocarditis and pericarditis data pertinent to mRNA COVID-19 vaccines (1 January 2021-11 February 2022) from EudraVigilance database were combined with European Centre for Disease Prevention and Control (ECDC)'s vaccination tracker data. The reporting rate was expressed as events (occurring within 28 days of the first dose) per 1 million individuals vaccinated. An observed-to-expected (OE) analysis quantified excess risk for myocarditis or pericarditis following the first mRNA COVID-19 vaccination. The reporting rate of myocarditis per 1 million individuals vaccinated was 17.27 (95% CI, 16.34-18.26) for CX-024414 and 8.44 (95% CI, 8.18-8.70) for TOZINAMERAN; and of pericarditis, 9.76 (95% CI, 9.06-10.51) for CX-

024414 and 5.79 (95% CI, 5.56-6.01) for TOZINAMERAN. Both vaccines produced a myocarditis standardized morbidity ratio (SMR) > 1, with the CX-024414 vaccine having a greater SMR than TOZINAMERAN. Regarding TOZINAMERAN, SMR for pericarditis was >1 when considering the lowest background incidence, but <1 when considering the highest background incidence. Our results suggest an excess risk of myocarditis following the first dose of the mRNA COVID-19 vaccine, but the relationship between pericarditis and the mRNA COVID-19 vaccine remains unclear.

Graves' disease after exposure to the SARS-CoV-2 vaccine: a case report and review of the literature. BACKGROUND: Autoimmune/inflammatory syndrome induced by adjuvants (ASIA) is characterized by immune system dysregulation after exposure to adjuvants, such as aluminum. Although cases of autoimmune thyroid diseases caused by ASIA have been reported, Graves' disease is one of the rarer diseases. There are some reports that vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) cause ASIA. Here, we describe a case of Graves' disease following SARS-CoV-2 vaccination and a review of the literature. CASE PRESENTATION: A 41-year-old woman was admitted to our hospital because of palpitations and fatigue. Two weeks after receiving the second SARS-CoV-2 vaccine (BNT162b2, Coronavirus Modified Uridine messenger RNA (mRNA) Vaccine, Pfizer), she developed fatigue and gradually worsened. On admission, she exhibited thyrotoxicosis (thyroid-stimulating hormone (TSH)â€‰<â€‰0.01 mIU/L (0.08-0.54), free triiodothyronine (FT3) 33.2Â pmol/L (3.8-6.3), and free thyroxine (FT4) 72.1Â pmol/L (11.6-19.3)) and palpitations associated with atrial fibrillation. TSH receptor antibody (TRAb) was positive (TRAb 5.0Â IU/L (<â€‰2.0)), and (99m)Tc scintigraphy showed diffuse uptake in the thyroid gland, suggesting that the thyrotoxicosis in this case was caused by Graves' disease. Thiamazole was prescribed to correct her condition, and soon after this treatment was initiated, her symptoms and thyroid hormone levels were significantly reduced. CONCLUSIONS: This case report reinforces the potential correlation between ASIA affecting the thyroid and SARS-CoV-2 mRNA vaccines. The clinical course suggests that it is essential to consider the possibility of developing ASIA, such as Graves' disease, after exposure to the SARS-CoV-2 vaccine.

Ocular Inflammatory Events Following COVID-19 Vaccination in the Paediatric Population: A Multinational Case Series. BACKGROUND: Ocular inflammatory events following COVID-19 vaccination have been reported in the adult population. METHODS: Multinational case series of patients under the age of 18 diagnosed with ocular inflammatory events within 28â€‰days of COVID-19 vaccination. RESULTS: Twenty individuals were included. The most common event was anterior uveitis (nâ€‰=â€‰8, 40.0%), followed by intermediate uveitis (7 patients, 35%), panuveitis (4 patients, 20%), and posterior uveitis (1 patient, 5%). The event was noticed in the first week after vaccination in 11 patients (55.0%). Twelve patients (60.0%) had a previous history of intraocular inflammatory event. Patients were managed with topical corticosteroids (nâ€‰=â€‰19, 95.0%), oral corticosteroids (nâ€‰=â€‰10, 50.0%), or increased dose of immunosuppressive treatment (nâ€‰=â€‰6, 30.0%). Thirteen patients (65.0%) had a complete resolution of the ocular event without complications. All patients had a final visual acuity unaffected or less than three lines of loss. CONCLUSION: Ocular inflammatory events may happen in the paediatric population following COVID-19 vaccination. Most events were successfully treated, and all showed a good visual outcome.

Assessing How Risk Communication Surveillance Prompts COVID-19 Vaccine Acceptance Among Internet Users by Applying the Situational Theory of Problem Solving: Cross-Sectional Study. BACKGROUND: The World Health Organization has recently raised concerns regarding the low number of people fully vaccinated against COVID-19. The low ratio of fully vaccinated people and the emergence of renewed infectious variants correspond to worsening public health. Global health managers have highlighted COVID-19 vaccine-related infodemics as a significant risk perception factor hindering mass vaccination campaigns. OBJECTIVE: Given the ambiguous digital communication

environment that has fostered infodemics, resource-limited nations struggle to boost public willingness to encourage people to fully vaccinate. Authorities have launched some risk communication-laden digital interventions in response to infodemics. However, the value of the risk communication strategies used to tackle infodemics needs to be evaluated. The current research using the tenets of the Situational Theory of Problem Solving is novel, as it explores the impending effects of risk communication strategies. The relationship between infodemic-induced risk perception of COVID-19 vaccine safety and risk communication actions to intensify willingness to be fully vaccinated was examined. METHODS: This study used a cross-sectional research design vis-Ã -vis a nationally representative web-based survey. We collected data from 1946 internet users across Pakistan. Participants voluntarily participated in this research after completing the consent form and reading ethical permissions. Responses were received over 3 months, from May 2022 to July 2022. RESULTS: The results delineated that infodemics positively affected risk perception. This realization pushed the public to engage in risky communicative actions through reliance on and searches for accurate information. Therefore, the prospect of managing infodemics through risk information exposure (eg, digital interventions) using the situational context could predict robust willingness to be fully vaccinated against COVID-19. CONCLUSIONS: These pioneering results offer strategic considerations for health authorities to effectively manage the descending spiral of optimal protection against COVID-19. This research concludes that the likelihood of managing infodemics using situational context through exposure to relevant information could improve one's knowledge of forfending and selection, which can lead to robust protection against COVID-19. Hence, more situation-specific information about the underlying problem (ie, the selection of an appropriate vaccine) can be made accessible through several official digital sources to achieve a more active public health response.

Seroprevalence of SARS-CoV-2 IgG and associated factors among people living with HIV over the first 12 months following the outbreak of COVID-19 in Burkina Faso, a sub-Saharan African country. OBJECTIVE: This study aimed to evaluate the seroprevalence of anti-SARS-CoV-2 IgG and factors associated with the infection among PLWHIV over the first 12 months following the outbreak of COVID-19 in Burkina Faso. DESIGN: A retrospective cross-sectional study of plasma samples collected from March 9, 2020, and March 8, 2021, at the outpatient HIV referral center, before the introduction of the SARS-CoV-2 vaccine in Burkina Faso. METHODS: Anti-SARS-CoV-2 IgG were detected in plasma using DS-Đ•IA-ANTI-SARS-CoV-2-G (S) kit. Logistic regressions were used to compare SARS-CoV-2 specific immune responses between groups and within subgroups. RESULTS AND DISCUSSION: A total of 419 plasma were subjected to serological diagnosis. None of the participants was vaccinated against COVID-19 during the period of sample collection, and 130 samples were positive for anti-SARS-CoV-2 IgG, giving a prevalence of 31.0% (95% CI 26.6-35.7). The median CD4 cell count was 661 cells/Î¼L (IQR,422-928). Retailers had half the risk of being infected compared to housemaids with an OR of 0.49 (p = 0.028, 95% CI 0.26-0.91). Likewise, the risk of infection was 1.69 times higher in patients on integrase inhibitors compared to that of patients on non-nucleoside reverse transcriptase inhibitors (p = 0.020, 95% CI 1.09-2.63). CONCLUSION: Our study reveals a high seroprevalence among PLWHIV to SARS-CoV-2 during the first year of the pandemic. In addition, PLWHIV on integrase inhibitors are 1.69 times more likely to be infected than PLWHIV on non-nucleoside inhibitors, and this observation remains an intriguing topic that still needs to be clarified.

Optic Neuritis After COVID-19 Vaccination: An Analysis of the Vaccine Adverse Event Reporting System. BACKGROUND: To investigate the association of optic neuritis (ON) after the COVID-19 vaccines. METHODS: Cases of ON from Vaccine Adverse Event Reporting System (VAERS) were collected and divided into the prepandemic, COVID-19 pandemic, and COVID-19 vaccine periods.

Reporting rates were calculated based on estimates of vaccines administered. Proportion tests and Pearson Ï‡ 2 test were used to determine significant differences in reporting rates of ON after vaccines within the 3 periods. Kruskal-Wallis testing with Bonferroni-corrected post hoc analysis and multivariable binary logistic regression was used to determine significant case factors such as age, sex, concurrent multiple sclerosis (MS) and vaccine manufacturer in predicting a worse outcome defined as permanent disability, emergency room (ER) or doctor visits, and hospitalizations. RESULTS: A significant increase in the reporting rate of ON after COVID-19 vaccination compared with influenza vaccination and all other vaccinations (18.6 vs 0.2 vs 0.4 per 10 million, $P < 0.0001$) was observed. However, the reporting rate was within the incidence range of ON in the general population. Using self-controlled and case-centered analyses, there was a significant difference in the reporting rate of ON after COVID-19 vaccination between the risk period and control period ($P < 0.0001$). Multivariable binary regression with adjustment for confounding variables demonstrated that only male sex was significantly associated with permanent disability. CONCLUSIONS: Some cases of ON may be temporally associated with the COVID-19 vaccines; however, there is no significant increase in the reporting rate compared with the incidence. Limitations of this study include those inherent to any passive surveillance system. Controlled studies are needed to establish a clear causal relationship.

Racial and Ethnic Disparities in Excess Deaths after COVID-19 Vaccine Deployment among Persons with Kidney Failure.

Multiple myeloma, COVID-19 vaccination, adverse effect, and blood viscosity.

COVID-19 vaccine in cancerous patient receiving chemotherapy: Effect on safety margin for avoiding hyperviscosity.

Sweet syndrome induced by SARS-CoV-2 vaccines: A systematic review of patient-report studies. Since COVID-19 became a global pandemic in 2020, the development and application of SARS-CoV-2 vaccines has become an important task to prevent the spread of the epidemic. In addition to the safety and efficacy of COVID-19 vaccines, the adverse reactions caused by vaccines in a small number of people also deserve our attention. We aimed to discuss and analyze the possible causes of Sweet syndrome caused by the COVID-19 vaccine by integrating the effective information from 16 patients and combining it with the latest views on the innate immune mechanism. We searched the PubMed and Embase databases for published patient reports on the occurrence or recurrence of Sweet syndrome after COVID-19 vaccination. We summarized the basic information of the patients, the type of vaccination, the presence of underlying diseases, and the clinical manifestations, clinical treatment and prognosis of the patients. The results were reported in narrative methods and were sorted into tables. We initially identified 53 studies. 16 articles were included through full-text screening. Based on the table we compiled, we generally concluded that the first dose of any type of COVID-19 vaccine was more likely to cause Sweet syndrome than subsequent doses. Sweet syndrome may occur after COVID-19 vaccination. Clinicians should consider Sweet syndrome in addition to common adverse reactions such as anaphylaxis and infection when a patient presents with acute fever accompanied by nodular erythema, pustules, and edematous plaques after COVID-19 vaccination.

Cutaneous Adverse Events After COVID-19 Vaccination. PURPOSE: The morphology and timing of cutaneous reactions after Coronavirus disease (COVID-19) vaccines have been well described; however, data on the rates and risk factors are limited. Therefore, this study aimed to measure the incidence of cutaneous adverse reactions (CARs) after COVID-19 vaccination in Thailand, describe the rash characteristics according to the doses or types of vaccine, and assess the risk factors for developing CARs. PATIENTS AND METHODS: This was a prospective observational study of adults who received COVID-19 vaccination and provided informed consent. Cutaneous diagnoses were made by expert dermatologists with supporting skin biopsies, as needed. Data were analyzed using descriptive statistics and logistic regression to examine the independent risk of developing a CAR. RESULTS:

Between July 2021 and January 2022, 7505 participants were vaccinated. Vaccine-related CARs occurred in 92 patients with an overall risk of 1.2%. CARs occurred after the first (n=41), second (n=23), third (n=27), and fourth (n=1) doses. Among the 92, 75 (81%) developed CARs within 7 days and 61 (66%) resolved within 7 days. Urticaria, injection site reaction, and a delayed (â‰¥ 3 days post vaccine) local reaction were the three most common CARs occurring in 59 cases (64%). In total, 51 (55%) patients received only symptomatic and supportive treatment. Underlying urticaria and psoriasis were the independent factors for developing a CAR: adjusted odd rations of 15.63 (6.02-40.57, $p < 0.001$) and 5.36 (1.57-18.36, $p = 0.007$), respectively. A total of 6/34 (17%) and 4/31 (12%) patients developed urticarial and psoriasis flare post vaccine. Our study found superficial perivascular and intraepidermal eosinophil infiltration, which may be unusual pathological findings in vaccine-induced pemphigus foliaceous. CONCLUSION: CARs after COVID-19 vaccination had a low incidence and were mostly mild in severity and transient in nature. Underlying urticaria and psoriasis were risk factors for CAR development.

Transient plasma viral rebound after SARS-CoV-2 vaccination in an exceptional HIV-1 elite controller woman. BACKGROUND: Elite controllers are able to control viral replication without antiretroviral therapy. Exceptional elite controllers do not show disease progression for more than 25 years. Different mechanisms have been proposed and several elements of both innate and adaptive immunity are implicated. Vaccines are immune stimulating agents that can promote HIV-RNA transcription; transient plasma HIV-RNA detectability has been described within 7-14 days after different vaccinations. The most reliable mechanism involved in virosuppressed people living with HIV is a generalized inflammatory response that activates bystander cells harboring latent HIV. So far no data about viral load increase in elite controllers after SARS-CoV-2 vaccination are reported in literature. CASE PRESENTATION: We report the case of a 65-year-old woman of European ancestry, diagnosed with HIV-1/HCV co-infection more than 25 years ago. Since then, HIV-RNA remained undetectable and she never received ARV therapy. In 2021 she was vaccinated with mRNA-BNT162b2 vaccine (Pfizer-BioNTechÂ®). She was administered with three doses in June, July and October 2021, respectively. The last available viral load was undetectable in March 2021. We observed an increase of VL at 32 cp/ml and 124 cp/mL, two and seven months after the second vaccine dose, respectively. During monthly follow-up, HIV-RNA gradually and spontaneously dropped becoming undetectable without ARV intervention. COVID-19 serology was positive with IgG 535 BAU/mL, showing response to vaccination. We measured total HIV-DNA at different time-points and we found it detectable both at the time of the higher plasma HIV-RNA (30 cp/10^6 PBMCs) and when it was undetectable (13 cp/10^6 PBMCs), in reduction. CONCLUSIONS: This case is the first report, to our knowledge, describing a rebound of plasma HIV-RNA in an elite controller after three doses of mRNA-BNT162b2 vaccine for SARS-CoV-2. Concomitantly with a spontaneous reduction of plasma HIV-RNA ten months after the third dose of mRNA-BNT162b2 vaccine (Pfizer-BioNTechÂ®) without antiretroviral therapy intervention, we observed a reduction of total HIV-DNA in peripheral mononuclear cells. The potential role of vaccinations in altering HIV reservoir, even in elite controllers when plasma HIV-RNA is undetectable, could be a valuable aspect to take into account for the future HIV eradication interventions.

Waning cellular immune responses and predictive factors in maintaining cellular immunity against SARS-CoV-2 six months after BNT162b2 mRNA vaccination. Several clinical trials have shown that the humoral response produced by anti-spike antibodies elicited by coronavirus disease 2019 (COVID-19) vaccines gradually declines. The kinetics, durability and influence of epidemiological and clinical factors on cellular immunity have not been fully elucidated. We analyzed cellular immune responses elicited by BNT162b2 mRNA vaccines in 321 health care workers using whole blood interferon-gamma (IFN-Î³) release assays. IFN-Î³, induced by CD4â€‰+â€‰and CD8â€‰+â€‰T cells stimulated

with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike epitopes (Ag2), levels were highest at 3 weeks after the second vaccination (6 W) and decreased by 37.4% at 3 months (4Â M) and 60.0% at 6 months (7Â M), the decline of which seemed slower than that of anti-spike antibody levels. Multiple regression analysis revealed that the levels of IFN-Î³ induced by Ag2 at 7Â M were significantly correlated with age, dyslipidemia, focal adverse reactions to full vaccination, lymphocyte and monocyte counts in whole blood, Ag2 levels before the second vaccination, and Ag2 levels at 6 W. We clarified the dynamics and predictive factors for the long-lasting effects of cellular immune responses. The results emphasize the need for a booster vaccine from the perspective of SARS-CoV-2 vaccine-elicited cellular immunity.

An unusual occurrence of autoimmune pancreatitis after gam-Covid-Vac (Sputnik V): A case report and literature review. The safety profile of the Sputnik V vaccine is generally reassuring. Nevertheless, an enhanced risk of new-onset of immune-mediated diseases has been increasingly reported following the adenoviral-based Covid-19 vaccine, including inflammatory arthritis, Guillain-BarrÃ© syndrome, optical neuromyelitis, acute disseminated encephalomyelitis, subacute thyroiditis and acute liver injury as well as glomerulopathy. However, no case of autoimmune pancreatitis has been reported yet. Herein, we describe a case of type I autoimmune pancreatitis that may be due to the Sputnik V Covid-19 vaccine.

Coronavac inactivated vaccine triggers durable, cross-reactive Fc-mediated phagocytosis activities. Although humoral responses elicited by infection or vaccine lost the ability to prevent transmission against Omicron, vaccine-induced antibodies may still contribute to disease attenuation through Fc-mediated effector functions. However, Fc effector function elicited by CoronaVac, as the most widely supplied inactivated vaccine globally, has not been characterized. For the first time, our study depicted Fc-mediated phagocytosis activity induced by CoronaVac, including antibody-dependent cellular phagocytosis (ADCP) and antibody-dependent neutrophil phagocytosis (ADNP) activities, and further compared with that from convalescent individuals and CoronaVac recipients with subsequent breakthrough infections. We showed that 2-dose of CoronaVac effectively induced both ADCP and ADNP, but was substantially lower compared to infection, whereas the booster dose further augmented ADCP and ADNP responses, and remained detectable for 52 weeks. Among CoronaVac recipients, ADCP and ADNP responses also demonstrated cross-reactivity against Omicron subvariants, and breakthrough infection could enhance the phagocytic response. Meanwhile, serum samples from vaccinees, convalescent individuals with wildtype infection, BA.2 and BA.5 breakthrough infection demonstrated differential cross-reactive ADCP and ADNP responses against Omicron subvariants, suggesting the different subvariants of spike antigen exposure might alter the cross-reactivity of Fc effector function. Further, ADCP and ADNP responses were strongly correlated with Spike-specific IgG responses and neutralizing activities, indicating coordinated neutralization activity, ADCP and ADNP responses triggered by CoronaVac. Of note, the ADCP and ADNP responses were more durable and cross-reactive than corresponding Spike-specific IgG titers and neutralizing activities. Our study has important implications for optimal boosting vaccine strategies that may induce potent and broad Fc-mediated phagocytic activities.

Role of vaccination and anti-SARS-CoV-2 antibodies in the clinical outcome of hospitalized COVID-19 patients. BACKGROUND: Although vaccination has considerably reduced the risk of hospitalization and death from COVID19, the impact of vaccination and anti-SARS-CoV-2 antibody status on the outcome of patients who required hospitalization has been poorly investigated. MATERIAL AND METHODS: A prospective observational study in 232 patients hospitalized for COVID19 was carried out from October 2021 to January 2022 to evaluate the role on patient outcome of their vaccination and anti-SARS-CoV-2 antibody status and titer, comorbidities, analytical determinations, clinical presentation at admission, treatments and requirements for respiratory

support. Cox regression and survival analyzes were performed. The SPSS and "R" programs were used. RESULTS: Patients with complete vaccination schedule had higher S-protein antibody titers (log10 3.73 [2.83-4.6]Â UI/ml vs 1.6 [2.99-2.61]Â UI/ml; pÂ <Â 0.001), lower probability of radiographic worsening (21.6% vs. 35.4%; pÂ =Â 0.005), less likely required high doses of dexamethasone (28.4% vs. 45.4%; pÂ =Â 0.012), high-flow oxygen (20.6% vs. 35.4%; pÂ =Â 0.02), ventilation (13.7% vs, 33.8%; pÂ =Â 0.001) and intensive care admissions (10.8% vs. 32.6%; pÂ <Â 0.001). Remdesivir (HRÂ =Â 0.38; pÂ <Â 0.001) and complete vaccination schedule (HRÂ =Â 0.34; pÂ =Â 0.008) were protective factors. No differences in antibody status were detected between groups (HRÂ =Â 0.58; pÂ =Â 0.219). CONCLUSIONS: SARS-CoV-2 vaccination was associated with higher S-protein antibody titers and lower probability of radiological progression, immunomodulators requirement and respiratory support or death. However, vaccination but not antibody titters protected from adverse events pointing a role of immune-protective mechanisms in addition to humoral response.

Immunogenicity of COVID-19 vaccines in adult patients with autoimmune inflammatory rheumatic diseases: A systematic review and meta-analysis. COVID-19 vaccines approved by the Food and Drug Administration have been studied mainly in healthy individuals and there is limited information on their immunogenicity in patients with autoimmune diseases. Therefore, the current systematic review and meta-analysis study, aimed to comprehensively investigate the immunogenicity of these vaccines in patients with autoimmune inflammatory rheumatoid diseases (AIRDs). A comprehensive literature search was performed on various databases, including Google Scholar, PubMed, Web of Science, EMBASE, and Cochrane Library, to select cohort and randomized clinical trial (RCT) studies up to January 2022. Also, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist protocol and the I(2) statistic were used for quality assessment and heterogeneity tests of the selected studies. Fixed and random-effects models were estimated based on the heterogeneity tests, and pooled data were determined as the ratio of mean (ROM) with a 95% confidence interval (CI). As a result, we found that vaccines can cause favorable immunogenicity and antibody response in vaccinated AIRD patients; however, older age and the concomitant consumption of conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) and biologic DMARDs (bDMARDs) could significantly reduce the vaccine immunogenicity. Consequently, our findings revealed significant humoral responses (seropositive) in AIRD patients following the administration of COVID-19 vaccines.

Barriers to COVID-19 vaccine surveillance: the issue of under-reporting adverse events. OBJECTIVES: This study investigated the reporting rates of adverse events following immunization (AEFIs) to the spontaneous reporting system (SRS) and its predictors among individuals with AEFIs after coronavirus disease 2019 (COVID-19) vaccination. METHODS: A cross-sectional, web-based survey was conducted from December 2, 2021 to December 20, 2021, recruiting participants >14 days after completion of a primary COVID-19 vaccination series. Reporting rates were calculated by dividing the number of participants who reported AEFIs to the SRS by the total number of participants who experienced AEFIs. We estimated adjusted odds ratios (aORs) using multivariate logistic regression to determine factors associated with spontaneous AEFIs reporting. RESULTS: Among 2,993 participants, 90.9% and 88.7% experienced AEFIs after the first and second vaccine doses, respectively (reporting rates, 11.6 and 12.7%). Furthermore, 3.3% and 4.2% suffered moderate to severe AEFIs, respectively (reporting rates, 50.5 and 50.0%). Spontaneous reporting was more prevalent in female (aOR, 1.54; 95% confidence interval [CI], 1.31 to 1.81); those with moderate to severe AEFIs (aOR, 5.47; 95% CI, 4.45 to 6.73), comorbidities (aOR, 1.31; 95% CI, 1.09 to 1.57), a history of severe allergic reactions (aOR, 2.02; 95% CI, 1.47 to 2.77); and those who had received mRNA-1273 (aOR, 1.25; 95% CI, 1.05 to 1.49) or ChAdOx1 (aOR, 1.62; 95% CI, 1.15 to 2.30) vaccines

versus BNT162b2. Reporting was less likely in older individuals (aOR, 0.98; 95% CI, 0.98 to 0.99 per 1-year age increment). CONCLUSIONS: Spontaneous reporting of AEFIs after COVID-19 vaccination was associated with younger age, female sex, moderate to severe AEFIs, comorbidities, history of allergic reactions, and vaccine type. AEFIs under-reporting should be considered when delivering information to the community and in public health decision-making.

New-onset acute psychosis as a manifestation of lupus cerebritis following concomitant COVID-19 infection and vaccination: a rare case report. BACKGROUND: Rare cases of COVID-19 infection- and vaccine-triggered autoimmune diseases have been separately reported in the literature. In this paper, we report the first and unique case of new onset acute psychosis as a manifestation of lupus cerebritis following concomitant COVID-19 infection and vaccination in a previously healthy 26-year-old Tunisian female. CASE PRESENTATION: A 26-years old female with a family history of a mother diagnosed with schizophrenia, and no personal medical or psychiatric history, was diagnosed with mild COVID-19 infection four days after receiving the second dose of Pfizer-BioNTech COVID-19 vaccine. One month after receiving the vaccine, she presented to the psychiatric emergency department with acute psychomotor agitation, incoherent speech and total insomnia evolving for five days. She was firstly diagnosed with a brief psychotic disorder according to the DSM-5, and was prescribed risperidone (2Â mg/day). On the seventh day of admission, she reported the onset of severe asthenia with dysphagia. Physical examination found fever, tachycardia, and multiple mouth ulcers. Neurological evaluation revealed a dysarthria with left hemiparesis. On laboratory tests, she had severe acute kidney failure, proteinuria, high CRP values, and pancytopenia. Immune tests identified the presence of antinuclear antibodies. Brain magnetic resonance imaging (MRI) revealed hyperintense signals in the left fronto-parietal lobes and the cerebellum. The patient was diagnosed with systemic lupus erythematosus (SLE) and put on anti-SLE drugs and antipsychotics, with a favorable evolution. CONCLUSIONS: The chronological relationship between COVID-19 infection, vaccination and the first lupus cerebritis manifestations is highly suggestive, albeit with no certainty, of the potential causal link. We suggest that precautionary measures should be taken to decrease the risk of SLE onset or exacerbation after COVID-19 vaccination, including a systematic COVID-19 testing before vaccination in individuals with specific predisposition.

COVID-19 vaccination exacerbates ex vivo IL-6 release from isolated PBMCs. Ex vivo culturing of isolated PBMCs from individuals vaccinated with the coronavirus disease 2019 (COVID-19) vaccine BNT162b1 revealed a pronounced T cell response in the presence of the receptor binding domain (RBD) of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein. The latter was 10-fold more pronounced than the ex vivo response of PBMCs from the same individuals to other common pathogen T cell epitope pools, suggesting COVID-19 vaccination to induce RBD-specific T cell responses and not to facilitate T cell (re)activity in general. In the current study we investigated whether COVID-19 vaccination long-lastingly affects plasma interleukin (IL)-6 concentrations, complete blood counts, ex vivo IL-6 and IL-10 secretion of PBMCs cultured under basal conditions or in the presence of concanavalin (Con) A and lipopolysaccharide (LPS), salivary cortisol and Î±-amylase, mean arterial pressure (MAP), heart rate (HR) as well as mental and physical health status. The study was initially designed to investigate whether the presence vs. absence of own pets during urban upbringing has protective effects against psychosocial stress-induced immune activation during adulthood. However, as COVID-19 vaccines were approved while the study was ongoing and as, therefore, both vaccinated and non-vaccinated individuals have been recruited, we were able to stratify our data set with respect to the COVID-19 vaccination status and to assess the long-lasting effects of COVID-19 vaccination on physiological immunological, cardiovascular and psychosomatic health parameters. This data is presented in the current study. We show that isolated PBMCs from individuals vaccinated against COVID-19 show aâ€‰~â€‰600-fold increase in basal and

aâ€‰~â€‰6000-fold increase in ConA-induced proinflammatory IL-6 secretion, and aâ€‰~â€‰2-fold increase in basal and ConA-induced antiinflammatory IL-10 secretion, both in comparison with non-vaccinated individuals. In contrast, LPS-induced ex vivo IL-6 and IL-10 secretions were not affected by vaccination status, as were plasma IL-6 concentrations, complete blood counts, salivary cortisol and Î±-amylase, cardiovascular measures and psychosomatic health. In summary, our findings are of relevance for many clinical studies ran before/during the pandemic, clearly indicating that consideration of participants' vaccination status is critical, at least when assessing ex vivo PBMC functionality.

Guillain-BarrÃ© syndrome following COVID-19 vaccination: An updated systematic review of cases. KEY CLINICAL MESSAGE: Guillain-BarrÃ© syndrome (GBS) is a rare but possible complication that may occur after COVID-19 vaccination. In this systematic review, we found that GBS presented in patients with an average age of 58. The average time for symptoms to appear was 14.4â€‰days. Health care providers should be aware of this potential complication. ABSTRACT: Most instances of Guillain-BarrÃ© syndrome (GBS) are caused by immunological stimulation and are discovered after vaccinations for tetanus toxoid, oral polio, and swine influenza. In this systematic study, we investigated at GBS cases that were reported after receiving the COVID-19 vaccination. Based on PRISMA guidelines, we searched five databases (PubMed, Google Scholar, Ovid, Web of Science, and Scopus databases) for studies on COVID-19 vaccination and GBS on August 7, 2021. To conduct our analysis, we divided the GBS variants into two groups, acute inflammatory demyelinating polyneuropathy and non-acute inflammatory demyelinating polyneuropathy (AIDP and non-AIDP), and compared the two groups with mEGOS and other clinical presentation In this systematic review, 29 cases were included in 14 studies. Ten cases belonged to the AIDP variant, 17 were non-AIDP (one case had the MFS variant, one AMAN variant, and 15 cases had the BFP variant), and the two remaining cases were not mentioned. Following COVID-19 vaccination, GBS cases were, on average, 58â€‰years of age. The average time it took for GBS symptoms to appear was 14.4â€‰days. About 56 percent of the cases (56%) were classified as Brighton Level 1 or 2, which defines the highest level of diagnostic certainty for patients with GBS. This systematic review reports 29 cases of GBS following COVID-19 vaccination, particularly those following the AstraZeneca/Oxford vaccine. Further research is needed to assess all COVID-19 vaccines' side effects, including GBS.

Serum vitamin D levels can be predictive of psoriasis flares up after COVID-19 vaccination: a retrospective case control study. INTRODUCTION: Many patients with chronic inflammatory dermatosis such as psoriasis usually ask about the safety of COVID-19 vaccination and if it would affect the course of their disease. Indeed, many case reports, case series and clinical studies, reporting psoriasis exacerbation following vaccination against COVID-19, were published during the pandemic. Also, many questions arise regarding the existence of exacerbating factors of these flare ups, including environmental triggers such as the insufficiency of vitamin D levels. METHODS: This is a retrospective study that measures alterations in psoriasis activity and severity index (PASI) not exceeding 2 weeks after the first and second dose of COVID-19 vaccinations in the reported cases and assesses whether such changes have any association with patients' vitamin D levels. We retrospectively reviewed the case records of all patients with a documented flare up after COVID-19 vaccination in our department as well as those who did not, during a year. RESULTS: Among them, we found 40 psoriasis patients that had reported vitamin D levels in the form of 25-hydroxy-vitamin D within 3 weeks after vaccination, including 23 with exacerbation and 17 without exacerbation. Performing Ï‡(2) and t-test controls for psoriasis patients with and without flare-ups, a statistically significant dependence emerged in the seasons of summer [Ï‡(2)(1) = 5.507, p = 0.019], spring [Ï‡(2)(1) = 11.429, p = 0.001] and in the categories of vitamin D [Ï‡(2)(2) = 7.932, p = 0.019], while the mean value of vitamin D for psoriasis patients who did not have exacerbation (31.14 Â± 6.67 ng/mL)

is statistically higher [t(38) = 3.655, p = 0.001] than the corresponding value of psoriasis patients who had an exacerbation (23.43 Â± 6.49 ng/mL). DISCUSSION: This study indicates that psoriasis patients with insufficient (21-29 ng/mL) or inadequate (<20 ng/mL) levels of vitamin D are more prone to postvaccination aggravation of the disease while vaccination in summer, a period with the most extent photo-exposition, can be a protective factor.

COVID-19 Vaccine Acceptance, Attitude, Hesitancy, and Its Associated Factors among Wolaita Sodo University Students: A Mixed-Method Study. BACKGROUND: Countries in the world have been experiencing the ongoing impact and spread of the coronavirus disease (COVID-19) virus pandemic. The health and financial burden of the pandemic has prompted the need for timely and effective vaccination to be considered as the best strategy for controlling disease transmission. However, vaccine acceptability remains an area of concern in developing countries like Ethiopia. OBJECTIVE: To assess attitude, hesitancy in the COVID-19 vaccine acceptance, and associated factors among health science students at Wolaita Sodo University. METHODS: A triangulated mixed-method study was conducted. Quantitative data were entered into SPSS Windows version 25 for analysis, and the qualitative data were transcribed using open code version 4.3. A binary logistic regression model was used to establish the association between dependent and independent variables. Adjusted odds ratio (AOR) with a 95% confidence interval (CI) was used to measure the strengths of the association. Thematic approach was used for qualitative data analysis. RESULTS: A total of 352 students participated in this study. Having family members who were infected with COVID-19, information about COVID-19 vaccine, the need for a vaccine with the level of concern, intention to take COVID-19 vaccine, and academic year were strongly associated with vaccine acceptability. Graduating class and other senior students were about 4 and 2 times more likely to accept vaccination as compared to freshman-year students (AORâ€‰=â€‰4.128; 95% CI: 1.351-12.610;P = 0.012) and (AORâ€‰=â€‰2.195; 95% CI: 1.182-4.077; P valueâ€‰=â€‰0.013), respectively. Even if 67% of students had a good attitude towards the vaccine, 56% of the students hesitated to take the vaccine. CONCLUSION: The majority of respondents had a constructive attitude towards the COVID-19 vaccine, and only a few of them were vaccinated against the COVID-19 virus. It is of utmost importance to design an evidence-based strategy to increase the uptake of vaccination for healthcare students and other nonhealth science students in universities.

Remitting Seronegative Symmetrical Synovitis with Pitting Oedema Following Administration of the Chadox1-S/NCOV-19 Coronavirus Vaccine. INTRODUCTION: We describe a case of remitting seronegative symmetrical synovitis with pitting oedema (RS3PE) syndrome following administration of the ChAdOx1-S/nCoV-19 [recombinant] vaccine, suggesting a possible causal link. CASE DESCRIPTION: A 72-year-old man presented to his general practitioner with swollen, oedematous hands and legs 2 weeks after receiving a coronavirus vaccine. He had raised inflammatory markers but remained systemically well. He was initially presumed to have cellulitis, but his symptoms persisted despite several courses of antibiotics. Deep vein thromboses, cardiac failure, renal failure and hypoalbuminaemia were ruled out. Upon Rheumatology review, he was diagnosed as having RS3PE syndrome with the Covid vaccine suspected of being an immunogenic trigger. Following initiation of steroid therapy, his symptoms improved dramatically, as is characteristic of RS3PE syndrome. DISCUSSION: The pathophysiology of RS3PE is unclear. It is known to have various triggers and associations including infections, certain vaccines and malignancy. This case highlights that a coronavirus vaccine (ChAdOx1-S/nCoV-19 [recombinant] vaccine) is also a possible trigger. Factors that make the diagnosis likely include an acute onset of symptoms including pitting oedema in a typical distribution, age above 50, and unremarkable autoimmune serology. Other learning points from this case include the importance of antibiotic stewardship and the need to explore non-infectious causes of illness when antibiotics do not improve symptoms. CONCLUSION: The ChAdOx1-

S/nCoV-19 [recombinant] vaccine is a possible trigger of RS3PE. However, the benefits of vaccines against coronavirus outweigh the risks in the majority of patients. LEARNING POINTS: This case demonstrates a possible link between the ChAdOx1-S/nCoV-19 [recombinant] vaccine and autoimmune conditions such as RS3PE.It is important to consider alternative diagnoses when antibiotic regimes fail to work.A barrier to accurate diagnosis includes an episodic approach, where a patient presents to multiple clinicians acutely rather than having a long-term, continuous relationship with a single multi-disciplinary team, where response to treatment can be monitored.

Reducedhumoral response against variants of concern in childhood solid cancer patients compared to adult patients and healthy children after SARS-CoV-2 vaccination. INTRODUCTION: Although there is extended research on the response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines in adult cancer patients (ACP), the immunogenicity to the variants of concern (VOCs) in childhood cancer patients (CCP) and safety profiles are now little known. METHODS: A prospective, multi-center cohort study was performed by recruiting children with a solid cancer diagnosis and childhood healthy control (CHC) to receive standard two-dose SARS-CoV-2 vaccines. An independent ACP group was included to match CCP in treatment history. Humoral response to six variants was performed and adverse events were followed up 3 months after vaccination. Responses to variants were compared with ACP and CHC by means of propensity score-matched (PSM) analysis. RESULTS: The analysis included 111 CCP (27.2%, median age of 8, quartile 5.5-15 years), 134 CHC (32.8%), and 163 ACP (40.0%), for a total 408 patients. Pathology included carcinoma, neural tumors, sarcoma, and germ cell tumors. Median chemotherapy time was 7 (quartile, 5-11) months. In PSM sample pairs, the humoral response of CCP against variants was significantly decreased, and serology titers (281.8 Â± 315.5 U/ml) were reduced, as compared to ACP ($p < 0.01$ for the rate of neutralization rate against each variant) and CHC ($p < 0.01$ for the rate of neutralization against each variant) groups. Chemotherapy time and age (Pearson r â‰¥ 0.8 for all variants) were associated with the humoral response against VOCs of the CHC group. In the CCP group, less than grade II adverse events were observed, including 32 patients with local reactions, and 29 patients had systemic adverse events, including fever (n = 9), rash (n = 20), headache (n = 3), fatigue (n = 11), and myalgia (n = 15). All reactions were well-managed medically. CONCLUSIONS: The humoral response against VOCs after the CoronaVac vaccination in CCP was moderately impaired although the vaccine was safe. Age and chemotherapy time seem to be the primary reason for poor response and low serology levels.

Functional CVIDs phenotype clusters identified by the integration of immune parameters after BNT162b2 boosters. INTRODUCTION: Assessing the response to vaccinations is one of the diagnostic criteria for Common Variable Immune Deficiencies (CVIDs). Vaccination against SARS-CoV-2 offered the unique opportunity to analyze the immune response to a novel antigen. We identify four CVIDs phenotype clusters by the integration of immune parameters after BTN162b2 boosters. METHODS: We performed a longitudinal study on 47 CVIDs patients who received the 3rd and 4th vaccine dose of the BNT162b2 vaccine measuring the generation of immunological memory. We analyzed specific and neutralizing antibodies, spike-specific memory B cells, and functional T cells. RESULTS: We found that, depending on the readout of vaccine efficacy, the frequency of responders changes. Although 63.8% of the patients have specific antibodies in the serum, only 30% have high-affinity specific memory B cells and generate recall responses. DISCUSSION: Thanks to the integration of our data, we identified four functional groups of CVIDs patients with different B cell phenotypes, T cell functions, and clinical diseases. The presence of antibodies alone is not sufficient to demonstrate the establishment of immune memory and the measurement of the in-vivo response to vaccination distinguishes patients with different immunological defects and clinical diseases.

Relapsing myocarditis following initial recovery of post COVID-19 vaccination in two adolescent males - Case reports. Whilst there has been significant public health benefits associated with global use

of COVID-19 spike protein vaccines, potential serious adverse events following immunization have been reported. Acute myocarditis is a rare complication of COVID19 vaccines and often it is self-limiting. WeÂ describeÂ two casesÂ experiencingÂ recurrent myocarditis following mRNA COVID-19 vaccine despite a prior episode with full clinical recovery.Â Between September 2021-September 2022 we observed two male adolescents with recurrent myocarditis related to mRNA-based-COVID19 vaccine. During the first episode both patients presented with fever and chest pain few days after their second dose of BNT162b2 mRNA Covid-19 Vaccine (ComirnatyÂ®). The blood exams showed increased cardiac enzymes. In addition, complete viral panel was run, showing HHV7 positivity in a single case. The left ventricular ejection fraction (LVEF) was normal at echocardiogram but cardiac magnetic resonance scanning (CMR) was consistent with myocarditis. They were treated with supportive treatment with full recovery. The 6Â months follow-up demonstrated good clinical conditions with normal cardiological findings. The CMR showed persistent lesions in left ventricle 's wall with LGE. After some monthsÂ the patients presented at emergency department with fever and chest pain and increased cardiac enzymes. No decreased LVEF was observed. The CMR showed new focal areas of edema in the first case report and stable lesions in the second one.Â They reached full recovery with normalization of cardiac enzymes after few days. These case reports outline the need of strict follow-up in patients with CMR consistent with myocarditis after mRNA-based-COVID19 vaccine. More efforts are necessary to depict the underlying mechanisms of myocarditis after SARS-CoV2 vaccination to understand the risk of relapsing and the long-term sequelae.

Defective T-cell response to COVID-19 vaccination in acute myeloid leukaemia and myelodysplastic syndromes. Limited data exist on COVID-19 vaccination efficacy in patients with acute myeloid leukemia and myelodysplasia with excess blasts (AML/MDS-EB2). We report results from a prospective study, PACE (Patients with AML and COVID-19 Epidemiology). 93 patients provided samples post-vaccine 2 or 3 (PV2, PV3). Antibodies against SARS-COV-2 spike antigen were detectable in all samples. Neutralization of the omicron variant was poorer than ancestral variants but improved PV3. In contrast, adequate T-cell reactivity to SARS-COV-2 spike protein was seen in only 16/47 (34%) patients PV2 and 23/52 (44%) PV3. Using regression models, disease response (not in CR/Cri), and increasing age predicted poor T cell response.

[Cryptogenic new-onset super-refractory status epilepticus following SARS-CoV-2 vaccination. A case report]. INTRODUCTION: New-onset super-refractory status epilepticus (NOSRSE) is a neurological emergency characterised by the development of status epilepticus in a patient without epilepsy or any known prior neurological disease and with no clear structural, toxic or metabolic cause, which recurs after 24 hours of induced coma. The most common identifiable cause is inflammatory-autoimmune. Consequently, we present a case of NOSRSE related to SARS-CoV-2 vaccination as an opportunity to investigate the dysimmune origin of this pathology. CASE REPORT: We report the case of a 40-year-old male who presented at the emergency department with fever and headache with no clear source of infection. His personal history included bacterial meningitis in childhood without any sequelae and protein S deficiency without treatment at the time, as well as vaccination with ChAdOx1 nCoV-19 21 days earlier. He was initially diagnosed with a urinary tract infection and treated with cefuroxime. Two days later, he was taken back to the emergency department with confusional symptoms and tonic-clonic seizures. He did not respond to midazolam and finally required sedation and orotracheal intubation for refractory status epilepticus. While in hospital, he required a number of lines of antiepileptic drugs, ketamine, a ketogenic diet, immunotherapy and plasmapheresis in order to successfully limit NOSRSE. The aetiological study offered normal results for serology, antineuronal antibodies in serum and cerebrospinal fluid, transthoracic echocardiography, testicular ultrasound and computed tomographic angiography. Only the control MRI scan showed a diffuse and bilateral alteration of the right hemispheric cortex and

thalamic pulvinar as the only finding. CONCLUSION: It is crucial to report suspected adverse reactions associated with SARS-CoV-2 vaccination, thereby allowing continued monitoring of the risk/benefit ratio of vaccination.

BNT162b2 immunization-related myocarditis in adolescents and consequent hospitalization: Report from a medical center. BACKGROUND: To investigate Pfizer-BioNTech 162b2 mRNA COVID-19 vaccine (BNT162b2) immunization-related myocarditis and describe the risk factors for consequent hospitalization in the pediatric intensive care unit (PICU) in children between 12 and 18 years. METHODS: Children and adolescents 12 years of age and older who presented with discomfort after BNT162b2 immunization (BNTI) and visited pediatric emergency room (PER) at Chang Gung Memorial Hospital from September 22, 2021 to March 21, 2022, were included for analysis. RESULTS: 681 children presented with discomfort after BNTI and visited our PER. The mean age was 15.1Â Â±Â 1.7 years. Three hundred and ninety-four (57.9%) and 287 (42.1%) events were after 1st and 2nd dose, respectively. 58.4% (nÂ =Â 398) were male. The most common complaints were chest pain (46.7%) and chest tightness (27.0%). The median (interquartile range [IQR]) interval of discomfort after BNTI was 3.0 (1.0-12.0) days. BNTI-related pericarditis, myocarditis and myopericarditis were diagnosed in 15 (2.2%), 12 (1.8%) and 2 (0.3%) patients, respectively. Eleven (1.6%) needed hospitalization in PICU. The median (IQR) hospital stay was 4.0 (3.0-6.0) days. There was no mortality. More patients were diagnosed myocarditis (pÂ =Â 0.004) after 2nd dose BNTI. PICU admission occurred more commonly after 2nd dose BNTI (pÂ =Â 0.007). Risk factors associated with hospitalization in PICU were abnormal EKG findings (pÂ =Â 0.047) and abnormal serum troponin levels (pÂ =Â 0.003) at PER. CONCLUSION: Myocarditis in children aged 12-18 years occurred more commonly following 2nd dose BNTI. Most cases were of mild or intermediate severity without death. Factors predicting BNTI-related myocarditis and consequent hospitalization in PICU were abnormal EKG findings and abnormal serum troponin levels at PER in this study.

Major cardiovascular events after COVID-19, event rates post-vaccination, antiviral or anti-inflammatory therapy, and temporal trends: Rationale and methodology of the CORONA-VTE-Network study. BACKGROUND: Coronavirus disease 2019 (COVID-19) is associated with excess risk of cardiovascular and thrombotic events in the early post-infection period and during convalescence. Despite the progress in our understanding of cardiovascular complications, uncertainty persists with respect to more recent event rates, temporal trends, association between vaccination status and outcomes, and findings within vulnerable subgroups such as older adults (aged 65Â years or older), or those undergoing hemodialysis. Sex-informed findings, including results among pregnant and breastfeeding women, as well as adjusted comparisons between male and female adults are similarly understudied. METHODS: Adult patients, aged â‰¥18Â years, with polymerase chain reaction-confirmed COVID-19 who received inpatient or outpatient care at the participating centers of the registry are eligible for inclusion. A total of 10,000 patients have been included in this multicenter study, with Brigham and Women's Hospital (Boston, MA) serving as the coordinating center. Other sites include Beth Israel Deaconess Medical Center, Anne Arundel Medical Center, University of Virginia Medical Center, University of Colorado Health System, and Thomas Jefferson University Health System. Data elements will be ascertained manually for accuracy. The two main outcomes are 1) a composite of venous or arterial thrombotic events, and 2) a composite of major cardiovascular events, defined as venous or arterial thrombosis, myocarditis or heart failure with inpatient treatment, new atrial fibrillation/flutter, or cardiovascular death. Clinical outcomes are adjudicated by independent physicians. Vaccination status and time of inclusion in the study will be ascertained for subgroup-specific analyses. Outcomes are pre-specified to be reported separately for hospitalized patients versus those who were initially receiving outpatient care. Outcomes will be reported at 30-day and 90-day follow-up. Data cleaning at the sites and the data coordinating center

and outcomes adjudication process are in-progress. CONCLUSIONS: The CORONA-VTE-Network study will share contemporary information related to rates of cardiovascular and thrombotic events in patients with COVID-19 overall, as well as within key subgroups, including by time of inclusion, vaccination status, patients undergoing hemodialysis, the elderly, and sex-informed analyses such as comparison of women and men, or among pregnant and breastfeeding women.

Immunological responses and adverse reactions of the heterologous second booster dose of BNT162b2 after two-dose CoronaVac for COVID-19 vaccination in healthcare workers of Faculty of Medicine, Naresuan University. BACKGROUND: The first COVID-19 vaccination campaign in Thailand began in April 2020, with healthcare workers receiving two doses of inactivated COVID-19 vaccine (CoronaVac). However, the emergence of the delta and omicron variants raised concerns about vaccine effectiveness. The Thai Ministry of Public Health provided the first booster dose (third dose) and second booster dose (fourth dose) of the mRNA vaccine (BNT162b2) for healthcare workers. This study investigated the immunity and adverse reactions elicited by a heterologous second booster dose of BNT162b2 after a two-dose CoronaVac vaccination for COVID-19 in healthcare workers of the Faculty of Medicine, Naresuan University. METHODS: IgG titres against the SARS-CoV-2-spike protein were measured four and 24Â weeks after the second booster dose of BNT162b2 in the study participants. Adverse reactions were recorded during the first three days, four weeks and 24Â weeks after the second booster dose of BNT162b2. RESULTS: IgG against the SARS-CoV-2-spike protein was positive (>10 U/ml) in 246 of 247 participants (99.6 %) at both four and 24Â weeks after the second booster dose of BNT162b2. The median specific IgG titres at four and 24Â weeks after the second booster dose of BNT162b2 were 299 U/ml (min: 2, max: 29,161) and 104 U/ml (min: 1, max: 17,920), respectively. The median IgG level declined significantly 24Â weeks after the second booster dose of the BNT162b2 vaccine. Of the 247 participants, 179 (72.5 %) experienced adverse reactions in the first three days after the second booster dose of BNT162b2. Myalgia, fever, headache, injection site pain and fatigue were the most common adverse reactions. CONCLUSION: This study demonstrated that a heterologous second booster dose of BNT162b2 after two doses of CoronaVac induced elevated IgG against the SARS-CoV-2-spike protein and caused minor adverse reactions in healthcare workers of the Faculty of Medicine, Naresuan University. This study was registered as Thailand Clinical Trials No. TCTR20221112001.

Bilateral Pulmonary Embolism and Impending Paradoxical Embolism After COVID-19 Vaccination.

Longitudinal data on humoral response and neutralizing antibodies against SARS-CoV-2 Omicron BA.1 and subvariants BA.4/5 and BQ.1.1 after COVID-19 vaccination in cancer patients. PURPOSE: The SARS-CoV-2 Omicron variant of concern (VOC) and subvariants like BQ.1.1 demonstrate immune evasive potential. Little is known about the efficacy of booster vaccinations regarding this VOC and subvariants in cancer patients. This study is among the first to provide data on neutralizing antibodies (nAb) against BQ.1.1. METHODS: Cancer patients at our center were prospectively enrolled between 01/2021 and 02/2022. Medical data and blood samples were collected at enrollment and before and after every SARS-CoV-2 vaccination, at 3 and 6Â months. RESULTS: We analyzed 408 samples from 148 patients (41% female), mainly with solid tumors (85%) on active therapy (92%; 80% chemotherapy). SARS-CoV-2 IgG and nAb titers decreased over time, however, significantly increased following third vaccination (pâ€‰<â€‰0.0001). NAb (ND(50)) against Omicron BA.1 was minimal prior and increased significantly after the third vaccination (pâ€‰<â€‰0.0001). ND(50) titers against BQ.1.1 after the third vaccination were significantly lower than against BA.1 and BA.4/5 (pâ€‰<â€‰0.0001) and undetectable in half of the patients (48%). Factors associated with impaired immune response were hematologic malignancies, B cell depleting therapy and higher age. Choice of vaccine, sex and treatment with chemo-/immunotherapy did not influence antibody response. Patients with breakthrough infections had significantly lower nAb titers after both 6Â months

(pâ€‰<â€‰0.001) and the third vaccination (pâ€‰=â€‰0.018). CONCLUSION: We present the first data on nAb against BQ.1.1 following the third vaccination in cancer patients. Our results highlight the threat that new emerging SARS-CoV-2 variants pose to cancer patients and support efforts to apply repeated vaccines. Since a considerable number of patients did not display an adequate immune response, continuing to exhibit caution remains reasonable.

Jerne's "immune network theory", of interacting anti-idiotypic antibodies applied to immune responses during COVID-19 infection and after COVID-19 vaccination. Niels Kaj Jerne has proposed the "immune network theory" of interactions among anti-idiotypic antibodies, able to interfere with humoral responses to certain antigens. After the occurrence of the primary generation of antibodies, against an antigenic epitope, idiotypes of these antibodies induce anti-idiotypic antibodies that modulate the intensity of the first response, and so on. Adverse effects following SARS-COV-2 COVID-19 vaccines are occasionally similar to the symptoms of COVID-19 infection. Rare events linked to SARS-CoV-2 vaccines also resemble some rarely reported COVID-19 complications. Safety data from product information by European Medicines Agency suggest that spectra do overlap for four main vaccines. The proposition is that vaccine events and COVID-19 complications are related to anti-idiotypic antibodies whose spatial shape can lead to interactions with ACE2 molecules, in individuals with a prolonged Spike protein synthesis. The vaccines target cells by their affinity to the vaccine vector, or to engulf lipid nanoparticles. Anti-idiotypic antibodies shaped similarly to the Spike protein possibly interact with ACE2 molecules and cause diverse signs and symptoms.

Frequency and Predictors of Relapses following SARS-CoV-2 Vaccination in Patients with Multiple Sclerosis: Interim Results from a Longitudinal Observational Study. Despite protection from severe COVID-19 courses through vaccinations, some people with multiple sclerosis (PwMS) are vaccination-hesitant due to fear of post-vaccination side effects/increased disease activity. The aim was to reveal the frequency and predictors of post-SARS-CoV-2-vaccination relapses in PwMS. This prospective, observational study was conducted as a longitudinal Germany-wide online survey (baseline survey and two follow-ups). Inclusion criteria were age â‰¥18 years, MS diagnosis, and â‰¥1 SARS-CoV-2 vaccination. Patient-reported data included socio-demographics, MS-related data, and post-vaccination phenomena. Annualized relapse rates (ARRs) of the study cohort and reference cohorts from the German MS Registry were compared pre- and post-vaccination. Post-vaccination relapses were reported by 9.3% PwMS (247/2661). The study cohort's post-vaccination ARR was 0.189 (95% CI: 0.167-0.213). The ARR of a matched unvaccinated reference group from 2020 was 0.147 (0.129-0.167). Another reference cohort of vaccinated PwMS showed no indication of increased post-vaccination relapse activity (0.116; 0.088-0.151) compared to pre-vaccination (0.109; 0.084-0.138). Predictors of post-vaccination relapses (study cohort) were missing immunotherapy (OR = 2.09; 1.55-2.79; $p < 0.001$) and shorter time from the last pre-vaccination relapse to the first vaccination (OR = 0.87; 0.83-0.91; $p < 0.001$). Data on disease activity of the study cohort in the temporal context are expected for the third follow-up.

[(18)F]FES PET Resolves the Diagnostic Dilemma of COVID-19-Vaccine-Associated Hypermetabolic Lymphadenopathy in ER-Positive Breast Cancer. Coronavirus disease (COVID-19) vaccination is known to cause a diagnostic dilemma due to false-positive findings on [(18)F]FDG PET in vaccine-associated hypermetabolic lymphadenopathy. We present two case reports of women with estrogen-receptor (ER)-positive cancer of the breast who were vaccinated for COVID-19 in the deltoid muscle. [(18)F]FDG positron emission tomography (PET) demonstrated primary breast cancer and multiple axillary lymph nodes with increased [(18)F]FDG uptake, diagnosed as vaccine-associated [(18)F]FDG-avid lymph nodes. Subsequent [(18)F]FES PET revealed single axillary lymph node metastasis in the vaccine-associated [(18)F]FDG-avid lymph nodes. To the best of our knowledge, this is the first study showing the usefulness of [(18)F]FES PET in diagnosing axillary lymph node metastasis in COVID-19-

vaccinated patients harboring ER-positive breast cancer. Thus, [(18)F]FES PET has potential applications in the detection of true-positive metastatic lymph nodes in patients with ER-positive breast cancer regardless of the ipsilateral or contralateral side, who have received COVID-19 vaccination.

Changes in Psychotropic Drug Blood Levels After SARS-CoV-2 Vaccination: A Two-Center Cohort Study. BACKGROUND: Limited evidence from case reports suggests that coronavirus disease 2019 (COVID-19) vaccination may interact with the treatment outcomes of psychiatric medications. Apart from clozapine, reports on the effect of COVID-19 vaccination on other psychotropic agents are scarce. This study aimed to investigate the impact of COVID-19 vaccination on the plasma levels of different psychotropic drugs using therapeutic drug monitoring. METHODS: Plasma levels of psychotropic agents, including agomelatine, amisulpride, amitriptyline, escitalopram, fluoxetine, lamotrigine, mirtazapine, olanzapine, quetiapine, sertraline, trazodone, and venlafaxine, from inpatients with a broad spectrum of psychiatric diseases receiving COVID-19 vaccinations were collected at 2 medical centers between 08/2021 and 02/2022 under steady-state conditions before and after vaccination. Postvaccination changes were estimated as a percentage of baseline. RESULTS: Data from 16 patients who received COVID-19 vaccination were included. The largest changes in plasma levels were reported for quetiapine (+101.2%) and trazodone (-38.5%) in 1 and 3 patients, respectively, 1 day postvaccination compared with baseline levels. One week postvaccination, the plasma levels of fluoxetine (active moiety) and escitalopram increased by 31% and 24.9%, respectively. CONCLUSIONS: This study provides the first evidence of major changes in the plasma levels of escitalopram, fluoxetine, trazodone, and quetiapine after COVID-19 vaccination. When planning COVID-19 vaccination for patients treated with these medications, clinicians should monitor rapid changes in bioavailability and consider short-term dose adjustments to ensure safety.

Factors associated with receipt of mRNA-1273 vaccine at a United States national retail pharmacy during the COVID-19 pandemic. INTRODUCTION: The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) prompted accelerated vaccine development of novel messenger RNA (mRNA)-based vaccines by Moderna and Pfizer, which received FDA Emergency Use Authorization in December 2020. The purpose of this study was to examine trends in primary series administration and multi-dose completion rates with Moderna's mRNA-1273 vaccine administered at a United States retail pharmacy. METHODS: Walgreens pharmacy data were joined to publicly available data sets to examine trends in mRNA-1273 primary series and multi-dose completion across patient race/ethnicity, age, gender, distance to first vaccination, and community characteristics. Eligible patients received their first dose of mRNA-1273 administered by Walgreens between December 18, 2020 and February 28, 2022. Variables significantly associated with on-time second dose (all patients) and third dose (immunocompromised patients) in univariate analyses were included in linear regression models. A subset of patients in selected states were studied to identify differences in early and late vaccine adoption. RESULTS: Patients (NÂ =Â 4,870,915) who receivedÂ â‰¥Â 1 dose of mRNA-1273 were 57.0% White, 52.6% female, and averaged 49.4Â years old. Approximately 85% of patients received a second dose during the study period. Factors associated with on-time second dose administration included older age, race/ethnicity, travelingÂ â‰¤Â 10 miles for the first dose, higher community-level health insurance, and residing in areas with low social vulnerability. Only 51.0% of immunocompromised patients received the third dose as recommended. Factors associated with third dose administration included older age, race/ethnicity, and small-town residence. Early adopters accounted for 60.6% of patients. Factors associated with early adoption included older age, race/ethnicity, and metropolitan residence. CONCLUSION: Over 80% of patients received their on-time second dose of mRNA-1273 vaccine per CDC recommendations. Patient demographics and community characteristics were associated with

vaccine receipt and series completion. Novel approaches to facilitate series completion during a pandemic should be further studied.

Comment on: Acute Myocarditis and Pericarditis After mRNA COVID-19 Vaccinations: A Single-Centre Retrospective Analysis. We have thoroughly reviewed the research conducted by Marina et al., titled "Acute Myocarditis and Pericarditis After mRNA COVID-19 Vaccinationsâ€"A Single-Centre Retrospective Analysis" [1]. We commend the authors for their diligent work in presenting a concise and informative report. While we agree with the overall findings of the study, which indicate a moderate risk of myopericarditis following mRNA COVID-19 vaccinations, particularly among young males, we would like to draw attention to several areas where the conclusion could have been strengthened. Firstly, it is crucial to acknowledge that retrospective studies possess inherent limitations such as recollection bias and potential inaccuracies in patient documentation. These issues could have been mitigated by including actual cases from the relevant period. Additionally, conducting the study across multiple hospitals or utilizing national databases would have helped address any bias arising from distinct socioeconomic, health, and environmental factors [2].

Updated guidance regarding the risk of allergic reactions to COVID-19 vaccines and recommended evaluation and management: AÂ GRADE assessment and international consensus approach. This guidance updates 2021 GRADE (Grading of Recommendations Assessment, Development and Evaluation) recommendations regarding immediate allergic reactions following coronavirus disease 2019 (COVID-19) vaccines and addresses revaccinating individuals with first-dose allergic reactions and allergy testing to determine revaccination outcomes. Recent meta-analyses assessed the incidence of severe allergic reactions to initial COVID-19 vaccination, risk of mRNA-COVID-19 revaccination after an initial reaction, and diagnostic accuracy of COVID-19 vaccine and vaccine excipient testing in predicting reactions. GRADE methods informed rating the certainty of evidence and strength of recommendations. AÂ modified Delphi panel consisting of experts in allergy, anaphylaxis, vaccinology, infectious diseases, emergency medicine, and primary care from Australia, Canada, Europe, Japan, South Africa, the United Kingdom, and the United States formed the recommendations. We recommend vaccination for persons without COVID-19 vaccine excipient allergy and revaccination after a prior immediate allergic reaction. We suggest against >15-minute postvaccination observation. We recommend against mRNA vaccine or excipient skin testing to predict outcomes. We suggest revaccination of persons with an immediate allergic reaction to the mRNA vaccine or excipients be performed by a person with vaccine allergy expertise in a properly equipped setting. We suggest against premedication, split-dosing, or special precautions because of a comorbid allergic history.

Incidence and clinical characteristics of adverse neurological events and stroke-like syndrome associated with immune stress-related response after COVID-19 vaccination in 2021 from Thailand. OBJECTIVES: AEFIs (adverse events following immunizations), especially ISRR (immune stress related response) which can cause stroke-like symptoms may affect the vaccine roll-out campaign to prevent the coronavirus 2019 outbreak. METHODS: This study aimed to describe the incidence and clinical characteristics of neurological AEFIs and stroke-like symptoms associated with ISRR after COVID-19 vaccination. Characteristics of ISRR were compared to minor ischemic stroke patients during the same period of the study. During March to September 2021, we retrospectively collected data of participants aged â‰¥Â 18 years who received COVID-19 vaccine and developed AEFIs from Thammasat university vaccination center (TUVC). Data of neurological AEFIs patients and minor ischemic stroke patients were collected from hospital electronic medical record system. RESULTS: COVID-19 vaccine were administered at TUVC for 245,799 doses. AEFIs were reported in 129,652 instances (52.6%). ChADOx-1 nCoV-19 viral vector vaccine has the most frequent occurrence of AEFIs (58.0%), and neurological AEFIs (12.6%). 83% of neurological AEFI was headache. Most were mild and

did not need medical attention. Of 119 patients who received COVID-19 vaccine from anywhere with neurological AEFIs and presented to TUH, ISRR was diagnosed in 107 patients (89.9%) and all patients who has follow-up data (30.8%) showed clinical improvement. In comparison with minor ischemic stroke (116 patients), ISRR patients had significantly less ataxia, facial weakness, weakness of arm/leg and speech disturbances (PÂ <Â 0.001). CONCLUSION: The incidence of neurological AEFIs after COVID-19 vaccination was higher among recipients of ChAdOx-1 nCoV-19 vaccine (12.6%) than inactivated vaccine (6.2%) and mRNA vaccine (7.5%). However, most neurological AEFIs were ISRR, had mild severity and resolved within 30 days. Stroke-like symptoms occurred less frequently than patients with minor ischemic stroke.

COVID-19-induced Esophageal Necrosis Requiring Emergent Total Esophagectomy in a Vaccinated Patient. Acute esophageal necrosis may be a potential complication of Coronavirus Disease 2019 (COVID-19). COVID-19 has been associated with a variety of sequelae, including acute respiratory distress syndrome, myocarditis, and thromboembolic events. Here, we present a case of a 43-year-old male who was admitted for acute necrotizing pancreatitis and found to have COVID-19 pneumonia. He subsequently developed acute esophageal necrosis requiring a total esophagectomy. Currently, there are at least five other reported cases of esophageal necrosis with concomitant COVID-19 infection. This case is the first requiring esophagectomy. Future studies may establish esophageal necrosis as a known complication of COVID-19.

Isolated thoracic aortitis following mRNA vaccination against SARS-CoV-2.

Longitudinal Assessment of Left Ventricular Function in Patients with Myopericarditis After mRNA COVID-19 Vaccination. BACKGROUND: Multiple reports have described myopericarditis following mRNA COVID-19 vaccination. However, data on the persistence of subclinical myocardial injury assessed by left ventricular (LV) longitudinal strain (LVLS) is limited. OBJECTIVES: Our aim was to assess LV function longitudinally in our cohort of COVID-19 vaccine-related myopericarditis using ejection fraction (EF), fractional shortening (FS), LVLS, and diastolic parameters. METHODS: Retrospective, single-center review of demographic, laboratory, and management data was performed on 20 patients meeting diagnostic criteria for myopericarditis after mRNA COVID-19 vaccination. Echocardiographic images were obtained on initial presentation (time 0), at a median of 12 days (7.5, 18.5; time 1), and at a median of 44 days (29.5, 83.5; time 2). FS was calculated by M-mode, EF by 5/6 area-length methods, LVLS by utilization of TOMTEC software, and diastolic function by tissue Doppler. All parameters were compared across pairs of these time points using Wilcoxon signed-rank test. RESULTS: Our cohort consisted predominantly of adolescent males (85%) with mild presentation of myopericarditis. The median EF was 61.6% (54.6, 68.0), 63.8% (60.7, 68.3), 61.4% (60.1, 64.6) at times 0, 1, and 2, respectively. Upon initial presentation, 47% of our cohort had LVLS < -18%. The median LVLS was -18.6% (-16.9, -21.0) at time 0, -21.2% at time 1 (-19.4, -23.5) (pâ€‰=â€‰0.004) and -20.8% (-18.7, -21.7) at time 2 (pâ€‰=â€‰0.004, as compared to time 0). CONCLUSIONS: Though many of our patients had abnormal strain during acute illness, LVLS improved longitudinally, indicating myocardial recovery. LVLS can be used as marker of subclinical myocardial injury and risk stratification in this population.

Patterns of adverse drug reactions in Jordan: a retrospective analysis of the National Pharmacovigilance Data Registry (2015-2021). BACKGROUND: Post-marketing surveillance of drugs is a cornerstone of pharmacovigilance. This study was conducted to characterize patterns of adverse drug reactions (ADRs) reported in Jordan. RESEARCH DESIGN AND METHODS: ADR reports submitted to the pharmacovigilance database of the Jordan Food and Drug Administration during 2015-2021 were retrospectively analyzed. The most commonly reported drugs, drug classes, ADRs, and ADRs consequences were explored. Logistic regression identified possible predictors of reporting serious ADRs. RESULTS: A total of 2744 ADR reports were included, among which 28.4% were

classified as serious. An annual increase in ADR reporting was observed. The most commonly implicated drug classes were antineoplastic and immunomodulating agents (24.0%), anti-infectives for systemic use (14.2%), and alimentary tract and metabolism (12.1%). Covid-19 vaccination was the most reported drug (22.8%). Fatigue (6.3%), injection site pain (6.1%), and headache (6.0%) were the top three common ADRs. Among ADRs with outcome information, 4.7% were fatal. Patient's age and intravenous medication use largely predicted reporting serious ADRs. CONCLUSIONS: This study provides contemporary insights into the post-marketing surveillance of drugs in Jordan. The findings are foundational for future studies exploring drug-ADRs causality relationships. Efforts that promote pharmacovigilance concepts should be sustained and enhanced at the national level.

Willingness to receive a COVID-19 booster vaccine and its associated factors among adults with chronic disease: A cross-sectional study in Putrajaya, Malaysia. INTRODUCTION: Booster vaccination has been shown to reduce transmission and serious infection with COVID-19. This study examined the willingness to receive a COVID-19 booster vaccine and its associated factors among high-risk patients at Klinik Kesihatan Putrajaya Presint 9. METHOD: A cross-sectional study was conducted among patients aged >18 years attending Klinik Kesihatan Putrajaya Presint 9 with a high risk of contracting COVID-19 recruited via systematic random sampling. Data were collected using a self-administered questionnaire. A multiple logistic regression analysis was performed to identify the associated factors. RESULTS: The response rate for this study was 97.4% (N=489). The median patient age was 55 years. Approximately 51.7% were men, and 90.4% were Malays. Approximately 81.2% were willing to receive a COVID-19 booster vaccine. The patients who perceived COVID-19 as a serious illness (Adjusted Odd Ratio, AOR=2.414), those who perceived COVID-19 booster vaccines as beneficial (AOR=7.796), those who disagreed that COVID-19 booster vaccines have many side effects (AOR=3.266), those who had no doubt about the content of COVID-19 vaccines (AOR=2.649) and those who were employed (AOR=2.559) and retired (AOR=2.937) were more likely to be willing to receive a booster vaccine than those who were unemployed and those who did not have close friends or family members who contracted severe COVID-19 (AOR=2.006). CONCLUSION: The majority of the participants were willing to receive a COVID-19 booster vaccine. Healthcare authorities should take initiatives to design targeted public intervention programmes to increase the willingness for COVID-19 booster vaccination.

Correspondence on Vitreous Hemorrhage and Long-Lasting Priapism After COVID-19 vaccination.

"Effect of COVID-19 Vaccination on Menstrual Cycle Patterns of Reproductive-Age Women: A Multi-centric Observational Study.". AIM: The study was conducted to know the impact of COVID-19 vaccination on menstrual cycle patterns and pre- and post-menstrual symptoms in women aged 18-45 years. BACKGROUND: COVID-19 vaccination was introduced to combat the dreadful impacts of human coronavirus infection. The two indigenously developed COVID-19 vaccines approved for use in India are COVISHILED and COVAXIN. OBJECTIVES: To investigate the effects of COVID-19 vaccination on the menstrual cycle, pre- and post-menstrual symptoms and to establish the correlation with the type of vaccine received. METHODS: Multi-centric observational study conducted in six institutes of national importance in different states of India over one year. A total of 5709 female participants fulfilling inclusion criteria were enrolled. Data about the impact of vaccines (COVISHIELD and COVAXIN) and prior COVID-19 infection on the menstrual cycle and its associated symptoms were obtained using all participants' online and offline interviews. RESULTS: Of 5709 participants, 78.2% received COVISHIELD and 21.8% COVAXIN. Of the total 5709 participants, 333(5.8%) developed post-vaccination menstrual disturbances, with 32.7% having frequent cycles, 63.7% prolonged cycles, and 3.6% inter-menstrual bleeding. A total of 301 participants noticed changes in the amount of bleeding, with 50.2% excessive, 48.8% scanty, and 0.99% amenorrhea followed by heavy bleeding. Furthermore, the irregularities of the menstrual cycle (p=0.011) and length (0.001) were significantly

higher in the COVAXIN group (7.2%) as compared to the COVISHIELD (5.3%) group. A total of 721 participants complained of newly developed/worsening pre- and post-menstrual symptoms. These symptoms were significantly higher in the COVISHIELD group (p=0.031), with generalized weakness and body pains as the main complaints (p=0.001). No significant difference was observed in the incidence of COVID-19 infection with these vaccines. No significant associations were observed when comparing menstrual abnormalities among those with COVID-19 infection (p>0.05). CONCLUSIONS: COVISHILED and COVAXIN vaccines were associated with menstrual cycle disturbances and pre-and post-menstrual symptoms in a small proportion of participants, with 94.7% having no change in the amount of bleeding during menstruation post-vaccination. The menstrual irregularities observed were significantly higher with the COVAXIN vaccine. Others: Further, long-term studies are required to confirm that the impact of COVID-19 vaccination on the menstrual cycle may be short-lasting, with no severe effects on women's menstrual health.

Predictors of Gross Hematuria After SARS-CoV-2 mRNA Vaccination in Patients with IgA Nephropathy. KEY POINTS: Little is known about the clinical characteristics of patients with immunoglobulin A nephropathy (IgAN) who present with gross hematuria in relation to SARS-CoV-2 mRNA vaccination. The relationship between the clinical features in patients with IgAN at the time of SARS-CoV-2 mRNA vaccination and the subsequent appearance of gross hematuria was investigated. This study demonstrates the clinical significance of microscopic hematuria in patients with IgAN as a predictor of gross hematuria after SARS-CoV-2 mRNA vaccination. BACKGROUND: There have been several reports of immunoglobulin A nephropathy (IgAN) patients with gross hematuria and acute deterioration of urinary findings and kidney function after severe acute respiratory syndrome coronavirus 2 mRNA vaccination. Recent case series studies have indicated a possible link between the status of urinary findings at the time of vaccination and the subsequent appearance of gross hematuria. In this study, we aimed to determine whether the status of prevaccination urinary findings was associated with postvaccination gross hematuria in patients already diagnosed with IgAN. METHODS: Outpatients with IgAN who had been followed up before vaccination were included. We analyzed the association between the remission of prevaccination microscopic hematuria (urine sediment <5 red blood cells/high-power field) or proteinuria (<0.3 g/gCr) and postvaccination gross hematuria. RESULTS: A total of 417 Japanese patients with IgAN (median age, 51 years; 56% female; eGFR, 58 ml/min per 1.73 m(2)) were included. The frequency of gross hematuria after vaccination was higher in 20 of 123 patients (16.3%) with microscopic hematuria than in 5 of 294 patients (1.7%) without microscopic hematuria before vaccination (P < 0.001). There was no association between prevaccination proteinuria and postvaccination gross hematuria. After adjusting for potential confounders, such as sex (female), age (younger than 50 years), eGFR (â‰¥60 ml/min per 1.73 m(2)), and histories of tonsillectomy and corticosteroid therapy, prevaccination microscopic hematuria was still associated with postvaccination gross hematuria (odds ratio, 8.98; P < 0.001). As the severity of prevaccination microscopic hematuria increased, the incidence of postvaccination gross hematuria increased (P < 0.001). CONCLUSIONS: Prevaccination microscopic hematuria in patients with IgAN is a major predictor of postvaccination gross hematuria, regardless of potential confounders, including previous treatments of IgAN.

Impact of pandemics and disruptions to vaccination on infectious diseases epidemiology past and present. Infectious diseases are a leading cause of morbidity and mortality worldwide with vaccines playing a critical role in preventing deaths. To better understand the impact of low vaccination rates and previous epidemics on infectious disease rates, and how these may help to understand the potential impacts of the current coronavirus disease 2019 (COVID-19) pandemic, a targeted literature review was conducted. Globally, studies suggest past suboptimal vaccine coverage has contributed to infectious disease outbreaks in vulnerable populations. Disruptions caused by the

COVID-19 pandemic have contributed to a decline in vaccination uptake and a reduced incidence in several infectious diseases; however, these rates have increased following the lifting of COVID-19 restrictions with modeling studies suggesting a risk of increased morbidity and mortality from several vaccine-preventable diseases. This suggests a window of opportunity to review vaccination and infectious disease control measures before we see further disease resurgence in populations and age-groups currently unaffected.

Post-acute COVID-19 in three doses vaccinated autoimmune rheumatic diseases patients: frequency and pattern of this condition. BACKGROUND: Data on post-acute COVID-19 in autoimmune rheumatic diseases (ARD) are scarce, focusing on a single disease, with variable definitions of this condition and time of vaccination. The aim of this study was to evaluate the frequency and pattern of post-acute COVID-19 in vaccinated patients with ARD using established diagnosis criteria. METHODS: Retrospective evaluation of a prospective cohort of 108 ARD patients and 32 non-ARD controls, diagnosed with SARS-CoV-2 infection (RT-PCR/antigen test) after the third dose of the CoronaVac vaccine. Post-acute COVID-19 (â‰¥â€‰4Â weeks and >â€‰12Â weeks of SARS-CoV-2 symptoms) were registered according to the established international criteria. RESULTS: ARD patients and non-ARD controls, balanced for age and sex, had high and comparable frequencies of â‰¥â€‰4Â weeks post-acute COVID-19 (58.3% vs. 53.1%, pâ€‰=â€‰0.6854) and >â€‰12Â weeks post-acute COVID-19 (39.8% vs. 46.9%, pâ€‰=â€‰0.5419). Regarding â‰¥â€‰4Â weeks post-acute COVID-19, frequencies of â‰¥â€‰3 symptoms were similar in ARD and non-ARD controls (54% vs. 41.2%, pâ€‰=â€‰0.7886), and this was also similar in >â€‰12Â weeks post-acute COVID-19 (68.3% vs. 88.2%, pâ€‰=â€‰0.1322). Further analysis of the risk factors for â‰¥â€‰4Â weeks post-acute COVID-19 in ARD patients revealed that age, sex, clinical severity of COVID-19, reinfection, and autoimmune diseases were not associated with this condition (pâ€‰>â€‰0.05). The clinical manifestations of post-acute COVID-19 were similar in both groups (pâ€‰>â€‰0.05), with fatigue and memory loss being the most frequent manifestations. CONCLUSION: We provide novel data demonstrating that immune/inflammatory ARD disturbances after third dose vaccination do not seem to be a major determinant of post-acute COVID-19 since its pattern is very similar to that of the general population. Clinical Trials platform (NCT04754698).

Predominantly defective CD8(+) T cell immunity to SARS-CoV-2 mRNA vaccination in lung transplant recipients. BACKGROUND: Although mRNA vaccines have overall efficacy preventing morbidity/mortality from SARS-CoV-2 infection, immunocompromised persons remain at risk. Antibodies mostly prevent early symptomatic infection, but cellular immunity, particularly the virus-specific CD8(+) T cell response, is protective against disease. Defects in T cell responses to vaccination have not been well characterized in immunocompromised hosts; persons with lung transplantation are particularly vulnerable to vaccine failure with severe illness. METHODS: Comparison groups included persons with lung transplantation and no history of COVID-19 (21 and 19 persons after initial mRNA vaccination and a third booster vaccination respectively), 8 lung transplantation participants recovered from COVID-19, and 22 non-immunocompromised healthy control individuals after initial mRNA vaccination (without history of COVID-19). Anti-spike T cell responses were assayed by stimulating peripheral blood mononuclear cells (PBMCs) with pooled small overlapping peptides spanning the SARS-CoV-2 spike protein, followed by intracellular cytokine staining (ICS) and flow cytometry for release of cytokines in response to stimulation, including negative controls (no peptide stimulation) and positive controls (phorbol myristate acetate [PMA] and ionomycin stimulation). To evaluate for low frequency memory responses, PBMCs were cultured in the presence of the mRNA-1273 vaccine for 14Â days before this evaluation. RESULTS: Ionophore stimulation of PBMCs revealed a less inflammatory milieu in terms of interleukin (IL)-2, IL-4, and IL-10 profiling in lung transplantation individuals, reflecting the effect of immunosuppressive treatments. Similar to what

we previously reported in healthy vaccinees, spike-specific responses in lung transplantation recipients were undetectable (<â€‰0.01%) when tested 2Â weeks after vaccination or later, but were detectable after in vitro culture of PBMCs with mRNA-1273 vaccine to enrich memory T cell responses. This was also seen in COVID-19-recovered lung transplantation recipients. Comparison of theirÂ enriched memory responses to controls revealed relatively similar CD4(+) T cell memory, but markedly reduced CD8(+) T cell memory both after primary vaccination or a booster dose. These responses were not correlated to age or time after transplantation. The vaccine-induced CD4(+) and CD8(+) responses correlated well in the healthy control group, but poorly in the transplantation groups. CONCLUSIONS: These results reveal a specific defect in CD8(+) T cells, which have key roles both in transplanted organ rejection but also antiviral effector responses. Overcoming this defect will require strategies to enhance vaccine immunogenicity in immunocompromised persons.

Morphologic and molecular analysis of liver injury after SARS-CoV-2 vaccination reveals distinct characteristics. BACKGROUND & AIMS: Liver injury after COVID-19 vaccination is very rare and shows clinical and histomorphological similarities with autoimmune hepatitis (AIH). Little is known about the pathophysiology of COVID-19 vaccine-induced liver injury (VILI) and its relationship to AIH. Therefore, we compared VILI with AIH. METHODS: Formalin-fixed and paraffin-embedded liver biopsy samples from patients with VILI (nÂ = 6) and from patients with an initial diagnosis of AIH (nÂ = 9) were included. Both cohorts were compared by histomorphological evaluation, whole-transcriptome and spatial transcriptome sequencing, multiplex immunofluorescence, and immune repertoire sequencing. RESULTS: Histomorphology was similar in both cohorts but showed more pronounced centrilobular necrosis in VILI. Gene expression profiling showed that mitochondrial metabolism and oxidative stress-related pathways were more and interferon response pathways were less enriched in VILI. Multiplex analysis revealed that inflammation in VILI was dominated by CD8(+) effector T cells, similar to drug-induced autoimmune-like hepatitis. In contrast, AIH showed a dominance of CD4(+) effector T cells and CD79a(+) B and plasma cells. T-cell receptor (TCR) and B-cell receptor sequencing showed that T and B cell clones were more dominant in VILI than in AIH. In addition, many T cell clones detected in the liver were also found in the blood. Interestingly, analysis of TCR beta chain and Ig heavy chain variable-joining gene usage further showed that TRBV6-1, TRBV5-1, TRBV7-6, and IgHV1-24 genes are used differently in VILI than in AIH. CONCLUSIONS: Our analyses support that SARS-CoV-2 VILI is related to AIH but also shows distinct differences from AIH in histomorphology, pathway activation, cellular immune infiltrates, and TCR usage. Therefore, VILI may be a separate entity, which is distinct from AIH and more closely related to drug-induced autoimmune-like hepatitis. IMPACT AND IMPLICATIONS: Little is known about the pathophysiology of COVID-19 vaccine-induced liver injury (VILI). Our analysis shows that COVID-19 VILI shares some similarities with autoimmune hepatitis, but also has distinct differences such as increased activation of metabolic pathways, a more prominent CD8+ T cell infiltrate, and an oligoclonal T and B cell response. Our findings suggest that VILI is a distinct disease entity. Therefore, there is a good chance that many patients with COVID-19 VILI will recover completely and will not develop long-term autoimmune hepatitis.

Fulminant myocarditis following SARS-CoV-2 mRNA vaccination.

Skin Diseases Associated With COVID-19: A Narrative Review. COVID-19 is an infectious disease caused by SARS-CoV-2, which emerged in China in 2019 and rapidly spread worldwide to become a pandemic in March 2020. Although the most severe manifestations concern the lower respiratory tract, COVID-19 is a multiorgan disease that also affects the skin. Several types of skin lesions have been reported to be associated with SARS-CoV-2 infection, though their causal relationship with the virus has not yet been well documented. In addition to the cutaneous manifestations that develop in patients with COVID-19-thought to be caused by the virus-other findings associated with the

pandemic in a broader sense include dermatoses triggered or aggravated by the infection, the adverse cutaneous effects due to the drugs and protective devices used to prevent or fight the infection, and the adverse cutaneous effects of COVID-19 vaccines. We provide an overview of these dermatoses associated with the COVID-19 pandemic.

Sudden Sensorineural Hearing Loss Following Immunization With BNT162b2 or mRNA-1273: A Danish Population-Based Cohort Study. OBJECTIVE: To compare the occurrence of sudden sensorineural hearing loss following immunization with BNT162b2 (ComirnatyÂ®; Pfizer BioNTech) or mRNA-1273 (SpikevaxÂ®; Moderna) to the occurrence among unvaccinated individuals. STUDY DESIGN: Cohort study. SETTING: Nationwide Danish health care registers comprised all Danish residents living in Denmark on October 1, 2020, who were 18 years or older or turned 18 in 2021. METHODS: We compared the occurrence of sudden sensorineural hearing loss following immunization with BNT162b2 (ComirnatyÂ®; Pfizer BioNTech) or mRNA-1273 (SpikevaxÂ®; Moderna) (first, second, or third dose) against unvaccinated person time. Secondary outcomes were a first-ever hospital diagnosis of vestibular neuritis and a hearing examination, by an ear-nose-throat (ENT) specialist, followed by a prescription of moderate to high-dose prednisolone. RESULTS: BNT162b2 or mRNA-1273 vaccine was not associated with an increased risk of receiving a discharge diagnosis of sudden sensorineural hearing loss (adjusted hazard ratio [HR]: 0.99, confidence interval [CI]: 0.59-1.64) or vestibular neuritis (adjusted HR: 0.94, CI: 0.69-1.24). We found a slightly increased risk (adjusted HR: 1.40,Â CI, 1.08-1.81) of initiating moderate to high-dose oral prednisolone following a visit to an ENT specialist within 21 days from receiving a messenger RNA (mRNA)-based Covid-19 vaccine. CONCLUSION: Our findings do not suggest an increased risk of sudden sensorineural hearing loss or vestibular neuritis following mRNA-based COVID-19 vaccination. mRNA-Covid-19 vaccination may be associated with a small excess risk of a visit to an ENT specialist visit followed by a prescription of moderate to high doses of prednisolone.

Scleromyxedema in an adult following Sinopharm BBIBP-CorV vaccination: An extremely rare phenomenon. INTRODUCTION: The Sinopharm BBIBP-CorV vaccine produces a variety of cutaneous adverse effects. Scleromyxedema is a mucinous connective tissue disorder that causes skin thickness and sclerodermoid changes. According to our findings, this is the first case of scleromyxedema induced by the Sinopharm immunization. CASE DESCRIPTION: We discuss the case of a 75-year-old woman who acquired progressive thickening of the skin in her limbs and trunk after getting the Sinopharm vaccination. Examination, laboratory testing, and a biopsy were used to verify scleromyxedema diagnosis. Intravenous immunoglobulins, mycophenolate mofetil, and prednisolone were used in the treatment of the patient. The outcomes from the 4-month follow-up were reassuring. CONCLUSION: This study emphasizes the need of considering scleromyxedema as a connective tissue pathology in patients who have recently received Sinopharm vaccine and have similar cutaneous signs.

Investigating the association between the COVID-19 vaccination and incident gastrointestinal symptomology: A comprehensive dataset. The coronavirus disease of 2019 (COVID-19) pandemic created a variety of symptoms from mild to acute in the general population. Additional disease burden was experienced in high-risk populations, such as older adults, people with disabilities or overweight, those from racial and ethnic minority groups, and patients with cancer, chronic kidney, lung or liver disease, or diabetes. Although it is well-known that SARS-CoV-2 mostly affects the respiratory tract, studies have revealed the presence of gastrointestinal (GI) symptoms in those patients diagnosed with COVID-19. The best protection against infection is through receipt of the COVID-19 vaccine, which is associated with a low incidence of adverse events. However, there is limited research on the lesser-known side effects experienced following receipt of the COVID-19 vaccination, amongst healthy and special needs populations. This study investigated the association

between the COVID-19 vaccination and, when it occurred, infection, and resulting gastrointestinal (GI) symptomology, focusing on both the general population and on those previously diagnosed with GI disorders, Irritable Bowel Syndrome (IBS) and Inflammatory Bowel Disease (IBD). Through a short, anonymous survey, 215 participants were assessed for acute onset of GI issues and/or worsening of pre-existing GI issues following the receipt of one or more COVID-19 vaccine doses and following contraction of COVID-19 itself, when applicable. All analyses were performed using SAS version 9.4, and prior to study initiation, the study protocol was reviewed and approved as exempt by the Stamford Hospital's Institutional Review Board of record. Data analysis included reporting of demographic variables as well as descriptive statistics regarding side effects experienced after receipt of the COVID-19 vaccine, as well as after contracting COVID-19, if it occurred. To assess for statistically significant differences between the groups, ANOVA was conducted for each survey item. Reporting of results consisted of the mean and standard deviation within each of the groups, and an omnibus p-value less than 0.05 ($p < 0.05$) was considered statistically significant. For the purposes of this report, a greater than 0.50 response difference between highest and lowest mean value will be presented. In the event of a statistically significant omnibus p-value, the Scheffe test was used as the post-hoc procedure. The database created through this research demonstrates the prevalence of post-COVID-19 vaccination side effects and can serve as preliminary data for gaining a better understanding of how both general and populations with a higher disease burden are being affected by the COVID-19 vaccine, booster doses, and incident COVID-19 infection in vaccinated individuals.

Association of systemic adverse reaction patterns with long-term dynamics of humoral and cellular immunity after coronavirus disease 2019 third vaccination. The objective of this study was to clarify the impact of adverse reactions on immune dynamics. We investigated the pattern of systemic adverse reactions after the second and third coronavirus disease 2019 (COVID-19) vaccinations and their relationship with immunoglobulin G against severe acute respiratory syndrome coronavirus 2 spike 1 protein titers, neutralizing antibody levels, peak cellular responses, and the rate of decrease after the third vaccination in a large-scale community-based cohort in Japan. Participants who received a third vaccination with BNT162b2 (Pfizer/BioNTech) or mRNA-1273 (Moderna), had two blood samples, had not had COVID-19, and had information on adverse reactions after the second and third vaccinations (nâ€‰=â€‰2198) were enrolled. We collected data on sex, age, adverse reactions, comorbidities, and daily medicine using a questionnaire survey. Participants with many systemic adverse reactions after the second and third vaccinations had significantly higher humoral and cellular immunity in the peak phase. Participants with multiple systemic adverse reactions after the third vaccination had small changes in the geometric values of humoral immunity and had the largest geometric mean of cellar immunity in the decay phase. Systemic adverse reactions after the third vaccination helped achieve high peak values and maintain humoral and cellular immunity. This information may help promote uptake of a third vaccination, even among those who hesitate due to adverse reactions.

Association between vaccination status and severe health consequences among community-dwelling COVID-19 patients during Omicron BA.1/BA.2 and BA.5-predominant periods in Japan. BACKGROUND: Many previous studies have reported that COVID-19 vaccine effectiveness decreased over time and declined with newly emerging variants. However, there are few such studies in Japan. Using data from a community-based retrospective study, we aimed to assess the association between vaccination status and severe COVID-19 outcomes caused by the Omicron variant, considering the length of time since the last vaccination dose. METHODS: We included all persons aged â‰¥12 diagnosed with COVID-19 by a doctor and notified to the Chuwa Public Health Center of Nara Prefectural Government during the Omicron BA.1/BA.2 and BA.5-predominant periods in Japan (January 1 to September 25, 2022). The outcome variable was severe health consequences (SHC) (i.e.,

COVID-19-related hospitalization or death). The explanatory variable was vaccination status of the individuals (i.e., the number of vaccinations and length of time since last dose). Covariates included gender, age, risk factors for aggravation, and the number of hospital beds per population. Using the generalized estimating equations of the multivariable Poisson regression models, we estimated the cumulative incidence ratio (CIR) and 95% confidence interval (CI) for SHC, with stratified analyses by period (BA.1/BA.2 or BA.5) and age (65 and older or 12-64 years). RESULTS: Of the 69,827 participants, 2,224 (3.2%) had SHC, 12,154 (17.4%) were unvaccinated, and 29,032 (41.6%) received â‰¥3 vaccine doses. Regardless of period or age, there was a significant dose-response relationship in which adjusted CIR for SHC decreased with an increased number of vaccinations and a longer time since the last vaccination. On the one hand, in the BA.5 period, those with â‰¥175 days after the third dose had no significant difference in people aged 65 and older (CIR 0.77; 95% CI, 0.53-1.12), but significantly lower CIR for SHC in people aged 12-64 (CIR 0.47; 95% CI, 0.26-0.84), compared with those with â‰¥14 days after the second dose. CONCLUSION: A higher number of vaccinations were associated with lower risk of SHC against both BA.1/BA.2 and BA.5 sublineages. Our findings suggest that increasing the number of doses of COVID-19 vaccine can prevent severe COVID-19 outcomes, and that a biannual vaccination is recommended for older people.

Comparison of the first and sixth waves of the SARS-COV-2 coronavirus pandemic in patients with immune-mediated disease. INTRODUCTION: Recent evidence shows that COVID-19 infection does not have a worse prognosis in patients with immune-mediated inflammatory diseases (IMID), although they develop a worse response to vaccination. OBJECTIVE: To compare the incidence of COVID-19 and clinical features in patients with IMID between the first and sixth waves. METHOD: Prospective observational study of two cohorts of IMID patients diagnosed with COVID-19. First cohort March to May 2020, and second cohort December/2021 to February/2022. Sociodemographic and clinical variables were collected and, in the second cohort, COVID-19 vaccination status. Statistical analysis established differences in characteristics and clinical course between the two cohorts. RESULTS: In total, 1627 patients were followed up, of whom 77 (4.60%) contracted COVID-19 during the first wave and 184 in the sixth wave (11.3%). In the sixth wave, there were fewer hospitalisations, intensive care unit admissions, and deaths than in the first wave (p=.000) and 180 patients (97.8%) had at least one dose of vaccine. CONCLUSION: Early detection and vaccination have prevented the occurrence of serious complications.

Spontaneously reported adverse events following COVID-19 basic and booster immunizations in the Netherlands. INTRODUCTION: The rapid roll-out of novel COVID-19 vaccines made near real-time post-marketing safety surveillance essential to identify rare and long-term adverse events following immunization (AEFIs). In light of the ongoing booster vaccination campaigns, it is key to monitor changes in observed safety patterns post-vaccination. The effect of sequential COVID-19 vaccinations, as well as heterologous vaccination sequences, on the observed post-vaccination safety pattern, remains largely unknown. METHODS: The primary objective of this study was to describe the profile of spontaneously reported AEFIs following COVID-19 vaccination in the Netherlands, including the primary and booster series. Reports from consumers and healthcare professionals were collected via a COVID-19 vaccine-tailored online reporting form by the National Pharmacovigilance Centre Lareb (Lareb) between 6 January 2021 and 31 August 2022. The data were used to describe the most frequently reported AEFIs per vaccination moment, the consumer experienced burden per AEFI, and differences in AEFIs reported for homologous and heterologous vaccination sequences. RESULTS: Lareb received 227,884 spontaneous reports over a period of twenty months. Overall, a high degree of similarity in local and systemic AEFIs per vaccination moment was observed, with no apparent change in the number of reports of serious adverse events after multiple COVID-19 vaccinations. No differences in the pattern of reported AEFIs per vaccination sequence was observed. CONCLUSION:

Spontaneous reported AEFIs demonstrated a similar reporting pattern for homologous and heterologous primary and booster series of COVID-19 vaccination in the Netherlands.
Symmetrical Drug-Related Intertriginous Flexural Exanthema Induced by the Pfizer/BioNTech Comirnaty COVID-19 Vaccine.
Vaccine-Induced Immune Thrombotic Thrombocytopenia Two Years Later: Should It Still Be on the Scientific Agenda? Vaccine-induced immune thrombotic thrombocytopenia (VITT) was recognized around 2 years ago, at the beginning of the anti-SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) vaccination campaign, as a rare but life-threatening complication of adenoviral vector vaccines. Two years later, the coronavirus disease 2019 (COVID-19) pandemic has been tamed, although not defeated, and the vaccines provoking VITT have been abandoned in most high-income countries, thus why should we still speak about VITT? Because a significant fraction of the world population has not been vaccinated yet, especially in low/middle-income countries that can only afford adenoviral vector-based vaccines, because the adenoviral vector platform is being used for the development of a large series of new vaccines for other transmissible diseases, and lastly because there are some clues suggesting that VITT may not be exclusive to anti-SARS-CoV-2 vaccines. Therefore, a deep understanding of this new syndrome is highly warranted as well as the awareness that we still miss some crucial insight into its pathophysiology and on some aspects of its management. This snapshot review aims to portray our knowledge on VITT, focusing on its clinical presentation, pathophysiological insight, diagnostic and management strategies, and to pinpoint the main unmet needs, highlighting the aspects on which research should focus in the near future.
Risk of myocarditis and pericarditis after a COVID-19 mRNA vaccine booster and after COVID-19 in those with and without prior SARS-CoV-2 infection: A self-controlled case series analysis in England. BACKGROUND: An increased risk of myocarditis or pericarditis after priming with mRNA Coronavirus Disease 2019 (COVID-19) vaccines has been shown but information on the risk post-booster is limited. With the now high prevalence of prior Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection, we assessed the effect of prior infection on the vaccine risk and the risk from COVID-19 reinfection. METHODS AND FINDINGS: We conducted a self-controlled case series analysis of hospital admissions for myocarditis or pericarditis in England between 22 February 2021 and 6 February 2022 in the 50 million individuals eligible to receive the adenovirus-vectored vaccine (ChAdOx1-S) for priming or an mRNA vaccine (BNT162b2 or mRNA-1273) for priming or boosting. Myocarditis and pericarditis admissions were extracted from the Secondary Uses Service (SUS) database in England and vaccination histories from the National Immunisation Management System (NIMS); prior infections were obtained from the UK Health Security Agency's Second-Generation Surveillance Systems. The relative incidence (RI) of admission within 0 to 6 and 7 to 14 days of vaccination compared with periods outside these risk windows stratified by age, dose, and prior SARS-CoV-2 infection for individuals aged 12 to 101 years was estimated. The RI within 27 days of an infection was assessed in the same model. There were 2,284 admissions for myocarditis and 1,651 for pericarditis in the study period. Elevated RIs were only observed in 16- to 39-year-olds 0 to 6 days postvaccination, mainly in males for myocarditis. Both mRNA vaccines showed elevated RIs after first, second, and third doses with the highest RIs after a second dose 5.34 (95% confidence interval (CI) [3.81, 7.48]; $p < 0.001$) for BNT162b2 and 56.48 (95% CI [33.95, 93.97]; $p < 0.001$) for mRNA-1273 compared with 4.38 (95% CI [2.59, 7.38]; $p < 0.001$) and 7.88 (95% CI [4.02, 15.44]; $p < 0.001$), respectively, after a third dose. For ChAdOx1-S, an elevated RI was only observed after a first dose, RI 5.23 (95% CI [2.48, 11.01]; $p < 0.001$). An elevated risk of admission for pericarditis was only observed 0 to 6 days after a second dose of mRNA-1273 vaccine in 16 to 39 year olds, RI 4.84 (95% CI [1.62, 14.01]; $p = 0.004$). RIs were lower in those with a prior SARS-CoV-2 infection than in those without, 2.47 (95% CI [1.32,4.63]; $p = 0.005$) versus 4.45 (95% [3.12, 6.34]; $p = 0.001$) after a second BNT162b2

dose, and 19.07 (95% CI [8.62, 42.19]; p < 0.001) versus 37.2 (95% CI [22.18, 62.38]; p < 0.001) for mRNA-1273 (myocarditis and pericarditis outcomes combined). RIs 1 to 27 days postinfection were elevated in all ages and were marginally lower for breakthrough infections, 2.33 (95% CI [1.96, 2.76]; p < 0.001) compared with 3.32 (95% CI [2.54, 4.33]; p < 0.001) in vaccine-naÃ¯ve individuals respectively. CONCLUSIONS: We observed an increased risk of myocarditis within the first week after priming and booster doses of mRNA vaccines, predominantly in males under 40 years with the highest risks after a second dose. The risk difference between the second and the third doses was particularly marked for the mRNA-1273 vaccine that contains half the amount of mRNA when used for boosting than priming. The lower risk in those with prior SARS-CoV-2 infection, and lack of an enhanced effect post-booster, does not suggest a spike-directed immune mechanism. Research to understand the mechanism of vaccine-associated myocarditis and to document the risk with bivalent mRNA vaccines is warranted.

The Common Systemic and Local Adverse Effects of the Sinovac COVID-19 Vaccine: An Observational Study From Pakistan. Background Vaccination acts by boosting the capacity of a person's immune system to identify and effectively resist infection-causing bacteria and viruses, as it stimulates the immune system to respond to the vaccine's antigens. The immunological response may include local and systemic symptoms, including pain at the injection site and fever, respectively. The Sinovac vaccine is an inactivated virus vaccine made in China and is one of the most widely used vaccines in many countries; however, the side effects of the Sinovac vaccine have not been well-studied in our population. Therefore, this study assessed the prevalence of side effects experienced by participants after receiving the Sinovac vaccine. Methodology This multicenter, cross-sectional study was conducted using a non-probability sampling method. The duration of the study wasÂ six months from May 1, 2022, to October 31, 2022. A total of 800 participants who were completely vaccinated with the Sinovac vaccine were included in the study. For categorical data, frequencies and percentages were documented, while for continuous data, such as age, height, weight, and the duration of comorbidities, means and standard deviations were evaluated. Results The study findings showed that out of 800 participants, 534 (66.8%) were males and 266 (33.3%) were females, with a mean age of 41.20 Â± 13.70 years. Among them, 162 (20.3%) had hypertension, and 104 (13.0%) had diabetes. Following the first dose of the Sinovac vaccine, fever was the most commonly reported side effect in 350 (43.8%) participants. Additionally, pain at the injection site in 238 (29.8%) participants, followed by swelling at the injection site in 228 (28.5%) recipients, were among other common side effects. Following the second dose of the Sinovac vaccine, fever was the most commonly reported side effect in 262 (32.8%) participants. Conclusions This study concluded that fever was the most frequent systemic side effect, whereas pain and swelling at the injection site were the most frequent local side effects following the administration of the first and second doses of the Sinovac vaccine. Both dosages of Sinovac were well-tolerated, and the majority of the adverse effects were minor and self-limiting.

Acute kidney disease following COVID-19 vaccination: a single-center retrospective study. BACKGROUND: Rare cases of de novo or relapsed kidney diseases associated with vaccination against coronavirus disease 2019 (COVID-19) have been increasingly reported. The aim of this study was to report the incidence, etiologies, and outcomes of acute kidney disease (AKD) following COVID-19 vaccination. METHODS: This retrospective study extracted cases from renal registry of a single medical center from 1 March 2021 to 30 April 2022, prior to the significant surge in cases of the Omicron variant of COVID-19 infection in Taiwan. Adult patients who developed AKD after COVID-19 vaccination were included. We utilized the Naranjo score as a causality assessment tool for adverse vaccination reactions and charts review by peer nephrologists to exclude other causes. The etiologies, characteristics, and outcomes of AKD were examined. RESULTS: Twenty-seven patients (aged 23 to 80

years) with AKD were identified from 1,897 vaccines (estimated rate of 13.6 per 1000 patient-years within the renal registry). A majority (77.8%) of vaccine received messenger RNA-based regimens. Their median (IQR) Naranjo score was 8 (6-9) points, while 14 of them (51.9%) had a definite probability (Naranjo score â‰¥ 9). The etiologies of AKD included glomerular disease (n = 16) consisting of seven IgA nephropathy, four anti-neutrophil cytoplasmic antibodies-associated glomerulonephritis (AAN), three membranous glomerulonephritis, two minimal change diseases, and chronic kidney disease (CKD) with acute deterioration (n = 11). Extra-renal manifestations were found in four patients. Over a median (IQR) follow-up period of 42 (36.5-49.5) weeks, six patients progressed to end-stage kidney disease (ESKD). CONCLUSION: Besides glomerulonephritis (GN), the occurrence of AKD following COVID-19 vaccination may be more concerning in high-risk CKD patients receiving multiple doses. Patients with the development of de novo AAN, concurrent extra-renal manifestations, or pre-existing moderate to severe CKD may exhibit poorer kidney prognosis.

Short-term adverse effects of COVID-19 vaccines after the first, second, and booster doses: a cross-sectional survey from Punjab, Pakistan, and the implications. BACKGROUND: Safety and efficacy concerns regarding coronavirus disease 2019 (COVID-19) vaccines are common among the public and have a negative impact on their uptake. We aimed to report the adverse effects currently associated with the vaccine in Pakistan to build confidence among the population for its adoption. METHODS: A cross-sectional study was conducted in five districts of the Punjab province of Pakistan between January and March 2022. The participants were recruited using convenience sampling. All data were analyzed using SPSS 22. RESULTS: We recruited 1622 people with the majority aged between 25-45 years. Of these, 51% were female, including 27 pregnant women and 42 lactating mothers. Most participants had received the Sinopharm (62.6%) or Sinovac (17.8%) vaccines. The incidences of at least one side effect after the first (N = 1622), second (N = 1484), and booster doses (N = 219) of the COVID-19 vaccine were 16.5%, 20.1%, and 32%, respectively. Inflammation/erythema at the injection site, pain at the injection site, fever, and bone/muscle pain were common side effects of vaccination. No significant differences were observed in the adverse effect scores between all demographic variables except for pregnancy (P = 0.012) after the initial dose. No significant association was observed between any variable and the side effect scores of the second and booster doses of the vaccine. CONCLUSIONS: Our study showed a 16-32% prevalence of self-reported side effects after the first, second, and booster COVID-19 vaccinations. Most adverse effects were mild and transient, indicating the safety of different COVID-19 vaccines.

Cogan's sign in a patient with suspected post-COVID-19 vaccine-associated myasthenia gravis. The Cogan's sign is indicative of myasthenia gravis. This is the first report of neurological signs in a patient with post-COVID-19 vaccine-associated myasthenia gravis in Brazil. In this case, a previously healthy 68-year-old woman presented with proximal limb weakness, left ptosis, and diplopia 1 month after receiving her fourth dose of the COVID-19 vaccine. Neurological examination revealed the presence of Cogan's sign, and she recovered rapidly after treatment. To our knowledge, this is the first reported case of myasthenia gravis associated with the COVID-19 vaccine in Brazil.

Icosapent ethyl (VASCEPA(Â®)) as treatment for post-acute sequelae of SARS CoV-2 (PASC) vaccine induced injury and infection. OBJECTIVES: As the COVID-19 pandemic continues, a prolonged post-infectious syndrome or "long COVID" has been reported. This is a multi-organ post viral syndrome that persists well after infection. Currently, there is no available treatment. Emerging evidence credits this "long COVID" syndrome to ongoing inflammatory response following resolution of symptoms during infection. An omega-three fatty acid derivative used in the treatment of hypertriglyceridemia, Icosapent Ethyl (IPE, VASCEPA(Â®)/Epadel(Â®)), was previously shown to reduce cardiovascular risk, likely via immunomodulatory effects. This study aims to evaluate the effectiveness of Icosapent Ethyl. METHODS: Following previous publications in treatment of severe

acute COVID-19, we analyze two case studies of adults treated with Icosapent Ethyl. RESULTS: After experiencing the symptoms of Long Covid, both individuals analyzed across two case studies experiences a resolution of symptoms after treatment with Icosapent Ethyl. CONCLUSION: After review and analysis we conclude that Icosapent Ethyl may have been a determining factor in Long COVID symptom resolution and should be studied further.

Evaluation of menstrual symptoms after Coronavirus disease 2019 vaccination in women with endometriosis. BACKGROUND: Vaccination can have an impact on menstruation, and this impact may be more notable in women with inflammatory gynecological pathologies such as endometriosis. OBJECTIVES: We aimed to investigate the impact of mRNA-based SARS-CoV-2 vaccines on menstrual cycle-related symptoms in women with endometriosis and assess the effect of hormonal therapy on potential SARS-CoV-2 vaccination-induced menstrual changes. DESIGN: A total of 848 women who received at least two doses of mRNA-based COVID-19 vaccines were prospectively recruited: 407 with endometriosis (endometriosis group) and 441 healthy controls (non-endometriosis group). METHODS: Data regarding demographics, clinical characteristics, hormonal treatment, and menstrual-associated symptoms in the first and second cycle after vaccination were collected through an online survey. RESULTS: A similar percentage of patients in both the endometriosis and the non-endometriosis group self-reported menstrual-associated changes the first (52.6% versus 48.8%, respectively) and second cycle after vaccination (29.0% versus 28.1%, respectively). Although the total symptoms recorded were not different between the two groups, several specific symptoms were statistically more frequent in the endometriosis group. These were pain disorders and fatigue in the first cycle after vaccination and pain disorders, menstrual headache and fatigue in the second cycle after vaccination. Bleeding frequency/regularity disorders were found to be more frequent in the non-endometriosis group in the first cycle after vaccination. Patients under hormonal treatment reported fewer changes in menstrual symptoms in the first and second cycle after vaccination compared with those not receiving this treatment. Similarly, patients in the endometriosis group receiving hormonal treatment reported fewer changes in menstrual-associated symptoms compared with those not following any hormonal treatment in the first and second menstrual cycle after the last vaccination. CONCLUSION: Women with endometriosis immunized with mRNA-based SARS-CoV-2 vaccines did not perceive greater worsening or new menstrual-associated symptoms after complete COVID-19 vaccination compared with healthy controls. Hormonal treatment may have a protective effect against worsened or new menstrual symptoms induced by COVID-19 vaccination.

Clinical features, diagnosis, and management of COVID-19 vaccine-associated Vogt-Koyanagi-Harada disease. Vogt-Koyanagi-Harada (VKH) disease is a rare and serious ocular adverse reaction following COVID-19 vaccination. This study aimed to evaluate the clinical features, diagnosis and management of COVID-19 vaccine-associated VKH disease. Case reports of VKH disease after COVID-19 vaccination were collected up to February 11, 2023 for retrospective analysis. Twenty-one patients (9 males and 12 females) were included, with a median age of 45â€‰years (range 19-78), from three main regions, Asia (12/21), the Mediterranean region (4/21), and South America (5/21). Fourteen patients developed symptoms after the first dose of the vaccine, and 8 after the second dose. Vaccines included mRNA vaccine (10 cases), virus vector vaccine (6 cases), and inactivated vaccine (5 cases). The average time interval from vaccination to onset of symptoms was 7.5â€‰days (range 12â€‰hours to 4â€‰weeks). All 21 patients experienced visual impairment after vaccination, with 20 cases involving both eyes. Sixteen patients showed symptoms of meningitis. Serous retinal detachment was observed in 16 patients, choroidal thickening was observed in 14, aqueous cell in 9, and subretinal fluid in 6. CSF pleocytosis was detected in 7 patients and skin symptoms were found in 3 patients. All patients received corticosteroid therapy, and 8 also received immunosuppressive agents. All patients recovered well, with a mean recovery time of 2â€‰months. Early diagnosis and

early treatment are crucial to the prognosis of patients with VKH after vaccination with COVID-19 vaccine. The risk of vaccination against COVID-19 in patients with a history of VKH disease should be evaluated clinically.

The role of blood groups, vaccine type and gender in predicting the severity of side effects among university students receiving COVID-19 vaccines. On March 11(th), 2020, the World Health Organization (WHO) declared the coronavirus disease 2019 (COVID-19) a pandemic. To control the pandemic, billions of vaccine doses have been administered worldwide. Predictors of COVID-19 vaccine-related side effects are inconsistently described in the literature. This study aimed to identify the predictors of side effects' severity after COVID-19 vaccination among young adult students at Taif University (TU) in Saudi Arabia. An online, anonymous questionnaire was used. Descriptive statistics were calculated for numerical and categorical variables. Possible correlations with other characteristics were identified using the chi-square test. The study included 760 young adult participants from TU. Pain at the injection site (54.7%), headache (45.0%), lethargy and fatigue (43.3%), and fever (37.5%) were the most frequently reported COVID-19 vaccine-related side effects after the first dose. The most frequent side effects were reported among the 20-25-year-old age group for all doses of all vaccines. Females experienced remarkably more side effects after the second (pâ€‰<â€‰0.001) and third doses (pâ€‰=â€‰0.002). Moreover, ABO blood groups significantly correlated with vaccine-related side effects after the second dose (pâ€‰=â€‰0.020). The participants' general health status correlated with the side effects after the first and second doses (pâ€‰<â€‰0.001 and 0.022, respectively). The predictors of COVID-19 vaccine-related side effects in young, vaccinated people were blood group B, female gender, vaccine type, and poor health status.

Necrotizing pancreatitis, microangiopathic hemolytic anemia and thrombocytopenia following the second dose of Pfizer/BioNTech COVID-19 mRNA vaccine. Implementing vaccines against severe acute respiratory syndrome coronavirusÂ 2 (SARS-CoV-2) is aÂ major asset in slowing down the coronavirus disease 2019 (COVID-19) pandemic. For mRNA vaccines, the main severe adverse events reported in pharmacovigilance systems and post-authorization studies were anaphylaxis and myocarditis. Pancreatitis after Pfizer/BioNTech COVID-19 vaccination has been reported only in 10Â patients.We report aÂ 31-year-old female with aÂ history of borderline personality disorder, intravenous drug abuse, allergic asthma, eating disorder, psoriatic arthritis treated with tofacitinib, neurogenic bladder disturbance, cholecystectomy, recurrent thoracic herpes zoster, vaginal candida infections and urinary tract infections, who developed pancreatitis associated with thrombotic microangiopathy and hemolytic-uremic syndrome 10Â days after the second vaccination, whereas the first has been well tolerated. She was treated by plasma exchange, and eventually by transgastric drainage with implantation of aÂ plastic stent to remove fluid abdominal retentions. She was discharged after 19Â days. Since then her condition has improved continuously. Computed tomography after 12Â months did not reveal retentions anymore.As other causes of pancreatitis have been excluded, this case of acute pancreatitis, microangiopathic hemolytic anemia and thrombocytopenia, temporally associated with the Pfizer-BioNTech COVID-19 vaccine, suggests aÂ causal link.

A deep learning predictive model for public health concerns and hesitancy toward the COVID-19 vaccines. Throughout the pandemic era, COVID-19 was one of the remarkable unexpected situations over the past few years, but with the decentralization and globalization of efforts and knowledge, a successful vaccine-based control strategy was efficiently designed and applied worldwide. On the other hand, excused confusion and hesitation have widely impacted public health. This paper aims to reduce COVID-19 vaccine hesitancy taking into consideration the patient's medical history. The dataset used in this study is the Vaccine Adverse Event Reporting System (VAERS) dataset

which was created as a corporation between the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to gather reported side effects that may be caused by PFIEZER, JANSSEN, and MODERNA vaccines. In this paper, a Deep Learning (DL) model has been developed to identify the relationship between a certain type of COVID-19 vaccine (i.e. PFIEZER, JANSSEN, and MODERNA) and the adverse reactions that may occur in vaccinated patients. The adverse reactions under study are the recovery condition, possibility to be hospitalized, and death status. In the first phase of the proposed model, the dataset has been pre-proceesed, while in the second phase, the Pigeon swarm optimization algorithm is used to optimally select the most promising features that affect the performance of the proposed model. The patient's status after vaccination dataset is grouped into three target classes (Death, Hospitalized, and Recovered). In the third phase, Recurrent Neural Network (RNN) is implemented for both each vaccine type and each target class. The results show that the proposed model gives the highest accuracy scores which are 96.031% for the Death target class in the case of PFIEZER vaccination. While in JANSSEN vaccination, the Hospitalized target class has shown the highest performance with an accuracy of 94.7%. Finally, the model has the best performance for the Recovered target class in MODERNA vaccination with an accuracy of 97.794%. Based on the accuracy and the Wilcoxon Signed Rank test, we can conclude that the proposed model is promising for identifying the relationship between the side effects of COVID-19 vaccines and the patient's status after vaccination. The study displayed that certain side effects were increased in patients according to the type of COVID-19 vaccines. Side effects related to CNS and hemopoietic systems demonstrated high values in all studied COVID-19 vaccines. In the frame of precision medicine, these findings can support the medical staff to select the best COVID-19 vaccine based on the medical history of the patient.

Changing Mindsets About Side Effects of the COVID-19 Vaccination: A Randomized Controlled Trial. BACKGROUND: Side-effect concerns are a major barrier to vaccination against COVID-19 and other diseases. Identifying cost- and time-efficient interventions to improve vaccine experience and reduce vaccine hesitancy-without withholding information about side effects-is critical. PURPOSE: Determine whether a brief symptom as positive signals mindset intervention can improve vaccine experience and reduce vaccine hesitancy after the COVID-19 vaccination. METHODS: English-speaking adults (18+) were recruited during the 15-min wait period after receiving their second dose of the Pfizer COVID-19 vaccination and were randomly allocated to the symptom as positive signals mindset condition or the treatment as usual control. Participants in the mindset intervention viewed a 3:43-min video explaining how the body responds to vaccinations and how common side effects such as fatigue, sore arm, and fever are signs that the vaccination is helping the body boost immunity. The control group received standard vaccination center information. RESULTS: Mindset participants (N = 260) versus controls (N = 268) reported significantly less worry about symptoms at day 3 [t(506)=2.60, p=.01, d=0.23], fewer symptoms immediately following the vaccine [t(484)=2.75, p=.006, d=0.24], and increased intentions to vaccinate against viruses like COVID-19 in the future [t(514)=-2.57, p=.01, d=0.22]. No significant differences for side-effect frequency at day 3, coping, or impact. CONCLUSIONS: This study supports the use of a brief video aimed at reframing symptoms as positive signals to reduce worry and increase future vaccine intentions. CLINICAL TRIAL INFORMATION: Australian New Zealand Clinical Trials Registry: ACTRN12621000722897p.

 Side-effect concerns are a major barrier to vaccination against COVID-19 and other diseases. Therefore, the purpose of this study was to determine whether a brief symptom as positive signals mindset intervention could improve vaccine experience and reduce vaccine hesitancy after the COVID-19 vaccination. Participants were recruited during the 15-min wait period after receiving their second dose of the Pfizer COVID-19 vaccination and were randomly allocated to a treatment as usual control condition or to a mindset intervention condition which entailed watching a 3:43-min video explaining

how the body responds to vaccinations and how common side effects such as fatigue, sore arm, and fever are signs that the vaccination is helping the body boost immunity. Compared with participants in the control condition, participants in the mindset intervention condition reported significantly less worry about symptoms at day 3, fewer symptoms immediately following the vaccine and increased intentions to vaccinate against viruses like COVID-19 in the future. No significant differences emerged for side-effect frequency at day 3, coping, or impact. These finding provide initial support for cost- and time-efficient interventions to improve vaccine experience and reduce vaccine hesitancy without withholding information about side effects.

Severe acute respiratory syndrome coronavirus-2 antibody response after Moderna vaccine booster on healthcare providers. INTRODUCTION: As an endeavor to control SARS-CoV-2 infection, the Moderna vaccine booster was given to healthcare workers to prevent reinfection and reduce the risk of complications from COVID-19. A heterologous booster vaccine is also thought to provide better protection against the current SARS-CoV-2 variants of concern. However, research that evaluates the effectiveness of the Moderna vaccine booster and the resulting SARS-CoV-2 antibody concentration is needed. OBJECTIVE: To evaluate the concentration of SARS-CoV-2 antibodies after the Moderna vaccine booster and the severity of SARS-CoV-2 infection before and after the Moderna vaccine booster. RESULTS: A total of 93 healthcare providers who received Moderna vaccine booster were included in the study. Examination of antibody concentration 3 months after the booster showed an average concentration of 10081.65 U/mL. There was an increase in antibody concentration before the booster and 3 months after, from a median of 1.7 U/mL to 9540 U/mL. Every subject showed a statistically significant increment of antibody concentration 3 months after the booster ($p < 0.01$). Thirty-seven (39.8%) subjects received two doses of the Sinovac vaccine and were confirmed to have COVID-19 with the Delta variant. After the booster, 26 (28%) subjects were infected with the Omicron Variant. Among the subjects who received two doses of the Sinovac vaccine and were confirmed with COVID-19, 36 (30.1%) had mild symptoms, and 1 (1.1%) was asymptomatic. CONCLUSIONS: Heterologous Moderna vaccine booster effectively increases antibody response against SARS-CoV-2 variants and shows mild symptoms of COVID-19 infection.

Associations between obstructive sleep apnea and COVID-19 infection and hospitalization among US adults. STUDY OBJECTIVES: Medical comorbidities increase the risk of severe COVID-19 infection. In some studies, obstructive sleep apnea (OSA) has been identified as a comorbid condition that is associated with an increased prevalence of COVID-19 infection and hospitalization, but few have investigated this association in a general population. This study aimed to answer the following research question: In a general population, is OSA associated with increased odds of COVID-19 infection and hospitalization and are these altered with COVID-19 vaccination? METHODS: This was a cross-sectional survey of a diverse sample of 15,057 US adults. RESULTS: COVID-19 infection and hospitalization rates in the cohort were 38.9% and 2.9%, respectively. OSA or OSA symptoms were reported in 19.4%. In logistic regression models adjusted for demographic, socioeconomic, and comorbid medical conditions, OSA was positively associated with COVID-19 infection (adjusted odds ratio: 1.58, 95% CI: 1.39-1.79) and COVID-19 hospitalization (adjusted odds ratio: 1.55, 95% CI: 1.17-2.05). In fully adjusted models, boosted vaccination status was protective against both infection and hospitalization. Boosted vaccination status attenuated the association between OSA and COVID-19 related hospitalization but not infection. Participants with untreated or symptomatic OSA were at greater risk for COVID-19 infection; those with untreated but not symptomatic OSA were more likely to be hospitalized. CONCLUSIONS: In a general population sample, OSA is associated with a greater likelihood of having had a COVID-19 infection and a COVID-19 hospitalization with the greatest impact observed among persons experiencing OSA symptoms or who were untreated for their OSA. Boosted vaccination status attenuated the association between OSA and COVID-19-related

hospitalization. CITATION: Quan SF, Weaver MD, Czeisler MÃ‰, etÂ al. Associations between obstructive sleep apnea and COVID-19 infection and hospitalization among U.S. adults. J Clin Sleep Med. 2023;19(7):1303-1311.
Erythema Multiforme Induced by Zonisamide and Triggered by the First Dose of COVID-19 Vaccine (Pfizer-BioNTech).
Fatal Myocarditis After COVID-19 Vaccination: Fourteen Autopsy-Confirmed Cases.
Health Belief Model Factors and Personal Characteristics Associated With COVID-19 Vaccination Behaviors in Adults. Prior studies have mainly examined factors regarding COVID-19 vaccination intentions. This study investigated the factors associated with COVID-19 vaccination behaviors in Korean adults. A total of 620 adults recruited from a survey company between July and August 2021 completed an online survey asking about their personal characteristics, health beliefs, and COVID-19 vaccination status. The collected data were analyzed using descriptive statistics, Pearson's Ï‡2 test, independent-samples t test, and logistic regression analysis. Less than half the participants received COVID-19 vaccinations, whereas 56.3% did not. The full regression model explained 33.3% of the variance in COVID-19 vaccination status. Age older than 60 years, perception of feeling healthy, presence of chronic diseases, past flu shot experiences, and five health belief model factors were significant factors associated with COVID-19 vaccination behaviors. COVID-19 vaccination intention was the most closely related factor (odds ratio, 12.37; 95% confidence interval, 3.54-43.26; P < .001). Vaccinated participants were more likely than unvaccinated to perceive susceptibility to COVID-19 infection, benefits, self-efficacy, moral responsibility, and subjective norms regarding COVID-19 vaccination. Based on the results, vaccinated and unvaccinated individuals showed different attitudes toward COVID-19 infection and vaccination. This study suggests that COVID-19 vaccination intentions lead to actual vaccination behavior.
Anetoderma after mRNA COVID-19 vaccine.
Safety of COVID-19 mRNA Vaccination Among Young Children in the Vaccine Safety Datalink.
SARS-CoV-2 infection (COVID-19) and male fertility: Something we should be worried about? As of 2021, roughly 5 million deaths were linked to SARS-CoV-2 infection based on World Health Organization estimates. The pandemic takes its staggering death toll, severely affecting the healthcare systems and leading to detrimental implications globally. While the severe impact on the respiratory system is well-established, the exact effect on male reproduction is still largely uncharted territory. When it comes to gender, men appear more vulnerable compared to women. Increasing evidence suggests that COVID-19 adversely affects spermatogenesis and hormonal balance in diverse ways. Semen parameters seem to be compromised at least temporarily, while long-term worsening needs to be clarified in studies with extended follow-up. For the time being, no data support the adverse effect of COVID-19 vaccines on a male's reproductive health. In the present article, we examine the available literature and briefly discuss the impact of the virus on reproduction and fertility. We further provide a comprehensive overview of the current status of vaccination and its potential effect on male fertility. Ultimately, we address the need for future well-designed large-scale trials before drawing definite conclusions on the exact impact of the virus on a male's fecundity.
Cerebral venous sinus thrombosis due to vaccine-induced immune thrombotic thrombocytopenia in middle-income countries. BACKGROUND: Adenovirus-based COVID-19 vaccines are extensively used in low- and middle-income countries (LMICs). Remarkably, cases of cerebral venous sinus thrombosis due to vaccine-induced immune thrombotic thrombocytopenia (CVST-VITT) have rarely been reported from LMICs. AIMS: We studied the frequency, manifestations, treatment, and outcomes of CVST-VITT in LMICs. METHODS: We report data from an international registry on CVST after COVID-19 vaccination. VITT was classified according to the Pavord criteria. We compared CVST-VITT cases from LMICs to cases from high-income countries (HICs). RESULTS: Until August 2022, 228

CVST cases were reported, of which 63 were from LMICs (all middle-income countries [MICs]: Brazil, China, India, Iran, Mexico, Pakistan, Turkey). Of these 63, 32 (51%) met the VITT criteria, compared to 103 of 165 (62%) from HICs. Only 5 of the 32 (16%) CVST-VITT cases from MICs had definite VITT, mostly because anti-platelet factor 4 antibodies were often not tested. The median age was 26 (interquartile range [IQR] 20-37) versus 47 (IQR 32-58) years, and the proportion of women was 25 of 32 (78%) versus 77 of 103 (75%) in MICs versus HICs, respectively. Patients from MICs were diagnosed later than patients from HICs (1/32 [3%] vs. 65/103 [63%] diagnosed before May 2021). Clinical manifestations, including intracranial hemorrhage, were largely similar as was intravenous immunoglobulin use. In-hospital mortality was lower in MICs (7/31 [23%, 95% confidence interval (CI) 11-40]) than in HICs (44/102 [43%, 95% CI 34-53], pâ€‰=â€‰0.039). CONCLUSIONS: The number of CVST-VITT cases reported from LMICs was small despite the widespread use of adenoviral vaccines. Clinical manifestations and treatment of CVST-VITT cases were largely similar in MICs and HICs, while mortality was lower in patients from MICs.
Association between distance to community health care facilities and COVID-19-related mortality across U.S. counties in the COVID-19-vaccine era. OBJECTIVE: COVID-19 has caused tremendous damage to U.S. public health, but COVID vaccines can effectively reduce the risk of COVID-19 infections and related mortality. Our study aimed to quantify the association between proximity to a community healthcare facility and COVID-19 related mortality after COVID vaccines became publicly available and explore how this association varied across racial and ethnic groups. RESULTS: Residents living farther from a facility had higher COVID-19-related mortality across U.S. counties. This increased mortality incidence associated with longer distances was particularly pronounced in counties with higher proportions of Black and Hispanic populations.
Immunogenicity, efficacy, and safety of CoronaVac and Pfizer/BioNTech mRNA vaccines in patients with psoriasis receiving systemic therapies: A prospective cohort study. BACKGROUND AND OBJECTIVES: Evidence of immune response to COVID-19 vaccine in psoriasis patients on biological agents is lacking. This study aimed to evaluate SARS-CoV-2 antibody levels following vaccination with CoronaVac or Pfizer/BioNTech mRNA in patients using biological agents or methotrexate, high-titer antibody levels achievement rate, and impact of medications on immunogenicity. METHODS: This noninterventional, prospective cohort study included 89 patients and 40 controls vaccinated with two doses of inactivated (CoronaVac) or Pfizer/BioNTech mRNA vaccines. Anti-spike and neutralising antibodies were analysed before and three to six weeks after the second dose. Adverse effects and symptomatic COVID-19 were assessed. RESULTS: Median anti-spike and neutralising antibody titers after CoronaVac were significantly lower in patients than controls (57.92 U/mL vs 125.4 U/mL, and 1/6 vs 1/32, respectively, pÂ <Â 0.05). Patients were less likely to achieve high-titer anti-spike antibody levels (25.6 % vs 50 %). Infliximab was associated with attenuated vaccine response. Pfizer/BioNTech vaccine induced comparable median anti-spike (2,080 U/mL vs 2,976.5 U/mL,) and neutralising antibody levels (1/96 vs 1/160) in patients and controls, respectively (pÂ >Â 0.05). High-titer anti-spike and neutralising antibodies development rates were comparable among patients and controls (95.2 % vs 100 %, and 30.4 % vs 50.0 %, respectively, pÂ >Â 0.05). Nine (10.1 %) COVID-19 cases- all mild - were identified. Psoriasis flare was seen in 6.74 %, mostly after Pfizer/BioNTech vaccine. CONCLUSION: Psoriasis patients treated with biological agents and methotrexate developed similar response to mRNA vaccine but weaker response to inactivated vaccine. Infliximab reduced response to the inactivated vaccine. Adverse effects were more frequent with mRNA vaccine, but none was severe.
Response to Letter "Only blames SARS-CoV-2 vaccination for facial palsy after alternative etiologies have been ruled out".
Myocarditis development after COVID-19 vaccination in an immunodeficient case.

Longitudinal Observation of Immune Response for 23 Months in COVID-19 Convalescent Patients After Infection and Vaccination. To better understand dynamic changes of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) immune response, a prospective, single-center, cohort study was conducted on longitudinal immune response in 34 COVID-19 convalescent patients over 23 months in Chongqing. Two blood samples from convalescent patients were collected, first sample collected during 10-13 months (M10-13) after infection (pre-SARS-CoV-2 vaccination) and second sample collected during 20-23 months (M20-23) after infection (post-SARS-CoV-2 vaccination). The SARS-CoV-2-specific humoral and cellular immunity were traced by testing total antibody (Ab), anti-nucleocapsid (NP) immunoglobulin M (IgM), anti-NP immunoglobulin G (IgG), and anti-spike (S) IgG Abs, lymphocyte subset count, and Th1 cytokines. Healthy donors (30) were also included in the study as the uninspected healthy controls. Our data showed significant change in mean titer of SARS-CoV-2-specific Ab response from M10-13 to M20-23 included, namely, SARS-CoV-2-specific total Ab as 219 AU/mL increasing to 750.9 AU/mL; anti-NP IgM as 3.5 AU/mL decreasing significantly (pâ€‰<â€‰0.001) to 0.6 AU/mL; anti-NP IgG as 7.9 AU/mL increasing to 87.1 AU/mL; and anti-S IgG as 499.0 RU/mL increasing to 1,802.3 RU/mL. Our observations suggested that one vaccine dose might have been sufficient for COVID-19 convalescent patients. Larger sample sizes are needed to compare better immune effect of protein subunit vaccine. Besides, compared to healthy donors, patients had decreased CD3+ and CD8+ T lymphocyte counts during two periods. Patients had most cytokines recovered normally within 2 years, but IL-6 level was significantly elevated; however, IL-6 was negatively correlated with IgM and positively correlated with IgG. Changes in cytokines might have been caused by SARS-CoV-2 infection or vaccination. Patients with comorbidities were associated with decreased CD3+ and CD8+ T lymphocytes and lower Ab titers following SARS-CoV-2 vaccination. Vaccination enormously increased humoral immunity beneficial in COVID-19 convalescent patients. Elderly COVID-19 convalescent patients with comorbidities needed more attention.

Platelet-neutrophil interaction in COVID-19 and vaccine-induced thrombotic thrombocytopenia. Coronavirus disease 2019 (COVID-19) is known to commonly induce a thrombotic diathesis, particularly in severely affected individuals. So far, this COVID-19-associated coagulopathy (CAC) has been partially explained by hyperactivated platelets as well as by the prothrombotic effects of neutrophil extracellular traps (NETs) released from neutrophils. However, precise insight into the bidirectional relationship between platelets and neutrophils in the pathophysiology of CAC still lags behind. Vaccine-induced thrombotic thrombocytopenia (VITT) is a rare autoimmune disorder caused by auto-antibody formation in response to immunization with adenoviral vector vaccines. VITT is associated with life-threatening thromboembolic events and thus, high fatality rates. Our concept of the thrombophilia observed in VITT is relatively new, hence a better understanding could help in the management of such patients with the potential to also prevent VITT. In this review we aim to summarize the current knowledge on platelet-neutrophil interplay in COVID-19 and VITT.

Anti-3-Hydroxy-3-Methylglutaryl-Coenzyme A Reductase Immune-Mediated Necrotizing Myopathy following mRNA SARS-CoV-2 Vaccination. The new coronavirus (COVID-19) pandemic has resulted in the unprecedented production of vaccines. In this context, the possible adverse effects remain to be identified and reported. In this article, we report the case of a young female patient who developed anti-3-hydroxy-3-methylglutaryl-coenzyme A reductase (anti-HMG-CoA) immune-mediated necrotizing myositis (IMNM) after receiving the Pfizer-BioNTech (BNT162b2) COVID-19 vaccine. The diagnosis of probable post-vaccination IMNM was made due to the absence of other factors that may have led to the development of autoantibodies (medicines; e.g., statins, drugs) and the temporal relationship between exposure and event. This case report is the first to suggest that a COVID-19 vaccine may trigger anti-HMG-CoA reductase necrotizing myopathy.

Association Between Cycle Threshold Value and Vaccination Status Among Severe Acute Respiratory Syndrome Coronavirus 2 Omicron Variant Cases in Ontario, Canada, in December 2021. BACKGROUND: Increased immune evasion by emerging severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants and occurrence of breakthrough infections raise questions about whether coronavirus disease 2019 vaccination status affects SARS-CoV-2 viral load among those infected. This study examined the relationship between cycle threshold (Ct) value, which is inversely associated with viral load, and vaccination status at the onset of the Omicron wave onset in Ontario, Canada. METHODS: Using linked provincial databases, we compared median Ct values across vaccination status among polymerase chain reaction-confirmed Omicron variant SARS-CoV-2 cases (sublineages B.1.1.529, BA.1, and BA.1.1) between 6 and 30 December 2021. Cases were presumed to be Omicron based on S-gene target failure. We estimated the relationship between vaccination status and Ct values using multiple linear regression, adjusting for age group, sex, and symptom status. RESULTS: Of the 27 029 presumed Omicron cases in Ontario, the majority were in individuals who had received a complete vaccine series (87.7%), followed by unvaccinated individuals (8.1%), and those who had received a booster dose (4.2%). The median Ct value for post-booster dose individuals (18.3 [interquartile range, 15.4-22.3]) was significantly higher than that for unvaccinated (17.9 [15.2-21.6]; P = .02) and post-vaccine series individuals (17.8 [15.3-21.5]; P = .005). Post-booster dose cases remained associated with a significantly higher median Ct value than cases in unvaccinated individuals (P â‰¤ .001), after adjustment for covariates. Compared with values in persons aged 18-29 years, Ct values were significantly lower among most age groups >50 years. CONCLUSIONS: While slightly lower Ct values were observed among unvaccinated individuals infected with Omicron compared with post-booster dose cases, further research is required to determine whether a significant difference in secondary transmission exists between these groups.

Stellate Ganglion Block for Complex Regional Pain Syndrome Treatment After SARS-CoV-2 Vaccine: A Case Report. Complex regional pain syndrome (CRPS) is a poorly understood neuropathic pain syndrome that may have different etiologies. Reports of this syndrome after vaccination are rare. We report a female patient with a medical history of acute stroke of the right carotid artery in the previous four months who developed hyperalgesia, allodynia, edema, and color changes in the upper left member compatible with CRPS one day after SARS-CoV-2 vaccination. A multimodal therapeutic approach was adopted, including a stellate ganglion block, with favorable results, including pain score reduction and increased mobility of the affected member.

Recurrent acute-onset of chronic inflammatory demyelinating polyneuropathy after COVID-19 vaccination. This is the case of 54-year-old male with a past medical history of Chronic Inflammatory Demyelinating Polyneuropathy (CIPD) who was found to have an acute exacerbation of CIPD shortly after receiving his 1st COVID 19 booster (3rd dose of vaccination series) and was successfully treated with intravenous immunoglobulin (IVIG) and then was found to have another acute exacerbation of CIDP 6 months later after receiving his 2nd COVID 19 booster (4th dose of vaccination series) that required intubation and long term tracheostomy. CIPD is an acquired immune-mediated polyneuropathy that mainly affects the peripheral nerve roots nerves. It typically presents with relapsing/remitting, or progressive symmetrical muscle weakness and sensory involvement and can cause decreased respiratory effort. COVID-19 is mainly a respiratory disease, but it has been associated with a wide variety of neurological conditions. Although there have been several findings of acute inflammatory demyelinating polyneuropathy in association with COVID-19, CIDP exacerbation as a result of COVID-19 has rarely been seen in the literature. Furthermore, CIDP exacerbation as a result of COVID-19 vaccination is even less frequently seen.

Bell's Palsy After Vaccination Against Covid-19: A Systematic Review and Meta-analysis. OBJECTIVE: This systematic review and meta-analysis aimed to identify studies reporting the

incidence of Bell's Palsy after vaccination against coronavirus disease 2019 (Covid-19) and assess whether this incidence is greater than among the general population. DATA SOURCES: PubMed, Embase, CINAHL, and Web of Science. REVIEW METHODS: A systematic review was performed in accordance with Preferred Reporting Items for Systematic Reviews and Meta-analysesÂ guidelines. Databases were searched from inception to May 9, 2022, for studies reporting the incidence of Bell's Palsy among individuals vaccinated against Covid-19 and control populations. Meta-analyses of odds ratios (ORs) were performed to compare the incidence of Bell's Palsy in these groups. RESULTS: We identified 7 studies reporting the incidence of Bell's Palsy after vaccination and among the general population, including 20,234,931 total vaccinated patients. The length of postvaccination follow-up ranged from 7 to 43 days in these studies. The incidence of Bell's Palsy was not significantly greater among vaccinated individuals (OR: 1.06; 95% confidence interval [CI]: 0.65-1.71; pâ€‰=â€‰.82). Stratifying by dose, the incidence of Bell's Palsy was not significantly greater after receiving either the first dose (OR: 0.84; 95% CI: 0.47-1.49; pâ€‰=â€‰.54) or second dose (OR: 1.02; 95% CI: 0.58-1.79; pâ€‰=â€‰.96). CONCLUSION: Among the available evidence, the incidence of Bell's Palsy after vaccination against Covid-19 is comparable to that of the general unvaccinated population. Patient counseling should provide reassurance that there is no known association between Bell's Palsy and Covid-19 vaccination.

Vertigo and Dizziness After Coronavirus Disease-2019 Vaccination: A Nationwide Analysis. BACKGROUND: Side effects occurring after COVID-19 vaccination can include vertigo and dizziness. Despite its high incidence, few studies to date have assessed dizziness/vertigo after vaccination. The present study investigated the incidence of dizziness/vertigo after COVID-19 vaccination in South Korea. METHODS: Adverse reactions to COVID-19 vaccination reported to the Korea Disease Control and Prevention Agency from February 26, 2021, to July 31, 2022 (week 74) were analyzed. The incidence rates of dizziness/vertigo in subjects vaccinated with 5 COVID-19 vaccines, AZD1222 (AstraZeneca), BNT162b2 (Pfizer-BioNTech), JNJ-78436735 (Janssen), mRNA-1273 (Moderna), and NVX-CoV2373 (Novavax), were determined. RESULTS: A total of 126 725 952 doses of COVID-19 vaccine were administered, with 473 755 suspected adverse reactions (374 per 100 000 vaccinations) reported. Vertigo/dizziness was reported after the administration of 68 759 doses, or 54.3 per 100 000 vaccinations, making it the third most common adverse reaction after headache and muscle pain. CONCLUSION: Dizziness/vertigo was generally a mild adverse reaction after COVID-19 vaccination, but it was the third most common adverse reaction in Korea. Studies are necessary to clarify the causal relationship between vaccination and dizziness/vertigo and to prepare subjects for this possible adverse reaction.

A Nationwide Survey of mRNA COVID-19 Vaccinee's Experiences on Adverse Events and Its Associated Factors. BACKGROUND: Although coronavirus disease 2019 (COVID-19) vaccines have been distributed worldwide under emergency use authorization, the real-world safety profiles of mRNA vaccines still need to be clearly defined. We aimed to identify the overall incidence and factors associated with adverse events (AEs) following mRNA COVID-19 vaccination. METHODS: We conducted web-based survey from December 2 to 10 in 2021 with a 2,849 nationwide sampled panel. Study participants were individuals who had elapsed at least two-weeks after completing two dosing schedules of COVID-19 vaccination aged between 18-49 years. We weighted the participants to represent the Korean population. The outcome was the overall incidence of AEs following mRNA COVID-19 vaccination and associated factors. We estimated the weighted odds ratios (ORs) using multivariable logistic regression models to identify the factors associated with AEs. RESULTS: Of the 2,849 participants (median [interquartile range] age, 35 [27-42] years; 51.6% male), 90.8% (n = 2,582) for the first dose and 88.7% (n = 2,849) for the second dose reported AEs, and 3.3% and 4.3% reported severe AEs, respectively. Occurrence of AEs was more prevalent in mRNA-1273 (OR, 2.06;

95% confidence interval [CI], 1.59-2.67 vs. BNT162b2), female sex (1.88; 1.52-2.32), and those with dermatologic diseases (2.51; 1.32-4.77). History of serious allergic reactions (1.96; 1.06-3.64) and anticoagulant medication use (4.72; 1.92-11.6) were associated with severe AEs. CONCLUSION: Approximately 90% of participants reported AEs following mRNA COVID-19 vaccination. Substantial factors, including vaccine type (mRNA-1273), female sex, and dermatologic diseases were associated with AEs. Our findings could aid policymakers in establishing vaccination strategies tailored to those potentially susceptible to AEs.

Clinicopathological Characteristics of Autoimmune-Like Hepatitis Induced by COVID-19 mRNA Vaccine (Pfizer-BioNTech, BNT162b2): A Case Report and Literature Review. Widespread use of vaccinations worldwide in the coronavirus disease (COVID-19) pandemic has resulted in various side effects. Here, we presented a 27-year-old man with autoimmune-like hepatitis after the first dose of the BNT162b2 (mRNA) COVID-19 vaccine and reviewed previous reports. He presented with sweating, febrile sensations, and general weakness. He did not have any medical histories. Although he was treated with biphenyl dimethyl dicarboxylate and ursodeoxycholic acid, the elevated liver enzyme levels persisted for 2 months. Liver biopsy demonstrated portal inflammation with rosette formation, interface hepatitis, and infiltration of lymphocytes, histiocytes, plasma cells, and eosinophils. Especially, centrilobular edema and necrosis were found. The symptoms and liver enzymes improved with prednisolone treatment. If persistently elevated liver enzymes are found after COVID-19 mRNA vaccination, the possibility of autoimmune-like hepatitis induced by the vaccine should be considered and a careful pathologic evaluation is required.

Medical outcomes of children with neurodevelopmental disorders after SARS-CoV-2 vaccination: A six-month follow-up study. INTRODUCTION: The BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) vaccines have been approved for children and adolescents for protecting against SARS-CoV-2 infection. This longitudinal study aimed to compare adverse outcomes after SARS-CoV-2 vaccination in children with neurodevelopmental disorders (ND) (e.g., attention-deficit/hyperactivity disorder [ADHD], autism spectrum disorder [ASD], communication disorders, intellectual disability, and tic disorders) and healthy control children. METHODS: A total of 1335 children who received the SARS-CoV-2 vaccination (762 children with ND and 573 healthy controls) were recruited. All subjects were followed-up for 180Â days, and outcome events were defined as outpatient department (OPD) or emergency department (ER) visits during follow-up. Multivariate Cox proportional hazards regression models were used to identify the potential differences in outcomes between the propensity score-matched ND group (nÂ =Â 311) and the control group (nÂ =Â 311), and to explore the factors associated with outcomes among all children with ND (nÂ =Â 762). RESULTS: Compared with the control group, children with ND exhibited a higher likelihood of subsequent OPD or ER visits and paediatric neurology OPD visits after the first dose of vaccination. However, we found that only a small proportion of the children visited the OPD or ER because of adverse vaccination-related effects. Among all children with ND, those with communication disorders showed a higher likelihood of any OPD or ER visit. Paediatric neurology OPD visits were associated with communication disorders, intellectual disability, and methylphenidate and aripiprazole prescriptions. ADHD and ASD were not associated with adverse outcomes. CONCLUSIONS: No specific ND diagnosis or medication use clearly increased the risk of adverse effects of SARS-CoV-2 vaccination. Children with ND can be reassured that the SARS-CoV-2 vaccination is a safe regimen to protect themselves.

One year safety and immunogenicity of AZD1222 (ChAdOx1 nCoV-19): Final analysis of a randomized, placebo-controlled phase 1/2 trial in Japan. BACKGROUND: Long duration trial data for two-dose COVID-19 vaccines primary series' are uncommon due to unblinding and additional doses. We report one-year follow-up results from a phase 1/2 trial of AZD1222 (ChAdOx1 nCoV-19) in Japan. METHODS: Adults (nÂ =Â 256) seronegative for severe acute respiratory syndrome coronavirus-2

(SARS-CoV-2) were stratified by age, 18-55 (nÂ =Â 128), 56-69 (nÂ =Â 86) and â‰¥70-year-old (nÂ =Â 42), and randomized 3:1 to AZD1222 or placebo. Safety, immunogenicity, and exploratory efficacy data were collected until study Day 365. RESULTS: Safety was consistent with previous reports. In AZD1222 vaccinees, humoral responses against SARS-CoV-2 steadily declined over time. By Day 365, anti-SARS-CoV-2 spike-binding (spike) and receptor-binding domain (RBD) mean antibody titers remained above Day 15 levels and pseudovirus neutralizing antibodies were undetectable in many participants. CONCLUSIONS: AZD1222 is immunogenic and well tolerated in Japanese adults. Expected waning in anti-SARS-CoV-2 humoral responses was observed; spike and RBD antibody titers remained elevated. (ClinicalTrials.gov: NCT04568031).

Retrospective Evaluation of COVID-19 Infection and COVID-19 Vaccines in Heart Transplant Patients. BACKGROUND: Patients who have performed solid organ transplantation in terms of COVID-19 infection are included in the high-risk group. In this study, it was aimed to evaluate the relationship between vaccination and retrospective evaluation of 32 patients who underwent a heart transplant in the clinic and tested positive for SARS-CoV-2 polymerase chain reaction. METHODS: In this study, demographic characteristics of the cases, comorbidities, timing of heart transplantation, immunosuppressive treatments, symptoms of COVID-19 infection, lung imaging findings, follow-up (outpatient/inpatient), treatments, 1-month mortality, and vaccination histories against COVID-19 infection were evaluated. The data obtained from the study were analyzed with SPSS version 25.0. RESULTS: The 3 most common symptoms are cough (37.5%), myalgia (28.1%), and fever (21.8%). COVID-19 infection was severe in 6.2% of the patients, moderate in 37.5%, and mild in 56.2%. Hospitalization was required in 5 patients (15.6%, 1 in the intensive care unit), and the other patients were followed up as an outpatient. Severe COVID-19 infection was seen more in 33% of unvaccinated patients; 93.5% were vaccinated. Nineteen patients (68%) were vaccinated before COVID-19 infection. Our patients received the CoronoVac (Sinovac, China) vaccine. CONCLUSION: COVID-19 infection is more likely to be severe and mortal in patients with heart transplant recipients. It is also crucial to comply with preventive measures other than immunization in this group of patients. This study is the largest series investigating COVID-19 infection in heart transplant recipient patients in our country.

Prostate-specific antigen level association with COVID-19 infection and vaccination. INTRODUCTION: The associations among SARS-CoV-2 infection, vaccination and total serum prostate serum antigen (PSA) levels in men undergoing screening for prostate cancer are unknown. METHODS: A retrospective analysis of data from a large health maintenance organization. Records of individuals aged 50 to 75 years with two serum PSA tests taken between March 2018 and November 2021 were included. Individuals with prostate cancer were excluded. Changes in PSA levels were compared between individuals who had at least 1 SARS-CoV-2 vaccination and/or infection between the two PSA tests and individuals who did not have an infection and were not vaccinated between the two PSA tests. Subgroup analyses were performed to assess the impact of the elapsed time between the event and the second PSA test on the results. RESULTS: The study and control groups included 6,733 (29%) and 16 286 (71%) individuals, respectively. Although the median time between PSA tests was shorter in the study vs. the control group (440 vs. 469 days, P<.001), PSA elevation between the tests was higher in the study group (0.04 vs. 0.02, P<.001). The relative risk for PSA elevation â‰¥1 ng/dL was 1.22 (95% CI 1.1, 1.35). Among individuals who were vaccinated, PSA increased by 0.03 ng/dL (IQR -0.12, 0.28) and 0.09 ng/dL (IQR -0.05, 0.34) after 1 and 3 doses, respectively (P<.001). Multivariate linear regression showed that SARS-CoV-2 events (Î² 0.043; 95% CI 0.026-0.06) were associated with a greater risk for PSA elevation, after adjusting for age, baseline PSA and days between PSA tests. CONCLUSION: SARS-CoV-2 infection and vaccinations are associated with a slight increase in PSA, with the third anti-COVID vaccine dose having a more prominent impact, but its

clinical significance is unknown yet. Any significant increase in PSA must be investigated and cannot be dismissed as secondary to SARS-CoV-2 infection or vaccination.

"Acute psychosis induced by mRNA-based COVID-19 vaccine in adolescents: A pediatric case report": Comment.

Response to the comments on "Acute psychosis induced by mRNA-based COVID-19 vaccine in adolescents".

The role of interleukin-21 in COVID-19 vaccine-induced B cell-mediated immune responses in patients with kidney disease and kidney transplant recipients. T-cell-mediated help to B cells is required for the development of humoral responses, in which the cytokine interleukin (IL)-21 is key. Here, we studied the mRNA-1273 vaccine-induced SARS-CoV-2-specific memory T-cell IL-21 response, memory B cell response, and immunoglobulin (Ig)G antibody levels in peripheral blood at 28 days after the second vaccination by ELISpot and the fluorescent bead-based multiplex immunoassay, respectively. We included 40 patients with chronic kidney disease (CKD), 34 patients on dialysis, 63 kidney transplant recipients (KTR), and 47 controls. We found that KTR, but not patients with CKD and those receiving dialysis, showed a significantly lower number of SARS-CoV-2-specific IL-21 producing T cells than controls ($P < .001$). KTR and patients with CKD showed lower numbers of SARS-CoV-2-specific IgG-producing memory B cells when compared with controls ($P < .001$ and $P = .01$, respectively). The T-cell IL-21 response was positively associated with the SARS-CoV-2-specific B cell response and the SARS-CoV-2 spike S1-specific IgG antibody levels (both Pearson $r = 0.5$; $P < .001$). In addition, SARS-CoV-2-specific B cell responses were shown to be IL-21 dependent. Taken together, we show that IL-21 signaling is important in eliciting robust B cell-mediated immune responses in patients with kidney disease and KTR.

Only blame SARS-CoV-2Â vaccination for facial palsy after alternative etiologies have been ruled out.

Development of giant cell arteritis after vaccination against SARS-CoV2: A case report and literature review. RATIONALE: Giant cell arteritis (GCA) is an autoimmune vasculitis that affects large and medium-sized blood vessels. The mRNA vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) has been associated with the development of immune-mediated diseases. In this article, we present a case of GCA that developed after vaccination against SARS-CoV2. PATIENT CONCERNS: A 77-year-old man developed fever, general fatigue, and headache 1 day after the third dose of vaccination against SARS-CoV2. Nodular swelling and tenderness of the bilateral temporal arteries were observed. DIAGNOSES: Although right temporal artery biopsies were negative, the patient was diagnosed with GCA based on criteria established by the American College of Rheumatology for the classification of GCA. INTERVENTIONS: The patient received methylprednisolone 1000â€‰mg for 3 days. This was followed by prednisolone 1â€‰mg/kg/d, which was decreased by 10â€‰mg every week to 30â€‰mg. From day 16 of hospitalization, the patient received tocilizumab 162â€‰mg/wk every other week. OUTCOMES: There was no occurrence of acute side effects. After 38 days of treatment, the condition improved and the patient was discharged from the hospital; as stated above, the dose of prednisolone was tapered to 30â€‰mg/d. LESSONS: We experienced a case of GCA that occurred immediately after vaccination against SARS-CoV2 with an mRNA vaccine. Early signs of GCA include fever, fatigue, and headache, and often resemble those noted after vaccination against SARS-CoV2. The potential presence of GCA should be determined in individuals with persistent fever and headache after vaccination against SARS-CoV2.

[SARS-CoV-2 antibodies after booster vaccination. Identification of subgroups with poor response]. OBJECTIVE: To determine which patients within the high-risk group are most likely to have insufficient post-vaccination immunity. METHODS: Determination of IgG titers against SARS-CoV-2 after the booster dose. Vaccine response was categorized as negative (IgG titers <Â 34 BAU/ml), indeterminate

(titers 34 - 259 BAU/ml) or positive (â‰¥ 260 BAU/ml). RESULTS: 765 patients were included (31.25% of those vaccinated). 54 (7.1%) on treatment with biologics, 90 (11.8%) with hematologic disease, 299 (39.1%) with oncologic pathology, 304 (39.7%) with solid organ transplant and 18 (2.4%) with immunosuppression for other reasons. 74 patients (9.7%) had negative serology and 45 (5.9%) had indeterminate titers. By diagnostic group, the patients with the highest proportion of negative or indeterminate serology were patients with biologic treatment (55.6%, mainly at expense of antiCD20), hematologic (35.4%) and transplant patients (17.8%, mainly lung and kidney). Oncology and other immunosuppressed patients had a favorable response to vaccination. CONCLUSION: Patients treated with antiCD20 drugs, hematologic patients and transplanted patients (mainly lung and kidney) have a higher risk of not achieving post-vaccination immunity. It is essential to identify them in order to individualize and optimize their management.

Analysis and comparison of SARS-CoV-2 variant antibodies and neutralizing activity for 6 months after a booster mRNA vaccine in a healthcare worker population. INTRODUCTION: In the context of recurrent surges of SARS-CoV-2 infections, a detailed characterization of antibody persistence over a 6-month period following vaccine booster dose is necessary to crafting effective public health policies on repeat vaccination. METHODS: To characterize the SARS-CoV-2 antibody profile of a healthcare worker population over a 6-month period following mRNA vaccination and booster dose. 323 healthcare workers at an academic medical center in Orange County, California who had completed primary vaccination and booster dose against SARS-CoV-2 were recruited for the study. A total of 690 blood specimens over a 6-month period were collected via finger-stick blood and analyzed for the presence of antibodies against 9 SARS-CoV-2 antigens using a coronavirus antigen microarray. RESULTS: The primary outcome of this study was the average SARS-CoV-2 antibody level as measured using a novel coronavirus antigen microarray. Additional outcomes measured include levels of antibodies specific to SARS-CoV-2 variants including Delta, Omicron BA.1, and BA.2. We also measured SARS-CoV-2 neutralization capacity for a subset of the population to confirm correlation with antibody levels. Although antibodies against SARS-CoV-2 wane throughout the 6-month period following a booster dose, antibody levels remain higher than pre-boost levels. However, a booster dose of vaccine based on the original Wuhan strain generates approximately 3-fold lower antibody reactivity against Omicron variants BA.1 and BA.2 as compared to the vaccine strain. Despite waning antibody levels, neutralization activity against the vaccine strain is maintained throughout the 6-month period. DISCUSSION: In the context of recurrent surges of SARS-CoV-2 infections, our data indicate that breakthrough infections are likely driven by novel variants with different antibody specificity and not by time since last dose of vaccination, indicating that development of vaccinations specific to these novel variants is necessary to prevent future surges of SARS-CoV-2 infections.

Antibody response and safety of inactivated SARS-CoV-2 vaccines in chronic hepatitis B patients with and without cirrhosis. BACKGROUND: The immune response and safety of inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines among patients with chronic hepatitis B (CHB), especially those with cirrhosis, are not clear. Therefore, this study was conducted to evaluate the efficacy and safety of inactivated SARS-CoV-2 vaccines among CHB patients with and without cirrhosis. PATIENTS AND METHODS: A total of 643 CHB patients who received two doses of inactivated SARS-CoV-2 vaccines (BBIBP-CorV and CoronaVac) were enrolled. Serum samples were collected and tested for SARS-CoV-2 S-receptor-binding domain (S-RBD) immunoglobulin G (IgG) at enrollment. Data on adverse events (AEs) within 7Â days after the second dose were obtained using a questionnaire. RESULTS: A total of 416 non-cirrhotic and 227 cirrhotic patients were included in the analysis. Cirrhotic patients had lower antibody titers than non-cirrhotic patients after adjusting for age, sex, and time interval (2.45 vs. 2.60Â ng/ml, pÂ =Â 0.034). Furthermore, the study revealed that cirrhotic patients demonstrated a slower rate of seropositivity increase, with the highest rate being

recorded at weekÂ 4 and reaching 94.7%. On the other hand, among non-cirrhotic patients, the seropositivity rate peak was observed at weekÂ 2 and reached 96.0%. In addition, cirrhotic patients displayed a more rapid decline in the seropositivity rate, dropping to 54.5% after â‰¥16Â weeks, while non-cirrhotic patients exhibited a decrease to 67.2% after the same time period. The overall incidence of AEs was low (18.4%), and all AEs were mild and self-limiting. In addition, 16.0% of participants had mild liver function abnormalities, and half of them returned to normality within the next 6Â months without additional therapy. The participants who experienced liver function abnormalities showed a higher seropositivity rate and antibody titer than those who did not (91.6% vs. 79.5%, pÂ =Â 0.005; 2.73 vs. 2.41Â ng/ml, pÂ <Â 0.001). CONCLUSION: Cirrhotic CHB patients had lower antibody titers to inactivated SARS-CoV-2 vaccines than non-cirrhotic patients. The vaccines were generally well tolerated in both non-cirrhotic and cirrhotic CHB patient groups. Patients with abnormal liver function may have a better antibody response than those without.

Cutaneous Adverse Drug Reactions (CADRs) to COVID19 Vaccines: A Case Series. Viral vector vaccines (Covishield) and inactivated vaccines (Covaxin) are now being administered worldwide to reduce the impact of life-threatening corona virus disease 19 (COVID-19). Various cutaneous adverse drug reactions (CADRs) have been reported following COVID-19 vaccination. Here, we are reporting series of CADRs following COVID-19 vaccination. Among 18 CADRs, 4 each were of acute urticaria and pityriasis rosea, 2 each of leukocytoclastic vasculitis and herpes zoster, 3 exacerbation of psoriasis, and 1 each of exacerbation of eczema, reactivation of herpes simplex virus 1 infection, and COVID arm. However, in 1 case there was remission of psoriasis. These CADRs occurred between 6 hours and 20 days after vaccination and were mild to moderate in severity. Only 1 needed hospitalization. Of the 18 CADRs, 10 developed after first dose and 8 after second dose. Causality assessment was done using World Health Organization causality assessment classification. Mass COVID-19 vaccination program is in progress worldwide. Many CADRs like COVID arm, urticaria, pityriasis rosea, leukocytoclastic vasculitis, herpes zoster etc., have been reported following vaccination. In our series only 1 developed cutaneous adverse drug reaction (CADR) to Covaxin. It was Covishield that was administered during the vaccination drive; hence, more cases were seen to that vaccine. Most of the CADRs were mild to moderate in intensity. Awareness of these adverse effects enables the healthcare professionals to be better equipped to recognize and manage them correctly.

Reactive Arthritis Following Vaccination against COVID-19: An Unexpected Adverse Reaction.

COVID-19-Induced Eosinophilic Lower Airway Inflammation in Those With Multiple COVID-19 Vaccinations. A 29-year-old woman was admitted with a diagnosis of ischemic enteritis. She had a coronavirus disease 2019 (COVID-19) infection four weeks before this visit and continued to experience a cough. Four months before, she received the third COVID-19 vaccine. Chest computer tomography revealed scattered ground-glass opacities in both upper lobes. Based on abnormalities in chest imaging, eosinophilia, and a high level of fractional exhaled nitric oxide, she was diagnosed with eosinophilic lower airway inflammation due to COVID-19. Since the visit, the patient had an intermittent fever and no radiological improvement, so systemic corticosteroid treatment was initiated, and the symptoms and clinical findings improved. Clinicians should know the potential association between COVID-19 and eosinophilic lower airway inflammation, which may still occur despite multiple vaccinations.

Benefits and Harms of COVID-19 Vaccines in Cardiovascular Disease: A Comprehensive Review. Patients with a history of cardiovascular disease (CVD) who contract coronavirus disease 2019 (COVID-19) tend to have a worse prognosis and more severe cardiovascular side effects. COVID-19 vaccines, which are intended to prevent COVID-19, may also potentially reduce the severity and complications (including cardiovascular sequelae) of COVID-19, especially in patients with a history of CVD. However, there have also been reports of cardiovascular side effects from COVID-19 vaccines of

various brands and types. The purpose of this study is to review the benefits and harms of COVID-19 vaccines in relation to CVD. In this thorough review of the most current evidence on the benefits and harms of COVID-19 vaccines, we present information about the characteristics of cardiovascular complications. Most of the evidence focuses on myocarditis or pericarditis, which are most strongly associated with mRNA vaccines and predominantly occur in young males within days of receiving the second dose. Meanwhile, post-vaccination myocardial infarction is more common in older males, and the first dose of adenoviral vector vaccines appears to play a greater role in this complication. This information may guide us in formulating alternative options and implementing targeted surveillance. Gaining more knowledge about the potential benefits and harms of COVID-19 vaccines will improve our ability to make informed decisions and judgments about the balance of these factors.

Clinicopathological and immunological features of new onset kidney disease: a rare event after SARS-CoV-2 vaccination. The onset of various kidney diseases has been reported after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. However, detailed clinical and pathological features are lacking. We screened and analyzed patients with newly diagnosed kidney diseases after inactivated SARS-CoV-2 vaccination in Peking University First Hospital from January 2021 to August 2021, and compared them with the reported cases in the literature. We obtained samples of blood, urine and renal biopsy tissues. Clinical and laboratory information, as well as light microscopy, immunostaining and ultrastructural observations, were described. The SARS-CoV-2 spike protein and nucleoprotein were stained using the immunofluorescence technique in the kidney biopsy samples. SARS-CoV-2 specific antibodies were tested using magnetic particle chemiluminescence immunoassay. The study group included 17 patients with a range of conditions including immune-complex-mediated kidney diseases (IgA nephropathy, membranous nephropathy and lupus nephritis), podocytopathy (minimal change disease and focal segmental glomerulosclerosis) and others (antineutrophil-cytoplasmic-antibody-associated vasculitis, anti-glomerular basement membrane nephritis, acute tubulointerstitial nephritis and thrombotic microangiopathy). Seven patients (41.18%) developed renal disease after the first dose and ten (58.82%) after the second dose. The kidney disease spectrum as well as clinicopathological features are similar across different types of SARS-CoV-2 vaccines. We found no definitive evidence of SARS-CoV-2 spike protein or nucleoprotein deposition in the kidney biopsy samples. Seropositive markers implicated abnormal immune responses in predisposed individuals. Treatment and follow-up (medianÂ =Â 86 days) showed that biopsy diagnosis informed treatment and prognosis in all patients. In conclusion, we observed various kidney diseases following SARS-CoV-2 vaccine administration, which show a high consistency across different types of SARS-CoV-2 vaccines. Our findings provide evidence against direct vaccine protein deposition as the major pathomechanism, but implicate abnormal immune responses in predisposed individuals. These findings expand our understanding of SARS-CoV-2 vaccine renal safety.

Ventricular arrhythmias related to COVID-19 infection and vaccination in patients with Brugada syndrome: The importance of a correct patient stratification.

COVID-19 vaccination-related myocarditis: a Korean nationwide study. AIMS: A comprehensive nationwide study on the incidence and outcomes of COVID-19 vaccination-related myocarditis (VRM) is in need. METHODS AND RESULTS: Among 44 276 704 individuals with at least 1 dose of COVID-19 vaccination, the incidence and clinical courses of VRM cases confirmed by the Expert Adjudication Committee of the Korea Disease Control and Prevention Agency were analyzed. COVID-19 VRM was confirmed in 480 cases (1.08 cases per 100 000 persons). Vaccination-related myocarditis incidence was significantly higher in men than in women (1.35 vs. 0.82 per 100 000 persons, $P < 0.001$) and in mRNA vaccines than in other vaccines (1.46 vs. 0.14 per 100 000 persons, $P < 0.001$). Vaccination-related myocarditis incidence was highest in males between the ages of 12 and 17 years (5.29 cases

per 100 000 persons) and lowest in females over 70 years (0.16 cases per 100 000 persons). Severe VRM was identified in 95 cases (19.8% of total VRM, 0.22 per 100 000 vaccinated persons), 85 intensive care unit admission (17.7%), 36 fulminant myocarditis (7.5%), 21 extracorporeal membrane oxygenation therapy (4.4%), 21 deaths (4.4%), and 1 heart transplantation (0.2%). Eight out of 21 deaths were sudden cardiac death (SCD) attributable to VRM proved by an autopsy, and all cases of SCD attributable to VRM were aged under 45 years and received mRNA vaccines. CONCLUSION: Although COVID-19 VRM was rare and showed relatively favorable clinical courses, severe VRM was found in 19.8% of all VRM cases. Moreover, SCD should be closely monitored as a potentially fatal complication of COVID-19 vaccination.

SARS-CoV-2 IgG Spike antibody levels and avidity in natural infection or following vaccination with mRNA-1273 or BNT162b2 vaccines. Certain aspects of the immunogenicity and effectiveness of the messenger ribonucleic acid (mRNA) vaccines (mRNA-1273 and BNT162b2) developed in response to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic are still uncharacterized. Serum or plasma samples from healthy donor recipients of either vaccine (BNT162b2 nâ€‰=â€‰53, mRNA-1273 nâ€‰=â€‰49; age 23-67), and individuals naturally infected with SARS-CoV-2 (nâ€‰=â€‰106; age 18-82) were collected 0-2â€‰months post-infection or 1- and 4 months after second dose of vaccination. Anti-Spike antibody levels and avidity were measured via an enzyme-linked immunosorbent assay (ELISA). Overall, vaccination induced higher circulating anti-Spike protein immunoglobulin G (IgG) antibody levels and avidity compared to infection at similar time intervals. Both vaccines produced similar anti-Spike IgG concentrations at 1â€‰month, while mRNA-1273 demonstrated significantly higher circulating antibody concentrations after 4â€‰months. mRNA-1273 induced significantly higher avidity at month 1 compared to BNT162b2 across all age groups. However, the 23-34 age group was the only group to maintain statistical significance by 4â€‰months. Male BNT162b2 recipients were approaching statistically significant lower anti-Spike IgG avidity compared to females by month 4. These findings demonstrate enhanced anti-Spike IgG levels and avidity following vaccination compared to natural infection. In addition, the mRNA-1273 vaccine induced higher antibody levels by 4â€‰months compared to BNT162b2.

Epigenomic landscape exhibits interferon signaling suppression in the patient of myocarditis after BNT162b2 vaccination. After the outbreak of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, a novel mRNA vaccine (BNT162b2) was developed at an unprecedented speed. Although most countries have achieved widespread immunity from vaccines and infections, yet people, even who have recovered from SARS-CoV-2 infection, are recommended to receive vaccination due to their effectiveness in lowering the risk of recurrent infection. However, the BNT162b2 vaccine has been reported to increase the risk of myocarditis. To our knowledge, for the first time in this study, we tracked changes in the chromatin dynamics of peripheral blood mononuclear cells (PBMCs) in the patient who underwent myocarditis after BNT162b2 vaccination. A longitudinal study of chromatin accessibility using concurrent analysis of single-cell assays for transposase-accessible chromatin with sequencing and single-cell RNA sequencing showed downregulation of interferon signaling and upregulated RUNX2/3 activity in PBMCs. Considering BNT162b2 vaccination increases the level of interferon-Î±/Î³ in serum, our data highlight the immune responses different from the conventional responses to the vaccination, which is possibly the key to understanding the side effects of BNT162b2 vaccination.

SARS-CoV-2 vaccination and relapse of glomerular disease.

Humoral response to COVID-19 vaccination and maintenance hemodialysis: Correspondence.

Retinal vein occlusion in the general population after COVID-19 vaccination and infection. INTRODUCTION: Retinal vein occlusion (RVO) is mostly a consequence of vascular risk factors (VRF). COVID-19 vaccines have been related to vascular and thrombotic events (VTE). OBJECTIVE: To assess

the RVO incidence in the general population in our health area and the possible relation with COVID-19 infection and vaccination. METHODS: Demographic features, classic VRF, thrombophilia data, COVID-19 status, and Framingham risk score were collected prospectively. RESULTS: 472 consecutive patients studied over 13 years with RVO were included (Valdecilla Cohort). Classic VRFs were present in 90%, antiphospholipid syndrome in 12.3%, and genetic thrombophilia in 13.5%. Ninety-one percent of RVO patients were vaccinated and 6.8% suffered COVID-19 infection. In the cohort, no patient had a new RVO after vaccination or infection. In the general population, 20 subjects had RVO after receiving the vaccine (0.006%). Overall, 8 cases occurred in the first-month post-vaccination and 12 after 30 days. In the early and late groups, there are 3 and 4 patients respectively, with a low-intermediate risk Framingham score. Twenty-nine patients in the cohort suffered SARS-CoV-2 infection, twenty-seven of them had RVO before infection. Two patients with low-risk Framingham scores had RVO after infection, one of them early (<1 month). CONCLUSIONS: Vaccination and COVID-19 might be involved in the development of RVO in some cases, mainly in patients without VRF, thrombophilia, or chronic inflammatory conditions and with a lower Framingham score, especially in the first month after vaccination or infection.

Acute myopericarditis and left shoulder capsulitis following second dose of mRNA SARS-CoV-2 Moderna vaccination. Vaccination against mRNA SARS-CoV-2 has been administered on a very large scale and various side effects have been described. The increased risk of myopericarditis is known, and only a few cases of shoulder capsulitis have been reported after vaccination. These two pathologies have never been reported in the same patient after vaccination. Our article presents the history of a man in his 40s who presented with myopericarditis a few days after vaccination against SARS-CoV-2 with mRNA(Messenger RNA) ModernaÂ® vaccine and who at the same time developed shoulder capsulitis. His cardiovascular symptoms resolved rapidly, and his shoulder symptoms improved/resolved within 1â€‰year. This case should make physicians aware of the possibility of several concomitant side effects following vaccination against SARS-CoV-2.

Increase in the number of new cases of ANCA-associated vasculitis in the COVID-19 vaccine era. Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) is an autoimmune vasculitis characterized by the production of antibodies against ANCA, with unclear pathogenesis. With the ongoing COVID-19 pandemic, COVID-19 mRNA vaccination has been available in Japan since February 2021. Although autoimmune symptoms have been reported after COVID-19 vaccinations, there have been no clinical investigations regarding the relationship between COVID-19 mRNA vaccines and the pathogenesis of AAV. Thus, the present study aimed to investigate whether the administration of COVID-19 mRNA vaccines affects the development of AAV. The study identified patients with new-onset AAV who were MPO-ANCA or PR3-ANCA positive and met the entry criteria of the AAV EMA classification algorithm. The study compared the number of new AAV cases per year before and after the start of the COVID-19 mRNA vaccine program in Japan. The study found that the annual number of new cases of AAV in Japan's Nagasaki Prefecture increased by approximately 1.5-fold since the COVID-19 vaccine program was initiated, suggesting a possible link between the COVID-19 mRNA vaccines and the development of AAV. Although the study provides insight into the clinical evaluation and management of autoimmune symptoms following COVID-19 vaccination, further investigation of the possible association between COVID-19 mRNA vaccines and the pathogenesis of AAV is required.

Pathways to Immunity: Patterns of Excess Death Across the United States and Within Closed Religious Communities. Public health officials promoted COVID-19 vaccines to limit burdens placed on the U.S. healthcare system and end the pandemic. People in some closed religious communities refused to vaccinate and likely acquired temporary immunity through infection. This paper compares the death rates in Amish, Old Order Mennonites, and conservative Mennonite groups to a rate estimated for the U.S. population. Approximately two-thirds of the U.S. population was immunized against

COVID-19, while few in the Amish/Mennonite community were. We find divergent patterns. Once vaccines became available, excess deaths declined in the general population and remained elevated among Amish and Mennonites. Vaccination campaigns must consider and value the cultural beliefs of closed religious communities to be effective.

Vaccine-induced immune thrombotic thrombocytopenia: what do we know hitherto? Vaccine-induced immune thrombotic thrombocytopenia (VITT), also known as thrombosis with thrombocytopenia syndrome, is a catastrophic and life-threatening reaction to coronavirus disease 2019 (COVID-19) vaccines, which occurs disproportionately in response to vaccination with non-replicating adenovirus vector (AV) vaccines. The mechanism of VITT is not well defined and it has not been resolved why cases of VITT are predominated by vaccination with AV vaccines. However, virtually all VITT patients have positive platelet-activating anti-platelet factor 4 (PF4) antibody titers. Subsequently, platelets are activated and depleted in an FcÎ³-receptor IIa (FcÎ³RIIa or CD32a)-dependent manner, but it is not clear why or how the anti-PF4 response is mounted. This review describes the pathogenesis of VITT and provides insight into possible mechanisms that prompt the formation of a PF4/polyanion complex, which drives VITT pathology, as an amalgam of current experimental data or hypotheses.

Acute myocarditis after the third dose of COVID-19 mRNA-1273 vaccine. Myocarditis caused by the mRNA-1273 coronavirus disease 2019 vaccine must be considered for patients complaining of acute constant general fatigue postvaccination.

Herpes Zoster Virus Reactivation in a 16 Year Old Female Post COVID-19 Vaccine. Case report and Review of the Literature. BACKGROUND: According to WHO, there have been 9205 fatal COVID-19 cases confirmed in Saudi Arabia out of 793,729 cases overall (5). During the development of COVID-19 vaccines, several technologies were used including DNA-based, RNA-based vaccines, non-replicating viral vector vaccines, and inactivated vaccines. OBJECTIVE: We present a case of varicella zoster virus reactivation post COVID-19 vaccine in a young medically free 16 years old female and review of the literature using the keywords "Herpes Zoster, "varicella zoster"," shingles", "post COVID-19 vaccine", "Post COVID-19 cutaneous manifestations". METHODS: The search was conducted in Google Scholar, Scopus, PubMed, and Web of Science data bases. RESULTS: We encountered 241 published studies in regard to post COVID-19 dermatologic manifestations including post COVID-19 vaccine herpes zoster reactivation in the English literature and one case in German. Our case and 4 other reported cases in the literature are patients aged of 20 years old and below. CONCLUSION: Varicella zoster virus falls under the family of Herpesviridae, It's characterized by its ability to escape host immune system and remain dormant in ganglionic neurons. Reactivation of the infection will result in herpes zoster manifesting as painful vesicles in a dermatomal distribution. Possible link is the suppression of type-one interferons caused by the mRNA-based vaccine such as COVID-19 vaccines. Yet, potential correlation remains to be demonstrated.

Deep vein thrombosis as thrombotic sequelae of vaccine-induced thrombotic thrombocytopenia. Administration of the ChAdOx1 nCoV-19 (AstraZeneca) vaccination has recently been associated with rare, unusual cases of thrombotic events. We report a case of a 55-year-old woman who presented to hospital with headaches, petechial rashes and bruising-7Â days after receiving her first vaccine dose. Blood tests showed low platelets, a markedly high d-dimer and positive anti-platelet factor 4 antibodies. Computed tomography (CT) of head and venogram showed features consistent with venous sinus thrombosis. She was immediately started on IV pooled immunoglobulin therapy, high-dose prednisolone and full anticoagulation. Subsequent magnetic resonance imaging of head and venogram supported the initial CT findings, with features suggestive of a small-volume venous sinus thrombosis. Additionally, CT pulmonary angiogram revealed a right-sided segmental pulmonary embolism. Our case highlights the importance of increased awareness of this complication after covid

vaccination and how searching for distal thrombotic events and liaison with tertiary centres influence clinical outcomes.

Association of fat-soluble vitamins (A, D, and E) status with humoral immune response to COVID-19 inactivated vaccination. BACKGROUND: Fat-soluble vitamins (A, D, and E) are essential for the proper functioning of the immune system and are of central importance for infection risk in humans. Vitamins A, D, and E have been reported to be associated with the immune response following vaccination; however, their effects on the immune response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination remain unknown. METHODS: We measured the neutralizing antibody titers against wild type and omicron within 98 days after the third homologous boosting shot of inactivated SARS-CoV-2 vaccine (BBIBP-CorV or CoronaVac) in 141 healthy adults in a prospective, open-label study. High-performance liquid chromatography-tandem mass spectroscopy was used to determine the concentrations of plasma vitamins A, D, and E. RESULTS: We found that the anti-wide-type virus and anti-omicron variant antibody levels significantly increased compared with baseline antibody levels ($P < 0.001$) after the third vaccination. 25(OH)D(3) was significantly negatively associated with the baseline anti-wide-type virus antibody concentrations [beta (95% CI) = -0.331 (-0.659 ~ -0.003)] after adjusting for covariates. A potentially similar association was also observed on day 98 after the third vaccination [beta (95% CI) = -0.317 (-0.641 ~ 0.007)]. After adjusting for covariates, we also found that 25(OH)D(3) was significantly negatively associated with the seropositivity of the anti-omicron variant antibody at day 98 after the third vaccination [OR (95% CI) = 0.940 (0.883 ~ 0.996)]. The association between plasma 25(OH)D(3) with anti-wild-type virus antibody levels and seropositivity of anti-omicron variant antibodies were persistent in subgroup analyses. We observed no association between retinol/Î±-tocopherol and anti-wide-type virus antibody levels or anti-omicron variant antibody seropositive in our study. CONCLUSION: The third inactivated SARS-CoV-2 vaccination significantly improved the ability of anti-SARS-CoV-2 infection in the human body. Higher vitamin D concentrations could significantly decrease the anti-wide-type virus-neutralizing antibody titers and anti-omicron variant antibody seropositive rate after the inactivated SARS-CoV-2 vaccination in people with adequate levels of vitamin D, better immune status, and stronger immune response; further studies comprising large cohorts of patients with different nutritional status are warranted to verify our results.

Modelling the impact of COVID-19 and routine MenACWY vaccination on meningococcal carriage and disease in the UK. Country-wide social distancing and suspension of non-emergency medical care due to the COVID-19 pandemic will undoubtedly have affected public health in multiple ways. While non-pharmaceutical interventions are expected to reduce the transmission of several infectious diseases, severe disruptions to healthcare systems have hampered diagnosis, treatment, and routine vaccination. We examined the effect of this disruption on meningococcal disease and vaccination in the UK. By adapting an existing mathematical model for meningococcal carriage, we addressed the following questions: What is the predicted impact of the existing MenACWY adolescent vaccination programme? What effect might social distancing and reduced vaccine uptake both have on future epidemiology? Will catch-up vaccination campaigns be necessary? Our model indicated that the MenACWY vaccine programme was generating substantial indirect protection and suppressing transmission by 2020. COVID-19 social distancing is expected to have accelerated this decline, causing significant long-lasting reductions in both carriage prevalence of meningococcal A/C/W/Y strains and incidence of invasive meningococcal disease. In all scenarios modelled, pandemic social mixing effects outweighed potential reductions in vaccine uptake, causing an overall decline in carriage prevalence from 2020 for at least 5Â years. Model outputs show strong consistency with recently published case data for England.

Systemic lupus erythematosus myocarditis and COVID-19 vaccination: Comment.

Female reproduction and abnormal uterine bleeding after COVID-19 vaccination. Coronavirus disease 2019 (COVID-19) vaccines have been widely administered throughout the global community to minimize the morbidity and mortality caused by the COVID-19 pandemic. Although generally well-tolerated, these vaccines have generated some unwanted consequences, including thrombosis and menstrual irregularities. The effect of vaccination on female reproductive function has also been questioned. The aim of this review is to give readers a clear understanding of the effects of COVID-19 vaccines on thrombosis, reproductive function, and menstrual irregularities by systemically analyzing the available literature. The available evidence suggests that COVID-19 vaccines have a minimal impact on ovarian reserve. Furthermore, in vitro fertilization outcomes after COVID-19 vaccination remain unimpaired compared to those who did not receive the vaccines. Current evidence supports a certain degree of impact of COVID-19 vaccines on the menstrual cycle, with the most frequent alteration being menstrual irregularity, followed by menorrhagia. These changes are generally well-tolerated and transient, lasting less than 2 months. This review, by providing information with up-to-date references on this issue, may enhance readers' understanding of the impact of COVID-19 vaccines on female reproductive function and the menstrual cycle.

Dose-Dependent Production of Anti-PEG IgM after Intramuscular PEGylated-Hydrogenated Soy Phosphatidylcholine Liposomes, but Not Lipid Nanoparticle Formulations of DNA, Correlates with the Plasma Clearance of PEGylated Liposomal Doxorubicin in Rats. PEGylated lipid nanoparticle-based Covid-19 vaccines, including Pfizer's BNT162b2 and Moderna's mRNA-1273, have been shown to stimulate variable anti-PEG antibody production in humans. Anti-PEG antibodies have the potential to accelerate the plasma clearance of PEGylated therapeutics, such as PEGylated liposomes and proteins, and compromise their therapeutic efficacy. However, it is not yet clear whether antibody titers produced by PEGylated Covid-19 vaccines significantly affect the clearance of PEGylated therapeutics. This study examined how anti-PEG IgM levels affect the pharmacokinetics of PEGylated liposomal doxorubicin (PLD) and compared the immunogenicity of a lipid nanoparticle formulation of linear DNA (DNA-LNP) to standard PEG-HSPC liposomes. DNA-LNP was prepared using the same composition and approach as Pfizer's BNT162b2, except linear double-stranded DNA was used as the genetic material. PEGylated HSPC-based liposomes were formulated using the lipid rehydration and extrusion method. Nanoparticles were dosed IM to rats at 0.005-0.5 mg lipid/kg body weight 1 week before evaluating the plasma pharmacokinetics of clinically relevant doses of PLD (1 mg/kg, IV) or PEGylated interferon Î±2a (Pegasys, 5 Î¼g/kg, SC). Plasma PEG IgM was compared between pre- and 1-week post-dose blood samples. The results showed that anti-PEG IgM production increased with increasing PEG-HSPC liposome dose and that IgM significantly correlated with the plasma half-life, clearance, volume of distribution, and area under the curve of a subsequent dose of PLD. The plasma exposure of Pegasys was also significantly reduced after initial delivery of 0.005 mg/ml PEG-HSPC liposome. However, a single 0.05 mg/kg IM dose of DNA-LNP did not significantly elevate PEG IgM and did not alter the IV pharmacokinetics of PLD. These data showed that PEGylated Covid-19 vaccines are less immunogenic compared to standard PEGylated HSPC liposomes and that there is an antibody threshold for accelerating the clearance of PEGylated therapeutics.

Bivalent mRNA COVID-19 Vaccine-Related Pericarditis on 18 F-FDG PET/CT. A 13-year-old boy was suspected with pericarditis after a second booster dose of bivalent mRNA COVID-19 vaccine. After specific preparation for cardiac inflammation with carbohydrate-free, high-fat diet, the 18 F-FDG PET/CT successfully demonstrated simultaneous presentation of vaccination-related axillary lymphadenopathy and pericarditis without the interference of physiological myocardial uptake.

Changing Severity and Epidemiology of Adults Hospitalized With Coronavirus Disease 2019 (COVID-19) in the United States After Introduction of COVID-19 Vaccines, March 2021-August 2022. INTRODUCTION: Understanding the changing epidemiology of adults hospitalized with coronavirus

disease 2019 (COVID-19) informs research priorities and public health policies. METHODS: Among adults (â‰¥18 years) hospitalized with laboratory-confirmed, acute COVID-19 between 11 March 2021, and 31 August 2022 at 21 hospitals in 18 states, those hospitalized during the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron-predominant period (BA.1, BA.2, BA.4/BA.5) were compared to those from earlier Alpha- and Delta-predominant periods. Demographic characteristics, biomarkers within 24 hours of admission, and outcomes, including oxygen support and death, were assessed. RESULTS: Among 9825 patients, median (interquartile range [IQR]) age was 60 years (47-72), 47% were women, and 21% non-Hispanic Black. From the Alpha-predominant period (Mar-Jul 2021; N = 1312) to the Omicron BA.4/BA.5 sublineage-predominant period (Jun-Aug 2022; N = 1307): the percentage of patients who had â‰¥4 categories of underlying medical conditions increased from 11% to 21%; those vaccinated with at least a primary COVID-19 vaccine series increased from 7% to 67%; those â‰¥75 years old increased from 11% to 33%; those who did not receive any supplemental oxygen increased from 18% to 42%. Median (IQR) highest C-reactive protein and D-dimer concentration decreased from 42.0 mg/L (9.9-122.0) to 11.5 mg/L (2.7-42.8) and 3.1 mcg/mL (0.8-640.0) to 1.0 mcg/mL (0.5-2.2), respectively. In-hospital death peaked at 12% in the Delta-predominant period and declined to 4% during the BA.4/BA.5-predominant period. CONCLUSIONS: Compared to adults hospitalized during early COVID-19 variant periods, those hospitalized during Omicron-variant COVID-19 were older, had multiple co-morbidities, were more likely to be vaccinated, and less likely to experience severe respiratory disease, systemic inflammation, coagulopathy, and death.

Correspondence on the evaluation of patients with COVID-19 vaccine side effects.

Answers to comments on "Comparison of severe acute respiratory syndrome coronavirus 2 (COVID-19) vaccine side effects by age groups".

The Prevalence of Side Effects of Sinopharm COVID-19 Vaccine: An Experience From Pakistan. Introduction Vaccination for coronavirus disease 2019 (COVID-19) helps develop protective immunity against COVID-19 without experiencing potentially severe illness. Many vaccines are used worldwide, but there is little data on the efficacy and side effects of the Sinopharm vaccine. Therefore, this study aimed to investigate the reported adverse effects of the Sinopharm vaccine among participants. Methods This prospective cross-sectional study was conducted in multiple hospitals in Karachi, Pakistan. The study was eight months, from April 1, 2022, to November 30, 2022. A total of 600 participants who gave informed consent and had received their first and second doses of the Sinopharm vaccine were included in the study. As hypertension and diabetes mellitus (DM) are common prevalent conditions in our population, the duration of DM and hypertension were documented as means and standard deviations apart from age, height, and weight. Side effects of the Sinopharm vaccine were reported as frequencies and percentages. Results The study findings showed that out of 600 participants, 376 (62.7%) were males and 224 (37.3%) were females; their mean age was 42.79Â±14.44 years. Among them, 130 (21.7%) had hypertension, and 138 (23.0%) had DM. All participants received the Sinopharm vaccine. Fever was the most frequently reported adverse effect following the first dose of the Sinopharm vaccine in 308 (51.3% of participants), followed by burning at the injection site in 244 (40.7% of participants) and pain at the injection site in 228 (38.0% of participants). Following the second dose of the Sinopharm vaccine, fever was the most frequently reported side effect in 254 (42.3%) participants, followed by pain at the injection site in 236 (39.5%) participants and burning at the site of injection in 210 (35.0%) participants. Moreover, joint pain in 194 (32.3%), shortness of breath in 170 (28.3%), swelling of glands in 168 (28.0%), chest pain in 164 (27.3%), and muscle pain were reported by 140 (23.3%) participants. The level of satisfaction showed that the majority of the participants, 334 (55.7%), were satisfied, 132 (22.0%) were very satisfied with their vaccination, and only 12 (2.0%) were dissatisfied. Conclusion This study concluded that fever

was the most frequent side effect after both doses of the Sinopharm vaccine. Pain and burning at the injection site and joint pain were among the other common side effects reported by most participants. The Sinopharm COVID-19 vaccine had mild, predictable, and non-life-threatening side effects after the first and second doses.

Coronavirus Disease 2019 Vaccine-Induced Flare-Up of Severe Bronchial Asthma Previously Controlled With Dupilumab: A Case Report. The widespread after-effects of the coronavirus disease 2019 (COVID-19) are still a grave threat worldwide. Among themÂ are adverse reactions to vaccines, including those most observed following Pfizer-BioNTech (BNT162b2) vaccine administration, namely, local reactions at the injection site, fatigue, headache, myalgia, chills, arthralgia, and fever. Patients with asthma particularly present with unique adverse reactions to the BNT162b2 vaccine, notably, an exacerbation in their asthma symptoms as highlighted through the current case report. In this case, a 50-year-old woman had been undergoing treatment for bronchial asthma in the form of inhalation steroids and dupilumab, as well as systemic steroid prednisolone as maintenance therapy. She had mild injection site reactions after her first three COVID-19 vaccinations. She also experienced acute exacerbation requiring hospitalization after the fourth and fifth doses. Her symptoms resolved following steroid therapy. The close association between the timing of vaccinations and the onset of clinical symptoms suggests that the exacerbation episodes were triggered by the vaccine. Therefore, although the BNT162b2 vaccine is safe to administer in patients with bronchial asthma, cases reporting patients sensitized to the BNT162b2 vaccine developing bronchial asthma or experiencing asthma exacerbations should not be neglected. Clinicians should be aware of the possibility of flare-ups induced by repeated COVID-19 vaccinations in such patients.

Thrombocytopenia Secondary to COVID-19 Vaccination: Side Effect or Coincidence? Â While widespread coronavirus disease 2019 (COVID-19) vaccination has helped achieve some control of the pandemic, vaccines have presented with side effects of their own, both common and rare. We present an unusual case of a 66-year-old who presented with severe thrombocytopenia following vaccination with the Pfizer-BioNTech mRNA vaccine. Our patient is a 66-year-old African American female with a known history of Sjogren's syndrome and hepatitis C who presented to our facility as a direct admit from our affiliated infusion clinic where routine lab work revealed a platelet count of 14,000. On arrival, she reported a one-month history of progressive tiredness, intermittent epistaxis, and bruising on her legs. Her physical exam was notable for multiple petechiae and non-palpable purpura on all four extremities. Further questioning revealed that she had received her COVID-19 vaccine booster (Pfizer-BioNTech) three weeks prior to presentation and that is when all the symptoms had started. Rheumatology was consulted and the patient was started on intravenous immunoglobulin infusion for two days and pulse dose prednisone. Her platelet count showed improvement after treatment, and she was discharged home with a platelet count of 42,000. Though largely safe and efficacious, COVID-19 vaccines can present with rare systemic side effects and physicians must have a high index of suspicion and report these cases so that more data is available for interpretation.

New-onset Thyroid Eye Disease after COVID-19 Vaccination in a Radioactive Iodine-Treated Graves' Disease Patient: A Case Report and Literature Review. Autoimmunity associated with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) has been well-described as the mechanism of development of thyroid dysfunction following Coronavirus Disease 19 (COVID-19) infection and SARS-CoV-2 vaccination. However, the occurrence of thyroid eye disease (TED) after SARS-CoV-2 vaccination is scarcely described. The postulated mechanisms include immune reactivation, molecular mimicry and the autoimmune/inflammatory syndrome induced by adjuvants (ASIA). We report a case of new-onset TED after receiving the SARS-CoV-2 vaccine.

Observational Study of Patients Hospitalized With Neurologic Events After SARS-CoV-2 Vaccination, December 2020-June 2021. BACKGROUND AND OBJECTIVES: The global spread of the COVID-19 pandemic accelerated the vaccine development time line, regulatory approval, and widespread implementation in the population underscoring the importance of postauthorization/postlicensure vaccine safety surveillance. To monitor for vaccine-related adverse events, we prospectively identified patients hospitalized for prespecified neurologic conditions who received mRNA or adenovirus COVID-19 vaccines and assessed cases for potential risk factors and alternative etiologies of the adverse event. METHODS: We identified prespecified neurologic conditions in hospitalized individuals within 6 weeks of receipt of a dose of any COVID-19 vaccination between December 11, 2020, and June 22, 2021 (Columbia University Irving Medical Center/New York Presbyterian Hospital, New York City, New York). Clinical data from electronic medical records in these vaccinated patients were reviewed for assessment of contributing risk factors and etiologies for these neurologic conditions by use of a published algorithm. RESULTS: Among 3,830 individuals screened for COVID-19 vaccination status and neurologic conditions, 138 (3.6%) cases were included in this study (126 after mRNA and 6 after Janssen vaccines). The 4 most prevalent neurologic syndromes included ischemic stroke (52, 37.7%), encephalopathy (45, 32.6%), seizure (22, 15.9%), and intracranial hemorrhage (ICH) (13, 9.4%). All 138 cases (100%) had 1 or more risk factors and/or evidence for established causes. Metabolic derangement was the most common etiology for seizures (24, 53.3%) and encephalopathy (5, 22.7%) while hypertension was the most significant risk factor in ischemic stroke (45, 86.5%) and ICH cases (4, 30.8%). DISCUSSION: All cases in this study were determined to have at least 1 risk factor and/or known etiology accounting for their neurologic syndromes. Our comprehensive clinical review of these cases supports the safety of mRNA COVID-19 vaccines.

Prolonged generalized immune response on (18)F-FDG PET/CT following COVID-19 vaccination. The Coronavirus disease 2019 (COVID-19) pandemic continues to be a major public health concern affecting millions of people globally. The COVID-19 vaccination has implications in medical assessment of cancer patients especially undergoing diagnostic imaging such as (18)F-fluoro-deoxyglucose (FDG) positron emission tomography with computed tomography (PET/CT). The inflammatory changes following vaccination can cause false positive findings on imaging. We present a case of a patient with esophageal carcinoma who had (18)F-FDG PET/CT scan, 8 weeks following booster dose of Moderna COVID-19 vaccination, which showed widespread FDG avid reactive lymph nodes and intense splenic uptake for prolonged duration of approximately 8 months (34 weeks) probably representing generalized immune response. It is important from radiological/nuclear medicine perspective to recognize imaging features of such rare effect of COVID-19 vaccination, which can pose a challenge in assessing (18)F-FDG PET/CT scans in cancer patients. It has also opened new avenues for future research evaluating such COVID-19 vaccine-related prolonged systemic immunological response in cancer patients.

Postural orthostatic tachycardia syndrome-like symptoms following COVID-19 vaccination: An overview of clinical literature. BACKGROUND: Postural Orthostatic Tachycardia Syndrome (POTS) is a common condition affecting more than 170 people per 100,000 population. However, POTS following COVID-19 vaccination remains a rare reporting in the medical literature. OBJECTIVE: We, herein, summarize and highlight the evidence that has been reported regarding POTS-like symptoms following COVID-19 vaccination. METHODS: We conducted a literature search and summarized the findings in the form of a narrative commentary. All types of publications (case reports/series, original articles, letters to editors, brief communications etc.) in English language were included. RESULTS: Whilst the exact pathogenetic mechanism behind POTS is yet to elucidated, there has been increasing evidence pointing towards an autoimmune dysfunction. Females were found to be predominantly affected (72%) with age range from 17 years to 52 years. Additionally, it seems that POTS-like

symptoms could be triggered after immunization with Pfizer- BioNTech, Moderna, and Oxford-AstraZeneca COVID-19 vaccines. The symptoms typically appear within the first week, depending upon previous exposure to the virus and presence of other systemic conditions. In some patients, the condition is self-resolving. However, in others, non-pharmacological interventions coupled with negative ionotropic medications can be used for symptomatic management of the patients. CONCLUSIONS: Timely diagnosis and proper treatment are quintessential for ensuring early alleviation (and in some cases complete resolution) of symptoms. Furthermore, there may be episodes of relapse. Overall prognosis of the new-onset POTS-like symptoms is difficult to predict based on current literature.

Immunity to COVID after vaccination in First Nations peoples is affected by comorbidities.

COVID-19 vaccine safety inquiries to the centers for disease control and prevention immunization safety office. BACKGROUND: Following the authorization and recommendations for use of the U.S. COVID-19 vaccines, the Centers for Disease Control and Prevention (CDC)'s Immunization Safety Office (ISO) responded to inquiries and questions from public health officials, healthcare providers, and the general public on COVID-19 vaccine safety. METHODS: We describe COVID-19 vaccine safety inquiries, by topic, received and addressed by ISO from December 1, 2020-August 31, 2022. RESULTS: Of the 1978 COVID-19 vaccine-related inquiries received, 1655 specifically involved vaccine safety topics. The most frequently asked-about topics included deaths following vaccination, myocarditis, pregnancy, and reproductive health outcomes, understanding or interpreting data from the Vaccine Adverse Event Reporting System (VAERS), and thrombosis with thrombocytopenia syndrome. CONCLUSIONS: Inquiries about vaccine safety generally reflect issues that receive media attention. ISO will continue to monitor vaccine safety inquiries and provide accurate and timely information to healthcare providers, public health officials, and the general public.

Infectious complications following CAR-t cell therapy for B cell non-Hodgkin lymphoma: a single-center experience and review of the literature. Chimeric antigen receptor T-cell (CAR-T) therapy targeting CD19 has significantly improved outcomes in the treatment of refractory or relapsed (R/R) B-cell non-Hodgkin lymphoma (NHL). Several risk factors including CAR-T cell-related toxicities and their treatments often lead to infectious complications (ICs); however, the pattern and timeline is not well established. We evaluated ICs in 48 patients with R/R B-cell NHL following CAR-T cell therapy at our institution. Overall, 15 patients experienced 22 infection events. Eight infections (4 bacterial, 3 viral and 1 fungal) occurred within the first 30 days and 14 infections (7 bacterial, 6 viral, 1 fungal) between days 31 to 180 following CAR-T infusion. Most infections were mild-to-moderate and fifteen infections involved the respiratory tract. Two patients developed mild-to-moderate COVID-19 infection and one patient a cytomegalovirus reactivation after CAR-T infusion. Two patients developed IFIs: one case each of fatal disseminated candidiasis and invasive pulmonary aspergillosis at day 16 and 77, respectively. Patients with more than 4 prior antitumor regimens and patient's â‰¥ 65 years had a higher infection rate. Infections in patients with relapsed/refractory B-cell NHL are common after CAR-T despite the use of infection prophylaxis. Age â‰¥ 65 years and having > 4 prior antitumor treatments were identified as risk factors for infection. Fungal infections carried significant impact in morbidity and mortality, suggesting a role for increase fungal surveillance and/or anti-mold prophylaxis following high-dose steroids and tocilizumab. Four of ten patients developed an antibody response following two doses of SARS-CoV-2 mRNA vaccine.

Safety, efficacy, and immunogenicity of the NVX-CoV2373 vaccine. INTRODUCTION: The coronavirus disease 2019 (COVID-19) pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has resulted in significant morbidity and mortality worldwide. As SARS-CoV-2 moves into endemic status, vaccination remains a key element in protecting the health of individuals, societies, and economies worldwide. AREAS COVERED: NVX-CoV2373 (Novavax,

Gaithersburg, MD) is a recombinant protein vaccine composed of SARS-CoV-2 spike trimer nanoparticles formulated with saponin-based Matrix-Mâ„¢ adjuvant (Novavax, Gaithersburg, MD). NVX-CoV2373 is authorized for emergency use in adults and adolescents aged â‰¥12â€‰years in the United States and numerous other countries. EXPERT OPINION: In clinical trials, NVX-CoV2373 showed tolerable reactogenicity and favorable safety profiles characterized by mostly mild-to-moderate adverse events of short duration and by low rates of severe and serious adverse events comparable to those seen with placebo. The two-dose primary vaccination series resulted in robust increases in anti-spike protein immunoglobulin G, neutralizing antibody titers, and cellular immune responses. NVX-CoV2373 vaccination was associated with complete protection against severe disease and a high (90%) rate of protection against symptomatic disease in adults, including symptomatic disease caused by SARS-CoV-2 variants. Additionally, the NVX-CoV2373 adjuvanted recombinant protein platform offers a means to address issues of COVID-19 vaccination hesitancy and global vaccine equity.

Safety and immunogenicity of homologous versus heterologous boosters and COVID-19 vaccine hesitancy: Is there any link?

Incidence of myopericarditis after mRNA COVID-19 vaccination: A meta-analysis with focus on adolescents aged 12-17Â years. BACKGROUND: The incidence of myopericarditis after mRNA COVID-19 vaccination among adolescents aged 12-17Â years remains unknown. Therefore, we conducted a study to pool the incidence of myopericarditis following COVID-19 vaccination in this age group. METHODS: We did a meta-analysis by searching 4 electronic databases until February 6, 2023. The following main keywords were used: "COVID-19", "vaccines", "myocarditis", "pericarditis", and "myopericarditis". Observational studies reporting on adolescents aged 12-17Â years who had myopericarditis in temporal relation to receiving mRNA COVID-19 vaccines were included. The pooled incidence of myopericarditis and 95 % confidence interval (CI) were calculated using a single-group meta-analysis. RESULTS: Fifteen studies were included. The pooled incidences of myopericarditis after mRNA COVID-19 vaccination among adolescents aged 12-17Â years were 43.5 (95 % CI, 30.8-61.6) cases per million vaccine doses for both BNT162b2 and mRNA-1273 (39 628 242 doses; 14 studies), and 41.8 (29.4-59.4) cases for BNT162b2 alone (38 756 553 doses; 13 studies). Myopericarditis was more common among males (66.0 [40.5-107.7] cases) than females (10.1 [6.0-17.0] cases) and among those receiving the second dose (60.4 [37.6-96.9] cases) than those receiving the first dose (16.6 [8.7-31.9] cases). The incidences of myopericarditis did not differ significantly when grouped by age, type of myopericarditis, country, and World Health Organization region. None of the incidences of myopericarditis pooled in the current study were higher than those after smallpox vaccinations and non-COVID-19 vaccinations, and all of them were significantly lower than those in adolescents aged 12-17Â years after COVID-19 infection. CONCLUSIONS: The incidences of myopericarditis after mRNA COVID-19 vaccination among adolescents aged 12-17Â years were very rare; they were not higher than other important reference incidences. These findings provide an important context for health policy makers and parents with vaccination hesitancy to weight the risks and benefits of mRNA COVID-19 vaccination among adolescents aged 12-17Â years.

Characteristics of immune response profile in patients with immediate allergic and autoimmune urticarial reactions induced by SARS-CoV-2 vaccines. Severe allergic reactions following SARS-COV-2 vaccination are generally rare, but the reactions are increasingly reported. Some patients may develop prolonged urticarial reactions following SARS-COV-2 vaccination. Herein, we investigated the risk factors and immune mechanisms for patients with SARS-COV-2 vaccines-induced immediate allergy and chronic urticaria (CU). We prospectively recruited and analyzed 129 patients with SARS-COV-2 vaccine-induced immediate allergic and urticarial reactions as well as 115 SARS-COV-2 vaccines-tolerant individuals from multiple medical centers during 2021-2022. The clinical

manifestations included acute urticaria, anaphylaxis, and delayed to chronic urticaria developed after SARS-COV-2 vaccinations. The serum levels of histamine, IL-2, IL-4, IL-6, IL-8, IL-17Â A, TARC, and PARC were significantly elevated in allergic patients comparing to tolerant subjects (P-valuesÂ =Â 4.5Â Ã—Â 10(-5)-0.039). Ex vivo basophil revealed that basophils from allergic patients could be significantly activated by SARS-COV-2 vaccine excipients (polyethylene glycol 2000 and polysorbate 80) or spike protein (P-values from 3.5Â Ã—Â 10(-4) to 0.043). Further BAT study stimulated by patients' autoserum showed positive in 81.3% of patients with CU induced by SARS-COV-2 vaccination (PÂ =Â 4.2Â Ã—Â 10(-13)), and the reactions could be attenuated by anti-IgE antibody. Autoantibodies screening also identified the significantly increased of IgE-anti-IL-24, IgG-anti-FcÎµRI, IgG-anti-thyroid peroxidase (TPO), and IgG-anti-thyroid-related proteins in SARS-COV-2 vaccines-induced CU patients comparing to SARS-COV-2 vaccines-tolerant controls (P-valuesÂ =Â 4.6Â Ã—Â 10(-10)-0.048). Some patients with SARS-COV-2 vaccines-induced recalcitrant CU patients could be successfully treated with anti-IgE therapy. In conclusion, our results revealed that multiple vaccine components, inflammatory cytokines, and autoreactive IgG/IgE antibodies contribute to SARS-COV-2 vaccine-induced immediate allergic and autoimmune urticarial reactions.

Relapse of minimal change disease following the third mRNA COVID-19 vaccination: a case report and literature review. Mass vaccination is the most important strategy to terminate the coronavirus disease 2019 (COVID-19) pandemic. Reports suggest the potential risk of the development of new-onset or relapse of minimal change disease (MCD) following COVID-19 vaccination; however, details on vaccine-associated MCD remain unclear. A 43-year-old man with MCD, who had been in remission for 29Â years, developed nephrotic syndrome 4Â days after receiving the third dose of the Pfizer-BioNTech vaccine. His kidney biopsy revealed relapsing MCD. Intravenous methylprednisolone pulse therapy followed by oral prednisolone therapy was administered, and his proteinuria resolved within 3Â weeks. This report highlights the importance of careful monitoring of proteinuria after COVID-19 vaccination in patients with MCD, even if the disease is stable and no adverse events occurred during previous vaccinations. Our case report and literature review of COVID-19 vaccine-associated MCD indicated that MCD relapse tends to occur later after vaccination and slightly more often following the second and subsequent vaccine doses than new-onset MCD.

Randomized trial to evaluate the safety, tolerability, and immunogenicity of a booster (third dose) of BNT162b2 COVID-19 vaccine coadministered with 20-valent pneumococcal conjugate vaccine in adultsÂ â‰¥65 years old. BACKGROUND: Older adults are at increased risk of adverse outcomes from pneumococcal disease and COVID-19. Vaccination is an established strategy for preventing both illnesses. This study evaluated the safety and immunogenicity of coadministration of the 20-valent pneumococcal conjugate vaccine (PCV20) and a booster (third dose) of BNT162b2 COVID-19 vaccine. METHODS: This phase 3, randomized, double-blind, multicentre study included 570 participants agedÂ â‰¥65Â years randomized 1:1:1 to PCV20 and BNT162b2 coadministered, or PCV20 or BNT162b2 only (administered with saline for blinding). Primary safety endpoints included local reactions, systemic events, adverse events (AEs) and serious AEs (SAEs). Secondary objectives were immunogenicity of PCV20 and BNT162b2 when administered together or separately. RESULTS: Coadministration of PCV20 and BNT162b2 was well tolerated. Local reactions and systemic events were generally mild-moderate; injection-site pain and fatigue were the most frequent local and systemic events, respectively. AE and SAE rates were low and similar across groups. No AEs led to discontinuation; no SAEs were considered vaccination-related. Robust immune responses were observed, with opsonophagocytic activity geometric mean fold rises (GMFRs; from baseline to 1Â month) of 2.5-24.5 and 2.3-30.6 across PCV20 serotypes in Coadministration and PCV20-only groups, respectively. GMFRs for full-length S-binding IgG of 35.5 and 39.0, and for neutralizing titres against SARS-CoV-2-wild type virus of 58.8 and 65.4, were observed in the Coadministration and

BNT162b2-only groups, respectively. CONCLUSIONS: Safety and immunogenicity of coadministered PCV20 and BNT162b2 were similar to those of PCV20 or BNT162b2 administered alone, suggesting that the 2 vaccines may be coadministered. TRIAL REGISTRATION: ClinicalTrials.gov, NCT04887948.

Evaluation of association of anti-PEG antibodies with anaphylaxis after mRNA COVID-19 vaccination. BACKGROUND: The mechanism for anaphylaxis following mRNA COVID-19 vaccination has been widely debated; understanding this serious adverse event is important for future vaccines of similar design. A mechanism proposed is type I hypersensitivity (i.e., IgE-mediated mast cell degranulation) to polyethylene glycol (PEG). Using an assay that, uniquely, had been previously assessed in patients with anaphylaxis to PEG, our objective was to compare anti-PEG IgE in serum from mRNA COVID-19 vaccine anaphylaxis case-patients and persons vaccinated without allergic reactions. Secondarily, we compared anti-PEG IgG and IgM to assess alternative mechanisms. METHODS: Selected anaphylaxis case-patients reported to U.S. Vaccine Adverse Event Reporting System December 14, 2020-March 25, 2021 were invited to provide a serum sample. mRNA COVID-19 vaccine study participants with residual serum and no allergic reaction post-vaccination ("controls") were frequency matched to cases 3:1 on vaccine and dose number, sex and 10-year age category. Anti-PEG IgE was measured using a dual cytometric bead assay (DCBA). Anti-PEG IgG and IgM were measured using two different assays: DCBA and a PEGylated-polystyrene bead assay. Laboratorians were blinded to case/control status. RESULTS: All 20 case-patients were women; 17 had anaphylaxis after dose 1, 3 after dose 2. Thirteen (65â€¯%) were hospitalized and 7 (35â€¯%) were intubated. Time from vaccination to serum collection was longer for case-patients vs controls (post-dose 1: median 105 vs 21â€¯days). Among Moderna recipients, anti-PEG IgE was detected in 1 of 10 (10â€¯%) case-patients vs 8 of 30 (27â€¯%) controls (pâ€¯=â€¯0.40); among Pfizer-BioNTech recipients, it was detected in 0 of 10 case-patients (0â€¯%) vs 1 of 30 (3â€¯%) controls (pâ€¯>nâ€¯0.99). Anti-PEG IgE quantitative signals followed this same pattern. Neither anti-PEG IgG nor IgM was associated with case status with both assay formats. CONCLUSION: Our results support that anti-PEG IgE is not a predominant mechanism for anaphylaxis post-mRNA COVID-19 vaccination.

Association between reactogenicity and immunogenicity after BNT162b2 booster vaccination: a secondary analysis of a prospective cohort study. OBJECTIVES: A weak correlation between symptom severity and antibody levels after primary immunization against COVID-19 has already been shown. This study aimed to describe the association between reactogenicity and immunogenicity after booster vaccination. METHODS: This secondary analysis of a prospective cohort study included 484 healthcare workers who received a booster vaccination with BNT162b2. Anti-receptor binding domain (RBD) antibodies were assessed at baseline and 28Â days after booster vaccination. Side effects were graded (none, mild, moderate, or severe) and reported daily for 7Â days after booster vaccination. Spearman correlation coefficient (rho) was used to determine the correlations between the severity of each symptom and anti-RBD levels before vaccination and 28Â days after. The Bonferroni method was used to adjust p values for multiple comparisons. RESULTS: Most of the 484 participants reported at least one local (451 [93.2%]) or systemic (437 [90.3%]) post-booster symptom. No correlations between the severity of local symptoms and antibody levels were found. Except for nausea, systemic symptoms showed weak but statistically significant correlations with 28-day anti-RBD levels (fatigue [rhoÂ =Â 0.23, pÂ <Â 0.01], fever [rhoÂ =Â 22, pÂ <Â 0.01], headache [rhoÂ =Â 0.15, p 0.03], arthralgia [rhoÂ =Â 0.2, pÂ <Â 0.01], myalgia [rhoÂ =Â 0.17, pÂ <Â 0.01]). There was no association between post-booster symptoms and pre-booster antibody levels. DISCUSSION: This study showed only a weak correlation between the severity of systemic post-booster symptoms and anti-SARS-CoV-2 antibody levels at 28Â days. Therefore, self-reported symptom severity cannot be used to predict immunogenicity after booster vaccination.

Safety of SARS-CoV-2 vaccines in patients with myasthenia gravis: a meta-analysis.

Short- and Long-Interval Prime-Boost Vaccination with the Candidate Vaccines MVA-SARS-2-ST and MVA-SARS-2-S Induces Comparable Humoral and Cell-Mediated Immunity in Mice. The COVID-19 pandemic caused significant human health and economic consequences. Due to the ability of SARS-CoV-2 to spread rapidly and to cause severe disease and mortality in certain population groups, vaccines are essential for controlling the pandemic in the future. Several licensed vaccines have shown improved protection against SARS-CoV-2 after extended-interval prime-boost immunizations in humans. Therefore, in this study, we aimed to compare the immunogenicity of our two Modified Vaccinia virus Ankara (MVA) based COVID-19 candidate vaccines MVA-SARS-2-S and MVA-SARS-2-ST after short- and long-interval prime-boost immunization schedules in mice. We immunized BALB/c mice using 21-day (short-interval) or 56-day (long-interval) prime-boost vaccination protocols and analyzed spike (S)-specific CD8 T cell immunity and humoral immunity. The two schedules induced robust CD8 T cell responses with no significant differences in their magnitude. Furthermore, both candidate vaccines induced comparable levels of total S, and S2-specific IgG binding antibodies. However, MVA-SARS-2-ST consistently elicited higher amounts of S1-, S receptor binding domain (RBD), and SARS-CoV-2 neutralizing antibodies in both vaccination protocols. Overall, we found very comparable immune responses following short- or long-interval immunization. Thus, our results suggest that the chosen time intervals may not be suitable to observe potential differences in antigen-specific immunity when testing different prime-boost intervals with our candidate vaccines in the mouse model. Despite this, our data clearly showed that MVA-SARS-2-ST induced superior humoral immune responses relative to MVA-SARS-2-S after both immunization schedules.

Booster Dose of SARS-CoV-2 mRNA Vaccine in Kidney Transplanted Patients Induces Wuhan-Hu-1 Specific Neutralizing Antibodies and T Cell Activation but Lower Response against Omicron Variant. Kidney transplanted recipients (KTR) are at high risk of severe SARS-CoV-2 infection due to immunosuppressive therapy. Although several studies reported antibody production in KTR after vaccination, data related to immunity to the Omicron (B.1.1.529) variant are sparse. Herein, we analyzed anti-SARS-CoV-2 immune response in seven KTR and eight healthy controls after the second and third dose of the mRNA vaccine (BNT162b2). A significant increase in neutralizing antibody (nAb) titers were detected against pseudoviruses expressing the Wuhan-Hu-1 spike (S) protein after the third dose in both groups, although nAbs in KTR were lower than controls. nAbs against pseudoviruses expressing the Omicron S protein were low in both groups, with no increase after the 3rd dose in KTR. Reactivity of CD4(+) T cells after boosting was observed when cells were challenged with Wuhan-Hu-1 S peptides, while Omicron S peptides were less effective in both groups. IFN-Î³ production was detected in KTR in response to ancestral S peptides, confirming antigen-specific T cell activation. Our study demonstrates that the 3rd mRNA dose induces T cell response against Wuhan-Hu-1 spike peptides in KTR, and an increment in the humoral immunity. Instead, humoral and cellular immunity to Omicron variant immunogenic peptides were low in both KTR and healthy vaccinated subjects.

Effect of Vaccination on Platelet Mitochondrial Bioenergy Function of Patients with Post-Acute COVID-19. BACKGROUND: Mitochondrial dysfunction and redox cellular imbalance indicate crucial function in COVID-19 pathogenesis. Since 11 March 2020, a global pandemic, health crisis and economic disruption has been caused by SARS-CoV-2 virus. Vaccination is considered one of the most effective strategies for preventing viral infection. We tested the hypothesis that preventive vaccination affects the reduced bioenergetics of platelet mitochondria and the biosynthesis of endogenous coenzyme Q(10) (CoQ(10)) in patients with post-acute COVID-19. MATERIAL AND METHODS: 10 vaccinated patients with post-acute COVID-19 (V + PAC19) and 10 unvaccinated patients with post-acute COVID-19 (PAC19) were included in the study. The control group (C) consisted of 16 healthy volunteers. Platelet mitochondrial bioenergy function was determined with

HRR method. CoQ(10), Î³-tocopherol, Î±-tocopherol and Î²-carotene were determined by HPLC, TBARS (thiobarbituric acid reactive substances) were determined spectrophotometrically. RESULTS: Vaccination protected platelet mitochondrial bioenergy function but not endogenous CoQ(10) levels, in patients with post-acute COVID-19. CONCLUSIONS: Vaccination against SARS-CoV-2 virus infection prevented the reduction of platelet mitochondrial respiration and energy production. The mechanism of suppression of CoQ(10) levels by SARS-CoV-2 virus is not fully known. Methods for the determination of CoQ(10) and HRR can be used for monitoring of mitochondrial bioenergetics and targeted therapy of patients with post-acute COVID-19.

Molecular Mimicry of the Viral Spike in the SARS-CoV-2 Vaccine Possibly Triggers Transient Dysregulation of ACE2, Leading to Vascular and Coagulation Dysfunction Similar to SARS-CoV-2 Infection. The benefits of SARS-CoV-2 spike mRNA vaccines are well known, including a significant decline in COVID-19 morbidity and a decrease in the mortality rate of SARS-CoV-2 infected persons. However, pharmacovigilance studies have revealed the existence of rare cases of cardiovascular complications after mass vaccination using such formulations. Cases of high blood pressure have also been reported but were rarely documented under perfectly controlled medical supervision. The press release of these warning signals triggered a huge debate over COVID-19 vaccines' safety. Thereby, our attention was quickly focused on issues involving the risk of myocarditis, acute coronary syndrome, hypertension and thrombosis. Rare cases of undesirable post-vaccine pathophysiological phenomena should question us, especially when they occur in young subjects. They are more likely to occur with inappropriate use of mRNA vaccine (e.g., at the time when the immune response is already very active during a low-noise infection in the process of healing), leading to angiotensin II (Ang II) induced inflammation triggering tissue damage. Such harmful effects observed after the COVID-19 vaccine evoke a possible molecular mimicry of the viral spike transiently dysregulating angiotensin converting enzyme 2 (ACE2) function. Although the benefit/risk ratio of SARS-CoV-2 spike mRNA vaccine is very favorable, it seems reasonable to suggest medical surveillance to patients with a history of cardiovascular diseases who receive the COVID-19 vaccine.

COVID-19 Vaccination in the WHO African Region: Progress Made in 2022 and Factors Associated. This study summarizes progress made in rolling out COVID-19 vaccinations in the African region in 2022, and analyzes factors associated with vaccination coverage. Data on vaccine uptake reported to the World Health Organization (WHO) Regional Office for Africa by Member States between January 2021 and December 2022, as well as publicly available health and socio-economic data, were used. A negative binomial regression was performed to analyze factors associated with vaccination coverage in 2022. As of the end of 2022, 308.1 million people had completed the primary vaccination series, representing 26.4% of the region's population, compared to 6.3% at the end of 2021. The percentage of health workers with complete primary series was 40.9%. Having carried out at least one high volume mass vaccination campaign in 2022 was associated with high vaccination coverage ($Î^2 = 0.91$, $p < 0.0001$), while higher WHO funding spent per person vaccinated in 2022 was correlated with lower vaccination coverage ($Î^2 = -0.26$, $p < 0.03$). All countries should expand efforts to integrate COVID-19 vaccinations into routine immunization and primary health care, and increase investment in vaccine demand generation during the transition period that follows the acute phase of the pandemic.

IgG4 Antibodies Induced by Repeated Vaccination May Generate Immune Tolerance to the SARS-CoV-2 Spike Protein. Less than a year after the global emergence of the coronavirus SARS-CoV-2, a novel vaccine platform based on mRNA technology was introduced to the market. Globally, around 13.38 billion COVID-19 vaccine doses of diverse platforms have been administered. To date, 72.3% of the total population has been injected at least once with a COVID-19 vaccine. As the immunity

provided by these vaccines rapidly wanes, their ability to prevent hospitalization and severe disease in individuals with comorbidities has recently been questioned, and increasing evidence has shown that, as with many other vaccines, they do not produce sterilizing immunity, allowing people to suffer frequent re-infections. Additionally, recent investigations have found abnormally high levels of IgG4 in people who were administered two or more injections of the mRNA vaccines. HIV, Malaria, and Pertussis vaccines have also been reported to induce higher-than-normal IgG4 synthesis. Overall, there are three critical factors determining the class switch to IgG4 antibodies: excessive antigen concentration, repeated vaccination, and the type of vaccine used. It has been suggested that an increase in IgG4 levels could have a protecting role by preventing immune over-activation, similar to that occurring during successful allergen-specific immunotherapy by inhibiting IgE-induced effects. However, emerging evidence suggests that the reported increase in IgG4 levels detected after repeated vaccination with the mRNA vaccines may not be a protective mechanism; rather, it constitutes an immune tolerance mechanism to the spike protein that could promote unopposed SARS-CoV2 infection and replication by suppressing natural antiviral responses. Increased IgG4 synthesis due to repeated mRNA vaccination with high antigen concentrations may also cause autoimmune diseases, and promote cancer growth and autoimmune myocarditis in susceptible individuals.

A Methodological Framework for Assessing the Benefit of SARS-CoV-2 Vaccination following Previous Infection: Case Study of Five- to Eleven-Year-Olds. Vaccination rates against SARS-CoV-2 in children aged five to eleven years remain low in many countries. The current benefit of vaccination in this age group has been questioned given that the large majority of children have now experienced at least one SARS-CoV-2 infection. However, protection from infection, vaccination or both wanes over time. National decisions on offering vaccines to this age group have tended to be made without considering time since infection. There is an urgent need to evaluate the additional benefits of vaccination in previously infected children and under what circumstances those benefits accrue. We present a novel methodological framework for estimating the potential benefits of COVID-19 vaccination in previously infected children aged five to eleven, accounting for waning. We apply this framework to the UK context and for two adverse outcomes: hospitalisation related to SARS-CoV-2 infection and Long Covid. We show that the most important drivers of benefit are: the degree of protection provided by previous infection; the protection provided by vaccination; the time since previous infection; and future attack rates. Vaccination can be very beneficial for previously infected children if future attack rates are high and several months have elapsed since the previous major wave in this group. Benefits are generally larger for Long Covid than hospitalisation, because Long Covid is both more common than hospitalisation and previous infection offers less protection against it. Our framework provides a structure for policy makers to explore the additional benefit of vaccination across a range of adverse outcomes and different parameter assumptions. It can be easily updated as new evidence emerges.

ANCA Associated Glomerulonephritis Following SARS-CoV-2 Vaccination: A Case Series and Systematic Review. Vaccines against SARS-CoV-2 (COVID-19) proved beneficial for COVID-19 disease attenuation and preventing virus spreading. Cumulative reports of the rarity of antineutrophil cytoplasmic autoantibodies (ANCA)-associated vasculitis (AAV) raise concerns about its relationship with COVID-19 vaccination. Several case reports described ANCA-associated pauci-immune glomerulonephritis (ANCA-GN) following COVID-19 vaccination with some uniqueness. We systematically reviewed COVID-19 vaccine-induced ANCA-GN from PubMed, SCOPUS, and Cochrane library databases until 1 January 2023 according to PRISMA guidelines and presented our three cases. Twenty-six cases from 25 articles, including our 3 cases, were analyzed. Most cases were diagnosed following the second dose of the COVID-19 vaccine (59%) with a median (IQR) interval onset of 14

(16) days. The highest prevalence was related to the mRNA-type vaccine. Anti-myeloperoxidase (MPO) ANCA was far more common than the other ANCAs, with various positive autoantibodies. Fourteen cases (out of 29 cases, 48%) had extra-kidney AAV manifestation. Although severe kidney injury was observed in 10/29 (34%), remission was achieved in 89% (25/28) with no death. The mechanisms of the vaccine-inducing ANCA-GN were postulated here. Since ANCA-GN after the COVID-19 vaccine was rare, the benefit of the COVID-19 vaccine could outweigh the risk of ANCA-GN side effects in the pandemic era.

Selection Effects and COVID-19 Mortality Risk after Pfizer vs. Moderna Vaccination: Evidence from Linked Mortality and Vaccination Records. Prior research generally finds that the Pfizer-BioNTech (BNT162b2) and Moderna (mRNA1273) COVID-19 vaccines provide similar protection against mortality, sometimes with a Moderna advantage due to slower waning. However, most comparisons do not address selection effects for those who are vaccinated and with which vaccine. We report evidence on large selection effects, and use a novel method to control for these effects. Instead of directly studying COVID-19 mortality, we study the COVID-19 excess mortality percentage (CEMP), defined as the COVID-19 deaths divided by non-COVID-19 natural deaths for the same population, converted to a percentage. The CEMP measure uses non-COVID-19 natural deaths to proxy for population health and control for selection effects. We report the relative mortality risk (RMR) for each vaccine relative to the unvaccinated population and to the other vaccine, using linked mortality and vaccination records for all adults in Milwaukee County, Wisconsin, from 1 April 2021 through 30 June 2022. For two-dose vaccinees aged 60+, RMRs for Pfizer vaccinees were consistently over twice those for Moderna, and averaged 248% of Moderna (95% CI = 175%,353%). In the Omicron period, Pfizer RMR was 57% versus 23% for Moderna. Both vaccines demonstrated waning of two-dose effectiveness over time, especially for ages 60+. For booster recipients, the Pfizer-Moderna gap is much smaller and statistically insignificant. A possible explanation for the Moderna advantage for older persons is the higher Moderna dose of 100 Î¼g, versus 30 Î¼g for Pfizer. Younger persons (aged 18-59) were well-protected against death by two doses of either vaccine, and highly protected by three doses (no deaths among over 100,000 vaccinees). These results support the importance of a booster dose for ages 60+, especially for Pfizer recipients. They suggest, but do not prove, that a larger vaccine dose may be appropriate for older persons than for younger persons.

Serological Response to SARS-CoV-2 after COVID-19 Vaccination in Lung Cancer Patients: Short Review. In comparison to the general population, lung cancer patients are more likely to suffer from severe Coronavirus disease (COVID-19) and associated mortality. Considering this increased risk, and in order to prevent symptoms and severe disease, patients with lung cancer have been prioritized for COVID-19 vaccination primary and booster doses. Despite this, the pivotal clinical trials did not include these patients, which leaves open questions regarding vaccine efficacy and humoral immune response. This review outlines the findings of recent investigations into the humoral responses of lung cancer patients to COVID-19 vaccination, particularly the primary doses and first boost.

Multisystem Inflammatory Syndrome in Children (MIS-C), Possibly Due to COVID-19 mRNA Vaccination. Multisystem inflammatory syndrome in children (MIS-C) is a potentially life-threatening childhood disease caused by SARS-CoV-2 infection, manifested by the persistence of fever and multi-organ dysfunction, elevated inflammatory markers, and the lack of an alternative diagnosis. It is still unknown if vaccination can precipitate or abrogate MIS-C or if a natural infection preceding or occurring at the time of vaccination plays any role. We present one case of MIS-C in a 16-year-old girl who was fully immunized against COVID-19 (Pfizer), with the second dose received three weeks prior to onset of the disease. She had no history of COVID-19 disease or contact with COVID-19 patients. At admission, she was somnolent, pale, and dehydrated, with cyanotic lips and cold extremities; she was hypotensive with tachycardia and poorly palpable pulses. Initial laboratory

results revealed elevated levels of inflammatory markers, and high level of SARS-CoV-2 IgG spike antibodies, while testing for SARS-CoV-2 acute infection and other inflammatory etiologies were negative. Vaccine-related MIS-C was suspected in our case due to the development of MIS-C three weeks following the second dose of the COVID-19 mRNA vaccine, the absence of previous infection or exposure to SARS-CoV-2, and a positive result for IgG anti-spike (S) antibodies.

Comparison of Adverse Effects of Two SARS-CoV-2 Vaccines Administered in Workers of the University of Padova. Introduction: In Italy, on December 2020, workers in the education sector were identified as a priority population to be vaccinated against COVID-19. The first authorised vaccines were the Pfizer-BioNTech mRNA (BNT162b2) and the Oxford-AstraZeneca adenovirus vectored (ChAdOx1 nCoV-19) vaccines. Aim: To investigate the adverse effects of two SARS-CoV-2 vaccines in a real-life preventive setting at the University of Padova. Methods: Vaccination was offered to 10116 people. Vaccinated workers were asked to voluntarily report symptoms via online questionnaires sent to them 3 weeks after the first and the second shot. Results: 7482 subjects adhered to the vaccination campaign and 6681 subjects were vaccinated with ChAdOx1 nCoV-19 vaccine and 137 (fragile subjects) with the BNT162b2 vaccine. The response rate for both questionnaires was high (i.e., >75%). After the first shot, the ChAdOx1 nCoV-19 vaccine caused more fatigue ($p < 0.001$), headache ($p < 0.001$), myalgia ($p < 0.001$), tingles ($p = 0.046$), fever ($p < 0.001$), chills ($p < 0.001$), and insomnia ($p = 0.016$) than the BNT162b2 vaccine. After the second dose of the BNT162b2 vaccine, more myalgia ($p = 0.033$), tingles ($p = 0.022$), and shivers ($p < 0.001$) than the ChAdOx1 nCoV-19 vaccine were elicited. The side effects were nearly always transient. Severe adverse effects were rare and mostly reported after the first dose of the ChAdOx1 nCoV-19 vaccine. They were dyspnoea (2.3%), blurred vision (2.1%), urticaria (1.3%), and angioedema (0.4%). Conclusions: The adverse effects of both vaccines were transient and, overall, mild in severity.

Uneventful Coadministration of Seasonal Influenza and COVID-19 BNT162b2 Vaccines Two Weeks Post-Influenza Vaccination in an Egg-Allergic Subject: A Case Report. The COVID-19 pandemic took the world by storm, and although it has taken the world's attention, it did not stop the spread of other communicable diseases. Seasonal influenza is a viral infection that could cause severe disease; therefore, annual influenza vaccination is highly recommended, especially among patients with a weakened immune system. However, such vaccination is contraindicated for people with hypersensitivity to the vaccine or any of its components, e.g., eggs. This paper describes a case of an egg-allergic individual who received an influenza vaccine containing egg protein, which only caused mild tenderness at the site of injection. Two weeks later, the subject received a double vaccination of a second booster dose of Pfizer-BioNTech and the seasonal influenza vaccine. The patient reported no local or systemic adverse reactions to the vaccine. This case report suggests vaccination safety for subjects with mild allergies to vaccine components.

Graves' Disease after mRNA COVID-19 Vaccination, with the Presence of Autoimmune Antibodies Even One Year Later. A 45-year-old man who had received his second mRNA COVID-19 vaccination one week earlier was presented to the emergency department with chest discomfort. Therefore, we suspected post-vaccination myocarditis; however, the patient showed no signs of myocarditis. After 2 weeks, he revisited the hospital complaining of palpitations, hand tremors, and weight loss. The patient exhibited high free thyroxine (FT4) (6.42 ng/dL), low thyroid-stimulating hormone (TSH) (<0.01 Î¼IU/mL), and high TSH receptor antibody (17.5 IU/L) levels, and was diagnosed with Graves' disease. Thiamazole was administered, and the patient's FT4 levels normalized after 30 days. One year later, the patient's FT4 is stable; however, their TSH receptor antibodies have not become negative and thiamazole has continued. This is the first case report to follow the course of Graves' disease one year after mRNA COVID-19 vaccination.

Varying Cellular Immune Response against SARS-CoV-2 after the Booster Vaccination: A Cohort Study from Fukushima Vaccination Community Survey, Japan. Booster vaccination reduces the incidence of severe cases and mortality related to COVID-19, with cellular immunity playing an important role. However, little is known about the proportion of the population that has achieved cellular immunity after booster vaccination. Thus, we conducted a Fukushima cohort database and assessed humoral and cellular immunity in 2526 residents and healthcare workers in Fukushima Prefecture in Japan through continuous blood collection every 3 months from September 2021. We identified the proportion of people with induced cellular immunity after booster vaccination using the T-SPOT.COVID test, and analyzed their background characteristics. Among 1089 participants, 64.3% (700/1089) had reactive cellular immunity after booster vaccination. Multivariable analysis revealed the following independent predictors of reactive cellular immunity: age < 40 years (adjusted odds ratio: 1.81; 95% confidence interval: 1.19-2.75; p-value: 0.005) and adverse reactions after vaccination (1.92, 1.19-3.09, 0.007). Notably, despite IgG(S) and neutralizing antibody titers of â‰¥500 AU/mL, 33.9% (349/1031) and 33.5% (341/1017) of participants, respectively, did not have reactive cellular immunity. In summary, this is the first study to evaluate cellular immunity at the population level after booster vaccination using the T-SPOT.COVID test, albeit with several limitations. Future studies will need to evaluate previously infected subjects and their T-cell subsets.

Polyethylene Glycol and Polysorbate 80 Skin Tests in the Context of an Allergic Risk Assessment for Hypersensitivity Reactions to Anti-SARS-CoV-2 mRNA Vaccines. Concern has arisen about hypersensitivity reactions in patients with allergic reactions to drugs containing polyethylene glycol (PEG) or polysorbate 80 (PS80), excipients of currently available anti-SARS-CoV-2 mRNA vaccines. However, the actual utility of PEG and PS80 skin allergy testing is currently still debated. We retrospectively analyzed all cases of patients on whom we performed allergometric skin tests for PEG and PS80 in the context of a pre-vaccination screening (for patients with multiple hypersensitivity reactions to drugs for which these excipients were among the suspected agents) or following suspected hypersensitivity reactions to anti-SARS-CoV-2 vaccines. A total of 134 tests were performed for PEG and PS80, eight of which produced uninterpretable results (due to dermographism or non-specific reactions). Of the remaining 126 cases (85 pre-vaccinal and 41 post-vaccine reactions), 16 (12.7%) were positive for PEG and/or PS80. Stratifying by clinical indication, there were no statistically significant differences in the proportion of positive tests between patients evaluated in the context of the pre-vaccination screening and those evaluated after a vaccine reaction (10.6% vs. 17.1%, respectively, p = 0.306). Allergometric skin tests for PEG and PS80 in our case series resulted positive in an unexpectedly high proportion of patients, suggesting that testing for allergy to these two excipients should not be ignored in case of reasonable clinical suspicion.

Desensitization Protocols for Anti-SARS-CoV-2 Vaccines in Patients with High Risk of Allergic Reactions. Vaccines for SAR-CoV-2 are the most effective preventive treatment able to reduce the risk of contracting the infection and experiencing worse outcomes whenever the infection is contracted. Despite their rarity, hypersensitivity reactions to the anti-SARS-CoV-2 vaccine have been described and could become the reason not to complete the vaccination. Desensitization protocols for other vaccines have been described and validated, while the use of this approach for anti-SARS-CoV-2 vaccines is still anecdotal. We herein describe our experience with 30 patients with previous allergic reactions to anti-SARS-CoV-2 vaccines or to any of their excipients, proving that they are effective and safe; only two patients experienced hypersensitivity reaction symptoms during the desensitization procedure. Moreover, in this article, we propose desensitization protocols for the most common anti-SARS-CoV-2 vaccines.

The Prevalence of Immediate Hypersensitivity Reactions to the BNT162b2 mRNA Vaccine against SARS-CoV-2: Data from the Vaccination Campaign in a Large Academic Hospital. The anti-SARS-

CoV-2 vaccination has probably been the most effective tool for preventing the infection and negative outcomes of the COVID-19 disease, and therefore for interrupting the pandemic state. The first licensed SARS-CoV-2 vaccine was BNT162b2, an mRNA vaccine that has been widely used since the earliest stages of the global vaccination campaign. Since the beginning of the vaccination campaign, some cases of suspected allergic reactions to BNT162b2 have been described. Epidemiological data, however, have provided reassuring results of an extremely low prevalence of these hypersensitivity reactions to anti-SARS-CoV-2 vaccines. In this article, we describe the results of a survey carried out through the use of a questionnaire, administered to all the health personnel of our university hospital after the first two doses of the BNT162b2 vaccine, which investigated the development of adverse reactions after a vaccination. We analyzed the responses of 3112 subjects subjected to the first dose of the vaccine; among these, 1.8% developed symptoms compatible with allergic reactions and 0.9% with clinical manifestations of possible anaphylaxis. Only 10.3% of the subjects who had allergic reactions after the first injection experienced similar reactions after the second dose and none of them experienced anaphylaxis. In conclusion, the anti-SARS-CoV-2 vaccination is rarely associated with severe allergic reactions and the second dose of vaccine is safe for this group of patients.

Humoral Response after a Fourth Dose with mRNA-1273 in Healthcare Workers with and without a History of SARS-CoV-2 Infection and Previously Vaccinated with Two Doses of BBIBP-CorV Plus BNT162b2 Vaccine. There is limited information on the kinetics of the humoral response elicited by a fourth dose with a heterologous mRNA1273 booster in patients who previously received a third dose with BNT162b2 and two doses of BBIBP-CorV as the primary regimen. We conducted a prospective cohort study to assess the humoral response using Elecsys(Â®) anti-SARS-CoV-2 S (anti-S-RBD) of 452 healthcare workers (HCWs) in a private laboratory in Lima, Peru at 21, 120, 210, and 300 days after a third dose with a BNT162b2 heterologous booster in HCW previously immunized with two doses of BBIBP-CorV, depending on whether or not they received a fourth dose with the mRNA1273 heterologous vaccine and on the history of previous SARS infection -CoV-2. Of the 452 HCWs, 204 (45.13%) were previously infected (PI) with SARS-CoV-2, and 215 (47.57%) received a fourth dose with a heterologous mRNA-1273 booster. A total of 100% of HCWs presented positive anti-S-RBD 300 days after the third dose. In HCWs receiving a fourth dose, GMTs 2.3 and 1.6 times higher than controls were observed 30 and 120 days after the fourth dose. No statistically significant differences in anti-S-RBD titers were observed in those HCWs PI and NPI during the follow-up period. We observed that HCWs who received a fourth dose with the mRNA1273 and those previously infected after the third dose with BNT162b2 (during the Omicron wave) presented higher anti-S-RBD titers (5734 and 3428 U/mL, respectively). Further studies are required to determine whether patients infected after the third dose need a fourth dose.

Before and After: Attitude and Adverse Effects Induced by the First and Second Doses of mRNA BNT162b2 Vaccine among Healthcare Professionals in the First Weeks after Their Introduction in Poland. BACKGROUND: In the last days of December 2020, the SARS-CoV-2 virus vaccine BNT162b2 (Comirnaty, Pfizer-BioNTech) was introduced, for the first time, for wide use in Poland. According to the vaccination schedule, healthcare workers were the first to receive the vaccine. The aim of this study was to analyse the attitudes of those who were determined to be vaccinated, with particular reference to their concerns, attitudes towards vaccination advocacy and sources of knowledge on vaccination, as well as the incidence of adverse reactions. METHODS: The study had a three-stage design. Respondents completed a self-administered questionnaire before receiving the 1st and 2nd vaccine doses and 2 weeks after receiving the 2nd dose. A total of 2247 responses were obtained (1340 responses in the first stage, 769 in the second and 138 in the third). RESULTS: The main source of knowledge on vaccination was the Internet (32%; n = 428). Of the respondents, 6% (n = 86) reported anxiety before the 1st dose of the vaccine, which increased to 20% (n = 157) before

the 2nd dose. A declaration of willingness to promote vaccination among their families was made by 87% (n = 1165). Among adverse reactions after the 1st dose of the vaccine, respondents most frequently observed pain at the injection site (n = 584; 71%), fatigue (n = 126; 16%) and malaise (n = 86; 11%). The mean duration of symptoms was 2.38 days (SD 1.88). After the 2nd dose of vaccine, similar adverse reactions-pain at the injection site (n = 103; 75%), fatigue (n = 28; 20%), malaise (n = 22; 16%)-predominated among respondents. Those who declared having had a SARS-CoV-2 virus infection (p = 0.00484) and with a history of adverse vaccination reactions (p = 0.00374) were statistically more likely to observe adverse symptoms after vaccination. CONCLUSIONS: Adverse postvaccinal reactions are relatively common after Comirnaty vaccination but are usually mild and transient in nature. It is in the interest of public health to increase the knowledge of vaccine safety.

Immune-Mediated Organ-Specific Reactions to COVID-19 Vaccines: A Retrospective Descriptive Study. Severe acute respiratory syndrome coronavirus 2 caused the global COVID-19 pandemic and public health crisis, and it led to the rapid development of COVID-19 vaccines, which can cause rare and typically mild hypersensitivity reactions (HRs). Delayed HRs to COVID-19 vaccines have been reported, and the excipients polyethylene glycol (PEG)2000 and polysorbate 80 (P80) are the suspected culprits. Skin patch tests do not help in diagnosing delayed reactions. We aimed to perform lymphocyte transformation tests (LTT) with PEG2000 and P80 in 23 patients with suspected delayed HRs. Neurological reactions (n = 10) and myopericarditis reactions (n = 6) were the most frequent complications. Seventy-eight percent (18/23) of the study patients were admitted to a hospital ward, and the median time to discharge was 5.5 (IQR, 3-8) days. Some 73.9% of the patients returned to baseline condition after 25 (IQR, 3-80) days. LTT was positive in 8/23 patients (5/10 neurological reactions, 2/4 hepatitis reactions and 1/2 rheumatologic reactions). All myopericarditis cases had a negative LTT. These preliminary results indicate that LTT with PEGs and polysorbates is a useful tool for identifying excipients as causal agents in HRs to COVID-19 vaccines and can play an important role in risk stratification in patients with HRs.

Is the Effect of the COVID-19 Vaccine on Heart Rate Variability Permanent? Background and Objectives: The risk of autonomic dysfunction with COVID-19 vaccines used worldwide in the COVID-19 pandemic remains a topic of debate. Heart rate variability has a number of parameters that can be used to assess autonomic nervous system dynamics. The aim of this study was to investigate the effect of a COVID-19 vaccine (Pfizer-BioNTech) on heart rate variability and autonomic nervous system parameters, and the duration of the effect. Materials and Methods: A total of 75 healthy individuals who visited an outpatient clinic to receive the COVID-19 vaccination were included in this prospective observational study. Heart rate variability parameters were measured before vaccination and on days 2 and 10 after vaccination. SDNN, rMSSD and pNN50 values were evaluated for time series analyses, and LF, HF, and LF/HV values for frequency-dependent analyses. Results: The SDNN and rMSDD values declined significantly on day 2 after vaccination, while the pNN50 and LF/HF values increased significantly on day 10. The values at pre-vaccination and at day 10 were comparable. The pNN50 and LF/HF values declined significantly on day 2 and increased significantly on day 10. The values at pre-vaccination and at day 10 were comparable. Conclusions: This study showed that the decline in HRV observed with COVID-19 vaccination was temporary, and that the Pfizer-BioNTech COVID-19 vaccination did not cause permanent autonomic dysfunction.

Dynamic Evolution of Humoral and T-Cell Specific Immune Response to COVID-19 mRNA Vaccine in Patients with Multiple Sclerosis Followed until the Booster Dose. This study characterizes antibody and T-cell immune responses over time until the booster dose of COronaVIrus Disease 2019 (COVID-19) vaccines in patients with multiple sclerosis (PwMS) undergoing different disease-modifying treatments (DMTs). We prospectively enrolled 134 PwMS and 99 health care workers (HCWs) having completed the two-dose schedule of a COVID-19 mRNA vaccine within the last 2-4

weeks (T0) and followed them 24 weeks after the first dose (T1) and 4-6 weeks after the booster (T2). PwMS presented a significant reduction in the seroconversion rate and anti-receptor-binding domain (RBD)-Immunoglobulin (IgG) titers from T0 to T1 ($p < 0.0001$) and a significant increase from T1 to T2 ($p < 0.0001$). The booster dose in PwMS showed a good improvement in the serologic response, even greater than HCWs, as it promoted a significant five-fold increase of anti-RBD-IgG titers compared with T0 ($p < 0.0001$). Similarly, the T-cell response showed a significant 1.5- and 3.8-fold increase in PwMS at T2 compared with T0 ($p = 0.013$) and T1 ($p < 0.0001$), respectively, without significant modulation in the number of responders. Regardless of the time elapsed since vaccination, most ocrelizumab- (77.3%) and fingolimod-treated patients (93.3%) showed only a T-cell-specific or humoral-specific response, respectively. The booster dose reinforces humoral- and cell-mediated-specific immune responses and highlights specific DMT-induced immune frailties, suggesting the need for specifically tailored strategies for immune-compromised patients to provide primary prophylaxis, early SARS-CoV-2 detection and the timely management of COVID-19 antiviral treatments.

Multiscale Geographically Weighted Regression in the Investigation of Local COVID-19 Anomalies Based on Population Age Structure in Poland. A growing number of various studies focusing on different aspects of the COVID-19 pandemic are emerging as the pandemic continues. Three variables that are most commonly used to describe the course of the COVID-19 pandemic worldwide are the number of confirmed SARS-CoV-2 cases, the number of confirmed COVID-19 deaths, and the number of COVID-19 vaccine doses administered. In this paper, using the multiscale geographically weighted regression, an analysis of the interrelationships between the number of confirmed SARS-CoV-2 cases, the number of confirmed COVID-19 deaths, and the number of COVID-19 vaccine doses administered were conducted. Furthermore, using maps of the local R(2) estimates, it was possible to visualize how the relations between the explanatory variables and the dependent variables vary across the study area. Thus, analysis of the influence of demographic factors described by the age structure and gender breakdown of the population over the course of the COVID-19 pandemic was performed. This allowed the identification of local anomalies in the course of the COVID-19 pandemic. Analyses were carried out for the area of Poland. The results obtained may be useful for local authorities in developing strategies to further counter the pandemic.

Humoral Immune Response after COVID-19 mRNA Vaccination in Patients with Liver Cirrhosis: A Prospective Real-Life Single Center Study. Coronavirus-disease-2019 (COVID-19) mRNA vaccination effectively reduces mortality and morbidity in cirrhotic patients, but the immunogenicity and safety of vaccination have been partially characterized. The study aimed to evaluate humoral response, predictive factors, and safety of mRNA-COVID-19 vaccination in cirrhotic patients compared to healthy subjects. A prospective, single-center, observational study enrolled consecutive cirrhotic patients who underwent mRNA-COVID-19 vaccination from April to May 2021. Anti-spike-protein (anti-S) and nucleocapsid-protein (anti-N) antibodies were evaluated before the first (T0) and the second (T1) doses and 15 days after completing the vaccination. An age and sex-matched healthy reference group was included. The incidence of adverse events (AEs) was assessed. In total, 162 cirrhotic patients were enrolled, 13 were excluded due to previous SARS-CoV-2 infection; therefore, 149 patients and 149 Health Care Workers (HCWs) were included in the analysis. The seroconversion rate was similar in cirrhotic patients and HCWs at T1 (92.5% vs. 95.3%, $p = 0.44$) and T2 (100% in both groups). At T2, anti-S-titres were significantly higher in cirrhotic patients compared to HCWs (2776.6 vs. 1756 BAU/mL, $p < 0.001$]. Male sex ($Î² = -0.32$ [-0.64, -0.04], $p = 0.027$) and past-HCV-infection ($Î² = -0.31$ [-0.59, -0.04], $p = 0.029$) were independent predictors of lower anti-S-titres on multiple-gamma-regression-analysis. No severe AEs occurred. The COVID-19-mRNA vaccination induces a high immunization rate and anti-S-titres in cirrhotic patients. Male sex and past-HCV infection are associated with lower anti-S-titres. The COVID-19-mRNA vaccination is safe.

SARS-CoV-2 Breakthrough Infections According to the Immune Response Elicited after mRNA Third Dose Vaccination in COVID-19-NaÃ¯ve Hospital Personnel. BACKGROUND: Vaccine-induced SARS-CoV-2-anti-spike antibody (anti-S/RBD) titers are often used as a marker of immune protection and to anticipate the risk of breakthrough infections, although no clear cut-off is available. We describe the incidence of SARS-CoV-2 vaccine breakthrough infections in COVID-19-free personnel of our hospital, according to B- and T-cell immune response elicited one month after mRNA third dose vaccination. METHODS: The study included 487 individuals for whom data on anti-S/RBD were available. Neutralizing antibody titers (nAbsT) against the ancestral Whuan SARS-CoV-2, and the BA.1 Omicron variant, and SARS-CoV-2 T-cell specific response were measured in subsets of 197 (40.5%), 159 (32.6%), and 127 (26.1%) individuals, respectively. RESULTS: On a total of 92,063 days of observation, 204 participants (42%) had SARS-CoV-2 infection. No significant differences in the probability of SARS-CoV-2 infection for different levels of anti-S/RBD, nAbsT, Omicron nAbsT, or SARS-CoV-2 T cell specific response, and no protective thresholds for infection were found. CONCLUSIONS: Routine testing for vaccine-induced humoral immune response to SARS-CoV-2 is not recommended if measured as parameters of 'protective immunity' from SARS-CoV-2 after vaccination. Whether these findings apply to new Omicron-specific bivalent vaccines is going to be evaluated.

Barriers and facilitators of HPV vaccination in sub-saharan Africa: a systematic review. BACKGROUND: Human Papilloma Virus (HPV) is the most common sexually transmitted infection worldwide. Globally, both men and women have a 50% risk of being infected at least once in their life. HPV prevalence is among the highest in sub-Saharan Africa (SSA), at an average of 24%. HPV causes different types of cancers, including cervical cancer (CC), which is the leading cause of cancer deaths among women in SSA. HPV-vaccination has been proven to be effective in reducing HPV induced cancers. SSA countries are delayed in reaching the WHO's target of fully vaccinating 90% of girls within the age of 15 by 2030. Our systematic review aims to identify barriers and facilitators of HPV-vaccination in SSA to inform national implementation strategies in the region. METHODS: This is a mixed method systematic review based on the PRISMA statement and The Joanna Briggs Institute Reviewers' Manual. Search strategies were adapted to each selected database: PubMed/MEDLINE, Livivo, Google Scholar, Science Direct, and African Journals Online for papers published in English, Italian, German, French and Spanish between 1 December 2011 and 31 December 2021. Zotero and Rayyan were the software used for data management. The appraisal was conducted by three independent reviewers. RESULTS: A total of 20 articles were selected for appraisal from an initial 536 articles. Barriers included: limited health system capacities, socio-economic status, stigma, fear and costs of vaccines, negative experience with vaccinations, COVID-19 pandemic, lack of correct information, health education (HE) and consent. Additionally, we found that boys are scarcely considered for HPV-vaccination by parents and stakeholders. Facilitators included: information and knowledge, policy implementation, positive experience with vaccinations, HE, stakeholders' engagement, women's empowerment, community engagement, seasonality, and target-oriented vaccination campaigns. CONCLUSIONS: This review synthesizes barriers and facilitators of HPV-vaccinations in SSA. Addressing these can contribute to the implementation of more effective HPV immunization programs targeted at eliminating CC in line with the WHO 90/70/90 strategy. REGISTRATION AND FUNDING: Protocol ID: CRD42022338609 registered in the International Prospective Register of Systematic Reviews (PROSPERO). Partial funds: German Centre for Infection research (DZIF) project NAMASTE: 8,008,803,819.

[Recurrent livedo-like skin lesions following aÂ vector-based COVID-19 vaccine]. Starting in 2020, the global health system faced unprecedent challenges due to the coronavirus disease 2019 (COVID-19) pandemic and the consequences are still felt. All the more fascinating and of particular importance for health policy was the development of potent vaccines within about one year by

several research groups after the first reports of COVID-19 infections. To date, three types of COVID-19 vaccines are available, i.e., messenger RNA-based vaccines, adenoviral vector vaccines, and inactivated whole-virus vaccines. We report aÂ woman who developed reddish, partially urticarial skin lesions on her right arm and flank shortly after the first dose with the corona vaccination from AstraZeneca/Oxford (ChAdOx1). The lesions were transient, however reoccurred in loco and at other locations over several days. The clinical presentation was unusual and was correctly assigned due to the clinical course.

Phase I randomized, observer-blinded, placebo-controlled study of a SARS-CoV-2 mRNA vaccine PTX-COVID19-B. Access to vaccines against SARS-CoV-2 virus was limited in poor countries during the COVID-19 pandemic. Therefore, a low-cost mRNA vaccine, PTX-COVID19-B, was produced and evaluated in a Phase 1 trial. PTX-COVID19-B encodes Spike protein D614G variant without the proline-proline (986-987) mutation present in other COVID-19 vaccines. The aim of the study was to evaluate safety, tolerability, and immunogenicity of PTX-COVID19-B vaccine in healthy seronegative adults 18-64Â years old. The trial design was observer-blinded, randomized, placebo-controlled, and tested ascending doses of 16-Âµg, 40-Âµg, or 100-Âµg in a total of 60 subjects who received two intramuscular doses, 4Â weeks apart. Participants were monitored for solicited and unsolicited adverse events after vaccination and were provided with a Diary Card and thermometer to report any reactogenicity during the trial. Blood samples were collected on baseline, days 8, 28, 42, 90, and 180 for serum analysis of total IgG anti-receptor binding domain (RBD)/Spike titers by ELISA, and neutralizing antibody titers by pseudovirus assay. Titers in BAU/mL were reported as geometric mean and 95% CI per cohort. After vaccination, few solicited adverse events were observed and were mild to moderate and self-resolved within 48Â h. The most common solicited local and systemic adverse event was pain at the injection site, and headache, respectively. Seroconversion was observed in all vaccinated participants, who showed high antibody titers against RBD, Spike, and neutralizing activity against the Wuhan strain. Neutralizing antibody titers were also detected against Alpha, Beta, and Delta variants of concerns in a dose dependent manner. All tested doses of PTX-COVID19-B were safe, well-tolerated, and provided a strong immunogenicity response. The 40-Âµg dose showed fewer adverse reactions than the 100-Âµg dose, and therefore was selected for a Phase 2 trial, which is currently ongoing.Clinical Trial Registration number: NCT04765436 (21/02/2021). (https://clinicaltrials.gov/ct2/show/NCT04765436).

Immunohistologic Features of Cerebral Venous Thrombosis Due to Vaccine-Induced Immune Thrombotic Thrombocytopenia. OBJECTIVES: Vaccine-induced immune thrombotic thrombocytopenia (VITT), a recently described entity characterized by thrombosis at unusual locations such as cerebral venous sinus and splanchnic vein, has been rarely described after adenoviral-encoded COVID-19 vaccines. In this study, we report the immunohistological correlates in 3 fatal cases of cerebral venous thrombosis related to VITT analyzed at an academic medical center. METHODS: Detailed neuropathologic studies were performed in 3 cases of cerebral venous thrombosis related to VITT after adenoviral COVID-19 vaccination. RESULTS: Autopsy revealed extensive cerebral vein thrombosis in all 3 cases. Polarized thrombi were observed with a high density of neutrophils in the core and a low density in the tail. Endothelial cells adjacent to the thrombus were largely destroyed. Markers of neutrophil extracellular trap and complement activation were present at the border and within the cerebral vein thrombi. SARS-CoV-2 spike protein was detected within the thrombus and in the adjacent vessel wall. DISCUSSION: Data indicate that neutrophils and complement activation associated with antispike immunity triggered by the vaccine is probably involved in the disease process.

Durability and determinants of anti-SARS-CoV-2 spike antibodies following the second and third doses of mRNA COVID-19 vaccine. OBJECTIVES: To examine the differences in durability and its

determinants of humoral immunity following 2- and 3-dose COVID-19 vaccination. METHODS: Throughout the pandemic, we evaluated the anti-spike IgG antibody titers of 2- and 3-dose mRNA vaccine recipients over time among the staff of a medical and research center in Tokyo. Linear mixed models were used to estimate trajectories of antibody titers from 14 to 180Â days after the last immune-conferred event (vaccination or infection) and compare antibody waning rates across prior infection and vaccination status, and across background factors in infection-naÃ¯ve participants. RESULTS: A total of 6901 measurements from 2964 participants (median age, 35Â years; 30% male) were analyzed. Antibody waning rate (percentage per 30Â days [95% CI]) was slower after 3 doses (25% [23-26]) than 2 doses (36% [35-37]). Participants with hybrid immunity (vaccination and infection) had further slower waning rates: 2-dose plus infection (16% [9-22]); 3-dose plus infection (21% [17-25]). Older age, male sex, obesity, coexisting diseases, immunosuppressant use, smoking, and alcohol drinking were associated with lower antibody titers, whereas these associations disappeared after 3 doses, except for sex (lower in female participants) and immunosuppressant use. Antibody waned slightly faster in older participants, females, and alcohol drinkers after 2 doses, whereas it did not differ after 3 doses across except sex. DISCUSSION: The 3-dose mRNA vaccine conferred higher durable antibody titers, and previous infection modestly enhanced its durability. The antibody levels at a given time point and waning speed after 2 doses differed across background factors; however, these differences mostly diminished after 3 doses.

Correction to: COVID arm that appeared in the contralateral upper extremity after mRNAâ€‘1273 booster inoculation. [This corrects the article DOI: 10.1007/s13691-023-00598-7.].

Long-term follow-up of cardiac magnetic resonance imaging in myocarditis following messenger ribonucleic acid COVID-19 vaccination: a case report. BACKGROUND: Presently, the association between myocarditis and messenger ribonucleic acid (mRNA) COVID-19 vaccination is well established. From the most current data, cases of myocarditis following COVID-19 vaccination seem to be mild with fast clinical recovery. Nevertheless, the complete resolution of the inflammatory process is still unclear. CASE SUMMARY: We report the case of a 13-year-old boy who developed chest pain following the second dose of the Pfizer-BioNTech COVID-19 vaccine with long-term follow-up of cardiac magnetic resonance (CMR) imaging. An electrocardiogram (ECG) revealed progressively ST-segment elevation on the 2nd day of admission with a rapid improvement within 3â€…hours where only mild ST-segment elevation remained. The peak level of high-sensitivity cardiac troponin T was 1546â€…ng/L with rapid reduction. Echocardiogram revealed depressed left ventricular septal wall motion. CMR mapping techniques showed myocardial oedema with an increase in native T1 and extracellular volume (ECV). On the other hand, T1-weighted and T2-weighted images and late gadolinium enhancement (LGE) did not detect inflammation. The patient's symptoms were relieved by oral ibuprofen. After 2 weeks, ECG and echocardiogram were unremarkable. However, the inflammation process was still present based on the CMR by mapping technique. During the 6-month follow-up, CMR returned to normal. DISCUSSION: In our case, the subtle myocardial inflammation was diagnosed by mapping technique with only a T1-based marker according to the updated Lake Louise Criteria and the inflammation of the myocardium returned to normal within 6 months after the onset of the disease. Further follow-up and larger studies are needed to determine the complete resolution of the disease.

Factors Associated With Coronavirus Disease 2019 Vaccine Uptake Among Pregnant Women and Nonpregnant Women of Reproductive Age in Jamaica. BACKGROUND: Despite high rates of coronavirus disease 2019 (COVID-19)-related maternal mortality, Jamaica currently has little data on COVID-19 vaccine uptake among pregnant women. METHODS: We conducted a cross-sectional, web-based survey of 192 reproductive-aged women in Jamaica from February 1 to 8, 2022. Participants were recruited from a convenience sample of patients, providers, and staff at a teaching hospital. We

assessed self-reported COVID-19 vaccination status and COVID-19-related medical mistrust (operationalized as vaccine confidence, government mistrust, and race-based mistrust). We used multivariable modified Poisson regression to test the association between vaccine uptake and pregnancy. RESULTS: Of 192 respondents, 72 (38%) were pregnant. Most (93%) were Black. Vaccine uptake was 35% in pregnant women versus 75% in nonpregnant women. Pregnant women were more likely to cite healthcare providers versus the government as trustworthy sources of COVID-19 vaccine information (65% vs 28%). Pregnancy, low vaccine confidence, and government mistrust were associated with a lower likelihood of COVID-19 vaccination (adjusted prevalence ratio [aPR] = 0.68 [95% confidence interval {CI}, .49-.95], aPR = 0.61 [95% CI, .40-.95], and aPR = 0.68 [95% CI, .52-.89], respectively). Race-based mistrust was not associated with COVID-19 vaccination in the final model. CONCLUSIONS: Pregnancy, low vaccine confidence, and government mistrust were associated with a lower likelihood of COVID-19 vaccination among reproductive-aged women in Jamaica. Future studies should evaluate the efficacy of strategies proven to improve maternal vaccination coverage, including standing "opt-out" vaccination orders and collaborative provider and patient-led educational videos tailored for pregnant individuals. Strategies that decouple vaccine messaging from government agencies also warrant evaluation.

T cell immunity following COVID-19 vaccination in adult patients with primary antibody deficiency - a 22-month follow-up. Primary antibody deficiencies, such as common variable immunodeficiency (CVID), are heterogenous disease entities consisting of primary hypogammaglobulinemia and impaired antibody responses to vaccination and natural infection. CVID is the most common primary immunodeficiency in adults, presenting with recurrent bacterial infections, enteropathy, autoimmune disorders, interstitial lung diseases and increased risk of malignancies. Patients with CVID are recommended to be vaccinated against SARS-CoV-2, but there are relatively few studies investigating humoral and cellular responses to immunization. We studied the dynamics of humoral and cell-mediated immunity responses up to 22 months in 28 patients with primary immunodeficiency and three patients with secondary immunodeficiency receiving ChAdOx1, BNT162b2 and mRNA-1273 COVID-19 vaccines. Despite inadequate humoral response to immunization, we demonstrate a robust T cell activation likely protecting from severe COVID-19.

Effects of Antibody Response after Booster Vaccination on SARS-CoV-2 Breakthrough Infections and Disease Outcomes in Advanced Cancer Patients: A Prospective Analysis of the Vax-on-Third Study. (1) Background: The clinical implications of COVID-19 outbreaks following SARS-CoV-2 vaccination in immunocompromised recipients are a worldwide concern. Cancer patients on active treatment remain at an increased risk of developing breakthrough infections because of waning immunity and the emergence of SARS-CoV-2 variants. There is a paucity of data on the effects of COVID-19 outbreaks on long-term survival outcomes in this population. (2) Methods: We enrolled 230 cancer patients who were on active treatment for advanced disease and had received booster dosing of an mRNA-BNT162b2 vaccine as part of the Vax-On-Third trial between September 2021 and October 2021. Four weeks after the third immunization, IgG antibodies against the spike receptor domain of SARS-CoV-2 were tested in all patients. We prospectively evaluated the incidence of breakthrough infections and disease outcomes. The coprimary endpoints were the effects of antibody titers on the development of breakthrough infections and the impact of COVID-19 outbreaks on cancer treatment failure. (3) Results: At a median follow-up of 16.3 months (95% CI 14.5-17.0), 85 (37%) patients developed SARS-CoV-2 infection. Hospitalization was required in 11 patients (12.9%) and only 2 (2.3%) deaths related to COVID-19 outbreaks were observed. Median antibody titers were significantly lower in breakthrough cases than in non-cases (291 BAU/mL (95% CI 210-505) vs. 2798 BAU/mL (95% CI 2323-3613), $p < 0.001$). A serological titer cut-off below 803 BAU/mL was predictive of breakthrough infection. In multivariate testing, antibody titers and cytotoxic chemotherapy were

independently associated with an increased risk of outbreaks. Time-to-treatment failure after booster dosing was significantly shorter in patients who contracted SARS-CoV-2 infection (3.1 months (95% CI 2.3-3.6) vs. 16.2 months (95% CI 14.3-17.0), $p < 0.001$) and had an antibody level below the cut-off (3.6 months (95% CI 3.0-4.5) vs. 14.6 months (95% CI 11.9-16.3), $p < 0.001$). A multivariate Cox regression model confirmed that both covariates independently had a worsening effect on time-to-treatment failure. (4) Conclusions: These data support the role of vaccine boosters in preventing the incidence and severity of COVID-19 outbreaks. Enhanced humoral immunity after the third vaccination significantly correlates with protection against breakthrough infections. Strategies aimed at restraining SARS-CoV-2 transmission in advanced cancer patients undergoing active treatment should be prioritized to mitigate the impact on disease outcomes.

Uncovering Resilience Disparities among Religious Groups in Israel's Mass COVID-19 Vaccination Drive: Lessons Learned to the Post-COVID Era. The aim of the current study was to examine the emotional resilience, satisfaction with life, social support, and anxiety during the vaccination process of the Israeli population after the end of the third lockdown, according to religiosity degree. We hypothesized that a higher degree of religiosity (ultra-Orthodox and religious participants) would be associated with higher levels of resilience and with lower levels of anxiety than in secular individuals. In addition, it was hypothesized that satisfaction with life, social support, anxiety, and religiosity will predict resilience and anxiety. Nine hundred and ninety-three native Jewish Hebrew-speaking respondents representing ultra-Orthodox, religious, observant, and secular Jews participated in this study. Ultra-Orthodox participants showed higher resilience and satisfaction with life than other groups, and lower levels of anxiety. Satisfaction with life and social support predicted higher resilience. It is suggested that religious faith as well as satisfaction with life may provide a source of strength and resilience in stressful life events.

Antibody Response to Inactive SARS-CoV-2 Vaccination in a Cohort of Elderly Patients Living with Obesity. INTRODUCTION: Obesity and aging negatively affect the immune system and host defense mechanisms, increasing vulnerability to and worsening prognosis of infectious diseases, leading to vaccine failure. Our aim was to investigate the antibody response against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike antigens and the risk factors affecting antibody levels in elderly patients living with obesity (PwO) after inactive SARS-CoV-2 vaccine (CoronaVac) administration. METHODS: One hundred twenty-three consecutive elderly patients with obesity (age â‰¥65 years, body mass index [BMI] â‰¥30 kg/m2) and 47 adults with obesity (age 18-64 years, BMI â‰¥30 kg/m2) admitted between August and November 2021 were enrolled. Seventy-five nonobese elderly people (age â‰¥65 years, BMI 18.5-29.9 kg/m2) and 105 nonobese adults (age 18-64 years, BMI 18.5-29.9 kg/m2) were recruited from subjects who visited the Vaccination Unit. SARS-CoV-2 spike protein antibody titers were measured in patients with obesity and nonobese controls who received two doses of CoronaVac. RESULTS: SARS-CoV-2 levels of patients with obesity were found to be significantly lower than those of nonobese elderly individuals who had non-prior infection. There was no difference in SARS-CoV-2 levels between patients with obesity and nonobese individuals with prior infection. Age and SARS-CoV-2 level were found to be highly correlated in the correlation analysis in the group of elderly individuals (r: -0.184). In multivariate regression analysis, when SARS-CoV-2 immunoglobulin class G (IgG) was regressed on age, sex, BMI, type 2 diabetes mellitus, and hypertension (HT), HT was found to be an independent factor of the SARS-CoV-2 level ($\hat{I}^2$: -2,730). CONCLUSION: In the non-prior infection group, elderly patients with obesity generated significantly reduced antibody titers against SARS-CoV-2 spike antigen after CoronaVac vaccine compared to nonobese people. It is anticipated that the results obtained will provide invaluable information about SARS-CoV-2 vaccination strategies in this vulnerable population. Antibody titers

may be measured, and booster doses should be delivered accordingly in elderly PwO for optimal protection.

Adverse Effects Post COVID-19 Vaccination and its Association with Age, Gender and Comorbid Disease in Basrah City Southern of Iraq. BACKGROUND: Vaccination against COVID-19 virus is the most valuable tool available for protection during the pandemic of coronavirus. The clinical manifestation post-vaccination is a barrier to vaccination for many people in Iraq and worldwide. OBJECTIVES: The objective of this study is identifying various clinical manifestations occurring after receiving vaccines among individuals in Basrah Governorate. Moreover, we examine its association with respondents' demographics and the type of vaccine they received. METHODS: A cross-section study was conducted in Basrah, southern Iraq. Research data were collected through an online questionnaire. The data were analyzed using both descriptive and analytic statistical tools using the SPSS program. RESULTS: Most of the participants (86.68%) received the vaccine. The side effects were reported in 71.61% of vaccinated individuals. Fever and muscle pain were the two most experienced clinical manifestations, while lymph node enlargement and disturbances in taste and/or smell sensations were reported infrequently. Adverse effects were mostly reported with the Pfizer BioNTech vaccine receiver. Females and those in the younger age group also reported a significantly higher incidence of side effects. CONCLUSION: Most adverse effects related to the COVID-19 vaccine were minor and could be tolerated without the need for hospital admission.

Corrigendum to Posterior Reversible Encephalopathy Syndrome (Pres) Secondary To Renal Artery Thrombosis Following Covid-19 Vaccination.

Seronegative acute encephalitis following COVID-19 vaccines: a case series of an overlooked diagnosis with literature review. PURPOSE: Autoimmune encephalitis is a neurological emergency of new-onset altered mental status, caused by an exaggerated immune-mediated response that targets the central nervous system. Autoimmune encephalitis has become an emerging differential diagnosis, when a classical infection cannot explain neurological symptoms. Displaying overlapping clinical presentations, ranging from the insidious onset of cognitive deficiency to more severe forms of encephalopathy with refractory seizures, autoimmune encephalitis can be challenging for clinicians. When evidence of malignancy is absent and pathogenic autoantibodies are undetected, with typical clinical and imaging features of autoimmune encephalitis, seronegative autoimmune encephalitis may be considered. Recently, vaccination-related autoimmune encephalitis and acute encephalitis after COVID-19 vaccination have attracted attention. METHODS AND RESULTS: We report a case series consisting of three patients with autoimmune encephalitis occurring shortly after COVID-19 vaccination and a current review of all previous reported autoimmune encephalitis related to COVID-19 vaccines. CONCLUSION: We emphasise on the prompt diagnosis of autoimmune encephalitis induced by Covid-19 vaccines and its timely treatment to improve the clinical outcome of this severe neurological condition. Post-licencing vaccine safety surveillance for potential adverse events is essential for vaccine safety and public confidence.

Immune Responses 6 Months After mRNA-1273 COVID-19 Vaccination and the Effect of a Third Vaccination in Patients with Inborn Errors of Immunity. PURPOSE: Patients with inborn errors of immunity (IEI) are at increased risk of severe coronavirus disease-2019 (COVID-19). Effective long-term protection against COVID-19 is therefore of great importance in these patients, but little is known about the decay of the immune response after primary vaccination. We studied the immune responses 6Â months after two mRNA-1273 COVID-19 vaccines in 473 IEI patients and subsequently the response to a third mRNA COVID-19 vaccine in 50 patients with common variable immunodeficiency (CVID). METHODS: In a prospective multicenter study, 473 IEI patients (including X-linked agammaglobulinemia (XLA) (Nâ€‰=â€‰18), combined immunodeficiency (CID) (Nâ€‰=â€‰22), CVID (Nâ€‰=â€‰203), isolated or undefined antibody deficiencies

(Nâ€‰=â€‰204), and phagocyte defects (Nâ€‰=â€‰16)), and 179 controls were included and followed up to 6Â months after two doses of the mRNA-1273 COVID-19 vaccine. Additionally, samples were collected from 50 CVID patients who received a third vaccine 6Â months after primary vaccination through the national vaccination program. SARS-CoV-2-specific IgG titers, neutralizing antibodies, and T cell responses were assessed. RESULTS: At 6Â months after vaccination, the geometric mean antibody titers (GMT) declined in both IEI patients and healthy controls, when compared to GMT 28Â days after vaccination. The trajectory of this decline did not differ between controls and most IEI cohorts; however, antibody titers in CID, CVID, and isolated antibody deficiency patients more often dropped to below the responder cut-off compared to controls. Specific T cell responses were still detectable in 77% of controls and 68% of IEI patients at 6Â months post vaccination. A third mRNA vaccine resulted in an antibody response in only two out of 30 CVID patients that did not seroconvert after two mRNA vaccines. CONCLUSION: A similar decline in IgG titers and T cell responses was observed in patients with IEI when compared to healthy controls 6Â months after mRNA-1273 COVID-19 vaccination. The limited beneficial benefit of a third mRNA COVID-19 vaccine in previous non-responder CVID patients implicates that other protective strategies are needed for these vulnerable patients.

COVID-19 vaccination, risk-compensatory behaviours, and contacts in the UK. The physiological effects of vaccination against SARS-CoV-2 (COVID-19) are well documented, yet the behavioural effects not well known. Risk compensation suggests that gains in personal safety, as a result of vaccination, are offset by increases in risky behaviour, such as socialising, commuting and working outside the home. This is potentially important because transmission of SARS-CoV-2 is driven by contacts, which could be amplified by vaccine-related risk compensation. Here, we show that behaviours were overall unrelated to personal vaccination, but-adjusting for variation in mitigation policies-were responsive to the level of vaccination in the wider population: individuals in the UK were risk compensating when rates of vaccination were rising. This effect was observed across four nations of the UK, each of which varied policies autonomously.

Assessment of long-term adverse events regarding different COVID-19 vaccine regimens within an 18-month follow-up study. Early reports on coronavirus disease 2019 (COVID-19) vaccines presented the short-term adverse events (AEs). This follow-up study investigated a standard regimen based on protein subunit vaccines, PastoCovac and PastoCovac Plus, and the combinational vaccine regimens including AstraZeneca/PastoCovac Plus and Sinopharm/PastoCovac Plus. The participants were followed up to 6 months post the booster shot. All the AEs were collected through in-depth interviews using a valid researcher-made questionnaire and were evaluated regarding the association with the vaccines. Of the 509 individuals, 6.2% of the combinational vaccine participants had late AEs, of whom 3.3% suffered from cutaneous manifestations, followed by 1.1% arthralgia complaints, 1.1% with neurologic disorders, 0.3% ocular problems and 0.3% metabolic complications, with no significant difference between the vaccine regimens. For the standard regimen, 2% of the individuals experienced late AEs as (1%), neurological disorders (0.3%), metabolic problems (0.3%) and involvement of joints (0.3%). Notably, 75% of the AEs were persistent up to the end of the study. A low number of late AEs were captured in 18 months as 12 improbable, 5 unclassifiable, 4 possible and 3 probable associated AEs with the vaccine regimens. The benefits of COVID-19 vaccination far exceed the potential risks and late AEs seem to be uncommon.

The effect of the coronavirus disease 2019 vaccine and infection on menstrual cycle length: an analysis of 12 months of continuous menstrual cycle data from 5,314 participants.

Atypical Anti-Glomerular Basement Membrane Nephritis After the First Dose of the Severe Acute Respiratory Syndrome Coronavirus 2 mRNA Vaccine. Atypical anti-glomerular basement membrane (GBM) nephritis is a slowly progressive characterized by linear deposition of

immunoglobulin (Ig) G in the GBM without circulating anti-GBM antibodies or lung involvement. There is no established therapy for this disease, and efficacy of the immunosuppressive treatment is questionable. A few cases of atypical anti-GBM nephritis have been reported after administration of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine. Classic anti-GBM disease has also been reported after the administration of the second dose of the SARS-CoV-2 vaccine. Herein, we present the case of a SARS-CoV-2 vaccine-induced atypical anti-GBM nephritis that developed after the first dose and was unresponsive to immunosuppressive therapy. A 57-year-old Japanese woman developed edema 11 days after the first dose of the SARS-CoV-2 mRNA vaccine. She developed nephrotic-range proteinuria and microscopic hematuria. Renal biopsy revealed endocapillary proliferative glomerulonephritis with linear IgG deposition. However, electron-dense deposits were not detected on electron microscopy. The patient tested negative for circulating anti-GBM antibodies and was diagnosed with atypical anti-GBM nephritis. Although steroids and mizoribine were administered, the patient's renal function deteriorated. In conclusion, atypical anti-GBM nephritis may have earlier onset than the classic anti-GBM disease. Given its uncertainty of effectiveness, immunosuppressive agents should be carefully used for SARS-CoV-2 mRNA vaccine-induced atypical anti-GBM nephritis.

Repeated Coronary Artery Thrombosis after COVID-19 Vaccination: Correspondence.

Prevalence and difference of COVID-19 symptoms, post-COVID conditions and duration of illness among the vaccinated and unvaccinated population: a cross-sectional study in Peshawar. Studies on coronavirus disease 2019 (COVID-19) symptoms, post-coronavirus disease (COVID) conditions, and vaccination outcomes in Pakistan are limited and inconsistent. The study investigated differences in symptoms and post-COVID conditions between vaccinated and unvaccinated individuals and the impact of vaccination on illness duration based on existing literature. METHODS: The study was a 3-month cross-sectional study conducted in Peshawar, Pakistan. It targeted individuals aged 16 and above who had contracted COVID-19 at least once during the recent pandemic, regardless of gender, and confirmed through reverse transcriptase polymerase chain reaction testing. The sample size was 250, determined using the WHO sample size calculator. Data were collected through questionnaires after obtaining verbal consent and analyzed using IBM SPSS version 26, taking into account their vaccination status along with other important variables. RESULTS: Among the 250 respondents, 143 (57.2%) were unvaccinated, while 107 (42.8%) were vaccinated at the time of contracting COVID-19. Unvaccinated subjects developed a greater variety of symptoms that lasted for longer durations ($P<0.001$) with symptoms like dyspnea [55 (38.5%, $P=0.011$)], anosmia [76 (53.1%, $P=0.001$)], and chest pain [24 (16.8%, $P=0.029$)] occurring at greater percentages. Sixty-one (42.7%) unvaccinated subjects reported post-COVID conditions as opposed to 29 (27.1%) among the vaccinated group [$P=0.011$; odds ratio (OR)=0.5; 95% CI=0.29-0.86]. CONCLUSION: The study found that COVID-19 vaccination can reduce the duration and frequency of symptoms, as well as post-COVID conditions. This is the first research of its kind conducted in Peshawar, Pakistan, and may serve as a foundation for future research in this demographic.

Partial infraspinatus tear with bursitis following an mRNA vaccination: a case report. We report a case of a shoulder injury related to vaccine administration (SIRVA) that developed symptoms 2 weeks following a coronavirus disease 2019 (COVID-19) vaccination and improved after receiving both intraarticular and subacromial corticosteroid injections. PRESENTATION OF CASE: A 52-year-old Thai female without preexisting shoulder pathology and symptom had developed left shoulder pain for 3 days. Two weeks prior to shoulder pain, she received an mRNA COVID-19 vaccination. She positioned her arm in combined internal rotation with 60Â° of arm abduction. Her symptoms were pain in all directions of shoulder motion and tenderness at the bicipital groove and over the deltoid area. The testing of the rotator cuff power of the infraspinatus tendon showed pain. INTERVENTION AND

OUTCOME: An MRI showed infraspinatus tendinosis with a low-grade (almost 50%) bursal-surface tear at the footprint of the superior fiber with associated overlying subacromial-subdeltoid bursitis. She was treated with both intraarticular and subacromial corticosteroid injections (triamcinolone acetate (40Â mg/ml) 1Â ml+1% lidocaine with adrenaline 9Â ml). She did not respond to oral naproxen but responded well to intraarticular and subacromial corticosteroid injections. RELEVANCE AND IMPACT: The best way to deal with SIRVA is to prevent this condition by using the correct injection technique. First, the injection site should be two or three fingerbreadths below the mid-acromion process. Second, the needle's direction should be perpendicular to the skin. Third, using the correct needle penetration depth.

Sustained cell-mediated but not humoral responses in rituximab-treated rheumatic patients after vaccination against SARS-CoV-2. OBJECTIVES: B cell depleting monoclonal antibodies are associated with increased COVID-19 severity and impaired immune response to vaccination. We aimed to assess the humoral and cell mediated (CMI) immune response after SARS-CoV-2 vaccination in rituximab (RTX)-treated rheumatic patients. METHODS: Serum and whole blood samples were collected from rituximab (RTX)-treated rheumatic patients 3-6â€‰months after last vaccination against SARS-CoV-2. Serum was tested by ELISA for quantitative detection of anti-spike SARS-CoV-2 IgG. Cell-mediated variant-specific SARS-CoV-2 immunity (CMI) was assessed by interferon-Î³ release assay Covi-FERON FIA. Patients were interviewed for breakthrough COVID-19 infection (BTI) 3â€‰months post sampling. RESULTS: Sixty patients were studied after a median (IQR) of 179 (117-221.5) days from last vaccine to sampling. Forty (66.7%) patients had positive Covi-FERON and 23 (38.3%) had detectable anti-spike IgG. Covi-FERON positive patients had lower median RTX cumulative dose [6 (4-10.75) vs 11 (6.75-14.75) grams, (p= 0.019). Patients with positive anti-spike IgG had received fewer RTX cycles [2 (2-4) vs 6 (4-8), p= 0.002) and cumulative dose [4 (3-7) vs 10 (6.25-13) grams, p= 0.002] and had shorter time from last vaccination to sampling [140 (76-199) vs 192 (128-230) days, p= 0.047). Thirty-seven percent were positive only for Covi-FERON and 7% only for anti-spike IgG. Twenty (33.3%) BTI occurred post sampling, exclusively during Omicron variant predominance. The proportion of patients with CMI response against Delta variant was lower in patients who experienced BTI (25% vs 55%, p= 0.03). CONCLUSIONS: Four out of ten RTX-treated vaccinated patients show lasting cell-mediated immune response despite undetectable anti-spike antibodies. Cumulative RTX dose affects both humoral and cell-mediated responses to SARS-CoV-2 vaccines. Cell-mediated immune responses call for attention as a vaccine efficacy marker against SARS-CoV-2.

Development of anti-NXP2 dermatomyositis following Comirnaty COVID-19 vaccination.

Safety of heterologous ChAdOx1-S/BNT162b2 primary schedule versus homologous BNT162b2 vaccination: Insights from an Italian post-marketing study, 2021. During COVID-19 vaccination campaign, possible ChAdOx1-S-associated risks of thrombosis with thrombocytopenia syndrome led to implement ChAdOx1-S/BNT162b2 heterologous vaccination, despite the limited information on its reactogenicity and safety. We conducted a prospective observational post-marketing surveillance study to assess the safety of this heterologous schedule. A casually selected sample of recipients (n: 85; age: 18-60â€‰years) of ChAdOx1-S/BNT162b2 at the vaccination hub of the Foggia Hospital, Italy, was matched with an equal sample of recipients of homologous BNT162b2. Safety was evaluated 7â€‰days, 1 month and 14â€‰weeks after the primary vaccination series using an adapted version of the "V-safe active surveillance for COVID-19 vaccine safety" CDC standardized questionnaire. After 7 days, local reactions were highly frequent (>80%) in both groups, and systemic reactions were less common (<70%). Moderate or severe pain at the injection site (ORâ€‰=â€‰3.62; 95%CI, 1.45-9.33), moderate/severe fatigue (ORâ€‰=â€‰3.40; 95%CI, 1.22-9.49), moderate/severe headache (ORâ€‰=â€‰4.72; 95%CI, 1.37-16.23), intake of antipyretics

(ORâ€‰=â€‰3.05; 95â€‰CI%, 1.35-6.88), inability to perform daily activities and work (ORâ€‰=â€‰2.64; 95%CI, 1.24-5.62) were significantly more common with heterologous than homologous vaccination. No significant difference in self-reported health status was recorded 1 month or 14â€‰weeks after the second dose with BNT162b2 or ChAdOx1-S/BNT162b2. Our study confirms the safety of both heterologous and homologous vaccination, with a slight increase in some short-term adverse events for the heterologous regimen. Therefore, administering a second dose of a mRNA vaccine to the recipients of a previous dose of viral vector vaccine may have represented an advantageous strategy to improve flexibility and to accelerate the vaccination campaign.

Safety and immunogenicity of SCB-2019, an adjuvanted, recombinant SARS-CoV-2 trimeric S-protein subunit COVID-19 vaccine in healthy 12-17 year-old adolescents. We previously demonstrated the efficacy of the COVID-19 vaccine candidate, SCB-2019, in adults in the SPECTRA phase 2/3 efficacy study. We extended the study to include 1278 healthy 12-17-year-old adolescents in Belgium, Colombia, and the Philippines who received either two doses of SCB-2019 or placebo 21â€‰days apart, to assess immunogenicity as neutralizing antibodies against prototype SARS-CoV-2 and variants of concern, and safety and reactogenicity as solicited and unsolicited adverse events with a comparator group of young adults (18-25â€‰years). In participants with no evidence of prior SARS-CoV-2 infection SCB-2019 immunogenicity in adolescents was non-inferior to that in young adults; respective geometric mean neutralizing titers (GMT) against prototype SARS-CoV-2 14â€‰days after the second vaccination were 271 IU/mL (95% CI: 211-348) and 144 IU/mL (116-178). Most adolescents (1077, 84.3%) had serologic evidence of prior SAR-CoV-2 exposure at baseline; in these seropositive adolescents neutralizing GMTs increased from 173 IU/mL (135-122) to 982 IU/mL (881-1094) after the second dose. Neutralizing titers against Delta and Omicron BA SARS-CoV-2 variants were also increased, most notably in those with prior exposure. SCB-2019 vaccine was well tolerated with generally mild or moderate, transient solicited and unsolicited adverse events that were comparable in adolescent vaccine and placebo groups except for injection site pain - reported after 20% of SCB-2019 and 7.3% of placebo injections. SCB-2019 vaccine was highly immunogenic against SARS-CoV-2 prototype and variants in adolescents, especially in those with evidence of prior exposure, with comparable immunogenicity to young adults. Clinical trial registration: EudraCT 2020-004272-17; ClinicalTrials.gov NCT04672395.

Effects of pneumococcal conjugate vaccines on reducing the risk of respiratory disease associated with coronavirus infection. Pneumococcal conjugate vaccines (PCVs) provide protection against vaccine-type pneumococcal disease in both children and adults. Growing evidence suggests that PCVs also reduce pneumonia and lower respiratory tract infections (LRTIs) more broadly, including protecting against viral-associated respiratory diseases. In this short narrative review, we highlight clinical studies investigating whether PCVs might have a role in reducing coronavirus disease, both those caused by endemic human coronaviruses (HCoVs) and severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). These studies include two randomized controlled trials assessing HCoV-associated pneumonia, one each in children and older adults, and two observational studies of PCV13 effectiveness against HCoV-associated LRTI and COVID-19 in adults. We discuss possible mechanisms for PCV protection including preventing viral pneumococcal co-infections and the possibility that pneumococci in the upper respiratory tract might modify the host immune response to SARS-CoV-2. Lastly, we identify knowledge gaps and further questions on the potential role of PCVs during the COVID-19 pandemic.

A case of APMPPE-like panuveitis presenting with extensive outer retinal layer impairment following COVID-19 vaccination. BACKGROUND: Vaccination against the worldwide pandemic coronavirus disease 2019 (COVID-19) is underway; however, some cases of new onset uveitis after vaccination have been reported. We report a case of bilateral acute posterior multifocal placoid pigment

epitheliopathy-like (AMPPE-like) panuveitis after COVID-19 vaccination in which the patient's pathological condition was evaluated using multimodal imaging. CASE PRESENTATION: A 31-year-old woman experienced bilateral hyperemia and blurred vision starting 6Â days after her second inoculation of the COVID-19 vaccination. At her first visit, her visual acuity was decreased bilaterally, and severe bilateral anterior chamber inflammation and bilateral scattering of cream-white placoid lesions on the fundus were detected. Optical coherence tomography (OCT) showed serous retinal detachment (SRD) and choroidal thickening in both eyes (OU). Fluorescein angiography (FA) revealed hypofluorescence in the early phase and hyperfluorescence in the late phase corresponding to the placoid legions. Indocyanine green angiography (ICGA) showed sharply marginated hypofluorescent dots of various sizes throughout the mid-venous and late phases OU. The patient was diagnosed with APMPPE and was observed without any medications. Three days later, her SRD disappeared spontaneously. However, her anterior chamber inflammation continued, and oral prednisolone (PSL) was given to her. Seven days after the patient's first visit, the hyperfluorescent lesions on FA and hypofluorescent dots on ICGA partially improved; however, the patient's best corrected visual acuity (BCVA) recovered only to 0.7 OD and 0.6 OS, and the impairment of the outer retinal layer was broadly detected as hyperautofluorescent lesions on fundus autofluorescence (FAF) examination and as irregularity in or disappearance of the ellipsoid and interdigitation zones on OCT, which were quite atypical for the findings of APMPPE. Steroid pulse therapy was performed. Five days later, the hyperfluorescence on FAF had disappeared, and the outer retinal layer improved on OCT. Moreover, the patient's BCVA recovered to 1.0 OU. Twelve months after the end of treatment, the patient did not show any recurrences. CONCLUSIONS: We observed a case of APMPPE-like panuveitis after COVID-19 vaccination featuring some atypical findings for APMPPE. COVID-19 vaccination may induce not only known uveitis but also atypical uveitis, and appropriate treatment is required for each case.

Author's reply. "Immunogenicity, effectiveness and safety of COVID-19 vaccine in older adults living in nursing homes: Comment".

Clinical characteristics of SARS-CoV-2 vaccine-related acute appendicitis. BACKGROUND: In a large nationwide mass vaccination setting, the SARS-CoV-2 vaccine was recently linked to myocarditis, lymphadenopathy, herpes zoster infection and appendicitis. We aimed to examine the characteristics and management of SARS-CoV-2 vaccine-related acute appendicitis. METHODS: We performed a retrospective cohort study in a large tertiary medical centre in Israel. All patients presenting with acute appendicitis within 21 days of receiving their SARS-CoV-2 vaccination (PCVAA group) were compared with patients who presented with acute appendicitis not related to the vaccination (N-PCVAA group). RESULTS: We reviewed the records of 421 patients with acute appendicitis from December 2020 to September 2021; 38 (9%) patients presented with acute appendicitis within 21 days of receiving their SARS-CoV-2 vaccination. Patients in the PCVAA group were older than those in the N-PCVAA group (mean 41 Â± 19 yr v. 33 Â± 15 yr, respectively, p = 0.008), with male predominance. More patients were managed nonsurgically during the pandemic than before the pandemic (24% v. 18%, p = 0.03). CONCLUSION: With the exception of older age, the clinical characteristics of patients presenting with acute appendicitis within 21 days of receiving the SARS-CoV-2 vaccination did not differ from those of patients who presented with acute appendicitis not related to the vaccination. This finding suggests that vaccine-related acute appendicitis is similar to "classic" acute appendicitis.

Severe rash after COVID-19 vaccination. The patient's recent vaccine was the most remarkable thing about his medical history.

Validation of myocarditis diagnoses in the Swedish patient register for analyses of potential adverse reactions to COVID-19 vaccines. BACKGROUND: Coronavirus disease 2019 (COVID-19) mRNA vaccines are associated with an increased risk of myocarditis using hospital discharge diagnoses as an

outcome. The validity of these register-based diagnoses is uncertain. METHODS: Patient records for subjects < 40 years of age and a diagnosis of myocarditis in the Swedish National Patient Register were manually reviewed. Brighton Collaboration diagnosis criteria for myocarditis were applied based on patient history, clinical examination, laboratory data, electrocardiograms, echocardiography, magnetic resonance imaging and myocardial biopsy. Poisson regression was used to estimate incidence rate ratios, comparing the register-based outcome variable to validated outcomes. Interrater reliability was assessed by a blinded re-evaluation. RESULTS: Overall, 95.6% (327/342) of cases registered as myocarditis were confirmed (definite, probable or possible myocarditis according to Brighton Collaboration diagnosis criteria, positive predictive value 0.96 [95% CI 0.93-0.98]). Of the 4.4% (15/342) cases reclassified as no myocarditis or as insufficient information, two cases had been exposed to the COVID-19 vaccine no more than 28 days before the myocarditis diagnosis, two cases were exposed >28 days before admission and 11 cases were unexposed to the vaccine. The reclassification had only minor impact on incidence rate ratios for myocarditis following COVID-19 vaccination. In total, 51 cases were sampled for a blinded re-evaluation. Of the 30 randomly sampled cases initially classified as either definite or probably myocarditis, none were re-classified after re-evaluation. Of the in all 15 cases initially classified as no myocarditis or insufficient information, 7 were after re-evaluation re-classified as probable or possible myocarditis. This re-classification was mostly due to substantial variability in electrocardiogram interpretation. CONCLUSION: This validation of register-based diagnoses of myocarditis by manual patient record review confirmed the register diagnosis in 96% of cases and had high interrater reliability. Reclassification had only a minor impact on the incidence rate ratios for myocarditis following COVID-19 vaccination.

Large Vessel Vasculitis After the Administration of Oxford-AstraZeneca COVID-19 Vaccine. We report a case of a 52-year-old female with Large Vessel Vasculitis (LVV) after vaccination with Oxford-AstraZeneca COVID-19 vaccine. She was presented with fever, started two weeks after the second dose of vaccine. Laboratory values, revealed elevated inflammatory markers and chronic disease anaemia. All the infectious causes were excluded, and immunology tests were negative. Computed Tomography (CT) demonstrated concentric wall thickening of ascending and descending aorta. Positron Emission Tomography (PET) scan showed increased vascular fluorodeoxyglucose (FDG), compatible with LVV. Within one month of treatment with high dose glucocorticoids and iv cyclophosphamide, laboratory findings normalised, and fever resolved.

Cardiac Adverse Events Following COVID-19 Vaccination in Patients With Prior Vaccine-Associated Myocarditis. BACKGROUND: Limited information exists to guide shared clinical decision making on COVID-19 vaccination in persons with a prior history of vaccine-associated myocarditis, pericarditis, or myopericarditis (VAMP). The objective of this retrospective observational case series was to characterize cardiac outcomes within 30 days following receipt of 1 or more COVID-19 vaccinations during 2021 in US service members diagnosed with prior non-COVID-19 VAMP between 1998 and 2019. METHODS: As part of the collaborative public health mission with the Centers for Disease Control and Prevention for enhanced vaccine adverse events surveillance, the Defense Health Agency Immunization Healthcare Division maintains a clinical database of service members and beneficiaries referred for suspected adverse events following immunizations. Cases in this database recorded between January 1, 2003, and February 28, 2022, were reviewed to identify individuals with prior VAMP who received a COVID-19 vaccine in 2021 and developed signs or symptoms suggestive of VAMP within 30 days following COVID-19 vaccination. RESULTS: Before the COVID-19 pandemic, 431 service members had verified VAMP. Among these 431 patients, 179 had records that confirmed receipt of a COVID-19 vaccine in 2021. Of these 179 patients, 171 (95.5%) were male. Their median age was 39 years (range, 21-67) at the time of COVID-19 vaccination. Most (n = 172; 96.1%) experienced their original VAMP episode after receipt of the live replicating smallpox vaccine. Eleven

patients experienced cardiac-suggestive symptoms (chest pain, palpitations, or dyspnea) within 30 days of COVID-19 vaccination. Four patients met the criteria for recurrent VAMP. Three men aged 49, 50, and 55 years developed myocarditis within 3 days of an mRNA COVID-19 vaccine. One 25-year-old man developed pericarditis within 4 days of receiving an mRNA vaccine. All 4 COVID-19 recurrent VAMP cases fully recovered with minimal supportive care within weeks (myocarditis) to months (pericarditis). CONCLUSIONS: As demonstrated by this case series, albeit rare, VAMP may reoccur after COVID-19 vaccination among patients who experienced cardiac injury after smallpox vaccination. The clinical characteristics and course of the 4 recurring cases were mild, appearing similar to the post-COVID-19 VAMP described in individuals without a history of VAMP. More research is warranted on factors that may predispose patients to vaccine-associated cardiac injury and which vaccine platforms or schedules may reduce the risk of recurrence among patients who have experienced these events.

Myocarditis Following COVID-19 Vaccination: A Systematic Review. COVID-19 vaccination has significantly reduced both the morbidity and mortality rates associated with SARS-CoV-2 infection. Vaccines, especially mRNA vaccines, have been proposed in several studies to complicate viral myocarditis. Thus, our systematic and meta-analysis review aims to further investigate the possibility of an association between COVID-19 vaccines and myocarditis. We systematically searched PubMed, Web of Science, Scopus, Ovid, and Google Scholar and did a gray search of other databases using the following keywords and terms: "Myocarditis ("Myocarditis" Mesh) OR "Chagas Cardiomyopathy" Mesh) AND "COVID-19 Vaccines" Mesh. The studies were limited to only English articles that reported myocardial inflammation or myocarditis associated with COVID-19 vaccines. Pooled risk ratio with its 95% confidence interval was analyzed by RevMan software (5.4) to perform the meta-analysis. Our study included 671 patients from 44 studies with a mean age of 14-40 years. Nevertheless, myocarditis was noted in a mean of (3.227) days, and 4.19 per million vaccination recipients experienced myocarditis. Most cases were clinically presented with manifestations of cough, chest pain, and fever. Laboratory tests revealed increased C-reactive protein, and troponin with all other cardiac markers in most patients. Cardiac magnetic resonance imaging (MRI) revealed late gadolinium enhancement with myocardial edema and cardiomegaly. Also, electrocardiograms revealed ST-segment elevation in most patients. Furthermore, the incidence of myocarditis was statistically significantly lower in the COVID-19 vaccine group as compared with the control group (RR = 0.15, 95% CI = 0.10-0.23, p-value < 0.00001). No significant association was found between COVID-19 vaccines and the incidence of myocarditis. The study's findings highlight the importance of implementing evidence-based COVID-19 prevention strategies, such as vaccination, to reduce the public health impact of COVID-19 and its associated complications.

Immune-Mediated Necrotizing Myopathy With Concurrent Statin Use After Routine COVID-19 Inoculation: A Case Report. SARS-CoV-2 has been associated with multiple disease processes and chronic sequela. Much less understood are the neurological effects, ranging from headaches, pro-thrombotic state, encephalitis, and myopathic processes. Many case reports have documented post-SARS-CoV-2 virus effects; however, this case highlights the possibility of a less commonly described neurological manifestation possibly related to the BNT162b2 mRNA Pfizer vaccine. There is scant literature on immune-mediated necrotizing myopathy (IMNM) triggered after COVID-19 vaccination. The BNT162b2 mRNA COVID-19 vaccine (Pfizer, BioNTech) has proven to be safe and effective in reducing transmission of COVID-19, but post-vaccination neurological events, including venous sinus thrombosis, transverse myelitis, and immune-mediated diseases, such as Guillain-BarrÃ© syndrome, have been reported. We report a case of IMNM with HMG-CoA reductase antibody positivity in the setting of BNT162b2 vaccination. The patient presented with progressive muscle weakness with rhabdomyolysis and necrotizing autoimmune myopathy proven on muscle biopsy after the second

dose of the BNT162b2 vaccine. Ultimately, this case report highlights the importance of clinical suspicion for early diagnosis and initiation of treatment after symptoms concerning necrotizing myopathy.

Safety of COVID-19 vaccine in patients with myasthenia gravis: a self-controlled case series study. BACKGROUND: The safety of COVID-19 vaccines has been clarified in clinical trials; however, some immunocompromised patients, such as myasthenia gravis (MG) patients, are still hesitant to receive vaccines. Whether COVID-19 vaccination increases the risk of disease worsening in these patients remains unknown. This study aims to evaluate the risk of disease exacerbation in COVID-19-vaccinated MG patients. METHODS: The data in this study were collected from the MG database at Tangdu Hospital, the Fourth Military Medical University, and the Tertiary Referral Diagnostic Center at Huashan Hospital, Fudan University, from 1 April 2022 to 31 October 2022.Â A self-controlled case series method was applied, and the incidence rate ratios were calculated in the prespecified risk period using conditional Poisson regression. RESULTS: Inactivated COVID-19 vaccines did not increase the risk of disease exacerbation in MG patients with stable disease status. A few patients experienced transient disease worsening, but the symptoms were mild. It is noted that more attention should be paid to thymoma-related MG, especially within 1 week after COVID-19 vaccination. CONCLUSION: COVID-19 vaccination has no long-term impact on MG relapse.

Menstrual abnormalities after COVID-19 vaccination in the Netherlands: A description of spontaneous and longitudinal patient-reported data. AIMS: During the COVID-19 vaccination campaigns, the number of reports of menstrual abnormalities increased rapidly. Here, we describe the nature and potential risk factors associated with menstrual abnormalities based on spontaneously reporting data as well as data from a prospective cohort event monitoring (CEM) study as these are poorly studied. METHODS: Reports of menstrual abnormalities received by the Netherlands Pharmacovigilance Centre Lareb in the spontaneous reporting system between February 2021 and April 2022 were summarized. In addition, logistic regression analysis was performed on the reported menstrual abnormalities in the CEM study to assess the association between person characteristics, prior SARS-CoV-2 infection and use of hormonal contraceptives and the occurrence of menstrual abnormalities after vaccination. RESULTS: We analysed over 24â€‰000 spontaneous reports of menstrual abnormalities and over 500 episodes (among 16â€‰929 included women) of menstrual abnormalities in the CEM study. The CEM study showed an incidence of 41.4 per 1000 women aged â‰¤54â€‰years. Amenorrhoea/oligomenorrhoea and heavy menstrual bleeding collectively accounted for about half of all abnormalities reported. Significant associations were observed for the age group 25-34â€‰years (odds ratio 2.18; 95% confidence interval 1.45-3.41) and the Pfizer vaccine (odds ratio 3.04; 95% confidence interval 2.36-3.93). No association was observed for body mass index and presence of most comorbidities assessed. CONCLUSION: The cohort study showed a high incidence of menstrual disorders among women aged â‰¤54â€‰years, and this observation was supported by the analysis of spontaneous reports. This suggests that a relation between COVID-19 vaccination and menstrual abnormalities is plausible and should be further investigated.

Type I Kounis syndrome induced by COVID-19 vaccination in China: a case report. BACKGROUND: Kounis syndrome is a rare clinical condition characterized by the occurrence of an acute coronary event induced by an acute allergic episode. The ongoing pandemic of coronavirus disease 2019 (COVID-19) has contributed to an increase in the incidence of allergic reactions to a certain extent, thereby increasing the incidence of Kounis syndrome. Timely diagnosis and effective management of this disease are important in clinical practice. CASE PRESENTATION: We report a 43-year-old woman who developed generalized pruritus, breathlessness, paroxysmal precordial crushing pain, and dyspnea after receiving the third dose of the COVID-19 vaccine. After anti-allergic treatment and therapy for acute myocardial ischemia, her symptoms resolved with improvement in cardiac function

and resolution of ST-segment changes. The prognosis was satisfactory, and the final diagnosis was type I Kounis syndrome. CONCLUSION: This patient with type I Kounis syndrome rapidly developed acute coronary syndrome (ACS) after an acute allergic reaction to the COVID-19 vaccine. â€‹Timely diagnosis of acute allergic reaction and ACS, and targeted treatment based on the relevant guidelines are the key to successful treatment of the syndrome.â€‹.

Adverse outcomes of SARS-CoV-2 infection with delta and omicron variants in vaccinated versus unvaccinated US veterans: retrospective cohort study. OBJECTIVES: To determine the association between covid-19 vaccination types and doses with adverse outcomes of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection during the periods of delta (B.1.617.2) and omicron (B.1.1.529) variant predominance. DESIGN: Retrospective cohort. SETTING: US Veterans Affairs healthcare system. PARTICIPANTS: Adults (â‰¥18 years) who are affiliated to Veterans Affairs with a first documented SARS-CoV-2 infection during the periods of delta (1 July-30 November 2021) or omicron (1 January-30 June 2022) variant predominance. The combined cohorts had a mean age of 59.4 (standard deviation 16.3) and 87% were male. INTERVENTIONS: Covid-19 vaccination with mRNA vaccines (BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna)) and adenovirus vector vaccine (Ad26.COV2.S (Janssen/Johnson & Johnson)). MAIN OUTCOME MEASURES: Stay in hospital, intensive care unit admission, use of ventilation, and mortality measured 30 days after a positive test result for SARS-CoV-2. RESULTS: In the delta period, 95â€‰336 patients had infections with 47.6% having at least one vaccine dose, compared with 184â€‰653 patients in the omicron period, with 72.6% vaccinated. After adjustment for patient demographic and clinical characteristics, in the delta period, two doses of the mRNA vaccines were associated with lower odds of hospital admission (adjusted odds ratio 0.41 (95% confidence interval 0.39 to 0.43)), intensive care unit admission (0.33 (0.31 to 0.36)), ventilation (0.27 (0.24 to 0.30)), and death (0.21 (0.19 to 0.23)), compared with no vaccination. In the omicron period, receipt of two mRNA doses were associated with lower odds of hospital admission (0.60 (0.57 to 0.63)), intensive care unit admission (0.57 (0.53 to 0.62)), ventilation (0.59 (0.51 to 0.67)), and death (0.43 (0.39 to 0.48)). Additionally, a third mRNA dose was associated with lower odds of all outcomes compared with two doses: hospital admission (0.65 (0.63 to 0.69)), intensive care unit admission (0.65 (0.59 to 0.70)), ventilation (0.70 (0.61 to 0.80)), and death (0.51 (0.46 to 0.57)). The Ad26.COV2.S vaccination was associated with better outcomes relative to no vaccination, but higher odds of hospital stay and intensive care unit admission than with two mRNA doses. BNT162b2 was generally associated with worse outcomes than mRNA-1273 (adjusted odds ratios between 0.97 and 1.42). CONCLUSIONS: In veterans with recent healthcare use and high occurrence of multimorbidity, vaccination was robustly associated with lower odds of 30 day morbidity and mortality compared with no vaccination among patients infected with covid-19. The vaccination type and number of doses had a significant association with outcomes.

Prevalence of post-vaccine side effects among COVID-19 immunized community of Southern Pakistan. BACKGROUND: The response to the vaccine may vary among individuals. Hence, it is important to know how often individuals experience side effects after immunization against COVID-19. OBJECTIVE: This study aimed to assess the incidence of side effects following COVID-19 vaccination across different vaccine recipients in Southern Pakistan and identify the potential factors associated with these side effects in the population. METHODS: The survey was conducted across Pakistan through Google-forms Links from August to October 2021. The questionnaire included demographic information and COVID-19 vaccine information. Chi-square (x2) was performed for comparative analysis to check the significance level with $P < 0.05$. The final analysis included 507 participants who had received COVID-19 vaccines. RESULTS: Of the total 507 COVID-19 vaccines recipients, 24.9% received CoronaVac, 36.5% received BBIBP-CorV, 14.2% received BNT162b2, 13.8% received AZD1222, and 10.7% received mRNA-1273. The most prominent side effects after the first

dose were fever, weakness, lethargy, and pain at the site of injection. Moreover, the most commonly reported side effects after the second dose were pain at the injection site, headache, body ache, lethargy, fever, chills, flu-like symptoms, and diarrhea. CONCLUSION: Our results suggested that the side effects due to COVID-19 vaccination can vary between the first and second doses and type of COVID-19 vaccine. Our findings suggest continuing monitoring of vaccine safety and the importance of individualized risk-benefit assessment for COVID-19 immunization.

Prevalence and functional profile of SARS-CoV-2 T cells in asymptomatic Kenyan adults. BackgroundSARS-CoV-2 infection in Africa has been characterized by a less severe disease profile than what has been observed elsewhere, but the profile of SARS-CoV-2-specific adaptive immunity in these mainly asymptomatic patients has not, to our knowledge, been analyzed.MethodsWe collected blood samples from residents of rural Kenya (n = 80), who had not experienced any respiratory symptoms or had contact with individuals with COVID-19 and had not received COVID-19 vaccines. We analyzed spike-specific antibodies and T cells specific for SARS-CoV-2 structural (membrane, nucleocapsid, and spike) and accessory (ORF3a, ORF7, ORF8) proteins. Pre-pandemic blood samples collected in Nairobi (n = 13) and blood samples from mild-to-moderately symptomatic COVID-19 convalescent patients (n = 36) living in the urban environment of Singapore were also studied.ResultsAmong asymptomatic Africans, we detected anti-spike antibodies in 41.0% of the samples and T cell responses against 2 or more SARS-CoV-2 proteins in 82.5% of samples examined. Such a pattern was absent in the pre-pandemic samples. Furthermore, distinct from cellular immunity in European and Asian COVID-19 convalescents, we observed strong T cell immunogenicity against viral accessory proteins (ORF3a, ORF8) but not structural proteins, as well as a higher IL-10/IFN-Î³ cytokine ratio profile.ConclusionsThe high incidence of T cell responses against different SARS-CoV-2 proteins in seronegative participants suggests that serosurveys underestimate SARS-CoV-2 prevalence in settings where asymptomatic infections prevail. The functional and antigen-specific profile of SARS-CoV-2-specific T cells in African individuals suggests that environmental factors can play a role in the development of protective antiviral immunity.FundingUS Centers for Disease Control and Prevention, Division of Global Health Protection; the Singapore Ministry of Health's National Medical Research Council (COVID19RF3-0060, COVID19RF-001, COVID19RF-008, MOH-StaR17Nov-0001).

New onset of hypomegakaryocytic thrombocytopenia with the potential for progression to aplastic anemia after BNT162b2 mRNA COVID-19 vaccination. Vaccination with a coronavirus disease-2019 (COVID-19) vaccine is an effective public health measure for reducing the risk of infection and severe complications from COVID-19. However, serious hematological complications after COVID-19 vaccination have been reported. Here, we report a case of new-onset hypomegakaryocytic thrombocytopenia (HMT) with the potential for progression to aplastic anemia (AA) that developed in a 46-year-old man 4Â days after the fourth mRNA COVID-19 vaccination. Platelet count rapidly decreased after vaccination and white blood cell count declined subsequently. Bone marrow examination immediately after disease onset showed severely hypocellular marrow (cellularity of almost 0%) in the absence of fibrosis, findings that were consistent with AA. Since the severity of pancytopenia did not meet the diagnostic criteria for AA, the patient was diagnosed with HMT that could progress to AA. Treatment with eltrombopag and cyclosporine was started immediately after diagnosis and cytopenia improved. Although it is difficult to determine whether the post-vaccination cytopenia was vaccine induced or accidental because the association was chronological, vaccination with an mRNA-based COVID-19 vaccine may be associated with development of HMT/AA. Therefore, physicians should be aware of this rare, but serious adverse event and promptly provide appropriate treatment.

Autoimmune skin disorders and SARS-CoV-2 vaccination - a meta-analysis. BACKGROUND AND OBJECTIVES: The coronavirus SARS-CoV-2, which is the cause of COVID-19 disease in infected

patients, has led to an ongoing worldwide pandemic. Although SARS-CoV-2 vaccination had a dramatic positive effect on the course of COVID-19, there has been increasing evidence of adverse effects after SARS-CoV-2 vaccination. This meta-analysis highlights the association between SARS-CoV-2 vaccination and de novo induction or aggravation of inflammatory and autoimmune skin diseases. MATERIAL AND METHODS: A systematic meta-analysis of the literature on new onset or worsening of inflammatory and autoimmune diseases after SARS-CoV-2 vaccination was performed according to the PRISMA guidelines. The search strategy included following terms: "COVID-19/SARS-CoV-2 vaccine bullous pemphigoid/pemphigus vulgaris/systemic lupus erythematosus/dermatomyositis/lichen planus/leukocytoclastic vasculitis." Moreover, we describe representative cases from our dermatology department. RESULTS: The database-search in MEDLINE identified 31 publications on bullous pemphigoid, 24 on pemphigus vulgaris, 65 on systemic lupus erythematosus, nine on dermatomyositis, 30 on lichen planus, and 37 on leukocytoclastic vasculitis until June 30th, 2022. Severity and response to treatment varied among the described cases. CONCLUSIONS: Our meta-analysis highlights a link between SARS-CoV-2 vaccination and new onset or worsening of inflammatory and autoimmune skin diseases. Moreover, the extent of disease exacerbation has been exemplified by cases from our dermatological department.

Immune Responses and Breakthrough Infections After COVID-19 Vaccination.

Immune Responses After Vaccination With Primary 2-Dose ChAdOx1 Plus a Booster of BNT162b2 or Vaccination With Primary 2-Dose BNT162b2 Plus a Booster of BNT162b2 and the Occurrence of Omicron Breakthrough Infection. BACKGROUND: Before the omicron era, health care workers were usually vaccinated with either the primary 2-dose ChAdOx1 nCoV-19 (Oxford-AstraZeneca) series plus a booster dose of BNT162b2 (Pfizer-BioNTech) (CCB group) or the primary 2-dose BNT162b2 series plus a booster dose of BNT162b2 (BBB group) in Korea. METHODS: The two groups were compared using quantification of the surrogate virus neutralization test for wild type severe acute respiratory syndrome coronavirus 2 (SVNT-WT), the omicron variant (SVNT-O), spike-specific IgG, and interferon-gamma (IFN-Î³), as well as the omicron breakthrough infection cases. RESULTS: There were 113 participants enrolled in the CCB group and 51 enrolled in the BBB group. Before and after booster vaccination, the median SVNT-WT and SVNT-O values were lower in the CCB (SVNT-WT [before-after]: 72.02-97.61%, SVNT-O: 15.18-42.29%) group than in the BBB group (SVNT-WT: 89.19-98.11%, SVNT-O: 23.58-68.56%; all $P < 0.001$). Although the median IgG concentrations were different between the CCB and BBB groups after the primary series (2.677 vs. 4.700 AU/mL, respectively, $P < 0.001$), they were not different between the two groups after the booster vaccination (7.246 vs. 7.979 AU/mL, respectively, $P = 0.108$). In addition, the median IFN-Î³ concentration was higher in the BBB group than in the CCB group (550.5 and 387.5 mIU/mL, respectively, $P = 0.014$). There was also a difference in the cumulative incidence curves over time (CCB group 50.0% vs. BBB group 41.8%; $P = 0.045$), indicating that breakthrough infection occurred faster in the CCB group. CONCLUSION: The cellular and humoral immune responses were low in the CCB group so that the breakthrough infection occurred faster in the CCB group than in the BBB group.

Circulating eosinophils associated with responsiveness to COVID-19 vaccine and the disease severity in patients with SARS-CoV-2 omicron variant infection. OBJECTIVE: This study aimed to investigate the longitudinal circulating eosinophil (EOS) data impacted by the COVID-19 vaccine, the predictive role of circulating EOS in the disease severity, and its association with T cell immunity in patients with SARS-CoV-2 Omicron BA.2 variant infection in Shanghai, China. METHODS: We collected a cohort of 1,157 patients infected with SARS-CoV-2 Omicron/BA.2 variant in Shanghai, China. These patients were diagnosed or admitted between Feb 20, 2022, and May 10, 2022, and were classified as asymptomatic (nâ€‰=â€‰705), mild (nâ€‰=â€‰286) and severe (nâ€‰=â€‰166) groups. We compiled and analyzed data of patients' clinical demographic characteristics, laboratory findings, and

clinical outcomes. RESULTS: COVID-19 vaccine reduced the incidence of severe cases. Severe patients were shown to have declined peripheral blood EOS. Both the 2 doses and 3 doses of inactivated COVID-19 vaccines promoted the circulating EOS levels. In particular, the 3rd booster shot of inactivated COVID-19 vaccine was shown to have a sustained promoting effect on circulating EOS. Univariate analysis showed that there was a significant difference in age, underlying comorbidities, EOS, lymphocytes, CRP, CD4, and CD8 T cell counts between the mild and the severe patients. Multivariate logistic regression analysis and ROC curve analysis indicate that circulating EOS (AUCâ€‰=â€‰0.828, pâ€‰=â€‰0.025), the combination of EOS and CD4 T cell (AUCâ€‰=â€‰0.920, pâ€‰=â€‰0.017) can predict the risk of disease severity in patients with SARS-CoV-2 Omicron BA.2 variant infection. CONCLUSIONS: COVID-19 vaccine promotes circulating EOS and reduces the risk of severe illness, and particularly the 3rd booster dose of COVID-19 vaccine sustainedly promotes EOS. Circulating EOS, along with T cell immunity, may have a predictive value for the disease severity in SARS-CoV-2 Omicron infected patients.

Immunovirological and environmental screening reveals actionable risk factors for fatal COVID-19 during post-vaccination nursing home outbreaks. Coronavirus Disease 2019 (COVID-19) vaccination has resulted in excellent protection against fatal disease, including in older adults. However, risk factors for post-vaccination fatal COVID-19 are largely unknown. We comprehensively studied three large nursing home outbreaks (20-35% fatal cases among residents) by combining severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) aerosol monitoring, whole-genome phylogenetic analysis and immunovirological profiling of nasal mucosa by digital nCounter transcriptomics. Phylogenetic investigations indicated that each outbreak stemmed from a single introduction event, although with different variants (Delta, Gamma and Mu). SARS-CoV-2 was detected in aerosol samples up to 52â€‰d after the initial infection. Combining demographic, immune and viral parameters, the best predictive models for mortality comprised IFNB1 or age, viral ORF7a and ACE2 receptor transcripts. Comparison with published pre-vaccine fatal COVID-19 transcriptomic and genomic signatures uncovered a unique IRF3 low/IRF7 high immune signature in post-vaccine fatal COVID-19 outbreaks. A multi-layered strategy, including environmental sampling, immunomonitoring and early antiviral therapy, should be considered to prevent post-vaccination COVID-19 mortality in nursing homes.

Safety, immunogenicity, and efficacy of the mRNA vaccine CS-2034 as a heterologous booster versus homologous booster with BBIBP-CorV in adults aged â‰¥18 years: a randomised, double-blind, phase 2b trial. BACKGROUND: Heterologous boosting is suggested to be of use in populations who have received inactivated COVID-19 vaccines. We aimed to assess the safety and immunogenicity of a heterologous vaccination with the mRNA vaccine CS-2034 versus the inactivated BBIBP-CorV as a fourth dose, as well as the efficacy against the SARS-CoV-2 omicron (BA.5) variant. METHODS: This trial contains a randomised, double-blind, parallel-controlled study in healthy participants aged 18 years or older (group A) and an open-label cohort in participants 60 years and older (group B), who had received three doses of inactivated whole-virion vaccines at least 6 months before enrolment. Pregnant women and people with major chronic illnesses or a history of allergies were excluded. Eligible participants in group A were stratified by age (18-59 years and â‰¥60 years) and then randomised by SAS 9.4 in a ratio of 3:1 to receive a dose of the mRNA vaccine (CS-2034, CanSino, Shanghai, China) or inactivated vaccine (BBIBP-CorV, Sinopharm, Beijing, China). Safety and immunogenicity against omicron variants of the fourth dose were evaluated in group A. Participants 60 years and older were involved in group B for safety observations. The primary outcome was geometric mean titres (GMTs) of the neutralising antibodies against omicron and seroconversion rates against BA.5 variant 28 days after the boosting, and incidence of adverse reactions within 28 days. The intention-to-treat group was involved in the safety analysis, while all patients in group A

who had blood samples taken before and after the booster were involved in the immunogenicity analysis. This trial was registered at the Chinese Clinical Trial Registry Centre (ChiCTR2200064575). FINDINGS: Between Oct 13, and Nov 22, 2022, 320 participants were enrolled in group A (240 in the CS-2034 group and 80 in the BBIBP-CorV group) and 113 in group B. Adverse reactions after vaccination were more frequent in CS-2034 recipients (158 [44Â·8%]) than BBIBP-CorV recipients (17 [21Â·3%], p<0Â·0001). However, most adverse reactions were mild or moderate, with grade 3 adverse reactions only reported by eight (2%) of 353 participants receiving CS-2034. Heterologous boosting with CS-2034 elicited 14Â·4-fold (GMT 229Â·3, 95% CI 202Â·7-259Â·4 vs 15Â·9, 13Â·1-19Â·4) higher concentration of neutralising antibodies to SARS-CoV-2 omicron variant BA.5 than did homologous boosting with BBIBP-CorV. The seroconversion rates of SARS-CoV-2-specific neutralising antibody responses were much higher in the mRNA heterologous booster regimen compared with BBIBP-CorV homologous booster regimen (original strain 47 [100%] of 47 vs three [18Â·8%] of 16; BA.1 45 [95Â·8%] of 48 vs two [12Â·5%] 16; and BA.5 233 [98Â·3%] of 240 vs 15 [18Â·8%] of 80 by day 28). INTERPRETATION: Both the administration of mRNA vaccine CS-2034 and inactivated vaccine BBIBP-CorV as a fourth dose were well tolerated. Heterologous boosting with mRNA vaccine CS-2034 induced higher immune responses and protection against symptomatic SARS-CoV-2 omicron infections compared with homologous boosting, which could support the emergency use authorisation of CS-2034 in adults. FUNDING: Science and Technology Commission of Shanghai, National Natural Science Foundation of China, Jiangsu Provincial Science Fund for Distinguished Young Scholars, and Jiangsu Provincial Key Project of Science and Technology Plan. TRANSLATION: For the Chinese translation of the abstract see Supplementary Materials section.

Adverse Events and Serological Responses After SARS-CoV-2 Vaccination in Individuals With Inflammatory Bowel Disease. INTRODUCTION: We determined adverse events after 4 doses of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccine in those with inflammatory bowel disease (IBD), associations between antibodies and injection site reactions (ISR), and risk of IBD flare. METHODS: Individuals with IBD were interviewed for adverse events to SARS-CoV-2 vaccine. Multivariable linear regression assessed the association between antibody titers and ISR. RESULTS: Severe adverse events occurred in 0.03%. ISR were significantly associated with antibody levels after the fourth dose (geometric mean ratio = 2.56; 95% confidence interval 1.18-5.57). No cases of IBD flare occurred. DISCUSSION: SARS-CoV-2 vaccines are safe for those with IBD. ISR after the fourth dose may indicate increased antibodies.

Detection of specific RBD(+) IgG(+) memory B cells by flow cytometry in healthcare workers and patients with inborn errors of immunity after BNT162b2 m RNA COVID-19 vaccination. INTRODUCTION: Inborn errors of immunity (IEI) are a heterogeneous group of diseases caused by intrinsic defects of the immune system. Estimating the immune competence of immunocompromised patients for an infection risk assessment or after SARS-CoV-2 vaccination constituted a challenge. METHODS: The aim of this study was to determine the humoral responses of patients with IEI through a comprehensive analysis of specific receptor-binding domain-positive (RBD+) IgG+ memory B cells (MBCs) by flow cytometry, together with routine S-specific IgG antibodies and QuantiFERON SARS-CoV-2 (T-cell response), before the vaccine and 3 weeks after a second dose. RESULTS AND DISCUSSION: We first analyzed the percentage of specific RBD+ IgG+ MBCs in healthy healthcare workers. Within the control group, there was an increase in the percentage of specific IgG+ RBD+ MBCs 21 days after the second dose, which was consistent with S-specific IgG antibodies.Thirty-one patients with IEI were included for the pre- and post-vaccination study; IgG+ RBD+ MBCs were not evaluated in 6 patients due to an absence of B cells in peripheral blood. We detected various patterns among the patients with IEI with circulating B cells (25, 81%): an adequate humoral response was observed in 12/25, consider by the detection of positive S-specific IgG antibodies and the presence of

specific IgG+ RBD+ MBCs, presenting a positive T-cell response; in 4/25, very low S-specific IgG antibody counts correlated with undetectable events in the IgG+ RBD+ MBC compartment but with positive cellular response. Despite the presence of S-specific IgG antibodies, we were unable to detect a relevant percentage of IgG+ RBD+ MBCs in 5/25; however, all presented positive T-cell response. Lastly, we observed a profound failure of B and T-cell response in 3 (10%) patients with IEI, with no assessment of S-specific IgG antibodies, IgG+ RBD+ MBCs, and negative cellular response. The identification of specific IgG+ RBD+ MBCs by flow cytometry provides information on different humoral immune response outcomes in patients with IEI and aids the assessment of immune competence status after SARS-CoV-2 mRNA vaccine (BNT162b2), together with S-specific IgG antibodies and T-cell responses.

Omicron infection-associated T- and B-cell immunity in antigen-naive and triple-COVID-19-vaccinated individuals. Since early 2022, various Omicron variants have dominated the SARS-CoV-2 pandemic in most countries. All Omicron variants are B-cell immune escape variants, and antibodies induced by first-generation COVID-19 vaccines or by infection with earlier SARS-CoV-2 variants largely fail to protect individuals from Omicron infection. In the present study, we investigated the effect of Omicron infections in triple-vaccinated and in antigen-naive individuals. We show that Omicron breakthrough infections occurring 2-3.5 months after the third vaccination restore B-cell and T-cell immune responses to levels similar to or higher than those measured 14 days after the third vaccination, including the induction of Omicron-neutralizing antibodies. Antibody responses in breakthrough infection derived mostly from cross-reacting B cells, initially induced by vaccination, whereas Omicron infections in antigen-naive individuals primarily generated B cells binding to the Omicron but not the Wuhan spike protein. Although antigen-naive individuals mounted considerable T-cell responses after infection, B-cell responses were low, and neutralizing antibodies were frequently below the limit of detection. In summary, the detection of Omicron-associated B-cell responses in primed and in antigen-naive individuals supports the application of Omicron-adapted COVID-19 vaccines, but calls into question their suitability if they also contain/encode antigens of the original Wuhan virus.

Thrombotic thrombocytopenic purpura following ChAdOx1 nCov-19 vaccination: A case report. Vaccine-associated thrombotic thrombocytopenic purpura (TTP) is a rare type of acquired TTP recently reported after COVID-19 vaccination. Merely four cases are ascribed to the ChAdOx1 nCoV-19 vaccine in the medical literature till the preparation of this study. In this case report, we describe a 43-year-old man who developed symptoms of TTP four days after receiving the second dose of the ChAdOx1 nCoV-19 vaccine. Peripheral blood smear demonstrated multiple schistocytes. Given a high plasmic score, he received plasma exchange, corticosteroids, and rituximab, and later, low ADAMTS 13 activity and high-titer ADAMTS inhibition antibody confirmed the diagnosis of COVID-19 vaccine-associated TTP. COVID-19 vaccine-associated TTP is an infrequent consequence of SARS-CoV-2 vaccination but with a substantial mortality rate which must be considered as one of the crucial differential diagnoses of post-COVID-19 vaccine thrombocytopenia besides vaccine-induced immune thrombotic thrombocytopenia and Immune thrombocytopenic purpura.

Occurrence of erythema multiforme following COVID-19 vaccination: a review. The fast development of vaccines against the novel coronavirus disease is among the most critical steps taken to control this potentially fatal viral disease. Like other vaccines, the coronavirus disease 2019 (COVID-19) vaccines can also cause unwanted reactions. Erythema multiforme (EM) is among the oral mucocutaneous side effects of COVID-19 vaccines. This study aimed to comprehensively review the reported cases of EM since the global onset of COVID-19 vaccination. Data from 31 relevant studies regarding the type and dose of COVID-19 vaccines administered, time of initiation of symptoms, age, and gender of patients, site of involvement, patients' medical history, and treatment options were

extracted. In total, 90 patients were identified with EM as a side effect of COVID-19 vaccination across studies. EM had the highest frequency after receiving the first dose of mRNA vaccines in older individuals. The first symptoms of EM appeared in less than 3 days in 45% and after 3 days in 55% of patients. EM is not a common side effect of COVID-19 vaccination, and fear of its occurrence should not impede vaccination.

Changes in SARS-CoV-2 antibody titers 6 months after the booster dose of BNT162b2 COVID-19 vaccine among health care workers. PURPOSE: In Japan, the data on severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody titers after the booster dose of the coronavirus disease 2019 (COVID-19) vaccine are insufficient. The aim of this study is to evaluate changes in SARS-CoV-2 antibody titers before, 1, 3, and 6 months after the booster dose of the BNT162b2 COVID-19 vaccine among health care workers. MATERIALS AND METHODS: A total of 268 participants who received the booster dose of the BNT162b2 vaccine were analyzed. SARS-CoV-2 antibody titers were measured before (baseline) and at 1, 3, and 6 months after the booster dose. Factors associated with changes in SARS-CoV-2 antibody titers at 1, 3, and 6 months were analyzed. Cutoff values at baseline were calculated to prevent infection of the omicron variant of COVID-19. RESULTS: The SARS-CoV-2 antibody titers at baseline, and 1, 3, and 6 months were 1,018.3 AU/mL, 21,396.5 AU/mL, 13,704.6 AU/mL, and 8,155.6 AU/mL, respectively. Factors associated with changes in SARS-CoV-2 antibody titers at 1 month were age and SARS-CoV-2 antibody titers at baseline, whereas changes in SARS-CoV-2 antibody titers at 3 and 6 months were associated with the SARS-CoV-2 antibody titers at 1 month. The cutoff values of the SARS-CoV-2 antibody titers at baseline were 515.4 AU/mL and 13,602.7 AU/mL at baseline and 1 month after the booster dose, respectively. CONCLUSION: This study showed that SARS-CoV-2 antibody titers increase rapidly at 1 month after the booster dose of the BNT162b2 vaccine and begin to decrease from 1 to 6 months. Hence, another booster may be needed as soon as possible to prevent infection.

Guillain-BarrÃ© syndrome associated with SARS-CoV-2 vaccination: how is it different? a systematic review and individual participant data meta-analysis. PURPOSE: An association between Guillain-BarrÃ© syndrome (GBS) and severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccination has been reported. We aimed to summarize the clinical features of GBS associated with SARS-CoV-2 vaccination and determine the contrasting features from coronavirus disease-19 (COVID-19) associated GBS and GBS following other causes. MATERIALS AND METHODS: We performed PubMed search for articles published between 1 December 2020 and 27 January 2022 using search terms related to "SARS-CoV-2 vaccination" and "GBS". Reference searching of the eligible studies was performed. Sociodemographic and vaccination data, clinical and laboratory features, and outcomes were extracted. We compared these findings with post-COVID-19 GBS and International GBS Outcome Study (IGOS) (GBS from other causes) cohorts. RESULTS: We included 100 patients in the analysis. Mean age was 56.88 years, and 53% were males. Six-eight received non-replicating virus vector and 30 took messenger RNA (mRNA) vaccines. The median interval between the vaccination and the GBS onset was 11 days. Limb weakness, facial palsy, sensory symptoms, dysautonomia, and respiratory insufficiency were seen in 78.65%, 53.3%, 77.4%, 23.5%, and 25%, respectively. The commonest clinical and electrodiagnostic subtype were sensory-motor variant (68%) and acute inflammatory demyelinating polyneuropathy (61.4%), respectively. And 43.9% had poor outcome (GBS outcome score â‰¥3). Pain was common with virus vector than mRNA vaccine, and the latter had severe disease at presentation (Hughes grade â‰¥3). Sensory phenomenon and facial weakness were common in vaccination cohort than post-COVID-19 and IGOS. CONCLUSION: There are distinct differences between GBS associated with SARS-CoV-2 vaccination and GBS due to other causes. Facial weakness and sensory symptoms were commonly seen in the former and outcomes poor.

Intracranial Hemorrhage After Pfizer-BioNTech (BNT162b2) mRNA COVID-19 Vaccination: A Case Report. The Coronavirus 2019 (COVID-19) pandemic has affected over 700 million people worldwide and caused nearly 7 million deaths. Vaccines currently developed or in development are the most effective tools for curbing the pandemic and mitigating its impacts. In Turkey, inoculation with the Pfizer-BioNTech COVID-19 vaccine (BNT162b2, also known as tozinameran) has been approved. We report a 56-year-old female patient with underlying essential hypertension who experienced intracranial hemorrhage after receiving her first dose of tozinameran. The patient underwent immediate surgical evacuation of the hematoma, during which a left middle cerebral artery bifurcation aneurysm was macroscopically identified and clipped. The patient was pronounced deceased on the second postoperative day. This is the second case of intracranial hemorrhage following tozinameran administration caused by a ruptured middle cerebral artery bifurcation aneurysm.Â Upon analyzing the case, there might be a connection between the vaccine's potential immune-triggering effect on hemodynamic patterns and the rupture of the previously unknown cerebral aneurysm. However, these severe complications do not justify avoiding vaccines; further studies are needed. This study emphasizes the need for increased vigilance in patients with underlying systemic comorbidities who have recently been vaccinated and to share our insights into the potential relationship between tozinameran and intracranial hemorrhage.

Safety of the BNT162b2 COVID-19 Vaccine in Children Aged 5 to 17 Years. IMPORTANCE: Active monitoring of health outcomes after COVID-19 vaccination offers early detection of rare outcomes that may not be identified in prelicensure trials. OBJECTIVE: To conduct near-real-time monitoring of health outcomes following BNT162b2 COVID-19 vaccination in the US pediatric population aged 5 to 17 years. DESIGN, SETTING, AND PARTICIPANTS: This population-based study was conducted under a public health surveillance mandate from the US Food and Drug Administration. Participants aged 5 to 17 years were included if they received BNT162b2 COVID-19 vaccination through mid 2022 and had continuous enrollment in a medical health insurance plan from the start of an outcome-specific clean window until the COVID-19 vaccination. Surveillance of 20 prespecified health outcomes was conducted in near real time within a cohort of vaccinated individuals from the earliest Emergency Use Authorization date for the BNT162b2 vaccination (December 11, 2020) and was expanded as more pediatric age groups received authorization through May and June 2022. All 20 health outcomes were monitored descriptively, 13 of which additionally underwent sequential testing. For these 13 health outcomes, the increased risk of each outcome after vaccination was compared with a historical baseline with adjustments for repeated looks at the data as well as a claims processing delay. A sequential testing approach was used, which declared a safety signal when the log likelihood ratio comparing the observed rate ratio against the null hypothesis exceeded a critical value. EXPOSURE: Exposure was defined as receipt of a BNT162b2 COVID-19 vaccine dose. The primary analysis assessed primary series doses together (dose 1 + dose 2), and dose-specific secondary analyses were conducted. Follow-up time was censored for death, disenrollment, end of the outcome-specific risk window, end of the study period, or a receipt of a subsequent vaccine dose. MAIN OUTCOMES: Twenty prespecified health outcomes: 13 were assessed using sequential testing and 7 were monitored descriptively because of a lack of historical comparator data. RESULTS: This study included 3â€¯017â€¯352 enrollees aged 5 to 17 years. Of the enrollees across all 3 databases, 1â€¯510â€¯817 (50.1%) were males, 1â€¯506â€¯499 (49.9%) were females, and 2â€¯867â€¯436 (95.0%) lived in an urban area. In the primary sequential analyses, a safety signal was observed only for myocarditis or pericarditis after primary series vaccination with BNT162b2 in the age group 12 to 17 years across all 3 databases. No safety signals were observed for the 12 other outcomes assessed using sequential testing. CONCLUSIONS AND RELEVANCE: Among 20 health outcomes that were monitored in near real time, a safety signal was identified for only myocarditis or pericarditis. Consistent with other

published reports, these results provide additional evidence that COVID-19 vaccines are safe in children.

Delirium after COVID-19 vaccination in older adults. The COVID-19 global pandemic has devastated the older adult population. Like all vaccines, adverse reactions of COVID-19 vaccines are possible. This article discusses the increased incidence of delirium and delirium-associated symptoms in older adults following COVID-19 vaccinations.

Covid-19 vaccine uptake and associated factors among health science University students in northeastern Ethiopia, a cross-sectional study. The aim of this study is to assess COVID-19 vaccine uptake and associated factors among health science students at Wollo University, Northeast Ethiopia. Institution based cross-sectional study was conducted among 403 health science students at Wollo University from 1 to 15 July, 2022. The data was collected using a structured self-administered questionnaire and analysis was performed using SPSS version 26. Adjusted Odds Ratio (AOR), with 95% CI and p-value <.05 were used to declare factors significantly associated with COVID-19 vaccine uptake. The prevalence of COVID-19 vaccine uptake was 23.3% (95% CI: 19.2, 27.4). Being in the age category of 22-25â€‰years old (AORâ€‰=â€‰0.392, 95% CI (0.197, 0.780)), being >25â€‰years old (AORâ€‰=â€‰0.253, 95% CI (0.086, 0.741)), have a known disease (AORâ€‰=â€‰0.202, 95% CI (0.044, 0.935)), source of income is self (AORâ€‰=â€‰2.504, 95% CI (1.104, 5.677)) and screened for COVID-19 disease (AORâ€‰=â€‰4.278, 95 % CI (2.418, 7.570)) before are significantly associated with uptake of COVID-19 vaccine. In conclusion, majority of the respondents didn't take COVID-19 vaccine with age greater than 22â€‰years and have a known disease found to be negative predictors of COVID-19 disease.

Vaccination status for mild and asymptomatic infections with SARS-CoV-2 Omicron BA.2 variant in Shanghai. This study aimed to evaluate the effects of different vaccine regimens on mild and asymptomatic infections with SARS-CoV-2 Omicron BA.2 variant in Shanghai. All asymptomatic patients and those with mild symptoms of Omicron infections were recruited from three major Fangcang shelter hospitals between March 26, 2022 and May 20, 2022. Nucleic acid for SARS-CoV-2 by real-time reverse-transcription polymerase chain reaction methods in nasopharyngeal swabs was assessed every day during the hospitalization. The value of cycle threshold lower than 35 was considered as positive result of SARS-CoV-2. A total of 214â€‰592 cases were included in this study. The proportion of the asymptomatic patients was 76.90% and 23.10% of the recruited patients had mild symptoms. The median (interquartile range [IQR]: 25-75) duration of viral shedding (DVS) was 7 (5-10) days among all participants. The DVS varied greatly among different age groups. Children and the elderly had longer DVS compared with the adults. The booster shot of inactivated vaccine contributed to the shorter DVS in patients aged â‰¥70 years compared with the unvaccinated patients (8 [6-11] vs. 9 [6-12] days, pâ€‰=â€‰0.002]. Full inactivated vaccine regimen contributed to the shorter DVS in patients aged 3-6 years (7 [5-9] vs. 8 [5-10] days, pâ€‰=â€‰0.001]. In conclusion, the full inactivated vaccine regimen on children aged 3-6 years and booster inactivated vaccine regimen on the elderly aged â‰¥70 years appeared to be effective in reducing DVS. The booster vaccine regimen should be rigorously promoted and implemented.

Comparison of the reactogenicity and immunogenicity between two-dose mRNA COVID-19 vaccine and inactivated COVID-19 vaccine followed by an mRNA vaccine in children aged 5-11 years. To compare the reactogenicity and immunogenicity between the two-dose mRNA COVID-19 vaccine regimen and one or two doses of inactivated vaccine followed by an mRNA vaccine regimen in healthy children between 5 and 11 years of age, a prospective cohort study was performed at King Chulalongkorn Memorial Hospital in Thailand between March to June 2022. Healthy children between 5 and 11 years of age were enrolled and received the two-dose mRNA COVID-19 vaccine (BNT162b2) regimen or the inactivated (CoronaVac) vaccine followed by the BNT162b2 vaccine

regimen. In addition, healthy children who received two doses of BBIBP-CorV between 1 and 3 months prior were enrolled to receive a heterologous BNT162b2 as a third dose (booster). Reactogenicity was assessed by a self-reported online questionnaire. Immunogenicity analysis was performed to determine binding antibodies to wild-type SARS-CoV-2. Neutralizing antibodies to Omicron variants (BA.2 and BA.5) were tested using the focus reduction neutralization test.Â Overall, 166 eligible children were enrolled. Local and systemic adverse events which occurred within 7 days after vaccination were mild to moderate and well-tolerated. The two-dose BNT162b2, CoronaVac followed by BNT162b2, and two-dose BBIBP-CorV followed by BNT162b2 groups elicited similar levels of anti-receptor-binding domain (RBD) IgG. However, the two-dose BNT162b2 and two-dose BBIBP-CorV followed by BNT162b2 groups elicited higher neutralizing activities against the Omicron BA.2 and BA.5 variant than the CoronaVac followed by BNT162b2 group.Â The CoronaVac followed by BNT162b2 group elicited low neutralizing activities against the Omicron BA.2 and BA.5 variant. A third dose (booster) mRNA vaccine should be prioritized for this group.
Oral side effects of COVID-19 vaccines in 32 European countries: Analysis of EudraVigilance reports. The recent reports of oral side effects (SEs) following COVID-19 vaccination warrant further investigation into their prevalence, severity, and aetiology. This study was conducted to synthesize the first-ever population-level evidence about oral SEs of COVID-19 vaccines in Europe. The European Union Drug Regulating Authorities Pharmacovigilance (EudraVigilance) database was accessed in August 2022 to extract summary data of all potential oral SEs reported after COVID-19 vaccination. The data were reported descriptively and cross-tabulated to facilitate sub-group analysis per vaccine type, sex, and age group. Dysgeusia was the most commonly reported oral SE (0.381 case per each 100 received reports), followed by oral paraesthesia (0.315%), ageusia (0.296%), lip swelling (0.243%), dry mouth (0.215%), oral hypoaesthesia (0.210%), swollen tongue (0.207%), and taste disorder (0.173%). Females had significantly (Sig.â€‰<â€‰0.001) a higher prevalence of all most common (top 20) oral SEs, except for salivary hypersecretion, which was equally prevalent among females and males. The present study revealed a low prevalence of oral SEs, with taste-related, other sensory and anaphylactic SEs being the most common SEs in Europe, similar to what was found earlier among the US population. Future studies should explore the potential risk factors of oral sensory and anaphylactic SEs to verify whether they are causally linked to COVID-19 vaccines.
Immunogenicity, effectiveness and safety of COVID-19 vaccine in older adults living in nursing homes: Comment.
Association between Covid-19 vaccination and incidence of type 1 diabetes in China: Evidence from 14.14 million registered residents between 2007 and 2021. AIMS: Reports have suggested that COVID-19 vaccination may cause Type 1 diabetes (T1D), particularly fulminant T1D (FT1D). This study aimed to investigate the incidence of T1D in a general population of China, where>90% of the people have received three injections of inactivated SARS-Cov-2 vaccines in 2021. METHODS: A population-based registry of T1D was performed using data from the Beijing Municipal Health Commission Information Center. Annual incidence rates were calculated by age group and gender, and annual percentage changes were assessed using Joinpoint regression. RESULTS: The study included 14.14 million registered residents, and 7,697 people with newly diagnosed T1D were identified from 2007 to 2021. T1D incidence increased from 2.77 in 2007 to 3.84 per 100,000 persons in 2021. However, T1D incidence was stable from 2019 to 2021, and the incidence rate did not increase when people were vaccinated in January-December 2021. The incidence of FT1D did not increase from 2015 to 2021. CONCLUSIONS: The findings suggest that COVID-19 vaccination did not increase the onset of T1D or have a significant impact on T1D pathogenesis, at least not on a large scale.
The efficacy and effectiveness of COVID-19 vaccines around the world: a mini-review and meta-analysis. OBJECTIVES: This meta-analysis evaluated the Efficacy and Effectiveness of several

COVID-19 vaccines, including AstraZeneca, Pfizer, Moderna, Bharat, and Johnson & Johnson, to better estimate their immunogenicity, benefits, or side effects. METHODS: Studies reporting the Efficacy and Effectiveness of COVID-19 vaccines from November 2020 to April 2022 were included. The pooled Effectiveness/Efficacy with a 95% confidence interval (95% CI) with Metaprop order was calculated. The results were presented in forest plots. Predefined subgroup analyses and sensitivity analyses were also performed. RESULTS: A total of twenty articles were included in this meta-analysis. After the first dose of the vaccine, the total effectiveness of all COVID-19 vaccines in our study was 71% (95% CI 0.65, 0.78). The total effectiveness of vaccines after the second dose was 91% (95% CI 0.88, 0.94)). The total efficacy of vaccines after the first and second doses was 81% (95% CI 0.70, 0.91) and 71% (95% CI 0.62, 0.79), respectively. The effectiveness of the Moderna vaccine after the first and second dose was the highest among other studied vaccines ((74% (95% CI, 0.65, 0.83) and 93% (95% CI, 0.89, 0.97), respectively). The highest first dose overall effectiveness of the studied vaccines was against the Gamma variant (74% (95% CI, 0.73, 0.75)), and the highest effectiveness after the second dose was observed against the Beta variant (96% (95% CI, 0.96, 0.96)). The Efficacy for AstraZeneca and Pfizer vaccines after the first dose was 78% (95% CI, 0.62, 0.95) and 84% (95% CI, 0.77, 0.92), respectively. The second dose Efficacy for AstraZeneca, Pfizer, and Bharat was 67% (95% CI, 0.54, 0.80), 93% (95% CI, 0.85, 1.00), and 71% (95% CI, 0.61, 0.82), respectively. The overall efficacy of first and second dose vaccination against the Alfa variant was 84% (95% CI, 0.84, 0.84) and 77% (95% CI, 0.57, 0.97), respectively, the highest among other variants. CONCLUSION: mRNA-based vaccines against COVID-19 showed the highest total efficacy and effectiveness than other vaccines. In general, administering the second dose produced a more reliable response and higher effectiveness than a single dose.

Disease relapse rate in children with autoimmune rheumatic diseases after COVID-19 infection and vaccination. BACKGROUND: Paediatric patients with autoimmune rheumatic diseases (pARD) are often immunocompromised because of the disease and/or the therapy they receive. At the beginning of COVID-19 pandemic there was a great concern about the possibility of severe SARS-CoV-2 infection in these patients. The best method of protection is vaccination, so as soon as vaccine was licenced, we aimed to vaccinate them. Data on disease relapse rate after COVID-19 infection and vaccination are scarce, but they play important role in everyday clinical decisions. METHODS: The aim of this study was to determine the relapse rate of autoimmune rheumatic disease (ARD) after COVID-19 infection and vaccination. Data on demographic, diagnosis, disease activity, therapy, clinical presentation of the infection and serology were collected from pARD who had COVID-19 and from pARD who were vaccinated against COVID-19, from March 2020 to April 2022. All vaccinated patients received two doses of the BNT162b2 BioNTech vaccine, on average, 3.7 (S.D.=1.4) weeks apart. Activity of the ARD was followed prospectively. Relapse was defined as a worsening of the ARD in a time frame of 8 weeks after infection or vaccination. For statistical analysis, Fisher's exact test and Mann-Whitney U test were used. RESULTS: We collected data from 115 pARD, which we divided into two groups. We included 92 pARD after infection and 47 after vaccination, with 24 in both groups (they were infected before/after vaccination). In 92 pARD we registered 103 SARS-CoV-2 infections. Infection was asymptomatic in 14%, mild in 67% and moderate in 18%, 1% required hospitalization; 10% had a relapse of ARD after infection and 6% after vaccination. There was a trend towards higher disease relapse rate after infection compared to vaccination, but the difference was not statistically significant (pâ€‰=â€‰0.76). No statistically significant difference was detected in the relapse rate depending on the clinical presentation of the infection (pâ€‰=â€‰0.25) or the severity of the clinical presentation of COVID-19 between vaccinated and unvaccinated pARD (pâ€‰=â€‰0.31). CONCLUSIONS: There is a trend towards a higher relapse rate in pARD after infection compared to

vaccination and connection between the severity of COVID-19 and vaccination status is plausible. Our results were, however, not statistically significant.

Impaired humoral immunity to BQ.1.1 in convalescent and vaccinated patients. Determining SARS-CoV-2 immunity is critical to assess COVID-19 risk and the need for prevention and mitigation strategies. We measured SARS-CoV-2 Spike/Nucleocapsid seroprevalence and serum neutralizing activity against Wu01, BA.4/5 and BQ.1.1 in a convenience sample of 1,411 patients receiving medical treatment in the emergency departments of five university hospitals in North Rhine-Westphalia, Germany, in August/September 2022. 62% reported underlying medical conditions and 67.7% were vaccinated according to German COVID-19 vaccination recommendations (13.9% fully vaccinated, 54.3% one booster, 23.4% two boosters). We detected Spike-IgG in 95.6%, Nucleocapsid-IgG in 24.0%, and neutralization against Wu01, BA.4/5 and BQ.1.1 in 94.4%, 85.0%, and 73.8% of participants, respectively. Neutralization against BA.4/5 and BQ.1.1 was 5.6- and 23.4-fold lower compared to Wu01. Accuracy of S-IgG detection for determination of neutralizing activity against BQ.1.1 was reduced substantially. We explored previous vaccinations and infections as correlates of BQ.1.1 neutralization using multivariable and Bayesian network analyses. Given a rather moderate adherence to COVID-19 vaccination recommendations, this analysis highlights the need to improve vaccine-uptake to reduce the COVID-19 risk of immune evasive variants. The study was registered as clinical trial (DRKS00029414).

A Case of Acute Kidney Injury Caused by Myoglobin Cast Nephropathy With Sars-Cov-2 Infection in a Living-Donor Kidney Transplant Recipient. When COVID-19 affects patients with risk factors such as chronic kidney disease or on immunosuppressive drugs, they often rapidly become seriously ill. We describe a 50-year-old man who was affected with SARS-CoV-2 and had undergone an ABO-compatible living-donor kidney transplantation from his father 14 years ago because of end-stage renal failure due to hypertensive nephrosclerosis. He had continued on immunosuppressive drugs and completed vaccination twice (9 months ago and 6 months ago) with messenger RNA (mRNA) vaccines against SARS-CoV-2. However, he was temporarily on a mechanical ventilator due to respiratory failure and hemodialysis due to acute kidney injury (AKI). He was finally weaned from the ventilator and hemodialysis by taking steroid and antiviral drugs. Echo-guided renal biopsy revealed myoglobin cast nephropathy. We experienced 14 outpatients after living-donor kidney transplantation infected with SARS-CoV-2, but only this case developed AKI.

Outcomes and Effects of Vaccination on Sars-Cov-2 Omicron Infection in Kidney Transplant Recipients. BACKGROUND: Kidney transplant recipients (KTRs) are at high risk of COVID-19. Vaccination is significantly effective at preventing infection and reducing infection severity. Omicron infections are less severe than infections by previous strains, but breakthrough disease is more common. Thus, we conducted this study to observe the vaccine efficacy in our KTRs. METHODS: During the surge in the Omicron variant, beginning in May 2022, we retrieved data from 365 KTRs who had received at least one dose of various COVID vaccines until June 30, 2022. Outcomes of the KTRs (nÂ =Â 168) after at least the 2nd vaccination were assessed until September 30, 2022, before the border was opened for tourism. RESULTS: The antibody response in KTRs after the 1st and 2nd doses of SARS-CoV-2 vaccines demonstrated a significant increase from the 1st dose (median: 0.4; IQR: 0.4-8.4 U/mL, $P < .001$) to the 2nd dose (median: 57.5; IQR: 0.4-799.2 U/mL), and the response rate rose from 32% to 65% ($P < .001$). SARS-CoV-2 infection was identified in 14/365 (3.8%) patients after at least the 1st dose and 7/187 (3.7%) patients at least 7 days beyond the 2nd dose. Most KTRs had a mild course, but 3 (17%) were hospitalized due to pneumonia. CONCLUSIONS: Our data demonstrate a lower response rate and anti-S titers after 2nd dose vaccination in KTRs than in the general population, but a lower incidence of SARS-CoV-2 infection after vaccination was observed during the Omicron outbreak. Owing to the breakthrough infections found in ordinarily vaccinated

KTRs, we must emphasize the importance of vaccination and boosters to prevent severe illness, hospitalizations, and death among those developing infections.

Study protocol for the use of time series forecasting and risk analyses to investigate the effect of the COVID-19 pandemic on hospital admissions associated with new-onset disability and frailty in a national, linked electronic health data setting. INTRODUCTION: Older people were at particular risk of morbidity and mortality during COVID-19. Consequently, they experienced formal (externally imposed) and informal (self-imposed) periods of social isolation and quarantine. This is hypothesised to have led to physical deconditioning, new-onset disability and frailty. Disability and frailty are not routinely collated at population level but are associated with increased risk of falls and fractures, which result in hospital admissions. First, we will examine incidence of falls and fractures during COVID-19 (January 2020-March 2022), focusing on differences between incidence over time against expected rates based on historical data, to determine whether there is evidence of new-onset disability and frailty. Second, we will examine whether those with reported SARS-CoV-2 were at higher risk of falls and fractures. METHODS AND ANALYSIS: This study uses the Office for National Statistics (ONS) Public Health Data Asset, a linked population-level dataset combining administrative health records with sociodemographic data of the 2011 Census and National Immunisation Management System COVID-19 vaccination data for England. Administrative hospital records will be extracted based on specific fracture-centric International Classification of Diseases-10 codes in years preceding COVID-19 (2011-2020). Historical episode frequency will be used to predict expected admissions during pandemic years using time series modelling, if COVID-19 had not occurred. Those predicted admission figures will be compared with actual admissions to assess changes in hospital admissions due to public health measures comprising the pandemic response. Hospital admissions in prepandemic years will be stratified by age and geographical characteristics and averaged, then compared with pandemic year admissions to assess more granular changes. Risk modelling will assess risk of experiencing a fall, fracture or frail fall and fracture, if they have reported a positive case of COVID-19. The combination of these techniques will provide insight into changes in hospital admissions from the COVID-19 pandemic. ETHICS AND DISSEMINATION: This study has approval from the National Statistician's Data Ethics Advisory Committee (NSDEC(20)12). Results will be made available to other researchers via academic publication and shared via the ONS website.

Anaphylaxis induced by mRNA COVID-19 vaccines: follow-up and booster dose after previous desensitization.

Risk factors and characteristics influencing humoral response to COVID-19 vaccination in patients after allogeneic stem cell transplantation. INTRODUCTION: Vaccination against severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) is approved and recommended for immunocompromised patients such as patients after allogeneic stem cell transplantation (allo-SCT). Since infections represent a relevant cause of transplant related mortality we analyzed the advent of immunization to SARS-CoV-2 vaccination in a bicentric population of allogeneic transplanted patients. METHODS: We retrospectively analyzed data of allo-SCT recipients in two German transplantation centers for safety and serologic response after two and three SARS-CoV-2 vaccinations. Patients received mRNA vaccines or vector-based vaccines. All patients were monitored for antibodies against SARS-CoV2-spike protein (anti-S-IgG) with an IgG ELISA assay or an EIA Assay after two and three doses of vaccination. RESULTS: A total of 243 allo-SCT patients underwent SARS-CoV-2 vaccination. The median age was 59 years (range 22-81). While 85% of patients received two doses of mRNA vaccines, 10% had vector-based vaccines and 5% received a mixed vaccination. The two vaccine doses were well tolerated with only 3% patients developing a reactivation of graft versus host disease (GvHD). Overall, 72% of patients showed a humoral response after two vaccinations. In the multivariate analysis age at time of allo-SCT (p=0.0065), ongoing immunosuppressive therapy (p=

0.029) and lack of immune reconstitution (CD4-T-cell counts <200/Î¼l, p< 0.001) were associated with no response. Sex, intensity of conditioning and the use of ATG showed no influence on seroconversion. Finally, 44 out of 69 patients that did not respond after the second dose received a booster and 57% (25/44) showed a seroconversion. DISCUSSION: We showed in our bicentric allo-SCT patient cohort, that a humoral response could be achieve after the regular approved schedule, especially for those patients who underwent immune reconstitution and were free from immunosuppressive drugs. In over 50% of the initial non-responders after 2-dose vaccination, a seroconversion can be achieved by boostering with a third dose.

A severe case of rhabdomyolysis after Moderna mRNA anti-COVID-19 vaccine with a literature review. The identification of rhabdomyolysis as a potential fatal adverse reaction to recent COVID-19 vaccines is essential. As the symptoms of rhabdomyolysis are not specific, the threshold to actively search for this complication should be low.

Acquired hemophilia A (AHA) due to anti-SARS-CoV-2 vaccination: A systematic review. Vaccination against SARS-CoV2 has been the largest vaccination campaign over the past two decades. The aim of this study is to qualitatively assess the reported cases of acquired hemophilia A (AHA) that developed after COVID-19 vaccination to further elaborate on incidence, presentation, treatment, and outcomes.We queried Medline (PubMed), Google Scholar, and Embase databases to find reported cases of AHA after COVID-19 vaccines. We found 14 studies (19 cases) for this descriptive analysis. Most patients were elderly (mean age 73 years) and males (n = 12) with multiple comorbidities. All cases developed after mRNA vaccines - BNT162b2 Pfizer-BioNTech (nÂ = 13) and mRNA-1273 Moderna (n = 6). All except one patient were treated, with the most common therapy being a combination of steroids, immunosuppression, and rFVIII (nÂ = 13). Two patients died due to acute respiratory distress, and gall bladder rupture with persistent bleeding, respectively. While evaluating a patient with bleeding diathesis after COVID-19 vaccination, AHA should be kept in the differential diagnosis. Given the low incidence, we believe that the benefit of vaccination still outweighs the risk of disease acquisition.

Parsonage-Turner syndrome: A case report of a rare side effect of COVID-19 booster vaccination. The mass vaccination against COVID-19 has saved millions of lives globally. The majority of people experience short-term mild side effects; however, in rare cases, some develop long-term severe adverse events. This case report illustrates the case of a middle-aged man with Parsonage-Turner syndrome, a rare adverse event following COVID-19 immunisation. The patient presented with pain and weakness of the right upper arm for 2 months, which developed 5 days after he received his mRNA COVID-19 booster vaccine. He sought medical attention after 9 weeks of experiencing weakness with obvious muscle wasting. He reported his condition only via a phone application, as he thought that his condition was self-limiting and will improve with time. Herein, we discuss the syndrome and highlight the importance of patient education and early recognition of serious adverse events related to vaccinations in the primary care setting.

Seroprevalence and durability of antibody responses to AstraZeneca vaccination in Ugandans with prior mild or asymptomatic COVID-19: implications for vaccine policy. INTRODUCTION: The duration and timing of immunity conferred by COVID-19 vaccination in sub-Saharan Africa are crucial for guiding pandemic policy interventions, but systematic data for this region is scarce. This study investigated the antibody response after AstraZeneca vaccination in COVID-19 convalescent Ugandans. METHODS: We recruited 86 participants with a previous rt-PCR-confirmed mild or asymptomatic COVID-19 infection and measured the prevalence and levels of spike-directed IgG, IgM, and IgA antibodies at baseline, 14 and 28 days after the first dose (priming), 14 days after the second dose (boosting), and at six- and nine-months post-priming. We also measured the prevalence and levels of nucleoprotein-directed antibodies to assess breakthrough infections. RESULTS: Within two

weeks of priming, vaccination substantially increased the prevalence and concentrations of spike-directed antibodies ($p < 0.0001$, Wilcoxon signed rank test), with 97.0% and 66% of vaccinated individuals possessing S-IgG and S-IgA antibodies before administering the booster dose. S-IgM prevalence changed marginally after the initial vaccination and barely after the booster, consistent with an already primed immune system. However, we also observed a rise in nucleoprotein seroprevalence, indicative of breakthroughs six months after the initial vaccination. DISCUSSION: Our results suggest that vaccination of COVID-19 convalescent individuals with the AstraZeneca vaccine induces a robust and differential spike-directed antibody response. The data highlights the value of vaccination as an effective method for inducing immunity in previously infected individuals and the importance of administering two doses to maintain protective immunity. Monitoring anti-spike IgG and IgA when assessing vaccine-induced antibody responses is suggested for this population; assessing S-IgM will underestimate the response. The AstraZeneca vaccine is a valuable tool in the fight against COVID-19. Further research is needed to determine the durability of vaccine-induced immunity and the potential need for booster doses.

Estimated US Pediatric Hospitalizations and School Absenteeism Associated With Accelerated COVID-19 Bivalent Booster Vaccination. IMPORTANCE: Adverse outcomes of COVID-19 in the pediatric population include disease and hospitalization, leading to school absenteeism. Booster vaccination for eligible individuals across all ages may promote health and school attendance. OBJECTIVE: To assess whether accelerating COVID-19 bivalent booster vaccination uptake across the general population would be associated with reduced pediatric hospitalizations and school absenteeism. DESIGN, SETTING, AND PARTICIPANTS: In this decision analytical model, a simulation model of COVID-19 transmission was fitted to reported incidence data from October 1, 2020, to September 30, 2022, with outcomes simulated from October 1, 2022, to March 31, 2023. The transmission model included the entire age-stratified US population, and the outcome model included children younger than 18 years. INTERVENTIONS: Simulated scenarios of accelerated bivalent COVID-19 booster campaigns to achieve uptake that was either one-half of or similar to the age-specific uptake observed for 2020 to 2021 seasonal influenza vaccination in the eligible population across all age groups. MAIN OUTCOMES AND MEASURES: The main outcomes were estimated hospitalizations, intensive care unit admissions, and isolation days of symptomatic infection averted among children aged 0 to 17 years and estimated days of school absenteeism averted among children aged 5 to 17 years under the accelerated bivalent booster campaign simulated scenarios. RESULTS: Among children aged 5 to 17 years, a COVID-19 bivalent booster campaign achieving age-specific coverage similar to influenza vaccination could have averted an estimated 5â€¯448â€¯694 (95% credible interval [CrI], 4â€¯936â€¯933-5â€¯957â€¯507) days of school absenteeism due to COVID-19 illness. In addition, the booster campaign could have prevented an estimated 10â€¯019 (95% CrI, 8756-11â€¯278) hospitalizations among the pediatric population aged 0 to 17 years, of which 2645 (95% CrI, 2152-3147) were estimated to require intensive care. A less ambitious booster campaign with only 50% of the age-specific uptake of influenza vaccination among eligible individuals could have averted an estimated 2â€¯875â€¯926 (95% CrI, 2â€¯524â€¯351-3â€¯332â€¯783) days of school absenteeism among children aged 5 to 17 years and an estimated 5791 (95% CrI, 4391-6932) hospitalizations among children aged 0 to 17 years, of which 1397 (95% CrI, 846-1948) were estimated to require intensive care. CONCLUSIONS AND RELEVANCE: In this decision analytical model, increased uptake of bivalent booster vaccination among eligible age groups was associated with decreased hospitalizations and school absenteeism in the pediatric population. These findings suggest that although COVID-19 prevention strategies often focus on older populations, the benefits of booster campaigns for children may be substantial.

COVID-19 Booster Vaccination in Early Pregnancy and Surveillance for Spontaneous Abortion. IMPORTANCE: Adherence to COVID-19 booster vaccine recommendations has lagged in pregnant and

nonpregnant adult populations. One barrier to booster vaccination is uncertainty regarding the safety of booster doses among pregnant people. OBJECTIVE: To evaluate whether there is an association between COVID-19 booster vaccination during pregnancy and spontaneous abortion. DESIGN, SETTING, AND PARTICIPANTS: This observational, case-control, surveillance study evaluated people aged 16 to 49 years with pregnancies at 6 to 19 weeks' gestation at 8 health systems in the Vaccine Safety Datalink from November 1, 2021, to June 12, 2022. Spontaneous abortion cases and ongoing pregnancy controls were evaluated during consecutive surveillance periods, defined by calendar time. EXPOSURE: Primary exposure was receipt of a third messenger RNA (mRNA) COVID-19 vaccine dose within 28 days before spontaneous abortion or index date (midpoint of surveillance period in ongoing pregnancy controls). Secondary exposures were third mRNA vaccine doses in a 42-day window or any COVID-19 booster in 28- and 42-day windows. MAIN OUTCOMES AND MEASURES: Spontaneous abortion cases and ongoing pregnancy controls were identified from electronic health data using a validated algorithm. Cases were assigned to a single surveillance period based on pregnancy outcome date. Eligible ongoing pregnancy time was assigned to 1 or more surveillance periods as an ongoing pregnancy-period control. Generalized estimating equations were used to estimate adjusted odds ratios (AOR) with gestational age, maternal age, antenatal visits, race and ethnicity, site, and surveillance period as covariates and robust variance estimates to account for inclusion of multiple pregnancy periods per unique pregnancy. RESULTS: Among 112â€¯718 unique pregnancies included in the study, the mean (SD) maternal age was 30.6 (5.5) years. Pregnant individuals were Asian, non-Hispanic (15.1%); Black, non-Hispanic (7.5%); Hispanic (35.6%); White, non-Hispanic (31.2%); and of other or unknown (10.6%); and 100% were female. Across eight 28-day surveillance periods, among 270â€¯853 ongoing pregnancy-period controls, 11â€¯095 (4.1%) had received a third mRNA COVID-19 vaccine in a 28-day window; among 14â€¯226 cases, 553 (3.9%) had received a third mRNA COVID-19 vaccine within 28 days of the spontaneous abortion. Receipt of a third mRNA COVID-19 vaccine was not associated with spontaneous abortion in a 28-day window (AOR, 0.94; 95% CI, 0.86-1.03). Results were consistent when using a 42-day window (AOR, 0.97; 95% CI, 0.90-1.05) and for any COVID-19 booster in a 28-day (AOR, 0.94; 95% CI, 0.86-1.02) or 42-day (AOR, 0.96; 95% CI, 0.89-1.04) exposure window. CONCLUSIONS AND RELEVANCE: In this case-control surveillance study, COVID-19 booster vaccination in pregnancy was not associated with spontaneous abortion. These findings support the safety of recommendations for COVID-19 booster vaccination, including in pregnant populations.

Serotonin Release Assay: Functional Assay for Heparin- and Vaccine-Induced (Immune) Thrombotic Thrombocytopenia. The serotonin release assay (SRA) has been the gold-standard assay for detection of heparin-dependent platelet-activating antibodies and integral for the diagnosis for heparin-induced thrombotic thrombocytopenia (HIT). In 2021, a thrombotic thrombocytopenic syndrome was reported after adenoviral vector COVID-19 vaccination. This vaccine-induced thrombotic thrombocytopenic syndrome (VITT) proved to be a severe immune platelet activation syndrome manifested by unusual thrombosis, thrombocytopenia, very elevated plasma D-dimer, and a high mortality even with aggressive therapy (anticoagulation and plasma exchange). While the platelet-activating antibodies in both HIT and VITT are directed toward platelet factor 4 (PF4), important differences have been found. These differences have required modifications to the SRA to improve detection of functional VITT antibodies. Functional platelet activation assays remain essential in the diagnostic workup of HIT and VITT. Here we detail the application of SRA for the assessment of HIT and VITT antibodies.

Whole Blood Procoagulant Platelet Flow Cytometry Protocol for Heparin-Induced Thrombocytopenia (HIT) and Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) Testing. Heparin-induced thrombocytopenia (HIT) is a well-characterized, iatrogenic complication of heparin anticoagulation with significant morbidity. In contrast, vaccine-induced immune thrombotic

thrombocytopenia (VITT) is a recently recognized severe prothrombotic complication of adenoviral vaccines, including the ChAdOx1 nCoV-19 (Vaxzevria, AstraZeneca) and Ad26.COV2.S (Janssen, Johnson & Johnson) vaccines against COVID-19. The diagnosis of HIT and VITT involve laboratory testing for antiplatelet antibodies by immunoassays followed by confirmation by functional assays to detect platelet-activating antibodies. Functional assays are critical to detect pathological antibodies due to the varying sensitivity and specificity of immunoassays. This chapter presents a protocol for a novel whole blood flow cytometry-based assay to detect procoagulant platelets in healthy donor blood in response to plasma from patients suspected of HIT or VITT. A method to identify suitable healthy donors for HIT and VITT testing is also described.

Multiple Electrode Aggregometry (Multiplate): Functional Assay for Vaccine-Induced (Immune) Thrombotic Thrombocytopenia (VITT). Vaccine-induced immune thrombotic thrombocytopenia (VITT) was first described in 2021 and represents an adverse reaction to adenoviral vector COVID-19 vaccines AstraZeneca ChAdOx1 nCoV-19 (AZD1222) and Johnson & Johnson Ad26.COV2.S vaccine. VITT is a severe immune platelet activation syndrome with an incidence of 1-2 per 100,000 vaccinations. The features of VITT include thrombocytopenia and thrombosis within 4-42Â days of first dose of vaccine. Affected individuals develop platelet-activating antibodies against platelet factor 4 (PF4). The International Society on Thrombosis and Haemostasis recommends both an antigen-binding assay (enzyme-linked immunosorbent assay, ELISA) and a functional platelet activation assay for the diagnostic workup of VITT. Here, the application of multiple electrode aggregometry (Multiplate) is presented as a functional assay for VITT.

Heparin-Induced Thrombotic Thrombocytopenia (HITT) and Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT): Similar but Different. Heparin-induced thrombocytopenia (HIT) represents an autoimmune process whereby antibodies are formed against heparin in complex with platelet factor 4 (PF4) after heparin administration. These antibodies can be detected by a variety of immunological assays, including ELISA (enzyme-linked immunosorbent assay) and by chemiluminescence on the AcuStar instrument. However, pathological HIT antibodies are those that activate platelets in a platelet activation assay and cause thrombosis in vivo. We would tend to call this condition heparin-induced thrombotic thrombocytopenia (HITT), although some workers instead use the truncated abbreviation HIT. Vaccine-induced (immune) thrombotic thrombocytopenia (VITT) instead reflects an autoimmune process whereby antibodies are formed against PF4 after administration of a vaccine, most notably adenovirus-based vaccines directed against COVID-19 (coronavirus disease 2019). Although both VITT and HITT reflect similar pathological processes, they have different origins and are detected in different ways. Most notable is that anti-PF4 antibodies in VITT can only be detected immunologically by ELISA assays, tending to be negative in rapid assays such as that using the AcuStar. Moreover, functional platelet activation assays otherwise used for HITT may need to be modified to detect platelet activation in VITT.

Uveitis including Vogt-Koyanagi-Harada syndrome following inactive covid-19 vaccination: a case series. BACKGROUND: Currently, large populations have been vaccinated against COVID-19. The whole inactivated Sinopharm COVID-19 vaccine has been the main available COVID-19 vaccine in Iran. Ocular inflammatory reactions have been reported following vaccination. The present case reports aim to introduce four cases of uveitis after the Sinopharm vaccine administration. CASE PRESENTATION: Our first reported case is a 38-year-old woman with a positive medical history of inactive ulcerative colitis. Active uveitis had developed following the second dose of the COVID-19 vaccination. The remaining three cases were healthy individuals who developed the first episode of uveitis, after the COVID-19 vaccine administration. Vogt-Koyanagi-Harada syndrome was the final diagnosis in one of the aforementioned cases. All four patients demonstrated favorable responses to corticosteroid treatment. CONCLUSION: These observations are in line with incoming reports from all

around the world and raise concerns about the possibility of post-vaccination uveitis development, especially in cases with a previous history of auto-immune systemic diseases or inactive uveitis.

Pole-to-pole involvement of varicella zoster virus reactivation following COVID-19 vaccination. The aim of this study is to report the clinical features, imaging findings including confocal imaging, corneal nerve fiber analysis, and management outcomes in a series of three cases of varicella zoster virus (VZV) reactivation following one dose of coronavirus disease 2019 (COVID-19) vaccination. This was a retrospective and observational study. All the patients who developed uveitis post-vaccination were pooled together. Patients who had VZV reactivation were included. Two cases had polymerase chain reaction positive for VZV from aqueous humor. At the time of presentation, IgG and IgM spike protein antibodies for severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) were tested. Out of this pool, three patients with classical features to describe pole-to-pole manifestations were chosen. A 36-year-old lady with post-vaccination sclerokeratouveitis associated with reactivation of herpes zoster ophthalmicus, a 56-year-old lady with post-vaccination acute anterior uveitis associated with herpes zoster ophthalmicus, and a 43-year-old gentleman with post-vaccination acute retinal necrosis were included. We present a possible link between anti-SARS-CoV-2 virus vaccination and varicella zoster reactivation in these patients and also describe the clinical features, imaging findings including confocal imaging, corneal nerve fiber analysis, and management with detailed discussion.

Response to comments on: Bilateral multifocal choroiditis with disc edema in a 15-year-old girl following COVID-19 vaccination.

Comments on: Bilateral multifocal choroiditis with disc edema following COVID-19 vaccination.

Uveitis following mRNA COVID-19 vaccination: Is it real?

Acute abducens nerve palsy with acute disseminated encephalomyelitis-like presentation following COVID-19 vaccination. We report two adult cases of abducens nerve palsy presenting immediately (within weeks) after they received the first dose of Covishield vaccination. Magnetic resonance imaging (MRI) of the brain obtained after the onset of diplopia demonstrated demyelinating changes. The patients had associated systemic symptoms. Post-vaccination demyelination typically known as acute disseminated encephalomyelitis (ADEM) associated with several vaccines is more common in children. Although the mechanism of the nerve palsy remains unclear, it is suspected to be related to the post-vaccine neuroinflammatory syndrome. Cranial nerve palsies and ADEM-like presentations may represent part of the neurologic spectrum following COVID-vaccination in adults, and ophthalmologists should be aware of these sequelae. Although cases of sixth nerve palsy following COVID vaccination are already reported, associated MRI changes have not been reported from India.

COVID-19 vaccination, dengue hepatitis, and recurrent unilateral anterior uveitis. A 36-year-old Asian Indian male presented with redness and pain in his right eye of 1 week duration. He was diagnosed to have right acute anterior uveitis and had a history of being admitted at a local hospital for dengue hepatitis a month earlier. He had been on adalimumab 40 mg three weekly once and oral methotrexate 20 mg/week for human leucocyte antigen (HLA) B27 spondyloarthropathy and recurrent anterior uveitis. Our patient had re-activation of his anterior chamber inflammation on three distinct occasions: first, 3 weeks following recovery from coronavirus disease 2019 (COVID-19), the second after the second dose of COVID-19 vaccination, and the third after recovery from dengue fever-associated hepatitis. We propose molecular mimicry and bystander activation as the postulated mechanisms for the re-activation of his anterior uveitis. In conclusion, patients with auto-immune diseases can have recurrent ocular inflammation following COVID-19 or its vaccination or dengue fever as seen in our patient. The anterior uveitis is usually mild and responds to topical steroids. Additional immuno-suppression may not be needed. Mild ocular inflammation following vaccination should not deter individuals from getting COVID-19 vaccination.

Headache following vaccination against COVID-19 among healthcare workers with a history of COVID-19 infection: a cross-sectional study in Iran with a meta-analytic review of the literature. BACKGROUND: There is evidence of the occurrence of headache after vaccination against COVID-19. However, only a few studies have examined the headache characteristics and related determinants, especially among healthcare workers with a history of COVID-19 infection. METHODS: We evaluated the incidence of headaches after injection of different types of COVID-19 vaccine to determine factors relating to the incidence of headache after vaccination among the Iranian healthcare workers who had previously contracted COVID-19. A group of 334 healthcare workers with a history of COVID-19 infection were included and vaccinated (at least one month after recovery without any COVID-19 related symptoms) with different COVID-19 vaccines. The baseline information, headache characteristics and vaccine specifications were recorded. RESULTS: Overall, 39.2% reported experiencing a post-vaccination headache. Of those with a previous history of headache, 51.1% reported migraine-type, 27.4% tension-type and 21.5% other types. The mean time between vaccination and headache appearance was 26.78â€‰Â±â€‰6.93Â h, with the headache appearing less than 24Â h after vaccination in most patients (83.2%). The headaches reached its peak within 8.62â€‰Â±â€‰2.41Â h. Most patients reported a compression-type headache. The prevalence of post-vaccination headaches was significantly different according to the type of vaccine used. The highest rates were reported for AstraZeneca, followed by Sputnik V. In regression analysis, the vaccine brand, female gender and initial COVID-19 severity were the main determinants for predicting post-vaccination headache. CONCLUSION: Participants commonly experienced a headache following vaccination against COVID-19. Our study results indicated that this was slightly more common in females and in those with a history of severe COVID-19 infection.

Profiling post-COVID-19 condition across different variants of SARS-CoV-2: a prospective longitudinal study in unvaccinated wild-type, unvaccinated alpha-variant, and vaccinated delta-variant populations. BACKGROUND: Self-reported symptom studies rapidly increased understanding of SARS-CoV-2 during the COVID-19 pandemic and enabled monitoring of long-term effects of COVID-19 outside hospital settings. Post-COVID-19 condition presents as heterogeneous profiles, which need characterisation to enable personalised patient care. We aimed to describe post-COVID-19 condition profiles by viral variant and vaccination status. METHODS: In this prospective longitudinal cohort study, we analysed data from UK-based adults (aged 18-100 years) who regularly provided health reports via the Covid Symptom Study smartphone app between March 24, 2020, and Dec 8, 2021. We included participants who reported feeling physically normal for at least 30 days before testing positive for SARS-CoV-2 who subsequently developed long COVID (ie, symptoms lasting longer than 28 days from the date of the initial positive test). We separately defined post-COVID-19 condition as symptoms that persisted for at least 84 days after the initial positive test. We did unsupervised clustering analysis of time-series data to identify distinct symptom profiles for vaccinated and unvaccinated people with post-COVID-19 condition after infection with the wild-type, alpha (B.1.1.7), or delta (B.1.617.2 and AY.x) variants of SARS-CoV-2. Clusters were then characterised on the basis of symptom prevalence, duration, demography, and previous comorbidities. We also used an additional testing sample with additional data from the Covid Symptom Study Biobank (collected between October, 2020, and April, 2021) to investigate the effects of the identified symptom clusters of post-COVID-19 condition on the lives of affected people. FINDINGS: We included 9804 people from the COVID Symptom Study with long COVID, 1513 (15%) of whom developed post-COVID-19 condition. Sample sizes were sufficient only for analyses of the unvaccinated wild-type, unvaccinated alpha variant, and vaccinated delta variant groups. We identified distinct profiles of symptoms for post-COVID-19 condition within and across variants: four endotypes were identified for infections due to the wild-type variant (in unvaccinated people), seven for the alpha variant (in unvaccinated people),

and five for the delta variant (in vaccinated people). Across all variants, we identified a cardiorespiratory cluster of symptoms, a central neurological cluster, and a multi-organ systemic inflammatory cluster. These three main clusers were confirmed in a testing sample. Gastrointestinal symptoms clustered in no more than two specific phenotypes per viral variant. INTERPRETATION: Our unsupervised analysis identified different profiles of post-COVID-19 condition, characterised by differing symptom combinations, durations, and functional outcomes. Our classification could be useful for understanding the distinct mechanisms of post-COVID-19 condition, as well as for identification of subgroups of individuals who might be at risk of prolonged debilitation. FUNDING: UK Government Department of Health and Social Care, Chronic Disease Research Foundation, The Wellcome Trust, UK Engineering and Physical Sciences Research Council, UK Research and Innovation London Medical Imaging & Artificial Intelligence Centre for Value-Based Healthcare, UK National Institute for Health Research, UK Medical Research Council, British Heart Foundation, UK Alzheimer's Society, and ZOE.

Anti-tumor necrosis factor therapy is associated with attenuated humoral response to SARS-COV-2 vaccines in patients with inflammatory bowel disease. BACKGROUND: Immunosuppressive therapy used in the treatment of inflammatory bowel disease (IBD) is known to reduce vaccine immunogenicity. AIMS: This study aimed to 1) predict the humoral response elicited by SARS-CoV-2 vaccination in IBD patients based on their ongoing treatment and other relevant patient and vaccine characteristics and 2) assess the humoral response to a booster dose of mRNA vaccine. METHODS: We conducted a prospective study in adult IBD patients. Anti-spike (S) IgG antibodies were measured after initial vaccination and again after one booster dose. A multiple linear regression model was created to predict anti-S antibody titer following initial complete vaccination in different therapeutic groups (no immunosuppression, anti-TNF, immunomodulators and combination therapy). A two-tailed Wilcoxon test for two dependent groups was performed to compare anti-S values before and after the booster dose. RESULTS: Our study included 198 IBD patients. The multiple linear regression identified anti-TNF and combination therapy (versus no immunosuppression), current smoking, viral vector (versus mRNA) vaccine and interval between vaccination and anti-S measurement as statistically significant predictors of the log anti-S antibody levels (pÂ <Â 0.001). No statistically significant differences were found between no immunosuppression and immunomodulators (pÂ =Â 0.349) and between anti-TNF and combination therapy (pÂ =Â 0.997). Statistically significant differences for anti-S antibody titer before and after the booster dose of mRNA SARS-CoV-2 vaccine were found, both for non-anti-TNF and anti-TNF groups. CONCLUSIONS: Anti-TNF treatment (either alone or in combination therapy) is associated with lower anti-S antibody levels. Booster mRNA doses seem to increase anti-S both in non-anti-TNF and anti-TNF treated patients. Special attention should be paid to this group of patients when planning vaccination schemes.

Menstrual disturbances following COVID-19 vaccination: A probable puzzle about the role of endocrine and immune pathways. Menstruation is a monthly shedding of the uterine wall, presented by menstrual bleeding in women of reproductive age. Menstruation is regulated by fluctuation of estrogen and progesterone, as well as other endocrine and immune pathways. Many women experienced menstrual disturbances after vaccination against the novel coronavirus in the last two years. Vaccine-induced menstrual disturbances have led to discomfort and concern among reproductive-age women, such that some decided not to receive the subsequent doses of the vaccine. Although many vaccinated women report these menstrual disturbances, the mechanism is still poorly understood. This review article discusses the endocrine and immune changes following COVID-19 vaccination and the possible mechanisms of vaccine-related menstrual disturbances.

Empyema with an extensive retroperitoneal abscess after the first dose of the COVID-19 vaccine, a case report. INTRODUCTION: The most common side effects were mild pain at the injection site

and fever after the COVID-19 vaccination. A retroperitoneal abscess is a rare disorder with a deceptive onset and difficult diagnosis. It has various reasons and is related to a high mortality rate. CASE PRESENTATION: A 29-year-old man with a recent history of first-dose Covid-19 vaccination, was referred for dyspnea, chest, and abdominal pain. Chest imaging revealed a lung abscess evacuated to pleural space. Left posterolateral thoracotomy surgery was done. Post-operation abdominopelvic imaging revealed increased fat stranding and fluid collection, suggesting retroperitoneal infection and abscess formation and the patient underwent drainage. CLINICAL DISCUSSION: Common side effects after COVID-19 vaccination were mild and expectable without hospitalization. But in our case, a rare complicated side effect was seen. CONCLUSION: Uncommon side effects should be observed to recognize whether they are related to the vaccine or not.

COVID-19 Vaccination and Sudden Sensorineural Hearing Loss: A Case Study. This article highlights a client with sensorineural hearing loss reported after 2 days of 2nd dose of COVID-19 vaccination. The audiological evaluations suggest unilateral hearing loss which recovered after the treatment. This article focuses on spreading awareness about the complications after vaccination and the importance of treatment.

Anti-SARS-CoV-2 antibody among SARS-CoV-2 vaccinated vs post-infected blood donors in a tertiary hospital, Bangkok, Thailand. SARS-CoV-2 virus infection has imposed a significant healthcare burden globally. To contain its spread and decrease infection-related mortality, several vaccines have been deployed worldwide in the past 3 years. We conducted a cross-sectional seroprevalence study to assess the immune response against the virus among blood donors at a tertiary care hospital, Bangkok, Thailand. From December 2021 to March 2022, total of 1,520 participants were enrolled, and their past history of SARS-CoV-2 infection and vaccination was recorded. Two serology test, namely, quantitative IgG spike protein (IgGSP) and qualitative IgG nucleocapsid antibody (IgGNC) were performed. The median age of study participants was 40 years (IQR 30-48) and 833 (54.8%) were men. Vaccine uptake was reported in 1,500 donors (98.7%) and 84 (5.5%) reported the past infection history. IgGNC was detected in 46/84 donors with the past infection history (54.8%) and in 36 out of the rest 1,436 (2.5%) with no past history. IgGSP positivity was observed in 1484 donors (97.6%). When compared to unvaccinated donors (n = 20), IgGSP level was higher in the donors who had received one vaccine dose ($p < 0.001$) and these antibody levels increased significantly among those with 3rd and 4th vaccine doses. Factors associated with low IgGSP (lowest quartile) by multivariate analysis included: no past infection history, homologous vaccination, < 3 vaccine doses, and > 90 days duration since last vaccination. In conclusion, vaccine uptake among our study donors was high (98.7%) and IgGSP antibody was observed in nearly all the vaccinated donors (97.6%). Previous SARS-CoV-2 infection, use of heterologous vaccination, vaccines â‰¥ 3 doses, and duration of the last vaccination >90 days affected IgGSP levels. Use of serological assays were found beneficial in the evaluation and differentiation of immune response to vaccination, and natural infection including the identification of previous asymptomatic infections.

Evaluation of Autoantibody Binding to Cardiac Tissue in Multisystem Inflammatory Syndrome in Children and COVID-19 Vaccination-Induced Myocarditis. IMPORTANCE: Cardiac dysfunction and myocarditis have emerged as serious complications of multisystem inflammatory syndrome in children (MIS-C) and vaccines against SARS-CoV-2. Understanding the role of autoantibodies in these conditions is essential for guiding MIS-C management and vaccination strategies in children. OBJECTIVE: To investigate the presence of anticardiac autoantibodies in MIS-C or COVID-19 vaccine-induced myocarditis. DESIGN, SETTING, AND PARTICIPANTS: This diagnostic study included children with acute MIS-C or acute vaccine myocarditis, adults with myocarditis or inflammatory cardiomyopathy, healthy children prior to the COVID-19 pandemic, and healthy COVID-19 vaccinated adults. Participants were recruited into research studies in the US, United Kingdom, and Austria

starting January 2021. Immunoglobulin G (IgG), IgM, and IgA anticardiac autoantibodies were identified with immunofluorescence staining of left ventricular myocardial tissue from 2 human donors treated with sera from patients and controls. Secondary antibodies were fluorescein isothiocyanate-conjugated antihuman IgG, IgM, and IgA. Images were taken for detection of specific IgG, IgM, and IgA deposits and measurement of fluorescein isothiocyanate fluorescence intensity. Data were analyzed through March 10, 2023. MAIN OUTCOMES AND MEASURES: IgG, IgM and IgA antibody binding to cardiac tissue. RESULTS: By cohort, there were a total of 10 children with MIS-C (median [IQR] age, 10 [13-14] years; 6 male), 10 with vaccine myocarditis (median age, 15 [14-16] years; 10 male), 8 adults with myocarditis or inflammatory cardiomyopathy (median age, 55 [46-63] years; 6 male), 10 healthy pediatric controls (median age, 8 [13-14] years; 5 male), and 10 healthy vaccinated adults (all older than 21 years, 5 male). No antibody binding above background was observed in human cardiac tissue treated with sera from pediatric patients with MIS-C or vaccine myocarditis. One of the 8 adult patients with myocarditis or cardiomyopathy had positive IgG staining with raised fluorescence intensity (median [IQR] intensity, 11â€¯060 [10â€¯223-11â€¯858] AU). There were no significant differences in median fluorescence intensity in all other patient cohorts compared with controls for IgG (MIS-C, 6033 [5834-6756] AU; vaccine myocarditis, 6392 [5710-6836] AU; adult myocarditis or inflammatory cardiomyopathy, 5688 [5277-5990] AU; healthy pediatric controls, 6235 [5924-6708] AU; healthy vaccinated adults, 7000 [6423-7739] AU), IgM (MIS-C, 3354 [3110-4043] AU; vaccine myocarditis, 3843 [3288-4748] AU; healthy pediatric controls, 3436 [3313-4237] AU; healthy vaccinated adults, 3543 [2997-4607] AU) and IgA (MIS-C, 3559 [2788-4466] AU; vaccine myocarditis, 4389 [2393-4780] AU; healthy pediatric controls, 3436 [2425-4077] AU; healthy vaccinated adults, 4561 [3164-6309] AU). CONCLUSIONS AND RELEVANCE: This etiological diagnostic study found no evidence of antibodies from MIS-C and COVID-19 vaccine myocarditis serum binding cardiac tissue, suggesting that the cardiac pathology in both conditions is unlikely to be driven by direct anticardiac antibody-mediated mechanisms.

Short- and long-term outcomes of patients with hyper or hypothyroidism following COVID vaccine. Since the beginning of the wide-scale anti-Coronavirus disease 2019 (COVID-19) vaccination program, sporadic cases of thyroid disease following vaccination have been reported. We describe 19 consecutive cases of COVID vaccine-related thyroid disease. Medical records were reviewed for 9 patients with Graves' disease (GD) and 10 with Thyroiditis, all of whom were diagnosed following COVID-19 vaccination. In the GD group, the median age was 45.5â€‰years, female/male(F/M) ratio 5:4, thyroid-stimulating immunoglobulins were elevated in seven patients. The median time from vaccination to diagnosis was 3â€‰months. Methimazole treatment was given to all but one patient. At a median follow-up of 8.5â€‰months from vaccination, three patients were still on methimazole, five went into remission (data were missing for one). In the Thyroiditis group, the median age was 47â€‰years, the F/M ratio 7:3. Thyroiditis was diagnosed after the first, second, and third doses in one, two, and seven patients, respectively. The median time from vaccination to diagnosis was 2â€‰months. TPO antibodies were positive in three patients. All patients were euthyroid off medication at the last visit. Six patients were diagnosed in the hypothyroid phase at 2.5â€‰months from vaccination. Four resolved spontaneously at 3, 6, 4, and 8â€‰months; the other two were treated with thyroxine at 1.5 and 2â€‰months from vaccination and remained on treatment at their last visit, at 11.5 and 8.5â€‰months, respectively. Thyroid disease should be included among possible complications of COVID-19 vaccine and either a late onset or delayed diagnosis should be considered.

Guillain-BarrÃ© Syndrome Following the BNT162b2 mRNA COVID-19 Vaccine. PURPOSE: The onset of the COVID-19 (SARS-CoV-2) pandemic in December 2019 created the need for multiple scientific research activities and clinical trials in an attempt to find solutions to mitigate the impact of

the virus. One of the important tools to combat the virus is the development of vaccination programs. All types of vaccines have been associated with a mild to severe risk of neurological adverse events. One of these severe adverse events is Guillain-BarrÃ© syndrome. CASE REPORT: Here, we describe a case of Guillain-BarrÃ© syndrome after the first dose of the BNT162b2 mRNA COVID-19 vaccine and review the literature to increase the current knowledge regarding this complication. CONCLUSION: Guillain-BarrÃ© syndrome after COVID-19 vaccination is responsive to treatment. The benefits of administering the vaccine outweigh the risks. Due to the negative impact of COVID-19, it is essential to recognize the development of neurological complications that are potentially associated with vaccination, including Guillain-BarrÃ© syndrome.

Myositis developing after Covid-19 mRNA vaccine: Case Report. Vaccine-related side effects are common. Usually, pain, edema, redness and tenderness may be seen at the injection site. Symptoms such as fever, fatigue, myalgia may occur. The coronavirus 2019 disease (Covid-19) has affected many people around the world. Although the vaccines that have been used play an active role in the fight against the pandemic, adverse events still continue to be reported. We present a 21-year-old patient who was diagnosed as having myositis after receiving covid vaccine with complaints of pain in her left arm two days after the 2nd dose of BNT162b2 mRNA Covid-19 vaccine, followed by inability to stand up from sitting and squatting and difficulty in going up and down stairs. Keywords: vaccine, myositis, creatine kinase, IVIG.

A case with prolonged headache after COVID-19 vaccination and later developed Bell's palsy. PURPOSE: During COVID-19 pandemic, the authorization of emergent usage of new vaccine has raised suspicions and doubts about potential adverse events related to vaccination. Among the reported adverse events related to ChAdOx1/nCoV-19 vaccine, facial paralysis did not have an incident rate higher than natural occurrence like mRNA vaccines. However, temporal association between vaccination and facial palsy have been documented in several studies. Here, we report a case of an otherwise healthy 23-year-old Taiwanese female who experienced prolonged headache since the second day postvaccination and developed facial palsy on the tenth day. CASE REPORT: A 23-year-old Taiwanese female who was previously healthy experienced intermittent right side throbbing headache, general malaise, myalgia and fever. Headache, transient ear pain and right scalp numbness developed in the next few days but quickly resolved. On day ten after vaccination, signs of facial palsy on the right side of her face was noticed. The results of brain Magnetic Resonance Imaging (MRI) with contrast displayed no abnormality. Facial stimulation and blink reflex tests were compatible with right facial neuropathy. CONCLUSION: Reactivation of latent herpes virus has been suggested as one of the possible mechanisms underlying the phenomenon, but the causal pathophysiology related to the symptom needs further validation. Moreover, in the event of facial palsy post-vaccination, alternative diagnoses such as Guillain-Barre syndrome (GBS), Ramsey-Hunt syndrome, Lyme disease, trauma, central nervous system infection (CNS) infection, or stroke should also be considered.

Orbital inflammation following COVID-19 vaccination: A case series and literature review. PURPOSE: The purpose of the study was to report three cases of orbital inflammation following administration of the COVID-19 vaccination, manifesting as Tolosa-Hunt syndrome (THS) and orbital myositis. METHOD: A retrospective case series and literature review of patients who developed orbital inflammation following a COVID-19 vaccination. RESULTS: One patient presented with Tolosa-Hunt syndrome (THS) 14Â days following her third (booster) COVID-19 vaccination, one patient developed orbital myositis 10Â days following his first COVID-19 vaccination and one patient developed recurrent orbital myositis 1 and 7Â days following her second and fourth COVID-19 vaccination. All patients received the Comirnaty vaccine (Pfizer-BioNTech). A thorough systemic autoimmune disease workup in both patients was unremarkable. Two patients had a prior history of orbital inflammation, with previous involvement of other different orbital structures. Characteristic

MRI features for each pathology were observed, supporting the clinical presentation of THS and orbital myositis. There was complete resolution of THS following corticosteroids, with no recurrence at 2Â months. Meanwhile, one case of orbital myositis self-resolved at 2Â months without use of systemic corticosteroids, while the other patient with orbital myositis required treatment with intra-orbital steroid injections and oral corticosteroids. CONCLUSION: Orbital inflammation has been recognised as a rare adverse effect following COVID-19 vaccination. We present a case series of THS and orbital myositis as varied presentations of this entity.

Th(1)-dominant cytokine responses in kidney patients after COVID-19 vaccination are associated with poor humoral responses. Cytokines are regulators of the immune response against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). However, the contribution of cytokine-secreting CD4(+) and CD8(+) memory T cells to the SARS-CoV-2-specific humoral immune response in immunocompromised kidney patients is unknown. Here, we profiled 12 cytokines after stimulation of whole blood obtained 28 days post second 100â€‰Î¼g mRNA-1273 vaccination with peptides covering the SARS-CoV-2 spike (S)-protein from patients with chronic kidney disease (CKD) stage 4/5, on dialysis, kidney transplant recipients (KTR), and healthy controls. Unsupervised hierarchical clustering analysis revealed two distinct vaccine-induced cytokine profiles. The first profile was characterized by high levels of T-helper (Th)(1) (IL-2, TNF-Î±, and IFN-Î³) and Th(2) (IL-4, IL-5, IL-13) cytokines, and low levels of Th(17) (IL-17A, IL-22) and Th(9) (IL-9) cytokines. This cluster was dominated by patients with CKD, on dialysis, and healthy controls. In contrast, the second cytokine profile contained predominantly KTRs producing mainly Th(1) cytokines upon re-stimulation, with lower levels or absence of Th(2), Th(17), and Th(9) cytokines. Multivariate analyses indicated that a balanced memory T cell response with the production of Th(1) and Th(2) cytokines was associated with high levels of S1-specific binding and neutralizing antibodies mainly at 6 months after second vaccination. In conclusion, seroconversion is associated with the balanced production of cytokines by memory T cells. This emphasizes the importance of measuring multiple T cell cytokines to understand their influence on seroconversion and potentially gain more information about the protection induced by vaccine-induced memory T cells.

Immunogenicity and safety of a single booster dose of NVX-CoV2373 (TAK-019) in healthy Japanese adults who had previously received a primary series of COVID-19 mRNA vaccine: Primary analysis report of a phase 3 open-label trial. BACKGROUND: We evaluated the immunogenicity and safety of a booster dose of NVX-CoV2373 in Japanese adults who had completed a primary series of COVID-19 mRNA vaccine 6-12Â months previously. METHODS: This single-arm, open-label, phase 3 study, conducted at two Japanese centres, enrolled healthy adultsÂ â‰¥Â 20Â years old. Participants received a booster dose of NVX-CoV2373. The primary immunogenicity endpoint was non-inferiority (lower limit of the 95Â % confidence interval [CI]Â â‰¥Â 0.67) of the geometric mean titre (GMT) ratio of titres of serum neutralizing antibodies (nAbs) against the SARS-CoV-2 ancestral strain 14Â days after booster vaccination (day 15) in this study, compared with those 14Â days after the second primary NVX-CoV2373 vaccination (day 36) in the TAK-019-1501 study (NCT04712110). Primary safety endpoints included local and systemic solicited adverse events (AEs) up to day 7 and unsolicited AEs up to day 28. RESULTS: Between 15 April 2022 and 10 May 2022, 155 participants were screened and 150, stratified by age (20-64Â years old [nÂ =Â 135] orÂ â‰¥Â 65Â years old [nÂ =Â 15]), received an NVX-CoV2373 booster dose. The GMT ratio between titres of serum nAbs against the SARS-CoV-2 ancestral strain on day 15 in this study and those on day 36 in the TAK-019-1501 study was 1.18 (95Â % CI, 0.95-1.47), meeting the non-inferiority criterion. Following vaccination, the proportion of participants who reported local and systemic solicited AEs up to day 7 was 74.0Â % and 48.0Â %, respectively. The most common local and systemic solicited AEs were tenderness (102 participants [68.0Â %]) and malaise (39 participants [26.0Â %]), respectively. Seven

participants (4.7Â %) reported unsolicited AEs between vaccination and day 28; all were severity gradeÂ â‰¤Â 2. DISCUSSION: A single heterologous NVX-CoV2373 booster induced rapid and robust anti-SARS-CoV-2 immune responses, addressing waning immunity in healthy Japanese adults, and had an acceptable safety profile. CLINICALTRIALS: gov identifier: NCT05299359.

Covid-19 vaccination and postmenopausal bleeding.

B-cell lymphoblastic lymphoma following intravenous BNT162b2 mRNA booster in a BALB/c mouse: A case report. Unprecedented immunization campaigns have been rolled out worldwide in an attempt to contain the ongoing COVID-19 pandemic. Multiple vaccines were brought to the market, among two utilizing novel messenger ribonucleic acid technology. Despite their undisputed success in decreasing COVID-19-associated hospitalizations and mortality, various adverse events have been reported. The emergence of malignant lymphoma is one of such rare adverse events that has raised concern, although an understanding of the mechanisms potentially involved remains lacking. Herein, we present the first case of B-cell lymphoblastic lymphoma following intravenous high-dose mRNA COVID-19 vaccination (BNT162b2) in a BALB/c mouse. Two days following booster vaccination (i.e., 16 days after prime), at only 14 weeks of age, our animal suffered spontaneous death with marked organomegaly and diffuse malignant infiltration of multiple extranodal organs (heart, lung, liver, kidney, spleen) by lymphoid neoplasm. Immunohistochemical examination revealed organ sections positive for CD19, terminal deoxynucleotidyl transferase, and c-MYC, compatible with a B-cell lymphoblastic lymphoma immunophenotype. Our murine case adds to previous clinical reports on malignant lymphoma development following novel mRNA COVID-19 vaccination, although a demonstration of direct causality remains difficult. Extra vigilance is required, with conscientious reporting of similar cases and a further investigation of the mechanisms of action explaining the aforementioned association.

Development of High-Grade Sarcoma After Second Dose of Moderna Vaccine. Coronavirus disease 2019 (COVID-19) is a disease characterized by predominantly respiratory symptoms, which can progress to respiratory failure. Due to the novelty of the vaccines, it is difficult to assess if there are any associated long-term side effects. Here, we present a case of an elderly female who received the Moderna COVID-19 vaccine and developed a high-grade sarcoma at the site of the injection. A 73-year-old female with a past medical history of hypertension, hyperlipidemia, and renal angiomyolipoma status post resection in 2019 presented with worsening right upper arm swelling for the past two weeks. She noticed the swelling two to four days after receiving her second dose of the Moderna vaccine within 1 cm from the prior injection site. Physical examination was remarkable for a 6 cm, circular, mobile, soft mass present in the right upper arm. MRI with and without contrast revealed a 5.2 cm soft tissue mass overlying the triceps region with irregular features concerning for malignancy. Fine needle aspiration revealed pathologic characteristics indicative of high-grade sarcoma. The patient ultimately had resection of the mass four months after the initial visit and was diagnosed as having grade 3, stage IIIA undifferentiated, pleomorphic high-grade sarcoma. Herein, we present a case demonstrating the development of high-grade sarcoma at the injection site in an elderly female patient within days of receiving the second dose of the Moderna COVID-19 vaccine. Currently, it is unclear whether there is a true association between the vaccines and malignancy or inflammatory response exacerbating underlying malignancy. This case highlights the necessity to investigate and be aware of such rare, adverse complications that may be associated with the novel COVID-19 vaccinations to guide physicians in their differential diagnosis.

Challenges and Progress in Designing Broad-Spectrum Vaccines Against Rapidly Mutating Viruses. Viruses evolve to evade prior immunity, causing significant disease burden. Vaccine effectiveness deteriorates as pathogens mutate, requiring redesign. This is a problem that has grown worse due to population increase, global travel, and farming practices. Thus, there is significant interest in

developing broad-spectrum vaccines that mitigate disease severity and ideally inhibit disease transmission without requiring frequent updates. Even in cases where vaccines against rapidly mutating pathogens have been somewhat effective, such as seasonal influenza and SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), designing vaccines that provide broad-spectrum immunity against routinely observed viral variation remains a desirable but not yet achieved goal. This review highlights the key theoretical advances in understanding the interplay between polymorphism and vaccine efficacy, challenges in designing broad-spectrum vaccines, and technology advances and possible avenues forward. We also discuss data-driven approaches for monitoring vaccine efficacy and predicting viral escape from vaccine-induced protection. In each case, we consider illustrative examples in vaccine development from influenza, SARS-CoV-2, and HIV (human immunodeficiency virus)-three examples of highly prevalent rapidly mutating viruses with distinct phylogenetics and unique histories of vaccine technology development.

Eosinophilic Annular Erythema due to Certolizumab Pegol Therapy for Rheumatoid Arthritis Post-COVID-19 Vaccine.

Severe Acute Respiratory Syndrome Coronavirus 2 Delta Variant Genomic Variation Associated With Breakthrough Infection in Northern California: A Retrospective Cohort Study. BACKGROUND: The association between severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) genomic variation and breakthrough infection is not well defined among persons with Delta variant SARS-CoV-2 infection. METHODS: In a retrospective cohort, we assessed whether individual nonlineage defining mutations and overall genomic variation (including low-frequency alleles) were associated with breakthrough infection, defined as SARS-CoV-2 infection after coronavirus disease 2019 primary vaccine series. We identified all nonsynonymous single-nucleotide polymorphisms, insertions, and deletions in SARS-CoV-2 genomes with â‰¥5% allelic frequency and population frequency of â‰¥5% and â‰¤95%. Using Poisson regression, we assessed the association with breakthrough infection for each individual mutation and a viral genomic risk score. RESULTS: Thirty-six mutations met our inclusion criteria. Among 12 744 persons infected with Delta variant SARS-CoV-2, 5949 (47%) were vaccinated and 6795 (53%) were unvaccinated. Viruses with a viral genomic risk score in the highest quintile were 9% more likely to be associated with breakthrough infection than viruses in the lowest quintile, but including the risk score improved overall predictive model performance (measured by C statistic) by only +0.0006. CONCLUSIONS: Genomic variation within SARS-CoV-2 Delta variant was weakly associated with breakthrough infection, but several potential nonlineage defining mutations were identified that might contribute to immune evasion by SARS-CoV-2.

Continued Infarction Growth and Penumbral Consumption After Reperfusion in Vaccine-Naive Patients With COVID-19: A Case-Control Study. BACKGROUND. Neurologic sequelae of SARS-CoV-2 include potentially malignant cerebrovascular events arising from complex hemodynamic, hematologic, and inflammatory processes occurring in concert. OBJECTIVE. This study concerns the hypothesis that despite angiographic reperfusion COVID-19 promotes continued consumption of at-risk tissue volumes after acute ischemic stroke (AIS), yielding critical insights into prognostication and monitoring paradigms in vaccine-naive patients experiencing AIS. METHODS. This retrospective study compared 100 consecutive COVID-19 patients with AIS presenting between March 2020 and April 2021 with a contemporaneous cohort of 282 AIS patients without COVID-19. Reperfusion classes were dichotomized into positive (extended thrombolysis in cerebral ischemia [eTICI] score = 2c-3) and negative (eTICI score < 2c) groups. All patients underwent endovascular therapy after initial CT perfusion imaging (CTP) to document infarction core and total hypoperfusion volumes. RESULTS. Ten COVID-positive (mean age Â± SD, 67 Â± 12 years; seven men, three women) and 144 COVID-negative patients (mean age, 71 Â± 16 years; 76 men, 68 women) undergoing endovascular reperfusion, with antecedent CTP and follow-up imaging, comprised the final dataset. Initial infarction core and total

hypoperfusion volumes (mean Â± SD) were 1.5 Â± 18 mL and 85 Â± 100 mL in COVID-negative patients and 30.5 Â± 34 mL and 117 Â± 80.5 mL in COVID-positive patients, respectively. Final infarction volumes were significantly larger in patients with COVID-19, with median volumes of 77.8 mL versus 18.2 mL among control patients (p = .01), as were normalized measures of infarction growth relative to baseline infarction volume (p = .05). In adjusted logistic parametric regression models, COVID positivity emerged as a significant predictor for continued infarct growth (OR, 5.10 [95% CI, 1.00-25.95]; p = .05). CONCLUSION. These findings support the potentially aggressive clinical course of cerebrovascular events in patients with COVID-19, suggesting greater infarction growth and ongoing consumption of at-risk tissues, even after angiographic reperfusion. CLINICAL IMPACT. SARS-CoV-2 infection may promote continued infarction progression despite angiographic reperfusion in vaccine-naive patients with large-vessel occlusion AIS. The findings carry potential implications for prognostication, treatment selection, and surveillance for infarction growth among revascularized patients in future waves of infection by novel viral strains.

SARS-CoV-2, vaccination or autoimmunity as causes of cardiac inflammation. Which form prevails? The causes of cardiac inflammation during the COVID-19 pandemic are manifold and complex, and may have changed with different virus variants and vaccinations. The underlying viral etiology is self-evident, but its role in the pathogenic process is diverse. The view of many pathologists that myocyte necrosis and cellular infiltrates are indispensable for myocarditis does not suffice and contradicts the clinical criteria of myocarditis, i.e., aÂ combination of serological evidence of necrosis based on troponins or MRI features of necrosis, edema, and inflammation based on prolonged T1 and T2Â times and late gadolinium enhancement. The definition of myocarditis is still debated by pathologists and clinicians. We have learned that myocarditis and pericarditis can be induced by the virus via different pathways of action such as direct viral damage to the myocardium through the ACE2 receptor. Indirect damage occurs via immunological effector organs such as the innate immune system by macrophages and cytokines, and then later the acquired immune system via TÂ cells, overactive proinflammatory cytokines, and cardiac autoantibodies. Cardiovascular diseases lead to more severe courses of SARS-CoVâ€‘2 disease. Thus, heart failure patients have aÂ double risk for complicated courses and lethal outcome. So do patients with diabetes, hypertension, and renal insufficiency. Independent of the definition, myocarditis patients benefitted from intensive hospital care, ventilation, if needed, and cortisone treatment. Postvaccination myocarditis and pericarditis affect primarily young male patients after the second RNA vaccine. Both are rare events but severe enough to deserve our full attention, because treatment according to current guidelines is available and necessary.

After COVID-19 vaccinations: what does living and working in nursing homes look like? BACKGROUND: Nursing homes were disproportionally affected by the COVID-19 pandemic. Vaccination was considered critical for the normalization of daily live of nursing home residents. The present study investigates the impact of the prolonged COVID-19 pandemic and the effect of vaccinations on the daily lives of residents and staff in Dutch nursing homes. SETTING AND PARTICIPANTS: The sample consisted of 78 nursing homes that participated in the Dutch national pilot on nursing home visits after the COVID-19 pandemic. One contact person per nursing home was approached for participation in this mixed-methods cross-sectional study. METHODS: Data was collected twice through questionnaires in April and December 2021. Quantitative questions focused on recent COVID-19 outbreaks, progress of vaccination, effects of vaccination on daily living in the nursing home and burden experienced by staff. Open-ended questions addressed the prolonged effect of the pandemic on residents, family members and staff. RESULTS: The overall vaccination rate of residents across nursing homes appeared to be high among both residents and staff. However, daily living in the nursing home had not returned to normal concerning personal interactions, visits,

the use of facilities and work pressure. Nursing homes continued to report a negative impact of the pandemic on residents, family members and staff. CONCLUSIONS: Restrictions to the daily lives of residents in nursing homes were stricter than restrictions imposed on society as a whole. Returning to a normal daily living and working was found to be complex for nursing homes. With the emergence of new variants of the virus, policies strongly focusing on risk aversion were predominantly present in nursing homes.

Guillain-BarrÃ© Syndrome Induced by Vaccination Against COVID-19: A Systematic Review and Meta-Analysis. Guillain-BarrÃ© syndrome (GBS) is a rare but serious immune-mediated neurological condition characterized by damage to the peripheral nervous system.Â Two-thirds of cases of GBS are diagnosed following infection; however, vaccination has also been linked to GBS pathogenesis. The aim of this systematic review and meta-analysis was to establish the prevalence of GBS following vaccination against the SARS-CoV-2 virus, which causes COVID-19, describe the clinical and neurophysiological characteristics, and identify potential determinants. A systematic review of the literature regarding post-vaccination GBS was conducted using the PubMed database. Seventy papers were included. The pooled prevalence of GBS after vaccination against COVID-19 per has been established to be 8.1 (95% CI 30-220) per 1,000,000 vaccinations. Vaccination with vector vaccines - but not mRNA - has been associated with an increased risk of GBS. More than 80% of the patients developed GBS within 21 days following the first dose of the vaccination. The interval between the vaccination and GBS was shorter in patients who were vaccinated with mRNA versus vector vaccines (9.7Â±6.7 days versus 14.2Â±6.6 days). Epidemiological findings regarding post-vaccination GBS revealed a higher prevalence in males and people between the ages of 40 and 60 years, with a mean age of 56.8Â±16.1 years. The most common type was the acute inflammatory demyelinating polyneuropathy type. Most cases responded well to treatment. In conclusion, vaccination against COVID-19 with vector vaccines seems to increase the risk of GBS. GBS occurring following vaccination does differ in characteristics from GBS during the pre-COVID-19 era.

Cardiac Tamponade as a Complication of Microscopic Polyangiitis: A Case Associated With a COVID-19 mRNA Vaccine. Widespread uptake of the coronavirus disease 2019 (COVID-19) vaccinations has become the world's championed defense against the global pandemic. Four vaccines have been either approved or authorized for emergency use by the FDA, and at this time, over 13 billion doses of these vaccines have been administered around the world. Unfortunately, uncommon and sometimes unforeseen side effects such as small-vessel vasculitis have been reported. In this case report, we present a 74-year-old woman with a history of hypertension, type 2 diabetes mellitus, and hypothyroidism who developed microscopic polyangiitis (MPA) following the second dose of the Pfizer-BioNTech mRNA vaccine for COVID-19. The diagnosis of MPA was confirmed by a kidney biopsy. The autoimmune condition progressed to pericardial effusion and eventual cardiac tamponade, which is occasionally seen in the disease. In this patient's case, we suspect there to be a temporal association between mRNA COVID-19 vaccination and the development of MPA. Direct causation has not been determined.

Side effects after COVID-19 vaccination: a comparison between the most common available vaccines in Iran. BACKGROUND AND OBJECTIVES: Since the coronavirus disease 2019 (COVID-19) pandemic began, several vaccines have been manufactured to subside it. This study aimed to determine the prevalence of side effects after injecting common COVID-19 vaccines available in Iran. MATERIALS AND METHODS: This cross-sectional study was accomplished on Shahid Beheshti University of Medical Sciences (Tehran, Iran) employees during January and September 2022. Eligible participants were selected based on the simple random method and interviewed about side effects after injecting COVID-19 vaccine. RESULTS: The mean age of 656 participants was 38.03 Â± 9.53 years, and 453 (69.1%) were female. The prevalence of post-vaccination side effects was higher after

receiving the first dose (53.2%) than the second (35.9%) and third (49.4%) doses. Across all three vaccine doses, the overall proportion of side effects was higher following AstraZeneca than the others. The most common side effect after the first dose of the vaccine was myalgia (41.9%), followed by fever (36.6%), chills (31.6%), local reactions (27.0%), headache (25.5%), and sweating (21.6%). People experienced mainly myalgia (23.3%) and fever (20.3%) after injecting the second dose of the vaccine. Additionally, the participants had myalgia (37.2%), fever (30.8%), chills (29.2%), local reactions (26.0%), and headache (24.4%) after the third dose of the vaccine. CONCLUSION: AstraZeneca had a higher proportion of post-vaccination adverse effects than Sputnik V, Pastocovac, and Sinopharm. The most common side effects were flu-like syndrome and local reactions at the injection site. Furthermore, people rarely experienced life-threatening side effects. Thus, the available COVID-19 vaccines in Iran are safe.

Platelet-rich plasma in the treatment of alopecia areata after COVID-19 vaccination. KEY CLINICAL MESSAGE: Alopecia areata may develop in patients after COVID-19 vaccination. Platelet-rich plasma (PRP) has an outstanding anti-inflammatory effect and could be an alternative treatment for alopecia patients who are refractory or intolerant to corticosteroids. ABSTRACT: A 34-year-old female with no systemic illness presented with non-scarring hair loss after the second COVID-19 vaccination shot 4â€‰weeks ago. The hair loss worsened and progressed to severe alopecia areata. We started double-spin PRP therapy. Her hair recovered completely after six courses of PRP treatment.

COVID-19, post-acute COVID-19 syndrome (PACS, "long COVID") and post-COVID-19 vaccination syndrome (PCVS, "post-COVIDvac-syndrome"): Similarities and differences. Worldwide there have been over 760 million confirmed coronavirus disease 2019 (COVID-19) cases, and over 13 billion COVID-19 vaccine doses have been administered as of April 2023, according to the World Health Organization. An infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) can lead to an acute disease, i.e. COVID-19, but also to a post-acute COVID-19 syndrome (PACS, "long COVID"). Currently, the side effects of COVID-19 vaccines are increasingly being noted and studied. Here, we summarise the currently available indications and discuss our conclusions that (i) these side effects have specific similarities and differences to acute COVID-19 and PACS, that (ii) a new term should be used to refer to these side effects (post-COVID-19 vaccination syndrome, PCVS, colloquially "post-COVIDvac-syndrome"), and that (iii) there is a need to distinguish between acute COVID-19 vaccination syndrome (ACVS) and post-acute COVID-19 vaccination syndrome (PACVS) - in analogy to acute COVID-19 and PACS ("long COVID"). Moreover, we address mixed forms of disease caused by natural SARS-CoV-2 infection and COVID-19 vaccination. We explain why it is important for medical diagnosis, care and research to use the new terms (PCVS, ACVS and PACVS) in order to avoid confusion and misinterpretation of the underlying causes of disease and to enable optimal medical therapy. We do not recommend to use the term "Post-Vac-Syndrome" as it is imprecise. The article also serves to address the current problem of "medical gaslighting" in relation to PACS and PCVS by raising awareness among the medical professionals and supplying appropriate terminology for disease.

Association Between Vaccination Status and Outcomes in Patients Admitted to the ICU With COVID-19. OBJECTIVES: Although COVID-19 vaccines can reduce the need for intensive care unit admission in COVID-19, their effect on outcomes in critical illness remains unclear. We evaluated outcomes in vaccinated patients admitted to the ICU with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections and the association between vaccination and booster status on clinical outcomes. DESIGN: Retrospective cohort. SETTING AND PATIENTS: All patients were admitted to an ICU between January 2021 (after vaccination was available) and July 2022 with a diagnosis of COVID-19 based on a SARS-CoV-2 polymerase chain reaction test in Alberta, Canada. INTERVENTIONS: None. MEASUREMENT: The propensity-matched primary outcome of all-cause in-hospital mortality

was compared between vaccinated and unvaccinated patients, and vaccinated patients were stratified by booster dosing. Secondary outcomes were mechanical ventilation (MV) duration ICU length of stay (LOS). MAIN RESULTS: The study included 3,293 patients: 743 (22.6%) were fully vaccinated (54.6% with booster), 166 (5.0%) were partially vaccinated, and 2,384 (72.4%) were unvaccinated. Unvaccinated patients were more likely to require invasive MV (78.4% vs 68.2%), vasopressor use (71.1% vs 66.6%), and extracorporeal membrane oxygenation (2.1% vs 0.5%). In a propensity-matched analysis, in-hospital mortality was similar (31.8% vs 34.0%, adjusted odds ratio [OR], 1.25; 95% CI, 0.97-1.61), but median duration MV (7.6 vs 4.7 d; $p < 0.001$) and ICU LOS (6.6 vs 5.2 d; $p < 0.001$) were longer in unvaccinated compared to fully vaccinated patients. Among vaccinated patients, greater than or equal to 1 booster had lower in-hospital mortality (25.5% vs 40.9%; adjusted OR, 0.50; 95% CI, 0.0.36-0.68) and duration of MV (3.8 vs 5.6 d; $p = 0.025$). CONCLUSIONS: Nearly one in four patients admitted to the ICU with COVID-19 after widespread COVID-19 vaccine availability represented a vaccine-breakthrough case. Mortality risk remains substantial in vaccinated patients and similar between vaccinated and unvaccinated patients after the onset of critical illness. However, COVID-19 vaccination is associated with reduced ICU resource utilization and booster dosing may increase survivability from COVID-19-related critical illness.

Use of Immunization Information Systems in Ascertainment of COVID-19 Vaccinations for Claims-Based Vaccine Safety and Effectiveness Studies. IMPORTANCE: Safety and effectiveness studies of COVID-19 vaccines are being conducted using clinical data, including administrative claims. However, claims data only partially capture administered COVID-19 vaccine doses for numerous reasons, such as vaccination at sites that do not generate claims for reimbursement. OBJECTIVE: To evaluate the extent to which Immunization Information Systems (IIS) data linked to claims data enhances claims-based COVID-19 vaccine capture for a commercially insured population and to estimate the magnitude of misclassification of vaccinated individuals as having unvaccinated status in the linked IIS and claims data. DESIGN, SETTING, AND PARTICIPANTS: This cohort study used claims data from a commercial health insurance database and obtained vaccination data from IIS repositories in 11 US states. Participants were individuals younger than 65 years who resided in 1 of 11 states of interest and who were insured in health plans from December 1, 2020, through December 31, 2021. MAIN OUTCOMES AND MEASURES: Estimated proportion of individuals with at least 1 dose of any COVID-19 vaccine and proportion of individuals with a completed vaccine series based on general population guidelines. Vaccination status estimates were calculated and compared using claims data alone and linked IIS and claims data. Remaining misclassification of vaccination status was assessed by comparing linked IIS and claims data estimates with estimates from external surveillance data sources (Centers for Disease Control and Prevention [CDC] and state Department of Health [DOH]) and capture-recapture analysis. RESULTS: This cohort study included 5â€¯112â€¯722 individuals (mean [SD] age, 33.5 [17.6] years; 2â€¯618â€¯098 females [51.2%]) from 11 states. Characteristics of those who received at least 1 vaccine dose and those who completed a vaccine series were similar to the overall study population. The proportion with at least 1 vaccine dose increased from 32.8% using claims data alone to 48.1% when the data were supplemented with IIS vaccination records. Vaccination estimates using linked IIS and claims data varied widely by state. The percentage of individuals who completed a vaccine series increased from 24.4% to 41.9% after the addition of IIS vaccine records and varied across states. The percentages of underrecording using linked IIS and claims data were 12.1% to 47.1% lower than those using CDC data, 9.1% to 46.9% lower than the state DOH, and 9.2% to 50.9% lower than capture-recapture analysis. CONCLUSION AND RELEVANCE: Results of this study suggested that supplementing COVID-19 claims records with IIS vaccination records substantially increased the number of individuals who were identified as

vaccinated, yet potential underrecording remained. Improvements in reporting vaccination data to IIS infrastructures could allow frequent updates of vaccination status for all individuals and all vaccines.

Assay Harmonization Study To Measure Immune Response to SARS-CoV-2 Infection and Vaccines: a Serology Methods Study. The Coronavirus disease 2019 (COVID-19) pandemic presented the scientific community with an immediate need for accurate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) serology assays, resulting in an expansion of assay development, some without following a rigorous quality control and validation, and with a wide range of performance characteristics. Vast amounts of data have been gathered on SARS-CoV-2 antibody response; however, performance and ability to compare the results have been challenging. This study seeks to analyze the reliability, sensitivity, specificity, and reproducibility of a set of widely used commercial, in-house, and neutralization serology assays, as well as provide evidence for the feasibility of using the World Health Organization (WHO) International Standard (IS) as a harmonization tool. This study also seeks to demonstrate that binding immunoassays may serve as a practical alternative for the serological study of large sample sets in lieu of expensive, complex, and less reproducible neutralization assays. In this study, commercial assays demonstrated the highest specificity, while in-house assays excelled in antibody sensitivity. As expected, neutralization assays demonstrated high levels of variability but overall good correlations with binding immunoassays, suggesting that binding may be reasonably accurate as well as practical for the study of SARS-CoV-2 serology. All three assay types performed well after WHO IS standardization. The results of this study demonstrate there are high performing serology assays available to the scientific community to rigorously dissect antibody responses to infection and vaccination. IMPORTANCE Previous studies have shown significant variability in SARS-CoV-2 antibody serology assays, highlighting the need for evaluation and comparison of these assays using the same set of samples covering a wide range of antibody responses induced by infection or vaccination. This study demonstrated that there are high performing assays that can be used reliably to evaluate immune responses to SARS-CoV-2 in the context of infection and vaccination. This study also demonstrated the feasibility of harmonizing these assays against the International Standard and provided evidence that the binding immunoassays may have high enough correlation with the neutralization assays to serve as a practical proxy. These results represent an important step in standardizing and harmonizing the many different serological assays used to evaluate COVID-19 immune responses in the population.

Antibody Response to the BA.5 Bivalent Vaccine Shot: a Two-Year Follow-Up Study following Initial COVID-19 mRNA Vaccination. Although many studies have been conducted on the increase in spike antibody levels after vaccination, there is insufficient prospective and longitudinal information on the BA.5-adapted bivalent vaccine up to the fifth vaccination. In this study, we conducted a follow-up study of spike antibody levels and infection history in 46 health care workers who received up to 5 vaccinations. Monovalent vaccines were administered for the first to fourth vaccinations, and a bivalent vaccine was administered for the fifth vaccination. 11 serum samples were collected from each participant, and antibody levels were measured in a total of 506 serum samples. During the observation period, 43 of the 46 health care workers had no infection history, and 3 had a history of infection. Spike antibody levels peaked at 1 week after the second booster vaccination and gradually declined until the 27th week after the second vaccination. After 2 weeks following the fifth BA.5-adapted bivalent vaccine, the spike antibody levels significantly increased (median: 23,756 [IQR: 16,450 to 37,326]), compared to those measured before vaccination (median: 9,354 [IQR: 5,904 to 15,784]) (paired Wilcoxon signed-rank test, Pâ€‰=â€‰5.7â€‰Ã—â€‰10(-14)). These changes in antibody kinetics were observed regardless of age or sex. These results suggest that booster vaccination increased the spike antibody levels. Regular vaccination is effective in maintaining long-term antibody levels. IMPORTANCE A COVID-19 bivalent mRNA vaccine was developed and

administered to health care workers. The COVID-19 mRNA vaccine induces a robust antibody response. However, little is known about the antibody response to vaccines in serially collected blood samples from the same individuals. Here, we provide two-year follow-up data on the humoral immune response to COVID-19 mRNA vaccines in health care workers who received up to five vaccinations, including the BA.5-adapted bivalent vaccine. The results suggest that regular vaccination is effective in maintaining long-term antibody levels and have implications for vaccine efficacy and booster dose strategies in health care settings.

Factors Associated With Marshallese and Hispanic Adults' Willingness to Receive a COVID-19 Booster Dose. INTRODUCTION/OBJECTIVES: New variants of the SARS-CoV-2 virus that causes COVID-19 will continue to develop and spread globally. The Omicron variant identified in November 2021 has many lineages. Variants spread quickly and can infect previously vaccinated individuals, prompting the Centers for Disease Control and Prevention to update vaccination recommendations. While ~230â€‰million Americans received the initially-recommended vaccine sequence, booster uptake has been much lower; less than half of fully vaccinated individuals report receiving a booster. Racial disparities also mark patterns of COVID-19 vaccination booster uptake. This study explored willingness and motivations to get a COVID-19 booster among a diverse sample of participants. METHODS: We used convenience sampling to recruit participants 18â€‰years of age or older who attended a community vaccine event. We conducted informal interviews during the recommended 15-min post-vaccination wait time with 55 participants who attended vaccine events at Marshallese and Hispanic community locations and comprised the recruitment pool for individual interviews. Using a qualitative descriptive design, we conducted in-depth follow-up interviews with 9 participants (Marshallese nâ€‰=â€‰5, Hispanic nâ€‰=â€‰4) to explore willingness and motivations to get boosted. We used rapid thematic template analysis to review informal interview summaries and formal interviews. The research team resolved data discrepancies by consensus. RESULTS: Participants reported high willingness to get boosted, especially if boosters were recommended in the future to protect against serious illness and mitigate the spread of COVID-19. This finding underscores how essential including recommendations to get a COVID-19 booster from trusted sources in health messaging and educational campaigns may be for increasing booster uptake. Participants described their preference for receiving future COVID-19 boosters, reporting that they would attend similar vaccine events, especially those held at faith-based organizations and facilitated by the same community partners, community health workers, and research staff. This finding shows how community engagement can overcome barriers to vaccination (ie, transportation, language, and fear of discrimination) by providing services in preferred community locations with trusted community partners. CONCLUSIONS: Findings document high willingness to get a COVID-19 booster, emphasize the role of recommendations from trusted sources in motivating booster uptake, and highlight the importance of community engagement to address disparities in vaccination coverage and reach.

Persistent Immunity against SARS-CoV-2 in Individuals with Oncohematological Diseases Who Underwent Autologous or Allogeneic Stem Cell Transplantation after Vaccination. The high morbimortality due to SARS-CoV-2 infection in oncohematological diseases (OHD) and hematopoietic stem cell transplant (HSCT) recipients in the pre-vaccine era has made vaccination a priority in this group. After HSCT, the immune responses against common vaccines such as tetanus, varicella, rubella, and polio may be lost. However, the loss of immunity developed by COVID-19 vaccination after HSCT has not been completely defined. In this study, both humoral and cellular immunity against SARS-CoV-2 were analyzed in 29 individuals with OHD who were vaccinated before receiving allogeneic (n = 11) or autologous (n = 18) HSCT. All participants had low but protective levels of neutralizing IgGs against SARS-CoV-2 after HSCT despite B-cell lymphopenia and immaturity. Although

antibody-dependent cellular cytotoxicity was impaired, direct cellular cytotoxicity was similar to healthy donors in participants with autologous-HSCT, in contrast to individuals with allogeneic-HSCT, which severely deteriorated. No significant changes were observed in the immune response before and after HSCT. During follow-up, all reported post-HSCT SARS-CoV-2 infections were mild. This data emphasizes that COVID-19 vaccination is effective, necessary, and safe for individuals with OHD and also supports the persistence of some degree of immune protection after HSCT, at least in the short term, when patients cannot yet be revaccinated.

Adult Patients with Cancer Have Impaired Humoral Responses to Complete and Booster COVID-19 Vaccination, Especially Those with Hematologic Cancer on Active Treatment: A Systematic Review and Meta-Analysis. The exclusion of patients with cancer in clinical trials evaluating COVID-19 vaccine efficacy and safety, in combination with the high rate of severe infections, highlights the need for optimizing vaccination strategies. The aim of this study was to perform a systematic review and meta-analysis of the published available data from prospective and retrospective cohort studies that included patients with either solid or hematological malignancies according to the PRISMA Guidelines. A literature search was performed in the following databases: Medline (Pubmed), Scopus, Clinicaltrials.gov, EMBASE, CENTRAL and Google Scholar. Overall, 70 studies were included for the first and second vaccine dose and 60 studies for the third dose. The Effect Size (ES) of the seroconversion rate after the first dose was 0.41 (95%CI: 0.33-0.50) for hematological malignancies and 0.56 (95%CI: 0.47-0.64) for solid tumors. The seroconversion rates after the second dose were 0.62 (95%CI: 0.57-0.67) for hematological malignancies and 0.88 (95%CI: 0.82-0.93) for solid tumors. After the third dose, the ES for seroconversion was estimated at 0.63 (95%CI: 0.54-0.72) for hematological cancer and 0.88 (95%CI: 0.75-0.97) for solid tumors. A subgroup analysis was performed to evaluate potential factors affecting immune response. Production of anti-SARS-CoV-2 antibodies was found to be more affected in patients with hematological malignancies, which was attributed to the type of malignancy and treatment with monoclonal antibodies according to the subgroup analyses. Overall, this study highlights that patients with cancer present suboptimal humoral responses after COVID-19 vaccination. Several factors including timing of vaccination in relevance with active therapy, type of therapy, and type of cancer should be considered throughout the immunization process.

Analysis of COVID-19 mRNA Vaccine-induced Mouth Ulcers Using the Japanese Adverse Drug Event Report Database. There are case reports of mouth ulcers caused by the coronavirus disease 2019 (COVID-19) messenger ribonucleic acid (mRNA) vaccine; however, the actual number and characteristics of cases are unknown. Therefore, we examined this issue using the Japanese Adverse Drug Event Report (JADER), a large Japanese database. We calculated the reported odds ratio (ROR) of drugs that may be specifically associated with mouth ulcers and assumed that a signal was present if the lower limit of the calculated ROR's 95% confidence interval (CI) was > 1. In addition, the time to symptom onset after administration of the COVID-19 mRNA and influenza HA vaccines was investigated. We found that the JADER database contained 4,661 mouth ulcer cases between April 2004 and March 2022. The COVID-19 mRNA vaccine was the eighth most common causative drug for mouth ulcers, with 204 reported cases. The ROR was 1.6 (95% CI, 1.4-1.9) and a signal was detected. There were 172 mouthulcer cases associated with the Pfizer-BioNTech's COVID-19 mRNA vaccine, 76.2% of which were female. The outcome was no unrecovered cases with the influenza HA vaccine, whereas the COVID-19 mRNA vaccine showed unrecovered cases (Pfizer-BioNTech: 12.2%, Moderna: 11.1%). The median time-to-onset of the mouth ulcers was two days for the COVID-19 mRNA vaccine and one day for the influenza HA vaccine, indicating that mouth ulcers caused by the COVID-19 mRNA vaccine were delayed adverse events. In this study, the COVID-19 mRNA vaccine was shown to cause mouth ulcers in a Japanese population.

Characterization of post-vaccination SARS-CoV-2 T cell subtypes in patients with different hematologic malignancies and treatments. BACKGROUND: To evaluate the benefits of SARS-CoV-2 vaccination in cancer patients it is relevant to understand the adaptive immune response elicited after vaccination. Patients affected by hematologic malignancies are frequently immune-compromised and show a decreased seroconversion rate compared to other cancer patients or controls. Therefore, vaccine-induced cellular immune responses in these patients might have an important protective role and need a detailed evaluation. METHODS: Certain T cell subtypes (CD4, CD8, Tfh, Î³Î´T), including cell functionality as indicated by cytokine secretion (IFN, TNF) and expression of activation markers (CD69, CD154) were assessed via multi-parameter flow cytometry in hematologic malignancy patients (N=12) and healthy controls (N=12) after a second SARS-CoV-2 vaccine dose. The PBMC of post-vaccination samples were stimulated with a spike-peptide pool (S-Peptides) of SARS-CoV-2, with CD3/CD28, with a pool of peptides from the cytomegalovirus, Epstein-Barr virus and influenza A virus (CEF-Peptides) or left unstimulated. Furthermore, the concentration of spike-specific antibodies has been analyzed in patients. RESULTS: Our results indicate that hematologic malignancy patients developed a robust cellular immune response to SARS-CoV-2 vaccination comparable to that of healthy controls, and for certain T cell subtypes even higher. The most reactive T cells to SARS-CoV-2 spike peptides belonged to the CD4 and Tfh cell compartment, being median (IQR), 3.39 (1.41-5.92) and 2.12 (0.55-4.14) as a percentage of IFN- and TNF-producing Tfh cells in patients. In this regard, the immunomodulatory treatment of patients before the vaccination period seems important as it was strongly associated with a higher percentage of activated CD4 and Tfh cells. SARS-CoV-2- and CEF-specific T cell responses significantly correlated with each other. Compared to lymphoma patients, myeloma patients had an increased percentage of SARS-CoV-2-specific Tfh cells. T-SNE analysis revealed higher frequencies of Î³Î´T cells in patients compared to controls, especially in myeloma patients. In general, after vaccination, SARS-CoV-2-specific T cells were also detectable in patients without seroconversion. CONCLUSION: Hematologic malignancy patients are capable of developing a SARS-CoV-2-specific CD4 and Tfh cellular immune response after vaccination, and certain immunomodulatory therapies in the period before vaccination might increase the antigen-specific immune response. A proper response to recall antigens (e.g., CEF-Peptides) reflects immune cellular functionality and might be predictive for generating a newly induced antigen-specific immune response as is expected after SARS-CoV-2 vaccination.

Anti-neutrophil Cytoplasmic Antibody-Associated Vasculitis With Periaortitis That Developed After mRNA COVID-19 Vaccination. Severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) has caused a global pandemic resulting in many deaths. As a result, vaccines to prevent the onset of coronavirus disease 2019 (COVID-19) have been developed and have demonstrated high efficacy in large-scale clinical trials. Adverse events that develop within a few days after vaccination are common, such as fever, malaise, body aches, and headaches, and have become widely known as transient reactions. However, as COVID-19 vaccines are administered worldwide, several studies have highlighted that long-term side effects associated with vaccines against SARS-CoV-2 may include serious adverse events. There has been an increase in reports of COVID-19 vaccinations being associated with the onset of autoimmune diseases, such as anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis. This is a report of ANCA-associated vasculitis with periaortitis following the second dose of COVID-19 mRNA vaccination, in which a 56-year-old man developed numbness and pain in his lower extremities three weeks after COVID-19 vaccination. Following the onset of sudden abdominal pain, a fluorodeoxyglucose-positron emission tomography scan revealed periaortic inflammation. Serum myeloperoxidase (MPO)-ANCA levels were significantly elevated, and renal biopsy revealed pauci-immune crescentic glomerulonephritis. Treatment with steroids and

cyclophosphamide alleviated abdominal pain and numbness in the lower limbs, resulting in a decrease in MPO-ANCA titers. The side effects of COVID-19 vaccination are still unclear. This report has indicated that side effects associated with vaccines against COVID-19 may include ANCA-associated vasculitis. However, a causal relationship between COVID-19 vaccination and the development of ANCA-associated vasculitis has not yet been clearly demonstrated. COVID-19 vaccination will continue internationally, so it is necessary to accumulate similar case reports in the future.

Neutralizing Antibody Responses to Messenger RNA Coronavirus Disease 2019 Vaccines Versus Severe Acute Respiratory Syndrome Coronavirus 2 Infection Among Pregnant Women and Vaccine-Induced Antibody Transfer to Infants. BACKGROUND: Early coronavirus disease 2019 (COVID-19) vaccine trials excluded pregnant women, resulting in limited data about immunogenicity and maternal-fetal antibody transfer, particularly by gestational timing of vaccination. METHODS: In this multicenter observational immunogenicity study, pregnant and nonpregnant women receiving COVID-19 vaccines were prospectively enrolled. Participants had sera collected before vaccination, at 14-28 days after each vaccine dose, at delivery (umbilical cord and peripheral), and from their infants at 3 and 6 months. Geometric mean titers (GMTs) of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) ID(50) neutralizing antibody (nAb) against D614G-like viruses were compared by participant characteristics. RESULTS: Overall, 23 nonpregnant and 85 pregnant participants (trimester of first vaccine dose: 10 first, 47 second, 28 third) were enrolled. Ninety-three percent (76/82 with blood samples) of pregnant participants had detectable SARS-CoV-2 nAb after 2 vaccine doses, but GMTs (95% confidence intervals) were lower in pregnant participants than nonpregnant participants (1722 [1136-2612] vs 4419 [2012-9703]; P = .04). By 3 and 6 months, 28% and 74% of infants, respectively, of vaccinated participants had no detectable nAb to D614G-like viruses. Among the 71 pregnant participants without detectable nAb before vaccination, cord blood GMTs at delivery were 5-fold higher among participants vaccinated during the third versus first trimester, and cord blood nAb titers appeared inversely correlated with weeks since first vaccine dose (R(2) = 0.06, P = .06). CONCLUSIONS: Though most pregnant women develop nAb after 2 doses of mRNA COVID-19 vaccines, this analysis suggests that infant protection from maternal vaccination varies by gestational timing of vaccination and wanes. Additional prevention strategies such as caregiver vaccination may warrant consideration to optimize infant protection.

Risk of autoimmune skin and connective tissue disorders after mRNA-based COVID-19 vaccination. BACKGROUND: Data on the association between the development of autoimmune diseases and COVID-19 vaccination are limited. OBJECTIVE: To investigate the incidence and risk of autoimmune connective tissue disorders following mRNA-based COVID-19 vaccination. METHODS: This nationwide population-based study was conducted in South Korea. Individuals who received vaccination between September 8, 2020-December 31, 2021, were identified. Historical prepandemic controls were matched for age and sex in 1:1 ratio. The incidence rate and risk of disease outcomes were compared. RESULTS: A total of 3,838,120 vaccinated individuals and 3,834,804 controls without evidence of COVID-19 were included. The risk of alopecia areata, alopecia totalis, primary cicatricial alopecia, psoriasis, vitiligo, anti-neutrophil cytoplasmic antibody-associated vasculitis, sarcoidosis, Behcet disease, Crohn disease, ulcerative colitis, rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, Sjogren syndrome, ankylosing spondylitis, dermato/polymyositis, and bullous pemphigoid was not significantly higher in vaccinated individuals than in controls. The risk was comparable according to age, sex, type of mRNA-based vaccine, and cross-vaccination status. LIMITATIONS: Possible selection bias and residual confounders. CONCLUSION: These findings suggest that most autoimmune connective tissue disorders are not associated with a significant increase in

risk. However, caution is necessary when interpreting results for rare outcomes due to limited statistical power.

Subacute THYROiditis Related to SARS-CoV-2 VAccine and Covid-19 (THYROVAC Study): A Multicenter Nationwide Study. CONTEXT: The aims of the study are to compare characteristics of subacute thyroiditis (SAT) related to different etiologies, and to identify predictors of recurrence of SAT and incident hypothyroidism. METHODS: This nationwide, multicenter, retrospective cohort study included 53 endocrinology centers in Turkey. The study participants were divided into either COVID-19-related SAT (Cov-SAT), SARS-CoV-2 vaccine-related SAT (Vac-SAT), or control SAT (Cont-SAT) groups. RESULTS: Of the 811 patients, 258 (31.8%) were included in the Vac-SAT group, 98 (12.1%) in the Cov-SAT group, and 455 (56.1%) in the Cont-SAT group. No difference was found between the groups with regard to laboratory and imaging findings. SAT etiology was not an independent predictor of recurrence or hypothyroidism. In the entire cohort, steroid therapy requirement and younger age were statistically significant predictors for SAT recurrence. C-reactive protein measured during SAT onset, female sex, absence of antithyroid peroxidase (TPO) positivity, and absence of steroid therapy were statistically significant predictors of incident (early) hypothyroidism, irrespective of SAT etiology. On the other hand, probable predictors of established hypothyroidism differed from that of incident hypothyroidism. CONCLUSION: Since there is no difference in terms of follow-up parameters and outcomes, COVID-19- and SARS-CoV-2 vaccine-related SAT can be treated and followed up like classic SATs. Recurrence was determined by younger age and steroid therapy requirement. Steroid therapy independently predicts incident hypothyroidism that may sometimes be transient in overall SAT and is also associated with a lower risk of established hypothyroidism.

COVID-19 vaccine-associated vitiligo: A cross-sectional study in a tertiary referral center and systematic review. As the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus continues to infect patients globally, vaccination remains one of the primary methods to combat this prolonged pandemic. However, there are growing reports of coronavirus disease 2019 (COVID-19) vaccines possibly triggering autoimmunity, irrespective of the vaccine's design. This phenomenon has been observed in patients with vitiligo, with a rising number of cases reporting new-onset or worsening vitiligo following COVID-19 vaccinations. In this study, the authors present the most extensive case series of COVID-19 vaccine-associated vitiligo to date, along with a systematic review of the literature. The aim is to assist physicians in the clinical evaluation of patients with vitiligo with regard to future vaccinations.

Immunosuppressive treatment for autoimmune blistering diseases does not impair production of neutralizing antibodies after "booster" dose of COVID-19 vaccine. Since vaccines against COVID-19 are available, it has been debated if immunosuppressed patients with autoimmune blistering diseases (AIBDs) should be advised to interrupt the immunosuppressive therapy before receiving the vaccine, with consequent risk to experience a flare of disease. In the present study, we measured the neutralizing antibodies production after anti-SARS-CoV-2 vaccination in patients with AIBDs on immunosuppressive treatment, compared to healthy controls. Our results give strength to the hypothesis that these patients do not need to discontinue their therapy to produce effective levels of neutralizing antibodies, in other words to achieve successful protection.

No association of vaccination with inactivated COVID-19 vaccines before conception with pregnancy complications and adverse birth outcomes: A cohort study of 5457 Chinese pregnant women.
Data on the safety of inactivated COVID-19 vaccines in pregnant women is limited and monitoring pregnancy outcomes is required. We aimed to examine whether vaccination with inactivated COVID-19 vaccines before conception was associated with pregnancy complications or adverse birth outcomes. We conducted a birth cohort study in Shanghai, China. A total of 7000 healthy pregnant women were enrolled, of whom 5848 were followed up through delivery. Vaccine administration

information was obtained from electronic vaccination records. Relative risks (RRs) of gestational diabetes mellitus (GDM), hypertensive disorders in pregnancy (HDP), intrahepatic cholestasis of pregnancy (ICP), preterm birth (PTB), low birth weight (LBW), and macrosomia associated with COVID-19 vaccination were estimated by multivariable-adjusted log-binomial analysis. After exclusion, 5457 participants were included in the final analysis, of whom 2668 (48.9%) received at least two doses of an inactivated vaccine before conception. Compared with unvaccinated women, there was no significant increase in the risks of GDM (RRâ€‰=â€‰0.80, 95% confidence interval [CI], 0.69, 0.93), HDP (RRâ€‰=â€‰0.88, 95% CI, 0.70, 1.11), or ICP (RRâ€‰=â€‰1.61, 95% CI, 0.95, 2.72) in vaccinated women. Similarly, vaccination was not significantly associated with any increased risks of PTB (RRâ€‰=â€‰0.84, 95% CI, 0.67, 1.04), LBW (RRâ€‰=â€‰0.85, 95% CI, 0.66, 1.11), or macrosomia (RRâ€‰=â€‰1.10, 95% CI, 0.86, 1.42). The observed associations remained in all sensitivity analyses. Our findings suggested that vaccination with inactivated COVID-19 vaccines was not significantly associated with an increased risk of pregnancy complications or adverse birth outcomes.

Neurologic Complications With Vaccines: What We Know, What We Don't, and What We Should Do. Over the previous half century, vaccines have shaped human life by eradicating or nearly eradicating infections that were once a major cause of morbidity and mortality. The number of infections for which vaccines are now available has steadily increased. The types of vaccines have evolved over the years from crude extracts to more refined messenger RNA or protein-based vaccines. With these well-defined manufacturing processes, the safety profile has also improved. Despite such measures, vaccines are not without side effects, including those that affect the nervous system. Numerous case reports and case series point to these possibilities. These issues have gathered much attention during the current mass vaccination against severe acute respiratory syndrome coronavirus 2 and have resulted in some members of the public raising concerns about vaccine safety. The vaccine manufacturers have legal protection against vaccine side effects; however, there are active and passive surveillance programs put in place by the Center for Disease Control and Prevention, the US Food and Drug Administration, the World Health Organization, and the European Union. Action is needed that brings together manufactures, healthcare agencies, clinical and bench scientists, and legislatures on a global platform to investigate vaccine-related neurologic adverse events and develop ways to prevent and treat them.

Side effects of COVID-19 vaccination and breast cancer.

Outcome and Morphofunctional Changes on Cardiac Magnetic Resonance in Patients With Acute Myocarditis Following mRNA COVID-19 Vaccination.

The incidence and clinical characteristics of myocarditis and pericarditis following mRNA-based COVID-19 vaccination in Republic of Korea adolescents from July 2021 to September 2022. OBJECTIVES: Age-specific information regarding myocarditis/pericarditis in adolescents following mRNA-based coronavirus disease 2019 (COVID-19) vaccination in Asia remains insufficient. This study investigated the incidence and clinical characteristics of myocarditis/pericarditis in Republic of Korea adolescents after mRNA-based COVID-19 vaccination. METHODS: This retrospective descriptive study utilized patient data from the Korea Immunization Management System. Incidence rates were calculated according to age and sex. Clinical characteristics (symptoms/signs, laboratory values, and imaging results) were compared between mild and severe cases. RESULTS: Between July 19, 2021 and September 30, 2022, 3,728,224 individuals aged 12 to 19 years received 6,484,165 mRNA-based COVID-19 vaccines, and 173 cases met the case definition for myocarditis/pericarditis: 151 mild (87.3%) and 22 severe (12.7%). The incidence was 3.8-fold higher in males than in females. Troponin I/ troponin T was elevated in 96% of myocarditis cases, demonstrating higher sensitivity than creatine kinase-myocardial band (67.6%) or C-reactive protein (75.2%). ST-segment or Twave on electrography

abnormalities were found in 60.3% (85/141). Paroxysmal/sustained atrial/ventricular arrhythmias were more common in severe than in mild cases (45.5% vs. 16.8%, p=0.008). Edema on T2-weighted magnetic imaging occurred in 21.6% (8/37) and 62.5% (5/8) of mild and severe cases, respectively (p=0.03). Abnormal pericardial fluid collection or pericardial inflammation was found in 75.4% of pericarditis cases (49/65). CONCLUSION: Myocarditis/pericarditis occurred in rare cases following mRNA-based COVID-19 vaccination. Most cases were mild, but the incidence was higher in adolescent males and after the second dose. As bivalent severe acute respiratory syndrome coronavirus 2 mRNA vaccination started in Republic of Korea in October 2022, the post-vaccination incidence of myocarditis/pericarditis should be closely monitored, considering clinical characteristics.

Self-reported adverse events after 2 doses of COVID-19 vaccine in Korea. OBJECTIVES: In Korea, a national coronavirus disease 2019 (COVID-19) vaccination program was implemented, including 4 vaccines against COVID-19. A text messaging-based survey, in addition to a passive adverse event reporting system, was launched to quickly report unusual symptoms post-vaccination. This study compared the frequency of adverse events after COVID-19 vaccination based on the vaccine type and the type of 2-dose regimen (homologous or heterologous). METHODS: Self-reported adverse events were collected through a text-message survey for 7 days after each vaccination. This study included 50,950 vaccine recipients who responded to the survey at least once. Informed consent to receive surveys via text was obtained from the vaccine recipients on the date of first vaccination. RESULTS: The recipients of mRNA vaccines reported local and systemic reactions 1.6 times to 2.8 times more frequently after dose 2 than after dose 1 (p<0.001), whereas ChAdOx1-S recipients reported significantly fewer local and systemic reactions after dose 2 than after dose 1 (p<0.001). Local and systemic reactions were approximately 2 times and 4 times more frequent for heterologous vaccination than for BNT162b2/BNT162b2 and ChAdOx1-S/ChAdOx1-S regimens, respectively. Young individuals, female, and those receiving heterologous vaccine regimens including ChAdOx1-S/BNT162b2 vaccines reported more adverse events than older participants, male, and those with homologous vaccine regimens. CONCLUSIONS: Although a heterologous regimen, youth, and female sex were associated with a higher risk of adverse reactions after COVID-19 vaccination, no critical issues were noted. Active consideration of heterologous schedules based on the evidence of efficacy and safety appears desirable.

LipschÃ¼tz ulcers after AstraZeneca COVID-19 vaccination.

Prolonged infective SARS-CoV-2 omicron variant shedding in a patient with diffuse large B cell lymphoma successfully cleared after three courses of remdesivir. We report a case of prolonged shedding of the infective SARS-CoV-2 omicron variant BA.1.1.2 in a 79-year-old male patient with diffuse large B-cell lymphoma, after receiving chemotherapy with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone (R-CHOP). The patient was admitted to our hospital in late March 2022 for the sixth course of R-CHOP chemotherapy. Initially, the patient tested negative for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) using an in-hospital loop-mediated amplification assay with a nasopharyngeal swab, both on the day of admission and three days later. However, the patient developed fever and was diagnosed with coronavirus disease (COVID-19) six days after admission and was suspected to have contracted the infection in the ward. Viral shedding continued for more than three months, with confirmed viral infectivity. As compared to the original Wuhan-Hu-1/2019 strain, amino acid substitutions including S36Â N in non-structural protein (NSP)2, S148P, S1265del and L1266I in NSP3,Â G105D in NSP4, G496S, A831V, or V987F in spike protein, and I45T in open-reading frame (ORF)9b were randomly detected in isolated viruses. Although the patient had received two doses of the BNT162b2 vaccine approximately six months earlier and the third dose on day 127 after the infection, both serum anti-spike and anti-nuclear protein IgG and IgM tests were

negative at day 92, 114, and 149 after the infection. The patient finally cleared the virus after the third course of remdesivir and did not have further recurrence.

Exacerbation of Chronic Spontaneous Urticaria Following Coronavirus Disease 2019 (COVID-19) Vaccination in Omalizumab-Treated Patients. BACKGROUND: The rapid development and rollout of vaccines against coronavirus disease 2019 (COVID-19) has led to more than half of the world's population being vaccinated to date. Real-world data have reported various adverse cutaneous reactions, including delayed-onset urticaria, which was highly ranked as a common manifestation across studies. However, the impact of these novel mRNA or viral vector COVID-19 vaccines on preexisting chronic spontaneous urticaria (CSU) remains largely unknown. OBJECTIVE: To investigate the impact of COVID-19 vaccination on the clinical status of patients with relatively stable CSU who are undergoing omalizumab treatment and to identify risk factors for exacerbation. METHODS: We conducted a questionnaire-based cross-sectional study in a tertiary hospital. Adult patients with relatively stable CSU under regular omalizumab treatments who had received at least one COVID-19 vaccination were included. RESULTS: There were 105 study subjects who received 230 COVID-19 vaccinations between March and December 2021. Fifteen patients (14.3%) experienced aggravation of urticaria at least once after COVID-19 vaccination. The demographics and clinical characteristics of the patients were comparable regardless of the exacerbation of CSU. However, case-level analysis revealed that the presence of urticaria (vs none) before vaccination (odds ratio [OR]Â = 4.99; 95% CI, 1.57-15.82) and the development of systemic reactogenicity (ORÂ = 4.57; 95% CI, 1.62-12.90) were associated with a higher risk for exacerbation. CONCLUSIONS: The novel COVID-19 vaccination induced exacerbation in more than one-tenth of patients with well-controlled CSU. The establishment of a proper management strategy during COVID-19 vaccination is necessary for patients with CSU.

Identifying and Managing Those at Risk for Vaccine-Related Allergy and Anaphylaxis. Immediate hypersensitivity reactions to vaccines, the most severe of which is anaphylaxis, are uncommon events occurring in fewer than 1 in a million doses administered. These reactions are infrequently immunoglobulin E-mediated. Because they are unlikely to recur, a reaction to a single dose of a vaccine is rarely a contraindication to redosing. This narrative review article contextualizes the recent knowledge we have gained from the coronavirus 2019 (COVID-19) pandemic rollout of the new mRNA platform with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines within the much broader context of what is known about immediate reactions to other vaccinations of routine and global importance. We focus on what is known about evidence-based approaches to diagnosis and management and what is new in our understanding of mechanisms of immediate vaccine reactions. Specifically, we review the epidemiology of immediate hypersensitivity vaccine reactions, differential diagnosis for immune-mediated and nonimmune reaction clinical phenotypes, including how to recognize immunization stress-related responses. In addition, we highlight what is known about mechanisms and review the rare but important contribution of excipient allergies and specifically when to consider testing for them as well as other key features that contribute to safe evaluation and management.

Thrombotic and Thromboembolic Complications After Vaccination Against COVID-19: A Systematic Review. Thromboembolic complications after the COVID-19 vaccination have been reported from all over the world. We aimed to identify the thrombotic and thromboembolic complications that can arise after receiving various types of COVID-19 vaccines, their frequency, and distinguishing characteristics. Articles published in Medline/PubMed, Scopus, EMBASE, Google Scholar, EBSCO, Web of Science, the Cochrane Library, the CDC database, the WHO database, ClinicalTrials.gov, and servers like medRxiv.org and bioRxiv.org, as well as the websites of several reporting authorities between December 1, 2019, and July 29, 2021, were searched. Studies were included if they reported any thromboembolic complications post-COVID-19 vaccination and excluded editorials, systematic

reviews, meta-analyses, narrative reviews, and commentaries. Two reviewers independently extracted the data and conducted the quality assessment. Thromboembolic events and associated hemorrhagic complications after various types of COVID-19 vaccines, their frequency, and distinguishing characteristics were assessed. The protocol was registered at PROSPERO (ID-CRD42021257862). There were 59 articles, enrolling 202 patients. We also studied data from two nationwide registries and surveillance. The mean age of presentation was 47 Â± 15.5 (mean Â± SD) years, and 71.1% of the reported cases were females. The majority ofÂ events were with the AstraZeneca vaccine and with the first dose. Of these, 74.8% were venous thromboembolic events, 12.7% were arterial thromboembolic events, and the rest were hemorrhagic complications. The most common reported event was cerebralÂ venous sinusÂ thrombosisÂ (65.8%), followed by pulmonary embolism, splanchnic vein thrombosis, deep vein thrombosis, and ischemic and hemorrhagic stroke. The majority had thrombocytopenia, high D-dimer, and anti-PF4 antibodies. The case fatality rate was 26.5%. In our study, 26/59 of the papers were of fair quality.Â The data from two nationwide registries and surveillance revealed 6347 venous and arterial thromboembolic events post-COVID-19 vaccinations. COVID-19 vaccinations have been linked to thrombotic and thromboembolic complications. However, the benefits far outweigh the risks. Clinicians should be aware of these complications because they may be fatal and because prompt identification and treatment can prevent fatalities.

'Granulomatosis with polyangiitis after Pfizer vaccination': a case report. The advent of COVID-19, caused by the SARS-CoV-2 virus, has resulted in over 541 million cases with 6.32 million deaths worldwide as of June 2022. The devastating consequences of this global pandemic resulted in the expedited generation of mRNA-based vaccines such as the Pfizer-BioNTech and Moderna vaccines. Although the vaccines have been effective, with recent data indicating greater than 95% effectiveness, rare complications have been reported, including manifestations of autoimmune phenomena. Herein, we report a rare case of Granulomatosis with polyangiitis (GPA) in an active duty military male soon after receiving the first dose of the Pfizer-BioNTech COVID-19 vaccine.

 A 27-year-old active duty marine was admitted to our hospital after being transferred from Hawaii with concern of new autoimmune disease after receiving the Pfizer vaccine. The patient initially presented to the emergency department with joint pain, fever, chest pain, hemoptysis, and a nose bleed. A comprehensive workup demonstrated elevated inflammatory markers, progressive renal dysfunction, and a positive antibody panel consistent with antineutrophil cytoplasmic antibodies (ANCA) vasculitis. Due to the limited capabilities in his deployed setting, he was transferred to our hospital for a higher level of care. We performed some additional tests to include computed tomography (CT) imaging of his lungs and a renal biopsy which came back consistent with GPA. The patient was started on high-dose prednisone and rituximab, and he achieved remission. He was discharged from the hospital with follow-up arranged with rheumatology and nephrology. He remained in remission on follow-up.

Guillain-BarrÃ© syndrome and COVID-19 vaccines: focus on adenoviral vectors. COVID-19 vaccination is a life-saving intervention. However, it does not come up without a risk of rare adverse events, which frequency varies between vaccines developed using different technological platforms. The increased risk of Guillain-BarrÃ© syndrome (GBS) has been reported for selected adenoviral vector vaccines but not for other vaccine types, including more widely used mRNA preparations. Therefore, it is unlikely that GBS results from the cross-reactivity of antibodies against the SARS-CoV-2 spike protein generated after the COVID-19 vaccination. This paper outlines two hypotheses according to which increased risk of GBS following adenoviral vaccination is due to (1) generation of anti-vector antibodies that may cross-react with proteins involved in biological processes related to myelin and axons, or (2) neuroinvasion of selected adenovirus vectors to the peripheral nervous

system, infection of neurons and subsequent inflammation and neuropathies. The rationale behind these hypotheses is outlined, advocating further epidemiological and experimental research to verify them. This is particularly important given the ongoing interest in using adenoviruses in developing vaccines against various infectious diseases and cancer immunotherapeutics.

Post COVID-19 Vaccination Encephalitis as a Cause of Subacute Progressive Dementia: A Case Report and Literature Review.

ANCA-associated Vasculitic Neuropathy Following Anti-SARS-CoV-2 Vaccination: An Epiphenomenon or Causal Association?

Delayed cutaneous hypersensitivities to COVID-19 vaccination: Phenotypic distribution and tolerability of vaccine rechallenge.

Spontaneous resolution of inflammatory myopathy involving the masseter muscle following COVID-19 mRNA vaccination. According to previous reports, most cases of inflammatory myopathy following messenger RNA (mRNA) vaccination can be classified as idiopathic inflammatory myopathy, particularly dermatomyositis, owing to their similar clinical features and courses. However, some patients have different clinical features and courses. We report a rare case of transient inflammatory myopathy involving the masseter muscle following the third dose of coronavirus disease 2019 (COVID-19) mRNA vaccination. An 80-year-old woman presented with a history of fever and fatigue for 3â€‰months soon after receiving the third COVID-19 mRNA vaccination. Her symptoms progressed to jaw pain and inability to open her mouth. She also experienced mild proximal muscle weakness in the lower limbs but no skin manifestations or daily difficulties. Fat-saturated T2-weighted magnetic resonance imaging showed bilateral high-intensity signals for the masseter and quadriceps muscles. The patient experienced spontaneous resolution of fever and improvement of symptoms 5â€‰months after onset. The timing of the onset of symptoms, the lack of detectable autoantibodies, and the atypical presentation of myopathy in the masseter muscles, in addition to the spontaneous mild course of the disease, all indicate the substantial role of mRNA vaccination in this myopathy. Since then, the patient has been followed up for 4â€‰months without any recurrence of symptoms or any additional treatment. It is important to recognise that the course of myopathy after COVID-19 mRNA vaccination could be different from that of typical idiopathic inflammatory myopathies.

Evaluation of Serial Testing After Exposure to COVID-19 in Early Care and Education Facilities, Illinois, March-May 2022. OBJECTIVE: To understand SARS-CoV-2 transmission in early care and education (ECE) settings, we implemented a Test to Stay (TTS) strategy, which allowed children and staff who were close contacts to COVID-19 to remain in person if they agreed to test twice after exposure. We describe SARS-CoV-2 transmission, testing preferences, and the number of in-person days saved among participating ECE facilities. METHODS: From March 21 through May 27, 2022, 32 ECE facilities in Illinois implemented TTS. Unvaccinated children and staff who were not up to date with COVID-19 vaccination could participate if exposed to COVID-19. Participants received 2 tests within 7â€‰days after exposure and were given the option to test at home or at the ECE facility. RESULTS: During the study period, 331 TTS participants were exposed to index cases (defined as people attending the ECE facility with a positive SARS-CoV-2 test result during the infectious period); 14 participants tested positive, resulting in a secondary attack rate of 4.2%. No tertiary cases (defined as a person with a positive SARS-CoV-2 test result within 10â€‰days after exposure to a secondary case) occurred in the ECE facilities. Most participants (366 of 383; 95.6%) chose to test at home. Remaining in-person after an exposure to COVID-19 saved approximately 1915 in-person days among children and staff and approximately 1870 parent workdays. CONCLUSION: SARS-CoV-2 transmission rates were low in ECE facilities during the study period. Serial testing after COVID-19 exposure among

children and staff at ECE facilities is a valuable strategy to allow children to remain in person and parents to avoid missing workdays.

Humoral and Cellular Response and Associated Variables Nine Months following BNT162b2 Vaccination in Healthcare Workers. In this study, we aimed to illustrate the trajectory of humoral and cellular immunity nine months after primary vaccination with the BNT162b2 mRNA vaccine among 189 healthcare workers (HCWs). Additionally, we endeavored to identify correlations between immunity parameters and a number of common variables and comorbidities. A total of 189 healthcare workers (HCWs), vaccinated against COVID-19, were finally included in the study. All of the subjects had received two doses of the BNT162b2 vaccine; had undergone antibody tests one, four and nine months post-vaccination; and had completed a medical questionnaire. Further samples taken at nine months were tested for cellular immunity. No participants had evidence of COVID-19 infection pre- or post-vaccination. An anti-S1 receptor binding domain (RBD) antibody assay was used to assess humoral response, and cellular immunity was estimated with an INF-Î³ release assay (IGRA). Statistical analysis was performed using STATA. We report a statistically significant antibody drop over time. Being above the age of 40 or a smoker reduces the rise of antibodies by 37% and 28%, respectively. More than half of the participants did not demonstrate T-cell activation at nine months. Female gender and antibody levels at four months predispose detection of cellular immunity at nine months post-immunization. This study furthers the qualitative, quantitative, and temporal understanding of the immune response to the BNT162b2 mRNA vaccine and the effect of correlated factors.

Immune Response following BNT162b2 mRNA COVID-19 Vaccination in Pediatric Cancer Patients. COVID-19 vaccinations are recommended for children with cancer but data on their vaccination response is scarce. This study assesses the antibody and T-cell response following a 2- or 3-dose vaccination with BNT162b2 mRNA COVID-19 vaccine in children (5-17 years) with cancer. For the antibody response, participants with a serum concentration of anti-SARS-CoV-2 spike 1 antibodies of >300 binding antibody units per milliliter were classified as good responders. For the T-cell response, categorization was based on spike S1 specific interferon-gamma release with good responders having >200 milli-international units per milliliter. The patients were categorized as being treated with chemo/immunotherapy for less than 6 weeks (Tx < 6 weeks) or more than 6 weeks (Tx > 6 weeks) before the first immunization event. In 46 patients given a 2-dose vaccination series, the percentage of good antibody and good T-cell responders was 39.3% and 73.7% in patients with Tx < 6 weeks and 94.4% and 100% in patients with Tx > 6 weeks, respectively. An additional 3rd vaccination in 16 patients with Tx < 6 weeks, increased the percentage of good antibody responders to 70% with no change in T-cell response. A 3-dose vaccination series effectively boosted antibody levels and is of value for patients undergoing active cancer treatment.

Continuous positive airway pressure in COVID-19-associated respiratory failure: improving patient care with a proforma. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the disease it causes (COVID-19) has proven to be the greatest challenge to modern global health care, infecting more than 450 million people worldwide and responsible for just over 6 million deaths. Over the past 2 years there have been major advances in the treatment of COVID-19, including a significant reduction in the number of individuals developing severe symptoms, since the introduction of COVID-19 vaccines and the advances in pharmacological treatments. However, for those individuals who become infected with COVID-19 and develop acute respiratory failure, the use of continuous positive airway pressure (CPAP) continues to be an essential management strategy that reduces mortality risk and the need for invasive mechanical ventilation. Without any standard regional or national guidelines on CPAP initiation and up-titration during the pandemic, a protocol proforma was devised for use in the author's clinical area. This was particularly useful for staff caring for seriously ill COVID-

19 patients who were unfamiliar with providing CPAP. It is hoped that this article will contribute to the knowledge base of nurses and may encourage them to create a similar proforma for use in their clinical area.

Hemostatic Profile and Serological Response of Patients with Immune Thrombotic Thrombocytopenic Purpura after Receiving BNT162b2 Vaccine: A Prospective Study. INTRODUCTION: â€ƒCoronavirus disease is a clinical challenge for patients with autoimmune conditions. Patients affected by immune thrombotic thrombocytopenic purpura (iTTP) are particularly vulnerable to SARS-CoV-2 infection. Protecting these patients with vaccination is therefore mandatory, although concerns may exist on a possible increased thrombotic risk or risk of disease relapse after vaccine exposure. So far, there is no information on serological response and hemostatic activation in iTTP patients after SARS-CoV-2 vaccination. MATERIALS AND METHODS: â€ƒIn this study, in April 2021, we enrolled iTTP patients in clinical remission and on regular outpatient follow-up to receive the first and second dose BNT162b2 vaccine as a part of a prospective trial aimed at monitoring for 6 months after vaccination the occurrence of subclinical laboratory signs of clotting activation, as well as overt thrombotic complications or disease relapse. The seroconversion response was monitored in parallel. The results were compared with those of control non-iTTP subjects. RESULTS: â€ƒA moderate decrease of ADAMTS-13 activity was recorded at 3 and 6 months in five patients with normal values at baseline, while an ADAMTS-13 relapse occurred at 6 months in one patient. Abnormalities in the endothelium activation biomarkers postvaccination were observed in iTTP patients compared with controls. The immunological response to vaccine was overall positive. No clinical iTTP relapses or thrombotic events manifested in the 6 month-follow-up after vaccination. CONCLUSION: â€ƒThe results of this study are in favor of efficacy and safety of mRNA vaccines in patients with iTTP, and highlight the importance of long-term monitoring of iTTP patients.

Cardiac Magnetic Resonance Findings of Coronavirus Disease 2019 (COVID-19) Vaccine-Associated Myopericarditis at Intermediate Follow-Up: A Comparison with Classic Myocarditis. OBJECTIVE: To report intermediate cardiac magnetic resonance (CMR) findings of coronavirus disease 2019 (COVID-19) vaccine-associated myopericarditis (C-VAM) and compare with classic myocarditis. STUDY DESIGN: Retrospective cohort study including children diagnosed with C-VAM from May 2021 through December 2021 with early and intermediate CMR. Patients with classic myocarditis from January 2015 through December 2021 and intermediate CMR were included for comparison. RESULTS: There were 8 patients with C-VAM and 20 with classic myocarditis. Among those with C-VAM, CMR performed at a median 3Â days (IQR 3, 7) revealed 2 of 8 patients with left ventricular ejection fraction <55%, 7 of 7 patients receiving contrast with late gadolinium enhancement (LGE), and 5 of 8 patients with elevated native T1 values. Borderline T2 values suggestive of myocardial edema were present in 6 of 8 patients. Follow-up CMRs performed at a median 107Â days (IQR 97, 177) showed normal ventricular systolic function, T1, and T2 values; 3 of 7 patients had LGE. At intermediate follow-up, patients with C-VAM had fewer myocardial segments with LGE than patients with classic myocarditis (4/119 vs 42/340, PÂ =Â .004). Patients with C-VAM also had a lower frequency of LGE (42.9 vs 75.0%) and lower percentage of left ventricular ejection fraction <55% compared with classic myocarditis (0.0 vs 30.0%), although these differences were not statistically significant. Five patients with classic myocarditis did not receive an early CMR, leading to some selection bias in study design. CONCLUSIONS: Patients with C-VAM had no evidence of active inflammation or ventricular dysfunction on intermediate CMR, although a minority had persistent LGE. Intermediate findings in C-VAM revealed less LGE burden compared with classic myocarditis.

A case of erythema elevatum diutinum after COVID-19 vaccination.

Optimization of Vaccine Responses in Solid Organ Transplant Recipients.

Humoral Response After Five Successive Doses of SARS-CoV-2 mRNA Vaccine in Kidney Transplant Patients.

Accelerated waning of the humoral response to COVID-19 vaccines in obesity. Obesity is associated with an increased risk of severe Coronavirus Disease 2019 (COVID-19) infection and mortality. COVID-19 vaccines reduce the risk of serious COVID-19 outcomes; however, their effectiveness in people with obesity is incompletely understood. We studied the relationship among body mass index (BMI), hospitalization and mortality due to COVID-19 among 3.6 million people in Scotland using the Early Pandemic Evaluation and Enhanced Surveillance of COVID-19 (EAVE II) surveillance platform. We found that vaccinated individuals with severe obesity (BMIâ€‰>â€‰40â€‰kg/m(2)) were 76% more likely to experience hospitalization or death from COVID-19 (adjusted rate ratio of 1.76 (95% confidence interval (CI), 1.60-1.94). We also conducted a prospective longitudinal study of a cohort of 28 individuals with severe obesity compared to 41 control individuals with normal BMI (BMI 18.5-24.9â€‰kg/m(2)). We found that 55% of individuals with severe obesity had unquantifiable titers of neutralizing antibody against authentic severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus compared to 12% of individuals with normal BMI (Pâ€‰=â€‰0.0003) 6â€‰months after their second vaccine dose. Furthermore, we observed that, for individuals with severe obesity, at any given anti-spike and anti-receptor-binding domain (RBD) antibody level, neutralizing capacity was lower than that of individuals with a normal BMI. Neutralizing capacity was restored by a third dose of vaccine but again declined more rapidly in people with severe obesity. We demonstrate that waning of COVID-19 vaccine-induced humoral immunity is accelerated in individuals with severe obesity. As obesity is associated with increased hospitalization and mortality from breakthrough infections, our findings have implications for vaccine prioritization policies.

COVID-19 Vaccination Safety Profiles in Patients with Solid Tumour Cancers: Comment.

Spontaneous Avascular Necrosis of the Humeral Head Following COVID-19 Vaccination. We report a case of a 40-year-old man who presented with left shoulder pain and marked functional impairment two days after receiving the second dose of the Pfizer COVID-19 vaccine. Advanced imaging demonstrated focal avascular necrosis (AVN) of his humeral head. Initial management included simple analgesics, activity modification, and an ultrasound-guided intra-articular hydrodilatation injection. The patient subsequently had an improved range of motion but persistent severe shoulder pain. He has now been offered surgical intervention. Despite having risk factors for developing AVN previously, the patient did not demonstrate any recent risk factors for developing the disease. COVID-19 vaccination is known to cause severe joint pain and stiffness rarely. However, avascular necrosis is not a known or documented side effect. His symptoms arose directly after the administration of the vaccine, with no other demonstrable cause. Therefore, we are reporting COVID-19 vaccination as a potential new risk factor for AVN of the humeral head.

HLA-DP diversity is associated with improved response to SARS-Cov-2 vaccine in hematopoietic stem cell transplant recipients. Allogeneic hematopoietic stem cell transplantation (allo-HSCT) recipients show lower humoral vaccine responsiveness than immunocompetent individuals. HLA diversity, measured by the HLA evolutionary divergence (HED) metrics, reflects the diversity of the antigenic repertoire presented to TÂ cells, and has been shown to predict response to cancer immunotherapy. We retrospectively investigated the association of HED with humoral response to SARS-CoV-2 vaccine in allo-HSCT recipients. HED was calculated as pairwise genetic distance between alleles at HLA-A, -B, -C, -DRB1, -DQB1, and -DPB1 loci in recipients and their donors. Low anti-spike IgG levels (<30 BAU/mL) were associated with short time from allo-SCT and low donor DPB1-HED, mostly related to donor DPB1 homozygosity. The diversity of donor HLA-DP molecules, assessed by

heterozygosity or sequence divergence, may thus impact the efficacy of donor-derived CD4 TÂ cells to sustain vaccine-mediated antibody response in allo-HSCT recipients.

Potential Adverse Effects of COVID-19 Vaccines on Iranian Healthcare Workers: Comparison of Four Available Vaccines in Tehran: A Retrospective Cross-sectional Study. OBJECTIVES: This study aimed to compare four COVID-19 vaccines for their potential extensive side effects and the relationship between the side effects and age, body mass index (BMI), and history of COVID-19 infection. METHODS: This cross-sectional study was conducted from June to August 2021 among 1474 healthcare workers of seven selected hospitals in Tehran, Iran. All the subjects were vaccinated (91.7% received two doses and 8.3% received one dose) with one of four vaccines, Sputnik, Covaxin, AstraZeneca, and Sinopharm, at least 10 days before the study. The incidence of 47 side effects was measured after vaccination. RESULTS: Over half of the participants (59.4%; n = 876) were 20-29 years of age, with the mean and average BMI being 26.1Â±9.0 and 23.5Â±3.4, respectively; 36.0% (n = 530) were previously diagnosed with COVID-19. There was no significant relationship between age and the incidence of side effects for AstraZeneca, Sputnik, and Covaxin; however, the occurrence of side effects of Sinopharm was significantly higher ($p < 0.001$) among younger healthcare workers. There was no significant relationship between BMI and the incidence of side effects for all four vaccines. However, in the group with a history of COVID-19 disease, health care workers vaccinated with the Sinopharm vaccine showed significantly ($p < 0.001$) more complications. The occurrence rate of at least one adverse effect and referral to medical centers for AstraZeneca, Sputnik, Covaxin, and Sinopharm vaccines were 24.9-93.9%, 18.2-86.0%, 14.8-77.0%, and 3.5-37.2%, respectively. The highest and lowest rates were found for AstraZeneca and Sinopharm showing a significant ($p < 0.001$) difference. The most commonly observed side effects for the AstraZeneca vaccine included fever (64.4%), fatigue (62.5%), and muscle pain (59.9%); for Sputnik muscle pain (59.8%), fever (49.5%), and fatigue (49.5%); for Covaxin fever (49.2%), topical reaction (41.0), and fatigue (34.4%); and for Sinopharm fever (18.7%), topical reaction (17.9%), and fatigue (16.6%). Inactivated virus vaccines (Sinopharm and Covaxin) showed a lower (39.7%) occurrence rate of side effects compared to viral vector vaccines (AstraZeneca and Sputnik; 90.6%). The most likely time for the vaccines to exert side effects was the first 24 hours after vaccination. CONCLUSIONS: We found no significant relationship between age, BMI, history of COVID-19 disease, and the incidence of side effects in healthcare workers vaccinated with any of the four vaccines. All four vaccines are safe and have controlled side effects.

Medically Attended Acute Adverse Events in Pregnant People After Coronavirus Disease 2019 (COVID-19) Booster Vaccination. In this multisite, observational, matched cohort study of more than 80,000 pregnant people, receipt of an mRNA monovalent coronavirus disease 2019 (COVID-19) booster vaccination in pregnancy was not associated with increased risk for thrombocytopenia, myocarditis, venous thromboembolism, ischemic stroke, or other serious adverse events within 21 or 42 days after booster vaccination. The mRNA monovalent COVID-19 booster in pregnancy was associated with an increased risk for medically attended malaise or fatigue within 7 days of vaccination (adjusted rate ratio [aRR] 3.64, 95% CI 2.42-5.48) and lymphadenopathy or lymphadenitis within 21 days (aRR 3.25, 95% CI 1.67-6.30) or 42 days (aRR 2.18, 95% CI 1.33-3.58) of vaccination. Our findings are consistent with prior evaluations of the primary COVID-19 vaccine series and are reassuring with respect to COVID-19 booster vaccination in pregnancy.

Transient Bell's palsy following Covid-19 vaccination. Bell's palsy is described as an acute, unilateral mononeuropathy of the facial nerve resulting in partial or complete paralysis of the face with no identifiable cause. Although facial palsy is often idiopathic, its development soon after the BB-152 Covid vaccine is exceedingly rare. We report a patient with transient acute-onset unilateral infranuclear facial palsy following vaccination, after an exhaustive work-up for other common causes

was negative. With no detectable aetiology the likelihood of an association of the Covid-19 vaccine and Bell's palsy remains.

COVID-19, Myocarditis and Pericarditis. Viral infections are a leading cause of myocarditis and pericarditis worldwide, conditions that frequently coexist. Myocarditis and pericarditis were some of the early comorbidities associated with SARS-CoV-2 infection and COVID-19. Many epidemiologic studies have been conducted since that time concluding that SARS-CoV-2 increased the incidence of myocarditis/pericarditis at least 15Ã— over pre-COVID levels although the condition remains rare. The incidence of myocarditis pre-COVID was reported at 1 to 10 cases/100 000 individuals and with COVID ranging from 150 to 4000 cases/100 000 individuals. Before COVID-19, some vaccines were reported to cause myocarditis and pericarditis in rare cases, but the use of novel mRNA platforms led to a higher number of reported cases than with previous platforms providing new insight into potential pathogenic mechanisms. The incidence of COVID-19 vaccine-associated myocarditis/pericarditis covers a large range depending on the vaccine platform, age, and sex examined. Importantly, the findings highlight that myocarditis occurs predominantly in male patients aged 12 to 40 years regardless of whether the cause was due to a virus-like SARS-CoV-2 or associated with a vaccine-a demographic that has been reported before COVID-19. This review discusses findings from COVID-19 and COVID-19 vaccine-associated myocarditis and pericarditis considering the known symptoms, diagnosis, management, treatment, and pathogenesis of disease that has been gleaned from clinical research and animal models. Sex differences in the immune response to COVID-19 are discussed, and theories for how mRNA vaccines could lead to myocarditis/pericarditis are proposed. Additionally, gaps in our understanding that need further research are raised.

Vaccination-Associated Myocarditis and Myocardial Injury. SARS-CoV-2 vaccine-associated myocarditis/myocardial injury should be evaluated in the contexts of COVID-19 infection, other types of viral myocarditis, and other vaccine-associated cardiac disorders. COVID-19 vaccine-associated myocardial injury can be caused by an inflammatory immune cell infiltrate, but other etiologies such as microvascular thrombosis are also possible. The clinical diagnosis is typically based on symptoms and cardiac magnetic resonance imaging. Endomyocardial biopsy is confirmatory for myocarditis, but may not show an inflammatory infiltrate because of rapid resolution or a non-inflammatory etiology. Myocarditis associated with SARS-COVID-19 vaccines occurs primarily with mRNA platform vaccines, which are also the most effective. In persons aged >16 or >12 years the myocarditis estimated crude incidences after the first 2 doses of BNT162b2 and mRNA-1273 are approximately 1.9 and 3.5 per 100 000 individuals, respectively. These rates equate to excess incidences above control populations of approximately 1.2 (BNT162b2) and 1.9 (mRNA-1273) per 100 000 persons, which are lower than the myocarditis rate for smallpox but higher than that for influenza vaccines. In the studies that have included mRNA vaccine and SARS-COVID-19 myocarditis measured by the same methodology, the incidence rate was increased by 3.5-fold over control in COVID-19 compared with 1.5-fold for BNT162b2 and 6.2-fold for mRNA-1273. However, mortality and major morbidity are less and recovery is faster with mRNA vaccine-associated myocarditis compared to COVID-19 infection. The reasons for this include vaccine-associated myocarditis having a higher incidence in young adults and adolescents, typically no involvement of other organs in vaccine-associated myocarditis, and based on comparisons to non-COVID viral myocarditis an inherently more benign clinical course.

COVID-19 Surveillance After Expiration of the Public Health Emergency Declaration - United States, May 11, 2023. On January 31, 2020, the U.S. Department of Health and Human Services (HHS) declared, under Section 319 of the Public Health Service Act, a U.S. public health emergency because of the emergence of a novel virus, SARS-CoV-2.* After 13 renewals, the public health emergency will expire on May 11, 2023. Authorizations to collect certain public health data will expire on that date as well. Monitoring the impact of COVID-19 and the effectiveness of prevention and control strategies

remains a public health priority, and a number of surveillance indicators have been identified to facilitate ongoing monitoring. After expiration of the public health emergency, COVID-19-associated hospital admission levels will be the primary indicator of COVID-19 trends to help guide community and personal decisions related to risk and prevention behaviors; the percentage of COVID-19-associated deaths among all reported deaths, based on provisional death certificate data, will be the primary indicator used to monitor COVID-19 mortality. Emergency department (ED) visits with a COVID-19 diagnosis and the percentage of positive SARS-CoV-2 test results, derived from an established sentinel network, will help detect early changes in trends. National genomic surveillance will continue to be used to estimate SARS-CoV-2 variant proportions; wastewater surveillance and traveler-based genomic surveillance will also continue to be used to monitor SARS-CoV-2 variants. Disease severity and hospitalization-related outcomes are monitored via sentinel surveillance and large health care databases. Monitoring of COVID-19 vaccination coverage, vaccine effectiveness (VE), and vaccine safety will also continue. Integrated strategies for surveillance of COVID-19 and other respiratory viruses can further guide prevention efforts. COVID-19-associated hospitalizations and deaths are largely preventable through receipt of updated vaccines and timely administration of therapeutics (1-4).

COVID-19 and Anti-COVID-19 Vaccination: Potential Damages to the Thyroid Gland.

Case report: Granulomatosis with polyangiitis (GPA) and facial paralysis after COVID-19 vaccination.

Identifying gaps in vaccination perception after mandating the COVID-19 vaccine in Saudi Arabia. OBJECTIVE: The burden of COVID-19 pandemic affected the globe, and it is unclear how it has impacted the general perception of other vaccines. We aimed to investigate the public awareness, knowledge, and attitude towards other complementary vaccines after the mandate of the COVID-19 vaccine. METHODS: A cross-sectional study was conducted in Saudi Arabia using a survey distributed via several social media platforms in June 2022. The questionnaire had three main sections; awareness; attitudes; and demographic information. Descriptive analysis was mainly used and supplemented with Chi-square test for correlation. All individuals over the age of 18 were eligible to participate in the study. RESULTS: A total of 1,045 participants from Saudi Arabia completed the survey. Of the respondents, 55.9% were female, and 95% were Saudi citizens. Public awareness towards vaccines after the mandate of COVID-19 vaccine was the highest with the influenza vaccine (98.2%), followed by human papillomavirus (HPV) (40.7%), tetanus, diphtheria, and pertussis (Tdap) (37.2%), and lastly, pneumococcal vaccine (17%). More than 50% of the participants expressed their willingness to receive any of the four vaccines if they knew about the benefits related to these vaccines. CONCLUSION: The study showed that participants were willing to receive the vaccination if they were aware of the general benefits of vaccinations. Therefore, health education and campaigns toward recommended vaccines for high-risk group are essential and needed.

Maternal and Cord Anti-SARS-CoV-2-Spike IgG following COVID-19 Vaccination versus Infection during Pregnancy: A Prospective Study, Israel October 2021-March 2022. OBJECTIVE: â€ƒDefining how pregnant women respond to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and vaccination is critical to optimize vaccination strategies that protect mother and infant at the epidemic. This study aimed to compare anti-SARS-CoV-2-spike immunoglobulin G (IgG) of vaccinated versus infected women and to determine the optimal timing of maternal vaccination during pregnancy at the time of epidemic. STUDY DESIGN: â€ƒWe collected maternal/cord blood at delivery (October 2021-March 2022) and measured anti-SARS-CoV-2-spike IgG geometric mean concentrations (IgG-GMCs) using a quantitative immunoassay. We compared groups according to timing and number of doses and correlated maternal and fetal IgG levels. We described the proportion of women with IgG levels above the 150 AU/mL positivity threshold according to the timing of infection/vaccination and performed a subanalysis for maternal IgG-GMC levels pre- and

during the Omicron wave. RESULTS: â€ƒWe included 238 vaccinated women, 125 who received two doses and 113 three doses, and 48 unvaccinated infected women. All groups infected/vaccinated in the second or third trimester had an IgG-GMC above the positivity threshold. Third-trimester vaccination (second/third dose) resulted in higher maternal and cord-blood IgG-GMC compared to the second trimester (maternal-IgG: 102,32 vs. 4,325 AU/mL, pâ€‰<â€‰0.001; cord-IgG: 12,113 vs. 8,112 AU/mL, pâ€‰<â€‰0.001). Compared with infected-only women, a higher proportion of vaccinated women with â‰¥2 doses and their newborns had IgG levels above the positivity threshold at all time points. In vaccinated women, there were higher maternal IgG-GMC levels during the Omicron wave than pre-Omicron. CONCLUSION: â€ƒAt the time of epidemic, receiving an additional COVID-19 vaccine dose in the third trimester resulted in a higher IgG-GMC compared to the second trimester. Relatively higher levels of maternal and cord IgG-GMC were achieved following vaccination than infection. Women infected during or before the first trimester might benefit from an additional third-trimester dose to prevent peripartum infection and to passively immunize their newborn. The higher levels of maternal IgG-GMC in the Omicron period are suggestive of hybrid immunity. KEY POINTS: Â· Higher maternal anti-SARS-IgGs in vaccinated â†’ infected.. Â· Higher cord anti-SARS-IgGs in vaccinated â†’ infected.. Â· Third-trimester vaccine resulted in high-cord IgG levels..

Commentary on "Characterization of otologic symptoms appearing after COVID-19 vaccination".

Protocol of a scoping review of systematic reviews and meta-analyses about COVID-19 vaccines and associated adverse events from vaccination. The continuous dissemination of coronavirus disease of 2019 (COVID-19) literature can inform decision-makers and the public. Since the widespread use of COVID-19 vaccines, more systematic reviews have summarized the effectiveness and reported adverse events associated with vaccination. Previous systematic and scoping reviews on COVID-19 summarized various aspects surrounding COVID-19, however, a scoping review is needed to summarize the characteristics of COVID-19 vaccines and associated adverse events reported in systematic reviews and meta-analyses to provide comprehensive evidence for informed medical decision-making. We will conduct a scoping review concerning COVID-19 vaccines and adverse events from vaccines. We will search from December 2019 to present in Epistemonikos, Campbell Library, CINAHL (Ovid), MEDLINE (Ovid), Scopus, CENTRAL (Ovid), Web of Science, WHO COVID-19 database, Joanna Briggs Institute of Excellence, and COVID-19 Evidence Reviews resource. We will include systematic reviews, meta-analyses, or both of randomized controlled trials and observational studies and exclude individual randomized controlled trials and observational studies. Abstracts and full-texts will be screened prior to selection. Investigators will independently use a calibrated quantitative and qualitative data extraction sheet and rate the quality of articles with AMSTAR, resolving disagreements to aim for good agreement (â‰¥80%). An updated scoping review of the characteristics and safety of COVID-19 vaccines would highlight the accuracy of the evidence to inform decision-making concerning COVID-19 vaccination.

Recent Human Papillomavirus Vaccination is Associated with a Lower Risk of COVID-19: A US Database Cohort Study. OBJECTIVE: To explore the association between human papillomavirus (HPV)Â vaccination and risk of coronavirus disease 2019 (COVID-19). Specifically, our study aimed to test the hypothesis that HPV vaccination may also induce trained immunity, which would potentially reduce the risk of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and improve clinical outcomes. BACKGROUND: Several vaccines have been reported to trigger non-specific immune reactions that could offer protection from heterologous infections. A recent case report showed that verruca vulgaris regressed after COVID-19, suggesting a possible negative association between COVID-19 and HPV infection. METHODS: We enrolled 57,584 women with HPV vaccination and compared them with propensity score-matched controls who never received HPV vaccination in relation to the risk of COVID-19 incidence. Cox proportional hazard regression analysis

was conducted to estimate hazard ratios (HRs) and 95% confidence intervals (CIs). Subgroup analyses stratified by age, race, comorbid asthma, and obesity were performed. RESULTS: The risk of COVID-19 incidence was significantly lower in those who had recently received the HPV vaccine (within 1 year after HPV vaccination, aHR: 0.818, 95% CI 0.764-0.876; within 1-2 years after HPV vaccination, aHR: 0.890, 95% CI 0.824-0.961). Several limitations were recognized in this study, including residual confounding, problems of misclassification due to the use of electronic health record data, and that we were unable to keep track of the patients' HPV infection status and the HPV antibody levels in those who had received the vaccine. CONCLUSIONS: Recent HPV vaccination was associated with a lower risk of incident COVID-19 and hospitalization. Based on the promising protective effect of HPV vaccine shown in this study, these findings should be replicated in an independent dataset. Further studies are needed to provide a better understanding of the underlying mechanisms and the differences in risks among 2-, 4-, or 9-valent HPV vaccine recipients.

Molnupiravir and risk of post-acute sequelae of covid-19: cohort study. OBJECTIVE: To examine whether treatment with the antiviral agent molnupiravir during the first five days of SARS-CoV-2 infection is associated with reduced risk of post-acute adverse health outcomes. DESIGN: Cohort study. SETTING: US Department of Veterans Affairs. PARTICIPANTS: 229â€‰286 participants who tested positive for SARS-CoV-2 between 5 January 2022 and 15 January 2023, had at least one risk factor for progression to severe covid-19, and survived the first 30 days after testing positive were enrolled. 11â€‰472 participants received a prescription for molnupiravir within five days of the positive test result and 217â€‰814 received no covid-19 antiviral or antibody treatment (no treatment group). MAIN OUTCOME MEASURES: Risks of post-acute sequelae of SARS-CoV-2 (PASC, defined based on a prespecified set of 13 post-acute sequelae), post-acute death, post-acute hospital admission, and each individual post-acute sequela between the molnupiravir group and no treatment group were examined after application of inverse probability weighting to balance the treatment and no treatment groups. Post-acute outcomes were ascertained from 30 days after the first SARS-CoV-2 positive test result until end of follow-up. Risks on the relative scale (relative risk or hazard ratio) and absolute scale (absolute risk reduction at 180 days) were estimated. RESULTS: Compared with no treatment, molnupiravir use within five days of a positive SARS-CoV-2 test result was associated with reduced risk of PASC (relative risk 0.86 (95% confidence interval 0.83 to 0.89); absolute risk reduction at 180 days 2.97% (95% confidence interval 2.31% to 3.60%)), post-acute death (hazard ratio 0.62 (0.52 to 0.74); 0.87% (0.62% to 1.13%)), and post-acute hospital admission (0.86 (0.80 to 0.93); 1.32% (0.72% to 1.92%)). Molnupiravir was associated with reduced risk of eight of the 13 post-acute sequelae: dysrhythmia, pulmonary embolism, deep vein thrombosis, fatigue and malaise, liver disease, acute kidney injury, muscle pain, and neurocognitive impairment. Molnupiravir was also associated with reduced risk of PASC in people who had not received a covid-19 vaccine, had received at one or two vaccine doses, and had received a booster dose, and in people with primary SARS-CoV-2 infection and reinfection. CONCLUSIONS: In people with SARS-CoV-2 infection and at least one risk factor for progression to severe covid-19, compared with no treatment, molnupiravir use within five days of infection was associated with reduced risk of PASC in people who had not received a covid-19 vaccine, had received one or two vaccine doses, and had received a booster dose, and in those with primary SARS-CoV-2 infection and reinfection. Among people at high risk of progression to severe covid-19, molnupiravir use within five days of SARS-CoV-2 infection may be a viable approach to reduce the risk of PASC.

Mucosal immunization with lactiplantibacillus plantarum-displaying recombinant SARS-CoV-2 epitopes on the surface induces humoral and mucosal immune responses in mice. BACKGROUND: The use of probiotic lactic acid bacteria as a mucosal vaccine vector is considered a promising alternative compared to the use of other microorganisms because of its "Generally

Regarded as Safe" status, its potential adjuvant properties, and its tolerogenicity to the host. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes coronavirus disease (COVID-19), is highly transmissible and pathogenic. This study aimed to determine the potential of Lactiplantibacillus plantarum expressing SARS-CoV-2 epitopes as a mucosal vaccine against SARS-CoV-2. RESULTS: In this study, the possible antigenic determinants of the spike (S1-1, S1-2, S1-3, and S1-4), membrane (ME1 and ME2), and envelope (E) proteins of SARS-CoV-2 were predicted, and recombinant L. plantarum strains surface-displaying these epitopes were constructed. Subsequently, the immune responses induced by these recombinant strains were compared in vitro and in vivo. Most surface-displayed epitopes induced pro-inflammatory cytokines [tumor necrosis factor alpha (TNF-Î± and interleukin (IL)-6] and anti-inflammatory cytokines (IL-10) in lipopolysaccharide-induced RAW 264.7, with the highest anti-inflammatory to pro-inflammatory cytokine ratio in the S1-1 and S1-2 groups, followed by that in the S1-3 group. When orally administered of recombinant L. plantarum expressing SARS-CoV-2 epitopes in mice, all epitopes most increased the expression of IL-4, along with induced levels of TNF-Î±, interferon-gamma, and IL-10, specifically in spike protein groups. Thus, the surface expression of epitopes from the spike S1 protein in L. plantarum showed potential immunoregulatory effects, suggesting its ability to potentially circumvent hyperinflammatory states relevant to monocyte/macrophage cell activation. At 35 days post immunization (dpi), serum IgG levels showed a marked increase in the S1-1, S1-2, and S1-3 groups. Fecal IgA levels increased significantly from 21 dpi in all the antigen groups, but the boosting effect after 35 dpi was explicitly observed in the S1-1, S1-2, and S1-3 groups. Thus, the oral administration of SARS-CoV-2 antigens into mice induced significant humoral and mucosal immune responses. CONCLUSION: This study suggests that L. plantarum is a potential vector that can effectively deliver SARS-CoV-2 epitopes to intestinal mucosal sites and could serve as a novel approach for SARS-CoV-2 mucosal vaccine development.

Predictors of long-term neutralizing antibody titers following COVID-19 vaccination by three vaccine types: the BOOST study. As concerns related to the COVID-19 pandemic continue, it is critical to understand the impact of vaccination type on neutralizing antibody response durability as well as to identify individual difference factors related to decline in neutralization. This was a head-to-head comparison study following 498 healthy, community volunteers who received the BNT162b2 (nâ€‰=â€‰287), mRNA-1273 (nâ€‰=â€‰149), and Ad26.COV2.S (nâ€‰=â€‰62). Participants completed questionnaires and underwent blood draws prior to vaccination, 1Â month, and 6Â months after the vaccination series, and neutralizing antibody (nAB) titers at 1- and 6-months post vaccination were quantified using a high-throughput pseudovirus assay. Over 6Â months of follow-up, nABs declined in recipients of BNT162b2 and mRNA-1273, while nABs in recipients of Ad26.COV2.S showed a significant increase. At the 6-month time point, nABs to Ad26.COV2.S were significantly higher than nABs to BNT162b2 and equivalent to mRNA-1273. Irrespective of follow-up timing, being older was associated with lower nAB for participants who received BNT162b2 and Ad26.COV2.S but not for those who received mRNA-1273. A higher baseline BMI was associated with a lower nAB for Ad26.COV2.S recipients but not for recipients of other vaccines. Women and non-smokers showed higher nAB compared to men and current smokers, respectively. The durability of neutralizing antibody responses differed by vaccine type and several sociodemographic factors that predicted response. These findings may inform booster recommendations in the future.

COVID-19 Vaccination Clinic for Individuals With Autism Spectrum Disorder and Related Disorders: Feasibility and Acceptability. INTRODUCTION: Autistic individuals often have comorbid medical conditions, which can increase the likelihood of being severely affected by COVID-19. The best prevention for this is vaccination. However, some autistic individuals engage in behaviors that might create a barrier to successful vaccination. AIMS: We describe the development and acceptability of a

clinic specializing in the administration of COVID-19 vaccines for individuals diagnosed with autism spectrum disorder (ASD) who exhibit challenging behavior. METHOD: The clinic utilized behavioral antecedent strategies and contingencies to increase compliance with the vaccine and decrease distress associated with the procedure. RESULTS: We achieved a 100% success rate with vaccine administration and caregivers reported high satisfaction with the clinic. CONCLUSIONS: The present vaccine clinic is adaptable to various settings and patients and was well-received overall by caregivers. Replication in different geographic regions may be beneficial when resources allow for this type of clinic.

Association of Virus Variation and Vaccination Status With Post-Acute Sequelae After Severe Acute Respiratory Syndrome Coronavirus 2 Infection.

An observational study on the safety of COVID-19 vaccination in patients with myasthenia gravis. OBJECTIVE: There is concern that the coronavirus disease (COVID-19) vaccine may trigger or worsen autoimmune diseases. The objective of this study was to determine the impacts of COVID-19 vaccination on symptom severity in patients with myasthenia gravis (MG). METHODS: A total of 106 enrolled patients with MG who were vaccinated against COVID-19 were followed up, and a questionnaire was used to document in detail the exacerbation of muscle weakness after vaccination and all other uncomfortable reactions after vaccination. Demographic, clinical characteristics, medication, and vaccination data were collected by follow-up interview. The main observation outcome was whether the MG symptoms of patients were exacerbated. The definition of exacerbation is according to the subjective feeling of the patient or a 2-point increase in daily life myasthenia gravis activity score relative to before vaccination, within 30 days after vaccination. RESULTS: Of 106 enrolled patients [median age (SD) 41.0 years, 38 (35.8%) men, 53 (50.0%) with generalized MG, 74 (69.8%) positive for acetylcholine receptor antibody, and 21 (19.8%) with accompanying thymoma], muscle weakness symptoms were stable in 102 (96.2%) patients before vaccine inoculation. Muscle weakness worsened in 10 (9.4%) people after vaccination, of which 8 patients reported slight symptom worsening that resolved quickly (within a few days). Two (1.9%) of patients showed serious symptom aggravation that required hospitalization. CONCLUSION: Our results suggest that inactivated virus vaccines against COVID-19 may be safe for patients with MG whose condition is stable. Patients with generalized MG may be more likely to develop increased muscle weakness after vaccination.

Eight-Month Follow-up After the Third Dose of BNT162b2 Vaccine in Healthcare Workers: The Question of a Fourth Dose. BACKGROUND: A fourth dose of vaccination is known to help reduce the severity and mortality rate of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. The South Korean vaccination guidelines for the fourth dose do not include healthcare workers (HCWs) as priority candidates. We investigated the necessity of the fourth dose in South Korean HCWs based on an 8-month follow-up period after the third vaccination. METHODS: Changes in the surrogate virus neutralization test (sVNT) inhibition (%) score were measured at one month, four months and eight months after the third vaccination. The sVNT values were analyzed between infected and uninfected groups, and their trajectories were compared. RESULTS: A total of 43 HCWs were enrolled in this study. In total, 28 cases (65.1%) were confirmed to be infected with SARS-CoV-2 (presumed omicron variant), and all had mild symptoms. Meanwhile, 22 cases (78.6%) were infected within four months of the third dose (median, 97.5 days). Eight months after the third dose, the SARS-CoV-2 (presumed omicron variant)-infected group showed significantly higher sVNT inhibition than that in the uninfected group (91.3% vs. 30.7%; $P < 0.001$). The antibody response due to hybrid immunity, provided by a combination of infection and vaccination, was maintained at sufficient levels for more than four months. CONCLUSION: For HCWs who had coronavirus disease 2019 infection after completing a third vaccination, a sufficient antibody response was maintained until eight

months after the third dose. The recommendation of the fourth dose may not be prioritized in subjects with hybrid immunity.

COVID-19: The disease, the vaccine and the heart. Coronavirus SARS-CoV-2 has fundamentally affected the health, healthcare delivery and daily life in all populations and age groups in Australia. The aim of this report is to summarise how it has affected the paediatric population with an emphasis on, but not limited to, the cardiac manifestations. A literature review and appraisal of data relating to SARS-CoV-2 cardiac manifestations and vaccination in the paediatric population was undertaken.The majority of children with SARS-CoV-2 infection recover well. However, a very small proportion may develop severe acute disease. In the sub-acute phase, children may also develop a Kawasaki like illness, Paediatric Inflammatory Multisystem Syndrome temporally associated with SARS-CoV-2. Whilst not directly cardiac in nature, SARS-CoV-2 also affected children in other profound ways. Public health measures with widespread lockdowns appeared to disproportionately affect the paediatric population causing physical deconditioning and psychological harm. Vaccination against SARS-CoV-2 has proven to be safe and effective, but the small rate of complications did disproportionately affect teenage children with risks of myocarditis and pericarditis. The long term outcomes following myocarditis related to SARS-Cov-2 vaccination are yet to be clarified. When treating children in the era of SARS-CoV-2, Paediatricians need to be well aware of the risks of infection in the acute and sub-acute phases, have a good understanding of the well-established recommendations for vaccination, and also be cognisant of psychological impacts.

Comment on: Kikuchi-Fujimoto disease following SARS-CoV-2 vaccination in a patient with previous history of rhabdomyosarcoma.

Correction to: Macrotroponin Complex as a Cause for Cardiac Troponin Increase after COVID-19 Vaccination and Infection.

Hesitancy, reactogenicity and immunogenicity of the mRNA and whole-virus inactivated Covid-19 vaccines in pediatric neuromuscular diseases. The mRNA-based BNT162b2 and inactivated whole-virus CoronaVac are two widely used COVID-19 vaccines that confer immune protection to healthy individuals. However, hesitancy toward COVID-19 vaccination appeared to be common for patients with neuromuscular diseases (NMDs) due to the paucity of data on the safety and efficacy in this high-risk patient population. Therefore, we examined the underlying factors associated with vaccine hesitancy across time for NMDs and assessed the reactogenicity and immunogenicity of these two vaccines. Patients aged 8-18â€‰years with no cognitive delay were invited to complete surveys in January and April 2022. Patients aged 2-21â€‰years were enrolled for COVID-19 vaccination between June 2021 and April 2022, and they recorded adverse reactions (ARs) for 7â€‰days after vaccination. Peripheral blood was obtained before and within 49â€‰days after vaccination to measure serological antibody responses compared to healthy children and adolescents. Forty-one patients completed vaccine hesitancy surveys for both timepoints, while 22 joined the reactogenicity and immunogenicity arm of the study. Two or more family members vaccinated against COVID-19 was positively associated with intention of vaccination (odds ratio 11.7, 95% CI 1.81-75.1, pâ€‰=â€‰.010). Pain at the injection site, fatigue, and myalgia were the commonest ARs. Most ARs were mild (75.5%, nâ€‰=â€‰71/94). All 19 patients seroconverted against the wildtype SARS-CoV-2 after two doses of either vaccine, similar to 280 healthy counterparts. There was lower neutralization against the Omicron BA.1 variant. BNT162b2 and CoronaVac were safe and immunogenic for patients with NMDs, even in those on low-dose corticosteroids.

Safety of COVID-19 vaccines in subjects with solid tumor cancers receiving immune checkpoint inhibitors. The incidence of severe immune-related adverse events (irAEs) in cancer subjects receiving immune checkpoint inhibitors (ICIs) following COVID-19 vaccination and the relationship between the incidence of severe irAE and the interval between COVID-19 vaccination and ICI dose

have not been established. We performed a retrospective study evaluating the incidence of irAEs in solid tumor subjects receiving ICI therapy who received any COVID-19 vaccinations since FDA authorization. irAEs were defined as severe with one or more grade 3 or above events (CTCAE v5.0), multiple organ involvement, or requiring hospitalization for management. Two hundred and eighty-four subjects who received COVID vaccinations from December 2020 and February 2022 were included in this analysis [median age at vaccination 67 years (IQR 59.0-75.0); 67.3% male]. Twenty-nine subjects (10.2%) developed severe irAEs, of which 12 subjects (41.4%) received ICI monotherapy, 10 subjects (34.5%) received combination ICI therapy with nivolumab and ipilimumab, and 7 subjects (24.1%) received ICI plus VEGFR-TKI therapy. Hospitalization occurred in 62% of subjects with severe irAEs, with a median duration of 3 days (IQR: 3.0-7.5 days). Immunosuppressive therapy was required in 79.3%, with a median duration of 103 days (IQR: 42.0-179.0). ICI therapy was discontinued in 51.7% of subjects with severe irAE; dosing was held or interrupted in 34.5%. Among severe irAEs, the median interval between vaccination and ICI treatment closest to the occurrence of severe irAE was 15.5 days (IQR: 10.0-23.0). In solid tumor cancer subjects receiving ICIs, COVID-19 vaccination is not associated with an increased incidence of severe irAEs compared to historical data and may be safely administered during ICI cancer therapy in subjects who lack contraindications.

Reduced ability to neutralize the Omicron variant among adults after infection and complete vaccination with BNT162b2, ChAdOx1, or CoronaVac and heterologous boosting. COVID-19 vaccines have dramatically reduced rates of severe infection requiring hospitalization. However, SARS-CoV-2 variants have reduced vaccine effectiveness at preventing any symptomatic infection. This real-world study analyzed binding and neutralizing antibodies generated after complete vaccination and boosting across three vaccine platforms. Binding antibodies decayed most slowly in people under 60 with hybrid immunity. Neutralizing antibodies against Omicron BA.1 were reduced compared to other variants. The anamnestic anti-spike IgG response to the first boost was more pronounced than after the second boost. Monitoring of the effects of SARS-CoV-2 mutations on disease severity and the effectiveness of therapeutics is warranted.

Frosted branch angiitis after booster vaccination with BNT162b2.

Risk of Adverse Events and Delirium after COVID-19 Vaccination in Patients Living with Dementia. OBJECTIVES: The aim of this study was to compare incidences of adverse events of special interest (AESI) and delirium in 3 cohorts: after COVID-19 vaccination, prepandemic, and SARS-CoV-2 polymerase chain reaction (PCR) test positive. DESIGN: This is a population-based cohort study using electronic medical records linked with vaccination records in Hong Kong. SETTING AND PARTICIPANTS: A total of 17,449 older people with dementia received at least 1 dose of CoronaVac (nÂ = 14,719) or BNT162b2 (nÂ = 2730) between February 23, 2021, and March 31, 2022. Moreover, 43,396 prepandemic and 3592 SARS-CoV-2 test positive patients were also included in this study. METHODS: The incidences of AESI and delirium up to 28Â days after vaccination in the vaccinated dementia cohort were compared with the prepandemic and SARS-CoV-2 test positive dementia cohorts by calculating incidence rate ratios (IRRs). Patients who received multiple doses were followed up separately for each dose, up to the third dose. RESULTS: We did not detect an increased risk of delirium and most AESI following vaccination compared to the prepandemic period and those tested positive for SARS-CoV-2. No AESI group nor delirium incidence exceeded 10 per 1000 person-days in vaccinated individuals. CONCLUSIONS AND IMPLICATIONS: The findings provide evidence for the safe use of COVID-19 vaccines in older patients with dementia. In the short run, benefit appears to outweigh the harm due to vaccine; however, longer follow-up should be continued to identify remote adverse events.

Side Effects Comparison of Coronavirus Vaccines Among Healthcare Workers in Shoushtar, Iran. OBJECTIVE: Vaccination is one of the effective ways to fight against COVID-19 disease. Various

vaccines have been designed during the coronavirus pandemic. Each of the used vaccines has beneficial effects as well as side effects. Healthcare workers were among the first vaccinated persons against COVID-19 in different countries. The current study aims to compare the side effects of AstraZeneca, Sinopharm, Bharat, and Sputnik V on healthcare workers in Iran. METHODS: This descriptive study was conducted from July 2021 to January 2022 on 1639 healthcare workers who received the COVID-19 vaccines. Data were collected using a checklist that contained questions related to systemic, local, and severe side effects of the vaccine. The collected data were analyzed using the Kruskal-Wallis, Chi-square, and trend chi-square. Pâ€‰<â€‰.05 was regarded as a significant statistical difference. RESULTS: The most commonly injected vaccines were Sinopharm (41.80%), Sputnik V (36.65%), AstraZeneca (17.75%), and Bharat (3.80%), respectively. At least 37.5% of participants reported one complication. The most common side effects after 72â€‰hours of the first and second doses were as follows: injection site pain, fatigue, fever, myalgia, headache, and chill. Overall complication rates were reported as follows: AstraZeneca (91.4%), Sputnik V (65.9%), Sinopharm (56.8%), and Bharat (98.4%). Bharat showed the highest overall side effects, while Sinopharm had the lowest overall side effects. Also, our results indicated that individuals with a previous history of positive COVID-19 infection had a higher rate of overall complications. CONCLUSIONS: The majority of participants did not show life-threatening side effects after the injection of 1 of the 4 studied vaccines. Since it was well accepted and tolerable by the participants, it can be used widely and safely against SARS-CoV-2.
Comparison of antibody responses following natural infection with Severe Acute Respiratory Syndrome Coronavirus 2 or receipt of CoronaVac or ChAdOx1 (AZD1222) vaccination in Chiang Mai, Thailand. BACKGROUND: In Thailand, early vaccination initiatives for SARS-CoV-2 relied on CoronaVac (Sinovac Life Sciences) and ChAdOx1 (Oxford-AstraZeneca) vaccines. However, the data of immunogenicity of these two vaccines in Thai populations is limited. This real time, head-to-head comparative study was conducted to investigate antibody (Ab) responses to SARS-CoV-2 following infection or receipt of either CoronaVac or ChAdOx1 vaccination in Chiang Mai, Thailand. METHODS: Sera was collected within two months from participants having a history of documented SARS-CoV-2 infection or at one month after the second dose of CoronaVac vaccine. Sera from participants with a history of receiving one dose of ChAdOx1 vaccination was collected twice, at one month following each vaccine dose. Neutralizing antibodies (NAbs) were assessed using the surrogate neutralization test and anti-spike protein antibodies were assessed using an in-house enzyme-linked immunosorbent assay. RESULTS: The prevalence of NAbs against SARS-CoV-2 was 92.1 %, 95.7 %, 64.1 % and 100 % in the infection group, CoronaVac group, ChAdOx1 group after 1st dose, and ChAdOx1 group after 2nd dose, respectively. The inhibition rate in individuals receiving two doses of ChAdOx1 vaccine (90.8%) was significantly higher than individuals who had recovered from natural infection (71.7%) or individuals who had received two doses of CoronaVac vaccine (66.7%). The prevalence of anti-spike Abs was 97.4 %, 97.8 %, 97.4 % and 100 % in the infection group, CoronaVac group, ChAdOx1 group after 1st dose, and ChAdOx1 group after 2nd dose, respectively. Significantly higher levels of anti-spike Abs were observed in the ChAdOx1 group after two doses of vaccination (1975 AU/mL) compared to those who had recovered from natural infection (468.5 AU/mL) and individuals who had received CoronaVac (554.4 AU/mL). Neutralizing activity had a statistically significant positive correlation with levels of anti-spike Abs. CONCLUSIONS: ChAdOx1 vaccine may provide superior immunogenicity than CoronaVac and natural infection.
Cutaneous vasculitis after COVID-19 vaccination in a 41-year-old male. Leukocytoclastic vasculitis could be a possible adverse event of different SARS-CoV-2 vaccines. Clinicians and manufacturers should be aware of this adverse event for appropriate diagnosis and treatment.
Dosing recommendations for Novavax and Johnson & Johnson vaccine COVID-19 vaccines.

Vaccination recommendations for bivalent mRNA COVID-19 vaccines.
Comparing the Use of a Mobile App and a Web-Based Notification Platform for Surveillance of Adverse Events Following Influenza Immunization: Randomized Controlled Trial. BACKGROUND: Vaccine safety surveillance is a core component ofÂ vaccine pharmacovigilance. In Canada, active, participant-centered vaccine surveillance is available for influenza vaccines and has been used for COVID-19 vaccines. OBJECTIVE: The objective of this study is to evaluate the effectiveness and feasibility of using a mobile app for reporting participant-centered seasonal influenza adverse events following immunization (AEFIs) compared to a web-based notification system. METHODS: Participants were randomized to influenza vaccine safety reporting via a mobile app or a web-based notification platform. All participants were invited to complete a user experience survey. RESULTS: Among the 2408 randomized participants, 1319 (54%) completed their safety survey 1 week after vaccination, with a higher completion rate among the web-based notification platform users (767/1196, 64%) than among mobile app users (552/1212, 45%; P<.001). Ease-of-use ratings were high for the web-based notification platform users (99% strongly agree or agree) and 88.8% of them strongly agreed or agreed that the system made reporting AEFIs easier. Web-based notification platform users supported the statement that a web-based notification-only approach would make it easier for public health professionals to detect vaccine safety signals (91.4%, agreed or strongly agreed). CONCLUSIONS: Participants in this study were significantly more likely to respond to a web-based safety survey rather than within a mobile app. These results suggest that mobile apps present an additional barrier for use compared to the web-based notification-only approach. TRIAL REGISTRATION: ClinicalTrials.gov NCT05794113; https://clinicaltrials.gov/show/NCT05794113.
A case of persistent, confluent maculopapular erythema following a COVID-19 mRNA vaccination is possibly associated with the intralesional spike protein expressed by vascular endothelial cells and eccrine glands in the deep dermis. Here, we report an 86-year-old Japanese woman presenting with confluent maculopapular erythema, which developed following the second dose of COVID-19 Messenger RNA (mRNA) vaccine (BNT162b2). Her skin lesions spread over time and persisted for more than 3â€‰months. Surprisingly, immunohistochemical staining of the lesion 100â€‰days after the disease onset revealed the COVID-19 spike protein expressed by vascular endothelial cells and eccrine glands in the deep dermis. As she had no episode of COVID-19 infection, it is highly likely that the spike protein was derived from the mRNA vaccine and it might be the cause of the development and persistence of her skin lesions. Her symptoms were prolonged and intractable until oral prednisolone was given.
Myopericarditis following COVID-19 vaccination in adolescent triplets. Multiple studies have reported myocarditis and pericarditis after the Pfizer-BioNTech coronavirus disease 2019 messenger ribonucleic acid vaccine. We describe male adolescent triplets who presented with myopericarditis within one week following vaccine administration.
Idiopathic inflammatory myopathies linked to vaccination against SARS-CoV-2: a systematic review. The COVID-19 pandemic represents a global health problem, which has been mitigated by the opportune introduction of vaccination programs. Although we already know the benefit that vaccines provide, these are not exempt from adverse events which can be mild to deadly, such as idiopathic inflammatory myopathies, in which a temporal association has not been defined. It is for this reason that we carried out a systematic review of all reported cases of vaccination against COVID-19 and myositis. To identify previously reported cases of idiopathic inflammatory myopathies associated with vaccination against SARS-CoV-2 we registered this protocol on the website of PROSPERO with identification number CRD42022355551. Of the 63 publications identified in MEDLINE and 117 in Scopus, 21 studies were included, reporting 31 cases of patients with vaccination-associated myositis. Most of these cases were women (61.3%); mean age was 52.3 years (range 19-76 years) and mean

time of symptom onset post-vaccination was 6.8 days. More than half of the cases were associated with Comirnaty, 11 cases (35.5%) were classified as dermatomyositis, and 9 (29%) as amyopathic dermatomyositis. In 6 (19.3%) patients another probable trigger was identified. Case reports of inflammatory myopathies associated with vaccination have heterogeneous presentations without any specific characteristics: as a consequence, it is not possible to ensure a temporal association between vaccination and the development of inflammatory myopathies. Large epidemiological studies are required to determine the existence of a causal association.
Immune response after vaccination using inactivated vaccine for coronavirus disease 2019.
A Case Series of Chronic Spontaneous Urticaria After COVID-19 Vaccination.
Effect of MMR Vaccination to Mitigate Severe Sequelae Associated With COVID-19: Challenges and Lessons Learned. Mortality in COVID-19 cases was strongly associated with progressive lung inflammation and eventual sepsis. There is mounting evidence that live attenuated vaccines commonly administered during childhood, also provide beneficial non-specific immune effects, including reduced mortality and hospitalization due to unrelated infections. It has been proposed that live attenuated vaccine-associated non-specific effects are a result of inducing trained innate immunity to function more effectively against broader infections. In support of this, our laboratory has reported that immunization with a live attenuated fungal strain induces a novel form of trained innate immunity which provides protection against various inducers of sepsis in mice via myeloid-derived suppressor cells. Accordingly, we initiated a randomized control clinical trial with the live attenuated Measles, Mumps, Rubella (MMR) vaccine in healthcare workers in the greater New Orleans area aimed at preventing/reducing severe lung inflammation/sepsis associated with COVID-19 (ClinicalTrials.gov Identifier: NCT04475081). Included was an outcome to evaluate the myeloid-derived suppressor cell populations in blood between those administered the MMR vaccine vs placebo. The unanticipated emergency approval of several COVID-19 vaccines in the midst of the MMR clinical trials eliminated the ability to examine effects of the MMR vaccine on COVID-19-related health status. Unfortunately, we were also unable to show any impact of the MMR vaccine on peripheral blood myeloid-derived suppressor cells due to several inherent limitations (low percentages of blood leukocytes, small sample size), that also included a collaboration with a similar trial (CROWN CORONATION; ClinicalTrials.gov Identifier: NCT04333732) in St. Louis, MO. In contrast, monitoring the COVID-19 vaccine response in trial participants revealed that high COVID-19 antibody titers occurred more often in those who received the MMR vaccine vs placebo. While the trial was largely inconclusive, lessons learned from addressing several trial-associated challenges may aid future studies that test the non-specific beneficial immune effects of live attenuated vaccines.
mRNA-1273 boost after BNT162b2 vaccination generates comparable SARS-CoV-2-specific functional responses in naÃ¯ve and COVID-19-recovered individuals. INTRODUCTION: COVID-19 vaccines based on mRNA have represented a revolution in the biomedical research field. The initial two-dose vaccination schedule generates potent humoral and cellular responses, with a massive protective effect against severe COVID-19 and death. Months after this vaccination, levels of antibodies against SARS-CoV-2 waned, and this promoted the recommendation of a third vaccination dose. METHODS: We have performed an integral and longitudinal study of the immunological responses triggered by the booster mRNA-1273 vaccination, in a cohort of health workers previously vaccinated with two doses of the BNT162b2 vaccine at University Hospital La Paz located in Madrid, Spain. Circulating humoral responses and SARS-CoV-2-specific cellular reactions, after ex vivo restimulation of both T and B cells (cytokines production, proliferation, class switching), have been analyzed. Importantly, all along these studies, the analyses have been performed comparing naÃ¯ve and subjects recovered from COVID-19, addressing the influence of a previous infection by SARS-CoV-2. Furthermore, as the injection of the third vaccination dose was contemporary to the rise of the Omicron BA.1 variant of

concern, T- and B-cell-mediated cellular responses have been comparatively analyzed in response to this variant. RESULTS: All these analyses indicated that differential responses to vaccination due to a previous SARS-CoV-2 infection were balanced following the boost. The increase in circulating humoral responses due to this booster dropped after 6 months, whereas T-cell-mediated responses were more stable along the time. Finally, all the analyzed immunological features were dampened in response to the Omicron variant of concern, particularly late after the booster vaccination. CONCLUSION: This work represents a follow-up longitudinal study for almost 1.5 years, analyzing in an integral manner the immunological responses triggered by the prime-boost mRNA-based vaccination schedule against COVID-19.

Three doses of a recombinant conjugated SARS-CoV-2 vaccine early after allogeneic hematopoietic stem cell transplantation: predicting indicators of a high serologic response-a prospective, single-arm study. BACKGROUND: Allogeneic hematopoietic stem cell transplant (allo-HSCT) recipients must be vaccinated against SARS-CoV-2 as quickly as possible after transplantation. The difficulty in obtaining recommended SARS-CoV-2 vaccines for allo-HSCT recipients motivated us to utilize an accessible and affordable SARS-CoV-2 vaccine with a recombinant receptor-binding domain (RBD)-tetanus toxoid (TT)-conjugated platform shortly after allo-HSCT in the developing country of Iran. METHODS: This prospective, single-arm study aimed to investigate immunogenicity and its predictors following a three-dose SARS-CoV-2 RBD-TT-conjugated vaccine regimen administered at 4-week (Â±Â 1-week) intervals in patients within 3-12 months post allo-HSCT. An immune status ratio (ISR) was measured at baseline and 4 weeks (Â±Â 1 week) after each vaccine dose using a semiquantitative immunoassay. Using the median ISR as a cut-off point for immune response intensity, we performed a logistic regression analysis to determine the predictive impact of several baseline factors on the intensity of the serologic response following the third vaccination dose. RESULTS: Thirty-six allo-HSCT recipients, with a mean age of 42.42 years and a median time of 133 days between hematopoietic stem cell transplant (allo-HSCT) and the start of vaccination, were analyzed. Our findings, using the generalized estimating equation (GEE) model, indicated that, compared with the baseline ISR of 1.55 [95% confidence interval (CI) 0.94 to 2.17], the ISR increased significantly during the three-dose SARS-CoV-2 vaccination regimen. The ISR reached 2.32 (95% CI 1.84 to 2.79; pÂ =Â 0.010) after the second dose and 3.87 (95% CI 3.25 to 4.48; pÂ =Â 0.001) after the third dose of vaccine, reflecting 69.44% and 91.66% seropositivity, respectively. In a multivariate logistic regression analysis, the female sex of the donor [odds ratio (OR) 8.67; pÂ =Â 0.028] and a higher level donor ISR at allo-HSCT (OR 3.56; pÂ =Â 0.050) were the two positive predictors of strong immune response following the third vaccine dose. No serious adverse events (i.e., grades 3 and 4) were observed following the vaccination regimen. CONCLUSIONS: We concluded that early vaccination of allo-HSCT recipients with a three-dose RBD-TT-conjugated SARS-CoV-2 vaccine is safe and could improve the early post-allo-HSCT immune response. We further believe that the pre-allo-HSCT SARS-CoV-2 immunization of donors may enhance post-allo-HSCT seroconversion in allo-HSCT recipients who receive the entire course of the SARS-CoV-2 vaccine during the first year after allo-HSCT.

Drug-induced liver injury after covid-19 mRNA vaccine: case report. CASE DESCRIPTION: A 22-year-old female patient received the first dose of Pfizer-BioNTech vaccine (RNAm) against COVID-19; 6 days later, she presented abdominal pain located in the right hypochondrium and epigastrium, associated with emetic episodes. Re-consultation 21 days later due to the same symptoms; three days after the second dose of the vaccine was administered. CLINICAL FINDINGS: Pain on palpation in the right hypochondrium. Laboratories reported hepatocellular lesion and cholestasis, with negative amylase, hepatotropic virus and autoimmune hepatitis tests. Liver and biliary tract ultrasound and cholangioresonance were normal. TREATMENT AND RESULTS: Hyoscine and intravenous fluids as support therapy. She presented improvement in abdominal pain and progressive decrease of

transaminases and bilirubin levels until normalization, and was discharged on the fifth day of hospitalization. A drug-associated hepatotoxicity (DILI) diagnosis was considered probable, in this case, secondary to vaccination against COVID-19. CLINICAL RELEVANCE: The current SARS CoV-2 pandemic has spurred the development of new vaccines, the safety of which remains a concern. There is a likely causal relationship between vaccination and liver involvement in this clinical case, rather than simply a sporadic occurrence.

Large Diffusion of Severe Acute Respiratory Syndrome Coronavirus 2 After the Successive Epidemiological Waves, Including Omicron, in Guinea and Cameroon: Implications for Vaccine Strategies. BACKGROUND: We aimed to estimate the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) seroprevalence among the general population in Conakry, Guinea and Yaounde, Cameroon after the coronavirus disease 2019 Omicron wave. METHODS: We conducted population-based, age-stratified seroprevalence surveys in Conakry and Yaounde (May and June 2022). We collected demographic and epidemiologic information and dried blood spot samples that were tested for SARS-CoV-2 immunoglobulin G (IgG) antibodies using recombinant nucleocapsid and spike proteins with Luminex technology. RESULTS: Samples were obtained from 1386 and 1425 participants in Guinea and Cameroon, respectively. The overall age-standardized SARS-CoV-2 IgG seroprevalence against spike and nucleocapsid proteins was 71.57% (95% confidence interval [CI], 67.48%-75.33%) in Guinea and 74.71% (95% CI, 71.99%-77.25%) in Cameroon. Seroprevalence increased significantly with age categories. Female participants were more likely than male participants to be seropositive. The seroprevalence in unvaccinated participants was 69.6% (95% CI, 65.5%-73.41%) in Guinea and 74.8% (95% CI, 72.04%-77.38%) in Cameroon. In multivariate analysis, only age, sex, and education were independently associated with seropositivity. CONCLUSIONS: These findings show a high community transmission after the different epidemiological waves including Omicron, especially among people aged >40 years. In addition, our results suggest that the spread of SARS-CoV-2 has been underestimated as a significant proportion of the population has already contracted the virus and that vaccine strategies should focus on vulnerable populations.

Humoral and cellular immune responses after three or four doses of BNT162b2 in patients with hematological malignancies. OBJECTIVES: Initial responses to coronavirus disease 2019 vaccination are impaired in patients with hematological malignancies. We investigated immune responses after three or four doses of BNT162b2 in patients with myeloid and lymphoid malignancies compared to controls, and identified risk factors for humoral and cellular nonresponse 1 year after first vaccination. METHODS: In 407 hematological patients (45 myeloid, 362 lymphoid) and 98 matched controls, we measured immunoglobulin G (IgG) and neutralizing antibodies specific for the receptor-binding domain of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) at baseline, 3â€‰weeks, 2, 6, and 12 months, and interferon-Î³ release at 12 months. RESULTS: In patients with lymphoid malignancies, SARS-CoV-2 receptor-binding domain IgG concentration and mean neutralizing capacity was lower than in controls at all time points. A diagnosis of chronic lymphocytic B-cell leukemia (CLL) or lymphoma was associated with humoral nonresponse at 12 months compared to having multiple myeloma/amyloidosis (pâ€‰<â€‰.001 and pâ€‰=â€‰.013). Compared to controls, patients with lymphoid malignancies had increased risk of cellular nonresponse. A lymphoma diagnosis was associated with lower risk of cellular nonresponse compared to patients with multiple myeloma/amyloidosis, while patients with CLL had comparable response rates to patients with multiple myeloma/amyloidosis (pâ€‰=â€‰.037 and pâ€‰=â€‰.280). CONCLUSIONS: In conclusion, long-term humoral and cellular immune responses to BNT162b2 were impaired in patients with lymphoid malignancies.

Hematologic adverse events reported after COVID-19 vaccination in the Philippines: A national database study. Vaccination is the most important strategy in preventing COVID-19. Vaccine

efficacy and safety have been established in clinical trials but real-world data are useful to determine occurrence of adverse events in a population with heterogeneous characteristics. Knowledge on the hematologic events associated with different COVID-19 vaccines would be beneficial for patients as well as hematologists who oversee the care of these patients. This study aimed to determine the rates and outcomes of hematologic adverse events after COVID-19 vaccination in the Philippines. In this self-controlled case series, there were 268 individuals reported to have hematologic adverse events. Most received Comirnaty at 29.85%. Majority (62.31%) reported hematologic adverse events following the first dose of the vaccine. The overall event rate was 0.0182 per 10,000 vaccine doses; and lymphadenopathy was the most common hematologic adverse effect with a rate of 0.011 per 10,000 vaccine doses, followed by anemia at 0.0034 per 10,000 vaccine doses and thrombocytopenia at 0.0017 per 10,000 vaccine doses. Autoimmune cytopenias were also reported with an event rate of 0.0007 per 10,000 vaccine doses for ITP. One-hundred thirty two (49.25%) were fully recovered and 23.88% were recovering from hematologic adverse events as of the time of writing. The study showed a low rate of hematologic adverse events post COVID-19 vaccination with the seven different vaccine brands administered in the Philippines.

Efficacy of primary series AZD1222 (ChAdOx1 nCoV-19) vaccination against SARS-CoV-2 variants of concern: Final analysis of a randomized, placebo-controlled, phase 1b/2 study in South African adults (COV005). COVID-19 vaccine efficacy (VE) has been observed to vary against antigenically distinct SARS-CoV-2 variants of concern (VoC). Here we report the final analysis of VE and safety from COV005: a phase 1b/2, multicenter, double-blind, randomized, placebo-controlled study of primary series AZD1222 (ChAdOx1 nCoV-19) vaccination in South African adults aged 18-65Â years. South Africa's first, second, and third waves of SARS-CoV-2 infections were respectively driven by the ancestral SARS-CoV-2 virus (wild type, WT), and SARS-CoV-2 Beta and Delta VoCs. VE against asymptomatic and symptomatic infection was 90.6% for WT, 6.7% for Beta and 77.1% for Delta. No cases of severe COVID-19 were documented ahead of unblinding. Safety was consistent with the interim analysis, with no new safety concerns identified. Notably, South Africa's Delta wave occurredÂ â‰¥Â 9Â months after primary series vaccination, suggesting that primary series AZD1222 vaccination offers a good durability of protection, potentially due to an anamnestic response. Clinical trial identifier: CT.gov NCT04444674.

Spectrum of Serious Neurological and Psychiatric Adverse Events in Indian COVID-19 Vaccine Recipients: A Systematic Review of Case Reports and Case Series. Indian data regarding serious neurological and psychiatric adverse events, following coronavirus disease 2019 (COVID-19) vaccination, are lacking. We, therefore, systematically evaluated cases of post-vaccinal serious neurological and psychiatric adverse reactions published from India. A systematic review of cases published from India, which were archived in PubMed, Scopus, and Google Scholar databases, was performed; pre-print databases along with ahead-of-print contents were searched in addition. Retrieved articles, as on June 27, 2022, were evaluated following PRISMA guidelines. EndNote 20 web tool was used to make a PRISMA flow chart. Individual patients' data were compiled in a tabular form. The protocol of the systematic review was registered with PROSPERO (CRD42022324183). A total of 64 records describing 136 instances of serious neurological and psychiatric adverse events were identified. More than 50% (36/64) reports were from the following four states, namely, Kerala, Uttar Pradesh, New Delhi, and West Bengal. The mean age of persons developing these complications was 44.89 Â± 15.77 years. In the majority, adverse events occurred within 2 weeks of administration of the first dose of COVISHIELD vaccine. Immune-mediated central nervous system (CNS) disorders were identified in 54 instances. Guillain-Barre syndrome and other immune-mediated peripheral neuropathies were reported in 21 cases. Post-vaccinal herpes zoster was recorded in 31 vaccine recipients. Psychiatric adverse events were recorded in six patients. In Indian recipients of COVID-19

vaccine, a variety of serious neurological complications were reported. The overall risk appears minuscule. Immune-mediated central and peripheral neuronal demyelinations were the most frequently reported post-vaccinal adverse events. A large number of cases of herpes zoster have also been reported. Immune-mediated disorders responded well to immunotherapy.

Pediatric glomerulopathy after COVID-19 vaccination: A case series and review of the literature. BACKGROUND: Cases of glomerulopathy after COVID-19 vaccination have been reported in the adult population, while only a few cases have been reported in children and adolescents. For better understanding of this association in pediatric population, we aimed to describe clinical course of patients with glomerulopathy within 60 days of COVID-19 vaccination who were under followed up in the pediatric nephrology department of National Taiwan University Children's Hospital. METHODS: We reviewed the clinical characteristics, vaccine types, and outcomes of patients with newly diagnosed glomerular diseases or relapse of underlying glomerulopathy within 60 days after COVID-19 vaccination at our facility between January 2021 and July 2022. RESULTS: Thirteen pediatric patients were found to have newly diagnosed glomerular diseases or relapse from their underlying glomerulopathy after receiving their first, second, or third COVID-19 vaccines in our facility. Of the five pediatric patients with newly diagnosed glomerulopathy after vaccination, thin basement membrane nephropathy, idiopathic nephrotic syndrome, and hematuria have been identified. Seven patients had relapse episodes of underlying nephrotic syndrome and one patient with underlying isolated microscopic hematuria developed subnephrotic proteinuria after COVID-19 vaccination. All patients experienced remission or improvement with either immunosuppressive or conservative treatment during the follow-up period. CONCLUSIONS: This is the largest case series to date of pediatric glomerulopathy after COVID-19 vaccination. From our report, patients with either newly diagnosed or relapse of glomerulopathy after vaccination had good outcomes, and receiving vaccination to prevent COVID-19 infection or complications should be encouraged in pandemic era under close monitoring kidney manifestations.

Analysis of Acquisition of COVID-2019 Neutralizing Antibodies in Organ Transplant Recipients. BACKGROUND: This study confirmed the kinetics of antibodies acquired by SARS-CoV-2 vaccination in solid-organ transplant recipients and examined their association with the development of COVID-19 and immunosuppressive status in organ transplant recipients. METHODS: We measured COVID-19 neutralizing antibody titer in 21 organ transplant recipients vaccinated with the COVID-19 vaccine and 14 nontransplant recipients (control group) 3 times before and at 1 and 6 months after the third dose of vaccine. By confirming the kinetics of the acquired antibodies, we examined the relevance of the background characteristics of organ transplant recipients, such as the development of infectious diseases and immunosuppressive status. RESULTS: The proportion of patients with neutralizing antibodies was significantly higher in the nontransplant group than in the transplant group. Neutralizing antibody titers were significantly lower in transplant recipients when they were compared before the third dose and 1 month later. In the transplant recipient group, 11 patients were positive, and 10 were negative for neutralizing antibodies. When the causal relationship between the neutralizing antibody titer and background was examined, a positive correlation was found between the antibody titer and the number of years since transplantation, and a negative correlation was found between the tacrolimus trough values, amount of mycophenolate mofetil or steroids taken internally, and antibody titer. CONCLUSION: This study suggests that the effectiveness of vaccination in transplant recipients is associated with the post-transplant period before vaccination and the dose of immunosuppressive agents.

Cerebellar and brainstem stroke possibly associated with booster dose of BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine. As COVID-19 vaccination becomes widely available and administered globally, there have been several reports of side effects attributed to the vaccine. This

report highlights a patient who developed stroke 2â€‰days following the administration of the COVID-19 vaccine, although its association remains uncertain. A man in his late 30s developed acute neurological symptoms 2â€‰days after receiving the booster dose of the BNT162b2 (Pfizer-BioNTech) mRNA COVID-19 vaccine. History and neurological examination suggested a posterior circulation stroke, which was confirmed by MRI, as a right-sided posterior inferior cerebellar artery stroke. Full workup did not suggest other causes of the stroke. Due to the patient's age and well-controlled risk factors, it was presumed to be a rare adverse effect of the vaccine. Medical management with aspirin, statin therapy and rehabilitation led to the improvement of symptoms and enabled ongoing restoration of function. Further cases of stroke following administration of COVID-19 vaccine have been documented in the literature, but the association is yet to be established.

Clinical characteristics and comorbidities associated with SARS-CoV-2 breakthrough infection in the University of California Healthcare Systems. BACKGROUND: To evaluate the degree to which clinical comorbidities or combinations of comorbidities are associated with SARS-CoV-2 breakthrough infection. MATERIALS AND METHODS: A breakthrough infection was defined as a positive test at least 14 days after a full vaccination regimen. Logistic regression was used to calculate aORs, which were adjusted for age, sex, and race information. RESULTS: A total of 110,380 patients from the UC CORDS database were included. After adjustment, stage 5 CKD due to hypertension (aOR: 7.33; 95% CI: 4.86-10.69; p<.001; power=1) displayed higher odds of infection than any other comorbidity. Lung transplantation history (aOR: 4.79; 95% CI: 3.25-6.82; p<.001; power= 1), coronary atherosclerosis (aOR: 2.12; 95% CI: 1.77-2.52; p<.001; power=1), and vitamin D deficiency (aOR: 1.87; 95% CI: 1.69-2.06; p<.001; power=1) were significantly correlated to breakthrough infection. Patients with obesity in addition to essential hypertension (aOR: 1.74; 95% CI: 1.51-2.01; p<.001; power=1) and anemia (aOR: 1.80; 95% CI: 1.47-2.19; p<.001; power=1) were at additional risk of breakthrough infection compared to those with essential hypertension and anemia alone. CONCLUSIONS: Further measures should be taken to prevent breakthrough infection for individuals with these conditions, such as acquiring additional doses of the SARS-CoV-2 vaccine to boost immunity.

Cytokinopathy with aberrant cytotoxic lymphocytes and profibrotic myeloid response in SARS-CoV-2 mRNA vaccine-associated myocarditis. Rare immune-mediated cardiac tissue inflammation can occur after vaccination, including after SARS-CoV-2 mRNA vaccines. However, the underlying immune cellular and molecular mechanisms driving this pathology remain poorly understood. Here, we investigated a cohort of patients who developed myocarditis and/or pericarditis with elevated troponin, B-type natriuretic peptide, and C-reactive protein levels as well as cardiac imaging abnormalities shortly after SARS-CoV-2 mRNA vaccination. Contrary to early hypotheses, patients did not demonstrate features of hypersensitivity myocarditis, nor did they have exaggerated SARS-CoV-2-specific or neutralizing antibody responses consistent with a hyperimmune humoral mechanism. We additionally found no evidence of cardiac-targeted autoantibodies. Instead, unbiased systematic immune serum profiling revealed elevations in circulating interleukins (IL-1Î², IL-1RA, and IL-15), chemokines (CCL4, CXCL1, and CXCL10), and matrix metalloproteases (MMP1, MMP8, MMP9, and TIMP1). Subsequent deep immune profiling using single-cell RNA and repertoire sequencing of peripheral blood mononuclear cells during acute disease revealed expansion of activated CXCR3(+) cytotoxic T cells and NK cells, both phenotypically resembling cytokine-driven killer cells. In addition, patients displayed signatures of inflammatory and profibrotic CCR2(+) CD163(+) monocytes, coupled with elevated serum-soluble CD163, that may be linked to the late gadolinium enhancement on cardiac MRI, which can persist for months after vaccination. Together, our results demonstrate up-regulation in inflammatory cytokines and corresponding lymphocytes with tissue-damaging capabilities, suggesting a cytokine-dependent pathology, which may further be accompanied by myeloid cell-associated cardiac fibrosis. These findings likely rule out some previously proposed

mechanisms of mRNA vaccine--associated myopericarditis and point to new ones with relevance to vaccine development and clinical care.

COVID Vaccine-Associated Uveitis. PURPOSE: Following the pandemic of coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2, different vaccines were developed and approved by the main medical authorities under emergency protocol regulations. Although highly effective and well-tolerated in most patients, vaccines can uncommonly cause ocular adverse effects. In this article, the current evidence related to vaccine-associated uveitis is reviewed. METHODS: A literature review of uveitis post various SARS-CoV-2 vaccinations. RESULTS: Uveitis was reported following various forms of vaccinations but was more commonly seen following the Pfizer mRNA vaccine which is the most used vaccination worldwide. In western countries, the most common uveitis is mild anterior uveitis, developing within a week of first or subsequent vaccination with good resolution following appropriate topical steroid therapy in most cases. Posterior uveitis and particularly Vogt-Koyanagi-Harada disease was more prevalent in Asia. Uveitis may develop among known uveitis patients and those with other autoimmune diseases. CONCLUSION: Uveitis following Covid vaccinations is uncommon and has a good prognosis.

The severity of COVID-19 across the spectrum of HIV. PURPOSE OF REVIEW: We review the intersection between the HIV and COVID-19 pandemics, particularly the impact of HIV infection on the development of severe COVID-19. RECENT FINDINGS: Studies early in the COVID-19 pandemic did not find a clear link between HIV infection and increased COVID-19 severity or mortality. People with HIV (PWH) were more likely to have severe COVID-19, but much of the risk for worse outcomes was related to high rates of comorbidities and social determinants of health. Although comorbidities and social determinants of health are certainly critically important reasons for severe COVID-19 among PWH, recent large studies have found HIV infection - particularly when the CD4 cell count is low or HIV RNA is not suppressed - is an independent risk factor for COVID-19 severity. The link between HIV and severe COVID-19 highlights the need to diagnose and treat HIV as well as the importance of COVID-19 vaccination and treatment among PWH. SUMMARY: People with HIV have faced increased challenges during the COVID-19 pandemic because of high rates of comorbidities and social determinants of health as well as the impact of HIV on COVID-19 severity. Information on the intersection of the two pandemics has been crucial to improving care for people with HIV.

Immune Cell Response during COVID-19 Infection and following SARS-CoV-2 Vaccination in Patients Admitted to Intensive Care Unit. BACKGROUND: Immune response plays a crucial role in virus clearance during COVID-19 infection and underpins vaccine efficacy. Herein, we aimed to assess the immune response during COVID-19 infection and following SARS-CoV-2 vaccination. METHODS: In this retrospective study, 94 confirmed COVID-19 patients admitted to the intensive care unit were categorized into unvaccinated patients (nâ€‰=â€‰50), including 33 deceased and 17 discharged patients, and vaccinated group (nâ€‰=â€‰44) with 26 deceased and 18 discharged patients. Records of patients with severe COVID-19 admitted to the ICU between March, 2021 and March, 2022 were gathered and analyzed. RESULT: The assessment of immune cell counts revealed a large rise of neutrophils associated to decrease number of lymphocytes in patients with COVID-19 infection. In dead patients, we detected a significant correlation between neutrophils and inflammatory parameters such as IL-6 and CRP. Moreover, analysis of immune cell count following vaccination did not reveal any significant difference. However, the most substantial result, herein, detected is the decrease level of IL-6 in vaccinated patients as compared to unvaccinated. The reduce level of IL-6 following vaccination is observed in discharged patients as compared to deceased. Regarding the level of mortality after vaccination, we showed that all patients who received the first dose were died (46.1%, nâ€‰=â€‰12) as compared to those who have received two doses (34.6%, nâ€‰=â€‰9) and the third dose of vaccine (19.23%, nâ€‰=â€‰3) (p=0.0018). Strikingly, studying

the inflammatory parameters after each vaccine dose, we revealed a significant decrease of IL-6 level after the booster dose (third dose), especially in vaccinated discharged patients. CONCLUSIONS: Neutrophils combined with IL-6 and CRP can be very useful markers to predict disease severity in patients admitted to ICU. The decrease level of IL-6 in vaccinated group pointed out the impact of vaccination to prevent inflammatory cytokine release.

AVP deficiency (central diabetes insipidus) following immunization with anti-COVID-19 BNT162b2 Comirnaty vaccine in adolescents: A case report. INTRODUCTION: The coronavirus disease 19 (COVID-19) pandemic has prompted the development of new vaccines to reduce the morbidity and mortality associated with this disease. Recognition and report of potential adverse effects of these novel vaccines (especially the urgent and life-threatening ones) is therefore essential. CASE PRESENTATION: A 16-year-old boy presented to the Paediatric Emergency Department with polyuria, polydipsia and weight loss over the last four months. His past medical history was unremarkable. Onset of symptoms was referred to be few days after first dose of anti-COVID-19 BNT162b2 Comirnaty vaccine and then worsened after the second dose. The physical exam was normal, without neurological abnormalities. Auxological parameters were within normal limits. Daily fluid balance monitoring confirmed polyuria and polydipsia. Biochemistry laboratory analysis and urine culture were normal. Serum osmolality was 297 mOsm/Kg H(2)O (285-305), whereas urine osmolality was 80 mOsm/Kg H(2)O (100-1100), suggesting diabetes insipidus. Anterior pituitary function was preserved. Since parents refused to give consent to water deprivation test, treatment with Desmopressin was administered and confirmed ex juvantibus diagnosis of AVP deficiency (or central diabetes insipidus). Brain MRI revealed pituitary stalk thickening (4Â mm) with contrast enhancement, and loss of posterior pituitary bright spot on T1 weighted imaging. Those signs were consistent with neuroinfundibulohypophysitis. Immunoglobulin levels were normal. Low doses of oral Desmopressin were sufficient to control patient's symptoms, normalizing serum and urinary osmolality values and daily fluid balance at discharge. Brain MRI after 2 months showed stable thicken pituitary stalk and still undetectable posterior pituitary. Due to persistence of polyuria and polydipsia, therapy with Desmopressin was adjusted by increasing dosage and number of daily administrations. Clinical and neuroradiological follow-up is still ongoing. CONCLUSION: Hypophysitis is a rare disorder characterized by lymphocytic, granulomatous, plasmacytic, or xanthomatous infiltration of the pituitary gland and stalk. Common manifestations are headache, hypopituitarism, and diabetes insipidus. To date, only time correlation between SARS-CoV-2 infection and development of hypophysitis and subsequent hypopituitarism has been reported. Further studies will be needed to deepen a possible causal link between anti-COVID-19 vaccine and AVP deficiency.

COVID-19 vaccination in patients with primary immunodeficiencies: an international survey on patient vaccine hesitancy and self-reported adverse events. INTRODUCTION: The Sars-CoV-2 pandemic caused great concern for this novel virus among patients with primary immunodeficiency (PID) or inborn errors of immunity (IEI) and their families. When COVID-19 vaccination program started, no data existed on adverse events (AEs) in this particular patient population, nor if patients felt hesitancy being vaccinated. OBJECTIVES: To explore i) reasons for COVID-19 vaccination hesitancy, ii) the number and symptoms of AEs and their severity, durability and management. METHOD: The organisations International Patient Organisation for Primary Immunodeficiencies (IPOPI), European Society for Immunodeficiencies (ESID) and International Nursing Group for Immunodeficiencies (INGID) distributed a global self-administered online survey. RESULTS: The survey was completed by 1317 patients (mean 47, range 12-100, years) from 40 countries. 41.7% of the patients denoted some hesitancy to COVID-19 vaccination, mainly having doubts about postvaccination protection related to their underlying PID and concerns about negative long-term effects. More women (22.6%) reported "very" or "pretty much" hesitancy compared to men (16.4%)

(P<0.05). The most common systemic AEs were fatigue, muscle/body pain and headache, usually the same day or the day after the vaccination and lasting for 1-2 days. 27.8% of the respondents reported severe systemic AEs after any dose of COVID-19 vaccine. Only a minority (7.8%) of these patients visited a health-care professional and 20 patients (1.5%) were hospitalized or seen at emergency room without specifying subsequent admission at the hospital. Significantly more local and systemic AEs were reported after the second dose. No differences regarding AEs were observed across different PID subgroups or vaccine types. CONCLUSION: At the time of the survey, almost half of the patients reported having felt hesitancy to COVID-19 vaccination highlighting the importance and need of developing joint international guidelines and education programs about COVID-19 vaccination. The types of AEs were comparable to healthy controls, but more frequent AEs were reported. Clinical studies and prospective, detailed registration of AEs related to COVID-19 vaccines in this patient population is of great importance. It is crucial to elucidate whether there is a coincidental or causal association between COVID-19 vaccine and some severe systemic AEs. Our data do not contradict that patients with PID can be advised to be vaccinated against COVID-19, in accordance with applicable national guidelines.

Acute encephalomyelitis in a 52-year-old male post messenger ribonucleic acid severe acute respiratory syndrome coronavirus 2 vaccination: a case report. BACKGROUND: Acute disseminated encephalomyelitis is a well-known, but rare, side effect of some vaccines, or symptom following a febrile illness. CASE: A 69-year-old, otherwise healthy Hispanic male presented with acute fever, confusion, and later progressive weakness after receiving the first dose of the mRNA-1273 (Moderna) severe acute respiratory syndrome coronavirus 2 vaccine. Considering the progressive deterioration of the patient, despite being on multiple immunosuppressive agents, a brain biopsy was obtained, which revealedÂ nonspecific meningoencephalitis. CONCLUSION: In this case, we highlight the need for a regulatory framework to assist clinicians and patients with coverage of treatment for acute disseminated encephalomyelitis. The use of intravenous immunoglobulin in conjunction with glucocorticoids seems to be an effective treatment option.

Omicron BA.1 neutralizing antibody response following Delta breakthrough infection compared with booster vaccination of BNT162b2. BACKGROUND: Longitudinal data are lacking to compare booster effects of Delta breakthrough infection versus third vaccine dose on neutralizing antibodies (NAb) against Omicron. METHODS: Participants were the staff of a national research and medical institution in Tokyo who attended serological surveys on June 2021 (baseline) and December 2021 (follow-up); in between, the Delta-dominant epidemic occurred. Of 844 participants who were infection-naÃ¯ve and had received two doses of BNT162b2 at baseline, we identified 11 breakthrough infections during follow-up. One control matched to each case was selected from boosted and unboosted individuals. We compared live-virus NAb against Wild-type, Delta, and Omicron BA.1 across groups. RESULTS: Breakthrough infection cases showed marked increases in NAb titers against Wild-type (4.1-fold) and Delta (5.5-fold), and 64% had detectable NAb against Omicron BA.1 at follow-up, although the NAb against Omicron after breakthrough infection was 6.7- and 5.2-fold lower than Wild-type and Delta, respectively. The increase was apparent only in symptomatic cases and as high as in the third vaccine recipients. CONCLUSIONS: Symptomatic Delta breakthrough infection increased NAb against Wild-type, Delta, and Omicron BA.1, similar to the third vaccine. Given the much lower NAb against Omicron BA.1, infection prevention measures must be continued irrespective of vaccine and infection history while the immune evasive variants are circulating.

Prediction of effective humoral response to SARS-CoV-2 vaccines in healthy subjects by cortical thickness of post-vaccination reactive lymphadenopathy. PURPOSE: To study the association between ultrasound cortical thickness in reactive post-vaccination lymph nodes and the elicited humoral response and to evaluate the performance of cortical thickness as a predictor of vaccine

effectiveness in patients with and without a previous history of COVID-19 infection. METHODS: A total of 156 healthy volunteers were recruited and followed prospectively after receiving two COVID-19 vaccination doses using different protocols. Within a week after receiving the second dose, an axillary ultrasound of the ipsilateral vaccinated arm was performed, and serial post-vaccination serologic tests (PVST) were collected. Maximum cortical thickness was chosen as a nodal feature to analyze association with humoral immunity. Total antibodies quantified during consecutive PVST in previously-infected patients and in coronavirus-naÃ¯ve volunteers were compared (Mann-Whitney U test). The association between hyperplastic-reactive lymph nodes and effective humoral response was studied (odds ratio). The performance of cortical thickness in detecting vaccination effectiveness was evaluated (area under the ROC curve). RESULTS: Significantly higher values for total antibodies were observed in volunteers with a previous history of COVID-19 infection (pÂ < 0.001). The odds ratio associating immunized coronavirus-naÃ¯ve volunteers after 90 and 180 days of the second dose with a cortical thickness â‰¥ 3 mm was statistically significant (95% CI 1.52-6.97 and 95% CI 1.47-7.29, respectively). The best AUC result was obtained comparing antibody secretion of coronavirus-naÃ¯ve volunteers at 180 days (0.738). CONCLUSIONS: Ultrasound cortical thickness of reactive lymph nodes in coronavirus-naÃ¯ve patients may reflect antibody production and a long-term effective humoral response elicited by vaccination. CLINICAL RELEVANCE STATEMENT: In coronavirus-naÃ¯ve patients, ultrasound cortical thickness of post-vaccination reactive lymphadenopathy shows a positive association with protective antibody titers against SARS-CoV-2, especially in the long term, providing new insights into previous publications. KEY POINTS: â€¢ Hyperplastic lymphadenopathy was frequently observed after COVID-19 vaccination. â€¢ Ultrasound cortical thickness of reactive post-vaccine lymph nodes may reflect a long-term effective humoral response in coronavirus-naÃ¯ve patients.

Blood unconjugated bilirubin and tacrolimus are negative predictors of specific cellular immunity in kidney transplant recipients after SAR-CoV-2 inactivated vaccination. The immunogenicity of SARS-CoV-2 vaccines is poor in kidney transplant recipients (KTRs). The factors related to poor immunogenicity to vaccination in KTRs are not well defined. Here, observational study demonstrated no severe adverse effects were observed in KTRs and healthy participants (HPs) after first or second dose of SARS-CoV-2 inactivated vaccine. Different from HPs with excellent immunity against SARS-CoV-2, IgG antibodies against S1 subunit of spike protein, receptor-binding domain, and nucleocapsid protein were not effectively induced in a majority of KTRs after the second dose of inactivated vaccine. Specific T cell immunity response was detectable in 40% KTRs after the second dose of inactivated vaccine. KTRs who developed specific T cell immunity were more likely to be female, and have lower levels of total bilirubin, unconjugated bilirubin, and blood tacrolimus concentrations. Multivariate logistic regression analysis found that blood unconjugated bilirubin and tacrolimus concentration were significantly negatively associated with SARS-CoV-2 specific T cell immunity response in KTRs. Altogether, these data suggest compared to humoral immunity, SARS-CoV-2 specific T cell immunity response are more likely to be induced in KTRs after administration of inactivated vaccine. Reduction of unconjugated bilirubin and tacrolimus concentration might benefit specific cellular immunity response in KTRs following vaccination.

Can psychological distress account for the associations between COVID-19 vaccination acceptance and socio-economic vulnerability? Socially disadvantaged individuals and communities consistently showed lower COVID-19 vaccination acceptance. We aimed to examine the psychological mechanisms that could explain such vaccination disparities. This study used data from serial population-based surveys conducted since the COVID-19 vaccination programme being launched in Hong Kong (Nâ€‰=â€‰28,734). We first assessed the correlations of community-level and individual-level social vulnerability with COVID-19 vaccination acceptance. Structural equation

modelling (SEM) was then conducted to test whether psychological distress measured by PHQ-4 can account for the associations between participants' socio-economic vulnerability and COVID-19 vaccination acceptance. The third part analysis examined whether perceived negativity of vaccine-related news and affect towards COVID-19 vaccines accounted for the association between psychological distress and COVID-19 vaccination. Communities with higher social vulnerability scores and participants who had more vulnerable socio-economic status showed lower COVID-19 vaccination acceptance. Individuals with more vulnerable socio-economic status reported higher psychological distress, which lowered COVID-19 vaccination acceptance. Furthermore, higher psychological distress was associated with lower vaccination acceptance through its psychological mechanisms of processing vaccine-related information. We proposed a renewed focus on tackling psychological distress rather than merely increasing vaccine accessibility in more socio-economic-disadvantaged groups for promoting COVID-19 vaccination acceptance.

COVID-19 adenovirus vector vaccine induces higher interferon and pro-inflammatory responses than mRNA vaccines in human PBMCs, macrophages and moDCs. BACKGROUND: During the COVID-19 pandemic multiple vaccines were rapidly developed and widely used throughout the world. At present there is very little information on COVID-19 vaccine interactions with primary human immune cells such as peripheral blood mononuclear cells (PBMCs), monocyte-derived macrophages and dendritic cells (moDCs). METHODS: Human PBMCs, macrophages and moDCs were stimulated with different COVID-19 vaccines, and the expression of interferon (IFN-Î»1, IFN-Î±1), pro-inflammatory (IL-1Î², IL-6, IL-8, IL-18, CXCL-4, CXCL-10, TNF-Î±) and Th1-type cytokine mRNAs (IL-2, IFN-Î³) were analyzed by qPCR. In addition, the expression of vaccine induced spike (S) protein and antiviral molecules were studied in primary immune cells and in A549 lung epithelial cells. RESULTS: Adenovirus vector (Ad-vector) vaccine AZD1222 induced high levels of IFN-Î»1, IFN-Î±1, CXCL-10, IL-6, and TNF-Î± mRNAs in PBMCs at early time points of stimulation while the expression of IFN-Î³ and IL-2 mRNA took place at later times. AZD1222 also induced IFN-Î»1, CXCL-10 and IL-6 mRNA expression in monocyte-derived macrophages and DCs in a dose-dependent fashion. AZD1222 also activated the phosphorylation of IRF3 and induced MxA expression. BNT162b2 and mRNA-1273 mRNA vaccines failed to induce or induced very weak cytokine gene expression in all cell models. None of the vaccines enhanced the expression of CXCL-4. AZD1222 and mRNA-1273 vaccines induced high expression of S protein in all studied cells. CONCLUSIONS: Ad-vector vaccine induces higher IFN and pro-inflammatory responses than the mRNA vaccines in human immune cells. This data shows that AZD1222 readily activates IFN and pro-inflammatory cytokine gene expression in PBMCs, macrophages and DCs, but fails to further enhance CXCL-4 mRNA expression.

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antibody Titer Levels in Pregnant Individuals After Infection, Vaccination, or Both. We examined differences in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody responses in pregnant individuals with natural, vaccine-induced, or combined immunity. Participants had live or nonlive births between 2020 and 2022, were seropositive (SARS-CoV-2 spike protein, anti-S), and had available mRNA vaccination and infection information (n=260). We compared titer levels among three immunity profiles: 1) natural immunity (n=191), 2) vaccine-induced immunity (n=37), and 3) combined immunity (ie, natural and vaccine-induced immunity; n=32). We applied linear regression to compare anti-S titers between the groups, controlling for age, race and ethnicity, and time between vaccination or infection (whichever came last) and sample collection. Anti-S titers were 57.3% and 94.4% lower among those with vaccine-induced and natural immunity, respectively, compared with those with combined immunity (P <.001, P =.005).

Humoral Immunity After COVID-19 Vaccination in Chronic Lymphocytic Leukemia and Other Indolent Lymphomas: A Single-Center Observational Study. BACKGROUND: Chronic lymphocytic leukemia

(CLL) and other non-Hodgkin's lymphomas (NHLs) lead to broad immunosuppression, conferring a greater risk for morbidity and mortality from SARS-CoV-2. Our study analyzed antibody (Ab) seropositivity from SARS-CoV-2 vaccination in patients with these cancers. METHODS: In the final analysis, 240 patients were involved, and seropositivity was defined as a positive total or spike protein Ab. RESULTS: Seropositivity was 50% in CLL, 68% in WM, and 70% in the remaining NHLs. Moderna vaccination led to higher seropositivity compared to Pfizer vaccination across all cancers (64% vs. 49%; P = .022) and specifically CLL patients (59% vs. 43%; P = .029). This difference was not explainable by differences in treatment status or prior anti-CD20 monoclonal Ab therapy. In CLL patients, current or prior cancer therapy led to lower seropositivity compared to treatment-naÃ¯ve patients (36% vs. 68%; P = .000019). CLL patients treated with Bruton's tyrosine kinase (BTK) inhibitors had better seropositivity after receiving the Moderna vaccination compared to Pfizer (50% vs. 23%; P = .015). Across all cancers, anti-CD20 agents within 1 year led to a lower Ab response compared to greater than one year (13% vs. 40%; P = .022), a difference which persisted after booster vaccination. CONCLUSION: Antibody response is lower in patients with indolent lymphomas compared to the general population. Lower Ab seropositivity was found in patients with a history of anti-leukemic agent therapy or those immunized with Pfizer vaccine. This data suggests that Moderna vaccination may confer a greater degree of immunity against SARS-CoV-2 in patients with indolent lymphomas.

Biochemical and histopathological evaluation of ChAdOx1-S and BBIBP-CorV vaccination in normal and streptozotocin-induced diabetic Wistar rats. Infection with Covid-19 has been associated with some medical complications namely diabetes, thrombosis, and hepatic and renal dysfunction among others. This situation has created some concern about the use of relevant vaccines which might cause similar complications. In that regard, we planned to evaluate the impact of two of the relevant vaccines namely ChAdOx1-S and BBIBP-CorV on some of the blood biochemical factors and also on liver and kidneys functions following the immunization of healthy and streptozotocin-induced diabetic rats. Evaluation of the level of neutralizing antibody among the rats indicated that immunization with ChAdOx1-S induced a higher level of neutralizing antibody among both the healthy and diabetic rats compared to the BBIBP-CorV vaccine. Furthermore, the neutralizing antibody levels against both types of vaccines were significantly lower in diabetic rats than in healthy ones. On the other hand, no alterations were observed in the rats' sera biochemical factors, coagulation values and histopathological images of the liver and kidneys. Altogether these data besides of confirming the effectiveness of both vaccines, indicate that both vaccines have no hazardous side effects on rats and probably humans though clinical investigations are required to validate our present data.

Evaluation of TÂ cell responses to naturally processed variant SARS-CoV-2 spike antigens in individuals following infection or vaccination. Most existing studies characterizing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-specificÂ TÂ cell responses are peptide based. This does not allow evaluation of whether tested peptides are processed and presented canonically. In this study, we use recombinant vaccinia virus (rVACV)-mediated expression of SARS-CoV-2 spike protein and SARS-CoV-2 infection of angiotensin-converting enzyme (ACE)-2-transduced B cell lines to evaluate overall TÂ cell responses in a small cohort of recovered COVID-19 patients and uninfected donors vaccinated with ChAdOx1 nCoV-19. We show that rVACV expression of SARS-CoV-2 antigen can be used as an alternative to SARS-CoV-2 infection to evaluate TÂ cell responses to naturally processed spike antigens. In addition, the rVACV system can be used to evaluate the cross-reactivity of memory TÂ cells to variants of concern (VOCs) and to identify epitope escape mutants. Finally, our data show that both natural infection and vaccination could induce multi-functional TÂ cell responses with overall TÂ cell responses remaining despite the identification of escape mutations.

Does COVID-19 Vaccination with BNT162b2 Influence HIV-Related Immunological and Virological Markers? Data from 235 Persons Living with HIV at Cotugno Hospital, Naples, Italy: Immune Response After Second and Third Doses, and Influence on Immunovirological Markers. Few data are available on the impact of COVID-19 vaccination on CD4 counts and HIV-RNA in persons living with HIV (PLWH). We present the data of 235 PLWH who were vaccinated with BNT162b2 in March 2021-February 2022 at the "Cotugno" hospital in Naples. PLWH treated at the "Cotugno" hospital, who were vaccinated at the hospital vaccination center, without prior COVID-19 and for whom immunological/virological data were available in the last 12 months and in the 6 months after vaccination were included. Antispike Ab were available for 187 and 64 PLWH after the second and third doses: PLWH with antispikes >33 binding antibodies units (BAU)/mL increased from 91% to 98%. Antinucleocapsid Ab performed in 147 and 56 patients identified 19 (13%) asymptomatic/paucisymptomatic COVID-19 infections after the second dose and an additional 15 (27%) after the third dose. Immunological/virological data were collected before vaccination (T0), after the second dose (T1), and after the third dose (T2). The absolute number of CD4 increased after the third dose (median 663, 657, and 707 at T0, T1, and T2; pâ€‰<â€‰0.000 T0 vs. T2). The proportion of patients with HIV-RNA <50 copies/mL increases significantly after the second dose (73%; 85.7%; 87.7%; pâ€‰<â€‰0.000 T0 vs. T2). The presence of COVID-19 asymptomatic/paucisymptomatic infections (demonstrated by the presence of antinucleocapsid Ab) significantly increases SARS-CoV-2 antispike Ab after second dose, but not after third dose. Asymptomatic/paucisymptomatic COVID-19 infections do not have influence on CD4 cell number and HIV-RNA level. Similarly, the presence of not-controlled HIV-RNA (HIV-RNA >50 copies/mL) does not influence antispike Ab response. According to our data, the response to SARS-CoV2 vaccination is effective in people living with HIV. Vaccination against COVID-19 appears to positively affect immunological and virological levels in people living with HIV.

Immunogenicity and reactogenicity of heterologous prime-boost vaccination with inactivated COVID-19 and ChAdOx1 nCoV-19 (AZD1222) vaccines, a quasi-experimental study. The global supply of COVID-19 vaccines has been limited, and concerns have arisen about vaccine supply chain disruptions in developing countries. Heterologous prime-boost vaccination, which involves using different vaccines for the first and second doses, has been proposed to enhance the immune response. We aimed to compare the immunogenicity and safety of a heterologous prime-boost vaccination using an inactivated COVID-19 vaccine and AZD1222 vaccine with that of a homologous vaccination using AZD1222. This pilot involved 164 healthy volunteers without prior SARS-CoV-2 infection aged 18â€‰years or older assigned to receive either the heterologous or homologous vaccination. The results showed that the heterologous approach was safe and well-tolerated, although the reactogenicity of the heterologous approach was higher. At 4â€‰weeks after receiving the booster dose, the heterologous approach elicited a non-inferior immune response compared to the homologous approach in neutralizing antibody and cell-mediated immune response. The percentage of inhibition was 83.88 (79.72-88.03) in the heterologous and 79.88 (75.50-84.25) in the homologous group, a mean difference of 4.60 (-1.67-10.88). The geometric mean of interferon-gamma was 1072.53 mIU/mL (799.29-1439.18) in the heterologous group and 867.67 mIU/mL (671.94-1120.40) in the homologous group, a GMR of 1.24 (0.82-1.85). However, the binding antibody test of the heterologous group was inferior to the homologous group. Our findings suggest that the use of heterologous prime-boost vaccination with different types of COVID-19 vaccines is a viable strategy, especially in settings where vaccine supply is limited or where vaccine distribution is challenging.

Impact of SARS-CoV-2 infection in patients with hereditary hemorrhagic telangiectasia: epidemiological and clinical data from the comprehensive Italian retrospective multicenter study. Rare Disease patients manifested high concern regarding the possible increased risk of severe

outcomes and worsening of disease-specific clinical manifestation due to the impact of COVID-19. Our aim was to assess the prevalence, outcomes, and impact of COVID-19 in patients with a rare disease such as Hereditary Hemorrhagic Telangiectasia (HHT) in Italian population. A nationwide, multicentric, cross-sectional observational study was conducted on patients with HHT from five Italian HHT centers by online survey. The association between COVID-19-related signs and symptoms and nosebleeds worsening, the impact of personal protective equipment on nosebleeds pattern, and the relationship between the presence of visceral AVMs and severe outcomes were analyzed. Out of 605 total survey responses and eligible for analysis, 107 cases of COVID-19 were reported. A mild-course COVID-19 disease, not requiring hospitalization, was observed in 90.7% of patients, while the remaining eight cases needed hospitalization, two of them requiring intensive-care access. No fatal outcome was recorded and 79.3% of patients reported a complete recovery. No difference in infection risk and outcome between HHT patients and general population was evidenced. No significative interference of COVID-19 on HHT-related bleeding was found. The majority of patients received COVID-19 vaccination, with relevant impact on symptoms and need for hospitalization in case of infection. COVID-19 in HHT patients had an infection profile similar to the general population. COVID-19 course and outcome were independent from any specific HHT-related clinical features. Moreover, COVID-19 and anti-SARS-CoV-2 measures did not seem to affect significantly HHT-related bleeding profile.

[Reasons for allergology consultations prior to COVID-19 vaccination and their outcomes : Two-year experience of an allergy center in North Rhine-Westphalia]. BACKGROUND: To counteract the coronavirus disease 2019 (COVID-19) pandemic, several severe acute respiratory syndrome coronavirus typeÂ 2 (SARS-CoV-2) vaccines have been licensed since December 2020. Shortly after the start of the vaccination campaigns, occasional allergic reactions related to vaccines were described, thus, leading to concerns in many patients with aÂ history of allergies. The aim of this work was to evaluate which anamnestic events represented aÂ reason for an allergology work-up before COVID-19 vaccination. Furthermore, the results of the allergology diagnostics are described. METHODS: We performed aÂ retrospective data analysis of all patients who presented at the Center for Dermatology, Allergology and Dermatosurgery of the Helios University Hospital Wuppertal during the years 2021 and 2022 for allergology work-up prior to COVID-19 vaccination. Demographic data, allergological history, reason for the consultation in the clinic and results of allergology diagnostic tests including reactions after vaccination were included. RESULTS: AÂ total of 93Â patients presented for allergology work-up with COVID-19 vaccines. In about half of the cases, the reasons for the presentation to the clinic were doubts and concerns about allergic reactions and side effects. In all, 26.9% (25/93) of the presented patients had not previously received aÂ COVID-19 vaccine yet and 23.7% (22/93) of patients developed non-allergic reactions after prior COVID-19 vaccine (e.g., headache, chills, fever, malaise). Of the patients, 46.2% (43/93) were successfully vaccinated in the clinic due to aÂ complex allergological history, while the remaining 53.8% (50/93) were subjected to outpatient vaccination in the vaccination practice. Only one patient with known chronic spontaneous urticaria developed aÂ mild angioedema of the lips aÂ few hours after vaccination; however, we do not consider this episode an allergic reaction to the vaccine due to the time delay. CONCLUSION: Allergic reactions after COVID-19 vaccines are rare, but many patients with aÂ positive medical history of allergies are concerned about allergic reactions after COVID-19 vaccination. Thus, public work by practicing allergologists is important during vaccination campaigns to meet the concerns and fears of the population, especially of patients with allergies in their medical history.

Effect of COVID-19 vaccination on influenza-associated respiratory infection (IARI): benefit or backfire. OBJECTIVE: Undoubtfully, COVID-19 vaccine (C19V) has significantly changed the pandemic's trajectory positively. At the same time, reports of transient local and systemic post-

vaccination reactions leave a concern about its unknown impact on common ailments. Its effect on IARI is unclear because the present IARI epidemic began immediately after C19V in the previous season. PATIENTS AND METHODS: A retrospective observational cohort study among 250 Influenza-associated respiratory infection (IARI) patients by a structured interview questionnaire was conducted with the comparison between 3 groups with 1 dose, 2 doses and 2 doses plus booster dose of C19V. The p<0.05 was considered significant in this study. RESULTS: Among samples 21.2% received one dose of the C19V, only 3.6% got Flu vaccination, 30% had â‰¥2 comorbidities such as diabetes (22.8%), hypertension (28.4%) and ionically, 77.2% were on chronic medications. Significant differences (p<0.05) were found between groups with duration of illness, cough, headache, fatigue, shortness of breath and hospital visits. The logistic regression analysis shows that the extended IARI symptoms and hospital visits were significantly high among Group 3 (OR=9.17, 95% CI=3.01-29.0) and the same trend remained significant after adjusting the incidence of comorbidities among samples, the chronic conditions (OR=5.13, 95% CI=1.37-14.91) and flu vaccination status (O=4.96, 95% CI=1.41-16.2). Also, 66.4% of the patients were indecisive about getting vaccinated further. CONCLUSIONS: It has been challenging to reach any definitive conclusions regarding the effects of C19V on IARI, conducting extensive, substantial population-based studies that integrate clinical and virological data from more than one season is absolutely required, despite the fact that the majority of the reported effects were mild and temporary.

Demographic and clinical feature disparity between progress and non-progress patients with vitiligo after COVID-19 vaccination: A cross-sectional study. There have been several case reports regarding newly developed vitiligo following the coronavirus disease 19 (COVID-19) vaccination. However, the relationship between COVID-19 vaccine and vitiligo progression remains unclear. To explore the relationship between COVID-19 vaccine and vitiligo progression and its potential influencing factors, A cross-sectional study was conducted on 90 patients with vitiligo who received inactivated COVID-19 vaccination. Detailed information covering demographic characteristics (age and sex), vitiligo clinical features (disease subtypes, duration, stage and comorbidities) and disease activity was collected through an electronic questionnaire. Ninety patients with vitiligo included 44.4% males, with an average age of 38.1â€‰years (standard deviation, SDâ€‰=â€‰15.0). Patients were divided into progress group (29, 32.2%) and normal group (61, 67.8%) based on whether they experienced vitiligo progression after inactivated COVID-19 vaccination. 41.3% of patients in the progress group experienced vitiligo progression within 1â€‰week after vaccination, and disease progression mainly occurred after the first dose inoculation (20, 69.0%). Logistic regression revealed that patients aged <45â€‰years (odds ratio (OR) was 0.87, 95% confidence interval (CI): 0.34-2.22) and male patients (ORâ€‰=â€‰0.84, 95% CI: 0.34-2.05) had lower risk for vitiligo progression, while patients with segmental vitiligo (SV) subtype (ORâ€‰=â€‰1.68, 95% CI: 0.53-5.33), with <5â€‰years disease duration (ORâ€‰=â€‰1.32, 95% CI: 0.51-3.47) had higher risk for vitiligo progression after COVID-19 vaccination, but without statistical significance. Over 30% patients experienced vitiligo progression after inactivated COVID-19 vaccination, and female patients, elder age, shorter disease duration and SV subtype are potential risk factors for vitiligo progression.

Evaluation of serum and cerebrospinal fluid biomarkers after vaccination against SARS-CoV-2. OBJECTIVE: Vaccines are a major achievement of science, and new vaccines against SARS-CoV-2 are protecting the entire population from a life-threatening infection. Although several neurological complications or worsening of pre-existing neurological conditions after vaccination have been observed, whether a biological plausibility exist between new vaccines against-SARS-CoV-2 and neurological consequences is unclear. The aim of this study is to evaluate whether vaccines against SARS-CoV-2 induce systemic or cerebrospinal fluid alterations in patients with neurological disorders. METHODS: Patients who underwent lumbar puncture (LP) between February 2021 and October 2022

were enrolled. Serum C-reactive protein (CRP), neutrophil to lymphocyte ratio (NLR), cerebrospinal fluid total protein content (CSF-TPc), glucose CSF/serum ratio, number of CSF cells per cubic millimeter, and CSF neurofilament light chain (CSF-NfL) were compared between unvaccinated and vaccinated patients. RESULTS: A total of 110 patients were included and fitted into three groups according firstly to vaccination status (vaccinated and unvaccinated) and then to time from last dose of vaccine to LP (within or after 3â€‰months). TPc, CSF/S(Glu) ratio, number of cells per cubic millimeter, CSF-NfL, CRP, and NLR were not different between groups (all pâ€‰>â€‰0.05), and also, they did not differ neither according to age nor diagnosis. No relevant differences between groups were also noticed when the at-risk time window was set to 6â€‰weeks. INTERPRETATION: No signs of neuroinflammation, axonal loss and systemic inflammation were found in patients with neurological disorders after anti-SARS-CoV-2 vaccination compared with unvaccinated ones.

COVID-19 vaccination status, side effects, and perceptions among breast cancer survivors: a cross-sectional study in China. INTRODUCTION: Breast cancer is the most prevalent malignancy in patients with coronavirus disease 2019 (COVID-19). However, vaccination data of this population are limited. METHODS: A cross-sectional study of COVID-19 vaccination was conducted in China. Multivariate logistic regression models were used to assess factors associated with COVID-19 vaccination status. RESULTS: Of 2,904 participants, 50.2% were vaccinated with acceptable side effects. Most of the participants received inactivated virus vaccines. The most common reason for vaccination was "fear of infection" (56.2%) and "workplace/government requirement" (33.1%). While the most common reason for nonvaccination was "worry that vaccines cause breast cancer progression or interfere with treatment" (72.9%) and "have concerns about side effects or safety" (39.6%). Patients who were employed (odds ratio, ORâ€‰=â€‰1.783, pâ€‰=â€‰0.015), had stage I disease at diagnosis (ORâ€‰=â€‰2.008, pâ€‰=â€‰0.019), thought vaccines could provide protection (ORâ€‰=â€‰1.774, pâ€‰=â€‰0.007), thought COVID-19 vaccines were safe, very safe, not safe, and very unsafe (ORâ€‰=â€‰2.074, pâ€‰<â€‰0.001; ORâ€‰=â€‰4.251, pâ€‰<â€‰0.001; ORâ€‰=â€‰2.075, pâ€‰=â€‰0.011; ORâ€‰=â€‰5.609, pâ€‰=â€‰0.003, respectively) were more likely to receive vaccination. Patients who were 1-3â€‰years, 3-5â€‰years, and more than 5â€‰years after surgery (ORâ€‰=â€‰0.277, pâ€‰<â€‰0.001; ORâ€‰=â€‰0.277, pâ€‰<â€‰0.001, ORâ€‰=â€‰0.282, pâ€‰<â€‰0.001, respectively), had a history of food or drug allergies (ORâ€‰=â€‰0.579, pâ€‰=â€‰0.001), had recently undergone endocrine therapy (ORâ€‰=â€‰0.531, pâ€‰<â€‰0.001) were less likely to receive vaccination. CONCLUSION: COVID-19 vaccination gap exists in breast cancer survivors, which could be filled by raising awareness and increasing confidence in vaccine safety during cancer treatment, particularly for the unemployed individuals.

Case report: mRNA-1273 COVID-19 vaccine-associated myopericarditis: Successful treatment and re-exposure with colchicine. INTRODUCTION: Vaccine-induced myocarditis is a rare complication of messenger RNA (mRNA) COVID-19 vaccines. CASE PRESENTATION: We report a case of acute myopericarditis in a recipient of allogeneic hematopoietic cells following the first dose of the mRNA-1273 vaccine and the successful administration of a second and third dose while on prophylactic treatment with colchicine to successfully complete the vaccination. CONCLUSION: Treatment and prevention of mRNA-vaccine-induced myopericarditis represent a clinical challenge. The use of colchicine is feasible and safe to potentially reduce the risk of this rare but severe complication and allows re-exposure to an mRNA vaccine.

Myopericarditis Following the Third Dose of COVID-19 mRNA Vaccination: A Case Report. Coronavirus disease 2019 (COVID-19) mRNA vaccine-related cases of pericarditis and myocarditis have been reported infrequently. Most of the patients usually present within a week of the vaccine, and on average, most of the cases were reported after the second dose of vaccine within two to four

days. Chest pain was the most common presentation, and feverÂ and shortness of breath were the other commonly reported symptoms. The patients can have positive cardiac markers and electrocardiogram (EKG) changes, and the cases can be mistaken for cardiac emergencies. We present aÂ 17-year-old male patient with sudden onset substernal chest pain for two days who got the third dose of the Pfizer-BioNTechÂ mRNA vaccine within 24 hours prior. EKG was remarkable for diffuse ST elevations, and troponins wereÂ elevated. Later, the cardiac magnetic resonance imaging confirmed the findings of myopericarditis. The patient was treated with colchicine and non-steroidal anti-inflammatory drugs (NSAIDs), completely recovered, and is doing fine to date. This case hights that post-vaccine myocarditis can be mistaken and early diagnosis and management can prevent unnecessary interventions.

The long-term antibody response after SARS-CoV-2 prime-boost vaccination in healthy individuals. The positive influence of extended between-dose intervals and heterologous schedule. INTRODUCTION: Anti-COVID vaccination in Argentina was carried out using different protocols and variations in periods between administrations, as well as combinations of different vaccine platforms. Considering the relevance of the antibody response in viral infections, we analyzed anti-S antibodies in healthy people at different points of time following the Sputnik immunization procedure. METHODS: We attended the vaccination centers in the city of Rosario, which had shorter versus longer intervals between both doses. A total of (1021) adults with no COVID-compatible symptoms (throughout the study period) were grouped according to the gap between both vaccine doses: 21 (Group A, n=528), 30 (Group B, n=147), and 70 days (Group C, n=82), as well as an additional group of individuals with heterologous vaccination (Sputnik/Moderna, separated by a 107-day interval, group D, n=264). RESULTS AND CONCLUSIONS: While there were no between-group differences in baseline levels of specific antibodies, data collected several weeks after administering the second dose showed that group D had the highest amounts of specific antibodies, followed by values recorded in Groups C, B, and A. The same pattern of group differences was seen when measuring anti-S antibodies at 21 or 180 days after the first and second doses, respectively. Delayed between-dose intervals coexisted with higher antibody titers. This happened even more when using a prime-boost heterologous schedule.

COVID-19 vaccine-associated autoimmune disorders: Comments.

Side Effects Reported by Moroccan Medical Students Who Received COVID-19 Vaccines. BACKGROUND: Low confidence in the safety of COVID-19 vaccines was found to be a key promoter of vaccine reluctance especially among youth. Furthermore, young adults are an important demographic for building herd immunity through vaccination. As a result, their reactions to getting COVID-19 vaccines are crucial in our fight against SARS-CoV-2. OBJECTIVE: The overall goal of this study was to look into the shortterm side effects experienced by Moroccan medical and pharmacy students after receiving COVID-19 vaccines. METHODS: A cross-sectional survey-based study to assess the COVID-19 vaccines' short-term AEFIs among Moroccan medical and pharmacy students. The validated questionnaire was delivered in a digital form to explore the side effects (SE) they encountered after the first or the second dose of one of three vaccines namely: AstraZeneca Vaxzevria, PfizerBioNTeck, and SinoPharm vaccines. RESULTS: There were 510 students in total who took part. After the first and second doses, approximately 72 percent and 78 percent of subjects, respectively, reported no SE. The remainder had localized injection site side effects (26%). Fatigue (21%), fever (19%), headache (17%), and myalgia (16%) were the most common systemic adverse effects after the first dose. There were no serious SEs reported. CONCLUSION: The majority of the reported AEFIs in our data were mild to moderate in intensity and lasted only one or two days. COVID-19 vaccinations are highly likely safe for young adults, according to the findings of this study.

COVID-19 vaccination elicited de novo and recurrence of cluster headache: A case series. BACKGROUND: Recent pharmacovigilance studies suggested that cluster headache could be a potential adverse effect after coronavirus disease-2019 (COVID-19) vaccination; however, the possibility of coincidence could not be excluded. Detailed case studies might help elucidate their potential link and implicate potential pathogenic mechanisms. METHODS: Patients who developed cluster headache in close temporal relationship to COVID-19 vaccination were identified from two tertiary medical centers in Japan and Taiwan respectively through 2021-2022. Detailed characteristics of the headaches and time between the onset of the index cluster episode and antecedent COVID-19 vaccination were reported. In patients with previous cluster headaches, the duration from previous bout was also recorded. RESULTS: Six patients with new cluster headache bout 3-17 days after COVID-19 vaccination were identified. Two of them were de novo cases. The others either had been attack-free for a long time or developed new cluster bout in seasons atypical to prior bouts. The vaccines included mRNA, viral vector, or protein subunit vaccines. CONCLUSIONS: COVID-19 vaccines, regardless of vaccine types, may elicit de novo or relapse of cluster headache. Future studies are needed to confirm the potential causality and explore the potential pathogenic mechanism.

Urticaria after breakthrough Omicron BA.5.1 severe acute respiratory syndrome coronavirus 2 infection in a triple-vaccinated (Pfizer) patient: a case report. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 continues to threaten public health. The virus is causing breakthrough infections in vaccinated individuals. Also, scarce information is available about cutaneous manifestations after severe acute respiratory syndrome coronavirus 2 infection. CASE PRESENTATION AND FINDINGS: A case of a triple-vaccinated (Pfizer) 37-year-old Hispanic American (Colombian) male who developed urticaria after Omicron BA.5.1 severe acute respiratory syndrome coronavirus 2 breakthrough infection is described. Virus isolation and whole genome sequencing along with immune and molecular assays were performed. Dermatological manifestations (skin rash and urticaria) after Omicron BA.5.1 infection were observed. Sequence analysis of the Omicron BA.5.1 isolate also revealed several important mutations. Hemogram analysis revealed leukocytosis and neutrophilia. Serology testing revealed anti-spike immunoglobulin G serum titers but negative detection of immunoglobulin M at 10Â days after symptom onset. Anti-nucleocapsid, anti-spike 1 immunoglobulin G, anti-spike trimer, and anti-receptor-binding-domain immunoglobulin G and immunoglobulin E sera were detected at different titers 10Â days after symptom onset. Several serum levels of chemokines/cytokines (Interferon-Î±, interferon-Î³, interleukin-12/interleukin-23p40, interleukin-18, interferon gamma-induced protein-10, monocyte chemoattractant protein-1, monokine induced by gamma, macrophage inflammatory protein-1Î±, chemokine (C-C motif) ligand-5 , tumor necrosis factor-Î²1, Tumor necrosis factor-Î±) were detected, but interleukin-2, interleukin-4, interleukin-6, interleukin-8, and interleukin-17A were below the limit of detection. INTERPRETATION AND CONCLUSIONS: To our knowledge, this is the first study describing skin effects of a severe acute respiratory syndrome coronavirus 2 Omicron BA.5 variant breakthrough infection in a triple-vaccinated patient in Colombia. Several important mutations were found in the spike glycoprotein of the virus isolated; these mutations are associated with immune evasion and changes in antigenic properties of the virus. Physicians overseeing coronavirus disease 2019 cases should be aware of the potential skin effects of the infection. Pathogenesis of severe acute respiratory syndrome coronavirus 2 infection and its association with proinflammatory cytokines and chemokines may enhance the development of urticaria and other skin manifestations in immunized individuals. However, further studies are needed to better understand the complexity of coronavirus disease in such situations.

Antibody response to SARS-CoV-2 WT and Omicron BA.4/5 of inactivated COVID-19 vaccine in patients with lung cancer after second and booster immunization. COVID-19 inactivated vaccine-induced humoral responses in patients with lung cancer (LCs) to SARS-CoV-2 wild-type (WT) strain

and variants BA.4/5 after the primary 2-dose and booster vaccination remained unknown. We conducted a cross-sectional study in 260 LCs, 140 healthy controls (HC) and additional 40 LCs with serial samples by detecting total antibodies, IgG anti-RBD and neutralizing antibodies (NAb) toward WT and BA.4/5. SARS-CoV-2-specific antibody responses were augmented by the booster dose of inactivated vaccines in LCs, whereas they were lower than that in HCs. Enhanced humoral responses waned over time after triple injection, notably in NAb against WT and BA.4/5. The NAb against BA.4/5 was much lower than WT. Ageâ€‰â‰¥â€‰65 was risk factor for immunization of NAb to WT. Undergoing treatment resulted in a lower antibody response than those without and radiotherapy was a also risk factor for seroconversion of NAb to WT. Lower lymphocyte counts contributed to a lower titer of IgG anti-RBD and NAb against BA.4/5 in LCs than HCs. Specifically, total B cells, CD4(+)T cells and CD8(+)T counts were correlated with the humoral response. These results should be taken into consideration for the elderly patients under treatment.

Association between SARS-CoV-2 vaccination and healthcare contacts for menstrual disturbance and bleeding in women before and after menopause: nationwide, register based cohort study. OBJECTIVES: To evaluate the risks of any menstrual disturbance and bleeding following SARS-CoV-2 vaccination in women who are premenopausal or postmenopausal. DESIGN: A nationwide, register based cohort study. SETTING: All inpatient and specialised outpatient care in Sweden from 27 December 2020 to 28 February 2022. A subset covering primary care for 40% of the Swedish female population was also included. PARTICIPANTS: 2â€‰946â€‰448 Swedish women aged 12-74 years were included. Pregnant women, women living in nursing homes, and women with history of any menstruation or bleeding disorders, breast cancer, cancer of female genital organs, or who underwent a hysterectomy between 1 January 2015 and 26 December 2020 were excluded. INTERVENTIONS: SARS-CoV-2 vaccination, by vaccine product (BNT162b2, mRNA-1273, or ChAdOx1 nCoV-19 (AZD1222)) and dose (unvaccinated and first, second, and third dose) over two time windows (one to seven days, considered the control period, and 8-90 days). MAIN OUTCOME MEASURES: Healthcare contact (admission to hospital or visit) for menstrual disturbance or bleeding before or after menopause (diagnosed with the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision codes N91, N92, N93, N95). RESULTS: 2â€‰580â€‰007 (87.6%) of 2â€‰946â€‰448 women received at least one SARS-CoV-2 vaccination and 1â€‰652â€‰472 (64.0%) 2â€‰580â€‰007 of vaccinated women received three doses before the end of follow-up. The highest risks for bleeding in women who were postmenopausal were observed after the third dose, in the one to seven days risk window (hazard ratio 1.28 (95% confidence interval 1.01 to 1.62)) and in the 8-90 days risk window (1.25 (1.04 to 1.50)). The impact of adjustment for covariates was modest. Risk of postmenopausal bleeding suggested a 23-33% increased risk after 8-90 days with BNT162b2 and mRNA-1273 after the third dose, but the association with ChAdOx1 nCoV-19 was less clear. For menstrual disturbance or bleeding in women who were premenopausal, adjustment for covariates almost completely removed the weak associations noted in the crude analyses. CONCLUSIONS: Weak and inconsistent associations were observed between SARS-CoV-2 vaccination and healthcare contacts for bleeding in women who are postmenopausal, and even less evidence was recorded of an association for menstrual disturbance or bleeding in women who were premenopausal. These findings do not provide substantial support for a causal association between SARS-CoV-2 vaccination and healthcare contacts related to menstrual or bleeding disorders.

Efficacy and Safety of a Protein-Based SARS-CoV-2 Vaccine: A Randomized Clinical Trial. IMPORTANCE: The protein-based SARS-CoV-2 vaccines FINLAY-FR-2 (Soberana 02) and FINLAY-FR-1A (Soberana Plus) showed good safety and immunogenicity in phase 1 and 2 trials, but the clinical efficacy of the vaccine remains unknown. OBJECTIVE: To evaluate the efficacy and safety of a 2-dose regimen of FINLAY-FR-2 (cohort 1) and a 3-dose regimen of FINLAY-FR-2 with FINLAY-FR-1A (cohort 2)

in Iranian adults. DESIGN, SETTING, AND PARTICIPANTS: A multicenter, randomized, double-blind, placebo-controlled, phase 3 trial was conducted at 6 cities in cohort 1 and 2 cities in cohort 2. Participants included individuals aged 18 to 80 years without uncontrolled comorbidities, coagulation disorders, pregnancy or breastfeeding, recent immunoglobulin or immunosuppressive therapy, and clinical presentation or laboratory-confirmed COVID-19 on enrollment. The study was conducted from April 26 to September 25, 2021. INTERVENTIONS: In cohort 1, 2 doses of FINLAY-FR-2 (nâ€‰=â€‰13â€¯857) or placebo (nâ€‰=â€‰3462) were administered 28 days apart. In cohort 2, 2 doses of FINLAY-FR-2â€‰plusâ€‰1 dose of FINLAY-FR-1A (nâ€‰=â€‰4340) or 3 placebo doses (nâ€‰=â€‰1081) were administered 28 days apart. Vaccinations were administered via intramuscular injection. MAIN OUTCOMES AND MEASURES: The primary outcome was polymerase chain reaction-confirmed symptomatic COVID-19 infection at least 14 days after vaccination completion. Other outcomes were adverse events and severe COVID-19. Intention-to-treat analysis was performed. RESULTS: In cohort 1 a total 17â€¯319 individuals received 2 doses and in cohort 2 5521 received 3 doses of the vaccine or placebo. Cohort 1 comprised 60.1% men in the vaccine group and 59.1% men in the placebo group; cohort 2 included 59.8% men in the vaccine group and 59.9% in the placebo group. The mean (SD) age was 39.3 (11.9) years in cohort 1 and 39.7 (12.0) years in cohort 2, with no significant difference between the vaccine and placebo groups. The median follow-up time in cohort 1 was 100 (IQR, 96-106) days and, in cohort 2, 142 (137-148) days. In cohort 1, 461 (3.2%) cases of COVID-19 occurred in the vaccine group and 221 (6.1%) in the placebo group (vaccine efficacy: 49.7%; 95% CI, 40.8%-57.3%) vs 75 (1.6%) and 51 (4.3%) in cohort 2 (vaccine efficacy: 64.9%; 95% CI, 49.7%-59.5%). The incidence of serious adverse events was lower than 0.1%, with no vaccine-related deaths. CONCLUSIONS AND RELEVANCE: In this multicenter, randomized, double-blind, placebo-controlled, phase 3 trial of the efficacy and safety of FINLAY-FR-2 and FINLAY-FR-1A, 2 doses of FINLAY-FR-2 plus the third dose of FINLAY-FR-1A showed acceptable vaccine efficacy against symptomatic COVID-19 as well as COVID-19-related severe infections. Vaccination was generally safe and well tolerated. Therefore, Soberana may have utility as an option for mass vaccination of the population, especially in resource-limited settings, because of its storage condition and affordable price. TRIAL REGISTRATION: isrctn.org Identifier: IRCT20210303050558N1.

Evaluation of Waning of SARS-CoV-2 Vaccine-Induced Immunity: A Systematic Review and Meta-analysis. IMPORTANCE: Estimates of the rate of waning of vaccine effectiveness (VE) against COVID-19 are key to assess population levels of protection and future needs for booster doses to face the resurgence of epidemic waves. OBJECTIVE: To quantify the progressive waning of VE associated with the Delta and Omicron variants of SARS-CoV-2 by number of received doses. DATA SOURCES: PubMed and Web of Science were searched from the databases' inception to October 19, 2022, as well as reference lists of eligible articles. Preprints were included. STUDY SELECTION: Selected studies for this systematic review and meta-analysis were original articles reporting estimates of VE over time against laboratory-confirmed SARS-CoV-2 infection and symptomatic disease. DATA EXTRACTION AND SYNTHESIS: Estimates of VE at different time points from vaccination were retrieved from original studies. A secondary data analysis was performed to project VE at any time from last dose administration, improving the comparability across different studies and between the 2 considered variants. Pooled estimates were obtained from random-effects meta-analysis. MAIN OUTCOMES AND MEASURES: Outcomes were VE against laboratory-confirmed Omicron or Delta infection and symptomatic disease and half-life and waning rate associated with vaccine-induced protection. RESULTS: A total of 799 original articles and 149 reviews published in peer-reviewed journals and 35 preprints were identified. Of these, 40 studies were included in the analysis. Pooled estimates of VE of a primary vaccination cycle against laboratory-confirmed Omicron infection and symptomatic disease were both lower than 20% at 6 months from last dose administration. Booster doses restored

VE to levels comparable to those acquired soon after the administration of the primary cycle. However, 9 months after booster administration, VE against Omicron was lower than 30% against laboratory-confirmed infection and symptomatic disease. The half-life of VE against symptomatic infection was estimated to be 87 days (95% CI, 67-129 days) for Omicron compared with 316 days (95% CI, 240-470 days) for Delta. Similar waning rates of VE were found for different age segments of the population. CONCLUSIONS AND RELEVANCE: These findings suggest that the effectiveness of COVID-19 vaccines against laboratory-confirmed Omicron or Delta infection and symptomatic disease rapidly wanes over time after the primary vaccination cycle and booster dose. These results can inform the design of appropriate targets and timing for future vaccination programs.

Long-Term Safety Analysis of the ChAdOx1-nCoV-19 Corona Virus Vaccine: Results from a Prospective Observational Study in Priority Vaccinated Groups in North India. INTRODUCTION: Various vaccines for protection against COVID-19 were provided emergency approval in late 2020 to early 2021. There is a scarcity of long-term safety data for many of these. OBJECTIVE: The main aim of this study is to provide the one-year safety results of the ChAdOx1-nCoV-19/AZD1222 vaccine and determine the risk factors of adverse events of special interest (AESIs) and persistent AESIs. METHODS: This was a prospective observational study conducted from February 2021 to April 2022 in a tertiary hospital in North India and its two associated centers. Health care workers, other frontline workers, and the elderly vaccinated with the ChAdOx1-nCoV-19 vaccine constituted the study population. Individuals were contacted telephonically at pre-decided intervals for one year and health issues of significant concern were recorded. Atypical adverse events developing after a booster dose of the COVID-19 vaccine were assessed. Regression analysis was conducted to determine risk factors of AESI occurrence and determinants of AESIs persisting for at least one month at the time of final telephonic contact. RESULTS: Of 1650 individuals enrolled, 1520 could be assessed at one-year post-vaccination. COVID-19 occurred in 44.1% of participants. Dengue occurred in 8% of participants. The majority of the AESIs belonged to the MedDRA(Â®) SOC of musculoskeletal disorders (3.7% of 1520). Arthropathy (knee joint involvement) was the most common individual AESI (1.7%). Endocrinal disorders such as thyroid abnormalities and metabolic disorders such as newly diagnosed diabetes developed in 0.4% and 0.3% of individuals, respectively. Regression analysis showed females, individuals with a pre-vaccination history of COVID-19, diabetes, hypothyroidism, and arthropathy had 1.78-, 1.55-, 1.82-, 2.47- and 3.9-times higher odds of AESI development. Females and individuals with hypothyroidism were at 1.66- and 2.23-times higher risk of persistent AESIs. Individuals receiving the vaccine after COVID-19 were at 2.85- and 1.94 times higher risk of persistent AESIs compared, respectively, to individuals with no history of COVID-19 and individuals developing COVID-19 after the vaccine. Among participants receiving a booster dose of the COVID-19 vaccine (n = 185), 9.7% developed atypical adverse events of which urticaria and new-onset arthropathy were common. CONCLUSION: Nearly half of the ChAdOx1-nCoV-19 vaccine recipients developed COVID-19 over one year. Vigilance is warranted for AESIs such as musculoskeletal disorders. Females, individuals with hypothyroidism, diabetes, and pre-vaccination history of COVID-19 are at higher risk of adverse events. Vaccines received after natural SARS-CoV-2 infection may increase the risk of persistence of adverse events. Sex and endocrinal differences and timing of the COVID-19 vaccine with respect to natural infection should be explored as determinants of AESIs in the future. Pathogenetic mechanisms of vaccine-related adverse events should be investigated along with comparisons with an unvaccinated arm to delineate the overall safety profile of COVID-19 vaccines.

Effect of COVID-19 vaccinations on menstrual cycle and postmenopausal bleeding among health care workers: A cross-sectional study. OBJECTIVE: To determine the effect of coronavirus disease 2019 (COVID-19) vaccination and its association with sociodemographic factors on the menstrual cycle in premenopausal women and on postmenopausal bleeding. METHODS: This is a retrospective cross-

sectional study conducted between September 22, 2022, and November 30, 2022, via a questionnaire distributed to 359 health care workers (HCWs) at Lebanese American University Medical Center-Rizk Hospital and St John's Hospital. Inclusion criteria included female Lebanese HCWs who were vaccinated and aged 18 to 65â€‰years. RESULTS: Change in cycle length was significantly associated with age (Pâ€‰=â€‰0.025 after the first dose and Pâ€‰=â€‰0.017 after the second dose), level of education (Pâ€‰=â€‰0.013 after the first dose and Pâ€‰=â€‰0.012 after the second dose), and fibroids (Pâ€‰=â€‰0.006 after the second dose and Pâ€‰=â€‰0.003 after the third dose). The change in cycle flow was significantly associated with age (Pâ€‰=â€‰0.028), fibroids (Pâ€‰=â€‰0.002 after the second dose and Pâ€‰=â€‰0.002 after the third dose), bleeding disorders (Pâ€‰=â€‰0.000), and chronic medications (Pâ€‰=â€‰0.007). The change in symptoms was associated with polycystic ovary syndrome (Pâ€‰=â€‰0.021), chronic medications (Pâ€‰=â€‰0.019 after the second dose and Pâ€‰=â€‰0.045 after the third dose), and fibroids (Pâ€‰=â€‰0.000). CONCLUSION: COVID-19 vaccination can influence the menstrual cycle. Age, body mass index, level of education, underlying comorbidities, and use of chronic medications are significantly associated with changes in menstrual length, flow, and symptoms following vaccination.

Evaluating the reactogenicity of COVID-19 vaccines from network-meta analyses. BACKGROUND: Evidence-based reassurances addressing vaccine-related concerns are crucial to promoting primary vaccination, completion of the primary series, and booster vaccination. By summarizing and comparing the reactogenicity of COVID-19 vaccines authorized by the European Medicines Agency, this analysis aims to support in-formed decision-making by the lay public and help overcome vaccine hesitancy. RESEARCH DESIGN AND METHODS: A systematic literature review identified 24 records reporting solicited adverse events for AZD1222, BNT162b2, mRNA-1273, NVX-Cov2373, and VLA2001 in individuals aged 16 or older. Network meta-analyses were conducted for each solicited adverse events reported for at least two vaccines that were not compared head-to-head but could be connected through a common comparator. RESULTS: A total of 56 adverse events were investigated through network meta-analyses within a Bayesian framework with random-effects models. Overall, the two mRNA vaccines were found to be the most reactogenic vaccines. VLA2001 had the highest likelihood of being the least reactogenic vaccine after the first and second vaccine dose, especially for systemic adverse events after the first dose. CONCLUSIONS: The reduced chance of experiencing an adverse event with some COVID-19 vaccines may help to overcome vaccine hesitancy in population groups with concerns about the side effects of vaccines.

Vaccination Status and Trends in Adult Coronavirus Disease 2019-Associated Hospitalizations by Race and Ethnicity: March 2020-August 2022. BACKGROUND: We sought to determine whether race/ethnicity disparities in severe coronavirus disease 2019 (COVID-19) outcomes persist in the era of vaccination. METHODS: Population-based age-adjusted monthly rate ratios (RRs) of laboratory-confirmed COVID-19-associated hospitalizations were calculated among adult patients from the COVID-19-Associated Hospitalization Surveillance Network, March 2020 - August 2022 by race/ethnicity. Among randomly sampled patients July 2021 - August 2022, RRs for hospitalization, intensive care unit (ICU) admission, and in-hospital mortality were calculated for Hispanic, Black, American Indian/Alaskan Native (AI/AN), and Asian/Pacific Islander (API) persons vs White persons. RESULTS: Based on data from 353 807 patients, hospitalization rates were higher among Hispanic, Black, and AI/AN vs White persons March 2020 - August 2022, yet the magnitude declined over time (for Hispanic persons, RR = 6.7; 95% confidence interval [CI], 6.5-7.1 in June 2020 vs RR < 2.0 after July 2021; for AI/AN persons, RR = 8.4; 95% CI, 8.2-8.7 in May 2020 vs RR < 2.0 after March 2022; and for Black persons RR = 5.3; 95% CI, 4.6-4.9 in July 2020 vs RR < 2.0 after February 2022; all P â‰¤ .001). Among 8706 sampled patients July 2021 - August 2022, hospitalization and ICU admission RRs were higher for Hispanic, Black, and AI/AN patients (range for both, 1.4-2.4) and lower for API (range for

both, 0.6-0.9) vs White patients. All other race and ethnicity groups had higher in-hospital mortality rates vs White persons (RR range, 1.4-2.9). CONCLUSIONS: Race/ethnicity disparities in COVID-19-associated hospitalizations declined but persist in the era of vaccination. Developing strategies to ensure equitable access to vaccination and treatment remains important.

Eosinophilic fasciitis following SARS-CoV-2 vaccination.

Complete childhood vaccination and associated factors among children aged 12-23 months in Dabat demographic and health survey site, Ethiopia, 2022. INTRODUCTION: Childhood immunization is one of the most cost-effective public health strategies to prevent children's mortality and morbidity from infectious diseases, but the Covid-19 pandemic and associated disruptions have strained health systems, and worldwide 25Â million children missing out on vaccination in 2021. Of the 25Â million, more than 60% of these children live in 10 countries including Ethiopia. Therefore, this study aimed to assess complete childhood vaccination coverage and associated factors in the Dabat district. METHOD: A community-based cross-sectional study was conducted from December 10/2020 to January 10/2021Gregorian Calendar. The data for this study was extracted from information collected for the assessment of maternal, Neonatal, and Child Health and health services utilization in the Dabat demographic and health survey site. Vaccine-related data were collected using an interviewer-administered questionnaire. An adjusted odds ratio with a 95% confidence interval was used to identify the presence and the direction of the association. RESULTS: Based on vaccination cards and mothers/caretakers' recall 30.9% (95%CI: 27.9-34.1%) of children aged 12-23 months in the Dabat district were completely immunized. Urban residency [AOR 1.813, 95% CI: (1.143, 2.878)], delivered in the health facility [AORâ€‰=â€‰5.925, 95% CI: (3.680, 9.540)], ANC follow-up during their pregnancy [AOR 2.023, 95% CI: (1.352, 3.027)], rich wealth index [AORâ€‰=â€‰2.392, 95% CI: (1.296, 4.415)], and parity [AOR 2.737, 95% CI: (1.664, 4.500)] were significantly associated with complete child vaccination. RECOMMENDATION AND CONCLUSION: Complete vaccination coverage among children aged 12-23 months in the Dabat district was lower than the Global vaccine plan and Ethiopian ministry of health goal in 2020. Therefore, Health care providers and other stakeholders should mobilize the community to improve mothers' health-seeking behavior toward pregnancy follow-up and health facility delivery to improve childhood vaccination. Besides, expanding the service to remote areas are necessary to increase the immunization access.

Risk assessment of retinal vascular occlusion after COVID-19 vaccination. Coronavirus disease 2019 (COVID-19) vaccines are associated with several ocular manifestations. Emerging evidence has been reported; however, the causality between the two is debatable. We aimed to investigate the risk of retinal vascular occlusion after COVID-19 vaccination. This retrospective cohort study used the TriNetX global network and included individuals vaccinated with COVID-19 vaccines between January 2020 and December 2022. We excluded individuals with a history of retinal vascular occlusion or those who used any systemic medication that could potentially affect blood coagulation prior to vaccination. To compare the risk of retinal vascular occlusion, we employed multivariable-adjusted Cox proportional hazards models after performing a 1:1 propensity score matching between the vaccinated and unvaccinated cohorts. Individuals with COVID-19 vaccination had a higher risk of all forms of retinal vascular occlusion in 2 years after vaccination, with an overall hazard ratio of 2.19 (95% confidence interval 2.00-2.39). The cumulative incidence of retinal vascular occlusion was significantly higher in the vaccinated cohort compared to the unvaccinated cohort, 2 years and 12 weeks after vaccination. The risk of retinal vascular occlusion significantly increased during the first 2 weeks after vaccination and persisted for 12 weeks. Additionally, individuals with first and second dose of BNT162b2 and mRNA-1273 had significantly increased risk of retinal vascular occlusion 2 years following vaccination, while no disparity was detected between brand and dose of vaccines.

This large multicenter study strengthens the findings of previous cases. Retinal vascular occlusion may not be a coincidental finding after COVID-19 vaccination.

Hypertension and myocarditis following COVID-19 vaccination. Two sides of the coin?

Letter re: SARS-CoV-2 vaccine in patients with thymic epithelial tumours with and without active or pre-existing autoimmune disorders: Brief report of a TYME network safety analysis.

Acute cardiac events after COVID-19 vaccines and during spontaneous SARS-CoV-2 infection.

SARS-CoV-2 vaccination in the first year after allogeneic hematopoietic cell transplant: a prospective, multicentre, observational study. BACKGROUND: The optimal timing for SARS-CoV-2 vaccines within the first year after allogeneic hematopoietic cell transplant (HCT) is poorly understood. METHODS: We conducted a prospective, multicentre, observational study of allogeneic HCT recipients who initiated SARS-CoV-2 vaccinations within 12 months of HCT. Participants were enrolled at 22 academic cancer centers across the United States. Participants of any age who were planning to receive a first post-HCT SARS-CoV-2 vaccine within 12 months of HCT were eligible. We obtained blood prior to and after each vaccine dose for up to four vaccine doses, with an end-of-study sample seven to nine months after enrollment. We tested for SARS-CoV-2 spike protein (anti-S) IgG; nucleocapsid protein (anti-N) IgG; neutralizing antibodies for Wuhan D614G, Delta B.1.617.2, and Omicron B.1.1.529 strains; and SARS-CoV-2-specific T-cell receptors (TCRs). The primary outcome was a comparison of anti-S IgG titers at the post-V2 time point in participants initiating vaccinations <4 months versus 4-12 months after HCT using a propensity-adjusted analysis. We also evaluated factors associated with high-level anti-S IgG titers (â‰¥2403 U/mL) in logistic regression models. FINDINGS: Between April 22, 2021 and November 17, 2021, 175 allogeneic HCT recipients were enrolled in the study, of whom all but one received mRNA SARS-CoV-2 vaccines. SARS-CoV-2 anti-S IgG titers, neutralizing antibody titers, and TCR breadth and depth did not significantly differ at all tested time points following the second vaccination among those initiating vaccinations <4 months versus 4-12 months after HCT. Anti-S IgG â‰¥2403 U/mL correlated with neutralizing antibody levels similar to those observed in a prior study of non-immunocompromised individuals, and 57% of participants achieved anti-S IgG â‰¥2403 U/mL at the end-of-study time point. In models adjusted for SARS-CoV-2 infection pre-enrollment, SARS-CoV-2 vaccination pre-HCT, CD19+ B-cell count, CD4+ T-cell count, and age (as applicable to the model), vaccine initiation timing was not associated with high-level anti-S IgG titers at the post-V2, post-V3, or end-of-study time points. Notably, prior graft-versus-host-disease (GVHD) or use of immunosuppressive medications were not associated with high-level anti-S IgG titers. Grade â‰¥3 vaccine-associated adverse events were infrequent. INTERPRETATION: These data support starting mRNA SARS-CoV-2 vaccination three months after HCT, irrespective of concurrent GVHD or use of immunosuppressive medications. This is one of the largest prospective analyses of vaccination for any pathogen within the first year after allogeneic HCT and supports current guidelines for SARS-CoV-2 vaccination starting three months post-HCT. Additionally, there are few studies of mRNA vaccine formulations for other pathogens in HCT recipients, and these data provide encouraging proof-of-concept for the utility of early vaccination targeting additional pathogens with mRNA vaccine platforms. FUNDING: National Marrow Donor Program, Leukemia and Lymphoma Society, Multiple Myeloma Research Foundation, Novartis, LabCorp, American Society for Transplantation and Cellular Therapy, Adaptive Biotechnologies, and the National Institutes of Health.

Atypical clinical features of post COVID-19 mucormycosis: A case series. OBJECTIVES: This case series aims to evaluate patients affected with post COVID-19 mucormycosis from clinical presentation to surgical and pharmacological treatment to improve the disease prognosis. MATERIAL AND METHODS: This case series was conducted at a specialized surgery hospital in Baghdad Medical City for over 10 months. Fifteen cases who had mild to severe COVID-19 infections followed by symptoms similar to aggressive periodontitis, such as mobility and bone resorption around the multiple

maxillary teeth, were included in this case series. RESULTS: All patients did not receive COVID-19 vaccination; seven had a history of diabetes mellitus type 2, another five patients had a history of diabetes-like syndrome during the COVID-19 infection, and the remaining three patients had no history of any systemic diseases. No intracranial involvement was seen in all patients, and bilateral sinus involvement was seen in three patients. CONCLUSION: Being highly suspicious of all patients affected with COVID-19 is highly recommended to avoid the complications of the late diagnosis of mucormycosis. In addition, our knowledge and methods in diagnosing and treating classical mucormycosis should be modified regarding post COVID-19 mucormycosis.

Anti-RBD IgG antibodies and neutralizing antibody levels after the second BNT162b2 dose in patients with plasma cell disorders. Patients with plasma cell disorders (PCD) are at an increased risk for severe morbidity and mortality due to COVID-19. Recent data have suggested that patients with hematological malignancies, including those with PCD, have suboptimal antibody response to COVID-19 vaccination. We compared the antibody titers of 213 patients with PCD to those of 213 immunocompetent healthcare workers after the second vaccine dose of the BNT162b2 mRNA vaccine. Blood samples were taken 2-4 weeks after the second vaccination and analyzed for anti-receptor binding-domain immunoglobulin G (RBD-IgG) antibodies and neutralizing antibodies (NA). At a median of 20 days after the second vaccine dose, 172 patients (80.8%) developed anti-RBD-IgG antibodies with a geometric mean titer (GMT) of 2.7 (95% confidence interval [CI], 2.4-3.1). In the control group 210 (98.9%) developed anti-RBD-IgG antibodies after a median of 21 days, with a GMT of 5.17 (95%CI, 4.8-5.6), p<0.0001. NA were observed in 151 patients with MM (70.9%) and in 210 controls (98.9%). The GMT of NA in patients with MM and controls was 84.4 (95% CI, 59.0-120.6), and 420.2 (95% CI, 341.4-517.1), respectively (p<0.0001). Multivariable logistic regression revealed that the number of prior therapy lines and age were significant predictors of poor humoral response among patients with MM. Injection site reaction, headache and fatigue were the most common adverse events after vaccination. Adverse events were less common in patients with MM than in controls. In conclusion, a significant percentage of patients with MM developed protecting NA to the BNT162b2 mRNA vaccine, which appears to be safe in this patient population.

Factors Associated With Influenza Vaccination During the COVID-19 Pandemic in Older Adults Residing in Brazil. The current study aimed to assess influenza vaccination coverage and explore factors related to vaccine uptake in older adults in 2020 amid the coronavirus disease 2019 pandemic. A cross-sectional study using an online questionnaire was performed with 380 older adults (aged â‰¥60 years), living in Brazil, from May 26 to June 29, 2020. Data regarding sociodemographic, health, and social support variables were collected. Data were analyzed using Poisson regression with robust variance. Influenza vaccination coverage in the sample was 85.5% (95% confidence interval [81.6, 88.7]). Older adults with increased age had higher vaccination coverage, whereas those who were smokers, not wearing masks, and sometimes and never/almost never received professional support had lower vaccination rates. Data show that vaccine coverage for influenza in 2020 was below that recommended by Brazilian authorities. We reinforce the importance of information about the influenza vaccine, especially for younger older adults, smokers, and those who do not wear masks. Reliable information from health care professionals and the media is essential for vaccination during a pandemic. [Journal of Gerontological Nursing, 49(5), 31-38.].

Collagenous colitis following SARS-Cov2 mRNA vaccination. A healthy 49-year-old female developed intractable watery diarrhea after the Pfizer SARS-Cov2 mRNA vaccination. She was subsequently diagnosed with collagenous colitis (CC). She had no prior history of medication use, suggesting of vaccination being the trigger. CC or lymphocytic colitis should be considered as differential diagnoses for persistent watery diarrhea after SARS-Cov2 mRNA vaccination.

A recombinant spike-XBB.1.5 protein vaccine induces broad-spectrum immune responses against XBB.1.5-included Omicron variants of SARS-CoV-2. The XBB.1.5 subvariant has drawn great attention owing to its exceptionality in immune evasion and transmissibility. Therefore, it is essential to develop a universally protective coronavirus disease 2019 vaccine against various strains of Omicron, especially XBB.1.5. In this study, we evaluated and compared the immune responses induced by six different spike protein vaccines targeting the ancestral or various Omicron strains of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in mice. We found that spike-wild-type immunization induced high titers of neutralizing antibodies (NAbs) against ancestral SARS-CoV-2. However, its activity in neutralizing Omicron subvariants decreased sharply as the number of mutations in receptor-binding domain (RBD) of these viruses increased. Spike-BA.5, spike-BF.7, and spike-BQ.1.1 vaccines induced strong NAbs against BA.5, BF.7, BQ.1, and BQ.1.1 viruses but were poor in protecting against XBB and XBB.1.5, which have more RBD mutations. In sharp contrast, spike-XBB.1.5 vaccination can activate strong and broadly protective immune responses against XBB.1.5 and other common subvariants of Omicron. By performing correlation analysis, we found that the NAbs titers were negatively correlated with the number of RBD mutations in the Omicron subvariants. Vaccines with more RBD mutations can effectively overcome the immune resistance caused by the accumulation of RBD mutations, making spike-XBB.1.5 the most promising vaccine candidate against universal Omicron variants.

Time Course of Antispike Antibody Titer after Administration of BNT162b2 mRNA COVID-19 Vaccine in a Patient with Rheumatoid Arthritis on Methotrexate. Methotrexate, an anchor drug for rheumatoid arthritis, hinders the immunogenicity of mRNA COVID-19 vaccines. Therefore, an optimal vaccine strategy for patients with rheumatoid arthritis receiving methotrexate is vital. We monitored antispike antibody titers after BNT162b2 mRNA COVID-19 vaccination in seven healthcare workers and one methotrexate-treated rheumatoid arthritis patient. The antispike antibody titers of healthcare workers significantly increased immediately after primary vaccination and then continued to decrease, whereas those of the rheumatoid arthritis patient were significantly lower immediately after primary vaccination and then increased. The titers in all participants dramatically increased 1-month postbooster. These changes over time may suggest that in the methotrexate-treated rheumatoid arthritis patient, the generation of short-lived plasma cells was strongly suppressed; in contrast, the generation of long-lived plasma cells and memory B cells was intact. For methotrexate-treated rheumatoid arthritis patients, it is important to complete the primary and booster vaccination series to ensure sufficient immunity against COVID-19.

Post-COVID-19 condition in patients with autoimmune rheumatic diseases: the COVID-19 Vaccination in Autoimmune Diseases (COVAD) study.

Real-world evidence of autoimmune hepatitis following COVID-19 vaccination: A population-based pharmacovigilance analysis. Objective: Autoimmune hepatitis (AIH) has occasionally been reported after administration of Coronavirus Disease 2019 (COVID-19) vaccine. The present study aimed to investigate the reported rate and disproportionality of AIH following COVID-19 vaccination. Methods: The Centers for Disease Control (CDC) COVID Data Tracker and the Vaccines Adverse Event Reporting System (VAERS) were queried between 11 December 2020 and 15 March 2022. Reported rates were calculated by cases of AIH divided by the number of vaccinated people. Disproportionate pattern of AIH for COVID-19 vaccination was accessed based on the reporting odds ratio and empirical bayes geometric mean (ROR and EBGM, respectively). Results: A total of 53 reports of AIH were identified after administration of COVID-19 vaccine during the study period. The overall reported rate of COVID-19 vaccination-related AIH was 0.21 (95% CI 0.16-0.27) per million people. The results found no disproportionate reporting of AIH following COVID-19 vaccination in the VAERS (overall: ROR 1.43, 95% CI 0.52-3.96; EBGM05 0.37. mRNA: ROR 1.42, 95% CI 0.51-3.94; EBGM05

0.37. Virus vector: ROR 1.57, 95% CI 0.42-5.85; EBGM05 0.34). Conclusion: COVID-19 vaccine did not increase the risk of AIH. The number of AIH cases reported to VAERS does not suggest a safety concern attributable to COVID-19 vaccine at this time.

Rapid evaluation of heterologous chimeric RBD-dimer mRNA vaccine for currently-epidemic Omicron sub-variants as booster shot after inactivated vaccine. With continuous mutations of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the severe immune escape of Omicron sub-variants urges the development of next-generation broad-spectrum vaccines, especially as booster jabs after high-level vaccination coverage of inactivated vaccines in China and many other countries. Previously, we developed a coronavirus disease 2019 (COVID-19) protein subunit vaccine ZF2001Â® based on the tandem homo-prototype receptor-binding domain (RBD)-dimer of the SARS-CoV-2 spike protein. We upgraded the antigen into a hetero-chimeric prototype (PT)-Beta or Delta-BA.1 RBD-dimer to broaden the cross-protection efficacy and prove its efficiency with protein subunit and mRNA vaccine platforms. Herein, we further explored the hetero-chimeric RBD-dimer mRNA vaccines and evaluated their broad-spectrum activities as booster jabs following two doses of inactivated vaccine (IV) in mice. Our data demonstrated that the chimeric vaccines significantly boosted neutralizing antibody levels and specific T-cell responses against the variants, and PT-Beta was superior to Delta-BA.1 RBD as a booster in mice, shedding light on the antigen design for the next-generation COVID-19 vaccines.

Comparison of the Onset and End of Specific and Major Side Effects in Iranian Teenage Participants Vaccinated With COVID-19 Vaccine: Sinopharm and Soberana. BACKGROUND: Clinical trials were conducted on children on side effects after vaccination. We tried to assess the frequency and onset of the main symptoms in children who were vaccinated. We aimed to evaluate early and delayed adverse effects after coronavirus disease 2019 (COVID-19) vaccine among Iranian pediatrics and adolescents in a national survey. METHODS: This cross-sectional study included people <18 years who received the Soberana (PastoCoVac) and Sinopharm vaccines since 2021. The basic information was gender, age, type of vaccine, and reaction after vaccination besides the main events that occurred for them. The required data were collected via a predetermined checklist by trained interviewers through phone calls by their parents or legal guardians. The independent t test and Fisher exact test were used. P values less than 0.05 were considered significant. RESULTS: A total of 11,042 participants (age range, 10-18 years) consisting of 5374 boys (47.8%) and 5768 girls (52.2%) were studied and 88.1% of the children (n = 9727) were vaccinated by Sinopharm and 11.9% (n = 1315) by Soberana. The data of kidney-related side effects had delayed improvement of side effects after the Sinopharm compared with the Soberana vaccines (P = 0.012). Cardiovascular and hematological side effects showed early-onset (P = 0.006) and delayed improvement of side effects (P = 0.002) after the Soberana vaccine compared with the Sinopharm vaccine. Neurological side effects showed delayed improvement of side effects after the Soberana vaccine compared with the Sinopharm vaccine (P = 0.027). Joint-related side effects showed early-onset (P = 0.004) and delayed improvement of side effects (P = 0.023) after the Soberana vaccine compared with the Sinopharm vaccine. Respiratory side effects showed delayed improvement of side effects after the Soberana vaccine compared with the Sinopharm vaccine (P = 0.013), and dermatological side effects showed early-onset (P = 0.050) and delayed improvement of side effects (P = 0.035) after the Soberana vaccine compared with the Sinopharm vaccine. There was not any statistically significant difference regarding gastrointestinal side effects between the 2 vaccines (P > 0.05). CONCLUSION: The cardiovascular and hematological, joint-related (non-neurologic musculoskeletal) and dermatological side effects after the Soberana vaccine appear earlier and end later compared with the Sinopharm vaccine. Improvement of renal side effects in the Sinopharm vaccine group and improvement of neurological and respiratory side effects in the Soberana vaccine group occurred with delay compared with other vaccines.

Adverse events following COVID-19 immunisation (AEFI) at a COVID-19 vaccination centre: An observational analytical study. OBJECTIVES: The aim of this study was to determine the adverse events following immunisation (AEFI) in various age groups after coronavirus disease 2019 (COVID-19) vaccination and assess the association of comorbidities with AEFI. METHODS: An observational analytical study was conducted among the general population who had received both doses of the COVID-19 vaccine. A total of 389 participants from the 18-44 years age group, 380 participants from the 45-60 years age group and 373 participants from the 60 plus age group were enrolled in the study after verbal and written consent. Simple random sampling was used to select the study participant in each group. Home visits were made to fill out the semi-structured questionnaire for information regarding any adverse event following COVID-19 immunisation. RESULTS: Overall, 31.9%, 19.74% and 15.17% of >60, 45-60 and 18-44 years, respectively, reported any AEFI after COVID-19 immunisation. The severity of AEFI was more among the 18-44 years age group (66.1%) followed by 45-60 years (30.67%) and less among the older one, that is, >60 years. Fever and pain with inflammation at the injection site were the most common AEFI reported after any dose. There was no association of comorbidity with the severity of AEFI. CONCLUSION: Since the AEFI reported are very less, most of them were of a minor type and were general immunogenic reactions of any vaccine. Hence the COVID-19 vaccines are very safe, and uptake should be high among all the recommended age groups to combat the severity of the COVID-19 disease.

Bipolar I Disorder Exacerbation and COVID-19 Vaccination: Correspondence.

Platelet-activating functional assay resolution in vaccine-induced immune thrombotic thrombocytopenia: differential alignment to PF4 ELISA platforms. BACKGROUND: Anti-platelet factor 4 (PF4) antibodies in vaccine-induced immune thrombotic thrombocytopenia (VITT) appear to be transient, with discrepant persistence depending on the platform used for detection. OBJECTIVES: We aimed to report a longitudinal study of antibody persistence using 2 ELISA platforms and 2 platelet-activating functional assays in a clinical cohort of patients with VITT referred for follow-up testing. METHODS: In total, 32 Australian patients with VITT or pre-VITT, confirmed by expert adjudication, with samples referred for clinical follow-up were included. Clinical follow-up assays, including Stago and Hyphen ELISAs, procoagulant platelet flow cytometry, and modified PF4-serotonin-release assay, were performed according to the pattern of reactivity for that patient at diagnosis. RESULTS: The median follow-up was 24 weeks after diagnosis. A general decline in anti-PF4 antibody levels and platelet-activating capacity over time was observed with a more rapid median time to resolution of 16 weeks by functional assay vs 24 weeks by Stago ELISA. Decline in platelet-activating antibody levels detected by functional assays mirrored Stago ELISA titer but not Hyphen. However, 87% of patients received a documented second vaccination and 74% received an mRNA booster with no reported adverse events. CONCLUSION: Anti-PF4 antibodies persist longer than functional platelet-activating antibodies in VITT but do not warrant avoidance of subsequent vaccinations. Persistence detection is assay-dependent. Stago ELISA may be a surrogate where functional assays are unavailable for follow-up testing of confirmed patients with VITT.

[Epstein-Barr virus-associated lymphoproliferative disorders after BNT162b2 mRNA COVID-19 vaccination]. Epstein-Barr virus-associated lymphoproliferative disorders (EBV-LPD) is a rare disease characterized by persistent or recurrent inflammation accompanied by EBV infection of T or NK cells that is not self-limiting, and it is fatal, if untreated. After receiving the first dose of the BNT162b2 mRNA COVID-19 vaccine, a 79-year-old male presented to the hospital with a 2-week history of fever. Laboratory results indicated pancytopenia, elevated liver transaminase levels, hyperferritinemia, and hypofibrinogenemia. Computed tomography revealed hepatosplenomegaly, but lymphadenopathy was not observed. A bone marrow biopsy, a random skin biopsy, and a liver biopsy revealed no malignancy, but an infectious evaluation revealed EBV viremia (5.19 Log IU/ml).

Flow cytometry and RT-PCR revealed that the EBV genome was localized in NK cells, suggesting the diagnosis of EBV-NK-LPD. We administered prednisolone, intravenous immunoglobulin, and etoposide, but the EBV-DNA load failed to decrease, and he died 2 months later. Recently, case reports of COVID-19 vaccination-related hemophagocytic lymphohistiocytosis have been published. Although the mechanisms and risk factors for EBV-LPD after BNT162b2 mRNA COVID-19 vaccination remain unknown, it is important to note the possibility of reactivation of EBV after COVID-19 vaccination to initiate early and targeted therapy.

Febrile Reactions Associated with High IgG Antibody Titers after the Second and Third BNT162b2 Vaccinations in Japan. Adverse events are potentially associated with an IgG response after BNT162b2 vaccination for severe acute respiratory syndrome coronavirus 2. In this study, we investigated the side effects of the BNT162b2 vaccine using a health questionnaire and examined its relationship with IgG antibody titers. Serum samples were collected from participants 3 months after the second vaccination, immediately before the third vaccination, and 1 and 3 months after the third vaccination. A total of 505 participants who received three doses of vaccine were eligible for inclusion in the analysis. The results showed that post-vaccination body temperature correlated with anti-spike-receptor-binding domain (anti-S-RBD) antibody titers measured 3 months after the second ($r = 0.30$, $P < 0.001$) and third ($r = 0.14$, $P < 0.001$) vaccinations. Multivariate linear regression analysis revealed that age and severe swelling were negatively associated, whereas female sex, body temperature, and heat sensation were positively associated with log-transformed anti-S-RBD antibody levels after the second vaccination. After the third vaccination, body temperature and fatigue were positively associated, and female sex was negatively associated, with the log-transformed anti-S-RBD antibody levels. These results suggest that post-vaccination fever may be a marker of a high antibody titer.

Sex differences in the efficacy and safety of SARS-CoV-2 vaccination in residents of long-term care facilities: insights from the GeroCovid Vax study. Despite the reported sex-related variations in the immune response to vaccination, whether the effects of SARS-CoV-2 vaccination differ by sex is still under debate, especially considering old vulnerable individuals, such as long-term care facilities (LTCFs) residents. This study aimed to evaluate COVID-19 infections, adverse events, and humoral response after vaccination in a sample of LTCF residents. A total of 3259 LTCF residents (71% females; mean age: 83.4â€‰Â±â€‰9.2Â years) were enrolled in the Italian-based multicenter GeroCovid Vax study. We recorded the adverse effects occurring during the 7Â days after vaccine doses and COVID-19 cases over 12Â months post-vaccination. In a subsample of 524 residents (69% females), pre- and post-vaccination SARS-CoV-2 trimeric S immunoglobulin G (Anti-S-IgG) were measured through chemiluminescent assays at different time points. Only 12.1% of vaccinated residents got COVID-19 during the follow-up, without any sex differences. Female residents were more likely to have local adverse effects after the first dose (13.3% vs. 10.2%, pâ€‰=â€‰0.018). No other sex differences in systemic adverse effects and for the following doses were recorded, as well as in anti-S-IgG titer over time. Among the factors modifying the 12-month anti-S-IgG titers, mobility limitations and depressive disorder were more likely to be associated with higher and lower levels in the antibody response, respectively; a significantly lower antibody titer was observed in males with cardiovascular diseases and in females with diabetes or cognitive disorders. The study suggests that, among LTCF residents, SARS-CoV-2 vaccination was effective regardless of sex, yet sex-specific comorbidities influenced the antibody response. Local adverse reactions were more common in females.

Changes in COVID-19-related mortality across key demographic and clinical subgroups in England from 2020 to 2022: a retrospective cohort study using the OpenSAFELY platform. BACKGROUND: COVID-19 has been shown to differently affect various demographic and clinical population subgroups. We aimed to describe trends in absolute and relative COVID-19-related mortality risks

across clinical and demographic population subgroups during successive SARS-CoV-2 pandemic waves. METHODS: We did a retrospective cohort study in England using the OpenSAFELY platform with the approval of National Health Service England, covering the first five SARS-CoV-2 pandemic waves (wave one [wild-type] from March 23 to May 30, 2020; wave two [alpha (B.1.1.7)] from Sept 7, 2020, to April 24, 2021; wave three [delta (B.1.617.2)] from May 28 to Dec 14, 2021; wave four [omicron (B.1.1.529)] from Dec 15, 2021, to April 29, 2022; and wave five [omicron] from June 24 to Aug 3, 2022). In each wave, we included people aged 18-110 years who were registered with a general practice on the first day of the wave and who had at least 3 months of continuous general practice registration up to this date. We estimated crude and sex-standardised and age-standardised wave-specific COVID-19-related death rates and relative risks of COVID-19-related death in population subgroups. FINDINGS: 18â€ˆ895â€ˆ870 adults were included in wave one, 19â€ˆ014â€ˆ720 in wave two, 18â€ˆ932â€ˆ050 in wave three, 19â€ˆ097â€ˆ970 in wave four, and 19â€ˆ226â€ˆ475 in wave five. Crude COVID-19-related death rates per 1000 person-years decreased from 4Â·48 deaths (95% CI 4Â·41-4Â·55) in wave one to 2Â·69 (2Â·66-2Â·72) in wave two, 0Â·64 (0Â·63-0Â·66) in wave three, 1Â·01 (0Â·99-1Â·03) in wave four, and 0Â·67 (0Â·64-0Â·71) in wave five. In wave one, the standardised COVID-19-related death rates were highest in people aged 80 years or older, people with chronic kidney disease stage 5 or 4, people receiving dialysis, people with dementia or learning disability, and people who had received a kidney transplant (ranging from 19Â·85 deaths per 1000 person-years to 44Â·41 deaths per 1000 person-years, compared with from 0Â·05 deaths per 1000 person-years to 15Â·93 deaths per 1000 person-years in other subgroups). In wave two compared with wave one, in a largely unvaccinated population, the decrease in COVID-19-related mortality was evenly distributed across population subgroups. In wave three compared with wave one, larger decreases in COVID-19-related death rates were seen in groups prioritised for primary SARS-CoV-2 vaccination, including people aged 80 years or older and people with neurological disease, learning disability, or severe mental illness (90-91% decrease). Conversely, smaller decreases in COVID-19-related death rates were observed in younger age groups, people who had received organ transplants, and people with chronic kidney disease, haematological malignancies, or immunosuppressive conditions (0-25% decrease). In wave four compared with wave one, the decrease in COVID-19-related death rates was smaller in groups with lower vaccination coverage (including younger age groups) and conditions associated with impaired vaccine response, including people who had received organ transplants and people with immunosuppressive conditions (26-61% decrease). INTERPRETATION: There was a substantial decrease in absolute COVID-19-related death rates over time in the overall population, but demographic and clinical relative risk profiles persisted and worsened for people with lower vaccination coverage or impaired immune response. Our findings provide an evidence base to inform UK public health policy for protecting these vulnerable population subgroups. FUNDING: UK Research and Innovation, Wellcome Trust, UK Medical Research Council, National Institute for Health and Care Research, and Health Data Research UK.

Neurological Adverse Reactions to SARS-CoV-2 Vaccines. SARS-CoV-2 vaccines are not free of side effects and most commonly affect the central or peripheral nervous system (CNS, PNS). This narrative review aims to summarise recent advances in the nature, frequency, management, and outcome of neurological side effects from SARS-CoV-2 vaccines. CNS disorders triggered by SARS-CoV-2 vaccines include headache, cerebro-vascular disorders (venous sinus thrombosis [VST], ischemic stroke, intracerebral hemorrhage, subarachnoid bleeding, reversible, cerebral vasoconstriction syndrome, vasculitis, pituitary apoplexy, Susac syndrome), inflammatory diseases (encephalitis, meningitis, demyelinating disorders, transverse myelitis), epilepsy, and a number of other rarely reported CNS conditions. PNS disorders related to SARS-CoV-2 vaccines include neuropathy of cranial nerves,

mono-/polyradiculitis (Guillain-Barre syndrome [GBS]), Parsonage-Turner syndrome (plexitis), small fiber neuropathy, myasthenia, myositis/dermatomyositis, rhabdomyolysis, and a number of other conditions. The most common neurological side effects are facial palsy, intracerebral hemorrhage, VST, and GBS. The underlying pathophysiology is poorly understood, but several speculations have been generated to explain the development of CNS/PNS disease after SARS-CoV-2 vaccination. In conclusion, neurological side effects develop with any type of SARS-CoV-2 vaccine and are diverse, can be serious and even fatal, and should be taken seriously to initiate early treatment and improve outcome and avoid fatalities.

Influence of epidemiological and clinical factors in the reactogenicity to ComirnatyÂ® vaccine in health care workers of a Spanish university teaching hospital (COVIVAC study). OBJECTIVE: ComirnatyÂ® is an mRNA vaccine against COVID-19 which has been administered to millions of people since the end of 2020. Our aim was to study epidemiological and clinical factors influencing reactogenicity and functional limitation after the first two doses of the vaccine in health care workers (HCWs). METHODS: Prospective post-authorization cohort study to monitor safety and effectiveness of the vaccine. RESULTS: Local side effects were mild and presented both with first and second dose of Comirnaty. Systemic side effects were more frequent after 2nd dose. Nevertheless, previous SARS-CoV-2 infection was associated with systemic effects after the first dose of the vaccine (OR ranging from 2 to 6). No severe adverse effects were reported. According to multivariate analysis, the degree of self-reported functional limitation after the first dose increased with age, female sex, previous COVID-19 contact, previous SARS-CoV-2 infection, and Charlson Comorbidity Index (CCI). After the second dose, the degree of functional limitation observed was lower in those with previous SARS-CoV-2 infection, and it was positively associated to the degree of functional limitation after the first dose. CONCLUSIONS: Systemic adverse effects were more frequent after the second dose of Comirnaty. Previous SARS-CoV-2 infection was associated with systemic effects after the first dose. Age, female sex, previous COVID-19, previous isolation due to COVID-19 contact, and CCI showed to be independent predictors of the degree of functional limitation after the 1st dose of ComirnatyÂ®. After the 2nd dose, the degree of functional limitation was lower in those who previously had SARS-CoV-2 infection.

BNT162b2 or CoronaVac Vaccinations Are Associated With a Lower Risk of Myocardial Infarction and Stroke After SARS-CoV-2 Infection Among Patients With Cardiovascular Disease. Background COVID-19 vaccines have demonstrated effectiveness against SARS-CoV-2 infection, hospitalization, and mortality. The association between vaccination and risk of cardiovascular complications shortly after SARS-CoV-2 infection among patients with cardiovascular disease remains unknown. Methods and Results A case-control study was conducted with cases defined as patients who had myocardial infarction or stroke within 28â€‰days after SARS-CoV-2 infection between January 1, 2022 and August 15, 2022. Controls were defined as all other patients who attended any health services and were not cases. Individuals without history of cardiovascular disease were excluded. Each case was randomly matched with 10 controls according to sex, age, Charlson comorbidity index, and date of hospital admission. Adjusted odds ratio with 95% CI was estimated using conditional logistic regression. We identified 808 cases matched with 7771 controls among all patients with cardiovascular disease. Results showed that vaccination with BNT162b2 or CoronaVac was associated with a lower risk of myocardial infarction or stroke after SARS-CoV-2 infection with a dose-response relationship. For BNT162b2, risk decreased from 0.49 (95% CI, 0.29-0.84) to 0.30 (95% CI, 0.20-0.44) and 0.17 (95% CI, 0.08-0.34) from 1 to 3 doses, respectively. Similar trends were observed for CoronaVac, with risk decreased from 0.69 (95% CI, 0.57-0.85) to 0.42 (95% CI, 0.34-0.52) and 0.32 (95% CI, 0.21-0.49) from 1 to 3 doses, respectively. Conclusions Vaccination with BNT162b2 or

CoronaVac is associated with a lower risk of myocardial infarction or stroke after SARS-CoV-2 infection among patients with cardiovascular disease.
Impaired CD4(+) T cell response in older adults is associated with reduced immunogenicity and reactogenicity of mRNA COVID-19 vaccination. Whether age-associated defects in T cells impact the immunogenicity and reactogenicity of mRNA vaccines remains unclear. Using a vaccinated cohort (nâ€‰=â€‰216), we demonstrated that older adults (aged â‰¥65 years) had fewer vaccine-induced spike-specific CD4(+) T cells including CXCR3(+) circulating follicular helper T cells and the T(H)1 subset of helper T cells after the first dose, which correlated with their lower peak IgG levels and fewer systemic adverse effects after the second dose, compared with younger adults. Moreover, spike-specific T(H)1 cells in older adults expressed higher levels of programmed cell death protein 1, a negative regulator of T cell activation, which was associated with low spike-specific CD8(+) T cell responses. Thus, an inefficient CD4(+) T cell response after the first dose may reduce the production of helper T cytokines, even after the second dose, thereby lowering humoral and cellular immunity and reducing systemic reactogenicity. Therefore, enhancing CD4(+) T cell response following the first dose is key to improving vaccine efficacy in older adults.
Insufficient epitope-specific T cell clones are responsible for impaired cellular immunity to inactivated SARS-CoV-2 vaccine in older adults. Aging is a critical risk factor for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine efficacy. The immune responses to inactivated vaccine for older adults, and the underlying mechanisms of potential differences to young adults, are still unclear. Here we show that neutralizing antibody production by older adults took a longer time to reach similar levels in young adults after inactivated SARS-CoV-2 vaccination. We screened SARS-CoV-2 variant strains for epitopes that stimulate specific CD8 T cell response, and older adults exhibited weaker CD8 T-cell-mediated responses to these epitopes. Comparison of lymphocyte transcriptomes from pre-vaccinated and post-vaccinated donors suggested that the older adults had impaired antigen processing and presentation capability. Single-cell sequencing revealed that older adults had less T cell clone expansion specific to SARS-CoV-2, likely due to inadequate immune receptor repertoire size and diversity. Our study provides mechanistic insights for weaker response to inactivated vaccine by older adults and suggests the need for further vaccination optimization for the old population.
Eating reflex epilepsy of presumed autoimmune etiology after SARS-CoV-2 vaccination.
Virus-induced breath biomarkers: A new perspective to study the metabolic responses of COVID-19 vaccinees. Coronavirus disease 2019 (COVID-19) vaccines can protect people from the infection; however, the action mechanism of vaccine-mediated metabolism remains unclear. Herein, we performed breath tests in COVID-19 vaccinees that revealed metabolic reprogramming induced by protective immune responses. In total, 204 breath samples were obtained from COVID-19 vaccinees and non-vaccinated controls, wherein numerous volatile organic compounds (VOCs) were detected by comprehensive two-dimensional gas chromatography and time-of-flight mass spectrometry system. Subsequently, 12 VOCs were selected as biomarkers to construct a signature panel using alveolar gradients and machine learning-based procedure. The signature panel could distinguish vaccinees from control group with a high prediction performance (AUC, 0.9953; accuracy, 94.42%). The metabolic pathways of these biomarkers indicated that the host-pathogen interactions enhanced enzymatic activity and microbial metabolism in the liver, lung, and gut, potentially constituting the dominant action mechanism of vaccine-driven metabolic regulation. Thus, our findings of this study highlight the potential of measuring exhaled VOCs as rapid, non-invasive biomarkers of viral infections. Furthermore, breathomics appears as an alternative for safety evaluation of biological agents and disease diagnosis.

Alterations of Fecal Metabolome Associated with BBIBP-CorV Vaccines against the SARS-CoV-2 Virus. BACKGROUND: The SARS-CoV-2 vaccine has been implemented in response to the 2019 Coronavirus Disease (COVID-19) pandemic worldwide. Dysregulation of gut metabolite is associated with COVID-19 patients. However, the effect of vaccination on the gut metabolite remains unknown, and it is critical to investigate the shifts in metabolic profiles following vaccine treatment. METHODS: In the present study, we conducted a case-control study to assess the fecal metabolic profiles between individuals who received two doses of intramuscular injection of an inactivated SARS-CoV-2 vaccine candidate (BBIBP-CorV) (n = 20), and matched unvaccinated controls (n = 20) using untargeted gas chromatography and time-of-flight mass spectrometry (GC-TOF/MS). RESULTS: Significant different metabolic profiles were observed between subjects receiving SARS-CoV-2 virus vaccines and the unvaccinated. Among a total of 243 metabolites from 27 ontology classes identified in the study cohort, 64 metabolic markers and 15 ontology classes were dramatically distinct between vaccinated and unvaccinated individuals. There were 52 enhanced (such as Desaminotyrosine, Phenylalanine) and 12 deficient metabolites (such as Octadecanol, 1-Hexadecanol) in vaccinated individuals. Along with altered metabolic compositions, multiple functional pathways in Small MoleculePathway Database (SMPDB) and Kyoto Encyclopedia of Genes and Genomes (KEGG) varied between groups. Our results indicated that urea cycle; alanine, aspartate, and glutamate metabolism; arginine and proline metabolism; phenylalanine metabolism and tryptophan metabolism were abundant after vaccination. Additionally, correlation analysis showed that intestinal microbiome was related to alteration in metabolite composition and functions. CONCLUSIONS: The present study indicated the alterations in the gut metabolome after COVID-19 vaccination and the findings provide a valuable resource for in-depth exploration of mechanisms between gut metabolite and SARS-CoV-2 virus vaccines.

Autoimmune hepatitis after SARS-CÂ¬Â¬oV-2 vaccination. Vaccination against SARS-CoV-2 have been reported like a potential trigger of some autoimmune diseases, like autoimmune hepatitis (HAI). We present three cases of AIH developed after the administration of the SARS-Cov-2 vaccine.

SARS-CoV-2 vaccination may trigger and exacerbate mucosal lichen planus.

Non-spike and spike-specific memory T cell responses after the third dose of inactivated COVID-19 vaccine. BACKGROUND: During the COVID-19 epidemic, vaccination has become the most safe and effective way to prevent severe illness and death. Inactivated vaccines are the most widely used type of COVID-19 vaccines in the world. In contrast to spike-based mRNA/protein COVID-19 vaccines, inactivated vaccines generate antibodies and T cell responses against both spike and non-spike antigens. However, the knowledge of inactivated vaccines in inducing non-spike-specific T cell response is very limited. METHODS: In this study, eighteen healthcare volunteers received a homogenous booster (third) dose of the CoronaVac vaccine at least 6 months after the second dose. CD4(+) and CD8(+) T cell responses against a peptide pool from wild-type (WT) non-spike proteins and spike peptide pools from WT, Delta, and Omicron SARS-CoV-2 were examined before and 1-2 weeks after the booster dose. RESULTS: The booster dose elevated cytokine response in CD4(+) and CD8(+) T cells as well as expression of cytotoxic marker CD107a in CD8(+) T cells in response to non-spike and spike antigens. The frequencies of cytokine-secreting non-spike-specific CD4(+) and CD8(+) T cells correlated well with those of spike-specific from WT, Delta, and Omicron. Activation-induced markers (AIM) assay also revealed that booster vaccination elicited non-spike-specific CD4(+) and CD8(+) T cell responses. In addition, booster vaccination produced similar spike-specific AIM(+)CD4(+) and AIM(+)CD8(+) T cell responses to WT, Delta, and Omicron, indicting strong cross-reactivity of functional cellular response between WT and variants. Furthermore, booster vaccination induced effector memory phenotypes of spike-specific and non-spike-specific CD4(+) and CD8(+) T cells.

CONCLUSIONS: These data suggest that the booster dose of inactive vaccines broadens both non-spike-specific and spike-specific T cell responses against SARS-CoV-2.

Measles outbreak in Ethiopia amid COVID-19: an effect of war-induced hampering of vaccination and pandemic. Measles, a highly infectious viral disease, is a leading cause of death among young children in many developing countries, including Ethiopia. Despite Ethiopia being the first large country to conduct a mass immunization campaign for measles in 2020 following coronavirus disease 2019 (COVID-19) outbreak, in which over 14.5 million children in the country were vaccinated, there was another outbreak of measles in the country in the year 2022, especially in the eastern parts of the country. According to the WHO, a total of 9850 measles cases were suspected, out of which 5806 cases were confirmed, with 56 deaths (CFR=0.6%) in Ethiopia from January to 30 September 2022. The total number of cases crossed 10Â 000 cases by the end of October 2022. Amid COVID-19 and war times in Ethiopia posed serious challenges for the under-5 children to get access to vaccination against measles. We, therefore, urge the Ethiopian government to reach an amicable and diplomatic agreement with the civilians causing internal and intraethnic wars in the country as soon as possible, as this would prevent further hampering of measles vaccination for the Ethiopian people, most especially the children.

Factors influencing scar formation following Bacille Calmette-GuÃ©rin (BCG) vaccination. The prevalence of scar formation following Bacille Calmette-GuÃ©rin (BCG) vaccination varies globally. The beneficial off-target effects of BCG are proposed to be stronger amongst children who develop a BCG scar. Within an international randomised trial ('BCG vaccination to reduce the impact of coronavirus disease 2019 (COVID-19) in healthcare workers'; BRACE Trial), this nested prospective cohort study assessed the prevalence of and factors influencing scar formation, as well as participant perception of BCG scarring 12 months following vaccination . Amongst 3071 BCG-recipients, 2341 (76%) developed a BCG scar. Scar prevalence was lowest in Spain and highest in UK. Absence of post-injection wheal (OR 0.4, 95%CI 0.2-0.9), BCG revaccination (OR 1.7, 95%CI 1.3-2.0), female sex (OR 2.0, 95%CI 1.7-2.4), older age (OR 0.4, 95%CI 0.4-0.5) and study country (Brazil OR 1.6, 95%CI 1.3-2.0) influenced BCG scar prevalence. Of the 2341 participants with a BCG scar, 1806 (77%) did not mind having the scar. Participants more likely to not mind were those in Brazil, males and those with a prior BCG vaccination history. The majority (96%) did not regret having the vaccine. Both vaccination-related (amenable to optimisation) and individual-related factors affected BCG scar prevalence 12 months following BCG vaccination of adults, with implications for maximising the effectiveness of BCG vaccination.

Immunogenicity and safety of Biological E's CORBEVAXâ„¢ vaccine compared to COVISHIELDâ„¢ (ChAdOx1 nCoV-19) vaccine studied in a phase-3, single blind, multicentre, randomized clinical trial. Optimum formulation of Biological-E's protein subunit CORBEVAXâ„¢ vaccine was selected in phase-1 and -2 studies and found to be safe and immunogenic in healthy adult population. This is a phase-3 prospective, single-blinded, randomized, active controlled study conducted at 18 sites across India in 18-80â€‰year-old subjects. This study has two groups; (i) immunogenicity-group, participants randomized either to CORBEVAXâ„¢ (nâ€‰=â€‰319) or COVISHIELDâ„¢ arms (nâ€‰=â€‰320). (ii) Safety-group containing single CORBEVAXâ„¢ arm (nâ€‰=â€‰1500) and randomization is not applicable. Healthy adults without a history of COVID-19 vaccination or SARS-CoV-2 infection were enrolled into immunogenicity arm and subjects seronegative to SARS-CoV-2 infection were enrolled into the safety arm. The safety profile of CORBEVAXâ„¢ vaccine was comparable to the comparator vaccine COVISHIELDâ„¢. Majority of reported AEs were mild in nature in both arms. The CORBEVAXâ„¢ to COVISHIELDâ„¢ GMT-ratios at day-42 time-point were 1Â·15 and 1Â·56 and the lower limit of the 95% confidence interval for the GMT-ratios was determined as 1Â·02 and 1Â·27 against Ancestral and Delta strains of SARS-COV-2 respectively. Both COVISHIELDâ„¢ and

CORBEVAXâ„¢ vaccines showed comparable seroconversion post-vaccination against anti-RBD-IgG response. The subjects in CORBEVAXâ„¢ cohort also exhibited higher interferon-gamma secreting PBMC's post-stimulation with SARS-COV-2 RBD-peptides than subjects in COVISHIELDâ„¢ cohort.

Exacerbation of acquired perforating dermatosis following SARS-CoV-2 vaccination.

Diagnosis of Acute Myocarditis Following mRNA Vaccines against SARS-CoV-2: A Methodological Review. The occurrence of acute myocarditis following the administration of mRNA vaccines against SARS-CoV-2 remains relatively rare, and it is associated with a very low mortality rate. The incidence varied by vaccine type, sex, and age and after the first, second, or third vaccination dose. However, the diagnosis of this condition often remains challenging. To further elucidate the relationship between myocarditis and SARS-CoV-2 mRNA vaccines, starting with two cases observed at the Cardiology Unit of the West Vicenza General Hospital located in the Veneto Region, which was among the first Italian areas hit by the COVID-19 pandemic, we performed a review of the available literature to highlight the clinical and diagnostic elements that could contribute to suspicion of myocarditis as an adverse event of SARS-CoV-2 immunization.

Dynamics of SARS-CoV-2 Antibody Responses up to 9 Months Post-Vaccination in Individuals with Previous SARS-CoV-2 Infection Receiving Inactivated Vaccines. Humoral immunity confers protection against COVID-19. The longevity of antibody responses after receiving an inactivated vaccine in individuals with previous SARS-CoV-2 infection is unclear. Plasma samples were collected from 58 individuals with previous SARS-CoV-2 infection and 25 healthy donors (HDs) who had been vaccinated with an inactivated vaccine. The neutralizing antibodies (NAbs) and S1 domain-specific antibodies against the SARS-CoV-2 wild-type and Omicron strains and nucleoside protein (NP)-specific antibodies were measured using a chemiluminescent immunoassay. Statistical analysis was performed using clinical variables and antibodies at different timepoints after SARS-CoV-2 vaccination. NAbs targeting the wild-type or Omicron strain were detected in individuals with previous SARS-CoV-2 infection at 12 months after infection (wild-type: 81%, geometric mean (GM): 20.3 AU/mL; Omicron: 44%, GM: 9.4 AU/mL), and vaccination provided further enhancement of these antibody levels (wild-type: 98%, GM: 53.3 AU/mL; Omicron: 75%, GM: 27.8 AU/mL, at 3 months after vaccination), which were significantly higher than those in HDs receiving a third dose of inactivated vaccine (wild-type: 85%, GM: 33.6 AU/mL; Omicron: 45%, GM: 11.5 AU/mL). The level of NAbs in individuals with previous infection plateaued 6 months after vaccination, but the NAb levels in HDs declined continuously. NAb levels in individuals with previous infection at 3 months post-vaccination were strongly correlated with those at 6 months post-vaccination, and weakly correlated with those before vaccination. NAb levels declined substantially in most individuals, and the rate of antibody decay was negatively correlated with the neutrophil-to-lymphocyte ratio in the blood at discharge. These results suggest that the inactivated vaccine induced robust and durable NAb responses in individuals with previous infection up to 9 months after vaccination.

Humoral and T Cell Immune Responses against SARS-CoV-2 after Primary and Homologous or Heterologous Booster Vaccinations and Breakthrough Infection: A Longitudinal Cohort Study in Malaysia. Vaccine efficacy against SARS-CoV-2 could be compromised by the emergence of SARS-CoV-2 variants and it is important to study how it impacts the booster vaccination regime. We investigated the humoral and T cell responses longitudinally in vaccinated uninfected (n = 25) and post-COVID-19 individuals (n = 8), and those who had received a BNT162b2 booster following complete two-doses regimes of either BNT162b2 (homologous) (n = 14) or ChAdOx1-S (heterologous) (n = 15) vaccines, by means of a SARS-CoV-2 pseudovirus neutralization test and QuantiFERON SARS-CoV-2 assay. Vaccinated post-COVID-19 individuals showed higher neutralizing antibodies with longer durability against SARS-CoV-2 wild type (WT) and Omicron spikes, but demonstrated similar declining T cell responses compared to the uninfected vaccinated. Two doses of BNT162b2 induced higher

neutralizing antibodies against WT and T cell responses than ChAdOx1-S for six months. The BNT162b2 booster confers a greater humoral response against WT, but a similar cross-neutralizing antibody against Omicron and T cell responses in the homologous booster group compared to the heterologous booster group. Breakthrough infection in the homologous booster group (n = 11) significantly increased the neutralizing antibody, but T cell responses remained low. Our data may impact government public health policy regarding the administration of mix-and-match vaccines, where both vaccination regimes can be employed should there be shortages of certain vaccines.

SARS-CoV-2 Neutralizing Antibodies to B.1 and to BA.5 Variant after Booster Dose of BNT162b2 Vaccine in HIV Patients COVID-NaÃ¯ve and on Successful Antiretroviral Therapy. Live virus neutralization is the gold standard to investigate immunity. This prospective observational study aimed to determine the magnitude of response against the original B.1 lineage and against the BA.5 lineage six months after the third BNT162b2 mRNA vaccine dose in patients with HIV infection on successful antiretroviral treatment and no previous SARS-CoV-2 infection. A total of 100 subjects (M/F 83/17, median age 54 years) were included in the analysis: 95 had plasma HIV RNA <40 copies/mL, the median CD4+ T cell count at the administration of the third dose was 580 cells/mm(3), and the median nadir CD4+ T cell count was 258 cells/mm(3). Neutralizing antibodies (NtAb) against B.1 were detectable in all the subjects, but those to BA.5 were only detected in 88 ($p < 0.001$). The median NtAb titer to B.1 was significantly higher than that to BA.5 (393 vs. 60, $p < 0.0001$), and there was a strong positive correlation between the paired measurements ($p < 0.0001$). Linear regression on a subset of 87 patients excluding outlier NtAb titers showed that 48% of the changes in NtAb titers to BA.5 are related to the changes in value titers to B.1. SARS-CoV-2 variants evolve rapidly, challenging the efficacy of vaccines, and data on comparative NtAb responses may help in tailoring intervals between vaccine doses and in predicting vaccine efficacy.

Longitudinal Changes in IgG-Type SARS-CoV-2 Antibody Titers after COVID-19 Vaccination and a Prominent Increase in Antibody Titers When Infected after Vaccination. OBJECTIVE: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody titers level and duration of elevated levels are considered important indicators for confirming the efficacy of coronavirus disease 2019 (COVID-19) vaccines. The objective of this study was to demonstrate the changes in antibody titers after the second and third doses of the COVID-19 vaccine, and to determine the antibody titers in cases of spontaneous infection with SARS-CoV-2 after vaccination. MATERIALS AND METHODS: From June 2021 to February 2023, IgG-type SARS-CoV-2 antibody titers were measured in 127 participants, including 74 outpatients and 53 members of staff, at the Osaka Dental University Hospital (64 males and 63 females, mean age 52.3 Â± 19.0 years). RESULTS: Consistent with previous reports, the SARS-CoV-2 antibody titer decreased with time, not only after the second dose but also after the third dose of the vaccine if there was no spontaneous COVID-19 infection. We also confirmed that the third booster vaccination was effective in increasing the antibody titer. A total of 21 cases of natural infections were observed after administering two or more doses of the vaccine. Thirteen of these patients had post-infection antibody titers exceeding 40,000 AU/mL, and some cases continued to maintain antibody titers in the tens of thousands of AU/mL even after more than 6 months had passed since infection. CONCLUSIONS: The rise in and duration of antibody titers against SARS-CoV-2 are considered important indicators for confirming the efficacy of novel COVID-19 vaccines. A longitudinal follow-up of antibody titers after vaccination in larger studies is warranted.

Social Media Sentiment about COVID-19 Vaccination Predicts Vaccine Acceptance among Peruvian Social Media Users the Next Day. Drawing upon theories of risk and decision making, we present a theoretical framework for how the emotional attributes of social media content influence risk behaviors. We apply our framework to understanding how COVID-19 vaccination Twitter posts influence acceptance of the vaccine in Peru, the country with the highest relative number of COVID-

19 excess deaths. By employing computational methods, topic modeling, and vector autoregressive time series analysis, we show that the prominence of expressed emotions about COVID-19 vaccination in social media content is associated with the daily percentage of Peruvian social media survey respondents who are vaccine-accepting over 231 days. Our findings show that net (positive) sentiment and trust emotions expressed in tweets about COVID-19 are positively associated with vaccine acceptance among survey respondents one day after the post occurs. This study demonstrates that the emotional attributes of social media content, besides veracity or informational attributes, may influence vaccine acceptance for better or worse based on its valence.

Humoral Response after SARS-CoV-2 Vaccination in Prostate Cancer Patients. Cancer is an important public health problem. Prostate cancer is one of the most common cancers among men. In Poland, the incidence of this type of cancer is constantly growing. Considering the appearance of a new coronavirus in December 2019 (SARS-CoV-2) and the fact that oncology patients, including those with prostate cancer, are particularly vulnerable to infection, it is recommended to get vaccinated against COVID-19. In our study, we determined the level and prevalence of antibodies against SARS-CoV-2 IgG in patients with prostate cancer compared to the control group and whether the patients' ages affected the level of antibodies. PCa patients and controls were divided into two age groups: 50-59 years and 60-70 years. We also analyzed the level of antibodies in patients belonging to the relevant risk groups for prostate cancer (the European Society of Urology risk group classification of prostate cancer). For the study, we used the Microblot-Array COVID-19 IgG test to detect antibodies against the three main SARS-CoV-2 antigens: NCP, RBD, and S2. Our results showed that prostate cancer patients had significantly lower levels of anti-SARS-CoV-2 IgG antibodies compared to controls. In addition, age also affected the decrease in the number of IgG antibodies. The level of antibodies in the intermediate/high-risk group was lower compared to the low-risk group.

Monkeypox Post-COVID-19: Knowledge, Worrying, and Vaccine Adoption in the Arabic General Population. BACKGROUND: The outbreak of monkeypox was declared a global public health emergency by the World Health Organization on 23 July 2022. There have been 60,000 cases reported worldwide, most of which are in places where monkeypox has never been seen due to the travel of people who have the virus. This research aims to evaluate the general Arabic population in regard to the monkeypox disease, fears, and vaccine adoption after the WHO proclaimed a monkeypox epidemic and to compare these attitudes to those of the COVID-19 pandemic. METHODS: This cross-sectional study was performed in some Arabic countries (Syria, Egypt, Qatar, Yemen, Jordan, Sudan, Algeria, and Iraq) between 18 August and 7 September 2022. The inclusion criteria were the general public residing in Arabic nations and being older than 18. This questionnaire has 32 questions separated into three sections: sociodemographic variables, prior COVID-19 exposure, and COVID-19 vaccination history. The second portion assesses the knowledge and anxieties about monkeypox, while the third section includes the generalized anxiety disorder (GAD7) scale. Logistic regression analyses were performed to compute the adjusted odds ratios (aOR) and their confidence intervals (95%CI) using STATA (version 17.0). RESULTS: A total of 3665 respondents from 17 Arabic countries were involved in this study. Almost two-thirds (n = 2427, 66.2%) of the participants expressed more worry about COVID-19 than monkeypox diseases. Regarding the major cause for concern about monkeypox, 39.5% of participants attributed their anxiety to the fear that they or a member of their family may contract the illness, while 38.4% were concerned about monkeypox becoming another worldwide pandemic. According to the GAD 7 score, 71.7% of the respondents showed very low anxiety toward monkeypox and 43.8% of the participants scored poor levels of knowledge about monkeypox disease. Participants with previous COVID-19 infection showed a 1.206 times greater acceptance to receive the monkeypox vaccine than those with no previous infection. A 3.097 times higher concern for monkeypox than COVID-19 was shown by the participants who

perceived monkeypox as dangerous and virulent than those who did not. Participants who have a chronic disease (aOR: 1.32; 95%CI: 1.09-1.60); participants worried about monkeypox (aOR: 1.21; 95%CI: 1.04-1.40), and perceived monkeypox as a dangerous and virulent disease (aOR: 2.25; 95%CI: 1.92-2.65); and excellent knowledge level (aOR: 2.28; 95%CI: 1.79-2.90) have emerged as significant predictors. CONCLUSIONS: Our study reported that three-fourths of the participants were more concerned about COVID-19 than monkeypox disease. In addition, most of the participants have inadequate levels of knowledge regarding monkeypox disease. Hence, immediate action should be taken to address this problem. Consequently, learning about monkeypox and spreading information about its prevention is crucial.

Myocarditis and Pericarditis following COVID-19 Vaccination in Thailand. BACKGROUND: Myocarditis and pericarditis cases following Coronavirus 2019 (COVID-19) vaccination were reported worldwide. In Thailand, COVID-19 vaccines were approved for emergency use. Adverse event following immunization (AEFI) surveillance has been strengthened to ensure the safety of the vaccines. This study aimed to describe the characteristics of myocarditis and pericarditis, and identify the factors associated with myocarditis and pericarditis following COVID-19 vaccination in Thailand. METHOD: We carried out a descriptive study of reports of myocarditis and pericarditis to Thailand's National AEFI Program (AEFI-DDC) between 1 March and 31 December 2021. An unpaired case-control study was conducted to determine the factors associated with myocarditis and pericarditis after the CoronaVac, ChAdOx1-nCoV, BBIBP-CorV, BNT162b2, and mRNA-1273 vaccines. The cases consisted of COVID-19 vaccine recipients who met the definition of confirmed, probable, or suspected cases of myocarditis or pericarditis within 30 days of vaccination. The controls were people who underwent COVID-19 vaccination between 1 March and 31 December 2021, with no adverse reactions documented after vaccination. RESULTS: Among the 31,125 events recorded in the AEFI-DDC after 104.63 million vaccinations, 204 cases of myocarditis and pericarditis were identified. The majority of them were male (69%). The median age was 15 years (interquartile range (IQR): 13-17). The incidence was highest following the BNT162b2 vaccination (0.97 cases per 100,000 doses administered). Ten deaths were reported in this study; no deaths were reported among children who received the mRNA vaccine. Compared with the age-specific incidence of myocarditis and pericarditis in Thailand before the introduction of the COVID-19 vaccination, the incidence of myocarditis and pericarditis after the BNT162b2 vaccine was greater in the 12-17 and 18-20 age groups in both males and females. It was higher after the second dose in 12- to 17-year-olds (2.68 cases per 100,000 doses administered) and highest after the second dose in male 12- to 17-year-olds (4.43 cases per 100,000 doses administered). Young age and a mRNA-based vaccination were associated with myocarditis and pericarditis following administration of the COVID-19 vaccine after multivariate analysis. CONCLUSIONS: Myocarditis and pericarditis following vaccination against COVID-19 were uncommon and mild, and were most likely to affect male adolescents. The COVID-19 vaccine offers the recipients enormous benefits. The balance between the risks and advantages of the vaccine and consistent monitoring of AEFI are essential for management of the disease and identification of AEFI.

COVID-19 mRNA Vaccines: The Molecular Basis of Some Adverse Events. Each injection of any known vaccine results in a strong expression of pro-inflammatory cytokines. This is the result of the innate immune system activation, without which no adaptive response to the injection of vaccines is possible. Unfortunately, the degree of inflammation produced by COVID-19 mRNA vaccines is variable, probably depending on genetic background and previous immune experiences, which through epigenetic modifications could have made the innate immune system of each individual tolerant or reactive to subsequent immune stimulations.We hypothesize that we can move from a limited pro-inflammatory condition to conditions of increasing expression of pro-inflammatory cytokines that can culminate in multisystem hyperinflammatory syndromes following COVID-19

mRNA vaccines (MIS-V). We have graphically represented this idea in a hypothetical inflammatory pyramid (IP) and we have correlated the time factor to the degree of inflammation produced after the injection of vaccines. Furthermore, we have placed the clinical manifestations within this hypothetical IP, correlating them to the degree of inflammation produced. Surprisingly, excluding the possible presence of an early MIS-V, the time factor and the complexity of clinical manifestations are correlated to the increasing degree of inflammation: symptoms, heart disease and syndromes (MIS-V).

Salivary Antibody Responses to Two COVID-19 Vaccines following Different Vaccination Regimens. Background: To date, little is known about the salivary mucosal immune response following different COVID-19 vaccine types or after a booster (3rd) dose of the BNT162b2 (BNT) vaccine. Methods: A total of 301 saliva samples were collected from vaccinated individuals and arranged into two cohorts: cohort 1 (n = 145), samples from individuals who had received two doses against SARS-CoV-2; cohort 2 (n = 156), samples from individuals who had received a booster of BNT vaccine. Cohorts 1 and 2 were sub-stratified into three groups based on the types of first and second doses (homologous BNT/BNT, homologous ChAdOx1/ChAdOx1, or heterologous BNT/ChAdOx1vaccinations). Salivary immunoglobulin G (IgG) response to SARS-CoV-2 spike glycoprotein was measured by ELISA, and clinical demographic data were collected from hospital records or questionnaires. Results: Salivary IgG antibody responses against different vaccines, whether homologous or heterogeneous vaccination regimens, showed similar levels in cohorts 1 and 2. Compiling all groups in cohort 1 and 2 showed significant, albeit weak, negative correlations between salivary IgG levels and time ($r = -0.2$, $p = 0.03$; $r = -0.27$, $p = 0.003$, respectively). In cohort 2, the durability of salivary IgG after a booster dose of BNT162b2 significantly dropped after 3 months compared to the <1 month and 1-3 months groups. Conclusions: Different COVID-19 vaccine types and regimens elicit similar salivary anti-SARS-CoV-2 IgG with modest waning over time. Boosting with BNT162b2 vaccine did not produce an evident increase in mucosal IgG response whereby COVID-19 recovered subjects show higher salivary IgG than naive, post-vaccination subjects. The ChAdOx1/ChAdOx1 regimen showed better correlation between salivary IgG levels and durability. These findings highlight the importance of developing oral or intra-nasal vaccines to induce stronger mucosal immunity.

Sociodemographic Factors Associated with COVID-19 Vaccination among People in Guatemalan Municipalities. The Republic of Guatemala's reported COVID-19 vaccination coverage is among the lowest in the Americas and there are limited studies describing the disparities in vaccine uptake within the country. We performed a cross-sectional ecological analysis using multi-level modeling to identify sociodemographic characteristics that were associated with low COVID-19 vaccination coverage among Guatemalan municipalities as of 30 November 2022. Municipalities with a higher proportion of people experiencing poverty (Î² = -0.25, 95% CI: -0.43--0.07) had lower vaccination coverage. Municipalities with a higher proportion of people who had received at least a primary education (Î² = 0.74, 95% CI: 0.38-1.08), children (Î² = 1.07, 95% CI: 0.36-1.77), people aged 60 years and older (Î² = 2.94, 95% CI: 1.70-4.12), and testing for SARS-CoV-2 infection (Î² = 0.25, 95% CI: 0.14-0.36) had higher vaccination coverage. In the simplified multivariable model, these factors explained 59.4% of the variation in COVID-19 vaccination coverage. Poverty remained significantly associated with low COVID-19 vaccination coverage in two subanalyses restricting the data to the time period of the highest national COVID-19-related death rate and to COVID-19 vaccination coverage only among those aged 60 years or older. Poverty is a key factor associated with low COVID-19 vaccination and focusing public health interventions in municipalities most affected by poverty may help address COVID-19 vaccination and health disparities in Guatemala.

Humoral Response in Hemodialysis Patients Post-SARS-CoV-2 mRNA Vaccination: A Systematic Review of Literature. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the

causative agent of coronavirus disease 2019 (COVID-19), has infected over 600 million individuals and caused nearly 7 million deaths worldwide (10 January 2023). Patients with renal disease undergoing hemodialysis are among those most adversely affected, with an increased predisposition to SARS-CoV-2 infection and death. This systematic review aimed to pool evidence assessing the humoral response of hemodialysis patients (HDP) post-mRNA SARS-CoV-2 vaccination. A systematic search of the literature was performed through MEDLINE, CINAHL, PubMed, EMBASE, and Web of Science databases, as well as medRxiv and bioRxiv preprint servers up to 10 January 2023. Cohort and case-control studies were included if they reported an immune response in one group of patients undergoing hemodialysis who received mRNA SARS-CoV-2 vaccination compared with another group of patients receiving the same vaccine but not on hemodialysis. The methodological quality was assessed using the Newcastle-Ottawa Scale. Meta-analysis was not deemed appropriate due to the high heterogeneity between studies. From the 120 studies identified, nine (n = 1969 participants) met the inclusion criteria. Most studies (n = 8/9, 88%) were of high or medium methodological quality (â‰¥6/9 stars). The results revealed that HDP developed lower antibody levels across all timepoints post-vaccination when compared with controls. Patients with chronic kidney disease elicited the highest antibody immune response, followed by HDP and, lastly, kidney transplant recipients. Overall, post-vaccination antibody titers were comparatively lower than in the healthy population. Current results imply that robust vaccination strategies are needed to address waning immune responses in vulnerable populations.

A Longitudinal Study in Turkiye of Host Ability to Produce Antibodies following a Third Homologous BNT162b2 Vaccination. Obesity is a multifaceted, complex condition that has negative impacts on one's health. There are conflicting reports regarding the COVID-19 vaccine's ability to induce antibody formation in obese people. Our study aimed to determine anti-S-RBD IgG and surrogate neutralizing antibody (snAb) levels before and after the third Pfizer-BioNTech (BNT162b2) vaccination (at 15, 60, 90, and 120 days) in normal-weight adults, overweight, and obese individuals without any comorbidity or previous SARS-CoV-2 infection history, but it did not evaluate the response to the first two doses. In this longitudinal prospective study in Istanbul, Turkey, a total of 323 consecutive adult individuals (141 normal weight, 108 overweight, and 74 patients with obesity) were included. Peripheral blood samples were collected. Anti-S-RBD IgG and surrogate neutralizing antibody levels were detected using the ELISA method. After the third dose of BNT162b2 vaccination, obese patients had significantly lower levels of snAb against SARS-CoV-2 compared with normal-weight controls, but the levels otherwise did not differ between the study groups. Across all individuals in our cohort, titers peaked about a month after this third vaccination and then gradually faded. Anti-S-RBD IgG and snAb IH% levels against SARS-CoV-2 were not correlated with IL-6 and TNF-Î± levels. In conclusion, anti-S-RBD IgG titers and snAb IH% levels against SARS-CoV-2 were determined longitudinally for 120 days after the third homologous BNT162b2 vaccination. Although there were no significant differences in anti-S-RBD IgG, we found significant differences in the snAb IH% levels against SARS-CoV-2 between obese and healthy control subjects.

Maintenance of Potent Cellular and Humoral Immune Responses in Long-Term Hemodialysis Patients after 1273-mRNA SARS-CoV-2 Vaccination. Continuous evaluation of the coronavirus disease 2019 (COVID-19) vaccine effectiveness in hemodialysis (HD) patients is critical in this immunocompromised patient group with higher mortality rates due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. The response towards vaccination in HD patients has been studied weeks after their first and second SARS-CoV-2 vaccination dose administration, but no further studies have been developed in a long-term manner, especially including both the humoral and cellular immune response. Longitudinal studies that monitor the immune response to COVID-19 vaccination in individuals undergoing HD are therefore necessary to prioritize vaccination strategies

and minimize the pathogenic effects of SARS-CoV-2 in this high-risk group of patients. We followed up HD patients and healthy volunteers (HV) and monitored their humoral and cellular immune response three months after the second (V2+3M) and after the third vaccination dose (V3+3M), taking into consideration previous COVID-19 infections. Our cellular immunity results show that, while HD patients and HV individuals secrete comparable levels of IFN-Î³ and IL-2 in ex vivo stimulated whole blood at V2+3M in both naÃ¯ve and COVID-19-recovered individuals, HD patients secrete higher levels of IFN-Î³ and IL-2 than HV at V3+3M. This is mainly due to a decay in the cellular immune response in HV individuals after the third dose. In contrast, our humoral immunity results show similar IgG binding antibody units (BAU) between HD patients and HV individuals at V3+3M, independently of their previous infection status. Overall, our results indicate that HD patients maintain strong cellular and humoral immune responses after repeated 1273-mRNA SARS-CoV-2 vaccinations over time. The data also highlights significant differences between cellular and humoral immunity after SARS-CoV-2 vaccination, which emphasizes the importance of monitoring both arms of the immune response in the immunocompromised population.

Effects of Gut Microbiome Modulation on Reducing Adverse Health Outcomes among Elderly and Diabetes Patients during the COVID-19 Pandemic: A Randomised, Double-Blind, Placebo-Controlled Trial (IMPACT Study). Gut microbiota is believed to be a major determinant of health outcomes. We hypothesised that a novel oral microbiome formula (SIM01) can reduce the risk of adverse health outcomes in at-risk subjects during the coronavirus disease 2019 (COVID-19) pandemic. In this single-centre, double-blind, randomised, placebo-controlled trial, we recruited subjects aged â‰¥65 years or with type two diabetes mellitus. Eligible subjects were randomised in a 1:1 ratio to receive three months of SIM01 or placebo (vitamin C) within one week of the first COVID-19 vaccine dose. Both the researchers and participants were blinded to the groups allocated. The rate of adverse health outcomes was significantly lower in the SIM01 group than the placebo at one month (6 [2.9%] vs. 25 [12.6], $p < 0.001$) and three months (0 vs. 5 [3.1%], $p = 0.025$). At three months, more subjects who received SIM01 than the placebo reported better sleep quality (53 [41.4%] vs. 22 [19.3%], $p < 0.001$), improved skin condition (18 [14.1%] vs. 8 [7.0%], $p = 0.043$), and better mood (27 [21.2%] vs. 13 [11.4%], $p = 0.043$). Subjects who received SIM01 showed a significant increase in beneficial Bifidobacteria and butyrate-producing bacteria in faecal samples and strengthened the microbial ecology network. SIM01 reduced adverse health outcomes and restored gut dysbiosis in elderly and diabetes patients during the COVID-19 pandemic.

Anti-SARS-CoV-2 Immunoglobulins in Human Milk after Coronavirus Disease or Vaccination-Time Frame and Duration of Detection in Human Milk and Factors That Affect Their Titers: A Systematic Review. Human milk (HM) of mothers infected with or vaccinated against SARS-CoV-2 contains specific immunoglobulins, which may protect their offspring against infection or severe disease. The time frame and duration after infection or vaccination, during which these immunoglobulins are detected in HM, as well as the major factors that influence their levels, have not been fully elucidated. This systematic review aimed to collect the existing literature and describe the immune response, specifically regarding the immunoglobulins in HM after COVID-19 disease or vaccination in non-immune women. We conducted a systematic search of PubMed and Scopus databases to identify studies published up until 19 March 2023. In total, 975 articles were screened, and out of which 75 were identified as being relevant and were finally included in this review. Infection by SARS-CoV-2 virus primarily induces an IgA immune response in HM, while vaccination predominantly elevates IgG levels. These immunoglobulins give HM a neutralizing capacity against SARS-CoV-2, highlighting the importance of breastfeeding during the pandemic. The mode of immune acquisition (infection or vaccination) and immunoglobulin levels in maternal serum are factors that seem to influence immunoglobulin levels in HM. Further studies are required to determine the impact of other factors,

such as infection severity, lactation period, parity, maternal age and BMI on immunoglobulin level in HM.

Effectiveness of Nutritional Supplements for Attenuating the Side Effects of SARS-CoV-2 Vaccines. Supplementation is known to enhance the immune response and reduce infection. Therefore, the association between immune nutrients and vaccine side effects needs to be investigated. Our aim was to analyze the relationship between vaccination side effects and supplement intake among the Italian population. The study included a questionnaire asking for personal data, anthropometric information, COVID-19 infection and immunity response, and COVID-19 vaccination and supplementation. The survey was conducted from 8 February to 15 June 2022. In the study, 776 respondents were included, aged between 18 and 86 (71.3% females). We observed a statistically significant correlation between supplement consumption and side effects at the end of the vaccination cycle ($p = 0.000$), which was also confirmed by logistic regression ($p = 0.02$). Significant associations were observed between supplement intake and side effects of diarrhea and nausea at the end of the vaccination cycle ($p = 0.001$; $p = 0.04$, respectively). Significant associations were observed between side effects and omega-3 and mineral supplementation at the start of the vaccination cycle ($p = 0.02$; $p = 0.001$, respectively), and between side effects and vitamin supplementation at the end of the vaccination cycle ($p = 0.005$). In conclusion, our study shows a positive impact of supplementation on vaccination response, increasing host immune defenses, and reducing side effects.

Redistribution and Activation of CD16brightCD56dim NK Cell Subset to Fight against Omicron Subvariant BA.2 after COVID-19 Vaccination. With the alarming surge in COVID-19 cases globally, vaccination must be prioritised to achieve herd immunity. Immune dysfunction is detected in the majority of patients with COVID-19; however, it remains unclear whether the immune responses elicited by COVID-19 vaccination function against the Omicron subvariant BA.2. Of the 508 enrolled patients infected with Omicron BA.2, 102 were unvaccinated controls, and 406 were vaccinated. Despite the presence of clinical symptoms in both groups, vaccination led to a significant decline in nausea or vomiting, abdominal pain, headache, pulmonary infection, and overall clinical symptoms and a moderate rise in body temperature. The individuals infected with Omicron BA.2 were also characterised by a mild increase in both serum pro- and anti-inflammatory cytokine levels after vaccination. There were no significant differences or trend changes between T- and B-lymphocyte subsets; however, a significant expansion of NK lymphocytes in COVID-19-vaccinated patients was observed. Moreover, the most effective CD16(bright)CD56(dim) subsets of NK cells showed increased functional capacities, as evidenced by a significantly greater IFN-Î³ secretion and a stronger cytotoxic potential in the patients infected with Omicron BA.2 after vaccination. Collectively, these results suggest that COVID-19 vaccination interventions promote the redistribution and activation of CD16(bright)CD56(dim) NK cell subsets against viral infections and that they could facilitate the clinical management of patients infected with Omicron BA.2.

Immune Response and Transplacental Antibody Transfer in Pregnant Women after COVID-19 Vaccination. COVID-19 infection is associated with increased risk of pregnancy complications, making vaccination during pregnancy critical for mother-neonate dyads. Few data, often with an unrepresentative sample size, are available on SARS-CoV-2 vaccine-induced humoral and cell-mediated response. Here, we evaluated anti-S antibody and interferon-gamma (IFN-Î³) production elicited by SARS-CoV-2 immunization in maternal and neonatal plasma. Pregnant women ($n = 230$) were prospectively enrolled and classified as unvaccinated ($n = 103$) and vaccinated ($n = 127$); after serological screening for previous infections, assays were performed on 126 dyads, 15 mothers and 17 newborns. Positive anti-S antibodies were found in most of the vaccinated subjects, regardless of timespan between immunization and delivery (range: 7-391 days). A total of 89 of 92 vaccinated

women showed a broad response to COVID-19 immunization and highly effective placental transfer, as attested by anti-S positive rates (maternal = 96.7%, cord = 96.6%). Most of our subjects had indeterminate results in an IGRA assay, preventing a conclusive evaluation of IFN-Î³ production. Indeed, pregnancy-related hormonal changes may influence T-cell response with an impact on IFN-Î³ production. Positive pregnancy and perinatal outcomes reinforce the evidence that the anti-SARS-CoV-2 immunization is effective and well-tolerated in pregnant women and also protective for the fetus/neonate, even though it was not possible to define the related IFN-Î³ production and role.

Vaccine coverage and factors associated with vaccine adherence in persons with HIV at an urban infectious disease clinic. Information on vaccination rates and factors associated with adherence in persons with HIV (PWH) is limited. We report vaccine adherence in 653 adult PWH attending an urban Infectious Disease Clinic from January 2015 to December 2021. Vaccines evaluated included influenza, pneumococcal, tetanus, hepatitis A virus (HAV) and hepatitis B virus (HBV), human papillomavirus (HPV), and zoster vaccines. Vaccine reminders were triggered at every visit, and all vaccines were accessible in the clinic. The mean age was 50â€‰y (Â±SD 13), male gender was 78.6%, and black race was 74.3%. The overall adherence to all recommended vaccines was 63.6%. Vaccine adherence was >90% for influenza, pneumococcal, and tetanus, >80% for HAV and HBV, and â‰¥60% for HPV and zoster vaccines. The main predictor of adherence to all vaccines was â‰¥2 annual clinic visits (odds ratio [OR] 3.45; 95% confidence interval [CI] 2.36-5.05; pâ€‰<â€‰.001). Other predictors included an assigned primary care provider within the system (OR 2.89 [95% CI 1.71-5.00, pâ€‰<â€‰.001]) and CD4â€‰>200 cell/mm(3) at entry into care (OR 1.91 [95% CI 1.24-2.94, p = .0003]). Retention in care combined with vaccine reminders and accessibility of vaccines in the clinic can achieve high vaccine uptake in PWH.

Pulmonary computed tomographic manifestations of COVID-19 in vaccinated and non-vaccinated patients. This study aimed to analyze computed tomographic (CT) imaging features of vaccinated and non-vaccinated COVID-19 patients. The study population of this retrospective single-center cohort study consisted of hospitalized COVID-19 patients who received a chest CT at the study site between July 2021 and February 2022. Qualitative scoring systems (RSNA, CO-RADS, COV-RADS), imaging pattern analysis and semi-quantitative scoring of lung changes were assessed. 105 patients (70,47% male, 62.1â€‰Â±â€‰16.79Â years, 53.3% fully vaccinated) were included in the data analysis. A significant association between vaccination status and the presence of the crazy-paving pattern was observed in univariate analysis and persisted after step-wise adjustment for possible confounders in multivariate analysis (RR: 2.19, 95% CI: [1.23, 2.62], Pâ€‰=â€‰0.024). Scoring systems for probability assessment of the presence of COVID-19 infection showed a significant correlation with the vaccination status in univariate analysis; however, the associations were attenuated after adjustment for virus variant and stage of infection. Semi-quantitative assessment of lung changes due to COVID-19 infection revealed no association with vaccination status. Non-vaccinated patients showed a two-fold higher probability of the crazy-paving pattern compared to vaccinated patients. COVID-19 variants could have a significant impact on the CT-graphic appearance of COVID-19.

Modulation of the Immune Response to Severe Acute Respiratory Syndrome Coronavirus 2 Vaccination by Nonsteroidal Anti-Inflammatory Drugs. Evidence is scarce to guide the use of nonsteroidal anti-inflammatory drugs (NSAIDs) to mitigate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine-related adverse effects, given the possibility of blunting the desired immune response. In this pilot study, we deeply phenotyped a small number of volunteers who did or did not take NSAIDs concomitant with SARS-CoV-2 immunizations to seek initial information on the immune response. A SARS-CoV-2 vaccine-specific receptor binding domain (RBD) IgG antibody response and efficacy in the evoked neutralization titers were evident irrespective of

concomitant NSAID consumption. Given the sample size, only a large and consistent signal of immunomodulation would have been detectable, and this was not apparent. However, the information gathered may inform the design of a definitive clinical trial. Here we report a series of divergent omics signals that invites additional hypotheses testing. SIGNIFICANCE STATEMENT: The impact of nonsteroidal anti-inflammatory drugs (NSAIDs) on the immune response elicited by repeat severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) immunizations was profiled by immunophenotypic, proteomic, and metabolomic approaches in a clinical pilot study of small sample size. A SARS-CoV-2 vaccine-specific immune response was evident irrespective of concomitant NSAID consumption. The information gathered may inform the design of a definitive clinical trial.

RNase2 is a possible trigger of acute-on-chronic inflammation leading to mRNA vaccine-associated cardiac complication. BACKGROUND: Post-mRNA vaccination-associated cardiac complication is a rare but life-threatening adverse event. Its risk has been well balanced by the benefit of vaccination-induced protection against severe COVID-19. As the rate of severe COVID-19 has consequently declined, future booster vaccination to sustain immunity, especially against infection with new severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants, may encounter benefit-risk ratios that are less favorable than at the start of the COVID-19 vaccination campaign. Understanding the pathogenesis of rare but severe vaccine-associated adverse events to minimize its risk is thus urgent. METHODS: Here, we report a serendipitous finding of a case of cardiac complication following a third shot of COVID-19 mRNA vaccine. As this case was enrolled in a cohort study, pre-vaccination and pre-symptomatic blood samples were available for genomic and multiplex cytokine analyses. FINDINGS: These analyses revealed the presence of subclinical chronic inflammation, with an elevated expression of RNASE2 at pre-booster baseline as a possible trigger of an acute-on-chronic inflammation that resulted in the cardiac complication. RNASE2 encodes for the ribonuclease RNase2, which cleaves RNA at the 3' side of uridine, which may thus remove the only Toll-like receptor (TLR)-avoidance safety feature of current mRNA vaccines. CONCLUSIONS: These pre-booster and pre-symptomatic gene and cytokine expression data provide unique insights into the possible pathogenesis of vaccine-associated cardiac complication and suggest the incorporation of additional nucleoside modification for an added safety margin. FUNDING: This work was funded by the NMRC Open Fund-Large Collaborative Grant on Integrated Innovations on Infectious Diseases (OFLCG19May-0034).

SARS-CoV-2 infection- induced seroprevalence among children and associated risk factors during the pre- and omicron-dominant wave, from January 2021 through December 2022, Thailand: A longitudinal study. BACKGROUND: Severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) infection can be asymptomatic in young children. Therefore, the true rate of infection is likely underestimated. Few data are available on the rate of infections in young children, and studies on SARS-CoV-2 seroprevalence among children during the omicron wave are limited. We assessed the SARS-CoV-2 infection-induced seroprevalence among children and estimated the associated risk factors for seropositivity. METHODS: A longitudinal serological survey was conducted from January 2021 through December 2022. The inclusion criteria were healthy children between 5 and 7 years old and their parents or legal guardians provided written informed consent. Samples were tested for anti-nucleocapsid (N) IgG and anti-receptor binding domain (RBD) IgG using a chemiluminescent microparticle immunoassay (CMIA), and total anti-RBD immunoglobulin (Ig) was detected using an electrochemiluminescence immunoassay (ECLIA). The vaccination and SARS-CoV-2 infection history were collected. RESULTS: In all, 457 serum samples were obtained from 241 annually followed-up children in this longitudinal serological survey. Of these, 201 participants provided samples at two serial time points-during the pre-omicron and omicron-dominant wave. Overall, seroprevalence induced by SARS-CoV-2 infection increased from 9.1% (22/241) during the pre-omicron to 48.8%

(98/201) during the omicron wave. Amongst seropositive individuals, the infection-induced seropositivity was lower in vaccinated participants with two doses of BNT162b2 than in the unvaccinated participants (26.4% vs. 56%; OR, 0.28; 95%CI: 0.14-0.58). Nevertheless, the ratio of seropositive cases per recalled infection was 1.63 during the omicron dominant wave. The overall seroprevalence induced by infection, vaccination, and hybrid immunity was 77.1% (155/201) between January and December 2022. CONCLUSIONS: We report an increase in infection-induced seroprevalence among children during the omicron wave. These findings highlight that a seroprevalence survey can help determine the true rate of infection, particularly in asymptomatic infection, and optimize public health policies and vaccine strategies in the pediatric population.

COVID-19 stigmatization after the development of effective vaccines: Vaccination behavior, attitudes, and news sources. OBJECTIVE: To compare COVID-19 stigmatization at two pandemic time points (1) August 2020-during lockdowns and prior to vaccine rollout, and (2) May 2021-during vaccine rollout, when approximately half of U.S. adults were vaccinated. METHODS: Comparison of COVID19-related stigmatization and associated factors in two national internet surveys conducted in August 2020 (N = 517) and May 2021 (N = 812). Factors associated with endorsing stigmatization were identified using regression analysis. The main outcomes included endorsement of stigmatization and behavioral restrictions towards persons with COVID-19 and towards persons of Chinese descent. A previously developed "stigmatizing attitudes and behavioral restrictions" scale was adapted to measure the intersection of negative attitudes toward COVID-19 disease and negative attitudes toward persons of Chinese descent. RESULTS: COVID-19 related stigmatization declined significantly from August 2020 to May 2021. Many factors were associated with stigmatizing in both surveys: full time employment, Black race, Hispanic ethnicity, worry about contracting COVID-19, probable depression, and Fox News and social media as sources of information (all positively associated), and self-assessed knowledge about COVID-19, contact with Chinese individuals, and publicly funded news as sources (all negatively associated). Positive attitudes toward vaccination were associated with stigmatization. CONCLUSIONS: COVID-19 related stigmatization reduced substantially over these two points in the pandemic, with many continuities in the factors associated with stigmatizing. Despite the reduction in stigmatizing, however, some stigmatizing attitudes for both COVID-19 and Chinese individuals remained.

Hospital Catchment Areas Characteristics and Geographic Regions Associated With Higher COVID-19 Veterans Health Administration Hospitalization During the Omicron Surge. CONTEXT: Surges in the ongoing coronavirus-19 (COVID-19) pandemic and accompanying increases in hospitalizations continue to strain hospital systems. Identifying hospital-level characteristics associated with COVID-19 hospitalization rates and clusters of hospitalization "hot spots" can help with hospital system planning and resource allocation. OBJECTIVE: To identify (1) hospital catchment area-level characteristics associated with higher COVID-19 hospitalization rates and (2) geographic regions with high and low COVID-19 hospitalization rates across catchment areas during COVID-19 Omicron surge (December 20, 2021-April 3, 2022). DESIGN: This observational study used Veterans Health Administration (VHA), US Health Resource & Services Administration's Area Health Resources File, and US Census data. We used multivariate regression to identified hospital catchment area-level characteristics associated with COVID-19 hospitalization rates. We used ESRI ArcMap's Getis-Ord Gi* statistic to identify catchment area clusters of hospitalization hot and cold spots. SETTING AND PARTICIPANTS: VHA hospital catchment areas in the United States (n = 143). MAIN OUTCOME MEASURES: Hospitalization rate. RESULTS: Greater COVID-19 hospitalization was associated with serving more high hospitalization risk patients (34.2 hospitalizations/10 000 patients per 10-percentage point increase in high hospitalization risk patients; 95% confidence intervals [CI]: 29.4, 39.0), fewer patients new to VHA during the pandemic (-3.9, 95% CI: -6.2, -1.6), and fewer COVID

vaccine-boosted patients (-5.2; 95% CI: -7.9, -2.5).We identified 2 hospitalization cold spots located in the Pacific Northwest and in the Great Lakes regions, and 2 hot spots in the Great Plains and Southeastern US regions. CONCLUSIONS: Within VHA's nationally integrated health care system, catchment areas serving a larger high hospitalization risk patient population were associated with more Omicron-related hospitalizations, while serving more patients fully vaccinated and boosted for COVID-19 and new VHA users were associated with lower hospitalization. Hospital and health care system efforts to vaccinate patients, particularly high-risk patients, can potentially safeguard against pandemic surges.Hospitalization hot spots within VHA include states with a high burden of chronic disease in the Great Plains and Southeastern United States.

Association of SARS-CoV-2 Vaccination or Infection With Bell Palsy: A Systematic Review and Meta-analysis. IMPORTANCE: Bell palsy (BP) has been reported as an adverse event following the SARS-CoV-2 vaccination, but neither a causative relationship nor a higher prevalence than in the general population has been established. OBJECTIVE: To compare the incidence of BP in SARS-CoV-2 vaccine recipients vs unvaccinated individuals or placebo recipients. DATA SOURCES: A systematic search of MEDLINE (via PubMed), Web of Science, Scopus, Cochrane Library, and Google Scholar from the inception of the COVID-19 report (December 2019) to August 15, 2022. STUDY SELECTION: Articles reporting BP incidence with SARS-CoV-2 vaccination were included. DATA EXTRACTION AND SYNTHESIS: This study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline and was conducted with the random- and fixed-effect models using the Mantel-Haenszel method. The quality of the studies was evaluated by the Newcastle-Ottawa Scale. MAIN OUTCOMES AND MEASURES: The outcomes of interest were to compare BP incidence among (1) SARS-CoV-2 vaccine recipients, (2) nonrecipients in the placebo or unvaccinated cohorts, (3) different types of SARS-CoV-2 vaccines, and (4) SARS-CoV-2-infected vs SARS-CoV-2-vaccinated individuals. RESULTS: Fifty studies were included, of which 17 entered the quantitative synthesis. Pooling 4 phase 3 randomized clinical trials showed significantly higher BP in recipients of SARS-CoV-2 vaccines (77â€¯525 vaccine recipients vs 66â€¯682 placebo recipients; odds ratio [OR], 3.00; 95% CI, 1.10-8.18; I2â€‰=â€‰0%). There was, however, no significant increase in BP after administration of the messenger RNA SARS-CoV-2 vaccine in pooling 8 observational studies (13â€¯518â€¯026 doses vs 13â€¯510â€¯701 unvaccinated; OR, 0.70; 95% CI, 0.42-1.16; I2â€‰=â€‰94%). No significant difference was found in BP among 22â€¯978â€¯880 first-dose recipients of the Pfizer/BioNTech vaccine compared with 22â€¯978â€¯880 first-dose recipients of the Oxford/AstraZeneca vaccine (OR, 0.97; 95% CI, 0.82-1.15; I2â€‰=â€‰0%). Bell palsy was significantly more common after SARS-CoV-2 infection (nâ€‰=â€‰2â€¯822â€¯072) than after SARS-CoV-2 vaccinations (nâ€‰=â€‰37â€¯912â€¯410) (relative risk, 3.23; 95% CI, 1.57-6.62; I2â€‰=â€‰95%). CONCLUSIONS AND RELEVANCE: This systematic review and meta-analysis suggests a higher incidence of BP among SARS-CoV-2-vaccinated vs placebo groups. The occurrence of BP did not differ significantly between recipients of the Pfizer/BioNTech vs Oxford/AstraZeneca vaccines. SARS-CoV-2 infection posed a significantly greater risk for BP than SARS-CoV-2 vaccination.

Trends in Antibody Titers after SARS-CoV-2 Vaccination-Insights from Self-Paid Tests at a General Internal Medicine Clinic. Background: The rise in antibody titers against the novel coronavirus (SARS-CoV-2) and its duration are considered an important indicator for confirming the effect of a COVID-19 vaccine, and self-paid tests of antibody titer are conducted in many facilities nationwide. Methods: The relationship between the number of days after the second and third dose of vaccines, age, and antibody titer was determined from the medical records of general internal medicine clinics that conducted self-paid testing of the SARS-CoV-2 antibody titer using Elecsys Anti-SARS-CoV-2 S (Roche Diagnostics); the relationship between the number of days after two or more doses of vaccines and antibody titer was also determined. We also examined the antibody titers in cases of

spontaneous infection with SARS-CoV-2 after two or more doses of the vaccine. Results: Log-transformed SARS-CoV-2 antibody titers measured within 1 month from the second or third dose of vaccine showed a negative correlation with age ($p < 0.05$). In addition, the log-transformed antibody titers also showed a negative correlation trend with the number of days after the second dose of vaccine ($p = 0.055$); however, there were no significant correlations between the log-transformed antibody titers and the number of days after the third dose of vaccine. The median antibody titer after the third vaccination was 18,300 U/mL, more than 10 times the median antibody titer after the second dose of vaccine, of 1185 U/mL. There were also some cases of infection after the third or fourth dose of vaccine, with antibody titers in the tens of thousands of U/ml after infection, but the patients still received further booster vaccinations after the infection. Conclusions: The antibody titers after the third vaccination did not attenuate after a short follow-up period of one month, while they tended to attenuate after the second vaccination. It is considered that many people in Japan received further booster vaccinations after spontaneous infection, even though they already had antibody titers in the tens of thousands of U/mL due to "hybrid immunity" after spontaneous infection following two or more doses of vaccine. The clinical significance of the booster vaccination in this population still needs to be thoroughly investigated and should be prioritized for those with low SARS-CoV-2 antibody titers.

Overview of the cardio-metabolic impact of the COVID-19 pandemic. Evidence has shown that cardiometabolic disorders (CMDs) are amongst the top contributors to COVID-19 infection morbidity and mortality. The reciprocal impact of COVID-19 infection and the most common CMDs, the risk factors for poor composite outcome among patients with one or several underlying diseases, the effect of common medical management on CMDs and their safety in the context of acute COVID-19 infection are reviewed. Later on, the changes brought by the COVID-19 pandemic quarantine on the general population's lifestyle (diet, exercise patterns) and metabolic health, acute cardiac complications of different COVID-19 vaccines and the effect of CMDs on the vaccine efficacy are discussed. Our review identified that the incidence of COVID-19 infection is higher among patients with underlying CMDs such as hypertension, diabetes, obesity and cardiovascular disease. Also, CMDs increase the risk of COVID-19 infection progression to severe disease phenotypes (e.g. hospital and/or ICU admission, use of mechanical ventilation). Lifestyle modification during COVID-19 era had a great impact on inducing and worsening of CMDs. Finally, the lower efficacy of COVID-19 vaccines was found in patients with metabolic disease.

Safety of COVID-19 Vaccines Among the Paediatric Population: Analysis of the European Surveillance Systems and Pivotal Clinical Trials. BACKGROUND AND OBJECTIVES: The European Medicine Agency extended the use of Comirnaty, Spikevax, and Nuvaxovid in paediatrics; thus, these vaccines require additional real-world safety evidence. Herein, we aimed to monitor the safety of COVID-19 vaccines through Covid-19 Vaccine Monitor (CVM) and EudraVigilance surveillance systems and the published pivotal clinical trials. METHODS: In a prospective cohort of vaccinees aged between 5 and 17 years, we measured the frequency of commonly reported (local/systemic solicited) and serious adverse drug events (ADRs) following the first and second doses of COVID-19 vaccines in Europe using data from the CVM cohort until April 2022. The results of previous pivotal clinical trials and data in the EudraVigilance were also analysed. RESULTS: The CVM study enrolled 658 first-dose vaccinees (children aged 5-11 years; n = 250 and adolescents aged 12-17 years; n = 408). Local/systemic solicited ADRs were common, whereas serious ADRs were uncommon. Among Comirnaty first and second dose recipients, 28.8% and 17.1% of children and 54.2% and 52.2% of adolescents experienced at least one ADR, respectively; injection-site pain (29.2% and 20.7%), fatigue (16.1% and 12.8%), and headache (22.1% and 19.3%) were the most frequent local and systemic ADRs. Results were consistent but slightly lower than in pivotal clinical trials. Reporting rates in Eudravigilance were

lower by a factor of 1000. CONCLUSIONS: The CVM study showed high frequencies of local solicited reactions after vaccination but lower rates than in pivotal clinical trials. Injection-site pain, fatigue, and headache were the most commonly reported ADRs for clinical trials, but higher than spontaneously reported data.

A case of rapidly progressive glomerulonephritis with double-positive anti-GBM antibody and MPO-ANCA after SARS-CoV-2 vaccination and relapse during 1Â year follow-up. Although mRNA vaccines for COVID-19 are highly beneficial and are recommended for patients with kidney disease, adverse reactions in some patients after vaccination have been problematic. Various vasculitis and renal disorders have been reported after vaccination; however, a causal relationship has not yet been identified. In this report, we describe a case of rapidly progressive glomerulonephritis that developed after SARS-CoV-2 vaccination, in which both anti-glomerular basement membrane (anti-GBM) and myeloperoxidase antineutrophil cytoplasmic antibodies (MPO-ANCA) were present. The patient's renal biopsy showed that of the 48 glomeruli in total, four showed global sclerosis and none showed segmental sclerosis. The biopsy showed 11 cellular glomerular crescents and 5 fibrocellular glomerular crescents. Renal function improved with steroids, rituximab, and plasma exchange. Approximately 9Â months later, MPO-ANCA was again elevated, and the pulmonary lesions worsened, again requiring multidisciplinary treatment. This case suggests that caution should be exercised in the development of double-positive disease after vaccination, and that long-term observation may be necessary because of the possibility of relapse.

Accelerated T-Cell Immunosenescence in Cytomegalovirus-Seropositive Individuals After Severe Acute Respiratory Syndrome Coronavirus 2 Infection. Cytomegalovirus (CMV) infection is a major driver of accelerated immunosenescence related to CD28null T cell expansion. CMV infection and these proatherogenic T cells have been independently associated with cardiovascular disease and coronavirus disease 2019 (COVID-19) severity. We investigated the potential contribution of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to immunosenescence and its relationship with CMV. Innate and adaptive immune subpopulations from individuals with mild or asymptomatic SARS-CoV-2 infection (mCOVID-19) and healthy donors were immunophenotyped. A significant increase in CD28nullCD57+CX3CR1+ T cell percentages (CD4+ [P â‰¤ .01], CD8+ [P â‰¤ .01], and TcRÎ³Î´ (CD4-CD8-) [P â‰¤ .001]) was found in unnvaccinated CMV-seropositive mCOVID-19 individuals stable up to 12 months after infection. This expansion did not occur in CMV-seronegative mCOVID-19 individuals or in CMV-seropositive individuals infected after SARS-CoV-2 vaccination. There were no significant differences between mCOVID-19 and aortic stenosis groups. Thus, individuals coinfected with SARS-CoV-2 and CMV have accelerated T cell senescence, which might lead to an increased risk of cardiovascular disease.

Manifestation of pityriasis rosea and pityriasis rosea-like eruptions after Covid-19 vaccine: A systematic review. BACKGROUND: After introducing Covid-19 vaccines, a few side effects were reported, pityriasis rosea being one of them. Therefore, this study will systematically review its manifestation afteradministration. METHODS: Databases were searched, covering a timeline from December 1, 2019 to February 28, 2022. Data were independently extracted and accessed for bias. SPSS statistical software version 25 was used for appropriate inferential statistics. RESULTS: Thirty-one studies were included for data extraction after screening following the eligibility criteria. A total of 111 people were identified to have developed pityriasis rosea or pityriasis rosea-like eruptions after vaccination, out of which 36 (55.38%) were female. The average age of incidence was calculated to be 44.92 years, and 63 (62.37%) people presented after administration of the first dose. It was found popularly in the trunk area, either asymptomatically or with mild symptoms. Meantime the onset, was 8.58 days, and meantime it took to recover, was 6.44 weeks. CONCLUSION: The association between pityriasis rosea and pityriasis rosea-like eruptions after Covid-19 vaccines was

established, but given the scarcity of studies, there is a need to conduct different clinical trials to confirm this association further and study the etiology and mechanism of the disease.

Rapidly progressing generalized bullous fixed drug eruption after the first dose of COVID-19 messenger RNA vaccination. Generalized bullous fixed drug eruption (GBFDE) is a rare type of life-threatening severe cutaneous adverse reaction that is considered a medical emergency because of its potential lethality. Currently, only a few cases of bullous adverse reactions have been reported after coronavirus disease 2019 (COVID-19) vaccination. We describe a patient with distinct clinical, histopathological, and immunological findings that are consistent with severe GBFDE, after Pfizer messenger RNA COVID-19 vaccination. An 83-year-old man presented with a fever and well-demarcated multiple erythematous patches that occurred only 4â€‰h after receiving the first dose of COVID-19 Pfizer vaccination. Over the next few days, the patches became generalized and turned into blisters covering approximately 30% of the body surface. The patient was started on intravenous methylprednisolone and oral cyclosporine. There were no additional blistering lesions after 10â€‰days of treatment, prompting a gradual dose reduction. Our case suggests that a stepwise vaccination adhering to the standard dosing schedule should be warranted with close monitoring for possible significant side effects.

ANCA-Associated Vasculitis after Moderna COVID-19 Vaccination. We experienced a case of myeloperoxidase antineutrophil cytoplasmic antibody (MPO-ANCA)-associated vasculitis after Moderna COVID-19 vaccination. An 82-year-old woman developed pyrexia and general malaise one month after her third booster vaccine, and the symptoms persisted. Blood testing revealed inflammation, a high level of MPO-ANCA, and microscopic hematuria. MPO-ANCA-associated vasculitis was diagnosed by renal biopsy. The symptoms improved with steroid therapy. Common adverse reactions to mRNA vaccines against COVID-19 include pyrexia and general malaise, but MPO-ANCA-associated vasculitis can also occur. If pyrexia, prolonged general malaise, urinary occult blood, or renal impairment is observed, the onset of MPO-ANCA-associated vasculitis should be considered.

Cerebral venous sinus thrombosis after a third dose of mRNA COVID-19 vaccine in an adolescent.

Third dose mRNA vaccination against SARS-CoV-2 reduces medical complaints seen in primary care: a matched cohort study. BACKGROUND: SARS-CoV-2 mRNA vaccination has been associated with both side effects and a reduction in COVID-related complaints due to the decrease in COVID-19 incidence. We aimed to investigate if individuals who received three doses of SARS-CoV-2 mRNA vaccines had a lower incidence of (a) medical complaints and (b) COVID-19-related medical complaints, both as seen in primary care, when compared to individuals who received two doses. METHODS: We conducted a daily longitudinal exact one-to-one matching study based on a set of covariates. We obtained a matched sample of 315,650 individuals aged 18-70Â years who received the 3rd dose at 20-30Â weeks after the 2nd dose and an equally large control group who did not. Outcome variables were diagnostic codes as reported by general practitioners or emergency wards, both alone and in combination with diagnostic codes of confirmed COVID-19. For each outcome, we estimated cumulative incidence functions with hospitalization and death as competing events. RESULTS: We found that the number of medical complaints was lower in individuals aged 18-44Â years who received three doses compared to those who received two doses. The differences in estimates per 100,000 vaccinated were as follows: fatigue 458 less (95% confidence interval: 355-539), musculoskeletal pain 171 less (48-292), cough 118 less (65-173), heart palpitations 57 less (22-98), shortness of breath 118 less (81-149), and brain fog 31 less (8-55). We also found a lower number of COVID-19-related medical complaints: per 100,000 individuals aged 18-44Â years vaccinated with three doses, there were 102 (76-125) fewer individuals with fatigue, 32 (18-45) fewer with musculoskeletal pain, 30 (14-45) fewer with cough, and 36 (22-48) fewer with shortness of breath. There were no or fewer differences in heart palpitations (8 (1-16)) or brain fog (0 (-â€‰1-8)).

We observed similar results, though more uncertain, for individuals aged 45-70Â years, both for medical complaints and for medical complaints that were COVID-19 related. CONCLUSIONS: Our findings suggest that a 3rd dose of SARS-CoV-2 mRNA vaccine administered 20-30Â weeks after the 2nd dose may reduce the incidence of medical complaints. It may also reduce the COVID-19-related burden on primary healthcare services.

Exploring the vaccine-induced immunity against severe acute respiratory syndrome coronavirus 2 in healthcare workers. We aimed to analyze the kinetics of T-cell-mediated and B-cell-mediated humoral immune responses against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) before and after booster vaccination, as well as the impacts of the in vitro test results the type of vaccination on the prediction of SARS-CoV-2 infection. A total of 240 healthcare workers vaccinated twice were serially tested using an interferon gamma release assay (IGRA) and a neutralizing antibody (nAb). At the end of the study, we investigated the history of SARS-CoV-2 infection of all the enrolled participants to analyze the effects of the test results and the type of vaccination on SARS-CoV-2 infection. Overall, the positive rates were 52.3% and 80.0% for IGRA and 84.6% and 100% for the nAb test before and after booster vaccination, respectively. However, the positive rates were 52.8% for IGRA and 100% for nAb 3Â months after booster vaccination. The in vitro test results and the type of vaccination were not associated with SARS-CoV-2 infection. The antibody response caused by the SARS-CoV-2 vaccination lasted more than 6Â months, although the response of the T-cells disappeared rapidly after 3Â months. However, these in vitro results and the type of vaccination cannot be used for predicting the risk of SARS-CoV-2 infection.

Remdesivir plus dexamethasone is associated to improvement in the clinical outcome of COVID-19 hospitalized patients regardless of their vaccination status. INTRODUCTION: Remdesivir seems to reduce the risk of hospitalization and improve clinical outcome in hospitalized patients with COVID-19. OBJECTIVES: To compare the clinical outcome of COVID-19 hospitalized patients treated with remdesivir plus dexamethasone versus dexamethasone alone, according to their vaccination status. MATERIAL AND METHODS: A retrospective observational study was carried out in 165 patients hospitalized for COVID-19 from October 2021 to January 2022. Multivariate logistic regression, Kaplan-Meier and the log-rank tests were used to evaluate the event (need for ventilation or death). RESULTS: Patients treated with remdesivir plus dexamethasone (n=87) compared with dexamethasone alone (n=78) showed similar age (60Â±16, 47-70 vs. 62Â±37, 51-74 years) and number of comorbidities: 1 (0-2) versus 1.5 (1-3). Among 73 fully vaccinated patients, 42 (47.1%) were in remdesivir plus dexamethasone and 31 (41%) in dexamethasone alone. Patients treated with remdesivir plus dexamethasone needed intensive care less frequently (17.2% vs. 31%; p=0.002), high-flow oxygen (25.3% vs. 50.0%; p=0.002) and non-invasive mechanical ventilation (16.1% vs. 47.4%; p<0.001). Furthermore, they had less complications during hospitalization (31.0% vs. 52.6%; p=0.008), need of antibiotics (32.2% vs. 59%; p=0.001) and radiologic worsening (21.8% vs. 44.9%; p=0.005). Treatment with remdesivir plus dexamethasone (aHR, 0.26; 95% CI: 0.14-0.48; p<0.001) and vaccination (aHR 0.39; 95% CI: 0.21-0.74) were independent factors associated with lower progression to mechanical ventilation or death. CONCLUSIONS: Remdesivir in combination with dexamethasone and vaccination independently and synergistically protects hospitalized COVID-19 patients requiring oxygen therapy from progression to severe disease or dead.

Pre-existing humoral immunity and CD4(+) T cell response correlate with cross-reactivity against SARS-CoV-2 Omicron subvariants after heterologous prime-boost vaccination. BACKGROUND: Information regarding the heterologous prime-boost COVID vaccination has been fully elucidated. The study aimed to evaluate both humoral, cellular immunity and cross-reactivity against variants after heterologous vaccination. METHODS: We recruited healthcare workers previously primed with Oxford/AstraZeneca ChAdOx1-S vaccines and boosted with Moderna mRNA-1273 vaccine boost to

evaluate the immunological response. Assay used: anti-spike RBD antibody, surrogate virus neutralizing antibody and interferon-Î³ release assay. RESULTS: All participants exhibited higher humoral and cellular immune response after the booster regardless of prior antibody level, but those with higher antibody level demonstrated stronger booster response, especially against omicron BA.1 and BA.2 variants. The pre-booster IFN-Î³ release by CD4(+) T cells correlates with post-booster neutralizing antibody against BA.1 and BA.2 variant after adjustment with age and gender. CONCLUSIONS: A heterologous mRNA boost is highly immunogenic. The pre-existing neutralizing antibody level and CD4(+) T cells response correlates with post-booster neutralization reactivity against the Omicron variant.

Safety and immunogenicity of a modified COVID-19 mRNA vaccine, SW-BIC-213, as a heterologous booster in healthy adults: an open-labeled, two-centered and multi-arm randomised, phase 1 trial. BACKGROUND: We assessed the safety and immunogenicity of a core-shell structured lipopolyplex (LPP) based COVID-19 mRNA vaccine, SW-BIC-213, as a heterologous booster in healthy adults. METHODS: We conducted an open-labeled, two-centered, and three-arm randomised phase 1 trial. Healthy adults, who had completed a two-dose of inactivated COVID-19 vaccine for more than six months, were enrolled and randomized to receive a booster dose of COVILO (inactivated vaccine) (nÂ =Â 20) or SW-BIC-213-25Î¼g (nÂ =Â 20), or SW-BIC-213-45Î¼g (nÂ =Â 20). The primary study endpoint was adverse events within 30 days post-boosting. The secondary endpoint wasÂ the titers of binding antibodies and neutralizing antibodies against the wild-type (WT) of SARS-CoV-2 as well as variants of concern in serum. The exploratory endpoint was the cellular immune responses. This trial was registered with http://www.chictr.org.cn (ChiCTR2200060355). FINDINGS: Between Jun 6 and Jun 22, 2022, 60 participants were enrolled and randomized to receive a booster dose of SW-BIC-213 (25Â Î¼g, nÂ =Â 20, or 45Â Î¼g, nÂ =Â 20) or COVILO (nÂ =Â 20). The baseline demographic characteristics of the participants at enrollment were similar among the treatment groups. For the primary outcome, injection site pain and fever were more common in the SW-BIC-213 groups (25Â Î¼g and 45Â Î¼g). Grade 3 fever was reported in 25% (5/20) of participants in the SW-BIC-213-45Î¼g group but was resolved within 48Â h after onset. No fatal events or adverse events leading to study discontinuation were observed. For secondary and exploratory outcomes, SW-BIC-213 elicited higher and longer humoral and cellular immune responses than that in the COVILO group. INTERPRETATION: SW-BIC-213, a core-shell structured lipopolyplex (LPP) based mRNA vaccine, was safe, tolerable, and immunogenic as a heterologous booster in healthy Chinese adults. FUNDING: Shanghai Municipal Government, the Science and Technology and Economic Commission of Shanghai Pudong New Area, and mRNA Innovation and Translation Center of Shanghai.

Correspondence on "COVID-19 vaccination and pregnancy".

Randomized Trial of BCG Vaccine to Protect against Covid-19 in Health Care Workers. BACKGROUND: The bacille Calmette-GuÃ©rin (BCG) vaccine has immunomodulatory "off-target" effects that have been hypothesized to protect against coronavirus disease 2019 (Covid-19). METHODS: In this international, double-blind, placebo-controlled trial, we randomly assigned health care workers to receive the BCG-Denmark vaccine or saline placebo and followed them for 12 months. Symptomatic Covid-19 and severe Covid-19, the primary outcomes, were assessed at 6 months; the primary analyses involved the modified intention-to-treat population, which was restricted to participants with a negative test for severe acute respiratory syndrome coronavirus 2 at baseline. RESULTS: A total of 3988 participants underwent randomization; recruitment ceased before the planned sample size was reached owing to the availability of Covid-19 vaccines. The modified intention-to-treat population included 84.9% of the participants who underwent randomization: 1703 in the BCG group and 1683 in the placebo group. The estimated risk of symptomatic Covid-19 by 6 months was 14.7% in the BCG group and 12.3% in the placebo group (risk difference, 2.4 percentage

points; 95% confidence interval [CI], -0.7 to 5.5; Pâ€‰=â€‰0.13). The risk of severe Covid-19 by 6 months was 7.6% in the BCG group and 6.5% in the placebo group (risk difference, 1.1 percentage points; 95% CI, -1.2 to 3.5; Pâ€‰=â€‰0.34); the majority of participants who met the trial definition of severe Covid-19 were not hospitalized but were unable to work for at least 3 consecutive days. In supplementary and sensitivity analyses that used less conservative censoring rules, the risk differences were similar but the confidence intervals were narrower. There were five hospitalizations due to Covid-19 in each group (including one death in the placebo group). The hazard ratio for any Covid-19 episode in the BCG group as compared with the placebo group was 1.23 (95% CI, 0.96 to 1.59). No safety concerns were identified. CONCLUSIONS: Vaccination with BCG-Denmark did not result in a lower risk of Covid-19 among health care workers than placebo. (Funded by the Bill and Melinda Gates Foundation and others; BRACE ClinicalTrials.gov number, NCT04327206.).

Obesity Is Associated with an Impaired Baseline Repertoire of Anti-Influenza Virus Antibodies. Obesity is a risk factor for severe disease and mortality for both influenza and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. While previous studies show that individuals with obesity generate antibody responses following influenza vaccination, infection rates within the obese group were twice as high as those in the healthy-weight group. The repertoire of antibodies raised against influenza viruses following previous vaccinations and/or natural exposures is referred to here as baseline immune history (BIH). To investigate the hypothesis that obesity impacts immune memory to infections and vaccines, we profiled the BIH of obese and healthy-weight adults vaccinated with the 2010-2011 seasonal influenza vaccine in response to conformational and linear antigens. Despite the extensive heterogeneity of the BIH profiles in both groups, there were striking differences between obese and healthy subjects, especially with regard to A/H1N1 strains and the 2009 pandemic virus (Cal09). Individuals with obesity had lower IgG and IgA magnitude and breadth for a panel of A/H1N1 whole viruses and hemagglutinin proteins from 1933 to 2009 but increased IgG magnitude and breadth for linear peptides from the Cal09 H1 and N1 proteins. Age was also associated with A/H1N1 BIH, with young individuals with obesity being more likely to have reduced A/H1N1 BIH. We found that individuals with low IgG BIH had significantly lower neutralizing antibody titers than individuals with high IgG BIH. Taken together, our findings suggest that increased susceptibility of obese participants to influenza infection may be mediated in part by obesity-associated differences in the memory B-cell repertoire, which cannot be ameliorated by current seasonal vaccination regimens. Overall, these data have vital implications for the next generation of influenza virus and SARS-CoV-2 vaccines. IMPORTANCE Obesity is associated with increased morbidity and mortality from influenza and SARS-CoV-2 infection. While vaccination is the most effective strategy for preventing influenza virus infection, our previous studies showed that influenza vaccines fail to provide optimal protection in obese individuals despite reaching canonical correlates of protection. Here, we show that obesity may impair immune history in humans and cannot be overcome by seasonal vaccination, especially in younger individuals with decreased lifetime exposure to infections and seasonal vaccines. Low baseline immune history is associated with decreased protective antibody responses. Obesity potentially handicaps overall responses to vaccination, biasing it toward responses to linear epitopes, which may reduce protective capacity. Taken together, our data suggest that young obese individuals are at an increased risk of reduced protection by vaccination, likely due to altered immune history biased toward nonprotective antibody responses. Given the worldwide obesity epidemic coupled with seasonal respiratory virus infections and the inevitable next pandemic, it is imperative that we understand and improve vaccine efficacy in this high-risk population. The design, development, and usage of vaccines for and in obese individuals may need critical evaluation, and immune history should be considered an alternate correlate of protection in future vaccine clinical trials.

Association of Perceived Stress With Depression Among Vaccinated Healthcare Workers During the SARS-CoV-2 Variant Outbreak: The Mediating Role of Compassion Fatigue. OBJECTIVE: Depression was common during coronavirus disease-2019 (COVID-19) pandemic, while the association of perceived stress with depression among vaccinated healthcare workers has not been investigated. This study aimed to address this issue. METHODS: We included a total of 898 fully vaccinated healthcare workers during the outbreak of severe acute respiratory syndrome coronavirus 2 Delta variant in Nanjing, 2021. Depression was ascertained by Patient Health Questionnaire-9, with a cut-off score of â‰¥5 indicative of mild-to-severe depression. Perceived stress, resilience, and compassion fatigue were assessed by Perceived Stress Scale-10, Resilience Scale-25, and Professional Quality of Life Scale version-5, respectively. Logistic regression analyses were used to estimate the odds ratio (OR) and 95% confidence interval (CI), along with subgroup and mediation analyses. RESULTS: The prevalence of mild-to-severe depression was 41.1% in vaccinated healthcare workers. The odd of mild-to-severe depression was increased with higher perceived stress. Compared with vaccinated healthcare workers with the lowest tertile of perceived stress, those with the highest tertile had increased odds of mild-to-severe depression by 120% (OR 2.20, 95% CI 1.46 to 3.31) after multivariable-adjustment. However, perceived stress was not associated with mild-to-severe depression in vaccinated healthcare workers with strong resilience, but was in those with weak resilience (pinteraction=0.004). Further analysis showed that compassion fatigue mediated the relationship between perceived stress and mild-to-severe depression, with a mediating effect of 49.7%. CONCLUSION: Perceived stress was related to an increased odd of mild-to-severe depression in vaccinated healthcare workers during COVID-19 pandemic, and this relationship might be explained by compassion fatigue.

A study of glycemic perturbations following two doses of COVID-19 vaccination for patients with diabetes: the impacts of vaccine type and anti-diabetes drugs. BACKGROUND: Glycemic monitoring has become critical during the COVID-19 pandemic because of poor prognosis in diabetes. Vaccines were key in reducing the spread of infection and disease severity but data were lacking on effects on blood sugar levels. The aim of the current study was to investigate the impact of COVID-19 vaccination on glycemic control. METHODS: We performed a retrospective study of 455 consecutive patients with diabetes who completed two doses of COVID-19 vaccination and attended a single medical center. Laboratory measurements of metabolic values were assessed before and after vaccination, while the type of vaccine and administrated anti-diabetes drugs were analyzed to find independent risks associated with elevated glycemic levels. RESULTS: One hundred and fifty-nine subjects received ChAdOx1 (ChAd) vaccines, 229 received Moderna vaccines, and 67 received Pfizer-BioNtech (BNT) vaccines. The average HbA1c was raised in the BNT group from 7.09 to 7.34% (Pâ€‰=â€‰0.012) and non-significantly raised in ChAd (7.13 to 7.18%, Pâ€‰=â€‰0.279) and Moderna (7.19 to 7.27%, Pâ€‰=â€‰0.196) groups. Both Moderna and BNT groups had around 60% of patients with elevated HbA1c following two doses of COVID-19 vaccination, and the ChAd group had only 49%. Under logistic regression modeling, the Moderna vaccine was found to independently predict the elevation of HbA1c (Odds ratio 1.737, 95% Confidence interval 1.12-2.693, Pâ€‰=â€‰0.014), and sodium-glucose co-transporter 2 inhibitor (SGLT2i) was negatively associated with elevated HbA1c (OR 0.535, 95% CI 0.309-0.927, Pâ€‰=â€‰0.026). CONCLUSIONS: Patients with diabetes might have mild glycemic perturbations following two doses of COVID-19 vaccines, particularly with mRNA vaccines. SGLT2i showed some protective effect on glycemic stability. Hesitancy in having vaccinations should not be indicated for diabetic patients with respect to manageable glycemic change. TRIAL REGISTRATION: Not applicable.

Outcome of COVID-19 mRNA Vaccination in Patients Treated With Clozapine WHO Previously Went Through SARS-COV-2 Infection. BACKGROUND: The outbreak of the severe acute respiratory

syndrome coronavirus 2 (SARS-CoV-2) pandemic had multiple consequences for the health care system, especially for patients with mental illnesses. Schizophrenia patients particularly appear to have a higher risk of complications due to coronavirus-19 (COVID-19). Clozapine remains the gold standard for treatment-resistant schizophrenia (TRS). However, the COVID-19 pandemic had an important negative impact on clozapine treatment, mainly because of its administration protocol, which was very difficult to follow during the restrictions imposed in the pandemic, and its side effects in patients with COVID-19 infection. Vaccination is an effective method of avoiding SARS-CoV-2 infection or its severe complications, especially in susceptible populations. Data on adverse events after vaccination against COVID-19 are limited, both in the general population and in schizophrenia patients. STUDY QUESTION: The study aimed to investigate the safety of COVID-19 vaccination in patients treated with clozapine for hematological parameters. STUDY DESIGN: We conducted an analytical cross-sectional study between July 1, 2021, and June 30, 2022. We compared 2 groups of COVID-19 vaccinated patients who had previously experienced SARS-CoV-2 infection: The first group was treated with clozapine, whereas the second group was treated with other antipsychotics. MEASURES AND OUTCOMES: The primary objective was to identify granulocytopenia, leukocytopenia, and lymphocytopenia. The results were measured after the second dose of the Pfizer-BioNTech vaccine. RESULTS: This study included 100 patients. White blood cell count changes were limited to a few cases of mild granulocytopenia (8.16% in the clozapine group and 3.92% in the nonclozapine group, P = 0.37) with no cases of severe granulocytopenia or agranulocytosis. CONCLUSIONS: As far as leukocyte counts are concerned, mRNA COVID-19 vaccination seems to be safe in patients treated with clozapine who previously had SARS-CoV-2 infection. Leukocyte changes had no clinical implications.

Outcomes of COVID-19 Infection and Vaccination Among Individuals With Myasthenia Gravis. IMPORTANCE: There are limited data regarding COVID-19 outcomes and vaccine uptake and safety among people with myasthenia gravis (MG). OBJECTIVE: To investigate COVID-19-related outcomes and vaccine uptake among a population-based sample of adults with MG. DESIGN, SETTING, AND PARTICIPANTS: This population-based, matched cohort study in Ontario, Canada, used administrative health data from January 15, 2020, and August 31, 2021. Adults with MG were identified using a validated algorithm. Each patient was matched by age, sex, and geographic area of residence to 5 controls from the general population and from a cohort of individuals with rheumatoid arthritis (RA). EXPOSURE: Patients with MG and matched controls. MAIN OUTCOMES AND MEASURES: Main outcomes were COVID-19 infection and related hospitalizations, intensive care unit admissions, and 30-day mortality among patients with MG vs controls. Secondary outcomes were uptake of COVID-19 vaccination among patients with MG vs controls. RESULTS: Among 11â€¯365â€¯233 eligible Ontario residents, 4411 patients with MG (mean [SD] age, 67.7 [15.6] years; 2274 women [51.6%]) were matched to 22â€¯055 general population controls (mean [SD] age, 67.7 [15.6] years; 11â€¯370 women [51.6%]) and 22â€¯055 controls with RA (mean [SD] age, 67.7 [15.6] years; 11â€¯370 women [51.6%]). In the matched cohort, 38â€¯861 of 44â€¯110 individuals (88.1%) were urban residents; in the MG cohort, 3901 (88.4%) were urban residents. Between January 15, 2020, and May 17, 2021, 164 patients with MG (3.7%), 669 general population controls (3.0%), and 668 controls with RA (3.0%) contracted COVID-19. Compared with general population controls and controls with RA, patients with MG had higher rates of COVID-19-associated emergency department visits (36.6% [60 of 164] vs 24.4% [163 of 669] vs 29.9% [200 of 668]), hospital admissions (30.5% [50 of 164] vs 15.1% [101 of 669] vs 20.7% [138 of 668]), and 30-day mortality (14.6% [24 of 164] vs 8.5% [57 of 669] vs 9.9% [66 of 668]). By August 2021, 3540 patients with MG (80.3%) vs 17â€¯913 general population controls (81.2%) had received 2 COVID-19 vaccine doses, and 137 (3.1%) vs 628 (2.8%), respectively had received 1 dose. Of 3461 first vaccine doses for patients with MG, fewer than 6 individuals were

hospitalized for MG worsening within 30 days of vaccination. Vaccinated patients with MG had a lower risk than unvaccinated patients with MG of contracting COVID-19 (hazard ratio, 0.43; 95% CI, 0.30-0.60). CONCLUSIONS AND RELEVANCE: This study suggests that adults with MG who contracted COVID-19 had a higher risk of hospitalization and death compared with matched controls. Vaccine uptake was high, with negligible risk of severe MG exacerbations after vaccination, as well as evidence of effectiveness. The findings support public health policies prioritizing people with MG for vaccination and new COVID-19 therapeutics.

COVID-19 vaccine uptake, reasons, and associated factors among older adults in Shenzhen, China. Evidence is limited on the actual uptake of the coronavirus disease 2019 (COVID-19) vaccine among older adults, especially those with chronic diseases, during the pandemic. To examine COVID-19 vaccine uptake, reasons, and associated factor among older adults, a cross-sectional survey was conducted between September 24 and October 20, 2021 among older adults aged 60 and above in Shenzhen, China. Logistic regression analysis was used to examine associations of COVID-19 vaccine uptake with sociodemographic characteristics, pneumonia vaccination history, and participation in health education activities among older adults and among those with chronic diseases. Of the 951 participants, 82.8% reported being vaccinated against COVID-19 during the study period, but this proportion was relatively lower among adults aged 80 and above (62.7%) and those with chronic diseases (77.9%). The top-rated reasons for not being vaccinated included doctors not recommending it due to underlying diseases (34.1%), not being ready for it (18.3%), and failure to make an appointment (9.1%). General older adults who were aged below 70, had a high school and above education, were permanent residents of Shenzhen, were with good health and had pneumonia vaccination history were more likely to take the COVID-19 vaccination. Yet, among older adults with chronic diseases, other than age and permanent residency status, health status was the only significant indicator of COVID-19 vaccine uptake. Our study added to evidence that health condition is the critical barrier to the actual uptake of the COVID-19 vaccine among Chinese older adults, especially those aged 80 and above and those with chronic diseases.

Analysis of Antibody Responses After COVID-19 Vaccination in Liver Transplant Recipients: A Single-Center Study. BACKGROUND: Liver transplant (LT) recipients were considered a vulnerable population during the coronavirus disease 2019 (COVID-19) pandemic. The clinical efficacy of the COVID-19 vaccine is unknown in immunocompromised patients. The purpose of this study was to provide evidence of antibody responses after COVID-19 vaccination in LT recipients. METHODS: This study enrolled 46 patients who underwent LT at Samsung Medical Center (Seoul, Korea) before implementation of the one-dose vaccine in Korea. Those who completed the two-dose COVID-19 vaccine between August 2021 and September 2021 were included and followed through December 2021. Semiquantitative anti-spike serologic testing was performed using the Roche Elecsys anti-SARS-CoV-2 S enzyme immunoassay (Roche Diagnostics, Rotkereuz, Switzerland) with a positive cutoff of at least 0.8 U/mL. RESULTS: Among all 46 participants, 40 (87%) demonstrated an antibody response after the second dose of a COVID-19 vaccine, while six (13%) had no antibody response after the second dose. Upon univariate analysis, patients with higher antibody titer had longer years since LT (2.3 Â± 2.8 vs. 9.4 Â± 5.0, P < 0.001). A lower median tacrolimus (TAC) level before vaccination and after the second dose of COVID-19 vaccine indicated a significantly higher antibody response (2.3 [1.6-3.2] vs. 7.0 [3.7-7.8], P = 0.006, 2.5 [1.6-3.3] vs. 5.7 [4.2-7.2], P = 0.003). Period between 2nd vaccination and serologic testing was significantly higher in the antibody-response group compared to the no-antibody-response group (30.2 Â± 24.0 vs. 65.9 Â± 35.0, P = 0.012). A multivariate analysis of antibody responses revealed TAC level before vaccination as a statistically significant factor. CONCLUSION: A higher TAC level before vaccination resulted in less effective vaccination in LT

patients. Booster vaccinations are required, especially for patients in the early stage after LT who have compromised immune function.

COVID-19 vaccine type and Guillain-BarrÃ© syndrome: Comment.

Rapidly progressive IgA nephropathy with membranoproliferative glomerulonephritis-like lesions in an elderly man following the third dose of an mRNA COVID-19 vaccine: a case report. BACKGROUND: As messenger RNA (mRNA)-based vaccines for coronavirus disease 2019 (COVID-19) have been administered to millions of individuals worldwide, cases of de novo and relapsing glomerulonephritis after mRNA COVID-19 vaccination are increasing in the literature. While most previous publications reported glomerulonephritis after the first or second dose of an mRNA vaccine, few reports of glomerulonephritis occurring after the third dose of an mRNA vaccine currently exist. CASE PRESENTATION: We report a case of rapidly progressive glomerulonephritis in a patient following the third dose of an mRNA COVID-19 vaccine. A 77-year-old Japanese man with a history of hypertension and atrial fibrillation was referred to our hospital for evaluation of anorexia, pruritus, and lower extremity edema. One year before referral, he received two mRNA vaccines (BNT162b2) for COVID-19. Three months before the visit, he received a third mRNA vaccine (mRNA-1273) for COVID-19. On admission, the patient presented severe renal failure with a serum creatinine level of 16.29Â mg/dL, which had increased from 1.67Â mg/dL one month earlier, prompting us to initiate hemodialysis. Urinalysis showed nephrotic-range proteinuria and hematuria. Renal biopsy revealed mild mesangial proliferation and expansion, a lobular appearance, and double contours of the glomerular basement membrane. Renal tubules had severe atrophy. Immunofluorescence microscopy showed strong mesangial staining for IgA, IgM, and C3c. Electron microscopy exhibited mesangial and subendothelial electron-dense deposits, leading to a diagnosis of IgA nephropathy with membranoproliferative glomerulonephritis-like changes. The kidney function remained unchanged after steroid therapy. CONCLUSIONS: Although the link between renal lesions and mRNA vaccines remains unclear, a robust immune response induced by mRNA vaccines may play a role in the pathogenesis of glomerulonephritis. Further studies of the immunological effects of mRNA vaccines on the kidney are warranted.

Anti-SARS-CoV-2 IgG antibody titer after BNT162b2 mRNA COVID-19 vaccination in Japanese patients who underwent renal replacement therapy, hemodialysis, peritoneal dialysis, and kidney transplantation. BACKGROUND: Coronavirus disease (COVID-19) vaccination is recommended for patients undergoing renal replacement therapy (RRT), including hemodialysis (HD), peritoneal dialysis (PD), and kidney transplantation (KT). However, the difference in the immune response between RRT patients and healthy individuals after mRNA vaccines remains uncertain. METHODS: This retrospective observational study evaluated the anti-severe-acute-respiratory-syndrome-coronavirus-2 (anti-SARS-CoV-2) IgG antibody acquisition, titers and their changes, normal response rate (reaching titers of healthy individuals), factors associated with a normal response, and effectiveness of booster vaccination in Japanese RRT patients. RESULTS: Most HD and PD patients acquired anti-SARS-CoV-2 IgG antibodies after the second vaccination; however, their antibody titers and normal response rates (62-75%) were low compared with those of healthy subjects. Approximately 62% of KT recipients acquired antibodies, but the normal response rate was low (23%). Anti-SARS-CoV-2 IgG antibody waning occurred in the control, HD, and PD groups, while negative or very low titers remained in KT recipients. Third booster vaccination was effective in most HD and PD patients. However, the effect was mild in KT recipients - only 58% reached a normal response level. Multivariate logistic regression analyses demonstrated that younger age, higher serum albumin level, and RRT other than KT were significantly associated with a normal response after the second vaccination. CONCLUSIONS: RRT patients, particularly KT recipients, exhibited poor vaccine responses. Booster vaccination would be

beneficial for HD and PD patients; however, its effect in KT recipients was mild. Further COVID-19 vaccinations using the latest vaccine or alternative procedures should be considered in RRT patients.

Impact of age and comorbidities on SARS-CoV-2 vaccine-induced T cell immunity. BACKGROUND: Older age and chronic disease are important risk factors for developing severe COVID-19. At population level, vaccine-induced immunity substantially reduces the risk of severe COVID-19 disease and hospitalization. However, the relative impact of humoral and cellular immunity on protection from breakthrough infection and severe disease is not fully understood. METHODS: In a study cohort of 655 primarily older study participants (median of 63â€‰years (IQR: 51-72)), we determined serum levels of Spike IgG antibodies using a Multiantigen Serological Assay and quantified the frequency of SARS-CoV-2 Spike-specific CD4â€‰+â€‰and CD8â€‰+â€‰T cells using activation induced marker assay. This enabled characterization of suboptimal vaccine-induced cellular immunity. The risk factors of being a cellular hypo responder were assessed using logistic regression. Further follow-up of study participants allowed for an evaluation of the impact of T cell immunity on breakthrough infections. RESULTS: We show reduced serological immunity and frequency of CD4â€‰+â€‰Spike-specific T cells in the oldest age group (â‰¥75â€‰years) and higher Charlson Comorbidity Index (CCI) categories. Male sex, age group â‰¥75â€‰years, and CCIâ€‰>â€‰0 is associated with an increased likelihood of being a cellular hypo-responder while vaccine type is a significant risk factor. Assessing breakthrough infections, no protective effect of T cell immunity is identified. CONCLUSIONS: SARS-CoV-2 Spike-specific immune responses in both the cellular and serological compartment of the adaptive immune system increase with each vaccine dose and are progressively lower with older age and higher prevalence of comorbidities. The findings contribute to the understanding of the vaccine response in individuals with increased risk of severe COVID-19 disease and hospitalization.

 Vaccination has proven very effective in protecting against severe disease and hospitalization of people with COVID-19, the disease caused by SARS-CoV-2. It is still unclear, however, how the different components of the immune system respond to SARS-CoV-2 vaccination and protect from infection and severe disease. Two of the most predominant components of the immune system are specialized proteins and cells. The proteins circulate in the blood and help clear the virus by binding to it, while the cells either kill the virus or help other cells to produce more antibodies. Here, we examined the response of these two components to the SARS-CoV-2 vaccine in 655 Danish citizens. The response of both components was lower in people over 75â€‰years old and with other diseases. These findings help in understanding the immune responses following SARS-CoV-2 vaccination in people at increased risk of severe symptoms of COVID-19.

Adverse effects, perceptions and attitudes related to BNT162b2, mRNA-1273 or JNJ-78436735 SARS-CoV-2 vaccines: Population-based cohort. Long-term control of SARS-CoV-2 requires effective vaccination strategies. This has been challenged by public mistrust and the spread of misinformation regarding vaccine safety. Better understanding and communication of the longer-term and comparative experiences of individuals in the general population following vaccination are required. In this population-based longitudinal study, we included 575 adults, randomly selected from all individuals presenting to a Swiss reference vaccination center, for receipt of BNT162b2, mRNA1273, or JNJ-78436735. We assessed the prevalence, onset, duration, and severity of self-reported adverse effects over 12 weeks following vaccination. We additionally evaluated participants' perceptions of vaccines, trust in public health authorities and pharmaceutical companies, and compliance with public health measures. Most participants reported at least one adverse effect within 12 weeks following vaccination. Adverse effects were mostly mild or moderate, resolved within three days, and rarely resulted in anaphylaxis or hospitalizations. Female sex, younger age, higher education, and receipt of mRNA-1273 were associated with reporting adverse effects. Compared to JNJ-78436735

recipients, a higher proportion of mRNA vaccine recipients agreed that vaccination is important, and trusted public health authorities. Our findings provide real-world estimates of the prevalence of adverse effects following SARS-CoV-2 vaccination and highlight the importance of transparent communication to ensure the success of current or future vaccination campaigns.

Neurological Considerations with COVID-19 Vaccinations. The benefits of coronavirus disease 2019 (COVID-19) vaccination significantly outweigh its risks on a public health scale, and vaccination has been crucial in controlling the spread of SARS-CoV-2. Nonetheless, several reports of adverse events following vaccination have been published.To summarize reports to date and assess the extent and quality of evidence regarding possible serious adverse neurological events following COVID-19 vaccination, focusing on Food and Drug Administration (FDA)-approved vaccines in the United States (BNT162b2, mRNA-1273, and Ad26.COV2.S).A review of literature from five major electronic databases (PubMed, Medline, Embase, Cochrane Library, and Google Scholar) was conducted between December 1, 2020 and June 5, 2022. Articles included in the review were systematic reviews and meta-analysis, cohort studies, retrospective studies, case-control studies, case series, and reports. Editorials, letters, and animal studies were excluded, since these studies did not include quantitative data regarding adverse side effects of vaccination in human subjects.Of 149 total articles and 97 (65%) were case reports or case series. Three phase 3 trials initially conducted for BNT162b2, MRNA-1273, and Ad26.COV2.S were included in the analysis.The amount and quality of evidence for possible neurological adverse events in the context of FDA-approved COVID-19 vaccinations is overall low tier. The current body of evidence continues to suggest that COVID-19 vaccinations have a high neurological safety profile; however, the risks and benefits of vaccination must continue to be closely monitored.

No Association Between Out-of-Hospital Cardiac Arrest and COVID-19 Vaccination.

Newly diagnosed extranodal NK/T-cell lymphoma, nasal type, at the injected left arm after BNT162b2 mRNA COVID-19 vaccination. Anti-SARS-CoV-2 vaccines were developed in response to the coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Although the BNT162b2 mRNA vaccine is effective, adverse effects have been reported. Here, we report a case of extranodal NK/T-cell lymphoma, nasal type (ENKL), of the left arm following BNT162b2 mRNA vaccination. A 73-year-old male presented with a lump in the left arm, which was the site where he received the BNT162b2 mRNA vaccine 3 months prior. He was treated with topical corticosteroids and debridement, but the tumor progressed. Additionally, fever, night sweats, and general fatigue were observed. Laboratory findings included thrombocytopenia, elevated lactate dehydrogenase, and soluble interleukin-2 receptor levels. Skin biopsy led to a diagnosis of ENKL. The patient was treated with a 50% dose of SMILE therapy and radiotherapy, resulting in regression of the tumor. It seems that latent Epstein-Barr virus (EBV)-infected NK/T cells were reactivated by vaccination and contributed to the onset of ENKL. This is the first report of ENKL after BNT162b2 mRNA vaccination. The present case highlights the possible risk of development of malignant lymphoma, including ENKL at the injection site, after BNT162b2 COVID-19 vaccination.

Role of Cytochrome P450 2C9 in COVID-19 Treatment: Current Status and Future Directions. The major human liver drug metabolising cytochrome P450 (CYP) enzymes are downregulated during inflammation and infectious disease state, especially during coronavirus disease 2019 (COVID-19) infection. The influx of proinflammatory cytokines, known as a 'cytokine storm', during severe COVID-19 leads to the downregulation of CYPs and triggers new cytokine release, which further dampens CYP expression. Impaired drug metabolism, along with the inevitable co-administration of drugs or 'combination therapy' in patients with COVID-19 with various comorbidities, could cause drug-drug interactions, thus worsening the disease condition. Genetic variability or polymorphism in CYP2C9 across different ethnicities could contribute to COVID-19 susceptibility. A number of drugs used in

patients with COVID-19 are inducers or inhibitors of, or are metabolised by, CYP2C9, and co-administration might cause pharmacokinetic and pharmacodynamic interactions. It is also worth mentioning that some of the COVID-19 drug interactions are due to altered activity of other CYPs including CYP3A4. Isoniazid/rifampin for COVID-19 and tuberculosis co-infection; lopinavir/ritonavir and cobicistat/remdesivir combination therapy; or multi-drug therapy including ivermectin, azithromycin, montelukast and acetylsalicylic acid, known as TNR4 therapy, all improved recovery in patients with COVID-19. However, a combination of CYP2C9 inducers, inhibitors or both, and plausibly different CYP isoforms could lead to treatment failure, hepatotoxicity or serious side effects including thromboembolism or bleeding, as observed in the combined use of azithromycin/warfarin. Further, herbs that are CYP2C9 inducers and inhibitors, showed anti-COVID-19 properties, and in silico predictions postulated that phytochemical compounds could inhibit SARS-CoV-2 virus particles. COVID-19 vaccines elicit immune responses that activate cytokine release, which in turn suppresses CYP expression that could be the source of compromised CYP2C9 drug metabolism and the subsequent drug-drug interaction. Future studies are recommended to determine CYP regulation in COVID-19, while recognising the involvement of CYP2C9 and possibly utilising CYP2C9 as a target gene to tackle the ever-mutating SARS-CoV-2.

A Pilot Single-Blinded, Randomized, Controlled Trial Comparing BNT162b2 vs. JNJ-78436735 Vaccine as the Third Dose After Two Doses of BNT162b2 Vaccine in Solid Organ Transplant Recipients.
Solid Organ Transplant (SOT) recipients are at significant higher risk for COVID-19 and due to immunosuppressive medication, the immunogenicity after vaccination is suboptimal. In the previous studies, booster method showed significant benefit in this population. In the current study, we compared using a mix-and-match method vs. same vaccine as a third dose in SOT recipients. This was a patient-blinded, single center, randomized controlled trial comparing BNT162b2 vs. JNJ-78436735 vaccine as the third dose after two doses of BNT162b2 vaccine. We included adult SOT recipients with functional graft who had received two doses of BNT162b2 vaccine. Participants were randomly assigned to receive either BNT162b2 or JNJ-78436735 in one-to-one ratio. Primary outcome was SARS-CoV-2 IgG positivity at 1Â month after the third dose. Sixty SOT recipients, including 36 kidney, 12 liver, 2 lung, 3 heart, and 5 combined transplants, were enrolled, and 57 recipients were analyzed per protocol. There were no statistically significant differences between the two vaccine protocols for IgG positivity (83.3% vs. 85.2% for BNT162b2 and JNJ-78436735, respectively, p = 0.85, Odds Ratio 0.95, 95% Confidence Interval 0.23-4.00). Comparison of the geometric mean titer demonstrated a higher trend with BNT162b2 (p = 0.09). In this pilot randomized controlled trial comparing mix and match method vs. uniform vaccination in SOT recipients, both vaccines were safely used. Since this was a small sample sized study, there was no statistically significant difference in immunogenicity; though, the mix and match method showed relatively lower geometric mean titer, as compared to uniform vaccine. Further studies need to be conducted to determine duration of this immunogenicity. Clinical Trial Registration:
https://clinicaltrials.gov/ct2/show/NCT05047640?term=20210641&draw=2&rank=1, identifier 20210641.

Subacute thyroiditis following COVID-19: A systematic review. BACKGROUND: Subacute thyroiditis (SAT) is a self-limiting thyroid inflammatory disease occurring specifically after upper respiratory tract infections. Since COVID-19 is a respiratory disease leading to multi-organ involvements, we aimed to systematically review the literature regarding SAT secondary to COVID-19. METHODS: We searched Scopus, PubMed/MEDLINE, Cochrane, Web of Science, ProQuest, and LitCovid databases using the terms "subacute thyroiditis" and "COVID-19" and their synonyms from inception to November 3, 2022. We included the original articles of the patients with SAT secondary to COVID-19. Studies reporting SAT secondary to COVID-19 vaccination or SAT symptoms'

manifestation before the COVID-19 infection were not included. RESULTS: Totally, 820 articles were retained. Having removed the duplicates, 250 articles remained, out of which 43 articles (40 case reports and three case series) with a total of 100 patients, were eventually selected. The patients aged 18-85 years (Mean: 42.70, SD: 11.85) and 68 (68%) were women. The time from the onset of COVID-19 to the onset of SAT symptoms varied from zero to 168 days (Mean: 28.31, SD: 36.92). The most common symptoms of SAT were neck pain in 69 patients (69%), fever in 54 (54%), fatigue and weakness in 34 (34%), and persistent palpitations in 31 (31%). The most common ultrasonographic findings were hypoechoic regions in 73 (79%), enlarged thyroid in 46 (50%), and changes in thyroid vascularity in 14 (15%). Thirty-one patients (31%) were hospitalized, and 68 (68%) were treated as outpatients. Corticosteroids were the preferred treatment in both the inpatient and outpatient settings (25 inpatients (81%) and 44 outpatients (65%)). Other preferred treatments were nonsteroidal anti-inflammatory drugs (nine inpatients (29%) and 17 outpatients (25%)) and beta-blockers (four inpatients (13%) and seven outpatients (10%)). After a mean duration of 61.59 days (SD: 67.07), 21 patients (23%) developed hypothyroidism and thus, levothyroxine-based treatment was used in six of these patients and the rest of these patients did not receive levothyroxine. CONCLUSION: SAT secondary to COVID-19 seems to manifest almost similarly to the conventional SAT. However, except for the case reports and case series, lack of studies has limited the quality of the data at hand.

Rare Cases of Polymyalgia Rheumatica After Receiving COVID-19 Vaccinations. Polymyalgia rheumatica (PMR) is a systemic rheumatic inflammatory disease of adults presenting with symmetrical proximal muscle stiffness and pain predominantly involving the shoulders, neck, and pelvic girdle. The coronavirus disease of 2019 (COVID-19) presented as a pandemic causing worldwide morbidity and mortality in large numbers. Rapid scientific research expedited preventative vaccine development and has helped tremendously in cutting down severe illness, hospitalizations, and death from COVID-19, with the messenger ribonucleic acid (mRNA) vaccines outperforming the others. We present two cases that showcase the incidence of polymyalgia rheumatica after receiving COVID-19 vaccination. Patient 1 is a 69-year-old female who developed arm and thigh stiffness a week before the second dose while receiving her primary Moderna vaccine series. She had an elevated C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR), so she was started on low-dose steroids, which were weaned down over a five-month period. Three weeks after receiving her Moderna booster, she had a recurrence of the classic polymyalgia rheumaticaÂ symptoms and elevatedÂ ESR.Â She responded to prednisone 15 mg with a successful taper over eight months. Patient 2 is a 74-year-old male who received his primary series and booster through Pfizer-BioNTech. Prior to the booster, he was treated for COVID-19 with monoclonal antibody therapy. He presented to the office with hip and shoulder pain and stiffnessÂ along with an elevated C-reactive protein. Consequently, he received 20 mg of prednisone but needed to increase his dose to 25 mg total to help with the control of his inflammation. The goal of this article is to prompt physicians about the possibility of PMR incidence after patients receive vaccinations for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). PMR can be debilitating to the quality of life of patients. Knowing this association allows for more timely and competent treatment. PMR following SARS-CoV-2 vaccinations is continuously being observed in the medical field. Increased knowledge may help prevent the recurrence with subsequent doses. Further studies on the follow-up of such cases and the effect on subsequent immunization would be helpful.

COVID 19 vaccine induced thrombotic thrombocytopenia, cerebral venous thrombosis and neurogenic stunned myocardium.

Generalized Eosinophilia Following Moderna COVID-19 Vaccine Administration: A Case Report. Coronavirus disease 19 (COVID-19) vaccination is considered an important part in improving health

outcomes globally. While various adverse events following vaccination against COVID-19 have been reported, eosinophilic diseases have rarely been documented in the literature and are poorly understood. Although vaccination is lauded as being "safe," it has become apparent that adverse reactions related to the vaccines can have detrimental health effects for certain individuals. We present a case of a death related to multiple severe preexisting comorbidities, complicated by new-onset gastrointestinal complaints which were temporally associated with recent COVID-19 vaccination and did not subside, but worsened prior to death. Autopsy revealed evidence of eosinophilic enteritis, associated with ascites, as well as eosinophilic inflammation elsewhere, including the lungs and heart. Histological examination revealed abundant eosinophils in tissues, including the small intestines, epicardium, and lungs. Whether or not the eosinophilic inflammatory process was caused by the recent vaccination cannot be stated with certainty; however, the temporal association between vaccination, symptom onset/progression, and death, and the literature which suggests a possible association between coronavirus vaccination and eosinophilic reactions leads to the conclusion that this death might have been related to an adverse reaction to COVID-19 vaccination.

New acute onset of ocular myasthenia gravis after COVID-19 vaccine: A case report. Reports have shown the association of coronavirus disease 2019 (COVID-19) with several neuromuscular disorders. Myasthenia gravis (MG) is an autoimmune disease in which antibodies bind to acetyl choline receptors in the postsynaptic membrane at the neuromuscular junction. The characteristic clinical feature of the disease is weakness of the ocular muscle, bulbar muscle, and extremity muscles; when the weakness is limited to the ocular muscle only, the condition is known as ocular myasthenia gravis. Diagnosis is usually confirmed by the acetylcholine receptor antibodies. Symptoms of MG may be aggravated by various types of infections and medications. Here, we are presenting a rare case of a new and acute onset of ocular MG presented after administration of Covishield vaccine.

Thyroid function and associated mood changes after COVID-19 vaccines in patients with Hashimoto thyroiditis. CONTEXT: Severe acute respiratory syndrome-coronavirus 2 (COVID-19) vaccines may incur changes in thyroid functions followed by mood changes, and patients with Hashimoto thyroiditis (HT) were suggested to bear a higher risk. OBJECTIVES: We primarily aim to find whether COVID-19 vaccination could induce potential subsequent thyroid function and mood changes. The secondary aim was to find inflammatory biomarkers associated with risk. METHODS: The retrospective, multi-center study recruited patients with HT receiving COVID-19-inactivated vaccines. C-reactive proteins (CRPs), thyroid-stimulating hormones (TSHs), and mood changes were studied before and after vaccination during a follow-up of a 6-month period. Independent association was investigated between incidence of mood state, thyroid functions, and inflammatory markers. Propensity score-matched comparisons between the vaccine and control groups were carried out to investigate the difference. RESULTS: Final analysis included 2,765 patients with HT in the vaccine group and 1,288 patients in the control group. In the matched analysis, TSH increase and mood change incidence were both significantly higher in the vaccine group (11.9% versus 6.1% for TSH increase and 12.7% versus 8.4% for mood change incidence). An increase in CRP was associated with mood change ($p< 0.01$ by the Kaplan-Meier method) and severity ($r = 0.75$) after vaccination. Baseline CRP, TSH, and antibodies of thyroid peroxidase (anti-TPO) were found to predict incidence of mood changes. CONCLUSION: COVID-19 vaccination seemed to induce increased levels and incidence of TSH surge followed by mood changes in patients with HT. Higher levels of pre-vaccine serum TSH, CRP, and anti-TPO values were associated with higher incidence in the early post-vaccine phase.

Autoantibody production is enhanced after mild SARS-CoV-2 infection despite vaccination in individuals with and without long COVID. Long COVID patients who experienced severe acute SARS-CoV-2 infection can present with humoral autoimmunity. However, whether mild SARS-CoV-2

infection increases autoantibody responses and whether vaccination can decrease autoimmunity in long COVID patients is unknown. Here, we demonstrate that mild SARS-CoV-2 infection increases autoantibodies associated with systemic lupus erythematosus (SLE) and inflammatory myopathies in long COVID patients with persistent neurologic symptoms to a greater extent than COVID convalescent controls at 8 months post-infection. Furthermore, high titers of SLE-associated autoantibodies in long COVID patients are associated with impaired cognitive performance and greater symptom severity, and subsequent vaccination/booster does not decrease autoantibody titers. In summary, we found that mild SARS-CoV-2 infection can induce persistent humoral autoimmunity in both long COVID patients and healthy COVID convalescents, suggesting that a reappraisal of vaccination and mitigation strategies is warranted.

Generalized Pustular Psoriasis Flare-Up after Both Doses of BBIBP-CorV Vaccination in a Patient under Adalimumab Treatment: A Case Report. Generalized pustular psoriasis is a possibly serious condition that can be triggered by various factors. Previous studies show a slight likelihood of disease exacerbation subsequent to COVID-19 vaccination. Here, we present the first (to the best of our knowledge) case of pustular psoriasis flare after each one of the two shots of the BBIBP-CorV (Sinopharm) vaccine despite adalimumab treatment.

Histopathological Spectrum of Cutaneous Reactions following COVID-19 Vaccine - An Observational Study. BACKGROUND: Owing to the myriad clinical presentations of COVID-19 vaccine-induced adverse events, clinicopathological correlation is the key to understanding the underlying pathophysiology of these reactions. However, there is still a dearth of such systematic studies across a wide spectrum of vaccine reactions. AIM AND OBJECTIVES: This study provides a clinical and histopathological correlation of COVID-19 vaccine-induced mucocutaneous reactions. MATERIALS AND METHODS: The study population included all the individuals developing any form of self-reported mucocutaneous adverse events within 4 weeks of receiving the COVID-19 vaccine. The clinical and histopathological features were recorded. RESULTS: A total of 126 cases were identified. Seven histopathological patterns were recognized. The most common histopathological feature was spongiotic dermatitis, seen in all the patients with "vaccine-related eruption of papules and plaques" (VREPP). Other patterns included lichenoid or interface dermatitis, dermal hypersensitivity reaction, leukocytoclastic vasculitis, subepidermal blistering, psoriasiform hyperplasia, and dermal granulomatous reaction. CONCLUSION: Owing to such myriad clinical presentations, utilizing a histopathological classification could ease categorizing the vaccine-induced mucocutaneous eruptions.

Progressive Central Artery Occlusion, Ophthalmic Artery Occlusion, and Hemispheric Intracranial Thrombosis after COVID-19 mRNA Vaccine Application: Case Report. Thromboembolic events as a result of COVID-19 mRNA vaccination are a rare, though life-threatening complication. In this case report, we describe a 40-year-old female patient who developed central retinal artery and ophthalmic artery occlusion progressing to intracranial thrombosis 3 weeks after vaccination with the Pfizer-BioNTech COVID-19 vaccine. Initially, she presented with progressive acute and painless unilateral vision loss in her left eye. Dilated fundoscopy of left eye showed macular whitening with sparing of the area of cilioretinal artery distribution. Labs revealed a normal erythrocyte sedimentation rate, C-reactive protein, and platelet count. Computerized tomography angiography of the head and neck showed an occlusion of the entire left cervical internal carotid artery and occlusion of the origin of the left external carotid artery. Despite treatment with heparin, her vision declined to no light perception. Ten days later, the patient presented with right peripheral vision loss and was found to have a new left posterior cerebral artery/posterior inferior cerebellar artery stroke. Seventeen days later, she presented to the hospital with nausea and vertigo and was found to have a subacute infarction in the left parietal lobe corresponding to left anterior communicating

artery/middle cerebral artery watershed territory. Hypercoagulable disorders, vasculitis, cardiac arrhythmias, and intraventricular thrombi were excluded. Fundus fluorescein angiography confirmed central retinal artery occlusion and ophthalmic artery occlusion with impressive retina and choroid changes in fluorescein angiography patterns. This complication of mRNA COVID-19 vaccination has not been previously described in the literature and should be considered even weeks after initial presentation.

Myositis unrelated to the inoculation site after COVID-19 vaccination: a case report. We describe the case of a 49-year-old right hand-dominant woman with myositis of the biceps brachii muscle unrelated to the inoculation site following Pfizer-BioNTech COVID-19 vaccination on the deltoid muscle of the left shoulder. Coronavirus disease 2019 (COVID-19) pandemic has involved global spread, and different vaccines including inactivated, protein, vectored, and nucleic acid vaccines have been developed and administered. Common side effects of COVID-19 vaccines include general manifestations such as headache, fever, and fatigue, and various musculoskeletal symptoms. Here, we present a case of myositis occurring in the biceps brachii muscle unrelated to the inoculation site, which has not been reported previously, accompanied by a literature review.

Letter to editor - observation on the article titled "Vaccine-Induced Thrombotic Thrombocytopenia (VITT): first report from India". The first case of Vaccine-Induced Thrombotic Thrombocytopenia (VITT) was reported in the letter-to-editor submission in the journal of Indian Journal of Hematology and Blood Transfusion which was published online on 29th Sep 2021. Whereas, an article published in your journal on 04th Mar 2022 has been titled as first report of VITT from India which is a very conflicting statistic. The former article under reference has been diagnosed by a confirmatory functional assay as per the recommended guidelines and is thus genuinely the first case reported in this country.

Acute disseminated encephalomyelitis and COVID-19 vaccination: Comment.

Background incidence rates of selected adverse events of special interest (AESI) to monitor the safety of COVID-19 vaccines. BACKGROUND: Determining background rates of medical conditions identified as adverse events of special interest (AESI) that may occur following COVID-19 vaccination is important for contextualising and investigating potential vaccine safety signals. METHODS: We conducted a retrospective population-based cohort study using linked emergency department, hospitalisation and death data for 2017 and 2018 from Australia's most populous state, New South Wales. Incident cases of select neurological conditions, arterial or venous thromboembolic conditions, secondary thrombocytopenia, myocarditis/pericarditis, and unique events of anaphylaxis and generalised convulsions were identified using internationally agreed upon diagnostic (ICD-10) codes. State-specific rates per 100,000 person-years were calculated, with further stratification by age group and sex where clinically relevant to the condition, and the number of expected cases nationally in one and 6Â weeks was estimated. RESULTS: Background rates of selected neurological conditions were low with the exception of generalised convulsions for which 1,599-1,872 cases were estimated nationally in a 1-week period in the absence of vaccination. Using a narrow case definition, rates of Guillain-BarrÃ© Syndrome (3.9 per 100,000 person-years) were higher than international rates reported elsewhere. Thromboembolic and cerebral venous sinus thrombosis event rates increased with age. Myocarditis occurred more commonly in males, and was highest in males aged 18-24Â years, with an estimated 1-4 cases expected nationally in a 1-week period. CONCLUSIONS: Using routinely collected linked healthcare data provides localised estimates of background rates of new onset or periodic AESI which enables rapid estimation of observed-versus-expected rates of events reported following COVID-19 vaccination. This Australian-specific analysis contributes AESI background rates which can be compared with those from other countries to enhance understanding

of geographic variability in the frequency of specific AESI in the absence of vaccination, and can be utilised for signal detection during program implementation.
Cytokine levels in maternal and infant blood after COVID-19 vaccination during pregnancy: Correspondence.
Quality of MedDRA(Â®) Coding in a Sample of COVID-19 Vaccine Medication Error Data. INTRODUCTION: In recent years, there has been increasing interest from regulatory agencies and scientific organisations into the recording, coding and reporting of medication errors. Accuracy and consistency in the handling of medication error reports ensure the safety and effectiveness of medicines and provide reliable information to both healthcare professionals and patients. OBJECTIVE: The authors have examined a sample of Medical Dictionary for Regulatory Activities (MedDRA(Â®)) coded reports that describe medication errors to assess the accuracy and consistency of MedDRA(Â®) coding, and to identify the main types of coding errors for the newly introduced COVID-19 vaccines. METHODS: The sample of coded terms was assessed by two MedDRA(Â®) experts applying the Four Eyes Principle. It included 1500 reported terms drawn from the Uppsala Monitoring Centre database reported up to 25 August, 2021, describing medication errors for COVID-19 vaccines with their assigned MedDRA(Â®) terms. RESULTS: One third of the records could not be assessed because of incomplete or unclear verbatims. In one third, MedDRA(Â®) term assignments were correct, but another third of the sample was not adequately coded. The most frequent coding errors corresponded to vague MedDRA(Â®) Preferred Term assignments despite more detailed information being available in the verbatim for a more precise coding. This observation is similar to findings in the EudraVigilance database, where some of the most frequently assigned MedDRA(Â®) terms for medication errors also represent vague concepts. CONCLUSIONS: The findings indicate that understanding of medication error documentation and of the importance of accurate extraction of information from case narratives, as well as knowledge of MedDRA(Â®) content and coding guidelines need to be reinforced. The authors provide useful references to training opportunities and to the applicable International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use-Endorsed Guides for MedDRA(Â®) users.
Kidney Transplantation from a Deceased Donor with COVID-19 Ad26.COV2-S Vaccine-Induced Thrombotic Thrombocytopenia. BACKGROUND Vaccine-induced thrombosis and thrombocytopenia is a rare immune disorder documented after adenoviral vector ChAdOx1 nCOV-19 (AstraZeneca) and Ad26.COV2-S (Janssen) vaccine administration against severe acute respiratory syndrome coronavirus 2. It is a rare adverse effect with an incidence of 1 case per 100 000 exposures. The disorder represents altered immune response with proliferation of antibodies that bind to platelet factor 4 (PF4), leading to formation of thrombi and consumptive coagulopathy. Thrombosis combined with thrombocytopenia generally occurs in the first month following vaccination and can lead to fatal outcome, even in young, previously healthy individuals. These young adults ultimately may become solid organ donors. The main concerns with vaccine-induced thrombosis and thrombocytopenia solid organ donors are anti-PF4 antibodies transmission potential, risk of early major graft thrombosis, and serious bleeding. CASE REPORT In our center, 2 kidney transplantations were performed from a single brain-dead vaccine-induced thrombosis and thrombocytopenia donor following Ad26.COV2-S COVID-19 (Janssen) vaccine in October 2021, which represents the first 2 cases of kidney transplantation from a deceased vaccine-induced thrombosis and thrombocytopenia donor after immunization with Ad26.COV2-S (Janssen) vaccine. Both recipients were closely monitored in the early post-transplantation period and after discharge from the hospital. To date, both recipients have a good functioning allograft, without any evidence of vaccine-induced thrombosis and thrombocytopenia transmission. CONCLUSIONS Our results are consistent with those of previously published cases of successful vaccine-induced thrombosis and thrombocytopenia donor

solid organ transplantation. Kidney allografts transplanted from vaccine-induced thrombosis and thrombocytopenia donors can have a good overall function with favorable outcomes.

Smoking habits predict adverse effects after mRNA COVID-19 vaccine: Empirical evidence from a pilot study. OBJECTIVES: The aim of this research was to investigate the possible association between smoking habits and the incidence of adverse effects (AEs) after mRNA COVID-19 vaccine. STUDY DESIGN: A longitudinal observational study was conducted on a sample of Italian healthcare workers. METHODS: Healthcare workers who were administered the mRNA COVID-19 vaccine (either BNT162b2 or mRNA-1273) were evaluated for the occurrence of AEs after three vaccine doses. Multivariate Poisson regression analyses were fitted to predict AE risk according to smoking characteristics - such as number of tobacco cigarettes smoked per day, smoking time, and use of electronic cigarette (e-cig). RESULTS: Of 320 total participants, 72 (22.5%) smoked cigarettes, and 50 (15.6%) used e-cig, 49 of which being dual users. Tobacco smoking significantly increased the risks of muscle and joint pain during the primary COVID-19 vaccination cycle and of chills during the whole vaccination series. The number of cigarettes smoked per day and vaping variously predicted AE onset during the whole cycle, with a tendency to respectively reduce and increase their risks. Duration of smoking did not affect any AE, except for headache after the booster dose. Most results remained significant after Bonferroni adjustment of significance level. CONCLUSION: Our pilot study indicated a possible effect of smoking habits on AE onset. Our research offers evidence that helps understanding possible predictors of the interindividual variability in COVID-19 vaccine response, serving as a reference for further studies on the effect of smoking on vaccine safety and effectiveness.

Vaccine-induced immune thrombotic thrombocytopenia post dose 2 ChAdOx1 nCoV19 vaccination: Less severe but remains a problem. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare but established complication of 1st dose ChAdOx1 nCoV19 vaccination (AZD1222), however this complication after dose 2 remains controversial. OBJECTIVES: To describe the clinicopathological features of confirmed cases of VITT post dose 2 AZD1222 vaccination in Australia, and to compare this cohort to confirmed cases of VITT post 1st dose. METHODS: Sequential cases of clinically suspected VITT (thrombocytopenia, D-DimerÂ >Â 5x upper limit normal and thrombosis) within 4-42Â days of dose 2 AZD1222 referred to Australia's centralised testing centre underwent platelet activation confirmatory testing in keeping with the national diagnostic algorithm. Final classification was assigned after adjudication by an expert advisory committee. Descriptive statistics were performed on this cohort and comparative analyses carried out on confirmed cases of VITT after 1st and 2nd dose AZD1222. RESULTS: Of 62 patients referred, 15 demonstrated presence of antibody mediated platelet activation consistent with VITT after dose 2 AZD1222. Four were immunoassay positive. Median time to presentation was 13Â days (range 1-53) platelet count 116x10^9/L (range 63-139) and D-dimer elevation 14.5xULN (IQR 11, 26). Two fatalities occurred. In each, the dosing interval was less than 30Â days. In comparison to 1st dose, dose 2 cases were more likely to be male (OR 4.6, 95% CI 1.3-15.8, pÂ =Â 0.03), present with higher platelet counts (pÂ =Â 0.05), lower D-Dimer (pÂ =Â 01) and less likely to have unusual site thromboses (OR 0.14, 95% CI 0.04-0.28, pÂ =Â 0.02). CONCLUSIONS: VITT is a complication of dose 2 AZD1222 vaccination. Whilst clinicopathological features are less severe, fatalities occurred in patients with concomitant factors.

Persistence of immune responses after heterologous and homologous third COVID-19 vaccine dose schedules in the UK: eight-month analyses of the COV-BOOST trial. BACKGROUND: COV-BOOST is a multicentre, randomised, controlled, phase 2 trial of seven COVID-19 vaccines used as a third booster dose in June 2021. Monovalent messenger RNA (mRNA) COVID-19 vaccines were subsequently widely used for the third and fourth-dose vaccination campaigns in high-income countries. Real-world vaccine effectiveness against symptomatic infections following third doses

declined during the Omicron wave. This report compares the immunogenicity and kinetics of responses to third doses of vaccines from day (D) 28 to D242 following third doses in seven study arms. METHODS: The trial initially included ten experimental vaccine arms (seven full-dose, three half-dose) delivered at three groups of six sites. Participants in each site group were randomised to three or four experimental vaccines, or MenACWY control. The trial was stratified such that half of participants had previously received two primary doses of ChAdOx1 nCov-19 (Oxford-AstraZeneca; hereafter referred to as ChAd) and half had received two doses of BNT162b2 (Pfizer-BioNtech, hereafter referred to as BNT). The D242 follow-up was done in seven arms (five full-dose, two half-dose). The BNT vaccine was used as the reference as it was the most commonly deployed third-dose vaccine in clinical practice in high-income countries. The primary analysis was conducted using all randomised and baseline seronegative participants who were SARS-CoV-2 naÃ¯ve during the study and who had not received a further COVID-19 vaccine for any reason since third dose randomisation. RESULTS: Among the 817 participants included in this report, the median age was 72 years (IQR: 55-78) with 50.7% being female. The decay rates of anti-spike IgG between vaccines are different among both populations who received initial doses of ChAd/ChAd and BNT/BNT. In the population that previously received ChAd/ChAd, mRNA vaccines had the highest titre at D242 following their vaccine dose although Ad26. COV2. S (Janssen; hereafter referred to as Ad26) showed slower decay. For people who received BNT/BNT as their initial doses, a slower decay was also seen in the Ad26 and ChAd arms. The anti-spike IgG became significantly higher in the Ad26 arm compared to the BNT arm as early as 3 months following vaccination. Similar decay rates were seen between BNT and half-BNT; the geometric mean ratios ranged from 0.76 to 0.94 at different time points. The difference in decay rates between vaccines was similar for wild-type live virus-neutralising antibodies and that seen for anti-spike IgG. For cellular responses, the persistence was similar between study arms. CONCLUSIONS: Heterologous third doses with viral vector vaccines following two doses of mRNA achieve more durable humoral responses compared with three doses of mRNA vaccines. Lower doses of mRNA vaccines could be considered for future booster campaigns.

Safety and effectiveness of vaccines against COVID-19 in children aged 5-11 years: a systematic review and meta-analysis. BACKGROUND: To date, more than 761 million confirmed SARS-CoV-2 infections have been recorded globally, and more than half of all children are estimated to be seropositive. Despite high SARS-CoV-2 infection incidences, the rate of severe COVID-19 in children is low. We aimed to assess the safety and efficacy or effectiveness of COVID-19 vaccines approved in the EU for children aged 5-11 years. METHODS: In this systematic review and meta-analysis, we included studies of any design identified through searching the COVID-19 LÂ·OVE (living overview of evidence) platform up to Jan 23, 2023. We included studies with participants aged 5-11 years, with any COVID-19 vaccine approved by the European Medicines Agency-ie, mRNA vaccines BNT162b2 (Pfizer-BioNTech), BNT162b2 Bivalent (against original strain and omicron [BA.4 or BA.5]), mRNA-1273 (Moderna), or mRNA-1273.214 (against original strain and omicron BA.1). Efficacy and effectiveness outcomes were SARS-CoV-2 infection (PCR-confirmed or antigen-test confirmed), symptomatic COVID-19, hospital admission due to COVID-19, COVID-19-related mortality, multisystem inflammatory syndrome in children (MIS-C), and long-term effects of COVID-19 (long COVID or post-COVID-19 condition as defined by study investigators or per WHO definition). Safety outcomes of interest were serious adverse events, adverse events of special interest (eg, myocarditis), solicited local and systemic events, and unsolicited adverse events. We assessed risk of bias and rated the certainty of evidence (CoE) using the Grading of Recommendations Assessment, Development and Evaluation approach. This study was prospectively registered with PROSPERO, CRD42022306822. FINDINGS: Of 5272 screened records, we included 51 (1Â·0%) studies (n=17 [33%] in quantitative synthesis). Vaccine effectiveness after two doses against omicron infections was

41Â·6% (95% CI 28Â·1-52Â·6; eight non-randomised studies of interventions [NRSIs]; CoE low), 36Â·2% (21Â·5-48Â·2; six NRSIs; CoE low) against symptomatic COVID-19, 75Â·3% (68Â·0-81Â·0; six NRSIs; CoE moderate) against COVID-19-related hospitalisations, and 78% (48-90, one NRSI; CoE very low) against MIS-C. Vaccine effectiveness against COVID-19-related mortality was not estimable. Crude event rates for deaths in unvaccinated children were less than one case per 100â€‰000 children, and no events were reported for vaccinated children (four NRSIs; CoE low). No study on vaccine effectiveness against long-term effects was identified. Vaccine effectiveness after three doses was 55% (50-60; one NRSI; CoE moderate) against omicron infections, and 61% (55-67; one NRSI; CoE moderate) against symptomatic COVID-19. No study reported vaccine efficacy or effectiveness against hospitalisation following a third dose. Safety data suggested no increased risk of serious adverse events (risk ratio [RR] 0Â·83 [95% CI 0Â·21-3Â·33]; two randomised controlled trials; CoE low), with approximately 0Â·23-1Â·2 events per 100â€‰000 administered vaccines reported in real-life observations. Evidence on the risk of myocarditis was uncertain (RR 4Â·6 [0Â·1-156Â·1]; one NRSI; CoE low), with 0Â·13-1Â·04 observed events per 100â€‰000 administered vaccines. The risk of solicited local reactions was 2Â·07 (1Â·80-2Â·39; two RCTs; CoE moderate) after one dose and 2Â·06 (1Â·70-2Â·49; two RCTs; CoE moderate) after two doses. The risk of solicited systemic reactions was 1Â·09 (1Â·04-1Â·16; two RCTs; CoE moderate) after one dose and 1Â·49 (1Â·34-1Â·65; two RCTs; CoE moderate) after two doses. The risk of unsolicited adverse events after two doses (RR 1Â·21 [1Â·07-1Â·38]; CoE moderate) was higher among mRNA-vaccinated compared with unvaccinated children. INTERPRETATION: In children aged 5-11 years, mRNA vaccines are moderately effective against infections with the omicron variant, but probably protect well against COVID-19 hospitalisations. Vaccines were reactogenic but probably safe. Findings of this systematic review can serve as a basis for public health policy and individual decision making on COVID-19 vaccination in children aged 5-11 years. FUNDING: German Federal Joint Committee.

Reactive arthritis after COVID-19 vaccination: 17 cases. OBJECTIVES: The aim of the study is to report a series of 17 cases of ankle bi-arthritis that occurred shortly after coronavirus disease 2019 RNA vaccination, and to discuss the potential role of these vaccines in the pathogenesis of this rheumatological manifestation. METHODS: All patients were examined in the same department and received a full work-up to investigate the usual causes of ankle bi-arthritis. No rheumatic inflammatory disease occurred after 9â€‰months of follow-up. A post-vaccination serological follow-up in search of anti-Spike antibodies was requested for all patients. RESULTS: All patients recovered with low dose of prednisolone within <2â€‰months, except one who could not be weaned off CS. The level of antibodies found was very high in all patients. CONCLUSION: The ankle bi-arthritis occurrence chronology, the follow-up and the similar clinical presentation might suggest a pathogenic role of RNA vaccination.

Flares in IIMs and the timeline following COVID-19 vaccination: a combined analysis of the COVAD-1 and -2 surveys. OBJECTIVES: Disease flares in the post-coronavirus disease 2019 (COVID-19) vaccination period represent a prominent concern, though risk factors are poorly understood. We studied these flares among patients with idiopathic inflammatory myopathies (IIMs) and other autoimmune rheumatic diseases (AIRDs). METHODS: The COVAD-1 and -2 global surveys were circulated in early 2021 and 2022, respectively, and we captured demographics, comorbidities, AIRDs details, COVID-19 infection history and vaccination details. Flares of IIMs were defined as (a) patient self-reported, (b) immunosuppression (IS) denoted, (c) clinical sign directed and (d) with >7.9-point minimal clinically significant improvement difference worsening of Patient-Reported Outcomes Measurement Information System (PROMIS) PROMISPF10a score. Risk factors of flares were analysed using regression models. RESULTS: Of 15â€Š165 total respondents, 1278 IIMs (age 63â€‰years, 70.3% female, 80.8% Caucasians) and 3453 AIRDs were included. Flares of IIM were seen in 9.6%,

12.7%, 8.7% and 19.6% patients by definitions (a) to (d), respectively, with a median time to flare of 71.5 (10.7-235) days, similar to AIRDs. Patients with active IIMs pre-vaccination (OR 1.2; 95% CI 1.03, 1.6, Pâ€‰=â€‰0.025) were prone to flares, while those receiving rituximab (OR 0.3; 95% CI 0.1, 0.7, Pâ€‰=â€‰0.010) and AZA (OR 0.3, 95% CI 0.1, 0.8, Pâ€‰=â€‰0.016) were at lower risk. Female gender and comorbidities predisposed to flares requiring changes in IS. Asthma (OR 1.62; 95% CI 1.05, 2.50, Pâ€‰=â€‰0.028) and higher pain visual analogue score (OR 1.19; 95% CI 1.11, 1.27, Pâ€‰<â€‰0.001) were associated with disparity between self-reported and IS-denoted flares. CONCLUSION: A diagnosis of IIMs confers an equal risk of flares in the post-COVID-19 vaccination period to AIRDs, with active disease, female gender and comorbidities conferring a higher risk. Disparity between patient- and physician-reported outcomes represents a future avenue for exploration.

The change in glycaemic control immediately after the 3rd COVID-19 vaccination in people with type 1 diabetes.

COVID-19 Vaccine Safety First Year Findings in Adolescents. BACKGROUND AND OBJECTIVES: The Food and Drug Administration expanded Emergency Use Authorization for use of Pfizer-BioNTech (BNT-162b2) coronavirus disease 2019 vaccine to include people ages 12 years and older on May 10, 2021. We describe adverse events observed during the first full year of the US coronavirus disease 2019 vaccination program for adolescents ages 12 to 17 years. METHODS: We conducted descriptive analyses using data from 2 complementary US vaccine safety monitoring systems: v-safe, a voluntary smartphone-based system that monitors reactions and health impacts, and the Vaccine Adverse Event Reporting System (VAERS), the national spontaneous reporting system. We reviewed reports and calculated adverse event reporting rates using vaccine administration data. RESULTS: Among 172â€‰032 adolescents ages 12 to 17 years enrolled in v-safe, most reported reactions following BNT-162b2 were mild to moderate, most frequently reported on the day after vaccination, and more common after dose 2. VAERS received 20â€‰240 adverse event reports; 91.5% were nonserious. Among adverse events of interest, we verified 40 cases of multisystem inflammation syndrome in children (1.2 cases per million vaccinations), 34 (85%) of which had evidence of prior severe acute respiratory syndrome coronavirus 2 infection; and 570 cases of myocarditis (17.7 cases per million vaccinations), most of whom (77%) reported symptom resolution at the time of report. CONCLUSIONS: During the first year BNT-162b2 was administered to adolescents ages 12 to 17 years, most reported adverse events were mild and appeared self-limited. Rates of myocarditis were lower than earlier reports. No new serious safety concerns were identified.

Recurrent ventricular tachycardia in a patient with COVID-19 vaccine-associated myocarditis: a case report. BACKGROUND: The development of coronavirus disease 2019 (COVID-19) vaccine-associated myocarditis has been reported. Most of the reported cases are mild, with quick clinical recovery and excellent short-term outcomes. Cases of COVID-19 vaccine-associated myocarditis presenting with sustained ventricular tachycardia (VT) are rare. CASE DESCRIPTION: A 46-year-old male patient with no prior cardiac history presented following two episodes of syncope. Two days earlier, he had received his second dose of COVID-19 mRNA vaccine (Pfizer)-first dose was administered three weeks earlier. He had an episode of VT while in the emergency room. His cardiac magnetic resonance imaging (MRI) findings were consistent with myocarditis. He was eventually diagnosed with COVID-19 vaccine-associated myocarditis after all other work up were unremarkable [echocardiogram, coronary angiogram, diagnostic electrophysiology study and later (18)F-fluorodeoxyglucose (FDG) metabolism cardiac sarcoid positron emission tomography (PET) study]. An implantable cardiac monitor was implanted to monitor for recurrence of VT. Seven months after initial presentation, he had recurrent VT and he underwent implantation of an implantable cardioverter defibrillator (ICD). He has received appropriate ICD therapies on account of recurrent VT

and he is currently maintained on an antiarrhythmic medication. CONCLUSIONS: Excellent short-term outcomes have been reported in patients with COVID-19 vaccine associated myocarditis. Our case shows that long-term outcomes may not be benign in everyone, particularly in those who develop myocardial scar.

Immune Thrombocytopenia Relapse in Patients Who Received mRNA COVID-19 Vaccines. BACKGROUND: Immune thrombocytopenia (ITP) is a blood disorder in which antibodies coating platelets cause platelet destruction in the spleen with a resultant low platelet count and an increased tendency for bleeding. Coronavirus disease 2019 (COVID-19) is an illness caused by SARS-CoV-2. Though pneumonia and respiratory failure are major causes of morbidity and mortality, multisystemic complications were identified, including hematological ones. Several ITP relapse cases post-mRNA SARS-CoV-2 vaccines have been reported, and different pathophysiological theories have been proposed. PURPOSE: The objective of this study is to identify the causal relationship between mRNA COVID-19 vaccines and ITP relapse, to highlight the longer-term effect of these vaccines on the platelet count more than 6 months after receiving the vaccine, and to identify if there is a statistical difference between Comirnaty and Spikevax vaccines on ITP relapse rate. PATIENTS AND METHODS: In this retrospective study, 67 patients with known ITP were followed before and after receiving the mRNA COVID-19 vaccine. The follow-up parameters included platelet counts when available and bleeding symptoms. All patients were adults over 18 years old, with no other identified causes of thrombocytopenia. Forty-seven patients received the Comirnaty vaccine, and 20 patients received the Spikevax vaccine. RESULTS: Data analysis showed 6% ITP relapse in the first 3 months, and a 10% relapse rate 3-6 months after receiving one of the mRNA COVID-19 vaccines, with no statically significant difference between the two vaccines. CONCLUSION: mRNA COVID-19 vaccines increase the risk of ITP relapse and can lead to a prolonged reduction in platelet count in a proportion of ITP patients, with no statistically significant difference between Comirnaty and Spikevax vaccines.

Decreased breadth of the antibody response to the spike protein of SARS-CoV-2 after repeated vaccination. INTRODUCTION: The rapid development of vaccines to prevent COVID-19 has raised the need to compare the capacity of different vaccines in terms of developing a protective humoral response. Previous studies have shown inconsistent results in this area, highlighting the importance of further research to evaluate the efficacy of different vaccines. METHODS: This study utilized a highly sensitive and reliable flow cytometry method to measure the titers of IgG1 isotype antibodies in the blood of healthy volunteers after receiving one or two doses of various vaccines administered in Spain. The method was also used to simultaneously measure the reactivity of antibodies to the S protein of the original Wuhan strain and variants B.1.1.7 (Alpha), B.1.617.2 (Delta), and B.1.617.1 (Kappa). RESULTS: Significant differences were observed in the titer of anti-S antibodies produced after a first dose of the vaccines ChAdOx1 nCov-19/AstraZeneca, mRNA-1273/Moderna, BNT162b2/Pfizer-BioNTech, and Ad26.COV.S/Janssen. Furthermore, a relative reduction in the reactivity of the sera with the Alpha, Delta, and Kappa variants, compared to the Wuhan strain, was observed after the second boosting immunization. DISCUSSION: The findings of this study provide a comparison of different vaccines in terms of anti-S antibody generation and cast doubts on the convenience of repeated immunization with the same S protein sequence. The multiplexed capacity of the flow cytometry method utilized in this study allowed for a comprehensive evaluation of the efficacy of various vaccines in generating a protective humoral response. Future research could focus on the implications of these findings for the development of effective COVID-19 vaccination strategies.

Reversible Vasoconstriction Syndrome Is a Complication of SARS-CoV-2 Infection/Vaccination Rather than That of Leigh Syndrome.

Exacerbations of Idiopathic Systemic Capillary Leak Syndrome following BNT162b2 mRNA COVID-19 Vaccine (Pfizer-BioNTech). A Japanese man experienced three episodes of hypovolemic shock and was diagnosed with systemic capillary leak syndrome (SCLS). He developed SCLS exacerbation 2 days after receiving a second dose of the Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine, 1 year after the third episode. After fluid therapy and albumin administration, we initiated terbutaline and theophylline prophylaxis for SCLS. A literature review revealed that SCLS attacks often occur 1-2 days after the second COVID-19 vaccination. Patients with a history of SCLS should avoid COVID-19 vaccination and be carefully monitored for 1-2 days if they receive the vaccine.

Human immune and gut microbial parameters associated with inter-individual variations in COVID-19 mRNA vaccine-induced immunity. COVID-19 mRNA vaccines induce protective adaptive immunity against SARS-CoV-2 in most individuals, but there is wide variation in levels of vaccine-induced antibody and T-cell responses. However, the mechanisms underlying this inter-individual variation remain unclear. Here, using a systems biology approach based on multi-omics analyses of human blood and stool samples, we identified several factors that are associated with COVID-19 vaccine-induced adaptive immune responses. BNT162b2-induced T cell response is positively associated with late monocyte responses and inversely associated with baseline mRNA expression of activation protein 1 (AP-1) transcription factors. Interestingly, the gut microbial fucose/rhamnose degradation pathway is positively correlated with mRNA expression of AP-1, as well as a gene encoding an enzyme producing prostaglandin E2 (PGE2), which promotes AP-1 expression, and inversely correlated with BNT162b2-induced T-cell responses. These results suggest that baseline AP-1 expression, which is affected by commensal microbial activity, is a negative correlate of BNT162b2-induced T-cell responses.

Safety and immunogenicity of homologous versus heterologous booster dose with AZD1222, mRNA-1273, or MVC-COV1901 SARS-CoV-2 vaccines in adults: An observer-blinded, multi-center, phase 2 randomized trial. OBJECTIVES: To report the safety and immunogenicity profile of a protein subunit vaccine (MVC-COV1901) compared to AZD1222 and mRNA-1273 when given as a third (booster) dose to individuals who have completed different primary vaccine regimens. METHODS: Individuals were classified according to their primary vaccine regimens, including two-dose MVC-COV1901, AZD1222, or mRNA-1273. A third dose of either half-dose MVC-COV1901, full-dose MVC-COV1901, standard-dose AZD1222, half-dose mRNA-1273 was administered in a 1:1:1:1 treatment ratio to individuals with an interval range of 84-365Â days after the second dose. Endpoints included safety, humoral immunogenicity, and cell-mediated immune response on trial days 15 and 29. Exploratory endpoint included testing against variants of concern (Omicron). RESULTS: Overall, 803 participants were randomized and boosted - 201 received half-dose MVC-COV1901, 196 received full-dose MVC-COV1901, 203 received AZD1222, and 203 received half-dose mRNA-1273. Reactogenicity was mild to moderate, and less in the MVC-COV1901 booster group. Heterologous boosting provided the best immunogenic response. Boosting with mRNA-1273 in MVC-COV1901 primed individuals induced the highest antibody titers, even against Omicron, and cell-mediated immune response. CONCLUSIONS: Overall, MVC-COV1901 as a booster showed the best safety profiles. MVC-COV1901 as a primary series, with either homologous or heterologous booster, elicited the highest immunogenic response. CLINICALTRIALS: gov registration NCT05197153.

The Association of Reported Experiences of Racial and Ethnic Discrimination in Health Care with COVID-19 Vaccination Status and Intent - United States, April 22, 2021-November 26, 2022. In 2021, the CDC Director declared that racism is a serious threat to public health,* reflecting a growing awareness of racism as a cause of health inequities, health disparities, and disease. Racial and ethnic disparities in COVID-19-related hospitalization and death (1,2) illustrate the need to examine root causes, including experiences of discrimination. This report describes the association between

reported experiences of discrimination in U.S. health care settings and COVID-19 vaccination status and intent to be vaccinated by race and ethnicity during April 22, 2021-November 26, 2022, based on the analysis of interview data collected from 1,154,347 respondents to the National Immunization Survey-Adult COVID Module (NIS-ACM). Overall, 3.5% of adults aged â‰¥18 years reported having worse health care experiences compared with persons of other races and ethnicities (i.e., they experienced discrimination), with significantly higher percentages reported by persons who identified as non-Hispanic Black or African American (Black) (10.7%), non-Hispanic American Indian or Alaska Native (AI/AN) (7.2%), non-Hispanic multiple or other race (multiple or other race) (6.7%), Hispanic or Latino (Hispanic) (4.5%), non-Hispanic Native Hawaiian or other Pacific Islander (NHOPI) (3.9%), and non-Hispanic Asian (Asian) (2.8%) than by non-Hispanic White (White) persons (1.6%). Unadjusted differences in prevalence of being unvaccinated against COVID-19 among respondents reporting worse health care experiences than persons of other races and ethnicities compared with those who reported that their health care experiences were the same as those of persons of other races and ethnicities were statistically significant overall (5.3) and for NHOPI (19.2), White (10.5), multiple or other race (5.7), Black (4.6), Asian (4.3), and Hispanic (2.6) adults. Findings were similar for vaccination intent. Eliminating inequitable experiences in health care settings might help reduce some disparities in receipt of a COVID-19 vaccine.
SAPHO syndrome after COVID-19 vaccination complicated with thyroid function abnormalities: a case report and literature review.
Defective Immunity Against SARS-CoV-2 Omicron Variants Despite Full Vaccination in Hematologic Malignancies. In patients with multiple myeloma, completion of mRNA-based vaccination schemes failed to yield detectable SARS-CoV-2 Omicron-neutralizing antibodies and S1-RBD-specific CD8+ T cells in approximately 60% and 80% of the cases, respectively. Patients who develop breakthrough infections exhibited very low levels of live-virus neutralizing antibodies and the absence of follicular T helper cells. See related article by Azeem et al., p. 106 (9). See related article by Chang et al., p. 1684 (10).
Immunity 6 months after COVID-19 vaccination in patients with psoriasis treated with immunomodulatory drugs.
New Onset Multiple Sclerosis Post-COVID-19 Vaccination and Correlation With Possible Predictors in a Case-Control Study. INTRODUCTION: Various inflammatory diseases have been associated with the administration of various vaccines. Several reports have associated vaccine administration with the demyelinating diseases of the central nervous system (CNS). However, no clear or strong scientific evidence exists to support the association of vaccine administration with the onset of demyelinating diseases. Some CNS demyelination diseases such as acute disseminated encephalomyelitis (ADEM) and neuromyelitis optica spectrum disorders (NMOSD) were reported following the administration of COVID-19 vaccines. In this study, new onset multiple sclerosis (MS) following COVID-19 vaccine administration was reported. METHODS: In this longitudinal observational case-control study, a total of 65 participants were studied, who were divided into two groups. Group A included 32 MS patients who were diagnosed post-COVID-19 vaccine administration and group B included 33 participants who received COVID-19 vaccines and did not develop MS. Group B was used as a control. The Chi-square test and logistic regression analysis were carried out using Statistical Product and Service Solutions (SPSS) (IBM SPSS Statistics for Windows, Armonk, NY)Â software. RESULTS: Univariate and multivariate logistic regression analysis was performed and a significant correlation between the risk factors and the development of MS post-COVID-19 vaccination was identified. CONCLUSION: The risk factors, identified in this study, can be used as significant independent predictors for developing MS post-COVID-19 vaccinations.

Cerebral venous sinus thrombosis following ChAdOx1 nCoV-19 AstraZeneca COVID-19 vaccine. A woman in her mid-twenties was admitted with headache, ultimately leading to a diagnosis of cerebral venous sinus thrombosis 10 days after receiving a first dose of the AstraZeneca ChAdOx1 nCoV-19 vaccine (Vaxzevria). We report this case from clinical investigations to outcomes and discuss the issues raised by it regarding the ChAdOx1 nCoV-19 vaccine.

Localised swelling at sites of dermal filler injections following administration of Covid-19 vaccines: a systematic review. INTRODUCTION: Localised swelling at sites of filler injections has been reported in the Moderna mRNA-1273 coronavirus disease 2019 (COVID-19) vaccine trial. METHODS: We conducted a review of the existing data and literature on the potential pathophysiology for this adverse event and its potential management. RESULTS: Data from the Moderna and Pfizer COVID-19 vaccine Phase 3 trial and one case series were available. Three out of 30,400 subjects developed possible filler reaction in the Moderna trial. Two other cases were reported after emergency use authorisation. Reactions occurred at a mean of 1.4 days post-vaccination. Fillers were injected at a mean of 14.1 months before vaccination. Areas involved included lips, infraorbital areas and tear troughs. Treatment included observation, corticosteroids, antihistamine, hyaluronidase and 5-fluorouracil. CONCLUSION: Rare, self-limiting adverse reactions to dermal fillers have been reported following COVID-19 vaccination. Clinicians should be aware of this clinical phenomenon and its management, as vaccination is carried out globally.

Delayed hypersensitivity reaction to cosmetic filler following two COVID-19 vaccinations and infection. BACKGROUND: With ongoing COVID-19 vaccination schedules and the popularity of cosmetic fillers, it is important to examine and record associated adverse reactions to a more general audience of health care professionals. Case reports exist in subspecialty journals outlining reactions after SARS-CoV-2 infection and vaccination. This is one of the first cases published in Canada, and it highlights priorities and challenges faced by physicians in assessing and managing patients presenting with adverse reactions post vaccination. CASE PRESENTATION: We present a case of a 43 -year-old women with delayed type 4 hypersensitivity reaction to hyaluronic acid cosmetic filler triggered by COVID-19 mRNA vaccination. We outline the clinical presentation, diagnosis, complications, and treatment of a late inflammatory reaction to hyaluronic acid filler and highlight the treatment priorities for clinicians faced with similar presentations. CONCLUSION: The differential diagnosis of delayed onset nodules formation post filler injection is broad and includes redistribution of fillers, inflammatory reaction to biofilm, and delayed hypersensitivity reaction. As result, in order to make the right diagnosis, administer the appropriate treatment and achieve great cosmetic results, we highly recommend seeking expert opinion from dermatologist, plastic surgeon and allergist immunologist in a timely manner.

Insights into new-onset autoimmune diseases after COVID-19 vaccination. Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has resulted in more than 670 million infections and almost 7 million deaths globally. The emergence of numerous SARS-CoV-2 has heightened public concern regarding the future course of the epidemic. Currently, the SARS-CoV-2 Omicron variant has rapidly become globally dominant in the COVID-19 pandemic due to its high infectivity and immune evasion. Consequently, vaccination implementation is critically significant. However, growing evidence suggests that COVID-19 vaccination may cause new-onset autoimmune diseases, including autoimmune glomerulonephritis, autoimmune rheumatic diseases, and autoimmune hepatitis. Nevertheless, the causal relationship between COVID-19 vaccines and these autoimmune diseases remains to be demonstrated. In this review, we provide evidence that vaccination induces autoimmunity and summarize possible mechanisms of action, such as molecular mimicry, activation by bystanders, and adjuvants. Our objective is not to refute the importance of vaccines, but to raise awareness about the potential risks of COVID-19 vaccination. In

fact, we believe that the benefits of vaccination far outweigh the possible risks and encourage people to get vaccinated.

Comment to: Post-vaccination incidence and side effects of COVID-19 in a cohort of Brazilian healthcare professionals: an internet-based survey.

Adverse Effects of the COVID-19 Vaccine in Patients With Psoriasis.

Fulminant myocarditis following SARS-CoV-2 mRNA vaccination rescued with venoarterial ECMO: A report of two cases. INTRODUCTION: Cases of myocarditis after COVID-19 messenger RNA (mRNA) vaccines administration have been reported. Although the majority follow a mild course, fulminant presentations may occur. In these cases, cardiopulmonary support with venoarterial extracorporeal membrane oxygenation (V-A ECMO) may be needed. RESULTS: We present two cases supported with V-A ECMO for refractory cardiogenic shock due to myocarditis secondary to a mRNA SARS-CoV2 vaccine. One of the cases was admitted for out-of-hospital cardiac arrest. In both, a peripheral V-A ECMO was implanted in the cath lab using the Seldinger technique. An intra-aortic balloon pump was needed in one case for left ventricle unloading. Support could be successfully withdrawn in a mean of five days. No major bleeding or thrombosis complications occurred. Whereas an endomyocardial biopsy was performed in both, a definite microscopic diagnosis just could be reached in one of them. Treatment was the same, using 1000mg of methylprednisolone/day for three days. A cardiac magnetic resonance was performed ten days after admission, showing a significant improvement of the left ventricular ejection fraction and diffuse oedema and subepicardial contrast intake in different segments. Both cases were discharged fully recovered, with CPC 1. CONCLUSIONS: COVID-19 vaccine-associated fulminant myocarditis has a high morbidity and mortality but presents a high potential for recovery. V-A ECMO should be established in cases with refractory cardiogenic shock during the acute phase.

An influenza hemagglutinin stem nanoparticle vaccine induces cross-group 1 neutralizing antibodies in healthy adults. Influenza vaccines could be improved by platforms inducing cross-reactive immunity. Immunodominance of the influenza hemagglutinin (HA) head in currently licensed vaccines impedes induction of cross-reactive neutralizing stem-directed antibodies. A vaccine without the variable HA head domain has the potential to focus the immune response on the conserved HA stem. This first-in-human dose-escalation open-label phase 1 clinical trial (NCT03814720) tested an HA stabilized stem ferritin nanoparticle vaccine (H1ssF) based on the H1 HA stem of A/New Caledonia/20/1999. Fifty-two healthy adults aged 18 to 70 years old enrolled to receive either 20 Î¼g of H1ssF once (nÂ =Â 5) or 60 Î¼g of H1ssF twice (nÂ =Â 47) with a prime-boost interval of 16 weeks. Thirty-five (74%) 60-Î¼g dose participants received the boost, whereas 11 (23%) boost vaccinations were missed because of public health restrictions in the early stages of the COVID-19 pandemic. The primary objective of this trial was to evaluate the safety and tolerability of H1ssF, and the secondary objective was to evaluate antibody responses after vaccination. H1ssF was safe and well tolerated, with mild solicited local and systemic reactogenicity. The most common symptoms included pain or tenderness at the injection site (nÂ =Â 10, 19%), headache (nÂ =Â 10, 19%), and malaise (nÂ =Â 6, 12%). We found that H1ssF elicited cross-reactive neutralizing antibodies against the conserved HA stem of group 1 influenza viruses, despite previous H1 subtype head-specific immunity. These responses were durable, with neutralizing antibodies observed more than 1 year after vaccination. Our results support this platform as a step forward in the development of a universal influenza vaccine.

Enlargement of a metastatic lymph node from differentiated thyroid cancer after COVID-19 vaccination. BACKGROUND: The massive vaccination campaign against COVID-19 has granted a high level of protection against the severe forms of the disease at the price of some mild adverse events. OBJECTIVE: To underline that COVID-19 vaccination can induce a transient enlargement of

lymph-node metastases in differentiated thyroid cancer patients. CASE PRESENTATION: We describe the clinical, laboratory, and imaging features of a 60-year-old woman affected by paratracheal lymph-node relapse of Hurtle Cell Carcinoma who came to our attention after full COVID-19 vaccination because of neck swelling and pain. In April 2021, after 5 years of stable structural disease, the patient presented an enlargement of the metastatic lymph node, associated with a rise of serum thyroglobulin (from 4.6 to 14.7â€‰pg/mL). Anti-inflammatory treatment was started and pain and swelling remitted after 15 days. At the subsequent evaluation, at neck ultrasound, the right paratracheal lesion was smaller and thyroglobulin dropped to 3.9â€‰pg/mL. CONCLUSIONS: We report the case of an enlargement of metastatic lymph node from differentiated thyroid cancer after COVID-19 vaccination. We warn clinicians to identify features of inflammatory response due to COVID-19 vaccination in order to prevent unwarranted surgical treatment.

New insights of antineutrophil cytoplasmic antibody-associated vasculitis from the perspective of COVID-19 vaccination. The occurrence of antineutrophil cytoplasmic antibodies (ANCA)-associated vasculitis (AAV) has been reported since the coronavirus disease 2019 (COVID-19) vaccination, but whether there is a causal relationship or coincidence remains to be verified. We combined the term COVID-19 vaccination with each word of AAV to search for case reports and case series published in PubMed, EMBASE, and Web of Science databases before 13 March 2023. A total of 56 patients who developed AAV after COVID-19 vaccination were identified from 44 research centers. Of the 56 subjects, 43 (76.7%) were vaccinated with the mRNA vaccine, followed by the adenovirus vaccine (14.3%) and inactivated vaccine (9.0%) (P = 0.015). Compared with relapsed AAV, new-onset AAV patients had at least two other diseases previously (P < 0.001). Twenty-five (44.6%) patients presented symptoms after the first injection, and the medium onset time was 12 (1-77) days, while Twenty-eight (50.0%) patients developed symptoms after the second dose, and their medium period was 14 (1-60) days. Forty-four (78.5%) patients achieved remission after immunosuppressive agents, plasma exchange, and hemodialysis. One (1.8%) patient died from progressive respiratory failure and nine (16.1%) did not recover, leaving five patients permanently dependent on hemodialysis. Pathogenic ANCA may be activated by enhanced immune response and epitope spreading after COVID-19 vaccination and induced the occurrence of AAV, especially in genetically susceptible populations.

Multicentre case-control study evaluating the safety of anti-SARS-CoV-2 vaccines in a cohort of patients with systemic vasculitis. OBJECTIVES: Data on the safety of anti-SARS-CoV-2 vaccines in patients with rare rheumatic diseases, such as systemic vasculitis (SV), are limited. The aim of this study was to evaluate the occurrence of a disease flare and the appearance of adverse events (AEs) following administration of anti-SARS-CoV-2 vaccine in a multicentre cohort of patients with SV. METHODS: Patients with SV and healthy controls (HC) from two different Italian rheumatology centres were asked to complete a questionnaire assessing disease flares occurrence, defined as new onset of clinical manifestations related to vasculitis needing an implementation of therapy, and local/systemic AEs appearance following anti SARS-CoV-2 vaccination. RESULTS: 107 patients with SV (57 ANCA-associated) and 107 HC were enrolled. A disease flare occurred in only one patient (0.93%) with microscopic polyangiitis after the first dose of an mRNA vaccine. After both the first and the second vaccine dose administration, no significant differences in AEs between patients with SV and HC were observed; no serious AEs were reported as well. CONCLUSIONS: These data suggest a good risk profile for anti-SARS-CoV-2 vaccine in patients with systemic vasculitis.

Kikuchi-Fujimoto disease following SARS-CoV-2 vaccination in a patient with previous history of rhabdomyosarcoma.

COVID-19 vaccine antibody responses in community-dwelling adults to 48Â weeks post primary vaccine series. We report a decentralized prospective cohort study of self-reported adverse

events and antibody responses to COVID vaccines derived from dried blood spots. Data are presented for 911 older (aged >70 years) and 375 younger (30-50 years) recruits to 48Â weeks after the primary vaccine series. After a single vaccine, 83% younger and 45% older participants had overall seropositivity (pÂ <Â 0.0001) increasing to 100/98% with the second dose, respectively (pÂ = 0.084). A cancer diagnosis (pÂ = 0.009), no mRNA-1273 vaccine doses (p <0 .0001), and older age (p <0 .0001) predicted lower responses. Antibody levels declined in both cohorts at 12 and 24Â weeks increasing with booster doses. At 48Â weeks, for participants with 3 vaccine doses, the median antibody levels were higher in the older cohort (pÂ = 0.04) with any dose of mRNA-1273 (p <0 .0001) and with COVID infection (p <0 .001). The vaccines were well tolerated. Breakthrough COVID infections were uncommon (16% older cohort, 29% younger cohort; pÂ <Â 0.0001) and mild.

The impact of SARS-CoV2 vaccines on the incidence of graft versus host disease in allogeneic hematopoietic stem cell transplant recipients: a single-center retrospective study. This study reports the incidence of chronic graft versus host disease (GvHD) in allogeneic hematopoietic stem cell transplant (alloHCT) recipients who received SARS-CoV2 vaccination. The overall rates of new and worsening chronic GvHD combined were 14%, with median time from vaccination to GVHD being approximately three to four weeks. A majority of the cases were of mild to moderate severity and primarily localized to either the skin, mouth, or joints. Prior chronic GVHD and recent transplant were associated with higher GVHD rates following COVID-19 vaccination. More prospective studies are needed to provide a definitive mechanism for the impact of SARS-CoV2 vaccination on alloHCT patients.

Predictive factors of delayed viral clearance of asymptomatic Omicron-related COVID-19 screened positive in patients with cancer receiving active anticancer treatment. OBJECTIVES: We sought to identify the predictors of delayed viral clearance in patients with cancer with asymptomatic COVID-19 when the SARS-CoV-2 Omicron variants prevailed in Hong Kong. METHODS: All patients with cancer who were attending radiation therapy for head and neck malignancies or systemic anticancer therapy saved their deep throat saliva or nasopharyngeal swabs at least twice weekly for SARS-CoV-2 screening between January 1 and April 30, 2022. The multivariate analyses identified predictors of delayed viral clearance (or slow recovery), defined as >21 days for the cycle threshold values rising to â‰¥30 or undetectable in two consecutive samples saved within 72 hours. Three machine learning algorithms evaluated the prediction performance of the predictors. RESULTS: A total of 200 (15%) of 1309 patients tested positive for SARS-CoV-2. Age >65 years (PÂ =Â 0.036), male sex (PÂ =Â 0.003), high Charlson comorbidity index (PÂ =Â 0.042), lung cancer (PÂ =Â 0.018), immune checkpoint inhibitor (PÂ =Â 0.036), and receipt of one or no dose of COVID-19 vaccine (PÂ =Â 0.003) were significant predictors. The three machine learning algorithms revealed that the mean Â± SD area-under-the-curve values predicting delayed viral clearance with the cut-off cycle threshold value â‰¥30 was 0.72 Â± 0.11. CONCLUSION: We identified subgroups with delayed viral clearance that may benefit from targeted interventions.

COVID-19 Vaccines Are Safely Tolerated in Adolescents with Cutaneous Mastocytosis. INTRODUCTION: The management of the COVID-19 vaccine in children with mastocytosis is unclear due to a lack of data. In the current study, we aimed to evaluate the adverse reactions following COVID-19 vaccination in adolescents with cutaneous mastocytosis (CM). METHODS: This study included 27 paediatric patients who were diagnosed with CM and were followed up in the paediatric allergy department of a tertiary care children's hospital. RESULTS: The median (IQR) age of the patients at the time of COVID-19 vaccination was 180 (156-203) months. Forty-four per cent of patients were vaccinated with the COVID-19 vaccine. Among all participants, the vaccination rate was found to be higher in older children, those who had been diagnosed with MPCM, and those who had not been infected with COVID-19 (p = 0.019, p = 0.009, p = 0.002, respectively). A total of 23 doses of

the COVID-19 vaccine, including two doses of Sinovac/CoronaVac and 21 doses of Pfizer/BioNTech, were administered to 12 paediatric patients with CM. One of the patients had a history of intense itch, erythematous urticarial plaques, and had an exacerbation of existing skin lesions within 24-48 h after both doses of Pfizer/BioNTech vaccination. CONCLUSION: The COVID-19 vaccination of patients with CM in this series seems to be safe, and the rate of adverse events was comparable to that in the general population. These results found in adolescents with CM are in line with the existing evidence that CM does not preclude vaccination in children.

Safety Signal Generation for Sudden Sensorineural Hearing Loss Following Messenger RNA COVID-19 Vaccination: Postmarketing Surveillance Using the French Pharmacovigilance Spontaneous Reporting Database. BACKGROUND: The World Health Organization recently described sudden sensorineural hearing loss (SSNHL) as a possible adverse effect of COVID-19 vaccines. Recent discordant pharmacoepidemiologic studies invite robust clinical investigations of SSNHL after COVID-19 messenger RNA (mRNA) vaccines. This postmarketing surveillance study, overseen by French public health authorities, is the first to clinically document postvaccination SSNHL and examine the role of potential risk factors. OBJECTIVE: This nationwide study aimed to assess the relationship between SSNHL and exposure to mRNA COVID-19 vaccines and estimate the reporting rate (Rr) of SSNHL after mRNA vaccination per 1 million doses (primary outcome). METHODS: We performed a retrospective review of all suspected cases of SSNHL after mRNA COVID-19 vaccination spontaneously reported in France between January 2021 and February 2022 based on a comprehensive medical evaluation, including the evaluation of patient medical history, side and range of hearing loss, and hearing recovery outcomes after a minimum period of 3 months. The quantification of hearing loss and assessment of hearing recovery outcomes were performed according to a grading system modified from the Siegel criteria. A cutoff of 21 days was used for the delay onset of SSNHL. The primary outcome was estimated using the total number of doses of each vaccine administered during the study period in France as the denominator. RESULTS: From 400 extracted cases for tozinameran and elasomeran, 345 (86.3%) spontaneous reports were selected. After reviewing complementary data, 49.6% (171/345) of documented cases of SSNHL were identified. Of these, 83% (142/171) of SSNHL cases occurred after tozinameran vaccination: Rr=1.45/1,000,000 injections; no difference for the rank of injections; complete recovery in 22.5% (32/142) of cases; median delay onset before day 21=4 days (median age 51, IQR 13-83 years); and no effects of sex. A total of 16.9% (29/171) of SSNHL cases occurred after elasomeran vaccination: Rr=1.67/1,000,000 injections; rank effect in favor of the first injection (P=.03); complete recovery in 24% (7/29) of cases; median delay onset before day 21=8 days (median age 47, IQR 33-81 years); and no effects of sex. Autoimmune, cardiovascular, or audiovestibular risk factors were present in approximately 29.8% (51/171) of the cases. SSNHL was more often unilateral than bilateral for both mRNA vaccines (P<.001 for tozinameran; P<.003 for elasomeran). There were 13.5% (23/142) of cases of profound hearing loss, among which 74% (17/23) did not recover a serviceable ear. A positive rechallenge was documented for 8 cases. CONCLUSIONS: SSNHL after COVID-19 mRNA vaccines are very rare adverse events that do not call into question the benefits of mRNA vaccines but deserve to be known given the potentially disabling impact of sudden deafness. Therefore, it is essential to properly characterize postinjection SSNHL, especially in the case of a positive rechallenge, to provide appropriate individualized recommendations.

Longitudinal Follow-Up of the Immunity to SARS-CoV-2 in Health Care Workers in Argentina: Persistence of Humoral Response and Neutralizing Capacity after Sputnik V Vaccination. SARS-CoV-2 vaccine protection has encountered waning of immune response and breakthrough infections. The hybrid immune response generated by the combination of vaccination and infection was shown to offer higher and broader protection. Here, we present a seroprevalence study of anti-SARS-CoV-2 spike/RBD IgG in 1,121 health care workers immunized with Sputnik V and a follow-up of humoral

response at 2 and 24 weeks postvaccination (wpv), including neutralizing antibody response (NAT) against ancestral, Gamma, and Delta variants. The first seroprevalence study showed that among 122 individuals with one dose, 90.2% were seropositive versus 99.7% seropositivity among volunteers with the complete two-dose regimen. At 24 wpv, 98.7% of the volunteers remained seropositive, although antibody levels decreased. IgG levels and NAT were higher in individuals that had acquired COVID-19 previous to vaccination than in naive individuals at 2 and 24 wpv. Antibody levels dropped over time in both groups. In contrast, IgG levels and NAT increased after vaccine breakthrough infection. At 2 wpv, 35/40 naive individuals had detectable NAT against SARS-CoV-2 Gamma and 6/40 against Delta. In turn, 8/9 previously infected individuals developed a neutralizing response against SARS-CoV-2 Gamma and 4/9 against Delta variants. NAT against variants followed a trajectory similar to NAT against ancestral SARS-CoV-2, and breakthrough infection led to an increase in NAT and complete seroconversion against variants. In conclusion, Sputnik V-induced humoral response persisted at 6 months postvaccination, and hybrid immunity induced higher levels of anti-S/RBD antibodies and NAT in previously exposed individuals, boosted the response after vaccination, and conferred wider breadth of protection. IMPORTANCE Since December 2020, Argentina has begun a mass vaccination program. The first vaccine available in our country was Sputnik V, which has been approved for use in 71 countries with a total population of 4 billion people. Despite all the available information, there are fewer published studies on the response induced by Sputnik V vaccination compared to that of other vaccines. Although the global political context has paralyzed the verification by the WHO of the efficacy of this vaccine, our work aims to add new clear and necessary evidence to Sputnik V performance. Our results contribute to general knowledge of the humoral immune response developed by vaccines based on viral vector technology, highlighting the higher immune protection conferred by hybrid immunity and reinforcing the importance of completing vaccination schedules and booster doses to maintain adequate antibody levels.

[Reactogenicity Study of mRNA Vaccines Against COVID-19]. OBJECTIVE: To compare the reactogenicity between the types of mRNA CommirnatyÂ® (Pfizer) and SpikevaxÂ® (Moderna) vaccines against COVID-19 in a healthcare population. METHODS: Cross sectional study of short-term adverse effects and their consequences (sick leave, limitations of daily life, etc.) after the administration of the first and second doses of both vaccines in professionals and students of a health institution. A questionnaire on symptoms and their consequences was administered seven days after each vaccination dose. The prevalence and 95% confidence interval (95%CI) were calculated. Differences between vaccines were quantified using the odds ratio (OR) and its 95%CI. RESULTS: The questionnaire was completed by 1924 and 1170 healthcare providers (response rates 62.2% and 39.1%) after the first and second doses, respectively, of the CommirnatyÂ® vaccine, and 410 (56.0%) and 107 (15.0%) of SpikevaxÂ®. After the first dose of ComirnatyÂ®, 67.4% presented some adverse effect, and 76.1% for SpikevaxÂ® (OR 1.5 95%CI 1.2-1.9). In general, women and young people showed greater reactogenicity and differences between vaccinSpain. Consequences of adverse effects were more frequent for SpikevaxÂ®. The reactogenicity was higher after the second than the first dose, for both vaccines (ComirnatyÂ®: 67.4% vs. 75.6%; SpikevaxÂ®: 76.1% vs. 87.9%. CONCLUSIONS: The greater reactogenicity and its consequences, for the first and second dose of the SpikevaxÂ® vaccine compared to ComirnatyÂ®, and of the second dose compared to the first dose of both vaccines, provides useful knowledge for planning vaccination against COVID-19 campaigns in healthcare settings.

Immunogenicity, effectiveness, and safety of SARS-CoV-2 vaccination in people with HIV. OBJECTIVES: People with HIV (PWH) experience a greater risk of morbidity and mortality following COVID-19 infection, and poorer immunological responses to several vaccines. We explored existing evidence regarding the immunogenicity, effectiveness, and safety of SARS-CoV-2 vaccines in PWH

compared with controls. METHODS: We conducted a systematic search of electronic databases from January 2020 until June 2022, in addition to conference databases, to identify studies comparing clinical, immunogenicity, and safety in PWH and controls. We compared results between those with low (<350â€Šcells/Î¼l) and high (>350â€Šcells/Î¼l) CD4 + T-cell counts where possible. We performed a meta-analysis of seroconversion and neutralization responses to calculate a pooled risk ratio as the measure of effect. RESULTS: We identified 30 studies, including four reporting clinical effectiveness, 27 immunogenicity, and 12 reporting safety outcomes. PWH were 3% [risk ratio 0.97, 95% confidence interval (95% CI) 0.95-0.99] less likely to seroconvert and 5% less likely to demonstrate neutralization responses (risk ratio 0.95, 95% CI 0.91-0.99) following a primary vaccine schedule. Having a CD4 + T-cell count less than 350â€Šcells/Î¼l (risk ratio 0.91, 95% CI 0.83-0.99) compared with a CD4 + T-cell count more than 350â€Šcells/Î¼l, and receipt of a non-mRNA vaccine in PWH compared with controls (risk ratio 0.86, 95% CI 0.77-0.96) were associated with reduced seroconversion. Two studies reported worse clinical outcomes in PWH. CONCLUSION: Although vaccines appear well tolerated in PWH, this group experience poorer immunological responses following vaccination than controls, particularly with non-mRNA vaccines and low CD4 + T-cell counts. PWH should be prioritized for mRNA COVID-19 vaccines, especially PWH with more advanced immunodeficiency.

A New Onset of Ulcerative Colitis Post-COVID-19: A Case Report. Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) can cause not only respiratory symptoms but also gastrointestinal symptoms. In addition, there is increased concern about the autoimmune complications of coronavirus disease 2019 (COVID-19). This report describes a 21-year-old non-smoking Caucasian male with a history of acute pancreatitis but no other medical issues or family history who developed a new onset of ulcerative colitis after the second episode of COVID-19. He had three doses of the BNT162b2 mRNA COVID-19 vaccine. Two months after the first episode of COVID-19, he had the third dose of the vaccine. Nine months after the third dose, he had the second episode of COVID-19, during which he was mildly unwell for three days, recovered, and did not require any anti-viral medication or antibiotics. One week post the second episode of COVID-19, he developed diarrhoea and abdominal pain. It then progressed to bloody diarrhea. We diagnosed ulcerative colitis based on his clinical symptoms, biopsy changes, and the exclusion of other causes. This case raises awareness of developing ulcerative colitis concurrently with or following COVID-19. It is essential to thoroughly investigate COVID-19 patients who have diarrhea or bloody diarrhea and not consider it a common gastroenteritis or a simple gastrointestinal manifestation of COVID-19. Although we cannot confirm the association with a case study, further research is needed to confirm the causal or incidental relationship and observe any increased incidence of ulcerative colitis in the future as secondary to COVID-19.

Acute vulvar ulcer as a possible adverse event of gene-based COVID-19 vaccines: A review of 14 cases. AIM: To evaluate whether an acute vulvar ulcer that developed after the COVID-19 vaccine administration is an adverse effect of the vaccine. METHODS: This is a descriptive study of two cases that we observed in addition to cases that have been reported in the literature. We searched for case reports in the PubMed. The consistency of clinical manifestations among cases and the association between ulceration and vaccination were assessed. RESULTS: Fourteen female patients were identified, including 12 patients from 8 literatures published in 2021 and 2022 and 2 patients from our cases. Of the 14 patients, 11 had received the BNT162b2 vaccine, 2 had received the ChAdOx1 nCoV-19 vaccine, and one had received the mRNA-1273 vaccine. The patient's ages were 16.9â€‰Â±â€‰5.0 (meanâ€‰Â±â€‰SD) years. Postvaccination, the disease progressed in the following sequence (time interval from vaccination): fever and other systemic inflammatory reactions (0.9â€‰Â±â€‰0.4â€‰days), development of vulvar ulcers (2.4â€‰Â±â€‰1.2â€‰days), and resolution of the ulcer (16.9â€‰Â±â€‰7.4â€‰days). The ulcers eventually healed in all cases,

except one where the prognosis was not noted. For two-dose vaccine recipients, more patients developed the ulcer after the full vaccination (the second or third doses) compared with after the first dose: nâ€‰=â€‰10 and nâ€‰=â€‰2, respectively. CONCLUSION: The acute vulvar ulcer was closely associated with COVID-19 vaccination in terms of temporality and vaccine doses, supporting the notion that a vulvar ulcer is an adverse event of the COVID-19 vaccines.

Experiences of persons with multiple sclerosis with the Covid-19 vaccination: A cross-sectional study of the Swiss Multiple Sclerosis Registry. BACKGROUND: Despite strong recommendations for coronavirus disease 2019 (Covid-19) vaccination by multiple sclerosis (MS) organizations, some persons with MS (pwMS) remain vaccine hesitant. The Swiss MS Registry conducted a survey to explore Covid-19 vaccine hesitancy, self-reported side effects and changes in MS symptoms following vaccination in adult pwMS. METHODS: Self-reported data were analyzed cross-sectionally. Multivariable logistic regression was used to explore participant characteristics associated with Covid-19 vaccine hesitancy. RESULTS: Of 849 respondents, 73 (8.6%) were unvaccinated. Hesitation to vaccinate was most often a personal preference (NÂ =Â 42, 57.53%). Factors negatively associated with vaccine hesitancy included older age (ORÂ =Â 0.97 per year, 95% CI [0.94, 0.99]) and regularly seeing healthcare professionals (ORÂ =Â 0.25, 95% CI [0.07, 0.85]). A history of confirmed Covid-19 infection (ORÂ =Â 3.38, 95% CI [1.69, 6.77]) and being underweight (ORÂ =Â 4.50, 95% CI [1.52, 13.36]) were positively associated with vaccine hesitancy. Of 768 participants who provided information, 320 (41.2%) and 351 (45.2%) reported vaccination side effects after the first and second vaccinations, respectively. Changes in MS symptoms were reported by 49 (6.3%) participants after the first and 67 (9.0%) participants after the second vaccination, and were most often described as increased or new-onset fatigue (NÂ =Â 17/49 (34.7%) after the first and NÂ =Â 21/67 (31.3%) after the second dose). CONCLUSIONS: Covid-19 vaccine hesitancy was low among surveyed pwMS. The risk of vaccine hesitancy was higher among younger pwMS, those with a history of Covid-19 infection, and those without regular contact with healthcare professionals.

A case of anti-LGI1 encephalitis after mRNA COVID-19 vaccination.

[Comparative Analyses of IgA Antibody Response of Non-COVID-19 Infected People Over 60 Years Old Following CoronaVac and Pfizer-BioNTech COVID-19 Vaccination]. The formation rate, magnitude, and duration of the antibody-mediated humoral immune response that develops against different viral proteins of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) are considered important in vaccine success. It is known that the response to vaccinations decreases due to immunosenescence in older adults. This study was aimed to investigate the levels of serum IgA response at 1st and 3rd month after vaccination of people over 60 years old who were immunized with CoronaVac and Pfizer-BioNTech. A total of 35 people living in the North Cyprus who have not previously had COVID-19 infection were included in the study. After the 2nd dose of vaccination, serum IgA levels were measured after the 1st and 3rd month with the anti-SARS-CoV-2 IgA (Euroimmun, Lubeck, Germany) kit. The statistical significance was determined as 0.05 in the whole study. SPSS and GraphPad Prism software were used for calculations, analyses and graphs. The possible effect of demographic variables on serum IgA level was compared between the vaccine groups and it was found that there was no statistically significant difference between them. For the IgA titer-positive individuals who had been vaccinated with the Pfizer-BioNTech vaccine, for both 1st and 3rd months were observed to be higher than CoronaVac vaccinated IgA titer-positive individuals. In individuals who received the CoronaVac vaccine, there was a statistically significant change in serum IgA levels between 1st and 3rd months, but there was no statistically significant change in the Pfizer-BioNTech vaccine administered group. When the Pfizer/BioNTech and CoronaVac vaccines were compared with each other in terms of serum IgA antibody titers, it was found that the mean serum IgA levels of the individuals in the Pfizer/BioNTech group were statistically higher at the 1st

and 3rd months than the CoronaVac group. Serum IgA titers in both vaccine groups were statistically significantly decreased from 1st month to 3rd month. This study showed that the Pfizer/BioNTech vaccine induced higher SARS-CoV-2 specific serum IgA antibodies than the CoronaVac vaccine and remained seropositive for a longer time in individuals aged 60 years and older. It is believed that the serum IgA levels that were determined may not reflect the serum IgA levels. However, these findings support the studies in other literature, showing that the Pfizer-BioNTech mRNA vaccine induces higher SARS-CoV-2 specific serum IgA antibodies than the inactive CoronaVac vaccine and that it remains seropositive for a longer period of time. This study is important as it is the first study to compare the SARS-CoV-2 IgA antibody responses of individuals over 60 years of age in the Turkish Republic of Northern Cyprus in two different vaccine groups.
Temporal association between COVID-19 vaccination and Raynaud's phenomenon: A case series. COVID-19 vaccine-related adverse events are mostly minor to moderate, and serious events are rare. Single cases of Raynaud's phenomenon (RP) in temporal proximity to COVID-19 vaccination have been reported. Demographic data, medical history, and detailed information regarding vaccination status and RP characteristics were obtained from patients with confirmed RP after COVID-19 vaccination. Fifteen participants reported the initial manifestation of RP, which occurred in 40% after the first, in 33% after the second, and in 27% after the third vaccination. RP development and occurrence of episodes were not linked to any specific vaccine type. New onset of disease was observed in 40% of the vaccinees after BNT162b2, in 33% after mRNA-1273, and in 27% after ChAdOx1 vaccination. Three out of four participants with preexisting RP prior to COVID-19 vaccination reported aggravation in frequency and intensity after immunization. Although COVID-19 vaccination is pivotal in controlling the pandemic, the observed temporal association between vaccine administration and RP occurrence warrants global activities to support pharmacovigilance for the detection of adverse reactions, one of which may include RP.
mRNA COVID 19 vaccine-induced recall dermatitis after topical imiquimod.
Inadvertent injection of COVID-19 vaccine into deltoid muscle vasculature may result in vaccine distribution to distance tissues and consequent adverse reactions.
Humoral profiles of toddlers and young children following SARS-CoV-2 mRNA vaccination. Although young children generally experience mild symptoms following infection with SARS-CoV-2, severe acute and long-term complications can occur. SARS-CoV-2 mRNA vaccines elicit robust immunoglobulin profiles in children ages 5 years and older, and in adults, corresponding with substantial protection against hospitalizations and severe disease. Whether similar immune responses and humoral protection can be observed in vaccinated infants and young children, who have a developing and vulnerable immune system, remains poorly understood. To study the impact of mRNA vaccination on the humoral immunity of infant, we used a system serology approach to comprehensively profile antibody responses in a cohort of children ages 6 months to 5 years who were vaccinated with the mRNA-1273 COVID-19 vaccine (25 Î¼g). Responses were compared with vaccinated adults (100 Î¼g), in addition to naturally infected toddlers and young children. Despite their lower vaccine dose, vaccinated toddlers elicited a stronger functional antibody response than adults, including against variant of concerns (VOCs), without report of side effects. Moreover, mRNA vaccination was associated with a higher IgG3-dependent humoral profile against SARS-CoV-2 compared to natural infection, supporting that mRNA vaccination is effective at eliciting a robust antibody response in toddlers and young children.
Longitudinal Analysis of Humoral and Cellular Immune Response Following SARS-CoV-2 Vaccination Supports Utilizing Point-Of-Care Tests to Enhance COVID-19 Booster Uptake. Individuals with weaker neutralizing responses show reduced protection with SARS-CoV-2 variants. Booster vaccines are recommended for vaccinated individuals, but the uptake is low. We present the feasibility of

utilizing point-of-care tests (POCT) to support evidence-based decision-making around COVID-19 booster vaccinations. Using infectious virus neutralization, ACE2 blocking, spike binding, and TCR sequencing assays, we investigated the dynamics of changes in the breadth and depth of blood and salivary antibodies as well as T-cell clonal response following mRNA vaccination in a cohort of healthcare providers. We evaluated the accuracy of two POCTs utilizing either blood or saliva to identify those in whom humoral immunity was inadequate. >4 months after two doses of mRNA vaccine, SARS-CoV-2 binding and neutralizing Abs (nAbs) and T-cell clones declined 40-80%, and 2/3rd lacked Omicron nAbs. After the third mRNA booster, binding and neutralizing Abs increased overall in the systemic compartment; notably, individuals with previously weak nAbs gained sharply. The third dose failed to stimulate secretory IgA, but salivary IgG closely tracked systemic IgG levels. Vaccine boosting increased Ab breadth against a divergent bat sarbecovirus, SHC014, although the TCR-beta sequence breadth was unchanged. Post 3rd booster dose, Ab avidity increased for the Wuhan and Delta strains, while avidity against Omicron and SHC014 increased to levels seen for Wuhan after the second dose. Negative results on POCTs strongly correlated with a lack of functional humoral immunity. The third booster dose helps vaccinees gain depth and breadth of systemic Abs against evolving SARS-CoV-2 and related viruses. Our findings show that POCTs are useful and easy-to-access tools to inform inadequate humoral immunity accurately. POCTs designed to match the circulating variants can help individuals with booster vaccine decisions and could serve as a population-level screening platform to preserve herd immunity. ONE SENTENCE SUMMARY: SARS-CoV-2 point-of-care antibody tests are valuable and easy-to-access tools to inform inadequate humoral immunity and to support informed decision-making regarding the current and future booster vaccination.

COVID-19 vaccine side effects on menstrual disturbances among Iranian women. BACKGROUND: Many studies reported of menstrual disturbances as possible side effects of COVID-19 vaccination. Our objective was to evaluate the association between vaccination and the occurrence of menstrual disturbances among Iranian women. METHODS: We used to google form questionnaires to collect reports of menstrual disturbances from 455 women aged 15-55 years in Iran. We estimated the relative risk of menstrual disturbances according to vaccination in a self-controlled case-series design after vaccination. We examined the occurrence of such disorders after the first, second and third doses of vaccine. RESULTS: Findings The prevalence of menstrual disturbance was more in latency and heavy bleeding than others disorder after vaccination, although Ö® %50 of women doesn't have any disturbance. We observed increased risks after vaccination also for other menstrual disturbances, in menopausal women too (>10%). DISCUSSION: Menstrual disturbances were generally common regardless of vaccination. We found a significant increase in menstrual disturbances after vaccination, particularly for latency and heavier bleeding than usual, longer duration and for short interval between menstruations. Mechanisms underlying these findings may involve bleeding disturbances in general, as well as endocrine alterations of immune system stimulation and relation to hormonal secretion.

Case Report: Psychiatric Symptoms Associated With the Moderna mRNA COVID-19 Vaccine Administration and Their Resolution. This case report describes the sudden presentation and successful cessation of psychiatric symptoms following the first administration of the Moderna mRNA vaccine against the SARS-CoV-2 virus during early 2021. The process of discovery of symptoms is described, along with an empirical procedure which identified St. John's wort as the mediating agent. Implications for self-medication of mild depression are discussed. Hypericin, a constituent agent in St. John's wort, interacts with the SARS-CoV-2 spike protein. Sensitization to hypericin following vaccine administration is consistent with the observed symptoms.

Breakthrough Hemolysis Associated With COVID-19 Vaccination and Active COVID-19 Infection in a Patient With Paroxysmal Nocturnal Hemoglobinuria Maintained on Pegcetacoplan: A Case Report.

Breakthrough hemolysis (BTH) is the return of hemolytic disease resulting in an overall increase in complement activation in a patient being treated for paroxysmal nocturnal hemoglobinuria (PNH) with complement inhibitors (CI). BTH after COVID-19 vaccination has only been reported in PNH patients treated with the traditional C5 CIÂ eculizumab and ravulizumab. We report on a new association of BTH in a newly COVID-19 vaccinated, previously stable PNH patient treated with pegcetacoplan, a C3 CI. The patient is a 29-year-old female diagnosed with PNH in 2017 and was started on eculizumab but was switched to pegcetacoplan in 2021 after continuing to exhibit symptomatic hemolysis. Subsequently, the patient returned to PNH remission serologically and symptomatically until her first COVID-19 vaccination. Since then, her lactate dehydrogenase (LDH) and hemoglobin counts have not fully returned to previous baseline levels, with significant exacerbations after her second COVID-19 vaccine and de novo COVID-19 infection. As of May 2022, the patient requires packed red blood cell transfusions every two to three months and has undergone a bone marrow transplant evaluation. This case study suggests that the administration of the upstream C3 CI, pegcetacoplan, is associated with active extravascular hemolysis in the setting of COVID-19 vaccinations and active COVID-19 infection. The pathophysiology of this hemolysis is unclear as hemolysis could be related to the underlying complement factor deficiency or amplification of complement factors causing extravascular hemolysis. There are conflicting reports in the literature regarding the mechanism by which COVID-19 vaccination and infection cause BTH in PNH patients, regardless of the choice of CI treatment. Bringing awareness to this case of BTH secondary to COVID-19 in a PNH patient treated with pegcetacoplan can further warrant the investigation of the role of COVID-19 in complement disruption and its role in BTH.

Fatal Post COVID mRNA-Vaccine Associated Cerebral Ischemia. BACKGROUND: Venous thromboses have been linked to several COVID-19 vaccines, but there is limited information on the Moderna vaccine's effect on the risk of arterial thrombosis. Here we describe a case of post-Moderna COVID-19 vaccination arterial infarct with vaccine-associated diffuse cortical edema that was complicated by refractory intracranial hypertension. CASE SUMMARY: 24Â hrs after receiving her first dose of the Moderna COVID-19 vaccine, a 30-year-old female developed severe headache. Three weeks later she was admitted with subacute headache and confusion. Imaging initially showed scattered cortical thrombosis with an elevated opening pressure on lumbar puncture. An external ventricular drain was placed, but she continued to have elevated intracranial pressure. Ultimately, she required a hemicraniectomy, but intractable cerebral edema resulted in her death. Pathology was consistent with thrombosis and associated inflammatory response. CONCLUSION: Though correlational, her medical team surmised that the mRNA vaccine may have contributed to this presentation. The side effects of COVID-19 infection and vaccination are still incompletely understood. Though complications are rare, clinicians should be aware of presentations like this one.

Delayed exacerbation of COVID-19 pneumonia in vaccinated kidney transplant recipients receiving immunosuppressants: a case series. Coronavirus disease 2019 (COVID-19) increases the risk of mortality and hospitalization in immunocompromised patients, including kidney transplant recipients (KTRs) receiving immunosuppressants. Several vaccines for COVID-19 have been developed and proven effective in decreasing the incidence of COVID-19 and the rate of progression to severe COVID-19. However, breakthrough infections have also been reported in vaccinated patients. We report cases from our center of delayed exacerbated pneumonia from COVID-19 in vaccinated KTRs receiving immunosuppressants. Of the 900 KTRs who had been vaccinated for COVID-19 and were followed up at our center from January 1, 2022, to April 30, 2022 (during the Omicron variant outbreak), 126 contracted COVID-19 (incidence rate, 14%). Thirty-four (27%) in this group were hospitalized due to COVID-19. Twenty patients did not have pneumonia but had symptoms of upper respiratory tract infection or diarrhea, which improved with conservative treatment. Nine of the 14

patients with pneumonia had delayed onset or exacerbated pneumonia 1 week after their COVID-19 diagnosis. They were treated with remdesivir, and most recovered. One patient died due to progressive pneumonia and pneumothorax. It is important that KTRs who are taking immunosuppressants be observed closely and for a prolonged period after a COVID-19 diagnosis, irrespective of their COVID-19 vaccination status.

Clinical outcome of SARS-CoV-2 infections occurring in multiple myeloma patients after vaccination and prophylaxis with tixagevimab/cilgavimab. INTRODUCTION: Patients with multiple myeloma (MM) frequently reported immune impairment with an increased risk for infection-related mortality. We aimed to evaluate the immune response in MM patients vaccinated for SARS-CoV-2 during active treatment. METHODS: We enrolled 158 patients affected by active MM or smoldering MM (SMM) and 40 healthy subjects. All subjects received 2 or 3 doses of the BNT162b2 (Pfizer/BioNTech) vaccine, and the anti-spike IgG values were evaluated after every dose. We applied the Propensity Score Matching (PSM) as a consequence of the limited sample size and its heterogeneity to adjust for differences in baseline clinical variables between MM patients who achieved or not a vaccine response after 2 or 3 doses. RESULTS: At 30 days from the second dose, the median antibodies level in MM was 25.2 AU/mL, lower than in SMM and in the control group. The same results were confirmed after the third dose, with lower median anti-spike IgG levels in MM, compared to SMM and control group. Following PSM, lack of response to SARS-CoV-2 complete vaccination plus boost was associated with age more than 70 years old and use of high-dose of steroids. We failed to identify an association between specific treatment types and reduced vaccine response. The use of prophylaxis with tixagevimab/cilgavimab for 40 non-responder patients after 3 doses of vaccine has proven to be an effective and safe approach in reducing the risk of serious illness in the event of a breakthrough SARS-CoV-2 infection, faced with a mild symptomatic course, and in providing protection instead of long-term humoral immune vaccine responses. Following PSM, only the high-risk cytogenetic abnormalities were associated with an increased risk of developing a breakthrough SARS-CoV-2 infection. CONCLUSION: Monitoring the immune response is fundamental in MM patients that remain highly vulnerable to SARS-CoV-2 despite the vaccine. The use of prophylaxis with tixagevimab/cilgavimab can guarantee better protection from the severe form of the disease.

Breakthrough infections due to SARS-CoV-2 Delta variant: relation to humoral and cellular vaccine responses. INTRODUCTION: COVID-19 vaccines are expected to provide effective protection. However, emerging strains can cause breakthrough infection in vaccinated individuals. The immune response of vaccinated individuals who have experienced breakthrough infection is still poorly understood. METHODS: Here, we studied the humoral and cellular immune responses of fully vaccinated individuals who subsequently experienced breakthrough infection due to the Delta variant of SARS-CoV-2 and correlated them with the severity of the disease. RESULTS: In this study, an effective humoral response alone was not sufficient to induce effective immune protection against severe breakthrough infection, which also required effective cell-mediated immunity to SARS-CoV-2. Patients who did not require oxygen had significantly higher specific (p=0.021) and nonspecific (p=0.004) cellular responses to SARS-CoV-2 at the onset of infection than those who progressed to a severe form. DISCUSSION: Knowing both humoral and cellular immune response could allow to adapt preventive strategy, by better selecting patients who would benefit from additional vaccine boosters. TRIAL REGISTRATION NUMBERS: https://clinicaltrials.gov, identifier NCT04355351; https://clinicaltrials.gov, identifier NCT04429594.

Pityriasis rosea and pityriasis rosea-like eruption after anti-SARS-CoV-2 vaccination: a report of five cases and review of the literature. Only a few cases of pityriasis rosea (PR)/pityriasis rosea-like eruption (PRLE) after anti-SARS-CoV-2 vaccination have been reported. In the period May 2021-February 2022 we observed five cases of clinically typical PR that appeared 2 to 3 weeks after anti-

SARS-CoV-2 vaccination with BNT162b2 (3 patients) or mRNA- 1273 (2 patients). In 4 patients PR appeared after the first vaccination; in one patient after the second one. In 3 patients a biopsy for histopathological examinations was carried out. Results were typical for PR. In all patients laboratory examinations were within normal ranges. All patients were treated with cetirizine. Complete remission was observed within 14-30 days. Four patients were subjected to the second vaccination, but no skin lesions appeared. All patients are currently in good general health. It is possible that a relationship between anti- Sars-CoV-2 vaccination and PR/PRLE exists; however, it is very rare, in consideration of millions of vaccinated subjects and the low number of reported cases of PR/PRLE. The pathogenesis of this relationship is unknown. However, some hypotheses may be advanced: PR/PRLE following anti-Sars-CoV-2 vaccination may be just a coincidence; anti-Sars-CoV-2 vaccines cause a reactivation of HHV-6 and/or HHV-7; vaccines can induce a delayed hypersensitivity response clinically similar to drug-induced PRLE.

Vascular thrombosis after single dose Ad26.COV2.S vaccine in healthcare workers in South Africa: open label, single arm, phase 3B study (Sisonke study). OBJECTIVE: To assess the rates of vascular thrombotic adverse events in the first 35 days after one dose of the Ad26.COV2.S vaccine (Janssen/Johnson & Johnson) in healthcare workers in South Africa and to compare these rates with those observed in the general population. DESIGN: Open label, single arm, phase 3B study. SETTING: Sisonke study, South Africa, 17 February to 15 June 2021. PARTICIPANTS: The Sisonke cohort of 477 234 healthcare workers, aged â‰¥18 years, who received one dose of the Ad26.COV2.S vaccine. MAIN OUTCOME MEASURES: Observed rates of venous arterial thromboembolism and vaccine induced immune thrombocytopenia and thrombosis in individuals who were vaccinated, compared with expected rates, based on age and sex specific background rates from the Clinical Practice Research Datalink GOLD database (database of longitudinal routinely collected electronic health records from UK primary care practices using Vision general practice patient management software). RESULTS: Most of the study participants were women (74.9%) and median age was 42 years (interquartile range 33-51). Twenty nine (30.6 per 100 000 person years, 95% confidence interval 20.5 to 44.0) vascular thrombotic events occurred at a median of 14 days (7-29) after vaccination. Of these 29 participants, 93.1% were women, median age 46 (37-55) years, and 51.7% had comorbidities. The observed to expected ratios for cerebral venous sinus thrombosis with thrombocytopenia and pulmonary embolism with thrombocytopenia were 10.6 (95% confidence interval 0.3 to 58.8) and 1.2 (0.1 to 6.5), respectively. Because of the small number of adverse events and wide confidence intervals, no conclusions were drawn between these estimates and the expected incidence rates in the population. CONCLUSIONS: Vaccine induced immune thrombocytopenia and thrombosis after one dose of the Ad26.COV2.S vaccine was found in only a few patients in this South African population of healthcare workers. These findings are reassuring if considered in terms of the beneficial effects of vaccination against covid-19 disease. These data support the continued use of this vaccine, but surveillance is recommended to identify other incidences of venous and arterial thromboembolism and to improve confidence in the data estimates. TRIAL REGISTRATION: ClinicalTrials.gov NCT04838795.

Delayed-type hypersensitivity reactions to Pfizer BioNTech SARS-CoV-2 vaccine.

Increased incidence of giant cell arteritis and associated stroke during the COVID-19 pandemic in Spain: A nation-wide population study. INTRODUCTION: SARS-CoV-2 infection and COVID-19 vaccines might have increased the incidence of giant-cell arteritis (GCA) and the risk of associated stroke in Spain. METHODS: Retrospective nation-wide observational analysis of all adults hospitalized with GCA in Spain during 5Â years (Jan-2016 and Dec-2021). The incidence and proportion of admissions with or because of GCA and GCA-associated stroke were compared between pre-pandemic (2016-2019) and pandemic (2020 and 2021) years. Sensitivity analyses were conducted for

the different COVID-19 waves and vaccine timing schedules. RESULTS: A total of 17,268 hospital admissions in patients diagnosed with GCA were identified. During 2020 there were 79.3 and 8.1 per 100,000 admissions of GCA and GCA-associated stroke, respectively. During 2021 these figures were 80.8 and 7.7 per 100,00 admissions, respectively. As comparison, yearly admissions due to GCA and GCA-associated stroke were 72.4 and 5.7 per 100,00, respectively, during the pre-pandemic period (pÂ <Â 0.05). Coincident with the third wave of COVID-19 (and first vaccine dosing), the rate of GCA-associated stroke admissions increased significantly (from 6.7 to 12%;Â pÂ <Â 0.001). Likewise, there was an increase in GCA-associated stroke (6.6% vs 4.1%, pÂ =Â 0.016) coincident with the third dose vaccination (booster) in patients older than 70 at the end of 2021. In multivariate analysis, only patients admitted during the third COVID-19 wave (and first vaccine dosing) (ORÂ =Â 1.89, 95% CI 1.22-2.93), and during the third vaccination dosing in patients older than 70 (booster) (ORÂ =Â 1.66, CI 1.11-2.49), presented a higher GCA-associated stroke risk than the same months of previous years after adjustment by age, sex, classical cardiovascular risk factors and COVID-19 diagnosis. CONCLUSIONS: The COVID-19 pandemic led to an increased incidence of GCA during 2020 and 2021. Moreover, the risk of associated stroke significantly risen accompanying times of COVID-19 vaccine dosing, hypothetically linked to an increased thrombotic risk of mRNA-SARS-CoV-2 vaccines. Hence, forthcoming vaccine policies and indications must weigh the risk of severe COVID-19 with the risk of flare or stroke in patients with GCA.

Dendrobium officinale aqueous extract influences the immune response following vaccination against SARS-CoV-2. BACKGROUND: Vaccination is the most effective way to prevent coronavirus disease 2019 (COVID-19). However, it is often less protective and does not significantly increase antibody levels, especially in individuals with impaired immune systems. Nevertheless, the immunocompetence can be enhanced using a natural immunomodulator, such as Dendrobium officinale aqueous extract (DoAE). METHODS: To determine whether DoAE promotes antibody production, we treated healthy volunteers with DoAE during COVID-19 vaccination. Meanwhile, the control volunteers were given a placebo (cornstarch) during the vaccination. Antibody levels were measured at three-week intervals in the DoAE and control groups. RESULTS: DoAE enhanced immunity and preserved immune cell homeostasis. However, the neutralizing antibody (nAb) levels in the DoAE group were lower than those in the control group. Analysis of the gut microbiota revealed that the abundance of anti-inflammatory flora was increased, while the pro-inflammatory flora was reduced in the DoAE group. CONCLUSION: DoAE has immunomodulatory and anti-inflammatory properties. Therefore, DoAE has the potential for COVID-19 prophylaxis, treatment, and recovery from the adverse effects of COVID-19. However, its anti-inflammatory activity affects the production of nAbs. Thus, DoAE may not be recommended for consumption during COVID-19 vaccination.

Myocarditis in Australian children following SARS-CoV-2 infection or COVID-19 vaccination: a retrospective case series.

SARS-CoV-2 pandemic as a model to assess the relationship between intercurrent viral infections and disease activity in Multiple Sclerosis: A propensity score matched case-control study. INTRODUCTION: An association between intercurrent viral respiratory infections and exacerbations of Multiple Sclerosis (MS) disease activity has been proposed by several studies. Considering the rapid spread of SARS-CoV2 worldwide and the systematic effort to immediately detect all incident cases with specific diagnostic tests, the pandemic can represent an interesting experimental model to assess the relationship between viral respiratory infections and MS disease activity. AIMS AND METHODS: In this study, we have performed a propensity score matched case-control study with a prospective clinical/MRI follow-up, on a cohort of relapsing-remitting MS (RRMS) patients who tested positive for SARS-CoV2 in the period 2020-2022, with the aim to evaluate if the SARS-CoV2 infection influences the short-term risk of disease activity. Controls (RRMS patients not exposed to SARS-CoV-

2, using 2019 as the reference period) were matched 1:1 with cases for age, EDSS, sex and disease-modifying treatment (DMT) (moderate efficacy vs high efficacy). Differences in relapses, MRI disease activity and confirmed disabilty worsening (CDW) between cases in the 6 months following the SARS-CoV-2 infection, and controls in a similar 6 months reference period in 2019 were compared. RESULTS: We identified 150 cases of SARS-CoV2 infection in the period March 2020 - March 2022, out of a total population of approximately 1500 MS patients, matched with 150 MS patients not exposed to SARS-CoV2 (controls). Mean age was 40.9Â Â±Â 12.0 years in cases and 42.0Â Â±Â 10.9 years in controls, mean EDSS was 2.54Â±1.36 in cases and 2.60Â±1.32 in controls. All patients were treated with a DMT, and a considerable proportion with a high efficacy DMT (65.3% in cases and 66% in controls), reflecting a typical real world RRMS population. 52.8% of patients in this cohort had been vaccinated with a mRNA Covid-19 vaccine. We did not observe a significant difference in relapses (4.0% cases, 5.3% controls; pÂ =Â 0.774), MRI disease activity (9.3% cases, 8.0% controls; pÂ =Â 0.838), CDW (5.3% cases, 6.7% controls; pÂ =Â 0.782) in the 6 months after SARS-CoV-2 infection between cases and controls. CONCLUSION: Using a propensity score matching design and including both clinical and MRI data, this study does not suggest an increased risk of MS disease activity following SARS-CoV-2 infection. All MS patients in this cohort were treated with a DMT, and a considerable number with a high efficacy DMT. These results therefore may not be applicable to untreated patients, for which the risk of increased MS disease activity after SARS-CoV-2 infection may not be excluded. A possible hypothesis explaining these results could be that SARS-CoV2 is less prone, compared to other viruses, to induce exacerbations of MS disease activity; another possible interpretation of these data might be that DMT is able to effectively suppress the increase of disease activity triggered by SARS-CoV2 infection.

Impact of SARS-CoV-2 vaccination and monoclonal antibodies on outcome post-CD19-directed CAR T-cell therapy: an EPICOVIDEHA survey. Patients with previous CD19-directed chimeric antigen receptor (CAR) T-cell therapy have a prolonged vulnerability to viral infections. Coronavirus disease 2019 (COVID-19) has a great impact and has previously been shown to cause high mortality in this population. Until now, real-world data on the impact of vaccination and treatment on patients with COVID-19 after CD19-directed CAR T-cell therapy are lacking. Therefore, this multicenter, retrospective study was conducted with data from the EPICOVIDEHA survey. Sixty-four patients were identified. The overall mortality caused by COVID-19 was 31%. Patients infected with the Omicron variant had a significantly lower risk of death due to COVID-19 compared with patients infected with previous variants (7% vs 58% [PÂ = .012]). Twenty-six patients were vaccinated at the time of the COVID-19 diagnosis. Two vaccinations showed a marked but unsignificant reduction in the risk of COVID-19-caused mortality (33.3% vs 14.2% [PÂ = .379]). In addition, the course of the disease appears milder with less frequent intensive care unit admissions (39% vs 14% [PÂ = .054]) and a shorter duration of hospitalization (7 vs 27.5Â days [PÂ = .022]). Of the available treatment options, only monoclonal antibodies seemed to be effective at reducing mortality from 32% to 0% (PÂ =Â .036). We conclude that survival rates of CAR T-cell recipients with COVID-19 improved over time and that the combination of prior vaccination and monoclonal antibody treatment significantly reduces their risk of death. This trial was registered at www.clinicaltrials.gov as #NCT04733729.

A systematic review and meta-analysis of the seroconversion rates and adverse effects of COVID-19 mRNA vaccine and COVID-19 viral vector vaccine in kidney transplant recipient patients. Patients received kidney transplantation (KTR) have a low seroconversion rate after vaccination. Our objective was to compare the seroconversion rates and adverse effects of additional different vaccinations in KTR patients in existing studies. Databases such as PubMed, Cochrane Library, Web of Science, Embase, ClinicalTrials.gov and others. Three high-quality RCT were included and showed no statistical difference in seroconversion rates between the two vaccines (RRâ€‰=â€‰0.93[0.76,1.13]). There

was no statistical difference in seroconversion rates between the sexes, for men (RRâ€‰=â€‰0.93[0.69,1.25]) and women (RRâ€‰=â€‰0.91[0.62,1.33]). Among the adverse effects there was no statistically significant difference in fever (RRâ€‰=â€‰1.06[0.44,2.57]), while for injection site pain there was a statistically significant difference (RRâ€‰=â€‰1.14[1.18,1.84]). There was no significant difference in seroconversion rates in patients with KTR who received the two additional vaccines. Patients injected with the viral vector vaccine were less painful than those injected with the mRNA vaccine.

Preserved T cell but attenuated antibody response in MS patients on fingolimod and ocrelizumab following 2nd and 3rd SARS-CoV-2 mRNA vaccine. BACKGROUND: There is limited knowledge about T cell responses in patients with multiple sclerosis (MS) after 3 doses of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine. OBJECTIVES: Assess the SARS-CoV-2 spike antibody and T cell responses in MS patients and healthy controls (HCs) after 2 doses (2-vax) and 3 doses (3-vax) of SARS-CoV-2 mRNA vaccination. METHODS: We studied seroconversion rates and T cell responses by flow cytometry in HC and MS patients on fingolimod or ocrelizumab. RESULTS: After 2-vax, 8/33 (24.2%) patients in ocrelizumab group, 5/7 (71.4%) in fingolimod group, and 29/29 (100%) in HC group (Pâ€‰=â€‰5.7â€‰Ã—â€‰10(-11)) seroconverted. After 3-vax, 9/22 (40.9%) patients in ocrelizumab group, 19/21 (90.5%) in fingolimod group, and 7/7 (100%) in HC group seroconverted (Pâ€‰=â€‰0.0003). The percentage of SARS-CoV-2 peptide reactive total CD4+ T cells increased in HC and ocrelizumab group but not in fingolimod group after 2-vax and 3-vax (Pâ€‰<â€‰0.0001). The percentage of IFNÎ³ and TNFÎ± producing total CD4+ and CD8+ T cells increased in fingolimod group as compared to HC and ocrelizumab group after 2-vax and 3-vax (Pâ€‰<â€‰0.0001). CONCLUSIONS: MS patients on ocrelizumab and fingolimod had attenuated humoral responses, but preserved cytokine producing T cell responses compared to HCs after SARS-CoV-2 mRNA vaccination. CLINICAL TRIALS REGISTRATION: NCT05060354.

Administration of the Second Dose of mRNA COVID-19 Vaccine to a Woman With Immediate Reaction to the First Dose. Vaccines constitute the most effectiveÂ public health intervention as theyÂ prevent the spread of infectious diseases and reduce disease severity and mortality. Allergic reactions can occur during vaccination. Systemic anaphylaxis is a severe, life-threatening allergic reaction which can rarely occur after vaccination. There is limited data suggesting that the majority of the patients with immediate and potentially allergic reactions after the first dose of coronavirus disease 2019 (COVID-19) can receive the second dose.Â A 39-year-old woman was admitted to our departmentÂ after presentingÂ anaphylactic reaction following the first dose of mRNA COVID-19 vaccine (BNT162b2).Â A few days later, she contacted our department and was admitted for an allergy work-up on mRNA COVID-19 vaccine and its compound polyethylene glycol (PEG). Thereafter, she completed the vaccination procedure having received pretreatment under our guidance. Confirmed allergic reactions to vaccines are customarily attributedÂ to the inactive ingredients, or excipients like PEG and polysorbate. The latest are used to improve water-solubility inÂ vaccines. PEG itself has not been previously used in a vaccine but polysorbate has been identified as a rare cause of allergic reactions to vaccines.Â It has been reported that the interaction of the immune system with lipidic nanoparticle therapeutics could result in hypersensitivity reactions (HSRs), referred to as complement activation related pseudoallergy (CARPA), which is classified as non-IgE-mediated pseudoallergy caused by the activation of the complement system.

Anaphylactic reactions after COVID-19 vaccination in Germany. . For the COVID-19 vaccines used in Germany, severe allergic (anaphylactic) reactions after vaccination have been reported in very rare cases. While Comirnaty and Spikevax are mRNA vaccines, Vaxzevria and Jcovden comprise vector vaccines, and Nuvaxovid a recombinant spike protein vaccine. The reporting rate of anaphylaxis after mRNA vaccination was higher in females receiving their first vaccination dose, with 0.97 and 1.12

reports per 100,000 vaccinations for Comirnaty and Spikevax, respectively, compared with vaccinated males and subsequent vaccinations. The Paul-Ehrlich-Institut (PEI) investigated 106 responses of 321 cases of confirmed anaphylactic reactions concerning subsequent allergy testing and revaccination with a COVID-19 vaccine. The collected data indicate that only a small proportion of cases (22%) were IgE-mediated reactions. A large proportion (73%) of patients could be revaccinated under precautionary measures without recurrence of anaphylaxis. The pathomechanism of the majority of anaphylactic reactions remains unclear and should be investigated in further studies.

Impact of the COVID-19 pandemic on a clinical trial of pneumococcal vaccine scheduling (PVS) in rural Gambia. The COVID-19 pandemic represents an unprecedented challenge for clinical research. The Pneumococcal Vaccine Schedules (PVS) study is a non-inferiority, interventional trial in which infants resident in 68 geographic clusters are randomised to two different schedules for pneumococcal vaccination. From September 2019 onwards, all infants resident in the study area became eligible for trial enrolment at all Expanded Programme on Immunisation (EPI) clinics in the study area. Surveillance for clinical endpoints is conducted at all 11 health facilities in the study area. PVS is conducted as a collaboration between the Medical Research Council Unit The Gambia (MRCG) at LSHTM and the Gambian Ministry of Health (MoH). The COVID-19 pandemic caused many disruptions to PVS. MRCG instructed interventional studies that participant enrolment be suspended on 26 March 2020, and a public health emergency was declared in The Gambia on 28 March 2020. Enrolment in PVS restarted on 1 July 2020 and was suspended again on 5 August 2020 after The Gambia experienced a sharp increase in COVID-19 cases in late July 2020 and restarted again on 1 September 2020. During periods of suspended enrolment of infants at EPI clinics, PVS continued safety surveillance at health facilities, albeit with disruptions. During the periods of suspended enrolment, infants who had been enrolled before 26 March 2020 continued to receive the PCV schedule to which they had been randomly allocated based on their village of residence, whereas all other infants received the standard PCV schedule. Throughout 2020 and 2021, the trial faced numerous technical and operational challenges: disruption to MoH delivery of EPI services and clinical care at health facilities; episodes of staff illness and isolation; disruption of MRCG transport, procurement, communications and human resource management; and also a range of ethical, regulatory, sponsorship, trial monitoring and financial challenges. In April 2021, a formal review concluded that the pandemic had not compromised the scientific validity of PVS and that the trial should continue as per protocol. The continuing challenges that COVID-19 poses to PVS, and other clinical trials will persist for some time.

Previous BCG vaccination is associated with less severe clinical progression of COVID-19. BACKGROUND: BCG vaccination, originally used to prevent tuberculosis, is known to "train" the immune system to improve defence against viral respiratory infections. We investigated whether a previous BCG vaccination is associated with less severe clinical progression of COVID-19 METHODS: A case-control study comparing the proportion with a BCG vaccine scar (indicating previous vaccination) in cases and controls presenting with COVID-19 to health units in Brazil. Cases were subjects with severe COVID-19 (O2 saturation < 90%, severe respiratory effort, severe pneumonia, severe acute respiratory syndrome, sepsis, and septic shock). Controls had COVID-19 not meeting the definition of "severe" above. Unconditional regression was used to estimate vaccine protection against clinical progression to severe disease, with strict control for age, comorbidity, sex, educational level, race/colour, and municipality. Internal matching and conditional regression were used for sensitivity analysis. RESULTS: BCG was associated with high protection against COVID-19 clinical progression, over 87% (95% CI 74-93%) in subjects aged 60 or less and 35% (95% CI -â€‰44-71%) in older subjects. CONCLUSIONS: This protection may be relevant for public health in settings where COVID-19 vaccine coverage is still low and may have implications for research to identify vaccine candidates for

COVID-19 that are broadly protective against mortality from future variants. Further research into the immunomodulatory effects of BCG may inform COVID-19 therapeutic research.

A comprehensive survey on the beliefs, perceptions, and clinical manifestations of pre and post Covid-19 vaccinations among physiotherapy students in the United Arab Emirates. The World Health Organization has defined Coronavirus Disease (COVID-19) as an infectious pandemic, caused by a newly discovered SARS-CoV-2 virus. Students relied heavily on the internet, social media, parents, and friends, in addition to medical advice for information on its presentation, complications, prevention, and management. It is evident from the literature that healthcare professionals including students who play an important role in the healthcare system may be lacking important information on COVID-19 vaccinations. Thus, the study aims to identify and compare the pre-post covid-19 vaccination-related essential information among Physical Therapy university students. A cross-sectional survey was conducted among physiotherapy university students in the United Arab Emirates using a self-administrated structured questionnaire. The questionnaire comprised three sections covering beliefs, perceptions, and clinical manifestations of the pre- and post-COVID- 19 vaccination. The survey was shared with more than 300 students through email and social platforms during the time between January 2022 till December 2022. Most of the physiotherapy students believed the vaccines to be safe (71.3%) due to multiple reasons while others did not believe in the effectiveness of the vaccine (28.7%). Some students did report unusual symptoms (painful periods, hair loss, forgetfulness) after the vaccine (10%). Similar findings were reported for family members as well (14%). Students had a positive perception of the vaccine and reported willingness to take it even if not mandatory (68%). Some students did believe in the safety of the vaccine due to multiple reasons while some did not due to fear of long-term side effects and personal choices. The finding of the study could be useful to create confidence as well as awareness among physiotherapy students as they are often invited to aid during medical pandemics such as Covid 19. Also, higher rates of vaccination among healthcare professionals will impart higher acceptance in the medical organization due to safety guidelines. This could also help to counsel other students against fear and apprehension towards the vaccination of such kind in the future.

No Red Flags for Risk of Retinal Vascular Occlusion After mRNA COVID-19 Vaccination.

Risk of New Retinal Vascular Occlusion After mRNA COVID-19 Vaccination Within Aggregated Electronic Health Record Data. IMPORTANCE: New-onset retinal vascular occlusion (RVO) occurring acutely after messenger RNA (mRNA) COVID-19 vaccination has been described in recent literature. Because RVO can cause vision loss or blindness, an epidemiologic investigation evaluating this potential association is of great importance to public health. OBJECTIVE: To investigate how often patients are diagnosed with new RVO acutely after the mRNA COVID-19 vaccine compared with influenza and tetanus, diphtheria, pertussis (Tdap) vaccines. DESIGN, SETTING, AND PARTICIPANTS: A retrospective population-based cohort design using the TriNetX Analytics platform, a federated, aggregated electronic health record (EHR) research network containing the deidentified EHR data of more than 103 million patients, was used to examine aggregate EHR data. Data were collected and analyzed on October 20, 2022. Data on patients within the TriNetX Analytics platform were searched for the presence of vaccination Common Procedural Technology codes, and instances of newly diagnosed RVO within 21 days of vaccination were recorded and reported. Propensity score matching based on demographic characteristics (age, sex, race and ethnicity) and comorbidities (diabetes, hypertension, and hyperlipidemia) was performed between vaccination groups for evaluation of relative risks (RRs). MAIN OUTCOMES AND MEASURES: The appearance of a new-encounter diagnosis of RVO within 21 days of the mRNA COVID-19 vaccination was the primary outcome. Historical comparison cohorts of patients receiving influenza and Tdap vaccinations allowed for evaluation of the RRs for RVO. RESULTS: Of 3â€¯108â€¯829 patients (mean [SD] age at vaccination, 50.7 [20.4]

years; 56.4% women) who received the mRNA COVID-19 vaccine, 104 (0.003%; 95% CI, 0.003%-0.004%) patients had a new diagnosis of RVO within 21 days of vaccination. After propensity score matching, the RR for new RVO diagnosis after the first dose of COVID-19 vaccination was not significantly different from that after influenza (RR, 0.74; 95% CI, 0.54-1.01) or Tdap (RR, 0.78; 95% CI, 0.44-1.38) vaccinations, but was greater when compared with the second dose of the COVID-19 vaccination (RR, 2.25; 95% CI, 1.33-3.81). CONCLUSIONS AND RELEVANCE: The findings of this study suggest that RVO diagnosed acutely after mRNA COVID-19 vaccination occurs extremely rarely at rates similar to those of 2 different historically used vaccinations, the influenza and Tdap vaccines. No evidence suggesting an association between the mRNA COVID-19 vaccination and newly diagnosed RVO was found.

Immunogenicity and safety of single booster dose of KD-414 inactivated COVID-19 vaccine in adults: An open-label, single-center, non-randomized, controlled study in Japan. Although vaccines for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) disease 2019 (COVID-19) induce effective immune responses, vaccination with booster doses is necessary because of waning immunity. We conducted an open-label, non-randomized, single-arm study in adults in Japan to assess the immunogenicity and safety of a single booster dose of the KD-414 purified whole-SARS-CoV-2-virion inactivated vaccine candidate after vaccination with a primary series of BNT162b2. The primary endpoint was serum neutralizing activity at 7â€‰days after booster injection compared with the primary series of BNT162b2. The SARS-CoV-2-structural protein-binding antibody level and T cell response against SARS-CoV-2-Spike (S) peptides were also examined as secondary endpoints, and safety profile assessments were conducted. Twenty subjects who participated in a previous study declined an injection of KD-414 (non-KD-414 group) and received a booster dose of BNT162b2 instead. The non-KD-414 group was compared to the KD-414 group as a secondary outcome. A single dose of KD-414 induced lower serum neutralizing activity against the wild-type virus within 7â€‰days compared to after the primary series of BNT162b2 but significantly induced anti-SARS-CoV-2-S1-receptor-binding domain-binding immunoglobulin G (IgG) antibodies and SARS-CoV-2-S peptide-specific CD4(+) and CD8(+) T cell responses. Local or systemic symptoms were significantly lower in the participants who received KD-414 than in those who received BNT162b2 as the third COVID-19 vaccine dose. The present data indicate that a single booster dose of KD-414 induces a substantial immune response in BNT162b2-primed individuals and has a good safety profile, thereby supporting further clinical trials to identify rational targets.

Inactivated COVID-19 vaccine-related herpes zoster and post-herpetic neuralgia: Three case reports. Vaccination programs against COVID-19 have been implemented all over the world since December 2020. Beside the common side effects of vaccines, there are also increasing reports of herpes zoster (HZ) activation. In this report, we describe three cases of HZ, one of them with post-herpetic neuralgia (PHN) after receiving inactivated COVID-19 vaccine. The first two patients developed HZ 8 and 10 days after vaccination, respectively. When pain could not be controlled with paracetamol and non-steroidal anti-inflammatories, the patients received weak opioid codeine. In addition, the first patient received gabapentin, and the second patient was applied erector spinae plane block. The third patient was admitted 4 months after the diagnosis of HZ and considered to have PHN and pain palliation was provided with tramadol. Although the exact cause has not yet been fully resolved, increased reports of HZ after vaccination suggests a link between vaccines and HZ. Considering that receiving COVID-19 vaccines will going on, HZ and PHN cases will continue to be seen. More epidemiological studies are needed to further evaluate the relationship between COVID-19 vaccines and HZ.

Low Peripheral B-Cell Counts in Patients With Systemic Rheumatic Diseases Due to Treatment With Belimumab and/or Rituximab Are Associated With Low Antibody Responses to Primary COVID-19

Vaccination. Background: Immunosuppressive agents inhibit COVID-19 vaccine antibody (Ab) responses in patients with systemic rheumatic diseases. Rituximab may fully block Ab responses when B cells become undetected. The effect of detected but low number of B cells due to treatment with a B-cell agent (belimumab and/or rituximab) has not been established. Purpose: We sought to examine whether there is an association between a low number of B cells due to treatment with belimumab and/or rituximab and impaired primary COVID-19 vaccination spike Ab responses in patients with systemic rheumatic diseases. Methods: We retrospectively examined Ab responses to COVID-19 vaccinations, especially in relation to B-cell counts after treatment with belimumab and/or rituximab, in 58 patients with systemic rheumatic diseases: 22 on and 36 not on B-cell agents. We used Kruskal-Wallis and Mann-Whitney U tests for comparison of Ab values between the groups and Fisher exact test for relative risk calculations. Results: Median (interquartile range) postvaccination Ab responses were lower in patients on versus those not on B-cell agents: 3.91 (0.77-20.00) versus 20.00 (14.32-20.00), respectively. Among patients on belimumab and/or rituximab, Ab responses of less than 25% of the assay's upper limit were exclusively observed in those with B-cell counts lower than 40/ÂµL. Patients with B-cell counts lower than 40/ÂµL exhibit a relative risk of 6.092 (95% CI: 2.75-14.24) for Ab responses of less than 25% of the upper limit compared with patients not on B-cell agents. This relative risk remained significant, even after excluding patients with undetected B cells. Conclusion: This retrospective study found an association between low B-cell counts (less than 40/ÂµL) and decreased Ab responses to primary COVID-19 vaccination in patients with systemic rheumatic diseases treated with belimumab and/or rituximab. Despite the small number of patients studied, these findings add to the accumulating evidence on the importance of B-cell count in predicting spike Ab responses to COVID-19 vaccination.

A Case of Transverse Myelitis After Moderna Severe Acute Respiratory Syndrome Coronavirus Vaccination. Transverse myelitis (TM) is an inflammatory syndrome of the spinal cord that presents with acute-to-subacute neurological deficits. The differential for TM is broad and includes demyelinating, infectious, neoplastic and paraneoplastic, autoimmune, and metabolic/toxic etiologies. With the novel severe acute respiratory syndrome coronavirus pandemic, more commonly referred to as the coronavirus infectious disease of 2019 (COVID-19), there have been increasing reports of neurological complications. In this case report, we describe a novel case of longitudinally-extensive TM associated with the Moderna vaccination.

Epidemiological pattern of COVID-19 and its association with periodontal health in an urban Indian cohort. BACKGROUND: Studies have highlighted a possible influence of gingival and periodontal disease (PD) on COVID-19 risk and severity. However, the evidence is based on hospital-based studies and community-level data are sparse. OBJECTIVES: We described the epidemiological pattern of SARS-CoV-2 infection in Delhi and evaluated the associations of gingival and PD with incident COVID-19 disease in a regionally representative urban Indian population. METHODS: In a prospective study nested within the Centre for Cardiometabolic Risk Reduction in South-Asia (CARRS) study, participants with clinical gingival and periodontal status available at baseline (2014-16) (nâ€‰=â€‰1,727) were approached between October 2021 to March 2022. Information on COVID-19 incidence, testing, management, severity was collected as per the WHO case criteria along with COVID-19 vaccination status. Absolute incidence of COVID-19 disease was computed by age, sex, and oral health. Differences in rates were tested using log-rank test. Poisson regression models were used to evaluate independent associations between gingival and PD and incidence of COVID-19, adjusted for socio-demographic and behavioral factors, presence of comorbidity, and medication use. RESULTS: Among 1,727 participants, the mean age was 44.0â€‰years, 45.7% were men, 84.5% participants had baseline gingival or PD and 89.4% participants had received at least one dose of COVID-19 vaccine. Overall, 35% (nâ€‰=â€‰606) participants were tested for COVID-19 and 24%

(nâ€‰=â€‰146/606) tested positive. As per the WHO criteria total number of cases was 210, constituting 12% of the total population. The age and sex-specific rates of COVID-19 were higher among men and older participants, but women aged >60â€‰years had higher rates than men of same age. The incidence rate did not differ significantly between those having gingival or PD and healthy periodontium (19.1 vs. 16.5/1,000 person-years) and there was no difference in risk of COVID-19 by baseline oral disease status. CONCLUSION: Gingival and PD were not associated with increased risk of COVID-19.

Cutaneous Sarcoidosis-like Eruption Following Second Dose of Moderna mRNA-1273 Vaccine: Case or Relationship? Various adverse reactions to SARS-CoV-2 vaccines have been described since the first months of the vaccination campaign. In addition to more frequent reactions, rare reactions, such as sarcoidosis-like, rashes have been reported. We present a case of a 23-year-old woman with a rash on the chin and peribuccal region, which developed approximately 3 weeks after the administration of the second dose of the Moderna mRNA-1273 vaccine. We briefly discuss other reports in the literature.

Influence of immunosuppressive therapy on longitudinal changes in anti-SARS-CoV-2 spike protein antibodies after two doses of mRNA vaccines in patients with rheumatic diseases.

Safety of COVID-19 vaccines.

Multiple Evanescent White Dot Syndrome Following Adenovirus Vector-Based COVID-19 Vaccine (Covishield). PURPOSE: To report a case of multiple evanescent white dot syndrome (MEWDS) following adenovirus vector-based Coronavirus disease 2019 (COVID-19) vaccine, Covishield and to present a summary of previously reported cases of MEWDS following COVID-19 vaccines. METHODS: Retrospective case report and review of literature. RESULTS: A 22-year-old Indian female presented with blurred vision, scotomata, and photopsias in her left eye, a day after administration of second dose of Covishield vaccine. Her clinical findings and imaging features confirmed the diagnosis of MEWDS. Her symptoms resolved spontaneously after 2â€‰weeks. CONCLUSION: This is the first reported case of MEWDS following an adenovirus vector-based COVID-19 vaccine. Comparison with previously reported cases of MEWDS following COVID-19 vaccination showed that patients are generally healthy, young to middle-aged women, who develop symptoms after a median time of one week and recover spontaneously over a median period of 4â€‰weeks.

Side Effects of COVID-19 Vaccines Among Diabetic Subjects and Healthy Individuals. Objectives Vaccinations protect against disease through various ways, but the process of developing immunity might result in side effects. This study determined the immediate side effects of coronavirus disease 2019 (COVID-19) vaccination among patients with diabetes and non-diabetic participants. Methods This multi-center, cross-sectional study was conducted in multiple hospitals in Karachi, Pakistan. The duration of the study was six months, from March 1, 2022, to August 31, 2022. A total of 1150 participants who received one of the COVID-19 vaccines, for instance, Sinopharm, AstraZeneca, Sinovac, and Pfizer (double or booster doses) were included in the study and allocated into two groups: diabetics (n=540) and non-diabetics (n=610). The chi-square test was used to compare the frequency of side effects between diabetic and non-diabetic participants. The association between means of demographic variables such as age and weight was compared using an independent t-test. Results The study findings showed that the mean age of the group with diabetes was 46.73Â±14.98 years and that of the non-diabetic group was 44.01Â±14.80 years with a significant difference between them (p=0.002). The majority of participants, 187 (34.6%) patients with diabetes received Pfizer, while 234 (38.4%) non-diabetic participants received Sinovac. Following the first dose, side effects were higher in patients with diabetes. Burning at the injection site, fever, and pain were the most commonly reported side effects in patients with diabetes following the first dose. Additionally, following the second dose, burning at the injection site, muscular pain, fever, and pain were the most

commonly observed side effects, with a significant association among diabetic and non-diabetic participants ($p<0.001$). Conclusion Diabetes is a prevalent comorbidity in individuals infected with COVID-19, and patients with diabetes report more side effects from immunization than non-diabetic participants. The most commonly reported side effectsÂ of the vaccine in diabetic participants were observed to be burning at the injection site, fever, muscle and joint pain, and swelling at the injection site. Additionally, participants with and without diabetes reported feeling satisfied with their vaccines.

Sneddon-Wilkinson disease following COVID-19 vaccination. Sneddon-Wilkinson disease, also known as subcorneal pustular dermatosis (SPD), is a rare disease characterized by vesicles or pustules that may rapidly expand and coalesce. Idiopathic in nature, SPD's clinical presentation of "half-half" blisters, with half of each blister containing pus and half containing clear fluid, is characteristic of this disease. We describe a previously healthy 21-year-old man who developed acute pustular vesicular eruptions consistent with SPD eight days following the Moderna COVID-19 vaccination.

Intra-articular haemorrhage caused by reduced recovery of PEGylated recombinant factor VIII due to an anti-PEG antibody developed after mRNA-1273 SARS-CoV-2 vaccination in haemophilia A.

Real-World Monitoring of COVID-19 Vaccines: An Industry Expert View on the Successes, Challenges, and Future Opportunities. Pharmacovigilance leaders from major vaccine developers describe the learnings from the coronavirus disease 2019 (COVID-19) pandemic in the area of pharmacovigilance and pharmacoepidemiology. The authors aim to raise awareness of the co-operation among vaccine developers, highlight common challenges, advocate for solutions, and propose recommendations for the future in the areas of real-world safety and effectiveness, safety reporting and evaluation, and regulatory submissions. To enable timely evaluation of real-world safety and effectiveness, multi-sponsor study platforms were implemented, resulting in quicker recruitment over wide geographical areas. Future gains could be derived by developing geographically flexible, common protocols and/or joint company-sponsored studies for multiple vaccines and a collective strategy to build low/middle-income country (LMIC) sentinel sites. Safety reporting, signal detection and evaluation was particularly challenging given the unprecedented number of adverse events reported. New methods were required to manage increased report volume while maintaining the ability to quickly identify and respond to new data that could impact the benefit-risk profile of each vaccine. Worldwide health authority submissions, requests for information and differing regulatory requirements imposed significant burden on regulators and industry. Industry consensus on the safety reporting requirements and joint meetings with regulatory authorities markedly reduced this burden for all stakeholders. The most impactful innovations should be undertaken rapidly and expanded to other vaccines and therapeutics, with a multi-stakeholder approach. The authors of this paper make future recommendations and have launched an initiative named BeCOME (Beyond COVID Monitoring Excellence) with a focus on actions in each of the highlighted areas.

Diagnosis and Treatment of Cerebral Venous Thrombosis. OBJECTIVE: Cerebral venous thrombosis (CVT), thrombosis of the dural sinus, cerebral veins, or both, is a rare cerebrovascular disease. Although mortality rates after CVT have declined over time, this condition can result in devastating neurologic outcomes. This article reviews the latest literature regarding CVT epidemiology, details new factors associated with the development of CVT, and describes advances in CVT treatment. It also contains a discussion of future directions in the field, including novel diagnostic imaging modalities, and potential strategies to reduce the risks associated with CVT. LATEST DEVELOPMENTS: The incidence of CVT may be as high as 2 per 100,000 adults per year. It remains a difficult condition to diagnose given its variable clinical manifestations and the necessity of neuroimaging for confirmation. The COVID-19 pandemic has revealed a novel CVT trigger, vaccine-

induced immune thrombotic thrombocytopenia (VITT), as well as an association between COVID-19 infection and CVT. Although VITT is a very rare event, timely diagnosis and treatment of CVT due to VITT likely improves patient outcomes. Direct oral anticoagulants are currently being used to treat CVT and emerging data suggest that these agents are as safe and effective as vitamin K antagonists. The role of endovascular therapy to treat CVT, despite a recent clinical trial, remains unproven. ESSENTIAL POINTS: The incidence of CVT has increased, outcomes have improved, and the use of direct oral anticoagulants to treat CVT represents an important advance in the clinical care of these patients. Rates of CVT as a complication of COVID-19 vaccines using adenoviral vectors are very low (<5 per million vaccine doses administered), with the benefits of COVID-19 vaccination far outweighing the risks.

Guillain-Barre syndrome after the first dose of Anti-SARS-CoV-2 vaccination is a rare side effect and the second jab is controversial in these cases.

Mid-term follow-up after COVID-19 vaccination in adults with CHD: a prospective study. BACKGROUND: Long-term data on COVID-19 vaccine safety, immunogenicity, and acceptance in adults with CHD are lacking. METHODS: This is a prospective study including adults with CHD patients undergoing COVID-19 vaccination from January 2021 to June 2022. Data on adverse events, antispike IgG titre, previous or subsequent COVID-19 infection, booster doses, and patients' attitude towards vaccination were collected. RESULTS: Four hundred and ninety CHD patients (36 Â± 13 years, 53% male, 94% with moderate/complex defects) were prospectively included: 433 (88%) received a Pfizer-BioNTech mRNA vaccine, 31 (6%) Moderna mRNA vaccine, 23 (5%) AstraZeneca-Oxford ChAdOx1 nCov-19 vaccine, and 3 (0.6%) Janssen Vaccine; 310 (63%) received a booster dose. Median follow-up after vaccination was 1.53 [1.41-1.58] years. No major adverse event was reported. Eighty-two fully vaccinated patients contracted COVID-19 during follow-up after a median of 5.4 [4.3-6.5] months from the last dose. One patient with Ebstein's disease died from severe COVID-19. Symptoms' duration in patients who tested positive after vaccination was significantly shorter than in the group tested positive before vaccination (5.5 [3-8] versus 9 [2.2-15] days, p = 0.04). Median antispike IgG titre measured in 280 individuals (57%) at a median of 1.4 [0.7-3.3] months from the last dose was 2381 [901-8307] BAU/ml. Sixty patients (12%) also showed positive antinucleocapsid antibodies, demonstrating previous SARS-COV2 exposure. Twenty-nine percent appeared to have concerns regarding vaccine safety and 42% reported fearing potential effects of the vaccine on their cardiac disease before discussing with their CHD cardiologist. CONCLUSION: COVID-19 vaccines appear safe in the mid-term follow-up in adults with CHD with satisfactory immunogenicity and reduction of symptoms' duration in case of infection.

Immunological Facet and Inception after Post-COVID-19 Vaccination. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) induced coronavirus disease 2019 (COVID-19) pandemic has produced an unparalleled setback for the world's economy and health. One of the best therapies to significantly lower severe illness and mortality from SARS-CoV-2 infection is vaccination. Worldwide vaccination campaigns are being implemented. New-onset autoimmune problems, such as immune thrombotic thrombocytopenia, autoimmune liver disorders, IgA nephropathy, Guillain-BarrÃ© syndrome, systemic lupus erythematosus, and rheumatoid arthritis, have recently been described more frequently after receiving COVID-19 vaccine. The creation of specific autoantibodies, molecular mimicry, and the function of specific vaccine adjuvants all emerge to play a significant role in autoimmunity. The post-acute sequelae of SARS-CoV-2, usually known as Long Covid Syndrome, are beginning to be better understood in terms of the disparities in immune responses seen in individuals with and without the condition. We anticipate that the knowledge gleaned from several COVID-19 investigations will be put to use in research on the inflammatory mechanisms implicated in serious and protracted illnesses, which is still a key unmet need.

Anti-S1/RBD-Specific Antibody Formation After SARS-CoV-2 Vaccination in Elderly Rheumatoid Arthritis Patients: Single-Center Prospective Observational Study. BACKGROUND: The guidelines of coronavirus disease 2019 (COVID-19) vaccination in patients with rheumatoid arthritis (RA) have been continuously updated, with extensive discussion on the effectiveness of the COVID-19 booster vaccines and antibody generation associated with the different types of vaccine. We investigated the effects of the third dose of the mRNA vaccine on antibody titer and the factors associated with antibody production in patients with RA who had previously received two doses of the ChAdOx1-S nCoV-19 vaccine. METHODS: Between October 14, 2021 and June 17, 2022, two patient groups diagnosed with RA were recruited prospectively: one with two doses of ChAdOx1-S nCoV-19 and the second group with the additional third mRNA vaccine. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody titers were determined through semiquantitative anti-SARS-CoV-2 spike (S) electrochemiluminescence immunoassay. Antibody titers were compared in both groups considering clinical features and medications. Multivariate logistic regression was performed to identify the factors associated with antibody production. Also, we followed up the antibody titers of whom completed the 3rd mRNA vaccination. RESULTS: Among 261 patients, all patients were over 60 years old except for 7 patients and the average age was 65 years; 153 had completed two doses of ChAdOx1-S nCoV-19, while 108 patients had also received the third mRNA vaccine. The positive rates of anti-SARS-CoV-2 anti-S1/receptor binding domain-specific antibody (titer > 0.8 U/mL) were 97% (149/153) and 99% (107/108) respectively. However, positive rates for high antibody titer (> 250 U/mL) were found in only 31% (47/153) of group 1 but 94% (102/108) of group 2. Multivariate analysis revealed that corticosteroid use (odds ratio [OR], 0.35; 95% confidence interval [CI], 0.16-0.75), older age (OR, 0.91; 95% CI, 0.860-0.98), and male sex (OR, 0.23; 95% CI, 0.07-0.74) were associated with a lower rate of high antibody titer acquisition after two doses of ChAdOx1-S nCoV-19. Waning of antibody titers was observed in only two of 46 patients who followed up twice after the third mRNA vaccine inoculation. CONCLUSION: Our findings suggest that the third dose of the mRNA vaccine could be beneficial in RA patients with risk factors including older age, male sex, and corticosteroid use after two doses of ChAdOx1-S nCoV-19.

COVID-19 Vaccine-Associated Pneumonitis in the Republic of Korea: A Nationwide Multicenter Survey. BACKGROUND: Recent reports have suggested that pneumonitis is a rare complication following vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, its clinical features and outcomes are not well known. The aim of this study was to identify the clinical characteristics and outcomes of patients with vaccine-associated pneumonitis following vaccination against SARS-CoV-2. METHODS: In this nationwide multicenter survey study, questionnaires were distributed to pulmonary physicians in referral hospitals. They were asked to report cases of development or exacerbation of interstitial lung disease (ILD) associated with the coronavirus disease 2019 vaccine. Vaccine-associated pneumonitis was defined as new pulmonary infiltrates documented on chest computed tomography within 4 weeks of vaccination and exclusion of other possible etiologies. RESULTS: From the survey, 49 cases of vaccine-associated pneumonitis were identified between February 27 and October 30, 2021. After multidisciplinary discussion, 46 cases were analyzed. The median age was 66 years and 28 (61%) were male. The median interval between vaccination and respiratory symptoms was 5 days. There were 20 (43%), 17 (37%), and nine (19%) patients with newly identified pneumonitis, exacerbation of pre-diagnosed ILD, and undetermined pre-existing ILD, respectively. The administered vaccines were BNT162b2 and ChAdOx1 nCov-19/AZD1222 each in 21 patients followed by mRNA-1273 in three, and Ad26.COV2.S in one patient. Except for five patients with mild disease, 41 (89%) patients were treated with corticosteroid. Significant improvement was observed in 26 (57%) patients including four patients who did not receive treatment. However, ILD aggravated in 9 (20%) patients despite treatment.

Mortality was observed in eight (17%) patients. CONCLUSION: These results suggest pneumonitis as a potentially significant safety concern for vaccines against SARS-CoV-2. Clinical awareness and patient education are necessary for early recognition and prompt management. Additional research is warranted to identify the epidemiology and characterize the pathophysiology of vaccine-associated pneumonitis.

Inflammatory Arthritis Associated with COVID-19 Vaccination. COVID-19 vaccines have been shown to be highly efficacious in preventing symptomatic COVID-19 infections throughout the pandemic. There have been emerging cases of inflammatory arthritis occurring in close relation to COVID-19 vaccination. We illustrate a case of new-onset inflammatory arthritis 10 days after receiving their second Vaxzevria COVID-19 vaccine. The patient responded dramatically to prednisolone treatment but subsequently required hydroxychloroquine due to persistent inflammatory joint symptoms. Inflammatory arthritis is an increasingly recognized rare adverse effect of COVID-19 vaccination and clinicians should actively consider this in patients with new or flares of inflammatory joint disease.

Differential T-cell and antibody responses induced by mRNA versus adenoviral vectored COVID-19 vaccines in patients with immunodeficiencies. BACKGROUND: Immunodeficient patients (IDPs) are at higher risk of contracting severe coronavirus disease 2019 (COVID-19). Targeted vaccination strategies have been implemented to enhance vaccine-induced protection. In this population, however, clinical effectiveness is variable and the duration of protection unknown. OBJECTIVE: We sought to better understand the cellular and humoral immune responses to mRNA and adenoviral vectored COVID-19 vaccines in patients with immunodeficiency. METHODS: Immune responses to severe acute respiratory syndrome coronavirus 2 spike were assessed after 2 doses of homologous ChAdOx1-nCoV-19 or BNT162b2 vaccines in 112 infection-naive IDPs and 131 healthy health care workers as controls. Predictors of vaccine responsiveness were investigated. RESULTS: Immune responses to vaccination were low, and virus neutralization by antibody was not detected despite high titer binding responses in many IDPs. In those exhibiting response, the frequency of specific T-cell responses in IDPs was similar to controls, while antibody responses were lower. Sustained vaccine specific differences were identified: T-cell responses were greater in ChAdOx1-nCoV-19- compared to BNT162b2-immunized IDPs, and antibody binding and neutralization were greater in all cohorts immunized with BNT162b2. The positive correlation between T-cell and antibody responses was weak and increased with subsequent vaccination. CONCLUSION: Immunodeficient patients have impaired immune responses to mRNA and viral vector COVID-19 vaccines that appear to be influenced by vaccine formulation. Understanding the relative roles of T-cell- and antibody-mediated protection as well as the potential of heterologous prime and boost immunization protocols is needed to optimize the vaccination approach in these high-risk groups.

Glucocorticoids selectively affect the memory T cell response to SARS-Cov2 spike in vaccinated and post-infected patients with systemic lupus erythematosus. Immune response to vaccines and pathogens remains unclear in patients with systemic lupus erythematosus (SLE). To investigate this, a single-center retrospective study was conducted with 47 SLE patients vaccinated against COVID-19, including 13 who subsequently developed an asymptomatic/mild disease. As compared to controls, post-vaccine response against Spike was reduced in SLE patients when considering both memory T-cells in a whole blood interferon gamma release assay (IGRA-S) and IgG anti-Spike antibody (Ab) responses. The SLE-associated defective IGRA-S response was associated with a serum albumin level below 40Â g/L and with the use of glucocorticoids, while a defective IgG anti-Spike Ab response was associated with lower levels of anti-dsDNA and anti-SSA/Ro 52Â kDa Abs. IGRA-S and IgG anti-Spike responses were independent from SLE activity and clinical phenotype, low complement, hypergammaglobulinemia, and lymphopenia. As compared to controls, SLE patients showed a rapid

decay of anti-Spike T-cell memory and stable IgG anti-Spike Ab responses. In conclusion, both T cell and humoral anti-Spike responses were independently affected in our SLE patients cohort, which supports the exploration of both responses in the follow-up of SLE patients and especially in those receiving glucocorticoids.

Omicron BA.1 breakthrough infections in inactivated COVID-19 vaccine recipients induced distinct pattern of antibody and T cell responses to different Omicron sublineages. The adaptive immunity against SARS-CoV-2 prototype strain and Omicron sublineages induced by BA.1 breakthrough infection in vaccinees of inactivated COVID-19 vaccines have not been well characterized. Here, we report that BA.1 breakthrough infection induced mucosal sIgA and resulted in higher IgG titers against prototype strain and Omicron sublineages in vaccinees than in vaccine naÃ¯ve-infected individuals. BA.1 breakthrough infection boosted antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis to prototype strain and BA.1, BA.1.1, BA.2, BA.2.12.1, and BA.2.75 but not BA.4/5 and induced neutralization against prototype strain and BA.1, BA.1.1, BA.2, BA.2.12.1, BA.2.75, and BA.4/5 but not BF.7, BQ.1, and XBB. In total, BA.1 breakthrough infection individuals produced less extensive sIgA, plasma IgG and NAb responses against Omicron sublineages compared with those against prototype strain. Further, BA.1 breakthrough infection induced recall B cell response to prototype strain and Omicron variant, primarily targeting memory B cells producing conserved epitopes. Memory T cell responses against Omicron is largely preserved. Individuals with vaccine booster did not induce more beneficial immune responses to Omicron sublineages upon BA.1 breakthrough infection than those with primary vaccine dose only. The breakthrough infection individuals produced stronger adaptive immunity than those of inactivated vaccine-healthy individuals. These data have important implications for understanding the vaccine effectiveness and adaptive immunity to breakthrough infection in individuals fully immunized with inactivated vaccines. Omicron sublineages, especially for those emerged after BA.4/5 strain, evade NAb responses induced by BA.1 breakthrough infection. It is urgent to optimize the vaccine immunogen design and formulations to SARS-CoV-2 variants.

Comparison of Axillary Lymph Nodes on Breast MRI Before and After COVID-19 Booster Vaccination. RATIONALE AND OBJECTIVES: Vaccine-related lymphadenopathy is a frequent finding following initial coronavirus disease 2019 (COVID-19) vaccination, but the frequency after COVID-19 booster vaccination is still unknown. In this study we compare axillary lymph node morphology on breast MRI before and after COVID-19 booster vaccination. MATERIALS AND METHODS: This retrospective, single-center, IRB-approved study included patients who underwent breast MRI between October 2021 and December 2021 after the COVID-19 booster vaccination. The axillary lymph node with the greatest cortical thickness ipsilateral to the side of vaccination was measured on MRI after booster vaccination and before initial COVID-19 vaccination. Comparisons were made between patients with and without increase in cortical thickness of â‰¥ 0.2 cm. Continuous covariates were compared using Wilcoxon rank-sum test and categorical covariates were compared using Fisher's exact test. Multiple comparison adjustment was made using the Benjamini-Hochberg procedure. RESULTS: All 128 patients were included. Twenty-four of 128 (19%) displayed an increase in lymph node cortical thickness of â‰¥ 0.2 cm. Patients who received the booster more recently were more likely to present cortical thickening, with a median of 9 days (IQR 5, 20) vs. 36 days (IQR 18, 59) ($p < 0.001$). Age (pÂ =Â 0.5) and type of vaccine (pÂ =Â 0.7) were not associated with thickening. No ipsilateral breast cancer or malignant lymphadenopathy were diagnosed on follow-up. CONCLUSION: Axillary lymphadenopathy on breast MRI following COVID-19 booster vaccination is a frequent finding, especially in the first 3 weeks after vaccination. Additional evaluation or follow-up may be omitted in patients with low concern for malignancy.

Evaluation of mortality risk after COVID-19 vaccination, Utah 2021. INTRODUCTION: In order to evaluate trends in death after COVID-19 vaccination we analyzed the timing of death relative to vaccination date and the causes of death in vaccinated Utahns in 2021. METHODS: We matched people in the Utah immunization registry with documented COVID-19 vaccinations between December 18, 2020 and December 31, 2021 to Utah's 2021 vital statistics death records. Vaccinated people were categorized as having one, two, orÂ â‰¥Â three COVID-19 vaccine doses in a time-updated metric. We examined crude mortality rates by dosing groups in two-week intervals for all deaths, and by COVID-19 versus non-COVID-19 causes, within the 44Â weeks following receipt of the most recent vaccine. RESULTS: We identified 2,072,908 individuals who received at least one dose of COVID-19 vaccine of whom 10,997 died in 2021. Only 17.5Â % of the total vaccinated population was age 65+, while 80.9Â % of those who died were over 65. In the four weeks following the first or second vaccination, all-cause mortality was low and then stabilized for the remainder of the evaluation period at a bi-weekly average of 33.0 and 39.0 deaths/100,000 people for one and two doses, respectively. Typical seasonal variation in death was observed among those with two doses. Small sample size precluded analysis of those withÂ â‰¥Â three doses, but trends were similar. CONCLUSIONS: Mortality rates in the 44Â weeks following the COVID-19 vaccination did not show trends suggesting an increase in mortality related to COVID-19 vaccination, reinforcing the safety of COVID-19 vaccines. This represents an accessible approach for local evaluation.

Safety and immunogenicity of heterologous ChAdOx1-nCoV19 and BNT162b2 vaccination: A meta-analysis of the heterologous COVID-19 vaccination outcomes. INTRODUCTION: Here, we systematically assessed the safety and immunogenicity of the heterologous ChAd/BNT vaccination regimens. MATERIALS AND METHODS: We evaluated the immunogenicity by the geometric mean titers ratio (GMTR) of the neutralizing antibody and anti-spike IgG. The safety of heterologous ChAd/BNT vaccination was evaluated using the pooled risk ratios (RRs) calculated by the random-effects model about the adverse events. Our study was registered with PROSPERO, CRD42021265165. RESULTS: Eleven studies were included in the analyses. Compared to the homologous ChAd/ChAd vaccination, the heterologous ChAd/BNT vaccination showed significantly higher immunogenicity in terms of the neutralizing antibody and GMTR of anti-spike IgG, but at the same time displayed higher incidence of total adverse reactions, especially for the local adverse reactions. Moreover, heterologous ChAd/BNT vaccination showed similar immunogenicity to the homologous BNT/BNT vaccination (GMTR of neutralizing antibody and anti-spike IgG) and similar safety. DISCUSSION: Heterologous ChAd/BNT vaccination showed robust immunogenicity and tolerable safety.

Development of a COVID-19 vaccine effectiveness and safety assessment system in Japan: The VENUS study. BACKGROUND: There are currently no COVID-19 vaccine assessment systems in Japan that allow for the active surveillance of both vaccinated and unvaccinated persons. Herein, we describe the development of Japan's first COVID-19 vaccine effectiveness and safety assessment system with active surveillance capabilities. METHODS: The Vaccine Effectiveness, Networking, and Universal Safety (VENUS) Study was developed as a multi-source database that links four data types at the individual resident level: Basic Resident Register (base population information), Vaccination Record System (vaccination-related information), Health Center Real-time Information-sharing System on COVID-19 (HER-SYS; information on COVID-19 occurrence), and health care claims data (information on diagnoses, hospitalizations, diagnostic tests, and treatments). These data were obtained from four municipalities. Individual residents were linked across the data types using five matching algorithms based on names, birth dates, and sex; the data were anonymized after linkage. To ascertain the viability of the VENUS Study's database for COVID-19 vaccine assessments, we examined the trends in COVID-19 vaccinations, COVID-19 cases, and polymerase chain reaction (PCR) test numbers. We also evaluated the linkage rates across the data types. RESULTS: Our multi-source database was able to

monitor COVID-19 vaccinations, COVID-19 cases, and PCR test numbers throughout the pandemic. Using the five algorithms, the data linkage rates between the COVID-19 occurrence information in the HER-SYS and the Basic Resident Register ranged from 85Â·4% to 91Â·7%. CONCLUSION: If used judiciously with an understanding of each data source's characteristics, the VENUS Study can provide a viable data platform that facilitates active surveillance and comparative analyses for population-based research on COVID-19 vaccine effectiveness and safety in Japan.
Acute myocarditis after administration of BNT162b2 vaccine against COVID-19.
Historical Perspectives on the Neurologic Manifestations of Viral Pandemics. Neurologic symptoms have been reported in over 30% of hospitalized patients with coronavirus disease 2019 (COVID-19), but the pathogenesis of these symptoms remains under investigation. Here, we place the neurologic complications of COVID-19 within the context of three historical viral pandemics that have been associated with neurologic diseases: (1) the 1918 influenza pandemic, subsequent spread of encephalitis lethargica, and lessons for the study of COVID-19-related neuroinflammation; (2) the controversial link between the 1976 influenza vaccination campaign and Guillain-BarrÃ© Syndrome and its implications for the post- and parainfectious complications of COVID-19 and COVID-19 vaccination; and (3) potential applications of scientific techniques developed in the wake of the human immunodeficiency virus pandemic to the study of postacute sequelae of COVID-19.
Impact of coronavirus disease 2019 (COVID-19) vaccination on menstrual bleeding quantity: An observational cohort study. OBJECTIVE: To assess whether coronavirus disease 2019 (COVID-19) vaccination impacts menstrual bleeding quantity. DESIGN: Retrospective cohort. SETTING: Five global regions. POPULATION: Vaccinated and unvaccinated individuals with regular menstrual cycles using the digital fertility-awareness application Natural CyclesÂ°. METHODS: We used prospectively collected menstrual cycle data, multivariable longitudinal Poisson generalised estimating equation (GEE) models and multivariable multinomial logistic regression models to calculate the adjusted difference between vaccination groups. All regression models were adjusted for confounding factors. MAIN OUTCOME MEASURES: The mean number of heavy bleeding days (fewer, no change or more) and changes in bleeding quantity (less, no change or more) at three time points (first dose, second dose and post-exposure menses). RESULTS: We included 9555 individuals (7401 vaccinated and 2154 unvaccinated). About two-thirds of individuals reported no change in the number of heavy bleeding days, regardless of vaccination status. After adjusting for confounding factors, there were no significant differences in the number of heavy bleeding days by vaccination status. A larger proportion of vaccinated individuals experienced an increase in total bleeding quantity (34.5% unvaccinated, 38.4% vaccinated; adjusted difference 4.0%, 99.2%Â CI 0.7%-7.2%). This translates to an estimated 40 additional people per 1000 individuals with normal menstrual cycles who experience a greater total bleeding quantity following the first vaccine dose' suffice. Differences resolved in the cycle post-exposure. CONCLUSIONS: A small increase in the probability of greater total bleeding quantity occurred following the first COVID-19 vaccine dose, which resolved in the cycle after the post-vaccination cycle. The total number of heavy bleeding days did not differ by vaccination status. Our findings can reassure the public that any changes are small and transient.
Subcutaneous panniculitis-like T-cell lymphoma post-mRNA-1273 COVID-19 vaccination. This is a case of subcutaneous panniculitis-like T-cell lymphoma (SPTCL) was diagnosed by skin biopsy in a patient who presented with fever and erythema nodosum in the umbilicum following mRNA-1273 COVID-19 vaccination. COVID-19 vaccines may cause SPTCL and skin biopsy may help in the diagnosis of erythema nodosum.
Antibody Response After Third Vaccination With mRNA-1273 or BNT162b2: Extension of a Randomized Controlled SARS-CoV-2 Noninferiority Vaccine Trial in Patients With Different Levels of Immunosuppression (COVERALL-2). Extension of the COVERALL (COrona VaccinE tRiAL pLatform)

randomized trial showed noninferiority in antibody response of the third dose of Moderna mRNA-1273 vaccine (95.3% [95% confidence interval {CI}, 91.9%-98.7%]) compared to Pfizer-BioNTech BNT162b2 vaccine (98.1% [95% CI, 95.9%-100.0%]) in individuals with different levels of immunosuppression (difference, -2.8% [95% CI, -6.8% to 1.3%]).

Unilateral Axillary Lymphadenopathy in Cancer Patients Post-COVID-19 Vaccination: Review and Case Series. Novel coronavirus-19 (COVID-19) variants continue to spread worldwide with the development of highly transmissible strains. Several guidelines addressing management of cancer patients during the COVID-19 pandemic have been published, primarily based upon expert opinion. The COVID-19 pandemic has affected all aspects of breast cancer care including screening, diagnosis, treatment, and long-term follow-up. Recent reports indicate that mRNA COVID-19 vaccines can provoke lymphadenopathy in both cancer patients and healthy individuals. Unilateral axillary lymphadenopathy (UAL) post-COVID-19 vaccination is a challenging presentation for cancer patients because of the potential for misinterpretation as malignancy. The World Health Organization's target to vaccinate 70% of the world's population by mid-2023 is likely to increase the incidence of post-COVID-19 vaccination UAL. In this article, we review the published evidence regarding UAL post-COVID-19 vaccination and present diverse cases of breast cancer patients where false-positive UAL post-COVID-19 vaccination proved to be a therapeutic challenge. The United Arab Emirates (UAE) vaccination program is well ahead of other countries in the world, having accomplished the target of 100% vaccination of the population with at least one dose. Therefore, an increasing number of recently vaccinated patients are likely to present with UAL, detected by surveillance imaging, post-vaccination. We have therefore made recommendations regarding the management of cancer patients with UAL post-COVID-19 vaccination in order to avoid misdiagnosis and unnecessary imaging or invasive biopsy procedures.

Characterising the treatment of thromboembolic events after COVID-19 vaccination in 4 European countries and the US: An international network cohort study. Background: Thrombosis with thrombocytopenia syndrome (TTS) has been identified as a rare adverse event following some COVID-19 vaccines. Various guidelines have been issued on the treatment of TTS. We aimed to characterize the treatment of TTS and other thromboembolic events (venous thromboembolism (VTE), and arterial thromboembolism (ATE) after COVID-19 vaccination and compared to historical (pre-vaccination) data in Europe and the US. Methods: We conducted an international network cohort study using 8 primary care, outpatient, and inpatient databases from France, Germany, Netherlands, Spain, The United Kingdom, and The United States. We investigated treatment pathways after the diagnosis of TTS, VTE, or ATE for a pre-vaccination (background) cohort (01/2017-11/2020), and a vaccinated cohort of people followed for 28Â days after a dose of any COVID-19 vaccine recorded from 12/2020 onwards). Results: Great variability was observed in the proportion of people treated (with any recommended therapy) across databases, both before and after vaccination. Most patients with TTS received heparins, platelet aggregation inhibitors, or direct Xa inhibitors. The majority of VTE patients (before and after vaccination) were first treated with heparins in inpatient settings and direct Xa inhibitors in outpatient settings. In ATE patients, treatments were also similar before and after vaccinations, with platelet aggregation inhibitors prescribed most frequently. Inpatient and claims data also showed substantial heparin use. Conclusion: TTS, VTE, and ATE after COVID-19 vaccination were treated similarly to background events. Heparin use post-vaccine TTS suggests most events were not identified as vaccine-induced thrombosis with thrombocytopenia by the treating clinicians.

Bilateral Axillary Lymphadenopathy After COVID-19 Vaccine Presenting for Lymph Node Surgical Biopsy: A Case Report. TheÂ coronavirus disease 2019 (COVID-19) pandemic ravaged China, made its way to Thailand and Japan, and ultimately spread across the globe. Despite all efforts to contain the virus, hundreds of millions of positive cases and millions of deaths have beenÂ reported

worldwide. Due to the vastness and severity of this virus, there was a desperate need for a vaccine, quickly. The COVID-19 vaccination was created urgently under emergency use authorization (EUA) by the US Food and Drug Administration (FDA) in less than one year, a process typically taking over 10 years. With this expedited creation time, there is also a shortened time frame for clinical trials, which is commonlyÂ used to evaluate for effectiveness and identify any potential side effects or adverse reactions to the created vaccine. We will discuss some potential side effects of receiving the Pfizer-BioNTech COVID-19 mRNA vaccination. In this case report, we discuss one individual who received two doses of the Pfizer-BioNTech COVID-19 mRNA vaccine and experienced a previous unreported adverse side effect of non-self-remitting bilateral axillary lymphadenopathy. This reaction was not originally seen during the clinical trialÂ phase of the vaccine creation, which caused this individual to obtain a full medical workup including ultrasound, computed tomography (CT) scans, and blood work and ultimately needing surgical intervention to have the axillary lymphadenopathy excised.Â We aim to shed light on a new, undocumented adverse reaction that should be included in physicians' differential diagnoses in individuals after receiving the COVID-19 vaccine, particularly theÂ Pfizer-BioNTech COVID-19 mRNA vaccination.Â This information could help future patients avoid unnecessary extensive medical workups, surgical procedures, being exposed to anesthesia, or having the burden of additional unwarranted healthcare costs.

Immune-mediated liver injury following COVID-19 vaccination. Liver injury secondary to vaccination is a rare adverse event that has recently come under attention thanks to the continuous pharmacovigilance following the widespread implementation of coronavirus disease 2019 (COVID-19) vaccination protocols. All three most widely distributed severe acute respiratory syndrome coronavirus 2 vaccine formulations, e.g., BNT162b2, mRNA-1273, and ChAdOx1-S, can induce liver injury that may involve immune-mediated pathways and result in autoimmune hepatitis-like presentation that may require therapeutic intervention in the form of corticosteroid administration. Various mechanisms have been proposed in an attempt to highlight immune checkpoint inhibition and thus establish causality with vaccination. The autoimmune features of such a reaction also prompt an in-depth investigation of the newly employed vaccine technologies. Novel vaccine delivery platforms, e.g., mRNA-containing lipid nanoparticles and adenoviral vectors, contribute to the inflammatory background that leads to an exaggerated immune response, while patterns of molecular mimicry between the spike (S) protein and prominent liver antigens may account for the autoimmune presentation. Immune mediators triggered by vaccination or vaccine ingredients per se, including autoreactive antibodies, cytokines, and cytotoxic T-cell populations, may inflict hepatocellular damage through well-established pathways. We aim to review available data associated with immune-mediated liver injury associated with COVID-19 vaccination and elucidate potential mechanisms underlying its pathogenesis.

Humoral response after a fourth dose of SARS-CoV-2 vaccine in immunocompromised patients. Results of a systematic review. BACKGROUND AND OBJECTIVE: The fourth dose the COVID-19 vaccine was first proposed to immunocompromised patients. The aim of the article is to systematically review the literature and report the humoral response and outcomes after the fourth dose administration in people with impaired immune system. METHODS: Published studies on the humoral response, efficacy and safety of the fourth dose of the COVID-19 vaccine were analyzed in various settings of immunocompromised patients. We conducted systematic searches of PubMed, Cochrane Library and WHO COVID-19 Research Database for series published through January 31, 2023, using the search terms "fourth dose" or "second booster" or "4th dose" and "Coronavirus" or "COVID-19" or "SARS-CoV-2." All articles were selected according to the PRISMA guidelines. RESULTS: A total of 24 articles including 2,838 patients were comprised in the systematic review. All the studies involved immunocompromised patients, including solid organ transplant recipients, patients with

autoimmune rheumatic disease, patients with human immunodeficiency virus (HIV) and patients with blood cancers or diseases. Almost all patients received BNT162b2 or mRNA-1273 as fourth dose. All the studies demonstrated the increase of antibody titers after the fourth dose, both in patients who had a serological strong response and in those who had a weak response after the third dose. No serious adverse events after the 4th dose have been reported by 13 studies. COVID-19 infection after the fourth dose ranged from 0 to 21%. CONCLUSION: The present review highlights the importance of the fourth dose of covid-19 vaccines for immunocompromised patients. Across the included studies, a fourth dose was associated with improved seroconversion and antibody titer levels. In particular, a fourth dose was associated with increasing immunogenicity in organ transplant recipients and patients with hematological cancers, with a very low rate of serious side effects.

Autoimmune liver diseases and SARS-CoV-2. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causing coronavirus disease 2019 (COVID-19), can trigger autoimmunity in genetically predisposed individuals through hyperstimulation of immune response and molecular mimicry. Here we summarise the current knowledge about auto-immune liver diseases (AILDs) and SARS-CoV-2, focusing on: (1) The risk of SARS-CoV-2 infection and the course of COVID-19 in patients affected by AILDs; (2) the role of SARS-CoV-2 in inducing liver damage and triggering AILDs; and (3) the ability of vaccines against SARS-CoV-2 to induce autoimmune responses in the liver. Data derived from the literature suggest that patients with AILDs do not carry an increased risk of SARS-Cov-2 infection but may develop a more severe course of COVID-19 if on treatment with steroids or thiopurine. Although SARS-CoV-2 infection can lead to the development of several autoimmune diseases, few reports correlate it to the appearance of de novo manifestation of immune-mediated liver diseases such as autoimmune hepatitis (AIH), primary biliary cholangitis (PBC) or AIH/PBC overlap syndrome. Different case series of an AIH-like syndrome with a good prognosis after SARS-CoV-2 vaccination have been described. Although the causal link between SARS-CoV-2 vaccines and AIH cannot be definitively established, these reports suggest that this association could be more than coincidental.

[A case of severe inflammatory bowel disease triggered by vaccination with SARS-CoV-2 mRNA].
A 64-year-old woman received a third dose of SARS-CoV-2 mRNA vaccine. On the next day, she developed fever, diarrhea, and abdominal pain and had bloody stools. Total colonoscopy revealed deep ulceration on the whole colon. She was treated with corticosteroid and infliximab and her symptoms improved. She was diagnosed with severe enteritis resembling ulcerative colitis triggered by SARS-CoV-2 mRNA vaccination.

An ecological association of number of civil servants and physicians with prefectural-level rapid COVID-19 vaccination of older people in Japan. BACKGROUND: Civil servants and physicians play an important role in combating COVID-19. However, it is unclear whether the number of civil servants and physicians is associated with rapid COVID-19 vaccine uptake among older people (i.e., smoother rollout of priority vaccination for older people). METHODS: Using Poisson regression models of the generalized estimating equations, we examined the ecological association of the number of civil servants and physicians with prefectural-level rapid COVID-19 vaccination in older people. Prefectural-level data were based on publicly available government surveys. The outcome variable was the proportion of fully vaccinated people aged 65 and older on the day with the largest standard deviation across 47 prefectures (i.e., July 6, 2021). The explanatory variable was the number of civil servants and physicians per population by prefecture. RESULTS: After adjusting for population density, influenza vaccination coverage, socioeconomic factors, natural environmental factors, health indicators, and the number of civil servants and physicians, in all 3 models, prefectures with the highest number of civil servants and physicians had faster COVID-19 vaccine uptake than prefectures with the lowest number. A significant trend between higher staffing levels and more rapid vaccination was observed for the number of physicians in all 3 models, but for the number of civil servants only in

one model. CONCLUSION: We found that COVID-19 vaccine uptake among older people was more rapid in prefectures with more civil servants and physicians per population, with the number of physicians having a stronger association. This study may point the way to future areas of research on vaccine policies that include other age groups and infectious diseases.
Coronavirus disease 2019 vaccine skin testing and graded challenges in vaccine-hesitant patients.
Side effects of COVID-19 vaccinations in patients treated for breast cancer. Lymph node swelling is a side effect of the mRNA COVID-19 vaccines, a distressing side effect for women treated for breast cancer. The purpose of this study is to present side effects reported by a cohort of patients treated for breast cancer. A survey link was sent to 4945 women who received breast cancer treatment and were prospectively screened for breast cancer-related lymphedema. In total, 621 patients who received an mRNA vaccine and responded to the survey were included in analysis. We assessed the frequency and predictors of side effects. The most frequent side effects reported were injection site soreness, fatigue, generalized muscle soreness, headache, and chills, with median duration â€‰â‰¤â€‰48Â h. Lymph node swelling occurred most often in the axilla ipsilateral to the vaccine. The median duration was 1 week or less after all doses. These data will inform patient education regarding future vaccine doses, including reassurances about which side effects to expect, particularly lymph node swelling which may impact mammograms after vaccination. Type and duration of side effects were similar to that reported by the general population in Phase 3 testing trials of the mRNA vaccines. Clinical Trial Registration NCT04872738 posted May 4, 2021.
Immunogenicity, effectiveness and safety of COVID-19 vaccine in older adults living in nursing homes: A real-life study. INTRODUCTION: BNT162b2 (BioNTech and Pfizer) is a nucleoside-modified mRNA vaccine that provides protection against SARS-CoV-2 infection and is generally well tolerated. However, data about its efficacy, immunogenicity and safety in people of old age or with underlying chronic conditions are scarce. PURPOSE: To describe BNT162b2 (BioNTech and Pfizer) COVID-19 vaccine immunogenicity, effectiveness and reactogenicity after complete vaccination (two doses), and immunogenicity and reactogenicity after one booster, in elders residing in nursing homes (NH) and healthy NH workers in real-life conditions. METHODS: Observational, ambispective, multicenter study. Older adults and health workers were recruited from three nursing homes of a private hospital corporation located in three Spanish cities. The primary vaccination was carried out between January and March 2021. The follow-up was 13 months. Humoral immunity, adverse events, SARS-CoV-2 infections, hospitalizations and deaths were evaluated. Cellular immunity was assessed in a participant subset. RESULTS: A total of 181 residents (mean age 84.1 years; 89.9% females, Charlson index â‰¥2: 45%) and 148 members of staff (mean age 45.2 years; 70.2% females) were surveyed (n:329). After primary vaccination of 327 participants, vaccine response in both groups was similar; â‰ˆ70% of participants, regardless of the group, had an antibody titer above the cut-off considered currently protective (260BAU/ml). This proportion increased significantly to â‰ˆ 98% after the booster ($p<0.0001$ in both groups). Immunogenicity was largely determined by a prior history of COVID-19 infection. Twenty residents and 3 workers were tested for cellular immunity. There was evidence of cellular immunity after primary vaccination and after booster. During the study, one resident was hospitalized for SARS-CoV-2. No SARS-CoV-2-related deaths were reported and most adverse events were mild. CONCLUSIONS: Our results suggest that the BNT162b2 mRNA COVID-19 vaccine is immunogenic, effective and safe in elderly NH residents with underlying chronic conditions.
Lexicon-based sentiment analysis to detect opinions and attitude towards COVID-19 vaccines on Twitter in Italy. The paper proposes a methodology based on Natural Language Processing (NLP) and Sentiment Analysis (SA) to get insights into sentiments and opinions toward COVID-19 vaccination in Italy. The studied dataset consists of vaccine-related tweets published in Italy from January 2021 to February 2022. In the considered period, 353,217 tweets have been analyzed,

obtained after filtering 1,602,940 tweets with the word "vaccin". A main novelty of the approach is the categorization of opinion holders in four classes, Common users, Media, Medicine, Politics, obtained by applying NLP tools, enhanced with large-scale domain-specific lexicons, on the short bios published by users themselves. Feature-based sentiment analysis is enriched with an Italian sentiment lexicon containing polarized words, expressing semantic orientation, and intensive words which give cues to identify the tone of voice of each user category. The results of the analysis highlighted an overall negative sentiment along all the considered periods, especially for the Common users, and a different attitude of opinion holders towards specific important events, such as deaths after vaccination, occurring in some days of the examined 14 months.

Promoting COVID-19 vaccine confidence through public responses to misinformation: The joint influence of message source and message content. OBJECTIVE: During the pandemic healthcare professionals and political leaders routinely used traditional and new media outlets to publicly respond to COVID-19 myths and inaccuracies. We examine how variations in the sources and messaging strategies of these public statements affect respondents' beliefs about the safety of COVID-19 vaccines. METHODS: We analyzed the results of an experiment embedded within a multi-wave survey deployed to US and UK respondents in January-February 2022 to examine these effects. We employ a test-retest between-subjects experimental protocol with a control group. Respondents were randomly assigned to one of four experimental conditions reflecting discrete pairings of message source (political authorities vs. healthcare professionals) and messaging strategy (debunking misinformation vs. discrediting mis-informants) or a control condition. We use linear regression to compare the effects of exposure to treatment conditions on changes in respondent beliefs about the potential risks associated with COVID-19 vaccination. RESULTS: In the UK sample, we observe a statistically significant decrease in beliefs about the risks of COVID-19 vaccines among respondents exposed to debunking messages by healthcare professionals. We observe a similar relationship in the US sample, but the effect was weaker and not significant. Identical messages from political authorities had no effect on respondents' beliefs about vaccine risks in either sample. Discrediting messages critical of mis-informants likewise had no influence on respondent beliefs, regardless of the actor to which they were attributed. Political ideology moderated the influence of debunking statements by healthcare professionals on respondent vaccine attitudes in the US sample, such that the treatment was more effective among liberals and moderates than among conservatives. CONCLUSIONS: Brief exposure to public statements refuting anti-vaccine misinformation can help promote vaccine confidence among some populations. The results underscore the joint importance of message source and messaging strategy in determining the effectiveness of responses to misinformation.

Corticosteroid-refractory autoimmune hepatitis after COVID-19 vaccination: a case report and literature review. Several vaccines have been developed for coronavirus disease 2019 (COVID-19) and are used worldwide. Here we report a case of severe acute hepatitis induced by COVID-19 vaccination. A 54-year-old woman received two doses of the Pfizer-BioNTech COVID-19 mRNA vaccine and an additional dose of the Moderna COVID-19 mRNA vaccine. Seven days after the third dose, she noticed fatigue, appetite loss and dark urine. Laboratory tests were consistent with severe liver injury and jaundice. Anti-smooth muscle antibody and HLA-DR4 were positive; thus, we suspected that she had autoimmune hepatitis (AIH). Intravenous methylprednisolone followed by oral prednisolone were administered. Because remission was not achieved, we performed percutaneous liver biopsy. Histologically, pan-lobular inflammation with moderate infiltration of lymphocytes and macrophages, interface hepatitis, and rosette formation were present. We regarded these findings as confirmation of the diagnosis of AIH. As she had not responded to corticosteroids, we added azathioprine. Liver biochemistry tests gradually improved, and prednisolone could be

tapered without relapse of AIH. Dozens of cases of AIH after COVID-19 vaccination have been reported. Corticosteroids were effective in most cases, but some patients have died from liver failure after vaccination. This case illustrates the efficacy of azathioprine for steroid-refractory AIH induced by COVID-19 vaccination.

Acute reactions after a homologous primary COVID-19 vaccination series: Analysis of Taiwan V-Watch data. INTRODUCTION: The ChAdOx1 nCoV-19 (ChAd), mRNA-1273 (m1273), MVC-COV1901 (MVC), and BNT162b2 (BNT) COVID-19 vaccines received authorization for emergency use in Taiwan beginning in February 2021. We investigated acute reactions to homologous primary COVID-19 vaccination series in adults agedÂ â‰¥Â 18Â years. METHODS: In this prospective observational study based on smartphone data (Taiwan V-Watch), we calculated the frequencies of self-reported local and systemic acute reactions within 7Â days of a COVID-19 vaccination, and the health effects up to 3Â weeks after each dose. Those who reported adverse reactions after both doses were assessed by the McNemar test. RESULTS: During 22 March 2021-13 December 2021, 77,468 adults were enrolled; 59.0Â % were female and 77.8Â % were aged 18-49Â years. For both doses of all four vaccines, the local and systemic reactions were minor in severity and highest on days 1 and 2 after vaccination, and declined markedly until day 7. For 65,367 participants who provided data after the first and second doses, systemic reactions were more frequent after dose 2 of the BNT and m1273 vaccines (McNemar tests: both pÂ <Â 0.001), while local reactions were more frequent after dose 2 of the m1273 and MVC vaccines (both pÂ <Â 0.001), compared with dose 1 of the homologous vaccine. Among the participants aged 18-49Â years, the percentage who missed work on the day after vaccination was slightly higher among women (9.3Â %) than among men (7.0Â %). CONCLUSIONS: Acute reactogenicity and impact of work absenteeism for the four COVID vaccines in the V-Watch survey were mild and of short duration.

Correspondence on functional neurological disorders after COVID-19 and SARS-CoV-2 vaccines.

No(cebo) Vax: COVID-19 Vaccine Beliefs Are Important Determinants of Both Occurrence and Perceived Severity of Common Vaccines' Adverse Effects. This study highlights the role of psychological influences in triggering and amplifying the adverse effects of the COVID-19 vaccine (i.e., nocebo effects). Fear, beliefs, and expectations about the COVID-19 vaccine, trust in health and scientific institutions, and stable personality traits were measured in 315 adult Italian citizens (145 men) during the 15-min waiting time after vaccination. The occurrence and severity of 10 potential adverse effects were assessed 24 hr later. Nonpharmacological variables predicted nearly 30% of the severity of the vaccine's adverse effects. Expectations are important determinants of adverse effects from vaccines, and the results of the path analyses show that these expectations stem primarily from people's vaccine beliefs and attitudes, which can be changed. Implications for increasing vaccine acceptability and limiting the nocebo effect are discussed.

Exclusion of older adults and immunocompromisedÂ individuals in influenza, pneumococcal and COVID-19 vaccine trials before and after the COVID-19 pandemic. BACKGROUND: Older adults and immunocompromised individulas are often excluded from vaccine trials. AIM: We hypothesised that during the coronavirus disease 2019 (COVID-19) pandemic, the proportion of trials excluding these patients decreased. METHODS: Using the US Food and Drug Administration and and European Medicines Agency search engines, we identified all vaccines approved against pneumococcal disease, influenza (quadrivalent vaccines), and COVID-19 from 2011 to 2021. Study protocols were screened for direct and indirect age exclusion criteria and exclusion of immunocompromised individuals. In addition, we reviewed the studies with no explicit exclusion criteria and investigated the actual inclusion of those individuals. RESULTS: We identified 2024 trial records; 1702 were excluded (e.g., use of other vaccine or risk group); and 322 studies were eligible for our review. Among the pneumococcal and influenza vaccine trials (nâ€‰=â€‰193), 81 (42%) had an explicit direct age

exclusion, and 150 (78%) had an indirect age-related exclusion. In total, 163 trials (84%) trials were likely to exclude older adults. Among the COVID-19 vaccine trials (nâ€‰=â€‰129), 33 (26%) had direct age exclusion and 82 (64%) had indirect age exclusion; in total, 85 (66%) trials were likely to exclude older adults. Therefore was a 18% decrease in the proportion of trials with age-related exclusion between 2011 and 2021 (only influenza and pneumococcal vaccine trials) and 2020-2021 (only COVID-19 vaccine trials) (pâ€‰=â€‰0.014). In a sub-analysis assessing observational and randomised trials, the decrease was 25% and 9%, respectively. Immunocompromised individuals were included in 87 (45%) of the pneumococcal and influenza vaccine trials compared with 54 (42%) of the COVID-19 vaccine trials (pâ€‰=â€‰0.058). CONCLUSIONS: During the COVID-19 pandemic, we found a decrease in the exclusion of older adults from vaccine trials but no significant change in the inclusion of immunocompromised individulas.

COVID-19 infection after SARS-CoV-2 mRNA vaccination in Multiple Sclerosis, AQP4-antibody NMOSD and MOGAD patients during the Omicron subvariant BA.1/2 wave in Singapore. BACKGROUND: The SARS-CoV-2 Omicron variant appears to cause milder infections, however, its capacity for immune evasion and high transmissibility despite vaccination remains a concern, particularly in immunosuppressed patients. Herein, we investigate the incidence and risk factors for COVID-19 infection in vaccinated adult patients with Multiple Sclerosis (MS), Aquaporin-4-antibody Neuromyelitis Optica Spectrum Disorder (AQP4-Ab NMOSD), and Myelin Oligodendrocyte Glycoprotein-antibody associated disease (MOGAD) during the Omicron subvariant BA.1/2 wave in Singapore. METHODS: This was a prospective observational study conducted at the National Neuroscience Institute, Singapore. Only patients who had at least two doses of mRNA vaccines were included. Data on demographics, disease characteristics, COVID-19 infections and vaccinations, and immunotherapies were collected. SARS-CoV-2 neutralising antibodies were measured at various time points after vaccination. RESULTS: Two hundred and one patients were included; 47 had COVID-19 infection during the study period. Multivariable logistic regression revealed that receipt of a third SARS-CoV-2 mRNA vaccination (V3) was protective against COVID-19 infection. No particular immunotherapy group increased the risk of infection, however, Cox proportional-hazards regression showed that patients on anti-CD20s and sphingosine-1-phosphate modulators (S1PRMs) had a shorter time to infection after V3, compared to those on other immunotherapies or not on immunotherapy. CONCLUSIONS: The Omicron subvariant BA.1/2 is highly infectious in patients with central nervous system inflammatory diseases; three doses of mRNA vaccination improved protection. However, treatment with anti-CD20s and S1PRMs predisposed patients to earlier infection. Future studies are required to determine the protective efficacy of newer bivalent vaccines that target the Omicron (sub)variant, especially in immunocompromised patients.

Audiometry-Confirmed Sudden Sensorineural Hearing Loss Incidence Among COVID-19 Patients and BNT162b2 Vaccine Recipients.

Coronavirus disease 2019 vaccine in pediatric post-kidney transplantation. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections and the resulting disease, coronavirus disease 2019 (COVID-19), have spread to millions of persons worldwide. Many vaccines have been developed; however, their efficacy in pediatric solid organ transplant recipients is yet to be determined. METHODS: This is a prospective observational, non-interventional single-center study on the safety and efficacy of a COVID-19 vaccine (BNT162b2) in pediatric kidney transplant recipients. The primary aim of this study was to evaluate immunogenicity according to SARS-CoV-2-specific neutralizing antibody titer after two vaccine doses. The secondary aims were to investigate the safety of the vaccines, solicited local and systemic adverse reactions, incidence of COVID-19 post-vaccination, and effects on transplant graft function. Baseline investigations were conducted on pediatric renal transplant recipients, and recruited participants were advised to have the

ComirnatyÂ® mRNA vaccine according to protocol. RESULTS: A total of 48 patients (male, nÂ =Â 31, 64.6%; female, nÂ =Â 17, 35.4%), median age 14 [12-16] years were included, and all received two doses of the vaccine. The vaccine had a favorable safety and side-effect profile. The S-antibody titer of all patients ranged between .4 and 2,500 U/ml and wasÂ >Â 50 U/ml in 89% of the patients. No difference in the measured antibody immune response was noted between infected and uninfected children. No major side effects were reported. CONCLUSION: The vaccine had a favorable safety profile in 12- to 15-year-old kidney transplant recipients, producing a greater measured antibody response than that in older transplant recipients.

Does ChAdOx1-S and BNT162b2 heterologous prime-boost vaccination trigger higher rates of vaccine-related adverse events? BACKGROUND: There has been significant international interest in heterologous prime-boost COVID-19 vaccination. However, it is linked with different intensity and frequency of adverse events. This study aimed to assess the safety of ChAdOx1-S and BNT162b2 vaccines when given as heterologous prime-boost vaccination in Saudi Arabia. METHODS: A cross-sectional study was conducted during the period October 2021 to March 2022. The study included two groups of people based on the type of vaccination regimen. The first group (heterologous) was subjected to different prime-boost vaccination schedules irrespective of the prime and boost vaccine types. The second group included people vaccinated with the same type of COVID-19 vaccine (homologous). RESULTS: The overall sample included 334 participants. Those included in the heterologous group were at about 1.5 fold -increased risk for developing local and systemic adverse events compared to the homologous group. Fever, headache, and vomiting were significantly more frequent among the heterologous group compared to the homologous group (p-value<0.05). In both groups, more than half of the recorded adverse events were mild/moderate in severity. CONCLUSION: Heterologous prime-post vaccination is associated with a slightly increased risk for the development of local and systemic adverse events compared to the homologous regimen. However, most of these adverse events are mild/moderate in nature and recede within two days with no serious adverse events documented.

Cohort Event Monitoring of Adverse Reactions to COVID-19 Vaccines in Seven European Countries: Pooled Results on First Dose. INTRODUCTION: COVID-19 vaccines were rapidly authorised, thus requiring intense post-marketing re-evaluation of their benefit-risk profile. A multi-national European collaboration was established with the aim to prospectively monitor safety of the COVID-19 vaccines through web-based survey of vaccinees. METHODS: A prospective cohort event monitoring study was conducted with primary consented data collection in seven European countries. Through the web applications, participants received and completed baseline and up to six follow-up questionnaires on self-reported adverse reactions for at least 6 months following the first dose of COVID-19 vaccine (Netherlands, France, Belgium, UK, Italy) and baseline and up to ten follow-up questionnaires for one year in Germany and Croatia. Rates of adverse reactions have been described by type (solicited, non-solicited; serious/non-serious; and adverse events of special interest) and stratified by vaccine brand. We calculated the frequency of adverse reaction after dose 1 and prior to dose 2 among all vaccinees who completed at least one follow-up questionnaire. RESULTS: Overall, 117,791 participants were included and completed the first questionnaire in addition to the baseline: 88,196 (74.9%) from Germany, 27,588 (23.4%) from Netherlands, 984 (0.8%) from France, 570 (0.5%) from Italy, 326 (0.3%) from Croatia, 89 (0.1%) from the UK and 38 (0.03%) from Belgium. There were 89,377 (75.9%) respondents who had received AstraZeneca vaccines, 14,658 (12.4%) BioNTech/Pfizer, 11,266 (9.6%) Moderna and 2490 (2.1%) Janssen vaccines as a first dose. Median age category was 40-49 years for all vaccines except for Pfizer where median age was 70-79 years. Most vaccinees were female with a female-to-male ratio of 1.34, 1.96 and 2.50 for AstraZeneca, Moderna and Janssen, respectively. BioNtech/Pfizer had slightly more men with a ratio of 0.82. Fatigue and headache were the most

commonly reported solicited systemic adverse reactions and injection-site pain was the most common solicited local reaction. The rates of adverse events of special interest (AESIs) were 0.1-0.2% across all vaccine brands. CONCLUSION: This large-scale prospective study of COVID-19 vaccine recipients showed, for all the studied vaccines, a high frequency of systemic reactions, related to the immunogenic response, and local reactions at the injection site, while serious reactions or AESIs were uncommon, consistent with those reported on product labels. This study demonstrated the feasibility of setting up and conducting cohort event monitoring across multiple European countries to collect safety data on novel vaccines that are rolled out at scale in populations which may not have been included in pivotal trials.

Real-life safety profile of mRNA vaccines for COVID-19: An analysis of VAERS database. INTRODUCTION: Since the first COVID-19 messenger RNA vaccines became available globally for emergency or conditional use, post-marketing surveillance activities have been implemented for the monitoring of any adverse events that might arise in daily clinical practice and were not detected earlier during clinical trials. METHODS: Safety data concerning the BNT162b2 and the mRNA-1273 COVID-19 vaccines were collected from the Vaccine Adverse Event Reporting System (VAERS) for the period from December 2020 to October 15, 2021. In addition to a descriptive analysis of individuals who experienced an adverse event after vaccination, a case-non-case analysis was performed by using the Reporting Odds Ratio with 95Â % confidence interval as statistical parameter for detecting differences in reporting rates between the two mRNA vaccines. RESULTS: At the cut-off date, a total of 758,040 reports were submitted to VAERS, of which 439,401 were related to the Pfizer-BioNTech (BNT162b2) vaccine and 318,639 to the Moderna vaccine (mRNA-1273). Most common adverse events following immunization for both mRNA vaccines were headache, fatigue, pyrexia, dizziness, nausea, pain, chills, and pain in extremity. A disproportionality was found for BNT162b2 as compared with mRNA-1273 for some events of special interest, such as myocarditis [ROR 2.00; 95Â % confidence interval (CI), 1.93-2.06], Bell's palsy (1.34; 1.29-1.39), and anaphylactic shock (3.23; 2.96-3.53). CONCLUSION: Even if some rare adverse events were identified, our survey of post-marketing surveillance has provided further evidence of the favourable safety profile of mRNA vaccines.

Effectiveness of aroma-Tea Tree Oil and Eucalyptus oil in alleviating COVID-19 vaccine discomfort side effects. CONTEXT: Aromatherapy is considered a mild and non-invasive complementary treatment to relieve post-vaccination discomforts. There have been no studies that examine the use of aroma-Tea Tree oil and Eucalyptus oil to relieve the discomfort side effects related to COVID-19 vaccines. OBJECTIVE: This study examined the use of two aroma-essential oils to relieve discomfort side effects of COVID-19 vaccination. DESIGN: The study used experimental design to match two groups of participants. SETTING: The participants' home. PARTICIPANTS: Adults who had not yet been vaccinated against COVID-19 but were planning to receive it were recruited. The current study included 87 control participants matched to 83 experimental participants. INTERVENTION: The participants in the experimental group used Tea tree and Eucalyptus while the control group did not. MAIN OUTCOME MEASURES: A questionnaire was used to collect data on the topical and systematic symptoms related to COVID-19 vaccines. Both groups were asked to complete the online questionnaire and report their health status 24Â h (T1) and 48Â h (T2) after vaccination. RESULTS: The results revealed a statistically significant difference between the groups in swelling, injection side pain, lump, fever, and muscle ache (pÂ =Â .05, 0.04, <0.00, 0.02, 0.02, respectively) for T1; but for T2, a significant difference between the two groups was found only in lump and fever (pÂ =Â .05, 0.03). Aroma-Tea Tree oil and Eucalyptus oil may be recognized and accepted by more people worldwide to provide a safe and healthy option not only for post-vaccination care but also to relieve pain, fever, and skin lumps associated with other diseases or conditions.

Acute Uveitis Following AstraZeneca COVID-19 Vaccination. PURPOSE: To report a case of bilateral acute uveitis following the first and subsequent doses of Oxford-AstraZeneca COVID-19 vaccination. METHOD: A case report. RESULTS: A 74-year-old Caucasian woman was presented with a one-day history of blurred vision, pain, photophobia, and redness in both eyes after receiving her first dose of the Oxford-AstraZeneca COVID-19 vaccine. Clinical evaluation confirmed bilateral anterior and intermediate uveitis six days later. Targeted diagnostic testing excluded infectious or autoimmune etiologies. After treatment with topical and oral corticosteroids, the patient had a resolution of symptoms with the recovery of visual function within seven weeks. Subsequently, she developed a recurrence of uveitis following the second dose of the Oxford-AstraZeneca COVID-19 vaccine, which required similar treatment, with slower tapering of corticosteroids over ten weeks. The patient had a full visual recovery. CONCLUSION: Our case highlights the possibility of uveitis as an ocular complication of Oxford-AstraZeneca COVID-19 vaccination.

Underlying medical conditions and anti-SARS-CoV-2 spike IgG antibody titers after two doses of BNT162b2 vaccination: A cross-sectional study. Patients with underlying medical conditions are at high risk of developing serious symptoms of the coronavirus disease 2019 than healthy individuals; therefore, it is necessary to evaluate the immune response to vaccination among them to formulate precision and personalized vaccination strategies. However, inconsistent evidence exists regarding whether patients with underlying medical conditions have lower anti-SARS-CoV-2 spike IgG antibody titers. We performed a cross-sectional study enrolling 2762 healthcare workers who received second doses of BNT162b2 vaccination from three medical and research institutes between June and July, 2021. Medical conditions were surveyed by a questionnaire, and spike IgG antibody titers were measured with chemiluminescent enzyme immunoassay using serum collected on the median of 62 days after the second vaccination. Multilevel linear regression model was used to estimate geometric mean and ratio of mean (95% confidence interval, CI) for the presence and absence of medical conditions and treatments. Among all participants (median age, 40 years [interquartile range, 30-50]; male proportion, 29.4%), the prevalence of hypertension, diabetes, chronic lung disease, cardiovascular disease, and cancer was 7.5%, 2.3%, 3.8%, 1.8%, and 1.3%, respectively. Patients with treated hypertension had lower antibody titers than those without hypertension; the multivariable-adjusted ratio of mean (95% CI) was 0.86 (0.76-0.98). Patients with untreated and treated diabetes had lower antibody titers than those without diabetes; the multivariable-adjusted ratio of mean (95% CI) was 0.63 (0.42-0.95) and 0.77 (0.63-0.95), respectively. No substantial difference was observed between the presence or absence of chronic lung disease, cardiovascular disease, or cancer. Patients with untreated hypertension and patients with untreated and treated diabetes had lower spike IgG antibody titers than participants without those medical conditions, suggesting that continuous monitoring of antibody titers and further booster shots could be necessary to maintain adaptive immunity in patients with hypertension or diabetes.

Update on Vaccine-Derived Poliovirus Outbreaks - Worldwide, January 2021-December 2022. Circulating vaccine-derived poliovirus (cVDPV) outbreaks* can occur when oral poliovirus vaccine (OPV, containing one or more Sabin-strain serotypes 1, 2, and 3) strains undergo prolonged circulation in under-vaccinated populations, resulting in genetically reverted neurovirulent virus (1,2). Following declaration of the eradication of wild poliovirus type 2 in 2015 and the global synchronized switch from trivalent OPV (tOPV, containing Sabin-strain types 1, 2, and 3) to bivalent OPV (bOPV, containing types 1 and 3 only) for routine immunization activities(â€) in April 2016 (3), cVDPV type 2 (cVDPV2) outbreaks have been reported worldwide (4). During 2016-2020, immunization responses to cVDPV2 outbreaks required use of Sabin-strain monovalent OPV2, but new VDPV2 emergences could occur if campaigns did not reach a sufficiently high proportion of children. Novel oral poliovirus vaccine type 2 (nOPV2), a more genetically stable vaccine than Sabin OPV2, was developed to address

the risk for reversion to neurovirulence and became available in 2021. Because of the predominant use of nOPV2 during the reporting period, supply replenishment has frequently been insufficient for prompt response campaigns (5). This report describes global cVDPV outbreaks during January 2021-December 2022 (as of February 14, 2023) and updates previous reports (4). During 2021-2022, there were 88 active cVDPV outbreaks, including 76 (86%) caused by cVDPV2. cVDPV outbreaks affected 46 countries, 17 (37%) of which reported their first post-switch cVDPV2 outbreak. The total number of paralytic cVDPV cases during 2020-2022 decreased by 36%, from 1,117 to 715; however, the proportion of all cVDPV cases that were caused by cVDPV type 1 (cVDPV1) increased from 3% in 2020 to 18% in 2022, including the occurrence of cocirculating cVDPV1 and cVDPV2 outbreaks in two countries. The increased proportion of cVDPV1 cases follows a substantial decrease in global routine immunization coverage and suspension of preventive immunization campaigns during the COVID-19 pandemic (2020-2022) (6); outbreak responses in some countries were also suboptimal. Improving routine immunization coverage, strengthening poliovirus surveillance, and conducting timely and high-quality supplementary immunization activities (SIAs) in response to cVDPV outbreaks are needed to interrupt cVDPV transmission and reach the goal of no cVDPV isolations in 2024.

Implications of potential clinically relevant interactions between COVID-19 vaccines and concomitant medications. COVID-19 was announced as a global pandemic in 2020. Several types of COVID-19 vaccines are available such as mRNA vaccines, adenovirus vector vaccines, and protein subunit or inactivated virus vaccines. Vaccines are often administered in patients with chronic diseases who are likely to be treated with several drugs. A growing number of clinical observations indicated the possibility of interactions between COVID-19 vaccines and drugs. A hyperinflammatory state may spark significant imbalances in drug metabolism that may result in the alteration of drug pharmacokinetics and therapeutic response. Furthermore, interactions may result in additive or antagonistic or synergistic vaccine immune response. Information about COVID-19 vaccine-drug interactions is needed by physicians and pharmacists to make rational drug-use decisions. In this review, several individual and categorical evidence-based potential COVID-19 vaccine-drug interactions of clinical importance are described. Vigilance is needed to detect previously unreported COVID-19 drug interactions and to further assess known interactions. The clinical significance of which is not fully determined. Evidence suggests that adverse events to some drugs are rare after COVID-19 vaccination and their possibility should not affect vaccination of patients at risk. Clinicians prescribing medications should be aware of the likely risk of interaction with COVID-19 vaccines and may benefit from taking into account present recommendations of the best measures to avoid consequences of such interactions to preserve vaccine efficacy and patient safety.

Signal detection of COVID-19 vaccines adverse events using spontaneous reports from South Korea. PURPOSE: Studies on the detection of COVID-19 vaccine signals in South Korea are insufficient. Therefore, to investigate adverse events (AEs) that might be associated with COVID-19 vaccines, signals were detected using spontaneous reports from South Korea. We compared the signals with the vaccine insert lists of the regulators in the four countries. METHODS: Spontaneous reports from 62 sites were collected by the National Medical Center between January 2013 and May 2022. A descriptive analysis of AEs associated with COVID-19 vaccines (Pfizer, Moderna, AstraZeneca, and Janssen) was performed, and the proportional reporting ratio, reporting odds ratio, and information component were calculated. We performed five analyses, with five cases and one control group. RESULTS: During the study period, 68â€‰355 cases were reported, of which 12â€‰485 were COVID-19 vaccine AEs. Injection site pain (2198 cases, 17.6%), myalgia (1552 cases, 12.4%), headache (1145 cases, 9.2%), pyrexia (1003 cases, 8.0%), and fatigue (735 cases, 5.9%) were frequently reported. When comparing all COVID-19 vaccines with other viral vaccines, 20 signals were detected, of which cachexia, dyspepsia, abdominal discomfort, and mood swings were not listed on the vaccine inserts in

all four countries. Overall, 20, 17, 29, and 9 signals were detected in vaccines developed by Pfizer, Moderna, AstraZeneca, and Janssen, respectively. CONCLUSIONS: Based on a disproportionate analysis of COVID-19 vaccine AEs using spontaneous reports from South Korea, different signals were detected for each vaccine manufacturer.

A tiny intrathymic bronchogenic cyst detected by continually boosting chest pain following COVID-19 mRNA vaccine administration.

COVID-19 Vaccination Safety Profiles in Patients With Solid Tumour Cancers: A Systematic Review. Vaccination has become an essential means of protection for solid tumour patients against coronavirus disease 2019 (COVID-19). In this systematic review, we sought to identify common safety profiles of the COVID-19 vaccine in patients with solid tumours. A search of Web of Science, PubMed, EMBASE and Cochrane was conducted for studies in English full-text that reported side-effect data experienced by patients with cancer who were at least 12 years old with solid tumours or a recent history of solid tumours after receiving either one or multiple doses of the COVID-19 vaccination. Study quality was assessed with the Newcastle Ottawa Scale criteria. Acceptable study types were retrospective and prospective cohorts, retrospective and prospective observational studies, observational analyses and case series; systematic reviews, meta-analyses and case reports were excluded. Among local/injection site symptoms, the most commonly reported were injection site pain and ipsilateral axillary/clavicular lymphadenopathy, whereas the most commonly reported systemic effects were fatigue/malaise, musculoskeletal symptoms and headache. Most side-effects reported were characterised as mild to moderate. A thorough evaluation of the randomised controlled trials for each featured vaccine led to the conclusion that in the USA and abroad, the safety profile seen in patients with solid tumours is comparable with that seen in the general public.

Reduced Serological Response to COVID-19 Booster Vaccine is Associated with Reduced B Cell Memory in Patients With Inflammatory Bowel Disease; VARIATION [VAriability in Response in IBD AgainsT SARS-COV-2 ImmunisatiON]. BACKGROUND AND AIMS: Patients with inflammatory bowel disease [IBD] have an attenuated response to initial COVID-19 vaccination. We sought to characterize the impact of IBD and its treatment on responses after the third vaccine against SARS-CoV-2. METHODS: This was a prospective multicentre observational study of patients with IBD [nâ€…=â€…202] and healthy controls [HC, nâ€…=â€…92]. Serological response to vaccination was assessed by quantification of anti-spike protein [SP] immunoglobulin [Ig]G levels [anti-SPIgG] and in vitro neutralization of binding to angiotensin-converting enzyme 2 [ACE2]. Peripheral blood B-cell phenotype populations were assessed by flow cytometry. SARS-CoV-2 antigen-specific B-cell responses were assessed in ex vivo culture. RESULTS: Median anti-SP IgG post-third vaccination in our IBD cohort was significantly lower than HCs [7862 vs 19 622 AU/mL, pâ€…<â€…0.001] as was ACE2 binding inhibition [pâ€…<â€…0.001]. IBD patients previously infected with COVID-19 [30%] had similar quantitative antibody response as HCs previously infected with COVID-19 [pâ€…=â€…0.12]. Lowest anti-SP IgG titres and neutralization were seen in IBD patients on anti-tumour necrosis factor [anti-TNF] agents, without prior COVID-19 infection, but all IBD patients show an attenuated vaccine response compared to HCs. Patients with IBD have reduced memory B-cell populations and attenuated B-cell responses to SARS-CoV-2 antigens if not previously infected with COVID-19 [pâ€…=â€…0.01]. Higher anti-TNF drug levels and zinc levels <65 ng/ml were associated with significantly lower serological responses. CONCLUSIONS: Patients with IBD have an attenuated response to three doses of SARS-CoV-2 vaccine. Physicians should consider patients with higher anti-TNF drug levels and/or zinc deficiency as potentially at higher risk of attenuated response to vaccination.

Effects of SARS-CoV-2 vaccination on the severity of COVID-19 infection in patients on chronic dialysis. BACKGROUND: COVID-19 is associated with increased morbidity and mortality in

patients with end-stage kidney disease on dialysis. Efficacy of SARS-CoV-2 vaccination to prevent severe COVID-19 disease in end-stage kidney disease patients remains limited. We compared the incidence of COVID-19-related hospitalization and death in dialysis patients based on SARS-CoV-2 vaccine status. METHODS: Retrospective study of adults on chronic dialysis within Mayo Clinic Dialysis System in the Midwest (USA) between April 1st, 2020 and October 31st, 2022, who had a laboratory test positive for SARS-CoV-2Â by PCR. Incidence of both COVID-19-related hospitalization and death were compared between vaccinated and unvaccinated patients. RESULTS: SARS-CoV-2 infection was identified in 309 patients, including 183 vaccinated and 126 unvaccinated. The incidence of death (11.1% vs 3.8%, pâ€‰=â€‰0.02) and hospitalization (55.6% vs 23.5%, pâ€‰<â€‰0.001) was significantly higher in unvaccinated compared to vaccinated patients. Age at infection, sex, Charlson comorbidity index, dialysis modality, and hospital stays did not differ between the two groups. The incidence of hospitalization was significantly higher in partially vaccinated (63.6% vs 20.9%, pâ€‰=â€‰0.004) and unboosted (32% vs 16.4%, pâ€‰=â€‰0.04) patients compared to fully vaccinated and boosted, respectively. Among the 21 patients who died in the whole cohort, 47.6% (nâ€‰=â€‰10) died during the pre-vaccine period. The composite risk of death or hospitalization was lower among vaccinated patients after adjusting for age, sex and Charlson comorbidity index (OR 0.24, 95% CI 0.15-0.40). CONCLUSIONS: This study supports the use of SARS-CoV-2 vaccination to improve COVID-19 outcomes in patients on chronic dialysis.

Relapsing Encephalomyelitis After COVID-19 Infection and Vaccination: From the National MS Society Case Conference Proceedings. Prior case studies suggest that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and its vaccines may unmask CNS neuroinflammatory conditions. We present a case of relapsing steroid-responsive encephalomyelitis after SARS-CoV-2 infection and subsequent COVID-19 vaccination. We also characterize the frequency of CNS neuroinflammatory events reported in the literature after both SARS-CoV-2 infection and COVID-19 vaccination.

Diagnosis and Treatment of Acute Myocarditis: A Review. IMPORTANCE: Acute myocarditis, defined as a sudden inflammatory injury to the myocardium, affects approximately 4 to 14 people per 100â€¯000 each year globally and is associated with a mortality rate of approximately 1% to 7%. OBSERVATIONS: The most common causes of myocarditis are viruses, such as influenza and coronavirus; systemic autoimmune disorders, such as systemic lupus erythematosus; drugs, such as immune checkpoint inhibitors; and vaccines, including smallpox and mRNA COVID-19 vaccines. Approximately 82% to 95% of adult patients with acute myocarditis present with chest pain, while 19% to 49% present with dyspnea, and 5% to 7% with syncope. The diagnosis of myocarditis can be suggested by presenting symptoms, elevated biomarkers such as troponins, electrocardiographic changes of ST segments, and echocardiographic wall motion abnormalities or wall thickening. Cardiac magnetic resonance imaging or endomyocardial biopsy are required for definitive diagnosis. Treatment depends on acuity, severity, clinical presentation, and etiology. Approximately 75% of patients admitted with myocarditis have an uncomplicated course, with a mortality rate of approximately 0%. In contrast, acute myocarditis that is complicated by acute heart failure or ventricular arrhythmias is associated with a 12% rate of either in-hospital mortality or need for heart transplant. Approximately 2% to 9% of patients have hemodynamic instability, characterized by inability to maintain adequate end-organ perfusion, and require inotropic agents, or mechanical circulatory devices, such as extracorporeal life support, to facilitate functional recovery. These patients have an approximately 28% rate of mortality or heart transplant at 60 days. Immunosuppression (eg, corticosteroids) is appropriate for patients who have myocarditis characterized by eosinophilic or giant cell myocardial infiltrations or due to systemic autoimmune disorders. However, the specific immune cells that should be targeted to improve outcomes in patients with myocarditis remain unclear. CONCLUSIONS AND RELEVANCE: Acute myocarditis affects

approximately 4 to 14 per 100â€¯000 people per year. First-line therapy depends on acuity, severity, clinical presentation, and etiology and includes supportive care. While corticosteroids are often used for specific forms of myocarditis (eg, eosinophilic or giant cell infiltrations), this practice is based on anecdotal evidence, and randomized clinical trials of optimal therapeutic interventions for acute myocarditis are needed.

Reader Comment Regarding "Vesiculobullous and Other Cutaneous Manifestations of COVID-19 Vaccines: A Scoping and Narrative Review".

Psychosocial and behavioral outcomes in the adult workforce during the COVID-19 pandemic: a 1-Year longitudinal survey. BACKGROUND: Efforts to limit the spread of COVID-19 have included public space closures, mask usage, and quarantining. Studies regarding the impact of these measures on the psychosocial and behavioral health outcomes of the workforce have focused frequently on healthcare employees. To expand the literature base, we deployed a one-year longitudinal survey among mostly non-healthcare employees assessing changes in select psychosocial outcomes, health behaviors, and COVID-19-related transmission prevention behaviors and perceptions. METHODS: We deployed the CAPTURE baseline survey across eight companies from November 20, 2020-February 8, 2021. The baseline survey included questions on psychosocial outcomes, health behaviors, and COVID-19 transmission prevention behaviors, with several questions containing a retrospective component to cover the time period prior to the pandemic. Additional questions on vaccination status and social support were subsequently added, and the updated survey deployed to the same baseline participants at three, six, and 12 months after baseline survey deployment. We analyzed data descriptively and performed Friedman's and subsequent Wilcoxon-signed rank tests, as appropriate, to compare data within and between time points. RESULTS: A total of 3607, 1788, 1545, and 1687 employees completed the baseline, 3-month, 6-month, and 12-month CAPTURE surveys, respectively, with 816 employees completing all four time points. Employees reported higher stress, anxiety, fatigue, and feelings of being unsafe across all time points compared to pre-pandemic. Time spent sleeping increased initially but returned to pre-pandemic levels at follow-up. Lower rates of physical activity and higher rates of non-work screen time and alcohol consumption relative to pre-pandemic were also reported. Over 90% of employees perceived wearing a mask, physical distancing, and receiving the COVID-19 vaccine as 'moderately' or 'very important' in preventing the spread of COVID-19 across all time points. CONCLUSIONS: Relative to pre-pandemic, poorer psychosocial outcomes and worsened health behaviors were observed across all time points, with values worse at the baseline and 12-month time points when COVID-19 surges were highest. While COVID-19 prevention behaviors were consistently deemed to be important by employees, the psychosocial outcome and health behavior data suggest the potential for harmful long-term effects of the pandemic on the well-being of non-healthcare employees.

Vaccine-Induced or Hybrid Immunity and COVID-19-Associated Mortality During the Omicron Wave. BACKGROUND: It is not yet entirely clear to what extent vaccine-induced or hybrid immunity offers protection from death during the omicron wave of the COVID-19 pandemic in Germany. METHODS: In this retrospective study, we evaluated 470 159 cases aged â‰¥ 60 years in the German federal state of Bavaria who tested positive for SARS-CoV-2 between 1 January and 30 June 2022. Cox models were used to estimate adjusted hazard ratios (aHR) for dying within 60 days of the infection, depending on sex, age, time of infection, and different levels of immunity. RESULTS: Over the period of observation, 3836 COVID-19-associated deaths were registered (case fatality rate 0.82%). The risk of death was significantly lower in cases with a higher level of immunity than in unvaccinated cases (aHR for a full primary level of immunity if reached less than 6 months before the date of the infection: 0.30, 95% confidence interval [0.23; 0.39]; if reached more than 6 months before: aHR 0.46 [0.35; 0.60]). A boosted level of immunity lowered the risk of death even further (if reached less than 3 months

before the infection: aHR 0.17 [0.15; 0.20]; if reached more than 3 months before: aHR 0.25 [0.21; 0.29]). CONCLUSION: Among elderly persons in Bavaria, a higher immunity level was associated with a substantial degree of protection against death during the Omicron wave; however, the strength of protection may have diminished somewhat over time.

Factors associated with receipt of COVID-19 vaccination and SARS-CoV-2 seropositivity among healthcare workers in Albania (February 2021-June 2022): secondary analysis of a prospective cohort study. BACKGROUND: Healthcare workers (HCWs) have been disproportionally affected by COVID-19. We investigated factors associated with two- and three-dose COVID-19 vaccine uptake and SARS-CoV-2 seropositivity among 1504 HCWs enrolled (19 February-7 May 2021) in a prospective COVID-19 vaccine effectiveness cohort in Albania through a secondary analysis. METHODS: We collected sociodemographic, occupational, health, prior SARS-CoV-2 infection, and COVID-19 vaccination data from all HCWs at enrollment. Vaccination status was assessed weekly through June 2022. A serum sample was collected from all participants at enrollment and tested for anti-spike SARS-CoV-2 antibodies. We analyzed HCWs characteristics and outcomes using multivariable logistic regression. FINDINGS: By 11 June 2022, 1337 (88.9%) HCWs had received two COVID-19 vaccine doses, of whom 255 (19.1%) received a booster. Factors significantly associated with receiving three doses (adjusted odds ratio (aOR), 95% CIs) were being â‰¥35 years (35-44 years: 1.76 (1.05-2.97); 45-54 years: 3.11 (1.92-5.05); â‰¥55 years: 3.38 (2.04-5.59)) and vaccinated against influenza (1.78; 1.20-2.64). Booster dose receipt was lower among females (0.58; 0.41-0.81), previously infected (0.67; 0.48-0.93), nurses and midwives (0.31; 0.22-0.45), and support staff (0.19; 0.11-0.32). Overall 1076 (72%) were SARS-CoV-2 seropositive at enrollment. Nurses and midwifes (1.45; 1.05-2.02), support staff (1.57; 1.03-2.41), and HCWs performing aerosol-generating procedures (AGPs) (1.40; 1.01-1.94) had higher odds of being seropositive, while smokers had reduced odds (0.55; 0.40-0.75). INTERPRETATION: In a large cohort of Albanian HCWs, COVID-19 vaccine booster dose uptake was very low, particularly among younger, female, and non-physician HCWs, despite evidence demonstrating the added benefit of boosters in preventing infection and severe disease. Reasons behind these disparities should be explored to develop targeted strategies in order to promote uptake in this critical population. SARS-CoV-2 seroprevalence was higher among non-physicians and HCWs performing APGs. A better understanding of the factors contributing to these differences is needed to inform interventions that could reduce infections in the future. FUNDING: This study was funded by the Task Force for Global Health (US Centers for Disease Control (CDC) cooperative agreement # NU51IP000873) and the World Health Organization, Regional Office for Europe.

Effects of Omicron Infection and Changes in Serum Antibody Response to Wild-Type, Delta, and Omicron After a Booster Dose With BNT163b2 Vaccine in Korean Healthcare Workers. BACKGROUND: Although the primary vaccine coverage rate for coronavirus disease 2019 (COVID-19) in South Korea has exceeded 80%, the coronavirus continues to spread, with reports of a rapid decline in vaccine effectiveness. South Korea is administering booster shots despite concerns about the effectiveness of the existing vaccine. METHODS: Neutralizing antibody inhibition scores were evaluated in two cohorts after the booster dose. For the first cohort, neutralizing activity against the wild-type, delta, and omicron variants after the booster dose was evaluated. For the second cohort, we assessed the difference in neutralizing activity between the omicron infected and uninfected groups after booster vaccination. We also compared the effectiveness and adverse events (AEs) between homologous and heterologous booster doses for BNT162b2 or ChAdOx1 vaccines. RESULTS: A total of 105 healthcare workers (HCWs) that were additionally vaccinated with BNT162b2 at Soonchunhyang University Bucheon Hospital were enrolled in this study. Significantly higher surrogate virus neutralization test (sVNT) inhibition (%) was observed for the wild-type and delta variants compared to sVNT (%) for the omicron after the booster dose (97%, 98% vs. 75%; $P < 0.001$).

No significant difference in the neutralizing antibody inhibition score was found between variants in the BNT/BNT/BNT group (n = 48) and the ChA/ChA/BNT group (n = 57). Total AEs were not significantly different between the ChA/ChA/BNT group (85.96%) and the BNT/BNT group (95.83%; P = 0.11). In the second cohort with 58 HCWs, markedly higher sVNT inhibition to omicron was observed in the omicron-infected group (95.13%) compared to the uninfected group (mean of 48.44%; P < 0.001) after four months of the booster dose. In 41 HCWs (39.0%) infected with the omicron variant, no difference in immunogenicity, AEs, or effectiveness between homogeneous and heterogeneous boosters was observed. CONCLUSION: Booster vaccination with BNT162b2 was significantly less effective for the neutralizing antibody responses to omicron variant compared to the wild-type or delta variant in healthy population. Humoral immunogenicity was sustained significantly high after 4 months of booster vaccine in the infected population after booster vaccination. Further studies are needed to understand the characteristics of immunogenicity in these populations.

Sequential provocation of Ekbom's syndrome and acute mania following AstraZeneca COVID-19 vaccination. ChAdOx1 nCoV-19 vaccine (so called AZ vaccine), is widely used to prevent the SARS-CoV-2 pandemic and shows powerful effectiveness to deter community transmission. There are common immunogenicity-related side effects such as fever, myalgia, lethargy, and headache; however, rare report on the neuropsychiatric problems (Ramasamy et al., 2021). In Taiwan, more than 15,200,000 doses of AZ vaccine were injected by the end of 2022. Here we presented a unique case with separated episode of Ekbom's syndrome, also called delusion of parasitosis, and mania following successive AZ vaccination in three-month interval.

Lack of association between vaccination rates and excess mortality in Cyprus during the COVID-19 pandemic. BACKGROUND: It has been claimed that COVID-19 vaccination is associated with excess mortality during the COVID-19 pandemic, a claim that contributes to vaccine hesitancy. We examined whether all-cause mortality has actually increased in Cyprus during the first two pandemic years, and whether any increases are associated with vaccination rates. METHODS: We calculated weekly excess mortality for Cyprus between January 2020 and June 2022, overall and by age group, using both a Distributed Lag Nonlinear Model (DLNM) adjusted for mean daily temperature, and the EuroMOMO algorithm. Excess deaths were regressed on the weekly number of confirmed COVID-19 deaths and on weekly first-dose vaccinations, also using a DLNM to explore the lag-response dimension. RESULTS: 552 excess deaths were observed in Cyprus during the study period (95% CI: 508-597) as opposed to 1306 confirmed COVID-19 deaths. No association between excess deaths and vaccination rates was found overall and for any age group except 18-49Â years, among whom 1.09 excess deaths (95% CI: 0.27-1.91) per 10,000 vaccinations were estimated during the first 8Â weeks post-vaccination. However, detailed cause-of-death examination identified just two such deaths potentially linked to vaccination, therefore this association is spurious and attributable to random error. CONCLUSIONS: Excess mortality was moderately increased in Cyprus during the COVID-19 pandemic, primarily as a result of laboratory-confirmed COVID-19 deaths. No relationship was found between vaccination rates and all-cause mortality, demonstrating the excellent safety profile of COVID-19 vaccines.

Safety of COVID-19 vaccines during pregnancy: A systematic review and meta-analysis. BACKGROUND: Assessment of COVID-19 vaccines safety during pregnancy is urgently needed. METHODS: We conducted a systematic review and meta-analysis to evaluate the safety of COVID-19 vaccines, including their components and technological platforms used in other vaccines during pregnancy and animal studies to complement direct evidence. We searched literature databases from its inception to September 2021 without language restriction, COVID-19 vaccine websites, and reference lists of other systematic reviews and the included studies. Pairs of reviewers independently selected, data extracted, and assessed the risk of bias of the studies. Discrepancies were resolved by

consensus. (PROSPERO CRD42021234185). RESULTS: We retrieved 8,837 records from the literature search; 71 studies were included, involving 17,719,495 pregnant persons and 389 pregnant animals. Most studies (94%) were conducted in high-income countries, were cohort studies (51%), and 15% were classified as high risk of bias. We identified nine COVID-19 vaccine studies, seven involving 309,164 pregnant persons, mostly exposed to mRNA vaccines. Among non-COVID-19 vaccines, the most frequent exposures were AS03 and aluminum-based adjuvants. A meta-analysis of studies that adjusted for potential confounders showed no association with adverse outcomes, regardless of the vaccine or the trimester of vaccination. Neither the reported rates of adverse pregnancy outcomes nor reactogenicity exceeded expected background rates, which was the case for ASO3- or aluminum-adjuvanted non-COVID-19 vaccines in the proportion meta-analyses of uncontrolled studies/arms. The only exception was postpartum hemorrhage after COVID-19 vaccination (10.40%; 95% CI: 6.49-15.10%), reported by two studies; however, the comparison with non-exposed pregnant persons, available for one study, found non-statistically significant differences (adjusted OR 1.09; 95% CI 0.56-2.12). Animal studies showed consistent results with studies in pregnant persons. CONCLUSION: We found no safety concerns for currently administered COVID-19 vaccines during pregnancy. Additional experimental and real-world evidence could enhance vaccination coverage. Robust safety data for non-mRNA-based COVID-19 vaccines are still needed.

Spontaneous pneumomediastinum after BNT162b2 COVID-19 vaccination in adolescents.

Corneal perforation on Mooren ulcer after anti-COVID-19 vaccination: Correspondence.

SARS-CoV-2 Omicron boosting induces de novo B cell response in humans. The primary two-dose SARS-CoV-2 mRNA vaccine series are strongly immunogenic in humans, but the emergence of highly infectious variants necessitated additional doses and the development of vaccines aimed at the new variants(1-4). SARS-CoV-2 booster immunizations in humans primarily recruit pre-existing memory B cells(5-9). However, it remains unclear whether the additional doses induce germinal centre reactions whereby re-engaged B cells can further mature, and whether variant-derived vaccines can elicit responses to variant-specific epitopes. Here we show that boosting with an mRNA vaccine against the original monovalent SARS-CoV-2 mRNA vaccine or the bivalent B.1.351 and B.1.617.2 (Beta/Delta) mRNA vaccine induced robust spike-specific germinal centre B cell responses in humans. The germinal centre response persisted for at least eight weeks, leading to significantly more mutated antigen-specific bone marrow plasma cell and memory B cell compartments. Spike-binding monoclonal antibodies derived from memory B cells isolated from individuals boosted with either the original SARS-CoV-2 spike protein, bivalent Beta/Delta vaccine or a monovalent Omicron BA.1-based vaccine predominantly recognized the original SARS-CoV-2 spike protein. Nonetheless, using a more targeted sorting approach, we isolated monoclonal antibodies that recognized the BA.1 spike protein but not the original SARS-CoV-2 spike protein from individuals who received the mRNA-1273.529 booster; these antibodies were less mutated and recognized novel epitopes within the spike protein, suggesting that they originated from naive B cells. Thus, SARS-CoV-2 booster immunizations in humans induce robust germinal centre B cell responses and can generate de novo B cell responses targeting variant-specific epitopes.

CVSARRP: A framework to predict the risk of adverse to severe adverse reactions for 10855 diseases after COVID-19 vaccination. COVID-19 vaccines greatly reduce the risk of infection with SARS-CoV-2. However, some people have adverse reactions after vaccination, and these can sometimes be severe. Gender, age, vaccines, and especially certain diseases histories are related to severe adverse reactions following COVID-19 vaccination. However, there are thousands of diseases and only some are known to be related to these severe adverse reactions. The risk of severe adverse reactions with other diseases remains unknown. Therefore, there is a need for predictive studies to provide improved medical care and minimize risk. Herein, we analyzed the statistical results of existing

COVID-19 vaccine adverse reaction data and proposed a COVID-19 vaccine severe adverse reaction risk prediction method, named CVSARRP. The performance of the CVSARRP method was tested using the leave-one-out cross-validation approach. The correlation coefficient between the predicted and real risk is greater than 0.86. The CVSARRP method predicts the risk from adverse reactions to severe adverse reactions after COVID-19 vaccination for 10855 diseases. People with certain diseases, such as central nervous system diseases, heart diseases, urinary system disease, anemia, cancer, and respiratory tract disease, among others, may potentially have increased of severe adverse reactions following vaccination against COVID-19 and experiencing adverse events.

Mix-and-match COVID-19 vaccines trigger high antibody response after the third dose vaccine in Moroccan health care workers. Recent studies have shown that in individuals who have received two doses of COVID-19 vaccine, the level of IgG antibodies decreased over time. In addition, the resurgence of the epidemic due to variants has led the authorities in several countries, including Morocco, to extend the third dose to the entire adult population. In this study, we included 43 healthcare workers (HCWs) who were vaccinated with three doses. They were vaccinated with ChAdOx1 nCoV-19 for the first two doses and with BNT 162b2 or BBIBP-CorV vaccine for the third dose. Humoral response was assessed on the day of injection of the third dose of vaccine and one month after the third dose by measuring anti-receptor-binding domain (RBD) IgG levels. Seven months after the second dose, the median titer of anti-RBD IgG was higher in the group with a history of SARS-CoV-2 infection than in the group with no history of infection (1038 AU/mL vs. 76.05 AU/mL, respectively, pÂ =Â 0.003). One month after the third dose, a significant increase in median level of anti-RBD in both groups was observed: from 76.05 AU/mL to 6127 AU/mL in the group with no history of infection and from 1038 AU/mL to 14,412 AU/mL in the group with history of infection. Notably, the BNT 162b2 vaccine elicits a high titer of anti-RBD antibody compared to the BBIBP-CorV vaccine. Median antibody titers were 21,991 AU/mL and 3640 AU/mL for BNT 162b2 and BBIBP-CorV vaccines, respectively (pÂ =Â 0.0002). 23% of HCWs were infected with SARS-CoV-2 within the first two months after the third dose injection. However, all these patients developed mild symptoms and tested negative by RT-qPCR between 10 and 15Â days after the onset of symptoms. Our findings support that the third dose of COVID-19 vaccine significantly improves the humoral response and protects against the severe disease.

A Case Report of Acute Severe Necrotizing Pancreatitis following the Johnson & Johnson Vaccine against the Novel SARS-CoV-2. Acute pancreatitis is an inflammatory condition, which is a leading gastrointestinal cause of hospitalization in the United States. Several conditions are associated with acute pancreatitis. More recently, there have been a few cases reported of acute pancreatitis following the Pfizer-BioNTech COVID-19 mRNA vaccine. To our knowledge, no cases of acute pancreatitis have been yet reported following the Johnson & Johnson's Janssen COVID-19 vaccine (J& J vaccine). Herein we report a 34-year-old male with no significant past medical history admitted with acute necrotizing pancreatitis, the day following the receipt of the J&J vaccine. Based on the Naranjo and the modified Naranjo scale, the patient met the requirements for probable drug induced pancreatitis. This case report has the objective to raise awareness of a potentially severe side effect of the J&J vaccine. We hope to use this case to support screening all patients for previous history of acute pancreatitis before administration of the J& J vaccine.

Case report: Coronavirus Disease 2019 (COVID-19) modified RNA vaccination-induced Adult-Onset Still's Disease with fulminant myocarditis as initial presentation. Myocarditis is a rare complication of Coronavirus Disease 2019 (COVID-19) vaccination. We report a case of an elderly female who presented initially with acute myocarditis, fulminant heart failure, and atrial fibrillation after receiving a modified ribonucleic acid (mRNA) vaccine (BNT162b2). Unlike other patients with vaccine-induced myocarditis, she developed persistent fever, sore throat, polyarthralgia, diffuse

macular rash, and lymphadenopathy. After extensive investigation, she was diagnosed with post-vaccination Adult-Onset Still's Disease. The systemic inflammation gradually subsided after the use of non-steroidal anti-inflammatory drugs and systemic steroids. She was discharged from hospital with stable hemodynamics. Methotrexate was subsequently given to maintain long-term remission.
Response: Commentary: Bullous pemphigoid associated with COVID-19 vaccines: An Italian multicenter study.
A Case Report of Reactive Arthritis After COVID-19 AstraZeneca Vaccination. In early 2021, multiple vaccinations for the coronavirus disease 2019 (COVID-19) in various immunological formulations were administered successfully to humans worldwide. Although numerous encountered side effects were expected, there were some effects that were unexpected. We report a case of a patient who experienced a rare occurrence of reactive arthritis in the right knee joint that manifested insidiously as pain, heat, and swelling on the second day following vaccination with the Oxford-AstraZeneca COVID-19 vaccine. The patient underwent a series of investigations, confirming the suspected diagnosis and ruling out other possible diseases. The case was refractory to oral non-steroidal anti-inflammatory drugs. Thus, the treatment was shifted to intra-articular steroids. Although the treatment plan improved the symptoms of the patient noticeably, it did not resolve them. A rare possible side effect following COVID-19 vaccination is reactive arthritis, which often occurs in young and healthy individuals with no significant comorbidities.
A rare case of bilateral optic neuritis post-Covishield (ChAdOx1-S [recombinant]) vaccination. Multiple adverse effects have been reported in people receiving the COVID-19 vaccinations including few reports of optic neuritis. However, there is no report till date, of bilateral optic neuritis post-ChAdOx1-S (recombinant) vaccination. We report here, for the first time, such a case in a previously healthy woman. Although a direct causal relationship cannot be proven, there was a temporal association between the vaccination and the onset of optic neuritis. Some vaccine adjuvants inciting disproportionate systemic inflammation, molecular mimicry, and the hypercoagulable state seen after COVID-19 vaccination could be the possible causes for the development of optic neuritis. Clinicians should be aware of this adverse effect apart from various other adverse effects of COVID-19 vaccination.
Generalized morphea following COVID-19 vaccine: Case report and literature review. Physicians should be vigilant for COVID-19 vaccine side effects and investigate any associated cutaneous manifestations. This will ultimately facilitate better understanding and recognition of various skin reactions related to the vaccine.
One year follow up for case series of myocarditis following mRNA vaccination against SARS-CoV-2. In 2021, the first rounds of modified mRNA vaccines against SARS-CoV-2 were tested and deployed. The vaccines themselves had great efficacy against severe infection, with rare and minimal side effects. One adverse effect that was reported, however, was incidence of myocarditis seen amongst mostly young males after their second vaccination dose. The disease course was self-limited. This study group published a case series in August of 2021 of four cases of this phenomenon. This paper is a followup to the original case series, providing an updated literature review and expert recommendations concerning the safety and benefits of the vaccines.
Humoral and cellular immunity to SARS-COV-2 after vaccination with mRNA vaccines in PLWH with discordant immune response. Influence of the vaccine administered. BACKGROUND: Data on SARS-CoV-2 mRNA vaccine immunogenicity in people living with human immunodeficiency virus (PLWH) and discordant immune response (DIR) are currently limited. Therefore, we compare the immunogenicity of these vaccines in DIR and immunological responders (IR). METHODS: A prospective cohort that enrolled 89 participants. Finally, 22 IR and 24 DIR were analyzed before vaccination (T(0)), one (T(1)) and six months (T(2)) after receiving BNT162b2 or mRNA-1273 vaccine.

Additionally, 10 IR and 16 DIR were evaluated after a third dose (T(3)). Anti-S-RBD IgG, neutralizing antibodies (nAb), neutralization activity, and specific memory B cells were quantified. Furthermore, specific CD4(+) and CD8(+) responses were determined by intracellular cytokine staining and polyfunctionality indexes (Pindex). RESULTS: At T(1), all participants developed anti-S-RBD. 100% IR developed nAb compared to 83.3% DIR. Spike-specific B cells were detected in all IR and 21/24 DIR. Memory CD4(+) T cells responded in 5/9 IR and 7/9 DIR, mainly based on the expression of IFN-Î³ and TNF-Î±, with a higher Pindex in DIR. Memory CD8(+) T cells responded in only four participants in each group. At T(2), anti-S-RBD and nAb titers were higher in DIR than in IR. In both groups, there was an increase in specific B memory cells, higher in DIR. Six IR and five DIR maintained a specific memory CD4(+) response. Memory CD8(+) response was preserved in IR but was lost in DIR. In a multivariate linear regression analysis, receiving mRNA-1273 instead of BNT162b2 played a prominent role in the results. CONCLUSIONS: Our data suggest that PLWH with DIR can mount an immune response similar to those with higher CD4(+), provided they receive the mRNA-1273 vaccine instead of others less immunogenic.

Optimal time for COVID-19 vaccination in rituximab-treated dermatologic patients. BACKGROUND: By depleting circulating B lymphocytes, rituximab time-dependently suppresses coronavirus disease 2019 (COVID-19) vaccines' humoral immunogenicity for a prolonged period. The optimal time to vaccinate rituximab-exposed immune-mediated dermatologic disease (IMDD) patients is currently unclear. OBJECTIVE: To estimate the vaccination timeframe that equalized the occurrence of humoral immunogenicity outcomes between rituximab-exposed and rituximab-naÃ¯ve IMDD patients. METHODS: This retrospective cohort study recruited rituximab-exposed and age-matched rituximab-naÃ¯ve subjects tested for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-specific immunity post-vaccination. Baseline clinical and immunological data (i.e., immunoglobulin levels, lymphocyte immunophenotyping) and SARS-CoV-2-specific immunity levels were extracted. The outcomes compared were the percentages of subjects who produced neutralizing antibodies (seroconversion rates, SR) and SARS-CoV-2-specific IgG levels among seroconverters. The outcomes were first analyzed using multiple regressions adjusted for the effects of corticosteroid use, steroid-spearing agents, and pre-vaccination immunological status (i.e., IgM levels, the percentages of the total, naÃ¯ve, and memory B lymphocytes) to identify rituximab-related immunogenicity outcomes. The rituximab-related outcome differences with a 95% confidence interval (CI) between groups were calculated, starting by including every subject and then narrowing down to those with longer rituximab-to-vaccination intervals (â‰¥3, â‰¥6, â‰¥9, â‰¥12 months). The desirable cut-off performances were <25% outcome inferiority observed among rituximab-exposed subgroups compared to rituximab-naÃ¯ve subjects, and the positive likelihood ratio (LR+) for the corresponding outcomes â‰¥2. FINDINGS: Forty-five rituximab-exposed and 90 rituximab-naive subjects were included. The regression analysis demonstrated a negative association between rituximab exposure status and SR but not with SARS-CoV-2-specific IgG levels. Nine-month rituximab-to-vaccination cut-off fulfilled our prespecified diagnostic performance (SR difference between rituximab-exposed and rituximab-naÃ¯ve group [95%CI]: -2.6 [-23.3, 18.1], LR+: 2.6) and coincided with the repopulation of naÃ¯ve B lymphocytes in these patients. CONCLUSIONS: Nine months of rituximab-to-vaccination interval maximize the immunological benefits of COVID-19 vaccines while avoiding unnecessary delay in vaccination and rituximab treatment for IMDD patients.

Antibodies to SARS-CoV-2 in follicular fluids and their association with assisted reproduction. INTRODUCTION: Every second woman suffering from infertility asks for medical help. There is public concern that vaccination-induced antibodies (Ab) are negatively associated with fertility. A recent study has demonstrated an association between SARS-CoV-2 vaccination and a lower pregnancy rate in the subsequent 60 days. Consequently, Ab could affect fertility success in assisted reproduction.

METHODS: To address this question, we compared fertilization outcomes of vaccinated (n=35) and nonvaccinated (n=34) women. Paired serum samples and multiple follicular fluids (FF) (up to 10 from the same donor) were collected during the course of assisted reproduction and characterized for oocyte quality, the presence of Ab and trace element concentrations. RESULTS: The results showed a positive correlation of vaccination-induced neutralizing activity of SARS-CoV-2-Ab in serum and FF. On average, Ab concentrations in serum were higher than in the corresponding FF. However, wide variations in SARS-CoV-2 Ab titers were observed between different FF, correlating to trace element levels, even when retrieved from the same donor. DISCUSSION: Overall, FF contents are highly variable, but no negative association was observed between Ab in serum or FF and fertilization success and oocyte development, supporting the safety of SARS-CoV-2 vaccination during assisted reproduction.

Heterologous prime-boost immunisation with mRNA- and AdC68-based 2019-nCoV variant vaccines induces broad-spectrum immune responses in mice. The ongoing evolution of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 or 2019-nCoV) variants has been associated with the transmission and pathogenicity of COVID-19. Therefore, exploring the optimal immunisation strategy to improve the broad-spectrum cross-protection ability of COVID-19 vaccines is of great significance. Herein, we assessed different heterologous prime-boost strategies with chimpanzee adenovirus vector-based COVID-19 vaccines plus Wuhan-Hu-1 (WH-1) strain (AdW) and Beta variant (AdB) and mRNA-based COVID-19 vaccines plus WH-1 strain (ARW) and Omicron (B.1.1.529) variant (ARO) in 6-week-old female BALB/c mice. AdW and AdB were administered intramuscularly or intranasally, while ARW and ARO were administered intramuscularly. Intranasal or intramuscular vaccination with AdB followed by ARO booster exhibited the highest levels of cross-reactive IgG, pseudovirus-neutralising antibody (PNAb) responses, and angiotensin-converting enzyme-2 (ACE2)-binding inhibition rates against different 2019-nCoV variants among all vaccination groups. Moreover, intranasal AdB vaccination followed by ARO induced higher levels of IgA and neutralising antibody responses against live 2019-nCoV than intramuscular AdB vaccination followed by ARO. A single dose of AdB administered intranasally or intramuscularly induced broader cross-NAb responses than AdW. Th1-biased cellular immune response was induced in all vaccination groups. Intramuscular vaccination-only groups exhibited higher levels of Th1 cytokines than intranasal vaccination-only and intranasal vaccination-containing groups. However, no obvious differences were found in the levels of Th2 cytokines between the control and all vaccination groups. Our findings provide a basis for exploring vaccination strategies against different 2019-nCoV variants to achieve high broad-spectrum immune efficacy.

Immunoglobulin G4-related Hepatopathy after COVID-19 Vaccination. An 84-year-old woman with IgG4-related disease presented with jaundice and liver dysfunction after coronavirus disease 2019 (COVID-19) vaccination. Serum IgG4 levels were elevated. Diagnostic imaging showed no stenotic lesions in the bile ducts. A liver biopsy was performed because of the enlarged liver. Infiltration of IgG4-positive plasma cells, which accounted for approximately 74% of total plasma cells, was found in the portal area, but there was no evidence of periportal hepatitis, and inflammatory cell infiltration into the lobular space was minimal. IgG4-related hepatopathy was diagnosed. The patient achieved spontaneous remission with no treatment and only follow-up and remains under observation at the time of writing.

Vaccine perceptions among Black adults with long COVID. OBJECTIVES: Low uptake of COVID vaccines within Black communities is a concern given the stark racial inequities associated with the pandemic. Prior research details COVID vaccine perceptions within the general population and Black communities specifically. However, Black individuals with long COVID may be more or less receptive to future COVID vaccination than their peers without long COVID. The impact of COVID vaccination on

long COVID symptoms is still controversial, since some studies suggest that vaccination can improve long COVID symptoms, whereas other studies report no significant change in symptoms or a worsening of symptoms. In this study, we aimed to characterize the factors influencing perceptions of COVID vaccines among Black adults with long COVID to inform future vaccine-related policies and interventions. DESIGN: We conducted 15 semi-structured, race-concordant interviews over Zoom with adults who reported physical or mental health symptoms that lingered for a month or more after acute COVID infection. We transcribed and anonymized the interviews and implemented inductive, thematic analysis to identify factors influencing COVID vaccine perceptions and the vaccine decision-making process. RESULTS: We identified five themes that influenced vaccine perceptions: (1) Vaccine safety and efficacy; (2) Social implications of vaccination status; (3) Navigating and interpreting vaccine-related information; (4) Possibility of abuse and exploitation by the government and scientific community; and (5) Long COVID status. Safety concerns were amplified by long COVID status and mistrust in social systems due to mistreatment of the Black community. CONCLUSIONS: Among the factors influencing COVID vaccine perceptions, participants reported a desire to avoid reinfection and a negative immune response. As COVID reinfection and long COVID become more common, achieving adequate uptake of COVID vaccines and boosters may require approaches that are tailored in partnership with the long COVID patient community.

Neutralization of Wild-Type and Alpha SARS-CoV-2 Variant by CoronaVacÂ® Vaccine and Natural Infection- Induced Antibodies. One of the immune responses desired to be achieved by SARS-CoV-2 vaccination is to create neutralizing antibodies (nAbs), thus preventing the development and spread of infection. The aim of this study was to investigate the seropositivity rate, anti-spike antibody levels, and neutralizing capacity of these antibodies against wild type (WT) and alpha variants in serum samples of individuals who had been naturally infected or vaccinated with CoronaVacÂ®. Total anti-spike antibody levels were determined in all samples. Neutralization assays were performed by the reduction of the cytopathic effect in Vero-E6 cells with infectious WT and alpha SARS-CoV-2 variants. Although both naturally infected and vaccinated individuals were all seropositive for antispike antibodies, 84.8% of the vaccinated group, and 89.3% of the naturally infected group had detectable nAbs. The nAbs titers were significantly higher in the naturally infected group for both WT and alfa variant of the virus as compared to the vaccinated individuals. In this study, it was observed that all individuals became seropositive six weeks after exposure to the vaccine or the virus. Moreover, naturally infected individuals had higher levels of nAbs than those vaccinated. The presence of nAbs against the alpha variant in both naturally infected and vaccinated individuals suggests that these antibodies may also be protective against infections, which may be caused by other variants, such as delta and omicron.

Patients with Post-COVID-19 Vaccination Myocarditis Have More Favorable Strain in Cardiac Magnetic Resonance Than Those With Viral Myocarditis. There have been reports of myocarditis following vaccination against COVID-19. We sought to describe cardiac magnetic resonance (CMR) findings among pediatric patients. Retrospective review at a large academic center of patients clinically diagnosed with post-vaccine myocarditis (PVM) undergoing CMR. Data collected included parametric mapping, ventricular function, and degree of late gadolinium enhancement (LGE). Post-processing strain analysis was performed using feature tracking. Strain values, T1/T2 values, and ventricular function were compared to age- and gender-matched controls with viral myocarditis using a Wilcoxon Signed Rank test. Among 12 patients with presumed PVM, 11 were male and 11 presented after the second vaccination dose, typically within 4Â days. All presented with chest pain and elevated troponin. 10 met MRI criteria for acute myocarditis. All had LGE typically seen in the lateral and inferior walls; only five had prolonged T1 values. 10 met criteria for edema based on skeletal muscle to myocardium signal intensity ratio and only 5 had prolonged T2 mapping values. Patients with PVM

had greater short-axis global circumferential and radial strain, right ventricle function, and cardiac output when compared to those with viral myocarditis. Patients with PVM have greater short-axis global circumferential and radial strains compared to those with viral myocarditis. LGE was universal in our cohort. Signal intensity ratios between skeletal muscle and myocardium may be more sensitive in identifying edema than T2 mapping. Overall, the impact on myocardial strain by CMR is less significant in PVM compared to more classic viral myocarditis.

SARS-CoV-2 variant transition dynamics are associated with vaccination rates, number of co-circulating variants, and convalescent immunity. BACKGROUND: Throughout the COVID-19 pandemic, the SARS-CoV-2 virus has continued to evolve, with new variants outcompeting existing variants and often leading to different dynamics of disease spread. METHODS: In this paper, we performed a retrospective analysis using longitudinal sequencing data to characterize differences in the speed, calendar timing, and magnitude of 16 SARS-CoV-2 variant waves/transitions for 230 countries and sub-country regions, between October 2020 and January 2023. We then clustered geographic locations in terms of their variant behavior across several Omicron variants, allowing us to identify groups of locations exhibiting similar variant transitions. Finally, we explored relationships between heterogeneity in these variant waves and time-varying factors, including vaccination status of the population, governmental policy, and the number of variants in simultaneous competition. FINDINGS: This work demonstrates associations between the behavior of an emerging variant and the number of co-circulating variants as well as the demographic context of the population. We also observed an association between high vaccination rates and variant transition dynamics prior to the Mu and Delta variant transitions. INTERPRETATION: These results suggest the behavior of an emergent variant may be sensitive to the immunologic and demographic context of its location. Additionally, this work represents the most comprehensive characterization of variant transitions globally to date. FUNDING: Laboratory Directed Research and Development (LDRD), Los Alamos National Laboratory.

COVID-19 vaccines and increased blood pressure.

Preclinical safety evaluation of intradermal SARS-CoV-2 inactivated vaccine (Vero cells) administration in macaques. Coronavirus disease 2019 (COVID-19) is an acute and highly pathogenic infectious disease in humans caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Six months after immunization with the SARS-CoV-2 vaccine, however, antibodies are almost depleted. Intradermal immunization could be a new way to solve the problem of nondurable antibody responses against SARS-CoV-2 or the poor immune protection against variant strains. We evaluated the preclinical safety of a SARS-CoV-2 vaccine for intradermal immunization in rhesus monkeys. The results showed that there were no obvious abnormalities in the general clinical condition, food intake, body weight or ophthalmologic examination except for a reaction at the local vaccination site. In the hematology examination, bone marrow imaging, serum biochemistry, and routine urine testing, the related indexes of each group fluctuated to different degrees after administration, but there was no dose-response or time-response correlation. The neutralization antibody and ELISpot results also showed that strong humoral and cellular immunity could be induced after vaccination, and the levels of neutralizing antibodies increased with certain dose- and time-response trends. The results of a repeated-administration toxicity test in rhesus monkeys intradermally inoculated with a SARS-CoV-2 inactivated vaccine showed good safety and immunogenicity.

Perniosis-like erythema after SARS-CoV2 infection reactivated by vaccination with inactivated virus.

Response to COVID-19 Vaccination Post-CAR T Therapy in Patients With Non-Hodgkin Lymphoma and Multiple Myeloma. COVID-19 adversely affects individuals with cancer. Several studies have found that seroconversion rates among patients with hematologic malignancies are suboptimal when compared to patients without cancer. Patients with non-Hodgkin lymphoma (NHL) and multiple

myeloma (MM) are immunocompromised due to impaired humoral and cellular immunity in addition to prescribed immunosuppressive therapy. Chimeric antigen receptor T-cell (CAR T) therapy is now widely used for NHL and MM, but little is known about seroconversion rates after COVID-19 vaccination among these populations. We evaluated SARS-CoV-2 spike-binding IgG antibody levels following COVID-19 vaccination among NHL and MM CAR T therapy recipients. Out of 104 CAR T infusions, 19 patients developed known COVID-19 infection post-CAR T. We tested 17 patients that received CAR T for antibody spike titers post COVID-19 vaccination, only 29 % (nÂ =Â 5) were able to mount a clinically relevant antibody response (>250 IU/mL).

Non-epileptic myoclonus status can be due to both SARS-CoV-2 infection and SARS-CoV-2 vaccination. SARS-CoV-2; Vaccination; Myoclonic status; EEG; COVID-19; Seizure.

The Association Between Receiving the Flu and COVID-19 Vaccines and Related Factors, Data from the StopFlu Campaign in Eight States and the District of Columbia, 2022. Given the evolving nature of the COVID-19 pandemic and the importance of vaccines, it is imperative to understand the relationships between receiving the COVID-19 vaccine and other vaccines, such as the flu vaccine. Data were obtained from a survey as part of an evaluation of the StopFlu Kaiser Permanente media campaign, promoting the flu and COVID-19 vaccines in communities of color across eight states and the District of Columbia. The outcome considered was receiving the COVID-19 vaccine. The exposure considered was receiving the flu vaccine. Covariates included demographic factors, and sources of trusted health information. Overall, 4,185 participants had complete data and were included the analysis. Logistic regression was used to assess the relationship between receiving the flu vaccine and COVID-19 vaccine. Among participants, 77.8% reported receiving the COVID-19 vaccine and 55.4% received the flu vaccine. After adjusting for demographics and sources of trusted health information, participants reporting receiving the flu vaccine had 5.18 times the odds of also receiving the COVID-19 vaccine [Adjusted Odds Ratio (AOR): 5.18 95% Confidence Interval (CI): 4.24-6.32]. Trusting advice from a doctor and healthcare organization also had increased odds of receiving the COVID-19 vaccine. (AOR: 1.84 95%CI: 1.45-2.33, AOR: 2.08 95%CI: 1.64-2.63). This study demonstrates that promotion of one vaccine may influence uptake of other vaccines, which is important given the highly politicized nature of the COVID-19 vaccine. Further research could provide more insight into how promotion of a vaccine could impact behavior with regards to another.

Association of herpes zoster with COVID-19 vaccination: A systematic review and meta-analysis.

Neuromuscular Complications of COVID-19: Evidence from the Third Year of the Global Pandemic. Accumulating evidence in the third year of the global pandemic suggests that coronavirus disease 2019 (COVID-19) can cause neuromuscular complications during or after the acute phase of infection. Direct viral infection and immune-mediated mechanisms have been hypothesized. Furthermore, in patients with underlying autoimmune neuromuscular diseases, COVID-19 infection may trigger a disease flare. COVID-19 vaccines appear to be safe and effective at preventing severe illness from COVID-19. Certain vaccines are associated with an increased risk of Guillain-BarrÃ© syndrome and possibly Bell's palsy, but the absolute incidence is low, and benefits likely outweigh the risks. Newer prophylactic therapies and treatments are also becoming available for patients who may not mount a sufficient response to vaccination or have contraindications. In this article, we discuss the current available evidence on neuromuscular complications of COVID-19 and clinical considerations regarding vaccination.

Intraocular inflammation following COVID-19 vaccination: the clinical presentations. PURPOSE: The purpose of the study was to describe the cases of intraocular inflammation following COVID-19 vaccination (Comirnaty mRNA vaccine and CoronaVac vaccine) in Hong Kong. METHODS: This was a retrospective case series. RESULTS: This series includes 16 eyes among 10 female patients, with a mean age of 49.4â€‰Â±â€‰17.4Â years. Eight patients (80%) received the Pfizer-BioNTech mRNA

vaccination. Anterior uveitis was the most common presentation of postvaccination uveitis (50%) observed in our series, followed by intermediate uveitis (30%) and posterior uveitis (20%), respectively. A case of retinal vasculitis in the form of frosted branch angiitis, previously only reported following COVID-19 infection, was observed following COVID-19 vaccination. The median time from vaccination to uveitis onset was 15.2Â days (range: 0-6Â weeks). Inflammation in 11 out 16 eyes (68.75%) was completely resolved with topical steroids. CONCLUSION: Anterior uveitis was the predominant presentations of uveitis flare-ups following COVID-19 in our case series, followed by intermediate uveitis. Aligning with the current global literature concerning this issue, most of the uveitis attacks presented as anterior uveitis and were completely resolved with topical steroids. Consequently, the risk of uveitis flare-ups should not deter the public from receiving COVID-19 vaccines.

Systemic sclerosis and COVID-19 vaccine safety: short-term insights from theÂ global COVID-19 vaccination in autoimmune disease (COVAD) survey. The safety profile of COVID-19 vaccines is understudied in patients with systemic sclerosis (SSc). We compared short-term adverse events (AEs) 7Â days following vaccination in patients with SSc vs other rheumatic (AIRDs), non-rheumatic autoimmune diseases (nrAIDs), and healthy controls (HCs). The COVID-19 Vaccination in autoimmune diseases (COVAD) self-reporting e-survey was circulated by a group ofâ€‰>â€‰110 collaborators in 94 countries from March to December 2021. AEs were analyzed between different groups using regression models. Of 10,679 complete respondents [73.8% females, mean age 43Â years, 53% Caucasians], 478 had SSc. 83% had completed two vaccine doses, Pfizer-BioNTech (BNT162b2) (51%) was the most common. Minor and major AEs were reported by 81.2% and 3.3% SSc patients, respectively, and did not differ significantly with disease activity or different vaccine types, though with minor symptom differences. Frequencies of AEs were not affected by background immunosuppression, though SSc patients receiving hydroxychloroquine experienced fatigue less commonly (OR 0.4; 95% CI 0.2-0.8). Frequency of AEs and hospitalisations were similar to other AIRDs, nrAIDs, and HC except a higher risk of chills (OR 1.3; 95% CI 1.0-1.7) and fatigue (OR 1.3; 95% CI 1.0-1.6) compared to other AIRDs. COVID-19 vaccines were largely safe and well tolerated in SSc patients in the short term. Background immunosuppression and disease activity did not influence the vaccination-related short-term AEs.

Risk of disease relapse, safety and tolerability of SARS-CoV-2 vaccination in patients with chronic inflammatory neuropathies. BACKGROUND AND PURPOSE: The aim was to evaluate the risk of relapse after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination, and its safety and tolerability, in patients with chronic inflammatory neuropathies. METHODS: In this multicenter, cohort and case-crossover study, the risk of relapse associated with SARS-CoV-2 vaccination was assessed by comparing the frequency of relapse in chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) and multifocal motor neuropathy (MMN) patients who underwent or did not undergo vaccination. Frequency of relapse in the 3â€‰months prior to and after vaccination, and safety and tolerability of SARS-CoV-2 vaccination, were also assessed. RESULTS: In all, 336 patients were included (278 CIDP, 58â€‰MMN). Three hundred and seven (91%) patients underwent SARS-CoV-2 vaccination. Twenty-nine patients (9%) did not undergo vaccination. Mild and transient relapses were observed in 16 (5%) patients (13 CIDP, 3â€‰MMN) after SARS-CoV-2 vaccination and in none of the patients who did not undergo vaccination (relative risk [RR] 3.21, 95% confidence interval [CI] 0.19-52.25). There was no increase in the specific risk of relapse associated with type of vaccine or diagnosis. Comparison with the 3-month control period preceding vaccination revealed an increased risk of relapse after vaccination (RR 4.00, 95% CI 1.35-11.82), which was restricted to CIDP patients (RR 3.25, 95% CI 1.07-9.84). The safety profile of SARS-CoV-2 vaccination was characterized by short-term, mild-to-moderate local and systemic adverse events.

CONCLUSIONS: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination in CIDP and MMN patients does not seem to be associated with an increased risk of relapse at the primary end-point, although a slightly increased risk in CIDP patients was found compared to the 3â€‰months before vaccination.

COVID-19 Vaccination Program for Children: An Electronic Assessment of Symptoms. BACKGROUND: The evolution of COVID-19 vaccinations, which are mostly seen as crucial to curb the epidemic, is a result of remarkable and ground-breaking researches by scientists around the world. OBJECTIVE: The main goal of this study was to identify the significant adverse reactions of these vaccines, specifically in Homo sapiens. METHODS: In this research, a trial version of Qualtrics CoreXM software was used, and 18 questionnaires were prototyped as part of an online survey that was done in the northern part of India. RESULTS: The dataset included survey responses from 286 vaccinated (Corbevax) respondents' samples detailing their demographics, daily activities, type of gastronomic preferences, and any prior illnesses. The data were collected between March 24, 2022, and April 26, 2022. After analysis, 70.98% of respondents who took the first dose of the medication experienced side effects, while 50.62% of respondents who took the second dose of the medication stated the same. The major side effects reported were injection site pain, fever, tiredness, body ache, headache, etc. CONCLUSION: After conducting a poll on children (aged 12-18) who had received the COVID-19 vaccination, we concluded that immunizations rarely cause moderate side effects that are manageable.

Late onset granulomatous interstitial nephritis after booster dose of COVID-19 vaccination: CaseÂ reportÂ andÂ review of literature. Billions of doses of COVID-19 vaccine have been administered to combat the coronavirus pandemic. Though the vaccine is generally well tolerated, several cases of new onset or relapsing glomerulonephritis have been reported. In comparison, post-vaccination tubulointerstitial nephritis (TIN) has rarely been reported, mostly after the first or the second dose of the vaccine. Acute interstitial nephritis after booster dose of COVID-19 vaccination has not yet been reported. We report a case of acute granulomatous TIN shortly after the booster dose of Moderna vaccine. Our patient had no clinical evidence of renal injury after the first two doses of vaccine. Renal dysfunction was incidentally observed ~Â 1 month after the booster dose of vaccine. The patient responded to steroids with rapid improvement in kidney function. While it is difficult to ascertain the causal relationship between the vaccination and development of TIN, it is important to be vigilant about such delayed side effects of the vaccine.

Myocarditis and Pericarditis Related to mRNA COVID-19 Vaccination: A Case Report. INTRODUCTION: Reported cases after the post-commercialization phase of mRNA vaccines against COVID-19 have revealed that myocarditis and pericarditis may occur predominantly in male adolescents after the second dose of the vaccine. CASE PRESENTATION: We report two cases of cardiac disorders associated with mRNA COVID-19 vaccination, both of them in 15 year-old males. One of the patients presented acute pericarditis and the second one presented acute myocarditis with left ventricular dysfunction at hospital discharge. DISCUSSION AND CONCLUSION: Physicians should be aware with the typical manifestations of these cardiovascular events after the vaccination and report suspicious cases to pharmacovigilance agencies as soon as possible. The population should rely on the pharmacovigilance system that continues to recommend vaccination as the most effective strategy to reduce the negative consequences of the pandemic.

Case of Pilomatricoma After Coronavirus Disease 2019 Vaccination. The coronavirus disease 2019 (COVID-19), which is an infection caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), spread worldwide including Japan. This COVID-19 pandemic has changed the way of life around the world. To prevent the spread of infection, several COVID-19 vaccines were rapidly developed and their vaccination is recommended. While safety and effectiveness of these vaccines

have been shown, various adverse reactions occur with a certain frequency. Pilomatricoma is a benign subcutaneous tumor. Cause of pilomatricoma is unclear, however, an external insult could be a cause of part of pilomatricoma. Herein, we report a rare case of pilomatricoma after COVID-19 vaccination. Pilomatricoma should be included in the differential diagnoses of nodular lesions arising after vaccination sites, including the COVID-19 vaccine.
Coronavirus Disease 2019 Vaccination Is Associated With Reduced Outpatient Antibiotic Prescribing in Older Adults With Confirmed Severe Acute Respiratory Syndrome Coronavirus 2: A Population-Wide Cohort Study. BACKGROUND: Antibiotics are frequently prescribed unnecessarily in outpatients with coronavirus disease 2019 (COVID-19). We sought to evaluate factors associated with antibiotic prescribing in outpatients with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. METHODS: We performed a population-wide cohort study of outpatients aged â‰¥66 years with polymerase chain reaction-confirmed SARS-CoV-2 from 1 January 2020 to 31 December 2021 in Ontario, Canada. We determined rates of antibiotic prescribing within 1 week before (prediagnosis) and 1 week after (postdiagnosis) reporting of the positive SARS-CoV-2 result, compared to a self-controlled period (baseline). We evaluated predictors of prescribing, including a primary-series COVID-19 vaccination, in univariate and multivariable analyses. RESULTS: We identified 13 529 eligible nursing home residents and 50 885 eligible community-dwelling adults with SARS-CoV-2 infection. Of the nursing home and community residents, 3020 (22%) and 6372 (13%), respectively, received at least 1 antibiotic prescription within 1 week of a SARS-CoV-2 positive result. Antibiotic prescribing in nursing home and community residents occurred, respectively, at 15.0 and 10.5 prescriptions per 1000 person-days prediagnosis and 20.9 and 9.8 per 1000 person-days postdiagnosis, higher than the baseline rates of 4.3 and 2.5 prescriptions per 1000 person-days. COVID-19 vaccination was associated with reduced prescribing in nursing home and community residents, with adjusted postdiagnosis incidence rate ratios (95% confidence interval) of 0.7 (0.4-1) and 0.3 (0.3-0.4), respectively. CONCLUSIONS: Antibiotic prescribing was high and with little or no decline following SARS-CoV-2 diagnosis but was reduced in COVID-19-vaccinated individuals, highlighting the importance of vaccination and antibiotic stewardship in older adults with COVID-19.
Covishieldâ„¢ (ChAdOx1 nCoV-19) Vaccine-Induced Systemic Drug-Related Intertriginous and Flexural Exanthema in a Young Girl: A Case Report and Literature Review.
Vaccine-Related Eruptions of Papules and Plaques Following COVID-19 Vaccination - A Case Series.
Exacerbation of Lupus Erythematosus Panniculitis After Administration of COVID-19 mRNA Vaccine.
ChAdOx1 COVID-19 Vaccine-Associated Erythema Multiforme Major and Erythema Multiforme-Like Vasculitis: A Tale of Two Cases.
Acute disseminated encephalomyelitis (ADEM)-like illness in a pediatric patient following COVID-19 vaccination. Since the inception of the COVID-19 pandemic, over 60 cases of acute disseminated encephalomyelitis (ADEM) or ADEM-like clinically isolated syndromes have been linked to COVID-19 infection. However, cases linked to COVID-19 vaccination remain exceptionally rare. To the author's knowledge, eight published cases of ADEM or ADEM-like clinically isolated syndrome have been described after patients received COVID-19 vaccinations, all of which occurred in adults. This report details the first documented case of an ADEM-like illness in a pediatric patient, which developed shortly after receiving the Pfizer (Pfizer-BioNTech, Germany) COVID-19 vaccination. The patient made a near complete clinical recovery over 10 days after receiving a 5-day course of intravenous immunoglobulin therapy.
Acceptance and attitude towards the traditional chinese medicine among asymptomatic COVID-19 patients in Shanghai Fangcang hospital. OBJECTIVE: The Coronavirus Disease 2019 (COVID-19) has brought severe damage to global health and socioeconomics. In China, traditional Chinese medicine (TCM) is the most important complementary and alternative medicine (CAM) and it has

shown a beneficial role in the prevention and treatment of COVID-19. However, it is unknown whether patients are willing to accept TCM treatment. The objective of our study is to investigate the acceptance, attitude, and independent predictors of TCM among asymptomatic COVID-19 patients admitted to Shanghai fangcang hospital during the outbreak of the COVID-19 pandemic in Shanghai in 2022. METHODS: A cross-sectional study was conducted on asymptomatic COVID-19 patients in the largest fangcang hospital in Shanghai, China, from April 22, 2022, to May 25, 2022. Based on the literature review of previous similar studies, a self-report questionnaire was developed to assess the patients' attitude and acceptance of TCM, and a multivariate logistic regression analysis was conducted to determine the independent predictors of TCM acceptance. RESULTS: A total of 1,121 patients completed the survey, of whom 91.35% were willing to accept CAM treatment whereas 8.65% of participants showed no willingness. Multivariate logistic regression analysis revealed that the patients who have received two doses of COVID-19 vaccine (ORâ€‰=â€‰2.069, 95%CI: 1.029-4.162, Pâ€‰=â€‰0.041 vs. not received), understood the culture of TCM (ORâ€‰=â€‰2.293, 95%CI: 1.029-4.162, Pâ€‰=â€‰0.014 vs. not understood), thought the TCM treatment is safe (ORâ€‰=â€‰2.856, 95%CI: 1.334-6.112, Pâ€‰=â€‰0.007 vs. not thought), thought the TCM treatment is effective (ORâ€‰=â€‰2.724, 95%CI: 1.249-5.940, Pâ€‰=â€‰0.012 vs. not thought), and those who informed their attending physician if using TCM for treatment (ORâ€‰=â€‰3.455, 95%CI:1.867-6.392, Pâ€‰<â€‰0.001 vs. not informed) were more likely to accept TCM treatment. However, patients who thought TCM might delay your treatment (ORâ€‰=â€‰0.256, 95%CI: 0.142-0.462, Pâ€‰<â€‰0.001 not thought) was an independent predictor for unwillingness to accept TCM treatment. CONCLUSION: This study preliminarily investigated the acceptance, attitude, and predictors of intention to receive TCM among asymptomatic COVID-19 patients. It is recommended to increase the publicity of TCM, clarify the impact of TCM and communicate with attending doctors that meet the healthcare needs of asymptomatic COVID-19 patients.

COVID-19 Vaccination and New Onset Glomerular Disease: Results from the IRocGN2 International Registry. KEY POINTS: IgAN and MCD are the most common de novo glomerular diseases reported after COVID-19 vaccination, particularly after mRNA vaccination. Membranous nephropathy, pauci-immune GN, and collapsing GN have also been attributed to COVID-19 vaccination, some with dual histologies. Recovery of kidney function and proteinuria remission is more likely in IgAN and MCD by 4â€“6 months compared with the other glomerular diseases. BACKGROUND: Patients with de novo glomerular disease (GD) with various renal histologies have been reported after vaccination against SARS-CoV-2. Causality has not been established, and the long-term outcomes are not known. To better characterize the GDs and clinical courses/outcomes, we created the International Registry of COVID-19 vaccination and Glomerulonephritis to study in aggregate patients with de novo GN suspected after COVID-19 vaccine exposure. METHODS: A REDCap survey was used for anonymized data collection. Detailed information on vaccination type and timing and GD histology were recorded in the registry. We collected serial information on laboratory values (before and after vaccination and during follow-up), treatments, and kidney-related outcomes. RESULTS: Ninety-eight patients with GD were entered into the registry over 11 months from 44 centers throughout the world. Median follow-up was 89 days after diagnosis. IgA nephropathy (IgAN) and minimal change disease (MCD) were the most common kidney diseases reported. Recovery of kidney function and remission of proteinuria were more likely in IgAN and MCD at 4â€“6 months than with pauci-immune GN/vasculitis and membranous nephropathy. CONCLUSIONS: The development of GD after vaccination against SARS-CoV-2 may be a very rare adverse event. Temporal association is present for IgAN and MCD, but causality is not firmly established. Kidney outcomes for IgAN and MCD are favorable. No changes in vaccination risk-benefit assessment are recommended based on these findings.

New Onset Glomerular Disease Post-COVID-19 Vaccination: Is There a Link?

Keeping you posted: analysis of fertility-related social media posts after introduction of the COVID-19 vaccine. PURPOSE: Our objective was to analyse information and sentiments posted regarding the COVID-19 vaccine on fertility-related social media. MATERIALS AND METHODS: The first fifty accounts on Instagram and Twitter were identified with the terms: fertility doctor, fertility, OBGYN, infertility, TTC, IVF. Accounts were categorised as physician (PH), individual (ID), or fertility center/organisation (FCO). The vaccine was approved on 12/11/2020 and Instagram and Twitter posts dated 12/1/2020â€‰-â€‰2/28/2021 were reviewed. Posts were analysed for sentiment, mention of research studies (RS), national guidelines (NG), personal experience (PE), side effects (SE), reproductive related (RR) content and activity, including likes and comments. RESULTS: A total of 276 accounts were included. Sentiments towards the vaccine were largely positive (PH 90.3%, ID 71.4%, FCO 70%), or neutral (PH 9.7%, ID 28.6%, FCO 30%). Instagram accounts showed an increase in activity on vaccine posts compared to baseline by likes (PH 4.86% v 3.76%*, ID 7.5% v 6.37%*, FCO 2.49% v 0.52%*) and comments (PH 0.35% v 0.28%, ID 0.90% v 0.69%,* FCO 0.10% v 0.02%*). CONCLUSION: Most posts expressed positive sentiments towards the vaccine. Evaluating the sentiment of the COVID-19 vaccine as it relates to fertility on social media represents an opportunity for understanding both the patient's and health care professional's opinion on the subject. Given the potential devastating effects of misinformation on public health parameters, like vaccination, social media offers one avenue for healthcare professionals to engage online and work to make their presences more effective and influential.SHORT CONDENSATIONThis article analyses content and sentiments posted regarding the COVID-19 vaccine on fertility-related social media in order to offer a deeper understanding of available information and beliefs.

Stroke After SARS-CoV-2 mRNA Vaccine: A Nationwide Registry Study. BACKGROUND: Whether the SARS-CoV-2 mRNA vaccines may cause a transient increased stroke risk is uncertain. METHODS: In a registry-based cohort of all adult residents at December 27, 2020, in Norway, we linked individual-level data on COVID-19 vaccination, positive SARS-CoV-2 test, hospital admissions, cause of death, health care worker status, and nursing home resident status extracted from the Emergency Preparedness Register for COVID-19 in Norway. The cohort was followed for incident intracerebral bleeding, ischemic stroke, and subarachnoid hemorrhage within the first 28 days after the first/second or third dose of mRNA vaccination until January 24, 2022. Stroke risk after vaccination relative to time not exposed to vaccination was assessed by Cox proportional hazard ratio, adjusted for age, sex, risk groups, health care personnel, and nursing home resident. RESULTS: The cohort included 4â€‰139â€‰888 people, 49.8% women, and 6.7% were â‰¥80 years of age. During the first 28 days after an mRNA vaccine, 2104 people experienced a stroke (82% ischemic stroke, 13% intracerebral hemorrhage, and 5% subarachnoid hemorrhage). Adjusted hazard ratios (95% CI) after the first/second and after the third mRNA vaccine doses were 0.92 (0.85-1.00) and 0.89 (0.73-1.08) for ischemic stroke, 0.81 (0.67-0.98) and 1.05 (0.64-1.71) for intracerebral hemorrhage, and 0.64 (0.46-0.87) and 1.12 (0.57-2.19) for subarachnoid hemorrhage, respectively. CONCLUSIONS: We did not find increased risk of stroke during the first 28 days after an mRNA SARS-CoV-2 vaccine.

Post-vaccination COVID-19 infection among health care workers in a medical college hospital. INTRODUCTION: The world witnessed the pandemic of coronavirus disease (COVID)-19, caused by the virus Severe acute respiratory syndrome coronavirus 2, wreaking havoc on all our lives. The healthcare sector in India was faced with numerous challenges and struggles. The health care workers of this developing country risked everything against this pandemic, which put them at a higher risk of transmission of this infection. The risk of contracting Covid infection was not nullified, even though vaccination was introduced and was made available to these healthcare workers at the earliest. Hence this study aimed to understand the severity of COVID-19 infection, post covid vaccination.

MATERIALS AND METHODS: A cross-sectional study was conducted among 95 health care workers of Father Muller Medical College hospital who were infected with COVID-19, post their vaccination. A validated preformed questionnaire was used to collect the data from the participants. Data were analyzed using IBM SPSS 21(st) version. Descriptive statistics were used. A value of $P < 0.05$ was considered significant. RESULTS: In our study, 34.7% of health care workers required hospital admission for COVID-19 treatment. The mean duration is taken by health care workers to return to work after COVID was 12.59 days (SD-4.43). The severity of COVID-19 infection was significantly higher among females, the younger population, and the nursing cadre. CONCLUSION: The severity of COVID-19 infection among health care workers and long COVID can be reduced by timely vaccination.

A deep look into the storm: Israeli multi-center experience of coronavirus disease 2019 (COVID-19) in patients with autoimmune inflammatory rheumatic diseases before and after vaccinations. OBJECTIVE: We aimed to characterize the course of COVID-19 in autoimmune inflammatory rheumatic disease (AIIRD) patients in Israel, taking into consideration several remarkable aspects, including the outcomes of the different outbreaks, the effect of vaccination campaigns, and AIIRD activity post-recovery. METHODS: We established a national registry of AIIRD patients diagnosed with COVID-19, including demographic data, AIIRD diagnosis, duration and systemic involvement, comorbidities, date of COVID-19 diagnosis, clinical course, and dates of vaccinations. COVID-19 was diagnosed by a positive SARS-CoV-2 polymerase chain reaction. RESULTS: Israel experienced 4 outbreaks of COVID-19 until 30.11.2021. The first three outbreaks (1.3.2020 - 30.4.2021) comprised 298 AIIRD patients. 64.9% had a mild disease and 24.2% had a severe course; 161 (53.3%) patients were hospitalized, 27 (8.9%) died. The 4(th) outbreak (delta variant), starting 6 months after the beginning of the vaccination campaign comprised 110 patients. Despite similar demographic and clinical characteristics, a smaller proportion of AIIRD patients had negative outcomes as compared to the first 3 outbreaks, with regards to severity (16 patients,14.5%), hospitalization (29 patients, 26.4%) and death (7 patients, 6.4%). COVID-19 did not seem to influence the AIIRD activity 1-3 months post-recovery. CONCLUSIONS: COVID-19 is more severe and has an increased mortality in active AIIRD patients with systemic involvement, older age and comorbidities. Vaccination with 3 doses of the mRNA vaccine against SARS-CoV-2 protected from severe COVID-19, hospitalization and death during the 4(th) outbreak. The pattern of spread of COVID-19 in AIIRD patients was similar to the general population.

Immune responses and disease biomarker long-term changes following COVID-19 mRNA vaccination in a cohort of rheumatic disease patients. OBJECTIVE: To evaluate seroreactivity and disease biomarkers after 2 or 3 doses of COVID-19 mRNA vaccines in a cohort of patients with rheumatic diseases. METHODS: We collected biological samples longitudinally before and after 2-3 doses of COVID-19 mRNA vaccines from a cohort of patients with systemic lupus erythematosus (SLE), psoriatic arthritis, Sjogren's syndrome, ankylosing spondylitis, and inflammatory myositis. Anti-SARS-CoV-2 spike IgG and IgA and anti-dsDNA concentration were measured by ELISA. A surrogate neutralization assay was utilized to measure antibody neutralization ability. Lupus disease activity was measured by Systemic Lupus Erythematosus Disease Activity Index (SLEDAI). Expression of type I interferon signature was measured by real-time PCR. The frequency of extrafollicular double negative 2 (DN2) B cells was measured by flow cytometry. RESULTS: Most of the patients generated high SARS-CoV-2 spike-specific neutralizing antibodies comparable to those in healthy controls after 2 doses of mRNA vaccines. The antibody level declined over time but recovered after the third dose of the vaccine. Rituximab treatment substantially reduced antibody level and neutralization ability. Among SLE patients, no consistent increase in SLEDAI scores was observed post-vaccination. The changes in anti-dsDNA antibody concentration and expression of type I IFN signature genes were highly variable but did not show consistent or significant increases. Frequency of DN2 B cells remained largely stable.

CONCLUSION: Rheumatic disease patients without rituximab treatment have robust antibody responses toward COVID-19 mRNA vaccination. Disease activity and disease-associated biomarkers remain largely stable over 3 doses of vaccines, suggesting that COVID-19 mRNA vaccines may not exacerbate rheumatic diseases. KEY MESSAGES: Patients with rheumatic diseases mount robust humoral immunity towards 3 doses of COVID-19 mRNA vaccines.Disease activity and biomarkers remain stable following 3 doses of COVID-19 mRNA vaccines.

SARS-CoV-2 Antibody Response and Sustainability after a Third Dose of BNT162b2 in Healthcare Workers at Health Promotion Centers. The aim of this study was to determine the antibody response and the sustainability of immunogenicity after a third dose of BNT162b2 (BNT) in homologous [ChAdOx1 (ChAd)/ChAd, BNT/BNT, and mRNA-1273 (Moderna)/Moderna] and heterologous (ChAd/BNT) vaccinations of two primary doses with different schemes. This prospective observational study recruited consenting healthcare workers from 16 health checkup centers in 13 Korean cities. Three-point blood tests were analyzed as the antibody response after the third vaccination: T3-1 (1 month after the third dose), T3-3 (3 months after the third dose), and T3-4-10 (4-10 months after the third dose). SARS-CoV-2 antibodies were measured using a chemiluminescence microparticle immunoassay with SARS-CoV-2 IgG II Quant in the ARCHITECT system (Abbott Diagnostics). The antibody levels were significantly higher in the Moderna /Moderna and BNT/BNT groups than in the ChAd/ ChAd and ChAd/BNT groups ($p < 0.05$) at T3-1. At T3-3, antibody levels had decreased by 29.1% in the BNT/BNT group and by 45.3% in the ChAd/ChAd group compared with the antibody levels at T3-1. The anti-SARS-CoV-2 S-RBD IgG levels at T3-1 were significantly associated with having received mRNA vaccines as the two primary doses ($p < 0.001$). The third dose of BNT induced an increased humoral immune response in various vaccination schemes, which was more prominent for the two primary doses of homologous mRNA vaccines. However, this immunogenicity decreased within 3-10 months after the third dose. These results suggest that another booster dose (a fourth dose), which would be able to counteract SARS-CoV-2 variants, is needed.

Intranasal Boosting with Spike Fc-RBD of Wild-Type SARS-CoV-2 Induces Neutralizing Antibodies against Omicron Subvariants and Reduces Viral Load in the Nasal Turbinate of Mice. The emergence of new immune-evasive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants and subvariants outpaces the development of vaccines specific against the dominant circulating strains. In terms of the only accepted immune correlate of protection, the inactivated whole-virion vaccine using wild-type SARS-CoV-2 spike induces a much lower serum neutralizing antibody titre against the Omicron subvariants. Since the inactivated vaccine given intramuscularly is one of the most commonly used coronavirus disease 2019 (COVID-19) vaccines in developing regions, we tested the hypothesis that intranasal boosting after intramuscular priming would provide a broader level of protection. Here, we showed that one or two intranasal boosts with the Fc-linked trimeric spike receptor-binding domain from wild-type SARS-CoV-2 can induce significantly higher serum neutralizing antibodies against wild-type SARS-CoV-2 and the Omicron subvariants, including BA.5.2 and XBB.1, with a lower titre in the bronchoalveolar lavage of vaccinated Balb/c mice than vaccination with four intramuscular doses of inactivated whole virion vaccine. The intranasally vaccinated K18-hACE2-transgenic mice also had a significantly lower nasal turbinate viral load, suggesting a better protection of the upper airway, which is the predilected site of infection by Omicron subvariants. This intramuscular priming and intranasal boosting approach that achieves broader cross-protection against Omicron variants and subvariants may lengthen the interval required for changing the vaccine immunogen from months to years.

Adjustment of Immunosuppressants to Facilitate Anti-COVID-19 Antibody Production after mRNA Vaccination in Liver Transplant Recipients. Liver transplant recipients are immunocompromised and have low immunogenicity to produce antibodies in anti-COVID-19 vaccination. Whether

immunosuppressant adjustment could facilitate anti-COVID-19 antibody production in anti-COVID-19 mRNA vaccination is undetermined. Our patients were informed to temporarily suspend mycophenolate mofetil (MMF) or everolimus (EVR) for 2 weeks during both the 1st and 2nd doses of Moderna mRNA-1273 vaccine. A total of 183 recipients receiving two doses of Moderna mRNA-1273 vaccine were enrolled and grouped into tacrolimus monotherapy (MT, n = 41), and dual therapy with non-adjustment (NA, n = 23), single suspension (SS, n = 19) and double suspension (DS, n = 100) of MMF/EVR in two-dose mRNA vaccination. A total of 155 (84.7%) patients had a humoral response to vaccines in this study. The humoral response rates were 60.9%, 89.5%, 91.0% and 80.5% in NA, SS, DS, and MT group patients, respectively (p = 0.003). Multivariate analysis showed that favorable factors for humoral response were temporary suspension of MMF/EVR and monotherapy, and unfavorable factors were deceased donor liver transplantation, WBC count < 4000/uL, lymphocyte < 20% and tacrolimus trough level â‰¥ 6.8 ng/mL. In conclusion, temporary two-week suspension of anti-proliferation immunosuppressants could create a window to facilitate antibody production during anti-COVID-19 mRNA vaccination. This concept may be applied to other vaccinations in liver transplant recipients.

Impact of Previous Common Human Coronavirus Exposure on SARS-CoV-2-Specific T-Cell and Memory B-Cell Response after mRNA-Based Vaccination. OBJECTIVE: T-cell responses against SARS-CoV-2 are observed in unexposed individuals, attributed to previous common human coronavirus (HCoV) infections. We evaluated the evolution of this T-cell cross-reactive response and the specific memory B-cells (MBCs) after the SARS-CoV-2 mRNA-based vaccination and its impact on incident SARS-CoV-2 infections. METHODS: This was a longitudinal study of 149 healthcare workers (HCWs) that included 85 unexposed individuals that were subdivided according to previous T-cell cross-reactivity, who were compared to 64 convalescent HCWs. Changes in specific T-cell response and memory B-cell (MBC) levels were compared at baseline and after two doses of the SARS-CoV-2 mRNA-based vaccine. RESULTS: A cross-reactive T-cell response was found in 59% of unexposed individuals before vaccination. Antibodies against HKU1 positively correlated with OC43 and 229E antibodies. Spike-specific MBCs was scarce in unexposed HCWs regardless of the presence of baseline T-cell cross-reactivity. After vaccination, 92% and 96% of unexposed HCWs with cross-reactive T-cells had CD4+ and CD8+ T-cell responses to the spike protein, respectively. Similar results to that were found in convalescents (83% and 92%, respectively). Contrarily, higher than that which was observed in unexposed individuals without T-cell cross-reactivity showed lower CD4+ and CD8+ T-cell responses (73% in both cases, p = 0.03). Nevertheless, previous cross-reactive T-cell response was not associated with higher levels of MBCs after vaccination in unexposed HCWs. During a follow-up of 434 days (IQR, 339-495) after vaccination, 49 HCWs (33%) became infected, with a significant positive correlation between spike-specific MBC levels and isotypes IgG+ and IgA+ after vaccination and a longer time to get infected. Interestingly, T-cell cross-reactivity did not reduce the time to vaccine breakthrough infections. CONCLUSION: While pre-existing T-cell cross-reactivity enhances the T-cell response after vaccination, it does not increase SARS-CoV-2-specific MBC levels in the absence of previous infection. Overall, the level of specific MBCs determines the time to breakthrough infections, regardless of the presence of T-cell cross-reactivity.

The Kinetics of Humoral and Cellular Responses after the Booster Dose of COVID-19 Vaccine in Inflammatory Arthritis Patients. Impaired immunogenicity of COVID-19 vaccinations in inflammatory arthritis (IA) patients results in diminished immunity. However, optimal booster vaccination regimens are still unknown. Therefore, this study aimed to assess the kinetics of humoral and cellular responses in IA patients after the COVID-19 booster. In 29 IA patients and 16 healthy controls (HC), humoral responses (level of IgG antibodies) and cellular responses (IFN-Î³ production) were assessed before (T0), after 4 weeks (T1), and after more than 6 months (T2) from the booster

vaccination with BNT162b2. IA patients, but not HC, showed lower anti-S-IgG concentration and IGRA fold change at T2 compared to T1 ($p = 0.026$ and $p = 0.031$). Furthermore, in IA patients the level of cellular response at T2 returned to the pre-booster level (T0). All immunomodulatory drugs, except IL-6 and IL-17 inhibitors for the humoral and IL-17 inhibitors for the cellular response, impaired the immunogenicity of the booster dose at T2. Our study showed impaired kinetics of both humoral and cellular responses after the booster dose of the COVID-19 vaccine in IA patients, which, in the case of cellular response, did not allow the vaccination effect to be maintained for more than 6 months. Repetitive vaccination with subsequent booster doses seems to be necessary for IA patients.

Sustained Low Incidence of Severe and Fatal COVID-19 Following Widespread Infection Induced Immunity after the Omicron (BA.1) Dominant in Gauteng, South Africa: An Observational Study. We conducted an epidemiologic survey to determine the seroprevalence of SARS-CoV-2 anti-nucleocapsid (anti-N) and anti-spike (anti-S) protein IgG from 1 March to 11 April 2022 after the BA.1-dominant wave had subsided in South Africa and prior to another wave dominated by the BA.4 and BA.5 (BA.4/BA.5) sub-lineages. We also analysed epidemiologic trends in Gauteng Province for cases, hospitalizations, recorded deaths, and excess deaths were evaluated from the inception of the pandemic through 17 November 2022. Despite only 26.7% (1995/7470) of individuals having received a COVID-19 vaccine, the overall seropositivity for SARS-CoV-2 was 90.9% (95% confidence interval (CI), 90.2 to 91.5) at the end of the BA.1 wave, and 64% (95% CI, 61.8 to 65.9) of individuals were infected during the BA.1-dominant wave. The SARS-CoV-2 infection fatality risk was 16.5-22.3 times lower in the BA.1-dominant wave compared with the pre-BA.1 waves for recorded deaths (0.02% vs. 0.33%) and estimated excess mortality (0.03% vs. 0.67%). Although there are ongoing cases of COVID-19 infections, hospitalization and death, there has not been any meaningful resurgence of COVID-19 since the BA.1-dominant wave despite only 37.8% coverage by at least a single dose of COVID-19 vaccine in Gauteng, South Africa.

Follow-Up of Side Effects throughout the Entire Course of Coronavirus Vaccination. Vaccines are considered the best protective means against coronavirus infection. There is increasing interest in reporting the side effects of vaccines, especially for individuals younger than 18 years old. Accordingly, this analytical cohort study aims to report on the side effects of adult and young individuals who received vaccination within 24 h, 72 h, 5 days, and 1 week through the entire course of vaccination (ECoV). A validated online survey was used to collect information. In total, 1069 individuals were completely followed. Most individuals received the Pfizer vaccine (59.6%). Most individuals had received two doses (69.4%). Very strong and statistically significant associations with side effects ($p < 0.05$, Phi ($\hat{I}¦$) > 0.25) throughout the ECoV were reported for the type of vaccine and female gender. Non-smokers reported weak statistically significant associations. Fatigue and localized pain were the most commonly reported side effect, with onset within 24 h and duration of less than 72 h. The prevalence of reported side effects was statistically significantly higher among young individuals (<18 years old) than among adults ($X(2)$ (1) $=7.6$, $p = 0.006$. Phi $Ï† = 0.11$).

Immune Response Related to Lymphadenopathy Post COVID-19 Vaccination. Mass vaccination against coronavirus disease 2019 (COVID-19) is a global health strategy to control the COVID-19 pandemic. With the increasing number of vaccinations, COVID-19 vaccine-associated lymphadenopathy (C19-VAL) has been frequently reported. Current findings emphasize the characteristics of C19-VAL. The mechanism of C19-VAL is complicated to explore. Accumulated reports separately show that C19-VAL incidence is associated with receiver age and gender, reactive change within lymph nodes (LN), etc. We constructed a systematic review to evaluate the associated elements of C19-VAL and provide the mechanism of C19-VAL. Articles were searched from PubMed, Web of Science and EMBASE by using the processing of PRISMA. The search terms included combinations of the COVID-19 vaccine, COVID-19 vaccination and lymphadenopathy. Finally, sixty-

two articles have been included in this study. Our results show that days post-vaccination and B cell germinal center response are negatively correlated with C19-VAL incidence. The reactive change within LN is highly related to C19-VAL development. The study results suggested that strong vaccine immune response may contribute to the C19-VAL development and perhaps through the B cell germinal center response post vaccination. From the perspective of imaging interpretation, it is important to carefully distinguish reactive lymph nodes from metastatic lymph node enlargement through medical history collection or evaluation, especially in patients with underlying malignancy.

Patients' Post-/Long-COVID Symptoms, Vaccination and Functional Status-Findings from a State-Wide Online Screening Study. (1) Background: Better understanding of post-/long-COVID and limitations in daily life due to the symptoms as well as the preventive potential of vaccinations is required. It is unclear whether the number of doses and timepoint interrelate with the trajectory of post-/long-COVID. Accordingly, we examined how many patients positively screened with post-/long-COVID were vaccinated and whether the vaccination status and the timepoint of vaccination in relation to the acute infection were related to post-/long-COVID symptom severity and patients' functional status (i.e., perceived symptom severity, social participation, workability, and life satisfaction) over time. (2) Methods: 235 patients suffering from post-/long-COVID were recruited into an online survey in Bavaria, Germany, and assessed at baseline (T1), after approximately three weeks (T2), and approximately four weeks (T3). (3) Results: 3.5% were not vaccinated, 2.3% were vaccinated once, 20% twice, and 53.3% three times. Overall, 20.9% did not indicate their vaccination status. The timepoint of vaccination was related to symptom severity at T1, and symptoms decreased significantly over time. Being vaccinated more often was associated with lower life satisfaction and workability at T2. (4) Conclusions: This study provides evidence to get vaccinated against SARS-CoV-2, as it has shown that symptom severity was lower in those patients who were vaccinated prior to the infection compared to those getting infected prior to or at the same time of the vaccination. However, the finding that being vaccinated against SARS-CoV-2 more often correlated with lower life satisfaction and workability requires more attention. There is still an urgent necessity for appropriate treatment for overcoming long-/post-COVID symptoms efficiently. Vaccination can be part of prevention measures, and there is still a need for a communication strategy providing objective information about the usefulness and risks of vaccinations.

End-Stage Kidney Disease Resulting from Atypical Hemolytic Uremic Syndrome after Receiving AstraZeneca SARS-CoV-2 Vaccine: A Case Report. Hemolytic uremic syndrome (HUS) is classically described as a triad of nonimmune hemolytic anemia, thrombocytopenia, and acute kidney injury. Atypical HUS (aHUS) is a rare variant of the disease, and it accounts for 5-10% of the cases. It has a poor prognosis, with a mortality rate exceeding 25% and a more than 50% chance of progressing into end-stage kidney disease (ESKD). Genetic or acquired dysregulation of the alternative complement pathway is highly implicated in the pathogenesis of aHUS. Multiple triggers for aHUS have been described in the literature, including pregnancy, transplantation, vaccination, and viral infections. Herein, we report a case of a previously healthy 38-year-old male who developed microangiopathic hemolytic anemia and severe kidney impairment one week after receiving the first dose of AstraZeneca SARS-CoV-2 vaccine. A diagnosis of aHUS was made after excluding other causes of thrombotic microangiopathies. Treatment with plasma exchange, prednisone, and rituximab (375 mg/m(2)) once weekly for four doses resulted in improvement of his hematological parameters. However, he progressed to ESKD.

BMI-Associated Anti-Apolipoprotein A-1 Positivity in Healthy Adults after mRNA-Vaccination against COVID-19. Elevated anti-apolipoprotein A-1 (AAA1) antibody levels associated with cardiovascular risk have been observed in previously SARS-CoV-2-infected or COVID-19-vaccinated individuals. Since patient safety is generally a priority in vaccination, we sought to investigate AAA1

antibody levels in healthy adults after mRNA vaccination. We conducted a prospective cohort study in healthy adult volunteers recruited from military workers of the Transport Air Base in Prague who had received two doses of mRNA vaccines. Anti-apolipoprotein A-1 antibody levels were determined using ELISA from serum samples obtained at three and four time points after the first and second vaccine doses, respectively, within almost 17 weeks of follow-up. The transient AAA1 positivity rate achieved 24.1% (95% confidence interval CI: 15.4-34.7%), i.e., 20 out of 83 participants had at least one positive post-vaccination sample, with a repeat positivity confirmed in only 5 of them. This rate was associated with a BMI > 26 kg/m(2), as documented by an adjusted odds ratio of 6.79 (95% CI: 1.53-30.01). In addition, the highest positivity rate of 46.7% (21.3-73.4%) was observed in obese subjects with >30 kg/m(2). Since the incidence rate of AAA1 positivity remained unchanged after the first and second vaccine doses, any relationship between AAA1 positivity and mRNA vaccination was inconclusive. The present study showed a transient AAA1 positivity rate associated with overweight or obesity without a proven association with mRNA vaccination.

CVAPPS: A Cross-Sectional Study of SARS-CoV-2 Vaccine Acceptance, Perceptions, and Post-Vaccination Side Effects among Rheumatic Disease Patients in Kuwait. Purpose: We analyzed data collected for ascertaining severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine acceptance, perceptions, and post-vaccination side effects among Kuwaiti inflammatory rheumatic disease (IRD) patients. Methods: The current cross-sectional study was conducted on patients attending governmental rheumatology clinics across seven hospitals in Kuwait between July and September 2021. We included adults of both sexes who are national/residents of the state of Kuwait and who had a confirmed diagnosis of any IRD disease. Data on patients' demographics, history of IRD, SARS-CoV-2 infection, vaccination status, as well as post-vaccination side effects and disease flare were collected from the included participants through a self-administered questionnaire. Stata MP/17 for macOS was used for statistical analyses. Results: We included 501 IRD patients, a group with a mean age of 43.38 years and a mean disease duration of 10.46 years. The majority of the included patients were female (79.8%), and the most common primary rheumatology diagnosis was rheumatoid arthritis (42.5%), followed by spondyloarthritis (19.4%) and systemic lupus erythematosus (19.0%). One hundred and five patients (21.0%) had SARS-CoV-2 infection confirmed by PCR-positive swab; of them, 17 patients were hospitalized. None of the included patients were using steroids alone. cDMARDs, bDMARDs, and sDMARDs were reported in 37.3%, 18.0%, and 3.8% of the patients, respectively. Three hundred and fifty-one patients (70.1%) were vaccinated; 40.9% received Pfizer/BioNTech, whereas 28.7% received AstraZeneca/Oxford vaccines. Fear that the vaccination will aggravate the condition or interfere with the present therapy and concerns about its effectiveness as well as its side effects were the most prevalent causes for refusing to accept the SARS-CoV-2 vaccine. Other patients were worried about the paucity of the data because individuals with IRD had been omitted from earlier research, resulting in a dearth of information. The commonly reported post-vaccination side effects were body ache/pain, fatigue, and pain at the injection site (32.1%, 30.3%, and 29.7%, respectively). IRD flare post-SARS-CoV-2 vaccination was self-reported in only 9 patients, and 342 did not report a flare. Conclusions: This study's findings highlight that SARS-CoV-2 vaccines have an acceptable safety profile, with the majority of their side effects being temporary and mild. The occurrence of flares was low after immunization. Reassurance and trust in the safety of the SARS-CoV-2 vaccination in IRD patients should be reassuring to rheumatologists and vaccine recipients.

New-Onset Arthritis Following COVID-19 Vaccination: A Systematic Review of Case Reports. Coronavirus disease 2019 (COVID-19) vaccine has effectively suppressed the spread of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and alleviated its symptoms, but there are also many adverse events. Joint diseases caused by COVID-19 vaccine have been reported in many

studies. Some are well-controlled arthritis patients who developed arthritis after COVID-19 vaccination, while others are new-onset joint pain and swelling problems after COVID-19 vaccination. The purpose of this systematic review is to examine the literature reports in existing databases and analyze the incidence of new-onset arthritis after COVID-19 vaccination. We included 31 eligible articles and described 45 patients, ranging in age from 17 to over 90, with more females than males. The majority (84.4%) of patients received the adenovirus vector vaccine (ChAdOx1) and the mRNA-based vaccine (BNT126b2 and mRNA-1273). Most (64.4%) patients developed joint-related symptoms after the first dose of vaccine, and 66.7% developed symptoms within the first week of vaccination. The joint symptoms involved were mainly joint swelling, joint pain, limited range of motion, and so on. A total of 71.1% of the patients involved multiple joints, both large and small; 28.9% of patients involved only a single joint. Some (33.3%) patients were confirmed by imaging, and the most common diagnoses were bursitis and synovitis. Two nonspecific inflammatory markers, erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP), were monitored in almost all cases, and all patients showed varying degrees of increase in these two markers. Most of the patients received the treatment of glucocorticoid drugs or nonsteroidal anti-inflammatory drugs (NSAIDs). Clinical symptoms markedly improved in most patients, with 26.7% making a full recovery and no relapse after a few months of follow-up. To determine whether there is a causal relationship between COVID-19 vaccination and the triggering of arthritis, large-scale and well-controlled research studies are needed in the future to verify this relationship and to further study its pathogenesis in detail. Clinicians should raise awareness of this complication with a view to early diagnosis and appropriate treatment.

Adverse Hematological Effects of COVID-19 Vaccination and Pathomechanisms of Low Acquired Immunity in Patients with Hematological Malignancies. The SARS-CoV-2 virus and the COVID-19 pandemic have spread across the world and severely impacted patients living with hematological conditions. Immunocompromised patients experience rapidly progressing symptoms following COVID-19 infection and are at high risk of death. In efforts to protect the vulnerable population, vaccination efforts have increased exponentially in the past 2 years. Although COVID-19 vaccination is safe and effective, mild to moderate side effects such as headache, fatigue, and soreness at the injection site have been reported. In addition, there are reports of rare side effects, including anaphylaxis, thrombosis with thrombocytopenia syndrome, Guillain-BarrÃ© Syndrome, myocarditis, and pericarditis after vaccination. Further, hematological abnormalities and a very low and transient response in patients with hematological conditions after vaccination raise concerns. The objective of this review is to first briefly discuss the hematological adverse effects associated with COVID-19 infection in general populations followed by critically analyzing the side effects and pathomechanisms of COVID-19 vaccination in immunocompromised patients with hematological and solid malignancies. We reviewed the published literature, with a focus on hematological abnormalities associated with COVID-19 infection followed by the hematological side effects of COVID-19 vaccination, and the mechanisms by which complications can occur. We extend this discussion to include the viability of vaccination efforts within immune-compromised patients. The primary aim is to provide clinicians with critical hematologic information on COVID-19 vaccination so that they can make informed decisions on how to protect their at-risk patients. The secondary goal is to clarify the adverse hematological effects associated with infection and vaccination within the general population to support continued vaccination within this group. There is a clear need to protect patients with hematological conditions from infection and modulate vaccine programs and procedures for these patients.

Is There a Difference in Immune Response to SARS-CoV-2 Vaccination between Liver and Lung Transplant Patients with Cystic Fibrosis? People with Cystic Fibrosis (CF), especially solid organ

transplant recipients, have been prioritized in the SARS-CoV-2 vaccination program. This study assesses antibody response of patients with CF who have undergone liver (CF-LI) or lung (CF-LU) transplantation, and compares results to published data of patients with solid organ transplantation without CF as underlying disease. Antibodies against the spike receptor-binding domain were measured within the routine visits at the CF Centre in Innsbruck, Austria, after the second and third doses of SARS-CoV-2 mRNA vaccines. We report on 13 adult CF patients who are recipients of solid organ transplant, including five CF-LI and eight CF-LU. Overall, 69% had measurable antibody response after two, and 83% after three doses of SARS-CoV-2 vaccines. In CF-LI, positive serological response amounted to 100% after two and three doses, while CF-LU showed only a 50% and a 71% response rate, respectively. Clear differences are seen between the CF-LI and CF-LU groups in our cohort, with worse response rate for lung transplant recipients. Immune response between CF-LI and CF-LU, therefore, must be considered in a differentiated manner, and the importance of booster vaccination is once more emphasized with these data.

T-Cell Response and Antibody Production Induced by the COVID-19 Booster Vaccine in Japanese Chronic Kidney Disease Patients Treated with Hemodialysis. Humoral and cellular responses are critical in understanding immune responses to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. Here, we evaluated these responses in hemodialysis (HD) patients after the booster vaccination. SARS-CoV-2 immunoglobulin (IgG) levels, neutralizing antibody titers, and the T-SPOT(Â®).COVID test (T-SPOT) were measured prior to, three weeks after, and three months after the booster administration. The HD group had significantly higher SARS-CoV-2 IgG levels and neutralizing antibody titers against the original strain at three weeks and three months after the booster vaccination compared to the control group, albeit the HD group had lower SARS-CoV-2 IgG levels and neutralizing antibody titers before the booster administration. Moreover, the HD group had significantly higher T-SPOT levels at all three time points compared to the control group. The HD group also had significantly higher local and systemic adverse reaction rates than the control group. By booster vaccination, HD patients could acquire more effective SARS-CoV-2-specific humoral and cellular immunity than the control group.

Levels of Neutralizing Antibodies against SARS-CoV-2 in Mothers and Neonates after Vaccination during Pregnancy. BACKGROUND: Maternal vaccination is safe and provides protection against COVID-19 in mothers and neonates, and it is necessary to evaluate its effect on the induction of immune responses through the levels of neutralizing antibodies present in maternal and neonatal blood. METHODS: An observational study with transversal analysis was carried out. Included in the research were neonates (<1 month) whose mothers had been immunized whilst pregnant with at least one dose of the vaccine BNT16b and had not shown any symptoms of COVID-19. The blood of the mothers and newborns was collected during the Guthrie test and sent to the laboratory for the detection of neutralizing antibodies against SARS-CoV-2. RESULTS: A total of 162 pairs of mothers and neonates were analyzed with an average age of 26.3 Â± 5.97 years and 13.4 Â± 6.90 days, respectively. All samples collected present neutralizing antibodies with an average percentage of 91% in the mothers and 92% in the neonates. The most satisfactory immune response was observed in neonates and mothers vaccinated during the second trimester of gestation. CONCLUSIONS: The vaccination of expectant mothers with the immunizer BNT162b2 has promoted a robust immunological response in both the mothers and the neonates.

Anaphylactic Reactions to COVID-19 Vaccines: An Updated Assessment Based on Pharmacovigilance Data. This study aimed at producing an updated assessment of the incidence of anaphylaxis associated with COVID-19 vaccines based on pharmacovigilance data. Anaphylactic reaction and anaphylactic shock data post-COVID-19-vaccination reported from week 52, 2020 to week 1 or week 2, 2023 were collected from the VAERS and EudraVigilance databases, respectively, and analyzed

comparatively. Incidence rates were calculated using the corresponding administered vaccine doses as denominators for all licensed vaccines and both platform types (mRNA or vectored). The latest data from the present analysis showed lower anaphylaxis incidence associated with COVID-19 vaccination compared to previous estimates from week 52, 2020 to week 39, 2021 (anaphylactic reaction: 8.96 (95% CI 8.80-9.11)/million doses overall (EEA: 14.19 (95% CI 13.92-14.47)/million/US: 3.17 (95% CI 3.03-3.31)/million); anaphylactic shock: 1.46 (95% CI 1.39-1.52)/million doses overall (EEA: 2.47 (95% CI 2.36-2.58)/million/US: 0.33 (95% CI 0.29-0.38)/million)). Incidence rates varied by vaccine and were higher as captured in EudraVigilance compared to the VAERS and for vectored compared to mRNA vaccines. Most reported cases had a favorable outcome. The extremely rare fatalities (overall rates across continents 0.04 (95% CI 0.03-0.06)/million doses for anaphylactic reaction and 0.02 (95% CI 0.01-0.03)/million vaccine doses for anaphylactic shock) were also associated with vector-rather than mRNA-based vaccines. The diminished incidence of anaphylaxis post-vaccination with COVID-19 vaccines offers assurance about their safety, as does the continuous potential adverse events monitoring through specialized pharmacovigilance databases.

Associations between the Self-Reported Likelihood of Receiving the COVID-19 Vaccine, Likelihood of Contracting COVID-19, Discrimination, and Anxiety/Depression by Sexual Orientation. There is limited evolving literature on COVID-19 vaccine uptake and its barriers among sexual minority populations (lesbian, gay, bisexual, transgender, and queer [LGBTQ]), despite their increased COVID-19 risk factors. We assessed the differences in intention to receive the COVID-19 vaccine by self-reported likelihood of contracting COVID-19, anxiety/depression, discrimination frequency, social distancing stress, and sociodemographic factors across sexual orientation. An online national cross-sectional survey was conducted in the United States between 13 May 2021, and 9 January 2022, among adults aged â‰¥18 (n = 5404). Sexual minority individuals had a lower intention of receiving the COVID-19 vaccine (65.62%) than heterosexual individuals (67.56%). Disaggregation by sexual orientation, however, showed that gay participants had a higher intention of COVID-19 vaccination (80.41%) and lesbian (62.63%), bisexual (64.08%), and non-heterosexual, non-LGB sexual minority (56.34%) respondents had lower intentions of receiving the COVID-19 vaccine than heterosexual respondents. Sexual orientation significantly moderated the association between the perceived likelihood of receiving the COVID-19 vaccine and the self-reported likelihood of contracting COVID-19, anxiety/depression symptoms, and discrimination. Our findings further underline the importance of improving vaccination efforts and access among sexual minority individuals and other vulnerable groups.

Encephalitis following COVID-19 Vaccination: A Systematic Review. BACKGROUND: Since the advent of global COVID-19 vaccination, several studies reported cases of encephalitis with its various subtypes following COVID-19 vaccinations. In this regard, we conducted a systematic review to investigate and characterize the clinical settings of these reported cases to aid in physician awareness and proper care provision. METHODS: We systematically searched PubMed, Web of Science, and Scopus and manually searched Google Scholar. Studies published until October 2022 were included. Demographic data, clinical features, vaccine data, treatment lines, and outcomes were extracted. RESULTS: A total of 65 patients from 52 studies were included. The mean age of patients was 46.82 Â± 19.25 years, 36 cases (55.4%) were males. AstraZeneca was the most-reported vaccine associated with encephalitis (38.5%) followed by Pfizer (33.8%), Moderna (16.9%), and others. Moat encephalitis cases occurred after the first dose of vaccination in 41/65 (66.1%). The mean time between vaccination and symptom onset was 9.97 Â± 7.16 days. Corticosteroids (86.2â€‰%) and immunosuppressants (81.5â€‰%) were the most used lines of treatment. The majority of affected individuals experienced a full recovery. CONCLUSION: Our study summarizes the current evidence of reported post-vaccination encephalitis, regarding clinical presentation, symptoms onset,

management, outcomes, and comorbid conditions; however, it fails to either acknowledge the incidence of occurrence or establish a causal relationship between various COVID-19 vaccines and encephalitis.

Is SARS-CoV-2 Vaccination of Subjects with a Prior History of Allergies Dangerous? Experiences in the Veneto Region of Italy. Adverse events after SARS-CoV-2 vaccinations have caused alarm to some individuals with previously diagnosed allergies. The aim of this study was to investigate whether the risk of adverse reactions was actually higher in this subgroup. To this end, we carried out an observational descriptive analysis of vaccines administered in a "protected setting" in the Veneto region of Italy between December 2020 and December 2022. Reactions were classified using systemic organic classification (SOC), and their severity was assessed using the criteria of the Italian Drug Agency (AIFA). A total of 421 subjects were vaccinated with 1050 doses, 95.0% of which were administered without adverse events. In all, 53 subjects reported 87 SOC reactions (1.6 reactions/person), and 18.3% of these reactions were severe. One person was hospitalized, but all subjects enjoyed complete remission. Reporting rates were 9.0%, 3.1%, and 1.2% for first, second, and third doses, respectively. The most frequent reactions involved the respiratory system (2.3%), the cutaneous and subcutaneous systems (2.1%), and the nervous system (1.7%). Multivariate analyses (adjOR (95% CI)) revealed that the probability of experiencing at least one reaction significantly declined with increases in age [0.95 (0.94-0.97)] and in the number of doses received, i.e., 75% [0.25 (0.13-0.49)] for second doses and 88% [0.12 (0.04-0.39)] for third doses. These results indicated that vaccinations could be safely administered; few reactions were reported, and there were no permanent adverse outcomes.

Could Prior COVID-19 Affect the Neutralizing Antibody after the Third BNT162b2 Booster Dose: A Longitudinal Study. Vaccination is an essential public health measure for preventing the spread of illness during this continuing COVID-19 epidemic. The immune response developed by the host or the continuation of the immunological response caused by vaccination is crucial since it might alter the epidemic's prognosis. In our study, we aimed to determine the titers of anti-S-RBD antibody and surrogate neutralizing antibody (snAb) formed before and after the third dose of the BNT162b2 vaccination (on the 15th, 60th, and 90th days) in healthy adults who did not have any comorbidity either with or without prior SARS-CoV-2 infection. In this longitudinal prospective study, 300 healthy persons were randomly included between January and February 2022, following two doses of BNT162b2 immunization and before a third dosage. Blood was drawn from the peripheral veins. SARS-CoV-2 NCP IgG and anti-S-RBD IgG levels were detected by the CMIA method, and a surrogate neutralizing antibody was seen by the ELISA method. Our study included 154 (51.3%) female and 146 (48.7%) male (total 300) participants. The participants' median age was 32.5 (IQR:24-38). It was discovered that 208 individuals (69.3%) had never been infected with SARS-CoV-2, whereas 92 participants (30.7%) had SARS-CoV-2 infections in the past. Anti-S-RBD IgG and nAb IH% levels increased 5.94- and 1.26-fold on day 15, 3.63- and 1.22-fold on day 60, and 2.33- and 1.26-fold on day 90 after the third BNT162b2 vaccine dosage compared to pre-vaccination values (Day 0). In addition, the decrease in anti-S-RBD IgG levels on the 60th and 90th days was significantly different in the group without prior SARS-CoV-2 infection compared to the group with past SARS-CoV-2 infection ($p < 0.05$). In conclusion, it was observed that prior SARS-CoV-2 infection and the third BNT162b2 vaccine dose led to a lower decrease in both nAb and anti-S-RBD IgG levels. To evaluate the vaccine's effectiveness and update immunization programs, however, it is necessary to perform multicenter, longer-term, and comprehensive investigations on healthy individuals without immune response issues, as there are still circulating variants.

Impact of the COVID-19 Pandemic on Influenza Vaccination and Associated Factors among Pregnant Women: A Cross-Sectional Study in Korea. Pregnant women are vulnerable to developing

influenza complications. Influenza vaccination during pregnancy is crucial to avoid infection. The COVID-19 pandemic might exacerbate fear and anxiety in pregnant women. The purpose of this study was to evaluate the effect of the COVID-19 pandemic on influenza vaccination and determine the factors associated with influenza vaccine acceptance among pregnant women in Korea. We conducted a cross-sectional study using an online survey in Korea. A survey questionnaire was distributed among pregnant or postpartum women within 1 year after delivery. Multivariate logistic regression analysis was performed to identify the factors associated with influenza vaccination among pregnant women. A total of 351 women were included in this study. Of them, 51.0% and 20.2% were vaccinated against influenza and COVID-19 during pregnancy, respectively. The majority of participants who had a history of influenza vaccination reported that the COVID-19 pandemic did not affect (52.3%, n = 171) or increased the importance (38.5%, n = 126) of their acceptance of the influenza vaccine. Factors associated with influenza vaccine acceptance were knowledge of influenza vaccine (OR 1.21; 95% CI 1.09, 1.35), trust in healthcare providers (OR 2.57; 95% CI 1.43, 4.65), and COVID-19 vaccination during pregnancy (OR 6.11, 95% CI 2.86, 13.01). Participants were more likely to accept the influenza vaccine when they received a COVID-19 vaccine during pregnancy, but the rate of influenza vaccination was not affected by the COVID-19 pandemic. This study showed that the COVID-19 pandemic did not influence influenza vaccine uptake in the majority of pregnant women in Korea. The results emphasize the necessity of appropriate education for pregnant women to enhance awareness of vaccination.

Clinical and Serological Follow-Up of 216 Patients with Hematological Malignancies after Vaccination with Pfizer-BioNT162b2 mRNA COVID-19 in a Real-World Study. Hematological malignancies (HMs) have heterogeneous serological responses after vaccination due to disease or treatment. The aim of this real-world study was to analyze it after Pfizer-BioNT162b2 mRNA vaccination in 216 patients followed up for 1 year. The first 43 patients had an initial follow-up by a telemedicine (TM) system with no major events reported. The anti-spike IgG antibodies were checked 3-4 weeks post-first vaccination and every 3-4 months, by two standard bioassays and a rapid serological test (RST). Vaccine boosts were given when the level was <7 BAU/mL. Patients who did not seroconvert after 3-4 doses received tixagevimab/cilgavimab (TC). Fifteen results were discordant between two standard bioassays. Good agreement was observed between the standard and RST in 97 samples. After two doses, 68% were seroconverted (median = 59 BAU/mL) with a median of 162 BAU/mL and 9 BAU/mL, respectively, in untreated and treated patients ($p < 0.001$), particularly for patients receiving rituximab. Patients with gammaglobulin levels < 5 g/L had reduced seroconversion compared to higher levels ($p = 0.019$). The median levels were 228 BAU/mL post-second dose if seroconverted post-first and second, or if seroconverted only post-second dose. A total of 68% of post-second dose negative patients were post-third dose positive. A total of 16% received TC, six with non-severe symptomatic COVID-19 within 15-40 days. Personalized serological follow-up should apply particularly to patients with HMs.

Guillain-BarrÃ© Syndrome due to COVID-19 Vero Cell Vaccination Associated with Concomitant COVID-19 Infection-induced ARDS and Treated Successfully by Therapeutic Plasma Exchange: A First Case Report from Vietnam. Post-vaccination adverse reactions have been reported with varying symptoms and severity owing to research and production time pressures during the coronavirus disease 2019 (COVID-19) pandemic. In this article, we report a rare case of Guillain-BarrÃ© syndrome (GBS) in a patient with COVID-19 with acute respiratory distress syndrome (ARDS) after receiving Sinopharm's Vero Cell vaccine (China). The patient who was initially negative for COVID-19 was diagnosed with GBS based on paralysis that developed from the lower extremities to the upper extremities, as confirmed by cytoalbuminologic dissociation in the cerebrospinal fluid. The patient's condition worsened with ARDS caused by COVID-19 infection during the hospital stay, and SpO(2)

decreased to 83% while receiving oxygen through a non-rebreather mask (15 l/min) on day 6. The patient was treated with standard therapy for severe COVID-19, invasive mechanical ventilation, and five cycles of therapeutic plasma exchange (TPE) with 5% albumin replacement on day 11 due to severe progression. The patient was weaned off the ventilator on day 28, discharged on day 42, and was completely healthy after 6Â months without any neurological sequelae until now. Our report showed the potential of TPE for GBS treatment in critically ill patients with COVID-19 after COVID-19 vaccination.
[Analysis of anti-SARS-CoV-2 IgG antibody titers after mRNA booster vaccination in patients with nonmalignant hematological disorders]. In our facility, anti-SARS-CoV-2 mRNA vaccines were given to 21 patients, including 8 with aplastic anemia (AA), 3 with pure red cell aplasia (PRCA), and 10 with immune thrombocytopenic purpura (ITP), and IgG antibody titers were assessed one month after vaccinations. After receiving both a second vaccine and a booster shot, all patients with AA/PRCA treated with cyclosporine A aside from one, had IgG titers that were lower than the median levels of healthy controls. Even if prednisolone (PSL) doses did not go over 10 mg/day, ITP patients receiving PSL therapy were unable to achieve adequate levels of IgG after booster immunizations.
Covid-19: Study reports no significant increase in deaths after vaccination but raises questions over AstraZeneca's vaccine.
A case of fatal multi-organ inflammation following COVID-19 vaccination. A 14-year-old Japanese girl died unexpectedly 2Â days after receiving the third dose of the BNT1262b2 mRNA COVID-19 vaccine. Autopsy findings showed congestive edema of the lungs, T-cell lymphocytic and macrophage infiltration in the lungs, pericardium, and myocardium of the left atria and left ventricle, liver, kidneys, stomach, duodenum, bladder, and diaphragm. Since there was no preceding infection, allergy, or drug toxicity exposure, the patient was diagnosed with post-vaccination pneumonia, myopericarditis, hepatitis, nephritis, gastroenteritis, cystitis, and myositis. Although neither type of inflammation is fatal by itself, arrhythmia is reported to be the most common cause of death in patients with atrial myopericarditis. In the present case, arrhythmia of atrial origin was assumed as the cause of cardiac failure and death. In sudden post-vaccination deaths, aggressive autopsy systemic search and histological examination involving extensive sectioning of the heart, including the atrium, are indispensable.
Tinnitus cases after COVID-19 vaccine administration, one institution's observations. OBJECTIVE: After the role out of the COVID-19 vaccine in the United States, there has been increase in case reports of tinnitus attributed to the vaccine reported. We present our institution's experience over the initial 13Â month period the vaccines were available. STUDY DESIGN: Retrospective chart review. SETTING: Tertiary academic otology and general otolaryngology practice. PATIENTS: Patients who received a COVID-19 vaccine and a tinnitus diagnosis code. INTERVENTIONS: Observation, steroids (oral and intratympanic), diagnostic imaging and audiometry. MAIN OUTCOME MEASURES: Patients who received a COVID-19 vaccine in the time frame of 12/1/2020-12/31/21 with a diagnosis of tinnitus, an audiogram, and at least one visit with one of our Otolaryngologists were included in the study. Twenty-seven of the 1254 patients identified met these criteria. The patients ranged in age from 41 to 84Â years old including seven male and twenty female patients. Sixteen received the Pfizer vaccine, seven received the Moderna vaccine and four patients received the Janssen vaccine. CONCLUSIONS: No definite correlation could be established between COVID-19 vaccine and tinnitus. Any concurrent sudden hearing loss should be treated as usual with oral or intratympanic steroids. Health care providers should be aware of the tinnitus onset and if new or recent onset, to refer for prompt audiogram and Otolaryngology evaluation.
Stroke, Myocardial Infarction, and Pulmonary Embolism after Bivalent Booster.

Adverse events following COVID-19 mRNA vaccines: A systematic review of cardiovascular complication, thrombosis, and thrombocytopenia. BACKGROUND AND OBJECTIVES: Since publishing successful clinical trial results of mRNA coronavirus disease 2019Â (COVID-19) vaccines in December 2020, multiple reports have arisen about cardiovascular complications following the mRNA vaccination. This study provides an in-depth account of various cardiovascular adverse events reported after the mRNA vaccines'Â first or second dose including pericarditis/myopericarditis, myocarditis, hypotension, hypertension, arrhythmia, cardiogenic shock, stroke, myocardial infarction/STEMI, intracranial hemorrhage, thrombosis (deep vein thrombosis, cerebral venous thrombosis,Â arterial or venous thrombotic events, portal vein thrombosis, coronary thrombosis, microvascular small bowel thrombosis), and pulmonary embolism. METHODS: A systematic review of original studies reporting confirmed cardiovascular manifestations post-mRNA COVID-19 vaccination was performed. Following the PRISMA guidelines, electronic databases (PubMed, PMC NCBI, and Cochrane Library) were searched until January 2022. Baseline characteristics of patients and disease outcomes were extracted from relevant studies. RESULTS: A total of 81 articles analyzed confirmed cardiovascular complications post-COVID-19 mRNA vaccines in 17,636 individuals and reported 284 deaths with any mRNA vaccine. Of 17,636 cardiovascular events with any mRNA vaccine, 17,192 were observed with the BNT162b2 (Pfizer-BioNTech) vaccine, 444 events with mRNA-1273 (Moderna). Thrombosis was frequently reported with any mRNA vaccine (nâ€‰=â€‰13,936), followed by stroke (nâ€‰=â€‰758), myocarditis (nâ€‰=â€‰511), myocardial infarction (nâ€‰=â€‰377), pulmonary embolism (nâ€‰=â€‰301), and arrhythmia (nâ€‰=â€‰254). Stratifying the results by vaccine type showed that thrombosis (80.8%) was common in the BNT162b2 cohort, while stroke (39.9%) was common with mRNA-1273 for any dose. The time between the vaccination dosage and the first symptom onset averaged 5.6 and 4.8 days with the mRNA-1273 vaccine and BNT162b2, respectively. The mRNA-1273 cohort reported 56 deaths compared to the 228 with BNT162b2, while the rest were discharged or transferred to the ICU. CONCLUSION: Available literature includes more studies with the BNT162b2 vaccine than mRNA-1273. Future studies must report mortality and adverse cardiovascular events by vaccine types.

Adverse Events Associated with COVID-19 Vaccination in Adolescents with Endocrinological Disorders: A Cross-Sectional Study. OBJECTIVE: The aim was to evaluate the adverse events seen after Coronavirus disease-2019 (COVID-19) vaccination in pediatric patients with diagnosed endocrinological problems and to compare them with healthy controls. METHODS: In this cross-sectional study, patients aged 12-18 years who attended a single department between January and May 2022 and were followed up for at least six months due to endocrine diseases, and healthy subjects in the same age group, all of whom had received a COVID-19 vaccine [BNT162b2 mRNA or inactivated vaccine] were included. Adverse events experienced after the vaccination were evaluated by questionnaire. RESULTS: A total of 160 subjects (85 patients, 75 healthy controls) with a median (25-75p) age of 15.5 (14.1-16.9) years were included. The frequency of adverse events was higher in those vaccinated with the mRNA vaccine compared to the inactivated one after the first dose (p=0.015). The incidence of adverse events observed after the first and second doses of both COVID-19 vaccines was similar in the patient and control groups (p=0.879 and p=0.495, respectively), with local reactions being the most common. The frequency of adverse events was similar among the patients who did or did not receive any endocrinological treatment (p>0.05). The incidence and severity of systemic reactions were similar to those in healthy subjects for both vaccine doses, regardless of the underlying diagnosis, autoimmunity state, or treatment regimen used in patients with endocrine diseases. CONCLUSION: The incidence and severity of adverse events associated with COVID-19 vaccinations in adolescents with endocrinological disorders were similar to healthy subjects, in the early post-vaccination period.

Systemic Sarcoidosis with Cutaneous Tattoo Involvement Following COVID-19 Vaccination.

A retrospective case-control study on menstrual cycle changes following COVID-19 vaccination and disease. There has been increasing public concern that COVID-19 vaccination causes menstrual disturbance regarding the relative effect of vaccination compared to SARS-CoV-2 infection. Our objectives were to test potential risk factors for reporting menstrual cycle changes following COVID-19 vaccination and to compare menstrual parameters following COVID-19 vaccination and COVID-19 disease. We performed a secondary analysis of a retrospective online survey conducted in the UK in March 2021. In pre-menopausal vaccinated participants (nÂ = 4,989), 18% reported menstrual cycle changes after their first COVID-19 vaccine injection. The prevalence of reporting any menstrual changes was higher for women who smoke, have a history of COVID-19 disease, or are not using estradiol-containing contraceptives. In a second sample including both vaccinated and unvaccinated participants (nÂ = 12,579), COVID-19 vaccination alone was not associated with abnormal menstrual cycle parameters, while a history of COVID-19 disease was associated with an increased risk of reporting heavier bleeding, "missed" periods, and inter-menstrual bleeding.

Chronic Bilateral Anterior Shoulder Fracture-Dislocation Following Febrile Seizure After COVID-19 Vaccine: A Case Report. Although the shoulder is one of the most commonly dislocated joints in the body, bilateral gleno-humeral joint dislocation is considered rare. Due to its complexity and paucity of cases reported in the literature, it represents both a diagnostic and therapeutic challenge. We report a rare case of an adolescent boy who suffered chronic bilateral anterior shoulder dislocations with proximal humerus fracture and Hill-Sachs lesion after febrile seizure following COVID-19 vaccination. An 18-year-old male presented with bilateral proximal humerus fracture with anterior shoulder dislocation following a first-time seizure. He was managed with a bilateral Latarjet procedure andÂ proximal humerus interlocking osteosynthesis (PHILOS) on the left side, and the right-side fracture was fixed with two 3.5 mm cannulated screws. After one year, the patient had a somewhat satisfactory outcome with a DASH (disabilities of the arm, shoulder, and hand) score of 31.8. Bilateral anterior shoulder dislocation with associated proximal humerus fracture remains one of the rare orthopedic injuries. Recurrent shoulder dislocations leadÂ to chronic glenoid bone loss, which needs fixation along with fracture.

Myocardial Inflammation on FDG PET/MRI and Clinical Outcomes in Symptomatic and Asymptomatic Participants after COVID-19 Vaccination. PURPOSE: To evaluate potential cardiac sequelae of COVID-19 vaccination at 2-month follow-up and relate cardiac symptoms to myocardial tissue changes on fluorodeoxyglucose (FDG) PET/MRI, blood biomarkers, health-related quality of life, and adverse outcomes. MATERIALS AND METHODS: In this prospective study (ClinicalTrials.gov: NCT04967807), a convenience sample of individuals aged â‰¥17 years were enrolled after COVID-19 vaccination and were categorized as symptomatic myocarditis (new cardiac symptoms within 14 days of vaccination and met diagnostic criteria for acute myocarditis), symptomatic no myocarditis (new cardiac symptoms but did not meet criteria for myocarditis), and asymptomatic (no new cardiac symptoms). Standardized evaluation was performed 2 months after vaccination, including cardiac fluorine 18 FDG PET/MRI, blood biomarkers, and health-related quality of life. Statistical analysis included Kruskal-Wallis and Fisher exact tests. RESULTS: Fifty-four participants were evaluated a median of 72 days (IQR: 42, 91) after COVID-19 vaccination, 17 symptomatic with myocarditis (36Â±[SD]15 years, 13 males), 17 symptomatic without myocarditis (42Â±12 years, 7 males), and 20 asymptomatic (45Â±14 years, 9 males). No participants in the symptomatic without myocarditis or asymptomatic groups had focal FDG-uptake, myocardial edema or impaired ventricular function. Two participants with symptomatic myocarditis had focal FDG-uptake, and three had high T2 on MRI. Health-related quality of life was lower in the symptomatic myocarditis group than the asymptomatic group. There were no adverse cardiac events beyond myocarditis in any participant. CONCLUSIONS:

At two-month follow-up, FDG PET/MRI showed evidence of myocardial inflammation in 2/17 participants diagnosed with acute myocarditis early after COVID-19 vaccination, but not in symptomatic and asymptomatic participants without acute myocarditis.Keywords: Myocarditis, Vaccination, COVID-19, PET/MRI, Cardiac MRI, FDG-PET.

Ph-Positive B-Cell Acute Lymphoblastic Leukemia Occurring after Receipt of Bivalent SARS-CoV-2 mRNA Vaccine Booster: A Case Report. The coronavirus disease 2019 (COVID-19) pandemic is a universal emergency public health issue. A large proportion of the world's population has had several spike antigen exposures to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections and/or COVID-19 vaccinations in a relatively short-term period. Although sporadic hematopoietic adverse events after COVID-19 vaccine inoculation were reported, there is currently no sufficient evidence correlating anti-spike protein immune responses and hematopoietic adverse events of vaccinations. We reported the first case of Ph-positive B-cell acute lymphoblastic leukemia (ALL) occurring after a bivalent mRNA COVID-19 vaccine inoculation. The otherwise healthy 43-year-old female patient had a total of six spike antigen exposures in the past 1.5 years. Informative pre-vaccine tests and bone marrow study results were provided. Although the causal relationship between bivalent vaccinations and the subsequent development of Ph-positive B-cell ALL cannot be determined in the case report, we propose that anti-spike protein immune responses could be a trigger for leukemia. Clinicians must investigate the hematopoietic adverse events closely after COVID-19 vaccinations. Further pre-clinical studies to investigate the safety of bivalent mRNA COVID-19 vaccine are required.

Case Series of Acute Peripheral Neuropathies in Individuals Who Received COVID-19 Vaccination. Background and Objectives: Vaccination has been critical to managing the COVID-19 pandemic. Autoimmunity of the nervous system, especially among a select set of high-risk groups, can be triggered or enhanced by the contents of vaccines. Here, we report a case series of acute peripheral neuropathies following vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). We report on 11 patients (range: 30-90 years old) who presented at our center between January 2021 and February 2022. Methods: We obtained the patients' history and performed clinical neurological examination and electromyoneurography on all subjects. If necessary, magnetic resonance imaging and laboratory testing, including cerebrospinal fluid analysis and specific antibody testing, were performed. Results: Patients presented with peripheral neuropathies of acute onset between 1 and 40 days after vaccination with different types of COVID-19 vaccines. Most cases (9/11) resolved with a rapid, complete or partial recovery. Conclusions: We found acute peripheral neuropathies in a set of individuals after they received vaccines against SARS-CoV-2. Albeit our observation shows that during extensive vaccination programs, negative side effects on the peripheral nervous system might occur, most of them showed benign clinical evolution. Thus, potential side effects should not hinder the prescription of vaccines. More extensive studies are needed to elucidate populations at risk of developing peripheral neuropathies and mechanisms of autoimmune response in the nervous system.

Relapse of Monoclonal Gammopathy of Renal Significance after mRNA COVID-19 Vaccination: A Case Report. This case report represents the first suspected case of light chain deposition disease relapse associated with mRNA COVID-19 vaccination. The 75-year-old female patient of Greek ethnicity was admitted to the clinic for the investigation of worsening renal function detected on routine lab examinations, two weeks after she received the second dose of the Moderna COVID-19 vaccine (mRNA-1273). Rapidly progressive glomerulonephritis and anemia were the most notable findings. She had a history of LCDD, which had remained stable for four years. Serum protein immunofixation showed monoclonal kappa zones, and a bone marrow biopsy revealed 5% plasma cell infiltration. These, along with other investigations, established the diagnosis of LCDD recurrence. The

patient was started on chemotherapy, which improved her immunological profile, but not her renal function. The patient has remained on hemodialysis since. The association between mRNA vaccinations and LCDD relapse may be grounds for investigations into the pathophysiology of MGRS, given the patient's previous long-term remission. This case report is not intended to directly inform changes in clinical practice. We must stress the importance of following all standardized vaccination protocols, especially in immunocompromised patients.

Unilateral Pleural Effusion after Third Dose of BNT162b2 mRNA Vaccination: Case Report. Vaccination remains the best strategy against coronavirus disease 2019 (COVID-19) in terms of prevention. The efficacy and safety of COVID-19 vaccines is supported by well-designed clinical trials that recruited many participants. It is well-known that vaccination is associated with local side effects related to the injection site, and mild, systemic side effects. However, there has been an increase in the occurrence of what is known as infrequent adverse effects in the population of vaccinated individuals in real life. We present the case of a 46-year-old woman with no past medical history, who presented with a sharp chest pain with deep inspiration, a few days after receiving the third dose of the Pfizer-BioNTech COVID-19 mRNA vaccine (BNT162b2). There is an association between the BNT16b2 vaccination and myocarditis, pericarditis, and even bilateral pleural effusions. To the best of our knowledge, this is the first report featuring a unilateral pleural effusion in a patient with no known past medical history, who did not develop cardiac involvement nor have any viral infection. The aim of our report is to inform health professionals of the possibility of encountering this rare adverse event in their daily practice, as the population of individuals who are receiving additional vaccine doses is increasing steadily.

Epidemiology of Immune-Mediated Glomerulopathies before and after SARS-CoV-2 Vaccination: A Tertiary Referral Hospital Experience. BACKGROUND: Vaccination is a known trigger for the appearance of immune-mediated glomerulopathies (IMG). The appearance of IMG after SARS-CoV-2 vaccination with suspected causality has been described. Our aim is to analyze the incidence of IMG flares before and after SARS-CoV-2 vaccination in our center. METHODS: All persons with native kidney biopsy (KB) from January 2019 to March 2022 in our center were included in the study. We compared the incidence of IMG before and after the start of vaccination. We also collected information about whether the patients had received a SARS-CoV-2 vaccine or have suffered from COVID in the six weeks before the IMG. We also evaluated the analytical characteristics of the outbreaks. RESULTS: A total of 386 KB were studied. Of them, 86/218 (39.4%) were IMG performed pre- and 85/168 (50.6%) post-SV (029). The incidence of idiopathic nephrotic syndrome (INS), studied separately, was also significantly increased post-vaccination (n = 18 (10.7%)) compared to pre-vaccination (n = 11 (5%)) (p = 0.036). There were no differences in the incidence of vasculitis or IgA nephropathy. Up to 17 (20%) flares occurred 6 weeks before SARS-CoV-2 vaccination and only 2 (2.4%) within the first 6 weeks after SARS-CoV-2 infection. Within those 17 flares, the most common diagnosis was IgAN (n = 5 (29.4%)); a total of 14 (82.4%) received an mRNA vaccine and 9 (52.9%) took place after the 1st vaccine dose. There were 13 cases of minimal change disease (MCD) with debut/recurrence pre-SV and 20 MCD with debut/recurrence post-SV (p = 0.002). CONCLUSIONS: The incidence of IMG, INS and MCD flares in our center increased significantly after SARS-CoV-2 vaccination. Importantly, 20% of IMG flares took place within the first 6 weeks after receiving a vaccine dose, with the first dose being the riskiest one and IgAN the most frequent diagnosis.

Hypereosinophilic Syndrome Following the BNT162b2 (BioNTech/Pfizer) Vaccine Successfully Treated with Mepolizumab: A Case Report and Review of the Literature. Although an increasing number of real-life data confirm large-scale clinical trial findings on the efficacy and safety of SARS-CoV-2 vaccines, rare but severe adverse reactions have begun to emerge. Here, we report a full-blown hypereosinophilic syndrome (HES) following a BNT162b2 (BioNTech/Pfizer) vaccine. A 48-year-old

man developed, 5 days after the first shot of the SARS-CoV-2 vaccine, erythematous and painful nodular lesions in the lower and upper limbs accompanied by widespread itching, acrocyanosis with gangrenous lesions at the tips of the first and fourth fingers of the right hand, as well as paresthesia in the right hand and foot. Investigations revealed isolated eosinophilia, occlusion of the right ulnar artery, and electromyography alteration compatible with multifocal sensory neuropathy, as well as minimal accentuation of the interstitial texture with some ground glass appearance. Despite treatment with prednisone in combination with warfarin, he developed thrombosis of the left ulnar artery. Therefore, therapy with an IL-5 inhibitor and acetylsalicylic was successfully added. Given the time interval between the onset of clinical manifestations and the vaccine shot, we believe that the mRNA vaccine triggered the eosinophilic response. This case evidences a possible link between HES and the SARS-CoV-2 vaccination. Mepolizumab, an IL-5 inhibitor, might be considered in steroid refractory cases.

The APSANTICO Study: A Prospective Observational Study to Evaluate Antiphospholipid Antibody Profiles in Patients with Thromboembolic Antiphospholipid Syndrome (APS) after COVID-19 Infection and/or Vaccination. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a new virus discovered in December 2019 that causes coronavirus disease 19 (COVID-19) and various vaccinations have been developed. The extent to which COVID-19 infections and/or COVID-19 vaccinations alter antiphospholipid antibodies (aPL) in patients with thromboembolic antiphospholipid syndrome (APS) remains unclear. Eighty-two patients with confirmed thromboembolic APS were included in this prospective non-interventional trial. Blood parameters including lupus anticoagulants, anticardiolipin IgG- and IgM-antibodies, and anti-ÃŸ2-glycoprotein I IgG- and IgM-antibodies were assessed prior to and after COVID-19 vaccination and/or COVID-19 infection. No increases in aPL in the total study population were detected. In fact, low but significant decreases were observed for anticardiolipin IgG- and anti-Î²2-glycoprotein I IgG-antibodies, while anticardiolipin IgM- and anti-b2-glycoprotein I IgM-antibodies slightly increased only in patients with COVID-19 infection and vaccination. Although the investigated patient group is known to have a high risk of recurrent thrombosis, only one arterial thrombotic event was diagnosed (1.2%, 1/82). This low recurrence rate was probably due to the high vaccination rates prior to infections and a high rate of effective anticoagulation. Our data show that COVID-19 infections and/or vaccinations do not deteriorate the clinical course of anticoagulated thromboembolic APS patients.

Does Physical Exercise Enhance the Immune Response after Vaccination? A Systematic Review for Clinical Indications of COVID-19 Vaccine. BACKGROUND: Stimulating protective immunity with vaccines appears to be the most promising option for providing widespread moderate to high protection against COVID-19 in people over the age of 18. Regular exercise improves the immune response, transmitting possible benefits against virus infections. The aim of this review is to study the effects of physical activity on vaccine injections, helping to develop new recommendations for COVID-19 vaccination campaigns. METHODS: A comprehensive review of the existing literature was undertaken using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The internal quality of the studies was assessed according to the Physiotherapy Evidence Database (PEDro) scale. The outcomes analyzed were antibody titer, the level of lymphocytes CD4, CD8, InterLeukin 6 (IL6), leukocytes level, the visual analogue scale (VAS) for overall pain rating, arm and forearm circumferences and volume of oxygen (VO2) peak. RESULTS: Fourteen articles were selected for the analysis. The majority of studies were randomized controlled trials (RCT) (n = 8) and controlled trials (CT) (n = 6). According to PEDro, the 'fair' category (n = 7) was the most represented, followed by 'good' (n = 6) and 'excellent' (n = 1). Physical training showed a positive effect on antibody titers of the vaccine; yet, different variables seem to influence antibody titers: higher new vs. old antigen in the vaccine, higher in younger vs. older individuals, and higher in females vs. males.

After exercise, when analyzing variables of direct response to the vaccine, such as the amount of CD4, IL-6 and leukocytes, higher levels were observed in the patients who performed physical exercise compared to the control group. In the same way, better results were observed in physiological variables such as VO2 and limb circumferences, or subjective variables such as pain, which showed better results than the control group. CONCLUSIONS: The immune response (antibody titers) depends on age, gender and the intensity of physical activity: long-term protocols at moderate intensity are the most recommended. All of these aspects also have to be carefully considered for the COVID-19 vaccination.

The Third Dose of BNT162b2 COVID-19 Vaccine Does Not "Boost" Disease Flares and Adverse Events in Patients with Rheumatoid Arthritis. Data on the risk of adverse events (AEs) and disease flares in autoimmune rheumatic diseases (ARDs) after the third dose of COVID-19 vaccine are scarce. The aim of this multicenter, prospective study is to analyze the clinical and immunological safety of BNT162b2 vaccine in a cohort of rheumatoid arthritis (RA) patients followed-up from the first vaccine cycle to the third dose. The vaccine showed an overall good safety profile with no patient reporting serious AEs, and a low percentage of total AEs at both doses (40/78 (51.3%) and 13/47 (27.7%) patients after the second and third dose, respectively ($p < 0.002$). Flares were observed in 10.3% of patients after the end of the vaccination cycle and 12.8% after the third dose. Being vaccinated for influenza was inversely associated with the onset of AEs after the second dose, at both univariable ($p = 0.013$) and multivariable analysis ($p = 0.027$). This result could allow identification of a predictive factor of vaccine tolerance, if confirmed in larger patient populations. A higher disease activity at baseline was not associated with a higher incidence of AEs or disease flares. Effectiveness was excellent after the second dose, with only 1/78 (1.3%) mild breakthrough infection (BI) and worsened after the third dose, with 9/47 (19.2%) BI ($p < 0.002$), as a probable expression of the higher capacity of the Omicron variants to escape vaccine recognition.

Oral Immunization with Escherichia coli Nissle 1917 Expressing SARS-CoV-2 Spike Protein Induces Mucosal and Systemic Antibody Responses in Mice. As of October 2022, the COVID-19 pandemic continues to pose a major public health conundrum, with increased rates of symptomatic infections in vaccinated individuals. An ideal vaccine candidate for the prevention of outbreaks should be rapidly scalable, easy to administer, and able to elicit a potent mucosal immunity. Towards this aim, we proposed an engineered Escherichia coli (E. coli) Nissle 1917 (EcN) strain with SARS-CoV-2 spike protein (SP)-coding plasmid, which was able to expose SP on its cellular surface by a hybridization with the adhesin involved in diffuse adherence 1 (AIDA1). In this study, we presented the effectiveness of a 16-week intragastrically administered, engineered EcN in producing specific systemic and mucosal immunoglobulins against SARS-CoV-2 SP in mice. We observed a time-dependent increase in anti-SARS-CoV-2 SP IgG antibodies in the sera at week 4, with a titre that more than doubled by week 12 and a stable circulating titre by week 16 (+309% and +325% vs. control; both $p < 0.001$). A parallel rise in mucosal IgA antibody titre in stools, measured via intestinal and bronchoalveolar lavage fluids of the treated mice, reached a plateau by week 12 and until the end of the immunization protocol (+300, +47, and +150%, at week 16; all $p < 0.001$ vs. controls). If confirmed in animal models of infection, our data indicated that the engineered EcN may be a potential candidate as an oral vaccine against COVID-19. It is safe, inexpensive, and, most importantly, able to stimulate the production of both systemic and mucosal anti-SARS-CoV-2 spike-protein antibodies.

Omicron BA.4/5 Neutralization and T-Cell Responses in Organ Transplant Recipients After Booster Messenger RNA Vaccine: A Multicenter Cohort Study. BACKGROUND: In solid organ transplant (SOT) recipients, the primary vaccination series against Coronavirus Disease 2019 is 3 doses followed by boosters. We determined whether a fourth dose booster induced Omicron BA.4/5 neutralizing antibodies (nAbs) and T cells in a large multicenter cohort study. METHODS: Serum was collected 4-6

weeks post-third and post-fourth doses of messenger RNA vaccine in 222 SOT recipients. nAbs were measured using a pseudovirus neutralization assay that targeted the Omicron BA.4/5 spike protein. A subset underwent T-cell testing. RESULTS: The median age of the cohort was 63 years (interquartile range [IQR], 50-68) with 61.7% men. BA.4/5 nAb detection increased from 26.6% (59 of 222) post-third dose to 53.6% (119 of 222) post-fourth dose (P < .0001). In patients with breakthrough infection prior to the fourth dose (n = 27), nAbs were detected in 77.8% and median nAb titers were significantly higher compared with those with 4 vaccine doses alone (P < .0001). Factors associated with a low BA.4/5 neutralization response after the fourth dose were older age (odds ratio [OR], 0.96; 95% confidence interval [CI], .94-.99), mycophenolate use (OR, 0.39; 95% CI, .20-.77) and prednisone use (OR, 0.34; 95% CI, .18-.63), and vaccine type (OR, 0.72; 95% CI, .51-.99), while breakthrough infection prior to the fourth dose (OR, 3.6; 95% CI, 1.3-9.9) was associated with a greater nAb response. Polyfunctional BA.4/5-specific CD4+ T cells significantly increased after 4 doses and were identified in 76.9% of patients at a median frequency of 213/106 cells (IQR, 98-650). CONCLUSIONS: In summary, a booster significantly increases BA.4/5-specific neutralization and polyfunctional CD4+ T-cell responses, suggesting protection from severe disease even with new Omicron variants. However, SOT recipients who are older and on mycophenolate and prednisone need additional preventative strategies.
Humoral immune responses remain quantitatively impaired but improve qualitatively in anti-CD20-treated patients with multiple sclerosis after three or four COVID-19 vaccinations. OBJECTIVE: To analyze anti-SARS-CoV-2-S1-IgG levels, avidity, Omicron BA.2 variant neutralizing capacity, and SARS-CoV-2-specific T cells in anti-CD20-treated patients with multiple sclerosis (aCD20pwMS) after two, three, or four COVID-19 vaccinations. RESULTS: Frequencies of aCD20pwMS with detectable SARS-CoV-2-S1-IgG increased moderately between two (31/61 (51%)), three (31/57 (54%)), and four (17/26 (65%)) vaccinations. However, among patients with detectable SARS-CoV-2-S1-IgG, frequencies of high avidity (6/31 (19%) vs 11/17 (65%)) and Omicron neutralizing antibodies (0/10 (0%) vs 6/10 (60%)) increased strongly between two and four vaccinations. SARS-CoV-2-specific T cells were detectable in >92% after two or more vaccinations. CONCLUSION: Additional vaccinations qualitatively improve SARS-CoV-2 antibody responses.
Stevens-Johnson syndrome/toxic epidermal necrolysis overlap case possibly induced by COVID-19 vaccine.
Non-Arteritic Ischemic Optic Neuropathy Following COVID-19 Vaccination in Korea: A Case Series. BACKGROUND: To report the clinical manifestations of non-arteritic anterior ischemic optic neuropathy (NAION) cases after coronavirus disease 2019 (COVID-19) vaccination in Korea. METHODS: This multicenter retrospective study included patients diagnosed with NAION within 42 days of COVID-19 vaccination. We collected data on vaccinations, demographic features, presence of vascular risk factors, ocular findings, and visual outcomes of patients with NAION. RESULTS: The study included 16 eyes of 14 patients (6 men, 8 women) with a mean age of 63.5 Â± 9.1 (range, 43-77) years. The most common underlying disease was hypertension, accounting for 28.6% of patients with NAION. Seven patients (50.0%) had no vascular risk factors for NAION. The mean time from vaccination to onset was 13.8 Â± 14.2 (range, 1-41) days. All 16 eyes had disc swelling at initial presentation, and 3 of them (18.8%) had peripapillary intraretinal and/or subretinal fluid with severe disc swelling. Peripapillary hemorrhage was found in 50% of the patients, and one (6.3%) patient had peripapillary cotton-wool spots. In eight fellow eyes for which we were able to review the fundus photographs, the horizontal cup/disc ratio was less than 0.25 in four eyes (50.0%). The mean visual acuity was logMAR 0.6 Â± 0.7 at the initial presentation and logMAR 0.7 Â± 0.8 at the final visit. CONCLUSION: Only 64% of patients with NAION after COVID-19 vaccination have known vascular and ocular risk factors relevant to ischemic optic neuropathy. This suggests that COVID-19 vaccination

may increase the risk of NAION. However, overall clinical features and visual outcomes of the NAION patients after COVID-19 vaccination were similar to those of typical NAION.

Acquired hemophilia A following COVID-19 vaccine: a case report. BACKGROUND: In the literature, reported cases of Acquired hemophilia A (AHA) induced by COVID-19 vaccination occurred after Adenoviral Vector Deoxyribonucleic Acid (DNA)- and SARS-CoV-2 Messenger Ribonucleic acid (mRNA)-Based vaccines. Here, and to the best of our knowledge, we report the first case of AHA occurring after an inactivated Sinovac-coronavac COVID-19 vaccine. CASE PRESENTATION: A 69-year-old Tunisian male patient consulted for severe left leg pain limiting physical mobility due to a 5*6Â cm large ecchymosis located at the left inner thigh, having spontaneously appeared 5Â days prior consultation and without notion of trauma. The patient had no known personal medical history. He had received the second dose of CoronaVac-SinoVac vaccine 30Â days prior to consultation. Further physical examination revealed the presence of two other ecchymoses: one at the inner face of the right forearm, starting at the wrist reaching the elbow and the other at the left flank of the abdomen. Diagnosis of AHA was based on clinical presentation and confirmed with prolonged a PTT, Factor VIII deficiency and the presence of an FVIII inhibitor. The patient was successfully treated with corticosteroids and low dose Rituximab. CONCLUSION: Clinicians should consider AHA in front of prolonged aPTT with or without spontaneous bleedings even after inactivated virus COVID-19.

Risk of death following COVID-19 vaccination or positive SARS-CoV-2 test in young people in England. Several studies have reported associations between COVID-19 vaccination and risk of cardiac diseases, especially in young people; the impact on mortality, however, remains unclear. We use national, linked electronic health data in England to assess the impact of COVID-19 vaccination and positive SARS-CoV-2 tests on the risk of cardiac and all-cause mortality in young people (12 to 29 years) using a self-controlled case series design. Here, we show there is no significant increase in cardiac or all-cause mortality in the 12 weeks following COVID-19 vaccination compared to more than 12 weeks after any dose. However, we find an increase in cardiac death in women after a first dose of non mRNA vaccines. A positive SARS-CoV-2 test is associated with increased cardiac and all-cause mortality among people vaccinated or unvaccinated at time of testing.

Expectations and Prior Experiences Associated With Adverse Effects of COVID-19 Vaccination. IMPORTANCE: Uptake of vaccination against COVID-19 is strongly affected by concerns about adverse effects. Research on nocebo effects suggests that these concerns can amplify symptom burden. OBJECTIVE: To investigate whether positive and negative expectations prior to COVID-19 vaccination are associated with systemic adverse effects. DESIGN, SETTING, AND PARTICIPANTS: This prospective cohort study analyzed the association of expected benefits and risks of vaccination, adverse effects at first vaccination, and observed adverse effects in close contacts with severity of systemic adverse effects among adults receiving a second dose of messenger RNA (mRNA)-based vaccines between August 16 and 28, 2021. A total of 7771 individuals receiving the second dose at a state vaccination center in Hamburg, Germany, were invited to participate; of these, 5370 did not respond, 535 provided incomplete information, and 188 were excluded retrospectively. The mobile application m-Path was used for data collection. MAIN OUTCOMES AND MEASURES: Primary outcome was a composite severity index of systemic adverse effects in 12 symptom areas measured once daily with an electronic symptom diary over 7 consecutive days. Data were analyzed by mixed-effects multivariable ordered logistic regression adjusted for prevaccine symptom levels and observation times. RESULTS: A total of 10â€¯447 observations from 1678 individuals receiving vaccinations (BNT162b2 [Pfizer BioNTech] in 1297 [77.3%] and mRNA-1273 [Moderna] in 381 [22.7%]) were collected. The participants' median age was 34 (IQR, 27-44) years, and 862 (51.4%) were women. The risk for more severe adverse effects was higher for persons expecting a lower benefit of vaccination (odds ratio [OR] for higher expectations,â€‰0.72 [95% CI,â€‰0.63-0.83]; Pâ€‰<â€‰.001),

expecting higher adverse effects of vaccination (OR,â€‰1.39 [95% CI,â€‰1.23-1.58]; Pâ€‰<â€‰.001), having experienced higher symptom burden at the first vaccination (OR,â€‰1.60 [95% CI,â€‰1.42-1.82]; Pâ€‰<â€‰.001), scoring higher on the Somatosensory Amplification Scale (OR,â€‰1.21 [95% CI,â€‰1.06-1.38]; Pâ€‰=â€‰.004), and if the vaccine mRNA-1273 was given rather than BNT162b2 (OR,â€‰2.45 [95% CI,â€‰2.01-2.99]; Pâ€‰<â€‰.001). No associations were seen for observed experiences. CONCLUSIONS AND RELEVANCE: In this cohort study, several nocebo effects occurred in the first week after COVID-19 vaccination. The severity of systemic adverse effects was associated not only with vaccine-specific reactogenicity but also more negative prior experiences with adverse effects from the first COVID-19 vaccination, more negative expectations regarding vaccination, and tendency to catastrophize instead of normalize benign bodily sensations. Clinician-patient interactions and public vaccine campaigns may both benefit from these insights by optimizing and contextualizing information provided about COVID-19 vaccines.

Twelve-Month Follow-up of the Immune Response After COVID-19 Vaccination in Patients with Genitourinary Cancers: A Prospective Cohort Analysis. BACKGROUND: Vaccinations against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have had a transformative impact on morbidity and mortality. However, the long-term impact of vaccination on patients with genitourinary cancers is currently unknown. MATERIALS AND METHODS: This study aimed to assess seroconversion rates in patients with genitourinary cancers receiving COVID-19 vaccination. Patients with prostate cancer, renal cell carcinoma, or urothelial cancer who had not been vaccinated for COVID-19 were included. Blood samples were obtained at baseline and after 2, 6, and 12 months of one dose of an FDA-approved COVID-19 vaccine. Antibody titer analysis was performed using the SCoV-2 Detect IgG ELISA assay, and the results were reported as immune status ratio (ISR). A paired t-test was used for comparison of ISR values between timepoints. In addition, T-cell receptor (TCR) sequencing was performed to assess for differences in TCR repertoire 2 months after vaccination. RESULTS: Out of 133 patients enrolled, 98 baseline blood samples were collected. At 2-, 6-, and 12-month time points 98, 70, and 50 samples were collected, respectively. Median age was 67 (IQR, 62-75), with the majority of patients diagnosed with prostate (55.1%) or renal cell carcinoma (41.8%). Compared to baseline (0.24 [95% CI, 0.19-0.31]) a significant increase in the geometric mean ISR values was observed at the 2-month timepoint (5.59 [4.76-6.55]) (Pâ€…<â€….001). However, at the 6-month timepoint, a significant decrease in the ISR values was observed (4.66 [95% CI, 4.04-5.38]; Pâ€…<â€….0001). Notably, at the 12-month timepoint, the addition of a booster dose resulted in an absolute increase in the ISR values compared to those who did not receive a booster dose (Pâ€…=â€….04). CONCLUSIONS: Only a minority of patients with genitourinary cancers did not ultimately achieve satisfactory seroconversion after receiving commercial COVID-19 vaccination. Cancer type or treatment rendered did not appear to affect the immune response mounted after vaccination.

Risk stratification through extensive allergy work-up in COVID-19-mRNA vaccine allergic reactions.

Recurrent Acute Disseminated Encephalomyelitis (ADEM) after COVID-19-vaccination and after subsequent COVID-19-infection: A case report (part II). Acute disseminated encephalomyelitis (ADEM) is an autoimmune disorder of the central nervous system (CNS), which is commonly associated to previous viral infection or immunization. Cases of ADEM with a potential relationship to both severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and vaccination have been reported. We recently published a rare case of a 65-year-old patient who suffered from a corticosteroid- and immunoglobulin-refractory multiple autoimmune syndrome including ADEM following Pfizer-BioNTech coronavirus disease (COVID)-19 vaccination, and whose symptoms largely resolved after repeated plasma exchange (PE). Four months later, the patient was diagnosed with SARS-CoV-2 omicron variant infection after experiencing mild upper respiratory tract symptoms. Few

days later, the patient developed severe tetraparesis with magnetic resonance imaging (MRI) showing multiple new inflammatory contrast-enhancing lesions in the left middle cerebellar peduncle, cervical spinal cord, and ventral conus medullaris. Repeated cerebrospinal fluid (CSF) analyses indicated blood-brain barrier damage (increased albumin ratio) without signs of SARS-CoV-2 invasion (mild pleocytosis, no intrathecal antibody production). SARS-CoV-2 specific immunoglobulin G (IgG) were detected in serum and to a much lower degree in CSF with close correlation between both concentrations over time, reflecting antibody dynamics of vaccine- and infection-induced immune response, and blood-brain barrier patency. Daily PE therapy was initiated. Given the patient's lack of improvement after seven PE, treatment with rituximab was considered. After a first dose, however, the patient suffered epididymo-orchitis leading to sepsis, and declined rituximab continuation. At 3-months follow-up, clinical symptoms had dramatically improved. The patient regained walking ability without assistance. This case of recurrent ADEM after COVID-19-vaccination and after subsequent COVID-19-infection strongly supports the hypotheses of neuroimmunological complications in these conditions being promoted by a systemic immune response and mediated by molecular mimicry of, both, viral and vaccine SARS-CoV-2 antigens and CNS self-antigens.

WINGED SCAPULA CAUSED BY PARSONAGE-TURNER SYNDROME AFTER BNT162B2 MRNA COVID-19 VACCINATION. A 45-year-old Japanese woman presented with difficulty moving her left shoulder. Ten months previously, the day after she had received her second dose of the BNT162b2 mRNA COVID-19 vaccine, a severe stabbing pain occurred in her entire left upper extremity. The pain resolved within 2 weeks, although she developed difficulty moving her left shoulder. A left winged scapula was observed. Electromyography showed left upper brachial plexopathy with acute axonal involvement and abundant acute denervation potentials, consistent with Parsonage-Turner syndrome (PTS). PTS should be considered in patients with post-neuralgic motor paralysis of the unilateral upper extremity, which can occur after COVID-19 vaccination. LEARNING POINTS: Parsonage-Turner syndrome (PTS), also referred to as idiopathic brachial plexopathy or neuralgic amyotrophy, is characterized by acute onset of unilateral upper extremity pain.PTS often results in a winged scapula due to paralysis of the long thoracic nerve.PTS should be considered in patients with post-neuralgic motor paralysis of the unilateral upper extremity, which can occur after COVID-19 vaccination.

New-Onset Amyotrophic Lateral Sclerosis in a Patient who Received the J&J/Janssen COVID-19 Vaccine.

Long-term systemic and mucosal SARS-CoV-2 IgA response and its association with persistent smell and taste disorders. INTRODUCTION: Current approved COVID-19 vaccines, notably mRNA and adenoviral vectored technologies, still fail to fully protect against infection and transmission of various SARS-CoV-2 variants. The mucosal immunity at the upper respiratory tract represents the first line of defense against respiratory viruses such as SARS-CoV-2 and is thus critical to develop vaccine blocking human-to-human transmission. METHODS: We measured systemic and mucosal Immunoglobulin A (IgA) response in serum and saliva from 133 healthcare workers from Percy teaching military hospital following a mild infection (SARS-CoV-2 Wuhan strain, n=58) or not infected (n=75), and after SARS-CoV-2 vaccination (VaxzevriaÂ®/Astrazeneca and/or ComirnatyÂ®/Pfizer). RESULTS: While serum anti-SARS-CoV-2 Spike IgA response lasted up to 16 months post-infection, IgA response in saliva had mostly fallen to baseline level at 6 months post-infection. Vaccination could reactivate the mucosal response generated by prior infection, but failed to induce a significant mucosal IgA response by itself. Early post-COVID-19 serum anti-Spike-NTD IgA titer correlated with seroneutralization titers. Interestingly, its saliva counterpart positively correlated with persistent smell and taste disorders more than one year after mild COVID-19. DISCUSSION: As breakthrough infections have been correlated with IgA levels, other vaccine platforms inducing a better mucosal immunity are needed to control COVID-19 infection in the future. Our results encourage further

studies to explore the prognosis potential of anti-Spike-NTD IgA in saliva at predicting persistent smell and taste disorders.
Localized Delayed T-cell Mediated Hypersensitivity After mRNA SARS-CoV-2 Vaccination. Since the emergency authorization of SARS-CoV-2 vaccines,Â the medical literature has been investigating the management of allergic reactions to the vaccines. Anaphylaxis has been reported among a minority of vaccinated individuals, and many trials monitoring the safety profile of the vaccines have identified cases of benign cutaneous reactions. Typical features of delayed benign cutaneous hypersensitivity reactions include localized erythema, pruritus, and rash. However, reports have described rare cases of rash and atopy at sites apart from the injection site following vaccine delivery. We will discuss a unique case of delayed benign cutaneous hypersensitivity presenting in the lower extremity after an upper-extremity administration of an mRNA SARS-CoV-2. Additionally, we describe management strategies to guide clinicians who encounter similar vaccine-induced hypersensitivity reactions.
C-Reactive protein rise in rheumatology patients following COVID-19 vaccination. OBJECTIVE: The aim was to determine the proportion of patients with inflammatory arthritis who have a flare of their rheumatological disease within 4â€‰weeks of receiving a coronavirus disease 2019 (COVID-19) vaccine, using CRP as a surrogate marker. METHODS: A retrospective review was conducted of notes for patients with inflammatory arthritis within 30â€‰days of their COVID-19 vaccine. An electronic database (DAWN) was used to identify all patients who were currently on a DMARD or biologic therapy. This was then correlated with vaccine data from the National Immunisation and Vaccination System (NIVS) and CRP within 30â€‰days of their vaccination. RESULTS: From the DAWN database, 1620 adults were identified (mean age 61â€‰years, 64% female). Three types of vaccinations were administered: AstraZeneca (AZ), BioNTech-Pfizer or Moderna. Vaccine uptake was 1542 of 1620 (95.2% for the first dose), 1550 of 1620 (95.7% for the second dose) and 1437 of 1620 (88.7% for the third dose). One hundred and ninety-two of 1542 patients (12.5%) had a CRP rise of >10â€‰mg/l within 30â€‰days of their vaccine, which was higher than the baseline flare rate of 8.6% (Pâ€‰=â€‰0.0004). CONCLUSION: Patients with inflammatory arthritis and on DMARDs have a high uptake of COVID-19 vaccine (95%), which is greater than the national average. A CRP rise >10â€‰mg/l within 30â€‰days of vaccination was observed in âˆ¼1 in 10 patients in our study population after all three doses. There might be a slight increase in disease flare in patients with inflammatory arthritis after COVID-19 vaccinations, and additional research is required to assess this association further.
Administration of sinopharm Covid-19 vaccine in cancer patients. For prevention against SARS-CoV-2, various vaccines have been approved globally including Pfizer, Sinopharam, Moderna, Johnson & Johnson etc which have proved quite effective. To evaluate the immunization and safety of Sinopharm vaccine in cancer patients. A prospective study was conducted in the Oncology Department of Nishtar Medical Hospital, Multan from March 2021- September 2021. A total of 150 cancer patients undergoing treatment were included in the study. All the patients were administered 0.5â€‰ml Sinopharm vaccine with 28 day difference between the two doses. A two-month follow-up was done to test the immunization using ELISA kits. Among all the patients, 16 patients (10.7%) had a history of COVID-19 before the administration of the vaccine. At the time of vaccination, 23.3% of patients were seropositive. After the vaccination, 130 patients (86.7%) developed immunity against the infection. 30.6% of participants developed a fever and 20.9% had fatigue. Other side effects were also observed including pain, redness, swelling, itching, chills, anorexia, nausea, vomiting, myalgia and diarrhea. Sinopharm vaccine is effective and safe for patients with malignancies especially in patients receiving radiaton therapy but still recommended for older patients and patients receiving chemotherapy.

A population-based assessment of myocarditis after messenger RNA COVID-19 booster vaccination among adult recipients. OBJECTIVES: We aimed to estimate the rate of myocarditis after the messenger RNA (mRNA) COVID-19 booster vaccination by vaccine type, age, and sex. METHODS: We used data from the British Columbia COVID-19 Cohort, a population-based cohort surveillance platform. The exposure was a booster dose of an mRNA vaccine. The outcome was diagnosis of myocarditis during hospitalization or an emergency department visit within 7-21 days of booster vaccination. RESULTS: The overall rate of myocarditis was lower for the booster dose (6.41, 95% confidence interval [CI]: 3.50-10.75) than the second dose (17.97, 95% CI: 13.78-23.04); (Rate ratio(booster vs dose-2)Â =Â 0.34, 95% CI: 0.17-0.61). This difference was more apparent for the mRNA-1273 vaccine type. After the second dose, the myocarditis rate in males was significantly lower for BNT162b2 than mRNA-1273 overall and among those aged 18-39 years. In contrast, after the booster dose, no significant differences between myocarditis and vaccine type was observed overall or within the specific age groups among males or females. CONCLUSION: Myocarditis after mRNA COVID-19 vaccines is a rare event. A lower absolute risk of myocarditis was observed after a booster dose of mRNA vaccine than the primary series second dose.

Persistent SARS-CoV-2-specific immune defects in kidney transplant recipients following third mRNA vaccine dose. Kidney transplant recipients (KTRs) show poorer response to SARS-CoV-2 mRNA vaccination, yet response patterns and mechanistic drivers following third doses are ill-defined. We administered third monovalent mRNA vaccines to n = 81 KTRs with negative or low-titer anti-receptor binding domain (RBD) antibody (n = 39 anti-RBD(NEG); n = 42 anti-RBD(LO)), compared with healthy controls (HCs, n = 19), measuring anti-RBD, Omicron neutralization, spike-specific CD8(+)%, and SARS-CoV-2-reactive T cell receptor (TCR) repertoires. By day 30, 44% anti-RBD(NEG) remained seronegative; 5% KTRs developed BA.5 neutralization (vs 68% HCs, P < .001). Day 30 spike-specific CD8(+)% was negative in 91% KTRs (vs 20% HCs; P = .07), without correlation to anti-RBD (r(s) = 0.17). Day 30 SARS-CoV-2-reactive TCR repertoires were detected in 52% KTRs vs 74% HCs (P = .11). Spike-specific CD4(+) TCR expansion was similar between KTRs and HCs, yet KTR CD8(+) TCR depth was 7.6-fold lower (P = .001). Global negative response was seen in 7% KTRs, associated with high-dose MMF (P = .037); 44% showed global positive response. Of the KTRs, 16% experienced breakthrough infections, with 2 hospitalizations; prebreakthrough variant neutralization was poor. Absent neutralizing and CD8(+) responses in KTRs indicate vulnerability to COVID-19 despite 3-dose mRNA vaccination. Lack of neutralization despite CD4(+) expansion suggests B cell dysfunction and/or ineffective T cell help. Development of more effective KTR vaccine strategies is critical. (NCT04969263).

Humoral Immune Response Following SARS-CoV-2 mRNA Vaccination and Infection in Pediatric-Onset Multiple Sclerosis. OBJECTIVE: Currently, there are no data available on SARS-CoV-2 vaccine responses in pediatric-onset multiple sclerosis (POMS), and little is known about the course of SARS-CoV-2 infection in this age group. We therefore investigated humoral immune responses after COVID-19 vaccination and/or infection in POMS. METHODS: We retrospectively analyzed seroconversion rates and SARS-CoV-2-specific antibody levels in 30 POMS and one pediatric CIS patient treated with no disease-modifying therapy (no DMT), immunomodulatory DMT (IM-DMT), or immunosuppressive DMT (IS-DMT) from two Austrian MS centers. RESULTS: The median age at MS onset was 15.39Â years (interquartile range [IQR]: 1.97). The median age at the first COVID-19 vaccination was 17.43Â years (IQR: 2.76). After two vaccine doses, seroconversion (â‰¥0.8 BAU/ml) was reached in 25 of 28 patients (89.3%). All patients with no DMT or IM-DMT generated robust immune responses to vaccination (seroconversion: no DMT: 6/6, IM-DMT: 7/7 [100%]; median titers: no DMT: 2075 BAU [IQR: 1268.50], IM-DMT: 2500 BAU [IQR: 0]). In the IS-DMT group, seroconversion was achieved in 12 of 14 patients (80%), and median titers were 50.8 BAU (IQR 254.63). Titers were significantly higher in

no DMT versus IS-DMT (PÂ =Â 0.012) and in IM-DMT versus IS-DMT (PÂ =Â 0.001). Infection with SARS-CoV-2 occurred in 11 of 31 patients, and symptoms were mild in all cases. One relapse occurred after infection, but no relapses were documented after vaccination. CONCLUSIONS: Generally, mRNA vaccinations were well tolerated in POMS patients with and without DMT. Immune response was significantly reduced in patients treated with IS-DMT. No unexpected adverse events or relapses related to vaccinations were observed.
Even after the fourth dose of a SARS-CoV-2 vaccine neurological complications may develop.
Differences in reporting of adverse drug reactions due to COVID-19 vaccines depending on the reporter.
Perceived high risk of COVID-19 vaccination: The revealing power of placebo.
Resident Factors Associated With Breakthrough SARS-CoV-2 Infections. OBJECTIVE: To examine incidence of and resident characteristics associated with breakthrough infections (BTIs) and severe illness among residents with 2 messenger RNA (mRNA) vaccinations. DESIGN: Retrospective cohort study. SETTING AND PARTICIPANTS: Nursing home (NH) residents who completed their primary series of mRNA COVID-19 vaccination by March 31,Â 2021. METHODS: Electronic health records and Minimum Data Set assessments from a multistate NH data consortium were used to identify BTI and severe illness (a composite measure of hospitalization and/or death within 30Â days of BTI) occurring prior to November 24, 2021. A t test for differences in means was used to compare covariates for residents with and without BTI. Finally, we estimated incidence rate ratios (IRRs) for BTI with 95% CIs using a modified Poisson regression approach, comparing residents with BTI vs residents without. We adjusted for facility fixed effects in our model. RESULTS: Our sample included 23,172 residents from 984 NHs who were at least 14Â days past their second mRNA vaccine dose. Of those, 1173 (5%) developed an incident COVID-19 BTI (mean follow-up time: 250Â days). Among residents with BTI, 8.6% were hospitalized or died within 30Â days of BTI diagnosis. Factors associated with severe illness included age â‰¥85Â years (IRR 2.08, 95% CI 1.08-4.02, reference age <65Â years), bowel incontinence (IRR 1.73, 95% CI 1.01-2.99), coronary artery disease (IRR 1.96, 95% CI 1.31-2.94), chronic kidney disease (IRR 1.65, 95% CI 1.07-2.54), and schizophrenia (IRR 2.38, 95% CI 1.19-4.75). CONCLUSIONS AND IMPLICATIONS: Among vaccinated NH residents, BTIs and associated severe illness are rare. Residents aged â‰¥85Â years and with certain comorbidities appear to be the most vulnerable. Given that the pandemic continues and testing policies have relaxed, these data provide prognostic information for NH facilities faced with continued outbreaks.
Response and duration of serum anti-SARS-CoV-2 antibodies induced by the third dose of an inactivated vaccine: A prospective longitudinal cohort study at 21 serial time points over 641 days. Given the prevalence of low-pathogenic but highly infectious Omicron variants, a cohort study was conducted to assess the response and duration of novel coronavirus-inactivated vaccine-induced antibodies 1 year after the third dose (Day 641). Blood samples were collected and anti-spike neutralizing antibodies (neutralizing antibody), total antibodies against the receptor-binding domain of the spike protein (total antibody), and immunoglobulin G antibodies against the spike protein (IgG antibody) were determined. Antibody kinetics and attenuation were evaluated. The results showed that the levels of neutralizing, total, and IgG antibodies on Day 641 were 98.05â€‰IU/mL, 152.8â€‰AU/mL, and 7.68â€‰S/CO, respectively. Levels of anti-SARS-CoV-2Â antibodies were higher in the younger subgroup than in the older subgroup at several time points after the second and third doses. The seropositive rate of neutralizing antibodies providing protection from infection or severe infection was 46.87% and 87.5%, and the seropositive rates of total antibody and IgG antibody were maintained at 100% and 90.63%, respectively. The half-lives of neutralizing, total, and IgG antibodies were 186.89, 363.04, and 417.50 days, respectively. Collectively, anti-SARS-CoV-2

antibodies may provide a certain degree of protection from infection 1 year after the third dose and high protection from severe infection.

Paediatric safety assessment of BNT162b2 vaccination in a multistate hospital-based electronic health record system in the USA: a retrospective analysis. BACKGROUND: The emergency use authorisation of BNT162b2 (tozinameran; Comirnaty, Pfizer-BioNTech) for children aged 5-17 years has resulted in rapid vaccination in the paediatric population. However, there are few studies of adverse events associated with vaccination in children. The aim of this study was to systematically assess the adverse events of two-dose BNT162b2 vaccination in the paediatric population. METHODS: We conducted a retrospective analysis of patient electronic health records (EHRs) of children aged 5-17 years who received the primary two-dose series of the BNT162b2 vaccine between Jan 5, 2021, and Aug 5, 2022, at the Mayo Clinic Health System (MN, FL, AZ, IA, and WI), USA. Using natural language processing, we automatically curated adverse events reported by physicians in EHR clinical notes before and after vaccination. To determine significant adverse events after BNT162b2 vaccination, we calculated risk differences, which was defined as the percentage difference between the rate of children with an adverse event after a vaccine dose and the baseline rate of children with an adverse event before vaccination. 95% CIs and p values were calculated using the Miettinen and Nurminen score method. FINDINGS: 56â€ˆ436 individuals aged 5-17 years (20â€ˆ227 aged 5-11 years and 36â€ˆ209 aged 12-17 years) with EHRs in the Mayo Clinic Health Systems were included in the study. Overall, the reporting of adverse events remained low in passive surveillance. Serious adverse events were rare after the first and second doses of BNT162b2, with rates of anaphylaxis (six [0Â·01%] of 56â€ˆ436), myocarditis (five [0Â·01%]), and pericarditis (three [0Â·01%]) consistent with previous studies. Among the 20â€ˆ227 5-11-year-olds, there were increased risks of fatigue (58 after second dose vs 41 before first dose; risk difference [RD](dose2) 0Â·08% [95% CI -0Â·01 to 0Â·18], p=0Â·044) and fever (104 after second dose vs 77 before first dose; RD(dose2) 0Â·13% [0Â·00 to 0Â·27], p=0Â·022) after the second dose. Among the 36â€ˆ209 12-17-year-olds, there were increased risks of arthralgia (69 after second dose vs 48 before first dose; RD(dose2) 0Â·06% [-0Â·00 to 0Â·12], p=0Â·026), chills (58 after second dose vs 40 before first dose; RD(dose2) 0Â·05% [-0Â·00 to 0Â·11], p=0Â·034), and myalgia (96 after second dose vs 73 before first dose; RD(dose2) 0Â·06% [-0Â·01 to 0Â·14], p=0Â·038) after the second dose. Although the overall incidence was low, there was an increased risk of myocarditis in males aged 12-17 years after the second dose (five after second dose vs zero before first dose; RD(dose2) 0Â·03% [0Â·01 to 0Â·07], p=0Â·013), with median age being 15 years (IQR 14 to 16). INTERPRETATION: Overall, this data suggests that vaccination with BNT162b2 in the paediatric population is generally safe and well-tolerated. Further research is warranted to investigate the basis for the increased risk of myocarditis in adolescent males. Additionally, further studies are needed to confirm whether the findings in our study population apply to the whole vaccinated paediatric population. FUNDING: nference.

Acute disseminated encephalomyelitis (ADEM) following COVID-19 vaccination: A systematic review. BACKGROUND: Although global vaccination against COVID-19 infection has its excellence, potential side effects are yet of concern. Several lines of evidence have proposed ADEM occurrence after SARS-CoV-2 infection. Moreover, a large number of case reports and case series have also suggested the casual association between ADEM and COVID-19 vaccination. To better understand the development of ADEM following COVID-19 vaccination and its potential association, we aimed to systematically review ADEM cases reported after COVID-19 vaccination. METHODS: We conducted a comprehensive systematic search using three databases including PubMed, Scopus, and Web of Science. Studies that reported ADEM after COVID-19 vaccination were eligible to include in our study. Observational studies, case reports, and case series which reported cases of ADEM with sufficient detail to confirm clinical diagnosis following COVID-19 vaccination were eligible to enter our study. RESULTS: Twenty

studies were included in our systematic review after the abstract and full-text screening with a total of 54 cases. Among included patients, 45 (85.1Â %) developed ADEM after the first dose of the COVID-19 vaccine, and seven (12.9Â %) cases experienced ADEM after the second dose. The median time interval between vaccination and neurological symptoms was 14Â days which ranged from 12Â h to 63Â days. Twelve (22.2Â %) patients experienced symptoms of muscle weakness, ten (18.5Â %) presented unconsciousness, nine (16.6Â %) patients had urinary complaints, nine (16.6Â %) had visual impairments, and five (9.2Â %) experienced a seizure. After treatments, four (13.8Â %) patients died. Forty-six patients had clinical improvement (85.1Â %), also improvement in brain MRI was observed among 44 (81.4Â %) patients. CONCLUSION: In conclusion, it is not clear that ADEM could be a potential complication of COVID-19 vaccination based on the current evidence and further studies are needed. However, this rare condition should not trigger stopping the mass vaccination programs since the only way to eradicate the current pandemic of COVID-19 is to extend the number of immunized people.

Human papillomavirus vaccine initiation and up-to-date vaccine coverage for adolescents after the implementation of school-entry policy in Puerto Rico. The human papillomavirus (HPV) vaccine has been proven effective in the prevention of infection with high-risk HPV types, which can lead to the development of six HPV-related cancers. Puerto Rico (PR) adopted a mandatory HPV vaccination school-entry policy that took effect in August 2018. While school-entry requirements are generally accepted as an effective approach for increasing vaccination rates, there are few studies that have documented their impact on improving HPV vaccination rates. The objective of this study was to evaluate the impact of the HPV school-entry policy in PR on HPV vaccine coverage. We used a pre-post natural experiment. The study population included adolescents registered in the PR Immunization Registry during 2008-2019. We calculated HPV vaccine initiation and up-to-date (UTD) vaccine coverage rates. We estimated age-standardized rates (ASR) and standardized rate ratio with 95%CI. Vaccine data corresponding to a total of 495,327 adolescents were included for analysis; 50.9% were male and 49.1% were females. After policy implementation, a marked increase in raw HPV vaccine initiation among 11- to 12-year-old adolescents was observed across years 2017 (a pre-policy year), 2018, and 2019 (58.3%, 76.3%, and 89.8%, respectively). UTD coverage also showed a moderate increase after policy implementation among 11- to 12-year-old adolescents. The gap between sexes in vaccine initiation and UTD coverage narrowed over time; the ASRs in 2019 showed an increase of 19% in initiation and 7% increase in UTD relative to 2017 for males and females combined (both significant at $p<0.05$). This study demonstrated evidence of improvement in HPV vaccination rates following implementation of the school-entry policy and a narrowed sex gap in vaccine rates over time in PR. Future analyses should assess how the policy continues to affect vaccine coverage in subsequent years and how the COVID-19 pandemic has impacted HPV vaccination uptake.

Safety of COVID-19 vaccines in pregnancy: a VAERS based analysis. PURPOSE: Since vaccination against COVID-19 is recommended in pregnant people, we aimed to provide further evidence on the safety profile of COVID-19 vaccines in pregnancy. METHODS: Data on COVID-19 vaccines adverse events following immunizations (AEFIs) in pregnant people were retrieved from the open-access Vaccine Adverse Event Reporting System (VAERS) from December 2020 to April 2022. RESULTS: From December 2020 to April 1, 2022, a total of 4,869 reports involving pregnant women at COVID-19 vaccination were reported to VAERS. Among vaccines recipients, most belonged to the age group between 30 and 39Â years old (3,029; 62.21%) and nearly half experienced an adverse event within 48Â h of immunization (2,344; 48.14%). Overall, 21,816 suspected adverse reactions associated with COVID-19 vaccines were reported, and for as many as 80.43% of patients, they were described as non-serious. Most reactions occurred after administration of the mRNA-1273 (53.34%) and the

BNT162b2 (40.68%) vaccines, while only a small proportion were related to the Johnson & Johnson's vaccine (5.69%). The most common non-pregnancy specific adverse events were headache (482; 2.21%), fatigue (472; 2.16%), and pyrexia (436; 2.00%), while adverse pregnancy outcomes with the highest reporting rate were abortions spontaneous (762; 3.49%), and vaginal haemorrhage (229; 1.05%). CONCLUSION: This post-marketing survey on VAERS data have provided updated evidence on the safety of COVID-19 vaccines during pregnancy, thus supporting clinicians in recommending maternal immunization.

Wave of COVID-19 outbreaks in Gold Coast residential aged care facilities after easing travel restrictions into Queensland. OBJECTIVE: This paper describes outbreaks of coronavirus disease 2019 (COVID-19) in Gold Coast residential aged care facilities (RACFs), in the two months following the easing of travel restrictions at Queensland's domestic border on 13 December 2021. METHODS: This audit reviewed all RACF COVID-19 outbreaks notified to the Gold Coast Public Health Unit between 13 December 2021 and 12 February 2022. An outbreak was defined by the Communicable Diseases Network Australia guidelines current at the time. RESULTS: There were 60 COVID-19 outbreaks across 57 RACFs during this period. In 44 outbreaks (73.3%), a staff member was identified as the primary or co-primary case. Transmission amongst residents occurred in 48 outbreaks (80.0%). The attack rates in staff and residents were 17.0% (n = 1,060) and 11.7% (n = 645) respectively. A higher number of males were hospitalised (n = 39: 57.4%) or died (n = 28: 66.7%) than were females (n = 29: 42.6%; n = 14: 33.3% respectively). Most resident cases (n = 565: 87.6%) had received two or more doses of a COVID-19 vaccine. In resident cases who were under-vaccinated (n = 76), twenty (26.3%) required hospitalisation and nine (11.8%) died. In resident cases who received two doses of vaccine (n = 484), forty-three (8.9%) were hospitalised and 27 (5.8%) died. In resident cases who had received three doses (n = 80), four (5.0%) were hospitalised and five (6.3%) died. CONCLUSIONS: COVID-19 caused significant morbidity and mortality in Gold Coast RACFs following the easing of border restrictions. Higher rates of hospitalisation and death occurred in males than in females, and in under-vaccinated resident cases than in those vaccinated with at least two doses of a COVID-19 vaccine. IMPLICATIONS FOR PUBLIC HEALTH: These data support the need for up-to-date COVID-19 vaccination of residents in RACFs, continued surveillance and timely and appropriate implementation of public health guidelines to manage COVID-19 outbreaks in RACFs.

COVID-19 vaccine acceptance and associated factors among adult clients at public hospitals in eastern Ethiopia using the health belief model: multicentre cross-sectional study. OBJECTIVE: Immunization is still one of the best ways to reduce viral-related morbidity and mortality . Therefore, this study aimed to assess COVID-19 vaccine acceptance and associated factors among adult clients at public hospitals in Eastern Ethiopia. METHOD: A multicentred facility-based cross-sectional study design was utilised. The systematic random sampling technique was used to select 420 study participants. The characteristics of individuals were described using descriptive statistical analysis such as frequency, median and IQR. Mean was used for health belief model components. The association was assessed using bivariate and multivariable logistic regression and described by the OR along with a 95% CI. Finally, a p-value<0.05 in the adjusted analysis was used to declare a significant association. OUTCOME MEASURE: COVID-19 vaccine acceptance and associated factors. RESULT: A total of 412 adult clients were interviewed, with a response rate of 98.1%. Of the total study participants, 225 (54.6%; 95%â€‰CI: 50.0% to -59.7%) were willing to accept the COVID-19 vaccine. Ageâ‰¥46 (adjusted OR, AOR=3.64, 95%â€‰CI: 1.35- to 9.86), college and above level of education (AOR=2.50, 95%â€‰CI: 1.30- to 4.81), having health insurance (AOR=1.79, 95%â€‰CI: 1.11- to 2.87) and experiencing chronic disease (AOR=1.96, 95%â€‰CI: 1.02- to 3.77) were predictor variables. Also, components of the health belief model were significantly associated with COVID-19 vaccine acceptance. CONCLUSION: COVID-19 vaccine acceptance among the adult population was low

compared to other study. Factors associated with COVID-19 vaccine acceptance were age, college and above level of education, having a chronic disease, having health insurance, perceived susceptibility, perceived severity, perceived benefit and perceived barrier.Improving awareness about COVID-19 among all sections of the population is crucial to improving vaccine acceptability.

Postoperative mortality and complications in patients with and without pre-operative SARS-CoV-2 infection: a service evaluation of 24 million linked records using OpenSAFELY. Surgical decision-making after SARS-CoV-2 infection is influenced by the presence of comorbidity, infection severity and whether the surgical problem is time-sensitive. Contemporary surgical policy to delay surgery is informed by highly heterogeneous country-specific guidance. We evaluated surgical provision in England during the COVID-19 pandemic to assess real-world practice and whether deferral remains necessary. Using the OpenSAFELY platform, we adapted the COVIDSurg protocol for a service evaluation of surgical procedures that took place within the English NHS from 17 March 2018 to 17 March 2022. We assessed whether hospitals adhered to guidance not to operate on patients within 7â€‰weeks of an indication of SARS-CoV-2 infection. Additional outcomes were postoperative all-cause mortality (30â€‰days, 6Â months) and complications (pulmonary, cardiac, cerebrovascular). The exposure was the interval between the most recent indication of SARS-CoV-2 infection and subsequent surgery. In any 6-month window, <â€‰3% of surgical procedures were conducted within 7â€‰weeks of an indication of SARS-CoV-2 infection. Mortality for surgery conducted within 2â€‰weeks of a positive test in the era since widespread SARS-CoV-2 vaccine availability was 1.1%, declining to 0.3% by 4â€‰weeks. Compared with the COVIDSurg study cohort, outcomes for patients in the English NHS cohort were better during the COVIDSurg data collection period and the pandemic era before vaccines became available. Clinicians within the English NHS followed national guidance by operating on very few patients within 7â€‰weeks of a positive indication of SARS-CoV-2 infection. In England, surgical patients' overall risk following an indication of SARS-CoV-2 infection is lower than previously thought.

SARS-CoV-2 specific T-cell humoral response assessment after COVID-19 vaccination using a rapid direct real-time PCR amplification. OBJECTIVES: The SARS-CoV-2 immune response is mediated by both humoral and cellular immunity. In this study, SARS-CoV-2 specific cellular immunity was tested by a novel direct real-time PCR (dRT-PCR) assay, targeting mRNA of CXCL10, and compared with respect to an ELISA measuring interferon gamma (IFN-Î³) release. METHODS: Whole blood (Li-He) and serum samples were collected from 92 healthcare workers (HCW), with three doses of homologous (Pfizer/BioNTech, n=74) or heterologous (Pfizer/BioNTech and Vaxzevria or Moderna, n=18) vaccinations. Li-He samples were incubated with SCV2 PANEL-1-T-ACTIVATION (Hyris srl, Lodi, Italy), or CoV-2 IGRA TUBE ELISA (Euroimmune, Lubeck, Germany). CXCL10 mRNA expression was analyzed by bCube/bApp (Hyris), while IFN-Î³ was evaluated by quant-T-Cell SARS-CoV-2 ELISA (Euroimmune). Anti-SARS-CoV-2 S-RBD IgG levels were measured in sera using a CLIA assay (Snibe, Shenzen, China). RESULTS: Imprecision of dRT-PCR assay was found to be satisfactory, and the two methods for measuring TÂ cell immunity to SARS-CoV-2 peptides agreed in 82/87 (94.2%) of results. At qualitative dRT-PCR analyses, 81 subjects (93.2%) resulted as reactive to SARS-CoV-2 peptides, 3 (3.4%) were borderline and 3 were negative (3.4%). At univariate and multivariate analyses of quantitative dRT-PCR mRNA of CXCL10 and IFN-Î³ release results showed no difference between HCW with previous infection, homologous/heterologous vaccination, or demographical features. Anti-SARS-CoV-2 S-RBD IgG was associated with the previous infection and theÂ time between the last vaccination or positivity. CONCLUSIONS: Direct RT-PCR appeared accurate for determining the presence or absence of immunoreactivity of SARS-CoV-2 specific TÂ cells, especially when rapid analyses are required, such as for organ transplantation.

Investigating Generation of Antibodies against the Lipid Nanoparticle Vector Following COVID-19 Vaccination with an mRNA Vaccine. Despite the success of mRNA-based vaccines against infectious diseases (including COVID-19), safety concerns have been raised relating to the lipid nanoparticles (LNPs) used to deliver the mRNA cargo. Antibodies against the polyethylene glycol (PEG) coating on these non-viral vectors are present in the general population and can in some instances induce allergic reactions. Furthermore, treatment with PEGylated therapeutics may increase the plasma concentration of such anti-PEG antibodies. The widespread use of PEGylated nanoparticles for mRNA vaccines concerns researchers and clinicians about a potential rise in future cases of allergic reactions against mRNA vaccines and cross-reactions with other PEGylated therapeutics. To determine if vaccination with Comirnaty increased the plasma concentration of antibodies against LNPs, we investigated the blood plasma concentration of anti-LNP antibodies in healthy individuals before and after vaccination with the mRNA-based COVID-19 vaccine Comirnaty (BNT162b2). Blood samples were acquired from 21 healthy adults before vaccination, 3-4 weeks after the first vaccination dose but before the second dose, and 2-6 months after the second (booster) dose. The blood plasma concentration of antibodies recognizing the LNPs was analyzed using a microscopy-based assay capable of measuring antibody-binding to individual authentic LNPs. No significant increase in anti-LNP antibodies was observed after two doses of Comirnaty. The LNPs used for intramuscular delivery of mRNA in the vaccine against COVID-19, Comirnaty, do, therefore, not seem to induce the generation of anti-vector antibodies.

Risk of relapse after SARS-CoV-2 vaccine in the Milan cohort of thrombotic thrombocytopenic purpura patients.

Vasospastic angina following COVID-19 vaccine-related myocarditis: comment.

Hypocomplementemic urticarial vasculitis case with hemophagocytic lymphohistiocytosis following SARS-CoV-2 mRNA vaccination. A 61-year-old man with no previous record of autoimmune disease developed fever, polyarthralgia, purpura, and urticaria-like rash 2â€‰weeks after the first dose of the Moderna mRNA-1273 vaccine, and symptoms deteriorated following the second dose. He presented reduced erythrocyte and platelet counts, hyperferritinemia, high sIL-2R levels, and severe hypocomplementemia. We diagnosed hypocomplementemic urticarial vasculitis (HUVS), and his symptoms as well as laboratory findings improved following treatment with mPSL 1000â€‰mg/day for 3â€‰days and PSL 40â€‰mg/day. Twelve weeks following treatment initiation, the patient relapsed with fever, sore throat, pancytopenia, and hyperferritinemia when the PSL dose was reduced to 12.5â€‰mg/day. Bone marrow biopsy and MRI presented fatty marrow and hemophagocytosis. The patient's blood cells started recovering using ATGâ€‰+â€‰CsAâ€‰+â€‰EPAG therapy for hemophagocytic lymphohistiocytosis (HLH). This is the first case report of HUVS and HLH following SARS-CoV-2 mRNA vaccination. It is presumed that SARS-CoV-2 mRNA vaccine can induce the excessive production of certain types of cytokines, such as TNF-Î±, IL-1, IL-4, IL-5, IL-6, and IL-17 as a consequence of IL-6 Amplification (IL-6 Amp). SARS-CoV-2 mRNA-vaccines can cause disruption of immune homeostasis in healthy individuals. An extremely rare disease of HUVS complicated by HLH can be developed as a consequence.

Rapid Onset Severe Immune Thrombocytopenia following mRNA COVID-19 Vaccine in a Young Patient. The coronavirus disease 2019 (COVID-19) pandemic has affected millions of people around the world. Vaccination against COVID-19 has been approved for the following three vaccines in the United States: Pfizer-BioNTech, Moderna, and Janssen. Hematological complications of vaccination have been reported in the literature but remain as a rare phenomenon. We present the case of a patient who developed severe thrombocytopenia within twenty-four hours following the Pfizer-BioNTech vaccination. Commonly encountered differentials including heparin-induced thrombocytopenia and common viral etiologies were ruled out, and other causes such as drug

reactions deemed unlikely as the etiology of this presentation after a broad workup. Nucleocapsid antibodies against COVID-19 were found to be positive which indicated that vaccination was at least the second encounter with this virus for our patient, which has been reported previously as the cause of immune thrombocytopenia (ITP), and this might be the culprit for sudden onset. He responded to the first-line ITP treatment with corticosteroids and intravenous immunoglobulin (IVIG) as evidenced by the fast recovery of platelet count and lack of recurrence of thrombocytopenia.

Comparison of Humoral Response in Kidney Transplant Recipients and Donors and Healthy Volunteers Following Second Dose of SARS-CoV-2 mRNA Vaccine. PURPOSE: To investigate the kinetics and durability of anti-spike glycoprotein (S) immunoglobulin G (IgG) after the second dose of mRNA-based SARS-CoV-2 vaccine in kidney transplant recipients (recipients) compared with those in kidney donors (donors) and healthy volunteers (HVs) and identify factors negatively associated with SARS-CoV-2 vaccine effectiveness in recipients. METHODS: We enrolled 378 recipients with no history of COVID-19 and no anti-S-IgG before the first vaccine and who received a second mRNA-based vaccine dose. Antibodies were detected using an immunoassay more than 4 weeks after the second vaccine dose. Anti-S-IgG <0.8, â‰¥0.8 to 15, and â‰¥15 U/mL were considered negative, weak positive, and strongly positive, respectively, whereas anti-nucleocapsid protein IgG was negative. Anti-S-IgG titer was determined in 990 HVs and 102 donors. RESULTS: Anti-S-IgG titers were 154, 2475, and 1181 U/mL in the recipient, HV, and donor groups, respectively, with values significantly lower in recipients. The anti-S-IgG-positivity rate of recipients gradually increased following the second vaccination, suggesting that recipients had a delayed response compared with the HV and donor groups, who had a 100% positivity rate at an earlier time point. Anti-S-IgG titers decreased in donors and HVs, whereas they remained stable in recipients, although at a significantly lower level. Independent negative factors associated with anti-S-IgG titers in recipients were age >60 years and lymphocytopenia (odds ratio: 2.35 and 2.44, respectively). CONCLUSIONS: Kidney transplant recipients demonstrate delayed and attenuated responses, with lower SARS-CoV-2 antibody titers after the second dose of the mRNA-based COVID-19 vaccine.

Severe Hepatitis-associated Aplastic Anemia Following COVID-19 mRNA Vaccination. We herein report a case of hepatitis-associated aplastic anemia (HAAA) that occurred after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. In this patient, progressive pancytopenia observed two months after acute hepatitis following the second dose of the SARS-CoV-2 vaccine indicated the development of HAAA. Although some reports have suggested that SARS-CoV-2 vaccination may be involved in the development of autoimmune diseases, no cases of HAAA developing after SARS-CoV-2 vaccination have been reported. SARS-CoV-2 vaccination in children has only started relatively recently, so the range of side effects in children has not yet been thoroughly described. Therefore, we need to strengthen surveillance for symptoms of children who are vaccinated.

Small fiber neuropathy with long-term, multifocal paresthesias after a SARS-CoV-2 vaccination.

LipschÃ¼tz acute vulvar ulcer related to COVID-19 vaccination: First case report in South America. LipschÃ¼tz ulcer is a non-sexually transmitted genital lesion of unknown etiology, which presents as a painful vulvar ulcer. LipschÃ¼tz ulcers have been described in most continents. This is the first case reported in Peru and South America. We present the case of a 33-year-old female patient with a LipschÃ¼tz ulcer after being vaccinated with the second dose of the AstraZeneca COVID-19 vaccine. She reported having had only one sexual partner in her lifetime. Laboratory results were negative for herpes simplex 2, Cytomegalovirus, Toxoplasma gondii, Epstein-Barr virus, and syphilis. The patient received symptomatic treatment. Ten days after the onset, the patient was significantly better during follow-up. This case report displays a potential adverse effect of the AstraZeneca COVID-19 vaccine as

a LipschÃ¼tz ulcer triggered by the host humoral immune response. However, further research is needed to establish the causal relationship between these two.

Vector-based SARS-CoV-2 vaccination is associated with improved T-cell responses in hematological neoplasia. In order to elucidate mechanisms for severe acute respiratory syndrome coronavirus 2 vaccination success in hematological neoplasia, we, herein, provide a comprehensive characterization of the spike-specific T-cell and serological immunity induced in 130 patients in comparison with 91 healthy controls. We studied 121 distinct T-cell subpopulations and the vaccination schemes as putative response predictors. In patients with lymphoid malignancies an insufficient immunoglobulin G (IgG) response was accompanied by a healthy CD4+ T-cell function. Compared with controls, a spike-specific CD4+ response was detectable in fewer patients with myeloid neoplasia whereas the seroconversion rate was normal. Vaccination-induced CD4+ responses were associated to CD8+ and IgG responses. Vector-based AZD1222 vaccine induced more frequently detectable specific CD4+ responses in study participants across all cohorts (96%; 27 of 28), whereas fully messenger RNA-based vaccination schemes resulted in measurable CD4+ cells in only 102 of 168 participants (61%; PÂ <Â .0001). A similar benefit of vector-based vaccination was observed for the induction of spike-specific CD8+ T cells. Multivariable models confirmed vaccination schemes that incorporated at least 1 vector-based vaccination as key feature to mount both a spike-specific CD4+ response (odds ratio, 10.67) and CD8+ response (odds ratio, 6.56). Multivariable analyses identified a specific CD4+ response but not the vector-based immunization as beneficial for a strong, specific IgG titer. Our study reveals factors associated with a T-cell response in patients with hematological neoplasia and mightÂ pave the way toward tailored vaccination schemes for vaccinees with these diseases. The study was registered at the German Clinical Trials Register as #DRKS00027372.

Editorial Comment: Duration of Axillary Lymphadenopathy After COVID-19 Vaccine Booster Administration.

Myocarditis: causes, mechanisms, and evolving therapies. INTRODUCTION: Myocarditis is a severe lymphocyte-mediated inflammatory disorder of the heart, mostly caused by viruses and immune checkpoint inhibitors (ICIs). Recently, myocarditis as a rare adverse event of mRNA vaccines for SARS-CoV-2 has caused global attention. The clinical consequences of myocarditis can be very severe, but specific treatment options are lacking or not yet clinically proven. AREAS COVERED: This paper offers a brief overview of the biology of viruses that frequently cause myocarditis, focusing on mechanisms important for viral entry and replication following host infection. Current and new potential therapeutic targets/strategies especially for viral myocarditis are reviewed systematically. In particular, the immune system in myocarditis is dissected with respect to infective viral and non-infective, ICI-induced myocarditis. EXPERT OPINION: Vaccination is an excellent emerging preventative strategy for viral myocarditis, but most vaccines still require further development. Anti-viral treatments that inhibit viral replication need to be considered following viral infection in host myocardium, as lower viral load reduces inflammation severity. Understanding how the immune system continues to damage the heart even after viral clearance will define novel therapeutic targets/strategies. We propose that viral myocarditis can be best treated using a combination of antiviral agents and immunotherapies that control cytotoxic T cell activity.

Humoral responses after primary and booster SARS-CoV-2 inactivated vaccination in patients with chronic hepatitis B virus infection: A longitudinal observational study. Given the pandemic of severe acute respiratory syndrome coronavirus 2 Omicron variants, booster vaccination (BV) using inactivated virus vaccines (the third dose) has been implemented in China. However, the immune responses after BV, especially those against Omicron, in patients with chronic hepatitis B virus (HBV) infection (CHB) are unclear. In this prospective longitudinal study, 114 patients with CHB and 68 healthy controls (HCs) were recruited after receiving inactivated vaccination. The anti-receptor-

binding domain (RBD) immunoglobulin G (IgG), neutralizing antibodies (NAbs), neutralization against Omicron (BA2.12.1, BA.4/5), and specific B/T cells were evaluated. In patients, anti-RBD IgG was elevated significantly after BV; the titers were as high as those in HCs. Similar results were obtained for the NAbs. However, compared with that against wild type (WT), the neutralization against Omicron was compromised after BV. The frequency of RBD(+) atypical memory B cells increased, but spike-specific cluster of differentiation 4(+) /8(+) T cells remained unchanged after BV. Moreover, no serious adverse events or HBV reactivation were observed after BV. These results suggest that BV significantly enhanced antibody responses against WT; however, it resulted in compromised antibody responses against Omicron in patients with CHB. Hence, new all-in-one vaccines and optimal vaccination strategies should be studied promptly.

Evaluation of metabolic changes in FDG PET/CT imaging after mRNA-based COVID-19 vaccination. BACKGROUND: It isimportant to evaluate the vaccine-related metabolic changes on FDG PET/CT to avoid confusing results. We here aimed to assess the frequency and intensity of regional and systemic metabolic PET/CT changes of patients who received the mRNAbased COVID-19 vaccine (BNT162b2-Pfizer/BioNTech) and to analyze possible factors affecting these changes. METHODS: Among the patients who underwent FDG PET/CT for any indication in our department between July 2021 and December 2021, 129 volunteer patients with a history of COVID-19 vaccination were included in this prospective observational study. Bilateral axillary lymph nodes, ipsilateral deltoid muscle, bone marrow, spleen, thyroid, and liver FDG uptakes were evaluated visually and semiquantitatively for each examination. RESULTS: The frequencies of positive axillary lymph nodes after vaccination were 40%, 44.4%, 32.6%, and 44.7% in all, 1st dose, 2nd dose, and heterologous vaccination regimens groups, respectively. Maximum standardized uptake values of spleen, liver, and bone marrow were statistically high in patients with positive axillary lymph nodes than with negative ones ($p < 0.05$). Positive deltoid muscle uptake and diffusely increased thyroid uptake findings were observed in 10 and 8 patients, respectively. The median time interval between vaccination and imaging was 9.5 days for patients with positive axillary lymph nodes and 17 days for patients with negative nodes. In our study group, only 8 patients had a positive documented history of COVID-19 infection. DISCUSSION: Regional and systemic metabolic changes were occasionally found on FDG PET/CT imaging in patients who received the mRNA-based COVID-19 vaccine. To avoid these timely decreasing changes, we recommend managing the ideal timing of imaging or vaccination and taking a careful history.

Impact of inactivated COVID-19 vaccines on lung injury in B.1.617.2 (Delta) variant-infected patients. BACKGROUND: Chest computerized tomography (CT) scan is an important strategy that quantifies the severity of COVID-19 pneumonia. To what extent inactivated COVID-19 vaccines could impact the COVID-19 pneumonia on chest CT is not clear. METHODS: This study recruited 357 SARS-COV-2 B.1.617.2 (Delta) variant-infected patients admitted to the Second Hospital of Nanjing from July to August 2021. An artificial intelligence-assisted CT imaging system was used to quantify the severity of COVID-19 pneumonia. We compared the volume of infection (VOI), percentage of infection (POI) and chest CT scores among patients with different vaccination statuses. RESULTS: Of the 357 Delta variant-infected patients included for analysis, 105 were unvaccinated, 72 were partially vaccinated and 180 were fully vaccinated. Fully vaccination had the least lung injuries when quantified by VOI (median VOI of 222.4Â cm(3), 126.6Â cm(3) and 39.9Â cm(3) in unvaccinated, partially vaccinated and fully vaccinated, respectively; pâ€‰<â€‰0.001), POI (median POI of 7.60%, 3.55% and 1.20% in unvaccinated, partially vaccinated and fully vaccinated, respectively; pâ€‰<â€‰0.001) and chest CT scores (median CT score of 8.00, 6.00 and 4.00 in unvaccinated, partially vaccinated and fully vaccinated, respectively; pâ€‰<â€‰0.001). After adjustment for age, sex, comorbidity, time from illness onset to hospitalization and viral load, fully vaccination but not partial vaccination was significantly associated with less lung injuries quantified by VOI {adjust coefficient[95%CI] for "full

vaccination": -Â 106.10(-Â 167.30,44.89); pâ€‰<â€‰0.001}, POI {adjust coefficient[95%CI] for "full vaccination": -Â 3.88(-Â 5.96, -Â 1.79); pâ€‰=â€‰0.001} and chest CT scores {adjust coefficient[95%CI] for "full vaccination": -Â 1.81(-Â 2.72, -Â 0.91); pâ€‰<â€‰0.001}. The extent of reduction of pulmonary injuries was more profound in fully vaccinated patients with older age, having underlying diseases, and being female sex, as demonstrated by relatively larger absolute values of adjusted coefficients. Finally, even within the non-severe COVID-19 population, fully vaccinated patients were found to have less lung injuries. CONCLUSION: Fully vaccination but not partially vaccination could significantly protect lung injury manifested on chest CT. Our study provides additional evidence to encourage a full course of vaccination.

Mortality and risk factors of vaccinated and unvaccinated frail patients with COVID-19 treated with anti-SARS-CoV-2 monoclonal antibodies: A real-world study. OBJECTIVES: There is a scarcity of data on the outcomes and predictors of therapeutic failure of monoclonal antibodies (mAbs) in frail patients with COVID-19. METHODS: Prospective study including consecutive COVID-19 outpatients referred by primary care physicians for mAb treatment. The outcomes evaluated were 60-day mortality, time to SARS-CoV-2 clearance, need for hospitalization, and O(2) therapy. RESULTS: Among 1026 COVID-19 patients enrolled, 60.2% received casirivamab/imdevimab and 39.8% sotrivimab. Median age was 63 years, 52.4% were males and median time from positive nasopharyngeal swab to mAbs administration was 3 days (interquartile range, 2-5). 78.1% were vaccinated. Overall, the 60-day mortality was 2.14%. No differences in outcomes were observed between the two mAbs used. No difference was observed in mortality between vaccinated and unvaccinated patients (PÂ =Â 0.925); although, lower rate of hospitalization (P <0.005), less need for O(2) therapy (P <0.0001) and reduced nasopharyngeal swab negativity time (P <0.0001) were observed in vaccinated patients. Early administration of mAbs was associated with lower mortality (P <0.007), whereas corticosteroid use worsened prognosis (P <0.004). The independent predictors associated with higher mortality were older age (P <0.0001), presence of active hematologic malignancies (P <0.0001), renal failure (P <0.041), and need for O(2) therapy (P <0.001). CONCLUSION: This study shows similar effectiveness among mAbs used, regardless of vaccination status and identifies patients with COVID-19 in whom mAbs have poor activity.

Strategies to Address COVID-19 Vaccine and Pregnancy Myths. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) poses risks to pregnant women and their infants. The spread of misinformation about COVID-19 vaccination is a barrier to optimizing vaccination rates among women of childbearing age. We conducted an environmental scan to identify misinformation about COVID-19 vaccination, pregnancy, and fertility, and a review to identify evidence to refute misinformation and strategies to correct and prevent the spread of misinformation. Seven identified themes of misinformation are: the vaccine causes female infertility; can cause miscarriage; and can decrease male fertility; mRNA vaccines attack the placenta; pregnant and breastfeeding persons should not get the vaccine; the vaccine can change menstrual cycles; and vaccinated people can spread infertility symptoms to unvaccinated people. Strategies that can be implemented by social media platforms to help prevent misinformation spread and correct existing health misinformation include improving information regulation by modifying community standards, implementing surveillance algorithms, and applying warning labels to potentially misleading posts. Health services organizations and clinicians can implement health misinformation policies, directly recommend vaccinations, provide credible explanations and resources to debunk misinformation, educate patients and populations on spotting misinformation, and apply effective communication strategies. More research is needed to assess longer-term effects of vaccination among women of childbearing age to strengthen the defense against misinformation and to evaluate strategies that aim to prevent and correct misinformation spread about COVID-19 vaccinations.

Relationship Between Coronavirus Disease 2019 Vaccination Rates and Rare But Potentially Fatal Adverse Events: A Regression Discontinuity Analysis of Western Countries. BACKGROUND: Owing to limited experience with the new vaccine platforms, discussion of vaccine safety is inevitable. However, media coverage of adverse events of special interest could influence the vaccination rate; thus, evaluating the outcomes of adverse events of special interest influencing vaccine administration is crucial. METHODS: We conducted regression discontinuity in time analysis to calculate the local average treatment effect (LATE) using datasets from Our World in Data and Johns Hopkins University Center for Systems Science and Engineering. For the United States, the United Kingdom, and Europe, the cutoff points were April 23rd and June 23rd, April 7th, and the 14th week of 2021, respectively. RESULTS: The LATE of the Advisory Committee on Immunization Practices (ACIP) meeting held on April 23rd was -0.249 for all vaccines, -0.133 (-0.189 to -0.076) for Pfizer, -0.064 (-0.115 to -0.012) for Moderna, and -0.038 (-0.047 to -0.030) for Johnson & Johnson. Discontinuities were observed for all three types of vaccines in the United States. The June 23rd meeting of the ACIP (mRNA vaccines and myocarditis) did not convene any discontinuities. Furthermore, there was no significant drop in the weekly average vaccination rates in Europe following the European Medicines Agency (EMA) statement on April 7th. Conversely, there was a significant drop in the first-dose vaccination rates in the United Kingdom related to the EMA report. The first-dose vaccination rate for all vaccines changed by -0.104 (-0.176 to -0.032). CONCLUSION: Although monitoring and reporting of adverse events of special interest are important, a careful approach towards public announcements is warranted.

Alopecia areata and subsequent Marie Antoinette syndrome following COVID-19 infection and vaccination: A case report. Numerous cutaneous manifestations related to the COVID-19 (severe acute respiratory syndrome coronavirus 2) viral infection have been reported in literature. In this case report, we describe two acute hair-associated manifestations-the first being alopecia areata and the second is a case of Marie Antoinette syndrome or Canities subita where all the scalp hair has become white almost overnight. Both entities of hair changes were seen in the same patient.

Real-World Association Between mRNA Vaccination and Infection From the Omicron Strain of SARS-CoV-2: A Population-Level Analysis. INTRODUCTION: Two mRNA vaccines approved in the U.S. have high efficacy against COVID-19 disease from the original strain of SARS-CoV-2. We evaluated the population-level association between vaccination status and COVID-19 infection by age group during the initial wave of the Omicron variant in a diverse population in the Mid-South U.S. METHODS: In this observational population-based cohort study, vaccination information and positive COVID-19 cases in Shelby County, Tennessee, from December 12, 2021 through January 22, 2022 were collected from surveillance data at the Shelby County Health Department (Memphis, Tennessee). Exposure groups included individuals who were unvaccinated, were fully vaccinated, and were fully vaccinatedÂ +Â booster. We calculated incidence rates of COVID-19 diagnosis per person-year among county adult (aged 18+ years) residents in crude form and stratified by age group. RESULTS: In this population-based study, we identified 64.56% fewer COVID-19 infections in the fully vaccinatedÂ +Â booster group and 41.08% fewer in the fully vaccinated group than in the unvaccinated group. CONCLUSIONS: These results confirm and extend the findings of recent immunologic and epidemiologic studies in a racially diverse region of the Mid-South U.S. In stratified analysis, we also found evidence suggesting that vaccine protection against Omicron may increase with age.

A bifurcation analysis and model of Covid-19 transmission dynamics with post-vaccination infection impact. SARS COV-2 (Covid-19) has imposed a monumental socio-economic burden worldwide, and its impact still lingers. We propose a deterministic model to describe the transmission dynamics of Covid-19, emphasizing the effects of vaccination on the prevailing epidemic. The proposed model

incorporates current information on Covid-19, such as reinfection, waning of immunity derived from the vaccine, and infectiousness of the pre-symptomatic individuals into the disease dynamics. Moreover, the model analysis reveals that it exhibits the phenomenon of backward bifurcation, thus suggesting that driving the model reproduction number below unity may not suffice to drive the epidemic toward extinction. The model is fitted to real-life data to estimate values for some of the unknown parameters. In addition, the model epidemic threshold and equilibria are determined while the criteria for the stability of each equilibrium solution are established using the Metzler approach. A sensitivity analysis of the model is performed based on the Latin Hypercube Sampling (LHS) and Partial Rank Correlation Coefficients (PRCCs) approaches to illustrate the impact of the various model parameters and explore the dependency of control reproduction number on its constituents parameters, which invariably gives insight on what needs to be done to contain the pandemic effectively. The foregoing notwithstanding, the contour plots of the control reproduction number concerning some of the salient parameters indicate that increasing vaccination coverage and decreasing vaccine waning rate would remarkably reduce the value of the reproduction number below unity, thus facilitating the possible elimination of the disease from the population. Finally, the model is solved numerically and simulated for different scenarios of disease outbreaks with the findings discussed.

Do different platforms of coronavirus vaccines have different impacts on psoriasis flares? This study evaluated the impacts on psoriasis flares of 3 vaccine platforms: inactivated, viral vector and mRNA. Respectively, 198 and 96 psoriasis patients with and without COVID-19 vaccination during the study period. Group comparison revealed no increased risk of psoriasis flaring after COVID-19 vaccination. The vaccinated group received 425 doses of vaccine (140 inactivated, 230 viral vector and 55 mRNA). Patients' self-reported symptoms included all three platforms causing psoriasis flare, but the highest was among patients administered with mRNA vaccines. Most flares were mild to moderate, and most patients (89.8%) managed their flare-up lesions without rescue therapy. In conclusion, our study showed that the rate of psoriasis flare was not significantly different between vaccinated and unvaccinated groups. Factors that might explain psoriasis flare include vaccine-related psychological stress and side effects from vaccination. Different platforms of corona vaccines seemed to have different impact of psoriasis flares. Based on our results and the recommendations of several consensus guidelines, the benefits of COVID vaccinations outweigh the risks to patients with psoriasis. Patients with psoriasis should receive a COVID vaccine as soon as one is available.

Effect of Thromboprophylaxis on Clinical Outcomes After COVID-19 Hospitalization. BACKGROUND: Patients hospitalized with COVID-19 have an increased incidence of thromboembolism. The role of extended thromboprophylaxis after hospital discharge is unclear. OBJECTIVE: To determine whether anticoagulation is superior to placebo in reducing death and thromboembolic complications among patients discharged after COVID-19 hospitalization. DESIGN: Prospective, randomized, double-blind, placebo-controlled clinical trial. (ClinicalTrials.gov: NCT04650087). SETTING: Done during 2021 to 2022 among 127 U.S. hospitals. PARTICIPANTS: Adults aged 18 years or older hospitalized with COVID-19 for 48 hours or more and ready for discharge, excluding those with a requirement for, or contraindication to, anticoagulation. INTERVENTION: 2.5 mg of apixaban versus placebo twice daily for 30 days. MEASUREMENTS: The primary efficacy end point was a 30-day composite of death, arterial thromboembolism, and venous thromboembolism. The primary safety end points were 30-day major bleeding and clinically relevant nonmajor bleeding. RESULTS: Enrollment was terminated early, after 1217 participants were randomly assigned, because of a lower than anticipated event rate and a declining rate of COVID-19 hospitalizations. Median age was 54 years, 50.4% were women, 26.5% were Black, and 16.7% were Hispanic; 30.7% had a World Health Organization severity score of 5 or greater, and 11.0% had an International Medical

Prevention Registry on Venous Thromboembolism risk prediction score of greater than 4. Incidence of the primary end point was 2.13% (95% CI, 1.14 to 3.62) in the apixaban group and 2.31% (CI, 1.27 to 3.84) in the placebo group. Major bleeding occurred in 2 (0.4%) and 1 (0.2%) and clinically relevant nonmajor bleeding occurred in 3 (0.6%) and 6 (1.1%) apixaban-treated and placebo-treated participants, respectively. By day 30, thirty-six (3.0%) participants were lost to follow-up, and 8.5% of apixaban and 11.9% of placebo participants permanently discontinued the study drug treatment. LIMITATIONS: The introduction of SARS-CoV-2 vaccines decreased the risk for hospitalization and death. Study enrollment spanned the peaks of the Delta and Omicron variants in the United States, which influenced illness severity. CONCLUSION: The incidence of death or thromboembolism was low in this cohort of patients discharged after hospitalization with COVID-19. Because of early enrollment termination, the results were imprecise and the study was inconclusive. PRIMARY FUNDING SOURCE: National Institutes of Health.

Response to: Correspondence on Bell's palsy as an adverse event following COVID-19 vaccination.

Survey of pediatric transplant center practices regarding COVID-19 vaccine mandates for transplant candidates and living donors and use of COVID-19-positive deceased organs. BACKGROUND: COVID-19 vaccine is recommended for individuals ages â‰¥6â€‰months; however, whether vaccination should be mandated for transplant candidates and living donors remains controversial. This study assessed COVID-19 policies at US pediatric solid organ transplant centers. METHODS: A 79-item survey was emailed between March and April 2022 to 200 UNOS Medical Directors detailing center COVID-19 vaccine policies for transplant candidates and living donors and use of grafts from COVID-19-positive deceased donors. RESULTS: The response rate was 77% (154/200). For children aged 5-15â€‰years, 23% (35/154 centers) have a COVID-19 vaccine mandate, 27% (42/154) anticipate implementing a future mandate, and 47% (72/154) have not considered or do not anticipate implementing a mandate. For children â‰¥16â€‰years, 32% (50/154 centers) have a COVID-19 vaccine mandate, 25% (39/154) anticipate implementing a future mandate, and 40% (62/154) have not considered or do not anticipate implementing a mandate. The top two reasons for not implementing a COVID-19 vaccine mandate were concerns about penalizing a child for their parent's decision and worsening inequities in transplant. Of 85 kidney and liver living donor centers, 32% (27/85) require vaccination of donors. Twenty percent (31/154) of centers accept organs from COVID-19-positive deceased donors. CONCLUSIONS: There is great variation among pediatric SOT centers in both the implementation and details of COVID-19 vaccine mandates for candidates and living donors. To guide more uniform policies, further data are needed on COVID-19 disease, vaccine efficacy, and use of grafts from donors positive for COVID-19 in the pediatric transplant population.

Primary cardiac mesothelioma presenting with fulminant recurrent pericarditis: a case report. BACKGROUND: Primary pericardial mesothelioma is an extremely rare disease. Prognosis is poor, with little effects of chemo- or radio-therapy. The majority of cases is diagnosed at autopsy. CASE SUMMARY: A 22-year-old man, who presented with recurrent pericarditis and large pericardial effusion 2 months after a second BNT162b2 COVID-19 vaccine, underwent pericardiocentesis and pericardial window. Pathology specimen of pericardium revealed benign mesothelial inflammation, consistent with acute pericarditis. Four months later, he presented with a large pericardial mass manifesting in heart failure and underwent urgent pericardiectomy. A new pathology specimen immunostaining and fluorescence in situ hybridization analysis revealed pericardial mesothelioma. Despite intensive care, the patient died 3 weeks later. DISCUSSION: Primary pericardial mesothelial should be considered in the differential diagnosis of refractory recurrent pericarditis, even with prior biopsy-proven pericarditis or when a putative trigger (COVID-19 mRNA prior vaccination) is suspected, as was the case in this patient. Tumour diagnosis and identification consist of multimodal imaging and laboratory tests. A multidisciplinary, individualized care approach should be performed.

Neuro-ophthalmic Manifestations of Coronavirus Disease 2019 and Its Vaccination: A Narrative Review. Coronavirus disease 2019 (COVID-19) is a current pandemic caused by SARS-CoV-2 that has vastly affected the whole world. Although respiratory disease is the most common manifestation of COVID-19, the virus can affect multiple organs. Neurotropic aspects of the virus are increasingly unfolding, in so far as some respiratory failures are attributed to brainstem involvement. The neuro-ophthalmic manifestations of COVID-19 and the neuro-ophthalmic side effects of vaccination were reviewed. The major findings are that the SARS-CoV-2 infection commonly causes headaches and ocular pain. It can affect the afferent and efferent visual pathways by ischemic or inflammatory mechanisms. Optic nerve may be the origin of transient or permanent visual loss from papillophlebitis, idiopathic intracranial hypertension, or optic neuritis. Cerebrovascular strokes are not uncommon and may lead to cortical visual impairment or optic nerve infarction. SARS-CoV-2 may affect the pupillomotor pathways, resulting in tonic pupil (Adie's syndrome) or Horner's syndrome. Cranial neuropathies including third, fourth, sixth, and seventh nerve palsies have all been reported. Rhino-orbital mucormycosis superinfections in COVID-19 patients receiving steroids or other immunosuppressive therapies may result in unilateral or bilateral visual loss and ophthalmoplegia. Autoimmune conditions such as Guillain-BarrÃ©, Miller-Fisher syndrome, and ocular myasthenia have been reported.

SARS-CoV-2 infection and COVID19 vaccination across eight immune-mediated inflammatory disorders: A prospective, real-life Belgian cohort study - the BELCOMID study. BACKGROUND: The risks and impact of COVID19 disease and vaccination in patients with Immune Mediated Inflammatory Diseases (IMID) remain incompletely understood. IMID patients and particularly patients receiving immunosuppressive treatment were excluded from the original, registrational phase-3 COVID19 vaccination efficacy and safety trials. Real-world observational data can help to fill this gap in knowledge. The BELCOMID study aims to explore the interaction between IMIDs, immune-modulating treatment modalities and SARS-CoV-2 infection and vaccination in a real-life patient cohort. METHODS: A multidisciplinary, prospective, observational cohort study was set up. Consecutive patients with IMIDs of the gut, joints and skin followed at two high-volume referral centers were invited. Both patients under conventional treatment or targeted immune modulating therapies were included. Patient data and serological samples were collected at 3 predefined periods (before COVID19 vaccination, before booster vaccination, after booster vaccination). Primary endpoints were positive PCR-test and SARS-CoV-2 serology reflecting previous SARS-CoV-2 infection or vaccination. Associations with IMID treatment modality and IMID disease activity were assessed. Results of the first two inclusion periods (before booster vaccination) are reported. RESULTS: At the first inclusion period data was assessed of 2165 IMID-patients before COVID19 vaccination. At the second inclusion period, data of 2065 patients was collected of whom 1547 had received complete baseline COVID19 vaccination and 222 were partially vaccinated. SARS-CoV-2 infection rate remained low in both groups. No significant increase in IMID flare-up rate was noted in patients with prior SARS-CoV-2 infection. Multiple logistic regression analyses did not show a significant influence of IMID-treatment modality or IMID activity on SARS-CoV-2 infection risk (based on PCR positivity or N-serology). Patients treated with conventional immunomodulators, systemic steroids, and patients on advanced therapies such as biologics or small molecules, had reduced S-antibody seroconversion. S-antibody response was also lower in patients without prior SARS-CoV-2 infection and in active smokers. A subset of patients (4.1%) had no S- nor N-antibody seroconversion following complete baseline vaccination. CONCLUSION: The BELCOMID study results confirm the benign course of COVID19 infection and vaccination in a large real-life IMID-population. However, our results underscore the need for repeated vaccination and smoking cessation in patients with IMIDs treated with immune-modulating therapies or systemic steroids during the pandemic.

Neutralizing activity against Omicron BA.5 after tixagevimab/cilgavimab administration comparable to those after Omicron BA.1/BA.2 breakthrough infections. INTRODUCTION: The effect of tixagevimab/cilgavimab (Evusheldâ„¢; AstraZeneca, UK) should be evaluated in the context of concurrent outbreak situations. METHODS: For serologic investigation of tixagevimab/cilgavimab during the BA.5 outbreak period, sera of immunocompromised (IC) hosts sampled before and one month after tixagevimab/cilgavimab administration and those of healthcare workers (HCWs) sampled one month after a 3(rd) shot of COVID-19 vaccines, five months after BA.1/BA.2 breakthrough infection (BI), and one month after BA.5 BI were investigated. Semi-quantitative anti-spike protein antibody (Sab) test and plaque reduction neutralizing test (PRNT) against BA.5 were performed. RESULTS: A total of 19 IC hosts (five received tixagevimab/cilgavimab 300 mg and 14 received 600 mg) and 41 HCWs (21 experienced BA.1/BA.2 BI and 20 experienced BA.5 BI) were evaluated. Baseline characteristics did not differ significantly between IC hosts and HCWs except for age and hypertension. Sab significantly increased after tixagevimab/cilgavimab administration (median 130.2 BAU/mL before tixagevimab/cilgavimab, 5,665.8 BAU/mL after 300 mg, and 10,217 BAU/mL after 600 mg; both $P < 0.001$). Sab of one month after the 3(rd) shot (12,144.2 BAU/mL) or five months after BA.1/BA.2 BI (10,455.8 BAU/mL) were comparable with that of tixagevimab/cilgavimab 600 mg, while Sab of one month after BA.5 BI were significantly higher (22,216.0 BAU/mL; $P < 0.001$). BA.5 PRNT ND(50) significantly increased after tixagevimab/cilgavimab administration (median ND(50) 29.6 before tixagevimab/cilgavimab, 170.8 after 300 mg, and 298.5 after 600 mg; both $P < 0.001$). The ND(50) after tixagevimab/cilgavimab 600 mg was comparable to those of five months after BA.1 BI (ND(50) 200.9) while ND(50) of one month after the 3(rd) shot was significantly lower (ND(50) 107.6; $P = 0.019$). The ND(50) of one month after BA.5 BI (ND(50) 1,272.5) was highest among tested groups, but statistical difference was not noticed with tixagevimab/cilgavimab 600 mg. CONCLUSION: Tixagevimab/cilgavimab provided a comparable neutralizing activity against the BA.5 with a healthy adult population who were vaccinated with a 3(rd) shot and experienced BA.1/BA.2 BI.

Comparison of humoral and cellular immune responses between ChAd-BNT heterologous vaccination and BNT-BNT homologous vaccination following the third BNT dose: A prospective cohort study. INTRODUCTION: The differential immune responses after two additional BNT162b2 (BNT) booster doses between ChAdOx1 nCoV-10 (ChAd)-primed and BNT-primed groups have not been elucidated. The aim of this study was to compare vaccine-induced humoral and cellular immune responses and evaluate breakthrough infection between the two vaccination strategies. METHODS: In 221 healthy subjects (111 in the ChAd group), longitudinal immune responses were monitored at 3, 4, and 6 months after the 2nd dose and 1, 3, and 6 months after the 3rd dose. Humoral immunity was measured by two fully automated chemiluminescent immunoassays (Elecsys and Abbott) and a surrogate virus neutralization test (sVNT). Cellular immunity was assessed by two interferon-Î³ (IFN-Î³) release assays (QuantiFERON SARS-CoV-2 and Covi-FERON). RESULTS: After the 2nd dose of BNT vaccination, total antibody levels were higher in the ChAd group, but IgG antibody and sVNT results were higher in the BNT group. Following the 3rd dose vaccination, binding antibody titers were significantly elevated in both groups (ChAD-BNT; 15.4 to 17.8-fold, BNT-BNT; 22.2 to 24.6-fold), and the neutralizing capacity was increased by 1.3-fold in both cohorts. The ChAd-BNT group had lower omicron neutralization positivity than the BNT-BNT group ($P = 0.001$) at 6 months after the 3rd dose. Cellular responses to the spike antigen also showed 1.7 to 3.0-fold increases after the 3rd dose, which gradually declined to the levels equivalent to before the 3rd vaccination. The ChAd cohort tended to have higher IFN-Î³ level than the BNT cohort for 3-6 months after the 2nd and 3rd doses. The frequency of breakthrough infection was higher in the ChAd group (44.8%) than in the BNT group (28.1%) ($P = 0.0219$). Breakthrough infection induced increased humoral responses in both groups, and increase of cellular response was significant in the ChAd group. DISCUSSION: Our study showed

differential humoral and cellular immune responses between ChAd-BNT-BNT heterologous and BNT-BNT-BNT homologous vaccination cohorts. The occurrence of low antibody levels in the ChAd-primed cohort in the humoral immune response may be associated with an increased incidence of breakthrough infections. Further studies are needed on the benefits of enhanced cellular immunity in ChAd-primed cohorts.

A systematic review and meta-analysis of the effectiveness and safety of COVID-19 vaccination in older adults. In the coronavirus disease 2019 (COVID-19) pandemic, vaccinations were essential in preventing COVID-19 infections and related mortality in older adults. The objectives of this study were to evaluate the effectiveness and safety of the COVID-19 vaccines in older adults. We systematically searched the electronic bibliographic databases of PubMed, Web of Science, Embase, Cochrane Library, ClinicalTrials.gov, Research Square, and OpenGrey, as well as other sources of gray literature, for studies published between January 1, 2020, and October 1, 2022. We retrieved 22 randomized controlled trials (RCTs), with a total of 3,404,696 older adults (aged over 60Â years) participating, that were included in the meta-analysis. No significant publication bias was found. In the cumulative meta-analysis, we found that the COVID-19 vaccines were effective in preventing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection (ORÂ =Â 0.38, 95% CIÂ =Â 0.23-0.65, pÂ =Â 0.0004) and in reducing the number of COVID-19-related deaths (ORÂ =Â 0.16, 95% CIÂ =Â 0.10-0.25, pÂ <Â 0.00001) in elderly people. Antibody seroconversion (AS) and geometric mean titer (GMT) levels significantly increased in vaccinated older adults [ORÂ =Â 24.42, 95% CIÂ =Â 19.29-30.92; standardized mean difference (SMD)Â =Â 0.92, 95% CIÂ =Â 0.64-1.20, respectively]. However, local and systemic adverse events after COVID-19 vaccine administration were found in older adults (ORÂ =Â 2.57, 95% CIÂ =Â 1.83-3.62, pÂ <Â 0.00001). Although vaccination might induce certain adverse reactions in the elderly population, the available evidence showed that the COVID-19 vaccines are effective and tolerated, as shown by the decrease in COVID-19-related deaths in older adults. It needs to be made abundantly clear to elderly people that the advantages of vaccination far outweigh any potential risks. Therefore, COVID-19 vaccination should be considered as the recommended strategy for the control of this disease by preventing SARS-CoV-2 infection and related deaths in older adults. More RCTs are needed to increase the certainty of the evidence and to verify our conclusions. SYSTEMATIC REVIEW REGISTRATION: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022319698, identifier CRD42022319698.

Case report: Clearance of longstanding, immune-deficiency-associated, vaccine-derived polio virus infection following remdesivir therapy for chronic SARS-CoV-2 infection. The global polio eradication campaign has had remarkable success in reducing wild-type poliovirus infection, largely built upon the live attenuated Sabin oral poliovirus vaccine. Whilst rare, vaccine poliovirus strains may cause infection and subsequently revert to a neurovirulent type, termed vaccine-derived poliovirus (VDPV). Persistent, vaccine derived infection may occur in an immunocompromised host (iVDPV), where it is a recognised complication following receipt of the Sabin vaccine. This has significant implications for the global polio eradication campaign and there is currently no agreed global strategy to manage such patients.Here we describe a case of a 50-year-old man with common variable immune deficiency, persistently infected with a neurovirulent vaccine-derived type 2 poliovirus following vaccination in childhood. iVDPV infection had proven resistant to multiple prior attempts at treatment with human breast milk, ribavirin and oral administration of a normal human pooled immunoglobulin product. His iVDPV infection subsequently resolved after 12 days treatment with remdesivir, an adenosine analogue prodrug that is an inhibitor of viral RNA-dependent RNA polymerase, administered as treatment for a prolonged, moderate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. iVDPV from the patient, isolated prior to treatment,

was subsequently demonstrated to be sensitive to remdesivir in vitro. Based on the observations made in this case, and the mechanistic rationale for use with iVDPV, there is strong justification for further clinical studies of remdesivir treatment as a potentially curative intervention in patients with iVDPV infection.

Serum titer of neutralizing antibodies after COVID-19 vaccination in Japanese patients with inflammatory bowel disease. Vaccination is an important strategy to reduce the infection rate and adverse events of coronavirus disease 2019 (COVID-19). However, the effect of COVID-19 vaccination for Japanese patients with inflammatory bowel disease (IBD) has not been fully elucidated. In the present study, we investigated the serum titer of neutralizing antibodies after COVID-19 vaccination in patients with IBD, treated with and without immunosuppressive therapy. The study consisted of 108 patients with IBD [76 with ulcerative colitis (UC) and 32 with Crohn's disease (CD)] from the gastroenterology outpatient clinic at the Hospital of the Kyoto Prefectural University of Medicine who underwent anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. The control group included 64 healthy subjects who received the anti-SARS-CoV-2 vaccine. When 10â€…AU/ml of neutralizing antibodies was used as cut-off value, the positive rates of neutralizing antibodies of patients with UC, patients with DC, and the control group were 97.3%, 84.3%, and 100%, respectively. The neutralizing antibody titer showed no difference between patients treated with and without immunosuppressive therapy. These results indicate that COVID-19 vaccination may be useful in patients with IBD, treated with or without immunosuppressive therapy.

Clinical outcomes of myocarditis after SARS-CoV-2 mRNA vaccination in four Nordic countries: population based cohort study. OBJECTIVE: To investigate the clinical outcomes of myocarditis associated with mRNA vaccines against the SARS-CoV-2 virus compared with other types of myocarditis. DESIGN: Population based cohort study. SETTING: Nationwide register data from four Nordic countries (Denmark, Finland, Norway, and Sweden), from 1 January 2018 to the latest date of follow-up in 2022. PARTICIPANTS: The Nordic myocarditis cohort; 7292 individuals aged â‰¥12 years who had an incident diagnosis of myocarditis as a main or secondary diagnosis, in a population of 23â€‰million individuals in Denmark, Finland, Norway, and Sweden. MAIN OUTCOME MEASURES: Heart failure, or death from any cause within 90 days of admission to hospital for new onset myocarditis, and hospital readmission within 90 days of discharge to hospital for new onset myocarditis. Clinical outcomes of myocarditis associated with SARS-CoV-2 mRNA vaccination, covid-19 disease, and conventional myocarditis were compared. RESULTS: In 2018-22, 7292 patients were admitted to hospital with new onset myocarditis, with 530 (7.3%) categorised as having myocarditis associated with SARS-CoV-2 mRNA vaccination, 109 (1.5%) with myocarditis associated with covid-19 disease, and 6653 (91.2%) with conventional myocarditis. At the 90 day follow-up, 62, nine, and 988 patients had been readmitted to hospital in each group (vaccination, covid-19, and conventional myocarditis groups, respectively), corresponding to a relative risk of readmission of 0.79 (95% confidence interval 0.62 to 1.00) and 0.55 (0.30 to 1.04) for the vaccination type and covid-19 type myocarditis groups, respectively, compared with the conventional myocarditis group. At the 90 day follow-up, 27, 18, and 616 patients had a diagnosis of heart failure or died in the vaccination type, covid-19 type, and conventional myocarditis groups, respectively. The relative risk of heart failure within 90 days was 0.56 (95% confidence interval 0.37 to 0.85) and 1.48 (0.86 to 2.54) for myocarditis associated with vaccination and covid-19 disease, respectively, compared with conventional myocarditis; the relative risk of death was 0.48 (0.21 to 1.09) and 2.35 (1.06 to 5.19), respectively. Among patients aged 12-39 years with no predisposing comorbidities, the relative risk of heart failure or death was markedly higher for myocarditis associated with covid-19 disease than for myocarditis associated with vaccination (relative risk 5.78, 1.84 to 18.20). CONCLUSIONS: Compared with myocarditis associated with covid-19 disease and conventional myocarditis, myocarditis after

vaccination with SARS-CoV-2 mRNA vaccines was associated with better clinical outcomes within 90 days of admission to hospital.
Adult-onset Still's disease after mRNA COVID-19 vaccination presenting with severe myocarditis with acute heart failure and cardiogenic shock: a case report.
Vulval Aphthous Ulcers in Adolescents Following COVID-19 Vaccination-Analysis of an International Case Series. STUDY OBJECTIVE: To review and characterize reports of vulval aphthous ulcers (VAUs) following COVID-19 vaccination in VigiBase, the World Health Organization global database of reported potential adverse effects of medicinal products, to demonstrate the importance and power of case reports for rare suspected adverse reactions and to investigate whether they suggest a potential for COVID-19 vaccination to be a trigger METHODS: Cases reporting the Medical Dictionary for Regulatory Activities' (MedDRA) preferred term "Vulvovaginal ulceration" and related preferred terms in adolescent patients aged 12-17 years in association with any COVID-19 vaccine were extracted from VigiBase. The cases were clinically reviewed, and causality was assessed by applying the Bradford Hill criteria to the obtained case series. RESULTS: As of June 30th, 2022, there were 444 reports for the selected Medical Dictionary for Regulatory Activities preferred terms following COVID-19 vaccination in VigiBase. Ninety-four de-duplicated reports concerned adolescent female patients. Thirty-seven cases were clinically consistent with the diagnosis of VAU. On causality assessment, the analyzed case series fulfilled 6 of the 9 Austen Bradford Hill criteria supporting a potential causal relationship. CONCLUSION: VAUs can be perceived as a traumatic experience, especially in adolescent patients. There is, furthermore, a risk that the ulcers will be misdiagnosed, resulting in avoidable investigation and treatment burdens for patients. We communicate our findings to support the small number of published case reports and raise awareness of VAUs occurring in a temporal association with COVID-19 vaccination. Furthermore, our analysis supports observations about the value of case reports for the recognition and assessment of rare adverse events.
Memantine treats psychosis and agitation associated with Moderna COVID-19 vaccine.
COVID-19 vaccination and menstrual disorders among women: Findings from a meta-analysis study. BACKGROUND: COVID - 19 vaccine can lead to various local and systemic side effects, including menstrual irregularities in women. There is no robust quantitative evidence of the association between the COVID - 19 vaccine and menstrual irregularities. A meta-analysis was performed to estimate the pooled prevalence of a range of menstrual disorders that may occur in women following COVID - 19 vaccination. METHODS: After searching for epidemiological studies, we systematically performed a meta-analysis on PubMed/Medline, EMBASE, and Science Direct. Sixteen studies were finally included in the study. We estimated the pooled prevalence and corresponding 95 % confidence intervals (CIs) for a group of menstrual disorders, including menorrhagia, polymenorrhea, abnormal cycle length, and oligomenorrhea. Heterogeneity was assessed using the I(2) statistic and the Q test. RESULTS: Overall, the pooled prevalence of menorrhagia was 24.24 % (pooled prevalence 24.24 %; 95 % CI: 12.8-35.6 %). The pooled prevalence of polymenorrhea was 16.2 % (pooled prevalence: 16.2 %; 95 % CI: 10.7-21.6 %). The pooled prevalence of abnormal cycle length was relatively lower than that of the other disorders (pooled prevalence: 6.6 %; 95 % CI: 5.0-8.2 %). The pooled prevalence of oligomenorrhea was 22.7 % (95 % CI: 13.5-32.0 %). CONCLUSION: The findings indicate that menorrhagia, oligomenorrhea, and polymenorrhea were the most common menstrual irregularities after vaccination. The findings also suggest that a relatively high proportion of women suffer from menstrual irregularities. Further longitudinal studies are needed to confirm the causal relationship between COVID-19 vaccination and menstrual irregularities.
Panuveitis following mRNA-based COVID-19 vaccine.
COVID-19 vaccination and thyroiditis. At the end of 2019, the world began to fight the coronavirus disease 2019 (COVID-19) pandemic caused by the severe acute respiratory syndrome

coronavirus-2. Many vaccines have quickly been developed to control the epidemic, and with the widespread use of vaccines globally, several vaccine-related adverse events have been reported. This review mainly focused on COVID-19 vaccination-associated thyroiditis and summarized the current evidence regarding vaccine-induced subacute thyroiditis, silent thyroiditis, Graves' disease, and Graves' orbitopathy. The main clinical characteristics of each specific disease were outlined, and possible pathophysiological mechanisms were discussed. Finally, areas lacking evidence were specified, and a research agenda was proposed.

Detection of antibodies to SARS-CoV-2 after vaccination in seminal plasma and their association to sperm parameters. There is a public concern that COVID-19 vaccination and SARS-CoV-2 antibodies (Abs) negatively affect male fertility. However, the evidence for the presence of SARS-CoV-2 Abs in seminal plasma (SP) is lacking. We examined whether Abs were detectable in SP after COVID-19 vaccination in 86 men using a direct Ab measurement and by quantification of their neutralizing activity. The results show the presence of SARS-CoV-2 Abs in SP, with a strong correlation to the serum Abs, increasing with the number of vaccinations. Furthermore, the Ab titers are correlating with the neutralization activity. The SARS-CoV-2 vaccination parameters showed no association with the markers of sperm quality. In conclusion, this study indicates substantial levels of Abs in SP after COVID-19 vaccination that correlate with serum Ab titers but do not associate with sperm quality.

Thrombosis with Thrombocytopenia Syndrome (TTS) After ChAdOx1 nCoV-19 Immunization: An Investigative Case Report. BACKGROUND Thrombosis with thrombocytopenia syndrome (TTS), including vaccine-induced immune thrombotic thrombocytopenia (VITT), is an extremely rare adverse effect, mostly seen after initial vaccination with the viral vector-based AstraZeneca-Oxford COVID-19 vaccine. It is characterized by mild to severe thrombocytopenia and venous or arterial thrombosis. CASE REPORT Herein, we present a case of an 18-year-old male patient who developed Level 1 TTS (probable VITT) eight days after immunization with the ChADOx1 nCOV-19 vaccine (Covishield; AZ-Oxford). Initial investigations revealed severe thrombocytopenia, hemiparesis, and intracranial hemorrhage, after which the patient was treated conservatively. However, a decompressive craniotomy was performed later due to patient deterioration. One week after surgery, the patient developed bilious vomiting, lower-gastrointestinal bleeding, and abdominal distension. An abdominal CT scan was performed that showed thrombosis of the portal vein with occlusion of the left iliac vein. The patient underwent an exploratory laparotomy followed by resection and anastomosis of the small bowel due to massive gut gangrene. Due to persistent thrombocytopenia after surgery, intravenous immune globulin (IVIG) was administered. The platelet count increased thereafter, and the patient stabilized. He was discharged on the 33rd day after admission and was followed up for a year. No post-hospitalization complications were observed in the follow-up period. CONCLUSIONS Although vaccines have been proven to be highly safe and effective to end the Coronavirus Disease 2019 (COVID-19) caused pandemic, there is still a small risk of developing rare complications, including TTS and VITT. Early diagnosis and prompt intervention are key for patient management.

COVID-19 vaccine hesitancy among people living with HIV in a low-resource setting: A multi-center study of prevalence, correlates and reasons. BACKGROUND: Hesitancy to COVID-19 vaccine may worsen the burden of COVID-19 among people living with HIV (PLHIV), who are at a higher risk of COVID-19-related hospitalization and death, compared to HIV non-infected individuals. Therefore, we evaluate the predictors and reasons for COVID-19 vaccine hesitancy among unvaccinated PLHIV in six antiretroviral therapy (ART) clinics across northern Nigeria. METHODOLOGY: In this cross-sectional study, conducted between October 2021 and February 2022 in six hospitals across two geopolitical regions of Nigeria, we utilized interviewer-administered questionnaires to assess COVID-19 vaccine hesitancy among a convenience sample of 790 eligible adult PLHIV. Hesitancy was defined as answering 'no' or 'maybe' to a question asking participants their willingness to accept the COVID-19

vaccine. A multivariate logistic regression model was used to estimate the adjusted odds ratio (aOR) and 95% confidence interval (CI) of the factors associated with COVID-19 vaccine hesitancy among PLHIV. RESULTS: Of the total 660 unvaccinated participants included in the analysis (61.82% female, mean age [SD] of 39.76 [10.75]), 381 (57.72%) were hesitant to COVID-19 vaccine. Being 50Â years and older (aOR: 0.43; 95% CI: 0.21-0.89), being unemployed (aOR: 0.57; 95% CI: 0.34-0.95), experiencing the adverse effects of ART (aOR: 0.36; 95% CI: 0.15-0.86), and perception of being at high risk of contracting COVID-19 (aOR: 0.22; 95% CI: 0.13-0.37) were associated with significantly lower odds of hesitancy. Conversely, being female (aOR: 1.64; 95% CI: 1.02-2.61) and attending ART clinics at state administrative capital cities (IIDH Kano [aOR: 2.40; 95% CI: 1.10-5.25], MMSH Kano [aOR: 5.59; 95% CI: 1.97-10.66], YSSH Damaturu [aOR: 9.88; 95% CI: 4.02-24.29] vs. GH Gashua) were associated with significantly higher odds of hesitancy. The most common reasons for hesitancy include fear of potential adverse effects, skepticism about vaccine efficacy, the rapid development of the COVID-19 vaccine, and the perceived lack of effort to develop a cure or vaccine for HIV/AIDS. CONCLUSION: Interventions aimed at combating misperceptions and misinformation regarding the COVID-19 vaccination program may reduce the prevalence of COVID-19 vaccine hesitancy among unvaccinated PLHIV.

Uptake of COVID-19 vaccines and associated factors among adults in Uganda: a cross-sectional survey. OBJECTIVE: COVID-19 pandemic remains one of the most significant public health challenges ever faced globally. Vaccines are key to ending the pandemic as well as minimise its consequences. This study determined the uptake of COVID-19 vaccines and associated factors among adults in Uganda. DESIGN, SETTING AND PARTICIPANTS: We conducted a cross-sectional mobile phone survey among adults in Uganda. MAIN OUTCOME VARIABLE: Participants reported their uptake of COVID-19 vaccines. RESULTS: Of the participants contacted, 94% (1173) completed the survey. Overall, 49.7% had received COVID-19 vaccines with 19.2% having obtained a full dose and 30.5% an incomplete dose. Among the unvaccinated, 91.0% indicated intention to vaccinate. Major reasons for vaccine uptake were protection of self from COVID-19 (86.8%) and a high perceived risk of getting the virus (19.6%). On the other hand, non-uptake was related to vaccine unavailability (42.4%), lack of time (24.1%) and perceived safety (12.5%) and effectiveness concerns (6.9%). The factors associated with receiving COVID-19 vaccines were older age (â‰¥65 years) (Adjusted Prevalence Ratio (APR)=1.32 (95% CI: 1.08 to 1.61)), secondary (APR=1.36 (95% CI: 1.12 to 1.65)) or tertiary education (APR=1.62 (95% CI: 1.31 to 2.00)) and health workers as a source of information on COVID-19 (APR=1.26 (95% CI: 1.10 to 1.45)). Also, reporting a medium-income (APR=1.24 (95% CI: 1.02 to 1.52)) and residence in Northern (APR=1.55, 95%â€‰CI: 1.18 to 2.02) and Central regions (APR=1.48, 95%â€‰CI: 1.16 to 1.89) were associated with vaccine uptake. CONCLUSIONS: Uptake of COVID-19 vaccines was moderate in this sample and was associated with older age, secondary and tertiary education, medium-income, region of residence and health workers as a source of COVID-19 information. Efforts are needed to increase access to vaccines and should use health workers as champions to enhance uptake.

Acute Disseminated Encephalomyelitis and Acute Encephalitis Following Vaccination Against SARS-CoV-2: Two Case Reports and Review of Literature. The spectrum of severe neurological complications following COVID-19 vaccination includes cerebrovascular events, inflammatory diseases of the CNS, cranial and peripheral nerve involvement and muscle affections. Post-vaccinal acute disseminated encephalomyelitis (ADEM) and acute encephalitis are rare. We report on a patient suffering from acute encephalitis and another with post-vaccinal monophasic ADEM. Beside imaging features typical for acute autoimmune associated inflammation, cranial MRI disclosed also transient haemorrhagic signal alterations in some cerebral lesions. To our best knowledge, this has not been mentioned before in literature. Competing causes were excluded by extensive laboratory

investigations including serial CSF analysis. In line with the literature, repeated iv high-dosage corticosteroid therapy resulted in impressive improvement of neurological symptoms in both patients.

The effects of obesity and metabolic abnormalities on severe COVID-19-related outcomes after vaccination: A population-based study. Breakthrough SARS-CoV-2 infections of vaccinated individuals are being reported globally, resulting in an increased risk of hospitalization and death among such patients. Therefore, it is crucial to identify the modifiable risk factors that may affect the protective efficacy of vaccine use against the development of severe COVID-19 and thus to initiate early medical interventions. Here, in population-based studies using the UK Biobank database and the 2021 National Health Interview Survey (NHIS), we analyzed 20,362 participants aged 50 years or older and 2,588 aged 18 years or older from both databases who tested positive for SARS-COV-2, of whom 33.1% and 67.7% received one or more doses of vaccine, respectively. In the UK Biobank, participants are followed from the vaccination date until October 18, 2021. We found that obesity and metabolic abnormalities (namely, hyperglycemia, hyperlipidemia, and hypertension) were modifiable factors for severe COVID-19 in vaccinated patients (all pÂ <Â 0.05). When metabolic abnormalities were present, regardless of obesity, the risk of severe COVID-19 was higher than that of metabolically normal individuals (all pÂ <Â 0.05). Moreover, pharmacological interventions targeting such abnormalities (namely, antihypertensive [adjusted hazard ratio (aHR) 0.64, 95% CI 0.48-0.86; pÂ = 0.003], glucose-lowering [aHR 0.55, 95% CI 0.36-0.83; pÂ = 0.004], and lipid-lowering treatments [aHR 0.50, 95% CI 0.37-0.68; pÂ <Â 0.001]) were significantly associated with a reduced risk for this outcome. These results show that more proactive health management of patients with obesity and metabolic abnormalities is critical to reduce the incidence of severe COVID-19 after vaccination.

Inflammatory rheumatic diseases developed after COVID-19 vaccination: presentation of a case series and review of the literature. OBJECTIVE: An increasing number of new on-set autoimmune-inflammatory rheumatic diseases (AIRD) after COVID-19 vaccination has begun to be reported in the literature. In this article, we present our patients with new-onset AIRD after vaccination for COVID-19 and review the literature on the subject. PATIENTS AND METHODS: We investigated the clinical characteristics and laboratory parameters of previously described "newly developed AIRD in individuals recently vaccinated for COVID-19", in 22 cases vaccinated with one of the COVID-19 vaccines (BNT162b2 or CoronaVac) approved in our country. RESULTS: We collected 22 cases (14 female, 63.6%) that developed an AIRD after COVID-19 vaccination. Mean age was 53Â±14.4 (24-87) years. The interval between the last dose of vaccination and the development of the first complaint was 23.9Â±19.5 (4-90) days. CoronaVac was administered to four patients, and the BNT162b2 to 18 patients. AIRD-related symptoms developed in 12 patients after the first dose, in 8 patients after the second dose, and in two patients after the third dose. Twelve out of the 22 (54.5%) cases were diagnosed with rheumatoid arthritis, two with SLE, and the remaining eight patients each with leukocytoclastic vasculitis, Sjogren's syndrome, psoriatic arthritis, ankylosing spondylitis, systemic sclerosis, mixed connective tissue disease, eosinophilic granulomatosis with polyangiitis, and inflammatory myositis, respectively. Six patients had a history of documented antecedent COVID-19 infection. CONCLUSIONS: Autoimmune/inflammatory rheumatic diseases may develop after COVID-19 vaccinations. In the era of the COVID-19 pandemic, vaccination should be questioned carefully in newly diagnosed AIRD patients.

Adverse events of a third dose of BNT162b2 mRNA COVID-19 vaccine among Korean healthcare workers. Due to the urgency of controlling the coronavirus disease 2019 pandemic, coronavirus disease 2019 messenger ribonucleic acid (mRNA) vaccines have been expeditiously approved and introduced in several countries without sufficient evaluation for adverse events. We analyzed adverse events among Korean healthcare workers who received all 3 doses of the BNT162b2 mRNA vaccine.

This survey was conducted among hospital workers of Inha University Hospital who had received the BNT162b2 mRNA vaccine for their first, second, third rounds, and using a diary card. The surveyed adverse events included local (redness, edema, and injection site pain) and systemic (fever, fatigue, headache, chill, myalgia, arthralgia, vomiting, diarrhea, pruritis, and urticaria) side effects and were divided into 5 grades (Grade 0â€…=â€…none - Grade 4â€…=â€…critical). Based on adverse events reported at least once after any of the 3 doses, the most common systemic adverse reactions were chills and headache (respectively, 62.6%, 62.4%), followed by myalgia (55.3%), arthralgia (53.4%), fatigue (51.6%), pruritus (38.1%), and fever (36.5%). The frequency and duration of adverse events were significantly greater in women (Pâ€…<â€….05) than men. Except for redness, pruritus, urticaria, and most adverse reactions had a higher rate of occurrence after the third dose in subjects who also had reactions with the second dose. However, grade 4 adverse events did occur with the third dose in some patients, even if there were no side effects with the first and second doses. Adverse events experienced with the first and second doses of the BNT162b2 mRNA vaccine in Korean healthcare workers increased the incidence of adverse events at the time of the third dose. On the other hand, grade 4 adverse events could still occur with the third dose even though there were no side effects with the first and second doses.

High-titer post-vaccine COVID-19 convalescent plasma for immunocompromised patients during the first omicron surge. BACKGROUND: Transplant and hematologic malignancy patients have high Coronavirus disease 2019 (COVID-19) mortality and impaired vaccination responses. Omicron variant evades several monoclonal antibodies previously used in immunocompromised patients. Polyclonal COVID-19 convalescent plasma (CCP) may provide broader neutralizing capacity against new variants at high titers. Vaccination increases severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) titer in convalescent donors. METHODS: We conducted a retrospective chart review of hospitalized immunocompromised patients with COVID-19 who received high-titer CCP during the first omicron surge, collected from vaccinated donors within 6 months of pre-omicron COVID-19. Data on safety and outcomes were extracted. RESULTS: A total of 44 immunocompromised patients were included, 59.1% with solid organ transplant, 22.7% with hematopoietic cell transplant, 11.4% with hematologic malignancy, and 6.8% with autoimmune disease. Overall, 95% of CCP units transfused were from recently recovered and vaccinated donors and had SARS-CoV-2 antibody results 8- to 37-fold higher than the Food and Drug Administration's cutoff for high-titer CCP. There were two mild transfusion reactions. A total of 30-day mortality was 4.5%. There were no differences in 100-day mortality by underlying diagnosis, levels of immunosuppression, and timing of CCP administration. Patients with higher immunosuppression had significantly higher mean World Health Organization clinical progression scores at 30-day post-CCP compared to those with lower immunosuppression. CONCLUSIONS: CCP is a safe, globally available treatment for immunocompromised patients with COVID-19. Mortality was lower in our cohort than that of COVID-19 patients with similar immunocompromising conditions. Post-vaccine CCP with very high titers should be prioritized for study in immunocompromised patients. Post-vaccine CCP has the potential to keep pace with new variants by overcoming mutations at sufficiently high titer.

Comments on "Recurrent Aseptic Meningoencephalitis Following BNT162b2 Vaccination for COVID-19".

Re: Comments on "Recurrent Aseptic Meningoencephalitis Following BNT162b2 Vaccination for COVID-19": The Authors Respond.

COVID-19 vaccine-associated myositis: a comprehensive review of the literature driven by a case report. Several cases of vaccine-associated manifestations have been published including cases of inflammatory myositis. Herein, we comprehensively review the literature on the occasion of case of a woman with inflammatory myositis following COVID-19 vaccination. A 67-year-old woman

presented with left arm edema, rash, and weakness after the 2(nd) dose of the BTN162b2 vaccine. Raised muscle enzymes and inflammatory markers with muscle edema on MRI and myositis findings on the electromyogram established the diagnosis. She was successfully treated with methylprednisolone pulses, intravenous immunoglobulin, methotrexate, and hydroxychloroquine. Cases of inflammatory myositis, dermatomyositis, or interstitial lung disease with myositis-specific autoantibodies or myositis-associated autoantibodies within 12Â weeks from SARS-CoV-2 vaccination were included. Cases with malignancy, prior or subsequent COVID-19 infection, preexisting myositis/interstitial lung disease (ILD)/dermatomyositis (DM), or other connective tissue diseases were excluded. From our search, 49 cases were identified (mean age: 56.55â€‰+â€‰17.17Â years), 59% were women, while 12 patients received the ChAdOx1 vaccine, 27 the BNT162b2, 8 the mRNA-1273, 1 the DB15806, and 1 the Ad26.COV2.S (overall, 70% received mRNA vaccines). Muscle involvement was the most common manifestation (79.5%), followed by skin involvement (53%) and ILD (34.6%), which were more common in the m-RNA vaccinees. Muscle biopsy, MRI findings, and autoantibody profile varied significantly, while successful immunosuppressive treatment was applied in most cases. Inflammatory myositis after COVID-19 vaccination has been well documented worldwide. Current evidence in support of a pathogenic link is challenging due to significant variation in clinical manifestations, radiological, histopathological, and immunological features.

[Allergy to Pfizer-BioNTechÂ® vaccine demonstrated by skin testing]. BACKGROUND: The Pfizer-BioNTechÂ® BNT162b2 vaccine, provides 95% effectiveness from the second dose onwards. The reported rate of anaphylaxis to COVID-19 vaccines is 4.7 cases/million doses administered. CASE REPORT: 30-year-old female, health professional, history of allergic rhinitis, asthma, reaction to eye cosmetics and adhesive tape: erythema, edema, and local pruritus. Immediately after application of the first dose of Pfizer-BioNTech vaccine, she presented grade III anaphylaxis. The patient was stratified, phenotyped and skin tests with PEG 3350 were positive. A recommendation was issued not to reapply vaccine containing polyethylene glycol and alternatives were offered. CONCLUSIONS: An adequate risk stratification should be performed before applying mRNA-based COVID-19 vaccines for the first time in at-risk groups. In case of anaphylaxis at the first dose, phenotyping and further study with PEG skin tests should be performed and vaccination alternatives should be offered.

[Importance of autoimmunity induced by SARS-CoV-2 and development of post-vaccination autoimmune diseases]. SARS-CoV-2, a virus belonging to the large family of coronavirus, aroused great interest following the outbreak of this new strain reported in 2019, in Wuhan China. Its clinical spectrum is highly variable, ranging from a self-limited disease to an acute respiratory distress syndrome with systemic clinical manifestations (COVID-19), in which the immune system plays a key role in the pathophysiology of this disease and in its severity; several studies show the prevalence of some autoimmune markers suggesting that they may lead to autoimmune states. The most important strategy worldwide to protect the population was the development of vaccines to induce immunity to severe COVID-19; however, vaccines have also been shown to have the ability to produce autoimmune states in a small percentage of the world's population; nevertheless, the best strategy remains vaccination. The aim of this review is to show the current overview of the mechanisms of SARS-CoV-2-induced autoimmunity and post-vaccination for a better understanding and identification of these in the population. Publications from 2019 to 2022 were reviewed in PubMed as the primary search source.

COVID-19 Vaccine Safety Surveillance in Early Pregnancy in the United States: Design Factors Affecting the Association Between Vaccine and Spontaneous Abortion. In the Vaccine Safety Datalink (VSD), we previously reported no association between coronavirus disease 2019 (COVID-19) vaccination in early pregnancy and spontaneous abortion (SAB). The present study aims to understand how time since vaccine rollout or other methodological factors could affect results. Using

a case-control design and generalized estimating equations, we estimated the odds ratios (ORs) of COVID-19 vaccination in the 28 days before a SAB or last date of the surveillance period (index date) in ongoing pregnancies and occurrence of SAB, across cumulative 4-week periods from December 2020 through June 2021. Using data from a single site, we evaluated alternative methodological approaches: increasing the exposure window to 42 days, modifying the index date from the last day to the midpoint of the surveillance period, and constructing a cohort design with a time-dependent exposure model. A protective effect (ORÂ = 0.78, 95% confidence interval: 0.69, 0.89), observed with 3-cumulative periods ending March 8, 2021, was attenuated when surveillance extended to June 28, 2021 (ORÂ = 1.02, 95% confidence interval: 0.96, 1.08). We observed a lower OR for a 42-day window compared with a 28-day window. The time-dependent model showed no association. Timing of the surveillance appears to be an important factor affecting the observed vaccine-SAB association.

Effects of COVID-19 vaccination on disease activity in patients with rheumatoid arthritis and psoriatic arthritis on targeted therapy in the COVIDSER study. OBJECTIVE: To investigate the influence of COVID-19 vaccination on disease activity in rheumatoid arthritis (RA) and psoriatic arthritis (PsA) patients under targeted therapies. PATIENTS AND METHODS: 1765 vaccinated patients COVID-19, 1178 (66.7%) with RA and 587 (33.3%) with PsA from the COVID-19 registry in patients with rheumatic diseases (COVIDSER) project, were included. Demographics, disease characteristics, Disease Activity Score in 28 joints (DAS28) and targeted treatments were collected. DAS28-based flare rates and categorised disease activity distribution prevaccination and post vaccination were analysed by log-linear regression and contingency analyses, respectively. The influence of vaccination on DAS28 variation as a continuous measure was evaluated using a random coefficient model. RESULTS: The distribution of categorised disease activity and flare rates was not significantly modified by vaccination. Log-linear regression showed no significant changes in the rate of flares in the 6-month period after vaccination compared with the same period prior to vaccination in neither patients with RA nor patients with PsA. When DAS28 variations were analysed using random coefficient models, no significant variations in disease activity were detected after vaccination for both groups of patients. However, patients with RA treated with Janus kinase inhibitors (JAK-i) (1) and interleukin-6 inhibitor (IL-6-i) experienced a worsening of disease activity (1.436Â±0.531, p=0.007,â€‰and 1.201Â±0.550, p=0.029, respectively) in comparison with those treated with tumour necrosis factor inhibitor (TNF-i). Similarly, patients with PsA treated with interleukin-12/23 inhibitor (IL-12/23-i) showed a worsening of disease activity (4.476Â±1.906, p=0.019) compared with those treated with TNF-i. CONCLUSION: COVID-19 vaccination was not associated with increased rate of flares in patients with RA and PsA. However, a potential increase in disease activity in patients with RA treated with JAK-i and IL-6-i and in patients with PsA treated with IL-12/23-i warrants further investigation.

New perspectives on the induction and acceleration of immune-associated thrombosis by PF4 and VWF. Platelet factor 4 (PF4), also known as chemokine (C-X-C motif) ligand 4 (CXCL4), is a specific protein synthesized from platelet Î± particles. The combination of PF4 and heparin to form antigenic complexes is an important mechanism in the pathogenesis of heparin-induced thrombocytopenia (HIT), but vaccine-induced immune thrombotic thrombocytopenia (VITT) related to the COVID-19 vaccine makes PF4 a research hotspot again. Similar to HIT, vaccines, bacteria, and other non-heparin exposure, PF4 can interact with negatively charged polyanions to form immune complexes and participate in thrombosis. These anions include cell surface mucopolysaccharides, platelet polyphosphates, DNA from endothelial cells, or von Willebrand factor (VWF). Among them, PF4-VWF, as a new immune complex, may induce and promote the formation of immune-associated thrombosis and is expected to become a new target and therapeutic direction. For both HIT and VITT, there is no effective and targeted treatment except discontinuation of suspected drugs. The research

and development of targeted drugs based on the mechanism of action have become an unmet clinical need. Here, this study systematically reviewed the characteristics and pathophysiological mechanisms of PF4 and VWF, elaborated the potential mechanism of action of PF4-VWF complex in immune-associated thrombosis, summarized the current status of new drug research and development for PF4 and VWF, and discussed the possibility of this complex as a potential biomarker for early immune-associated thrombosis events. Moreover, the key points of basic research and clinical evaluation are put forward in the study.

Alopecia Areata after COVID-19 Vaccines. INTRODUCTION: Alopecia areata (AA) is a common autoimmune disease characterized by non-scarring hair loss. New onsets of AA have been associated with coronavirus disease 2019 (COVID-19). Various skin diseases have already been reported because of the vaccines (the Pfizer-BioNTech COVID-19 vaccine, the Moderna COVID-19 vaccine, the AstraZeneca vaccine) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). CASE PRESENTATION: We report 5 cases of AA after COVID-19 vaccination. The trend shown by patients in this study is an initial worsening after the first dose of the vaccine with the stability of the disease even with subsequent doses. However, it is worth highlighting the case reported by one of our patients who suffered a "booster effect" of the disease with progressive and worsening alopecia with each vaccine booster. DISCUSSION: The possible mechanism of action lies in the ability of COVID-19 vaccines to induce spike protein, which can lead to molecular mimicry phenomena. In an organism predisposed to autoimmunity, the mRNA vaccine acts as a trigger. Furthermore, we would like to point out how even cytokine storm and simple oxidative stress from SARS-CoV-2 infection can induce not only AA but also other types of hair loss such as telogen effluvium. Thus, this highlights how complex and multifaceted the phenomenon is.

Transverse myelitis caused by herpes zoster following COVID-19 vaccination: A case report. BACKGROUND: Transverse myelitis (TM) is characterized by sudden lower extremity progressive weakness and sensory impairment, and most patients have a history of advanced viral infection symptoms. A variety of disorders can cause TM in association with viral or nonviral infection, vascular, neoplasia, collagen vascular, and iatrogenic, such as vaccination. Vaccination has become common through the global implementation against coronavirus disease 2019 (COVID-19) and reported complications like herpes zoster (HZ) activation has increased. CASE SUMMARY: This is a 68-year-old woman who developed multiple pustules and scabs at the T6-T9 dermatome site 1 wk after vaccination with the COVID-19 vaccine (Oxford/AstraZeneca ([ChAdOx1S{recombinant}]). The patient had a paraplegia aggravation 3 wk after HZ symptoms started. Spinal magnetic resonance imaging (MRI) showed transverse myelitis at the T6-T9 Level. Treatment was acyclovir with steroids combined with physical therapy. Her neurological function was slowly restored by Day 17. CONCLUSION: HZ developed after COVID-19 vaccination, which may lead to more severe complications. Therefore, HZ treatment itself should not be delayed. If neurological complications worsen after appropriate management, an immediate diagnostic procedure, such as magnetic resonance imaging and laboratory tests, will start and should treat the neurological complications.

Changes in serum-neutralizing antibody potency and breadth post-SARS-CoV-2 mRNA vaccine boost. A better understanding of the durability and breadth of serum-neutralizing antibody responses against multiple severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants elicited by COVID-19 vaccines is crucial in addressing the current pandemic. In this study, we quantified the decay of serum neutralization antibodies (nAbs) after second and third doses of the original COVID-19 mRNA vaccine. Using an authentic virus-neutralization assay, we found that decay half-lives of WA1- and Delta-nAbs were both âˆ¼60Â days after second and third vaccine dose. Unexpectedly, the durability of serum antibodies that neutralize three different Omicron subvariants (BA.1.1, BA.5, BA.2.12.1) was substantially better, with half-lives of â‰¥6Â months. A booster dose of the original

COVID-19 vaccine was also found to broaden antibody responses against SARS-CoV and four other sarbecoviruses, in addition to multiple SARS-CoV-2 strains. These findings suggest that repeated vaccinations with the COVID-19 vaccine may confer a degree of protection against future spillover of sarbecoviruses from animal reservoirs.
Subacute monomelic radiculoplexus neuropathy following ComirnatyÂ© (Pfizer-BioNTech COVID-19) vaccination: A case report.
Safety and efficacy of inactivated COVID-19 vaccines in women vaccinated during the first trimester of pregnancy. OBJECTIVES: This study aimed to investigate the safety of the inactivated COVID-19 vaccines in early pregnant women in view of their adverse-effect profile and associated maternal-fetal complications, as well as to evaluate their immunogenicity. METHODS: In this prospective observational cohort study, 232 women in their first trimester or those in the periconception period who inadvertently received two doses of inactivated COVID-19 vaccine between January 21, 2021, and January 14, 2022 were analyzed. Meanwhile, 735 unvaccinated early pregnancy women were also included in the study at a case-to-control ratio of 1:3. RESULTS: The vaccination group did not have an increased miscarriage rate compared with that of the control group (PÂ =Â 0.918). Furthermore, the birth defect rates in the vaccine group and control group were 0.83% and 1.0%, respectively. Vaccination did not increase the risk of small for gestational age, gestational diabetes mellitus, preterm, or hypertensive disorders of pregnancy (P >0.01). Within 12 weeks after the second dose, the inactivated vaccine effectively produced neutralizing antibody (NAb) against SARS-CoV-2. The NAb levels in the paired umbilical cord serum and maternal serum samples during delivery were negative in both groups. The T-cell subset remained within the normal range in both groups. CONCLUSION: Therefore, our study proves that inactivated COVID-19 vaccines are safe for mothers and fetuses and also effective in producing NAb against SARS-CoV-2.
[Facing COVID-19 : myocarditis following vaccination with mRNA SARS-CoV-2]. Myocarditis is a relatively uncommon and underdiagnosed heart disease. Its clinical presentation is variable, from pauci-symptomatic to a symptomatology of sudden chest pain. The latter mimics cardiological emergencies and must therefore be quickly discerned to guide the rest of the treatment. The treatment is mainly supportive and rarely directly etiological. This is a pathology that resurfaced with the onset of the COVID-19 pandemic but also with vaccination. We present here the case of a mRNA SARS-CoV-2 vaccine-induced myocarditis whose clinical manifestations impose a rapid decision concerning the differential diagnosis with an acute coronary syndrome.
Guillain-BarrÃ© syndrome following the second dose of COVID AstraZeneca vaccine in a 78-year-old male: a case report from Nepal. Guillain-BarrÃ© syndrome (GBS) is a rare acute idiopathic demyelinating polyneuropathy that causes bilateral, symmetrical, and progressive weakness of muscles. AstraZeneca vaccine is a genetically modified spike glycoprotein vaccine of an adenovirus vector. GBS following the second dose of the AstraZeneca vaccine dose is rare and not frequently noted. CASE PRESENTATION: A 78-year-old male presented to the hospital with complaints of bilateral weakness of the lower limbs over 4 days following the second dose of the AstraZeneca vaccine. On examination, the power and tone of the limbs were diminished. The sensitivity pinprick test revealed low sensitivity in the right lower limb than in the left lower limb. Nerve conduction studies revealed acute inflammatory demyelinating polyneuropathy and the patient was diagnosed with GBS. After admission, the patient was successfully treated with intravenous immunoglobulins along with physiotherapy. CLINICAL DISCUSSION: GBS can be diagnosed clinically with nerve conduction studies and Brighton's criteria. The robust causal relationships between COVID-19 infections, COVID-19 vaccination, and GBS are still unclear. The evaluation of the potential association and risk of GBS with vaccines warrants the need for precise post-vaccination surveillance measures and results. CONCLUSION: Only a few cases of GBS following the second dose of AstraZeneca are

reported so far and there is a need for strong and accurate diagnosis of the disease and proper post-vaccination surveillance for the evaluation of risk associated with COVID vaccines.

The functional views on response of host rabbit post coronavirus vaccination via ACE2 PET. Molecular imaging can dynamically and quantitatively record the biochemical changes in a systemic view. In this research, SARS-CoV-2 pseudovirus was intramuscularly injected to simulate the vaccination with inactivated virus. New Zealand white rabbits were evaluated with (18)F-FDG PET for inflammation and (68)Ga-cyc-DX600 PET for ACE2 fluctuation, which were performed before and at 3, 7 and 14 days post injection (d P.I.); furthermore, one rabbit was vaccinated with two cycles with interval of 14 days for a longer period evaluation. Different with the vaccination-induced inflammatory response that was random and individual, ACE2 regulation was systemic and organ-specific: the liver and spleen were of a moderate decrease post injection but rebound at 14 d P.I., while there were a downward trend in heart, testis and bone marrow; besides, similar pattern of ACE2 regulation were recorded after the second injection with a relatively greater volatility. In conclusion, ACE2 PET gave a more comprehensive view on host response post vaccination, hold substantial promise in continuous monitoring of coronavirus vaccine administration and effectiveness.

Factors associated with postpartum depression symptoms among postpartum women in five countries during the COVID-19 pandemic: an online cross-sectional study. BACKGROUND: This study aimed to examine factors associated with postpartum depression (PPD) symptoms during the COVID-19 pandemic among postpartum women in five countries, a subject that has not been investigated thus far. METHODS: A multi-country, cross-sectional, online survey was conducted with a convenience sample of 3,523 postpartum women in Brazil, South Korea, Taiwan, Thailand, and the United Kingdom, from July to November 2021. Sociodemographic and obstetric data, food insecurity, COVID-19 positive status, COVID-19 vaccination, infant feeding, breastfeeding belief score, and social support were investigated. PPD and social support were measured using the Edinburgh Postnatal Depression Scale and Maternal Social Support Scale, respectively. Descriptive statistics, chi-squared tests, and t-tests were used to identify associations with PPD symptoms. A binary logistic regression model was used to identify explanatory factors associated with PPD and adjusted odds ratios (OR) and 95% confidence intervals (CIs) were calculated. RESULTS: Women in Taiwan (AORâ€‰=â€‰0.5; 95%CI 0.34, 0.73) and Thailand (AORâ€‰=â€‰0.68; 95%CI 0.46, 0.99) had a lower risk of PPD symptoms than those in Brazil. In addition, women with planned pregnancies had a lower risk of PPD (AORâ€‰=â€‰0.74; 95%CI 0.60, 0.91). Younger women (AORâ€‰=â€‰1.62; 95%CI 1.05, 2.51), health problems during pregnancy, delivery, or postpartum (AORâ€‰=â€‰1.71; 95%CI 1.42, 2.06), and no change or worse food insecurity during COVID-19 (AORâ€‰=â€‰1.66; 95%CI 1.21, 1.27 for no change and AORâ€‰=â€‰1.68; 95%CI 1.27, 1.23, respectively) presented a higher likelihood of having PPD. Feeding babies with expressed human milk (AORâ€‰=â€‰1.25; 95%CI 1.03, 1.50) and/or complementary food (AORâ€‰=â€‰1.51; 95%CI 1.17, 1.94) were associated with PPD symptoms. Women who received low (AORâ€‰=â€‰7.74; 95%CI 5.43, 11.03) or medium support (AORâ€‰=â€‰3.25; 95%CI 2.71, 3.88) had higher likelihoods of PPD. CONCLUSION: PPD symptoms during the pandemic were high in young women, particularly Brazilian women, with health problems in the puerperal pregnancy cycle who fed their babies expressed breast milk and/or complementary food. Low social support also impacted PPD symptoms. This study highlights the need for the professional screening for PPD and provision of virtual or personal support.

Successful clearance of persistent SARS-CoV-2 asymptomatic infection following a single dose of Ad5-nCoV vaccine. Persistent asymptomatic (PA) SARS-CoV-2 infections have been identified. The immune responses in these patients are unclear, and the development of effective treatments for these patients is needed. Here, we report a cohort of 23 PA cases carrying viral RNA for up to 191

days. PA cases displayed low levels of inflammatory and interferon response, weak antibody response, diminished circulating follicular helper T cells (cTfh), and inadequate specific CD4(+) and CD8(+) T-cell responses during infection, which is distinct from symptomatic infections and resembling impaired immune activation. Administration of a single dose of Ad5-nCoV vaccine to 10 of these PA cases elicited rapid and robust antibody responses as well as coordinated B-cell and cTfh responses, resulting in successful viral clearance. Vaccine-induced antibodies were able to neutralize various variants of concern and persisted for over 6 months, indicating long-term protection. Therefore, our study provides an insight into the immune status of PA infections and highlights vaccination as a potential treatment for prolonged SARS-CoV-2 infections.
COVID-19 vaccine adverse events in a population aged 5-17 years: a study from the VAERS database.
COVID-19 Vaccination as a Trigger of IgA Vasculitis: Truth or Illusion?
Influence of age, gender, previous SARS-CoV-2 infection, and pre-existing diseases in antibody response after COVID-19 vaccination: A review. Vaccines induce specific long-term immunological memory against pathogens, preventing the worsening of diseases. The COVID-19 health emergency has caused more than 6 million deaths and started a race for vaccine development. Antibody response to COVID-19 vaccines has been investigated primarily in healthcare workers. The heterogeneity of immune responses and the behavior of this response in particular groups were still very little explored. In this review, we discuss whether antibody responses after vaccination are influenced by age, gender, previous SARS-CoV-2 infection, or pre-existing diseases.
Clinical prediction rules for adverse evolution in patients with COVID-19 by the Omicron variant. OBJECTIVE: We identify factors related to SARS-CoV-2 infection linked to hospitalization, ICU admission, and mortality and develop clinical prediction rules. METHODS: Retrospective cohort study of 380,081 patients with SARS-CoV-2 infection from March 1, 2020 to January 9, 2022, including a subsample of 46,402 patients who attended Emergency Departments (EDs) having data on vital signs. For derivation and external validation of the prediction rule, two different periods were considered: before and after emergence of the Omicron variant, respectively. Data collected included sociodemographic data, COVID-19 vaccination status, baseline comorbidities and treatments, other background data and vital signs at triage at EDs. The predictive models for the EDs and the whole samples were developed using multivariate logistic regression models using Lasso penalization. RESULTS: In the multivariable models, common predictive factors of death among EDs patients were greater age; being male; having no vaccination, dementia; heart failure; liver and kidney disease; hemiplegia or paraplegia; coagulopathy; interstitial pulmonary disease; malignant tumors; use chronic systemic use of steroids, higher temperature, low O2 saturation and altered blood pressure-heart rate. The predictors of an adverse evolution were the same, with the exception of liver disease and the inclusion of cystic fibrosis. Similar predictors were found to be related to hospital admission, including liver disease, arterial hypertension, and basal prescription of immunosuppressants. Similarly, models for the whole sample, without vital signs, are presented. CONCLUSIONS: We propose risk scales, based on basic information, easily-calculable, high-predictive that also function with the current Omicron variant and may help manage such patients in primary, emergency, and hospital care.
Flare and change in disease activity among patients with stable rheumatoid arthritis following coronavirus disease 2019 vaccination: A prospective Chinese cohort study. BACKGROUND: Vaccination has been shown effective in controlling the global coronavirus disease 2019 (COVID-19) pandemic and reducing severe cases. This study was to assess the flare and change in disease activity after COVID-19 vaccination in patients with stable rheumatoid arthritis (RA). METHODS: A prospective cohort of RA patients in remission or with low disease activity was divided into a vaccination group and a non-vaccination group based on their COVID-19 vaccination status. Each of them was examined

every 3 to 6 months. In the vaccination group, disease activity was compared before and after vaccination. The rates of flare defined as disease activity scores based on 28-joint count (DAS28) >3.2 with Î”DAS28 â‰¥0.6 were compared between vaccination and non-vaccination groups. RESULTS: A total of 202 eligible RA patients were enrolled. Of these, 98 patients received no vaccine shot (non-vaccination group), and 104 patients received two doses of vaccine (vaccination group). The median time interval from pre-vaccination visit to the first immunization and from the second dose of vaccine to post-vaccination visit was 67 days and 83 days, respectively. The disease activity scores at pre-vaccination and post-vaccination visits in the vaccination group patients were similar. At enrollment, gender, RA disease course, seropositivity, and disease activity were comparable across the two groups. Flare was observed in five (4.8%) of the vaccination group patients and nine (9.2%) of the non-vaccination group patients at post-vaccination assessment (P â€Š=â€Š0.221). In terms of safety, 29 (27.9%) patients experienced adverse events (AEs) after vaccination. No serious AEs occurred. CONCLUSIONS: COVID-19 vaccinations had no significant effect on disease activity or risk of flare in RA patients in remission or with low disease activity. Patients with stable RA should be encouraged to receive the COVID-19 vaccination.

Risk and Benefit of mRNA COVID-19 Vaccines for the Omicron Variant by Age, Sex, and Presence of Comorbidity: A Quality-Adjusted Life Years Analysis. The development of the mutant omicron variant of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during the coronavirus disease 2019 (COVID-19) pandemic raised the importance of reevaluating the risk and benefit of COVID-19 vaccines. With a decision tree model, we calculated the benefit-risk ratio and the benefit-risk difference of receiving monovalent messenger RNA (mRNA) COVID-19 vaccine (primary 2 doses, a third dose, and a fourth dose) in the 4-5 months after vaccination using quality-adjusted life years. The analysis was stratified by age, sex, and the presence of comorbidity. Evidence from peer-reviewed publications and gray literature was reviewed on September 16, 2022, to inform the study. Benefit-risk ratios for receipt ofÂ the BNT162b2 vaccine (Pfizer-BioNTech) ranged from 6.8 for males aged 12-17 years without comorbidity for the primary doses to 221.3 for females aged â‰¥65 years with comorbidity for the third dose. The benefit-risk ratios for receipt of the mRNA-1273 vaccine (Moderna) ranged from 7.2 for males aged 18-29 years without comorbidity for the primary doses to 101.4 for females aged â‰¥65 years with comorbidity for the third dose. In all scenarios of the one-way sensitivity analysis, the benefit-risk ratios were more than 1, irrespective of age, sex, comorbidity status, and type of vaccine, for both primary and booster doses. The benefits of mRNA COVID-19 vaccines in protecting against the omicron variant outweigh the risks, irrespective of age, sex, and comorbidity.

Nephrotic syndrome caused by IgA vasculitis flare up following COVID-19 vaccination.

Observed-over-Expected analysis as additional method for pharmacovigilance signal detection in large-scaled spontaneous adverse event reporting. BACKGROUND: The large-scale COVID-19 vaccination campaigns in 2021 and 2022 led to a rapid increase in numbers of received adverse event reports in spontaneous reporting systems. As background incidences of naturally occurring medical events became increasingly relevant for causality assessment of potential associations with the vaccines, a novel approach for signal detection was warranted. OBJECTIVES: This article illustrates the Observed-over-Expected (O/E) analysis as an additional method for signal detection and risk assessment in large-scaled spontaneous reporting systems. METHODS: All individual case safety reports (ICSRs) concerning idiopathic peripheral facial paralysis or Bell's palsy following administration of the COVID-19 vaccines (nÂ =â€‰291) manufactured by Pfizer/BioNTech (Comirnaty), Moderna (Spikevax), AstraZeneca (Vaxzevria) and Janssen (JCOVDEN) received by the National Pharmacovigilance Centre Lareb until 24th March 2022 were included in the O/E analysis, within a risk window of 7 and 14â€‰days following immunisation. Dutch background incidence rates

from 2019 and exposure of the Dutch population to the vaccines were obtained from the PHARMO institute and RIVM. The data was stratified in age groups, gender and administered dose in order to differentiate between population subgroups. RESULTS: Bell's palsy was reported more frequently than expected in several population subgroups following administration of all four COVID-19 vaccines, including children and adolescents. Among children, a high O/E ratio was found for boys aged 5-14â€‰years after receiving the Pfizer/BioNTech vaccine. Regarding adolescents and young adults, women aged 15-24â€‰years receiving Pfizer/BioNTech and Moderna, and men aged 15-24â€‰years receiving Janssen developed Bell's palsy more often than expected. Furthermore, O/E ratios were high for individuals aged 25-64, regarding females receiving Pfizer, Moderna and AstraZeneca and males receiving Janssen. As facial paralysis was not labelled as an adverse event for the Janssen vaccine, this analysis contributed to signalling the association and warranting further regulatory action. CONCLUSIONS: The O/E method is a useful approach for signal detection of potential adverse reactions when handling large numbers of ICSRs. Further research is needed to attest to the causality on a clinical basis.

Exposure of low-temperature plasma after vaccination in tongue promotes systemic IgM induction against spike protein of SARS-CoV-2. COVID-19 has been pandemic since 2020 with persistent generation of new variants. Cellular receptor for SARS-CoV-2 is angiotensin-converting enzyme 2 (ACE2), where transmembrane serine protease-2 (TMPRSS2) is essential for viral internalization. We recently reported abundant expression of ACE2 and TMPRSS2 in the oral cavity of humans and mice. Therefore, oral cavity may work for COVID-19 infection gates. Here we undertook to evaluate whether vaccination in the tongue harbors any merit in comparison to subcutaneous injection. Low-temperature plasma (LTP) is the fourth physical state of matters with ionization above gas but at body temperature. LTP provides complex chemistry, eventually supplying oxidative and/or nitrosative stress on the interface. LTP-associated cellular death has been reported to cause apoptosis and/or ferroptosis. However, there is few data available on immunogenicity retention after LTP exposure. We therefore studied the effect of LTP exposure after the injection of keyhole limpet hemocyanin (KLH) or spike 2 protein of SARS-CoV-2 to the tongue of six-week-old male BALB/c mice, compared to subcutaneous vaccination. Whereas LTP did not change the expression of ACE2 and TMPRSS2 in the tongue, repeated LTP exposure after tongue vaccination significantly promoted systemic and specific IgM production at day 11. In contrast, repeated LTP exposure after subcutaneous vaccination of KLH decreased systemic IgM production. Of note, tongue injection produced significantly higher titer of IgM and IgG in the case of KLH. In conclusion, LTP significantly reinforced humoral immunity by IgM after tongue injection. Vaccination to the tongue can be a novel strategy to acquire immediate immunity.

Effects of COVID-19 vaccine type on Guillain-BarrÃ© syndrome: Two cases and a literature review. Guillain-BarrÃ© syndrome (GBS) is a rare but severe complication of COVID-19 vaccination. We report two cases of GBS following vaccination with the adenovirus vector vaccine ChAdOx1 nCoV-19 (Vaxzevria, AstraZeneca) and review the relevant literature. Relevant studies published between December 2020 and May 2022 including 881 patients with GBS were reviewed. GBS incidence and the need for mechanical ventilation were reported at a higher level among patients receiving Vaxzevria (nâ€‰=â€‰400). However, incidence cannot be accurately estimated from case reports. Thus, the true GBS rates following COVID-19 vaccination should be determined by population-based data.

Pityriasis Rosea after COVID-19 Infection. Dear Editor, Pityriasis rosea (PR) is a common, self-limited erythematous papulosquamous dermatosis that mainly affects young adults. It is believed to represent a delayed reaction to viral infections and is usually associated with endogenous systemic reactivation of human herpesvirus (HHV) 6 and / or 7 (1). A 46-year-old man presented to our Department with a two-week history of skin rash associated with mild pruritus. He described the

appearance of an erythematous centrally scaled lesion at the right part of his abdomen, followed by the spreading of red oval mildly scaling lesions on the trunk, neck, and proximal parts of the upper extremities, which showed in the physical examination (Figure 1, a and b). He was otherwise healthy and taking no medications. Six weeks prior to the appearance of the initial skin lesion, the patient had coronavirus disease 2019 (COVID-19) infection with mild clinical presentation (fever up to 38 Â°C lasting for four days and mild headache) and with symptoms of post COVID-19 syndrome (excessive tiredness). He denied oropharyngeal lesions. Potassium hydroxide, syphilis, and laboratory tests were within normal limits. Within two weeks of topical betamethasone dipropionate treatment, the lesions disappeared completely. In addition to reactivation of HHV-6 or HHV-7, PR can be triggered by some drugs (like angiotensin-converting enzyme inhibitors alone or in combination with hydrochlorothiazide, sartans plus hydrochlorothiazide, allopurinol, nimesulide, and acetyl salicylic acid (2) and vaccines (such as smallpox, poliomyelitis, influenza, human papillomavirus, diphtheria, tuberculosis, hepatitis B, pneumococcus, and yellow fever vaccines) (3). There is a growing number of published cases that link PR to COVID-19 infection, with PR appearing either in the acute phase of COVID-19 or, as in our patient, in the post COVID-19 period (4-9). Unlike in our patient, oropharyngeal lesions were observed in approximately 16% of patients with typical PR (10). It has been suggested that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) induces reactivation of other viruses, such as HHV-6, HHV-7, varicella zoster virus, and Epstein-Barr virus (5). PR has also been reported to follow COVID-19 vaccination (11). As our patient did not receive a COVID-19 vaccine, we cannot evaluate the latter based on the present case. We speculate that PR could be a delayed skin manifestation of COVID-19 infection, triggered either by SARS-CoV-2 immediately or indirectly by the reactivation of other viruses such as HHV-6 or HHV-7. However, the etiopathogenetic mechanisms remain largely unknown and further studies are needed in order to clarify the correlation between SARS-CoV-2 and PR.

Short-term Side Effects of mRNA-based COVID-19 Vaccine Among Jordanian Population; a Cross-sectional Study. INTRODUCTION: One type of the developed COVID-19 vaccines that received emergency permission and was approved by the food and drug administration (FDA) is the mRNA-based vaccine. The aim of this study is to gather information on the Jordanian population's experience with the vaccine's side effects. METHODS: The study objectives were addressed through a cross-sectional study, which collected information regarding the short-term side effects experienced by the vaccinated individuals within one month following the injection of an mRNA-based COVID-19 vaccine. Data collection was carried out in August 2021. Participants were invited to take part in a self-administered web-based survey created using Google Forms. RESULTS: Among the study's participants (n= 533), about 56% experienced side effects after the first dose of the mRNA-based COVID-19 vaccine. The most commonly reported side effects after the first dose were sore arm at the injection site (91.6%), and fatigue (83.06%). The female gender was significantly associated with experiencing fatigue, discomfort, chills, and hair loss. Being over 30 years old was significantly associated with experiencing cough. Being a smoker was significantly associated with experiencing shortness of breath and gastrointestinal symptoms. CONCLUSION: The mRNA-based COVID-19 vaccine side effects were common, yet, mild, local, and self-limited. The local pain at the injection site was the most commonly reported side effect. Hopefully, the study's findings will aid in lowering resistance to vaccination.

Co-morbidity associated with development of severe COVID-19 before vaccine availability: a retrospective cohort study in the first pandemic year among the middle-aged and elderly in JÃ¶nkÃ¶ping county, Sweden. BACKGROUND: In preparation of future pandemics, it is important to recognise population-level determinants associated with development of severe illness before efficient vaccines and evidence-based therapeutic measures are available. The aim of this study was

to identify pre-pandemic diagnoses recorded in a middle-aged and elderly population that were associated with development of severe COVID-19 during the first pandemic year. METHODS: A cohort study design was used. Severe COVID-19 was defined as a course of illness that resulted in hospital admission or death. A retrospective analysis was performed that comprised all individuals aged 39 years and older (Nâ€‰=â€‰189,951) living in JÃ¶nkÃ¶ping County, Sweden. All diagnosed morbidity recorded in contacts with health care during the pre-pandemic year 2019 was used to identify which diagnoses that were associated with development of severe COVID-19 in the first pandemic year 2020. The analyses were performed separately for each diagnosis using binary logistic regression with adjustment for sex and age. RESULTS: Severe COVID-19 was suffered by 0.67% (Nâ€‰=â€‰1,280) of the middle-aged and elderly population in the first pandemic year. Individuals previously diagnosed with dementia, cerebral palsy, kidney failure, type 2 diabetes mellitus, hypertension, and obesity were at higher risk of developing severe COVID-19. For patients with Type 2 diabetes mellitus, the odds ratio (OR) was 2.18 (95% confidence interval, 1.92-2.48). Type 1 diabetes mellitus was not associated with increased risk. CONCLUSION: Diagnoses suggesting service provision at long-term healthcare facilities and co-morbidity with components of the metabolic syndrome were associated with an increased risk of developing severe COVID-19 in a middle-aged and elderly population before vaccines were available.

A case of acute tubulointerstitial nephritis following administration of the Oxford-AstraZeneca COVID-19 vaccine: a case report. BACKGROUND: More than 4 billion doses of the Coronavirus disease (COVID-19) vaccine have been administered worldwide but the relationship between the different vaccines and the development of renal disease is unknown. We present a case of tubulointerstitial nephritis following administration of the Oxford-AstraZeneca COVID-19 vaccine. CASE PRESENTATION: A previously fit and well 51-year-old female presented on 27th May 2021 with a one-month history of weight loss, fatigue, nausea, and a metallic taste. She had an acute kidney injury with a creatinine of 484 umol/L. She was on no regular medications and denied taking any over-the-counter or alternative medicines. She had received her first dose of the Oxford-AstraZeneca vaccine on 23rd March 2021 and her second dose on 20th May 2021. A renal biopsy was performed the following day. The 19 glomeruli appeared normal to light microscopy but the tubulointerstitial compartment contained a dense inflammatory infiltrate including many eosinophils. There was widespread acute tubular injury with tubulitis, but no established or longstanding atrophy. A diagnosis was made of an acute tubulointerstitial nephritis. She was commenced on oral prednisolone and her renal function improved. She did not require renal replacement therapy at any time. CONCLUSIONS: To our knowledge, this was the first described case of acute tubulointerstitial nephritis following administration of the Oxford-AstraZeneca COVID-19 vaccine, although a number of cases have emerged more recently. In our case the patient was very fit and well, had no previous past medical history and had not taken any recent prescribed, over-the-counter or alternative medications. The absence of these provoking factors in our case makes the vaccine the most likely explanation for the development of tubulointerstitial nephritis although the pathophysiology behind this remains unknown. Given the unprecedented number of vaccinations being delivered around the world, nephrologists should be aware of this possible link although more research into the topic is required.

Association of SARS-CoV-2 BA.4/BA.5 Omicron lineages with immune escape and clinical outcome. Expansion of the SARS-CoV-2 BA.4 and BA.5 Omicron subvariants in populations with prevalent immunity from prior infection and vaccination, and associated burden of severe COVID-19, has raised concerns about epidemiologic characteristics of these lineages including their association with immune escape or severe clinical outcomes. Here we show that BA.4/BA.5 cases in a large US healthcare system had at least 55% (95% confidence interval: 43-69%) higher adjusted odds of prior

documented infection than time-matched BA.2 cases, as well as 15% (9-21%) and 38% (27-49%) higher adjusted odds of having received 3 and â‰¥4 COVID-19 vaccine doses, respectively. However, after adjusting for differences in epidemiologic characteristics among cases with each lineage, BA.4/BA.5 infection was not associated with differential risk of emergency department presentation, hospital admission, or intensive care unit admission following an initial outpatient diagnosis. This finding held in sensitivity analyses correcting for potential exposure misclassification resulting from unascertained prior infections. Our results demonstrate that the reduced severity associated with prior (BA.1 and BA.2) Omicron lineages, relative to the Delta variant, has persisted with BA.4/BA.5, despite the association of BA.4/BA.5 with increased risk of breakthrough infection among previously vaccinated or infected individuals.

Sex-based differences in risk of ischaemic stroke or systemic embolism after BNT162b2 or CoronaVac COVID-19 vaccination in patients with atrial fibrillation: a self-controlled case series and nested case-control study. AIMS: Patients with atrial fibrillation (AF) have a higher risk of ischaemic stroke or systemic embolism, with a greater risk for female patients. This study aims to evaluate the risk of ischaemic stroke or systemic embolism and bleeding following COVID-19 vaccination in patients with AF and the sex differences. METHODS AND RESULTS: Self-controlled case series (SCCS) analysis was conducted to evaluate the risk of ischaemic stroke or systemic embolism and bleeding following BNT162b2 or CoronaVac in patients with AF, using the territory-wide electronic medical records from the Hospital Authority and vaccination records from the Department of Health in Hong Kong. Patients with a primary diagnosis of ischaemic stroke, systemic embolism, or bleeding in the inpatient setting between 23 February 2021 and 31 March 2022 were included. A nested case-control analysis was also conducted with each case randomly matched with 10 controls according to sex, age, Charlson comorbidity index, and date of hospital admission. Conditional Poisson regression was used in the SCCS analysis, and conditional logistic regression was used in the nested case-control analysis to assess the risks, and all analyses were stratified by sex and type of vaccines. Among 51â€‰158 patients with AF, we identified an increased risk of ischaemic stroke or systemic embolism after the first dose of BNT162b2 in SCCS analysis during 0-13 days [incidence rate ratio 6.60, 95% confidence interval (CI) 1.51-28.77] and 14-27 days (6.53, 95% CI 1.31-32.51), and nested case-control analysis during 0-13 days (adjusted odds ratio 6.21, 95% CI 1.14-33.91) and 14-27 days (5.52, 95% CI 1.12-27.26) only in female patients. The increased risk in female patients following the first dose of CoronaVac was only detected during 0-13 days (3.88, 95% CI 1.67-9.03) in the nested case-control analysis. No increased risk of ischaemic stroke or systemic embolism was identified in male patients, and no increased risk of bleeding was detected in all patients with AF for both vaccines. An increased risk of ischaemic stroke or systemic embolism after COVID-19 was also observed in both females (17.42, 95% CI 5.08-59.73) and males (6.63, 95% CI 2.02-21.79). CONCLUSIONS: The risk of ischaemic stroke or systemic embolism after COVID-19 vaccination was only increased in female patients with AF. However, as the risk after COVID-19 was even higher, proactive uptake of COVID-19 vaccines is recommended to prevent the potential severe outcomes after infection.

Distinct platelet crosstalk with adaptive and innate immuneÂ cells after adenoviral and mRNA vaccination against SARS-CoV-2. BACKGROUND: Genetic-based COVID-19 vaccines have proved to be highly effective in reducing the risk of hospitalization and death. Because they were first distributed in a large-scale population, the adenoviral-based vaccines were linked to a very rare thrombosis with thrombocytopenia syndrome, and the interplay between platelets and vaccinations increasingly gained attention. OBJECTIVES: The objective of this article was to study the crosstalk between platelets and the vaccine-induced immune response. METHODS: We prospectively enrolled young healthy volunteers who received the mRNA-based vaccine, BNT162b2 (nÂ = 15), or the adenovirus-based vaccine, AZD1222 (nÂ = 25) and studied their short-term platelet and immune

response before and after vaccine injections. In a separate cohort, we retrospectively analyzed the effect of aspirin on the antibody response 1 and 5 months after BNT162b2 vaccination. RESULTS: Here, we show that a faster antibody response to either vaccine is associated with the formation of platelet aggregates with marginal zone-like B cells, a subset geared to bridge the temporal gap between innate and adaptive immunities. However, although the mRNA-based vaccine is associated with a more gradual and tolerogenic response that fosters the crosstalk between platelets and adaptive immunity, the adenovirus-based vaccine, the less immunogenic of the 2, evokes an antiviral-like response during which the platelets are cleared and less likely to cooperate with B cells. Moreover, subjects taking aspirin (nÂ = 56) display lower antibody levels after BNT162b2 vaccination compared with matched individuals. CONCLUSION: Platelets are a component of the innate immune pathways that promote the B-cell response after vaccination. Future studies on the platelet-immune crosstalk post-immunization will improve the safety, efficacy, and strategic administration of next-generation vaccines.

Sudden Death Associated With Possible Flare-Ups of Multiple Sclerosis After COVID-19 Vaccination and Infection: A Case Report and Literature Review. We present an autopsy case of a 19-year-old man with a history of epilepsy whose unwitnessed sudden death occurred unexpectedly in the night. About 4 years before death, he was diagnosed with unilateral optic neuritis (ON). Demyelinating disease was suspected, but he was lost to follow up after the recovery. Six months before death, he received a second dose of mRNA coronavirus disease 2019 (COVID-19) vaccine. Three months before death, he experienced epileptic seizures for the first time. Seventeen days before death, he was infected with COVID-19, which showed self-limited course under home isolation. Several days before death, he complained of seizures again at night. Autopsy revealed multifocal gray-tan discoloration in the cerebrum. Histologically, the lesions consisted of active and inactive demyelinated plaques in the perivenous area of the white matter. Perivascular lymphocytic infiltration and microglial cell proliferation were observed in both white matter and cortex. The other major organs including heart and lung were unremarkable. Based on the antemortem history and postmortem findings, the cause of death was determined to be multiple sclerosis with suspected exacerbation. The direct or indirect involvement of cortex and deep gray matter by exacerbated multiple sclerosis may explain the occurrence of seizures. Considering the absence of other structural abnormalities except the inflammatory demyelination of the cerebrum, fatal arrhythmia or laryngospasm in the terminal epileptic seizure may explain his sudden unexpected death in the benign circumstances. In this case, the onset of seizure was preceded by COVID-19 vaccination, and the exacerbation of seizure was preceded by COVID-19 infection, respectively. Literature reporting first manifestation or relapse of multiple sclerosis temporally associated with COVID-19 vaccination or infection are reviewed.

Management of Atopic Dermatitis During the COVID-19 Pandemic: Key Questions and Review of the Current Evidence. Since the outbreak of COVID-19, management of atopic dermatitis (AD) has been widely discussed. Key issues include the risk of COVID-19 infection and related outcomes in AD patients, the efficacy and safety of COVID-19 vaccination in AD populations, and management of AD in the COVID-19 pandemic. Recent studies have shown that patients with AD have a slightly increased risk of COVID-19 infection but are not associated with a worse outcome than the non-AD population. COVID-19 vaccination is generally effective and safe in patients with AD. However, temporary discontinuation of certain systemic immunomodulatory agents after vaccination is suggested. During the pandemic, continuation of all immunomodulating agents is suggested, but these agents should be paused when patients with AD are infected with COVID-19 until recovery. Further studies are warranted to investigate the long-term interaction between AD and COVID-19 to aid clinical decisions during the pandemic.

Duplex Electrochemical Microfluidic Sensor for COVID-19 Antibody Detection: Natural versus Vaccine-Induced Humoral Response. The rapid transmission and resilience of coronavirus disease 2019 (COVID-19) have led to urgent demands in monitoring humoral response for effective vaccine development, thus a multiplex co-detection platform to discriminate infection-induced from vaccine-induced antibodies is needed. Here a duplex electrochemical immunosensor for co-detection of anti-nucleocapsid IgG (N-IgG) and anti-spike IgG (S-IgG) is developed by using a two-working electrode system, via an indirect immunoassay, with antibody quantification obtained by differential pulse voltammetry. The screen-printed electrodes (SPEs) are modified by carbon black and electrodeposited gold nanoflowers for maximized surface areas, enabling the construction of an immunological chain for S-IgG and N-IgG electrochemical detection with enhanced performance. Using an optimized immunoassay protocol, a wide linear range between 30-750 and 20-1000Â ngÂ mL(-1) , and a limit of detection of 28 and 15Â ngÂ mL(-1) are achieved to detect N-IgG and S-IgG simultaneously in serum samples. This duplex immunosensor is then integrated in a microfluidic device to obtain significantly reduced detection time (â‰¤ 7Â min) while maintaining its analytical performance. The duplex microfluidic immunosensor can be easily expanded into multiplex format to achieve high throughput screening for the sero-surveillance of COVID-19 Â and other infectiousÂ diseases.

Influencing factors of nucleic acid negative conversion in patients with mild and common COVID-19 induced by the Omicron variant of SARS-COV-2. OBJECTIVE: To observe the clinical characteristics of mild and common COVID-19 patients infected with the Omicron variant, and to analyze related factors affecting the time to negative conversion of viral nucleic acid detection. METHODS: Clinical data of 1781 patients with coronavirus disease 2019 (COVID-19) admitted to a cabin hospital in Shanghai from April 12 to May 26, 2022, were retrospectively analyzed, including age, gender, height, weight, clinical symptoms, comorbid diseases, COVID-19 vaccination, treatment, and nucleic acid negative conversion time. Univariate and multivariate logistic regression analyses were used to analyze the influencing factors of nucleic acid negative conversion time. RESULTS: Among the 1781 patients, 995 were male and 786 were female, with a median age of 39 (30, 52)â€…years. There were 727 patients (40.8%) with overweight and obesity [body mass index (BMI) > 24â€…kg/cm (2)) and 413 patients (23.2%) had comorbid diseases. 205 cases (11.5%) were not vaccinated while 1576 cases were vaccinated. There were 1233 cases (69.2%) with one or more symptoms. The main clinical symptoms were cough (60.3%), expectoration (50.4%) and fever (36.9%). 1444 cases (81.0%) were treated with Chinese medicine, 78 cases (4.4%) were treated with western medicine, 14 cases (0.8%) were treated with integrated Chinese and western medicine, and 245 cases (13.8%) did not receive any medical treatment. All patients improved and were discharged. The median nucleic acid negative conversion time was 10.3 (7.4, 12.4)â€…d. Univariate and multivariate analysis showed that, age â‰¥ 60â€…years (ORï¼•1.537, 95% CI: 1.116 - 2.115, P<0.01), BMI > 24â€…kg/cm (2) (ORï¼•1.344, 95% CI: 1.106 - 1.634, P<0.01) and hypertension (ORï¼•1.518, 95% CI: 1.094 - 2.106, P<0.05) were independent risk factors for prolonged nucleic acid negative conversion. COVID-19 vaccination (OR=0.548, 95% CI: 0.398 - 0.755, P<0.01) was a protective factor, that is, vaccination shortened the time for the nucleic acid test to become negative. CONCLUSIONS: The symptoms of the Omicron variant infection were relatively mild and occult. Age â‰¥ 60â€…years old, comorbid hypertension, no vaccination and BMI > 24â€…kg/cm (2) are independent influencing factors for prolonged nucleic acid negative conversion.

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Free-living core body temperature monitoring using a wrist-worn sensor after COVID-19 booster vaccination: a pilot study. Core body temperature (CBT) is a key vital sign and fever is an important indicator of disease. In the past decade, there has been growing interest for vital sign monitoring technology that may be embedded in wearable devices, and the COVID-19 pandemic has highlighted the need for remote patient monitoring systems. While wrist-worn sensors allow continuous assessment of heart rate and oxygen saturation, reliable measurement of CBT at the wrist remains challenging. In this study, CBT was measured continuously in a free-living setting using a novel technology worn at the wrist and compared to reference core body temperature measurements, i.e., CBT values acquired with an ingestible temperature-sensing pill. Fifty individuals who received the COVID-19 booster vaccination were included. The datasets of 33 individuals were used to develop the CBT prediction algorithm, and the algorithm was then validated on the datasets of 17 participants. Mean observation time was 26.4Â h and CBTâ€‰>â€‰38.0Â Â°C occurred in 66% of the participants. CBT predicted by the wrist-worn sensor showed good correlation to the reference CBT (râ€‰=â€‰0.72). Bland-Altman statistics showed an average bias of 0.11Â Â°C of CBT predicted by the wrist-worn device compared to reference CBT, and limits of agreement were -Â 0.67 toâ€‰+â€‰0.93Â Â°C, which is comparable to the bias and limits of agreement of commonly used tympanic membrane thermometers. The small size of the components needed for this technology would allow its integration into a variety of wearable monitoring systems assessing other vital signs and at the same time allowing maximal freedom of movement to the user.

A case of acquired idiopathic generalized anhidrosis following severe acute respiratory syndrome coronavirus 2 vaccination.

Generalized painful papulovesicular eruption following the COVID-19 BNT162b2 mRNA vaccine.

Antibody acquisition after second and third SARS-CoV-2 vaccinations in Japanese kidney transplant patients: a prospective study. BACKGROUND: Kidney transplant patients have lower antibody acquisition after SARS-CoV-2 vaccination. The efficacy of vaccines in Japanese kidney transplant patients with specific characteristics, such as predominant living-donor, ABO-incompatible kidney transplant, and low-dose immunosuppression, requires verification. METHODS: We conducted a

prospective study to estimate anti-SARS-CoV-2 antibody levels in 105 kidney transplant patients and 57 controls. Blood samples were obtained before vaccination, 1, 3, and 6Â months after second vaccination, and 1Â month after third vaccination. We investigated antibody acquisition rates, antibody levels, and factors associated with antibody acquisition. RESULTS: One month after second vaccination, antibody acquisition was 100% in the controls but only 36.7% in the kidney transplant group (Pâ€‰<â€‰0.001). Antibody levels in positive kidney transplant patients were also lower than in the controls (median, 4.9 arbitrary units vs 106.4 arbitrary units, respectively, Pâ€‰<â€‰0.001). Years after kidney transplant (odds ratio 1.107, 95% confidence interval 1.012-1.211), ABO-incompatible kidney transplant (odds ratio 0.316, 95% confidence interval 0.101-0.991) and mycophenolate mofetil use (odds ratio 0.177, 95% confidence interval 0.054-0.570) were significant predictors for antibody acquisition after second vaccination. After third vaccination, antibody positivity in the kidney transplant group increased to 75.3%, and antibody levels in positive patients were 71.7 arbitrary units. No factors were associated with de novo antibody acquisition. CONCLUSIONS: In Japanese kidney transplant patients, years after kidney transplant, ABO-incompatible kidney transplant and mycophenolate mofetil use were predictors for antibody acquisition after second vaccination. Third vaccination improves antibody status even in patients who were seronegative after the second vaccination.

The relationship between COVID-19 vaccines and increased blood pressure: A word of caution.

Short term outcome of myocarditis and pericarditis following COVID-19 vaccines:Â a cardiac magnetic resonance imaging study. To evaluate clinical and cardiac magnetic resonance (CMR) short-term follow-up (FU) in patients with vaccine-associated myocarditis, pericarditis or myo-pericarditis (VAMP) following COVID-19 vaccination. We retrospectively analyzed 44 patients (2 women, mean age: 31.7â€‰Â±â€‰15.1Â years) with clinical and CMR manifestations of VAMP, recruited from 13 large tertiary national centers. Inclusion criteria were troponin raise, interval between the last vaccination dose and onset of symptomsâ€‰<â€‰25Â days and symptoms-to-CMRâ€‰<â€‰20Â days. 29/44 patients underwent a short-term FU-CMR with a median time of 3.3Â months. Ventricular volumes and CMR findings of cardiac injury were collected in all exams. Mean interval between the last vaccination dose and the onset of symptoms was 6.2â€‰Â±â€‰5.6Â days. 30/44 patients received a vaccination with Comirnaty, 12/44 with Spikevax, 1/44 with Vaxzevria and 1/44 with Janssen (18 after the first dose of vaccine, 20 after the second and 6 after the "booster" dose). Chest pain was the most frequent symptom (41/44), followed by fever (29/44), myalgia (17/44), dyspnea (13/44) and palpitations (11/44). At baseline, left ventricular ejection fraction (LV-EF) was reduced in 7 patients; wall motion abnormalities have been detected in 10. Myocardial edema was found in 35 (79.5%) and LGE in 40 (90.9%) patients. Clinical FU revealed symptoms persistence in 8/44 patients. At FU-CMR, LV-EF was reduced only in 2 patients, myocardial edema was present in 8/29 patients and LGE in 26/29. VAMPs appear to have a mild clinical presentation, with self-limiting course and resolution of CMR signs of active inflammation at short-term follow-up in most of the cases.

Public Interest in Myocarditis during the SARS-CoV-2 Pandemic. OBJECTIVE: Public interest in the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines has been rising with regard to associated myocarditis. Thus, the objective of our study was to assess trends in public interest in myocarditis during the course of the pandemic and the SARS-CoV-2 vaccine rollout in the United States. METHODS: We conducted a longitudinal assessment of public interest in myocarditis, and its association with actual coronavirus disease 2019 (COVID-19) -related myocarditis during the first wave of the pandemic and SARS-CoV-2 vaccine-related myocarditis following vaccine rollout. To complete this objective, we used data from 3 sources: a report from the Morbidity and Mortality Weekly Report, the Vaccine Adverse Event Reporting database, and from Google Trends. RESULTS:

Results show that Relative Search Interest (RSI) was low before and during the initial phase of the pandemic and peaked in April 2021, during the initial vaccine push. The ratio of myocarditis related to the SARS-CoV-2 vaccines was considerably lower than the ratio of myocarditis from natural infection. CONCLUSIONS: Search interest in myocarditis was low until SARS-CoV-2 vaccines were rolled out, in which media coverage intensely focused on a relatively small number of cases. This study highlights both the benefits of COVID-19 vaccine uptake and the impact of the media on public interest.

The role of lymphocyte transformation tests (LTT) in suspected severe delayed hypersensitivity reactions following COVID-19 vaccination. Coronavirus (COVID-19) vaccines have proved to be effective in the pandemic response but can cause adverse events such as delayed hypersensitivity reactions (DHRs). Delayed-reading intradermal tests (IDT) to vaccines are limited by false-positive results and may reflect a cell-mediated rather than IgE-mediated immune response. Lymphocyte transformation test (LTT), which has been utilized in the diagnosis of drug allergy, may be helpful in suspected COVID-19 vaccine and/or its excipient-related DHRs. To investigate the use of LTT in two suspected cases of COVID-19 vaccine-induced DHRs, two patients with suspected DHRs to COVID-19 vaccination were tested by delayed-reading IDT and LTT against vaccines and their excipients. A 47-year-old man developed acute mixed-pattern hepatitis after the second dose of ChAdOx1 vaccine. LTT performed at 2 months post-vaccination revealed reactivity to the ChAdOx1 vaccine, polysorbate 80 and mildly to PEG 2050 but not BNT162b2 vaccine. Delayed-reading IDT returned negative to both vaccines and excipients. He tolerated BNT162b2 vaccination with no adverse events. A 36-year-old woman presented with subacute morbilliform eruption and hepatitis after the first dose of BNT162b2 vaccine. LTT performed 3 months later revealed reactivity to the BNT162b2 but not PEG 2050. Repeat LTT following subsequent natural Severe Acute Respiratory Coronavirus-2 (SARS-CoV-2) infection revealed reactivity to ChAdOx1 and NVX-CoV2373 vaccines but not polysorbate 80. Delayed-reading IDT remained negative. She proceeded with NVX-CoV2373 vaccination with no symptom recurrence. LTT may be a useful tool in suspected COVID-19 vaccine-related DHRs. Further evaluation with a larger patient cohort is required.

Gross Hematuria following SARS-CoV-2 Vaccination. In the setting of the rapid development of currently available vaccines for coronavirus disease of 2019 (COVID-19), little is known about their less frequent potential side effects. Raising the awareness of clinicians and front-line healthcare workers about the less well-known potential side effects of vaccination is important. We describe the self-limited occurrence of gross hematuria in two elderly men on a combination of aspirin and another antiplatelet or anticoagulant following their second dose of the Moderna COVID-19 vaccination. While the bleeding seems to be self-limited, the long-term course currently remains elusive.

Single-cell RNA-seq analysis identifies distinct myeloid cells in a case with encephalitis temporally associated with COVID-19 vaccination. Recently accumulating evidence has highlighted the rare occurrence of COVID-19 vaccination-induced inflammation in the central nervous system. However, the precise information on immune dysregulation related to the COVID-19 vaccination-associated autoimmunity remains elusive. Here we report a case of encephalitis temporally associated with COVID-19 vaccination, where single-cell RNA sequencing (scRNA-seq) analysis was applied to elucidate the distinct immune signature in the peripheral immune system. Peripheral blood mononuclear cells (PBMCs) were analyzed using scRNA-seq to clarify the cellular components of the patients in the acute and remission phases of the disease. The data obtained were compared to those acquired from a healthy cohort. The scRNA-seq analysis identified a distinct myeloid cell population in PBMCs during the acute phase of encephalitis. This specific myeloid population was detected neither in the remission phase of the disease nor in the healthy cohort. Our findings illustrate induction of a unique myeloid subset in encephalitis temporally associated with COVID-19 vaccination. Further

research into the dysregulated immune signature of COVID-19 vaccination-associated autoimmunity including the cerebrospinal fluid (CSF) cells of central nervous system (CNS) is warranted to clarify the pathogenic role of the myeloid subset observed in our study.
New-Onset Myasthenia Gravis Following COVID-19 Vaccination.
Consider Alternative Causes of Death to SARS-CoV-2 Vaccination-Related Guillain-Barre Syndrome without Dysautonomia.
Bilateral Serous Detachments with Roth Spots after COVID-19 Vaccination: A Case Report. With the rise of novel types of vaccines during the pandemic, new side effects are encountered. The aim of this paper is to describe an atypical case of bilateral serous detachments with Roth spots after COVID-19 vaccination using an mRNA vaccine. A healthy, 38-year-old male presented with a central scotoma and metamorphopsia in his left eye, 4 days after his second COVID-19 booster shot. Bilateral serous detachments were seen, with one area showing Roth spots. Patient's symptoms resolved spontaneously without any treatment. Although serous detachment after COVID-19 vaccination has been described in the context of other diseases, such as Vogt-Koyanagi-Harada disease, central serous chorioretinopathy, and posterior scleritis, this is the first report of serous detachments with Roth spots as an isolated entity.
Heterologous vaccination with subunit protein vaccine induces a superior neutralizing capacity against BA.4/5-included SARS-CoV-2 variants than homologous vaccination of mRNA vaccine. BA.4 and BA.5 (BA.4/5), the subvariants of Omicron, are more transmissible than BA.1 with more robust immune evasion capability because of its unique spike protein mutations. In light of such situation, the vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is in desperate need of the third booster. It has been reported that heterologous boosters might produce more effective immunity against wild-type SARS-CoV-2 and the variants. Additionally, the third heterologous protein subunit booster should be considered potentially. In the present study, we prepared a Delta full-length spike protein sequence-based mRNA vaccine as the "priming" shot and developed a recombinant trimeric receptor-binding domain (RBD) protein vaccine referred to as RBD-HR/trimer as a third heterologous booster. Compared to the homologous mRNA group, the heterologous group (RBD-HR/trimer vaccine primed with two mRNA vaccines) induced higher neutralizing antibody titers against BA.4/5-included SARS-CoV-2 variants. In addition, heterologous vaccination exhibited stronger cellular immune response and long-lasting memory response than the homologous mRNA vaccine. In conclusion, a third heterologous boosting with RBD-HR/trimer following two-dose mRNA priming vaccination should be a superior strategy than a third homologous mRNA vaccine. The RBD-HR/trimer vaccine becomes an appropriate candidate for a booster immune injection.
Impact of Age and Severe Acute Respiratory Syndrome Coronavirus 2 Breakthrough Infection on Humoral Immune Responses After Three Doses of Coronavirus Disease 2019 mRNA Vaccine. BACKGROUND: Longer-term immune response data after 3 doses of coronavirus disease 2019 (COVID-19) mRNA vaccine remain limited, particularly among older adults and after Omicron breakthrough infection. METHODS: We quantified wild-type- and Omicron-specific serum immunoglobulin (Ig)G levels, angiotensin-converting enzyme 2 displacement activities, and live virus neutralization up to 6 months after third dose in 116 adults aged 24-98â€…years who remained COVID-19 naive or experienced their first severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection during this time. RESULTS: Among the 78 participants who remained COVID-19 naive throughout follow up, wild-type- and Omicron-BA.1-specific IgG concentrations were comparable between younger and older adults, although BA.1-specific responses were consistently significantly lower than wild-type-specific responses in both groups. Wild-type- and BA.1-specific IgG concentrations declined at similar rates in COVID-19-naive younger and older adults, with median

half-lives ranging from 69 to 78â€…days. Antiviral antibody functions declined substantially over time in COVID-19-naive individuals, particularly in older adults: by 6 months, BA.1-specific neutralization was undetectable in 96% of older adults, versus 56% of younger adults. Severe acute respiratory syndrome coronavirus 2 infection, experienced by 38 participants, boosted IgG levels and neutralization above those induced by vaccination alone. Nevertheless, BA.1-specific neutralization remained significantly lower than wild-type, with BA.5-specific neutralization lower still. Higher Omicron BA.1-specific neutralization 1 month after third dose was an independent correlate of lower SARS-CoV-2 infection risk. CONCLUSIONS: Results underscore the immune benefits of the third COVID-19 mRNA vaccine dose in adults of all ages and identify vaccine-induced Omicron-specific neutralization as a correlate of protective immunity. Systemic antibody responses and functions however, particularly Omicron-specific neutralization, decline rapidly in COVID-19-naive individuals, particularly in older adults, supporting the need for additional booster doses.

Emergence of Post COVID-19 Vaccine Autoimmune Diseases: A Single Center Study.
INTRODUCTION: Severe acute respiratory syndrome coronavirus 2 (SARS CoV-2) became a major concern since the announcement that it is a pandemic in early 2020. Vaccine trials were started in November 2020, and completed rapidly due to the urgency to get over the infection. Side effects to vaccines started to be reported. There were minor side effects including site of injection pain and heaviness and constitutional symptoms like fever which are considered minor. One of the rare adverse events is post vaccine new onset autoimmune diseases. METHODS: Data were obtained from one center in the eastern province of Saudi Arabia (King Fahd Hospital of University). All patient events reported occurred in the study period March 2021 to February 2022. We identified patients presenting with autoimmune diseases with exclusively new onset presentations. RESULTS: We identified 31 cases of immune-mediated disease: 18 females (58%); 13 males (42%). Only 4 of them (13%) had an autoimmune background before COVID-19 vaccination. The average time between vaccination and new-onset disease symptoms was 7 days. Among all the cases in our study, 7 patients (22.5%) had new-onset vasculitis, 2 cases had IgA vasculitis and 5 cases had ANCA vasculitis, 6 cases had neurological diseases (19.3%), 4 cases (12.9%) had new-onset systemic lupus erythematosus (SLE), 3 cases (9.6%) presented with new-onset inflammatory arthritis, and one had Sjogren's syndrome (3.2%). CONCLUSION: Our study is unique as it is the first study to include the largest number (31 patients) of new onsets of confirmed autoimmune diseases related to Covid-19 vaccines.

Vaccine-induced neutralizing antibodies against SARS-CoV-2 Omicron variant isolated in Osaka, Japan.
To study vaccine-induced neutralizing antibodies against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants isolated in Osaka, Japan, microneutralization tests were performed on serum samples from 32subjects who received a second dose of vaccination, and 10 of those who received the third dose of vaccination. Geometric mean titres (GMTs) for the D614G strain, Alpha variant, Delta variant, and Omicron BA.1 of the subjects after the second dose of vaccination were 19.5, 21.8, 6.3 and 2.0, respectively. The GMT for the Delta variant was significantly lower than that for the D614G strain and Alpha variant, and the GMT for the Omicron BA.1 was significantly lower than that for the Delta variant. Among the subjects who received three doses of vaccination, the GMTs for the Omicron BA.1 (62.8) and BA.2 (38.6) were significantly higher than that for the Omicron BA.1 after the second dose. Thus, in the present study, the second dose of vaccination induced neutralizing antibodies against SARS-CoV-2 strains, and the reactivity of neutralizing antibodies to the variants was thought to be enhanced by the third dose of vaccination. The serum samples used in this study will be useful in evaluating the reactivity of vaccine-induced antibodies to newly emerging variants.

New-onset of juvenile systemic lupus erythematosus following COVID-19 vaccination: First case report.

Chest pain and Raynaud's phenomenon after COVID-19 vaccination in a patient previously diagnosed with systemic lupus erythematosus: a case report. BACKGROUND: Cardiovascular events, including pericarditis, myocarditis, and myocardial ischaemia, have been reported as complications following COVID-19 vaccination. CASE SUMMARY: A 28-year-old Japanese woman diagnosed 10 years earlier with systemic lupus erythematosus and antiphospholipid syndrome was admitted to our hospital because of chest pain and Raynaud's phenomenon. She had received a second dose of the COVID-19 BNT162b2 mRNA vaccine 28 days earlier. (123)I-Î²-methyl iodophenyl pentadecanoic acid (BMIPP) and (201)thallium dual myocardial single-photon emission computed tomography demonstrated mildly reduced perfusion of BMIPP in the mid-anterior wall of the left ventricle. Coronary angiography revealed normal coronary arteries; additionally, an endomyocardial biopsy was performed. Histopathological evaluation revealed a normal myocardium without cell infiltration. However, immunostaining for the severe acute respiratory coronavirus (SARS-CoV)/severe acute respiratory coronavirus 2 (SARS-CoV-2) spike protein was positive in the small intramural coronary arteries. The administration of azathioprine (50â€…mg/day) and amlodipine (5â€…mg/day) and increases in her prednisolone (10â€…mg/day) and aspirin doses led to improvements in the symptoms of the patient. DISCUSSION: Our data lead us to speculate that two events in the timeline of the patient, namely, receiving COVID-19 vaccination and the presence of SARS-CoV/SARS-CoV-2 spike protein in small intramural coronary arteries, may be related to the myocardial microangiopathy observed in this patient.

Physical activities pre- and post-COVID-19 vaccination and its implementations: A narrative review. Coronavirus disease 2019 is a severe communicable pulmonary medical problem that has been a challenging disease for everyone in the globe, but vaccines development and administration against this severe acute respiratory syndrome-inducing disease (coronavirus disease 2019) are currently yielding fabulous results. The mean duration of the coronavirus disease 2019 pandemic for this study spanned from 2020 until 2022. These manifestations are accompanied by symptoms of respiratory tract illnesses such as non-productive cough, sore throat, and nasal discharge. Relevant reviews on coronavirus disease 2019 manifestations and outcomes, consisting mainly of the infections/outbreaks, experimental information, and pre- and post-serovaccination details that occurred, were described. After a typical vaccination course, the study aims to summarize and understand more about the effectiveness of exercise on the pre-and post-coronavirus disease 2019 vaccination and its implementations. Physical activity is an immunological function adjuvant to decrease communicable disease risk and enhance immunity post-viral infection vaccination. Moderate-intensity resistance exercisesession directly before getting the influenza vaccine decreases vaccine responses in older adults, such as redness, pain, or inflammation at the injection spot or other adverse consequences compared to the inactive circumstance. However, it was reported that exercise after a shot is generally safe as long as vaccinated people feel well enough. Though exercise before or after vaccination has no negative impact on the protection afforded by the vaccine, people can exercise immediately after receiving the vaccine, as any changes in blood flow will not affect the vaccine's response. One episode of light-to-moderate-intensifying exercise after vaccination may improve the antibody reactions to influenza or the coronavirus disease 2019 vaccine. Vaccination administered pre- and post-regular exercise is an effective approach for boosting antibody responses due to its immunostimulant effects. Future research should investigate how different vaccine antibodies respond to low, moderate, and high physical activity levels.

Parsonage-Turner Syndrome Post-COVID-19 Oxford/AstraZeneca Vaccine Inoculation: A Case Report and Brief Literature Review. Parsonage-Turner syndrome (PTS) is a rare brachial plexus neuropathy that typically presents as a severe, sudden-onset pain followed by atrophic weakness with slow recovery, which may occurÂ after an identifiable triggering event.Â Vaccination is one of

several known triggers of PTS, and this syndrome has already been reported in other patients who were vaccinated against coronavirus disease. We report the case of a 75-year-old Caucasian man who received the third dose of the coronavirus disease 2019 (COVID-19) Oxford/AstraZeneca vaccine and was diagnosed with PTS. A week after inoculation, the patient, with no history of trauma, developed a sudden-onset left shoulder mechanical pain and later reported an abduction deficit. Neurological examination showed an atrophy of the proximal muscles of the left upper limb. No bulbar weakness or pathological upper motor neuron signs were seen. The MRI excluded rotator cuff pathology, including ruptures and tendinopathy. Electroneuromyography findings carried out 10 months after the onset of symptoms indicated left brachial panplexopathy, suggestive of PTS. The raised consciousness of PTS and vaccine association is crucial for prompt identification and diagnosis and, therefore, better clinical outcomes.

Polymyalgia Rheumatica (PMR) Lacking Shoulder Pain Following COVID-19 Vaccination. This case highlights a 77-year-old woman with polymyalgia rheumatica (PMR) following coronavirus disease 2019 (COVID-19) vaccination without shoulder pain and its characteristic positron emission tomography-computed tomography (PET-CT) findings. Some cases of PMR following COVID-19 vaccination have been reported. However, patients without shoulder pain orÂ PET-CT findings without uptake at the shoulders are not described. Our case suggests that PMR should be considered in the differential diagnosis of patients with neck pain following COVID-19 vaccination, even if they lack shoulder pain.

Neutropenia Secondary to SARS-Cov2 Vaccination in Post-Hematopoietic Stem Cell Transplant (HSCT) Patients.

SARS-CoV-2-specific antibody responses following BNT162b2 vaccination in individuals with multiple sclerosis receiving different disease-modifying treatments. INTRODUCTION: The study aims to evaluate the concentration of IgG antibodies against the receptor-binding domain of the SARS-CoV-2 spike1 protein (S1RBD) in BNT162b2- vaccinated relapsing-remitting multiple sclerosis (RRMS) individuals receiving disease-modifying treatments (DMTs). METHODS: Serum from 126 RRMS volunteers was collected 3 months after the administration of the second dose of the Pfizer-BioNTech BNT162b2 vaccine. Additional samples were analyzed after the administration of the booster dose in fingolimod- treated MS. Anti-S1RBD IgG antibody concentrations were quantified using the ABBOTT SARS-CoV-2 IgG II Quant assay. RESULTS: Anti-S1RBD IgG antibody concentrations in RRMS individuals receiving natalizumab, interferons, teriflunomide, and dimethyl fumarate showed no significant difference to those in healthy controls. However, fingolimod-treated MS individuals showed a marked inability to produce SARS-CoV-2- specific antibodies ($p < 0.0001$). Furthermore, a booster dose was not able to elicit the production of IgG antibodies in a large portion of matched individuals. DISCUSSION: A possible explanation for the altered immune response in fingolimod- treated MS individuals could be due to the medication inhibiting the circulation of lymphocytes, and possibly in turn inhibiting antibody production. Overall, patients on DMTs are generally of no disadvantage toward mounting an immune response against the vaccine. Nevertheless, further studies require evaluating non-humoral immunity against SARS-CoV-2 following vaccination, as well as the suitability of such vaccinations on patients treated with fingolimod.

Analysis of participant-reported adverse events following the first dose of inactivated SARS-Cov-2 vaccine (TURKOVACâ„¢) through telephone survey in TÃ¼rkiye. BACKGROUND/OBJECTIVE(S)/INTRODUCTION: TURKOVACâ„¢ is a whole-virion inactivated COVID-19 vaccine, which was developed and recently granted emergency use authorization (conditional marketing authorization) in TÃ¼rkiye. The objective of this study is to assess the spectrum and the distribution of adverse events reported following the administration of the first 150,000 doses as primary and booster vaccine doses in 22 state hospitals of 17 provinces in TÃ¼rkiye.

PATIENTS/MATERIALS AND METHODS: In this cohort study, a verbal survey was conducted via telephone calls between 10 January and 17 January 2022, utilizing a structured questionnaire algorithm on a sample group of 20,000 persons on the third- and seventh-days following vaccination. The algorithm consisted of two parts focusing on both systemic and local adverse effects. Other adverse events reported by the participants were also recorded. 6023 people and 5345 people agreed to participate in the telephone survey on the 3rd- and 7th- days of having received the first dose of the vaccine, respectively. RESULTS: Thirty-six-point-six percent of the participants on the 3rd day and 22.5% of the participants on the 7th day reported any adverse event following the first dose of the vaccine. On both follow-up days, the most commonly reported (29.7% for Day 3 and 13.1% for Day 7) adverse events were on the injection site. Among the local adverse events, the most frequently reported one was the pain on the injection site (27.9% for Day 3 and 12.4% for Day 7), induration (4.8% for Day 3 and 2.7% for Day 7) and swelling (3.5% for Day 3 and 2.0% for Day 7). Fatigue/weakness (9.6% for Day 3 and 8.3% for Day 7) and headache (7.9% for Day 3 and 8.0% for Day 7) were the most frequent systemic adverse events. Younger age, vaccine dose, and female sex were associated with having any adverse event and pain (on the injection site). Female sex was associated with more swelling (on the injection site), induration (on the injection site), fever, and a higher impact on daily living. CONCLUSION(S): In this study, we conducted a rapid assessment of adverse events following the first dose of the TURKOVAC vaccine. The vaccine appears to have a good safety profile in the first 7â€‰days following vaccination. Younger age, vaccine dose, and female sex are associated with any adverse event and pain (on the injection site). These results present valuable information for the community and may contribute to increasing vaccine confidence.KEY MESSAGESAs a whole-virion inactivated SARS-CoV-2 vaccine, the TURKOVACâ„¢ vaccine, which has a favorable safety profile, can be an alternative to other COVID-19 vaccines including mRNA and viral vector vaccines.

Antibody dependent disease enhancement (ADE) after COVID-19 vaccination and beta glucans as a safer strategy in management. A potential risk associated with vaccines for COVID-19 is antibody-dependent disease enhancement (ADE) in which vaccine induced antibody mediated immune responses may lead to enhanced SARS CoV- 2 acquisition or increased disease severity. Though ADE has not been clinically demonstrated with any of the COVID-19 vaccines so far, when neutralizing antibodies are suboptimal, the severity of COVID-19 has been reported to be greater. ADE is presumed to occur via abnormal macrophages induced by the vaccine based immune response by antibody-mediated virus uptake into Fc gamma receptor IIa (FcÎ³RIIa) or by the formation of Fc-mediated excessive antibody effector functions. Beta-glucans which are naturally occurring polysaccharides known for unique immunomodulation by capability to interact with macrophages, eliciting a specific beneficial immune-response and enhancing all arms of the immune system, importantly without over-activation are suggested as safer nutritional supplement-based vaccine adjuvants for COVID-19.

The present evidence summary of SARS-CoV-2 vaccine-associated liver injury: A rapid systematic review.

Post-Acute Sequelae After Severe Acute Respiratory Syndrome Coronavirus 2 Infection by Viral Variant and Vaccination Status: A Multicenter Cross-Sectional Study. BACKGROUND: Disentangling the effects of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants and vaccination on the occurrence of post-acute sequelae of SARS-CoV-2 (PASC) is crucial to estimate and reduce the burden of PASC. METHODS: We performed a cross-sectional analysis (May/June 2022) within a prospective multicenter healthcare worker (HCW) cohort in north-eastern Switzerland. HCWs were stratified by viral variant and vaccination status at time of their first positive SARS-CoV-2 nasopharyngeal swab. HCWs without positive swab and with negative serology served as controls.

The sum of 18 self-reported PASC symptoms was modeled with univariable and multivariable negative-binomial regression to analyze the association of mean symptom number with viral variant and vaccination status. RESULTS: Among 2912 participants (median age: 44 years; 81.3% female), PASC symptoms were significantly more frequent after wild-type infection (estimated mean symptom number: 1.12; P < .001; median time since infection: 18.3 months), after Alpha/Delta infection (0.67 symptoms; P < .001; 6.5 months), and after Omicron BA.1 infections (0.52 symptoms; P = .005; 3.1 months) versus uninfected controls (0.39 symptoms). After Omicron BA.1 infection, the estimated mean symptom number was 0.36 for unvaccinated individuals versus 0.71 with 1-2 vaccinations (P = .028) and 0.49 with â‰¥3 prior vaccinations (P = .30). Adjusting for confounders, only wild-type (adjusted rate ratio [aRR]: 2.81; 95% confidence interval [CI]: 2.08-3.83) and Alpha/Delta infections (aRR: 1.93; 95% CI: 1.10-3.46) were significantly associated with the outcome. CONCLUSIONS: Previous infection with pre-Omicron variants was the strongest risk factor for PASC symptoms among our HCWs. Vaccination before Omicron BA.1 infection was not associated with a clear protective effect against PASC symptoms in this population.

Fulminant Myocarditis and Cardiogenic Shock Following COVID-19 Infection Versus COVID-19 Vaccination: A Systematic Literature Review. BACKGROUND: Myocarditis, diagnosed by symptoms and troponin elevation, has been well-described with COVID-19 infection, as well as shortly after COVID-19 vaccination. The literature has characterized the outcomes of myocarditis following COVID-19 infection and vaccination, but clinicopathologic, hemodynamic, and pathologic features following fulminant myocarditis have not been well-characterized. We aimed to compare clinical and pathological features of fulminant myocarditis requiring hemodynamic support with vasopressors/inotropes and mechanical circulatory support (MCS), in these two conditions. METHODS: We analyzed the literature on fulminant myocarditis and cardiogenic shock associated with COVID-19 and COVID-19 vaccination and systematically reviewed all cases and case series where individual patient data were presented. We searched PubMed, EMBASE, and Google Scholar for "COVID", "COVID-19", and "coronavirus" in combination with "vaccine", "fulminant myocarditis", "acute heart failure", and "cardiogenic shock". The Student's t-test was used for continuous variables and the Ï‡2 statistic was used for categorical variables. For non-normal data distributions, the Wilcoxon Rank Sum Test was used for statistical comparisons. RESULTS: We identified 73 cases and 27 cases of fulminant myocarditis associated with COVID-19 infection (COVID-19 FM) and COVID-19 vaccination (COVID-19 vaccine FM), respectively. Fever, shortness of breath, and chest pain were common presentations, but shortness of breath and pulmonary infiltrates were more often present in COVID-19 FM. Tachycardia, hypotension, leukocytosis, and lactic acidosis were seen in both cohorts, but patients with COVID-19 FM were more tachycardic and hypotensive. Histologically, lymphocytic myocarditis dominated both subsets, with some cases of eosinophilic myocarditis in both cohorts. Cellular necrosis was seen in 44.0% and 47.8% of COVID-19 FM and COVID-19 vaccine FM, respectively. Vasopressors and inotropes were used in 69.9% of COVID-19 FM and in 63.0% of the COVID-19 vaccine FM. Cardiac arrest was observed more in COVID-19 FM (p = 0.008). Venoarterial extracorporeal membrane oxygenation (VA-ECMO) support for cardiogenic shock was also used more commonly in the COVID-19 fulminant myocarditis group (p = 0.0293). Reported mortality was similar (27.7%) and 27.8%, respectively) but was likely worse for COVID-19 FM as the outcome was still unknown in 11% of cases. CONCLUSIONS: In the first series to retrospectively assess fulminant myocarditis associated with COVID-19 infection versus COVID-19 vaccination, we found that both conditions had a similarly high mortality rate, while COVID-19 FM had a more malignant course with more symptoms on presentation, more profound hemodynamic decompensation (higher heart rate, lower blood pressure), more cardiac arrests, and higher temporary MCS requirements including VA-ECMO. In terms of pathology, there was no difference in most biopsies/autopsies that demonstrated

lymphocytic infiltrates and some eosinophilic or mixed infiltrates. There was no predominance of young males in COVID-19 vaccine FM cases, with male patients representing only 40.9% of the cohort.

Association between the Seroprevalence of Antibodies against Seasonal Alphacoronaviruses and SARS-CoV-2 Humoral Immune Response, COVID-19 Severity, and Influenza Vaccination. The present study assesses the seroprevalence of antibodies against seasonal human alphacoronaviruses 229E and NL63 among adult patients infected with SARS-CoV-2, and its association with the humoral response to SARS-CoV-2 infection and its severity, and influenza vaccination. A serosurvey was conducted to quantify the presence of IgG antibodies against the nucleocapsid of 229E (anti-229E-N) and NL63 (anti-NL63-N), and anti-SARS-CoV-2 IgG antibodies (against nucleocapsid, receptor-binding domain, S2 domain, envelope, and papain-like protease) for 1313 Polish patients. The seroprevalence of anti-229E-N and anti-NL63 in the studied cohort was 3.3% and 2.4%. Seropositive individuals had a higher prevalence of anti-SARS-CoV-2 IgG antibodies, higher titers of the selected anti-SARS-CoV2 antibodies, and higher odds of an asymptomatic SARS-CoV-2 infection (OR = 2.5 for 229E and OR = 2.7 for NL63). Lastly, the individuals vaccinated against influenza in the 2019/2020 epidemic season had lower odds of seropositivity to 229E (OR = 0.38). The 229E and NL63 seroprevalence was below the expected pre-pandemic levels (up to 10%), likely due to social distancing, increased hygiene, and face masking. The study also suggests that exposure to seasonal alphacoronaviruses may improve humoral responses to SARS-CoV-2 while decreasing the clinical significance of its infection. It also adds to accumulating evidence of the favorable indirect effects of influenza vaccination. However, the findings of the present study are of a correlative nature and thereby do not necessarily imply causation.

Effect of SARS-CoV-2 mRNA-Vaccine on the Induction of Myocarditis in Different Murine Animal Models. In the course of the SARS-CoV-2 pandemic, vaccination safety and risk factors of SARS-CoV-2 mRNA-vaccines were under consideration after case reports of vaccine-related side effects, such as myocarditis, which were mostly described in young men. However, there is almost no data on the risk and safety of vaccination, especially in patients who are already diagnosed with acute/chronic (autoimmune) myocarditis from other causes, such as viral infections, or as a side effect of medication and treatment. Thus, the risk and safety of these vaccines, in combination with other therapies that could induce myocarditis (e.g., immune checkpoint inhibitor (ICI) therapy), are still poorly assessable. Therefore, vaccine safety, with respect to worsening myocardial inflammation and myocardial function, was studied in an animal model of experimentally induced autoimmune myocarditis. Furthermore, it is known that ICI treatment (e.g., antibodies (abs) against PD-1, PD-L1, and CTLA-4, or a combination of those) plays an important role in the treatment of oncological patients. However, it is also known that treatment with ICIs can induce severe, life-threatening myocarditis in some patients. Genetically different A/J (most susceptible strain) and C57BL/6 (resistant strain) mice, with diverse susceptibilities for induction of experimental autoimmune myocarditis (EAM) at various age and gender, were vaccinated twice with SARS-CoV-2 mRNA-vaccine. In an additional A/J group, an autoimmune myocarditis was induced. In regard to ICIs, we tested the safety of SARS-CoV-2 vaccination in PD-1(-/-) mice alone, and in combination with CTLA-4 abs. Our results showed no adverse effects related to inflammation and heart function after mRNA-vaccination, independent of age, gender, and in different mouse strains susceptible for induction of experimental myocarditis. Moreover, there was no worsening effect on inflammation and cardiac function when EAM in susceptible mice was induced. However, in the experiments with vaccination and ICI treatment, we observed, in some mice, low elevation of cardiac troponins in sera, and low scores of myocardial inflammation. In sum, mRNA-vaccines are safe in a model of experimentally

induced autoimmune myocarditis, but patients undergoing ICI therapy should be closely monitored when vaccinated.

Increased incidence of adult-onset Still's disease in association with COVID-19 vaccination and SARS-CoV-2 infection. BACKGROUND: Adult-onset Still's disease (AOSD) is a multi-system, auto-inflammatory disease characterized by fever, arthralgia, typical rash, leukocytosis, sore throat, and liver dysfunction, among other symptoms. Retrospective studies about the frequencies of AOSD have shown that this disease is very rare. However, there has been an increased scientific interest in the last 2 years, as numerous case studies on AOSD have been published. These case studies describe the occurrence of AOSD after SARS-CoV-2 infection and/or COVID-19 vaccination. METHODS: We analyzed the incidence of AOSD to examine a potential association between AOSD and SARS-CoV-2 infection and/or COVID-19 vaccination. The TriNetX dataset consists of 90 million patients. We found 8474 AOSD cases, which we analyzed regarding SARS-CoV-2 infection and/or vaccination status. We also analyzed the cohorts considering demographic data, lab values, co-diagnoses and treatment pathways. RESULTS: We divided the AOSD cases into four cohorts: primary cohort (AOSD), Cov cohort (AOSDâ€‰+â€‰SARS-CoV-2 infection), Vac cohort (AOSDâ€‰+â€‰COVID-19 vaccination) and Vacâ€‰+â€‰Cov cohort (AOSDâ€‰+â€‰COVID-19 vaccinationâ€‰+â€‰SARS-CoV-2 infection). For the primary cohort, we found an annual incidence of 0.35 per 100.000. We found an association between AOSD and SARS-CoV-2 infection and/or COVID-19 vaccination. According to the numerical analysis, the incidence of AOSD doubled for the Cov cohort and Vac cohort. Moreover, the incidence of AOSD was 4.82 times higher for Vacâ€‰+â€‰Cov cohort. The lab values for inflammatory markers were increased. Co-diagnoses such as rash, sore throat, and fever appeared in all AOSD cohorts, with the highest occurrences in the AOSDâ€‰+â€‰COVID-19 vaccinationâ€‰+â€‰SARS-CoV-2 infection cohort. We identified several lines of treatments, mainly in association with adrenal corticosteroids. CONCLUSIONS: This research supports the assumption of an association between AOSD and SARS-CoV-2 infection and/or COVID-19 vaccination. However, AOSD remains a rare disease and the usage of vaccines to fight the COVID-19 pandemic should not be questioned because of the increased incidence of AOSD.

Reactogenicity within the first week after Sinopharm, Sputnik V, AZD1222, and COVIran Barekat vaccines: findings from the Iranian active vaccine surveillance system. BACKGROUND: This study aimed to evaluate the reactogenicity effects of COVID-19 vaccines, used in Iran. METHODS: At least 1000 people were followed up with phone calls or self-report in a mobile application within 7Â days after vaccination. Local and systemic reactogenicities were reported overall and by subgroups. RESULTS: The presence of one or more local and systemic adverse effects after the first dose of vaccines was 58.9% [(95% Confidence Intervals): 57.5-60.3)] and 60.5% (59.1-61.9), respectively. These rates were reduced to 53.8% (51.2-55.0) and 50.8% (48.8-52.7) for the second dose. The most common local adverse effect reported for all vaccines was pain in the injection site. During the first week after the first dose of vaccines, the frequency of the pain for Sinopharm, AZD1222, Sputnik V, and Barekat was 35.5%, 86.0%, 77.6%, and 30.9%, respectively. The same rates after the second dose were 27.3%, 66.5%, 63.9%, and 49.0%. The most common systemic adverse effect was fatigue. In the first dose, it was 30.3% for Sinopharm, 67.4% for AZD1222, 47.6% for Sputnik V, and 17.1% for Barekat. These rates were reduced to 24.6%, 37.1%, 36.5%, and 19.5%, in the second dose of vaccines. AZD1222 had the highest local and systemic adverse effects rates. The odds ratio of local adverse effects of the AZD1222 vaccine compared to the Sinopharm vaccine were 8.73 (95% CI 6.93-10.99) in the first dose and 4.14 (95% CI 3.32-5.17) in the second dose. Barekat and Sinopharm had the lowest frequency of local and systemic adverse effects. Compared to Sinopharm, systemic adverse effects were lower after the first dose of Barekat (ORâ€‰=â€‰0.56; 95% CI 0.46-0.67). Reactogenicity events were higher in women and younger people. Prior COVID-19 infection increased

the odds of adverse effects only after the first dose of vaccines. CONCLUSIONS: Pain and fatigue were the most common reactogenicities of COVID-19 vaccination. Reactogenicities were less common after the second dose of the vaccines. The adverse effects of AZD1222 were greater than those of other vaccines.
Safety and immunogenicity of aerosolised Ad5-nCoV, intramuscular Ad5-nCoV, or inactivated COVID-19 vaccine CoronaVac given as the second booster following three doses of CoronaVac: a multicentre, open-label, phase 4, randomised trial. BACKGROUND: Aerosolised Ad5-nCoV is the first approved mucosal respiratory COVID-19 vaccine to be used as a booster after the primary immunisation with COVID-19 vaccines. This study aimed to evaluate the safety and immunogenicity of aerosolised Ad5-nCoV, intramuscular Ad5-nCoV, or inactivated COVID-19 vaccine CoronaVac given as the second booster. METHODS: This is an open-label, parallel-controlled, phase 4 randomised trial enrolling healthy adult participants (â‰¥18 years) who had completed a two-dose primary immunisation and a booster immunisation with inactivated COVID-19 vaccines (CoronaVac only) at least 6 months before, in Lianshui and Donghai counties, Jiangsu Province, China. We recruited eligible participants from previous trials in China (NCT04892459, NCT04952727, and NCT05043259) as cohort 1 (with the serum before and after the first booster dose available), and from eligible volunteers in Lianshui and Donghai counties, Jiangsu Province, as cohort 2. Participants were randomly assigned at a ratio of 1:1:1, using a web-based interactive response randomisation system, to receive the fourth dose (second booster) of aerosolised Ad5-nCoV (0Â·1 mL of 1Â·0â€‰Ã—â€‰10(11) viral particles per mL), intramuscular Ad5-nCoV (0Â·5 mL of 1Â·0â€‰Ã—â€‰10(11) viral particles per mL), or inactivated COVID-19 vaccine CoronaVac (0Â·5 mL), respectively. The co-primary outcomes were safety and immunogenicity of geometric mean titres (GMTs) of serum neutralising antibodies against prototype live SARS-CoV-2 virus 28 days after the vaccination, assessed on a per-protocol basis. Non-inferiority or superiority was achieved when the lower limit of the 95% CI of the GMT ratio (heterologous group vs homologous group) exceeded 0Â·67 or 1Â·0, respectively. This study was registered with ClinicalTrials.gov, NCT05303584 and is ongoing. FINDINGS: Between April 23 and May 23, 2022, from 367 volunteers screened for eligibility, 356 participants met eligibility criteria and received a dose of aerosolised Ad5-nCoV (n=117), intramuscular Ad5-nCoV (n=120), or CoronaVac (n=119). Within 28 days of booster vaccination, participants in the intramuscular Ad5-nCoV group reported a significantly higher frequency of adverse reactions than those in the aerosolised Ad5-nCoV and intramuscular CoronaVac groups (30% vs 9% and 14%, respectively; p<0Â·0001). No serious adverse events related to the vaccination were reported. The heterologous boosting with aerosolised Ad5-nCoV triggered a GMT of 672Â·4 (95% CI 539Â·7-837Â·7) and intramuscular Ad5-nCoV triggered a serum neutralising antibody GMT of 582Â·6 (505Â·0-672Â·2) 28 days after the booster dose, both of which were significantly higher than the GMT in the CoronaVac group (58Â·5 [48Â·0-71Â·4]; p<0Â·0001). INTERPRETATION: A heterologous fourth dose (second booster) with either aerosolised Ad5-nCoV or intramuscular Ad5-nCoV was safe and highly immunogenic in healthy adults who had been immunised with three doses of CoronaVac. FUNDING: National Natural Science Foundation of China, Jiangsu Provincial Science Fund for Distinguished Young Scholars, and Jiangsu Provincial Key Project of Science and Technology Plan.
Palinacousis or Auditory Perseverations Following COVID-19 Vaccination.
COVID-19 vaccination and idiopathic sudden sensorineural hearing loss: comment.
Cardiac inflammation associated with COVID-19 mRNA vaccination in patients with and without previous myocarditis. BACKGROUND: mRNA COVID-19 vaccines have been associated with myocarditis in the general population. However, application of gold standard techniques is often missing, and data about patients with history of myocarditis have not been reported yet. METHODS: We evaluated 21 patients (median age 27, 86% males) for suspected myocarditis after receiving

mRNA COVID-19 vaccine. We divided cases with previous diagnosis of myocarditis (PM, N.=7), from naÃ¯ve controls (NM, N.=14). All patients were investigated thoroughly by cardiac magnetic resonance (100%) with or without endomyocardial biopsy (14%). RESULTS: Overall, 57% of patients met updated Lake Louise criteria and none fulfilled Dallas criteria, with no remarkable differences between groups. Acute coronary syndrome-like presentation was more frequent in NM with earlier normalization of troponin than PM. NM and PM already healed from myocarditis were clinically comparable, whereas PM with active inflammation had subtle presentation and were evaluated for immunosuppressive therapy modulation. None had fulminant myocarditis and/or malignant ventricular arrhythmia at presentation. No major cardiac events occurred by 3 months. CONCLUSIONS: In this study, the suspicion of mRNA COVID-19 vaccine-associated myocarditis was inconstantly confirmed by gold standard diagnostics. Myocarditis was uncomplicated in both PM and NM patients. Larger studies with longer follow-up are needed to validate COVID-19 vaccination in this population.

Third COVID-19 vaccine dose for people with multiple sclerosis who did not seroconvert following two doses of BBIBP-CorV (Sinopharm) inactivated vaccine: A pilot study on safety and immunogenicity. BACKGROUND: People with multiple sclerosis (pwMS) on anti-CD20 therapies (aCD20) and fingolimod have shown inadequate humoral responses to COVID-19 vaccines. OBJECTIVE: The objective of the study was to pilot larger studies by demonstrating the safety and comparing the immunogenicity of different types of third doses in seronegative pwMS after two doses of BBIBP-CorV inactivated vaccine. METHODS: In December 2021, subject to receiving their third dose, being COVID-19-naiive, and receiving no corticosteroid within two months, we measured the level of anti-SARS-CoV-2-Spike IgG in pwMS seronegative after two shots of BBIBP-CorV inactivated vaccine. RESULTS: We included 20/29 pwMS who received adenoviral vector (AV), 7/29 who received inactivated, and 2/29 who received conjugated third doses. No serious adverse events were reported two weeks post-third dose. The pwMS receiving AV third doses showed significantly increased IgG concentrations, while only the ones not on aCD20 and fingolimod responded to inactivated third doses. An ordinal logistic multivariable generalized linear model indicated that age (per year Î²: -0.10, P = 0.04), type of disease-modifying therapy (aCD20 Î²: -8.36, P <0.01; fingolimod Î²: -8.63, P = 0.01; others: reference), and type of third dose (AV or conjugated Î²: 2.36, P = 0.02; inactivated: reference) are predictive of third dose immunogenicity among pwMS who remain seronegative after two shots of BBIBP-CorV vaccine. Statistical significance was not achieved for variables sex, MS duration, EDSS, duration of DMT, duration of third dose to IgG test, and duration from last aCD20 infusion to third dose. CONCLUSION: This preliminary pilot study highlights the need for further research to determine the optimal COVID-19 third dose vaccination strategy for pwMS living in areas where BBIBP-CorV vaccine has been used.

SARS-CoV-2 mRNA vaccines decouple anti-viral immunity from humoral autoimmunity. mRNA-based vaccines dramatically reduce the occurrence and severity of COVID-19, but are associated with rare vaccine-related adverse effects. These toxicities, coupled with observations that SARS-CoV-2 infection is associated with autoantibody development, raise questions whether COVID-19 vaccines may also promote the development of autoantibodies, particularly in autoimmune patients. Here we used Rapid Extracellular Antigen Profiling to characterize self- and viral-directed humoral responses after SARS-CoV-2 mRNA vaccination in 145 healthy individuals, 38 patients with autoimmune diseases, and 8 patients with mRNA vaccine-associated myocarditis. We confirm that most individuals generated robust virus-specific antibody responses post vaccination, but that the quality of this response is impaired in autoimmune patients on certain modes of immunosuppression. Autoantibody dynamics are remarkably stable in all vaccinated patients compared to COVID-19 patients that exhibit an increased prevalence of new autoantibody reactivities. Patients with vaccine-associated

myocarditis do not have increased autoantibody reactivities relative to controls. In summary, our findings indicate that mRNA vaccines decouple SARS-CoV-2 immunity from autoantibody responses observed during acute COVID-19.

Humeral and cellular immune responses to SARS-CoV-2 vaccination in patients on peritoneal dialysis. BACKGROUND: Patients with chronic kidney disease are at high risk for coronavirus disease 2019. Little is known about immune response to severe acute respiratory syndrome coronavirus 2 vaccination in patients on peritoneal dialysis (PD). METHOD: We prospectively enrolled 306 PD patients receiving two doses of vaccines (ChAdOx1-S: 283, mRNA-1273: 23) from July 2021Â at a medical center. Humeral and cellular immune responses were assessed by anti-spike IgG concentration and blood T cell interferon-Î³ production 30 days after vaccination. Antibody â‰¥0.8 U/mL and interferon-Î³ â‰¥ 100 mIU/mL were defined as positive. Antibody was also measured in 604 non-dialysis volunteers (ChAdOx1-S: 244, mRNA-1273: 360) for comparison. RESULT: PD patients had less adverse events after vaccinations than volunteers. After the first dose of vaccine, the median antibody concentrations were 8.5 U/mL and 50.4 U/mL in ChAdOx1-S group and mRNA-1273 group of PD patients, and 66.6 U/mL and 195.3 U/mL in ChAdOx1-S group and mRNA-1273 group of volunteers, respectively. And after the second dose of vaccine, the median antibody concentrations were 344.8 U/mL and 9941.0 U/mL in ChAdOx1-S group and mRNA-1273 group of PD patients, and 620.3 U/mL and 3845.0 U/mL in ChAdOx1-S group and mRNA-1273 group of volunteers, respectively. The median IFN-Î³ concentration was 182.8 mIU/mL in ChAdOx1-S group, which was substantially lower than the median concentration 476.8 mIU/mL in mRNA-1273 group of PD patients. CONCLUSION: Both vaccines were safe and resulted in comparable antibody seroconversion in PD patients when compared with volunteers. However, mRNA-1273 vaccine induced significantly higher antibody and T cell response than ChAdOx1-S in PD patients. Booster doses are recommended for PD patients after two doses of ChAdOx1-S vaccination.

Parsonage-Turner Syndrome After COVID-19 Vaccination in a Child. Parsonage-Turner syndrome (PTS) is a peripheral neuropathy involving the brachial plexus very rare in childhood. To date, no cases of PTS after COVID-19 vaccination have been reported in children. We report a case of a 15-year-old boy affected by PTS after the second dose of the BNT162b2 (Comirnaty, Pfizer-BioNTech) COVID-19 vaccine.

Localized Vitiligo and Post-Inflammatory Hypopigmentation at the Injection Site of a COVID-19 mRNA Vaccine.

Cutaneous reactions following COVID-19 vaccination assessed by dermatologists: a single-institutional study in Germany. BACKGROUND AND OBJECTIVES: Cutaneous reactions following COVID-19 vaccination have been frequently described, whereas larger case series by dermatologists are lacking. This study assesses SARS-CoV-2 vaccination-associated skin reactions, severity, treatment, course, eliciting vaccines, allergy test results and tolerance to revaccination. PATIENTS AND METHODS: Single-institutional, non-interventional study of dermatologists assessing cutaneous manifestations in 83 patients in Germany. RESULTS: 93 reactions were presented. Manifestations clustered into immediate (nÂ =Â 51, 54.8%) and delayed hypersensitivity reactions (nÂ =Â 10, 10.8%), chronic inflammatory skin diseases (nÂ =Â 13, 14.0%), reactivation of latent herpes virus infection (pityriasis rosea/herpes zoster; nÂ =Â 9; 9.7%) and others (nÂ =Â 10, 10.8%). Vaccination was associated with new (76.3%) - mostly hypersensitivity reactions - or exacerbation of known skin diseases (23.7%), in this case predominantly chronic inflammatory skin diseases. Reactions occurred primarily within the first week (72.8%) and after first vaccination (62.0%). Treatment was required in 83.9% and hospitalization in 19.4%. In 48.8% revaccination led to recurrence of the same reactions. Disease was ongoing at last consultation in 22.6%, primarily in chronic inflammatory skin diseases. Allergy tests were performed in 15 patients (18.1%) and resulted negative. CONCLUSIONS: It can be assumed that

vaccination may trigger immune activation-related reactions especially in those patients predisposed to develop respective skin diseases.

Facial fat necrosis after autologous fat transfer possibly associated with SARS-CoV-2 vaccine. A 52-year-old female patient developed facial fat necrosis presenting with cutaneous induration three weeks after minimal access cranial suspension (MACS) lift with autologous fat grafting from the abdomen. Given that the patient received the Moderna SARS-CoV-2 vaccine one week after surgery, we hypothesize that the former predisposed her to tissue ischemia leading to fat necrosis. Histological findings after biopsy were consistent with fat necrosis, which included marked dermal fibrosis with areas of focal fat necrosis, lipophages, multinucleated giant cells, and siderophages. It is our hope that documenting this rare development in literature may serve as encouragement for adverse effect reporting after the SARS-CoV-2 vaccine administration and may boost inspection and monitoring of other health consequences by regulating agencies.

Loss of anti-spike antibodies following mRNA vaccination for COVID-19 among patients with multiple myeloma. BACKGROUND: Multiple myeloma (MM) patients have variable responses to mRNA vaccination to COVID-19. Little is known regarding their vaccine-induced antibody levels over time. METHODS: We monitored spike IgG antibody levels over 24â€‰weeks among a subset of 18â€‰MM patients who showed a full response after two mRNA vaccinations. RESULTS: MM patients had a more rapid decline in antibody levels as compared to eight healthy controls, with power law half-lives of 72â€‰days (vs. 107â€‰days) and exponential half-lives of 37â€‰days (vs. 51â€‰days). The patients with longer SARS-CoV-2 antibody half-lives were more likely to have undetectable monoclonal protein than those with shorter half-lives, suggesting better disease control may correlate with longer duration of vaccine-induced antibodies. Regardless, by 16â€‰weeks post-second dose of mRNA vaccination, the majority of patients had antibody levels below 250 binding arbitrary units per milliliter, which would be unlikely to contribute to preventing COVID-19. CONCLUSIONS: Thus, even MM patients who respond adequately to vaccination are likely to require more frequent booster doses than the general population.

[Efficacy and safety of inactivated novel coronavirus vaccine inoculation in patients with chronic hepatitis B]. Objective: To explore the safety of inactivated novel coronavirus vaccine inoculation and the fluctuating neutralizing antibody in patients with chronic hepatitis B (CHB). Methods: Retrospective and prospective epidemiological research methods were employed. 153 CHB patients who visited the Department of Infectious Diseases at the First Hospital of Shanxi Medical University from September 2021 to February 2022 were selected as the research subjects. Information on vaccination-related adverse reactions was collected. Colloidal gold immunochromatography was used to identify neutralizing antibodies in the body after 3-6 months of vaccination. Statistical analysis was performed using the Ï‡(2)-test or Fisher's exact test. Results: The positive rates of neutralizing antibodies after inactivated novel coronavirus vaccine inoculation in 153 patients with CHB were 45.50%, 44.70%, 40.00% and 16.20%, respectively, at 3, 4, 5, and 6 months. The neutralizing antibody concentrations were 10.00 (2.95, 30.01) U/ml, 6.08 (3.41, 24.50) U/ml, 5.90 (3.93, 14.68) U/ml, and 1.25 (0.92, 3.75) U/ml, respectively. The difference was not statistically significant (P>0.05) when the neutralizing antibody positivity rates in hepatitis B virus (HBV) DNA-negative and positive patients and HBeAg-negative and positive patients at different time points were compared. The overall incidence of adverse reactions following vaccination was 18.30%. Pain at the site of inoculation and fatigue were the main presentations, and no serious adverse reactions occurred. Conclusion: CHB patients, when inoculated with an inactivated novel coronavirus vaccine, can produce neutralizing antibodies, which can stay at certain levels for 3, 4, and 5 months. However, the neutralizing antibody level gradually decreases over time, and the decrease is remarkable at 6 months. So, it is recommended to boost vaccinations at an appropriate time. Additionally, the results of the study suggest that HBV

replication status has little effect on the production of neutralizing antibodies in CHB patients with relatively stable liver function, which means the inactivated novel coronavirus vaccine has a good safety profile.
Cutaneous reactions after COVID-19 vaccination in Turkey: Questions and answers.
Aseptic pleocytosis eight days after the first dose of a vector-based SARS-CoV-2 vaccine. OBJECTIVES: Vaccination against SARS-CoV-2 is considered beneficial by the majority, but side effects occur in some cases. RESULTS AND CONCLUSIONS: We report on a 28-year-old female who developed fever within 3 days of an initial dose with a vector-based SARS-CoV-2 vaccine. Eight days after vaccination, she developed paresthesias and dysesthesias of all four limbs. Cerebral imaging showed two non-specific and non-enhancing lesions in the left white matter. Cerebrospinal fluid (CSF) studies revealed pleocytosis of 82/3 cells. Examination for multiple sclerosis, neuromyelitis optica, acute, demyelinating encephalomyelitis, and Guillain-Barre syndrome was negative. She received steroids, which resulted in complete resolution of the neurological abnormalities. In summary, SARS-CoV-2 vaccination can occasionally be complicated by an inflammatory CSF syndrome, which resolves on administration of steroids.
[Monitoring the safety of drugs and COVID-19 vaccines by the French Pharmacovigilance Centers during the pandemic: a win-win bet with Health Authorities!]. The pandemic subsequent to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus resulted, for the French institutional pharmacovigilance, in a "health crisis" in 2 phases: the coronavirus disease 2019Â - Â "COVID-19" phase during which the missions of the Regional Pharmacovigilance Centres (RPVC) were to detect a possible impact of drugs on this disease, as whether existed a possible aggravating role of certain drugs, or the safety profile of drugs used for the management of COVID-19 could evolve. The second phase followed the availability of COVID-19 vaccines, during which the RPVCs' missions were to detect as early as possible any new serious adverse effect, source of a potential signal that would modify the benefit/risk ratio of a vaccine and require the implementation of health safety measures. During these two periods, signal detection remained the core business of the RPVCs. The RPVCs had to organize themselves to handle an historical surge of declarations and requests for advice, whereas the RPVCs in charge of monitoring vaccines had to deal with an extraordinary dense activity over a long period of time, in order to produce in real time and on a weekly basis, a summary of all the declarations and an analysis of safety signals. The national organization put in place made it possible to meet the challenge of real-time pharmacovigilance monitoring of 4 vaccines with conditional marketing authorizations. Short-circuit efficient exchanges with the French Regional Pharmacovigilance Centres Network was paramount for the French National Agency for medicines and health products (Agence nationale de sÃ©curitÃ© du mÃ©dicament et des produits de santÃ©) to develop an optimal collaborative partnership. The RPVC network has shown agility and flexibility, has been able to adapt swiftly and demonstrated its effectiveness in the early detection of safety signals. This crisis confirmed the superiority of manual/human signal detection as the most effective and powerful tool to date, to rapidly detect a new adverse drug reaction and enable to elaborate rapid measures of risk reduction. In order to maintain the performance of French RPVCs in signal detection and to monitor all drugs as they should and as expected by our fellow citizens, a new funding model correcting the inadequacy of RPVCs' expertise resources in relation to the volume of reports should be considered.
Functional neurological disorders after COVID-19 and SARS-CoV-2 vaccines: a national multicentre observational study.
Risk of COVID-19 among unvaccinated and vaccinated patients with systemic lupus erythematosus: a general population study. OBJECTIVE: To compare the risk of SARS-CoV-2 infection and its related severe sequelae between patients with systemic lupus erythematosus (SLE) and the general

population according to COVID-19 vaccination status. METHODS: We performed cohort studies using data from The Health Improvement Network to compare the risks of SARS-CoV-2 infection and severe sequelae between patients with SLE and the general population. Individuals aged 18-90 years with no previously documented SARS-CoV-2 infection were included. We estimated the incidence rates and HRs of SARS-CoV-2 infection and severe sequelae between patients with SLE and the general population according to COVID-19 vaccination status using exposure score overlap weighted Cox proportional hazards model. RESULTS: We identified 3245 patients with SLE and 1â€‰755â€‰034 non-SLE individuals from the unvaccinated cohort. The rates of SARS-CoV-2 infection, COVID-19 hospitalisation, COVID-19 death and combined severe outcomes per 1000 person-months were 10.95, 3.21, 1.16 and 3.86 among patients with SLE, and 8.50, 1.77, 0.53 and 2.18 among general population, respectively. The corresponding adjusted HRs were 1.28 (95% CI: 1.03 to 1.59), 1.82 (95% CI: 1.21 to 2.74), 2.16 (95% CI: 1.00 to 4.79) and 1.78 (95% CI: 1.21 to 2.61). However, no statistically significant differences were observed between vaccinated patients with SLE and vaccinated general population over 9â€‰months of follow-up. CONCLUSION: While unvaccinated patients with SLE were at higher risk of SARS-CoV-2 infection and its severe sequelae than the general population, no such difference was observed among vaccinated population. The findings indicate that COVID-19 vaccination provides an adequate protection to most patients with SLE from COVID-19 breakthrough infection and its severe sequelae.

IgG4-related Disease Emerging after COVID-19 mRNA Vaccination. A 78-year-old Japanese woman with no history of rheumatic disease received 2 doses of the BNT162b2 COVID-19 mRNA vaccine. Two weeks later, she noticed bilateral swelling in the submandibular region. Blood tests showed hyper-immunoglobulin (Ig)G4emia, and (18)F-fluorodeoxyglucose (FDG)-positron emission tomography (PET) revealed the strong accumulation of FDG in the enlarged pancreas. She was diagnosed with IgG4-related disease (IgG4-RD) according to the American College of Rheumatology (ACR)/the European League Against Rheumatism (EULAR) classification criteria. Treatment was started with prednisolone at 30 mg/day, and the organ enlargement improved. We herein report a case of IgG4-RD that may have been associated with an mRNA vaccine.

COVID-19 Vaccination and the Development of Autoimmune Diseases.

Long post-COVID-vaccination syndrome manifesting as temperature-sensitive myalgia and hyper-CKemia.

Safety and effectiveness of the booster dose of mRNA COVID-19 vaccines in people with multiple sclerosis: A monocentric experience. BACKGROUND: Long-term data on the effectiveness and safety of the booster dose of anti-SARS-CoV-2 vaccines in people affected by multiple sclerosis (pwMS) are lacking, hence a retrospective monocentric study exploring these issues was undertaken. MATERIALS AND METHODS: PwMS who had received the booster dose of anti-COVID19 mRNA vaccines (either Comirnaty or Spikevax) according to the national regulation were included. The occurrence of adverse events or disease reactivation and SARS-CoV-2 infection were recorded up to last follow-up. Factors predictive of COVID-19 were explored using logistic regression analyses. A two-tailed p-value <0.05 was considered significant. RESULTS: One hundred and fourteen pwMS were included: 80 females (70%); median age at the booster dose 42 years (range 21 - 73); 106/114 patients (93%) were receiving a disease-modifying treatment at vaccination. The median follow-up after the booster dose was 6 (range 2 - 7) months. Adverse events were experienced in 58% of the patients, being mild to moderate in most cases; 4 reactivations of MS were observed, two of which occurring within 4 weeks after the booster. SARS-CoV-2 infection was reported in 24/114 (21%) cases, occurring a median of 74 days (5-162) after the booster dose and requiring hospitalisation in 2 patients. Six cases received direct antiviral drugs. Age at vaccination and time between the primary vaccination cycle and the booster dose were independently and inversely associated with the risk of

COVID-19 (HR 0.95 and 0.98, respectively). CONCLUSIONS: The administration of the booster dose in pwMS showed an overall good safety profile and protected 79% of the patients from SARS-CoV-2 infection. The observed association between the risk of infection after the booster dose and both younger age at vaccination and shorter interval period to the booster dose suggest that unobserved confounders, possibly including behavioural and social factors, play a relevant role in determining the individual propensity to get infected with COVID-19.

Immunogenicity and safety of a recombinant adenovirus type-5 COVID-19 vaccine in adults: Data from a randomised, double-blind, placebo-controlled, single-dose, phase 3 trial in Russia. BACKGROUND: To determine the immunogenicity, efficacy, reactogenicity, and safety of a single dose of recombinant adenovirus type-5 vectored COVID-19 vaccine (Ad5-nCoV, 5 Ã— 1010 viral particles per 0.5 mL dose), we conducted a single-dose, randomised, double-blind, placebo-controlled, parallel group (3:1 Ad5-nCoV:placebo), phase 3 trial (Prometheus). METHODS: From 11-September-2020 to 05-May-2021, across six sites in the Russian Federation, 496 participants were injected with either placebo or Ad5-nCoV expressing the full-length spike (S) protein from the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). RESULTS: Seroconversion (the primary endpoint) rates of 78.5% (95% CI: 73.9; 82.6) against receptor binding domain (RBD), 90.6% (95% CI: 87.2; 93.4) against S protein and 59.0% (95% CI: 53.3; 64.6) seroconversion of neutralising antibodies against SARS-CoV-2 at 28 days post-vaccination were observed. Geometric mean titres (GMTs) were also elevated for antibodies against the RBD (405 [95% CI: 366; 449]) and S protein (677 [95% CI: 608; 753]) compared to the GMT of neutralising antibodies against SARS-CoV-2 (16.7 [95% CI: 15.3; 18.3]). Using an IFN-Î³ ELISpot assay after stimulating the cells with recombinant S protein ectodomain we showed that the Ad5-nCoV vaccine induced the most robust cellular immune response on Days 14 and 28. Up to Day 28, the primary and all secondary endpoints of the Ad5-nCoV vaccine were statistically significant compared with the placebo (Ñ€<0.001). Systemic reactions were reported in 113 of 496 (22.8%) participants (Ad5-nCoV, 26.9%; Placebo, 10.5%), and local reactions were reported in 108 (21.8%) participants (Ad5-nCoV, 28.5%; Placebo, 1.6%). These were generally mild and resolved within 7 days after vaccination. Of the six serious adverse events reported, none of the events were vaccine related. There were no deaths or premature withdrawals. CONCLUSION: A single-dose of Ad5-nCoV vaccine induced a marked specific humoral and cellular immune response with a favourable safety profile. TRIAL REGISTRATION: Trial registration: ClinicalTrials.gov: NCT04540419.

Scleritis and Episcleritis following Coronavirus Disease (COVID-19) Vaccination. INTRODUCTION: Coronavirus disease (COVID-19) vaccines have been reported to have ocular side effects including scleritis and episcleritis. PURPOSE: To report scleritis and episcleritis within a month following administration of COVID-19 vaccine. METHODS: Retrospective case series. RESULTS: 15 eyes of 12 consecutive patients with scleritis and episcleritis from March 2021 to September 2021 were included. The mean time of onset of symptoms in patients with scleritis was 15.7Â days (range, 4-30) and for episcleritis it was 13.2Â days (range 2-30). Patients received COVISHIELDâ„¢ (10 patients) and COVAXINâ„¢ (2 patients). Five patients had denovo inflammation and seven had recurrent inflammation. Episcleritis patients were treated with topical steroids and systemic COX2 inhibitors while patients with scleritis were treated with topical steroids/oral steroids/antiviral medications depending on the aetiology. CONCLUSION: Scleritis and episcleritis following COVID-19 vaccination are milder and do not require intensive immunosuppression except in rare cases.

Axillary Lymphadenopathy After a COVID-19 Vaccine Booster Dose: Time to Resolution on Ultrasound Follow-Up and Associated Factors. BACKGROUND. Because administration of booster doses of COVID-19 vaccines is ongoing, radiologists are continuing to encounter COVID-19 vaccine-related axillary lymphadenopathy on imaging. OBJECTIVE. The purposes of this study were to assess time to resolution of COVID-19 vaccine-related axillary lymphadenopathy identified on breast ultrasound

after administration of a booster dose and to assess factors potentially associated with time to resolution. METHODS. This retrospective single-institution study included 54 patients (mean age, 57 years) with unilateral axillary lymphadenopathy ipsilateral to the site of injection of a booster dose of messenger RNA COVID-19 vaccine visualized on ultrasound (whether an initial breast imaging examination or follow-up to prior screening or diagnostic breast imaging) performed between September 1, 2021, and December 31, 2022, and who underwent follow-up ultrasound examinations until resolution of lymphadenopathy. Patient information was extracted from the EMR. Univariable and multivariable linear regression analyses were used to identify predictors of time to resolution. Time to resolution was compared with that in a previously described sample of 64 patients from the study institution that was used to evaluate time to resolution of axillary lymphadenopathy after the initial vaccination series. RESULTS. Six of the 54 patients had a history of breast cancer, and two had symptoms related to axillary lymphadenopathy (axillary pain in both patients). Among the 54 initial ultrasound examinations showing lymphadenopathy, 33 were screening examinations and 21 were diagnostic examinations. Lymphadenopathy had resolved a mean of 102 Â± 56 (SD) days after administration of the booster dose and 84 Â± 49 days after the initial ultrasound showing lymphadenopathy. Age, vaccine booster type (Moderna vs Pfizer-BioNTech), and history of breast cancer were not significantly associated with time to resolution in univariable or multivariable analyses (all $p > .05$). Time to resolution after administration of a booster dose was significantly shorter than time to resolution after administration of the first dose in the initial series (mean, 129 Â± 37 days) ($p = .01$). CONCLUSION. Axillary lymphadenopathy after administration of a COVID-19 vaccine booster dose has a mean time to resolution of 102 days, shorter than the time to resolution after the initial vaccination series. CLINICAL IMPACT. The time to resolution after administration of a booster dose supports the current recommendation for a follow-up interval of at least 12 weeks when vaccine-related lymphadenopathy is suspected.

COVID-19 infection-associated platelet and neutrophil activation is blunted by previous anti-SARS-CoV-2 vaccination. The effectiveness of vaccination against SARS-CoV-2 in preventing COVID-19 or in reducing severe illness in subjects hospitalized for COVID-19 despite vaccination has been unequivocally shown. However, no studies so far have assessed if subjects who get COVID-19 despite vaccination are protected from SARS-CoV-2-induced platelet, neutrophil and endothelial activation, biomarkers associated with thrombosis and worse outcome. In this pilot study, we show that previous vaccination blunts COVID-19-associated platelet activation, assessed by circulating platelet-derived microvesicles and soluble P-selectin, and neutrophil activation, assessed by circulating neutrophil extracellular trap (NET) biomarkers and matrix metalloproteinase-9, and reduces COVID-19-associated thrombotic events, hospitalization in intensive-care units and death.

Real-world data on the incidence and risk of Guillain-BarrÃ© syndrome following SARS-CoV-2 vaccination: a prospective surveillance study. Increasing evidence suggests an association between SARS-CoV-2 vaccines and Guillain-BarrÃ© syndrome (GBS). Nevertheless, little is understood about the contributing risk factors and clinical characteristics of GBS post SARS-CoV-2 vaccination. In this prospective surveillance study of 38,828,691 SARS-CoV-2 vaccine doses administered from February 2021 to March 2022 in the Gyeonggi Province, South Korea, 55 cases of GBS were reported post vaccination. We estimated the incidence rate of GBS per million doses and the incidence rate ratio for the vaccine dose, mechanism, age, and sex. Additionally, we compared the clinical characteristics of GBS following mRNA-based and viral vector-based vaccinations. The overall incidence of GBS following SARS-CoV-2 vaccination was 1.42 per million doses. Viral vector-based vaccines were associated with a higher risk of GBS. Men were more likely to develop GBS than women. The third dose of vaccine was associated with a lower risk of developing GBS. Classic sensorimotor and pure motor subtypes were the predominant clinical subtypes, and demyelinating

type was the predominant electrodiagnostic subtype. The initial dose of viral-vector based vaccine and later doses of mRNA-based vaccine were associated with GBS, respectively. GBS following SARS-CoV-2 vaccination may not be clinically distinct. However, physicians should pay close attention to the classic presentation of GBS in men receiving an initial dose of viral vector-based SARS-CoV-2 vaccines.

Prolonged angioedema after Pfizer-BioNTech COVID-19 vaccine. This case reports a woman in her 40s with a history of allergic reaction to shellfish and iodine who presented with tongue angioedema, difficulty breathing and chest tightness after receiving the first dose of the Pfizer-BioNTech (BNT162b2) COVID-19 vaccine. Her angioedema remained for 10 days post-exposure to the vaccine, requiring 3â€‰days of epinephrine infusion. She was discharged with advice to avoid further mRNA vaccines. This case highlights the increasing awareness needed of polyethylene glycol (PEG) allergy and the protracted nature of her reaction. A firm conclusion cannot be reached based on a single case report. More research is needed to understand whether there is a causal relationship between the BNT162b2 vaccine and PEG allergy. Awareness regarding PEG allergy and the complexities associated with it is important and needs to be raised due to its prevalent use in diverse industries.

SARS-CoV-2 vaccination in liver transplant recipients: We still haven't found what we are looking for.

COVID-19 Vaccines for Children: An Update. The coronavirus disease 2019 (COVID-19) pandemic has had a large effect on the pediatric population, with 16,000,000 cases and counting. Currently, there are two messenger RNA (mRNA)-based and a single adjuvanted, protein-based COVID-19 vaccine approved for use in children and adolescents in the United States. Multiple studies have highlighted that these vaccines are safe for use in children and adolescents and are effective at reducing COVID-19 infection and complications. Given the risk of the SARS-CoV-2 virus to the pediatric population and ongoing global viral transmission, it is advised that providers emphasize the value of COVID-19 vaccination for children and adolescents. [Pediatr Ann. 2023;52(3):e83-e88.].

Rituximab for COVID-19 Vaccine-Associated Pemphigus Vulgaris.

Subacute cutaneous lupus erythematosus induced by Pfizer COVID-19 vaccine.

Subacute cutaneous lupus erythematosus after COVID-19 vaccine.

Rising CA-125 (Cancer Antigen 125) Levels: Cancer Recurrence or a Vaccine Reaction? Cancer antigen 125 (CA-125) is a transmembrane glycoprotein, and it is known to be an essential biomarker in detecting treatment response and recurrence of ovarian cancer. It may also be used in monitoring colorectal cancer. It tends to rise in states of inflammation. Recent studies have demonstrated a temporary rise in CA-125 levels and other cancer biomarkers in patients suffering from coronavirus disease 2019 (COVID-19) infection.Â However, in the following case report, we hope to shed light on a possible association between CA-125 levels and the COVID-19 mRNA vaccine. We present the case of a 79-year-old woman with moderately differentiated adenocarcinoma of the right adnexa, who had a transient increase in CA-125 levels after a period, during which she underwent treatment for COVID-19 infection and received the first dose of COVID-19 mRNA (Pfizer-BioNTech) vaccine with no evidence of disease progression on imaging.

Cerebral Sinus Thrombosis and Immune Thrombocytopenia Post COVID-19 Vaccination: A Case Report and Narrative Review. Vaccine-induced immune thrombocytopenia and thrombosis (VITT) following the adenoviral vector COVID-19 vaccine is a rare adverse event. Although the risk of VITT following the COVID-19 vaccine appears to be low, early diagnosis and management can be lifesaving. We present a case of VITT in a young female who presented with persistent headaches and fevers followed by anisocoria and right-sided hemiplegia. Initial imaging was unremarkable, and labs showed thrombocytopenia and elevated d-dimers. Repeat imaging revealed thrombosis in the left transverse and superior sagittal sinuses,Â and she was diagnosed with VITT. She received combined treatment

with intravenous immunoglobulins and systemic anticoagulation, resulting in an increased platelet count and resolution of her neurological symptoms.

Incidence, features, and outcome of disease relapse after COVID-19 vaccination in patients with idiopathic inflammatory myopathies. INTRODUCTION/AIMS: Vaccination against coronavirus disease 2019 (COVID-19) is relatively safe in patients with idiopathic inflammatory myopathies (IIM); however, myositis flares following vaccination have been poorly studied. We aimed to evaluate the frequency, features, and outcomes of disease relapses in patients with IIM following COVID-19 vaccination. METHODS: A cohort of 176 IIM patients were interviewed after the third wave of the COVID-19 pandemic and followed prospectively. Relapses were determined using the disease state criteria and the outcome of the flares with myositis response criteria, calculating the total improvement score (TIS). RESULTS: A total of 146 (82.9%) patients received a vaccination, 17/146 (11.6%) patients had a relapse within 3Â mo, and 13/146 (8.9%) patients within 1Â mo. The relapse rate of unvaccinated patients was 3.3%. Three months after the post-vaccination relapses, 70.6% of the patients (12/17) achieved an improvement of disease activity (average TIS score: 30â€‰Â±â€‰15.81; seven minor, five moderate, and zero major improvements). Six months after flares improvement was detected in 15/17(88.2%) of relapsed patients (average TIS score: 43.1â€‰Â±â€‰19.53; 3 minimal, 8 moderate, and 4 major). Forward stepwise logistic regression analysis revealed that the active state of myositis at the time of injection (pâ€‰<â€‰.0001; odds ratio, 33; confidence interval, 9-120) was significantly associated with the occurrence of a relapse. DISCUSSION: A minority of the vaccinated IIM patients had a confirmed disease flare after COVID-19 vaccination and the majority of the relapses improved after individualized treatment. An active disease state at the time of vaccination probably contributes to the increased risk of a post vaccination myositis flare.

Pfizer-BioNTech vaccine induces the production of cross-reactive antibodies against Trypanosoma cruzi proteins: A preliminary study. OBJECTIVE: To evaluate the presence of cross-reactivity by anti-severe acute respiratory syndrome coronavirus 2 antibodies induced by the Pfizer-BioNTech vaccine against Trypanosoma cruzi proteins in a screening test. METHODS: Forty-three serum samples were obtained from personnel at the Hospital General Naval de Alta Especialidad in Mexico City who received one or two doses of the vaccine and were tested for T. cruzi infection using four tests: two 'in house' enzyme-linked immunosorbent assays (ELISAs), a commercial ELISA diagnostic kit and an immunoblot test. RESULTS: IgG antibodies against the T. cruzi proteins were present in the serum of unvaccinated subjects and subjects who had received one or two doses of the vaccine. The positivity of the samples against T. cruzi was ruled out by means of a Western Blot assay, where all samples were negative for T. cruzi. CONCLUSION: The data suggest that people convalescing from coronavirus disease 2019 and those who received the Pfizer-BioNTech vaccine exhibit cross-reactive antibodies against T. cruzi antigens in ELISA assays.

Higher plasma levels of thymosin-Î±1 are associated with a lower waning of humoral response after COVID-19 vaccination: an eight months follow-up study in a nursing home. BACKGROUND: Older people achieve lower levels of antibody titers than younger populations after Covid-19 vaccination and show a marked waning humoral immunity over time, likely due to the senescence of the immune system. Nevertheless, age-related predictive factors of the waning humoral immune response to the vaccine have been scarcely explored. In a cohort of residents and healthcare workers from a nursing home that had received two doses of the BNT162b2 vaccine, we measured specific anti-S antibodies one (T1), four (T4), and eight (T8) months after receiving the second dose. Thymic-related functional markers, including thymic output, relative telomere length, and plasma thymosin-Î±1 levels, as well as immune cellular subsets, and biochemical and inflammatory biomarkers, were determined at T1, and tested for their associations with the magnitude of the vaccine response (T1) and the durability of

such response both, at the short- (T1-T4) and the long-term (T1-T8). We aimed to identify age-related factors potentially associated with the magnitude and persistence of specific anti-S immunoglobulin G (IgG)-antibodies after COVID-19 vaccination in older people. RESULTS: Participants (100% men, nâ€‰=â€‰98), were subdivided into three groups: young (<â€‰50â€‰years-old), middle-age (50-65â€‰years-old), and older (â‰¥65â€‰years-old). Older participants achieved lower antibody titers at T1 and experienced higher decreases in both the short- and long-term. In the entire cohort, while the magnitude of the initial response was mainly associated with the levels of homocysteine [Î² (95% CI); -â€‰0.155 (-â€‰0.241 to -â€‰0.068); pâ€‰=â€‰0.001], the durability of such response at both, the short-term and the long-term were predicted by the levels of thymosin-Î±1 [-â€‰0.168 (-â€‰0.305 to -â€‰0.031); pâ€‰=â€‰0.017, andâ€‰-â€‰0.123 (-â€‰0.212 to -â€‰0.034); pâ€‰=â€‰0.008, respectively]. CONCLUSIONS: Higher plasma levels of thymosin-Î±1 were associated with a lower waning of anti-S IgG antibodies along the time. Our results suggest that plasma levels of thymosin-Î±1 could be used as a biomarker for predicting the durability of the responses after COVID-19 vaccination, possibly allowing to personalize the administration of vaccine boosters.

HLA typing of patients who developed subacute thyroiditis and Graves' disease after SARS-CoV-2 vaccination: a case report. BACKGROUND: Cases of subacute thyroiditis (SAT) after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination have been reported. A human leukocyte antigen (HLA) allele, HLA-B*35, appears to be involved in the pathogenesis of SAT. CASE PRESENTATION: We conducted HLA typing of one patient with SAT and another with both SAT and Graves' disease (GD), which developed after SARS-CoV-2 vaccination. Patient 1, a 58-year-old Japanese man, was inoculated with a SARS-CoV-2 vaccine (BNT162b2; Pfizer, New York, NY, USA). He developed fever (38â€‰Â°C), cervical pain, palpitations, and fatigue on day 10 after vaccination. Blood chemistry tests revealed thyrotoxicosis and elevated serum C-reactive protein (CRP) and slightly increased serum antithyroid-stimulating antibody (TSAb) levels. Thyroid ultrasonography revealed the characteristic findings of SAT. Patient 2, a 36-year-old Japanese woman, was inoculated twice with a SARS-CoV-2 vaccine (mRNA-1273; Moderna, Cambridge, MA, USA). She developed fever (37.8â€‰Â°C) and thyroid gland pain on day 3 after the second vaccination. Blood chemistry tests revealed thyrotoxicosis and elevated serum CRP, TSAb, and antithyroid-stimulating hormone receptor antibody levels. Fever and thyroid gland pain persisted. Thyroid ultrasonography revealed the characteristic findings of SAT (i.e., slight swelling and a focal hypoechoic area with decreased blood flow). Prednisolone treatment was effective for SAT. However, thyrotoxicosis causing palpitations relapsed thereafter, for which thyroid scintigraphy with (99m)technetium pertechnetate was conducted, and the patient was diagnosed with GD. Thiamazole treatment was then initiated, which led to improvement in symptoms. CONCLUSION: HLA typing revealed that both patients had the HLA-B*35:01, -C*04:01, and -DPB1*05:01 alleles. Only patient 2 had the HLA-DRB1*11:01 and HLA-DQB1*03:01 alleles. The HLA-B*35:01 and HLA-C*04:01 alleles appeared to be involved in the pathogenesis of SAT after SARS-CoV-2 vaccination, and the HLA-DRB1*11:01 and HLA-DQB1*03:01 alleles were speculated to be involved in the postvaccination pathogenesis of GD.

Estimating immunity with mathematical models for SARS-CoV-2 after COVID-19 vaccination. Tools that can be used to estimate antibody waning following COVID-19 vaccinations can facilitate an understanding of the current immune status of the population. In this study, a two-compartment-based mathematical model is formulated to describe the dynamics of the anti-SARS-CoV-2 antibody in healthy adults using serially measured waning antibody concentration data obtained in a prospective cohort study of 673 healthcare providers vaccinated with two doses of BNT162b2 vaccine. The datasets of 165 healthcare providers and 292 elderly patients with or without hemodialysis were used for external validation. Internal validation of the model demonstrated 97.0%

accuracy, and external validation of the datasets of healthcare workers, hemodialysis patients, and nondialysis patients demonstrated 98.2%, 83.3%, and 83.8% accuracy, respectively. The internal and external validations demonstrated that this model also fits the data of various populations with or without underlying illnesses. Furthermore, using this model, we developed a smart device application that can rapidly calculate the timing of negative seroconversion.
Vaccine inequity-induced COVID-19 dilemma: Time to sober up. The ongoing coronavirus disease 2019 pandemic has not only posed a serious threat to public health but has also imposed a heavy burden on medical systems and global economies. To combat this challenge, unprecedented efforts have been made by governments and the scientific community in the development and production of vaccines. As a result, less than a year elapsed between identification of a novel pathogen sequence and large-scale vaccine rollout. However, much of the focus and debate has increasingly shifted to the looming risk of global vaccine inequity and whether we could do more to modify this risk. In this paper, we first outline the scope of inequitable vaccine distribution and identify its truly catastrophic consequences. Then, from the perspectives of political will, free markets and profit-driven enterprises based on patent and intellectual property protection, we analyze in-depth the root causes why this phenomenon is so difficult to combat. Apart from these, some specific and crucial solutions that should be undertaken in the long term were also put forward, in order to provide a useful reference for the authorities, stakeholders and researchers involved in addressing this global crisis and the next one.
Successful Management of Erythema Dyschromicum Perstans Following Topical Ruxolitinib Therapy. Erythema dyschromicum perstans (EDP) is a rare cutaneous disorder in which patients develop gray or blue-brown macules or patches on their bodies.1 This condition does not appear to have a gender or age predilection. The diagnosis of EDP is essentially clinical, with histopathology findings being nonspecific. To date, treatment for EDP varies. The use of several therapies, including dapsone, clofazimine, retinoid A, tacrolimus, and ultraviolet light have been reported but with minimal effectiveness.5 We report a case of EDP occurring in a patient following the COVID-19 vaccine that was given topical ruxolitinib with success in treatment. To our knowledge, this is the first report of the use of topical ruxolitinib in treatment of EDP with successful management. J Drugs Dermatol. 2022;22(3): doi:10.36849/JDD.7156.
Letter by Donzelli Regarding Article, "Risk of Myocarditis After Sequential Doses of COVID-19 Vaccine and SARS-CoV-2 Infection by Age and Sex".
Risk of Incident Thromboembolic and Ischemic Events After COVID-19 Vaccination Compared With SARS-CoV-2 Infection.
Response by Mills et al Regarding Article, "Risk of Myocarditis After Sequential Doses of COVID-19 Vaccine and SARS-CoV-2 Infection by Age and Sex".
Susac syndrome following COVID-19 vaccination: a case-based review. COVID-19 vaccine circulation approval was a turning point for the coronavirus pandemic. The current approved COVID-19 vaccines, including messenger ribonucleic acid (mRNA)-based and adenovirus vector-based vaccines, were shown to significantly reduce the disease mortality and severity, and its adverse reactions are mainly mild ones. However, few cases of autoimmune conditions, both flare-ups and new-onset, were described in association with these vaccines. Susac vasculitis (SaS) is a rare autoimmune disease characterized by the clinical triad of encephalopathy, visual disturbances, and sensorineural hearing loss. Its pathogenesis is still not fully understood but is believed to be related to autoimmune processes, including autoantibodies to anti-endothelial cells and cellular immune processes that lead to microvascular damage and, consequently, micro-occlusions of the cerebral, inner ear, and retinal vessels. It has been previously described following vaccination and, most recently, few cases following coronavirus vaccines. We here describe a case of a previously healthy

49-year-old man diagnosed with SaS 5 days following the first dose of the BNT162b2 COVID-19 vaccine.
Short-Lived Antibody-Mediated Saliva Immunity against SARS-CoV-2 after Vaccination. Knowledge about the effect of vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) on immunity reflected in the saliva is sparse. We examined the antibody response in saliva compared to that in serum 2 and 6â€‰months after the first vaccination with the BNT162b2 vaccine. Four hundred fifty-nine health care professionals were included in a prospective observational study measuring antibody levels in saliva and corresponding serum samples at 2 and 6â€‰months after BNT162b2 vaccination. Vaccinated, previously SARS-CoV-2-infected individuals (hybrid immunity) had higher IgG levels in saliva at 2â€‰months than vaccinated, infection-naive individuals (Pâ€‰<â€‰0.001). After 6â€‰months, saliva IgG levels declined in both groups (Pâ€‰<â€‰0.001), with no difference between groups (Pâ€‰=â€‰0.37). Furthermore, serum IgG levels declined from 2 to 6â€‰months in both groups (Pâ€‰<â€‰0.001). IgG antibodies in saliva and serum correlated in individuals with hybrid immunity at 2 and 6â€‰months (Ï•â€‰=â€‰0.58, Pâ€‰=â€‰0.001, and Ï•â€‰=â€‰0.53, Pâ€‰=â€‰0.052, respectively). In vaccinated, infection-naive individuals, a correlation was observed at 2â€‰months (Ï•â€‰=â€‰0.42, Pâ€‰<â€‰0.001) but not after 6â€‰months (Ï•â€‰=â€‰0.14, Pâ€‰=â€‰0.055). IgA and IgM antibodies were hardly detectable in saliva at any time point, regardless of previous infection. In serum, IgA was detected at 2â€‰months in previously infected individuals. BNT162b2 vaccination induced a detectable IgG anti-SARS-CoV-2 RBD response in saliva at both 2 and 6â€‰months after vaccination, being more prominent in previously infected than infection-naive individuals. However, a significant decrease in salivary IgG was observed after 6â€‰months, suggesting a rapid decline in antibody-mediated saliva immunity against SARS-CoV-2, after both infection and systemic vaccination. IMPORTANCE Knowledge about the persistence of salivary immunity after SARS-CoV-2 vaccination is limited, and information on this topic could prove important for vaccine strategy and development. We hypothesized that salivary immunity would wane rapidly after vaccination. We measured anti-SARS-CoV-2 IgG, IgA, and IgM concentrations in saliva and serum in both previously infected and infection-naive individuals, 2 and 6â€‰months after first vaccination with BNT162b2, in 459 hospital employees from Copenhagen University Hospital. We observed that IgG was the primary salivary antibody 2â€‰months after vaccination in both previously infected and infection-naive individuals, but dropped significantly after 6â€‰months. Neither IgA nor IgM was detectable in saliva at either time point. Findings indicate that salivary immunity against SARS-CoV-2 rapidly declines following vaccination in both previously infected and infection-naive individuals. We believe this study shines a light on the workings of salivary immunity after SARS-CoV-2 infection, which could prove relevant for vaccine development.
Seroconversion following a booster dose of COVID-19 vaccine in liver transplant recipients: a systematic review and meta-analysis. INTRODUCTION: Although it is well established that 2 doses of COVIDâ€‘19 vaccines are associated with reduced immune responses in liver transplant recipients (LTRs), studies regarding their immunogenicity and tolerability after a booster dose are limited. OBJECTIVES: We aimed to review the available literature data regarding antibody responses and safety of the third dose of COVIDâ€‘19 vaccines in LTRs. METHODS: We searched PubMed and Google Scholar for eligible studies. The primary outcome was to compare the rates of seroconversion after the second and third dose of COVIDâ€‘19 vaccine in LTRs. This metaâ€‘analysis was performed using a generalized linear mixed model and the Clopper and Pearson method was employed to calculate the 2â€‘sided CIs. RESULTS: Six prospective studies involving 596 LTRs met the inclusion criteria. The pooled rate of antibody response before the third dose was 71% (95% CI, 56%-83%; heterogeneity, I2 = 90%; P <0.001), while after the third dose it was 94% (95% CI, 91%-96%; heterogeneity, I2 = 17%; P

= 0.31). There was no difference in antibody responses after the third dose in relation to the use of calcineurin inhibitors (P = 0.44) or mammalian target of rapamycin inhibitors (P = 0.33), while the pooled rate of antibody responses in the patients on mycophenolate mofetil (MMF) was 88% (95% CI, 83%-92%; heterogeneity, I2 = 0%; P = 0.57). It was significantly lower (P <0.001), as compared with those on MMFâ€'free immunosuppression (pooled rate, 97%; 95% CI, 95%-98%; heterogeneity, I2 = 30%; P = 0.22). No safety concerns were reported for the booster dose. CONCLUSIONS: Our metaâ€'analysis demonstrated that the third dose of COVIDâ€'19 vaccines induced adequate humoral and cellular immune responses in LTRs, while MMF remained a negative predictor of immunologic responses.

Case report of new-onset ulcerative colitis after MVC-COVI1901 vaccine injection for SARS-CoV-2. A 23-year-old man suffered from diarrhea after receiving the MVC-COVI1901 vaccine. The patient then presented to our emergency department due to swelling and pain in his right knee. Synovial effusion studies of the right knee revealed inflammation. Gram and acid-fast stains reported negative results and no crystals were found under a polarized light microscope. During his hospitalization, the patient underwent a colonoscopy and computed tomography (CT) due to bloody stool. Pancolitis was suspected under colonoscopy and an abdominal CT scan supported our diagnosis showing wall thickening and mucosal enhancement. Pathology showed distorted crypt architecture and acute cryptitis with abscesses. After excluding other causes of ulcerative colitis (UC), the patient was diagnosed with MVC-COV1901 vaccine-related UC and inflammatory bowel disease arthropathy. Subsequent presentation of UC and inflammatory bowel disease-related arthropathy after receiving the MVC-COVI1901 vaccine has not previously been reported. We speculate that the pathogenesis could be correlated to the vaccine's components (spike protein S-2P adjuvanted with CpG 1018 and aluminum hydroxide) through the combination of 2 effects: the activation of Toll-like receptor (TLR) 4 by S-2P, and the activation of TLR9 and expression of interleukin-13 by CpG-1018 adjuvant. In conclusion, it is remarkable that the MVC-COVI1901 vaccine may lead to the incidence of autoinflammatory diseases such as UC.

Reported COVID-19 vaccines side effects among Algerian athletes: a comparison between inactivated virus, adenoviral vector, and mRNA COVID-19 vaccines. OBJECTIVES: Many types of COVID19 vaccines are administered globally, yet there is not much evidence regarding their side effects among athletes. This study evaluated the selfreported postvaccination side effects of inactivated virus, adenoviral vector, and mRNA COVID19 vaccines among Algerian athletes. METHODS: A cross-sectional survey-based study was carried out in Algeria between March 01 and 4 April 2022. The study used a validated questionnaire with twenty-five multiple-choice items covering the participants' anamnestic characteristics, post-vaccination side effects (their onset and duration), post-vaccination medical care, and risk factors. RESULTS: A total of 273 athletes completed the survey. Overall, (54.6%) of the athletes reported at least one local side effect, while (46.9%) reported at least one systemic side effect. These side effects were more prevalent among the adenoviral vector group compared to the inactivated virus and mRNA groups. The most common local side effect was injection site pain (29.9%), while Fever (30.8%) was the most prevalent systemic side effect. The age group of 31-40Â years, allergy, previous infection with COVID-19, and the first dose of vaccines were associated with an increased risk of side effects for all groups of COVID-19 vaccines. Logistic regression analysis further revealed that compared to males, the incidence of reported side effects was significantly higher in females (odd ratio (OR)Â =Â 1.16; P =Â 0.015*) only for the adenoviral vector vaccine group. In addition, a significantly higher percentage of athletes group of high dynamic/moderate static or high dynamic /high static components suffered from post-vaccination side effects compared to the group of athletes with high dynamic/low static components (ORÂ =Â 14.68 and 14.71; P <Â 0.001, respectively). CONCLUSIONS: The adenoviral vector vaccines have the highest rate of side effects,

followed by the inactivated virus and mRNA COVID-19 vaccines. COVIDâ€‘19 vaccines were well-tolerated among Algerian athletes and there were no reports of serious side effects. Nevertheless, further long-term follow-up study with a larger sample size of athletes (from different types and sports categories) is warranted to establish the long-term safety of the COVID-19 vaccine.

Unilateral Episcleritis Following COVID-19 Booster Vaccination of a Crohn's Disease Patient: A Case Report and Review of the Literature. PURPOSE: The Coronavirus Disease 2019 (COVID-19) pandemic spurred vaccine development and resulted in the development of the novel mRNA COVID-19 vaccine and with it, a growing public concern of vaccine side effects. There are reports of ocular inflammatory processes such as episcleritis being possible side effects of COVID-19 vaccination. Here we reported the first case of unilateral episcleritis in a Crohn's disease patient following her third mRNA COVID-19 vaccination booster shot. PATIENT AND METHODS: A 27-year-old female presented with a 1-day history of right eye redness, itching, and burning. Patient reported developing these symptoms within 3-4 hours after vaccination. Her past medical history was relevant for Crohn's disease. Ophthalmic examination revealed right 2+ conjunctival injection that blanched with phenylephrine drops. Otherwise, her ophthalmic exam was unremarkable. The patient was started on artificial tears and ibuprofen 200 mg three times daily for one week. After one week all symptoms resolved, and ophthalmic examination was back to baseline. CONCLUSION: This is the first case in the literature of ophthalmic side effects in a Crohn's disease patient after the third mRNA COVID-19 booster. Patients with Crohn's disease may respond differently to booster vaccination. This case report may help healthcare providers when counselling Crohn's disease patients about future COVID-19 mRNA vaccine side effects.

Minimal Change Nephrotic Syndrome with Acute Kidney Injury after the Administration of Pfizer-BioNTech COVID-19 Vaccine. Nephrotic syndrome progresses with various metabolic disturbances, such as proteinuria over 3.5 grams in 24 hours, hypoalbuminemia, and hypercoagulability. Patients usually complain about diffuse edema throughout the body, which is secondary to hypoalbuminemia. It has many primary and secondary causes. Patients may require a renal biopsy to confirm the diagnosis. Besides, many secondary causes of nephrotic syndrome should be examined and excluded. Although many vaccines were developed due to the COVID-19, many side effects are still reported because of the Pfizer-BioNTech COVID-19 vaccine (COVID-19 mRNA and BNT162b2), which is widely used in Turkey. This study examines a case of nephrotic syndrome with acute renal injury after Pfizer-BioNTech vaccine.

Willingness to pay for a COVID-19 vaccine and its associated determinants in Iran. INTRODUCTION: Understanding the individuals' willingness to pay (WTP) for the COVID-19 vaccine could help design policy interventions to control the COVID-19 pandemic. This study aimed to estimate the individuals' willingness to pay (WTP) for a COVID-19 vaccine and to identify its associated determinants. METHODS: A cross-sectional survey was conducted on 526 Iranian adults using a web-based questionnaire. A double-bounded contingent valuation approach was used to estimate WTP for the COVID-19 vaccine. The parameters of the model were estimated based on the maximum likelihood method. RESULTS: A considerable proportion of participants (90.87%) were willing to pay for a COVID-19 vaccine. Based on our discrete choice model, the estimated mean WTP for a COVID-19 vaccine was US$ 60.13 (CI: 56.80-63.46; $p < 0.01$). Having a higher perceived risk of being contaminated with COVID-19, higher average monthly income, higher education level, pre-existence of chronic diseases, previous experience of vaccination, and belonging to higher age groups were significant determinants associated with WTP for COVID-19 vaccination. CONCLUSION: The present study indicates a relatively high WTP and acceptance of a COVID-19 vaccine among the Iranian population. Average monthly income, risk perception, education level, the preexistence of chronic disease, and previous vaccination experience increased the likelihood of WTP for a vaccine.

Subsidizing the COVID-19 vaccine for the low-income population and raising risk perception among the population should be considered in formulating vaccine-related interventions.

Factors associated with the humoral response after three doses of COVID-19 vaccination in kidney transplant recipients. INTRODUCTION: Kidney transplant recipients showed a weak humoral response to the mRNA COVID-19 vaccine despite receiving three cumulative doses of the vaccine. New approaches are still needed to raise protective immunity conferred by the vaccine administration within this group of high-risk patients. METHODS: To analyze the humoral response and identify any predictive factors within these patients, we designed a prospective monocentric longitudinal study of Kidney transplant recipients (KTR) who received three doses of mRNA-1273 COVID-19 vaccine. Specific antibody levels were measured by chemiluminescence. Parameters related to clinical status such as kidney function, immunosuppressive therapy, inflammatory status and thymic function were analyzed as potential predictors of the humoral response. RESULTS: Seventy-four KTR and sixteen healthy controls were included. One month after the administration of the third dose of the COVID-19 vaccine, 64.8% of KTR showed a positive humoral response. As predictive factors of seroconversion and specific antibody titer, we found that immunosuppressive therapy, worse kidney function, higher inflammatory status and age were related to a lower response in KTR while immune cell counts, thymosin-a1 plasma concentration and thymic output were related to a higher humoral response. Furthermore, baseline thymosin-a1 concentration was independently associated with the seroconversion after three vaccine doses. DISCUSSION: In addition to the immunosuppression therapy, condition of kidney function and age before vaccination, specific immune factors could also be relevant in light of optimization of the COVID-19 vaccination protocol in KTR. Therefore, thymosin-a1, an immunomodulatory hormone, deserves further research as a potential adjuvant for the next vaccine boosters.

Guillain-Barre syndrome following COVID-19 vaccines: A review of literature. OBJECTIVE: This study aimed to retrospectively analyze reported Guillain-BarrÃ© syndrome (GBS) cases that occurred after COVID-19 vaccination. METHODS: Case reports of GBS following COVID-19 vaccination that were published before May 14, 2022, were retrieved from PubMed. The cases were retrospectively analyzed for their basic characteristics, vaccine types, the number of vaccination doses before onset, clinical manifestations, laboratory test results, neurophysiological examination results, treatment, and prognosis. RESULTS: Retrospective analysis of 60 case reports revealed that post-COVID-19 vaccination GBS occurred mostly after the first dose of the vaccination (54 cases, 90%) and was common for DNA vaccination (38 cases, 63%), common in middle-aged and elderly people (mean age: 54.5 years), and also common in men (36 cases, 60%). The mean time from vaccination to onset was 12.3 days. The classical GBS (31 cases, 52%) was the major clinical classification and the AIDP subtype (37 cases, 71%) was the major neurophysiological subtype, but the positive rate of anti-ganglioside antibodies was low (7 cases, 20%). Bilateral facial nerve palsy (76% vs 18%) and facial palsy with distal paresthesia (38% vs 5%) were more common for DNA vaccination than for RNA vaccination. CONCLUSION: After reviewing the literature, we proposed a possible association between the risk of GBS and the first dose of the COVID-19 vaccines, especially DNA vaccines. The higher rate of facial involvement and a lower positive rate of anti-ganglioside antibodies may be a characteristic feature of GBS following COVID-19 vaccination. The causal relationship between GBS and COVID-19 vaccination remains speculative, more research is needed to establish an association between GBS and COVID-19 vaccination. We recommend surveillance for GBS following vaccination, because it is important in determining the true incidence of GBS following COVID-19 vaccination, as well as in the development of a more safer vaccine.

Myopericarditis After BNT162b2 mRNA Vaccination With Incidental Intramyocardial Bridging. Myocarditis and pericarditis are inflammatory conditions affecting the myocardium and pericardium,

respectively. They are caused by infectious and non-infectious conditions, including autoimmune disorders, drugs, and toxins. Vaccine-induced myocarditis has been reported with viral vaccines, including influenza and smallpox. The BNT162b2 mRNA vaccine (Pfizer-BioNTech) has shown â€Žgreat efficacy against symptomatic, severe coronavirus disease 2019 (COVID-19), hospital admissions, and â€Ždeaths.â€Ž The US FDA issued an emergency use authorization for the Pfizer-BioNTech COVID-19 mRNA vaccine for the prevention of COVID-19 in individuals â‰¥ five years. However, concerns were raised after reports of new cases of myocarditis following mRNA COVID-19 vaccines, especially among adolescents and young adults. Most cases developed symptoms after receiving the second dose. Here, we present a case of a previously healthy 34-year-old male who developed sudden and severe chest pain a week after the second dose of the Pfizer-BioNTech COVID-19 mRNA vaccine. Cardiac catheterization showed no angiographically obstructive coronary artery disease but it revealed intramyocardial bridging. This case report demonstrates that the mRNA COVID-19 vaccine can be associated with acute myopericarditis and the clinical presentation can mimic acute coronary syndrome. Despite that, acute myopericarditis associated with the mRNA COVID-19 vaccine is usually mild and can be managed conservatively. Incidental findings such as intramyocardial bridging should not exclude the diagnosis of myocarditis and should be carefully evaluated. COVID-19 infection has high mortality and morbidity even in young individuals, and all different COVID-19 vaccines were found effective in the prevention of severe COVID-19 infection and in decreasing COVID-19 mortality.

Thyrotoxicosis in patients with a history of Graves' disease after SARS-CoV-2 vaccination (adenovirus vector vaccine): Two case reports. BACKGROUND: Vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) which were approved for emergency use have been administered on a large scale globally to contain the pandemic coronavirus disease 2019 (COVID-19) and to save lives. Vaccine safety is one of the issues under surveillance and a possible correlation between vaccines and thyroid function has been reported. However, reports of the impact of coronavirus vaccines on those with Graves' disease (GD) are rare. CASE SUMMARY: This paper presents two patients with underlying GD in remission, both developed thyrotoxicosis and one developed thyroid storm following the adenovirus-vectored vaccine (Oxford-AstraZeneca, United Kingdom). The objective of this article is to raise awareness regarding a possible association between COVID-19 vaccination and the onset of thyroid dysfunction in patients with underlying GD in remission. CONCLUSION: Receiving either the mRNA or an adenovirus-vectored vaccine for SARS-CoV-2 could be safe under effective treatment. Vaccine induced thyroid dysfunction has been reported, but the pathophysiology still not well understood. Further investigation is required to evaluate the possible predisposing factors for developing thyrotoxicosis especially in patients with underlying GD. However, early awareness of thyroid dysfunction following vaccination could avoid a life-threatening event.

Characteristics of patients with hematologic malignancies without seroconversion post-COVID-19 third vaccine dosing. OBJECTIVES: The objective of this study is to explore the characteristics of the subset of patients with hematologic malignancies (HMs) who had little to no change in SARS-CoV-2 spike antibody index value levels after a third mRNA vaccine dose (3V) and to compare the cohort of patients who did and did not seroconvert post-3V to get a better understanding of the demographics and potential drivers of serostatus. STUDY DESIGN: This retrospective cohort study analyzed SARS-CoV-2 spike IgG antibody index values pre and post the 3V data on 625 patients diagnosed with HM across a large Midwestern United States healthcare system between 31 October 2019 and 31 January 2022. METHODS: To assess the association between individual characteristics and seroconversion status, patients were placed into two groups based on IgG antibody status pre and post the 3V dose, (-/+) and (-/-). Odds ratios were used as measures of association for all categorical variables. Logistic regressions were used to measure the association between HM

condition and seroconversion. RESULTS: HM diagnosis was significantly associated with seroconversion status (P = 0.0003) with patients non-Hodgkin lymphoma six times the odds of not seroconverting compared with multiple myeloma patients (P = 0.0010). Among the participants who were seronegative prior to 3V, 149 (55.6%) seroconverted after the 3V dose and 119 (44.4%) did not. CONCLUSION: This study focuses on an important subset of patients with HM who are not seroconverting after the COVID mRNA 3V. This gain in scientific knowledge is needed for clinicians to target and counsel these vulnerable patients.

Case report: First manifestation of multiple sclerosis temporally correlated with COVID-19 vaccination. There are several case reports describing a temporal correlation between the first clinical manifestation of multiple sclerosis (MS) and the occurrence of relapses with vaccination against SARS-CoV-2. Here we report a case of a 33-year-old male who developed partial right upper and lower extremities numbness 2 weeks after receiving Johnson & Johnson's Janssen COVID-19 vaccine. The brain MRI performed during diagnostics in the Department of Neurology detected several demyelinating lesions, one with enhancement. Oligoclonal bands were present in the cerebrospinal fluid. The patient was treated with high-dose glucocorticoid therapy with improvement and the diagnosis of MS was made. It seems plausible that the vaccination revealed the underlying autoimmune condition. Cases like the one we reported here are rare, and-based on current knowledge-the benefits of vaccination against SARS-CoV-2 far outweigh the potential risks.

Concurrent hypereosinophilic syndrome and deep vein thrombosis after Pfizer-BioNTech COVID-19 vaccination: A case report. Herein, we report a case of eosinophilia syndrome and deep vein thrombosis presenting concurrently after the administration of the BNT162b2 mRNA-based coronavirus disease 2019 (COVID-19) vaccine. It is extremely rare to have both hypereosinophilic syndrome and deep vein thrombosis simultaneously. Both are serious diseases and should be treated with caution.

Granulomatous anterior uveitis following mRNA-based COVID-19 vaccination: A case report. A 23-year-old patient presented with complaints of redness, pain, photophobia, and blurred vision in the right eye 15 days after she received the third dose of BNT162b2 vaccination. Ocular examination revealed 2+ cellular reactions in the anterior chamber and mutton fat keratic precipitate with no vitritis or retinal alterations. Active uveitis findings regressed with corticosteroid and cycloplegic eye drops. We present a case of unilateral granulomatous anterior uveitis following the BNT162b2 vaccination, with no etiologic factor in uveitis work-up and no previous history of uveitis before vaccination. This report demonstrates a potential causal association of coronavirus disease 2019 (COVID-19) vaccine with granulomatous anterior uveitis.

DALK rejection following vaccination against SARS-CoV-2: 2 case reports. PURPOSE: To report two cases of deep anterior lamellar keratoplasty (DALK) rejection occurring in association with SARS-CoV-2 vaccination. METHODS: Two patients with prior history of DALK developed immunologic rejection after SARS-CoV-2 vaccination. The first patient, a 15-year-old girl, had a stromal and sub-epithelial rejection nine days after receiving the first dose of the SARS-CoV-2 vaccine BBV152(COVAXIN(TM), Bharat Biotech, India). The second patient, an 18-year-old male, had a stromal rejection 13 days after receiving the second dose of the ChAdOx1 SARS-CoV-2 vaccine (COVISHIELD(TM), Serum Institute of India, India). RESULTS: Both patients received frequent topical corticosteroids. The first patient recovered within four weeks and the second patient recovered within two weeks of initiating therapy. Both patients experienced complete resolution of corneal edema and had improvement in their visual acuity. CONCLUSIONS: DALK rejection is a rare but distinct possibility in patients following SARS-CoV-2 immunization. Further studies are required before establishing clear guidelines regarding risk, follow-up and treatment strategies in such a scenario.

Anaphylaxis rates following mRNA COVID-19 vaccination in children and adolescents: Analysis of data reported to EudraVigilance. AIM: The present study aimed to estimate the anaphylaxis rates following mRNA COVID-19 vaccination in children and adolescents in Europe. METHODS: We retrieved data on 371 anaphylaxis cases following mRNA COVID-19 vaccination in childrenÂ â‰¤Â 17Â years old notified to EudraVigilance as of October 8, 2022. Overall, 27,120,512 doses of BNT162b2 vaccine and 1,400,300 doses of mRNA-1273 vaccine have been delivered to children during the study period. RESULTS: The overall mean anaphylaxis rate was 12.81 [95% confidence interval (CI): 11.49-14.12] per 10(6) mRNA vaccine doses [12.14 (95% CI: 6.37-17.91) per 10(6) doses for mRNA-1273 and 12.84 (95% CI: 11.49-14.19) per 10(6) doses for BNT162b2]. Children 12-17Â years old accounted for 317 anaphylaxis cases, followed by 48 cases in children 3-11Â years old, and 6 cases in children 0-2Â years old. Children 10-17Â years old had a mean anaphylaxis rate of 13.52 (95% CI: 12.03-15.00) cases per 10(6) mRNA vaccine doses and children 5-9Â years old had a mean anaphylaxis rate of 9.51 (95% CI: 6.82-12.20) cases per 10(6) mRNA vaccine doses. There were two fatalities, both in the 12-17Â years age group. The fatal anaphylaxis rate was 0.07 cases per 10(6) mRNA vaccine doses. CONCLUSIONS: Anaphylaxis is a rare adverse event after receiving an mRNA COVID-19 vaccine in children. Continuous surveillance of serious adverse events is needed to guide vaccination policies as we move towards SARS-CoV-2 endemicity. Larger real-world studies on COVID-19 vaccination in children, using clinical case confirmation, are imperative.

Attitudes and factors affecting decision-making regarding COVID-19 vaccination among autoimmune rheumatic disease patients. BACKGROUND: Coronavirus disease-2019 (COVID-19) vaccine hesitancy is a significant threat to the success of COVID-19 vaccination programs. OBJECTIVES: We aimed to assess attitudes and factors affecting the decision-making vis-Ã -vis COVID-19 vaccination among patients with autoimmune rheumatic diseases (ARDs). METHOD: A cross-sectional survey of adults with ARDs was conducted between January 2022 and April 2022. All enrolled ARDs patients were asked to answer a questionnaire about their attitudes regarding COVID-19 vaccination. RESULTS: Three hundred patients were included with a female-to-male ratio of 2.5:1. The mean age of the patients was 49.2â€‰Â±â€‰15.6â€‰years. Around 37% of patients who hesitated to get the COVID-19 vaccination were apprehensive regarding potential adverse events from the vaccine. About 25% (76 cases) were hesitant about vaccination, of which 15% were uncertain about the vaccine's efficacy, and 15% thought the vaccine was unnecessary because they lived in rural areas where they practiced social distancing. "Family role as a non-working member" was the only factor strongly associated with hesitancy for vaccination (odds ratio of 2.42; 95% CI 1.06-5.57). The attitudes to vaccination showed that the patients were concerned about disease flaring and believed all medicine should be stopped before vaccination. CONCLUSION: Around one-quarter of ARDs sufferers hesitated to get COVID-19 vaccination. In addition, some patients were disinclined to get vaccinated because they were worried about its efficacy and/or associated adverse events. The findings help healthcare providers plan to counter negative attitudes toward vaccination in ARDs patients to protect them during the COVID-19 era.

Safety of COVID-19 Vaccines among Patients with Type 2 Diabetes Mellitus: Real-World Data Analysis. BACKGROUND: Little is known about the adverse events (AEs) associated with coronavirus disease 2019 (COVID-19) vaccination in patients with type 2 diabetes mellitus (T2DM). METHODS: This study used vaccine AE reporting system data to investigate severe AEs among vaccinated patients with T2DM. A natural language processing algorithm was applied to identify people with and without diabetes. After 1:3 matching, we collected data for 6,829 patients with T2DM and 20,487 healthy controls. Multiple logistic regression analysis was used to calculate the odds ratio for severe AEs. RESULTS: After COVID-19 vaccination, patients with T2DM were more likely to experience eight severe AEs than controls: cerebral venous sinus thrombosis, encephalitis myelitis encephalomyelitis,

Bell's palsy, lymphadenopathy, ischemic stroke, deep vein thrombosis (DVT), thrombocytopenia (TP), and pulmonary embolism (PE). Moreover, patients with T2DM vaccinated with BNT162b2 and mRNA-1273 were more vulnerable to DVT and TP than those vaccinated with JNJ-78436735. Among patients with T2DM administered mRNA vaccines, mRNA-1273 was safer than BNT162b2 in terms of the risk of DVT and PE. CONCLUSION: Careful monitoring of severe AEs in patients with T2DM may be necessary, especially for those related to thrombotic events and neurological dysfunctions after COVID-19 vaccination.
A systems immunology study comparing innate and adaptive immune responses in adults to COVID-19 mRNA and adenovirus vectored vaccines. Identifying the molecular mechanisms that promote optimal immune responses to coronavirus disease 2019 (COVID-19) vaccination is critical for future rational vaccine design. Here, we longitudinally profile innate and adaptive immune responses in 102 adults after the first, second, and third doses of mRNA or adenovirus-vectored COVID-19 vaccines. Using a multi-omics approach, we identify key differences in the immune responses induced by ChAdOx1-S and BNT162b2 that correlate with antigen-specific antibody and TÂ cell responses or vaccine reactogenicity. Unexpectedly, we observe that vaccination with ChAdOx1-S, but not BNT162b2, induces an adenoviral vector-specific memory response after the first dose, which correlates with the expression of proteins with roles in thrombosis with potential implications for thrombosis with thrombocytopenia syndrome (TTS), a rare but serious adverse event linked to adenovirus-vectored vaccines. The COVID-19 Vaccine Immune Responses Study thus represents a major resource that can be used to understand the immunogenicity and reactogenicity of these COVID-19 vaccines.
Summary of Safety and Efficacy of COVID Vaccination in Patients with Multiple Sclerosis. BACKGROUND: The SARS-CoV-2 pandemic represents one of the most challenging issues that have recently influenced everyday life in countries all over the world. Understanding the risk of this disease is of high importance in patients with multiple sclerosis (MS) as they represent a vulnerable population through their treatment with disease-modifying therapies (DMTs). Infective episodes may trigger relapses and lead to deterioration of the health condition. SUMMARY: Vaccination is an important preventive measure against infectious diseases. In MS patients, concerns have been raised about the effectiveness of vaccines in patients on various immunomodulatory drugs and about their possible adverse effects including impairment of neurological functions. The objectives of this article were to summarize the current knowledge on immune responses to the COVID-19 vaccines and their safety in MS patients and to provide practical guidance based on the data available to date. KEY MESSAGES: Although MS is not associated with a higher risk of COVID-19, this infection can trigger relapses or pseudo-relapses. Vaccines against SARS-CoV-2 are recommended for all MS patients who are not in the active phase of the disease, despite the fact that there is still a lack of long-term reliable data on the effectiveness and safety of vaccines against COVID-19. Some DMTs can reduce vaccine humoral responses, but might still provide some protection and adequate T-cell response. To optimize the effectiveness of vaccination, the ideal timing of vaccine application and DMTs dosing regimen is crucial.
Inflammatory and senescence-associated mediators affect the persistence of humoral response to COVID-19 mRNA vaccination in transfusion-dependent beta-thalassemic patients.
The effects of Covid-19 mRNA vaccine on adolescence gynecological well-being. KEY MESSAGE: Menstruation of adolescent girls might be influenced by Covid-19 mRNA vaccine, however, the ovarian reserve estimated by AMH is not compromised. BACKGROUND: Recent studies have suggested that the acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine causes menstrual abnormalities which led to concerns regarding its influence on the reproductive system. This study aims to investigate the influence of the SARS-CoV-2 mRNA vaccine on gynecologic well-

being and future fertility of adolescent girls. METHODS: This is a prospective cohort study conducted at a university affiliated medical center between June and July 2021. Adolescent girls aged 12-16Â years who were vaccinated by two Pfizer-BioNTech Covid-19 vaccines (21Â days apart) were included in the study. All participants completed a computerized questionnaire regarding their general medical and gynecological background at recruitment and 3 months later. Blood samples were collected for AMH levels before and 3 months following the first mRNA vaccine RESULTS: The study group consisted of 35 girls, and of them, follow-up was completed by questionnaire and AMH sampling in 35 (90%) and 22 (56%) girls, respectively. Among the 22/35 girls who reported regular menstruation before vaccination, seven (31.8%) experienced irregularities post-vaccination. Four of the eight pre-menarche girls included in the study reported on menarche on follow-up. Median AMH levels were 3.09 (IQR 1.96-4.82) Î¼g/L and 2.96 (2.21-4.73) Î¼g/L at baseline and after 3 months, respectively (pâ€‰=â€‰0.07). After controlling for age, BMI and presentation of side effects, no association was demonstrated to the change in AMH levels (AMH2-AMH1). CONCLUSIONS: Although menstruation of adolescent girls might be influenced by Covid-19 mRNA vaccine, it seems that the ovarian reserve estimated by AMH is not compromised. CLINICAL TRIAL REGISTRATION: National Institutes of Health (NCT04748172).

Durability and breadth of neutralisation following multiple antigen exposures to SARS-CoV-2 infection and/or COVID-19 vaccination. BACKGROUND: Given the importance of vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the prevention of severe coronavirus disease 2019 (COVID-19), detailed long-term analyses of neutralising antibody responses are required to inform immunisation strategies. METHODS: In this study, longitudinal neutralising antibody titres to an ancestral SARS-CoV-2 isolate and cross-neutralisation to delta and omicron isolates were analysed in individuals previously infected with SARS-CoV-2, vaccinated against COVID-19, or a complex mix thereof with up to two years of follow-up. FINDINGS: Both infection-induced and vaccine-induced neutralising responses against SARS-CoV-2 appeared to follow similar decay patterns. Following vaccination in previously infected individuals, neutralising antibody responses were more durable than prior to vaccination. Further, this study shows that vaccination after infection, as well as booster vaccination, increases the cross-neutralising potential to both delta and omicron SARS-CoV-2 variants. INTERPRETATION: Taken together, these results suggest that neither type of antigen exposure is superior for neutralising antibody durability. However, these results support vaccination to increase the durability and cross-neutralisation potential of neutralising responses, thereby enhancing protection against severe COVID-19. FUNDING: This work was supported by grants from The Capital Region of Denmark's Research Foundation, the Novo Nordisk Foundation, the Independent Research Fund Denmark, the Candys Foundation, and the Danish Agency for Science and Higher Education.

Effect of anxiety and depression on self-reported adverse reactions to COVID-19 vaccine: a cross-sectional study in Shanghai, China. BACKGROUND: The association of anxiety and depression with adverse reactions after receipt of coronavirus disease 2019 (COVID-19) vaccine is not clear among the general population. This study aims to evaluate the effect of anxiety and depression on self-reported adverse reactions to COVID-19 vaccine. METHODS: The cross-sectional study was conducted during April-July 2021. Participants completing the two doses of vaccine were included in this study. Sociodemographic information, anxiety and depression levels and adverse reactions after the first dose of vaccine for all participants were collected. The anxiety and depression levels were assessed by the Seven-item Generalized Anxiety Disorder Scale and the Nine-item Patient Health Questionnaire Scale, respectively. The multivariate logistic regression analysis was used to examine the association between anxiety and depression and adverse reactions. RESULTS: A total of 2161 participants were enrolled in this study. The prevalence of anxiety and depression was 13% (95%

confidence interval (CI), 11.3-14.2%) and 15% (95%CI, 13.6-16.7%), respectively. Of the 2161 participants, 1607 (74%; 95% CI, 73-76%) reported at least one adverse reaction after the first dose of the vaccine. Pain at the injection site (55%) and fatigue and headache (53% and 18%, respectively) were the most commonly reported local and systemic adverse reactions, respectively. Participants with anxiety or depression or both were more likely to report local and systemic adverse reactions (Pâ€‰<â€‰0.05). CONCLUSION: The results suggest that anxiety and depression increase the risk of self-reported adverse reactions to COVID-19 vaccine. Consequently, appropriate psychological interventions before vaccination will help to reduce or alleviate symptoms of vaccination.

Single immunizations of self-amplifying or non-replicating mRNA-LNP vaccines control HPV-associated tumors in mice. As mRNA vaccines have proved to be very successful in battling the coronavirus disease 2019 (COVID-19) pandemic, this new modality has attracted widespread interest for the development of potent vaccines against other infectious diseases and cancer. Cervical cancer caused by persistent human papillomavirus (HPV) infection is a major cause of cancer-related deaths in women, and the development of safe and effective therapeutic strategies is urgently needed. In the present study, we compared the performance of three different mRNA vaccine modalities to target tumors associated with HPV-16 infection in mice. We generated lipid nanoparticle (LNP)-encapsulated self-amplifying mRNA as well as unmodified and nucleoside-modified non-replicating mRNA vaccines encoding a chimeric protein derived from the fusion of the HPV-16 E7 oncoprotein and the herpes simplex virus type 1 glycoprotein D (gDE7). We demonstrated that single low-dose immunizations with any of the three gDE7 mRNA vaccines induced activation of E7-specific CD8(+) T cells, generated memory T cell responses capable of preventing tumor relapses, and eradicated subcutaneous tumors at different growth stages. In addition, the gDE7 mRNA-LNP vaccines induced potent tumor protection in two different orthotopic mouse tumor models after administration of a single vaccine dose. Last, comparative studies demonstrated that all three gDE7 mRNA-LNP vaccines proved to be superior to gDE7 DNA and gDE7 recombinant protein vaccines. Collectively, we demonstrated the immunogenicity and therapeutic efficacy of three different mRNA vaccines in extensive comparative experiments. Our data support further evaluation of these mRNA vaccines in clinical trials.

Correspondence on Bell's palsy as an adverse event following COVID-19 vaccination.

Outcome of COVID-19 patients with haematological malignancies after the introduction of vaccination and monoclonal antibodies: results from the HM-COV 2.0 study. Patients with haematological malignancies (HM) and SARS-CoV-2 infection present a higher risk of severe COVID-19 and mortality. The aim of the study was to investigate whether vaccination and monoclonal antibodies (mAbs) have modified the outcomes of HM patients with COVID-19. This is a single-centre retrospective study in HM patients hospitalized due to SARS-CoV-2 infection from March 2020 to April 2022. Patients were divided into PRE-V-mAb group (patients hospitalized before the introduction of vaccination and mAbs) and POST-V-mAb group (patients hospitalized after the use of vaccine and mAbs). A total of 126 patients were included (65 PRE-V-mAb and 61 POST-V-mAb). POST-V-mAb patients showed a significantly lower risk of intensive care unit (ICU) admission (8.2% vs. 27.7%, pâ€‰=â€‰0.005), shorter viral shedding [17 (IQR 10-28) vs. 24Â days (IQR 15-50), pâ€‰=â€‰0.011] and shorter hospitalization length [13 (IQR 7-23) vs. 20 (IQR 14-41) days, pâ€‰=â€‰0.0003] compared to the PRE-V-mAb group. Nevertheless, both in-hospital and 30-day mortality rates did not significantly differ between the two groups (29.5% POST-V-mAb vs. 36.9% PRE-V-mAb and 21.3% POST-V-mAb vs. 29.2% PRE-V-mAb, respectively). At the multivariable analysis, an active malignancy (pâ€‰=â€‰0.042), a critical COVID-19 at admission (pâ€‰=â€‰0.025) and the need for high-level of oxygen support at respiratory worsening [either HFNC/CPAP (pâ€‰=â€‰0.022) or mechanical ventilation (pâ€‰=â€‰0.011)] were independently associated

with in-hospital mortality. In the subgroup of POST-V-mAb patients, receiving therapy with mAbs was a protective factor (pâ€‰=â€‰0.033). Despite the new therapeutic and preventive strategies available, HM patients with COVID-19 disease represent an extremely vulnerable group with still high mortality rates.

Cutaneous Eruption after SARS-CoV-2 Vaccine in Psoriatic Patient Treated with Methotrexate.

Ruxolitinib treatment in myelofibrosis and polycythemia vera causes suboptimal humoral immune response following standard and booster vaccination with BNT162b2 mRNA COVID-19 vaccine. Patients affected by myelofibrosis (MF) or polycythemia vera (PV) and treated with ruxolitinib are at high risk for severe coronavirus disease 2019. Now a vaccine against the virus SARS-CoV-2, which is responsible for this disease, is available. However, sensitivity to vaccines is usually lower in these patients. Moreover, fragile patients were not included in large trials investigating the efficacy of vaccines. Thus, little is known about the efficacy of this approach in this group of patients. In this prospective single-center study, we evaluated 43 patients (30 MF patients and 13 with PV) receiving ruxolitinib as a treatment for their myeloproliferative disease. We measured anti-spike and anti-nucleocapsid IgG against SARS-CoV2 15-30 days after the second and the third BNT162b2 mRNA vaccine booster dose. Patients receiving ruxolitinib showed an impaired antibody response to complete vaccination (2 doses), as 32.5% of patients did not develop any response. After the third booster dose with Comirnaty, results slightly improved, as 80% of these patients produced antibodies above the threshold positivity. However, the quantity of produced antibodies was well below that reached than those reported for healthy individuals. PV patients elicited a better response than patients affected by MF. Thus, different strategies should be considered for this high-risk group of patients.

Case Report: A case of multisystem inflammatory syndrome in an 11-year-old female after COVID-19 inactivated vaccine. BACKGROUND: Multisystem inflammatory syndrome in children (MIS-C), also known as pediatric inflammatory, multisystem syndrome temporally associated with SARS-CoV-2, is a rare but serious complication of SARS-CoV-2 infection in children that typically occurs 2-6 weeks after SARS-CoV-2 infection. The pathophysiology of MIS-C is unknown. MIS-C, first recognized in April 2020, is characterized by fever, systemic inflammation, and multi-system organ involvement. Post-vaccination adverse effects have increased with COVID-19 vaccinations, and MIS linked to immunization with COVID-19 vaccines has also been observed. CASE REPORT: An 11-year-old Chinese girl presented with a high-grade fever, rash, and dry cough for 2 days. She had her 2nd SARS-CoV-2 inactivated vaccination dose five days before hospital admission. On day 3 & 4, she experienced bilateral conjunctivitis, hypotension (66/47â€…mmHg), and a high CRP level. She was diagnosed with MIS-C. The patient's condition deteriorated rapidly, necessitating intensive care unit admission. The patient's symptoms improved after intravenous immunoglobulin, methylprednisolone, and oral aspirin therapy. She was discharged from the hospital after 16 days as her general condition, and laboratory biomarkers returned to normal. CONCLUSION: Inactivated Covid-19 vaccination might trigger MIS-C. Further research is needed to evaluate whether a correlation exists between COVID-19 vaccination and MIS-C development.

People having hematological disorders and hypercoagulability state need extra precautions because of the increased risk of thrombosis after COVID-19 vaccination.

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Impact of immunosuppressive treatment and type of SARS-CoV-2 vaccine on antibody levels after three vaccinations in patients with chronic kidney disease or kidney replacement therapy. BACKGROUND: Patients with chronic kidney disease (CKD) or kidney replacement therapy

demonstrate lower antibody levels after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination compared with healthy controls. In a prospective cohort, we analysed the impact of immunosuppressive treatment and type of vaccine on antibody levels after three SARS-CoV-2 vaccinations. METHODS: Control subjects (nÂ =Â 186), patients with CKD G4/5 (nÂ =Â 400), dialysis patients (nÂ =Â 480) and kidney transplant recipients (KTR) (nÂ =Â 2468) were vaccinated with either mRNA-1273 (Moderna), BNT162b2 (Pfizer-BioNTech) or AZD1222 (Oxford/AstraZeneca) in the Dutch SARS-CoV-2 vaccination programme. Third vaccination data were available in a subgroup of patients (nÂ =Â 1829). Blood samples and questionnaires were obtained 1Â month after the second and third vaccination. Primary endpoint was the antibody level in relation to immunosuppressive treatment and type of vaccine. Secondary endpoint was occurrence of adverse events after vaccination. RESULTS: Antibody levels after two and three vaccinations were lower in patients with CKD G4/5 and dialysis patients with immunosuppressive treatment compared with patients without immunosuppressive treatment. After two vaccinations, we observed lower antibody levels in KTR using mycophenolate mofetil (MMF) compared with KTR not using MMF [20 binding antibody unit (BAU)/mL (3-113) vs 340 BAU/mL (50-1492), PÂ <Â .001]. Seroconversion was observed in 35% of KTR using MMF, compared with 75% of KTR not using MMF. Of the KTR who used MMF and did not seroconvert, eventually 46% seroconverted after a third vaccination. mRNA-1273 induces higher antibody levels as well as a higher frequency of adverse events compared with BNT162b2 in all patient groups. CONCLUSIONS: Immunosuppressive treatment adversely affects the antibody levels after SARS-CoV-2 vaccination in patients with CKD G4/5, dialysis patients and KTR. mRNA-1273 vaccine induces a higher antibody level and higher frequency of adverse events.

Impaired antibody response to inactivated COVID-19 vaccines in hospitalized patients with type 2 diabetes. Patients with type 2 diabetes (T2D) are at an increased risk of morbidity and mortality of coronavirus disease 2019 (COVID-19). Data on the antibody response to COVID-19 vaccines in T2D patients are less studied. This study aimed to evaluate IgG antibody response to inactivated COVID-19 vaccines in hospitalized T2D patients. Hospitalized patients with no history of COVID-19 and received two doses of inactivated COVID-19 vaccines (Sinopharm or CoronaVac) were included in this study from March to October 2021. SARS-CoV-2 specific IgG antibodies were measured 14-60â€‰days after the second vaccine dose. A total of 209 participants, 96 with T2D and 113 non-diabetes patients, were included. The positive rate and median titer of IgG antibody against receptor-binding domain (anti-RBD) of spike (S) protein of SARS-CoV-2 in T2D group were lower than in control group (67.7% vs 83.2%, pâ€‰=â€‰.009; 12.93 vs 17.42 AU/ml, pâ€‰=â€‰.014) respectively. Similarly, seropositivity and median titers of IgG antibody against the nucleocapsid (N) and S proteins of SARS-CoV-2 (anti-N/S) in T2D group were lower than in control group (68.8% vs 83.2%, pâ€‰=â€‰.032; 18.81 vs 29.57 AU/mL, pâ€‰=â€‰.012) respectively. After adjustment for age, sex, BMI, vaccine type, days after the second vaccine dose, hypertension, kidney disease, and heart disease, T2D was identified as an independent risk factor for negative anti-RBD and anti-N/S seropositivity, odd ratio 0.42 (95% confidence interval 0.19, 0.89) and 0.42 (95% CI 0.20, 0.91), respectively. T2D is associated with impaired antibody response to inactivated COVID-19 vaccine.

Characteristics and predictors of persistent symptoms post-COVID-19 in children and young people: a large community cross-sectional study in England. OBJECTIVE: To estimate the prevalence of, and associated risk factors for, persistent symptoms post-COVID-19 among children aged 5-17 years in England. DESIGN: Serial cross-sectional study. SETTING: Rounds 10-19 (March 2021 to March 2022) of the REal-time Assessment of Community Transmission-1 study (monthly cross-sectional surveys of random samples of the population in England). STUDY POPULATION: Children aged 5-17 years in the community. PREDICTORS: Age, sex, ethnicity, presence of a pre-existing health condition, index of multiple deprivation, COVID-19 vaccination status and dominant UK circulating SARS-CoV-2 variant at

time of symptom onset. MAIN OUTCOME MEASURES: Prevalence of persistent symptoms, reported as those lasting â‰¥3 months post-COVID-19. RESULTS: Overall, 4.4% (95% CI 3.7 to 5.1) of 3173 5-11â€‰year-olds and 13.3% (95% CI 12.5 to 14.1) of 6886 12-17â€‰year-olds with prior symptomatic infection reported at least one symptom lasting â‰¥3 months post-COVID-19, of whom 13.5% (95% CI 8.4 to 20.9) and 10.9% (95% CI 9.0 to 13.2), respectively, reported their ability to carry out day-to-day activities was reduced 'a lot' due to their symptoms. The most common symptoms among participants with persistent symptoms were persistent coughing (27.4%) and headaches (25.4%) in children aged 5-11 years and loss or change of sense of smell (52.2%) and taste (40.7%) in participants aged 12-17 years. Higher age and having a pre-existing health condition were associated with higher odds of reporting persistent symptoms. CONCLUSIONS: One in 23 5-11â€‰year-olds and one in eight 12-17â€‰year-olds post-COVID-19 report persistent symptoms lasting â‰¥3 months, of which one in nine report a large impact on performing day-to-day activities.

Myocarditis Following COVID-19 Vaccination. Myocarditis is an established but rare adverse event following administration of messenger RNA-based coronavirus disease 2019 (COVID-19) vaccines and is most common in male adolescents and young adults. Symptoms typically develop within a few days of vaccine administration. Most patients have mild abnormalities on cardiac imaging with rapid clinical improvement with standard treatment. However, longer term follow-up is needed to determine whether imaging abnormalities persist, to evaluate for adverse outcomes, and to understand the risk associated with subsequent vaccination. The purpose of the review is to evaluate the current literature related to myocarditis following COVID-19 vaccination, including the incidence, risk factors, clinical course, imaging findings, and proposed pathophysiologic mechanisms.

Review of Immunologic Manifestations of COVID-19 Infection and Vaccination. We herein summarize currently available and clinically relevant information regarding the human immune responses to SARS-CoV-2 infection and vaccination, in relation to COVID-19 outcomes with a focus on acute respiratory distress syndrome (ARDS) and myocarditis.

The Cardiovascular Manifestations of COVID-19. The Coronavirus 2019 (COVID-19) pandemic, caused by the Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) virus, has resulted in unprecedented morbidity and mortality worldwide. While COVID-19 typically presents as viral pneumonia, cardiovascular manifestations such as acute coronary syndromes, arterial and venous thrombosis, acutely decompensated heart failure (HF), and arrhythmia are frequently observed. Many of these complications are associated with poorer outcomes, including death. Herein we review the relationship between cardiovascular risk factors and outcomes among patients with COVID-19, cardiovascular manifestations of COVID-19, and cardiovascular complications associated with COVID-19 vaccination.

Antibody response to the COVID-19 ChAdOx1nCov-19 and BNT162b vaccines after temporary suspension of DMARD therapy in immune-mediated inflammatory disease: an extension study (RESCUE 2). The persistence of immunogenicity in patients with immune-mediated inflammatory diseases (IMID) on disease-modifying antirheumatic therapy (DMARD) has been less well studied. This extension study evaluates the SARS-CoV2 antibody decay kinetics 6 months following two doses of ChAdO1nCov-19 (AZ) and BNT162b (Pfizer) and subsequent response following an mRNA booster. RESULTS: 175 participants were included. Six months after initial AZ vaccination, 87.5%, 85.4% and 79.2% (p=0.756) in the withhold, continue and control groups remained seropositive compared with 91.4%, 100% and 100% (p=0.226), respectively, in the Pfizer group. Both vaccine groups developed robust humoral immune responses following a booster with seroconversion rates being 100% for all three intervention categories. The mean SARS-CoV-2 antibody levels were significantly lower in the targeted synthetic DMARD (tsDMARD) group that continued therapy compared with the control (2.2 vs 4.8â€‰U/mL, p=0.010). The mean time interval until loss of protective antibodies in the IMID

group was 61 days for the AZ and 137.5â€‰days for the Pfizer vaccine. Within each DMARD class the interval until loss of protective antibody titres in the csDMARD, bDMARD and tsDMARD groups were 68.3, 71.8 and 64.0â€‰days in the AZ group and 185.5, 137.5 and 116.0â€‰days in the Pfizer group, respectively. CONCLUSION: Antibody persistence was longer in the Pfizer group due to a higher peak antibody level following second vaccination with levels of protection in IMID on DMARD therapy similar to controls except in those on tsDMARDs where it was lower. A third mRNA vaccine booster can restore immunity in all groups.

The clinical and pathologic spectrum of mucocutaneous reactions after COVID-19 vaccinations in three tertiary referral centers of northern Italy. Adverse cutaneous reactions after COVID-19 vaccinations have increased, highlighting not only how SARS-CoV-2 infection but also COVID-19 vaccines may induce adverse cutaneous manifestations. We evaluated the clinical and pathologic spectrum of mucocutaneous reactions after COVID-19 vaccinations, observed consecutively within three large tertiary centers of the Metropolitan City of Milan (Lombardy), comparing our results with the currently available literature. We retrospectively reviewed medical records and skin biopsies of patients diagnosed with mucocutaneous adverse events after COVID-19 vaccinations and followed at three Italian tertiary referral centers in the Metropolitan City of Milan. One hundred twelve patients (77 women and 35 men (112 total); median age, 60 years) have been included in the present study; a cutaneous biopsy was performed in 41 cases (36%). The trunk and arms were the most involved anatomic areas. Autoimmune reactions after COVID-19 vaccinations, urticaria, morbilliform eruptions, and eczematous dermatitis have been the most commonly diagnosed disorders. Compared to the currently available literature, we performed many more histologic examinations, allowing us to make more precise diagnoses. Most of the cutaneous reactions were self-healing and/or responded to topical and systemic steroids and systemic antihistamines, thus not discouraging the general population from carrying out vaccinations, which currently have a good safety profile.

Serious adverse event following immunization and thromboembolic events associated with COVID19 vaccination: An analysis of nationwide causality assessment from India. BACKGROUND: Vaccines against the COVID-19 pandemic were introduced in late 2020. The present study has been conducted to study the serious Adverse Events Following Immunization (AEFIs) reported for COVID-19 vaccines from India. METHODS: Secondary data analysis of the causality assessment reports for the 1112 serious AEFIs published by the Ministry of Health & Family Welfare, Government of India, was conducted. For the current analysis, all the reports published till 29.03.2022 were included. The primary outcome variables analyzed were the consistent causal association and the thromboembolic events. RESULTS: The majority of the serious AEFIs assessed were either coincidental (578, 52%) or vaccine product related (218, 19.6%). All the serious AEFIs were reported among the Covishield (992, 89.2%) and COVAXIN (120, 10.8%) vaccines. Among these, 401 (36.1%) were deaths, and 711 (63.9%) were hospitalized and recovered. On adjusted analysis, females, the younger age group and non-fatal AEFIs showed a statistically significant consistent causal association with COVID-19 vaccination. Thromboembolic events were reported among 209 (18.8%) of the analyzed participants, with a significant association with higher age and case fatality rate. CONCLUSION: Deaths reported under serious AEFIs were found to have a relatively lower consistent causal relationship with the COVID-19 vaccines than the recovered hospitalizations in India. No consistent causal association was found between the thromboembolic events and the type of COVID-19 vaccine administered in India.

Safety and incidence of COVID-19 following ChAdOx1(AZD1222) COVID-19 vaccination in Botswana.

Evolution of long-term vaccine-induced and hybrid immunity in healthcare workers after different COVID-19 vaccine regimens. BACKGROUND: Both infection and vaccination, alone or in combination, generate antibody and TÂ cell responses against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, the maintenance of such responses-and hence protection from

disease-requires careful characterization. In a large prospective study of UK healthcare workers (HCWs) (Protective Immunity from T Cells in Healthcare Workers [PITCH], within the larger SARS-CoV-2 Immunity and Reinfection Evaluation [SIREN] study), we previously observed that prior infection strongly affected subsequent cellular and humoral immunity induced after long and short dosing intervals of BNT162b2 (Pfizer/BioNTech) vaccination. METHODS: Here, we report longer follow-up of 684 HCWs in this cohort over 6-9Â months following two doses of BNT162b2 or AZD1222 (Oxford/AstraZeneca) vaccination and up to 6Â months following a subsequent mRNA booster vaccination. FINDINGS: We make three observations: first, the dynamics of humoral and cellular responses differ; binding and neutralizing antibodies declined, whereas T and memory B cell responses were maintained after the second vaccine dose. Second, vaccine boosting restored immunoglobulin (Ig) G levels; broadened neutralizing activity against variants of concern, including Omicron BA.1, BA.2, and BA.5; and boosted TÂ cell responses above the 6-month level after dose 2. Third, prior infection maintained its impact driving larger and broader TÂ cell responses compared with never-infected people, a feature maintained until 6Â months after the third dose. CONCLUSIONS: Broadly cross-reactive TÂ cell responses are well maintained over time-especially in those with combined vaccine and infection-induced immunity ("hybrid" immunity)-and may contribute to continued protection against severe disease. FUNDING: Department for Health and Social Care, Medical Research Council.

A third SARS-CoV-2 mRNA vaccine dose in people receiving hemodialysis overcomes B cell defects but elicits a skewed CD4(+) TÂ cell profile. Cellular immune defects associated with suboptimal responses to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccination in people receiving hemodialysis (HD) are poorly understood. We longitudinally analyze antibody, B cell, CD4(+), and CD8(+) TÂ cell vaccine responses in 27 HD patients and 26 low-risk control individuals (CIs). The first two doses elicit weaker B cell and CD8(+) TÂ cell responses in HD than in CI, while CD4(+) TÂ cell responses are quantitatively similar. In HD, a third dose robustly boosts B cell responses, leads to convergent CD8(+) TÂ cell responses, and enhances comparatively more T helper (T(H)) immunity. Unsupervised clustering of single-cell features reveals phenotypic and functional shifts over time and between cohorts. The third dose attenuates some features of T(H) cells in HD (tumor necrosis factor alpha [TNFÎ±]/interleukin [IL]-2 skewing), while others (CCR6, CXCR6, programmed cell death protein 1 [PD-1], and HLA-DR overexpression) persist. Therefore, a third vaccine dose is critical to achieving robust multifaceted immunity in hemodialysis patients, although some distinct T(H) characteristics endure.

Safety, immunogenicity, and effectiveness of COVID-19 vaccines for pregnant persons: A protocol for systematic review and meta analysis. INTRODUCTION: Numerous vaccines have been evaluated and approved for coronavirus disease 2019 (COVID-19). Since pregnant persons have been excluded from most clinical trials of COVID-19 vaccines, sufficient data regarding the safety of these vaccines for the pregnant person and their fetus have rarely been available at the time of product licensure. However, as COVID-19 vaccines have been deployed, data on the safety, reactogenicity, immunogenicity, and efficacy of COVID-19 vaccines for pregnant persons and neonates are becoming increasingly available. A living systematic review and meta-analysis of the safety and effectiveness of COVID-19 vaccines for pregnant persons and newborns could provide the information necessary to help guide vaccine policy decisions. METHODS AND ANALYSIS: We aim to conduct a living systematic review and meta-analysis based on biweekly searches of medical databases (e.g., MEDLINE, EMBASE, CENTRAL) and clinical trial registries to systematically identify relevant studies of COVID-19 vaccines for pregnant persons. Pairs of reviewers will independently select, extract data, and conduct risk of bias assessments. We will include randomized clinical trials, quasi-experimental studies, cohort, case-control, cross-sectional studies, and case reports. Primary outcomes will be the safety, efficacy, and

effectiveness of COVID-19 vaccines in pregnant persons, including neonatal outcomes. Secondary outcomes will be immunogenicity and reactogenicity. We will conduct paired meta-analyses, including prespecified subgroup and sensitivity analyses. We will use the grading of recommendations assessment, development, and evaluation approach to evaluate the certainty of evidence.

COVID-19 Vaccination in Patients With Cancer and Recipients of Cellular Therapy. COVID-19 continues to disproportionately affect patients with cancer because of their underlying immunocompromised state. Strategies to mitigate the impact of COVID-19 on patients with cancer include vaccination, which has demonstrated some level of protection, at least against serious complications such as respiratory failure and death, with limited safety concerns. In this narrative review, we discuss the current COVID-19 vaccines that are available in the United States, the published data regarding vaccine efficacy and safety in patients with cancer, current vaccination guidelines, and future directions.

IgA antibody dynamics in healthcare workers after CoronaVacÂ® vaccination and heterologous ComirnatyÂ® booster dose. BACKGROUND: This study is aimed at calculating the IgA antibody dynamic range in healthcare workers (HCWs) after immunization with CoronaVacÂ® and ComirnatyÂ® booster dose. METHODS: A total of 118 HCW serum samples from Southern Brazil were collected the day before the first vaccine dose (day 0) and + 20, + 40, + 110, + 200 days following the vaccine's first dose, and + 15 days after a ComirnatyÂ® booster dose. Immunoglobulin A (IgA) was quantified using immunoassays for anti-S1 (spike) protein antibodies (Euroimmun, LÃ¼beck, Germany). RESULTS: Seroconversion for the S1 protein occurred in 75 (63.56%) and 115 (97.47%) HCWs by day + 40 and day + 15 after the booster dose, respectively. There was an absence of IgA antibodies after the booster dose in two (1.69%) HCWs undergoing biannual rituximab administration and one (0.85%) HCW for no apparent reason. CONCLUSION: Complete vaccination showed a significant IgA antibody production response, and the booster dose considerably increased this response.

Recurrent generalized anhidrosis following COVID-19 vaccinations.

Systemic lupus, immunosuppressives, COVID-19 vaccination, and antibody response: comment on the article by Petri et al.

Post-Vaccination/Post-COVID Immune-Mediated Demyelination of the Brain and Spinal Cord: A Novel Neuroimaging Finding. INTRODUCTION: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causes coronavirus disease 2019 (COVID-19), which not only produces respiratory symptoms but is known to involve almost every system, and its neuroinvasive properties have been well demonstrated throughout the pandemic. Also, to combat the pandemic, there was rapid development and induction of various vaccination drives, following which many adverse events following immunization (AEFIs) have been reported, which include neurological complications as well. METHOD: We present a series of three cases, post vaccination, with and without a history of COVID illness that showed remarkably similar findings on magnetic resonance imaging (MRI). RESULT: A 38-year-old male presented with complaints of weakness of the bilateral lower limbs with sensory loss and bladder disturbance a day after receiving his first dose of ChadOx1 nCoV-19 (COVISHIELD) vaccine. A 50-year-old male with hypothyroidism characterized by autoimmune thyroiditis and impaired glucose tolerance experienced difficulty in walking 11.5 weeks after being administered with COVID vaccine (COVAXIN). A 38-year-old male presented with subacute onset progressive symmetric quadriparesis 2 months after their first dose of a COVID vaccine. The patient also had sensory ataxia, and his vibration sensation was impaired below C7. All three patients had typical pattern of involvement of the brain and spine on MRI with signal changes in bilateral corticospinal tracts, trigeminal tracts in the brain, and both lateral and posterior columns in the spine. CONCLUSION: This pattern of brain and spine involvement on MRI is a novel finding and is likely a result of post-vaccination/post-COVID immune-mediated demyelination.

Impact of barriers to SARS-Cov-2 vaccination uptake in HIV-infected patients. HIV-positive (PLWH) persons should take the SARS-CoV-2 vaccination first due to the increased risk of developing a deadly strain of COVID-19. That's why it's important to monitor population vaccination rates and identify PLWH who aren't immunized. PLWH were examined for SARS-CoV-2 immunization and non-vaccination. It was a cross-sectional study, conducted in the Tehsil Headquarters Hospital Sohawa from May-October 2021. Ninety five HIV-positive patients of both genders were presented. 14-60 years were the age of patients. HIV, demographics and vaccination status were collected after written informed consent. Clinically adverse outcomes were assessed among vaccinated and non-vaccinated HIV infected patients. There were 56 (58.9%) males and 39 (41.1%) females. Frequency of homosexual transmission group was higher among 48 (50.2%) cases, followed by heterosexual group 25 (26.3%), 15 (15.8%) patients with injected drugs and 7 (7.4%) patients were HIV-infected with other reason. We found that 54 (56.8%) patients were vaccinated and 41 (43.2%) patients were unvaccinated. Frequency of ICU stay and mortality was significantly higher among non-vaccinated patients with p value <0.005. Non-vaccinated patients cited no-safety, medical facility distrust and covid-19 as a transient illness. This study found HIV-unvaccinated people had increased odds of unfavorable outcomes.

Association of Cytomegalovirus Serostatus With Severe Acute Respiratory Syndrome Coronavirus 2 Vaccine Responsiveness in Nursing Home Residents and Healthcare Workers. BACKGROUND: Latent cytomegalovirus (CMV) infection is immunomodulatory and could affect mRNA vaccine responsiveness. We sought to determine the association of CMV serostatus and prior severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection with antibody (Ab) titers after primary and booster BNT162b2 mRNA vaccinations in healthcare workers (HCWs) and nursing home (NH) residents. METHODS: Nursing home residents (N = 143) and HCWs (N = 107) were vaccinated and serological responses monitored by serum neutralization activity against Wuhan and Omicron (BA.1) strain spike proteins, and by bead-multiplex immunoglobulin G immunoassay to Wuhan spike protein and its receptor-binding domain (RBD). Cytomegalovirus serology and levels of inflammatory biomarkers were also measured. RESULTS: Severe acute respiratory syndrome coronavirus 2-naive CMV seropositive (CMV(+)) HCWs had significantly reduced Wuhan-neutralizing Ab (P = .013), anti-spike (P = .017), and anti-RBD (P = .011) responses 2 weeks after primary vaccination series compared with responses among CMV seronegative (CMV(-)) HCWs, adjusting for age, sex, and race. Among NH residents without prior SARS-CoV-2 infection, Wuhan-neutralizing Ab titers were similar 2 weeks after primary series but were reduced 6 months later (P = .012) between CMV(+) and CMV(-) subjects. Wuhan-neutralizing Ab titers from CMV(+) NH residents who had prior SARS-CoV-2 infection consistently trended lower than titers from SARS-CoV-2 experienced CMV(-) donors. These impaired Ab responses in CMV(+) versus CMV(-) individuals were not observed after booster vaccination or with prior SARS-CoV-2 infection. CONCLUSIONS: Latent CMV infection adversely affects vaccine-induced responsiveness to SARS-CoV-2 spike protein, a neoantigen not previously encountered, in both HCWs and NH residents. Multiple antigenic challenges may be required for optimal mRNA vaccine immunogenicity in CMV(+) adults.

Upper extremity deep venous thrombosis after BNT162b2 mRNA COVID-19 vaccine case report. We describe a case of an otherwise healthy 60-year-old female patient who presented 6â€‰days after receipt of the second dose of the BNT162b2 mRNA COVID-19 (Pfizer/BioNTech) vaccine and was found to have upper extremity deep venous thrombosis.

Syncope With Sinus Arrest Following a Single Dose of a COVID-19 Vaccine. Vaccines against the severe acute respiratory syndrome coronavirus 2(SARS-CoV-2) are of paramount importance in combating the current coronavirus disease 2019 (COVID-19) pandemic.Â Syncopal episodes following routine vaccinations are well-reported; however, only a few cases of syncope following SARS-CoV-2

vaccines exist in the literature. This is a case report of a 21-year-old female patient who developed recurrent syncopal attacks over three months that started one day after receiving the first dose of the Pfizer-BioNTech COVID-19 vaccine (Pfizer, New York City; BioNTech,Â Mainz, Germany). Holter monitoring during successive episodes showed progressive bradycardia followed by a prolonged sinus arrest. The patient eventually requiredÂ pacemaker placement that resulted in the total resolution of her symptoms.Â Further studies are required to investigate a possible correlation and the mechanisms involved.

Are some COVID-19 vaccines better than others regarding the short-term side effects? Controlling the pandemic is primarily achieved through vaccination against COVID-19. Although various COVID-19 vaccines are used worldwide, little is known about their safety and side effects. As a result, the objectives of this research are to identify the shortterm side effects of the different COVID-19 vaccines used in Iraq. Furthermore, exploring the association between experienced side effects and the brand of vaccine received. The current study evaluated the shortterm side effects of Pfizer, Sinopharm and AstraZeneca vaccines among healthcare workers in Iraq. The study used a questionnaire that consisted of dedicated sections to collect demographic data, the brand of COVID-19 vaccine received, the short-term side effects, and the willingness to receive a third booster dose. Regarding the post-vaccination side effects, the studied COVID-19 vaccines showed a comparable range of side effects, such as headaches, fever, muscle pain, joint pain, malaise, tenderness, redness, as well as pain at the site of vaccination. However, the Pfizer vaccine showed a higher incidence of pain and tenderness at the site of injection and fever compared to AstraZeneca and Sinopharm, respectively. On the other hand, the Sinopharm vaccine was associated with a higher occurrence of headaches, muscle pain, joint pain, and malaise in comparison to the Pfizer and AstraZeneca vaccines, respectively. In summary, the short-term side effects of the three vaccines were comparable; however, the AstraZeneca vaccine was associated with a lower risk of side effects.

Surgical Thrombectomy for Extensive Cerebral Venous Sinus Thrombosis after COVID-19 Vaccination : A Novel Surgical Technique and Literature Review. Surgical treatment of refractory and extensive cerebral venous sinus thrombosis (CVST) has limited applications. Here, we describe an open, direct sinus thrombectomy in the early phase of extensive CVST. A 49-year-old man with extensive CVST that occurred after the coronavirus disease 2019 (COVID-19) vaccination and affected the drainage of the LabbÃ© vein presented with clinical deterioration and left temporal hemorrhagic infarction. Since the patient had extensive CVST, we determined that systemic anticoagulation and endovascular treatment were not suitable treatment options. Therefore, we decided on an emergency surgical treatment and performed direct surgical thrombectomy. We followed extended suboccipital approach and made multiple incisions on the sinuses, exposing the posterior superior sagittal sinus to the transverse sigmoid junction. Consequently, the clinical condition of the patient dramatically improved, resulting in a favorable outcome with a modified Rankin Scale score of 0. Performing emergency open surgical thrombectomy was a technically feasible treatment option that recanalized obstructed sinuses. Importantly, the patient recovered with a good clinical outcome. Early maximal surgical thrombectomy is an effective and lifesaving method to treat extensive CVST with hemorrhagic infarction.

Myelin Oligodendrocyte Glycoprotein Antibody-Associated Encephalomyelitis and Optic Neuritis After COVID-19 Vaccination and Relapsing Optic Neuritis After COVID-19 Infection.

Myelin oligodendrocyte glycoprotein antibody-associated optic neuritis following third dose of BNT162b2 COVID-19 vaccine in a patient with systemic lupus erythematosus.

Alopecia areata induced by the booster shot of Sinovac COVID-19 vaccination: a case report.

Side effects following first dose of COVID-19 vaccination in Ho Chi Minh City, Vietnam. Vaccines are strongly recommended globally as an effective measure to prevent serious illness from and

spread of COVID-19. Concerns about safety following vaccination continue to be the most common reason that people do not accept the vaccine. This retrospective study was carried out on 4341 people who received the first dose of ChAdOx1 nCoV-19, BBIBP-CorV, or mRNA-1273 vaccine at Jio Health Clinic in Ho Chi Minh City, Vietnam. Post-injection side effects were either reported by participants or actively collected by health care staff by means of telemedicine. Local side effects were reported by 35.5% of all individuals, with pain being the most common symptom (33.3%). Systemic side effects were reported by 44.2% of individuals, with fever (25.3%) and fatigue (21.4%) being the most common. Ageâ€‰â‰¤60â€‰years, female gender, and ChAdOx1 nCoV-19 were significant independent risk factors for both local and systemic side effects, while a history of allergy was significant as a risk factor for local side effects. A total of 43 individuals (1.0%) reported concerning symptoms of rare severe complications, which were addressed and treated by physicians via Jio Health app.

Immune Thrombocytopenia and Cerebral Venous Sinus Thrombosis Following COVID-19 Vaccination: A Case Report. Mass vaccination against coronavirus disease 2019 (COVID-19) has been safe and effective. The ongoing emergence of vaccine-induced complications has challenged the public trust in vaccination programs and, though uncommon, can lead to significant morbidity and mortality. Vaccine-induced immune thrombocytopenia and thrombosis (VITT) is a rare and fatal complication of the COVID-19 vaccine. We present a rare case of VITT in a young female who presented with worsening headache, body rash with deteriorating neurological deficit after 12 days of the second dose of the ChAdOx1 COVID-19 vaccine. Initial blood tests showed thrombocytopenia with deranged clotting time and D-dimer levels. Her computed tomography venogram showed thrombosis in the left transverse sinus, and she was diagnosed with a provisional diagnosis of VITT. She initially managed with dexamethasone, intravenous immunoglobulins, and apixaban to reverse the autoimmune process. Our case highlights the clinical course, diagnosis, and management of VITT, which will assist physicians in the timely recognition and adequate management of VITT.

Hyperacute optic neuritis in a patient with COVID-19 infection and vaccination: a case report. BACKGROUND: As scientific knowledge continues to grow regarding coronavirus disease 2019 (COVID-19) infection, several neuro-ophthalmological manifestations have emerged, including rare reports of optic neuritis. Optic neuritis is an inflammatory demyelinating condition of the optic nerve that typically presents as subacute, unilateral vision loss and pain on eye movement. Several cases of COVID-19 infection and COVID-19 vaccination related cases of optic neuritis have been reported. We present a case of hyperacute, unilateral optic neuritis after both recent COVID-19 infection and subsequent booster vaccination. CASE PRESENTATION: Within two hours after receiving her COVID-19 booster vaccination, a 58-year-old female began experiencing bilateral eye pain, worsened by eye movements. The patient had previously contracted a mild COVID-19 infection three weeks prior to receiving her booster vaccination, confirmed by a rapid antigen test. The pain persisted in her right eye for a week at which time she presented to an ophthalmology clinic. She denied any changes to her visual acuity. Neuroimaging revealed right optic nerve enhancement, and the patient was admitted to the hospital for a course of intravenous steroids, which quickly resolved her eye pain. CONCLUSION: To our knowledge, this is the first reported case of COVID-19 related optic neuritis following both COVID-19 infection and vaccination. High clinical suspicion is needed to make the appropriate diagnosis, as cases of COVID-19 related optic neuritis may exhibit mild presentations, as was the case with our patient.

SARS-CoV-2-reactive antibody waning, booster effect and breakthrough SARS-CoV-2 infection in hematopoietic stem cell transplant and cell therapy recipients at one year after vaccination. The kinetics of SARS-CoV-2 reactive IgG antibodies after full vaccination and booster in allogeneic and autologous stem cell transplantation (allo-HSCT, ASCT) and chimeric antigen receptor T-cell therapy

(CAR-T) are of utmost importance for estimating risk of infection. A prospective multicenter registry-based cohort study, conducted from December 2020 to July 2022 was used to analyze antibody waning over time, booster effect and the relationship of antibody response and breakthrough infection in 572 recipients (429 allo-HSCT, 121 ASCT and 22 CAR-T cell therapy). A significant decline in antibody titers was observed at 3 and 6 months after full vaccination in recipients without pre-vaccine SARS-CoV-2 infection, whereas recipients infected prior to vaccination showed higher and stable antibody titers over time. In poor responders, a booster dose was able to increase antibody titers in 83% of allo-HSCT and 58% of ASCT recipients but not in CART-T cell recipients [0%] (pâ€‰<â€‰0.01). One-year cumulative incidence of breakthrough infection was 15%, similar among cell therapy procedures. Immunosuppressive drugs at the time of vaccination [hazard ratio (HR) 1.81, pâ€‰=â€‰0.0028] and reduced intensity conditioning (HR 0.49, pâ€‰=â€‰0.011) were identified as the only conditions associated with different risk of breakthrough infection in allo-HSCT recipients. Antibody titers were associated with breakthrough infection and disease severity. No death was observed among the 72 breakthrough infections. Antibody level decay after the first two vaccine doses was common except in recipients with pre-vaccination SARS-CoV-2 infection. Poorly responding allo-HSCT recipients showed a response advantage with the booster as compared to ASCT and, especially, the null response found in CAR-T cell recipients. Antibody titers were positively correlated with the risk of breakthrough SARS-CoV-2 infection which was mainly driven by the immunosuppression status.

Reports of Guillain-Barre Syndrome Following COVID-19 Vaccination in the USA: An Analysis of the VAERS Database. BACKGROUND AND PURPOSE: An association between Guillain-Barre syndrome and its variants (GBS/V) and vaccines has led to hesitancy toward vaccination. COVID-19 vaccines could theoretically provoke GBS/V via immune activation. We analyzed reports of GBS/V after COVID-19 vaccination in the vaccine adverse event reporting system (VAERS). METHODS: The VAERS database is a surveillance system used to report vaccination events in the USA, and is open for consumers and physicians to access. It was queried for reports of GBS/V following COVID-19 vaccination. Reports were reviewed by four neurologists. Modified diagnostic criteria were used to classify reports into definite, possible, and not GBS/V or insufficient data. Descriptive statistics were used to describe the sample, chi-square tests and one-way ANOVAs were used to compare intergroup differences, and t-test were used to compare group means. RESULTS: In 2021, 815 reports of GBS/V were filed. The completion rate for the variables in VAERS was 93.5%. The median age was 55 years (interquartile range [IQR]=5-86 years) and 50% of the subjects were male. The median time of onset was 10 days (IQR=0-298 days), 11% reported onset on the day of vaccination, and 13% reported onset after 6 weeks. Hospitalization was reported by 77%, with a median stay of 7 days (IQR=1-150 days). Lack of recovery, permanent disability, and death constituted 57%, 46%, and 2% of the reports, respectively. Based on GBS/V criteria, 47% of the cases were definite, 16% were possible, and 37% were not GBS/V or insufficient data. An alternate diagnosis was provided in 9% of cases. CONCLUSIONS: GBS/V reports following COVID-19 vaccination were common, but many occurred outside of the expected timelines for GBS/V. Only 47% of cases represented definite GBS/V.

Two Case Reports of Chronic Inflammatory Demyelinating Polyneuropathy After COVID-19 Vaccination. The occurrence of chronic inflammatory demyelinating polyneuropathy (CIDP) related to coronavirus disease 2019 (COVID-19) has rarely been reported. We describe two patients who were diagnosed with CIDP after COVID-19 vaccination. A 72-year-old man presented with a progressive tingling sensation and weakness below both knees for two weeks. He had been vaccinated against COVID-19 (mRNA-1273 vaccine) a month before the appearance of symptoms. Demyelinating polyneuropathy was observed in the nerve conduction studies (NCS). Intravenous immunoglobulin (IVIg) was administered under the diagnosis of Guillain-BarrÃ© syndrome (GBS), and

his symptoms were improved. However, his symptoms relapsed at 10 weeks from the onset. Oral prednisolone, azathioprine, and IVIg were administered as treatment. The second case was a 50-year-old man who complained of a bilateral leg tingling sensation and gait disturbance lasting four weeks. He had received the Ad26.COV2.S vaccine against COVID-19 five weeks prior. Demyelinating polyneuropathy was observed in the NCS. He was treated with oral prednisolone, azathioprine, and IVIg for CIDP because his symptoms had lasted for more than 12 weeks from the onset. A causal relationship has not been established between COVID-19 vaccination and CIDP; however, CIDP may follow COVID-19 vaccination. As CIDP treatment is different from that for GBS, clinicians should closely monitor patients diagnosed with GBS associated with COVID-19 whether they deteriorate after initial treatment.

A Brief Survey of Post-COVID-19 Vaccination Mucocutaneous and Dermatological Reactions in Children and Adolescents: Answer to Many Highly Questioned Concerns.

Suspected COVID-19 mRNA Vaccine-Induced Postural Orthostatic Tachycardia Syndrome. We present a case of a 15-year-old South Asian male who developed suspected postural orthostatic tachycardia syndrome (POTS) two weeks after receiving the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine booster, which was successfully managed with low-dose fludrocortisone and ivabradine.Â Clinicians should be aware of the Pfizer-BioNTech COVID-19 vaccine being implicated with the onset of POTS.

SARS-CoV-2 Vaccine-Induced T-Cell Response after Three Doses in People Living with HIV on Antiretroviral Therapy Compared to Seronegative Controls (CTN 328 COVAXHIV Study). People living with HIV (PLWH) may be at risk for poor immunogenicity to certain vaccines, including the ability to develop immunological memory. Here, we assessed T-cell immunogenicity following three SARS-CoV-2 vaccine doses in PLWH versus uninfected controls. Blood was collected from 38 PLWH on antiretroviral therapy and 24 age-matched HIV-negative controls, pre-vaccination and after 1st/2nd/3rd dose of SARS-CoV-2 vaccines, without prior SARS-CoV-2 infection. Flow cytometry was used to assess ex vivo T-cell immunophenotypes and intracellular Tumor necrosis factor (TNF)-Î±/interferon(IFN)-Î³/interleukin(IL)-2 following SARS-CoV-2-Spike-peptide stimulation. Comparisons were made using Wilcoxon signed-rank test for paired variables and Mann-Whitney for unpaired. In PLWH, Spike-specific CD4 T-cell frequencies plateaued post-2nd dose, with no significant differences in polyfunctional SARS-CoV-2-specific T-cell proportions between PLWH and uninfected controls post-3rd dose. PLWH had higher frequencies of TNFÎ±+CD4 T-cells and lower frequencies of IFNÎ³+CD8 T-cells than seronegative participants post-3rd dose. Regardless of HIV status, an increase in naive, regulatory, and PD1+ T-cell frequencies was observed post-3rd dose. In summary, two doses of SARS-CoV-2 vaccine induced a robust T-cell immune response in PLWH, which was maintained after the 3rd dose, with no significant differences in polyfunctional SARS-CoV-2-specific T-cell proportions between PLWH and uninfected controls post-3rd dose.

R-DOTAP Cationic Lipid Nanoparticles Outperform Squalene-Based Adjuvant Systems in Elicitation of CD4 T Cells after Recombinant Influenza Hemagglutinin Vaccination. It is clear that new approaches are needed to promote broadly protective immunity to viral pathogens, particularly those that are prone to mutation and escape from antibody-mediated immunity. Prototypic pathogens of this type are influenza and SARS-CoV-2, where the receptor-binding protein exhibits extremely high variability in its receptor-binding regions. T cells, known to target many viral proteins, and within these, highly conserved peptide epitopes, can contribute greatly to protective immunity through multiple mechanisms but are often poorly recruited by current vaccine strategies. Here, we have studied a promising novel pure enantio-specific cationic lipid 1,2-dioleoyl-3-trimethylammonium-propane (R-DOTAP), which was previously recognized for its ability to generate anti-tumor immunity through the induction of potent cytotoxic CD8 T cells. Using a preclinical mouse model, we have

assessed an R-DOTAP nanoparticle adjuvant system for its ability to promote CD4 T cell responses to vaccination with recombinant influenza protein. Our studies revealed that R-DOTAP consistently outperformed a squalene-based adjuvant emulsion, even when it was introduced with a potent TLR agonist CpG, in the ability to elicit peptide epitope-specific CD4 T cells when quantified by IFN-Î³ and IL-2 ELISpot assays. Clinical testing of R-DOTAP containing vaccines in earlier work by others has demonstrated an acceptable safety profile. Hence, R-DOTAP can offer exciting opportunities as an immune stimulant for next-generation prophylactic recombinant protein-based vaccines.

Humoral SARS-CoV-2 Immune Response in COVID-19 Recovered Vaccinated and Unvaccinated Individuals Related to Post-COVID-Syndrome. BACKGROUND: The duration of anti-SARS-CoV-2-antibody detectability up to 12 months was examined in individuals after either single convalescence or convalescence and vaccination. Moreover, variables that might influence an anti-RBD/S1 antibody decline and the existence of a post-COVID-syndrome (PCS) were addressed. METHODS: Forty-nine SARS-CoV-2-qRT-PCR-confirmed participants completed a 12-month examination of anti-SARS-CoV-2-antibody levels and PCS-associated long-term sequelae. Overall, 324 samples were collected. Cell-free DNA (cfDNA) was isolated and quantified from EDTA-plasma. As cfDNA is released into the bloodstream from dying cells, it might provide information on organ damage in the late recovery of COIVD-19. Therefore, we evaluated cfDNA concentrations as a biomarker for a PCS. In the context of antibody dynamics, a random forest-based logistic regression with antibody decline as the target was performed and internally validated. RESULTS: The mean percentage dynamic related to the maximum measured value was 96 (Â±38)% for anti-RBD/S1 antibodies and 30 (Â±26)% for anti-N antibodies. Anti-RBD/S1 antibodies decreased in 37%, whereas anti-SARS-CoV-2-anti-N antibodies decreased in 86% of the subjects. Clinical anti-RBD/S1 antibody decline prediction models, including vascular and other diseases, were cross-validated (highest AUC 0.74). Long-term follow-up revealed no significant reduction in PCS prevalence but an increase in cognitive impairment, with no indication for cfDNA as a marker for a PCS. CONCLUSION: Long-term anti-RBD/S1-antibody positivity was confirmed, and clinical parameters associated with declining titers were presented. A fulminant decrease in anti-SARS-CoV-2-anti-N antibodies was observed (mean change to maximum value 30 (Â±26)%). Anti-RBD/S1 antibody titers of SARS-CoV-2 recovered subjects boosted with a vaccine exceeded the maximum values measured after single infection by 235 Â± 382-fold, with no influence on preexisting PCS. PCS long-term prevalence was 38.6%, with an increase in cognitive impairment compromising the quality of life. Quantified cfDNA measured in the early post-COVID-19 phase might not be an effective marker for PCS identification.

A Synthetic Biology Approach for Vaccine Candidate Design against Delta Strain of SARS-CoV-2 Revealed Disruption of Favored Codon Pair as a Better Strategy over Using Rare Codons. The SARS-CoV-2 delta variant (B.1.617.2) appeared for the first time in December 2020 and later spread worldwide. Currently available vaccines are not so efficacious in curbing the viral pathogenesis of the delta strain of COVID; therefore, the development of a safe and effective vaccine is required. In the present study, we envisaged molecular patterns in the structural genes' spike, nucleoprotein, membrane, and envelope of the SARS-CoV-2 delta variant. The study was based on determining compositional features, dinucleotide odds ratio, synonymous codon usage, positive and negative codon contexts, rare codons, and insight into relatedness between the human host isoacceptor tRNA and preferred codons from the structural genes. We found specific patterns, including a significant abundance of T nucleotide over all other three nucleotides. The underrepresentation of GpA, GpG, CpC, and CpG dinucleotides and the overrepresentation of TpT, ApA, CpT, and TpG were observed. A preference towards ACT- (Thr), AAT- (Asn), TTT- (Phe), and TTG- (Leu) initiated codons and aversion towards CGG (Arg), CCG (Pro), and CAC (His) was present in the structural genes of the delta strain. The interaction between the host tRNA pool and preferred codons of the envisaged structural genes

revealed that the virus preferred the codons for those suboptimal numbers of isoacceptor tRNA were present. We see this as a strategy adapted by the virus to keep the translation rate low to facilitate the correct folding of viral proteins. The information generated in the study helps design the attenuated vaccine candidate against the SARS-CoV-2 delta variant using a synthetic biology approach. Three strategies were tested: changing TpT to TpA, introducing rare codons, and disrupting favored codons. It found that disrupting favored codons is a better approach to reducing virus fitness and attenuating SARS-CoV-2 delta strain using structural genes.

Incidence and Associated Factors of SARS-CoV-2 Infection Post-mRNA-1273 Booster Vaccination in Health-Care Workers. The COVID-19 pandemic has caused significant morbidity and mortality worldwide, especially among health-care workers. One of the most important preventive measures is vaccination. This study examined factors associated with the incidence rate of SARS-CoV-2 infection after mRNA-1273 booster vaccination (preceded by the CoronaVac primary vaccination) and the antibody profile of health-care workers at one of the tertiary hospitals in Indonesia. This was a combined retrospective cohort and cross-sectional study. Three hundred health-care workers who were given the mRNA-1273 booster vaccine a minimum of 5 months prior to this study were randomly selected. Participants were then interviewed about their history of COVID-19 vaccination, history of SARS-CoV-2 infection, and comorbidities. Blood samples were taken to assess IgG sRBD antibody levels. The median antibody level was found to be 659 BAU/mL (min 37 BAU/mL, max 5680 BAU/mL, QIR 822 BAU/mL) after the booster, and this was not related to age, sex, comorbidities, or adverse events following immunization (AEFI) after the booster. SARS-CoV-2 infection after the booster was correlated with higher antibody levels. In sum, 56 participants (18.6%) experienced SARS-CoV-2 infection after the mRNA-1273 booster vaccination within 5 months. Incidence per person per month was 3.2%. Age, sex, diabetes mellitus type 2, hypertension, obesity, and post-booster AEFI were not related to COVID-19 incidence after the booster. History of SARS-CoV-2 infection before the booster vaccination was significantly associated with a reduced risk of SARS-CoV-2 infection after booster vaccination, with a relative risk (RR) of 0.21 (95% CI 0.09-0.45, $p < 0.001$).

Development of Autoantibodies Following BNT162b2 mRNA COVID-19 Vaccination and Their Association with Disease Flares in Adult Patients with Autoimmune Inflammatory Rheumatic Diseases (AIIRD) and the General Population: Results of 1-Year Prospective Follow-Up Study. Development of autoantibodies following BNT162b2 mRNA COVID-19 vaccination and their association with disease flares in adult patients with autoimmune inflammatory rheumatic diseases (AIIRD) and the general population: results of 1-year prospective follow-up study. We conducted a prospective study aimed at investigating the incidence of appearance of autoantibodies (antinuclear, antiphospholipid, and rheumatoid factor) in the sera of 463 adult patients with AIIRD compared to 55 controls from the general population prior to, and following the second and third vaccine doses, and at 1-year of follow-up. Pre- and post-vaccination disease activity indices and the association of autoantibodies with rheumatic disease flares and new onset AIIRD were examined. Autoantibody development of any type in AIIRD patients vs. the controls was 4.0% (vs. 6.7%, $p = 0.423$) following two vaccine doses and 7.6% (vs. 0%, $p = 0.152$) after three doses. There was no significant difference in sex, age, or disease-type among individuals with and without autoantibody development, regardless of the immunosuppressant use. More patients developed autoantibodies following the third than the second vaccine dose ($p = 0.004$). Disease flares occurred in 5.8% and 7.2% of AIIRD patients following second and third vaccine doses, respectively, with autoantibody production increasing the risk of flares following the second ($p = 0.002$) and third ($p = 0.004$) vaccine doses. BNT162b2 vaccination resulted in the development of autoantibodies in a minority of AIIRD patients and controls. Autoantibody development was associated with disease flares in patients, but no new-onset autoimmunity was observed.

Case Report of Serum Sickness-like Reaction following the First Dose of the Chimpanzee Adenovirus-Vectored AstraZeneca COVID-19 Vaccine, ChAdOx1. Serum sickness-like reaction from serum sickness is critical. Serum sickness-like reaction has comparable symptoms to serum sickness, but their underlying pathophysiology is distinct. This delayed hypersensitivity response was first characterized as a drug-induced reaction and is uncommon in adults; it is more common in children. COVID-19 vaccinations are now being routinely given in the COVID-19 period, and adverse reactions to immunization have been recorded. We present a case of COVID-19 vaccination-induced serum sickness-like reaction which developed after receiving the first dose of AstraZeneca COVID-19 vaccine.

Renal Biopsy Diagnosis of Acute Tubular Injury after Pfizer-BioNTech COVID-19 Vaccination: A Case Report. Coronavirus disease 2019 (COVID-19) is a severe respiratory infection that can be fatal in unvaccinated individuals; however, acute kidney injury (AKI) is a rare adverse reaction to COVID-19 vaccination. AKI resulting from multiple conditions can have severe consequences, including end-stage renal failure, if not treated with immunosuppressive agents. However, acute tubular injury (ATI) as the sole cause of AKI has not been previously reported. Herein, we discuss an obese 54-year-old man with type 2 diabetes who received four COVID-19 vaccines; three from Pfizer and one from Moderna. Diabetic retinopathy, urinary protein, and occult blood were absent with no other underlying diseases. There was no history of COVID-19 infection. He was referred to our hospital 5 days after receiving the fourth Pfizer-BioNTech COVID-19 vaccine dose with stage 3 AKI. Urinary findings revealed new proteinuria and glomerular occult blood. Physical examination and infection testing were unremarkable. Steroids were introduced on admission for rapidly progressive glomerulonephritis. A renal biopsy performed on Day 2 revealed only ATI. Therefore, steroids were discontinued on Day 5, after which renal function recovered spontaneously, and urinalysis abnormalities disappeared. Renal function remained normal during follow-up. We report a case of AKI with severe renal dysfunction after COVID-19 vaccination, wherein renal biopsy effectively determined the disease status (ATI), which did not require immunosuppressive treatment.

Platelet Activation and Cytokine Release of Interleukin-8 and Interferon-Gamma-Induced Protein 10 after ChAdOx1 nCoV-19 Coronavirus Vaccine Injection. Coronavirus disease 2019 (COVID-19) vaccines are associated with serious thromboembolic or thrombocytopenic events including vaccine-induced immune thrombocytopenia and thrombosis and immune thrombocytopenia, particularly AZD1222/ChAdOx1. According to the proposed mechanism, COVID-19 vaccines stimulate inflammation and platelet activation. In this study, we analyzed the role of AZD1222/ChAdOx1 vaccines in the activation of platelets and the release of anti-PF4 antibodies and inflammatory cytokines in a cohort of healthy donors without vaccine-induced immune thrombotic thrombocytopenia (VITT). Forty-eight healthy volunteers were enrolled in this study. Blood samples were collected from peripheral blood at three time points: before vaccination and 1 and 7 days after vaccination. Compared with the prevaccination data, a decrease in the leukocyte and platelet counts was observed 1 day after vaccination, which recovered 7 days after injection. The percentage of activated GPIIb/IIIa complex (PAC-1) under high ADP or thrombin receptor-activating peptide stimulation increased 1 day after vaccination. Furthermore, interluekin-8 (IL-8) and interferon-gamma-induced protein 10 (IP-10) increased significantly. Additionally, platelet activation and inflammation, with the release of cytokines, were observed; however, none of the individuals developed VITT. Mild thrombocytopenia with platelet activation and inflammation with an elevation of IL-8 and IP-10 were observed after AZ vaccination.

A Case Series and Literature Review of Telogen Effluvium and Alopecia Universalis after the Administration of a Heterologous COVID-19 Vaccine Scheme. COVID-19 vaccines have positively changed the course of the pandemic. They entered the market after only one year of the initial trials,

which that yielded positive results in terms of safety and efficacy. However, after inoculating billions of people in the most extensive vaccination campaign worldwide, mild but common and some rare but potentially fatal adverse events have been reported. Among several self-reported adverse events, hair loss and alopecia have been linked to COVID-19 mRNA or viral vector vaccines. We tracked and followed a series of five cases with post-vaccine telogen effluvium and alopecia development in Ecuador. Here, we reported the clinical presentation of two women and three men with the diagnosis of post-vaccine hair loss. All patients received a heterologous vaccination scheme (mRNA and attenuated virus vaccine) with an additional viral vector booster associated with the apparition of telogen effluvium and alopecia universalis between 3 and 17 days after the vaccine was administered.

Differential COVID-19 Vaccination Uptake and Associated Factors among the Slum and Estate Communities in Uganda: A Cross-Sectional Population-Based Survey. Vaccination against COVID-19 remains one of the ultimate solutions to the ongoing pandemic. This study examined and compared the completion of primary COVID-19 vaccination series and associated factors in the slum and estate communities of Uganda. This was a cross-sectional survey conducted among 1025 slum and estate residents. Logistic regression models were fitted. Of the 1025 participants, 511 were slum residents and 514 were estate residents. Completion of COVID-19 vaccination was 43.8% in the slum community and 39.9% in the estate community ($p = 0.03$). Having more knowledge about COVID-19 was positively associated with completing COVID-19 vaccination in both communities. Perceived benefits and cues to action also had a positive association, but only among the slum residents. However, perceiving people infected with COVID-19 as having a high death rate, perceived barriers such as serious side effects and long distances, and depressive symptoms had negative associations with vaccine uptake among the slum community, but not in the estate community. Addressing barriers to vaccination, strengthening and utilizing the various cues to action, engagement of religious and cultural leaders, and continued community education and sensitization tailored to the needs of each community are potentially vital strategies in raising vaccination rates. Consideration of socioeconomic impact-alleviation strategies, especially among the urban poor, would also be beneficial.

COVID-19 Vaccine-Induced Lichenoid Eruptions-Clinical and Histopathologic Spectrum in a Case Series of Fifteen Patients with Review of the Literature. Lichen planus is a distinctive mucocutaneous disease with well-established clinical and histopathologic criteria. Lichenoid eruptions closely resemble lichen planus and may sometimes be indistinguishable from it. Systemic agents previously associated have included medications, viral infections and vaccines. Sporadic case reports of lichen planus and lichenoid reactions associated with COVID-19 vaccines have recently emerged. Herein, we review the world literature (31 patients) and expand it with a case series of 15 patients who presented with vaccine-induced lichenoid eruption (V-ILE). The spectrum of clinical and histopathologic findings is discussed with emphasis on the subset whose lesions manifested in embryologic fusion lines termed lines of Blaschko. This rare Blaschkoid distribution appeared in seven of the 46 patients studied. Of interest, all seven were linked to the mRNA COVID-19 vaccines. We believe that all lichenoid eruptions should be approached with a heightened index of suspicion and patients should be specifically questioned with regards to their vaccination history. When diagnosed early in its course, V-ILE is easily treated and resolves quickly in almost all patients with or without hyperpigmentation. Additional investigative studies regarding its immunopathology and inflammatory signaling pathways may offer insight into other Th1-driven autoimmune phenomena related to COVID-19 vaccination.

Self-Reported Allergic Adverse Events Following Inactivated SARS-CoV-2 Vaccine (TURKOVACâ„¢) among General and High-Risk Population. TURKOVACâ„¢ is a whole-virion inactivated COVID-19 vaccine which was developed and granted emergency use and conditional marketing authorization in

December 2021 in TÃ¼rkiye. The objective of this study is to assess the distribution and the severity of allergic adverse events following the administration of the vaccine as the primary or the booster dose in 15 provinces in TÃ¼rkiye. In this cohort study, between February and May 2022, in the selected 15 provinces having an adequate number of health care personnel in the community health centers to conduct the study, 32,300 people having the first, the second, or the booster dose of the vaccine were invited to the survey. A total of 29,584 people voluntarily agreed to participate to the survey and were given a structured questionnaire after a minimum of 10 days following the vaccination. In our study, only 0.5% of the participants (142 persons) reported to experience any allergic reaction, and 12 of them (8.5%) reported to be given medical treatment in a health center. Male predominance (55.6%) was observed among participants reported to experience any allergic reaction. No hospitalization was recorded. Of the participants, 4.4% (1315 people) reported to have a history of allergy. The most reported allergens were drugs. Among the participants without a known history of allergy (n = 28,269), 0.4% of them (110 people) reported to experience an allergic reaction following the vaccination, and 5.4% of the allergic reactions (six people) were reported to be treated in a health center. The percentage of the participants given any medical treatment among the participants without a known history of allergy is 0.02%. No immediate or anaphylactic reaction was reported. Among the participants with a known history of allergy (n = 1315), 32 people (2.4% of them) reported to experience an allergic reaction following the vaccination, and 18.7% of the allergic reactions (six people) were reported to be prescribed a medical treatment. The percentage of the participants given any medical treatment among the participants with a known history of allergy is 0.4%. A known history of allergy increased the risk of having an allergic experience by approximately six times following vaccination. As a whole-virion inactivated SARS-CoV-2 vaccine, the TURKOVACâ„¢ vaccine, with a low allergic reaction-related adverse event profile, can be an alternative to other COVID-19 vaccines.

New Onset of Giant Cell Arteritis following ChAdOx1-S (Vaxevria(Â®)) Vaccine Administration. We report a 78-year-old man presenting with persistent headaches in vertex and temporo-parietal area; fatigue, worsening after walking; jaw claudication; scotomas; pharyngodynia; and dry cough after the second dose of the SARS-CoV-2 vaccine (ChAdOx1-S) administration. Laboratory findings showed an elevated C-reactive protein level and FDG-CT PET showed evidence of active large vessel vasculitis with diffuse abnormal artery uptake. Under suspicion of vasculitis, a temporal arteries biopsy was performed; the histopathologic findings demonstrated the transmural inflammatory infiltrate with giant cells, compatible with giant cell arteritis. Although the overall incidence of vaccine-triggered autoimmunity is low, rheumatologists worldwide should be aware of autoimmune diseases as a new potential adverse event of vaccines.

Investigation of Neurological Complications after COVID-19 Vaccination: Report of the Clinical Scenarios and Review of the Literature. Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), broke out in 2019 and became a pandemic in 2020. Since then, vaccines have been approved to prevent severe illness. However, vaccines are associated with the risk of neurological complications ranging from mild to severe. Severe complications such as vaccine-induced immune thrombotic thrombocytopenia (VITT) associated with acute ischaemic stroke have been reported as rare complications post-COVID-19 vaccination. During the pandemic era, VITT evaluation is needed in cases with a history of vaccination within the last month prior to the event. Cerebral venous sinus thrombosis (CVST) should be suspected in patients following immunization with persistent headaches who are unresponsive to analgesics. In this article, we investigated neurological complications after COVID-19 vaccination and provided more subsequent related clinical studies of accurate diagnosis, pathophysiological mechanisms, incidence, outcome, and management.

Associations of HLA Polymorphisms with Anti-SARS-CoV-2 Spike and Neutralizing Antibody Titers in Japanese Rheumatoid Arthritis Patients Vaccinated with BNT162b2. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causes Coronavirus Disease 2019. Anti-SARS-CoV-2 spike (S) and neutralizing antibodies (Abs) are measured to evaluate the efficacy of vaccines. Human leukocyte antigen (HLA) may be associated with vaccine efficacy. Here, we investigated the association of HLA polymorphisms with the production of anti-SARS-CoV-2 S or neutralizing Abs in vaccinated rheumatoid arthritis (RA) patients in Japan. Genotyping of DRB1 and DQB1 was conducted in 87 Japanese RA patients vaccinated with BNT162b2. Associations of allele or haplotype carrier frequencies with anti-SARS-CoV-2 S or neutralizing Abs were examined. DRB1*12:01 was significantly positively associated with the production of S Ab ($p = 0.0225$, odds ratio [OR] 6.08, 95% confidence interval [CI] 1.32-28.03). The DQB1*03:01 allele carrier frequency tended to be higher in high responders of S Ab. Allele carrier frequencies of DRB1*15:01 ($p = 0.0102$, OR 9.26, 95% CI 1.65-52.01) and DQB1*06:02 ($p = 0.0373$, OR 7.00, 95% CI 1.18-41.36) were higher in responders of neutralizing Ab. Haplotype and two-locus analyses of DRB1 and DQB1 suggested that DRB1 alleles were the primary drivers of these associations. Logistic regression analysis showed associations of these alleles independent of clinical characteristics. Independent associations were found between HLA alleles and anti-SARS-CoV-2 Ab production by vaccinated RA patients.

Histopathological Patterns of Cutaneous Adverse Reaction to Anti-SARS-CoV-2 Vaccines: The Integrative Role of Skin Biopsy. The advent of vaccines represented a milestone to allow the slowing down and then containing of the exponential increase in ongoing infections and deaths of COVID-19. Since the first months of the vaccination campaign in various continents, there has been a certain number of reports of adverse events, including skin reactions. We conducted a systematic review, searching on PubMed, Web of Science, Scopus, and Cochrane Library for the words: COVID vaccine, dermatopathology, skin, eruptions, rash, cutaneous, BNT162b2 (Pfizer-BioNTech), ChAdOX1 (AstraZeneca), and mRNA-1273 (Moderna). A total of 28 records were initially identified in the literature search of which two were duplicates. After screening for eligibility and inclusion criteria, 18 publications were ultimately included. Various clinical cutaneous manifestations and histopathological patterns following vaccination have been described in literature. The most frequent clinical-pathological presentations were erythematous maculo-papular eruptions in different way of distribution with histopathological pictures mostly represented by interface changes and mixed peri-vascular and peri-adnexal cell infiltrate. Other presentations included new onset of pemphigoid bullous disease (n = 15), delayed T-cell-mediated hypersensitivity reaction (injection site reactions) (n = 10), purpuric skin rash (n = 13), mostly localized on the legs bilaterally and symmetrically with histological pictures characterized by extravasation of erythrocytes in the superficial and middle dermis, and other types of reactions. New studies with large case series and further literature reviews are needed to improve the clinical management of patients and optimize the timeline for carrying out histological biopsy for confirmatory, supportive, and differential diagnosis purposes.

Adverse Reactions after BNT162b2 Messenger RNA Vaccination for Coronavirus Disease 2019 in Healthcare Workers Compared with Influenza Vaccination. This study aimed to compare adverse reactions following BNT162b2 and influenza vaccinations in healthcare workers. This study included healthcare workers who received the BNT162b2 vaccine and/or inactivated influenza vaccine, quadrivalent (IIV4), on 18-29 October 2021 at a tertiary hospital in Korea. IIV4 was administered and BNT162b2 was subsequently administered one week later. The participants responded to a mobile questionnaire regarding adverse events. The overall adverse reaction rates were 90.6% in the BNT162b2 + IIV4 group, 90.4% in the BNT162b2 alone group, and 44.1% in the IIV4 alone group ($p < 0.001$). Fever occurred in 19.5%, 26.9%, and 3.3% of participants in the BNT162b2 + IIV4, BNT162b2 alone, and IIV4 alone groups, respectively ($p < 0.001$). The most common local and systemic adverse

reactions were injection site pain (65.0%) and fatigue (58.6%), respectively. Injection-site pain was experienced by 88.7%, 88.5%, and 37.5% of the BNT162b2 + IIV4, BNT162b2 alone, and IIV4 alone groups, respectively ($p < 0.001$). Fatigue was experienced by 74.8%, 78.8%, and 38.6% of the BNT162b2 + IIV4, BNT162b2 alone, and IIV4 alone groups, respectively ($p < 0.001$). Adverse reactions occurred at a significantly higher frequency after BNT162b2 than after IIV4. The frequency of adverse reactions one week after vaccination with IIV4 and BNT162b2 was not different from that after vaccination with BNT162b2 alone. Therefore, coadministration of influenza vaccine with BNT162b2 can be expected to be safe.

Central Retinal Vein Occlusion in a Young Woman with Diabetes and Hypertension after mRNA-Based COVID-19 Vaccination-A Case Report and Brief Review of the Literature. A 25-year-old female with diabetes and hypertension presented with progressive painless blurred vision in her left eye ten days after she received her third dose of the SARS-CoV-2 mRNA vaccine BNT162b2 (Pfizer-BioNTech). The clinical examination confirmed the diagnosis of Central Retinal Vein Occlusion (CRVO) complicated with macular edema. Three doses of anti-vascular endothelial growth factor (VEGF) were injected intravitreally. Visual acuity was improved from 20/100 to 20/30, but recurrence was noted at 6 months. Several cases of retinal vein occlusion (RVO) after COVID-19 vaccination have been reported. However, the present case is the youngest female individual documented to have CRVO after SARS-CoV-2 vaccination. This case demonstrates that the macular edema might be recurrent in patients with risk factors for CRVO who receive SARS-CoV-2 vaccination, suggesting the need for careful consideration of the treatment strategy and close follow-up. Although the definite pathogenesis still needs to be carefully determined, this report highlights the possible association between RVO and mRNA-based COVID-19 vaccination, even in young individuals.

Comparison of COVID-19 Vaccine-Associated Myocarditis and Viral Myocarditis Pathology. The COVID-19 pandemic has led to significant loss of life and severe disability, justifying the expedited testing and approval of messenger RNA (mRNA) vaccines. While found to be safe and effective, there have been increasing reports of myocarditis after COVID-19 mRNA vaccine administration. The acute events have been severe enough to require admission to the intensive care unit in some, but most patients fully recover with only rare deaths reported. The pathways involved in the development of vaccine-associated myocarditis are highly dependent on the specific vaccine. COVID-19 vaccine-associated myocarditis is believed to be primarily caused by uncontrolled cytokine-mediated inflammation with possible genetic components in the interleukin-6 signaling pathway. There is also a potential autoimmune component via molecular mimicry. Many of these pathways are similar to those seen in viral myocarditis, indicating a common pathophysiology. There is concern for residual cardiac fibrosis and increased risk for the development of cardiomyopathies later in life. This is of particular interest for patients with congenital heart defects who are already at increased risk for fibrotic cardiomyopathies. Though the risk for vaccine-associated myocarditis is important to consider, the risk of viral myocarditis and other injury is far greater with COVID-19 infection. Considering these relative risks, it is still recommended that the general public receive vaccination against COVID-19, and it is particularly important for congenital heart defect patients to receive vaccination for COVID-19.

Long-Term Immunological Memory of SARS-CoV-2 Is Present in Patients with Primary Antibody Deficiencies for up to a Year after Vaccination. Some studies have found increased coronavirus disease-19 (COVID-19)-related morbidity and mortality in patients with primary antibody deficiencies. Immunization against COVID-19 may, therefore, be particularly important in these patients. However, the durability of the immune response remains unclear in such patients. In this study, we evaluated the cellular and humoral response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigens in a cross-sectional study of 32 patients with primary antibody deficiency (n = 17 with

common variable immunodeficiency (CVID) and n = 15 with selective IgA deficiency) and 15 healthy controls. Serological and cellular responses were determined using enzyme-linked immunosorbent assay and interferon-gamma release assays. The subsets of B and T lymphocytes were measured using flow cytometry. Of the 32 patients, 28 had completed the vaccination regimen with a median time after vaccination of 173 days (IQR = 142): 27 patients showed a positive spike-peptide-specific antibody response, and 26 patients showed a positive spike-peptide-specific T-cell response. The median level of antibody response in CVID patients (5.47 ratio (IQR = 4.08)) was lower compared to healthy controls (9.43 ratio (IQR = 2.13)). No difference in anti-spike T-cell response was found between the groups. The results of this study indicate that markers of the sustained SARS-CoV-2 spike-specific immune response are detectable several months after vaccination in patients with primary antibody deficiencies comparable to controls.

Prevalence and Predictors of Seasonal Influenza Vaccine Uptake in Saudi Arabia Post COVID-19: A Web-Based Online Cross-Sectional Study. In the fall of 2022, the number of influenza-like illnesses (ILIs) and severe acute respiratory infections (SARIs) in Saudi Arabia had significantly increased compared with the corresponding period in previous years. Concerns regarding the population's seasonal influenza vaccine (SIV) uptake rates have emerged. In particular, the SIV uptake rates may have dropped post the COVID-19 pandemic compared with rates prior to the COVID-19 era. In this study, we aimed to estimate the prevalence and predictors of SIV uptake in Saudi Arabia post the COVID-19 pandemic. We conducted a cross-sectional study utilizing an online survey platform. We mainly collected sociodemographic information and determined whether the respondent was a healthcare professional or had a chronic disease. The overall SIV uptake prevalence was 31.8%. A lower SIV uptake was observed among those aged 55 years or older, females, residents of the central region, non-health practitioners, and those without chronic diseases. Several factors were associated with SIV uptake. Those aged 35-44 were over three-fold more likely to receive an SIV than those aged 55 years or older (OR: 3.66; 95% CI: 1.33-10.05). In addition, males had 73% higher odds of SIV uptake than females (OR: 1.73; 95% CI: 1.18-2.55). Health practitioners were more likely to receive an SIV than non-health practitioners (OR: 2.11; 95% CI: 1.45-3.06). Similarly, those with chronic diseases had 86% higher odds of SIV uptake than those without chronic diseases (OR: 1.86; 95% CI: 1.18-2.95). These findings can provide insights into the low prevalence and predictors of SIV uptake in Saudi Arabia. Future studies should be conducted to further explore the potential factors associated with such a low prevalence of SIV uptake post COVID-19 in Saudi Arabia.

Predictors of Seasonal Influenza Vaccination Willingness among High-Risk Populations Three Years after the Onset of the COVID-19 Pandemic. High-risk populations are at increased risk of severe influenza-related illness, hospitalization, and death due to influenza. The aim of our study was to assess the willingness of high-risk populations to take the influenza vaccine for the 2022-2023 season, and to investigate the factors associated with such willingness. We conducted a cross-sectional study in Greece in September 2022 using a convenience sample. We considered demographic characteristics, COVID-19-related variables, resilience, social support, anxiety, depression, and COVID-19-related burnout as potential predictors. Among participants, 39.4% were willing to accept the seasonal influenza vaccine, 33.9% were unwilling, and 26.8% were hesitant. Multivariable analysis identified that increased age and increased family support were associated with increased influenza vaccination willingness. Moreover, participants that have received COVID-19 booster doses were more willing to accept the influenza vaccine. In contrast, adverse effects because of COVID-19 vaccination and exhaustion due to measures against COVID-19 reduced influenza vaccination willingness. We found that the intention of high-risk populations to receive the influenza vaccine was low. Our study contributes to an increased understanding of the factors that affect vaccination

willingness. Public health authorities could use this information to update vaccination programs against influenza. Emphasis should be given on safety and effectiveness issues.

Lack of Evidence on Association between Iron Deficiency and COVID-19 Vaccine-Induced Neutralizing Humoral Immunity. Iron is a crucial micronutrient for immunity induction in response to infections and vaccinations. This study aimed to investigate the effect of iron deficiency on COVID-19-vaccine-induced humoral immunity. We investigated the effectiveness of COVID-19 vaccines (BNT162b2, mRNA-1273, and ChAdOx nCov-2019) in iron-deficient individuals (n = 63) and provide a side-by-side comparison to healthy controls (n = 67). The presence of anti-SARS-CoV-2 spike (S) and anti-nucleocapsid (NP) IgG were assessed using in-house S- and NP-based ELISA followed by serum neutralization test (SNT). High concordance between S-based ELISA and SNT results was observed. The prevalence of neutralizing antibodies was 95.24% (60/63) in the study group and 95.52% (64/67) in the controls with no significant difference. The presence/absence of past infection, period since vaccination, vaccine type, and being iron-deficient or having iron-deficiency anemia did not exert any significant effect on the prevalence or titer of anti-SARS-CoV-2 neutralizing antibodies. NP-based ELISA identified individuals unaware of exposure to SARS-CoV-2. Moreover, absence of anti-NP IgG was noted in participants who were previously diagnosed with COVID-19 suggesting the unpredictability of after-infection immunity. To sum up, this study demonstrated an initial lack of evidence on the association between iron deficiency and the effectiveness of COVID-19-vaccine-induced neutralizing humoral immunity. Similar studies with larger sample size remain necessary to obtain comprehensive conclusions about the effect or lack of effect of iron on COVID-19-vaccine effectiveness.

ATAK Complex (Adrenaline, Takotsubo, Anaphylaxis, and Kounis Hypersensitivity-Associated Coronary Syndrome) after COVID-19 Vaccination and Review of the Literature. Anaphylactic events triggered by mRNA COVID-19 vaccines are neither serious nor frequent. Kounis syndrome is described as the concomitant occurrence of acute coronary events and hypersensitivity reactions induced by vasospastic mediators after an allergic event. Kounis syndrome caused by vaccines is very rare. Up to now, only a few cases of allergic myocardial infarction after mRNA COVID-19 vaccine administration have been reported. Takotsubo cardiomyopathy is a syndrome characterized by transient wall movement abnormalities of the left ventricular apex, mid-ventricle, or other myocardial distribution, usually triggered by intense emotional or physical stress. Takotsubo cardiomyopathy after COVID-19 vaccine administration has been reported, usually with a delayed onset. A new entity characterized by the association of adrenaline administration, Takotsubo cardiomyopathy, anaphylaxis, and Kounis hypersensitivity was recently described: the ATAK complex. Here, we report a case of Takotsubo cardiomyopathy that occurred together with an anaphylactic reaction to an mRNA COVID-19 vaccine that required the use of adrenaline. The timing of the allergic reaction and the referenced clinical symptoms could not exclude the idea that Kounis syndrome occurred. Therefore, we can assume the patient presented the ATAK complex. We believe that highlighting on this ATAK complex will aid the application of proper diagnostic, preventive and therapeutic measures.

A Retrospective Evaluation of Self-Reported Adverse Events Following Immunization with Different COVID-19 Vaccines in TÃ¼rkiye. BACKGROUND: The Sinovac and BioNTech vaccines were the first to be introduced in TÃ¼rkiye to fight the ongoing global COVID-19 pandemic. As these vaccines had shown some side-effects in its clinical trial, we aimed to conduct a survey study to assess the short-term adverse events following immunization (AEFIs) in TÃ¼rkiye. METHOD: A cross-sectional study was conducted using social and electronic media platforms by delivering a pre-formed and validated online questionnaire among people who had received at least one dose of the COVID-19 vaccine. This survey study focused on mass populations from different regions in TÃ¼rkiye. A total of 603 responses were collected. Among these, 602 were selected based on complete answers and used for

the assessment. The collected data were then analyzed to evaluate the various parameters related to the AEFIs of the respondents. RESULTS: Among the total 602 participants, 20.8% were male, and 78.7% were female, actively answering all of the constructive questions. Most of the respondents were between 18-30 years of age. We found that a total of 23.3% of the total respondents had been infected with the SARS-CoV-2 virus. Our survey revealed that out of 602 volunteers, the rate of experiencing physical discomfort was higher in participants who had received the Pfizer-BioNTech vaccine at all three doses than in those who had received the Sinovac vaccine. When all vaccine types were examined, the most common side effect was pain at the injection site, reported by 75.19% participants. When the side effects were compared according to vaccine types, there was a significant difference only in terms of fever. Fever rates in those who had received the Pfizer-BioNTech vaccine (20.96%) were found to be significantly higher than those who had received the Sinovac vaccine (8%). CONCLUSIONS: The studied vaccines showed minor side effects and there was no significant difference between the vaccines in terms of other side effects. Moreover, further research is needed to determine the efficacy of the existing vaccines in preventing SARS-CoV-2 infections or after-infection hospitalization.

The Influence of Booster Shot and SARS-CoV-2 Infection on the Anti-Spike Antibody Concentration One Year after the First COVID-19 Vaccine Dose Administration. This study pictures the humoral response of 100 vaccinees to Pfizer/BioNTech COVID-19 vaccine over a year, with particular focus on the influence of a booster shot administered around 10 months after the primary immunization. The response to the vaccination was assessed with Diasorin's SARS-CoV-2 TrimericSpike IgG. Abbott's SARS-CoV-2 Nucleocapsid IgG immunoassay was used to identify SARS-CoV-2 contact, even asymptomatic. In contrast to the gradual decline of the anti-spike IgG between 30 and 240 days after the first dose, an increase was noted between days 240 and 360 in the whole cohort. However, a statistically significant rise was seen only in boosted individuals, and this effect of the booster decreased over time. An increase was also observed in non-boosted but recently infected participants and a decrease was reported in non-boosted, non-infected subjects. These changes were not statistically significant. On day 360, a percentage of new SARS-CoV-2 infections was statistically lower in the boosted vs. non-boosted subgroups. The booster immunization is the most efficient way of stimulating production of anti-spike, potentially neutralizing antibodies. The response is additionally enhanced by the natural contact with the virus. Individuals with a low level of anti-spike antibodies may benefit the most from the booster dose administration.

Death and Disability Reported with Cases of Vaccine Anaphylaxis Stratified by Administration Setting: An Analysis of the Vaccine Adverse Event Reporting System from 2017 to 2022. The serious nature of post-vaccination anaphylaxis requires healthcare professionals to be adequately trained to respond to these hypersensitivity emergencies. The aim of this study was to compare outcomes reported with cases of vaccine anaphylaxis stratified by administration setting. We queried reports in the Vaccine Adverse Event Reporting System (VAERS) database from 2017 to 2022 and identified cases involving anaphylaxis with an onset within one day of vaccine administration. The primary outcome was the combined prevalence of death or disability for each setting while the secondary outcome was the prevalence of hospitalization. Adjusted (age, sex, prior history of allergy, vaccine type) odds ratios (aOR) and associated 95% confidence intervals (CI) were calculated using logistic regression analysis. A total of 2041 cases of anaphylaxis comprised the primary study cohort with representation in the sample from all 50 US states and the District of Columbia. The mean age was 43.3 Â± 17.5 years, and most cases involved women (79.9%). Cases of anaphylaxis were reported after receiving a coronavirus vaccine (85.2%), influenza vaccine (5.9%), tetanus vaccine (2.2%), zoster vaccine (1.6%), measles vaccine (0.7%), and other vaccine (4.5%). Outcomes associated with reports of vaccine anaphylaxis included 35 cases of death and disability and 219 hospitalizations. Compared

with all other settings, the aOR of death and disability when anaphylaxis occurred was 1.92 (95% CI, 0.86-4.54) in a medical provider's office, 0.85 (95% CI, 0.26-2.43) in a pharmacy and 1.01 (95% CI, 0.15-3.94) in a public health clinic. Compared with all other settings, the aOR of hospitalization when anaphylaxis occurred was 1.02 (95% CI, 0.71-1.47) in a medical provider's office, 1.06 (95% CI, 0.72-1.54) in a pharmacy, and 1.12 (95% CI, 0.61-1.93) in a public health clinic. An analysis of a national database across six years revealed no significant differences in the odds of death/disability and odds of hospitalization associated with post-vaccination anaphylaxis in the medical office, pharmacy, and public health clinic compared with all other settings. This study expands our understanding of the safety of immunization services and reinforces that all settings must be prepared to respond to such an emergency.

Evaluating the Adverse Events Associated with Three Doses of the COVID-19 Vaccination in Adults in the Western Region of Saudi Arabia: A Cross-Sectional Study. The Kingdom of Saudi Arabia was one of the countries earliest affected by the coronavirus 2019 (COVID-19) pandemic and had taken precautions including compulsory COVID-19 vaccination. Both the ChAdOx1 nCoV-19 vaccine (Oxford AstraZeneca) and the BNT162b2 vaccine (Pfizer) were approved by the Saudi Ministry of Health, followed by mRNA-1273 (Moderna), all of which were used for population-wide vaccination. This study aimed to assess the short-term side effects following the COVID-19 vaccinations among participants who had received all three doses in the western region of Saudi Arabia. An online survey was distributed to the participants who received either BNT162b2, ChAdOx1 nCoV-19, or mRNA-1273 vaccines, and the type of side effects and their severity were evaluated. Fatigue and headache, pain at the site of the injection and muscle pain were the most common side effects in all three doses. However, the severity depending on the type of vaccination was significant only for the first and second dose, but not the third dose. In contrast, there was a higher percentage of participants who encountered severe side effects from the third dose compared to the first and second. Nevertheless, the majority of participants described all three doses' side effects to be moderately severe. A future evaluation could be made to access the individual types of vaccination and compare between the side effects of the BNT162b2, ChAdOx1 nCoV-19, and mRNA-1273 vaccines specifically for the booster dose.

Antibody and T-Cell Responses against SARS-CoV-2 after Booster Vaccination in Patients on Dialysis: A Prospective Observational Study. Intensive vaccination is recommended for populations more vulnerable to COVID-19 infection, although data regarding the built of immunity after vaccination for dialysis patients are lacking. This prospective, observational cohort study of maintenance hemodialysis patients examined IgG antibody levels against the SARS-CoV-2 spike (S1) protein, neutralizing activity, and interferon gamma levels after the third dose of the BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna) vaccine. Humoral immunity was repeatedly measured for up to two months. The study includes 58 patients on hemodialysis. Median neutralizing antibodies reached a maximum at 56 and 9 days after booster vaccination with BNT162b2 and mRNA-1273, respectively. The median IgG antibody titer reached a maximum of 3104.38 and 7209.13 AU/mL after 16 days of booster dose, and cellular immunity was positive in 61.9% and 100% of patients with BNT162b2 and mRNA-1273 vaccination, respectively. By repeating the measurements over a period of two months, we clarified the chronological aspects of the acquisition of humoral immunity in dialysis patients after a booster COVID-19 vaccination; most dialysis patients acquired not only humoral immunity, but also cellular immunity against SARS-CoV-2. Future research should investigate the continued long-term dynamics of antibody titers and cellular immunity after the third or further vaccinations, evaluating the need for additional vaccinations for hemodialysis patients.

Skin Testing and Basophil Activation Testing Is Useful for Assessing Immediate Reactions to Polyethylene Glycol-Containing Vaccines. BACKGROUND: The mechanism of immediate reactions

to drugs or vaccines containing polyethylene glycol (PEG) and PEG derivatives is not fully elucidated. It is considered in many instances to be IgE-mediated. Diagnosis and management of PEG allergy is topical, as BNT162b and mRNA-1273 contain PEG (2[PEG-2000]-N), and ChAdOx1-S and NVX-CoV2373 contain polysorbate 80. mRNA vaccines contain PEG 2000, which encapsulates the mRNA to impair its degradation. This PEG MW is specific to mRNA vaccines and is not used in other drugs and vaccines. PEG 2000 allergy is not well studied, as higher PEG molecular weights are implicated in most of the PEG allergy published in the literature. METHODS: We performed a literature review on PEG allergy and sought to evaluate the safety and effectiveness of our protocol for assessment of PEG 2000 and polysorbate 80 reactions in an outpatient clinic setting. All patients referred to our drug allergy service between 1 July 2021 and 31 December 2021 with suspected immediate allergy to PEG or its derivatives were eligible for the study. Skin testing (ST) and basophil activation testing (BAT) were performed for all patients to multiple PEG molecular weights (MWs). RESULTS: We reviewed twenty patients during the study period. Five patients were allergic. Fifteen patients had a masquerade of allergy and were enrolled as control patients. PEG 2000, polysorbate 80, BNT162b, and ChAdOx1-S had excellent performance characteristics on skin testing. BAT showed high specificity for all vaccines and PEG MWs. DISCUSSION: In our small study, we found ST and BAT to add useful information, particularly for PEG 2000 allergy. Further study of our protocol in larger patient cohorts will provide more information on its performance characteristics and usefulness.

Risk of Repeated Adverse Effects following Booster Dose of mRNA COVID-19 Vaccine: Results from the MOSAICO Study. The successful deployment of safe and effective vaccines against coronavirus disease 2019 (COVID-19) has been crucial in reducing the global disease burden. Owing to the need for vaccination series over time, continuous observational studies are needed to estimate the COVID-19 vaccine response in real-world conditions. In particular, the detection, assessment, and understanding of adverse effects following immunization (AEFI) with a COVID-19 vaccine are crucial to better address vaccination strategies. Therefore, this study aimed to investigate the risk of repeated AEFI post-administration of a booster dose of mRNA COVID-19 vaccine in a sample of healthcare workers (HCWs) in an Italian teaching hospital. The data on any local and systemic AEFI were studied in multivariate Poisson regression analyses to model the association between the incidence of each postvaccination symptom and its prior reporting after the administration of the previous doses. Overall, compared with the primary vaccination series, the majority of post-third dose AEFI were less reported. The results from multivariable models showed that the likelihood of reporting an AEFI after the third dose was higher in those who experienced the same postvaccination symptom after the second dose (all AEFI except for itch at injection site) and, although not significant for all AEFI, after the first dose. Any associations with age, gender, smoking habits, previous SARS-CoV-2 infection and other characteristics, as well as the health impact of AEFI were also assessed. Taken together, the results from this research support reframe AEFI symptoms as signals of a robust postvaccination reaction as well as of common vaccine response, and they add important data to inform booster vaccination strategies in HCWs and, extensively, in the adult population.

Humoral Responses against BQ.1.1 Elicited after Breakthrough Infection and SARS-CoV-2 mRNA Vaccination. The Omicron BQ.1.1 variant is now the major SARS-CoV-2 circulating strain in many countries. Because of the many mutations present in its Spike glycoprotein, this variant is resistant to humoral responses elicited by monovalent mRNA vaccines. With the goal to improve immune responses against Omicron subvariants, bivalent mRNA vaccines have recently been approved in several countries. In this study, we measure the capacity of plasma from vaccinated individuals, before and after a fourth dose of mono- or bivalent mRNA vaccine, to recognize and neutralize the ancestral (D614G) and the BQ.1.1 Spikes. Before and after the fourth dose, we observe a significantly better recognition and neutralization of the ancestral Spike. We also observe that fourth-dose

vaccinated individuals who have been recently infected better recognize and neutralize the BQ.1.1 Spike, independently of the mRNA vaccine used, than donors who have never been infected or have an older infection. Our study supports that hybrid immunity, generated by vaccination and a recent infection, induces higher humoral responses than vaccination alone, independently of the mRNA vaccine used.

Adverse Effects of Pfizer (BioNTech), Oxford-AstraZeneca (ChAdOx1 CoV-19), and Moderna COVID-19 Vaccines among the Adult Population in Saudi Arabia: A Cross-Sectional Study. The Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) outbreak has caused massive damage to the global healthcare system and economy. To compete with the SARS-COV-2 pandemic, several vaccines have been proposed to immunize the population. The present study aimed to investigate the adverse effects following the three doses of COVID-19 vaccination, Pfizer (BioNTech), (Oxford-AstraZeneca (ChAdOx1 CoV-19), and Moderna among the adult population in the Eastern province of Saudi Arabia. In this study, the total number of participants were 426, among them 277 (65%) were females and 149 (35%) were males. An online survey using Google forms in the English language and translated into the Arabic language was used to record the information. The questionnaire was distributed to participants who received either Pfizer-BioNTech, Oxford-AstraZeneca or Moderna vaccines. The general characteristics of participants were obtained, alongside an evaluation of the vaccination's adverse effects. The results revealed that Pfizer-BioNTech COVID-19 vaccines caused significantly less adverse effects than Oxford-AstraZeneca (ChAdOx1) and Moderna ($p < 0.001$), and females experienced more adverse effects after vaccination compared to males. Injection site pain was the most common adverse event among the participants (60.6%), followed by fatigue, headache, and pain (43.9%), muscle and joint pain (32.4%), increased body temperature and shivering (24.2%). In addition, the group of individuals under the age of sixty was more likely to experience side effects than the participants with other age groups. All three vaccines, Pfizer-BioNTech, Oxford-AstraZeneca (ChAdOx1 CoV-19) and Moderna, cause post-vaccinal adverse effects; however, Moderna and Oxford-AstraZeneca (ChAdOx1) causes adverse effects more frequently than the Pfizer-BioNTech.

The safety and immunogenicity of inactivated COVID-19 vaccine in old pulmonary tuberculosis patients. The immunogenicity and safety of vaccines against coronavirus disease 2019 (COVID-19) remain unknown in patients with a history of pulmonary tuberculosis (OPTB). Therefore, the safety and effectiveness of inactivated vaccines against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) were assessed in patients with a history of PTB. The study cohort included 106 healthy controls and 93 adult patients with OPTB who received a two-dose vaccination. The study period was 21 to 105Â days. Concentrations of antibodies (Abs) against receptor-binding domain (RBD) IgG and SARS-CoV-2 neutralizing Abs (NAbs) were measured, in addition to the frequencies of SARS-CoV-2-specific B and a portion T cells. The incidence of adverse events was similar between the OPTB patients and healthy controls. No severe adverse events occurred. Concentrations of Abs against RBD-IgG and CoV-2 neutralizing Abs in addition to the frequencies of RBD-specific memory B cells proportions were lower in OPTB patients than the healthy controls (all, pâ€‰<â€‰0.05), while the frequencies of cytotoxic T-lymphocyte-associated protein 4 (CTLA-4(+)) cells were higher (pâ€‰=â€‰0.023). There was no obvious correlation between age and blood concentrations of Abs against RBD-IgG and CoV-2 neutralizing Abs, while immune responses were similar in the fibrosis and calcification groups. The period of time following full-course vaccination and lymphocyte counts were associated to anti-RBD-IgG responses. Inactivated COVID-19 vaccinations were well tolerated in OPTB patients, although immunogenicity was limited in this population. This study has been registered at ClinicalTrials.gov (NCT05043246).

Mucous Membrane Pemphigoid Following the Administration of COVID-19 Vaccine.

Author Response: Acute Arterial Ischemic Stroke Following COVID-19 Vaccination: A Systematic Review and Meta-analysis.
Reader Response: Acute Arterial Ischemic Stroke Following COVID-19 Vaccination: A Systematic Review and Meta-analysis.
Editors' Note: Acute Arterial Ischemic Stroke Following COVID-19 Vaccination: A Systematic Review and Meta-analysis.
An Unusual Presentation Of Steven-Johnson Syndrome After Bnt162b2 Covid-19 Vaccination. We present a 23-year-old white British male that presented to the Accident and Emergency Department, two weeks after the second dose of the BNT162b2 (BioNTech/Pfizer) vaccine. No similar use has been documented previously in literature. We report one potential complication of the Pfizer COVID-19 vaccine: A known case of Stevens-Johnson syndrome (SJS) that occurred after the second dose of the Pfizer COVID-19 vaccine alone without exposure to any other drug. Despite a significantly severe adverse drug reaction, the patient demonstrated completed recovery. The risk of developing severe cutaneous drug reaction from subsequent COVID-19 vaccinations in these patients is still unclear and remains a dilemma to date.
Peripheral facial palsy post SARS-CoV-2 vaccine: A regional pharmacovigilance cases series. Peripheral facial palsy (PFP) is a rare adverse reaction identified from clinical trials of coronavirus disease 2019 (COVID-19) vaccines (messenger ribonucleic acid [mRNA] and viral vector). Few data are available on their onset patterns and risk of recurrence after re-injection of a COVID-19 vaccine; the objective of this study was to describe PFP cases attributed to COVID-19 vaccines. All cases of facial paralysis reported to the Regional Pharmacovigilance Center of Centre-Val de Loire area between January and October 2021, in which the role of a COVID-19 vaccine was suspected, were selected. Based on initial data and following additional information requested, each case was reviewed and analyzed to include only confirmed cases of PFP for which the role of the vaccine could be retained. From the 38 cases reported, 23 were included (15 excluded because of diagnosis not retained). They occurred in 12 men and 11 women (median age of 51 years). The first clinical manifestations occurred with a median time of 9 days after COVID-19 vaccine injection, and the paralysis was homolateral to the vaccinated arm in 70%. The etiological workup, always negative, included brain imaging (48%), infectious serologies (74%) and Covid-19 PCR (52%). Corticosteroid therapy was prescribed for 20 (87%) patients, combined with aciclovir in 12Â (52%). At 4-month follow-up, clinical manifestations had regressed completely or partially in 20 (87%) of the 23 patients (median time of 30Â days). From them 12 (60%) received another dose of COVID-19 vaccine and none had a recurrence and the PFP regressed despite the second dose in 2 of the 3 patients not fully recovered at 4 months. The potential mechanism of PFP after COVID-19 vaccine, which don't have a specific profile, is probably the interferon-Î³. Moreover, the risk of recurrence after a new injection appears to be very low, which makes it possible to continue the vaccination.
Initial Two Doses of COVID-19 Vaccine mRNA-1273 for an Individual Previously Vaccinated with Two Doses of an Inactivated Vaccine CoronaVac That Has Not Been Approved in Japan. The inactivated coronavirus disease 2019 vaccine CoronaVac has not been approved in Japan. Little information is available on cases in Japan in which an approved mRNA vaccine was administered as the initial (first or second) dose after two doses of CoronaVac. Furthermore, the safety and efficacy of this combination are not established. We here evaluated the safety and efficacy in a patient who showed an antibody response to an approved vaccine, mRNA-1273, after a previous vaccination with CoronaVac. The adverse events consisted of only mild local and systemic common reactions and were transient. In addition, a strong and persistent antibody response was observed.
Epidemiological situation of SARS-CoV-2 infection in Douala, the most populated and highly heterogeneous town of Cameroon: a post-vaccination update. This study aimed at providing an

update of SARS-CoV-2 epidemiology in Douala, the most populated and highly heterogeneous town of Cameroon. A hospital-based cross sectional study was conducted from January to September 2022. A questionnaire was used to collect sociodemographic, anthropometric, and clinical data. Retrotranscriptase quantitative polymerase chain reaction was used to detect SARS-CoV-2 in nasopharyngeal samples. Of the 2354 individuals approached, 420 were included. The mean age of patients was 42.3 Â± 14.4 years (range 21 - 82). The prevalence of SARS-CoV-2 infection was 8.1%. The risk of infection with SARS-CoV-2 was increased more than seven times in patients aged â‰¥ 70 years old (aRRÂ =Â 7.12, pÂ =Â 0.001), more than six times in married (aRRÂ =Â 6.60, pÂ =Â 0.02), more than seven times in those having completed secondary studies (aRRÂ =Â 7.85, pÂ =Â 0.02), HIV-positive patients (aRRÂ =Â 7.64, p < 0.0001) and asthmatic patients (aRRÂ =Â 7.60, pÂ =Â 0.003), and more than nine times in those seeking health care regularly (aRRÂ =Â 9.24, pÂ =Â 0.001). In contrast, the risk of SARS-CoV-2 infection was reduced by 86% in patients attending Bonassama hospital (aRRÂ =Â 0.14, pÂ =Â 0.04), by 93% in patients of blood group B (aRRÂ =Â 0.07, pÂ =Â 0.04), and by 95% in COVID-19 vaccinated participants (aRRÂ =Â 0.05, pÂ =Â 0.005). There is need for ongoing surveillance of SARS-CoV-2 in Cameroon, given the position and importance of Douala.

Aggravation of hyperthyroidism following severe acute respiratory syndrome coronavirus-2 mRNA vaccine booster administration in a patient with Graves' disease.

Myocarditis or Pericarditis Events After BNT162b2 Vaccination in Individuals Aged 12 to 17 Years in Ontario, Canada. IMPORTANCE: The risk of myocarditis or pericarditis after COVID-19 messenger RNA vaccines varies by age and sex, and there is some evidence to suggest increasing risk with shorter intervals between dose 1 and 2 (ie, interdose interval). OBJECTIVE: To estimate the incidence of reported myocarditis or pericarditis after BNT162b2 vaccine among adolescents and to describe the clinical information associated with these events. DESIGN, SETTING, AND PARTICIPANTS: This was a population-based cohort study using passive vaccine safety surveillance data linked to the provincial COVID-19 vaccine registry. Included in the study were all adolescents aged 12 to 17 years in Ontario, Canada, who received 1 or more doses of BNT162b2 vaccine between December 14, 2020, and November 21, 2021, and reported an episode of myocarditis or pericarditis. Data were analyzed from December 15, 2021, to April 22, 2022. EXPOSURE: Receipt of BNT162b2 (Comirnaty [Pfizer-BioNTech]) vaccine. MAIN OUTCOMES AND MEASURE: Reported incidence of myocarditis or pericarditis meeting level 1 to 3 of the Brighton Collaboration case definition per 100â€¯000 doses of BNT162b2 administered by age group (12-15 years vs 16-17 years), sex, dose number, and interdose interval. All clinical information associated with symptoms, health care usage, diagnostic test results, and treatment at the time of the acute event were summarized. RESULTS: There wereâ€‰approximatelyâ€‰1.65 million doses of BNT162b2 administered and 77 reports of myocarditis or pericarditis among those aged 12 to 17 years, which met the inclusion criteria during the study period. Of the 77 adolescents (mean [SD] age, 15.0 [1.7] years; 63 male individuals [81.8%]), 51 (66.2%) developed myocarditis or pericarditis after dose 2 of BNT162b2. Overall, 74 individuals (96.1%) with an event were assessed in the emergency department, and 34 (44.2%) were hospitalized (median [IQR] length of stay, 1 [1-2] day). The majority of adolescents (57 [74.0%]) were treated with nonsteroidal anti-inflammatory drugs only, and 11 (14.3%) required no treatment. The highest reported incidence was observed among male adolescents aged 16 to 17 years after dose 2 (15.7 per 100â€¯000; 95% CI, 9.7-23.9). Among those aged 16 to 17 years, the reporting rate was highest in those with a short (ie, â‰¤30 days) interdose interval (21.3 per 100â€¯000; 95% CI, 11.0-37.2). CONCLUSIONS AND RELEVANCE: Results of this cohort study suggest that there was variation in the reported incidence of myocarditis or pericarditis after BNT162b2 vaccine among adolescent age groups. However, the risk of these events after vaccination remains very rare and should be considered in relation to the benefits of COVID-19 vaccination.

A Review of the Data Supporting Use of COVID-19 Vaccinations in the Pediatric Population. OBJECTIVE: The objective of this study was to review the effectiveness and safety of COVID-19 vaccinations in the pediatric population. DATA SOURCES: PubMed/Medline (September 2020 to December 2022), the Centers for Disease Control and Prevention, and Food and Drug Administration (FDA) websites. STUDY SELECTION AND DATA EXTRACTION: Publications regarding the safety and efficacy of COVID-19 vaccinations in children were included. DATA SYNTHESIS: Vaccines authorized for use in children include two monovalent mRNA vaccines (â‰¥6 months old) and one monovalent protein subunit adjuvant vaccine (adolescents only). Omicron-specific mRNA bivalent boosters are authorized for children â‰¥6 months old. Studies after monovalent vaccine authorization illustrated efficacy in children >5 to 6 years of age, specifically decreased severe COVID-19 (including mortality) and multisystem inflammatory response syndrome occurrence (including during Omicron predominance). Available data for children <5 to 6 years suggests efficacy, although data are limited. Monovalent vaccine efficacy against Omicron infections may wane as early as 2 months, but protection against severe disease complications may last longer, and bivalent Omicron boosters are anticipated to increase effectiveness. Myocarditis/pericarditis is a safety concern associated with the COVID-19 vaccinations but occurs less frequently then COVID-19 complications and thus the benefit outweighs the risks. RELEVANCE TO PATIENT CARE AND CLINICAL PRACTICE: Caregivers seek information from health care professionals regarding vaccine safety and efficacy. Pharmacists can use the objective information in this review to educate caregivers and effectively administer COVID-19 vaccines to patients. CONCLUSIONS: There is sufficient and continually growing safety and efficacy data available to recommend COVID-19 vaccinations for children â‰¥6 months of age.

Anti-human leukocyte antigen and anti-ABO antibodies after SARS-CoV-2 mRNA vaccination in kidney transplant recipients. INTRODUCTION: In this study, we evaluated whether SARS-CoV-2 mRNA vaccines induce anti-human leukocyte antigen (HLA) antibodies and anti- ABO blood type antibodies (ABOAb) in kidney transplant recipients (KTRs). METHODS: Sixty-three adult KTRs with functioning grafts who received two doses of the SARS-CoV-2 mRNA vaccine were enrolled in this cohort. Changes in anti-ABO blood type immunoglobulin IgM and IgG antibody titers, flow panel reactive antibody (PRA), de novo donor-specific anti-human leukocyte antigen antibodies (DSA), and kidney allograft function before and after vaccination were evaluated. RESULTS: Only one patient experienced conversion from negative to positive flow PRA after vaccination. However, there was no DSA in single antigen flow-bead assays. The mean fluorescence intensity (MFI) in the eight DSA-positive recipients did not significantly change before and after vaccination (pÂ =Â .383), and no additional DSA was produced after vaccination in those patients. No significant elevation of ABOAb titer was observed for either IgM (pÂ =Â .438) or IgG (pÂ =Â .526) after vaccination. There was no significant deterioration in estimated glomerular filtration rate (eGFR) after vaccination (pÂ =Â .877) or elevation of the urine protein-to-creatinine ratio (pÂ =Â .209) after vaccination. One episode of AMR was observed in addition to a preexisting acute cellular rejection. CONCLUSIONS: The SARS-CoV-2 mRNA vaccine did not induce anti-HLA antibody or ABOAb production in KTRs.

Focal Crescentic Glomerulonephritis Following COVID-19 Viral Vector Vaccination. Vaccination is a vital tool aimed at curbing the COVID-19 pandemic, and the FDA has authorized several vaccines for emergency use to combat COVID-19. Our patient presented with acute kidney injury two weeks after receiving the first dose of the COVID-19 Janssen (Johnson & Johnson) vaccine. Renal biopsy confirmed focal crescentic glomerulonephritis. The patient has been unable to achieve remission after diagnosis and is now a candidate for a kidney transplant. In conclusion, this case report provides insight into the possible relationship between glomerular disease following COVID-19 Janssen (Johnson & Johnson) vaccination. Based on this presented case, new-onset or relapse of glomerular diseases presenting

post-COVID-19 vaccination should be observed as a possible adverse event to large-scale COVID-19 vaccination.

Humoral response after BNT162b2 vaccine in Japanese hemodialysis patients. BACKGROUND: Hemodialysis patients are more likely to be severely affected if infected by COVID-19. Contributing factors include chronic kidney disease, old age, hypertension, type 2 diabetes, heart disease, and cerebrovascular disease. Therefore, action against COVID-19 for hemodialysis patients is an urgent issue. Vaccines are effective in preventing COVID 19 infection. In hemodialysis patients, however, responses to hepatitis B and influenza vaccines are reportedly weak. The BNT162b2 vaccine has shown an efficacy rate of about 95% in the general population, but as far as we know there are only several reports of efficacy data in hemodialysis patients in Japan. METHODS: We assessed serum anti-SARS-CoV-2 IgG antibody (Abbott SARS-CoV-2 IgG II Quan) in 185 hemodialysis patients and 109 health care workers. The exclusion criterion was positivity for SARS-CoV-2 IgG antibody before vaccination. Adverse reactions to BNT162b2 vaccine were evaluated through interviews. RESULTS: Following vaccination, 97.6% of the hemodialysis group and 100% of the control group were positive for the anti-spike antibody. The median level of anti-spike antibody was 2,728.7 AU/mL (IQR, 1,024.2-7,688.2 AU/mL) in the hemodialysis group and 10,500 AU/ml (IQR, 9,346.1-2,4500 AU/mL) in the health care workers group. The factors involved in the low response to the BNT152b2 vaccine included old age, low BMI, low Cr index, low nPCR, low GNRI, low lymphocyte count, steroid administration, and complications related to blood disorders. CONCLUSIONS: Humoral responses to BNT162b2 vaccine in hemodialysis patients are weaker than in a healthy control sample. Booster vaccination is necessary for hemodialysis patients, especially those showing a weak or non-response to the two-dose BNT162b2 vaccine.Trial registration UMIN, UMIN000047032. Registered 28 February 2022, https://center6.umin.ac.jp/cgi-bin/ctr/ctr_reg_rec.cgi.

Acute pulmonary thromboembolism after messenger RNA vaccination against coronavirus disease 2019: A case report. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is defined as thrombosis after inoculation of adenovirus vector vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). VITT rarely occurs with messenger RNA vaccines, and the use of heparin for VITT is also controversial. A 74-year-old female patient with no risk factors for thrombosis was brought to our hospital after loss of consciousness. Nine days before admission, she had received the third vaccine against SARS-CoV-2 (mRNA1273, Moderna). Immediately after transport, cardiopulmonary arrest occurred, prompting extracorporeal membrane oxygenation (ECMO). Pulmonary angiography showed translucent images of both pulmonary arteries, resulting in the diagnosis of acute pulmonary thromboembolism. Unfractionated heparin was administered, but D-dimer subsequently became negative. Pulmonary thrombosis remained in large volume, indicating that heparin was ineffective. Treatment was shifted to anticoagulant therapy using argatroban, which increased D-dimer level and improved respiratory status. The patient was successfully weaned from ECMO and ventilator. Anti-platelet factor 4 antibody examined after treatment initiation showed negative results; however, VITT was considered as an underlying condition because of the time of onset after vaccination, the ineffectiveness of heparin, and the absence of other causes of thrombosis. In case heparin is not effective, argatroban can be an alternative therapy against thrombosis. LEARNING OBJECTIVE: During the coronavirus disease 2019 pandemic, treatment with vaccine against severe acute respiratory syndrome coronavirus 2 has been widely performed. Vaccine-induced immune thrombotic thrombocytopenia is the most common thrombosis after adenovirus vector vaccines. However, thrombosis can also occur after messenger RNA vaccination. Though commonly used for thrombosis, heparin may be ineffective. Non-heparin anticoagulants should be considered.

Orbital Inflammation and Dacryoadenitis after COVID-19 Vaccination. The aim of this paper was to report the case of a patient with orbital inflammation and dacryoadenitis after COVID-19 vaccination. During the COVID-19 pandemic, we noticed an increase of post-viral syndromes, both linked to infection and to vaccination. A 53-year-old male presented with proptosis, chemosis, hypotropia, and ophthalmoplegia of the right eye, 1 day after his COVID-19 booster shot. Anecdotally, he suffered similar symptoms after his initial two vaccinations. Idiopathic orbital inflammation and dacryoadenitis were diagnosed, and the patient was successfully treated with oral steroids. Orbital inflammation and dacryoadenitis after infection or vaccination are no new entities, but due to the scale of the current pandemic and the associated vaccination programs, these rare ocular diseases could be encountered more often.

Adverse Reactions of COVID-19 Vaccines: A Scoping Review of Observational Studies. The COVID-19 pandemic had a severe global impact. A range of campaigns and activities, including vaccines, are being implemented to counteract this pandemic. Using observational data, the goal of this scoping review is to identify adverse events connected with COVID-19 vaccinations. We conduct a scoping study and searched three databases from the start of the COVID-19 pandemic in 2020 through June 2022. Based on our criteria and searched keywords, the review included eleven papers in total, with the majority of the studies being conducted in developed countries. The study populations varied and included general community populations, healthcare professionals, military forces, and patients with systemic lupus and cancer. This study includes vaccines from Pfizer-BioNTech, Oxford-AstraZeneca, Sinopharm, and Moderna. The COVID-19 vaccine-related adverse events were classified into three types: local side effects, systemic side effects, and other side effects such as allergies. The adverse reactions to COVID-19 vaccines are mild to moderate in severity, with no significant influence or interference in individual daily activities and no unique patterns in cause of death among vaccine-related deaths. According to the findings of these investigations, the COVID-19 vaccine is safe to administer and induces protection. It is vital to convey accurate information to the public about vaccination side effects, potential adverse responses, and the safety level of the vaccines supplied. Multiple strategies must be implemented at the individual, organizational, and population levels to eliminate vaccine hesitance. Future studies could investigate the vaccine's effect on people of various ages and medical conditions.

Comparison of antibody responses before and after booster doses with the Pfizer-BioNTech or Oxford-AstraZeneca vaccines in healthcare workers in Thailand. The severe acute respiratory syndrome 2 (SARS-CoV-2) has spread rapidly worldwide, not only causing significant morbidity and mortality but also dramatically increasing health care spending. To manage this in Thailand, healthcare workers first received two doses of the CoronaVac vaccine followed by a booster vaccine with either BNT162b2 vaccine (Pfizer-BioNTech; PZ) or ChAdOx1 nCoV-19 vaccine (Oxford-AstraZeneca; AZ). Given that the difference in anti-SARS-CoV-2 levels following vaccination may vary depending on the vaccine and on demographic characteristics, we measured the antibody response after the second CoronaVac dose and after the booster with either the PZ or AZ vaccine. Our results in 473 healthcare workers show that the variation in antibody response to the full CoronaVac dose depends on demographic characteristics such as age, gender, body mass index, and underlying disease. After receiving a booster dose, anti-SARS-CoV-2 levels were significantly higher in participants who received the PZ vaccine than in people who received the AZ vaccine. Overall, however, receiving a booster dose of either the PZ or AZ vaccine promoted strong antibody responses, even in the old and those with obesity or diabetes mellitus. In conclusion, our results support the use of a booster vaccination program after full vaccination with the CoronaVac vaccine. This approach effectively enhances immunity against SARS-CoV-2, especially in clinically vulnerable groups and healthcare workers.

Detailed characterization of SARS-CoV-2-specific T and B cells after infection or heterologous vaccination. The formation of a robust long-term antigen (Ag)-specific memory, both humoral and cell-mediated, is created following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection or vaccination. Here, by using polychromatic flow cytometry and complex data analyses, we deeply investigated the magnitude, phenotype, and functionality of SARS-CoV-2-specific immune memory in two groups of healthy subjects after heterologous vaccination compared to a group of subjects who recovered from SARS-CoV-2 infection. We find that coronavirus disease 2019 (COVID-19) recovered patients show different long-term immunological profiles compared to those of donors who had been vaccinated with three doses. Vaccinated individuals display a skewed T helper (Th)1 Ag-specific T cell polarization and a higher percentage of Ag-specific and activated memory B cells expressing immunoglobulin (Ig)G compared to those of patients who recovered from severe COVID-19. Different polyfunctional properties characterize the two groups: recovered individuals show higher percentages of CD4(+) T cells producing one or two cytokines simultaneously, while the vaccinated are distinguished by highly polyfunctional populations able to release four molecules, namely, CD107a, interferon (IFN)-Î³, tumor necrosis factor (TNF), and interleukin (IL)-2. These data suggest that functional and phenotypic properties of SARS-CoV-2 adaptive immunity differ in recovered COVID-19 individuals and vaccinated ones.

COVID-19 vaccine uptake, hesitancy and clinical effects on patients with Takayasu's arteritis: A web-based questionnaire survey from a large cohort. OBJECTIVE: This study aimed to investigate the Coronavirus disease 2019 (COVID-19) vaccination rate, reasons for vaccine hesitancy and clinical effects on patients with Takayasu's arteritis (TAK). METHODS: A web-based survey was administered to a TAK cohort established by the Department of Rheumatology, Zhongshan Hospital through WeChat in April, 2022. Responses from a total of 302 patients were received. The Sinovac or Sinopharm inactivated vaccination rate, side effects, and vaccine hesitancy reasons were analyzed. In addition, disease flare, new disease onset, and changes of immune-related parameters after vaccination were analyzed in vaccinated patients. RESULTS: Among 302 patients, 93 (30.79%) received the inactivated COVID-19 vaccination. Among the 209 unvaccinated patients, the most common reason for hesitancy were concern about side effects (136, 65.07%). Vaccinated patients had a longer disease duration ($p = 0.08$) and lower use of biologic agents ($p < 0.001$); 16 (17.20%) of the 93 vaccinated patients developed side effects, and most of them were mild; 8 (8.60%) developed disease flares or new-onset disease 12-128 days post-vaccination and 2 (2.15%) developed serious adverse effects (vision defect and cranial infarction). Immune-related parameters of 17 patients indicated decreases in IgA and IgM after vaccination ($p < 0.05$). Eighteen (19.35%) of the 93 vaccinated patients were diagnosed post-vaccination.These patients had a significantly higher percentage of CD19(+) B cells at disease onset ($p < 0.05$) than the unvaccinated patients diagnosed at the same time. CONCLUSION: The vaccination rate was low in TAK, which was mainly caused by concerns about negative effects of vaccination on their disease. An acceptable safety profile was observed in vaccinated patients. The risk of disease flare associated with COVID-19 vaccination warrants further investigation.

Predictors for reactogenicity and humoral immunity to SARS-CoV-2 following infection and mRNA vaccination: A regularized, mixed-effects modelling approach. INTRODUCTION: The influence of pre-existing humoral immunity, inter-individual demographic factors, and vaccine-associated reactogenicity on immunogenicity following COVID vaccination remains poorly understood. METHODS: Ten-fold cross-validated least absolute shrinkage and selection operator (LASSO) and linear mixed effects models were used to evaluate symptoms experienced by COVID+ participants during natural infection and following SARS-CoV-2 mRNA vaccination along with demographics as predictors for antibody (AB) responses to recombinant spike protein in a longitudinal cohort study.

RESULTS: In previously infected individuals (n=33), AB were more durable and robust following primary vaccination when compared to natural infection alone. Higher AB were associated with experiencing dyspnea during natural infection, as was the total number of symptoms reported during the COVID-19 disease course. Both local and systemic symptoms following 1(st) and 2(nd) dose (n=49 and 48, respectively) of SARS-CoV-2 mRNA vaccines were predictive of higher AB after vaccination. Lastly, there was a significant temporal relationship between AB and days since infection or vaccination, suggesting that vaccination in COVID+ individuals is associated with a more robust immune response. DISCUSSION: Experiencing systemic and local symptoms post-vaccine was suggestive of higher AB, which may confer greater protection.

Cirrhosis is associated with lower serological responses to COVID-19 vaccines in patients with chronic liver disease. BACKGROUND & AIMS: The response of patients with chronic liver disease (CLD) to COVID-19 vaccines remains unclear. Our aim was to assess the humoral immune response and efficacy of two-dose COVID-19 vaccines among patients with CLD of different aetiologies and disease stages. METHODS: A total of 357 patients were recruited in clinical centres from six European countries, and 132 healthy volunteers served as controls. Serum IgG (nM), IgM (nM), and neutralising antibodies (%) against the Wuhan-Hu-1, B.1.617, and B.1.1.529 SARS-CoV-2 spike proteins were determined before vaccination (T0) and 14 days (T2) and 6 months (T3) after the second-dose vaccination. Patients fulfilling inclusion criteria at T2 (nÂ = 212) were stratified into 'low' or 'high' responders according to IgG levels. Infection rates and severity were collected throughout the study. RESULTS: Wuhan-Hu-1 IgG, IgM, and neutralisation levels significantly increased from T0 to T2 in patients vaccinated with BNT162b2 (70.3%), mRNA-1273 (18.9%), or ChAdOx1 (10.8%). In multivariate analysis, age, cirrhosis, and type of vaccine (ChAdOx1 > BNT162b2 > mRNA-1273) predicted 'low' humoral response, whereas viral hepatitis and antiviral therapy predicted 'high' humoral response. Compared with Wuhan-Hu-1, B.1.617 and, further, B.1.1.529 IgG levels were significantly lower at both T2 and T3. Compared with healthy individuals, patients with CLD presented with lower B.1.1.529 IgGs at T2 with no additional key differences. No major clinical or immune IgG parameters associated with SARS-CoV-2 infection rates or vaccine efficacy. CONCLUSIONS: Patients with CLD and cirrhosis exhibit lower immune responses to COVID-19 vaccination, irrespective of disease aetiology. The type of vaccine leads to different antibody responses that appear not to associate with distinct efficacy, although this needs validation in larger cohorts with a more balanced representation of all vaccines. IMPACT AND IMPLICATIONS: In patients with CLD vaccinated with two-dose vaccines, age, cirrhosis, and type of vaccine (Vaxzevria > Pfizer BioNTech > Moderna) predict a 'lower' humoral response, whereas viral hepatitis aetiology and prior antiviral therapy predict a 'higher' humoral response. This differential response appears not to associate with SARS-CoV-2 infection incidence or vaccine efficacy. However, compared with Wuhan-Hu-1, humoral immunity was lower for the Delta and Omicron variants, and all decreased after 6 months. As such, patients with CLD, particularly those older and with cirrhosis, should be prioritised for receiving booster doses and/or recently approved adapted vaccines.

Herpes zoster ophthalmicus after COVID-19 vaccine booster in healthy younger adult: a case report. There were growing reports of herpes zoster reactivation after the coronavirus disease 2019 (COVID-19) vaccination, including a more severe form, herpes zoster ophthalmicus (HZO). A 35-year-old male presented HZO in his left V1 dermatome 10 days after his COVID-19 vaccine booster with Moderna (messenger RNA-1273). He had no history of chronic disease, immunocompromised, autoimmune, malignancy, or long-term immunosuppressive drug use. The rash improved without any further complications after being treated with oral valacyclovir for 7 days. This was a unique case of HZO after the COVID-19 vaccine in a booster setting in healthy younger adults. The association of herpes zoster after a COVID vaccine remained inconclusive and potentially coincidental, especially without

the known risk factor. However, we would like to add a report to increase awareness among physicians and the general population, for early recognition and treatment with an antiviral.
Humoral immune response to SARS-CoV-2 mRNA vaccines is associated with choice of vaccine and systemic adverse reactions. PURPOSE: Although the fast development of safe and effective messenger RNA (mRNA) vaccines against severe acute respiratory syndrome coronavirus 2 has been a success, waning humoral immunity has led to the recommendation of booster immunization. However, knowledge of the humoral immune response to different booster strategies and the association with adverse reactions is limited. MATERIALS AND METHODS: We investigated adverse reactions and anti-spike protein immunoglobulin G (IgG) concentrations among health care workers who received primary immunization with mRNA-1273 and booster immunization with mRNA-1273 or BNT162b2. RESULTS: Adverse reactions were reported by 85.1% after the first dose, 94.7% after the second dose, 87.5% after a third dose of BNT162b2, and 86.0% after a third dose of mRNA-1273. They lasted for a median of 1.8, 2.0, 2.5, and 1.8 days, respectively; 6.4%, 43.6%, and 21.0% of the participants were unable to work after the first, second, and third vaccination, respectively, which should be considered when scheduling vaccinations among essential workers. Booster immunization induced a 13.75-fold (interquartile range, 9.30-24.47) increase of anti-spike protein IgG concentrations with significantly higher concentrations after homologous compared to heterologous vaccination. We found an association between fever, chills, and arthralgia after the second vaccination and anti-spike protein IgG concentrations indicating a linkage between adverse reactions, inflammation, and humoral immune response. CONCLUSION: Further investigations should focus on the possible advantages of homologous and heterologous booster vaccinations and their capability of stimulating memory B-cells. Additionally, understanding inflammatory processes induced by mRNA vaccines might help to improve reactogenicity while maintaining immunogenicity and efficacy.
Seroconversion rates in kidney transplant recipients following SARS-CoV-2 vaccination and its association with immunosuppressive agents: a systematic review and meta-analysis. This systematic and meta-analysis aims to evaluate humoral and cellular responses to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine among kidney transplant recipients (KTRs). We conducted a systematic literature search across databases to evaluate seroconversion and cellular response rates in KTRs receiving SARS-CoV-2 vaccines. We extracted studies that assessed seroconversion rates described as the presence of antibody de novo positivity in KTRs following SARS-CoV-2 vaccination published up to January 23rd, 2022. We also performed meta-regression based on immunosuppression therapy used. A total of 44 studies involving 5,892 KTRs were included in this meta-analysis. The overall seroconversion rate following complete dose of vaccines was 39.2% (95% confidence interval [CI], 33.3%-45.3%) and cellular response rate was 41.6% (95% CI, 30.0%-53.6%). Meta-regression revealed that low antibody response rate was significantly associated with the high prevalence of mycophenolate mofetil/mycophenolic acid (p=0.04), belatacept (p=0.02), and anti-CD25 induction therapy uses (p=0.04). Conversely, tacrolimus use was associated with higher antibody response (p=0.01). This meta-analysis suggests that postvaccination seroconversion and cellular response rates in KTRs are still low. And seroconversion rate was correlated with the type of immunosuppressive agent and induction therapy used. Additional doses of the SARS-CoV-2 vaccine for this population using a different type of vaccine are considered.
Psoriasis flares after COVID-19 vaccination: adherence to biologic therapy reduces psoriasis exacerbations: a case-control study. This study aimed to evaluate if patients under biologics have a lower risk of psoriasis flares after coronavirus disease 2019 (COVID-19) vaccination than other psoriatic patients. Of 322 recently vaccinated patients admitted for psoriasis at the Dermatological Psoriasis Unit during January and February 2022, 316 (98%) had no psoriasis flares after COVID-19 vaccination (79% under biologic treatment, 21% not biologically treated) and 6 (2%) presented

psoriasis flares after COVID-19 vaccination (33.3% under biologic treatment, 66.6% not biologically treated). Overall, psoriasis patients under biologic treatment, developed fewer psoriasis flares after COVID-19 vaccination (33.3%), than patients not under biologic treatment (66.6%) (p=0.0207; Fisher's exact test).

CD4â€‰+â€‰Count: a Variable to Be Considered to Prioritize COVID-19 Vaccination in PLHIV. The outbreak of the COVID-19 propagates, pressurizing the healthcare system by emphasizing and worsening the inequities. While many vaccines have shown excellent efficacy in protecting the general public from the COVID-19 infection, the efficacy of these vaccines for people living with HIV (PLHIV), especially those having a different range of CD4â€‰+â€‰T-cell, has yet to be thoroughly investigated. Few studies have uncovered the escalated infection and death rates due to the COVID-19 infection in individuals with low CD4â€‰+â€‰T-cells. Additionally, PLHIV has a low CD4â€‰+â€‰count; furthermore, specific CD4â€‰+â€‰T cells for coronavirus have a vigorous Th1 role and are related to the protective antibody responses. Follicular helper T cells (TFH) are vulnerable to HIV and virus-specific CD4 & CD8 T-cells which are essential for viral infection clearance and defective immune responses which further contributes to the development of illness. The specific CD8 & CD4â€‰+â€‰T-cell reaction to severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) was identified in almost all COVID-19 recovered individuals, which is related to the size of antibodies of immunoglobulin G. It has previously been demonstrated that PLHIV has decreased responses to certain vaccines and that these responses are reliant on CD4â€‰+â€‰T-cell levels. COVID-19 vaccines will likely have a lower response or limited effect, in PLHIV having low CD4â€‰+â€‰T-cells.

The accelerated waning of immunity and reduced effect of booster in patients treated with bDMARD and tsDMARD after SARS-CoV-2 mRNA vaccination. OBJECTIVES: This study aimed to assess the duration of humoral responses after two doses of SARS-CoV-2 mRNA vaccines in patients with inflammatory joint diseases and IBD and booster vaccination compared with healthy controls. It also aimed to analyze factors influencing the quantity and quality of the immune response. METHODS: We enrolled 41 patients with rheumatoid arthritis (RA), 35 with seronegative spondyloarthritis (SpA), and 41 suffering from inflammatory bowel disease (IBD), excluding those receiving B-cell-depleting therapies. We assessed total anti-SARS-CoV-2 spike antibodies (Abs) and neutralizing Ab titers 6 months after two and then after three doses of mRNA vaccines compared with healthy controls. We analyzed the influence of therapies on the humoral response. RESULTS: Patients receiving biological or targeted synthetic disease-modifying antirheumatic drugs (b/tsDMARDs) showed reduced anti-SARS-CoV-2 S Abs and neutralizing Ab titers compared with HC or patients receiving conventional synthetic (cs)DMARDs 6 months after the first two vaccination doses. Anti-SARS-CoV-2 S titers of patients with b/tsDMARDs declined more rapidly, leading to a significant reduction in the duration of vaccination-induced immunity after two doses of SARS-CoV-2 mRNA vaccines. While 23% of HC and 19% of patients receiving csDMARDs were without detectable neutralizing Abs 6 months after the first two vaccination doses, this number was 62% in patients receiving b/tsDMARDs and 52% in patients receiving a combination of csDMARDs and b/tsDMARDs. Booster vaccination led to increased anti-SARS-CoV-2 S Abs in all HC and patients. However, anti-SARS-CoV-2 S Abs after booster vaccination was diminished in patients receiving b/tsDMARDs, either alone or in combination with csDMARDs compared to HC. CONCLUSION: Patients receiving b/tsDMARDs have significantly reduced Abs and neutralizing Ab titers 6 months after mRNA vaccination against SARS-CoV-2. This was due to a faster decline in Ab levels, indicating a significantly reduced duration of vaccination-induced immunity compared with HC or patients receiving csDMARDs. In addition, they display a reduced response to a booster vaccination, warranting earlier booster vaccination strategies in patients under b/tsDMARD therapy, according to their specific Ab levels.

COVID arm that appeared in the contralateral upper extremity after mRNA-1273 booster inoculation. We report the findings of a 60-year-old female patient with metastatic breast cancer who presented with severe edema and neuralgia in the contralateral arm after receiving the third COVID-19 vaccine dose. The patient did not report any reaction to the first two doses of the BNT162b2 (Pfizer-BioNTech) vaccine. However, after a booster dose with the mRNA-1273 (Moderna) vaccine, the patient developed a high fever persisting for one week after the shot, and sequential severe swelling, inflammation, and pain in the contralateral arm lasting for three weeks.

[Antibody production capacity after COVID-19 vaccination in immune-mediated neuromuscular diseases under immunotherapy]. The post-vaccination antibody response in patients with immune-mediated neuromuscular diseases under immuno-suppressive therapy has not been sufficiently verified. The Japanese Society of Neurology has stated that coronavirus disease 2019 (COVID-19) vaccination should be given priority in patients with immunotherapy-associated neuromuscular diseases; however, data on antibody production to a novel mRNA vaccine are scarce in these patients. In this study, we aimed to measure residual antibody titers after the second dose and produced antibodies after the third dose of SARS-CoV-2 mRNA vaccine in 25 patients with neuromuscular diseases under immuno-suppressive therapy (disease group). We compared the disease group antibody titers with those of 829 healthy employees in our hospital (control group). The disease group included 17 patients with myasthenia gravis, 4 with multiple sclerosis, 3 with inflammatory muscle disease, and 1 with chronic inflammatory demyelinating polyneuropathies. Seven cases of the disease group showed negative antibody levels (<15.0Â s/co) before the third vaccination, and antibody titers in the positive cases ranged from 16.9 to 4,589.0Â s/co. Three of the seven antibody-negative cases turned positive after the third vaccination, and all but one of the antibody-positive cases showed a booster effect, with antibody titers after the third dose ranging from 245.1 to 85,374.0Â s/co (1.0 to 885.0 times higher than those before vaccination). Although the immune response in the disease group was modest compared to the control group, in which antibody titers after the third vaccination ranged from 67.8 to 150,000Â s/co (0.9 to 5,402.1 times higher than those before vaccination), the result indicated that a constant immune response was achieved under immuno-suppressive therapy. Even in the control group, three participants tested negative for residual antibody before the third inoculation, and four of the antibody-positive participants (27.7-24,054.0Â s/co) lacked a booster effect after the third vaccination.

A randomized phase I/II safety and immunogenicity study of the Montanide-adjuvanted SARS-CoV-2 spike protein-RBD-Fc vaccine, AKS-452. BACKGROUND: Previous interim data from a phase I study of AKS-452, a subunit vaccine comprising an Fc fusion of the respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein receptor binding domain (SP/RBD) emulsified in the water-in-oil adjuvant, Montanideâ„¢ ISA 720, suggested a good safety and immunogenicity profile in healthy adults. This phase I study was completed and two dosing regimens were further evaluated in this phase II study. METHODS: This phase II randomized, open-labelled, parallel group study was conducted at a single site in The Netherlands with 52 healthy adults (18 - 72Â years) receiving AKS-452 subcutaneously at one 90Â Âµg dose (cohort 1, 26 subjects) or two 45Â Âµg doses 28Â days apart (cohort 2, 26 subjects). Serum samples were collected at the first dose (day 0) and at days 28, 56, 90, and 180. Safety and immunogenicity endpoints were assessed, along with induction of IgG isotypes, cross-reactive immunity against viral variants, and IFN-Î³ T cell responses. RESULTS: All AEs were mild/moderate (grades 1 or 2), and no SAEs were attributable to AKS-452. Seroconversion rates reached 100% in both cohorts, although cohort 2 showed greater geometric mean IgG titers that were stable through day 180 and associated with enhanced potencies of SP/RBD-ACE2 binding inhibition and live virus neutralization. AKS-452-induced IgG titers strongly bound mutant SP/RBD from several SARS-CoV-2 variants (including Omicrons) that were predominantly of the favorable

IgG1/3 isotype and IFN-Î³-producing T cell phenotype. CONCLUSION: These favorable safety and immunogenicity profiles of the candidate vaccine as demonstrated in this phase II study are consistent with those of the phase I study (ClinicalTrials.gov: NCT04681092) and suggest that a total of 90Â Âµg received in 2 doses may offer a greater duration of cross-reactive neutralizing titers than when given in a single dose.

Cardiovascular complications of COVID-19 vaccines: A review of case-report and case-series studies. BACKGROUND: There are multiple reviews on cardiovascular aspects of COVID-19 disease on cardiovascular system in different population but there is lack of evidence about cardiovascular adverse effects of COVID vaccines. OBJECTIVES: The purpose of this study was to compare the cardiac complications of COVID19 vaccines, based on vaccine type (mRNA, vector-based, and inactivated vaccines). METHODS: A systematic search was performed covering PubMed for English case-reports and case-series studies, and finally 100 studies were included. RESULTS: Myocarditis (with overall rate around 1.62%) was shown to be the most common post-COVID19 immunization cardiac event. More than 90% of post-COVID19 vaccination myocarditis occurred after receiving mRNA vaccines (Moderna & Pfizer-BioNTech), but the report of this event was less in the case of vector-based vaccinations and/or inactivated vaccines. Myocarditis was reported more commonly in men and following the second dose of the immunization. Takotsubo cardiomyopathy (TTC) was reported after mRNA (more commonly) and vector-based vaccinations, with no case report after inactivated vaccines. When mRNA and vector-based vaccinations were used instead of inactivated vaccines, a greater frequency of vaccine-induced thrombotic thrombocytopenia (VITT) and pulmonary emboli (PE) was reported. Myocardial infarction/cardiac arrest was recorded in those beyond the age of 75 years. CONCLUSION: The personal and public health benefits of COVID-19 vaccination much outweigh the minor cardiac risks. Reporting bias, regarding more available mRNA vaccines in developed countries, may conflict these results.

Immunological response after SARS-CoV-2 infection and mRNA vaccines in patients with myasthenia gravis treated with Rituximab. In this study we employed a comprehensive immune profiling approach to determine innate and adaptive immune response to SARS-CoV-2 infection and mRNA vaccines in patients with myasthenia gravis receiving rituximab. By multicolour cytometry, dendritic and natural killer cells, B- and T-cell subsets, including T-cells producing IFN-Î³ stimulated with SARS-CoV-2 peptides, were analysed after infection and mRNA vaccination. In the same conditions, anti-spike antibodies and cytokines' levels were measured in sera. Despite the impaired B cell and humoral response, rituximab patients showed an intact innate, CD8 T-cell and IFN-Î³ specific CD4+ and CD8+ T-cell response after infection and vaccination, comparable to controls. No signs of cytokine mediated inflammatory cascade was observed. Our study provides evidence of protective immune response after SARS-CoV-2 infection and mRNA vaccines in patients with myasthenia gravis on B cell depleting therapy and highlights the need for prospective studies with larger cohorts to clarify the role of B cells in SARS-CoV-2 immune response.

Long COVID symptoms in hospital employees after post-vaccination SARS-CoV-2 infection in Austria: A study on self-reported incidence and associated factors. PURPOSE: Post acute sequelae of SARS-CoV-2 infection are defined by persistence or re-occurrence of symptoms six to 12 weeks after SARS-CoV-2 infections. METHODS: Twice vaccinated hospital employees after mild to moderate post-vaccination SARS-CoV-2 infection completed a questionnaire on the incidence of general, respiratory, neuropsychiatric, dermatological and gastrointestinal symptoms, experienced during their acute infection and eight weeks after recovery. Post acute sequelae of SARS-CoV-2 infection were analysed in relation to socio-demographic-, health-, virus- and acute infection-related characteristics. RESULTS: 73 participants, 25 women and 48 men with a mean age of 40.9 years, with a post-vaccination SARS-CoV-2 infection completed the survey. Out of these 93 % reported at least one symptom at time of

initial SARS-CoV-2 infection, 31.5 %, predominantly women, reported post acute sequelae at least eight weeks after the acute infection stage. Fatigue, dysgeusia and dysosmia, headache or difficulty concentrating and shortness of breath during acute infection, BMI>Â 25 and pre-existing pulmonary disorders were associated with post acute sequelae of SARS-CoV-2 infection. Participants with initially more than five symptoms were four times more likely to report post acute sequelae. CONCLUSION: It is suggested that the multiplicity of symptoms during acute SARS-CoV-2 infections increases the risk for post acute symptoms.

Autoimmunity, COVID-19, Post-COVID19 Syndrome and COVID-19 Vaccination.

Monitoring and immunogenicity of SARS-CoV-2 vaccination of laboratory rhesus monkeys (Macaca mulatta). The availability of effective vaccines and a high vaccination rate allowed the recent mitigation, or even withdrawal, of many protective measures for containing the SARS CoV-2 pandemic. At the same time, new and highly mutated variants of the virus are found to have significantly higher transmissibility and reduced vaccine efficacy, thus causing high infection rates during the third year of the pandemic. The combination of reduced measures and increased infectivity poses a particular risk for unvaccinated individuals, including animals susceptible to the virus. Among the latter, non-human primates (NHPs) are particularly vulnerable. They serve as important models in various fields of biomedical research and because of their cognitive capabilities, they receive particular attention in animal welfare regulations around the world. Yet, although they played an extraordinarily important role for developing and testing vaccines against SARS-CoV-2, the protection of captive rhesus monkeys against Covid-19 has rarely been discussed. We here report upon twofold mRNA vaccination of a cohort of 19 elderly rhesus monkeys (Macaca mulatta) against infection by SARS-CoV-2. All animals were closely monitored on possible side effects of vaccination, and were tested for neutralising antibodies against the virus. The data show that vaccination of rhesus monkeys is a safe and reliable measure to protect these animals against SARS-CoV-2.

Incidence determinants and serological correlates of reactive symptoms following SARS-CoV-2 vaccination. Prospective population-based studies investigating associations between reactive symptoms following SARS-CoV-2 vaccination and serologic responses to vaccination are lacking. We therefore conducted a study in 9003 adults from the UK general population receiving SARS-CoV-2 vaccines as part of the national vaccination programme. Titres of combined IgG/IgA/IgM responses to SARS-CoV-2 spike (S) glycoprotein were determined in eluates of dried blood spots collected from all participants before and after vaccination. 4262 (47.3%) participants experienced systemic reactive symptoms after a first vaccine dose. Factors associating with lower risk of such symptoms included older age (aOR per additional 10 years of age 0.85, 95% CI: 0.81-0.90), male vs. female sex (0.59, 0.53-0.65) and receipt of an mRNA vaccine vs. ChAdOx1 nCoV-19 (0.29, 0.26-0.32 for BNT162b2; 0.06, 0.01-0.26 for mRNA-1273). Higher risk of such symptoms was associated with SARS-CoV-2 seropositivity and COVID-19 symptoms prior to vaccination (2.23, 1.78-2.81), but not with SARS-CoV-2 seropositivity in the absence of COVID-19 symptoms (0.94, 0.81-1.09). Presence vs. absence of self-reported anxiety or depression at enrolment associated with higher risk of such symptoms (1.24, 1.12-1.39). Post-vaccination anti-S titres were higher among participants who experienced reactive symptoms after vaccination vs. those who did not (Pâ€‰<â€‰0.001). We conclude that factors influencing risk of systemic symptoms after SARS-CoV-2 vaccination include demographic characteristics, pre-vaccination SARS-CoV-2 serostatus and vaccine type. Participants experiencing reactive symptoms following SARS-CoV-2 vaccination had higher post-vaccination titres of IgG/A/M anti-S antibodies. Improved public understanding of the frequency of reactogenic symptoms and their positive association with vaccine immunogenicity could potentially increase vaccine uptake.

A review of neurological side effects of COVID-19 vaccination. Following the COVID-19 virus epidemic, extensive, coordinated international research has led to the rapid development of effective

vaccines.Â AlthoughÂ vaccines are now considered the best way to achieve collective safety and control mortality, due to the critical situation, these vaccines have been issued the emergency use licenses andÂ some of theirÂ potentialÂ subsequence side effects have been overlooked. At the same time, there are many reports of side effects after getting a COVID-19 vaccine. According to these reports, vaccination can have an adverse event, especially on nervous system. The most important and common complicationsÂ are cerebrovascularÂ disorders including cerebral venous sinus thrombosis, transient ischemic attack, intracerebral hemorrhage, ischemic stroke, and demyelinatingÂ disorders including transverse myelitis, first manifestation of MS, and neuromyelitis optica. These effects are often acute and transient, but they can be severe and even fatal in a few cases. Herein, we have provided a comprehensive review of documents reporting neurological side effects of COVID-19 vaccines in international databases from 2020 to 2022 and discussed neurological disorders possibly caused by vaccination.

Chronic spontaneous urticaria following vaccination against SARS-CoV-2.

Acute Myocarditis and Pericarditis After mRNA COVID-19 Vaccinations-A Single-Centre Retrospective Analysis. BACKGROUND: With the rapid rollout of COVID-19 vaccinations, numerous associated and suspected adverse events have been reported nationally and worldwide. Literature reporting confirmed cases of pericarditis and myocarditis following SARS-CoV-2 mRNA vaccinations has evolved, with a predominance in adolescent males following the second dose. METHODS: This was a retrospective analysis of all patients presenting to St Vincent's Hospital, Sydney, Australia with suspected COVID-19 vaccine-related myocarditis and pericarditis. The Brighton Collaboration Case Definitions of Myocarditis and Pericarditis were used to categorise patients into groups based on diagnostic certainty. Cardiac magnetic resonance imaging findings were reviewed against updated Lake Louise Criteria for diagnosing patients with suspected myocarditis. RESULTS: We report 10 cases of confirmed, possible or probable myocarditis and pericarditis. The mean age of presentation in the vaccine group was 33Â±9.0 years. The most common presenting symptom was pleuritic chest pain (n=8, 80%). Eight patients (80%) had electrocardiogram (ECG) abnormalities (n=6 pericarditis, n=2 myocarditis). Five patients (50%) had a minimum 24 hours of cardiac monitoring. One patient had multisystem inflammatory syndrome following vaccination (MIS-V) with severely impaired left ventricular ejection fraction and required admission to the intensive care unit. DISCUSSION AND CONCLUSION: Cardiac complications post mRNA vaccines are rare. Our case series reflects the worldwide data that vaccine-related myocarditis and pericarditis most frequently occur in young males, following the second dose of the vaccine. These cardiac side effects are mild and self-limiting, with adequate responses to oral anti-inflammatories. One patient developed a severe reaction, with no fatal cases.

Encephalopathy after COVID-19 vaccination during treatment with nivolumab: A case report. Vaccination is useful for the prevention of COVID-19 and is recommended for everyone, especially people with a weakened immune system. However, various neurological complications have been reported following vaccination. Here, we report the case of a 25 years-old, Japanese man, who presented with acute encephalopathy two days after the second dose of the COVID-19 vaccine. He had been treated with nivolumab, a medication used to treat cancer. He had a high fever and was confused upon admission, and the antibody test was positive for anti-myelin oligodendrocyte glycoproteins. Abnormal signal intensity at the splenium corporis callosi was observed on diffusion-weighted imaging of the brain. We diagnosed him with autoimmune encephalitis and initiated intravenous methylprednisolone, after which, the patient's symptoms rapidly subsided.

Acute central nervous system inflammation following COVID-19 vaccination: An observational cohort study. BACKGROUND: Reports suggest a potential association between coronavirus disease 2019 (COVID-19) vaccines and acute central nervous system (CNS) inflammation. OBJECTIVE: The main

objective of this study is to describe features of acute CNS inflammation following COVID-19 vaccination. METHODS: A retrospective observational cohort study was performed at the BARLO MS Centre in Toronto, Canada. Clinicians reported acute CNS inflammatory events within 60â€‰days after a COVID-19 vaccine from March 2021 to August 2022. Clinical characteristics were evaluated. RESULTS: Thirty-eight patients (median age 39 (range: 20-82)â€‰years; 60.5% female) presented within 0-55 (median 15)â€‰days of a receiving a COVID-19 vaccine and were diagnosed with relapsing remitting multiple sclerosis (MS) (nâ€‰=â€‰16), post-vaccine transverse myelitis (nâ€‰=â€‰7), clinically isolated syndrome (nâ€‰=â€‰5), MS relapse (nâ€‰=â€‰4), tumefactive demyelination (nâ€‰=â€‰2), myelin oligodendrocyte glycoprotein antibody disease (nâ€‰=â€‰1), neuromyelitis optica spectrum disorder (nâ€‰=â€‰1), chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids (nâ€‰=â€‰1) and primary autoimmune cerebellar ataxia (nâ€‰=â€‰1). Twenty-two received acute treatment and 21 started disease-modifying therapy. Sixteen received subsequent COVID-19 vaccination, of which 87.5% had no new or worsening neurological symptoms. CONCLUSION: To our knowledge, this is the largest study describing acute CNS inflammation after COVID-19 vaccination. We could not determine whether the number of inflammatory events was higher than expected.

COVID-19 Vaccination and Alcohol Consumption: Justification of Risks. Since the beginning of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, pharmaceutical companies and research institutions have been actively working to develop vaccines, and the mass roll-out of vaccinations against COVID-19 began in January 2021. At the same time, during lockdowns, the consumption of alcoholic beverages increased. During the peak of vaccination, consumption remained at high levels around the world, despite the gradual relaxation of quarantine restrictions. Two of the popular queries on search engines were whether it is safe to drink alcohol after vaccination and whether this will affect the effectiveness of vaccines. Over the past two years, many studies have been published suggesting that excessive drinking not only worsens the course of an acute respiratory distress syndrome caused by the SARS-CoV-2 virus but can also exacerbate post-COVID-19 syndrome. Despite all sorts of online speculation, there is no specific scientific data on alcohol-induced complications after vaccination in the literature. Most of the published vaccine clinical trials do not include groups of patients with a history of alcohol-use disorders. This review analyzed the well-known and new mechanisms of action of COVID-19 vaccines on the immune system and the effects of alcohol and its metabolites on these mechanisms.

Vaccines and Autoimmunity-From Side Effects to ASIA Syndrome. Since vaccines are in fact manufactured chemical compounds such as drugs, the appearance of side effects following their use is not surprising. Similarly, as the main goal of vaccines is to stimulate the immune system bringing out the production of protective antibodies, autoimmune-related side effects as a consequence of increased immune activity do not seem irrational. Fortunately, the rate of such side effects is low; however, the importance of reporting adverse events following vaccinations, understanding the mechanisms behind their appearance, making early diagnosis, and appropriate treatment cannot be overemphasized. In fact, autoimmune-related side effects of vaccines, particularly those based on adjuvants, were reported long before the introduction of the autoimmune/inflammatory syndrome induced by adjuvants (ASIA). Nevertheless, ASIA gathered and united the side effects of vaccines under one title, a step which helped organize the research and call for better immune stimulators than adjuvants. New technologies and methods of making vaccines were clearly noticed during the pandemic of COVID-19 after the introduction of mRNA-based vaccines. In our current paper, we introduce the notion of side effects to vaccines, particularly those of autoimmune nature, the mechanisms of ASIA, and the main vaccines linked with the syndrome including the recent COVID-19 vaccines. The transition from side effects to ASIA is the main idea behind our work.

Cellular and Humoral Responses in Dialysis Patients after Vaccination with the BNT162b2 or mRNA-1273 Vaccines. The outbreak of SARS-CoV-2 has raised considerable concern about the detrimental effects it can induce in public health, with the interest of the scientific community being focused on the development of preventive and therapeutic approaches. Patients with end-stage renal disease (ESRD) are amongst vulnerable populations for critical illness owing to the presence of other comorbidities, their defective immune system, and their inability of self-isolation. To date, vaccination constitutes the most promising method to manage viral dispersion. Therefore, it is particularly important to investigate the effectiveness of available vaccines against SARS-CoV-2 in this risk group. Here, we summarize initial experience regarding the humoral and cellular immune responses elicited in dialysis patients after completion of the recommended vaccination regimen, as well as after booster dose administration, with one of the two mRNA vaccines, namely, BNT162b2 and mRNA-1273. In conclusion, a significantly diminished and delayed immune pattern was observed in ESRD patients compared to healthy population, with a peak in antibody titers occurring 3-5 weeks after the second dose. A booster dose significantly augmented the immune response in dialysis patients with either mRNA-based vaccine. Variables adversely correlating with the weak immunogenicity observed in dialysis patients include immunosuppressive therapy, older age, comorbidities, longer time in hemodialysis treatment, and higher body mass index. On the contrary, previous COVID-19 infection and administration of the mRNA-1273 vaccine are deemed to induce a more favorable immune response. Further investigation is needed to thoroughly understand the efficacy of mRNA-based vaccines in hemodialysis patients and define predictive factors that can influence it.

Cerebral Venous Sinus Thrombosis Following an mRNA COVID-19 Vaccination and Recent Oral Contraceptive Use. Rising concerns of cerebral venous sinus thrombosis (CVST) and other forms of venous thromboembolism have been associated with the SARS-CoV-2 vaccinations. Adverse effects with vector-based vaccines are well documented in the literature, while less is known about the mRNA vaccines. This report documents a case of CVST in a 32-year-old female patient who received her second Pfizer mRNA COVID-19 vaccination 16 days prior to hospital admission and had started oral combined contraceptives approximately 4 months beforehand. Clinicians should be cognizant of the possibility that mRNA vaccines, when combined with other risk factors like oral contraceptive pill use, may enhance one's hypercoagulable status.

Sleep and Circadian Rhythm in Relation to COVID-19 and COVID-19 Vaccination-National Sleep Survey of South Korea 2022. BACKGROUND: Currently, information on sleep and circadian patterns in relation to COVID-19 or vaccination remains limited. We aimed to investigate sleep and circadian patterns according to history of COVID-19 and COVID-19 vaccination side effects. METHODS: We used data from the National Sleep Survey of South Korea 2022, a nationwide cross-sectional population-based survey regarding sleep-wake behaviors and sleep problems among Korean adults. Analysis of covariance (ANCOVA) and logistic regression analyses were performed to explore the different sleep and circadian patterns according to the history of COVID-19 or self-reported side effects of the COVID-19 vaccination. RESULTS: The ANCOVA showed that individuals with a history of COVID-19 presented a later chronotype than individuals without a history of COVID-19. Individuals who had experienced vaccine-related side effects had a shorter sleep duration, poorer sleep efficiency, and worse insomnia severity. Multivariable logistic regression analysis showed a later chronotype related to COVID-19. A short sleep duration, poorer sleep efficiency, and worse insomnia severity were associated with self-reported side effects of the COVID-19 vaccination. CONCLUSIONS: Individuals who recovered from COVID-19 had a later chronotype than those without a history of COVID-19. Individuals who had experienced vaccine-related side effects presented with poorer sleep than those without side effects.

Sustained Myocarditis following Messenger RNA Vaccination against Coronavirus Disease 2019: Relation to Neutralizing Antibody and Amelioration by Low-Dose Booster Vaccination. We recently reported that sub-acute myocarditis occurred following the initial two doses of messenger RNA-based vaccination against coronavirus disease 2019 (0.3 mL Comirnaty(Â®)) in elderly Japanese patients with cardiac dysfunction. The present retrospective study of 76 patients revealed that myocarditis following the initial doses persisted for 12 months, was associated with low levels of neutralizing antibodies, and was ameliorated by reducing the third vaccine dose. Low neutralizing antibody levels (<220 U/mL) after the initial doses were an independent predictor of persistent clinical events, defined as death or marked changes in brain natriuretic peptide levels. When the third dose was reduced (0.1 mL), changes in brain natriuretic peptide levels were significantly smaller ($p = 0.02$, $n = 25$), no deaths occurred due to heart failure, and neutralizing antibody levels increased 41-fold ($p < 0.001$) compared with the initial doses. Reduced booster doses could facilitate the worldwide distribution of messenger RNA vaccines.

Bilateral Branch Retinal Vein Occlusion after mRNA-SARS-CoV-2 Booster Dose Vaccination. PURPOSE: We report a case of a patient with a bilateral branch retinal vein occlusion (BRVO) 24 h after a booster vaccination with the mRNA-1237 vaccine. OBSERVATIONS: Fluorescein angiography, performed at three weeks follow-up, showed vascular leakage and blockage, corresponding to hemorrhage areas associated with ischemic areas in the macula and along the arcades involved in the occlusion. CONCLUSIONS: The patient was scheduled for urgent injections of intravitreal ranibizumab and laser photocoagulation of the ischemic areas. To the best of our knowledge, this is the first case described of concomitant bilateral RVO after COVID-19 vaccination. The rapid onset of the side effects in a patient with multiple risk factors for thrombotic events suggests that vulnerable microvascular conditions require detailed investigations before administration of a COVID-19 vaccine.

Association between Glutathione S-Transferases Gene Variants and COVID-19 Severity in Previously Vaccinated and Unvaccinated Polish Patients with Confirmed SARS-CoV-2 Infection. As the outcome of COVID-19 is associated with oxidative stress, it is highly probable that polymorphisms of genes related to oxidative stress were associated with susceptibility and severity of COVID-19. The aim of the study was to assess the association of glutathione S-transferases (GSTs) gene polymorphisms with COVID-19 severity in previously vaccinated and unvaccinated Polish patients with confirmed SARS-CoV-2 infection. A total of 92 not vaccinated and 84 vaccinated patients hospitalized due to COVID-19 were included. The WHO COVID-19 Clinical Progression Scale was used to assess COVID-19 severity. GSTs genetic polymorphisms were assessed by appropriate PCR methods. Univariable and multivariable analyses were performed, including logistic regression analysis. GSTP1 Ile/Val genotype was found to be associated with a higher risk of developing a severe form of the disease in the population of vaccinated patients with COVID-19 (OR: 2.75; $p = 0.0398$). No significant association was observed for any of the assessed GST genotypes with COVID-19 disease severity in unvaccinated patients with COVID-19. In this group of patients, BMI > 25 and serum glucose level > 99 mg% statistically significantly increased the odds towards more severe COVID-19. Our results may contribute to further understanding of risk factors of severe COVID-19 and selecting patients in need of strategies focusing on oxidative stress.

Epidemiological Predictors of Positive SARS-CoV-2 Polymerase Chain Reaction Test in Three Cohorts: Hospitalized Patients, Healthcare Workers, and Military Population, Serbia, 2020. (1) Background: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and its resulting coronavirus disease 2019 (COVID-19) has caused a fast-moving pandemic. Diagnostic testing, aimed to identify patients infected with SARS-CoV-2, plays a key role in controlling the COVID-19 pandemic in different populations. (2) Methods: This retrospective cohort study aimed to investigate predictors associated with positive polymerase chain reaction (PCR) SARS-CoV-2 test results in hospitalized patients,

healthcare workers (HCWs), and military personnel (MP) during 2020, before the widespread availability of COVID-19 vaccines. Persons with a positive test result were compared with persons with a negative test result in three cohorts during the study period. (3) Results: A total of 6912 respondents were tested, and 1334 (19.3%) of them had positive PCR SARS-CoV-2 test results. Contact with a known COVID-19 case within 14 days ($p < 0.001$; OR: 1.48; 95% CI: 1.25-1.76), fever ($p < 0.001$; OR: 3.66; 95% CI: 3.04-4.41), cough ($p < 0.001$; OR: 1.91; 95% CI: 1.59-2.30), headache ($p = 0.028$; OR: 1.24; 95% CI: 1.02-1.50), and myalgia/arthralgia ($p < 0.001$; OR: 1.99; 95% CI: 1.65-2.42) were independently associated with positive PCR SARS-CoV-2 test results in the cohort of MP. Furthermore, fever ($p < 0.001$; OR: 2.75; 95% CI: 1.83-4.13), cough ($p < 0.001$; OR: 2.04; 95% CI: 1.32-3.13), headache ($p = 0.008$; OR: 1.76; 95% CI: 1.15-2.68), and myalgia/arthralgia ($p = 0.039$; OR: 1.58; 95% CI: 1.02-2.45) were independently associated with positive PCR SARS-CoV-2 test results in the cohort of HCWs. Moreover, independent predictors of positive PCR SARS-CoV-2 test results in hospitalized patients were contact with a known COVID-19 case within 14 days ($p < 0.001$; OR: 2.56; 95% CI: 1.71-3.83), fever ($p < 0.001$; OR: 1.89; 95% CI: 1.38-2.59), pneumonia ($p = 0.041$; OR: 1.45; 95% CI: 1.01-2.09), and neurological diseases ($p = 0.009$; OR: 0.375; 95% CI: 0.18-0.78). (4) Conclusions: According to data gathered from cohorts of hospitalized patients, HCWs, and MP, before the widespread availability of COVID-19 vaccines in Serbia, we can conclude that predictors of positive PCR SARS-CoV-2 test results in MP and HCWs were similar. Accurate estimates of COVID-19 in different population groups are important for health authorities.

Cessation of Face Mask Use after COVID-19 Vaccination in Patients with Diabetes: Prevalence and Determinants. Studies on the cessation of face mask use after a COVID-19 vaccine in patients with diabetes are not available, despite their greater predisposition to complications. We estimated the prevalence of cessation of face mask use after receiving the COVID-19 vaccine in patients with diabetes and identified which factor was most strongly associated with non-use. This was a cross-sectional study in patients with diabetes 18-70 years with at least one dose of vaccine against COVID-19 (n = 288). Participants were asked to respond face-to-face to a questionnaire in a primary care center. Descriptive statistics, chi-square tests, and multivariate binary logistic regression were used for analyzing the association between vulnerability, benefits, barriers, self-efficacy, vaccine expectations (independent variables), and cessation of use (dependent variable), controlling for sociodemographic, smoking, medical, vaccine, and COVID-19 history. The prevalence of cessation of face masks was 25.3% (95% CI 20.2, 30.5). Not feeling vulnerable to hospitalization increased the odds of non-use (adjusted OR = 3.3, 95% CI 1.2, 8.6), while perceiving benefits did the opposite (adjusted OR = 0.4, 95% CI 0.2, 0.9). The prevalence was low, and only two factors were associated with the cessation of face mask use after COVID-19 vaccination in patients with type 2 diabetes.

Immune Response and Molecular Mechanisms of Cardiovascular Adverse Effects of Spike Proteins from SARS-CoV-2 and mRNA Vaccines. The SARS-CoV-2 (severe acute respiratory syndrome coronavirus responsible for the COVID-19 disease) uses the Spike proteins of its envelope for infecting target cells expressing on the membrane the angiotensin converting enzyme 2 (ACE2) enzyme that acts as a receptor. To control the pandemic, genetically engineered vaccines have been designed for inducing neutralizing antibodies against the Spike proteins. These vaccines do not act like traditional protein-based vaccines, as they deliver the message in the form of mRNA or DNA to host cells that then produce and expose the Spike protein on the membrane (from which it can be shed in soluble form) to alert the immune system. Mass vaccination has brought to light various adverse effects associated with these genetically based vaccines, mainly affecting the circulatory and cardiovascular system. ACE2 is present as membrane-bound on several cell types, including the mucosa of the upper respiratory and of the gastrointestinal tracts, the endothelium, the platelets, and in soluble form in the plasma. The ACE2 enzyme converts the vasoconstrictor angiotensin II into peptides with

vasodilator properties. Here we review the pathways for immunization and the molecular mechanisms through which the Spike protein, either from SARS-CoV-2 or encoded by the mRNA-based vaccines, interferes with the Renin-Angiotensin-System governed by ACE2, thus altering the homeostasis of the circulation and of the cardiovascular system. Understanding the molecular interactions of the Spike protein with ACE2 and the consequent impact on cardiovascular system homeostasis will direct the diagnosis and therapy of the vaccine-related adverse effects and provide information for development of a personalized vaccination that considers pathophysiological conditions predisposing to such adverse events.

Vaccination and mortality from COVID-19: a comparative study between hemodialysis, peritoneal dialysis, and non-dialysis adult population in Panama. PURPOSE: Dialysis patients have a different response than the non-dialysis population to infection with COVID-19. This study evaluates the prevalence of infection and lethality in patients receiving hemodialysis or peritoneal dialysis in Panama, compared to non-dialysis adult population, and reports of adverse events of vaccination. METHODS: This is a prospective, multi-center cohort study of spatients aged 18Â years or older and receiving in-center hemodialysis or ambulatory peritoneal dialysis in 13 centers in Panama from March 2021 to 2022. For comparison with general population, the study used an extended period of two years. RESULTS: A total of 1531 patients receiving dialysis treatment accepted to participate. PD patients represented an 18% of study patients. Lethality was higher in peritoneal dialysis patients with COVID-19 infection than in hemodialysis in the study group (p 0.02). Total deaths in dialysis patients for 2020 were 156 patients, before vaccination; 79 in 2021; and 25 for the first trimester of 2022. Lethality for the period of 2020-2022 was 9.3% for dialysis patients and 0.2% for non-dialysis population. There was no difference in symptoms in first dose, but with second dose, hemodialysis patients reported fewer symptoms than peritoneal dialysis patients (pâ€‰<â€‰0.0001). CONCLUSION: Ninety one percent of people in the country received BNT162b2 Pfizer BionTech vaccine. Lethality decreased from 30 to 5% once vaccination was available. There were no severe adverse effects and symptoms reported were less frequent than in general population, probably due to low reactogenicity in dialysis patients, or better tolerance to pain.

Concomitant Severe Psoriasis and Bullous Pemphigoid Induced by COVID-19. Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), first isolated in Wuhan, China, is currently a pandemic. At the beginning of the pandemic, pulmonary issues were the most discussed and studied. However, now 3 years later, the role of the dermatologist has become increasingly central. Often the diversity in the presentation of these manifestations has made it difficult for the dermatologist to recognize them. In addition to the common symptoms involving fever, cough, dyspnea, and hypogeusia/hyposmia that have been widely discussed in the literature, much attention has been paid to dermatologic manifestations in the past year. The vaccination campaign has been the most important strategy to combat the COVID-19 pandemic. Specifically, two viral vector-based vaccines [Vaxzervria(Â®) (AstraZeneca; AZD1222) and COVID-19 Janssen(Â®) vaccine (Johnson & Johnson; Ad26.COV2. S)] and two mRNA-based vaccines [Comirnaty(Â®) (Pfizer/BioNTech; BNT162b2) and Spikevax(Â®) (Moderna; mRNA-1273)]. However, several cutaneous adverse reactions have been reported following vaccination, making the dermatologist's role critical. It is possible to group these adverse reactions according to a classification with six main clinical pictures: urticarial rash, erythematous/maculopapular/morbid rash, papulovesicular rash, chilblain-like acral pattern, livedo reticularis/racemose-like, and purpuric "vasculitic" pattern. Beyond this classification, there are several reports of other dermatologic manifestations associated with the infection, such as pityriasis rosea, herpes zoster, or, particularly, the worsening of pre-existing chronic inflammatory dermatologic diseases. Here we report the case of a 61-year-old patient who presented at our clinic with a diffuse psoriasiform eruption mixed with a

concomitant blistering rash induced by COVID-19. The uniqueness of our case has two features: the first is the concomitance of the two events after infection that seems to be unprecedented; the second is the management of the patient that could help dermatology colleagues in the management of these conditions during infection.

A retrospective evaluation of seroconversion after COVID-19 during the early Omicron wave in fully vaccinated multiple sclerosis patients receiving anti-CD20 therapies. BACKGROUND: Patients with multiple sclerosis (MS) are commonly treated with anti-CD20 therapies. Reduced seroconversion following COVID-19 vaccination in patients receiving certain anti-CD20 therapies has been reported; however, the immune response following natural infection is poorly characterised. This study aimed to retrospectively evaluate COVID-19 antibody responses after vaccination and natural infection in patients treated with anti-CD20 therapies. METHODS: We performed a retrospective review evaluating COVID-19 seroconversion and anti-spike glycoprotein antibody titres in double-vaccinated patients with MS, or related neuroinflammatory conditions, treated with anti-CD20 therapies (NÂ =Â 30) with a confirmed history of natural severe acute respiratory syndromeÂ coronavirus 2 (SARS-CoV-2) infection (nÂ =Â 14) or without infection (control; nÂ =Â 16). This single-centre study was performed at the Yale Multiple Sclerosis Center, where patients treated with anti-CD20 therapies (ocrelizumab, nÂ =Â 21; rituximab, nÂ =Â 5; ofatumumab, nÂ =Â 4) were systematically checked for SARS-CoV-2 anti-spike antibody levels throughout the pandemic. Data were collected from March 2020 to March 2022. All patients had received at least two doses of a Food and Drug Administration (FDA)-approved COVID-19 vaccine. Qualitative anti-spike antibody seropositivity was determined based on test-specific laboratory reference ranges. For a subset of patients (nÂ =Â 18), quantitative anti-spike antibody levels were assessed via DiaSorin LIAISONÂ® chemiluminescence immunoassay (positive titre was defined as â‰¥ 13). Vaccination and infection dates were also recorded, and patients were monitored for adverse COVID-19-related health effects. RESULTS: Overall, 15/30 (50.0%) patients seroconverted following double vaccination. After infection, 13/14 (92.9%) seroconverted, while 6/16 (37.5%) uninfected patients seroconverted after vaccination. For the 18 patients with quantitative anti-spike antibody titres, mean titre post-vaccination was 37.4. Mean antibody titres were significantly higher after infection: 540.3 versus 20.1 in the control group ($p < 0.05$). Of the 14 infected patients, 13 had mild COVID-19 symptoms and one was asymptomatic. No hospitalisations or deaths were reported. CONCLUSIONS: This study reports that SARS-CoV-2 anti-spike antibody titres in double-vaccinated MS patients treated with anti-CD20 therapies were significantly increased post-infection compared with the control group. Patients treated with anti-CD20 therapy who had confirmed infections displayed mild or asymptomatic infection. These results provide reassurance that anti-CD20 therapies in double-vaccinated patients do not preclude an appropriate SARS-CoV-2 antibody response post-infection.

Low Omicron BA.4 and BA.5 neutralising activity and breakthrough COVID-19 following pre-exposure prophylaxis with tixagevimab plus cilgavimab in vaccinated patients with autoimmune disease.

Is Vaccination Against COVID-19 Associated With Inflammatory Bowel Disease Flare? Self-Controlled Case Series Analysis Using the UK CPRD. INTRODUCTION: To investigate the association between vaccination against coronavirus disease 2019 (COVID-19) and inflammatory bowel disease (IBD) flare. METHODS: Patients with IBD vaccinated against COVID-19 who consulted for disease flare between December 1, 2020, and December 31, 2021, were ascertained from the Clinical Practice Research Datalink. IBD flares were identified using consultation and corticosteroid prescription records. Vaccinations were identified using product codes and vaccination dates. The study period was partitioned into vaccine-exposed (vaccination date and 21 days immediately after), prevaccination (7 days immediately before vaccination), and the remaining vaccine-unexposed periods. Participants contributed data with multiple vaccinations and IBD flares. Season-adjusted incidence rate ratios

(aIRR) and 95% confidence intervals (CI) were calculated using self-controlled case series analysis. RESULTS: Data for 1911 cases with IBD were included; 52% of them were female, and their mean age was 49 years. Approximately 63% of participants had ulcerative colitis (UC). COVID-19 vaccination was not associated with increased IBD flares in the vaccine-exposed period when all vaccinations were considered (aIRR [95% CI] 0.89 [0.77-1.02], 0.79 [0.66-0.95], and 1.00 [0.79-1.27] in IBD overall, UC, and Crohn's disease, respectively). Analyses stratified to include only first, second, or third COVID-19 vaccinations found no significant association between vaccination and IBD flares in the vaccine-exposed period (aIRR [95% CI] 0.87 [0.71-1.06], 0.93 [0.75-1.15], and 0.86 [0.63-1.17], respectively). Similarly, stratification by COVID-19 before vaccination and by vaccination with vectored DNA or messenger RNA vaccine did not reveal an increased risk of flare in any of these subgroups. DISCUSSION: Vaccination against COVID-19 was not associated with IBD flares regardless of prior COVID-19 infection and whether messenger RNA or DNA vaccines were used.

National assessment strategy for adults and children with a history of vaccine allergy shows low utility of COVID-19 vaccine skin testing.

Effectiveness and safety of coronavirus disease 2019 vaccines. PURPOSE OF REVIEW: To review and summarise recent evidence on the effectiveness of coronavirus disease 2019 (COVID-19) vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and COVID-19 hospitalisation and death in adults as well as in specific population groups, namely pregnant women, and children and adolescents. We also sought to summarise evidence on vaccine safety in relation to cardiovascular and neurological complications. In order to do so, we drew primarily on evidence from two our own data platforms and supplement these with insights from related large population-based studies and systematic reviews. RECENT FINDINGS: All studies showed high vaccine effectiveness against confirmed SARS-CoV-2 infection and in particular against COVID-19 hospitalisation and death. However, vaccine effectiveness against symptomatic COVID-19 infection waned over time. These studies also found that booster vaccines would be needed to maintain high vaccine effectiveness against severe COVID-19 outcomes. Rare cardiovascular and neurological complications have been reported in association with COVID-19 vaccines. SUMMARY: The findings from this paper support current recommendations that vaccination remains the safest way for adults, pregnant women, children and adolescents to be protected against COVID-19. There is a need to continue to monitor the effectiveness and safety of COVID-19 vaccines as these continue to be deployed in the evolving pandemic.

Variant-specific deleterious mutations in the SARS-CoV-2 genome reveal immune responses and potentials for prophylactic vaccine development. Introduction: Coronavirus disease 2019 (COVID-19), caused by SARS-CoV-2, has had a disastrous effect worldwide during the previous three years due to widespread infections with SARS-CoV-2 and its emerging variations. More than 674 million confirmed cases and over 6.7 million deaths have been attributed to successive waves of SARS-CoV-2 infections as of 29th January 2023. Similar to other RNA viruses, SARS-CoV-2 is more susceptible to genetic evolution and spontaneous mutations over time, resulting in the continual emergence of variants with distinct characteristics. Spontaneous mutations of SARS-CoV-2 variants increase its transmissibility, virulence, and disease severity and diminish the efficacy of therapeutics and vaccines, resulting in vaccine-breakthrough infections and re-infection, leading to high mortality and morbidity rates. Materials and methods: In this study, we evaluated 10,531 whole genome sequences of all reported variants globally through a computational approach to assess the spread and emergence of the mutations in the SARS-CoV-2 genome. The available data sources of NextCladeCLI 2.3.0 (https://clades.nextstrain.org/) and NextStrain (https://nextstrain.org/) were searched for tracking SARS-CoV-2 mutations, analysed using the PROVEAN, Polyphen-2, and Predict SNP mutational analysis tools and validated by Machine Learning models. Result: Compared to the Wuhan-Hu-1

reference strain NC 045512.2, genome-wide annotations showed 16,954 mutations in the SARS-CoV-2 genome. We determined that the Omicron variant had 6,307 mutations (retrieved sequence:1947), including 67.8% unique mutations, more than any other variant evaluated in this study. The spike protein of the Omicron variant harboured 876 mutations, including 443 deleterious mutations. Among these deleterious mutations, 187 were common and 256 were unique non-synonymous mutations. In contrast, after analysing 1,884 sequences of the Delta variant, we discovered 4,468 mutations, of which 66% were unique, and not previously reported in other variants. Mutations affecting spike proteins are mostly found in RBD regions for Omicron, whereas most of the Delta variant mutations drawn to focus on amino acid regions ranging from 911 to 924 in the context of epitope prediction (B cell & T cell) and mutational stability impact analysis protruding that Omicron is more transmissible. Discussion: The pathogenesis of the Omicron variant could be prevented if the deleterious and persistent unique immunosuppressive mutations can be targeted for vaccination or small-molecule inhibitor designing. Thus, our findings will help researchers monitor and track the continuously evolving nature of SARS-CoV-2 strains, the associated genetic variants, and their implications for developing effective control and prophylaxis strategies.

Ischemic stroke after COVID-19 bivalent vaccine administration in patients aged 65 years and older: analysis of nation-wide patient electronic health records in the United States. IMPORTANCE: The Centers for Disease Control and Prevention (CDC) announced in January 2023 that they were investigating a potential connection between administration of the Pfizer novel coronavirus disease-2019 (COVID-19) bivalent vaccine booster and ischemic stroke (IS). OBJECTIVE: To explore the relationship between Pfizer bivalent booster administration and IS in older patients in the United States and compare it to other COVID-19 vaccines. DESIGN: A retrospective cohort study was conducted to compare hazard of IS among patients aged 65 years or over who received the Pfizer bivalent, Moderna bivalent, or Pfizer/Moderna monovalent COVID-19 booster vaccine 1-21 and 22-42 days after vaccination. SETTING: Patient data were collected from TriNetX, a cloud-based analytics platform that includes electronic health record data from over 90 million unique patients in the United States. PARTICIPANTS: Patients in the United States aged 65 years or over at the time of administration of a Pfizer bivalent (n = 43,216), Moderna bivalent (n = 4,267), or Pfizer/Moderna monovalent (n = 100,583) booster were included for analysis. Cohorts were propensity-score matched by demographic factors and risk factors for IS and severe COVID-19. EXPOSURES: Pfizer bivalent, Moderna bivalent, or Pfizer/Moderna monovalent COVID-19 booster administration. MAIN OUTCOMES: The hazard ratio (HR) and 95% confidence interval (CI) for IS in the cohorts at 1-21 and 22-42 days after administration. RESULTS: After matching, the Pfizer bivalent cohort included 4,267 patients, with an average age of 73.7 years (44.43% male, 76.59% white). The Moderna bivalent cohort included 4,267 patients, with an average age of 74.0 years (44.08% male, 77.39% white). There was no significant difference in the hazard of IS encounters between the Pfizer bivalent versus Moderna bivalent cohorts at 1-21- or 22-42-days post-administration: HR = 0.59 (0.31, 1.11), 0.73 (0.33, 1.60). The hazard for IS was lower in the Pfizer bivalent cohort than in the Pfizer/Moderna monovalent cohort at both timepoints: HR = 0.24 (0.19, 0.29), 0.25 (0.20, 0.31). CONCLUSIONS AND RELEVANCE: Older adults administered the Pfizer bivalent booster had similar hazard for IS encounters compared to those administered the Moderna bivalent booster vaccine, but lower hazard than those administered the Pfizer/Moderna monovalent boosters.

Moderna COVID-19 Vaccine: A New Player in Vaccine-Induced Thrombosis Without Thrombocytopenia. This is a case of a 31-year-old male with no past medical history who developed extensive pulmonary embolism (PE) and deep venous thrombosis (DVT) three days after receiving the second dose of the Moderna vaccine. The patient presented with left calf swelling and mild shortness of breath, with no fever or hemodynamic instability. Doppler ultrasound of the left

lower extremity showed thrombus in the common femoral, superior, mid-, and distal femoral, popliteal, and posterior tibial veins. Chest CT angiography (CTA) visualized extensive pulmonary emboli in the bilateral main pulmonary, lobar, and segmental arteries. Comprehensive hypercoagulable workup was unrevealing. The leading diagnosis was postulated as vaccine-induced thrombosis (VIT). Due to the diagnosis of bilateral sub-massive PE, the patient was initiated on enoxaparin and continued on direct-acting oral anticoagulation for at least one year. Our report showcases a plausible link between the Moderna vaccine and thrombosis due to the extensive and unprovoked nature of DVT/PE in this patient with a negative hypercoagulable workup. Although the mechanisms behind the messenger ribonucleic acid (mRNA) and double-stranded deoxyribonucleic acid (dsDNA) vaccines vary, the possibility of vaccine-induced thrombosis (VIT) after the Moderna vaccine is highly probable. Vaccine-induced thrombosis should be considered in a patient presenting with unprovoked thrombosis after the Moderna COVID-19 vaccine, and further research needs to be conducted to ascertain the correlation. However, these findings should not dissuade the use of the Moderna vaccine given its proven benefits.

National seroepidemiological study of COVID-19 after the initial rollout of vaccines: Before and at the peak of the Omicron-dominant period in Japan. BACKGROUND: Based on routine surveillance data, Japan has been affected much less by COVID-19 compared with other countries. To validate this, we aimed to estimate SARS-CoV-2 seroprevalence and examine sociodemographic factors associated with cumulative infection in Japan. METHODS: A population-based serial cross-sectional seroepidemiological investigation was conducted in five prefectures in December 2021 (pre-Omicron) and February-March 2022 (Omicron [BA.1/BA.2]-peak). Anti-nucleocapsid and anti-spike antibodies were measured to detect infection-induced and vaccine/infection-induced antibodies, respectively. Logistic regression was used to identify associations between various factors and past infection. RESULTS: Among 16â€‰296 participants (median age: 53 [43-64] years), overall prevalence of infection-induced antibodies was 2.2% (95% CI: 1.9-2.5%) in December 2021 and 3.5% (95% CI: 3.1-3.9%) in February-March 2022. Factors associated with past infection included those residing in urban prefectures (Tokyo: aOR 3.37 [95% CI: 2.31-4.91], Osaka: aOR 3.23 [95% CI: 2.17-4.80]), older age groups (60s: aOR 0.47 [95% CI 0.29-0.74], 70s: aOR 0.41 [95% CI 0.24-0.70]), being vaccinated (twice: aOR 0.41 [95% CI: 0.28-0.61], three times: aOR 0.21 [95% CI: 0.12-0.36]), individuals engaged in occupations such as long-term care workers (aOR: 3.13 [95% CI: 1.47-6.66]), childcare workers (aOR: 3.63 [95% CI: 1.60-8.24]), food service workers (aOR: 3.09 [95% CI: 1.50-6.35]), and history of household contact (aOR: 26.4 [95% CI: 20.0-34.8]) or non-household contact (aOR: 5.21 [95% CI:3.80-7.14]) in February-March 2022. Almost all vaccinated individuals (15â€‰670/15â€‰681) acquired binding antibodies with higher titers among booster dose recipients. CONCLUSIONS: Before Omicron, the cumulative burden was >10 times lower in Japan (2.2%) compared with the US (33%), the UK (25%), or global estimates (45%), but most developed antibodies owing to vaccination.

Impact of vaccination status and anticoagulation on venous thromboembolism risk and outcomes in coronavirus disease 2019 patients.

Surveillance for Multisystem Inflammatory Syndrome in US Children Aged 5-11 Years Who Received Pfizer-BioNTech COVID-19 Vaccine, November 2021 through March 2022. Multisystem inflammatory syndrome in children (MIS-C) is a complication of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection; in the United States, reporting of MIS-C after coronavirus disease 2019 (COVID-19) vaccination is required for vaccine safety monitoring. Pfizer-BioNTech COVID-19 vaccine was authorized for children aged 5-11 years on 29 October 2021. Covering a period when approximately 7 million children received vaccine, surveillance for MIS-C â‰¤ 90 days postvaccination using passive systems identified 58 children with MIS-C and laboratory evidence of past/recent SARS-CoV-2 infection, and 4 without evidence. During a period with extensive SARS-CoV-

2 circulation, MIS-C illness in children after COVID-19 vaccination who lacked evidence of SARS-CoV-2 infection was rare (<1 per million vaccinated children).

Evaluation of patients of vaccine side effects after the COVID-19 vaccine. OBJECTIVE: Postvaccine side effects were evaluated in patients presenting to our emergency department with complaints of vaccine side effects after taking COVID-19 vaccine, and new unknown side effects ranging from mild complaints to life-threatening risks, and frequency of all side effects were investigated. This study aimed to establish a scientific resource to identify the potential side effects of the vaccine. METHODS: Patients' demographic information, clinical characteristics, epicrisis reports, COVID-19 disease and vaccination histories, vital values, and blood values were examined. The SPSS 20.0 package program was used for statistical evaluation. $p<0.05$ was considered statistically significant. RESULTS: Notably, 13.1% of patients presenting to the emergency department started to have complaints after taking Sinovac vaccine, whereas 86.9% of them had complaints after taking BioNTech vaccine. Also, 36.9% of patients stated that they had COVID-19. All patients had a Glasgow coma scale score of 15 during admission. No patient was hospitalized, ventilator was not needed, and all patients were discharged. While the most common presenting complaint to the emergency department after vaccination was fatigue in 29.7%, the most common diagnoses after examination in the emergency department were myalgia in 32.1% and upper respiratory tract infection in 28.6%. CONCLUSION: Results and conclusions of our study will guide healthcare workers and patients on the side effects of COVID-19 vaccine.

A Case of Disseminated Herpes Zoster With Polyneuropathy Following the Third Dose of the Pfizer-BioNTech Vaccine. SARS-CoV-2 pandemic resulted in the fast development of new vaccines, which helped contain the pandemic, but some adverse events started to rise. Recently, post-administration of mRNA-based vaccines, varicella-zoster virus (VZV) reactivation was reported. We report a case of disseminated herpes zoster with polyneuropathy and cerebrospinal fluid (CSF) findings following the Pfizer-BioNTechvaccine. Our observation aims to increase clinicians' awareness of a possible relationship between herpes zoster reactivation and SARS-CoV-2 vaccines.

Willingness to receive COVID-19 vaccination and adverse effects after vaccination in breast cancer survivors during the COVID-19 pandemic: a cross-sectional retrospective study of a Chinese population. BACKGROUND: Breast cancer (BC) patients have a higher mortality rate after COVID-19 infection, but data on vaccination of BC patients and attitude towards COVID-19 vaccination and safety after vaccination are lacking. We wanted to understand the willingness and factors of BC survivors to receive a COVID-19 vaccine, and their adverse reactions. The purpose is to judge the safety of vaccination, and find strategies to promote vaccination in BC patients. METHODS: Offline and online questionnaire surveys were provided in outpatient clinics and on an online follow-up platform, respectively, to collect information. Factors influencing vaccination willingness were analyzed by univariate and multivariate logistic regression. All statistical tests were performed bilaterally, and a P value <0.05 was considered statistically significant. Patients who have been vaccinated need to fill in questions about the impact on quality of life after vaccination, the type and frequency of vaccination, and side effects. RESULTS: A total of 497 valid questionnaires were collected; 289 (58.1%) BC survivors were vaccinated with a COVID-19 vaccine, and 379 (76.26%) BC survivors had a fully or basically accepting attitude toward vaccination. Survivors over 70 years of age, educated only to high school level, and those receiving chemotherapy had significantly lower levels of acceptance of COVID-19 vaccines. Multivariate logistic regression analyses suggested that treatment status and cognitive attitude were independent factors influencing COVID-19 vaccination among BC survivors. The main reason for being vaccinated was "doctor recommendation" (57.26%). Unwillingness to receive a COVID-19 vaccine was mainly due to "the unknown safety of the vaccine in cancer patients" (67.80%). A total of 97.56% of the survivors believed that vaccination had no or

almost no effect on their quality of life. Among the BC survivors, 18 (6.23%) had adverse reactions after vaccination. All adverse reactions were grade 1 or 2, and no adverse reactions of grade 3 or above were reported. The adverse reactions reported by 15 survivors (83.33%) markedly improved within 1 week. CONCLUSIONS: In terms of cognitive attitudes toward COVID-19 vaccines, elderly individuals and those with a lower education level were less receptive to vaccination. Therefore, attention to elderly survivors can help improve the vaccination rate.

Association Between COVID-19 Vaccination and Abortion: A Cross-Sectional Study in Jeddah. BACKGROUND: Clinical trials for COVID-19 vaccines initially excluded pregnant women. However, observational studies revealed a relative safety of the vaccine during pregnancy therefore association between different types of COVID-19 vaccination and the risk of abortion must be studied.Â Objectives: The objective is to explore the possible association between abortion and different types of COVID-19 vaccination in Jeddah. METHODS: This was a retrospective cross-sectional study done in three private general hospitals in Jeddah using electronic medical records and phone interviews of pregnant women who were admitted with abortion. Women were then interviewed for their vaccination dataÂ (type, dose) and their current pregnancy outcome (aborted or not). RESULTS: Medical records of 214 women diagnosed with abortion were included; 13.1% of them managed to continue their pregnancy. Vaccinated women (86%) had significantly earlier gestational age (p=0.031), higher hypertension (<0.001), and lower positive consanguinity (<0.001) compared to non-vaccinated women. The type (p=0.636) and number (p=0.331) of vaccination did not differ significantly among vaccinated women with and without abortion. Significant predictors of abortion were age>35 years (OR: 3.1, 95% CI: 1.34-6.97, p=0.008), diabetes (OR: 0.09, 95% CI: 0.01-0.89, p=0.040), and positive consanguinity (OR: 0.12, 95% CI: 0.02-0.63, p=0.012). However, spontaneous abortion did not have an increased odds of exposure to COVID-19 vaccinesÂ (OR: 1.07, 95% CI: 0.21-5.49, p=0.937). CONCLUSION: Â COVID-19 vaccination is notÂ associated with an increased risk of abortion in womenÂ vaccinated during their first or second trimesters. Further clinical trials are needed to support the evidence of the safety of early vaccination of pregnant women.

Guillain-BarrÃ© Syndrome Following the First Dose of Inactivated SARS-CoV-2 Vaccine, BBIBP-CorV. We present a case report of Guillain-BarrÃ© syndrome (GBS) following inactivated whole virus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine, BBIBP-CorV. A man presented with paresthesia in both upper and lower limbs with bifacial weakness, onset 18 days after receiving the first BBIBP-CorV vaccine. A bifacial palsy with a paresthesia variant of GBS was diagnosed, and the patient was treated with intravenous immunoglobulin, arresting the progression of neurological symptoms. Clinicians need to be aware of the possibility of GBS following vaccination with BBIBP-CorV, an inactivated SARS-CoV-2 vaccine.

Bilateral Axillo-Brachial Artery Stenosis Following Messenger Ribonucleic Acid (mRNA) Vaccination Against Severe Acute Respiratory Coronavirus 2 (COVID-19). The following case report is an overview of an unusual presentation of bilateral axillo-brachial artery occlusion following messenger ribonucleic acid (mRNA) vaccination against severe acute respiratory coronavirus 2 (COVID-19). A 64-year-old female presented with symptoms initially consistent with polymyalgia rheumatica five weeks following the first booster of the Pfizer-BioNTech COVID-19 vaccine. She was successfully treated with prednisone therapy; however, despite the normalization of inflammatory markers, she later presented with bilaterally occluded axillo-brachial arteries. She successfully underwent endovascular management for the treatment of her symptoms. To our knowledge, this is the first case report of chronically occluded bilateral axillo-brachial artery disease following mRNA vaccination for COVID-19 successfully treated with endovascular therapy. The unusual pathogenesis of upper extremity arterial disease is reviewed and a review of endovascular treatment options is presented. A literature review of the types of vasculitis seen following mRNA COVID-19 vaccination is also presented.

IgA Vasculitis Following COVID-19 Vaccination. As new variants of SARS-CoV-2 continue to emerge worldwide, countries are striving to fully vaccinate their population in a bid to prevent severe disease, subsequent hospitalizations, and the associated strain on their healthcare systems and death. In this context, there is growing evidence of rare, potential side effects associated with COVID-19 vaccines. IgA vasculitis is a systemic, IgA-mediated vasculitis characterized by palpable purpura, arthralgia, abdominal pain, and renal involvement. It is the most common type of vasculitis in childhood, sporadically affecting the adult population. However, there have been multiple reports of IgA vasculitis following vaccination against COVID-19. Herein, we present the case of a 72-year-old patient with palpable purpura that developed two weeks after receiving the Pfizer BioNTech vaccine. Laboratory investigations revealed elevated serum creatinine (2.6 mg/dL), macroalbuminuria (8.6 g/24 h), and macroscopic hematuria. Histopathological examination confirmed necrotizing vasculitis, and a diagnosis of IgA vasculitis was established. Considering the clinical presentation, the laboratory and histopathological findings, and the time interval between the vaccination and the development of symptoms, we strongly believe that IgA vasculitis in this patient arose as a side effect of the Pfizer BioNTech vaccine.

Breakthrough SARS-CoV-2 infections among patients with cancer following two and three doses of COVID-19 mRNA vaccines: a retrospective observational study from the COVID-19 and Cancer Consortium. BACKGROUND: Breakthrough SARS-CoV-2 infections following vaccination against COVID-19 are of international concern. Patients with cancer have been observed to have worse outcomes associated with COVID-19 during the pandemic. We sought to evaluate the clinical characteristics and outcomes of patients with cancer who developed breakthrough SARS-CoV-2 infections after 2 or 3 doses of mRNA vaccines. METHODS: We evaluated the clinical characteristics of patients with cancer who developed breakthrough infections using data from the multi-institutional COVID-19 and Cancer Consortium (CCC19; NCT04354701). Analysis was restricted to patients with laboratory-confirmed SARS-CoV-2 diagnosed in 2021 or 2022, to allow for a contemporary unvaccinated control population; potential differences were evaluated using a multivariable logistic regression model after inverse probability of treatment weighting to adjust for potential baseline confounding variables. Adjusted odds ratios (aOR) and 95% confidence intervals (CI) are reported. The primary endpoint was 30-day mortality, with key secondary endpoints of hospitalization and ICU and/or mechanical ventilation (ICU/MV). FINDINGS: The analysis included 2486 patients, of which 564 and 385 had received 2 or 3 doses of an mRNA vaccine prior to infection, respectively. Hematologic malignancies and recent receipt of systemic anti-neoplastic therapy were more frequent among vaccinated patients. Vaccination was associated with improved outcomes: in the primary analysis, 2 doses (aOR: 0.62, 95% CI: 0.44-0.88) and 3 doses (aOR: 0.20, 95% CI: 0.11-0.36) were associated with decreased 30-day mortality. There were similar findings for the key secondary endpoints of ICU/MV (aOR: 0.60, 95% CI: 0.45-0.82 and 0.37, 95% CI: 0.24-0.58) and hospitalization (aOR: 0.60, 95% CI: 0.48-0.75 and 0.35, 95% CI: 0.26-0.46) for 2 and 3 doses, respectively. Importantly, Black patients had higher rates of hospitalization (aOR: 1.47, 95% CI: 1.12-1.92), and Hispanic patients presented with higher rates of ICU/MV (aOR: 1.61, 95% CI: 1.06-2.44). INTERPRETATION: Vaccination against COVID-19, especially with additional doses, is a fundamental strategy in the prevention of adverse outcomes including death, among patients with cancer. FUNDING: This study was partly supported by grants from the National Cancer Institute grant number P30 CA068485 to C-YH, YS, SM, JLW; T32-CA236621 and P30-CA046592 to C.R.F; CTSA 2UL1TR001425-05A1 to TMW-D; ACS/FHI Real-World Data Impact Award, P50 MD017341-01, R21 CA242044-01A1, Susan G. Komen Leadership Grant Hunt to MKA. REDCap is developed and supported by Vanderbilt Institute for Clinical and Translational Research grant support (UL1 TR000445 from NCATS/NIH).

Nanocell COVID-19 vaccine triggers a novel immune response pathway producing high-affinity antibodies which neutralize all variants of concern. Most current anti-viral vaccines elicit a humoral and cellular immune response via the pathway of phagocytic cell mediated viral antigen presentation to B and T cell surface receptors. However, this pathway results in reduced ability to neutralize S-protein Receptor Binding Domains (RBDs) from several Variants of Concern (VOC) and the rapid waning of memory B cell response requiring vaccine reformulation to cover dominant VOC S-proteins and multiple boosters. Here we show for the first time in mice and humans, that a bacterially derived, non-living, nanocell (EDV; EnGeneIC Dream Vector) packaged with plasmid expressed SARS-CoV-2 S-protein and Î±-galactosyl ceramide adjuvant (EDV-COVID-Î±GC), stimulates an alternate pathway due to dendritic cells (DC) displaying both S-polypeptides and Î±GC thereby recruiting and activating iNKT cells with release of IFNÎ³. This triggers DC activation/maturation, activation of follicular helper T cells (T(FH)), cognate help to B cells with secretion of a cytokine milieu promoting B cell maturation, somatic hypermutation in germinal centers to result in high affinity antibodies. Surrogate virus neutralization tests show 90-100% neutralization of ancestral and early VOC in mice and human trial volunteers. EDV-COVID-Î±GC as a third dose booster neutralized Omicron BA. 4/5. Serum and PBMC analyses reveal long lasting S-specific memory B and T cells. In contrast, control EDVs lacking Î±GC, did not engage the iNKT/DC pathway resulting in antibody responses unable to neutralize all VOCs and had a reduced B cell memory. The vaccine is lyophilized, stored and transported at room temperature with a shelf-life of over a year.

Myocardial infarction or myocarditis? A case report and review of a myocardial adverse event associated with mRNA vaccine. A 23-year-old man started with chest pain 8 h after his first Pfizer-BioNTech COVID-19 vaccination. ECG evaluation showed sinus tachycardia with ST-segment elevation in D1, AVL, V5, and V6, the findings compatible with acute subepicardial myocardial damage. However, cardiac MRI documented myocardial fibrosis, with cardiac late enhancement non-ischemic pattern with diffuse edema. He had no other symptoms to suggest another etiology than the vaccination. The patient was hospitalized and received corticosteroid (prednisolone) daily. Then, 2 weeks after hospitalization, all laboratory parameters and ECG were normal and the patient was discharged from the hospital. The patient had a history of Wolf-Parkinson White that was corrected with ablation when he was 11 years old. This report calls attention to myocardial adverse reaction risk for mRNA COVID-19 vaccines for people with a previous cardiac disease history.

Axillary Lymph Node Uptake on (18)F-FDG PET/CT after COVID-19 Vaccination: A Direct Comparison Study with Influenza Vaccination. OBJECTIVES: To compare vaccinated-side axillary lymph node uptake on (18)F-fluorodeoxyglucose (FDG) positron emission tomography/computed tomography (PET/CT) after coronavirus disease-2019 (COVID-19) and influenza vaccination. METHODS: We retrospectively analyzed 177 patients who underwent (18)F-FDG PET/CT after COVID-19 or influenza vaccination. We compared the uptake of the vaccinated-side axillary lymph nodes of 109 COVID-19 vaccinated patients with those of a lot of influenza-vaccinated patients. We also compared the uptake between 66 patients who received the first COVID-19 vaccination with 43 who received the second COVID-19 vaccination. RESULTS: (18)F-FDG-avid axillary lymph nodes on the vaccinated side were significantly more frequently observed in the COVID-19 group (45%) than in the influenza group (19%) ($p<0.001$). When the interval between vaccination to PET/CT was within 7 days, there was no significant difference in the frequency of (18)F-FDG-avid vaccinated-side axillary lymph nodes between the groups (COVID-19 group: 41% vs. influenza group: 45%, $p=0.724$). When the interval was over 7 days, (18)F-FDG-avid lymph nodes were much more frequent in the COVID-19 group (47%) than in the influenza group (7%) ($p<0.001$). Comparing the first and second COVID-19 groups, (18)F-FDG-avid lymph nodes were more frequent in the second vaccination group than in the first vaccination group, but the difference was not significant. CONCLUSION: (18)F-FDG-avid vaccinated-

side axillary lymph nodes were more frequently observed in the COVID-19 group than in the influenza group. In the case of the COVID-19 vaccine, a delay of (18)F-FDG PET/CT examination is recommended by a longer interval from vaccination than in the influenza vaccine.

COVID-19 symptom duration: associations with age, severity and vaccination status in Brunei Darussalam, 2021. OBJECTIVE: This retrospective, cross-sectional, observational study assessed the duration of coronavirus disease 2019 (COVID-19) symptoms during the second wave in Brunei Darussalam. METHODS: Data from COVID-19 cases admitted to the National Isolation Centre during 7-30 August 2021 were included in the study. Symptom onset and daily symptom assessments were entered into a database during hospitalization and disease was categorized by severity. The time between symptom onset and hospital admission, the duration of symptoms and length of hospitalization were assessed separately by age group, disease severity and vaccination status using one-way analysis of variance with Bonferroni post hoc corrections. RESULTS: Data from 548 cases were included in the study: 55.7% (305) of cases were male, and cases had a mean age of 33.7Â years. Overall, 81.3% (446) reported symptoms at admission (mean number of symptoms and standard deviation: 2.8Â Â±Â 1.6), with cough (59.1%; 324), fever (38.9%; 213) and sore throat (18.4%; 101) being the most common. Being older, having more severe disease and being unvaccinated were significantly associated with the time between symptom onset and hospital admission, symptom duration and length of hospitalization. DISCUSSION: Knowing which factors predict the duration of COVID-19 symptoms can help in planning management strategies, such as the duration of isolation, predict the length of hospitalization and treatment, and provide more accurate counselling to patients regarding their illness.

The impact of COVID-19 disease on the natural course of cirrhosis: Before and after starting vaccination. BACKGROUND: Cirrhosis has been reported as an important risk factor for death in coronavirus disease 2019 (COVID-19) disease. In this study, we aimed to investigate the effects of COVID-19 on the natural course of cirrhosis before and after starting vaccination. METHODS: The cirrhosis patients in our cohort (n: 140; median age:56; 71 female) were included in this study. The median MELD (Model For End-stage Liver Disease) score was 11 (6-25) and CCI (Charlson Comorbidity Index) score was 4 (1-11). In total, 85 had CTP (Child-Turcotte-Pugh)-A, 44 had CTP-B and 11 had CTP-C cirrhosis. The course of COVID-19 in this patient group was evaluated before and after COVID-19 vaccination. RESULTS: Between March 2020 and January 2021, 36 of the 140 cirrhosis patients had developed COVID-19. Cirrhosis (+)/COVID-19 (+) and Cirrhosis (+)/COVID-19 (-) groups did not differ in terms of age, CCI and MELD-Na scores, or gender. There were six deaths in the Cirrhosis (+)/COVID-19 (+) group and five in the Cirrhosis (+)/COVID-19 (-) group [6/36 (16.6%) vs. 5/104 (4.8%); p: 0.03]. Patients who died were older, had higher CCI and MELD-Na scores, and lower albumin levels. Having had COVID-19 [6.45 (1.43-29.4); p: 0.015], higher MELD-Na score [1.35 (1.18-1.60); p: 0.001] and higher CCI score [1.65 (1.14-2.39); p: 0.008] were found to be independent predictors of mortality. After effective vaccination started in Turkey, only 11 of the remaining 129 patients developed COVID-19, and only one patient died, who was unvaccinated. DISCUSSION: In our cirrhotic cohort, COVID-19 disease was associated with 16% mortality in the pre-vaccination period. COVID-19 vaccination prevents serious illness and death due to COVID-19 in cirrhotic patients.

Impact of chronic liver disease on SARS-CoV-2 infection outcomes: Roles of stage, etiology and vaccination. Since the first identification in December of 2019 and the fast spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, it has represented a dramatic global public health concern. Though affecting mainly the respiratory system, SARS-CoV-2 disease, defined as coronavirus disease 2019 (COVID-19), may have a systemic involvement leading to multiple organ dysfunction. Experimental evidence about the SARS-CoV-2 tropism for the liver and the increasing of hepatic cytolysis enzymes during infection support the presence of a pathophysiological relationship

between liver and SARS-CoV-2. On the other side, patients with chronic liver disease have been demonstrated to have a poor prognosis with COVID-19. In particular, patients with liver cirrhosis appear extremely vulnerable to infection. Moreover, the etiology of liver disease and the vaccination status could affect the COVID-19 outcomes. This review analyzes the impact of the disease stage and the related causes on morbidity and mortality, clinical outcomes during SARS-CoV-2 infection, as well as the efficacy of vaccination in patients with chronic liver disease.

Side Effects Associated With Homologous and Heterologous COVID-19 Vaccines: A Cross-Sectional Study in Saudi Arabia. BACKGROUND: Numerous studies on coronavirus disease 2019 (COVID-19) vaccination safety have been conducted in Saudi Arabia. Even thoughÂ there is less evidence comparing the side effects of different vaccines and a few of them studied the side effects of mixing different platforms of vaccines. OBJECTIVES: This study aimed to evaluate the type and severity of adverse effects following COVID-19 vaccination based on the type and platform of received vaccine and to determine factors that contribute to the occurrence of these side effects. METHODS: This cross-sectional comparative study was conducted in Saudi Arabia from January to the end of February 2022 among COVID-19 vaccine recipients through an online survey.Â Based on the type of vaccines received, we categorized our participants into two groups - those who received two doses of either the Pfizer or the AstraZeneca COVID-19 vaccines, and those who received mixed vaccination regimen (one dose of Pfizer and one dose of AstraZeneca). RESULTS: The study included 1,340 participants, of which 56.3% received two doses of the Pfizer vaccine while (7%) received two doses of the AstraZeneca vaccine, and 8.8% received mixed vaccines (one dose of the Pfizer vaccine and one dose of the AstraZeneca vaccine). Pain at the injection site was the most frequent local symptom (37.9%) followed by swellingÂ±redness (27.6%). The local adverse reactions were nearly equal in AstraZeneca and Pfizer vaccines, whereas these were significantly lower in those who received mixed doses ($p<0.001$). Fever was significantly higher in mixed vaccination regimens compared to other types ($p<0.001$). The male gender who received the Pfizer vaccine were at higher risk of developing an adverse reaction following vaccination. Unusual side effects (sleep disorders, menstrual irregularities, and symptoms suggestive of diabetic neuropathy) were also reported. CONCLUSION: The results suggest the overall safety of Pfizer and AstraZeneca vaccines as well as the mixed vaccination protocol. A heterologous regimen was associated with fewer side effects compared to homologous vaccines. Further studies are needed to assess the long-term side effects.

New-onset retroperitoneal fibrosis following COVID-19 mRNA vaccination: Coincidental or vaccine-induced phenomenon? The Pfizer-BioNTech mRNA vaccine is a US Food and Drug Administration-approved coronavirus disease 2019 (COVID-19) vaccine. Although it is reported to be safe and effective, immune dysregulation leading to autoimmunity has become an area of concern. Retroperitoneal fibrosis (RPF) is an immune-mediated fibroinflammatory disease characterized by the deposition of fibrous tissues, primarily around the abdominal aorta and iliac arteries. Herein, we report a case of RPF following Pfizer BioNTech COVID-19 mRNA vaccination. To the best of our knowledge, there have been no published reports on RPF after COVID-19 mRNA vaccination. A 58-year-old woman with no history of autoimmune diseases presented with acute onset of epigastric pain 5â€‰weeks after the second dose of the Pfizer-BioNTech vaccine. She had been diagnosed with stage I breast cancer 9â€‰years ago and was in complete remission on admission. Abdominal computed tomography showed preaortic soft-tissue infiltration around the origin of the superior mesenteric artery but no evidence of breast cancer recurrence. Considering the temporal relationship between current symptoms and vaccination and the absence of other possible causes, she was diagnosed with RPF secondary to Pfizer-BioNTech vaccine-induced autoimmunity. This case may raise awareness of the possibility of RPF development following COVID-19 mRNA vaccination.

Cohort event monitoring for safety signal detection in adult individuals 18 years and above after immunisation with coronavirus disease 2019 vaccines in Nigeria. INTRODUCTION: In Nigeria, immunisation with coronavirus disease 2019 (COVID-19) vaccines commenced in March 2021. COVISHIELD from AstraZeneca (AZ), a viral vector vaccine, was the brand administered in the first phase of vaccinations for pre-determined eligible adults 18 years and above. As more brands of COVID-19 vaccines have been introduced in Nigeria, identifying effective and safe vaccine brands is essential to pharmacovigilance and public health. The current study assessed the safety of the AZ-AZD1222 (ChAdOx1) COVID-19 vaccine in adults during the first phase of the vaccination exercise in Nigeria. METHODOLOGY: We conducted a descriptive analysis of safety data from selected vaccination sites across six states in Nigeria between June 2021 and September 2021. Respondents were monitored over 3 months for local and systemic reactions, as well as hospitalisation and mortality. Measures obtained from respondents include age, sex, pre-existing comorbidity, local and systemic reactions to vaccines, timing onset of reactions, hospitalisation and mortality. Bivariate and multivariable regression models were used to assess factors associated with vaccine reactogenicity. RESULTS: A total of 1284 individuals were enrolled in the cohort study from the six selected states (Anambra, Borno, Edo, Katsina, Lagos and Plateau) representing the geopolitical zones of Nigeria. A total of 675 individuals or 52.6% of enrolees reported non-serious adverse effects, and only one individual or 0.08% reported a serious adverse event following immunisation in the first 7 days after vaccination. None of the enrolled participants reported adverse events requiring hospitalisation. The most common self-reported symptoms amongst vaccine recipients were tenderness at the injection site 20.9% and fever 20.3%. A majority of symptoms (55.5%) occurred on or before the 3(rd) day after vaccination. Multivariable logistic regression model showed that age 60 years or above (vs. 18-24 years) was significantly associated with a lower likelihood of a vaccine-related symptomatic reaction (adjusted odds ratio: 0.35; 95% confidence interval: 0.20-0.61). There was no reported mortality amongst all the enrolled and followed-up vaccine recipients. CONCLUSION: Our findings suggest that the safety profile of the AZ vaccine is acceptable, and the observed symptoms were mild and mostly within the first 3 days following vaccination. Vaccine recipients will benefit from counselling about potential transient reactions, and improving public awareness can potentially encourage the uptake of vaccines and reduce the spread of the COVID-19 pandemic.

Risk of retinal vein occlusion following COVID-19 vaccination: a self-controlled case series. BACKGROUND: To evaluate the association between COVID-19 vaccination and retinal vein occlusion (RVO). METHODS: This multicentre self-controlled case series included patients with RVO seen in five tertiary referral centres in Italy. All adults who received at least one dose of the BNT162b2, ChAdOx1 nCoV-19, mRNA-1273 or Ad26.COV2.S vaccine and had a first diagnosis of RVO between January 01, 2021, and December 31, 2021 were included. Incidence rate ratios (IRRs) of RVO were estimated using Poisson regression, comparing rates of events in a 28-day period following each dose of vaccination and in the unexposed control periods. RESULTS: 210 patients were included in the study. No increased risk of RVO was observed after the first dose (1-14 days IRR: 0.87, 95% CI: 0.41-1.85; 15-28 days IRR: 1.01, 95% CI: 0.50-2.04; 1-28 days IRR: 0.94, 95% CI: 0.55-1.58) and second dose of vaccination (1-14 days IRR: 1.21, 95% CI: 0.62-2.37; 15-28 days IRR: 1.08, 95% CI: 0.53-2.20; 1-28 days IRR: 1.16, 95% CI: 0.70-1.90). No association between RVO and vaccination was found in subgroup analyses by type of vaccine, gender and age. CONCLUSIONS: This self-controlled case series found no evidence of an association between RVO and COVID-19 vaccination.

Reporting rates for VAERS death reports following COVID-19 vaccination, December 14, 2020-November 17, 2021. PURPOSE: Despite widely available safety information for the COVID-19 vaccines, vaccine hesitancy remains a challenge. In some cases, vaccine hesitancy may be related to concerns about the number of reports of death to the Vaccine Adverse Event Reporting System

(VAERS). We aimed to provide information and context about reports of death to VAERS following COVID-19 vaccination. METHODS: This is a descriptive study evaluating reporting rates for VAERS death reports for COVID-19 vaccine recipients in the United States between December 14, 2020, and November 17, 2021. Reporting rates were calculated as death events per million persons vaccinated and compared to expected all-cause (background) death rates. RESULTS: 9201 death events were reported for COVID-19 vaccine recipients aged 5â€‰years and older (or age unknown). Reporting rates for death events increased with increasing age, and males generally had higher reporting rates than females. For death events within 7â€‰days and 42â€‰days of vaccination, respectively, observed reporting rates were lower than the expected all-cause death rates. Reporting rates for Ad26.COV2.S vaccine were generally higher than for mRNA COVID-19 vaccines, but still lower than the expected all-cause death rates. Limitations of VAERS data include potential reporting bias, missing or inaccurate information, lack of a control group, and reported diagnoses, including deaths, are not causally verified diagnoses. CONCLUSIONS: Reporting rates for death events were lower than the all-cause death rates expected in the general population. Trends in reporting rates reflected known trends in background death rates. These findings do not suggest an association between vaccination and overall increased mortality.

Impact of Vaccination on Major Adverse Cardiovascular Events in Patients With COVID-19 Infection. Taken from the largest U.S. cohort of patients with SARS-CoV2, our results demonstrate the association of even partial vaccination with lower risk of MACE after SARS-CoV-2 infection.

Side effects of Sputnik V, Oxford-AstraZeneca, Sinopharm, and Covaxin and their associations with other variables among healthcare workers of a tertiary hospital in Iran. BACKGROUND: Misinformation about the prevalence of COVID-19 vaccines' side effects (SEs) has led to concerns about and mistrust of vaccine safety. Thus, this study aimed to evaluate the prevalence of COVID-19 vaccines' SEs. METHODS: In a cross-sectional survey-based study on the healthcare workers (HCWs) of a tertiary hospital in Iran, the SEs of Sputnik V, Oxford-AstraZeneca, Sinopharm, and Covaxin were evaluated through a face-to-face interview by a researcher-made questionnaire. RESULTS: A total of 368 HCWs received at least one dose of a COVID-19 vaccine. The prevalence of people with at least one SE was higher among those who received the Oxford-AstraZeneca (95.8Â %) and Sputnik V (92.1Â %) vaccines than those who received Covaxin (70.5Â %) or Sinopharm (66.7Â %). Following the first and second doses, injection site pain (50.3Â % and 58.2Â %), body/muscle pain (53.5Â % and 39.4Â %), fever (54.5Â % and 32.9Â %), headache (41.3Â % and 36.5Â %), and fatigue (44.4Â % and 32.4Â %) were the most common SEs. Overall, SEs were often initiated within 12Â h and subsided within 72Â h of vaccination. The prevalence of SEs after the first dose of Sputnik V was higher among those agedÂ â‰¤Â 31Â years (93.3Â %) than those agedÂ >Â 31Â years (80.5Â %). In the Sputnik V group, the number of SEs experienced after the first dose was higher in women with underlying diseases than those without such diseases. Furthermore, the body mass index of participants with SEs was lower than that of participants without SEs. CONCLUSION: Compared to Sinopharm or Covaxin, the Sputnik V and Oxford-AstraZeneca vaccines were associated with a higher prevalence of SEs, a greater number of SEs per individual, and more severe SEs.

Post COVID-19 condition after Wildtype, Delta, and Omicron SARS-CoV-2 infection and prior vaccination: Pooled analysis of two population-based cohorts. BACKGROUND: Post COVID-19 condition (PCC) is an important complication of SARS-CoV-2 infection, affecting millions worldwide. This study aimed to evaluate the prevalence and severity of post COVID-19 condition (PCC) with novel SARS-CoV-2 variants and after prior vaccination. METHODS: We used pooled data from 1350 SARS-CoV-2-infected individuals from two representative population-based cohorts in Switzerland, diagnosed between Aug 5, 2020, and Feb 25, 2022. We descriptively analysed the prevalence and severity of PCC, defined as the presence and frequency of PCC-related symptoms six months after

infection, among vaccinated and non-vaccinated individuals infected with Wildtype, Delta, and Omicron SARS-CoV-2. We used multivariable logistic regression models to assess the association and estimate the risk reduction of PCC after infection with newer variants and prior vaccination. We further assessed associations with the severity of PCC using multinomial logistic regression. To identify groups of individuals with similar symptom patterns and evaluate differences in the presentation of PCC across variants, we performed exploratory hierarchical cluster analyses. RESULTS: We found strong evidence that vaccinated individuals infected with Omicron had reduced odds of developing PCC compared to non-vaccinated Wildtype-infected individuals (odds ratio 0.42, 95% confidence interval 0.24-0.68). The odds among non-vaccinated individuals were similar after infection with Delta or Omicron compared to Wildtype SARS-CoV-2. We found no differences in PCC prevalence with respect to the number of received vaccine doses or timing of last vaccination. The prevalence of PCC-related symptoms among vaccinated, Omicron-infected individuals was lower across severity levels. In cluster analyses, we identified four clusters of diverse systemic, neurocognitive, cardiorespiratory, and musculoskeletal symptoms, with similar patterns across variants. CONCLUSION: The risk of PCC appears to be lowered with infection by the Omicron variant and after prior vaccination. This evidence is crucial to guide future public health measures and vaccination strategies.

Adverse Events to SARS-CoV-2 (COVID-19) Vaccines and Policy Considerations that Inform the Funding of Safety Surveillance in Low- and Middle-Income Countries: A Mixed Methods Study. INTRODUCTION/OBJECTIVE: Rapid global approval of coronavirus disease 2019 (COVID-19) vaccines and concurrent introduction in high-income countries and low- and middle-income countries (LMIC) highlights the importance of equitable safety surveillance of adverse events following immunization (AEFIs). We profiled AEFIs to COVID-19 vaccines, explored reporting differences between Africa and the rest of the world (RoW), and analyzed policy considerations that inform strengthening of safety surveillance in LMICs. METHODS: Using a convergent mixed-methods design we compared the rate and profile of COVID-19 vaccines' AEFIs reported to VigiBase by Africa versus the RoW, and interviewed policymakers to elicit considerations that inform the funding of safety surveillance in LMICs. RESULTS: With 87,351 out of 14,671,586 AEFIs, Africa had the second-lowest crude number and a reporting rate of 180 adverse events (AEs) per million administered doses. Serious AEs (SAEs) were 27.0%. Death accounted for about 10.0% of SAEs. Significant differences were found in reporting by gender, age group, and SAEs between Africa and the RoW. AstraZeneca and Pfizer BioNTech vaccines were associated with a high absolute number of AEFIs for Africa and RoW; Sputnik V contributed a considerably high rate of AEs per 1 million administered doses. Funding decisions for safety surveillance in LMICs were not based on explicit policies but on country priorities, perceived utility of data, and practical implementation issues. CONCLUSION: African countries reported fewer AEFIs relative to the RoW. To enhance Africa's contribution to the global knowledge on COVID-19 vaccine safety, governments must explicitly consider safety monitoring as a priority, and funding organizations need to systematically and continuously support these programs.

XBB.1.5 neutralizing antibodies upon bivalent COVID-19 vaccination are similar to XBB but lower than BQ.1.1.

A 1-year analysis of adverse events following COVID-19 vaccination in Lebanon: a retrospective study. BACKGROUND: Since the deployment of Coronavirus Disease 2019 (COVID-19) vaccines, skepticism about the safety, incidence, and severity of Adverse Events Following Immunization (AEFI) was a concern. The study has two main objectives. First, to analyze AEFIs following COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik, and Sinopharm) during the vaccination campaign in Lebanon and correlate them with age and gender. Second, to correlate Pfizer-BioNTech and AstraZeneca vaccines' AEFI with the dose administered. METHODS: A retrospective study was carried out between

February 14th, 2021, and February 14th, 2022. AEFI case reports received to the Lebanese Pharmacovigilance (PV) Program were cleaned, validated, and analyzed using SPSS software. RESULTS: A total of 6808 AEFI case reports were received to the Lebanese PV Program during the period of this study. Case reports were mostly received from females (60.7%) and from vaccine recipients aged 18-44Â years. As for the vaccine type, AEFIs occurred more frequently with the AstraZeneca vaccine compared to the Pfizer-BioNTech vaccine. The latter had AEFIs mainly following dose 2, whereas AEFIs with the AstraZeneca vaccine were more frequently reported after dose 1, with general body pain being the most reported systemic AEFI with PZ (34.6%), while fatigue was the most reported AEFI with AZ vaccine (56.5%). CONCLUSIONS: The AEFI reported with COVID-19 vaccines in Lebanon were aligned with those reported worldwide. The incidence of rare serious AEFIs should not discourage the public from getting vaccinated. Further studies are needed to evaluate their long-term potential risk.

Update on Covid-19: vaccines, timing of transplant after COVID-19 infection and use of positive donors. PURPOSE OF REVIEW: SARS-CoV-2 resulted in a global pandemic that had a chilling effect on transplantation early in the pandemic and continues to result in significant morbidity and mortality of transplant recipients. Over the past 2.5â€Šyears, our understanding of the clinical utility of vaccination and mAbs to prevent COVID-19 in solid organ transplant (SOT) recipients has been studied. Likewise, approach to donors and candidates with SARS-CoV-2 has been better understood. This review will attempt to summarize our current understanding of these important COVID-19 topics. RECENT FINDINGS: Vaccination against SARS-CoV-2 is effective in reducing the risk of severe disease and death among transplant patients. Unfortunately, humoral and, to a lesser extent, cellular immune response to existing COVID-19 vaccines is reduced in SOT recipients compared with healthy controls. Additional doses of vaccine are required to optimize protection of this population and still may be insufficient in those who are highly immunosuppressed, those receiving belatacept, rituximab and other B-cell active mAbs. Until recently, mAbs were options for the prevention of SARS-CoV-2 but are markedly less effective with recent omicron variants. SARS-CoV-2-infected donors can generally be used for nonlung, nonsmall bowel transplants unless they have died of acute severe COVID-19 or COVID-19-associated clotting disorders. SUMMARY: Our transplant recipients require a three-dose mRNA or adenovirus-vector and one dose of mRNA vaccine to be optimally protected initially; they then need to receive a bivalent booster 2+ months after completing their initial series. Most nonlung, nonsmall bowel donors with SARS-CoV-2 can be utilized as organ donors.

Small-Fiber Neuropathy After Vaccination With mRNA-1273 SARS-CoV-2 Vaccine.

Unilateral Facial Palsy After SARS-CoV-2 Booster Vaccination.

Guillain-Barre Syndrome After the Third BNT162b2 Dose in an Adolescent Without Side Effects After the First and Second Jab.

Acute and Chronic Demyelinating Neuropathies After COVID-19 Vaccination: A Report of 4 Cases. OBJECTIVES: To report demyelinating neuropathies after COVID-19 vaccination. METHODS: Case report. RESULTS: Four cases of demyelinating neuropathies after COVID-19 vaccination were identified at the University of Nebraska Medical Center from May to September 2021. Three were male and 1 was a female, ages 26-64 years. Three cases received Pfizer-BioNTech vaccine and 1 Johnson & Johnson. Symptom onset ranged from 2 to 21 days after vaccination. Two cases had progressive limb weakness, 3 had facial diplegia, and all had sensory symptoms and areflexia. The diagnosis was acute inflammatory demyelinating polyneuropathy in 1 case and chronic inflammatory demyelinating polyradiculoneuropathy in 3. All cases received treatment with intravenous immunoglobulin, with significant improvement in 3 of 4 who had a long-term outpatient follow-up. CONCLUSIONS: Continued identification and reporting of cases of demyelinating neuropathies after COVID-19 vaccination is essential to determine whether a causative association is present.

Trajectory of Humoral Responses to Two Doses of ChAdOx1 nCoV-19 Vaccination in Patients Receiving Maintenance Hemodialysis. The ChAdOx1 nCoV-19 (AZD1222) vaccine is one of the most commonly delivered SARS-CoV-2 vaccines worldwide; however, few clinical studies have investigated its immunogenicity in dialysis patients. We prospectively enrolled 123 patients on maintenance hemodialysis at a medical center in Taiwan. All patients were infection-naive, had received two doses of the AZD1222 vaccine, and were monitored for 7â€‰months. The primary outcomes were anti-SARS-CoV-2 receptor-binding domain (RBD) antibody concentrations before and after each dose and 5â€‰months after the second dose and neutralization capacity against ancestral SARS-CoV-2, delta, and omicron variants. The anti-SARS-CoV-2 RBD antibody titers significantly increased with time following vaccination, with a peak at 1â€‰month after the second dose (median titer, 498.8 U/mL; interquartile range, 162.5 to 1,050 U/mL), and a 4.7-fold decrease at 5â€‰months. At 1â€‰month after the second dose, 84.6, 83.7, and 1.6% of the participants had neutralizing antibodies against the ancestral virus, delta variant, and omicron variant, respectively, measured by a commercial surrogate neutralization assay. The geometric mean 50% pseudovirus neutralization titers for the ancestral virus, delta variant, and omicron variant were 639.1, 264.2, and 24.7, respectively. The anti-RBD antibody titers correlated well with neutralization capacity against the ancestral virus and delta variant. Transferrin saturation and C-reactive protein were associated with neutralization against the ancestral virus and delta variant. Although two doses of the AZD1222 vaccine initially elicited high anti-RBD antibody titers and neutralization against the ancestral virus and delta variant in hemodialysis patients, neutralizing antibodies against omicron variant were rarely detected, and the anti-RBD and neutralization antibodies waned over time. Additional/booster vaccinations are warranted in this population. IMPORTANCE Patients with kidney failure have worse immune response following vaccination compared to general population, but few clinical studies have investigated immunogenicity of ChAdOx1 nCoV-19 (AZD1222) vaccination in hemodialysis patients. Here, we showed two doses of AZD1222 vaccines lead to high seroconversion rate of anti-SARS-CoV-2 receptor-binding domain (RBD) antibodies, and more than 80% patients acquired neutralizing antibodies against ancestral virus and delta variant. However, seldom did they obtain neutralizing antibodies against the omicron variant. The geometric mean 50% pseudovirus neutralization titer against the ancestral virus was 25.9-fold higher than that against the omicron variant. Also, there was a substantial decay in anti-RBD titers with time. Our findings provided evidence supporting that more protective measures, including additional/booster vaccinations, is warranted in these patients during the current COVID-19 pandemic.

Cutaneous leukocytoclastic vasculitis after second dose of mRNA COVID-19 vaccine. Numerous cutaneous reactions following COVID-19 vaccination have already been described. Vasculitis, however, is a rare adverse event, occurring mainly after the first COVID-19 vaccination. Herein, we report a patient with IgA-positive cutaneous leukocytoclastic vasculitis, unresponsive to a moderate dose of systemic corticosteroid that erupted after the second dose of the Pfizer/BioNTech vaccine. Since booster vaccinations are being administered, we intend to raise awareness among clinicians and to highlight this potential reaction and its therapeutic approach.

Increasing the COVID-19 immunization rate through allergy testing. BACKGROUND: Vaccination of the population is required to combat the COVID-19 pandemic. Allergy testing could reduce anxiety towards COVID-19 vaccination and thereby may increase vaccination rate, however, its effectiveness remains unclear. METHODS: One hundred and thirty prospective real-life patients in need of but not daring to get vaccinated asked for allergy workup for COVID-19 vaccine hypersensitivity in 2021/2022. Characterization of patients, identification of anxieties, decrease of patient's anxiety levels, overall vaccination rate and adverse reactions after vaccination were assessed. RESULTS: Tested patients were characterized by being female (91.5%) and having a high rate of previous allergies (e.g. to food

55.4%, drugs 54.6%, or previous vaccinations 50%) and dermatological disease (29.2%) but not always had medical contraindications for COVID-19 vaccination. Sixty one patients (49.6%) were highly concerned (4-6, Likert scale 0-6) about vaccination and 47 (37.6%) expressed resolving thoughts about vaccinaion anaphylaxis (3-6, Likert scale 0-6). However only 35 patients (28.5%) were scared of getting COVID-19 within 2 months (4-6, Likert scale 0-6) and only 11 (9%) patients had high expectations of getting COVID-19 (4-6, Likert scale 0-6). Allergy testing significantly (pÂ <â€‰0.01 to pÂ <â€‰0.05 respectively) reduced the median anxiety of allergic symptoms following vaccination: dyspnoea (4.2-3.1), to faint (3.7-2.7), long-term consequences (3.6-2.2), pruritus (3.4-2.6), skin rash (3.3-2.6) and death (3.2-2.6). After allergy testing, most patients (108/122, 88.5%) let themselves be vaccinated within 60â€‰days. Revaccinated patients with previous symptoms experienced a reduction of symptoms (pÂ <â€‰0.05) upon revaccination. CONCLUSIONS: Patients not daring to get vaccinated have more anxiety towards vaccination than to acquire COVID-19. For those, allergy testing excludes vaccine allergy, and is a tool to increase vaccination willingness and thereby helps to combat vaccination hesitancy.

COVID-19 vaccination in myasthenia gravis: safe, but predictors of disease exacerbation yet to be determined.

COVID-19 post-vaccination lymphadenopathy: A review of the use of fine needle aspiration cytology. COVID-19 vaccine-associated clinical lymphadenopathy (C19-LAP) and subclinical lymphadenopathy (SLDI), which are mainly detected by 18F-FDG PET-CT, have been observed after the introduction of RNA-based vaccines during the pandemic. Lymph node (LN) fine needle aspiration cytology (FNAC) has been used to diagnose single cases or small series of SLDI and C19-LAP. In this review, clinical and LN-FNAC features of SLDI and C19-LAP are reported and compared to non-Covid (NC)-LAP. A search for studies on C19-LAP and SLDI histopathology and cytopathology was performed on PubMed and Google Scholar, on 11 January 2023. Reports on LN-FNAC of C19-LAP were retrieved. A total of 14 reports, plus one unpublished case of C19-LAP observed in our institution, diagnosed by LN-FNAC were included in a pooled analysis and compared to the corresponding histopathological reports. In total, 26 cases were included in this review, with a mean age of 50.5â€‰years. Twenty-one lymphadenopathies assessed by LN-FNAC were diagnosed as benign, and three cases as atypical lymphoid hyperplasia; the latter were subsequently confirmed as benign (one by repetition of LN-FNAC, two by histological control). One case of mediastinal lymphadenopathy in a patient suffering from melanoma was reported as reactive granulomatous inflammation, while one unsuspected case was diagnosed as metastasis from melanoma. In all cases, the cytological diagnoses were confirmed by follow-up or excisional biopsy. The high diagnostic value of LN-FNAC in excluding malignant processes was extremely useful in this context and may be particularly valuable when CNB or histological excisions are difficult to perform, as was the case during Covid lockdowns.

Diagnostic Performance of a Particle Gel Immunoassay in Vaccine-Induced Immune Thrombotic Thrombocytopenia. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare but serious complication of adenoviral vector-based COVID-19 vaccines. Similar to heparin-induced thrombocytopenia (HIT), antibodies reacting to platelet factor 4 (PF4) are responsible for platelet activation in VITT. The diagnosis of VITT includes the detection of anti-PF4 antibodies. Particle gel immunoassay (PaGIA) is one of the rapid immunoassays that is commonly used in the diagnosis of HIT to detect anti-PF4 antibodies. The aim of this study was to investigate the diagnostic performance of PaGIA in patients suspected of VITT. In this retrospective, single-center study, the correlation between PaGIA, enzyme immunoassay (EIA), and modified heparin-induced platelet aggregation assay (HIPA) in patients with findings suggestive of VITT was investigated. A commercially available PF4 rapid immunoassay (ID PaGIA H/PF4, Bio-Rad-DiaMed GmbH, Switzerland) and an anti-PF4/heparin EIA (ZYMUTEST HIA IgG, Hyphen Biomed) were used according to manufacturer's

instructions. Modified HIPA was accepted as the gold standard test. Between March 8 and November 19, 2021, a total of 34 samples from clinically well-characterized patients (14 males, 20 females, mean age: 48.2â€‰Â±â€‰18.2 years) were analyzed with PaGIA, EIA, and modified HIPA. VITT was diagnosed in 15 patients. Sensitivity and specificity of PaGIA were 54 and 67%, respectively. Anti-PF4/heparin optical density values were not significantly different between PaGIA positive and negative samples (pâ€‰=â€‰0.586). The sensitivity and specificity of EIA, on the other hand, were 87 and 100%, respectively. In conclusion, PaGIA is not reliable in the diagnosis of VITT because of its low sensitivity and specificity.

Evaluation of QuantiFERON SARS-CoV-2 interferon-Î³ release assay following SARS-CoV-2 infection and vaccination. T cells are important in preventing severe disease from SARS-CoV-2, but scalable and field-adaptable alternatives to expert T-cell assays are needed. The interferon-gamma release assay QuantiFERON platform was developed to detect T-cell responses to SARS-CoV-2 from whole blood with relatively basic equipment and flexibility of processing timelines. Forty-eight participants with different infection and vaccination backgrounds were recruited. Whole blood samples were analysed using the QuantiFERON SARS-CoV-2 assay in parallel with the well-established 'Protective Immunity from T Cells in Healthcare workers' (PITCH) ELISpot, which can evaluate spike-specific T-cell responses. The primary aims of this cross-sectional observational cohort study were to establish if the QuantiFERON SARS-Co-V-2 assay could discern differences between specified groups and to assess the sensitivity of the assay compared with the PITCH ELISpot. The QuantiFERON SARS-CoV-2 distinguished acutely infected individuals (12-21 days post positive PCR) from naÃ¯ve individuals (Pâ€…<â€…0.0001) with 100% sensitivity and specificity for SARS-CoV-2 T cells, whilst the PITCH ELISpot had reduced sensitivity (62.5%) for the acute infection group. Sensitivity with QuantiFERON for previous infection was 12.5% (172-444 days post positive test) and was inferior to the PITCH ELISpot (75%). Although the QuantiFERON assay could discern differences between unvaccinated and vaccinated individuals (55-166 days since second vaccination), the latter also had reduced sensitivity (44.4%) compared to the PITCH ELISpot (66.6%). The QuantiFERON SARS-CoV-2 assay showed potential as a T- cell evaluation tool soon after SARS-CoV-2 infection but has lower sensitivity for use in reliable evaluation of vaccination or more distant infection.

Cox regression using a calendar time scale was unbiased in simulations of COVID-19 vaccine effectiveness & safety. BACKGROUND: Observational studies on corona virus disease 2019 (COVID-19) vaccines compare event rates in vaccinated and unvaccinated person time using Poisson or Cox regression. In Cox regression, the chosen time scale needs to account for the time-varying incidence of severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) infection and COVID-19 vaccination.We aimed to quantify bias in person-time based methods, with and without adjustment for calendar time, using simulations and empirical data analysis. METHODS: We simulated 500,000 individuals who were followed for 365Â days, and a point exposure resembling COVID-19 vaccination (cumulative incidence 80%). We generated an effectiveness outcome, emulating the incidence of severe acute respiratory syndrome corona virus 2 infection in Denmark during 2021 (risk 10%), and a safety outcome with seasonal variation (myocarditis, risk 1/5,000). Incidence rate ratios (IRRs) were set to 0.1 for effectiveness and 5.0 for safety outcomes. IRRs and hazard ratios (HRs) were estimated using Poisson and Cox regression with a time under observation scale, and a calendar time scale. Bias was defined as estimated IRR or HR-true IRR. Further, we obtained estimates for both outcomes using data from the Danish health registries. RESULTS: Unadjusted IRRs (bias(effectivenes) +0.16; bias(safety) -2.09) and HRs estimated using a time-under-observation scale (+0.28;-2.15) were biased. Adjustment for calendar time reduced bias in Cox (+0.03; +0.33) and Poisson regression (0.00; -0.28). Cox regression using a calendar time scale was least biased (0.00, +0.12). When analyzing empirical data, adjusted Poisson and Cox regression using a calendar time scale yielded estimates in

accordance with existing evidence. CONCLUSION: Lack of adjustment for the time-varying incidence of COVID-19 related outcomes may severely bias estimates.
Development of myocarditis and pericarditis after COVID-19 vaccination: A deeperÂ insight.
Development of myocarditis and pericarditis after COVID-19 vaccination: Comment.
SARS-CoV-2 vaccine-induced humoral and cellular immunity in patients with hematologic malignancies. Patients with hematologic conditions have a higher risk of severe COVID-19 and COVID-19-related death. This is related to immune deficiencies induced by hematologic conditions and/or the treatment thereof. Prospective vaccine immunogenicity studies have demonstrated that in the majority of patients, a 3-dose COVID-19 vaccination schedule leads to antibody concentrations comparable to levels obtained in healthy adults after a 2-dose schedule. In B cell depleted patients, humoral responses are poor, however vaccination did induce potent cellular immune responses. The effect of 3-dose vaccination schedules and COVID-19 booster vaccinations on the protection of patients with hematologic malignancies against severe COVID-19 and COVID-19 related death remains to be confirmed by population-based vaccine effectiveness studies.
Prevalence of chemosensitive disorders with Omicron infections and the possible impacts of vaccination.
Correspondence on "Effect of female COVID-19 vaccination on assisted reproductive outcomes: a systematic review and meta-analysis".
BQ.1.1, XBB.1, and XBB.1.5 neutralization after bivalent mRNA COVID-19 booster in patients with cancer. Ehmsen et al. evaluate the neutralizing capacity to current SARS-CoV-2 variants in patients with cancer before and after receiving the BNT162b2 bivalent mRNA vaccine booster. Bivalent vaccine provides some protection against BQ.1.1 but fails to protect against XBB.1 and XBB.1.5 in patients with cancer.
Risk of myocarditis and pericarditis following coronavirus disease 2019 messenger RNA Vaccination-A nationwide study. BACKGROUND: An extended interval between the two primary doses may reduce the risk of myocarditis/pericarditis after COVID-19Â mRNA vaccination. Taiwan has implemented a two-dose regimen with a 12-week interval for adolescents. Here we present nationwide data of myocarditis/pericarditis following COVID-19 vaccinations. METHODS: Data on adverse events of myocarditis/pericarditis were from the Taiwan Vaccine Adverse Events Reporting System between March 22, 2021, and February 9, 2022. The reporting rates according to sex, age, and vaccine type were calculated. We investigated the rates among young individuals under different two-dose intervals and among those who received two doses of different vaccines. RESULTS: Among 204 cases who met the case definition of myocarditis/pericarditis, 75 cases occurred after the first dose and 129 after the second. The rate of myocarditis/pericarditis after COVID-19 vaccination varied across sex and age groups and was highest after the second dose in males aged 12-17 years (126.79 cases per million vaccinees) for the BNT162b2 vaccine and in males aged 18-24 years (93.84 cases per million vaccinees) for the mRNA-1273 vaccine. The data did not suggest an association between longer between-dose interval and lower rate of myocarditis/pericarditis among males and females aged 18-24 or 25-29 years who received two doses of the BNT162b2 or mRNA-1273 vaccine. Rates of myocarditis/pericarditis in males and females aged 18-49 years after receiving ChAdOx1-S - mRNA-1273 vaccination was significantly higher than after ChAdOx1-S - ChAdOx1-S vaccination. CONCLUSIONS: Myocarditis and pericarditis are rare following mRNA vaccination, with higher risk occurring in young males after the second dose.
COVID-19 infection and vaccines: potential triggers of Herpesviridae reactivation. Since the onset of the COVID-19 outbreak, numerous articles have highlighted a possible link between COVID-19 vaccination or infection and Herpesviridae co-infection or reactivation. The authors conducted an exhaustive literature review on this topic, the results of which are presented individually for each

member of the Herpesviridae family: Herpes Simplex Virus (HSV) types-1 (HSV-1) and 2 (HSV-2); Varicella-Zoster Virus (VZV); Epstein-Barr Virus (EBV); Cytomegalovirus (CMV); HHV-6; HHV-7; and HHV-8. These human herpesviruses can serve as prognostic markers for the COVID-19 infection and may even underlie some of the clinical manifestations initially attributed to SARS-CoV-2. In addition to SARS-CoV-2 infection, all corresponding vaccines approved to date in Europe appear capable of inducing herpesvirus reactivation. It is important to consider all viruses of the Herpesviridae family when managing patients infected with or recently vaccinated against COVID-19.

The impact of side effect framing on COVID-19 booster vaccine intentions in an Australian sample. OBJECTIVE: To evaluate the effect of presenting positively attribute-framed side effect information on COVID-19 booster vaccine intention relative to standard negatively-framed wording and a no-intervention control. DESIGN AND PARTICIPANTS: A representative sample of Australian adults (NÂ =Â 1204) were randomised to one of six conditions within a factorial design: Framing (Positive; Negative; Control)Â Ã—Â Vaccine (Familiar (Pfizer); Unfamiliar (Moderna)). INTERVENTION: Negative Framing involved presenting the likelihood of experiencing side effects (e.g., heart inflammation is very rare, 1 in every 80,000 will be affected), whereas Positive Framing involved presenting the same information but as the likelihood of not experiencing side effects (e.g., 79,999 in every 80,000 will not be affected). PRIMARY OUTCOME: Booster vaccine intention measured pre- and post-intervention. RESULTS: Participants were more familiar with the Pfizer vaccine (t(1203)Â =Â 28.63, pÂ <.001, Cohen's d(z)Â =Â 0.83). Positive Framing (MÂ =Â 75.7, SEÂ =Â 0.9, 95% CIÂ =Â [73.9, 77.4]) increased vaccine intention relative to Negative Framing (MÂ =Â 70.7, SEÂ =Â 0.9, 95% CIÂ =Â [68.9, 72.4]) overall (F(1, 1192)Â =Â 4.68, pÂ =.031, Î·(p)(2)Â =Â 0.004). Framing interacted with Vaccine and Baseline Intention (F(2, 1192)Â =Â 6.18, pÂ =.002, Î·(p)(2)Â =Â 0.01). Positive Framing was superior, or at least equal, to Negative Framing and Control at increasing Booster Intention, irrespective of participants' pre-intervention level of intent and vaccine type. Side effect worry and perceived severity mediated the effect of Positive vs. Negative Framing across vaccines. CONCLUSION: Positive framing of side effect information appears superior for increasing vaccine intent relative to the standard negative wording currently used. PRE-REGISTRATION: See: aspredicted.org/LDX_2ZL.

Genetic and epidemiological description of an outbreak of circulating vaccine-derived polio-virus type 2 (cVDPV2) in Angola, 2019-2020. After six years without any detection of poliomyelitis cases, Angola reported a case of circulating vaccine-derived poliovirus type 2 (cVDPV2) with paralysis onset date of 27 March 2019. Ultimately, 141 cVDPV2 polio cases were reported in all 18 provinces in 2019-2020, with particularly large hotspots in the south-central provinces of Luanda, Cuanza Sul, and Huambo. Most cases were reported from August to December 2019, with a peak of 15 cases in October 2019. These cases were classified into five distinct genetic emergences (emergence groups) and have ties with cases identified in 2017-2018 in the Democratic Republic of Congo. From June 2019 to July 2020, the Angola Ministry of Health and partners conducted 30 supplementary immunization activity (SIA) rounds as part of 10 campaign groups, using monovalent OPV type 2 (mOPV2). There were Sabin 2 vaccine strain detections in the environmental (sewage) samples taken after mOPV2 SIAs in each province. Following the initial response, additional cVDPV2 polio cases occurred in other provinces. However, the national surveillance system did not detect any new cVDPV2 polio cases after 9 February 2020. While reporting subpar indicator performance in epidemiological surveillance, the laboratory and environmental data as of May 2021 strongly suggest that Angola successfully interrupted transmission of cVDPV2 early in 2020. Additionally, the COVID-19 pandemic did not allow a formal Outbreak Response Assessment (OBRA). Improving the sensitivity of the surveillance system and the completeness of AFP case investigations will be vital to promptly detect and interrupt viral transmission if a new case or sewage isolate are identified in Angola or central Africa.

Safety and immunogenicity of a protein subunit COVID-19 vaccine (ZF2001) in healthy children and adolescents aged 3-17 years in China: a randomised, double-blind, placebo-controlled, phase 1 trial and an open-label, non-randomised, non-inferiority, phase 2 trial. BACKGROUND: ZF2001 is a recombinant protein subunit vaccine against SARS-CoV-2 that has been approved for use in China, Colombia, Indonesia, and Uzbekistan in adults aged 18 years or older, but not yet in children and adolescents younger than 18 years. We aimed to evaluate the safety and immunogenicity of ZF2001 in children and adolescents aged 3-17 years in China. METHODS: The randomised, double-blind, placebo-controlled, phase 1 trial and the open-label, non-randomised, non-inferiority, phase 2 trial were done at the Xiangtan Center for Disease Control and Prevention (Hunan Province, China). Healthy children and adolescents aged 3-17 years, without a history of SARS-CoV-2 vaccination, without a history of COVID-19, without COVID-19 at the time of the study, and without contact with patients with confirmed or suspected COVID-19 were included in the phase 1 and phase 2 trials. In the phase 1 trial, participants were divided into three groups according to age (3-5 years, 6-11 years, and 12-17 years). Each group was randomly assigned (4:1), using block randomisation with five blocks, each with a block size of five, to receive three 25 Î¼g doses of the vaccine, ZF2001, or placebo intramuscularly in the arm 30 days apart. The participants and investigators were masked to treatment allocation. In the phase 2 trial, participants received three 25 Î¼g doses of ZF2001 30 days apart and remained stratified by age group. For phase 1, the primary endpoint was safety and the secondary endpoint was immunogenicity (humoral immune response on day 30 after the third vaccine dose: geometric mean titre [GMT] of prototype SARS-CoV-2 neutralising antibodies and seroconversion rate, and geometric mean concentration [GMC] of prototype SARS-CoV-2 receptor-binding domain [RBD]-binding IgG antibodies and seroconversion rate). For phase 2, the primary endpoint was the GMT of SARS-CoV-2 neutralising antibodies with seroconversion rate on day 14 after the third vaccine dose, and the secondary endpoints included the GMT of RBD-binding antibodies and seroconversion rate on day 14 after the third vaccine dose, the GMT of neutralising antibodies against the omicron BA.2 subvariant and seroconversion rate on day 14 after the third vaccine dose, and safety. Safety was analysed in participants who received at least one dose of the vaccine or placebo. Immunogenicity was analysed in the full-analysis set (ie, participants who received at least one dose and had antibody results) by intention to treat and in the per-protocol set (ie, participants who completed the whole vaccination course and had antibody results). Non-inferiority in the phase 2 trial (neutralising antibody titre of participants from this trial aged 3-17 years vs that of participants aged 18-59 years from a separate phase 3 trial) for clinical outcome assessment was based on the geometric mean ratio (GMR) and was considered met if the lower bound of the 95% CI for the GMR was 0Â·67 or greater. These trials are registered with ClinicalTrials.gov, NCT04961359 (phase 1) and NCT05109598 (phase 2). FINDINGS: Between July 10 and Sept 4, 2021, 75 children and adolescents were randomly assigned to receive ZF2001 (n=60) or placebo (n=15) in the phase 1 trial and were included in safety and immunogenicity analyses. Between Nov 5, 2021, and Feb 14, 2022, 400 participants (130 aged 3-7 years, 210 aged 6-11 years, and 60 aged 12-17 years) were included in the phase 2 trial and were included in the safety analysis; six participants were excluded from the immunogenicity analyses. 25 (42%) of 60 participants in the ZF2001 group and seven (47%) of 15 participants in the placebo group in phase 1, and 179 (45%) of 400 participants in phase 2, had adverse events within 30 days after the third vaccination, without a significant difference between groups in phase 1. Most adverse events were grade 1 or 2 (73 [97%] of 75 in the phase 1 trial, and 391 [98%] of 400 in the phase 2 trial). One participant in the phase 1 trial and three in the phase 2 trial who received ZF2001 had serious adverse events. One serious adverse event (acute allergic dermatitis) in the phase 2 trial was possibly related to the vaccine. In the phase 1 trial, on day 30 after the third dose, in the ZF2001 group, seroconversion of neutralising antibodies against SARS-CoV-2 was observed in 56 (93%; 95% CI 84-98) of 60 participants, with a GMT of 176Â·5

(95% CI 118Â·6-262Â·8), and seroconversion of RBD-binding antibodies was observed in all 60 (100%; 95% CI 94-100) participants, with a GMC of 47Â·7 IU/mL (95% CI 40Â·1-56Â·6). In the phase 2 trial, on day 14 after the third dose, seroconversion of neutralising antibodies against SARS-CoV-2 was seen in 392 (99%; 95% CI 98-100) participants, with a GMT of 245Â·4 (95% CI 220Â·0-273Â·7), and seroconversion of RBD-binding antibodies was observed in all 394 (100%; 99-100) participants, with a GMT of 8021 (7366-8734). On day 14 after the third dose, seroconversion of neutralising antibodies against the omicron subvariant BA.2 was observed in 375 (95%; 95% CI 93-97) of 394 participants, with a GMT of 42Â·9 (95% CI 37Â·9-48Â·5). For the non-inferiority comparison of participants aged 3-17 years with those aged 18-59 years for SARS-CoV-2 neutralising antibodies, the adjusted GMR was 8Â·6 (95% CI 7Â·0-10Â·4), with the lower bound of the GMR greater than 0Â·67. INTERPRETATION: ZF2001 is safe, well tolerated, and immunogenic in children and adolescents aged 3-17 years. Vaccine-elicited sera can neutralise the omicron BA.2 subvariant, but with reduced activity. The results support further studies of ZF2001 in children and adolescents. FUNDING: Anhui Zhifei Longcom Biopharmaceutical and the Excellent Young Scientist Program from National Natural Science Foundation of China. TRANSLATION: For the Chinese translation of the abstract see Supplementary Materials section.

Myocarditis and coronavirus disease 2019 vaccination: A systematic review and meta-summary of cases. Vaccination is significant to control, mitigate, and recover from the destructive effects of coronavirus disease 2019 (COVID-19). The incidence of myocarditis following COVID-19 vaccination has been increasing and growing public concern; however, little is known about it. This study aimed to systematically review myocarditis following COVID-19 vaccination. We included studies containing individual patient data of myocarditis following COVID-19 vaccination published between January 1, 2020 and September 7, 2022 and excluded review articles. Joanna Briggs Institute critical appraisals were used for risk of bias assessment. Descriptive and analytic statistics were performed. A total of 121 reports and 43 case series from five databases were included. We identified 396 published cases of myocarditis and observed that the majority of cases was male patients, happened following the second dose of mRNA vaccine administration, and experienced chest pain as a symptom. Previous COVID-19 infection was significantly associated ($p < 0.01$; OR, 5.74; 95% CI, 2.42-13.64) with the risk of myocarditis following the administration of the first dose, indicating that its primary mechanism is immune-mediated. Moreover, 63 histopathology examinations were dominated by non-infective subtypes. Electrocardiography and cardiac marker combination is a sensitive screening modality. However, cardiac magnetic resonance is a significant noninvasive examination to confirm myocarditis. Endomyocardial biopsy may be considered in confusing and severe cases. Myocarditis following COVID-19 vaccination is relatively benign, with a median length of hospitalization of 5 days, intensive care unit admission of <12%, and mortality of <2%. The majority was treated with nonsteroidal anti-inflammatory drugs, colchicine, and steroids. Surprisingly, deceased cases had characteristics of being female, older age, non-chest pain symptoms, first-dose vaccination, left ventricular ejection fraction of <30%, fulminant myocarditis, and eosinophil infiltrate histopathology.

Analysis of COVID-19 vaccine adverse event using language model and unsupervised machine learning. BACKGROUND: After the COVID-19 pandemic, the world has made efforts to recover from the chaotic situation. Vaccination is a way to help control infectious diseases, and many people have been vaccinated against COVID-19 by this point. However, an extremely small number of those who received the vaccine have experienced diverse side effects. METHODS AND FINDINGS: In this study, we examined people who experienced adverse events with the COVID-19 vaccine by gender, age, vaccine manufacturer, and dose of vaccinations by using the Vaccine Adverse Event Reporting System datasets. Then we used a language model to vectorize symptom words and reduced their dimensionality. We also clustered symptoms by using unsupervised machine learning and analyzed

the characteristics of each symptom cluster. Lastly, to discover any association rules among adverse events, we used a data mining approach. The frequency of adverse events was higher for women than men, for Moderna than for Pfizer or Janssen, and for the first dose than for the second dose. However, we found that characteristics of vaccine adverse events, including gender, vaccine manufacturer, age, and underlying diseases were different for each symptom cluster, and that fatal cases were significantly related to a particular cluster (associated with hypoxia). Also, as a result of the association analysis, the {chills â† pyrexia} and {vaccination site pruritus â† vaccination site erythema} rules had the highest support value of 0.087 and 0.046, respectively. CONCLUSIONS: We aim to contribute accurate information on the adverse events of the COVID-19 vaccine to relieve public anxiety due to unconfirmed statements about vaccines.

Did the temporary suspension of Vaxzveria vaccinations influence COVID-19 vaccination intentions, vaccination perceptions and trust in the vaccination campaign? A repeated survey study in the Netherlands. In spring 2021, several countries, among which the Netherlands, suspended vaccinations against COVID-19 with the Vaxzevria vaccine from AstraZeneca after reports of rare but severe adverse events. This study investigates the influence of this suspension on the Dutch public's perceptions of COVID-19 vaccinations, trust in the government's vaccination campaign, and COVID-19 vaccination intentions. We conducted two surveys in a population of general Dutch public (18Â +Â), one shortly before the pause of AstraZeneca vaccinations and one shortly thereafter (N eligible for analysisÂ =Â 2628). Our results suggest no changes in perceptions nor intentions regarding the COVID-19 vaccines in general but do suggest a decline in trust in the government's vaccination campaign. In addition, after the suspension, perceptions of the AstraZeneca vaccines were more negative in comparison to those of COVID-19 vaccinations in general. AstraZeneca vaccination intentions were also considerably lower. These results stress the need to adapt vaccination policies to anticipated public perceptions and responses following a vaccine safety scare, as well as the importance of informing citizens about the possibility of very rare adverse events prior to the introduction of novel vaccines.

Microsurgical complication associated with vaccine-induced immune thrombotic thrombocytopenia (VITT): A case report. RATIONALE: The use of ChAdOx1 nCoV-19 (Astra Zeneca) vaccine has proven beneficial, but in a limited number of the general population, it was found to be associated with vaccine-induced immune thrombotic thrombocytopenia (VITT). However, there have been no reports of this complication occurring in a microsurgical free tissue transfer. PATIENT CONCERNS: A 49-year-old man developed an acute myocardial infarction 3 weeks after receiving his first dose of ChAdOx1 nCoV-19 in June 2021. Three months later, he presented with right third toe wet gangrene with extension into the plantar foot nine days after receiving his second dose of ChAdOx1 nCoV-19 vaccine. DIAGNOSIS: Based on recent exposure to vaccination, the timing of inoculation before the development of his symptoms, and serology tests (platelet, D-dimer, and anti-PF4 antibodies), the patient was diagnosed with VITT. INTERVENTIONS: Fasciectomy and sequestrectomy were performed for wound bed preparation. Limb salvage was done using free vastus lateralis muscle flap and skin graft for reconstruction. OUTCOME: The flap was complicated by persistent microthrombi leading to superficial necrosis without vascular pedicle compromise. Repeated debridement of the superficial necrosis was done. Three months after the development of VITT, no further new superficial necrosis was seen. A well-contoured flap was seen 5 months after the initial surgery. LESSONS: We believe this is the first case describing microthrombi in the free flap due to VITT after microsurgical reconstruction. Patients and surgeons should be advised of this possible risk when contemplating microsurgery once VITT has developed after ChAdOx1 nCoV-19 administration.

Metabotropic glutamate receptor 5-related autoimmune encephalitis with reversible splenial lesion syndrome following SARS-CoV-2 vaccination. RATIONALE: Metabotropic glutamate receptor 5

(mGluR5)-related autoimmune encephalitis (AE) has been rarely reported; however, there are no reports on mGluR5-related AE with reversible splenial lesion syndrome following vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). PATIENT CONCERNS: A 29-year-old man was admitted with a history of headache and fever for 9 days and 6 days, respectively. DIAGNOSIS: He was initially diagnosed with an intracranial infection, however the final diagnosis was corrected as anti-mGluR5-related AE with reversible splenial lesion syndrome. INTERVENTIONS: He had received an inactivated SARS-CoV-2 vaccine 3 weeks prior to the examination and was initially diagnosed with an intracranial infection. Physical examination revealed bilateral horizontal nystagmus, ataxia, and neck rigidity. Antiinfective therapy was minimally helpful. An analysis of the cerebrospinal fluid did not reveal pathogens for sequencing. Magnetic resonance imaging displayed abnormal signals in the splenium of the corpus callosum. OUTCOMES: We identified mGluR5 antibodies in the cerebrospinal fluid and serum. Subsequently, intravenous methylprednisolone pulse and gamma-globulin pulse therapies were administered, which substantially improved the symptoms. Follow-up did not reveal abnormal neurological symptoms, and the lesion in the corpus callosum had resolved. LESSONS: AE with mGluR5 antibodies could arise from SARS-CoV-2 vaccination, which warrants the awareness of healthcare workers. Reversible splenial lesion syndrome may accompany mGluR5-related AE and mimic intracranial infection. Thus, early treatment can prevent serious residual signs and symptoms.

Reported rates of all-cause serious adverse events following immunization with BNT-162b in 5-17-year-old children in the United States. Vaccine development against COVID-19 has mitigated severe disease. However, reports of rare but serious adverse events following immunization (sAEFI) in the young populations are fuelling parental anxiety and vaccine hesitancy. With a very early season of viral illnesses including COVID-19, respiratory syncytial virus (RSV), influenza, metapneumovirus and several others, children are facing a winter with significant respiratory illness burdens. Yet, COVID-19 vaccine and booster uptake remain sluggish due to the mistaken beliefs that children have low rates of severe COVID-19 illness as well as rare but severe complications from COVID-19 vaccine are common. In this study we examined composite sAEFI reported in association with COVID-19 vaccines in the United States (US) amongst 5-17-year-old children, to ascertain the composite reported risk associated with vaccination. Between December 13, 2020, and April 13, 2022, a total of 467,890,599 COVID-19 vaccine doses were administered to individuals aged 5-65 years in the US, of which 180 million people received at least 2 doses. In association with these, a total of 177,679 AEFI were reported to the Vaccine Adverse Event reporting System (VAERS) of which 31,797 (17.9%) were serious. The rates of ED visits per 100,000 recipients were 2.56 (95% CI: 2.70-3.47) amongst 5-11-year-olds, 18.25 (17.57-18.95) amongst 12-17-year-olds and 33.74 (33.36-34.13) amongst 18-65-year olds; hospitalizations were 1.07 (95% CI 0.87-1.32) per 100,000 in 5-11-year-olds, 6.83 (6.42-7.26) in 12-17-year olds and 8.15 (7.96-8.35) in 18-65 years; life-threatening events were 0.14 (95% CI: 0.08-0.25) per 100,000 in 5-11-year olds, 1.22 (1.05-1.41) in 12-17-year-olds and 2.96 (2.85-3.08) in 18-65 year olds; and death 0.03 (95% CI 0.01-0.10) per 100,000 in 5-11 year olds, 0.08 (0.05-0.14) amongst 12-17-year olds and 0.76 (0.71-0.82) in 18-65 years age group. The results of our study from national population surveillance data demonstrate rates of reported serious AEFIs amongst 5-17-year-olds which appear to be significantly lower than in 18-65-year-olds. These low risks must be taken into account in overall recommendation of COVID-19 vaccination amongst children.

Covid-19 vaccination and pregnancy: a systematic review of maternal and neonatal outcomes. OBJECTIVES: Although the vaccination against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS Cov-2) is considered safe during pregnancy, vaccine hesitancy among pregnant women is high. The results of published observational studies addressing the issue of Covid-19 vaccination's efficacy and safety during pregnancy need to be summarized. CONTENT: This systematic review compares the

incidence ofÂ major maternal and neonatal outcomes between SARS Cov-2 vaccinated and unvaccinated pregnant women. The included studies enrolled pregnant women of any age and any trimester. Medline-Pubmed, Scopus, Cochrane Library, and grey literature were searched until the 28th of May 2022, and 2,947 studies were found. SUMMARY: Seven observational cohort studies, enrolling 67,274 pregnant women, were selected. When comparing vaccinated and unvaccinated pregnant women, SARS Cov-2 vaccines were not associated with major maternal and neonatal adverse events. The rate of SARS Cov-2 infections among vaccinated pregnant women compared to unvaccinated is significantly reduced by 43%. OUTLOOK: SARS Cov-2 vaccination in pregnant women is effective and safe. The results are promising, but caution isÂ advised due to some limitations: only observational studies addressing this issue were found. Parallelly, the enrolled populations and the intervention (vaccination type and the number of doses) were not homogeneous.

The association between COVID-19 vaccination and idiopathic sudden sensorineural hearing loss, clinical manifestation and outcomes. PURPOSE: Previous data demonstrated an increased incidence of Idiopathic Sensorineural Hearing Loss (ISSNHL) in 2021 compared to 2019-2020, suggesting an association with the anti-COVID-19 vaccine. We aimed to assess our center's incidence and compare the clinical manifestations and outcomes of vaccinated vs. unvaccinated patients. METHODS: A retrospective chart review of all patients diagnosed with ISSNHL during 2021 was conducted and compared to patients who presented in 2018-2020. Patient demographics, audiometry features, vaccination status, and prognosis were evaluated. RESULTS: Throughout 2021, 51 patients were diagnosed with ISSNHL, compared with 31 during 2020, 38 in 2019, and 41 in 2018, demonstrating a 64%, 34%, and 24% increase, respectively. Among patients who presented in 2021, 13 (25.4%) received the anti-COVID-19 vaccine within 30Â days before their presentation, and 4 received it within 96Â h. Most presented after receiving the second or third dose. Patient characteristics, audiometry features, and prognosis did not significantly differ between vaccinated and unvaccinated patients. CONCLUSIONS: A marked incline was seen in the 2021 ISSNHL incidence at our medical center, of which 25% of cases were within a month post-anti-COVID-19 vaccination. No significant difference was found in clinical manifestations and outcomes between vaccinated and nonvaccinated patients. While other justifications could be sought, an association cannot be ruled out, and further research is needed.

Retinal Vasculitis Following COVID-19 Vaccination: Causation or Coincidence? BACKGROUND: With the popularity of coronavirus disease 2019 (COVID-19) vaccination, some rare ocular adverse events have gradually been reported. This report shows a rare case of retinal vasculitis following COVID-19 vaccination. DESCRIPTION: A 37-year-old male complained of unilateral severe vision loss 13Â days after the first dose of an inactivated COVID-19 vaccine. The initial eye examination showed gray-white edema in the macula, and scattered patchy gray-white lesions in the peripheral retina, accompanied by peripheral retinal small vessel occlusion. After glucocorticoid treatment, the gray-white lesions gradually subsided. However, due to the initial severe damage in the fundus, macular and peripheral retinal lesions were significantly atrophied, and the vision recovery was poor. CONCLUSION: The ocular adverse event in this report may be related to the inactivated COVID-19 vaccination, however, it is difficult to rule out the accidental rare adverse events after a large number of vaccinations.

Intranasal COVID-19 vaccine: a modern vaccination approach.

Incidence and characteristics of post-COVID-19 parkinsonism and dyskinesia related to COVID-19 vaccines. BACKGROUND: Coronavirus disease 2019 (COVID-19) is an infectious disease mainly affecting the respiratory system; however, a significant prevalence of neurological symptoms has been noted. OBJECTIVES: To investigate the incidence and characteristics of post-COVID-19 parkinsonism and to study dyskinesia related to COVID-19 vaccines. MATERIAL AND METHODS: The

MEDLINE, PubMed, Scopus, and Web of Science databases were searched for all manuscripts relevant to post-COVID-19 parkinsonism and dyskinesia related to COVID-19 vaccines. Subsequently, we extracted and analysed data from the manuscripts in a structured manner. RESULTS: We found 24 patients with post-COVID-19 parkinsonism, with a mean onset age of 58 years after a mean of 30 days from the COVID-19 onset. Akinetic-rigid (n = 11) and mixed (n = 6) subtypes were the most common. Asymmetry was present in 13/15 patients. Brain MRI was unremarkable in 11/19, whereas dopaminergic system imaging was abnormal in 8/8 patients. Responsiveness to dopaminergic treatment was observed in 12/15 patients. Four patients improved after immunomodulatory therapy. Comorbidities were present in 9/24, encephalopathy symptoms in 11/24, and loss of smell in 9/13 patients. Most patients (n = 14) suffered serious COVID-19- related complications and three were treated with haloperidol. Parkinsonism improved (n = 5) or resolved (n = 4) during the follow-up. Five patients, with a mean age of 52, developed dyskinesia at a mean of 25 hours after receiving the COVID-19 mRNA vaccines. One patient had a history of neuropsychiatric symptoms and developed functional dyskinesia of the tongue. Four patients had a previous history of Parkinson's Disease (PD) with a mean duration of 10 years and developed dyskinesia and dystonia, which resolved (n = 2) or improved (n = 2) during the follow-up. CONCLUSIONS: Post-COVID-19 parkinsonism is a very rare complication, and it is likely that this is an umbrella syndrome that includes many different etiologies. Dyskinesia due to COVID-19 vaccines is exceedingly rare and probably has the same pathophysiological basis as in other conditions with exacerbation of PD symptoms.

Hyperkinetic movement disorders following SARS-CoV-2 infection and vaccination - an update.
The aim of this review was to summarise current knowledge regarding hyperkinetic movement disorders related to SARS-CoV-2 infection and vaccination in terms of phenomenology, epidemiology, pathogenesis and treatment. After a thorough review of the PubMed and Google Scholar databases (2020-2022), we identified myoclonus and ataxia sometimes accompanied by opsoclonus (AMS) as the two most frequent COVID-19 sequelae, with chorea, tremor and dystonia being very rare. The pathogenesis seems to be variable, but in the majority of AMS cases it was autoimmunological, with good response and recovery after corticosteroids or intravenous immunoglobulins infusions. Vaccination may be complicated by hyperkinetic movement disorders (e.g. tremor, dystonia), but this is very rare. Patients with Deep Brain Simulation depletion should not be postponed due to lockdowns as this may result in fatal outcomes.

COVID-19 Vaccination Status and Operative Outcomes after Kidney Transplantation.
BACKGROUND: Kidney transplantation remains the best available treatment for end-stage renal disease. However, promoting graft longevity and preventing allosensitization requires strict adherence with a stringent immunosuppression regimen. The COVID-19 pandemic has offered new challenges for kidney transplant patients and many transplant centers are denying transplantation to unvaccinated patients. The aim of this study was to evaluate whether unvaccinated patients had inferior adherence after kidney transplantation along with a reduction in graft survival. STUDY DESIGN: Patients undergoing a deceased donor kidney transplantation at a single academic medical center from February 2021 to May 2022 were retrospectively reviewed. February 2021 was chosen as the start date for record review because it was 3 months after the first COVID-19 vaccination was authorized for emergency use. Patients were considered to be vaccinated if they received at least 1 dose of any mRNA vaccine by their transplantation date. RESULTS: Of the 301 patients who met study criteria, 234 were vaccinated and 67 were unvaccinated. Cohorts stratified by vaccination status were well matched. Younger age was an independent risk factor for nonvaccination. Interestingly, unvaccinated patients had worse postoperative adherence with a greater average number of missed postoperative clinic visits ($p = 0.03$) and a strong trend toward missing 3 or more postoperative clinic visits ($p = 0.07$). Finally, unvaccinated patients had statistically more subtherapeutic tacrolimus

troughs (p = 0.01). CONCLUSIONS: Patients not vaccinated against COVID-19 had higher rate of postoperative nonadherence in key areas of immunosuppression monitoring and clinic visit attendance. Providers should be cognizant that an unvaccinated status may be a harbinger for poor adherence; therefore, stricter strategies for patient outreach are critical to ensure graft success in this vulnerable patient population.

Pain paths among post-COVID-19 condition subjects: A prospective cross-sectional study with in-person evaluation. BACKGROUND: New-onset chronic pain has been acknowledged as part of the post-COVID-19 condition. However, available fine-grained data about its clinical phenotype, trajectories and main associated characteristics remain scarce. We described the distinct temporal evolutions of post-COVID-19 pain and their epidemiological and phenotypical features. METHODS: A prospective cross-sectional study enrolled post-COVID-19 condition patients (i.e. who had persisting COVID-19-related symptoms over 30â€‰days since their first positive laboratory test), whose COVID-19 diagnosis had been supported by RT-PCR of oral/nasopharyngeal swab or serology. They underwent in-person evaluations with a structured interview, pain and quality-of-life-related questionnaires and thorough physical examination. Chronic pain (CP) and probable neuropathic pain (NP) were defined according to IASP criteria. RESULTS: The present study included 226 individuals, 177 (78.3%) of whom presented over 3â€‰months since their first COVID-19 symptom. New-onset pain occurred in 170 (75.2%) participants and was chronic in 116 (68.2%). A chronic course was associated with COVID-19-related hospitalization, new-onset fatigue, lower cognitive performance, motor and thermal sensory deficits, mood and sleep impairments and overall lower quality-of-life levels. Probable NP occurred in only 7.6% new-onset pain patients, and was associated with pain chronification, new-onset fatigue, motor and thermal sensory deficits, mechanical allodynia and lower rates of SARS-CoV-2 vaccination. Previous CP was reported by 86 (38.1%) individuals and had aggravated after the infection in 66 (76.7%) of them, which was associated with orthostatic hypotension. CONCLUSIONS: Post-COVID pain phenomena follow different paths, which are associated with specific clinical and epidemiological features, and possibly distinct underlying mechanisms, prognostic and therapeutic implications. SIGNIFICANCE: COVID-19-related pain usually follows a chronic course and is non-neuropathic. Its possible courses and phenotypes are associated with distinct clinical and epidemiological features. This suggests differing underlying mechanisms, which may have significant prognostic and therapeutic implications.

Characteristics of patients with SARS-COV-2 PCR re-positivity after recovering from COVID-19.
The purpose of this study was to analyse the clinical characteristics of patients with severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) PCR re-positivity after recovering from coronavirus disease 2019 (COVID-19). Patients (n = 1391) from Guangzhou, China, who had recovered from COVID-19 were recruited between 7 September 2021 and 11 March 2022. Data on epidemiology, symptoms, laboratory test results and treatment were analysed. In this study, 42.7% of recovered patients had re-positive result. Most re-positive patients were asymptomatic, did not have severe comorbidities, and were not contagious. The re-positivity rate was 39%, 46%, 11% and 25% in patients who had received inactivated, mRNA, adenovirus vector and recombinant subunit vaccines, respectively. Seven independent risk factors for testing re-positive were identified, and a predictive model was constructed using these variables. The predictors of re-positivity were COVID-19 vaccination status, previous SARs-CoV-12 infection prior to the most recent episode, renal function, SARS-CoV-2 IgG and IgM antibody levels and white blood cell count. The predictive model could benefit the control of the spread of COVID-19.

The association between adverse events of COVID-19 vaccination and anxiety and willingness to receive a booster dose. Many countries have initiated a booster dose for COVID-19 vaccination. However, little is known about the association between adverse events to vaccination and individual

psychological status and willingness to receive the booster dose. From December 1, 2021 to February 1, 2022, 474 participants answered a questionnaire in a university town in China, and information about previous adverse events, anxiety status, and vaccination intention were collected. Chi-square test and logistic regression models were used to analyze the factors associated with willingness to receive booster dose of vaccine. Previous adverse events, such as pain at the injection site, fatigue, muscle pain and headache were associated with anxiety of the participants. About 76.2% of the participants were willing to receive booster dose of vaccine. However, adverse event was not associated with their willingness to receive the booster dose. Participants with age â‰¤25 were less willing to receive the booster dose, although the association was not statistically significant in the multivariable model. In conclusion, the adverse events of COVID-19 vaccination were associated with psychology status of the vaccinated people. It is still necessary to strengthen the public education on COVID-19 vaccination to improve the vaccination willingness of people, especially among the young people.

Atrial Fibrillation After mRNA-1273 SARS-CoV-2 Vaccination: Case Report with Literature Review. IMPORTANCE: COVID-19 vaccination has been associated with various adverse outcomes. Although studies have reported cases of arrhythmia after COVID-19 vaccination, the precise underlying mechanism remains to be elucidated. OBJECTIVE: Here, we report the case of a patient who developed atrial fibrillation after receiving the mRNA-1273 vaccine and describe our findings in light of relevant cases in the literature. DESIGN SETTING AND PARTICIPANTS: This is a case report and a review of the relevant literature. A 55-year-old woman presented to our clinic with a history of paroxysmal atrial fibrillation, hypertension, and mild mitral valve prolapse. The patient developed atrial fibrillation 3 days after receiving a COVID-19 vaccine. She was diagnosed with moderate-to-severe tricuspid regurgitation and severe mitral regurgitation, and underwent valve repair surgery. To obtain relevant articles (December 2020 through August 2022), we searched the following key words on PubMed: atrial fibrillation and COVID-19 vaccination. RESULTS: A total of 5 relevant case reports were identified. COVID-19 vaccination led to arrhythmia, including atrial fibrillation, within 14 days. CONCLUSIONS AND RELEVANCE: Cases of patients developing arrhythmia after COVID-19 vaccination have been increasingly reported. Although the underlying mechanism remains unclear, we hypothesize that mRNA vaccination may lead to arrhythmia and associated valve diseases. Thus, before administering mRNA-1273 vaccines to patients with a history of valvular heart disease or atrial fibrillation, the patients' cardiologists must be consulted.

Intramuscular mRNA BNT162b2 vaccine against SARS-CoV-2 induces neutralizing salivary IgA. Intramuscularly administered vaccines stimulate robust serum neutralizing antibodies, yet they are often less competent in eliciting sustainable "sterilizing immunity" at the mucosal level. Our study uncovers a strong temporary neutralizing mucosal component of immunity, emanating from intramuscular administration of an mRNA vaccine. We show that saliva of BNT162b2 vaccinees contains temporary IgA targeting the receptor-binding domain (RBD) of severe acute respiratory syndrome coronavirus-2 spike protein and demonstrate that these IgAs mediate neutralization. RBD-targeting IgAs were found to associate with the secretory component, indicating their bona fide transcytotic origin and their polymeric multivalent nature. The mechanistic understanding of the high neutralizing activity provided by mucosal IgA, acting at the first line of defense, will advance vaccination design and surveillance principles and may point to novel treatment approaches and new routes of vaccine administration and boosting.

Prior vaccination enhances immune responses during SARS-CoV-2 breakthrough infection with early activation of memory T cells followed by production of potent neutralizing antibodies. SARS-CoV-2 infection of vaccinated individuals is increasingly common but rarely results in severe disease, likely due to the enhanced potency and accelerated kinetics of memory immune responses. However,

there have been few opportunities to rigorously study early recall responses during human viral infection. To better understand human immune memory and identify potential mediators of lasting vaccine efficacy, we used high-dimensional flow cytometry and SARS-CoV-2 antigen probes to examine immune responses in longitudinal samples from vaccinated individuals infected during the Omicron wave. These studies revealed heightened Spike-specific responses during infection of vaccinated compared to unvaccinated individuals. Spike-specific CD4 T cells and plasmablasts expanded and CD8 T cells were robustly activated during the first week. In contrast, memory B cell activation, neutralizing antibody production, and primary responses to non-Spike antigens occurred during the second week. Collectively, these data demonstrate the functionality of vaccine-primed immune memory and highlight memory T cells as rapid responders during SARS-CoV-2 infection.

Primary ChAdOx1 vaccination does not reactivate pre-existing, cross-reactive immunity. Currently available COVID-19 vaccines include inactivated virus, live attenuated virus, mRNA-based, viral vectored and adjuvanted protein-subunit-based vaccines. All of them contain the spike glycoprotein as the main immunogen and result in reduced disease severity upon SARS-CoV-2 infection. While we and others have shown that mRNA-based vaccination reactivates pre-existing, cross-reactive immunity, the effect of vector vaccines in this regard is unknown. Here, we studied cellular and humoral responses in heterologous adenovirus-vector-based ChAdOx1 nCOV-19 (AZ; Vaxzeria, AstraZeneca) and mRNA-based BNT162b2 (BNT; Comirnaty, BioNTech/Pfizer) vaccination and compared it to a homologous BNT vaccination regimen. AZ primary vaccination did not lead to measurable reactivation of cross-reactive cellular and humoral immunity compared to BNT primary vaccination. Moreover, humoral immunity induced by primary vaccination with AZ displayed differences in linear spike peptide epitope coverage and a lack of anti-S2 IgG antibodies. Contrary to primary AZ vaccination, secondary vaccination with BNT reactivated pre-existing, cross-reactive immunity, comparable to homologous primary and secondary mRNA vaccination. While induced anti-S1 IgG antibody titers were higher after heterologous vaccination, induced CD4(+) T cell responses were highest in homologous vaccinated. However, the overall TCR repertoire breadth was comparable between heterologous AZ-BNT-vaccinated and homologous BNT-BNT-vaccinated individuals, matching TCR repertoire breadths after SARS-CoV-2 infection, too. The reasons why AZ and BNT primary vaccination elicits different immune response patterns to essentially the same antigen, and the associated benefits and risks, need further investigation to inform vaccine and vaccination schedule development.

Serological response to vaccination in post-acute sequelae of COVID. BACKGROUND: Individuals with post-acute sequelae of COVID (PASC) may have a persistence in immune activation that differentiates them from individuals who have recovered from COVID without clinical sequelae. To investigate how humoral immune activation may vary in this regard, we compared patterns of vaccine-provoked serological response in patients with PASC compared to individuals recovered from prior COVID without PASC. METHODS: We prospectively studied 245 adults clinically diagnosed with PASC and 86 adults successfully recovered from prior COVID. All participants had measures of humoral immunity to SARS-CoV-2 assayed before or after receiving their first-ever administration of COVID vaccination (either single-dose or two-dose regimen), including anti-spike (IgG-S and IgM-S) and anti-nucleocapsid (IgG-N) antibodies as well as IgG-S angiotensin-converting enzyme 2 (ACE2) binding levels. We used unadjusted and multivariable-adjusted regression analyses to examine the association of PASC compared to COVID-recovered status with post-vaccination measures of humoral immunity. RESULTS: Individuals with PASC mounted consistently higher post-vaccination IgG-S antibody levels when compared to COVID-recovered (median log IgG-S 3.98 versus 3.74, Pâ€‰<â€‰0.001), with similar results seen for ACE2 binding levels (median 99.1 versus 98.2, Pâ€‰=â€‰0.044). The post-vaccination IgM-S response in PASC was attenuated but persistently

unchanged over time (Pâ€‰=â€‰0.33), compared to in COVID recovery wherein the IgM-S response expectedly decreased over time (Pâ€‰=â€‰0.002). Findings remained consistent when accounting for demographic and clinical variables including indices of index infection severity and comorbidity burden. CONCLUSION: We found evidence of aberrant immune response distinguishing PASC from recovered COVID. This aberrancy is marked by excess IgG-S activation and ACE2 binding along with findings consistent with a delayed or dysfunctional immunoglobulin class switching, all of which is unmasked by vaccine provocation. These results suggest that measures of aberrant immune response may offer promise as tools for diagnosing and distinguishing PASC from non-PASC phenotypes, in addition to serving as potential targets for intervention.

COVID-19 Vaccination in
 Pregnant Women: Exploring Serious Adverse Events. Null.

Subjects who developed SARS-CoV-2 specific IgM after vaccination show a longer humoral immunity and a lower frequency of infection. BACKGROUND: We have previously shown that eliciting SARS-CoV-2-specific IgM after vaccination is associated with higher levels of SARS-CoV-2 neutralizing IgG. This study aims to assess whether IgM development is also associated with longer-lasting immunity. METHODS: We analysed anti-SARS-CoV-2 spike protein IgG and IgM (IgG-S, IgM-S), and anti-nucleocapsid IgG (IgG-N) in 1872 vaccinees at different time points: before the first dose (D1; w0), before the second dose (D2; w3) at three (w6) and 23 weeks (w29) after D2; moreover, 109 subjects were further tested at the booster dose (D3, w44), at 3 weeks (w47) and 6 months (w70) after D3. Two-level linear regression models were used to evaluate the differences in IgG-S levels. FINDINGS: In subjects who had no evidence of a previous infection at D1 (non-infected, NI), IgM-S development after D1 and D2 was associated with higher IgG-S levels at short (w6, pÂ <Â 0.0001) and long (w29, pÂ <Â 0.001) follow-up. Similar IgG-S levels were observed after D3. The majority (28/33, 85%) of the NI subjects who had developed IgM-S in response to vaccination did not experience infection. INTERPRETATION: The development of anti-SARS-CoV-2 IgM-S following D1 and D2 is associated with higher IgG-S levels. Most individuals who developed IgM-S never became infected, suggesting that IgM elicitation may be associated with a lower risk of infection. FUNDING: "Fondi Ricerca Corrente" and "Progetto Ricerca Finalizzata" COVID-2020 (Italian Ministry of Health); FUR 2020 Department of Excellence 2018-2022 (MIUR, Italy); the Brain Research Foundation Verona.

Humoral and cellular immune responses in persons with rheumatoid arthritis after a third dose of mRNA COVID-19 vaccine. OBJECTIVE: Disease-modifying anti-rheumatic drugs (DMARDs) that treat rheumatoid arthritis (RA) may reduce immune responses to COVID-19 vaccination. We compared humoral and cell-mediated immunity before and after a 3rd dose of mRNA COVID vaccine in RA subjects. METHODS: RA patients that received 2 doses of mRNA vaccine enrolled in an observational study in 2021 before receiving a 3rd dose. Subjects self-reported holding or continuing DMARDs. Blood samples were collected pre- and 4 weeks after the 3rd dose. 50 healthy controls provided blood samples. Humoral response was measured with in-house ELISA assays for anti-Spike IgG (anti-S) and anti-receptor binding domain IgG (anti-RBD). T cell activation was measured after stimulation with SARS-CoV-2 peptide. Spearman's correlations assessed the relationship between anti-S, anti-RBD, and frequencies of activated T cells. RESULTS: Among 60 subjects, mean age was 63 years and 88% were female. 57% of subjects held at least 1 DMARD around the 3rd dose. 43% (anti-S) and 62% (anti-RBD) had a normal humoral response at week 4, defined as ELISA within 1 standard deviation of the healthy control mean. No differences in antibody levels were observed based on holding DMARDs. Median frequency of activated CD4 T cells was significantly greater post- vs. pre-3rd dose. Changes in antibody levels did not correlate with change in frequency of activated CD4 T cells. CONCLUSION: Virus-specific IgG levels significantly increased in RA subjects using DMARDs after completing the primary vaccine series, though fewer than two-thirds achieved a humoral response like healthy controls. Humoral and cellular changes were not correlated.

Reactivation of Graves' Disease and Thyroid Eye Disease following COVID-19 Vaccination - A Case Report. A 51-year-old male had a history of well-controlled Graves' disease (GD) under regular follow-up, and thyroid eye disease (TED) with post bilateral orbital decompression. However, after COVID-19 vaccination, recrudescence of GD and moderate-to-severe TED were diagnosed by increased thyroxine levels and decreased thyrotropin levels in serum, and positive results of thyrotropin receptor antibody and thyroid peroxidase antibody. Weekly intravenous methylprednisolone was prescribed. Symptoms gradually improved accompanied with reduction in proptosis: 1.5 mm of the OD and 2.5 mm of the OS. Possible pathophysiological mechanisms discussed included molecular mimicry theory, autoimmune/inflammatory syndrome induced by adjuvants, and certain genetic predisposition of human leukocyte antigen. Physicians should remind patients to seek treatment if the symptoms and signs of TED recur following COVID-19 vaccination.

Vaccination Intention Following Receipt of Vaccine Information Through Interactive Simulation vs Text Among COVID-19 Vaccine-Hesitant Adults During the Omicron Wave in Germany. CONCLUSIONS AND RELEVANCE: In this cross-sectional study, vaccine-hesitant adults presented with an interactive risk ratio simulation were more likely to show positive change in COVID-19 vaccination intention and benefit-to-harm assessment than those presented with a conventional text-based information format. These findings suggest that the interactive risk communication format can be an important tool in addressing vaccination hesitancy and fostering public trust. DESIGN, SETTING, AND PARTICIPANTS: Cross-sectional study conducted online with 1255 COVID-19 vaccine-hesitant adult residents of Germany in April and May 2022, surveyed using a probability-based internet panel maintained by respondi, a research and analytics firm. Participants were randomized to 1 of 2 presentations on the benefits and adverse events associated with vaccination. EXPOSURE: Participants were randomized to a text-based description vs an interactive simulation presenting age-adjusted absolute risks of infection, hospitalization, ICU admission, and death after exposure to coronavirus in vaccinated vs unvaccinated individuals relative to the possible adverse effects as well as additional (population-level) benefits of COVID-19 vaccination. IMPORTANCE: Hesitancy toward COVID-19 vaccination is a major factor in stagnating uptake rates and in the risk of health care systems becoming overwhelmed. MAIN OUTCOMES AND MEASURES: Absolute change in respondents' COVID-19 vaccination intention category and benefit-to-harm assessment category. OBJECTIVE: To compare an interactive risk ratio simulation (intervention) with a conventional text-based risk information format (control) and analyze change in participants' COVID-19 vaccination intention and benefit-to-harm assessment. RESULTS: Participants were 1255 COVID-19 vaccine-hesitant residents of Germany (660 women [52.6%]; mean [SD] age, 43.6 [13.5] years). A total of 651 participants received a text-based description, and 604 participants received an interactive simulation. Relative to the text-based format, the simulation was associated with greater likelihood of positive change in vaccination intentions (19.5% vs 15.3%, respectively; absolute difference, 4.2%; adjusted odds ratio [aOR], 1.45; 95% CI, 1.07-1.96; Pâ€‰=â€‰.01) and benefit-to-harm assessments (32.6% vs 18.0%; absolute difference, 14.6%; aOR, 2.14; 95% CI, 1.64-2.80; Pâ€‰<â€‰.001). Both formats were also associated with some negative change. However, the net advantage (positive - negative change) of the interactive simulation over the text-based format was 5.3 percentage points for vaccination intention (9.8% vs 4.5%) and 18.3 percentage points for benefit-to-harm assessment (25.3% vs 7.0%). Positive change in vaccination intention (but not in benefit-to-harm assessment) was associated with some demographic characteristics and attitudes to COVID-19 vaccination; negative changes were not.

Steroid resistant nephrotic syndrome with collapsing focal segmental glomerulosclerosis in a 12-year-old Japanese female after SARS-CoV-2 vaccination.

COVID-19 and Mixed Cryoglobulinemia Syndrome: Long-Term Survey Study on the Prevalence and Outcome, Vaccine Safety, and Immunogenicity. PURPOSE: Mixed cryoglobulinemia syndrome (MCs) is a rare immunoproliferative systemic disorder with cutaneous and multiple organ involvement. Our multicenter survey study aimed to investigate the prevalence and outcome of COVID-19 and the safety and immunogenicity of COVID-19 vaccines in a large MCs series. METHODS: The survey included 430 unselected MCs patients (130 M, 300 F; mean age 70 Â± 10.96 years) consecutively collected at 11 Italian referral centers. Disease classification, clinico-serological assessment, COVID-19 tests, and vaccination immunogenicity were carried out according to current methodologies. RESULTS: A significantly higher prevalence of COVID-19 was found in MCs patients compared to Italian general population (11.9% vs 8.0%, $p < 0.005$), and the use of immunomodulators was associated to a higher risk to get infected ($p = 0.0166$). Moreover, higher mortality rate was recorded in MCs with COVID-19 compared to those without ($p < 0.01$). Patients' older age (â‰¥ 60 years) correlated with worse COVID-19 outcomes. The 87% of patients underwent vaccination and 50% a booster dose. Of note, vaccine-related disease flares/worsening were significantly less frequent than those associated to COVID-19 ($p = 0.0012$). Impaired vaccination immunogenicity was observed in MCs patients compared to controls either after the first vaccination ($p = 0.0039$) and also after the booster dose ($p = 0.05$). Finally, some immunomodulators, namely, rituximab and glucocorticoids, hampered the vaccine-induced immunogenicity ($p = 0.029$). CONCLUSIONS: The present survey revealed an increased prevalence and morbidity of COVID-19 in MCs patients, as well an impaired immunogenicity even after booster vaccination with high rate of no response. Therefore, MCs can be included among frail populations at high risk of infection and severe COVID-19 manifestations, suggesting the need of a close monitoring and specific preventive/therapeutical measures during the ongoing pandemic.

Humoral and cellular response after BNT162b2 vaccine booster in hemodialysis patients and kidney transplant recipients. BACKGROUND: Vulnerable populations, such as hemodialysis (HD) patients and kidney transplant (RTx) recipients, have priority for anti-COVID-19 vaccination, because of their impaired immune status. Here, we investigated the immune response after vaccination with BNT162b2 (two doses plus booster) in HD and RTx patients. METHODS: A prospective, observational study was started in two homogeneous groups of 55 HD and 51 RTx patients previously matched from a cohort of 336 patients. Anti-RBD IgG levels, assayed after the second dose with BNT162b2 mRNA, were used to stratify subjects into quintiles. After the second dose and after booster, anti-RBD and IGRA test were evaluated in RTx and HD, belonging to the first and fifth quintiles. RESULTS: After the second dose of vaccine, the median circulating levels of anti-RBD IgG were significantly higher in HD (1456 AU/mL) compared to RTx (27.30 AU/mL). IGRA test showed significantly higher values in the HD (382 mIU/mL) compared with the RTx (73 mIU/mL). After the booster, humoral response increased significantly in both HD (pâ€‰=â€‰0.0002) and RTx groups (pâ€‰=â€‰0.009), whereas the T-cellular immunity remained essentially stable in most patients. In RTx patients with a low humoral response after the second dose, the third dose did not significantly strengthen either humoral or cellular immunity. CONCLUSIONS: For HD and RTx, there is great variability in the humoral response to anti-COVID-19 vaccination, with a stronger response in the HD group. The booster dose was ineffective at reinforcing the humoral and cellular immune response in most RTx patients hyporesponsive to the second dose.

Analysis of hematologic adverse events reported to a national surveillance system following COVID-19 bivalent booster vaccination. Hematologic complications, including vaccine-induced immune thrombotic thrombocytopenia (VITT), immune thrombocytopenia (ITP), and autoimmune hemolytic anemia (AIHA), have been associated with the original severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines. However, on August 31, 2022, new formulations of the Pfizer-BioNTech and

Moderna vaccines were approved for use without clinical trial testing. Thus, any potential adverse hematologic effects with these new vaccines remain unknown. We queried the US Centers for Disease Control Vaccine Adverse Event Reporting System (VAERS), a national surveillance database, through February 3, 2023, all reported hematologic adverse events that occurred within 42Â days of administration of either the Pfizer-BioNTech or Moderna Bivalent COVID-19 Booster vaccine. We included all patient ages and geographic locations and utilized 71 unique VAERS diagnostic codes pertaining to a hematologic condition as defined in the VAERS database. Fifty-five reports of hematologic events were identified (60.0% Pfizer-BioNTech, 27.3% Moderna, 7.3% Pfizer-BioNTech bivalent booster plus influenza, 5.5% Moderna bivalent booster plus influenza). The median age of patients was 66Â years, and 90.9% (50/55) of reports involved a description of cytopenias or thrombosis. Notably, 3 potential cases of ITP and 1 case of VITT were identified. In one of the first safety analyses of the new SARS-CoV-2 booster vaccines, we identified few adverse hematologic events (1.05 per 1,000,000 doses), most of which could not be definitively attributed to vaccination. However, three reports of possible ITP and one report of possible VITT highlight the need for continued safety monitoring of these vaccines as their use expands and new formulations are authorized.

[Factors associated with the duration of SARS-CoV-2 infection in healthcare professionals at a second-level public hospital in the Community of Madrid (Spain) during the sixth wave.]. OBJECTIVE: The incidence of COVID-19 infections among health professionals during the sixth wave has suffered an exponential increase, mainly due to the rapid community transmission caused by the Omicron variant. The main objective of the study was to evaluate the time to negativization in COVID-positive health professionals during the sixth wave, according to the PDIA result; and secondarily, to evaluate the possible influence of other factors (previous infection, vaccination, sex, age, job position) on the time to get negative status. METHODS: A descriptive, longitudinal, observational and retrospective study was carried out at Infanta SofÃ-a University Hospital (Madrid, Spain). Made from the registry of the Occupational Risk Prevention Service of suspected or confirmed cases of SARS-COV-2 infection in health professionals, during the period between November 1, 2021 and February 28, 2022. Bivariate comparisons were made using Mann Whitney, Kruskal Wallis or Chi-square test (or exact test) according to variables. Subsequently, logistic regression (explanatory model) was performed. RESULTS: The cumulative incidence of SARS-COV-2 infection in health professionals was 23.07%. The mean time to become negative was 9.94 days. Only the history of previous SARS-COV-2 infection had a statistically significant influence on the time to negativization of PDIA. The variables vaccination, sex and age had no effect on the time to negativization of PDIA. CONCLUSIONS: Professionals with a history of COVID-19 infection present lower times of negativization than those who had not have the disease. The results of our study confirm the immune escape of the vaccine against COVID-19, since more than 95% of those infected had received a complete vaccination schedule.

Shedding Light on Mechanisms of Myocarditis With COVID-19 mRNA Vaccines.

A Case of Leukocytoclastic Vasculitis and Associated Conjunctivitis Following MMR Vaccine Administration. INTRODUCTION: Leukocytoclastic vasculitis (LCV) is a small-vessel vasculitis characterized by immune complex deposition in the walls of dermal capillaries and venules. With the COVID-19 pandemic, more adults are receiving the MMR vaccine, as it may enhance innate immune responses against COVID-19 infection. Here, we report a case of LCV and associated conjunctivitis arising in a patient secondary to immunization with the MMR vaccine. METHODS AND RESULTS: A 78-year-old man on lenalidomide therapy for multiple myeloma presented to an outpatient dermatology clinic with a two-day history of a painful rash consisting of scattered pink dermal papules on bilateral dorsal and palmar hands, as well as bilateral conjunctival erythema. Histopathological findings-which revealed an inflammatory infiltrate with papillary dermal edema, as well as nuclear dust within small

blood vessel walls with extravasation of red blood cells-were most consistent with LCV. It then became known that the patient had received an MMR vaccine two weeks prior to the onset of the rash. The rash was resolved with the use of topical clobetasol ointment, and the patient's eyes were cleared as well. CONCLUSIONS: This is an interesting presentation of MMR vaccine-related LCV occurring only on the upper extremities with associated conjunctivitis. Had the patient's oncologist not known about the recent vaccination, it is likely that the treatment of his multiple myeloma would have been postponed or altered, as lenalidomide can also cause LCV.

Double-Positive Anti-Glomerular Basement Membrane Antibody and Myeloperoxidase Antineutrophil Cytoplasmic Autoantibody-Associated Glomerulonephritis Post COVID-19 mRNA vaccine: A Case Series of 4 Patients. RATIONALE: Vaccines remain central to the management of COVID-19 pandemic, including the need for repeat doses of vaccines to boost immunity. There has been an accumulating case count of glomerulopathies temporally associated with COVID-19 vaccination. This case series presents 4 patients who developed double-positive anti-glomerular basement membrane antibody (anti-GBM) and myeloperoxidase (MPO) antineutrophil cytoplasmic autoantibody (ANCA)-associated glomerulonephritis after COVID-19 mRNA vaccination. This report contributes to our collective knowledge about the pathophysiology and clinical outcomes associated with this rare complication. PRESENTING CONCERNS OF THE PATIENT: Four patients developed nephritic syndrome within 1 to 6 weeks after receiving a COVID-19 mRNA vaccine (3 post Pfizer-BioNTech and 1 post Moderna vaccination). Three of the 4 patients also had hemoptysis. DIAGNOSIS: Three of the 4 patients had double-positive serology, whereas the fourth patient had renal biopsy findings consistent with double-positive disease, although anti-GBM serology was negative. All patients had renal biopsy findings consistent with double-positive anti-GBM and ANCA-associated glomerulonephritis. INTERVENTIONS: All 4 patients were treated with pulse steroids, cyclophosphamide, and plasmapheresis. OUTCOMES: Of the 4 patients, 1 demonstrated complete remission, 2 remained dialysis-dependent, and the fourth is deceased. Of the 2 patients who received repeat vaccination with COVID-19 mRNA vaccine, 1 patient had second serologic flare of anti-GBM in response to the vaccine. NOVEL FINDINGS: This case series reinforces growing evidence that COVID-19 mRNA vaccine-induced glomerulonephritis is a rare but real phenomenon. Dual ANCA and anti-GBM nephritis can present after the first dose of COVID-19 mRNA vaccine or after several administrations of the vaccine. We are the first to report cases of double-positive MPO ANCA and anti-GBM nephritis after Pfizer-BioNTech vaccination. To our knowledge, we are also the first to report outcomes of repeat COVID-19 vaccination in patients with de novo flare of ANCA and anti-GBM nephritis temporally associated with COVID-19 vaccination.

Associations of COVID-19 vaccination during pregnancy with adverse neonatal and maternal outcomes: A systematic review and meta-analysis. OBJECTIVES: The low COVID-19 vaccine uptake rate among pregnant women is mainly due to safety concerns about COVID-19 vaccines due to limited safety evidence. Our goal was to evaluate the safety of COVID-19 vaccination during pregnancy with up-to-date evidence. METHODS: A comprehensive search of MEDLINE, EMBASE, the Cochrane Library, and clinicaltrials.gov was performed on April 5th, 2022, and updated on May 25th, 2022. Studies evaluating the association of COVID-19 vaccination during pregnancy with adverse maternal and neonatal outcomes were included. Two reviewers independently performed the risk of bias assessment and data extraction. Inverse variance random effect meta-analyses were performed to pool outcome data. RESULTS: Forty-three observational studies were included. COVID-19 vaccination [96,384 (73.9%) BNT162b2, 30,889 (23.7%) mRNA-1273, and 3,172 (2.4%) other types] during pregnancy [23,721 (18.3%) in the first trimester, 52,778 (40.5%) in the second trimester, and 53,886 (41.2%) in the third trimester].was associated with reduced risks of stillbirth or neonatal death (OR, 0.74; 95% CI, 0.60-0.92). Sensitivity analysis restricted to studies in participants without COVID-

19 showed that the pooled effect was not robust. COVID-19 vaccination during pregnancy was not associated with congenital anomalies (OR, 0.83; 95% CI, 0.63-1.08), preterm birth (OR, 0.98; 95% CI, 0.90-1.06), NICU admission or hospitalization (OR, 0.94; 95% CI, 0.84-1.04), an Apgar score at 5 min <7 (OR, 0.93; 95% CI, 0.86-1.01), low birth weight (OR, 1.00; 95% CI, 0.88-1.14), miscarriage (OR, 0.99; 95% CI, 0.88-1.11), cesarean delivery (OR, 1.07; 95% CI, 0.96-1.19), or postpartum hemorrhage (OR, 0.91; 95% CI, 0.81-1.01). CONCLUSIONS: COVID-19 vaccination during pregnancy was not associated with any of the adverse neonatal or maternal outcomes studied. Interpretation of study findings is limited by the types and timing of vaccination. The vaccinations in our study received during pregnancy were primarily mRNA vaccines administered in the second and third trimester. Future RCTs and meta-analysis are warranted to evaluate the efficacy and long-term effects of the COVID-19 vaccines. SYSTEMATIC REVIEW REGISTRATION: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022322525, identifier: PROSPERO, CRD42022322525.

COVID-19 Vaccine-Induced Latent Autoimmune Diabetes in Adults. Since 2019, COVID-19 has plagued the world with its unfortunate death toll; however, with the introduction of multiple COVID vaccines, mortality and morbidity rates have severely declined. There have been misconceptions surrounding these vaccines, and at the same time, many documented conditions precipitated by the vaccines. This case highlights a speculated relationship between new-onset Latent Autoimmune Diabetes in Adults (LADA) (presenting with diabetic ketoacidosis) and the COVID-19 vaccine. There have been articles suggesting the precipitation of diabetic ketoacidosis /hyperosmolar hyperglycemic syndrome, as well as new-onset diabetes mellitus (DM) with the COVID-19 vaccines but no documented link between LADA and the vaccine. The endpoint of this case is not only to highlight a newfound side-effect of the vaccine but also to urge primary care providers and physicians to closely monitor glucose levels and patient's A1C after vaccine administration to prevent the formation of these hyperglycemic crises, as well as to consider autoimmune conditions in the differential diagnosis post-vaccination.

Sex-disaggregated outcomes of adverse events after COVID-19 vaccination: A Dutch cohort study and review of the literature. BACKGROUND: Albeit the need for sex-disaggregated results of adverse events after immunization (AEFIs) is gaining attention since the COVID-19 pandemic, studies with emphasis on sexual dimorphism in response to COVID-19 vaccination are relatively scarce. This prospective cohort study aimed to assess differences in the incidence and course of reported AEFIs after COVID-19 vaccination between males and females in the Netherlands and provides a summary of sex-disaggregated outcomes in published literature. METHODS: Patient reported outcomes of AEFIs over a six month period following the first vaccination with BioNTech-Pfizer, AstraZeneca, Moderna or the Johnson&Johnson vaccine were collected in a Cohort Event Monitoring study. Logistic regression was used to assess differences in incidence of 'any AEFI', local reactions and the top ten most reported AEFIs between the sexes. Effects of age, vaccine brand, comorbidities, prior COVID-19 infection and the use of antipyretic drugs were analyzed as well. Also, time-to-onset, time-to-recovery and perceived burden of AEFIs was compared between the sexes. Third, a literature review was done to retrieve sex-disaggregated outcomes of COVID-19 vaccination. RESULTS: The cohort included 27,540 vaccinees (38.5% males). Females showed around two-fold higher odds of having any AEFI as compared to males with most pronounced differences after the first dose and for nausea and injection site inflammation. Age was inversely associated with AEFI incidence, whereas a prior COVID-19 infection, the use of antipyretic drugs and several comorbidities were positively associated. The perceived burden of AEFIs and time-to-recovery were slightly higher in females. DISCUSSION: The results of this large cohort study correspond to existing evidence and contribute to the knowledge gain necessary to disentangle the magnitude of the effect sex in response to

vaccination. Whilst females have a significant higher probability of experiencing an AEFI than males, we observed that the course and burden is only to a minor extent different between the sexes.

Increased incidence of immune thrombocytopenia (ITP) in 2021 correlating with the ongoing vaccination campaign against COVID-19 in a tertiary center - A monocentric analysis. Immune thrombocytopenia (ITP) was reported as a rare complication of COVID-19 vaccines. We conducted a retrospective single-center analysis of all ITP cases detected in 2021 and compared the quantity with the pre-vaccination years, from 2018 to 2020. In 2021, a two-fold increase in ITP cases was identified compared to previous years; 11 of 40 cases (27.5%) were considered COVID-19-vaccine related. Our study highlights an increase in ITP cases at our institution, probably related to COVID-19 vaccinations. Further studies are needed to investigate this finding globally.

Safety of COVID-19 vaccines: A comparison between adverse drug reactions among vaccines marketed in Europe.

Mining adverse events in large frequency tables with ontology, with an application to the vaccine adverse event reporting system. Many statistical methods have been applied to VAERS (vaccine adverse event reporting system) database to study the safety of COVID-19 vaccines. However, none of these methods considered the adverse event (AE) ontology. The AE ontology contains important information about biological similarities between AEs. In this paper, we develop a model to estimate vaccine-AE associations while incorporating the AE ontology. We model a group of AEs using the zero-inflated negative binomial model and then estimate the vaccine-AE association using the empirical Bayes approach. This model handles the AE count data with excess zeros and allows borrowing information from related AEs. The proposed approach was evaluated by simulation studies and was further illustrated by an application to the Vaccine Adverse Event Reporting System (VAERS) dataset. The proposed method is implemented in an R package available at https://github.com/umich-biostatistics/zGPS.AO.

Age-dependent impairment in antibody responses elicited by a homologous CoronaVac booster dose. The emergence of the SARS-CoV-2 Omicron sublineages resulted in increased transmission rates and reduced protection from vaccines. To counteract these effects, multiple booster strategies were used in different countries, although data comparing their efficiency in improving protective immunity remain sparse, especially among vulnerable populations, including older adults. The inactivated CoronaVac vaccine was among the most widely distributed vaccine worldwide and was essential in the early control of SARS-CoV-2-related hospitalizations and deaths. However, it is not well understood whether homologous versus heterologous booster doses in those fully vaccinated with CoronaVac induce distinct humoral responses or whether these responses vary across age groups. We analyzed plasma antibody responses from CoronaVac-vaccinated younger or older individuals who received a homologous CoronaVac or heterologous BNT162b2 or ChAdOx1 booster vaccine. All three evaluated boosters resulted in increased virus-specific IgG titers 28 days after the booster dose. However, we found that both IgG titers against SARS-CoV-2 Spike or RBD and neutralization titers against Omicron sublineages were substantially reduced in participants who received homologous CoronaVac compared with the heterologous BNT162b2 or ChAdOx1 booster. This effect was specifically prominent in recipients >50 years of age. In this group, the CoronaVac booster induced low virus-specific IgG titers and failed to elevate neutralization titers against any Omicron sublineage. Our results point to the notable inefficiency of CoronaVac immunization and boosting in mounting protective antiviral humoral immunity, particularly among older adults, during the Omicron wave. These observations also point to benefits of heterologous regimens in high-risk populations fully vaccinated with CoronaVac.

Evaluation of BNT162b2 Covid-19 Vaccine in Children Younger than 5 Years of Age. BACKGROUND: Safe and effective vaccines against coronavirus disease 2019 (Covid-19) are urgently

needed in young children. METHODS: We conducted a phase 1 dose-finding study and are conducting an ongoing phase 2-3 safety, immunogenicity, and efficacy trial of the BNT162b2 vaccine in healthy children 6 months to 11 years of age. We present results for children 6 months to less than 2 years of age and those 2 to 4 years of age through the data-cutoff dates (April 29, 2022, for safety and immunogenicity and June 17, 2022, for efficacy). In the phase 2-3 trial, participants were randomly assigned (in a 2:1 ratio) to receive two 3-Î¼g doses of BNT162b2 or placebo. On the basis of preliminary immunogenicity results, a third 3-Î¼g dose (â‰¥8 weeks after dose 2) was administered starting in January 2022, which coincided with the emergence of the B.1.1.529 (omicron) variant. Immune responses at 1 month after doses 2 and 3 in children 6 months to less than 2 years of age and those 2 to 4 years of age were immunologically bridged to responses after dose 2 in persons 16 to 25 years of age who received 30 Î¼g of BNT162b2 in the pivotal trial. RESULTS: During the phase 1 dose-finding study, two doses of BNT162b2 were administered 21 days apart to 16 children 6 months to less than 2 years of age (3-Î¼g dose) and 48 children 2 to 4 years of age (3-Î¼g or 10-Î¼g dose). The 3-Î¼g dose level was selected for the phase 2-3 trial; 1178 children 6 months to less than 2 years of age and 1835 children 2 to 4 years of age received BNT162b2, and 598 and 915, respectively, received placebo. Immunobridging success criteria for the geometric mean ratio and seroresponse at 1 month after dose 3 were met in both age groups. BNT162b2 reactogenicity events were mostly mild to moderate, with no grade 4 events. Low, similar incidences of fever were reported after receipt of BNT162b2 (7% among children 6 months to <2 years of age and 5% among those 2 to 4 years of age) and placebo (6 to 7% among children 6 months to <2 years of age and 4 to 5% among those 2 to 4 years of age). The observed overall vaccine efficacy against symptomatic Covid-19 in children 6 months to 4 years of age was 73.2% (95% confidence interval, 43.8 to 87.6) from 7 days after dose 3 (on the basis of 34 cases). CONCLUSIONS: A three-dose primary series of 3-Î¼g BNT162b2 was safe, immunogenic, and efficacious in children 6 months to 4 years of age. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04816643.).

Short-term improvement of mental health after a COVID-19 vaccination. INTRODUCTION: The role of COVID-19 vaccination on the mental health of the general population remains poorly understood. This study aims to assess the short-term change in depressive and anxiety symptoms in relation to COVID-19 vaccination among Swedish adults. METHODS: A prospective study of 7,925 individuals recruited from ongoing cohort studies at the Karolinska Institutet, Stockholm, Sweden, or through social media campaigns, with monthly data collections on self-reported depressive and anxiety symptoms from December 2020 to October 2021 and COVID-19 vaccination from July to October 2021. Prevalence of depressive and anxiety symptoms (defined as a self-reported total score of â‰¥10 in PHQ-9 and GAD-7, respectively) was calculated one month before, one month after the first dose, and, if applicable, one month after the second dose. For individuals not vaccinated or choosing not to report vaccination status (unvaccinated individuals), we selected three monthly measures of PHQ-9 and GAD-7 with 2-month intervals in-between based on data availability. RESULTS: 5,079 (64.1%) individuals received two doses of COVID-19 vaccine, 1,977 (24.9%) received one dose, 305 (3.9%) were not vaccinated, and 564 (7.1%) chose not to report vaccination status. There was a lower prevalence of depressive and anxiety symptoms among vaccinated, compared to unvaccinated individuals, especially after the second dose. Among individuals receiving two doses of vaccine, the prevalence of depressive and anxiety symptoms was lower after both first (aRR = 0.82, 95%CI 0.76-0.88 for depression; aRR = 0.81, 95%CI 0.73-0.89 for anxiety) and second (aRR = 0.79, 95%CI 0.73-0.85 for depression; aRR = 0.73, 95%CI 0.66-0.81 for anxiety) dose, compared to before vaccination. Similar results were observed among individuals receiving only one dose (aRR = 0.76, 95%CI 0.68-0.84 for depression; aRR = 0.82, 95%CI 0.72-0.94 for anxiety), comparing after first dose to before vaccination. CONCLUSIONS: We observed a short-term improvement in depressive and

anxiety symptoms among adults receiving COVID-19 vaccines in the current pandemic. Our findings provide new evidence to support outreach campaigns targeting hesitant groups.

Commentary to Ocular dysmotility after SARS-CoV-2 vaccination requires the exclusion of all differential causes.

Optic Neuritis After SARS-CoV-2 Vaccination. BACKGROUND: To describe recent cases of optic neuritis in patients who received a vaccine for COVID-19. METHODS: Retrospective case series of patients diagnosed with optic neuritis after a recent COVID-19 vaccination with BNT162b2 (Pfizer-BioNTech), in one university-affiliated tertiary hospital, from January 2021 to June 2021. Data were obtained from medical charts. RESULTS: We describe 7 patients who developed optic neuritis after immunization with the BNT162b2 vaccine. CONCLUSIONS: A causal relationship cannot be deduced, and the importance of COVID-19 vaccination is not challenged. However, the authors encourage a prospective monitoring and reporting system for all patients receiving COVID-19 vaccines, to further assess the spectrum of adverse events in large databases.

SARS-CoV-2 Infection, Vaccination, and Neuro-Ophthalmic Complications.

SARS-CoV-2 live virus neutralization after four COVID-19 vaccine doses in people with HIV receiving suppressive antiretroviral therapy. OBJECTIVE: Limited data exist regarding the immune benefits of fourth COVID-19 vaccine doses in people with HIV (PWH) receiving antiretroviral therapy (ART), particularly now that most have experienced a SARS-CoV-2 infection. We quantified wild-type, Omicron-BA.5 and Omicron-BQ.1-specific neutralization up to 1 month post-fourth COVID-19 vaccine dose in 63 (19 SARS-CoV-2-naive and 44 SARS-CoV-2-experienced) PWH. DESIGN: A longitudinal observational cohort. METHODS: Quantification of wild-type-, Omicron-BA.5, and Omicron-BQ.1-specific neutralization using live virus assays. RESULTS: Participants received monovalent (44%) and bivalent (56%) mRNA fourth doses. In COVID-19-naive PWH, fourth doses enhanced wild-type and Omicron-BA.5-specific neutralization modestly above three-dose levels (P â€Š=â€Š0.1). In COVID-19-experienced PWH, fourth doses enhanced wild-type specific neutralization modestly (P â€Š=â€Š0.1) and BA.5-specific neutralization substantially (P â€Š=â€Š0.002). Consistent with humoral benefits of 'hybrid' immunity, COVID-19-experienced PWH exhibited the highest neutralization post-fourth dose, wherein those with Omicron-era infections displayed higher wild-type specific (P â€Š=â€Š0.04) but similar BA.5 and BQ.1-specific neutralization than those with pre-Omicron-era infections. Nevertheless, BA.5-specific neutralization was significantly below wild-type in everyone regardless of COVID-19 experience, with BQ.1-specific neutralization lower still (both P â€Š<â€Š0.0001). In multivariable analyses, fourth dose valency did not affect neutralization magnitude. Rather, an mRNA-1273 fourth dose (versus a BNT162b2 one) was the strongest correlate of wild-type specific neutralization, while prior COVID-19, regardless of pandemic era, was the strongest correlate of BA.5 and BQ.1-specific neutralization post-fourth dose. CONCLUSION: Fourth COVID-19 vaccine doses, irrespective of valency, benefit PWH regardless of prior SARS-CoV-2 infection. Results support recommendations that all adults receive a fourth COVID-19 vaccine dose within 6â€Šmonths of their third dose (or their most recent SARS-CoV-2 infection).

Vesiculobullous and Other Cutaneous Manifestations of COVID-19 Vaccines: a Scoping and Narrative Review. As coronavirus disease (COVID-19) vaccines continue to be administered, dermatologists play a critical role in recognizing and treating the cutaneous manifestations (CM) associated with the vaccines. Adverse cutaneous reactions of COVID-19 vaccines reported in the literature range from common urticarial to rare vesiculobullous reactions. In this study, we performed a (1) scoping review to assess the occurrences of vesicular, papulovesicular, and bullous CMs of COVID-19 vaccines and their respective treatments, and (2) a narrative review discussing other common and uncommon CMs of COVID-19 vaccines. Thirty-six articles were included in the scoping review, and 66 articles in the narrative review. We found that vesicular, papulovesicular, and bullous lesions are infrequent,

reported mostly after the first dose of Moderna or Pfizer vaccines. Eleven of the 36 studies reported vesicular reactions consistent with activation or reactivation of the herpes zoster virus. Most vesicular and bullous lesions were self-limited or treated with topical corticosteroids. Other CMs included injection-site, urticarial or morbilliform reactions, vasculitis, toxic epidermal necrolysis, and flaring of or new-onset skin diseases such as psoriasis. Treatments for CMs included topical or oral corticosteroids, antihistamines, or no treatment in self-limited cases. Although most CMs are benign and treatable, the data on the effect of systemic corticosteroids and immunosuppressive therapies on the immunogenicity of COVID-19 vaccines is limited. Some studies report reduced immunogenicity of the vaccines after high-dose corticosteroids use. Physicians may consult local guidelines where available when recommending COVID-19 vaccines to immunosuppressed patients, and when using corticosteroids to manage the CMs of COVID-19 vaccines.
Mycophenolic Acid Exposure Determines Antibody Formation Following SARS-CoV-2 Vaccination in Kidney Transplant Recipients: A Nested Cohort Study. Despite (repeated) boosting, kidney transplant recipients (KTRs) may remain at increased risk of severe COVID-19 since a substantial number of individuals remain seronegative or with low antibody titers. In particular, mycophenolic acid use has been shown to affect antibody formation negatively and may be an important modifiable risk factor. We investigated the exposure-response relationship between mycophenolic acid 12-hour area under the curve (AUC(0-12h)) exposure and seroconversion including antibody titers after vaccination using mRNA-1273 SARS-CoV-2 vaccine (Moderna) in 316 KTRs from our center that participated in the national Dutch renal patients COVID-19 vaccination - long term efficacy and safety of SARS-CoV-2 vaccination in kidney disease patients vaccination study. After two vaccination doses, 162 (51%) KTRs seroconverted. KTRs treated with mycophenolic acid showed less seroconversion and lower antibody titers compared with KTRs without mycophenolic acid (44% vs. 77%, and 36 binding antibody units (BAU)/mL vs. 340 BAU/mL; Pâ€‰<â€‰0.001). The mean mycophenolic acid AUC(0-12h) exposure was significantly lower in KTRs who seroconverted compared with KTRs who did not (39 vs. 29â€‰mgâ‹…h/L; Pâ€‰<â€‰0.001). High mycophenolic acid exposure (Â±90â€‰mgâ‹…h/L) and no exposure to mycophenolic acid resulted in a seroconversion rate ranging from 10% to 80%. Every 10â€‰mgâ‹…h/L increase in mycophenolic acid AUC(0-12h) gave an adjusted odds ratio for seroconversion of 0.87 (95% confidence interval (CI), 0.79-0.97; PÂ =Â 0.010) and 0.89 (95% CI, 0.85-0.93; Pâ€‰<â€‰0.001) for KTRs on dual and triple maintenance immunosuppressive therapy, respectively. Higher mycophenolic acid AUC(0-12h) correlated with lower antibody titers (R = 0.44, Pâ€‰<â€‰0.001). This study demonstrates the exposure-response relationship between gold standard mycophenolic acid exposure and antibody formation to support interventional studies investigating mycophenolic acid adjustment to improve antibody formation after further boosting.
Post COVID-19 vaccination and adverse events: correspondence.
Post-COVID-19 vaccine acute encephalitis in an adult patient: A case report and literature review. Several vaccines were approved after COVID-19 pandemic, which have been fast-tracked for emergency use. The short- and long-term safety profile has been an area of concern. We presented a patient with encephalitis followed by hyponatremia who developed hallucination and seizure 1 day after receiving the second dose of Sinopharm vaccine.
Corona Virus Disease-19 Vaccine-associated Autoimmune Disorders. Coronavirus disease is a highly infectious viral disease caused by severe acute respiratory syndrome virus (SARS nCoV2). It was declared a pandemic within a few months of identification of its index case. The spread of COVID-19 across the globe was rampant, overwhelming healthcare systems and crippling global economies. Since the world was caught off guard by the pandemic, vaccine programs had to be rolled out in emergency to curb its spread. Ten vaccines have been granted Emergency Use Authorization thus far. Much of the side effects we know today are post-marketing adverse effects. Most of them are mild

like myalgia and injection-site reactions, but a few of them such as post-vaccination autoimmune diseases have alerted the medical community. These include vaccine-induced thrombotic thrombocytopenia, autoimmune hepatitis, myocarditis, and Graves' disease. We attempt to summarize the diverse autoimmune phenomena reported after COVID-19 vaccination, with an aim to sensitize the medical community so that they can be better equipped in management when confronted with these diseases. This review by no means refutes the potential benefit of COVID-19 vaccination which has consolidated its place in preventing infections and substantially reducing severity and mortality.

Polyarteritis Nodosa Following mRNA-1273 COVID-19 Vaccination: Case Study and Review of Immunological Mechanisms. Numerous post-vaccine complications have been reported secondary to the COVID-19 vaccine. Many of these complications are believed to be due to a hyperactive immune system. A 59-year-old woman developed diffuse abdominal pain two days after receiving the mRNA-1273 COVID-19 vaccine (Moderna). A computerized tomography (CT) angiogram of the abdomen and pelvis revealed the presence of numerous vascular irregularities in the celiac axis, bilateral renal arteries, and inferior mesenteric artery consistent with polyarteritis nodosa (PAN), a medium-vessel vasculitis. The patient was managed with intravenous methylprednisolone 500 mg daily for three days and was then placed on oral methotrexate (MTX) 12.5 mg daily for immunosuppressive maintenance treatment. Until now, a limited number of cases of polyarteritis nodosa secondary to the COVID-19 vaccine have been reported.Â Major mechanisms of post-vaccine autoimmunity are molecular mimicry and autoantibody production. Although rare adverse events from COVID-19 vaccination are possible, there remains an immense benefit to vaccination in preventing COVID-19-related morbidity and mortality.

Extensive Cerebral Venous Sinus Thrombosis Post COVID-19 Vaccination. Extensive cerebral sinus thrombosis following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination is rare. We report the case of a 42-year-old man who presented with a severe generalized headache that was not relieved by analgesics for nine days. It started four days after he received the third dose of BNT162b2 (BioNTech/Pfizer). He also complained of numbness at the back of the neck, vomiting, mild blurring of vision, and diplopia. The visual acuity (VA) in the right eye was 6/9 (improved to 6/7.5 with a pinhole) and 6/6 in the left eye. He was not able to abduct both eyes and noticed a double image at lateral gaze. Fundoscopy showed swollen optic discs with the presence of disc hemorrhages. A computed tomography venogram (CTV) of the brain showed loss of normal signal void with filling defects in the superior sagittal sinus, straight sinus, bilateral transverse sinuses, bilateral sigmoid sinuses, and bilateral internal jugular veins. The nasopharyngeal swab sample was negative for SARS-CoV-2. His platelet was normal (271x10(9)/L) and his coagulation profileÂ was normal. Workup for connective tissue disease was negative. He was diagnosed with extensive cerebral vascular thrombosis post-vaccination. He received a one-week course of subcutaneous clexane, followed by oral anticoagulant treatment. After treatment, his headache was relieved, and the diplopia subsided. The venous thrombosis was partially resolved. Both the swollen optic discs improved, and his VA improved to 6/6 in both eyes.

Facial Dermal Filler Injection and Vaccination: A 12-Year Review of Adverse Event Reporting and Literature Review. BACKGROUND: Following authorization of 2 COVID-19 vaccines in December 2020, media attention increased towards postvaccine adverse events (AEs) in patients with facial dermal filler injections. OBJECTIVES: The purpose of this study was to characterize vaccine-related facial dermal filler AEs by scrutinizing the FDA's Manufacturer and User Facility Device Experience (MAUDE) database. METHODS: The MAUDE database was queried from January 1, 2011 to January 28, 2023 for facial dermal filler medical device reports (MDRs) discussing vaccination-related AEs. A PubMed (National Institutes of Health, Bethesda, MD) literature review on dermal filler AEs was then

conducted. Data were analyzed with descriptive statistics. RESULTS: Of 10,637 MDRs identified, 33 were included. There were 25 MDRs (75.8%) related to COVID-19 vaccination. Hyaluronic acid-based fillers were described in 31 MDRs (93.9%). AEs were mostly reported within days postinjection (n = 7, 21.2%), but ranged from immediately (n = 2, 6.1%) to months (n = 6, 18.2%) postinjection. Most AEs were reported postvaccine (n = 17, 51.5%) vs postfiller (n = 14, 42.4%). In 26 reports (78.8%), AEs occurred at the site of filler injection. Most MDRs described inflammation/swelling (n = 21, 28.0%). The literature review returned 302 articles, of which 14 were included. Only 1 article (7.1%) was published in a plastic surgery journal. CONCLUSIONS: Although the pandemic brought attention to COVID-19 vaccine-related facial dermal filler AEs, this study shows a low incidence compared with the millions of vaccine and filler injections administered. Reactions with non-COVID-19 vaccines were also documented. Increased awareness may help providers counsel patients undergoing vaccination and dermal filler implantation.

Humoral immune response to SARS-CoV-2 vaccination in patients with inflammatory bowel disease on immunosuppressive medication: association to serum drug levels and disease type. OBJECTIVES: Immune responses following SARS-CoV-2 vaccination in patients with inflammatory bowel disease (IBD) are not well characterized. The aims of this study were to explore the serological response associated with IBD, and immunosuppressive medications including serum concentrations of biologics and thiopurine metabolites. MATERIALS AND METHODS: This prospective, observational study included adult patients with ulcerative colitis (UC) and Crohn's disease (CD), and healthy controls. Antibodies to the receptor-binding domain of SARS-CoV-2 spike proteins, and serum concentrations of ongoing biologic and immunomodulatory medications were assessed prior to, and 2-5â€‰weeks after the second vaccine dose. Serologic response was defined as anti-Spike antibodies â‰¥70â€‰AU/ml. RESULTS: In 958 IBD patients (380 UC, 578â€‰CD) and 323 healthy controls, the median (Q(1;) Q(3)) anti-Spike antibody level (AU/ml) was lower in patients (618 (192; 4370)) compared to controls (3355 (896; 7849)) (pâ€‰<â€‰0.001). The antibody levels were lower in CD (439 (174; 3304)) compared to UC (1088 (251; 5975)) (pâ€‰<â€‰0.001). No associations were demonstrated between antibody levels and serum drug concentrations for TNF inhibitor (TNFi), vedolizumab and ustekinumab. Patients receiving TNFiâ€‰+â€‰thiopurines with a subtherapeutic 6-thioguanine nucleotide (6-TGN) level had higher response rate (93%) compared to patients with 6-TGN within the therapeutic range (53%) (pâ€‰=â€‰0.003). A diagnosis of UC, mRNA-1273 vaccine, and other treatments than TNFiâ€‰+â€‰thiopurines were associated with humoral response. CONCLUSIONS: Patients with CD had an attenuated humoral response to SARS-COV-2 vaccination as compared to patients with UC. The lack of association between serum levels of biologics and serologic response indicates vaccination regardless of proximity to drug administration.

Immune profiling of SARS-CoV-2 epitopes in asymptomatic and symptomatic pediatric and adult patients. BACKGROUND: The infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has unpredictable manifestations of coronavirus disease (COVID-19) and variable clinical course with some patients being asymptomatic whereas others experiencing severe respiratory distress, or even death. We aimed to evaluate the immunoglobulin G (IgG) response towards linear peptides on a peptide array containing sequences from SARS-CoV-2, Middle East respiratory syndrome-related coronavirus (MERS) and common-cold coronaviruses 229E, OC43, NL63 and HKU1 antigens, in order to identify immunological indicators of disease outcome in SARS-CoV-2 infected patients. METHODS: We included in the study 79 subjects, comprising 19 pediatric and 30 adult SARS-CoV-2 infected patients with increasing disease severity, from mild to critical illness, and 30 uninfected subjects who were vaccinated with one dose of SARS-CoV-2 spike mRNA BNT162b2 vaccine. Serum samples were analyzed by a peptide microarray containing 5828 overlapping 15-mer synthetic peptides corresponding to the full SARS-CoV-2 proteome and selected linear epitopes of

spike (S), envelope (E) and membrane (M) glycoproteins as well as nucleoprotein (N) of MERS, SARS and coronaviruses 229E, OC43, NL63 and HKU1 (isolates 1, 2 and 5). RESULTS: All patients exhibited high IgG reactivity against the central region and C-terminus peptides of both SARS-CoV-2 N and S proteins. Setting the threshold value for serum reactivity above 25,000 units, 100% and 81% of patients with severe disease, 36% and 29% of subjects with mild symptoms, and 8% and 17% of children younger than 8-years reacted against N and S proteins, respectively. Overall, the total number of peptides in the SARS-CoV-2 proteome targeted by serum samples was much higher in children compared to adults. Notably, we revealed a differential antibody response to SARS-CoV-2 peptides of M protein between adults, mainly reacting against the C-terminus epitopes, and children, who were highly responsive to the N-terminus of M protein. In addition, IgG signals against NS7B, NS8 and ORF10 peptides were found elevated mainly among adults with mild (63%) symptoms. Antibodies towards S and N proteins of other coronaviruses (MERS, 229E, OC43, NL63 and HKU1) were detected in all groups without a significant correlation with SARS-CoV-2 antibody levels. CONCLUSIONS: Overall, our results showed that antibodies elicited by specific linear epitopes of SARS-CoV-2 proteome are age dependent and related to COVID-19 clinical severity. Cross-reaction of antibodies to epitopes of other human coronaviruses was evident in all patients with distinct profiles between children and adult patients. Several SARS-CoV-2 peptides identified in this study are of particular interest for the development of vaccines and diagnostic tests to predict the clinical outcome of SARS-CoV-2 infection.

Persistence of Antibodies Six Months after Three COVID-19 mRNA Vaccine Doses in Patients with Inflammatory Bowel Disease. We evaluated antibody concentrations 6 months after a third coronavirus disease 2019 messenger RNA vaccine dose in patients with inflammatory bowel diseases. Almost all patients had an antibody response, and those with a previous SARS-CoV-2 infection had higher antibody concentrations.

Thrombotic and immunological phenomena following COVID-19 vaccination: experience from a case series.

Myocarditis post-SARS-CoV-2 vaccination-the definitive review.

Association of COVID-19 Vaccination With Risk for Incident Diabetes After COVID-19 Infection. This cohort study compares the risk of new-onset hypertension, hyperlipidemia, and diabetes before and after COVID-19 infection among patients who were vaccinated vs unvaccinated before infection.

Early vs Deferred Non-Messenger RNA COVID-19 Vaccination Among Chinese Patients With a History of Inactive Uveitis: A Randomized Clinical Trial. IMPORTANCE: Improper host response to COVID-19 vaccines could trigger immune-mediated adverse events. The question remains whether COVID-19 vaccination should be postponed until complete remission in patients with uveitis, a preexisting immune-related condition. OBJECTIVE: To compare recommendations for early and deferred COVID-19 vaccination with respect to uveitis outcomes. DESIGN, SETTING, AND PARTICIPANTS: This open-label, randomized clinical trial at a large, specialized teaching center for uveitis care in China enrolled unvaccinated patients with inactive uveitis between August 10, 2021, and February 22, 2022, with follow-up to June 6, 2022. INTERVENTIONS: Participants were randomly assigned to receive recommendation for early or deferred COVID-19 vaccination after complete remission of uveitis. Non-messenger RNA (non-mRNA) COVID-19 vaccines were available in China during the trial. MAIN OUTCOMES AND MEASURES: The primary outcome was the time to symptomatic uveitis worsening during 3 months of follow-up. Secondary outcomes included uveitis activity and best-corrected visual acuity at 3 months. RESULTS: Of the 543 participants (304 women [56.0%]; median age, 35 [IQR, 26-49] years), 262 were recommended for early vaccination and 281 for deferred vaccination. By month 3, 109 patients (41.6%) in the early group had been vaccinated compared with 14 (5.0%) in the deferred recommendation group. In the intention-to-treat population, the time to symptomatic

uveitis worsening was shorter in the early group than in the deferred group (hazard ratio, 1.68 [95% CI, 1.09-2.59]; Pâ€‰=â€‰.01 by log-rank test). Changes in anterior chamber cells, vitreous haze, and best-corrected visual acuity from baseline to month 3 appeared similar in the 2 groups in the evaluable population after the month 3 in-person visit. CONCLUSIONS AND RELEVANCE: In this randomized clinical trial of patients with inactive uveitis, recommendation for early non-mRNA COVID-19 vaccination resulted in a higher incidence of self-reported symptomatic uveitis worsening with possible reporting bias compared with recommendation for deferred vaccination, but no adverse effects were observed in disease and visual prognosis at 3 months. These findings would be useful to guide the individual timing choices of non-mRNA COVID-19 vaccination in this clinically vulnerable population. TRIAL REGISTRATION: Chinese Clinical Trial Registry: ChiCTR2100049467.

Optimizing Safety Surveillance for COVID-19 Vaccines at the Swedish Medical Products Agency.

Clinical and immunological impact of booster immunization with recombinant mRNA vaccines for SARS-CoV-2 in patients with pemphigus and bullous pemphigoid.

Covid-19 Vaccine Side Effects and Its Associated Factors Among Healthcare Workers at Dessie Hospital, Ethiopia. BACKGROUND: Vaccines are a powerful choice to stop disease outbreaks, including covid-19. However, people are hesitant to take vaccinations due to uncertainty about side effects. So, this study aimed to assess covid-19 vaccine side-effect and its associated factors among healthcare workers in Dessie comprehensive specialized hospital, in Ethiopia. METHODS: An institution-based cross-sectional study was conducted at Dessie Comprehensive and Specialized Hospital among 351 vaccinated healthcare workers from April 25 to May 25, 2021. Self-administrated questionnaires were used by consented health workers. Variance inflation factor (VIF) was used to assess the multicollinearity of independent variables. Bivariable and multivariable binary logistic regression were used to identify significant factors of vaccine side effects. The adjusted odds ratio (AOR) with a 95% confidence interval (CI) was reported as the effect size. Statistical significance was considered at p-value <0.05. RESULTS: Overall, of vaccinated healthcare workers, 56.98% (95% CI, 50.86-61.26%) experienced at least one side effect. The majority of the side effects were fever (44.44%), headache (39.03%), fatigue (27.35%), injection site pain (25.93%), and nausea (24.22%). Healthcare workers with (â‰¥10 years) of work experience (AOR: 3.74, 95% CI, 1.32-10.59), Hesitancy to take the first dose of the Covid-19 vaccine (AOR: 3.01, 95% CI, 1.82-4.99), underlying chronic disease (AOR: 14.41, 95% CI, (5.07-40.92)), being on antihypertensive medication (AOR: 0.15; 95% CI (0.02-0.93)), and unsafe perception of vaccine safety (AOR:3.50; 95% CI, 1.43-8.57) were independent factors of Covax vaccine side effect development. CONCLUSION: Overall, common vaccine side effects were identified in healthcare workers who have taken the Covax vaccine. Healthcare workers with (â‰¥10 years) of work experience, Hesitancy to take the first dose, unsafe perception of vaccine safety, and underlined chronic disease were predictors of vaccine side effect occurrence. So, providing vaccine-related information to the community to be vaccinated is mandatory to reduce hesitancy and flaws regarding vaccine safety.

Risk and characteristics of Bell's palsy in adults as an adverse event following COVID-19 vaccination: a retrospective study. BACKGROUND: Although an association between COVID-19 vaccination and Bell's palsy (BP) has been reported, a clear causal relationship has not been elucidated. We investigated the risk and clinical characteristics of BP after COVID-19 vaccination. METHODS: This retrospective chart review evaluated the association between COVID-19 vaccination and BP by comparing the number of patients diagnosed with BP during the pre-COVID-19 vaccination period (March 2018-February 2021) and the COVID-19 mass vaccination period (March 2021-February 2022). We then compared vaccine-related (time between vaccination and BP onsetâ€‰<â€‰42Â days) and -unrelated (time intervalâ€‰â‰¥â€‰42Â days or non-vaccination) clinical characteristics in newly diagnosed patients with BP. RESULTS: BP occurred more during the COVID-19 vaccination period than

in the previous three pre-vaccination years. Thirteen patients developed BP within 42Â days of vaccination. All patients, except one, developed BP after mRNA-based vaccination, with most cases (9/13, 69.2%) occurring after the second or third dose. Thirteen patients with vaccine-related BP were younger (age 43.92â€‰Â±â€‰13.14 vs. 54.32â€‰Â±â€‰16.01Â years; pâ€‰=â€‰0.033) and more frequently experienced taste changes (58.8% vs. 10.9%; pâ€‰=â€‰0.002) than 52 patients with vaccine-unrelated BP. Patients with vaccine-related BP had a greater likelihood of good and faster (pâ€‰=â€‰0.042) facial nerve function recovery than those with vaccine-unrelated BP (100% vs. 78%). CONCLUSION: COVID-19 vaccines, especially mRNA-based vaccines, may be associated with BP cases with distinctive clinical characteristics, which occur more frequently in young individuals, are frequently accompanied by taste changes, and have fast and good recovery.

Evaluation of the safety profile of COVID-19 vaccines in patients with MS, NMOSD, and MOGAD. INTRODUCTION: Vaccination against the coronavirus disease 2019 (COVID-19) is recommended for patients with multiple sclerosis (MS), neuromyelitis optica spectrum disorder (NMOSD), and myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD). However, vaccine safety in these patients taking immunotherapeutic agents is unclear as they were not included in the vaccine trials. OBJECTIVES: To evaluate the safety of COVID-19 vaccines in patients with MS, NMOSD, and MOGAD. METHODS: We reviewed the medical records of MS, NMOSD, and MOGAD patients at the Keimyung University Dongsan Hospital. Information regarding vaccination schedules and adverse events was collected. RESULTS: A total of 56 patients (19, 22, and 15 patients with MS, NMOSD, and MOGAD, respectively) with a median age of 48.18â€‰Â±â€‰15.72Â years (range, 16-81Â years) were included. Of them, 42 (75.0%) were female. In total, 76.8% (43/56) of all patients were vaccinated, and the vaccination rate was the highest for NMOSD patients (81.8%) and the lowest for MS patients (68.4%). All vaccinated patients were administered mRNA vaccines at least once in single or multiple vaccination doses. Only 3 of 43 (7.0%) vaccinated patients experienced clinical relapse following vaccination. Facial sensory changes with a brainstem lesion developed in an MS patient taking dimethyl fumarate, while myelitis occurred in a MOGAD patient receiving azathioprine maintenance therapy. The first episode of optic neuritis occurred in a patient who was later diagnosed with MOGAD. CONCLUSIONS: Our study demonstrated a favorable safety profile with no serious adverse events associated with COVID-19 vaccines in patients with MS, NMOSD, and MOGAD.

A Case of Neuroretinitis following Inactivated Virion COVID-19 Vaccination. PURPOSE: We report a rare presentation of neuroretinitis following vaccination with inactivated virion vaccine (COVAXIN). METHODS: Interventional Case Report. OBSERVATION: A 14-year-old female presented with sudden unilateral vision loss 3 days following COVID-19 vaccination. The clinical and radiological evaluation was consistent with classical neuroretinitis; the serological and immunological workup was negative. The patient responded well to the pulse steroid therapy and regained complete vision. CONCLUSION: The COVID-19 vaccine related adverse ocular events are beginning to emerge slowly and thus warrants close monitoring of all such cases. Also, ophthalmologists should be encouraged to seek vaccination status of patients presenting with inflammatory ocular conditions.

Persons with HIV Develop Spike-Specific Lymph Node Germinal Center Responses following SARS-CoV-2 Vaccination. COVID-19 disproportionately affects persons with HIV (PWH) in worldwide locations with limited access to SARS-CoV-2 vaccines. PWH exhibit impaired immune responses to some, but not all, vaccines. Lymph node (LN) biopsies from PWH demonstrate abnormal LN structure, including dysregulated germinal center (GC) architecture. It is not clear whether LN dysregulation prevents PWH from mounting Ag-specific GC responses in the draining LN following vaccination. To address this issue, we longitudinally collected blood and draining LN fine needle aspiration samples before and after SARS-CoV-2 vaccination from a prospective, observational cohort of 11 PWH on antiretroviral therapy: 2 who received a two-dose mRNA vaccine series and 9 who received a single

dose of the Ad26.COV2.S vaccine. Following vaccination, we observed spike-specific Abs, spike-specific B and T cells in the blood, and spike-specific GC B cell and T follicular helper cell responses in the LN of both mRNA vaccine recipients. We detected spike-specific Abs in the blood of all Ad26.COV2.S recipients, and one of six sampled Ad26.COV2.S recipients developed a detectable spike-specific GC B and T follicular helper cell response in the draining LN. Our data show that PWH can mount Ag-specific GC immune responses in the draining LN following SARS-CoV-2 vaccination. Due to the small and diverse nature of this cohort and the limited number of available controls, we are unable to elucidate all potential factors contributing to the infrequent vaccine-induced GC response observed in the Ad26.COV2.S recipients. Our preliminary findings suggest this is a necessary area of future research.

Lower T cell response against SARS-CoV-2 variants of concern after mRNA vaccine and risk of breakthrough infections in people with HIV. OBJECTIVES: We evaluated T-cell immune responses against SARS-CoV-2 variants of concern (VOC) after vaccination in people with HIV (PWH), and their impact on the incidence of disease. METHODS: A prospective cohort study. Peripheral blood mononuclear cells (PBMCs) were collected a median of 53â€Šdays after second dose of mRNA vaccine. Humoral response and T cell responses against the spike (S) glycoprotein of wild-type SARS-CoV-2 (ancestral Wuhan variant) and mutated S-protein regions found in the Delta and Omicron variants were assessed by flow cytometry analysis. RESULTS: In 142 PWH without preceding SARS-CoV-2 infection, bivariate correlations showed a close association between T-cell responses to the different variants. However, despite at least 70% of PWH having a cellular immune response to any variant, CD4 + and CD8 + T cell responses against VOC were lower in frequency and magnitude (-3% and -20% for Delta, -33% and -28% for Omicron variant) compared with that observed against the Wuhan strain. A higher magnitude of SARS-CoV-2 spike-specific CD8 + T cell responses against all the variants was observed in those PWH with greater immune reconstitution. Notably, 27 symptomatic breakthrough infections (19%) in the setting of Delta and Omicron transmission were observed during follow-up, associated with a significant lower humoral and T-cell response to ancestral strain and VOC. On the contrary, only one PWH with COVID-19 (4%) required hospitalization. CONCLUSION: A blunted T-cell response against Delta and Omicron variant is observed in PWH who received two doses of mRNA vaccine. This lower immune response is associated with breakthrough SARS-CoV-2 infections.

Fulminant myocarditis with complete atrioventricular block after mRNA COVID-19 vaccination: A case report. A 71-year-old man was transferred urgently to our hospital after collapsing near his home post the first shot of the BNT162b2 coronavirus disease 2019 vaccine (Pfizer-BioNTech, ComirnatyÂ®). Immediately after arrival at our hospital, cardiac arrest due to complete atrioventricular block with no ventricular escaped beats was observed on electrocardiogram. Echocardiography showed preserved left ventricular ejection fraction, however, diffuse severe hypokinesia was revealed after 3â€¯weeks, and he died 3â€¯months after admission because of worsening heart failure. An autopsy examination revealed eosinophilic myocarditis or hypersensitivity myocarditis with extensive fibrosis and widespread myocardial dropout throughout the heart. LEARNING OBJECTIVE: 1. Severe myocarditis occurs extremely rarely after mRNA coronavirus disease 2019 (COVID-19) vaccination. 2. Myocarditis after mRNA COVID-19 vaccination might cause complete atrioventricular block, followed by a course of decreased left ventricular ejection fraction. 3. Histologically, severe myocarditis after mRNA COVID-19 vaccination seems to present as fulminant necrotizing eosinophilic myocarditis or hypersensitivity myocarditis.

Risk of adverse events following CoronaVac's COVID-19 vaccination in women with and without autoimmunity. INTRODUCTION: Adverse Events Following Immunization (AEFI) of the COVID-19 vaccine is one of the important considerations, especially in patients with autoimmunity. This study

aims to compare the number of CoronaVac AEFIs in women with and without autoimmunity. METHODOLOGY: This is a retrospective cohort study with an unpaired comparative analytic design with a retrospective cohort method. We recruited 602 volunteers, 182 women with autoimmunity and 420 without autoimmunity. We included women who received the CoronaVac vaccine, aged 17-65 years. Data were analyzed using the chi-square or fisher exact method as an alternative. RESULTS: We found a generally increased risk for AEFI in women with autoimmunity (RRÂ =Â 1.179; 95% CI 1.059-1.313; pÂ =Â 0.007) compared to women without autoimmunity, especially for systemic (RRÂ =Â 1.1271; 95% CI 1.045-1.545; pÂ =Â 0.025), allergic (RRÂ =Â 2.052; 95% CI 1.070-3.932; pÂ =Â 0.045), fever (RRÂ =Â 2.163 95%; CI 1.093-4.282; pÂ =Â 0.039), fatigue (RRÂ =Â 2.182 95%; CI 1.558-3.056; pÂ =Â 0.001), and headache (RRÂ =Â 1.619 95%; CI 1.164-2.251; pÂ =Â 0.006). On the other hand, we found no increased risk for the overall severity of AEFI (RRÂ =Â 0.851 95% CI; 0.655-1.105; pÂ =Â 0.256). We also found a relapse of autoimmune condition in 10.4% (nÂ =Â 19) after CoronaVac vaccination. CONCLUSIONS: There is an increased risk of AEFI after CoronaVac vaccination in women with autoimmunity compared to those without the condition. Although the severity of AEFIs and risk of autoimmune relapse were relatively low.

Effect of SARS-CoV-2 BNT162b2 mRNA vaccine on thyroid autoimmunity: A twelve-month follow-up study. OBJECTIVES: Graves' disease (GD) has been highlighted as a possible adverse effect of the respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccine. However, it is unknown if the SARS-CoV-2 vaccine disrupts thyroid autoimmunity. We aimed to present long-term follow-up of thyroid autoimmunity after the SARS-CoV-2 BNT162b2 mRNA vaccine. METHODS: Serum samples collected from seventy Japanese healthcare workers at baseline, 32 weeks after the second dose (pre-third dose), and 4 weeks after the third dose of the vaccine were analyzed. The time courses of anti-SARS-CoV-2 spike immunoglobulin G (IgG) antibody, thyroid-stimulating hormone receptor antibody (TRAb), and thyroid function were evaluated. Anti-thyroglobulin antibodies (TgAb) and anti-thyroid peroxidase antibodies (TPOAb) were additionally evaluated in thirty-three participants. RESULTS: The median age was 50 (IQR, 38-54) years and 69% were female. The median anti-spike IgG antibody titer was 17627 (IQR, 10898-24175) U/mL 4 weeks after the third dose. The mean TRAb was significantly increased from 0.81 (SD, 0.05) IU/L at baseline to 0.97 (SD, 0.30) IU/L 4 weeks after the third dose without functional changes. An increase in TRAb was positively associated with female sex (Î² = 0.32, P = 0.008) and low basal FT4 (Î² = -0.29, P = 0.02) and FT3 (Î² = -0.33, P = 0.004). TgAb was increased by the third dose. Increase in TgAb was associated with history of the thyroid diseases (Î² = 0.55, P <0.001). CONCLUSIONS: SARS-CoV-2 BNT162b2 mRNA vaccine can disrupt thyroid autoimmunity. Clinicians should consider the possibility that the SARS-CoV-2 vaccine may disrupt thyroid autoimmunity.

Mathematical modelling of the waning of anti-RBD IgG SARS-CoV-2 antibody titers after a two-dose BNT162b2 mRNA vaccination. BACKGROUND: After exposure to SARS-CoV-2 and/or vaccination there is an increase in serum antibody titers followed by a non-linear waning. Our aim was to find out if this waning of antibody titers would fit to a mathematical model. METHODS: We analyzed anti-RBD (receptor binding domain) IgG antibody titers and the breakthrough infections over a ten-month period following the second dose of the mRNA BNT162b2 (Pfizer-BioNtech.) vaccine, in a cohort of 54 health-care workers (HCWs) who were either never infected with SARS-CoV-2 (naÃ¯ve, nHCW group, n=27) or previously infected with the virus (experienced, eHCW group, n=27). Two mathematical models, exponential and power law, were used to quantify antibody waning kinetics, and we compared the relative quality of the goodness of fit to the data between both models was compared using the Akaik Information Criterion. RESULTS: We found that the waning slopes were significantly more pronounced for the naÃ¯ve when compared to the experienced HCWs in exponential (p-value: 1.801E-9) and power law (p-value: 9.399E-13) models. The waning of anti-RBD IgG antibody levels

fitted significantly to both exponential (average-R2: 0.957 for nHCW and 0.954 for eHCW) and power law (average-R2: 0.991 for nHCW and 0.988 for eHCW) models, with a better fit to the power law model. In the nHCW group, titers would descend below an arbitrary 1000-units threshold at a median of 210.6 days (IQ range: 74.2). For the eHCW group, the same risk threshold would be reached at 440.0 days (IQ range: 135.2) post-vaccination. CONCLUSION: Two parsimonious models can explain the anti-RBD IgG antibody titer waning after vaccination. Regardless of the model used, eHCWs have lower waning slopes and longer persistence of antibody titers than nHCWs. Consequently, personalized vaccination booster schedules should be implemented according to the individual persistence of antibody levels.

Neutralizing antibodies to Omicron after the fourth SARS-CoV-2 mRNA vaccine dose in immunocompromised patients highlight the need of additional boosters. INTRODUCTION: Immunocompromised patients have been shown to have an impaired immune response to COVID-19 vaccines. METHODS: Here we compared the B-cell, T-cell and neutralizing antibody response to WT and Omicron BA.2 SARS-CoV-2 virus after the fourth dose of mRNA COVID-19 vaccines in patients with hematological malignancies (HM, n=71), solid tumors (ST, n=39) and immune-rheumatological (IR, n=25) diseases. The humoral and T-cell responses to SARS-CoV-2 vaccination were analyzed by quantifying the anti-RBD antibodies, their neutralization activity and the IFN-Î³ released after spike specific stimulation. RESULTS: We show that the T-cell response is similarly boosted by the fourth dose across the different subgroups, while the antibody response is improved only in patients not receiving B-cell targeted therapies, independent on the pathology. However, 9% of patients with anti-RBD antibodies did not have neutralizing antibodies to either virus variants, while an additional 5.7% did not have neutralizing antibodies to Omicron BA.2, making these patients particularly vulnerable to SARS-CoV-2 infection. The increment of neutralizing antibodies was very similar towards Omicron BA.2 and WT virus after the third or fourth dose of vaccine, suggesting that there is no preferential skewing towards either virus variant with the booster dose. The only limited step is the amount of antibodies that are elicited after vaccination, thus increasing the probability of developing neutralizing antibodies to both variants of virus. DISCUSSION: These data support the recommendation of additional booster doses in frail patients to enhance the development of a B-cell response directed against Omicron and/or to enhance the T-cell response in patients treated with anti-CD20.

COVID-19 Associated Fulminant Myocarditis in a Fully-Vaccinated Female: A Case Report with Clinical Follow-up. BACKGROUND: Myocarditis is considered a serious adverse event after COVID-19 infection. The risk and severity of myocarditis after COVID-19 disease decreased significantly in the vaccinated population. We present a case of cardiac magnetic resonance proven fulminant myocarditis following COVID-19 disease in a young female who was previously vaccinated with 2 doses of the BIBP (Sinopharm) vaccine. CASE SUMMARY: A 29-year-old female was referred to the hospital with acute chest pain, dyspnea, and nausea. Her electrocardiogram revealed ST-segment elevation in anterolateral leads with reciprocal changes in inferior leads. She was primarily diagnosed with ST-elevation myocardial infarction following spontaneous coronary artery dissection (SCAD) according to her age and gender. Her coronary angiography was normal. RT-PCR nasopharyngeal swab was positive for SARS-COV-2 infection. According to her history and excluding coronary artery diseases, she was clinically diagnosed with myocarditis and received corticosteroids, IVIG, and colchicine. She was discharged in a favorable condition after 11â€‰days of hospitalization. Cardiac magnetic resonance imaging confirmed the diagnosis of myocarditis according to the updated lake Louise criteria. On her 4-month follow-up, she was asymptomatic, and her echocardiography showed improvement in biventricular function. DISCUSSION: The diagnosis of myocarditis caused by COVID-19 infection may be challenging as the symptoms of myocarditis, and COVID-19 disease may overlap.

It should be considered when patients have acute chest pain, palpitation, elevated cardiac biomarkers, and new abnormalities in ECG or echocardiography. Cardiac MRI is a non-invasive gold standard modality for diagnosing and follow-up of myocarditis and should be used in clinically suspected myocarditis. The long-term course of myocarditis following COVID-19 disease is still unclear, but some evidence suggests it may have a favorable mid-term outcome.

Acute limb ischemia secondary to vaccine-induced thrombotic thrombocytopenia. Vaccine-associated thrombosis has previously been described in patients presenting with cerebral sinus thrombosis, deep venous thrombosis/pulmonary embolism, or mesenteric venous thrombosis. Only recently has arterial thrombosis gained attention. A new entity known as vaccine-induced thrombotic thrombocytopenia (VITT) has been associated with the coronavirus disease of 2019 (COVID-19) vaccines produced by AstraZeneca and Johnson & Johnson. We describe a case series of three patients who presented with acute limb ischemia with vaccine-associated arterial occlusions, one of whom was diagnosed with VITT.

No association of malignant B-cell non-Hodgkin lymphomas with ipsilateral SARS-CoV-2 vaccination. PURPOSE: SARS-CoV-2 vaccines cause acute ipsilateral lymph node swelling in an important proportion of vaccines. Thus far, no malignant lymphadenopathies have been reported in temporal context to vaccination in the ipsilateral draining lymph node areas. EXPERIMENTAL DESIGN: Prompted by two cases with unilateral axillary lymphomas that occurred ipsilaterally to prior SARS-CoV-2 vaccination, we systematically retrieved all B-cell non-Hodgkin lymphomas at two German University Medical Centers diagnosed before and after introduction of SARS-CoV-2 vaccines in Germany. Available lymphoma tissue (n=19) was subjected to next-generation immunosequencing of the IGH locus. Malignant clonotypes were mined in the CoVabDab database and published data sets from 342 uninfected individuals, 55 individuals 28 days after anti-SARS-CoV-2 vaccination and 139 individuals with acute COVID-19 together encompassing over 1 million CDR3 sequences in total. RESULTS: Of 313 newly diagnosed cases in the two centers and observation periods, 27 unilateral manifestations in the defined deltoid draining regions were identified. The majority thereof were diffuse large B-cell lymphomas (18 of 27 cases). Eleven unilateral cases were diagnosed in the era of SARS-CoV-2 vaccination and 16 in the control period before introduction of such vaccines. Of the 11 unilateral lymphomas that occurred during the vaccination period, ten had received a SARS-CoV-2 vaccine prior to lymphoma diagnosis. These cases were further evaluated. While left-sided were more frequent than right-sided lymphomas (19 vs 8 cases), no statistically significant association of vaccination site and laterality of the lymphoma manifestation was found. The unilateral lymphomas showed a normal range of B-cell receptors typically found in these lymphoma subtypes with no evidence for anti-SARS-CoV-2 sequences in the malignant clonotype. CONCLUSIONS: Together, we found no evidence that the current SARS-CoV-2 vaccines could serve as a trigger for lymphomagenesis in the draining lymph node areas of the deltoid region used for vaccination.

The impact of COVID-19 on select considerations in patients of reproductive age: Brief talking points for pharmacists. The coronavirus disease 2019 (COVID-19) pandemic has elicited many health concerns, including the impact of the infection and vaccine on reproductive health. Although robust evidence demonstrates the safety of all available COVID-19 vaccines, misinformation and disinformation related to the vaccine continue to circulate. As accessible and essential health care workers, it is crucial that pharmacists are informed of the evidence related to effects of the COVID-19 infection and vaccinations on reproductive health care. Menstrual cycle changes have been noted owing to COVID-19 infection, pandemic stress, and COVID-19 vaccination. COVID-19 infection and vaccination have not been shown to influence female fertility, pregnancy rates, and lactation. The use of exogenous estrogen may further contribute to an increased risk of thromboembolism with COVID-19 infection, and differences in the risk of cerebral venous sinus thrombosis appear to exist between

the types of vaccines. The benefits of COVID-19 vaccination outweigh any risks. Shared decision-making is necessary when discussing vaccination with patients. Pharmacists play a vital role in dispelling misinformation and disinformation related to the impact of COVID-19 illness and vaccination on reproductive health care.
Vogt-Koyanagi-Harada disease following ChAdOx1 nCoV-19 and mRNA-1273 vaccination. Almost all vaccines have been reported to be associated with ocular inflammation, which has caused some concern regarding global mass COVID-19 vaccination efforts. Vogt-Koyanagi-Harada disease (VKHD) is a granulomatous inflammation caused by an autoimmune response against antigens in melanocytes, including those in the eyes. The mechanism by which COVID-19 vaccines are associated with VKHD is still unclear. Here, we report two cases of VKHD following COVID-19 vaccination. The first is a case of probable VKHD that presented with bilateral vision loss after administration of the adenovirus-vectored vaccine ChAdOx1 nCoV-19 (AstraZeneca). The condition improved after intravenous methylprednisolone 1g daily for 3days, followed by oral methotrexate and a slow taper of oral corticosteroids. The second case is a patient with an established diagnosis of well-controlled VKHD who developed a reactivation of the disease after receiving the mRNA-based vaccine (mRNA-1273, Moderna). VKHD is a potential ocular event that could follow COVID-19 vaccination. Awareness of this association is key to early detection and treatment to prevent loss of vision.
SARS-CoV-2 infection, vaccination and acquired hemophilia: Correspondence.
[Acquired hemophilia A that developed after BNT162b2 mRNA COVID-19 vaccination and worsened following re-vaccination]. An 86-year-old Japanese male patient visited a nearby hospital with painful swelling in his left upper and lower limbs 35 days after the second dose of the BNT162b2 mRNA coronavirus disease-2019 (COVID-19) vaccine. He was referred to our hematological department due to a prolonged activated partial thromboplastin time and was urgently admitted. He was diagnosed with acquired hemophilia A (AHA) based on factor VIII (FVIII) activity of 1.7%, FVIII inhibitor of 152.3 BU/ml, and FVIII-binding antibodies detected by enzyme-linked immunosorbent assay. Immunosuppressive therapy with prednisolone (PSL) at 0.5 mg/kg/day was started owing to the risk of infection due to old age and poor activities of daily living. Hemostasis treatment with bypass hemostatic preparations (rFVIIa preparation, FVIIa/FX) was administered for each bleeding event, such as intramuscular and knee joint bleeding, resulting in good hemostatic effects. Coagulative complete remission was achieved on day 69 with PSL treatment; however, FVIII activity decreased with PSL tapering. AHA relapse with rectus abdominis muscle hematoma was observed after the third vaccination. This is the first Japanese report of AHA after COVID-19 vaccination and the world's first case, in which the presence of anti-FVIII-binding antibodies were observed.
[Acquired hemophilia A following BNT162b2 mRNA COVID-19 vaccination]. Acquired hemophilia A (AHA) is a rare disease characteized by bleeding symptoms caused by decreased factor VIII activity due to the appearance of inhibitors to factor VIII triggered by malignancy or collagen disease. An 86-year-old woman developed purpura on her extremities after the first dose of the BNT162b2 mRNA COVID-19 vaccine. This symptom subsided after a few days. After the second dose of the BNT162b2 mRNA COVID-19 vaccine, purpura appeared again, and the patient was referred to our hospital Her APTT was remarkably prolonged to 110 seconds, and a cross-mixing test revealed an inhibitor pattern. Since FVIII activity was <1% and FVIII inhibitor was 51.6 BU, she was diagnosed with AHA. Prednisolone therapy was started, and coagulative complete remission was achieved. Because acquired hemophilia can develop after mRNA COVID-19 vaccination, as in this case, it is critical to monitor the appearance of bleeding symptom.
Durability of neutralization against Omicron subvariants after vaccination and breakthrough infection. Booster immunizations and breakthrough infections can elicit severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron subvariant neutralizing activity. However, the durability of the

neutralization response is unknown. We characterize the sensitivity of BA.1, BA.2, BA.2.75, BA.4/BA.5, BF.7, BQ.1.1, and XBB against neutralizing antibodies from vaccination, hybrid immunity, and breakthrough infections 4-6Â months after vaccination and infection. We show that a two-dose CoronaVac or a third-dose ZF2001 booster elicits limited neutralization against Omicron subvariants 6Â months after vaccination. Hybrid immunity as well as Delta, BA.1, and BA.2 breakthrough infections induce long-term persistence of the antibody response, and over 70% of sera neutralize BA.1, BA.2, BA.4/BA.5, and BF.7. However, BQ.1.1 and XBB, followed by BA.2.75, are more resistant to neutralization, with neutralizing titer reductions of âˆ¼9- to 41-fold, âˆ¼16- to 63-fold, and âˆ¼4- to 25-fold, respectively. These data highlight additional vaccination in CoronaVac- or ZF2001-vaccinated individuals and provide insight into the durability of neutralization against Omicron subvariants.

[Acute lumbar radiculopathy due to varicella-zoster herpes virus infection, following an anti-COVID-19 BioNTech/Pfizer vaccination in an elderly patient].

Assessing the adverse effects of COVID-19 vaccine in different scenarios in Saudi Arabia: A cross-sectional study. OBJECTIVES: To assess the different side effects of COVID-19 vaccines at different scenarios in Saudi Arabia. METHODS: This cross-sectional study sought to investigate the side effects of COVID-19 vaccines through an online survey of 2,718 participants in Saudi Arabia. RESULTS: People can manage their expectations about vaccine side effects and deal with symptoms better by knowing beforehand that they are likely to experience mild side effects for a short period, symptoms that are manifested regardless of age, and infection before or after vaccination. There are certain uncommon side effects that affect more people who got infected, and not before vaccination; there are side effects that disproportionately impact women, and also the side effects that wane after the second dose. CONCLUSION: These findings can assist in evaluating the concerns regarding vaccine acceptance. The public should be made aware that they are likely to experience at least one side effect, with temporary post-injection inflammation, musculoskeletal pain, fever, and headache as the most commonly reported side effects across the board. However, the common symptoms are mild to moderate, and the side effects last for a short period for most people.

Lichen planus, COVID-19 infection and vaccination: correspondence.

Response to Commentary on Lichen planus after COVID-19 infection and vaccination.

Decompressive surgery in cerebral venous sinus thrombosis due to vaccine-induced immune thrombotic thrombocytopenia. BACKGROUND AND PURPOSE: Cerebral venous sinus thrombosis due to vaccine-induced immune thrombotic thrombocytopenia (CVST-VITT) is an adverse drug reaction occurring after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. CVST-VITT patients often present with large intracerebral haemorrhages and a high proportion undergoes decompressive surgery. Clinical characteristics, therapeutic management and outcomes of CVST-VITT patients who underwent decompressive surgery are described and predictors of in-hospital mortality in these patients are explored. METHODS: Data from an ongoing international registry of patients who developed CVST within 28â€‰days of SARS-CoV-2 vaccination, reported between 29 March 2021 and 10 May 2022, were used. Definite, probable and possible VITT cases, as defined by Pavord et al. (N Engl J Med 2021; 385: 1680-1689), were included. RESULTS: Decompressive surgery was performed in 34/128 (27%) patients with CVST-VITT. In-hospital mortality was 22/34 (65%) in the surgical and 27/94 (29%) in the non-surgical group (pâ€‰<â€‰0.001). In all surgical cases, the cause of death was brain herniation. The highest mortality rates were found amongst patients with preoperative coma (17/18, 94% vs. 4/14, 29% in the non-comatose; pâ€‰<â€‰0.001) and bilaterally absent pupillary reflexes (7/7, 100% vs. 6/9, 67% with unilaterally reactive pupil, and 4/11, 36% with bilaterally reactive pupils; pÂ =Â 0.023). Postoperative imaging revealed worsening of index haemorrhagic lesion in 19 (70%) patients and new haemorrhagic lesions

in 16 (59%) patients. At a median follow-up of 6â€‰months, 8/10 of surgical CVST-VITT who survived admission were functionally independent. CONCLUSIONS: Almost two-thirds of surgical CVST-VITT patients died during hospital admission. Preoperative coma and bilateral absence of pupillary responses were associated with higher mortality rates. Survivors often achieved functional independence.

Humoral and T-Cell Mediated Response after the Third Dose of mRNA Vaccines in Patients with Systemic Lupus Erythematosus on Belimumab. OBJECTIVE: To evaluate humoral and T-cell cellular-mediated immune response after three doses of SARS-CoV-2 mRNA vaccines in patients with systemic lupus erythematosus (SLE) under Belimumab. PATIENTS AND METHODS: 12 patients on Belimumab and 13 age-matched healthy volunteers were recruited. Patients were in remission or in low disease activity, and they were taking no corticosteroids or only low doses. None of the patients and controls had detectable anti-SARS-CoV-2 antibodies due to previous exposure to the virus. All the patients received three doses of mRNA anti-SARS-CoV-2 vaccines and the humoral and cellular-mediated response were tested 4 weeks after the second dose (T0), 6 months after the second dose (T1) and 4 weeks after the third dose (T2). Comparison with the control group was performed at time T0 (i.e., 4 weeks after the second dose). Total anti-SARS-CoV-2 RBD antibodies were analyzed using a diagnostic assay, while cellular-mediated response was evaluated using the interferon-gamma release assay (IGRA). RESULTS: A humoral response was documented in all the patients at T0 (median 459; IQR 225.25-758.5), but the antibody titer significantly declined from T0 to T1 (median 44.7; IQR: 30.3-202; $p = 0.0066$). At T2, the antibody titer significantly increased from T1 (median 2500; IQR: 2500-2500), and it was not different from T0 (respectively $p < 0.0001$, $p = 0.66$). Cellular-mediated response significantly declined from T0 to T1 ($p = 0.003$) but not from T0 to T2 ($p = 0.3$). No differences were found between patients and controls at T0 as regards both humoral and cellular responses ($p = 1.0$ and $p = 0.09$ for humoral and cellular responses, respectively). CONCLUSION: The third dose of mRNA COVID-19 vaccine can restore both humoral and cellular immune response in SLE patients on Belimumab.

Detection of SARS-CoV-2-Specific Antibodies in Human Breast Milk and Their Neutralizing Capacity after COVID-19 Vaccination: A Systematic Review. SARS-CoV-2 is the virus that causes the infectious disease known as Corona Virus Disease 2019 (COVID-19). The severe impact of the virus on humans is undeniable, which is why effective vaccines were highly anticipated. As of 12 January 2022, nine vaccines have obtained Emergency Use Listing by the World Health Organization (WHO), and four of these are approved or authorized by the Centers for Disease Control and Prevention (CDC) in the United States. The initial clinical trials studying COVID-19 vaccine efficacy excluded pregnant and lactating individuals, meaning that data on the effects of the vaccine on breast milk were lacking. Until today, none of the authorized vaccines have been approved for use in individuals under six months. During the first months of life, babies do not produce their own antibodies; therefore, antibodies contained in their mothers' breastmilk are a critical protective mechanism. Several studies have shown the presence of SARS-CoV-2 antibodies in the breast milk of women who have been vaccinated or had been naturally infected. However, whether these are protective is still unclear. Additionally, research on the BNT162b2 mRNA vaccine developed by Pfizer-BioNTech and the mRNA-1273 vaccine developed by Moderna suggests that these vaccines do not release significant amounts, if any, of mRNA into breast milk. Hence, there is no evidence that vaccination of the mother poses any risk to the breastfed infant, while the antibodies present in breast milk may offer protection against the virus. The primary objective of this systematic review is to summarize the current understanding of the presence of immunoglobulins in human milk that are elicited by SARS-CoV-2 vaccines and to evaluate their ability to neutralize the virus. Additionally, we aim to quantify the side effects experienced by lactating mothers who have been vaccinated, as well as the potential for

adverse effects in their infants. This study is critical because it can help inform decision-making by examining the current understanding of antibody secretion in breastmilk. This is particularly important because, although the virus tends to be less severe in younger individuals, infants who contract the disease are at a higher risk of requiring hospitalization compared to older children.

Factors Associated with Telehealth Utilization among Older African Americans in South Los Angeles during the COVID-19 Pandemic. BACKGROUND: The COVID-19 pandemic transformed healthcare delivery with the expansive use of telemedicine. However, health disparities may result from lower adoption of telehealth among African Americans. This study examined how under-resourced, older African Americans with chronic illnesses use telehealth, including related sociodemographic and COVID-19 factors. METHODS: Using a cross-sectional design, 150 middle-aged and older African Americans were recruited from faith-based centers from March 2021 to August 2022. Data collected included sociodemographics, comorbidities, technological device ownership, internet usage, and attitudes toward COVID-19 disease and vaccination. Descriptive statistics and multivariable regression models were conducted to identify factors associated with telehealth use. RESULTS: Of the 150 participants, 32% had not used telehealth since the COVID-19 pandemic, with 75% reporting no home internet access and 38% having no cellular/internet network on their mobile device. Age, access to a cellular network on a mobile device, and wireless internet at home were significantly associated with the utilization of telehealth care. Higher anxiety and stress with an increased perceived threat of COVID-19 and positive attitudes toward COVID-19 vaccination were associated with telehealth utilization. DISCUSSION: Access and integration of telehealth services were highlighted as challenges for this population of African Americans. To reduce disparities, expansion of subsidized wireless internet access in marginalized communities is necessitated. Education outreach and training by healthcare systems and community health workers to improve uptake of telehealth currently and post-COVID-19 should be considered.

A Literature Review on SARS-CoV-2 and Other Viruses in Thyroid Disorders: Environmental Triggers or No-Guilty Bystanders? A growing number of findings indicate a relationship between COVID-19 infection and thyroid dysfunction. This association is also strengthened by knowledge on the potential of viral infections to trigger thyroid disorders, although the exact underlying pathogenetic process remains to be elucidated. This review aimed to describe the available data regarding the possible role of infectious agents, and in particular of SARS-CoV-2, in the development of thyroid disorders, summarizing the proposed mechanisms and levels of evidence (epidemiological, serological or direct presence of the viruses in the thyroid gland) by which the infection could be responsible for thyroid abnormalities/diseases. Novel data on the association and mechanisms involved between SARS-CoV-2 vaccines and thyroid diseases are also discussed. While demonstrating a clear causal link is challenging, numerous clues at molecular and cellular levels and the large amount of epidemiological data suggest the existence of this relationship. Further studies should be taken to further investigate the true nature and strength of this association, to help in planning future preventive and therapeutic strategies for more personal and targeted care with attention to the underlying causes of thyroid dysfunction.

Association between Risk Communication Format and Perceived Risk of Adverse Events after COVID-19 Vaccination among US Adults. The format used to communicate probability-verbal versus numerical descriptors-can impact risk perceptions and behaviors. This issue is salient for the Coronavirus disease 2019 (COVID-19), where concerns about vaccine-related risks may reduce uptake and verbal descriptors have been widely used by public health, news organizations and on social media, to convey risk. Because the effect of risk-communication format on perceived COVID-19 vaccine-related risks remains unknown, we conducted an online randomized survey among 939 US adults. Participants were given risk information, using verbal or numerical descriptors and were asked

to report their perceived risk of experiencing headache, fever, fatigue or myocarditis from COVID-19 vaccine. Associations between risk communication format and perceived risk were assessed using multivariable regression. Compared to numerical estimates, verbal descriptors were associated with higher perceived risk of headache (Î² = 5.0 percentage points, 95% CI = 2.0-8.1), fever (Î² = 27 percentage points, 95% CI = 23-30), fatigue (Î² = 4.9 percentage points, 95% = CI 1.8-8.0) and myocarditis (Î² = 4.6 percentage points, 95% CI = 2.1-7.2), as well as greater variability in risk perceptions. Social media influence was associated with differences in risk perceptions for myocarditis, but not side effects. Verbal descriptors may lead to greater, more inaccurate and variable vaccine-related risk perceptions compared to numerical descriptors.
Vaccination Coverage and Associated Factors of COVID-19 Uptake in Adult Primary Health Care Users in Greece. In our study, attitudes and perceptions of adult primary health care users regarding COVID-19 vaccination were evaluated. A single-center, cross-sectional study was conducted during a 1-year period (March 2021-March 2022) in a rural area in Crete, Greece. A sample of 626 self-reported questionnaires was collected at the end of the study period. Overall, 78% of respondents stated that they had received the COVID-19 vaccine. The reasons behind vaccine uptake were mainly personal beliefs and the desire to avoid professional constraints. The presence of diabetes type 2, fear of infection, and high perceived efficacy of vaccine previous flu vaccination, living with vulnerable persons, and the influence of scientific information were all significant predictors of COVID-19 vaccine uptake. On the contrary, unwillingness and/or uncertainty to be vaccinated was associated with fear of vaccine side effects, information insufficiency, media/internet information, older age, the presence of inflammatory arthritis, previous COVID-19 infection, the belief that infection confers much greater immunity than the vaccine, and attitudes against vaccinations in general were predictors against COVID-19 vaccination. In conclusion, taking into account all of the above predictors and particularly those regarding safety and vaccine effectiveness may guide future strategies appropriately tailored to specific characteristics and needs of different geographic populations.
Cytokine levels in maternal and infant blood after COVID-19 vaccination during pregnancy in comparison with unvaccinated controls. The objective of this study was to compare maternal and infant cytokine profiles at delivery among those vaccinated against SARS-CoV-2 during pregnancy to unvaccinated controls. Mother-infant dyads were enrolled in this prospective cohort study, and maternal blood and infant and/or cord blood collected. Samples were analyzed utilizing a LEGENDplex 13-plex human anti-viral response cytokine panel. Maternal IP-10 and IFN-Î»2/3 were lower in the vaccinated cohort. In the infants, levels were lower for IL-1Î², IFN-Î»2/3, and GM-CSF, and higher for IFN-Î»1 in the vaccinated cohort. Vaccination against SARS-CoV-2 during pregnancy did not lead to elevations in cytokines in mothers or infants.
Responses to AstraZeneca COVID-19 vaccines in patients with immune-mediated skin diseases.
Is vaccination against COVID-19 associated with psoriasis or eczema flare? Self-controlled case series analysis using data from the Clinical Practice Research Datalink (Aurum).
Letter to the Editor on "New-Onset Myasthenia Gravis Confirmed by Electrodiagnostic Studies After a Third Dose of SARS-CoV-2 mRNA-1273 Vaccine".
Various aspects of the relationship between vitiligo and the COVID-19 pandemic or SARS-CoV-2 vaccines: Clinical pearls for dermatologists. BACKGROUND: Coronavirus disease 2019 (COVID-19) has given rise to several new onset or exacerbated dermatologic disorders including vitiligo. AIM AND METHOD: Here, we present different aspects of relationship between SARS-CoV-2 infection or its associated vaccines and vitiligo and aim to provide solutions to overcome the potential challenges. RESULTS AND CONCLUSION: In brief, as the benefits overweigh the risks and since vaccine-triggered de novo or flares of vitiligo are uncommon and benign, these patients are recommended to get SARS-CoV-2 vaccines. Moreover, in individuals with previously recognized vitiligo, who are at risk of

developing SARS-CoV-2 infection or those who are currently infected, special dermatologic consultation is needed in order to balance the immunosuppressive agents in their therapeutic regimen to prevent COVID-related morbidity and mortality.

T cell immunity ameliorates COVID-19 disease severity and provides post-exposure prophylaxis after peptide-vaccination, in Syrian hamsters. BACKGROUND: The emergence of novel SARS-CoV-2 variants that resist neutralizing antibodies drew the attention to cellular immunity and calls for the development of alternative vaccination strategies to combat the pandemic. Here, we have assessed the kinetics of T cell responses and protective efficacy against severe COVID-19 in pre- and post-exposure settings, elicited by PolyPEPI-SCoV-2, a peptide based T cell vaccine. METHODS: 75 Syrian hamsters were immunized subcutaneously with PolyPEPI-SCoV-2 on D0 and D14. On D42, hamsters were intranasally challenged with 10(2) TCID(50) of the virus. To analyze immunogenicity by IFN-Î³ ELISPOT and antibody secretion, lymphoid tissues were collected both before (D0, D14, D28, D42) and after challenge (D44, D46, D49). To measure vaccine efficacy, lung tissue, throat swabs and nasal turbinate samples were assessed for viral load and histopathological changes. Further, body weight was monitored on D0, D28, D42 and every day after challenge. RESULTS: The vaccine induced robust activation of T cells against all SARS-CoV-2 structural proteins that were rapidly boosted after virus challenge compared to control animals (~4-fold, $p<0.05$). A single dose of PolyPEPI-SCoV-2 administered one day after challenge also resulted in elevated T cell response ($p<0.01$). The vaccination did not induce virus-specific antibodies and viral load reduction. Still, peptide vaccination significantly reduced body weight loss ($p<0.001$), relative lung weight ($p<0.05$) and lung lesions ($p<0.05$), in both settings. CONCLUSION: Our study provides first proof of concept data on the contribution of T cell immunity on disease course and provide rationale for the use of T cell-based peptide vaccines against both novel SARS-CoV-2 variants and supports post-exposure prophylaxis as alternative vaccination strategy against COVID-19.

Safety of SARS-CoV2 vaccination and COVID-19 short-term outcome in pediatric acquired demyelinating disorders of central nervous system: A single center experience. INTRODUCTION: Concern of a correlation between disease relapse in patients with acquired demyelinating disorders of central nervous system (CNS) and SARS-CoV2 vaccines has been raised. In this single center study, we retrospectively evaluated safety of SARS-CoV2 vaccination and COVID-19 short-term outcome in pediatric acquired demyelinating disorders of CNS. MATERIALS AND METHODS: Patients with multiple sclerosis (MS), myelin oligodendrocyte glycoprotein antibody associated disease (MOGAD) and neuromyelitis optica spectrum disorder (NMOSD) with disease onset before 18 years of age were included. Demographic and clinical data, and information regarding previous SARS-CoV-2 infection and vaccination were collected. RESULTS: We included nine patients with MOGAD. Six patients received SARS-CoV2 vaccination and complained pain at injection site while only one had fever and fatigue. Median follow-up was 28 weeks (range 20-48). Seven patients had COVID-19 occurring with mild flu-like symptoms and median follow-up was 28 weeks (range 24-34). Nobody had disease relapse. Five patients with NMOSD were included. All patients received SARS-CoV2 vaccination (BNT162b2-Pfizer-BioNTech). The median follow-up was 20 weeks (range 14-24) and only two patients complained pain at injection site, fever and fatigue. Three patients had also COVID-19 with mild flu-like symptoms, despite two of them being under immunosuppressive treatment. Lastly, forty-three patients with MS were included. 35 out of 43 received SARS-CoV2 vaccination with a median follow-up of 24 weeks (range 8-36). Fourteen patients had no side effects, while 21 complained mild side effects (mainly pain at injection site) and one experienced a disease relapse with complete recovery after steroid therapy. At vaccination, all but one were under treatment. Sixteen patients had COVID-19 occurring with mild symptoms. DISCUSSION: COVID-19 outcome was good although many patients were under immunosuppressive treatment. Vaccine-related side effects were frequent but

were mild and self-limited. Only one MS patient had a post-vaccination relapse with complete recovery after steroid therapy. In conclusion, our data support the safety of SARS-CoV-2 vaccines in pediatric MS, MOGAD and NMOSD.

COVID-19 vaccine acceptance and associated factors in 13 African countries: A systematic review and meta-analysis. BACKGROUND: The COVID-19 pandemic has severely affected the entire world, especially sub-Saharan Africa. As a result, researchers and government agencies are working to create effective COVID-19 vaccinations. While vaccination campaigns are moving rapidly in high-income nations, COVID-19 is still ruthlessly affecting people in low-income nations. However, this difference in the spread of the disease is not because of a lack of a COVID-19 vaccine but mainly due to people's reluctance. As a result, this review summarized the data on COVID-19 vaccination adoption and factors related among nations in sub-Saharan Africa. METHOD: Comprehensive searches were conducted using PubMed, Embase, Medline, Web of Science, Google Scholar, and the Cochrane Library databases. The risk of bias and methodological quality of each published article that fit the selection criteria were evaluated using Critical Appraisal Checklist tools. All statistical analysis was done by STATA 16. RESULTS: This review was based on 29 studies with 26,255 participants from sub-Saharan Africa. Using a random-effects model, the pooled prevalence of COVID-19 vaccine acceptance among study participants was 55.04% (95 % CI: 47.80-62.27 %), I(2) = 99.55%. Being male [POR = 1.88 (95% CI: 1.45, 2.44)], having a positive attitude toward the COVID-19 vaccine [POR = 5.56 (95% CI: 3.63, 8.51)], having good knowledge in the COVID-19 vaccine [POR = 4.61 (95% CI: 1.24, 8.75)], having government trust [POR = 7.10 (95% CI: 2.37, 21.32)], and having undergone COVID-19 testing in the past [POR = 4.41 (95%CI: (2.51, 7.75)] were significant predictor variables. CONCLUSION: This analysis showed that respondents had a decreased pooled prevalence of COVID-19 vaccination acceptance. Sex, attitude, knowledge, government trust, and COVID-19 testing were statistically significantly correlated characteristics that affected the acceptability of the COVID-19 vaccine. All stakeholders should be actively involved in increasing the uptake of the COVID-19 vaccine and thereby reducing the consequences of COVID-19. The acceptance of the COVID-19 vaccination can be increased by using this conclusion as an indicator for governments, healthcare professionals, and health policymakers in their work on attitude, knowledge, government trust, and COVID-19 testing.

Evidences that SARS-CoV-2 Vaccine-Induced apoplexy may not be solely due to ASIA or VITT syndrome', Commentary on Pituitary apoplexy and COVID-19 vaccination: A case report and literature review.

Enhanced cross-recognition of SARS-CoV-2 Omicron variant by peptide vaccine-induced antibodies. Current vaccines against SARS-CoV-2, based on the original Wuhan sequence, induce antibodies with different degrees of cross-recognition of new viral variants of concern. Despite potent responses generated in vaccinated and infected individuals, the Omicron (B.1.1.529) variant causes breakthrough infections, facilitating viral transmission. We previously reported a vaccine based on a cyclic peptide containing the 446-488 S1 sequence (446-488cc) of the SARS-CoV-2 spike (S) protein from Wuhan isolate. To provide the best immunity against Omicron, here we compared Omicron-specific immunity induced by a Wuhan-based 446-488cc peptide, by a Wuhan-based recombinant receptor-binding domain (RBD) vaccine and by a new 446-488cc peptide vaccine based on the Omicron sequence. Antibodies induced by Wuhan peptide 446-488cc in three murine strains not only recognized the Wuhan and Omicron 446-488 peptides similarly, but also Wuhan and Omicron RBD protein variants. By contrast, antibodies induced by the Wuhan recombinant RBD vaccine showed a much poorer cross-reactivity for the Omicron RBD despite similar recognition of Wuhan and Omicron peptide variants. Finally, although the Omicron-based 446-488cc peptide vaccine was poorly immunogenic in mice due to the loss of T cell epitopes, co-immunization with Omicron peptide 446-

488cc and exogenous T cell epitopes induced strong cross-reactive antibodies that neutralized Omicron SARS-CoV-2 virus. Since mutations occurring within this sequence do not alter T cell epitopes in humans, these results indicate the robust immunogenicity of 446-488cc-based peptide vaccines that induce antibodies with a high cross-recognition capacity against Omicron, and suggest that this sequence could be included in future vaccines targeting the Omicron variant.

Comment on evaluation of patients with antiphospholipid syndrome subsequently COVID-19 vaccinations: AÂ retrospective cohort study.

Changes in Older Adults' Frequency of Going Outside between 2020 and 2021: Associations with Health Status and Environmental Factors. OBJECTIVES: To examine the changes in the frequency of going outside among U.S. older adults between 2020 and 2021 (post-COVID vaccine) and correlates of those changes. METHODS: We used the 2019-2021 National Health and Aging Trend Study (NHATS) (NÂ =Â 3,063, age 70+) and multinomial logistic regression to analyze associations of increased and decreased frequencies in going outside with physical, psychosocial, and cognitive health, environmental (COVID concerns and transportation) factors, and social media use as the independent variables. RESULTS: In 2021 compared to 2020, 13% and 16% of those age 70+Â reported increased and decreased frequencies, respectively. Increased frequency was associated with social media use. Decreased frequency was associated with poor physical health, depression/anxiety, and perceived memory decline. COVID concerns and transportation problems, as well as female gender, age 90+, and being non-Hispanic Black, were also significant correlates of decreased frequency. CONCLUSIONS: Most U.S. adults age 70+Â appear to have resumed their 2019 level of frequency of going outside in 2021 after the COVID vaccines became available; however, 16% reported decreased frequency of going outside in 2021 compared to 2020. CLINICAL IMPLICATIONS: Older adults with physical, mental, and cognitive health challenges need help to increase their frequency of going outside.

Anti-SARS-CoV-2 spike immunoglobulinÂ G and immunoglobulinÂ M titers decline as interval from the second inactivated vaccine dose to the onset of illness is prolonged in breakthrough infection patients. BACKGROUND: Understanding of the early immune response in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) breakthrough infections is limited. METHODS: Ninety-eight patients with coronavirus disease 2019 (COVID-19) breakthrough infections were divided into two groups, with intervals from receiving the second dose of inactivated vaccine to the onset of illness <60 or â‰¥60â€‰days. RESULTS: The median lymphocyte count and the median anti-SARS-CoV-2 spike immunoglobulin G (IgG) and immunoglobulin M (IgM) titers were higher in the <60-day interval group compared with the corresponding medians in the â‰¥60-day interval group (pâ€‰=â€‰0.005, pâ€‰=â€‰0.001, and pâ€‰=â€‰0.001, respectively). The median interleukin-6 (IL-6) level in the <60-day interval group was significantly lower than the median IL-6 level in the â‰¥60-day interval group (pâ€‰<â€‰0.001). CONCLUSIONS: Our results highlight the different anti-SARS-CoV-2 spike IgG and IgM antibody titers among patients with different intervals from receiving the second dose of inactivated vaccine to the onset of illness.

[COVID-19 and adenovirus vaccines: French experience of enhanced pharmacovigilance]. As part of the COVID-19 vaccination campaign, the National Agency for the Safety of Medicines and Health Products and all 31 regional pharmacovigilance centers were mobilized in an exceptional reinforced vaccine pharmacovigilance surveillance system. Concerning adenovirus vaccines, VaxzÃ©vriaÂ® and JcovdenÂ®, this national system, based on the daily analysis of notified cases of adverse events, has allowed the early identification of safety signals, some of which have been validated, others still under analysis, common to mRNA vaccines or more specific of adenovirus vaccines such as Vaccine Induced Immune Thrombocytopenia. Complementing european and international actions, this follow-up has contributed to a better definition of the safety profile of these vaccines and has led to redefine the vaccine strategy in our country. Although today these two vaccines have no longer place in the

national vaccine strategy, they are still used in other countries, where the experience acquired could be useful and will contribute to fuel the reflection on future therapies involving viral vectors.

Immunogenicity and Safety of Vaccines against Coronavirus Disease in Actively Treated Patients with Solid Tumors: A Prospective Cohort Study. PURPOSE: We aimed to assess the humoral response to and reactogenicity of coronavirus disease 2019 (COVID-19) vaccination according to the vaccine type and to analyze factors associated with immunogenicity in actively treated solid cancer patients (CPs). MATERIALS AND METHODS: Prospective cohorts of CPs, undergoing anticancer treatment, and healthcare workers (HCWs) were established. The participants had no history of previous COVID-19 and received either mRNA-based or adenovirus vector-based (AdV) vaccines as the primary series. Blood samples were collected before the first vaccination and after 2 weeks for each dose vaccination. Spike-specific binding antibodies (bAbs) in all participants and neutralizing antibodies (nAbs) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) wild-type, Delta, and Omicron variants in CPs were analyzed and presented as the geometric mean titer. RESULTS: Age-matched 20 HCWs and 118 CPs were included in the analysis. The bAb seroconversion rate and antibody concentrations after the first vaccination were significantly lower in CPs than in HCWs. After the third vaccination, antibody levels in CPs with a primary series of AdV were comparable to those in HCWs, but nAb titers against the Omicron variant did not quantitatively increase in CPs with AdV vaccine as the primary series. The incidence and severity of adverse reactions post-vaccination were similar between CPs and HCWs. CONCLUSION: CPs displayed delayed humoral immune response after SARS-CoV-2 vaccination. The booster dose elicited comparable bAb concentrations between CPs and HCWs, regardless of the primary vaccine type. Neutralization against the Omicron variant was not robustly elicited following the booster dose in some CPs, implying the need for additional interventions to protect them from COVID-19.

BCG vaccination induces enhanced humoral responses in elderly individuals. BACKGROUND: Studies have reported the beneficial effects of Bacillus Calmette Guerin (BCG) vaccination, including non-specific cross-protection against other infectious diseases. METHODS: We investigated the impact of BCG vaccination on the frequencies of B cell subsets as well as total antibody levels in healthy elderly individuals at one month post vaccination. We also compared the above-mentioned parameters in post-vaccinated individuals to unvaccinated controls. RESULTS: Our results demonstrate that BCG vaccination induced enhanced frequencies of immature, classical and activated memory B cells and plasma cells and diminished frequencies of naÃ¯ve and atypical memory B cells. BCG vaccination induced significantly increased levels of total IgG subclass isotypes compared to baseline. Similarly, all of the above parameters were significantly higher in vaccinated individuals compared to unvaccinated controls. CONCLUSION: BCG vaccination was associated with enhanced B cell subsets, suggesting its potential utility by enhancing heterologous immunity.

Global incidence pattern and factors associated with common cutaneous reactions related to COVID-19 vaccination of 2.55 million participants in real-world settings: A systematic review and meta-analysis. BACKGROUND: Understanding the incidence pattern of cutaneous reactions is crucial for promoting COVID-19 vaccination. We aimed to report the global incidence pattern of, and factors associated with common cutaneous reactions related to COVID-19 vaccination in real-world settings. METHODS: We searched five databases (PubMed, Web of Science, Embase, CNKI, and Wanfang) from inception to May 13, 2022, for studies reporting the incidence of common cutaneous reactions related to COVID-19 vaccines in real-world settings. The outcomes were the systematic skin reactions (rash and urticaria) and the local injection site reactions (pain, swelling, redness, and erythema). We conducted random-effects meta-analyses and explored associated factors using multi-step statistical analyses. RESULTS: We included 35 studies and assessed 2â€‰549â€‰968 participants from 23 countries. The pooled incidence of overall systemic skin reactions was 3.8% (95% confidence interval

(CI)â€‰=â€‰2.4%-5.5%) with short duration (about one week). Specifically, the pooled incidence rates of rash and urticaria were 3.0% (95% CIâ€‰=â€‰2.1%-3.9%) and 1.1% (95% CIâ€‰=â€‰0.7%-1.5%), respectively. For overall local injection site reactions, the pooled incidence was 72.4% (95% CIâ€‰=â€‰65.7%-78.7%) with short duration (1 to 4.5 days). Except for local pain (72.2%, 95% CIâ€‰=â€‰65.3%-78.5%), other localized reactions had low incidence, including swelling (13.3%, 95% CIâ€‰=â€‰9.5%-17.7%), redness (11.5%, 95% CIâ€‰=â€‰5.7%-19.0%), and erythema (5.8%, 95% CIâ€‰=â€‰0.7%-15.4%). Geographically, different distribution patterns were observed for these reactions. Regarding associated factors, mRNA vaccines showed lower incidence of urticaria (Pâ€‰<â€‰0.001). Asia population showed higher incidence of urticaria (Pâ€‰<â€‰0.001). We observed lower incidence rates of overall local injection site reactions and pain among inactivated vaccines (Pâ€‰<â€‰0.001). We found no significant difference among reactions between the first and the second dose of vaccines. CONCLUSIONS: We examined the global incidence pattern of common cutaneous reactions related to COVID-19 vaccination and found low incidence and short duration of systemic skin reactions and local injection site reactions (except for pain); discrepancies in these reactions were observed across different vaccine types. The cutaneous side effects related to COVID-19 vaccination do not seem to cause concern. REGISTRATION: PROSPERO: CRD42021258012.

Resolution of persistent SARS-CoV-2 infection with prolonged intravenous remdesivir and vaccination in a patient post CAR-T. SARS-CoV-2 virus is a single-stranded enveloped RNA virus, which causes coronavirus disease. Most of the immunocompetent patients with SARS-CoV-2 infection do have mild to moderate respiratory illness; however, in immunocompromised patients, the course of infection is unpredictable with high rates of infectivity and mortality. So, it is important to identify the immunocompromised patients early and establish the course of treatment accordingly. Here, we describe a 25-year-old male with background of B cell ALL, post-BMT and CAR-T therapy who received treatment with remdesivir and vaccination and was followed up for six months from the onset of symptoms to post vaccination, which showed resolution of symptoms and improvement of immunological markers. Here, we review the literature concerning the course and treatment of SARS-CoV-2 infection aimed at achieving cure in this patient.

Gadolinium changes detected on cardiovascular magnetic resonance imaging following COVID-19 vaccine-related myocarditis in adolescents.

Effects of SARS-CoV-2 vaccine (Vero cells) on disease activity in patients with inflammatory bowel disease in China: a multicenter study. AIMS: To evaluate the impact of SARS-CoV-2 vaccine on IBD activity. METHODS: Adult IBD patients from five large IBD centers in China were enrolled and followed up for 6Â months. Patients were divided into vaccinated and unvaccinated groups according to vaccination status. Demographic and clinical data were collected. RESULTS: A total of 280 individuals (213 UC and 67 CD patients) were enrolled in the study. The unvaccinated and vaccinated groups of UC patients were comparable for basic characteristics, including age (tâ€‰=â€‰-â€‰0.8, pâ€‰=â€‰0.425), sex (Ï‡(2)â€‰=â€‰0.980, pâ€‰=â€‰0.322), course of disease (zâ€‰=â€‰-â€‰0.513, pâ€‰=â€‰0.608), surgical conditions (Ï‡(2)â€‰=â€‰1.042, pâ€‰=â€‰0.838), disease extent (Ï‡(2)â€‰=â€‰4.853, pâ€‰=â€‰0.088), or baseline drug therapy (Ï‡(2)â€‰=â€‰7.784, pâ€‰=â€‰0.064). In the subgroup of UC patients, there was no association between vaccination and disease activities, according to the medium disease activity scores for two groups: unvaccinated patients having scores (IQR) 1(2.75), 1(2), 1(2), and 1(2) at baseline, 1, 3, and 6Â months, respectively, whereas vaccinated patients having scores (IQR) 1(2), 1(2), 1(2), and 1(2). Similar conclusions were also derived in the subgroup of CD patients. There were also no statistically significant differences in age (tâ€‰=â€‰-â€‰1.48, pâ€‰=â€‰0.144), sex (Ï‡(2)â€‰=â€‰0.003, pâ€‰=â€‰0.957), course of disease (zâ€‰=â€‰-â€‰0.074, pâ€‰=â€‰0.941), surgical conditions (Ï‡(2)â€‰=â€‰0.613, pâ€‰=â€‰0.594), localization (Ï‡(2)â€‰=â€‰6.261, pâ€‰=â€‰0.199), or baseline drug therapy

(Ï‡(2)â€‰=â€‰5.881, pâ€‰=â€‰0.114) between 2 groups of CD patients. The medium disease activity scores (IQR) of the unvaccinated group at baseline, 1, 3, and 6Â months were 1(4), 1(3), 1(3), and 1(3), respectively, whereas those of vaccinated group were 2.5(3.75), 2.5(3.75), 3(2), and 2(2), respectively. Overall, very few participants in this study described worsening IBD disease activity requiring a change or addition of medication. CONCLUSIONS: SARS-CoV-2 vaccine has no adverse effect on disease activity in IBD population. IBD patients should be recommended to receive SARS-CoV-2 vaccine in time.

CARD (Comfort Ask Relax Distract) for community pharmacy vaccinations in children: Effect on immunization stress-related responses and satisfaction. INTRODUCTION: CARD (Comfort Ask Relax Distract) is a vaccine delivery program demonstrated to reduce pain, fear and associated immunization stress-related responses (ISRR) in children undergoing vaccinations at school. This study evaluated CARD's clinical impact when integrated into community pharmacy-based pediatric vaccinations. METHODS: This was a before-and-after CARD implementation study in 5 independent pharmacies offering COVID-19 vaccinations to children aged 5-11 years. No changes were made to practices in the "before" phase. CARD interventions were integrated in the "after" phase (e.g., children prepared a coping plan using a checklist, distraction toolkits were placed in waiting and vaccination spaces, vaccinations were performed with privacy, needles were obscured). Children self-reported ISRR, including fear, pain and dizziness during vaccination, and both children and parents/caregivers (herein, parents) compared the child's experience to their last needle (better, same, worse). In the "after" phase, parents and children reported how much CARD helped (not at all, a little bit, a moderate amount, a lot). RESULTS: The study was conducted between January 16 and March 20, 2022. Altogether, 152 children participated (71 before and 81 after CARD); demographic characteristics did not differ. Children's self-reported fear was lower after CARD, when assessed continuously (2.5 vs 3.7 out of 10; p = 0.02) or dichotomously, using a cut-off of 0 vs >0 (58% vs 80%; p = 0.01). Pain was lower when assessed dichotomously (<2 vs â‰¥2; p = 0.03). There was no difference in dizziness. After CARD, children and parents reported more positive experiences compared to the child's last needle (p = 0.01, both analyses) and more children and parents reported that distraction and child participation in the process were helpful (p < 0.001, both analyses). Overall, 92% of children and 91% of parents said CARD helped. CONCLUSION: CARD reduced children's fear and improved vaccination experiences for children and parents when integrated in community pharmacy-based vaccinations.

Persistent T cell-mediated immune responses against Omicron variants after the third COVID-19 mRNA vaccine dose. INTRODUCTION: The prime-boost COVID-19 mRNA vaccination strategy has proven to be effective against severe COVID-19 disease and death. However, concerns have been raised due to decreasing neutralizing antibody levels after COVID-19 vaccination and due to the emergence of new immuno-evasive SARS-CoV-2 variants that may require additional booster vaccinations. METHODS: In this study, we analyzed the humoral and cell-mediated immune responses against the Omicron BA.1 and BA.2 subvariants in Finnish healthcare workers (HCWs) vaccinated with three doses of COVID-19 mRNA vaccines. We used enzyme immunoassay and microneutralization test to analyze the levels of SARS-CoV-2 specific IgG antibodies in the sera of the vaccinees and the in vitro neutralization capacity of the sera. Activation induced marker assay together with flow cytometry and extracellular cytokine analysis was used to determine responses in SARS-CoV-2 spike protein stimulated PBMCs. RESULTS: Here we show that within the HCWs, the third mRNA vaccine dose recalls both humoral and T cell-mediated immune responses and induces high levels of neutralizing antibodies against Omicron BA.1 and BA.2 variants. Three weeks after the third vaccine dose, SARS-CoV-2 wild type spike protein-specific CD4(+) and CD8(+) T cells are observed in 82% and 71% of HCWs, respectively, and the T cells cross-recognize both Omicron BA.1 and BA.2 spike

peptides. Although the levels of neutralizing antibodies against Omicron BA.1 and BA.2 decline 2.5 to 3.8-fold three months after the third dose, memory CD4(+) T cell responses are maintained for at least eight months post the second dose and three months post the third vaccine dose. DISCUSSION: We show that after the administration of the third mRNA vaccine dose the levels of both humoral and cell-mediated immune responses are effectively activated, and the levels of the spike-specific antibodies are further elevated compared to the levels after the second vaccine dose. Even though at three months after the third vaccine dose antibody levels in sera decrease at a similar rate as after the second vaccine dose, the levels of spike-specific CD4(+) and CD8(+) T cells remain relatively stable. Additionally, the T cells retain efficiency in cross-recognizing spike protein peptide pools derived from Omicron BA.1 and BA.2 subvariants. Altogether our results suggest durable cellmediated immunity and protection against SARS-CoV-2.

Pharmacovigilance follow-up of patients in the context of the COVID-19 pandemic. INTRODUCTION: In the context of COVID-19 pandemic, a national pharmacovigilance survey was set up in March 2020. The purpose of this survey was to ensure continuous monitoring of adverse drug reactions (ADRs) in patients with COVID-19, not only related to the drugs used in this indication but also related to all drugs administered to these patients or suspected of having promoted the infection. MATERIAL AND METHODS: This descriptive study was based on data extracted from the French Pharmacovigilance Database from 1 January 2020 to 30 September 2021. Misuse was also analysed through the MESANGE project. The ADRs were classified according to three groups: "drugs used to treat COVID-19", "other drugs administered to COVID-19 positive patients" and "drugs suspected of having promoted COVID-19". The data were also presented according to 2 periods (period one was from January to June 2020 and period two from July 2020 onwards). RESULTS: Among 2189 included cases, 67.1% were serious. Cases were mainly related to "other drugs administrated to COVID-19 positive patients" (58.5%) followed by "drugs used to treat COVID-19" (33.7%) and "drugs suspected of having promoted COVID-19" (7.8%). Drugs used to treat COVID-19 and their main safety profile were different depending on the period: mostly hydroxychloroquine (51%) with heart injury and lopinavir/ritonavir (42%) with liver injury for the first period, and dexamethasone (46%) with hyperglycemia and tocilizumab (28%) with liver injury for the second period. The drugs suspected of worsening COVID-19 differed in both periods especially for non-steroidal anti-inflammatory drugs mainly reported in period 1 (41.5% versus 8.2% in period 2). Other immunosuppressive drugs were in the majority in the second period (85.7%), with mainly methotrexate (15.3%), anti-CD20 (15.3%) and anti-TNF alpha (10.5%). No confirmed safety signal was identified among other drugs administered to patients with COVID-19. The profile of ADRs and suspected drugs was similar between the 2 periods. The study of misuse in outpatient settings identified in both periods mainly hydroxychloroquine, azithromycin, ivermectin and zincÂ±vitamin C. DISCUSSION: This survey, based on real-time pharmacological and medical assessment of ADRs and weekly meetings in a specific national committee, made it possible to identify relevant safety signals which contribute to patient care with no delay. The main safety signal highlighted was serious cardiac damage under hydroxychloroquine, alone or combined with azithromycin and also with lopinavir/ritonavir. This signal has contributed to the evolution of the recommendations for these 2 drugs. The methodology of this survey has been taken over and is still going on for the pharmacovigilance monitoring of vaccines against COVID-19, for monoclonal antibodies used against COVID-19 and also for PaxlovidÂ® (nirmatrelvir/ritonavir) which benefit from dedicated surveys.

Immune-mediated necrotizing myopathy following vaccination with the AstraZeneca (AZD1222) COVID-19 vaccine: A case report and brief review. Immune-Mediated Necrotizing Myopathy (IMNM) after vaccination has been reported previously, however it is rare after COVID-19 vaccination. We report the first case of IMNM two weeks after vaccination with the AstraZeneca

(AZD1222) COVID-19 vaccine. There was a probable temporal relationship between the COVID-19 vaccination and the development of IMNM due to lack of known causative factors for IMNM. This may have been due to 1) autoimmunity directly caused by the vaccine, 2) exacerbation of autoimmunity triggered by the vaccine or 3) autoimmune syndrome triggered by the vaccine adjutants. Further studies are needed to assess the underlying mechanisms.

Syncope after COVID-19 Vaccination in a Young Man with Unmasking Brugada Syndrome. A 23-year-old man with no significant medical history was rushed to a hospital due to transient loss of consciousness with incontinence. The patient had developed a fever after his second dose of coronavirus disease 2019 (COVID-19) vaccine, and the patient was found groaning in bed approximately 40 hours after the vaccination in the early morning. The patient was diagnosed with Brugada syndrome (BrS) based on a drug-provocation test. His father had been diagnosed with BrS and died suddenly at 51 years of age. Young adults with a family history of BrS should be cautioned about fever following COVID-19 vaccination.

Comparable efficacy and safety of COVID-19 vaccines for patients receiving tegafur-uracil as postoperative adjuvant chemotherapy. PURPOSE: Many effective vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been developed, but a weaker response in individuals undergoing anticancer treatment has been reported. This study evaluates the immunogenic status and safety of SARS-CoV-2 vaccines for patients with non-small-cell lung cancer (NSCLC), receiving tegafur-uracil (UFT) as postoperative adjuvant chemotherapy. METHODS: The subjects of this prospective study were 40 patients who underwent surgery for NSCLC and received SARS-CoV-2 vaccines postoperatively. We compared the antibody titers of SARS-CoV-2 vaccines and the adverse events between patients who received adjuvant UFT and patients who did not. RESULTS: The mean anti-S1 IgG titers were not significantly different between the UFT and without-UFT groups (mean optimal density, 0.194 vs. 0.205; Pâ€‰=â€‰0.76). Multivariate analysis identified the period after the second vaccination as an independent predictor of anti-S1 IgG titer (Pâ€‰=â€‰0.049), but not the UFT status (with or without-UFT treatment; Pâ€‰=â€‰0.47). The prevalence of adverse events did not differ significantly between the groups, and no severe adverse events occurred. CONCLUSIONS: The efficacy and safety of the SARS-CoV-2 vaccines for NSCLC patients who received postoperative adjuvant UFT chemotherapy were comparable to those for NSCLC patients who did not receive postoperative adjuvant UFT chemotherapy. CLINICAL TRIAL REGISTRATION: This study was registered with the University Hospital Medical Information Network (UMIN) in Japan (UMIN000047380).

COVID-19 Vaccination and the Incidence of De Novo or Recurrent Rheumatoid Arthritis: A French and International (VigiBase) Signal Detection Study. COVID-19 vaccination is critical in frequently immunocompromised patients with rheumatoid arthritis (RA). However, there is a question about the risk of RA flares following vaccination. Our study intended to find out about cases of new RA or flare-ups in people who already had RA that were reported in French and international pharmacovigilance databases after COVID-19 vaccination. We performed a "case-noncase" method in the international pharmacovigilance database VigiBase to identify the risk of RA following COVID-19 vaccination compared with other nonlive vaccines. Using the French Pharmacovigilance Database (FPVD), a descriptive analysis was carried out for RA cases after COVID-19 immunization and a multivariate logistic regression analysis was conducted to compare variables in the new-onset vs. flare-up groups. In 2021, 2,387 cases of RA were reported from 2,817,902 adverse drug reactions associated with COVID-19 vaccines recorded in VigiBase. The reporting odds ratio of RA onset with COVID-19 vaccines compared with the other nonlive vaccines was 0.66 (Pâ€‰<â€‰0.0001). The FPVD reported 161 cases of RA with COVID-19 vaccines, including 77 new-onset RA and 84 cases of RA flare-up. In 88 cases (84.7%), RA occurred after the first dose. The mean time between vaccination and disease

onset was 14â€‰Â±â€‰21â€‰days, and the delay was significantly shorter in the flare-up group. We do not show a higher risk of RA after COVID-19 vaccination compared with other nonlive vaccines in adults. De novo RA was more likely to happen quickly, be more severe, and have a worse outcome than flares in patients with RA.

Coronavirus disease 2019 and severe asthma. PURPOSE OF REVIEW: The relationship between severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and the most severe forms of asthma has been an object of discussion. Indeed, it is not clear whether asthma is among the risk factors for the occurrence of severe coronavirus disease 2019 (COVID-19) disease, or rather it plays a protective role against the worsening of the respiratory involvement in the SARS-CoV-2 infection. On the other hand, the extent to which coronavirus infection may trigger asthma attacks is still partly unknown. The current investigation aims at reviewing the available literature on the topic to address factors influencing this relationship. RECENT FINDINGS: Based on recent observations, it is likely that type 2 inflammation plays a protective role against SARS-CoV-2 infection and disease. In particular, asthmatics show different expression of angiotensin-converting enzyme2 (ACE2) and Transmembrane protease, serine 2 (TMPRSS2) that are responsible for a reduced risk of infection as well as lower risk of hospitalization. Interestingly, studies showed a safe profile of inhaled corticosteroids and biological drugs in SARS-CoV-2 infection. In addition, inhaled corticosteroid could play a protective role against worsening of asthma. SUMMARY: The current findings suggest that current treatment for asthma should be maintained to avoid severe exacerbations. Severe asthmatics under biological treatment should continue their medications, and be encouraged to receive COVID-19 vaccines.

Malignant middle cerebral artery syndrome with thrombotic thrombocytopenia following vaccination against SARS-CoV-2. Cases of thromboses at unusual sites with thrombocytopenia have been reported following vaccination against Sars-CoV-2. This new syndrome, christened vaccine-induced thrombotic thrombocytopenia (VITT), mainly results in venous thromboses. We report the case of a young woman with a right middle cerebral artery stroke following vaccination with ChAdOx1 nCoV-19. A diagnosis of VITT was made and platelet counts began to recover shortly after commencing treatment with argatroban, intravenous immunoglobulins and corticosteroids. On day 6 following admission, the patient deteriorated neurologically and decision made to proceed with decompressive hemicraniectomy. There were no perioperative complications and anticoagulation with argatroban was reinitiated on the first postoperative day. VITT is a rare condition resembling auto-immune heparin-induced thrombocytopenia. All critical care staff should be aware of the rare link between vaccination against SARS-CoV-2 and VITT and the need to rapidly commence both anticoagulation, using heparin alternatives, and immunomodulation.

Impaired antibody responses were observed in patients with type 2 diabetes mellitus after receiving the inactivated COVID-19 vaccines. BACKGROUND: Patients with type 2 diabetes mellitus (T2DM) have been reported to be more susceptible to 2019 novel coronavirus (2019-nCoV) and more likely to develop severe pneumonia. However, the safety and immunological responses of T2DM patients after receiving the inactivated vaccines are not quite definite. Therefore, we aimed to explore the safety, antibody responses, and B-cell immunity of T2DM patients who were vaccinated with inactivated coronavirus disease 2019 (COVID-19) vaccines. METHODS: Eighty-nine patients with T2DM and 100 healthy controls (HCs) were enrolled, all of whom had received two doses of full-course inactivated vaccines. At 21-105Â days after full-course vaccines: first, the safety of the vaccines was assessed by questionnaires; second, the titers of anti-receptor binding domain IgG (anti-RBD-IgG) and neutralizing antibodies (NAbs) were measured; third, we detected the frequency of RBD-specific memory B cells (RBD-specific MBCs) to explore the cellular immunity of T2DM patients. RESULTS: The overall incidence of adverse events was similar between T2DM patients and HCs, and no serious adverse events were recorded in either group. Compared with HCs, significantly lower

titers of anti-RBD-IgG (pâ€‰=â€‰0.004) and NAbs (pâ€‰=â€‰0.013) were observed in T2DM patients. Moreover, the frequency of RBD-specific MBCs was lower in T2DM patients than in HCs (pâ€‰=â€‰0.027). Among the 89 T2DM patients, individuals with lower body mass index (BMI) had higher antibody titers (anti-RBD-IgG: pâ€‰=â€‰0.009; NAbs: pâ€‰=â€‰0.084). Furthermore, we found that sex, BMI, and days after vaccination were correlated with antibody titers. CONCLUSIONS: Inactivated COVID-19 vaccines were safe in patients with T2DM, but the antibody responses and memory B-cell responses were significantly decreased compared to HCs. TRIAL REGISTRATION NUMBER AND DATE: NCT05043246. September 14, 2021. (Clinical Trials.gov).

Effect of COVID-19 (SARS-CoV-2) Vaccination on Patients with Atopic Dermatitis Treated with Dupilumab: A Multicenter, Observational Study. BACKGROUND: Atopic dermatitis (AD) patients usually wonder if their condition will worsen after vaccination or if they should continue with the treatment they are receiving. Considering that many patients treated with dupilumab had previously experienced severe AD symptoms and flares, the concerns are more understandable. OBJECTIVE: This study aimed to investigate the safety of the coronavirus disease 2019 (COVID-19) vaccination in patients with AD treated with dupilumab. METHODS: We enrolled 133 patients (101 dupilumab-treated and 32 systemic oral agents-treated as control group) with AD from six hospitals. Patients were asked about worsening pruritus and AD (5-point Likert scale) after vaccination. AD variables (eczema area and severity index [EASI], investigator's global assessment [IGA], itch numerical rating scale [NRS], sleep NRS, and patient-oriented eczema measure [POEM]) were compared pre- and post-vaccination. Adverse reactions to the COVID-19 vaccination were observed. RESULTS: The incidence of adverse reactions to COVID-19 vaccines and worsening AD symptoms in dupilumab-treated patients were not significantly different compared with that in the control group. The itch NRS score increased significantly after vaccination ($p<0.001$). However, there were no statistically significant differences between the pre-and post-EASI, IGA, and POEM scores. Eight patients (7.9%) had worse EASI scores and required rescue therapy; however, most were easily managed with low-dose steroids or topical agents. None of the patients discontinued dupilumab treatment. CONCLUSION: No serious adverse reactions were observed in patients with AD after COVID-19 vaccination. Exacerbation of pruritus and AD symptoms was observed but was mostly mild and transient.

Vaccination, Acute Myocardial Infarction, and Ischemic Stroke After COVID-19 Infection.

Vaccination, Acute Myocardial Infarction, and Ischemic Stroke After COVID-19 Infection-Reply.

Unilateral Grover-like Skin Eruption Following Pfizer COVID-19 Vaccine.

Antibody, cell-mediated response and infection susceptibility in allogeneic hematopoietic stem cell recipients after COVID-19 mRNA vaccination. BACKGROUND: Patients undergoing allogeneic stem-cell transplantation (allo-SCT) have reduced responses to vaccines due to immunosuppressive status linked to GvHD prophylaxis and treatment. In our study, we compared humoral responses to anti-SARS-CoV-2 mRNA vaccine, and infection onset, according to patients and transplant features; we also evaluated cellular response in patients without seroconversion. METHODS: We tested antibodies titer after second and third vaccine doses. Antibodies were detected through an immune-enzymatic assay. In a patients' subgroup without seroconversion, we tested cell-mediated responses evaluating interferon-gamma release by T-lymphocytes exposed to virus spike protein. RESULTS: Seroconversion rate increased from 66% at 30 days to 81% at 90 days after the second dose; it was 97% at 150 days after the third dose. We found a significant association between seroconversion after the second dose and two variables: shorter interval between allo-SCT and vaccination; ongoing immunosuppression. Twelve of 19 patients (63%) without antibodies after the second dose did not show cellular responses. Nineteen percent of patients developed SARS-CoV-2 infection after the third dose, with favorable outcome in all cases. Patients within 12 months after allo-SCT showed a significantly higher infection risk. CONCLUSIONS: Our study suggests that an interval shorter than 12

months between allo-SCT and first vaccine dose and/or ongoing immunosuppression were associated with humoral and cellular response deficiency after two doses. Third dose induced an increased and sustained humoral response in the majority of patients. However, patients within 1 year after allo-SCT remained at higher infection risk and may be candidate for prophylaxis with anti-SARS-CoV-2 monoclonal antibodies.
Vaccine-elicited B and T cell immunity to SARS-CoV-2 is impaired in chronic lung disease patients. The protection afforded by vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to individuals with chronic lung disease is not well established. To understand how chronic lung disease impacts SARS-CoV-2 vaccine-elicited immunity we performed deep immunophenotyping of the humoral and cell mediated SARS-CoV-2 vaccine response in an investigative cohort of vaccinated patients with diverse pulmonary conditions including asthma, chronic obstructive pulmonary disease (COPD), and interstitial lung disease (ILD). Compared to healthy controls, 48% of vaccinated patients with chronic lung diseases had reduced antibody titers to the SARS-CoV-2 vaccine antigen as early as 3-4 months after vaccination, correlating with decreased vaccine-specific memory B cells. Vaccine-specific CD4 and CD8 T cells were also significantly reduced in patients with asthma, COPD, and a subset of ILD patients compared to healthy controls. These findings reveal the complex nature of vaccine-elicited immunity in high-risk patients with chronic lung disease.
Herpes zoster after COVID-19 vaccination, aspect of pain medicine: a retrospective, single-center study. BACKGROUND: Herpes zoster (HZ) is one of the most common cutaneous adverse reactionsassociated with the coronavirus disease 2019 (COVID-19) vaccine and has been widely reported. This study aimed to evaluate HZ following COVID-19 vaccination from the viewpointof pain management. METHODS: A retrospective study was conducted on 42 patients with HZ who visited the painclinic between August 2021 and October 2021. Medical records were reviewed to comparepain severity, treatment methods, treatment duration, and incidence rate of postherpeticneuralgia (PHN) in patients who received COVID-19 vaccination within 6 weeks prior to developing symptoms compared with other patients with HZ. RESULTS: Fourteen patients developed HZ within 6 weeks after vaccination and were significantly younger than the other HZ groups. There were no significant differences in the frequency of prodromal pain, location of pain, pain severity, treatment methods, treatmentduration, or incidence of PHN compared with the other HZ groups. CONCLUSIONS: COVID-19 vaccination-related HZ showed clinical features similar to those ofthe other HZ.
Reactive arthritis after vaccination against SARS-CoV-2: A case series and a mini-review. The rapid development of COVID-19 vaccines became essential for addressing the global pandemic. Reactive arthritis after vaccination has been a rare phenomenon. Here, we present a case series of three patients with joint inflammation possibly attributed to COVID-19 immunization (mRNA and live adenovirus vectored vaccine). Symptoms were alleviated using non-steroid anti-inflammatory drugs and glucocorticoids. After follow-up, the patients have not been diagnosed with any other rheumatic disease. Reactive arthritis after the COVID-19 vaccine is an unusual adverse effect and poses a negligible risk in comparison to the benefits of immunization, but it should be considered in differential diagnostics by a practicing rheumatologist who cares for patients with new-onset arthritis without apparent cause at the time of pandemic.
COVID-19 vaccination in patients with cancer receiving immune checkpoint inhibitors: a systematic review and meta-analysis. BACKGROUND: Immune checkpoint inhibitors (ICI) can cause off-target inflammatory and immune-related adverse events (irAE). Conceivably, COVID-19 vaccination could trigger an inflammatory and immune response that could induce or aggravate irAE. METHODS: The objective of this systematic review is to appraise the efficacy and safety of COVID-19 vaccination in

patients with cancer treated with ICI. The literature search was performed in PubMed and Embase in English from December 2019 to February 2022. The review included clinical trials, observational cohort studies, case series, and case reports reporting on the clinical efficacy and safety of COVID-19 vaccines on patients with cancer treated with ICI. Outcomes of interest included seroconversion, SARS-CoV-2 infection rate, severe COVID-19, COVID-19 mortality rate. Incidence of ICI irAEs was also ascertained as well as vaccine adverse events. A meta-analysis was conducted to estimate the pooled effect sizes of the outcomes when possible, using random effects models. RESULTS: Overall, 19 studies were included for the analysis (n=10â€‰865 with 2477 receiving ICI). We analyzed 15 cohort studies, 1 cross-sectional study, and 3 case reports. There were no statistically significant differences in seroconversion rates after the second dose of the vaccine when comparing patients with cancer receiving ICI with patients without cancer (risk ratio, RR 0.97, 95%â€‰CI 0.92 to 1.03) or with patients with cancer without active treatment (RR 1.00, 95%â€‰CI 0.96 to 1.04). There was a higher probability of seroconversion in patients with cancer treated with ICI compared with patients with cancer treated with chemotherapy (RR 1.09, 95%â€‰CI 1.00 to 1.18). In a single study in patients receiving ICI, no differences were observed in risk of irAE between those receiving inactivated vaccine and those unvaccinated (pneumonitis RR 0.88, 95%â€‰CI 0.33 to 2.3; rash RR 1.03, 95%â€‰CI 0.66 to 1.62; arthralgia RR 0.94, 95%â€‰CI 0.51 to 1.75). There were no studies for other types of vaccines comparing vaccinated vs not vaccinated in patients treated with ICI. The most common vaccine-related adverse events were local pain or fatigue. Overall, the quality of evidence was rated as very low. CONCLUSION: COVID-19 vaccination appears to be effective and safe in patients with cancer receiving ICI.

Evaluation of retinal and optic disc vascular structures in individuals before and after Pfizer-BioNTech vaccination. INTRODUCTION: We conducted this study to detect possible changes in posterior segment structures using the optical coherence tomography angiography (OCTA) in individuals vaccinated with the Pfizer-BioNTech vaccine. MATERIALS AND METHODS: The study included healthcare professionals who presented to the Ophthalmology Clinic of Health Sciences University Antalya Training and Research Hospital, who were scheduled to receive the first dose of the Pfizer-BioNTech vaccine. The exclusion criteria were any eye pathology (e.g., glaucoma, uveitis, diabetic retinopathy, amblyopia), myopia with the absolute value of refractive error >6, axial length >26Â mm, history of eye surgery, and presence of systemic disease.OCTA was performed to 40 healthcare professionals before vaccination and on the third day after vaccination. RESULTS: After Pfizer-BioNTech vaccination, there was a statistically significant decrease in the total vascular, foveal vascular, parafoveal vascular and perifoveal vascular density of the superficial capillary plexus and the perifoveal vascular density of the deep capillary plexus and a statistically significant increase in the retinal foveal thickness and total retinal parafoveal thickness compared to the pre-vaccination values (pÂ <Â 0.0001, pÂ =Â 0.009, pÂ <Â 0.0001, pÂ =Â 0.001, pÂ =Â 0.04, pÂ =Â 0.03, and pÂ =Â 0.05, respectively). CONCLUSION: We consider that the decrease in the retinal vascular density may be due to vascular endothelial damage and inflammation in vaccinated people. It can be suggested that increased inflammation plays a role in the retinal thickness in vaccinated people similar to patients with a history of COVID-19. We also consider that spike protein may be effective in these processes.

Audiological and vestibular symptoms following COVID-19 and COVID-19 vaccination in children: Correspondence.

Association between attitudes toward the COVID-19 vaccines and mental health among 140,259 college students in China. BACKGROUND: With the launch of the COVID-19 vaccines, the vaccination rate has become a hot issue of concern. However, the evidence for the relationship between college students' attitudes toward vaccines and anxiety and depressive symptoms has been limited. METHODS: In total, 140,259 college students were recruited using a cluster sampling method

in Zhengzhou, Xinxiang, Xinyang city of Henan Province, China, May 21-27, 2021. Anxiety symptoms were determined by the Generalized Anxiety Disorder tool (GAD-7) and depressive symptoms were determined by the Patient Health Questionnaire (PHQ-9). Multiple logistic regression was performed to estimate the association between students' attitudes toward the vaccines and anxiety and depressive symptoms. RESULTS: The results indicate that 22.45% of students are unclear whether the vaccine can protect them from infection and 45.57% are unclear whether the vaccine is safe and has no side effects. In addition, after adjusting, the model showed that students who think vaccines can protect them and are safe had 0.128 (95%CI 0.110-0.150; P(trend) < 0.001) times lower risk of anxiety compared to their counterparts who think vaccines can neither protect them nor are safe. Similar ORs were found in depression (aOR = 0.157; 95%CI 0.137-0.180). CONCLUSION: This large-scale study has shown an association between symptoms of anxiety and depression and reluctance to obtain vaccination. SUPPLEMENTARY INFORMATION: The online version contains supplementary material available at 10.1007/s10389-023-01830-7.

Rehabilitation outcomes in patients with post-COVID-19 vaccine-associated Guillain-Barre syndrome. OBJECTIVE: With COVID-19 vaccination campaign worldwide, associated Guillain-Barre syndrome (GBS) is being increasingly reported from different countries. The objectives of the study were to observe the clinical profile and rehabilitation outcomes in patients with post-COVID-19 vaccine-associated GBS. MATERIAL AND METHOD: This prospective study was conducted in neurological rehabilitation unit with in-patients. A detailed customized rehabilitation program was formulated based on the clinical status and associated complications. Outcome measures were documented on the day of admission and at discharge and compared. RESULTS: The study included 16 patients (eight males) of which 15 (93.75%) received the CoviShield (AstraZeneca) and 1 Covaxin (Bharat Biotech) vaccine. The median (IQR) duration of first symptom was 9 (18.25) days and for motor symptoms 18 (12.75) days. Functional improvement was observed in patients using Barthel index scores and Hughes disability scores and overall neuropathy limitation scale. All rehabilitation outcomes showed a statistically significant improvement (P < 0.05) from the time of admission to discharge. At discharge, complete independence in activities of daily living was achieved in 4 (25%) patients and 5 (31.25%) were minimally dependent. Three (18.75%) patients were walking independently, seven (43.75%) with minimal support, and four with walker (25%). Nine (56.25%) patients needed bilateral ankle-foot orthosis and two bilateral knee gaiters for locomotion. CONCLUSION: Comprehensive inpatient rehabilitation interventions in patients with post-COVID-19 vaccine-associated GBS result in significant functional recovery.

SARS-CoV-2 antibody response after BBIBP-CorV (Sinopharm) vaccination in cancer patients: A case-control study. BACKGROUND: Long-term safety and efficacy of BBIBP-CorV vaccine especially in individuals with chronic diseases, like cancer, is under investigation. In the present prospective study, we aimed to evaluate severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) antibody response with BBIBP-CorV vaccine in Iranian cancer patients. METHODS: All the patients registered to receive BBIBP-CorV (Sinopharm) vaccine were divided into two groups of with (cases = 107) and without (controls = 45) history of cancer. Serum levels of SARS-CoV anti-spike recombinant receptor binding domain (anti-sRBD) and anti-nucleocapsid (anti-N) IgG serum levels were measured on days 0 (phase 0), 28-32 (phase I), and 56-64 (phase II) of vaccination. The data were analyzed using SPSS, version 22. RESULTS: Totally, 152 individuals (67.1% females) with the mean age of 46.71 Â± 15.36 years were included. Solid cancers included 87.8% of the cancer cases (46.7% gynecological and 31.8% gastrointestinal cancer). At Phases I and II, positive anti-sRBD IgG and anti-N IgG were significantly lower among the cases in total analysis. Side effects were not significantly different between the cases and controls. The lowest positive anti-sRBD IgG test was observed among the cancer patients who were simultaneously receiving chemotherapy (35.3%). Anti-sRBD IgG and anti-N

IgG serum levels significantly increased at phases I and II in total analysis and in each group. In addition, serum anti-sRBD IgG increased during the three phases and it was significantly higher in the control group. CONCLUSION: Full vaccination of COVID-19 by BBIBP-CorV in immunocompromised patients such as cancer patients is safe and effective and could induce antibody response but in lower levels compared to healthy people. Probable causes to have minor antibody response found in males, older ages, individuals with BMI â‰¥ 25, those without past history of COVID-19 and with hematologic cancers. No significant side effects after vaccination were seen.

It Can't Be a Coincidence: A Comparison of Cases of Autoimmune Hepatitis After Vaccination Against COVID-19. While rare, there is now a documented cohort of patients presenting with autoimmune hepatitis secondary to vaccination against COVID-19. With this case report, we aim to compare the published cases in order to discern any unifying characteristics among those affected, and share the story of a seventy-two-year old patient presenting with autoimmune hepatitis less than two weeks after receiving his first dose of the Pfizer COVID-19 vaccine.

Sequential orbital apex syndrome following the COVID-19 vaccination: A case report. BACKGROUND: Many kinds of vaccines have been developed worldwide to bring the coronavirus disease 2019 (COVID-19) to an end. We report a case of recurrent orbital apex syndrome following the first and third doses of SARS-CoV-2 vaccination. CASE PRESENTATION: A 71-year-old woman presented with acute painless diplopia and visual disturbance for two days. She had received the first dose of the COVID-19 vaccine two weeks before. She showed decreased visual acuity and ophthalmoplegia in the right eye. An orbital magnetic resonance image (MRI) revealed a hyperintense lesion with enhanced bulging in the right cavernous sinus. Following the steroid pulse therapy, she fully recovered. However, six months after the first attack, painful ophthalmoplegia with decreased visual acuity recurred in her left eye after the booster vaccination for COVID-19. MRI also showed a well-enhanced hyperintense lesion in the left orbital apex. Fortunately, her visual acuity and ocular motility returned to normal after the steroid therapy. CONCLUSIONS: Immunologic reactions from COVID-19 vaccines may cause multiple cranial neuropathies. Diverse individual immunologic states should be considered before any kind of vaccine.

Venereal disease research laboratory serology after COVID-19 vaccination: The first report.

CD4+ count change after COVID-19 vaccination: Observation on HIV-infected vaccine recipient.

Small Fiber Neuropathy Triggered by COVID-19 Vaccination: Association with FGFR3 Autoantibodies and Improvement during Intravenous Immunoglobulin Treatment. Multiple case series have demonstrated the emergence of small fiber neuropathy following acute coronavirus disease 2019 (COVID-19) infections. Further, one large case supports that the COVID-19 vaccine has been reported to result in small fiber neuropathy. We report a case of a patient with confirmed small fiber neuropathy post-COVID-19 vaccination with positive FGFR3 antibodies. The effect of intravenous immunoglobulin (IVIG) has been recently explored for treatment of presumed autoimmune small fiber neuropathy. To our knowledge, this is the first published case report of COVID vaccination-induced FGFR3-associated small fiber neuropathy improving in the context of IVIG administration as demonstrated by normalization of small fiber density measured by skin biopsy accompanied by marked improvement in the patient's symptoms.

Analysis of neutralizing antibodies to COVID-19 inactivated or subunit recombinant vaccines in hospitalized patients with liver dysfunction. BACKGROUND: The neutralizing antibodies (NAbs) response after COVID-19 vaccination after liver dysfunction is unclear. In this study, we evaluated the NAbs response after COVID-19 vaccination in hospitalized patients suffering from liver dysfunction. METHODS: In this cross-sectional study with longitudinal follow-up, we enrolled eligible patients with liver dysfunction and healthy volunteers with full-course COVID-19 vaccination. Blood samples were collected for the NAbs testing at the time of admission and after treatment. Multiple regression

analysis to assess independent risk factors affecting NAbs response. RESULTS: A total of 137 patients and 134 healthy controls (HC) were enrolled. Both seropositivity (65.7% vs 80.6%, p<0.01) and titer (3.95 vs 4.94 log(2) AU/ml, p<0.001) of NAbs in patients were significantly lower than that in HC. The decrease of antibody titer in patients was significantly faster than that in HC. After adjusting for potential confounding factors, males (odds ratio [OR]: 0.17; 95% confidence interval [CI]: 0.06, 0.46; p<0.001) and severe liver damage (OR: 0.30; 95% CI: 0.12, 0.71; p<0.01) were significantly associated with reduction of the probability of NAbs seropositivity in the multiple regression analysis. Males (Î² =-1.18; 95% CI: -1.73,-0.64) and chronic liver diseases (Î² =-1.45; 95% CI: -2.13, -0.76) were significantly associated with lower NAbs titers. In 26 patients with liver failure, both antibody seropositivity (53.8% vs 84.6%, p<0.05) and titer (3.55 vs 4.32 log(2) AU/ml, p<0.001) did not decrease but increased after artificial liver plasmapheresis. CONCLUSIONS: NAbs response to COVID-19 inactivated or subunit recombinant vaccines was waning in patients with liver dysfunction. Moreover, patients with male sex, severe liver injury and chronic liver diseases have an increased risk of poor antibody responses.
Longitudinal monitoring of mRNA-vaccine-induced immunity against SARS-CoV-2. BACKGROUND: Worldwide vaccination campaigns significantly reduced mortality caused by SARS-CoV-2 infection and diminished the devastating effects of the pandemic. The first approved vaccines are based on novel mRNA technology and elicit potent immune responses offering high levels of protection from severe disease. METHODS: Here we longitudinally assessed adaptive immune responses during a 12-month follow-up period after the initial immunization with 2 doses of mRNA vaccines and after the booster dose in blood and saliva. RESULTS: Our findings demonstrate a rapid waning of the anti-spike IgG titers between months 3 and 6 after the initial vaccination (1.7- and 2.5-fold decrease in plasma and saliva, respectively; P<0.0001). Conversely, the frequency of spike-specific memory B cells increased during this period (2.4-fold increase; P<0.0001) while the frequency of spike-specific CD4+ and CD8+ T cells remained stable for all assessed functions: cytotoxicity, IFNÎ³, IL-2, and TNFÎ± expression. Booster vaccination significantly improved the antibody response in plasma and saliva, with the most profound changes observed in the neutralization capacity against the currently circulating omicron variant (25.6-fold increase; P<0.0001). The positive effect of booster vaccination was also evident for spike-specific IgG+ memory B cell (2.4-fold increase; P<0.0001) and cytotoxic CD4+ and CD8+ T cell responses (1.7- and 1.9-fold increase respectively; P<0.05). CONCLUSIONS: Collectively, our findings offer a detailed insight into the kinetics of adaptive immune response following SARS-CoV-2 vaccination and underline the beneficial effects of a booster vaccination.
Subacute cutaneous lupus erythematosus after mRNA-based SARS-CoV-2 vaccination.
A Case of Vaccine-Induced Thrombocytopenic Thrombosis Manifesting as Cerebral Venous Thrombosis and Intracerebral Bleed. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare but detrimental syndrome that has been most commonly reported after the administration of vaccination for the prevention of viral infections. VITT often presents with thrombosis at unusual sites such as cerebral venous sinuses, portal, splanchnic or hepatic veins, in association with thrombocytopenia and elevated anti-platelet factor 4 (aPF-4) antibodies. We describe the case of a young male patient who developed thrombocytopenia, cerebral sinus venous thrombosis, and intracerebral bleed 12 days after receiving the Ad26.COV2.S (Janssen/Johnson&Johnson) COVID-19 vaccine.
SARS-CoV-2 infection, vaccination and acquired hemophilia: Reply.
Presenteeism in front-line physicians involved in COVID-19-related clinical practice: a national survey of employed physician members of the Japan Medical Association. BACKGROUND: The coronavirus disease 2019 (COVID-19) pandemic may have increased the rate of presenteeism among front-line physicians. Presenteeism is the term used to describe attendance at work despite ill health

that would normally prompt rest or absence from work. This study aimed to examine the associations between COVID-19 clinical practice and presenteeism among physicians. METHODS: A cross-sectional study was conducted from December 2021 to January 2022. The questionnaires were distributed to 21,737 employed physicians who were members of the Japan Medical Association. Presenteeism was measured by the Work Functioning Impairment Scale. Multiple logistic regression analysis was used to evaluate the association between COVID-19 clinical practice and presenteeism. RESULTS: Overall, 3,968 participants were included in the analysis, and presenteeism was observed in 13.9% of them. The rate of presenteeism significantly increased with both the number of COVID-19 patients treated and the percentage of work time spent treating these patients (both P values for trend < 0.001). In comparison to those not currently engaged in the treatment of COVID-19 patients, presenteeism was significantly higher among front-line (adjusted odds ratio [aOR] = 1.71, 95% confidence interval [CI]: 1.16-2.53) and second-line physicians supporting those in the front-line (aOR = 1.45, 95% CI: 1.17-1.78). There was no association between involvement in COVID-19 vaccination services and presenteeism. CONCLUSIONS: The burden on front-line and second-line physicians in COVID-19 clinical practice must be minimized. Employed physicians also need to recognize the importance of communicating with their workplaces about presenteeism.

COVID-19 vaccine safety during pregnancy in women with systemic lupus erythematosus. COVID-19 vaccination has been shown to be safe in patients with systemic lupus erythematosus (SLE), but data on vaccine-associated adverse events (AEs) during the antenatal and lactation period are scarce or lacking. We investigated COVID-19 vaccination-related AEs in pregnant SLE patients from the COVAD study, a global esurvey involving 157 collaborators from 106 countries. A total of 9201 complete responses were extracted. Among 6787 (73.8%) women, we identified 70 (1.1%) who were exposed to at least one COVID-19 vaccine dose during pregnancy, 11 with SLE. Delayed onset (>7Â days) vaccine-related AEs were triangulated with disease activity, treatment changes due to flare after vaccination, and COVID-19 infections in vaccinated pregnant women. Health-related quality of life and physical function was recorded using PROMIS. Age of patients ranged from 28 to 39Â years; 5/11 women were of Asian origin. None of these patients reported major vaccine AEs or change in the status of their autoimmune disease. Although minor AEs were common, they did not impair daily functioning, and the symptoms resolved after a median of 3 (IQR: 2.5-5.0) days. All patients reported good to excellent health status. No adverse pregnancy outcomes were reported. Importantly, none of the patients reported thrombotic events post-vaccination, which provides reassurance in a patient population with a high risk for cardiovascular comorbidity and thrombosis, especially in the presence of antiphospholipid antibodies or the antiphospholipid syndrome, a considerable portion of SLE patients. Our findings provide reassurance and can contribute to informed decisions regarding vaccination in patients with SLE and high-risk pregnancies due to their background autoimmune disease. The risk/benefit ratio of COVID-19 vaccination appears favourable, with vaccines both providing passive immunisation to the fetus and active immunisation to the mother with no signals of exacerbation of the mother's autoimmune disease.

The association of neonatal SARS-CoV-2 anti-spike protein receptor-binding domain antibodies at delivery with infant SARS-CoV-2 infection under the age of 6Â months: a prospective cohort study. OBJECTIVES: The aim of this study was to assess the association between neonatal SARS-CoV-2 antibody level at delivery and infant SARS-CoV-2 infection under the age of 6Â months and to identify predictive factors for neonatal antibody level at delivery. METHODS: In a prospective observational study, conducted between September 2021 and mid-February 2022, cord blood sera were tested for SARS-CoV-2 anti-spike receptor-binding domain antibodies after maternal BNT162b2 vaccination or infection. Infants were followed up for 6Â months for SARS-CoV-2 infection. RESULTS: Sixty-seven mother-infant dyads were enrolled; nine of those did not meet the eligibility criteria. Of the 58

mother-infant dyads included, 6-month follow-up data were available for 57 mother-infant dyads. The meanÂ Â±Â standard deviation log SARS-CoV-2 anti-spike antibody level at delivery was lower among infants who were COVID-19 positive versus negative during follow-up (3.41Â Â±Â 0.74 AU/mL, nÂ =Â 12; vs. 3.87Â Â±Â 0.84 AU/mL, nÂ =Â 46; p 0.036); a log titre of â‰¥4.07 AU/mL (11Â 750) at delivery was associated with a significantly lower likelihood of infant infection (1/26 vs. 11/32 in infants with antibody level of <4.07 log AU/mL, ORÂ =Â 0.076 [95% CI, 0.076, 0.64], p 0.018). A spline curve model showed a linear decrease in antibody levels when the last dose was administered at â‰¤30Â weeks of gestation (50Â days before delivery), after which the antibody levels increased (R(2)Â =Â 0.50). In multivariate analysis, more vaccine doses, prior maternal infection, and last administered dose at â‰¥31Â weeks of gestation were associated with higher antibody levels at delivery. DISCUSSION: Higher anti-spike antibodies at delivery were associated with decreased risk of COVID-19 at the age of <6Â months; the antibody level decreased linearly when the last dose was administered at â‰¤30Â weeks of gestation. Future research should assess the effectiveness of a second booster during pregnancy against infant infection.

[COVID-19 infections and effectiveness of the vaccination among healthcare workers]. INTRODUCTION: New variants of the SARS-CoV-2 coronavirus are constantly appearing, causing the COVID-19 pandemic. From November 2021, most infections were caused by the Omicron coronavirus variant. OBJECTIVE: The aim of this prospective observational cohort study was to estimate the incidence of COVID-19 infections in the high-risk healthcare workers after two BNT162b2 mRNA Pfizer-BioNTech vaccines and the subsequent booster vaccine, as well as the effectiveness, the safety and the humoral immune response of the vaccines. METHOD: We started the two Pfizer-BioNTech ((BNT162b29) vaccinations of healthcare workers of the Polyclinic of the Hospitaller Brothers of St. John between January 07 and March 08, 2021. The choice of the type and timing of the third booster vaccination was voluntary. The workers were followed up between January 07, 2021 and June 29, 2022. The infection rate, adverse events of the vaccination, risk factors to infection and the kinetics of anti-spike (S) antibody and anti-nucleocapsid (N) antibody serum level were evaluated. RESULTS: The data of 294 healthcare workers - 96 medical doctors, 127 nurses and 71 workers in hospital - who had at least three antibody level measurements were analyzed. The third booster vaccine was given to 280 workers, the distribution of the vaccines was the following: Pfizer-BioNTech (BNT162b29) vaccine (n = 210), Moderna COVID-19 (mRNA-1273) vaccine (n = 37), Sinopharm COVID-19 vaccine (n = 21), Janssen COVID-19 (n = 10), AstraZeneca (ChAdOx1 nCoV-19) vaccine (n = 2). Infection occurred in 121 cases (41%) during the observation period. The course of the COVID-19 infections was mostly mild (97%) and recovered within a week. During the observational period, 2 workers died: a 56-year-old woman died after two vaccinations for reason unrelated to COVID-19 infection, and a 58-year-old man died after the booster vaccination, following COVID-19 infection. The incidence of infection did not correlate with age, sex, comorbidities, smoking, occupation and BMI. The median titre of anti-S antibody serum level increased one month after the second vaccination of the basic immunization (1173.0 U/ml) and decreased slowly until the 8th month (678.5-625.8-538.0 U/ml) after the basic vaccination. One month after the booster vaccination, the median titre of anti-S antibody serum level increased significantly (16Â 535 U/ml), and showed a decreasing trend in the 3rd month after the booster vaccination (9697.7 U/ml). An exceptionally high S antibody serum level increasing after the basic (>10Â 000 U/mL) and booster (>60Â 000 U/m) vaccination showed a correlation with prior COVID-19 infection. The median cut-off index (COI) of anti-N antibody was not affected by vaccination, the increasing of the titre is related to the infection. CONCLUSION: The booster vaccination had less effect on the infection caused by Omicron variant, but the course of the infection was milder. Compared to the basic immunisation, the booster vaccination caused a significant

increase in the S antibody level. An exceptionally high S antibody level correlated with prior COVID-19 infection. Orv Hetil. 2023; 164(5): 163-171.

Augmented humoral and cellular immunity against severe acute respiratory syndrome coronavirus 2 after breakthrough infection in kidney transplant recipients who received 3 doses of coronavirus disease 2019 vaccine. Diminished immune response to coronavirus disease 2019 (COVID-19) vaccines and breakthrough infection (BI) is a major concern for solid organ transplant recipients. Humoral and cellular immune responses of kidney transplant (KT) recipients after a third COVID-19 vaccination were investigated compared to matched health care workers. Anti-severe acute respiratory syndrome coronavirus 2 spike protein antibody and severe acute respiratory syndrome coronavirus 2 specific interferon-gamma releasing assay (IGRA) were assessed. A total of 38 KT recipients, including 20 BI and 18 noninfection, were evaluated. In the KT BI group, antibody titers were significantly increased (median 5 to 724, binding antibody units/mL (P = 0.002) after the third vaccination, but IGRA responses were negligible. After BI, antibody titers increased (median 11 355 binding antibody unit/mL; P < 0.001) and there was a significant increase of IGRA responses to spike proteins (Spike(1)-Nil, median 0.05 to 0.41 IU/mL; P = 0.009). Antibody titers and IGRA responses were significantly higher in the BI than in the noninfection group after 6 months. Immune responses were stronger in the health care worker than in the KT cohort, but the gap became narrower after BI. In conclusion, KT recipients who experienced BI after 3 COVID-19 vaccinations acquired augmented humoral and cellular immune responses.

Systemic lupus erythematosus myocarditis after COVID-19 vaccination. INTRODUCTION: Cases of acute myocarditis have been after administration of the BNT162b2 and Ad26.COV2.S vaccine. OBJECTIVE: Describe another possible mechanism of myocarditis after COVID-19 vaccination. CASE PRESENTATION: We describe the clinical case of a 72-year-old female with pleuritic chest pain one week after the third of the BNT162b2 mRNA vaccine. Serological tests for cardiotropic pathogens were negative, and autoimmunity screening was positive with anti-nuclear antibody (ANA) in 1:160 dilution, Anti-double-stranded DNA (anti-dsDNA), and anti-histone antibodies. (18)F-fluoro-deoxy-glucose (FDG) positron emission tomography/computed tomography (PET/CT) showed a focal myocardial and pericardial inflammatory process in the cardiac apex. RESULTS AND DISCUSSION: Systemic lupus erythematosus (SLE) diagnosis was made with myocardial affection. As far as we know, this is the first report of a case of lupus myocarditis after the COVID-19 vaccine. CONCLUSION: Given the pathogenic rationales, the association between SLE and myocarditis should be considered.

Assessing the Self-reported After Events Following Immunization of COVID-19 Vaccines in Turkey and Bangladesh. Though mass vaccination programs helped to reduce the severity of the ongoing pandemic, various unwanted effects were reported in Turkey and Bangladesh after taking vaccines. The purpose of this study was to evaluate and compare the adverse effects of several vaccines in Turkey and Bangladesh and how the population of both countries prioritizes the continuation of vaccination compared to the side effects. An online survey with a pretest was conducted to gather data over the research period from July 10, 2021 to December 10, 2021. Finally, the questionnaire was shared with the mass population of Turkey and Bangladesh who have received at least one or two doses of the COVID-19 vaccines. The quality of the questionnaire was evaluated with Cronbach's alpha test. The study consisted of 1508 respondents from Bangladesh and 602 respondents from Turkey. Among the total 2110 respondents, 50.0% were male 66.8% were from the 18-30Â years age range, and 77.5% reported living in the city area. Among all the respondents, 64.99% of those vaccinated in Bangladesh and 67.28% of those vaccinated in Turkey reported side effects after vaccinations. Participants receiving mRNA vaccines (Pfizer and Moderna) experienced the most side effects, with many reporting pain at the injection site in both nations. Following that, fever, body pain, and headache were common in Bangladesh, whereas body pain, fatigue, and arm numbness

were common in Turkey. The study found no significant adverse events reported in Turkey and Bangladesh following the first and second doses of COVID-19 vaccination. These COVID-19 vaccines showed similar patterns of efficacy and safety during the short period of analysis. Vaccines from different manufacturers showed a non-significant level of adverse events during this binational AEFI approach to COVID-19 vaccines. More studies are recommended on the efficacy and safety of several vaccines to discover unexpected effects.

SARS-CoV-2 elicits non-sterilizing immunity and evades vaccine-induced immunity: implications for future vaccination strategies. Neither vaccination nor natural infection result in long-lasting protection against SARS-COV-2 infection and transmission, but both reduce the risk of severe COVID-19. To generate insights into optimal vaccination strategies for prevention of severe COVID-19 in the population, we extended a Susceptible-Exposed-Infectious-Removed (SEIR) mathematical model to compare the impact of vaccines that are highly protective against severe COVID-19 but not against infection and transmission, with those that block SARS-CoV-2 infection. Our analysis shows that vaccination strategies focusing on the prevention of severe COVID-19 are more effective than those focusing on creating of herd immunity. Key uncertainties that would affect the choice of vaccination strategies are: (1) the duration of protection against severe disease, (2) the protection against severe disease from variants that escape vaccine-induced immunity, (3) the incidence of long-COVID and level of protection provided by the vaccine, and (4) the rate of serious adverse events following vaccination, stratified by demographic variables.

Ocular motility disorders after SARS-CoV-2 vaccination require the exclusion of all differential causes.

Pemphigus aggravation following Pfizer-BioNTech vaccination: A case report and review of literature.

Comparative severity of COVID-19 cases caused by Alpha, Delta or Omicron SARS-CoV-2 variants and its association with vaccination. BACKGROUND: This study compares the severity of SARS-CoV-2 infections caused by Alpha, Delta or Omicron variants in periods of co-circulation in Spain, and estimates the variant-specific association of vaccination with severe disease. METHODS: SARS-CoV-2 infections notified to the national epidemiological surveillance network with information on genetic variant and vaccination status were considered cases if they required hospitalisation or controls otherwise. Alpha and Delta were compared during June-July 2021; and Delta and Omicron during December 2021-January 2022. Adjusted odds ratios (aOR) were estimated using logistic regression, comparing variant and vaccination status between cases and controls. RESULTS: We included 5,345 Alpha and 11,974 Delta infections in June-July and 5,272 Delta and 10,578 Omicron in December-January. Unvaccinated cases of Alpha (aOR: 0.57; 95% CI: 0.46-0.69) or Omicron (0.28; 0.21-0.36) had lower probability of hospitalisation vs. Delta. Complete vaccination reduced hospitalisation, similarly for Alpha (0.16; 0.13-0.21) and Delta (June-July: 0.16; 0.14-0.19; December-January: 0.36; 0.30-0.44) but lower from Omicron (0.63; 0.53-0.75) and individuals aged 65+ years. CONCLUSION: Results indicate higher intrinsic severity of the Delta variant, compared with Alpha or Omicron, with smaller differences among vaccinated individuals. Nevertheless, vaccination was associated to reduced hospitalisation in all groups.

Anti-SARS-CoV-2 cellular response after 2 and 3 doses of BNT162b2 mRNA vaccine in lymphoma patients receiving anti-CD20 antibodies. Patients receiving anti-CD20 antibodies showed limited efficacy of a booster dose of BNT162b2. Patients with lymphomas combine such immunotherapies with cytotoxic chemotherapies that could result in an even greater alteration of the immune response to vaccination. We report here the impact of a third vaccine dose on T cell specific responses in a small cohort of patients treated in our center by anti-CD20 therapies and cytotoxic chemotherapies for lymphoid malignancies. Our results showed that a third dose in these severely immune suppressed patients could improve the expansion on CD4(+)Th1(+)T cell responses while the effect CD8Â +Â T cell responses was marginal.

Association of a third vaccination with antibody levels and side reactions in essential workers: A prospective cohort study. OBJECTIVE: To evaluate the relationship between the change of titer and adverse events after the third vaccination for COVID-19 among healthcare workers. DESIGN AND SETTING: This was a prospective cohort study, and the follow-up period was from December 2021 to November 2023. PARTICIPANTS: A total of 392 healthcare workers aged over 20Â years who worked at the facility and wished to have vaccine antibody titers measured participated in this study. EXPOSURES: A third dose of BNT162b2 COVID-19 vaccine was administered to healthcare workers working at the hospital, and we evaluated the changes in antibody titers before and after the vaccine, as well as adverse reactions after vaccination. MAIN OUTCOMES AND MEASURES: The primary endpoints were adverse reactions within 7Â days after the third dose of COVID-19 vaccine and the rate of increase in COVID-19 vaccine antibody titer at 4Â weeks. RESULTS: A total of 392 people participated in the study, of whom 358 participants had their antibody titers measured before and after the booster vaccination. The overall IgG geometric mean was 609 U/mL (561-663) before booster vaccination and increased to 18,735 U/mL (17,509-20,049) at 4Â weeks after vaccination (pÂ <Â 0.001). Multivariate analysis showed no statistically significant relationship between the primary endpoints, such as a change in antibody titer due to the presence of fever after vaccination or a change in antibody titer due to swelling at the vaccination site. Factors affecting the rate of increase in antibody titer, evaluated as secondary endpoints, were suggested to be age (1.02 (95Â % confidence interval (CI): 1.01-1.03)) and hypertension (0.66 (95Â % CI: 0.47-0.93)). CONCLUSIONS AND RELEVANCE: In relation to the booster effect of the third dose of COVID-19 vaccination, there was no statistically significant difference in the presence of fever or use of antipyretic or other drugs.

Bilateral Persistent Placoid Maculopathy Following COVID-19 Vaccines: Real or Coincidence? COVID-19 vaccinations have been accompanied by reports of inflammatory uveitis. Herein, we report the first case of bilateral persistent placoid maculopathy (PPM) following COVID-19 vaccinations in a previously healthy 58-year-old man who presented with bilateral decrease in vision approximately 2 weeks after the second dose of AstraZenacaÂ® ChAdOx1-S/nCoV-19 vaccine. Fundus examination revealed bilateral well-delineated whitish plaque-like macular lesions involving the fovea. Clinical and multimodal imaging findings were suggestive of PPM. Infective and autoimmune screen were all negative except for a raised MPO-ANCA. Medical review excluded systemic autoimmune and infectious diseases. Patient was monitored closely and his visual acuity improved and stabilised after a tapering regime of oral prednisolone. Mycophenolate mofetil was given as long-term steroid sparing immunosuppression. Our case demonstrated a likely localised autoimmune inflammatory response to the COVID-19 vaccine affecting choriocapillaris. Further research is needed to clarify the association between COVID-19 vaccines and inflammatory placoid lesions of the retina.

Impact of Donor and Recipient SARS-CoV-2 Vaccination or Infection on Immunity after Hematopoietic Cell Transplantation. The role of donor and recipient Coronavirus disease 2019 (COVID-19) immunologic status pre-transplantation has not been fully investigated in allogeneic hematopoietic stem cell transplantation (HSCT) recipients. Given the poor immunogenicity to vaccines in this population and the serious outcomes of COVID-19, adoptive transfer of immunity may offer important insight into improving protection for this vulnerable population. In this study, we evaluated the role of adoptive transfer of immunity at 1 month post-transplantation and 6 months post-transplantation after vaccination of recipients, based on pre-transplantation severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination and infection exposures of both recipient and donor. Using banked specimens from related donor allogeneic HSCT recipients and clinical data from both donors and recipients, anti-Spike (S) IgG titers were analyzed at 1, 3, and 6 months post-transplantation according to prior SARS-CoV-2 immunologic exposures. Recipients were excluded if they had received SARS-CoV-2 monoclonal antibodies or had infection in the first 6 months post-

transplantation. Of the 53 recipient-donor pairs, 29 donors and 24 recipients had prior SARS-CoV-2 immunologic exposure. Recipient-donor pairs with no prior SARS-CoV-2 exposure (D0R0) had significantly lower anti-S IgG titers at 1 month compared to those with prior exposures (D1R1) (D0R0: median, 2.43 [interquartile range (IQR), .41 to 3.77]; D1R1: median, 8.42; IQR, 5.58 to 12.20]; PÂ =Â .008). At 6 months, anti-S IgG titers were higher in recipients who were vaccinated at 3 months post-transplantation in the D1R1 cohort (median IgG, 148.34; IQR, 92.36 to 204.33) compared with the D0R0 cohort (median IgG, 38.74; IQR, 8.93 to 119.71). Current strategies should be optimized to enhance SARS-CoV-2 protection for HSCT recipients, including augmentation of the immune response for both donors and recipients prior to transplantation.

Probable association between mRNA COVID-19 vaccine and opsoclonus-myoclonus-ataxia syndrome. Opsoclonus-myoclonus-ataxia syndrome (OMAS) in children is most often of paraneoplastic origin, but it can also result from infectious processes, toxic and metabolic disorders, and organic events that cause damage to the brainstem or cerebellum. Post-vaccination OMAS has also been reported. We report the case of a 15-year-old girl who developed OMAS 24 hours after her first dose of mRNA COVID-19 (BioNTech) vaccine.

Pregnancy Outcomes in Patients After Completion of the mRNA Coronavirus Disease 2019 (COVID-19) Vaccination Series Compared With Unvaccinated Patients. OBJECTIVE: To compare frequency of perinatal death between pregnant patients who completed the mRNA coronavirus disease 2019 (COVID-19) vaccination series and unvaccinated patients. METHODS: This retrospective cohort study included 15,865 pregnant patients who delivered 16,132 newborns after 20 weeks of gestation within a large regional health system between January 1, 2021, and December 31, 2021. Patients who received two doses of mRNA vaccine (Pfizer-BioNTech [BNT162b2] or Moderna [mRNA-1273]) were included in the vaccinated group and were compared with unvaccinated patients. Exclusions included partial vaccination, viral-vector vaccine, major congenital anomalies, and higher-order multiple gestation. Our primary outcome was perinatal death, including stillbirth and neonatal death, which was evaluated by logistic regression. Unadjusted odds ratios and adjusted odds ratios (aORs) were reported, controlling for age, body mass index (BMI), diabetes, hypertension, smoking, twin gestation, and insurance status. Propensity score matching was also performed. RESULTS: A total of 15,865 patients were included in the final analysis: 2,069 in the vaccination group and 13,796 in the control group. Only 13.0% of the cohort was included in the vaccination group; however, the vaccination rate increased over the course of the study period as the vaccine became more widely available and accepted. Vaccinated patients were older, with higher rates of people of non-Black racial non-Hispanic ethnic backgrounds, people with private insurance, and those with higher BMIs. Vaccination was associated with a lower incidence of perinatal death (0.5% vaccinated group vs 0.8% unvaccinated group, aOR 0.20 0.05-0.88). Vaccination against COVID-19 was also associated with lower rates of preterm delivery (aOR 0.63, 0.48-0.82), neonates with very low birth weight (aOR 0.35, 0.15-0.84), and neonatal intensive care unit (NICU) admission (aOR 0.66, 0.52-0.85). The association between vaccination and lower rates of perinatal death was no longer significant after propensity score matching. CONCLUSION: In a large retrospective cohort study, receipt of the primary mRNA COVID-19 vaccination series was associated with a lower rate of several adverse pregnancy outcomes, including perinatal death, preterm delivery, neonates with very low birth weight, and NICU admission. Although the decreased rates of perinatal death did not remain significant after propensity score matching, there was evidence of directional benefit for vaccinated patients.

Heterologous versus homologous primary and booster COVID-19 vaccination do not increase flare rate in patients with psoriasis and/or psoriatic arthritis: Insights from a real-life, multicenter, case-control study.

Vaccine hesitancy decreases in rheumatic diseases, long-term concerns remain in myositis: a comparative analysis of the COVAD surveys. OBJECTIVE: COVID-19 vaccines have a favorable safety profile in patients with autoimmune rheumatic diseases (AIRDs) such as idiopathic inflammatory myopathies (IIMs); however, hesitancy continues to persist among these patients. Therefore, we studied the prevalence, predictors and reasons for hesitancy in patients with IIMs, other AIRDs, non-rheumatic autoimmune diseases (nrAIDs) and healthy controls (HCs), using data from the two international COVID-19 Vaccination in Autoimmune Diseases (COVAD) e-surveys. METHODS: The first and second COVAD patient self-reported e-surveys were circulated from March to December 2021, and February to June 2022 (ongoing). We collected data on demographics, comorbidities, COVID-19 infection and vaccination history, reasons for hesitancy, and patient reported outcomes. Predictors of hesitancy were analysed using regression models in different groups. RESULTS: We analysed data from 18â€‰882 (COVAD-1) and 7666 (COVAD-2) respondents. Reassuringly, hesitancy decreased from 2021 (16.5%) to 2022 (5.1%) (OR: 0.26; 95% CI: 0.24, 0.30, Pâ€‰<â€‰0.001). However, concerns/fear over long-term safety had increased (OR: 3.6; 95% CI: 2.9, 4.6, Pâ€‰<â€‰0.01). We noted with concern greater skepticism over vaccine science among patients with IIMs than AIRDs (OR: 1.8; 95% CI: 1.08, 3.2, Pâ€‰=â€‰0.023) and HCs (OR: 4; 95% CI: 1.9, 8.1, Pâ€‰<â€‰0.001), as well as more long-term safety concerns/fear (IIMs vs AIRDs - OR: 1.9; 95% CI: 1.2, 2.9, Pâ€‰=â€‰0.001; IIMs vs HCs - OR: 5.4 95% CI: 3, 9.6, Pâ€‰<â€‰0.001). Caucasians [OR 4.2 (1.7-10.3)] were likely to be more hesitant, while those with better PROMIS physical health score were less hesitant [OR 0.9 (0.8-0.97)]. CONCLUSION: Vaccine hesitancy has decreased from 2021 to 2022, long-term safety concerns remain among patients with IIMs, particularly in Caucasians and those with poor physical function.

SARS-CoV-2 Infection in Winter 2021/2022: The Association of Varying Clinical Manifestations With and Without Prior Vaccination. Importance SARS-CoV-2 is a rapidly evolving virus with many strains. Although vaccines have proven to be effective against earlier strains of the virus, the efficacy of vaccination status against later strains is still an area of active research. Objective To determine if vaccination status was associated with symptomatology due to infection by later strains of SARS-CoV-2. Design This cross-sectional survey was sent to an adult Jewish population from December 2021 to March 2022. Setting This is a population-based study of Jewish communities throughout the tristate area. The subjects were recruited by local Jewish not-for-profit and social service organizations. Participants Surveys were sent to 14,714 adults who were recruited by local Jewish not-for-profit and social service organizations; 966 respondents completed the survey (6.57%). Only participants who received a positive COVID-19 nasal swab 10 weeks since December 1, 2021, were included in the main outcome. Exposure Participants were grouped by vaccine type (i.e., Johnson & Johnson {J&J}, Moderna, or Pfizer) and vaccination status (i.e., unvaccinated, single, full, or booster). Main outcomes and measures The primary study outcome was an association between immunization status and somatological presentation. Symptom severity classes were built using latent class analysis (LCA). Results Out of 14,714 recipients,Â 966 completed the survey (6.57%). The participants were mainly self-described Ashkenazi Jewish (97%) with a median age of 41. The LCA resulted in four classes: highly symptomatic (HS), less symptomatic (LS), anosmia, and asymptomatic (AS). Vaccinated participants were less likely to be in symptomatic groups than the unvaccinated participants (odds ratio {OR}: 0.326; 95% confidence interval {CI}: 0.157-0.679; p=0.002). Boosted participants were less likely to be in symptomatic groups than fully vaccinated participants (OR: 0.267; 95% CI: 0.122-0.626; p=0.002). Additionally, there was no association between symptomatology and vaccination type (p=0.353). Conclusions and relevance Participants who received COVID-19 vaccinations or booster shots were less likely to be symptomatic after Omicron infection compared to unvaccinated participants and vaccinated participants without boosters, respectively. There's no association

between vaccination type and symptomatology. These results enhance our understanding that COVID-19 vaccinations improve clinical symptomatology, even in an unforeseen COVID-19 strain.

Depression, anxiety and stress after COVID-19 vaccination: A retrospective cross-sectional study among health care providers. BACKGROUND: Corona virus disease (COVID-19) is a health concern that produced considerable psychological and physical health challenges to Health care providers (HCPs) internationally. AIMS: This study aims to determine the level of depression, anxiety, and stress after receiving the COVID-19 vaccine among HCPs in Iraq. METHODS: A retrospective cross-sectional study design was used in this study. The participants involved were 700 Iraqi HCPs who received one or two doses from COVID-19 vaccines. The questionnaire was designed and brought to them electronically using Google form and distributed by social media. Then mental health status was measured using a specific depression, anxiety and stress scale named DASS-21. Each domain of the DASS scale was calculated for each subject and DASS-21 scores were compared between different demographic groups. RESULTS: Females represented a large percentage of participants (80%). The majority of participants had a normal level of DASS-21 after receiving the vaccine. Higher scores were obtained among graduated young age groups also among individuals who have side effects associated with the vaccine. CONCLUSIONS: To the best of our knowledge, this is the first study that assesses mental health after receiving the COVID-19 vaccine in the middle east. The study concluded that HCPs have low DASS-21 scores and this gives us promising results for the use of the COVID-19 vaccine in future.

Immunogenicity and reactogenicity of accelerated regimens of fractional intradermal COVID-19 vaccinations. INTRODUCTION: This phase I study explored the immunogenicity and reactogenicity of accelerated, Q7 fractional, intradermal vaccination regimens for COVID-19. METHODS: Participants (n = 60) aged 18-60 years, naÃ¯ve to SARS-CoV-2 infection or vaccination, were randomly allocated into one of four homologous or heterologous accelerated two-dose, two-injection intradermal regimens seven days apart:(1) BNT162b2-BNT162b2(n= 20),(2) ChAdOx1- BNT162b2 (n = 20), (3) CoronaVac-ChAdOx1 (n = 10), and (4) ChAdOx1-ChAdOx1 (n = 10). CoronaVac and ChAdOx1 were 20%, and BNT162b2 17%, of their standard intramuscular doses (0.1 mL and 0.05 mL per injection, respectively). Humoral immune responses were measured through IgG response towards receptor binding domains (RBD-IgG) of ancestral SARS-CoV-2 spike protein and pseudovirus neutralization tests (PVNT50). Cellular immune responses were measured using ELISpot for ancestral protein pools. RESULTS: Immunogenicity was highest in regimen (2), followed by (1), (4), and (3) 2 weeks after the second dose ($P < 0.001$ for anti-RBD-IgG and $P= 0.01$ for PVNT50). Each group had significantly lower anti-RBD IgG (by factors of 5.4, 3.6, 11.6, and 2.0 for regimens (1) to (4), respectively) compared to their respective standard intramuscular regimens ($P < 0.001$ for each). Seroconversion rates for PVNT50 against the ancestral strain were 75%, 90%, 57% and 37% for regimens (1) to (4), respectively. All participants elicited ELISpot response to S-protein after vaccination. Adverse events were reportedly mild or moderate across cohorts. DISCUSSION: We concluded that accelerated, fractional, heterologous or homologous intradermal vaccination regimens of BNT162b2 and ChAdOx1 were well tolerated, provided rapid immune priming against SARS-CoV-2, and may prove useful for containing future outbreaks.

Safety, effectiveness and hesitancy of COVID-19 vaccination in children: A cross-sectional study in Pakistan. BACKGROUND: The elevated risk of serious complications like myocarditis and pericarditis after COVID-19 vaccination, especially in adolescent has been reported in some instances that need to be tested in regional populations and different ethnicity groups. The purpose of the study was to evaluate the side effects, hesitancy, and effectiveness outcomes following COVID-19 vaccination among children in Pakistan. METHODS: The study was planned using a cross-sectional design and data from Children and Adolescents (CA) was collected through a convenient sampling

method using a validated questionnaire between February to July 2022. A total of 1,108 CA between the age of 12-18 years who received one or two doses of vaccine were selected and data were collected through direct interviews with respondents. RESULTS: The results showed that among 99.8% of respondents who received the Pfizer COVID-19 vaccine, 72.3% of respondents were partially vaccinated (with one dose) while 27.7% were fully vaccinated (with two doses). COVID vaccination regime had a favorable safety profile in children as compared to adults. Vaccine hesitancy in children was reported to be 52.4% and the most common reasons for hesitance were the assumption that the vaccine is not safe (23.7%), the vaccine is not required (19.6%) and the vaccine is not effective (10.4%). The reported side effects were mainly mild (88.5%) followed by moderate (10.6%) and only 0.8% were of severe intensity. Post-vaccination local side effects of mild intensity were common with an onset of an average of 24 h (68%) and a duration of 2-3 days (60.6%). The reported side effects were significantly associated with gender ($p = 0.00$) while age had no significant effect on the occurrence of side effects. Overall, the vaccine was well tolerated by children and adolescents and was effective in preventing the reoccurrence of COVID-19 infection in 99.9% of participants. CONCLUSION: COVID-19 vaccine by Pfizer approved by the FDA for use in CA 12-18 years of age was well tolerated with a good safety profile and no serious adverse drug reactions were reported. The vaccine side effects were mild (88.5%) and lasted for an average of 2-3 days only (60.4%). The vaccine was effective in safeguarding Children against COVID-19 infection.

Nonepisodic angioedema with eosinophilia after COVID-19 vaccination: a case successfully treated with reslizumab. BACKGROUND: Angioedema with eosinophilia (AE) is a rare allergic disease classified as episodic or nonepisodic. AE is characterized by angioedema, urticaria, fever, weight gain, and eosinophilia, but its etiology and pathogenesis have not yet been clarified. CASE PRESENTATIONS: We present a 70-year-old woman presented with generalized edema and urticaria after Moderna COVID-19 vaccination. Peripheral blood eosinophil count was marked elevated and echocardiography and Doppler ultrasonography of both the upper and lower extremities were unremarkable. Her symptoms and peripheral blood eosinophil count were improved after systemic steroid therapy, but she failed to respond to steroid tapering. Reslizumab (anti-interluekin-5) was administered intravenously, and she remained symptom free with a normal eosinophil count during 8Â months of reslizumab treatment without steroids. CONCLUSIONS: We report a case of nonepisodic AE after COVID-19 vaccination that was successfully treated with reslizumab.

SARS-CoV-2 humoral and cellular immunity following different combinations of vaccination and breakthrough infection. The elicited anti-SARS-CoV-2 immunity is becoming increasingly complex with individuals receiving a different number of vaccine doses paired with or without recovery from breakthrough infections with different variants. Here we analyze the immunity of individuals that initially received two doses of mRNA vaccine and either received a booster vaccination, recovered from a breakthrough infection, or both. Our data suggest that two vaccine doses and delta breakthrough infection or three vaccine doses and optionally omicron or delta infection provide better B cell immunity than the initial two doses of mRNA vaccine with or without alpha breakthrough infection. A particularly potent B cell response against the currently circulating omicron variant (B. 1.1.529) was observed for thrice vaccinated individuals with omicron breakthrough infection; a 46-fold increase in plasma neutralization compared to two vaccine doses (pâ€‰<â€‰0.0001). The T cell response after two vaccine doses is not significantly influenced by additional antigen exposures. Of note, individuals with hybrid immunity show better correlated adaptive immune responses compared to those only vaccinated. Taken together, our data provide a detailed insight into SARS-CoV-2 immunity following different antigen exposure scenarios.

Presence of symptoms 6 weeks after COVID-19 among vaccinated and unvaccinated US healthcare personnel: a prospective cohort study. OBJECTIVES: Although COVID-19 vaccines offer protection

against infection and severe disease, there is limited information on the effect of vaccination on prolonged symptoms following COVID-19. Our objective was to determine differences in prevalence of prolonged symptoms 6 weeks after onset of COVID-19 among healthcare personnel (HCP) by vaccination status, and to assess differences in timing of return to work. DESIGN: Cohort analysis of HCP with COVID-19 enrolled in a multicentre vaccine effectiveness study. HCP with COVID-19 between December 2020 and August 2021 were followed up 6 weeks after illness onset. SETTING: Health systems in 12 US states. PARTICIPANTS: HCP participating in a vaccine effectiveness study were eligible for inclusion if they had laboratory-confirmed symptomatic SARS-CoV-2 with mRNA vaccination (symptom onset â‰¥14 days after two doses) or no prior vaccination. Among 681 eligible participants, 419 (61%) completed a follow-up survey to assess symptoms reported 6 weeks after illness onset. EXPOSURES: Two doses of a COVID-19 mRNA vaccine compared with no COVID-19 vaccine. MAIN OUTCOME MEASURES: Prevalence of symptoms 6 weeks after onset of COVID-19 illness and days to return to work. RESULTS: Among 419 HCP with COVID-19, 298 (71%) reported one or more COVID-like symptoms 6 weeks after illness onset, with a lower prevalence among vaccinated participants compared with unvaccinated participants (60.6% vs 79.1%; adjusted risk ratio 0.70, 95% CI 0.58 to 0.84). Following their illness, vaccinated HCP returned to work a median 2.0 days (95% CI 1.0 to 3.0) sooner than unvaccinated HCP (adjusted HR 1.37, 95% CI 1.04 to 1.79). CONCLUSIONS: Receipt of two doses of a COVID-19 mRNA vaccine among HCP with COVID-19 illness was associated with decreased prevalence of COVID-like symptoms at 6 weeks and earlier return to work.

Impact of study design on vaccine effectiveness estimates of 2 mRNA COVID-19 vaccine doses in patients with stage 5 chronic kidney disease. [Figure: see text]

Imaging for Cardiovascular Complications of COVID-19: Cardiac Manifestations in Context. After the first confirmed case in 2019, COVID-19 rapidly spread worldwide and overwhelmed the medical community. In the intervening time, we have learned about COVID-19's clinical manifestations and have developed effective therapies and preventative vaccines. Severe COVID-19 infection is associated with many cardiovascular disorders in the acute phase, and patients recovered from illness can also manifest long-term sequelae, including long COVID syndrome. Furthermore, severe acute respiratory syndrome-related coronavirus-2 messenger RNA (mRNA) vaccination can trigger rare cases of myopericarditis. We have gained significant knowledge of the acute and long-term cardiovascular complications of COVID-19- and mRNA vaccine-associated myocarditis through clinical and investigative studies using cardiac imaging. In this review, we describe how cardiovascular imaging can be used to understand the cardiovascular complications and cardiac injury associated with acute COVID-19 infection, review the imaging findings in patients recovered from illness, and discuss the role and limitations of cardiac imaging in COVID-19 mRNA vaccine-associated myocarditis.

COVID-19 VACCINE-INDUCED ACUTE EXUDATIVE POLYMORPHOUS VITELLIFORM MACULOPATHY: CASE REPORTS. BACKGROUND: Acute exudative polymorphous vitelliform maculopathy is a presumed retinal pigment epithelium abnormality that has been reported in patients with neoplasms and under certain classes of drugs. The pathophysiology remains unclear, despite the typical clinical features. PURPOSE: To report two cases of acute exudative polymorphous vitelliform maculopathy occurring after vaccination with a COVID-19 vaccine. CASE REPORTS: Two adult patients presented with visual disturbance after inoculation with a COVID-19 vaccine. The patients were otherwise healthy and have no family history of retinal dystrophies. Both cases exhibited the following features on multimodal imaging: multifocal hyporeflective lesions involving the macula, elongated photoreceptors, accumulated vitelliform material exhibiting autofluorescence, and lack of fluorescein dye leakage. Evidence of retinal pigment epithelium dysfunction was confirmed by electrooculography. CONCLUSION: Two cases of acute exudative polymorphous vitelliform maculopathy occurring after COVID-19 vaccination were reported. A relationship between the

vaccine and the retinal pigment epithelial abnormality development that led to acute exudative polymorphous vitelliform maculopathy was postulate, possibly through autoantibodies against the severe acute respiratory syndrome coronavirus 2 virus structural surface glycoprotein antigens that cross react with the normal retinal pigment epithelial cells.

Multiple MIS-C Readmissions and Giant Coronary Aneurysm After COVID-19 Illness and Vaccination: A Case Report. BACKGROUND: Multisystem inflammatory syndrome in children (MIS-C) rarely involves delayed giant coronary aneurysms, multiple readmissions or occurrence after COVID-19 vaccination. METHODS: We describe a child with all 3 of these unusual features. We discuss his clinical presentation, medical management, review of the current literature and CDC guidance recommendations regarding further vaccinations. RESULTS: A 5-year-old boy had onset of MIS-C symptoms 55 days after COVID-19 illness and 15 days after receiving his first BNT162b2 COVID-19 vaccination. He was admitted 3 times for MIS-C, and twice after his steroid dose was tapered. On his initial admission, he was given intravenous immunoglobulin and steroids. During his second admission, new, moderate coronary dilation was noted, and he was treated with intravenous immunoglobulin and steroids. At his last admission, worsening coronary dilation was noted, and he was treated with infliximab and steroids. During follow-up, he had improvement in his coronary artery dilatation. However, his inflammatory markers increased after steroid wean, and his steroid taper was further extended, after which time his inflammatory markers improved. This is the only such reported case of a patient who was admitted 3 times for MIS-C complications after COVID-19 vaccination. CONCLUSION: MIS-C rarely involves delayed giant coronary aneurysms, multiple readmissions, or occurrence after COVID-19 vaccination. Whether our patient's COVID-19 vaccine 6 weeks after COVID-19 illness contributed to his MIS-C is unknown. After consultation with the CDC-funded Clinical Immunization Safety Assessment Project, the patient's care team decided against further COVID-19 vaccination until at least 3 months post normalization of inflammatory markers.

Incidence and Predictors of Breakthrough and Severe Breakthrough Infections of SARS-CoV-2 After Primary Series Vaccination in Adults: A Population-Based Survey of 22 575 Participants. BACKGROUND: Breakthrough infections of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are well documented. The current study estimates breakthrough incidence across pandemic waves, and evaluates predictors of breakthrough and severe breakthrough infections (defined as those requiring hospitalization). METHODS: In total, 89 762 participants underwent longitudinal antibody surveillance. Incidence rates were calculated using total person-days contributed. Bias-corrected and age-adjusted logistic regression determined multivariable predictors of breakthrough and severe breakthrough infection, respectively. RESULTS: The incidence was 0.45 (95% confidence interval [CI], .38-.50) during pre-Delta, 2.80 (95% CI, 2.25-3.14) during Delta, and 11.2 (95% CI, 8.80-12.95) during Omicron, per 10 000 person-days. Factors associated with elevated odds of breakthrough included Hispanic ethnicity (vs non-Hispanic white, OR = 1.243; 95% CI, 1.073-1.441), larger household size (OR = 1.251 [95% CI, 1.048-1.494] for 3-5 vs 1 and OR = 1.726 [95% CI, 1.317-2.262] for more than 5 vs 1 person), rural versus urban living (OR = 1.383; 95% CI, 1.122-1.704), receiving Pfizer or Johnson & Johnson versus Moderna, and multiple comorbidities. Of the 1700 breakthrough infections, 1665 reported on severity; 112 (6.73%) were severe. Higher body mass index, Hispanic ethnicity, vaccine type, asthma, and hypertension predicted severe breakthroughs. CONCLUSIONS: Breakthrough infection was 4-25 times more common during the Omicron-dominant wave versus earlier waves. Higher burden of severe breakthrough infections was identified in subgroups.

Persistence of the immune response after two doses of ChAdOx1 nCov-19 (AZD1222): 1 year of follow-up of two randomized controlled trials. The trajectory of immune responses following the primary dose series determines the decline in vaccine effectiveness over time. Here we report on

maintenance of immune responses during the year following a two-dose schedule of ChAdOx1 nCoV-19/AZD1222, in the absence of infection, and also explore the decay of antibody after infection. Total spike-specific IgG antibody titres were lower with two low doses of ChAdOx1 nCoV-19 vaccines (two low doses) (P = 0.0006) than with 2 standard doses (the approved dose) or low dose followed by standard dose vaccines regimens. Longer intervals between first and second doses resulted in higher antibody titres (P < 0.0001); however, there was no evidence that the trajectory of antibody decay differed by interval or by vaccine dose, and the decay of IgG antibody titres followed a similar trajectory after a third dose of ChAdOx1 nCoV-19. Trends in post-infection samples were similar with an initial rapid decay in responses but good persistence of measurable responses thereafter. Extrapolation of antibody data, following two doses of ChAdOx1 nCov-19, demonstrates a slow rate of antibody decay with modelling, suggesting that antibody titres are well maintained for at least 2 years. These data suggest a persistent immune response after two doses of ChAdOx1 nCov-19 which will likely have a positive impact against serious disease and hospitalization.
Cerebral Venous Sinus Thrombosis and Papilledema in Vaccine-Induced Thrombotic Thrombocytopenia After SARS-CoV-2 Vaccination.
COVID-19 Vaccine Reactogenicity and Vaccine Attitudes Among Children and Parents/Guardians After Multisystem Inflammatory Syndrome in Children or COVID-19 Hospitalization: September 2021-May 2022. BACKGROUND: Multisystem inflammatory syndrome in children (MIS-C) is a multiorgan hyperinflammatory condition following SARS-CoV-2 infection. Data on COVID-19 vaccine adverse events and vaccine attitudes in children with prior MIS-C are limited. We described characteristics associated with COVID-19 vaccination, vaccine adverse events and vaccine attitudes in children with a history of MIS-C or COVID-19 and their parents/guardians. METHODS: We enrolled children previously hospitalized for MIS-C or COVID-19 from 3 academic institutions. We abstracted charts and interviewed children and parents/guardians regarding vaccine adverse events and acceptability. RESULTS: Of 163 vaccine-eligible children enrolled with a history of MIS-C and 70 with history of COVID-19, 51 (31%) and 34 (49%), respectively, received mRNA COVID-19 vaccine a median of 10 (Interquartile Range 6-13) months after hospital discharge. Among 20 children with MIS-C and parents/guardians who provided interviews, local injection site reaction of brief duration (mean 1.8 days) was most commonly reported; no children required medical care within 2 weeks postvaccination. Vaccine survey results of interviewed, vaccinated children and their parents/guardians: of 20 children with MIS-C and 15 children with COVID-19, 17 (85%) and 13 (87%), respectively, listed doctors in the top 3 most trusted sources for vaccine information; 13 (65%) and 9 (60%) discussed vaccination with their doctor. CONCLUSIONS: COVID-19 vaccination was well tolerated in children with prior MIS-C or COVID-19 participating in our investigation. Parents/guardians regarded their children's doctors as a trusted source of information for COVID-19 vaccines, and most vaccinated children's parents/guardians had discussed COVID-19 vaccination for their child with their doctor.
Severe coronary artery spasm after administration of a 5-hydroxytryptamine type 1 receptor agonist and SARS-CoV2 vaccination: Comment.
Adverse events and SARS-CoV-2 antibody responses after immunization with Sputnik V, ChAdOx1-S, and BBIBP-CorV vaccines in people with HIV. OBJECTIVE: This study describes adverse events following immunization (AEFIs) and the development of SARS-COV-2 antibodies after Sputnik V, AstraZeneca, and Sinopharm COVID-19 vaccination in people with HIV (PWH). METHODS: In total, 595 adult PWH at an HIV center in Argentina from March to December 2021 were enrolled. Analysis included participants who received COVID-19 vaccination with Sputnik V, AstraZeneca, and Sinopharm, and did not receive mRNA COVID-19 vaccines. Clinical data, and local or systemic AEFI variables were collected using an online questionnaire after the first dose. Detection of S1-RBD IgG

antibodies was performed between days 28 and 60 after the second dose in a subsample (SARS-CoV-2 IgG chemiluminescent immunoassay; Siemens). A multivariable logistic regression and spearman test were used for analyses. RESULTS: Mean age was 46.1â€Šyears (SDâ€Š=â€Š11.8); 70.4% were men; and median CD4 + T cells count was 659 (500-852) cells/Î¼l. AEFIs were reported in 214 (36.0%) participants. More participants reported AEFIs after Sputnik V (29.4%) and AstraZeneca (47.5%) than Sinopharm (13.9%) (Ï‡ 2 â€Šâ€Š35.85, P â€Š<â€Š0.001). Higher odds of reporting an AEFIs were associated with receiving Sputnik V [aORâ€Šâ€Š2.90; 95% confidence interval (95% CI) = 1.40-6.04; P â€Šâ€Š0.004] and AstraZeneca (aORâ€Šâ€Š5.38; 95% CI = 2.63-11.01; P â€Š<â€Š0.001) compared with Sinopharm. Lower odds were associated with age (aORâ€Šâ€Š0.97; 95% CI = 0.95-0.99; P â€Š<â€Š0.001). Overall, 76 (95.0%) individuals assessed for the presence of SARS-CoV-2 antibody reached S1-RBD IgG antibody titers at least 1â€ŠU/ml; mean titer was 51.3 (SDâ€Š=â€Š51.07) U/ml. Higher antibody titers correlated with higher CD4 + T cells count (Rhoâ€Š=â€Š0.280; P â€Š=â€Š0.012). CONCLUSION: NonmRNA vaccines showed a good safety profile and adequate SARS-CoV-2 antibody responses among PWH suggesting adequate protection to SARS-CoV-2.

Case Report: Acquired Brown Syndrome after COVID-19 Vaccination. SIGNIFICANCE: Brown syndrome, or superior oblique tendon sheath syndrome, is characterized by limitation of elevation on adduction. The disorder is thought to involve the trochlea/superior oblique tendon complex through traumatic, surgical, and inflammatory mechanisms. It could be an indication of multiple underlying immunological or rheumatological disorders. PURPOSE: This study aimed to report an unusual strabismus after receiving the first dose of a live attenuated coronavirus disease 2019 (COVID-19) vaccine. CASE REPORT: A 31-year-old female patient presented with painful vertical diplopia and tenderness of the left trochlear area 3 days after the first dose of COVID-19 vaccination. She had a compensatory chin elevation and face turn to the right, as well as a left 10-prism-diopter hypotropia in the primary position, which increased to 15 prism diopters in the right gaze and disappeared in the left gaze. Ocular motility revealed the limitation of elevation on adduction. The patient denied any history of ocular trauma and was consequently investigated for dysthyroid disease and various immunological and rheumatological disorders, which were excluded. A Hess chart was obtained to document the motility disorder. CONCLUSIONS: We report a case of acquired Brown syndrome in a 31-year-old otherwise healthy woman shortly after COVID-19 vaccination. It is possible that the patient may have developed trochleitis and/or superior oblique tenosynovitis brought on by cross-reacting antibodies generated by the immune response to the vaccine. In the age of the widest vaccination campaign in human history, it is highly likely that we will continue to observe many unexpected potential adverse effects of these vaccines in our clinical practice.

Ventricular Arrhythmia and COVID-19 Vaccine-associated Myocarditis. 17-year-old male presented with COVID-19 vaccine-associated myocarditis. Six months later, due to chest discomfort with exercise, the patient underwent an exercise stress test that revealed a 3-beat run of nonsustained ventricular tachycardia at 230 bpm at peak exercise. The long-term outcomes of COVID-19 vaccine-associated myocarditis are unclear. This patient had nonsustained ventricular tachycardia over 6 months after diagnosis.

Acute bilateral central serous chorioretinopathy in a young male after the first dose of Oxford/AstraZeneca AZD1222 (Covishield) vaccine. We case of acute bilateral central serous chorioretinopathy (CSCR) after receiving the first dose of Covishield vaccine in a young, otherwise healthy male with no associated risk factors.

Lack of seroresponse to SARS-CoV-2 booster vaccines given early post-transplant in patients primed pre-transplantation. SARS-CoV-2 vaccines are recommended pre-transplantation, however, waning immunity and evolving variants mandate booster doses. Currently there no data to inform the optimal timing of booster doses post-transplant, in patients primed pre-transplant. We investigated

serial serological samples in 204 transplant recipients who received 2 or 3 SARS-CoV-2 vaccines pre-transplant. Spike protein antibody concentrations, [anti-S], were measured on the day of transplantation and following booster doses post-transplant. In infection-naÃ¯ve patients, post-booster [anti-S] did not change when V3 (1(st) booster) was given at 116(78-150) days post-transplant, falling from 122(32-574) to 111(34-682) BAU/ml, p=0.78. Similarly, in infection-experienced patients, [anti-S] on Day-0 and post-V3 were 1090(133-3667) and 2207(650-5618) BAU/ml respectively, p=0.26. In patients remaining infection-naÃ¯ve, [anti-S] increased post-V4 (as 2(nd) booster) when given at 226(208-295) days post-transplant, rising from 97(34-1074) to 5134(229-5680) BAU/ml, p=0.0016. Whilst in patients who had 3 vaccines pre-transplant, who received V4 (as 1(st) booster) at 82(49-101) days post-transplant, [anti-S] did not change, falling from 981(396-2666) to 871(242-2092) BAU/ml, p=0.62. Overall, infection pre-transplant and [anti-S] at the time of transplantation predicted post-transplant infection risk. As [Anti-S] fail to respond to SARS-CoV-2 booster vaccines given early post-transplant, passive immunity may be beneficial to protect patients during this period.

Analysis of spontaneous reports of suspected adverse reactions after vaccination against COVID-19 in Slovakia. Introduction: The COVID-19 pandemic has resulted in more than 6.5 million deaths worldwide yet. Vaccination against the SARS-CoV-2 virus is a reliable way out of the pandemic, however, vaccination rate reaches only 58% in the Slovak Republic. Concerns about the adverse reactions of vaccines are one of the reasons for the low vaccination rate. Objective: The aim of our analysis was to review reported suspicions of adverse reactions (ARs) of registered COVID-19 vaccines (Comirnaty, Vaxzevria, Spikevax), which State Institute for Drug Control received from healthcare professionals and patients in the period from 1 January 2021 to 31 May 2021. Methods: Data were collected from the State Institute for Drug Control database, a retrospective analysis was carried out focusing on trends in the number of all reports of suspicions of adverse reactions sent to the State Institute for Drug Control during the previously mentioned period. We analysed the Retrieved data were analysed with the usage of descriptive statistics and comparison to historical data on drug adverse reactions in Slovakia was performed. Results: During the evaluation period, 5,763 reported suspicions of adverse reactions were analysed, overall, there was a significant ($p < 0.0001$) increase in the number of reported adverse reactions fivefold. 93% of ARs (n = 5,346) were reported for COVID-19 vaccines. In comparison of the extentof all adverse reactions, there is clearly a statistically significant difference between all types of vaccines administered at that time (p â‰¤ 0.0001). No statistically significant difference (p â‰¤ 0.238) was identified between Spikevax and Comirnaty in the proportion of serious adverse reactions. However, a significantly higher (p â‰¤ 0.00001) proportion of reported suspicions of serious adverse reactions was observed after the administration of Vaxzevria. Conclusion: This is the first analysis conducted in Slovakia aimed to reported adverse reactions in relation to the administration of COVID-19 vaccines. The rate of spontaneously reported suspected adverse reactions has been insufficient in the past for a long time; during the period from January to May 2021 the reporting rate increased due active calls for adverse reactions reporting. In concordance with European data, Vaxzevria had a significantly higher ratio of reported suspicions of serious adverse reactions.

Immune thrombocytopenia following SARS-CoV-2 vaccination in a female: Report of one case.

Persistent short nighttime sleep duration is associated with a greater post-COVID risk in fully mRNA-vaccinated individuals. Short nighttime sleep duration impairs the immune response to virus vaccination, and long nighttime sleep duration is associated with poor health status. Thus, we hypothesized that short (<6â€‰h) and long (>9â€‰h) nighttime sleepers have a higher post-COVID risk than normal nighttime sleepers, despite two doses of mRNA vaccine (which has previously been linked to lower odds of long-lasting COVID-19 symptoms). Post-COVID was defined as experiencing at

least one core COVID-19 symptom for at least three months (e.g., shortness of breath). Multivariate logistic regression adjusting for age, sex, BMI, and other factors showed in 9717 respondents (age span 18-99) that two mRNA vaccinations lowered the risk of suffering from post-COVID by about 21% (pâ€‰<â€‰0.001). When restricting the analysis to double-vaccinated respondents (nâ€‰=â€‰5918), short and long sleepers exhibited a greater post-COVID risk than normal sleepers (adjusted OR [95%-CI], 1.56 [1.29, 1.88] and 1.87 [1.32, 2.66], respectively). Among respondents with persistent sleep duration patterns during the pandemic compared to before the pandemic, short but not long sleep duration was significantly associated with the post-COVID risk (adjusted OR [95%-CI], 1.59 [1.24, 2.03] and 1.18 [0.70, 1.97], respectively). No significant association between sleep duration and post-COVID symptoms was observed in those reporting positive SARS-CoV-2 test results (nâ€‰=â€‰538). Our findings suggest that two mRNA vaccinations against SARS-CoV-2 are associated with a lower post-COVID risk. However, this protection may be less pronounced among those sleeping less than 6â€‰h per night. Our findings warrant replication in cohorts with individuals with confirmed SARS-CoV-2 infection.

Impact of COVID-19 vaccination in post-COVID cardiac complications. BACKGROUND: After the acute infection, COVID-19 can produce cardiac complications as well as long-COVID persistent symptoms. Although vaccination against COVID-19 represented a clear reduction in both mortality and ICU admissions, there is very little information on whether this was accompanied by a decrease in the prevalence of post-COVID cardiac complications. The aim of this study was to analyze the relationship between COVID-19 vaccination and the prevalence of post-COVID cardiac injury assessed by echocardiogram, and long-COVID persistent cardiac symptoms. METHODS: All patients who consulted for post-COVID evaluation 14 days after discharge from acute illness were included. Patients with heart disease were excluded. The relationship between complete vaccination scheme (at least two doses applied with 14 days or more since the last dose) and pathological echocardiographic findings, as well as the relationship of vaccination with persistent long-COVID symptoms, were evaluated by multivariate analysis, adjusting for age, sex and clinical variables that would have shown significant differences in univariate analysis. RESULTS: From 1883 patients, 1070 patients (56.8%) suffered acute COVID-19 without a complete vaccination scheme. Vaccination was associated with lower prevalence of cardiac injury (1.35% versus 4.11%, adjusted OR 0.33; 95% CI 0.17-0.65, p=0.01). In addition, vaccinated group had a lower prevalence of persistent long-COVID symptoms compared to unvaccinated patients (10.7% versus 18.3%, adjusted OR 0.52; 95% CI 0.40-0.69, p<0.001). CONCLUSION: Vaccination against COVID-19 was associated with lower post-COVID cardiac complications and symptoms, reinforcing the importance of fully vaccinating the population.

Anti-glomerular Basement Membrane Disease Concomitant with MPO-ANCA Positivity Concurrent with High Serum Levels of Interleukin-26 Following Coronavirus Disease 2019 Vaccination. As coronavirus disease 2019 (COVID-19) vaccine booster campaigns progress worldwide, new reports of complications following COVID-19 vaccination have emerged. We herein report a case of new-onset anti-glomerular basement membrane (GBM) disease concomitant with myeloperoxidase-antineutrophil cytoplasmic antibody positivity concurrent with high levels of interleukin (IL)-26 following the second dose of the Pfizer-BioNTech COVID-19 vaccine. The temporal association with vaccination in this case suggests that an enhanced neutrophilic immune response through IL-26 may have triggered necrotizing glomerulonephritis and a T-cell-mediated immune response to GBMs, leading to the development of anti-GBM antibodies, with an enhanced B-cell response after the vaccination triggering anti-GBM IgG and the onset of anti-GBM disease.

Allergy to Omalizumab: Lessons from a Reaction to the Coronavirus 2019 Vaccine. Omalizumab can cause hypersensitivity reactions. We herein report the first case of an 18-year-old woman with refractory cough-predominant asthma that correlated with allergic reactions caused by omalizumab

and the coronavirus disease 2019 (COVID-19) vaccine. The patient developed angioedema after taking omalizumab. She had previously experienced intense coughing immediately after receiving a COVID-19 vaccine. A skin prick test was positive for polysorbate 20, which was probably the cause of the allergic reactions to omalizumab and the COVID-19 vaccine. Clinicians should check for an allergic reaction, irrespective of its intensity, triggered by polysorbate and be careful when prescribing biologics to patients in order to avoid allergic reactions.

Incidence of Chronic Spontaneous Urticaria Following Receipt of the COVID-19 Vaccine Booster in Switzerland. This cohort study examines the association of the COVID-19 vaccine booster with chronic spontaneous urticaria in Swiss patients.

Reports of Guillain-BarrÃ© Syndrome After COVID-19 Vaccination in the United States. IMPORTANCE: Because of historical associations between vaccines and Guillain-BarrÃ© syndrome (GBS), the condition was a prespecified adverse event of special interest for COVID-19 vaccine monitoring. OBJECTIVE: To evaluate GBS reports to the Vaccine Adverse Event Reporting System (VAERS) and compare reporting patterns within 21 and 42 days after vaccination with Ad26.COV2.S (Janssen), BNT162b2 (Pfizer-BioNTech), and mRNA-1273 (Moderna) COVID-19 vaccines. DESIGN, SETTING, AND PARTICIPANTS: This retrospective cohort study was conducted using US VAERS reports submitted during December 2020 to January 2022. GBS case reports verified as meeting the Brighton Collaboration case definition for GBS in US adults after COVID-19 vaccination were included. EXPOSURES: Receipt of the Ad26.COV2.S, BNT162b2, or mRNA-1273 COVID-19 vaccine. MAIN OUTCOMES AND MEASURES: Descriptive analyses of GBS case were conducted. GBS reporting rates within 21 and 42 days after Ad26.COV2.S, BNT162b2, or mRNA-1273 vaccination based on doses administered were calculated. Reporting rate ratios (RRRs) after receipt of Ad26.COV2.S vs BNT162b2 or mRNA-1273 within 21- and 42-day postvaccination intervals were calculated. Observed-to-expected (OE) ratios were estimated using published GBS background rates. RESULTS: Among 487â€¯651â€¯785 COVID-19 vaccine doses, 17â€¯944â€¯515 doses (3.7%) were Ad26.COV2.S, 266â€¯859â€¯784 doses (54.7%) were BNT162b2, and 202â€¯847â€¯486 doses (41.6%) were mRNA-1273. Of 295 verified reports of individuals with GBS identified after COVID-19 vaccination (12 Asian [4.1%], 18 Black [6.1%], and 193 White [65.4%]; 17 Hispanic [5.8%]; 169 males [57.3%]; median [IQR] age, 59.0 [46.0-68.0] years), 275 reports (93.2%) documented hospitalization. There were 209 and 253 reports of GBS that occurred within 21 days and 42 days of vaccination, respectively. Within 21 days of vaccination, GBS reporting rates per 1â€¯000â€¯000 doses were 3.29 for Ad26.COV.2, 0.29 for BNT162b2, and 0.35 for mRNA-1273 administered; within 42 days of vaccination, they were 4.07 for Ad26.COV.2, 0.34 for BNT162b2, and 0.44 for mRNA-1273. GBS was more frequently reported within 21 days after Ad26.COV2.S than after BNT162b2 (RRRâ€‰=â€‰11.40; 95% CI, 8.11-15.99) or mRNA-1273 (RRRâ€‰=â€‰9.26; 95% CI, 6.57-13.07) vaccination; similar findings were observed within 42 days after vaccination (BNT162b2: RRRâ€‰=â€‰12.06; 95% CI, 8.86-16.43; mRNA-1273: RRRâ€‰=â€‰9.27; 95% CI, 6.80-12.63). OE ratios were 3.79 (95% CI, 2.88-4.88) for 21-day and 2.34 (95% CI, 1.83-2.94) for 42-day intervals after Ad26.COV2.S vaccination and less than 1 (not significant) after BNT162b2 and mRNA-1273 vaccination within both postvaccination periods. CONCLUSIONS AND RELEVANCE: This study found disproportionate reporting and imbalances after Ad26.COV2.S vaccination, suggesting that Ad26.COV2.S vaccination was associated with increased risk for GBS. No associations between mRNA COVID-19 vaccines and risk of GBS were observed.

Bilateral Lymphadenopathy After COVID Vaccine in 18F-Choline PET/MRI Performed for Hyperparathyroidism. We describe a case of a 56-year-old woman with primary hyperparathyroidism. 18F-Choline PET/MRI revealed incidental bilateral axillary lymphadenopathy with mild-moderate increased 18F-choline uptake. The patient had her first and third doses of COVID-19 vaccines from the left arm and second dose of vaccine from the right arm before PET examination.

Immunogenicity and reactogenicity of heterologous immunization schedules with COVID-19 vaccines: a systematic review and network meta-analysis. BACKGROUND: Data on the immunogenicity and safety of heterologous immunization schedules are inconsistent. This study aimed to evaluate the immunogenicity and safety of homologous and heterologous immunization schedules. METHODS: Multiple databases with relevant studies were searched with an end date of October 31, 2021, and a website including a series of Coronavirus disease 2019 studies was examined for studies before March 31, 2022. Randomized controlled trials (RCTs) that compared different heterologous and homologous regimens among adults that reported immunogenicity and safety outcomes were reviewed. Primary outcomes included neutralizing antibodies against the original strain and serious adverse events (SAEs). A network meta-analysis (NMA) was conducted using a random-effects model. RESULTS: In all, 11 RCTs were included in the systematic review, and nine were ultimately included in the NMA. Among participants who received two doses of CoronaVac, another dose of mRNA or a non-replicating viral vector vaccine resulted in a significantly higher level of neutralizing antibody than a third CoronaVac 600 sino unit (SU); a dose of BNT162b2 induced the highest geometric mean ratio (GMR) of 15.24, 95% confidence interval [CI]: 9.53-24.39. Following one dose of BNT162b2 vaccination, a dose of mRNA-1273 generated a significantly higher level of neutralizing antibody than BNT162b2 alone (GMRâ€Š=â€Š1.32; 95% CI: 1.06-1.64), NVX-CoV2373 (GMRâ€Š=â€Š1.60; 95% CI: 1.16-2.21), or ChAdOx1 (GMRâ€Š=â€Š1.80; 95% CI: 1.25-2.59). Following one dose of ChAdOx1, a dose of mRNA-1273 was also more effective for improving antibody levels than ChAdOx1 (GMRâ€Š=â€Š11.09; 95% CI: 8.36-14.71) or NVX-CoV2373 (GMRâ€Š=â€Š2.87; 95% CI: 1.08-3.91). No significant difference in the risk for SAEs was found in any comparisons. CONCLUSIONS: Relative to vaccination with two doses of CoronaVac, a dose of BNT162b2 as a booster substantially enhances immunogenicity reactions and has a relatively acceptable risk for SAEs relative to other vaccines. For primary vaccination, schedules including mRNA vaccines induce a greater immune response. However, the comparatively higher risk for local and systemic adverse events introduced by mRNA vaccines should be noted. REGISTRATION: PROSPERO; https://www.crd.york.ac.uk/PROSPERO/ ; No. CRD42021278149.

Immunogenicity, effectiveness, and safety of COVID-19 vaccines among children and adolescents aged 2-18Â years: an updated systematic review and meta-analysis. BACKGROUND: During the coronavirus disease 2019 (COVID-19) pandemic, there is an urgent need for safe and effective COVID-19 vaccines to protect children and adolescents. This study aims to provide scientific evidence and recommendations for the application of COVID-19 vaccines in children and adolescents by analyzing the latest studies. METHODS: We systematically searched MEDLINE (accessed through PubMed), Embase, and Web of Science from January 1, 2020, to October 8, 2022. Eligible clinical trials, cohort studies, caseâ€’control studies, and cross-sectional studies with extractable data were included in immunogenicity, effectiveness, and safety analyses. According to the heterogeneity, we chose a fixed-effect model (when I(2)â€‰â‰¤â€‰50) or a random-effects model (when I(2)â€‰>â€‰50) to pool effect values. RESULTS: A total of 88 articles were included. The seroconversion rates after the first, second, and third doses of the vaccines were 86.10%, 96.52%, and 99.87%, respectively. After the first and second doses, vaccine effectiveness (VE) against severe acute respiratory syndrome coronavirus 2 infection was 42.87% [95% confidence interval (CI)â€‰=â€‰27.09%-58.65%] and 63.33% (95% CIâ€‰=â€‰52.09%-74.56%), respectively. After the first and second doses, VE against COVID-19 was 60.65% (95% CIâ€‰=â€‰44.80%-76.50%) and 75.77% (95% CIâ€‰=â€‰63.99%-87.56%), respectively. VE against hospitalization due to COVID-19 after the first and second doses was 72.74% (95% CIâ€‰=â€‰51.48%-94.01%) and 82.78% (95% CIâ€‰=â€‰75.78%-89.78%), respectively. The most common adverse events were injection site pain, fatigue/asthenia/tiredness, headache, myalgia/muscle pain, and chills. The incidence rate of myocarditis or pericarditis was

2.42/100,000 people. In addition, the subgroup analysis showed that children agedâ€‰â‰¤â€‰5Â years had the lowest incidence of adverse events, and the incidence rate of adverse events was higher for mRNA vaccines than for inactivated vaccines. CONCLUSIONS: COVID-19 vaccines have good immunogenicity, effectiveness, and safety among children and adolescents. We recommend that children and adolescents be vaccinated as soon as possible to protect them and slow the spread of COVID-19.

Effectiveness of Three Doses of mRNA COVID-19 Vaccines in the Hemodialysis Population during the Omicron Period. BACKGROUND: Coronavirus disease 2019 (COVID-19) vaccine effectiveness studies in the hemodialysis population have demonstrated that two doses of mRNA COVID-19 vaccines are effective against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and severe complications when Alpha and Delta were predominant variants of concern. Vaccine effectiveness after a third dose versus two doses for preventing SARS-CoV-2 infection and severe COVID-19 in the hemodialysis population against Omicron is not known. METHODS: We conducted a retrospective cohort study in Ontario, Canada, between December 1, 2021, and February 28, 2022, in the maintenance hemodialysis population who had received two versus three doses of mRNA COVID-19 vaccines. COVID-19 vaccination, SARS-CoV-2 infection, and related hospitalization and death were determined from provincial databases. The primary outcome was the first RT-PCR confirmed SARS-CoV-2 infection, and the secondary outcome was a SARS-CoV-2-related severe outcome, defined as either hospitalization or death. RESULTS: A total of 8457 individuals receiving in-center hemodialysis were included. At study initiation, 2334 (28%) individuals received three doses, which increased to 7468 (88%) individuals by the end of the study period. The adjusted hazard ratios (aHR) for SARS-CoV-2 infection (aHR, 0.58; 95% confidence interval [CI], 0.50 to 0.67) and severe outcomes (hospitalization or death) (aHR, 0.40; 95% CI, 0.28 to 0.56) were lower after three versus two doses of mRNA vaccine. Prior infection, independent of vaccine status, was associated with a lower risk of reinfection, with an aHR of 0.44 (95% CI, 0.27 to 0.73). CONCLUSIONS: Three-dose mRNA COVID-19 vaccination was associated with lower incidence of SARS-CoV-2 infection and severe SARS-CoV-2-related outcomes during the Omicron period compared with two doses.

Kidney Biopsy Findings in Patients with SARS-CoV-2 Infection or After COVID-19 Vaccination. BACKGROUND: Emerging case series described a temporal association between severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination and de novo or relapsing kidney diseases. We aimed to further understand vaccination- and coronavirus disease 2019 (COVID-19)-associated kidney diseases. METHODS: We present findings from native kidney biopsies of patients recently vaccinated against SARS-CoV-2 (n =27) and those with COVID-19 (n =15), reviewed at a single German center. Diagnoses were compared among all native kidney biopsies (n =10,206) obtained between the prepandemic (2019), pandemic (2020), and vaccination periods (2021) to determine whether there was an increase in kidney diseases in the observed periods. RESULTS: Biopsy indication was increased serum creatinine and/or new-onset proteinuria. Glomerulopathies (20/27, 74%) were more common than tubulointerstitial diseases in postvaccination patients, with necrotizing GN (8/27, 30%) and primary podocytopathies and other GN types (6/27, 22% each) the most common forms. Acute tubular injury was the most common kidney disease in patients with COVID-19, followed by thrombotic microangiopathy (TMA) and necrotizing GN. The postvaccination and COVID-19 infection groups had similar kidney function recovery rates (69% and 73%, respectively). Furthermore, the frequencies of necrotizing GN, pauci-immune GN, TMA, or primary podocytopathies at our center did not increase between 2019 and 2021. CONCLUSIONS: We observed differences in entity frequencies between the SARS-CoV-2 vaccination or COVID-19 groups, with glomerulopathies being more common in patients after vaccination and tubulointerstitial diseases in patients with COVID-19. Cases of TMA were observed only in the COVID-19 group. We

detected no increase in the frequency of necrotizing GN, TMA, or podocytopathies between 2019 and 2021. CLINICAL TRIAL REGISTRY NAME AND REGISTRATION NUMBER: Kidney Histopathology After COVID-19 and SARS-CoV-2 Vaccination, NCT05043168.

Adhesive Capsulitis After COVID-19 Vaccination: A Case Series. Of the many bizarre complications of administration of the COVID 19 vaccine, adhesive capsulitis is almost unheard of, although shoulder injury related to vaccine administration, which by definition has symptom onset within 48 hrs and is caused by faulty injection technique, has been rarely reported. Nine cases of adhesive capsulitis, five males and four females with a mean age of 48.7 Â± 12.7 yrs, presenting within 1 mo of intramuscular Covishield vaccine on the ipsilateral deltoid and fulfilling the standard UK FROST Multicenter Study diagnostic criteria are reported. The mean time interval from vaccination until symptom onset was 12.3 Â± 3.1 days, and mean symptom duration was 9.4 Â± 2.4 wks. Conventional treatment with nonsteroidal anti-inflammatory drugs, followed by intra-articular steroid injection coupled with suprascapular nerve steroid block, improved the pain score and range of movement in 8 wks. The exact pathogenesis remains an enigma, although mechanisms such as local spread via deltoid muscle microvasculature, nerves, or shoulder injury related to vaccine administration causing secondary adhesive capsulitis have been hypothesized. While adhesive capsulitis is a very common diagnosis in the physiatric outpatient setting, the possible association with Covishield vaccination, the Indian version of the Oxford AstraZeneca recombinant ChAdOx1 nCoV-19 vaccine, is almost absent in existing literature and hence likely to be missed by clinicians, which necessitates this report.

Limited enhancement of antibody and B-cell responses to prototype booster vaccination following SARS-CoV-2 Delta breakthrough infection.

Safety of COVID-19 vaccines in multiple sclerosis: A systematic review and meta-analysis. BACKGROUND: Data are sparse regarding the safety of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines in patients with multiple sclerosis (MS). OBJECTIVE: To estimate (1) the pooled proportion of MS patients experiencing relapse among vaccine recipients; (2) the rate of transient neurological worsening, adverse events, and serious adverse events; (3) the previous outcomes of interest for different SARS-CoV-2 vaccine types. METHODS: Systematic review and meta-analysis of pharmacovigilance registries and observational studies. RESULTS: Nineteen observational studies comprising 14,755 MS patients who received 23,088 doses of COVID-19 vaccines were included. Mean age was 43.3â€‰years (95% confidence interval (CI): 40-46.6); relapsing-remitting, secondary-progressive, primary-progressive MS and clinically isolated syndrome were diagnosed in 82.6% (95% CI: 73.9-89.8), 12.6% (95% CI: 6.3-20.8), 6.7% (95% CI: 4.2-9.9), and 2.9% (95% CI: 1-5.9) of cases, respectively. The pooled proportion of MS patients experiencing relapse at a mean time interval of 20â€‰days (95% CI: 12-28.2) from vaccination was 1.9% (95% CI: 1.3%-2.6%; I(2)â€‰=â€‰78%), with the relapse risk being independent of the type of administered SARS-CoV-2-vaccine (p for subgroup differencesâ€‰=â€‰0.7 for messenger RNA (mRNA), inactivated virus, and adenovector-based vaccines). After vaccination, transient neurological worsening was observed in 4.8% (95% CI: 2.3%-8.1%) of patients. Adverse events and serious adverse events were reported in 52.8% (95% CI: 46.7%-58.8%) and 0.1% (95% CI: 0%-0.2%) of vaccinations, respectively. CONCLUSION: COVID-19 vaccination does not appear to increase the risk of relapse and serious adverse events in MS. Weighted against the risks of SARS-CoV-2-related complications and MS exacerbations, these safety data provide compelling pro-vaccination arguments for MS patients.

Assessment of humoral and cellular immunity after bivalent BNT162b2 vaccination and potential association with reactogenicity. OBJECTIVES: This study investigated the feasibility and clinical value of using a novel, automated and high-throughput SARS-CoV-2 Interferon Gamma Release Assay (IGRA), combined with total anti-SARS-CoV-2 antibodies assessment, for evaluating the immune response after bivalent BNT162b2 vaccination. METHODS: A cohort of healthcare workers, who

already underwent primary vaccination and boosting with monovalent BNT162b2 vaccine, received a booster dose of the new BNT162b2 bivalent formulation. Blood samples were taken immediately before vaccination (T0) and 1Â month afterwards (T1). Humoral and cellular immunity were assayed with Roche Elecsys Anti-SARS-CoV-2 and Roche Elecsys IGRA SARS-CoV-2, respectively. RESULTS: The study population consisted of 51 subjects (median age: 43Â years; 51% females). Total anti-SARS-CoV-2 antibodies and IGRA SARS-CoV-2 values increased at T1 from 9,050 to 25,000Â BAU/mL ($p<0.001$), and from 0.44 to 0.78Â IU/mL ($p=0.385$), accounting for median increase of 2.0 and 1.6 folds, respectively. Increased T1 values of total anti-SARS-CoV-2 antibodies and IGRA SARS-CoV-2 were recorded in 100% and 68.6% subjects, respectively. In those with baseline values below the median, post-vaccine levels displayed larger increases of 3.3 and 5.1 folds for anti-SARS-CoV-2 total antibodies and IGRA SARS-CoV-2, respectively. The variation of total anti-SARS-CoV-2 antibodies was inversely associated with their T0 values ($r=-0.97$; $p<0.001$), whilst that of IGRA SARS-CoV-2 was inversely associated with its T0 value ($r=-0.58$; $p<0.001$). No other signifcant associations were found with demographical or clinical variables, including side effects. CONCLUSIONS: The bivalent BNT162b2 vaccine booster enhances humoral and cellular immunity against SARS-CoV-2, especially in recipients with lower baseline biological protection.

A third dose of COVID-19 mRNA vaccine induces limited humoral response in stem cell transplant recipients who got two vaccine doses before transplant.

Multimorbidity and Its Effect on Self-Reported Adverse Effects Following COVID-19 Vaccination. Introduction The coronavirus disease 2019 (COVID-19) vaccination has been suggested for those with comorbidities, although there are concerns regarding the vaccine's safety. This study aimed to compare the severity and incidence of post-vaccination side effects in people with and without comorbidities. Another aim of this study was also to look for the effect of multimorbidity on adverse events. Methods This observational study was conducted from November 2021 to February 2022. Data were collected from all over Pakistan using a self-administered online questionnaire that inquired about the subject's demographic, clinical, and COVID-19 vaccination profiles. Data analysis was done by using SPSS software version 22.0. (Chicago, IL, IBM Corp.). Results A total of 421 participants were included in the study, and 31.4% of individuals had underlying comorbidity. The overall mean age was 33 years (range: 13-85 years). This study included recipients of all major types of COVID-19 vaccines being used in Pakistan. Only 67.4% ofÂ the subjects had only underlying comorbidity, and hypertension was the most common one out of all comorbidities. Participants with comorbidities were not at a greater risk to produce vaccine-related adverse events when compared to those with no comorbidities. Comorbidity was also found to be statistically non-significant to the severity of the side effects. Only one subject with comorbidity produced a side effectÂ and required hospitalization. Multimorbidity was not associated with a greater incidence of side effects. Multimorbidity was not significantly linked with the severity of the adverse effects, except muscle pain ($p<0.05$) and breathlessness ($p<0.05$). Conclusion It can be concluded that comorbidities do not affect the COVID-19 vaccine's reactogenicity but studies on an extensive scale should be conducted regarding individuals with multiple pre-existing comorbidities.

Short-term Side Effects of COVID-19 Vaccines (Astrazeneca, Sputnik-V, and Sinopharm) in Health Care Workers: A Cross-Sectional Study in Iran. Background: The occurrence of side effects of vaccines plays an important role in their acceptance by people. Therefore, the aim of this study was to evaluate the side effects of COVID-19 vaccines (Sputnik-V, AstraZeneca, and Sinopharm) in Neyshabur health care workers (HCWs). Methods: A cross-sectional study was performed to evaluate the side effects of COVID-19 vaccines among the HCWs of the Neyshabur University of Medical Sciences from July 31, 2021, to September 6, 2021, by using a self-report checklist. We sent our checklist via an internet link to collect data such as demographic data of participants, previous COVID-19 infection

(PCR+), vaccine information and side effects of vaccines. Mean, median and standard deviation were used to determine descriptive statistics and a logistic regression model was also used to determine the relationship between the type of vaccine and its side effects. Results: 317 participants filled out the checklist; among them 47% (N= 149), 21.14% (N= 67), and 31.86% (N= 101) have been vaccinated with Sputnik-V, AstraZeneca, and Sinopharm, respectively. The percentage of side effects after the first dose was 62.15% (N= 197). The Percentage of local side effects was 76% (N= 241) and systemic side effects were 29.36% (N= 95). The most common side effects in all three vaccines were injection site pain (75.08%, N= 240), muscle pain (62.46%, N=198) and headache (52.05%, N=165). Also, the odds ratio of injection site pain, chill and sweating in those who received the AstraZeneca vaccine was 3.9(95% CI, 1.7-9.3), 3.7 (95% CI, 1.8-7.3), and 3.2 (95% CI, 1.7-63), of those who received the Sputnik V vaccine (p â‰¤ 0.001). Conclusion: The most common side effects among our participants were injection site pain, muscle pain, and headache. Most of the post-vaccination side effects are mild to moderate in severity and self-limited. Reported side effects were more common in recipients with AstraZeneca than in those with Sputnik-V and Sinopharm.

Factors associated with COVID-19 vaccine uptake in people with kidney disease: an OpenSAFELY cohort study. OBJECTIVE: To characterise factors associated with COVID-19 vaccine uptake among people with kidney disease in England. DESIGN: Retrospective cohort study using the OpenSAFELY-TPP platform, performed with the approval of NHS England. SETTING: Individual-level routine clinical data from 24 million people across GPs in England using TPP software. Primary care data were linked directly with COVID-19 vaccine records up to 31 August 2022 and with renal replacement therapy (RRT) status via the UK Renal Registry (UKRR). PARTICIPANTS: A cohort of adults with stage 3-5 chronic kidney disease (CKD) or receiving RRT at the start of the COVID-19 vaccine roll-out was identified based on evidence of reduced estimated glomerular filtration rate (eGFR) or inclusion in the UKRR. MAIN OUTCOME MEASURES: Dose-specific vaccine coverage over time was determined from 1 December 2020 to 31 August 2022. Individual-level factors associated with receipt of a 3-dose or 4-dose vaccine series were explored via Cox proportional hazards models. RESULTS: 992â€‰205 people with stage 3-5 CKD or receiving RRT were included. Cumulative vaccine coverage as of 31 August 2022 was 97.5%, 97.0% and 93.9% for doses 1, 2 and 3, respectively, and 81.9% for dose 4 among individuals with one or more indications for eligibility. Delayed 3-dose vaccine uptake was associated with younger age, minority ethnicity, social deprivation and severe mental illness-associations that were consistent across CKD severity subgroups, dialysis patients and kidney transplant recipients. Similar associations were observed for 4-dose uptake. CONCLUSION: Although high primary vaccine and booster dose coverage has been achieved among people with kidney disease in England, key disparities in vaccine uptake remain across clinical and demographic groups and 4-dose coverage is suboptimal. Targeted interventions are needed to identify barriers to vaccine uptake among under-vaccinated subgroups identified in the present study.

Induction and subsequent decline of S1-specific T cell reactivity after COVID-19 vaccination. We analyzed magnitude and duration of SARS-CoV-2-specific T cell responses in healthy, infection-naÃ¯ve subjects receiving COVID-19 vaccines. Overlapping peptides spanning the N-terminal spike 1 (S1) domain of the spike protein triggered secretion of the T cell-derived cytokine interleukin-2 ex vivo in 94/94 whole blood samples from vaccinated subjects at levels exceeding those recorded in all 45 pre-vaccination samples. S1-specific T cell reactivity was stronger in vaccinated subjects compared with subjects recovering from natural COVID-19 and decayed with an estimated half-life of 134Â days in the first six months after the 2nd vaccination. We conclude that COVID-19 vaccination induces robust T cell immunity that subsequently declines. EudraCT 2021-000349-42. https://www.clinicaltrialsregister.eu/ctr-search/search?query=2021-000349-42.

Hypereosinophilia after vaccination with the SARS-CoV-2 mRNA vaccines.

Inequities in COVID-19 vaccine and booster coverage across Massachusetts ZIP codes after the emergence of Omicron: A population-based cross-sectional study. BACKGROUND: Inequities in Coronavirus Disease 2019 (COVID-19) vaccine and booster coverage may contribute to future disparities in morbidity and mortality within and between Massachusetts (MA) communities. METHODS AND FINDINGS: We conducted a population-based cross-sectional study of primary series vaccination and booster coverage 18 months into the general population vaccine rollout. We obtained public-use data on residents vaccinated and boosted by ZIP code (and by age group: 5 to 19, 20 to 39, 40 to 64, 65+) from MA Department of Public Health, as of October 10, 2022. We constructed population denominators for postal ZIP codes by aggregating census tract population estimates from the 2015-2019 American Community Survey. We excluded nonresidential ZIP codes and the smallest ZIP codes containing 1% of the state's population. We mapped variation in ZIP code-level primary series vaccine and booster coverage and used regression models to evaluate the association of these measures with ZIP code-level socioeconomic and demographic characteristics. Because age is strongly associated with COVID-19 severity and vaccine access/uptake, we assessed whether observed socioeconomic and racial/ethnic inequities persisted after adjusting for age composition and plotted age-specific vaccine and booster coverage by deciles of ZIP code characteristics. We analyzed data on 418 ZIP codes. We observed wide geographic variation in primary series vaccination and booster rates, with marked inequities by ZIP code-level education, median household income, essential worker share, and racial/ethnic composition. In age-stratified analyses, primary series vaccine coverage was very high among the elderly. However, we found large inequities in vaccination rates among younger adults and children, and very large inequities in booster rates for all age groups. In multivariable regression models, each 10 percentage point increase in "percent college educated" was associated with a 5.1 (95% confidence interval (CI) 3.9 to 6.3, $p < 0.001$) percentage point increase in primary series vaccine coverage and a 5.4 (95% CI 4.5 to 6.4, $p < 0.001$) percentage point increase in booster coverage. Although ZIP codes with higher "percent Black/Latino/Indigenous" and higher "percent essential workers" had lower vaccine coverage (-0.8, 95% CI -1.3 to -0.3, $p < 0.01$; -5.5, 95% CI -7.3 to -3.8, $p < 0.001$), these associations became strongly positive after adjusting for age and education (1.9, 95% CI 1.0 to 2.8, $p < 0.001$; 4.8, 95% CI 2.6 to 7.1, $p < 0.001$), consistent with high demand for vaccines among Black/Latino/Indigenous and essential worker populations within age and education groups. Strong positive associations between "median household income" and vaccination were attenuated after adjusting for age. Limitations of the study include imprecision of the estimated population denominators, lack of individual-level sociodemographic data, and potential for residential ZIP code misreporting in vaccination data. CONCLUSIONS: Eighteen months into MA's general population vaccine rollout, there remained large inequities in COVID-19 primary series vaccine and booster coverage across MA ZIP codes, particularly among younger age groups. Disparities in vaccination coverage by racial/ethnic composition were statistically explained by differences in age and education levels, which may mediate the effects of structural racism on vaccine uptake. Efforts to increase booster coverage are needed to limit future socioeconomic and racial/ethnic disparities in COVID-19 morbidity and mortality.

European Working Group on SARS-CoV-2: Current Understanding, Unknowns, and Recommendations on the Neurological Complications of COVID-19. Background: The emergence of COVID-19 was rapidly followed by infection and the deaths of millions of people across the globe. With much of the research and scientific advancement rightly focused on reducing the burden of severe and critical acute COVID-19 infection, the long-term effects endured by those who survived the acute infection has been previously overlooked. Now, an appreciation for the post-COVID-19 condition, including its neurological manifestations, is growing, although there remain many unknowns regarding the

etiology and risk factors of the condition, as well as how to effectively diagnose and treat it. Methods: Here, drawing upon the experiences and expertise of the clinicians and academics of the European working group on COVID-19, we have reviewed the current literature to provide a comprehensive overview of the neurological sequalae of the post-COVID-19 condition. Results: In this review, we provide a summary of the neurological symptoms associated with the post-COVID-19 condition, before discussing the possible mechanisms which may underly and manifest these symptoms. Following this, we explore the risk factors for developing neurological symptoms as a result of COVID-19 and the post-COVID-19 condition, as well as how COVID-19 infection may itself be a risk factor for the development of neurological disease in the future. Lastly, we evaluate how the post-COVID condition could be accurately diagnosed and effectively treated, including examples of the current guidelines, clinical outcomes, and tools that have been developed to aid in this process, as well as addressing the protection provided by COVID-19 vaccines against the post-COVID-19 condition. Conclusions: Overall, this review provides a comprehensive overview of the neurological sequalae of the post-COVID-19 condition. Impact statement With our understanding of the neurological complications of the post-COVID-19 condition currently lacking sufficient depth, this review aimed at highlighting the current knowns and unknowns of the post-COVID-19 condition. In this review, we draw upon the experiences and expertise of the clinicians and academics of the European working group on COVID-19, as well as explore the current published literature, to evaluate a range of topics associated with the neurological complications of the post-COVID-19 condition. As a result, we have provided a comprehensive review of the topic. The European Working Group on SARS-CoV-2 Many essential questions surrounding COVID-19 remain unanswered, including its neurological complications and associated sequalae. In this review, we aim at identifying the current gaps in our understanding of post-COVID-19 neurological sequalae and suggest how future studies should be undertaken to fill these gaps. This review will draw upon the current biological and mechanistic understanding of COVID-19 and post-COVID-19 complications to discuss the clinically relevant aspects associated with the neurological manifestations of post-COVID-19 syndrome. From our discussions, the following questions were considered highly relevant for contemplation.
Salivary and serum IgA and IgG after COVID-19 and after immunization with COVID-19 vaccines.
Safety and immunogenicity of COVID-19 vaccination in immunocompromised patients. The coronavirus disease 2019 (COVID-19) pandemic poses a great threat to public health. Individuals who are immunocompromised because of the progression of the primary disease or receiving immunosuppressive medications are prone to severe COVID-19 complications and poor outcomes. Abundant data have shown that many COVID-19 vaccines are safe and effective in large-scale populations; however, these clinical trials have excluded immunocompromised populations. Available evidence indicates that immunocompromised populations have a blunted immune response to other vaccines, raising concerns regarding the efficacy of COVID-19 vaccination in these populations. Thus, there is an urgent need to delineate the efficacy of COVID-19 vaccines in these vulnerable populations. Here, we review the characteristics of specific humoral and cellular responses to COVID-19 vaccination in immunocompromised populations, including HIV-infected patients and those receiving immunosuppressive treatment, especially solid organ transplant recipients and those undergoing anti-CD20 treatment. We also addressed the challenges that immunocompromised populations will face in the future pandemic and the need for basic and clinical translational studies to highlight the best vaccination strategies for these populations.
The impact of Omicron pandemic and COVID-19 vaccination on the pancreatic adenocarcinoma patients. BACKGROUND: The coronavirus disease 2019 (COVID-19) pandemic resulted in enormous medical and economic burden worldwide during the past 3 years. The vaccination was deemed the effective option to prevent the severe symptoms, and especially recommended among

cancer patients. Shanghai experienced the first lockdown during the recent Omicron pandemic since 2019. How patients with pancreatic adenocarcinoma (PAC) suffered from the pandemic and how vaccination influenced their oncological outcomes were unexplored yet. METHOD: The retrospective study was carried out in a high-volume referral center including 1157 consecutively enrolled patients with PAC experiencing the COVID-19 pandemic. The primary outcome was the overall survival (OS). RESULTS: Limited postoperative patients (9.21%) received the vaccination. The lockdown in Shanghai (April to May, 2022) was not observed impacting the survival prognoses of patients with PAC. Though vaccination was not significantly associated with OS itself (adjusted hazard ratio (aHR): 2.032 [0.940-4.391], p = 0.071), it was discovered to synergistically improve the chemotherapy effect in the multivariate analyses (interaction p = 0.023). CONCLUSION: The vaccination itself did not influence the survival prognoses of patients with PAC. A potential positive interaction was observed between chemotherapy and vaccination despite the limited follow-up time. The postoperative patients should consider the vaccination more. The patients with PAC did not suffer worse prognostic outcomes from the strict sanitary policy during the wave of COVID-19 pandemic in Shanghai.

B cell response after SARS-CoV-2 mRNA vaccination in people living with HIV. BACKGROUND: Limited longitudinal data are available on immune response to mRNA SARS-CoV-2 vaccination in people living with HIV (PLWHIV); therefore, new evidence on induction and persistence of spike-specific antibodies and B cells is needed. METHODS: In this pilot study we investigated the spike-specific humoral and B cell responses up to six months after vaccination with two doses of mRNA vaccines in 84 PLWHIV under antiretroviral therapy compared to 79 healthy controls (HCs). RESULTS: Spike-specific IgG persisted six months in PLWHIV with no significant differences compared to HCs, even though a significantly lower IgG response was observed in patients with CD4(+) T cells <Â 350/mmc. The frequency of subjects with antibodies capable of inhibiting ACE2/RBD binding was comparable between PLWHIV and HCs a month after the second vaccine dose, then a higher drop was observed in PLWHIV. A comparable percentage of spike-specific memory B cells was observed at month six in PLWHIV and HCs. However, PLWHIV showed a higher frequency of spike-specific IgD(-) CD27(-) double-negative memory B cells and a significantly lower rate of IgD(-) CD27(+) Ig-switched memory B cells compared to HCs, suggesting a reduced functionality of the antigen-specific memory B population. CONCLUSIONS: The mRNA vaccination against SARS-CoV-2 elicits humoral and B cell responses quantitatively similar between PLWHIV and HCs, but there are important differences in terms of antibody functionality and phenotypes of memory B cells, reinforcing the notion that tailored vaccination policies should be considered for these patients.

 SARS-CoV-2 vaccination has been demonstrated to protect people from severe COVID-19 and death. This is achieved through the induction of a specific immune response that recognizes and responds to the virus. Limited data are available on the immune response to SARS-CoV-2 vaccination in people living with HIV (PLWHIV). In this study, we evaluated the immune response up to six months after vaccination with two doses of vaccines in PLWHIV being treated with the standard antiretroviral therapy. We show that the immune response observed in PLWHIV is broadly similar to that in healthy subjects but that there are some differences in the cells induced as part of the immune response. We therefore suggest that specific vaccination policies should be considered for these PLWHIV.

A case series of bacillus Calmette-GuÃ©rin scar reactivation after administration of both mRNA and viral vector COVID-19 vaccines. AIM: Reactivation of the scar resulting from intradermal injection of bacillus Calmette-GuÃ©rin (BCG) is a common specific reaction in Kawasaki's disease. It has also sporadically been associated with viral infections, multisystem inflammatory syndrome in children, influenza vaccination and mRNA COVID-19 vaccination. In this case series, characteristics of BCG scar reactivation after different COVID-19 vaccinations are presented and possible mechanisms are discussed. METHODS: Data were collected from the spontaneous reporting system of the

Netherlands Pharmacovigilance Centre Lareb. Descriptives were made for the case reports in which a BCG scar reactivation was detected. RESULTS: Since the start of the COVID-19 vaccination campaign in January 2021, the Netherlands Pharmacovigilance Centre Lareb has received 22 case reports of BCG reactivation after vaccination with a COVID-19 vaccine. In 20 case reports, it concerned mRNA COVID-19 vaccines Moderna (14) and Pfizer (6). In two case reports, the viral vector COVID-19 vaccine AstraZeneca was administered. Erythema and pain were the most frequently reported symptoms and the size of the inflammation was between 1.5 and 5 cm. BCG scar reactivation occurred with a median time to onset of 2 days after the second or booster COVID-19 vaccination, whereas the median time to onset was 7 days after the first COVID-19 vaccination. None of the BCG scar reactivations were treated. CONCLUSIONS: The exact mechanism of the occurrence of BCG scar reactivation remains unknown, but involvement of heat shock protein 65 is suggested. BCG scar reactivation is a nonserious, self-limiting reaction that can occur after vaccination with both mRNA and viral vector COVID-19 vaccines.

Concurrent facial and trigeminal nerve palsies in a child following COVID-19 vaccination with the Pfizer vaccine. We present the case of a teenaged boy who attended our Ear, Nose and Throat Emergency clinic with a left-sided lower motor neuron (LMN) facial nerve paralysis associated with sensory loss in the distribution of the ophthalmic (V1) and maxillary (V2) divisions of the trigeminal nerve. This happened 3 days following a first dose of the Pfizer-BioNTech BNT162b2 vaccine. He had a House-Brackmann grade V facial palsy, with marked inability to close the left eye. He was treated with a 10-day course of oral steroids and referred to ophthalmology for eye care. He had an MRI scan of the head, which revealed no space occupying lesions or other abnormalities. Over the 6-week period of follow-up, the patient's V1 and V2 sensation gradually resolved, along with improvement of his LMN facial nerve palsy to House-Brackmann grade 3. Despite the potential temporal relationship, it is not possible to establish a causal relationship between the patient's symptoms and the Pfizer-BioNTech BNT162b2 vaccine, thus further research is required.

COVID-19 lateral flow IgG seropositivity and serum neutralising antibody responses after primary and booster vaccinations in Chile: a cross-sectional study. BACKGROUND: By June 30, 2022, 92Â·6% of the Chilean population older than 18 years had received a full primary SARS-CoV-2 vaccine series, mostly with CoronaVac (Sinovac Biotech), and 78Â·4% had received a booster dose, mostly heterologous with BNT162b2 (Pfizer-BioNTech) and ChAdOx1 (AstraZeneca). We previously reported national seroprevalence data from lateral flow testing of IgG SARS-CoV-2 antibodies up to 16 weeks after primary vaccination. Our aim here was to study IgG seropositivity dynamics up to 30 weeks after primary vaccination and, in CoronaVac recipients, up to 26 weeks after booster vaccination, and to establish the correlation between lateral flow tests and neutralising antibody titres. METHODS: In this cross-sectional study, testing stations for SARS-CoV-2 IgG detection were selected and installed from March 12, 2021, in hotspots in 24 large Chilean cities, and were maintained until March 31, 2022. Individuals voluntarily approaching the testing stations were invited to perform a rapid lateral flow test via a finger prick and complete a questionnaire. Between Aug 12, 2021, and April 1, 2022, volunteers seeking medical care in the Mutual de Seguridad de la CÃ¡mara Chilena de la ConstrucciÃ³n provided blood samples for lateral flow testing and neutralising antibody studies; inclusion criteria were age at least 18 years, history of complete primary vaccination series with CoronaVac, BNT162b2, or ChAdOx1, or no vaccine, and no previous COVID-19 diagnosis. We tested the difference in IgG positivity across time, and between primary and booster doses, in all eligible participants with complete records, controlling for age, gender, and comorbidities. We also assessed the predictive power of neutralising antibody titres and sociodemographic characteristics on the probability of IgG positive results using multivariable logistic regression. FINDINGS: Of 107â€‰220 individuals recruited at the testing stations, 101â€‰070 were included in our analysis (59â€‰862

[59Â·2%] women and 41â€‰208 [40Â·8%] men). 65â€‰902 (65Â·2%) received primary vaccination series with CoronaVac, 18â€‰548 (18Â·4%) with BNT162b2, and 606 (0Â·6%) with ChAdOx1, and 16â€‰014 (15Â·8%) received no vaccine. Among the 61â€‰767 individuals with a complete primary vaccination series with CoronaVac, 608 (1Â·0%) received a CoronaVac booster, 10â€‰095 (16Â·3%) received a BNT162b2 booster, and 5435 (8Â·8%) received a ChAdOx1 booster. After ChAdOx1 primary vaccination, seropositivity peaked at week 5 after the second dose, occurring in 13 (92Â·9%, 95% CI 79Â·4-100Â·0) of 14 individuals. In participants who received a complete CoronaVac primary series, the decline in seropositivity stabilised at week 18 after the second dose (86 [44Â·7%, 95% CI 41Â·8-47Â·7] of 1087 individuals), whereas after receiving BNT162b2, seropositivity declined slightly by week 25 after the second dose (161 [94Â·2%, 90Â·6-97Â·7] of 171). A lower proportion of individuals who received the CoronaVac primary series and a homologous booster were seropositive (279 [85Â·6%, 95% CI 81Â·8-89Â·4] of 326) by weeks 2-18 than those who received a BNT162b2 booster (7031 [98Â·6%, 98Â·4-98Â·9] of 7128) or a ChAdOx1 booster (2893 [98Â·0%, 97Â·5-98Â·5] of 2953). The correlation between IgG positivity and log of the infectious dose in 50% of neutralising antibodies was moderate, with a sensitivity of 81Â·4% (95% CI 76Â·3-86Â·6) and specificity of 92Â·5% (73Â·3-100Â·0). INTERPRETATION: Dynamic monitoring of IgG positivity to SARS-CoV-2 can characterise antibody waning over time in the absence or presence of booster doses, providing relevant data for the design of vaccination strategies. The correlation between lateral flow test IgG titres and neutralising antibody concentrations suggests that they could be a quick and effective surveillance tool to measure protection against SARS-CoV-2. FUNDING: Instituto Sistemas Complejos de IngenierÃ-a, SubsecretarÃ-a de Redes Asistenciales, Ministry of Health, Chile, and Mutual de Seguridad de la CÃ¡mara Chilena de la ConstrucciÃ³n.

Response to: "Audiological and vestibular symptoms following COVID-19 and COVID-19 vaccination in children: Correspondence".

Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis Overlap After the Third Dose of BNT162b2 mRNA COVID-19 Vaccination and Literature Review.

Side Effects With a Focus on Lymphadenopathy Following COVID-19 Vaccination in Pediatric and AYA Oncology Patients. The Coronavirus Disease 2019 (COVID-19) pandemic led to the swift development of multiple vaccinations. Vaccine side effects were well-documented in the healthy adult cohort and included fever and lymphadenopathy, however, side effects in the pediatric immunocompromised population have not been reported. This retrospective study investigated vaccine-eligible children and adolescent young adult oncology patients 12 to 35 years old. We found uncommon, mild, and self-limiting side effects among pediatric cancer patients and survivors. This data will help guide pediatric and AYA oncologists in providing anticipatory guidance and serve as a guide to managing lymphadenopathy as a potential confounder of malignancy.

Adverse events following the first, second and third doses of a COVID-19 vaccine in hemodialysis patients. BACKGROUND: This study aimed to identify adverse events following the first three doses of COVID-19 vaccines in hemodialysis (HD) patients. Risk factors associated with postvaccination adverse events were explored. METHODS: Postvaccination adverse events in 438â€‰HD patients who received 3 doses of COVID-19 vaccines were prospectively assessed. The adverse events among three doses were compared using generalized linear mixed models. Factors associated with adverse events were assessed with multivariate analyses. RESULTS: The vast majority of participants received Oxford/AstraZeneca ChAdOx1 as their first two doses and Moderna mRNA-1273 as their third dose. Overall, 79%, 50% and 84% of the participants experienced at least one adverse event after their first, second, and third doses, respectively. These adverse events were mostly minor, short-lived and less than 5% reported daily activities being affected. Compared with the first dose, the second dose caused a lower rate of adverse events. Compared with the first dose,

the third dose elicited a higher rate of injection site reactions and a lower rate of systemic reactions. Multivariate analyses showed that every 10-year increase of age (odds ratio 0.67, 95% confidence intervals 0.57-0.79) was associated with decreased risk of adverse events, while female sex (2.82, 1.90-4.18) and arteriovenous fistula (1.73, 1.05-2.84) were associated with increased risk of adverse events. Compared with Oxford/AstraZeneca ChAdOx1, Moderna mRNA-1273 was associated with an increased risk of injection site reactions. CONCLUSIONS: COVID-19 vaccination was well tolerated in HD patients. Age, sex, dialysis vascular access and vaccine types were associated with postvaccination adverse events.

Two cases of systemic lupus erythematosus after administration of severe acute respiratory syndrome coronavirus 2 vaccine. Although there is a great demand for increased coronavirus disease 2019vaccination worldwide, rare side effects of the vaccines in susceptible individuals are attracting attention. We recently treated two patients who developed systemic lupus erythematosus after administration of a severe acute respiratory syndrome coronavirus 2 vaccine from Pfizer-BioNTech or Moderna. While causal relationships between vaccination and adverse events are difficult to discern due to both confounding and masking factors, our findings suggest that attention to possible adjuvant-related autoimmune diseases in certain individuals receiving severe acute respiratory syndrome coronavirus 2 vaccines is appropriate.

Reactive arthritis after Gam-COVID-Vac vaccination: A case report. Although the safety and efficacy of vaccinations have been evaluated through clinical trials, medical experts and authorities are very interested in the reporting and investigation of adverse events following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) immunisation in the general public. This article reports about a 41-year-old man without a history of underlying diseases, complaining of continuous morning stiffness and acute discomfort in his left elbow joint, 20â€‰days after taking the first dosage of Sputnik V. The case was extensively studied, and a possible diagnosis of reactive arthritis was made.

Surveillance of gynecologic cancer patients post-COVID-19 vaccine: Are CA-125 levels reliable? OBJECTIVE: The COVID-19 vaccine is known to instigate an inflammatory response that impacts cancer testing. We aimed to evaluate carbohydrate antigen 125 (CA-125) trends in gynecologic oncology patients in surveillance following COVID-19 vaccination to inform clinical practice. METHODS: This was a single institution retrospective study of patients who received a COVID-19 vaccine while undergoing surveillance of gynecologic cancers with serial serum CA-125 measurements. CA-125 levels from the three months before and after vaccination were included in analysis. Differences between mean and median pre- and post-vaccination CA-125 levels for each patient were calculated. The mean and median of these differences were calculated, as well as the distribution of change. Demographic and cancer-related variables were also recorded. RESULTS: Twenty-six patients who received a COVID-19 vaccine and were followed with surveillance serum CA-125 levels were identified. The mean age was 68.2Â years; 92Â % received a two-vaccine series. Forty-six percent had endometrial cancer and 54Â % had ovarian cancer. The mean change from pre- to post-vaccine mean CA-125 level was 0.16 (Â±7.17) U/mL and the median change from pre- to post-vaccine median CA-125 level was -0.30 (IQR 3.66) U/mL. The range in change from pre- to post-vaccine mean was -16.50 to 24.00 U/mL, with 73Â % of patients between -4 andÂ +4 U/mL. CONCLUSION: We found no clinically significant change in CA-125 level after patients under surveillance for gynecologic cancers were vaccinated against COVID-19, suggesting that that the vaccine does not impact the utility of CA-125 as a tool to monitor disease in this population.

Impact of Vaccination on Cost and Course of Hospitalization Associated with COVID-19 Infection. OBJECTIVE: Examine the impact of vaccination status on hospital cost and course for patients admitted with COVID-19 infection. DESIGN: Retrospective cohort study characterizing vaccinated and

unvaccinated individuals hospitalized for COVID-19 between April 2021 to January 2022. SETTING: Large academic medical center. METHODS: Patients were included if they were greater than 18 years old, fully vaccinated or unvaccinated against COVID-19, and admitted for COVID-19 infection. PATIENTS: 437 consecutively admitted patients for COVID-19 infection met inclusion criteria. Of these, 79 were excluded for unknown or partial vaccination status, transfer from an outside hospital, or multiple COVID-19 related admissions. RESULTS: Overall, 279 (77.9%) unvaccinated patients compared to 79 (22.1%) vaccinated patients were hospitalized with a diagnosis of COVID-19. Average length of stay was significantly lower in the vaccinated group (6.47 days versus 8.92 days, P = 0.03). Vaccinated patients experienced a 70.6% lower risk of ICU admission (OR = 0.29, 95% CI 0.12-0.71, P = 0.006). The unadjusted cost of hospitalization was not found to be statistically significant ($119,630 versus $191,146, P = 0.06). After adjusting for age and comorbidities, vaccinated patients experienced a 26% lower cost of hospitalization compared to unvaccinated patients (P = 0.004). Unvaccinated patients incurred a significantly higher cost of hospitalization per day ($29,425 vs $13,845 P < 0.0001). Unvaccinated patients (n = 118, 42.9%) were more likely than vaccinated patients (n = 16, 20.3%) to require high-flow oxygen or mechanical ventilation (OR = 2.95, 95% CI 1.62-5.38, P = 0.0004). CONCLUSION: Vaccinated patients experienced a lower cost of hospitalization after adjusting for age and comorbidities and shorter length of stay compared to unvaccinated patients admitted for COVID-19.

Incidence of sudden sensorineural hearing loss associated with BNT162b2 COVID-19 vaccine: Pooled results from register-based nationwide studies.

mRNA vaccines against SARS-CoV-2 induce comparably low long-term IgG Fc galactosylation and sialylation levels but increasing long-term IgG4 responses compared to an adenovirus-based vaccine. BACKGROUND: The new types of mRNA-containing lipid nanoparticle vaccines BNT162b2 and mRNA-1273 and the adenovirus-based vaccine AZD1222 were developed against SARS-CoV-2 and code for its spike (S) protein. Several studies have investigated short-term antibody (Ab) responses after vaccination. OBJECTIVE: However, the impact of these new vaccine formats with unclear effects on the long-term Ab response - including isotype, subclass, and their type of Fc glycosylation - is less explored. METHODS: Here, we analyzed anti-S Ab responses in blood serum and the saliva of SARS-CoV-2 naÃ¯ve and non-hospitalized pre-infected subjects upon two vaccinations with different mRNA- and adenovirus-based vaccine combinations up to day 270. RESULTS: We show that the initially high mRNA vaccine-induced blood and salivary anti-S IgG levels, particularly IgG1, markedly decrease over time and approach the lower levels induced with the adenovirus-based vaccine. All three vaccines induced, contrary to the short-term anti-S IgG1 response with high sialylation and galactosylation levels, a long-term anti-S IgG1 response that was characterized by low sialylation and galactosylation with the latter being even below the corresponding total IgG1 galactosylation level. Instead, the mRNA, but not the adenovirus-based vaccines induced long-term IgG4 responses - the IgG subclass with inhibitory effector functions. Furthermore, salivary anti-S IgA levels were lower and decreased faster in naÃ¯ve as compared to pre-infected vaccinees. Predictively, age correlated with lower long-term anti-S IgG titers for the mRNA vaccines. Furthermore, higher total IgG1 galactosylation, sialylation, and bisection levels correlated with higher long-term anti-S IgG1 sialylation, galactosylation, and bisection levels, respectively, for all vaccine combinations. CONCLUSION: In summary, the study suggests a comparable "adjuvant" potential of the newly developed vaccines on the anti-S IgG Fc glycosylation, as reflected in relatively low long-term anti-S IgG1 galactosylation levels generated by the long-lived plasma cell pool, whose induction might be driven by a recently described T(H1)-driven B cell response for all three vaccines. Instead, repeated immunization of naÃ¯ve individuals with the mRNA vaccines increased the proportion of the IgG4 subclass over time which might influence the long-term Ab effector functions. Taken together, these

data shed light on these novel vaccine formats and might have potential implications for their long-term efficacy.

Safety of COVID-19 vaccination in women undergoing IVF/ICSI treatment - Clinical study and systematic review. BACKGROUND: It was suggested that vaccination in general might affect reproductive health. Safety of COVID-19 vaccination in women undergoing assisted reproductive techniques (ART) treatment is not well established. METHODS: We performed a retrospective study including 536 women undergoing fresh embryo transfer after IVF/ICSI treatment in a huge IVF center in southern China to investigate the effect of COVID-19 vaccination on oocyte maturation, fertilization rate, blastulation rate, implantation rate, clinical pregnancy rate and miscarriage rate. In addition, we performed a systematic review of existing studies on the safety of COVID-19 vaccination in women undergoing ART treatment. RESULTS: In our study, 268 women received inactivated or recombinant COVID-19 vaccination and 268 controls were enrolled based on propensity score matching. We observed a decreased fertilization rate and signs for impaired oocyte maturation in vaccinated women. Besides our study, there were 15 studies analyzing the safety of COVID-19 vaccination in women undergoing ART treatment. For the mRNA vaccines, no adverse signals were reported concerning oocyte maturation, fertilization rate, blastulation rate, implantation rate, clinical pregnancy rate and miscarriage rate. In women being vaccinated with an inactivated vaccine, implantation rate, clinical pregnancy rate and miscarriage rate were not affected, whereas oocyte maturation and fertilization rate were impaired. CONCLUSIONS: Vaccination against COVID-19 in women undergoing ART treatment seems to be safe especially for women getting mRNA vaccines. The effects on oocyte maturation and fertilization rate of inactivated and recombinant COVID-19 vaccinations might be a safety signal and need further investigation and independent confirmation.

Humoral and T-cell response 12 months after the first BNT162b2 vaccination in solid organ transplant recipients and controls: Kinetics, associated factors, and role of SARS-CoV-2 infection. INTRODUCTION: We investigated humoral and T-cell responses within 12 months after first BNT162b2 vaccine in solid organ transplant (SOT) recipients and controls who had received at least three vaccine doses. Furthermore, we compared the immune response in participants with and without previous SARS-CoV-2 infection. METHODS: We included adult liver, lung, and kidney transplant recipients, and controls were selected from a parallel cohort of healthcare workers. RESULTS: At 12th-month, the IgG geometric mean concentrations (GMCs) (P<0.001), IgA GMCs (P=0.003), and median IFN-Î³ (P<0.001) were lower in SOT recipients than in controls. However, in SOT recipients and controls with previous infection, the neutralizing index was 99%, and the IgG, and IgA responses were comparable. After adjustment, female-sex (aOR: 3.6, P<0.009), kidney (aOR: 7.0, P= 0.008) or lung transplantation (aOR: 7.5, P= 0.014), and use of mycophenolate (aOR: 5.2, P=0.03) were associated with low IgG non response. Age (OR:1.4, P=0.038), time from transplantation to first vaccine (OR: 0.45, P<0.035), and previous SARS-CoV-2 infection (OR: 0.14, P<0.001), were associated with low IgA non response. Diabetes (OR:2.4, P=0.044) was associated with T-cell non response. CONCLUSION: In conclusion, humoral and T-cell responses were inferior in SOT recipients without previous SARS-CoV-2 infection but comparable to controls in SOT recipients with previous infection.

Protein post-translational modification in SARS-CoV-2 and host interaction. SARS-CoV-2 can cause lung diseases, such as pneumonia and acute respiratory distress syndrome, and multi-system dysfunction. Post-translational modifications (PTMs) related to SARS-CoV-2 are conservative and pathogenic, and the common PTMs are glycosylation, phosphorylation, and acylation. The glycosylation of SARS-CoV-2 mainly occurs on spike (S) protein, which mediates the entry of the virus into cells through interaction with angiotensin-converting enzyme 2. SARS-CoV-2 utilizes glycans to cover its epitopes and evade the immune response through glycosylation of S protein. Phosphorylation of SARS-CoV-2 nucleocapsid (N) protein improves its selective binding to viral RNA

and promotes viral replication and transcription, thereby increasing the load of the virus in the host. Succinylated N and membrane(M) proteins of SARS-CoV-2 synergistically affect virus particle assembly. N protein regulates its affinity for other proteins and the viral genome through acetylation. The acetylated envelope (E) protein of SARS-CoV-2 interacts with bromodomain-containing protein 2/4 to influence the host immune response. Both palmitoylation and myristoylation sites on S protein can affect the virus infectivity. Papain-like protease is a domain of NSP3 that dysregulates host inflammation by deubiquitination and impinges host IFN-I antiviral immune responses by deISGylation. Ubiquitination of ORF7a inhibits host IFN-Î± signaling by blocking STAT2 phosphorylation. The methylation of N protein can inhibit the formation of host stress granules and promote the binding of N protein to viral RNA, thereby promoting the production of virus particles. NSP3 macrodomain can reverse the ADP-ribosylation of host proteins, and inhibit the cascade immune response with IFN as the core, thereby promoting the intracellular replication of SARS-CoV-2. On the whole, PTMs have fundamental roles in virus entry, replication, particle assembly, and host immune response. Mutations in various SARS-CoV-2 variants, which lead to changes in PTMs at corresponding sites, cause different biological effects. In this paper, we mainly reviewed the effects of PTMs on SARS-CoV-2 and host cells, whose application is to inform the strategies for inhibiting viral infection and facilitating antiviral treatment and vaccine development for COVID-19.

Duration of immunity to SARS-CoV-2 in children after natural infection or vaccination in the omicron and pre-omicron era: A systematic review of clinical and immunological studies. BACKGROUND: Duration of humoral and cellular memory in children previously infected SARS-CoV-2 or vaccinated and subsequent risk of reinfection is still not fully elucidated. METHODS: Systematic review of studies retrieved from medical databases and article reference lists. RESULTS: From 2420 identified articles, 24 met the inclusion criteria. Children infected during the pre-omicron era developed long lasting (at least 10-12 months) humoral and cellular immunity against pre-Omicron SARS-CoV-2 variants, but have reduced in vitro cross-reactivity against Omicron. Conversely, although vaccination has a limited efficacy in preventing new infection with pre-Omicron and Omicron variants, in vitro studies suggested that vaccine-induced immunity provides better in vitro cross-neutralization against pre-Omicron and Omicron variants. Preprints published after the period of inclusion of our review suggested that overall risk of infection after Omicron infection is reduced, but children developed weak neutralizing responses in about half cases. CONCLUSIONS: Available evidence, although limited, suggested a long-lasting but unperfect protection of previous infections or vaccination against pre-Omicron and Omicron variants. Based on our findings, it might be reasonable to offer families of children infected before Omicron a booster vaccination. A similar indication should be proposed also for those infected with Omicron, specifically for more fragile children at higher risk of COVID-19-related complications, based on better cross-variant neutralisation induced by vaccination. SYSTEMATIC REVIEW REGISTRATION: PROSPERO, identifier ID 353189.

Therapeutic and vaccine-induced cross-reactive antibodies with effector function against emerging Omicron variants. Currently circulating SARS-CoV-2 variants acquired convergent mutations at receptor-binding domain (RBD) hot spots. Their impact on viral infection, transmission, and efficacy of vaccines and therapeutics remains poorly understood. Here, we demonstrate that recently emerged BQ.1.1. and XBB.1 variants bind ACE2 with high affinity and promote membrane fusion more efficiently than earlier Omicron variants. Structures of the BQ.1.1 and XBB.1 RBDs bound to human ACE2 and S309 Fab (sotrovimab parent) explain the altered ACE2 recognition and preserved antibody binding through conformational selection. We show that sotrovimab binds avidly to all Omicron variants, promotes Fc-dependent effector functions and protects mice challenged with BQ.1.1, the variant displaying the greatest loss of neutralization. Moreover, in several donors vaccine-elicited plasma antibodies cross-react with and trigger effector functions against Omicron variants despite

reduced neutralizing activity. Cross-reactive RBD-directed human memory B cells remained dominant even after two exposures to Omicron spikes, underscoring persistent immune imprinting. Our findings suggest that this previously overlooked class of cross-reactive antibodies, exemplified by S309, may contribute to protection against disease caused by emerging variants through elicitation of effector functions.

The impact of delayed access to COVID-19 vaccines in low- and lower-middle-income countries. INTRODUCTION: A majority of low-income (LIC) and lower-middle-income countries (LMIC) were unable to achieve at least 10% population coverage during initial vaccine rollouts, despite the rapid development of the coronavirus disease 2019 (COVID-19) vaccines. Nearly three years into this pandemic, evaluating the impact of inequities in vaccine access, uptake, and availability is long overdue. We hypothesized that a delay in receiving COVID-19 vaccines was associated with an increased toll on cumulative cases and mortality. Furthermore, this relationship was modified by the size of a country's economy. METHODS: We performed an ecological study assessing these relationships, in which a country's economic standing was assessed by world bank income classification, gross domestic product based on the purchasing power parity (GDP PPP) per capita category, and crude GDP PPP. RESULTS: Countries with the smallest economies reported first vaccination much later than larger economies on all three rankings, as much as 100 days longer. Among low-income countries, a one-day increase until the first vaccination was associated with a 1.92% (95% CI: 0.100, 3.87) increase in cumulative cases when compared to high-income countries (p = 0.0395) when adjusting for population size, median age, and testing data availability. Similarly, among the lowest GDP PPP countries a one-day increase until the first vaccination was associated with a 2.73% (95% CI: 0.100, 5.44) increase in cumulative cases when compared to the highest GDP PPP countries (p = 0.0415). When modeling cumulative mortality, effects in the same direction and magnitude were observed, albeit statistically non-significant. CONCLUSION: Economic standing modified the effects of delayed access to COVID-19 vaccination on cumulative cases and mortality, in which LMICs tended to fare worse in outcomes than high-income countries despite the eventual rollout of vaccines. These findings highlight the importance of prioritizing equitable and timely access to COVID-19 vaccines across all countries, irrespective of economic size. Future studies should examine the impacts that vaccine inequities had on local transmission dynamics.

Anti-SARS-CoV-2 spike IgG following injection of the third dose vaccine: A systematic review with meta-analysis of heterologous versus homologous vaccination. BACKGROUND: The mass vaccination is a key strategy to prevent and control the coronavirus disease 2019 (COVID-19) pandemic. Today, several different types of vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been developed worldwide. These vaccines are usually administered in a two-dose schedule, and the third dose is currently being administered in most countries. This study aimed to systematically review and meta-analyze the immunogenicity of heterologous vs. homologous vaccination after administration of the third dose of COVID-19 vaccines. METHODS: Electronic databases and websites including Scopus, PubMed, Web of Science, and Google scholar were searched for relevant randomized clinical trial (RCT) studies. After applying the inclusion and exclusion criteria, a total of three RCTs were included in the study. These RCTs were included 2,613 healthy adults (18 years or older and without a history of laboratory-confirmed COVID-19) with 15 heterologous and five homologous prime-boost vaccination regimens. Anti-SARS-CoV-2-spike IgG levels at day 28 after administration of the third dose, were compared between the heterologous and homologous regimens. RESULTS: The highest antibody responses had been reported for the homologous vaccination regimen of m1273/m1273/m1273 (Moderna), followed by the heterologous regimen of BNT/BNT/m1273. In addition, the immunogenicity of viral vector and inactivated vaccines was remarkably enhanced when they had been boosted by a heterologous vaccine, especially mRNA

vaccines. CONCLUSION: This systematic review suggests that mRNA vaccines in a homologous regimen induce strong antibody responses to SARS-CoV-2 compared to other vaccine platforms. In contrast, viral vector and inactivated vaccines show a satisfactory immunogenicity in a heterologous regimen, especially in combination with mRNA vaccines.

Posner-Schlossman syndrome relapse following inactivated COVID-19 vaccination in China. INTRODUCTION: This retrospective study aims to present the characteristics of Posner-Schlossman syndrome (PSS) relapse following inactivated COVID-19 vaccination. METHODS: From 2020 to 2022, 12 out of 106 PSS patients undergoing relapses after any dose of inactivated COVID-19 vaccines were enrolled. Medical histories, information on the vaccination and systemic adverse events were collected. Patients were treated with corticosteroids, intraocular pressure (IOP)-lowering drugs and systemic immunosuppressive agents (if needed). Daily regimen and release course were noted. RESULTS: The recurrence rate after vaccination was 11.32% (12/106, 95% CI: 5.29%-17.35%) among 106 PSS patients we surveyed. All the 12 patients were inoculated with inactivated COVID-19 vaccines developed by Sinopharm, China. The mean time of relapse was 5.27 Â± 3.72 days (range: 1-13 days, median: 4 days). Higher IOP and more keratic precipitates (KPs) were seen in the relapse following vaccination (33.55 Â± 12.99 mmHg, 91.67% had KPs compared to 25.38 Â± 3.80 mmHg, 33.33% had KPs in previous relapse, P = 0.009). The mean release course was 30.71 Â± 34.74 days for the relapse following vaccination and 7.33 Â± 6.51 days for previous relapses. The attack frequency before and after vaccination was 3.56 Â± 2.07 and 9.11 Â± 7.34 times per year (P = 0.044). Higher daily doses of corticosteroids, IOP-lowering drugs and ganciclovir were needed to maintain stable course, though the difference did not reach statistical significance. DISCUSSION: More frequent relapses and harder control of IOP were found in PSS relapse following COVID-19 vaccination. Ophthalmologists need to be aware of the group vulnerability and take precautions, though the pathogenesis is still under investigation.

Influenza Vaccine and COVID-19 Pandemic: Could This Vaccine Help Limit the Potential Adverse Consequences of SARS-CoV-2? The COVID-19 pandemic has prompted researchers to find treatments and vaccines to control SARS-CoV-2. There are some hypotheses about the benefit of respiratory virus vaccines, like MMR, for COVID-19 pneumonia severity, morbidity, and mortality. The influenza vaccine is one of the most frequently used respiratory virus vaccines covered by one of the Iranian insurance institutes. We have a symmetrical group of participants that have received this vaccine that could be compared with each other. We compared 3,379 persons aged 20 - 75 years for the effect of the influenza vaccine on COVID-19 mortality. We ultimately found that it does not affect mortality caused by COVID-19 pneumonia, but it can decrease the hospitalization cost in people over 65 years with a history of chronic disease.

Discussion on the Clinical Course of Adverse Effects after COVID-19 Vaccination: A Retrospective Analysis of Case Series in an Outpatient Department. BACKGROUND: A total of 8,303 individuals (4.3%) with adverse reactions (n=191,860) after vaccination developed serious conditions or died. Such health developments could cause people not vaccinated yet or waiting for a booster shot to become fearful of the vaccination. METHODS: The 3-month (July-September 2021) clinical data of 41 patients from the family medicine department of a single medical center were analyzed retrospectively to determine risk factors and to investigate the clinical course to identify the cause of symptoms in detail. RESULTS: A significant number of older adults aged over 50 years reported experiencing general weakness (P=0.026) but fewer incidences of fever than patients aged 50 years or younger (P=0.011). Eighteen of the 41 patients were requested to visit more than twice or consult a specialist. In 14 patients, the symptoms were explained by other medical causes. CONCLUSION: The primary physician has a pivotal role in thoroughly evaluating patients who complain of adverse effects after vaccination, considering the broad multitude of symptoms and medical conditions

presented. To thoroughly evaluate and appropriately advise patients with adverse reactions to their chosen vaccine, taking detailed medical history and nutritional counseling are required to identify possible underlying causes, resolve symptoms, and educate them on self-care and regarding vaccines.

Social communication pathways to COVID-19 vaccine side-effect correspondence.

Vulvar Aphthous Ulcers in Perimenarchal Adolescents after COVID-19 Vaccination: A Multicenter Case Series. This case series from 3 academic hospital-based pediatric and adolescent gynecology services outlines the temporal association between vulvar ulcers in female adolescents and COVID-19 vaccination. We identified 8 cases and describe each patient's presentation, differential diagnosis, diagnostic workup, complications, treatment modalities, and overall course of illness. All cases seek to illustrate the clinical experiences of patients and providers interfacing with vulvar aphthous ulcers and contribute to the emerging literature exploring the novel association between vulvar aphthous ulcers and COVID-19 vaccination. To date, this is the largest described case series of this association in the literature. Key Words: COVID-19, Vaccine, Aphthous ulcers, Vulva, Adolescent.

Reply to: COVID-19 Vaccination in Patients who Develop COVID-19 After Cancer Surgery: Correspondence by Mungmunpuntipantip and Wiwanitkit.

Neuropsychiatric post-acute sequelae of COVID-19: prevalence, severity, and impact of vaccination. The potential long-term neuropsychiatric effects of COVID-19 are of global concern. This study aimed to determine the prevalence and predictors of neuropsychiatric post-acute sequelae of COVID-19 among Egyptian COVID-19 survivors and to study the impact of full vaccination before COVID-19 infection on the occurrence and severity of these manifestations. Three months after getting COVID-19 infection, 1638 COVID-19 survivors were screened by phone for possible neuropsychiatric sequelae. Subjects suspected to suffer from these sequelae were invited to a face-to-face interview for objective evaluation. They were requested to rate the severity of their symptoms using visual analogue scales (VAS). The mean age of participants was 38.28â€‰Â±â€‰13Â years. Only 18.6% were fully vaccinated before COVID-19 infection. Neuropsychiatric post-acute sequelae of COVID-19 were documented in 598 (36.5%) subjects, fatigue was the most frequent one (24.6%), followed by insomnia (16.4%), depression (15.3%), and anxiety (14.4%). Moderate and severe COVID-19 infection and non-vaccination increased the odds of developing post-COVID-19 neuropsychiatric manifestations by 2 times (OR 1.95, 95% CIâ€‰=â€‰1.415-2.683), 3.86 times (OR 3.86, 95% CIâ€‰=â€‰2.358-6.329), and 1.67 times (OR 1.67, 95% CIâ€‰=â€‰1.253-2.216), respectively. Fully vaccinated subjects before COVID-19 infection (nâ€‰=â€‰304) had significantly lesser severity of post-COVID-19 fatigue, ageusia/hypogeusia, dizziness, tinnitus, and insomnia (P valueâ€‰=â€‰0.001, 0.008, <â€‰0.001, 0.025, and 0.005, respectively) than non-vaccinated subjects. This report declared neuropsychiatric sequelae in 36.5% of Egyptian COVID-19 survivors, fatigue being the most prevalent. The effectiveness of COVID-19 vaccines in reducing the severity of some post-COVID-19 neuropsychiatric manifestations may improve general vaccine acceptance.

COVIDâ€‘19 vaccine hesitancy among pregnant women and their reported reasons for vaccine refusal - A prospective study in Tehran, Iran. OBJECTIVE: Evaluation of covidâ€‘19 vaccine hesitancy among pregnant women and their reported reasons for vaccine refusal. METHODS: This prospective study was performed in Arash women's Hospital, Tehran, Iran, between December 1, 2021 and January 1, 2022. All pregnant women who were attended to prenatal care unit were considered eligible for inclusion. A validated questionnaire was used for data gathering. Written informed consent was obtained from all participants. RESULTS: Finally, 477 pregnant women were recruited and were divided into two groups according the status of vaccine acceptance (237 accepted and 240 women refused vaccination). The mean age of accepted participants was higher (31.65Â Â±Â 5.69 vs 30.39Â Â±Â 5.5; PÂ =Â 0.01). There was a significant statistical difference between the groups regarding education level. Access to internet and social media were also significantly different

between the two groups (94.8% in accepted vs 86.6% in refused group; PÂ =Â 0.002). There was more rate of severe COVID-19 infection in friends or relatives of accepted group (50% vs 38%). we did not find any statistically significant differences in obstetric characteristics and the rate of obstetric complications between the two groups. The most common reasons reported by participants for vaccine refusal, was fear of vaccination side effects on the fetus (86.5%), and the less common reported reasons were husband's disagreement (9.7%), use of traditional medicine (5.6%), religious beliefs (3.7%), and information obtained from social media (2.8%). After advices from medical staff, most of these mothers (86.5%) still refused vaccination. CONCLUSION: Based on the results of the present study,rate of COVID-19 vaccine hesitancy was about 50% and its most common reported reason was fear of probable side effects of vaccine on the fetus.

Mechanisms of Thrombosis in Heparin-Induced Thrombocytopenia and Vaccine-Induced Immune Thrombotic Thrombocytopenia. Heparin-induced thrombocytopenia (HIT) and vaccine-induced immune thrombotic thrombocytopenia (VITT) are rare, iatrogenic immune-mediated conditions with high rates of thrombosis-related morbidity and mortality. HIT is a long-recognized reaction to the administration of the common parenterally administered anticoagulant heparin (or its derivatives), while VITT is a new, distinct syndrome occurring in response to adenovirus-based vaccines against coronavirus disease 2019 and potentially other types of vaccines. A feature of both HIT and VITT is paradoxical thrombosis despite a characteristic low platelet count, mediated by the presence of platelet-activating antibodies to platelet factor 4. Several additional factors have also been suggested to contribute to clot formation in HIT and/or VITT, including monocytes, tissue factor, microparticles, endothelium, the formation of neutrophil extracellular traps, complement, procoagulant platelets, and vaccine components. In this review, we discuss the literature to date regarding mechanisms contributing to thrombosis in both HIT and VITT and explore the pathophysiological similarities and differences between the two conditions.

The case of T-ALL presenting with NK phenotype after COVID-19 vaccination. NK-lymphoblastic leukemia/lymphoma (NK-LL) is an extremely rare hematopoietic tumor consisting of natural killer (NK) precursor cells, and their lineage overlaps with T-cells, making it challenging to diagnose. COVID-19 vaccination is recommended for people with a risk of aggravation such as cancer-bearing patients, including hematopoietic tumors. We present a 55-year-old man who had cervical lymph node swelling post vaccination for COVID-19. Hematological malignancy was suspected due to the presence of atypical lymphoid cells with an elevated IL-2R in laboratory data. Tumor cells were positive for CD7, CD56, cyCD3, and terminal deoxynucleotidyl transferase (TdT) evidenced through flow cytometry of the bone marrow and the lymph node. The histopathological findings showed monotonous tumor cell proliferation, the cells being positive for CD3 and TdT in the bone marrow and they were positive for CD3, TdT, and CD56 in lymph node. Even though these findings suggested NK-LL, clonal T-cell receptor (TCR) Î² gene rearrangement by Southern blot hybridization was observed in the bone marrow. TCRÎ² rearrangement led to the final diagnosis of T-cell lymphoblastic leukemia (T-ALL). The causal relationship between COVID-19 vaccination and carcinogenesis is not clear, and more cases need to be studied in order to elucidate the relationship between the two factors.

Accelerated waning of immune responses to a third COVID-19 vaccination in patients with immune-mediated inflammatory diseases. BACKGROUND: A 3(rd) COVID-19 vaccination is currently recommended for patients under immunosuppression. However, a fast decline of antibodies against the SARS-CoV-2 receptor-binding domain (RBD) of the spike protein has been observed. Currently it remains unclear whether immunosuppressive therapy affects kinetics of humoral and cellular immune responses. METHODS: 50 patients under immunosuppression and 42 healthy controls (HCs) received a 3(rd) dose of an mRNA-based vaccine and were monitored over a 12-weeks period. Humoral immune response was assessed 4 and 12 weeks after 3(rd) dose. Antibodies were quantified

using the Elecsys Anti-SARS-CoV-2 Spike immunoassay against the receptor-binding domain (RBD) of the spike protein. SARS-CoV-2-specific T cell responses were quantified by IFN-Î³ ELISpot assays. Adverse events, including SARS-CoV-2 infections, were monitored over a 12-week period. RESULTS: At week 12, reduced anti-RBD antibody levels were observed in IMID patients as compared to HCs (median antibody level 5345 BAU/ml [1781-10,208] versus 9650 BAU/ml [6633-16,050], pÂ <Â 0.001). Reduction in relative antibody levels was significantly higher in IMID patients as compared to HCs at week 12 (pÂ <Â 0.001). Lowest anti-RBD antibody levels were detected in IMID patients who received biological disease-modifying anti-rheumatic drugs (DMARDs) or a combination therapy with conventional synthetic and biological DMARDs. Number of SARS-CoV-2-specific T cells against wildtype and Omicron variants remained stable over 12 weeks in IMID patients. No serious adverse events were reported. CONCLUSION: Due to a fast decline in anti-RBD antibodies in IMID patients an early 4(th) vaccination should be considered in this vulnerable group of patients.
Herpetic Eye Disease After SARS-CoV-2 Vaccination: A CDC-VAERS Database Analysis. PURPOSE: The aim of this study was to evaluate the cases of herpes simplex and zoster ophthalmicus after SARS-CoV-2 vaccination and assess the clinical presentations in patients. METHODS: A retrospective analysis of cases reported to the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS) between December 11, 2020, and July 1, 2022. Patients diagnosed with herpes simplex ophthalmicus (HSO) and herpes zoster ophthalmicus (HZO) after vaccination with BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and Ad26.COV2.S (Janssen) were included in the study. We performed a descriptive analysis of patient demographics, history, and ophthalmic and systemic clinical presentations. The correlations between vaccine type and continuous variables were assessed by the one-way analysis of variance test. In addition, we used the Pearson Ï‡ 2 test to assess the association between 3 vaccines and categorical variables. A post hoc analysis was performed between HSO and HZO onset intervals after vaccination, dose, and vaccine type. The 30-day risk analysis was also performed for HSO and HZO onset postvaccination using the reverse Kaplan-Meier analysis. RESULTS: A total of 1180 cases of HZO (983, 83.30%) and HSO (180, 15.25%) were reported. The mean age of patients with HZO and HSO was 59.02 Â± 19.05 and 52.68 Â± 17.83 years, respectively. Most of the cases of HZO (795, 80.87%) and HSO (131, 72.78%) were reported in patients who received BNT162b2. In the cohort, 63.28% and 65.56% diagnosed with HZO and HSO were women. About one third of HZO (36.52%) and HSO (35.56%) cases were reported after the first dose. More than half of the cases of HZO (61.34%) and HSO (64.45%) were reported within the first 2 weeks after vaccination. The estimated crude reporting rate (per million doses) in the United States was 0.25, 0.22, and 0.47 for BNT162b2, mRNA-1273, and Ad26.COV2.S, respectively. The onset interval for HZO was significantly shorter in patients who received BNT162b2 (20.51 Â± 56.20 days, P = 0.030) compared with patients who received mRNA-1273 (36.56 Â± 108.67 days) and Ad26.COV2.S (39.66 Â± 60.15 days) vaccines. The 30-day risk analysis showed a significantly higher risk of HZO after BNT162b2 than the other 2 vaccines (P = 0.011). CONCLUSIONS: The low crude reporting rate suggests that HZO and HSO after SARS-CoV-2 vaccination occur rarely. This study provides insights into the possible temporal association between reported HSO and HZO after SARS-CoV-2 vaccines; however, further investigations are required to delineate the possible underlying immunological mechanisms.
Diagnosing SARS-CoV-2 vaccination-related rhabdomyolysis requires the exclusion of all differential causes.
Comment on "Cutaneous adverse reactions of COVID-19 vaccines: A systematic review".
Cardiac magnetic resonance imaging findings in COVID-19 vaccine-related myocarditis.
Persistence of salivary antibody responses after COVID-19 vaccination is associated with oral microbiome variation in both healthy and people living with HIV. Coevolution of microbiome and

immunity at mucosal sites is essential for our health. Whether the oral microbiome, the second largest community after the gut, contributes to the immunogenicity of COVID-19 vaccines is not known. We investigated the baseline oral microbiome in individuals in the COVAXID clinical trial receiving the BNT162b2 mRNA vaccine. Participants (n=115) included healthy controls (HC; n=57) and people living with HIV (PLHIV; n=58) who met the study selection criteria. Vaccine-induced Spike antibodies in saliva and serum from 0 to 6 months were assessed and comparative analyses were performed against the individual salivary 16S ASV microbiome diversity. High- versus low vaccine responders were assessed on general, immunological, and oral microbiome features. Our analyses identified oral microbiome features enriched in high- vs. low-responders among healthy and PLHIV participants. In low-responders, an enrichment of Gram-negative, anaerobic species with proteolytic activity were found including Campylobacter, Butyrivibrio, Selenomonas, Lachnoanaerobaculum, Leptotrichia, Megasphaera, Prevotella and Stomatobaculum. In high-responders, enriched species were mainly Gram-positive and saccharolytic facultative anaerobes: Abiotrophia, Corynebacterium, Gemella, Granulicatella, Rothia, and Haemophilus. Combining identified microbial features in a classifier using the area under the receiver operating characteristic curve (ROC AUC) yielded scores of 0.879 (healthy controls) to 0.82 (PLHIV), supporting the oral microbiome contribution in the long-term vaccination outcome. The present study is the first to suggest that the oral microbiome has an impact on the durability of mucosal immunity after Covid-19 vaccination. Microbiome-targeted interventions to enhance long-term duration of mucosal vaccine immunity may be exploited.

Evaluation of post-vaccination immunoglobulin G antibodies and T-cell immune response after inoculation with different types and doses of SARS-CoV-2 vaccines: A retrospective cohort study. INTRODUCTION: The induction and speed of production of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) immune biomarkers may vary by type and number of inoculated vaccine doses. This study aimed to explore variations in SARS-CoV-2 anti-spike (anti-S), anti-nucleocapsid (anti-N), and neutralizing immunoglobulin G (IgG) antibodies, and T-cell response by type and number of SARS-CoV-2 vaccine doses received. METHODS: In a naturally exposed and SARS-CoV-2-vaccinated population, we quantified the anti-S, anti-N, and neutralizing IgG antibody concentration and assessed T-cell response. Data on socio-demographics, medical history, and history of SARS-CoV-2 infection and vaccination were collected. Furthermore, nasal swabs were collected to test for SARS-CoV-2 infection. Confounder-adjusted association between having equal or more than a median concentration of the three IgG antibodies and T-cell response by number and type of the inoculated vaccines was quantified. RESULTS: We surveyed 952 male participants with a mean age of 35.5 years Â± 8.4 standard deviations. Of them, 52.6% were overweight/obese, and 11.7% had at least one chronic comorbidity. Of the participants, 1.4, 0.9, 20.2, 75.2, and 2.2% were never vaccinated, primed with only one dose, primed with two doses, boosted with only one dose, and boosted with two doses, respectively. All were polymerase chain reaction-negative to SARS-CoV-2. BBIBP-CorV (Sinopharm) was the most commonly used vaccine (92.1%), followed by rAd26-S + rAd5-S (Sputnik V Gam-COVID-Vac) (1.5%) and BNT162b2 (Pfizer-BioNTech) (0.3%). Seropositivity to anti-S, anti-N, and neutralizing IgG antibodies was detected in 99.7, 99.9, and 99.3% of the study participants, respectively. The T-cell response was detected in 38.2% of 925 study participants. Every additional vaccine dose was significantly associated with increased odds of having â‰¥median concentration of anti-S [adjusted odds ratio (aOR), 1.34; 95% confidence interval (CI): 1.02-1.76], anti-N (aOR, 1.35; 95% CI: 1.03-1.75), neutralizing IgG antibodies (aOR, 1.29; 95% CI: 1.00-1.66), and a T-cell response (aOR, 1.48; 95% CI: 1.12-1.95). Compared with boosting with only one dose, boosting with two doses was significantly associated with increased odds of having â‰¥median concentration of anti-S (aOR, 13.8; 95% CI: 1.78-106.5), neutralizing IgG antibodies (aOR, 13.2; 95% CI: 1.71-101.9), and T-cell response (aOR, 7.22; 95% CI: 1.99-26.5) although not with anti-N (aOR, 0.41; 95% CI: 0.16-1.08).

Compared with priming and subsequently boosting with BBIBP-CorV, all participants who were primed with BBIBP-CorV and subsequently boosted with BNT162b2 had â‰¥median concentration of anti-S and neutralizing IgG antibodies and 14.6-time increased odds of having a T-cell response (aOR, 14.63; 95% CI: 1.78-120.5). Compared with priming with two doses, boosting with the third dose was not associated, whereas boosting with two doses was significantly associated with having â‰¥median concentration of anti-S (aOR, 14.20; 95% CI: 1.85-109.4), neutralizing IgG (aOR, 13.6; 95% CI: 1.77-104.3), and T-cell response (aOR, 7.62; 95% CI: 2.09-27.8). CONCLUSION: Achieving and maintaining a high blood concentration of protective immune biomarkers that predict vaccine effectiveness is very critical to limit transmission and contain outbreaks. In this study, boosting with only one dose or with only BBIBP-CorV after priming with BBIBP-CorV was insufficient, whereas boosting with two doses, particularly boosting with the mRNA-based vaccine, was shown to be associated with having a high concentration of anti-S, anti-N, and neutralizing IgG antibodies and producing an efficient T-cell response.

Autoimmune blistering skin diseases triggered by COVID-19 vaccinations: An Australian case series. Autoimmune blistering skin diseases (AIBD) can be induced or flared by a multitude of sources, however, there have been some reports suggesting that this occurrence is due to COVID-19 vaccinations. At a single academic blistering disease centre in Sydney, Australia, a retrospective review was conducted, identifying 59 patients with AIBD seen between February 2021 and November 2022. Secondary to recent COVID-19 vaccination, four patients had induction of bullous pemphigoid, three patients had a flare of pre-existing bullous pemphigoid, one patient had induction of pemphigus, and two patients had a flare of pre-existing pemphigus vulgaris. This adds to our understanding of the role of vaccinations in the activity of AIBD.

Outcomes following COVID-19 vaccination and associated factors among healthcare professionals in Oromia region, Ethiopia. Vaccines are not free from adverse outcomes. However, the evidence of adverse outcomes following COVID-19 vaccination among health-care professionals (HCPs) in the study setting was scanty. Aimed to assess outcomes following COVID-19 vaccination and associated factors among health-care professionals in Oromia region, Ethiopia. An online cross-sectional survey was conducted from 1 October to 30 October 2021. Data were collected using questionnaire created on Google forms. A snowball sampling technique through the authors' network on the popular social media was used. Data analysis was performed using SPSS version 25. The Adjusted Odd Ratio (AOR) along with the 95% confidence level and variables with a p value <.05 were considered to declare the statistical significance. About 93.9% of the participants had experienced mild-to-moderate adverse outcomes following COVID-19 vaccination. Being married [AORâ€‰=â€‰4.19, 95% CI:2.07,8.45] ,family size >5 [AORâ€‰=â€‰5.17, 95% CI: 1.74, 15.34], family not tested for COVID-19 [AORâ€‰=â€‰0.39, 95% CI: 0.15,0.97], lack of family support to take the vaccine [AORâ€‰=â€‰3.58, 95% CI: 1.75, 7.33], heard anything bad about the vaccine [AORâ€‰=â€‰4.17, 95% CI: 1.90,9.13] and very concerned as the vaccine could cause Adverse Events Following Immunization (AEFI) [AORâ€‰=â€‰6.24, 95% CI: 1.96,19.86] were statistically associated with the outcome. The study showed that over nine out-of-often participants had experienced mild-to-moderate adverse outcomes following COVID-19 vaccination. However, severe adverse outcome experienced was very low, which could not hinder to take the vaccine due to fear of its side effects. Marital status, family size, family tested for COVID-19, lack of family support to take the vaccine, hearing anything bad about the vaccine, and being concerned about as the vaccine could cause adverse events were factors associated with the outcome.

Characteristics associated with influenza vaccination uptake in pregnancy: a retrospective cohort study. BACKGROUND: Pregnant women are at increased risk from influenza, yet maternal influenza vaccination levels remain suboptimal. AIM: To estimate associations between

sociodemographic and health characteristics and seasonal influenza vaccination uptake among pregnant women, and to understand trends over time to inform interventions to improve vaccine coverage. DESIGN AND SETTING: Retrospective cohort study using linked electronic health records of women in North West London with a pregnancy overlapping an influenza season between September 2010 and February 2020. METHOD: A multivariable mixed-effects logistic regression model was used to identify associations between characteristics of interest and the primary outcome of influenza vaccination. RESULTS: In total, 451 954 pregnancies, among 260 744 women, were included. In 85 376 (18.9%) pregnancies women were vaccinated against seasonal influenza. Uptake increased from 8.4% in 2010/11 to 26.4% in 2017/18, dropping again to 21.1% in 2019/20. Uptake was lowest among women aged 15-19 years (11.9%; reference category) or â‰¥40 years (15.2%; odds ratio [OR] 1.17, 95% confidence interval [CI] = 1.10 to 1.24); of Black (14.1%; OR 0.55, 95% CI = 0.53 to 0.57) or unknown ethnicity (9.9%; OR 0.42, 95% CI = 0.39 to 0.46); who lived in more deprived areas (OR least versus most deprived [reference category] 1.16, 95% CI = 1.11 to 1.21); or with no known risk factors for severe influenza. CONCLUSION: Seasonal influenza vaccine uptake in pregnant women increased in the decade before the COVID-19 pandemic, but remained suboptimal. Targeted approaches are recommended to reducing inequalities in access to vaccination and should focus on women of Black ethnicity, younger and older women, and women living in deprived areas.

Anti-SARS-CoV-2 vaccination in adolescent and adult patients with juvenile-onset systemic lupus erythematosus: tolerability and impact on disease activity. OBJECTIVES: JSLE has a severe presentation and a remitting course. Patients with JSLE carry an increased vulnerability to infections, which also act as triggers of disease flare. Thus, vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is an important tool in JSLE. The objective of this study is to evaluate the tolerability and the safety of anti-SARS-CoV-2 vaccination, including the booster, in a monocentric cohort of JSLE patients. METHODS: Clinical records of JSLE patients who received at least one dose of any anti-SARS-CoV-2 vaccine were retrospectively reviewed. Data about disease activity, treatment, anti-SARS-CoV-2 vaccination and COVID-19 infection were collected. RESULTS: Sixty-five JSLE patients received at least one dose of anti-SARS-CoV-2 vaccination, while 46 patients completed the schedule with the booster. The rate of mild-moderate adverse events was 66%, mainly comprising fever, fatigue, arthromyalgias and pain at injection site. The rate of adverse events after the booster was similar to that registered after the first two doses. No significant changes after SARS-CoV-2 vaccination in BILAG and SLEDAI were observed. Disease flare rate (mainly LN) after immunization was 10.8%. Flares occurred predominantly in patients with moderate disease activity before immunization; accordingly, SLEDAI â‰¥4 identified patients at risk of flare while Lupus Low Disease Activity State (LLDAS) plays a protective role against post-vaccination flare. CONCLUSIONS: This study confirms that anti-SARS-CoV-2 vaccination in JSLE is well tolerated; a strict clinical monitoring and a thoughtful choice of vaccination timing should be devoted to patients not in LLDAS due to the risk of post-vaccine flare.

Effect of female coronavirus disease 2019 vaccination on assisted reproductive outcomes: a systematic review and meta-analysis. IMPORTANCE: The effect of coronavirus disease 2019 (COVID-19) vaccination on fertility warrants clarification in women undergoing assisted reproductive treatment. OBJECTIVE: To study the association between female COVID-19 vaccination and outcomes of assisted reproductive treatment. DATA SOURCES: PubMed, Embase, the Web of Science, Cochrane Library, and medRxiv and bioRxiv were searched for eligible studies from December 1, 2019, to November 30, 2022, with no language restrictions. STUDY SELECTION AND SYNTHESIS: Observational studies comparing assisted reproductive outcomes between women with and without COVID-19 vaccination were included. The pooled estimates were calculated using the random-effects models as mean differences (MDs), standardized MDs, or odds ratios with 95% confidence intervals (CIs).

Heterogeneity was evaluated using the I(2) statistic. MAIN OUTCOMES: The number of oocytes retrieved and clinical pregnancy rate. RESULTS: Twenty-one cohort studies involving a total of 19,687 treatment cycles were included. In a comparison of the vaccinated vs. unvaccinated groups, the pooled MD for oocyte number was -0.06 (95% CI, -0.51 to 0.39; I(2) = 0), and the pooled odds ratio for clinical pregnancy was 0.95 (95% CI, 0.85-1.05; I(2) = 0). Similarly, there were no statistically significant adverse effects identified in other outcomes determined a priori, including 4 cycle characteristics, 6 laboratory parameters, and 3 pregnancy indicators. Most results were consistently unchanged in subgroup and sensitivity analyses, with no evidence of publication bias according to Egger's test. CONCLUSION AND RELEVANCE: Our work did not find significant differences in assisted reproductive outcomes between vaccinated and unvaccinated women. However, more data are warranted to confirm the safety of COVID-19 vaccination for assisted reproductive treatment and in female fertility in general.

Immediate and 6-month seizure outcomes following first and second SARS-CoV2 mRNA vaccinations: A multicenter study with a nationwide survey. OBJECTIVE: This study aimed to identify seizure outcomes in people with epilepsy (PWE) following severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) messenger RNA vaccination. METHODS: We examined PWE (nÂ =Â 332, ageÂ â‰¥Â 14Â years) treated in four tertiary hospitals between 2021 and 2022 to assess the incidence of seizure worsening following vaccination using closed questions. We identified the clinical factors associated with worsening and 6-month vaccination outcomes. We also conducted a nationwide survey on self-reported seizure worsening using open questions, to which 261 general practitioners from 99 institutes contributed. RESULTS: Of the 282 PWE vaccinated in the four hospitals, 16 (5.7%) exhibited seizure worsening; most of them emerged within 48Â h of vaccination and were not sustained. Thus, all PWE were at baseline condition 6Â months after their vaccination. PWE with seizure worsening were more significantly associated with focal impaired awareness seizures (pÂ <Â 0.001), high seizure frequency (pÂ =Â 0.025), and drug-resistant epilepsy (pÂ =Â 0.007) at baseline compared to PWE without worsening. Multivariate logistic regression analysis revealed that focal impaired awareness seizures were independently associated with worsening (odds ratio, 7.0; 95% confidence interval, 1.50-32.77). A nationwide survey of 5156 PWE data (real-world data) confirmed an extremely low incidence rate of self-reported seizure worsening (0.43%). SIGNIFICANCE: Some PWE, particularly refractory focal epilepsy, exhibit seizure worsening. However, the worsening events were infrequent, non-sustainable, and probably under-reported by PWE, suggesting that there is little evidence that worsening seizures discourage current and future vaccinations.

SARS-CoV-2 Antibody Responses to the Ancestral SARS-CoV-2 Strain and Omicron BA.1 and BA.4/BA.5 Variants in Nursing Home Residents After Receipt of Bivalent COVID-19 Vaccine - Ohio and Rhode Island, September-November 2022. Introduction of monovalent COVID-19 mRNA vaccines in late 2020 helped to mitigate disproportionate COVID-19-related morbidity and mortality in U.S. nursing homes (1); however, reduced effectiveness of monovalent vaccines during the period of Omicron variant predominance led to recommendations for booster doses with bivalent COVID-19 mRNA vaccines that include an Omicron BA.4/BA.5 spike protein component to broaden immune response and improve vaccine effectiveness against circulating Omicron variants (2). Recent studies suggest that bivalent booster doses provide substantial additional protection against SARS-CoV-2 infection and severe COVID-19-associated disease among immunocompetent adults who previously received only monovalent vaccines (3).* The immunologic response after receipt of bivalent boosters among nursing home residents, who often mount poor immunologic responses to vaccines, remains unknown. Serial testing of anti-spike protein antibody binding and neutralizing antibody titers in serum collected from 233 long-stay nursing home residents from the time of their primary

vaccination series and including any subsequent booster doses, including the bivalent vaccine, was performed. The bivalent COVID-19 mRNA vaccine substantially increased anti-spike and neutralizing antibody titers against Omicron sublineages, including BA.1 and BA.4/BA.5, irrespective of previous SARS-CoV-2 infection or previous receipt of 1 or 2 booster doses. These data, in combination with evidence of low uptake of bivalent booster vaccination among residents and staff members in nursing homes (4), support the recommendation that nursing home residents and staff members receive a bivalent COVID-19 booster dose to reduce associated morbidity and mortality (2).

COVID-19 thromboembolism is reduced in ambulatory, but not hospitalized patients, following COVID-19 vaccination.

No difference in anti-spike antibody and surrogate viral neutralization following SARS-CoV-2 booster vaccination in persons with HIV compared to controls (CO-HIV Study). BACKGROUND: Understanding the immune response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination will enable accurate counseling and inform evolving vaccination strategies. Little is known about antibody response following booster vaccination in people living with HIV (PLWH). METHODS: We enrolled SARS-CoV-2 vaccinated PLWH and controls without HIV in similar proportions based on age and comorbidities. Participants completed surveys on prior SARS-CoV-2 infection, vaccination, and comorbidities, and provided self-collected dried blood spots (DBS). Quantitative anti-spike IgG and surrogate viral neutralization assays targeted wild-type (WT), Delta, and Omicron variants. We also measured quantitative anti-nucleocapsid IgG. The analysis population had received full SARS-CoV-2 vaccination plus one booster dose. Bivariate analyses for continuous outcomes utilized Wilcoxon tests and multivariate analysis used linear models. RESULTS: The analysis population comprised 140 PLWH and 75 controls with median age 58 and 55 years, males 95% and 43%, and DBS collection on 112 and 109 days after the last booster dose, respectively. Median CD4 count among PLWH was 760 cells/mm(3) and 91% had an undetectable HIV-1 viral load. Considering WT, Delta, and Omicron variants, there was no significant difference in mean quantitative anti-spike IgG between PLWH (3.3, 2.9, 1.8) and controls (3.3, 2.9, 1.8), respectively (p-values=0. 771, 0.920, 0.708). Surrogate viral neutralization responses were similar in PLWH (1.0, 0.9, and 0.4) and controls (1.0, 0.9, 0.5), respectively (p-values=0.594, 0.436, 0.706). CONCLUSIONS: PLWH whose CD4 counts are well preserved and persons without HIV have similar anti-spike IgG antibody levels and viral neutralization responses after a single SARS-CoV-2 booster vaccination.

Six-month longitudinal immune kinetics after mRNA-1273 vaccination: Correlation of peak antibody response with long-term, cross-reactive immunity. BACKGROUND: The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants and the persistence of the pandemic, even with mass coronavirus disease 2019 (COVID-19) vaccination, have raised questions about the durability of immunity and extent of cross-reactive immunity after vaccination. This study aimed to characterize the humoral and cellular immune response to the mRNA-1273 vaccine using a prospective longitudinal cohort. METHODS: We recruited 177 young SARS-CoV-2 infection-naive adults. Two doses of mRNA-1273 vaccine were administered at 28-day intervals, and blood samples were collected at five time points: pre-vaccination (T0), 4 weeks after the first (T1) and second dose (T2), and 3 months (T3) and 6 months (T4) after the first dose. Anti-SARS-CoV-2 spike protein (anti-S) IgG antibody, neutralizing antibody, and T-cell immune responses were evaluated. RESULTS: The two-dose mRNA-1273 vaccination induced robust anti-SARS-CoV-2 antibody responses, which remained higher than the titers at T1 until T4. A higher peak anti-S antibody titer at T2 was associated with better cross-reactive immunity against Delta and Omicron variants and long-lasting (anti-S IgG and neutralizing antibody) humoral immunity up to T4. The overall T-cell immune response was not correlated with peak antibody titers (T-lymphocyte subpopulation analysis was not performed). CONCLUSION: This study showed that an early strong antibody response is predictive of longer

humoral immunity and better cross-reactive neutralizing immunity against Delta and Omicron variants.

Immune Thrombocytopenia Following Booster Dose of the Moderna mRNA-1273 Vaccine. Vaccine-mediated immune thrombocytopenia, although previously reported, is considered exceedingly rare. The probability of the incidence of profound thrombocytopenia following the COVID-19 mRNA-based vaccine has been less elucidated.Â We present the case of an 81-year-old female patient who became profoundly thrombocytopenic with bleeding manifestations six days after the Moderna mRNA-1273 vaccine administration. Fortunately, she exhibited platelet count recovery after treatment with intravenous immunoglobulins and steroid therapy. Furthermore, we show that the inherent risk of COVID-19 infection leading to thrombocytopenia significantly outweighs the vaccine's risk.

Correction: Bullous Pilomatrixoma After COVID-19 Vaccination. [This corrects the article DOI: 10.7759/cureus.32370.].

Frequency of COVID-19 vaccine side effects and its associated factors amongÂ the vaccinated population of Pakistan: A cross-sectional study. BACKGROUND: Coronavirus disease 2019Â (COVID-19) vaccine side effects have an important role in the hesitancy of the general population towardÂ vaccine administration. Therefore, this study was conducted to document the COVID-19 vaccine side effects in our population. MATERIALS AND METHODS: An online survey-based, cross-sectional study was carried out from September 1, 2021, to October 1, 2021, to document the side effects of the COVID-19 vaccine among the general public. The questionnaire included participants' sociodemographic data, type of vaccine, comorbidities, previous COVID-19 infection, and assessment of side effects reported by them. RESULTS: The majority of the participants were <20 years of age (62.2%), females (74.9%), belonged to the educational sector (58.1%), residents of Sindh (65.7%), and were previously unaffected by COVID-19 infection (73.3%). Sinovac (38.7%) followed by Sinopharm (30.4%) and Moderna (18.4%) were administered more frequently. Commonly reported side effects were injection site pain (82%), myalgia (55%), headache (46%), fatigue/malaise (45%), and fever (41%).Â Vaccine side effects were more likely to be reported with the first dose as compared to the second dose. On regression analysis, factors associated with occurrence of side effects included younger age (odds ratio [OR]: 6.000 [2.065-17.431], pâ€‰<â€‰0.001), female gender (OR: 2.373 [1.146-4.914], pâ€‰=â€‰0.020), marital status (OR: 0.217 [0.085-0.556], pâ€‰<â€‰0.001), graduate level of education (OR: 0.353 [0.153-0.816], pâ€‰=â€‰0.015), and occupation being either retired, freelancers, or social workers (OR: 0.310 [0.106-0.909]), pâ€‰=â€‰0.033). Previous infection with COVID-19 (pâ€‰=â€‰0.458) and comorbidities were found unrelated (pâ€‰=â€‰0.707) to the occurrence of side effects. CONCLUSION: The overall prevalence of local side effects was quite higher than the systemic ones. Further large-scale studies on vaccine safety are required to strengthen public confidence in the vaccination drive.

Efficacy of mRNA and Inactivated Whole Virus Vaccines Against COVID-19 in Patients with Chronic Respiratory Diseases. BACKGROUND: While different COVID-19 vaccines have been developed, there has been lack of data on the efficacy comparison between mRNA and inactivated whole virus vaccine among patients with chronic respiratory diseases, including asthma, chronic obstructive pulmonary disease (COPD), and bronchiectasis. METHODS: This was a retrospective case control study on the efficacy of BNT162b2 (mRNA vaccine) and CoronaVac (inactivated whole virus vaccine) against COVID-19 in patients with chronic respiratory diseases. A total of 327 patients were included, with 109 patients infected with COVID-19 matched with 218 patients without COVID-19. The co-primary outcomes were vaccine effectiveness against symptomatic COVID-19, COVID-19-related hospitalization and COVID-19-related respiratory failure. Vaccine effectiveness was calculated using the formula (1-adjusted odds ratio) x 100. RESULTS: Patients who received at least 2 doses of

CoronaVac had lower risk of being hospitalized for COVID-19 and developing respiratory failure than those who did not have vaccination, with adjusted odds ratio (OR) of 0.189 (95% CI = 0.050-0.714, p = 0.014) and 0.128 (95% CI = 0.026-0.638, p = 0.012) respectively. Patients who received at least 2 doses of BNT162b2 had lower risk of being hospitalized for COVID-19 and developing respiratory failure than those who did not have vaccination with adjusted OR of 0.207 (95% CI = 0.043-0.962, p = 0.050) and 0.093 (95% CI = 0.011-0.827, p = 0.033) respectively. There was no statistically significant difference in the risks of being hospitalized for COVID-19 and developing respiratory failure between patients who received at least 2 doses of CoronaVac or BNT162b2. CONCLUSION: BNT162b2 and CoronaVac vaccines are effective in preventing hospitalization for COVID-19 and respiratory failure complicating COVID-19 among patients with chronic respiratory diseases. Patients with chronic respiratory diseases should be encouraged to have COVID-19 vaccination.

Vaccine-induced immune thrombotic thrombocytopenia (VITT) after SARS-CoV-2 vaccination: Two cases from Germany with unusual presentation. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare clinical condition that has emerged during the mass immunization against SARS-CoV-2. Reports indicate that VITT may also be induced by other vaccines, such as the human papillomavirus vaccine, or occur independently of vaccination. Its recognition requires a high index of suspicion, especially in patients presenting with thrombocytopenia and thrombosis several days after vaccination with an adenoviral vector-based vaccine against SARS-CoV-2. Bleeding manifestations do not exclude VITT, as initially assumed. It is of great importance to perform the appropriate diagnostic tests early in the course of the disease, as false-negative results may occur and many aspects of VITT are not fully understood. These two cases from Germany demonstrate unusual presentations of VITT.

How severe would prioritization-induced bottlenecks need to be offset the benefits from prioritizing COVID-19 vaccination to those most at risk in New York City? BACKGROUND: Prioritization of higher-risk people for COVID-19 vaccination could prevent more deaths, but could slow vaccination speed. We used mathematical modeling to examine the trade-off between vaccination speed and prioritization for individuals age 65+ and essential workers. METHODS: We used a stochastic, discrete-time susceptible-exposed-infected-recovered (SEIR) model with age- and comorbidity-adjusted COVID-19 outcomes (infections, hospitalizations, and deaths). The model was calibrated to COVID-19 hospitalizations, ICU census, and deaths in NYC. We assumed 10,000 vaccinations per day, initially restricted to healthcare workers and nursing home populations, and subsequently expanded to other populations at alternative times (4, 5, or 6â€‰weeks after vaccine launch) and speeds (20,000, 50,000, 100,000, or 150,000 vaccinations per day), as well as prioritization options (+/- prioritization of people age 65+ and essential workers). In sensitivity analyses, we examined the effect of a SARS-COV-2 variant with greater transmissibility. RESULTS: To be beneficial, prioritization must not create a bottleneck that decreases vaccination speed by >â€‰50% without a more transmissible variant, or by >â€‰33% with the emergence of the more transmissible variant. More specifically, prioritizing people age 65+ and essential workers increased the number of lives saved per vaccine dose delivered: 3000 deaths could be averted by delivering 83,000 vaccinations per day without prioritization or 50,000 vaccinations per day with prioritization. Other tradeoffs involve vaccination speed and timing. Compared to the slowest-examined vaccination speed of 20,000 vaccinations per day, achieving the fastest-examined vaccination speed of 150,000 vaccinations per day would avert additional 313,700 (28.6%) infections and 1693 (24.1%) deaths. Emergence of a more transmissible variant would double COVID-19 infections, hospitalizations, and deaths over the first 6 months of vaccination. The fastest-examined vaccination speed could only offset the harm of the more transmissible variant if achieved within 5â€‰weeks of vaccine launch. CONCLUSIONS: Faster vaccination speed with sooner vaccination expansion would save more lives. Prioritization of COVID-

19 vaccines to higher-risk populations would be more beneficial only if it does not create an excessive vaccine delivery bottleneck.

Comparing the SARS-CoV-2-specific antibody response in human milk after homologous and heterologous booster vaccinations. Human milk contains SARS-CoV-2-specific antibodies after COVID-19 vaccination. These milk antibodies decrease several months post-vaccination. Whether booster immunization restores human milk antibody levels, potentially offering prolonged passive immunity for the infant, remains unknown. In this prospective follow-up study, we investigated the longitudinal SARS-CoV-2-specific antibody response in human milk of 26 lactating women who received a COVID-19 booster dose of an mRNA-based vaccine. Moreover, we evaluated whether the booster-induced human milk antibody response differs for participants who received a similar or different vaccine type in their primary vaccination series. All participants (100%) who received a homologous booster vaccination showed SARS-CoV-2-specific immunoglobulin A (IgA) and immunoglobulin G (IgG) in their milk. Heterologous booster vaccination resulted in milk conversion for 9 (69%) and 13 (100%) participants for IgA and IgG respectively. Findings of this study indicate that both homologous and heterologous boosting schedules have the potential to enhance SARS-CoV-2-specific IgA and IgG in human milk.

The v-safe after vaccination health checker: Active vaccine safety monitoring during CDC's COVID-19 pandemic response. The Centers for Disease Control and Prevention (CDC) developed and implemented the v-safe after vaccination health checker (v-safe) to monitor COVID-19 vaccine safety and as an active surveillance supplement to existing CDC vaccine safety monitoring programs. V-safe allows persons who received COVID-19 vaccines to report on post-vaccination experiences and how symptoms affected their health at daily, weekly, and monthly timepoints after vaccination. Text message reminders are sent linking to Internet-based health check-in surveys. Surveys include questions to identify v-safe participants who may be eligible to enroll in a separate pregnancy registry activity that evaluates maternal and infant outcomes in those pregnant at the time of vaccination or receiving vaccine in the periconception period. We describe the development of and enhancements to v-safe, data management, promotion and communication to vaccination sites and partners, publications, strengths and limitations, and implications for future systems. We also describe enrollment in v-safe over time and demographics of persons participating in v-safe during the first year of operation (December 14, 2020 - December 13, 2021). During this time, 9,342,582 persons submitted 131,543,087 v-safe surveys. The majority of participants were female (62.3Â %) and non-Hispanic White (61.2Â %); median age was 49.0Â years. Most participants reported receiving an mRNA COVID-19 vaccine as their first recorded dose (95.0Â %). V-safe contributed to CDC's vaccine safety assessments for FDA-authorized COVID-19 vaccines by enabling near real-time reporting of reactogenicity once the COVID-19 vaccination program began in the community, encouraging reports to the Vaccine Adverse Event Reporting System and facilitating enrollment in a large post-vaccination pregnancy registry. Given that v-safe is an integral component of the most comprehensive safety monitoring program in U.S. history, we believe that this approach has promise as a potential application for future pandemic response activities as well as rollout of novel vaccines in a non-pandemic context.

Comment on vaccine associated benign headache and cutaneous hemorrhage after ChAdOx1 nCoV-19 vaccine.

Long-term transition of antibody titers in healthcare workers following the first to fourth doses of mRNA COVID-19 vaccine: Comparison of two automated SARS-CoV-2 immunoassays. Anti-spike receptor binding domain (S-RBD) antibody against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) which best correlates with virus-neutralizing antibody is useful for estimating the period of protection and identifying the timing of additional booster doses. Long-term transition of the S-

RBD antibody titer and the antibody responses among healthy individuals remain unclear. In the present study, therefore, we monitored the S-RBD antibody titers of 16 healthcare workers every 4 weeks for 76 weeks after vaccination with a fourth dose of mRNA-1273 (Moderna) following three doses of BNT162b2 (Pfizer/BioNTech) using two commercial automated immunoassays (Roche and Abbott). Two antibody responses to the vaccine were similar with an up-down change before and after the second (weeks 3), third (weeks 40) and fourth (week 72) vaccinations, but the titer did not fall below the assay's positivity threshold in any individual. The peak level of the geometric mean titer (GMT) in the Roche assay was highest after the third vaccination, and that in Abbott assay was highest after the fourth vaccination but almost equal to that after the third vaccination. Both the geometric mean fold rise (GMFR) demonstrated by the Roche and Abbott assays were highest after the third vaccination. Antibody titers determined by the Roche and Abbott assays showed a positive strong correlation (correlation coefficient: 0.70 to 0.99), but the ratio (Roche/Abbott) of antibodies demonstrated by both assays increased 0.46- to 8.26-fold between weeks 3 and 76. These findings will be helpful for clinicians when interpreting results for SARS-CoV-2 antibody levels and considering future vaccination strategies.
Large Cohort Study Finds Possible Association Between Postural Orthostatic Tachycardia Syndrome and COVID-19 Vaccination but Far Stronger Link With SARS-CoV-2 Infection. This Medical News story discusses a study that found possible associations between postural orthostatic tachycardia syndrome (POTS) and COVID-19 vaccination and SARS-CoV-2 infection.
SARS-CoV-2 breakthrough infections in vaccinated individuals requiring ventilatory support for severe acute respiratory failure.
High levels of antibodies 6 months after COVID-19 vaccination in children with severe chronic diseases: A prospective longitudinal case series.
Hepatic and pulmonary involvement in a patient with PR3-ANCA vasculitis following SARS-CoV-2 vaccination: A case report. We here report the first case of anti-proteinase 3-positive anti-neutrophil cytoplasmic antibodies (ANCA)-associated vasculitis following the severe acute respiratory syndrome coronavirus 2 Pfizer-BioNTech vaccine presenting with prominent liver involvement and alveolar haemorrhage. Two weeks after vaccination, a 49-year-old man developed inflammatory arthralgias and hypertransaminasaemia. Two months later, fever and haemoptysis appeared; the patient tested positive for anti-proteinase 3 autoantibodies. High-dose steroids and rituximab were started, and complete remission was achieved. Systemic autoimmune diseases, including ANCA-associated vasculitis, should always be considered in the differential diagnosis of hypertransaminasaemia, especially when the clinical context is suspicious.
Adverse events following first and second dose COVID-19 vaccination in England, October 2020 to September 2021: a national vaccine surveillance platform self-controlled case series study. BackgroundPost-authorisation vaccine safety surveillance is well established for reporting common adverse events of interest (AEIs) following influenza vaccines, but not for COVID-19 vaccines.AimTo estimate the incidence of AEIs presenting to primary care following COVID-19 vaccination in England, and report safety profile differences between vaccine brands.MethodsWe used a self-controlled case series design to estimate relative incidence (RI) of AEIs reported to the national sentinel network, the Oxford-Royal College of General Practitioners Clinical Informatics Digital Hub. We compared AEIs (overall and by clinical category) 7 days pre- and post-vaccination to background levels between 1 October 2020 and 12 September 2021.ResultsWithin 7,952,861 records, 781,200 individuals (9.82%) presented to general practice with 1,482,273 AEIs, 4.85% within 7 days post-vaccination. Overall, medically attended AEIs decreased post-vaccination against background levels. There was a 3-7% decrease in incidence within 7 days after both doses of Comirnaty (RI:Â 0.93; 95%Â CI: 0.91-0.94 and RI:Â 0.96; 95%Â CI: 0.94-0.98, respectively) and Vaxzevria (RI:Â 0.97; 95%Â CI:Â 0.95-0.98). A 20%

increase was observed after one dose of Spikevax (RI:â€‰1.20; 95% CI: 1.00-1.44). Fewer AEIs were reported as age increased. Types of AEIs, e.g. increased neurological and psychiatric conditions, varied between brands following two doses of Comirnaty (RI: 1.41; 95%Â CI: 1.28-1.56) and Vaxzevria (RI: 1.07; 95% CI: 0.97-1.78).ConclusionCOVID-19 vaccines are associated with a small decrease in medically attended AEI incidence. Sentinel networks could routinely report common AEI rates, contributing to reporting vaccine safety.

The effect of immunomodulators on seroconversion after BNT162b2 and AZD1222 vaccines in patients with immune-mediated inflammatory diseases: a prospective cohort study. BACKGROUND: Biologic and nonbiologic immunomodulators, used to treat immune-mediated inflammatory diseases (IMIDs), could impair the immune response to COVID-19 vaccines and thus vaccine effectiveness. OBJECTIVES: Our objective was to investigate the association between biologic and nonbiologic immunomodulators and seroconversion following the first and second dose of COVID-19 vaccines in patients with IMIDs. METHODS: Serum samples were collected following the first or second dose of the BNT162b2 or AZD1222 vaccines from patients receiving biologic and/or nonbiologic immunomodulators for one or more of psoriasis, psoriatic arthritis, rheumatoid arthritis, inflammatory bowel disease or systemic lupus erythematosus. Seroconversion was defined as a positive Roche ElecsysÂ® Anti-SARS-CoV-2 S (spike protein subunit S1/receptor binding domain) immunoassay (â‰¥ 0.8â€…U mL-1). Association between immunomodulator exposure and seroconversion was assessed using logistic regression, adjusting for age and sex. RESULTS: After excluding those with prior COVID-19, post-first vaccine dose samples from 193 participants and post-second dose samples from 312 participants were included in the analysis. Following the first vaccine dose, 17.6% (n = 34) of participants did not seroconvert. Seroconversion was reduced for those on nonbiologic [adjusted odds ratio (OR) 0.29, 95% confidence interval (CI) 0.12-0.69] or combined nonbiologic and biologic treatment (adjusted OR 0.14, 95% CI 0.045-0.45) compared with those on biologic monotherapy. Subgroup analysis demonstrated reduced odds of seroconversion in those on methotrexate (adjusted OR 0.097, 95% CI 0.19-0.49) or prednisolone treatment (adjusted OR 0.044, 95% CI 0.002-1.00) relative to tumour necrosis factor-Î± inhibitor monotherapy. No participants receiving rituximab (n < 5) seroconverted after the first vaccine dose. Following the second vaccine dose, 1.6% of all participants did not seroconvert. Non-seroconversion was associated with receiving rituximab (n = 3 of 4) compared with those receiving other therapies (n = 2 of 308, P < 0.001). Post hoc analyses demonstrated that non-seroconversion was associated with age [adjusted OR 0.18, 95% CI 0.037-0.93 for those aged 60â€…years and over (reference category age 18-39â€…years)], but not sex, ethnicity or vaccine type. CONCLUSIONS: Treatment with nonbiologics, particularly methotrexate, is associated with impaired seroconversion following two BNT162b2 or AZD1222 vaccine doses, in patients with IMIDs. These findings are consistent with those of other published studies. While this could indicate reduced protection against COVID-19, the immunological parameters that correlate most closely with vaccine effectiveness need to be defined to reach this conclusion.

Cerebral venous sinus thrombosis after COVID-19 vaccination: a case report and literature review. As COVID-19 vaccines became widely available, there have been reports of neurovascular complications. In this article, we aim to report a case of cerebral venous sinus thrombosis (CVST) induced by COVID-19 vaccination, with a literature review on similar cases as well as the potential pathophysiological mechanisms. Our case is a healthy male who developed headache, vomiting, photophobia and diplopia after receiving the Ad26.COV2.S vaccine. Fundus examination showed papilledema, and magnetic resonance imaging of the brain and cerebral veins showed CVST involving the superior sagittal sinus and right transverse sinus extending into the right jugular vein. Hypercoagulability workup was unremarkable, and the patient received immunotherapy and

anticoagulation. Following this treatment, symptoms resolved, and he had no residual neurologic deficits. Developing neurologic manifestations, especially severe headaches with papilledema, after COVID-19 vaccination should warrant neuroimaging. Early recognition and management of CVST are essential for good clinical outcomes.

A Case of Multiple Sclerosis Uncovered Following Moderna SARS-CoV-2 Vaccination. Multiple sclerosis is a demyelinating disorder of the central nervous system characterized by lesions disseminated in time and space. The diagnostic criteria for laboratory-supported definite multiple sclerosis involve two episodes of symptoms, evidence of at least one white matter lesion on MRI, and abnormal oligoclonal bands in cerebrospinal fluid. Patients usually present in their early 20s and on average have up to one flare-up per year. While vaccines play an important role in the prevention of many diseases, they have often been purported as a potential trigger of multiple sclerosis and multiple sclerosis relapses. The medical literature provides reliable information concerning the risk of developing multiple sclerosis and multiple sclerosis relapses following the administration of most vaccines, but not much is known about the novel Moderna severe acute respiratory syndrome coronavirus 2 (SARSâ€‘CoVâ€‘2) vaccine. We report the case of a 24-year-old male who presented with right-sided facial weakness, dizziness, and dysarthria two days after receiving his first dose of the Moderna coronavirus disease 2019 (COVID-19) vaccine. Imaging studies noted both acute and chronic central nervous system lesions. He met the diagnostic criteria for laboratory-supported definite multiple sclerosis. His acute flare was treated with intravenous corticosteroids and the patient was subsequently started on ocrelizumab. This case serves as an important example of the novel Moderna SARS-CoV-2 vaccine as a potential trigger of multiple sclerosis relapse. In addition, we review the literature for similar occurrences with the other COVID-19 vaccines and provide reliable guidance for COVID-19 vaccination for patients with multiple sclerosis.

Effects of the COVID-19 Pandemic on Patients With NMO Spectrum Disorders and MOG-Antibody-Associated Diseases: COPANMO(G)-Study. BACKGROUND AND OBJECTIVES: To evaluate the effects of the coronavirus disease 2019 (COVID-19) pandemic on the life of patients with neuromyelitis optica spectrum disorders (NMOSD) and myelin oligodendrocyte glycoprotein antibody-associated diseases (MOGAD). METHODS: This multicenter, cross-sectional study included data of 187 patients recruited from 19 different German and Austrian Neuromyelitis Optica Study Group (NEMOS) centers between July 2021 and March 2022. The effects of the pandemic on immunotherapeutic treatment and access to care, the possible severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, and the potential effect of vaccination against SARS-CoV-2 on disease incidence and relapse risk were assessed using a patient questionnaire. Health-related quality of life (HRQoL) was measured with the EuroQoL Group 5-Dimension 5-Level Scale (EQ-5D-5L). Demographic and clinical characteristics were retrieved from the NEMOS database. RESULTS: One hundred eighty-seven patients (75% women; median age 47 [range 21-86] years; median disease duration 5.5 [range 0-67] years; median Expanded Disability Status Scale 2.0 [range 0-8.0]; 51% aquaporin-4 immunoglobulin G (AQP4-IgG)-positive, 36% myelin oligodendrocyte glycoprotein (MOG)-IgG-positive 13% double-seronegative) were analyzed. Most patients maintained excellent access to healthcare services throughout the pandemic. Immunotherapy was not changed in 88% of patients. Ninety-one percent of all patients were satisfied with medical care during the pandemic. Nearly two-thirds (64%) of patients rated their risk of infection with SARS-CoV-2 as low or moderate. Among this study sample, 23 patients (12%) knowingly acquired an infection with SARS-CoV-2 and predominantly had a nonsevere course of illness (n = 22/23, 96%). The SARS-CoV-2 vaccination rate was 89%, with 4 cases of confirmed attack or first manifestation of NMOSD/MOGAD occurring in temporal association with the vaccination (range 2-9 days). The reported HRQoL did not decline compared with a prepandemic assessment (mean EQ-5D-5L index value 0.76, 95% bootstrap

confidence interval [CI] 0.72-0.80; mean EQ-VAS 66.5, 95% bootstrap CI 63.5-69.3). DISCUSSION: This study demonstrates that, overall, patients with NMOSD/MOGAD affiliated with specialized centers received ongoing medical care during the pandemic. Patients' satisfaction with medical care and HRQoL did not decrease.

Acceptance, safety and immunogenicity of a booster dose of inactivated SARS-CoV-2 vaccine in adults with tuberculosis.

Neutralizing antibodies after three doses of the BNT162b2 vaccine, breakthrough infection, and symptoms during the Omicron-predominant wave. OBJECTIVES: To investigate the role of immunogenicity after the third vaccine dose against Omicron infection and COVID-19-compatible symptoms of infection. METHODS: First, we examined vaccine effectiveness (VE) of the third dose against the second dose during the Omicron wave among the staff at a tertiary hospital in Tokyo. In a case-control study of third vaccine recipients, we compared the preinfection live-virus neutralizing antibodies (NAb) against Omicron between breakthrough cases and their controls who had close contact with patients with COVID-19. Among these cases, we examined the association between NAb levels and the number of COVID-19-compatible symptoms. RESULTS: Among the 1456 participants for VE analysis, 60 breakthrough infections occurred during the Omicron wave. The third dose VE for infection was 54.6%. Among the third dose recipients, NAb levels against Omicron did not differ between the cases (nÂ =Â 22) and controls (nÂ =Â 21). Among the cases, those who experienced COVID-19-compatible symptoms had lower NAb levels against Omicron than those who did not. CONCLUSION: The third vaccine dose was effective in decreasing the risk of SARS-CoV-2 infection during Omicron wave compared with the second dose. Among third dose recipients, higher preinfection NAb levels may not be associated with a lower risk of Omicron infection. Contrarily, they may be associated with fewer symptoms of infection.

Antibody levels following vaccination against SARS-CoV-2: associations with post-vaccination infection and risk factors in two UK longitudinal studies. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody levels can be used to assess humoral immune responses following SARS-CoV-2 infection or vaccination, and may predict risk of future infection. Higher levels of SARS-CoV-2 anti-Spike antibodies are known to be associated with increased protection against future SARS-CoV-2 infection. However, variation in antibody levels and risk factors for lower antibody levels following each round of SARS-CoV-2 vaccination have not been explored across a wide range of socio-demographic, SARS-CoV-2 infection and vaccination, and health factors within population-based cohorts. METHODS: Samples were collected from 9361 individuals from TwinsUK and ALSPAC UK population-based longitudinal studies and tested for SARS-CoV-2 antibodies. Cross-sectional sampling was undertaken jointly in April-May 2021 (TwinsUK, N=4256; ALSPAC, N=4622), and in TwinsUK only in November 2021-January 2022 (N=3575). Variation in antibody levels after first, second, and third SARS-CoV-2 vaccination with health, socio-demographic, SARS-CoV-2 infection, and SARS-CoV-2 vaccination variables were analysed. Using multivariable logistic regression models, we tested associations between antibody levels following vaccination and: (1) SARS-CoV-2 infection following vaccination(s); (2) health, socio-demographic, SARS-CoV-2 infection, and SARS-CoV-2 vaccination variables. RESULTS: Within TwinsUK, single-vaccinated individuals with the lowest 20% of anti-Spike antibody levels at initial testing had threefold greater odds of SARS-CoV-2 infection over the next 6-9 months (OR = 2.9, 95% CI: 1.4, 6.0), compared to the top 20%. In TwinsUK and ALSPAC, individuals identified as at increased risk of COVID-19 complication through the UK 'Shielded Patient List' had consistently greater odds (two- to fourfold) of having antibody levels in the lowest 10%. Third vaccination increased absolute antibody levels for almost all individuals, and reduced relative disparities compared with earlier vaccinations. CONCLUSIONS: These findings quantify the association between antibody level and risk of subsequent infection, and support a policy of triple

vaccination for the generation of protective antibodies. FUNDING: Antibody testing was funded by UK Health Security Agency. The National Core Studies program is funded by COVID-19 Longitudinal Health and Wellbeing - National Core Study (LHW-NCS) HMT/UKRI/MRC ([MC_PC_20030] and [MC_PC_20059]). Related funding was also provided by the NIHR 606 (CONVALESCENCE grant [COV-LT-0009]). TwinsUK is funded by the Wellcome Trust, Medical Research Council, Versus Arthritis, European Union Horizon 2020, Chronic Disease Research Foundation (CDRF), Zoe Ltd and the National Institute for Health Research (NIHR) Clinical Research Network (CRN) and Biomedical Research Centre based at Guy's and St Thomas' NHS Foundation Trust in partnership with King's College London. The UK Medical Research Council and Wellcome (Grant ref: [217065/Z/19/Z]) and the University of Bristol provide core support for ALSPAC.

 Vaccination against the virus that causes COVID-19 triggers the body to produce antibodies that help fight future infections. But some people generate more antibodies after vaccination than others. People with lower levels of antibodies are more likely to get COVID-19 in the future. Identifying people with low antibody levels after COVID-19 vaccination is important. It could help decide who receives priority for future vaccination. Previous studies show that people with certain health conditions produce fewer antibodies after one or two doses of a COVID-19 vaccine. For example, people with weakened immune systems. Now that third booster doses are available, it is vital to determine if they increase antibody levels for those most at risk of severe COVID-19. Cheetham et al. show that a third booster dose of a COVID-19 vaccine boosts antibodies to high levels in 90% of individuals, including those at increased risk. In the experiments, Cheetham et al. measured antibodies against the virus that causes COVID-19 in 9,361 individuals participating in two large long-term health studies in the United Kingdom. The experiments found that UK individuals advised to shield from the virus because they were at increased risk of complications had lower levels of antibodies after one or two vaccine doses than individuals without such risk factors. This difference was also seen after a third booster dose, but overall antibody levels had large increases. People who received the Oxford/AstraZeneca vaccine as their first dose also had lower antibody levels after one or two doses than those who received the Pfizer/BioNTech vaccine first. Positively, this difference in antibody levels was no longer seen after a third booster dose. Individuals with lower antibody levels after their first dose were also more likely to have a case of COVID-19 in the following months. Antibody levels were high in most individuals after the third dose. The results may help governments and public health officials identify individuals who may need extra protection after the first two vaccine doses. They also support current policies promoting booster doses of the vaccine and may support prioritizing booster doses for those at the highest risk from COVID-19 in future vaccination campaigns.

Attitudes towards receiving COVID-19 vaccine and its associated factors among Southwest Ethiopian adults, 2021. INTRODUCTION: Many countries around the world are still affected by the global pandemic of coronavirus disease. The vaccine is the most effective method of controlling Coronavirus Disease 2019 (COVID-19). However, attitudes toward vaccination are heavily affected by different factors besides vaccine availability. OBJECTIVES: This study aimed to determine community attitudes toward the COVID-19 vaccine in Gurage Zone, Ethiopia. METHODS: A community-based cross-sectional study was conducted from November 15th to December 15th, 2021. A simple random sampling technique was used to select 364 participants in the study area. An interview-administered structured questionnaire was used to collect the data; the data was entered into Epidata 3.1 version, and then exported to SPSS version 23 for further analysis. Descriptive statistics were used to determine the characteristics of study participants. Binary and multivariable logistic regression analyses with a p-value of less than 0.05 were used as a measure of significance. RESULTS: In this study, 44.7% of study participants had a favorable attitude toward the COVID-19 vaccine. Perceived potential vaccine harm [AOR: 1.85; 95% CI (1.15-2.96)], Having ever had a chronic disease [AOR: 3.22;

95% CI (2.02-5.14)], community belief on the effectiveness of the vaccine [AOR: 2.02; 95% CI (1.27-3.22)], and average monthly income 3001-5000 ETB [AOR: 0.54; 95% CI (0.30-0.97)], average monthly income 5001-10000 ETB [AOR: 0.48; 95% CI(0.27-0.86)] were statistically significantly towards COVID-19 vaccination. CONCLUSIONS: Overall, less than half of the participants had a favorable attitude toward the COVID-19 vaccine. Perceived potential vaccine harm, having ever had a chronic disease, community belief in the effectiveness of the vaccine, and average monthly income were determinant factors of the community's attitude toward COVID-19 vaccination. As a result, information conversation with the community's awareness of the COVID-19 vaccination in reducing vaccine-related suspicion.

Assessment of Efficacy and Safety of mRNA COVID-19 Vaccines in Children Aged 5 to 11 Years: A Systematic Review and Meta-analysis. IMPORTANCE: Evidence of the efficacy and safety of messenger RNA (mRNA) COVID-19 vaccines in children aged 5 to 11 years has been emerging. Collecting these data will inform clinicians, families, and policy makers. OBJECTIVE: To evaluate the efficacy and safety of mRNA COVID-19 vaccines in children aged 5 to 11 years in a systematic review and meta-analysis. DATA SOURCES: PubMed and Embase databases were searched on September 29, 2022, without language restrictions. STUDY SELECTION: Randomized clinical trials and observational studies comparing vaccinated vs unvaccinated children aged 5 to 11 years and reporting efficacy or safety outcomes were included. Studies reporting safety outcomes in vaccinated children only (ie, no control group) were also included. DATA EXTRACTION AND SYNTHESIS: Two investigators independently extracted relevant data from each study. Odds ratios (ORs) for efficacy and safety outcomes and incidences of adverse events (AEs) following vaccination were synthesized using a random-effects model. This study followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses and Meta-analysis of Observational Studies in Epidemiology reporting guidelines. MAIN OUTCOMES AND MEASURES: The primary outcome was SARS-CoV-2 infections with or without symptoms. The secondary outcomes included symptomatic SARS-CoV-2 infections, hospitalizations, and multisystem inflammatory syndrome in children. The incidences of each AE following vaccination were also evaluated. RESULTS: Two randomized clinical trials and 15 observational studies involving 10â€¯935â€¯541 vaccinated children (median or mean age range, 8.0-9.5 years) and 2â€¯635â€¯251 unvaccinated children (median or mean age range, 7.0-9.5 years) were included. Two-dose mRNA COVID-19 vaccination compared with no vaccination was associated with lower risks of SARS-CoV-2 infections with or without symptoms (OR, 0.47; 95% CI, 0.35-0.64), symptomatic SARS-CoV-2 infections (OR, 0.53; 95% CI, 0.41-0.70), hospitalizations (OR, 0.32; 95% CI, 0.15-0.68), and multisystem inflammatory syndrome in children (OR, 0.05; 95% CI, 0.02-0.10). Two randomized clinical trials and 5 observational studies investigated AEs among vaccinated children. Most vaccinated children experienced at least 1 local AE following the first injection (32â€¯494 of 55â€¯959 [86.3%]) and second injection (28â€¯135 of 46â€¯447 [86.3%]). Vaccination was associated with a higher risk of any AEs compared with placebo (OR, 1.92; 95% CI, 1.26-2.91). The incidence of AEs that prevented normal daily activities was 8.8% (95% CI, 5.4%-14.2%) and that of myocarditis was estimated to be 1.8 per million (95% CI, 0.000%-0.001%) following the second injection. CONCLUSIONS AND RELEVANCE: In this systematic review and meta-analysis, COVID-19 mRNA vaccines among children aged 5 to 11 years were associated with measures of efficacy in preventing SARS-CoV-2 infection and severe COVID-19-related illnesses. While most children developed local AEs, severe AEs were rare, and most of AEs resolved within several days. These data provide evidence for future recommendations.

Antibody levels following booster SARS-CoV-2 vaccination among dialysis patients initially vaccinated with adenovirus vector-based vaccine.

COVID-19 BNT162b2 mRNA vaccine induced myocarditis with left ventricular thrombus in a young male.

Corneal Allograft Endothelial Rejection after Sinopharm COVID-19 Vaccination; Report of Six Cases. AIM: To report the clinical characteristics of six patients with corneal allograft endothelial rejection after COVID-19 vaccination with Sinopharm and to review the literature. METHODS: This is a prospective case series describing corneal allograft rejection among subjects having received Sinopharm (BBIBP-CorV) vaccine, coming to cornea clinic at a university-based hospital (Rassoul Akram Hospital, Tehran, Iran) from September 2021 to March 2022 for regular follow-up examinations. Data on demographics, vaccination (based on vaccine card), and graft condition (based on recent examination and previous medical documents) were recorded. RESULTS: Out of 54 eyes (46 patients), 6 eyes (6 patients) had corneal allograft endothelial rejection after 3 to 117Â days, post-vaccination. Three out of six rejections occurred within two weeks following vaccination. All of them were male with the mean age of 53.00Â Â±Â 19.66Â years. The graft type of all patients was penetrating keratoplasty (PKP). The adverse event developed on average at 40.67Â Â±Â 34.33Â months after surgery. Four patients were under maintenance treatment by topical steroid at the time of vaccination. One also received systemic immunomodulatory medication. Four grafts ended up with partial or complete graft failure. One case had received two doses of vaccine before undergoing the second corneal graft transplantation. CONCLUSION: COVID-19 vaccination with Sinopharm may trigger corneal allograft endothelial rejection even in individuals with low-risk graft and under maintenance topical and/or systemic immunomodulatory medications.

Quantification of Severe Acute Respiratory Syndrome Coronavirus 2 Binding Antibody Levels To Assess Infection and Vaccine-Induced Immunity Using WHO Standards. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) binding antibody (Ab) levels following vaccination or natural infection could be used as a surrogate for immune protection if results of serological assays were standardized to yield quantitative results using an international standard. Using a bead-based serological assay (Luminex xMAP), anti-receptor binding domain (anti-RBD) Ab levels were determined for 1,450 participants enrolled in the Los Angeles Pandemic Surveillance Cohort (LAPSC) study. For 123 participants, SARS-CoV-2 binding antibody unit (BAU) levels were also quantified using WHO standards and then compared to the semiquantitative results. Samples were chosen to represent the range of results and time from vaccination. Antibody levels and decay rates were then compared using unadjusted and adjusted linear regression models. The linear range of the assay used in this study was determined to be 300 to 5,000 mean fluorescence intensity units (MFI). Among the fully vaccinated groups (vaccinated only and vaccinated with past infection), 84.8% had anti-RBD MFI values above the linear range ofâ€‰>5,000 MFI, and 33.8% had valuesâ€‰of >15,000 MFI. Among vaccinated participants with past infection (hybrid immunity), 97% had anti-RBD values of >5,000 MFI and 70% (120/171) had anti-RBD values ofâ€‰>15,000 MFI. In the subgroup quantified using the WHO control, BAU levels were significantly higher than the semiquantitative MFI results. In vaccinated participants, Ab decay levels were similar between infected and noninfected groups (Pâ€‰=â€‰0.337). These results demonstrate that accurate quantitation is possible if standardized with an international standard. BAU can then be compared over time or between subjects and would be useful in clinical decision making. IMPORTANCE Accurate quantification of SARS-CoV-2-specific antibodies can be achieved using a universal standard with sample dilution within the linear range. With hybrid immunity being now common, it is critical to use protocols adapted to high Ab levels to standardize serological results. We validated this approach with the Los Angeles Pandemic Surveillance Cohort by comparing the antibody decay rates in vaccinated participants and vaccinated infected participants.

Dynamics of Different Classes and Subclasses of Antibody Responses to Severe Acute Respiratory Syndrome Coronavirus 2 Variants after Coronavirus Disease 2019 and CoronaVac Vaccination in Thailand. The humoral immune response plays a key role in protecting the population from SARS-CoV-2 transmission. Patients who recovered from COVID-19 as well as fully vaccinated individuals have elevated levels of antibodies. The dynamic levels of the classes and subclasses of antibody responses to new variants that occur in different populations remain unclear. We prospectively recruited 60 participants, including COVID-19 patients and CoronaVac-vaccinated individuals, in Thailand from May to August 2021. Plasma samples were collected on day 0, day 14, and day 28 to determine the dynamic levels of the classes and subclasses of plasma antibodies against the receptor-binding domain (RBD) in the spike protein (S) of four SARS-CoV-2 strains (Wuhan, Alpha, Delta, and Omicron) via enzyme-linked immunosorbent assay. Our results indicated that the patients with SARS-CoV-2 infections had broader class and subclass profiles as well as higher levels of anti-S RBD antibodies to the Wuhan, Alpha, and Delta strains than did the CoronaVac-vaccinated individuals. The median antibody levels increased and subsequently declined in a month in the COVID-19 patients and in the vaccinated group. Correlations of the classes and subclasses of antibodies were observed in the COVID-19 patients but not in the vaccinated individuals. The levels of all of the anti-S RBD antibodies against the Omicron variant were low in the patients and in the vaccinated individuals. Our study revealed distinct antibody profiles between the two cohorts, suggesting different pathways of immune activation. This could have an impact on protection from infections by new variants of concern (VOC). IMPORTANCE The antibody responses to new SARS-CoV-2 variants that occur in different populations remain unclear. In this study, we recruited 60 participants, including COVID-19 patients and CoronaVac-vaccinated individuals, in Thailand and determined the dynamic levels of the IgG, IgA, IgM, and IgG subclasses of antibodies against the spike protein (S) of four SARS-CoV-2 strains. Our results showed that the patients with SARS-CoV-2 infections had broader profiles and higher levels of antibodies to the Wuhan, Alpha, and Delta strains than did the CoronaVac-vaccinated individuals. The antibody levels of both groups increased and subsequently decreased within 1 month. Higher and functional correlations of these antibodies were observed in the COVID-19 patients. The levels of all anti-S RBD antibodies against the Omicron variant were low in patients and vaccinated individuals. Our study revealed distinct antibody responses between the two groups, suggesting different pathways of immune response, which may have an impact on protection from infections by new SARS-CoV-2 variants.

Pityriasis Lichenoides Following SARS-CoV-2 Infection/Vaccination. PURPOSE OF REVIEW: Pityriasis lichenoides (PL) is a spectrum of dermatological conditions involving polymorphous lesions. Natural history of the condition ranges from acute to chronic. Cases of PL following SARS-CoV-2 infection/vaccination have been reported, but not yet comprehensively reviewed. Hence, the objective of this article is to review and summarize cases of PL following SARS-CoV-2 infection/vaccination in order to guide clinicians in its diagnosis and management. RECENT FINDINGS: PubMed, Embase, and Web of Science were searched for relevant articles. Thirteen articles, consisting of 14 cases of PL following SARS-CoV-2 infection/vaccination, were identified. Males represented 64.3% of cases, and the average age of those affected was 41.4Â years. The majority of cases (Nâ€‰=â€‰9, 64.3%) were following SARS-CoV-2 vaccination, the most commonly implicated being Pfizer-BioNTech (nâ€‰=â€‰8/10, 80%), while four (28.6) followed infection. The overall latency period ranged from 5Â days to 1Â month. Treatments varied greatly. However, at the time of follow-up, 12/14 patients (85.7%) had either marked improvement or complete resolution of lesions. SUMMARY: This review cannot determine causality. However, a temporal association was observed with the case reports, and one case of PL followed SARS-CoV-2 infection and recurred with subsequent vaccination, suggesting an association. Nevertheless, risk of developing PL following

SARS-CoV-2 infection/vaccination is likely extremely low. There is also the possibility these cases are purely coincidental. Still, clinicians should be aware of this possible etiology when diagnosing a new or exacerbated case of PL. Finally, given that the majority of patients had marked improvement or complete resolution of lesions at the time of follow-up, clinicians should provide reassurance to their affected patients.

Sleep quality was associated with adverse reactions after coronavirus disease 2019 vaccination among healthcare workers: A longitudinal paired study. BACKGROUND: Many countries have currently relied on various types of vaccines for the public to control the coronavirus disease 2019 (COVID-19) pandemic. The adverse reactions (ARs) after vaccination may affect vaccination coverage and confidence. However, whether sleep quality was associated with ARs after vaccination remains unclear. METHODS: We designed a longitudinal paired study within a hospital setting. We collected data about the side effects within 7 days after two doses of scheduled vaccination among healthcare workers (HCWs). All HCWs were asked to complete a sleep survey indexed by the Pittsburgh Sleep Quality Index (PSQI) before vaccination and after a 1-month follow-up. Then, we explored the relationship between sleep quality before or after vaccination and the occurrence of ARs. RESULTS: A total of 345 HCWs were recruited to receive COVID-19 vaccination. The sleep quality became worse after vaccination. All local and systemic reactions were mild or moderate in severity (32.46%), and no serious adverse event was reported. Binary logistic regression showed participants with poor sleep quality (PSQI > 5) than good sleep quality (PSQI â‰¤ 5) before the two doses of vaccination, respectively, exhibited 1.515 and 1.107 times risk of ARs after each vaccination (both $p < 0.001$). CONCLUSION: There is an apparently complex bidirectional relationship between sleep quality and COVID-19 vaccination adverse effects. Poor sleep quality significantly increases the risk of mild ARs after vaccination, while vaccination may cause a temporary decline in sleep quality.

Drug-induced sarcoidosis-like reaction three months after BNT162b2 mRNA COVID-19 vaccination: A case report and review of literature. BACKGROUND: A 70-year-old man with hepatitis C virus-related recurrent hepatocellular carcinoma was admitted for further diagnosis of a 1 cm iso-hyperechoic nodule in segment (S) 5. CASE SUMMARY: Gadolinium ethoxybenzyl diethylenetriamine pentaacetic acid-enhanced magnetic resonance imaging (EOB-MRI) revealed the nodule in S5 with a defect at the hepatobiliary phase, hyperintensity on diffusion weighted imaging (DWI) and hypointensity on apparent diffusion coefficient (ADC) map. Contrast-enhanced computed tomography revealed hypervascularity at the early phase, and delayed contrast-enhancement was observed at the late phase. Contrast-enhanced ultrasound (US) revealed incomplete defect at the late vascular phase. Inflammatory liver tumor, lymphoproliferative disease, intrahepatic cholangiocarcinoma (small duct type) and bile duct adenoma were suspected through the imaging studies. US guided biopsy, however, showed a noncaseating hepatic sarcoid-like epithelioid granuloma (HSEG), and histopathological analysis disclosed spindle shaped epithelioid cells harboring Langhans-type multinucleated giant cells. One month after admission, EOB-MRI signaled the disappearance of the defect at the hepatobiliary phase, of hyperintensity on DWI, of hypointensity on ADC map, and no stain at the early phase. CONCLUSION: That the patient had received BNT162b2 messenger RNA (mRNA) coronavirus disease 2019 vaccination 3 mo before the occurrence of HSEG, and that its disappearance was confirmed 4 mo after mRNA vaccination suggested that the drug-induced sarcoidosis-like reaction (DISR) might be induced by the mRNA vaccination. Fortunately, rechallenge of drug-induced DISR with the third mRNA vaccination was not confirmed.

X-linked Charcot-Marie-Tooth disease after SARS-CoV-2 vaccination mimicked stroke-like episodes: A case report. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccinations have been administered worldwide, with occasional reports of associated neurological complications. Specifically, the impact of vaccinations on individuals with X-linked Charcot-Marie-

Tooth disease type 1 (CMTX1) is unclear. Patients with CMTX1 can have stroke-like episodes with posterior reversible encephalopathy syndrome on magnetic resonance imaging (MRI), although this is rare. CASE SUMMARY: A 39-year-old man was admitted with episodic aphasia and dysphagia for 2 d. He received SARS-CoV-2 vaccination 39 d before admission. Physical examination showed pes cavus and reduced tendon reflexes. Brain MRI showed bilateral, symmetrical, restricted diffusion with T2 hyperintensities in the cerebral hemispheres. Nerve conduction studies revealed peripheral nerve damage. He was diagnosed with Charcot-Marie-Tooth disease, and a hemizygous mutation in the GJB1 gene on the X chromosome, known to be pathogenic for CMTX1, was identified. Initially, we suspected transient ischemic attack or demyelinating leukoencephalopathy. We initiated treatment with antithrombotic therapy and immunotherapy. At 1.5 mo after discharge, brain MRI showed complete resolution of lesions, with no recurrence. CONCLUSION: SARS-CoV-2 vaccination could be a predisposing factor for CMTX1 and trigger a sudden presentation.

Evaluation of the Effect of COVID-19 Vaccination on Exacerbations of Chronic Obstructive Pulmonary Disease: A Single-Center Study. BACKGROUND AND AIM: Â Vaccinations have been one of the main approaches to reducing mortality and exacerbations caused by infectious agents in chronic obstructive pulmonary disease (COPD). Among viral pathogens, coronaviruses have been described to play a role. This study aims to investigate the role of coronavirus disease 2019 (COVID-19) vaccination on exacerbation reduction in patients with COPD. METHODS: Patients diagnosed with COPD prior to the study date were considered the study population. Exacerbations of COPD before and after the COVID-19 vaccination were recorded. Patients with influenza and/or pneumococcal vaccination were excluded from the study due to their known role in reducing exacerbations of COPD. RESULTS: The study included 152 patients with a mean age of 67.5 Â± 9.7 years. Most patients were classified under Global Initiative for Chronic Obstructive Lung Disease (GOLD) stages 2 and 3. In fully vaccinated patients, COPD exacerbation was observed to be higher than in those without full vaccination (70.5% vs. 55.3%, respectively). Total risk status and vaccination status, however, were seen to be in a positive correlation, with higher risk and complete vaccination status presenting with a higher count of COPD exacerbation. CONCLUSION: Although it is known that the administration of COVID-19 vaccines in patients in risk groups reduces the risk of disease, there is no study showing a positive effect on COPD exacerbations alone. In our study, it was observed that only the COVID-19 vaccine was ineffective in attacks without influenza and pneumococcal vaccines.

Anti-N-Methyl-D-Aspartate Receptor Encephalitis after BNT162b2 COVID-19 Vaccination. After the coronavirus disease 2019 (COVID-19) pandemic emerged, the development of vaccines was accelerated. Neurologic complications of COVID-19 vaccination had been reported, which included encephalitis. In this study, we report a very rare case of a female with anti-N-methyl-D-aspartate receptor encephalitis associated with ovarian teratoma that would be triggered by BNT162b2 m-RNA COVID-19 vaccination.

SARS-CoV-2 antibody response after mRNA vaccination in healthcare workers with and without previous COVID-19, a follow-up study from a university hospital in Poland during 6 months 2021. INTRODUCTION: Healthcare workers (HCWs) from the beginning of the pandemic have been at risk of exposure to SARS-CoV-2, so they were vaccinated as first. OBJECTIVES: The purpose of the study was to determine the level of antibodies against SARS-CoV-2 in HCWs before and after vaccination with mRNA preparations according to previous COVID- 19. PATIENTS AND METHODS: The HCWs from the University Hospital in Krakow completed two surveys: the baseline survey before receiving the first dose of vaccine (in January 2021) and the follow-up survey in June 2021. In parallel, two blood samples were collected from each participant at baseline and at follow-up. Total anti-SARS-CoV-2 antibody levels were measured using the ECLIA technique. RESULTS: At baseline, 41.1% of HCWs had positive antibody test results, and at follow-up, the vaccinated HCWs had almost 100 times higher

antibody levels than the unvaccinated HCWs. Participants under 30 years of age had significantly higher antibody levels in June than older HCWs. Among participants with positive antibody test results in January, HCWs who had experienced asymptomatic COVID-19 had more than five times higher antibody levels in June than HCWs self-reported severe COVID-19. In total, 86.9% of HCWs received Comirnaty or Spikevax. The incidence rate of COVID-19 in the unvaccinated vs. vaccinated group was 13 times higher, 20.5% and 1.9% respectively. CONCLUSIONS: These results confirm the effectiveness of vaccination in the prevention of COVID-19 in HCWs. It is worth getting vaccinated regardless of previous infection. Furthermore, vaccination among HCWs under 30 years of age induced more effective antibody production compared to older individuals.

Functional changes in cytotoxic CD8+ T-cell cross-reactivity against the SARS-CoV-2 Omicron variant after mRNA vaccination. Understanding the T-cell responses involved in inhibiting COVID-19 severity is crucial for developing new therapeutic and vaccine strategies. Here, we characterized SARS-CoV-2 spike-specific CD8(+) T cells in vaccinees longitudinally. The BNT162b2 mRNA vaccine can induce spike-specific CD8(+) T cells cross-reacting to BA.1, whereas the T-cell receptor (TCR) repertoire usages decreased with time. Furthermore the mRNA vaccine induced spike-specific CD8(+) T cells subpopulation expressing Granzyme A (GZMA), Granzyme B (GZMB) and Perforin simultaneously in healthy donors at 4 weeks after the second vaccination. The induced subpopulation was not maintained at 12 weeks after the second vaccination. Incorporating factors that efficiently induce CD8(+) T cells with highly cytotoxic activity could improve future vaccine efficacy against such variants.

Acute pancreatitis following COVID-19 vaccine: A case report and brief literature review. Vaccination is the most effective way to overcome COVID-19 morbidity and mortality. However, Covid-19 vaccines may cause potential adverse effects. We reported a 28-year-old healthy woman who was referred to the emergency department with a chief complaint of severe abdominal pain, nausea and hemoptysis. She has received two doses of COVID-19 vaccine (Sinopharm BIBP). Similar this time, three days after the injection of the second dose of the Sinopharm BIBP COVID-19 vaccine, abdominal and flank pain appeared, for which she has referred to the emergency department. After necessary tests and pancreatitis was confirmed, we started fluid therapy, plasmapheresis, gemfibrozil and insulin for patient management. The COVID-19 vaccines may lead to acute pancreatitis. The mechanism of pancreatitis caused by COVID-19 vaccines is unclear. Acute pancreatitis can develop after COVID-19 vaccination. This process can even happen a few months later. Therefore, to better diagnosis and prevention of long-term complications, it is necessary to measuring the lipase or amylase in patients that received COVID-19 vaccine if abdominal pain was occurred.

No changes in hemostasis after COVID-19-heterologous vaccination schedule: A subanalysis of the phase 2 CombiVacS study. BACKGROUND: Several cases of unusual thrombotic events and thrombocytopenia were described after vaccination with recombinant adenoviral vectors encoding the spike protein antigen of SARS-CoV-2. OBJECTIVES: The objective of this study was to elucidate the impact of a COVID-19 heterologous vaccination schedule, including priming with adenovirus vaccine, on hemostasis profiles. METHODS: The present study is a subanalysis of the CombiVacS clinical trial initiated in April 2021 that included adult participants previously vaccinated with a single dose of ChAdOx1-S. Between 8 and 12 weeks after vaccination, they were randomly assigned (2:1) to receive either BNT162b2 vaccine (intervention group, nÂ = 99) or continue observation (control group, nÂ = 50). Samples drawn before and 28 days after a vaccination with BNT162b2 were analyzed for platelet count and markers of hemostasis (D-dimer, anti-PF4 antibodies, cfDNA, PAI-1, thrombin generation, and serum capacity to activate platelets). RESULTS: Platelet count from all participants after receiving BNT162b2 was within the normal range. Anti-PF4 antibodies were present in 26% and 18% of the subjects from the control and intervention groups, respectively, at day 28. In most cases, the levels of

anti-PF4 antibodies were high before receiving BNT162b2. Serum from these participants did not activate platelets from healthy controls. There were no differences between the groups in PAI-1 and cfDNA plasma levels. According to the D-dimer plasma concentration, the thrombin generation test showed that none of the participants had a procoagulant profile. CONCLUSION: Our data suggest that the heterologous vaccination against COVID-19 with ChAdOx1-S and a second dose with BNT162b2 might be safe in terms of haemostasis.

Assessment of acceptance, concerns and side effects towards COVID-19 vaccination among the community: A cross-sectional study from Baghdad, Iraq. INTRODUCTION: The newly developed and marketed vaccines along with concerns about vaccine safety and long-term side effects has been raised an alarming in the general population. The aim of this study was to assess the rate of acceptance, perceptions and concerns towards receiving COVID-19 vaccines and to explore the incidence of vaccines' side effects among Iraqi population in Baghdad province, Iraq. METHOD: This was a descriptive, cross-sectional study conducted via direct interviews among a convenient sample size of Iraqi population using a structured validated questionnaire consisting of using 24-item questionnaire to assess acceptance, concerns and the incidence of vaccines' side effects towards receiving COVID-19 vaccines. RESULTS: A total of 500 participants with an average age of 27.8Â Â±Â 3.7 years were included. Majority were females (70.6%). 43.4% had a history of COVID-19, and 46% received the Pfizer BioNTech vaccine. 73.4% (PÂ <Â 0.0001) agreed about the importance of receiving the vaccination to protect the community against the COVID-19.46.8% (PÂ <Â 0.0001) were unsure about the adverse effects and long-term vaccine safety. 72.8% reported that transmission of COVID-19 infection to family members is the main concern for accepting vaccination. Fatigue (60%), injection site reactions (55.8%) were the most common vaccine's side effects. Young age (PÂ =Â 0.001), females (PÂ <Â 0.0001), and university educational (PÂ <Â 0.0001) were the most significant determents for accepting vaccination. CONCLUSION: This study highlights that the Iraqi population showed a considerable acceptance rate for the COVID-19 vaccines. However, vaccine safety is considered a high priority concern associated with the willingness of the population to vaccinate.

Case series in Indonesia: B.1.617.2 (delta) variant of SARS-CoV-2 infection after a second dose of vaccine. BACKGROUND: The B.1.617.2 (delta) variant of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first discovered in Maharashtra in late 2020 and has rapidly expanded across India and worldwide. It took only 2 mo for this variant to spread in Indonesia, making the country the new epicenter of the delta variant as of July 2021. Despite efforts made by accelerating massive rollouts of current vaccines to protect against infection, cases of fully-vaccinated people infected with the delta variant have been reported. AIM: To describe the demographic statistics and clinical presentation of the delta variant infection after the second dose of vaccine in Indonesia. METHODS: A retrospective, single-centre case series of the general consecutive population that worked or studied at Faculty of Medicine, Universitas Indonesia with confirmed Delta Variant Infection after a second dose of vaccine from 24 June and 25 June 2021. Cases were collected retrospectively based on a combination of author recall, reverse transcription-polymerase chain reaction (RT-PCR), and whole genome sequencing results from the Clinical Microbiology Laboratory, Faculty of Medicine, Universitas Indonesia. RESULTS: Between 24 June and 25 June 2021, 15 subjects were confirmed with the B.1.617.2 (delta) variant infection after a second dose of the vaccine. Fourteen subjects were vaccinated with CoronaVac (Sinovac) and one subject with ChAdOx1 nCoV-19 (Oxford-AstraZeneca). All of the subjects remained in home isolation, with fever being the most common symptom at the onset of illness (n = 10, 66.67%). The mean duration of symptoms was 7.73 d (Â± 5.444). The mean time that elapsed from the first positive swab to a negative RT-PCR test for SARS-CoV-2 was 17.93 d (Â± 6.3464). The median time that elapsed from the second dose of vaccine

to the first positive swab was 87 d (interquartile range: 86-128). CONCLUSION: Although this case shows that after two doses of vaccine, subjects are still susceptible to the delta variant infection, currently available vaccines remain the most effective protection. They reduce clinical manifestations of COVID-19, decrease recovery time from the first positive swab to negative swab, and lower the probability of hospitalization and mortality rate compared to unvaccinated individuals.

Cutaneous adverse reaction following COVID-19 vaccination: Report from a southern Italian referral centre. Comment on "cutaneous adverse reactions following the Pfizer/BioNTech COVID-19 vaccine" by Luo et al.

Association of death or illness from COVID-19 among family and friends on vaccine uptake within four months of the Emergency Use Authorization. Findings from a national survey in the United States. OBJECTIVE: To examine the relationship between knowing that a friend or family member became ill with, or died from, COVID-19 and receiving a vaccine dose within four months of the FDA's Emergency Use Authorization. METHODS: A national sample of 1,517 respondents were surveyed from April 7 to April 12, 2021, 1,193 of whom were eligible for the vaccine when the data were collected. RESULTS: Respondents who knew someone who became ill with COVID-19 (AORÂ =Â 2.32, 95Â % CI 1.74-3.09) or knew someone who died (AORÂ =Â 2.29, 95Â % CI 1.32-3.99) from COVID-19 were more likely to receive at least a single COVID-19 vaccine dose. CONCLUSION: Encouraging people to share their COVID-19 illness and bereavement experiences with their local network such as friends, families, social-networks and via social media might help increase vaccine uptake.

Coincidence of BNT162b2 mRNA COVID-19 vaccination and hashimoto thyroiditis presenting as atrioventricular block: Causality or casualty.

Association between vaccination status and COVID-19-related health outcomes among community-dwelling COVID-19 patients in Nara, Japan. BACKGROUND: Many previous studies have reported COVID-19 vaccine effectiveness, but there are few studies in Japan. This community-based, retrospective observational study investigated the association between vaccination status and COVID-19-related health outcomes in COVID-19 patients by SARS-CoV-2 variant type. METHODS: The study participants were 24,314 COVID-19 patients aged 12 or older whose diagnoses were reported to the Nara Prefecture Chuwa Public Health Center from April 2021 to March 2022, during periods when the alpha, delta, and omicron variants of COVID-19 were predominant. The outcome variables were severe health consequences (SHC) (i.e., ICU admission and COVID-19-related death), hospitalization, and extension of recovery period. The explanatory variable was vaccination status at least 14 days prior to infection. Covariates included gender, age, population size, the number of risk factors for aggravation, and the number of symptoms at diagnosis. The generalized estimating equations of the multivariable Poisson regression models were used to estimate the adjusted incidence proportion (AIP) and 95% confidence interval (CI) for each health outcome. We performed stratified analyses by SARS-CoV-2 variant type, but the association between vaccination status and COVID-19-related health outcomes was stratified only for the delta and omicron variants due to the small number of vaccinated patients during the alpha variant. RESULTS: Of the 24,314 participants, 255 (1.0%) had SHC; of the 24,059 participants without SHC, 2,102 (8.7%) were hospitalized; and of the 19,603 participants without SHC, hospitalization, and missing data on recovery period, 2,960 (15.1%) had extension of recovery period. Multivariable Poisson regression models showed that regardless of SARS-CoV-2 variant type or health outcome, those who received two or more vaccine doses had significantly lower risk of health outcomes than those who did not receive the vaccine, and there was a dose-response relationship in which the AIP for health outcomes decreased with an increased number of vaccinations. CONCLUSION: A higher number of vaccinations were associated with lower risk of COVID-19-related health outcomes, not only in the delta variant but also in the

omicron variant. Our findings suggest that increasing the number of COVID-19 vaccine doses can prevent severe disease and lead to early recovery of patients not requiring hospitalization.

Immunogenicity of a fractional or full third dose of AZD1222 vaccine or BNT162b2 messenger RNA vaccine after two doses of CoronaVac vaccines against the Delta and Omicron variants. OBJECTIVES: The study aimed to compare the immunogenicity and safety of fractional (half) third doses of heterologous COVID-19 vaccines (AZD1222 or BNT162b2) to full doses after the two-dose CoronaVac and when boosting after three different extended intervals. METHODS: At 60-<90, 90-<120, or 120-180 days intervals after the two-dose CoronaVac, participants were randomized to full-dose or half-dose AZD1222 or BNT162b2, followed up at day 28, 60, and 90. Vaccination-induced immune responses to Ancestral, Delta, and Omicron BA.1 strains were evaluated by antispike, pseudovirus, and microneutralization and T cell assays. Descriptive statistics and noninferiority cut-offs were reported as geometric mean concentration or titer and concentration or titer ratios comparing baseline to day 28 and day 90 and different intervals. RESULTS: No safety concerns were detected. All assays and intervals showed noninferior immunogenicity between full doses and half doses. However, full-dose vaccines and/or longer 120-180-day intervals substantially improved the immunogenicity (measured by antispike or measured by pseudotyped virus neutralizing titers 50; P <0.001). Seroconversion rates were over 90% against the SARS-CoV-2 strains by all assays. Immunogenicity waned more quickly with half doses than full doses but remained high against the Ancestral or Delta strains. Against Omicron, the day 28 immunogenicity increased with longer intervals than shorter intervals for full-dose vaccines. CONCLUSION: Immune responses after day 28 when boosting at longer intervals after the two-dose CoronaVac was optimal. Half doses met the noninferiority criteria compared with the full dose by all the immune assays assessed.

The COVID-19 Vaccines International Pregnancy Exposure Registry (C-VIPER): Protocol and Methodological Considerations. INTRODUCTION: The advent of the coronavirus disease 2019 (COVID-19) pandemic has led to the development of vaccines against severe acute respiratory syndrome coronavirus 2. Prospective evidence regarding safety for pregnant people and their developing fetuses is lacking. The aim of the COVID-19 Vaccines International Pregnancy Exposure Registry (C-VIPER) is to estimate the relative risk of obstetric, neonatal, and infant outcomes by comparing participants vaccinated against COVID-19 during pregnancy to a reference group of people enrolled in the Pregistry International Pregnancy Exposure Registry (PIPER) who remained unvaccinated during pregnancy. METHODS: The C-VIPER and the PIPER are international, non-interventional, real-world cohort studies. Participants receiving a COVID-19 vaccine during pregnancy will be matched in the analyses by country and gestational age at enrollment to unvaccinated individuals. Self-enrolled and self-consented participants complete online questionnaires at enrollment, during pregnancy, and for 12 months after the delivery of a live infant. Where possible, outcomes are verified by medical records. The study aims to recruit at least 500 pregnancies for each approved or authorized vaccine and will last for 5 years for each product. CONCLUSIONS: By collecting data for each vaccine brand, the C-VIPER will be able to determine individual safety profiles. The study design allows for analysis of the effects of exposure to COVID-19 vaccines during specific etiologically relevant periods of gestation. Although the sample size may be too small to detect associations with rare outcomes, the study will be used to generate hypotheses for future research. Ultimately, the C-VIPER should provide data that will allow pregnant people and their healthcare providers to make informed decisions about COVID-19 vaccination. CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov NCT04705116. Registered on 12 January, 2021. EU PAS EUPAS39096. Registered on 20 January, 2021.

Transverse myelitis after Johnson & Johnson COVID-19 vaccine: illustrative case. BACKGROUND: Transverse myelitis is a rare neurological occurrence with varied presentation. Imaging is necessary to

properly diagnose this condition; however, identifying the cause of this condition may often be difficult. OBSERVATIONS: An otherwise healthy patient presented to the clinic with peculiar neurological symptoms without an obvious underlying cause. Imaging evidenced no significant structural defects but did lead to discovery of cord enhancement compatible with a diagnosis of transverse myelitis. Corticosteroid treatment was initiated rapidly to address this pathology, and the patient recovered without deficits. To identify the underlying cause, patient medical history was reviewed thoroughly and compared with existing literature. Previous tuberculosis infection could be a less likely cause of the neurological symptoms. However, recent vaccination with the Johnson & Johnson coronavirus disease 2019 (COVID-19) vaccine could be a more likely cause of the transverse myelitis, which has been rarely reported. LESSONS: Transverse myelitis after COVID-19 infection has been an escalating phenomenon. However, transverse myelitis after COVID-19 vaccination is a rare occurrence that is also on the rise. Given the increased rates of vaccination, transverse myelitis should not be overlooked as a potential pathology, due to the severity of neurological impairment if this condition is not treated rapidly.

Reply to: 'Severe bullous pemphigoid following Covid-19 vaccination resistant to rituximab and successfully treated with dupilumab' by Baffa et al.

Eosinophilic lymph node abscesses following a COVID-19 vaccination: A case report. In this paper, we reported a 37-year-old man who developed several lymphadenopathies after using the second dose of Pfizer-BioNtech vaccination against SARS-CoV-2. The excisional lymph node biopsy showed eosinophil-rich inflammation with micro-abscesses. Although eosinophilic dermatosis and eosinophilic myocarditis have been described previously following COVID-19 vaccinations, eosinophilic lymph node abscess was not reported in the literature. In our case, all lesions were completely recovered with steroid treatment. The patient has been doing well and no recurrence has been observed for six months.

A case of acute interstitial nephritis following the Pfizer-BioNTech COVID-19 vaccine.

Cholesterol pericarditis following COVID-19 vaccination.

First-in-human use of a modular capsid virus-like vaccine platform: an open-label, non-randomised, phase 1 clinical trial of the SARS-CoV-2 vaccine ABNCoV2. BACKGROUND: Capsid virus-like particles (cVLP) have proven safe and immunogenic and can be a versatile platform to counter pandemics. We aimed to clinically test a modular cVLP COVID-19 vaccine in individuals who were naive to SARS-CoV-2. METHODS: In this phase 1, single-centre, dose-escalation, adjuvant-selection, open-label clinical trial, we recruited participants at the Radboud University Medical Center in Nijmegen, Netherlands, and sequentially assigned them to seven groups. Eligible participants were healthy, aged 18-55 years, and tested negative for SARS-CoV-2 and anti-SARS-CoV-2 antibodies. Participants were vaccinated intramuscularly on days 0 and 28 with 6 Î¼g, 12 Î¼g, 25 Î¼g, 50 Î¼g, or 70 Î¼g of the cVLP-based COVID-19 vaccine (ABNCoV2). A subgroup received MF59-adjuvanted ABNCoV2. Follow-up was for 24 weeks after second vaccination. The primary objectives were to assess the safety and tolerability of ABNCoV2 and to identify a dose that optimises the tolerability-immunogenicity ratio 14 days after the first vaccination. The primary safety endpoint was the number of related grade 3 adverse events and serious adverse events in the intention-to-treat population. The primary immunogenicity endpoint was the concentration of ABNCoV2-specific antibodies. The trial is registered with ClinicalTrials.gov, NCT04839146. FINDINGS: 45 participants (six to nine per group) were enrolled between March 15 and July 15, 2021. Participants had a total of 249 at least possibly related solicited adverse events (185 grade 1, 63 grade 2, and one grade 3) within a week after vaccination. Two serious adverse events occurred; one was classified as a possible adverse reaction. Antibody titres were dose-dependent with levels plateauing at a vaccination dose of 25-70 Î¼g ABNCoV2. After second vaccination, live virus neutralisation activity against major SARS-CoV-2

variants was high but was lower with an omicron (BA.1) variant. Vaccine-specific IFNÎ³(+) CD4(+) T cells were induced. INTERPRETATION: Immunisation with ABNCoV2 was well tolerated, safe, and resulted in a functional immune response. The data support the need for additional clinical development of ABNCoV2 as a second-generation SARS-CoV-2 vaccine. The modular cVLP platform will accelerate vaccine development, beyond SARS-CoV-2. FUNDING: EU, Carlsberg Foundation, and the Novo Nordisk Foundation.

The pituitary gland in SARS-CoV-2 infections, vaccinations, and post-COVID syndrome.

Generation and Characterization of a SARS-CoV-2-Susceptible Mouse Model Using Adeno-Associated Virus (AAV6.2FF)-Mediated Respiratory Delivery of the Human ACE2 Gene. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the aetiological agent of coronavirus disease 2019 (COVID-19) that has caused a pandemic with millions of human infections. There continues to be a pressing need to develop potential therapies and vaccines to inhibit SARS-CoV-2 infection to mitigate the ongoing pandemic. Epidemiological data from the current pandemic indicates that there may be sex-dependent differences in disease outcomes. To investigate these differences, we proposed to use common small animal species that are frequently used to model disease with viruses. However, common laboratory strains of mice are not readily infected by SARS-CoV-2 because of differences in the angiotensin-converting enzyme 2 (ACE2), the cellular receptor for the virus. To overcome this limitation, we transduced common laboratory accessible strains of mice of different sexes and age groups with a novel a triple AAV6 mutant, termed AAV6.2FF, encoding either human ACE2 or luciferase via intranasal administration to promote expression in the lung and nasal turbinates. Infection of AAV-hACE2-transduced mice with SARS-CoV-2 resulted in high viral titers in the lungs and nasal turbinates, establishment of an IgM and IgG antibody response, and modulation of lung and nasal turbinate cytokine profiles. There were insignificant differences in infection characteristics between age groups and sex-related differences; however, there were significant strain-related differences between BALB/c vs. C57BL/6 mice. We show that AAV-hACE2-transduced mice are a useful for determining immune responses and for potential evaluation of SARS-CoV-2 vaccines and antiviral therapies, and this study serves as a model for the utility of this approach to rapidly develop small-animal models for emerging viruses.

Vaccine Side Effects in Health Care Workers after Vaccination against SARS-CoV-2: Data from TÃ¼SeRe:exact Study. As the Corona Disease 2019 (COVID-19) caused by SARS-CoV-2 persists, vaccination is one of the key measures to contain the spread. Side effects (SE) from vaccination are one of the reasons for reluctance to vaccinate. We systematically investigated self-reported SE after the first, second, and booster vaccinations. The data were collected during the TÃ¼SeRe: exact study (TÃ¼binger Monitoring Studie zur exakten Analyse der Immunantwort nach Vakzinierung). Employees of health and research institutions were invited to participate. Study participants were asked to fill out an online questionnaire and report their SE after each dose of SARS-CoV-2 vaccination. A total of 1046 participants (mean age: 44 Â± 12.9 years; female, n = 815 (78%); male, n = 231 (22%)) were included in the analysis. Local and systemic SE were more frequent after receiving the vector-based vaccine ChAdOx1 nCoV-19 in the first vaccination. However, local and systemic SE were more common after receiving mRNA vaccines (BNT162b2, mRNA-1273) in the second vaccination. Compared to the BNT162b2 vaccine, more SE have been observed after receiving the mRNA-1273 vaccine in the booster vaccination. In multivariate analysis, local and systemic side effects were associated with vaccine type, age and gender. Local and systemic SE are common after SARS-CoV-2 vaccines. The frequency of self-reported local and systemic SE differ significantly between mRNA and vector-based vaccines.

Only Subclinical Alterations in the Haemostatic System of People with Diabetes after COVID-19 Vaccination. People with diabetes have an increased risk of experiencing adverse COVID-19

outcomes. COVID-19 vaccination is, therefore, highly recommended. However, people with diabetes have an inherently elevated risk of thrombotic events and the impact of the vaccination on the coagulation system in this patient population remains to be elucidated. The aim of this study was to investigate the impact of COVID-19 vaccination on the haemostatic system in people with type 1 or type 2 diabetes. We evaluated the effects of COVID-19 vaccination (BioNTech Pfizer, Moderna, AstraZeneca) on standard coagulation parameters, whole blood coagulation (Thrombelastometry), platelet function (impedance aggregation), and thrombin generation (calibrated automated thrombography) in people with type 1 diabetes mellitus (n = 41) and type 2 diabetes mellitus (n = 37). Blood sampling points were prior to vaccination and two weeks after the respective vaccination. Thrombelastometry measurements indicated moderately increased clot formation post-vaccination in people with type 1, as well as with type 2, diabetes: "Clot formation times" were significantly shorter, and both "maximum clot firmness" and "alpha angles" were significantly higher, as compared to the respective pre-vaccination values. Therefore, TEM parameters were not altered after vaccination in patients receiving ASA. Moreover, platelet aggregation was enhanced in people with type 1 diabetes, and plasma levels of D-Dimer were increased in people with type 2 diabetes, following COVID-19 vaccination. All other standard coagulation parameters, as well as thrombin generation, were not affected by the vaccination. The coagulation responses of people with diabetes to COVID-19 vaccination were only subclinical and comparable to those observed in healthy individuals. Our findings suggest that people with diabetes do not face an increased activation of the coagulation post-vaccination.

COVID-19 Vaccination Is Not Associated with Psychiatric Adverse Events: A Meta-Analysis. Coronavirus disease 2019 (COVID-19) has been a global health problem since December 2019. Vaccination has been widely considered the best way to prevent COVID-19 pandemic, but public concerns about the safety of vaccines remain. There have been many studies reporting adverse events in the vaccinated. However, to date, no meta-analysis of the association of COVID-19 vaccination with psychiatric adverse events has been conducted yet. In this meta-analysis, studies on depression, anxiety and distress after COVID-19 vaccination were searched in the PubMed, Cochrane and Embase from January 2020 to April 2022. The OR of depression in four studies with a total sample size of 462,406 is obtained as 0.88 (95% CI; 0.75, 1.03), and the OR of anxiety as 0.86 (95% CI; 0.71, 1.05). However, there were no statistically significant differences between the groups. The mean difference of distress in two studies was âˆ’0.04 (95%CI; âˆ’0.05, âˆ’0.02; $p < 0.0001$). As a result of the moderator analysis, married people experienced less depression and anxiety after vaccination, and in White people, depression after vaccination was lower than others. We also found that people with a history of COVID-19 infection were more depressed and anxious after vaccination. We suggest that COVID-19 vaccination was not associated with a worsening of depression and anxiety.

Exploring Factors Associated with Chinese-Americans' Willingness to Receive an Additional Hypothetical Annual Dose of the COVID-19 Vaccine. Chinese-Americans are one of the largest groups of Asian-Americans in the US with distinctive behavioral and cultural characteristics that influence health service use. Although Chinese-Americans have significantly higher COVID-19-related mortality rates, relative to other racial and ethnic groups, limited literature is available examining their willingness to accept the COVID-19 vaccine. With recent development of the combination influenza-COVID-19 vaccine by biotechnology companies to mitigate COVID-19 infection, we examined factors associated with Chinese-Americans' acceptance of hypothetical annual doses of COVID-19 vaccination before the vaccine rollout. A total of 241 Chinese-Americans who received at least one dose of the COVID-19 vaccine completed an online questionnaire developed and based on health behavior theories. Our results indicated that Chinese-American participants who were satisfied

with their prior COVID-19 vaccination experience, who had more accurate knowledge and perceived higher susceptibility of getting COVID-19, were more willing to receive the annual COVID-19 vaccine in the future. The findings of our current study may be used to guide the development of strategic messages to promote uptake of the annual COVID-19 vaccine by Chinese-Americans in the U.S.

Adverse Reactions after Booster SARS-CoV-2 Vaccination Have Less Impact on Antibody Response than after Basic Vaccination Scheme. BACKGROUND: It is known that adverse reactions following SARS-CoV-2 vaccinations show a positive correlation with the subsequent antibody titer. However, it is not clear how the adverse reactions following the booster vaccination are related to the antibody levels that can be measured after a 3rd dose. The primary goal of this study was to investigate whether the adverse reactions following the booster vaccination show a correlation with subsequent antibody levels. METHODS: Adverse reactions occurring within 7 days after the 3rd vaccination were recorded and the anti-SARS-CoV-2 spike protein immunoglobulin (Ig) level in the venous blood was measured on post-vaccination 14th, 60th and 120th days. RESULTS: A total of 218 volunteers were included in the study. MAIN FINDINGS: (i) The adverse reactions that appeared after the booster dose did not show a positive correlation with the subsequent antibody level, except a correlation in the case of fever; (ii) there were more symptomatic patients in the group receiving heterologous booster vaccine, (iii) fever after the 2nd dose was independently associated with a reduction in the likelihood of COVID-19 positivity after the booster dose. CONCLUSION: No adverse reactions, but fever showed a correlation with the antibody level after the booster SARS-CoV-2 vaccine.

Corneal Adverse Events Associated with SARS-CoV-2/COVID-19 Vaccination: A Systematic Review. Vaccines against coronavirus disease 2019 (COVID-19) have played an important global role in reducing morbidity and mortality from COVID-19 infection. While the benefits of vaccination greatly outweigh the risks, adverse events do occur. Non-ocular adverse effects of the vaccines have been well-documented, but descriptions of ophthalmic effects remain limited. This systematic review aims to provide an overview of reported cases of corneal adverse events after receiving vaccination against COVID-19 and to compile existing clinical data to bring attention to these phenomena. Our review discusses corneal graft rejection, including proposed mechanisms, herpetic keratitis, and other reported corneal complications. Ophthalmologists and primary care physicians should be aware of such possible associations.

Cutaneous Manifestations of SARS-CoV-2, Cutaneous Adverse Reactions to Vaccines Anti-SARS-CoV-2 and Clinical/Dermoscopical Findings: Where We Are and Where We Will Go. From the very first months of the pandemic, it became apparent that a variety of skin reactions could occur during COVID-19 disease, starting with 'erythema-pernio'-type lesions, similar to chilblains [...].

Immune Response to Vaccination against COVID-19 at Different Second-Dose Intervals and Their Associations with Metabolic Parameters. Obesity and diabetes are associated with severe outcomes of coronavirus disease (COVID-19). Vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been proven protective against infection and severe COVID-19. However, the immune response of metabolically burdened individuals to the vaccines remains unclear. Thus, we aimed to assess whether the metabolic status of individuals affects their humoral immune responses to the vaccination. Moreover, we evaluated whether the interval between the first two doses influenced antibody concentration. Sixty-seven individuals (21 males, 46 females) were vaccinated with the BNT162b2 mRNA COVID-19 vaccine. Fifty-four individuals were vaccinated with the second dose after 3 weeks and 13 after 5 weeks. We measured the antibody titers in all participants during the 19-week follow-up period. Patients diagnosed with COVID-19 were excluded. In the 5-week interval group, a significantly higher level of maximal antibody titers was observed. However, there were no differences in antibody concentrations after 19 weeks and no significant correlation between cardiometabolic factors and humoral response. The elongation of second-dose

timing to 5 weeks leads to a higher acute antibody response but does not change long-term levels of antibody titers. Moreover, dysregulation of metabolic parameters does not lead to a diminished immune response to vaccination.

Assessment of Antibody-Titer Changes after Second and Third Severe Acute Respiratory Syndrome Coronavirus 2 mRNA Vaccination in Japanese Post-Kidney-Transplant Patients. Post-renal-transplant patients have a relatively low antibody-acquisition rate following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccination. In this study, antibody titers were measured 5âˆ’6 months and 3 weeks to 3 months after the second and third SARS-CoV-2 mRNA vaccinations, respectively. Post-renal-transplant patients visiting our hospital who had received three SARS-CoV-2 mRNA vaccine doses were included in the study. SARS-CoV-2 immunoglobulin G antibody titers were measured three times: between 3 weeks and 3 months after the second vaccination, 5âˆ’6 months after the second vaccination, and between 3 weeks and 3 months after the third vaccination. A total of 62 (40 men and 22 women) were included, 44 of whom (71.0%) were antibody positive after their third vaccination. On comparing the antibody-acquired and antibody-non-acquired groups, body mass index (BMI, odds ratio [OR]: 1.44, 95% confidence interval [CI]: 1.07âˆ’1.93, $p < 0.05$) and the estimated glomerular filtration rate (eGFR, OR: 1.14, 95% CI: 1.06âˆ’1.24, $p < 0.01$) were associated with antibody acquisition. Therefore, in Japanese post-kidney-transplant patients, increases in the antibody-acquisition rate and absolute antibody titer after the third vaccination were observed, with BMI and eGFR associated with the antibody-acquisition rate.

Psychological Distress and Physical Adverse Events of COVID-19 Vaccination among Healthcare Workers in Taiwan. The COVID-19 pandemic places high pressure on everyone, including healthcare workers (HCWs), thus causing them to experience psychological distress. HCWs have priority in receiving the COVID-19 vaccine. However, few studies have identified adverse events (AEs) and psychological distress in the HCWs group. Therefore, we investigated the association between psychological distress and AEs and the determinants of protective behaviors in Taiwanese HCWs. A longitudinal measurement was conducted among HCWs at National Cheng Kung University Hospital (NCKUH), Tainan, Taiwan (n = 483, mean age = 37.55 years). All HCWs completed an online questionnaire on psychological distress, COVID-19 vaccination AEs, and protective behaviors. We used generalized estimating equations (GEE) to analyze the correlation between psychological distress and AEs, and used multivariable logistic regressions to explore the predictors of protective behaviors. Depression and distress and anger were significantly associated with various physical AEs ($p = 0.045$ to $p < 0.001$). Suicidal thoughts became a significant independent variable of systemic AEs after COVID-19 vaccination ($p = 0.014$ to $p < 0.001$). People of older ages or females engaged more in washing their hands, wearing masks, and reducing their presence in crowded places. Suicidal thoughts were related to the occurrence of systemic AEs among HCWs. Doctors performed better at preventive behaviors compared to nurses and other HCWs. HCWs who experienced anxiety and nervousness tended to avoid crowds.

Risks of Cardiac Arrhythmia Associated with COVID-19 Vaccination: A Systematic Review and Meta-Analysis. This systematic review and meta-analysis aimed to summarize the current evidence regarding the association between coronavirus disease 2019 (COVID-19) vaccination and the risk of cardiac arrhythmia. MEDLINE, via PubMed and OVID, Scopus, CENTRAL, and Web of Science were searched using the relevant keywords to identify the relevant citations. Comprehensive Meta-analysis and Review Manager 5.4.1 were used for all the statistical analyses. Seventeen studies (n = 567,033,087 patients) were included. The pooled analysis showed that the incidence of cardiac arrhythmia post-COVID-19 vaccination with Pfizer, Moderna, AstraZeneca, CoronaVac, and Sinopharm was 0.22%, 95% CI: (0.07% to 0.66%), 0.76%, 95% CI: (0.04% to 12.08%), 0.04%, 95% CI: (0.00% to 0.98%), 0.01%, 95% CI: (0.00% to 0.03%), and 0.03%, 95% CI: (0.00% to 18.48%),

respectively. Compared to CoronaVac, Pfizer, Moderna, AstraZeneca, and Sinopharm had a higher incidence ratio rate (IRR; 22-times, 76-times, 4-times, and 3-times higher), respectively. Likewise, Pfizer, Moderna, and AstraZeneca showed a higher IRR than Sinopharm (7.3-times, 25.3-times, and 1.3-times higher). The current evidence shows that the incidence rate (IR) of cardiac arrhythmia post-COVID-19 vaccination is rare and ranges between 1 and 76 per 10,000. mRNA vaccines were associated with a higher IR of arrhythmia compared to vector-based vaccines. Inactivated vaccines showed the lowest IR of arrhythmia.

Adverse Effects of Sinopharm COVID-19 Vaccine among Vaccinated Medical Students and Health Care Workers. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) disease caused a highly problematic situation worldwide. Various vaccines were launched to combat the COVID-19 pandemic. This study aims to investigate the adverse effects of first and second doses of the Sinopharm vaccine among vaccinated medical and dental students and healthcare workers. A well-established questionnaire was distributed online, and 414 medical and dental students and healthcare workers (HCW) comprising 355 females (85.7%) and 59 males (14.3%) participated; all were vaccinated with two doses of Sinopharm. The most common side effect was pain at the injection site after dose one in 253 respondents (61.3%) and after dose two in 161 respondents (38.9%). Other symptoms included general lethargy in 168 (40.6%), myalgia/body pain in 99 (23.9%), low-grade fever in 93 (22.4%), and headache in 87 (21%) respondents. Common side effects reported after the second dose of the vaccine following pain at the injection site included general lethargy in 21.3% (88), headache in 10.4% (43), myalgia/body pain in 9.9% (41), and low-grade fever in 6.1% (25) of the respondents. In conclusion, common adverse effects of the Sinopharm vaccine were pain at the injection site, general lethargy, myalgia, body pain, low-grade fever, and headache. These adverse effects were mild in intensity for both doses but slightly more frequent and severe for the first dose than the second dose.

SARS-CoV-2 mRNA Dual Immunization Induces Innate Transcriptional Signatures, Establishes T-Cell Memory and Coordinates the Recall Response. BACKGROUND: mRNA vaccines have played a crucial role in controlling the SARS-CoV-2 global pandemic. However, the immunological mechanisms involved in the induction, magnitude and longevity of mRNA-vaccine-induced protective immunity are still unclear. METHODS: In our study, we used whole-RNA sequencing along with detailed immunophenotyping of antigen-specific T cells and humoral RBD-specific response to dual immunization with the Pfizer-BioNTech mRNA vaccine (BNT162b2) and correlated them with response to an additional dose, administered 10 months later, in order to comprehensively profile the immune response of healthy volunteers to BNT162b2. RESULTS: Primary dual immunization induced upregulation of the Type I interferon pathway and generated spike protein (S)-specific IFN-Î³+ and TNF-Î±+ CD4 T cells, S-specific memory CD4 T cells, and RBD-specific antibodies against SARS-CoV-2. S-specific CD4 T cells induced by the primary series correlated with the RBD-specific antibody titers to a third dose. CONCLUSIONS: This study demonstrates the induction of both innate and adaptive immunity in response to the BNT162b2 mRNA vaccine in a coordinated manner and identifies the central role of primarily induced CD4+ T cells as a predictive biomarker of the magnitude of anamnestic immune response.

Durability of ChAdOx1 nCoV-19 (Covishield(Â®)) Vaccine Induced Antibody Response in Health Care Workers. (i) Background: ChAdOx1 nCoV-19 (CovishieldÂ®) vaccine is widely used in India. We studied the CovishieldÂ® induced antibody response and its durability among health care workers (HCWs) (ii) Method: HCWs received two doses (0.5 mL) four weeks apart. Blood specimens, collected before each dose, day (D)60, D150 and D270 after second dose, were tested for anti-spike antibody (ASAb) titre and neutralising antibody (%) (NAb) using Elecsys Anti-SARS-CoV-2 S (Roche) and SARS-CoV-2 NAb ELISA Kit (Invitrogen), respectively. Data are expressed as proportions and median

(interquartile range) and compared using non-parametric (iii) Result: Among 135 HCWs (83 males; age 45 (37âˆ’53); 36 had pre-existing ASAb), 29 (21.5%) acquired COVID-19 after 60 (39âˆ’68) days of vaccination. ASAb titre before second dose and at D60, D150, D270 were 77.2 (19.4âˆ’329.4), 512 (114.5âˆ’9212), 149 (51.6âˆ’2283) and 2079 (433.9âˆ’8644) U/mL, respectively. Compared to those without pre-existing ASAb, titres were significantly higher before second dose (5929 vs. 41, p < 0.001), D60 (3395 vs. 234, p = 0.007) and D150 (1805 vs. 103, p < 0.001) in participants with pre-existing ASAb; NAb were also higher (80 vs. 18, p < 0.001) before second dose. Between those who acquired infection or not after vaccination, ASAb titres were comparable before second dose (77 vs. 78, p = 0.362) but significantly higher at D60 (14,019 vs. 317, p < 0.001) and D150 (2062 vs. 121, p = 0.002) in the former group, though NAb percentage were higher at D60 (87 vs. 27, p < 0.001) and D150 (79 vs. 25, p = 0.007) only (iv) Conclusions: CovishieldÂ® induces a higher antibody titre in those with pre-existing ASAb. The vaccine induced antibody starts falling 5 months after vaccination.

Humoral Response after Two Doses of BNT162b2 mRNA Vaccine Has a Role in Predicting Response after Three Doses That Is Related to Plasma HIV Viremia and Nadir CD4+ Cell Count in HIV-Positive Patients. We investigated the spike IgG levels of HIV+ patients on antiretroviral therapy six months after they received their second dose (T2) and six months after the third dose (T3) of the BNT162b2 mRNA vaccine, as well as the influence of different levels of plasma HIV viremia of overall CD4+ cell count and nadir value on the humoral time course. One hundred eighty-four patients were enrolled. The median age was 55 years, the median CD4+ cell count was 639 cells/mm3 and the median nadir value was 258 cells/mm3. On the basis of all tests performed during the study period, persistently undetectable plasma HIV RNA (PUD) was found in 66 patients, low-level viremia (LLV) in 57 and ongoing viremia (OV) in 61. Serum levels of IgG antibodies against a trimeric S-protein antigen were tested with DiaSorin Liaison SARS-CoV-2 TrimericS IgG and the response was classified as optimal (>75th percentile), intermediate (50thâˆ’25th percentile) and low (<25th percentile). The frequencies of the three different patterns of plasma HIV viremia (PUD, LLV and OV) were comparable in patients with low, intermediate and optimal IgG response evaluated at T2, with no difference in overall CD4+ cell count or nadir count. At T3, 92.9% of patients achieved an optimal response: T2 response proved to be the most important factor in predicting T3 optimal response in patients with LLV and OV.A nadir value â‰¤ 330 cells/mm3 had 100% sensitivity in predicting a non-optimal response. In conclusion, we demonstrated the persistence of anti-spike IgG, with high serum levels occurring in most patients six months after the third dose of the BNT162b2 mRNA vaccine and a predictive role of humoral response at T2 in subjects with detectable plasma HIV viremia. Immunological alterations related to past immunodeficiency may persist despite immune reconstitution, and the nadir value could be a useful tool for elaborating personalized vaccine schedules.

Membranous Nephropathy following Full-Dose of Inactivated SARS-CoV-2 Virus Vaccination: A Case Report and Literature Review. Vaccination against the SARS-CoV-2 virus (COVID-19) has proven to be the most effective measure to prevent the spread and reduce infection severity. A case report of de novo membranous nephropathy (MN) following immunization with inactivated virus vaccine (CoronaVac(Â®), Sinovac Biotech) is presented here. A 53-year-old man presented with a sudden onset of leg edema a week after receiving an inactivated virus vaccine and a relapse of nephrotic syndrome (NS) with acute kidney injury (AKI) after a booster dose. Screening for serum anti-phospholipase A2 receptor antibody and secondary causes of MN were negative. Kidney biopsy revealed an early MN pattern with focal spike formation, whilst numerous subepithelial electron-dense deposits and a few small deposits in the mesangial area were observed through electron microscopy. A short course of steroids and oral cyclophosphamide was prescribed, resulting in the complete remission of NS and AKI. MN following SARS-CoV-2 vaccination should call for medical

importance. Awareness of the association between vaccination and MN should be kept in mind to avoid unnecessary treatment with long-term immunosuppressive agents.
The Characteristics of COVID-19 Vaccine-Associated Uveitis: A Summative Systematic Review. Numerous complications following COVID-19 vaccination has been reported in the literature, with an increasing body of evidence reporting vaccination-associated uveitis (VAU). In this systematic review, we searched six electronic databases for articles reporting the occurrence of VAU following COVID-19 vaccination. Data were synthesized with emphasis on patients' characteristics [age, gender], vaccination characteristics [type, dose], and outcome findings [type, nature, laterality, course, location, onset, underlying cause, and associated findings]. Data are presented as numbers (percentages) for categorical data and as mean (standard deviation) for continuous data. Sixty-five studies were finally included [43 case reports, 16 case series, four cohort, one cross-sectional, and one registry-based study]. VAU occurred in 1526 cases, most commonly in females (68.93%) and middle-aged individuals (41-50 years: 19.71%), following the first dose (49.35%) of vaccination, especially in those who received Pfizer (77.90%). VAU occurred acutely (71.77%) as an inflammatory reaction (88.29%) in unilateral eyes (77.69%), particularly in the anterior portion of the uvea (54.13%). Importantly, most cases had a new onset (69.92%) while only a limited portion of cases had a reactivation of previous uveitis condition. In conclusion, although rare, uveitis following COVID-19 vaccination should be considered in new-onset and recurrent cases presenting with either acute or chronic events.
Analysis of Antibody Neutralisation Activity against SARS-CoV-2 Variants and Seasonal Human Coronaviruses NL63, HKU1, and 229E Induced by Three Different COVID-19 Vaccine Platforms. Coronaviruses infections, culminating in the recent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic beginning in 2019, have highlighted the importance of effective vaccines to induce an antibody response with cross-neutralizing activity. COVID-19 vaccines have been rapidly developed to reduce the burden of SARS-CoV-2 infections and disease severity. Cross-protection from seasonal human coronaviruses (hCoVs) infections has been hypothesized but is still controversial. Here, we investigated the neutralizing activity against ancestral SARS-CoV-2 and the variants of concern (VOCs) in individuals vaccinated with two doses of either BNT162b2, mRNA-1273, or AZD1222, with or without a history of SARS-CoV-2 infection. Antibody neutralizing activity to SARS-CoV-2 and the VOCs was higher in BNT162b2-vaccinated subjects who were previously infected with SARS-CoV-2 and conferred broad-spectrum protection. The Omicron BA.1 variant was the most resistant among the VOCs. COVID-19 vaccination did not confer protection against hCoV-HKU1. Conversely, antibodies induced by mRNA-1273 vaccination displayed a boosting in their neutralizing activity against hCoV-NL63, whereas AZD1222 vaccination increased antibody neutralization against hCoV-229E, suggesting potential differences in antigenicity and immunogenicity of the different spike constructs used between various vaccination platforms. These data would suggest that there may be shared epitopes between the HCoVs and SARS-CoV-2 spike proteins.
Increase in the Immune Response in Balb/c Mice after the Co-Administration of a Vector-Based COVID-19 Vaccine with Cytosine Phosphoguanine Oligodeoxynucleotide. The effects of cytosine phosphoguanine oligodeoxynucleotides (CPG ODNs) on immune response have been demonstrated for different vaccines; however, such information is limited for the vector-based Coronavirus disease 2019 (COVID-19). This paper aims to demonstrate the potential effect of CPG ODNs on immunological response against the vector-based COVID-19 vaccine on Balb/c mice using a JNJ-78436735 Ad26.COV2-S recombinant as a model vaccine. A total of 18 BALB/c mice clustered into six groups were used. All groups were observed for 14- and 28-days post immunization. Qualitative determination of IgG was performed using indirect Enzyme-Linked Immunosorbent Assay (ELISA) and qPCR for cytokine profiling. A significant (p â‰¤ 0.001) rise in antibody response was observed for

groups 3 and 4, who also showed increased expression levels of Tumor Necrosis Factor (TNF) and Interferon Gamma (IFN-Î³). Immunological parameters for toxicity were normal in all treatment groups. We conclude that supplementing vector-based COVID-19 vaccines with CpG ODNs has the potential to boost the body's immune responses to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.

COVID-19 Vaccination Did Not Increase the Risk of Potentially Related Serious Adverse Events: 18-Month Cohort Study in an Italian Province. This cohort study on the entire population of an Italian Province assessed the incidence of potentially vaccine-related serious adverse events (PVR-SAEs) by COVID-19 vaccination status. From January 2021 to July 2022, we extracted all deaths and hospitalizations due to several cardiovascular diseases, pulmonary embolism, and deep vein thrombosis from National Healthcare System official data. During the follow-up, 5743 individuals died, and 2097 were hospitalized for PVR-SAEs. Vaccinated subjects (n = 259,821) did not show an increased risk of all-cause death, non-COVID death, or any PVR-SAEs, as compared to the unvaccinated (n = 56,494). These results were consistent across genders, age-classes, vaccine types, and SARS-CoV-2 infection status and did not vary in Cox models adjusting for age, gender, SARS-CoV-2 infection, and selected comorbidities. In the infected population, any dose of vaccine was associated with a lower likelihood of death and PVR-SAE. In the uninfected population, subjects who received one or two doses showed a significantly higher incidence of most outcomes, likely due to a large selection bias introduced by the Italian restriction policies targeting uninfected subjects who received less than three doses. In conclusion, COVID-19 vaccination was not associated with an increase of mortality or selected PVR-SAEs incidence. Further research is warranted to evaluate the long-term safety of COVID-19 vaccines.

Association between COVID-19 Primary Vaccination and Severe Disease Caused by SARS-CoV-2 Delta Variant among Hospitalized Patients: A Belgian Retrospective Cohort Study. We aimed to investigate vaccine effectiveness against progression to severe COVID-19 (acute respiratory distress syndrome (ARDS), intensive care unit (ICU) admission and/or death) and in-hospital death in a cohort of hospitalized COVID-19 patients. Mixed effects logistic regression analyses were performed to estimate the association between receiving a primary COVID-19 vaccination schedule and severe outcomes after adjusting for patient, hospital, and vaccination characteristics. Additionally, the effects of the vaccine brands including mRNA vaccines mRNA-1273 and BNT162b2, and adenovirus-vector vaccines ChAdOx1 (AZ) and Ad26.COV2.S (J&J) were compared to each other. This retrospective, multicenter cohort study included 2493 COVID-19 patients hospitalized across 73 acute care hospitals in Belgium during the time period 15 August 2021-14 November 2021 when the Delta variant (B1.617.2) was predominant. Hospitalized COVID-19 patients that received a primary vaccination schedule had lower odds of progressing to severe disease (OR (95% CI); 0.48 (0.38; 0.60)) and in-hospital death (OR (95% CI); 0.49 (0.36; 0.65)) than unvaccinated patients. Among the vaccinated patients older than 75 years, mRNA vaccines and AZ seemed to confer similar protection, while one dose of J&J showed lower protection in this age category. In conclusion, a primary vaccination schedule protects against worsening of COVID-19 to severe outcomes among hospitalized patients.

Non-Hodgkin Lymphoma Developed Shortly after mRNA COVID-19 Vaccination: Report of a Case and Review of the Literature. We report on a 66-year-old man who presented with a right axillary lymphadenopathy approximately 10 days after receiving the third dose of the BNT162b2 vaccine. The lymphadenopathy gradually enlarged, and physical examination and ultrasound (US) revealed one right axillary 6.99 cm and one right supraclavicular 2.36 cm lymphadenopathy. Histologic examination of the right axillary nodule revealed anaplastic large-cell lymphoma that was ALK negative and CD30 positive. A total body computerized tomography (CT) scan, positron emission tomography (PET) and

bone-marrow biopsy showed a stage-II non-Hodgkin lymphoma (NHL). The patient was treated with chemotherapy and a scheme of Brentuximab Vedotin, Cyclophosphamide, Doxorubicin and Prednisone (BV-CHP) for six cycles and is now well and in complete remission. The revision of the literature revealed eight additional cases of NHL developed shortly after COVID-vaccination. There were four cases of diffuse large-B-cell lymphoma (DLBCL) (one in a patient who was a heart transplant recipient and developed an Epstein-Bar-virus-positive DLBCL), one case of extranodal NK/T-cell lymphoma, one patient with subcutaneous panniculitis-like T-cell lymphoma, one case of marginal zone B-cell lymphoma and one primary cutaneous anaplastic large-cell lymphoma (PC-ALCL). In five cases, the lymphoma developed after BNT162b2 mRNA vaccination, including one case after ChAdOx1 nCOV-19, one case after the adenovirus type 26 (Ad26) vaccine and one after mRNA-1273/Spikevax (ModernaTX). We are aware that the link between COVID-19 vaccination and lymphoma most likely is a chance phenomenon, and that COVID-19 vaccines represent very efficient products for many people around the world. However, we believe that clinical events, even if only temporally associated with novel treatments or novel vaccines, should be reported for the benefit of the patients and the scientific community.

Takotsubo Syndrome Occurring after mRNA COVID-19 Vaccination in a Patient with Graves' Disease. Cardiovascular events such as myocarditis following mRNA COVID-19 vaccination are increasing. We present a 67-year-old postmenopausal woman with Takotsubo Syndrome and Graves' disease after mRNA COVID-19 vaccination. She developed chest pain and shortness of breath one week after vaccination. An electrocardiogram revealed ST elevation in the precordial leads. Coronary angiography revealed the absence of obstructive coronary artery disease, and the left ventriculography showed a typical feature with apical ballooning. Laboratory workup showed the elevation of free T4 and thyrotropin receptor antibodies. It was presumed that Takotsubo Syndrome and Graves' disease were probably related to the COVID-19 mRNA vaccination. The patient was treated with low-dose bisoprolol, diuretics, carbimazole, and steroid and discharged uneventfully. The mRNA COVID-19 vaccination is still safe and effective to defend against COVID-19 pandemic. However, clinicians should be aware of the possible cardiovascular adverse events other than myocarditis following vaccination.

Post-COVID-19 Symptoms and Heart Disease: Incidence, Prognostic Factors, Outcomes and Vaccination: Results from a Multi-Center International Prospective Registry (HOPE 2). BACKGROUND: Heart disease is linked to worse acute outcomes after coronavirus disease 2019 (COVID-19), although long-term outcomes and prognostic factor data are lacking. We aim to characterize the outcomes and the impact of underlying heart diseases after surviving COVID-19 hospitalization. METHODS: We conducted an analysis of the prospective registry HOPE-2 (Health Outcome Predictive Evaluation for COVID-19-2, NCT04778020). We selected patients discharged alive and considered the primary end-point all-cause mortality during follow-up. As secondary main end-points, we included any readmission or any post-COVID-19 symptom. Clinical features and follow-up events are compared between those with and without cardiovascular disease. Factors with $p < 0.05$ in the univariate analysis were entered into the multivariate analysis to determine independent prognostic factors. RESULTS: HOPE-2 closed on 31 December 2021, with 9299 patients hospitalized with COVID-19, and 1805 died during this acute phase. Finally, 7014 patients with heart disease data were included in the present analysis, from 56 centers in 8 countries. Heart disease (+) patients were older (73 vs. 58 years old), more frequently male (63 vs. 56%), had more comorbidities than their counterparts, and suffered more frequently from post-COVID-19 complications and higher mortality (OR (heart disease): 2.63, 95% CI: 1.81-3.84). Vaccination was found to be an independent protector factor (HR (all-cause death): 0.09; 95% CI: 0.04-0.19). CONCLUSIONS: After surviving the acute phase, patients with underlying heart disease continue to present a more complex clinical profile and worse

outcomes including increased mortality. The COVID-19 vaccine could benefit survival in patients with heart disease during follow-up.

Immunogenicity and Safety of the BNT162b2 COVID-19 Vaccine in Patients with Cystic Fibrosis with or without Lung Transplantation. Cystic fibrosis (CF) is characterized by a progressive decline in lung function, which may be further impaired by viral infections. CF is therefore considered a comorbidity of coronavirus disease 2019 (COVID-19), and SARS-CoV-2 vaccine prioritization has been proposed for patients with (pw)CF. Poor outcomes have been reported in lung transplant recipients (LTR) after SARS-CoV-2 infections. LTR have also displayed poor immunization against SARS-CoV-2 after mRNA-based BNT162b2 vaccination, especially in those undergoing immunosuppressive treatment, mostly those receiving mycophenolate mofetil (MMF) therapy. We aimed to determine here the immunogenicity and safety of the BNT162b2 vaccine in our cohort of 260 pwCF, including 18 LTR. Serum levels of neutralizing anti-SARS-CoV-2 IgG and IgA antibodies were quantified after the administration of two doses. PwCF displayed a vaccine-induced IgG and IgA antiviral response comparable with that seen in the general population. We also observed that the immunogenicity of the BNT162b2 vaccine was significantly impaired in the LTR subcohort, especially in patients undergoing MMF therapy. The BNT162b2 vaccine also caused minor adverse events as in the general population, mostly after administration of the second dose. Overall, our results justify the use of the BNT162b2 vaccine in pwCF and highlight the importance of a longitudinal assessment of the anti-SARS-CoV-2 IgG and IgA neutralizing antibody response to COVID-19 vaccination.

Associations between Tobacco Use, Surges, and Vaccination Status over Time in the COVID-19 Era. Because COVID-19 is a respiratory and cardiovascular disease, understanding behaviors that impact cardiopulmonary health, such as tobacco use, is particularly important. While early studies suggested no change in prevalence of tobacco use as COVID-19 emerged, pandemic fatigue, shifting levels of COVID-19 transmission, and vaccine availability have all changed since the start of the pandemic. The current study examined whether time, COVID-19 surges, and/or vaccination status were associated with likelihood of daily and non-daily tobacco use over the first 24 months of the pandemic. Data were obtained from electronic health records of healthcare visits (n = 314,787) to four Southern California VA healthcare systems. Multinomial logistic regression analyses indicated that the likelihood of reporting both daily and non-daily tobacco use (versus non-use) increased over time. Daily and non-daily tobacco use were less common at visits that occurred during COVID-19 surges, as well as among veterans vaccinated against COVID-19. Our findings provide new insight into changes of tobacco use patterns and correlates across the first two years of this pandemic, and understanding these associations may facilitate understanding of health-related behaviors and inform clinical treatment of tobacco use disorder during the COVID-19 pandemic.

Evaluation of Antibody Responses in Patients with B-Cell Malignancies after Two and Three Doses of Anti-SARS-CoV-2 S Vaccination-A Retrospective Cohort Study. Patients with B-cell malignancies are at a higher risk of severe SARS-CoV-2 infections. Nevertheless, extensive data on the immune responses of hematological patients and the efficacy of the third dose of the vaccine are scarce. The goal of this study was to determine standardized anti-SARS-CoV-2 S antibody levels and to evaluate differences between treatment modalities in response to the second and third vaccines among patients with B-cell malignancies treated at the University Hospital Krems and the University Hospital of Vienna. The antibody levels of a total of 80 patients were retrospectively analyzed. The results indicate a significant increase in antibody production in response to the third vaccination. The highest increases could be observed in patients in a "watchful-waiting" and "off-therapy" setting. Encouragingly, approximately one-third of patients who did not develop antibodies in response to two vaccinations achieved seroconversion after the third vaccination. "Watchful-waiting", "off-therapy" and treatment with BTK inhibitors were indicative for increased antibody response after the

third dose compared to anti-CD19 CAR T-cell and anti-CD-20 antibody treatment. In summary, the results of this study underline the pre-eminent role of the need for complete vaccination with three doses for the development of protective immunity in patients with B-cell malignancies.

COVID-19 vaccination during pregnancy: a systematic review and meta-analysis. BACKGROUND: SARS-CoV-2 exposure during pregnancy is related to adverse effects for both the mother and the infant. SARS-CoV-2 vaccination has lowered the risk of symptomatic disease substantially. Recently published studies have evaluated the outcomes of women who received the COVID-19 vaccine during pregnancy; systematic evidence regarding vaccination safety is crucial to ensure that COVID-19 vaccination is not associated with adverse pregnancy and neonatal outcomes. METHODS: Pubmed/MEDLINE, EMBASE, Scopus, Web of Science, and Clinicaltrials.gov were searched from each database's inception through April 7, 2022. All interventional and observational studies comparing neonatal or pregnancy outcomes between pregnant women who received COVID-19 vaccines during their pregnancy and unvaccinated pregnant women were included. The random-effects model was used in the meta-analyses. RESULTS: A total of 11 studies comprising 756,098 pregnant mothers were included. The rate of neonates with 5-min Apgar scoreâ€‰â‰¤â€‰7 (log RR -0.08 (95% CI: -0.15 to -0.00), (Pâ€‰=â€‰0.03)) and pregnant mothers with preterm birth (log RR -0.11 (95% CI: -0.21 to -0.01), (Pâ€‰=â€‰0.02)) was significantly lower among vaccinated group. No significant difference was observed in adverse neonatal outcomes (log RR -0.07 (95% CI: -0.17 to 0.03)), small for gestational age (log RR -0.06 (95% CI: -0.14 to 0.02)), caesarean delivery (log RR 0.05 (95% CI: -0.05 to 0.15)), postpartum hemorrhage (log RR -0.05 (95% CI: -0.13 to 0.02)), stillbirth (log RR -0.05 (95% CI: -0.54 to 0.45)). CONCLUSIONS AND RELEVANCE: In this systematic review and meta-analysis, no evident differences were observed when comparing vaccinated pregnant mothers with those who had not received COVID-19 vaccines. Based on low certainty of evidence, vaccination during pregnancy was accompanied by a favorable Apgar score in neonates and fewer preterm births.

Longitudinal efficacy and toxicity of SARS-CoV-2 vaccination in cancer patients treated with immunotherapy. Despite more than 2â€‰years having elapsed since the onset of SARS-CoV-2 pandemic, a level of hesitation around increased SARS-CoV-2 vaccine toxicity in cancer patients receiving immunotherapy (IO) remains. This hesitation stems from the idea that IO agents could elicit an overwhelming immune stimulation post vaccination and therefore increase the risk of vaccine-related toxicity. The aim of our study was to explore serological responses to SARS-CoV-2 vaccination in patients treated with IO and describe the level of immune stimulation using parameters such as blood cytokines, autoantibody levels and immune related adverse events (irAEs) post vaccination. Fifty-one evaluable patients were enrolled in this longitudinal study. Absolute levels and neutralization potential of anti-SARS-CoV-2 antibodies were not significantly different in the IO group compared to non-IO. Chemotherapy adversely affected seroconversion when compared to IO and/or targeted treatment. Following vaccination, the prevalence of grade â‰¥2 irAEs in patients treated with IO was not higher than the usual reported IO toxicity. We report, for the first time, that anti-SARS-CoV-2 vaccination, elicited the generation of five autoantibodies. The significantly increased autoantibodies were IgM autoantibodies against beta-2 glycoprotein (pâ€‰=â€‰0.02), myeloperoxidase (pâ€‰=â€‰0.03), nucleosome (pâ€‰=â€‰0.041), SPLUNC2 (pâ€‰<â€‰0.001) and IgG autoantibody against Myosin Heavy Chain 6 (MYH6) (pâ€‰<â€‰0.001). Overall, comprehensive analysis of a small cohort showed that co-administration of SARS-CoV-2 vaccine and IO is not associated with increased irAEs. Nevertheless, the detection of autoantibodies post anti-SARS-CoV-2 vaccination warrants further investigation (NCT03702309).

Safety of co-administration of mRNA COVID-19 and seasonal inactivated influenza vaccines in the vaccine adverse event reporting system (VAERS) during July 1, 2021-June 30, 2022. BACKGROUND: COVID-19 vaccines may be co-administered with other recommended vaccines,

including seasonal influenza vaccines. However, few studies have evaluated the safety of co-administration of mRNA COVID-19 and seasonal influenza vaccines. OBJECTIVE: To describe reports to the Vaccine Adverse Event Reporting System (VAERS) after co-administration of mRNA COVID-19 and seasonal influenza vaccines. METHODS: We searched the VAERS database for reports of adverse events (AEs) following co-administration of mRNA COVID-19 and seasonal influenza vaccines and following a first booster dose mRNA COVID-19 vaccine alone, during July 1, 2021-June 30, 2022. We assessed the characteristics of these reports and described the most frequently reported MedDRA preferred terms (PTs). Clinicians reviewed available medical records for serious reports and reports of adverse events of special interest (AESI) and categorized the main diagnosis by system organ class. RESULTS: From July 1, 2021 through June 30, 2022, VAERS received 2,449 reports of adverse events following co-administration of mRNA COVID-19 and seasonal influenza vaccines. Median age of vaccinees was 48Â years (IQR: 31, 66); 387 (15.8%) were classified as serious. Most reports (1,713; 69.3%) described co-administration of a first booster dose of an mRNA COVID-19 vaccine with seasonal influenza vaccine. The most common AEs among non-serious reports were injection site reactions (193; 14.5%), headache (181; 13.6%), and pain (171; 12.8%). The most common AEs among reports classified as serious were dyspnea (38; 14.9%), COVID-19 infection (32; 12.6%), and chest pain (27; 10.6%). DISCUSSION: This review of reports to VAERS following co-administration of mRNA COVID-19 and seasonal influenza vaccines did not reveal any unusual or unexpected patterns of AEs. Increased reporting of certain events (e.g., COVID-19 disease) was expected. CDC will continue to monitor the safety of co-administration of mRNA COVID-19 and seasonal influenza vaccines, including co-administration involving bivalent mRNA COVID-19 booster vaccines that have been recommended for people agesÂ â‰¥Â 6Â months in the United States.
Comment on 'Pityriasis rubra pilaris-like eruption following mRNA COVID-19 vaccine'.
Comment on 'Eosinophilic pustular folliculitis developing at the site of COVID-19 vaccination'.
Vaccine-induced immune thrombotic thrombocytopenia. Within the first months of the COVID-19 vaccination campaign, previously healthy recipients who developed severe thrombosis (often cerebral and/or splanchnic vasculature) and thrombocytopenia typically after adenoviral vector-based vaccination were identified. Similarities between this syndrome, vaccine-induced immune thrombotic thrombocytopenia (VITT), and heparin-induced thrombocytopenia prompted recognition of the role of antiplatelet factor 4 (PF4) antibodies and management strategies based on IV immunoglobulin and nonheparin anticoagulants, which improved outcome. We update current understanding of VITT and potential involvement of anti-PF4 antibodies in thrombotic disorders.
Study of covid-19 vaccine-related cutaneous adverse events following immunization and establishing a causal association.
Risk-benefit profiles associated with receiving Moderna COVID-19 (mRNA-1273) vaccine as an additional pre-booster dose in immune-mediated dermatologic disease patients with low SARS-CoV-2-specific immunity following the primary series: A prospective cohort study.
Venous thromboembolism after COVID-19 vaccination in patients with thrombophilia. Patients with thrombophilia remain concerned about venous thromboembolism (VTE) risk with COVID-19 vaccinations. The aim of this study was to examine VTE outcomes in patients with inherited or acquired thrombophilia who were vaccinated for COVID-19. Vaccinated patients â‰¥18â€‰years between November 1, 2020 and November 1, 2021 were analyzed using electronic medical records across the Mayo Clinic enterprise. The primary outcome was imaging confirmed acute VTE occurring 90â€‰days before and after the date of the first vaccine dose. Thrombophilia patients were identified through laboratory testing results and ICD-10 codes. A total of 792â€‰010 patients with at least one COVID-19 vaccination were identified. Six thousand sixty-seven of these patients were found to have a thrombophilia, among whom there was a total of 39 VTE events after compared to 51

VTE events before vaccination (0.64% vs. 0.84%, pÂ =Â .20). In patients with Factor V Leiden or prothrombin gene mutation, VTE occurred in 27 patients before and in 29 patients after vaccination (0.61 vs. 0.65%, pÂ =Â .79). In patients with antiphospholipid syndrome, VTE occurred in six patients before and four patients after vaccination (0.59% vs. 0.39%, pÂ =Â .40). No difference was observed in the overall VTE rate when comparing the postvaccination 90â€‰days to the prevaccination 90â€‰days, adjusted hazard ratio 0.81 (95% confidence interval: 0.53-1.23). In this subgroup of COVID-19 vaccinated patients with thrombophilia, there was no increased risk for acute VTE postvaccination compared to the prevaccination timeframe. These results are consistent with prior studies and should offer additional reassurance to patients with inherited or acquired thrombophilia.
The Levels of Anti-SARS-CoV-2 Spike Protein IgG Antibodies Before and After the Third Dose of Vaccination Against COVID-19. PURPOSE: The COVID-19 pandemic has been going on for almost three years, and so far, many preventive and therapeutic strategies have been developed. The issue of subsequent booster vaccinations is currently being discussed. We aimed to analyze how the third dose of vaccination against COVID-19 correlates with the dynamics of IgG anti-SARS-CoV-2 spike protein antibody levels in a group of healthy people. PATIENTS AND METHODS: The prospective study included 93 participants before and after a second booster of COVID-19 vaccination, from whom 4 blood samples were collected at intervals. The levels of IgG anti-SARS-CoV-2 in serum were identified using the chemiluminescent immunoassay specific for the receptor-binding domain (RBD) of the S1 protein. The analysis of the results was performed using appropriate statistical methods, considering $p < 0.05$ as a statistically significant value. RESULTS: The IgG levels were significantly higher and less diverse after the same follow-up time from the second booster vaccination compared to the first booster. The antibody levels were positively correlated with female, healthcare workers, the elderly and participants with a negative COVID-19 history. Furthermore, the increase in IgG antibodies after the second booster vaccination correlated inversely with the baseline level of antibodies before the vaccination. The latest results showed that antibody levels dropped 1.5-fold after approx. 10 months from the second booster vaccination but still remained at a protective level. CONCLUSION: Booster vaccinations seem to better stimulate immune memory, and in the case of borderline IgG level induces the greatest increase in antibodies. It is worth considering the individual parameters of patients and measuring antibodies before vaccination.
Humoral Immune Response after anti-SARS-CoV-2 Vaccine "Booster" Dose in Patients with Monoclonal Gammopathy of Undetermined Significance (MGUS).
Ocular inflammatory manifestations following COVID-19 vaccinations in Taiwan: A case series. As a continuing demand for booster shots against SARS-CoV-2, ocular adverse events following the coronavirus disease-2019 (COVID-19) vaccines can cause significant visual impairment, and they warrant a high awareness and detailed documentation of possible ocular inflammatory manifestations. We present a case series of 11 patients presenting with ocular manifestations relevant to vaccine-associated autoimmune response within 6 weeks after the vaccination of the Oxford-AstraZeneca, the Moderna, and Pfizer-BioNTech vaccines at the main tertiary referral center in the most populated and most vaccinated city in Taiwan. Their diagnosis included five acute anterior uveitis, two multiple evanescent white dot syndrome, one probable Vogt-Koyanagi-Harada disease, one anterior scleritis, one relapsed idiopathic panuveitis, and one autoantibody-related central retinal artery occlusion. This report presented a broad spectrum of the ocular inflammatory events following the vaccination of COVID-19. Early recognition of the clinical manifestations mentioned herein with prompt management is crucial in recovering the patients' vision.
Occlusive retinal vasculopathy following AstraZeneca COVID-19 vaccination: A case report.
Multiple sclerosis (MS) and neuromyelitis optica spectrum disorder (NMOSD) following COVID-19 vaccines: A systematic review. BACKGROUND: The global COVID-19 pandemic began in March

2019, and given the number of casualties and adverse effects on the economy, society, and all aspects of the health system, efforts have been made to develop vaccines from the beginning of the pandemic. Numerous vaccines against COVID-19 infection have been developed in several technologies and have spread rapidly. There have been reported multiple complications of the COVID-19 vaccines as with other vaccines. A number of studies have reported multiple sclerosis (MS) and neuromyelitis optica spectrum disorder (NMOSD) as complications of COVID-19 vaccines. METHODS: First, we found 954 studies from 4 databases (PubMed, Embase, Scopus, and Web of Science) from inception to March 1(st), 2022. Next, duplicate articles were eliminated, and 476 studies remained. Then 412 studies were removed according to inclusion and exclusion criteria. After obtaining the full text of 64 articles, 12 studies were selected finally. RESULTS: The data were extracted from included studies in a table. Our data includes demographic data, comorbidities, vaccines information and side effects, NMOSD and MS symptoms, laboratory and cerebrospinal fluid (CSF) findings, magnetic resonance imaging (MRI) results, treatment, and outcome of all cases. CONCLUSION: MS and NMOSD are two neuroinflammatory disorders that arise in the CNS. Cases of MS and NMOSD have been reported following COVID-19 vaccination. Nevertheless, more studies with more subjects are needed to assess any possible relationship between the COVID-19 vaccine and central nervous system demyelination.

Safety of primary immunization using inactivated SARS-CoV-2 vaccine (CoronaVacÂ®) among population aged 3Â years and older in a large-scale use: A multi-center open-label study in China. OBJECTIVE: To evaluate the safety of primary immunization using CoronaVacÂ® among population aged 3Â years and above in a large-scale use. METHOD: A multi-center open-label study was carried out in 11 provinces of China. Individuals aged 3Â years and older who had no history of COVID-19 vaccination or had received only one dose of CoronaVacÂ® were enrolled in this study. Adults and elderly with or without underlying medical conditions(UMCs) were also recruited. Eligible participants received one or two doses of CoronaVacÂ® with an interval of 28Â days. Demographic information, vaccination and the occurrence of adverse events were recorded by participants or guardians using data collection system designed for this study. All adverse events occurred within 6Â months after the second dose of vaccination were collected. The incidence of adverse events that cannot be ruled out as being caused by the vaccine were calculated to assess the safety of CoronaVacÂ®. This study is registered with ClinicalTrials. Gov (NCT04911790 and NCT04992208). RESULTS: A total of 162,691 participants have been included in this study and 89.50Â % had finished primary immunization. Among adults and elderly, people with UMCs accounted for 25.85Â %, with the top five disease being hypertension, diabetes, chronic gastritis, coronary heart disease(CHD) and kidney stone. The overall incidence of adverse reactions (ARs) within 6Â months after the second vaccination was 2.70Â %, with incidence for children and adolescents, adults, and elderly being 2.03Â %, 3.46Â %, and 1.90Â %, respectively. Most ARs were mild (grade 1). Pain at the injection sites, fatigue, induration/swelling, and headache were the most common symptoms, occurring in 1.64Â %, 0.46Â %, 0.31Â % and 0.24Â %, respectively. No serious adverse events related to vaccines were reported. No adverse events of special interest (AESIs) were identified. For children and adolescents, children aged 3-5Â years had the highest incidence of ARs of 3.29Â %. The incidence of ARs among those aged 18Â years and older with and without UMCs were 2.81Â % and 2.99Â %, respectively, with no statistical significance between two groups(PÂ =Â 0.089). And people with coronary heart disease had higher AR incidence compared to those with other UMCs, but the most common symptoms was pain at the injection site. CONCLUSION: CoronaVacÂ® is safe in a large-scale use and shows well-tolerance for children and adolescents and people with underlying medical conditions. Further studies need to be conducted to explore the relation of ARs incidence to age or different kinds of UMCs.

[Vaccination before and after autologous hematopoietic cell transplantationÂ for autoimmune diseases: Guidelines from the Francophone Society of Bone Marrow Transplantation and Cellular Therapy (MATHEC-SFGM-TC)]. The Francophone Society of Bone Marrow Transplantation and Cellular Therapy (SFGM-TC) organized the 12th workshop on hematopoietic stem cell transplantation clinical practices harmonization procedures on September 2021 in Lille, France. In the absence of specific national or international recommendation, the French working group for autologous stem Cell transplantation in Auto-immune Diseases (MATHEC) proposed guidances for vaccinations of patients undergoing autologous hematopoietic stem cell transplantation for autoimmune disease, including in the context of SARS-Cov-2 pandemic.

Bivalent BNT162b2 mRNA original/omicron BA.4-5 booster vaccination: adverse reactions and inability to work compared with the monovalent COVID-19 booster.

Spike recognition and neutralization of SARS-CoV-2 Omicron subvariants elicited after the third dose of mRNA vaccine. Several severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron subvariants have recently emerged, becoming the dominant circulating strains in many countries. These variants contain a large number of mutations in their spike glycoprotein, raising concerns about vaccine efficacy. In this study, we evaluate the ability of plasma from a cohort of individuals that received three doses of mRNA vaccine to recognize and neutralize these Omicron subvariant spikes. We observed that BA.4/5 and BQ.1.1 spikes are markedly less recognized and neutralized compared with the D614G and other Omicron subvariant spikes tested. Also, individuals who have been infected before or after vaccination present better humoral responses than SARS-CoV-2-naive vaccinated individuals, thus indicating that hybrid immunity generates better humoral responses against these subvariants.

Predictors of low spike antibody response in patients with systemic rheumatic disease after an initial course of COVID-19 vaccination. BACKGROUND: Patients with rheumatic disease may mount a suboptimal serologic response to COVID-19 vaccination. We evaluated predictors of low antibody response in a clinic-based cohort. METHODS: We conducted a cross-sectional study using electronic health record (EHR) data at Brigham and Women's Hospital, Boston, MA. Patients with systemic rheumatic disease that had SARS-CoV-2 spike antibody (Ab) tested using the Roche Elecsys immunoassay, February-August 2021, after 2 doses of mRNA vaccine or 1 dose of adenovirus vector vaccine were identified. Demographics, systemic rheumatic disease, vaccination dates, and disease-modifying antirheumatic drugs (DMARDs) were extracted. The primary outcome was low spike Ab (â‰¤ 200 U/mL). Logistic regression models estimated predictors of low spike Ab. RESULTS: Among 382 patients, the mean age was 57 years, 77% were female, and 37% had low spike Ab. Older age (OR 1.03, 95% CI [1.02, 1.05]), SLE (OR 4.81 [2.08, 8.43], reference: inflammatory arthritis), prednisone (OR 1.67 [1.03, 2.74]), and rituximab (OR 22.91 [9.85, 53.29]) were significantly associated with higher odds of low spike Ab. Use of csDMARD monotherapy (OR 0.12 [0.04, 0.33]) and JAK inhibitors (OR 0.41 [0.18, 0.92]) were associated with significantly lower odds for low spike Ab. After adjusting for systemic rheumatic disease and DMARDs, SLE and rituximab remained significantly associated with low spike Ab. CONCLUSIONS: Over a third of patients with systemic rheumatic disease with spike Ab tested in routine care had low spike Ab after 2 doses of mRNA or 1 dose of adenovirus vector COVID-19 vaccine. SLE and rituximab were significant risk factors for low spike Ab. KEY POINTS: â€¢ More than one-third of patients with systemic rheumatic disease that had spike Ab tested in routine care had low spike Ab after 2 doses of mRNA or 1 dose of adenovirus vector COVID-19 vaccine. â€¢ Diagnosis of SLE, use of prednisone, and use of rituximab were significantly associated with greater odds of low spike antibodies. â€¢ These data underscore the importance of additional doses of COVID-19 vaccine and prophylactic Evusheld in immunosuppressed patients with systemic rheumatic disease as recommended by the US Centers for Disease Control.

Post-vaccination antibodies against SARS-CoV-2: Correspondence. Dear Editor, we would like to share ideas on the publication "Post-vaccination antibodies against SARS-CoV-2 in a cohort of workers of a general hospital"(1). In the cohort and with fresh SARS-CoV-2 infections, Sabater Vidal et al. noticed a general decrease in IgG-S and IgG-NP antibodies following the second dosage of the Pfizer-BioNTech vaccine (1). Additionally, Sabater Vidal et al. advocated booster shots, continuing preventative measures, and further research to determine the vaccine's protection threshold(1). We concur that the COVID-19 can boost resistance in research subjects. Recognizing the impact of earlier asymptomatic COVID-19 is crucial, though. Asymptomatic COVID-19 is not unusual, and anyone can have had it in the past(2). It is important to take into account any potential confounding effects from earlier asymptomatic COVID-19 when interpreting the vaccination's effects.

[Possible vaccine-induced immune thrombotic thrombocytopenia in a patient with diabetes and chronic kidney disease or random association?]. We report the case of a 75-year-old man who developed acute myocardial infarction 12 hours after the first dose of ChAdOx1 nCov-19 vaccine. The event was associated with a transient decrease of platelet count and the detection of anti-PF4 antibodies approximately 45 days after the event. Vaccine-induced thrombotic thrombocytopenia (VITT) is characterized by the onset of venous or arterial thrombosis in temporal relationship to the administration of anti-Sars-Cov-2 viral vector vaccines (ChAdOx1 nCov-19 and Ad26.COV2.S), thrombocytopenia and the production of anti-PF4 antibodies. It occurs mainly at a young age, even if the median age is 54 years; it is often associated with thrombosis in atypical sites, such as the cerebral sinus. Our reported case does not present all the diagnostic criteria of VITT. However, the close temporal relationship between ChAdOx1 nCov-19 vaccine administration, thrombosis, and concomitant anti-PF4 antibodies positivity makes the case suggestive of a possible slight form of VITT.

Pediatric Minimal Change Disease and AKI following the Pfizer-BioNTech COVID-19 Vaccine: causal or incidental correlation? The global coronavirus 2019 (COVID-19) pandemic required vaccination even in children to reduce infection. We report on the development of acute kidney injury (AKI) and minimal change disease (MCD) nephrotic syndrome (NS), shortly after the first injection BNT162b2 COVID-19 vaccine (Pfizer-BioNTech). A 12-year-old previously healthy boy was referred to our hospital with complaints of peripheral edema and nephrotic range proteinuria. Nine days earlier he had received his first injection BNT162b2 COVID-19 vaccine (Pfizer-BioNTech). Seven days after injection, he developed leg edema, which rapidly progressed to anasarca with significant weight gain. On admission, serum creatinine was 1.3 mg/dL and 24-hour urinary protein excretion was 4 grams with fluid overload. As kidney function continued to decline over the next days, empirical steroid treatment and renal replacement therapy with ultrafiltration were started and kidney biopsy was performed. Seven days after steroid therapy, kidney function began to improve, gradually returning to normal. The association of MCD, nephrotic syndrome and AKI hasn't been previously described following the Pfizer-BioNTech COVID-19 vaccine in pediatric population, but this triad has been reported in adults. We need further similar case reports to establish the real incidence of this possible vaccine side effect.

Effect of medical staff training on vaccination coverage in outpatients with cancer: An interventional multicenter before-and-after study. PURPOSE: Despite widely disseminated guidelines, pneumococcal and influenza vaccination coverage (VC) remains insufficient in patients with cancer receiving cancer treatment. We performed an interventional study to evaluate VC in patients with cancer treated at the medical oncology departments of three North-of-France hospitals and to assess the effect of medical staff training on VC in these patients. METHODS: A standardized questionnaire assessed VC in adult patients with cancer receiving anticancer treatment at three day hospitals during December 2-7, 2019. Subsequently (January 2020), we organized educational training sessions for medical staff from each hospital to discuss the current vaccination guidelines. To assess the impact of

training on pneumococcal and influenza VC, we re-administered the same questionnaire in March 2020. Because there are no specific guidelines on Diphtheria-Tetanus-Pertussis (DTP) vaccination and no improvement was expected, DTP VC acted as an internal control. RESULTS: In total, 272 patients from all three hospitals were enrolled in the "before study"; 156 patients from only two hospitals were enrolled in the "after study" as medical training and data collection at the third were impossible because of administrative reasons and COVID-19 pandemic. The predictors were age for DTP VC; treatment center for pneumococcal VC; and age, sex, and tumor histology (adenocarcinoma vs. others) for influenza VC. Neither influenza VC (42.6% vs. 55.1%, pÂ =Â 0.08), nor pneumococcal VC were significantly improved post-intervention (11.8% vs. 15.4%, pÂ =Â 1). There seems to be a small effect in the most fragile for influenza VC. CONCLUSION: As expected, VC was very low in patients with cancer, consistent with the literature. There was no impact of the intervention for pneumococcal and influenza VC.

A comparison of post-COVID vaccine myocarditis classification using the Brighton Collaboration criteria versus Centre for Disease Control criteria.

Thrombotic outcomes in patients in a large clinical enterprise following COVID-19 vaccination. Vaccination against COVID-19 reduces infection-related mortality. Unfortunately, reports of vaccine-induced immune thrombotic thrombocytopenia (VITT) in individuals administered adenovirus-vector-based vaccines (ChAdOx1 nCoV-19 and Ad26.COV2.S) have spurred side effect concerns. To address vaccine hesitancy related to this, it is essential to determine the incidence of VITT (defined by a 50% decrease in platelet count and positive anti-PF4 immunoassay within 4-28 days after vaccination) among patients administered two doses of an mRNA-based COVID-19 vaccination.Â We identified a retrospective cohort of 223,345 patients in the Cleveland Clinic Enterprise administered a COVID-19 vaccine at any location in Northeast Ohio and Florida from 12/4/2020 to 6/6/2021. 97.3% of these patients received an mRNA-based vaccination. Patients with: (1) a serial complete blood count both before and after vaccination and (2) a decrease in platelet count of â‰¥â€‰50% were selected for chart review. The primary outcome was the incidence of thrombotic events, including venous thromboembolism (VTE) and arterial thrombosis, 4-28 days post vaccination.Â Of 74 cohort patients with acute thrombosis, 72 (97.3%) demonstrated clear etiologies, such as active malignancy. Of two patients with unprovoked thrombosis, only one had findings concerning for VITT, with a strongly positive anti-PF4 antibody assay.Â In this large, multi-state, retrospective cohort, of 223,345 patients (97.2% of whom received the mRNA-based mRNA-1273 or BNT162b2 vaccines), we detected a single case that was concerning for VITT in a patient who received an mRNA vaccine. The overwhelming majority of patients with a thrombotic event 4-28 days following vaccination demonstrated clear etiologies.

Comparative analysis of risk factors for COVID-19 mortality before, during and after the vaccination programme in Mexico. OBJECTIVES: The purpose of this study was to compare case fatality rates (CFRs) and odds for mortality by risk factors of patients with COVID-19 in Mexico, before, during and after the implementation of the national COVID-19 vaccination programme. STUDY DESIGN: A large database including COVID-19 monitoring cases was used to perform an observational retrospective study. METHODS: The Chi-squared test and multivariate logistic regression analyses were applied to data from COVID-19-positive patients in Mexico. Data were analysed over 3 years, 2020, 2021 and 2022, corresponding with pre-, during and post-vaccination periods. The unadjusted odds ratios and 95% confidence interval were used to estimate the risk factors for COVID-19 mortality in each of the years. RESULTS: Statistically significant differences in CFR and odds ratio were found in the studied years, favouring postvaccination period. Significant changes in CFR by age, sex and main comorbidities indicated changes in the epidemic dynamics after the implementation of the COVID-19 vaccination campaign. The likelihood of death increased for hospitalised cases and for patients who

were middle-aged or older in 2021 and 2022, whereas the odds of death associated with sex and comorbidities remained similar or reduced over the 3 years. CONCLUSIONS: Implementation of the COVID-19 vaccination programme during 2021 showed positive consequences on CFR. The increased odds of dying in hospitalised patients are likely to be due to the unvaccinated proportion of patients.

Bivalent Omicron BA.1-Adapted BNT162b2 Booster in Adults Older than 55 Years. BACKGROUND: The emergence of immune-escape variants of severe acute respiratory syndrome coronavirus 2 warrants the use of sequence-adapted vaccines to provide protection against coronavirus disease 2019. METHODS: In an ongoing phase 3 trial, adults older than 55 years who had previously received three 30-Î¼g doses of the BNT162b2 vaccine were randomly assigned to receive 30 Î¼g or 60 Î¼g of BNT162b2, 30 Î¼g or 60 Î¼g of monovalent B.1.1.529 (omicron) BA.1-adapted BNT162b2 (monovalent BA.1), or 30 Î¼g (15 Î¼g of BNT162b2â€‰+â€‰15 Î¼g of monovalent BA.1) or 60 Î¼g (30 Î¼g of BNT162b2â€‰+â€‰30 Î¼g of monovalent BA.1) of BA.1-adapted BNT162b2 (bivalent BA.1). Primary objectives were to determine superiority (with respect to 50% neutralizing titer [NT(50)] against BA.1) and noninferiority (with respect to seroresponse) of the BA.1-adapted vaccines to BNT162b2 (30 Î¼g). A secondary objective was to determine noninferiority of bivalent BA.1 to BNT162b2 (30 Î¼g) with respect to neutralizing activity against the ancestral strain. Exploratory analyses assessed immune responses against omicron BA.4, BA.5, and BA.2.75 subvariants. RESULTS: A total of 1846 participants underwent randomization. At 1 month after vaccination, bivalent BA.1 (30 Î¼g and 60 Î¼g) and monovalent BA.1 (60 Î¼g) showed neutralizing activity against BA.1 superior to that of BNT162b2 (30 Î¼g), with NT(50) geometric mean ratios (GMRs) of 1.56 (95% confidence interval [CI], 1.17 to 2.08), 1.97 (95% CI, 1.45 to 2.68), and 3.15 (95% CI, 2.38 to 4.16), respectively. Bivalent BA.1 (both doses) and monovalent BA.1 (60 Î¼g) were also noninferior to BNT162b2 (30 Î¼g) with respect to seroresponse against BA.1; between-group differences ranged from 10.9 to 29.1 percentage points. Bivalent BA.1 (either dose) was noninferior to BNT162b2 (30 Î¼g) with respect to neutralizing activity against the ancestral strain, with NT(50) GMRs of 0.99 (95% CI, 0.82 to 1.20) and 1.30 (95% CI, 1.07 to 1.58), respectively. BA.4-BA.5 and BA.2.75 neutralizing titers were numerically higher with 30-Î¼g bivalent BA.1 than with 30-Î¼g BNT162b2. The safety profile of either dose of monovalent or bivalent BA.1 was similar to that of BNT162b2 (30 Î¼g). Adverse events were more common in the 30-Î¼g monovalent-BA.1 (8.5%) and 60-Î¼g bivalent-BA.1 (10.4%) groups than in the other groups (3.6 to 6.6%). CONCLUSIONS: The candidate monovalent or bivalent omicron BA.1-adapted vaccines had a safety profile similar to that of BNT162b2 (30 Î¼g), induced substantial neutralizing responses against ancestral and omicron BA.1 strains, and, to a lesser extent, neutralized BA.4, BA.5, and BA.2.75 strains. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04955626.).

Persistent COVID-19 Symptoms at 6 Months After Onset and the Role of Vaccination Before or After SARS-CoV-2 Infection. IMPORTANCE: Understanding the factors associated with post-COVID conditions is important for prevention. OBJECTIVE: To identify characteristics associated with persistent post-COVID-19 symptoms and to describe post-COVID-19 medical encounters. DESIGN, SETTING, AND PARTICIPANTS: This cohort study used data from the Epidemiology, Immunology, and Clinical Characteristics of Emerging Infectious Diseases With Pandemic Potential (EPICC) study implemented in the US military health system (MHS); MHS beneficiaries aged 18 years or older who tested positive for SARS-CoV-2 from February 28, 2020, through December 31, 2021, were analyzed, with 1-year follow-up. EXPOSURES: SARS-CoV-2 infection. MAIN OUTCOMES AND MEASURES: The outcomes analyzed included survey-reported symptoms through 6 months after SARS-CoV-2 infection and International Statistical Classification of Diseases and Related Health Problems, Tenth Revision diagnosis categories reported in medical records 6 months following SARS-CoV-2 infection vs 3 months before infection. RESULTS: More than half of the 1832 participants in these analyses were aged 18 to 44 years (1226 [66.9%]; mean [SD] age, 40.5 [13.7] years), were male (1118 [61.0%]), were

unvaccinated at the time of their infection (1413 [77.1%]), and had no comorbidities (1290 [70.4%]). A total of 728 participants (39.7%) had illness that lasted 28 days or longer (28-89 days: 364 [19.9%]; â‰¥90 days: 364 [19.9%]). Participants who were unvaccinated prior to infection (risk ratio [RR], 1.39; 95% CI, 1.04-1.85), reported moderate (RR, 1.80; 95% CI, 1.47-2.22) or severe (RR, 2.25; 95% CI, 1.80-2.81) initial illnesses, had more hospitalized days (RR per each day of hospitalization, 1.02; 95% CI, 1.00-1.03), and had a Charlson Comorbidity Index score of 5 or greater (RR, 1.55; 95% CI, 1.01-2.37) were more likely to report 28 or more days of symptoms. Among unvaccinated participants, postinfection vaccination was associated with a 41% lower risk of reporting symptoms at 6 months (RR, 0.59; 95% CI, 0.40-0.89). Participants had higher risk of pulmonary (RR, 2.00; 95% CI, 1.40-2.84), diabetes (RR, 1.46; 95% CI, 1.00-2.13), neurological (RR, 1.29; 95% CI, 1.02-1.64), and mental health-related medical encounters (RR, 1.28; 95% CI, 1.01-1.62) at 6 months after symptom onset than at baseline (before SARS-CoV-2 infection). CONCLUSIONS AND RELEVANCE: In this cohort study, more severe acute illness, a higher Charlson Comorbidity Index score, and being unvaccinated were associated with a higher risk of reporting COVID-19 symptoms lasting 28 days or more. Participants with COVID-19 were more likely to seek medical care for diabetes, pulmonary, neurological, and mental health-related illness for at least 6 months after onset compared with their pre-COVID baseline health care use patterns. These findings may inform the risk-benefit ratio of COVID-19 vaccination policy.

Preliminary results of COVID-19 vaccination among Taiwanese pregnant women: A single-center, prospective, case-control study. OBJECTIVE: To evaluate the impacts of messenger RNA coronavirus disease 2019 (COVID-19) vaccines in Taiwanese pregnant women in terms of obstetrical and neonatal outcomes. METHODS: The authors prospectively followed up 450 pregnant women receiving vaccination at a single center. Patients recorded prespecified adverse reactions via a mobile application up to 30â€‰days after the first and second doses. Obstetrical and neonatal outcomes were compared with those of pregnant women, during the same period, who did not undergo vaccination. RESULTS: Among the 387 women who received the first dose and were followed up for 30â€‰days, injection site pain, fatigue, injection site swelling, muscle ache, and headache were the most prevalent side effects. There were 4.7-, 5.7-, 7.1-, and 9.3-fold increases in fatigue, injection site swelling, muscle ache, and headache, respectively, among the 231 women who received the second dose. Most of the side effects resolved by 14â€‰days and all resolved by 30â€‰days after each doses. There were no significant differences (Pâ€‰>â€‰0.05) in obstetrical and neonatal morbidity or mortality between the vaccinated and unvaccinated cohorts. CONCLUSION: No serious adverse reactions were noted among pregnant women receiving messenger RNA vaccinations with comparable obstetrical and neonatal outcomes to unvaccinated pregnant women.

Morphea at the site of anti-COVID-19 vaccination: the first reported case?

New-onset erythema elevatum diutinum following COVID-19 vaccination.

COVID-19 infection- and vaccination-related exacerbation of Darier's disease in a single patient. Darier's disease (DD) is a rare autosomal dominantly inherited disorder. DD patients usually present with widespread keratotic eruptions with itching in the seborrheic regions that are exacerbated by various factors, including heat, sweat, and physical trauma. The SARS-CoV-2 (COVID-19) pandemic has stirred confusion among the medical community, including dermatologists, as this infection has been implicated in various skin conditions. Only a handful of reports have documented DD associated with COVID-19. Here, we report a 30-year-old male with Darier's disease whose symptoms were exacerbated following both COVID-19 vaccination and COVID-19 infection. The patient had noticed slight eruptions 7â€‰years prior, but was not particularly concerned. After COVID-19 vaccination and infection, he had erythematous maculopapular lesions in large areas of the trunk and extremities. The previously reported pathogenic variant c.2255_2257del (p.(Ile752_Tyr753delinsAsn)) in ATP2A2 was

detected in the present patient. Oral etretinate greatly improved his DD manifestations. As far as we know, the present patient is the first genetically confirmed DD case who showed both COVID-19 infection- and vaccination-related DD exacerbations independently. We think that the further accumulation of DD cases exacerbated by COVID-19 infection/vaccination is needed to clarify the mechanisms of DD aggravation.

Subclinical myocardial assessment after BNT162b2 messenger RNA COVID-19 vaccination in adolescents with chronic heart disease: a speckle-tracking echocardiography study. PURPOSE: Case reports of the development of perimyocarditis in adolescents and young adults after BNT162b2 messenger RNA (mRNA) COVID-19 vaccination have raised concerns about the cardiac side effects of the vaccine. The aim of the study was to evaluate clinical follow-up and subclinical myocardial function after mRNA COVID-19 vaccine in adolescents with chronic heart disease. METHODS: Forty-one adolescents aged 12-18 who were followed up at paediatric cardiology clinic between December 2021 and May 2022, and who had received two doses of the Pfizer-BioNTech COVID-19 mRNA vaccine were included in the study. The patients were evaluated five times in total - before the vaccination, one week after receiving the first dose, one month after receiving the first dose, one week after receiving the second dose, and one month after receiving the second dose. Cardiac assessment for all patients included an electrocardiogram, transthoracic echocardiography, and two-dimensional speckle-tracking strain echocardiography for left ventricular subclinical myocardial function. RESULTS: The mean age of the adolescents was 16.2 Â± 1.5 years, and 56% (n = 23) were male. There was no statistically significant difference in patients' echocardiographic measurements including left ventricular global longitudinal strain and electrocardiogram parameters including PR, QRS, and QTc intervals through the follow-up. Seven patients reported cardiac complaints at post-vaccination follow-up visits, but laboratory and echocardiographic evidence of cardiac involvement was not observed. CONCLUSIONS: Based on the results of our study, the mRNA COVID-19 vaccine did not cause impairment in subclinical myocardial function assessed by speckle-tracking echocardiography in adolescents with chronic heart disease.

Herpes Zoster Following COVID-19 Vaccine Booster. BACKGROUND Herpes zoster is a condition in which there is reactivation of varicella zoster virus (VZV), which is usually seen in the elderly and those with immunocompromised states. Recently, however, there have been many reports of herpes zoster after administration of COVID-19 vaccines, although initial trials showed that these vaccines have good safety and immunogenicity profiles. At the time of writing, about 5 billion people worldwide had received their full course of COVID-19 vaccination. This case report describes an elderly man who developed herpes zoster after receiving a booster dose of the Pfizer-BioNTech (BNT162b2) vaccine, with no adverse effects after the first and second dose. CASE REPORT An 82-year-old man with underlying type 2 diabetes mellitus, hypertension, dyslipidemia, and cerebrovascular disease presented with left-sided chest and upper back pain. The pain was intermittent, burning in nature, and disturbed his sleep. A week prior to his presentation, he received a COVID-19 vaccine (BNT162b2) booster dose. Examination revealed multiple vesicles along his anterior and posterior T3 dermatome. He was diagnosed with herpes zoster and treated with a course of oral acyclovir. Upon review 7 days later, he had recovered well, with resolution of his vesicles and pain. CONCLUSIONS COVID-19 vaccination remains an important measure to prevent transmission of infection and to reduce the mortality and morbidity caused by it. However, healthcare practitioners should be aware of the possible association between COVID-19 vaccination and herpes zoster. Appropriate explanation and safety advice on the possible adverse events following COVID-19 vaccination, including herpes zoster infection, should be given to patients. This will facilitate early recognition and treatment of this condition.

Implementation of data triangulation and dashboard development for COVID-19 vaccine adverse event following immunisation (AEFI) data in Nigeria. Nigeria began administering COVID-19 vaccines on 5 March 2021 and is working towards the WHO's African regional goal to fully vaccinate 70% of their eligible population by December 2022. Nigeria's COVID-19 vaccination information system includes a surveillance system for COVID-19 adverse events following immunisation (AEFI), but as of April 2021, AEFI data were being collected and managed by multiple groups and lacked routine analysis and use for action. To fill this gap in COVID-19 vaccine safety monitoring, between April 2021 and June 2022, the US Centers for Disease Control and Prevention, in collaboration with other implementing partners led by the Institute of Human Virology Nigeria, supported the Government of Nigeria to triangulate existing COVID-19 AEFI data. This paper describes the process of implementing published draft guidelines for data triangulation for COVID-19 AEFI data in Nigeria. Here, we focus on the process of implementing data triangulation rather than analysing the results and impacts of triangulation. Work began by mapping the flow of COVID-19 AEFI data, engaging stakeholders and building a data management system to intake and store all shared data. These datasets were used to create an online dashboard with key indicators selected based on existing WHO guidelines and national guidance. The dashboard went through an iterative review before dissemination to stakeholders. This case study highlights a successful example of implementing data triangulation for rapid use of AEFI data for decision-making and emphasises the importance of stakeholder engagement and strong data governance structures to make data triangulation successful.

Coronavirus Disease 2019 (COVID-19) Vaccination in Pregnancy. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in pregnancy is associated with significant maternal morbidity and mortality, and its risks can be mitigated with coronavirus disease 2019 (COVID-19) vaccination. Vaccination against COVID-19 in pregnancy results in protection against both maternal and neonatal SARS-CoV-2 infection, as well as maternal critical illness. Vaccination during pregnancy is safe, with no documented risks of pregnancy loss, preterm delivery, congenital anomalies, or other adverse perinatal outcomes. For these reasons, COVID-19 vaccination is recommended in pregnancy by the Centers for Disease Control and Prevention, the American College of Obstetricians and Gynecologists, and the Society for Maternal-Fetal Medicine, as well as other national and international professional organizations. In this review, we will summarize the published literature demonstrating the benefit and safety of these vaccines.

Safety and Efficacy of Coronavirus Disease 2019 (COVID-19) mRNA Vaccines During Lactation. In this review, we summarize the data on the safety and side-effect profile of coronavirus disease 2019 (COVID-19) vaccines during lactation to date, review what is known about mRNA vaccine components in breast milk, and discuss the efficacy of COVID-19 vaccines in providing immune protection for the breastfeeding infant. The Centers for Disease Control and Prevention and the American College of Obstetricians and Gynecologists recommend that lactating individuals receive COVID-19 mRNA vaccines and stay up to date on booster doses, including the bivalent COVID-19 booster. The lack of serious side effects in mothers or infants across numerous large studies and registries of COVID-19 vaccination in pregnancy and lactation is reassuring. Although small quantities of mRNA may be transiently detectable in breast milk after maternal vaccination, there are no data demonstrating that vaccine mRNA can survive the infant gastrointestinal tract and no evidence that breast milk from lactating individuals who have received a COVID-19 mRNA vaccine can cause harm to breastfeeding infants. In contrast, numerous studies demonstrate that the breast milk of vaccinated individuals contains severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-specific functional antibodies and T cells, which benefit the breastfeeding infant's developing immune system. Transfer of SARS-CoV-2-specific antibodies from mother to infant is highest when vaccination occurs during pregnancy

compared with lactation, because the breastfeeding infant receives both long-lasting antibodies through the placenta and breast-milk antibodies through breast milk. With clear data demonstrating efficacy and safety and no data demonstrating harm to mother or infant after COVID-19 vaccine administration during lactation, any recommendations to avoid vaccination while breastfeeding or to withhold breast milk from the infant for any period of time after vaccination are not supported by available evidence.

Kinetics of Anti-SARS-CoV-2 Antibody Response Following Two Doses of the BNT162b2 mRNA Vaccine: A Japanese Single-Center Primary Care Clinic Report Involving Volunteers and Patients with Autoimmune Disease. Despite the promising effectiveness of the coronavirus disease 2019 vaccination using an mRNA vaccine, the short efficacy duration and some poor responses to the vaccination remain major concerns. We aimed to clarify the monthly kinetics of the anti-SARS-CoV-2 spike receptor-binding domain antibody response after two doses of the BNT162b2 vaccine in a Japanese population. A chemiluminescent enzyme immunoassay (CLIA) and an enzyme-linked immunosorbent assay were used to measure the antibody levels in 81 Japanese adults (age, <65 years). The antibody levels increased 10-fold at 2â^'3 weeks following the second dose of BNT162b2 and declined thereafter to approximately 50%, 20%, and 10% of the peak levels at 2, 3, and 6 months, respectively. To compare the antibody titers among different groups, older adults (age, >65 years; n = 38) and patients with systemic lupus erythematosus (SLE, n = 14) were also investigated. A decline in the mean relative antibody titers was observed in older men compared with younger men and in patients with SLE compared with individuals aged <65 years. Although the antibody levels increased drastically following two BNT162b2 doses, they then declined rapidly. Furthermore, poor responders to the vaccination were observed. Repeated vaccinations are required to maintain high antibody levels.

[Not Available].

An impressive case of alopecia universalis after COVID-19 vaccination: a coincidental finding or a consequence? BACKGROUND: Several cutaneous manifestations in patients undergoing COVID-19 vaccination have been described in literature. CASE REPORT: Herein, we present a case of alopecia universalis that occurred after the first and second dose of Comirnaty vaccine. A bibliographic search was conducted and a total of 14 studies concerning the association were reviewed. CONCLUSIONS: Given the autoimmune pathogenesis of the disease, we discussed the potential role of SARS-CoV-2 infection and vaccination as a trigger for the development of hair loss. Physicians should be aware of SARS-CoV-2 vaccine-related hair loss and properly treat this undesirable effect.

Cerebral venous thrombosis after ChAdOx1 nCoV-19 vaccination: a systematic review. OBJECTIVE: To perform a systematic review of case reports or case series regarding thrombosis with thrombocytopenia syndrome (TTS) and cerebral venous thrombosis (CVT) related to ChAdOx1 nCoV-19 vaccination to address the clinical features, laboratory findings, treatment modalities, and prognosis related with CVT. SUBJECTS AND METHODS: We included 64 TTS patients from 19 articles, 6 case series and 13 case reports, in which thrombosis occurred after the first dose of ChAdOx1 nCoV-19 vaccination published up to 30 June 2021 in Embase, ePubs, Medline/PubMed, Scopus, and Web of Science databases. RESULTS: Of the 64 TTS patients, 38 (59.3%) had CVT. Patients with CVT were younger (median 36.5 vs. 52.5 years, p<0.001), had lower fibrinogen levels (130 vs. 245 mg/dL, p=0.008), had more frequent history of intracerebral hemorrhage (ICH), and had higher mortality rate (48.6% vs. 19.2%, p=0.020) than that of patients without CVT. In multivariable analysis, the possibility of presence of CVT was higher in younger age groups [odd ratio (OR): 0.91, 95% confidence interval (CI): (0.86-0.97, p<0.001)] and those with accompanying intracerebral hemorrhage (ICH) (OR: 13.60, 95% CI (1.28-144.12, p=0.045). CONCLUSIONS: Our study demonstrated that CVT related to ChAdOx1 nCoV-19 vaccination was associated with younger age, low levels of fibrinogen, presence of ICH and

more frequent mortality compared to those of non-CVT. If TTS occurs after ChAdOx1 nCoV-19 vaccination, the presence of CVT in patients with young age or ICH should be considered.

SARS-CoV-2 spike mRNA vaccine sequences circulate in blood up to 28â€‰days after COVID-19 vaccination. In Denmark, vaccination against Severe Acute Respiratory Syndrome Corona Virus 2 (SARS-CoV-2) has been with the Pfizer-BioNTech (BTN162b2) or the Moderna (mRNA-1273) mRNA vaccines. Patients with chronic hepatitis C virus (HCV) infection followed in our clinic received mRNA vaccinations according to the Danish roll-out vaccination plan. To monitor HCV infection, RNA was extracted from patient plasma and RNA sequencing was performed on the Illumina platform. In 10 of 108 HCV patient samples, full-length or traces of SARS-CoV-2 spike mRNA vaccine sequences were found in blood up to 28â€‰days after COVID-19 vaccination. Detection of mRNA vaccine sequences in blood after vaccination adds important knowledge regarding this technology and should lead to further research into the design of lipid-nanoparticles and the half-life of these and mRNA vaccines in humans.

SARS-CoV-2 vaccines and in vitro fertilization outcomes: so far, so good!

Spotlight on mycobacterial lipid exploitation using nanotechnology for diagnosis, vaccines, and treatments. Tuberculosis (TB), historically the most significant cause of human morbidity and mortality, has returned as the top infectious disease worldwide, under circumstances worsened by the COVID-19 pandemic's devastating effects on public health. Although Mycobacterium tuberculosis, the causal agent, has been known of for more than a century, the development of tools to control it has been largely neglected. With the advancement of nanotechnology, the possibility of engineering tools at the nanoscale creates unique opportunities to exploit any molecular type. However, little attention has been paid to one of the major attributes of the pathogen, represented by the atypical coat and its abundant lipids. In this review, an overview of the lipids encountered in M. tuberculosis and interest in exploiting them for the development of TB control tools are presented. Then, the amalgamation of nanotechnology with mycobacterial lipids from both reported and future works are discussed.

Relationship between Anti-SARS-CoV-2 S Abs and IFN-Î»3 Levels in the Administration of Oxygen following COVID-19 Vaccination. Although the effectiveness of vaccination at preventing hospitalization and severe coronavirus disease (COVID-19) has been reported in numerous studies, the detailed mechanism of innate immunity occurring in host cells by breakthrough infection is unclear. One hundred forty-six patients were included in this study. To determine the effects of vaccination and past infection on innate immunity following SARS-CoV-2 infection, we analyzed the relationship between anti-SARS-CoV-2 S Abs and biomarkers associated with the deterioration of COVID-19 (IFN-Î»3, C-reactive protein, lactate dehydrogenase, ferritin, procalcitonin, and D-dimer). Anti-S Abs were classified into two groups according to titer: high titer (â‰¥250 U/ml) and low titer (<250 U/ml). A negative correlation was observed between anti-SARS-CoV-2 S Abs and IFN-Î»3 levels ($r = -0.437$, $p < 0.001$). A low titer of anti-SARS-CoV-2 S Abs showed a significant association with oxygen demand in patients, excluding aspiration pneumonia. Finally, in a multivariate analysis, a low titer of anti-SARS-CoV-2 S Abs was an independent risk factor for oxygen demand, even after adjusting for age, sex, body mass index, aspiration pneumonia, and IFN-Î»3 levels. In summary, measuring anti-SARS-CoV-2 S Abs and IFN-Î»3 may have clinical significance for patients with COVID-19. To predict the oxygen demand of patients with COVID-19 after hospitalization, it is important to evaluate the computed tomography findings to determine whether the pneumonia is the result of COVID-19 or aspiration pneumonia.

[Headache associated with COVID-19 vaccination: how to classify?]. INTRODUCTION: In the setting of acute COVID-19 infection, headache occurs in 10-60% of patients and may last for days and, in aÂ smaller proportion of patients, weeks (about 10%). However, it is less recognized that headache

may also occur after vaccination with aÂ short latency and may persist for aÂ longer period in aÂ still unclear number of patients. METHODS: Retrospective description of headache and course in aÂ case series ofÂ 32 outpatients with headache that changed or recurred after COVID-19 vaccination. RESULTS: The majority of patients experienced an exacerbation of migraine headache; rare headache syndromes such as intracranial hypertension or thunderclap headache occurred in 2Â patients. Headache manifested in more than 50% of patients within the first 48â€¯h after vaccination. Over 50% of patients who received aÂ triptan improved. CONCLUSION: The pathophysiological relationship between vaccination and persistent headache is not yet clearly understood. The short latency, partial efficacy of cortisone, and initial findings showing an increase of various inflammatory markers during the course of headache in COVID infection suggest aÂ possible involvement of the innate immune system and here the inflammasome. Furthermore, the response to triptan in aÂ proportion of patients also indicates activation of the trigeminovascular system.

Serologic response to COVID-19 vaccines in patients with inflammatory bowel disease: a prospective study. BACKGROUND AND AIMS: response to the SARS-CoV-2 vaccine can be altered in patients with immune-mediated diseases, such as inflammatory bowel disease, and in patients under immunosuppressive treatment. The aims of this study were to evaluate the serologic response to the SARS-CoV-2 vaccine in patients with inflammatory bowel disease, to analyze the influence of immunosuppressive drugs on response, and to describe any adverse events in this population. METHODS: this was a prospective study that included adult patients with inflammatory bowel disease. Baseline characteristics, concomitant treatments and previous COVID-19 symptoms were collected. Patients underwent serological testing before the first and after the second vaccine dose. RESULTS: a total of 265 patients were consecutively included. Patients received one of the following vaccines: messenger RNA vaccines from Pfizer/BioNTech and Moderna; and adenovirus vaccines from AstraZeneca and Janssen. All adverse events were mild, and the most frequent was injection site pain in 141 (86 %) patients. The seroconversion rate according to the treatment that patients were receiving was: 100 % for those without treatment, 92.5 % for patients treated with mesalazine, 90.3 % for those receiving immunomodulators, 88.9 % for patients with biological monotherapy and 92.5 % for patients on combined treatment. The generation of antibodies according to the vaccine administered was: Pfizer 92.9 %, Moderna 93.3 %, AstraZeneca 98.4 %, and Janssen 12.5 %. CONCLUSION: the antibody response after vaccination against SARS-CoV-2 is high in patients with inflammatory bowel disease. However, patients treated with immunosuppressive or biologic drugs had a lower response. Adverse events were frequent, but not serious.

Vaccination effects on post-infection outcomes in the Omicron BA.2 outbreak in Shanghai. Omicron and its sublineages are currently predominant and have triggered epidemiological waves of SARS-CoV-2 around the world due to their high transmissibility and strong immune escape ability. Vaccines are key measures to control the COVID-19 burden. Omicron BA.2 caused a large-scale outbreak in Shanghai since March 2022 and resulted in over 0.6 million laboratory-confirmed infections. The vaccine coverage of primary immunization among residents aged 3 years and older in Shanghai exceeded 90%, and inactivated COVID-19 vaccines were mainly delivered. In the context of high vaccine coverage, we conducted a cohort study to assess vaccine effects on reducing the probability of developing symptoms or severity of disease in infections or nonsevere cases. A total of 48,243 eligible participants were included in this study, the majority of whom had asymptomatic infections (31.0%) and mild-to-moderate illness (67.9%). Domestically developed COVID-19 vaccines provide limited protection to prevent asymptomatic infection from developing into mild-to-moderate illness and durable protection to prevent nonsevere illness from progressing to severe illness caused by Omicron BA.2. Partial vaccination fails to provide effective protection in any situation. The level of vaccine effects on disease progression in the elderly over 80 years old was relatively lower compared

with other age groups. Our study results added robust evidence for the vaccine performance against Omicron infection and could improve vaccine confidence.

Utility of Roche Elecsys anti-SARS-CoV-2 S in ascertaining post-vaccine neutralizing antibodies. With widespread global COVID-19 vaccine coverage, a scalable, cost-effective, and standardized tool to ascertain post-vaccine immunity is a dire need. Neither clinical evaluations of vaccine efficacy, nor live virus antibody neutralization assays fulfill these criteria. Commercially available anti-S binding immunological assays have the potential to fill this gap, but need to be systematically evaluated for their utility to serve as surrogates for the aforementioned, widely accepted tools of determining vaccine efficacy. In this study, we evaluated an anti-S binding immunological assay (Roche Elecsys Anti-SARS-CoV-2 S) by utilizing two hundred and fifty-five archived serum specimens, either pre-pandemic, or those exposed to natural infections or vaccines with their neutralizing titers pre-determined through a live virus, pseudotyped antibody neutralization assay. Roche Elecsys Anti-SARS-CoV-2 S demonstrated good sensitivity (98%) and specificity (99%), just as has been reported in some other previously conducted studies using this assay. Only a mild correlation, however, with the live virus pseudotyped lentivirus antibody neutralization assay (Spearman's rÂ =Â 0.26) was observed. We conclude that, as such, Elecsys Anti-SARS-CoV-2 S has a high sensitivity and specificity for detecting anti-SARS-CoV-2 S proteins, though the assay does not always correlate well with live virus assays for quantitative outcomes.

A simple point-of-care assay accurately detects anti-spike antibodies after SARS-CoV-2 vaccination. OBJECTIVE: Lateral flow assays (LFA) are sensitive for detecting antibodies to SARS-CoV-2 proteins within weeks after infection. This study tested samples from immunocompetent adults, and those receiving treatments for chronic inflammatory diseases (CID), before and after mRNA SARS-CoV-2 vaccination. METHODS: We compared results obtained with the COVIBLOCK Covid-19 LFA to those obtained by anti-spike (S) ELISA. RESULTS: The LFA detected anti-S antibodies in 29 of 29 (100%) of the immunocompetent and 110 of 126 (87.3%) of the CID participants after vaccination. Semiquantitative LFA scores were statistically significantly lower in samples from immunosuppressed participants, and were significantly correlated with anti-S antibody levels measured by ELISA. CONCLUSIONS: This simple LFA test is a practical alternative to laboratory-based assays for detecting anti-S antibodies after infection or vaccination. This type of test may be most useful for testing people in outpatient or resource-limited settings.

Severe hyponatraemia with cerebral oedema after Pfizer BNT162b2 mRNA vaccination against COVID-19. BACKGROUND: Severe hyponatraemia can lead to serious neurological complications including coma, seizure and death. Hyponatraemia and the Syndrome of Inappropriate Antidiuretic Hormone (SIADH) has been previously described in cases of COVID-19, however there have been few reports post vaccination. We describe a case of severe hyponatraemia post second Pfizer BNT162b2 mRNA vaccination against COVID-19. CASE PRESENTATION: A 48-year-old previously well woman presented to the emergency department with severe headaches and confusion one day after she received her second Pfizer COVID-19 vaccination. She reported no more than 2.5Â L fluid intake. Vital signs were normal. Laboratory investigation revealed serum sodium 113Â mmol/L, potassium 3.4Â mmol/L, urea 3.5Â mmol/L and serum osmolality 266Â mmol/kg. TSH, random cortisol and C-reactive protein levels were normal. She was found to be in urinary retention and developed marked polyuria post in dwelling catheter insertion. Following this she underwent spontaneous and rapid correction of serum sodium without intervention. Retrospective analysis showed an inappropriately high copeptin of 4.4Â pmol/L. CONCLUSIONS: It is important to be cautioned and aware of hyponatraemia as an immediate side effect of COVID-19 vaccination. The exact mechanism is unknown and further research is required to understand the acute endocrine effects which may arise in response to COVID-19 vaccination.

Rapid Waning of Immune Memory Against SARS-CoV-2 in Maintenance Hemodialysis Patients After mRNA Vaccination and Impact of a Booster Dose.

Antibody binding and neutralization of live SARS-CoV-2 variants including BA.4/5 following booster vaccination of patients with B-cell malignancies. Non-Hodgkin lymphoma and chronic lymphocytic leukemia (NHL/CLL) patients elicit inadequate antibody responses after initial SARS-CoV-2 vaccination and remain at high risk of severe COVID-19 disease. We investigated IgG, IgA, and IgM responses after booster vaccination against recent SARS-CoV-2 variants including Omicron BA.5 in 67 patients. Patients had lower fold increase and total anti-spike binding titers after booster than healthy individuals. Antibody responses negatively correlated with recent anti-CD20 therapy and low B cell numbers. Antibodies generated after booster demonstrated similar binding properties against SARS-CoV-2 variants compared to those generated by healthy controls with lower binding against Omicron variants. Importantly, 43% of patients showed anti-Omicron BA.1 neutralizing antibodies after booster and all these patients also had anti-Omicron BA.5 neutralizing antibodies. NHL/CLL patients demonstrated inferior antibody responses after booster vaccination, particularly against Omicron variants. Prioritization of prophylactic and treatment agents and vaccination of patients and close contacts with updated vaccine formulations are essential.

Immune profile of healthcare professionals six months after vaccination or exposure to SARS-CoV-2 in Angola. BACKGROUND AND AIMS: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection is a public health concern. Until 2021, more than 2 million cumulative deaths were reported worldwide. Herein, we investigated the immune profile of healthcare professionals 6 months after vaccination or exposure to SARS-CoV-2 in Angola. METHODS: This was a prospective study conducted with 1068 Angolan healthcare professionals between August and December 2021. Participants were screened for the presence of IgG and IgM against SARS-CoV-2. RESULTS: About 9.6% and 98.2% of the participants had prior exposure to SARS-CoV-2 or vaccination against it, respectively. Participants aged between 20 and 40 years (11.2%), female (12.4%), with higher educational level (12.8%), from Luanda (60.3%), and nonhealthcare professionals (8.1%) were the most affected by the SARS-CoV-2. Gender, education, and local residence were related to SARS-CoV-2 exposure (pâ€‰<â€‰0.05). About 7.3% and 98% of the exposed population developed IgM and IgG after 3 months of exposure, respectively. The AstraZeneca vaccine was the most used, followed by the Jonhson & Johnson and Sputinik. Almost all (98%) participants vaccinated with AstraZeneca had immunity >3 months. Individuals who received only the first dose regardless of the type of vaccine had a higher immunity duration (>3 months) than those who received two doses. For individuals who received the Sputnik and Johnson, the average immunity was lower (<3 months), especially among those who were older (over 40 years old) and exposed to SARS-CoV-2. CONCLUSION: We observed a high adherence rate to vaccination and a long immunity duration. The immunity duration depended on the type of vaccine. Further studies on the immunity profile in the population exposed to SARS-CoV-2 must be carried out in the general population from Angola to assess antibody-waning periods.

A Case Report: Long Post-COVID Vaccination Syndrome During the Eleven Months After the Third Moderna Dose. It is undisputed that anti-SARS-CoV-2 vaccines can have side effects. Long post-COVID vaccination syndrome (LPCVS) is one of them and is often neglected. It persists 11 months after the third mRNA-1273 (Moderna) vaccine dose has not been reported. Our patient is a 39-year-old male with a largely uneventful previous history who developed severe adverse reactions immediately after the third dose of the mRNA-1273 (Moderna) vaccine. In addition to brief fever, headache, flickering eyes, skin rashes, tiredness, disorientation, dizziness (brain fog), tiredness, impaired thinking and concentration, and emotional disorders occurred as a result. Cerebral MRI showed non-specific white matter lesions in a frontotemporal distribution. Some of the immune parameters were deflected. Non-steroidal anti-inflammatory drugs, antihistamines, sartans, and

statins have occasionally provided temporary relief. In conclusion, LPCVS is a definite complication of anti-SARS-CoV-2 vaccinations and can severely impact the quality of life and lead to disability. Despite extensive work-up, a clear cause for the long-term neuro-cognitive deficits cannot be identified. Symptomatic treatment can provide some relief. Patients with LPCVS should be taken seriously and treated appropriately.

Serum biomarkers for nutritional status as predictors in COVID-19 patients before and after vaccination. The aim of this study was to characterize serum protein biomarkers for nutritional status that may be used as predictors for disease symptomatology in COVID-19 patients before and after vaccination. In pre-vaccine cohorts, proteomics analysis revealed significant differences between groups, with serum proteins alpha-1-acid glycoproteins (AGPs) 1 and 2, C-reactive protein (CRP) and retinol binding protein (RBP) increasing with COVID-19 severity, in contrast with serum albumin, transthyretin (TTR) and serotransferrin (TF) reduction as the symptomatology increased. Immunoassay reproduced and validated proteomics results of serum proteins albumin and RBP. In post-vaccine cohorts, the results showed the same pattern as in pre-vaccine cohorts for serum proteins AGPs, CRP, albumin and TTR. However, TF levels were similar between groups and RBP presented a slight reduction as COVID-19 symptomatology increased. In these cohorts, immunoassay validated proteomics results of serum proteins albumin, TTR and TF. Additionally, immune response to Î±-Gal in pre-vaccine cohorts varied in predominant immunoglobulin type profile, while post-vaccine groups presented mainly anti-Î±-Gal protective IgG antibodies. The study identified serum nutritional biomarkers that could potentially predict an accurate prognostic of COVID-19 disease to provide an appropriate nutritional care and guidance in non-vaccinated and vaccinated individuals against SARS-CoV-2. These results highlight the importance of designing personalized nutrition protocols to improve diet along with the application of prebiotics or probiotics for the control of COVID-19 and other infectious diseases.

Acute disseminated encephalomyelitis following the COVID-19 vaccine Ad26.COV2.S, a case report. BACKGROUND: The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) pandemic has been leading to dramatic health, social and economic problems around the world. It was necessary to introduce worldwide vaccination program against SARS-CoV-2 virus. Vaccination of billions of people around the world leads to many questions about risk of vaccines and possible side effects. It is well known that acute disseminated encephalomyelitis (ADEM) is a rare, but possible complication of vaccines. Previously, cases of ADEM following various COVID-19 vaccines, including the vaccines from AstraZenica, Pfizer, Sputnik V, SinoVac, Moderna, Sinopharm, have been described. In this case report, we present the first documented case of ADEM following the COVID-19 vaccine Ad26.COV2.S from Johnson & Johnson. CASE PRESENTATION: We present the case of a 31-year-old female with gradually progression of right-sided weakness and numbness during a three-week period. Four weeks prior to symptom onset, the patient received the single-dose SARS-CoV-2 vaccine Ad26.COV2.S. Neuroimaging revealed five large juxtacortical T2 FLAIR hyperintense lesions with incomplete contrast enhancement on post-contrast T1 images located supratentorial: one in the right cerebral hemisphere and four in left cerebral hemisphere. The patient was followed up for four months. Symptom debut, clinical picture and MRI were typical for ADEM and the patient completely recovered after high dose intravenous methylprednisolone treatment. CONCLUSIONS: This is, to the best of our knowledge, the first case report of ADEM following the COVID-19 vaccine Ad26.COV2.S. This case illustrates, although ADEM is a rare complication following SARS-CoV-2 vaccines, the necessity of maintaining a vaccine safety monitoring system to identify patients at high risk from developing severe complications from the vaccines.

Acute Adverse Events at a Mass Vaccination Site after the Third and Fourth COVID-19 Vaccinations in Japan. The third and fourth doses of the vaccine against coronavirus disease 2019 (COVID-19)

were widely administered in Japan since December 2021. Currently, however, data are scarce regarding acute adverse events with the third and fourth doses. The present study reports the profiles of acute adverse events after the third and fourth COVID-19 vaccine doses, seen at the site of a mass vaccination center in Japan. Between December 2021 and July 2022, 267,515 individuals received the third, and 32,934 received the fourth COVID-19 vaccine dose at the mass vaccination center, of whom 442 recipients of the third (0.19%), and 22 recipients of the fourth (0.07%) dose reported acute adverse events and were examined by doctors on site. The most common diagnosis was vasovagal syncope/presyncope (incidence: 0.01-0.10%), followed by other miscellaneous complaints, acute allergic reactions (0.05-0.005%), and anaphylaxis (< 0.005%). Vasovagal syncope/presyncope occurred most frequently in recipients in those in their 20s, whereas acute allergic reactions were most frequent in those in their 40s. Both reactions were more frequent in women than men. The peak occurrence of vasovagal syncope/presyncope was earlier than 15 min after the injection, whereas that of acute allergic reaction was later than 15 min after the injection. The incidence of acute allergic reactions appeared to differ between various vaccine manufacturers, whereas that of vasovagal syncope/presyncope did not. These real-world data may benefit the safe and efficient implementation of mass vaccination campaigns for citizens who want to receive COVID-19 vaccines now and in the future.

Spike-specific T cells are enriched in breastmilk following SARS-CoV-2 mRNA vaccination. Human breastmilk is rich in T cells; however, their specificity and function are largely unknown. We compared the phenotype, diversity, and antigen specificity of T cells in breastmilk and peripheral blood of lactating individuals who received SARS-CoV-2 messenger RNA (mRNA) vaccination. Relative to blood, breastmilk contained higher frequencies of T effector and central memory populations that expressed mucosal-homing markers. T cell receptor sequence overlap was limited between blood and breastmilk. Overabundant breastmilk clones were observed in all individuals, were diverse, and contained complementarity-determining regions in three sequences with known epitope specificity, including to SARS-CoV-2 spike. SARS-CoV-2 spike-specific T cell receptors were more frequent in breastmilk compared to blood and expanded in breastmilk following a 3(rd) mRNA vaccine dose. Our observations indicate that the lactating breast contains a distinct T cell population that can be modulated by maternal vaccination with potential implications for passive infant protection.

Acute psychosis induced by mRNA-based COVID-19 vaccine in adolescents: A pediatric case report.

Immunogenicity and safety in healthy adults of full dose versus half doses of COVID-19 vaccine (ChAdOx1-S or BNT162b2) or full-dose CoronaVac administered as a booster dose after priming with CoronaVac: a randomised, observer-masked, controlled trial in Indonesia. BACKGROUND: Inactivated COVID-19 vaccines effectively prevent death, but their effectiveness for preventing infection or severe illness is known to decrease within 3-6 months following the second priming dose. Here we aimed to evaluate the immunogenicity and safety of three potential booster vaccines administered as a full-dose homologous booster or full-dose or half-dose heterologous boosters among individuals primed with CoronaVac. METHODS: We did an observer and participant masked, randomised controlled trial study of healthy Indonesian adults from five recruitment sites in Bandung and Jakarta, Indonesia, aged 18 years and older who had previously received two doses of CoronaVac within 3 to less than 6 months or 6 to 9 months before the booster dose. Participants were randomly assigned (1:1:1:1:1) by means of stratified randomisation with random block size to a homologous booster with full-dose CoronaVac or heterologous boosters with ChAdOx1-S or BNT162b2 in full dose or half dose. The primary outcome was to evaluate the seropositive, seroconversion rate, and the geometric mean titres of IgG anti-spike-receptor binding domain and neutralising antibodies, 28 days after booster dose vaccination in the per-protocol population. Safety was assessed as a secondary outcome in all vaccinated booster participants by the incidence rate and intensity of adverse events

within 24 h, 7 days, and 28 days after the booster dose. This study is registered with ina-registry.org, INA-GO0HLGB, and is complete. FINDINGS: Between Nov 26 and Dec 16, 2021, 1015 people were screened, and 960 healthy adults were enrolled; 190-193 were included in each group. 28 days after receiving the booster, combining the 3 to less than 6 months and 6 to 9 months groups, the proportions of seroconversion rates in each vaccine group were ChAdOx1-S 75 (82%) of 92 to 87 (88%) of 99 for full dose and half dose, BNT162b2 92 (92%) of 100 to 90 (98%) of 92 for full dose and half dose, and CoronaVac in 38 (41%) of 92 to 65 (66%) of 98. All booster groups achieved 100% seropositivity 28 days after the booster dose. Participants in the 6 to 9 months priming group achieved higher titres compared with participants in the 3 to less than 6 months priming group. The geometric mean titres in participants in the 6 to 9 months priming group in each vaccine group were ChAdOx1-S 11258Â·69 (9562Â·43-13â€‰255Â·85) and 7853Â·04 (6698Â·92-9206Â·00) for full dose and half dose, BNT162b2 19999Â·84 (17â€‰720Â·58-22â€‰572Â·25) and 17â€‰017Â·62 (14â€‰694Â·40-19â€‰708Â·16) for full dose and half dose and CoronaVac 1440Â·55 (1172Â·81-1769Â·42) achieved higher titres compared with participants in the 3 to less than 6 months priming group which in each vaccine group were ChAdOx1-S 7730Â·39 (6401Â·87-9334Â·60) and 6684Â·34 (5678Â·94-7867Â·73) for full dose and half dose, BNT162b2 16594Â·08 (13â€‰993Â·08-19â€‰678Â·55) and 12â€‰121Â·67 (9925Â·21-14â€‰804Â·19) for full dose and half dose, and CoronaVac 1210Â·23 (976Â·49-1499Â·92). The median percentage inhibition for the surrogate virus neutralisation test against the delta B.1.617.2 and wild-type (WT) variant before the booster and 28 days after the booster dose was very high in all groups (p<0Â·001), all with greater than 90% inhibition against both delta and WT strains. No serious adverse events were associated with the vaccines. Within the heterologous booster groups, the adverse event rates in the half-dose groups were lower compared with the full-dose groups. INTERPRETATION: Geometric mean titre values between participants in the 6 to 9 months priming group and the 3 to less than 6 months priming group before the booster dose and between half-dose and full-dose groups 28 days before the booster were not significantly different for half-dose ChAdOx1-S, full-dose BNT162b2, and CoronaVac and were significantly different for full-dose ChAdOx1-S and half-dose BNT162b2. Among individuals primed with CoronaVac, boosting with BNT162b2 (full dose or half dose) or ChAdOx1-S (full dose or half dose) produces substantially better immune responses than in those boosted with CoronaVac. Full-dose and half-dose boosting with either BNT162b2 or ChAdOx1-S produced similar responses. Heterologous booster with half-dose might be considered in adults primed with two doses of CoronaVac vaccine. FUNDING: Ministry of Health, Indonesia. TRANSLATION: For the Indonesian translation of the abstract see Supplementary Materials section.

Short- and mid-term outcomes in systemic lupus erythematosus patients presenting with disease exacerbation after SARS-CoV-2 mRNA vaccination: A cohort study from Puerto Rico. OBJECTIVE: To determine if SARS-CoV-2 mRNA vaccination has an impact on the clinical course of systemic lupus erythematosus (SLE). METHODS: Puerto Ricans with SLE who received mRNA COVID-19 vaccines were studied. Demographic parameters, clinical manifestations, disease activity (per Systemic Lupus Erythematosus Disease Activity Index (SLEDAI), disease damage (per Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index), emergency room visits, hospitalizations, and pharmacologic therapy were determined. Baseline variables (prior to vaccination) were compared between patients with and without exacerbation after SARS-CoV-2 vaccination. Among those with exacerbation, clinical outcomes were determined up to 1Â year after vaccination. RESULTS: Of the entire cohort (n = 247), 14 (5.7%) had post-vaccination exacerbations. Photosensitivity, oral ulcers, anti-Ro antibodies, higher SLEDAI score, and corticosteroids exposure were associated with post-vaccination flares. Among those with post-vaccination flares, 10 (71.4%) had major organ involvement. No significant differences were observed for mean SLEDAI scores,

emergency room visits, hospitalizations, disease damage, and exposure to immunosuppressive drugs before and after SARS-CoV-2 mRNA vaccination. At 12Â months of follow-up, all patients were fully controlled without evidence of active disease. CONCLUSION: In our group of SLE patients, 5.7% had a disease flare after SARS-CoV-2 mRNA vaccination. Most had exacerbations involving major organs/systems. Mucocutaneous manifestations, anti-Ro antibodies, disease activity, and corticosteroids were associated with flares. Awareness of these factors and the possibility of a major lupus flare after vaccination with COVD-19 vaccines is critical to provide timely and effective therapy.

Impacts of delta and omicron variants on inactivated SARS-CoV-2 vaccine-induced T cell responses in patients with autoimmune diseases and healthy controls. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection causes coronavirus disease 2019 (COVID-19), which is still devastating economies and communities globally. The increasing infections of variants of concern (VOCs) in vaccinated population have raised concerns about the effectiveness of current vaccines. Patients with autoimmune diseases (PAD) under immunosuppressant treatments are facing higher risk of infection and potentially lower immune responses to SARS-CoV-2 vaccination. METHODS: Blood samples were collected from PAD or healthy controls (HC) who finished two or three doses of inactivated vaccines. Spike peptides derived from wild-type strain, delta, omicron BA.1 were utilisedÂ to evaluate T cell responses and their cross-recognition of delta and omicron in HC and PAD by flow cytometry and ex vivo IFNÎ³-ELISpot. RESULTS: We found that inactivated vaccine-induced spike-specific memory T cells were long-lasting in both PAD and HC. These spike-specific T cells were highly conserved and cross-recognized delta and omicron. Moreover, a third inactivated vaccine expanded spike-specific T cells that responded to delta and omicron spike peptides substantially in both PAD and HC. Importantly, the polyfunctionality of spike-specific memory T cells was preserved in terms of cytokine and cytotoxic responses. Although the extent of T cell responses was lower in PAD after two-dose, T cell responses were boosted to a greater magnitude in PAD by the third dose, bringing comparable spike-specific T cell immunity after the third dose. CONCLUSION: Inactivated vaccine-induced spike-specific T cells remain largely intact against delta and omicron variants. This study expands our understanding of inactivated vaccine-induced T cell responses in PAD and HC, which could have important indications for vaccination strategy.

Background rate estimations for thrombosis with thrombocytopaenia: challenges in evaluating rare safety signals following vaccination in real time during a pandemic. OBJECTIVES: During COVID-19 vaccination programmes, new safety signals have emerged for vaccines, including extremely rare cases of thrombosis with thrombocytopaenia syndrome (TTS). Background event rates before and during the pandemic are essential for contextualisation of such infrequent events. In the literature, most studies do not report an overall TTS event rate. Rather, background rates are mainly reported for subtypes of thrombotic/thromboembolic diagnoses included in the TTS clinical definition mostly by anatomical location, with reported rates for TTS subtypes varying widely. The objective of this study was to report prepandemic TTS background event rates in the general population. METHODS: Prepandemic background TTS rates were generated via secondary data analysis using a cohort design in the IBM Truven MarketScan (now Merative MarketScan) US health insurance claims database, from 1 January 2019 to 31 December 2019. Two algorithms were applied: thrombocytopaenia occurringÂ±7 days (algorithm 1) or occurring 1 day prior to â‰¤14 days after the thrombotic/thromboembolic event (algorithm 2). RESULTS: The study population derived from the MarketScan database analysis included approximately 9.8 million adults (aged â‰¥18 years; mean age 45 years, 52% females). Using this study population, prepandemic background TTS incidence was estimated as 9.8-11.1 per 100 000 person-years. Event rates were higher in males and increased with age. Similar patterns were observed with both algorithms. CONCLUSIONS: This study presents an estimate of aggregate prepandemic background TTS event rates including by type of

thrombosis/thromboembolism and age group. The background event rates are dependent on the precision of capturing underlying TTS events in variable data sources, and the ability of electronic health records or insurance claims databases to reflect the TTS clinical definition. Differences between reported event rates demonstrate that estimating background event rates for rare, unprecedented safety events is methodologically challenging.

Granuloma annulare after SARS-CoV-2 vaccination: A case report and a literature review. INTRODUCTION: During the Cov-19 pandemic, many studies reported a broad spectrum of cutaneous reactions presenting as erythematous rashes or pernio-like, urticaria-like or vesicular/bullous patterns associated with Cov-19-infection and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. METHODS: The authors documented the clinical and histopathological features of an unexpected case of granuloma annulare (GA) arising a few days after the SARS-CoV-2 vaccination and reviewed all GAs reported in the literature following the SARS-CoV-2 vaccination and Cov-19-infection. CASE REPORT: A 69-year-old woman developed a single reddish lesion on the left deltoid region, where the SARS-CoV-2 vaccine seven days earlier was injected. The clinicians performed a punch skin biopsy, and histology revealed an interstitial GA. CONCLUSIONS: Clinicians should be aware of the potential, though rare, GA occurrence as a possible adverse event after the SARS-CoV-2 vaccination. This additional case, like what happens after the administration of other vaccines, supports the idea that GA may result from the immune system activation following the vaccination. However, notwithstanding, they should encourage their patients to obtain immunization to assist the public health systems in overcoming the COVID-19 pandemic.

Higher Troponin Levels on Admission are associated With Persistent Cardiac Magnetic Resonance Lesions in Children Developing Myocarditis After mRNA-Based COVID-19 Vaccination. BACKGROUND: Acute pericarditis/myocarditis is a rare complication of the mRNA-based vaccines and although mostly self-limiting, long-term sequelae remain unclear. METHODS: We enrolled all patients admitted to the emergency department between September 2021 and February 2022 meeting the CDC work case definition, with symptoms onset after mRNA-based COVID-19 vaccine. Alternative virologic causes were excluded. Clinical data, laboratory values, cardiologic evaluation, electrocardiogram (ECG), and echocardiogram (ECHO) were collected on admission, at discharge, and during follow-up in all patients. Cardiac Magnetic Resonance (CMR) was performed only in those with signs consistent with myocarditis. RESULTS: We observed 13 patients (11M and 2F), median age 15 years, affected by acute pericarditis/myocarditis after COVID-19 mRNA vaccination (11 after ComirnatyÂ® and 2 after SpikevaxÂ®). Symptoms'onset occurred at a median of 5 days (range, 1 to 41 days) after receiving mRNA vaccine (13 Prizer 2 Moderna): 4 patients (31%) after the 1st dose, 6 (46%) after the 2nd, and 3 (23%) after 3rd dose. Increased levels of high-sensitive troponin T (hsTnT) (median 519,5â€‰ng/mL) and N-terminal-pro hormone BNP (NT-proBNP) (median 268 pg/mL) and pathognomonic ECG and ECHO abnormalities were detected. On admission, 7 of 13 (54%) presented with myopericarditis, 3 (23%) with myocarditis, and 3 (23%) with pericarditis; CMR was performed in 5 patients upon pediatric cardiologist prescription and findings were consistent with myocarditis. At 12 weeks of follow-up, all but one patient (92%), still presenting mild pericardial effusion at ECHO, were asymptomatic with normal hsTnT and NT-proBNP levels and ECG. On CMR 6 of 9 patients showed persistent, although decreased, myocardial injury. Higher hsTnT levels on admission significantly correlated with persistent CMR lesions. CONCLUSION: Evidence of persistent CMR lesions highlights the need for a close and standardized follow-up for those patients who present high hsTnT levels on admission.

Psoriasiform Dermatitis Associated With the Moderna COVID-19 Messenger RNA Vaccine.

Adverse events of COVID-19 vaccines in pregnant and postpartum women in Brazil: A cross-sectional study. BACKGROUND: By the fact that pregnant and postpartum women are currently using

COVID-19 vaccines, ensure their safety is critical. So, more safety evidence is crucial to include this new technology to their vaccine's calendar and to develop public policies regarding the support and training of Health Care Personnel. This study aims to describe the adverse events (AE) of COVID-19 vaccines in pregnant and postpartum women in the early stage of vaccination campaign in Brazil. METHODS: An observational cross-sectional study using data from the Brazilian surveillance information system to characterize the AE of COVID-19 vaccines (Sinovac/Butantan, Pfizer/BioNTech, AstraZeneca and Janssen) in Brazilian pregnant and postpartum women from April to August 2021. Frequency and incidence rate of AE for COVID-19 vaccines were assessed. RESULTS: 3,333 AE following immunization were reported for the study population. AE incidence was 309.4/100,000 doses (95% CI 297.23, 321.51). Within the vaccines available, Sinovac/Butantan had the lowest incidence (74.08/100,000 doses; 95% CI 63.47, 84.69). Systemic events were the most frequent notified (82.07%), followed by local (11.93%) and maternal (4.74%), being most of them classified as non-severe (90.65%). CONCLUSION: Our results corroborate the recommendation of vaccination for these groups. Even though, further studies appraising a longer observation time are still needed to provide a broader safety aspect for the vaccines currently under use for this population.

Racial Disparities in the Clinical Prognosis of Gastrointestinal Cancer Patients with COVID-19: a Retrospective Study in UC CORDS. BACKGROUND: Cancer patients are highly vulnerable to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Few studies have examined racial disparities of clinical prognosis among gastrointestinal (GI) cancer patients with COVID-19, especially after the approval of COVID-19 vaccines. METHODS: We conducted a retrospective study based on the University of California COVID Research Data Set (UC CORDS). Patients agedâ€‰â‰¥â€‰18 with GI cancer as well as SARS-CoV-2 infection between March 10, 2020, and May 8, 2022, were included. We examined racial disparities using multivariable logistic regression. RESULTS: Among the 1054 GI cancer cases included, 117 (11.1%) patients were Asian and Pacific Islander, 51 (4.8%) were Black patients, 377 (35.8%) were Hispanic patients, 403 (38.2%) were White patients, and 106 (10.1%) belonged to other or unknown races. Fully adjusted logistic models revealed a significantly increased risk of COVID-19-related hospitalization or emergency room visits among the Black (ORâ€‰=â€‰2.26, 95% CIâ€‰=â€‰1.08-4.70), the Hispanic (ORâ€‰=â€‰2.24, 95% CIâ€‰=â€‰1.48-3.39), and the patients of other or unknown races (ORâ€‰=â€‰1.80, 95% CIâ€‰=â€‰1.00-3.26) compared with the White patients. No significant racial disparities in 30-day all-cause mortality and mechanical ventilation rate were found. Vaccination, age, cancer type, recent cancer diagnoses in UC CORDS, metastatic cancer or secondary malignant neoplasm, and Charlson comorbidity index score were associated with the prognosis of GI cancer patients with COVID-19. CONCLUSIONS: GI cancer patients belonging to racial minorities experience worse COVID-19 outcomes. Vaccination status is a crucial factor associated with GI cancer patients' prognosis among different race/ethnicity groups. Targeted communication in the context of cancer is needed to encourage vaccination uptake in this vulnerable population.

Skin atrophy after skin tests with corticosteroids for the diagnosis of SARS-CoV-2 vaccine excipients hypersensitivity.

A real-world prospective cohort study of immunogenicity and reactogenicity of ChAdOx1-S[recombinant] among patients with immune-mediated dermatological diseases. BACKGROUND: Immunogenicity and reactogenicity of COVID-19 vaccines have been established in various groups of immunosuppressed patients; however, studies involving patients with immune-mediated dermatological diseases (IMDDs) are scarce. OBJECTIVES: To investigate the influence of IMDDs on the development of SARS-CoV-2-specific immunity and side-effects following ChAdOx1-S[recombinant] vaccination. METHODS: This prospective cohort study included 127 patients with IMDDs and 97 participants without immune-mediated diseases who received ChAdOx1-

S[recombinant]. SARS-CoV-2-specific immunity and side-effect profiles were assessed at 1 month postvaccination and compared between groups. Immunological (primary) outcomes were the percentages of participants who tested positive for neutralizing antibodies [seroconversion rate (SR)] and those who developed T-cell-mediated immunity demonstrated by an interferon-Î³-releasing assay (IGRA) [positive IGRA rate (+IGRA)]. Reactogenicity-related (secondary) outcomes were the unsolicited adverse reactions and worsening of IMDD activity reflected by the uptitration of immunosuppressants during and within 1 month of vaccination. RESULTS: Overall, the SR for the IMDD group was similar to that of participants without immune-mediated conditions (75Â·6 vs. 84Â·5, P = 0Â·101), whereas + IGRA was lower (72Â·4 vs. 88Â·7, P = 0Â·003). Reactogenicity was similar between groups. No severe adverse reaction was reported. By stratifying the participants in the IMDD group according to individual disease, the immunogenicity of the vaccine was lowest in patients with autoimmune bullous diseases (AIBD) (SR 64Â·5%, +IGRA 62Â·9%) and highest in patients with psoriasis (SR 87Â·7%, +IGRA 80Â·7%). The reverse trend was found for vaccine-related reactions. Immunosuppressants were uptitrated in 15Â·8% of cases; 75% of these were patients with AIBD. CONCLUSIONS: Among participants with IMDDs, ChAdOx1-S[recombinant] showed good immunogenicity among patients with psoriasis, but demonstrated lower levels of immunogenicity for patients with AIBD. Some patients, especially patients with AIBD, should be closely monitored as they may require treatment escalation within 1 month postvaccination.

Relationship Between Immune Response to Severe Acute Respiratory Syndrome Coronavirus 2 Vaccines and Development of Breakthrough Infection in Solid Organ Transplant Recipients: The CONTRAST Cohort. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination in solid organ transplant (SOT) recipients is associated with poorer antibody response (AbR) compared with non-SOT recipients. However, its impact on the risk of breakthrough infection (BI) has yet to be assessed. METHODS: Single-center prospective longitudinal cohort study enrolling adult SOT recipients who received SARS-CoV-2 vaccination during a 1-year period (February 2021 - January 2022), end of follow-up April 2022. Patients were tested for AbR at multiple time points. The primary end-point was BI (laboratory-confirmed SARS-CoV-2 infection â‰¥14 days after the second dose). Immunization (positive AbR) was considered an intermediate state between vaccination and BI. Probabilities of being in vaccination, immunization, and BI states were obtained for each type of graft and vaccination sequence using multistate survival analysis. Then, multivariable logistic regression was performed to analyze the risk of BI related to AbR levels. RESULTS: 614 SOT (275 kidney, 163 liver, 137 heart, 39 lung) recipients were included. Most patients (84.7%) received 3 vaccine doses. The first 2 consisted of BNT162b2 and mRNA-1273 in 73.5% and 26.5% of cases, respectively. For the third dose, mRNA-1273 was administered in 59.8% of patients. Overall, 75.4% of patients reached immunization and 18.4% developed BI. Heart transplant recipients showed the lowest probability of immunization (0.418) and the highest of BI (0.323); all mRNA-1273 vaccine sequences showed the highest probability of immunization (0.732) and the lowest of BI (0.098). Risk of BI was higher for non-high-level AbR, younger age, and shorter time from transplant. CONCLUSIONS: SOT patients with non-high-level AbR and shorter time from transplantation and heart recipients are at highest risk of BI.

Cutaneous manifestations of COVID-19 and COVID-19 vaccination. In December 2019, a new infectious pathogen named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was identified in Wuhan, China. Transmitted through respiratory droplets, SARS-CoV-2 is the causative pathogen of coronavirus disease 2019 (COVID-19). Although this new COVID-19 infection is known to cause primarily interstitial pneumonia and respiratory failure, it is often associated with cutaneous manifestations as well. These manifestations with COVID-19 can be classified into seven categories: (i) chilblain-like skin eruption (e.g., COVID toes), (ii) urticaria-like skin eruption, (iii) maculopapular

lesions, (iv) vesicular eruptions, (v) purpura, (vi) livedo reticularis and necrotic lesions, (vii) urticarial vasculitis, and others such as alopecia and herpes zoster. The pathogenesis of skin eruptions can be broadly divided into vasculitic and inflammatory skin eruptions. Various cutaneous adverse reactions have also been observed after COVID-19 mRNA vaccination. The major cutaneous adverse reactions are type I hypersensitivity (urticaria and anaphylaxis) and type IV hypersensitivity (COVID arm and erythema multiform). Autoimmune-mediated reactions including bullous pemphigus, vasculitis, vitiligo, and alopecia areata have also been reported. Several cases with chilblain-like lesions and herpes zoster after COVID-19 mRNA vaccination have been published. Various skin diseases associated with COVID-19 and COVID-19 vaccination have been reported, and the mechanism has been partly elucidated. In the process, for example, some papers have reported that it is not related to COVID-19 infection, although it was initially called COVID-toe and considered a COVID-19-associated cutaneous eruption. In fact, some COVID-19-associated skin reactions are indistinguishable from drug eruptions. In the future, the mechanisms of COVID-19- or COVID-19 vaccine-associated skin reactions need to be elucidated and verification of causal relationships is required.

Two Cases of Rare Intratumoral Hemorrhage Following COVID-19 Vaccination. The increase in the rate of mRNA vaccination againstÂ coronavirus disease 2019 (COVID-19) worldwide has been accompanied by reports of an increase in the side effects of the vaccine. In the field of neurosurgery, several cases of venous thrombosis have been reported as possible complications after COVID-19 vaccination. However, no such side effects have been reported in patients with brain tumors, and COVID-19 vaccination is considered safe for this patient population. In this report, we present the cases of two patients with brain tumors who experienced intratumoral hemorrhage as a possible side effect of the COVID-19 vaccine. In the first case, a 54-year-old man who had received CyberKnife treatment for a vestibular schwannoma eight years prior presented with tongue discomfort, right-side facial numbness, and dizziness since the day after his COVID-19 vaccination. MRI revealed intratumoral hemorrhage of the vestibular schwannoma. The second patient was a 60-year-old woman who presented with a sudden-onset headache and vomiting that had started three days after her COVID-19 vaccination. CT revealed a meningioma with intratumoral hemorrhage. Both patients had undergone surgery prior to this presentation, and their symptoms had improved. They had no risk factors for intratumoral hemorrhage, suggesting that it may be a side effect of the mRNA vaccine against COVID-19. Although the causal relationship is unclear, acute inflammation with predominantly lymphocytic infiltration and thrombogenicity after COVID-19 vaccination may damage the fragile microcirculation of the tumor.

Bullous Pilomatrixoma After COVID-19 Vaccination. Pilomatrixoma, or calcifying epithelioma of Malherbe, is a benign tumor with differentiation toward the hair matrix cells and is one of childhood's most common epithelial tumors. Bullous pilomatrixoma has an extremely low incidence of occurrence, usually appears in the upper extremities, and is frequently associated with trauma. We report the case of a bullous pilomatrixoma in a patient with a rapid-growing neoformation one month after receiving a coronavirus disease 2019 (COVID-19) vaccine in his left upper arm, and we discuss whether the bullous appearance is part of the biology of the tumor or a secondary anetoderma.

Rhabdomyolysis after COVID-19 Comirnaty Vaccination: A Case Report. Rhabdomyolysis is an acute disruption in skeletal muscle integrity, leading to the rapid release of 4 muscle contents into the bloodstream, such as creatine kinase (CK). It can have various causes, including infections. Throughout the pandemic, multiple cases of rhabdomyolysis following COVID-19 infections have been reported. However, rhabdomyolysis subsequent to COVID-19 vaccinations appears to be relatively rare. Here, we report such a case after a second COVID-19 Comirnaty (BioNTech/Pfizer) vaccination. Our patient developed rhabdomyolysis 1 day after the second Comirnaty vaccination with high creatine kinase (CK) levels, generalized weakness, and kidney failure. CK levels and muscle weakness

resolved after treatment with intravenous fluids, but unfortunately, he remained hemodialysis dependent after discharge. To our knowledge, this is one of the first case reports describing a patient with rhabdomyolysis after a Comirnaty vaccination. However, as millions of people have received the Comirnaty vaccine, it is unclear whether the rhabdomyolysis in our patient is a rare side effect or an unrelated, coincidental event. Large observational studies are needed to elucidate the causality between the Comirnaty vaccination and rhabdomyolysis. Awareness is warranted in patients with myalgia and muscle weakness shortly after COVID-19 vaccination, in order to initiate treatment early and prevent life-threatening complications.

CNS demyelinating disease following inactivated or viral vector SARS-CoV-2 vaccines: A case series. BACKGROUND: Several reports have been documented in possible association with the administration of different severe acute respiratory coronavirus 2 (SARS-CoV-2) vaccines and central nervous systemÂ (CNS)demyelinating disorders, specifically post mRNA vaccines. We report twelve cases of developing Multiple sclerosis (MS) or Neuromyelitis Optica spectrum disorders (NMOSD) following neither the first nor second dose of inactivated or viral vector COVID-19 vaccine. METHODS: We retrospectively compiled twelve patients' medical information with a new onset of MS or NMOSD in their first six weeks following a COVID-19 vaccine. RESULTS: We report twelve cases of MS (nÂ =Â 9), clinically isolated syndrome (CIS)(nÂ =Â 1), and NMOSD (nÂ =Â 2) following COVID-19 inactivated vaccines (nÂ =Â 11) or viral vector vaccines (nÂ =Â 1), within some days following either the first (nÂ =Â 3), second dose (nÂ =Â 8), or third dose (nÂ =Â 1). Their median age was 33.3Â years, ranging from 19 to 53 years. Ten were women (83Â %). All patients fully (nÂ =Â 5) or partially (nÂ =Â 2) recovered after receiving 3 doses of Corticosteroids. Common medications were Natalizumab, Teriflunomide, Dimethyl fumarate, and Rituximab. Also, Interferon beta 1-a was administered to one patient with severe symptoms of numbness. CONCLUSION: Our case series identifies the Sinopharm BBIBP-CorV and the AstraZeneca AZD1222 vaccines as potential triggers for CNS demyelinating diseases. Vaccine administration routines are not affected by these rare and coincidental events. However, these manifestations are not deniable and require serious attention. Further investigations are needed to clarify the actual mechanisms and real associations.

Characteristics and outcomes of unvaccinated and vaccinated COVID-19 patients with acute respiratory failure treated with CPAP in a medical intermediate care unit.

The gut microbiota and metabolome are associated with diminished COVID-19 vaccine-induced antibody responses in immunosuppressed inflammatory bowel disease patients. BACKGROUND: Patients with inflammatory bowel disease (IBD) treated with anti-TNF therapy exhibit attenuated humoral immune responses to vaccination against SARS-CoV-2. The gut microbiota and its functional metabolic output, which are perturbed in IBD, play an important role in shaping host immune responses. We explored whether the gut microbiota and metabolome could explain variation in anti-SARS-CoV-2 vaccination responses in immunosuppressed IBD patients. METHODS: Faecal and serum samples were prospectively collected from infliximab-treated patients with IBD in the CLARITY-IBD study undergoing vaccination against SARS-CoV-2. Antibody responses were measured following two doses of either ChAdOx1 nCoV-19 or BNT162b2 vaccine. Patients were classified as having responses above or below the geometric mean of the wider CLARITY-IBD cohort. 16S rRNA gene amplicon sequencing, nuclear magnetic resonance (NMR) spectroscopy and bile acid profiling with ultra-high-performance liquid chromatography mass spectrometry (UHPLC-MS) were performed on faecal samples. Univariate, multivariable and correlation analyses were performed to determine gut microbial and metabolomic predictors of response to vaccination. FINDINGS: Forty-three infliximab-treated patients with IBD were recruited (30 Crohn's disease, 12 ulcerative colitis, 1Â IBD-unclassified; 26 with concomitant thiopurine therapy). Eight patients had evidence of prior SARS-CoV-2 infection. Seventeen patients (39.5%) had a serological response below the geometric mean. Gut microbiota

diversity was lower in below average responders (pÂ =Â 0.037). Bilophila abundance was associated with better serological response, while Streptococcus was associated with poorer response. The faecal metabolome was distinct between above and below average responders (OPLS-DA R(2)X 0.25, R(2)Y 0.26, Q(2) 0.15; CV-ANOVA pÂ =Â 0.038). Trimethylamine, isobutyrate and omega-muricholic acid were associated with better response, while succinate, phenylalanine, taurolithocholate and taurodeoxycholate were associated with poorer response. INTERPRETATION: Our data suggest that there is an association between the gut microbiota and variable serological response to vaccination against SARS-CoV-2 in immunocompromised patients. Microbial metabolites including trimethylamine may be important in mitigating anti-TNF-induced attenuation of the immune response. FUNDING: JLA is the recipient of an NIHR Academic Clinical Lectureship (CL-2019-21-502), funded by Imperial College London and The Joyce and Norman Freed Charitable Trust. BHM is the recipient of an NIHR Academic Clinical Lectureship (CL-2019-21-002). The Division of Digestive Diseases at Imperial College London receives financial and infrastructure support from the NIHR Imperial Biomedical Research Centre (BRC) based at Imperial College Healthcare NHS Trust and Imperial College London. Metabolomics studies were performed at the MRC-NIHR National Phenome Centre at Imperial College London; this work was supported by the Medical Research Council (MRC), the National Institute of Health Research (NIHR) (grant number MC_PC_12025) and infrastructure support was provided by the NIHR Imperial Biomedical Research Centre (BRC). The NIHR Exeter Clinical Research Facility is a partnership between the University of Exeter Medical School College of Medicine and Health, and Royal Devon and Exeter NHS Foundation Trust. This project is supported by the National Institute for Health Research (NIHR) Exeter Clinical Research Facility. The views expressed are those of the authors and not necessarily those of the NIHR or the UK Department of Health and Social Care.

Thrombotic events following the BNT162b2 mRNA COVID-19 vaccine (Pfizer-BioNTech) in Aotearoa New Zealand: A self-controlled case series study. BACKGROUND: An association between thrombotic events and SARS-CoV-2 infection and the adenovirus-based COVID-19 vaccines has been established, leading to concern over the risk of thrombosis after BNT162b2 COVID-19 vaccination. OBJECTIVES: To evaluate the risk of arterial thrombosis, cerebral venous thrombosis (CVT), splanchnic thrombosis, and venous thromboembolism (VTE) following BNT162b2 vaccination in New Zealand. METHODS: This was a self-controlled case series using national hospitalisation and immunisation records to calculate incidence rate ratios (IRR). The study population included individuals aged â‰¥12Â years, unvaccinated, or vaccinated with BNT162b2, who were hospitalised with one of the thrombotic events of interest from 19 February 2021 through 19 February 2022. The risk period was 0-21Â days after receiving a primary or booster dose of BNT162b2. RESULTS: 6039 individuals were hospitalised with one of the thrombotic events examined, including 5127 with VTE, 605 with arterial thrombosis, 272 with splanchnic thrombosis, and 35 with CVT. The proportion of individuals vaccinated with at least one dose of BNT162b2 ranged from 82.7Â % to 91.4Â %. Compared with the control unexposed period, the IRR (95Â % CI) of VTE, arterial thrombosis, splanchnic thrombosis, and CVT were 0.87 (0.76-1.00), 0.73 (0.56-0.95), 0.71 (0.43-1.16), and 0.87 (0.31-2.50) in the 21Â days after BNT162b2 vaccination, respectively. There was no statistically significant increased risk of thrombosis following BNT162b2 in different ethnic groups in New Zealand. CONCLUSION: The BNT162b2 vaccine was not found to be associated with thrombosis in the general population or different ethnic groups in New Zealand, providing reassurance for the safety of the BNT162b2 vaccine.

Prevalence and epidemiological trends in mortality due to COVID-19 in Saudi Arabia. OBJECTIVES: This article describes the prevalence and epidemiological trends of COVID-19 mortality in the largest registry in the Kingdom of Saudi Arabia (KSA). STUDY DESIGN: A prospective epidemiological cohort

study using data from all healthcare facilities in KSA collected between March 23, 2020, and April 30, 2022. Data on the number of daily deaths directly related to COVID-19 were gathered, analyzed, and reported. METHOD: Data analysis was carried out using national and regional crude case fatality rate and death per 100,000 population. Descriptive statistics using numbers and proportions were used to describe age, gender, nationality, and comorbidities. The mortality trend was plotted and compared with international figures. In addition, the most common comorbidities associated with mortality and the proportion of patients who received COVID-19 vaccine were reported. RESULTS: The total reported number of deaths between March 23, 2020, and April 30, 2022, was 9085. Crude case fatality rate was 1.21%, and death per 100,000 population was 25.38, which compared favorably to figures reported by several developed countries. The highest percentages of deaths were among individuals aged between 60 and 69 years, males (71%), and individuals with diabetes (60%). Only 2.8% of mortalities occur in patients who received COVID-19 vaccine. Diabetes, hypertension, and heart failure had the highest attributable risk of mortality among patients who died due to COVID-19. CONCLUSION: Case fatality rate and death per 100,000 population in KSA are among the lowest in the world due to multiple factors. Several comorbidities have been identified, namely, diabetes, hypertension, obesity, and cardiac arrhythmias.

Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Children Aged 5-11 Years - United States, October 12-January 1, 2023. On October 12, 2022, the Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUAs) for bivalent (mRNA encoding the spike protein from the SARS-CoV-2 ancestral strain and BA.4/BA.5 Omicron variants) formulations of Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines for use as a single booster dose â‰¥2 months after completion of primary series or monovalent booster vaccination for children aged 5-11 years (Pfizer-BioNTech) and 6-17 years (Moderna); on December 8, 2022, FDA amended the EUAs to include children aged â‰¥6 months (1,2). The Advisory Committee on Immunization Practices (ACIP) recommends that all persons aged â‰¥6 months receive an age-appropriate bivalent mRNA booster dose (3). The safety of bivalent mRNA booster doses among persons aged â‰¥12 years has previously been described (4). To characterize the safety of bivalent mRNA booster doses among children aged 5-11 years after receipt of bivalent Pfizer-BioNTech and Moderna booster doses, CDC reviewed adverse events and health impacts reported to v-safe,* a voluntary, smartphone-based U.S. safety surveillance system established by CDC to monitor adverse events after COVID-19 vaccination, and to the Vaccine Adverse Event Reporting System (VAERS), a U.S. passive vaccine safety surveillance system co-managed by CDC and FDA(â€) (5). During October 12-January 1, 2023, a total of 861,251 children aged 5-11 years received a bivalent Pfizer-BioNTech booster, and 92,108 children aged 6-11 years received a bivalent Moderna booster.(Â§) Among 3,259 children aged 5-11 years registered in v-safe who received a bivalent booster dose, local (68.7%) and systemic reactions (49.5%) were commonly reported in the week after vaccination. Approximately 99.8% of reports to VAERS for children aged 5-11 years after bivalent booster vaccination were nonserious. There were no reports of myocarditis or death after bivalent booster vaccination. Eighty-four percent of VAERS reports were related to vaccination errors, 90.5% of which did not list an adverse health event. Local and systemic reactions reported after receipt of a bivalent booster dose are consistent with those reported after a monovalent booster dose; serious adverse events are rare. Vaccine providers should provide this information when counseling parents or guardians about bivalent booster vaccination. Preliminary safety findings from the first 11 weeks of bivalent booster vaccination among children aged 5-11 years are reassuring. Compared with the low risk of serious health effects after mRNA COVID-19 vaccination, the health effects of SARS-CoV-2 infection include death and serious long-term sequalae (6). ACIP recommends that all persons aged â‰¥6 months receive an age-appropriate

bivalent mRNA booster dose â‰¥2 months after completion of a COVID-19 primary series or receipt of a monovalent booster dose.(Â¶).
Progressive multifocal leukoencephalopathy or severe multiple sclerosis relapse following COVID-19 vaccine: a diagnostic challenge.
Long-term clinical outcomes of patients with COVID-19 and chronic liver disease: US multicenter COLD study. BACKGROUND: COVID-19 is associated with higher morbidity and mortality in patients with chronic liver diseases (CLDs). However, our understanding of the long-term outcomes of COVID-19 in patients with CLD is limited. METHODS: We conducted a multicenter, observational cohort study of adult patients with CLD who were diagnosed with COVID-19 before May 30, 2020, to determine long-term clinical outcomes. We used a control group of patients with CLD confirmed negative for COVID-19. RESULTS: We followed 666 patients with CLD (median age 58 years, 52.8% male) for a median of 384 (interquartile range: 31-462) days. The long-term mortality was 8.1%; with 3.6% experiencing delayed COVID-19-related mortality. Compared to a propensity-matched control group of patients with CLD without COVID-19 (n=1332), patients with CLD with COVID-19 had worse long-term survival [p<0.001; hazards ratio (HR): 1.69; 95% CI: 1.19-2.41] and higher rate of hospitalization (p<0.001, HR: 2.00, 1.62-2.48) over a 1-year follow-up period. Overall, 29.9% of patients reported symptoms of long-COVID-19. On multivariable analysis, female sex (p=0.05, HR: 2.45, 1.01-2.11), Hispanic ethnicity (p=0.003, HR: 1.94, 1.26-2.99), and severe COVID-19 requiring mechanical ventilation (p=0.028, HR: 1.74, 1.06-2.86) predicted long-COVID-19. In survivors, liver-related laboratory parameters showed significant improvement after COVID-19 resolution. COVID-19 vaccine status was available for 72% (n=470) of patients with CLD and history of COVID-19, of whom, 70% (n=326) had received the COVID-19 vaccine. CONCLUSIONS: Our large, longitudinal, multicenter study demonstrates a high burden of long-term mortality and morbidity in patients with CLD and COVID-19. Symptoms consistent with long-COVID-19 were present in 30% of patients with CLD. These results illustrate the prolonged implications of COVID-19 both for recovering patients and for health care systems.
[Self-reported maternal adverse events of covid-19 vaccination during pregnancy]. OBJECTIVE: To describe the self-reported maternal adverse events (AEs) of covid-19 vaccination during pregnancy. DESIGN: The Dutch Pregnancy Drug Register ("Moeders van Morgen"), is a prospective cohort study among pregnant women in the Netherlands. METHOD: Using online questionnaires, women reported whether they received a covid-19 vaccination and the self-perceived AEs after vaccination. We included women who received their first covid-19 vaccination during pregnancy. We assessed the maternal AEs by vaccine dose, type of vaccine (BioNTech/Pfizer, Moderna, AstraZeneca, and Janssen) and moment of vaccination in pregnancy. RESULTS: 4348 women received their first covid-19 vaccination during pregnancy and were included. Of these, 2787 women also reported a second dose during pregnancy. After the first dose, AEs were less often reported for BioNTech/Pfizer (56% â‰¥1 AE), compared to Moderna (68% â‰¥1 AE) or AstraZeneca (87% â‰¥1 AE). After the second dose, AEs were less often reported for BioNTech/Pfizer (44% â‰¥1 AE) compared to Moderna (76% â‰¥1 AE). Injection site reactions, myalgia and fatigue were reported most frequently. There was large variation in the percentage reporting pyrexia/fever between the different vaccines (3%, 22%, and 10% after the second dose of BioNTech/Pfizer, Moderna, and Astrazeneca respectively). There were no major differences in the rates of AEs between vaccination in the first, second, or third trimester. CONCLUSION: The adverse event proï¬•le among women who were vaccinated against covid-19 during pregnancy do not indicate any safety concerns. Considering the reported maternal AEs, the BioNTech/Pfizer vaccine seems best for vaccination during pregnancy.
COVID-19 vaccination and liver disease. Various vaccines against severe acute respiratory syndrome coronavirus 2 have been developed in response to the coronavirus disease 2019 (COVID-

19) global pandemic, several of which are highly effective in preventing COVID-19 in the general population. Patients with chronic liver diseases (CLDs), particularly those with liver cirrhosis, are considered to be at a high risk for severe COVID-19 and death. Given the increased rates of disease severity and mortality in patients with liver disease, there is an urgent need to understand the efficacy of vaccination in this population. However, the data regarding efficacy and safety of COVID-19 vaccination in patients with CLDs is limited. Indeed, several organ-specific or systemic immune-mediated side effects following COVID-19 vaccination, including liver injury similar to autoimmune hepatitis, have been recently reported. Although the number of cases of vaccine-related liver injury is increasing, its frequency, clinical course, and mechanism remain unclear. Here, we review the current findings on COVID-19 vaccination and liver disease, focusing on: (1) The impact of COVID-19 in patients with CLD; (2) The efficacy, safety, and risk-benefit profiles of COVID-19 vaccines in patients with CLD; and (3) Liver injury following COVID-19 vaccination.
Epstein-Barr Virus-Positive Hemophagocytic Lymphohistiocytosis Following COVID-19 Vaccination in a Pediatric Patient.
Why do Athletes Develop Very Severe or Fatal Forms of COVID after Intense Exercise Following SARS-CoV-2 Infection or Anti-COVID Vaccination?
Anti-SARS-CoV-2 antibodies following vaccination are associated with lymphocyte count and serum immunoglobulins in SLE. OBJECTIVES: Patients with Systemic Lupus Erythematosus are known to have dysregulated immune responses and may have reduced response to vaccination against COVID-19 while being at risk of severe COVID-19 disease. The aim of this study was to identify whether vaccine responses were attenuated in SLE and to assess disease- and treatment-specific associations. METHODS: Patients with SLE were matched by age, sex and ethnic background to healthcare worker healthy controls (HC). Anti-SARS-CoV-2 spike glycoprotein antibodies were measured at 4-8Â weeks following the second COVID-19 vaccine dose (either BNT162b2 or ChAdOx1 nCoV-19) using a CE-marked combined ELISA detecting IgG, IgA and IgM (IgGAM). Antibody levels were considered as a continuous variable and in tertiles and compared between SLE patients and HC and associations with medication, disease activity and serological parameters were determined. RESULTS: Antibody levels were lower in 43 SLE patients compared to 40 HC ($p < 0.001$). There was no association between antibody levels and medication, lupus disease activity, vaccine type or prior COVID infection. Higher serum IgA, but not IgG or IgM, was associated with being in a higher anti-SARS-CoV-2 antibody level tertile (OR [95% CI] 1.820 [1.050, 3.156] $p = 0.033$). Similarly, higher lymphocyte count was also associated with being in a higher tertile of anti-SARS-CoV-2 (OR 3.330 [1.505, 7.366] $p = 0.003$). CONCLUSION: Patients with SLE have lower antibody levels following 2 doses of COVID-19 vaccines compared to HC. In SLE lower lymphocyte counts and serum IgA levels are associated with lower antibody levels post vaccination, potentially identifying a subgroup of patients who may therefore be at increased risk of infection.
Correlation of adverse effects and antibody responses following homologous and heterologous COVID-19 prime-boost vaccinations.
Bivalent Covid-19 Vaccines - A Cautionary Tale.
Analysis of immune responses in patients with CLL after heterologous COVID-19 vaccination. Patients with chronic lymphocytic leukemia (CLL) treated with B-cell pathway inhibitors and anti-CD20 antibodies exhibit low humoral response rates following SARS-CoV-2 vaccination. To investigate this observation, a prospective single-institution study was conducted comparing peripheral blood mononuclear cell transcriptional response with antibody and T-cell response rates following heterologous BNT162b2/ChAdOx1 vaccination of 15 patients with CLL/small lymphocytic lymphoma (SLL). Two-dose antibody response rate was 40%, increasing to 53% after booster. Patients on Bruton tyrosine kinase inhibitor (BTKi) and venetoclaxÂ Â± anti-CD20 antibody within 12Â months of

vaccination responded inferiorly compared with those under BTKi alone. The 2-dose-T-cell response rate was 80%, which increased to 93% after the booster dose. Key transcriptional findings were that interferon-mediated signaling activation including activation of the JAK-STAT pathway generally occurred within days of vaccination, but was independent from the magnitude of the antibody response. Increasing counts of IGHV genes were associated with B-cell reconstitution and improved humoral response rate in the vaccinated patients. T-cell responses in patients with CLL appeared independent of treatment status, whereas higher humoral response rate was associated with BTKi treatment and B-cell reconstitution. Boosting was particularly effective when intrinsic immune status was improved by CLL treatment. Limitations included studying a relatively small cohort, with different treatments and vaccination schedules.
Expert consensus on vaccination in patients with inflammatory bowel disease in Japan. Immunosuppressive therapies can affect the immune response to or safety of vaccination in patients with inflammatory bowel disease (IBD). The appropriateness of vaccination should be assessed prior to the initiation of IBD treatment because patients with IBD frequently undergo continuous treatment with immunosuppressive drugs. This consensus was developed to support the decision-making process regarding appropriate vaccination for pediatric and adult patients with IBD and physicians by providing critical information according to the published literature and expert consensus about vaccine-preventable diseases (VPDs) [excluding cervical cancer and coronavirus disease 2019 (COVID-19)] in Japan. This consensus includes 19 important clinical questions (CQs) on the following 4 topics: VPDs (6 CQs), live attenuated vaccines (2 CQs), inactivated vaccines (6 CQs), and vaccination for pregnancy, childbirth, and breastfeeding (5 CQs). These topics and CQs were selected under unified consensus by the members of a committee on intractable diseases with support by a Health and Labour Sciences Research Grant. Physicians should provide necessary information on VPDs to their patients with IBD and carefully manage these patients' IBD if various risk factors for the development or worsening of VPDs are present. This consensus will facilitate informed and shared decision-making in daily IBD clinical practice.
Mortality rates and epidemiological changes in critically ill Coronavirus Disease 2019 patients after a vaccination program in Brazil.
Scleroderma kidney disease exacerbated by COVID-19 vaccination.
Bilateral retinal vein occlusion after COVID-19 vaccination: Correspondence.
Vasospastic angina following COVID-19 vaccine-related myocarditis: an underlying cause of chest pain. We present a 13-year-old boy who had recurrent chest pain with elevated cardiac enzymes and abnormal ST segments in electrocardiogram 36 hours after the second dose of BNT162b2 vaccination. Cardiac MRI and coronary angiography with acetylcholine provocation confirmed myocarditis and vasospastic angina, respectively. Coronary vasospasm may play a pivotal role in the chest pain in COVID-19 vaccine-related myocarditis.
Lower limb arterial thrombosis followed by sub-massive pulmonary thromboembolism after Sinopharm BBIBP-CorV COVID-19 vaccination. The global COVID-19 vaccination had an undeniable influence on the pandemic management, despite of having reported rare but life-threatening side-effects of vaccines. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare autoimmune complication determined by thrombocytopenia and thrombosis propensity in the circulatory system. The activation of antibodies against platelet factor-4 (PF-4) which mimics the heparin-induced thrombocytopenia (HIT) characteristic is the main known pathogenicity of the disease. Herein, we reported a case of VITT in a middle-aged woman with no previous history of thrombophilia or other medical conditions who presented with thrombosis of the left superficial femoral artery 3-days after receiving the second dose of inactivated BBIBP-CorV (Sinopharm) vaccine. The patient underwent bypass vascular surgery and received none-heparin anticoagulation consistent

with high-dose intravenous immunoglobin. Eight days after the discharge, she was subsequently referred to our center with the presentation of sub-massive pulmonary thromboembolism in spite of receiving the prophylactic anticoagulants during follow-up period. Details on side-effects of COVID-19 vaccines, specifically the inactivated ones are yet to be fully ascertained. Clinicians should consider the history of COVID-19 vaccines in thromboembolism patients who do not have well-acknowledged risk factors. Further studies about the necessity of prophylactic anticoagulants and clinical judgment for receiving other vaccines in such patients are required.

Contralateral Recurrences of Post-vaccination Multiple Evanescent White Dot Syndrome. We report on a case of multiple evanescent white dot syndrome (MEWDS) following the simultaneous administration of the human papillomavirus and meningococcal (conjugate) vaccines and two recurrences of MEWDS following the administration of the second dose of the human papillomavirus (HPV) vaccine and the COVID-19 vaccine and COVID-19 viral infection. A 17-year-old Hispanic female presented with a one-week history of photopsia and blurred vision in her left eye following the simultaneous administration of the human papillomavirus and meningococcal (conjugate) vaccines. Upon a comprehensive examination, her best-corrected visual acuity was 20/20 in the right eye and 20/100Â in the left eye. A left fundus examination revealed multiple white dots in the macula and nasal periphery, consistent with a diagnosis of MEWDS. Ancillary testing, including fundus autofluorescence, fluorescein angiography, indocyanine green angiography, and optical coherence tomography, supported the diagnosis. One month following her initial diagnosis, the patient's symptoms had resolved without any therapy, and a fundus examination revealed multiple relatively ill-defined brown-colored subretinal lesions in the nasal midperiphery, corresponding to the location of the previous MEWDS lesions. Subsequently, she received the second dose of the HPV vaccine and then developed a mild COVID-19 infection. Four months after the initial presentation, she received the first dose of the BNT162b2Â COVID-19 vaccine, followed by the second dose a month later. Eight months following her initial presentation, she presented with photopsia in the right eye. Her visual acuity remained 20/20 in the right eye and improved to 20/20 in the left eye, and white dots were identified nasal to the disk and surrounding the peripapillary region; the contralateral MEWDS diagnosis was confirmed by the previously mentioned ancillary tests. At her one-month follow-up, she presented new onset photopsia of the right eye. Her visual acuity remained 20/20 in both eyes, and a fundus examination revealed white lesions suggestive of active MEWDS temporal to the macula and brown-colored spots nasal to the disk, suggestive of recovering MEWDS, nasally. The aforementioned testing confirmed the coexistence of new and resolving lesions; nonetheless, the patient's symptoms resolved without any therapy, and she received the third dose of the BNT162b2Â COVID-19 vaccine 11 months after her initial presentation. Our case suggests that vaccines may serve as immunological triggers of MEWDS. Recurrent MEWDS may occur when an individual is exposed to a powerful immune challenge, such as receiving a wide array of vaccinations in a short period of time. We believe this case constitutes a previously undescribed finding of multiple relatively ill-defined brown-colored subretinal lesions present in late MEWDS.

COVID-19 Vaccination in Patients Who Develop COVID-19 following Cancer Surgery: Correspondence.

Severe cutaneous adverse reactions after COVID-19 vaccination: A systematic review.

Pityriasis Rubra Pilaris After Moderna COVID-19 Vaccination: A Case Report and Literature Review. To date, over 60% of the world's population has received at least 1 dose of coronavirus disease 2019 (COVID-19) vaccination, with over 12 billion doses administered globally. Commonly reported adverse effects of COVID-19 vaccination include fever, headache, myalgia, and injection site reactions. The spectrum of documented cutaneous reactions after COVID-19 vaccination is broad; however, pityriasis rubra pilaris (PRP) or PRP-like eruption secondary to COVID-19 vaccine is exceedingly rare, with only 17 cases previously reported to date in the English literature. In this article, we describe an

additional case of COVID-19 vaccination-associated PRP in a 50-year-old woman with a history of metastatic breast carcinoma, who developed a widespread cutaneous eruption characteristic of PRP, including palmoplantar keratoderma, 10 days after her third dose of Moderna COVID-19 vaccine. Punch biopsy specimen showed epidermal hyperplasia with overlying hyperkeratosis, alternating orthokeratosis and parakeratosis and focal follicular plugging, supporting the diagnosis of PRP. The patient improved within weeks of initiating oral acitretin and topical steroids, with resolution achieved after 3 months of continued therapy. To the best of our knowledge, this is the third reported case of Moderna COVID-19 vaccination-associated PRP and collectively the 18 th after the administration of all COVID-19 vaccines currently available, including Pfizer-BioNTech, and AstraZeneca.

COVID-19 Outcomes by Cancer Status, Site, Treatment, and Vaccination. BACKGROUND: Studies have shown an increased risk of severe SARS-CoV-2-related (COVID-19) disease outcome and mortality for patients with cancer, but it is not well understood whether associations vary by cancer site, cancer treatment, and vaccination status. METHODS: Using electronic health record data from an academic medical center, we identified a retrospective cohort of 260,757 individuals tested for or diagnosed with COVID-19 from March 10, 2020, to August 1, 2022. Of these, 52,019 tested positive for COVID-19 of whom 13,752 had a cancer diagnosis. We conducted Firth-corrected logistic regression to assess the association between cancer status, site, treatment, vaccination, and four COVID-19 outcomes: hospitalization, intensive care unit admission, mortality, and a composite "severe COVID" outcome. RESULTS: Cancer diagnosis was significantly associated with higher rates of severe COVID, hospitalization, and mortality. These associations were driven by patients whose most recent initial cancer diagnosis was within the past 3 years. Chemotherapy receipt, colorectal cancer, hematologic malignancies, kidney cancer, and lung cancer were significantly associated with higher rates of worse COVID-19 outcomes. Vaccinations were significantly associated with lower rates of worse COVID-19 outcomes regardless of cancer status. CONCLUSIONS: Patients with colorectal cancer, hematologic malignancies, kidney cancer, or lung cancer or who receive chemotherapy for treatment should be cautious because of their increased risk of worse COVID-19 outcomes, even after vaccination. IMPACT: Additional COVID-19 precautions are warranted for people with certain cancer types and treatments. Significant benefit from vaccination is noted for both cancer and cancer-free patients.

Veterinarian COVID-19 vaccine uptake was widespread, but safety and efficacy concerns held some back: descriptive results from a survey of AVMA members' perceptions of COVID-19. OBJECTIVE: Assess COVID-19 vaccine uptake among veterinarians and describe unvaccinated veterinarians' perceptions of COVID-19 disease and vaccines. SAMPLE: 2,721 (14%) of 19,654 randomly sampled AVMA members. PROCEDURES: A survey of AVMA members was conducted between June 8 and June 18, 2021. Information was collected on COVID-19 experience, vaccination intention, and perceptions of COVID-19 disease and vaccines. RESULTS: A total of 2,721 AVMA members completed the survey. Most respondents reported receiving a COVID-19 vaccine (89% [2,428/2,721]). Most unvaccinated respondents disagreed with concerns about contracting (67% [196/292]) or being harmed by (65% [187/287]) COVID-19 but agreed with concerns about short- (79% [228/290]) and long-term (89% [258/289]) side effects of COVID-19 vaccines. Over 91% (268/292) did not agree that COVID-19 vaccine benefits outweigh the risk. Although 83% (244/293) of unvaccinated respondents reported being unlikely to get a COVID-19 vaccine, 47% (137/291) agreed they would be more likely if they knew people vaccinated without serious side effects. Perceptions of COVID-19 disease severity and susceptibility, beliefs about COVID-19 vaccine benefits, and barriers and facilitators to COVID-19 vaccination varied with vaccination intention. CLINICAL RELEVANCE: Results of the AVMA survey suggested that COVID-19 vaccination was widespread among veterinarians in June 2021.

Understanding unvaccinated respondents' health beliefs about COVID-19 and COVID-19 vaccines may facilitate veterinarian vaccination participation. Veterinarians who abstained from COVID-19 vaccination cited concerns about the safety, efficacy, and necessity of COVID-19 vaccines. Our results suggested that demonstrating vaccine safety and a favorable risk-to-benefit ratio of vaccination may help reduce vaccine hesitancy and increase uptake of COVID-19 vaccines among veterinarians.

The location of unilateral axillary lymphadenopathy after COVID-19 vaccination compared with that of metastasis from breast cancer without vaccination. PURPOSE: Unilateral axillary lymphadenopathy is known to occur after coronavirus disease (COVID-19) vaccination. Post-vaccination lymphadenopathy may mimic the metastatic lymph nodes in breast cancer, and it is challenging to distinguish between them. This study investigated whether the localization of axillary lymphadenopathy on magnetic resonance imaging (MRI) could be used to distinguish reactive lymphadenopathy after COVID-19 vaccines from metastatic nodes. MATERIALS AND METHODS: We retrospectively examined preoperative MRI images of 684 axillae in 342 patients who underwent breast cancer surgery from June to October 2021. Lymphadenopathy was defined as cortical thickening or short axisâ€‰â‰¥â€‰5Â mm. The axilla was divided into ventral and dorsal parts on the axial plane using a perpendicular line extending from the most anterior margin of the muscle group, including the deltoid, latissimus dorsi, or teres major muscles, relative to a line along the lateral chest wall. We recorded the presence or absence of axillary lymphadenopathy in each area and the number of visible lymph nodes. RESULTS: Of 80 axillae, 41 and 39 were included in the vaccine and metastasis groups, respectively. The median time from the last vaccination to MRI was 19Â days in the vaccine group. The number of visible axillary lymph nodes was significantly higher in the vaccine group (median, 15 nodes) than in the metastasis group (7 nodes) (Pâ€‰<â€‰0.001). Dorsal lymphadenopathy was observed in 16 (39.0%) and two (5.1%) axillae in the vaccine and metastasis groups, respectively (Pâ€‰<â€‰0.001). If the presence of both ventral and dorsal lymphadenopathy is considered indicative of vaccine-induced reaction, this finding has a sensitivity of 34.1%, specificity of 97.4%, and positive and negative predictive values of 93.3ï¼… and 58.5%, respectively. CONCLUSION: The presence of deep axillary lymphadenopathy may be an important factor for distinguishing post-vaccination lymphadenopathy from metastasis. The number of axillary lymph nodes may also help.

Progression of hemolysis in a patient with hereditary spherocytosis after the second dose of COVID-19 mRNA vaccine. Herein, we report the case of a 22-year-old woman with hereditary spherocytosis (HS) whose condition worsened after administration of the coronavirus disease 2019 (COVID-19), mRNA vaccine 'BNT162b2 Pfizer-BioNTech.' The woman had been diagnosed with HS in 2005, and her condition remained stable until February 2021. In March 2021, she received the first dose of the above vaccine and experienced pain at the injection site. After the second dose in April 2021, she developed fever and general malaise. Investigations revealed progression of hemolysis, which improved after a few days. To the best of our knowledge, this is the first report of progression of hemolysis in a patient with HS after administration of the mRNA vaccine COVID-19, BNT162b2 'Pfizer-BioNTech.'

Self-Adjuvanting Protein Vaccine Conjugated with a Novel Synthetic TLR4 Agonist on Virus-Like Liposome Induces Potent Immunity against SARS-CoV-2. Exploring potent adjuvants and new vaccine strategies is crucial for the development of protein vaccines. In this work, we synthesized a new TLR4 agonist, structurally simplified lipid A analogue GAP112, as a potent built-in adjuvant to improve the immunogenicity of SARS-CoV-2 spike RBD protein. The new TLR4 agonist GAP112 was site-selectively conjugated on the N-terminus of RBD to construct an adjuvant-protein conjugate vaccine in a liposomal formulation. It is the first time that a TLR4 agonist is site-specifically and quantitatively conjugated to a protein antigen. Compared with an unconjugated mixture of

GAP112/RBD, a two-dose immunization of the GAP112-RBD conjugate vaccine strongly activated innate immune cells, elicited a 223-fold increase in RBD-specific antibodies, and markedly enhanced T-cell responses. Antibodies induced by GAP112-RBD also effectively cross-neutralized SARS-CoV-2 variants (Delta/B.1.617.2 and Omicron/B.1.1.529). This conjugate strategy provides an effective method to greatly enhance the immunogenicity of antigen in protein vaccines against SARS-CoV-2 and other diseases.

Adult-Onset Type 1 Diabetes Development Following COVID-19 mRNA Vaccination. During the coronavirus disease 2019 (COVID-19) pandemic, COVID-19 vaccination-induced hyperglycemia and related complications have been reported. However, there have been few reports of type 1 diabetes triggered by COVID-19 vaccines in subjects without diabetes. Here, we report the case of a 56-year-old female patient who developed hyperglycemia after the second dose of COVID-19 mRNA-based vaccination without a prior history of diabetes. She visited our hospital with uncontrolled hyperglycemia despite administration of oral hyperglycemic agents. Her initial glycated hemoglobin level was high (11.0%), and fasting serum C-peptide level was normal. The fasting serum C-peptide level decreased to 0.269 ng/mL 5 days after admission, and the anti-glutamic acid decarboxylase antibody was positive. The patient was discharged in stable condition with insulin treatment. To our knowledge, this is the first case of the development of type 1 diabetes without diabetic ketoacidosis after mRNA-based COVID-19 vaccination, and is the oldest case of type 1 diabetes development under such circumstances.

A Rare Cutaneous Manifestation: Leukocytoclastic Vasculitis after Pfizer-BioNTech COVID-19 Vaccination. There is growing evidence that vaccines against SARS-CoV-2 can cause various skin reactions, many of which have autoimmune origins. These specific vaccine-induced autoimmune conditions with cutaneous manifestations include lupus erythematosus, bullous pemphigoid, vitiligo, alopecia areata, and leukocytoclastic vasculitis (LCV). In particular, LCV, which is also called hypersensitivity vasculitis, is an inflammation of small blood vessels. We present a case of an 81-year-old male evaluated in the emergency department for a bilateral purpuric non-blanching rash that appeared ten days after receiving the Pfizer-BioNTech booster vaccine against SARS-CoV-2. Results of a skin biopsy indicated LCV, and the rash completely resolved three weeks after clinical presentation.

Audiometry-Confirmed Sudden Sensorineural Hearing Loss Incidence among COVID-19 Patients and BNT162b2 Vaccine Recipients. OBJECTIVE: To compare sudden sensorineural hearing loss (SSNHL) incidence rates over the coronavirus disease 2019 (COVID-19) outbreak and the COVID-19 vaccination campaign periods to pre-COVID-19 periods. STUDY DESIGN: Retrospective cohort. SETTING: Secondary hospital. PATIENTS: Patients >12 years with auditory-confirmed SSNHL were enrolled. COVID-19 status and BNT162 inoculation records â‰¤28 days before SSNHL diagnosis were retrieved. Patients were categorized according to their date of presentation over four equal periods: 1) July 2018-April 2019 (first prepandemic period), 2) May 2019-February 2020 (second prepandemic period), 3) March 2020-December 2020 (COVID-19 outbreak), and 4) January 2021-October 2021 (BNT162b2 vaccinations campaign). INTERVENTIONS: Pre- and post-COVID-19 emergence; BNT162b2 vaccine. MAIN OUTCOME MEASURES: Incidence rate ratios (IRRs) were calculated to compare SSNHL cases during the COVID-19 and vaccination periods with pre-COVID-19 periods. RESULTS: Of the 100 patients with SSNHL over the four periods, 1 had COVID-19 and 8 were vaccinated. The annual SSNHL incidence was 12.87, 12.28, 13.45, and 19.89 per 100,000 over periods 1 to 4, respectively. SSNHL incidence over the third period was not significantly different than the first/second periods (IRR = 1.045, 95% confidence interval [CI] = 0.629-1.85, Ï• = 0.788, and IRR = 1.095, 95% CI = 0.651-1.936, Ï• = 0.683, respectively), whereas SSNHL incidence rate over the fourth period was higher (IRR = 1.545, 95% CI = 0.967-2.607, Ï• = 0.068, and IRR = 1.619, 95% CI = 1-2.73, Ï• = 0.05, respectively). SSNHL incidence in vaccine recipients was lower than prepandemic unvaccinated patients (IRR = 0.584, 95%

CI =0.464-1.67, Ï• = 0.984, and IRR = 0.612, 95% CI =0.48-1.744, Ï• = 0.92, respectively). CONCLUSION: There were fewer SSNHL cases during the first COVID-19 months. Although the SSNHL rate over the COVID-19 vaccination campaign increased, it was not higher for patients who received the BNT162b2 vaccine.

Re: Singh etÂ al.: Vaccine-associated uveitis following COVID-19 vaccination: vaccine adverse event reporting system database analysis (Ophthalmology. 2023;130:179-186).

Automatic Identification of Self-Reported COVID-19 Vaccine Information from Vaccine Adverse Events Reporting System. BACKGROUND: The short time frame between the coronavirus disease 2019 (COVID-19) pandemic declaration and the vaccines authorization led to concerns among public regarding the safety and efficacy of the vaccines. The Food and Drug Administration uses the Vaccine Adverse Events Reporting System (VAERS) where general population can report their vaccine side effects in the text box. This information could be utilized to determine self-reported vaccine side effects. OBJECTIVE: To develop a supervised and unsupervised natural language processing (NLP) pipeline to extract self-reported COVID-19 vaccination side effects, location of the side effects, medications, and possibly false/misinformation seeking further investigation in a structured format for analysis and reporting. METHODS: We utilized the VAERS dataset of COVID-19 vaccine reports from November 2020 to August 2022 of 725,246 individuals. We first developed a gold-standard (GS) dataset of randomly selected 1,500 records. Second, the GS was split into training, testing, and validation sets. The training dataset was used to develop the NLP applications (supervised and unsupervised) and testing and validation datasets were used to test the performances of the NLP application. RESULTS: The NLP application automatically extracted vaccine side effects, body locations of the side effects, medication, and possibly misinformation with moderate to high accuracy (84% sensitivity, 82% specificity, and 83% F-1 measure). We found that 23% people (386,270) faced arm soreness, 31% body swelling (226,208), 23% fatigue/body weakness (168,160), and 22% (159,873) cold/flue-like symptoms. Most of the complications occurred in the body locations such as the arm, back, chest, neck, face, and head. Over-the-counter pain medications such as Tylenol and Ibuprofen and allergy medication like Benadryl were most reported self-reported medications. Death due to COVID-19, changes in the DNA, and infertility were possible false/misinformation reported by people. CONCLUSION: Some self-reported side effects such as syncope, arthralgia, and blood clotting need further clinical investigations. Our NLP application may help in extracting information from big free-text electronic datasets to help policy makers and other researchers with decision making.

Association between COVID-19 vaccines and the menstrual cycle in young Japanese women. INTRODUCTION: Although several studies have investigated the association between coronavirus disease 2019 (COVID-19) vaccines and the menstrual cycle, available data are limited. Therefore, this study investigated the effect of COVID-19 vaccines on the menstrual cycle and the effect of the menstrual cycle phase on the vaccine side effects during vaccine administration in Japan. METHODS: A self-administered questionnaire was used to collect data on the date of vaccination; type of vaccine; type, grade, and duration of the side effects; regularity of menstruation; normal length of the menstrual cycle; and the day one date of menstruation around vaccination. The survey was conducted from October 2021 to March 2022. RESULTS: The difference between the predicted and actual menstrual cycle length was 1.9Â Â±Â 3.0, 1.6Â Â±Â 2.8 (pÂ =Â 0.557), and 2.5Â Â±Â 3.8 (pÂ =Â 0.219) days before vaccination and after the first and second dose of the vaccine, respectively. In participants who received vaccinations twice within a single menstrual cycle, this difference was 1.3Â Â±Â 3.5 and 3.9Â Â±Â 3.3 (pÂ =Â 0.045) days before and after vaccination, respectively. The grade and proportion of the side effects after the second dose of the vaccine was highest during the menstrual period and lowest during the ovulation period, with a significant effect on headache and chills. CONCLUSION: COVID-19 vaccines tended to prolong the menstrual cycle. The side effects of the

COVID-19 vaccine tended to be at a maximum when vaccination occurred during the menstrual period and minimal during the ovulation period.
Acquired idiopathic generalized anhidrosis diagnosed following mRNA COVID-19 vaccination-A case series.
Durability of Vaccine-Induced and Natural Immunity Against COVID-19: A Narrative Review. Vaccines developed against SARS-CoV-2 have proven to be highly effective in preventing symptomatic infection. Similarly, prior infection with SARS-CoV-2 has been shown to provide substantial protection against reinfection. However, it has become apparent that the protection provided to an individual after either vaccination or infection wanes over time. Waning protection is driven by both waning immunity over time since vaccination or initial infection, and the evolution of new variants of SARS-CoV-2. Both antibody and T/B-cells levels have been investigated as potential correlates of protection post-vaccination or post-infection. The activity of antibodies and T/B-cells provide some potential insight into the underlying causes of waning protection. This review seeks to summarise what is currently known about the waning of protection provided by both vaccination and/or prior infection, as well as the current information on the respective antibody and T/B-cell responses.
Bilateral anterior ischemic optic neuropathy after COVID-vaccination.
Short-term outcome of late gadolinium changes detected on cardiovascular magnetic resonance imaging following coronavirus disease 2019 Pfizer/BioNTech vaccine-related myocarditis in adolescents. BACKGROUND: Rare cases of cardiac inflammation following vaccination for severe acute respiratory coronavirus 2 (SARS-CoV-2) have been reported. OBJECTIVE: To study paediatric patients with clinical findings of acute inflammation post coronavirus disease 2019 (COVID-19) Pfizer/BioNTech vaccination using cardiovascular magnetic resonance imaging (MRI) in acute and subacute phases. MATERIALS AND METHODS: We enrolled adolescents younger than 18Â years who presented at one of two institutions between July 2021 and August 2022 with clinical and laboratory findings of acute myocarditis shortly following COVID-19 Pfizer/BioNTech vaccination. They all underwent cardiovascular MRI using the institutional myocarditis protocol. RESULTS: Five adolescents (four boys) underwent eight scans between 3 days and 109Â days (mean 49Â days) after the onset of symptoms following COVID-19 vaccination. Myocardial oedema appeared on short tau inversion recovery (STIR) T2-weighted images in three adolescents at presentation (3-12Â days after symptom onset). In these children, the myocardial oedema/acute inflammation had resolved at follow-up cardiovascular MRI (53-68Â days after first MRI). However, in all three adolescents, a persistent area of late gadolinium enhancement was evident at follow-up, suggesting post-myocarditic fibrosis. One adolescent scanned only once, 66Â days after being symptomatic, had no acute inflammation but persistent fibrotic changes. This last adolescent, who underwent the first scan 109Â days after symptom onset, had findings compatible with an episode of previous myocarditis, with mild ongoing regional myocardial oedema/inflammation. CONCLUSION: This study on post-vaccine myocarditis demonstrates residual lesions with persistent areas of late gadolinium enhancement/myocardial fibrosis with ongoing myocardial oedema after resolution of the initial myocardial oedema a few weeks after Pfizer/BioNTech vaccination. There is an urgent need to recognise and fully investigate the outcome of post-vaccination myocarditis.
Anti-SARS-CoV-2 vaccine-induced myocarditis - real but, in general, rare and mild: A consensus statement from the Studies Committee of the Portuguese Society of Cardiology. Acute myocarditis (especially) and pericarditis have been consistently associated with the administration of vaccines against SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), generating anxiety in the general population, uncertainty in the scientific community and obstacles to ambitious mass vaccination programs, especially in foreign countries. Like some of its European counterparts, the Portuguese Society of Cardiology (SPC), through its Studies Committee, decided to take a position on

some of the most pressing questions related to this issue: (i) How certain are we of this epidemiological association? (ii) What is the probability of its occurrence? (iii) What are the pathophysiological bases of these inflammatory syndromes? (iv) Should their diagnosis, treatment and prognosis follow the same steps as for typical idiopathic or post-viral acute myopericarditis cases? (v) Is the risk of post-vaccine myocarditis great enough to overshadow the occurrence of serious COVID-19 disease in unvaccinated individuals? In addition, the SPC will issue clinical recommendations and offer its outlook on the various paths this emerging disease may take in the future.
Tachycardia, adverse effect, COVID-19 vaccine: Correspondence.
Reply to "Tachycardia, adverse effect, COVID-19 vaccine".
No evidence of an increased risk for cardiac complications following mRNA COVID-19 vaccines.
Neuralgic Amyotrophy After COVID-19 Vaccination in an Adolescent: Successful Intravenous Immunoglobulin Treatment.
Disease activity in patients with immune-mediated inflammatory diseases after SARS-CoV-2 vaccinations. For patients with immune-mediated inflammatory diseases (IMIDs), concerns exist about increased disease activity after vaccination. We aimed to assess changes in disease activity after SARS-CoV-2 vaccination in patients with IMIDs, and determine risk factors for increased disease activity. In this substudy of a prospective observational cohort study (Target-to-B!), we included patients with IMIDs who received a SARS-CoV-2 vaccine. Patients reported changes in disease activity on a five-point Likert scale every 60 days for up to twelve months after first vaccination. In case of self-reported increased activity, hospital records were screened whether the treating physician reported increased activity, and for potential intensification of immunosuppressive (ISP) treatment. Mixed models were used to study determinants for self-reported increased disease activity. In total, 2111 patients were included for analysis after primary immunization (mean age 49.7 years [SD 13.7], 1329/2111 (63.0%) female), from which 1266 patients for analysis after first additional vaccination. Increased disease activity at 60 days after start of primary immunization was reported by 223/2111 (10.6%). In 96/223 (43.0%) the increase was confirmed by the treating physician and in 36/223 (16.1%) ISP treatment was intensified. Increased disease activity at seven to 60 days after additional vaccination, was reported by 139/1266 (11.0%). Vaccinations were not temporally associated with self-reported increased disease activity. Conversely, increased disease activity before first vaccination, neuromuscular disease, and multiple sclerosis were associated. Altogether, self-reported increased disease activity after vaccination against SARS-CoV-2 was recorded in a minority of patients and was generally mild. Moreover, multivariate analyses suggest that disease related factors, but not vaccinations are the major determinants for self-reported increased disease activity.
Echocardiographic Evolution of PosteroLateral Left Ventricular Aneurysm with Normal Coronary Arteries in Patient Recently COVID-19 Vaccinated: A Complicated Atypical Case of Takotsubo Syndrome Vaccine-related? A 72-year-old woman, recently COVID-19 vaccinated with a third dose, was referred to our center for acute chest pain and dyspnea. On admission, the electrocardiography showed a STEMI on inferior derivations and the dyskinesia of the inferior wall was found at the first transthoracic echocardiogram. The coronary angiography did not show coronary artery disease. After 1 week, a huge posterolateral left ventricular (LV) aneurysm with initial signs of rupture was found and the patient underwent a Dor's procedure to exclude the LV aneurysm. As far as we know, this is the first reported case of Takotsubo following the COVID-19 vaccination requiring cardiac surgery.
Comparison between viral vector and mRNA based COVID-19 vaccination in prevalence and severity of regional immune reactions, and (18)F-FDG PET/CT features. OBJECTIVES: The coronavirus pandemic caused by SARS-CoV-2 commenced in late 2019, and global wide vaccination appears to be

the only reasonable solution to fight this dreadful virus. There are two main types of COVID-19 immunization using viral vector and mRNA-based vaccines. However, the impact of each of type on (18)F-FDG PET/CT needs to be accurately assessed. This study aimed to compare the (18)F-FDG PET/CT features of these two types of COVID-19 vaccines. METHODS: A total of 188 patients referred for (18)F-FDG PET/CT with a recent history of either BioNTech/Pfizer or AstraZeneca COVID-19 vaccination, and a control group of 40 patients with no history of any type of recent vaccination, were included in the study. (18)F-FDG PET/CT studies of vaccinated patients assessed for injection site uptake and regional nodal and systemic reactions post vaccination. The data were compared to the control group and to the contralateral side for each patient. The findings were compared between patients who received Pfizer and AstraZeneca vaccines. RESULTS: (18)F-FDG PET/CT was semiquantitatively positive in 50.5% of the studied population for vaccine-related features. The ipsilateral axillary and infra- and supraclavicular lymph nodes were significantly larger in size and exhibited higher metabolic activity compared to the contralateral lymph nodes after both types of vaccination. The prevalence of regional nodal reactions post Pfizer and AstraZeneca vaccination was 39% and 17.9% on visual, and 61% and 47.6% on semiquantitative assessments, respectively. Patients receiving the Pfizer vaccine exhibited higher metabolic activity in the ipsilateral regional lymph nodes ($p<0.05$). No significant difference in the intensity of regional nodal reaction post vaccination was noted between the first four weeks. CONCLUSION: Significant local and regional nodal reactions are observed after both viral vector and mRNA COVID-19 vaccination with a tendency to extend toward the infra- and supraclavicular nodal stations but not to the pulmonary hilum. The greater intensity and extension of the nodal reaction after Pfizer vaccination suggests a higher possibility of false-positive results on (18)F-FDG PET/CT studies using mRNA vaccination technology.

The safety of COVID-19 vaccines in patients with myasthenia gravis: A scoping review. BACKGROUND: COVID-19 vaccines are required for individuals with myasthenia gravis (MG), as these patients are more likely to experience severe pneumonia, myasthenia crises, and higher mortality rate. However, direct data on the safety of COVID-19 vaccines in patients with MG are lacking, which results in hesitation in vaccination. This scoping was conducted to collect and summarize the existing evidence on this issue. METHODS: PubMed, Cochrane Library, and Web of Science were searched for studies using inclusion and exclusion criteria. Article titles, authors, study designs, demographics of patients, vaccination information, adverse events (AEs), significant findings, and conclusions of included studies were recorded and summarized. RESULTS: Twenty-nine studies conducted in 16 different countries in 2021 and 2022 were included. Study designs included case report, case series, cohort study, cross-sectional study, survey-based study, chart review, and systemic review. A total of 1347 patients were included. The vaccines used included BNT162b2, mRNA-1273, ChAdOx1 nCoV-19, inactivated vaccines, and recombinant subunit vaccines. Fifteen case studies included 48 patients reported that 23 experienced new-onset, and five patients experienced flare of symptoms. Eleven other types of studies included 1299 patients reported that nine patients experienced new-onset, and 60 participants experienced flare of symptoms. Common AEs included local pain, fatigue, asthenia, cephalalgia, fever, and myalgia. Most patients responded well to treatment without severe sequelae. Evidence gaps include limited strength of study designs, type and dose of vaccines varied, inconsistent window of risk and exacerbation criteria, limited number of participants, and lack of efficacy evaluation. CONCLUSION: COVID-19 vaccines may cause new-onset or worsening of MG in a small proportion of population. Large-scale, multicenter, prospective, and rigorous studies are required to verify their safety.

Ferric carboxymaltose and SARS-CoV-2 vaccination-induced immunogenicity in kidney transplant recipients with iron deficiency: The COVAC-EFFECT randomized controlled trial. BACKGROUND: Kidney transplant recipients (KTRs) have an impaired immune response after vaccination against

severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). Iron deficiency (ID) may adversely affect immunity and vaccine efficacy. We aimed to investigate whether ferric carboxymaltose (FCM) treatment improves humoral and cellular responses after SARS-CoV-2 vaccination in iron-deficient KTRs. METHODS: We randomly assigned 48 iron-deficient KTRs to intravenous FCM (1-4 doses of 500mg with six-week intervals) or placebo. Co-primary endpoints were SARS-CoV-2-specific anti-Receptor Binding Domain (RBD) Immunoglobulin G (IgG) titers and T-lymphocyte reactivity against SARS-CoV-2 at four weeks after the second vaccination with mRNA-1273 or mRNA-BNT162b2. RESULTS: At four weeks after the second vaccination, patients receiving FCM had higher plasma ferritin and transferrin saturation (P<0.001 vs. placebo) and iron (P=0.02). However, SARS-CoV-2-specific anti-RBD IgG titers (FCM: 66.51 [12.02-517.59] BAU/mL; placebo: 115.97 [68.86-974.67] BAU/mL, P=0.07) and SARS-CoV-2-specific T-lymphocyte activation (FCM: 93.3 [0.85-342.5] IFN-É£ spots per 10(6) peripheral blood mononuclear cells (PBMCs), placebo: 138.3 [0.0-391.7] IFN-É£ spots per 10(6) PBMCs, P=0.83) were not significantly different among both arms. After the third vaccination, SARS-CoV-2-specific anti-RBD IgG titers remained similar between treatment groups (P=0.99). CONCLUSIONS: Intravenous iron supplementation efficiently restored iron status but did not improve the humoral or cellular immune response against SARS-CoV-2 after three vaccinations.

A case of ischemic stroke and transient thrombocytopenia in a young female following adenoviral vector-based COVID-19 vaccination: Was the association incidental or causal? Since March 2021, cases with unusual clots, particularly cerebral venous sinus thrombosis and splanchnic vein thrombosis, have been reported worldwide following adenoviral vector-based coronavirus disease 2019 (COVID-19) vaccination. This entity has been termed vaccine-induced thrombotic thrombocytopenia (VITT). We report a 23-year-old healthy female who developed seizures, altered sensorium, and left hemiparesis, 20 days after receiving the first dose of adenoviral vector-based COVID-19 vaccine "Covishieldâ„¢." The patient had transient thrombocytopenia. The D-dimer level was 2460 ng/mL. Magnetic resonance imaging (MRI) demonstrated occlusion of M2 segment of the middle cerebral artery and cerebral infarction. Platelet factor-4 antibodies level was normal. Treatment with aspirin and antiepileptic drugs resulted in a remarkable recovery. This is the first Indian case report of ischemic stroke and transient thrombocytopenia following SARS-CoV-2 ChAdOx1 nCoV-19 vaccination. Our case had clinical features consistent with the diagnosis of probable VITT. Familiarity with VITT is crucial because timely treatment with non-heparin anticoagulants and intravenous immunoglobulin improves the outcome.

Telogen effluvium after COVID-19 vaccination among public in Saudi Arabia. BACKGROUND: Number of reports linked Telogen effluvium to coronavirus disease 2019 (COVID-19) infection. However, data about Telogen effluvium after COVID-19 vaccination are limited. OBJECTIVES: To estimate prevalence of Telogen effluvium among those who received COVID-19 vaccination. METHODS: A cross-sectional study was performed during July 2021. Adults who received one of recognized COVID-19 vaccine irrespective of previous COVID-19 infection were asked to fill a questionnaire. RESULTS: The majority of participants were females (90.3%). The most common age group was between 21 and 30 years (51.9%). Out of 991 participants who were included in the current analysis, 670 (67.6%) reported post-vaccination hair fall. The probable causes of post-vaccination hair fall were vaccine-related in 185 (27.6%) participants, other causes in 326 (48.7%) participants, and unclear in 326 (48.7%) participants. Post-vaccination hair fall was significantly higher among females compared with males (68.5% versus 57.9%, P = 0.036), those who did not suffer compared with those who suffered from hair fall before vaccination (72.1% versus 63.4%, P = 0.003), and those who did not report compared with those who reported preexisting conditions that might be related to hair fall (74.5% versus 57.3%, P < 0.001). CONCLUSION: We are reporting a high prevalence of post-vaccination hair fall, which affected approximately two-thirds of participants who

received COVID-19 vaccines. Only 28% of these participants were apparently vaccine related. The role of COVID-19 infection and stress caused by infection and vaccine cannot be excluded. Primary care physician and dermatologist need to consider the possibility of COVID-19 vaccine as a potential cause of hair loss.

Factors associated with development of adverse events after taking COVID-19 vaccine in a tribal state of India: Regression analysis. BACKGROUND: Coronavirus disease (COVID-19) vaccination becomes a crucial weapon in the pandemic's control. Two vaccines, Covishield and Covaxin, are approved in India to vaccinate against the virus. Hence, the present study was done to determine the factors associated with the development of adverse events after taking the COVID-19 vaccine in a tribal state of India. MATERIALS AND METHODS: This was a cross-sectional analytical study. All persons who were willing to participate in our study and had received the first or second dose of the COVID-19 vaccine from January 1 to March 31, 2021, were included. We got 1497 complete responses via (free, web-based Google Docs Editors suite offered by google, Founders- Larry Page Sergey Brin. Menlo Park, California, United States). So our final sample size came out to be 1497 in which analysis was done. The data was compiled in MS excel sheets (Microsoft version 2013, Microsoft Corporation, Redmond, Washington, United States) and a template was generated which was further analyzed in SPSS version 20 (version 25.0; IBM Corp., Armonk, NY, USA). RESULTS: The total number of respondents who participated in the surveillance of adverse events following immunization (AEFI) was 1497. Among them, a majority have taken the Covishield vaccine followed by Covaxin. The majority of participants were female of age group less than 30 years and above 18 years with a mean age of 33.63 Â± 51.51. The most common AEFI was pain at the site of injection, after the first and second dose followed by fever after the first and second dose within 24 h following immunization. CONCLUSION: We conclude that factors like the type of vaccine, gender, and participants who have allergies have a higher risk of presenting the adverse events after the COVID-19 vaccination.

Minimal change disease (MCD) following vaccination with ChAdOx1 nCoV-19 vaccine in a young Indian male: A case report. Various vaccines against coronavirus disease 2019 (COVID-19) have been developed amidst the ongoing pandemic. Few cases of glomerulonephritis after COVID-19 vaccination have been reported globally. We present a case of nephrotic syndrome due to minimal change disease (MCD) most likely associated with the ChAdOx1 nCoV-19 vaccine. A 24-year-old male presented with anasarca and frothy urine after receiving the first dose of the COVID-19 vaccine. On admission, the patient had normal serum creatinine with 24-h urinary protein excretion of 4.1 g/day and severe hypoalbuminemia. Kidney biopsy revealed nonproliferative glomerular morphology with relatively unremarkable-appearing glomeruli on light microscopy and diffuse effacement of the odocyte foot processes on electron microscopy, consistent with diagnosis of MCD. This case highlights the risk of new-onset nephrotic syndrome due to MCD after COVID-19 vaccination.

COVID-19 vaccination in pregnancy: Need for global pharmaco-vigilance. Coronavirus infectious disease has been around for more than 2â€‰years as a pandemic, but now appears to have taken the form of an endemic. COVID-19 vaccination in pregnant women is presently being recommended and followed in most countries. However, robust scientific evidence on safety of the vaccine in the medium or long term, or regarding any adverse effects, is lacking. We searched the PubMed and gray literature for evidence on medium- or long-term effects of COVID-19 vaccination during pregnancy on the mother or her fetus/newborn and found limited data on this subject. Moreover, available evidence comes almost exclusively from the Western world. Any adverse effects of COVID-19 vaccination during or after pregnancy may take time to manifest. Therefore, there is a need to keep the cohort of vaccinated women and their children under scrutiny for any possible adverse effects. This is also needed to build confidence in the long term in the vaccines. A global pharmaco-vigilance

or post-marketing surveillance network covering pregnant recipients of COVID-19 vaccines can identify and help to address any medium- or long-term adverse effects of the COVID-19 vaccines on pregnancy and the newborn.

Immune Response to COVID-19 mRNA Vaccination in Previous Nonresponder Kidney Transplant Recipients After Short-term Withdrawal of Mycophenolic Acid 1 and 3 Months After an Additional Vaccine Dose. BACKGROUND: The impaired immune response to coronavirus disease 2019 (COVID-19) vaccination in kidney transplant recipients (KTRs) leads to an urgent need for adapted immunization strategies. METHODS: Sixty-nine KTRs without seroconversion after â‰¥3 COVID-19 vaccinations were enrolled, and humoral response was determined after an additional full-dose mRNA-1273 vaccination by measuring severe acute respiratory syndrome coronavirus 2-specific antibodies and neutralizing antibody activity against the Delta and Omicron variants 1 and 3 mo postvaccination. T-cell response was analyzed 3 mo postvaccination by assessing interferon-Î³ release. Mycophenolic acid (MPA) was withdrawn in 41 KTRs 1â€‰wk before until 4â€‰wk after vaccination to evaluate effects on immunogenicity. Graft function, changes in donor-specific anti-HLA antibodies, and donor-derived cell-free DNA were monitored in KTRs undergoing MPA withdrawal. RESULTS: Humoral response to vaccination was significantly stronger in KTRs undergoing MPA withdrawal 1 mo postvaccination; however, overall waning humoral immunity was noted in all KTRs 3 mo after vaccination. Higher anti-S1 immunoglobulin G levels correlated with better neutralizing antibody activity against the Delta and Omicron variants, whereas no significant association was detected between T-cell response and neutralizing antibody activity. No rejection occurred during study, and graft function remained stable in KTRs undergoing MPA withdrawal. In 22 KTRs with Omicron variant breakthrough infections, neutralizing antibody activity was better against severe acute respiratory syndrome coronavirus 2 wild-type and the Delta variants than against the Omicron variant. CONCLUSIONS: MPA withdrawal to improve vaccine responsiveness should be critically evaluated because withdrawing MPA may be associated with enhanced alloimmune response, and the initial effect of enhanced seroconversion rates in KTRs with MPA withdrawal disappears 3 mo after vaccination.

Coronavirus-Specific Antibody and T Cell Responses Developed after Sputnik V Vaccination in Patients with Chronic Lymphocytic Leukemia. The clinical course of the new coronavirus disease 2019 (COVID-19) has shown that patients with chronic lymphocytic leukemia (CLL) are characterized by a high mortality rate, poor response to standard treatment, and low virus-specific antibody response after recovery and/or vaccination. To date, there are no data on the safety and efficacy of the combined vector vaccine Sputnik V in patients with CLL. Here, we analyzed and compared the magnitudes of the antibody and T cell responses after vaccination with the Sputnik V vaccine among healthy donors and individuals with CLL with different statuses of preexposure to coronavirus. We found that vaccination of the COVID-19-recovered individuals resulted in the boosting of pre-existing immune responses in both healthy donors and CLL patients. However, the COVID-19-naÃ¯ve CLL patients demonstrated a considerably lower antibody response than the healthy donors, although they developed a robust T cell response. Regardless of the previous infection, the individuals over 70 years old demonstrated a decreased response to vaccination, as did those receiving anti-CD20 therapy. In summary, we showed that Sputnik V, like other vaccines, did not induce a robust antibody response in individuals with CLL; however, it provided for the development of a significant anti-COVID-19 T cell response.

Longitudinal Analysis of Antiphospholipid Antibody Dynamics after Infection with SARS-CoV-2 or Vaccination with BNT162b2. Antiphospholipid antibodies (aPL) comprise a group of autoantibodies that reflect prothrombotic risk in antiphospholipid syndrome (APS) but may also be present in a small proportion of healthy individuals. They are often transiently elevated in infections,

including SARS-CoV-2, and may also be associated with vaccine-induced autoimmunity. Therefore, we aimed to investigate the dynamics of aPL in COVID-19 patients and in individuals (healthcare professionals-HCPs) after receiving BNT162b2 vaccine and to compare aPL levels and positivity with those found in APS patients. We measured solid-phase identifiable aPL, including anticardiolipin (aCL), anti-Î²2 glycoprotein I (anti-Î²2GPI), and anti-prothrombin/phosphatidylserine (aPS/PT) antibodies in 58 HCPs before and after vaccination (at 3 weeks, 3, 6, and 9 months after the second dose, and 3 weeks after the third booster dose), in 45 COVID-19 patients hospitalized in the ICU, in 89 COVID-19 patients hospitalized in the non-ICU (at admission, at hospital discharge, and at follow-up), and in 52 patients with APS. The most frequently induced aPL in COVID-19 patients (hospitalized in non-ICU) were aCL (50.6% of patients had positive levels at at least one time point), followed by anti-Î²2GPI (21.3% of patients had positive levels at at least one time point). In 9/89 COVID-19 patients, positive aPL levels persisted for three months. One HCP developed aCL IgG after vaccination but the persistence could not be confirmed, and two HCPs developed persistent anti-Î²2GPI IgG after vaccination with no increase during a 1-year follow-up period. Solid-phase aPL were detected in 84.6% of APS patients, in 49.4% of COVID-19 patients hospitalized in the non-ICU, in 33.3% of COVID-19 patients hospitalized in the ICU, and in only 17.2% of vaccinated HCPs. aPL levels and multiple positivity were significantly lower in both infected groups and in vaccinated individuals compared with APS patients. In conclusion, BNT162b2 mRNA vaccine may have induced aPL in a few individuals, whereas SARS-CoV-2 infection itself results in a higher percentage of aPL induction, but the levels, persistence, and multiple positivity of aPL do not follow the pattern observed in APS.

COVID-19 Vaccination and Late-Onset Myasthenia Gravis: A New Case Report and Review of the Literature. Myasthenia gravis (MG) is a rare autoimmune disease that is potentially threatening for patient life. Auto-antibodies targeting structures of the neuromuscular junction, particularly the acetylcholine receptor (AchR), are often found in the serum of MG patients. New-onset MG after SARS-CoV-2 vaccination has rarely been reported since the introduction of vaccination. Infections and COVID-19 infection have also been reported as possible triggers for a myasthenic crisis. We report a case of new-onset MG after receiving the mRNA COVID-19 vaccination. The patient was a 73-year-old male initially presenting with ocular symptoms and a rapid generalization. We also performed a literature revision of 26 described cases of MG after SARS-CoV-2 immunization. The patients were a majority of males with generalized late-onset MG occurring after the first dose of vaccine, similar to our patient. Only our patient showed a thymoma. Thymic mass and the positivity of AchR antibodies suggest that vaccination might have triggered a subclinical pre-existing MG with symptoms flaring. Clinicians should be aware of possible new-onset MG after COVID-19 vaccination, particularly in at-risk patients. Even though COVID-19 vaccination should be recommended in MG patients, particularly in well-compensated patients. However, more studies need to be performed in the future.

Exploring the Association between Socioeconomic and Psychological Factors and Breastfeeding in the First Year of Life during the COVID-19 Pandemic in Thailand. Breastfeeding is essential for the survival, nutrition, and development of infants and young children. As a result of COVID-19â€™s effects of economic crises and psychological difficulties, breastfeeding outcomes have declined. The purpose of this study was to examine the association between socioeconomic and psychological factors with breastfeeding duration in the first year of life during the COVID-19 pandemic. Cross-sectional online surveys (n = 390) were conducted between August and November 2021. The participants were women aged 15 years and above who had given birth within 6â^'12 months before data collection and delivered in public hospitals in the top three provinces with the worst COVID-19 outbreaks during the second wave in Thailand. The average breastfeeding duration in this study was 6.20 months (Â±2.5) with a range of 1â^'12 months. Of mothers, 44.9% continued to breastfeed until between 6 and 12 months of age. In a multiple regression analysis, family income (Beta = 0.112, t =

1.988, p < 0.05), breastfeeding intention (beta = 0.097, t = 2.142, p < 0.05), intended breastfeeding duration (beta = 0.391, t = 8.355, p < 0.05), intention to receive vaccination (beta =0.129, t = 2.720, p < 0.05), and anxiety (beta = 0.118, t = 2.237, p < 0.05) were associated with breastfeeding duration in the first year of life (F (7, 382) = 20.977, p < 0.05, R2 = 0.278, R2 Adjusted = 0.264). During COVID-19, psychological factors were more strongly associated with breastfeeding duration in the first year of life than socioeconomic factors. Healthcare providers should promote breastfeeding intention, motivate COVID-19 vaccination intention, and support mental health among lactating mothers, particularly in the event of a pandemic.

Adverse Effects of COVID-19 Vaccination: Machine Learning and Statistical Approach to Identify and Classify Incidences of Morbidity and Postvaccination Reactogenicity. Good vaccine safety and reliability are essential for successfully countering infectious disease spread. A small but significant number of adverse reactions to COVID-19 vaccines have been reported. Here, we aim to identify possible common factors in such adverse reactions to enable strategies that reduce the incidence of such reactions by using patient data to classify and characterise those at risk. We examined patient medical histories and data documenting postvaccination effects and outcomes. The data analyses were conducted using a range of statistical approaches followed by a series of machine learning classification algorithms. In most cases, a group of similar features was significantly associated with poor patient reactions. These included patient prior illnesses, admission to hospitals and SARS-CoV-2 reinfection. The analyses indicated that patient age, gender, taking other medications, type-2 diabetes, hypertension, allergic history and heart disease are the most significant pre-existing factors associated with the risk of poor outcome. In addition, long duration of hospital treatments, dyspnoea, various kinds of pain, headache, cough, asthenia, and physical disability were the most significant clinical predictors. The machine learning classifiers that are trained with medical history were also able to predict patients with complication-free vaccination and have an accuracy score above 90%. Our study identifies profiles of individuals that may need extra monitoring and care (e.g., vaccination at a location with access to comprehensive clinical support) to reduce negative outcomes through classification approaches.

Development of ANCA-associated vasculitis followed by SARS-CoV-2 vaccination in a patient with HLA-DRB1*09:01 allele. Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), presents with severe pneumonia and fatal systemic complications. Currently, SARS-CoV-2 vaccines are effective in reducing the risk of new onset and getting worse of the disease. However, autoimmune diseases such as antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) have been reported to develop after COVID-19 vaccine administration. A 71-year-old woman presented with fever, malaise, urinary abnormalities, and renal dysfunction after receiving the COVID-19 vaccine (Pfizer-BioNTech). We clinically diagnosed AAV with her manifestations and serological test (myeloperoxidase-ANCA-positive). Her clinical findings were improved after immunosuppressive therapy. We examined her genetic susceptibility to AAV, and we found that her allele was HLA-DRB1*09:01, which is a risk allele of myeloperoxidase-AAV. Mechanistically, SARS-CoV-2 vaccines would activate immunity, including neutrophils, and trigger AAV onset in this patient with a genetic risk to develop AAV. The pathophysiology of this case would share with that of autoimmune/inflammatory syndrome induced by adjuvants in the absence of external adjuvants.

Anxiety and depression among medical staff facing SARS-CoV-2 vaccination in China. BACKGROUND: SARS-COV-2 vaccination is being carried out worldwide. However, little is known about the effect of SARS-COV-2 vaccination on psychological problems faced by the medical staff. This study aimed to examine the prevalence and factors contributing to anxiety and depression among medical staff facing SARS-COV-2 vaccination. METHODS: The GAD-7 and the PHQ-9 scales

were used to investigate the anxiety and depression among participants involved in SARS-CoV-2 vaccination. Multivariate logistics regression analysis method was used to assess the risk factors related to anxiety or depression. RESULTS: A total of 6984 people responded to all the surveyed questions in our study, including 2707 medical staff and 4277 nonmedical staff. Of the participants, 680 reported anxiety, while 1354 reported depression. Higher anxiety levels were observed among medical staff (13.1Â % vs. 7.6Â % among the non-medical staff). Participants suffered from depression with higher numbers among medical staff (24.7Â % vs. 16.0Â % among the non-medical staff). Multivariate logistic regression analysis showed that female medical staff was at higher risk of anxiety and depression compared to their male counterparts (ORÂ =Â 1.497; ORÂ =Â 1.417). Pregnancy intention increased the risk of anxiety and depression among medical staff (ORÂ =Â 1.601; ORÂ =Â 1.724). LIMITATIONS: Our findings may not be extrapolated to other countries. CONCLUSION: Medical staff facing SARS-CoV-2 vaccination were more likely to suffer from anxiety or depression, especially the females planning for pregnancy. These results should assist in updating intervention guidelines for the mental health of medical staff facing vaccination.

Subunit microparticulate vaccine delivery using microneedles trigger significant SARS-spike-specific humoral and cellular responses in a preclinical murine model. The objective of this "proof-of-concept" study was to evaluate the synergistic effect of a subunit microparticulate vaccine and microneedles (MN) assisted vaccine delivery system against a human coronavirus. Here, we formulated PLGA polymeric microparticles (MPs) encapsulating spike glycoprotein (GP) of SARS-CoV as the model antigen. Similarly, we formulated adjuvant MPs encapsulating AlhydrogelÂ® and AddaVaxâ„¢. The antigen/adjuvant MPs were characterized and tested in vitro for immunogenicity. We found that the antigen/adjuvant MPs were non-cytotoxic in vitro. The spike GP MPsÂ +Â AlhydrogelÂ® MPsÂ +Â AddaVaxâ„¢ MPs showed enhanced immunogenicity in vitro as confirmed through the release of nitrite, autophagy, and antigen presenting molecules with their co-stimulatory molecules. Next, we tested the in vivo efficacy of the spike GP MP vaccine with and without adjuvant MPs in mice vaccinated using MN. The spike GP MPsÂ +Â AlhydrogelÂ® MPsÂ +Â AddaVaxâ„¢ MPs induced heightened spike GP-specific IgG, IgG1 and IgG2a antibodies in mice. Also, spike GP MPsÂ +Â AlhydrogelÂ® MPsÂ +Â AddaVaxâ„¢ MPs enhanced expression of CD4+ and CD8+ T cells in secondary lymphoid organ like spleen. These results indicated spike GP-specific humoral immunity and cellular immunity in vivo. Thus, we employed the benefits of both the subunit vaccine MPs and dissolving MN to form a non-invasive and effective vaccination strategy against human coronaviruses.

AZD1222-induced nasal antibody responses are shaped by prior SARS-CoV-2 infection and correlate with virologic outcomes in breakthrough infection. The nasal mucosa is an important initial site of host defense against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. However, intramuscularly administered vaccines typically do not achieve high antibody titers in the nasal mucosa. We measure anti-SARS-CoV-2 spike immunoglobulin G (IgG) and IgA in nasal epithelial lining fluid (NELF) following intramuscular vaccination of 3,058 participants from the immunogenicity substudy of a phase 3, double-blind, placebo-controlled study of AZD1222 vaccination (ClinicalTrials.gov: NCT04516746). IgG is detected in NELF collected 14Â days following the first AZD1222 vaccination. IgG levels increase with a second vaccination and exceed pre-existing levels in baseline-SARS-CoV-2-seropositive participants. Nasal IgG responses are durable and display strong correlations with serum IgG, suggesting serum-to-NELF transudation. AZD1222 induces short-lived increases to pre-existing nasal IgA levels in baseline-seropositive vaccinees. Vaccinees display a robust recall IgG response upon breakthrough infection, with overall magnitudes unaffected by time between vaccination and illness. Mucosal responses correlate with reduced viral loads and shorter durations of viral shedding in saliva.

Axillary lymphadenopathy following bivalent COVID-19 booster vaccination.

A population-based matched cohort study of major congenital anomalies following COVID-19 vaccination and SARS-CoV-2 infection. Evidence on associations between COVID-19 vaccination or SARS-CoV-2 infection and the risk of congenital anomalies is limited. Here we report a national, population-based, matched cohort study using linked electronic health records from Scotland (May 2020-April 2022) to estimate the association between COVID-19 vaccination and, separately, SARS-CoV-2 infection between six weeks pre-conception and 19 weeks and six days gestation and the risk of [1] any major congenital anomaly and [2] any non-genetic major congenital anomaly. Mothers vaccinated in this pregnancy exposure period mostly received an mRNA vaccine (73.7% Pfizer-BioNTech BNT162b2 and 7.9% Moderna mRNA-1273). Of the 6731 babies whose mothers were vaccinated in the pregnancy exposure period, 153 had any anomaly and 120 had a non-genetic anomaly. Primary analyses find no association between any vaccination and any anomaly (adjusted Odds Ratio [aOR] = 1.01, 95% Confidence Interval [CI]â€‰=â€‰0.83-1.24) or non-genetic anomalies (aOR = 1.00, 95% CIâ€‰=â€‰0.81-1.22). Primary analyses also find no association between SARS-CoV-2 infection and any anomaly (aORâ€‰=â€‰1.02, 95% CIâ€‰=â€‰0.66-1.60) or non-genetic anomalies (aOR = 0.94, 95% CIâ€‰=â€‰0.57-1.54). Findings are robust to sensitivity analyses. These data provide reassurance on the safety of vaccination, in particular mRNA vaccines, just before or in early pregnancy.

Vulval (LipschÃ¼tz) ulcers in young females associated with SARS-CoV-2 infection and COVID-19 vaccination: case series.

COVID arm as a common cutaneous manifestation after mRNA-1273 vaccination: a systematic review. BACKGROUND: By August 2022, CoronaVirus Disease-2019 (COVID-19) had caused 600 million illnesses and 6.5 million fatalities globally. A massive vaccination program is being implemented worldwide to suppress this condition. Several works of literature stated that mRNA COVID-19 vaccination, specifically with the mRNA-1273 vaccine, is followed by clear evidence of the COVID arm effects associated with this vaccine. OBJECTIVE: To analyze the latest evidence of COVID arm as a common effect of mRNA-1273 vaccination with the ultimate goal of improvingÂ vaccine counseling to help healthcare professionals and reassure patients. METHODS: A comprehensive search was performed on topics that assess the COVID arm as a cutaneous manifestation following mRNA-1273 vaccination from inception up until July 2022. RESULTS: Eighteen studies with a total of 1129 participants after the first and second dose of mRNA-1273 vaccination reported that most participants had COVID arm following the first dose administration. The characteristics of the patients were a mean age of 43.8Â years old, and females representedâ€‰â‰¥â€‰50% in most studies, with a mean onset of 6.9Â days after the first dose administration. Symptoms resolved within seven days following the treatment and were harmless. CONCLUSIONS: This study found that the COVID arm condition is most common following the first mRNA-1273 vaccination in the female and middle-aged group. The correlation between demographic variables and COVID arm risk elucidates that the reaction is a type IV allergic skin reaction.

Longitudinal adaptive immune responses following sequential SARS-CoV-2 vaccinations in MS patients on anti-CD20 therapies and sphingosine-1-phosphate receptor modulators. BACKGROUND: Adequate response to the SARS-CoV-2 vaccine represents an important treatment goal in caring for patients with multiple sclerosis (MS) during the ongoing COVID-19 pandemic. Previous data so far have demonstrated lower spike-specific IgG responses following two SARS-CoV-2 vaccinations in MS patients treated with sphingosine-1-phosphate (S1P) receptor modulators and anti-CD20 monoclonal antibodies (mAb) compared to other disease modifying therapies (DMTs). It is unknown whether subsequent vaccinations can augment antibody responses in these patients. OBJECTIVES: The goal of this observational study was to determine the effects of a third SARS-CoV-2

vaccination on antibody and T cell responses in MS patients treated with anti-CD20 mAb or S1P receptor modulators. METHODS: Vaccine responses in patients treated with anti-CD20 antibodies (ocrelizumab and ofatumumab) or S1P receptor modulators (fingolimod and siponimod) were evaluated before and after third SARS-CoV-2 vaccination as part of an ongoing longitudinal study. Total spike protein and spike receptor binding domain (RBD)-specific IgG responses were measured by Luminex bead-based assay. Spike-specific CD4+ and CD8+ T cell responses were measured by activation-induced marker expression. RESULTS: MS patients and healthy controls were enrolled before and following SARS-CoV-2 vaccination. A total of 31 MS patients (nÂ =Â 10 ofatumumab, nÂ =Â 13 ocrelizumab, nÂ =Â 8 S1P) and 10 healthy controls were evaluated through three SARS-CoV-2 vaccinations. Compared to healthy controls, total spike IgG was significantly lower in anti-CD20 mAb-treated patients and spike RBD IgG was significantly lower in anti-CD20 mAb and S1P-treated patients following a third vaccination. While seropositivity was 100% in healthy controls after a third vaccination, total spike IgG and spike RBD IgG seropositivity were lower in ofatumumab (60% and 60%, respectively), ocrelizumab (85% and 46%, respectively), and S1P-treated patients (100% and 75%, respectively). Longer treatment duration, including prior treatment history, appeared to negatively impact antibody responses. Spike-specific CD4+ and CD8+ T cell responses were well maintained across all groups following a third vaccination. Finally, immune responses were also compared in patients who were vaccinated prior to or following ofatumumab treatment. Antibody responses were significantly higher in those patients who received their primary SARS-CoV-2 vaccination prior to initiating ofatumumab treatment. CONCLUSIONS: This study adds to the evolving understanding of SARS-CoV-2 vaccine responses in people with MS treated with disease-modifying therapies (DMTs) known to suppress humoral immunity. Our findings provide important information for optimizing vaccine immunity in at-risk MS patient populations.

Same-Day Deaths After COVID-19 Vaccinations: Autopsy Findings in 54 Cases.

The association of demographic and socioeconomic factors with COVID-19 during pre- and post-vaccination periods: A cross-sectional study of Virginia. Sociodemographic factors have been found to be associated with the transmission of coronavirus disease 2019 (COVID-19), yet most studies focused on the period before the proliferation of vaccination and obtained inconclusive results. In this cross-sectional study, the infections, deaths, incidence rates, case fatalities, and mortalities of Virginia's 133 jurisdictions during the pre-vaccination and post-vaccination periods were compared, and their associations with demographic and socioeconomic factors were studied. The cumulative infections and deaths and medians of incidence rates, case fatalities, and mortalities of COVID-19 in 133 Virginia jurisdictions were significantly higher during the post-vaccination period than during the pre-vaccination period. A variety of demographic and socioeconomic risk factors were significantly associated with COVID-19 prevalence in Virginia. Multiple linear regression analysis suggested that demographic and socioeconomic factors contributed up to 80% of the variation in the infections, deaths, and incidence rates and up to 53% of the variation in the case fatalities and mortalities of COVID-19 in Virginia. The demographic and socioeconomic determinants differed during the pre- and post-vaccination periods. The developed multiple linear regression models could be used to effectively characterize the impact of demographic and socioeconomic factors on the infections, deaths, and incidence rates of COVID-19 in Virginia.

COVID-19 vaccines adverse events: potential molecular mechanisms. COVID-19 is an infectious disease caused by a single-stranded RNA (ssRNA) virus, known as SARS-CoV-2. The disease, since its first outbreak in Wuhan, China, in December 2019, has led to a global pandemic. The pharmaceutical industry has developed several vaccines, of different vector technologies, against the virus. Of note, among these vaccines, seven have been fully approved by WHO. However, despite the benefits of COVID-19 vaccination, some rare adverse effects have been reported and have been associated with

the use of the vaccines developed against SARS-CoV-2, especially those based on mRNA and non-replicating viral vector technology. Rare adverse events reported include allergic and anaphylactic reactions, thrombosis and thrombocytopenia, myocarditis, Bell's palsy, transient myelitis, Guillen-Barre syndrome, recurrences of herpes-zoster, autoimmunity flares, epilepsy, and tachycardia. In this review, we discuss the potential molecular mechanisms leading to these rare adverse events of interest and we also attempt an association with the various vaccine components and platforms. A better understanding of the underlying mechanisms, according to which the vaccines cause side effects, in conjunction with the identification of the vaccine components and/or platforms that are responsible for these reactions, in terms of pharmacovigilance, could probably enable the improvement of future vaccines against COVID-19 and/or even other pathological conditions.

Protracted course of SARS-CoV-2 pneumonia in moderately to severely immunocompromised patients. There have been few studies comparing the clinical characteristics and outcomes of SARS-CoV-2 pneumonia in individuals with and without moderately to severely immunocompromised conditions. We reviewed adult patients with SARS-CoV-2 infection who had radiologic evidence of pneumonia at a tertiary hospital in Seoul, South Korea, from February 2020 to April 2022. Moderately to severely immunocompromised status was defined as medical conditions or treatments that resulted in increased risk of severe COVID-19 and weakened immune response to COVID-19 vaccine as recommended by Centers for Disease Control and Prevention. The time to pneumonia development was defined as the time from symptom onset to the time when radiologic evidence of pneumonia was obtained. Viral clearance was defined as a Ct valueâ€‰>â€‰30. COVID-19-related death was defined as 90-day death following imaging-confirmed pneumonia without any other plausible cause of death. A total of 467 patients with SARS-CoV-2 pneumonia were analyzed. Of these, 102 (22%) were moderately to severely immunocompromised. The median (IQR) time to pneumonia development was significantly longer in moderately to severely immunocompromised patients (9.5 [6-14] days) than the comparator (6 [3-8] days), pâ€‰<â€‰0.001), as was the median time to viral clearance (21 versus 12Â days, pâ€‰<â€‰0.001). Moderately to severely immunocompromised status (aOR, 18.39; 95% CI, 5.80-58.30; pâ€‰<â€‰0.001) was independently associated with COVID-19-related death. Patients with moderately to severely immunocompromised conditions are likely to experience a more protracted course of SARS-CoV-2 pneumonia and a worse outcome than those without these conditions.

Drug-induced radiation recall reactions and non-anticancer drugs: A descriptive analysis from VigiBaseÂ®. Radiation recall reactions are inflammatory reactions confined to previously irradiated tissues, often of drug-induced etiology, particularly with anticancer therapies. Other drugs, in particular COVID-19 vaccines, may also be involved. To describe radiation recall reactions under non-anticancer drugs more precisely, we extracted the cases of radiation recall reactions associated with non-anticancer drugs from WHO pharmacovigilance database VigiBaseÂ®. We performed two analyses from this extraction: a global analysis and an analysis focusing on vaccination-related issues. We extracted 120 cases corresponding to 269 drugs, of which 130 were non-anticancer (22 vaccines). Among the non-anticancer drugs, tozinameran was the most reported treatment (4.46% of cases), followed by levofloxacin (2.97%) and folinic acid (2.60%), dexamethasone (2.23), and ChAdOx1 nCoV-19 vaccine and prednisone (1.86% each). Among vaccines, tozinameran (54.55% of cases) was the most reported, followed by ChAdOx1 nCoV-19 (22.73%), HPV and inactivated influenza vaccine (9.09% each), and elasomeran (4.55%). Our study first describes the occurrence of radiation recall reactions during non-anticancer treatment. It also highlights a potential safety signal with COVID-19 vaccines.

Headache attributed to SARS-CoV-2 infection, vaccination and the impact on primary headache disorders of the COVID-19 pandemic: A comprehensive review. OBJECTIVE: The objective is to

summarize the knowledge on the epidemiology, pathophysiology and management of secondary headache attributed to SARS-CoV-2 infection and vaccination; as well as to delineate their impact on primary headache disorders. METHODS: This is a narrative review of the literature regarding primary and secondary headache disorders in the setting of COVID-19 pandemic. We conducted a literature search in 2022 on PubMed, with the keywords "COVID 19" or "vaccine" and "headache" to assess the appropriateness of all published articles for their inclusion in the review. RESULTS: Headache is a common and sometimes difficult-to-treat symptom of both the acute and post-acute phase of SARS-CoV-2 infection. Different pathophysiological mechanisms may be involved, with the trigeminovascular system as a plausible target. Specific evidence-based effective therapeutic options are lacking at present. Headache attributed to SARS-CoV-2 vaccinations is also common, its pathophysiology being unclear. People with primary headache disorders experience headache in the acute phase of COVID-19 and after vaccination more commonly than the general population. Pandemic measures, forcing lifestyle changes, seemed to have had a positive impact on migraine, and changes in headache care (telemedicine) have been effectively introduced. CONCLUSIONS: The ongoing COVID-19 pandemic is a global challenge, having an impact on the development of secondary headaches, both in people with or without primary headaches. This has created opportunities to better understand and treat headache and to potentiate strategies to manage patients and ensure care.

Multispectral optoacoustic tomography to differentiate between lymph node metastases and coronavirus-19 vaccine-associated lymphadenopathy. INTRODUCTION: Worldwide mass vaccination for COVID-19 started in late 2020. COVID-19 vaccines cause benign hypermetabolic lymphadenopathies. Clinical stratification between vaccine-associated benign lymphadenopathies and malignant lymphadenopathies through ultrasound, MRI or FDG PET-CT is not feasible. This leads to unnecessary lymph node biopsies, excisions and even radical lymph node dissections. Therefore, to avoid unnecessary surgeries, we assessed whether noninvasive multispectral optoacoustic tomography (MSOT) enables a better differentiation between benign and malignant lymphadenopathies. PATIENTS AND METHODS: All patients were vaccinated for COVID-19. We used MSOT to image deoxy- and oxyhaemoglobin levels in lymph nodes of tumour patients to assess metastatic status. MSOT imaging results were compared with standard ultrasound and pathological lymph node analysis. We also evaluated the influences of gender, age and time between vaccination and MSOT measurement of lymph nodes on the measured deoxy- and oxyhaemoglobin levels in patients with reactive lymph node changes. RESULTS: Multispectral optoacoustic tomography was able to identify cancer-free lymph nodes in vivo without a single false negative (33 total lymph nodes), with 100% sensitivity and 50% specificity. A statistically significant higher deoxyhaemoglobin content was detected in patients with tumour manifestations in the lymph node (pÂ =â€‰0.02). There was no statistically significant difference concerning oxyhaemoglobin (pÂ =â€‰0.65). Age, sex and time between vaccination and MSOT measurement had statistically non-significant impact on deoxy- and oxyhaemoglobin levels in patients with reactive lymph nodes. CONCLUSION: Here, we show that MSOT measurement is an advantageous clinical approach to differentiate between vaccine-associated benign lymphadenopathy and malignant lymph node metastases based on the deoxygenation level in lymph nodes.

Epidermal necrolysis after COVID-19 vaccination: An exploratory analysis using World Health Organization VigiBase.

Cutaneous reactions after COVID-19 vaccination: A single-center retrospective study in China with 61 cases.

Autoimmunity-related neutrophilic dermatosis after coronavirus disease 2019 vaccination: A case report and literature review. Autoimmune diseases triggered by coronavirus disease 2019

(COVID-19) mRNA vaccination have been emerging. Here, we report the case of a 27-year-old Japanese man with autoimmunity-related neutrophilic dermatosis, occurring as an initial cutaneous manifestation of systemic lupus erythematosus with SjÃ¶gren syndrome after the second dose of the Pfizer/BioNTech COVID-19 vaccination. The patient presented with urticarial erythema and partially annular erythema on the trunk and extremities with severe pruritus. Histopathological analysis showed vacuolar degeneration at the dermo-epidermal junction and interstitial neutrophil infiltration. We reviewed eight patients, including the aforementioned patient, with exacerbation or new-onset of SLE after COVID-19 vaccination and found the patient had relatively mild symptoms, itchy annular erythema, and positive anti-SS-A/SS-B antibodies. COVID-19 mRNA vaccination can induce the production of type-I interferon, which plays a crucial role in the pathogenesis of SLE and may cause autoimmunity-related neutrophilic dermatosis in susceptible individuals. In the case that itchy annular erythema develops approximately 2â€‰weeks after the vaccination, the possibility of systemic or cutaneous lupus erythematosus should be considered. For an accurate diagnosis, dermatologists should obtain a recent vaccination history and perform complete antibody profiling and skin biopsy for patients presenting with annular or erythema multiforme-like lesions.

Psycho-behavioural responses of the general population to COVID-19 after mass vaccination: a cross-sectional study. BACKGROUND: Previous studies have examined public psycho-behavioural responses in the early stages of the epidemic, little is known after mass vaccination has been implemented. This study aimed to investigate the public's behavioural (adoption of COVID-19 precautionary measures) and psychological (depression, anxiety and stress) responses to COVID-19 and their relationships after the launch of the territory-wide vaccination programme in Hong Kong. METHODS: A cross-sectional survey study using anonymous online or face-to-face questionnaires was conducted between June 2021 and September 2021. A convenience sample of Hong Kong Chinese residents aged â©¾18 years were recruited online by referrals and from a university-run community vaccination centre. RESULTS: A total of 1893 valid questionnaires were received. The results showed that Hong Kong residents have high levels of adoption of precautionary measures and low levels of depression, anxiety and stress after the mass vaccination. Hierarchical regression analysis identified that in the fully adjusted model, the adoption of precautionary measures was a consistent protective factor ($Î^2$ ranged -1.51 to -1.67, $p < 0.001$) for depression, anxiety and stress amid the COVID-19 pandemic. CONCLUSIONS: This study offers new information on the public's psycho-behavioural responses to the pandemic, as well as insights into public health planning after introducing the mass vaccination.

SARS-CoV-2 vaccine excipients polyethylene glycol and trometamol do not induce mast cell degranulation, in an in vitro model for non-IgE-mediated hypersensitivity. The development of vaccines against SARS-CoV2 brought about several challenges, including the management of hypersensitivity reactions to these formulations. The search for underlying mechanisms involved in these adverse events initially focused on excipients which may trigger mast cell activation responses via non-IgE pathways: polyethylene glycol and trometamol. We sought to determine whether these components, in their pure form, were capable of stimulating mast cells directly. To test this hypothesis, we used an in vitro model for non-IgE-mediated activation that has previously shown degranulation responses induced via MRGPRX2 with known drug agonists of the receptor. Human LAD2 mast cells were incubated with different concentrations (1, 10, 50 mg/ml) of trometamol and of purified polyethylene glycol/Macrogol (molecular weights: 2,000, 3,350, 4,000, and 6,000). Mast cell degranulation was assessed using a beta-hexosaminidase read-out. Interestingly, degranulation responses for all reagents tested showed no significant differences from those obtained from the negative control (basal degranulation). Receptor-silencing assays were therefore not conducted. In summary, purified PEG and trometamol did not induce mast cell degranulation in this in vitro model

for the study of non-IgE mechanisms of drug hypersensitivity, previously shown to be useful in the investigation of MRGPRX2 ligands. Studies using complete vaccine formulations, lipid conjugates, and receptor gene variants are needed to further clarify mechanisms of vaccine hypersensitivity.

Evidence of exhausted lymphocytes after the third anti-SARS-CoV-2 vaccine dose in cancer patients. INTRODUCTION: Evidence is scant regarding the long-term humoral and cellular responses Q7 triggered by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccines in cancer patients after repeated booster doses. The possibility of T-cell exhaustion following these booster doses in this population has not yet been fully studied and remains uncertain. METHODS: In this single-center prospective observational study, we explored the specific humoral and cellular response to S1 antigen in 36 patients with solid malignancies at baseline, and after the second and third doses of the mRNA-1273 vaccine. RESULTS: A dual behavior was observed: 24 (66.7%) patients showed partial specific IFN-Î³ response after the second dose that was further enhanced after the third dose; and 11 (30.5%) already showed an optimal response after the second dose and experienced a marked fall-off of specific IFN-Î³ production after the third (4 patients negativization), which might suggest T cell exhaustion due to repetitive priming to the same antigen. One (2.8%) patient had persistently negative responses after all three doses. Seroconversion occurred in all patients after the second dose. We then studied circulating exhausted CD8+ T-cells in 4 patients from each of the two response patterns, those with increase and those with decrease in cellular response after the third booster. The patients with decreased cellular response after the booster had a higher expression of PD1(+)CD8(+) and CD57(+)PD1(+)CD8(+) exhausted T cells compared with those with an increased cellular response both in vivo and in vitro. The proportion of PD1(+)CD8(+) and CD57(+)PD1(+)CD8(+) exhausted T cells inversely correlated with IFN-Î³ production. DISCUSSION: Our preliminary data show that the two-dose SARS-CoV-2 vaccine regimen was beneficial in all cancer patients of our study. An additional booster seems to be beneficial in suboptimal vaccine seroconverters, in contrast to maximal responders that might develop exhaustion. Our data should be interpreted with caution given the small sample size and highlight the urgent need to validate our results in other independent and larger cohorts. Altogether, our data support the relevance of immunological functional studies to personalize preventive and treatment decisions in cancer patients.

Neuro-ophthalmologic symptoms after coronavirus disease 2019 vaccination: a retrospective study. BACKGROUND: There have been several studies on inflammatory ophthalmic diseases; however, few studies have reported neuro-ophthalmological symptoms, such as diplopia and ocular motor nerve palsy, after coronavirus disease 2019 (COVID-19) vaccination. Therefore, this study aimed to report neuro-ophthalmological symptoms in patients after COVID-19 vaccination. METHODS: This was a retrospective study based on the medical records of 10 patients who visited our ophthalmology clinic in 2021 with symptoms, such as diplopia (nine patients) and decreased visual acuity (one patient), and showed findings, such as ocular motor nerve palsy, after vaccination against COVID-19. RESULTS: One patient had third nerve palsy, two had sixth nerve palsy, and five had fourth nerve palsy. One patient complained of subjective binocular diplopia but all test results were normal. One patient presented with decreased visual acuity accompanied by a sudden increase in intraocular pressure and orbital cellulitis in the other eye. The symptoms improved gradually in most patients. Compared with previous studies, this study reported three cases of antiplatelet therapy that was initiated due to the older age of the patients and underlying diseases. CONCLUSION: As COVID-19 vaccines can cause neuro-ophthalmological diseases, such as ocular motor nerve palsy, patients' age and underlying diseases should be considered while administering them.

Side effects of Pfizer/BioNTech (BNT162b2) COVID-19 vaccine reported by the Birzeit University community. BACKGROUND: The Pfizer BioNTech COVID-19 vaccine was the first to receive emergency authorization and approval from the FDA. Therefore, it is preferred by most recipients;

however, many people are concerned about the vaccine's side effects. At the time of the study, December 2021, Palestine lacked a national reporting system for monitoring adverse vaccine effects. Therefore, this study investigates the post-vaccine adverse events following the Pfizer/BioNTech COVID-19 Vaccine administration in Palestine and identifies the occurrence, extent, and severity among university staff, employees, and students at Birzeit University. METHOD: A questionnaire-based retrospective cross-sectional study was conducted using a university website (Ritaj), social media platforms (e.g., Facebook and Telegram), and in-person interviews. The Chi-square, Fisher's exact, and McNemar's tests were used to investigate significant relationships. Data were analyzed using SPSS version 22. RESULTS: In total, 1137 participants completed the questionnaire, 33.2% were males, and the mean age was 21.163Â years. All participants received at least one dose of the Pfizer-BioNTech COVID-19 vaccine. Approximately one-third of participants reported no adverse effects after receiving the first, second, or third doses (34%, 33.6%, and 32.5%, respectively). The most commonly reported adverse events were fever, chills, headache, fatigue, pain and swelling at the injection site, muscle pain, and joint pain. Allergic reactions were reported by 12.7% of the participants; furthermore, participants with a history of allergy or anaphylaxis before vaccination had a significantly higher tendency for post-vaccination allergic reactions. Eight participants reported rare side effects, including 7 (0.6%) cases of thrombocytopenia and one (0.1%) case of myocarditis. Males aged less than 20Â years and smokers were significantly less likely to complain of adverse events. The number of reported side effects was significantly higher after the second vaccine dose than after the first dose. Finally, participants infected with COVID-19 before vaccination was significantly associated with side effects such as fever, chills, shortness of breath, and persistent cough. CONCLUSION: In this study, the most commonÂ post- BNT162b2 Vaccination reported self-limiting side effects similar to those reported by Pfizer/BioNTech Company. However, higher rates of allergic reactions were reported in this sample. Rare side effects, such as thrombocytopenia and myocarditis, were reported by 8 participants. COVID vaccines have been developed at an accelerated pace, and vaccine safety is a top priority; therefore, standard monitoring through a national adverse event reporting system is necessary for safety assurance. Continuous monitoring and long-term studies are required to ensure vaccine safety.

COVID-19 Vaccine-Associated Immune Thrombosis and Thrombocytopenia (VITT): Diagnostic Discrepancies and Global Implications. Vaccine-induced immune thrombotic thrombocytopenia (VITT) has been reported in association with the coronavirus disease 2019 preventative adenovirus vector-based vaccines ChAdOx1 nCoV-19 (Oxford/AstraZeneca) and Ad26.COV2.S (Janssen/Johnson & Johnson) in hundreds of recipients across the globe. VITT is characterized by thrombosis, typically at unusual sites, low fibrinogen, and elevated plasma D-dimer, generally manifesting between 4 and 28 days following vaccination. Detection of anti-platelet factor antibodies using an enzyme-linked immunosorbent assay (ELISA) is often confirmatory. Although several similar principles subside in most diagnostic criteria for VITT, the presentation of a positive ELISA assay, use of expert hematology and neurology opinion, and exclusion of possible VITT cases outside the "standard" 4 to 28-day timeframe have contributed a lack of global standardization for defining VITT. Accordingly, the global and regional incidence of VITT differs according to the diagnostic pathway and case definition used. This has influenced the public perception of VITT's severity and the decision to use adenovirus vector-based vaccines for limiting severe acute respiratory syndrome coronavirus 2 infection. We hereby delineate the recognized pathogenic mechanisms, global incidence, discrepancies in diagnostic criteria, recommended treatments, and global implications to vaccine hesitancy from this coagulopathy.

A Comprehensive Analysis of COVID-19 Vaccine Discourse by Vaccine Brand on Twitter in Korea: Topic and Sentiment Analysis. BACKGROUND: The unprecedented speed of COVID-19 vaccine

development and approval has raised public concern about its safety. However, studies on public discourses and opinions on social media focusing on adverse events (AEs) related to COVID-19 vaccine are rare. OBJECTIVE: This study aimed to analyze Korean tweets about COVID-19 vaccines (Pfizer, Moderna, AstraZeneca, Janssen, and Novavax) after the vaccine rollout, explore the topics and sentiments of tweets regarding COVID-19 vaccines, and examine their changes over time. We also analyzed topics and sentiments focused on AEs related to vaccination using only tweets with terms about AEs. METHODS: We devised a sophisticated methodology consisting of 5 steps: keyword search on Twitter, data collection, data preprocessing, data analysis, and result visualization. We used the Twitter Representational State Transfer application programming interface for data collection. A total of 1,659,158 tweets were collected from February 1, 2021, to March 31, 2022. Finally, 165,984 data points were analyzed after excluding retweets, news, official announcements, advertisements, duplicates, and tweets with <2 words. We applied a variety of preprocessing techniques that are suitable for the Korean language. We ran a suite of analyses using various Python packages, such as latent Dirichlet allocation, hierarchical latent Dirichlet allocation, and sentiment analysis. RESULTS: The topics related to COVID-19 vaccines have a very large spectrum, including vaccine-related AEs, emotional reactions to vaccination, vaccine development and supply, and government vaccination policies. Among them, the top major topic was AEs related to COVID-19 vaccination. The AEs ranged from the adverse reactions listed in the safety profile (eg, myalgia, fever, fatigue, injection site pain, myocarditis or pericarditis, and thrombosis) to unlisted reactions (eg, irregular menstruation, changes in appetite and sleep, leukemia, and deaths). Our results showed a notable difference in the topics for each vaccine brand. The topics pertaining to the Pfizer vaccine mainly mentioned AEs. Negative public opinion has prevailed since the early stages of vaccination. In the sentiment analysis based on vaccine brand, the topics related to the Pfizer vaccine expressed the strongest negative sentiment. CONCLUSIONS: Considering the discrepancy between academic evidence and public opinions related to COVID-19 vaccination, the government should provide accurate information and education. Furthermore, our study suggests the need for management to correct the misinformation related to vaccine-related AEs, especially those affecting negative sentiments. This study provides valuable insights into the public discourses and opinions regarding COVID-19 vaccination.

Outcomes of COVID-19 in patients vaccinated and unvaccinated against SARS-CoV-2 and suffering from pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. INTRODUCTION: Pulmonary arterial hypertension (PAH) and chronic thromboembolic pulmonary hypertension (CTEPH) lead to progressive right heart failure. The mortality rates in PAH and CTEPH patients due to COVIDâ€‘19 are high, and vaccination against COVIDâ€‘19 is recommended in this group. OBJECTIVES: We analyzed the incidence and outcomes of COVIDâ€‘19in the PAH/CTEPH patients for 2 years of the pandemic, as well as the predictors of worse outcomes of COVIDâ€‘19 in this group. PATIENTS AND METHODS: PAH/CTEPH patient data for this observational, cohort study were obtained from 3 pulmonary hypertension centers between March 11, 2020 and March 11, 2022. RESULTS: A total of 364 consecutive patients with PAH/CTEPH (248/122; 232 women [64%]; median [interquartile range] age, 61 years [18-92]) were included in the study. All the patients had advanced pulmonary hypertension at baseline. Eightyâ€‘five patients (23%) suffered from COVIDâ€‘19. Seven of them (8%), all of whom were unvaccinated, died of COVIDâ€‘19. The unvaccinated patients suffered from COVIDâ€‘19 more often than the vaccinated ones (46% vs 9%; P <0.001). As many as 31% of the PAH/CTEPH patients with COVIDâ€‘19 needed hospitalization, in 8% of cases in the intensive care unit. Age equal to or above 65 years and severe pulmonary hypertension defined as a World Health Organization functional class 3 or 4 were associated with severe COVIDâ€‘19 in the PAH/CTEPH patients. CONCLUSIONS: The vaccinated PAH/CTEPH patients suffered from COVIDâ€‘19 less frequently than the unvaccinated ones. The mortality rate and hospitalization due to COVIDâ€‘19

were higher in the PAH/CTEPH patients than in the general population. All efforts should be made to convince the PAH/CTEPH patients to vaccinate against COVIDâ€‘19.

Changes of ECG parameters after BNT162b2 vaccine in the senior high school students. The purpose of this study is to determine the ECG parameter change and the efficacy of ECG screening for cardiac adverse effect after the second dose of BNT162b2 vaccine in young population. In December 2021, in cooperation with the school vaccination system of Taipei City government, we performed a ECG screening study during the second dose of BNT162b2 vaccines. Serial comparisons of ECGs and questionnaire survey were performed before and after vaccine in four male-predominant senior high schools. Among 7934 eligible students, 4928 (62.1%) were included in the study. The male/female ratio was 4576/352. In total, 763 students (17.1%) had at least one cardiac symptom after the second vaccine dose, mostly chest pain and palpitations. The depolarization and repolarization parameters (QRS duration and QT interval) decreased significantly after the vaccine with increasing heart rate. Abnormal ECGs were obtained in 51 (1.0%) of the students, of which 1 was diagnosed with mild myocarditis and another 4 were judged to have significant arrhythmia. None of the patients needed to be admitted to hospital and all of these symptoms improved spontaneously. Using these five students as a positive outcome, the sensitivity and specificity of this screening method were 100% and 99.1%, respectively.Â Conclusion: Cardiac symptoms are common after the second dose of BNT162b2 vaccine, but the incidences of significant arrhythmias and myocarditis are only 0.1%. The serial ECG screening method has high sensitivity and specificity for significant cardiac adverse effect but cost effect needs further discussed. What is Known: â€¢ The incidence of cardiac adverse effects was reported to be as high as 1.5 per 10 000 persons after the second dose BNT162b2 COVID-19 vaccine in the young male population based on the reporting system. What is New: â€¢ Through this mass ECG screening study after the second dose of BNT162b2 vaccine we found: (1) The depolarization and repolarization parameters (QRS duration and QT interval) decreased significantly after the vaccine with increasing heart rate; (2) the incidence of post-vaccine myocarditis and significant arrhythmia are 0.02% and 0.08%; (3) The serial ECG screening method has high sensitivity and specificity for significant cardiac adverse effect.

Memory impairment among recovered COVID-19 patients: The prevalence and risk factors, a retrospective cohort study. The aim of this study is to demonstrate the prevalence of the long-term side effects of COVID-19, namely memory impairment among recovered patients, and obtaining the associated factors that link with memory impairment. It is a cross-sectional retrospective cohort study, that has been conducted from September to November 2022 in Iraq. People who were previously infected with COVID-19 were included. The study was performed by asking people to complete a questionnaire platform by either online or face-to-face interview. The Memory Assessment Clinic-Q (MAC-Q) test was utilized, scores that are equal or higher than 25 are indicative of memory decline. Thousand two hundred and eighty-seven participated in this study. However, only 1157 were included in the final analysis. Three hundred ninety-nine (34.49%) have memory impairment after COVID-19 recovery. Female gender, older age group, repeated exposure to COVID-19 infections, severe diseases, and exposure to multiple SARS-CoV-2 variants were independent risk factors of memory deficit in post-COVID-19 survivors with a p-value of 0.0001, 0.02, 0.0001, 0.001, 0.0001 respectively. It is crucial to pay particular attention to psychosocial rehabilitation of such risky groups. COVID-19 vaccine administrations with booster shots are necessary steps to decrease the disease incidence and avoid subsequent post-COVID-19 symptoms.

Acute Retinal Pigment Epitheliitis following Vaccination. We present a rare case of acute retinal pigment epitheliitis (ARPE) following vaccination. An 18-year-old Japanese man visited our hospital with a 5-day history of a central scotoma in the right eye. He had received the second dose of coronavirus disease 2019 vaccination (BNT162b2 mRNA, Pfizer-BioNTech) 1 month prior, following

which he developed a low-grade fever of 37.3-37.5Â°C for 2 days accompanied by joint pain. Although he had received influenza vaccination 5 days prior to this presentation, no systemic symptoms other than injection site pain were observed. Blood test results were unremarkable. Ophthalmological examination revealed a decimal best-corrected visual acuity (BCVA) of 0.8 and 1.2 in the right and left eyes, respectively. Intraocular pressure was 15 mm Hg in both eyes. Intraocular inflammation was not observed. Fundus examination revealed a localized lesion of pigment stippling associated with yellowish hypopigmentation in the fovea. Fluorescein angiography revealed slight transmission hyperfluorescence without leakage. Optical coherence tomography (OCT) revealed disruption of the external limiting membrane (ELM), ellipsoid zone (EZ), and interdigitation zone (IZ). We diagnosed the patient with ARPE in the right eye. The patient was followed up without treatment. Five weeks after onset, the central scotoma in the right eye disappeared, and patient's BCVA in the right eye improved to 1.5. OCT showed improvement in ELM and EZ continuity in the right eye, but IZ remained disruptive. Although the exact pathophysiology of the association between ARPE and these vaccinations is unclear, ARPE may develop after the vaccination.

Vaccine adverse event reporting system (VAERS): Evaluation of 31 years of reports and pandemics' impact. BACKGROUND: Vaccine adverse event reporting system (VAERS) was established in the United States (U.S.) as an early warning system with a main purpose of collecting post-marketing Adverse events following immunizations (AEFIs) reports to monitor the vaccine safety and to mitigate the risks from vaccines. During the coronavirus diseases 2019 (COVID-19) pandemic, VAERS got more attention as its important role in monitoring the safety of the vaccines. The aim of this study was to investigate VAERS patterns, reported AEFI, vaccines, and impact of different pandemics since its inception. METHODS: This was an observational study using VARES data from 2/7/1990 to 12/11/2021. Patterns of reports over years were first described, followed by a comparison of reports statistics per year. Furthermore, a comparison of incidents (death, ER visits, etc.) statistics over years, in addition to statistics of each vaccine were calculated. Moreover, each incident's statistics for each vaccine were calculated and top vaccines were reported. All analyses were conducted using R (Version 1.4.1717) and Excel for Microsoft 365. RESULTS: There were 1,396,280 domestic and 346,210 non-domestic reports during 1990-2021, including 228 vaccines. For both domestic and non-domestic reports, year of 2021 had the highest reporting rate (48.52Â % and 70.33Â %), in addition a notable change in AEFIs patterns were recorded during 1991, 1998, 2000, 2006, 2009, 2011, and 2017. AEFIs were as follow: deaths (1.00Â % and 4.08Â %), ER or doctor visits (13.37Â % and 2.27Â %), hospitalizations (5.84Â % and 27.78Â %), lethal threat (1.42Â % and 4.38Â %), and disabilities (1.4Â % and 7.96Â %). Pyrexia was the top reported symptom during the past 31Â years, except for 2021 where headache was the top one. COVID-19 vaccines namely Moderna, Pfizer-Biontech, and Janssen were the top 3 reported vaccines with headache, pyrexia, and fatigue as the top associated AEFIs. Followed by Zoster, Seasonal Influenza, Pneumococcal, and Human papillomavirus vaccines. CONCLUSIONS: The large data available in VARES make it a useful tool for detecting and monitoring vaccine AEFIs. However, its usability relies on understating the limitations of this surveillance system, the impact of governmental regulations, availability of vaccines, and public health recommendations on the reporting rate.

COVID-19 and thyroid function: What do we know so far? Coronavirus disease 2019 (COVID-19) was characterized as a pandemic in March, 2020 by the World Health Organization. COVID-19 is a respiratory syndrome that can progress to acute respiratory distress syndrome, multiorgan dysfunction, and eventually death. Despite being considered a respiratory disease, it is known that other organs and systems can be affected in COVID-19, including the thyroid gland. Thyroid gland, as well as hypothalamus and pituitary, which regulate the functioning of most endocrine glands, express angiotensin-converting enzyme 2 (ACE2), the main protein that functions as a receptor to which

SARS-CoV-2 binds to enter host cells. In addition, thyroid gland is extremely sensitive to changes in body homeostasis and metabolism. Immune system cells are targets for thyroid hormones and T3 and T4 modulate specific immune responses, including cell-mediated immunity, natural killer cell activity, the antiviral action of interferon (IFN) and proliferation of T- and B-lymphocytes. However, studies show that patients with controlled hypothyroidism and hyperthyroidism do not have a higher prevalence of COVID-19, nor do they have a worse prognosis when infected with the virus. On the other hand, retrospective observational studies, prospective studies, and case reports published in the last two years reported abnormal thyroid function related to acute SARS-CoV-2 infection or even several weeks after its resolution. Indeed, a variety of thyroid disorders have been documented in COVID-19 patients, including non-thyroidal illness syndrome (NTIS), subacute thyroiditis and thyrotoxicosis. In addition, thyroid disease has already been reported as a consequence of the administration of vaccines against SARS-CoV-2. Overall, the data revealed that abnormal thyroid function may occur during and in the convalescence post-COVID condition phase. Although the cellular and molecular mechanisms are not completely understood, the evidence suggests that the "cytokine storm" is an important mediator in this context. Thus, future studies are needed to better investigate the pathophysiology of thyroid dysfunction induced by COVID-19 at both molecular and clinical levels.

The Influence of Two Priming Doses of Different Anti-COVID-19 Vaccines on the Production of Anti-SARS-CoV-2 Antibodies After the Administration of the Pfizer/BioNTech Booster. INTRODUCTION: A global vaccination program was implemented in late 2020 to end the pandemic caused by the SARS-CoV-2 virus. However, the immune response elicited by the vaccines proved to be insufficient due to the rapid emergence of new viral mutations. Therefore, the factors influencing cellular and humoral immune responses after the administration of different vaccines against SARS-CoV2 need to be identified. MATERIALS: In the present study, anti-SARS-CoV-2 antibody titers were analyzed 20 to 50 days after the administration of a third (booster) dose of the BNT162b2 vaccine in 192 residents of the city of Olsztyn (Poland) primed with two AstraZeneca or Pfizer/BioNTech vaccines. METHODS: Antibody titers were determined in venous blood serum in the ECLIA test using the Cobas e411 Roche analyzer. RESULTS: The study revealed that persons who received three doses of the Pfizer/BioNTech vaccine had significantly higher antibody titers than those who received two doses of AstraZeneca and a booster dose of Pfizer/BioNTech.

Commentary: Bullous pemphigoid associated with COVID-19 vaccines: An Italian multicenter study.

Case report: A rare case of Rosai-Dorfman-Destombes disease after the COVID-19 infection. Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is known to cause immune dysregulation and, therefore, has varied and often rare presentations. Rosai-Dorfman-Destombes disease (RDD) is an unusual non-Langerhans cell (non-LC) histiocytosis presenting with massive lymphadenopathy and various systemic symptoms. A 55-year-old Asian-American woman with no significant medical history or recent use of new drugs initially presented with cervical lymphadenopathy and urticarial rash 1 week after receiving the COVID-19 messenger RNA (mRNA) vaccine (Moderna, mRNA-1273) against SARS-CoV-2. The biopsy of the skin rash was consistent with a drug reaction. Approximately 2 months later, she developed mild flu-like symptoms and was diagnosed with a COVID-19 infection. Her symptoms were mild and self-resolving. Approximately 3 months later, she developed a generalized patchy erythematous rash on the face and the body that gradually worsened; diffuse lymphadenopathy involving the bilateral cervical, axillary, and inguinal areas; and constitutional symptoms. Laboratory results were consistent with lymphopenia, anemia, and an elevated sedimentation rate. Supraclavicular lymph node biopsy showed Rosai-Dorfman disease with a marked polyclonal plasmacytosis. She was started on a tapering dose of corticosteroids and showed clinical improvements over the next few weeks. Herein,

we present a rare case of a histiocytic disorder that developed after contracting the SARS-COV2 infection in the event of receiving a recent mRNA COVID vaccination.

Omicron B.1.1.529 variant infections associated with severe disease are uncommon in a COVID-19 under-vaccinated, high SARS-CoV-2 seroprevalence population in Malawi. BACKGROUND: The B.1.1.529 (Omicron) variant of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has resulted in the fourth COVID-19 pandemic wave across the southern African region, including Malawi. The seroprevalence of SARS-CoV-2 antibodies and their association with epidemiological trends of hospitalisations and deaths are needed to aid locally relevant public health policy decisions. METHODS: We conducted a population-based serosurvey from December 27, 2021 to January 17, 2022, in 7 districts across Malawi to determine the seroprevalence of SARS-CoV-2 antibodies. Serum samples were tested for antibodies against SARS-CoV-2 receptor binding domain using WANTAI SARS-CoV-2 Receptor Binding Domain total antibody commercial enzyme-linked immunosorbent assay (ELISA). We also evaluated COVID-19 epidemiologic trends in Malawi, including cases, hospitalisations and deaths from April 1, 2021 through April 30, 2022, collected using the routine national COVID-19 reporting system. A multivariable logistic regression model was developed to investigate the factors associated with SARS-CoV-2 seropositivity. FINDINGS: Serum samples were analysed from 4619 participants (57% female; 60% aged 18-50 years), of whom 878/3794 (23%) of vaccine eligible adults had received a single dose of any COVID-19 vaccine. The overall assay-adjusted seroprevalence was 83.7% (95% confidence interval (CI), 79.3%-93.4%). Seroprevalence was lowest among children <13 years of age (66%) and highest among adults 18-50 years of age (82%). Seroprevalence was higher among vaccinated compared to unvaccinated participants (1 dose, 94% vs. 77%, adjusted odds ratio 4.89 [95% CI, 3.43-7.22]; 2 doses, 97% vs. 77%, aOR 6.62 [95% CI, 4.14-11.3]). Urban residents were more likely to be seropositive than those from rural settings (91% vs. 78%, aOR 2.76 [95% CI, 2.16-3.55]). There was at least a two-fold reduction in the proportion of hospitalisations and deaths among the reported cases in the fourth wave compared to the third wave (hospitalisations, 10.7% (95% CI, 10.2-11.3) vs. 4.86% (95% CI, 4.52-5.23), pÂ <Â 0.0001; deaths, 3.48% (95% CI, 3.18-3.81) vs. 1.15% (95% CI, 1.00-1.34), pÂ <Â 0.0001). INTERPRETATION: We report reduction in proportion of hospitalisations and deaths from SARS-CoV-2 infections during the Omicron variant dominated wave in Malawi, in the context of high SARS-CoV-2 seroprevalence and low COVID-19 vaccination coverage. These findings suggest that COVID-19 vaccination policy in high seroprevalence settings may need to be amended from mass campaigns to targeted vaccination of reported at-risk populations. FUNDING: Supported by the Bill and Melinda Gates Foundation (INV-039481).

Post-COVID vaccination Guillain-Barre syndrome.

Post-COVID-19 condition at 6 months and COVID-19 vaccination in non-hospitalised children and young people. OBJECTIVES: To describe the physical and mental health of children and young people (CYP) 6â€‰months after infection with SARS-CoV-2 and explore whether this varies by COVID-19 vaccination. DESIGN: A non-hospitalised, national cohort of people aged 11-17â€‰years old with PCR-confirmed SARS-CoV-2 infection and PCR negatives matched at study invitation, by age, sex, region and date of testing who completed questionnaires 6â€‰months after PCR testing. The questionnaire included 21 symptoms and standardised scales (eg, EQ-5D-Y and Chalder Fatigue Scale). RESULTS: 6407 test-positive and 6542 test-negative CYP completed the 6-month questionnaire: 60.9% of test-positive vs 43.2% of test-negative CYP reported at least one symptom 6â€‰months post-test; 27.6% of test-positive vs 15.9% of test-negative CYP reported 3+ symptoms. Common symptoms at 6â€‰months were tiredness and shortness of breath among both test-positive and test-negative CYP; however, the prevalence of both was higher in test-positive (38.4% and 22.8%, respectively) compared with test-negative CYP (26.7% and 10.9%, respectively). 24.5% test-positive vs 17.8% test-negative CYP met the Delphi research definition of long COVID. Mental

health, well-being, fatigue and health-related quality of life scores were similar among test-positive and test-negative CYP 6â€‰months post-test. Similarly, symptomatology was similar among COVID-19-vaccinated and COVID-19-unvaccinated test-positive and test-negative CYP. CONCLUSIONS: Six-months post-PCR testing, CYP who tested positive for SARS-CoV-2 had similar symptoms to those who tested negative, but test-positive CYP had higher symptom prevalence. Mental health, well-being, fatigue and health-related quality of life were similar among test-positive and test-negative CYP, and symptoms at 6â€‰months were similar in COVID-19 vaccinated and unvaccinated. TRIAL REGISTRATION NUMBER: ISRCTN 34804192.

A postmortem study of patients vaccinated for SARS-CoV-2 in Colombia. INTRODUCTION AND OBJECTIVE: A new coronavirus produces a disease designated as coronavirus disease 2019 (COVID-19). Vaccination against COVID-19 has resulted in decreased mortality. Postmortems of vaccinated patients play an important part in the forensic analysis of adverse effects after vaccination, which is essential for determining its efficacy and security. The main objective of this study was to describe the results of autopsies of patients vaccinated for SARS-CoV-2 carried out in two major centers in Colombia. MATERIALS AND METHODS: A descriptive cross-sectional study of 121 autopsies was performed following Colombian regulations in two main hospitals in BogotÃ¡, Colombia, between March 1st and April 31st, 2021. RESULTS: 118 of the 121 patients (97.52%) had been vaccinated with CoronaVac (Sinovac); only 3 had received other vaccines. Sudden cardiac death was the leading cause of death, with pulmonary embolism another critical finding. No relation between the cause of death and vaccination against SARS-CoV-2 was found. CONCLUSIONS: A clinical autopsy is a vital for an accurate post-mortem diagnosis. Any relation between the SARS-CoV-2 vaccine and the cause of death should be carefully studied in order to provide the general public with evidence-based information about the safety of the vaccination.

Immunisation schedule of the Spanish Association of Paediatrics: 2023 Recommendations. As it does every year, the CAV-AEP publishes the update of its recommendations for the use of vaccines in children, adolescents and pregnant women residing in Spain. The 2â€¯+â€¯1 schedule is maintained in infants (at 2, 4 and 11 months), including preterm infants, with the hexavalent vaccine (DTaP-IPV-Hib-HB) and the pneumococcal 13-valent conjugate vaccine. A booster dose with DTaP-IPV is needed at 6 years for those who received the 2â€¯+â€¯1 series with hexavalent vaccine as infants, in addition to 1 dose of dTap in adolescence. Routine vaccination of pregnant women with a dose of dTap is recommended in each pregnancy, preferably between weeks 27 and 32 of gestation, although can be given from 20 weeks if there is risk of preterm delivery. All infants should receive the rotavirus vaccine (2-3 doses) and the 4CMenB vaccine (2â€¯+â€¯1 series). All children aged 6-59 months should be vaccinated against influenza each year. The MenACWY vaccine should be given routinely at 12 months of age and in adolescence between ages 12 and 18 years. The recommendations for the MMR vaccine (12 months and 3-4 years) and varicella vaccine (15 months and 3-4 years) also remain unchanged, using the MMRV vaccine for the second dose. Recommendations for the use of SARS-CoV-2 vaccines in the paediatric age group will be updated periodically on the CAV-AEP website. The HPV vaccine is indicated in all adolescents, regardless of sex, at age 12 years. Novelties include the recommendation of routine administration of nirsevimab to neonates and infants aged less than 6 months for passive immunization against RSV, and the recommendations regarding the hexavalent vaccine are consolidated in a single section.

Retinal vascular occlusions in COVID-19 infection and vaccination: a literature review. PURPOSE: Abnormal hypercoagulability and increased thromboembolic risk are common in patients with coronavirus disease (COVID-19). COVID-19 has been suggested to cause retinal vascular damage, with several studies on COVID-19 patients with retinal vascular occlusions. We reviewed and investigated studies on retinal vascular occlusions in patients diagnosed with COVID-19 and in those vaccinated for

COVID-19. METHODS: Studies that reported retinal vascular occlusion in COVID-19 patients or in vaccinated people were identified using the terms "retinal occlusion," together with "severe acute respiratory syndrome coronavirus 2", "SARS-CoV-2," "COVID-19," "coronavirus," and "vaccine," through systematic searches of PubMed and Google Scholar databases until January 7, 2022. RESULTS: Thirteen cases of retinal artery occlusion (RAO) and 14 cases of retinal vein occlusion (RVO) were identified among patients diagnosed with COVID-19. Half of the patients with RAO or RVO revealed no systemic disorders except current or past COVID-19, and ocular symptoms were the initial presentation in five cases. Among patients with RAO, most presented with central RAO at 1-14Â days of COVID-19 diagnosis, with abnormal coagulation and inflammatory markers. Among those with RVO, two-thirds presented with central RVO and one-third with RVO. Eleven cases with acute macular neuroretinopathy (AMN) and/or paracentral acute middle maculopathy (PAMM) were reported among patients with COVID-19, presenting scotoma resolved spontaneously in most cases. Among the 26 cases vaccinated with either mRNA or adenoviral vector vaccines for COVID-19 and presenting retinal vascular occlusions, there were more RVO cases than RAO cases, and ocular symptoms mostly occurred within 3Â weeks after vaccination. One case presented bilateral AMN and PAMM after COVID-19 vaccination. CONCLUSION: Retinal vascular occlusions might be a manifestation of COVID-19, although rare, especially in patients at risk of systemic hypercoagulability and thromboembolism. For COVID-19 vaccines, the causal relationship is controversial because there are few case reports of retinal vascular occlusions after COVID-19 vaccination.

Chronic pain in post-COVID syndrome. Our body senses two types of pain, acute and chronic. Acute pain lasts for a short time. It occurs when our body wants to protect us from a dangerous situation. This way, our nerves are telling us that something is wrong. But if some time passes since our injury, treatment or surgery and the pain or discomfort persists, we are speaking of chronic pain. It is often difficult to determine its intensity or even prove its existence. The discomfort and pain are not relieved and physical pain may be accompanied by mental issues. At present, during the COVID-19 pandemic, chronic pain is becoming more prominent, and it is also associated with the post-COVID syndrome. In their efforts to help patients suffering from COVID-19, many new treatment protocols have been prepared and various antiviral drugs and other potentially useful drugs have been used (often without prior approval or testing). Basically, it was a kind of 'experimental' treatment. At present, thanks to quick therapy decisions and as part of COVID-19 prevention, we have succeeded in stabilising the situation all over the world. A relatively fast development of vaccines against SARS-CoV-2 with a view to achieve collective immunity has greatly contributed to this. On the other hand, 'quick decisions' have contributed to other significant issues which we are beginning to deal with now, i.e, in the effort to defeat the virus, many experts regarded the adverse effects of the medications used to be of secondary importance. In the article we would like to point out the other side of the 'successful' treatment of COVID-19, namely the possible iatrogenic conditions which significantly contribute to the post-COVIDâ€‘19 syndrome and chronic pain. The importance of preventive measures over uncertain result of COVID-19 treatment is emphasised (Tab. 4, Fig. 1, Ref. 50). Text in PDF www.elis.sk Keywords: iatrogenic conditions; chronic pain; co-morbidity; pain syndrome; pandemic; post-COVIDâ€‘19 syndrome.

Antibody response, neutralizing potency, and transplacental antibody transfer following SARS-CoV-2 infection versus mRNA-1273, BNT162b2 COVID-19 vaccination in pregnancy. OBJECTIVE: To improve our understanding of the immune response, including the neutralization antibody response, following COVID-19 vaccination in pregnancy. METHODS: This was a prospective cohort study comprising patients with PCR-confirmed SARS-CoV-2 infection and patients who received both doses of mRNA COVID-19 vaccine (mRNA-1273, BNT162b2) in pregnancy recruited from two hospitals in Atlanta, GA, USA. Maternal blood and cord blood at delivery were assayed for anti-receptor binding

domain (RBD) IgG, IgA and IgM, and neutralizing antibody. The detection of antibodies, titers, and maternal to fetal transfer ratios were compared. RESULTS: Nearly all patients had detectable RBD-binding IgG in maternal and cord samples. The vaccinated versus infected cohort had a significantly greater proportion of cord samples with detectable neutralizing antibody (94% vs. 28%, PÂ <â€‰0.001) and significantly higher transfer ratios for RBD-specific IgG and neutralizing antibodies with a transfer efficiency of 105% (vs. 80%, PÂ <â€‰0.001) and 110% (vs. 90%, PÂ <â€‰0.001), respectively. There was a significant linear decline in maternal and cord blood RBD-specific IgG and neutralizing antibody titers as time from vaccination to delivery increased. CONCLUSIONS: Those who receive the mRNA COVID-19 vaccine mount an immune response that is equivalent to-if not greater than-those naturally infected by SARS-CoV-2 during pregnancy.

Type of vaccine and immunosuppressive therapy but not diagnosis critically influence antibody response after COVID-19 vaccination in patients with rheumatic disease. OBJECTIVE: The development of sufficient COVID-19 vaccines has been a big breakthrough in fighting the global SARS-CoV-2 pandemic. However, vaccination effectiveness can be reduced in patients with autoimmune rheumatic diseases (AIRD). The aim of this study was to identify factors that lead to a diminished humoral vaccination response in patients with AIRD. METHODS: Vaccination response was measured with a surrogate virus neutralisation test and by testing for antibodies directed against the receptor-binding-domain (RBD) of SARS-CoV-2 in 308 fully vaccinated patients with AIRD. In addition, 296 immunocompetent participants were investigated as a control group. Statistical adjusted analysis included covariates with a possible influence on antibody response. RESULTS: Patients with AIRD showed lower antibody responses compared with immunocompetent individuals (median neutralising capacity 90.8% vs 96.5%, p<0.001; median anti-RBD-IgG 5.6 S/CO vs 6.7 S/CO, p<0.001). Lower antibody response was significantly influenced by type of immunosuppressive therapy, but not by rheumatic diagnosis, with patients under rituximab therapy developing the lowest antibody levels. Patients receiving mycophenolate, methotrexate or janus kinase inhibitors also showed reduced vaccination responses. Additional negative influencing factors were vaccination with AZD1222, old age and shorter intervals between the first two vaccinations. CONCLUSION: Certain immunosuppressive therapies are associated with lower antibody responses after vaccination. Additional factors such as vaccine type, age and vaccination interval should be taken into account. We recommend antibody testing in at-risk patients with AIRD and emphasise the importance of booster vaccinations in these patients.

Mild COVID-19 despite inadequate antibody response after repeated vaccinations in rheumatic disease patients with rituximab-induced B cell depletion: a case series.

Circulating Spike Protein Detected in Post-COVID-19 mRNA Vaccine Myocarditis. BACKGROUND: Cases of adolescents and young adults developing myocarditis after vaccination with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-targeted mRNA vaccines have been reported globally, but the underlying immunoprofiles of these individuals have not been described in detail. METHODS: From January 2021 through February 2022, we prospectively collected blood from 16 patients who were hospitalized at Massachusetts General for Children or Boston Children's Hospital for myocarditis, presenting with chest pain with elevated cardiac troponin T after SARS-CoV-2 vaccination. We performed extensive antibody profiling, including tests for SARS-CoV-2-specific humoral responses and assessment for autoantibodies or antibodies against the human-relevant virome, SARS-CoV-2-specific T-cell analysis, and cytokine and SARS-CoV-2 antigen profiling. Results were compared with those from 45 healthy, asymptomatic, age-matched vaccinated control subjects. RESULTS: Extensive antibody profiling and T-cell responses in the individuals who developed postvaccine myocarditis were essentially indistinguishable from those of vaccinated control subjects, despite a modest increase in cytokine production. A notable finding was that markedly elevated levels

of full-length spike protein (33.9Â±22.4 pg/mL), unbound by antibodies, were detected in the plasma of individuals with postvaccine myocarditis, whereas no free spike was detected in asymptomatic vaccinated control subjects (unpaired t test; P<0.0001). CONCLUSIONS: Immunoprofiling of vaccinated adolescents and young adults revealed that the mRNA vaccine-induced immune responses did not differ between individuals who developed myocarditis and individuals who did not. However, free spike antigen was detected in the blood of adolescents and young adults who developed post-mRNA vaccine myocarditis, advancing insight into its potential underlying cause.

Severe coronary artery spasm after administration of a 5-hydroxytryptamine type 1 receptor agonist in a patient with new-onset Graves' disease and myocarditis after SARS-CoV2 vaccination. BACKGROUND: Coronary artery spasm is a well-known potential side effect of selective 5-hydroxytryptamine type 1 (5HT1) receptor agonists and, therefore, contraindicated in patients with cardiovascular disease. SARS-CoV-2 vaccination has been associated with myocarditis, mainly in young men. CASE SUMMARY: A 55-year-old man with longstanding cluster headache, treated with the 5HT1-agonist Sumatriptan for ten years, received the mRNA-1273 SARS-CoV-2 booster vaccine. Four days later, he developed severe retrosternal pain several minutes after administering Sumatriptan with electrographic ST-elevation and a raised high-sensitivity cardiac troponin-T (hs-cTnT). Coronary angiogram was normal, but a diagnosis of acute myocarditis and hyperthyroidism secondary to Graves' disease was made. DISCUSSION: We present a case of severe coronary artery spasm induced by a 5HT1-agonist secondary to newly diagnosed Graves' disease and myocarditis. The mRNA-1273 SARS-CoV-2 booster vaccine administered four days before admission probably triggered both immunoreactions.

Deep Vein Thrombosis after COVID-19 mRNA Vaccination in a Young Man with Inferior Vena Cava Anomaly Leading to Recurrent Deep Vein Thrombosis. Severe side effects of adenoviral-vectored-DNA COVID-19 vaccines such as thrombosis have been reported. Herein, we report a case of sudden massive deep vein thrombosis (DVT) in a young man with inferior vena cava anomaly 20 hours after the second dose of the mRNA vaccine for COVID-19. There was recurrence of iliofemoral DVT after one year, despite complete resolution and administration of prophylactic anticoagulants. We suggest that the sudden episode was triggered by the vaccine rather than the venous anomaly, which can be associated with recurrence due to inadequate venous return through the small and tortuous infrarenal veins or increased venous pressure and stasis. There are no standard guidelines for the management of DVT following mRNA vaccination. However, we highlight the importance of initial workups, regular follow-ups, and standard treatment options, including the continuous administration of prophylactic anticoagulants which should be considered to prevent recurrence.

SARS-CoV-2 mRNA vaccination exposes progressive adaptive immune dysfunction in patients with chronic lymphocytic leukemia. Chronic lymphocytic leukemia (CLL) patients have lower seroconversion rates and antibody titers following SARS-CoV-2 vaccination, but the reasons for this diminished response are poorly understood. Here, we studied humoral and cellular responses in 95 CLL patients and 30 healthy controls after two BNT162b2 or mRNA-2173 mRNA immunizations. We found that 42% of CLL vaccinees developed SARS-CoV-2-specific binding and neutralizing antibodies (NAbs), while 32% had no response. Interestingly, 26% were seropositive, but had no detectable NAbs, suggesting the maintenance of pre-existing endemic human coronavirus-specific antibodies that cross-react with the S2 domain of the SARS-CoV-2 spike. These individuals had more advanced disease. In treatment-naÃ¯ve CLL patients, mRNA-2173 induced 12-fold higher NAb titers and 1.7-fold higher response rates than BNT162b2. These data reveal a graded loss of immune function, with pre-existing memory being preserved longer than the capacity to respond to new antigens, and identify mRNA-2173 as a superior vaccine for CLL patients.

Personalized predictions of adverse side effects of the COVID-19 vaccines. BACKGROUND: Misconceptions about adverse side effects are thought to influence public acceptance of the Coronavirus disease 2019 (COVID-19) vaccines negatively. To address such perceived disadvantages of vaccines, a novel machine learning (ML) approach was designed to generate personalized predictions of the most common adverse side effects following injection of six different COVID-19 vaccines based on personal and health-related characteristics. METHODS: Prospective data of adverse side effects following COVID-19 vaccination in 19943 participants from Iran and Switzerland was utilized. Six vaccines were studied: The AZD1222, Sputnik V, BBIBP-CorV, COVAXIN, BNT162b2, and the mRNA-1273 vaccine. The eight side effects were considered as the model output: fever, fatigue, headache, nausea, chills, joint pain, muscle pain, and injection site reactions. The total input parameters for the first and second dose predictions were 46 and 54 features, respectively, including age, gender, lifestyle variables, and medical history. The performances of multiple ML models were compared using Area Under the Receiver Operating Characteristic Curve (ROC-AUC). RESULTS: The total number of people receiving the first dose of the AZD1222, Sputnik V, BBIBP-CorV, COVAXIN, BNT162b2, and mRNA-1273 were 6022, 7290, 5279, 802, 277, and 273, respectively. For the second dose, the numbers were 2851, 5587, 3841, 599, 242 and 228. The Logistic Regression model for predicting different side effects of the first dose achieved ROC-AUCs of 0.620-0.686, 0.685-0.716, 0.632-0.727, 0.527-0.598, 0.548-0.655, 0.545-0.712 for the AZD1222, Sputnik V, BBIBP-CorV, COVAXIN, BNT162b2 and mRNA-1273 vaccines, respectively. The second dose models yielded ROC-AUCs of 0.777-0.867, 0.795-0.848, 0.857-0.906, 0.788-0.875, 0.683-0.850, and 0.486-0.680, respectively. CONCLUSIONS: Using a large cohort of recipients vaccinated with COVID-19 vaccines, a novel and personalized strategy was established to predict the occurrence of the most common adverse side effects with high accuracy. This technique can serve as a tool to inform COVID-19 vaccine selection and generate personalized factsheets to curb concerns about adverse side effects.

Systematic review and meta-analysis of neonatal outcomes of COVID-19 vaccination in pregnancy. BACKGROUND: The safety of coronavirus disease 2019 (COVID-19) vaccines during pregnancy is a particular concern. Here, we addressed the neonatal outcomes after maternal vaccination of COVID-19 during pregnancy. METHODS: We systematically searched PubMed, EMBASE, and the WHO COVID-19 Database for studies on neonatal outcomes after maternal COVID-19 vaccination from inception to 3 July 2022. Main neonatal outcomes were related to preterm, small for gestation (SGA), NICU admission, low Apgar score at 5â€‰min (<7), and additional neonatal outcomes such as gestation <34 weeks, low birth weight and some neonatal morbidity were all also analyzed. RESULTS: A total of 15 studies were included. We found that maternal vaccination during pregnancy was related to the reduction rates of Preterm, SGA, Low Apgar score at 5â€‰min (<7). In addition, there was no evidence of a higher risk of adverse neonatal outcomes after maternal vaccination of COVID-19 during pregnancy, including NICU admission, preterm birth with gestation <34 weeks, low birth weight, very low birth weight, congenital anomalies, and so on. CONCLUSIONS: COVID-19 vaccination in pregnant women does not raise significant adverse effects on neonatal outcomes and is related to a protective effect on some neonatal outcomes. IMPACT: Present study has addressed the neonatal outcomes after maternal vaccination of COVID-19 during pregnancy. COVID-19 vaccination in pregnant women does not raise significant adverse effects on neonatal outcomes and is related to a protective effect on some neonatal outcomes. The present study could encourage pregnant women to be vaccinated against COVID-19.

SARS-CoV-2 Breakthrough Infection after mRNA-1273 Booster among CoronaVac-Vaccinated Healthcare Workers. It remains unknown whether the Indonesian healthcare workers (HCWs) who had received two doses of CoronaVac vaccine and one dose of mRNA-1273 booster could be protected during the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron wave.

In total, 125 infection-naÃ¯ve and 10 previously infected HCWs were recruited. The mRNA-1273 booster substantially increased titer of anti-SARS-CoV-2 spike protein receptor-binding domain antibodies. However, the monitoring revealed that 34 out of 125 infection-naÃ¯ve (27.2%) and 3 out of 10 previously infected HCWs (30.0%) were infected during the Omicron wave. All infected HCWs were either asymptomatic or having mild coronavirus disease 2019 (COVID-19) and subsequently fully recovered, supporting the heterologous prime-boost strategy against COVID-19.

Update in cutaneous manifestations of COVID-19: Special populations. Cutaneous abnormalities were among the first clinical findings reported in patients infected with SARS-CoV-2 at the onset of the COVID-19 pandemic, but the significance was initially unclear. Correlations have since been drawn between many of these cutaneous eruptions and their diagnostic or prognostic value. Additionally, COVID-19 vaccines have generated acute and delayed cutaneous reactions with which clinicians should be familiar. In this narrative review, we update the cutaneous abnormalities associated with COVID-19 infection for pediatric and non-White populations, and common cutaneous reactions to COVID-19 vaccines.

Effect of Cholesterol Content of Lipid Composition in mRNA-LNPs on the Protein Expression in the Injected Site and Liver After Local Administration in Mice. Delivery of messenger RNA (mRNA) using lipid nanoparticles (LNPs) is expected to be applied to various diseases following the successful clinical use of the mRNA COVID-19 vaccines. This study aimed to evaluate the effect of the cholesterol molar percentage of mRNA-LNPs on protein expression in hepatocellular carcinoma-derived cells and in the liver after intramuscular or subcutaneous administration of mRNA-LNPs in mice. For mRNA-LNPs with cholesterol molar percentages reduced to 10Â mol% and 20Â mol%, we formulated neutral charge particles with a diameter of approximately 100Â nm and polydispersity index (PDI) <0.25. After the intramuscular or subcutaneous administration of mRNA-LNPs with different cholesterol molar percentages in mice, protein expression in the liver decreased as the cholesterol molar percentage in mRNA-LNPs decreased from 40Â mol% to 20Â mol% and 10Â mol%, suggesting that reducing the cholesterol molar percentage in mRNA-LNPs decreases protein expression in the liver. Furthermore, in HepG2 cells, protein expression decreased as cholesterol in mRNA-LNPs was reduced by 40Â mol%, 20Â mol%, and 10Â mol%. These results suggest that the downregulated expression of mRNA-LNPs with low cholesterol content in the liver involves degradation in systemic circulating blood and decreased protein expression after hepatocyte distribution.

Users' Reactions to Announced Vaccines Against COVID-19 Before Marketing in France: Analysis of Twitter Posts. BACKGROUND: Within a few months, the COVID-19 pandemic had spread to many countries and had been a real challenge for health systems all around the world. This unprecedented crisis has led to a surge of online discussions about potential cures for the disease. Among them, vaccines have been at the heart of the debates and have faced lack of confidence before marketing in France. OBJECTIVE: This study aims to identify and investigate the opinions of French Twitter users on the announced vaccines against COVID-19 through sentiment analysis. METHODS: This study was conducted in 2 phases. First, we filtered a collection of tweets related to COVID-19 available on Twitter from February 2020 to August 2020 with a set of keywords associated with vaccine mistrust using word embeddings. Second, we performed sentiment analysis using deep learning to identify the characteristics of vaccine mistrust. The model was trained on a hand-labeled subset of 4548 tweets. RESULTS: A set of 69 relevant keywords were identified as the semantic concept of the word "vaccin" (vaccine in French) and focused mainly on conspiracies, pharmaceutical companies, and alternative treatments. Those keywords enabled us to extract nearly 350,000 tweets in French. The sentiment analysis model achieved 0.75 accuracy. The model then predicted 16% of positive tweets, 41% of negative tweets, and 43% of neutral tweets. This allowed us to explore the semantic concepts of positive and negative tweets and to plot the trends of each sentiment. The main negative rhetoric

identified from users' tweets was that vaccines are perceived as having a political purpose and that COVID-19 is a commercial argument for the pharmaceutical companies. CONCLUSIONS: Twitter might be a useful tool to investigate the arguments for vaccine mistrust because it unveils political criticism contrasting with the usual concerns on adverse drug reactions. As the opposition rhetoric is more consistent and more widely spread than the positive rhetoric, we believe that this research provides effective tools to help health authorities better characterize the risk of vaccine mistrust.

Gross hematuria and IgA nephropathy flare-up following the first dose of Moderna vaccine: A case report. BACKGROUND: Since the mass vaccination for COVID-19, several case reports indicated the risk of autoimmune disease flare-ups after the vaccination. Among them, COVID-19 vaccine-induced glomerular diseases have drawn attention worldwide. The cases demonstrating the association between the mRNA vaccine and IgA nephropathy (IgAN) exacerbation had been noticed. Mostly mentioned, the flare-ups usually occurred after the second dose. METHODS: We present a Taiwanese female with IgAN who developed gross hematuria within only six hours after the first dose of the Moderna vaccine. RESULTS: Six hours after the first dose of Moderna vaccine on 8 June 2021, the patient developed gross hematuria and significantly decreased urine output. All symptoms resolved spontaneously on the fifth day after the vaccination without any intervention. On the fourth day after the vaccination, the patient were able to back to her original condition. CONCLUSION: This was an intriguing case of IgAN flare-up following the first dose of mRNA-based COVID-19 vaccination.

Examination of Adverse Reactions After COVID-19 Vaccination Among Patients With a History of Multisystem Inflammatory Syndrome in Children. IMPORTANCE: Data are limited regarding adverse reactions after COVID-19 vaccination in patients with a history of multisystem inflammatory syndrome in children (MIS-C). The lack of vaccine safety data in this unique population may cause hesitancy and concern for many families and health care professionals. OBJECTIVE: To describe adverse reactions following COVID-19 vaccination in patients with a history of MIS-C. DESIGN, SETTING, AND PARTICIPANTS: In this multicenter cross-sectional study including 22 North American centers participating in a National Heart, Lung, and Blood Institute, National Institutes of Health-sponsored study, Long-Term Outcomes After the Multisystem Inflammatory Syndrome in Children (MUSIC), patients with a prior diagnosis of MIS-C who were eligible for COVID-19 vaccination (age â‰¥5 years; â‰¥90 days after MIS-C diagnosis) were surveyed between December 13, 2021, and February 18, 2022, regarding COVID-19 vaccination status and adverse reactions. EXPOSURES: COVID-19 vaccination after MIS-C diagnosis. MAIN OUTCOMES AND MEASURES: The main outcome was adverse reactions following COVID-19 vaccination. Comparisons were made using the Wilcoxon rank sum test for continuous variables and the Ï‡2 or Fisher exact test for categorical variables. RESULTS: Of 385 vaccine-eligible patients who were surveyed, 185 (48.1%) received at least 1 vaccine dose; 136 of the vaccinated patients (73.5%) were male, and the median age was 12.2 years (IQR, 9.5-14.7 years). Among vaccinated patients, 1 (0.5%) identified as American Indian/Alaska Native, non-Hispanic; 9 (4.9%) as Asian, non-Hispanic; 45 (24.3%) as Black, non-Hispanic; 59 (31.9%) as Hispanic or Latino; 53 (28.6%) as White, non-Hispanic; 2 (1.1%) as multiracial, non-Hispanic; and 2 (1.1%) as other, non-Hispanic; 14 (7.6%) had unknown or undeclared race and ethnicity. The median time from MIS-C diagnosis to first vaccine dose was 9.0 months (IQR, 5.1-11.9 months); 31 patients (16.8%) received 1 dose, 142 (76.8%) received 2 doses, and 12 (6.5%) received 3 doses. Almost all patients received the BNT162b2 vaccine (347 of 351 vaccine doses [98.9%]). Minor adverse reactions were observed in 90 patients (48.6%) and were most often arm soreness (62 patients [33.5%]) and/or fatigue (32 [17.3%]). In 32 patients (17.3%), adverse reactions were treated with medications, most commonly acetaminophen (21 patients [11.4%]) or ibuprofen (11 [5.9%]). Four patients (2.2%) sought medical evaluation, but none required testing or hospitalization. There were no patients with any serious adverse events, including myocarditis or recurrence of MIS-C. CONCLUSIONS AND

RELEVANCE: In this cross-sectional study of patients with a history of MIS-C, no serious adverse events were reported after COVID-19 vaccination. These findings suggest that the safety profile of COVID-19 vaccination administered at least 90 days following MIS-C diagnosis appears to be similar to that in the general population.

Adhesive capsulitis after COVID-19 vaccine injection: a peculiar case treated with combined bursa distention and glenohumeral capsular hydrodilatation. Frozen shoulder is a common and self-limiting condition affecting the soft tissues of the shoulders, characterized by severe pain, impaired range of motion (ROM) and limitation of daily activities. Its prevalence is 5% and it occurs most commonly in the fifth and sixth decades of life; women are more affected [DePalma in Clin Orthop Relat Res 466:552-560, 2008]. It can be idiopathic or associated with other conditions such as metabolic disorders, diabetes, thyroid diseases, prolonged immobilization, trauma [DePalma in Clin Orthop Relat Res 466:552-560, 2008], or complications after vaccine administration known as SIRVA (Shoulder injury related to vaccine administration). SIRVA is not caused by the vaccine itself but by inappropriate vaccination techniques [MartÃ-n Arias et al. in Vaccine 35:4870-4876, 2017]. The natural history of the frozen shoulder is a progression through three stages based on clinical and arthroscopic presentations: freezing, frozen and thawing [DePalma in Clin Orthop Relat Res 466:552-560, 2008; Do et al. in Orthop J Sport Med 9:232596712110036, 2021]. The onset is characterized by disabling pain, that worsens at night; it is induced by inflammation and hypervascularity and lasts from 10 to 36Â weeks [Do et al. in Orthop J Sport Med 9:232596712110036, 2021]. The second stage is predominated by stiffness and severe reduction of ROM. This phase typically lasts from 9 to 12Â months [Do et al. in Orthop J Sport Med 9:232596712110036, 2021]. Eventually, a recovery phase occurs, with a gradual recovery of the ROM that can last between 12 and 42Â months. Ultrasound is an emerging diagnostic tool that contributes to differential diagnosis and treatment [Zappia et al. in Insights Imaging 7:365-371, 2016; Ricci et al. in J Ultrasound Med 39:633-635, 2020]: signs of adhesive capsulitis consist of thickening of the inferior recess of the glenohumeral joint capsule, thickening of the coracohumeral ligament and soft tissue structures in the rotator cuff interval, with hypervascularity. An unspecific sign is increased fluid in the tendon sheath of the long head of the biceps [MartÃ-n Arias et al. in Vaccine 35:4870-4876, 2017; Tandon et al. in J Ultrasound 20:227-236, 2017].

SARS-CoV-2 Infection after Vaccination: A Comparative Profile between Dose 1 and Dose 2. Since the initial shipment of vaccination campaign against SARS-CoV-2 infection, it was a major concern all over the world regarding appropriate gapping between the first and second dose and also the necessity of booster dose after being vaccinated with the second dose. This cross-sectional type of comparative study was conducted at Kuwait Bangladesh Friendship Government Hospital, from the period of March 01 2021 to August 31 2021, on 148 hospitalized patients who were vaccinated with Astra Zeneca. They were divided into two groups on the background of 1st dose and 2nd dose. Collected data were entered into SPSS-26 version and after data cleaning, descriptive analysis was done with frequency distribution. To find out the significant difference between the two groups considering clinico-demographic information, disease severity, and duration of the last dose of vaccine; the Pearson Chi-square test was done with a significance level â‰¤0.05. The patients from both groups were mostly male and above 60 years. There were no significant age or sex variations between the two groups. SARS-CoV-2 infection was common after 38 days of dose 1 and after 63 days of dose 2. Fever, cough, running nose, shortness of breath, fatigue, nausea, vomiting, lower oxygen saturation, radiological involvement were comparatively more in patients who got only a single dose. Mild pneumonia (70.7%) was the commonest presentation in both doses of vaccinated patients and single dose vaccinated patients mostly (45.5%) presented with severe pneumonia. Elderly clinically risks group patients were mostly hospitalized with infection after 1 month of the 1st

dose and on the other hand after 2 months of completing the 2nd dose. Symptomatic infection and disease severity were more in 1st dose vaccine recipients in comparison to 2nd dose.

Development of myocarditis and pericarditis after COVID-19 vaccination in children and adolescents: A systematic review. Myocarditis and pericarditis have been reported after COVID-19 vaccine administration in children and adolescents, raising the concern about their possible association with these vaccines. The objective was to explore the incidence, clinical presentation, and association of myocarditis and pericarditis with COVID-19 vaccines in children and adolescents. We conducted a systematic literature search on three databases, that is,Â Cochrane, MEDLINE/PubMed, and EMBASE from inception till March 2022. A total of three case reports, four case series, and six observational studies were included in the review. For case reports and case series, the mean age of the patients was 17.4 years, with 96.9% being male. Chest pain (nâ€‰=â€‰31, 93.9%), fever (nâ€‰=â€‰18, 54.5%), myalgias (nâ€‰=â€‰15, 45.4%) and headache (nâ€‰=â€‰9, 27.2%) were the most common presentations. Out of 33 patients, 32 (96.9%) of patients received Pfizer-BioNTech whereas only one (3.03%) received Moderna (mRNA 1273). Clinical investigations revealed ST elevation (nâ€‰=â€‰32, 97%), and elevated CRP (nâ€‰=â€‰9, 27.2%) and cardiac troponin (nâ€‰=â€‰29, 87.8%). The pooled incidence of myocarditis and pericarditis from observational studies was (0.00063%) and (0.000074%) %, respectively. Myocarditis and pericarditis in children and adolescents after the COVID-19 vaccines were more prevalent among males and more commonly observed after the second dose of Pfizer. Though the overall incidence was low, however, the clinicians should consider myocarditis and pericarditis as probable diagnosis when encountering young patients, with a history of vaccine administration, presenting with suggestive findings.

The Influence of the Rapid Increase in the Number of Adverse Event Reports for COVID-19 Vaccine on the Disproportionality Analysis Using JADER. BACKGROUND/AIM: The COVID-19 prophylactic vaccine for the prevention of coronavirus infection was approved in Japan on February 14, 2021. Adverse event reports for the vaccine were collected from the Japan Adverse Drug Event Relief (JADER) database, similar to those for drugs. Reported odds ratios (RORs) and proportional reporting ratios (PRRs) are commonly used in disproportionality analysis to detect safety signals. Therefore, adverse event reports from the vaccinated population may affect the detection of safety signals for the registered drugs. This study determined the impact of adverse event reports on the detection of safety signals for a COVID-19 prophylactic vaccine by analyzing the JADER database using disproportionality analysis. PATIENTS AND METHODS: We extracted data from the JADER dataset, in which the COVID-19 vaccine was reported as a suspected drug, and selected the top 10 adverse events in terms of the number of reports. We then extracted the top 30 drugs by the amount of information in the selected 10 adverse events and compared the changes in the number of signal detections with and without the COVID-19 vaccine report data. RESULTS: The total number of adverse events reported in the JADER database during the study period was 2,002,564. Of the total number of reports, 85,489 (4.3%) reported adverse events related to the COVID-19 vaccine. Of the top 30 drugs reported in the 10 selected adverse events, the ROR and PRR were found to be lower with the inclusion of COVID-19 vaccine data than without. Detection by ROR excluded 23 out of 245 drugs, and detection by PRR excluded 34 out of 204 drugs. CONCLUSION: The rapid increase in the number of adverse event reports for the COVID-19 vaccine in JADER may affect the detection of safety signals by disproportionality analysis.

Comprehensive description of adult-onset Still's disease after COVID-19 vaccination. Cases of adult-onset Still's disease (AOSD) have been reported after COVID-19 vaccination. Here we provide a comprehensive description and analysis of all cases of AOSD reported in the literature and in pharmacovigilance databases through April 2022. Disproportionality analyses of pharmacovigilance data were performed in order to further explore the association between vaccination and AOSD. We

included 159 patients, 144 from the World Health Organization pharmacovigilance database and 15 from the literature. Detailed clinical characteristics were described for the cases from the literature and from the French pharmacovigilance database (nÂ =Â 9). The cases of AOSD after COVID-19 vaccination concerned women in 52.2% of cases. The median age was 43.4 years. More than 80% of AOSD reports occurred during the first three weeks and concerned mostly the BNT162b2 mRNA vaccine. We identified 14.5% of disease flare with a median time-to-onset of AOSD flare-up significantly shorter than for the new onset form. More than 90% patients received steroids. Although all cases were considered serious and required hospitalization, most cases presented a favorable outcome (67.1%) with a good response to corticosteroid therapy with a mean time to recovery of 7.2 days. Disproportionality analyses suggested that AOSD was associated with COVID-19 vaccines as well as other vaccines. AOSD was nearly five times more frequently reported with COVID-19 vaccines than with all other drugs. Clinicians should be informed about the potential risk of AOSD onset or flare following COVID vaccines and the importance of its early detection to optimize its management.
Tozinameran (Pfizer-BioNTech COVID-19 vaccine)-induced AGEP-DRESS syndrome.
mRNA-1273 COVID-19 vaccine-induced Steven-Johnson syndrome.
Rash, Abdominal Pain, Proteinuria, and AKI after COVID-19 Vaccination.
Attenuated humoral responses in HIV after SARS-CoV-2 vaccination linked to B cell defects and altered immune profiles. We assessed a cohort of people living with human immunodeficiency virus (PLWH) (nÂ = 110) and HIV negative controls (nÂ = 64) after 1, 2 or 3 SARS-CoV-2 vaccine doses. At all timepoints, PLWH had significantly lower neutralizing antibody (nAb) titers than HIV-negative controls. We also observed a delayed development of neutralization in PLWH that was underpinned by a reduced frequency of spike-specific memory B cells (MBCs). Improved neutralization breadth was seen against the Omicron variant (BA.1) after the third vaccine dose in PLWH but lower nAb responses persisted and were associated with global MBC dysfunction. In contrast, SARS-CoV-2 vaccination induced robust TÂ cell responses that cross-recognized variants in PLWH. Strikingly, individuals with low or absent neutralization had detectable functional TÂ cell responses. These PLWH had reduced numbers of circulating T follicular helper cells and an enriched population of CXCR3(+)CD127(+)CD8(+)T cells after two doses of SARS-CoV-2 vaccination.
Social participation and mental health of immunocompromised individuals before and after COVID-19 vaccination-Results of a longitudinal observational study over three time points. INTRODUCTION: The coronavirus disease 2019 (COVID-19) pandemic impacted how people perform their daily lives in manifold and sometimes massive ways. Particularly, individuals who are at high risk for a severe disease progression, like immunocompromised people, may have experienced drastic changes in social participation during the pandemic. A COVID-19 basic vaccination may have changed the safety behavior of immunocompromised individuals in terms of infection risk and thereby influence social participation and mental wellbeing. METHODS: This study aims to investigate self-perceived social participation at baseline before and at follow-up 1 and 6 months after basic vaccination. Beginning in March 2021, 274 immunocompromised persons 18 years or older were enrolled in the COVID-19 Contact Immune study (CoCo study) in Lower Saxony, Germany. Measurements were performed at three time points regarding social participation [Index for the Assessment of Health Impairments (IMET)], mental health [Patient Health Questionnaire-4 (PHQ-4)], subjective health status (five-point Likert-scale) and quality of life (five-point Likert-scale). RESULTS: In total, 126 participants were included in the final analysis. About 60% of the participants showed increasing social participation over time. The greatest increase in social participation was observed within the first month after basic vaccination ($p < 0.001$). During the following 5 months, social participation remained stable. The domains "social activities," "recreation and leisure" and "close personal relationships" were

responsible for the overall change in social participation. No association was found between social participation and mental health, sociodemographic or medical factors (except hypertension). DISCUSSION: It is unclear why social participation increased after basic vaccination. Perceived vaccine efficacy and a feeling of being protected by the vaccine may have caused relaxed social distancing behaviors. Reducing safety behaviors may, however, increase the risk of a COVID-19 infection for immunocompromised individuals. Further investigations are needed to explore the health-related consequences of more social participation among immunocompromised persons.

Acute adverse events of Sars-CoV2 vaccines: Experiences from a health care worker vaccination campaign in two municipal hospitals in northwest Germany. Vaccination is considered the best measure to overcome the Sars-Cov2 pandemic. However, changing national recommendations on sequence and time frame necessitate the collection of real-word data on adverse events of Sars-CoV2 vaccination protocols outside of pivotal trials. We report results from a survey on the adverse events and the operational consequences of a Sars-CoV2 vaccination campaign with partly mixed vaccination protocol as well as booster vaccination. While the spectrum of adverse effects in our cohort appeared to be similar to pivotal studies, there were substantial differences in both frequency and distribution with only 3 out of 10 participants staying symptom-free. In over 26% of vaccinees symptoms were so severe, that they stayed at home with mean days on sick leave being 1.5 per person using mixed vaccination protocol. Being aware, that these results might partially be attributable to nocebo effects they are of importance for future vaccination campaigns.

COVID-19 Vaccination-Associated Myocarditis: A Literature Review. Myocarditis is defined as a non-ischemic inflammation of the middle layer of the heart. It ensues changes that can lead to acute heart failure, dilated cardiomyopathy, and sudden death. Myocarditis is caused by several infectious and non-infectious agents. Vaccines are also known to cause myocarditis. The use of the coronavirus disease (COVID-19) vaccination was started to combat the severity of the COVID-19 infection and reduce the mortality and morbidity associated with it. The vaccination, however, caused side effects like myocarditis, among others. In order to investigate the association between the COVID-19 vaccination and myocarditis in adults and adolescents, we conducted a literature review by searching three databases: Google Scholar, PubMed, and ScienceDirect. From the published literature, we found that, though it is rare, the various vaccinations available can cause symptoms of myocarditis as a side effect more commonly in patients who have received both doses of a particular vaccine and that there are significant changes in cardiac magnetic resonance imaging (CMRI) and other biochemical markers, with young males being more commonly affected. Further prospective trial-based studies are required to establish a concrete relationship between myocarditis and the COVID-19 vaccine.

T-Cell Mediated Response after Primary and Booster SARS-CoV-2 Messenger RNA Vaccination in Nursing Home Residents. OBJECTIVES: Nursing home (NH) residents have been significantly affected by the coronavirus disease 2019 (COVID-19) pandemic. Studies addressing the immune responses induced by COVID-19 vaccines in NH residents have documented a good postvaccination antibody response and the beneficial effect of a third booster vaccine dose. Less is known about vaccine-induced activation of cell-mediated immune response in frail older individuals in the long term. The aim of the present study is to monitor messenger RNA SARS-CoV-2 vaccine-induced T-cell responses in a sample of Italian NH residents who received primary vaccine series and a third booster dose and to assess the interaction between T-cell responses and humoral immunity. DESIGN: Longitudinal cohort study. SETTING AND PARTICIPANTS: Thirty-four residents vaccinated with BNT162b2 messenger RNA SARS-CoV-2 vaccine between February and April 2021 and who received a third BNT162b2 booster dose between October and November 2021 were assessed for vaccine-induced immunity 6 (prebooster) and 12 (postbooster) months after the first BNT162b2 vaccine dose.

METHODS: Pre- and postbooster cell-mediated immunity was assessed by intracellular cytokine staining of peripheral blood mononuclear cells stimulated inÂ vitro with peptides covering the immunodominant sequence of SARS-CoV-2 spike protein. The simultaneous production of interferon-Î³, tumor necrosis factor-Î±, and interleukin-2 was measured. Humoral immunity was assessed in parallel by measuring serum concentration of antitrimeric spike IgG antibodies. RESULTS: Before the booster vaccination, 31 out of 34 NH residents had a positive cell-mediated immunity response to spike. Postbooster, 28 out of 34 had a positive response. Residents without a previous history of SARS-CoV-2 infection, who had a lower response prior the booster administration, showed a greater increase of T-cell responses after the vaccine booster dose. Humoral and cell-mediated immunity were, in part, correlated but only before booster vaccine administration. CONCLUSIONS AND IMPLICATIONS: The administration of the booster vaccine dose restored spike-specific T-cell responses in SARS-CoV-2 naÃ¯ve residents who responded poorly to the first immunization, while a previous SARS-CoV-2 infection had an impact on the magnitude of vaccine-induced cell-mediated immunity at earlier time points. Our findings imply the need for a continuous monitoring of the immune status of frail NH residents to adapt future SARS-CoV-2 vaccination strategies.

Evaluation of a point of care lateral flow assay for antibody detection following SARS CoV-2 mRNA vaccine series. BACKGROUND: Breakthrough cases of SARS-CoV-2 infection correlate with decreased antibody immunity following mRNA vaccination. Measuring kinetics of vaccine efficacy using traditional laboratory approaches is more expensive and can be impractical. In this study, we evaluated the diagnostic performance of a validated COVID-19 point-of-care lateral flow assay (LFA) kit in detecting post-vaccination antibody response. METHODS: We conducted a prospective cohort study of whole blood and plasma samples to evaluate the performance of a LFA in detecting SARS-CoV-2-specific antibodies following mRNA vaccination compared to enzyme-linked immunosorbent assays (ELISAs). Health care workers at 2 tertiary centers who completed an initial BNT162b2 (nÂ =Â 103) or mRNA-1273 (nÂ =Â 35) vaccine series were enrolled between June and August of 2021. We performed an exploratory analysis to correlate band strength and antibody concentration of LFAs and ELISAs respectively. RESULTS: When compared to the ELISA, LFA results showed similar test positivity for plasma samples (PÂ =Â 0.55), but not for whole blood samples (PÂ <Â 0.001). For whole blood samples on the LFA, antibody detection differed between BNT162b2 (68.9%, 95% CI: 59.1%-77.7%) and mRNA-1273 (100%, 95% CI: 90.0%-100%, PÂ <Â 0.001) vaccines. Higher plasma antibody concentrations correlated with greater LFA sensitivity. Samples with thick LFA bands had higher antibody concentrations compared to samples having faint LFA bands (81.8 arbitrary unit [AU]/mL vs. 57.1Â AU/mL, PÂ <Â 0.01). CONCLUSIONS: The performance of a LFA in detecting SARS-CoV-2 antibodies was significantly better when plasma samples were used. The strength of label bands on the LFA may correlate with antibody concentration and could be a useful point-of-care monitoring tool for post-vaccine antibody status.

Co-VAN study: COVID-19 vaccine associated neurological diseases- an experience from an apex neurosciences centre and review of the literature. BACKGROUND: Recent studies have shown various neurological adverse events associated with COVID-19 vaccine. OBJECTIVE: We aimed to retrospectively review and report the neurological diseases temporally associated with COVID-19 vaccine. METHODS: We performed a retrospective chart review of admitted patients from 1st February 2021 to 30th June 2022. A total of 4672 medical records were reviewed of which 51 cases were identified to have neurological illness temporally associated with COVID-19 vaccination. RESULTS: Out of 51 cases, 48 had probable association with COVID-19 vaccination while three had possible association. Neurological spectrum included CNS demyelination (nÂ =Â 39, 76.5Â %), Guillain-BarrÃ©-syndrome (nÂ =Â 3, 5.9Â %), stroke (nÂ =Â 6, 11.8Â %), encephalitis (nÂ =Â 2, 3.9Â %) and myositis (nÂ =Â 1, 2.0Â %). Female gender had a greater predisposition (F:M, 1.13:1).

Neurological events were more commonly encountered after the first-dose (nÂ =Â 37, 72.5%). The mean latency to onset of symptoms was 13.2Â Â±Â 10.7Â days after the last dose of vaccination. COVIShield (ChAdOx1) was the most commonly administered vaccine (nÂ =Â 43, 84.3Â %). Majority of the cases with demyelination were seronegative (nÂ =Â 23, 59.0Â %) which was followed by anti-Myelin oligodendrocyte-glycoprotein associated demyelination (MOGAD) (nÂ =Â 11, 28.2Â %) and Neuromyelitis optica (NMOSD) (nÂ =Â 5, 12.8Â %). Out of 6Â Stroke cases, 2 cases (33.3Â %) had thrombocytopenia and coagulopathy. At discharge, 25/51 (49.0Â %) of the cases had favourable outcome (mRS 0 to 1). Among six patients of stroke, only one of them had favourable outcome. CONCLUSION: In this series, we describe the wide variety of neurological syndromes temporally associated with COVID-19 vaccination. Further studies with larger sample size and longer duration of follow-up are needed to prove or disprove causality association of these syndromes with COVID-19 vaccination.

COVID-19 vaccination: Evaluation of humoral and cellular immunity after the booster dose in chronic lymphocytic leukemia patients.

Adverse event reports of anaphylaxis after Comirnaty and Vaxzevria COVID-19 vaccinations, Western Australia, 22 February to 30 June 2021. Within the first 4 months of the Western Australian COVID-19 immunisation programme, 49 suspected anaphylaxis cases were reported to the vaccine safety surveillance system. Twelve reports met Brighton Collaboration case definition, corresponding to rates of 15.9 and 17.7 per million doses of Vaxzevria and Comirnaty administered respectively.

Cohort Profile:The Danish National Cohort Study of Effectiveness and Safety of SARS-CoV-2 vaccines (ENFORCE). PURPOSE: The ENFORCE cohort is a national Danish prospective cohort of adults who received a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine as part of the Danish National SARS-CoV-2 vaccination programme. It was designed to investigate the long-term effectiveness, safety and durability of SARS-CoV-2 vaccines used in Denmark. PARTICIPANTS: A total of 6943 adults scheduled to receive a SARS-CoV-2 vaccine in the Danish COVID-19 vaccination programme were enrolled in the study prior to their first vaccination. Participants will be followed for a total of 2â€‰years with five predetermined follow-up visits and additional visits in relation to any booster vaccination. Serology measurements are performed after each study visit. T-cell immunity is evaluated at each study visit for a subgroup of 699 participants. Safety information is collected from participants at visits following each vaccination. Data on hospital admissions, diagnoses, deaths and SARS-CoV-2 PCR results are collected from national registries throughout the study period. The median age of participants was 64 years (IQR 53-75), 56.6% were women and 23% were individuals with an increased risk of a serious course of COVID-19. A total of 340 (4.9%) participants tested positive for SARS-CoV-2 spike IgG at baseline. FINDINGS TO DATE: Results have been published on risk factors for humoral hyporesponsiveness and non-durable response to SARS-CoV-2 vaccination, the risk of breakthrough infections at different levels of SARS-CoV-2 spike IgG by viral variant and on the antibody neutralising capacity against different SARS-CoV-2 variants following primary and booster vaccinations. FUTURE PLANS: The ENFORCE cohort will continuously generate studies investigating immunological response, effectiveness, safety and durability of the SARS-CoV-2 vaccines. TRIAL REGISTRATION NUMBER: NCT04760132.

Kikuchi-Fujimoto-like lymphadenopathy following COVID-19 vaccine: diagnosis and management. A woman in her mid 40s presented for breast imaging after 1â€‰week of painful and enlarged right axillary lymphadenopathy. She denied history of fever, weight loss, night sweats fatigue, cat scratch or other trauma. She received the second dose of Pfizer COVID-19 vaccine 3 months previously on the contralateral arm. A mammogram demonstrated a single, asymmetric, large and dense right axillary lymph node. Ultrasound confirmed a 2.5â€‰cm lymph node with cortical thickening of 0.6â€‰cm. Ultrasound-guided core biopsy showed necrotising lymphadenitis with associated aggregates of

histiocytes and plasmacytoid dendritic cells. Potential causes of necrotising adenitis including Bartonella, tuberculosis, Epstein-Barr Virus, herpes simplex virus, systemic lupus erythematosus and lymphoma were excluded. In the absence of any identifiable infectious or autoimmune causes, and given the temporal relatedness with vaccine administration, it was determined that the Kikuchi-Fujimoto-like necrotising lymphadenitis was likely secondary to the COVID-19 vaccine. To date, there has been no casual association made between the COVID-19 vaccine and KFD necrotising lymphadenitis.
Complex regional pain syndrome after mRNA-based COVID-19 vaccination. We describe the case of a 17-year-old woman diagnosed with complex regional pain syndrome (CRPS) at a pain clinic after the second dose of the COVID-19 vaccine. She was referred to our department for surgical treatment of movement disorder seven months after the second inoculation. Baclofen (50Â Âµg), administered intrathecally, improved the involuntary movements of her right hand. After administration of zolpidem (5Â mg), involuntary movements of the right index finger almost disappeared. However, neither zolpidem nor intrathecal baclofen improved the limited range of motion of the first joint of the left-hand finger. Despite various reports on CRPS development after vaccination, only one case post COVID-19 vaccination has been reported. Therefore, healthcare providers should keep in mind that CRPS can appear after the COVID-19 vaccination.
Severe Panic Disorder After Vaccination With the Pfizer-BioNTech Vaccine: A Case Report.
Acute Psychosis After Immunization With Whole-Virion Inactivated COVID-19 Vaccine; A Case Report From Central India.
Acute myocarditis after a first dose of COVID-19 mRNA vaccination: an uncommon but potentially serious adverse effect.
Antigen rapid diagnostic test monitoring for SARS-CoV-2 in asymptomatic and fully vaccinated cancer patients: Is it cost-effective? BACKGROUND: Routine testing for cancer patients not presenting COVID-19-related symptoms and fully vaccinated for SARS-CoV-2 prior to cancer treatment is controversial. METHODS: In this retrospective study we evaluated whether antigen-rapid-diagnostic-test (Ag-RDT) monitoring for SARS-CoV-2 in a large cohort of consecutive asymptomatic (absence of SARS-CoV-2-related symptoms such as fever, cough, sore throat or nasal congestion) and fully vaccinated cancer patients enrolled in a short period during cancer treatment has an impact on the therapeutic path of cancer patients. RESULTS: From December 27, 2021, to February 11, 2022, 2439 cancer patients were screened through Ag-RDT for SARS-CoV-2 before entering the hospital for systemic treatment. Fifty-three patients (2.17%) tested positive, of whom 7 (13.2%) subsequently developed COVID-related symptoms, generally mild. Cancer treatment was discontinued, as a precaution, in 49 patients (92.5%) due to the test positivity. CONCLUSION: SARS-CoV-2 screening in asymptomatic and fully vaccinated cancer patients during systemic treatment appeared to be not cost-effective: the low rate of SARS-CoV-2 positive patients and the low percentage of overt associated infection do not seem proportional to the direct costs (nursing work for swabs, costs of materials and patient monitoring) and indirect costs (dedicated rooms, extension of waiting times for patients and oncologists in delivering therapy as well as its discontinuation in the positive ones). It can, on the other hand, be detrimental when systemic cancer treatment is suspended as a precaution. Given the small number of patients testing positive and the rapid and favorable trend of the infection, it is recommended to always consider continuing systemic oncological treatment, especially when this impacts patient survival as in the adjuvant or neoadjuvant setting.
Side effects following COVID-19 vaccination in pediatric patients with sickle cell disease. Vulnerable patient populations have seen decreased rates of vaccination against SARS-CoV2-19 (COVID-19) due to hesitancies and distrust, magnified by a paucity of data for certain populations. The rate of COVID-19 vaccination in children with sickle cell disease (SCD) remains low despite the risk

for severe complications, resulting in continued infections and hospitalizations from COVID-19. We sought to describe vaccine reactions, including vaso-occlusive crises, emergency department visits, and hospitalizations, in children with SCD. Our findings will start to provide the necessary vaccine side effect data to inform patients, caregivers, and clinicians considering the COVID-19 primary vaccination series.

Prevalence of common adverse events experienced following COVID-19 vaccination and its associated factors in Ghana: Cross-sectional study design. BACKGROUND AND AIMS: The novel severe acute respiratory syndrome coronavirus 2Â (SARS-CoV-2) (COVID-19) pandemic devasted the general life of people and various human activities across the globe, and Ghana is of no exception. This led to development of vaccines within record time to combat morbidity and mortality associated with the virus. In Ghana, COVID-19 vaccines were introduced in addition to existing COVID-19 protocols. However, the vaccines have adverse events among those who received them. In this study, we determined the prevalence of some common adverse events of the COVID-19 vaccines and its associated sociodemographic factors in Ghana. METHODS: An online snowball cross-sectional survey was conducted between April and June 2021 among 240 people who had taken at least one dose of any of the COVID-19 vaccines approved in Ghana. The penalized binary logistic regression model was used to assess the factors associated with experience of at least one adverse event and the experience of number of adverse events using Stata version 16. RESULTS: Among the 240 participants, 88.2% had experienced at least one adverse event. The most common adverse event after the first dose was pain at injection site (65.8%), headache (57.5%), tiredness (55.8%), fever (51.7%), chills (39.6%), and muscle pains (38.3%). Experience of adverse events was 16 times higher among those who took their vaccines in Ghana (adjusted odd ratio [AOR]: 16.2, 95% confidence interval [CI]: 1.98-132.56, pâ€‰=â€‰0.009), 94% less among those who took AstraZeneca (India) compared to AstraZeneca (Oxford) (AOR: 0.06, 95% CI: 0.01-0.37, pâ€‰=â€‰0.002) and 86% less among 40-49 years compared with less than 30 years old (AOR: 0.14, 95% CI: 0.03-0.58, pâ€‰=â€‰0.007). CONCLUSION: Pain at the injection site, headache, tiredness, fever, chills, and muscle pains were the most frequently reported adverse events. The study identified country of vaccination, country of origin of AstraZeneca vaccine and age to be associated with adverse events of vaccination.

Immune responses to SARS-CoV-2 in vaccinated patients receiving checkpoint blockade immunotherapy for cancer. Vaccination against SARS-CoV-2 has been successful in protecting patients with cancer from severe infections, but how immune responses against COVID-19 vaccination interact with those elicited during cancer immunotherapy has not been fully described. Immune checkpoint blockade (ICB) disrupts inhibitory pathways in immune cells to improve function and induce tumor immunity but can often cause serious immune related adverse events (IRAEs). Because COVID-19 vaccination and ICB both boost immune responses, it is imperative to understand if combining these regimens causes synergistic enhancement of the immune system. Specifically, whether ICB impacts anti-vaccine immunity in previously vaccinated patients is important since a large percentage of newly diagnosed cancer patients eligible for immunotherapy will have already been vaccinated against COVID-19. To address this, we investigated the influence of ICB on SARS-CoV-2-spike protein (SP) antibody titers and T cell responses in cancer patients previously vaccinated against COVID-19. Human blood samples were collected from 29 vaccinated patients and 12 unvaccinated control patients at baseline (prior to ICB) and following two rounds of ICB infusion. Anti-SARS-CoV-2-SP IgG titers and T cell responses were quantified. Compared to responses at baseline, there was no significant difference in these immune responses after immunotherapy in vaccinated individuals (P=0.4583, P=0.4571, respectively). We interpret these results as evidence that ICB immunotherapy does not significantly enhance SARS-CoV-2-specific antibody titers or T cell

responses. Although our study lacks corresponding IRAE rates, the results provide humoral and cellular immunological data that support recent reports documenting the clinical safety and efficacy of COVID-19 vaccination in patients receiving ICB. Additional longitudinal prospective studies, such as the VOICE study (ClinicalTrials.gov identifier NCT04715438) and CAPTURE study (ClinicalTrials.gov identifier NCT03226886), are warranted and will provide broader safety and immunological data defining the effect of systemic cancer therapies on COVID-19 immunity.

Syndrome of inappropriate antidiuretic hormone and status epilepticus associated with mRNA-based SARS-CoV-2 vaccination.

Urticaria after COVID-19 vaccination and vaccine hesitancy.

Adverse Events Related to COVID-19 Vaccines in Pregnant Women: Correspondence.

Association of COVID-19 Vaccination Rates of Staff and COVID-19 Illness and Death Among Residents and Staff in US Nursing Homes. IMPORTANCE: It is important to understand the association between staff vaccination rates and adverse COVID-19 outcomes in nursing homes. OBJECTIVE: To assess the extent to which staff vaccination was associated with preventing COVID-19 cases and deaths among residents and staff in nursing homes. DESIGN, SETTING, AND PARTICIPANTS: This longitudinal cohort study used data on COVID-19 outcomes in Medicare- and Medicaid-certified nursing homes in the US between May 30, 2021, and January 30, 2022. Participants included the residents of 15â€¯042 US nursing homes that reported COVID-19 data to the Centers for Disease Control and Prevention and passed Centers for Medicare & Medicaid Services data quality checks in the National Healthcare Safety Network. EXPOSURES: Weekly staff vaccination rates. MAIN OUTCOMES AND MEASURES: Main outcomes are weekly COVID-19 cases and deaths among residents and weekly COVID-19 cases among staff. The treatment variable is the primary 2-dose staff vaccination rate in each facility each week. RESULTS: In the primary analysis of 15â€¯042 nursing homes before the Omicron variant wave (May 30 to December 5, 2021) using fixed effects of facility and week, increasing weekly staff vaccination rates by 10 percentage points was associated with 0.13 (95% CI, -0.20 to -0.10) fewer weekly COVID-19 cases per 1000 residents, 0.02 (95% CI, -0.03 to -0.01) fewer weekly COVID-19 deaths per 1000 residents, and 0.03 (95% CI, -0.04 to -0.02) fewer weekly COVID-19 staff cases. In the secondary analysis of the Omicron wave (December 5, 2021, to January 30, 2022), increasing staff vaccination rates were not associated with lower rates of adverse COVID-19 outcomes in nursing homes. CONCLUSIONS AND RELEVANCE: The findings of this cohort study suggest that before the Omicron variant wave, increasing staff vaccination rates was associated with lower incidence of COVID-19 cases and deaths among residents and staff in US nursing homes. However, as newer, more infectious and transmissible variants of the virus emerged, the original 2-dose regimen of the COVID-19 vaccine as recommended in December 2020 was no longer associated with lower rates of adverse COVID-19 outcomes in nursing homes. Policy makers may want to consider longer-term policy options to increase the uptake of booster doses among staff in nursing homes.

Association of COVID-19 Vaccination With Breakthrough Infections and Complications in Patients With Cancer. IMPORTANCE: Patients with cancer are known to have increased risk of COVID-19 complications, including death. OBJECTIVE: To determine the association of COVID-19 vaccination with breakthrough infections and complications in patients with cancer compared to noncancer controls. DESIGN, SETTING, AND PARTICIPANTS: Retrospective population-based cohort study using linked administrative databases in Ontario, Canada, in residents 18 years and older who received COVID-19 vaccination. Three matched groups were identified (based on age, sex, type of vaccine, date of vaccine): 1:4 match for patients with hematologic and solid cancer to noncancer controls (hematologic and solid cancers separately analyzed), 1:1 match between patients with hematologic and patients with solid cancer. EXPOSURES: Cancer diagnosis. MAIN OUTCOMES AND MEASURES:

Outcomes occurring 14 days after receipt of second COVID-19 vaccination dose: primary outcome was SARS-CoV-2 breakthrough infection; secondary outcomes were emergency department visit, hospitalization, and death within 4 weeks of SARS-CoV-2 infection (end of follow-up March 31, 2022). Multivariable cumulative incidence function models were used to obtain adjusted hazard ratio (aHR) and 95% CIs. RESULTS: A total of 289â€¯400 vaccinated patients with cancer (39â€¯880 hematologic; 249â€¯520 solid) with 1â€¯157â€¯600 matched noncancer controls were identified; the cohort was 65.4% female, and mean (SD) age was 66 (14.0) years. SARS-CoV-2 breakthrough infection was higher in patients with hematologic cancer (aHR, 1.33; 95% CI, 1.20-1.46; Pâ€‰<â€‰.001) but not in patients with solid cancer (aHR, 1.00; 95% CI, 0.96-1.05; Pâ€‰=â€‰.87). COVID-19 severe outcomes (composite of hospitalization and death) were significantly higher in patients with cancer compared to patients without cancer (aHR, 1.52; 95% CI, 1.42-1.63; Pâ€‰<â€‰.001). Risk of severe outcomes was higher among patients with hematologic cancer (aHR, 2.51; 95% CI, 2.21-2.85; Pâ€‰<â€‰.001) than patients with solid cancer (aHR, 1.43; 95% CI, 1.24-1.64; Pâ€‰<â€‰.001). Patients receiving active treatment had a further heightened risk for COVID-19 severe outcomes, particularly those who received anti-CD20 therapy. Third vaccination dose was associated with lower infection and COVID-19 complications, except for patients receiving anti-CD20 therapy. CONCLUSIONS AND RELEVANCE: In this large population-based cohort study, patients with cancer had greater risk of SARS-CoV-2 infection and worse outcomes than patients without cancer, and the risk was highest for patients with hematologic cancer and any patients with cancer receiving active treatment. Triple vaccination was associated with lower risk of poor outcomes.

Comment to: Disseminated cutaneous herpes simplex, COVID-19 vaccination and rheumatoid arthritis patient: a case report and review. Not available.

Covid-19 vaccination in patients with immune-mediated thrombotic thrombocytopenic purpura: a single-referral center experience.

Fatal Acute Disseminated Encephalomyelitis Post-COVID-19 Vaccination: A Rare Case Report. Acute disseminated encephalomyelitis (ADEM) is a disease of the brain and spinal cord that is an immune-mediated inflammatory and demyelinating disorder, which is commonly preceded by an infection. Some reports have also shown the association of acute demyelination of the central nervous system (CNS) with vaccination. Primarily, the involvement of the white matter of the cerebral hemispheres, brain stem, and spinal cord is observed. Such lesions should be considered as the differentials of ADEM. We would like to report a case of a 77-year-old female who was of post-COVID-19 vaccination status and presented to us with altered sensorium with imaging revealing acute demyelination.

Amyloid Î²-related angiitis of the central nervous system occurring after COVID-19 vaccination: A case report. BACKGROUND: Although coronavirus disease 2019 (COVID-19) vaccines have been effective in controlling the COVID-19 pandemic, a variety of post-vaccination neurological complications have been reported worldwide. Amyloid Î²-related angiitis (ABRA) is a rare neurological disease. The underlying cause of ABRA is unknown, but several studies suggest that it is caused by an excessive immune response to amyloid-Î² deposited in blood vessels. In addition, limited attention has been paid to potential triggers of ABRA, such as infection or vaccination. CASE SUMMARY: We report a case of ABRA that developed 2 wk after COVID-19 vaccination. A 75-year-old woman developed a frontal headache after receiving a second dose of COVID-19 BNT162b2 vaccine (Pfizer-BioNTech). Diffusion-weighted magnetic resonance imaging (DW-MRI) of the head showed abnormal hyperintensity, suggesting cerebral infarctions in the left parietal and occipital lobes. We diagnosed her condition as ABRA based on a brain biopsy. We administered steroid pulse therapy and the patient's symptoms and DW-MRI abnormalities improved. This case had a good outcome due to

prompt diagnosis and treatment. CONCLUSION: We report a case of ABRA that may have been triggered by COVID-19 vaccination.

Intricacies Affiliated With Post-COVID Vaccine Complications in Makkah Province, Saudi Arabia. Introduction COVID-19 vaccine side effects have a fundamental role in public confidence in the vaccine and its uptake process. Thus far, evidence on vaccine safety has been exclusively obtained from manufacturer-sponsored studies; therefore, this study is designed to assess post-COVID-19 vaccine complications in Makkah province, Saudi Arabia. Method A cross-sectional study included 840 subjects conducted from August to November 2022 to collect data about COVID-19 vaccineÂ side effects. A validated questionnaire was used with 21 multiple-choice items covering demographic data, COVID-19 vaccination type, side effects, and medication used to relieve side effects. The online Raosoft sample size calculator (Raosoft Inc., Seattle, Washington) was utilized for sample size calculation. The Statistical Package for the Social Sciences version 22.0 (IBM Inc., Armonk, New York) was utilized to carry out descriptive statistics. The Shapiro-Wilk test was used to evaluate normal data distribution. Significance of categorized data made by the Pearson's Chi-Squared test and of the vaccination side effects experienced in general wellbeing on a scale of 1-10 by the Kruskal-Wallis test. Result The survey found that most participants in the 18-26 age group were from Jeddah, women, and Saudis. Only 7.1% of participants had comorbidities alone, and 63.1% of participants had previously had COVID-19. The vaccine types used in this study were primarily Pfizer (83.3%), AstraZeneca (9.5%), Moderna (3.6%), and combination vaccines (3.6%). The majority of the participants received vaccination up to the third dose. No side effects were reported by 9.5% of participants, while mild and severe side effects were reported by 90.5% and 23.8% of participants, respectively. Mild side effects included injection site pain, redness, tenderness, or itching (34.5%), fatigue (22.6%), low-grade fever, chills, diarrhea, headache (17.9%), and myalgia (14.3%). Conclusion The majority of the side effects of COVID-19 vaccination were minor reactions (90.5%), but 23.8% were found to be serious side effects, most of which lasted one to three days. More independent studies are needed to investigate gender differences, COVID-19 vaccine efficacy, and the prevalence of side effects in other populations conducted by academic institutions. Additional independent research on vaccine safety is urgently needed to increase public confidence in vaccines and to better understand risk factors for vaccine side effects.

COVID-19 vaccination-related hemophagocytic lymphohistiocytosis presenting as acute liver failure. Acute liver failure following COVID-19 infection and/or vaccination is very rare and can be secondary to hemophagocytic lymphohistiocytosis (HLH). Liver injury in such cases appears to be extrinsic and thus treatment hinges on prompt diagnosis and reversal of the primary disease. We describe a patient who developed acute liver failure secondary to HLH after receiving a second dose of the Pfizer COVID-19 vaccine. Persistently elevated liver function tests, fevers, and cytopenia following COVID-19 vaccination should prompt clinicians to calculate an H-score to evaluate for the presence of HLH.

Comprehensive assessment of SARS-CoV-2 antibodies against various antigenic epitopes after naive COVID-19 infection and vaccination (BNT162b2 or ChAdOx1 nCoV-19). Comprehensive assessment of SARS-CoV-2 antibodies against antigenic epitopes and cross-neutralization on variants is essential to monitor after infection or vaccination. From 32 COVID-19 patients and 40 vaccinated individuals [20 Oxford-AstraZeneca (AZ) and 20 Pfizer-BioNTech (BNT)], 348 serial sera are collected until 40 days after infection and 3 months after homologous booster vaccination. Antibody levels were monitored using a multiplex-bead assay including variant spike antigens, Roche (S1/RBD total) and a surrogate virus neutralization test (GenScript). Anti-S/S1/RBD levels were higher than anti-S2/N levels from 2 weeks after infection and were higher in severe infection ($P < 0.05$). Vaccination showed highest antibody levels after 1-month booster and had consistently high levels in the order of anti-full S, anti-RBD, anti-S1 and anti-S2. Infection induced higher anti-S2/N levels than prime vaccination ($P <$

0.05). Three months after BNT/BNT vaccination, antibody levels against S1/RBD and 23 variant antigens were higher than post-infection or AZ groups ($P < 0.05$). Regarding intraindividual changes from post-prime to post-boost vaccination, boost induced a 1.1- to 3.9-fold increase on multiplex-bead assay, 22.8- to 24.2-fold on Roche assay and 22.8- to 24.2-fold on GenScript assay. Post-prime levels by multiplex-bead assay predicted post-boost levels, but Roche and GenScript results were not predictive in the AZ group. The kinetics of SARS-CoV-2 antibody levels vary depending on the antigenic epitopes, assay kit, disease severity or vaccine type. Assessing seroconversion using multiplex-bead assays may contribute to monitoring the disease course, adjusting vaccination strategies, and accelerating vaccination efficacy.

SARS-CoV-2 vaccine-triggered conversion from systemic lupus erythematosus (SLE) to bullous SLE and dipeptidyl peptidase 4 inhibitors-associated bullous pemphigoid. Bullous systemic lupus erythematosus (BSLE) is a rare blistering disease in patients with SLE. BSLE is a heterogenous disease caused by autoantibodies to the basement membrane, mainly type VII collagen. The pathogenesis of the development of autoantibodies in BSLE remains unknown. We report a case of SLE taking dipeptidyl peptidase 4 inhibitors (DPP4i) who developed tense blister lesions after administration of SARS-CoV-2 vaccine. Initial erythematous lesion before administration of SARS-CoV-2 vaccine had not shown IgG deposition at basement membrane both direct and indirect immunofluorescence (IIF). However, the result of those examinations became positive after the administration of SARS-CoV-2 vaccine. Furthermore, IIF test results using NaCl split skin had shown positive against epidermal side. These observations suggest that SARS-CoV-2 vaccination triggered production of autoantibodies that cause bullous SLE. The present case fulfills the diagnostic criteria for both BSLE and DPP4i-associated bullous pemphigoid. Skin lesions were cleared after withdrawal of DPP4i. Therefore, physicians should ask patients who develop blisters after the vaccination whether they are taking DPP4i.

Admission and follow-up cardiac magnetic resonance imaging findings in BNT162b2 Vaccine-Related myocarditis in adolescents. BACKGROUND: There is limited data on the pattern and severity of myocardial injury in patients with COVID-19 vaccination associated myocarditis. OBJECTIVE: We aimed to define the myocardial damage occurring after BNT162b2 vaccination, raise awareness about adverse reactions developing after vaccination, and determine the patterns and scope of Cardiac magnetic resonance imaging (MRI) findings. PATIENTS/METHODS: A total of 9 patients diagnosed with vaccine-associated myopericarditis were followed up. RESULTS: The mean age of the patient at diagnosis was 15.3â€‰Â±â€‰1.0 (range: 14-17) years, and all patients were male. Seven patients presented with myocarditis symptoms after their second vaccine dose, one patient presented with pericarditis symptoms after his first dose, and the other patient presented with myocarditis symptoms after his booster dose. The median time at presenting to the hospital was 3 (range: 2-22) days. Seven (77.7%) patients had abnormal electrocardiography (ECG) findings, and the most prevalent finding was diffuse ST-segment elevation. Initial cardiac MRI results were abnormal in all patients, where 8 (88.8%) patients had late gadolinium enhancement, and 5 (55.5%) had myocardial edoema. Three patients showed local left ventricular wall-motion abnormalities. In their follow-up MRIs 3-6â€‰months later, myocardial edoema was present in 2 (28.5%) patients, while late gadolinium enhancement was present in all patients (7/7, 100%, 2 patients did not have control MRI time). Hypokinetic segments were still present in one of the 3 patients. No negative cardiac events were observed in the short-term follow-up of any patient. CONCLUSION: Further follow-up evaluation and larger multicenter studies are needed to determine the clinical significance of persistent cardiac MRI abnormalities.

Effect of 2 vs 3 Doses of COVID-19 Vaccine in Patients With Inflammatory Bowel Disease: A Population-based Propensity Matched Analysis. AIM: There are limited data on the impact of 2 vs 3 doses of COVID-19 vaccine in patients with inflammatory bowel disease (IBD). The primary aim of

the study was to assess the efficacy of COVID-19 vaccine based on number of administered doses in patients with IBD. METHODS: We conducted a retrospective cohort study using TriNetX, a multi-institutional database to compare patients with IBD who received 1, 2, or 3 doses of BNT162b2 or mRNA-1273 to unvaccinated IBD patients (1.1.2020-7.26.2022) to assess the risk of COVID-19 after 1:1 propensity score matching. We also evaluated the impact of vaccine on a composite of severe COVID-19 outcomes including hospitalization, intubation, intensive care unit care, acute kidney injury, or mortality. RESULTS: After propensity score matching, vaccinated patients with 2 (adjusted OR [aOR], 0.8; 95% confidence interval [CI], 0.6-0.9) and 3 doses (aOR, 0.7; 95% CI, 0.5-0.9) were found to have a lower risk of COVID-19 compared with unvaccinated patients. Vaccinated patients with IBD had a lower risk of severe COVID-19 outcomes (aOR, 0.7; 95% CI, 0.6-0.9) compared with unvaccinated patients. There was no difference in the risk of COVID-19 in IBD patients with 2 compared with 3 doses (aOR, 0.97; 95% CI, 0.7-1.3). However, IBD patients with 2 doses were at an increased risk for hospitalization due to COVID-19 (aOR, 1.78; 95% CI, 1.02-3.11) compared with those that received 3 doses. CONCLUSION: Vaccinated patients with IBD had a lower risk of severe COVID-19 outcomes compared with unvaccinated patients. A third dose of COVID-19 vaccine compared with 2 doses decreases the risk of hospitalization but not breakthrough infection in patients with IBD.

Skin manifestations following anti-COVID-19 vaccination: AÂ multicentricstudy from Turkey. PURPOSE: After the emergence of the pandemic caused by the COVID-19 virus, vaccination with various vaccines has started to be implemented across the world. To identify dermatological reactions developing after the COVID-19 vaccines administered in Turkey and determine their clinical features and risk factors that may play a role in their development. MATERIALS AND METHODS: The study included patients aged â‰¥18â€‰years, who presented to 13 different dermatology clinics in Turkey between July 2021 and September 2021 after developing dermatological reactions following the administration of the COVID-19 vaccine. After providing written consent, the patients were asked to complete a standard survey including questions related to age, gender, occupation, comorbidities, the regular medication used, the onset of cutaneous reactions after vaccination, and localization of reactions. Dermatological reactions were categorized according to whether they developed after the first or second dose of the vaccine or whether they occurred after the inactivated or messenger RNA (mRNA) vaccine. The relationship between dermatological reactions and some variables such as gender and comorbidities was also evaluated. RESULTS: A total of 269 patients [116 women (43.1%), 153 men (56.9%)] were included in the study. It was observed that the dermatological diseases and reactions that most frequently developed after vaccination were urticaria (25.7%), herpes zoster (24.9%), maculopapular eruption (12.3%), and pityriasis rosea (4.5%). The rate of dermatological reactions was 60.6% after the administration of the mRNA vaccine and 39.4% after that of the inactivated vaccine. There was a statistically significantly higher number of reactions among the patients that received the mRNA vaccine (pÂ =Â 0.001). CONCLUSION: The most common reactions in our sample were urticaria, herpes zoster, and maculopapular eruption. Physicians should know the dermatological side effects of COVID-19 vaccines and their clinical features.

Cutaneous reactions after CoronaVac and BioNTech vaccines.

A first-in-human trial on the safety and immunogenicity of COVID-eVax, a cellular response-skewed DNA vaccine against COVID-19. The COVID-19 pandemic and the need for additional safe, effective, and affordable vaccines gave new impetus into development of vaccine genetic platforms. Here we report the findings from the phase 1, first-in-human, dose-escalation study of COVID-eVax, a DNA vaccine encoding the receptor binding domain (RBD) of the SARS-CoV-2 spike protein. Sixty-eight healthy adults received two doses of 0.5, 1, orÂ 2Â mg 28Â days apart, or a single 2-mg dose, via intramuscular injection followed by electroporation, and they were monitored for 6Â months. All participants completed the primary safety and immunogenicity assessments after 8Â weeks. COVID-

eVax was well tolerated, with mainly mild to moderate solicited adverse events (tenderness, pain, bruising, headache, and malaise/fatigue), less frequent after the second dose, and it induced an immune response (binding antibodies and/or TÂ cells) at all prime-boost doses tested in up to 90% of the volunteers at the highest dose. However, the vaccine did not induce neutralizing antibodies, while particularly relevant was the TÂ cell-mediated immunity, with a robust Th1 response. This TÂ cell-skewed immunological response adds significant information to the DNA vaccine platform and should be assessed in further studies for its protective capacity and potential usefulness also in other therapeutic areas, such as oncology.

Diabetic ketoacidosis after the second dose of SARS-CoV-2 mRNA vaccination in a patient with pembrolizumab-induced fulminant type 1 diabetes. We report a case of 77-year-old woman with fulminant type 1 diabetes (T1D) who developed diabetic ketoacidosis (DKA) after the second dose of SARS-CoV-2 vaccine tozinameran. The patient had been diagnosed as having T1D associated with an immune-related adverse event caused by pembrolizumab at the age of 75. After the second dose of tozinameran, she developed DKA and needed intravenous insulin infusion and mechanical ventilation. Although the direct causal relationship between the vaccination and the DKA episode could not be proven in this case, published literatures had suggested the possibility of developing DKA after SARS-CoV-2 vaccination in patients with T1D. As the magnitude of the risk of the combination of the known adverse drug reactions of SARS-CoV-2 mRNA vaccine and T1D patients' vulnerability to sick-day conditions is not yet thoroughly assessed, future studies such as a non-interventional study with adequate sample size would be required to address this issue.

Vaccine-associated corneal graft rejection following SARS-CoV-2 vaccination: a CDC-VAERS database analysis. PURPOSE: To evaluate the cases of corneal graft rejection following SARS-CoV-2 vaccination reported to Centers for Disease Control and Prevention Vaccine Adverse Event Reporting System. METHODS: A descriptive analysis of the demographics, clinical history and presentation was performed. We evaluated the correlation between the vaccines and duration of vaccine-associated graft rejection (VAR) onset following vaccination using a one-way analysis of variance test. A post hoc analysis was performed between VAR onset-interval following vaccination dose and vaccine type. Finally, a 30-day cumulative incidence analysis was performed to assess the risk of VAR in short term following different doses, vaccines and type of corneal transplantation. RESULTS: A total of 55 eyes of 46 patients were diagnosed with VAR following vaccination with BNT162b2 (73.91%) and mRNA-1273 (26.09%). The mean age of the patients was 62.76Â±15.83 years, and 28 (60.87%) were female. The patients diagnosed with VAR had undergone penetrating keratoplasty (61.82%), Descemet membrane endothelial keratoplasty (12.73%), descemet stripping endothelial keratoplasty (18.18%), anterior lamellar keratoplasty (3.64%) and corneal limbal allograft transplantation (1.82%). The mean time for VAR since penetrating and endothelial keratoplasty was 8.42Â±9.23 years and 4.18Â±4.40 years, respectively. 45.65% of the cases of VAR were reported after the second dose of vaccine. The duration of VAR onset was significantly shorter after the second dose compared with the first and booster doses (p=0.0165) and in patients who underwent endothelial keratoplasty compared with penetrating keratoplasty (p=0.041). CONCLUSIONS: This study outlines a possible temporal relationship between corneal graft rejection and SARS-CoV-2 vaccination. An earlier onset of VAR was observed in patients who had a history of endothelial keratoplasty and following the second dose of vaccination.

Colitis with Hypereosinophilia following the Second Dose of the BNT162b2 mRNA COVID-19 Vaccine: A Case Report with a Literature Review. A 61-year-old man presented with a 7-day history of watery diarrhea and loss of appetite after receiving the second dose of the Pfizer-BioNTech COVID-19 vaccine. Laboratory studies showed significant eosinophilia and an elevated IgE level (white cell count, 18.4Ã—10(9)/L; eosinophil count, 9.5Ã—10(9)/L; and IgE level, 540 IU/L). Symptoms resolved

10 days after vaccination without any steroids or antiallergic medications, and the eosinophil count had also returned to within normal limits 2 months later. Several cases of eosinophilic disorders following receipt of any type of injectable COVID-19 vaccine have been reported, so the etiology should be examined.

Relapsing Anti-MOG Antibody-associated Disease following COVID-19 Vaccination: A Rare Case Report and Review of the Literature. Anti-myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) is an autoimmune demyelinating disorder that mainly occurs post-infection or post-vaccination. MOGAD after inoculation with coronavirus disease 2019 (COVID-19) vaccines is rare, and we herein report a rare case of a patient with MOGAD after vaccination using the Pfizer-BioNTech COVID-19 vaccine (BNT162b2, Pfizer Japan, Tokyo). Our report highlights the fact that MOGAD following inoculation with COVID-19 vaccine may show clinical relapse during reduction of the oral steroid dose, and continuous treatments with immunological agents is needed to prevent disease recurrence.

Optic neuromyelitis after vaccination against SARS-CoV-2. Neuromyelitis optica is an autoimmune demyelinating astrocytopathy of the central nervous system that primarily affects the optic nerve and spinal cord. It is considered a multifactorial disease associated with antibodies against aquaporin 4, with complement cascade activation and lymphocytic infiltration leading to axonal loss and causing significant morbidity and disability. In addition, cases of inflammatory diseases of the central nervous system have been described after vaccination against SARS-CoV-2, mainly acute disseminated encephalomyelitis. Also, a few cases of neuromyelitis optica spectrum disorder, mostly aquaporin 4+, have been reported. We describe a patient who developed symptoms suggestive of acute disseminated encephalomyelitis the next day after vaccination against SARS-CoV-2. Three months later, a longitudinally extensive transverse myelitis compatible with aquaporin 4+ neuromyelitis optica was successfully treated with an interleukin 6 inhibitor. There is no proven association and research is needed to establish whether optic neuromyelitis is related to vaccination; this is a single case report from which no conclusion can be drawn.

Recommendation for broad use of Covid-19 mRNA vaccine boosters due to waning vaccine effectiveness is taking the easy way out.

Conception and reality: Outcome of SARS-CoV-2 infection and vaccination among Hungarian IBD patients on biologic treatments. INTRODUCTION: Inflammatory bowel disease potentially elevates the risk of infections, independently from age, while the disease activity and medical treatment(s) can also increase the risks. Nevertheless, it is necessary to clarify these preconceptions as well during the COVID-19 pandemic. METHODS: An observational, questionnaire based study was conducted in Hungary between February and August 2021. 2 questionnaires were completed. The first questionnaire surveyed the impact of the pandemic on patients with biologic treatments and assessed the severity and outcome of the infection, whereas the second one assessed vaccination rate and adverse events. RESULTS: 472 patients participated in the study. 16.9Â % of them acquired the infection and 6.3Â % needed hospitalization. None of them required ICU care. Male sex elevated the risk of infection (pÂ =Â 0.008), while glove (pÂ =Â 0.02) and mask wearing (pÂ =Â 0.005) was the most effective prevention strategy. Nevertheless, abstaining from community visits or workplace did not have an impact on the infection rate. Smoking, age, and disease type did not elevate the risk. UC patients had poorer condition during the infection (pÂ =Â 0.003); furthermore, the disease activity could potentially worsen the course of infection (pÂ =Â 0.072). The different biological treatments were equally safe; no difference was observed in the infection rate, course of COVID-19. Azathioprine and corticosteroids did not elevate the infection rate. 28 patients (35.0Â %) suspended the ongoing biologic treatment, but it had no impact on the disease course. However, it resulted in changing the current treatment (pÂ =Â 0.004). 9.8Â % of the respondents were sceptic about being vaccinated, and

90Â % got vaccinated. In one case, a serious flare-up occurred. DISCUSSION: Most patients acquired the infection at workplace. Biologic therapies had no effect on the COVID-19 infection, whereas male sex, an active disease, and UC could be larger threat than treatments. Vaccination was proved to be safe, and patient education is important to achieve mass vaccination of the population.

Two Cases of Possible Exacerbation of Chronic Rejection After Anti-SARS-CoV-2 Messenger RNA Vaccination: A Case Report. In post-liver transplant recipients, SARS-CoV-2 infection is a health threat, and novel messenger RNA vaccines such as Pfizer BioNTech BNT162b2 and Moderna mRNA-1273 are aggressively recommended. However, there are few reports on their adverse effects, some of which may be potentially fatal. We have experienced 2 post-liver transplant recipients with exacerbated chronic rejection after vaccination, one of whom had to undergo retransplant and the other who is still in the process of liver function without improvement. These alarming cases will be presented as case reports.

Booster shot of inactivated SARS-CoV-2 vaccine induces potent immune responses in people living with HIV. This study aimed to investigate the immunogenicity to SARS-CoV-2 and evasive subvariants BA.4/5 in people living with HIV (PLWH) following a third booster shot of inactivated SARS-CoV-2 vaccine. We conducted a cross-sectional study in 318 PLWH and 241 healthy controls (HC) using SARS-CoV-2 immunoassays. Vaccine-induced immunological responses were compared before and after the third dose. Serum levels of IgG anti-RBD and inhibition rate of NAb were significantly elevated at the "post-third dose" sampling time compared with the pre-third dose in PLWH, but were relatively decreased in contrast with those of HCs. Induced humoral and cellular responses attenuated over time after triple-dose vaccination. The neutralizing capacity against BA.4/5 was also intensified but remained below the positive inhibition threshold. Seropositivity of SARS-CoV-2-specific antibodies in PLWH was prominently lower than that in HC. We also identified age, CD4 cell counts, time after the last vaccination, and WHO staging type of PLWH as independent factors associated with the seropositivity of antibodies.Â PLWH receiving booster shot of inactivated vaccines generate higher antibody responses than the second dose, but lower than that in HCs. Decreased anti-BA.4/5 responses than that of WT impede the protective effect of the third dose on Omicron prevalence.

Risk of waning humoral responses after inactivated or subunit recombinant SARS-CoV-2 vaccination in patients with chronic diseases: Findings from a prospective observational study in China. Heterogeneity of antibody responses has been reported in SARS-CoV-2 vaccination recipients with underlying diseases. We investigated the impact of the presence of comorbidities on the humoral response to SARS-CoV-2 vaccination in patients with chronic disease (PWCD) and assessed the effect of the number of comorbidities on the humoral response to vaccination. In this study, neutralizing antibodies (NAbs) and IgG antibodies against the receptor-binding domain (RBD-IgG) were monitored following a full-course vaccination. In total, 1400 PWCD (82.7%, inactivated vaccines; 17.3%, subunit recombinant vaccine) and 245 healthy controls (65.7% inactivated vaccines, 34.3% subunit recombinant vaccine) vaccinated with inactivated or subunit recombinant SARS-CoV-2 vaccines, were included. The seroconversion and antibody levels of the NAbs and RBD-IgG were different in the PWCD group compared with those in the control group. Chronic hepatitis B (odds ratio [OR]: 0.65; 95% confidence interval [CI]: 0.46-0.93), cancer (OR: 0.65; 95% CI: 0.42-0.99), and diabetes (OR: 0.50; 95% CI: 0.28-0.89) were associated with lower seroconversion of NAbs. Chronic kidney disease (OR: 0.29; 95% CI: 0.11-0.76), cancer (OR: 0.38; 95% CI: 0.23-0.62), and diabetes (OR: 0.37; 95% CI: 0.20-0.69) were associated with lower seroconversion of RBD-IgG. Only the presence of autoimmune disease showed significantly lower NAbs and RBD-IgG titers. Patients with most types of chronic diseases showed similar responses to the controls, but humoral responses were still significantly

associated with the presence of â‰¥2 coexisting diseases. Our study suggested that humoral responses following SARS-CoV-2 vaccination are impaired in patients with certain chronic diseases.

Association of inactivated COVID-19 vaccination with in vitro fertilization and early pregnancy outcomes.

Prevalence of Adenopathy at Chest Computed Tomography After Vaccination for Severe Acute Respiratory Syndrome Coronavirus 2. OBJECTIVE: This study aimed to determine the prevalence of axillary and subpectoral (SP) lymph nodes after ipsilateral COVID-19 vaccine administration on chest computed tomography (CT). METHODS: Subjects with chest CTs between 2 and 25 days after a first or second vaccine dose, December 15, 2020, to February 12, 2021, were included. Orthogonal measures of the largest axillary and SP nodes were recorded by 2 readers blinded to vaccine administration and clinical details. A mean nodal diameter discrepancy of â‰¥6 mm between contralateral stations was considered positive for asymmetry. Correlation with the side of vaccination, using a Spearman rank correlation, was performed on the full cohort and after excluding patients with diseases associated with adenopathy. RESULTS: Of the 138 subjects (81 women, 57 men; mean [SD] age, 74.4 Â± 11.7 years), 48 (35%) had asymmetrically enlarged axillary and/or SP lymph nodes, 42 (30%) had ipsilateral, and 6 (4%) had contralateral to vaccination (P = 0.003). Exclusion of 29 subjects with conditions associated with adenopathy showed almost identical correlation, with asymmetric nodes in 32 of 109 (29%) ipsilateral and in 5 of 109 (5%) contralateral to vaccination (P = 0.002). CONCLUSIONS: Axillary and/or SP lymph nodes ipsilateral to vaccine administration represents a clinical conundrum. Asymmetric nodes were detected at CT in 30% of subjects overall and 29% of subjects without conditions associated with adenopathy, approximately double the prevalence rate reported to the Centers for Disease Control and Prevention by vaccine manufacturers. When interpreting examinations correlation with vaccine administration timing and site is important for pragmatic management.

Post-pandemic healthcare for COVID-19 vaccine: Tissue-aware diagnosis of cervical lymphadenopathy via multi-modal ultrasound semantic segmentation. With the widespread deployment of COVID-19 vaccines all around the world, billions of people have benefited from the vaccination and thereby avoiding infection. However, huge amount of clinical cases revealed diverse side effects of COVID-19 vaccines, among which cervical lymphadenopathy is one of the most frequent local reactions. Therefore, rapid detection of cervical lymph node (LN) is essential in terms of vaccine recipients' healthcare and avoidance of misdiagnosis in the post-pandemic era. This paper focuses on a novel deep learning-based framework for the rapid diagnosis of cervical lymphadenopathy towards COVID-19 vaccine recipients. Existing deep learning-based computer-aided diagnosis (CAD) methods for cervical LN enlargement mostly only depend on single modal images, e.g., grayscale ultrasound (US), color Doppler ultrasound, and CT, while failing to effectively integrate information from the multi-source medical images. Meanwhile, both the surrounding tissue objects of the cervical LNs and different regions inside the cervical LNs may imply valuable diagnostic knowledge which is pending for mining. In this paper, we propose an Tissue-Aware Cervical Lymph Node Diagnosis method (TACLND) via multi-modal ultrasound semantic segmentation. The method effectively integrates grayscale and color Doppler US images and realizes a pixel-level localization of different tissue objects, i.e., lymph, muscle, and blood vessels. With inter-tissue and intra-tissue attention mechanisms applied, our proposed method can enhance the implicit tissue-level diagnostic knowledge in both spatial and channel dimension, and realize diagnosis of cervical LN with normal, benign or malignant state. Extensive experiments conducted on our collected cervical LN US dataset demonstrate the effectiveness of our methods on both tissue detection and cervical lymphadenopathy diagnosis. Therefore, our proposed framework can guarantee efficient diagnosis

for the vaccine recipients' cervical LN, and assist doctors to discriminate between COVID-related reactive lymphadenopathy and metastatic lymphadenopathy.

Effect of inactivated COVID-19 vaccines on seizure frequency in patients with epilepsy: A multicenter, prospective study. OBJECTIVES: Several COVID-19 vaccines list "uncontrolled epilepsy" as a contraindication for vaccination. This consequently restricts vaccination against COVID-19 in patients with epilepsy (PWE). However, there is no strong evidence that COVID-19 vaccination can exacerbate conditions in PWE. This study aims to determine the impact of COVID-19 vaccination on PWE. METHODS: PWE were prospectively recruited from 25 epilepsy centers. We recorded the seizure frequency at three time periods (one month before the first vaccination and one month after the first and second vaccinations). A generalized linear mixed-effects model (GLMM) was used for analysis, and the adjusted incidence rate ratio (AIRR) with 95% CI was presented and interpreted accordingly. RESULTS: Overall, 859 PWE were included in the analysis. Thirty-one (3.6%) and 35 (4.1%) patients were found to have increased seizure frequency after the two doses, respectively. Age had an interaction with time. The seizure frequency in adults decreased by 81% after the first dose (AIRR=0.19, 95% CI:0.11-0.34) and 85% after the second dose (AIRR=0.16, 95% CI:0.08-0.30). In juveniles (<18), it was 25% (AIRR=0.75, 95% CI:0.42-1.34) and 51% (AIRR=0.49, 95% CI:0.25-0.95), respectively. Interval between the last seizure before vaccination and the first dose of vaccination (ILSFV) had a significant effect on seizure frequency after vaccination. Seizure frequency in PWE with hereditary epilepsy after vaccination was significantly higher than that in PWE with unknown etiology (AIRR=1.95, 95% CI: 1.17-3.24). Two hundred and seventeen (25.3%) patients experienced non-epileptic but not serious adverse reactions. DISCUSSION: The inactivated COVID-19 vaccine does not significantly increase seizure frequency in PWE. The limitations of vaccination in PWE should focus on aspects other than control status. Juvenile PWE should be of greater concern after vaccination because they have lower safety. Finally, PWE should not reduce the dosage of anti-seizure medication during the peri-vaccination period.

Humoral immune response following a third SARS-CoV-2 mRNA vaccine dose in solid organ transplant recipients compared with matched controls. BACKGROUND: Solid organ transplant (SOT) recipients have shown suboptimal antibody response following COVID-19 vaccination. Several risk factors for the diminished response have been identified including immunosuppression and older age, but the influence of different comorbidities is not fully elucidated. METHOD: This case-control study consisted of 420 Danish adult SOT recipients and 840 sex- and age-matched controls, all vaccinated with a third homologous dose of either BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna) vaccine. The primary outcome was differences in humoral immune response. The secondary outcome was breakthrough infections. Additionally, we looked for factors that could predict possible differences between the two groups. RESULTS: Response rate increased from 186/382 (49%) to 275/358 (77%) in SOT recipients and remained on 781/790 (99%) to 601/609 (99%) in controls following a third vaccine dose. SOT recipients had significantly lower median antibody concentrations after third dose compared to controls (332.6 BAU/ml vs 46,470.0 BAU/ml, p <0.001). Lowest median antibody concentrations were seen in SOT recipients with liver disease (10.3 BAU/ml, IQR 7.1-319) and diabetes (275.3 BAU/ml, IQR 7.3-957.4). Breakthrough infections occurred similarly frequent, 150 (40%) among cases and 301 (39%) among controls (p = 0.80). CONCLUSION: A third COVID-19 vaccine dose resulted in a significant increase in humoral immunogenicity in SOT recipients and maintained high response rate in controls. Furthermore, SOT recipients were less likely to produce antibodies with overall lower antibody concentrations and humoral immunity was highly influenced by the presence of liver disease and diabetes. The prevalence of breakthrough infections was similar in the two groups.

Preclinical evaluation of safety and immunogenicity of a primary series intranasal COVID-19 vaccine candidate (BBV154) and humoral immunogenicity evaluation of a heterologous prime-boost strategy with COVAXIN (BBV152). Most if not all vaccine candidates developed to combat COVID-19 due to SARS-CoV-2 infection are administered parenterally. As SARS-CoV-2 is transmitted through infectious respiratory fluids, vaccine-induced mucosal immunity could provide an important contribution to control this pandemic. ChAd-SARS-CoV-2-S (BBV154), a replication-defective chimpanzee adenovirus (ChAd)-vectored intranasal (IN) COVID-19 vaccine candidate, encodes a prefusion-stabilized version of the SARS-CoV-2 spike protein containing two proline substitutions in the S2 subunit. We performed preclinical evaluations of BBV154 in mice, rats, hamsters and rabbits. Repeated dose toxicity studies presented excellent safety profiles in terms of pathology and biochemical analysis. IN administration of BBV154 elicited robust mucosal and systemic humoral immune responses coupled with Th1 cell-mediated immune responses. BBV154 IN vaccination also elicited potent variant (omicron) cross neutralization antibodies. Assessment of anti-vector (ChAd36) neutralizing antibodies following repeated doses of BBV154 IN administration showed insignificant titers of ChAd36 neutralizing antibodies. However, the immune sera derived from the same animals displayed significantly higher levels of SARS-CoV-2 virus neutralization ($p<0.003$). We also evaluated the safety and immunogenicity of heterologous prime-boost vaccination with intramuscular (IM) COVAXIN-prime followed by BBV154 IN administration. COVAXIN priming followed by BBV154 IN-booster showed an acceptable reactogenicity profile comparable to the homologous COVAXIN/COVAXIN or BBV154/BBV154 vaccination model. Heterologous vaccination of COVAXIN-prime and BBV154 booster also elicited superior ($p<0.005$) and cross variant (omicron) protective immune responses ($p<0.013$) compared with the homologous COVAXIN/COVAXIN schedule. BBV154 has successfully completed both homologous and heterologous combination schedules of human phase 3 clinical trials and received the restricted emergency use approval (in those aged above 18 years) from the Drugs Controller General of India (DCGI).

Persistence of SARS-CoV-2 neutralizing antibodies and anti-Omicron IgG induced by BNT162b2 mRNA vaccine in patients with autoimmune inflammatory rheumatic disease: an explanatory study in Japan. BACKGROUND: Autoimmune inflammatory rheumatic disease (AIRD) patients are at high risk of the coronavirus disease 2019 (COVID-19), but the medium-term effects of immunosuppressants on vaccine efficacy are unknown. WeÂ investigated the duration of humoral responses against severe acute respiratory syndrome coronavirus 2Â (SARS-CoV-2) wild-type and Omicron variant in AIRD patients administered with two doses of the BNT162b2 (Pfizer-BioNTech) vaccine. METHODS: Serum-neutralizing antibody (NAb) and anti-receptor-binding domain (RBD)/spike antibody levels were measured. Short- and medium-term effects of immunosuppressants were analyzed pre-vaccination (Term 1) and 14-42 days (Term 2) and 100-200 days (Term 3) after the second vaccination. FINDINGS: From Feb 1, 2021, to Feb 28, 2022, 439 AIRD patients and 146 healthy controls were investigated. The seropositivity rate and log(10)-NAb titers were significantly lower in AIRD patients than in controls at Terms 2 and 3. In rheumatoid arthritis patients, tumor necrosis factor-Î± inhibitors (TNFis) at Term 3, and older age, glucocorticoids, and abatacept at Terms 2 and 3 were risk factors for reduced responses. Anti-Omicron RBD/spike IgG levels strongly correlated with NAb titers. INTERPRETATION: Glucocorticoids, TNFis, and abatacept treatments negatively affect the longevity of humoral responses to SARS-CoV-2, including Omicron, after two vaccine doses. These findings may inform the timing of additional vaccination for AIRD patients. FUNDING: Cloud Funding of Peace Winds Japan; Center of Innovation Program from the Ministry of Education, Culture, Sports, Science and Technology of Japan; Japan Society for the Promotion of Science KAKENHI; Japan Agency for Medical Research and Development; Kansai Economic Federation; Mitsubishi Zaidan; and Research Grant

from Japan Agency for Medical Research and Development-Core Research for Evolutional Science and Technology.
[Third-degree atrioventricular block associated with the SARS-CoV-2 mRNA vaccine].
Myoglobinuria-induced Acute Kidney Injury Secondary to Covishield(TM) Vaccination. Vaccination is the best strategy for the development of herd immunity and for the control of the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) pandemic. As the number of immunizations across the globe reaches a record number, random cases of diverse adverse effects of the vaccines are being documented. We report a case of renal biopsy-proven myoglobin-induced acute tubular injury requiring dialytic support post-Covishield(TM) vaccination. Awareness of this rare complication is necessary so that it can be recognized early, and renal injury avoided.
Post COVID Vaccination (COVAXINâ„¢ -BB152 V) Pauci-immune Crescentic Glomerulonephritis. Coronavirus disease 2019 (COVID-19) pandemic is responsible for widespread morbidity and mortality. The vaccination against the severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) infection, the cause of the COVID-19 pandemic, is currently ongoing across the globe. Rapid vaccination is of paramount importance to mitigate this pandemic. Although considered safe in general, these vaccines have their share of rare adverse events. We report a case of antineutrophil cytoplasmic antibody (ANCA)-associated pauci-immune crescentic glomerulonephritis 15 days post 2(nd) dose of a killed COVID-19 (COVAXINâ„¢ -BB152 V) vaccine. We hypothesize that vaccination triggered a systemic immune response in a susceptible patient to develop ANCA-associated vasculitis (AAV), leading to rapidly progressive glomerulonephritis (RPGN).
Severe acute respiratory syndrome corona virus-2 (SARS-CoV-2) serology in the vaccination era and post booster vaccination. BACKGROUND: The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) pandemic has caused over 6 million deaths world-wide. In the pre-vaccination era, we noted a 5Â·3% SARS-CoV-2 IgG antibody positivity rate in 81,624 subjects. METHODS: Utilizing assays for serum SARS-CoV-2 spike (S) protein antibody (Roche) and neutralizing antibody (Diazyme), both >90% IgG, we measured antibodies in 13,189 subjects in the post-vaccination era, and in 69 subjects before and 60 days after booster vaccination. RESULTS: In 2021, in 10,267 subjects, 25Â·0% had negative S protein levels (<0.80 U/L), 24Â·4% had low positive levels (0.80-250 U/L), and 50Â·7% had high positive levels (>250 U/L). Median neutralizing antibody levels were 1Â·16 and 2Â·06 AU/mL in the low and high positive groups, respectively. In 2022, we evaluated 2,016 subjects where samples were diluted 1:100 if S protein antibody levels were >250 U/L. Median S protein and neutralizing antibody levels were 2,065 U/L (86.3% positivity) and 2Â·68 AU/mL (68.0% positivity), respectively. Antibody levels were also measured in 69 subjects before and 60 days after receiving SARS-CoV-2 booster vaccinations. Treatment resulted in a 15-fold increase in S protein antibody levels from 1,010 to 17,236 U/L, and a 6-fold increase in neutralizing antibody from 1Â·51 to 12Â·51 AU/mL in neutralizing antibody levels, respectively (both P<0.00001), with a wide variability in response. CONCLUSIONS: Our data indicate that by early 2022 86% of subjects had positive SARS-CoV-2 S protein antibody levels, and that these levels and neutralizing antibody levels were increased 15-fold and 6-fold, respectively, 60 days after SARS-Cov-2 booster vaccination.
COVID19 vaccine in myasthenia gravis patients: safety and possible predictors of disease exacerbation.
Association of dual COVID-19 and seasonal influenza vaccination with COVID-19 infection and disease severity. The clinical guideline states that COVID-19 vaccination can be administered concurrently with Influenza (flu) vaccination (dual vaccination). Using data from the 2021 National Health Interview Survey, we conducted descriptive analysis and multivariate logistic regressions to examine the association between dual vaccination status and self-reported COVID-19 infection and severity. Among 21,387 (weighted 185,251,310) U.S. adults, about 22% did not receive either the flu

or COVID-19 vaccine, 6.0% received the flu vaccine only, 29.1% received the COVID-19 vaccine only, and 42.5% received both vaccines. In the multivariate analysis, individuals with dual vaccination (OR, 0.65, 95% CI, 0.56-0.75) and COVID-19 vaccine only (OR, 0.71, 95% CI, 0.61-0.82) were significantly less likely to report COVID-19 infection when compared with those unvaccinated. There was no significant difference in self-reported COVID-19 symptom severity by vaccination status. The results suggest that dual vaccination may be an effective strategy to reduce the contagious respiratory disease burden.

Molnupiravir plus usual care versus usual care alone as early treatment for adults with COVID-19 at increased risk of adverse outcomes (PANORAMIC): an open-label, platform-adaptive randomised controlled trial. BACKGROUND: The safety, effectiveness, and cost-effectiveness of molnupiravir, an oral antiviral medication for SARS-CoV-2, has not been established in vaccinated patients in the community at increased risk of morbidity and mortality from COVID-19. We aimed to establish whether the addition of molnupiravir to usual care reduced hospital admissions and deaths associated with COVID-19 in this population. METHODS: PANORAMIC was a UK-based, national, multicentre, open-label, multigroup, prospective, platform adaptive randomised controlled trial. Eligible participants were aged 50 years or older-or aged 18 years or older with relevant comorbidities-and had been unwell with confirmed COVID-19 for 5 days or fewer in the community. Participants were randomly assigned (1:1) to receive 800 mg molnupiravir twice daily for 5 days plus usual care or usual care only. A secure, web-based system (Spinnaker) was used for randomisation, which was stratified by age (<50 years vs â‰¥50 years) and vaccination status (yes vs no). COVID-19 outcomes were tracked via a self-completed online daily diary for 28 days after randomisation. The primary outcome was all-cause hospitalisation or death within 28 days of randomisation, which was analysed using Bayesian models in all eligible participants who were randomly assigned. This trial is registered with ISRCTN, number 30448031. FINDINGS: Between Dec 8, 2021, and April 27, 2022, 26â€‰411 participants were randomly assigned, 12â€‰821 to molnupiravir plus usual care, 12â€‰962 to usual care alone, and 628 to other treatment groups (which will be reported separately). 12â€‰529 participants from the molnupiravir plus usual care group, and 12â€‰525 from the usual care group were included in the primary analysis population. The mean age of the population was 56Â·6 years (SD 12Â·6), and 24â€‰290 (94%) of 25â€‰708 participants had had at least three doses of a SARS-CoV-2 vaccine. Hospitalisations or deaths were recorded in 105 (1%) of 12â€‰529 participants in the molnupiravir plus usual care group versus 98 (1%) of 12â€‰525 in the usual care group (adjusted odds ratio 1Â·06 [95% Bayesian credible interval 0Â·81-1Â·41]; probability of superiority 0Â·33). There was no evidence of treatment interaction between subgroups. Serious adverse events were recorded for 50 (0Â·4%) of 12â€‰774 participants in the molnupiravir plus usual care group and for 45 (0Â·3%) of 12â€‰934 in the usual care group. None of these events were judged to be related to molnupiravir. INTERPRETATION: Molnupiravir did not reduce the frequency of COVID-19-associated hospitalisations or death among high-risk vaccinated adults in the community. FUNDING: UK National Institute for Health and Care Research.

Immune responses related to the immunogenicity and reactogenicity of COVID-19 mRNA vaccines. Vaccination for the prevention of severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) infection is considered the most promising approach to control the pandemic of coronavirus disease 2019 (COVID-19). Although various COVID-19 vaccines have been developed worldwide using several modalities, the vaccines that have shown the highest efficacy to date are mRNA vaccines. Despite their extensive usage, the mechanisms that stimulate the immune responses associated with their immunogenicity and reactogenicity remain largely unknown. In this review, we summarize and discuss current knowledge on immune responses to COVID-19 mRNA vaccines, including potential immune responses and correlating factors underlying the immunogenicity and reactogenicity of

mRNA vaccines. We also describe recent trends in the optimization of lipid nanoparticles and vaccination routes. Further understanding of vaccine-elicited immune responses will guide the development of more effective and safe vaccines.

The need to shed light on potential insidious SARS-CoV-2 post-vaccination pituitary lesions.

Vaccination in children with immune-mediated disorders. OBJECTIVE: To present an updated review of recommendations for the vaccination of children with immune-mediated diseases, with an emphasis on rheumatic and inflammatory diseases. SOURCE OF DATA: Studies published in the PubMed and Scielo databases between 2002 and 2022, Guidelines of Brazilian Scientific Societies, Manuals and Technical Notes of the Ministry of Health of Brazil, on current immunization schedules for special populations. DATA SYNTHESIS: Immunosuppressive drugs and biological agents reduce the immunogenicity of vaccines and favor susceptibility to infections. The safety and efficacy of immunogens are important points for vaccination in children with immune-mediated diseases. The safety threshold of a vaccine applied to immunocompromised individuals can be reduced when compared to healthy individuals. Very often, the recommendations for the immunization of children with immune-mediated diseases follow the recommendations for immunocompromised patients. Vaccination against COVID-19, on the other hand, should ideally occur when the disease is stabilized and in the absence of a low degree of immunosuppression. The patients should be informed about the possibility that the immunization may fail during treatment with immunosuppressants. Specific vaccination schedules should be considered to ensure better protection. CONCLUSIONS: Recent studies have allowed updating the recommendations on the safety and immunogenicity of vaccination in children with immune-mediated diseases, especially for live attenuated vaccines. There is a scarcity of data on the safety and efficacy of COVID-19 vaccines in patients, particularly pediatric patients, with rheumatic diseases. The completion of ongoing studies is expected to help guide recommendations on COVID-19 vaccines in this group of patients.

Lower frequency of SARS-CoV-2-associated severe respiratory infections among adults vaccinated against the 2021/22 season influenza.

Management of cardiovascular symptoms after Pfizer-BioNTech COVID-19 vaccine in teenagers in the emergency department. BACKGROUND: Cardiovascular complications after Pfizer-BioNTech COVID-19 (BNT) vaccination are a concern, especially in adolescents. We analyzed the risk factors for myocarditis after BNT vaccination. METHODS: We used a special evaluation protocol for all patients aged 12-18 years who presented to our emergency department with cardiovascular symptoms after BNT vaccination. RESULTS: A total of 195 patients (109 boys and 86 girls) were enrolled. Eleven (5.6%) patients presented with arrhythmia (arrhythmia group), 14 (7.2%) had a diagnosis of pericarditis/myocarditis (the peri/myocarditis group), and the remaining 170 were controls (no cardiac involvement). Chest pain (77.6%) was the most common symptom. The median time from vaccination to symptom onset was 3 days. In the peri/myocarditis group (13 myocarditis and 1 pericarditis), the median time to the peak troponin T level was 5 days after vaccination. Abnormal electrocardiographic changes, including ST-T changes and conduction blocks, were more commonly detected in the peri/myocarditis group (85.7% vs. 12.4% in the control group, pÂ <Â 0.01). Echocardiography revealed normal ventricular function in all patients. Symptoms were resolved before discharge in all, with the median duration of hospital stay being 4 days. The electrocardiography was the most appropriate screening tool for myocarditis, with a sensitivity and specificity of 85.7% and 87.6%, respectively. CONCLUSION: Pericarditis or myocarditis was diagnosed in 7.2% of adolescents presenting to the emergency department with cardiovascular symptoms after BNT vaccination. In addition to the troponin T level, ECG change listed above can be used as a screening tool for vaccine-induced cardiac complications.

Correlation of adverse effects and antibody responses following homologous and heterologous COVID19 prime-boost vaccinations. BACKGROUND: Studies correlating reactogenicity and immunogenicity of COVID-19 vaccines are limited to BNT162b2, with inconsistent results. We investigated whether adverse reactions after other COVID-19 vaccines reliably predict humoral responses. METHODS: Adult volunteers were recruited for homologous or heterologous prime-boost vaccinations with adenoviral (ChAdOx1, AstraZeneca) and/or mRNA (mRNA-1273, Moderna) vaccines administered either 4 or 8 weeks apart. Adverse effects were routinely solicited and recorded by subjects in a standard diary card for up to 84 days post booster vaccination. Anti-SARS-CoV-2 IgG titers were measured pre- (visit 1), and post-booster dose at days 14 (visit 2) and 28 (visit 3). RESULTS: A total of 399 participants (75% women) with a median age of 41 (interquartile range, 33-48 IQR) years were included. Vaccine-induced antibody titers at days 14 and 28 were significantly higher among subjects who reported local erythema, swelling, pain, as well as systemic fever, chills, headache, myalgia, arthralgia, fatigue compared to those who did not experience local or systemic reactogenicity. Post-vaccination humoral responses did not correlate with the occurrence of skin rash and correlated weakly with gastrointestinal symptoms. A significant correlation between post-vaccination peak body temperature and anti-SARS-CoV-2 spike IgG at Day 14, independent of vaccine type and schedule, was found. CONCLUSION: Specific symptoms of reactogenicity such as post-vaccination injection site pain, swelling, erythema and fever, myalgia and fatigue are significantly predictive of the magnitude of the anti-SARS-CoV-2 antibody response.

A safety study evaluating non-COVID-19 mortality risk following COVID-19 vaccination. BACKGROUND: The safety of COVID-19 vaccines plays an important role in addressing vaccine hesitancy. We conducted a large cohort study to evaluate the risk of non-COVID-19 mortality after COVID-19 vaccination while adjusting for confounders including individual-level demographics, clinical risk factors, health care utilization, and community-level socioeconomic risk factors. METHODS: The retrospective cohort study consisted of members from seven Vaccine Safety Datalink sites from December 14, 2020 through August 31, 2021. We conducted three separate analyses for each of the three COVID-19 vaccines used in the US. Crude non-COVID-19 mortality rates were reported by vaccine type, age, sex, and race/ethnicity. The counting process model for survival analyses was used to analyze non-COVID-19 mortality where a new observation period began when the vaccination status changed upon receipt of the first dose and the second dose. We used calendar time as the basic time scale in survival analyses to implicitly adjust for season and other temporal trend factors. A propensity score approach was used to adjust for the potential imbalance in confounders between the vaccinated and comparison groups. RESULTS: For each vaccine type and across age, sex, and race/ethnicity groups, crude non-COVID-19 mortality rates among COVID-19 vaccinees were lower than those among comparators. After adjusting for confounders with the propensity score approach, the adjusted hazard ratios (aHRs) were 0.46 (95% confidence interval [CI], 0.44-0.49) after dose 1 and 0.48 (95% CI, 0.46-0.50) after dose 2 of the BNT162b2 vaccine, 0.41 (95% CI, 0.39-0.44) after dose 1 and 0.38 (95% CI, 0.37-0.40) after dose 2 of the mRNA-1273 vaccine, and 0.55 (95% CI, 0.51-0.59) after receipt of Ad26.COV2.S. CONCLUSION: While residual confounding bias remained after adjusting for several individual-level and community-level risk factors, no increased risk was found for non-COVID-19 mortality among recipients of three COVID-19 vaccines used in the US.

Autoimmune haemolytic anaemia and immune thrombocytopenia following SARS-CoV-2 and non-SARS-CoV-2 vaccination: 32â€‰Years of passive surveillance data. Autoimmune haemolytic anaemia (AIHA) and immune thrombocytopenia (ITP) are two uncommon haematologic autoimmune conditions that can rarely arise secondary to vaccination. Prior studies using the US Centers for Disease Control's (CDC) Vaccine Adverse Event Reporting System (VAERS) have demonstrated this

infrequency, but contemporary data as well as comparison with current information regarding SARS-CoV-2 vaccination has not been assessed. In this study, we reviewed VAERS database reports from 1990 to 2022 to characterize the incidence and clinical and laboratory findings of non-SARS-CoV-2-associated AIHA and ITP and SARS-CoV-2 vaccine-associated AIHA and ITP. We discovered a total of 863 AIHA and ITP reports following vaccination with 15 non-SARS-CoV-2 and four SARS-CoV-2 vaccines submitted to the CDC VAERS database. AIHA and ITP reporting was low for both groups, with a large proportion excluded due to a lack of clinical details. ITP was reported the most frequently in both groups and was significantly more common with measles-mumps-rubella (MMR) vaccination (pâ€‰<â€‰0.001) in the non-SARS-CoV-2 group. AIHA and ITP cases were higher in the SARS-CoV-2 vaccine group, though ultimately still very infrequent. Autoimmune haematologic disease is vanishingly rare after immunization and rates are lower than in the general population according to passive reporting.

The Evolving Impact of Myocardial Injury in Patients With COVID-19 Amid the Omicron Wave of the Pandemic. COVID-19 with myocardial injury, defined as troponin elevation, is associated with worse outcomes. The temporal changes in outcomes during various phases of the pandemic remain unclear. We evaluated outcomes during the Omicron phase compared with previous phases of the pandemic. We analyzed patients who were COVID-19-positive with evidence of myocardial injury who presented to the MedStar Health system (11 hospitals in Washington, District of Columbia, and Maryland) during phase 1 of the pandemic (March to June 2020), phase 2 (October 2020 to January 2021), and phase 3 (Omicron; December 2021 to March 2022), comparing their characteristics and outcomes. The primary end point was in-hospital mortality. The cohort included 2,079 patients admitted who were COVID-19 positive and for whom troponin was elevated (phase 1: nÂ =Â 150, phase 2: nÂ =Â 854, phase 3: nÂ =Â 1,075). Baseline characteristics were similar overall. Inflammatory markers were significantly elevated in phase 1 compared with phases 2 and 3. The use of remdesivir and dexamethasone was highest in phase 2. In phase 3, 52.6% of patients were fully vaccinated. In-hospital mortality, though high, was lower in phase 3 than in phases 1 and 2 (59.3% vs 28.1% vs 23.3%; p <0.001). Patients who were vaccinated showed more favorable in-hospital outcomes than did those who were unvaccinated (18.3% vs 24.2%, pÂ =Â 0.042). In conclusion, patients with COVID-19 with elevated troponin during phase 3 tended to have improved outcomes when compared with patients in earlier waves of the pandemic. This improvement could be attributed to the implementation of the COVID-19 vaccines, advances in COVID-19 treatment options, provider experience, and less virulent variants.

Insulin allergy manifesting soon after COVID-19 vaccination (BNT162b2). We experienced a case with insulin allergy which manifested soon after COVID-19 vaccination.

Dyslipidemia and SARS-CoV-2 spike antibody titres after the second and third doses of the BNT162b2 vaccine among healthcare workers in Japan. OBJECTIVE: This study aimed to examine the sex-associated differences in the relationship between dyslipidemia and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike immunoglobulin (Ig)G antibodies among BNT162b2 vaccine recipients. METHODS: Participants were staff members (aged 21-75Â years) of a medical and research institution who underwent an anti-SARS-CoV-2 spike IgG antibody test after the second (nÂ =Â 1872) and third doses (nÂ =Â 1075) of the BNT162b2 vaccine. Dyslipidemia was defined as triglyceride level â‰¥150Â mg/dl, high-density lipoprotein-cholesterol level <40Â mg/dl, low-density lipoprotein-cholesterol level â‰¥140Â mg/dl, or lipid-lowering medication use. Multivariable linear regression was used to calculate the ratio of means for SARS-CoV-2 spike IgG titre according to dyslipidemia status. RESULTS: The prevalence of dyslipidemia was 38.0% in men and 19.6% in women. The relationship between dyslipidemia and SARS-CoV-2 spike IgG titres after the second dose differed markedly by sex (P for interaction <0.001). In men, dyslipidemia was associated with significantly

lower IgG titres: the ratio of means (95% confidence interval) was 0.82 (0.72-0.93). However, this association disappeared after the third dose (0.96 [0.78-1.18]). Of the dyslipidemia components, hypertriglyceridemia was inversely associated with SARS-CoV-2 spike IgG antibody titre after both the second and third doses (ratio of means: 0.82 [0.70-0.95] and 0.73 [0.56-0.95], respectively). In women, IgG titres did not differ according to dyslipidemia or hypertriglyceridemia status after either dose. CONCLUSIONS: These results suggest a detrimental role of hypertriglyceridemia in the humoral immune response to the BNT162b2 vaccine for COVID-19 in men but not in women.

Immune thrombocytopenic purpura secondary to COVID-19 vaccination: A systematic review. INTRODUCTION: This systematic review aimed to retrieve patients diagnosed with de novo immune thrombocytopenic purpura (ITP) after COVID-19 immunization to determine their epidemiological characteristics, clinical course, therapeutic strategies, and outcome. MATERIALS AND METHODS: We conducted the review using four major databases, comprising PubMed, Scopus, Web of Science, and the Cochrane library, until April 2022. A systematic search was performed in duplicate to access eligible articles in English. Furthermore, a manual search was applied to the chosen papers' references to enhance the search sensitivity. Data were extracted and analyzed with the SPSS 20.1 software. RESULTS: A total of 77 patients with de novo COVID-19 vaccine-associated ITP were identified from 41 studies, including 31 case reports and 10 case series. The median age of patients who developed COVID-19 vaccine-associated ITP was 54â€‰years (IQR 36-72â€‰years). The mRNA-based COVID-19 vaccines, including BNT16B2b2 and mRNA-1273, were most implicated (75.4%). Those were followed by the adenovirus vector-based vaccines, inclusive of ChAdOx1 nCoV-19 and vAd26.COV2.S. No report was found relating ITP to other COVID-19 vaccines. Most cases (79.2%) developed ITP after the first dose of COVID-19 vaccination. 75% of the patients developed ITP within 12â€‰days of vaccination, indicating a shorter lag time compared to ITP after routine childhood vaccinations. Sixty-seven patients (87%) patients were hospitalized. The management pattern was similar to primary ITP, and systemic glucocorticoids, IVIg, or both were the basis of the treatment in most patients. Most patients achieved therapeutic goals; only two individuals required a secondary admission, and one patient who presented with intracranial hemorrhage died of the complication. CONCLUSIONS: De novo ITP is a rare complication of COVID-19 vaccination, and corresponding reports belong to mRNA-based and adenovirus vector-based vaccines, in order of frequency. This frequency pattern may be related to the scale of administration of individual vaccines and their potency in inducing autoimmunity. The more the COVID-19 vaccine is potent to induce antigenic challenge, the shorter the lag time would be. Most patients had a benign course and responded to typical treatments of primary ITP.

Correlation between the severity of COVID-19 vaccine-related adverse events and the blood group of the vaccinees in Saudi Arabia: A web-based survey. Background: Recent epidemiological studies have reported an association between the ABO blood group and the acquisition, symptom severity, and mortality rate of coronavirus disease 2019 (COVID-19). However, the association between the ABO blood group antigens and the type and severity of COVID-19 vaccine-related adverse reactions has not been elucidated. Patients and Methods: We conducted a cross-sectional, questionnaire-based study in Saudi Arabia from February to April 2022. The study cohort included adults who had received or were willing to receive at least two doses of a COVID-19 vaccine of any type. We used Chi-square test to assess the association between the ABO blood groups and vaccine-related adverse reactions. p values of <0.05 were considered significant. Results: Of the 1180 participants, approximately half were aged 18-30 years old, 69.2% were female, and 41.6% reported their blood group as O. The most frequent COVID-19 vaccine-related adverse reactions were fatigue (65%), pain at the injection site (56%), and headache (45.9%). These adverse reactions demonstrated significant correlations with the education level (p = 0.003) and nationality (p = 0.018) of the participants following the first dose, with

gender ($p < 0.001$) following the second dose, and with the general health status ($p < 0.001$) after all the doses. Remarkably, no correlation was observed between the severity of the vaccine-related adverse reactions and ABO blood groups. Conclusion: Our findings do not support a correlation between the severity of COVID-19 vaccine-related adverse reactions and the ABO blood groups of the vaccinees. The creation of a national database is necessary to account for population differences.

Side Effects after mRNA COVID-19 Vaccine as a Booster in Health Workers. BACKGROUND: In Indonesia, around 400 health workers died due to Covid-19 between June-July 2021, therefore the health workers need to be given further immunity. Health workers were among the first to get a booster shoot. However, they may experience side effects after vaccination. We aimed to describe side effects of Moderna vaccine as a booster in health workers. METHODS: A cross sectional study was conducted on health workers who received mRNA Covid-19 vaccine booster (Moderna) at Sulianti Saroso Infectious Disease Hospital, Indonesia and had filled the questionnaire assessing side effects form. We associated the form of the questionnaire assessing side effects from the originating source of hospital immunization unit in September 2021. RESULTS: A total of 101 health workers who received mRNA Covid-19 vaccine booster in Jul-Aug 2021 were included. Most of health worker experienced more than 3 side effects. The side effects were sore arm (100%); chills (72%); fatigue (57%); headache (53%) and fever (51%), other symptoms (28%). The side effects mostly happened a day of receiving a booster shot (61.4%). There was no association between age, gender, comorbid to amount of side effects ($P>0.05$). CONCLUSION: Since the public must fulfil the immunization program during pandemic, it is the responsibility of the healthcare provider to inform about the potential side effects and benefits of a new Covid-19 vaccine.

COVID-19 Vaccination in Patients with Chronic Liver Disease. Vaccination against SARS-CoV-2 has become a central public health issue, primarily for vulnerable populations such as individuals with Chronic Liver Disease (CLD). Increased COVID-19-related mortality and disease severity has been noted in this subgroup of patients. Severe COVID-19 tends to further deregulate liver function in patients with chronic liver failure or cirrhosis and even reactivate hepatitis in people living with HBV or HCV. In addition, impaired hepatic function leads to several limitations in possible therapeutic interventions. Chronic hepatic dysregulation, along with the underlying cirrhosis-associated immune dysfunction (CAID), leads to a decreased immune response to vaccination that, in turn, may result in reduced efficacy rates and lowered lasting protection. According to current guidelines, timely vaccination and frequent booster shot administration are deemed necessary in this context. Vaccination-related adverse events are mostly mild in nature and similar to those reported in the general population, whereas the incidence of liver injury following vaccination is relatively rare. We aimed to review available evidence and recommendations associated with COVID-19 vaccination in patients with chronic liver disease, and provide insight to current issues and future directions.

Defective Interfering Particles of Influenza Virus and Their Characteristics, Impacts, and Use in Vaccines and Antiviral Strategies: A Systematic Review. Defective interfering particles (DIPs) are particles containing defective viral genomes (DVGs) generated during viral replication. DIPs have been found in various RNA viruses, especially in influenza viruses. Evidence indicates that DIPs interfere with the replication and encapsulation of wild-type viruses, namely standard viruses (STVs) that contain full-length viral genomes. DIPs may also activate the innate immune response by stimulating interferon synthesis. In this review, the underlying generation mechanisms and characteristics of influenza virus DIPs are summarized. We also discuss the potential impact of DIPs on the immunogenicity of live attenuated influenza vaccines (LAIVs) and development of influenza vaccines based on NS1 gene-defective DIPs. Finally, we review the antiviral strategies based on influenza virus DIPs that have been used against both influenza virus and SARS-CoV-2. This review provides systematic insights into the theory and application of influenza virus DIPs.

The Risk of Autoimmunity Development following mRNA COVID-19 Vaccination. The broad spectrum of interactions between autoimmune diseases and the SARS-CoV-2 vaccination is not fully understood. This study aims to evaluate the prevalence of anti-nuclear antibodies (ANA), anti-ENA, anticardiolipin antibodies (ACL), and anti-beta-2 glycoprotein I antibodies (anti-Î²2GPI) before and after the SARS-CoV-2 mRNA vaccination in a real-life setting in healthcare professionals. The identification of risk factors associated with vaccine immunogenicity was evaluated. The study group consisted of employees of two hospitals (354 individuals). Samples for antibody assays were collected before vaccination and at 7-9 months after complete immunisation. There was no significant increase in the prevalence of ANA, ACL or anti-Î²2GPI antibodies, or autoimmune diseases in subjects who were vaccinated 7-9 months after complete immunisation. In terms of detected anti-ENA, the anti-DFS70 antibodies were found in 6 times more subjects than before vaccination at the second blood draw (in 18 and 3 subjects, respectively) ($p = 0.001$). There were no significant relationships between a SARS-CoV-2 infection history, humoral response, cellular response, subject category, smoking, sex, body weight, ANA, anti-ENA, ACL, or anti-Î²2GPI. This study revealed a possible association between the severity of vaccine adverse events (VAEs) and ANA titre. Individuals with more severe VAEs (>10 points) after the second dose of the vaccine had significantly higher ANA titre after complete immunization. When analysing the significance of time between the ANA, anti-ENA, ACL, and anti-Î²2GPI assays and complete immunisation antibody values, no qualitative result was statistically significant. There was correlation between the time since complete immunization and ANA after.

Neutralizing Antibody and T-Cell Responses against SARS-CoV-2 Wild-Type and Variants of Concern in Chronic Obstructive Pulmonary Disease Subjects after ChAdOx-1/ChAdOx-1 Homologous Vaccination: A Preliminary Study. Data on immunogenicity of adenovirus-vectored vaccine in chronic obstructive pulmonary disease (COPD) patients is limited. Therefore, we aimed to determine the humoral and cellular immune responses after homologous ChAdOx-1 vaccination in subjects with COPD. COPD subjects and age- and sex-matched healthy elderly receiving ChAdOx-1 homologous vaccination were included. The levels of neutralizing antibodies (NAb) and specific CD4 and CD8 T-cell responses against SARS-CoV-2 wild-type (WT) and variants of concern (VOCs: Alpha, Beta, Delta, and Omicron) were measured. Eight COPD patients were matched with eight control participants. After vaccination for 4 and 12 weeks, % inhibition of NAb against Alpha, Beta, and Delta in both groups were comparable and significantly higher than baseline. The percentage inhibition of NAb at the 12th week was significantly dropped from the 4th week in each group. The NAb against the Omicron variant, however, were much lower than Alpha, Beta, Delta variants. The increasing trend in the number of CD4 T-cells producing TNF-Î±, IFN-Î³, IL-10, and FasL upon stimulation with spike peptides of WT and VOCs was observed in COPD patients compared to the healthy group. These responses were not observed in CD8 T-cells. Homologous ChAdOx-1 vaccination could induce comparable NAb against the SARS-CoV-2 WT, Alpha, Beta, Delta, and Omicron variants between COPD and healthy elderly. The CD4 T-cell responses did not differ between COPD patients and healthy control.

Peripheral Nervous System Adverse Events after the Administration of mRNA Vaccines: A Systematic Review and Meta-Analysis of Large-Scale Studies. Although neurological complications after the administration of vaccines against coronavirus disease 2019 (COVID-19) are rare, they might result in long-term morbidity. This study was designed to determine the risk of peripheral nervous system (PNS) adverse events after the administration of mRNA vaccines against COVID-19. Large-scale randomized controlled trials (RCTs) and cohort studies were systematically searched in databases, and 15 cohort studies were included in the synthesis. Among all PNS adverse events, only Bell's palsy and Guillain-BarrÃ© syndrome (GBS) had sufficient data and were included for further analysis. Individuals who received mRNA vaccines had a higher risk of Bell's palsy than the unvaccinated group, and the risk of Bell's palsy after BNT162b2 was significantly higher than after mRNA-1273. Regarding

GBS, no significant difference in the risk was observed between BNT162b2 and the unvaccinated group, but BNT126b2 introduced a higher risk of post-vaccinated GBS than mRNA-1273. In conclusion, PNS adverse events, especially Bell's palsy, should be carefully observed after mRNA vaccination against COVID-19. With the opportunity of vaccination campaigns on such a large scale, further investigation and surveillance of post-vaccination neurological adverse events should also be established.

COVID-19: Impact of Original, Gamma, Delta, and Omicron Variants of SARS-CoV-2 in Vaccinated and Unvaccinated Pregnant and Postpartum Women. This study compares the clinical characteristics and disease progression among vaccinated and unvaccinated pregnant and postpartum women who tested positive for different variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) using the Brazilian epidemiological data. Data of pregnant or postpartum patients testing positive for SARS-CoV-2 and presenting with coronavirus disease 2019 (COVID-19) from February 2020 to July 2022 were extracted from Brazilian national database. The patients were grouped based on vaccination status and viral variant (original, Gamma, Delta, and Omicron variants), and their demographics, clinical characteristics, comorbidities, symptoms, and outcomes were compared retrospectively. Data of 10,003 pregnant and 2361 postpartum women were extracted from the database. For unvaccinated postpartum women, intensive care unit (ICU) admission was more likely; invasive ventilation need was more probable if they tested positive for the original, Gamma, and Omicron variants; and chances of death were higher when infected with the original and Gamma variants than when infected with other variants. Vaccinated patients had reduced adverse outcome probability, including ICU admission, invasive ventilation requirement, and death. Postpartum women showed worse outcomes, particularly when unvaccinated, than pregnant women. Hence, vaccination of pregnant and postpartum women should be given top priority.

Higher Immunological Response after BNT162b2 Vaccination among COVID-19 Convalescents-The Data from the Study among Healthcare Workers in an Infectious Diseases Center. Introduction: The BNT162b2 vaccination studies did not specifically focus on groups that were heavily exposed to SARS-CoV-2 infection. Therefore, we aimed to assess the safety and efficacy of the BNT162b2 vaccine among healthcare workers (HCWs). Methods: Study participants were recruited from hospital employees who received BNT162b2 vaccination at the Hospital for Infectious Diseases in Warsaw. Blood samples were collected before and after each vaccination dose. At each timepoint, the levels of anti-SARS CoV-2 IgM, anti-n SARS-CoV-2 IgG, and S-RBD antibodies were measured. Data on concomitant diseases and the vaccineâ€™s adverse events (VAE) were collected after each vaccination dose. In the statistical analyses, non-parametric tests were used. Results: In total, 170 healthcare workers were included in the analysis. Their median age was 51 years (interquartile range (IQR): 41â€’60 years); most of them were women (n = 137, 80.6%) working in direct contact with patients (n = 137, 73.2%); and 46 (27.0%) had concomitant diseases. More than one fifth of subjects had COVID-19 before their first dose of vaccination (n = 38, 22.6%). In terms of immunological responses, our investigations showed a high level of efficacy for the BNT162b2 mRNA vaccination as measured by S-RBD antibody concentrations: these were positive in 100% of participants 14 days after the second dose of the vaccine. It was also observed that employees with high S-RBD antibodies (>=433 BAU/mL) were more likely to be COVID-19 convalescents before receiving the first vaccine dose ($p < 0.001$). Conclusion: The BNT162b2 vaccine is safe and effective among HCWs. Vaccine adverse events occurred, but serious events were not observed. Moreover, the BNT162b2 vaccine is effective against symptomatic and severe COVID-19â€”none of the workers that acquired a SARS-CoV-2 infection after vaccination required hospitalization or medical care. We also observed higher immunological responses among COVID-19 convalescents.

Ocular Vascular Events following COVID-19 Vaccines: A Systematic Review. The main aim of this study is to investigate the current evidence regarding the association between COVID-19 vaccination and ocular vascular events. The protocol is registered on PROSPERO (CRD42022358133). On 18 August 2022, an electronic search was conducted through five databases. All original articles reporting individuals who were vaccinated with COVID-19 vaccines and developed ophthalmic vascular events were included. The methodological quality of the included studies was assessed using the NIH tool. A total of 49 studies with 130 ocular vascular cases were included. Venous occlusive events were the most common events (54.3%), which mostly occurred following the first dose (46.2%) and within the first five days following vaccination (46.2%). Vascular events occurred more with the Pfizer and AstraZeneca vaccines (81.6%), and mostly presented unilaterally (73.8%). The most frequently reported treatment was intravitreal anti-VEGF (n = 39, 30.4%). The majority of patients (90.1%) demonstrated either improvement (p = 0.321) or persistence (p = 0.414) in the final BCVA. Ophthalmic vascular events are serious vision-threatening side effects that have been associated with COVID-19 vaccination. Clinicians should be aware of the possible association between COVID-19 vaccines and ocular vascular events to provide early diagnosis and treatment.

Side Effects of COVID-19 Vaccines Primer Doses: Experience of Saudi Healthcare Workers Participating in CoVaST-SA. BACKGROUND: Side effects emerging after COVID-19 vaccines may adversely impact public confidence in vaccines. Therefore, this study was designed to explore the short-term side effects of COVID-19 vaccines as a part of the COVID-19 Vaccines Safety Tracking (CoVaST) study. METHODS: A cross-sectional survey-based study was carried out to collect data from healthcare workers (HCWs) in Saudi Arabia. The study was initiated between June and December 2021. A validated questionnaire was used in this study consisting of four categories, including demographic characteristics and medical anamnesis of the participants, COVID-19-associated anamnesis, and side effects of vaccine uptake. RESULTS: The study included 1039 participants, of which 70.2% were females, and their median age was 34. About 82.9% and 52.3% of the participants reported a minimum of both one local and systemic side effect, respectively. Females, young participants (â‰¤34 years old), and non-obese participants had more potential to disclose post-vaccination side effects than their counterparts. Heterologous schedules and viral vector-based vaccines were linked with a greater rate of systemic side effects, whereas homologous vaccination schedules and mRNA-based vaccines were linked with a greater rate of local side effects. CONCLUSION: Future studies on COVID-19 vaccines should focus on the role of BMI, previous infection, and vaccination schedule in terms of vaccine safety and reactogenicity.

Stimulated Reporting of Adverse Events Following Immunization with COVID-19 Vaccines. In India, up until December 2021, Covishield and Covaxin vaccines against COVID-19 were being used for mass vaccination programs. In view of the urgency of fighting the ongoing pandemic, many vaccines have been granted emergency use approval while phase 2/3 clinical trials were still underway. Even for vaccines that have completed phase 3 trials, safety data may not be comprehensive. This retrospective observational study was conducted at a designated Regional Training Centre for Pharmacovigilance cum Adverse Drug Reaction Monitoring Centre (AMC) under the Pharmacovigilance Programme of India. The data sources were stimulated spontaneous reports of Adverse Events Following Immunization (AEFI) due to the COVID-19 vaccines from 10 January to 31 December 2021. A total of 51,010 COVID vaccine doses were administered during the study period. There were 330 AEFI reported (AEFI rate: 0.65%). Six AEFI were serious events among which three were Adverse Events of Special Interest. The majority of the AEFI were systemic, reported after the first dose, and with an onset between 1 and 24 h after vaccination. On comparing Covishield and Covaxin, there were no statistically significant differences in the AEFI reported with either vaccine in terms of gender, seriousness, lag period, duration, recovery, causality, treatment received for AEFI,

presence of co-morbidity, or history of COVID-19 infection. Overall, the rates of AEFI was uncommon, and serious AEFI were rare with both Covishield and Covaxin, with a higher rate after the first dose. Whether immunological tolerance or allayed anxiety was responsible for the lower AEFI risk with the second dose remains to be investigated.

Immune Responses against the Omicron Variant of SARS-CoV-2 after a Third Dose of COVID-19 Vaccine in Patients Living with Human Immunodeficiency Virus (PLWH): Comparison with Healthcare Workers. We compared immune responses against the omicron variant of SARS-CoV-2 after a third dose of the coronavirus disease 2019 (COVID-19) vaccine between people living with human immunodeficiency (PLWH) and healthcare workers (HCWs). In this prospective observational study, PLWH and HCWs vaccinated with at least two doses of vaccine were enrolled. We analyzed neutralizing responses using the GenScript SARS-CoV-2 surrogate virus neutralization test kit. Twenty-nine PLWH and 114 HCWs were included to analyze immune responses after the third vaccination. Most PLWH (86.2%) had fully suppressed viral loads and CD4 T cell counts were well-controlled (median 670.0 cells/Î¼L). The neutralizing responses against the omicron variant in PLWH were not significantly different from those in HCWs (43.94% vs. 51.77%, p = 0.42). However, neutralizing responses against the omicron variant were significantly impaired by about 50% compared with wild type SARS-CoV-2 in PLWH (43.94% vs. 97.46%, p < 0.001) and HCWs (51.77% vs. 97.74%, p < 0.001). Although neutralizing responses against the omicron variant in well-controlled PLWH were comparable to those of HCWs, the responses were much lower than those against wild type in both PLWH and HCWs. Therefore, the risk of breakthrough SARS-CoV-2 infection due to the currently circulating omicron variant is still high despite three doses of vaccine in PLWH and will not differ from HCWs.

Determinants of the Level of Anti-SARS-CoV-2 IgG ANTibodiEs after Vaccination (DANTE-SIRIO 7) Study in a Large Cohort of Healthcare Workers. The aim of this study was to determine anti-SARS-CoV-2 IgG concentrations and their major determinants in healthcare workers (HCWs) after full vaccination with the BNT162b2 vaccine. We recruited 847 individuals vaccinated with two doses of the BNT162b2 vaccine, who completed the questionnaire, and whose antibody concentrations were tested after 3 and 6 months after full vaccination. Anti-SARS-CoV-2 IgG levels were measured on the routinely employed Siemens Atellica system. The cutoff for positivity was â‰¥21.8 BAU/mL. Three and 6 months after vaccination, the majority of participants were seropositive. Median concentrations of anti-SARS-CoV-2 IgG significantly decreased from 1145 BAU/mL (IQR: 543-2095) to 225 BAU/mL (IQR: 100-510). Major positive determinants of antibody levels were fever after both doses of vaccine, prior-COVID-19 exposure, and muscle pain after the first dose. Lack of symptoms after the second dose and time since vaccination were significant negative determinants of anti-SARS-CoV-2 IgG concentrations. No other factors, including age and gender, or underlying comorbidities had a significant effect on antibody levels in HCWs. The anti-SARS-CoV-2 response after two doses of BNT162b2 vaccine was independently associated with prior-COVID-19 exposure, time since vaccination, and the occurrence of symptoms after either dose of vaccine. Easily reportable adverse reactions may facilitate the identification of immune response in HCWs.

Correlation between Baseline 25(OH) Vitamin D Levels and Both Humoral Immunity and Breakthrough Infection Post-COVID-19 Vaccination. Objective: Vaccines against COVID-19 induce specific antibodies whose titer is perceived as a reliable correlate of protection. Vitamin D confers complex regulatory effects on the innate and adaptive immunity. In this study, we explored a plausible impact of baseline vitamin D content on achieved immunity following COVID-19 vaccination. Methods: A retrospective observational study comprising 73,254 naÃ¯ve subjects insured by the Leumit Health Service HMO, who were vaccinated between 1 February 2020 and 30 January 2022, with one available vitamin D level prior to vaccination, was performed. The association between

25(OH) vitamin D levels, SARS-CoV-2 antibody titer, and post-vaccination PCR results were evaluated. Results: Of the study population, 5026 (6.9%) tested positive for COVID-19. The proportion of low 25(OH)D levels (<30 ng/mL) was significantly higher in the PCR-positive group (81.5% vs. 79%, p < 0.001). Multivariate analysis showed a higher incidence of breakthrough infection among non-smokers [1.37 (95% CI 1.22âˆ’1.54, p < 0.001)] and lower incidences among subjects with sufficient 25(OH)D levels (>30 ng/mL) [0.87 (95% CI 0.79âˆ’0.95, pâ€”0.004)], hyperlipidemia [0.84 (95% CI 0.76âˆ’0.93, p < 0.001], depression [OR-0.87 (95% CI: 0.79âˆ’0.96, p < 0.005], socio-economic status >10 [0.67 (95% CI 0.61âˆ’0.73, p < 0.001)], and age >44 years. SARS-CoV-2 antibody titers were available in 3659 vaccinated individuals. The prevalence of antibody titers (<50 AU) among PCR-positive subjects was 42% compared to 28% among PCR-negative subjects (p < 0.001). Baseline 25(OH)D levels showed an inverse relation to total antibody titers. However, no association was found with an antibody titer <50 AU/mL fraction. Conclusion Baseline 25(OH)D levels correlated with the vaccination-associated protective COVID-19 immunity. Antibody titers <50 AU/mL were significantly linked to breakthrough infection but did not correlate with 25(OH)D levels.

Neutralizing Antibodies against the SARS-CoV-2 Delta and Omicron BA.1 following Homologous CoronaVac Booster Vaccination. Emerging severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants have reduced susceptibility to neutralization by vaccines. In response to the constantly updated variants, a global vaccine booster vaccination program has been launched. In this study, we detected neutralizing antibody levels against wild-type (WT), Delta (B1.617.2), and Omicron BA.1 viruses in serum after each dose of CoronaVac vaccination. We found that booster vaccination significantly increased the levels of neutralizing antibodies against WT, Delta, and Omicron BA.1. Compared with only one vaccination, neutralizing antibody levels increased by 19.2-21.6-fold after a booster vaccination, whilst two vaccinations only produced a 1.5-3.4-fold increase. Our results support the conclusion that the CoronaVac vaccine booster can increase neutralizing antibody levels and cross-reactivity and enhance the body's ability to effectively resist the infection of new coronavirus variants, emphasizing the need for booster vaccination.

Antibodies Induced by Homologous or Heterologous Inactivated (CoronaVac/BBIBP-CorV) and Recombinant Protein Subunit Vaccines (ZF2001) Dramatically Enhanced Inhibitory Abilities against B.1.351, B.1.617.2, and B.1.1.529 Variants. Safe and effective vaccines for Corona Virus Disease 2019 (COVID-19) can prevent the virus from infecting human populations and treat patients infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). In this study, we discuss the inhibitory abilities of primary and booster vaccine-induced antibodies inhibitory ability toward the SARS-CoV-2 wild-type strain, as well as B.1.1.7, B.1.351, P.1, B.1.617.2, and B.1.1.529. We confirmed these antibodies had the strongest inhibitory effects on the wild-type strain and cross-inhibition activities against other mutant strains after two inactivated vaccine doses. However, the B.1.351, B.1.617.2 and B.1.1.529 mutants exhibit antibody resistance in the vaccine serum. Antibodies induced by homologous inactivated vaccines (n = 92) presented more effective inhibition against tested SARS-CoV-2 strains (p < 0.0001), especially B.1.351, B.1.617.2, and B.1.1.529 mutant strains, which had strong immune escape characteristics. In addition, a heterologous booster vaccination (n = 50) of a protein subunit vaccine ZifiVax (ZF2001) significantly restored humoral immune responses and even showed an increasing response against wild-type, B.1.351, B.1.617.2, and B.1.1.529 than homologous inactivated vaccines. Our analysis of the humoral immune response elicited by the different vaccine regimens, including inhibiting antibodies, indicated that a booster, whether homologous or heterologous, could be essential for achieving greater efficacy against SARS-CoV-2.

Adverse Events of COVID-19 Vaccination among the Saudi Population: A Systematic Review and Meta-Analysis. This systematic review and meta-analysis aimed to synthesize the evidence on the adverse events (AEs) of coronavirus disease 2019 (COVID-19) vaccinations in Saudi Arabia. A

computerized search in MEDLINE via PubMed and OVID, Scopus, CENTRAL, and Web of Science was conducted using relevant keywords. The NIH tools were used for the quality assessment. A total of 14 studies (16 reports) were included. The pooled analysis showed that the incidence of AEs post-COVID-19 vaccination was 40.4% (95% CI:6.4% to 87%). Compared to the AstraZeneca vaccine, the Pfizer-BioNTech vaccine was associated with a lower risk ratio (RR) of wheezing (RR = 0.04), fever (RR = 0.32), chills (RR = 0.41), headache (RR = 0.47), dizziness (RR = 0.49), and joint pain (RR = 0.51). The Pfizer-BioNTech vaccine was associated with significantly higher RR of general allergic reactions (RR = 1.62), dyspnea (RR = 1.68), upper respiratory tract symptoms (RR = 1.71), and lymphadenopathy (RR = 8.32). The current evidence suggests that the incidence of AEs following COVID-19 vaccines is 40%; however, most of these AEs were mild and for a short time. The overall number of participants with AEs was higher in the Pfizer group compared to the AstraZeneca group; however, the AstraZeneca vaccine was associated with a higher RR of several AEs.

Comparison of General Anxiety among Healthcare Professionals before and after COVID-19 Vaccination. Vaccination plays a crucial role in controlling the rate of coronavirus transmission and infectivity. Healthcare professionals are, in fact, at the greatest risk of contracting coronavirus due to their proximity and prolonged exposure to infected patients; this certitude alone enhances the stress and anxiety among patients and professionals alike. In this study, we aimed to assess the levels of anxiety experienced by healthcare professionals in their practices before and after getting vaccinated. This cross-sectional study was carried out in 2021. An electronic survey was distributed among the non-vaccinated and vaccinated healthcare workers. The survey consisted of the following parts: demographic characteristics, coronavirus-related questions, questions related to the specific field of healthcare professions, general anxiety questions, and working-hour-related questions. The Modified General Anxiety Scale (GAD-7) was used along with the paired t-test, Mann-Whitney U test, and Spearmen's test for comparison. p â‰¤ 0.05 was considered statistically significant. A total of 798 healthcare professionals participated in the study. In this study, the majority of participants were females, with 598 (74.9%) being between the ages of 21 and 30, and 646 (80.9%) participants were graduates, with the majority being dentists. Non-vaccinated healthcare professionals had severe anxiety (30.9%), whereas, in vaccinated participants, anxiety levels were minimal (56.9%). A statistically significant correlation was discovered when comparing the scores of the vaccinated and non-vaccinated individuals as well as when comparing the professions of vaccinated participants, whereas no association was found with the gender and education level of participants. Vaccination is necessary for all entitled individuals to control the spread of coronavirus. It was discovered that there was an increase in anxiety levels before the vaccination was introduced. The anxiousness was greatly lessened following mass immunizations. Our research will help to raise public awareness of stigmatized mental health disorders in the healthcare industry.

Vaccine-Related Autoimmune Hepatitis: Emerging Association with SARS-CoV-2 Vaccination or Coincidence? BACKGROUND: There is an increasing number of liver injury cases resembling autoimmune hepatitis (AIH) following SARS-CoV-2 vaccination; however, an association has not yet been established. METHODS/MATERIALS: A literature review was performed to identify articles regarding the association of AIH with vaccination, emphasizing on SARS-CoV-2 vaccines, and the proposed mechanisms. We then performed a literature search for AIH-like cases following SARS-CoV-2 vaccination, and we evaluated the included cases for AIH diagnosis using simplified diagnostic criteria (SDC), and for vaccination causality using the Naranjo score for adverse drug reactions. RESULTS: We identified 51 AIH-like cases following SARS-CoV-2 vaccination. Forty cases (80%) were characterized as "probable", "at least probable", or "definite" for AIH diagnosis according to SDC. Forty cases (78.4%) were characterized as "probable", four (7.8%) as "possible", and three (5.8%) as "definite" for vaccine-related AIH according to the Naranjo score. CONCLUSION: SARS-CoV-2 vaccine-

related AIH carries several phenotypes and, although most cases resolve, immunosuppressive therapy seems to be necessary. Early diagnosis is mandatory and should be considered in any patient with acute or chronic hepatitis after SARS-CoV-2 vaccination, especially in those with pre-existing liver disease.

Adverse Maternal Outcomes in Pregnant Women Affected by Severe-Critical COVID-19 Illness: Correlation with Vaccination Status in the Time of Different Viral Strains' Dominancy. This is a monocentric and cross-sectional study conducted at the COVID-19 Division of the Obstetrical and Gynecological Unit and Intensive Care Units (ICUs) of Policlinico di Bari, in Bari, Italy, between September 2020 and April 2022. This study aimed to identify the prevalence of severe-critical COVID-19 illness requiring access to the Intensive Care Unit (ICU) among 287 pregnant patients, and possible correlations between the SARS-CoV-2 variants, the specific pandemic wave (dominated by wild, Alpha, Delta, and Omicron strains), and severe-critical adverse maternal outcomes. The prevalence of severe-critical COVID-19 illness was 2.8% (8/287), reaching 4.9% (8/163) excluding the 4th wave (Omicron dominant). The Delta variant determined the highest risk ratio and odds for access to the ICU due to severe-critical COVID-19-related symptoms compared to the other variants (wild, Alpha, Omicron). During the third wave (Delta), the ICU cases underwent a higher rate of hyperimmune plasma infusion (75%), antibiotic therapy (75%), and remdesivir (33%); all of the patients were intubated. During the Omicron wave, the patients were asymptomatic or with few symptoms: most of them (70%) were vaccinated with a median of two doses. The maternal outcome worsened in the case of Alpha and, especially, Delta variants for severe-critical COVID-19-related symptoms and ICU access.

Resistance towards ChadOx1 nCoV-19 in an 83 Years Old Woman Experiencing Vaccine Induced Thrombosis with Thrombocytopenia Syndrome. BACKGROUND: in this report, we describe the case of an 83-year-old woman vaccinated with ChadOx1 nCoV-19 who developed a so-called vaccine-induced thrombosis with thrombocytopenia syndrome and who did not develop any antibodies against the spike protein of SARS-CoV-2 at 30 days following the administration of her first dose of ChadOx1 nCoV-19. Experimental section: two serum samples from the patient and 5 serum samples from 5 control individuals having received the two-dose regimen vaccination with ChadOx1 nCoV-19 were evaluated. In order to investigate the lack of response to the vaccination, a cell model was developed. This model permits to evaluate the interaction between responsive cells (A549) possessing the Coxsackievirus and Adenovirus Receptor (CAR), a defined concentration of ChadOx1 nCoV-19 and serial dilution of the patient or the control serum. The aim was to assess the impact of these sera on the production of the spike (S) protein induced by the transfection of the genetic material of ChadOx1 nCoV-19 into the A549 cells. The S protein is measured in the supernatant using an ELISA technique. RESULTS: interestingly, the serum from the patient who developed the vaccine-induced thrombosis with thrombocytopenia syndrome impaired the production of S protein by the A549 cells transfected with ChadOx1 nCoV-19. This was not observed with the controls who did not interfere with the transfection of ChadOx1 nCoV-19 into A549 cells since the S protein is retrieved in the supernatant fraction. CONCLUSION: based on the data coming from the clinical and the cell model information, we found a possible explanation on the absence of antibody response in our patient. She has, or has developed, characteristics that prevent the production of the S protein in contrast to control subjects. We were not able to investigate the entire mechanism behind this resistance which deserve further investigations. A link between this resistance and the development of the thrombosis with thrombocytopenia syndrome following vaccination with ChadOx1 nCoV-19 cannot be excluded.

Study of Excipients in Delayed Skin Reactions to mRNA Vaccines: Positive Delayed Intradermal Reactions to Polyethylene Glycol Provide New Insights for COVID-19 Arm. BACKGROUND: Skin

local reactions to mRNA COVID-19 vaccines have been linked to the use of vaccine excipients. The aim of the study is to evaluate the role of skin testing excipients in delayed skin reactions due to mRNA COVID-19 vaccines. METHODS: Skin testing among a group of healthcare workers with skin reactions due to mRNA vaccines was performed. Patch testing and intradermal testing (IDT) with polyethylene glycol (PEG)-400, PEG-2000, trometamol, and 1,2-dimyristoyl-sn-glycero-3-phosphocholine were performed. Healthcare workers without skin reactions to vaccines were used for skin testing as controls. RESULTS: Thirty-one healthcare workers (from a total of 4315 vaccinated healthcare workers) experienced cutaneous adverse vaccine reactions. Skin testing was performed in sixteen of the healthcare workers (11 delayed large local reactions (DLLR) and 5 widespread reactions). Positive IDT for PEG-2000 1% in DLLR was seen in 10 (90.9%) patients, in comparison with one (16.6%) individual with a delayed widespread reaction. Delayed positive IDT reactions for PEG-2000 1% on day 2 were observed in three (27.3%) patients with DLLR. Patch testing of the excipients was negative. Among 10 controls, only one exhibited a transient positive IDT reaction to PEG-2000 1%. CONCLUSIONS: Immediate and delayed reactions to IDT are frequently detected in patients with DLLR. The observation of positive delayed intradermal reactions to PEG disclosed only in patients with DLLR reinforces a possible role of PEG in the development of these reactions. Skin testing of other excipients is of little importance in clinical practice.

Fatal Acute Hemorrhagic Encephalomyelitis and Antiphospholipid Antibodies following SARS-CoV-2 Vaccination: A Case Report. Acute hemorrhagic encephalomyelitis (AHEM) is a rare hyperacute form of acute disseminated encephalomyelitis (ADEM). The disease is characterized by fulminant inflammation and demyelination in the brain and spinal cord and is often preceded by an infection or vaccination. This case report presents a 53-year-old male with rheumatoid arthritis and ongoing treatment with methotrexate and etanercept who developed fatal AHEM following the second dose of the COVID-19 vaccine. The disease course was complicated by multiorgan thromboembolic disease and the presence of high/moderate levels of cardiolipin IgG antibodies and anti-beta-2 glycoprotein 1 IgG antibodies suggesting a possible antiphospholipid syndrome. Treatment with immunosuppressive therapies failed to improve the course. The report comprises comprehensive clinical, neuroimaging, and neuropathological findings. The case highlights diagnostic challenges in a patient with several preceding risk factors, including autoimmune disease, immunotherapy, and vaccination, with possible pathophysiological implications. The temporal association with the COVID-19 vaccination may suggest possible causality although evidence cannot be ascertained. Reporting possible adverse events following COVID-19 vaccination is important to identify at-risk populations and to accomplish control of the current pandemic.

Immediate Adverse Events Following COVID-19 Vaccination in Australian Pharmacies: A Retrospective Review. BACKGROUND: Four COVID-19 vaccines are approved for use in Australia: Pfizer-BioNTech BNT162b2 (Comirnaty), AstraZeneca ChAdOx1 (Vaxzevria), Moderna mRNA-1273 (Spikevax), and Novavax NVX-CoV2373 (Nuvaxovid). We sought to examine the type and management of immediate adverse events following immunisation (I-AEFI) after COVID-19 vaccination. METHODS: Retrospective review of I-AEFI recorded between July 2021 and June 2022 in 314 community pharmacies in Australia. RESULTS: I-AEFI were recorded in 0.05% (n = 526/977,559) of all COVID-19 vaccinations (highest: AstraZeneca (n = 173/161,857; 0.11%); lowest: Pfizer (n = 50/258,606; 0.02%)). The most common reactions were: (1) syncope, after the first dose of AstraZeneca (n = 105/67,907; 0.15%), Moderna (n = 156/108,339; 0.14%), and Pfizer (n = 22/16,287; 0.14%); and (2) Nausea/vomiting after the first dose of Pfizer (n = 9/16,287; 0.06%), Moderna (n = 55/108,339; 0.05%), and AstraZeneca (n = 31/67,907; 0.05%) vaccines. A total of 23 anaphylactic reactions were recorded (n = 23/977,559; 0.002%), and 59 additional I-AEFI were identified using MedDRA(Â®) terminology. Pharmacists primarily managed syncope by laying the patient down (n =

227/342; 66.4%); nausea/vomiting was managed primarily by laying the patient down (n = 62/126; 49.2%), giving water (n = 38/126; 30.2%), or monitoring in the pharmacy (n = 29/126; 23.0%); anaphylactic reaction was treated with adrenaline (n = 18/23; 78.3%) and n = 13/23 (56.5%) anaphylactic reactions were treated with the combination of: administered adrenaline, called ambulance, and laid patient down. CONCLUSION: The most commonly recorded I-AEFI was syncope after COVID-19 vaccination in pharmacy; I-AEFI are similar to those previously reported. Pharmacists identified and managed serious and non-serious I-AEFI appropriately and comprehensively.

SARS-CoV-2 Specific Humoral Immune Responses after BNT162b2 Vaccination in Hospital Healthcare Workers. BACKGROUND: COVID-19 pandemic has led to a loss of human life in millions and devastating socio-economic consequences worldwide. So far, vaccination is the most effective long-term strategy to control and prevent severe COVID-19 disease. The aim of the current study was to evaluate the humoral immune responses raised against the BNT162b2 vaccine in hospital healthcare workers. METHODS: Total number of 173 healthcare workers enrolled in the study. Their blood samples were collected in three different time intervals after the second SARS-CoV-2 vaccination and evaluated by the ELISA method to detect anti-spike protein IgM and IgG antibodies. The baseline characteristics of all participants were collected using questionnaires and were evaluated for finding any significant data. RESULTS: Our results demonstrated that the levels of antibodies were higher in the young group (21-30 years old) and also among male participants. Moreover, the highest levels of antibodies were detected from the group that received the third shot vaccination. CONCLUSIONS: Our results indicate that age, gender and third-dose vaccination can affect the levels of humoral immune responses against the BNT162b2 vaccine in healthcare workers.

COVID-19 Vaccination in Young People with Functional Neurological Disorder: A Case-Control Study. BACKGROUND: The emergence of acute-onset functional neurological symptoms, the focus of this study, is one of three stress responses related to immunisation. This case-control study documents the experience of 61 young people with past or current functional neurological disorder (FND) in relation to the COVID-19 vaccination program in Australia. METHODS: Information about the young person's/parent's choice and response pertaining to COVID-19 vaccination was collected as part of routine clinical care or FND research program follow-up. RESULTS: 61 young people treated for FND (47 females, mean age = 16.22 years) and 46 healthy controls (34 females, mean age = 16.37 years) were included in the study. Vaccination rates were high: 58/61 (95.1%) in the FND group and 45/46 (97.8%) in the control group. In the FND group, 2 young people (2/61, 3.3%) presented with new-onset FND following COVID-19 vaccination; two young people with resolved FND reported an FND relapse (2/36, 5.56%); and two young people with unresolved FND (2/20, 10.0%) reported an FND exacerbation. In the control group no FND symptoms were reported. CONCLUSIONS: Acute-onset FND symptoms following COVID-19 vaccination are uncommon in the general population. In young people prone to FND, COVID-19 vaccination can sometimes trigger new-onset FND, FND relapse, or FND exacerbation.

Severe Thrombocytopenia, Thrombosis and Anti-PF4 Antibody after Pfizer-BioNTech COVID-19 mRNA Vaccine Booster-Is It Vaccine-Induced Immune Thrombotic Thrombocytopenia? Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a serious and life-threatening complication occurring after adenovirus-vector COVID-19 vaccines, and is rarely reported after other vaccine types. Herein, we report a case of possible VITT after the Pfizer-BioNTech mRNA vaccine booster, who presented with extensive lower limb deep vein thrombosis, severe thrombocytopenia, markedly elevated D-dimer and positive anti-PF4 antibody occurring 2 weeks post-vaccination, concurrent with a lupus anticoagulant. A complete recovery was made after intravenous immunoglobulin, prednisolone and anticoagulation with the oral direct Xa inhibitor rivaroxaban. The presenting features of VITT may overlap with those of antiphospholipid syndrome associated with anti-PF4 and immune

thrombocytopenia. We discuss the diagnostic considerations in VITT and highlight the challenges of performing VITT confirmatory assays in non-specialized settings. The set of five diagnostic criteria for VITT is a useful tool for guiding initial management, but may potentially include patients without VITT. The bleeding risks of severe thrombocytopenia in the face of thrombosis, requiring anticoagulant therapy, present a clinical challenge, but early recognition and management can potentially lead to favorable outcomes.

Maternal and Neonatal Immune Responses Following COVID-19 Infection and Vaccinations in Pregnancy. The objective of the study was to compare the maternal and neonatal humoral immune responses among different groups of women, namely those vaccinated by the BNT162b2 vaccine, not vaccinated, and COVID-19-recovered parturient women at the time of delivery. This is a prospective cohort study of pregnant women, divided into four groups: Group A "Recovered"-recovered and not vaccinated. Group B "Second Vaccination"-first and second doses only. Group C "Third Vaccination"-third dose. Group D "No Third Vaccination"-women eligible for the third dose of the vaccine but did not receive it. Maternal and umbilical cord blood were sampled and tested for SARS-CoV-2 IgG antibodies on admittance to labor and immediately postpartum, respectively. Maternal serum SARS-CoV-2 IgG levels were significantly higher among Group C compared to Group B (741.6 (514.5-1069) vs. 333.5 (327-340.2), respectively). Both groups had higher antibody levels compared to Groups A and D (113.5 (61.62-209.1) and 57.99 (32.93-102.1), respectively). Similarly, umbilical cord blood SARS-CoV-2 IgG levels were also highest among Group C compared to the other three groups (1269 (953.4-1690) vs. Group B, 322.6 (305.6-340.5), Group A, 109 (49.01-242.6), and Group D, 103.9 (48.59-222), respectively). In conclusion, pregnant women who were fully vaccinated with three dosages before delivery generated the highest levels of maternal and neonatal SARS-CoV-2 IgG antibodies.

Prevalence and Risk Factors of Adverse Effects and Allergic Reactions after COVID-19 Vaccines in a Mexican Population: An Analytical Cross-Sectional Study. Vaccinations have helped to control the COVID-19 pandemic; however, few studies focus on the adverse effects and allergic reactions of these vaccines and fewer have a scope in the Latin American population. The objective of this study was to assess the associations between vaccinations, sex, age, allergic reactions, and adverse effects. This was an analytical cross-sectional study conducted between 1 July and 1 October 2022. The sample consisted of 443 surveyed participants, with a total of 1272 COVID-19 vaccine doses. Seven vaccines (Pfizer BioNTech, Oxford-AstraZeneca, CanSino, Moderna, Johnson and Johnson, Sinovac, and Sputnik V) were evaluated. A total of 12.6% of those surveyed had at least one allergic reaction posterior to vaccination, and females had a greater chance of developing one ($p < 0.001$, OR 3.1). The most common allergic reaction was chest pain, and Pfizer-BioNTech and Oxford-AstraZeneca were associated with the onset of allergic reactions ($p < 0.005$). A total of 54.6% of those surveyed developed adverse effects, the most common of which were myalgia, fever, cephalea, asthenia or adynamia, and arthralgia; moreover, older age was associated with the onset of adverse effects ($p < 0.5$). This study concludes that the BNT162b2 (Pfizer BioNTech) and ChAdOX1 nCOV-19 (Oxford-AstraZeneca) vaccines are strongly associated with the onset of allergic reactions, with ORs of 1.6 (CI 95%, 1.18 to 2.3) and 1.87 (CI 95%, 1.35 to 2.6), respectively. In addition, females have a greater chance of developing allergic reactions associated with COVID-19 vaccinations, and there was a relation found between older age and a greater prevalence of comorbidities, adverse effects after vaccination, and COVID-19 infection after vaccination.

Waning of Humoral Immunity and the Influencing Factors after BNT162b2 Vaccination: A Cohort Study with a Latent Growth Curve Model in Fukushima. Measuring long-term antibody titer kinetics and subsequent coronavirus disease 2019 (COVID-19) vaccinations are crucial for identifying vulnerable populations. Our aim was to determine the association between long-term antibody

kinetics, including peak titers and factors, up to seven months post-second vaccination. A three-time antibody survey was conducted in 2021 among healthcare workers in Japan to investigate the changes in humoral immunity using chemiluminescence immunoassay. The study involved 205 participants who had received the second vaccine dose, completed the three-time survey, and were not infected with SARS-CoV-2. A latent growth curve model was used to identify factors affecting the peak titer and decreasing the antibody slope. Of the eligible participants, the mean titers of immunoglobulin G (IgG) against the spike (S) protein and the neutralizing activity 7 months after the second vaccination decreased to 154.3 (8.8% of the peak titer) and 62.1 AU/mL (9.5% of the peak titer), respectively. The IgG growth model showed that age significantly affected peak titers ($p < 0.001$); however, a significant difference was not found for the decreasing slope. Ultimately, aging adults had significantly low peak antibody titers; however, age was unrelated to the slope of log-transformed IgG against the S protein.

Pilot Findings on SARS-CoV-2 Vaccine-Induced Pituitary Diseases: A Mini Review from Diagnosis to Pathophysiology. Since the emergence of the COVID-19 pandemic at the end of 2019, a massive vaccination campaign has been undertaken rapidly and worldwide. Like other vaccines, the COVID-19 vaccine is not devoid of side effects. Typically, the adverse side effects of vaccination include transient headache, fever, and myalgia. Endocrine organs are also affected by adverse effects. The major SARS-CoV-2 vaccine-associated endocrinopathies reported since the beginning of the vaccination campaign are thyroid and pancreas disorders. SARS-CoV-2 vaccine-induced pituitary diseases have become more frequently described in the literature. We searched PubMed/MEDLINE for commentaries, case reports, and case series articles reporting pituitary disorders following SARS-CoV-2 vaccination. The search was reiterated until September 2022, in which eight case reports were found. In all the cases, there were no personal or familial history of pituitary disease described. All the patients described had no previous SARS-CoV-2 infection prior to the vaccination episode. Regarding the type of vaccines administered, 50% of the patients received (BNT162b2; Pfizer-BioNTech) and 50% received (ChAdOx1 nCov-19; AstraZeneca). In five cases, the pituitary disorder developed after the first dose of the corresponding vaccine. Regarding the types of pituitary disorder, five were hypophysitis (variable clinical aspects ranging from pituitary lesion to pituitary stalk thickness) and three were pituitary apoplexy. The time period between vaccination and pituitary disorder ranged from one to seven days. Depending on each case's follow-up time, a complete remission was obtained in all the apoplexy cases but in only three patients with hypophysitis (persistence of the central diabetes insipidus). Both quantity and quality of the published data about pituitary inconveniences after COVID-19 vaccination are limited. Pituitary disorders, unlike thyroid disorders, occur very quickly after COVID-19 vaccination (less than seven days for pituitary disorders versus two months for thyroid disease). This is partially explained by the ease of reaching the pituitary, which is a small gland. Therefore, this gland is rapidly overspread, which explains the speed of onset of pituitary symptoms (especially ADH deficiency which is a rapid onset deficit with evocative symptoms). Accordingly, these pilot findings offer clinicians a future direction to be vigilant for possible pituitary adverse effects of vaccination. This will allow them to accurately orient patients for medical assistance when they present with remarkable symptoms, such as asthenia, polyuro-polydipsia, or severe headache, following a COVID-19 vaccination.

Anti-SARS-CoV-2 IgG Antibodies Post-COVID-19 or Post-Vaccination in Libyan Population: Comparison of Four Vaccines. Measurement of strength and durability of SARS-COV-2 antibody response is important to understand the waning dynamics of immune response to both vaccines and infection. The study aimed to evaluate the level of IgG antibodies against SARS-CoV-2 and their persistence in recovered, naÃ¯ve, and vaccinated individuals. We investigated anti-spike RBD IgG antibody responses in 10,000 individuals, both following infection with SARS-CoV-2 and immunization with

SARS-COV-2 AstraZeneca, Sputnik V, Sinopharm, and Sinovac. The mean levels of anti-spike IgG antibodies were higher in vaccinated participants with prior COVID-19 than in individuals without prior COVID-19. Overall, antibody titers in recovered vaccinee and naÃ¨ve vaccinee persisted beyond 20 weeks. Vaccination with adenoviral-vector vaccines (AstraZeneca and Sputnik V) generates higher antibody titers than with killed virus vaccine (Sinopharm and Sinovac). Approximately two-thirds of asymptomatic unvaccinated individuals had developed virus-specific antibodies. A single dose of vaccine is likely to provide greater protection against SARS-CoV-2 infection in individuals with apparent prior SARS-CoV-2 infection, than in SARS-CoV-2-naive individuals. In addition, the high number of seropositivity among asymptomatic unvaccinated individuals showed that the number of infections are probably highly underestimated. Those vaccinated with inactivated vaccine may require more frequent boosters than those vaccinated with adenoviral vaccine. These findings are important for formulating public health vaccination strategies during COVID-19 pandemic.

A Possibility of Vasospastic Angina after mRNA COVID-19 Vaccination. We report a case of vasospastic angina (VSA) following COVID-19 mRNA vaccination. Despite the widespread occurrence of myocarditis, there have been few reports of post-vaccinal VSA. A 41-year-old male patient was referred for chest pain at rest following mRNA vaccination; he had never experienced chest pain prior to vaccination. He was diagnosed by an acetylcholine (Ach) provocation test that showed multivessel vasospasm. After the initiation of treatment with a calcium channel blocker and nitrate, no further exacerbation of chest pain was observed. To our knowledge, this constitutes the first reported case of VSA proven by Ach provocation test after COVID-19 vaccination. The vaccination may increase coronary artery spasticity. VSA should be ruled out in post-vaccine new onset resting chest pain.

A Novel Finding of an HLA Allele's and a Haplotype's Relationship with SARS-CoV-2 Vaccine-Associated Subacute Thyroiditis. Subacute thyroiditis (SAT) is a thyroid disease associated with viral infections. Its relationship with major histocompatibility complex (MHC) antigens was shown before. SAT cases triggered by different types of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines have been reported. In this study, human leukocyte antigen (HLA) genotypes of 27 SAT patients (13 vaccine-associated (V-SAT) and 14 non-SARS-CoV-2-infection non-vaccine-associated (non-V-SAT)) were compared with those of 362 healthy donors. HLA analyses were performed with low-resolution DNA-based sequence-specific oligonucleotide or sequence-specific primer methods. Statistical analyses were performed using IBM SPSS Statistics 25 and Stata/MP 14.1 with the hapipf function. Allele and haplotype frequencies were estimated by PyPop and gene[RATE] tool programs. The allele frequencies of HLA-A*11, HLA-B*35, and HLA-C*04 were higher in the patient groups. Both the allele frequency of HLA-A*11 and the haplotype frequency of A*11-B*35-C*04 were higher in the V-SAT group. The A*11-B*35-C*04 haplotype, including all three loci of MHC class I genes, is shown to be associated with the disease for the first time, especially in the V-SAT group. This finding will contribute to a better understanding of the etiopathogenesis of vaccine-associated SAT and the role of HLA genotypes in the functioning mechanisms of the SARS-CoV-2 vaccines.

Impaired VEGF-A-Mediated Neurovascular Crosstalk Induced by SARS-CoV-2 Spike Protein: A Potential Hypothesis Explaining Long COVID-19 Symptoms and COVID-19 Vaccine Side Effects? Long coronavirus disease-19 (COVID-19) is a newly discovered syndrome characterized by multiple organ manifestations that persist for weeks to months, following the recovery from acute disease. Occasionally, neurological and cardiovascular side effects mimicking long COVID-19 have been reported in recipients of COVID-19 vaccines. Hypothetically, the clinical similarity could be due to a shared pathogenic role of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) spike (S) protein produced by the virus or used for immunization. The S protein can bind to neuropilin (NRP)-1, which normally functions as a coreceptor for the vascular endothelial growth factor (VEGF)-

A. By antagonizing the docking of VEGF-A to NRP-1, the S protein could disrupt physiological pathways involved in angiogenesis and nociception. One consequence could be the increase in unbound forms of VEGF-A that could bind to other receptors. SARS-CoV-2-infected individuals may exhibit increased plasma levels of VEGF-A during both acute illness and convalescence, which could be responsible for diffuse microvascular and neurological damage. A few studies suggest that serum VEGF-A may also be a potential biomarker for long COVID-19, whereas evidence for COVID-19 vaccines is lacking and merits further investigation.

Surveillance of Side Effects after Two Doses of COVID-19 Vaccines among Patients with Comorbid Conditions: A Sub-Cohort Analysis from Saudi Arabia. Background: Individuals with underlying chronic illnesses have demonstrated considerable hesitancy towards COVID-19 vaccines. These concerns are primarily attributed to their concerns over the safety profile. Real-world data on the safety profile among COVID-19 vaccinees with comorbid conditions are scarce. This study aimed to ascertain the side-effects profile after two doses of COVID-19 vaccines among chronic-disease patients. Methodology: A cross-sectional questionnaire-based study was conducted among faculty members with comorbid conditions at a public educational institute in Saudi Arabia. A 20-item questionnaire recorded the demographics and side effects after the two doses of COVID-19 vaccines. The frequency of side effects was recorded following each dose of vaccine, and the association of the side-effects score with the demographics was ascertained through appropriate statistics. Results: A total of 204 patients with at least one comorbid condition were included in this study. A total of 24 side effects were reported after the first dose and 22 after second dose of the COVID-19 vaccine. The incidence of at least one side effect was 88.7% and 95.1% after the first and second doses of the vaccine, respectively. The frequent side effects after the first dose were pain at the injection site (63.2%), fatigue (58.8%), fever (47.5%), muscle and joint pain (38.7%), and headache (36.3%). However, pain at the injection site (71.1%), muscle and joint pain (62.7%), headache (49.5%), fever (45.6%), and stress (33.3%) were frequent after the second dose. The average side-effects score was 4.41 Â± 4.18 (median: 3, IQR: 1, 6) and 4.79 Â± 3.54 (median 4, IQR: 2, 6) after the first and second dose, respectively. Female gender, diabetes mellitus, hypertension, hyperlipidemia, comorbidity > 2, family history of COVID-19, and the AstraZeneca vaccine were significantly associated with higher side-effect scores. Only 35.8% of study participants were satisfied with the safety of COVID-19 vaccines. Conclusions: Our analysis showed a high proportion of transient and short-lived side effects of Pfizer and AstraZeneca vaccines among individuals with chronic illnesses. However, the side-effects profile was comparable with the safety reports of phase 3 clinical trials of these vaccines. The frequency of side effects was found to be associated with certain demographics, necessitating the need for further investigations to establish a causal relationship. The current studyâ€™s findings will help instill confidence in the COVID-19 vaccines among people living with chronic conditions, overcome vaccine hesitancy, and increase vaccine coverage in this population.

BNT162b2 COVID-19 Vaccination and Its Effect on Blood Pressure. Background and Objectives: The objective of this study is to examine the effect of the BNT162b2 vaccine on systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and pulse pressure (PP) before and 15 min after two doses that were given 21 days apart. Materials and Methods: This active surveillance study of vaccine safety was conducted on 15 and 16 March (for the first dose) and 5 and 6 April (for the second dose) 2021 in an academic hospital. For both doses, SBP, DBP, MAP, and PP levels were measured before and 15 min after both doses were given to healthcare workers over the age of 18. The results of the study were based on measurements of the mean blood pressure (BP), the mean changes in BP, and the BP trends. Results: In total, 287 individuals received the vaccine. After the first dose, 25% (n = 72) of individuals had a decrease in DBP of at least 10 mmHg (mean DBP decrease: 15 mmHg, 95% CI: 14-17 mmHg), and after the second dose it was 12.5% (mean DBP

decrease: 13 mmHg, 95% CI: 12-15 mmHg). After the first dose, 28.6% (n = 82) had a PP that was wider than 40 mmHg. After the first dose, 5.2% and 4.9% of the individuals experienced an increase or decrease in SBP, respectively, of more than 20 mmHg. After the second dose, the SBP of 11% (n = 32) decreased by at least 20 mmHg. Conclusions: Improved understanding of vaccine effects on BP may help address vaccine hesitancy in healthcare workers.

Signs, Symptoms, and Side-Effects Presented by Different Types of COVID-19 Vaccines: A Prospective Cohort Study. The concern about post-COVID-19 vaccine complications still remains. In addition, the evidence on Sinopharm, Sputnik V, Covaxin, and, in particular, COVIran Barekat, as well as comparisons between them by dosage after post-vaccination, is scarce. This study aimed to investigate and compare the prevalence of self-reported post-vaccination signs and symptoms following the first and second doses of different types of COVID-19 vaccines. Research design and methods: This prospective cohort study was conducted on more than 1500 health professionals who had received at least one dose of any type of Sputnik V, Sinopharm, Oxford AstraZeneca, Covaxin, and COVIran Barekat vaccines in Iran. The survey questionnaire was sent to participants online, 28 days after receiving each dose of the vaccine. Results: About 73% of health professionals reported at least one post-vaccination sign or symptom, developing mostly within the first 12 h (69.9%) and lasting up to 12 h (59.0%). Pain and tenderness at the injection site, fever, and muscle pain were the most common post-vaccination signs and symptoms in all vaccines, which were significantly higher in the Oxford AstraZeneca vaccine ($p < 0.001$) for both the first and second doses. The incidence rate of all post-vaccination signs and symptoms was significantly higher in the first dose than in the second dose ($p < 0.05$). Conclusion: The Oxford AstraZeneca vaccine showed the highest incidence rate, onset, and lasting time of signs and symptoms in both doses; however, they were not life-threatening. The onset time of signs and symptoms was significantly higher for the COVIran Barekat and Oxford AstraZeneca vaccines in both the first and second doses.

Late Hypersensitivity Reactions to the BNT162b2 SARS-CoV-2 Vaccine Are Linked to Delayed Skin Sensitization and Prior Exposure to Hyaluronic Acid. Background: Late hypersensitivity reactions (HSRs) to the BNT162b2-vaccine have raised concerns regarding its safety, particularly as further immunizations are required. The yield of skin testing with the BNT162b2v is unclear, as well as the risk factors and outcomes of re-immunization after late HSRs. Objective: We studied a series of patients with late HSRs to BNT162b2v. Methods: Patients referred to the Sheba medical center from December 2020 to May 2021 with late HSRs to the first dose of BNT162b2 were included. HSRs were defined as late if they appeared or lasted >24 h after inoculation. We compared late HSRs to immediate HSRs that appeared within minutesâˆ’2 h after vaccination. Intradermal testing with PEG-containing medication and BNT162b2v was performed. Results: A total of 17 patients that presented with late HSRs (study group) were compared to 34 patients with immediate HSRs (control group). Delayed sensitivity to intradermal testing of the BNT162b2v was observed in 9/17 (53%) of the study group compared to 4/34 (12%) in the control group ($p = 0.01$). Former exposure to a dermal filler with hyaluronic acid was documented among 7/17 (41%) vs. 2/34 (6%) in the study and control groups, respectively, ($p = 0.0038$). All patients who presented with late HSRs were advised to receive subsequent doses of the BNT162b2v vaccine with or without concomitant medication, and all were re-immunized successfully. Conclusions: Late HSRs to BNT162b2v were linked with positive responses to intradermal testing with the vaccine and prior exposure to derma fillers with hyaluronic acid. This may elude to an immune mechanism triggered by former exposures. Although further studies are needed, late HSRs to the BNT162b2-vaccine did not prevent patients from receiving subsequent doses of the vaccines.

Immune-Mediated Diseases Following COVID-19 Vaccination: Report of a Teaching Hospital-Based Case-Series. The occurrence and course of immune-mediated diseases (IMDs) following COVID-

19 vaccination has been little explored so far. We retrieved, among adult patients hospitalized at the Internal Department of a French university hospital up to May 2022, all those who had developed, or relapsed to, an IMD less than 3 weeks following COVID-19 vaccination, without other triggers. Twenty-seven (24 new-onset) post-COVID-19 vaccine IMDs were recorded. They comprised giant cell arteritis or polymyalgia rheumatica (n = 16, HLA-DRB1*04 in 58% of 12 assessed GCA cases), immune-mediated necrotizing myositis or acute rhabdomyolysis, systemic vasculitis, immune thrombocytopenic purpura, rheumatoid arthritis, anti-synthetase syndrome, and adult-onset Still's disease. The causative vaccines were mRNA-based (20 cases) or viral vector-based (7 cases). The IMD typically occurred after the first vaccine dose, with an average delay of 8 (5 SD) days. The patients' mean age was 67 years, and 58% were women. The IMDs had protracted courses in all but three of the patients and typically required high-dose glucocorticoids, in combination with immunomodulators in 13 patients. One patient died of intractable rhabdomyolysis, whereas five suffered permanent damage from IMDs. Eleven patients with well-controlled IMDs completed their COVID-19 vaccination schedule, and two suffered mild IMD relapses. There is a risk of IMDs, notably GCA/PMR, and muscle disorders, following COVID-19 vaccination. Such adverse reactions typically occurred after the first dose, raising concern about subsequent COVID-19 vaccinations. However, early re-challenge in well-controlled IMDs appeared safe.

SARS-CoV-2 Spike Protein Induces Hemagglutination: Implications for COVID-19 Morbidities and Therapeutics and for Vaccine Adverse Effects. Experimental findings for SARS-CoV-2 related to the glycan biochemistry of coronaviruses indicate that attachments from spike protein to glycoconjugates on the surfaces of red blood cells (RBCs), other blood cells and endothelial cells are key to the infectivity and morbidity of COVID-19. To provide further insight into these glycan attachments and their potential clinical relevance, the classic hemagglutination (HA) assay was applied using spike protein from the Wuhan, Alpha, Delta and Omicron B.1.1.529 lineages of SARS-CoV-2 mixed with human RBCs. The electrostatic potential of the central region of spike protein from these four lineages was studied through molecular modeling simulations. Inhibition of spike protein-induced HA was tested using the macrocyclic lactone ivermectin (IVM), which is indicated to bind strongly to SARS-CoV-2 spike protein glycan sites. The results of these experiments were, first, that spike protein from these four lineages of SARS-CoV-2 induced HA. Omicron induced HA at a significantly lower threshold concentration of spike protein than the three prior lineages and was much more electropositive on its central spike protein region. IVM blocked HA when added to RBCs prior to spike protein and reversed HA when added afterward. These results validate and extend prior findings on the role of glycan bindings of viral spike protein in COVID-19. They furthermore suggest therapeutic options using competitive glycan-binding agents such as IVM and may help elucidate rare serious adverse effects (AEs) associated with COVID-19 mRNA vaccines, which use spike protein as the generated antigen.

Hypermetabolic Ipsilateral Supraclavicular and Axillary Lymphadenopathy: Optimal Time Point for Performing an (18)F-FDG PET/CT after COVID-19 Vaccination. Background: We aimed to evaluate the incidence of severe acute respiratory syndrome coronavirus type-2 (SARS-CoV2) vaccine-related hypermetabolic lymphadenopathy (HLA) and evaluate which time point produces the least number of false-positive findings in an 18F-2-Fluor-2-desoxy-D-glucose positron emission tomography/computed tomography (18F-FDG PET/CT). Methods: For this retrospective, multi-center imaging study, patients with any form of SARS-CoV2 vaccination prior to an 18F-FDG-PET/CT were included between January 2021 and December 2021. Patients were divided into six groups according to the time point of vaccination prior to their 18F-FDG-PET/CT imaging, e.g., group one (0â^'6 days) and group six (35â^'80 days). As the reference standards, the SUVmax of the mediastinal blood pool (MBP) and the SUVmax contralateral reference lymph node (RL) were determined. (A) The absolute SUVmax of HLA, (B) the

ratio of SUVmaxHLA/SUVmax mediastinal blood pool (rHLA/MBP), (C) the ratio SUVmax HLA vs. SUVmax contralateral reference lymph node (rHLA/RL), (D) and the incidence of HLA defined as rHLA/MBP > 1.5 were assessed. Results: Group one (days 0âˆ’6) showed the highest incidence of HLA 16/23 (70%) and rHLA/MBP (2.58 Â± 2.1). All three parameters for HLA reduced statistically significantly in the comparison of Groups 1âˆ’3 (days 0âˆ’20) versus Groups 4âˆ’6 (days 21âˆ’80) (p-values < 0.001). Conclusions: If feasible, an FDG PET should be postponed by at least 3 weeks after SARS-CoV2 vaccination, especially if an accurate evaluation of axillary status is required.

Fourth Dose of mRNA COVID-19 Vaccine Transiently Reactivates Spike-Specific Immunological Memory in People Living with HIV (PLWH). Background: People Living With HIV (PLWH), with advanced disease, lower CD4+ T cell counts or an unsuppressed HIV viral load can have a suboptimal vaccine response. For this reason, in the current COVID-19 pandemic, they represent a prioritized population for the SARS-CoV-2 fourth (or second booster) vaccine dose. This work aims to investigate the effects of a second booster on the reactivation of the spike-specific humoral and cell-mediated immune responses in PLWH. Methods: A total of eight PLWH, who received a fourth dose of the original mRNA vaccines were enrolled. They were evaluated before and then 7 days, 1 month and 2 months after the injection. The humoral response was assessed via a chemiluminescent immunoassay. Immunophenotyping and the functional evaluation of the SARS-CoV-2-specific cellular immune responses were performed via flow cytometry. Results: Anti-spike IgG levels were above the cut-off value for all subjects at all timepoints. The spike-specific CD4+ T cell response was reactivated one week after the fourth vaccine dose, and on average declined at two months post-vaccination. A similar trend was observed for the spike-specific B cells. A low percentage of spike-specific CD4+ T cells was activated by the B.1.1.529 BA.1 Omicron-spike mutated peptides, and the majority of these cells were reactive to the conserved portions of the spike protein. Similarly, the majority of the spike-specific memory B cells were able to bind both Wuhan and Omicron-spike entire protein. Conclusions: Spike-specific adaptive immune responses are transiently reactivated in PLWH following the fourth mRNA vaccine dose. The breadth of the immune responses to the mutated spike protein provides insight on the possible cross-reactivity for the SARS-CoV-2 variants of concern (VOCs).

Immune Response after COVID-19 mRNA Vaccination in Multiple Sclerosis Patients Treated with DMTs. The impact of disease-modifying therapies (DMTs) on the immune response to coronavirus disease-2019 (COVID-19) vaccines in persons with multiple sclerosis (pwMS) needs further elucidation. We investigated BNT162b2 mRNA COVID-19 vaccine effects concerning antibody seroconversion, inflammatory mediators' level and immunophenotype assessment in pwMS treated with cladribine (c-pwMS, n = 29), fingolimod (f-pwMS, n = 15) and ocrelizumab (o-pwMS, n = 54). Anti-spike immunoglobulin (Ig)-G detection was performed by an enzyme immunoassay; molecular mediators (GrB, IFN-Î³ and TNF-Î±) were quantified using the ELLA platform, and immunophenotype was assessed by flow cytometry. ANCOVA, Student's t-test and Pearson correlation analyses were applied. Only one o-pwMS showed a mild COVID-19 infection despite most o-pwMS lacking seroconversion and showing lower anti-spike IgG titers than c-pwMS and f-pwMS. No significant difference in cytokine production and lymphocyte count was observed in c-pwMS and f-pwMS. In contrast, in o-pwMS, a significant increase in GrB levels was detected after vaccination. Considering non-seroconverted o-pwMS, a significant increase in GrB serum levels and CD4+ T lymphocyte count was found after vaccination, and a negative correlation was observed between anti-spike IgG production and CD4+ T cells count. Differences in inflammatory mediators' production after BNT162b2 vaccination in o-pwMS, specifically in those lacking anti-spike IgG, suggest a protective cellular immune response.

Before Attributing Polyradiculitis to an Anti-SARS-CoV-2 Vaccine, Differential Etiologies need to be Ruled Out. N/A.

Adaptive immune responses and cytokine immune profiles in humans following prime and boost vaccination with the SARS-CoV-2 CoronaVac vaccine. BACKGROUND: Adaptive immune response has been thought to play a key role in SARS-CoV-2 infection. The role of B cells, CD4(+)T, and CD8(+)T cells are different in vaccine-induced immune response, thus it is imperative to explore the functions and kinetics of adaptive immune response. We collected blood samples from unvaccinated and vaccinated individuals. To assess the mechanisms contributing to protective immunity of CoronaVac vaccines, we mapped the kinetics and durability of humoral and cellular immune responses after primary and boost vaccination with CoronaVac vaccine in different timepoints. MATERIALS AND METHODS: We separate PBMC and plasma from blood samples. The differentiation and function of RBD-spcific CD4(+)T and CD8(+)T cells were analyzed by flow cytometry and ELISA. Antibodies response was analyzed by ELISA. ELISPOT analysis was perfomed to detected the RBD-spcific memory B cells. CBA analysis was performed to detected the cytokine immune profiles. Graphpad prism 8 and Origin 2021 were used for statistical analysis. RESULTS: Vaccine-induced CD4(+)T cell responses to RBD were more prominent than CD8(+)T cell responses, and characterized by a predominant Th1 and weak Th17 helper response. CoronaVac vaccine triggered predominant IgG1 antibody response and effectively recalled specific antibodies to RBD protein after booster vaccination. Robust antigen-specific memory B cells were detected (pâ€‰<â€‰0.0001) following booster vaccination and maintained at 6Â months (pâ€‰<â€‰0.0001) following primary vaccination. Vaccine-induced CD4(+)T cells correlated with CD8(+)T cells (râ€‰=â€‰0.7147, 0.3258, pâ€‰<â€‰0.0001, pâ€‰=â€‰0.04), memory B cell responses (râ€‰=â€‰0.7083, pâ€‰<â€‰0.0001), and IgG and IgA (râ€‰=â€‰0.6168, 0.5519, pâ€‰=â€‰0.0006, 0.003) after vaccination. In addition, vaccine induced a broader and complex cytokine pattern in plasma at early stage. CONCLUSION: Taken together, these results highlight the potential role of B cell and T cell responses in vaccine-induced long-term immunity.

The COVID-19 vaccination hesitancy among Chinese individuals with diabetes and the impact on glycemic control of vaccination: a questionnaire study. OBJECTIVE: The study aimed to investigate the attitudes of people with diabetes mellitus (DM) on COVID-19 vaccination and its influence on the glycemic control. METHODS: Data were collected from a consecutive series of adults (ageâ€‰>â€‰18Â years) with type 2 diabetes under regular follow-ups in the Integrated Care Diabetes Outpatient Clinic of Peking University First Hospital from December 1(st) to December 31(st) 2021. An online interview questionnaire was conducted, and demographic data including age, sex category, history of drug allergy, history of hypertension, the duration of diabetes, reasons for vaccine hesitancy (VH) and adverse reactions after each injection of vaccines was collected. Glucose levels were collected from medical records. RESULTS: Thirty-nine (22.9%) subjects experienced VH and 131 (77.1%) people living with diabetes received inactivated vaccine against COVID-19. Hesitant individuals had a higher proportion of female gender (vaccinated group vs. VH group, 62/131 vs. 26/39, pâ€‰=â€‰0.044), higher baseline glycosylated hemoglobin A(1c) (HbA(1c)) (vaccinated group vs. VH group, 6.56â€‰Â±â€‰0.95% vs. 7.54â€‰Â±â€‰2.01%, pâ€‰<â€‰0.001) and elevated baseline postprandial blood glucose (PBG) (vaccinated group vs. VH group, 8.32â€‰Â±â€‰1.97Â mmol/L vs. 9.44â€‰Â±â€‰2.94Â mmol/L, pâ€‰=â€‰0.015). Subjects of male gender (pâ€‰=â€‰0.025) and history of hypertension (pâ€‰=â€‰0.021) were likely to get vaccinated, while higher HbA1c was negatively associated with an elevated propensity to receive anti-COVID-19 vaccine (pâ€‰=â€‰0.003). Most common reasons for hesitating to receive COVID-19 vaccination were worrying about the possibility of leading to other diseases (30.8%), followed by fearing of glucose variation (17.9%). Systemic adverse reactions were reported in 30.5% individuals after the first injection of inactivated vaccines, and resolved within 3Â days in medium. Fasting blood glucose (FBG) decreased significantly after the third injection compared with FBG after the second

dose (second vs. third, 6.78â€‰Â±â€‰1.24Â mmol/L vs. 6.41â€‰Â±â€‰1.30Â mmol/L, pâ€‰=â€‰0.027). HbA(1c) reduced significantly from 6.56% before vaccination to 6.35% after the second injection (pâ€‰=â€‰0.012). CONCLUSIONS: Our study demonstrated that vaccine hesitancy was lower among male subjects and people with hypertension, while vaccine confidence was reduced in people with poor glycemic control. HbA(1c) level was lower along with vaccination.

Anti-PEG antibodies before and after a first dose of ComirnatyÂ® (mRNA-LNP-based SARS-CoV-2 vaccine). The early and massive vaccination campaign in Israel with the mRNA-LNP ComirnatyÂ® (Pfizer-BioNTech) vaccine against the SARS-CoV-2 virus made available large amounts of data regarding the efficacy and safety of this vaccine. Adverse reactions to mRNA-based SARS-CoV-2 vaccines are rare events, but due to large mediatic coverage they became feared and acted as a potential source of delay for the vaccination of the Israeli population. The experience with the reactogenicity of the polyethylene glycol (PEG) moiety of PEGylated liposomes, PEGylated proteins and other PEGylated drugs raised the fear that similar adverse effects can be associated with the PEG lipid which is an essential component of currently used mRNA-LNP vaccines against COVID-19. In this study we quantified the levels of anti-PEG IgG, IgM and IgE present in the blood of 79 volunteers immediately before and 3Â weeks after receiving a first dose of ComirnatyÂ® vaccine. Our in vitro results show that different humanized anti-PEG antibodies bind the PEGylated nano-liposomes in a concentration-dependent manner, but they bind with a lower affinity to the Comirnaty vaccine, despite it having a high mole% of neutral PEG(2000)-lipid on its surface. We found an increase in IgG concentration in the blood 3Â weeks after the first vaccine administration, but no increase in IgM or IgE. In addition, no severe signs of adverse reactions to the Comirnaty vaccine were observed in the population studied despite the significant pre-existing high titers of IgG before the first dose of vaccine in 2 donors.

Impact of asymptomatic and mild COVID-19 infection on fetal growth during pregnancy. BACKGROUND: During pregnancy, certain viral infections are known to significantly affect fetal development. Data regarding the impact of COVID-19 viral infection in pregnancy, specifically in asymptomatic or mild cases, remains limited. This presents a challenge in providing prenatal counseling and antepartum surveillance in pregnancies complicated by COVID-19 infection. Placenta studies have demonstrated that vascular malperfusion patterns attributed to COVID-19 appear to depend on the timing of infection. Given these placental changes, we aim to evaluate the impact of COVID-19 on fetal growth in pregnant patients with asymptomatic or mild disease, stratified by trimester of infection. We hypothesize that COVID-19 infection, especially early in pregnancy, increases the risk of fetal growth restriction (FGR). STUDY DESIGN: This is a single institution, retrospective cohort study of patients ages 16-55Â years old with a singleton delivery between December 10, 2020, and April 19, 2021 who had not received a COVID-19 vaccination prior to delivery. COVID-19 infection during pregnancy was defined as a positive SARS-CoV-2 RT-PCR test. FGR was defined as an estimated fetal weight less than the 10th percentile for gestational age or abdominal circumference less than the 10th percentile for gestational age. Maternal and fetal characteristics, including FGR, were compared between women with versus without COVID-19 infection during pregnancy. RESULTS: Among 1971 women with a singleton delivery, 208 (10.6Â %) had a prior asymptomatic or mild COVID-19 infection during pregnancy. With the exception in the median prenatal BMI being significantly higher in the COVID-19 group (median, 27.5 vs 26.3, pÂ =Â 0.04), there were no significant differences in demographics, baseline maternal comorbidities or gestational age between those with versus without COVID-19 infection during pregnancy, or in the proportion of their offspring with FGR (3.4Â % (7/208) vs 4.8Â % (84/1763), pÂ =Â 0.36). When the 208 women were stratified by the timing of their COVID-19 infection, the proportion with an offspring with FGR was 8.7Â % (2/23), 1.2Â % (1/84), and 4.0Â % (4/101), for those first diagnosed with COVID-

19 during the 1st, 2nd, and 3rd trimesters, respectively (pÂ =Â 0.72 Cochran-Armitage test for trend). CONCLUSION: Asymptomatic or mild COVID-19 infection in pregnancy, regardless of timing of infection, does not appear to be associated with FGR. Routine serial fetal growth assessment may not be warranted solely for history of COVID-19 infection.

Class switch toward noninflammatory, spike-specific IgG4 antibodies after repeated SARS-CoV-2 mRNA vaccination. RNA vaccines are efficient preventive measures to combat the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. High levels of neutralizing SARS-CoV-2 antibodies are an important component of vaccine-induced immunity. Shortly after the initial two mRNA vaccine doses, the immunoglobulin G (IgG) response mainly consists of the proinflammatory subclasses IgG1 and IgG3. Here, we report that several months after the second vaccination, SARS-CoV-2-specific antibodies were increasingly composed of noninflammatory IgG4, which were further boosted by a third mRNA vaccination and/or SARS-CoV-2 variant breakthrough infections. IgG4 antibodies among all spike-specific IgG antibodies rose, on average, from 0.04% shortly after the second vaccination to 19.27% late after the third vaccination. This induction of IgG4 antibodies was not observed after homologous or heterologous SARS-CoV-2 vaccination with adenoviral vectors. Single-cell sequencing and flow cytometry revealed substantial frequencies of IgG4-switched B cells within the spike-binding memory B cell population [median of 14.4%; interquartile range (IQR) of 6.7 to 18.1%] compared with the overall memory B cell repertoire (median of 1.3%; IQR of 0.9 to 2.2%) after three immunizations. This class switch was associated with a reduced capacity of the spike-specific antibodies to mediate antibody-dependent cellular phagocytosis and complement deposition. Because Fc-mediated effector functions are critical for antiviral immunity, these findings may have consequences for the choice and timing of vaccination regimens using mRNA vaccines, including future booster immunizations against SARS-CoV-2.

High seroprevalence of Immunoglobulin G (IgG) and IgM antibodies to SARS-CoV-2 in asymptomatic and symptomatic individuals amidst vaccination roll-out in western Kenya. The population's antibody response is a key factor in comprehending SARS-CoV-2 epidemiology. This is especially important in African settings where COVID-19 impact, and vaccination rates are relatively low. This study aimed at characterizing the Immunoglobulin G (IgG) and Immunoglobulin M (IgM) in both SARS-CoV-2 asymptomatic and symptomatic individuals in Kisumu and Siaya counties in western Kenya using enzyme linked immunosorbent assays. The IgG and IgM overall seroprevalence in 98 symptomatic and asymptomatic individuals in western Kenya between December 2021-March 2022 was 76.5% (95% CI = 66.9-84.5) and 29.6% (95% CI = 20.8-39.7) respectively. In terms of gender, males had slightly higher IgG positivity 87.5% (35/40) than females 68.9% (40/58). Amidst the ongoing vaccination roll-out during the study period, over half of the study participants (55.1%, 95% CI = 44.7-65.2) had not received any vaccine. About one third, (31.6%, 95% CI = 22.6-41.8) of the study participants had been fully vaccinated, with close to a quarter (13.3% 95% CI = 7.26-21.6) partially vaccinated. When considering the vaccination status and seroprevalence, out of the 31 fully vaccinated individuals, IgG seropositivity was 81.1% (95% CI = 70.2-96.3) and IgM seropositivity was 35.5% (95% CI = 19.22-54.6). Out of the participants that had not been vaccinated at all, IgG seroprevalence was 70.4% (95% CI 56.4-82.0) with 20.4% (95% CI 10.6-33.5) seropositivity for IgM antibodies. On PCR testing, 33.7% were positive, with 66.3% negative. The 32 positive individuals included 12(37.5%) fully vaccinated, 8(25%) partially vaccinated and 12(37.5%) unvaccinated. SARs-CoV-2 PCR positivity did not significantly predict IgG (p = 0.469 [95% CI 0.514-4.230]) and IgM (p = 0.964 [95% CI 0.380-2.516]) positivity. These data indicate a high seroprevalence of antibodies to SARS-CoV-2 in western Kenya. This suggests that a larger fraction of the population was infected with SARS-CoV-2 within the defined period than what PCR testing could cover.

Association of SARS-CoV-2 Spike Protein Antibody Vaccine Response With Infection Severity in Patients With Cancer: A National COVID Cancer Cross-sectional Evaluation. IMPORTANCE: Accurate identification of patient groups with the lowest level of protection following COVID-19 vaccination is important to better target resources and interventions for the most vulnerable populations. It is not known whether SARS-CoV-2 antibody testing has clinical utility for high-risk groups, such as people with cancer. OBJECTIVE: To evaluate whether spike protein antibody vaccine response (COV-S) following COVID-19 vaccination is associated with the risk of SARS-CoV-2 breakthrough infection or hospitalization among patients with cancer. DESIGN, SETTING, AND PARTICIPANTS: This was a population-based cross-sectional study of patients with cancer from the UK as part of the National COVID Cancer Antibody Survey. Adults with a known or reported cancer diagnosis who had completed their primary SARS-CoV-2 vaccination schedule were included. This analysis ran from September 1, 2021, to March 4, 2022, a period covering the expansion of the UK's third-dose vaccination booster program. INTERVENTIONS: Anti-SARS-CoV-2 COV-S antibody test (Elecsys; Roche). MAIN OUTCOMES AND MEASURES: Odds of SARS-CoV-2 breakthrough infection and COVID-19 hospitalization. RESULTS: The evaluation comprised 4249 antibody test results from 3555 patients with cancer and 294â€¯230 test results from 225â€¯272 individuals in the noncancer population. The overall cohort of 228â€¯827 individuals (patients with cancer and the noncancer population) comprised 298â€¯479 antibody tests. The median age of the cohort was in the age band of 40 and 49 years and included 182â€¯741 test results (61.22%) from women and 115â€¯737 (38.78%) from men. There were 279â€¯721 tests (93.72%) taken by individuals identifying as White or White British. Patients with cancer were more likely to have undetectable anti-S antibody responses than the general population (199 of 4249 test results [4.68%] vs 376 of 294â€¯230 [0.13%]; Pâ€‰<â€‰.001). Patients with leukemia or lymphoma had the lowest antibody titers. In the cancer cohort, following multivariable correction, patients who had an undetectable antibody response were at much greater risk for SARS-CoV-2 breakthrough infection (odds ratio [OR], 3.05; 95% CI, 1.96-4.72; Pâ€‰<â€‰.001) and SARS-CoV-2-related hospitalization (OR, 6.48; 95% CI, 3.31-12.67; Pâ€‰<â€‰.001) than individuals who had a positive antibody response. CONCLUSIONS AND RELEVANCE: The findings of this cross-sectional study suggest that COV-S antibody testing allows the identification of patients with cancer who have the lowest level of antibody-derived protection from COVID-19. This study supports larger evaluations of SARS-CoV-2 antibody testing. Prevention of SARS-CoV-2 transmission to patients with cancer should be prioritized to minimize impact on cancer treatments and maximize quality of life for individuals with cancer during the ongoing pandemic.

COVID-19 Adenoviral Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), COVID-19-Related Thrombosis, and the Thrombotic Thrombocytopenic Syndromes. Adenoviral-based vaccines such as ChadoX1 CoV-19 (AstraZeneca) and Ad26.COV2.S (J&J) were developed to prevent infection and reduce hospitalization or death in Coronavirus Disease 2019 (COVID-19) patients. Although these vaccines passed safety and efficacy trials with excellent neutralizing capabilities against SARS-CoV-2, very rare reports of acute thrombotic thrombocytopenic events following administration emerged in certain populations, which triggered a series of clinical investigations that gave rise to a novel phenomenon called vaccine-induced immune thrombotic thrombocytopenia (VITT). Several converging pathways exist between VITT and other forms of thrombotic thrombocytopenic syndromes, specifically that of heparin-induced thrombocytopenia, which involves the formation of anti-PF4 antibodies and the activation of platelets leading to thrombocytopenia and thrombin-mediated clotting. Interestingly, certain differences in the presentation also exist in VITT, and guidelines have been published in recent months to assist clinicians in recognizing VITT to achieve desired outcomes. In this paper, we first discuss the clotting phenomenon in COVID-19 and delineate it from VITT, followed by a review of current knowledge on the clinical manifestations of VITT in lieu

of other thrombotic thrombocytopenic syndromes. Likewise, emerging evidence on the role of adenoviral vectors and vaccine constituents is also discussed briefly.

Antibody Avidity Maturation Following Recovery From Infection or the Booster Vaccination Grants Breadth of SARS-CoV-2 Neutralizing Capacity. BACKGROUND: Cross-neutralizing capacity of antibodies against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants is important in mitigating (re-)exposures. Role of antibody maturation, the process whereby selection of higher affinity antibodies augments host immunity, to determine SARS-CoV-2 neutralizing capacity was investigated. METHODS: Sera from SARS-CoV-2 convalescents at 2, 6, or 10 months postrecovery, and BNT162b2 vaccine recipients at 3 or 25 weeks postvaccination, were analyzed. Anti-spike IgG avidity was measured in urea-treated ELISAs. Neutralizing capacity was assessed by surrogate neutralization assays. Fold change between variant and wild-type neutralization inferred the breadth of neutralizing capacity. RESULTS: Compared with early-convalescent, avidity indices of late-convalescent sera were significantly higher (median, 37.7 [interquartile range 28.4-45.1] vs 64.9 [57.5-71.5], $P < .0001$). Urea-resistant, high-avidity IgG best predicted neutralizing capacity (Spearman $r = 0.49$ vs 0.67 [wild-type]; 0.18-0.52 vs 0.48-0.83 [variants]). Higher-avidity convalescent sera better cross-neutralized SARS-CoV-2 variants ($P < .001$ [Alpha]; $P < .01$ [Delta and Omicron]). Vaccinees only experienced meaningful avidity maturation following the booster dose, exhibiting rather limited cross-neutralizing capacity at week 25. CONCLUSIONS: Avidity maturation was progressive beyond acute recovery from infection, or became apparent after the booster vaccine dose, granting broader anti-SARS-CoV-2 neutralizing capacity. Understanding the maturation kinetics of the 2 building blocks of anti-SARS-CoV-2 humoral immunity is crucial.

Best practice implementation on reporting of coronavirus disease 2019 vaccine adverse events following immunization in Uasin Gishu County, Kenya. OBJECTIVES: This project's aim was to implement vaccine safety surveillance best practices to improve reporting of adverse events following immunization (AEFI) during coronavirus disease 2019 (COVID-19) vaccination roll out in Uasin Gishu County. INTRODUCTION: Weak vaccine safety surveillance systems in developing countries has contributed to underreporting of AEFIs undermining public confidence in immunization efforts, contributing to low uptake of vaccines critical in the fight against communicable diseases. METHODS: The JBI Practical Application of Clinical Evidence System (JBI PACES) and Getting Research into Practice (GRiP) audit tool for promoting change in healthcare practice was utilized. Preimplementation and postimplementation audit cycles carried out utilized six best practice recommendations. Context-specific strategies and resources were used to address the gaps identified. RESULTS: Less than half of the AEFIs reported were in accordance with the local policy recommendation, and most of the AEFIs reported were submitted in a timely manner in the baseline and follow-up cycle. Slight improvement was recorded in the number of health facilities with AEFIs reporting forms. An improvement of 33.7% was recorded in the number of health workers providing COVID-19 vaccination services who had received education and practical training on vaccine pharmacovigilance. CONCLUSION: Underreporting and delayed submission of COVID-19 vaccine AEFI was evident among the healthcare providers offering COVID-19 vaccination services, the majority of healthcare providers had received training on vaccine pharmacovigilance, and AEFI hard copy reporting forms were not adequate in the health facilities. Public education on vaccine safety before administration of vaccine needs emphasis in order to improve reporting of AEFI.

Antibody response durability following three-dose coronavirus disease 2019 vaccination in people with HIV receiving suppressive antiretroviral therapy. BACKGROUND: Limited data exist regarding longer term antibody responses following three-dose coronavirus disease 2019 (COVID-19) vaccination, and the impact of a first SARS-CoV-2 infection during this time, in people with HIV (PWH) receiving suppressive antiretroviral therapy (ART). We quantified wild-type-specific, Omicron BA.1-

specific and Omicron BA.5-specific responses up to 6 months post-third dose in 64 PWH and 117 controls who remained COVID-19-naive or experienced their first SARS-CoV-2 infection during this time. DESIGN: Longitudinal observational cohort. METHODS: We quantified wild-type-specific and Omicron-specific anti-Spike receptor-binding domain IgG concentrations, ACE2 displacement activities and live virus neutralization at 1, 3 and 6 months post-third vaccine dose. RESULTS: Third doses boosted all antibody measures above two-dose levels, but BA.1-specific responses remained significantly lower than wild-type-specific ones, with BA.5-specific responses lower still. Serum IgG concentrations declined at similar rates in COVID-19-naive PWH and controls post-third dose (median wild-type-specific and BA.1-specific half-lives were between 66 and 74â€Šdays for both groups). Antibody function also declined significantly yet comparably between groups: 6 months post-third dose, BA.1-specific neutralization was undetectable in more than 80% of COVID-19 naive PWH and more than 90% of controls. Breakthrough SARS-CoV-2 infection boosted antibody concentrations and function significantly above vaccine-induced levels in both PWH and controls, though BA.5-specific neutralization remained significantly poorer than BA.1 even post-breakthrough. CONCLUSION: Following three-dose COVID-19 vaccination, antibody response durability in PWH receiving ART is comparable with controls. PWH also mounted strong responses to breakthrough infection. Due to temporal response declines, however, COVID-19-naive individuals, regardless of HIV status, would benefit from a fourth dose within 6â€Šmonths of their third.

Spontaneous intramedullary hematoma following COVID-19 vaccination: A case report. A 67-year-old female was hospitalized due to right-sided hemiparesis and neck pain with rapid deterioration to a deep coma. She had received the Sinopharm vaccine 2â€‰days earlier. MRI showed extensive cervicothoracic hematomyelia. She received intensive medical care for 2â€‰months and was discharged. An 18-month follow-up showed significant neurological recovery.

Kidney injury associated with COVID-19 infection and vaccine: A narrative review. The respiratory tract is the main infection site for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), resulting in many admissions to intensive care centers in several countries. However, in addition to lung involvement, kidney injury caused by the novel coronavirus has proven to be a significant factor related to high morbidity and mortality, alarming experts worldwide. The number of deaths has drastically reduced with the advent of large-scale immunization, highlighting the importance of vaccination as the best way to combat the pandemic. Despite the undeniable efficacy of the vaccine, the renal side effects associated with its use deserve to be highlighted, especially the emergence or reactivation of glomerulopathies mentioned in some case reports. This study aimed to identify the main renal morphological findings correlated with COVID-19 infection and its vaccination, seeking to understand the pathophysiological mechanisms, main clinical features, and outcomes.

Quality of life is associated with vaccine reluctance via mental health and fear of covid-19: an exploratory investigation on a Palestinian sample. Quality of life (QoL) has been studied as an antecedent of good mental health in contexts characterized by extreme poverty and acute conflict. The covid-19 crisis exacerbated the risks of health-related consequences in such contexts. Vaccination campaigns have been started worldwide to contain the virus outbreak with high rates of hesitancy and refusal. Our exploratory study sheds light on the relationship between QoL and vaccine reluctance via mental health and fear of covid-19 in a Palestinian population affected by military occupation or socioeconomic marginalization. Who-QolBref, Fcov-19, and Dass were administered to 1122 Palestinian adults living in the occupied territories and Israel. Structural equation modelling was applied to test the relations between variables. Results showed that fear of COVID-19, stress, anxiety and depression mediated the association between QoL and vaccination reluctance with a good model fit (Ï‡(2) ((5))â€‰=â€‰828.37; pâ€‰=â€‰.001; GFI=.93; AGFI=.94; RMSEA=.046; NFI=.94; CFI=.95). QoL and mental health were negatively associated with stress (Î²(X, Y)â€‰=â€‰- .35;

pâ€‰<â€‰.001), depression (Î²X, Yâ€‰=â€‰-.37; pâ€‰<â€‰.001), and anxiety (Î²X, Yâ€‰=â€‰-.36; pâ€‰<â€‰.001). QoL and fear of COVID- 19 (Î²X, Yâ€‰=â€‰-.16; pâ€‰<â€‰.001) were inversely correlated. A positive effects was found between stress (Î²(M, Y)â€‰=â€‰.17; pâ€‰<â€‰.001), anxiety (Î²M, Yâ€‰=â€‰.18; pâ€‰<â€‰.001), and depression (Î²M, Yâ€‰=â€‰.17; pâ€‰<â€‰.001), fear of COVID-19 and vaccination reluctance (Î²X, Yâ€‰=â€‰.23; pâ€‰<â€‰.001). According to our findings, Public health measures to ease the social suffering of people with low QoL due to conflict and social marginality might favour the acceptance of the vaccine.

[Short-term persistent symptoms in preschool children with mild/common coronavirus disease 2019 caused by Omicron variant infection after discharge: a follow-up study]. OBJECTIVES: To investigate the persistent symptoms in preschool children after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron variant infection, and to provide a basis for developing follow-up plans after infection and reducing and preventing related symptoms after infection. METHODS: The children, aged 0-5 years, who had Omicron BA.2 infection and were discharged from the pediatric ward of Shanghai Renji Hospital South Branch from April 13 to May 8, 2022, were enrolled as subjects, and related demographic and clinical data were collected. The children were followed up from the time to SARS-CoV-2 clearance for two consecutive tests with an interval of >24 hours till 4-5 weeks after clearance, and telephone follow-up was performed on the primary caregivers to investigate related persistent symptoms. RESULTS: Among the 103 children who met the inclusion criteria, there were 61 boys and 42 girls, with a median age of 18 months. The primary caregivers who had received two or more doses of COVID-19 vaccine accounted for 64.1% (66/103). Fever (98.1%, 101/103) was the most common symptom in these children, followed by cough/expectoration (63.1%, 65/103), gastrointestinal problems (37.9%, 39/103), loss of appetite (30.1%, 31/103), weakness (27.2%, 28/103), and nasal obstruction/runny nose (16.5%, 17/103). The follow-up at 1 month after discharge reported that 44 children (42.7%) had at least one persistent symptom, including respiratory symptoms in 14 children (13.6%) and gastrointestinal problems in 19 children (18.4%). The children whose primary caregivers received two or more doses of COVID-19 vaccine had a significantly shorter time to SARS-CoV-2 clearance than those whose primary caregivers did not receive or only received one dose of COVID-19 vaccine ($P<0.05$), while there was no significant difference between the two groups in the proportion of children with at least one persistent symptom ($P>0.05$). CONCLUSIONS: Nearly half of the preschool children may have related persistent symptoms after SARS-CoV-2 Omicron variant infection, mainly gastrointestinal and respiratory symptoms. Most of the symptoms may be mild, and continuous follow-up is needed to observe their outcomes. Vaccination of COVID-19 vaccine for primary caregivers has a certain protective effect on children.

Prevalence of Anti-PF4 Antibodies After First and Second ChAdOx1 nCoV-19 Vaccinations in Women With Adverse Events: A Brief Report and Literature Review.

A Rare Reaction Due to COVID-19 Vaccination.

Potent high-avidity neutralizing antibodies and T cell responses after COVID-19 vaccination in individuals with B cell lymphoma and multiple myeloma. Individuals with hematologic malignancies are at increased risk for severe coronavirus disease 2019 (COVID-19), yet profound analyses of COVID-19 vaccine-induced immunity are scarce. Here we present an observational study with expanded methodological analysis of a longitudinal, primarily BNT162b2 mRNA-vaccinated cohort of 60 infection-naive individuals with B cell lymphomas and multiple myeloma. We show that many of these individuals, despite markedly lower anti-spike IgG titers, rapidly develop potent infection neutralization capacities against several severe acute respiratory syndrome coronavirus 2 variants of concern (VoCs). The observed increased neutralization capacity per anti-spike antibody

unit was paralleled by an early step increase in antibody avidity between the second and third vaccination. All individuals with hematologic malignancies, including those depleted of B cells and individuals with multiple myeloma, exhibited a robust T cell response to peptides derived from the spike protein of VoCs Delta and Omicron (BA.1). Consistently, breakthrough infections were mainly of mild to moderate severity. We conclude that COVID-19 vaccination can induce broad antiviral immunity including ultrapotent neutralizing antibodies with high avidity in different hematologic malignancies.

SARS-CoV-2-specific nasal IgA wanes 9 months after hospitalisation with COVID-19 and is not induced by subsequent vaccination. BACKGROUND: Most studies of immunity to SARS-CoV-2 focus on circulating antibody, giving limited insights into mucosal defences that prevent viral replication and onward transmission. We studied nasal and plasma antibody responses one year after hospitalisation for COVID-19, including a period when SARS-CoV-2 vaccination was introduced. METHODS: In this follow up study, plasma and nasosorption samples were prospectively collected from 446 adults hospitalised for COVID-19 between February 2020 and March 2021 via the ISARIC4C and PHOSP-COVID consortia. IgA and IgG responses to NP and S of ancestral SARS-CoV-2, Delta and Omicron (BA.1) variants were measured by electrochemiluminescence and compared with plasma neutralisation data. FINDINGS: Strong and consistent nasal anti-NP and anti-S IgA responses were demonstrated, which remained elevated for nine months (pÂ <Â 0.0001). Nasal and plasma anti-S IgG remained elevated for at least 12 months (pÂ <Â 0.0001) with plasma neutralising titres that were raised against all variants compared to controls (pÂ <Â 0.0001). Of 323 with complete data, 307 were vaccinated between 6 and 12 months; coinciding with rises in nasal and plasma IgA and IgG anti-S titres for all SARS-CoV-2 variants, although the change in nasal IgA was minimal (1.46-fold change after 10 months, pÂ =Â 0.011) and the median remained below the positive threshold determined by pre-pandemic controls. Samples 12 months after admission showed no association between nasal IgA and plasma IgG anti-S responses (RÂ =Â 0.05, pÂ =Â 0.18), indicating that nasal IgA responses are distinct from those in plasma and minimally boosted by vaccination. INTERPRETATION: The decline in nasal IgA responses 9 months after infection and minimal impact of subsequent vaccination may explain the lack of long-lasting nasal defence against reinfection and the limited effects of vaccination on transmission. These findings highlight the need to develop vaccines that enhance nasal immunity. FUNDING: This study has been supported by ISARIC4C and PHOSP-COVID consortia. ISARIC4C is supported by grants from the National Institute for Health and Care Research and the Medical Research Council. Liverpool Experimental Cancer Medicine Centre provided infrastructure support for this research. The PHOSP-COVD study is jointly funded by UK Research and Innovation and National Institute of Health and Care Research. The funders were not involved in the study design, interpretation of data or the writing of this manuscript.

Association between SARS-CoV-2 infection or vaccination and acquired hemophilia A: A case report and literature update.

The Ethical Significance of Post-Vaccination COVID-19 Transmission Dynamics. The potential for vaccines to prevent the spread of infectious diseases is crucial for vaccination policy and ethics. In this paper, I discuss recent evidence that the current COVID-19 vaccines have only a modest and short-lived effect on reducing SARS-CoV-2 transmission and argue that this has at least four importantÂ ethical implications. First, getting vaccinated against COVID-19Â should be seen primarily as a self-protective choice for individuals. Second, moral condemnation of unvaccinated people for causing direct harm to others is unjustified. Third, the case for a harm-based moral obligation to get vaccinated against COVID-19Â is weak. Finally, and perhaps most significantly, coercive COVID-19Â vaccination policies (e.g., measuresÂ that exclude unvaccinated people from society) cannot be directly justified by the harm principle.

Acute Myocarditis after mRNA COVID-19 Vaccine: A CorrespondenceReplyAcute Myocarditis Following mRNA COVID-19 VaccineMyocarditis after BNT162b2 mRNA Vaccine Against Covid-19 in IsraelMyocarditis after Covid-19 Vaccination in a Large Health Care OrganizationReceipt of mRNA Vaccine against Covid-19 and Myocarditis.
Immunity after mRNA COVID-19 vaccine and immunosuppressive therapy: correspondence.
SARS-CoV-2 infection and vaccination in patients with hairy-cell leukaemia. Little is known of the course of COVID-19 and the antibody response to infection or vaccination in patients with hairy-cell leukaemia (HCL). Among a total of 58 HCL cases we studied in these regards, 37 unvaccinated patients, mostly enjoying a relatively long period free from anti-leukaemic treatment, developed COVID-19 between March 2020 and December 2021 with a usually favourable outcome (fatality rate: 5/37, 14%); however, active leukaemia, older age and more comorbidities were associated with a worse course. Postinfection (nÂ =â€‰11 cases) and postvaccination (nÂ =â€‰28) seroconversion consistently developed, except after recent anti-CD20 or venetoclax therapy, correlating with perivaccine B-cell count. Vaccination appeared to protect from severe COVID-19 in 11 patients with breakthrough infection.
Effect of COVID-19 vaccination on epileptic seizures in patients with epilepsy: Correspondence human vaccines & immunotherapeutics. This correspondence discusses on effect of COVID-19 vaccination on epileptic seizures in patients with epilepsy. Confounding factors might be possible and might affect the outcome of the study.
Lower limb lymphedema and cellulitis as a complication of COVID-19 vaccine: A case report. A 68-year-old man without complications following his first dose of Sinopharm (BBIBP-CorV) COVID-19 vaccine developed left foot and ankle edema, extending to his left leg 3â€‰days after his second dose. Color-Doppler sonography and lymphoscintigraphy showed extensive soft tissue swelling and fat edema in both legs, proposing lymphatic drainage disorder.
Possible oral manifestation after vaccination against COVID-19: a case report. The coronavirus disease 2019 (COVID-19) vaccines are not absolutely safe, and side effects might include oral manifestations, such as rash on the mucous membrane of the mouth and gingival hypertrophy. A 34-year-old male presented to the university dental clinic with malaise, high fever, weakness, tender gums, gingival hypertrophy, rashes on the mucous membrane of the oral cavity and halitosis. Dental professionals must be able to identify and differentiate between lesions of different varieties. This manifestation may be a new feature that can be checked during the history recording and examination part of treatment for patients vaccinated against the severe acute respiratory syndrome coronavirus 2 virus.
A Case Report of Exfoliative Bullous Rash Following AstraZeneca Vaccine. The coronavirus disease 2019 (COVID-19) pandemic has affected globally; but thanks to vaccines, the effect has been countered with the help of a vaccination programme. We report a case of exfoliative bullous rash in a 69-year-old lady admitted to the acute medicine unit with complaints of rash post-AstraZeneca (AZ) vaccine administration. The rash initially started under her breast and had spread to other parts of the body without mucosal involvement. She was noted to have neutrophilia and raised inflammatory markers and subsequently commenced on antibiotics. Histology showed sub-epidermal blistering but negative immunofluorescence which excluded immune-bullous disease. A significant improvement was seen, and the presentation subsided after treatment with antibiotics and emollient therapy.
COVID-19 Vaccine-Induced Acute Perimyocarditis: A Case Report. Perimyocarditis is the inflammation of the pericardium along with the myocardium. Presentation is similar to acute pericarditis, but it is associated with myocardial damage, leading to an elevation in serum troponin and a left ventricular dysfunction (manifested as an ejection fraction of less than 55 percent). Perimyocarditis is mostly managed like acute myocarditis. Etiology is generally idiopathic and likely

secondary to viral infections. Cases of vaccine-associated myocarditis have been infrequently reported in past, most recently with the COVID-19 mRNA vaccine. We present a rare case of a young healthy adolescent male who developed perimyocarditis after the first booster dose of the COVID-19 mRNA vaccine.
"Original Antigenic Sin" in SARS-CoV-2 Vaccination Followed by Infection. Although the "original antigenic sin" (OAS) effects have been predicted against new variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), only a few pieces of evidence are available regarding its impact on the safety and effectiveness of coronavirus disease 2019 (COVID-19) vaccines. This article aims to provide an immunological explanation for the delayed side effects of a SARS-CoV-2 vaccine during an episode of natural infection. We reported a case of a 39-year-old male healthcare worker who complained about pruritus and discomfort around the injection site of an inactivated SARS-CoV-2 vaccine administrated 18, 17, and 13 months earlier. Those symptoms resembled the side effects previously experienced with one of the booster doses, and a sole erythematous papule was also documented. The patient was diagnosed with COVID-19Â one or two days after noticing these local signs and symptoms, and high serum titers of immunoglobulin M (IgM) and immunoglobulin E (IgE) were found five weeks after the onset, along with SARS-CoV-2-specific immunoglobulin G (IgG) antibodies. Therefore, the OAS might be a plausible phenomenon to consider in individuals immunized with inactivated vaccines and exposed secondarily to a wild virus with antigenic variations.
SARS-CoV-2 Vaccination: Long-Term Follow-Up of Pre-existing and De Novo Immune Thrombocytopenia.
The type of SARS-CoV-2 vaccine does not affect ovarian function in assisted reproduction cycle. OBJECTIVE: To assess whether vaccination or the type of vaccine against SARS-CoV-2 affects ovarian function in an assisted reproduction treatment. DESIGN: A retrospective and observational study. SETTING: University-affiliated private inÂ vitro fertilization (IVF) center. PATIENT(S): Five hundred one patients who had received the complete vaccination schedule. INTERVENTION(S): Treatment before and after vaccination. MAIN OUTCOME MEASURE(S): Parameters for both reproductive outcomes and IVF results in patients vaccinated RESULT(S): We included 510 patients, distributed as follows: 13.5% (n = 69) received a viral vector vaccine, either the adenovirus serotype 26 vector vaccine (Ad26.CoV2.S; Janssen; n = 31) or the chimpanzee adenovirus vector vaccine (ChAdOx; AstraZeneca; n = 38). The remaining 86.5% (n = 441) received an messenger RNA vaccine from either Pfizer-BioNTech (n = 336) or Moderna (n = 105). Sample size for the unexposed women was n = 1190. No differences were found in any of the evaluated parameters for both reproductive outcomes and IVF results in patients vaccinated with any adenovirus or messenger RNA vaccine. When we compared the results after vaccination with different types of vaccines between the exposed and unexposed groups, and similar results were obtained in the days of stimulation or the doses of administered follicle stimulating hormone. Finally, the numbers of oocytes were as follows: Johnson & Johnson (9.2 Â± 2.6), AstraZeneca (7.7 Â± 1.2), Moderna (11.3 Â± 1.8), Pfizer (12.6 Â± 1.0), and the unvaccinated group (10.2 Â± 1.5), P=0.057. CONCLUSION(S): These early results suggest no measurable detrimental effect on reproductive outcomes, regardless of the type of vaccine received.
COVID-19 vaccination and changes in the menstrual cycle among vaccinated persons. OBJECTIVE: To describe the characteristics of people who experience changes to their menstrual cycle after COVID-19 vaccination. DESIGN: Longitudinal study. PATIENT(S): We recruited a volunteer sample with and without a history of SARS-CoV-2 infection who enrolled in the Arizona COVID-19 Cohort (CoVHORT) study and participated in a reproductive sub-cohort who were pre-menopausal, not pregnant, and had received a COVID-19 vaccine in 2021 (n = 545). EXPOSURE(S): Demographic and reproductive characteristics were collected via self-reports. MAIN OUTCOME MEASURE(S):

Information on self-reported changes in the menstrual cycle after COVID-19 vaccination was collected from May 2021 to December 2021. We looked at demographic and reproductive characteristics as predictors of menstrual cycle change. RESULT(S): The majority of our vaccinated sample received the Pfizer-BioNTech vaccine (58%), and were 26-35 years old (51%), non-Hispanic (84%), and White (88%). Approximately 25% of vaccinated participants reported a change in their menstrual cycle after vaccination; the majority reported changes after their second dose (56%) as compared with their first (18%) and third (14%) doses. The most commonly reported changes were irregular menstruation (43%), increased premenstrual symptoms (34%), increased menstrual pain or cramps (30%), and abnormally heavy or prolonged bleeding (31%). High self-reported perceived stress levels compared with low perceived stress (OR, 2.22; 95% CI 1.12-4.37) and greater body mass index (OR, 1.04; 95% CI 1.00-1.07) were associated with greater odds of experiencing the menstrual cycle changes after the vaccination. Participants having a history of SARS-CoV-2 infection were less likely to report changes in their menstrual cycle after vaccination compared with the participants with no history of SARS-CoV-2 infection (OR, 0.58; 95% CI 0.32-1.04). CONCLUSION(S): Among vaccinated participants, approximately 25% of them reported predominantly temporary changes in the menstrual cycle, however, we are unable to determine whether these changes are due to normal cycle variability. The COVID-19 vaccines are safe and effective for everyone, including pregnant people and people trying to conceive; hence, these findings should not discourage vaccination.

Tuberculosis following two-dose SARS-CoV-2 vaccination with messenger RNA vaccine (BNT162b2) and inactivated virus vaccine (CoronaVac).

Navigating Coronavirus Disease 2019 Vaccination and Uveitis: Identifying the Rates and Risk of Recurrent Uveitis after Coronavirus Disease Vaccination. PURPOSE: To identify rates of uveitis reactivation both before and after the coronavirus disease (COVID) 2019 vaccine in subjects with a previous diagnosis of uveitis. DESIGN: Retrospective study. PARTICIPANTS: Subjects were identified from the Inflammatory Eye Disease Registry at Auckland District Health Board diagnosed with uveitis between January 1, 2010, and December 31,Â 2020. METHODS: Date of COVID vaccination was determined from the patient clinical record. Rate of flare was calculated for 3 months before vaccination and 3 months after each vaccination. MAIN OUTCOME MEASURE: Uveitis flare was defined as the presence of new uveitis activity or increased activity that required a change in uveitis treatment. RESULTS: A total of 4184 eyes of 3008 patients were included in the study with a total of 8474 vaccinations given during the study period. Median age was 54.8 years, and 1474 (49.0%) were female. Noninfectious etiology was most common, occurring in 2296 patients (76.3%) and infectious etiology occurring in 712 patients (23.7%). Rate of uveitis flare was 12.3 per 1000 patient-months at baseline, 20.7 after the first dose, 15.0 after the second dose, 12.8 after the third dose, and 23.9 after the fourth dose. The median period of quiescence before flare was 3.9 years. An increase in uveitis flare was seen in both infectious uveitis (baseline 13.1 compared with 20.2 after first dose, 154% increase) and noninfectious uveitis (baseline 12.4 compared with 20.9 after first dose, 169% increase). Risk factors for uveitis flare were identified to be recurrent uveitis, chronic uveitis, shorter period of quiescence, and first dose of vaccine. Median time to uveitis flare was 0.53 months after the first vaccination, 1.74 months after the second vaccination, and 1.35 months after the third vaccination. CONCLUSIONS: The current study demonstrates an increased risk of uveitis flare after the first dose of COVID vaccination. This risk was highest in those with previous recurrences, chronic uveitis, and shorter period of quiescence. FINANCIAL DISCLOSURE(S): Proprietary or commercial disclosure may be found after the references.

Menstrual cycle changes: A cross-sectional study of Saudi females following SARS-CoV-2 infection. Temporary changes in the menstrual cycle have recently been reported following SARS-CoV-2 vaccination. In the current study, we aimed to screen menstrual cycle changes following SARS-CoV-2

infection in Saudi Arabia. The type and duration of these changes have been screened in relation to the severity of coronavirus disease symptoms and vaccination status. In total, 956 individuals responded: sixty-nine did not get the COVID-19 vaccine, while the remaining were vaccinated with either a single dose of ChAdOx1 vaccine (n:45) or BNT162b2 vaccine (n: 142) or two doses of the vaccine (n:700) using BNT162b2 (n:477), ChAdOx1 (n:89) or ChAdOx1/ BNT162b2 (n:134). Approximately 26.1% (18/69) of the subjects who did not receive the SARS-CoV-2 vaccine and 15.3% (29/188) and 26.4% (185/700) of the subjects who received single and double doses of the vaccines, respectively, reported menstrual cycle changes. The persistence of menstrual cycle changes for more than six months was reported by 6.4% (61/956) of the participants. These changes were significantly correlated with the severity of COVID-19 infection. We concluded that menstrual cycle changes, associated with COVID-19 infection, increase due to the severity of COVID-19 infection. Thus, menstrual cycle changes are among the long-term effects associated with COVID-19 infection.

Cross-Clade Memory Immunity in Adults Following SARS-CoV-1 Infection in 2003. IMPORTANCE: Knowledge of the longevity and breath of immune response to coronavirus infection is crucial for the development of next-generation vaccines to control the COVID-19 pandemic. OBJECTIVES: To determine the profile of SARS-CoV-2 antibodies among persons infected with the closely related virus, SARS-CoV-1, in 2003 (SARS03 survivors) and to characterize their antibody response soon after the first and second doses of COVID-19 vaccines. DESIGN, SETTING, AND PARTICIPANTS: This prospective cohort study examined SARS-CoV-2 antibodies among SARS03 survivors compared with sex- and age-matched infection-naive controls. Participants received the COVID-19 vaccines between March 1 and September 30, 2021. INTERVENTIONS: One of the 2 COVID-19 vaccines (inactivated [CoronaVac] or messenger RNA [BNT162b2]) available in Hong Kong. Two doses were given according to the recommended schedule. The vaccine type administered was known to both participants and observers. MAIN OUTCOMES AND MEASURES: SARS-CoV-2 antibodies were measured prevaccination, 7 days after the first dose, and 14 days after the second dose. RESULTS: Eighteen SARS03 adult survivors (15 women and 3 men; median age, 46.5 [IQR, 40.0-54.3] years) underwent prevaccination serologic examination. The vast majority retained a detectable level of antibodies that cross-reacted with SARS-CoV-2 (16 of 18 [88.9%] with nucleocapsid protein antibodies and 17 of 18 [94.4%] with receptor-binding domain of spike protein antibodies); a substantial proportion (11 of 18 [61.1%]) had detectable cross-neutralizing antibodies. Twelve SARS03 adult survivors (10 women and 2 men) underwent postvaccination serologic examination. At 7 days after the first dose of vaccine, SARS03 survivors mounted significantly higher levels of neutralizing antibodies compared with controls (median inhibition: 89.5% [IQR, 77.1%-93.7%] vs 13.9% [IQR, 11.8%-16.1%] for BNT162b2; 64.9% [IQR, 60.8%-69.5%] vs 13.4% [IQR, 9.5%-16.8%] for CoronaVac; P < .001 for both). At 14 days after the second dose, SARS03 survivors generated a broader antibody response with significantly higher levels of neutralizing antibodies against variants of concern compared with controls (eg, median inhibition against Omicron variant, 52.1% [IQR, 35.8%-66.0%] vs 14.7% [IQR, 2.5%-20.7%]; Pâ€‰<â€‰.001). CONCLUSIONS AND RELEVANCE: The findings of this prospective cohort study suggest that infection with SARS-CoV-1 was associated with detectable levels of antibodies that cross-react and cross-neutralize SARS-CoV-2, which belongs to a distinct clade under the same subgenus Sarbecovirus. These findings support the development of broadly protective vaccines to cover sarbecoviruses that caused 2 devastating zoonotic outbreaks in humans over the last 2 decades.

A Prospective Validation of a Diagnostic Algorithm for Hypersensitivity Reactions to COVID-19 Vaccines.

A Case Report of Sudden Sensorineural Hearing Loss (SSNHL) After Administration of the COVID-19 Vaccine. Since the issuance of the emergency use authorization (EUA) of 3 coronavirus disease 2019 (COVID-19) vaccines, there have been over 180 million individuals fully vaccinated in the United

States (US). With the increasing administration of COVID-19 vaccinations, there have been over 550,000 adverse events reported in the Vaccine Adverse Event Reporting System (VAERS) with approximately 230,000 experienced after receipt of the Pfizer-BioNTech COVID-19 Vaccine as of September 23(rd) 2021. Audio-vestibular symptoms (including Sudden Sensorineural Hearing Loss (SSNHL)) secondary to immunizations has previously been evaluated. However, this report describes the first case of bilateral sudden sensorineural hearing loss potentially due to the Pfizer-BioNTech COVID-19 vaccine. We further review the available literature regarding the treatment of Sudden Sensorineural Hearing Loss, and the association of SSNHL with previous immunizations and COVID-19 infection. Lastly, we hypothesize the underlying potential mechanisms between SSNHL and the Pfizer-BioNTech COVID-19 vaccine.

[Acute genital ulceration following COVID-19 vaccination and infection].

Presentation of SLE after COVID vaccination in a pediatric patient. BACKGROUND: The outbreak of severe acute respiratory syndrome coronavirus 2 has had an enormous impact on global health. Vaccination remains one of the most effective interventions for disease prevention. Clinically significant vaccine side effects are uncommon, though autoimmune-mediated disease occurs in a small percentage of vaccine recipients. Systemic lupus erythematosus (SLE) is a multisystem autoimmune disease that is associated with significant morbidity and mortality. Childhood-onset SLE tends to have more severe disease manifestations than adult-onset SLE. In adults, there are a few reported cases of SLE developing soon after coronavirus disease 2019 (COVID-19) mRNA vaccination. CASE PRESENTATION: A 14-year-old previously healthy male developed laboratory and clinical evidence of SLE, including maculopapular malar rash, arthritis, pleuritic chest pain, and class V (membranous) lupus nephritis, 2 days after his third dose of the Pfizer-BioNTech COVID-19 vaccine. The patient's symptoms improved after initiation of prednisone and mycophenolate mofetil. We also summarize eleven prior case reports describing SLE after COVID-19 vaccine in adults. CONCLUSION: To our knowledge, this is the first reported pediatric patient with new onset SLE following COVID-19 mRNA vaccination. While potential mechanistic links exist between COVID-19 vaccination and SLE development, additional studies are necessary to elucidate the exact nature of this relationship.

Dynamic changes in peripheral lymphocytes and antibody response following a third dose of SARS-CoV-2 mRNA-BNT162b2 vaccine in cancer patients. The aim of this study was to evaluate the association of circulating lymphocytes profiling with antibody response in cancer patients receiving the third dose of COVID-19 mRNA-BNT162b2 vaccine. Immunophenotyping of peripheral blood was used to determine absolute counts of lymphocyte subsets, alongside detection of IgG antibodies against receptor-binding-domain (RBD) of the SARS-CoV-2 Spike protein (S1) before booster dosing (timepoint-1) and four weeks afterward (timepoint-2). An IgG titerâ€‰â‰¥â€‰50 AU/mL defined a positive seroconversion response. An IgG titerâ€‰â‰¥â€‰4446 AU/mL was assumed as a correlate of 50% vaccine efficacy against symptomatic infections. A total of 258 patients on active treatment within the previous six months were enrolled between September 23 and October 7, 2021. The third dose resulted in an exponential increase in median anti-RBD-S1 IgG titer (Pâ€‰<â€‰0.001), seroconversion rates (Pâ€‰<â€‰0.001), and 50% vaccine efficacy rates (Pâ€‰<â€‰0.001). According to ROC curve analysis, T helper and B cells were significantly associated with seroconversion responses at timepoint-1, whereas only B cells were relevant to 50% vaccine efficacy rates at timepoint-2. A positive linear correlation was shown between anti-RBD-S1 IgG titers and these lymphocyte subset counts. Multivariate analysis ruled out a potential role of T helper cells but confirmed a significant interaction between higher B cell levels and improved antibody response. These findings suggest that peripheral counts of B cells correlate with humoral response to the third dose of mRNA-BNT162b2 vaccine in actively treated cancer patients and could provide insights into a more comprehensive assessment of vaccination efficacy.

A broad assessment of covid-19 vaccine safety using tree-based data-mining in the vaccine safety datalink. BACKGROUND: Except for spontaneous reporting systems, vaccine safety monitoring generally involves pre-specifying health outcomes and post-vaccination risk windows of concern. Instead, we used tree-based data-mining to look more broadly for possible adverse events after Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccination. METHODS: Vaccine Safety Datalink enrollees receivingÂ â‰¥1 dose of COVID-19 vaccine in 2020-2021 were followed for 70Â days after Pfizer-BioNTech or Moderna and 56Â days after Janssen vaccination. Incident diagnoses in inpatient or emergency department settings were analyzed for clustering within both the hierarchical ICD-10-CM code structure and the post-vaccination follow-up period. We used the self-controlled tree-temporal scan statistic and TreeScan software. Monte Carlo simulation was used to estimate p-values; pÂ =Â 0.01 was the pre-specified cut-off for statistical significance of a cluster. RESULTS: There were 4.1, 2.6, and 0.4 million Pfizer-BioNTech, Moderna, and Janssen vaccinees, respectively. Clusters after Pfizer-BioNTech vaccination included: (1) unspecified adverse effects, (2) common vaccine reactions, such as fever, myalgia, and headache, (3) myocarditis/pericarditis, and (4) less specific cardiac or respiratory symptoms, all with the strongest clusters generally after Dose 2; and (5) COVID-19/viral pneumonia/sepsis/respiratory failure in the first 3Â weeks after Dose 1. Moderna results were similar but without a significant myocarditis/pericarditis cluster. Further investigation suggested the fifth signal group was a manifestation of mRNA vaccine effectiveness after the first 3Â weeks. Janssen vaccinees had clusters of unspecified or common vaccine reactions, gait/mobility abnormalities, and muscle weakness. The latter two were deemed to have arisen from confounding related to practices at one site. CONCLUSIONS: We detected post-vaccination clusters of unspecified adverse effects, common vaccine reactions, and, for the mRNA vaccines, chest pain and palpitations, as well as myocarditis/pericarditis after Pfizer-BioNTech Dose 2. Unique advantages of this data mining are its untargeted nature and its inherent adjustment for the multiplicity of diagnoses and risk intervals scanned.

An Updated Comparative Study on the Impact of COVID-19 Infection and Vaccination in Patients with Inflammatory Bowel Disease and Irritable Bowel Syndrome. BACKGROUND AND AIMS: This study assessed the differences in swabbing rates, vaccine uptake, COVID-19 infection, hospitalization rates and outcomes in patients suffering from inflammatory bowel disease (IBD) on immunomodulation and patients diagnosed with irritable bowel syndrome (IBS). METHODS: A population consisting of 250 IBD and 250 IBS patients was randomly selected from the local database. Apart from demographic data, the following data was collected: number of COVID-19 swabs taken, vaccination rates, type of vaccine administered, infection secondary to COVID-19, hospitalization and outcomes. RESULTS: IBD patients performed significantly more swabs tests for SARS-CoV-2 detection compared with IBS patients in both phases of the study. Whilst the IBS cohort recorded a larger number of COVID-19 infection and less hospitalisations whilst infected, IBD patients had a better outcome whilst infected since hospitalisation reason in the latter was not related to COVID-19 infection. IBD patients had a larger uptake of COVID-19 vaccines. CONCLUSIONS: This study was the first of its nature locally and internationally as it compared two unrelated cohorts of patients followed up in gastroenterology. Vaccination rates in both cohorts were higher than those reported internationally. In concordance with international studies, IBD patients are not at an increased risk of worse outcomes from COVID-19 infection compared to non-IBD cohorts.

Reduced early response to SARS-CoV2 vaccination in people with type 1 and type 2 diabetes, a 6Â months follow-up study: The CoVaDiab study I. INTRODUCTION: Diabetes mellitus worsens the prognosis of SARS-CoV-2 infection, and vaccination has been the major tool for reducing the risk of hospitalisation, and mortality. The primary aim of this study was to evaluate the response to the SARS-CoV-2 vaccine in subjects with diabetes and controls. Differences between type 1 (T1D) and

type 2 (T2D) diabetes and clinical determinants of vaccination response were also evaluated. METHODS: 128 subjects with diabetes (60 with T1D and 62 with T2D) and 202 subjects acting as controls who completed a full vaccination cycle with two doses of mRNA vaccine were enroled. People with previous SARS-CoV-2 infection were excluded. Antibodies (Ab) directed against the spike protein of the SARS-CoV-2 were evaluated at one and 6Â months after vaccination. RESULTS: In the whole cohort, the Ab level was higher among women than in men (pÂ =Â 0.011) and negatively correlated with age (rhoÂ =Â -0.155, pÂ =Â 0.005). Subjects with diabetes showed decreased levels of Ab after one month compared to controls (1217[747-1887]BAU/mL vs. 1477[942-2556]BAU/mL, pÂ =Â 0.002), even after correction for age and gender (pÂ =Â 0.002). No difference was found between subjects with T1D and T2D. After 6Â months, antibody levels significantly decreased in people with and without diabetes, with no differences between groups, although some subjects were lost at follow-up. In subjects with diabetes, only a significant correlation was found between Ab level and renal function (rho 0.190, pÂ =Â 0.042). CONCLUSIONS: Both T1D and T2D are associated with a reduced early response to vaccination. The serum concentration of Ab significantly reduced over time in both groups, highlighting the relevance of vaccination boosters independently of the presence of diabetes.

COVID-19 vaccination and Atypical hemolytic uremic syndrome. INTRODUCTION: COVID-19 vaccination has been associated with rare but severe complications characterized by thrombosis and thrombocytopenia. METHODS AND RESULTS: Here we present three patients who developed de novo or relapse atypical hemolytic uremic syndrome (aHUS) in native kidneys, a median of 3 days (range 2-15) after mRNA-based (Pfizer/BioNTech's, BNT162b2) or adenoviral (AstraZeneca, ChAdOx1 nCoV-19) COVID-19 vaccination. All three patients presented with evident hematological signs of TMA and AKI, and other aHUS triggering or explanatory events were absent. After eculizumab treatment, kidney function fully recovered in 2/3 patients. In addition, we describe two patients with dubious aHUS relapse after COVID-19 vaccination. To assess the risks of vaccination, we retrospectively evaluated 29 aHUS patients (n=8 with native kidneys) without complement-inhibitory treatment, who received a total of 73 COVID-19 vaccinations. None developed aHUS relapse after vaccination. CONCLUSION: In conclusion, aHUS should be included in the differential diagnosis of patients with vaccine-induced thrombocytopenia, especially if co-occuring with mechanical hemolytic anemia (MAHA) and acute kidney injury (AKI). Still, the overall risk is limited and we clearly advise continuation of COVID-19 vaccination in patients with a previous episode of aHUS, yet conditional upon clear patient instruction on how to recognize symptoms of recurrence. At last, we suggest monitoring serum creatinine (sCr), proteinuria, MAHA parameters, and blood pressure days after vaccination.

Incidence of SARS-CoV-2 infection in hospital workers before and after vaccination programme in East Java, Indonesia-AÂ retrospective cohort study. BACKGROUND: The incidence of the Coronavirus Disease 2019 (COVID-19) among healthcare workers (HCWs) is widespread. It is important to understand COVID-19 characteristics among HCWs before and after vaccination. We evaluated the incidence of COVID-19 among HCWs in East Java, Indonesia comparing the characteristics of the disease between the pre- vs post-vaccination periods. METHODS: A retrospective observational study was conducted among HCWs in two major hospitals in East Java, Indonesia, between April 01, 2020, and Oct 31, 2021. All HCWs were offered vaccination with inactivated viral vaccine (CoronaVac) from Jan 15, 2021. Therefore, we divided the time of the study into the pre-vaccination period (between April 01, 2020, and Jan 14, 2021) and post-vaccination period (between Jan 15 and Oct 31, 2021). We then compared the pattern of COVID-19 infections, and hospitalisations between these periods. FINDINGS: A total of 434 (15.1%) and 649 (22.6%) SARS-CoV-2 infections were reported among study participants (nÂ =Â 2878) during the pre-vaccination and post-vaccination periods, respectively. The vaccine effectiveness was 73.3% during the first 3-4 months after vaccination but this decreased to

17.6% at 6-7 months after vaccination, which coincided with the emergence of the delta variant. The overall hospitalisation rate was reduced from 23.5% in the pre-vaccination period to 14.3% in the post-vaccination period. Hypertension appeared to be the strongest risk factor affecting hospitalisation in the pre-vaccination period. However, the risk due to hypertension was reduced in the post-vaccination period. INTERPRETATION: The risk to contract COVID-19 remains high among HCWs in East Java, Indonesia. Vaccination is important to reduce infection and hospitalisation. It is essentially important to evaluate the characteristics of COVID-19 infection, hospitalisation, the impact of co-morbidities and vaccine effectiveness in order to improve the measures applied in protecting HCWs during the pandemic. FUNDING: Mandate Research Grant No:1043/UN3.15/PT/2021, Universitas Airlangga, Indonesia.

LipschÃ¼tz ulceration in a 12-year-old girl following second dose of Comirnaty (Pfizer) COVID-19 vaccine.

Host genetics impact on SARS-CoV-2 vaccine-induced immunoglobulin levels and dynamics: The role of TP53, ABO, APOE, ACE2, HLA-A, and CRP genes. Background: Development and worldwide availability of safe and effective vaccines against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) to fight severe symptoms of coronavirus disease 2019 (COVID-19) and block the pandemic have been a great achievement and stimulated researchers on understanding the efficacy and duration of different vaccine types. Methods: We investigated the levels of anti-SARS-CoV-2 antibodies (IgG) and neutralizing antibodies (NAbs) in 195 healthy adult subjects belonging to the staff of the University-Hospital of Ferrara (Italy) starting from 15 days up to 190 days (about 6 months) after the second dose of the BNT162b2 (Pfizer-BioNTech) mRNA-based vaccine (n = 128) or ChAdOx1 (AstraZeneca) adenovirus-based vaccine (n = 67) using a combined approach of serological and genomics investigations. Results: A strong correlation between IgG and NAb levels was detected during the 190 days of follow-up ($r(2) = 0.807$; $p < 0.0001$) and was confirmed during the first 90 days (T1) after vaccination ($r(2) = 0.789$; $p = 0.0001$) and 91-190 days (T2) after vaccination ($r(2) = 0.764$; $p = 0.0001$) for both vaccine types ($r(2) = 0.842$; $p = 0.0001$ and $r(2) = 0.780$; $p = 0.0001$ for mRNA- and adenovirus-based vaccine, respectively). In addition to age ($p < 0.01$), sex ($p = 0.03$), and type of vaccine ($p < 0.0001$), which partially accounted for the remarkable individual differences observed in the antibody levels and dynamics, interesting genetic determinants appeared as significant modifiers of both IgG and NAb responses among the selected genes investigated (TP53, rs1042522; APOE, rs7412/rs429358; ABO, rs657152; ACE2, rs2285666; HLA-A rs2571381/rs2499; CRP, rs2808635/rs876538; LZTFL1, rs35044562; OAS3, rs10735079; SLC6A20, rs11385942; CFH, rs1061170; and ACE1, ins/del, rs4646994). In detail, regression analysis and mean antibody level comparison yielded appreciable differences after genotype stratification (P(1) and P(2), respectively, for IgG and NAb distribution) in the whole cohort and/or in the mRNA-based vaccine in the following genes: TP53, rs1042522 ($P(1) = 0.03$; $P(2) = 0.04$); ABO, rs657152 ($P(1) = 0.01$; $P(2) = 0.03$); APOE, rs7412/rs429358 ($P(1) = 0.0018$; $P(2) = 0.0002$); ACE2, rs2285666 ($P(1) = 0.014$; $P(2) = 0.009$); HLA-A, rs2571381/rs2499 ($P(1) = 0.02$; $P(2) = 0.03$); and CRP, rs2808635/rs876538 ($P(1) = 0.01$ and $P(2) = 0.09$). Conclusion: High- or low-responsive subjects can be identified among healthy adult vaccinated subjects after targeted genetic screening. This suggests that favorable genetic backgrounds may support the progression of an effective vaccine-induced immune response, though no definite conclusions can be drawn on the real effectiveness ascribed to a specific vaccine or to the different extent of a genotype-driven humoral response. The interplay between data from the polygenic predictive markers and serological screening stratified by demogeographic information can help to recognize the individual humoral response, accounting for ethnic and geographical differences, in both COVID-19 and anti-SARS-CoV-2 vaccinations.

Evolution of anti-SARS-CoV-2 spike protein titers after two-dose of COVID-19 vaccination among people living with HIV. BACKGROUND: A community COVID-19 outbreak caused by the B.1.1.7 SARS-CoV-2 variant occurred in Taiwan in May 2021. High-risk populations such as people living with HIV (PLWH) were recommended to receive two doses of COVID-19 vaccines. While SARS-CoV-2 vaccines have demonstrated promising results in general population, real-world information on the serological responses remains limited among PLWH. METHODS: PLWH receiving the first dose of SARS-CoV-2 vaccine from 2020 to 2021 were enrolled. Determinations of anti-SARS-CoV-2 spike IgG titers were performed every one to three months, the third dose of the SARS-CoV-2 vaccine or confirmed SARS-CoV-2 infection. All serum samples were tested for anti-nucleocapsid antibody and those tested positive were excluded from analysis. RESULTS: A total of 1189 PLWH were enrolled: 829 (69.7%) receiving two doses of the AZD1222 vaccine, 232 (19.5%) of the mRNA-1273 vaccine, and 128 (10.8%) of the BNT162b2 vaccine. At all time-points, PLWH receiving two doses of mRNA vaccines had consistently higher antibody levels than those receiving the AZD1222 vaccine (pÂ <0.001 for all time-point comparisons). Factors associated with failure to achieve an anti-spike IgG titer >141 BAU/mL within 12 weeks, included type 2 diabetes mellitus (DM) (adjusted odds ratio [aOR], 2.24; 95% CI, 1.25-4), a CD4 T cell count <200Â cells/mm(3) upon receipt of the first dose of vaccination (aOR, 3.43; 95% CI, 1.31-9) and two homologous AZD1222 vaccinations (aOR, 16.85; 95%CI, 10.13-28). For those receiving two doses of mRNA vaccines, factors associated with failure to achieve an anti-spike IgG titer >899 BAU/mL within 12 weeks were a CD4 T cell count <200Â cells/mm(3) on first-dose vaccination (aOR, 3.95; 95% CI, 1.08-14.42) and dual BNT162b2 vaccination (aOR, 4.21; 95% CI, 2.57-6.89). CONCLUSIONS: Two doses of homologous mRNA vaccination achieved significantly higher serological responses than vaccination with AZD1222 among PLWH. Those with CD4 T cell counts <200Â cells/mm(3) and DM had consistently lower serological responses.

A Rare Case of MDA-5-Positive Amyopathic Dermatomyositis with Rapidly Progressive Interstitial Lung Disease Following COVID-19 mRNA Vaccination - a Case Report. We report a rare case of new-onset MDA-5-positive amyopathic dermatomyositis with rapidly progressive interstitial lung disease (RP-ILD) following the second dose of the COVID-19 mRNA vaccine. Our patient was a previously healthy Asian female in her 60Â s who presented with fatigue, dyspnea on exertion, and typical dermatomyositis (DM) rashes without muscle involvement twoÂ weeks after receiving the second dose of the COVID-19 mRNA BNT162b2 vaccine. Workup revealed high titer MDA-5 antibodies, abnormal pulmonary function tests, and ground-glass opacities on chest imaging. She had good response to early aggressive therapy with high-dose steroids, intravenous (IV) rituximab, mycophenolate mofetil, and intravenous immunoglobulin (IVIG). This case highlights the potential immunogenicity of COVID-19 mRNA vaccines and the possibility of new-onset systemic rheumatic syndromes after vaccination. More studies are needed to understand a definitive causal relationship and improve surveillance of adverse immunological events following COVID-19 vaccinations.

CNS inflammatory demyelinating events after COVID-19 vaccines: A case series and systematic review. BACKGROUND: Vaccinations provided the most effective tool to fight the SARS-CoV-2 pandemic. It is now well established that COVID-19 vaccines are safe for the general population; however, some cases of rare adverse events following immunization have been described, including CNS Inflammatory Demyelinating Events (CIDEs). Although observational studies are showing that these events are rare and vaccines' benefits highly outweigh the risks, collecting and characterizing post-COVID-19 vaccine CIDEs might be relevant to single out potential risk factors and suggest possible underlying mechanisms. METHODS: Here we describe six CIDEs, including two acute transverse myelitis (ATM), three multiple sclerosis (MS), and one neuromyelitis optica spectrum disorder (NMOSD), occurring between 8 and 35 days from a COVID-19 vaccine. Moreover, we performed a systematic literature search of post-COVID-19 vaccines CIDEs, including ATM, ADEM, MS,

and NMOSD/MOGAD, published worldwide between December 2020 and December 2021, during 1 year of the vaccination campaign. Clinical/MRI and CSF/serum characteristics were extracted from reviewed studies and pooled-analyzed. RESULTS: Forty-nine studies were included in the systematic review, reporting a total amount of 85 CIDEs. Considering our additional six cases, 91 CIDEs were summarized, including 24 ATM, 11 ADEM, 47 MS, and nine NMOSD/MOGAD. Overall, CIDEs occurred after both mRNA (n = 46), adenoviral-vectored (n = 37), and inactivated vaccines (n = 8). Adenoviral-vectored vaccines accounted for the majority of ADEM (55%) and NMOSD/MOGAD (56%), while mRNA vaccines were more frequent in MS new diagnoses (87%) and relapses (56%). Age was heterogeneous (19-88) and the female sex was prevalent. Time from vaccine to symptoms onset was notably variable: ADEM and NMOSD/MOGAD had a longer median time of onset (12.5 and 10 days) compared to ATM and MS (6 and 7 days) and further timing differences were observed between events following different vaccine types, with ATM and MS after mRNA-vaccines occurring earlier than those following adenoviral-vectored ones. CONCLUSION: Both the prevalence of vaccine types for certain CIDEs and the heterogeneity in time of onset suggest that different mechanisms-with distinct dynamic/kinetic-might underly these events. While epidemiological studies have assessed the safety of COVID-19 vaccines, descriptions and pooled analyses of sporadic cases may still be valuable to gain insights into CIDE's pathophysiology.

Factors of influenza vaccine inoculation and non-inoculation behavior of community-dwelling residents in Japan: Suggestions for vaccine policy and public health ethics after COVID-19. The aim of this study is to provide basic information that contributes to vaccine inoculation policy after COVID-19. We used the secondary data of the influenza vaccine inoculation behavior survey for community-dwelling adults conducted in 2011, before the COVID-19 pandemic, but after the 2009 novel influenza A (H1N1) pdm 09 pandemic. All factors such as socio-demographic characteristics, health-related behaviors, family environment, physical and social environment, and area of residence were adjusted, and factors related to vaccine inoculation behavior were analyzed. Those living with pregnant women had a significantly higher odds ratio of inoculation; this was self-evident in that those people considered infection to their family. Regarding the social environment, those aged 20-64Â years with a significantly higher adjusted odds ratio of inoculation were those with "at least five people with which they interacted in the neighborhood". This result can be interpreted in two ways relating to altruism in Japan. Finally, we indicated the importance of learning from the past, including the case of 2009.

Indolent cutaneous lymphoma with gamma/delta expression after COVID-19 vaccination.

IgG anti-RBD levels during 8-month follow-up post-vaccination with BNT162b2 and mRNA-1273 vaccines in healthcare workers: A one-center study. INTRODUCTION: Since the COVID-19 outbreak, specific mRNA-based anti-SARS-CoV-2 vaccines have been developed and distributed worldwide. Because this is the first time that mRNA vaccines have been used, there are several questions regarding their capacity to confer immunity and the durability of the specific anti-SARS-CoV-2 response. Therefore, the objective of this study was to recruit a large cohort of healthcare workers from the Gregorio MaraÃ±Ã³n Hospital vaccinated with the mRNA-1273 or BNT126b2 vaccines and to follow-up on IgG anti-RBD levels at 8 months post-vaccination. METHODS: We recruited 4,970 volunteers and measured IgG anti-RBD antibodies on days 30 and 240 post-vaccination. RESULTS: We observed that both vaccines induced high levels of antibodies on day 30, while a drastic wane was observed on day 240, where mRNA-1273 vaccinated induced higher levels than BNT162b2. Stratifying by vaccine type, age, gender, and comorbidities, we identified that older mRNA-1273-vaccinated volunteers had higher antibody levels than the younger volunteers, contrary to what was observed in the BNT162b2-vaccinated volunteers. DISCUSSION: In conclusion, we

observed that mRNA-1273 has a higher capacity to induce a humoral response than BNT162b2 and that age is a factor in the specific response.

The BNT162b2 mRNA SARS-CoV-2 vaccine induces transient afucosylated IgG1 in naive but not in antigen-experienced vaccinees. BACKGROUND: Afucosylated IgG1 responses have only been found against membrane-embedded epitopes, including anti-S in SARS-CoV-2 infections. These responses, intrinsically protective through enhanced Fcî³RIIIa binding, can also trigger exacerbated pro-inflammatory responses in severe COVID-19. We investigated if the BNT162b2 SARS-CoV-2 mRNA also induced afucosylated IgG responses. METHODS: Blood from vaccinees during the first vaccination wave was collected. Liquid chromatography-Mass spectrometry (LC-MS) was used to study anti-S IgG1 Fc glycoprofiles. Responsiveness of alveolar-like macrophages to produce proinflammatory cytokines in presence of sera and antigen was tested. Antigen-specific B cells were characterized and glycosyltransferase levels were investigated by Fluorescence-Activated Cell Sorting (FACS). FINDINGS: Initial transient afucosylated anti-S IgG1 responses were found in naive vaccinees, but not in antigen-experienced ones. All vaccinees had increased galactosylated and sialylated anti-S IgG1. Both naive and antigen-experienced vaccinees showed relatively low macrophage activation potential, as expected, due to the low antibody levels for naive individuals with afucosylated IgG1, and low afucosylation levels for antigen-experienced individuals with high levels of anti-S. Afucosylation levels correlated with FUT8 expression in antigen-specific plasma cells in naive individuals. Interestingly, low fucosylation of anti-S IgG1 upon seroconversion correlated with high anti-S IgG levels after the second dose. INTERPRETATION: Here, we show that BNT162b2 mRNA vaccination induces transient afucosylated anti-S IgG1 responses in naive individuals. This observation warrants further studies to elucidate the clinical context in which potent afucosylated responses would be preferred. FUNDING: LSBR1721, 1908; ZonMW10430012010021, 09150161910033, 10430012010008; DFG398859914, 400912066, 390884018; PMI; DOI4-Nr. 3; H2020-MSCA-ITN 721815.

The spike effect of acute respiratory syndrome coronavirus 2 and coronavirus disease 2019 vaccines on blood pressure. Among the various comorbidities potentially worsening the clinical outcome in patients hospitalized for the acute respiratory syndrome coronavirus-2 (SARS-CoV-2), hypertension is one of the most prevalent. However, the basic mechanisms underlying the development of severe forms of coronavirus disease 2019 (COVID-19) among hypertensive patients remain undefined and the direct association of hypertension with outcome in COVID-19 is still a field of debate. Experimental and clinical data suggest that SARS-CoV-2 infection promotes a rise in blood pressure (BP) during the acute phase of infection. Acute increase in BP and high in-hospital BP variability may be tied with acute organ damage and a worse outcome in patients hospitalized for COVID-19. In this context, the failure of the counter-regulatory renin-angiotensin-system (RAS) axis is a potentially relevant mechanism involved in the raise in BP. It is well recognized that the efficient binding of the Spike (S) protein to angiotensin converting enzyme 2 (ACE2) receptors mediates the virus entry into cells. Internalization of ACE2, downregulation and malfunction predominantly due to viral occupation, dysregulates the protective RAS axis with increased generation and activity of angiotensin (Ang) II and reduced formation of Ang(1,7). Thus, the imbalance between Ang II and Ang(1-7) can directly contribute to excessively rise BP in the acute phase of SARS-CoV-2 infection. A similar mechanism has been postulated to explain the raise in BP following COVID-19 vaccination ("Spike Effect" similar to that observed during the infection of SARS-CoV-2). S proteins produced upon vaccination have the native-like mimicry of SARS-CoV-2 S protein's receptor binding functionality and prefusion structure and free-floating S proteins released by the destroyed cells previously targeted by vaccines may interact with ACE2 of other cells, thereby promoting ACE2 internalization and degradation, and loss of ACE2 activities.

Effect of inactivated COVID-19 vaccination on pregnancy outcomes following frozen-thawed embryo transfer: A retrospective cohort study. OBJECTIVE: To investigate the effect of inactivated coronavirus disease 2019 (COVID-19) vaccination on frozen-thawed embryo transfer (FET) outcomes. METHODS: This retrospective cohort study enrolled 1,210 patients undergoing FET cycles in a single university-affiliated hospital between July 1, 2021, and May 1, 2022. Of them, 387 women with two full doses of inactivated SARS-CoV-2 vaccines (CoronaVac or BBIBP-CorV) after oocyte retrieval were assigned to the vaccinated group, while 823 were unvaccinated as controls. Propensity score matching and multiple regression analysis were applied to control for baseline and cycle characteristics (19 covariates in total). RESULTS: There were 265 patients in each group after matching. The rates of clinical pregnancy (58.5% vs. 60.8%; PÂ =Â 0.595) and live birth (44.4% vs. 48.8%; PÂ =Â 0.693) were similar between vaccinated and unvaccinated patients, with adjusted odds ratios of 0.89 (95% confidence interval [CI] 0.61-1.29) and 1.31 (95% CI 0.37-4.56), respectively. Consistently, no significant differences were found in serum human chorionic gonadotropin levels as well as biochemical pregnancy, biochemical pregnancy loss, and embryo implantation rates. Based on the time interval from vaccination to FET, vaccinated patients were further subdivided into two categories of â‰¤2Â months and >2Â months, and the outcomes remained comparable. CONCLUSION: Our study showed that inactivated COVID-19 vaccination in women did not have measurable detrimental impact on implantation performance and live birth outcome during FET treatment cycles. This finding denies the impairment of endometrial receptivity and trophoblast function by vaccine-induced antibodies at the clinical level.

Imprecision in adverse event reports following immunization against HPV in Japan and COVID-19 in the USA, UK, and Japan-and the effects of vaccine hesitancy and government policy. INTRODUCTION: Erroneous reports of adverse events following immunization (AEFIs) likely exacerbated the 2013 collapse of Japan's HPV immunization program. A similar phenomenon characterized the first months of COVID-19 immunization programs in the USA, UK, and Japan with high rates of reportedÂ anaphylaxis. These reports illustrate the susceptibility of supposedly objective medical judgments to public anxiety. PURPOSE AND METHODS: This study documents inaccuracies in reportedÂ AEFIs using three quantitative methods. RESULTS: One of these quantitative methods revealed that false-positive rates for anaphylaxis reports following HPV and later COVID-19 vaccination ranged from 74 to 91 percent. However, unlike HPV vaccinations in Japan, anaphylaxis reportsÂ following COVID-19 vaccines fell in Japan, the USA and theÂ UK in the latter months of 2021. Nevertheless, false-positive rates for anaphylaxis reports remained high, suggesting a high degree of imprecision in serious AEFI reports from many countriesÂ for many vaccines. Japan's HPV immunization program indicates that media reports, patient hesitancy, healthcare providers' perspectives on vaccine safety, and consistency of government messaging, all influence report number and accuracy. A parallel publication analyzes in depth how such factors affect AEFI reports. CONCLUSION: Confidence in the safety of the COVID-19 vaccines may have been bolstered trough rapid monitoring of AEFI reports and communication ofÂ these findings. This may partly explain the different trajectories of serious AEFI following HPV immunizations in Japan and COVID-19 immunizations in the USA, UK, and Japan.

Impact of prenatal COVID-19 vaccination on delivery and neonatal outcomes: Results from a New York City cohort. Research suggest prenatal vaccination against coronavirus disease-19 (COVID-19) is safe. However, previous studies utilized retrospectively collected data or examined late pregnancy vaccinations. We investigated the associations of COVID-19 vaccination throughout pregnancy with delivery and neonatal outcomes. We included 1,794 mother-neonate dyads enrolled in the Generation C Study with known prenatal COVID-19 vaccination status and complete covariate and outcome data. We used multivariable quantile regressions to estimate the effect of prenatal

COVID-19 vaccination on birthweight, delivery gestational age, and blood loss at delivery; and Poisson generalized linear models for Caesarean delivery (CD) and Neonatal Intensive Care Unit (NICU) admission. Using the above methods, we estimated effects of trimester of vaccine initiation on these outcomes. In our sample, 13.7% (nÂ =Â 250) received at least one prenatal dose of any COVID-19 vaccine. Vaccination was not associated with birthweight (Î²Â =Â 12.42Â g [-90.5, 114.8]), gestational age (Î²Â =Â 0.2Â days [-1.1, 1.5]), blood loss (Î²Â =Â -50.6Â ml [-107.0, 5.8]), the risks of CD (RRÂ =Â 0.8; [0.6, 1.1]) or NICU admission (RRÂ =Â 0.9 [0.5, 1.7]). Trimester of vaccine initiation was also not associated with these outcomes. Our findings suggest that there is no associated risk between prenatal COVID-19 vaccination and adverse delivery and neonatal outcomes in a cohort sample from NYC.

Factors Associated with Intention to Vaccinate Children 0-11 Years of Age Against COVID-19. BACKGROUND: Millions of children have tested positive for SARS-CoV-2, and over 1000 children have died in the US. However, vaccination rates for children 5 to 11â€‰years old are low. METHODS: Starting in August 2020, we conducted a prospective SARS-CoV-2 household surveillance study in Spanish and English-speaking households in New York City and Utah. From October 21 to 25, 2021, we asked caregivers about their likelihood of getting COVID-19 vaccine for their child, and reasons that they might or might not vaccinate that child. We compared intent to vaccinate by site, demographic characteristics, SARS-CoV-2 infection detected by study surveillance, and parents' COVID-19 vaccination status using Chi-square tests and a multivariable logistic regression model, accounting for within-household clustering. RESULTS: Among parents or caregivers of 309 children (0 to 11â€‰years) in 172 households, 87% were very or somewhat likely to intend to vaccinate their child. The most prevalent reasons for intending to vaccinate were to protect family and friends and the community; individual prevention was mentioned less often. The most prevalent reasons for not intending to vaccinate were side effect concerns and wanting to wait and see.In multivariable analysis, parents had much lower odds of intending to vaccinate if someone in the household had tested SARS-CoV-2-positive during the study (adjusted odds ratio = 0.09; 95% confidence interval, 0.03-0.3). CONCLUSION: This study highlighted several themes for clinicians and public health officials to consider including the importance and safety of vaccination for this age-group even if infected previously, and the benefits of vaccination to protect family, friends, and community.

COVID-associated acute limb ischemia during the Delta surge and the effect of vaccines. OBJECTIVE: Hypercoagulability is common in severe acute respiratory syndrome coronavirus 2 and has been associated with arterial thrombosis leading to acute limb ischemia (ALI). Our objective was to determine the outcomes of concurrent coronavirus disease 2019 (COVID-19) infection and ALI, particularly during the Delta variant surge and the impact of vaccination status. METHODS: A retrospective review was performed of patients treated at a single health care system between March 2020 and December 2021 for ALI and recent (<14Â days) COVID-19 infection or who developed ALI during hospitalization for the same disease. Patients were grouped by year as well as by pre and post Delta variant emergence in 2021 based on the World Health Organization timeline (January to May vs June to December). Baseline demographics, imaging, interventions, and outcomes were evaluated. A control cohort of all patients with ALI requiring surgical intervention for a 2-year period prior to the pandemic was used for comparison. Primary outcomes were in-hospital mortality and amputation-free survival. Kaplan-Meier survival and Cox proportional hazards analysis were performed. RESULTS: Forty acutely ischemic limbs were identified in 36 patients with COVID-19, the majority during the Delta surge (52.8%) and after the wide availability of vaccines. The rate of COVID-19-associated ALI, although low overall, nearly doubled during the Delta surge (0.37% vs 0.20%; PÂ = .09). Intervention (open or endovascular revascularization vs primary amputation) was performed on 31 limbs in 28 individuals, with the remaining eight treated with systemic anti-coagulation.

Postoperative mortality was 48%, and overall mortality was 50%. Major amputation following revascularization was significantly higher with COVID-19 ALI (25% vs 3%; PÂ = .006) compared with the pre-pandemic group. Thirty-day amputation-free survival was significantly lower (log-rank PÂ < .001). COVID-19 infection (adjusted hazard ratio, 6.2; PÂ < .001) and age (hazard ratio, 1.1; PÂ = .006) were associated with 30-day amputation in multivariate analysis. Severity of COVID-19 infection, defined as vasopressor usage, was not associated with post-revascularization amputation. There was a higher incidence of re-thrombosis in the latter half of 2021 with the Delta surge, as reintervention forÂ recurrent ischemia of the same limb was more common than our previous experience (21% vs 0%; PÂ = .55). COVID-19-associated limb ischemia occurred almost exclusively in non-vaccinated patients (92%). CONCLUSIONS: ALI observed with Delta appears more resistant to standard therapy. Unvaccinated status correlated highly with ALI occurrence in the setting of COVID-19 infection. Information of limb loss as a COVID-19 complication among non-vaccinated patients may help to increase compliance.

Characterization of otologic symptoms appearing after COVID-19 vaccination. OBJECTIVES: Anecdotal reports of sudden sensorineural hearing loss (SSNHL) following COVID-19 vaccination have emerged in the otolaryngology community. Studies have demonstrated no association between COVID-19 vaccination and SSNHL. We aim to characterize the spectrum of otologic symptoms following COVID-19 vaccination. METHODS: A cross-sectional study of patients seen in the otology clinic at an academic center was performed. Patients completed a questionnaire on the development of new otologic symptoms within 4Â weeks of COVID-19 vaccination. Diagnostic and audiometric data was collected retrospectively for patients reporting otologic symptoms. RESULTS: Between May and July 2021, 500 patients were screened. Median age was 56.6Â years old, with 59.4Â % female and 40.2Â % male. 420 patients (84.0Â %) were vaccinated, with 58.4Â % receiving Pfizer, 29.1Â % receiving Moderna, and 3.8Â % receiving Johnson & Johnson. 61 patients (14.5Â %) reported one or more otologic symptoms within 4Â weeks of vaccination, including 21 (5.0Â %) with hearing loss, 26 (6.2Â %) with tinnitus, 33 (7.9Â %) with dizziness, and 19 (4.5Â %) with vertigo. Of the 16 patients (3.2Â %) reporting tinnitus with no associated hearing loss, 8 were diagnosed with subjective tinnitus and 4 were diagnosed with temporomandibular joint syndrome. Of the 18 patients reporting hearing loss, 11 had exacerbations of underlying pathologies (e.g. Meniere's disease, presbycusis) and 7 were newly diagnosed with SSNHL (1.4Â %). CONCLUSIONS: Patients reporting otologic symptoms following COVID-19 vaccination received various diagnoses of uncertain etiology. The incidence of SSNHL in these patients is comparable to the general otology patient population. Additional studies are required to determine the incidence of specific diagnoses following vaccination.

Association Between COVID-19 Vaccination and Artificial Insemination Outcomes for Couples Experiencing Infertility. This cohort study investigates the association between COVID-19 vaccination status and artificial insemination by partner outcomes among couples experiencing infertility in China.

Antibody Response to SARS-CoV-2 mRNA Vaccine Among Kidney Transplant Recipients.

A Comparative Study on the Variation in Seropositivity Rates After 2-Dose COVID-19 Vaccination Before or After Transplant: A Single-Center Analysis. OBJECTIVES: Many researchers have demonstrated that the seropositivity rate after SARS-CoV-2 coronavirus vaccination is lower in patients receiving oral immunosuppressants. In this article, we report on a comparative study on the seropositivity rate after 2 doses of coronavirus vaccine before or after kidney transplant. MATERIALS AND METHODS: We studied 111 recipients vaccinated after transplant, 19 patients vaccinated before transplant, and 10 healthy patients. We retrospectively measured antibody titers using preserved serum samples. The antibody testing was performed 1 month and 3 months after vaccination. The measurement was via LABScreen COVID Plus, which enables simultaneous determination of 5

coronavirus protein antigens. RESULTS: Seropositivity to coronavirus antibodies was observed in all 19 patients vaccinated before transplant (100%) and in all the 10 healthy patients (100%). Forty- six of the 111 recipients (42%) vaccinated after transplant developed seropositivity. Analyzed at each time point after vaccination, the mean fluorescence intensity of antibodies was unchanged between 1 month and 3 months after vaccination in transplant recipients who were vaccinated after transplant and developed seropositivity. On the other hand, the antibody mean fluorescence intensity in patients vaccinated before transplant was markedly lower at 3 months (posttransplant). CONCLUSIONS: All patients with renal failure who were vaccinated before transplant showed a high seropositivity rate, similar to that in healthy patients. The seropositivity rate for each of the viral fragment antibodies in patients vaccinated before transplant was maintained, as seen in healthy patients. However, in patients vaccinated before transplant who tested positive for antibody production at 1 month after vaccination,the antibody mean fluorescence intensity at 3 months after vaccination (posttransplant) was remarkedly lower than the mean fluorescence intensity at 1 month, which was probably caused by the types of immunosuppressive regimens used atthe time of transplant.

Chronic graft vs. host disease and hypogammaglobulinemia predict a lower immunological response to the BNT162b2 mRNA COVID-19 vaccine after allogeneic hematopoietic stem cell transplantation. OBJECTIVE: Due to the high mortality rate of COVID-19, the assessment of BNT162b2 SARS-CoV-2 mRNA vaccine (Pfizer-BioNTech) efficacy in allogeneic hematopoietic stem cell transplant (HSCT) recipients is mandatory. PATIENTS AND METHODS: We conducted a single-center pilot study with the main objective of evaluating the immunogenicity of the BNT162b2 mRNA vaccine in 31 hematological patients who underwent hematopoietic stem cell transplantation within the previous 12 months and/or were affected by chronic graft-vs.-host-disease (cGVHD), by the assessment of antibody levels at 30-45 days after the second dose of vaccine. RESULTS: After the second dose of vaccine, 23 out of 31 patients (74%) showed a positive immune response. The presence of severe cGVHD or Ig deficiency identified 7 out of 8 (85%) of non-responders. The median absolute cluster of differentiation 19 (CD19) count was significantly lower in non-responders vs. responders (109/ÂµI vs. 351/ÂµI). Underlying pathology, comorbidities, type of donor, time intervals from transplant and cluster of differentiation 3/cluster of differentiation 4/cluster of differentiation 8 (CD3/CD4/CD8) subsets were not significantly associated with an effective immune response to vaccination. CONCLUSIONS: Despite the limited sample of patients enrolled, our findings suggest that hypogammaglobulinemia and cGVHD could be associated with poor humoral response to the BNT162b2.

Safety Monitoring of COVID-19 Vaccines: Perspective from the European Medicines Agency. Prior to deployment of coronavirus disease 2019 (COVID-19) vaccines in the European Union in 2021, a high vaccine uptake leading to an unprecedented volume of safety data from spontaneous reports and real-world evidence, was anticipated. The European Medicines Agency (EMA) implemented specific activities to ensure enhanced monitoring of emerging vaccine safety information, including intensive monitoring of reports of adverse events of special interest and the use of observed-to-expected analyses. The EMA also commissioned several independent observational studies using a large network of electronic healthcare databases and primary data collection via mobile and web-based applications. This preparedness was key for two high-profile safety signals: thrombosis with thrombocytopenia syndrome (TTS), a new clinical entity associated with adenovirus-vectored vaccines, and myocarditis/pericarditis with messenger RNA vaccines. With no existing case definition nor background rates, the signal of TTS posed particular challenges. Nevertheless, it was rapidly identified, evaluated, contextualized and the risk minimized thanks to close surveillance and an efficient use of available evidence, clinical expertise and flexible regulatory tools. The two signals

illustrated the complementarity between spontaneous and real-world data, the former enabling rapid risk identification and communication, the latter enabling further characterization. The COVID-19 pandemic has tremendously enhanced the development of tools and methods to harness the unprecedented volume of safety data generated for the vaccines. Areas for further improvement include the need for better and harmonized data collection across Member States (e.g., stratified vaccine exposure) to support signal evaluation in all population groups, risk contextualization, and safety communication.

Factors associated with hospitalisations and deaths of residential aged care residents with COVID-19 during the Omicron (BA.1) wave in Queensland. OBJECTIVE: To identify characteristics associated with the hospitalisation and death of people with COVID-19 living in residential aged care facilities (RACFs). DESIGN: Retrospective cohort study. SETTING, PARTICIPANTS: All confirmed (polymerase chain reaction testing) or probable SARS-CoV-2 infections (rapid antigen tests) in residents of the 86 RACFs in the Metro South Hospital and Health Service area (southeast Queensland), 13 December 2021 - 24 January 2022. MAIN OUTCOME MEASURES: Hospitalisation within 14 days or death within 28 days of COVID-19 diagnosis. RESULTS: Of 1071 RACF residents with COVID-19, 151 were hospitalised within 14 days and 126 died within 28 days of diagnosis. Likelihood of death increased with age (per five years: adjusted odds ratio [aOR], 1.38; 95% confidence interval [CI], 1.21-1.57), but not that of hospitalisation. Men were more likely to be hospitalised (aOR, 1.7; 95% CI, 1.2-2.4) or die (aOR, 2.5; 95% CI, 1.7-3.6) than women. The likelihood of hospitalisation was greater for those with dementia (aOR, 1.9; 95% CI, 1.2-3.0), heart failure (aOR, 1.7; 95% CI, 1.1-2.7), chronic kidney disease (aOR, 1.7; 95% CI, 1.1-2.5), or asthma (aOR, 2.2; 95% CI, 1.2-3.8). The likelihood of death was greater for residents with dementia (aOR, 2.2; 95% CI, 1.3-3.7), diabetes mellitus (aOR, 1.9; 95% CI, 1.3-3.0), heart failure (aOR, 2.0; 95% CI, 1.1-3.3), or chronic lung disease (aOR, 1.7; 95% CI, 1.1-2.7). The likelihood of hospitalisation and death were each higher for residents who had received two or fewer vaccine doses than for those who had received three doses. CONCLUSIONS: Most characteristics that influenced the likelihood of hospitalisation or death of RACF residents with COVID-19 were non-modifiable factors linked with frailty and general health status. Having received three COVID-19 vaccine doses was associated with much lower likelihood of hospitalisation or death.

Erroneous diagnosis of COVID-19 mRNA vaccine-associated acute myocarditis due to false-positive high-sensitive troponin I assay: a case report. BACKGROUND: Coronavirus disease 2019 (COVID-19) mRNA vaccine-associated acute myocarditis has been well described, and the demonstration of elevated high-sensitivity cardiac troponin (hs-cTn) is crucial for its diagnosis. However, falsely elevated hs-cTn can occasionally occur, leading to incorrect diagnosis. Here, we report the case of a patient who was given an erroneous diagnosis of COVID-19 mRNA vaccine-associated acute myocarditis due to falsely elevated hs-cTn, likely from assay interference. CASE SUMMARY: A 29-year-old Chinese male presented with 3 months of chest pain, dyspnoea, and palpitations starting a few days after his second dose of mRNA-1273 (Moderna) vaccine. High-sensitivity cardiac troponin I was elevated at presentation, which rose further 4â€…h later. The provisional diagnosis was acute myocarditis after a computed tomography coronary angiogram showed normal coronaries. Cardiac magnetic resonance was also negative for myocardial inflammation. The hs-cTn I levels fluctuated but remained elevated on outpatient serial testing, despite no new symptoms or clinical events. A paired serum sample showed elevated hs-cTn I but normal hs-cTn T, confirming a diagnosis of false-positive hs-cTn I. Further investigations, including blood tests before and after a subsequent uneventful mRNA-1273 booster vaccination, were performed to investigate for assay interference. DISCUSSION: Widespread COVID-19 mRNA vaccination has resulted in an awareness of vaccine-related acute myocarditis and a more thorough evaluation of post-vaccination cardiac symptoms. Although false-positive hs-cTn rarely occurs, extensive testing will inevitably result in a significant number of patients

with falsely elevated hs-cTn. Clinicians should exclude this possibility and consider using alternative hs-cTn assay when investigation results and clinical presentation appear discordant.

Toxic epidermal necrosis following Sinopharm COVID-19 vaccine (BBIBP-CorV): A case report and literature review. This study reports a patient developing TEN after the first dose of (BBIBP-CorV). He developed numerous purpuric and dusky patches with flaccid bullae and areas of epidermal detachment covered more than 30% of the body area within 6â€‰days. After treatment with dexamethasone and cyclosporin, he recovered within 14â€‰days.

Similar deposition of neutrophil extracellular traps in the dermis among COVID-19-associated IgA vasculitis, post-COVID-19 vaccination IgA vasculitis, and COVID-19-unrelated IgA vasculitis.

IgA vasculitis presenting as nephrotic syndrome following COVID-19 vaccination: a case report. BACKGROUND: Following the strong recommendation for coronavirus disease 2019 (COVIDâ€‘19) vaccination, many patients with medical comorbidities are being immunized. However, the safety of vaccination in patients with autoimmune diseases has not been well established. We report a new case of biopsy-proven IgA vasculitis with nephritis presenting as a nephrotic syndrome after mRNA COVID-19 vaccination in a patient with a history of leukocytoclastic vasculitis. CASE PRESENTATION: A 76-year-old man with a history of cutaneous leukocytoclastic vasculitis presented with purpura in both lower limbs, followed by nephrotic syndrome after the second dose of BNT162b2 mRNA COVID-19 vaccination. Skin and renal biopsy revealed IgA vasculitis with nephritis. The patient's past medical history of leukocytoclastic vasculitis and features of chronicity in renal pathology suggest an acute exacerbation of preexisting IgA vasculitis after COVID-19 vaccination. After the steroid and renin-angiotensin system inhibitor use, purpura and acute kidney injury recovered within a month. Subnephrotic proteinuria with microscopic hematuria remained upon follow-up. CONCLUSION: Physicians should keep in mind the potential (re)activation of IgA vasculitis following mRNA COVID-19 vaccines. It is important to closely monitor COVID-19 vaccinated patients, particularly those with autoimmune diseases.

COVID-19 infection and vaccine have no impact on in-vitro fertilization (IVF) outcome. To investigate the effect of COVID-19 infection or vaccine on IVF outcome. This is a multicenter retrospective study. Data were collected from all patients treated in the ART units between September and November 2021 after the vaccination of the general population began. Medical records of all patients who had IVF/intracytoplasmic sperm injection (ICSI) were retrospectively reviewed. Patients were categorized into four groups: previously infected by COVID-19, vaccinated by COVID vaccine, previously infected and vaccinated, or neither infected nor vaccinated. Total number of participants 151 (vaccinated only 66, infected only 18, vaccinated and previously infected 34, and control 33. Outcomes (ET on day of trigger, number of oocytes retrieved, quality of oocytes, number of fertilized oocytes, number and quality of embryos, number of embryos transferred, number of embryos frozen, implantation rate and clinical pregnancy rate) were compared between these four groups. Moreover, we compared the outcome before and post infection, as well as before and post vaccine in a group of patients. No evidence was found to suggest that COVID-19 disease or SARS-CoV-2 Vaccine adversely affects Clinical pregnancy rates (positive fetal heartbeat) (OR 0.9, CI 0.5-1.9, OR 1.8, CI 0.9-3.6, respectively) and the following parameters: fertilization rate, implantation rate, positive bHcg) (OR 0.9, CI 0.5-1.8, OR 1.5, CI 0.7-2.9, respectively). Although a limitation of our study is the small comparison groups, and the wide confidence intervals in the Odds Ratio estimates.

Longitudinal characterisation of B and T-cell immune responses after the booster dose of COVID-19 mRNA-vaccine in people with multiple sclerosis using different disease-modifying therapies. BACKGROUND: The decline of humoral response to COVID-19 vaccine led to authorise a booster dose. Here, we characterised the kinetics of B-cell and T-cell immune responses in patients with multiple sclerosis (PwMS) after the booster dose. METHODS: We enrolled 22 PwMS and 40 healthcare workers

(HCWs) after 4-6 weeks from the booster dose (T3). Thirty HCWs and 19 PwMS were also recruited 6 months (T2) after the first dose. Antibody response was measured by anti-receptor-binding domain (RBD)-IgG detection, cell-mediated response by an interferon (IFN)-Î³ release assay (IGRA), Th1 cytokines and T-cell memory profile by flow cytometry. RESULTS: Booster dose increased anti-RBD-IgG titers in fingolimod-treated, cladribine-treated and IFN-Î²-treated patients, but not in ocrelizumab-treated patients, although antibody titres were lower than HCWs. A higher number of fingolimod-treated patients seroconverted at T3. Differently, T-cell response evaluated by IGRA remained stable in PwMS independently of therapy. Spike-specific Th1-cytokine response was mainly CD4(+) T-cell-mediated, and in PwMS was significantly reduced ($p<0.0001$) with impaired IL-2 production compared with HCWs at T3. In PwMS, total Th1 and IFN-Î³ CD4(+) T-cell responders to spike protein were increased from T2 to T3.Compared with HCWs, PwMS presented a higher frequency of CD4(+) and CD8(+) terminally differentiated effector memory cells and of CD4(+) effector memory (T(EM)) cells, independently of the stimulus suggesting the association of this phenotype with MS status. CD4(+) and CD8(+) T(EM) cell frequency was further increased at T3 compared with T2. CONCLUSIONS: COVID-19 vaccine booster strengthens humoral and Th1-cell responses and increases T(EM) cells in PwMS.

Potential benefit of extended dose schedules of human papillomavirus vaccination in the context of scarce resources and COVID-19 disruptions in low-income and middle-income countries: a mathematical modelling analysis. BACKGROUND: The WHO Strategic Advisory Group of Experts recommended that an extended interval of 3-5 years between the two doses of the human papillomavirus (HPV) vaccine could be considered to alleviate vaccine supply shortages. However, three concerns have limited the introduction of extended schedules: girls could be infected between the two doses, the vaccination coverage for the second dose could be lower at ages 13-14 years than at ages 9-10 years, and identifying girls vaccinated with a first dose to give them the second dose could be difficult. Using mathematical modelling, we examined the potential effect of these concerns on the population-level impact and efficiency of extended dose HPV vaccination schedules. METHODS: We used HPV-ADVISE, an individual-based, transmission-dynamic model of multitype HPV infection and disease, calibrated to country-specific data for four low-income and middle-income countries (India, Viet Nam, Uganda, and Nigeria). For the extended dose scenarios, we varied the vaccination coverage of the second dose among girls previously vaccinated, the one-dose vaccine efficacy, and the one-dose vaccine duration of protection. We also examined a strategy in which girls aged 14 years were vaccinated irrespective of their previous vaccination status. We used a scenario of girls-only two-dose vaccination at age 9 years (vaccine=9 valent, vaccine-type efficacy=100%, duration of protection=lifetime, and coverage=80%) as our comparator. We estimated two outcomes: the relative reduction in the age-standardised cervical cancer incidence (population-level impact) and the number of cervical cancers averted per 100â€ˆ000 doses (efficiency). FINDINGS: Our model projected substantial reductions in cervical cancer incidence over 100 years with the two-dose schedule (79-86% depending on the country), compared with no vaccination. Projections for the 5-year extended schedule, in which the second dose is given only to girls previously vaccinated at age 9 years, were similar to the current two-dose schedule, unless vaccination coverage of the second dose is very low (reductions in cervical cancer incidence of 71-78% assuming 30% coverage at age 14 years among girls vaccinated at age 9 years). However, when the dose at age 14 years is given to girls irrespective of vaccination status and assuming high vaccination coverage, the model projected a substantially greater reduction in cervical cancer incidence compared with the current two-dose schedule (reductions in cervical cancer incidence of 86-93% assuming 70% coverage at age 14 years, irrespective of vaccination status). Efficiency of the extended schedule was greater than the two-dose schedule, even with a drop in vaccination coverage. INTERPRETATION: The three concerns are

unlikely to have a substantial effect on the population-level impact of extended dose schedules. Hence, extended dose schedules will likely provide similar cervical cancer reductions as two-dose schedules, while reducing the number of doses required in the short-term, providing a more efficient use of scarce resources, and offering a 5-year time window to reassess the necessity of the second dose. FUNDING: WHO, Canadian Institute of Health Research Foundation, Fonds de recherche du QuÃ©bec-SantÃ©, Digital Research Alliance of Canada, and Bill & Melinda Gates Foundation.

B Cell Reconstitution is Associated With COVID-19 Booster Vaccine Responsiveness in Patients Previously Seronegative Treated With Rituximab. OBJECTIVE: To assess factors associated with serologic response to the coronavirus 2019 (COVID-19) booster vaccine in patients with autoimmune rheumatic diseases treated with rituximab (RTX) who were previously serologically unresponsive to the initial vaccine series. METHODS: A retrospective chart review of patients treated with RTX who failed to demonstrate a serologic response to the first SARS-CoV-2 vaccination series and subsequently received an mRNA vaccine booster was performed. Serologic response â‰¥ 4 weeks after the booster was the primary outcome. Fisher exact tests, t tests, and Wilcoxon rank-sum tests were used for comparisons. RESULTS: In 31 patients who were previously seronegative, 68% seroconverted following a booster of the COVID-19 vaccine. B cell reconstitution was significantly different between those with positive (median 1.79, IQR 0.65-3.00) and negative (median 0, IQR 0-0) serologic responses to the booster. The days from last RTX dose were also statistically different among seroconverters (median 301, IQR 251-368) vs nonseroconverters (median 188, IQR 169-245). Demographic characteristics were not associated with serologic positivity. Positive predictive value of B cell presence was 90.9% (95% CI 70.8-98.9) and negative predictive value was 100% (95% CI 59-100) for serologic response to the mRNA booster vaccine. Positive predictive value of time â‰¥ 6 months from last RTX dose to booster was 78.3% (95% CI 56.3-92.5) and the negative predictive value was 62.5% (95% CI 24.5-91.5). CONCLUSION: Detectable B cells and longer time from last RTX exposure were associated with the development of anti-SARS-CoV-2 spike protein antibodies following the booster vaccine. These findings should be considered in timing boosters in patients treated with RTX.

Sudden Hearing Loss Following Vaccination Against COVID-19. IMPORTANCE: Spontaneous adverse reaction reports of sudden hearing loss have been observed, and a population-based cohort study conducted in Israel showed an increase in the incidence of sudden sensorineural hearing loss (SSNHL) following vaccination with messenger RNA COVID-19 vaccine BNT162b2 (Pfizer-BioNTech). However, in this setting, the possibility of confounding remained. OBJECTIVE: To assess a potential association between COVID-19 vaccinations and SSNHL. DESIGN, SETTING, AND PARTICIPANTS: This register-based country-wide retrospective cohort study of 5.5 million Finnish residents was conducted from January 1, 2019, to April 20, 2022, and included all individuals who were identified from the population information system who were alive or born during the study period except individuals who had SSNHL during 2015 to 2018 according to specialized care derived diagnosis codes for SSNHL (International Statistical Classification of Diseases and Related Health Problems, Tenth Revision [ICD-10] code H91.2) as a primary or secondary diagnosis. EXPOSURES: The a priori primary risk period was 0 to 54 days following each COVID-19 vaccination. The risk periods for different vaccine doses did not overlap so that a later vaccine exposure ended the previous risk period. The secondary risk period was from 55 days following each COVID-19 vaccination until a subsequent COVID-19 vaccination. A secondary analysis included a risk time from 0 to 54 days following a positive polymerase chain reaction test result for SARS-CoV-2. MAIN OUTCOMES AND MEASURES: The incidences of SSNHL following COVID-19 vaccination were compared with the incidences before the COVID-19 epidemic in Finland. The Poisson regression model included calendar time, age, sex, diabetes, cardiovascular disease, other chronic diseases, and the number of visits in primary health care. RESULTS: For the 5.5 million Finnish residents included in the study, the comparison time

comprised 6.5 million person-years, the primary risk time of 1.7 million person-years, and the secondary risk time of 2.1 million person-years. Before the COVID-19 epidemic in Finland, 18.7/100â€¯000 people received a diagnosis of SSNHL annually. The study data suggested no increased risk for SSNHL following any COVID-19 vaccination. In particular, adjusted incidence rate ratios with 95% confidence intervals for the BNT162b2 vaccine's 3 doses were 0.8 (95% CI, 0.6-1.0), 0.9 (95% CI, 0.6-1.2), and 1.0 (95% CI, 0.7-1.4), respectively. There was no association between SARS-CoV-2 infection and an increased incidence of SSNHL. CONCLUSIONS AND RELEVANCE: The results of this cohort study show no evidence of an increased risk of SSNHL following COVID-19 vaccination. The study accounted for previous disease and other potential confounding factors. These results are based on diagnosis codes in specialized care but still need to be verified in settings that are capable of evaluating the degree of hearing loss.

Prevalence of Post-Coronavirus Disease Condition 12 Weeks After Omicron Infection Compared With Negative Controls and Association With Vaccination Status. BACKGROUND: Post-coronovirus disease (COVID) symptoms can persist several months after severe acute respiratory syndrome coronavirus 2 infection. Little is known, however, about the prevalence of post-COVID condition following infections from Omicron variants and how this varies according to vaccination status. This study evaluates the prevalence of symptoms and functional impairment 12 weeks after an infection by Omicron variants (BA.1 and BA.2) compared with negative controls tested during the same period. METHODS: Outpatient individuals who tested positive or negative for COVID-19 infection between December 2021 and February 2022 at the Geneva University Hospitals were followed 12 weeks after their test date. RESULTS: Overall, 11.7% of Omicron cases had symptoms 12 weeks after the infection compared with 10.4% of individuals who tested negative during the same period ($P < .001$), and symptoms were much less common in vaccinated versus nonvaccinated individuals with Omicron infection (9.7% vs 18.1%; $P < .001$). There were no significant differences in functional impairment at 12 weeks between Omicron cases and negative controls, even after adjusting for multiple potential confounders. CONCLUSIONS: The differential prevalence of post-COVID symptoms and functional impairment attributed to Omicron BA.1 and BA.2 infection is low when compared with negative controls. Vaccination is associated with lower prevalence of post-COVID symptoms.

Strong Neutralizing Antibody Responses to SARS-CoV-2 Variants Following a Single Vaccine Dose in Subjects With Previous SARS-CoV-2 Infection. BACKGROUND: Previous severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection primes the immune system; thus individuals who have recovered from infection have enhanced immune responses to subsequent vaccination (hybrid immunity). However, it remains unclear how well hybrid immunity induced by severe or mild infection can cross-neutralize emerging variants. We aimed to compare the strength and breadth of antibody responses in vaccinated recovered and uninfected subjects. METHODS: We measured spike-specific immunoglobulin (Ig)G and neutralizing antibodies (NAbs) from vaccinated subjects including 320 with hybrid immunity and 20 without previous infection. From 29 subjects with a previous severe or mild infection, we also measured NAb responses against Alpha (B.1.1.7), Beta (B.1.351), Delta (B.1.617.2), and Omicron (B.1.1.529/BA.1) variants following vaccination. RESULTS: A single vaccine dose induced 2-fold higher anti-spike IgG concentrations and up to 4-fold higher neutralizing potency of antibodies in subjects with a previous infection compared with vaccinated subjects without a previous infection. Hybrid immunity was more enhanced after a severe than a mild infection, with sequentially decreasing NAb titers against Alpha, Beta, Delta, and Omicron variants. We found similar IgG concentrations in subjects with a previous infection after 1 or 2 vaccine doses. CONCLUSIONS: Hybrid immunity induced strong IgG responses, particularly after severe infection. However, the NAb titers were low against heterologous variants, especially against Omicron.

Preserved T-cell response in anti-CD20-treated multiple sclerosis patients following SARS-CoV-2 vaccination. BACKGROUND: The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has tremendous implications for the management of patients with autoimmune conditions such as multiple sclerosis (MS) under immune therapies targeting CD20(+) B cells (aCD20). OBJECTIVES: Here, we investigated humoral and cellular immune responses, including anti-spike titers, neutralization against SARS-CoV-2 wild-type (WT), delta, and omicron variant and T cell responses of aCD20-treated relapsing-remitting MS patients following SARS-CoV-2 vaccination compared with healthy controls. METHODS: Blood samples were collected within 4-8 weeks following the second vaccination against SARS-CoV-2. Sera were analyzed for anti-SARS-CoV-2 spike antibodies and neutralization capacity against pseudovirus for wild-type (WT), delta, and omicron variant. Peripheral blood mononuclear cells (PBMCs) were stimulated with a SARS-CoV-2 peptide pool and analyzed via flow cytometry. RESULTS: The aCD20-treated MS patients had lower anti-SARS-CoV-2-spike titers, which correlated with B cell repopulation. Sera of aCD20-treated patients had reduced capacity to neutralize WT, delta, and omicron pseudoviruses in vitro. On the contrary, PBMCs of aCD20-treated patients elicited higher frequencies of CD3(+) T cells and CD4(+) T cells and comparable response of cytotoxic T cells, while Th1 response was reduced following restimulation with SARS-CoV-2. CONCLUSION: In summary, aCD20-treated patients have a reduced humoral immune response, depending on B cell repopulation, in accordance with preserved cellular immune response, suggesting partial cellular protection against SARS-CoV-2.

From trial to practice: incidence and severity of COVID-19 vaccine side effects in a medically at-risk and vaccine-hesitant community. BACKGROUND: The rapid authorization and widespread rollout of COVID-19 vaccines in the United States demonstrated a need for additional data on vaccine side effects, both to provide insight into the range and severity of side effects that might be expected in medically-diverse populations as well as to inform decision-making and combat vaccine hesitancy going forward. Here we report the results of a survey of 4825 individuals from southcentral Kentucky who received two doses of either the Pfizer-BioNTech (BNT162b2) or Moderna (mRNA-1273) vaccine between December 14, 2020 and May 1, 2021. As new versions of the vaccine are rolled-out, local initiatives such as this may offer a means to combat vaccine hesitancy in reference to COVID-19, but are also important as we face new viral threats that will necessitate a rapid vaccine rollout, and to combat a growing public distrust of vaccines in general. METHODS: Individuals that received two doses of either BNT162b2 or mRNA-1273 between December 14, 2020 and May 1, 2021 were sent a survey, created by the research team. Respondents were asked to rate the incidence and severity of 15 potential side effects and two related outcomes following each of their two doses of the vaccine. All statistical analyses were carried out using SYSTAT, version 13. The data were analyzed utilizing a range of statistical tests, including chi-square tests of association, Cohen's h, Kruskal-Wallis test one-way nonparametric ANOVA, least-squares regression, and Wilcoxon signed-ranks test. Significance was assessed using Bonferroni-adjusted criteria within families of tests. RESULTS: In general, the pattern and severity in side effects was similar to both clinical trial data as well as other published studies. Responses to the mRNA-1273 vaccine were more severe than to BNT162b2, though all were generally in the mild to moderate category. Individuals who reported having previously tested positive for COVID-19 reported stronger responses following the first dose of either vaccine relative to COVID-naÃ¯ve individuals. The reported severity to the COVID-19 vaccine was positively correlated with self-reported responses to other vaccines. CONCLUSIONS: Our findings allow broad-scale estimates of the nature and severity of reactions one might expect following vaccination within a clinically-diverse community, and provide a context for addressing vaccine hesitancy in communities such as ours, where locally-generated data and communication may be more influential than national trends and statistics in convincing individuals to become vaccinated. Further, we argue this

community-based approach could be important in the future in three key ways: 1) as new boosters and modified vaccines re-volatilize vaccine hesitancy, 2) as new vaccines receive similar testing and rapid authorization, and 3) to combat vaccine hesitancy in other arenas (e.g., annual vaccines, childhood vaccines).
Antibody and T cell responses against wild-type and Omicron SARS-CoV-2 after third-dose BNT162b2 in adolescents. The high effectiveness of the third dose of BNT162b2 in healthy adolescents against Omicron BA.1 has been reported in some studies, but immune responses conferring this protection are not yet elucidated. In this analysis, our study (NCT04800133) aims to evaluate the humoral and cellular responses against wild-type and Omicron (BA.1, BA.2 and/or BA.5) SARS-CoV-2 before and after a third dose of BNT162b2 in healthy adolescents. At 5 months after 2 doses, S IgG, S IgG Fc receptor-binding, and neutralising antibody responses waned significantly, yet neutralising antibodies remained detectable in all tested adolescents and S IgG avidity increased from 1 month after 2 doses. The antibody responses and S-specific IFN-Î³(+) and IL-2(+) CD8(+) T cell responses were significantly boosted in healthy adolescents after a homologous third dose of BNT162b2. Compared to adults, humoral responses for the third dose were non-inferior or superior in adolescents. The S-specific IFN-Î³(+) and IL-2(+) CD4(+) and CD8(+) T cell responses in adolescents and adults were comparable or non-inferior. Interestingly, after 3 doses, adolescents had preserved S IgG, S IgG avidity, S IgG FcÎ³RIIIa-binding, against Omicron BA.2, as well as preserved cellular responses against BA.1 S and moderate neutralisation levels against BA.1, BA.2 and BA.5. Sera from 100 and 96% of adolescents tested at 1 and 5 months after two doses could also neutralise BA.1. Our study found high antibody and T cell responses, including potent cross-variant reactivity, after three doses of BNT162b2 vaccine in adolescents in its current formulation, suggesting that current vaccines can be protective against symptomatic Omicron disease.
[Corneal perforation on Mooren ulcer after anti-COVID-19Â vaccination: A case report].
Superior Vena Cava Syndrome and COVID-19 Vaccine Reaction.
The prevalence of adverse reactions among individuals with three-dose COVID-19 vaccination. BACKGROUND: Considering the adverse reactions to vaccination against coronavirus disease 2019 (COVID-19), some people, particularly the elderly and those with underlying medical conditions, are hesitant to be vaccinated. This study aimed to explore the prevalence of adverse reactions and provide direct evidence of vaccine safety, mainly for the elderly and people with underlying medical conditions, to receive COVID-19 vaccination. METHODS: From 1st March to 30th April 2022, we conducted an online survey of people who had completed three doses of COVID-19 vaccination by convenience sampling. Adverse reaction rates and 95% confidence intervals were calculated. In addition, conditional logistic regression was used to compare the differences in adverse reactions among the elderly and those with underlying medical conditions with the general population. RESULTS: A total of 3339 individuals were included in this study, of which 2335 (69.9%) were female, with an average age of 32.1Â Â±Â 11.4 years. The prevalence of adverse reactions after the first dose of inactivated vaccine was 24.6% (23.1-26.2%), 19.2% (17.8-20.7%) for the second dose, and 19.1% (17.7-20.6%) for the booster dose; among individuals using messenger RNA vaccines, the prevalence was 42.7% (32.3-53.6%) for the first dose, 47.2% (36.5-58.1%) for the second dose, and 46.1% (35.4-57.0%) for the booster dose. Compared with the general population, the prevalence of adverse events did not differ in individuals with underlying medical conditions and those aged 60 and above. CONCLUSIONS: For individuals with underlying medical conditions and those aged 60 and above, the prevalence of adverse reactions is similar to that of the general population, which provides a scientific basis regarding vaccination safety for these populations.
Association of Time to Surgery After COVID-19 Infection With Risk of Postoperative Cardiovascular Morbidity. IMPORTANCE: The time interval between COVID-19 infection and surgery is a

potentially modifiable but understudied risk factor for postoperative complications. OBJECTIVE: To examine the association between time to surgery after COVID-19 diagnosis and the risk of a composite of major postoperative cardiovascular morbidity events within 30 days of surgery. DESIGN, SETTING, AND PARTICIPANTS: This single-center, retrospective cohort study was conducted among 3997 adult patients (aged â‰¥18 years) with a previous diagnosis of COVID-19, as documented by a positive polymerase chain reaction test result, who were undergoing surgery from January 1, 2020, to December 6, 2021. Data were obtained through Structured Query Language access of an existing perioperative data warehouse. Statistical analysis was performed March 29, 2022. EXPOSURE: The time interval between COVID-19 diagnosis and surgery. MAIN OUTCOMES AND MEASURES: The primary outcome was the composite occurrence of major cardiovascular comorbidity, defined as deep vein thrombosis, pulmonary embolism, cerebrovascular accident, myocardial injury, acute kidney injury, and death within 30 days after surgery, using multivariable logistic regression. RESULTS: A total of 3997 patients (2223 [55.6%]; median age, 51.3 years [IQR, 35.1-64.4 years]; 667 [16.7%] African American or Black; 2990 [74.8%] White; and 340 [8.5%] other race) were included in the study. The median time from COVID-19 diagnosis to surgery was 98 days (IQR, 30-225 days). Major postoperative adverse cardiovascular events were identified in 485 patients (12.1%). Increased time from COVID-19 diagnosis to surgery was associated with a decreased rate of the composite outcome (adjusted odds ratio, 0.99 [per 10 days]; 95% CI, 0.98-1.00; Pâ€‰=â€‰.006). This trend persisted for the 1552 patients who had received at least 1 dose of COVID-19 vaccine (adjusted odds ratio, 0.98 [per 10 days]; 95% CI, 0.97-1.00; Pâ€‰=â€‰.04). CONCLUSIONS AND RELEVANCE: This study suggests that increased time from COVID-19 diagnosis to surgery was associated with a decreased odds of experiencing major postoperative cardiovascular morbidity. This information should be used to better inform risk-benefit discussions concerning optimal surgical timing and perioperative outcomes for patients with a history of COVID-19 infection.

Physician hesitancy to recommend COVID-19 vaccination in pregnancy as a cause of maternal deaths - Robert Brent was prescient.

Generalized fixed drug eruption following Pfizer-BioNtech COVID-19 vaccination. Fixed drug eruption is a cutaneous drug reaction which recurs at the same site when the individual is exposed to the causative drug, characterized by single or multiple round sharply demarcated erythematous-to-violaceous patches. Here, we report a patient with generalized non-bullous fixed drug eruption following mRNA-based Pfizer-BioNTech COVID-19 vaccine.

Thrombotic thrombocytopenic purpura developed after pegylated interferon treatment for hepatitis B infection. BACKGROUND: Thrombotic thrombocytopenic purpura (TTP) is a rare and life-threatening thrombotic microangiopathy characterized by microangiopathic hemolytic anemia, severe thrombocytopenia, and organ ischemia. It is related to severe deficiency in ADAMTS13, which is usually acquired via ADAMTS13 autoantibodies or inherited via mutations of the ADAMTS13 gene. The etiology of acquired TTP including HIV infection, pregnancy, autoimmune disease, organ transplantation, drugs, malignancy and so on. Here, we firstly reported a patient diagnosed as acquired TTP after pegylated interferon therapy for hepatitis B and COVID-19 vaccination. CASE PRESENTATION: A 36-year-old male attended to our unit with a five-day history of intermittent hematuria and progressive fatigue on January 5th, 2022. He had a 13Â years history of hepatitis B infection and undergone pegylated interferon treatment (which was paused for two months because of COVID-19 vaccination) for nearly 3Â years. Laboratory evaluation revealed a haemoglobin level of 61Â g/L, platelet count of 11â€‰Ã—â€‰10(9)/L, lactate dehydrogenase 2133 U/L. The direct and indirect Coombs test were both negative. On a peripheral blood smear, there were about 18.8% schistocytes. Meanwhile, the results of ADAMTS 13 activity and antibody wereâ€‰<â€‰5% and 181.34Â ng/ml (131.25-646.5), respectively CONCLUSION: This case firstly reported the rare

complication of TTP after pegylated interferon treatment for hepatitis B and COVID-19 vaccine injection. This unique sign warrants more attention as an early cue of diagnosis of TTP and be aware of the rarity adverse effect of interferon therapy and COVID-19 vaccination.

Multisystem inflammatory syndrome in children after BNT162b2 messenger RNA SARS-CoV-2 vaccination.

Hilar lymphadenopathy, development of tubulointerstitial nephritis, and dense deposit disease following Pfizer-BioNTech COVID-19 vaccination. Despite the reports on glomerulonephritis associated with COVID-19 mRNA vaccines, no study has reported about the dense deposit disease (DDD). Here, we present a case of hilar lymphadenopathy after the COVID-19 mRNA vaccination, following which the patient developed tubulointerstitial nephritis (TIN) and DDD. A 74-year-old man received his second dose of mRNA vaccine, and on the next day, he developed fever, urticaria, and dyspnea. On further examination, he had pleural effusion and right hilar lymphadenopathies, which were improved with conservative therapy. After 48Â days of the second vaccination, he developed renal dysfunction and new-onset hematuria. Light microscopy findings by renal biopsy revealed apparent mesangial cell proliferation, increased mesangial matrix in the glomeruli, and diffuse inflammatory cell infiltration in the interstitium. Immunofluorescence analysis revealed 1â€‰+â€‰positive results for IgG and IgM, negative results for IgA, and 2â€‰+â€‰positive results for C3 with a garland pattern on the capillary walls. Electron microscopy revealed that severe cell proliferation in the capillary rumen, and continuous, thickened, and highly dark-stained spotty dense deposits in the glomerular basement membrane; and noncontinuous spotty dense deposits in the tubular basement membrane. Based on the decrease in C3 and pathological findings, TIN accompanied with DDD was diagnosed. The mRNA vaccine might have contributed to the development of lymphadenopathies, TIN, and DDD in this case. Moreover, TIN and DDD might be associated with the activated alternative pathway induced by the mRNA vaccine.

Even after COVID, the world's vaccine strategy is failing.

Vaccines and nephrotic syndrome: efficacy and safety. Vaccines represent the most important medical evolution in the last two centuries allowing prevention and formally eradication of a wide number of infectious diseases. Safety and effectiveness are main issues that still require an open discussion. A few clinical reports described a critical temporal relationship between vaccination and acute nephrotic syndrome, indirectly suggesting an association. For this review, the literature was reviewed to identify articles reporting associations of nephrotic syndrome with vaccines against a vast array of infectious diseases (including bacteria, virus and Sars-Cov-2). As specific aims, we evaluated effectiveness and safety in terms of occurrence of either "de novo" nephrotic syndrome in health subjects or "relapse" in those already affected by the disease. In total, 377 articles were found; 166 duplicates and 71 non-full text, animal studies or non-English language were removed. After excluding another 50 articles not containing relevant data on generic side effects or on relapses or new onset nephrotic syndrome, 90 articles met the search criteria. Overall, studies reported the effect of vaccines in 1015 patients, plus 4 nationwide epidemiologic investigations. Limited experience on vaccination of NS patients with measles, mumps, and rubella live attenuated vaccines does not allow any definitive conclusion on their safeness. VZV has been administered more frequently without side effects. Vaccines utilizing virus inactivated, recombinant, and toxoid can be utilized without risks in NS. Vaccines for influenza reduce the risk of infections during the pandemic and are associated with reduced risk of relapse of NS typically induced by the infection. Vaccines for SARS-CoV-2 (all kinds) offer a concrete approach to reduce the pandemic. "De novo" NS or recurrence are very rare and respond to common therapies.

Impaired SARS-CoV-2 Variant Neutralization and CD8+ T-cell Responses Following 3 Doses of mRNA Vaccines in Myeloma: Correlation with Breakthrough Infections. Patients with multiple myeloma

(MM) mount suboptimal neutralizing antibodies (nAb) following 2 doses of SARS-CoV-2 mRNA vaccines. Currently, circulating SARS-CoV-2 variants of concern (VOC) carry the risk of breakthrough infections. We evaluated immune recognition of current VOC including BA.1, BA.2, and BA.5 in 331 racially representative patients with MM following 2 or 3 doses of mRNA vaccines. The third dose increased nAbs against WA1 in 82%, but against BA variants in only 33% to 44% of patients. Vaccine-induced nAbs correlated with receptor-binding domain (RBD)-specific class-switched memory B cells. Vaccine-induced spike-specific T cells were detected in patients without seroconversion and cross-recognized variant-specific peptides but were predominantly CD4+ T cells. Detailed clinical/immunophenotypic analysis identified features correlating with nAb/B/T-cell responses. Patients who developed breakthrough infections following 3 vaccine doses had lower live-virus nAbs, including against VOC. Patients with MM remain susceptible to SARS-CoV-2 variants following 3 vaccine doses and should be prioritized for emerging approaches to elicit variant-nAb and CD8+ T cells. SIGNIFICANCE: Three doses of SARS-CoV-2 mRNA vaccines fail to yield detectable VOC nAbs in nearly 60% and spike-specific CD8+ T cells in >80% of myeloma patients. Patients who develop breakthrough infections following vaccination have low levels of live-virus nAb. This article is highlighted in the In This Issue feature, p. 101.

Dermato-neuro Syndrome after COVID-19 Vaccination in a Patient with Scleromyxoedema Previously Controlled with Bortezomib and Intravenous Immunoglobulins.

Exacerbation of Chronic Cutaneous Lupus Erythematosus Triggered by Vaccine Against COVID-19.

Pfizer-BioNTech (BNT162b2), Moderna (mRNA-1273) COVID-19 mRNA vaccines and hypersensitivity reactions. The SARS-CoV-2 Virus (COVID-19) is responsible for over 239 million cases and 4.8 million deaths globally (Data source WHO COVID-19 Dashboard accessed on October 14, 2021). It continues to surge and ravage countries, leaving healthcare systems in constant struggle and uncertainty. A variety of vaccines were developed to combat the spread of the COVID-19 Virus. Reports of possible allergic reactions with COVID-19 vaccines are a significant cause of public concern, especially among those with a known history of a severe allergic reaction (e.g., anaphylaxis). Here we review articles relevant to COVID-19 vaccines and their excipients (especially PEG (Polyethylene glycol) and hypersensitivity reactions associated with COVID-19 vaccines (including clinical features, pathophysiology, special populations receiving COVID-19 vaccinations, potential diagnostic tests, and preventive measures that can be taken to minimize the risks of hypersensitivity reactions with COVID-19 vaccines).

The effect of COVID-19 vaccines on sperm parameters: a systematic review and meta-analysis. Published data were gathered for a meta-analysis to determine the difference in sperm parameters before and after administration of different types of coronavirus disease 2019 (COVID-19) vaccines, because the reproductive toxicity of COVID-19 vaccines has not yet been evaluated in clinical trials and COVID-19 has been associated with decreases in sperm quality. The preferred procedures for systematic reviews and meta-analyses were followed in the conduct and reporting of this study. The average sperm parameters of all sperm donors' multiple sperm donations were compared before and after receiving various COVID-19 vaccinations. Semen volume, total sperm motility, total sperm count, morphological change, and sperm concentration were the primary outcome measures. We compiled and analyzed the results of six studies on total sperm motility, six studies on semen volume, six studies on sperm concentration, two studies on morphological change, and two studies on total sperm count. Parameter comparisons with patients who had and had not been vaccinated were only reported in one of the included studies. When different types of COVID-19 vaccine injections were compared, no discernible differences in parameters were observed. According to the available data, the parameters of semen are unaffected by inactivated or messenger RNA (mRNA) COVID-19 vaccinations. To support these findings, additional prospectively designed research is required.

COVID-19 vaccine insights: The news beyond the headlines. Here is key intelligence on the recommended primary series, boosters, breakthrough infection, adverse events, special population vaccination, vaccine myths, and what the future might hold.

Factors associated with reluctancy to acquire COVID-19 vaccination: A cross-sectional study in Shiraz, Iran, 2022. BACKGROUND: Vaccination is a crucial action that can end the COVID-19 pandemic and reduce its detrimental effect on public health. Despite the availability of various vaccines, this study was conducted to better understand the factors behind individuals refusing to get vaccinated. METHOD: The current cross-sectional study was conducted with individuals above 18 years of age in Shiraz, Iran, who were eligible but refused to receive the COVID-19 vaccination. Demographic features and factors related to their hesitancy and willingness to participate in the vaccination program were recorded in a questionnaire. RESULT: Out of 801 participants in the current study, 427 (53.3%) were men, with a mean age of 37.92 years (Â± 14.16). The findings revealed that 350 (43.7%) participants claimed the side effects of the vaccine outweigh the benefits as one reason for their reluctance toward COVID-19 vaccination, followed by the unknown efficacy of vaccines (40.4%) and a lack of trust in vaccine companies (32.8%). Ensuring the safety of the vaccine (43.7%) and verifying its effectiveness (34.5%) were the most prevalent factors behind participating in the vaccination program. Those who reported their socio-economic status as low were significantly reluctant toward vaccination because of a self-presumption of high immunity (p-value < 0.001), the unclear efficacy of vaccines (p-value < 0.001), the side effects outweighing the benefits of vaccines (p-value < 0.001), distrust of vaccine companies (p-value < 0.001), usage of mask, gloves, and sanitizers (p-value < 0.001), contradictory speech of health authorities regarding vaccines (p-value = 0.041), and the unavailability of trusted vaccines (p-value = 0.002). It should also be noted that participants reported a greater likelihood to obtain information about vaccination reluctance from family and friends (p-value <0.001) and complementary medicine professionals (p-value <0.001). CONCLUSION: Avoiding vaccination is an undeniable public and individual health concern in Iran, as demonstrated in the current study. Concern about vaccine efficacy and side effects is the most reported cause of vaccination reluctance among individuals, which could be altered by emphasizing mass education and averting an infodemic by forming dedicated multidisciplinary organizations.

Adverse Events Related to SARS-CoV-2 Vaccine in a Nationwide Cohort of Patients With Inflammatory Bowel Disease. INTRODUCTION: There are limited data on the safety profile of the severe acute respiratory syndrome coronavirus-2 vaccine among patients taking immunosuppressive medications. Our aim was to evaluate the adverse events related to the vaccines in a nationwide cohort of patients with inflammatory bowel disease on diverse immunosuppressive medications. METHODS: This was a retrospective cohort study using data from the Veterans Health Administration. The primary outcome was any adverse event of special interest (cerebrovascular accident, venous thromboembolism, acute myocardial infarction, Bell palsy) within 90 days of vaccination. RESULTS: A total of 17,201 patients were included, and 12,351 patients (71.8%) received at least 1 vaccine dose. The most common adverse events were acute myocardial infarction and venous thromboembolism. In inverse probability treatment weighting-adjusted logistic regression, full vaccination was not significantly associated with increased adverse events through 90 days, relative to unvaccinated patients. DISCUSSION: Full severe acute respiratory syndrome coronavirus-2 vaccination was not associated with an increased rate of key adverse events relative to unvaccinated individuals among patients with inflammatory bowel disease.

Serial cross-sectional estimation of vaccine-and infection-induced SARS-CoV-2 seroprevalence in British Columbia, Canada. BACKGROUND: The evolving proportion of the population considered immunologically naive versus primed for more efficient immune memory response to SARS-CoV-2 has implications for risk assessment. We sought to chronicle vaccine- and infection-induced

seroprevalence across the first 7 waves of the COVID-19 pandemic in British Columbia, Canada. METHODS: During 8 cross-sectional serosurveys conducted between March 2020 and August 2022, we obtained anonymized residual sera from children and adults who attended an outpatient laboratory network in the Lower Mainland (Greater Vancouver and Fraser Valley). We used at least 3 immunoassays per serosurvey to detect SARS-CoV-2 spike and nucleocapsid antibodies. We assessed any seroprevalence (vaccineor infection-induced, or both), defined by positivity on any 2 assays, and infection-induced seroprevalence, also defined by dual-assay positivity but requiring both antinucleocapsid and antispike detection. We used estimates of infection-induced seroprevalence to explore underascertainment of infections by surveillance case reports. RESULTS: By January 2021, we estimated that any seroprevalence remained less than 5%, increasing with vaccine rollout to 56% by May-June 2021, 83% by September-October 2021 and 95% by March 2022. Infection-induced seroprevalence remained less than 15% through September-October 2021, increasing across Omicron waves to 42% by March 2022 and 61% by July-August 2022. By August 2022, 70%-80% of children younger than 20 years and 60%-70% of adults aged 20-59 years had been infected, but fewer than half of adults aged 60 years and older had been infected. Compared with estimates of infection-induced seroprevalence, surveillance case reports underestimated infections 12-fold between September 2021 and March 2022 and 92-fold between March 2022 and August 2022. INTERPRETATION: By August 2022, most children and adults younger than 60 years had evidence of both SARS-CoV-2 vaccination and infection. As previous evidence suggests that a history of both exposures may induce stronger, more durable hybrid immunity than either exposure alone, older adults - who have the lowest infection rates but highest risk of severe outcomes - continue to warrant prioritized vaccination.

Immune response and homeostasis mechanism following administration of BBIBP-CorV SARS-CoV-2 inactivated vaccine. The BBIBP-CorV severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) inactivated vaccine has been authorized for emergency use and widely distributed. We used single-cell transcriptome sequencing to characterize the dynamics of immune responses to the BBIBP-CorV inactivated vaccine. In addition to the expected induction of humoral immunity, we found that the inactivated vaccine induced multiple, comprehensive immune responses, including significantly increased proportions of CD16(+) monocytes and activation of monocyte antigen presentation pathways; TÂ cell activation pathway upregulation in CD8(+) TÂ cells, along with increased activation of CD4(+) TÂ cells; significant enhancement of cell-cell communications between innate and adaptive immunity; and the induction of regulatory CD4(+) TÂ cells and co-inhibitory interactions to maintain immune homeostasis after vaccination. Additionally, comparative analysis revealed higher neutralizing antibody levels, distinct expansion of naive TÂ cells, a shared increased proportion of regulatory CD4(+) TÂ cells, and upregulated expression of functional genes in booster dose recipients with a longer interval after the second vaccination. Our research will support a comprehensive understanding of the systemic immune responses elicited by the BBIBP-CorV inactivated vaccine, which will facilitate the formulation of better vaccination strategies and the design of new vaccines.

Humoral and T-cell mediated response after administration of mRNA vaccine BNT162b2 in frail populations. Patients with frailty are considered to be at greater risk to get severe infection from SARS-CoV-2. One of the most effective strategies is vaccination. In our study we evaluated both the humoral immune response elicited by the vaccination at different time points, and the T-cell response in terms of interferon (IFN)-Î³ production in frail patients and healthy donors. Fifty-seven patients (31 patients undergoing hemodialysis and 26 HIV positive subjects) and 39 healthcare workers were enrolled. All participants received two doses of the mRNA vaccine BNT162b2. Healthcare workers showed a significantly higher antibody titer than patients twenty-one days after the first dose (pÂ <Â 0.001). From the same time point we observed for both groups a decay of the antibody levels

with a steeper slope of decline in the patients group. Regarding T-cell response the only significant difference between non-reactive and reactive subjects was found in median antibody levels, higher in the responders group than in non-responders. The healthcare workers seem to better respond to the vaccination in terms of antibodies production; the lack of T-cell response in about 50% of the participants seems to suggest that in our study population both humoral and cell-mediated response decline over time remarking the importance of the booster doses, particularly for frail patients.

Dynamics of anti-spike IgG antibody after a third BNT162b2 COVID-19 vaccination in Japanese health care workers. OBJECTIVES: Many countries are administering a third dose of some coronavirus disease 2019 (COVID-19) vaccines, but the evaluation of vaccine-induced immunity after boosting in East Asia is insufficient. This study aimed to evaluate anti-spike immunoglobulin G [IgG(S)] titers after the third BNT162b2 vaccination. METHODS: The dynamics of IgG(S) titers were assessed two months following the third BNT162b2 vaccination in 52 participants. All participants received the primary series of vaccination with BNT162b2 and received the third dose eight months after the second vaccination. Associations among the IgG(S) titer, baseline characteristics, and adverse reactions were also evaluated. RESULTS: The geometric mean titer of IgG(S) one month after the third vaccination was 17,400 AU/ml, which increased by approximately 30 times that immediately before the third vaccination. The rate of IgG(S) titer decline was significantly slower after the third vaccination (35.7%) than after the second vaccination (59.1%). The IgG(S) titer was significantly negatively associated with age (r = -0.31). Participants who had a headache at the time of vaccination showed significantly higher IgG(S) titers than those without a headache. CONCLUSIONS: The IgG(S) titer induced by primary immunization with BNT162b2 waned over time. The third dose of BNT162b2 substantially increased the IgG(S) titer, with a slower rate of decline.

Ocular adverse effects of COVID-19 vaccines: A systematic review. The COVID-19 pandemic has led to the development and rollout of several vaccines worldwide at unprecedented pace. This systematic review of published literature has been undertaken to spread awareness among general physicians and ophthalmologists about the various reported adverse effects in the eye following COVID-19 vaccination. A systematic search was performed on 25 January 2022 through PuBMed, Medline and Google scholar for publications on ocular adverse effects after COVID-19 vaccination. One brief communication, four retrospective case series, sixteen case reports, and five letters to editors were included. Ocular manifestations most commonly appear in the uvea and retina. Other manifestations are seen on the eyelid, cornea and ocular surface, and in cranial nerves innervating the eye. The incidence rate of these manifestations is quite low after COVID-19 vaccinations. Our systematic review meticulously enumerates various adverse effects of COVID -19 vaccine on the eye. Most of these adverse effects are transient and observed to resolve without any sequelae except for cases of retinal and ophthalmic vascular occlusions and corneal graft rejections. An emphasis on close follow-up and a need to delay vaccination and modified therapy to control flare up of signs and symptoms in certain sub-populations, Graves' disease (autoimmune etiology), pre-existing uveal inflammation and corneal graft cases are warranted. We need long-term, larger, multicentric studies to substantiate our findings and establish the causal relationship with certainty. Mass vaccinations to curb this pandemic after outweighing the ocular risks associated with it is warranted.

Autoimmune hepatitis after COVID-19 vaccination. Vaccination is one of the most vigorous ways to intervene in the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. Cases of autoimmune hepatitis (AIH) after coronavirus disease (COVID-19) vaccination have been increasingly reported. Twenty-seven cases of AIH are summarized in this study, providing emerging evidence of autoimmune reactions in response to various COVID-19 vaccines, including in patients with special disease backgrounds such as primary sclerosing cholangitis (PSC), liver transplantation, and previous hepatitis C virus (HCV) treatment. Molecular mimicry, adjuvants, epitope spreading, bystander

activation, X chromosome, and sceptical hepatotropism of SARS-CoV-2 may account for, to some extent, such autoimmune phenomena. Immunosuppressive corticosteroids perform well with or without azathioprine in such post-COVID-19-vaccination AIH. However, determination of the exact mechanism and establishment of causality require further confirmation.

"Spontaneous" Coronary Artery Dissection After SARS-CoV-2 Messenger RNA Vaccination.

Multiple Keratoacanthomas Following Moderna Messenger RNA-1273 COVID-19 Vaccination Resolved With 5-Fluorouracil Treatment: Case Report. Cutaneous reactions have been commonly associated with the Moderna messenger RNA (mRNA) COVID-19 vaccine. Among the reported cutaneous side effects, there have not been any associations reported yet regarding keratoacanthoma development after COVID-19 mRNA vaccination. We report a novel case of an 86-year-old man who experienced an eruption of multiple keratoacanthomas 2 weeks after inoculation with the Moderna mRNA-1273 vaccine that resolved following treatment with intralesional 5-fluorouracil.

Pityriasis rubra pilaris following inactivated SARS-CoV-2 vaccine (CoronaVac).

Systemic drug-related intertriginous and flexural exanthema-like eruption after Oxford-AstraZeneca COVID-19 vaccine. Systemic drug-related intertriginous and flexural exanthema (SDRIFE) is an adverse drug reaction which manifests as a symmetrical erythematous rash involving the skin folds after systemic drug exposure. A vast array of possible side effects associated with administration of different anti-SARS-CoV-2 vaccines have been reported in literature since the beginning of the COVID-19 pandemic, but only few times SDRIFE-like eruptions have been described in this context. We discuss here a case of SDRIFE-like eruption following the second dose of Oxford-Astrazeneca Vaxzevria vaccine.

Antibody persistence and safety after heterologous boosting with orally aerosolised Ad5-nCoV in individuals primed with two-dose CoronaVac previously: 12-month analyses of a randomized controlled trial. Antibody persistence and safety up to 12 months of heterologous orally administered adenovirus type-5 vector-based COVID-19 vaccine (Ad5-nCoV) in individuals who were primed with two-dose inactivated SARS-CoV-2 vaccine (CoronaVac) previously, has not been reported yet. This randomized, open-label, single-centre trial included Chinese adults who have received two-dose CoronaVac randomized to low-dose or high-dose aerosolised Ad5-nCoV group, or CoronaVac group. In this report, we mainly evaluated the geometric mean titres (GMTs) of neutralizing antibodies (NAbs) against live wild-type SARS-CoV-2 virus and omicron BA.4/5 pseudovirus at 12 months after the booster dose and the incidence of serious adverse events (SAEs) till month 12. Of 419 participants, all were included in the safety analysis and 120 (28.64%) were included in the immunogenicity analysis. Serum NAb GMT against live wild-type SARS-CoV-2 was 204.36 (95% CI 152.91, 273.14) in the low-dose group and 171.38 (95% CI 121.27, 242.19) in the high-dose group at month 12, significantly higher than the GMT in the CoronaVac group (8.00 [95% CI 4.22, 15.17], pâ€‰<â€‰0.0001). Serum NAb GMT against omicron BA.4/5 pseudovirus was 40.97 (95% CI 30.15, 55.67) in the low-dose group and 35.08 (95% CI 26.31, 46.77) in the high-dose group at month 12, whereas the GMT in the CoronaVac group was below the lower limit of detection. No vaccine-related SAEs were observed. Orally administered aerosolised Ad5-nCoV following two-dose CoronaVac priming has a good safety profile and is persistently more immunogenic than three-dose CoronaVac within 12 months after the booster dose.Trial registration: ClinicalTrials.gov identifier: NCT05043259..

Risk factors for COVID-19 hospitalization after COVID-19 vaccination: a population-based cohort study in Canada. OBJECTIVES: With the uptake of COVID-19 vaccines, there is a need for population-based studies to assess risk factors for COVID-19-related hospitalization after vaccination and how they differ from unvaccinated individuals. METHODS: We used data from the British Columbia COVID-19 Cohort, a population-based cohort that includes all individuals (aged â‰¥18 years) who tested

positive for SARS-CoV-2 by real-time reverse transcription-polymerase chain reaction from January 1, 2021 (after the start of vaccination program) to December 31, 2021. We used multivariable logistic regression models to assess COVID-19-related hospitalization risk by vaccination status and age group among confirmed COVID-19 cases. RESULTS: Of the 162,509 COVID-19 cases included in the analysis, 8,546 (5.3%) required hospitalization. Among vaccinated individuals, an increased odds of hospitalization with increasing age was observed for older age groups, namely those aged 50-59 years (odds ratio [OR]Â =Â 2.95, 95% confidence interval [CI]: 2.01-4.33), 60-69 years (ORÂ =Â 4.82, 95% CI: 3.29, 7.07), 70-79 years (ORÂ =Â 11.92, 95% CI: 8.02, 17.71), and â‰¥80 years (ORÂ =Â 24.25, 95% CI: 16.02, 36.71). However, among unvaccinated individuals, there was a graded increase in odds of hospitalization with increasing age, starting at age group 30-39 years (ORÂ =Â 2.14, 95% CI: 1.90, 2.41) to â‰¥80 years (ORÂ =Â 41.95, 95% CI: 35.43, 49.67). Also, comparing all the age groups to the youngest, the observed magnitude of association was much higher among unvaccinated individuals than vaccinated ones. CONCLUSION: Alongside a number of comorbidities, our findings showed a strong association between age and COVID-19-related hospitalization, regardless of vaccination status. However, age-related hospitalization risk was reduced two-fold by vaccination, highlighting the need for vaccination in reducing the risk of severe disease and subsequent COVID-19-related hospitalization across all population groups.

Vertigo/dizziness following COVID-19 vaccination. PURPOSE: This study assessed the vertigo/dizziness in patients following COVID-19 vaccination. PATIENTS AND METHODS: From July 2021 to June 2022, totaling 50 patients with dizzy spells following COVID-19 vaccination by AZ (AstraZeneca-Oxford University, AZD1222), BNT (Pfizer-BioNTech, BNT162b2) or Moderna (Moderna, mRNA-1273) vaccine were enrolled in this study. The interval from vaccination to the onset of vertigo/dizziness was compared with inter-episodic interval of vertigo/dizziness in the same patients, but without vaccination, during past one year (2020). RESULTS: The incidences of severe systemic complication per 10(6) shots were 0.86 for Moderna vaccine, 1.22 for AZ vaccine, and 1.23 for BNT vaccine. Conversely, rate of post-vaccination vertigo/dizziness was noted in the Moderna group (66Â %), followed by the AZ group (20Â %) and the BNT (14Â %) group, meaning that type of COVID-19 vaccine may affect various organ systems. The median time to the onset of vertigo/dizziness following vaccination is 10d, which is consistent with the onset of IgG production, and significantly less than inter-episodic interval (84d) in the same patients without vaccination. CONCLUSION: Post-vaccination vertigo/dizziness can manifest as exacerbation of previous neurotological disorder. The median time to the onset of vertigo/dizziness following COVID-19 vaccination is 10d. Since the outcome is fair after supportive treatment, the immunomodulatory effect of the vaccines does not undermine the necessity of the COVID-19 vaccination.

Clinical and Economic Impact of COVID-19 on Agricultural Workers, Guatemala(1). We evaluated clinical and socioeconomic burdens of respiratory disease in banana farm workers in Guatemala. We offered all eligible workers enrollment during June 15-December 30, 2020, and annually, then tracked them for influenza-like illnesses (ILI) through self-reporting to study nurses, sentinel surveillance at health posts, and absenteeism. Workers who had ILI submitted nasopharyngeal swab specimens for testing for influenza virus, respiratory syncytial virus, and SARS-CoV-2, then completed surveys at days 0, 7, and 28. Through October 10, 2021, a total of 1,833 workers reported 169 ILIs (12.0 cases/100 person-years), and 43 (25.4%) were laboratory-confirmed infections with SARS-CoV-2 (3.1 cases/100 person-years). Workers who had SARS-CoV-2â€'positive ILIs reported more frequent anosmia, dysgeusia, difficulty concentrating, and irritability and worse clinical and well-being severity scores than workers who had test resultâ€'negative ILIs. Workers who had positive results also had greater absenteeism and lost income. These results support prioritization of farm workers in Guatemala for COVID-19 vaccination.

Plant Spices as a Source of Antimicrobial Synergic Molecules to Treat Bacterial and Viral Co-Infections. The COVID-19 pandemic exposed the lack of antiviral agents available for human use, while the complexity of the physiological changes caused by coronavirus (SARS-CoV-2) imposed the prescription of multidrug pharmacotherapy to treat infected patients. In a significant number of cases, it was necessary to add antibiotics to the prescription to decrease the risk of co-infections, preventing the worsening of the patient's condition. However, the precautionary use of antibiotics corroborated to increase bacterial resistance. Since the development of vaccines for COVID-19, the pandemic scenario has changed, but the development of new antiviral drugs is still a major challenge. Research for new drugs with synergistic activity against virus and resistant bacteria can produce drug leads to be used in the treatment of mild cases of COVID-19 and to fight other viruses and new viral diseases. Following the repurposing approach, plant spices have been searched for antiviral lead compounds, since the toxic effects of plants that are traditionally consumed are already known, speeding up the drug discovery process. The need for effective drugs in the context of viral diseases is discussed in this review, with special focus on plant-based spices with antiviral and antibiotic activity. The activity of plants against resistant bacteria, the diversity of the components present in plant extracts and the synergistic interaction of these metabolites and industrialized antibiotics are discussed, with the aim of contributing to the development of antiviral and antibiotic drugs. A literature search was performed in electronic databases such as Science Direct; SciELO (Scientific Electronic Library Online); LILACS (Latin American and Caribbean Literature on Health Sciences); Elsevier, SpringerLink; and Google Scholar, using the descriptors: antiviral plants, antibacterial plants, coronavirus treatment, morbidities and COVID-19, bacterial resistance, resistant antibiotics, hospital-acquired infections, spices of plant origin, coronaviruses and foods, spices with antiviral effect, drug prescriptions and COVID-19, and plant synergism. Articles published in English in the period from 2020 to 2022 and relevant to the topic were used as the main inclusion criteria.

COVID-19 Vaccines, Effectiveness, and Immune Responses. The COVID-19 pandemic, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has captivated the globe's attention since its emergence in 2019. This highly infectious, spreadable, and dangerous pathogen has caused health, social, and economic crises. Therefore, a worldwide collaborative effort was made to find an efficient strategy to overcome and develop vaccines. The new vaccines provide an effective immune response that safeguards the community from the virus' severity. WHO has approved nine vaccines for emergency use based on safety and efficacy data collected from various conducted clinical trials. Herein, we review the safety and effectiveness of the WHO-approved COVID-19 vaccines and associated immune responses, and their impact on improving the public's health. Several immunological studies have demonstrated that vaccination dramatically enhances the immune response and reduces the likelihood of future infections in previously infected individuals. However, the type of vaccination and individual health status can significantly affect immune responses. Exposure of healthy individuals to adenovirus vectors or mRNA vaccines causes the early production of antibodies from B and T cells. On the other hand, unhealthy individuals were more likely to experience harmful events due to relapses in their existing conditions. Taken together, aligning with the proper vaccination to a patient's case can result in better outcomes.

The Interplay of Lung Cancer, COVID-19, and Vaccines. Patients with cancer are more susceptible to a higher risk of coronavirus infection and its severe complications than the general population. In addition, these patients were not included in the pivotal clinical trials for COVID-19 vaccines. Therefore, considerable uncertainty remains regarding the management of cancer patients during the COVID-19 pandemic and the safety of COVID-19 vaccinations in cancer patients. In this review, we summarize the current knowledge generated from the beginning of the COVID-19 pandemic on the vulnerability of cancer patients to the coronavirus disease, as well as the effectiveness of COVID-19

vaccines in this population. We also discuss the available data on the effects of anticancer treatment with immune checkpoint inhibitors on the immune responses to SARS-CoV-2 in cancer patients. Special attention in this review will be given to patients with lung cancer, as such patients are at an increased risk for severe effects from COVID-19.

Immune Responses to COVID-19 Vaccines in Patients with Chronic Kidney Disease and Lead Exposure. Literature data regarding the response rate to COVID-19 vaccination in chronic kidney disease (CKD) patients remain inconclusive. Furthermore, studies have reported a relationship between lead exposure and susceptibility to viral infections. This study examined immune responses to COVID-19 vaccines in patients with CKD and lead exposure. Between October and December 2021, 50 lead-exposed CKD patients received two doses of vaccination against COVID-19 at Chang Gung Memorial Hospital. Patients were stratified into two groups based on the median blood lead level (BLL): upper (â‰¥1.30 Î¼g/dL, n = 24) and lower (<1.30 Î¼g/dL, n = 26) 50th percentile. The patients were aged 65.9 Â± 11.8 years. CKD stages 1, 2, 3, 4 and 5 accounted for 26.0%, 20.0%, 22.0%, 8.0% and 24.0% of the patients, respectively. Patients in the lower 50th percentile of BLL had a lower proportion of CKD stage 5 than patients in the upper 50th percentile BLL group (p = 0.047). The patients in the lower 50th percentile BLL group also received a higher proportion of messenger RNA vaccines and a lower proportion of adenovirus-vectored vaccines than the patients in the upper 50th percentile BLL group (p = 0.031). Notably, the neutralizing antibody titers were higher in the lower 50th percentile than in the upper 50th percentile BLL group. Furthermore, the circulating levels of granulocyte-colony stimulating factor, interleukin-8, monocyte chemoattractant protein-1 and macrophage inflammatory protein-1Î± were higher in the upper 50th percentile than in the lower 50th percentile BLL group. Therefore, it was concluded that lead-exposed CKD patients are characterized by an impaired immune response to COVID-19 vaccination with diminished neutralizing antibodies and augmented inflammatory reactions.

Basophil Activation Test with Different Polyethylene Glycols in Patients with Suspected PEG Hypersensitivity Reactions. Allergic reactions to COVID-19 vaccine components are rare but should be considered. Polyethylene glycol (PEG) is responsible for anaphylaxis in mRNA vaccines. Skin tests have been used in the allergological work-up programs for COVID-19 vaccine evaluation. However, the reproducibility of the skin prick test is time-dependent and the reactivity declines over time. Therefore, we combined the administration of the skin tests with the basophil activation test (BAT) using PEG2000, PEG4000 and DMG-PEG2000, where the BAT was considered positive when the percentage of activated basophils was higher than 6%, 5% and 6.5%, for PEG 4000, PEG2000 and DMG-PEG2000, respectively. To this end, among the subjects that underwent allergy counseling at the Allergy Unit of our Institution during the 2020/2021 vaccination campaign, 13 patients had a suggested medical history of PEG/drug hypersensitivity and were enrolled together with 10 healthy donors. Among the enrolled patients 2 out of 13 tested patients were positive to the skin test. The BAT was negative in terms of the percentages of activated basophils in all analyzed samples, but the stimulation index (SI) was higher than 2.5 in 4 out of 13 patients. These data evidenced that, when the SI is higher than 2.5, even in the absence of positivity to BAT, the BAT to PEG may be a useful tool to be coupled to skin tests to evidence even low-grade reactions.

COVID-19 Vaccination Is Associated with a Better Outcome in Acute Ischemic Stroke Patients: A Retrospective Observational Study. Background: It is unclear whether and how COVID-19 vaccination may affect the outcome of patients with acute ischemic stroke (AIS). We investigated this potential association in a retrospective study by comparing previously vaccinated (VAX) versus unvaccinated (NoVAX) stroke patients. Methods: We collected clinical reports for all consecutive AIS patients admitted to our hospital and evaluated the outcome predictors in VAX and NoVAX groups. Adjustments were made for possible confounders in multivariable logistic regression analysis, and

adjusted hazard ratios were calculated. Results: A total of 466 AIS patients (287 VAX and 179 NoVAX) were included in this study. The NIHSS score at discharge and mRS score at a 3-month follow-up visit were significantly lower in VAX patients compared to NoVAX patients ($p < 0.001$). Good outcomes (mRS 0â^'2) were significantly associated with COVID-19 vaccination before AIS (adjusted hazard ratio, 0.400 [95% CI = 0.216â^'0.741]). Conclusions: The observation that COVID-19 vaccination can influence the outcome of AIS provides support for further studies investigating the role of immunity in ischemic brain damage.

High Anti-CoV2S Antibody Levels at Hospitalization Are Associated with Improved Survival in Patients with COVID-19 Vaccine Breakthrough Infection. BACKGROUND: Although vaccination against COVID-19 is highly effective, breakthrough infections occur, often leading to severe courses and death. The extent of protection provided by individual antibody levels in breakthrough infections is still unknown and cut-off levels have yet to be determined. METHODS: In 80 consecutive fully vaccinated patients hospitalized between August and December 2021 with COVID-19 breakthrough infection (Delta variant), anti-CoV2S antibody levels were analyzed for the endpoint of death. RESULTS: Ten out of the 12 patients who died (83.3%) had antibody levels < 600 U/mL; 5 (41.7%) of these had antibody levels < 200 U/mL. Only 2 patients with a level of >600 U/mL died from vaccine breakthrough infection. Correction for the number of comorbidities and age revealed that anti-CoV2S antibody levels at the time of hospitalization were a significant predictor for reduced risk of death (OR = 0.402 for every 1000 U/mL, $p = 0.018$). CONCLUSIONS: In this retrospective data analysis, we show that almost all patients who died from COVID-19 vaccine breakthrough infection had antibody levels < 600 U/mL, most of them below 200 U/mL. In logistic regression corrected for the number of comorbidities and age, anti-CoV2S antibody levels at the time of hospitalization proved to be a significantly protective predictor against death.

Acute macular neuroretinopathy and COVID-19 vaccination: Case report and literature review. OBJECTIVE: To review cases of acute macular neuroretinopathy (AMN) after COVID-19 vaccination and add a similar case to the literature. METHODS: A thorough PubMed search was conducted, and data from studies describing AMN after COVID-19 vaccination were extracted, tabulated, pooled, and reviewed. RESULTS: We present a case of AMN in a young woman 5 days after immunization with the BBIBP-CorV (Sinopharm) COVID-19 vaccine. Data from 21 cases were pooled and reviewed. The most frequent vaccines among the cases were recombinant ones (13/21), followed by mRNA-based (6/21) and inactivated vaccines (2/21). Only one patient (5%) was male. Seventeen over twenty-one (81%) were young women, ages 18-33. Most cases (14/21; 67%) reported recent/concurrent use of contraceptive medication. In 90% of cases (19/21), symptoms appeared within 8 days of vaccination. A confined wedge-/oval-shaped lesion morphology was more frequent than a diffuse, semilunar one. Resolution of symptoms took 4 to over 15 weeks. CONCLUSION: Attention should be paid to the history of vaccination and contraceptive use in patients with sudden-onset visual symptoms. Optical coherence tomography is integral to the detection of AMN-related abnormalities.

Surveillance of COVID-19 vaccine safety among elderly persons aged 65Â years and older. BACKGROUND: Monitoring safety outcomes following COVID-19 vaccination is critical for understanding vaccine safety especially when used in key populations such as elderly persons age 65Â years and older who can benefit greatly from vaccination. We present new findings from a nationally representative early warning system that may expand the safety knowledge base to further public trust and inform decision making on vaccine safety by government agencies, healthcare providers, interested stakeholders, and the public. METHODS: We evaluated 14 outcomes of interest following COVID-19 vaccination using the US Centers for Medicare & Medicaid Services (CMS) data covering 30,712,101 elderly persons. The CMS data from December 11, 2020 through Jan 15, 2022 included 17,411,342 COVID-19 vaccinees who received a total of 34,639,937 doses. We conducted

weekly sequential testing and generated rate ratios (RR) of observed outcome rates compared to historical (or expected) rates prior to COVID-19 vaccination. FINDINGS: Four outcomes met the threshold for a statistical signal following BNT162b2 vaccination including pulmonary embolism (PE; RRÂ =Â 1.54), acute myocardial infarction (AMI; RRÂ =Â 1.42), disseminated intravascular coagulation (DIC; RRÂ =Â 1.91), and immune thrombocytopenia (ITP; RRÂ =Â 1.44). After further evaluation, only the RR for PE still met the statistical threshold for a signal; however, the RRs for AMI, DIC, and ITP no longer did. No statistical signals were identified following vaccination with either the mRNA-1273 or Ad26 COV2.S vaccines. INTERPRETATION: This early warning system is the first to identify temporal associations for PE, AMI, DIC, and ITP following BNT162b2 vaccination in the elderly. Because an early warning system does not prove that the vaccines cause these outcomes, more robust epidemiologic studies with adjustment for confounding, including age and nursing home residency, are underway to further evaluate these signals. FDA strongly believes the potential benefits of COVID-19 vaccination outweigh the potential risks of COVID-19 infection.

Serology results after COVID vaccine in multiple sclerosis patients treated with fingolimod. INTRODUCTION: While it is recommended that patients with multiple sclerosis (MS) be vaccinated against COVID-19, it is unknown what the vaccine response is in MS patients treated with fingolimod, an agent which modulates the humoral response. We aimed to characterize the immune response to the COVID-19 vaccine in MS patients treated with fingolimod and to explore which factors influenced response. METHOD: We collected the following data from 59 MS patients treated with fingolimod and vaccinated against COVID-19: age, sex, duration of treatment, number of vaccine doses, date of last vaccination, type of vaccine, lymphocyte count, history of COVID-19, and serology to measure the vaccine response. We used Student's t-test and Chi(2) test to see whether there was a relationship between these variables and seropositivity. A multivariate logistic regression model was used to identify factors influencing the serology result. A multivariate linear regression model was used to identify factors influencing the antibody titer. RESULTS: Twenty-eight participants (47%) developed a positive serology. Age (P<0.001) and the duration of treatment (P=0.002) were significantly related to seropositivity. Gender (P=0.73), number of vaccinations (P=0.78), lymphocyte count (P=0.46), and the time between the last vaccine dose and blood sampling (P=0.84) were not significant variables. Multivariate analysis using logistic regression (n=59) showed that age (P=0.003, RRÂ =Â 2.28, 95%CIÂ =Â 1.28, 4.07) and duration of treatment (P=0.04, RR=1.91, 95%CI=1.04, 3.50) were significantly and independently correlated with COVID serology. Multivariate linear regression analysis of the antibody titer (n=59) found the duration of treatment to be significant (PÂ =Â 0.015), but not age (PÂ =Â 0.53). After removing three outliers, age (PÂ =Â 0.005, RR=6.82, 95%CI=1.66, 27.98) and duration of treatment (PÂ =Â 0.008, RR=5.12, 95%CI=1.24, 21.03) were significantly correlated with the antibody titer. CONCLUSION: COVID-19 seropositivity was present in 47% of our sample of 59 MS patients on fingolimod. A strong relationship was found between antibody development, age, and duration of treatment, as well as between antibody titer and age and duration of treatment.

COVID-19 vaccination-related exacerbation of seizures in persons with epilepsy. Although vaccines are generally safe in persons with epilepsy (PWE), seizures can be associated with vaccination, including COVID-19. This study assessed the occurrence of COVID-19 vaccination-related seizure exacerbations in PWE. Adult PWE who had received a COVID-19 vaccine were consecutively recruited at a tertiary epilepsy clinic between June 2021 and April 2022. Patient demographics, including epilepsy history, vaccination details, and reported adverse effects were recorded. Seizure exacerbation, defined as occurring within one week of vaccination, was assessed. Five hundred and thirty PWE received the COVID-19 vaccine. 75Â % received the Comirnaty (Pfizer) vaccine as their initial dose. Most patients (72Â %) were takingÂ â‰¥Â 2 antiseizure medications (ASM) and had focal

epilepsy (73Â %). One-third were 12Â months seizure free at their first vaccination. 13 patients (2.5Â %) reported a seizure exacerbation following their first vaccination, three of whom required admission. None were seizure-free at baseline. Six of these patients (46Â %) had a further exacerbation of seizures with their second vaccine. An additional four patients reported increased seizures only with the second vaccine dose. Seizure exacerbations are infrequently associated with COVID-19 vaccination, mainly in patients with ongoing seizures. The likelihood of COVID-19 infection complications in PWE outweighs the risk of vaccination-related seizure exacerbations.

Psychological factors associated with reporting side effects following COVID-19 vaccination: A prospective cohort study (CoVAccS - Wave 3). OBJECTIVE: To investigate symptom reporting following the first and second COVID-19 vaccine doses, attribution of symptoms to the vaccine, and factors associated with symptom reporting. METHODS: Prospective cohort study (T1: 13-15 January 2021, T2: 4-15 October 2021). Participants were aged 18Â years or older, living in the UK. Personal, clinical, and psychological factors were investigated at T1. Symptoms were reported at T2. We used logistic regression analyses to investigate associations. RESULTS: After the first COVID-19 vaccine dose, 74.1% (95% CI 71.4% to 76.7%, nÂ =Â 762/1028) of participants reported at least one injection-site symptom, while 65.0% (95% CI 62.0% to 67.9%, nÂ =Â 669/1029) reported at least one other (non-injection-site) symptom. Symptom reporting was associated with being a woman and younger. After the second dose, 52.9% (95% CI 49.8% to 56.0%, nÂ =Â 532/1005) of participants reported at least one injection-site symptom and 43.7% (95% CI 40.7% to 46.8%, nÂ =Â 440/1006) reported at least one other (non-injection-site) symptom. Symptom reporting was associated with having reported symptoms after the first dose, having an illness that put one at higher risk of COVID-19 (non-injection-site symptoms only), and not believing that one had enough information about COVID-19 to make an informed decision about vaccination (injection-site symptoms only). CONCLUSIONS: Women and younger people were more likely to report symptoms from vaccination. People who had reported symptoms from previous doses were also more likely to report symptoms subsequently, although symptom reporting following the second vaccine was lower than following the first vaccine. Few psychological factors were associated with symptom reporting.

Caution regarding immune-mediated encephalitis post-COVID-19 vaccination.

Intracranial Hypertension and Papilledema: An Unusual Complication After the Adenoviral DNA Vector-Based Coronavirus Disease 2019 Vaccination in an Air Medical Transportation Pilot. A 32-year-old male, Mil Mi-17 (air medical transport) helicopter pilot presented to the emergency department with a headache and visual blurring 12 days after the first dose of the Sputnik V vaccine. He had no past medical history; he successfully passed his last annual medical examination, and his vital signs were in the normal range. The significant findings were decreased visual acuity, papilledema, severe visual field narrowing, and increased nerve fiber layer thickness in both eyes. The aviation medical examiner suspended him from flight duties and referred him for a complete neuro-ophthalmic investigation. The patient underwent a lumbar puncture; his cerebrospinal fluid pressure was 39 cm H(2)O, and his cerebrospinal fluid biochemical analysis and blood tests were normal. He refused ventriculoperitoneal shunt surgery and received methylprednisolone with acetazolamide. After 10 days, the patient reported a significant improvement. One month later, his visual acuity and visual field were better, papilledema resolved, and disc pallor appeared. Three months later, he needed no medical treatment; he had normal visual acuity and near-normal visual fields. Based on the aviation medical regulations and the importance of flight safety in air medical transportation operations, he cannot return to flight duties until full neuro-ophthalmic recovery is confirmed.

Vaccine-induced immune thrombotic thrombocytopenia. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is primarily a complication of adenoviral vector-based covid-19 vaccination. In VITT, thrombocytopenia and thrombosis mediated by anti-platelet factor 4 (PF4) antibodies can be

severe, often characterized by thrombosis at unusual sites such as the cerebral venous sinus and splanchnic circulation. Like in heparin-induced thrombocytopenia (HIT) and spontaneous HIT, VITT antibodies recognize PF4-polyanion complexes and activate PF4-treated platelets but additionally bind to un-complexed PF4, a critical finding that could be leveraged for more specific detection of VITT. Intravenous immunoglobulin and non-heparin-based anticoagulation remain the mainstay of treatment. Second dose/boosters of mRNA covid-19 vaccines appear safe in patients with adenoviral vector-associated VITT. Emerging data is consistent with the possibility that ultra-rare cases of VITT may be seen in the setting of mRNA and virus-like particle (VLP) technology-based vaccinations and until more data is available, it is prudent to consider VITT in the differential diagnosis of all post-vaccine thrombosis and thrombocytopenia reactions.
Acute Exacerbation of Interstitial Lung Disease After SARS-CoV-2 Vaccination: A Case Series. An acute exacerbation of interstitial lung disease (ILD) is an acute deterioration that can occur at any time and is associated with significant morbidity and mortality rates. We herein report three patients with ILD who experienced acute respiratory failure after SARS-CoV-2 messenger RNA vaccination. All the patients were male; the mean age was 77 years. They had a smoking history that ranged from 10 to 30 pack-years. Duration from the vaccination to the onset of respiratory failure was 1Â day in two patients and 9Â days in one patient. In an autopsied case, lung pathologic evidence indicated diffuse alveolar damage superimposed on usual interstitial pneumonia. In the other two cases, CT scans showed diffuse ground-glass opacities and subpleural reticulation, which suggests acute exacerbation of ILD. Two patients were treated successfully with high-dose methylprednisolone. Although benefits of vaccination outweigh the risks associated with uncommon adverse events, patients with chronic lung diseases should be observed carefully after SARS-CoV-2 vaccination.
Before blaming SARS-CoV-2 vaccination for aortic dissection, alternative causes need to be ruled out.
Bullous Pemphigoid After Vaccination With the Inactivated Severe Acute Respiratory Syndrome Coronavirus 2 Vaccine: Two Cases in China. BACKGROUND: Coronavirus disease-2019 (COVID-19) led to a global pandemic in March 2020 that has involved tens of millions of people. To date, prophylactic vaccines have been found to be the most effective method to contain the pandemic. Bullous pemphigoid (BP) is an autoimmune skin disease that mainly affects older individuals. CASE REPORTS: The authors report 2 confirmed cases of BP in patients with history of cerebral infarction who received the inactivated severe acute respiratory syndrome coronavirus 2 vaccine. A 67-year-old woman was hospitalized for a generalized rash that appeared 7 days after the first dose of inactivated COVID-19 vaccine. The rash was aggravated after the second dose. The second patient was a 66-year-old woman who was hospitalized for a generalized rash that appeared 10 days after the first dose of inactivated COVID-19 vaccine. There were no abnormalities in the baseline blood tests. Laboratory and histologic examinations confirmed the diagnosis of BP. The patients were treated with systemic glucocorticoids, antibiotics, topical corticosteroids, and emollients, which resulted in a significant reduction in pruritus and regression of lesions after 2 weeks. CONCLUSION: Two patients with a genetic background of HLA-DQB1*0302 had BP after vaccination in China. However, there is not enough evidence to indicate a requirement for genetic screening before receiving inactivated severe acute respiratory syndrome coronavirus 2 vaccines.
Toxic epidermal necrolysis and Stevens-Johnson syndrome after COVID-19 infection and vaccination. Stevens-Johnson Syndrome (SJS) is a rare but severe skin reaction characterized by blistering and peeling of the skin and ulcerations of mucous membranes; toxic epidermal necrolysis (TEN) is a subset of SJS characterized by the involvement of >30% of the skin. Though previously associated with drugs and infections, discussions on the association between TEN/SJS and COVID-19 have been limited. We present a review of TEN/SJS after COVID-19 infection and vaccination. Literature searches were conducted on PubMed and Google Scholar from 2019 to 8/2022. Thirty-eight articles were

selected based on subject relevance, and references within selected articles were also screened for relevance. As of 8/2022, there have been 34 published cases of TEN, SJS, and SJS-TEN overlap after COVID-19 infection and vaccination, including 12 cases after vaccination and 22 cases after infection. Multiple authors hypothesize that virotopes or excipients in COVID-19 vaccines can activate T-cells or cytokines to induce TEN/SJS. Meanwhile, some hypothesize that COVID-19 infection induces immune activation that can trigger TEN/SJS or increase susceptibility to drug-induced TEN/SJS. Treatments for post-infection and post-vaccination TEN/SJS vary significantly. We recommend remaining vigilant for this rare and severe potential complication.

A Systematic Review of Histopathologic Surveys on Mucocutaneous Biopsies in Patients Developed COVID-19 Vaccine-Related Dermatologic Manifestations. Coronavirus 2 is an infectious agent primarily identified as the cause of a pandemic viral pneumonia. With the mass vaccination against this virus, one of the health issues is the safety of currently available vaccines considering their adverse reactions. This systematic review was conducted to assess and summarize all reported data on histopathologic findings associated with mucocutaneous reactions that developed after COVID-19 vaccination for a better pathophysiology interpretation and clinical management of these reactions. A systematic search was performed in PubMed, Web of Science, and Scopus databases as well as Google Scholar engine for relevant English articles published till July 1, 2022. This review includes 131 studies with a total number of 287 cases. Eruptions that underwent a biopsy were mostly described as erythematous maculopapular, papulosquamous, vasculitis-like, lichenoid, or urticarial lesions. Histopathology revealed spongiosis, interstitial, and perivascular lymphohistiocytic infiltration, erythrocyte extravasation, parakeratosis, endothelial inflammation, and the like. Findings were highly consistent with morbilliform erythema, psoriasiform dermatosis, leukocytoclastic vasculitis, and lichenoid or urticarial drug reactions. The majority of these reactions had a mild nature and were primarily observed in patients with underlying health conditions. Microscopic evaluation was also consistent with transient inflammatory changes, and features like neutrophilic infiltrates, subcorneal pustules, and vasculopathy were less frequently reported than what seen in COVID infection. Therefore, dermatologic reactions developing after vaccination in the general population should not hinder a complete vaccination.

Effectiveness of mRNA, protein subunit vaccine and viral vectors vaccines against SARS-CoV-2 in people over 18 years old: a systematic review. INTRODUCTION: Vaccines prevent disease and disability; save lives and represent a good assessment of health interventions. Several systematic reviews on the efficacy and effectiveness of COVID-19 vaccines have been published, but the immunogenicity and safety of these vaccines should also be addressed. AREAS COVERED: This systemic investigation sought to explain the efficacy, immunogenicity, and safety of new vaccination technologies against SARS-CoV-2 in people over 18Â years old. Original research studying the effectiveness on mRNA, protein subunit vaccines, and viral vector vaccines against SARS-CoV-2 in people over 18Â years old was analyzed. Several databases (Web of Science, Scopus, MEDLINE and EMBASE) were searched between 2012 and November 2022 for English-language papers using text and MeSH terms related to SARS-CoV-2, mechanism, protein subunit vaccine, viral vector, and mRNA. The protocol was registered on PROSPERO, CRD42022341952. Study quality was assessed using the NICE methodology. We looked at a total of six original articles. All studies gathered and presented quantitative data. EXPERT OPINION: Our results suggest that new vaccinations could have more than 90% efficacy against SARS-CoV-2, regardless of the technology used. Furthermore, adverse reactions go from mild to moderate, and good immunogenicity can be observed for all vaccine types.

Unmasking sarcoidosis following SARS-CoV-2 vaccination: A case report. Sarcoidosis is an inflammatory and granulomatous disorder, developed due to dysregulation between immune response and certain environmental antigens. We hereby report an interesting case of sarcoidosis

following COVID-19 vaccination (COVIran Barekat), which presented with inflammation of previous tattoo sites as well as the development of erythema nodosum and systemic lymphadenopathy, suggested a possible link between the COVID vaccination and dysregulation of the inflammatory process and served as a reminder for clinicians to have enough vigilance before proposing a vaccine booster to these patients.

Multiple cranial nerve palsies with small angle exotropia following COVID-19 mRNA vaccination in an adolescent: A case report. BACKGROUND: Several vaccines against the severe acute respiratory syndrome coronavirus 2 have been approved and widely distributed, raising public concerns regarding the side effects of immunization, as the incidence of ease. Although many adverse events following the coronavirus disease 2019 (COVID-19) vaccine have been reported, neurological complications are relatively uncommon. Herein, we report a rare case of multiple cranial palsies following COVID-19 vaccination in an adolescent patient. CASE SUMMARY: A previously healthy, 14-year-old Asian girl with facial palsy presented to the emergency department with inability to close the right eye or wrinkle right side of the forehead, and pain in the right cheek. She had received second dose of the COVID-19 mRNA vaccine (Pfizer-BioNTech) 18 days before onset of symptoms. She was diagnosed with Bell's palsy and prescribed a steroid (1 mg/kg/day methylprednisolone) based on symptoms and magnetic resonance imaging findings. However, the next day, all sense of taste was lost with inability to swallow solid food; the gag reflex was absent. Horizontal diplopia was also present. Due to worsening of her condition, she was given high-dose steroids (1 g/day methylprednisolone) for 3 days and then discharged with oral steroids. Improvement in the symptoms was noted 4 days post steroid treatment completion. At the most recent follow-up, her general condition was good with no symptoms except diplopia; ocular motility disturbances were noted. Hence, prism glasses were prescribed for diplopia relief. CONCLUSION: Small-angle exotropia was observed in the facial, trigeminal, and glossopharyngeal nerve palsies, in our patient. The etiology of this adverse effect following vaccination was thought to be immunological.

Case mistaken for leukemia after mRNA COVID-19 vaccine administration: A case report. BACKGROUND: Following the global outbreak of coronavirus disease 2019 (COVID-19), unlike other vaccines, COVID-19 vaccines were developed and commercialized in a relatively short period of time. The large-scale administration of this vaccine in a short time-period led to various unexpected side effects, including severe cytopenia and thrombosis with thrombocytopenia syndrome. Despite many reports on adverse reactions, vaccination was necessary to prevent the spread of COVID-19; thus, it is essential to understand and discuss various cases of adverse reactions after vaccination. CASE SUMMARY: A 77-year-old woman was administered the second dose of Pfizer mRNA COVID-19 vaccine. After vaccination she experienced fever, myalgia, and weakness. Antibiotics were subsequently administered for several days, but there was no improvement in the symptoms. The patient showed severe thrombocytopenia and leukocytosis. Thoracic and abdominopelvic computed tomography showed no infection related findings, but splenomegaly and cirrhotic liver features were observed. A large number of immature cells were observed in the peripheral blood smear; thus, bone marrow examination was performed for acute leukemia. However, there were no abnormalities. The patient recovered after administration of hepatotoxins and transfusion treatment for cytopenia and was diagnosed with an adverse reaction to COVID-19 vaccination. CONCLUSION: Adverse reactions of vaccination could be mistaken for hematologic malignancies including leukemia. We report a patient with leukocytosis following COVID-19 vaccination.

Severe acute respiratory coronavirus virus 2 (SARS-CoV-2) infections occurring in healthcare workers after booster vaccination: A comparison of delta versus omicron variants. In this study, we used genomic sequencing to identify variants of severe acute respiratory coronavirus virus 2 (SARS-CoV-2) in healthcare workers with coronavirus disease 2019 (COVID-19) after receiving a booster vaccination.

We compared symptoms, comorbidities, exposure risks, and vaccine history between the variants. Postbooster COVID-19 cases increased as the SARS-CoV-2 omicron variant predominated.

Adverse COVID-19 vaccination effects in Finnish patients with MÃ©niÃ¨re's disease: a cross-sectional study. Background: The association between reporting adverse coronavirus disease 2019 (COVID-19) vaccination effects and those with a history of audiovestibular difficulties is unknown. The aim of this research is therefore to investigate adverse vaccination effects in adults with a history of MÃ©niÃ¨re's disease. Specifically, the incidence of adverse effects, the factors associated with those reporting adverse effects and the relationship between the reporting of audiovestibular and other adverse effects. Methods: A mixed-methods exploratory cross-sectional survey study design was used. Data were collected from 333 members of the Finnish MÃ©niÃ¨re Association. The survey was designed to obtain demographic information that may be associated with having adverse effects or not, vaccination-specific information and adverse vaccination effects. Both health and audiovestibular adverse events were identified. Data analysis included comparing those reporting and not reporting adverse vaccination effects. Results: The mean age was 63 years with 81% being female. Of the 327 respondents who had one of the COVID-19 vaccinations (Comirnatry/ Pfizer, Astra Zeneca, or Moderna), 203 (62%) reported no adverse effects. The type of or number of vaccinations were not related to the reporting of adverse effects. The most frequently reported adverse effects were injection site tenderness (38%), arm pain (21%), fever (15%) and headaches (15%). Post-vaccination tinnitus and vertigo (both 7%) were the most frequently reported audiovestibular-related symptoms, followed by aural fullness (6%) and hearing loss (4%). Those reporting previous pre-vaccination vertigo were more likely to have post-vaccination vertigo. The presence of post-vaccination tinnitus, hearing loss, and aural fullness, predicted the presence of post-vaccination vertigo. Conclusions: A small proportion of patients with a history of MÃ©niÃ¨re's disease may experience adverse post-vaccination effects. Further research is required to explore whether adverse post-vaccination audiovestibular effects are more prevalent in those with a history of otological disorders compared with the general population.

Evans' syndrome following vaccination with ChAdOx1 nCoV-19 in a patient with new-onset localized scleroderma. Growing evidence suggests that COVID-19 vaccines can induce hematological conditions. Here, we report a case of Evans' syndrome, a combination of immune thrombocytopenic purpura and autoimmune hemolytic anemia following administration of the ChAdOx1 nCoV-19 vaccine. The present case further supports the notion that COVID-19 vaccines can trigger in rare cases severe persistent autoimmune-mediated hematological conditions which may predominantly occur in patients with underlying autoimmune conditions.

Alopecia areata after COVID- 19 vaccination: Two cases and review of the literature. Alopecia Areata (AA) is an autoimmune disorder characterized by hair loss, due to a T-lymphocyte-mediated inflammatory response targeting anagen-phase hair follicles. Former studies have suggested that vaccination and viral infections may play a role in the onset of AA through a variety of different mechanisms. We report here two cases of AA following COVID-19 vaccination.

Association between presence of Bacillus Calmette-Guerin vaccine scar and coronavirus disease 2019. Bacillus Calmette-Guerin vaccine is administered for protection against tuberculosis and may also have beneficial effects against some viral respiratory tract infections. In this study, it was aimed to investigate the relationship between Bacillus Calmette-Guerin vaccination which is confirmed by BCG scar, and the frequency and course of Coronavirus disease 2019 (COVID-19). Among 490 patients, 400 patients who accepted to participate in the study were included. After the consent of patients, age, gender, body mass index, comorbidities, smoking, history, and the progress of COVID-19 of these patients were investigated; the presence and number of Bacillus Calmette-Guerin scars were recorded by a physician. Data from groups with and without COVID-19 history were compared. There

was no relation between presence and number of the BCG scar and COVID-19 related hospitalization and intensive care unit admission. When groups with and without COVID-19 history compared, no statistically significant difference was found with the presence and number of Bacillus Calmette-Guerin scars (Pâ€…>â€…0,05). No association was found between the presence or number of BCG scars and the frequency and course of COVID-19 in individuals with Bacillus Calmette-Guerin vaccination history confirmed by the presence of Bacillus Calmette-Guerin vaccine scars. Currently, the most important protection against COVID-19 is the COVID-19 vaccine.

Two possible etiologies of Guillain-BarrÃ© syndrome: mRNA-1273 (Moderna) vaccination and scrub typhus: A case report. RATIONALE: Guillain-BarrÃ© syndrome (GBS) is an acute inflammatory polyneuropathy related to infection with bacteria or virus and vaccination. Cases of GBS after coronavirus infection-19 (COVID-19) vaccination have been reported. However, cases of GBS after inoculation with mRNA-based COVID-19 vaccines, especially mRNA-1273, have rarely been reported compared to after inoculation with adenovirus vector-based COVID-19 vaccines. On 1 hand, GBS occurring after scrub typhus is often reported, but the exact pathological mechanism has not been elucidated. We report the case of a patient with GBS after inoculation with mRNA-1273 COVID-19 vaccine and scrub typhus. PATIENT CONCERNS: A 47-year-old man received COVID-19 vaccination 4 weeks before admission. He had a fever, rash and general weakness 1 day after vaccination. After 3 weeks, the muscle strength of the extremities deteriorated to the extent that walking was impossible. DIAGNOSIS, INTERVENTIONS, AND OUTCOMES: The patient developed quadriplegia with areflexia, axonal-type sensorimotor polyneuropathy was confirmed by nerve conduction study. The patient was diagnosed as GBS. Scrub typhus was also diagnosed as eschar was observed in the chest area and the serologic test of anti-R-tsutsugamushi antibody showed a strongly positive result. The patient received treatment with intravenous immunoglobulin at 0.4â€‰g/kg daily for 5 days. Mechanical ventilation was applied during the intensive care unit. He was treated for scrub typhus simultaneously. Six months after the onset of the disease, the patient showed improvement to the point where he could work and exercise alone. LESSONS: When GBS is suspected, early evaluation and treatment can lead to favorable outcomes. Considering that cases of GBS after COVID-19 vaccination have been reported, it is important to conduct early evaluation and management of patients with muscle weakness after COVID-19 vaccination to ensure early detection of GBS. And even if fever and rash are side effects that can occur frequently after vaccination, it is necessary to consider other diseases in addition to the side effects of the vaccine. This is to prevent delay in diagnosis and treatment of other diseases.

Comparison of Levels of Nasal, Salivary, and Plasma Antibody to Severe Acute Respiratory Syndrome Coronavirus 2 During Natural Infection and After Vaccination. BACKGROUND: Most studies of immunity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) measure antibody or cellular responses in blood; however, the virus infects mucosal surfaces in the nose and conjunctivae and infectious virus is rarely if ever present in the blood. METHODS: We used luciferase immunoprecipitation assays to measure SARS-CoV-2 antibody levels in the plasma, nose, and saliva of infected persons and vaccine recipients. These assays measure antibody that can precipitate the SAR-CoV-2 spike and nucleocapsid proteins. RESULTS: Levels of plasma anti-spike antibody declined less rapidly than levels of anti-nucleocapsid antibody in infected persons. SARS-CoV-2 anti-spike antibody levels in the nose declined more rapidly than antibody levels in the blood after vaccination of infected persons. Vaccination of previously infected persons boosted anti-spike antibody in plasma more than in the nose or saliva. Nasal and saliva anti-spike antibody levels were significantly correlated with plasma antibody in infected persons who had not been vaccinated and after vaccination of uninfected persons. CONCLUSIONS: Persistently elevated SARS-CoV-2 antibody in plasma may not indicate persistence of antibody at mucosal sites such as the nose. The strong correlation of SARS-CoV-2

antibody in the nose and saliva with that in the blood suggests that mucosal antibodies are derived primarily from transudation from the blood rather than local production. While SARS-CoV-2 vaccine given peripherally boosted mucosal immune responses in infected persons, the increase in antibody titers was higher in plasma than at mucosal sites. Taken together, these observations indicate the need for development of mucosal vaccines to induce potent immune responses at sites where SARS-CoV-2 infection occurs. CLINICAL TRIALS REGISTRATION: NCT01306084.

Optic disc hemorrhage in a young female following mRNA coronavirus disease 2019 vaccination: aÂ case report. BACKGROUND: Since the development of the coronavirus disease 2019 vaccine, there have been many reports of its adverse effects. While respiratory symptoms are common, many other symptoms in various organs have been reported. Herein, we report a case of optic disc and retinal hemorrhage that developed immediately after coronavirus disease 2019 vaccination. CASE PRESENTATION: A healthy 18-year-old Japanese female noticed floater in the left eye 1Â day after the second vaccination for coronavirus disease 2019 (Pfizer Inc.). Her visual acuity was 20/20 in the left eye, and Goldmann visual field test showed a relative scotoma around blind spot and in the temporal lower quadrant. It was considered due to subretinal hemorrhage and optic disc swelling. Fundus examination revealed retinal and optic disc hemorrhage. Pupillary reflex was intact and central critical flicker was not impaired, indicating that optic nerve was not involved. There was no sign of inflammation, vascular abnormality, nor history of an intense Valsalva maneuver. The hemorrhage resolved spontaneously within 5Â months. CONCLUSION: This case expands the clinical presentation of coronavirus disease 2019 vaccination-associated ocular adverse events, and it should be kept in mind when patients with similar symptoms visit clinics. The case report will help clinicians avoid unnecessary and invasive examinations and treatment.

Prolonged peripheral seronegative spondyloarthritis following BioNTech coronavirus disease 2019 vaccination: A case report. A female 17-year-old diagnosed with seronegative spondyloarthritis (SpA) following the first jab of the BioNTech162b2 (BNT162b2) vaccine presented with recurrent swelling and painful knee accompanied by posterior heel tenderness over the past 1.5Â months. Laboratory investigations revealed elevated serum erythrocyte sedimentation rate and C-reactive protein. Synovial aspiration yielded level 3 crystal-free, aseptic and inflammatory effusion. She tested positive for the human leukocyte antigen-B27 and was diagnosed with peripheral SpA. She received daily celecoxib (400â€‰mg), methylprednisolone (8Â mg), and sulfasalazine (2Â g), but the effect was limited. Nonetheless, her symptoms improved significantly with weekly subcutaneous etanercept administration (50â€‰mg). Four weeks later, her arthritis was completely resolved. To our knowledge, this is the first case report of newly diagnosed seronegative peripheral SpA in an autoimmunity-disease-free individual following messenger RNA BNT coronavirus disease 2019 vaccination.

A lack of an association between COVID-19 vaccination and corneal graft rejection: results of a large multi-country population based study. PURPOSE: The aim of the study was to present the rates of corneal transplant rejection from 2018 to 2022 at both Moorfields Eye Hospital UK, and Ospedali Privati Forli (OPF) "Villa Igea", Italy and evaluate the purported association between COVID-19 vaccination and rejection. METHODS: We performed a retrospective review of rejection cases presenting to the two units. Monthly rates were correlated against regional vaccination programme rates. At OPF, conditional Poisson regression model was employed to estimate the incidence risk ratio (IRR) of graft rejection following COVID-19 vaccination risk period compared with the control period. RESULTS: Between January 2018 and March 2022, there were 471 (Moorfields), 95 (OPF) episodes of rejection. From the start of vaccination programme in the UK in late January 2021, the median number of graft rejections per month at Moorfields was 6 (range: 5-9), which was not significantly different to post-lockdown, pre-vaccination programme (March 2020-January 2021),

pâ€‰=â€‰0.367. At OPF, the median rates of rejection before and after initiation of the vaccination programme were not significantly different (pâ€‰=â€‰0.124). No significant increase in incidence rate of rejection in the risk period following COVID-19 vaccination was found (IRRâ€‰=â€‰0.53, pâ€‰=â€‰0.71). CONCLUSION: No notable increase in rates of transplant rejection was noted in year 2021 when COVID-19 vaccination was broadly implemented. The apparent temporal relationship between COVID-19 vaccination and corneal graft rejection highlighted in several case reports may not represent a causative association.

Tree-based data mining for safety assessment of first COVID-19 booster doses in the Vaccine Safety Datalink. BACKGROUND: The Centers for Disease Control and Prevention's Vaccine Safety Datalink (VSD) has been performing safety surveillance for COVID-19 vaccines since their earliest authorization in the United States. Complementing its real-time surveillance for pre-specified health outcomes using pre-specified risk intervals, the VSD conducts tree-based data-mining to look for clustering of a broad range of health outcomes after COVID-19 vaccination. This study's objective was to use this untargeted, hypothesis-generating approach to assess the safety of first booster doses of Pfizer-BioNTech (BNT162b2), Moderna (mRNA-1273), and Janssen (Ad26.COV2.S) COVID-19 vaccines. METHODS: VSD enrollees receiving a first booster of COVID-19 vaccine through April 2, 2022 were followed for 56Â days. Incident diagnoses in inpatient or emergency department settings were analyzed for clustering within both the hierarchical ICD-10-CM code structure and the follow-up period. The self-controlled tree-temporal scan statistic was used, conditioning on the total number of cases for each diagnosis. P-values were estimated by Monte Carlo simulation; pÂ =Â 0.01 was pre-specified as the cut-off for statistical significance of clusters. RESULTS: More than 2.4 and 1.8 million subjects received Pfizer-BioNTech and Moderna boosters after an mRNA primary series, respectively. Clusters of urticaria/allergy/rash were found during Days 10-15 after the Moderna booster (pÂ =Â 0.0001). Other outcomes that clustered after mRNA boosters, mostly with pÂ =Â 0.0001, included unspecified adverse effects, common vaccine-associated reactions like fever and myalgia, and COVID-19. COVID-19 clusters were in Days 1-10 after booster receipt, before boosters would have become effective. There were no noteworthy clusters after boosters following primary Janssen vaccination. CONCLUSIONS: In this untargeted data-mining study of COVID-19 booster vaccination, a cluster of delayed-onset urticaria/allergy/rash was detected after the Moderna booster, as has been reported after Moderna vaccination previously. Other clusters after mRNA boosters were of unspecified or common adverse effects and COVID-19, the latter evidently reflecting immunity to COVID-19 after 10Â days.

Neutralising antibody potency against SARS-CoV-2 wild-type and omicron BA.1 and BA.4/5 variants in patients with inflammatory bowel disease treated with infliximab and vedolizumab after three doses of COVID-19 vaccine (CLARITY IBD): an analysis of a prospective multicentre cohort study. BACKGROUND: Anti-TNF drugs, such as infliximab, are associated with attenuated antibody responses after SARS-CoV-2 vaccination. We aimed to determine how the anti-TNF drug infliximab and the anti-integrin drug vedolizumab affect vaccine-induced neutralising antibodies against highly transmissible omicron (B.1.1.529) BA.1, and BA.4 and BA.5 (hereafter BA.4/5) SARS-CoV-2 variants, which possess the ability to evade host immunity and, together with emerging sublineages, are now the dominating variants causing current waves of infection. METHODS: CLARITY IBD is a prospective, multicentre, observational cohort study investigating the effect of infliximab and vedolizumab on SARS-CoV-2 infection and vaccination in patients with inflammatory bowel disease (IBD). Patients aged 5 years and older with a diagnosis of IBD and being treated with infliximab or vedolizumab for 6 weeks or longer were recruited from infusion units at 92 hospitals in the UK. In this analysis, we included participants who had received uninterrupted biological therapy since recruitment and without a previous SARS-CoV-2 infection. The primary outcome was neutralising antibody responses against

SARS-CoV-2 wild-type and omicron subvariants BA.1 and BA.4/5 after three doses of SARS-CoV-2 vaccine. We constructed Cox proportional hazards models to investigate the risk of breakthrough infection in relation to neutralising antibody titres. The study is registered with the ISRCTN registry, ISRCTN45176516, and is closed to accrual. FINDINGS: Between Sept 22 and Dec 23, 2020, 7224 patients with IBD were recruited to the CLARITY IBD study, of whom 1288 had no previous SARS-CoV-2 infection after three doses of SARS-CoV-2 vaccine and were established on either infliximab (n=871) or vedolizumab (n=417) and included in this study (median age was 46Â·1 years [IQR 33Â·6-58Â·2], 610 [47Â·4%] were female, 671 [52Â·1%] were male, 1209 [93Â·9%] were White, and 46 [3Â·6%] were Asian). After three doses of SARS-CoV-2 vaccine, 50% neutralising titres (NT50s) were significantly lower in patients treated with infliximab than in those treated with vedolizumab, against wild-type (geometric mean 2062 [95% CI 1720-2473] vs 3440 [2939-4026]; p<0Â·0001), BA.1 (107Â·3 [86Â·40-133Â·2] vs 648Â·9 [523Â·5-804Â·5]; p<0Â·0001), and BA.4/5 (40Â·63 [31Â·99-51Â·60] vs 223Â·0 [183Â·1-271Â·4]; p<0Â·0001) variants. Breakthrough infection was significantly more frequent in patients treated with infliximab (119 [13Â·7%; 95% CI 11Â·5-16Â·2] of 871) than in those treated with vedolizumab (29 [7Â·0% [4Â·8-10Â·0] of 417; p=0Â·00040). Cox proportional hazards models of time to breakthrough infection after the third dose of vaccine showed infliximab treatment to be associated with a higher hazard risk than treatment with vedolizumab (hazard ratio [HR] 1Â·71 [95% CI 1Â·08-2Â·71]; p=0Â·022). Among participants who had a breakthrough infection, we found that higher neutralising antibody titres against BA.4/5 were associated with a lower hazard risk and, hence, a longer time to breakthrough infection (HR 0Â·87 [0Â·79-0Â·95]; p=0Â·0028). INTERPRETATION: Our findings underline the importance of continued SARS-CoV-2 vaccination programmes, including second-generation bivalent vaccines, especially in patient subgroups where vaccine immunogenicity and efficacy might be reduced, such as those on anti-TNF therapies. FUNDING: Royal Devon University Healthcare NHS Foundation Trust; Hull University Teaching Hospital NHS Trust; NIHR Imperial Biomedical Research Centre; Crohn's and Colitis UK; Guts UK; National Core Studies Immunity Programme, UK Research and Innovation; and unrestricted educational grants from F Hoffmann-La Roche, Biogen, Celltrion Healthcare, Takeda, and Galapagos.

Working towards a comprehensive appraisal of vaccine-induced immunity against SARS-CoV-2 in IBD.

COVID-19 Vaccine Myocarditis: Cautious Reassurance in an Era of Dynamic Uncertainty. [Figure: see text]

Prognosis of Myocarditis Developing After mRNA COVID-19 Vaccination Compared With Viral Myocarditis. BACKGROUND: Association between messenger RNA (mRNA) COVID-19 vaccines and myocarditis has aroused public concern over vaccine safety. OBJECTIVES: The goal of this study was to compare the prognosis of this condition with viral infection-related myocarditis over 180Â days. METHODS: A territory-wide electronic public health care database in Hong Kong linked with population-based vaccination records was used to conduct a retrospective cohort study. Since the roll-out of BNT162b2 (Pfizer-BioNTech), patients agedÂ â‰¥12 years hospitalized with myocarditis within 28Â days after BNT162b2 vaccination were compared against viral infection-related myocarditis recorded before the pandemic (2000-2019), over a 180-day follow-up period (starting from diagnosis of myocarditis). All-cause mortality, heart failure, dilated cardiomyopathy, heart transplant, and postdischarge health care utilization were examined with Cox proportional hazards models. RESULTS: A total of 866 patients were included for analysis. Over the follow-up period, 1 death (1.0%) of 104 patients with postvaccination myocarditis and 84 deaths (11.0%) of 762 patients with viral infection-related myocarditis were identified. One case (1.0%) of dilated cardiomyopathy and 2 cases (1.9%) of heart failure were identified in the postvaccination group, compared with 28 (3.7%) and 93 (12.2%) in the viral infection-related myocarditis group, respectively. Adjusted analysis showed that the postvaccination myocarditis group had a 92% lower mortality risk

(adjusted HR: 0.08; 95%Â CI: 0.01-0.57). No significant differences in other prognostic outcomes were seen. CONCLUSIONS: This study found a significantly lower rate of mortality among individuals with myocarditis after mRNA vaccination compared with those with viral infection-related myocarditis. Prognosis of this iatrogenic condition may be less severe than naturally acquired viral infection-related myocarditis.

COVID-19 Booster Dose Vaccination Coverage and Factors Associated with Booster Vaccination among Adults, United States, March 2022. The Centers for Disease Control and Prevention recommends a COVID-19 vaccine booster dose for all persons >18 years of age. We analyzed data from the National Immunization Survey-Adult COVID Module collected during February 27-March 26, 2022 to assess COVID-19 booster dose vaccination coverage among adults. We used multivariable logistic regression analysis to assess factors associated with vaccination. COVID-19 booster dose coverage among fully vaccinated adults increased from 25.7% in November 2021 to 63.4% in March 2022. Coverage was lower among non-Hispanic Black (52.7%), and Hispanic (55.5%) than non-Hispanic White adults (67.7%). Coverage was 67.4% among essential healthcare personnel, 62.2% among adults who had a disability, and 69.9% among adults who had medical conditions. Booster dose coverage was not optimal, and disparities by race/ethnicity and other factors are apparent in coverage uptake. Tailored strategies are needed to educate the public and reduce disparities in COVID-19 vaccination coverage.

Post COVID-19 vaccination side effects and associated factors among vaccinated health care providers in Oromia region, Ethiopia in 2021. BACKGROUND: Severe Acute Respiratory Syndrome (SARS COV-2) known as COVID-19 since its outbreak in 2019, more than 375 and 5.6 million were infected and dead, respectively. Its influence in all disciplines stimulated different industries to work day to night relentlessly to develop safe and effective vaccines to reduce the catastrophic effect of the disease. With the increasing number of people globally who have been vaccinated, the reports on possible adverse events have grown and gained great public attention. This study aims to determine post-COVID-19 vaccination adverse effects and associated factors among vaccinated Health care providers in the Oromia region, Ethiopia in 2021. METHODS: A cross-sectional study was conducted among 912 health care workers working in government hospitals in the central Oromia region from November 20 to December 15/2021. Respondents absent from work due to different reasons were excluded during the interview. The outcome variable was COVID-19 side effects (response as Yes/No). A descriptive analysis displayed findings in the form of the frequencies and percentages, and logistic regression was employed to see the association of different variables with side effects experienced. RESULT: Overall, 92.1% of the participants experienced side effects either in 1st or 2nd doses of post-COVID-19 vaccination; 84.0% and (71.5%) of participants experienced at least one side effect in the 1st and 2nd dose of the vaccines, respectively. COVID-19 infection preventive protocols like keeping distance, hand wash using soap, wearing mask and using sanitizer were decreased post vaccination. About 74.3% of the respondents were worried about the adverse effects of the COVID-19 vaccine they received. The majority (80.2%) of the respondent felt fear while receiving the vaccine and 22.5% of the respondents suspect the effectiveness of the vaccine they took. About 14.8% of the vaccinated Health workers were infected by COVID-19 post-vaccination. Engaging in moderate physical activity and feeling fear when vaccinated were the independent factors associated with reported side effects of post-COVID-19 vaccination using multiple logistic regression. Respondents who did not engage in physical activity were 7.54 fold more likely to develop post-COVID-19 vaccination side effects compared to those who involved at least moderate-intensity physical activity[AOR = 7.54, 95% CI;2.46,23.12]. The odds of experiencing side effects among the respondents who felt fear when vaccinated were 10.73 times compared not felt fear (AOR = 10.73, 95% CI; 2.47,46.64), and similarly, those who felt little fear were 4.28 times more likely to experience side effects(AOR = 4.28, 95% CI;

1.28, 14.39). CONCLUSION: Significant numbers of the respondents experienced side effects post COVID-19 vaccination. It is recommended to provide pre-awareness about the side effects to reduce observed anxiety related to the vaccine. It is also important to plan monitoring and evaluation of the post-vaccine effect using standard longitudinal study designs to measure the effects directly.

A narrative review of vaccine pharmacovigilance during mass vaccination campaigns: Focus on myocarditis and pericarditis after COVID-19 mRNA vaccination. Vaccines have had a tremendous impact on reducing the burden of infectious diseases; however, they have the potential to cause adverse events following immunization (AEFIs). Prelicensure clinical trials are limited in their ability to detect rare AEFIs that may occur in less than one per thousand individuals. While postmarketing surveillance systems have shown COVID-19 mRNA vaccines to be safe, they led to the identification of rare cases of myocarditis and pericarditis after COVID-19 vaccination that were not initially detected in clinical trials. In this narrative review, we highlight concepts of vaccine pharmacovigilance during mass vaccination campaigns and compare the approaches used in the context of myocarditis and pericarditis following COVID-19 vaccination to historical examples. We describe mechanisms of passive and active surveillance, their strengths and limitations, and how they interacted to identify and characterize the safety signal of myocarditis and pericarditis after COVID-19 mRNA vaccination. Articles were synthesized from a PubMed search using relevant keywords for articles published on vaccine surveillance systems and myocarditis and pericarditis after COVID-19 vaccination, as well asÂ the authors' collections of relevant publications and grey literature reports. The global experience around the identification and monitoring of myocarditis and pericarditis after COVID-19 mRNA vaccination has provided important lessons for vaccine safety surveillance and highlighted its importance in maintaining public trust in mass vaccination programmes in a pandemic context.

Vaccination Against SARS-CoV-2 Decreases Risk of Adverse Events in Patients who Develop COVID-19 Following Cancer Surgery.

Sleep Disturbance and SARS-CoV-2 Vaccinations in Patients With Chronic Inflammatory Disease. OBJECTIVE: Immunocompromised patients with chronic inflammatory disease (CID) may have experienced additional psychosocial burden during the COVID-19 pandemic due to their immunocompromised status. This study was undertaken to determine if vaccination would result in improved patient-reported outcomes longitudinally among individuals with CID undergoing SARS-CoV-2 vaccination regardless of baseline anxiety. METHODS: Data are from a cohort of individuals with CID from 2 sites who underwent SARS-CoV-2 vaccination. Participants completed 3 study visits before and after 2 messenger RNA vaccine doses in the initial vaccination series when clinical data were collected. Patient-reported outcomes were measured using the Patient-Reported Outcomes Measurement Information System 29-item Health Profile and expressed as T scores, with 2 groups stratified by high and low baseline anxiety. Mixed-effects models were used to examine longitudinal changes, adjusting for age, sex, and study site. RESULTS: A total of 72% of the cohort was female with a meanâ€‰Â±â€‰SD age of 48.1â€‰Â±â€‰15.5â€‰years. Overall, sleep disturbance improved following both doses of SARS-CoV-2 vaccinations, and anxiety decreased after the second dose. Physical function scores worsened but did not meet the minimally important difference threshold. When stratifying by baseline anxiety, improvement in anxiety, fatigue, and social participation were greater in the high anxiety group. Physical function worsened slightly in both groups, and sleep disturbance improved significantly in the high anxiety group. CONCLUSION: Sleep disturbance decreased in a significant and meaningful way in patients with CID upon vaccination. In patients with higher baseline anxiety, social participation increased, and anxiety, fatigue, and sleep disturbance decreased. Overall, results suggest that SARS-CoV-2 vaccination may improve mental health and well-being, particularly among those with greater anxiety.

A Possible Case of Autoimmune Encephalitis After mRNA COVID-19 Booster Vaccine: A Case Report. As the use of COVID-19 vaccines gains more prevalence, rare and uncommon side effects are reported in the medical literature. This is a case report of a 75-year-old male patient who presented on the second day after receiving the Moderna Bivalent mRNA COVID-19Â booster vaccine with abrupt onset behavioral changes and global aphasia with no focal deficits. Stroke and infectious meningitis/encephalitis were ruled out. Signs of aseptic inflammation were seen on cerebrospinal fluid (CSF) analysis. Workup for autoimmune and paraneoplastic encephalitis was unyielding. The observation of rapid clinical improvement promptedÂ watchful waiting that concluded in the resolution of clinical manifestations within less than a week of onset.Â This case is reported to support the currently limited knowledge of rare neurological sequelae of mRNA vaccine and is in line with recently published few cases that suggest vaccine-related encephalitis.

Case report: Myocarditis with nonsustained ventricular tachycardia following COVID-19 mRNA vaccination in a female adolescent. Children with underlying medical conditions potentially develop severe illness from Coronavirus disease 2019 (COVID-19). The use of vaccines against COVID-19 is currently recommended for the pediatric population. The COVID-19 vaccine has a temporal association with the occurrence of myocarditis. Although most patients with COVID-19 vaccination-associated myocarditis (C-VAM) exhibit a mild clinical course and rapid recovery, C-VAM potentially causes electrical instability and sudden cardiac death. Herein, we report the case of a 17-year-old woman who presented with chest pain and syncope following the first dose of the messenger RNA COVID-19 vaccine. The patient's heart function was impaired, and nonsustained ventricular tachycardia was frequent. Cardiac magnetic resonance (CMR) imaging satisfied the criteria for myocarditis. Despite the administration of immunomodulatory drugs, the patient's heart function was not fully restored, and the concentration of cardiac enzymes remained above the normal range. Persistence of late gadolinium enhancement was observed on short-term follow-up CMR imaging. Although most patients with C-VAM exhibit mild symptoms, significant cardiac arrhythmias potentially occur. Furthermore, some patients with C-VAM demonstrate prolonged impaired heart function and sustained late gadolinium enhancement on follow-up CMR imaging. Therefore, monitoring of electrical and functional cardiac abnormalities in patients with C-VAM is crucial and the long-term outcomes and prognosis of patients with C-VAM require further investigation.

The mRNA-Based Coronavirus Disease-2019 Vaccine-induced Severe Cardiomyopathy: A Rare Incident. We are presenting a case of severe dilated cardiomyopathy (DCM) post-mRNA-based coronavirus disease-2019 (COVID-19) vaccine (Pfizer-BioNTech) in a young healthy man. After the second dose of the vaccine, his health rapidly declined, and he developed severe DCM with reduced ejection fraction. Investigations for other causes of DCM were unremarkable. Severe DCM following COVID-19 vaccine injection is a rare but serious condition. It also highlights the importance of close follow-up of pericarditis and perimyocarditis cases post-COVID-19 vaccine and we recommend clinicians have a low threshold for using echocardiography for early diagnosis and management.

COVID-19 vaccine-induced vasculitis in a patient with sarcoidosis: A case report. A 55-year-old lady with a nine-year history of controlled sarcoidosis developed vasculitis after Sinopharm COVID-19 vaccine (BBIBP- CorV). She was ultimately diagnosed with mononeuritis multiplex based on EMG-NCV findings and administered methylprednisolone and cyclophosphamide pulse therapy for 5â€‰days, and then continue with prednisolone and a monthly pulse of cyclophosphamide.

Safety and immunogenicity of mRNA COVID-19 vaccine in inpatients with muscular dystrophy. INTRODUCTION/AIMS: Due to muscular weakness and cardiopulmonary dysfunction, patients with muscular dystrophy (MD) have an increased risk of serious complications from coronavirus disease-2019 (COVID-19). Although vaccination is recommended, COVID-19 vaccination safety and immunogenicity in these patients are unknown. We investigated reaction frequency, post-vaccine

antibody titers after two mRNA COVID-19 vaccine doses, and clinical predictors of antibody response among patients with MD. METHODS: We recruited 171 inpatients with MD receiving two BNT162b2 mRNA COVID-19 vaccine doses from seven hospitals. Blood samples were obtained from 53 inpatients before the first dose and 28 to 30â€‰days after the second dose, and antibody titers were measured. RESULTS: Overall, 104 (60.8%) and 115 (67.6%) patients had side effects after the first and second doses, respectively. These were generally mild and self-limited. Multiple logistic regression analysis showed that a bedridden state was associated with reduced side effects (odds ratio [OR] =â€‰0.29; 95% confidence interval [CI], 0.12 to 0.71). The antibody titers of all participants changed from negative to positive after two vaccine doses. The geometric mean titer (GMT) of the inpatients was 239 (95% CI, 159.3 to 358.7). Older age (relative risk [RR]Â =Â 0.97; 95% CI, 0.95 to 0.99) and bedridden state (RRÂ =Â 0.27; 95% CI, 0.14 to 0.51) were associated with a lower antibody titer. Patients with myotonic dystrophy type 1 (DM1) had a lower GMT than patients with other MDs (RRÂ =Â 0.42; 95% CI, 0.21 to 0.85). DISCUSSION: COVID-19 vaccination is safe and immunogenic in inpatients with MD. Patients with DM1 appear to have a poorer COVID-19 antibody response than those with other MDs.

Maternal and neonatal safety of COVID-19 vaccination during the peri-pregnancy period: A prospective study. BACKGROUND: To investigate the safety of inactivated COVID-19 vaccine in Chinese pregnant women and their fetuses when inoculated during the peri-pregnancy period. METHODS: Eligible pregnant women were prospectively collected and divided into a vaccine group (nâ€‰=â€‰93) and control group (nâ€‰=â€‰160) according to whether they had been vaccinated against COVID-19 within 3 months before their last menstruation period (LMP) and after pregnancy. Demographic data of couples, complications during pregnancy and delivery of pregnant women, and data of newborns at birth were collected. RESULTS: Sixty-six women were vaccinated with a median time of 35.5 (rangeâ€‰=â€‰0-91) days before LMP, and 27 women were vaccinated with a median time of 17 (rangeâ€‰=â€‰1-72) days after LMP. The incidence of premature rupture of membrane (PROM) in the vaccine group was significantly higher than that in the control group (16.13% vs. 6.88%, pâ€‰=â€‰0.019). Multivariate logistic regression analysis revealed that maternal peri-pregnancy COVID-19 vaccination was not an independent risk factor for PROM (odds ratio: 2.407, 95% confidence interval: 0.932-6.216, pâ€‰=â€‰0.069). There was no difference in the incidence of other complications during pregnancy and delivery between the two groups. A total of 253 neonates were delivered, including two cases with congenital abnormalities in each group. The incidence of congenital abnormalities between the two groups was similar (2.15% vs. 1.25%, pâ€‰=â€‰0.626). There was no difference in neonatal length, weight, head circumference, and Apgar score between the two groups (pâ€‰>â€‰0.05), but the incidence of neonatal jaundice in the vaccine group was significantly higher than that in the control group (20.43% vs. 7.5%, pâ€‰=â€‰0.002). Multivariate logistic regression analysis revealed that maternal peri-pregnancy vaccination, postpartum blood loss, cesarean section, 1-min Apgar score, and paternal smoking were independent risk factors for neonatal jaundice. CONCLUSIONS: It is safe for pregnant women and their fetuses to be inoculated the inactivated COVID-19 vaccine during the peri-pregnancy period, but attention should be paid to neonatal jaundice.

COVID-19 Vaccination and Diabetes Mellitus: How Much Has It Made a Difference to Outcomes Following Confirmed COVID-19 Infection? INTRODUCTION: Since early 2020 the whole world has been challenged by the SARS-CoV-2 virus (COVID-19), its successive variants and the associated pandemic caused. We have previously shown that for people living with type 2 diabetes (T2DM), the risk of being admitted to hospital or dying following a COVID-19 infection progressively decreased through the first months of 2021. In this subsequent analysis we have examined how the UK COVID-19 vaccination programme impacted differentially on COVID-19 outcomes in people with T1DM or

T2DM compared to appropriate controls. METHODS: T1DM and T2DM affected individuals were compared with their matched controls on 3:1 ratio basis. A 28-day hospital admission or mortality was used as the binary outcome variable with diabetes status and vaccination for COVID-19 as the main exposure variables. RESULTS: A higher proportion of T1DM individuals vs their controls was found to be vaccinated at the point of their first recorded positive COVID-19 test when compared to T2DM individuals vs their controls. Regarding the 28-day hospital admission rate, there was a greater and increasing protective effect of subsequent vaccination dosage (one, two or three) in mitigating the effects of COVID-19 infection versus no vaccination in T1DM than in T2DM individuals when compared with matched controls. Similar effects were observed in T2DM for death. Across both diabetes and non-diabetes individuals, those at greater socio-economic disadvantage were more likely to test positive for COVID-19 in the early phase of the pandemic. For T2DM individuals socio-economic disadvantage was associated with a greater likelihood of hospital admission and death, independent of vaccination status. Age and male sex were also independently associated with 28-day hospital admission in T2DM and to 28-day mortality, independent of vaccination status. African ethnicity was also an additional factor for hospital admission in people with T2DM. CONCLUSION: A beneficial effect of COVID-19 vaccination was seen in mitigating the harmful effects of COVID-19 infection; this was manifest in reduced hospital admission rate in T1DM individuals with a lesser effect in T2DM when compared with matched controls, regarding both hospital admission and mortality. Socio-economic disadvantage influenced likelihood of COVID-19 confirmed infection and the likelihood of hospital admission/death independent of the number of vaccinations given in T2DM.

Longitudinal study comparing IgG antibodies induced by heterologous prime-boost COVID-19 vaccine. Vaccines are critical cost-effective tools to control the COVID-19 pandemic. The heterologous prime-boost vaccination has been used by many countries to overcome supply issues, so the effectiveness and safety of this strategy need to be better clarified. This study aims to verify the effect of heterologous prime-boost COVID-19 vaccination on healthcare professionals from Dante Pazzanese Hospital in Brazil. It was performed serological assays of vaccinated individuals after 2-dose of CoronaVac (Sinovac;Â nâ€‰=â€‰89) or ChAdOx1 nCoV-19 (Oxford-AstraZeneca;Â nâ€‰=â€‰166) followed by a BNT162b2 booster (Pfizer-BioNTech;Â nâ€‰=â€‰255). The serum antibodies anti-S (spike), anti-N (nucleocapsid), and anti-RBD (receptor binding domain) were assessed by enzyme-linked immunosorbent assay. The heterologous booster dose induced a 10-fold higher anti-Spike antibody regardless of the 2-dose of a prime vaccine. It was strikingly observed that BNT162b2 enhanced levels of anti-spike antibodies, even in those individuals who did not previously respond to the 2-dose of CoronaVac. In conclusion, the heterologous scheme of vaccination using mRNA as a booster vaccine efficiently enhanced the antibody response against SARS-CoV-2, especially benefiting those elderly who were seronegative with a virus-inactivated vaccine.

Evaluation and follow-up of antibody formation after CoronaVac vaccine. OBJECTIVE: The aim of this study was to monitor the time-dependent change by evaluating the antibody levels at the 4th, 7th, 10th, 13th, and 16th weeks after the second dose of the CoronaVac vaccine. METHODS: The study group (n=65) were between 21 and 60 years old and received two doses of the CoronaVac vaccine. Blood samples were collected after 4th, 7th, 10th, 13th, and 16th weeks of the second dose of the vaccine administration. There was a coronavirus disease 2019 recovered group (n=29) who were SARS-CoV-2 real-time PCR test result positive before the vaccination period, and no coronavirus disease 2019 history group (n=36). Age, BMI, gender, smoking, comorbidity, coronavirus disease 2019 contact history, and working in the coronavirus disease 2019 service history of the individuals were recorded. RESULTS: No statistically significant difference was found in the descriptive findings of the individuals according to coronavirus disease 2019 recovered group and no coronavirus disease 2019 history group. It was observed that antibody levels in the coronavirus disease 2019 recovered group

were found to be higher for each period of serum collection compared to the no coronavirus disease 2019 history group, which were statistically significant. The distribution curves of the antibody levels according to the timing of blood collection in coronavirus disease 2019 recovered group, no coronavirus disease 2019 history group, and total subjects were extrapolated, and it was observed that the estimated time for the antibodies to reach the threshold value of the test was 214, 145, and 166 days after vaccination. CONCLUSION: It is important to make booster doses, as the CoronaVac vaccine will lose its effect after the fifth month due to the decrease in Ab levels. In addition, since the antibody levels decrease later in those who have a history of coronavirus disease 2019 infection and are vaccinated, individuals who have no previous history of coronavirus disease 2019 should be given priority for vaccination.
Mixed outcomes following a third SARS-CoV-2 vaccine dose in previously unresponsive people with HIV.
Systemic Lupus Erythematosus Following COVID-19 Vaccination.
Immunogenicity and Reactogenicity Following 2- and 3-Dose SARS-CoV-2 Vaccination in Persons With HIV.
T-cell responses induced by ChAdOx1 nCoV-19 (AZD1222) vaccine to wild-type severe acute respiratory syndrome coronavirus 2 among people with and without HIV in South Africa. OBJECTIVES: This study aimed to investigate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-specific T-cell responses 14â€Šdays after single-dose ChAdOx1 nCoV-19 (AZD1222) vaccination in black Africans with and without HIV in South Africa, as well as determine the effect of AZD1222 vaccination on cell-mediated immune responses in people with HIV (PWH) with prior SARS-CoV-2 infection. METHODS: A total of 70 HIV-uninfected people and 104 PWH were prospectively enrolled in the multicentre, randomized, double-blinded, placebo-controlled, phase Ib/IIa trial (COV005). Peripheral blood mononuclear cells (PBMCs) were collected from trial participants 14â€Šdays after receipt of first dose of study treatment (placebo or AZD1222 vaccine). T-cell responses against the full-length spike (FLS) glycoprotein of wild-type SARS-CoV-2 and mutated S-protein regions found in the Alpha, Beta and Delta variants were assessed using an ex-vivo ELISpot assay. RESULTS: Among AZD1222 recipients without preceding SARS-CoV-2 infection, T-cell responses to FLS of wild-type SARS-CoV-2 were similarly common in PWH and HIV-uninfected people (30/33, 90.9% vs. 16/21, 76.2%; Pâ€Š=â€Š0.138); and magnitude of response was similar among responders (78 vs. 56 SFCs/106 PBMCs; Pâ€Š=â€Š0.255). Among PWH, AZD1222 vaccinees with prior SARS-CoV-2 infection, displayed a heightened T-cell response magnitude compared with those without prior infection (186 vs. 78â€ŠSFCs/106 PBMCs; Pâ€Š=â€Š0.001); and similar response rate (14/14, 100% vs. 30/33, 90.9%; Pâ€Š=â€Š0.244). CONCLUSION: Our results indicate comparable T-cell responses following AZD1222 vaccination in HIV-uninfected people and PWH on stable antiretroviral therapy. Our results additionally show that hybrid immunity acquired through SARS-CoV-2 infection and AZD1222 vaccination, induce a heightened T-cell response.
Bilateral Carpal Tunnel Syndrome Following COVID-19 Vaccination: A Case Report. Coronavirus disease 2019 (COVID-19) continues to pose significant health challenges, with insights into long-term disease sequelae emerging. The post-viral effects resulting from COVID-19 are being investigated and 'long COVID-19' is now a recognised phenomenon. As part of the spectrum of comorbidities, acute-onset neuropathy is associated with infection. The public health response aimed at limiting morbidity and mortality is rooted in vaccination programmes. With the extensive roll-out of novel vaccinations, there has been careful monitoring of temporally associated health problems. Some of the documented associations include neuropathy and entrapment neuropathies. This case report details a patient presenting with bilateral carpal tunnel syndrome (CTS) post their second dose of AZD1222 (ChAdOx1 nCoV-19) vaccination. Though we do not claim causality, the emerging post-vaccination

immune-mediated effects may ultimately be proven to include neuropathy exacerbation. Meticulous recording of such associations is required as it is of great relevance to the hand surgeon managing CTS. Level of Evidence: Level V (Therapeutic).

How immunosuppressive therapy impaires on COVID-19 mRNA-vaccine response in rheumatic diseases.

COVID-19 Vaccine Side Effects among Early-Vaccinated Healthcare Workers: Correspondence.

Overlapping Myocarditis and Postural Orthostatic Tachycardia Syndrome After COVID-19 Messenger RNA Vaccination: A Case Report. The worldwide spread of the coronavirus disease 2019 (COVID-19) pandemic and the significant morbidity and mortality rate associated with it led to the rapid development of several COVID-19 vaccines. While serious side effects related to the vaccines are rare,Â various adverse events have been reported to occur after COVID-19 messenger RNA (mRNA) vaccination, including myocarditis, Guillain-BarrÃ© syndrome, and thrombosis. Postural orthostatic tachycardia syndrome (POTS) is a chronic cardiovascular dysautonomia among young and middle-aged individuals. Although the pathophysiology of POTS is thought to be heterogeneous, vaccine-induced immune-mediated autonomic dysfunction is hypothesized to be one cause of the syndrome. In this report, we present a case of myocarditis and POTS occurring in a 13-year-old male following COVID-19 mRNA vaccination. He presented with persistent severe fatigue and headache. The patient's symptoms improved after intravenous immunoglobulin for myocarditis, non-pharmacologic interventions, and multiple medications for POTS.

Parsonage-Turner syndrome after SARS-CoV-2 vaccination: A case report. Parsonage-Turner syndrome is a neurological disease characterized by pain, muscle weakness, sensory deficits, and reflex abnormalities. Although its exact etiology is unknown, it can be observed after infection, surgery, trauma, and vaccination. This syndrome, which can occur after various vaccines, has been reported in a few cases worldwide after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. In this case report, Parsonage-Turner syndrome developed after the SARS-CoV-2 BioNTech vaccination in a 56-year-old male patient. To the best of our knowledge, this is the first case reported in TÃ¼rkiye.

Mixed formulation of mRNA and protein-based COVID-19 vaccines triggered superior neutralizing antibody responses. Integrating different types of vaccines into a singular immunization regimen is an effective and accessible approach to strengthen and broaden the immunogenicity of existing coronavirus disease 2019 (COVID-19) vaccine candidates. To optimize the immunization strategy of the novel mRNA-based vaccine and recombinant protein subunit vaccine that attracted much attention in COVID-19 vaccine development, we evaluated the immunogenicity of different combined regimens with the mRNA vaccine (RNA-RBD) and protein subunit vaccine (PS-RBD) in mice. Compared with homologous immunization of RNA-RBD or PS-RBD, heterologous prime-boost strategies for mRNA and protein subunit vaccines failed to simultaneously enhance neutralizing antibody (NAb) and Th1 cellular response in this study, showing modestly higher serum neutralizing activity and antibody-dependent cell-mediated cytotoxicity for "PS-RBD prime, RNA-RBD boost" and robust Th1 type cellular response for "RNA-RBD prime, PS-RBD boost". Interestingly, immunizing the mice with the mixed formulation of the two aforementioned vaccines in various proportions further significantly enhanced the NAb responses against ancestral, Delta, and Omicron strains and manifested increased Th1-type responses, suggesting that a mixed formulation of mRNA and protein vaccines might be a more prospective vaccination strategy. This study provides basic research data on the combined vaccination strategies of mRNA and protein-based COVID-19 vaccines.

REACTIVE NON-REGIONAL LYMPHADENOPATHY FROM THE COVID-19 mRNA VACCINE: A NOVEL SIDE-EFFECT.

The Effects of SARS-CoV-2 Virus Type and of Vaccination Status on Causes of Death Over the Course of the COVID-19 Pandemic.

COVID-19 vaccination side effects among the child age group: a large cross-sectional online based survey in Saudi Arabia. BACKGROUND: Multiple vaccines have been tested in clinical trials for their efficacy and safety. In Saudi Arabia, Pfizer-BioNTech or Moderna were approved for children, however, previous studies to report their safety profile are limited. This research aims to understand the side effect of children's vaccination against SARS-CoV-2 infection in Saudi Arabia. METHODS: This was an observational retrospective cross-sectional study was conducted using an online survey in Saudi Arabia from March to May 2022. The inclusion criteria were parents aged 18Â years and above who live in Saudi Arabia and have vaccinated their children. The self-reported questionnaire was adopted from published studies to investigate the study objectives Descriptive statistics were used to describe patients' demographic characteristics, continuous data were reported as meanâ€‰Â±â€‰S.D., categorical data were reported as percentages (frequencies), and logistic regression was used to identify predictors of persistent post-COVID-19 symptoms. RESULTS: This study had a total of 4,069 participants. Only 41.9% of the participants reported that their child(ren) had been infected with the coronavirus. 2.00 was the median number of children (IQR: 1.00-4.00). More than half of the study participants (64.2%) reported that a family member had been infected with the coronavirus. Both parents received COVID-19 vaccination, according to most participants (88.7%). Most participants (70.5%) stated that all children who met the vaccination criteria had received the vaccine. Most participants (83.5%) said their child or children had two doses of their vaccine, and about half (50.4%) of those who received the vaccine reported experiencing side effects. In addition, the majority (78.9%) reported that the side effects appeared within one day of receiving the vaccine, and nearly two-thirds (65.7%) reported that the side effects lasted between one and three. A total of 11,831 side effects cases were documented. Pain at the injection site, hyperthermia, and fatigue were the most reported side effects, accounting for 15.3%, 14.1%, and 13.2%, respectively. CONCLUSION: It appears that the side effects of the COVID-19 vaccine for children are minor, tolerable, and like those described previously in clinical trials. Our data should encourage the public about the safety of receiving the COVID-19 vaccine for children.

Can Google Trends analysis confirm the public's need for information about the rare association of facial nerve paralysis with COVID-19 or the COVID-19 vaccination? Facial nerve paralysis or Bell's palsy have been suggested as possible consequences of SARS-CoV-2 infections, as well as possible side effects of COVID-19 vaccinations. Google Trends data have been used to evaluate worldwide levels of public awareness for these topics for pre- and post-pandemic years. The results demonstrate a relatively low public interest in facial nerve paralysis in comparison to other more common COVID-19 related topics. Some peaks of interest in Bell's palsy can most likely be explained as triggered by the media. Therefore, Google Trends has shown public's relatively low awareness of this rare neurological phenomenon during the pandemic.

Post-mRNA vaccine flares in autoimmune inflammatory rheumatic diseases: Results from the COronavirus National Vaccine registry for ImmuNe diseases SINGapore (CONVIN-SING). BACKGROUND: Studies of flares of autoimmune inflammatory rheumatic diseases (AIIRD) after COVID-19 mRNA vaccination are limited by small sample size, short follow up or at risk of selection bias. METHODS: A national retrospective cohort study of consecutive AIIRD patients â‰¥12 years old, across 8 hospitals who received at least one dose of a COVID-19 mRNA vaccine. Patients were included from the date of 1st vaccine dose and censored at the time of flare or on the date of the clinic visit at least 3 months from cohort entry, whichever came first. Predictors of flare were determined by Cox proportional hazards analysis. FINDINGS: 4627 patients (73% Chinese, 71% female) of median (IQR) age 61 (48, 70) years were included; 42% Rheumatoid arthritis, 14% Systemic

lupus erythematosus and 11% Psoriatic arthritis. 47% were in remission, 41% low disease activity, 10% moderate disease activity and 1% in high disease activity. 18% patients flared, of which 11.7% were within the 3-month period of interest. 11.8% patients improved. Median (IQR) time-to-flare was 60 (30, 114) days. 25% flares were self-limiting, 61% mild-moderate and 14% severe. Older patients (53-65 years and >66 years) had a lower risk of flare [HR 0.6 (95% CI 0.5-0.8) and 0.7 (0.6-0.8) respectively]. Patients with inflammatory arthritis and with active disease had a higher risk of flare [HR 1.5 (1.2-2.0) and 1.4 (1.2-1.6), respectively]. Treatment with conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs), immunosuppression and prednisolone was also associated with an increased risk of flare [HR 1.5 (1.1-2), 1.2 (1.1-1.4) and 1.5 (1.2-1.8) for prednisolone â‰¤7.5Â mg respectively]. INTERPRETATION: There was a moderately high rate of AIIRD flares after mRNA vaccination but also improvement in several patients. Severe flares and hospitalisation were rare. Thus, vaccination remains safe and highly recommended.

COVID-19 Vaccination in Korea: Past, Present, and the Way Forward. Since its first emergence in late 2019, severe acute respiratory syndrome coronavirus-2 has claimed more than 6.5 million lives worldwide and continues to infect hundreds of thousands of people daily. To combat this once-in-a-century disaster, several vaccines have been developed at unprecedented speeds. Novel vaccine platforms (messenger ribonucleic acid vaccines and adenoviral vector vaccines) have played a major role in the current pandemic. In Korea, six vaccines, including a domestically developed recombinant vaccine, have been approved. As in other countries, vaccines have been proven to be safe and highly effective in Korea. However, rare serious adverse events and breakthrough infections have undermined public trust in the vaccines, even while the benefits of vaccination far outweigh the risks. The rise of the omicron variant and the subsequent increase in excess mortality demonstrated that while vaccines are a key component of the pandemic response, it alone can fail without non-pharmaceutical interventions like masking and social distancing. The pandemic of coronavirus disease has revealed both the strengths and weaknesses of our healthcare system and pandemic preparedness. When the next pandemic arrives, improved risk communication and vaccine development should be prioritized. To enable timely vaccine development, it is essential to make strategic and sufficient investments in vaccine research and development.

[When are antibody determinations in serum before or after vaccination indicated and when not?]. Questions about the usefulness of determining antibody values or titers to demonstrate protection often arise before or after vaccinations in immunization clinics. Such measurements may be useful in exceptional situations, e.g., in immunocompromised patients or those with suspected immunodeficiency, in patients with unknown vaccination status, and in certain defined risk situations (e.g., hepatitisÂ B serology after needlestick injuries or after COVID-19 vaccination in patients with certain forms of immunodeficiency). In contrast, individual serological antibody measurements are neither recommended nor useful after generally recommended vaccinations. This is because either it is known from licensure studies or long-term use that there is aÂ sufficiently high individual probability of protection (e.g., >â€¯99% for tetanus) when the recommended vaccination schedules are adhered to or because the vaccination strategy is primarily aimed at indirect protection of the population and not at protection of each individual person. The few individuals who are not sufficiently protected after vaccination (vaccination failures) will still benefit indirectly from the reduced risk of exposure. This has been demonstrated with oral poliomyelitis vaccination in the 1960s, MMR vaccination since the 1970s, and Hib vaccination since the 1990s. This statement of our committee shows the evidence for aÂ sensible approach, when and which antibody determinations are helpful and meaningful after or before vaccination and which are not. The statement is based on Germany's Standing Committee on Vaccination (STIKO) recommendations and their administration

instructions. We advise not to comply with the wish of some parents for titer determinations in their child that are not medically justified.

Lichen planus after COVID-19 infection and vaccination. Lichen planus (LP) is an inflammatory disorder believed to result from CD8â€‰+â€‰cytotoxic T-cell (CTL)-mediated autoimmune reactions against basal keratinocytes. We present a review of LP following COVID-19 infection and vaccination. Literature searches were conducted on PubMed and Google Scholar from 2019 to 7/2022. 36 articles were selected based on subject relevance, and references within articles were also screened. 39 cases of post-vaccination LP and 6 cases of post-infection LP were found among case reports and case series. 152 cases of post-vaccination LP and 12 cases of post-infection LP were found in retrospective and prospective studies. LP is a rare complication of COVID-19 infection and vaccination that may be mediated by overstimulation of T-cell responses and proinflammatory cytokine production. However, it does not represent a limitation against COVID-19 vaccination, and the benefits of vaccination considerably outweigh the risks.

Vaccine hesitancy prospectively predicts nocebo side-effects following COVID-19 vaccination. The directionality between vaccine hesitancy and COVID-19 vaccine side-effects has not been hitherto examined. We hypothesized a nocebo effect, whereby vaccine hesitancy towards the second Pfizer vaccination dose predicts subsequent side-effects for a booster dose, beyond other effects. We expected these nocebo effects to be driven by (mis)information in malesÂ and prior experience in females. A representative sample of older adults (nâ€‰=â€‰756, mean ageâ€‰=â€‰68.9â€‰Â±â€‰3.43) were questioned in a typical cross-lagged design (wave 1 following a second Pfizer dose, wave 2 after their booster). As hypothesized, earlier vaccine hesitancy predicted subsequent booster side-effects for females (Î²â€‰=â€‰0.10 pâ€‰=â€‰0.025, fâ€‰(2)â€‰=â€‰0.02) and males (Î²â€‰=â€‰0.34, pâ€‰<â€‰0.001, fâ€‰(2)â€‰=â€‰0.16); effects were stronger in males (Ï‡(2)Î” (1)â€‰=â€‰4.34, pâ€‰=â€‰0.03). The (W1-to-W2) side-effect autoregression was stronger in females (Î²â€‰=â€‰.34, pâ€‰<â€‰0.001; males Î²â€‰=â€‰0.18, pâ€‰<â€‰0.001), Ï‡(2)Î” (1)â€‰=â€‰26.86, pâ€‰<â€‰0.001. Results show that a quantifiable and meaningful portion of COVID-19 vaccine side-effects is predicted by vaccine hesitancy, demonstrating that side-effects comprise a psychosomatic nocebo component in vaccinated individuals. The data reveal distinct risk levels for future side-effects, suggesting the need to tailor public health messaging.

COVID Vaccine Hesitancy and Risk of a Traffic Crash. BACKGROUND: Coronavirus disease (COVID) vaccine hesitancy is a reflection of psychology that might also contribute to traffic safety. We tested whether COVID vaccination was associated with the risks of a traffic crash. METHODS: We conducted a population-based longitudinal cohort analysis of adults and determined COVID vaccination status through linkages to individual electronic medical records. Traffic crashes requiring emergency medical care were subsequently identified by multicenter outcome ascertainment of all hospitals in the region over a 1-month follow-up interval (178 separate centers). RESULTS: A total of 11,270,763 individuals were included, of whom 16% had not received a COVID vaccine and 84% had received a COVID vaccine. The cohort accounted for 6682 traffic crashes during follow-up. Unvaccinated individuals accounted for 1682 traffic crashes (25%), equal to a 72% increased relative risk compared with those vaccinated (95% confidence interval, 63-82; P < 0.001). The increased traffic risks among unvaccinated individuals extended to diverse subgroups, was similar to the relative risk associated with sleep apnea, and was equal to a 48% increase after adjustment for age, sex, home location, socioeconomic status, and medical diagnoses (95% confidence interval, 40-57; P < 0.001). The increased risks extended across the spectrum of crash severity, appeared similar for Pfizer, Moderna, or other vaccines, and were validated in supplementary analyses of crossover cases, propensity scores, and additional controls. CONCLUSIONS: These data suggest that COVID vaccine hesitancy is

associated with significant increased risks of a traffic crash. An awareness of these risks might help to encourage more COVID vaccination.

Factors associated with COVID-19 vaccination for patients in an inpatient forensic psychiatric hospital. OBJECTIVE: The aim of this study was to assess factors associated with SARS-CoV-2 (COVID-19) vaccination in patients in 2 inpatient forensic psychiatric hospitals. METHODS: This was a retrospective chart review evaluating factors associated with COVID-19 vaccination for patients residing in two inpatient forensic psychiatric hospitals between January 1, 2021 and February 28, 2022. Data was collected through electronic medical records utilizing MetaCare Enterpriseâ„¢ and secure facility computer drives, individual patient paper charts, and Missouri's vaccination records database, ShowMeVax. Several variables were collected to assess factors associated with COVID-19 vaccination. Additionally, COVID-19 vaccination rates were compared to the influenza vaccination rates at these hospitals. RESULTS: Overall, 229 patients (84.5%) were vaccinated against COVID-19 during or before the study period and 42 (15.5%) were unvaccinated. Patients who were deemed incompetent to stand trial were less likely to receive the COVID-19 vaccine. Those that had a higher body mass index (BMI), were diagnosed with multiple comorbid conditions, not prescribed involuntary medications, were offered incentives, and received the influenza vaccine were more likely to receive the COVID-19 vaccine. Education level, race, sex, age, and being prescribed psychiatric medications did not affect vaccination status. CONCLUSIONS: Patient specific factors should be used when educating and offering COVID-19 vaccines to patients in an inpatient forensic psychiatric unit. Awareness of these results can facilitate targeted interventions for optimal care in a psychiatric population.

The impact of sphingosine-1-phosphate receptor modulators on COVID-19 and SARS-CoV-2 vaccination. BACKGROUND: Sphingosine-one phosphate receptor (S1PR) modulation inhibits S1PR1-mediated lymphocyte migration, lesion formation and positively-impacts on active multiple sclerosis (MS). These S1PR modulatory drugs have different: European Union use restrictions, pharmacokinetics, metabolic profiles and S1PR receptor affinities that may impact MS-management. Importantly, these confer useful properties in dealing with COVID-19, anti-viral drug responses and generating SARS-CoV-2 vaccine responses. OBJECTIVE: To examine the biology and emerging data that potentially underpins immunity to the SARS-CoV-2 virus following natural infection and vaccination and determine how this impinges on the use of current sphingosine-one-phosphate modulators used in the treatment of MS. METHODS: A literature review was performed, and data on infection, vaccination responses; S1PR distribution and functional activity was extracted from regulatory and academic information within the public domain. OBSERVATIONS: Most COVID-19 related information relates to the use of fingolimod. This indicates that continuous S1PR1, S1PR3, S1PR4 and S1PR5 modulation is not associated with a worse prognosis following SARS-CoV-2 infection. Whilst fingolimod use is associated with blunted seroconversion and reduced peripheral T-cell vaccine responses, it appears that people on siponimod, ozanimod and ponesimod exhibit stronger vaccine-responses, which could be related notably to a limited impact on S1PR4 activity. Whilst it is thought that S1PR3 controls B cell function in addition to actions by S1PR1 and S1PR2, this may be species-related effect in rodents that is not yet substantiated in humans, as seen with bradycardia issues. Blunted antibody responses can be related to actions on B and T-cell subsets, germinal centre function and innate-immune biology. Although S1P1R-related functions are seeming central to control of MS and the generation of a fully functional vaccination response; the relative lack of influence on S1PR4-mediated actions on dendritic cells may increase the rate of vaccine-induced seroconversion with the newer generation of S1PR modulators and improve the risk-benefit balance IMPLICATIONS: Although fingolimod is a useful asset in controlling MS, recently-approved S1PR modulators may have beneficial biology related to pharmacokinetics, metabolism and more-

restricted targeting that make it easier to generate infection-control and effective anti-viral responses to SARS-COV-2 and other pathogens. Further studies are warranted.

Safety and immunogenicity of a bivalent SARS-CoV-2 proteinÂ booster vaccine, SCTV01C, in adults previously vaccinated with mRNA vaccine: a randomized, double-blind, placebo-controlled phase 1/2 clinical trial. BACKGROUND: Booster vaccination is an efficient way to address the waning protection of vaccines and immune escape of SARS-CoV-2 variants. We aimed to assess the safety and immunogenicity of SCTV01C, a novel bivalent protein vaccine as a booster for people who previously received two doses of mRNA vaccine. METHODS: In this randomized, phase 1/2 trial, adults fully vaccinated with mRNA vaccines 3-24 month earlier were enrolled. Participants received SCTV01C at 20Â Î¼g, 40Â Î¼g or placebo. The primary endpoints were adverse reactions within 7 days and immunogenicity on Day 28 after vaccination. This trial was registered with ClinicalTrials.gov (NCT05043311). FINDINGS: Between January 27 and April 28, 2022, 234 adults were randomly assigned to receive SCTV01C or placebo. The most common solicited adverse events (AEs) were Grade 1 injection-site pain (10.7%) and pyrexia (6.3%). There were no reports of Grade 3 or above solicited AE, serious AEs or AEs of special interests. On Day 28 post the booster, the geometric mean concentrations (GMCs) of the specific binding IgG antibodies to spike protein for placebo, 20Â Î¼g and 40Â Î¼g SCTV01C were 1649, 4153 and 5354 BAU/mL, with fold of increase from baseline of 1.0, 2.8 and 3.4-fold, respectively. GMTs of neutralizing antibodies against live Delta variant were 1280, 3542, and 4112, with fold of increase of 1.1, 3.9 and 4.1-fold, respectively; GMTs of neutralizing antibodies against live Omicron variant were 218, 640, and 1083, with fold of increase of 1.1, 4.4 and 5.1-fold, respectively. Participants with low neutralizing antibody titers at baseline (below the lower limit of quantitation) had 64.0 and 49.4-fold of increase in GMTs for Delta and Omicron, respectively. INTERPRETATION: The heterologous booster of SCTV01C was safe, and induced uniformly high cross-neutralization antibody responses against Delta and Omicron variants. FUNDING: Beijing Science and Technology Plan Project (Z221100007922012) and the National Key Research and Development Program of China (2022YFC0870600) supported this study.

Primary and booster vaccination in reducing severe clinical outcomes associated with Omicron NaÃ¯ve infection. BACKGROUND: Little is known about long-term effectiveness of COVID-19 vaccine in reducing severity and deaths associated with Omicron VOC not perturbed by prior infection and independent of oral anti-viral therapy and non-pharmaceutical (NPI). METHODS: A retrospective observational cohort study was applied to Taiwan community during the unprecedent large-scale outbreaks of Omicron BA.2 between April and August, 2022. Primary vaccination since March, 2021 and booster vaccination since January, 2022 were offered on population level. Oral Anti-viral therapy was also offered as of mid-May 2022. The population-based effectiveness of vaccination in reducing the risk of moderate and severe cases of and death from Omicron BA.2 with the consideration of NPI and oral anti-viral therapy were assessed by using Bayesian hierarchical models. RESULTS: The risks of three clinical outcomes associated with Omicron VOC infection were lowest for booster vaccination, followed by primary vaccination, and highest for incomplete vaccination with the consistent trends of being at increased risk for three outcomes from the young people aged 12 years or below until the elderly people aged 75 years or older with 7 age groups. Before the period using oral anti-viral therapy, complete primary vaccination with the duration more than 9 months before outbreaks conferred the statistically significant 47 % (23-64 %) reduction of death, 48 % (30-61 %) of severe disease, and 46 % (95 % CI: 37-54 %) of moderate disease after adjusting for 10-20 % independent effect of NPI. The benefits of booster vaccination within three months were further enhanced to 76 % (95 % CI: 67-86 %), 74 % (95 % CI: 67-80 %), and 61 % (95 % CI: 56-65 %) for three corresponding outcomes. The additional effectiveness of oral anti-viral therapy in reducing moderate disease was 13 % for the booster group and 5.8 % for primary vaccination. CONCLUSIONS: We corroborated

population effectiveness of primary vaccination and its booster vaccination, independent of oral anti-viral therapy and NPI, in reducing severe clinical outcomes associated with Omicron BA.2 naÃ¨ve infection population.
The Prevalence, Features, Influencing Factors, and Solutions for COVID-19 Vaccine Misinformation: Systematic Review. BACKGROUND: During the COVID-19 pandemic, infodemic spread even more rapidly than the pandemic itself. The COVID-19 vaccine hesitancy has been prevalent worldwide and hindered pandemic exiting strategies. Misinformation around COVID-19 vaccines is a vital contributor to vaccine hesitancy. However, no evidence systematically summarized COVID-19 vaccine misinformation. OBJECTIVE: This review aims to synthesize the global evidence on misinformation related to COVID-19 vaccines, including its prevalence, features, influencing factors, impacts, and solutions for combating misinformation. METHODS: We performed a systematic review by searching 5 peer-reviewed databases (PubMed, Embase, Web of Science, Scopus, and EBSCO). We included original articles that investigated misinformation related to COVID-19 vaccines and were published in English from January 1, 2020, to August 18, 2022. We excluded publications that did not cover or focus on COVID-19 vaccine misinformation. The Appraisal tool for Cross-Sectional Studies, version 2 of the Cochrane risk-of-bias tool for randomized trials (RoB 2), and Critical Appraisal Skills Programme Checklist were used to assess the study quality. The review was guided by PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) and registered with PROSPERO (CRD42021288929). RESULTS: Of the 8864 studies identified, 91 observational studies and 11 interventional studies met the inclusion criteria. Misinformation around COVID-19 vaccines covered conspiracy, concerns on vaccine safety and efficacy, no need for vaccines, morality, liberty, and humor. Conspiracy and safety concerns were the most prevalent misinformation. There was a great variation in misinformation prevalence, noted among 2.5%-55.4% in the general population and 6.0%-96.7% in the antivaccine/vaccine hesitant groups from survey-based studies, and in 0.1%-41.3% on general online data and 0.5%-56% on antivaccine/vaccine hesitant data from internet-based studies. Younger age, lower education and economic status, right-wing and conservative ideology, and having psychological problems enhanced beliefs in misinformation. The content, format, and source of misinformation influenced its spread. A 5-step framework was proposed to address vaccine-related misinformation, including identifying misinformation, regulating producers and distributors, cutting production and distribution, supporting target audiences, and disseminating trustworthy information. The debunking messages/videos were found to be effective in several experimental studies. CONCLUSIONS: Our review provides comprehensive and up-to-date evidence on COVID-19 vaccine misinformation and helps responses to vaccine infodemic in future pandemics. TRIAL REGISTRATION: PROSPERO CRD42021288929; https://tinyurl.com/2prejtfa.
COVID-19 vaccine short-term adverse events in the real-life family practice in Krakow, Poland. BACKGROUND: In manufacturers' trials, vaccination against COVID-19 proved to be safe and effective. The officially reported frequency of vaccine adverse events (VAEs) in Poland is lower than that declared by the manufacturers. The anti-vaccination activists questioned the trustworthiness of official data. OBJECTIVES: The aim was to explore the real-life prevalence of VAEs in general practice settings and the factors that may influence it. METHODS: In this pragmatic, mixed prospective and retrospective study, patients vaccinated against COVID-19 between May and October 2021 in three GP practices in Krakow, Poland, were enrolled. Their demographic (age, sex, level of education) and clinical data (weight and height, smoking status, history of allergies, COVID-19 and chronic diseases) were collected. Then, they were interviewed about VAEs they experienced. RESULTS: Out of 1530 patients invited to participate, 1051 (69%) agreed and were eligible for analyses. Only 8.8% did not report any VAE. Pain at the injection site was the most frequently reported reaction (800, 76.2%). The most prevalent systemic ones were excessive fatigue/lethargy (527, 50.6%), sleep/circadian rhythm

disturbances (433, 41.6%) and headache (399, 38.3%). Fifty required medical assistance - 39 experienced presyncope (3.7%) and 11 loss of consciousness (1.1%). Only two others were hospitalised. Females, younger adults, those with higher education and with a history of COVID-19 reported systemic VAEs more frequently, while those who were older and obese were less likely to report local reactions. CONCLUSION: Although more than 90% of patients vaccinated against COVID-19 in general practice settings may experience VAEs, in short-term observation, the vast majority are localised and mild.

Myopericarditis After COVID-19 mRNA Vaccination Among Adolescents and Young Adults: A Systematic Review and Meta-analysis. IMPORTANCE: Published data on COVID-19 mRNA vaccine-associated myopericarditis in adolescents and young adults have been derived from small case series, national population-based studies, or passive reporting systems. Pooled evidence from a larger, international cohort is scarce. OBJECTIVE: To investigate the clinical features and early outcomes associated with myopericarditis after COVID-19 mRNA vaccination in a heterogeneous population of adolescents and young adults. DATA SOURCES: PubMed and EMBASE were searched through August 2022. Language restrictions were not applied. STUDY SELECTION: Observational studies and case series describing COVID-19 vaccine-associated myopericarditis in adolescents and young adults aged 12 to 20 years and reporting clinical characteristics and early outcomes were included. DATA EXTRACTION AND SYNTHESIS: Two independent investigators extracted relevant data from each study. One-group meta-analysis in a random effects model was performed. The Preferred Reporting Items for Systematic Reviews and Meta-analysis and Meta-analysis of Observational Studies in Epidemiology reporting guidelines were followed. MAIN OUTCOMES AND MEASURES: The primary outcomes were clinical features and early outcomes for COVID-19 mRNA vaccine-associated myopericarditis, including incident rate, cardiac findings, hospitalization, intensive care unit (ICU) admission, and in-hospital mortality. RESULTS: A total of 23 observational studies were identified, including 854 individuals (mean age, 15.9 [95% CI, 15.5-16.2] years) with COVID-19 vaccine-associated myopericarditis. Male sex was predominant, at 90.3% (95% CI, 87.3%-93.2%) of individuals. The incident rate was higher after the second dose than the first dose, with 74.4% (95% CI, 58.2%-90.5%) of events occurring after the second dose. Most patients (84.4% [95% CI, 80.5%-88.3%] of patients) had preserved left ventricular (LV) function. Of the 15.6% (95% CI, 11.7%-19.5%) of patients with LV systolic dysfunction (LV ejection fraction [LVEF] <55%), most (14.1% [95% CI, 10.2%-18.1%]) were mild (ie, LVEF 45%-54%), and only 1.3% (95% CI, 0%-2.6%) of patients had severe LV systolic dysfunction (ie, LVEF<35%). Interestingly, cardiac magnetic resonance imaging revealed late gadolinium enhancement in 87.2% (95% CI, 79.8%-94.7%) of patients. Although 92.6% (95% CI, 87.8%-97.3%) of patients were hospitalized and 23.2% (95% CI, 11.7%-34.7%) of patients required ICU admission, inotropes were used in only 1.3% (95% CI, 0%-2.7%) of patients, no patients died or required mechanical support, and the hospital length of stay was 2.8 (95% CI, 2.1-3.5) days. CONCLUSIONS AND RELEVANCE: This systematic review and meta-analysis found low incidence rate and largely favorable early outcomes of COVID-19 mRNA vaccine-associated myopericarditis in adolescents and young adults from a wide range of populations. These findings are reassuring but continued follow-up is warranted.

Impact of COVID-19 and effects of BNT162b2 on patient-reported outcomes: quality of life, symptoms, and work productivity among US adult outpatients. BACKGROUND: Although there is extensive literature on the clinical benefits of COVID-19 vaccination, data on humanistic effects are limited. This study evaluated the impact of SARS-CoV-2 infection on symptoms, Health-Related Quality of Life (HRQoL) and Work Productivity and Impairment (WPAI) prior to and one month following infection between individuals vaccinated with BNT162b2 and those unvaccinated. METHODS: Subjects withâ€‰â‰¥â€‰1 self-reported symptom and positive RT-PCR for SARS-CoV-2

at CVS Health US test sites were recruited between 01/31/2022 and 04/30/2022. Socio-demographics, clinical characteristics and vaccination status were evaluated. Self-reported symptoms, HRQoL, and WPAI outcomes were assessed using questionnaires and validated instruments (EQ-5D-5L, WPAI-GH) across acute COVID time points from pre-COVID to Week 4, and between vaccination groups. Mixed models for repeated measures were conducted for multivariable analyses, adjusting for several covariates. Effect size (ES) of Cohen's d was calculated to quantify the magnitude of outcome changes within and between vaccination groups. RESULTS: The study population included 430 subjects: 197 unvaccinated and 233 vaccinated with BNT162b2. Mean (SD) age was 42.4Â years (14.3), 76.0% were female, 38.8% reported prior infection and 24.2% at least one comorbidity. Statistically significant differences in outcomes were observed compared with baseline and between groups. The EQ-Visual analogue scale scores and Utility Index dropped in both cohorts at Day 3 and increased by Week 4 but did not return to pre-COVID levels. The mean changes were statistically lower in the BNT162b2 cohort at Day 3 and Week 4. The BNT162b2 cohort reported lower prevalence and fewer symptoms at index date and Week 4. At Week 1, COVID-19 had a large impact on all WPAI-GH domains: the work productivity time loss among unvaccinated and vaccinated was 65.0% and 53.8%, and the mean activity impairment was 50.2% and 43.9%, respectively. Except for absenteeism at Week 4, the BNT162b2 cohort was associated with statistically significant less worsening in all WPAI-GH scores at both Week 1 and 4. CONCLUSIONS: COVID-19 negatively impacted HRQoL and work productivity among mildly symptomatic outpatients. Compared with unvaccinated, those vaccinated with BNT162b2 were less impacted by COVID-19 infection and recovered faster.
Real-world data on primary cutaneous lymphoproliferative disorders following SARS-CoV-2 vaccination: A multicentre experience from tertiary referral hospitals.
Linear IgA bullous dermatosis after COVID-19 vaccination.
Post SARS-CoV-2 vaccination effluvium.
'Wine Glass' sign following COVID-19 vaccination in a previously healthy adult.
Bilateral subscapular hematoma following SARS-CoV-2 vaccination.
Prospective longitudinal analysis of antibody response after standard and booster doses of SARS-COV2 vaccination in patients with early breast cancer. INTRODUCTION: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and its variants brought waves of pandemics with breakthrough infections in vaccinated individuals. We analyzed the antibody responses after primary and booster vaccination in healthy controls (HC) and patients with early breast cancer (BC). METHODS: In this prospective longitudinal cohort study, the binding activity of serum antibody level against spike proteins and antigens of SARS-CoV-2 variants was measured within 21 days after each vaccination in the BC group and HC group. RESULTS: All participants, 40 in the BC and 20 in the HC group, had increased antibody response after vaccination. BC group, however, had weaker humoral responses than the HC group (IgG: 1.5, 2.3, 2.5-folds in BC vs. 1.9, 3.6, 4.0-folds in HC after each dose; IgA: 2.1, 3.0, 3.6-folds in BC vs. 4.2, 10.4, 5.2-folds in HC after each dose, respectively). Those under concurrent cytotoxic chemotherapy had weaker antibody response than the non-cytotoxic treatment group and HC. Adjunct use of steroids and age were not significant risk factors. The levels of binding antibody against the Delta and the Omicron (BA1) variants were lower than the wild-type, especially in BC. CONCLUSION: In the waves of new sub-variants, our study suggests that an additional dose of vaccinations should be recommended according to the anti-cancer treatment modality in patients with BC who had received booster vaccination.
Differentially induced immunity in buccal and nasal mucosae after vaccination for SARS-CoV-2: Prospects for mass scale immunity-screening in large populations. INTRODUCTION: Humoral immunity after SARS-CoV-2 vaccination has been extensively investigated in blood. Aim of this study

was to develop an ELISA method in order to determine the prevalence of IgG and IgA SARS-CoV-2 domain 1 spike-protein (S) specific antibodies (Abs) in buccal and nasal mucosal surfaces of vaccinees. METHODS: To this end, we analyzed 69 individuals who received their first vaccine dose between February and July 2021. Vaccines administered were BNT162b2, mRNA-1273 or ChAdOx1-nCoV-19. Detection of IgG and IgA Abs was performed using commercial ELISA kits for both blood and swab samples after protocol modification for the latter. RESULTS: Anti-spike IgG and IgA Abs in the buccal and/or nasal swabs were detectable in >81% of the study subjects after the second dose. The IgG measurements in buccal swabs appeared to correlate in a more consistent way with the respective measurements in blood with a correlation coefficient of r=0.74. It is of note that IgA Abs appeared to be significantly more prevalent in the nasal compared to the buccal mucosa. Optimal selection of the assay cut-off for the IgG antibody detection in buccal swabs conferred a sensitivity of 91.8% and a specificity of 100%. Last, individuals vaccinated with mRNA-based vaccines exhibited higher antibody levels in both blood and mucosal surfaces compared to those receiving ChAdOx1-nCoV-19 confirming previously reported results. CONCLUSION: In conclusion, our findings show a differential prevalence of anti-S Abs on mucosal surfaces after vaccination for SARS-CoV-2, while they also set the basis for potential future use of IgG antibody detection in buccal swabs for extended immunity screening in large populations.

Knowledge, attitude, acceptance, and practice of COVID-19 vaccination and associated factors complemented with constructs of health belief model among the general public in South Gondar, Ethiopia: A community-based study. INTRODUCTION: Understanding the epidemiological dynamics of disease control, as well as the effectiveness, compliance, and success of the vaccination program requires an understanding of the local population's knowledge, attitude, and practice regarding the Corona Virus Disease of 2019 (COVID-19) vaccine. Thus, the objective of this study was to assess knowledge, attitude, and practice toward COVID-19 vaccination and associated factors among the general public. METHODS: A cross-sectional study was conducted in the South Gondar Zone, among residents above the age of 18 years. The study used objective measures and the constructs of the Health Belief Model. Binary logistic regression was used and the result of the final model was presented in terms of adjusted odds ratio (AOR) and 95% confidence intervals (CI), and statistical significance was taken and considered at a P-value < 0.05. RESULTS: The study was conducted on 1,111 study participants. The mean age is 30.83 Â± 7.106. About 575 (51.8%) of the respondents have good knowledge about the COVID-19 vaccination and 43.4% have a positive attitude toward COVID-19 vaccination. About 361 (32.5%) of the respondents were willing to take the vaccine if it is available and 113 (10.2%) of them were vaccinated. Participants with a positive attitude and good knowledge, those with a secondary level of education AOR = 5.70, 95% CI (2.60-12.60), those with a monthly income of >2,000 birr AOR = 6.30, 95% CI (2.50-15.60), those having a television (TV), and those who use Facebook AOR = 17.70, 95% CI (10.10-30.90) had a higher level of acceptance of COVID-19 vaccination. The Health Belief Model's constructs of perceived susceptibility AOR = 1.53, 95% CI (1.26-1.85), perceived benefit AOR = 1.49, 95% CI (1.28-1.75), and cues to action AOR = 0.54, 95% CI (0.45-0.65) were all linked to COVID-19 vaccine acceptability. CONCLUSION: The level of acceptance of COVID-19 vaccination is much lower. Having a positive attitude score and good knowledge score, level of education, monthly income, presence of TV, the use of Facebook, and knowing the means of transmission of COVID-19 increase the level of acceptance of COVID-19 vaccination.

Localized eczematous rash affecting left and right regions of breast and shoulder after Ad26.COV2.S vaccine against COVID-19 in aÂ 30-year-old woman with comorbidities.

Autoimmune Hepatitis Following mRNA COVID-19 Vaccination in a Very Old Patient With Preexisting SjÃ¶gren's Syndrome: A Case Report. A case of autoimmune hepatitis (AIH) following COVID-

19Â vaccination in a very old patient is presented. An 85-year-old womanÂ who had preexisting SjÃ¶gren's syndrome (SS)Â but had never shown evidence of liver diseaseÂ was admitted to our hospital due to jaundice and liver dysfunction. Further laboratory tests, imaging studies, and liver histology proved this to be a case of definite AIH. Eight weeks before the disease onset, she had received the second dose of mRNA COVID-19 vaccination. To our knowledge, this is the first case of AIH following COVID-19 vaccination in a patient with a history of SS.

Pituitary apoplexy and COVID-19 vaccination: a case report and literature review. A 50-year-old man was admitted to our hospital for vomit, nausea, diplopia, and headache resistant to analgesic drugs. Symptoms started the day after his third COVID-19 mRNA vaccine (Moderna) whereas SARS-CoV-2 nasal swab was negative. Pituitary MRI showed recent bleeding in macroadenoma, consistent with pituitary apoplexy. Adverse Drug Reaction was reported to AIFA (Italian Medicines Agency).A stress dexamethasone dose was administered due to the risk of adrenal insufficiency and to reduce oedema. Biochemistry showed secondary hypogonadism; inflammatory markers were elevated as well as white blood cells count, fibrinogen and D-dimer. Pituitary tumour transsphenoidal resection was performed and pathology report was consistent with pituitary adenoma with focal haemorrhage and necrosis; we found immunohistochemical evidence for SARS-CoV-2 proteins next to pituitary capillaries, in the presence of an evident lymphocyte infiltrate.Few cases of pituitary apoplexy after COVID-19 vaccination and infection have been reported. Several hypotheses have been suggested to explain this clinical picture, including cross-reactivity between SARS-CoV-2 and pituitary proteins, COVID-19-associated coagulopathy, infection-driven acutely increased pituitary blood demand, anti-Platelet Factor 4/heparin antibodies development after vaccine administration. Ours is the first case of SARS-CoV-2 evidence in pituitary tissue, suggesting that endothelial infection of pituitary capillaries could be present before vaccination, possibly due to a previous asymptomatic SARS-CoV-2 infection. Our case underlines that SARS-CoV-2 can associate with apoplexy by penetrating the central nervous system, even in cases of negative nasal swab. Patients with pituitary tumours may develop pituitary apoplexy after exposure to SARS-CoV-2, therefore clinicians should be aware of this risk.

Anti-GBM Disease after Oxford-AstraZeneca ChAdOx1 nCoV-19 Vaccination: A Report of Two Cases. There have been reports of rare de novo glomerular diseases following vaccination for coronavirus disease 2019 (COVID-19). We report two cases of anti-glomerular basement membrane (GBM) disease in previously healthy females after Oxford-AstraZeneca COVID-19 vaccine (ChAdOx1 nCoV-19). The first case was a 69-year-old female who developed lethargy and anuria approximately 8 weeks after her first dose of Oxford-AstraZeneca COVID-19 vaccine. The second case was a 72-year-old female who developed malaise and diarrhoea approximately 3 weeks after her second dose of Oxford-AstraZeneca COVID-19 vaccine. Both cases had severe acute kidney injury, raised anti-GBM antibody titres, and renal biopsies consistent with anti-GBM disease. Both cases were commenced on haemodialysis and treated with high dose glucocorticoids, cyclophosphamide, and plasmapheresis. Neither patient had recovery of renal function, and both remain dialysis dependent. These cases add to the previously reported cases of anti-GBM disease after mRNA COVID-19 vaccination. As more COVID-19 vaccinations are administered worldwide, it would be important for clinicians to be aware of this possible association, and continued surveillance is warranted.

Infection of healthcare workers despite a high vaccination rate during the fifth wave of COVID-19 due to Omicron variant in Hong Kong. BACKGROUND: No nosocomial infection was recorded in our healthcare workers (HCWs) during the early phase of the coronavirus disease 2019 (COVID-19) pandemic. With the emergence of the Omicron variant of increased transmissibility, infection in HCWs occurred as expected. We aimed to study the epidemiology of infection in HCWs and to describe the infection control measures during the outbreak of the Omicron variant. METHODS: With daily rapid antigen testing and molecular confirmation test for COVID-19, infected HCWs were

interviewed by infection control nurses (ICNs) to investigate the potential source of infection. The epidemiology of COVID-19 in Hong Kong served as reference. RESULTS: During the fifth wave of COVID-19 (31 December 2021 to 31 May 2022), 1,200,068 cases were reported (incidence 95 times higher than in preceding waves in Hong Kong; 162,103 vs 1,707 per million population respectively, P<0.001). The proportion of infected HCWs was significantly higher than that of the general population (24.9%, 1,607/6,452 vs 16.2%, 1,200,068/7,403,100 respectively; P<0.01). The proportion of infected non-clinical staff was significantly higher than that of clinical staff (31.8%, 536/1,687 vs 22.5%, 1,071/4,765 respectively; P<0.001). Of 82.8% (1,330/1,607) infected HCWs interviewed by ICNs, 99.5% (1,324/1,330) had been fully vaccinated; 49.5% (659/1,330) had no identifiable source; 40.7% (541/1,330) were probably infected from household members; 9.8% (130/1,330) had possible exposure to confirmed patients or HCWs, but no lapse in infection control measures or inappropriate use of personal protective equipment was recalled. CONCLUSION: Omicron variant is highly transmissible such that breakthrough infection occurred despite high level of vaccination.
Functionally impaired antibody response to BNT162b2 booster vaccination in CVID IgG responders. BACKGROUND: Although previous studies described the production of IgG antibodies in a subgroup of patients with common variable immunodeficiency (CVID) following messenger RNA vaccinations with BNT162b2 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (CVID responders), the functionality of these antibodies in terms of avidity as measured by the dissociation rate constant (k(dis)) and the antibody response to booster immunization has not been studied. OBJECTIVE: We sought to analyze in CVID responders and healthy individuals, the avidity of anti-SARS-CoV-2 serum antibodies and their neutralization capacity as measured by surrogate virus-neutralizing antibodies in addition to IgG-, IgM-, and IgA-antibody levels and the response of circulating (peripheral blood) follicular T-helper cells after a third vaccination with BNT162b2 SARS-CoV-2 messenger RNA vaccine. METHODS: Binding IgG, IgA, and IgM serum levels were analyzed by ELISA in patients with CVID responding to the primary vaccination (CVID responders, nÂ = 10) and healthy controls (nÂ = 41). The binding avidity of anti-spike antibodies was investigated using biolayer interferometry in combination with biotin-labeled receptor-binding-domain of SARS-CoV-2 spike protein and streptavidin-labeled sensors. Antigen-specific recall T-cell responses were assessed by measuring activation-induced markers by flow cytometry. RESULTS: After the third vaccination with BNT162b2, IgG-, IgM-, and IgA-antibody levels, surrogate virus-neutralizing antibody levels, and antibody avidity were lower in CVID responders than in healthy controls. In contrast, anti-SARS-CoV-2 spike protein avidity was comparable in CVID responders and healthy individuals following primary vaccination. Follicular T-helper cell response to booster vaccination in CVID responders was significantly reduced when compared with that in healthy individuals. CONCLUSIONS: Impaired affinity maturation during booster response provides new insight into CVID pathophysiology.
Leukocytoclastic Vasculitis and SARS-COV-2 Vaccination.
SARS-CoV-2 vaccine booster elicits robust prolonged maternal antibody responses and passive transfer to the offspring via the placenta and breastmilk.
Thrombosis with thrombocytopenia after vaccination with the ChAdOx1 nCoV-19 vaccine (Oxford-AstraZeneca): implications of gender-specific tissue-factor gene polymorphisms?
Safety and immunogenicity of an inactivated whole virion SARS-CoV-2 vaccine, TURKOVAC, in healthy adults: Interim results from randomised, double-blind, placebo-controlled phase 1 and 2 trials. BACKGROUND: Development of safe and effective vaccine options is crucial to the success of fight against COVID-19 pandemic. Herein, we report interim safety and immunogenicity findings of the phase 1&2 trials of ERUCoV-VAC, an inactivated whole virion SARS-CoV-2 vaccine. METHODS: Double-blind, randomised, single centre, phase 1 and 2 trials included SARS-CoV-2 seronegative healthy adults aged 18-55 years (18-64 in phase 2). All participants, except the first 4 in phase 1 who received

ERUCoV-VAC 3 Î¼g or 6 Î¼g unblinded and monitored for 7 days for safety purposes, were assigned to receive two intramuscular doses of ERUCoV-VAC 3 Î¼g or 6 Î¼g (an inactivated vaccine containing alhydrogel as adjuvant) or placebo 21 days apart (28 days in phase 2) according to computer-generated randomisation schemes. Both trials are registered at ClinicalTrials.gov (phase 1, NCT04691947 and phase 2, NCT04824391). RESULTS: Forty-four participants (3 Î¼g [n:17], 6 Î¼g [n:17], placebo [n:10]) in phase 1 and 250 (3 Î¼g [n:100], 6 Î¼g [n:100], placebo [n:50]) in phase 2 received â‰¥1 dose. In phase 1 trial, 25 adverse events AEs (80â€¯% mild) occured in 15 participants (34.1â€¯%) until day 43. There was no dose-response relationship noted in safety events in ERUCoV-VAC recipients (pâ€¯=â€¯0.4905). Pain at injection site was the most common AE (9/44;20.5â€¯%). Both doses of ERUCoV-VAC 3 Î¼g and 6 Î¼g groups were comparable in inducing SARS-CoV-2 wild-type neutralising antibody (MNT50): GMTs (95â€¯%CI) were 8.3 (6.4-10.3) vs. 8.6 (7.0-10.2) at day 43 (pâ€¯=â€¯0.7357) and 9.7 (6.0-13.4) vs. 10.8 (8.8-12.8) at day 60 (pâ€¯=â€¯0.8644), respectively. FRNT50 confirmed MNT50 results: SARS-CoV-2 wild-type neutralising antibody GMTs (95â€¯%CI) were 8.4 (6.3-10.5) vs. 9.0 (7.2-10.8) at day 43 (pâ€¯=â€¯0.5393) and 11.0 (7.0-14.9) vs. 12.3 (10.3-14.5) at day 60 (pâ€¯=â€¯0.8578). Neutralising antibody seroconversion rates (95â€¯%CI) were 86.7â€¯% (59.5-98.3) vs 94.1â€¯% (71.3-99.8) at day 43 (pâ€¯=â€¯0.8727) and 92.8â€¯% (66.1-99.8) vs. 100â€¯% (79.4-100.0) at day 60 (pâ€¯=â€¯0.8873), in ERUCoV-VAC 3 Î¼g and 6 Î¼g groups, respectively. In phase 2 trial, 268 AEs, (67.2â€¯% moderate in severity) occured in 153 (61.2â€¯%) participants. The most common local and systemic AEs were pain at injection site (23 events in 21 [8.4â€¯%] subjects) and headache (56 events in 47 [18.8â€¯%] subjects), respectively. Pain at injection site was the only AE with a significantly higher frequency in the ERUCoV-VAC groups than in the placebo arm in the phase 2 study (pâ€¯=â€¯0.0322). ERUCoV-VAC groups were comparable in frequency of AEs (pâ€¯=â€¯0.4587). ERUCoV-VAC 3 Î¼g and 6 Î¼g groups were comparable neutralising antibody (MNT(50)): GMTs (95â€¯%CI) were 30.0 (37.9-22.0) vs. 34.9 (47.6-22.1) at day 43 (pâ€¯=â€¯0.0666) and 34.2 (23.8-44.5) and 39.6 (22.7-58.0) at day 60, (pâ€¯=â€¯0.2166), respectively. FRNT50 confirmed MNT50 results: SARS-CoV-2 wildtype neutralising antibody GMTs were 28.9 (20.0-37.7) and 30.1 (18.5-41.6) at day 43 (pâ€¯=â€¯0.3366) and 34.2 (23.8-44.5) and 39.6 (22.7-58.0) at day 60 (pâ€¯=â€¯0.8777). Neutralising antibody seroconversion rates (95â€¯%CI) were 95.7â€¯% (91.4-99.8) vs. 98.9â€¯% (96.9-100.0) at day 43 (pâ€¯=â€¯0.8710) and 96.6â€¯% (92.8-100.0) vs 98.9â€¯% (96.7-100.0) at day 60 (pâ€¯=â€¯0.9129) in ERUCoV-VAC 3 Î¼g and 6 Î¼g groups, respectively. CONCLUSIONS: Two-dose regimens of ERUCoV-VAC 3 Î¼g and 6 Î¼g 28 days both had an acceptable safety and tolerability profile and elicited comparable neutralising antibody responses and seroconversion rates exceeding 95â€¯% at day 43 and 60 after the first vaccination. Data availability Data will be made available on request.

An observational study of adverse drug reactions to COVID-19 vaccines reported to the New Mexico poison center hotline. INTRODUCTION: Post-marketing data on coronavirus vaccines are limited. This study evaluated adverse reactions reported to a statewide hotline after the administration of a coronavirus disease-2019 (COVID-19) vaccine. METHODS: We collected reports between 1 December 2020 through 30 August 2021 of any individual 12â€‰years of age and older who received an FDA EUA-approved vaccine and experienced an adverse reaction. For each case, we collected vaccine brand, demographics, adverse reaction type, severity, onset of reaction, duration, and outcome. Relative risk analyses were conducted to investigate factors associated with vaccine adverse reactions. RESULTS: 638 adverse drug reaction cases were recorded. The majority identified as female (70.8%) and the median age was 56. Implicated brands were Pfizer BNT162b2 (46.6%), Moderna mRNA-1273 (43.41%), and Janssen Ad26.COV2.S (8.78%). Although the lowest number of cases was with Janssen, this vaccine had the highest incident rate based on reactions per 100,000 doses. Adverse reactions with the highest incidence were systemic reactions (92.7%), injection-site reactions

(8.5%), and local non-injection-site reactions (10.4%), with most judged as minor severity. Relative risk was higher for Moderna compared to Pfizer for injection-site non-severe (RR 2.01) and injection-site severe (RR 1.94) reactions. Janssen had a higher risk of headache, dyspnea, and vision changes compared to Pfizer, and a higher risk of headache compared to Moderna. The relative risk for fever, chills, and lymphadenopathy was higher for the second dose than the first dose for all patients. CONCLUSION: This observational study analyzing adverse drug reactions of the COVID-19 vaccine found that most complaints concerned systemic reactions. We found reaction differences among vaccine brands, between first and second doses for some effects, and selected recurrent events. Poison control centers are uniquely positioned to conduct post-marketing surveillance for the new vaccines as they are available 24/7 to the public and are healthcare providers. Further post-marketing studies are essential to provide a holistic safety profile of COVID-19 vaccines.

[Investigation of the Relationship Between the Immune Responses due to COVID-19 Vaccine and Peripheral Bloodlymphocyte Subtypes of Healthcare Workers]. Worldwide vaccination is the best strategy to limit the Coronavirus disease-2019 (COVID-19) pandemic. The aim of this study was to investigate the antibody levels and hemogram parameters and the prediction of T-helper, T-cytotoxic and B lymphocyte subtypes in the peripheral blood for the development of these antibodies in the selected group of healthcare workers who were vaccinated with CoronaVacÂ® (Sinovac, China). In a previous study with the same researchers, blood samples were taken from healthcare workers one month after the second vaccination, and anti-RBD anti-severe acute respiratory syndrome coronavirus-2 (anti-SARS-CoV-2) IgG antibodies were measured by enzyme linked immunosorbent assay (ELISA) method. Test results were classified as binding antibody <25.6 BAU/mL unresponsive, 25.6-35.1 BAU/mL weak response, <35.2 BAU/mL strong response, according to the assay manufacturer's recommendations. According to these criteria, it was determined that 22 (8.3%) people had no response, 25 (9.5%) people had a moderate response, and 217 (82.2%) people had a strong response. According to these results, 30 people from each group were invited. The results of three individuals were excluded from the evaluation due to chronic illness. A total of 87 health workers were included in the study. Twenty-two of these people had no response, 25 had a moderate response, and 40 had a good response. Flow cytometry was used to examine the peripheral blood lymphocyte percentage distribution. Statistical analyzes were performed with SPSS 26 software. The conformity of the variables to the normal distribution was examined using analytical methods (Kolmogorov-Smirnov/ Shapiro-Wilk tests). Pearson's Chi-square test was used to compare categorical variables. The correlation between the antibody level and the measurement results of hemogram parameters and lymphocyte indicators was evaluated by Pearson's correlation analysis. The model was established by performing linear regression analysis with the variables correlated with the antibody level. Cases with a p value below 0.05 were considered statistically significant. The age range of the participants in the study was 22-69. The mean age was 45.5 Â± 10.4 years. Antibodies against SARS-CoV-2 virus were detected by ELISA method in 65 (74.7%) of the healthcare professionals, while no antibodies were detected in 22 (25.3%) of them. Lymphocyte count (p= 0.002), CD3 count (p= 0.0004), CD4 count (p= 0.0001), CD3/CD19 ratio (p= 0.011), CD4 percentage (p= 0.004) in the antibody positive group was found to be significant. According to the level of correlation between antibody level and lymphocyte indicators, a statistically significant negative correlation was found in CD3, CD4, CD8 and CD19 positive lymphocytes, respectively, and the best correlation was observed in CD3 positive lymphocytes. The formula f (Antibody level)= y= 358002 -0.176 x CD3 + 0.469 x CD19 was created using the linear regression model. In the light of the data of this study, the central role of T and B cells in COVID-19 immunization emerges. The vaccine-related antibody level-related formula may be useful for healthcare professionals in patient follow-up. It is thought that

conducting vaccine related immune response studies involving larger populations will contribute more to the literature.

[Comparison of Two Different Quantitative Tests for Anti-Spike Measurement After Two Doses of Inactivated SARS-CoV-2 Vaccine in Healthcare Professionals]. Serological tests developed to detect antibodies against severe acute respiratory syndrome Coronavirus disease-2 (SARS-CoV-2) antigens are used to demonstrate immunity level, vaccine efficacy and duration of protection. However, the evaluation of these tests and the interpretation of the results are still under investigation. In this study, it was aimed to compare the anti-spike measurement values in healthcare workers who have not experienced Coronavirus-2019 (COVID-19) after vaccination with two doses of inactivated SARS-CoV-2 vaccine with two commercial quantitative antibody detection tests which were used to give results in the same unit and work with different methods. The results obtained with Elecys Anti-SARS-CoV-2 S (Roche Diagnostics, Mannheim, Germany) and Aeskulisa Anti-SARS-CoV-2 S1 (Aesku diagnostics, Wendelsheim, Germany) kits of the serum samples of 90 healthcare workers were evaluated qualitatively and quantitatively in line with the recommendations of both manufacturers. Quantitative values given as units/mL (U/mL) were also evaluated by converting the binding antibody unit (BAU)/mL with the conversion factor obtained as a result of the studies carried out by the manufacturers with the World Health Organization anti-SARS-CoV-2 international standard. Positive results were obtained in 86 (95.6%) samples and negative results in 4 (4.4%) samples with the Elecsys kit; 55 (61.1%) positive, 20 (22.2%) negative and 15 (16.7%) intermediate results were obtained with the Aeskulisa kit. In common with both kits, negative results were obtained in four samples, and positive results were obtained in 55 samples. While the percent agreement observed with both kits was found to be 78.6 in 75 samples, excluding 15 samples in the intermediate with Aeskulisa kit, Cohen's kappa value was calculated as 0.26, indicating a close to moderate agreement, statistically. A high correlation was observed in the correlation analysis of the measurements of both kits (r= 0.611). When the scattering of the differences against the mean of the quantitative measurements made with both kits was examined by Bland-Altman analysis; higher measurements were determined with the Elecsys kit than with the Aeskulisa kit and the mean difference was found to be 58.68 Â± 52.62. As a result of the studies carried out by the manufacturers, it was observed that the average difference decreased to 41.09 Â± 50.22 when the U/mL values were converted to BAU/mL with the conversion factor. In the whole sampling, the measurements determined with the Elecsys kit were found to be 4.58 Â± 3.44 times higher on average compared to the Aeskulisa kit while the measurements were found to be 2.35 Â± 1.77 when the BAU/mL values were recalculated. The measurement values found with the Elecsys kit used in our study were found to be higher than that of Aeskulisa kit and qualitatively more positive results were obtained with Elecsys kit than with the Aeskulisa kit. In this study, Elecsys kit measurements were on average 4.06 times higher than Aeskulisa kit in samples (n= 55) with results compatible with both kits. The increase in these rates to 4.30 and 7.72 values, respectively, for 15 samples reported as intermediate and 16 as negative with the Aeskulisa kit, suggested that the success of quantitation decreased with the Aeskulisa kit at low antibody values. Since the harmonization of anti-SARS-CoV-2 tests has not yet been achieved, individual immune monitoring should be performed using the same method and even the results converted to BAU/mL should be specific to the antigen subunit.

Polythylene glycol severe allergy and SARS-CoV-2 vaccines: usefulness of testing with PEG 1500 extract. Background. Polyethylene glycol (PEG) is being used for first time as an excipient for mRNA anti-SARS-CoV-2 vaccines containing PEG 2000, highlighting it as a potential cause of anaphylaxis. Methods. We evaluated 126 patients with moderate-high risk of allergy to SARS-CoV-2 vaccines referred to our department from March-December 2021. Skin tests were performed with PEG 1500 extract (Roxall), using a stepwise approach, with readings at 30 minutes: prick tests with

0.1%, 1% and 10% concentrations; if negative, intradermal tests with 0.0001%, 0.001% and 0.01% concentrations. The same protocol was applied to 5 healthy controls Results. Six patients had positive immediate intradermal tests with PEG 1500, all with severe PEG allergy: one with a near-fatal anaphylaxis after glucocorticoid injection containing PEG 3350 and five with systemic allergic reactions after mRNA vaccines containing PEG 2000 (Pfizer-BioNTech or Moderna). One patient developed anaphylaxis during intradermal test. These six patients were negative to polysorbate 80. The remaining 120 patients had negative tests to PEG 1500; seven had positive tests to polysorbate 80. All controls had negative tests. Conclusions. To our knowledge this is the first study describing the allergy work-up testing with PEG 1500 commercial extract in the scope of SARS-CoV-2 vaccination. The algorithm designed for skin tests revealed to be a useful tool. Severe PEG allergy was diagnosed in 5% of patients, contraindicating PEG-containing vaccines. PEG allergy was excluded in one hundred patients that afterwards took SARS-CoV-2 vaccines containing PEG 2000. Investigation should be conducted in specialized drug allergy centers..

Kikuchi-Fujimoto Disease and COVID-19 vaccination: pharmacovigilance approach. Background. Kikuchi-Fujimoto Disease (KFD) or histiocytic necrotizing lymphadenitys is a rare disorder characterized by subacute necrotizing regional lymphadenopathy. It is usually presented as painful cervical nodes and associated with fever, headache, night sweats, nausea, vomiting and sore throat. Etiology of KFD is still unclear, two theories have been proposed: infections and autoimmune origin. Due to recent reports of KFD related to COVID-19 vaccination, the novelty of the mechanism of these vaccines and the immunomodulated role of both matters, a literature and adverse event databases review was carried out in order to shed light on the relationship between these two matters. Methods. A search in the Spanish and the European adverse events databases (FEDRA and Eudravigilance) was performed. Search criteria were any drug and the diagnosis "Histiocytic necrotizing lymphadenitis" according to the Medical Dictionary for Medical Activities version 25.0. All adverse events registered as June 2, 2022, were included. Results. FEDRA encompassed two KFD reports, one related to a mRNA COVID-19 vaccine. Eudravigilance included a total of 62 KFD cases, 14 of them associated to COVID-19 vaccines and eight to other vaccines. Conclusions. Pharmacovigilance is of utter importance in detecting adverse events caused by new vaccines. More research is needed to establish a final connection between KFD and COVD-19 vaccines, but due to the physiopathology of the condition, how vaccines stimulate the immune system and the high number of reported KFD cases with vaccines given its rare incidence, it is plausible to think that both entities are related.

COVID-19 vaccine-associated immunization-related anxiety presenting as dissociative symptoms and pseudoseizure: A case report and potential role in public health.

A case report of subacute thyroiditis after inactivated SARS-CoV-2 vaccine. Subacute thyroiditis is an inflammatory thyroid disorder. It is often triggered following viral infections. Amid the current COVID-19 pandemic, several cases of subacute thyroiditis were reported worldwide related to SARS-CoV-2 infection and vaccines. We report a rare case of subacute thyroiditis possibly related to immunization with inactivated SARS-CoV-2 vaccine Sinopharm BIBP. A 29-year-old previously healthy Sri Lankan woman presented with anterior neck pain, low-grade fever and fatigue appearing 7â€‰days after immunization with the second dose of inactivated SARS-CoV-2 vaccine Sinopharm BIBP. She apparently reported similar symptoms which subsided spontaneously within a few days, following immunization with first dose of vaccine. On examination, she had tenderness over the anterior neck. She was afebrile, not tachycardic and clinically euthyroid. Her inflammatory markers were elevated. An ultrasound scan of the neck demonstrated two low echogenic micronodules of 6 x 3â€‰mm(2) and 5 x 3â€‰mm(2) and low background thyroid vascularity. Technetium 99â€‰m pertechnetate (Tc - 99â€‰m) thyroidal uptake scan shows reduced thyroidal uptake suggestive of subacute thyroiditis. Thyroid function tests were normal at the time of the assessment. The patient

was treated symptomatically with non-steroidal anti-inflammatory drugs. Her neck pain and tenderness resolved gradually. Serial measurements of thyroid functions during follow-up were within normal limits. Inflammatory markers normalized over the course of follow-up. Subacute thyroiditis following COVID-19 vaccination is a rare occurrence. However, due to its mild clinical course, it could very well be underreported. It is a mild and self-limiting illness with transient thyroid dysfunction; thus, it should be emphasized that the benefits of COVID-19 vaccination outweigh any rare and mild side effects reported.

Serological responses triggered by different SARS-CoV-2 vaccines against SARS-CoV-2 variants in Taiwan. Broadly neutralizing ability is critical for developing the next-generation SARS-CoV-2 vaccine. We collected sera samples between December 2021-January 2022 from 113 Taiwan naÃ¯ve participants after their second dose of homologous vaccine (AZD1222, mRNA-1273, BNT162-b2, and MVC-COV1901) and compared the differences in serological responses of various SARS-CoV-2 vaccines. Compared to AZD1222, the two mRNA vaccines could elicit a higher level of anti-S1-RBD binding antibodies with higher broadly neutralizing ability evaluated using pseudoviruses of various SARS-CoV-2 lineages. The antigenic maps produced from the neutralization data implied that Omicron represents very different antigenic characteristics from the ancestral lineage. These results suggested that constantly administering the vaccine with ancestral Wuhan spike is insufficient for the Omicron outbreak. In addition, we found that anti-ACE2 autoantibodies were significantly increased in all four vaccinated groups compared to the unvaccinated pre-pandemic group, which needed to be investigated in the future.

Relapsed focal segmental glomerulosclerosis and severe acute kidney injury after Oxford-AstraZeneca (AZ) COVID-19 vaccine.

Assessment of the post-SARS-CoV-2 vaccination response depending on the epidemiological status, demographic parameters and levels of selected cytokines in medical personnel. INTRODUCTION: SARS-CoV-2 is responsible for causing the COVID-19 disease, which affected 174 million people worldwide. After vaccines were launched, the focus was on their effectiveness and the degree of their safety. AIM: The authors try to find factors that may affect the response to vaccination. MATERIAL AND METHODS: The study was conducted in 47 adults (39 women and 8 men; age: 47.3 Â±11.2). Participants were vaccinated with two doses of the Comirnaty mRNA vaccine. Each patient had a medical history taken and the concentration of specific sIgG antibodies against S1 protein and SARS-CoV-2 N protein, as well as of selected cytokines (IL-8, TGF-Î², IFN-Î³) was determined before and 3 weeks after the first and second dose of the vaccine. RESULTS: There were 18 convalescents among the respondents. A statistically significant increase in the concentration of specific sIgG S1 in subsequent determinations was observed. Higher levels of sIgG S1 were found after the first dose of the vaccine in COVID-19 convalescents. There was no statistically significant influence of age, body mass index and sex on the increase in the concentration of antibodies and the concentration of the determined cytokines. It was shown that the higher the initial TGF-Î² concentration, the greater the increase in sIgG S1 after administration of the vaccine. CONCLUSIONS: Vaccination did not increase the levels of IL-8, IFN-Î² and TGF-Î³. A higher concentration of serum TGF-Î² before vaccination correlated with the higher concentration of sIgG S1 antibodies after the first dose of the vaccine.

What impact does the attitude toward COVID-19 vaccination have on physicians as vaccine providers? A cross sectional study from the German outpatient sector. BACKGROUND: COVID-19 vaccination is recognized as a key component in addressing the COVID-19 pandemic. Physicians' attitudes toward vaccination are known to play a defining role in the management and dissemination of medical advice to patients. In Germany, outpatient practitioners are predominantly responsible for the dissemination of vaccines. METHOD: Using a cross-sectional online survey, 932 outpatient general practitioners, gynecologists, and pediatricians in Germany were asked in fall, 2021, about their attitude toward

COVID-19 vaccination and - among others - their communication in vaccine discussions, their assessment of vaccine safety, and reporting of suspected adverse events. Physicians were divided into two groups along their attitudes toward COVID-19 vaccination. In addition, multivariate linear regression models were constructed to assess differences in communication strategies. RESULTS: 92Â % of physicians had a positive or very positive attitude toward COVID-19 vaccination. Own vaccination status, practice-based vaccination delivery, and estimated vaccination coverage among patients were significantly associated with the attitude toward vaccination. Confidence in vaccine safety was significantly lower among physicians with negative attitudes. There were no differences between the two groups in self-assessment of the ability to detect suspected adverse events, but there were differences in the observing and reporting of adverse events. For the linear regression models, we found that a more negative attitude toward COVID-19 vaccination was significantly associated with increased acceptance of patient refusal of COVID-19 vaccination and empathic behavior for patient concerns. In contrast, willingness to engage in a detailed persuasion consultation was significantly lower. Pediatricians showed significantly higher empathy for patient-side concerns compared to general practitioners, whereas gynecologists showed less empathy than general practitioners. DISCUSSION: The physician's attitude toward COVID-19 vaccination influences the physician's practices as a vaccine provider. However, when providing medical advice and healthcare, the physician should focus on the actual needs of the patient.

SARS-CoV-2 antibody responses post-vaccination in UK healthcare workers with pre-existing medical conditions: a cohort study. OBJECTIVES: To examine antibody responses after the second vaccination in healthcare workers (HCWs) with underlying health conditions. DESIGN: Cohort study. SETTING: Oxford University Hospitals in the United Kingdom. PARTICIPANTS: Healthcare workers who had SARS-CoV-2 serological data available and received two SARS-CoV- 2 vaccinations. PRIMARY OUTCOME: Peak SARS-CoV-2 anti-spike IgG responses after the second vaccination and associations with underlying health conditions and the estimated risk of severe COVID-19 using an occupational health risk assessment tool. METHODS: We used univariable and multivariable linear regression models to investigate associations between antibody levels and demographics (age, sex, ethnicity), healthcare role, body mass index, underlying health conditions, vaccination status, prior infection and the Association of Local Authority Medical Advisors COVID-age risk score. RESULTS: 1635 HCWs had anti-spike IgG measurements 14-84â€‰days after second vaccination and data on any underlying health conditions. Only five HCWs (0.3%), all on immunosuppressive treatment, (including four organ transplant recipients), did not seroconvert after second vaccination. Antibody levels were independently lower with older age, diabetes, immunosuppression, respiratory disorders other than asthma and markedly so in organ transplant recipients. Levels were independently lower in ChAdOx1 versus BNT162b2 recipients and higher following previous infection. HCWs with 'very high' COVID-age risk scores had lower median antibody levels than those with 'low', 'medium' or 'high' risk scores; 4379 AU/mL, compared with 12â€‰337 AU/mL, 9430 AU/mL and 10â€‰524 AU/mL, respectively. CONCLUSIONS: Two vaccine doses are effective in generating antibody responses among HCWs, including those with a high occupational risk. However, HCWs with underlying health conditions, especially diabetes, immunosuppression and organ transplant, had lower antibody levels, and vaccine response monitoring may be needed.

Tfh cells and the germinal center are required for memory B cell formation & humoral immunity after ChAdOx1 nCoV-19 vaccination. Emergence from the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has been facilitated by the rollout of effective vaccines. Successful vaccines generate high-affinity plasma blasts and long-lived protective memory B cells. Here, we show a requirement for T follicular helper (Tfh) cells and the germinal center reaction for optimal serum antibody and memory B cell formation after ChAdOx1 nCoV-19 vaccination. We found

that Tfh cells play an important role in expanding antigen-specific B cells while identifying Tfh-cell-dependent and -independent memory B cell subsets. Upon secondary vaccination, germinal center B cells generated during primary immunizations can be recalled as germinal center B cells again. Likewise, primary immunization GC-Tfh cells can be recalled as either Tfh or Th1 cells, highlighting the pluripotent nature of Tfh cell memory. This study demonstrates that ChAdOx1 nCoV-19-induced germinal centers are a critical source of humoral immunity.

Association between primary or booster COVID-19 mRNA vaccination and Omicron lineage BA.1 SARS-CoV-2 infection in people with a prior SARS-CoV-2 infection: A test-negative case-control analysis. BACKGROUND: The benefit of primary and booster vaccination in people who experienced a prior Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection remains unclear. The objective of this study was to estimate the effectiveness of primary (two-dose series) and booster (third dose) mRNA vaccination against Omicron (lineage BA.1) infection among people with a prior documented infection. METHODS AND FINDINGS: We conducted a test-negative case-control study of reverse transcription PCRs (RT-PCRs) analyzed with the TaqPath (Thermo Fisher Scientific) assay and recorded in the Yale New Haven Health system from November 1, 2021, to April 30, 2022. Overall, 11,307 cases (positive TaqPath analyzed RT-PCRs with S-gene target failure [SGTF]) and 130,041 controls (negative TaqPath analyzed RT-PCRs) were included (median age: cases: 35 years, controls: 39 years). Among cases and controls, 5.9% and 8.1% had a documented prior infection (positive SARS-CoV-2 test record â‰¥90 days prior to the included test), respectively. We estimated the effectiveness of primary and booster vaccination relative to SGTF-defined Omicron (lineage BA.1) variant infection using a logistic regression adjusted for date of test, age, sex, race/ethnicity, insurance, comorbidities, social venerability index, municipality, and healthcare utilization. The effectiveness of primary vaccination 14 to 149 days after the second dose was 41.0% (95% confidence interval (CI): 14.1% to 59.4%, p 0.006) and 27.1% (95% CI: 18.7% to 34.6%, p < 0.001) for people with and without a documented prior infection, respectively. The effectiveness of booster vaccination (â‰¥14 days after booster dose) was 47.1% (95% CI: 22.4% to 63.9%, p 0.001) and 54.1% (95% CI: 49.2% to 58.4%, p < 0.001) in people with and without a documented prior infection, respectively. To test whether booster vaccination reduced the risk of infection beyond that of the primary series, we compared the odds of infection among boosted (â‰¥14 days after booster dose) and booster-eligible people (â‰¥150 days after second dose). The odds ratio (OR) comparing boosted and booster-eligible people with a documented prior infection was 0.79 (95% CI: 0.54 to 1.16, p 0.222), whereas the OR comparing boosted and booster-eligible people without a documented prior infection was 0.54 (95% CI: 0.49 to 0.59, p < 0.001). This study's limitations include the risk of residual confounding, the use of data from a single system, and the reliance on TaqPath analyzed RT-PCR results. CONCLUSIONS: In this study, we observed that primary vaccination provided significant but limited protection against Omicron (lineage BA.1) infection among people with and without a documented prior infection. While booster vaccination was associated with additional protection against Omicron BA.1 infection in people without a documented prior infection, it was not found to be associated with additional protection among people with a documented prior infection. These findings support primary vaccination in people regardless of documented prior infection status but suggest that infection history may impact the relative benefit of booster doses.

Bilateral choroidal effusion following vaccination against SARS-CoV-2 virus. An 80-year-old systemically stable female presented with sudden blurring of vision post the first dose of Covishield(TM), a non-replicating viral vector vaccine. On examination, she was found to have bilateral serous choroidal effusions. A thorough systemic and ocular workup was performed to rule out other causes of choroidal effusion. The effusions resolved with tapering doses of oral and

systemic steroids. To the best of our knowledge, at the time of submission, this is the first case of choroidal effusion being reported after the coronavirus disease 2019 (COVID-19) vaccine.

COVID-19 vaccination and recurrent anterior uveitis. A 35-year-old Asian Indian female previously diagnosed with bilateral anterior uveitis and on oral methotrexate developed bilateral anterior uveitis following first/second dose of coronavirus disease 2019 (COVID-19) vaccination. She had skipped her weekly dose of oral methotrexate following first dose of vaccination. Following the second dose, she reduced her oral methotrexate from 25 to 15 mg on her own, but did not stop like the previous occasion. She had extensive workup for her uveitis in the past with only positive severe acute respiratory syndrome coronavirus (SARS-CoV-2) antibodies. She developed unilateral anterior uveitis after she had COVID-19 in July 2022, which resolved with topical steroids and continuation of immunosuppression. This report illustrates that COVID-19 or its vaccination may presumably play a role in triggering the immune system and can cause recurrent ocular inflammation even in the absence of an extraocular inflammation.

Effect of Inactivated and mRNA COVID-19 Vaccination on Thyroid Function Among Patients Treated for Hyperthyroidism. CONTEXT: Reports of thyroid dysfunction following COVID-19 vaccination included cases of relapse of Graves' disease and worsening of pre-existing Graves' disease. Little is known about the thyroid-specific outcomes among patients treated for hyperthyroidism who have received COVID-19 vaccination. OBJECTIVE: Among patients treated for hyperthyroidism, we evaluated factors associated with not receiving the COVID-19 vaccination and whether COVID-19 vaccination was associated with thyroid function instability. METHODS: We included consecutive patients treated for hyperthyroidism attending the thyroid clinic at a teaching hospital between January and September 2021. They were categorized into vaccinated and unvaccinated groups. The index date was the date of first-dose vaccination for the vaccinated group, and the first date of attendance in the inclusion period for the unvaccinated group. They were followed up until March 2022 or occurrence of thyroid function instability (worsening of thyroid function/increase in antithyroid drug dosage), whichever was earlier. RESULTS: A total of 910 patients were included (mean age 51.6 years; 82.1% female). Of these, 86.2% had Graves disease and 67.3% were vaccinated (67.3% BNT162b2; 30.6% CoronaVac; 2.1% heterologous). Abnormal thyroid function and cardiovascular comorbidities were independently associated with unvaccinated status. Upon median follow-up of 5.3 months, thyroid function instability occurred in 15.9% of patients. COVID-19 vaccination did not increase risks of thyroid function instability (hazard ratio 0.78, 95% CI 0.56-1.09, P = .151); this was consistent in Graves disease, both types of vaccines, and regardless of whether baseline thyroid function was normal. Twenty-seven patients overtly thyrotoxic at the time of vaccination received COVID-19 vaccines without triggering a thyroid storm or difficulty in subsequent thyroid function control. CONCLUSION: Among patients treated for hyperthyroidism, abnormal thyroid function was a factor predicting unvaccinated status. Our results should encourage patients treated for hyperthyroidism to receive COVID-19 vaccination to protect themselves from adverse outcomes and potential long-term sequelae of COVID-19.

Safety of COVID-19 vaccination in pregnant women: A study of the adverse perinatal outcomes. OBJECTIVE: To compare adverse perinatal outcome among coronavirus disease 2019 (COVID-19)-vaccinated and -unvaccinated pregnant women. METHOD: Retrospective equivalence cohort study comparing 930 women who received at least one BNT162b2 (Pfizer/BioNTech) COVID-19 vaccine during the second or third trimester of pregnancy and 964 unvaccinated women. The primary outcome was a composite adverse perinatal outcome including at least one of the following: preterm delivery <35â€‰weeks of gestation, intrauterine fetal death >23â€‰weeks of gestation, intrauterine growth restriction defined as birth weightâ€‰<â€‰10th percentile, 5-min APGAR scoreâ€‰â‰¤â€‰7, and neonatal care unit admission. RESULTS: The authors found no effect of the

COVID-19 vaccine on the rate of the individual adverse perinatal outcomes. At least one adverse perinatal outcome was found in 108 (11.25%) of unvaccinated women versus 82 (8.82%) of vaccinated pregnant women (PÂ =â€‰0.080). The observed proportion difference (unvaccinated minus vaccinated) was 0.024. In the equivalence analysis with a margin of 0.05, the 90% confidence interval (0.01-0.05) was entirely within the equivalence zone (-0.05 to 0.05) with a P value of 0.032. CONCLUSION: The present study demonstrated an equivalent rate of adverse perinatal outcomes among vaccinated and unvaccinated women, thus supporting vaccine safety during the second and third trimesters of pregnancy. The authors believe this information is useful in counseling pregnant women regarding COVID-19 vaccination during pregnancy.

Anaphylaxis is rare due to CoronaVac in a population of healthcare workers. BACKGROUND: CoronaVac, the first coronavirus disease 2019 vaccine administered in our country, was found safe in clinical trials. OBJECTIVE: We aimed to reveal the rate and features of CoronaVac vaccine-associated allergic reactions among vaccinated healthcare workers (HCWs) in real-life. METHODS: This study was planned as a questionnaire-based study. Participants who reported a postvaccination allergic reaction were interviewed on phone and their medical records were also checked for confirmation. RESULTS: A total of 2,488 HCWs took part in the study and 4,054 postvaccination complete questionnaire-responses were obtained. Twenty-one HCWs (female: male, 17:4) with a mean age of 40.95 Â± 10.09 stated that they had an allergic reaction after a total of 23 vaccine injections. Accordingly, the reaction rate was 0.56% among all vaccine doses. The most common reactions were systemic skin reactions (2.7%) consisting of generalized pruritus, diffuse pruritic erythema, urticaria, and maculopapular rash. That was followed by local injection site reaction (0.12%). Anaphylaxis was reported in 4 cases (0.09%) with a mean onset time of 12 Â± 6 minutes. One of them had a history of anaphylaxis with 2 drugs, another had venom and food allergy. Three of the subjects had level 2 diagnostic certainty according to the Brighton Collaboration criteria and one had level 3. All anaphylaxis cases were discharged within 24 hours and none of them required intensive care. CONCLUSION: Our study demonstrated that allergic reactions to CoronaVac were rare and mostly mild. Although anaphylaxis was also rare, the importance of early intervention with close follow-up was once again emphasized.

A retrospective analysis of clinically confirmed long post-COVID vaccination syndrome. BACKGROUND AND AIM: Long post-COVID vaccination syndrome (LPCVS) is an increasingly recognized disease that occurs after SARS-CoV-2 vaccinations and lasts >4 weeks. However, little is known about the clinical presentation, underlying pathophysiology, treatment, and outcome of LPCVS. This study aims to present a series of patients with LPCVS, their treatment, and outcomes. METHODS: This was a retrospective analysis of three patients with LPCVS. RESULTS: In an observation period of 2 months (January and February 2022), three patients were collected in whom side effects after vaccination against COVID-19 lasted >4 weeks and in whom instrumental examinations were largely unremarkable. All three patients received only symptomatic therapy and only partially recovered within 6-8 months after vaccination. LPCVS significantly impaired the quality of life of the included patients. CONCLUSIONS: SARS-CoV-2 vaccinations may cause not only short-term but also long-term side effects that include not only known diseases but also non-specific symptoms with normal or slightly abnormal clinical and instrumental findings. Although LPCVS leads to long-term disability, it is not widely recognized and not always accepted by manufacturers, health authorities, and even scientists. LPCVS should not be dismissed as a functional disorder and patients with LPCVS should be taken seriously. RELEVANCE FOR PATIENTS: The possible causal relation between some long side effects and SARS-CoV-2 vaccines cannot be ignored. The pathophysiology of LPCVS should be further studied to lay a foundation for further improvement of the vaccines.

Pilot genome-wide association study of antibody response to inactivated SARS-CoV-2 vaccines. Vaccines are a key weapon against the COVID-19 pandemic caused by SARS-CoV-2. However, there are inter-individual differences in immune response to SARS-CoV-2 vaccines and genetic contributions to these differences have barely been investigated. Here, we performed genome-wide association study (GWAS) of antibody levels in 168 inactivated SARS-CoV-2 vaccine recipients. A total of 177 SNPs, corresponding to 41 independent loci, were identified to be associated with IgG, total antibodies or neutral antibodies. Specifically, the rs4543780, the intronic variant of FAM89A gene, was associated with total antibodies level and was annotated as a potential regulatory variant affecting gene expression of FAM89A, a biomarker differentiating bacterial from viral infections in febrile children. These findings might advance our knowledge of the molecular mechanisms driving immunity to SARS-CoV-2 vaccine.

Deep vein thrombosis and acute hepatitis after ChAdOx1 nCov-19 vaccination in a Charcot-Marie-Tooth patient: a case report. Monitoring of side effects after coronavirus disease 2019 (COVID-19) vaccination has become an important issue for health systems worldwide to ensure its safety. Recently cases of deep vein thrombosis (DVT), vaccine-induced immune thrombotic thrombocytopenia, and autoimmune hepatitis have been described: the underlying pathophysiological mechanisms are still debated. We report on a patient who presented with DVT and acute hepatitis 8 days after receiving the first dose of the ChAdOx1 nCoV-19 adenoviral vector vaccine against COVID-19. The patient is a 56-year-old male who was already affected by a rare form of axonal Charcot-Marie-Tooth disease linked to MME (membrane metalloendopeptidase) gene variation and associated with mild symptoms. His blood exams did not have any evidence of thrombocytopenia but D-dimer, troponin T, alanine transaminase, and aspartate aminotransferase were abnormal, suggesting the presence of a blood clot and acute hepatitis. The patient was treated with subcutaneous enoxaparin for 15 days and with rivaroxaban for the following 8 months: his symptoms improved and his exams showed recanalization of the veins and a healed liver. The pathogenesis of thrombosis and hepatitis after vaccination is still unclear, especially in subjects affected by rare comorbidities and this may affect the safety of vaccination in this type of population. We highlight the importance of careful monitoring of side effects after vaccination: clinical suspicion must rise when patients complain of symptoms that differ from their usual presentation.

Livedo reticularis following administration of ChAdOx1 nCoV-19 vaccine (AZD1222): a report of two cases. The cutaneous appearance of transient or persistent livedo reticularis is characterized by violaceous, mottled, ring-shaped interconnecting lesions that form a reticular or net-like pattern. It can occur physiologically in response to cold exposure, such as in cutis marmorata, but can also be induced by pathological conditions such as vascular obliterans or venodilation. We report two cases of livedo reticularis that occurred on the lower limbs of two patients post ChAdOx1 nCoV-19 vaccination. As the patients had no other likely causes of livedo reticularis, the reticular skin lesions were suspected to occur in association with the ChAdOx1 nCoV-19 vaccination. Livedo reticularis is an uncommon adverse reaction, with few cases being reported post ChAdOx1 nCoV-19 vaccination.

Factors associated with intention to take COVID-19 vaccine among the university students in Bangladesh. PURPOSE: This study examined the Bangladeshi university students' intention to take coronavirus disease 2019 (COVID-19) vaccines by assessing the Health Belief Model and Theory of Planned Behavior. MATERIALS AND METHODS: University students were queried on their intention to take COVID-19 vaccines. The sample used in this study (n=310) was obtained through an online survey among university students (age, 18-25 years old) from August 7 to September 18, 2021. RESULTS: Although over 90% of respondents showed their willingness to take the COVID-19 vaccine, around 37.3% of respondents still desired to wait and see to take the vaccine. The most frequently cited reasons for vaccines hesitancy were concerns over side effects (62.4%). There is still an unmet

need for adequate information on COVID-19 vaccines (81.4%). Results of the binary logistic regression model showed that students from private universities (odds ratio [OR], 0.19; 95% confidence interval [CI], 0.04-0.97), respondents who concerned about the vaccine safety (OR, 0.07; 95% CI, 0.01-0.44) and side effects of vaccine (OR, 0.21; 95% CI, 0.05-0.89) were less willing to take COVID-19 vaccine. On the other hand, desire to wait to take COVID-19 vaccines was associated with marital status (OR, 7.76; 95% CI, 1.50-40.27); COVID-19 preventive behavior, including use of facemask (OR, 0.25; 95% CI, 0.09-0.70) and maintain social distance (OR,1.75; 95% CI, 1.00-3.07); COVID-19 infection (OR, 0.50; 95% CI, 0.26-0.99); provide more information on vaccines (OR, 2.32; 95% CI, 1.06-5.09); the perceived side effects (OR, 2.82; 95% CI, 1.54-5.17); and effectiveness of COVID-19 vaccines (OR, 2.41; 95% CI, 1.16-5.01). CONCLUSION: Public health managers should provide adequate information on COVID-19 vaccines to address the concerns about the safety and side effects of the vaccines.

Quick drop of platelet counts in children with chronic immune thrombocytopenia after COVID-19 mRNA vaccination: case reports. Immune thrombocytopenia (ITP) is an autoimmune disorder characterized by isolated thrombocytopenia. Many viruses and some vaccines have been identified as triggering the autoimmune process, including parvovirus, human immunodeficiency virus, Epstein-Barr virus, rubella, and measles. However, ITP in association with coronavirus disease 2019 (COVID-19) vaccination has not been reported so far. We describe the cases of two young girls affected by ITP presenting a quick reduction of platelet count after receiving Pfizer-BioNTech COVID-19 vaccine.

Brain perfusion single photon emission computed tomography abnormality in MRI-negative stroke-like patients post COVID-19 vaccination. Stroke-like symptoms after COVID-19 vaccination was thought to be functional if there was no anatomical image abnormality. We aimed to analyze brain perfusion changes in these patients. A case-control study of brain perfusion single photon emission computed tomography (SPECT) of 12 vaccinated patients with left-sided stroke-like symptoms were compared with 12 age- and gender-matched normal interictal brain SPECTs using voxel-based analysis. Significant hyperperfusion was seen on the right side in postcentral, inferior parietal, mid temporal, parahippocampal, and caudate regions, and on the left side in the thalamus, hippocampus, and mid temporal areas. In addition, there were hypoperfused bilateral superior frontal gyri and right mid/posterior cingulate cortex (Family-wise-error corrected p-values â€…<â€….05). Both hypoperfusion and hyperperfusion in the brain are demonstrated. We hypothesize that these findings might be the result of the functional neurological disorder. However, based on other previous studies, circulating spike protein in the patients' plasma early after vaccination might also be the cause.

Erythema nodosum after COVID-19 vaccine: Report of two pediatric cases. With the introduction of large-scale COVID-19 vaccination programs, a variety of cutaneous manifestations have been described. We present two girls (ages 12 and 5â€‰years) who developed erythema nodosum (EN) 3 and 14â€‰days after Pfizer-BioNTech COVID-19 vaccination, respectively. While EN after COVID-19 vaccination has been reported in adults, it is can also occur in children.

Early-stage antibody kinetics after the third dose of BNT162b2 mRNA COVID-19 vaccination measured by a point-of-care fingertip whole blood testing. Amid the Coronavirus Disease 2019 pandemic, we aimed to demonstrate the accuracy of the fingertip whole blood sampling test (FWT) in measuring the antibody titer and uncovering its dynamics shortly after booster vaccination. Mokobio SARS-CoV-2 IgM & IgG Quantum Dot immunoassay (Mokobio Biotechnology R&D Center Inc., MD, USA) was used as a point-of-care FWT in 226 health care workers (HCWs) who had received two doses of the BNT162b2 mRNA vaccine (Pfizer-BioNTech) at least 8Â months prior. Each participant tested their antibody titers before and after the third-dose booster up to 14-days. The effect of the booster was observed as early as the fourth day after vaccination, which exceeded the detection limit (>â€‰30,000Â U/mL) by 2.3% on the fifth day, 12.2% on the sixth day, and 22.5% after the seventh

day. Significant positive correlations were observed between the pre- and post-vaccination (the seventh and eighth days) antibody titers (correlation coefficient, 0.405; pâ€‰<â€‰0.001). FWT is useful for examining antibody titers as a point-of-care test. Rapid response of antibody titer started as early as the fourth day post-vaccination, while the presence of weak responders to BNT162b2 vaccine was indicated.

Kinetics of Neutralizing Antibodies against Omicron Variant in Vietnamese Healthcare Workers after Primary Immunization with ChAdOx1-S and Booster Immunization with BNT162b2. We studied the development and persistence of neutralizing antibodies against SARS-CoV-2 ancestral strain, and Delta and Omicron (BA.1 and BA.2) variants in Vietnamese healthcare workers (HCWs) up to 15 weeks after booster vaccination. We included 47 HCWs, including group 1 (G1, N = 21) and group 2 (G2; N = 26) without and with breakthrough Delta variant infection before booster immunization, respectively). The study participants had completed primary immunization with ChAdOx1-S and booster vaccination with BNT162b2. Neutralizing antibodies were measured using a surrogate virus neutralization assay. Of the 21 study participants in G1, neutralizing antibodies against ancestral strain, Delta variant, BA.1, and BA.2 were (almost) abolished at month 8 after the second dose, but all had detectable neutralizing antibodies to the study viruses at week 2 post booster dose. Of the 26 study participants in G2, neutralizing antibody levels to BA.1 and BA.2 were significantly higher than those to the corresponding viruses measured at week 2 post breakthrough infection and before the booster dose. At week 15 post booster vaccination, neutralizing antibodies to BA.1 and BA.2 dropped significantly, with more profound changes observed in those without breakthrough Delta variant infection. Booster vaccination enhanced neutralizing activities against ancestral strain and Delta variant compared with those induced by primary vaccination. These responses were maintained at high levels for at least 15 weeks. Our findings emphasize the importance of the first booster dose in producing cross-neutralizing antibodies against Omicron variant. A second booster to maintain long-term vaccine effectiveness against the currently circulating variants merits further research.

Post-vaccination incidence and side effects of COVID-19 in a cohort of Brazilian healthcare professionals: an internet-based survey. OBJECTIVE: So far, at least 18 different severe acute respiratory syndrome coronavirus-2 vaccines have been approved. Until October 2022, 12.8 billion doses had been administered all over the world. Vaccination of high-risk groups and healthcare professionals was initially prioritized. This cross-sectional survey aimed to investigate the occurrence of vaccine side effects, as well as the incidence of COVID-19 among vaccinated healthcare professionals. METHODS: A survey was structured and shared with healthcare professionals using a digital platform to collect data between May and June 2021. RESULTS: This study included 6,115 participants. The most prevalent age group was 30-39 years (31.3%), 67.3% were female and 73.2% accounted for physicians, and nearly half worked in frontline care for COVID-19. Approximately, two-thirds of them were vaccinated with CoronaVac, and about 60% reported at least one side effect following the vaccination. Nevertheless, minor reactions were more frequent, such as pain at site of injection, fatigue, and headache. Our data could be used to inform people on the likelihood of side effects of COVID-19 vaccines, particularly CoronaVac, since this is the largest study about vaccine reactions using this vaccine, to our best knowledge. CONCLUSION: The incidence of side effects in Brazilian healthcare professionals was 60%, and the most common side effects included local swelling/pain, fatigue/tiredness, fever, headache, and limb pain.

Guillain-BarrÃ© syndrome after COVID-19 vaccination: report of two cases from Vietnam. Coronavirus disease 2019 (COVID-19) was declared a pandemic by the World Health Organization in March 2020 and since then it has spread to almost every country around the world. Vaccines against COVID-19 are considered an essential measure to curb this pandemic. However, side effects, including local and systemic reactions, after administering the COVID-19 vaccine have been defined,

and some side effects have been reported. We present two cases of Guillain-BarrÃ© Syndrome (GBS) after receiving the ChAdOx1 nCoV-19 vaccine (Oxford- AstraZeneca). Both cases were admitted to the 108 Military Central Hospital, Vietnam, and received plasmapheresis therapy with satisfactory recovery after treatment.

Can a supranational medicines agency restore trust after vaccine suspensions? The case of Vaxzevria. Over the first half of March 2021, the majority of European governments suspended Astrazeneca's Vaxzevria vaccine as a precaution following media reports of rare blood clots. We analyse the impact of the European Medicines Agency's (EMA) March 18th statement assuring the public of the safety of Vaxzevria and the immediate reinstatement of the vaccine by most countries on respondents' intention to get vaccinated. By relying on survey data collected in Luxembourg and neighbouring areas between early March and mid-April, we observe that the willingness to be vaccinated was severely declining in the days preceding the EMA statement. We implement a regression discontinuity design exploiting the time at which respondents completed the survey and find that the vaccine reinstatement substantially restored vaccination intentions.

Systemic lupus erythematosus with acrocyanosis after AstraZeneca COVID-19 vaccination.

Thyroid eye disease following administration of the BNT162B2 COVID-19 vaccine.

Changes in blood pressure after Messenger RNA COVID-19 vaccination. The SARS-Cov-2 (COVID-19) vaccination began in Malaysia in March 2021 among frontliners and healthcare workers. Everyone at our hospital received the tozinameran (BNT162b2) Messenger RNA COVID-19 vaccine. Although hypertension has not been mentioned explicitly as an adverse event, concerns were raised after some healthcare staff observed an increase in their blood pressures. In response to that, the hospital began collecting vital signs during second-dose appointments. Vital signs were measured before, immediately after and 15-30 minutes postvaccination. We report our findings from the institution-wide effort to monitor changes in blood pressure among its staff and respond to any possible unwanted events.

Adverse events following immunisation of COVID-19 vaccine among health care workers in the first phase of vaccination. INTRODUCTION: The new COVID-19 vaccine was met with worldwide overwhelming uncertainties pertaining to its safety profile, effectiveness, and potential adverse reactions when it was first introduced. This led to vaccine refusal and delay in vaccine uptake in many countries including Malaysia. The objective of this study was to determine the Adverse Events Following Immunization (AEFI) to the COVID-19 vaccine. MATERIALS AND METHODS: A retrospective cross-sectional study was conducted among healthcare workers who received the COVID-19 vaccine during the first phase of immunisation from eight public primary clinics in Johor Bahru district. Data were collected between May and September 2021 using a self-administered questionnaire. RESULTS: A total of 240 healthcare workers participated and all of them received the Pfizer Messenger RNA vaccine. Our study found that a large majority of vaccine recipients (87.5%, n=210) experienced AEFI to COVID-19 vaccine for either the first, second, or both doses. More than 80% of them experienced more than one type of AEFI. The most common AEFI reported during the first and second dose was localised symptom such as pain at injection site (60-68%), pain on the injected arm (52-61%), and swelling at injection site (32-33%). Common systemic symptoms were fever (22- 57%), myalgia (20-45%), and dizziness (24-26%). Although a large majority experienced AEFI, these reactions were mostly of mild to moderate severity (47.3-73.6%). The mean duration of AEFI onset was within 30 minutes to about 1 day (0.33-22.5 hours) of injection and lasted between 30 minutes and 2.5 days. There was no association between demographic characteristic of participants and severity of AEFI to COVID-19 vaccine. Mean duration of fever was significantly (p=0.005) longer after the second dose (34.2 hours) of vaccine compared to first (20.6 hours) CONCLUSION: This study shows that a large majority of COVID-19 vaccine recipients experienced AEFI; however, these reactions were mostly of

mild to moderate severity and lasted between 30 minutes and 2.5 days. A large majority experienced more than one type of AEFI. The most common AEFI was localised reactions consisting of pain and swelling at the injection site and pain on the injected arm. The most common systemic reactions were fever, myalgia, and dizziness. Duration of fever was significantly longer after the second dose.

Durability of humoral and cell-mediated immune response after SARS-CoV-2 mRNA vaccine administration. Vaccination against the SARS-Cov-2 virus is an effective way to protect against the disease and the severe course of COVID-19. Forty-nine fully vaccinated with mRNA vaccines (BNT162b2 or mRNA-1273) SARS-CoV-2 infection-naÃ¯ve volunteers aged 33-89 were enrolled in the study. Evaluation of the cellular and humoral immune response was performed within 1 to 3 months (T1) and 6-9 months (T2) after the second injection, and within 2-3 months (T3) after a booster dose. Additionally, a comparative analysis of the specific immune status was made between two age groups-below 60 (nâ€‰=â€‰22) and over 60 (nâ€‰=â€‰27) years. SARS-CoV-2-specific T-cell response was evaluated by IFN-Î³-producing spot forming cells (SFCs) using a standardized ELISPOT assay. Virus neutralizing antibodies (VNA) against SARS-CoV-2 were measured by a blocking ELISA test and spike protein specific IgG (S-IgG) and IgA (S-IgA) antibodies-by semiquantitative ELISA. IFN-Î³-producing SFCs, S-IgG, S-IgA and VNA significantly decreased 6-9 months after the second dose. After the third injection S-IgG and S-IgA markedly increased compared to T2 and reached the levels at T1. Of note, the highest values of VNA were observed at T3. No differences in the tested immune parameters were found between the two age groups. Data obtained showed that for a long period-6-9 months after a full course of immunization with mRNA vaccine, immune reactivity is present, but both cellular and humoral immune responses gradually decrease. The administration of a third dose mainly restores the specific humoral immune response against the SARS-CoV-2 virus.

SARS-CoV-2 vaccines are not associated with hypercoagulability in apparently healthy people. BACKGROUND: SARS-CoV-2 adenoviral vector DNA vaccines have been linked to the rare but serious thrombotic postvaccine complication vaccine-induced immune thrombotic thrombocytopenia. This has raised concerns regarding the possibility of increased thrombotic risk after any SARS-CoV-2 vaccines. OBJECTIVES: To investigate whether SARS-CoV-2 vaccines cause coagulation activation leading to a hypercoagulable state. METHODS: This observational study included 567 health care personnel; 521 were recruited after the first dose of adenoviral vector ChAdOx1-S (Vaxzevria, AstraZeneca) vaccine and 46 were recruited prospectively before vaccination with a messenger RNA (mRNA) vaccine, either Spikevax (Moderna, nÂ = 38) or Comirnaty (Pfizer-BioNTech, nÂ = 8). In the mRNA group, samples were acquired before and 1 to 2 weeks after vaccination. In addition to the prevaccination samples, 56 unvaccinated blood donors were recruited as controls (total nÂ = 102). Thrombin generation, D-dimer levels, and free tissue factor pathway inhibitor (TFPI) levels were analyzed. RESULTS: No participant experienced thrombosis, vaccine-induced immune thrombotic thrombocytopenia, or thrombocytopenia (platelet count <100Â Ã— 10(9)/L) 1 week to 1 month postvaccination. There was no increase in thrombin generation, D-dimer level, or TFPI level in the ChAdOx1-S vaccine group compared with controls or after the mRNA vaccines compared with baseline values. Eleven of 513 (2.1%) participants vaccinated with ChAdOx1-S had anti-PF4/polyanion antibodies without a concomitant increase in thrombin generation. CONCLUSION: In this study, SARS-CoV-2 vaccines were not associated with thrombosis, thrombocytopenia, increased thrombin generation, D-dimer levels, or TFPI levels compared with baseline or unvaccinated controls. These findings argue against the subclinical activation of coagulation post-COVID-19 vaccination.

Temporal association of vitreous hemorrhage and hypertension after COVID-19 mRNA vaccines. Vitreous hemorrhage as common eye presentation and hypertension as common systemic presentation are difficult to designate whether they are coincidental or causal in terms of adverse

events of COVID-19 vaccinations. Temporal association of hypertension and vitreous hemorrhage was noted in a patient repeatedly after the second and third COVID-19 vaccinations.

Interim analysis from a phase 2 randomized trial of EuCorVac-19: a recombinant protein SARS-CoV-2 RBD nanoliposome vaccine. BACKGROUND: Numerous vaccine strategies are being advanced to control SARS-CoV-2, the cause of the COVID-19 pandemic. EuCorVac-19 (ECV19) is a recombinant protein nanoparticle vaccine that displays the SARS-CoV-2 receptor-binding domain (RBD) on immunogenic nanoliposomes. METHODS: Initial study of a phase 2 randomized, observer-blind, placebo-controlled trial to assess the immunogenicity, safety, and tolerance of ECV19 was carried out between July and October 2021. Two hundred twenty-nine participants were enrolled at 5 hospital sites in South Korea. Healthy adults aged 19-75 without prior known exposure to COVID-19 were vaccinated intramuscularly on day 0 and day 21. Of the participants who received two vaccine doses according to protocol, 100 received high-dose ECV19 (20Â Î¼g RBD), 96 received low-dose ECV19 (10Â Î¼g RBD), and 27 received placebo. Local and systemic adverse events were monitored. Serum was assessed on days 0, 21, and 42 for immunogenicity analysis by ELISA and neutralizing antibody response by focus reduction neutralization test (FRNT). RESULTS: Low-grade injection site tenderness and pain were observed in most participants. Solicited systemic adverse events were less frequent, and mostly involved low-grade fatigue/malaise, myalgia, and headache. No clinical laboratory abnormalities were observed. Adverse events did not increase with the second injection and no serious adverse events were solicited by ECV19. On day 42, Spike IgG geometric mean ELISA titers were 0.8, 211, and 590 Spike binding antibody units (BAU/mL) for placebo, low-dose and high-dose ECV19, respectively (pâ€‰<â€‰0.001 between groups). Neutralizing antibodies levels of the low-dose and high-dose ECV19 groups had FRNT(50) geometric mean values of 129 and 316, respectively. Boosting responses and dose responses were observed. Antibodies against the RBD correlated with antibodies against the Spike and with virus neutralization. CONCLUSIONS: ECV19 was generally well-tolerated and induced antibodies in a dose-dependent manner that neutralized SARS-CoV-2. The unique liposome display approach of ECV19, which lacks any immunogenic protein components besides the antigen itself, coupled with the lack of increased adverse events during boosting suggest the vaccine platform may be amenable to multiple boosting regimes in the future. Taken together, these findings motivate further investigation of ECV19 in larger scale clinical testing that is underway. TRIAL REGISTRATION: The trial was registered at ClinicalTrials.gov as # NCT04783311.

Willingness to receive a vaccine is influenced by adverse events following immunisation experienced by others. An adverse event following immunization (AEFI) can have consequences for an individual's future decision making and may contribute to vaccine hesitancy. AEFIs vary in severity and can be experienced directly (by an individual themselves) or indirectly (through witnessed or recounted events). We sought to measure the prevalence of specific AEFIs and understand which AEFIs have the greatest associations with reduced willingness to receive a vaccine and how injection anxiety may moderate the relationship. We conducted a cross-sectional online survey with both qualitative and quantitative elements in a sample of adults aged 18Â years and over in Australia. Nineteen percent of the 1050 respondents reported experiencing an AEFI that they found stressful. Those who experienced an AEFI reported significantly higher levels of injection anxiety than those who did not. Within the group who reported experiencing an AEFI, respondents were significantly less likely to be willing to receive a COVID-19 vaccine if they reported: indirect exposure to an uncommon/rare AEFI compared with other AEFIs (aOR:0.39; 95% CI: 0.18-0.87); indirect exposure to a scientifically unsupported AEFI compared with other AEFIs (aOR:0.18; 95% CI: 0.05-0.57). Direct exposure to an AEFI was not associated with willingness to receive a COVID-19 vaccine. For those who reported experiencing an AEFI, the odds of willingness to receive a COVID-19 vaccine decreased significantly with an increase in injection anxiety (aOR:0.94; 95% CI: 0.9-0.98). Our results suggest that

more is needed to mitigate the consequences of AEFIs on vaccine willingness. Empathically acknowledging at a community level, the experience of both real and perceived AEFIs and incorporating accounts of positive vaccination experiences in vaccine hesitancy interventions may be useful.

Background rates of 41 adverse events of special interest for COVID-19 vaccines in 10 European healthcare databases - an ACCESS cohort study. BACKGROUND: In May 2020, the ACCESS (The vACCine covid-19 monitoring readinESS) project was launched to prepare real-world monitoring of COVID-19 vaccines. Within this project, this study aimed to generate background incidence rates of 41 adverse events of special interest (AESI) to contextualize potential safety signals detected following administration of COVID-19 vaccines. METHODS: A dynamic cohort study was conducted using a distributed data network of 10 healthcare databases from 7 European countries (Italy, Spain, Denmark, The Netherlands, Germany, France and United Kingdom) over the period 2017 to 2020. A common protocol (EUPAS37273), common data model, and common analytics programs were applied for syntactic, semantic and analytical harmonization. Incidence rates (IR) for each AESI and each database were calculated by age and sex by dividing the number of incident cases by the total person-time at risk. Age-standardized rates were pooled using random effect models according to the provenance of the events. FINDINGS: A total number of 63,456,074 individuals were included in the study, contributing to 211.7 million person-years. A clear age pattern was observed for most AESIs, rates also varied by provenance of disease diagnosis (primary care, specialist care). Thrombosis with thrombocytopenia rates were extremely low ranging from 0.06 to 4.53/100,000 person-years for cerebral venous sinus thrombosis (CVST) with thrombocytopenia (TP) and mixed venous and arterial thrombosis with TP, respectively. INTERPRETATION: Given the nature of the AESIs and the setting (general practitioners or hospital-based databases or both), background rates from databases that show the highest level of completeness (primary care and specialist care) should be preferred, others can be used for sensitivity. The study was designed to ensure representativeness to the European population and generalizability of the background incidence rates. FUNDING: The project has received support from the European Medicines Agency under the Framework service contract nr EMA/2018/28/PE.

Autopsy Histopathologic Cardiac Findings Following the Second COVID-19 Vaccine Dose.

Recombinant vesicular stomatitis virus-vectored vaccine induces long-lasting immunity against Nipah virus disease. The emergence of the novel henipavirus, Langya virus, received global attention after the virus sickened over three dozen people in China. There is heightened concern that henipaviruses, as respiratory pathogens, could spark another pandemic, most notably the deadly Nipah virus (NiV). NiV causes near-annual outbreaks in Bangladesh and India and induces a highly fatal respiratory disease and encephalitis in humans. No licensed countermeasures against this pathogen exist. An ideal NiV vaccine would confer both fast-acting and long-lived protection. Recently, we reported the generation of a recombinant vesicular stomatitis virus-based (rVSV-based) vaccine expressing the NiV glycoprotein (rVSV-Î”G-NiVBG) that protected 100% of nonhuman primates from NiV-associated lethality within a week. Here, to evaluate the durability of rVSV-Î”G-NiVBG, we vaccinated African green monkeys (AGMs) one year before challenge with an uniformly lethal dose of NiV. The rVSV-Î”G-NiVBG vaccine induced stable and robust humoral responses, whereas cellular responses were modest. All immunized AGMs (whether receiving a single dose or prime-boosted) survived with no detectable clinical signs or NiV replication. Transcriptomic analyses indicated that adaptive immune signatures correlated with vaccine-mediated protection. While vaccines for certain respiratory infections (e.g., COVID-19) have yet to provide durable protection, our results suggest that rVSV-Î”G-NiVBG elicits long-lasting immunity.

Neurological Complications Following COVID-19 Vaccination. PURPOSE OF REVIEW: A variety of neurological complications have been reported following the widespread use of the COVID-19 vaccines which may lead to vaccine hesitancy and serve as a major barrier to the public health aim of achieving protective herd immunity by vaccination. In this article, we review the available evidence regarding these neurological adverse events reported, to provide clarity regarding the same so that unfounded fears maybe put to rest. RECENT FINDINGS: There is a greater than expected occurrence of severe neurological adverse events such as cortical sinus venous thrombosis, Bell's palsy, transverse myelitis, and Guillain-BarrÃ© syndromes along with other common effects such as headaches following different kinds of COVID-19 vaccination. Precipitation of new onset demyelinating brain lesions with or without detection of specific antibodies and worsening of pre-existing neurological disorders (like epilepsy, multiple sclerosis) are also a matter of great concern though no conclusive evidence implicating the vaccines is available as of now. The COVID-19 pandemic is far from being over. Till such time that a truly effective anti-viral drug is discovered, or an appropriate therapeutic strategy is developed, COVID-appropriate behavior and highly effective mass vaccination remain the only weapons in our armamentarium to fight this deadly disease. As often occurs with most therapeutic means for the treatment and prevention of any disease, vaccination against COVID-19 has its hazards. These range from the most trivial ones like fever, local pain and myalgias to several potentially serious cardiac and neurological complications. The latter group includes conditions like cerebral venous thrombosis (curiously often with thrombocytopenia), transverse myelitis and acute inflammatory demyelinating polyneuropathy amongst others. Fortunately, the number of reported patients with any of these serious complications is far too low for the total number of people vaccinated. Hence, the current evidence suggests that the benefits of vaccination far outweigh the risk of these events in majority of the patients. As of now, available evidence also does not recommend withholding vaccination in patients with pre-existing neurological disorders like epilepsy and MS, though adenoviral vaccines should be avoided in those with history of thrombotic events.

Effects of COVID-19 Pandemic and Post-Vaccination Period on Gastroenterology Practice in Turkey. BACKGROUND: The sudden and intense burden due to the novel coronavirus (coronavirus disease 2019) pandemic has changed the priority of many health services. The highly contagious new variants and vaccination services have greatly impacted the daily practice of gastroenterologists. In the present study, we tried to evaluate the change in the daily practice of Turkish gastroenterologists in the coronavirus disease 2019 pandemic and the post-vaccination periods. METHODS: A questionnaire was prepared using Google forms and sent online to 214 gastroenterologists registered with the Turkish Gastroenterology Association. RESULTS: Approximately half of the gastroenterologists moved their endoscopy unit or gastroenterology clinic to another location in the hospital during the pandemic and about one-third of the endoscopy units were completely closed. About 56% of the respondents reported the interruption of endoscopic procedures and inpatient services. In total, 85% of gastroenterologists thought that follow-up and treatment of chronic patients were disrupted due to patients obtaining their medicine directly from pharmacies. After the first case in Turkey, 74% of gastroenterologists worked in coronavirus disease 2019 patient care services, 28% of gastroenterologists were infected with coronavirus disease 2019, and 3% believed they had a cross-infected patient(s). A total of 78% of gastroenterologists reported that patient management became difficult due to the change in the priority of other departments, and 60% of gastroenterologists confirmed that they experienced a decrease in income. In the post-vaccination period, 70% of gastroenterologists returned to their pre-pandemic working schedule and 31% noticed an increase in endoscopic cancer detection. CONCLUSION: Prolongation of the pandemic has seriously damaged the practice of gastroenterology and multidisciplinary patient management.

Rituximab-treated rheumatic patients: B cells predict seroconversion after COVID-19 boost or revaccination in initial vaccine non-responders. OBJECTIVES: To investigate the effect of either a booster vaccine (one dose) or revaccination (two doses 3â€‰weeks apart) on the antibody response to the COVID-19 mRNA vaccines in patients with rheumatic disease (RD) treated with rituximab (RTX) who had not produced vaccine-reactive antibodies after the initial two vaccine doses. Further, to examine if B cell levels in peripheral blood predicted seroconversion. METHODS: We included 91 RTX-treated RD patients previously vaccinated against COVID-19. Patients were offered revaccination or a single booster vaccination with an mRNA vaccine. Serum total antibodies against SARS-CoV-2 spike protein were measured before and 6â€‰weeks after the last vaccine dose. B cells (CD19+CD45+) were measured by flow cytometry at inclusion. RESULTS: Of RD patients with undetectable SARS-CoV-2 antibody levels before inclusion, seroconversion was seen in 38% 6â€‰weeks after the booster dose and 32% after revaccination. Patients receiving revaccination had significantly higher antibody levels than patients receiving a booster dose (Pâ€‰<â€‰0.001). In both univariate and multivariate logistic regression analysis, only B cells higher than 10/Âµl before boost or revaccination were associated with seroconversion (Pâ€‰=â€‰0.009 and Pâ€‰=â€‰0.01, respectively). Seroconversion was independent of age, gender, diagnosis, cumulative RTX dose, RTX treatment time and time since last RTX treatment. CONCLUSION: Continuously impaired humoral response to mRNA vaccines was found in most RTX-treated patients after a booster dose or revaccination. Seroconversion was observed in approximately one-third of the patients. Measurable B cells before boosting or revaccination was the strongest predictor of antibody response after boost or revaccination.

Reactogenicity and Immunogenicity of the ChAdOx1 nCOV-19 Coronavirus Disease 2019 Vaccine in South Korean Healthcare Workers. PURPOSE: The association between reactogenicity and immunogenicity of the ChAdOx1 nCOV-19 is controversial. We aimed to evaluate this association among South Korean healthcare workers (HCWs). MATERIALS AND METHODS: Participants received two doses of the ChAdOx1vaccine 12 weeks apart. Blood samples were tested for anti-severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) spike protein receptor binding domain antibodies about 2 months after the first and second doses using the Elecsys Anti-SARS-CoV-2 S assay kits. Adverse events were noted using an online self-reporting questionnaire. RESULTS: Among the 232 HCWs, pain (85.78% after the first dose vs. 58.62% after the second dose, p<0.001) was the most prominent local reaction, and myalgia or fatigue (84.05% vs. 53.02%, p<0.001) was the most prominent systemic reaction. The frequency of all adverse events was significantly reduced after the second dose. After the first dose, the anti-SARS-CoV-2 S showed significantly higher titer in the group with swelling, itching, fever, and nausea. Also, the anti-SARS-CoV-2 S titer significantly increased as the grade of fever (p=0.007) and duration of fever (p=0.026) increased; however, there was no significant correlation between immunogenicity and adverse event after the second dose. The group with pain after the first dose showed a greater increase in the anti-SARS-CoV-2 S difference between the second and first doses compared to the group without pain (542.2 U/mL vs. 363.8 U/mL, p=0.037). CONCLUSION: The frequency of adverse events occurring after the first dose of the ChAdOx1 was significantly reduced after the second dose. Interestingly, the elevation of anti-SARS-CoV-2 S titer was significantly increased in the group with pain after the first dose.

Maternal vaccination-current status, challenges, and opportunities. AIM: Maternal vaccination is a promising strategy for protecting pregnant women and newborns against severe infections. This review aims to describe the current status and challenges associated with maternal vaccination against seasonal influenza, tetanus-diphtheria-pertussis (Tdap/DTaP), and novel coronavirus disease of 2019 (COVID-19) in Japan and other countries, mainly the United States and the United Kingdom. METHODS: A literature search was conducted in PubMed and other public websites (e.g., Centers for

Disease Control and Prevention) to obtain information on maternal vaccination. RESULTS: Inactivated vaccines are recommended for pregnant women by gynecologic societies in Japan, the United States, and the United Kingdom. Among pregnant Japanese women, the influenza and COVID-19 (two doses) vaccine coverage rates were 27.0%-53.5% (six studies) and 73.6% (one study), respectively; there are no studies on maternal vaccination with DTaP. Concerns regarding vaccine safety are a major barrier to maternal vaccination across countries. Maternal vaccination is effective in preventing severe disease in pregnant women and protecting infants aged <6Â months, is generally safe, and does not increase the risk of adverse maternal and fetal outcomes. Providing accurate information regarding vaccination through healthcare providers and the government and government funding for vaccines may help improve maternal vaccination rates in Japan. CONCLUSION: Current coverage for maternal vaccination is still low globally mainly because of vaccine hesitancy among pregnant women. The government, drug-regulatory authorities, and healthcare professionals must educate pregnant women about the effectiveness and safety of maternal vaccines and encourage vaccination when the benefits outweigh the risks.

Effectiveness and safety of COVID-19 vaccine in pregnant women: A systematic review with meta-analysis. BACKGROUND: There are limited data regarding COVID-19 vaccination during pregnancy. OBJECTIVES: To evaluate the effects of COVID-19 vaccination received during pregnancy on SARS-CoV-2 infection, COVID-19-related hospitalisation, COVID-19-related intensive care unit (ICU) admission and maternal-fetal complications. SEARCH STRATEGY: MEDLINE, CINHAL, Embase, Scopus and CENTRAL databases, as well as ClinicalTrials.gov, reference lists, related articles and grey literature sources. SELECTION CRITERIA: Randomised controlled trials, non-randomised studies of interventions, pregnant women, COVID-19 vaccination during pregnancy. DATA COLLECTION AND ANALYSIS: Study selection, risk-of-bias assessment, data extraction and assessment of the certainty of evidence using the GRADE method were performed independently by two authors. Meta-analyses were performed using Cochrane RevManÂ 5.4. PROSPERO registration number: CRD42022308849. MAIN RESULTS: We included 14 observational studies (362â€‰353 women). The administration of a COVID-19 vaccine during pregnancy resulted in a statistically significant reduction in SARS-CoV-2 infection (ORÂ 0.46, 95%Â CI 0.28-0.76) and COVID-19-related hospitalisation (ORÂ 0.41, 95%Â CI 0.33-0.51). The effect appeared to be greater in fully vaccinated women, for both infection (ORÂ 0.31, 95%Â CI 0.16-0.59) and hospitalisation (ORÂ 0.15, 95%Â CI 0.10-0.21). However, the certainty of evidence was very low. The difference in COVID-19-related ICU admission between vaccinated and unvaccinated individuals did not reach statistical significance (ORÂ 0.58, 95%Â CI 0.13-2.58). Finally, there were no statistically significant differences in any of the maternal-fetal complications considered in the included studies. CONCLUSIONS: COVID-19 vaccination administered during pregnancy seems to reduce SARS-CoV-2 infection and COVID-19-related hospitalisation, with no significant effects on maternal-fetal complications.

Post-COVID mRNA vaccine myocarditis in children: report of two cases. The SARS-COV-2 pandemic led to the development of several vaccinations to contain the disease. The Pfizer-BioNTech COVID-19 (BNT162b2) vaccine was recommended on May 2021 for use in children above 12 years and older. The vaccine is safe, well tolerated and highly effective. Initial reports showed no serious adverse events; however, cases of myocarditis in young healthy male adolescents have been reported. We report two cases of myocarditis/perimyocarditis who presented with short history of chest pain following administration of the second dose of the MRN COVID-19 vaccine.

Humoral response and safety of the BNT162b2 and mRNA-1273 COVID-19 vaccines in allogeneic hematopoietic stem cell transplant recipients: An observational study. BACKGROUND: The effectiveness of mRNA COVID-19 vaccines and the optimal timing of vaccine administration in allogeneic hematopoietic stem cell transplantation (Allo-HSCT) recipients remains inadequately

investigated. We examine the effectiveness and safety of mRNA COVID-19 vaccines in allo-HSCT recipients. METHOD: This prospective observational study included 44 allo-HSCT recipients and 38 healthy volunteers. The proportion of subjects acquiring anti-S1 IgG antibodies were considered as the primary endpoint. The occurrence of adverse events after vaccination and objective deterioration of chronic graft-versus-host disease (GVHD) were defined as secondary endpoints. In addition, we compared the geometric mean titers (GMT) of anti-S1 antibody titers in subgroups based on time interval between transplantation and vaccination. RESULTS: A humoral response to the vaccine was evident in 40 (91%) patients and all 38 healthy controls. The GMT of anti-S1 titers in patients and healthy controls were 277 (95% confidence interval [CI]: 120-643) BAU/mL and 532 (95% CI 400-708) BAU/mL, respectively. (pÂ =Â 0.603). A short time interval between transplantation and vaccination (â‰¤6 months) was associated with low anti-S1 IgG antibody titers. No serious adverse events and deterioration of chronic GVHD were observed. Only one case of new development of mild chronic GVHD was recorded. CONCLUSION: Messenger RNA COVID-19 vaccines induce humoral responses in allo-HSCT recipients and can be administered safely.
Pyoderma gangrenosum after COVID-19 infection and vaccination.
Skin necrosis after COVID-19 vaccines.
Safety and efficacy of SARS-CoV-2 vaccination in 1237 patients with primary SjÃ¶gren syndrome. OBJECTIVES: To investigate the safety and efficacy of SARS-Cov-2 vaccination in patients with primary SjÃ¶gren syndrome (pSS) due to scarcity of data in this population. METHODS: By the first week of May 2021, all Big Data SS Consortium centres patients who had received at least one dose of any SARS-CoV-2 vaccine were included in the study. The in-charge physician asked patients about local and systemic reactogenicity to collect SARS-CoV-2 vaccination data. RESULTS: The vaccination data of 1237 patients were received. A total of 835 patients (67%) reported any adverse events (AEs), including local (53%) and systemic (50%) AEs. Subjective symptoms (63%) were the most common local AEs, followed by objective signs at the injection site (16%), and general symptoms were the most commonly reported systemic AEs (46%), followed by musculoskeletal (25%), gastrointestinal (9%), cardiopulmonary (3%), and neurological (2%). In addition, 141 (11%) patients reported a significant worsening/exacerbation of their pre-vaccination sicca symptoms and fifteen (1.2%) patients reported active involvement in the glandular (n=7), articular (n=7), cutaneous (n=6), pulmonary (n=2), and peripheral nervous system (n=1) domains due to post-vaccination SS flares. In terms of vaccination efficacy, breakthrough SARS-CoV-2 infection was confirmed after vaccination in three (0.24 %) patients, and positive anti-SARS-Cov-2 antibodies were detected in approximately 95% of vaccinated SS patients, according to data available. CONCLUSIONS: Our data suggest that patients with pSS develop adequate humoral response and no severe AEs after SARS-CoV-2 vaccination and therefore raise no concerns about the vaccine's efficacy or safety profile in this population.
COVID-19 Vaccine-Related Myocardial and Pericardial Inflammation. PURPOSE OF REVIEW: To review myocarditis and pericarditis developing after COVID-19 vaccinations and identify the management strategies. RECENT FINDINGS: COVID-19 mRNA vaccines are safe and effective. Systemic side effects of the vaccines are usually mild and transient. The incidence of acute myocarditis/pericarditis following COVID-19 vaccination is extremely low and ranges 2-20 per 100,000. The absolute number of myocarditis events is 1-10 per million after COVID-19 vaccination as compared to 40 per million after a COVID-19 infection. Higher rates are reported for pericarditis and myocarditis in COVID-19 infection as compared to COVID-19 vaccines. COVID-19 vaccine-related inflammatory heart conditions are transient and self-limiting in most cases. Patients present with chest pain, shortness of breath, and fever. Most patients have elevated cardiac enzymes and diffuse ST-segment elevation on electrocardiogram. Presence of myocardial edema on T2 mapping and evidence of late gadolinium enhancement on cardiac magnetic resonance imaging are also helpful

additional findings. Patients were treated with non-steroidal anti-inflammatory drugs and colchicine with corticosteroids reserved for refractory cases. At least 3-6Â months of exercise abstinence is recommended in athletes diagnosed with vaccine-related myocarditis. COVID-19 vaccination is recommended in all age groups for the overall benefits of preventing hospitalizations and severe COVID-19 infection sequela.

Macrophage Activation Syndrome Complicated by Toxic Epidermal Necrolysis Following SARS-CoV-2 mRNA Vaccination.

Lot-to-lot consistency, immunogenicity, and safety of an inactivated SARS-CoV-2 vaccine (CoronaVac) in healthy adults: A randomized, double-blind, phase IV trial. Previous phase I to III clinical trials have shown that the inactivated SARS-CoV-2 vaccine namely CoronaVac has good efficacy, safety, and immunogenicity. This phase IV trial aims to evaluate the lot-to-lot consistency, immunogenicity, and safety on a commercial scale in healthy adults, which could provide data to support stable manufacturing. In this single-center, randomized, double-blind study, 1,080 healthy adults aged 26-45 years were randomly assigned into three groups to receive one of three lots of vaccines. All subjects received two doses of CoronaVac with an interval of 28 days. Serum samples were collected before the first dose and 28 days after the second dose to assess the immunogenicity. Solicited local and systemic adverse events (AEs) within 7 days and unsolicited AEs within 28 days after each dose of vaccination were recorded. A total of 1,039 participants completed the study and were included in the per-protocol set (PPS). The GMTs were 75.2 (68.5,82.6), 65.0 (59.0,71.7), and 65.3 (59.4,71.8), respectively, and the seroconversion rates of neutralizing antibody were all higher than 98%. The GMT ratios of each pair of lots were 1.16 (1.01,1.32), 1.15 (1.01, 1.32), and 0.99 (0.87, 1.14), respectively, meeting the immunological equivalence criteria. The incidence rates of adverse reactions (ARs) were 19.17%, 13.89%, and 18.33%, with no statistical difference. The ARs were all in grade 1 and grade 2, with incidences of 15.46% and 2.50%. Non-vaccine-related serious adverse events (SAEs) were reported. These results showed robust lot-to-lot consistency, immunogenicity, and safety. The stable production indicated that CoronaVac is suitable for large-scale use.Trial registration number: NCT04894227 (ClinicalTrials.gov).

Histological and serological features of acute liver injury after SARS-CoV-2 vaccination. BACKGROUND & AIMS: Liver injury with autoimmune features after vaccination against severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) is increasingly reported. We investigated a large international cohort of individuals with acute hepatitis arising after SARS-CoV-2 vaccination, focusing on histological and serological features. METHODS: Individuals without known pre-existing liver diseases and transaminase levels â‰¥5x the upper limit of normal within 3 months after any anti-SARS-CoV-2 vaccine, and available liver biopsy were included. Fifty-nine patients were recruited; 35 females; median age 54 years. They were exposed to various combinations of mRNA, vectorial, inactivated and protein-based vaccines. RESULTS: Liver histology showed predominantly lobular hepatitis in 45 (76%), predominantly portal hepatitis in 10 (17%), and other patterns in four (7%) cases; seven had fibrosis Ishak stage â‰¥3, associated with more severe interface hepatitis. Autoimmune serology, centrally tested in 31 cases, showed anti-antinuclear antibody in 23 (74%), anti-smooth muscle antibody in 19 (61%), anti-gastric parietal cells in eight (26%), anti-liver kidney microsomal antibody in four (13%), and anti-mitochondrial antibody in four (13%) cases. Ninety-one percent were treated with steroids Â± azathioprine. Serum transaminase levels improved in all cases and were normal in 24/58 (41%) after 3 months, and in 30/46 (65%) after 6 months. One patient required liver transplantation. Of 15 patients re-exposed to SARS-CoV-2 vaccines, three relapsed. CONCLUSION: Acute liver injury arising after SARS-CoV-2 vaccination is frequently associated with lobular hepatitis and positive autoantibodies. Whether there is a causal relationship between liver damage and SARS-CoV-2 vaccines remains to be established. A close follow-up is warranted to assess

the long-term outcomes of this condition. IMPACT AND IMPLICATIONS: Cases of liver injury after vaccination against severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) have been published. We investigated a large international cohort of individuals with acute hepatitis after SARS-CoV-2 vaccination, focusing on liver biopsy findings and autoantibodies: liver biopsy frequently shows inflammation of the lobule, which is typical of recent injury, and autoantibodies are frequently positive. Whether there is a causal relationship between liver damage and SARS-CoV-2 vaccines remains to be established. Close follow-up is warranted to assess the long-term outcome of this condition.
Repeated Coronary Artery Thrombosis after mRNA-1273 COVID-19 Vaccination.
Fulminant Myocarditis in a 76-Year-Old Lady after Spikevax Vaccination: A Case Report.
Acute Pericarditis with High Anti-Nuclear Antibody Titers Following BNT162b2 mRNA COVID-19 Vaccination.
Endocrine system after 2 years of COVID-19 vaccines: A narrative review of the literature. PURPOSE: The purpose of this study was to describe the current knowledge on the potential endocrine adverse effects post-COVID-19 vaccines. METHODS: A PubMed/MEDLINE, Web of Science, and Scopus research was performed. Case reports, case series, original studies, and reviews written in English and published online up to 31 July 2022 were selected and reviewed. The final reference list was defined based on the relevance of each paper to the scope of this review. RESULTS: The available data showed that endocrine side effects are generally rare and with favorable outcome, being thyroid disorders the most common. Conversely, data on type 1 diabetes mellitus are rare; adrenal and pituitary events are even anecdotal. Finally, the available clinical studies suggest no impact on female reproductive system and on male and couple fertility. CONCLUSION: Overall, these data show that, after 2 years of COVID-19 vaccines, the endocrine system is not heavily threatened.
Cardiac magnetic resonance follow-up of COVID-19 vaccine associated acute myocarditis. BACKGROUND: Mass COVID-19 vaccination campaigns have helped impede the COVID-19 pandemic. In rare cases, some vaccines have led to vaccine associated myocarditis in a specific subset of the population, usually young males. Cardiac magnetic resonance (CMR) can reliably diagnose vaccine associated myocarditis, but follow-up data of CMR proven acute myocarditis is scarce. MATERIALS AND METHODS: Nine patients with acute vaccine associated myocarditis underwent baseline and follow-up CMR examinations and were compared to baseline parameters at initial presentation and to a group of 20 healthy controls. CMR protocol included functional assessment, T1 and T2 mapping, T2 signal intensity ratio, strain feature tracking, and late gadolinium enhancement (LGE). RESULTS: Myocarditis patients (n = 9, aged 24 Â± 6 years, 8 males) underwent CMR follow-up after an average of 5.8 Â± 4.3 months. All patients showed a complete resolution of visual myocardial edema while also demonstrating a reduction in overall LGE extent from baseline to follow-up (4.2 Â± 2.1 vs. 0.9 Â± 0.8%, p < 0.001), although visual LGE was still noted in all patients. Left ventricular ejection fraction was normal at baseline and at follow-up (58 Â± 6 vs. 62 Â± 4%, p = 0.10) as well as compared to a healthy control group (60 Â± 4%, p = 0.24). T1 (1024 Â± 77 vs. 971 Â± 34 ms, p = 0.05) and T2 relaxations times (57 Â± 6 vs. 51 Â± 3 ms, p = 0.03) normalized at follow-up. Most patients reported a resolution of clinical symptoms, while two (22%) reported new onset of exertional dyspnea. CONCLUSION: Patients with COVID-19 vaccine associated acute myocarditis showed a complete, uncomplicated resolution of myocardial inflammation on follow-up CMR, which was associated with a near complete resolution of symptoms. Minor, residual myocardial scarring was present on follow-up LGE imaging. The long-term implications of the remaining myocardial scar-tissue after vaccine associated myocarditis remain unknown warranting further studies.
Acute myocardial infarction complicated by severe left ventricle systolic dysfunction in a young patient after Covid 19 vaccination: a case report. We report the case of a 23 years old patient

who developed an acute myocardial infarction one day after his second dose of COVID-19 BIBP vaccination, complicated by severe left ventricle systolic dysfunction with an ejection fraction measured at 32%, associated with left ventricular wall motion abnormalities well evolved under treatment of heart failure with reduced EF combining :angiotensin-converting enzyme inhibitor, beta blocker, mineralocorticoid receptor antagonists and sodium-glucose cotransporter 2 inhibitors. Coronary arteries were normal at angiography suggesting initially the diagnostic of myocarditis. Therefore, a cardiac magnetic resonance imaging was performed to confirm the latter, which showed an image consistent with a recent left ventricular subendocardial infarction, remarkably prominent in the left anterior descending artery territory and the absence of signs of myocarditis. The patient had no previous past medical history or other clinical features explaining this coronary event onset. Thus, the vaccine was potentially to be implicated in the pathophysiology of the event. Overall, complications associated with COVID-19 vaccines are extremely rare, and their benefit is well established. That's why they continue to be recommended by public health experts despite of their rare side effects.

Acute Inflammatory Pericarditis following First Dose of COVID-19 Vaccine (AstraZeneca). BACKGROUND: Clinical trials of the COVID-19 vaccine reported the safety and efficacy of mRNA vaccines (AstraZeneca) to help control the disease. Few previous reports have shown various side effects associated with COVID-19 vaccines that vary in severity. The possibility of pericarditis and myocarditis has been observed in people who have received an mRNA COVID-19 vaccine which we are reporting. Acute inflammatory pericarditis can be a rare presentation after receiving the first dose of this vaccine, and it is enriching to share such rare presentations in the era of COVID-19 for better management and outcomes after vaccination. Case Presentation. This is a case of acute inflammatory pericarditis with a small pericardial effusion after receiving the first dose of AstraZeneca COVID-19 vaccine in a healthy adult patient who had no other symptoms suggestive of other viral illness in addition to the negative COVID-19 PCR. A 48-year-old healthy male presented nine days after receiving the first dose of COVID-19 AstraZeneca vaccine. The symptoms started three days after the vaccine, when he complained of progressive retrosternal chest pain with low-grade fever and generalized fatigue, followed by exertional dyspnea after a few days. The diagnosis of acute inflammatory pericarditis with small pericardial effusion was established, and the patient was accordingly treated. One week later, the patient showed significant clinical improvement with the resolution of his pericardial effusion. After 39 days, there was a significant radiological resolution of signs of acute pericarditis. CONCLUSION: The ongoing COVID-19 outbreak is still under investigation, and guidelines are regularly modified since we are continuously learning about this novel disease, although multiple vaccines have been shown to be effective against COVID-19. However, we report a case of unique clinical manifestation that has not been reported widely in the literature, after receiving the first dose of AstraZeneca COVID-19 vaccine, and that it may help raise awareness of the possible diagnosis and the possibility of inflammatory pericarditis after COVID-19 vaccination.

A Case of Myopericarditis After the Second Dose of mRNA COVID-19 Vaccine in a Patient With a History of Myopericarditis. Vaccination is important for the prevention of coronavirus-induced disease 2019 (COVID-19) caused by SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) and to protect persons with a high risk for complications. There have been reports of myopericarditis following COVID-19 vaccination, especially in adolescent males and young adults. Breakthrough infections, such as the Delta or Omicron variant of SARS-CoV-2, have raised great concern about the necessity for repeated doses of the vaccine. A case of myopericarditis after the second dose of COVID-19 mRNA-1273 (Moderna) vaccine in a 23-year-old man with a prior episode of viral myopericarditis is presented. He received the second dose of the COVID-19 mRNA vaccine, after which he developed persistent midsternal chest pain and he was subsequently transferred to our

emergency department. An echocardiogram showed a trivial inferior pericardial effusion with diffuse left ventricular systolic dysfunction. He was treated with colchicine from the first day of hospitalization with a diagnosis of myopericarditis. His chest pain had resolved by the third day, and left ventricular wall motion was dramatically improved by the seventh day of hospitalization. A strong response to the second vaccination in the present case suggests that the prior history of myopericarditis is evidence of strong congenital or acquired immunological features in this individual. Individuals with such a strong immune response may be more likely to develop myopericarditis after mRNA vaccination. Immunization against COVID-19 is currently recommended from a risk-benefit standpoint. We advised the patient to avoid additional COVID-19 mRNA vaccines because of this episode. The risk of COVID-19 weighed against myopericarditis associated with the mRNA vaccination should be considered on a case-by-case basis. This case may help us better understand the mechanism of myopericarditis following COVID-19 mRNA vaccination.

Severe acute respiratory syndrome coronavirus 2 virus-like particles induce dendritic cell maturation and modulate T cell immunity. Dendritic cells (DCs) are professional antigen-presenting cells that play an important role in both innate and acquired immune responses against pathogens. However, the role of DCs in coronavirus disease 2019 (COVID-19) is unclear. Virus-like particles (VLPs) that structurally mimic the original virus are one of the candidates COVID-19 vaccines. In the present study, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) VLPs were used as an alternative to live virus to evaluate the interaction of the virus with DCs. The results revealed that SARS-CoV-2 VLPs induced DC maturation by augmenting cell surface molecule expression (CD80, CD86, and major histocompatibility complex class II (MHC-II)) and inflammatory cytokine production (tumor necrosis factor-Î±, interleukin (IL)-1Î², IL-6, and IL-12p70) in DCs via the mitogen-activated protein kinase and nuclear factor-ÎºB signaling pathways. In addition, mature DCs induced by SARS-CoV-2 VLPs promoted T cell proliferation, which was dependent on VLPs concentration. Our results suggest that SARS-CoV-2 VLPs regulate the immune response by interacting with DCs. These findings will improve the understanding of SARS-CoV-2 pathogenesis and SARS-CoV-2 vaccine development.

A Study to Assess Symptom Profile and Break Through Infections Among Health Care Workers Post Covid Vaccination at Tertiary Care Health Facility. INTRODUCTION: Breakthrough infections in fully vaccinated persons pose a major challenge to the ongoing vaccine campaign against SARS-CoV-2 globally. OBJECTIVES: To investigate the occurrence of breakthrough infections and the association of Covid symptoms with the vaccination status of health care workers (HCWs). MATERIAL AND METHODS: Done in Government Medical College, Patiala among Covid-positive HCWs who have received one or both doses of Covid vaccine, using pretested semi-structured validated Proforma and telephonic interview from April 1, 2021 to June 15, 2021. RESULTS: Among 3388 HCWs, 115 vaccinated HCWs (1(st) or 2(nd) dose) became Covid positive. Among vaccinated Covid positive HCWs, 54 received the first dose and 61 both doses. Breakthrough infections (â‰¥14 days post 2(nd) dose) occurred in 4.6% (47 of 1021) HCWs. The vaccine is significantly protective as shown by an odds ratio of 0.27; thus, vaccinated HCWs are 73% less likely to get Covid infection as compared to non-vaccinated HCWs. There was no statistically significant difference between symptom profiles of cases whether they took one or both doses of vaccine, except headache. Only tiredness and headache were reported significantly higher in the unvaccinated group in comparison to vaccinated HCWs. CONCLUSION: Research is needed on tracking the immune response and viral genomic sequence of samples of vaccinated Covid-positive HCWs to have constant vigilance on remerging new strains of the SARS-CoV-2.

Corrigendum: Ocular effects caused by viral infections and corresponding vaccines: An overview of varicella zoster virus, measles virus, influenza viruses, hepatitis B virus, and SARS-CoV-2. [This corrects the article DOI: 10.3389/fmed.2022.999251.].

Two cases of challenging cutaneous lymphoid infiltrates presenting in the context of COVID-19 vaccination: A reactive lymphomatoid papulosis-like eruption and a bona fide lymphoma. COVID-19 infection and vaccination may be associated with a wide variety of cutaneous and immune manifestations. Here, we describe two patients who presented with monoclonal cutaneous T-cell infiltrates that showed cytologic and immunophenotypic features concerning for lymphoma shortly following COVID-19 vaccination. In one case, the eruption completely resolved. The second patient showed initial resolution, but her disease recurred and progressed following a breakthrough SARS-CoV-2 infection. These cases suggest that immune stimulation following exposure to SARS-Cov-2 protein(s) in vaccine or infection may facilitate the development of a lymphoma or lymphoproliferative disorder in susceptible individuals. Moreover, they show that separating these cases from pseudolymphomatous reactive conditions is often challenging and requires close clinical correlation.

Regarding: Factors associated with severe or fatal clinical manifestations of SARS-CoV-2 infection after receiving the third dose of vaccine.

Capillaritis as cutaneous adverse reaction to SARS-COV-2 primary and booster vaccination: A series of eight cases.

Glomerulopathies after vaccination against COVID-19. Four cases with three different vaccines in Argentina.

Autopsy-based histopathological characterization of myocarditis after anti-SARS-CoV-2-vaccination. Cases of myocarditis, diagnosed clinically by laboratory tests and imaging have been described in the context of mRNA-based anti-SARS-CoV-2 vaccination. Autopsy-based description of detailed histological features of vaccine-induced myocarditis is lacking. We describe the autopsy findings and common characteristics of myocarditis in untreated persons who received anti-SARS-CoV-2 vaccination. Standardized autopsies were performed on 25 persons who had died unexpectedly and within 20Â days after anti-SARS-CoV-2 vaccination. In four patients who received a mRNA vaccination, we identified acute (epi-)myocarditis without detection of another significant disease or health constellation that may have caused an unexpected death. Histology showed patchy interstitial myocardial T-lymphocytic infiltration, predominantly of the CD4 positive subset, associated with mild myocyte damage. Overall, autopsy findings indicated death due to acute arrhythmogenic cardiac failure. Thus, myocarditis can be a potentially lethal complication following mRNA-based anti-SARS-CoV-2 vaccination. Our findings may aid in adequately diagnosing unclear cases after vaccination and in establishing a timely diagnosis in vivo, thus, providing the framework for adequate monitoring and early treatment of severe clinical cases.

Anaphylaxis: Revision of the Brighton collaboration case definition. The Brighton Collaboration (BC) has formulated a number of case definitions which have primarily been applied to adverse events of special interest in the context of vaccine safety surveillance. This is a revision of the 2007 BC case definition for anaphylaxis. Recently, the BC definition has been widely used for evaluating reports of suspected anaphylaxis following COVID-19 vaccination. This has led to debate about the performance of the BC definition in comparison with those from the US National Institute of Allergy and Infectious Disease/Food Allergy Anaphylaxis Network (NIAID/FAAN) and the World Allergy Organization (WAO). BC convened an expert working group to revise the case definition based on their usual process of literature review and expert consensus. This manuscript presents the outcome of this process and proposes a revised case definition for anaphylaxis. Major and minor criteria have been re-evaluated with an emphasis on the reporting of observable clinical signs, rather than subjective symptoms, and a clearer approach to the ascertainment of levels of certainty is provided. The BC case definition has also been aligned with other contemporary and international case definitions for anaphylaxis.

Impact of media coverage on side effect reports from the COVID-19 vaccine. OBJECTIVE: Past research shows that media coverage of medicine side effects can produce a nocebo response. New Zealand news media discussed myocarditis following the Pfizer COVID-19 vaccine. This study examined whether side effects mentioned in the media increased compared to control symptoms not mentioned. METHODS: The study analysed 64,086 vaccine adverse reaction reports, retrieved from the medicine safety authority. Generalised linear regressions compared the side effect rate during three discrete periods of media reporting (August 2021, December 2021, April 2022) with the pre-media baseline rate. The outcomes were weekly reports of chest discomfort, monthly reports of chest, heart and breathing symptoms, and myocarditis, pericarditis, and anxiety. Control symptoms were fever, numbness, and musculoskeletal pain. Logistic regressions investigated factors associated with side effect reporting. RESULTS: The reporting rate of chest discomfort was 190% greater in the five weeks after the first media item (pÂ <Â .001). The monthly reporting rates of the symptoms mentioned in the media were significantly greater after the news coverage (psÂ â‰¤Â 0.001). There was no effect of media on the control side effect fever (pÂ =Â .06). There was an effect of media on myocarditis, pericarditis and anxiety (psÂ <Â 0.001). Anxiety, male gender, and younger age were significantly associated with side effects. CONCLUSION: The results indicate that a media-induced nocebo response occurred. This is most likely due to increased expectations and awareness of COVID-19 vaccine side effects, elevated symptom experience from anxiety, and consequently greater reporting of the symptoms in line with the media coverage.

Hypermetabolic lymphadenopathy following the administration of COVID-19 vaccine and immunotherapy in a lung cancer patient: a case report. BACKGROUND: Given the current climate of the pandemic, lung cancer patients are especially vulnerable to complications from severe acute respiratory syndrome coronavirus 2 infection. As a high-risk population group, these patients are strongly advised to receive coronavirus disease 2019 vaccination in accordance with Center for Disease Control and Prevention guidelines to minimize morbidity and mortality. In recent years, immunotherapy has taken a preeminent role in the treatment of non-small cell lung cancer with dramatic improvement in overall survival. Reactive lymphadenopathy following the administration of a coronavirus disease 2019 vaccination can confound the radiographic interpretation of positron emission tomography-computed tomography or computed tomography scans from lung cancer patients receiving immunotherapy. CASE PRESENTATION: Here, we present a case of a 61-year-old Caucasian female and former smoker who developed cervical, hilar, supraclavicular, mediastinal, and left retroauricular lymphadenopathy following her coronavirus disease 2019 booster vaccination. At the time, she had been receiving long-term immunotherapy for the treatment of advanced lung adenocarcinoma. Biopsy was pursued owing to concerns of treatment failure and confirmed recurrent malignancy. CONCLUSION: This case report highlights the importance of lymph node biopsies in lung cancer patients who present with contralateral lymphadenopathy following coronavirus disease 2019 vaccination to rule out tumor recurrence in this deserving patient population.

Humoral response after a fourth "booster" dose of coronavirus disease 2019 vaccination and outcome of Japan's seventh wave of coronavirus disease 2019 infections in hemodialysis patients: A single-center experience.

Prurigo pigmentosa following booster dose of COVID-19 vaccine.

Corneal Complications after COVID-19 Vaccination: A Systemic Review. Multiple vaccines are now being used across the world, and several studies have described cases of corneal graft rejection following the administration of the COVID-19 vaccine. The purpose of this article is to review the corneal adverse event that occurred following COVID-19 vaccine administration. The literature search was conducted in March 2022 using MEDLINE, PubMed, and the Cochrane Database of Systematic

Reviews. A total of 27 articles, including 37 cases, have documented corneal adverse events that occurred following COVID-19 vaccination. The mean age was 60 Â± 14.9 years (range, 27-83 years). The most common events were acute corneal graft rejection (n = 21, 56.8%), followed by herpes zoster ophthalmicus (n = 11, 29.7%) and herpes simplex keratitis (n = 2, 5.4%). The mean time from vaccination to the event was 10 Â± 8.5 days (range, 1-42 days) after the first or second dose of vaccine. All patients with corneal graft rejection, immune-mediated keratolysis, and peripheral ulcerative keratitis (PUK) (n = 24, 64.9%) were managed topically with or without oral corticosteroids. Patients with herpes zoster ophthalmicus and herpes simplex keratitis were managed with oral antiviral agents. Two patients received penetrating keratoplasty due to keratolysis after invalid topical treatment. Disease resolution was noted in 29 patients (78.3%), whereas 3 (8.1%) had persistent corneal edema after graft rejection, 1 (2.7%) had corneal infiltration after HZO, and 4 (10.8%) were not mentioned in the articles. Corneal adverse events could occur after COVID-19 vaccination. After timely treatment with steroids or antiviral agents, most of the events were mild and had a good visual outcome. Administrating or increasing steroids before vaccination may be useful for the prevention of corneal graft rejection. However, the prophylactic use of antiviral treatments in patients with a herpes viral infection history is not recommend.

Management of Femur Fractures during COVID-19 Pandemic Period: The Influence of Vaccination and Nosocomial COVID-19 Infection. The COVID-19 pandemic management has led to a significant change in orthopedic surgical activity. During the pandemic, femur fractures in patients over 65 years of age have maintained a constant incidence. Our study will focus on this fragile population, analyzing the incidence of SARS-CoV-2 infection during hospital stays and the clinical and radiographic orthopedic outcomes. We also evaluated the va\riation of COVID-19 infection after health professionals' vaccinations, and the influence of inter-hospital transfers caused by logistical and organizational aspects of the pandemic. Material and Methods: This is a descriptive and prospective study from 13 October 2020 to 15 March 2021. Participants were patients over 65 years of age with diagnoses of proximal femoral fractures with r surgical treatments indicated. We compared the SARS-CoV-2 infected patients during the stay with non-infected cases. A second evaluation was carried out dividing the patients into those who underwent inter-hospital transfers and a group without transfers. We subdivided the study period into two, according to the percentage of healthcare workers vaccinated against SARS-CoV-2. The reported clinical variables included the Parker and Palmer Score, the Nottingham Hip Fracture Score, the Harris Hip Score, mortality, the Rush Score, and evaluation of reduction in radio-lucent lines in prosthetic implants. Results: Ninety-three patients were studied. The whole positive COVID cohort (11.83%) was hospitalized during the period when less than 80% of health workers were vaccinated ($p = 0.02$). The COVID cohort and the patients transferred before surgery had longer stays in the Emergency Room ($p = 0.019$; $p = 0.00007$) and longer lengths of stay compared to the other patients ($p = 0.00001$; $p = 0.001$). Mortality was higher both in the infected group and in the patients who underwent a transfer before the surgical procedure (18.18% vs. 1.22 %; $p = 0.003$. 25% vs. 6.85%; $p = 0.02$). In terms of orthopedic outcomes measured through the third month of follow-up, we found worse score results in functional and radiographic outcomes in the COVID positive cohort and in the transferred patients' cohort. Conclusions: The impact of the COVID-19 pandemic on patients treated for proximal femur fracture was statistically significant. Patients with Coronavirus during hospitalization obtained poor short-term radiographic and functional results and increased peri-operative mortality. The incidence of intra-hospital infection was high during the period in which health professionals were not yet covered by the anti-COVID vaccination cycle. Patients who were transferred between two hospitals due to pandemic-related management issues also achieved reduced outcomes compared to non-transferred cases, with increased mortality.

The rs1883832 Polymorphism (CD40-1C>T) Affects the Intensity of IgA Responses after BNT162b2 Vaccination. The effectiveness of coronavirus disease 2019 (COVID-19) vaccination strategies is affected by several factors, including the genetic background of the host. In our study, we evaluated the contribution of the functional polymorphism rs1883832 affecting the Kozak sequence of the TNFSF5 gene (c.-1C>T), encoding CD40, to humoral immune responses after vaccination with the spike protein of SARS-CoV-2. The rs1883832 polymorphism was analyzed by PCR-RFLP in 476 individuals (male/female: 216/260, median age: 55.0 years, range: 20â˜'105) of whom 342 received the BNT162b2 mRNA vaccine and 134 received the adenovirus-based vector vaccines (67 on ChAdOx1-nCoV-19 vaccine, 67 on Ad.26.COV2.S vaccine). The IgG and IgA responses were evaluated with chemiluminescent microparticle and ELISA assays on days 21, 42, and 90 after the first dose. The T allele of the rs1883832 polymorphism (allele frequency: 32.8%) was significantly associated with lower IgA levels and represented, as revealed by multivariable analysis, an independent risk factor for reduced anti-spike protein IgA levels on days 42 and 90 following BNT162b2 mRNA vaccination. Similar to serum anti-spike IgA levels, a trend of lower anti-spike IgA concentrations in saliva was found in individuals with the T allele of rs1883832. Finally, the intensity of IgA and IgG responses on day 42 significantly affected the prevalence of COVID-19 after vaccination. The rs1883832 polymorphism may be used as a molecular predictor of the intensity of anti-spike IgA responses after BNT162b2 mRNA vaccination.

Side-Effects following Oxford/AstraZeneca COVID-19 Vaccine in Tororo District, Eastern Uganda: A Cross-Sectional Study. Effective, safe and proven vaccines would be the most effective strategy against the COVID-19 pandemic but have faced rollout challenges partly due to fear of potential side-effects. We assessed the prevalence, profiles, and predictors of Oxford/AstraZeneca vaccine side-effects in Tororo district of Eastern Uganda. We conducted telephone interviews with 2204 participants between October 2021 and January 2022. Multivariable logistic regression was conducted to assess factors associated with Oxford/AstraZeneca vaccine side-effects using Stata version 15.0. A total of 603/2204 (27.4%) of the participants experienced one or more side-effects (local, systemic, allergic, and other side-effects). Of these, 253/603 (42.0%) experienced local side-effects, 449/603 (74.5%) experienced systemic side-effects, 11/603 (1.8%) experienced allergic reactions, and 166/603 (27.5%) experienced other side-effects. Ten participants declined to receive the second dose because of side-effects they had experienced after the first dose. Previous infection with COVID-19 (adjusted odds ratio (AOR): 4.3, 95% confidence interval (95% CI): 2.7-7.0), being female (AOR: 1.3, 95% CI: 1.1-1.6) and being a security officer (AOR: 0.4, 95% CI: 0.2-0.6) were associated with side-effects to the Oxford/AstraZeneca vaccine. We recommend campaigns to disseminate correct information about potential side-effects of the Oxford/AstraZeneca vaccine and strengthen surveillance for adverse events following vaccination.

Non-Myelofibrosis Chronic Myeloproliferative Neoplasm Patients Show Better Seroconversion Rates after SARS-CoV-2 Vaccination Compared to Other Hematologic Diseases: A Multicentric Prospective Study of KroHem. Disease- and treatment-mediated immunodeficiency might render SARS-CoV-2 vaccines less effective in patients with hematologic diseases. We performed a prospective non-interventional study to evaluate humoral response after one and two doses of mRNA-1273, BNT162b2, or ChAdOx1 nCoV-19 vaccine in 118 patients with different malignant or non-malignant hematologic diseases from three Croatian treatment centers. An electrochemiluminescent assay was used to measure total anti-SARS-CoV-2 S-RBD antibody titers. After one vaccine dose, 20/66 (33%) achieved seropositivity with a median antibody titer of 6.1 U/mL. The response rate (58/90, 64.4%) and median antibody titer (>250 U/mL) were higher after two doses. Seropositivity varied with diagnosis (overall $p < 0.001$), with the lowest rates in lymphoma (34.6%) and chronic lymphocytic leukemia (52.5%). The overall response rate in chronic myeloproliferative neoplasms (CMPN) was

81.3% but reached 100% in chronic myeloid leukemia and other non-myelofibrosis CMPN. At univariable analysis, age > 67 years, non-Hodgkinâ€™s lymphoma, active treatment, and anti-CD20 monoclonal antibody therapy increased the likelihood of no vaccine response, while hematopoietic stem cell recipients were more likely to respond. Age and anti-CD20 monoclonal antibody therapy remained associated with no response in a multivariable model. Patients with the hematologic disease have attenuated responses to SARS-CoV-2 vaccines, and significant variations in different disease subgroups warrant an individualized approach.

Acute adrenal insufficiency in a patient with panhypopituitarism after vaccination against COVID-19 (BNT162b2 Pfizer-BioNTech).

Memory B Cells and Memory T Cells Induced by SARS-CoV-2 Booster Vaccination or Infection Show Different Dynamics and Responsiveness to the Omicron Variant. Although the immunological memory produced by BNT162b2 vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been well studied and established, further information using different racial cohorts is necessary to understand the overall immunological response to vaccination. We evaluated memory B and T cell responses to the severe acute respiratory syndrome coronavirus 2 spike protein before and after the third booster using a Japanese cohort. Although the Ab titer against the spike receptor-binding domain (RBD) decreased significantly 8 mo after the second vaccination, the number of memory B cells continued to increase, whereas the number of memory T cells decreased slowly. Memory B and T cells from unvaccinated infected patients showed similar kinetics. After the third vaccination, the Ab titer increased to the level of the second vaccination, and memory B cells increased at significantly higher levels before the booster, whereas memory T cells recovered close to the second vaccination levels. In memory T cells, the frequency of CXCR5+CXCR3+CCR6- circulating follicular Th1 was positively correlated with RBD-specific Ab-secreting B cells. For the response to variant RBDs, although 60-80% of memory B cells could bind to the omicron RBD, their avidity was low, whereas memory T cells show an equal response to the omicron spike. Thus, the persistent presence of memory B and T cells will quickly upregulate Ab production and T cell responses after omicron strain infection, which prevents severe illness and death due to coronavirus disease 2019.

Clinical and laboratory profile and outcomes of hospitalized COVID-19 patients with type 2 diabetes mellitus in Ghana - AÂ single-center study. BACKGROUND: In sub-Saharan Africa and particularly in Ghana, there is scarcity of published literature specifically on the impact of DM on outcomes in COVID-19 patients. Based on the difference in genetic makeup and demographic patterns in Africans compared to the Western world and with the rising burden of DM and other non-communicable diseases in Ghana there is a need to define the impact DM has on persons with COVID-19. This would ensure adequate risk stratification and surveillance for such patients as well as appropriate scale up of therapeutic management if needed. AIMS: This single-center study describes the clinical and laboratory profile and outcomes of COVID-19 in-patients with type 2 diabetes mellitus (DM) in Ghana. MATERIALS AND METHODS: Retrospective analysis was undertaken of the medical records of adults with COVID-19 hospitalized at a facility in Ghana from March to October 2020. Clinical, laboratory and radiological data and outcomes were analysed. Comparisons between COVID-19 patients with DM and non-diabetics were done with an independent t-test or a Mann-Whitney test when normality was not attained. Odds ratios (95% CI) were calculated using univariate logistic regression. RESULTS: Out of 175 COVID-19 patients, 64 (36.6%) had DM. Overall mean age was 55.9â€‰Â±â€‰18.3â€‰years; DM patients were older compared to non-diabetics (61.1â€‰Â±â€‰12.8 vs. 53.0â€‰Â±â€‰20.2â€‰years, pÂ =Â .049). Compared to non-diabetics, diabetics were more likely to have higher blood glucose at presentation, have hypertension, be on angiotensin 2 receptor blockers [OR, 95% CI 3.3 (1.6-6.7)] and angiotensin converting enzyme inhibitors [OR, 95% CI 3.1 (1.3-7.4)]; and be HIV negative (pâ€‰<â€‰.05). Although the values were normal, diabetics had a higher

platelet count but decreased lymphocytes, aspartate transaminase and alkaline phosphatase compared to non-diabetics (pâ€‰<â€‰.05). There was no difference in clinical symptoms, severity or mortality between the two groups. DISCUSSION: The clinical profile of patients studied are similar to prior studies. However the outcome of this study showed that DM was not associated with worse clinical severity and in-hospital mortality. This could have been due to majority of DM patients in this study having relatively good blood glucose control on admission. Secondly, DM alone may not be a risk factor for mortality. Rather its concurrent existence with multiple co-morbidities (especially cardiovascular co-morbidities which may predispose to pro-inflammatory and pro-thrombotic states) may be driving the rise in severity and mortality risks reported in other studies. Furthermore, this study was conducted among an African population and Africa has been shown to be generally less severely hit by the COVID-19 pandemic compared to other regions outside the continent. This has been postulated to be due, among other factors, to inherent protective mechanisms in Africans due to early and repeated exposure to parasitic and other organisms resulting in a robust innate immunity. CONCLUSIONS: This study suggested that DM was not associated with more severe clinical symptoms or worse outcomes among hospitalized COVID-19 patients. Despite this, it is important that DM patients adhere to their therapy, observe the COVID-19 containment protocols and are prioritized in the administration of the COVID-19 vaccines. STUDY HIGHLIGHTS: In this retrospective, single-centre study on the clinical and laboratory profile and outcome of hospitalized DM patients with COVID-19, patients with DM did not have a more severe clinical profile or worse outcomes. They were, however, significantly older, more likely to have higher admission blood glucose, have hypertension, be on angiotensin 2 receptor blockers and angiotensin converting enzyme inhibitors; and be HIV negative compared to the cohort without DM. DM patients should be a priority group for the COVID-19 vaccines.

Pyoderma Gangrenosum Triggered by COVID-19 Vaccination in a Patient with Ulcerative Colitis: A Case Report. Pyoderma gangrenosum (PG) is a rare inflammatory skin disease that is difficult to diagnose. PG may be an extra-intestinal manifestation of ulcerative colitis (UC). In recent times, coronavirus disease (COVID-19) vaccines have caused various adverse cutaneous reactions. However, to the best our knowledge, combinations thereof have not been reported. We encountered a case of PG triggered by COVID-19 vaccination in a patient with UC. A 40-year-old woman developed severe pain and an abscess in the dorsum of the left foot after receiving the first dose of the messenger RNA (mRNA)-based Pfizer/BioNTech BNT162b2 COVID-19 vaccine. Severe painful ulcers with purulent necrosis and gaseous gangrene progressed rapidly along the extensor tendons and muscles to the toes and ankle. Although surgical debridement can worsen PG by triggering pathergy, we nonetheless performed wide debridement including partial extensor tenotomy with abscess drainage to prevent progression to pyogenic ankle arthritis and to rescue the toes. Antibiotics, corticosteroids, and anticoagulants were prescribed during surgical wound management via negative pressure therapy. After the lesion improved, the skin and soft tissue defect were covered using a superficial circumflex iliac artery perforator free flap and a split-thickness skin graft. The patient was satisfied with the foot salvage, and could walk unaided (without a brace or cane) from 8 weeks after the final surgery. PG may be rare even in UC patients, but mRNA-based COVID-19 vaccines may find an immunosuppressive niche. A high level of caution and suspicion of skin manifestations after vaccination is essential.

Safety and immunogenicity of heterologous recombinant protein subunit vaccine (ZF2001) booster against COVID-19 at 3-9-month intervals following two-dose inactivated vaccine (CoronaVac). BACKGROUND: In response to SARS-CoV-2 mutations and waning antibody levels after two-dose inactivated vaccines, we assessed whether a third dose of recombinant protein subunit vaccine (ZF2001) boosts immune responses. METHODS: An open-label single-center non-random trial was

conducted on people aged 18 years and above at five sites in China. All participants received a two-dose inactivated vaccine (CoronaVac) as their prime doses within 3-9 months of the trial. Primary outcomes were safety and immunogenicity, primarily the geometric mean titers (GMTs) of neutralizing antibodies to live wildtype SARS-CoV-2. RESULTS: A total of 480 participants (median age, 51; range 21-84 years) previously vaccinated with two-dose CoronaVac received a third booster dose of ZF2001 3-4, 5-6, or 7-9-months later. The overall incidence of adverse reactions within 30 days after vaccination was 5.83% (28/480). No serious adverse reactions were reported after the third dose of ZF2001. GMTs in the 3-4-, 5-6-, and 7-9-month groups before vaccination were 3.96, 4.60, and 3.78, respectively. On Day 14, GMTs increased to 33.06, 47.51, and 44.12, respectively. After the booster, GMTs showed no significant difference among the three prime-boost interval groups (all P>0.05). Additionally, GMTs in older adults were lower than those in younger adults on Day 14 for the three groups (P=0.0005, P<0.0001, and P<0.0001). CONCLUSION: Heterologous boosting with ZF2001 was safe and immunogenic, and prime-boost intervals did not affect the immune response. The immune response was weaker in older than younger adults.

Complications of COVID-19 Vaccines during Pregnancy; a Systematic Review. INTRODUCTION: Rare serious complications have been documented after COVID-19 vaccination as clinical research proceeded and new target populations, such as children and â€Žpregnant women, were included. In this study, we attempted to review the literature relevant to â€Žpregnancy complications and maternal outcomes of COVID-19 immunization in pregnant women. â€Ž. METHODS: We searched the databases of PubMed, Scopus, Cochrane, and Web of Science on 31 August 2022. The records were downloaded and underwent a two-step screening; 1) title/abstract and then 2) full-text screening to identify the eligible studies. We included English original studies that evaluated the adverse effects of COVID-19 vaccines during pregnancy. Information such as the type of â€Žstudy, geographical location, type of vaccine injected, gestational age, maternal underlying diseases, and â€Žcomplications following the vaccination were extracted into pre-designed tables. RESULTS: According to the findings of included studies, in most of them vaccination had a positive impact and no negative effects were observed. Also, no medical history was reported in 11 articles, and pregnant women had no underlying diseases. Some serious adverse events were reported after â€Žvaccination, including miscarriage, paresthesia, uterine contraction, vaginal bleeding, preterm birth, major â€Žcongenital anomalies, intrauterine growth restriction, and seizure. â€Ž. CONCLUSION: Because of limited data availability and the cross-sectional design of most studies, we could neither infer â€Žcausation between vaccines and incidence of adverse effects nor comment with certainty about any â€Žpossible adverse outcome of COVID-19 vaccines in vaccinated pregnant women. Consequently, more longitudinal and experimental studies are needed to define the exact adverse effects of COVID-19 vaccines in pregnant women.

Adult-onset Still's disease after ChAdOx1 nCoV-19 vaccine: a possible association. With emergent Sars-Cov-2, a highly transmissive virus that caused millions of deaths worldwide, the development of vaccines became urgent to combat COVID-19. Although rare, important adverse effects had been described in a hypothetical scenario of immune system overstimulation or overreaction. Still's disease is a rare inflammatory syndrome of unknown etiology. It manifests as a cytokine storm, mainly IL-18 and IL-1Î², and presents itself with fever spikes, joint pain, maculopapular evanescent salmon-pink skin rash, and sore throat, among other symptoms. Here, we report a case of a 44-year-old healthy male who developed adult-onset Still's disease (AOSD) with atypical symptoms after both doses of ChAdOx1 nCoV-19 vaccine with 3 months of dose interval. The medical team suspected Still's disease and started prednisone 1 mg/kg (40mg). The next day the patient showed a marked improvement in articular and chest pains and had no other fever episodes. Therefore, he was discharged to continue

the treatment in outpatient care. On the six-month follow-up, the patient was free of complaints, and the progressive corticoid withdrawal plan was already finished.
Post COVID-19 vaccination headache: A clinical and epidemiological evaluation. INTRODUCTION: This study aimed to assess the prevalence and clinical characteristics of headaches, in particular secondary headaches. MATERIALS AND METHODS: This observational study was performed at the ASST Spedali Civili of Brescia, Italy. Visits to the Emergency Department (ED) and subsequent hospitalizations regarding a new or worsening headache in the 16 days following the administration of the COVID-19 vaccine between January 2021 and January 2022 were recorded and compared with those of January 2019-January 2020. RESULTS: The ratio between ED admissions due to headaches and total ED admissions was significantly higher in 2021 compared with 2019 (4.84% vs. 4.27%; pâ€‰<â€‰0.0001). Two-hundred and eighty-nine ED headache admissions (10.8% of all ED headache admissions) were time-correlated to the COVID-19 vaccination, of which 40 were hospitalized in order to exclude a symptomatic etiology. At discharge, 32 patients had a diagnosis of benign headache not attributed to any cranial/extracranial disorder and eight patients of secondary headache, whose diagnoses were the following: Headache attributed to cranial and/or cervical vascular disorder (nâ€‰=â€‰4); headache attributed to nonvascular intracranial disorder (nâ€‰=â€‰2); headache or facial pain attributed to disorder of the cranium, neck, eyes, ears, nose, sinuses, teeth, mouth, or other facial or cervical structure (nâ€‰=â€‰1); and painful lesions of the cranial nerves (nâ€‰=â€‰1). The headache most frequently reported by patients had migraine-like characteristics: the localization was predominantly frontal or temporal, the pain was described as throbbing and severe in intensity and it was frequently accompanied by nausea/vomit, and photo-phonophobia. Over half-regardless of the final diagnosis-of hospitalized patients had a history of primary headaches. CONCLUSIONS: Following the spread of COVID-19 vaccination, the number of ED admissions due to headaches significantly increased. However, less than 14% of all the ED visits due to a headache time-correlated to the COVID-19 vaccination were actually hospitalized, with most patients documenting a benign headache, possibly related to the generic side effects of the vaccination. Only 8/40 hospitalized patients were diagnosed with a secondary headache. These benign headaches would actually fulfill diagnostic criteria for 8.1 Headaches attributed to the use of or exposure to a substance (ICHD-3), although, at the time being, it does not include vaccines as possible substances.The headache migraine-like characteristics' reported by most patients could suggest activation of the trigeminovascular pathway by all the cytokines and other pro-inflammatory molecules released following the vaccination.
Drug reaction with eosinophilia and systemic symptoms syndrome (DRESS) associated with pancreatitis and hepatitis following Pfizer-BioNTech mRNA COVID-19 vaccination.
COVID-19 vaccination hesitancy and safety among adult people with epilepsy in eastern China. OBJECTIVE: This study assesses the hesitancy and safety of vaccination administration for the novel 2019 Coronavirus Disease (COVID-19) among adult people with epilepsy (PWE). METHODS: We recruited adult PWE who visited the outpatient epilepsy clinic from August 2021 to February 2022. We administered a structured questionnaire and a face-to-face interview regarding demographic factors, epilepsy characteristics, and relevant vaccine issues to all patients. Factors related to receiving a vaccine and epilepsy-related events after vaccination were then analyzed. RESULTS: A total of 501 PWE were surveyed; 288 were unvaccinated and 213 were vaccinated. Patients without jobs (OR: 0.59; 95% CI: 0.37-0.95, pÂ =Â 0.03) were less likely to receive the vaccine compared to students or those with jobs. Other factors associated with vaccination were a higher number of anti-seizure medications (OR: 0.72; 95% CI: 0.55-0.95, pÂ =Â 0.02) and a lower pre-vaccine seizure frequency (OR: 2.21; 95% CI: 1.06-4.59, pÂ =Â 0.03). Of the 213 vaccinated patients, 10 (4.70%) reported at least one local and/or systemic side effect. Most patients (92.50%) did not report worse

seizures within one month of vaccination. Poor ASM adherence (OR: 15.06; 95% CI: 1.75-129.87, pÂ =Â 0.01) and fatigue/stimulant drinks such as caffeine (OR: 50.59; 95% CI: 7.57-337.94, pÂ <Â 0.01) were significantly associated with seizure worsening within one month of receiving the COVID-19 vaccination. CONCLUSION: Almost two-fifths of patients with adult PWE have received a COVID-19 vaccine. Attention should be paid to educating epilepsy patients without jobs on the significance and safety of the vaccine. There was a low risk of seizure worsening in the short term after vaccination in PWE.

Humoral response after the fourth dose of the SARS-CoV-2 vaccine in the CKD spectrum: a prespecified analysis of the SENCOVAC study. BACKGROUND: There is scarce evidence on the fourth dose of severe acute respiratory syndrome coronavirus 2 vaccines in chronic kidney disease (CKD) patients. We evaluated the humoral response and effectivity of the fourth dose in the CKD spectrum: non-dialysis CKD (ND-CKD), haemodialysis (HD), peritoneal dialysis (PD) and kidney transplant (KT) recipients. METHODS: This is a prespecified analysis of the prospective, observational, multicentric SENCOVAC study. In patients with CKD who had received a complete initial vaccination and one or two boosters and had anti-Spike antibody determinations 6 and 12Â months after the initial vaccination, we analysed factors associated with persistent negative humoral response and higher anti-Spike antibody titres as well as the efficacy of vaccination on coronavirus disease 2019 (COVID-19) severity. RESULTS: Of 2186 patients (18% KT, 8% PD, 69% HD and 5% ND-CKD), 30% had received a fourth dose. The fourth dose increased anti-Spike antibody titres in HD (PÂ =Â .001) and ND-CKD (PÂ =Â .014) patients and seroconverted 72% of previously negative patients. Higher anti-Spike antibody titres at 12Â months were independently associated with repeated exposure to antigen (fourth dose, previous breakthrough infections), previous anti-Spike antibody titres and not being a KT recipient. Breakthrough COVID-19 was registered in 137 (6%) patients, 5% of whom required admission. Admitted patients had prior titres <620Â UI/ml and median values were lower (PÂ =Â .020) than in non-admitted patients. CONCLUSIONS: A fourth vaccine dose increased anti-Spike antibody titres or seroconverted many CKD patients, but those with the highest need for a vaccine booster (i.e. those with lower pre-booster antibody titres or KT recipients) derived the least benefit in terms of antibody titres. Admission for breakthrough COVID-19 was associated with low anti-Spike antibody titres.

A Case of Purpura Annularis Telangiectodes of Majocchi after Anti-SARS-CoV-2 Pfizer-BioNTech Vaccine: Is There an Association? The advent of vaccines has drastically reduced the incidence, morbidity, and mortality related to COVID-19, and with the increase in the number of vaccinated subjects, there have been reports of some adverse events, including skin reactions. In this paper, we report a clinical case of Purpura Annularis Telangiectodes of Majocchi following a third-dose administration of the Pfizer-BioNTech COVID-19 vaccine. Almost 30 days after the third dose, the patient presented erythematous annular patches on the lower limbs with purpuric peripheral areas and a central clearing with no other symptoms. A dermoscopic examination showed capillaritis, reddish-brown dot-clods on a coppery-red background caused by leaky capillaries. To date, the causes of Majocchi's disease are not well-defined; in the literature, three vaccination-related cases have been reported: one after a flu vaccination and two after an anti-SARS-CoV-2 one. Dermatologists should be trained to promptly recognize these clinical manifestations after vaccination, which will likely become a common finding in daily clinical practice, especially given the large diffusion of SARS-CoV-2 vaccinations.

Portal Vein and Mesenteric Artery Thrombosis Following the Administration of an Ad26.COV2-S Vaccine-First Case from Romania: A Case Report. COVID-19 has significantly affected public health, social life, and economies worldwide. The only effective way to combat the pandemic is through vaccines. Although the vaccines have been in use for some time, safety concerns have still

been raised. The most typical adverse effects of receiving a COVID-19 vaccine are localized reactions near the injection site, followed by general physical symptoms such as headaches, fatigue, muscle pain, and fever. Additionally, some people may experience VITT (vaccine-induced immune thrombotic thrombocytopenia), a rare side effect after vaccination. We present the case of a 60-year-old female patient that developed VITT-like symptoms with spleno-portal thrombosis and intestinal ischemia two weeks after the administration of the Ad26.COV2-S vaccine. Surgical treatment consisted of extensive bowel resection with end jejunostomy and feeding ileostomy. Two weeks after the first operation, a duodenal-ileal anastomosis was performed. The patient was discharged five weeks after the onset of the symptoms. Although some rare adverse effects are associated with the SARS-CoV-2 vaccines, the risk of hospitalization from these harmful effects is lower than the risk of hospitalization from COVID-19. Therefore, recognizing VITT is significant for ensuring the early treatment of clots and proper follow-up.

Long-Term CD4(+) T-Cell and Immunoglobulin G Immune Responses in Oncology Workers following COVID-19 Vaccination: An Interim Analysis of a Prospective Cohort Study. We conducted a prospective study to evaluate immune responses to SARS-CoV-2 in oncology workers in which we collected blood and clinical data every 6 months. Spike-specific CD4(+) T-cells and immunoglobulin G responses were measured using interferon-gamma enzyme-linked immunosorbent spot and enzyme-linked immunosorbent assay, respectively. Sixty (81%) vaccinated and 14 (19%) unvaccinated individuals were enrolled. CD4(+) T-cell responses of those individuals currently naturally infected were comparable to those who were 6 months from receiving their last dose of the vaccine; both responses were significantly higher than among those who were unvaccinated. Unvaccinated participants who became vaccinated while in the study showed a significant increase in both types of spike-specific immune responses. Previously vaccinated individuals who received a third dose (booster) showed a similar response to the spike protein. However, this response decreases as soon as 3 months but does not dip below the established response following two doses. Response to variants of concern B.1.617.2 (Delta) and B.1.1.529 (Omicron) also increased, with the Omicron variant having a significantly lower response when compared to Delta and the wild type. We conclude that antibody and T-cell responses increase in oncology workers after serial vaccination but can wane over time.

Breakthrough SARS-CoV-2 Infections after Vaccination in North Carolina. We characterize the overall incidence and risk factors for breakthrough infection among fully vaccinated participants in the North Carolina COVID-19 Community Research Partnership cohort. Among 15,808 eligible participants, 638 reported a positive SARS-CoV-2 test after vaccination. Factors associated with a lower risk of breakthrough in the time-to-event analysis included older age, prior SARS-CovV-2 infection, higher rates of face mask use, and receipt of a booster vaccination. Higher rates of breakthrough were reported by participants vaccinated with BNT162b2 or Ad26.COV2.S compared to mRNA-1273, in suburban or rural counties compared to urban counties, and during circulation of the Delta and Omicron variants.

Fulminant Type 1 Diabetes Mellitus after SARS-CoV-2 Vaccination: A Case Report. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines have been used worldwide to control the coronavirus disease pandemic. However, several adverse effects have been reported following vaccination. Therefore, further research on the adverse effects in individuals predisposed to life-threatening conditions is needed. Herein, we present a 39-year-old woman without any systemic disease who developed fulminant type 1 diabetes mellitus (T1DM) (low glycohemoglobin levels, despite hyperglycemia and diabetic ketoacidosis (DKA)) following SARS-CoV-2 vaccination. The patient was initially misdiagnosed as having fresh type 2 diabetes mellitus after the first episode of DKA, which was resolved by short-term insulin therapy and treated with oral anti-diabetic agents

after the DKA was resolved. This made her develop a second episode of DKA shortly after treatment. The course and presentation of our case are noteworthy for alerting clinicians to vaccine-related fulminant T1DM.

Association between COVID-19 vaccination and relapse of glomerulonephritis. BACKGROUND: Vaccines for coronavirus disease 2019 (COVID-19) have been developed and are recommended for patients with chronic kidney disease; however, it has been reported that glomerulonephritis worsens after vaccination. We aimed to elucidate the incidence and association between COVID-19 vaccination and glomerulonephritis relapse. METHODS: We investigated the onset of renal events and adverse reactions after COVID-19 vaccination in 111 patients diagnosed with glomerulonephritis. Renal events were defined as worsening hematuria, increased proteinuria, and an increased creatine level over 1.5-fold from baseline. RESULTS: Patients were 57â€‰Â±â€‰18Â years old (55.9% female) and had an estimated glomerular filtration rate of 57.0â€‰Â±â€‰25.0Â ml/min/1.73Â m(2). A pathological diagnosis of IgA nephropathy was confirmed in 55.0%, minimal change disease in 22.5%, and membranous nephropathy in 10.8% of the patients. The BNT162b2 (Pfizer) and mRNA-1273 (Moderna) vaccines were administered in 88.2% and 11.7% of the cases, respectively. Renal events were observed in 22.5% of patients, 10.8% had increased proteinuria, 12.6% had worsening hematuria, and 1.8% received additional immunosuppressive treatment. Only 0.9% required temporary hemodialysis from exacerbation of renal dysfunction. Renal events were higher in younger patients (Pâ€‰=â€‰0.02), being highest in those with IgA nephropathy, but there was no difference in the incidence between pathological diagnoses. There was a significantly higher incidence of renal events in patients with fever (Pâ€‰=â€‰0.02). CONCLUSIONS: COVID-19 vaccination and glomerulonephritis relapse may be related, but further research is needed.

Correlation between Clinical and Immunological Variables and Humoral Response to SARS-CoV-2 Vaccination in Adult Patients with Antibody Deficiency Disorders. BACKGROUND: Prophylactic vaccination has proven to be the most effective strategy to fight the COVID-19 pandemic. METHODS: This was a prospective observational cohort study involving 30 predominantly antibody deficiency disorders (ADD)-afflicted adult patients on immunoglobulin replacement therapy vaccinated with three doses of the mRNA-1273 COVID-19 vaccine, and 10 healthy controls. Anti-RBD IgG antibodies were determined in plasma samples collected just before the first dose of mRNA-based COVID-19 vaccine and on weeks 4, 8, 24, and 28 following the first vaccination. Patients were categorized based on the levels of anti-RBD antibodies determined on w8 as non-, low-, and responders. Chi-square and Kruskal-Wallis tests were used to see if any variables correlated with humoral response levels. Any adverse effects of the mRNA-based vaccine were also noted. RESULTS: The COVID-19 vaccine was safe and well-tolerated. The humoral response elicited at w8 after vaccination depended on the type of ADD, the type of immunoglobulin deficiency, the presence of granulomatous lymphocytic interstitial lung disease, recent use of immunosuppressive drugs, and the switched memory B cells counts. The third vaccine dose boosted humoral response in previous responders to second dose but seldom in non-responders. CONCLUSIONS: The humoral response of patients with predominant ADD depends mostly on the type of immunodeficiency and on the frequency of B and T cell populations.

Post-vaccination adverse reactions, decision regret, and willingness to pay for the booster dose of COVID-19 vaccine among healthcare workers: A mediation analysis. This study aimed to explore the relationship between post-vaccination adverse reactions, decision regret, and willingness to pay (WTP) for the booster dose. An online survey was conducted in Taizhou, China. Questionnaires were completed by 1,085 healthcare workers (HCWs) and 1,054 (97.1%) have received two doses of the COVID-19 vaccine. Mediation analysis method was adopted. Our study presented that post-vaccination adverse reactions in HCWs could decrease their WTP for the booster dose. Of note, HCWs experienced adverse reactions after vaccination would more likely regret their previous vaccination

decisions, which, in turn, further reduced their WTP for a booster shot. Decision regret mediated the relationship between adverse post-vaccination reactions and WTP for the booster dose. The findings implied inextricable relationships among post-vaccination adverse reactions, decision regret, and WTP of the booster dose. It suggested that these post-vaccination adverse reactions should be further incorporated into vaccine campaigns to improve vaccine intention and potentially increase willingness to pay for booster doses of COVID-19 vaccine.

Unilateral Axillary Lymphadenopathy after the Inactivated SARS-COV-2 (CoronaVac) Vaccine: Ultrasonographic Imaging. BACKGROUND: Currently, unilateral clinical and subclinical axillary adenopathy cases associated with the Pfizer-BioNTech and Moderna vaccines are increasingly reported. However, only one study on axillary adenopathy due to the CoronaVac vaccine is published. AIMS: To present the incidence, severity, and ultrasonographic findings of axillary adenopathy that developed in healthcare professionals in Turkey after they were vaccinated with CoronaVac against coronavirus disease-19. STUDY DESIGN: A prospective study. METHODS: In Turkey, the first dose of the CoronaVac vaccine for coronavirus disease-19 was administered to healthcare professionals on January 14, 2021, and the second dose on February 11, 2021. This study covered the period from January 21, 2021 (1 week after the first dose), and April 15, 2021 (9 weeks after the second dose). Individuals who had a history of COVID-19 more than 3 weeks after vaccine doses, systemic disease, and diagnosis and treatment history of breast cancer were excluded. The axillary lymph nodes of the vaccinated and contralateral arms were evaluated in 101 volunteer healthcare professionals using axillary ultrasonography. RESULTS: A significant difference was found in the cortical thicknesses of the lymph nodes between the vaccinated and contralateral axilla after both the first (*p < 0.01) and second (*p < 0.01) doses. Accordingly, the rates of subclinical lymphatic hyperplasia on the vaccinated side were 25.7% (n = 26/101) after the first and 31.1% (n = 28/90) after the second dose. Lymph nodes with pathological appearance based on a reduced echogenic hilum with marked cortical thickening were found only in 2.2%. Among the 39 cases in which antibodies (immunoglobulin G and immunoglobulin M) were measured, the antibody level was classified as <10 and â‰¥10. No statistically significant difference was found in the cortical thickness of the axillary lymph nodes between patients with high antibody levels (â‰¥10) and those with low antibody levels (<10) (p > 0.05). CONCLUSION: In this study, clinical signs of axillary lymph node hyperplasia were not detected after vaccination with CoronaVac. Mild and diffuse thickening of the CoronaVac vaccine-induced lymph nodes was more common than pathological and palpable lymph nodes.

Controversies Around COVID-19 Vaccines and Antidepressants: Scope and Perspective in Malaysia. BACKGROUND: Individuals with severe mental illness are prone to severe COVID-19 infection with increased morbidity and mortality. Psychiatric patients are often concerned about the potential interactions between the newly approved COVID-19 vaccines in Malaysia and psychotropic drugs like antidepressants. To date, such data are unavailable. OBJECTIVES: This review aims to clear the polemics of COVID-19 vaccine-antidepressants interaction in these 3 aspects: (1) cytokines and cytochrome P450 pathway, (2) blood-brain barrier (BBB) involvement and (3) and its interaction with polyethylene glycol (PEG), the potential allergenic culprit following COVID-19 vaccination. METHODS: A scoping approach was employed to search for peer-reviewed journal articles across four healthcare and scientific databases (PubMed, MEDLINE, PsycINFO and Cumulative Index to Nursing and Allied Health Literature (CINAHL)). RESULTS: Antidepressants metabolism often involves the CYP450 enzymes. Vaccine-antidepressants interactions are probable, likely to be triggered by interactions of CYP450 enzymes and inflammatory cytokines, resulting in diminished drug metabolism and chemical detoxification. Aside, PEG, the excipient in mRNA-based COVID-19 vaccines and antidepressants, has been reported as an anaphylaxis causative allergen. However, whether it leads to synergistic, potentiation or antagonistic effects when used in combination remains to be elucidated.

CONCLUSION: Psychotropic medications, including antidepressants, showed potentially relevant safety risks for COVID-19 patients. These vulnerable patient group must be prioritized for early access to safe and efficacious COVID-19 vaccines, as vaccination remains the most important public health intervention to tackle the ongoing COVID-19 pandemic.

Recent developments in the immunopathology of COVID-19. There has been an important change in the clinical characteristics and immune profile of Coronavirus disease 2019 (COVID-19) patients during the pandemic thanks to the extensive vaccination programs. Here, we highlight recent studies on COVID-19, from the clinical and immunological characteristics to the protective and risk factors for severity and mortality of COVID-19. The efficacy of the COVID-19 vaccines and potential allergic reactions after administration are also discussed. The occurrence of new variants of concerns such as Omicron BA.2, BA.4, and BA.5 and the global administration of COVID-19 vaccines have changed the clinical scenario of COVID-19. Multisystem inflammatory syndrome in children (MIS-C) may cause severe and heterogeneous disease but with a lower mortality rate. Perturbations in immunity of T cells, B cells, and mast cells, as well as autoantibodies and metabolic reprogramming may contribute to the long-term symptoms of COVID-19. There is conflicting evidence about whether atopic diseases, such as allergic asthma and rhinitis, are associated with a lower susceptibility and better outcomes of COVID-19. At the beginning of pandemic, the European Academy of Allergy and Clinical Immunology (EAACI) developed guidelines that provided timely information for the management of allergic diseases and preventive measures to reduce transmission in the allergic clinics. The global distribution of COVID-19 vaccines and emerging severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants with reduced pathogenic potential dramatically decreased the morbidity, severity, and mortality of COVID-19. Nevertheless, breakthrough infection remains a challenge for disease control. Hypersensitivity reactions (HSR) to COVID-19 vaccines are low compared to other vaccines, and these were addressed in EAACI statements that provided indications for the management of allergic reactions, including anaphylaxis to COVID-19 vaccines. We have gained a depth knowledge and experience in the over 2â€‰years since the start of the pandemic, and yet a full eradication of SARS-CoV-2 is not on the horizon. Novel strategies are warranted to prevent severe disease in high-risk groups, the development of MIS-C and long COVID-19.

Post-vaccination SARS-CoV-2 seroprevalence in children aged 3-11 years and the positivity in unvaccinated children: A retrospective, single-center study. OBJECTIVE: To analyze the positivity and levels of SARS-CoV-2 antibodies in vaccinated children to evaluate the humoral immune response of vaccination on pediatric population. Analysis on the causes of antibody positivity in unvaccinated children. METHODS: A retrospective study was conducted on children who were admitted to the Children's Hospital Affiliated to Capital Institute of Pediatrics. The clinical data of serological testing of SARS-CoV-2 immunoglobulin M (IgM) and IgG antibodies were collected from SARS-CoV-2 vaccinated or unvaccinated children with no evidence of prior novel coronavirus infection. Chemiluminescence immunoassay was utilized for the in vitro determination of SARS-CoV-2 antibodies. RESULTS: A total of 3,321 healthy children aged 6-11 years received two doses of inactivated SARS-CoV-2 vaccine. At 1 month after the second dose, the positive rate (96.5%) and levels [8.039 (interquartile range (IQR), 6.067-9.098)] of SARS-CoV-2 IgG antibodies reached the peak and remained at a high level for 2-3 months, after which the positive rate and level of vaccine-induced IgG antibody gradually decreased. Compared with 1 month after the second dose of vaccine, the positive rate of IgG antibody decreased to 70.4% at 7 months, and the antibody level decreased by 69.0%. A total of 945 children aged 3-5 years received one or two doses of inactivated vaccine. The positive rate and levels of SARS-CoV-2 IgG antibody in participants remained high for 3 months after vaccination. There was no gender-based difference in positive rate of IgG antibody in children aged 3-11 years old (P>0.05). Among the 5,309 unvaccinated children aged 0 day to 11 years, 105 (2.0%) were positive for SARS-CoV-2 IgG antibody,

which was associated with passive infusion. The maternal humoral response to COVID-19 vaccination in noninfected pregnant women was transferred through the placenta to the fetus, and some children obtained SARS-CoV-2-positive antibodies through blood transfusion. CONCLUSIONS: Inactivated SARS-CoV-2 vaccines could induce robust humoral immune response that gradually declined within several months after the second dose. Therefore, it helps to determine whether children receive a booster dose and elicit a long-term memory immune response. Positive SARS-CoV-2 antibodies in unvaccinated children were associated with passive IgG antibody infusion.

Myocarditis presentation following COVID-19 virus infection versus COVID-19 vaccination. Coronavirus disease 2019 (COVID-19) vaccine-induced cardiac injury has recently emerged as a major public health concern around the globe. There are reported cases of COVID-19 vaccine-induced myocarditis, but they are generally extremely rare and mild. In contrast, COVID-19 infection can cause acute cardiac injury with poor prognosis and high mortality rates. Herein, we describe the difference in patients' presentation by comparing two cases of myocarditis. One after contracting COVID-19 virus infection with a severe clinical course, and the other patient developed myocarditis post-COVID-19 vaccine.

A case series of dermatomyositis following SARS-CoV-2 vaccination. BACKGROUND/OBJECTIVE: The most significant adverse events following SARS-CoV-2 vaccination are myocarditis and pericarditis. Myositis and dermatomyositis have been reported following SARS-CoV-2 infection, but vaccine-induced dermatomyositis (DM) has not been reported. Our case series aimed to characterize new onset dermatomyositis or disease-related flares following SARS-CoV-2 vaccination. MATERIALS AND METHODS: A total of 53 patients from our institution with a new or pre-existing diagnosis of DM were recruited and consented. Phone interviews were conducted to obtain vaccination status and symptoms following vaccination. Electronic medical records were reviewed to extract age, sex, autoantibody profiles, comorbidities, immunomodulatory therapies, creatine kinase (CK) values, and SARS-CoV-2 vaccination dates from the provincial vaccination registry. For patients who reported disease flares, records were reviewed for the onset and nature of symptoms, extent of organ involvement and changes in immunomodulation. RESULTS: On average, patients received 2.62 vaccine doses (range 1-3 doses). A total of 3 of 51 patients (5.88%) experienced dermatomyositis symptoms following vaccination. Two patients were newly diagnosed with dermatomyositis, one requiring hospitalization. Reported symptom onset following vaccination ranged from 1 to 30 days. Of note, all of these patients had normal CK values, even though there was muscle biopsy-confirmed myositis in one patient. Eight patients in the cohort (15.1%) had asymptomatic CK elevation (<1.5 X ULN). CONCLUSION: New onset dermatomyositis or flare up of pre-existing dermatomyositis may be a rare complication in SARS-CoV-2 vaccination although no studies can support a true correlation. Several pathophysiologic mechanisms are proposed.

Serious adverse reaction associated with the COVID-19 vaccines of BNT162b2, Ad26.COV2.S, and mRNA-1273: Gaining insight through the VAERS. Background and purpose: Serious adverse events following immunization (AEFI) associated with the COVID-19 vaccines, including BNT162b2 (Pfizer-BioNTech), Ad26.COV2.S (Janssen), and mRNA-1273 (Moderna), have not yet been fully investigated. This study was designed to evaluate the serious AEFI associated with these three vaccines. Methods: A disproportionality study was performed to analyze data acquired from the Vaccine Adverse Event-Reporting System (VAERS) between 1 January 2010 and 30 April 2021. The reporting odds ratio (ROR) method was used to identify the association between the COVID-19 vaccines BNT162b2, Ad26.COV2.S, and mRNA-1273 and each adverse event reported. Moreover, the ratio of the ROR value to the 95% CI span was applied to improve the credibility of the ROR. The median values of time from vaccination to onset (TTO) for the three vaccines were analyzed. Results: Compared with BNT162b2 and mRNA-1273, Ad26.COV2.S vaccination was associated with a lower

death frequency ($p < 0.05$). Ad26.COV2.S vaccination was associated with a lower birth defect and emergency room visit frequency than BNT162b2 ($p < 0.05$). There were 6,605, 830, and 2,292 vaccine recipients who suffered from COVID-19-related symptoms after vaccination with BNT162b2, Ad26.COV2.S, and mRNA-1273, respectively, including people who were infected by COVID-19, demonstrated a positive SARS-CoV-2 test, and were asymptomatic. Serious AEFI, including thromboembolism, hemorrhage, thrombocytopenia, cardiac arrhythmia, hypertension, and hepatotoxicity, were associated with all three vaccines. Cardiac failure and acute renal impairment events were associated with BNT162b2 and mRNA-1273, while seizure events were associated with BNT162b2 and Ad26.COV2.S. The median values of TTO associated with the three vaccinations were similar. Conclusion: These findings may be useful for health workers and the general public prior to inoculation, especially for patients with underlying diseases; however, the risk/benefit profile of these vaccines remains unchanged. The exact mechanism of SARS-CoV-2 vaccine-induced AEFI remains unknown, and further studies are required to explore these phenomena.
Headache After Vaccination: An Update on Recent Clinical Trials and Real-World Reporting. PURPOSE OF REVIEW: The aim of this review is to characterize headache as a vaccine adverse event (VAE) in clinical trials. RECENT FINDINGS: Of the recent phase III vaccine RCTs (non-COVID-19), 53 studies reported on headache (13 infectious agents). The median rate (interquartile range) of headache was 15.6% (IQR: 9.6-37.6%). Of these, 24.5% of the RCTs reported headache greater in the vaccine group compared to the placebo/control group. In the herpes zoster vaccination trials, headache was more common in all active groups: median rate 33.9% (IQR: 29.7-40.5%) as compared to placebo: median rate 17.7% (IQR: 15.4-23.8%). Influenza and HPV vaccination trials were the 2nd and 3rd most common to have headache as a VAE. Of the 6 widely distributed COVID-19 vaccinations, median rate of post-vaccination headache was 39% (IQR: 28-50%). Headache is a common VAE in vaccine trials. Standardized grading methods, predictors of persistence, and treatment regimens are warranted.
Thrombosis and thrombocytopenia after vaccination against and infection with SARS-CoV-2 in Catalonia, Spain. Population-based studies can provide important evidence on the safety of COVID-19 vaccines. Here we compare rates of thrombosis and thrombocytopenia following vaccination against SARS-CoV-2 with the background (expected) rates in the general population. In addition, we compare the rates of the same adverse events among persons infected with SARS-CoV-2 with background rates. Primary care and linked hospital data from Catalonia, Spain informed the study, with participants vaccinated with BNT162b2 or ChAdOx1 (27/12/2020-23/06/2021), COVID-19 cases (01/09/2020-23/06/2021) or present in the database as of 01/01/2017. We included 2,021,366 BNT162b2 (1,327,031 with 2 doses), 592,408 ChAdOx1, 174,556 COVID-19 cases, and 4,573,494 background participants. Standardised incidence ratios for venous thromboembolism were 1.18 (95% CI 1.06-1.32) and 0.92 (0.81-1.05) after first- and second dose BNT162b2, and 0.92 (0.71-1.18) after first dose ChAdOx1. The standardised incidence ratio for venous thromboembolism in COVID-19 was 10.19 (9.43-11.02). Standardised incidence ratios for arterial thromboembolism were 1.02 (0.95-1.09) and 1.04 (0.97-1.12) after first- and second dose BNT162b2, 1.06 (0.91-1.23) after first-dose ChAdOx1 and 4.13 (3.83-4.45) for COVID-19. Standardised incidence ratios for thrombocytopenia were 1.49 (1.43-1.54) and 1.40 (1.35-1.45) after first- and second dose BNT162b2, 1.28 (1.19-1.38) after first-dose ChAdOx1 and 4.59 (4.41- 4.77) for COVID-19. While rates of thrombosis with thrombocytopenia were generally similar to background rates, the standardised incidence ratio for pulmonary embolism with thrombocytopenia after first-dose BNT162b2 was 1.70 (1.11-2.61). These findings suggest that the safety profiles of BNT162b2 and ChAdOx1 are similar, with rates of adverse events seen after vaccination typically similar to background rates. Meanwhile, rates of adverse events are much increased for COVID-19 cases further underlining the importance of vaccination.

Thrombosis and thrombocytopenia after vaccination against and infection with SARS-CoV-2 in the United Kingdom. Population-based studies can provide important evidence on the safety of COVID-19 vaccines. Using data from the United Kingdom, here we compare observed rates of thrombosis and thrombocytopenia following vaccination against SARS-CoV-2 and infection with SARS-CoV-2 with background (expected) rates in the general population. First and second dose cohorts for ChAdOx1 or BNT162b2 between 8 December 2020 and 2 May 2021 in the United Kingdom were identified. A further cohort consisted of people with no prior COVID-19 vaccination who were infected with SARS-Cov-2 identified by a first positive PCR test between 1 September 2020 and 2 May 2021. The fourth general population cohort for background rates included those people in the database as of 1 January 2017. In total, we included 3,768,517 ChAdOx1 and 1,832,841 BNT162b2 vaccinees, 401,691 people infected with SARS-CoV-2, and 9,414,403 people from the general population. An increased risk of venous thromboembolism was seen after first dose of ChAdOx1 (standardized incidence ratio: 1.12 [95% CI: 1.05 to 1.20]), BNT162b2 (1.12 [1.03 to 1.21]), and positive PCR test (7.27 [6.86 to 7.72]). Rates of cerebral venous sinus thrombosis were higher than otherwise expected after first dose of ChAdOx1 (4.14 [2.54 to 6.76]) and a SARS-CoV-2 PCR positive test (3.74 [1.56 to 8.98]). Rates of arterial thromboembolism after vaccination were no higher than expected but were increased after a SARS-CoV-2 PCR positive test (1.39 [1.21 to 1.61]). Rates of venous thromboembolism with thrombocytopenia were higher than expected after a SARS-CoV-2 PCR positive test (5.76 [3.19 to 10.40]).

Fulminant Myocarditis and Acute Appendicitis after COVID-19 Vaccination. A 19-year-old Japanese man was hospitalized for cardiogenic shock 28 days after receiving a second dose of the coronavirus disease 2019 (COVID-19) mRNA-1273 vaccine. He had had a high fever for three days with vomiting and abdominal pain before arriving at our hospital. The patient visited a local hospital and was diagnosed with heart failure and acute appendicitis. An endomyocardial biopsy specimen showed myocarditis. Thereafter, Impella CP left ventricular assist device implantation and venoarterial peripheral extracorporeal membranous oxygenation were initiated immediately along with inotropic support and steroid pulse therapy. Given these findings, he was finally diagnosed with multiple inflammatory syndrome and fulminant myocarditis.

Antibody response after vaccination against SARS-CoV-2 in adults with hematological malignancies: a systematic review and meta-analysis. Vaccines against SARS-CoV-2 have shown remarkable efficacy and thus constitute an important preventive option against coronavirus disease 2019 (COVID-19), especially in fragile patients. We aimed to systematically analyze the outcomes of patients with hematological malignancies who received vaccination and to identify specific groups with differences in outcomes. The primary end point was antibody response after full vaccination (2 doses of mRNA or one dose of vector- based vaccines). We identified 49 studies comprising 11,086 individuals. Overall risk of bias was low. The pooled response for hematological malignancies was 64% (95% confidence interval [CI]: 59-69; IÂ²=93%) versus 96% (95% CI: 92-97; IÂ²=44%) for solid cancer and 98% (95% CI: 96-99; IÂ²=55%) for healthy controls (P<0.001). Outcome was different across hematological malignancies (P<0.001). The pooled response was 50% (95% CI: 43-57; IÂ²=84%) for chronic lymphocytic leukemia, 76% (95% CI: 67-83; IÂ²=92%) for multiple myeloma, 83% (95% CI: 69-91; IÂ²=85%) for myeloproliferative neoplasms, 91% (95% CI: 82-96; IÂ²=12%) for Hodgkin lymphoma, and 58% (95% CI: 44-70; IÂ²=84%) for aggressive and 61% (95% CI: 48-72; IÂ²=85%) for indolent non-Hodgkin lymphoma. The pooled response for allogeneic and autologous hematopoietic cell transplantation was 82% and 83%, respectively. Being in remission and prior COVID-19 showed significantly higher responses. Low pooled response was identified for active treatment (35%), anti-CD20 therapy â‰¤1 year (15%), Bruton kinase inhibition (23%), venetoclax (26%), ruxolitinib (42%), and chimeric antigen receptor T-cell therapy (42%). Studies on timing, value of boosters, and long-

term efficacy are needed. This study is registered with PROSPERO (clinicaltrials gov. Identifier: CRD42021279051).

Multisystem inflammatory syndrome and lymphohistiocytic myocarditis after Covid-19 vaccine in a middle-aged woman. We describe a 51-year-old otherwise healthy woman hospitalized for hypotension, fever, and weakness 4Â days after the second-dose Covid-19 mRNA vaccine. Elevated inflammatory markers, natriuretic peptide levels and troponin levels, and slightly reduced left ventricular ejection fraction of 50% were noted. We also found the multiple organ damage, including mucocutaneous, gastrointestinal, and neurologic systems. In addition, we revealed the positive results for anti-nucleocapsid SARS-CoV-2 IgG, albeit negative for SARS-CoV-2 polymerase chain reaction testing, suggesting the prior asymptomatic Covid-19 infection. We finally diagnosed her as multisystem inflammatory syndrome after vaccination. Of note, we obtained myocardial specimen from the patients and demonstrated the lymphohistiocytic myocarditis, which is a rare form of myocarditis.

A multicenter study of ocular inflammation after COVID-19 vaccination. PURPOSE: To report the characteristics of a case series of ocular inflammatory events following COVID-19 vaccination in Japan. STUDY DESIGN: Retrospective multicenter study METHODS: In this retrospective multicenter survey, a questionnaire was sent to 16 Japanese hospitals that had uveitis specialty clinics. Information on patients who developed ocular inflammatory events within 14 days of COVID-19 vaccination between February 2021 and December 2021 was collected. RESULTS: Thirty-seven patients were diagnosed with ocular inflammatory events following COVID-19 vaccination. The mean age was 53.4 Â± 16.4 years (range, 26-86 years), and the mean time to onset after vaccination was 6.3 Â± 4.2 days (range, 1-14 days). Vogt-Koyanagi-Harada disease (VKH) was the most common event (n = 17 patients, 46%), followed by anterior uveitis (n = 6), infectious uveitis (n = 3), acute zonal occult outer retinopathy (AZOOR) (n = 2), sarcoidosis-associated uveitis (n = 1), acute posterior multifocal placoid pigment epitheliopathy (APMPPE) (n = 1), optic neuritis (n = 1), multiple evanescent white dot syndrome (MEWDS) (n = 1), Posner-Schlossman syndrome (n = 1), and unclassified uveitis (n = 4). Twenty-eight cases occurred after BNT162b2 vaccination (Pfizer-BioNTech) and 8 after mRNA-1273 vaccination (Moderna), whilst 1 patient had no information about vaccine type. CONCLUSIONS: COVID-19 vaccination can be related to various types of ocular inflammatory events. When we encounter patients with ocular inflammatory disease, we should consider that it may be an adverse effect of COVID-19 vaccination.

Associations between COVID-19 vaccine uptake, race/ethnicity, and political party affiliation. Despite widespread availability of vaccines, COVID-19 is a leading cause of death in the United States (US), and sociodemographic disparities in vaccine uptake remain. Race/ethnicity, partisanship, and perception of peer vaccination status are strong predictors of vaccine uptake, but research is limited among some racial/ethnic groups with small populations. The current study used an online survey to examine the relationship between these factors among a diverse sample of US adults (nâ€‰=â€‰1,674), with oversampling of racial and ethnic minorities. Respondents provided sociodemographic information and answered questions regarding COVID-19 vaccination status, political affiliation, perception of peers' vaccination status, COVID-19 death exposure, and previous COVID-19 infection. Respondents who identified as Asian American had higher odds of being vaccinated, whereas those who identified as Black/African American or American Indian or Alaska Native (AIAN) had lower odds. Respondents who identified as Independent/Other or Republican had lower vaccination odds. Respondents who perceived anything less than nearly all of their peers were vaccinated had lower vaccination odds. Further, lack of a primary care provider, younger age, and lower educational attainment were associated with lower vaccination odds. Findings may help to determine where additional work is needed to improve vaccine uptake in the US. Results indicate the

need for intentional and tailored vaccination programs in Black/African American and AIAN communities; the need to understand how media and political actors develop vaccination messaging and impact vaccine uptake; and the need for additional research on how people estimate, understand, and form decisions around peer vaccination rates.
Morbilliform eruption and systemic inflammatory response syndrome following mRNA COVID-19 vaccination in a patient receiving penicillamine.
Local bullous reaction as a cutaneous reaction after mRNA-boosted vaccination in a post-COVID patient. Coronavirus disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The spectrum of symptomatic infection ranges from mild to critical with multiple severe complications. Many vaccines have been developed to prevent COVID-19 disease, including an mRNA vaccine. Different adverse effects were reported as delayed large local reactions, swelling, erythema, urticarial, and morbilliform rashes. Among these, bullous reactions from the vaccine are considered rare. Here, we described a local bullous reaction after an mRNA booster vaccination in a post-COVID patient.
Role of the immune system and possible mechanisms in COVID-19 vaccine-induced thyroiditis: Case report and literature review. INTRODUCTION: Subacute thyroiditis (SAT) is an inflammatory disease that has different trigger factors. Recent studies show the possible role of COVID-19 vaccine-induced thyroiditis in its initiation. Herein we report the first case of post-Sputnik V vaccination SAT. CASE PRESENTATION: A 42-year-old man without any specific disease was admitted due to tremors, palpation and sweating, and neck tenderness on the thyroid gland. Laboratory markers and radiologic assessments highlighted thyroiditis for him, and his symptoms were relieved by administering NSAIDs and corticosteroids. DISCUSSION: There are several hypotheses for the etiology of post-COVID-19 immunization SAT; among them, immunologic reactions like the interactivity of human proteome with viral components and autoimmune/inflammatory syndrome induced by adjuvantsÂ (ASIA) are more probable than other discussed possibilities. We suggest further studies to discover the exact SAT pathophysiology to prevent the underlying causes among future vaccine candidates.
Antineutrophil Cytoplasmic Autoantibody-Associated Glomerulonephritis as a Possible Side Effect of COVID-19 Vaccination. Vaccination is the principal tool aimed at curbing the COVID-19 pandemic that has, so far, affected tens of millions of individuals in the United States. The two available mRNA vaccines developed by Pfizer-BioNTech and Moderna possess high efficacy in preventing infection and illness severity. However, there are multiple side effects associated with these vaccines, some impacting different organs. Renal pathology is variable, with increasing cases of glomerulonephritis being observed. We report a rare acute kidney injury case due to antineutrophil cytoplasmic autoantibody (ANCA)-mediated glomerulonephritis after administering a second dose of the Pfizer-BioNTech mRNA SARS-CoV-2 vaccine. Aggravation and/or development of autoimmunity after mRNA vaccination may involve multiple immune mechanisms leading to de novo and recurrent glomerular diseases with an autoimmune basis.
Full and Booster Doses of SARS-CoV-2 mRNA-1273 Vaccine Increase Waning Antibody Levels After Completed Vaccination Among Dialysis Patients at a Large Dialysis Organization.
Effects of inactivated SARS-CoV-2 vaccination on male fertility: A retrospective cohort study. Numerous studies have revealed severe damage to male fertility from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, raising concerns about the potential adverse impact on reproductive function of the coronavirus disease 2019 (COVID-19) vaccine developed based on the virus. Interestingly, there are several researchers who have studied the impact of the COVID-19 mRNA vaccine since then but have come up with conflicting results. As a near-ideal candidate for mass immunization programs, inactivated SARS-CoV-2 vaccine has been widely used in many countries, particularly in less wealthy nations. However, little is known about its effect on male

fertility.Â Here, we conducted a retrospective cohort study at a single large center for reproductive medicine in China between December 2021 and August 2022. Five hundred and nineteenÂ fertile men with no history of laboratory-confirmed COVID-19 were included and categorized into four groups based on their vaccination status: unvaccinated group (nâ€‰=â€‰168), one-dose vaccinated group (nâ€‰=â€‰8), fully vaccinated group (nâ€‰=â€‰183), and booster group (nâ€‰=â€‰160). All of them underwent a semen analysis and most had serum sex hormone levels tested.Â There were no significant differences in all semen parameters and sex hormone levels between the unvaccinated group and either vaccinated group. To account for possible vaccination-to-test interval-specific changes, sub-analyses were performed for two interval groups: â‰¤90 and >90 days. As expected, most of the semen parameters and sex hormone levels remained unchanged between the control and vaccinated groups. However, participants in vaccinated group (â‰¤90 days) have decreased total sperm motility and increased follicle-stimulating hormoneÂ level compared with the ones in unvaccinated group. Moreover, some trends similar to those found during COVID-19 infection and recovery were observed in our study. Fortunately, all values are within the normal range. In addition, vaccinated participants reported few adverse reactions. No special medical intervention was required, and no serious adverse reactions happened.Â Our study suggests that inactivated SARS-CoV-2 vaccination does not impair male fertility, possibly due to the low frequency of adverse effects. This information reassures young male population who got this vaccine worldwide, and helps guide future vaccination efforts.

Kikuchi-Fujimoto disease following SARS-CoV-2 vaccination. A previously healthy Japanese woman in her 20s was admitted to our hospital with a 2-week history of fever (39.0Â°C) and a 1-week history of painful cervical lymphadenopathy. The day before fever onset, she had received her first Pfizer-BioNTech SARS-CoV-2 vaccine in her left arm. She had previously been treated with empirical antibiotics with no improvement. Physical examination revealed painful lymphadenopathy in both posterior cervical regions. CT showed symmetrical lymphadenopathies in the neck, supraclavicular, axillary and inguinal regions as well as hepatosplenomegaly. We suspected lymphoma and performed a lymph node biopsy in the right inguinal region, which revealed necrotising histiocytic lymphadenitis. The patient was, therefore, diagnosed with Kikuchi-Fujimoto disease (KFD). She improved after the corticosteroid therapy. This report highlights the importance of including KFD as a differential diagnosis of lymphadenopathy after SARS-CoV-2 vaccination. Additionally, lymph node biopsy is helpful for diagnosing KFD because it rules out other entities.

Diagnostic challenges of functional neurological disorders after covid-19 disease or vaccination: case series and review of the literature. BACKGROUND: Functional neurological disorders have rarely been described in patients recovering from Covid-19 or after vaccination but they are probably under diagnosed. MATERIAL AND METHODS: Six patients referred for rehabilitation of persistent symptoms and/or sequelae of Coronavirus disease 2019 (COVID-19) were diagnosed with functional neurological disorders. A literature review was conducted to identify reported cases of functional neurological disorders after Covid-19 infection or vaccination. RESULTS: In the current case series, patients diagnosed with functional neurological disorders presented high variability of clinical symptoms including hemiplegia, lower limb unilateral or bilateral paralysis, myoclonus, dystonia, tremor and sensory impairment. Four patients were young females with mild Covid-19 infection without hospital admission. Their neurological symptoms developed over the course of 4Â weeks after the beginning of Covid-19 symptoms or vaccine administration with normal ancillary exams. One patient presented overlapping functional neurological symptoms and mild impairment of the left common peroneal nerve after prolonged ICU stay. In addition, all patients in our case series reported other non-motor symptoms such as fatigue, cognitive impairment and diffuse pain or dysesthesia, which are compatible with post Covid-19 condition. CONCLUSIONS: It is important that clinicians recognize

functional neurological symptoms and consider it as a differential diagnosis in patients with neurological complications of Covid-19 infection and vaccination.
Safety and tolerance of vaccines against SARS-CoV-2 infection in systemic lupus erythematosus: results from the COVAD study. OBJECTIVE: To determine COVID-19 vaccine-related adverse events (AEs) in the seven-day post-vaccination period in patients with SLE vs autoimmune rheumatic diseases (AIRDs), non-rheumatic autoimmune diseases (nrAIDs), and healthy controls (HC). METHODS: Data were captured through the COVID-19 Vaccination in Autoimmune Diseases (COVAD) questionnaire (March-December 2021). Multivariable regression models accounted for age, gender, ethnicity, vaccine type and background treatment. RESULTS: Among 9462 complete respondents, 583 (6.2%) were SLE patients (mean age: 40.1â€‰years; 94.5% females; 40.5% Asian; 42.9% Pfizer-recipients). Minor AEs were reported by 83.0% of SLE patients, major by 2.6%, hospitalization by 0.2%. AE and hospitalization frequencies were similar between patients with active and inactive SLE. Rashes were more frequent in SLE patients vs HC (OR; 95% CI: 1.2; 1.0, 1.5), chills less frequent in SLE vs AIRDs (0.6; 0.4, 0.8) and nrAIDs (0.5; 0.3, 0.8), and fatigue less frequent in SLE vs nrAIDs (0.6; 0.4, 0.9). Pfizer-recipients reported higher overall AE (2.2; 1.1, 4.2) and injection site pain (2.9; 1.6, 5.0) frequencies than recipients of other vaccines, Oxford/AstraZeneca-recipients more body ache, fever, chills (OR: 2.5, 3.0), Moderna-recipients more body ache, fever, chills, rashes (OR: 2.6, 4.3). Hospitalization frequencies were similar across vaccine types. AE frequencies were similar across treatment groups, although chills were less frequent in antimalarial users vs non-users (0.5; 0.3, 0.9). CONCLUSION: While COVID-19 vaccination-related AEs were reported by four-fifths of SLE patients, those were mostly minor and comparable to AEs reported by healthy individuals, providing reassurance regarding COVID-19 vaccination safety in SLE.
Seroconversion and side effects after COVID vaccination among persons with type 2 diabetes in urban, rural, and tribal areas in Kerala, India. BACKGROUND: Persons with type 2 diabetes mellitus (T2DM) are at high-risk for COVID-19 infection and are a priority group for vaccination. OBJECTIVES: The objective of this study is to estimate the seroconversion and determine the side effects after COVID-19 vaccination among persons with T2DM in urban, rural, and tribal areas in Kerala. METHODS: A cross-sectional study was conducted in urban, rural, and tribal field practice areas of a medical college in Central Kerala, among 396 persons with T2DM. The participants were selected by simple random sampling from the 200-250 diabetic patients visiting each health center. Qualitative and quantitative estimation of antibodies were done by WANTAI Ab enzyme-linked immunosorbent assay kit and Abbott SARS COV-2 IgG Quantitative assay, respectively. RESULTS: The mean age of the respondents was 59.40 Â± 12.25 years. A majority (65.5%) had received both doses of vaccine. About half (51.5%) experienced side effects after vaccination. Antibodies (IgG or IgM) were detected in 93.2% (95% confidence interval [CI] 90.2, 95.5) of participants. Those with a duration of diabetes â‰¥5 years, with a single dose of vaccine, were five times (adjusted odds ratio [aOR] - 5.23,95% CI 1.86, 14.66) and four times (aOR - 4.11, 95% CI 1.66, 10.13) more likely, respectively, to be seronegative. Those who took medication for diabetes were protected against a no antibody (aOR - 0.05, 95% CI 0.02, 0.148) response. The median antibody titer in a subset (150) of participants was 365.2 (90-1587) AU/ml. Past COVID infection was an independent determinant of high IgG titers (aOR - 4.95, 95% CI 1.50, 16.36). CONCLUSION: Reinforcing the importance of vaccination particularly among those with longer duration of diabetes is imperative.
The effect of COVID-19 vaccination on epileptic seizures in patients with epilepsy: A clinical observation in China. This observational retrospective study was conducted on patients with epilepsy (PWE) in China who had at least one dose of COVID-19 vaccine and it investigated the safety of vaccination by analyzing changes in epileptic seizures and their influencing factors. Consecutive PWE who were followed up in the epilepsy clinic between June 2021 and May 2022 were enrolled.

Data on vaccine type, demographic information, clinical characteristics of epilepsy, and treatment were collected through a questionnaire survey and retrospectively analyzed. PWE were divided into a stable seizure group and a worsening seizure group based on seizure episodes at least 90â€‰days after the first vaccine dose. A total of 79 PWE were included. After vaccination, 14 patients (17.7%) had worsening seizures, 92.9% of whom had an increased seizure frequency. Compared with patients in the stable seizure group, patients in the worsening seizure group had significant differences in baseline monthly seizure frequency (Pâ€‰=â€‰.012), improper antiseizure medication (ASM) administration (Pâ€‰=â€‰.003) and a disrupted sleep routine (Pâ€‰=â€‰.016). Multivariate logistic regression analysis showed that improper ASM administration (OR 6.186, 95% confidence interval [CI] 1.312-29.170; pâ€‰=â€‰.021) and a disrupted sleep routine (OR 6.326, 95% CI 1.326-30.174; pâ€‰=â€‰.021) were significantly associated with seizure worsening. In short, COVID-19 vaccination is safe for PWE, and only those with poor seizure control have the possibility of seizure exacerbation after COVID-19 vaccination. The vaccination per se does not represent a major influencing factor, but the improper use of ASMs and a disrupted sleep routine may be correlated with seizure aggravation after vaccination.

Meta-summaries effective for improving awareness and understanding of COVID-19 vaccine safety research. Despite the efficacy, safety, and availability of COVID-19 vaccines, a lack of awareness and trust of vaccine safety research remains an important barrier to public health. The goal of this research was to design and test online meta-summaries-transparent, interactive summaries of the state of relevant studies-to improve people's awareness and opinion of vaccine safety research. We used insights from a set of co-design interviews (nâ€‰=â€‰22) to develop meta-summaries to highlight metascientific information about vaccine safety research. An experiment with 863 unvaccinated participants showed that our meta-summaries increased participants' perception of the amount, consistency, and direction of vaccine safety research relative to the U.S. Center for Disease Control (CDC) webpage, and that participants found them more trustworthy than the CDC page as well. They were also more likely to discuss it with others in the week following. We conclude that direct summaries of scientific research can be a useful communication tool for controversial scientific topics.

AZD7442 (Tixagevimab/Cilgavimab) for Post-Exposure Prophylaxis of Symptomatic Coronavirus Disease 2019. BACKGROUND: This phase 3 trial assessed AZD7442 (tixagevimab/cilgavimab) for post-exposure prophylaxis against symptomatic coronavirus disease 2019 (COVID-19). METHODS: Adults without prior severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection or COVID-19 vaccination were enrolled within 8 days of exposure to a SARS-CoV-2-infected individual and randomized 2:1 to a single 300-mg AZD7442 dose (one 1.5-mL intramuscular injection each of tixagevimab and cilgavimab) or placebo. Primary end points were safety and first post-dose SARS-CoV-2 reverse-transcription polymerase chain reaction (RT-PCR)-positive symptomatic COVID-19 event before day 183. RESULTS: A total of 1121 participants were randomized and dosed (AZD7442, n = 749; placebo, n = 372). Median (range) follow-up was 49 (5-115) and 48 (20-113) days for AZD7442 and placebo, respectively. Adverse events occurred in 162 of 749 (21.6%) and 111 of 372 (29.8%) participants with AZD7442 and placebo, respectively, mostly mild/moderate. RT-PCR-positive symptomatic COVID-19 occurred in 23 of 749 (3.1%) and 17 of 372 (4.6%) AZD7442- and placebo-treated participants, respectively (relative risk reduction, 33.3%; 95% confidence interval [CI], -25.9 to 64.7; P = .21). In predefined subgroup analyses of 1073 (96%) participants who were SARS-CoV-2 RT-PCR-negative (n = 974, 87%) or missing an RT-PCR result (n = 99, 9%) at baseline, AZD7442 reduced RT-PCR-positive symptomatic COVID-19 by 73.2% (95% CI, 27.1 to 90.1) vs placebo. CONCLUSIONS: This study did not meet the primary efficacy end point of post-exposure prevention of symptomatic COVID-19. However, analysis of participants who were SARS-CoV-2 RT-PCR-negative or missing an RT-

PCR result at baseline support a role for AZD7442 in preventing symptomatic COVID-19. Clinical Trials Registration. NCT04625972.

Immunosuppressant and SARS-CoV-2 Vaccine Antibody Response After Lung Transplantation. BACKGROUND: There are insufficient reports on the immunogenicity and safety of the COVID-19 vaccination after lung transplantation in Korea. METHODS: Between April and September 2021, lung transplant recipients (nÂ =Â 52) and healthy controls (nÂ =Â 22) underwent vaccination. The levels of antibodies were assessed prospectively at 4 weeks after priming and second dose. RESULTS: Of a total of 52 lung transplant recipients, there were 84.6% nonresponders, 15.4% second-dose responders, and 0% primary dose responders. Among healthy controls, 63.6% were priming responders, and 18.2% were second-dose responders, and 18.2% were nonresponders. Compared with the control group, lung recipients were less likely to develop antibodies (P < .001). Antibody formation tended to be higher in recipients more than 1 year after transplantation (0 vs 20.5%, PÂ =Â .076). No major safety events were reported, and the adverse symptoms were mild and consistent with those of the general population. In a multivariate regression analysis, mycophenolic acid levels (Âμg/mL) (odds ratio 0.25, PÂ =Â .005) and tacrolimus level (ng/mL) (odds ratio 0.65, PÂ =Â .035) were significantly associated with antibody formation. CONCLUSIONS: The immunogenicity of the second dose of COVID-19 vaccination with various combinations was substantially low in lung transplants. A booster of the COVID-19 vaccine is warranted in lung transplants, especially a year later.

Acute Inflammatory Diseases of the Central Nervous System After SARS-CoV-2 Vaccination. BACKGROUND AND OBJECTIVES: Acute inflammatory CNS diseases include neuromyelitis optica spectrum disorders (NMOSDs) and myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD). Both MOGAD and acute disseminated encephalomyelitis (ADEM) have been reported after vaccination. Consequently, the mass SARS-CoV-2 vaccination program could result in increased rates of these conditions. We described the features of patients presenting with new acute CNS demyelination resembling NMOSDs or MOGAD within 8 weeks of SARS-CoV-2 vaccination. METHODS: The study included a prospective case series of patients referred to highly specialized NMOSD services in the UK from the introduction of SARS-CoV-2 vaccination program up to May 2022. Twenty-five patients presented with new optic neuritis (ON) and/or transverse myelitis (TM) Â± other CNS inflammation within 8 weeks of vaccination with either AstraZeneca (ChAdOx1S) or Pfizer (BNT162b2) vaccines. Their clinical records and paraclinical investigations including MRI scans were reviewed. Serologic testing for antibodies to myelin oligodendrocyte glycoprotein (MOG) and aquaporin 4 (AQP4) was performed using live cell-based assays. Patients' outcomes were graded good, moderate, or poor based on the last clinical assessment. RESULTS: Of 25 patients identified (median age 38 years, 14 female), 12 (48%) had MOG antibodies (MOGIgG+), 2 (8%) had aquaporin 4 antibodies (AQP4IgG+), and 11 (44%) had neither. Twelve of 14 (86%) antibody-positive patients received the ChAdOx1S vaccine. MOGIgG+ patients presented most commonly with TM (10/12, 83%), frequently in combination with ADEM-like brain/brainstem lesions (6/12, 50%). Transverse myelitis was longitudinally extensive in 7 of the 10 patients. A peak in new MOGAD cases in Spring 2021 was attributable to postvaccine cases. Both AQP4IgG+ patients presented with brain lesions and TM. Four of 6 (67%) seronegative ChAdOx1S recipients experienced longitudinally extensive TM (LETM) compared with 1 of 5 (20%) of the BNT162b2 group, and facial nerve inflammation was reported only in ChAdOx1S recipients (2/5, 40%). Guillain-Barre syndrome was confirmed in 1 seronegative ChAdOx1S recipient and suspected in another. DISCUSSION: ChAdOx1S was associated with 12/14 antibody-positive cases, the majority MOGAD. MOGAD patients presented atypically, only 2 with isolated ON (1 after BNT162b2 vaccine) but with frequent ADEM-like brain lesions and LETM. Within the seronegative group, phenotypic differences were observed between ChAdOx1S and BNT162b2 recipients. These observations might support a causative role of the ChAdOx1S vaccine in

inflammatory CNS disease and particularly MOGAD. Further study of this cohort could provide insights into vaccine-associated immunopathology.

Observed versus expected rates of myocarditis after SARS-CoV-2 vaccination: a population-based cohort study. BACKGROUND: Postmarketing evaluations have linked myocarditis to SARS-CoV-2 mRNA vaccines. We sought to estimate the incidence of myocarditis after mRNA vaccination against SARS-CoV-2, and to compare the incidence with expected rates based on historical background rates in British Columbia. METHODS: We conducted an observational study using population health administrative data from the BC COVID-19 Cohort from Dec. 15, 2020, to Mar. 10, 2022. The primary exposure was any dose of an mRNA vaccine against SARS-CoV-2. The primary outcome was incidence of hospital admission or emergency department visit for myocarditis or myopericarditis within 7 and 21 days postvaccination, calculated as myocarditis rates per 100 000 mRNA vaccine doses, expected rates of myocarditis cases and observedto-expected ratios. We stratified analyses by age, sex, vaccine type and dose number. RESULTS: We observed 99 incident cases of myocarditis within 7 days (0.97 cases per 100 000 vaccine doses; observed v. expected ratio 14.81, 95% confidence interval [CI] 10.83-16.55) and 141 cases within 21 days (1.37 cases per 100 000 vaccine doses; observed v. expected ratio 7.03, 95% CI 5.92-8.29) postvaccination. Cases of myocarditis per 100 000 vaccine doses were higher for people aged 12-17 years (2.64, 95% CI 1.54-4.22) and 18-29 years (2.63, 95% CI 1.94-3.50) than for older age groups, for males compared with females (1.64, 95% CI 1.30-2.04 v. 0.35, 95% CI 0.21-0.55), for those receiving a second dose compared with a third dose (1.90, 95% CI 1.50-2.39 v. 0.76, 95% CI 0.45-1.30) and for those who received the mRNA-1273 (Moderna) vaccine compared with the BNT162b2 (Pfizer-BioNTech) vaccine (1.44, 95% CI 1.06-1.91 v. 0.74, 95% CI 0.56-0.98). The highest observed-to-expected ratio was seen after the second dose among males aged 18-29 years who received the mRNA-1273 vaccine (148.32, 95% CI 95.03-220.69). INTERPRETATION: Although absolute rates of myocarditis were low, vaccine type, age and sex are important factors to consider when strategizing vaccine administration to reduce the risk of postvaccination myocarditis. Our findings support the preferential use of the BNT162b2 vaccine over the mRNA-1273 vaccine for people aged 18-29 years.

Combined monitoring of IgG and IgA anti-Spike and anti-Receptor binding domain long term responses following BNT162b2 mRNA vaccination in Greek healthcare workers. Studies on the humoral response to homologous BNT162b2 mRNA-vaccination focus mainly on IgG antibody dynamics, while long-term IgA kinetics are understudied. Herein, kinetics of IgG and IgA levels against trimeric-Spike (S) and Receptor-Binding-Domain (RBD) were evaluated by in-house ELISAs in 146 two-dose vaccinated Greek healthcare workers (HCWs) in a 9-month period at six time points (up to 270 days after the first dose). The effect of a homologous booster third dose was also studied and evaluated. The peak of immune response was observed 21 days after the second dose; 100% seroconversion rate for anti-S and anti-RBD IgG, and 99.7% and 96.3% respectively for IgA. IgG antibody levels displayed higher increase compared to IgA. Declining but persistent anti-SARS-CoV-2 antibody levels were detected 9 months after vaccination; IgG and IgA anti-S levels approached those after the first dose, while a more rapid reduction rate for anti-RBD antibodies led to significantly lower levels for both classes, supporting the need for a booster dose. Indeed, a homologous booster third dose resulted in enhanced levels of anti-S of both classes, whereas anti-RBD didn't exceed the peak levels after the second dose. Previous SARS-CoV-2 infection, flu vaccination, BMI<35 and the occurrence of an adverse event upon vaccination, were associated with higher IgG antibody levels over time, which however were negatively affected by age increase and the presence of chronic diseases. Overall, after concurrently using the S and RBD target-antigens in in-house ELISAs, we report in addition to IgG, long-term persistence of IgA antibodies. Regarding antibody levels, homologous mRNA vaccination gives rise to an effective anti-viral protection up to 9 months

negatively correlated to age. Considering that COVID-19 is still a matter of public concern, booster vaccine doses remain critical to vulnerable individuals.
Cutaneous reactions following COVID-19 vaccination: The evidence says "less fear".
Biopsy-proven acute interstitial nephritis after SARS-CoV-2 mRNA vaccination-adverse vaccine side effect or unrelated complication from self-medication? Lessons for the clinical nephrologist.
Humoral immune response and live-virus neutralization of the SARS-CoV-2 omicron (BA.1) variant after COVID-19 mRNA vaccination in children and young adults with chronic kidney disease. BACKGROUND: Data on humoral immune response to standard COVID-19 vaccination are scarce in adolescent patients and lacking for children below 12Â years of age with chronic kidney disease including kidney transplant recipients. METHODS: We therefore investigated in this retrospective two-center study (DRKS00024668; registered 23.03.2021) the humoral immune response to a standard two-dose mRNA vaccine regimen in 123 CKD patients aged 5-30Â years. A live-virus assay was used to assess the serum neutralizing activity against the SARS-CoV-2 omicron (BA.1) variant. RESULTS: Children aged 5-11Â years had a comparable rate and degree of immune response to adolescents despite lower vaccine doses (10Â Âµg vs. 30Â Âµg BNT162b2). Treatment with two (odds ratio 9.24) or three or more (odds ratio 17.07) immunosuppressants was an independent risk factor for nonresponse. The immune response differed significantly among three patient cohorts: 48 of 77 (62.3%) kidney transplant recipients, 21 of 26 (80.8%) patients on immunosuppressive therapy, and 19 of 20 (95.0%) patients with chronic kidney disease without immunosuppressive therapy responded. In the kidney transplant recipients, immunosuppressive regimens comprising mycophenolate mofetil, an eGFR ofâ€‰<â€‰60Â mL/min/1.73 m(2), and female sex were independent risk factors for nonresponse. Two of 18 (11.1%) and 8 of 16 (50.0%) patients with an anti-S1-RBD IgG of 100-1411 andâ€‰>â€‰1411 BAU/mL, respectively, showed a neutralization activity against the omicron variant. CONCLUSION: A standard mRNA vaccine regimen in immunosuppressed children and adolescents with kidney disease elicits an attenuated humoral immune response with effective live virus neutralization against the omicron variant in approximately 10% of the patients, underlying the need for omicron-adapted vaccination. A higher resolution version of the Graphical abstract is available as Supplementary information.
Severe rhabdomyolysis secondary to COVID-19 mRNA vaccine in a teenager. BACKGROUND: Rhabdomyolysis, the breakdown of skeletal muscles following an insult or injury, has been established as a possible complication of SARS-CoV-2 infection. Despite being highly effective in preventing COVID-19-related morbidity and mortality, several cases of COVID-19 mRNA vaccination-induced rhabdomyolysis have been identified. We provide the second description of a pediatric case of severe rhabdomyolysis presenting after COVID-19 mRNA vaccination. CASE: DIAGNOSIS/TREATMENT: A 16-year-old male reported to the emergency department with a 2-day history of bilateral upper extremity myalgias and dark urine 2Â days after his first dose of COVID-19 vaccine (Pfizer-BioNtech). The initial blood work showed an elevated creatinine kinase (CK) of 141,300 units/L and a normal creatinine of 69 umol/L. The urinalysis was suggestive of myoglobinuria, with the microscopy revealing blood but no red blood cells. Rhabdomyolysis was diagnosed, and the patient was admitted for intravenous hydration, alkalinization of urine, and monitoring of kidney function. CK levels declined with supportive care, while his kidney function remained normal, and no electrolyte abnormalities developed. The patient was discharged 5Â days after admission as his symptoms resolved. CONCLUSION: While vaccination is the safest and most effective way to prevent morbidity from COVID-19, clinicians should be aware that rhabdomyolysis could be a rare but treatable adverse event of COVID-19 mRNA vaccination. With early recognition and diagnosis and supportive management, rhabdomyolysis has an excellent prognosis.

Safety and Immunogenicity of Additional SARS-CoV-2 Vaccinations in a Patient With Myasthenia Gravis on Mycophenolate: A Case Report.
Neuralgic Amyotrophy After ChAdOx1 nCoV-19 COVID-19 Vaccination.
Alopecia Areata as a Sequela of COVID-19 Vaccination: A Systematic Review.
Factors Associated With Vaccine-Induced T-Cell Immune Responses Against Severe Acute Respiratory Syndrome Coronavirus 2 in Kidney Transplant Recipients. Vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is an important prophylactic measure in kidney transplant recipients (KTRs), but the immune response is often impaired. Here, we examined the T-cell immune response against SARS-CoV-2 in 148 KTRs after 3 or 4 vaccine doses, including 35 KTRs with subsequent SARS-CoV-2 infection. The frequency of spike-specific T cells was lower in KTRs than in immunocompetent controls and was correlated with the level of spike-specific antibodies. Positive predictors for detection of vaccine-induced T cells were detection of spike-specific antibodies, heterologous immunization with messenger RNA and a vector vaccine, and longer time after transplantation. In vaccinated KTRs with subsequent SARS-CoV-2 infection, the T-cell response was greatly enhanced and was significantly higher than in vaccinated KTRs without SARS-CoV-2 infection. Overall, the data show a correlation between impaired humoral and T-cell immunity to SARS-CoV-2 vaccination and provide evidence for greater robustness of hybrid immunity in KTRs.
Cerebral vein thrombosis after ChAdOx1 nCov-19 vaccination: Long-term outcome of four patients.
Vaccine safety in Australia during the COVID-19 pandemic: Lessons learned on the frontline. Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC), Victoria's vaccine safety service for reporting adverse events following immunisation (AEFI), has provided integrated spontaneous surveillance and clinical services for individuals affected by AEFI since 2007. We describe SAEFVIC's response to the COVID-19 vaccine program, and reflect on lessons learned for vaccine safety. The massive scale of the Australian COVID-19 vaccine program required rapid adaptations across all aspects of SAEFVIC's vaccine safety services. Collection of AEFI reports was streamlined and expanded, incorporating both spontaneous and active surveillance data. Dramatically increased report volumes were managed with additional staffing, and innovations to automate, filter, and triage reports for priority follow up. There were two major adverse events of special interest (AESI): thrombosis with thrombocytopaenia syndrome and myocarditis, with multiple other AESI also investigated. Rapid escalation mechanisms to respond to AESI were established, along with AESI-specific databases for enhanced monitoring. Vaccine education and training resources were developed and public-facing vaccine safety reports updated weekly. Frequent communication with local and national government and regulatory bodies, and consultation with specialist groups was essential. The COVID-19 vaccine program has highlighted the importance of vaccine safety in supporting public confidence in vaccines and informing evidence-based immunisation policy. Supporting the COVID-19 vaccine program has required flexibility in adapting to policy changes and evolving vaccine safety signals, careful triage and prioritisation, informatics innovation, and enhanced engagement with the public regarding vaccine safety. Long-term investment to continue strengthening vaccine safety systems, building on lessons learned, will be essential for the ongoing success of Australian vaccination programs.
ANCA-associated vasculitis following the CoronaVac vaccination. With the coronavirus disease 2019 (COVID-19) pandemic, vaccination has become one of the cornerstones to contain the outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Large clinical trials have shown high efficacy and safety of SARS-CoV-2 vaccination against COVID-19. However, with the widespread use of SARS-CoV-2 vaccines worldwide, an increasing number of reports describe the onset of glomerular disease. Here, we report a case of a 70-year-old Chinese woman who developed new antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis within 4 h post the first dose of

CoronaVac. CoronaVac is an inactivated SARS-CoV-2 vaccine developed by Sinovac Life Sciences (Beijing, China). Her clinical symptoms were nausea, fatigue, acute kidney injury, and proteinuria. Laboratory tests showed markedly elevated serum myeloperoxidase titers, and the renal biopsy showed microcellular fibrous crescent formation. Renal function of the patient responded favorably after treatment with steroids and cyclophosphamide. Although there is no direct evidence of a link between vasculitis and vaccination, similar complications should be monitored as potential adverse events with widespread vaccination globally.

Thyroiditis after mRNA Vaccination for COVID-19. BACKGROUND: SARS-CoV-2 has been known to cause multisystemic involvement, gaining entry through ACE-2 and TMPRSS2 receptors. COVID-19 vaccine-associated thyroiditis cases are now being reported. Case Report. Case 1. A 36-year-old woman with a history of right hemithyroidectomy for a benign thyroid nodule, on a stable dose of levothyroxine with euthyroid labs, presented with progressively worsening left neck pain, episodic palpitations, and heat intolerance after the second dose of mRNA1273 (Moderna) vaccine. Examination revealed an enlarged and tender left lobe of the thyroid with suppressed TSH but normal free T4 and ESR, signifying subacute thyroiditis. She was managed conservatively without corticosteroids or beta-blockers, and her symptoms resolved. A follow-up revealed increasing TSH, and levothyroxine was restarted. Case 2. A 33-year-old man with a history of anxiety disorder on Sertraline, presented with a two-week history of palpitations, heat intolerance, and 10-pound weight loss after the second dose of BNT162b2 (Pfizer-BioNTech) vaccine. Examination revealed a normal thyroid gland with no tenderness with elevated thyroid peroxidase and thyroglobulin antibodies. Ultrasound showed a diffusely heterogeneous thyroid with increased vascularity, suggesting silent thyroiditis. Follow-up revealed a hypothyroid phase with high TSH for which levothyroxine supplementation was started. Discussion. COVID-19 vaccine-associated subacute and silent thyroiditis have occurred following all three kinds of available vaccines, characterized by an initial thyrotoxic phase, followed by a hypothyroid phase and a recovery phase. Hypotheses include an immune response triggering thyroid inflammation or cross-reactivity with viral proteins. CONCLUSIONS: COVID-19 vaccine-associated thyroiditis is rare, but long-term monitoring of these patients is essential to ensure appropriate diagnosis and management of the potential hypothyroid phase.

Myocardial infarction following COVID-19 vaccine administration; a systematic review. INTRODUCTION: Covid-19 vaccines have been assessed in randomized trials, which are designed to establish efficacy and safety, but are insufficient in power to detect rare adverse outcomes. Among the adverse cardiac events associated with mRNA COVID-19 vaccines are inflammations (e.g., pericarditis or myocarditis), thrombosis, and ischemia. OBJECTIVE: This systematic review aims to evaluate the reported cases of myocardial infarction (MI) after COVID-19 vaccinations. METHOD: Web of Science, MEDLINE on OVID, PubMed, and Google Scholar were searched for English-language papers published until March 25, 2022. RESULTS: This study included 15 papers (10 case reports and 5 case series). In total, 20 individuals were included who had received COVID-19 vaccines and experienced MI. Males (55%) reported more adverse occurrences than females (45%) across the majority of event categories. The mean time from the administration of the vaccine to the onset of symptoms was 2 days (0-10 days). The AstraZeneca vaccine was responsible for more than half of the reported events. In the majority of cases, the event developed after receiving the first dose of vaccination. CONCLUSION: MI related to COVID19 vaccination is a rare, but serious and life-threatening condition. Chest discomfort should be regarded as a warning sign, particularly in people who have been administered a dose of the vaccine within the previous two days.

Apropos of menstrual changes and abnormal uterine bleeding after COVID-19 vaccination. It is news of 28 October 2022 that the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency has recommended to add heavy menstrual bleeding among the side effects of

unknown frequency inside the package insert of nucleoside-modified messenger ribonucleic acid vaccines to prevent coronavirus disease 2019 (COVID-19). The decision has been made in the light of the numerous reports of unexpected menstrual changes or abnormal uterine bleeding following COVID-19 vaccination. Here we advance a possible involvement of the particular adenohypophyseal microcirculation in these strange and still unexplained events.

Resolution of recalcitrant verruca following Moderna COVID-19 vaccination in a person with HIV.

Shoulder injury related to vaccine administration following SARS-CoV-2 inoculation: Case series and review of literature. INTRODUCTION: Shoulder Injuries Related to Vaccine Administration (SIRVA), describes those cases of shoulder severe post-inoculation complications, including pain and prolonged disability. Most of the reported cases have been secondary to influenza vaccination. This study retrospectively describes a series of 18 patients following SARS-CoV-2 inoculation and compares the findings with those previously reported for other vaccines. MATERIALS AND METHODS: Inclusion criteria was onset of symptoms within 48Â h after injection, symptoms duration of at least seven days, and restricted range of motion in absence of symptoms prior to vaccination. Average age was 59.4 years old (38-76), and 72.2% were women. RESULTS: In many cases (58%) the initial diagnosis was not clear, which lead to incorrect treatment. The most common pathological finding was subacromial-subdeltoid bursitis (66.6%). All patients who received depot corticosteroids followed by a gentle rehabilitation program showed strong clinical improvement but did not completely resolve the symptoms at 7.2 months average final follow-up. Surgical intervention was necessary in one of the patients due to the persistence of symptoms despite conservative treatment. CONCLUSIONS: Shoulder injury related to vaccine administration is rare, but when present, its torpid evolution makes it difficult to treat. We have found in our case series a similar pattern to that already described for other vaccines. A high index of suspicion helps to pick up the condition promptly and early treatment can bring satisfactory outcome.

Case report: Early onset Marin-Amat syndrome after receiving ChAdOx1 nCoV-19 vaccination. While vaccination against COVID-19 is still ongoing, some rare adverse events temporally related to vaccinations have been reported, particularly with ChAdOx1 nCoV-19. Here, a 77-year-old male presented to our outpatient department with persistent ptosis of his left eye for 1 month. He initially received vaccination with ChAdOx1 nCoV-19 and developed symptoms of Bell's palsy 3 days later. He received a 14-day course of prednisolone, but the ptosis persisted. Marin-Amat syndrome was compatible with his symptoms of ptosis exacerbation during orbicularis oris exertion. A temporal correlation between ChAdOx1 nCoV-19 vaccination and Bell's palsy without infectious or autoimmune diseases was delineated. Further studies are needed to clarify the possible relationship between these two events.

A retrospective evaluation of side-effects associated with the booster dose of Pfizer-BioNTech/BNT162b2 COVID-19 vaccine among females in Eastern Province, Saudi Arabia. BACKGROUNDS: The development of several types of vaccines to avert COVID-19 has taken place. Despite several reports of undesirable reactions noted post-COVID-19 vaccine administration, later remains one of the best prevention and management tools in fighting the spread of the virus and its variants and reducing the harshness of this viral attack. The purpose of the current paper was to explore the side-effects experienced by the females in the Eastern Province of Saudi Arabia directly after receiving the booster dose of the Pfizer-BioNTech/BNT162b2 COVID-19 vaccine. METHODS: A descriptive cross-sectional study among adults living in the East-ern Province, Saudi Arabia was applied. A survey link was, distributed through WhatsApp, SMS, or e-mail to community members. Respondent's demographic information was acquired, as well as information about any local and systemic side-effects reported following booster dose of BioNTech/BNT162b2 COVID-19 vaccine. RESULTS: A total of 72.36% (432/597) of the respondents who participated in this study reported at

least one side-effect. Pain and redness at the injection site (75.93%), myalgia (71.99%), headache (53.24%), fever (33.56%), and fatigue (43.78%) were the highest frequently stated side-effects. Furthermore, 9.25% of the respondents had to see a physician due to side effects, plus merely four participants were admitted to the hospital. The respondents working in the non-healthcare-related sector had a 1.677-fold more possibility of side effects in comparison with the other respondents (adjusted odds ratioÂ =Â 1.677; 95% CIÂ =Â 1.363, 2.064). CONCLUSIONS: All reported side-effects were mild to moderate. These findings might persuade pessimists and refusers to get the COVID-19 vaccine. Myalgia and pain or redness at the site of injection were the most common reported side-effects in our study.

An evaluation of the safety and immunogenicity of MVC-COV1901: Results of an interim analysis of a phase III, parallel group, randomized, double-blind, active-controlled immunobridging study in Paraguay. BACKGROUND: Data from previous studies of the MVC-COV1901 vaccine, a subunit vaccine against SARS-CoV-2 based on the stable prefusion spike protein (S-2P) adjuvanted with CpG 1018 adjuvant and aluminum hydroxide, suggest that the vaccine is generally safe and elicits a good immune response in healthy adults and adolescents. By comparing with AZD1222, this study adds to the findings from previous trials and further evaluates the breadth of protection offered by MVC-COV1901. METHODS: In this phase 3, parallel group, randomized, double-blind, active-controlled trial conducted in 2 sites in Paraguay, we assigned adults aged 18-91Â years in a 1:1 ratio to receive intramuscular doses of MVC-COV1901 or AZD1222 administered as scheduled in the clinical trial. Serum samples were collected on the day of vaccination and 14Â days after the second dose. Primary and secondary safety and immunogenicity endpoints were assessed. In addition, other outcomes investigated were cross-reactive immunity against the Omicron strain and the induction of IgG subclasses. RESULTS: A total of 1,030 participants underwent randomization. Safety data was derived from this set while primary immunogenicity data involved a per-protocol immunogenicity (PPI) subset including 225 participants. Among the participants, 58% are seropositive at baseline. When compared against AZD1222, MVC-COV1901 exhibited superiority in terms of neutralizing antibody titers and non-inferiority in terms of seroconversion rates. Reactogenicity was generally mild and no serious adverse event was attributable to MVC-COV1901. Both vaccines have a Th1-biased response predominated by the production of IgG1 and IgG3 subclasses. Omicron-neutralizing titers were 44.5 times lower compared to wildtype-neutralizing titers among seronegative individuals at baseline. This fold-reduction was 3.0 times among the seropositive. CONCLUSION: Safety and immunogenicity data of MVC-COV1901 from the study in Paraguay confirm previous results. The previous infection coupled with vaccination of this vaccine may offer protection against the Omicron strain though its durability is still unknown.

Background rates of adverse events of special interest for COVID-19 vaccine safety monitoring in the United States, 2019-2020. BACKGROUND: The U.S. Food and Drug Administration (FDA) Biologics Effectiveness and Safety (BEST) Initiative conducts active surveillance of adverse events of special interest (AESI) after COVID-19 vaccination. Historical incidence rates (IRs) of AESI are comparators to evaluate safety. METHODS: We estimated IRs of 17 AESI in six administrative claims databases from January 1, 2019, to December 11, 2020: Medicare claims for adultsâ€¯â‰¥â€¯65â€¯years and commercial claims (Blue Health IntelligenceÂ®, CVS Health, HealthCore Integrated Research Database, IBMÂ® MarketScanÂ® Commercial Database, Optum pre-adjudicated claims) for adultsâ€¯<â€¯65â€¯years. IRs were estimated by sex, age, race/ethnicity (Medicare), and nursing home residency (Medicare) in 2019 and for specific periods in 2020. RESULTS: The study included >100 million enrollees annually. In 2019, rates of most AESI increased with age. However, compared with commercially insured adults, Medicare enrollees had lower IRs of anaphylaxis (11 vs 12-19 per 100,000 person-years), appendicitis (80 vs 117-155), and narcolepsy (38 vs 41-53). Rates were higher

in males than females for most AESI across databases and varied by race/ethnicity and nursing home status (Medicare). Acute myocardial infarction (Medicare) and anaphylaxis (all databases) IRs varied by season. IRs of most AESI were lower during March-May 2020 compared with March-May 2019 but returned to pre-pandemic levels after May 2020. However, rates of Bell's palsy, Guillain-BarrÃ© syndrome, narcolepsy, and hemorrhagic/non-hemorrhagic stroke remained lower in multiple databases after May 2020, whereas some AESI (e.g., disseminated intravascular coagulation) exhibited higher rates after May 2020 compared with 2019. CONCLUSION: AESI background rates varied by database and demographics and fluctuated in March-December 2020, but most returned to pre-pandemic levels after May 2020. It is critical to standardize demographics and consider seasonal and other trends when comparing historical rates with post-vaccination AESI rates in the same database to evaluate COVID-19 vaccine safety.

Mass "psychogenic transient loss of consciousness" after COVID-19 vaccination.

Distinct and dynamic activation profiles of circulating dendritic cells and monocytes in mild COVID-19 and after yellow fever vaccination. Dysregulation of the myeloid cell compartment is a feature of severe disease in hospitalized COVID-19 patients. Here, we investigated the response of circulating dendritic cell (DC) and monocyte subpopulations in SARS-CoV-2 infected outpatients with mild disease and compared it to the response of healthy individuals to yellow fever vaccine virus YF17D as a model of a well-coordinated response to viral infection. In SARS-CoV-2-infected outpatients circulating DCs were persistently reduced for several weeks whereas after YF17D vaccination DC numbers were decreased temporarily and rapidly replenished by increased proliferation until 14 days after vaccination. The majority of COVID-19 outpatients showed high expression of CD86 and PD-L1 in monocytes and DCs early on, resembling the dynamic after YF17D vaccination. In a subgroup of patients, low CD86 and high PD-L1 expression were detected in monocytes and DCs coinciding with symptoms, higher age, and lower lymphocyte counts. This phenotype was similar to that observed in severely ill COVID-19 patients, but less pronounced. Thus, prolonged reduction and dysregulated activation of blood DCs and monocytes were seen in a subgroup of symptomatic non-hospitalized COVID-19 patients while a transient coordinated activation was characteristic for the majority of patients with mild COVID-19 and the response to YF17D vaccination.

Open-label phase I/II clinical trial of SARS-CoV-2 receptor binding domain-tetanus toxoid conjugate vaccine (FINLAY-FR-2) in combination with receptor binding domain-protein vaccine (FINLAY-FR-1A) in children. OBJECTIVES: To evaluate a heterologous vaccination scheme in children 3-18 years old (y/o) combining two SARS-CoV-2r- receptor binding domain (RBD)protein vaccines. METHODS: A phase I/II open-label, adaptive, and multicenter trial evaluated the safety and immunogenicity of two doses of FINLAY-FR-2 (subsequently called SOBERANA 02) and the third heterologous dose of FINLAY-FR-1A (subsequently called SOBERANA Plus) in 350 children 3-18 y/o in Havana Cuba. Primary outcomes were safety (phase I) and safety/immunogenicity (phase II) measured by anti-RBD immunoglobulin (Ig)G enzyme-linked immunoassay (ELISA), molecular and live-virus neutralization titers, and specific T-cells response. A comparison with adult immunogenicity and predictions of efficacy were made based on immunological results. RESULTS: Local pain was the unique adverse event with frequency >10%, and none was serious neither severe. Two doses of FINLAY-FR-2 elicited a humoral immune response similar to natural infection; the third dose with FINLAY-FR-1A increased the response in all children, similar to that achieved in vaccinated young adults. The geometric mean (GMT) neutralizing titer was 173.8 (95% confidence interval [CI] 131.7; 229.5) vs Alpha, 142 (95% CI 101.3; 198.9) vs Delta, 24.8 (95% CI 16.8; 36.6) vs Beta and 99.2 (95% CI 67.8; 145.4) vs Omicron. CONCLUSION: The heterologous scheme was safe and immunogenic in children 3-18 y/o. TRIAL REGISTRY: https://rpcec.sld.cu/trials/RPCEC00000374.

Safety and immunogenicity of a bivalent SARS-CoV-2 recombinant protein vaccine, SCTV01C in unvaccinated adults: A randomized, double-blinded, placebo-controlled, phase I clinical trial.

Vaccine associated benign headache and cutaneous hemorrhage after ChAdOx1 nCoV-19 vaccine: A cohort study. OBJECTIVES: Fatal complications have occurred after vaccination with ChAdOx1 nCoV-19, a vaccine against Covid-19. Vaccine-induced immune thrombotic thrombocytopenia (VITT) with severe outcome is characterized by venous thrombosis, predominantly in cerebral veins, thrombocytopenia and anti-PF4/polyanion antibodies. Prolonged headaches and cutaneous hemorrhages, frequently observed after the ChAdOx1 nCoV-19 vaccine, have therefore caused anxiety among vaccinees. We investigated whether these symptoms represent a mild form of VITT, with a potential for aggravation, e.g. in case of a second vaccination dose, or a different entity of vaccine complications MATERIALS AND METHODS: We included previously healthy individuals who had a combination of headache and spontaneous severe cutaneous hemorrhages emerging after the 1(st) dose of the ChAdOx1 nCoV-19 vaccine. Twelve individuals were found to meet the inclusion criteria, and a phone interview, cerebral MRI, assessment of platelet counts, anti PF4/polyanion antibodies and other laboratory tests were performed. RESULTS: None of the symptomatic vaccinees had cerebral vein thrombosis, hemorrhage or other pathology on MRI. Platelet counts were within normal range and no anti-PF4/polyanion platelet activating antibodies were found. Moreover, vasculitis markers, platelet activation markers and thrombin generation were normal. Furthermore, almost all symptoms resolved, and none had recurrence of symptoms after further vaccination with mRNA vaccines against Covid-19. CONCLUSIONS: The combination of headaches and subcutaneous hemorrhage did not represent VITT and no other specific coagulation disorder or intracranial pathology was found. However, symptoms initially mimicking VITT demand vigilance and low threshold for a clinical evaluation combined with platelet counts and D-dimer.

Attitudes toward harm reduction and low-threshold healthcare during the COVID-19 pandemic: qualitative interviews with people who use drugs in rural southern Illinois. BACKGROUND: Chronic health conditions associated with long-term drug use may pose additional risks to people who use drugs (PWUD) when coupled with COVID-19 infection. Despite this, PWUD, especially those living in rural areas, may be less likely to seek out health services. Previous research has highlighted the increased disease burden of COVID-19 among PWUD. Our manuscript supplements this literature by exploring unique attitudes of PWUD living in rural areas toward the pandemic, COVID-19 vaccination, and the role of harm reduction (HR) organizations in raising health awareness among PWUD. METHODS: Semi-structured interviews were conducted with 20 PWUD living in rural southern Illinois. Audio recordings were professionally transcribed. A preliminary codebook was created based on interview domains. Two trained coders conducted iterative coding of the transcripts, and new codes were added through line-by-line coding and thematic grouping. RESULTS: Twenty participants (45% female, mean age of 38) completed interviews between June and November 2021. Participants reported negative impacts of the pandemic on mental health, financial wellbeing, and drug quality. However, the health impacts of COVID-19 were often described as less concerning than its impacts on these other aspects of life. Many expressed doubt in the severity of COVID-19 infection. Among the 16 unvaccinated participants who reported receiving most of their information from the internet or word of mouth, uncertainty about vaccine contents and distrust of healthcare and government institutions engendered wariness of the vaccination. Distrust of healthcare providers was related to past stigmatization and judgement, but did not extend to the local HR organization, which was unanimously endorsed as a positive institution. Among participants who did not access services directly from the HR organization, secondary distribution of HR supplies by other PWUD was a universally cited form of health maintenance. Participants expressed interest in low-threshold healthcare, including COVID-19 vaccination, should it be offered in the local HR organization's office

and mobile units. CONCLUSION: COVID-19 and related public health measures have affected this community in numerous ways. Integrating healthcare services into harm reduction infrastructures and mobilizing secondary distributors of supplies may promote greater engagement with vaccination programs and other healthcare services. TRIAL NUMBER: NCT04427202.

Incidence and outcomes of splanchnic vein thrombosis after diagnosis of COVID-19 or COVID-19 vaccination: a systematic review and meta-analysis. Coronavirus disease 2019 (COVID-19) and COVID-19 vaccination may cause splanchnic vein thrombosis (SVT), which is potentially fatal. The present study aims to pool the incidence and outcomes of SVT patients with COVID-19 or having received COVID-19 vaccines. The PubMed, EMBASE, and Cochrane databases were searched. Based on the data from cohort studies, meta-analyses were performed to evaluate the incidence of SVT in COVID-19 patients or people having received COVID-19 vaccines. Pooled proportions were calculated. Based on the individual data from case reports, logistic regression analyses were performed to identify factors associated with death in SVT patients. Odds ratios (ORs) were calculated. Among 654 papers initially identified, 135 were included. Based on 12 cohort studies, the pooled incidence of SVT in COVID-19 patients was 0.6%. Data were insufficient to estimate the incidence of SVT after COVID-19 vaccination. Based on 123 case reports, the mortality was 14% (9/64) in SVT patients with COVID-19 and 25% (15/59) in those who received COVID-19 vaccines. Univariate analyses demonstrated that age (ORâ€‰=â€‰1.061; pâ€‰=â€‰0.017), diabetes mellitus (ORâ€‰=â€‰14.00; pâ€‰=â€‰0.002), anticoagulation (ORâ€‰=â€‰0.098; pâ€‰=â€‰0.004), and bowel resection (ORâ€‰=â€‰16.00; pâ€‰=â€‰0.001) were significantly associated with death in SVT patients with COVID-19; and anticoagulation (ORâ€‰=â€‰0.025; pâ€‰=â€‰0.003) and intravenous immunoglobulin (ORâ€‰=â€‰0.175; pâ€‰=â€‰0.046) were significantly associated with death in SVT patients who received COVID-19 vaccines. Multivariate analyses did not identify any independent factor for death in both patients. SVT in COVID-19 patients and in subjects who received COVID-19 vaccines carries a high mortality, but may be improved by anticoagulation. PROSPERO Identifier CRD42022315254.

Durability of COVID-19 vaccine induced T-cell mediated immune responses measured using the QuantiFERON SARS-CoV-2 assay.

Immunogenicity and Safety of SpikoGen, an Adjuvanted Recombinant SARS-CoV-2 Spike Protein, as a Heterologous Third Booster Dose in Kidney Transplant Patients: A Single-arm Clinical Trial. PURPOSE: Studies have found that immunocompromised patients have suboptimal responses to COVID-19 vaccines, leading to approval of a need for booster doses in this population. SpikoGenÂ® is a subunit recombinant spike protein vaccine combined with Advax-CpG55.2â„¢ adjuvant to protect against COVID-19. Previous clinical trials found this vaccine to be tolerable, immunogenic, and efficacious in reducing the risk of COVID-19, including severe disease. However, the effects of this vaccine have not been assessed in immunocompromised patients. This study sought to assess the immunogenicity and safety of the SpikoGen vaccine as a third booster dose in patients undergoing kidney transplant who were receiving immunosuppressive therapy and had received their primary vaccination based on an inactivated whole virus platform (Sinopharm). METHODS: This single-arm trial was performed with 43 patients undergoing kidney transplant. The participants received a single booster dose of the SpikoGen vaccine 1 to 3 months after primary vaccination with 2 doses of the Sinopharm vaccine. Immunogenicity assessments were performed at baseline and 30 days after the booster dose. The primary outcomes were seroconversion rates of anti-S(1) and surrogate virus neutralizing antibodies. Safety outcomes included the incidence of solicited and unsolicited adverse events in the 7 days and 1 month after the booster dose, respectively. FINDINGS: The SpikoGen vaccine induced positive humoral and cellular responses 30 days after the booster dose in those patients who were seropositive or seronegative after 2 primary doses of the Sinopharm vaccine.

Thirty days after the SpikoGen vaccine booster, seroconversion rates were 35.29% (95% CI, 19.75%-53.51%) to anti-S(1) and 29.41% (95% CI, 13.27%-46.57%) to surrogate neutralizing antibodies. The most common local and systemic reported solicited adverse events were injection site pain and fatigue, which were largely mild and transient. No serious adverse events were reported. IMPLICATIONS: A single booster dose of SpikoGen vaccine given 1 to 3 months after primary vaccination with 2 doses of Sinopharm vaccine induced positive humoral and cellular immune responses in immunosuppressed patients undergoing renal transplant, thereby achieving spike antibody levels predictive of protection. This study was performed as a single-center study, and it will be important for future large multicenter studies to extend these results to other immunocompromised patient groups.

BNT162b2 mRNA Vaccine-Induced Immune Response in Oral Fluids and Serum. OBJECTIVES: The COVID-19 vaccine is currently being administered worldwide to address the ongoing pandemic. Although these vaccines have proven effective in preventing severe disease, the level of immunity required to prevent respiratory mucosal infection remains less well understood. Therefore, it is desirable to develop a noninvasive screening strategy such as oral fluid to monitor secreted antibodies longitudinally as potential surrogates of mucosal immunity. METHODS: We evaluated the anti-spike protein antibodies in gingival crevicular fluid (GCF) and saliva and compared them to immune responses in the blood of 50 healthy health care workers following 2 doses of intramuscular Pfizer/BioNTech-BNT162b2 vaccine. RESULTS: The antibodies to SARS-CoV-2 spike and subdomain proteins (RBD, S1, S2, and NTD) were significantly higher in serum than oral fluids but showed a greater detection rate and higher median titres in GCF than saliva. For all tested SARS-CoV-2 antigens, IgG in GCF (as opposed to saliva) showed a more significant and stronger correlation with IgG in serum. Serum-neutralising antibodies (Nab) titres also displayed a significant and stronger correlation with anti-spike protein and their subdomains in GCF than saliva. Interestingly, the time post-second dose of vaccine and sex had a similar influence on IgG in serum and GCF. However, interferon (IFN)-Î³-producing T-cell responses showed no association with SARS-Cov-2 IgG antibodies in serum, GCF, or saliva and neutralisation antibodies in serum. The correlation matrix of all measured parameters grouped serum and GCF IgG parameters separately from salivary IgG parameters indicating that GCF better represents the humoural response in serum than saliva. CONCLUSIONS: Within limitations, we propose that GCF could be a less invasive alternative to serum and more appropriate than saliva to detect antibody responses by current COVID-19 vaccines if the GCF collection procedure could be standardised. Further research is needed to investigate the suitability of GCF for community immune surveillance for vaccines.

COVID-19 vaccine-related psychiatric adverse events: Mechanisms and considerations.

Effect of vaccination against Covid-19 one year after its introduction in Brazil. BACKGROUND: Worldwide, several efforts have been made to develop, distribute and administer safe and effective vaccines to reduce morbidity and mortality and control the Covid-19 pandemic. This study aimed to analyze the effect of vaccination against Covid-19, one year after its introduction in Brazil. METHODS: An ecological study that analyzed the general effect of vaccination against Covid-19 on disease morbidity and mortality indicators among the Brazilian population aged 18Â years or older per epidemiological week (EW), comparing the pre and postvaccination period. Morbidity and mortality indicators were calculated from secondary databases (hospitalization rate, severity, case fatality rate and mortality) and vaccination coverage by age groups (18 to 59Â years and 60Â years or older). Morbimortality trends were estimated using the JoinPoint model and their association with vaccine coverage using the Poisson model. RESULTS: The average weekly percentage change (AWPC) of morbidity and mortality indicators reduced after the introduction of Covid-19 vaccination: hospitalization rate (from 15.3% to -6.0%), severity (from 0.4% to -0.2%), case fatality rate (from 0.3%

to -0.2%) and mortality (from 20.5% to -4.3%). The following indicators were inversely associated with the increase in vaccine coverage against Covid-19: hospitalization (IRR: 0.974), mortality (IRR: 0.975) and lethality for people aged 60Â years or older (IRR: 0.997). CONCLUSIONS: In spite of the three epidemic waves and the circulation of variants of concern, the general effect of vaccination against Covid-19 in reducing the trend of morbidity and mortality from the disease in Brazil was demonstrated. These findings contribute to a better understanding of the mass vaccination program against Covid-19 and may inform future public health policies.

Diminished neutralization responses towards SARS-CoV-2 Omicron VoC after mRNA or vector-based COVID-19 vaccinations. SARS-CoV-2 variants accumulating immune escape mutations provide a significant risk to vaccine-induced protection against infection. The novel variant of concern (VoC) Omicron BA.1 and its sub-lineages have the largest number of amino acid alterations in its Spike protein to date. Thus, they may efficiently escape recognition by neutralizing antibodies, allowing breakthrough infections in convalescent and vaccinated individuals in particular in those who haveÂ only receivedÂ a primary immunization scheme. We analyzed neutralization activity of sera from individuals after vaccination with all mRNA-, vector- or heterologous immunization schemes currently available in Europe by in vitro neutralization assay at peak response towards SARS-CoV-2 B.1, Omicron sub-lineages BA.1, BA.2, BA.2.12.1, BA.3, BA.4/5, Beta and Delta pseudotypes and also provide longitudinal follow-up data from BNT162b2 vaccinees. All vaccines apart from Ad26.CoV2.S showed high levels of responder rates (96-100%) towards theÂ SARS-CoV-2 B.1 isolate, and minor to moderate reductions in neutralizing Beta and Delta VoC pseudotypes. The novel Omicron variant and its sub-lineages had the biggest impact, both in terms of response rates and neutralization titers. Only mRNA-1273 showed a 100% response rate to Omicron BA.1 and induced the highest level of neutralizing antibody titers, followed by heterologous prime-boost approaches. Homologous BNT162b2 vaccination, vector-based AZD1222Â and Ad26.CoV2.S performed less well with peak responder rates of 48%, 56% and 9%, respectively. However, Omicron responder rates in BNT162b2 recipients were maintained in our six month longitudinal follow-up indicating that individuals with cross-protection against Omicron maintain it over time. Overall, our data strongly argue for booster doses in individuals who were previously vaccinated with BNT162b2, or a vector-based primary immunization scheme.

Analysis of Risk Factors for a Low Immune Response to Messenger RNA COVID-19 Vaccine in Kidney Transplant Recipients and Differences Between Second and Third Dose. BACKGROUND: The efficacy of the response to SARS-CoV-2 vaccination in kidney transplant recipients is low. The aim of our study was to evaluate the risk factors correlated with the low antibody response and whether there was an improvement between the second and the third dose. METHODS: A prospective study was conducted on 176 kidney transplant recipients who received the second and the third dose of the anti-SARS-CoV-2 mRNA Comirnaty vaccine. We evaluated the seroconversion process after administration of the second and the third dose and assessed a possible correlation with age, time between transplant and vaccination, and type of immunosuppressive therapy. RESULTS: A total of 98 of the 176 patients (55.7%) responded positively after the inoculation of the second dose and according to the multivariable logistic regression analysis the lack of seroconversion was independently associated with patient age â‰¥60 (PÂ =Â .025; odds ratio [OR], 2.094), time since transplant of 1 to 3 months (PÂ =Â .032; OR, 2.118), and triple therapy (PÂ =Â .044; OR, 2.327). After the vaccine third dose, the seroconversion increased to 62.5%, and it was negatively influenced by calcineurin inhibitor use (12/21, 57.1% vs 71/78, 91.0%, PÂ =Â .0006) and triple therapy (13/21, 61.9% vs 72/78, 92.3%, PÂ =Â .0014). The median of antispike antibody response significantly increased from 18.5 IU/mL after the second dose to 316.9 IU after the third dose (P < .0001). CONCLUSIONS: We demonstrated a correlation between older age and shorter distance from the

transplant and triple immunosuppressive therapy with the lack of seroconversion. We noticed a significant improvement in antibody response by a third dose of messenger RNA vaccine.

Correspondence on 'COVID-19 vaccine triggered autoimmune hepatitis: case report' by Mathew et al.

Social communication pathways to COVID-19 vaccine side-effect expectations and experience. OBJECTIVE: Negative beliefs about medication and vaccine side-effects can spread rapidly through social communication. This has been recently documented with the potential side-effects from the COVID-19 vaccines. We tested if pre-vaccination social communications about side-effects from personal acquaintances, news reports, and social media predict post-vaccination side-effect experiences. Further, as previous research suggests that side-effects can be exacerbated by negative expectations, we assessed if personal expectations mediate the relationships between social communication and side-effect experience. METHOD: In a prospective longitudinal survey (NÂ =Â 551), COVID-19 vaccine side-effect information from three sources-social media posts, news reports, and first-hand accounts from personal acquaintances-as well as side-effect expectations, were self-reported pre-vaccination. Vaccination side-effect experience was assessed post-vaccination. RESULTS: In multivariate regression analyses, the number of pre-vaccination social media post views (Î²Â =Â 0.17) and impressions of severity conveyed from personal acquaintances (Î²Â =Â 0.42) significantly predicted an increase in pre-vaccination side-effect expectations, and the same variables (Î²sÂ =Â 0.11, 0.14, respectively) predicted post-vaccination side-effect experiences. Moreover, pre-vaccination side-effect expectations mediated the relationship between both sources of social communication and experienced side-effects from a COVID-19 vaccination. CONCLUSIONS: This study identifies links between personal acquaintance and social media communications and vaccine side-effect experiences and provides evidence that pre-vaccination expectations account for these relationships. The results suggest that modifying side-effect expectations through these channels may change the side-effects following a COVID-19 vaccination as well as other publicly discussed vaccinations and medications.

Assessment of COVID-19 vaccination among healthcare workers in Iraq; adverse effects and hesitancy. Several messenger ribonucleic acid (mRNA) and inactivated COVID-19 vaccines are available to the global population as of 2022. The acceptance of the COVID-19 vaccine will play a key role in combating the worldwide pandemic. Public confidence in this vaccine is largely based on its safety and effectiveness. This study was designed to provide independent evidence of the adverse effects associated with COVID-19 vaccines among healthcare workers in Iraq and to identify the attitudes of healthcare workers who rejected the vaccination. We conducted a cross-sectional study to collect data on the adverse effects of the Pfizer, AstraZeneca, and Sinopharm vaccines. Data were collected between October 2021 and February 2022. A total of 2,202 participants were enrolled in the study: (89.97%) received injections of the COVID-19 vaccines and (10.03%) were hesitant to receive the vaccination. Participants received either the Pfizer vaccine (62.9%), AstraZeneca vaccine (23.5%) or Sinopharm vaccine (13.6%). Most adverse effects were significantly less prevalent in the second dose than in the first dose. Notably, the adverse effects associated with the Pfizer vaccine were significantly more prevalent in females than in males. Following the first dose, the participants experienced more adverse effects with the AstraZeneca vaccine. Following the second dose, more adverse effects were associated with the Pfizer vaccine. Interestingly, the prevalence of COVID-19 infection in participants who received two doses of the Pfizer vaccine was significantly reduced compared to those who received two doses of either the AstraZeneca or Sinopharm vaccines. According to vaccine-hesitated participants, insufficient knowledge (29.9%), expeditious development (27.6%) and lack of trust in the vaccines (27.1%) were the three major reasons for refusing the vaccines. The results of our study indicated that these adverse effects do not present a significant problem and should not prevent successful control of the COVID-19 pandemic.

Increase in SARS-CoV-2 RBD-Specific IgA and IgG Antibodies in Human Milk From Lactating Women Following the COVID-19 Booster Vaccination. BACKGROUND: The United States Centers for Disease Control and Prevention recommended a third dose or booster of the Pfizer-BioNTech Comirnaty (BNT162b2) COVID-19 mRNA vaccine in September 2021 for high-risk individuals. Pregnant and high-risk lactating women were encouraged to receive the booster to obtain potential prolonged protection for themselves and their infants. RESEARCH AIM: To investigate the ability of the booster vaccine to increase IgA and IgG antibodies specific to the receptor-binding domain of the SARS-CoV-2 spike protein in human milk compared to levels pre-booster. METHODS: This was a prospective one-group study with a pretest-posttest design. Six of 12 participants were recruited prospectively. Participants were instructed to collect â‰¥ 2 ounces of milk in the morning at 30 days and 1-day pre-booster, and 7, 14, 21, 30, 45, and 60 days post-booster. Levels of IgA and IgG antibodies specific to the receptor-binding domain of the SARS-CoV-2 spike protein were quantified in human milk via an ELISA assay. RESULTS: We found a significant increase in anti-receptor-binding domain-specific IgA and IgG antibodies in human milk 1-2 weeks after the Pfizer-BioNTech booster and at the study endpoint (45- and 60-days post-booster). CONCLUSIONS: This suggests that the booster vaccination enhances SARS-CoV-2 specific immunity in human milk, which may be protective for infants.

Perceptions of COVID-19 Vaccination in Patients with Genitourinary Cancers: Correspondence.

Guillain-BarrÃ© syndrome after COVID-19 vaccines: A Tunisian case series. As the COVID-19 vaccination campaign progresses worldwide, Guillain-BarrÃ© syndrome (GBS) vaccine-related cases have been reported. We carried out a retrospective, descriptive study of GBS patients following COVID-19 vaccine, submitted to the National Pharmacovigilance Center of Tunis during the period between March 2021 and May 2022. Our study aimed to identify epidemiological and clinical features of COVID-19 vaccine-associated GBS. We found 9 cases of GBS post COVID-19 vaccination; 5 of them were excluded due to the lack of information, whereas 4 cases were included in this study. Men represented 75% (3/4) of the cases. The most frequently reported vaccine type was ChAdOx1 nCoV-19 vaccine (nÂ =â€‰2 reports [50%]), Ad26.COV2.S vaccine and BNT162b2 vaccine in 1. The mean time interval from vaccination to symptom onset was 15.3â€‰days. Clinical manifestations were different: classical GBS in two cases and GBS with unilateral facial palsy in the other 2 cases. All patients were treated with a course of intravenous immunoglobulin for 5â€‰days. Three patients reported clinical improvement while one case (25%) showed treatment-related fluctuations. Our observations suggest that COVID-19 vaccines may be associated with GBS. Continuous surveillance and further studies are warranted to assess the significance of the association.

Cerebral venous sinus thrombosis following intracerebral hemorrhage after COVID-19 AstraZeneca vaccination: AÂ case report. The patient was a 55-year-old female patient who presented with sudden onset of left hemiplegia, facial hemiparesis, and hypoesthesia. She has received her first dose of the AstraZeneca COVID-19 vaccine. This case indicates that vaccination may raise the hypercoagulable state even in a condition of post-ICH and anticoagulant prophylaxis.

COVID-19 vaccination uptake and adverse events following COVID-19 immunization in pregnant women in Northern India: a prospective, comparative, cohort study. Objectives: The most commonly used vaccine in India, Covishield, is a recombinant adenovirus vector vaccine for which safety data in pregnant women are not available. The present study was conducted to assess the uptake of COVID-19 vaccines and monitor adverse events following COVID-19 immunization among pregnant women in northern India. Patients and Methods: A prospective cohort study was conducted among pregnant women registered with the antenatal clinics in Chandigarh Union Territory (U.T.) in northern India. The study included 247 pregnant women and a comparative group of age-matched, non-pregnant women (247) who received the first dose of the COVID-19 vaccine and were followed up by telephone interviews for adverse events following immunization at three time points until 28

days after vaccination. Multivariate regression (logistic and linear) was used for the adjusted analysis, with adverse events following immunization and the duration of adverse events following immunization as the outcomes. Results: The COVID-19 vaccination uptake rate was 66.8% among the pregnant women. The 28-day incidence rate of adverse events following immunization among the pregnant women was 76.5%. The overall 28-day incidence of adverse events following immunization in pregnant women did not differ significantly from that of non-pregnant women (P=0.153). Conclusion: The Covishield vaccine is safe for pregnant women in India. Further follow-up of the cohort for feto-maternal outcomes needs to be conducted with an adequate sample size to confirm the overall safety profile of the vaccine.
Persistent hiccups as main COVID-19 manifestation with transient cytotoxic lesion of the corpus callosum splenium during the Omicron wave in the post-vaccination era.
Novel (68)Ga-FAPI PET/CT Offers Oncologic Staging Without COVID-19 Vaccine-Related Pitfalls. In the setting of ongoing coronavirus disease 2019 vaccination, vaccine-related tracer uptake in locoregional lymph nodes has become a well-known issue in tumor staging by (18)F-FDG PET/CT. (68)Ga-fibroblast-activation protein inhibitor (FAPI) PET/CT is a new oncologic imaging tool that may overcome this limitation. Methods: We assessed postvaccine head-to-head and same-day (18)F-FDG and (68)Ga-FAPI-46 PET/CT findings in a series of 11 patients from a large, prospective imaging registry. All patients with documented tracer uptake in locoregional lymph nodes on PET/CT or PET/MRI, after vaccination within 6 wk, were eligible for investigation. Result: Significant visual lymph node uptake adjacent to the injection site was noted in 11 of 11 (100%) patients with (18)F-FDG PET/CT, versus 0 of 11 (0%) with (68)Ga-FAPI PET/CT. (18)F-FDG detected 73% and (68)Ga-FAPI PET/CT 94% of all tumor lesions. Conclusion: In this case-series study, (68)Ga-FAPI showed its potential to avoid (18)F-FDG PET/CT postvaccination pitfalls and presented superior tumor localization.
Giant cell arteritis after COVID-19 vaccination/disease: suggestions for further shots?
Low COVID-19 Immunoglobulin G Titers Following Vaccination and Breakthrough Infection in Patients Taking Clozapine.
Persistent Rash After COVID-19 Vaccination: Challenge.
COVID-19 vaccination and menstruation. COVID-19 vaccination causes small changes to menstruation that quickly resolve.
COVID-19 Vaccination Status and Capsular Contracture Following Prosthetic Breast Reconstruction: A Retrospective, Multicenter Nested Case-Control Study. BACKGROUND: Capsular contracture (CC) is a common long-term complication following prosthetic-based breast reconstruction (PBBR). Seven cases of CC following mRNA vaccination for coronavirus 2019 (COVID-19) are reported in the literature. OBJECTIVES: The aim of this study was to determine whether receiving the COVID-19 vaccine was associated with CC development following PBBR. METHODS: A retrospective, multicenter nested case-control study was performed from January 2014 to July 2022 of adult female patients who underwent PBBR with acellular dermal matrix placement. Cases of CC were selected if no adjuvant radiation was received and they presented for follow-up between December 2020 and July 2022. Controls included patients who met inclusion criteria but who did not experience CC in either breast. Patient demographics, breast cancer characteristics, reconstructive surgery details, postoperative complications, and COVID-19 exposure details were analyzed and correlated with CC development. RESULTS: Of a total of 230 patients (393 breasts) who received PBBR, 85 patients (135 breasts) met inclusion criteria, of whom 12 patients (19 breasts) developed CC and 73 patients (116 breasts) did not. At the time of median follow-up of 18.1 months (n = 85; interquartile range, 12.2-33.6 months), no statistically significant differences were observed between the short- or long-term complications in cases or controls. There were no significant differences in COVID-19 vaccination

status, number of vaccine doses, or vaccination type between cases and controls. Vaccination status was not associated with greater odds of CC development (odds ratio, 1.44; 95% CI, 0.42-5.37; P > .05). CONCLUSIONS: Direct association between CC and COVID-19 vaccination is difficult to prove. Given the known risk of severe COVID-19 infection among immunocompromised patients, those with breast cancer who undergo PBBR should be properly counseled on the benefits and risks of vaccination.

Response to the letter to the editor: two cases of subacute thyroiditis after different types of SARS-CoV-2 vaccination.

Chronic dermatoses exacerbation after COVID-19 vaccination-A systematic review.

SARS-CoV-2 tetrameric RBD protein blocks viral infection and induces potent neutralizing antibody response. The pandemic of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has posed serious threats to global health and economy and calls for the development of safe treatments and effective vaccines. The receptor-binding domain in the spike protein (S(RBD)) of SARS-CoV-2 is responsible for its binding to angiotensin-converting enzyme 2 (ACE2) receptor. It contains multiple dominant neutralizing epitopes and serves as an important antigen for the development of COVID-19 vaccines. Here, we showed that dimeric S(RBD)-Fc and tetrameric 2xS(RBD)-Fc fusion proteins bind ACE2 with different affinity and block SARS-CoV-2 pseudoviral infection. Immunization of mice with S(RBD)-Fc fusion proteins elicited high titer of RBD-specific antibodies with robust neutralizing activity against pseudoviral infections. As such, our study indicates that the polymeric S(RBD)-Fc fusion protein can serve as a treatment agent as well as a vaccine for fighting COVID-19.

Association between the side effect induced by COVID-19 vaccines and the immune regulatory gene polymorphism. People often worry about the side effects after vaccination, reducing the willingness to vaccinate. Thus, we tried to find out the risk of single nucleotide polymorphism (SNP) vaccines to improve the willingness and confidence in vaccination. Allergic and inflammatory reactions are the common vaccine side effects caused by immune system overreaction. In addition, a previous study showed significantly higher frequency of febrile reactions to measles vaccines in American Indians than in Caucasian children, indicating that the side effects varied in accordance with genetic polymorphisms in individuals. Thus, SNPs of immune regulatory genes, cytotoxic T-lymphocyte-associated protein 4 (CTLA4), CD28, tumor necrosis factor ligand superfamily member 4 (TNFSF4) and programmed cell death protein 1 (PDCD1) were included in this study to analyze their association with vaccine side effects. Moreover, 61 healthy participants were asked on the number of doses they received, the brand of the vaccine, and the side effects they suffered. We found that several SNPs were associated with side effects after the first or second dose of mRNA or adenoviral vector vaccines. Furthermore, these SNPs were associated with several autoimmune diseases and cancer types; thus, they played an important role in immune regulation. Moreover, rs3181096 and rs3181098 of CD28, rs733618 and rs3087243 of CTLA, and rs1234314 of TNFSF4 were associated with mild vaccine side effects induced by mRNA and adenoviral vector vaccines, which would play a potential role in vaccine-induced immune responses and may further lead to fatal side effects. These results could serve as a basis for investigating the mechanism of vaccine side effects. Furthermore, it was hoped that these results would address public concerns about the side effects of the COVID-19 vaccination. In clinical application, a rapid screening test can be performed to assess the risk of vaccine side effects before vaccination and provide immediate treatment.

Ocular effects caused by viral infections and corresponding vaccines: An overview of varicella zoster virus, measles virus, influenza viruses, hepatitis B virus, and SARS-CoV-2. Many viral infections can affect vision and the visual system. Vaccination to prevent diseases is commonplace today, acting by stimulating an immune response without developing the pathology. It involves the production of persisting antibodies against the pathogen and the activation of T cells. Certain diseases have already

been eradicated by rigorous vaccination campaigns, while others are hoped to be eliminated soon. Vaccines currently available on the market are largely safe, even if they can rarely cause some adverse effects, such as ocular complications. Analyzing existing literature, we aimed to compare the pathological effects on the eye due to the most common viral infections [in particular varicella zoster virus (VZV), measles virus, influenza viruses, hepatitis B virus, and SARS-CoV-2] with the possible ocular adverse effects of their relative vaccines, in order to establish a risk-benefit relationship from an ophthalmological point of view.

May bullous pemphigoid be worsened by COVID-19 vaccine?

Humoral and cellular immune response after severe acute respiratory syndrome coronavirus 2 messenger ribonucleic acid vaccination in heart transplant recipients: An observational study in France. INTRODUCTION: Heart transplant (HT) recipients have a high risk of developing severe COVID-19. Immunoglobulin G antibodies are considered to provide protective immunity and T-cell activity is thought to confer protection from severe disease. However, data on T-cell response to mRNA vaccination in a context of HT remains limited. METHODS: In 96 HT patients, a IFN-Î³ release assay and an anti-Spike antibody test were used to evaluate the ability of SARS-CoV-2 mRNA vaccines to generate cellular and humoral immune response. Blood samples were collected few weeks to 7 months after vaccination. Multiple fractional polynomial and LASSO regression models were used to define predictors of T-cell response. RESULTS: Three to five months after vaccination, three doses of vaccine induced a positive SARS-CoV-2 T-cell response in 47% of recipients and a positive humoral response in 83% of recipients, 11.1% of patients remained negative for both T and B cell responses. Three doses were necessary to reach high IgG response levels (>590 BAU/mL), which were obtained in a third of patients. Immunity was greatly amplified in the group who had three vaccine doses plus COVID-19 infection. CONCLUSION: Our study revealed that T and B immunity decreases over time, leading us to suggest the interest of a booster vaccination at 5 months after the third dose. Moreover, a close follow-up of immune response following vaccination is needed to ensure ongoing immune protection. We also found that significant predictors of higher cellular response were infection and active smoking, regardless of immunosuppressive treatment with mycophenolate mofetil (MMF).

Adverse events following immunization of COVID-19 vaccine among children aged 6-11 years. INTRODUCTION: Starting in December 2021, the Indonesian Government has recommended inactivated SARS-CoV-2 vaccine (CoronaVac) for children aged 6-11 years. This study aims to determine the prevalence and determinant factors of adverse events following immunization (AEFI) of the first dose and the second dose of the COVID-19 vaccine among children aged 6-11 years old. MATERIALS AND METHODS: We conducted a cross-sectional study in Bantul District, Yogyakarta, Indonesia, in February-March 2022. Data were collected by trained interviews with 1,093 parents of children 6-11 years old who received the first dose and the second dose of the COVID-19 vaccine. Data were analyzed with chi-square and logistic regression. RESULTS: The prevalence of AEFI in the first dose of the COVID-19 vaccine was 16.7%, while the second dose was 22.6%. The most common symptoms of AEFI at the first dose were local site pain and fever, while at the second dose were cough and cold. Determinants of AEFI of COVID-19 vaccination among children were girls with OR 1.31 (95% CI 1.0-1.7; P 0.04), mass-setting of vaccination with OR 0.70 (95% CI 0.5-0.9; P 0.01), the history of AEFI in childhood vaccination with OR 1.63 (95% CI 1.2-2.2; P < 0.01) and administering other vaccines within 1 month before COVID-19 vaccination, with OR 5.10 (95% CI 2.1-12.3 P < 0.01). CONCLUSION: The prevalence of AEFI in the first and the second dose of inactivated COVID-19 vaccine was comparable to that reported in the clinical trial study and the communities. Risk communication should be provided to the child and their parents regarding the risk of mild AEFI of the COVID-19 vaccine, especially for children with a history of AEFI in childhood vaccination and who

received other vaccines containing the same adjuvant with CoronaVac within 1 month. A mass-setting of vaccination should be taken as an advantage to educate parents about the risk of AEFI and also about the reporting pathways.

Cutaneous Reactions Following COVID-19 Vaccination: A Review of the Current Literature. The outbreak of coronavirus disease 2019 (COVID-19) represented a new worldwide challenge, strongly impacting on the global economy, overall health and lifestyle. Since then, several strategies have been adopted to contain the widespread of infection. Among these, vaccination is currently the most important measure to fight against the pandemic. However, several concerns such as slower-than-hoped-for rollout, the hurried approval with limited data, the mechanism of action (in particular mRNA-based), and the uncertain duration of protection they afforded were initially raised. Moreover, even if cutaneous reactions have been rarely reported in clinical trials, global mass vaccination showed several dermatologic reactions not initially recognized, leaving dermatologists to decide how to diagnose and treat them. In this scenario, dermatologists should be ready to promptly recognize these clinical manifestations. Thus, the aim of this manuscript is to review current literature on cutaneous reactions following COVID-19 vaccination, particularly inflammatory dermatological diseases, in order to help clinicians to better understand these dermatological conditions and to provide an extensive overview of all the vaccine-related skin manifestations.

Risk of Adverse Events of Live-Attenuated COVID-19 Vaccination Among Atopic Patients. PURPOSE: Atopic patients have more risk of adverse drug reactions. COVID-19 vaccination is very important in the current situation. We still do not have data about risks of adverse effects from vaccine in atopic patients. The goal of our study was to evaluate atopic risks and adverse effects of live-attenuated Oxford/AstraZeneca COVID-19 vaccination. PATIENTS AND METHODS: Data was collected using a prospective descriptive cohort study from participants 18 years old and above who came to the Outpatient Department, Panyananthaphikkhu Chonprathan Medical Center for live-attenuated COVID-19 vaccination between March and December 2021. The sample size was 3016 individuals. The information about adverse reactions at 6, 2, 72 hours and 7.30 and 60 days after each live-attenuated Oxford/AstraZeneca COVID-19 vaccination was collected by telephone. Participants with history of severe allergic reaction to vaccine components were excluded. RESULTS: There were 732 atopic patients and 2284 non-atopic patients. Atopic patients included 556 with allergic rhinitis, 83 with asthma, 23 with urticaria and 73 with food allergies. The underlying diseases of hypertension, hyperlipidemia and hyperthyroidism were more common in non-allergic patients, with p-value <0.001, <0.001 and 0.042, respectively. Atopic patients developed significantly more fever, nausea and vomiting, skin rash (urticaria), and local reaction than non-atopic patients, with p-values of <0.001, 0.018, <0.001 and <0.001, respectively. CONCLUSION: Atopic patients had more risk of adverse reactions to live-attenuated Oxford/AstraZeneca COVID-19 vaccination. No life-threatening adverse reaction was seen. Physicians should screen atopic risks in people who are getting vaccinated. Atopic patients should be knowledgeable about their risk and how to monitor clinical reactions by themselves.

Small fiber neuropathy as a complication of SARS-CoV-2 vaccinations. Generally, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccinations are not free of side effects. A rarely reported adverse reaction to SARS-CoV-2 vaccinations is small fiber neuropathy (SFN). Here, we present three patients with SFN after the second dose of messenger ribonucleic acid-based SARS-CoV-2 vaccines. Data for this study were collected via the self-made platform "Pubbly" for reporting side effects of SARS-CoV-2 vaccinations. Three patients with post-SARS-CoV-2 vaccination SFN were identified: a 40 yo Caucasian female (patient 1), a 52 yo Caucasian female (patient 2), and a 32 yo Caucasian female (patient 3). Patient 1 complained about fatigue, dizziness, flushing, palpitations, diarrhea, muscle weakness, and gait disturbance 10 days after the second Pfizer jab. Patient 2

reported dizziness, balance problems, brain fog, palpitations, dysphagia, and sleep problems. Patient 3 complained about profound fatigue, brain fog, vertigo, pre-syncopal sensations, hair loss, chest pain, dyspnea, palpitations, paresthesias, irregular menstrual cycles, muscle weakness, and hives 1 day after the second Moderna dose. All three patients underwent skin biopsy upon which SFN was diagnosed. Patient 1 profited from immunoglobulins, but patient 2 did not require any treatment. Symptoms in patient 3 resolved upon symptomatic treatment. Despite treatment, patient 1 did not completely recover. SFN can be a rare side effect of SARS-CoV-2 vaccinations. Post-SARS-CoV-2 vaccination SFN can be mild or severe and may or may not require treatment. Post-SARS-CoV-2 vaccination SFN is most likely immune-mediated as it responds to intravenous immunoglobulins.
Lichen planus after COVID-19 infection and vaccination: A systematic review.
A review of the potential neurological adverse events of COVID-19 vaccines. Despite the advantages of getting access to the coronavirus disease 2019 (COVID-19) vaccines, their potential ability to induce severe adverse events (AEs) has been a significant concern. Neurological complications are significant among the various adverse events following immunization (AEFI) due to their likely durability and debilitating sequelae. Neurological AEs following COVID-19 vaccination can either exacerbate or induce new-onset neuro-immunologic diseases, such as myasthenia gravis (MG) and Guillain-Barre syndrome (GBS). The more severe spectrum of AEs post-COVID19 vaccines has included seizures, reactivation of the varicella-zoster virus, strokes, GBS, Bell's palsy, transverse myelitis (TM), and acute disseminated encephalomyelitis (ADEM). Here, we discuss each of these neurological adverse effects separately.
Miller-Fisher syndrome after first dose of Oxford/AstraZeneca coronavirus disease 2019 vaccine: a case report. INTRODUCTION: Miller-Fisher Syndrome (MFS) is a variant of Guillain-BarrÃ© syndrome (GBS), an acute immune-mediated neuropathy, which manifests as a rapidly evolving areflex motor paralysis. This syndrome presents as a classic triad: ophthalmoplegia, areflexia, and ataxia. MFS is usually benign and self-limited. CASE REPORT: A Caucasian patient was admitted to our hospital with the flu, loss of bilateral strength in the lower limbs and upper limbs and sudden-onset ataxia 7 days after receiving a first dose of the Oxford/AstraZeneca COVID-19 vaccine. On neurological examination, the patient had Glasgow Coma Scale score of 15, with absence of meningeal signs; negative Babinski sign; grade 2 strength in the lower limbs and grade 4 strength in the upper limbs; axial and appendicular cerebellar ataxia; and peripheral facial diparesis predominantly on the right, without conjugate gaze deviation. Cerebrospinal fluid (CSF) was collected on admission, and analysis revealed albuminocytological dissociation with CSF protein of 148.9 mg/dL; leukocytes, 1; chlorine, 122; glucose, 65 mg/mL; red cells, 2; and non-reactive venereal disease research laboratory test result. The COVID-19 IgG/IgM rapid immunological test was negative. Electroneuromyography revealed a recent moderate-grade and primarily sensory and motor demyelinating polyneuropathy with associated proximal motor block. DISCUSSION AND CONCLUSION: Miller-Fisher Syndrome may be related to events other than infections prior to neuropathy, as in the case reported here. The patient presented strong correlations with findings for MFS reported in the literature, such as the clinical condition, the results of electroneuromyography, and results of the CSF analysis typical for MFS. When treatment was provided as proposed in the literature, the disease evolved with improvement. Ultimately, the diagnosis of incomplete MFS was made, including acute ataxic neuropathy (without ophthalmoplegia).
A longitudinal study of humoral immune responses induced by a 3-dose inactivated COVID-19 vaccine in an observational, prospective cohort. BACKGROUND: To determine the dynamic SARS-CoV-2 specific antibody levels induced by 3 doses of an inactivated COVID-19 vaccine, CoronaVac. An observational, prospective cohort study was performed with 93 healthy healthcare workers from a tertiary hospital in Nanjing, China. Serum SARS-CoV-2 specific IgM, IgG, and neutralizing antibodies

(NAb) were measured at different time points among participants who received 3 doses of inactivated COVID-19 vaccine. RESULTS: 91.3% (85/93) and 100% (72/72) participants showed positive both for SARS-CoV-2 specific IgG and NAb after 2-dose CoronaVac and after 3-dose CoronaVac, respectively. Anti-SARS-CoV-2 IgG responses reached 91.21 (55.66-152.06) AU/mL, and surrogate NAb was 47.60 (25.96-100.81) IU/mL on day 14 after the second dose. Anti-SARS-CoV-2 IgG responses reached 218.29 (167.53-292.16) AU/mL and surrogate NAb was 445.54 (171.54-810.90) IU/mL on day 14 after the third dose. Additionally, SARS-CoV-2 specific surrogate neutralizing antibody titers were highly correlated with serum neutralization activities against Ancestral, Omicron, and Delta strains. Moreover, significantly higher SARS-CoV-2 IgG responses, but not NAb responses, were found in individuals with breakthrough infection when compared to that of 3-dose CoronaVac recipients. CONCLUSIONS: CoronaVac elicited robust SARS-CoV-2 specific humoral responses. Surrogate NAb assay might substitute for pseudovirus neutralization assay. Monitoring SARS-CoV-2 antibody responses induced by vaccination would provide important guidance for the optimization of COVID-19 vaccines.

Multiple COVID reinfections in a vaccinated psoriatic patient receiving adalimumab. Currently, psoriasis patients are advised to follow their standard therapeutic regimen, and are advised to be vaccinated against Covid-19. However, the data about the antibody responses, induced by the various kinds of SARS-CoV-2 vaccines in psoriasis patients who require systemic immunosuppressive treatment is scant. In this case report, we describe antibody responses induced by COVID-19 vaccine, in a 26-year-old male patient with psoriasis being treated with anti-TNF biotherapy, adalimumab biosimilar every two weeks. The patient was vaccinated against COVID-19, according to the national protocol. He experienced three episodes of symptomatic COVID-19. His first and second exposures did not result in antibody production. After the third episode of COVID-19, The SARS-CoV-2 anti-spike antibody (IgG) was more than 100 Ru/mL (ELISA; â‰¥8 Ru/mL is considered positive), and SARS-CoV-2 neutralizing antibody (total) was more than 40 micg/mL (ELISA; â‰¥2.5 micg/mL is considered positive). This is the first case with weak antibody response to vaccination and multiple episodes of COVID infection in a psoriatic patient with adalimumab biosimilar. However, we cannot assume causality due to the treatment.

Patterns of vestibular function in patients with dizziness after COVID-19 vaccination; dual tertiary referral center study. BACKGROUND: Although dizziness is a common symptom after vaccination, the mechanism, and prognosis are not well understood. AIMS/OBJECTIVES: This study aimed to investigate patients with dizziness after COVID-19 vaccination by analyzing objective information. METHODS: A retrospective study of patients who visited the outpatient clinics of two institutes with a complaint of dizziness occurring within 72â€‰h after a COVID-19 vaccination. RESULTS: In most cases, patients experienced only a single event of dizziness, and the subjective symptom was relieved after a few weeks. All patients decreased gain of vestibular ocular reflex (VOR). The vestibular function test results showed signs of central vestibulopathy in some cases. We separated patients into two groups; the direction-fixed nystagmus (DFN) group and the direction-changing nystagmus (DCN) group. All patients showed decreased gain on the rotational chair test (RCT). The DFN group showed an 80% decrease in video head impulse test (vHIT) gain, whereas the DCN group only showed a decrease of 25%. In RCT, 66% of the DFN group showed asymmetry compared to 20% showing asymmetry in the DCN group. CONCLUSION AND SIGNIFICANCE: The patients who suffered from dizziness after the COVID-19 vaccination exhibited decreased VOR gain and in some cases signs of central vestibulopathy.

Assessment of Herpes Zoster Risk Among Recipients of COVID-19 Vaccine. IMPORTANCE: Herpes zoster infection after COVID-19 vaccination has been reported in numerous case studies. It is not known whether these cases represent increased reporting or a true increase in risk. OBJECTIVE: To

assess whether COVID-19 vaccination is associated with an increased risk of herpes zoster infection. DESIGN, SETTING, AND PARTICIPANTS: This cohort study used a self-controlled risk interval (SCRI) design to compare the risk of herpes zoster in a risk interval of 30 days after COVID-19 vaccination or up to the date of the second vaccine dose with a control interval remote from COVID-19 vaccination (defined as 60-90 days after the last recorded vaccination date for each individual, allowing for a 30-day washout period between control and risk intervals). A supplemental cohort analysis was used to compare the risk of herpes zoster after COVID-19 vaccination with the risk of herpes zoster after influenza vaccination among 2 historical cohorts who received an influenza vaccine in the prepandemic period (January 1, 2018, to December 31, 2019) or the early pandemic period (March 1, 2020, to November 30, 2020). Data were obtained from Optum Labs Data Warehouse, a US national deidentified claims-based database. A total of 2 039 854 individuals who received any dose of a COVID-19 vaccine with emergency use authorization (BNT162b2 [Pfizer-BioNTech], mRNA-1273 [Moderna], or Ad26.COV2.S [Johnson & Johnson]) from December 11, 2020, through June 30, 2021, were eligible for inclusion. Individuals included in the SCRI analysis were a subset of the COVID-19-vaccinated cohort who had herpes zoster during either a risk or control interval. EXPOSURES: Any dose of a COVID-19 vaccine. MAIN OUTCOMES AND MEASURES: Incident herpes zoster, defined by International Statistical Classification of Diseases and Related Health Problems, Tenth Revision codes and a prescription of a new antiviral medication or a dose increase in antiviral medication within 5 days of diagnosis. RESULTS: Among 2â€¯039â€¯854 individuals who received any dose of a COVID-19 vaccine during the study period, the mean (SD) age was 43.2 (16.3) years; 1â€¯031â€¯149 individuals (50.6%) were female, and 1â€¯344â€¯318 (65.9%) were White. Of those, 1451 patients (mean [SD] age, 51.6 [12.6] years; 845 [58.2%] female) with a herpes zoster diagnosis were included in the primary SCRI analysis. In the SCRI analysis, COVID-19 vaccination was not associated with an increased risk of herpes zoster after adjustment (incidence rate ratio,â€‰0.91; 95% CI, 0.82-1.01; Pâ€‰=â€‰.08). In the supplementary cohort analysis, COVID-19 vaccination was not associated with a higher risk of herpes zoster compared with influenza vaccination in the prepandemic period (first dose of COVID-19 vaccine: hazard ratio [HR], 0.78 [95% CI, 0.70-0.86; Pâ€‰<â€‰.001]; second dose of COVID-19 vaccine: HR, 0.79 [95% CI, 0.71-0.88; Pâ€‰<â€‰.001]) or the early pandemic period (first dose of COVID-19 vaccine: HR, 0.89 [95% CI, 0.80-1.00; Pâ€‰=â€‰.05]; second dose: HR, 0.91 [95% CI, 0.81-1.02; Pâ€‰=â€‰.09]). CONCLUSIONS AND RELEVANCE: In this study, there was no association found between COVID-19 vaccination and an increased risk of herpes zoster infection, which may help to address concerns about the safety profile of the COVID-19 vaccines among patients and clinicians.

Ocular motility disorders following coronavirus disease-19 vaccination. PURPOSE: To describe clinical manifestations and short-term prognosis of ocular motility disorders following coronavirus disease-2019 (COVID-19) vaccination. METHODS: Ocular motility disorders were diagnosed by clinical assessment, high-resolution magnetic resonance imaging, and laboratory testing. Clinical manifestations, short-term prognosis, and rate of complete recovery were analyzed. RESULTS: Sixty-three patients (37 males, 26 females) with a mean age of 61.6â€‰Â±â€‰13.3Â years (range, 22-81Â years) were included in this study. Among 61 applicable patients with sufficient information regarding medical histories, 38 (62.3%) had one or more significant underlying past medical histories including vasculopathic risk factors. The interval between initial symptoms and vaccination was 8.6â€‰Â±â€‰8.2 (range, 0-28) days. Forty-two (66.7%), 14 (22.2%), and 7 (11.1%) patients developed symptoms after the first, second, and third vaccinations, respectively. One case of internuclear ophthalmoplegia, 52 cases of cranial nerve palsy, two cases of myasthenia gravis, six cases of orbital diseases (such as myositis, thyroid eye disease, and IgG-related orbital myopathy), and two cases of comitant vertical strabismus with acute onset diplopia were found. Among 42

patients with follow-up data (duration: 62.1â€‰Â±â€‰40.3Â days), complete improvement, partial improvement, no improvement, and exacerbation were shown in 20, 15, 3, and 4 patients, respectively. CONCLUSION: This study provided various clinical features of ocular motility disorders following COVID-19 vaccination. The majority of cases had a mild clinical course while some cases showed a progressive nature. Close follow-up and further studies are needed to elucidate the underlying mechanisms and long-term prognosis.

Inactivated Vaccine-Induced SARS-CoV-2 Variant-Specific Immunity in Children. Multiple vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been evaluated in clinical trials. However, trials addressing the immune response in the pediatric population are scarce. The inactivated vaccine CoronaVac has been shown to be safe and immunogenic in a phase 1/2 clinical trial in a pediatric cohort in China. Here, we report interim safety and immunogenicity results of a phase 3 clinical trial for CoronaVac in healthy children and adolescents in Chile. Participants 3 to 17â€‰years old received two doses of CoronaVac in a 4-week interval until 31 December 2021. Local and systemic adverse reactions were registered for volunteers who received one or two doses of CoronaVac. Whole-blood samples were collected from a subgroup of 148 participants for humoral and cellular immunity analyses. The main adverse reaction reported after the first and second doses was pain at the injection site. Four weeks after the second dose, an increase in neutralizing antibody titer was observed in subjects relative to their baseline visit. Similar results were found for activation of specific CD4(+) T cells. Neutralizing antibodies were identified against the Delta and Omicron variants. However, these titers were lower than those for the D614G strain. Importantly, comparable CD4(+) T cell responses were detected against these variants of concern. Therefore, CoronaVac is safe and immunogenic in subjects 3 to 17â€‰years old, inducing neutralizing antibody secretion and activating CD4(+) T cells against SARS-CoV-2 and its variants. (This study has been registered at ClinicalTrials.gov under no. NCT04992260.) IMPORTANCE This work evaluated the immune response induced by two doses of CoronaVac separated by 4 weeks in healthy children and adolescents in Chile. To date, few studies have described the effects of CoronaVac in the pediatric population. Therefore, it is essential to generate knowledge regarding the protection of vaccines in this population. Along these lines, we reported the anti-S humoral response and cellular immune response to several SARS-CoV-2 proteins that have been published and recently studied. Here, we show that a vaccination schedule consisting of two doses separated by 4 weeks induces the secretion of neutralizing antibodies against SARS-CoV-2. Furthermore, CoronaVac induces the activation of CD4(+) T cells upon stimulation with peptides from the proteome of SARS-CoV-2. These results indicate that, even though the neutralizing antibody response induced by vaccination decreases against the Delta and Omicron variants, the cellular response against these variants is comparable to the response against the ancestral strain D614G, even being significantly higher against Omicron.

COVID-19 excess deaths in Eastern European countries associated with weaker regulation implementation and lower vaccination coverage. BACKGROUND: Since winter 2020, excess deaths due to COVID-19 have been higher in Eastern Europe than most of Western Europe, partly because regulatory enforcement was poor. METHODS: This paper analysed data from 50 countries in the WHO European Region, in addition to data from USA and Canada. Excess mMortality and vaccination data were retrieved from "Our World In Data" and regulation implementation was assessed using standard methods. Multiple linear regression was used to assess the association between mortality and each covariate. RESULTS: Excess mortality increased by 4.1 per 100 000 (P = 0.038) for every percentage decrease in vaccination rate and with 6/100 000 (p=0.011) for every decreased unit in the regulatory implementation score a country achieved in the Rule of Law Index. CONCLUSION: Degree of regulation enforcement, likely including public health measure enforcement, may be an important factor in controlling COVID-19's deleterious health impacts.

Images in Vascular Medicine: SARS-CoV-2 vaccine-induced ulcerations.
SARS-CoV-2 Infection Incidence and Outcome Before and After Full Vaccination in Patients With Monoclonal Gammopathy of Undetermined Significance.
Mammographic Findings of Diffuse Axillary Tail Trabecular Thickening After the Second Booster of COVID-19 Vaccination. Axillary adenopathy post-coronavirus disease 2019 (COVID-19) vaccination has been well-documented and is seen with other types of vaccinations. Isolated trabecular thickening on mammography, however, is singular to COVID-19 vaccination, which implies that this finding may result from a distinct pathophysiologic mechanism. Herein, we describe the first case of axillary tail trabecular thickening resulting from the second booster of the COVID-19 vaccination series. Both breast cancer and mastitis may present similar findings. Ipsilateral injection of COVID-19 vaccine/booster and spontaneous resolution on follow-up provide clues to the etiology. It has been hypothesized that proinflammatory conditions may predispose to axillary tail trabecular thickening on mammography post-COVID-19 vaccination. Proinflammatory conditions such as hypertension, obesity, and diabetes may also predispose to breast cancer, making this scenario even more of a diagnostic dilemma. This scenario would more likely be seen in lower socioeconomic communities, African Americans, and Hispanics, who demonstrate a higher prevalence of these diseases, and who are also more vulnerable due to health care disparities negatively affecting these groups. We discuss our case and the importance of this public health issue. Sequela of COVID vaccination and boosters will be encountered inÂ the foreseeable future and could pose a diagnostic dilemma, thus potentially straining the healthcare system with unnecessary biopsies and patient anxiety if not recognized and appropriately managed.
Antineutrophil Cytoplasmic Antibody (ANCA)-Associated Renal Vasculitis Following COVID-19 Vaccination: A Case Report and Literature Review. Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) is an immune-mediated disorder of small and medium-sized vessels, characterized by the production of autoantibodies that target the neutrophilic antigens leading to mononuclear cell infiltration and destruction of blood vessels in lungs, skin, and kidneys. Although rare, the coronavirus disease 2019 (COVID-19) vaccine may trigger autoimmune vasculitis. We report a rare case of ANCA-associated renal vasculitis following COVID-19 vaccination in a 59-year-old male who presented with flu-like symptoms and deranged renal function tests. He received his second dose of the Pfizer COVID-19 vaccine 17 days ago. His clinical picture, serological testing, and radiological imaging were concerned with glomerular disease. His serum was positive for ANCAs, and the renal biopsy specimen revealed pauci-immune glomerulonephritis. He was diagnosed with AAV-associated renal vasculitis following COVID-19 vaccination because no other etiology was identified. His clinical improvement after starting rituximab and steroids reinforced the diagnosis.
Increasing but insufficient neutralizing activity against Omicron-BA.1 after a second booster dose of mRNA-1273 vaccine in chronic haemodialysis patients.
Development of crescentic membranoproliferative glomerulonephritis after COVID-19 vaccination. Membranoproliferative glomerulonephritis (MPGN) comprises a histologic pattern of glomerular injury with different underlying diseases. Here we report on a 47-year-old female with rapidly progressive glomerulonephritis (RPGN) on top of a previously diagnosed idiopathic MPGN after receiving the first dose of the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) mRNA vaccine. After aggressive immunosuppression her serum creatinine returned to normal values, along with reduction of proteinuria. Recently, numerous publications have reported an association of glomerular diseases with COVID-19 vaccination. Our case presents to the best of our knowledge the first occurrence of possible association of COVID-19 mRNA vaccination with a crescentic form of MPGN.
Acute Myocarditis After COVID-19 Vaccination.

Cardiac complications of COVID-19 vaccination: now we know more. The proliferation of good quality observational studies on the potential adverse effects of COVID-19 vaccination has greatly increased our knowledge on myocarditis and pericarditis, and also, more recently, on arterial hypertension. According to some recent studies, the incidence of a significant increase in blood pressure after COVID-19 vaccination is about 3.2% (95% CI: 1.62-6.21). The incidence of serious hypertensive emergencies or stage III hypertension has been reported as 0.6%. It is well known that the 'spike protein' of the Sars-CoV-2 virus, the synthesis of which is induced by vaccines, binds to ACE(2) receptors, inducing their migration towards the inside of the cell. This would result in a lack of ACE(2) activity on cell surfaces and therefore a relative deficiency of angiotensin(1-7) with a relative excess of angiotensin II, which could explain, at least in part, the blood pressure increases. Regarding myo-pericarditis, there is evidence that the advantages of COVID-19 vaccination over non-vaccination remain preponderant in terms of prevented hospitalizations and serious complications of COVID-19, compared with the risk of developing myocarditis. In the age group most at risk of COVID-19 vaccine myocarditis (12-29 years), for every 100 000 vaccinated, compared to about four more cases of myocarditis we have 56 fewer hospitalizations, 13.8 admissions to intensive care and 0.6 fewer deaths. Several studies have shown that post vaccine myocarditis/pericarditis are generally short-lasting phenomena with favourable clinically course.

Attenuated humoral responses in HIV infection after SARS-CoV-2 vaccination are linked to global B cell defects and cellular immune profiles. People living with HIV (PLWH) on suppressive antiretroviral therapy (ART) can have residual immune dysfunction and often display poorer responses to vaccination. We assessed in a cohort of PLWH (n=110) and HIV negative controls (n=64) the humoral and spike-specific B-cell responses following 1, 2 or 3 SARS-CoV-2 vaccine doses. PLWH had significantly lower neutralizing antibody (nAb) titers than HIV-negative controls at all studied timepoints. Moreover, their neutralization breadth was reduced with fewer individuals developing a neutralizing response against the Omicron variant (BA.1) relative to controls. We also observed a delayed development of neutralization in PLWH that was underpinned by a reduced frequency of spike-specific memory B cells (MBCs) and pronounced B cell dysfunction. Improved neutralization breadth was seen after the third vaccine dose in PLWH but lower nAb responses persisted and were associated with global, but not spike-specific, MBC dysfunction. In contrast to the inferior antibody responses, SARS-CoV-2 vaccination induced robust T cell responses that cross-recognized variants in PLWH. Strikingly, a subset of PLWH with low or absent neutralization had detectable functional T cell responses. These individuals had reduced numbers of circulating T follicular helper cells and an enriched population of CXCR3 (+) CD127 (+) CD8 (+) T cells after two doses of SARS-CoV-2 vaccination, which may compensate for sub-optimal serological responses in the event of infection. Therefore, normalisation of B cell homeostasis could improve serological responses to vaccines in PLWH and evaluating T cell immunity could provide a more comprehensive immune status profile in these individuals and others with B cell imbalances.

Demographic characteristics, outcomes and experience of patients using virtual urgent care services from 14 emergency department led sites in Ontario. INTRODUCTION: As part of the COVID-19 pandemic response, the Ontario Ministry of Health funded a virtual care pilot program intended to support emergency department (ED) diversion of patients with low acuity complaints and reduce the need for face-to-face contact. The objective was to describe the demographic characteristics, outcomes and experience of patients using the provincial pilot program. METHODS: This was a prospective cohort study of patients using virtual care services provided by 14 ED-led pilot sites from December 2020 to September 2021. Patients who completed a virtual visit were invited by email to complete a standardized, 25-item online survey, which included questions related to satisfaction and patient-reported outcome measures. RESULTS: There were 22,278 virtual visits. When patients were

asked why they contacted virtual urgent care, of the 82.7% patients who had a primary care provider, 31.0% said they could not make a timely appointment with their family physician. Rash, fever, abdominal pain, and COVID-19 vaccine queries represented 30% of the presenting complaints. Of 19,613 patients with a known disposition, 12,910 (65.8%) were discharged home and 3,179 (16.2%) were referred to the ED. Of the 2,177 survey responses, 94% rated their overall experience as 8/10 or greater. More than 80% said they had answers to all the questions they had related to their health concern, believed they were able to manage the issue, had a plan they could follow, and knew what to do if the issue got worse or came back. CONCLUSIONS: Many presenting complaints were low acuity, and most patients had a primary care provider, but timely access was not available. Future work should focus on health equity to ensure virtual care is accessible to underserved populations. We question if virtual urgent careÂ can be safely and more economically provided by non-emergency physicians.

A Rare Case of BIA-ALCL Mass Associated with Mastectomy Skin Flap Erythema After Immunization with COVID-19. BACKGROUND: The immune response to breast implants after COVID-19 disease or COVID-19 vaccine administration includes acute inflammatory manifestations, capsular contracture and seroma. Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a very rare tumor in which numerous up-regulated pro-inflammatory immunological pathways activate a T cell lymphoproliferative disorder. METHODS: The first reported case of a BIA-ALCL hidden mass clinically manifesting with inflammatory signs after SARS-CoV-2 infection and vaccinations is here described. RESULTS: Complete capsulectomy and adjuvant chemotherapy were performed and immediately after the surgical procedure local inflammatory signs disappeared; no evidence of disease was present 1 year later. CONCLUSIONS: Immunological stimulation by COVID-19 disease and vaccines may highlight some rare clinical manifestations of BIA-ALCL; persistent inflammatory symptomatology over breast implants should be investigated using second-level imaging. LEVEL OF EVIDENCE V: This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266 .

Anti-Ad26 humoral immunity does not compromise SARS-COV-2 neutralizing antibody responses following Gam-COVID-Vac booster vaccination. Replication-incompetent adenoviral vectors have been extensively used as a platform for vaccine design, with at least four anti-COVID-19 vaccines authorized to date. These vaccines elicit neutralizing antibody responses directed against SARS-CoV-2 Spike protein and confer significant level of protection against SARS-CoV-2 infection. Immunization with adenovirus-vectored vaccines is known to be accompanied by the production of anti-vector antibodies, which may translate into reduced efficacy of booster or repeated rounds of revaccination. Here, we used blood samples from patients who received an adenovirus-based Gam-COVID-Vac vaccine to address the question of whether anti-vector antibodies may influence the magnitude of SARS-CoV-2-specific humoral response after booster vaccination. We observed that rAd26-based prime vaccination with Gam-COVID-Vac induced the development of Ad26-neutralizing antibodies, which persisted in circulation for at least 9 months. Our analysis further indicates that high pre-boost Ad26 neutralizing antibody titers do not appear to affect the humoral immunogenicity of the Gam-COVID-Vac boost. The titers of anti-SARS-CoV-2 RBD IgGs and antibodies, which neutralized both the wild type and the circulating variants of concern of SARS-CoV-2 such as Delta and Omicron, were independent of the pre-boost levels of Ad26-neutralizing antibodies. Thus, our results support the development of repeated immunization schedule with adenovirus-based COVID-19 vaccines.

Adverse events following administration of COVID-19 vaccines in Saudi Arabia. Previous studies investigated the frequency of different adverse events of COVID-19 vaccines. However, this study compares these adverse events between the two main COVID-19 vaccines used in Saudi Arabia

(Pfizer-BioNTech and Oxford-AstraZeneca) using telemedicine technology. A cross-sectional study was conducted among 958 individuals, 7Â days after receiving either Pfizer-BioNTech or Oxford-AstraZeneca vaccines during June 2021. Immediate adverse events were reported by 1.04% and 2.09% for Pfizer-BioNTech and Oxford-AstraZeneca vaccines, respectively, with no serious events. Recipients of Pfizer-BioNTech vaccine had a higher percentage of local adverse events (24.8% versus 9.8% in AstraZeneca vaccine). The most common reported systemic adverse events in both vaccines respectively were general fatigue (23.1% and 25.1%), fever (18.5% and 27.2%), myalgia (20.6% and 20.3%), and headache (15.2% and 17.2%). No significant difference was recorded between both vaccines regarding overall systemic adverse events; however, they were more frequent following the first dose of AstraZeneca vaccine compared to Pfizer-BioNTech vaccine, while the reverse was observed for the second dose. Adverse events were more frequent in females and younger age groups for both vaccines. Most of systemic and local adverse events were mild in nature. Further cohort studies are recommended to investigate the long-term adverse events of COVID-19 vaccines.

Sequential use of Ad26-based vaccine regimens in NHP to induce immunity against different disease targets. The adenovirus (Ad)26 serotype-based vector vaccine Ad26.COV2.S has been used in millions of subjects for the prevention of COVID-19, but potentially elicits persistent anti-vector immunity. We investigated if vaccine-elicited immunity to Ad26 vector-based vaccines significantly influences antigen-specific immune responses induced by a subsequent vaccination with Ad26 vector-based vaccine regimens against different disease targets in non-human primates. A homologous Ad26 vector-based vaccination regimen or heterologous regimens (Ad26/Ad35 or Ad26/Modified Vaccinia Ankara [MVA]) induced target pathogen-specific immunity in animals, but also persistent neutralizing antibodies and T-cell responses against the vectors. However, subsequent vaccination (interval, 26-57 weeks) with homologous and heterologous Ad26 vector-based vaccine regimens encoding different target pathogen immunogens did not reveal consistent differences in humoral or cellular immune responses against the target pathogen, as compared to responses in naÃ¯ve animals. These results support the sequential use of Ad26 vector-based vaccine regimens targeting different diseases.

Clinical and immune response characteristics among vaccinated persons infected with SARS-CoV-2 delta variant: a retrospective study. OBJECTIVES: This study aimed to observe the clinical and immune response characteristics of vaccinated persons infected with the delta variant of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in Yangzhou, China. METHODS: We extracted the medical data of 129 patients with delta-variant infection who were admitted to Northern Jiangsu People's Hospital (Yangzhou, China) between August and September, 2021. The patients were grouped according to the number of vaccine doses received into an unvaccinated group: a one-dose group and a two-dose group. The vaccine used was SARS-CoV-2-inactivated vaccine developed by Sinovac. We retrospectively analyzed the patients' epidemiological, clinical, laboratory, and imaging data. RESULTS: Almost all patients with delta-variant infection in Yangzhou were elderly, and patients with severe/critical illness were over 70 years of age. The rates of severe/critical illness (P=0.006), fever (P=0.025), and dyspnea (P=0.045) were lower in the two-dose group than in the unvaccinated group. Compared to the unvaccinated group, the two-dose group showed significantly higher lymphocyte counts and significantly lower levels of C-reactive protein (CRP), interleukin-6 (IL-6), and D-dimer during hospitalization and a significantly higher positive rate of immunoglobulin G (IgG) antibodies at admission (all P<0.05). The cumulative probabilities of hospital discharge and negative virus conversion were also higher in the two-dose group than in the unvaccinated group (P<0.05). CONCLUSIONS: Two doses of the SARS-CoV-2-inactivated vaccine were highly effective at limiting symptomatic disease and reducing immune response, while a single dose did not seem to be effective.

COVID-19 Vaccination as a Trigger of IgA Vasculitis: A Global Pharmacovigilance Study. OBJECTIVE: IgA vasculitis (IgAV) can occur after vaccination. We aimed to assess a potential safety signal on the association between coronavirus disease 2019 (COVID-19) vaccines and IgAV. METHODS: Cases of IgAV involving COVID-19 vaccines were retrieved in VigiBase. Disproportionate reporting was assessed using the Bayesian information component (IC) with all other drugs and vaccines as control groups. RESULTS: Three hundred thirty patients with de novo IgAV from 24 countries were included, mostly from the United States (193/330, 58%). Fifty percent (163/328) were female and median age was 32 years (IQR 15-59), of which 33% (84/254) were young (1-17 yrs). Median time to onset of IgAV was 7 days (IQR 2-16; n = 256) and 85% (280/330) of patients were vaccinated with mRNA vaccines. Seriousness was reported in 188/324 (58%) cases. Sixty-five percent (95/147) recovered and 1% (2/147) died. A positive rechallenge was reported for 3 of 4 patients (75%). A total of 996 cases of IgAV were identified with other vaccines. There was a small significant increase in IgAV reporting with COVID-19 vaccines compared with all other drugs (IC 0.22, 95% credible interval [CrI] 0.04 to 0.35). No disproportionality signal was found between COVID-19 vaccines and other vaccines (IC -1.42, 95% CrI -1.60 to -1.28). There was no significant difference between mRNA vaccines and viral vector COVID-19 vaccines. Men and children had a significant overreporting of IgAV compared with women and adults, respectively. CONCLUSION: This study provides reassuring results regarding the safety of COVID-19 vaccines in the occurrence of IgAV compared to other vaccines.

Evaluate the side effect associated with COVID-19 vaccine on adolescents in Riyadh, Saudi Arabia: A cross-section study. OBJECTIVES: To investigate the side effects of Pizer- BioNTech mRNA (BNT162b2) and Spikevax (mRNA- 1273) Coronavirus disease 2019 (COVID-19) vaccines on adolescents in Riyadh, Saudi Arabia. METHODS: A cross-sectional study using an online questionnaire was carried out among COVID-19 vaccine adolescent recipients in Riyadh, Saudi Arabia. After receiving at least one dose of each vaccine, general and demographic data were collected, and vaccine-related side effects were evaluated. RESULTS: The final sample consisted of 604 participants with a majority age group of 16-17 years old. Approximately 89.1% of the study participants were female. Most participants reported pain at the injection site (85.1% 1st dose, 79.8% 2nd dose), feeling tired, and headache (58.6% 1st dose, 64.2% 2nd dose). Moreover, we found that patients who took the first dose and had a chronic disease had 2.4 times higher odds of having menstrual disorder (females) than non-chronic disease patients (p=0.03) and 4.5 times higher odds of exhibiting breathing congestion (p=0.01). In addition, patients with chronic disease had 2.4 times higher odds of exhibiting muscle and joint pain and dizziness than non-chronic disease patients (p=0.01, p=0.02). Males were less likely to have dizziness after the first dose than females (OR=0.26, p=0.01). CONCLUSION: This study investigates the adverse effects of COVID-19 vaccines among adolescents in Riyadh. As a result, this study creates a database to inform people about the risk of experiencing side effects based on their gender, age, and the vaccine type; more investigation is needed to better understand the link between risk factors and the development of adverse effects.

Acute myocarditis after COVID-19 vaccination. Heart muscle inflammations were reported following SARS-CoV-2 messenger ribonucleic acid (RNA) vaccination by the Disease Control Centers in America, and cases of these inflammations reported as adverse effects of this COVID-19 vaccine application increased 1000 times since April 2021. A male individual, 18-year-old received vaccination with mRNA-1273 vaccine, and after a while attended the Emergency Department at King Abdulaziz University Hospital, Jeddah, Saudi Arabia. Upon presentation, the patient complained of a history of chest pain, and he had a high troponin level along with new-onset electrocardiogram changes. During his stay in hospital the patient's blood circulation status remained stable, and no evidence of another infectious or immune cases was found. Although these vaccines are a must and very advantageous in

fighting COVID-19 and their benefits are far beyond their risks, although it seems that there is a risk of myopericarditis cases. Under such conditions it is essential to rely on early diagnosis for control and deal with the possible cases of morbidity and mortality associated with these conditions.

COVID-19 and Bangladeshi health professionals: Infection status, vaccination and its immediate health consequences. Healthcare professionals play a pivotal role in protecting and saving the lives of general people. As health workers are more likely to be infected with COVID-19, it is inevitable to safeguard them through vaccination in advance to continue healthcare services. Hence the study aimed to explore the infection and vaccination status along with immediate health consequences among these frontiers. This was a cross-sectional, web-delivered study conducted among the 300 healthcare frontiers working at COVID-19 dedicated hospitals in eight divisions of Bangladesh. The study questionnaire encompasses infection, vaccination status with dose information, and demographical and organizational information among the respondents. A multivariate logistic regression model and Chi-square test was used for the analytical exploration. Adjusted and Unadjusted Odds Ratio with a 95% confidence interval was calculated for the specified setting indicators. The study revealed that 49% of all respondents tested positive whereas 98% of them were found vaccinated of which mostly (52.3%) had their 2nddoses and 68.7% faced immediate health consequences for having the vaccination. As predictor for COVID-19 infection status, young and senior adult group (30-39 years: AOR = 2.01/0.03; 95% CI: 1.08-3.76; >50 years: AOR = 4.36/0.01; 95% CI: 1.65-11.55) and respondents who received Sinopharm as their vaccine found to have more significant positive infection history. The predictors regarding experiencing immediate health effects after vaccination, surprisingly female (AOR = 3.31/0.01; 95% CI: 1.82-6.04) health professionals of the capital city (AOR = 1.91/0.03; 95% CI: 1.06-3.46) were observed to have health consequences on vaccination. As the older female group (>50 years) in the nursing profession was found more infected with COVID-19 and a significant number of health professionals especially the age group (30-39 years) in the nursing profession experienced immediate health effects of COVID-19 vaccination, implementation of specific strategies and policies are needed to ensure the safety precaution and effective vaccination among the health professionals of Bangladesh.

Graves' orbitopathy post-SARS-CoV-2 vaccines: report on six patients. CONTEXT: Autoimmune and inflammatory thyroid diseases (Graves' disease, subacute thyroiditis, chronic autoimmune thyroiditis) have been reported following SARS-CoV-2 vaccines but Graves' orbitopathy (GO) post-COVID-19 vaccination is uncommon. METHODS: We describe six new patients seen in Endocrinology Departments with Outpatient Clinics for GO following SARS-CoV-2 vaccines in France. RESULTS: After COVID-19 vaccination, GO was observed in six patients (three men, three women, mean age 53â€‰Â±â€‰6Â years) with a personal past history of Graves' disease (5/6) or orbitopathy (4/6). New-onset (nâ€‰=â€‰2) or recurrence (nâ€‰=â€‰4) of GO was observed following mRNA vaccines after the first (3/6) or second (3/6) dose, with the mean time from vaccination to GO at 23.8â€‰Â±â€‰10.4Â days. In one patient, thyrotoxicosis was confirmed by increased free T4 and low TSH concentrations while others had normal TSH levels, during chronic levothyroxine treatment in three patients. Four patients had significant anti-TSH receptor antibodies levels. According to the severity and activity of GO, the patients were treated using selenium (nâ€‰=â€‰2), intravenous glucocorticoids (nâ€‰=â€‰2), teprotumumab (nâ€‰=â€‰1), tocilizumab (nâ€‰=â€‰2) and orbital decompression (nâ€‰=â€‰1) with a significant improvement in GO signs and symptoms observed by most patients. CONCLUSION: In this study, we report the main data from six new patients with GO following SARS-CoV-2 vaccines. Clinicians need to be aware of the risk of new-onset or recurrent GO in predisposed patients with autoimmune thyroid diseases after COVID-19 vaccination. This study should not raise any concerns regarding SARS-CoV-2 vaccination since the risk of COVID-19 undoubtedly outweighs the incidence of uncommon GO after SARS-CoV-2 vaccination.

Association between influenza vaccination and SARS-CoV-2 infection and its outcomes: systematic review and meta-analysis. BACKGROUND: World Health Organization recommends that influenza vaccines should benefit as much of the population as possible, especially where resources are limited. Corona virus disease 2019 (COVID-19) has become one of the greatest threats to health systems worldwide. The present study aimed to extend the evidence of the association between influenza vaccination and COVID-19 to promote the former. METHODS: In this systematic review, four electronic databases, including the Cochrane Library, PubMed, Embase, and Web of Science, were searched for related studies published up to May 2022. All odds ratios (ORs) with 95% confidence intervals (CIs) were pooled by meta-analysis. RESULTS: A total of 36 studies, encompassing 55,996,841 subjects, were included in this study. The meta-analysis for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection provided an OR of 0.80 (95% CI: 0.73-0.87). The statistically significant estimates for clinical outcomes were 0.83 (95% CI: 0.72-0.96) for intensive care unit admission, 0.69 (95% CI: 0.57-0.84) for ventilator support, and 0.69 (95% CI: 0.52-0.93) for fatal infection, while no effect seen in hospitalization with an OR of 0.87 (95% CI: 0.68-1.10). CONCLUSION: Influenza vaccination helps limit SARS-CoV-2 infection and severe outcomes, but further studies are needed. REGISTRATION: PROSPERO, CRD42022333747.

Seroprevalence of IgM and IgG Against SARS-CoV-2 after Two Doses of Pfizer-BioNTech COVID-19 Vaccine in Women with Breast Cancer. BACKGROUND: This study evaluates the seroprevalence of immunoglobulin M (IgM) and G (IgG) antibodies against SARS-CoV-2 after two doses of Pfizer-BioNTech COVID-19 vaccination from women with breast cancer in Jazan city Kingdom of Saudi Arabia, antibody detections were performed one month and three months after the administration of the second dose. METHODS: Overall, 103 breast cancer patients were included. Individuals who had had two doses of Pfizer-BioNTech vaccine, patients who were earlier diagnosed with COVID-19 infection, had not finalized immunization plan, or who received the second dose recently were excluded from the study. The antibodies detection test was run according to the manufacturer's directions of Viva Diagâ„¢ SARS-CoV-2 IgM/IgG Rapid Test (COVID-19 IgM/IgG Rapid Test). RESULTS: This study included 62 (60.2%) and 41 (39.8%) patients with invasive ductal carcinoma and invasive lobular carcinoma, respectively. The age, median and interquartile range (IQR) was 54.0 (26) years. Regarding reactivity of antibodies, after one month IgM antibody showed 64 (62.1%) positive and 39 (37.9%) negative while IgG antibody showed positive results in all patients. After three months IgM antibody showed 44 (42.7%) positive and 59 (57.3%) negative, while IgG showed 87 (84.5%) positive and 16 (15.5%) negative. There were significant differences in the IgM and IgG seropositivity. There were 19.3% patients with ductal carcinoma who were positive and then turned negative versus 17.7% who were positive and then turned negative, respectively ($p < 0.001$). There were significant differences in IgM antibody positivity among different age groups. CONCLUSIONS: Our results recommend the importance of screening for an antibody response for breast cancer patient after immunization in order to reveal persons who need early and late extra enhancing vaccine dose. Upcoming studies recommended to estimate different methods that raise cancer patients' immune response.

COVID-19 vaccine-induced Sweet syndrome presenting as fingertip pustules.

High incidence of multisystem inflammatory syndrome and other autoimmune diseases after SARS-CoV-2 infection compared to COVID-19 vaccination in children and adolescents in south central Europe. OBJECTIVES: To estimate the incidence and describe the spectrum of inflammatory and autoimmune diseases linked to SARS-CoV-2 infection and COVID-19 vaccination in children from two neighbouring south central European countries. METHODS: We performed a multi-centre prospective cohort study of children under 18 years diagnosed with inflammatory/autoimmune diseases linked to SARS-CoV-2 infection or COVID-19 vaccination, who were admitted to the paediatric tertiary care

hospitals in Slovenia and Friuli Venezia Giulia, Italy, from January 1, 2020, to December 31, 2021. Disease incidence was calculated based on laboratory-confirmed cases only. RESULTS: Inflammatory and autoimmune diseases linked to SARS-CoV-2 were diagnosed in 192 children (127 laboratory-confirmed), of whom 112 had multisystem inflammatory syndrome (MIS-C), followed by vasculitis, neurological and cardiac diseases. Calculated risk of MIS-C was 1 in 860 children after SARS-CoV-2 infection and cumulative incidence of MIS-C was 18.3/100,000 of all children. Fifteen children had severe COVID-19. Two patients with MIS-C and a patient with myositis presented after COVID-19 vaccination. All 3 had at presentation also a serologically proven recent SARS-CoV-2 infection. After MIS-C, nine patients were vaccinated against COVID-19 and 25 patients had a SARS-CoV-2 reinfection, without recurrence of MIS-C. CONCLUSIONS: Autoimmune diseases following SARS-CoV-2 infection in children were 8.5 times as common as severe COVID-19. MIS-C was the most common manifestation and its incidence in this predominantly white population was higher than previously reported. MIS-C does not seem to recur after SARS-CoV-2 reinfection or COVID-19 vaccination. Autoimmune diseases were much more common after SARS-CoV-2 infection than after COVID-19 vaccination.

Erythema annulare centrifugum triggered by COVID-19 vaccination with complete response to prolonged azithromycin treatment.

Quantifying Antibody Persistence After a Single Dose of COVID-19 Vaccine Ad26.COV2.S in Humans Using a Mechanistic Modeling and Simulation Approach. Understanding persistence of humoral immune responses elicited by vaccination against coronavirus disease 2019 (COVID-19) is critical for informing the duration of protection and appropriate booster timing. We developed a mechanistic model to characterize the time course of humoral immune responses in severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2)-seronegative adults after primary vaccination with the Janssen COVID-19 vaccine, Ad26.COV2.S. The persistence of antibody responses was quantified through mechanistic modeling-based simulations. Two biomarkers of humoral immune responses were examined: SARS-CoV-2 neutralizing antibodies determined by wild-type virus neutralization assay (wtVNA) and spike protein-binding antibodies determined by indirect spike protein enzyme-linked immunosorbent assay (S-ELISA). The persistence of antibody responses was defined as the period of time during which wtVNA and S-ELISA titers remained above the lower limit of quantification. A total of 442 wtVNA and 1,185â€‰S-ELISA titers from 82 and 220 participants, respectively, were analyzed following administration of a single dose of Ad26.COV2.S (5â€‰Ã—â€‰10(10) viral particles). The mechanistic model adequately described the time course of observed wtVNA and S-ELISA serum titers and its associated variability up to 8â€‰months following vaccination. Mechanistic model-based simulations show that single-dose Ad26.COV2.S elicits durable but waning antibody responses up to 24â€‰months following immunization. Of the estimated model parameters, the production rate of memory B cells was decreased in older adults relative to younger adults, and the antibody production rate mediated by long-lived plasma cells was increased in women relative to men. A steeper waning of antibody responses was predicted in men and in older adults.

Type 1 lepra reaction induced by a COVID-19 vaccine.

Associations between COVID-19 and hospitalisation with respiratory and non-respiratory conditions: a record linkage study. OBJECTIVES: To assess associations between SARS-CoV-2 infection and the incidence of hospitalisation with selected respiratory and non-respiratory conditions in a largely SARS-CoV-2 vaccine-naÃ¯ve population . DESIGN, SETTING, PARTICIPANTS: Self-control case series; analysis of population-wide surveillance and administrative data for all laboratory-confirmed COVID-19 cases notified to the Victorian Department of Health (onset, 23 January 2020 - 31 May 2021; ie, prior to widespread vaccination rollout) and linked hospital admissions data (admission dates to 30 September 2021). MAIN OUTCOME MEASURES: Hospitalisation of people with acute COVID-19; incidence rate ratios (IRRs) comparing incidence of hospitalisations with defined conditions (including

cardiac, cerebrovascular, venous thrombo-embolic, coagulative, and renal disorders) from three days before to within 89â€‰days of onset of COVID-19 with incidence during baseline period (60-365â€‰days prior to COVID-19 onset). RESULTS: A total of 20â€‰594 COVID-19 cases were notified; 2992 people (14.5%) were hospitalised with COVID-19. The incidence of hospitalisation within 89â€‰days of onset of COVID-19 was higher than during the baseline period for several conditions, including myocarditis and pericarditis (IRR, 14.8; 95% CI, 3.2-68.3), thrombocytopenia (IRR, 7.4; 95% CI, 4.4-12.5), pulmonary embolism (IRR, 6.4; 95% CI, 3.6-11.4), acute myocardial infarction (IRR, 3.9; 95% CI, 2.6-5.8), and cerebral infarction (IRR, 2.3; 95% CI, 1.4-3.9). CONCLUSION: SARS-CoV-2 infection is associated with higher incidence of hospitalisation with several respiratory and non-respiratory conditions. Our findings reinforce the value of COVID-19 mitigation measures such as vaccination, and awareness of these associations should assist the clinical management of people with histories of SARS-CoV-2 infection.

Autoimmune encephalitis after BBIBP-CorV (Sinopharm) COVID-19 vaccination: a case report. BACKGROUND: Vaccination is an important public health strategy; however, many neurological adverse effects are associated with COVID-19 vaccination, being encephalitis a rare manifestation. CASE PRESENTATION: We present the case of a 33-year-old woman who received the first dose of the BBIBP-CorV vaccine against COVID-19 on April 4 and the second dose on April 28, 2021. Three days after receiving the second dose, she experienced a subacute episode of headache, fever, insomnia, and transient episodes of environment disconnection. We obtained negative results for infectious, systemic, and oncological causes. Brain magnetic resonance imaging showed lesions in the bilateral caudate nucleus and nonspecific demyelinating lesions at the supratentorial and infratentorial compartments. The results of the neuronal autoantibodies panel were negative. She had an adequate response to immunoglobulin and methylprednisolone; however, she experienced an early clinical relapse and received a new cycle of immunosuppressive treatment followed by a satisfactory clinical evolution. CONCLUSIONS: We report the first case of severe encephalitis associated with BBIBP-CorV (Sinopharm) vaccination in Latin America. The patient had atypical imaging patterns, with early clinical relapse and a favorable response to corticosteroid therapy.

Changes in spike protein antibody titer over 90 days after the second dose of SARS-CoV-2 vaccine in Japanese dialysis patients. OBJECTIVES: There is no report on antibody titers after vaccination against SARS-CoV-2 in Japanese dialysis patients. As dialysis is different between Japan and other countries, changes in antibody titers were examined. METHODS: Baseline characteristics and anti-spike protein antibody titers (Roche) over 90Â days after administration of the BNT162b2 messenger RNA vaccine were investigated in dialysis patients. RESULTS: The maximum anti-spike protein antibody titer after the second dose was 738 (327 to 1143) U/mL and was reached at 19 (17 to 24) days after the second dose. Antibody titers decreased over time, with titers of 770 (316 to 1089) U/mL at 15Â days, 385 (203 to 690) U/mL at 30Â days, 254 (138 to 423) U/mL at 60Â days, and 208 (107 to 375) U/mL at 90Â days after the second dose. When an antibody titer of 137 U/mL was assumed to be a measure related to breakthrough infection, the proportion of subjects with antibody titers exceeding this level was 90.1% at 15Â days, 85.3% at 30Â days, 75.0% at 60Â days, and 65.4% at 90Â days after the second dose. When a decrease in antibody titers below the assumed breakthrough level was defined as an event, subjects with a pre-dialysis albuminâ€‰â‰¥â€‰3.5Â g/dL were significantly less likely to experience an event than subjects with a pre-dialysis albuminâ€‰<â€‰3.5Â g/dL. CONCLUSIONS: The presence of anti-spike protein levelsâ€‰â‰¥â€‰313 U/mL at 30Â days after the second vaccine dose might be a factor in maintaining enough antibody titers at 90Â days after. Whether an additional vaccine dose is needed should be determined based on indicators serving as factors in maintaining antibody titers as well as the status of the spread of infection.

Quantifying the Vaccine-Induced Humoral Immune Response to Spike-Receptor Binding Domain as a Surrogate for Neutralization Testing Following mRNA-1273 (Spikevax) Vaccination Against COVID-19. INTRODUCTION: There is a need for automated, high-throughput assays to quantify immune response after SARS-CoV-2 vaccination. This study assessed the combined utility of the Elecsys(Â®) Anti-SARS-CoV-2Â S (ACOV2S) and the Elecsys Anti-SARS-CoV-2 (ACOV2N) assays using samples from the mRNA-1273 (Spikevaxâ„¢) phaseÂ 2 trial (NCT04405076). METHODS: Samples from 593 healthy participants in two age cohorts (18-54 and â‰¥â€‰55Â years), who received two injections with placebo (nâ€‰=â€‰198) or mRNA-1273 (50Â Î¼g [nâ€‰=â€‰197] or 100Â Î¼g [nâ€‰=â€‰198]), were collected at daysÂ 1 (first vaccination), 15, 29 (second vaccination), 43, and 57. ACOV2S results were used to assess humoral response to vaccination in different subgroups and were compared to live virus microneutralization assay. Samples from patients with either previous or concomitant infection (identified per ACOV2N) were analyzed separately. RESULTS: Receptor-binding domain-specific antibodies were readily detectable by ACOV2S for the vast majority of participants (174/189, 92.1% [50Â Î¼g dose] and 178/192, 92.7% [100Â Î¼g dose]) at the first post-vaccination assessment, with non-converters predominantly older in age. Seroconversion for all participants was observed at dayÂ 29 (before the second vaccine dose). Two weeks after the first dose, geometric mean concentration (GMC) of antibody levels was 1.37-fold higher in the 100 versus 50Â Î¼g group (pâ€‰=â€‰0.0098), reducing to 1.09-fold 2Â weeks after the second dose (pâ€‰=â€‰0.0539, n.s.). In both dose groups, a more pronounced response was observed in the younger versus older age group on dayÂ 15 (50Â Î¼g, 2.49-fold [pâ€‰<â€‰0.0001]; 100Â Î¼g, 3.94-fold [pâ€‰<â€‰0.0001] higher GMC, respectively), and dayÂ 29 (1.93-fold, pâ€‰=â€‰0.0002, and 2.44-fold, pâ€‰<â€‰0.0001). Eight subjects had previous or concomitant SARS-CoV-2 infection; vaccination boosted their humoral response to very high ACOV2S results compared to infection-naÃ¯ve recipients. ACOV2S strongly correlated with microneutralization (Pearson's râ€‰=â€‰0.779; pâ€‰<â€‰0.0001), including good qualitative agreement. CONCLUSION: These results confirmed that ACOV2S is a highly valuable assay for tracking vaccine-related immune responses. Combined application with ACOV2N enables monitoring for breakthrough infection or stratification of previous natively infected individuals. The adaptive measuring range and high resolution of ACOV2S allow for early identification of seroconversion and resolution of very high titers and longitudinal differences between subgroups. Additionally, good correlation with live virus microneutralization suggests that ACOV2S is a reliable estimate of neutralization capacity in routine diagnostic settings.

Safety and immunogenicity of a prefusion non-stabilized spike protein mRNA COVID-19 vaccine: a phase I trial. Effective mRNA SARS-CoV-2 vaccines are available but need to be stored in freezers, limiting their use to countries that have appropriate storage capacity. ChulaCov19 is a prefusion non-stabilized SARS-CoV-2 spike-protein-encoding, nucleoside-modified mRNA, lipid nanoparticle encapsulated vaccine that we report to be stable when stored at 2-8â€‰Â°C for up to 3â€‰months. Here we report safety and immunogenicity data from a phase I open-label, dose escalation, first-in-human trial of the ChulaCov19 vaccine (NCT04566276). Seventy-two eligible volunteers, 36 of whom were aged 18-55 (adults) and 36 aged 56-75 (elderly), were enroled. Two doses of vaccine were administered 21â€‰d apart at 10, 25 or 50â€‰Î¼g per dose (12 per group). The primary outcome was safety and the secondary outcome was immunogenicity. All three dosages of ChulaCov19 were well tolerated and elicited robust dose-dependent and age-dependent B- and T-cell responses. Transient mild/moderate injection site pain, fever, chills, fatigue and headache were more common after the second dose. Four weeks after the second dose, in the adult cohort, MicroVNT-50 geometric mean titre against wild-type SARS-CoV-2 was 848 (95% CI, 483-1,489), 736 (459-1,183) and 1,140 (854-1,522) IUâ€‰ml(-1) at 10, 25 and 50â€‰Î¼g doses, respectively, versus 285 (196-413) IUâ€‰ml(-1) for human convalescent sera. All dose levels elicited 100% seroconversion, with

geometric mean titre ratios 4-8-fold higher than for human convalescent sera (Pâ€‰<â€‰0.01), and high IFNÎ³ spot-forming cells per million peripheral blood mononuclear cells. The 50â€‰Î¼g dose induced better cross-neutralization against Alpha, Beta, Gamma and Delta variants than lower doses. ChulaCov19 at 50â€‰Î¼g is well tolerated and elicited higher neutralizing antibodies than human convalescent sera, with strong T-cell responses. These antibodies cross-neutralized four variants of concern. ChulaCov19 has proceeded to phase 2 clinical trials. We conclude that the mRNA vaccine expressing a prefusion non-stabilized spike protein is safe and highly immunogenic.

Short-term safety of COVID-19 mRNA vaccines with respect to all-cause mortality in the older population in Norway. BACKGROUND: There have been concerns about COVID-19 vaccination safety among frail older individuals. We investigated the relationship between COVID-19 mRNA vaccination and mortality among individuals agedÂ â‰¥Â 70Â years and whether mortality varies across four groups of health services used. METHODS: In this nationwide cohort study, we included 688,152 individuals agedÂ â‰¥Â 70Â years at the start of the Norwegian vaccination campaign (December 27, 2020). We collected individual-level data from theNorwegian Emergency Preparedness Register for COVID-19. Vaccinated and unvaccinated individuals were matched (1:1 ratio) on the date of vaccination based on sociodemographic and clinical characteristics. The main outcome was all-cause mortality during 21Â days after first dose of COVID-19 mRNA vaccination. Kaplan-Meier survival functions were estimated for the vaccinated and unvaccinated groups. We used Cox proportional-hazards regression to estimate hazard ratios (HRs) of death between vaccinated and unvaccinated individuals, with associated 95% confidence intervals (CIs), overall and by use of health services (none, home-based, short- and long-term nursing homes) and age group. RESULTS: Between December 27, 2020, and March 31, 2021, 420,771 older individuals (61.1%) were vaccinated against COVID-19. The Kaplan-Meier estimates based on the matched study sample showed a small absolute risk difference in all-cause mortality between vaccinated and unvaccinated individuals, with a lower mortality in the vaccinated group (overall HR 0.28 [95% CI: 0.24-0.31]). Similar results were obtained in analyses stratified by use of health services and age group. CONCLUSION: We found no evidence of increased short-term mortality among vaccinated individuals in the older population after matching on sociodemographic and clinical characteristics affecting vaccination and mortality.

Post-acute symptoms 3-15 months after COVID-19 among unvaccinated and vaccinated individuals with a breakthrough infection. OBJECTIVE: We aimed to describe post-acute sequelae of SARS-CoV-2 infection (PASC) related symptoms 3-15 months after a positive test in SARS-CoV-2 unvaccinated and vaccinated participants with a breakthrough infection. METHODS: Participants of the Norwegian COVID-19 cohort, without a positive SARS-CoV-2 test, completed a questionnaire about PASC-related symptoms between November 2020 and January 2021. About a year later, a second questionnaire (which also included the Everyday Memory Questionnaire [EMQ]-13) was completed by the same participants, most still without a positive SARS-CoV-2 test, but also by unvaccinated and vaccinated participants with a positive test 3-15 months before the questionnaire. Laboratory-confirmed SARS-CoV-2 status (positive or negative swab test determined by reverse transcriptase quantitative polymerase chain reaction) at the time of completing the questionnaire was ascertained from the Mandatory Norwegian Surveillance System for Communicable Diseases. RESULTS: No differences were found in the self-reported PASC symptoms, dyspnea, fatigue, smell/taste changes, concentration problems, or the EMQ-13 score between unvaccinated and vaccinated participants 3-15 months after the positive test. Fewer memory problems were reported among vaccinated than unvaccinated participants. CONCLUSION: SARS-CoV-2 vaccines offer minor protection against PASC symptoms, although fewer memory problems were reported among the vaccinated than the unvaccinated participants.

Patient-Reported Outcomes of COVID-19 Vaccine Breakthrough Infection-Associated Changes in Glucose Control in Subjects With Type 1 Diabetes (PRO-VACS 2 Study).

Association of COVID-19 Vaccination With Influenza Vaccine History and Changes in Influenza Vaccination. This survey study assesses how COVID-19 vaccination differs across historical influenza vaccination patterns and whether influenza vaccination changed during the COVID-19 pandemic.

Safety of mRNA COVID-19 Vaccines in Patients with Inborn Errors of Immunity: an Italian Multicentric Study. PURPOSE: Little is known about vaccine safety in inborn errors of immunity (IEI) patients during the current vaccination campaign for COVID-19. To better investigate the reactogenicity and adverse event profile after two, three, and four doses of mRNA vaccines, we conducted an observational, multicentric study on 342 PID patients from four Italian Referral Centres. METHODS: We conducted a survey on self-reported adverse reactions in IEI patients who received mRNA vaccine by administering a questionnaire after each dose. RESULTS: Over the whole study period, none of the patients needed hospitalization or had hypersensitivity reactions, including anaphylaxis and delayed injection site reaction. After two vaccination doses, 35.4% of patients showed only local reactogenicity-related symptoms (RrS), 44.4% reported both systemic and local RrS, and 5% reported only systemic RrS. In more than 60% of cases, local or systemic RrS were mild. After the first and second booster doses, patients showed fewer adverse events (AEs) than after the first vaccination course. Patients aged 50Â years and older reported adverse events and RrS less frequently. Among AEs requiring treatment, one common variable immune deficiency patient affected by T cell large granular lymphocytic leukemia developed neutropenia and one patient had Bell's paralysis perhaps during herpes zoster reactivation. CONCLUSION: Although our follow-up period is relatively short, the safety data we reported are reassuring. This data would help to contrast the vaccine hesitancy often manifested by patients with IEI and to better inform their healthcare providers.

Occupations Associated With Severe Acute Respiratory Syndrome Coronavirus 2 Infection and Vaccination, US Blood Donors, May 2021-December 2021. BACKGROUND: There are limited data on the risk of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in the United States by occupation. We identified occupations at higher risk for prior SARS-CoV-2 infection as defined by the presence of infection-induced antibodies among US blood donors. METHODS: Using a nested case-control study design, blood donors during May-December 2021 with anti-nucleocapsid (anti-N) testing were sent an electronic survey on employment status, vaccination, and occupation. The association between previous SARS-CoV-2 infection and occupation-specific in-person work was estimated using multivariable logistic regression adjusting for sex, age, month of donation, race and ethnicity, education, vaccination, and telework. RESULTS: Among 85 986 included survey respondents, 9504 (11.1%) were anti-N reactive. Healthcare support (20.3%), protective service (19.9%), and food preparation and serving related occupations (19.7%) had the highest proportion of prior infection. After adjustment, prior SARS-CoV-2 infection was associated with healthcare practitioners (adjusted odds ratio [aOR], 2.10; 95% confidence interval [CI], 1.74-2.54) and healthcare support (aOR, 1.82; 95% CI, 1.39-2.40) occupations compared with computer and mathematical occupations as the referent group. Lack of coronavirus disease 2019 vaccination (aOR, 16.13; 95% CI, 15.01-17.34) and never teleworking (aOR, 1.17; 95% CI, 1.05-1.30) were also independently associated with prior SARS-CoV-2 infection. Construction and extraction occupations had the highest proportion of unvaccinated workers (30.5%). CONCLUSIONS: Workers in healthcare, protective services, and food preparation had the highest prevalence of prior SARS-CoV-2 infection. Occupational risks for SARS-CoV-2 infection remained after adjusting for vaccination, telework, and demographic factors. These findings underscore the need for mitigation measures and personal protection in healthcare settings and other workplaces.

Perception and safety analysis of COVID-19 vaccination in cancer patients: A multicenter, real-world study. BACKGROUND: Although various coronavirus disease 2019 (COVID-19) vaccines have been delivered to the public worldwide, data on cancer populations are limited. Vaccine hesitancy related to safety concerns is observed among cancer patients. We report the perception of COVID-19 vaccines and their safety profile after vaccination among cancer patients. MATERIALS AND METHODS: Between April and November 2021, a multicenter survey was conducted on 318 patients treated in any hemato-oncology outpatient clinic among three hospitals under the Korea University Medical Center. The medical records of the patients were reviewed to obtain detailed clinical and hematological toxicity data. RESULTS: A perception survey was conducted among 293 patients. Among them, 53.9% were concerned about developing vaccine-related adverse events (VRAEs) and 23.5%, about negative effects on cancer treatment. During the study period, 255 and 186 patients participated in a safety survey after the first and second doses, respectively. After the first dose, 62% of patients reported VRAEs (2.4%, grade 3), whereas 48.9% reported VRAEs (2.7%, grade 3) after the second dose. For both doses, injection-site pain and sore arm pain were the most common VRAEs, followed by myalgia, fatigue, and headache. No grade 4/5 VRAEs were observed, and there were no differences in complete blood count after vaccination. Multivariate analysis revealed female sex, active cancer treatment, and mRNA vaccines as independent risk factors for VRAE development in cancer patients. CONCLUSION: Despite high levels of concern, COVID-19 vaccines were well tolerated by cancer patients, with a safety profile consistent with that of the general population.

Enhanced virulence and waning vaccine-elicited antibodies account for breakthrough infections caused by SARS-CoV-2 delta and beyond. Here we interrogate the factors responsible for SARS-CoV-2 breakthrough infections in a K18-hACE2 transgenic mouse model. We show that Delta and the closely related Kappa variant cause viral pneumonia and severe lung lesions in K18-hACE2 mice. Human COVID-19 mRNA post-vaccination sera after the 2(nd) dose are significantly less efficient in neutralizing Delta/Kappa than early 614G virus inÂ vitro and inÂ vivo. By 5Â months post-vaccination, â‰¥50% of donors lack detectable neutralizing antibodies against Delta and Kappa and all mice receiving 5-month post-vaccination sera die after the lethal challenges. Although a 3(rd) vaccine dose can boost antibody neutralization against Delta inÂ vitro and inÂ vivo, the mean log neutralization titers against the latest Omicron subvariants are 1/3-1/2 of those against the original 614D virus. Our results suggest that enhanced virulence, greater immune evasion, and waning of vaccine-elicited protection account for SARS-CoV-2 variants caused breakthrough infections.

Varicella zoster virus reactivation following COVID-19 vaccination in patients with autoimmune inflammatory rheumatic diseases: A cross-sectional Chinese study of 318 cases. Recently, varicella-zoster virus (VZV) reactivation has been observed after the administration of coronavirus disease 2019 (COVID-19) vaccines. Autoimmune inflammatory rheumatic diseases (AIIRDs) patients are at a higher risk for VZV reactivation for immunocompromised status. The study aimed to investigate the adverse events (AEs), especially VZV reactivation, following vaccination against Â severe acute respiratory syndrome coronavirus-2Â in a Chinese cohort of AIIRD patients. A cross-sectional survey using an online questionnaire was conducted among AIIRD patients and healthy controls (HCs). Multivariate logistic regression was used to identify potential factors associated with VZV reactivation. 318 AIIRD patients and 318 age and sex-matched HCs who got COVID-19 inactivated vaccines were recruited. The main AIIRDs are rheumatoid arthritis (31.8%) and systemic lupus erythematous (23.9%). Most of patients (85.5%) had stable disease and 13.2% of them had aggravation after vaccination. Compared to HCs, patients had higher rates of rash (pâ€‰=â€‰0.001), arthralgia (pâ€‰<â€‰0.001) and insomnia (pâ€‰=â€‰0.007). In addition, there were 6 (1.9%) AIIRD patients and 5 (1.6%) HCs reported VZV reactivation after the COVID-19 vaccination (pâ€‰=â€‰0.761). Multivariate logistic regression analysis illustrated that diabetes

mellitus (odd ratio [OR], 20.69; 95% confidence interval [CI], 1.08-396.79; pâ€‰=â€‰0.044), chronic hepatitis B virus infection (OR, 24.34; 95%Â CI, 1.27-466.74; pâ€‰=â€‰0.034), and mycophenolate mofetil (OR, 40.61; 95%Â CI, 3.33-496.15; pâ€‰=â€‰0.004) independently identified patients with VZV reactivation. Our findings showed that the inactivated COVID-19 vaccination was safe for AIIRD patients though some patients could suffer from VZV reactivation.

Safety of mRNA-COVID-19 Vaccines in Patients With Thoracic Cancers. BACKGROUND: Pivotal trials of COVID-19 vaccines did not include cancer patients with questions remaining in this population. Particularly in patients with thoracic malignancies receiving anticancer treatments, the safety of these vaccines has so far been little investigated. METHODS: This is a prospective trial of patients with thoracic cancer receiving anticancer treatments and COVID-19 vaccines at the Division of Thoracic Oncology of European Institute of Oncology between February and September 2021. RESULTS: A total 207 patients affected by thoracic cancers (199 lung cancers and 8 mesotheliomas) had received Covid-19 vaccines (206 mRNA vaccines and 1 virus-vectored vaccine). The majority of patients had at least one comorbidity (76.3%). They were concomitantly treating with targeted therapy (TT) (45.9%), immunotherapy (IO) (22.7%), and chemotherapy (CT) (14%). A total of 64 AEs (15.6%) were observed after administration of Sars-Cov-2 vaccine. The majority of AEs were grade 1 [G1] (6.3%) and G2 (8.8%), only two events were G3 (0.5%). The median follow-up was 9 months (range 1-22 months), during this follow-up 21 patients (10.1%) had a positive nasal swab, most of the patients were asymptomatic (67%) and the symptomatic ones (33%) had mild symptoms and fewer complications and hospitalizations. CONCLUSIONS: COVID-19 m-RNA vaccines appear to be safe in the cohort of patients with thoracic malignances in active treatment, including those receiving immunotherapy. Considering the high morbidity and mortality associated with COVID-19 in patients with lung cancer receiving active treatments, our study supports the current vaccine prioritization, third and/or fourth dose, of all cancer patients with active treatment.

Association between COVID-19 vaccination status, time elapsed since the last vaccine dose, morbidity, and absenteeism among healthcare personnel: A prospective, multicenter study. AIM: We assessed the impact of COVID-19 vaccination status and time elapsed since the last vaccine dose on morbidity and absenteeism among healthcare personnel (HCP) in the context of a mandatory vaccination policy. METHODS: We followed 7592 HCP from November 15, 2021 through April 17, 2022. Full COVID-19 vaccination was defined as a primary vaccination series plus a booster dose at least six months later. RESULTS: There were 6496 (85.6Â %) fully vaccinated, 953 (12.5Â %) not fully vaccinated, and 143 (1.9Â %) unvaccinated HCP. A total of 2182 absenteeism episodes occurred. Of 2088 absenteeism episodes among vaccinated HCP with known vaccination status, 1971 (94.4Â %) concerned fully vaccinated and 117 (5.6Â %) not fully vaccinated. Fully vaccinated HCP had 1.6 fewer days of absence compared to those not fully vaccinated (8.1 versus 9.7; p-valueÂ <Â 0.001). Multivariable regression analyses showed that full vaccination was associated with shorter absenteeism compared to not full vaccination (OR: 0.56; 95Â % CI: 0.36-0.87; p-valueÂ =Â 0.01). Compared to a history ofÂ â‰¤Â 17.1Â weeks since the last dose, a history ofÂ >Â 17.1Â weeks since the last dose was associated with longer absenteeism (OR: 1.22, 95Â % CI:1.02-1.46; p-valueÂ =Â 0.026) and increased risk for febrile episode (OR: 1.33; 95Â % CI: 1.09-1.63; p-valueÂ =Â 0.004), influenza-like illness (OR: 1.53, 95Â % CI: 1.02-2.30; p-valueÂ =Â 0.038), and COVID-19 (OR: 1.72; 95Â % CI: 1.24-2.39; p-valueÂ =Â 0.001). CONCLUSIONS: The COVID-19 pandemic continues to impose a considerable impact on HCP. The administration of a vaccine dose in less than four months before significantly protected against COVID-19 and absenteeism duration, irrespective of COVID-19 vaccination status. Defining the optimal timing of boosters is imperative.

Association between history of SARS-CoV-2 infection and severe systemic adverse events after mRNA COVID-19 vaccination among U.S. adults. BACKGROUND: Risk of experiencing a systemic adverse

event (AE) after mRNA coronavirus disease 2019 (COVID-19) vaccination may be greater among persons with a history of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection; data on serious events are limited. We assessed if adults reporting systemic AEs resulting in emergency department visits or hospitalizations during days 0-7 after mRNA COVID-19 vaccine dose 1 were more likely to have a history of prior SARS-CoV-2 infection compared with persons who reported no or non-severe systemic AEs. METHODS: We conducted a nested case-control study using v-safe surveillance data. Participants wereÂ â‰¥Â 18Â years and received dose 1 during December 14, 2020â"€May 9, 2021. Cases reported severe systemic AEs 0-7Â days after vaccination. Three controls were frequency matched per case by age, vaccination date, and days since vaccination. Follow-up surveys collected SARS-CoV-2 histories. RESULTS: Follow-up survey response rates were 38.6Â % (potential cases) and 56.8Â % (potential controls). In multivariable analyses including 3,862 case-patients and 11,586 controls, the odds of experiencing a severe systemic AE were 2.4 (Moderna, mRNA-1273; 95Â % confidence interval [CI]: 1.89, 3.09) and 1.5 (Pfizer-BioNTech, BNT162b2; 95Â % CI: 1.17, 2.02) times higher among participants with pre-vaccination SARS-CoV-2 histories compared with those without. Medical attention of any kind for symptoms during days 0-7 following dose 2 was not common among case-patients or controls. CONCLUSIONS: History of SARS-CoV-2 infection was significantly associated with severe systemic AEs following dose 1 of mRNA COVID-19 vaccine; the effect varied by vaccine received. Most participants who experienced severe systemic AEs following dose 1 did not require medical attention of any kind for symptoms following dose 2. Vaccine providers can use these findings to counsel patients who had pre-vaccination SARS-CoV-2 infection histories, experienced severe systemic AEs following dose 1, and are considering not receiving additional mRNA COVID-19 vaccine doses.

The Trajectory of the COVID-19 Vaccine Antibody Titers Over Time and the Association of Mycophenolate Mofetil in Solid Organ Transplant Recipients. The COVID-19 vaccine will be safe and effective in solid organ transplant recipients (SOTs). However, the blunted antibody responses were also of concern. Few studies have reported prolonged serologic follow-up after 2 doses of BNT162b2 vaccine in SOTs. We performed a single-center, prospective observational study of 78 SOTs who received 2 doses of BNT162b2 vaccine. We identified the trajectory of antibody titers after vaccination among SOTs with or without mycophenolate mofetil (MMF) or withdrawn from MMF. We found low seroconversion rates (29/42: 69%) and low antibody titers in SOTs treated with MMF. An inverse linear relationship between neutralizing antibody titers and MMF concentration was confirmed in restricted cubic spline plots (P for effect < .01, P for nonlinearityâ€¯=â€¯.08). For the trajectory of antibody responses, seroconversion and improved antibody titers were observed after withdrawal from MMF in SOTs who showed seronegative or low antibody titers at the first visit after 2 doses of vaccine (P for effect < .01, P for nonlinearity < .05, and P for interaction < .01). We identified increased B-cell counts after withdrawal from MMF (P < .01). The recovery of antibody responses was seen in SOTs withdrawn from MMF. The trajectories of antibody responses were modified by MMF administration.

Auricular acupressure for adverse events following immunization after COVID-19 vaccine injection: A multicentre, blinded, randomized controlled trial. BACKGROUND: Some adverse events following immunization (AEFI) were observed in potential corelation with COVID-19 vaccination but without prevention or ongoing trial for it. We aimed to investigate efficacy of auricular acupressure (AuriAc) therapy in preventing AEFI after first dosage of the vaccine. METHODS: We performed a multicentre randomized controlled trial with three arms, including AuriAc, SAuriAc (sham auricular acupressure), and TrAsU (treatment as usual) group, carried out in four medical institutions in Chengdu, China, from March 17th to April 23rd, 2021. We enrolled participants based on eligibility criteria and randomized them into three groups: AuriAc (AEFI-specific auricular points applied, nÂ =Â 52), SAuriAc (nÂ =Â 51)

or TrAsU (nÂ =Â 44) group. Primary outcomes were percentages of any AEFI and local pain, and secondary outcomes were percentages who reported other AEFI. They were followed at 1, 3, 5, 7, and 14 days, by phone or online, with severity evaluated. RESULTS: 147 participants (73.47% females) were included with median age as 31 years (25-45, IQR). One day after the injection, participants in AuriAc group reported significant reduction on percentages of any AEFI [intention-to-treat, difference of percentage (DP) =Â -20.13, 95%CI: -Â 0.39, -Â 0.02, pÂ =Â 0.01; per-protocol, DP =Â -22.21, 95%CI: -Â 0.40, -Â 0.03, PÂ =Â 0.02] and local pain (per-protocol, DP = -18.40, 95%CI: -0.36, -0.01, PÂ =Â 0.04), compared with TrAsU group. The effects were slight at other follow-up days and for other outcomes, and with a low percentage of mild local allergic reactions. CONCLUSIONS: We firstly explored potential of AuriAc for preventing AEFI related to COVID-19 vaccine injection, which is beneficial for the vaccine recipients, but evidence is limited. TRIAL REGISTRATION: chictr.org.cn no. ChiCTR2100043210 (http://www.chictr.org.cn/showproj.aspx?proj=121519).

New-onset inflammatory arthritis after COVID-19 vaccination: A systematic review. AIM: To analyze the clinical patterns of new-onset inflammatory arthritis after COVID-19 vaccination among patients without pre-existing rheumatic or autoimmune diseases. METHOD: Case reports and series of new-onset inflammatory arthritis after COVID-19 vaccination were collected before April 2022. Clinical characteristics including diagnosis, age, gender, vaccine types, time interval between events, joint involvement (poly- or oligo-/monoarthritis), and laboratory data reflecting inflammatory status were sorted and P values between these parameters are calculated with independent sample Student's t test or 2â€‰Ã—â€‰2 Fisher's exact test. RESULTS: Among 39 cases with new-onset post-vaccination arthritis including 25 females and 13 males (1 unknown), the most common diagnosis is adult-onset Still's disease (AoSD, 10 cases), and the most common vaccine types are BNT162b2 (16 cases) and AZD-1222 (or ChAdOx1-nCoV19, 15 cases). Sub-analysis reveals that post-vaccination polyarthritis is more common among females (PÂ =Â .016, by 2â€‰Ã—â€‰2 Fisher's exact test, compared with male patients) and older patients (PÂ =Â .006, by Student's t test). The C-reactive protein level is significantly higher in cases with post-vaccination inflammatory polyarthritis than oligoarthritis (PÂ =Â .029), as well as in cases with AoSD than other causes of post-vaccination arthritis (PÂ =Â .004). However, serum level of erythrocyte sedimentation rate in patients with post-vaccination AoSD are independent of other clinical variables in the analysis. CONCLUSION: New-onset post-vaccination polyarthritis are more common in females and older patients. Although COVID-19 vaccines may lead to inflammatory arthritis, the benefits of vaccination substantially outweigh the potential risks of such serious adverse effects due to their rarity.

Evaluation of patients with antiphospholipid syndrome subsequently COVID-19 vaccinations: A retrospective cohort study. The aim of this study is to evaluate development of side effects, thrombotic or obstetric complications in our antiphospholipid syndrome (APS) patient group, after vaccination against coronavirus disease 2019 (COVID-19). A cohort was formed from patients who have previously been followed up with a diagnosis of APS. The patients of the cohort were evaluated retrospectively to find out if they were vaccinated with CoronaVac and/or BNT162b2 vaccines which are being used in our country. To evaluate the side effects seen after the vaccination, the information was collected by the patients in their outpatient appointments or making a phone call. Thirty-five APS patients who had received at least 1 dose of any of the COVID-19 vaccines were included in the study. Median (min-max) number of vaccine doses per patient was 2 (1-3). Eleven patients had a booster dose after primary vaccination. Twenty patients were ever vaccinated with BNT162b2 and 18 with CoronaVac. Among BNT162b2 recipients, 9 (45.0%) and among CoronaVac recipients 15 (42.9%) reported an adverse event after a vaccine administration. The most common adverse events were myalgia and malaise after any dose of both vaccines. No vaccine-related new thrombotic events or APS flares were observed. Our results were comparable with those reported in the literature.

Comprehensive large-scale studies are needed for more accurate results on the evaluation of side effects after COVID-19 vaccination in APS patients.

A post-marketing safety assessment of COVID-19 mRNA vaccination for serious adverse outcomes using administrative claims data linked with vaccination registry in a city of Japan. INTRODUCTION: The safety profiles of COVID-19 vaccines are incompletely evaluated in Japan. OBJECTIVES: To examine the risk of serious adverse effects after COVID-19 mRNA vaccination (BNT162b2 and mRNA-1273) in cohort studies and self-controlled case series (SCCS). METHODS: Using an administrative claims database linked with the COVID-19 vaccination registry in a city in Japan between September 2020 and September 2021, we identified health insurance enrolees agedÂ â‰¥Â 18Â years. We evaluated the risk of acute myocardial infarction, appendicitis, Bell's palsy, convulsions/seizures, disseminated intravascular coagulation, immune thrombocytopenia, pulmonary embolism, haemorrhagic or ischemic stroke, venous thromboembolism, and all-cause mortality, 21Â days following any COVID-19 mRNA vaccination, compared with non-vaccination periods. For the cohort studies, we estimated incidence rate ratios (IRRs) by Poisson regression and rate differences (IRDs) by weighted least-squares regression, adjusting for sex, age, and Charlson comorbidity index. We applied a modified SCCS design to appropriately treat outcome-dependent exposures. For the modified SCCS, we estimated within-subject IRRs by weighted conditional Poisson regression. Subgroup analyses stratified by sex and age were also conducted. RESULTS: We identified 184,491 enrolees [male: 87,218; mean (standard deviation) age: 64.2 (19.5) years] with 136,667 first and 127,322Â s dose vaccinations. The risks of any outcomes did not increase in any analyses, except for the fact that the modified SCCS indicated an increased risk of pulmonary embolism after the first dose in women (within-subject IRR [95%CI]: 3.97 [1.18-13.32]). CONCLUSION: The findings suggested that the COVID-19 mRNA vaccine was generally safe, whilst a signal of pulmonary embolism following the first dose of the COVID-19 mRNA vaccine was observed.

Increased risk of myocarditis and pericarditis and reduced likelihood of severe clinical outcomes associated with COVID-19 vaccination: a cohort study in Lombardy, Italy. INTRODUCTION: We aimed to assess harms (post-vaccine myocarditis and pericarditis) and benefits (preventing severe disease) of COVID-19 vaccination. METHODS: We conducted a population-based retrospective cohort study. Using the integrated platform of the vaccination campaign of Lombardy Region (Italy), after the exclusion of 24,188 individuals not beneficiaries of the Regional Health Service, 9,184,146 citizens candidates to vaccine at December 27, 2020 were followed until November 30, 2021 (the loss to follow-up rate was 0.5%). From the date of administration of each vaccine dose to day 28 post-administration, three periods that covered exposure to the first, second, and third dose were defined. The benefit-risk profile of vaccines was performed by comparing the number needed to harm (NNH) and number needed to treat (NNT) by sex, age, and vaccine type. RESULTS: Incidence rates of myocarditis were 9.9 and 5.2 per million person-months during the exposure and no-exposure periods, respectively, and the incidence rates of pericarditis were 19.5 and 15.9 per million person-months, respectively. The risk of myocarditis was highest following exposure to the second dose of the Moderna vaccine (adjusted HR: 5.5, 95% CI: 3.7 to 8.1). Exposure to the Moderna vaccine was also associated with an increased risk of pericarditis (adjusted HR 2.2, 1.5 to 3.1). NNT was higher than NNH (9471 vs. 7213) for 16 to 19-year-old men who received the Moderna vaccine, while all other sex, age, and vaccine subgroups had a favourable harm-benefit profile. CONCLUSIONS: Men 16 to 19Â years of age has the highest rates of myocarditis within a few days after receiving the Moderna vaccines. The balance between harms and benefits was almost always in favour of vaccination.

COVID-19 vaccine safety during the antenatal period in women with idiopathic inflammatory myopathies.

Immunogenicity and safety of COVID-19 vaccine in lung cancer patients receiving anticancer treatment: A prospective multicenter cohort study. This study assessed the immunogenicity and safety of the BNT162b2 mRNA vaccine in lung cancer patients receiving anticancer treatment. We enrolled lung cancer patients receiving anticancer treatment and non-cancer patients; all participants were fully vaccinated with the BNT162b2 vaccine. Blood samples were collected before the first and second vaccinations and 4â€‰Â±â€‰1â€‰weeks after the second vaccination. Anti-severe respiratory syndrome coronavirus-2 (SARS-CoV-2) spike protein S1 subunit receptor-binding domain antibody titers were measured using the Architect SARS-CoV-2 IgG II Quant and Elecsys Anti-SARS-CoV-2 S assays. Fifty-five lung cancer patients and 38 non-cancer patients were included in the immunogenicity analysis. Lung cancer patients showed significant increase in the geometric mean antibody concentration, which was significantly lower than that in the non-cancer patients after the first (30 vs. 121 AU/mL, pâ€‰<â€‰.001 on Architect; 4.0 vs 1.2â€‰U/mL, pâ€‰<â€‰.001 on Elecsys) and second vaccinations (1632 vs. 3472 AU/mL, pâ€‰=â€‰.005 on Architect; 213 vs 573 A/mL, pâ€‰=â€‰.002 on Elecsys). The adjusted odds ratio (aOR) for seroprotection was significantly lower (pâ€‰<â€‰.05) in lung cancer patients than that in non-cancer patients. Analysis of the anticancer treatment types showed that the aOR for seroprotection was significantly lower (pâ€‰<â€‰.05) in lung cancer patients receiving cytotoxic agents. They showed no increase in adverse reactions. BNT162b2 vaccination in lung cancer patients undergoing anticancer treatment significantly increased (pâ€‰<â€‰.05) antibody titers and showed acceptable safety. Immunogenicity in these patients could be inadequate compared with that in non-cancer patients.

Inflammatory ocular events after inactivated COVID-19 vaccination. To report potential vaccine-induced inflammatory ocular adverse events following inactivated COVID-19 vaccination. Retrospective study of patients with uveitis and other ocular complications following inactivated coronavirus disease 2019 (COVID-19) vaccination at a tertiary referral center between May 2021 and August 2021. Data collection consisted of demographic and clinical data. The study included 8 eyes of 5 patients (4 females, 1 male), with a mean age of 37.2Â Â±Â 12.5Â years (range 28-59Â years). Mean time between vaccination and ocular complications onset was 13.2Â Â±Â 11.9Â days (range 3-30Â days), including two patients after the first dose of the vaccine and 3 patients after the second dose. The cases reported were three anterior uveitis, one herpetic keratitis and iridocyclitis, and one posterior uveitis. Patients received treatment with local and/or systemic steroids and all the patients had good visual outcomes. Ocular inflammatory events may occur after vaccination with possible gender preponderance. However, they are rare and manageable. Overall, the efficacy and safety of vaccination should be emphasized.

Long-lasting T-cell response to SARS-CoV-2 antigens after vaccination-a prospective cohort study of HCWs working with COVID-19 patients. BACKGROUND: Vaccination against SARS-CoV-2 reduces the risk of hospitalisation and death, but vaccine-induced IgG antibodies against the spike protein (IgG S) decline over time. Less is known about the nature of the vaccine-induced T-cell response to SARS-CoV-2 antigens. METHODS: IgG antibodies against nucleocapsid protein (IgG N), IgG S, and T-cell response towards SARS-CoV-2 antigens were determined in samples taken between November 2020 and November 2021 from a cohort of healthcare workers at an Infectious Diseases Department. RT-PCR screening for SARS-CoV-2 was encouraged once every four weeks in addition to testing when symptomatic or identified through contact tracing. Vaccination data were collected at the end of the study. RESULTS: At inclusion, T-cell response to SARS-CoV-2 antigens was found in 10/15 (66.7%) of participants with a previous/current COVID-19 infection and in 9/54 (16.7%) of participants with no prior/current history of COVID-19 infection. All participants with complete follow-up (nâ€‰=â€‰59) received two doses of a SARS-CoV-2 vaccine during the study. All participants demonstrated detectable IgG (S) antibodies at the end of the study, in median 278â€‰days (IQR 112) after the

second vaccine dose. All but four participants displayed T-cell responses towards SARS-CoV-2 antigens. IgG S antibody levels correlated with time since the second vaccine dose. In addition, previous COVID-19 infection and the strength of the S1 T-cell response correlated with IgG S antibody levels. However, no correlation was demonstrated between the strength of the T-cell response and time since the second vaccine dose. CONCLUSION: COVID-19 vaccination induces robust T-cell responses that remain for at least nine months.

New-onset Evans syndrome in a patient with SLE post SARS-CoV2 mRNA vaccination.

High-temporal resolution profiling reveals distinct immune trajectories following the first and second doses of COVID-19 mRNA vaccines. Knowledge of the mechanisms underpinning the development of protective immunity conferred by mRNA vaccines is fragmentary. Here, we investigated responses to coronavirus disease 2019 (COVID-19) mRNA vaccination via high-temporal resolution blood transcriptome profiling. The first vaccine dose elicited modest interferon and adaptive immune responses, which peaked on days 2 and 5, respectively. The second vaccine dose, in contrast, elicited sharp day 1 interferon, inflammation, and erythroid cell responses, followed by a day 5 plasmablast response. Both post-first and post-second dose interferon signatures were associated with the subsequent development of antibody responses. Yet, we observed distinct interferon response patterns after each of the doses that may reflect quantitative or qualitative differences in interferon induction. Distinct interferon response phenotypes were also observed in patients with COVID-19 and were associated with severity and differences in duration of intensive care. Together, this study also highlights the benefits of adopting high-frequency sampling protocols in profiling vaccine-elicited immune responses.

Humoral Response to the Fourth BNT162b2 Vaccination and Link Between the Fourth Dose, Omicron Infection, and Disease Severity in Renal Transplant Recipients. BACKGROUND: The effectiveness of the fourth BNT162b2 vaccination in reducing the rate and severity of coronavirus disease 2019 (COVID-19) caused by the Omicron variant in renal transplant recipients (RTRs) is unknown. METHODS: Interviews were conducted with 447 RTRs regarding the status and timing of the fourth vaccination, prior vaccinations, and preceding COVID-19 infection. RTRs with polymerase chain reaction-confirmed COVID-19 infection from December 1, 2021, to the end of March 2022 were considered to have been infected with the Omicron variant and were interviewed to determine their disease severity. In a subgroup of 74 RTRs, the humoral response to the fourth dose was analyzed. In 30 RTRs, microneutralization assays were performed to reveal the humoral response to wild-type, Delta, and Omicron variant isolates before and after the fourth dose. RESULTS: Of 447 RTRs, 144 (32.2%) were infected with the Omicron variant, with 71 (49.3%) of the infected RTRs having received the fourth vaccine dose. RTRs who did not receive the fourth dose before the infection had more serious illness. In a subgroup of 74 RTRs, the fourth dose elicited a positive humoral response in 94.6% (70/74), with a significant increase in geometric mean titer for receptor-binding domain immunoglobulin G and neutralizing antibodies (P â€‰<â€‰0.001). The humoral responses to the Omicron variant before and after the fourth dose were significantly lower than the responses to the wild-type and the Delta variants. CONCLUSIONS: Overall, the fourth BNT162b2 dose was effective in reducing the rate and severity of Omicron disease in RTRs, despite the reduced humoral response to the variant.

Safety of COVID-19 Pfizer-BioNtech (BNT162b2) mRNA vaccination in adolescents aged 12-17 years: A systematic review and meta-analysis. The COVID-19 pandemic has severely affected adolescents. Safe and effective vaccines are pivotal tools in controlling this pandemic. We reviewed the safety profile of the BNT162b2 COVID-19 vaccine in adolescents using mostly real-world data to assist decision-making. We used random-effects model meta-analysis to derive pooled rates of single or grouped adverse events following immunization (AEFI) after each primary and booster dose, as well

as after combining all doses. Reporting on over one million participants with safety data were included. The most-reported local and systemic AEFIs were pain/swelling/erythema/redness and fatigue/headache/myalgia, respectively. AESIs were rarely reported but were more frequent after the second dose than they were after the first and the booster doses. Health impact was less common among adolescents after receiving BNT162b2 vaccine. Rare life-threatening AEFIs were reported across all doses in real-world studies. Our findings highlight the significance of enhancing national and regional vaccination programs to ensure public confidence.

The Association of Time of Day of ChAdOx1 nCoV-19 Vaccine Administration With SARS-CoV-2 Anti-Spike IgG Antibody Levels: An Exploratory Observational Study. Data from human and animal studies are highly suggestive of an influence of time of day of vaccine administration on host immune responses. In this population-based study, we aimed to investigate the effect of time of day of administration of a COVID-19 vector vaccine, ChAdOx1 nCoV-19 (AstraZeneca), on SARS-CoV-2 anti-spike S1 immunoglobulin (IgG) levels. Participants were 803 university employees who received their first vaccine dose in March 2021, had serology data at baseline and at 3â€‰weeks, and were seronegative at baseline. Antibody levels were determined in binding antibody units (BAU/mL) using enzyme-linked immunosorbent assay (ELISA). Generalized additive models (GAM) and linear regression were used to evaluate the association of time of day of vaccination continuously and in hourly bins with antibody levels at 3â€‰weeks. Participants had a mean age of 42â€‰years (SD: 12; range: 21-74) and 60% were female. Time of day of vaccination was associated non-linearly ("reverse J-shape") with antibody levels. Morning vaccination was associated with the highest (9:00-10:00 h: mean 292.1 BAU/mL; SD: 262.1), early afternoon vaccination with the lowest (12:00-13:00 h: mean 217.3 BAU/mL; SD: 153.6), and late afternoon vaccination with intermediate (14:00-15:00 h: mean 280.7 BAU/mL; SD: 262.4) antibody levels. Antibody levels induced by 12:00-13:00 h vaccination (but not other time intervals) were significantly lower compared to 9:00-10:00 h vaccination after adjusting for potential confounders (beta coefficient = -75.8, 95% confidence interval [CI] = -131.3, -20.4). Our findings show that time of day of vaccination against SARS-CoV-2 has an impact on the magnitude of IgG antibody levels at 3â€‰weeks. Whether this difference persists after booster vaccine doses and whether it influences the level of protection against COVID-19 needs further evaluation.

Recurrent Aseptic Meningoencephalitis Following BNT162b2 Vaccination for COVID-19.

AI-CoV Study: Autoimmune Encephalitis Associated With COVID-19 and Its Vaccines-A Systematic Review. BACKGROUND AND PURPOSE: Autoimmune encephalitis (AIE) following coronavirus disease 2019 (COVID-19) is an underexplored condition. This study aims to systematically review the clinico-investigational and pathophysiologic aspects of COVID-19 and its vaccines in association with AIE, and identify the factors predicting neurological severity and outcomes. METHODS: Relevant data sources were searched using appropriate search terms on January 15, 2022. Studies meeting the criteria for AIE having a temporal association with COVID-19 or its vaccines were included. RESULTS: Out of 1,894 citations, we included 61 articles comprising 88 cases: 71 of COVID-19-associated AIE, 3 of possible Bickerstaff encephalitis, and 14 of vaccine-associated AIE.There were 23 definite and 48 possible seronegative AIE cases. Anti-NMDAR (N-methyl-D-aspartate receptor; n=12, 16.9%) was the most common definite AIE. Males were more commonly affected (sex ratio=1.63) in the AIE subgroup. The neurological symptoms included alteredmental state (n=53, 74.6%), movement disorders (n=28, 39.4%), seizures (n=24, 33.8%), behavioural (n=25, 35.2%), and speech disturbances (n=17, 23.9%). The median latency to AIE diagnosis was 14 days (interquartile range=4-22 days). Female sex and ICU admission had higherrisks of sequelae, with odds ratio (OR) of 2.925 (95% confidence interval [CI]=1.005-8.516)and 3.515 (95% CI=1.160-10.650), respectively. Good immunotherapy response was seen in42/48 (87.5%) and 13/13 (100%) of COVID-19-associated and

vaccine-associated AIE patients, respectively. Sequelae were reported in 22/60 (36.7%) COVID-19 associated and 10/13 (76.9%) vaccine-associated cases. CONCLUSIONS: The study has revealed diagnostic, therapeutic, and pathophysiological aspects of AIE associated with COVID-19 and its vaccines, and its differences from postinfectious AIE. SYSTEMATIC REVIEW REGISTRATION: PROSPERO registration number CRD42021299215.

Spectrum of Neurological Complications Following COVID-19 Vaccination in India. BACKGROUND AND PURPOSE: According to WHO statistics, approximately 6.9 billion people worldwide had been vaccinated against SARS-CoV-2 as at October 27, 2021, including around 1.0 billion people in India. Most Indian recipients received the Covishield (ChAdOx1-S/nCoV-19) vaccine, followed by the Covaxin (an inactivated SARS-CoV-2 antigen) vaccine. This study was conducted to characterize the neurological phenotypic spectrum of patients with adverse events following immunization with any of the available COVID-19 vaccines in India (Covishield or Covaxin) during the study period and their temporal relationship with vaccination. METHODS: This ambispective multicenter hospital-based cohort study covered the period from March to October 2021. The study included all cases suspected of having neurological complications following COVID-19 vaccination. RESULTS: We report a spectrum of serious postvaccination neurological complications comprising primary central nervous system demyelination (4 cases), cerebral venous thrombosis (3 cases), Guillain-Barre syndrome (2 cases), vaccine-induced prothrombotic immune thrombocytopenia syndrome (2 cases), cranial nerve palsies (2 cases), primary cerebral hemorrhage (1 case), vestibular neuronitis (1 case), chronic inflammatory demyelinating polyneuropathy (1 case), generalized myasthenia (1 case), and seizures (1 case). CONCLUSIONS: Although the benefits of vaccination far outweigh its risks, clinicians must be aware of possible serious adverse events associated with COVID-19 vaccinations.

Risk of glomerular diseases, proteinuria and hematuria following mRNA (BNT162b2) and inactivated (CoronaVac) SARS-CoV-2 vaccines. BACKGROUND: With accruing case reports on de novo or relapsing glomerular diseases (GD) following different severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines, we evaluated the risk of GD following BNT162b2 and CoronaVac vaccines. METHODS: A modified self-controlled case series analysis was conducted using anonymized, territory-wide SARS-CoV-2 vaccination records in Hong Kong. All Hong Kong residents aged 18 years or above with outcomes of interest were included. Outcomes of interest were GD, proteinuria or hematuria within 42 days following each dose of SARS-CoV-2 vaccines. Incidence per 100Â 000 doses of SARS-CoV-2 vaccines administered was calculated, and incidence rate ratios (IRRs) were estimated using conditional Poisson regression with seasonality adjustment. RESULTS: Between 23 February 2021 and 31 March 2022, 4062 patients had an incident diagnosis of GD, proteinuria or hematuria, with 2873 of them being vaccinated during the observation period. The incidences of the composite events 1-41 days after vaccination were 3.7 (95% CI 3.1-4.4) per 100Â 000 doses of BNT162b2 administered, and 6.5 (95% CI 5.7-7.5) per 100Â 000 doses CoronaVac administered. There was no significant increase in the risks of composite events following the first (BNT162b2: IRRÂ =Â 0.76, 95% CI 0.56-1.03; CoronaVac: IRRÂ =Â 0.92, 95% CI 0.72-1.19), second (BNT162b2: IRRÂ =Â 0.92, 95% CI 0.72-1.17; CoronaVac: IRRÂ =Â 0.88. 95% CI 0.68-1.14) or third (BNT162b2: IRRÂ =Â 0.39. 95% CI 0.15-1.03; CoronaVac: IRRÂ =Â 1.18. 95% CI 0.53-2.63) dose of SARS-CoV-2 vaccines. CONCLUSIONS: There was no evidence of increased risks of de novo or relapsing GD with either BNT162b2 or CoronaVac vaccines.

Functional disorders as a common motor manifestation of COVID-19 infection or vaccination. BACKGROUND AND PURPOSE: There have been over 500 million confirmed cases of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), also known as coronavirus disease 2019 (COVID-19), across the globe. To date, a broad spectrum of neurological manifestations following acute infections as well as COVID-19 vaccines have been reported. The aim of this study was to describe the

spectrum of neurological manifestations seen in the 'COVID-19 clinic' established in a tertiary Movement Disorders clinic. METHODS: In this consecutive case-series study over the period March 2020-January 2022, clinical information regarding demographic data, clinical history and examination findings, investigation results and video recordings of outpatients with motor manifestations associated with COVID-19 infection or vaccination were reviewed. RESULTS: Twenty-one adult patients were reviewed in this ad hoc clinic at Toronto Western Hospital. The majority of the patients were female (76%) and the mean (range) age was 50.7Â Â±â€‰17.2Â (21-80)Â years. Nine patients (43%) presented with motor manifestations following COVID-19 infection. Twelve patients (57%) developed neurological symptoms following at least one dose of the mRNA or viral vector-based COVID-19 vaccine. The most common manifestation observed was a functional movement disorder (43%). The vaccine group demonstrated a higher number of functional disorders compared to the infection group (58% vs. 22%; pÂ =â€‰0.08). CONCLUSION: Functional motor manifestations can be associated with COVID-19 and are likely to be under-reported. In view of the co-existence of functional symptoms, movement disorders and mental health conditions observed in this study, we would advocate the use of dedicated COVID-19 Neurology clinics with full access to an experienced multidisciplinary team.

The Association Between Prebooster Vaccination Antibody Levels and the Risk of Severe Acute Respiratory Syndrome Coronavirus 2 Infection. The correlation between anti-severe acute respiratory syndrome coronavirus 2 antibody levels and infection was reported. Here, we estimated the role of pre-fourth dose levels using data from 1098 healthcare workers. The risk of infection was reduced by 46% (95% confidence interval, 29%-59%) for each 10-fold increase in prebooster levels. Prebooster antibody levels could be used to optimally time boosters.

Characterizing Longitudinal Antibody Responses in Recovered Individuals Following COVID-19 Infection and Single-Dose Vaccination: A Prospective Cohort Study. BACKGROUND: Investigating antibody titers in individuals who have been both naturally infected with SARS-CoV-2 and vaccinated can provide insight into antibody dynamics and correlates of protection over time. METHODS: Human coronavirus (HCoV) IgG antibodies were measured longitudinally in a prospective cohort of qPCR-confirmed, COVID-19 recovered individuals (k = 57) in British Columbia pre- and post-vaccination. SARS-CoV-2 and endemic HCoV antibodies were measured in serum collected between Nov. 2020 and Sept. 2021 (n = 341). Primary analysis used a linear mixed-effects model to understand the effect of single dose vaccination on antibody concentrations adjusting for biological sex, age, time from infection and vaccination. Secondary analysis investigated the cumulative incidence of high SARS-CoV-2 anti-spike IgG seroreactivity equal to or greater than 5.5 log10 AU/mL up to 105 days post-vaccination. No re-infections were detected in vaccinated participants, post-vaccination by qPCR performed on self-collected nasopharyngeal specimens. RESULTS: Bivariate analysis (complete data for 42 participants, 270 samples over 472 days) found SARS-CoV-2 spike and RBD antibodies increased 14-56 days post-vaccination ($p < 0.001$) and vaccination prevented waning (regression coefficient, B = 1.66 [95%CI: 1.45-3.46]); while decline of nucleocapsid antibodies over time was observed (regression coefficient, B = -0.24 [95%CI: -1.2-(-0.12)]). A positive association was found between COVID-19 vaccination and endemic human Î²-coronavirus IgG titer 14-56 days post vaccination (OC43, p = 0.02 & HKU1, p = 0.02). On average, SARS-CoV-2 anti-spike IgG concentration increased in participants who received one vaccine dose by 2.06 log10 AU/mL (95%CI: 1.45-3.46) adjusting for age, biological sex, and time since infection. Cumulative incidence of high SARS-CoV-2 spike antibodies (>5.5 log10 AU/mL) was 83% greater in vaccinated compared to unvaccinated individuals. CONCLUSIONS: Our study confirms that vaccination post-SARS-CoV-2 infection provides multiple benefits, such as increasing anti-spike IgG titers and preventing decay up to 85 days post-vaccination.

Multiple Venous and Pulmonary Artery Thrombosis as the Presenting Features of Spontaneously Reversible Nephrotic Syndrome after Exposure to SARS-CoV-2 Virus (Pfizer/BioNTech BNT162b2) Vaccination. We report an unusual case of nephrotic syndrome and multiple venous thromboembolism (VTE) four days after BNT162b2 injection. The patient presented with a three-day history of foamy urine and one-day history of right leg swelling. The investigation showed 9.5 g of 24 hr urine protein, hypoalbuminemia (2.6 gm/dL), and hypercholesterolemia (320 mg/dL). The duplex ultrasonography revealed VTE of the right lower extremity veins (common femoral vein, saphenous vein, and popliteal vein). Computed tomography (CT) showed thrombosis of the infrarenal inferior vena cava (IVC) extending to both iliac veins and acute pulmonary embolism. Kidney biopsy was performed. The diagnosis of minimal change disease was made. The patient received anticoagulation without steroid or immunosuppressive medications. The nephrosis was spontaneously resolved in 20 days; thus, it strongly suggested the diagnosis of vaccine-induced minimal change nephropathy. Reports of kidney adverse events and clinical characteristics are further needed in the circumstances of worldwide SARS-CoV-2 vaccine usage.

Bilateral Optic Neuritis after COVID-19 Vaccination: A Case Report. BACKGROUND: Neuro-ophthalmic manifestations after vaccines are rare, with optic neuritis (ON) being the most common presentation. Patients with vaccine-related ON are similar to those with idiopathic ON. The temporal relationship between vaccination against and the occurrence of ON is vital. Here, we report a case of bilateral ON after the administration of the ChAdOx1-S nCoV-19 SARS-CoV-2 vaccine. CASE: A 49-year-old healthy Asian female presented with sudden onset of bilateral blurred vision within 2 days. She complained of photophobia and extraocular pain upon movement over 3 days. Upon examination, her best corrected visual acuity (BCVA) was 20/30 in the right eye and 20/200 in the left eye. Anterior segment findings were unremarkable, with normal intraocular pressure. Fundoscopic examination revealed bilateral disc edema with vessel engorgement. Visual field examination revealed profound visual field defect in both eyes. She denied any trauma, use of new medication or medical history. She had received the ChAdOx1 nCoV-19 SARS-CoV-2 vaccine 14 days prior. Under suspicion of vaccine-related optic neuritis, she was given intravenous methylprednisolone 1 gm/day for 3 days, shifting to oral prednisolone under gradual tapering for 2 weeks. CONCLUSIONS: Typically presenting with sudden-onset visual decline and extraocular pain during movement, acute ON is generally idiopathic. Bilateral ON is rare, but quick identification is important because it can potentially lead to permanent loss of vision if left untreated. Vaccination-induced ON is even rarer but not difficult to treat. However, such patients require further evaluation and long-term follow-up because they may be prone to other neurological disorders in the future.

COVID-19 Vaccine-Associated Ocular Adverse Effects: An Overview. BACKGROUND: To address the pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), vaccination efforts were initiated across the globe in December 2020 and are continuing. We report the onset interval and clinical presentations of ocular adverse effects following SARS-CoV-2 vaccination. METHODS: For this narrative review, articles in the English language, published between 1 January 2020 to 1 September 2022, were included to formulate a list of the reported ocular adverse effects of different COVID-19 vaccines. RESULTS: During this period, ocular adverse effects have been reported with BNT162b2 (Pfizer), mRNA-1273 (Moderna), AZD-1222 (AstraZeneca), and Ad26.COV2.S (Johnson & Johnson) vaccines. Endothelial graft rejection, herpes simplex virus keratitis, herpes zoster ophthalmicus, anterior uveitis, eyelid edema, purpuric rashes, ischemic optic neuropathy, and cranial nerve palsies were the most reported with BNT163b2. Retinal hemorrhages, vascular occlusions, and angle closure glaucoma were the most reported with AZD-1222. Most of the ocular adverse effects reported in the literature had a good to fair prognosis with appropriate management. CONCLUSIONS: Evidence regarding the ocular adverse effects does not outweigh the benefits of SARS-CoV-2

vaccination in patients with pre-existing systemic or ophthalmic diseases. This review provides insights into the possible temporal association between reported ocular adverse events and SARS-CoV-2 vaccines; however, further investigations are required to identify the link between potential causality and pathological mechanisms.

BNT162b2 (Pfizer/BioNTech) COVID-19 Vaccination Was Not Associated with the Progression of Activity of the Exudative Form of Age-Related Macular Degeneration during Anti-VEGF Therapy. BACKGROUND: Evaluation of the activity of the exudative form of age-related macular degeneration (AMD) during anti-vascular endothelial growth factor (anti-VEGF) therapy before and after administration of BNT162b2 (Pfizer/BioNTech) vaccination. METHODS: The optical coherence tomography and best corrected visual acuity (BCVA) records of the two previous visits before the first dose of BNT162b2 (first pre-vaccination visit marked as "V-1", the previous pre-vaccination "V-2"), and two subsequent visits after the second dose of vaccination (first visit after the second dose marked as "V1", second visit after the second dose marked as "V2") were collected for 63 eyes of 59 patients. RESULTS: The difference in the average retinal thickness was observed between the last and each other checkpoint for the aflibercept group and in the overall outcome. The maximum thickness from the inner retinal surface to the inner border of RPE decreased during the observation; differences were observed comparing visits -2 and 1. Subretinal complex thickness decreased during follow-up, and the differences were observed between visits -2 and 2. There were no statistically significant differences in the BCVA and the occurrence of intraretinal cystoid fluid, serous PED, subretinal hyperreflective material, and retinal hemorrhage. CONCLUSION: In the present study, the activity of the exudative form of AMD did not deteriorate after the administration of the BNT162b2 vaccine.

Investigation of Adverse Events Experienced by Healthcare Workers following Immunization with Homologous orHeterologous COVID-19 Booster Vaccinations. OBJECTIVE: A comparative analysis was performed to investigate the potential risk factors of Adverse Events Following Immunization (AEFI) after receiving different booster vaccines. METHODS: From 18 January 2021 to 21 January 2022, the Health Care Workers (HCWs) of Guizhou Provincial Staff Hospital (Guizhou Province, China) who received a third Booster vaccine, that was either homologous (i.e., (i) a total of three doses of Vero cell vaccine or (ii) three doses of CHO cell vaccine) or (iii) heterologous with two first doses of Vero cell vaccine, being either CHO cell vaccine or adenovirus type-5 (Ad5) vectored COVID-19 vaccine, were asked to complete a self-report questionnaire form to provide information on any AEFI that may have occurred in the first 3 days after vaccination with the booster. The frequency of AEFI corresponding to the three different booster vaccines was compared, and the risk factors for predicting AEFI were determined by multivariate logistic regression analysis. RESULTS: Of the 904 HCWs who completed the survey, 792 met the inclusion criteria. The rates of AEFI were 9.8% (62/635) in the homologous Vero cell booster group, 17.3% (13/75) in the homologous CHO cell booster group, and 20.7% (17/82) in the heterologous mixed vaccines booster group, and the rates were significantly different (c(2) = 11.5, p = 0.004) between the three groups of vaccines. Multivariate logistic regression analysis showed that: (1) compared to the homologous Vero cell booster group, the risk of AEFI was about 2.1 times higher (OR = 2.095, 95% CI: 1.056-4.157, p = 0.034) in the CHO cell booster group and 2.5 times higher (OR = 2.476, 95% CI: 1.352-4.533, p = 0.003) in the mixed vaccines group; (2) the odds for women experiencing AEFI were about 2.8 times higher (OR = 2.792, 95% CI: 1.407-5.543, p = 0.003) than men; and (3) compared to the non-frontline HCWs, the risk of AEFI was about 2.6 times higher (OR = 2.648, 95% CI: 1.473-4.760, p = 0.001) in the doctors. CONCLUSION: The AEFI in all three booster groups are acceptable, and serious adverse events are rare. The risk of AEFI was higher in doctors, which may be related to the high stress during the COVID-

19 epidemic. Support from government and non-governmental agencies is important for ensuring the physical and mental health of HCWs.

Short- and Long-Term Self-Reported Symptoms in Adolescents Aged 12-19 Years after Vaccination against SARS-CoV-2 Compared to Adolescents Not Vaccinated-A Danish Retrospective Cohort Study. This study investigated self-reported short- and long-term symptoms among adolescents receiving the BNT162b2 (Pfizer/BioNTech) vaccine against SARS-CoV-2 and those who did not. A retrospective cohort study based on Danish national survey (collected between 20 July and 15 September 2021) and register data was conducted. Differences in short-term (<14 days) and long-term (>two months) symptoms were explored using logistic regression adjusted for confounders. A total of 747 vaccinated (first dose n = 326; second dose n = 421) and 6300 unvaccinated adolescents were included in analyses of short-term symptoms and 32 vaccinated and 704 unvaccinated adolescents in long-term symptom analyses. In the first 14 days after the first and second vaccine dose the most reported symptoms included headache and muscle or joint symptoms. In both vaccinated and unvaccinated adolescents, the 15â^'19-year-olds reported significantly higher proportions of all symptoms compared to the 12â^'14-year-olds. After the second vaccine dose vaccinated 12â^'14-year-olds reported significantly more headache in adjusted analyses (OR 2.20 (95% CI 1.24; 3.90)). Among the 15â^'19-year-olds, significantly more vaccinated adolescents reported gastrointestinal symptoms (1.38 (1.06; 1.81)), headache (1.66 (1.24; 2.22)), and tiredness (1.44 (1.08; 1.93)). No differences were found in long-term symptoms. Vaccinated adolescents reported significantly more short-term symptoms including headache, tiredness, and gastrointestinal symptoms after the second vaccine dose than unvaccinated adolescents. Long-term symptom results should be interpreted with caution due to limited sample size.

Serological Immune Response Following ChAdOx1 nCoV-19 Vaccine (Covishield(Â®)) in Patients with Liver Cirrhosis. Introduction: Data are limited on antibody response to the ChAdOx1 nCoV-19 vaccine (AZD1222; CovishieldÂ®) in cirrhosis. We studied the antibody response following two doses of the ChAdOx1 vaccine, given 4â^'12 weeks apart, in cirrhosis. Methods: Prospectively enrolled, 131 participants (71% males; age 50 (43â^'58); alcohol-related etiology 14, hepatitis B 33, hepatitis C 46, cryptogenic 21, autoimmune 9, others 8; Childâ^'Turcottâ^'Pugh class A/B/C 52/63/16). According to dose intervals, the participants were grouped as â‰¤6 weeks (group I), 7â^'12 weeks (group II), and 13â^'36 weeks (group III). Blood specimens collected at â‰¥4 weeks after the second dose were tested for anti-spike antibody titre (ASAb; positive â‰¥ 0.80 U/mL) and neutralizing antibody (NAb; positive â‰¥20% neutralization) using Elecsys Anti-SARS-CoV-2 S (Roche) and SARS-CoV-2 NAb ELISA Kit (Invitrogen), respectively. Data are expressed as number (proportion) and median (interquartile range) and compared using non-parametric tests. Results: Overall, 99.2% and 84% patients developed ASAb (titre 5440 (1719â^'9980 U/mL)) and NAb (92 (49.1â^'97.6%)), respectively. When comparing between the study groups, the ASAb titres were significantly higher in group II than in group I (2613 (310â^'7518) versus 6365 (2968â^'9463), p = 0.027) but were comparable between group II and III (6365 (2968â^'9463) versus 5267 (1739â^'11,653), p = 0.999). Similarly, NAb was higher in group II than in group I (95.5 (57.6â^'98.0) versus 45.9 (15.4â^'92.0); p < 0.001), but not between the groups II and III (95.5 (57.6â^'98.0) versus 92.4 (73.8â^'97.5); p = 0.386). Conclusion: CovishieldÂ® induces high titres of ASAb and NAb in cirrhosis. A higher titre is achieved if two doses are given at an interval of more than six weeks.

The Association of Health Literacy with Intention to Vaccinate and Vaccination Status: A Systematic Review. Despite health literacy (HL) being recognized as a driver of health-promoting behavior, its influence on the vaccination decision-making process remains unclear. This study summarized current evidence on the association between HL and both intention to vaccinate and vaccination status. We searched PubMed, Scopus, and Web of Science, retrieving observational studies published

until January 2022 that used HL-validated tools to investigate the above associations for any vaccine. Quality was assessed using the Newcastle-Ottawa scale. Twenty-one articles were included; of these, six investigated the intention to vaccinate and the remainder vaccination status. Articles on intention looked at SARS-CoV-2 vaccination using heterogeneous HL tools and were of high/fair quality. Vaccination status, mainly for influenza or pneumococcal vaccines, was explored using various HL tools; the quality was generally high. We found inconsistent results across and within vaccine types, with no clear conclusion for either vaccination intention or status. A weak but positive association was reported between a high HL level and influenza vaccination uptake for individuals aged more than 65 years. HL did not seem to significantly influence behavior towards vaccination. Differences in the methods used might explain these results. Further research is needed to investigate the role of HL in the vaccination decision-making process.

Longitudinal Analyses after COVID-19 Recovery or Prolonged Infection Reveal Unique Immunological Signatures after Repeated Vaccinations. To develop preventive and therapeutic measures against coronavirus disease 2019, the complete characterization of immune response and sustained immune activation following viral infection and vaccination are critical. However, the mechanisms controlling intrapersonal variation in antibody titers against SARS-CoV-2 antigens remain unclear. To gain further insights, we performed a robust molecular and cellular investigation of immune responses in infected, recovered, and vaccinated individuals. We evaluated the serum levels of 29 cytokines and their correlation with neutralizing antibody titer. We investigated memory B-cell response in patients infected with the original SARS-CoV-2 strain or other variants, and in vaccinated individuals. Longitudinal correlation analyses revealed that post-vaccination neutralizing potential was more strongly associated with various serum cytokine levels in recovered patients than in naÃ¯ve individuals. We found that IL-10, CCL2, CXCL10, and IL-12p40 are candidate biomarkers of serum-neutralizing antibody titer after the vaccination of recovered individuals. We found a similar distribution of virus-specific antibody gene families in triple-vaccinated individuals and a patient with COVID-19 pneumonia for 1 year. Thus, distinct immune responses occur depending on the viral strain and clinical history, suggesting that therapeutic options should be selected on a case-by-case basis. Candidate biomarkers that correlate with repeated vaccination may support the efficacy and safety evaluation systems of mRNA vaccines and lead to the development of novel vaccine strategies.

Reactogenicity and Humoral Immune Response after Heterologous Vaxzevria/Comirnaty Vaccination in a Group of Individuals Vaccinated in the AOU Policlinic "G. Martino" (Messina, Italy): A Retrospective Cohort Study. On 11 June 2021, the Italian Ministry of Health authorized the heterologous vaccination schedule. The goals of our retrospective study were to (a) evaluate the undesirable effects after the administration of Vaxzevria and Comirnaty vaccines; (b) evaluate the antibody response after 28 days from the administration of the second dose; and (c) compare the antibody responses after the homologous and heterologous vaccination regimens. The undesirable effects were collected using a survey; IgG Spike was quantified using the electrochemiluminescence method; the comparison between the antibody responses was carried out using the sample of a homologous vaccine schedule previously analyzed. Pain at the injection site is the most common undesirable effect after the administration of both vaccines (62.1% after Vaxzevria vs. 82.75% after Comirnaty); swelling at the injection site is more frequent after the administration of Vaxzevria than after the administration of Comirnaty: (15.52% vs. 5.17%); headache is more frequent in women than in men for both the vaccination types ($p < 0.05$); 49.09% of the sample reported IgG Spike â‰¥ 12,500 U/mL; the antibody titer of the heterologous schedule is higher than that of the homologous vaccination. Our study demonstrated that the undesirable effects after the administration of the second dose are less frequent and less severe than after the administration of the first dose, and that the immunogenicity of the heterologous vaccinations is higher than that of the homologous ones.

Renal Side Effects of COVID-19 Vaccination. Background: The COVID-19 pandemic has imposed a challenge on global healthcare and has tremendously impacted everyone's lives. Vaccination is one of the most effective and vital strategies to halt the pandemic. However, new-onset and relapsed kidney diseases have been reported after COVID-19 vaccination. This narrative review was conducted to collect published data and generalize some hypotheses for the pathogenesis of renal side effects of COVID-19 vaccines. Methods: A systematic literature search of articles reporting renal adverse reactions, including in adults and children, in the PubMed and Web of Science databases until August 2022 was performed. Results: A total of 130 cases reporting a renal adverse reaction following COVID-19 vaccination from 90 articles were included in this review, of which 90 (69%) were new-onset kidney diseases, while 40 (31%) were relapsed kidney diseases. The most frequent renal side effects of COVID-19 vaccination were minimal change disease (52 cases), IgA nephropathy (48 cases), antineutrophil cytoplasmic autoantibody vasculitis (16 cases), and acute interstitial nephritis (12 cases). Other renal side effects occurred at a much lower frequency. Follow-up data were available for 105 patients, and 100 patients (95%) responded to the treatments. Conclusions: The number of reported cases is far less than the hundreds of millions of vaccinations, and the benefit of COVID-19 vaccination far outweighs its risks. This review will assist healthcare professionals, particularly nephrologists, who should be aware of these side effects and recognize them early and treat them efficiently.

Short-Term Adverse Effects Following Booster Dose of Inactivated-Virus vs. Adenoviral-Vector COVID-19 Vaccines in Algeria: A Cross-Sectional Study of the General Population. COVID-19 booster vaccines have been adopted in almost all countries to enhance the immune response and combat the emergence of new variants. Algeria adopted this strategy in November 2021. This study was conducted to consider the self-reported side effects of COVID-19 booster vaccines by Algerians who were vaccinated with a booster dose of one of the approved inactivated-virus vaccines, such as BBIBP-CorV and CoronaVac, or one of the adenoviral-vector-based vaccines, such as Gam-COVID-Vac, AZD1222 and Ad26.COV2.S, and to determine the eventual risk factors. A cross-sectional study using an online self-administered questionnaire (SAQ) was conducted in Algeria between 28 April 2022, and 20 July 2022. A descriptive analysis of the 196 individuals who were included showed a nearly equal distribution of adenoviral- (52%) and inactivated-virus vaccines (48%) and of males (49.5%) and females (50.5%). The results showed that 74.7% of the studied population reported at least one local or systemic side effect. These side effects were more frequent among adenoviral-vector vaccinees (87.3%) than inactivated-virus vaccinees (60.6%) (sig. < 0.001). Injection site pain (40.3%), heat at the injection site (21.4%), and arm pain (16.3%) were the most common local side effects. These signs generally appeared in the first 12 h (73.3%) and generally lasted less than 24 h (32.8%). More interestingly, these signs differed from those that followed the administration of primer doses (48.5%) and were generally more severe (37%). The same observation was reported for systemic side effects, where the signs were especially most severe in the adenoviral-vaccinated group (49.4% vs. 20.8%; sig. = 0.001). These signs generally appeared within the first day (63.6%) and mostly disappeared before two days (50.8%), with fatigue (41.8%), fever (41.3%), and headache (30.1%) being the most common. Adenoviral-vector vaccinees (62.7%) were more likely to use medications to manage these side effects than were inactivated-virus vaccinees (45.7%) (sig. = 0.035) and paracetamol (48.5%) was the most used medication. Adenoviral-based vaccines were the types of vaccines that were most likely to cause side effects. In addition, being female increased the risk of developing side effects; regular medication was associated with local side effects among inactivated-virus vaccinees; and previous infection with COVID-19 was associated with systemic and local side effects among adenovirus-based vaccinees. These results support the short-term safety of booster vaccines, as has been reported for primer doses.

Adverse Reactions after the Third Dose of the BNT162b2 mRNA COVID-19 Vaccine among Medical School Residents in a Regional Reference University Hospital in Italy. The recent emergence of new variants of concern (VOCs) of SARS-CoV-2 and the uncertain duration of protection provided by the primary immunization cycle have highlighted the need for COVID-19 booster vaccinations. However, only a few studies have assessed the safety and reactogenicity profile of mRNA booster doses. Therefore, we conducted an online survey with the aim of assessing the adverse reaction profile in the 7 days following a third dose of the BNT162b2 vaccine in a population of resident physicians who had already been investigated after the primary vaccination. Among the 512 resident physicians (female = 53.2%, mean age = 29.8 years) invited to participate in the survey, 222 completed the survey (56.5% female, mean age of 29.9 years), with an average time from second to third dose of 8.6 months. The most common adverse reactions were local pain (88.3%), fatigue (58.1%), muscle/joint pain (44.1%), and headache (38.3%), all subsiding in 48-72 h. While the local reaction rate was similar to that following the first two doses, the systemic reactions were considerably less common and milder compared to the second vaccination. Nonetheless, over one third (36.1%) of participants reported interference with their normal activities. These results complement our previous findings and could aid occupational and public health professionals in the counselling of vaccinees.

Recurrent Multiple Evanescent White Dot Syndrome (MEWDS) Following First Dose and Booster of the mRNA-1273 COVID-19 Vaccine: Case Report and Review of Literature. To report a rare case of a patient with two recurrent episodes of Multiple Evanescent White Dot Syndrome (MEWDS) associated with the second dose and second booster of the mRNA-1273 COVID-19 vaccine (Moderna), and to perform a literature review on COVID-19-vaccine-associated MEWDS. Case Report: A 31-year-old female was evaluated for a temporal scotoma and photopsias that started two weeks after the second dose of the Moderna COVID-19 vaccine. Dilated fundus findings were remarkable for unilateral, small whitish-yellow dots scattered around posterior pole of the left eye, consistent with a diagnosis of MEWDS. The symptoms resolved three months later without treatment. Approximately one year after the first vaccine, the patient received the second Moderna COVID-19 vaccine booster and experienced a recurrence of symptoms with an enlarged scotoma and similar examination findings. The patient was treated with a course of systemic corticosteroids with subsequent clinical improvement. Conclusion: Although uveitis following COVID-19 vaccines is rare, our case highlights a need for increased awareness amongst practitioners regarding COVID-19-vaccine-associated onset or recurrence of ocular inflammatory diseases.

Genomic Transcriptome Benefits and Potential Harms of COVID-19 Vaccines Indicated from Optimized Genomic Biomarkers. COVID-19 vaccines can be the tugboats for preventing SARS-CoV-2 infections when they are practical and, more importantly, without adverse effects. However, the reality is that they may result in short-term or long-term impacts on COVID-19-related diseases and even trigger the formation of new variants of SARS-CoV-2. Using published data, we use a set of optimized-performance COVID-19 genomic biomarkers (MND1, CDC6, ZNF282) to study the benefits and adverse effects of the BNT162b2 vaccine. We found that the vaccine lowered the expression values of genes MND1 and CDC6 while heightening the expression values of ZNF282 in individuals who are SARS-CoV-2 naÃ¯ve, which is expected and satisfies the biological equivalence between the COVID-19 disease and the genomic signature patterns established in the literature. However, we also found that COVID-19-convalescent octogenarians responded reversely. The vaccine heightened the expression values of MND1 and CDC6. In addition, it lowered the expression values of ZNF282. Such adverse effects raise outstanding concerns about whether or not COVID-19-convalescent individuals should take the current vaccine or when they can take it. These findings are new at the genomic level

and can provide insights into developing next-generation vaccines, antiviral drugs, and pandemic management guidance.

Reply to Ã‡Ä±nar et al. Comment on "Zamfir et al. Hematologic Malignancies Diagnosed in the Context of the mRNA COVID-19 Vaccination Campaign: A Report of Two Cases. Medicina 2022, 58, 874". We would like to thank Ã‡Ä±nar et al. for their appreciation and insightful discussions presented in their comment [...].

Comment on Zamfir et al. Hematologic Malignancies Diagnosed in the Context of the mRNA COVID-19 Vaccination Campaign: A Report of Two Cases. Medicina 2022, 58, 874. The SARS-CoV-2 spike protein mRNA-based vaccines have prevented countless mortality and morbidity, and have an excellent risk/benefit ratio. However, various adverse events may rarely occur after the BNT162b2 vaccine, like any other medical intervention. The COVID-19 itself and the spike protein produced endogenously by mRNA vaccines may have immunological, microenvironmental, prothrombotic, and neoplastic effects. As a contribution to the published report, we would like to share our experience regarding four cases in which myeloid neoplasms emerged following the vaccination. Conclusions: There is no doubt that vaccination could continue along the lines of established universal recommendations. Meanwhile, all hematological adverse events must be closely monitored and reported. Further efforts should be focused on the probable pathobiological mechanisms and causalities of spike protein-related toxicity and clonal myeloid disorders.

Pathological Findings in COVID-19 and Non-COVID-19 Vaccine-Associated Lymphadenopathy: A Systematic Review. COVID-19 vaccine-associated lymphadenopathy (C19-VAL) is increasingly encountered with the widespread use of the vaccine in controlling the outbreak. We aim to characterize the pathological findings of COVID-19 and non-COVID-19 vaccine-associated lymphadenopathy (NC19-VAL). A search for studies that reported pathological findings in vaccine-associated lymphadenopathy on PubMed and Google Scholar was performed on 11 December 2021. C19-VAL studies were pooled for analysis. These studies were split into clinical lymphadenopathy (CL) and subclinical lymphadenopathy detected on imaging (SLDI) for subgroup analysis. A total of 25 studies were related to COVID-19 vaccines, and 21 studies were included in the pooled analysis. The pooled analysis included 37 patients with a mean age of 47.8 Â± 19.1 years old, and 62.2% were females. The mean duration from last vaccination to development of CL/SLDI was 14.5 Â± 11.0 days. Most were diagnosed as reactive or negative for malignancy (28/37, 75.5%), followed by Kikuchi-Fujimoto disease (KFD) (3/37, 8.1%), florid lymphoid hyperplasia (2/37, 5.4%), and granulomatous inflammation (2/37, 5.4%). Metastases were reported in two patients with a history of malignancy (2/37, 5.4%). Cases with florid lymphoid hyperplasia and KFD were younger than those with reactive changes. A total of 14 studies were related to non-COVID-19 vaccines. Caseating granulomatous inflammation was reported in BCG vaccine-associated lymphadenopathy, while other vaccines were associated with reactive lymphoid hyperplasia, florid post-vaccinal reactions, and KFD. Although most C19-VAL cases were reported as reactive or negative for malignancy, other diagnoses included florid lymphoid hyperplasia, KFD, and granulomatous inflammation. Metastases were reported in lymphadenopathy of patients with a history of malignancy, who had been incidentally vaccinated. In conclusion, C19-VAL can yield different histopathological diagnoses when sampled, most of which require clinical and radiological correlation for optimal patient management.

Microarray Profiling of Vaccination-Induced Antibody Responses to SARS-CoV-2 Variants of Interest and Concern. Mutations in surface proteins enable emerging variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to escape a substantial fraction of neutralizing antibodies and may thus weaken vaccine-driven immunity. To compare available vaccines and justify revaccination, rapid evaluation of antibody (Ab) responses to currently circulating SARS-CoV-2 variants of interest (VOI) and concern (VOC) is needed. Here, we developed a multiplex protein microarray-based system

for rapid profiling of anti-SARS-CoV-2 Ab levels in human sera. The microarray system was validated using sera samples from SARS-CoV-2-free donors and those diagnosed with COVID-19 based on PCR and enzyme immunoassays. Microarray-based profiling of vaccinated donors revealed a substantial difference in anti-VOC Ab levels elicited by the replication-deficient adenovirus vector-base (Sputnik V) and whole-virion (CoviVac Russia COVID-19) vaccines. Whole-virion vaccine-induced Abs showed minor but statistically significant cross-reactivity with the human blood coagulation factor 1 (fibrinogen) and thrombin. However, their effects on blood clotting were negligible, according to thrombin time tests, providing evidence against the concept of pronounced cross-reactivity-related side effects of the vaccine. Importantly, all samples were collected in the pre-Omicron period but showed noticeable responses to the receptor-binding domain (RBD) of the Omicron spike protein. Thus, using the new express Ab-profiling system, we confirmed the inter-variant cross-reactivity of the anti-SARS-CoV-2 Abs and demonstrated the relative potency of the vaccines against new VOCs.

Social Vulnerability and COVID-19 Vaccine in Spain. Different analyses show that the design of vaccination policies should especially protect the most vulnerable social groups, since the level of acceptance is determined by the population's knowledge, attitude and concerns about the safety and efficacy of vaccines. The objective of this work will be to detect the most socially vulnerable groups with respect to COVID-19 and to analyze the factors that influence predisposition to vaccination. This is a cross-sectional study using data from the Centro de Investigaciones SociolÃ³gicas (CIS) on the Effects and Consequences of Coronavirus (Study 3346 of December 2021). Sociodemographic variables (sex, age, employment status, studies and subjective class identification) were extracted, as well as the answers to the questions indicating the attitude towards vaccination, corresponding to questions 7,8,10 and 11 of the study. The most vulnerable group was lower class women (self-perceived), under 45 years of age with lower educational level, unemployed or performing unpaid work in the home. Most of them are not predisposed to vaccinate only because of the obligation to do so, mainly due to lack of belief in the power and efficacy of vaccines, as well as fear of health risks/collateral side effects. The lower vaccine uptake in this vulnerable population group may be due to a lack of awareness and lower trust in the authorities, as well as the benefits of the vaccine, which could be related to a lack of policy targeting the most socially vulnerable populations.

Arrhythmias after SARS-CoV-2 Vaccination in Patients with a Cardiac Implantable Electronic Device: A Multicenter Study. One of the most concerning adverse events related to the SARS-CoV-2 vaccination is arrhythmia. To ascertain the relationship between vaccination and arrhythmic events, we studied the occurrence of arrhythmia in patients with cardiac implantable electronic devices (CIEDs) before and after a SARS-CoV-2 vaccination. Patients with CIEDs aged â‰¥18 who visited the CIED clinic at King Chulalongkorn Memorial Hospital and Vajira hospital from August 2021 to February 2022 were included. Information about the SARS-CoV-2 vaccination and side effects was obtained. One hundred eighty patients were included in our study, which compared the incidence of arrhythmias in the 14 days post-vaccination to the 14 days before vaccination. The median age was 70 years. The number of patients who received one, two, and three doses of the vaccine was 180, 88, and 4, respectively. ChAdOx1 was the primary vaccine used in our institutes, accounting for 86% of vaccinations. The vaccination was significantly associated with a 73% increase incidence of supraventricular tachycardia (SVT). In an adjusted model, factors associated with the incidence of SVT were the post-vaccination period, female sex, increasing BMI, chronic kidney disease, and a history of atrial fibrillation. Increased ventricular arrhythmia (VA) episodes were also associated with the post-vaccination period, female sex, decreasing BMI, and chronic kidney disease, but to a lesser degree than those with SVT episodes. No life-threatening arrhythmia was noted in this study. In conclusion, the incidence of arrhythmia in patients implanted with CIEDs was significantly increased after the SARS-CoV-2 vaccination.

Association between RNAm-Based COVID-19 Vaccines and Permanency of Menstrual Cycle Alterations in Spanish Women: A Cross-Sectional Study. Introduction: The purpose of this study was to delve more deeply into the medium and long-term relation between mRNA-based vaccines and changes in menstrual pain, cycle length, and amount of bleeding in Spanish women. Material and Methods: A total of 746 women (63% between 18âˆ’30 and 37% between 31âˆ’45 years old) participated in the study. A numerical rating scale was used for recording pain intensity, a pictorial chart for menstrual bleeding, and data from menstrual cycle duration, type of vaccine, number of doses and time from vaccination. Results: Sixty-five per cent of the women perceived changes in their menstrual cycle after receiving the vaccines, irrespective of type of vaccine or number of doses; all p values were >0.05. Most of them (n = 316 out of 484) reported more than one alteration in their menstrual cycle. Almost half of the participants had been vaccinated over 5 months (45%), 3âˆ’4 months (15%) 2âˆ’3 months (26%), and one month or less (13%) before. The percentage of women that reported alterations remained strongly constant across time, p > 0.05, ranging from 64 to 65%. Conclusions: Reported alterations in Spanish women after COVID vaccination remained more than 5 months after the last dose.

Spatial modeling of vaccine deserts as barriers to controlling SARS-CoV-2. BACKGROUND: COVID-19 vaccine distribution is at risk of further propagating the inequities of COVID-19, which in the United States (US) has disproportionately impacted the elderly, people of color, and the medically vulnerable. We sought to measure if the disparities seen in the geographic distribution of other COVID-19 healthcare resources were also present during the initial rollout of the COVID-19 vaccine. METHODS: Using a comprehensive COVID-19 vaccine database (VaccineFinder), we built an empirically parameterized spatial model of access to essential resources that incorporated vaccine supply, time-willing-to-travel for vaccination, and previous vaccination across the US. We then identified vaccine deserts-US Census tracts with localized, geographic barriers to vaccine-associated herd immunity. We link our model results with Census data and two high-resolution surveys to understand the distribution and determinates of spatially accessibility to the COVID-19 vaccine. RESULTS: We find that in early 2021, vaccine deserts were home to over 30 million people, >10% of the US population. Vaccine deserts were concentrated in rural locations and communities with a higher percentage of medically vulnerable populations. We also find that in locations of similar urbanicity, early vaccination distribution disadvantaged neighborhoods with more people of color and older aged residents. CONCLUSION: Given sufficient vaccine supply, data-driven vaccine distribution to vaccine deserts may improve immunizationÂ rates and help control COVID-19.

 COVID-19 has affected the elderly, people of color, and individuals with chronic illnesses more than the general population. Large barriers to accessing the COVID-19 vaccine could make this problem worse. We used a website called VaccineFinder, which has information on the location of most COVID-19 vaccineÂ doses in the US, to measure vaccine accessibility in early 2021. We then identified vaccine deserts, defined as small US regions with poor access to the COVID-19 vaccine. We found that over 10% of the US lived in a vaccine desert. Overall, we found that vaccines were less available to people in rural areas, people of color, and individuals with chronic illnesses. It will be important to reverse this pattern and ensure enough vaccines are sent to these communities to help reduce the spread of COVID-19.

Body fat percentage is independently and inversely associated with serum antibody responses to SARS-CoV-2 mRNA vaccines. Vaccination is widely considered the most effective preventative strategy to protect against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection. An individual's exercise habits, and physical fitness have been shown to impact the immune response following vaccination using traditional vaccine platforms, but their effects are not well characterized following administration of newer vaccination technology (mRNA vaccines). We investigated these

effects on the magnitude of antibody responses following SARS-CoV-2 mRNA vaccination while accounting for known covariates (age, sex, time since vaccination, and the type of vaccine administered). Adults of varying fitness levels (18-65Â years; Nâ€‰=â€‰50) who had received either the Moderna or Pfizer SARS-CoV-2 mRNA vaccine between 2Â weeks and 6Â months prior, completed health history and physical activity questionnaires, had their blood drawn, body composition, cardiorespiratory fitness, and strength assessed. Multiple linear regressions assessed the effect of percent body fat, hand grip strength, cardiorespiratory fitness, and physical activity levels on the magnitude of receptor binding domain protein (RBD) and spike protein subunit 1 (S1) and 2 (S2) while accounting for known covariates. Body fat percentage was inversely associated with the magnitude of S1 (pâ€‰=â€‰0.006, Î²â€‰=â€‰-â€‰366.56), RBD (pâ€‰=â€‰0.003, Î²â€‰=â€‰-â€‰249.30), and S2 (pâ€‰=â€‰0.106, Î²â€‰=â€‰-â€‰190.08) antibodies present in the serum following SARS-CoV-2 mRNA vaccination. Given the increasing number of infections, variants, and the known waning effects of vaccination, future mRNA vaccinations such as boosters are encouraged to sustain immunity; reducing excess body fat may improve the efficacy of these vaccinations.

Guillain-BarrÃ© syndrome temporally associated with COVID-19 vaccines in Victoria, Australia. Guillain-BarrÃ© syndrome (GBS) is an adverse event of special interest (AESI) for surveillance systems monitoring adverse events following immunisation (AEFI) with COVID-19 vaccines. Emerging data support a temporal association between GBS and adenovirus-vector COVID-19 vaccines. We present a case series of GBS reports submitted between February and November 2021 to our enhanced spontaneous surveillance system (SAEFVIC) in Victoria, Australia, following vaccination with either the adenovirus-vector vaccine Vaxzevria ChadOx1-S (AstraZeneca) or an mRNA vaccine (Comirnaty BNT162b2 [Pfizer-BioNTech] or Spikevax mRNA-1273 [Moderna]). For each report, Brighton Collaboration case definitions were used to describe diagnostic certainty. Severity was graded using the GBS Disability Score. The observed incidence of GBS following immunisation against COVID-19 was compared to expected background ICD10-AM G61.0 coded hospitalisations. There were 41 total cases of GBS reported to SAEFVIC following Vaxzevria (nÂ =Â 38), Comirnaty (nÂ =Â 3), or Spikevax (nÂ =Â 0) vaccines. The observed GBS incidence rate exceeded the expected background rate for Vaxzevria only, with 1.85 reports per 100,000 doses following dose 1, higher than the expected rate of 0.39 hospital admissions per 100,000 adults within 42Â days of vaccination. Of 38 GBS reports following Vaxzevria, the median age at vaccination was 66Â years and median onset of symptoms was 14Â days following immunisation. There was one death. Four cases initially categorised as GBS were later reclassified as acute-onset chronic inflammatory demyelinating polyneuropathy. Fatigue was the predominant persisting symptom reported at follow up. Additional global studies are required to characterise risk factors, clinical variability, and to provide precision and generalizability regarding AEFI risks such as GBS associated with different vaccine platforms, which will help inform communication of the potential benefits and risks of COVID19 vaccination.

The early evolution of COVID-19 incidence and mortality among people aged under 80Â years or 80Â years and above after COVID-19 vaccine implementation in the state of Bahia, Brazil. This study evaluates the early effects of COVID-19 vaccine implementation in the number of cases and deaths due to COVID-19 among those agedÂ <Â 80Â years orÂ â‰¥Â 80Â years in the state of Bahia, Brazil. For that, we used data from the Bahia state Secretary of Health platform of cases and deaths due to COVID-19 in all age groups, between March 2020 and May 2021, when 82% of COVID-19 vaccines were CoronaVac. Overall, there were 1,012,200 cases and 21,241 deaths due to COVID-19, of which, respectively, 2.3% and 25.3% occurred in patients agedÂ â‰¥Â 80Â years. The median proportion of deaths in thoseÂ â‰¥Â 80Â years decreased from 29.8% (27.8%-30.4%) in the pre- to 18.8% (15.6%-18.8%) in the post-vaccine periods (pÂ =Â 0.04). Significant reduction in the median proportion of deaths from COVID-19 among those agedÂ â‰¥Â 80Â years after COVID-19 vaccine

implementation was found, which suggests CoronaVac effectiveness against death from COVID-19 in the elderly.
Sputnik V vaccine-related complications and its impression on inflammatory biomarkers in healthcare providers. PURPOSE: The current pandemic made scientists create new platforms of vaccines to fight against SARS-CoV-2. Without a doubt, the new forms of present vaccines could develop a diversity of unknown complications. Sputnik V vaccine with two different adenovirus vectors (Ad26 priming and Ad5 boost) was first announced safe and effective by Russia. However, there are controversies surrounding this vaccine such as the possible decline of its immunogenicity and diminished neutralizing capacity against some Covid-19 variants. In addition, its impression on serum biomarkers is not clearly surveyed. The present study aimed to evaluate the frequency of Sputnik V vaccine-related complications and its impression on inflammatory and hematologic biomarkers. MATERIALS &METHODS: An observational cohort study was performed to evaluate the side effects and serum biomarkers changes in healthcare workers receiving Sputnik V vaccine. The vaccine adverse events were recorded daily within 60 days. The blood samples were obtained before vaccination, and on the10th day after each dose of vaccination. The prevalence of all complications and inflammatory biomarkers levels were compared between two doses. All analyses were performed using SPSS software version 22.0. RESULTS: Totally, 126 participants completed the study. The mean age was 37.19Â â€‹Â±Â â€‹7.73 years. The prevalence of all complications was higher following the first dose than the second dose. The most common side effects were pain at the injection site, body pain, fever, headache, weakness, vertigo, sore throat and sleep disorder. The hematocrit, mean corpuscular volume of red blood cells and neutrophils count declined following vaccination significantly (P-value; 0.04, 0.039, 0.000 respectively). CONCLUSION: It seems the side effects of Sputnik-V vaccine are mild and decrease significantly after the second dose. The decreasing level of hematocrit, MCV and neutrophil count was found significant following vaccination.
Follow-Up Cardiovascular Magnetic Resonance Findings in Patients With COVID-19 Vaccination-Associated Acute Myocarditis.
Myocarditis Following COVID-19 Vaccination: A Follow-up Magnetic Resonance Imaging Study.
Short-Term Outcomes After Myopericarditis Related to COVID-19Â Vaccination.
Miller Fisher syndrome after Pfizer BioNTech vaccine booster responsive to intravenous Ig treatment.
Comparative Risk of Myocarditis/Pericarditis Following Second Doses ofÂ BNT162b2 and mRNA-1273 CoronavirusÂ Vaccines. BACKGROUND: Postmarketing evaluations have linked myocarditis to COVID-19 mRNA vaccines. However, few population-based analyses have directly compared the safety of the 2 mRNA COVID-19 vaccines. OBJECTIVES: This study aimed to compare the risk of myocarditis, pericarditis, and myopericarditis between BNT162b2 and mRNA-1273. METHODS: We used data from the British Columbia COVID-19 Cohort (BCC19C), a population-based cohort study. The exposure was the second dose of an mRNA vaccine. The outcome was diagnosis of myocarditis, pericarditis, or myopericarditis during a hospitalization or an emergency department visit within 21Â days of the second vaccination dose. We performed multivariable logistic regression to assess the association between vaccine product and the outcomes of interest. RESULTS: The rates of myocarditis and pericarditis per million second doses were higher for mRNA-1273 (nÂ =Â 31, rate 35.6; 95%Â CI: 24.1-50.5; and nÂ =Â 20, rate 22.9; 95%Â CI: 14.0-35.4, respectively) than BNT162b2 (nÂ =Â 28, rate 12.6; 95%Â CI: 8.4-18.2 and nÂ =Â 21, rate 9.4; 95%Â CI: 5.8-14.4, respectively). mRNA-1273 vs BNT162b2 had significantly higher odds of myocarditis (adjusted OR [aOR]: 2.78; 95%Â CI: 1.67-4.62), pericarditis (aOR: 2.42; 95%Â CI: 1.31-4.46) and myopericarditis (aOR: 2.63; 95%Â CI: 1.76-3.93). The association between mRNA-1273 and myocarditis was stronger for men (aOR: 3.21; 95%Â CI: 1.77-5.83) and younger age group (18-39 years; aOR: 5.09; 95%Â CI: 2.68-9.66). CONCLUSIONS: Myocarditis/pericarditis following mRNA COVID-19 vaccines is rare, but we observed

a 2- to 3-fold higher odds among individuals who received mRNA-1273 vs BNT162b2. The rate of myocarditis following mRNA-1273 receipt is highest among younger men (ageÂ 18-39 years) and does not seem to be present at older ages. Our findings may have policy implications regarding the choice of vaccine offered.

The effect of COVID-19 vaccination on the menstrual pattern and mental health of the medical students: A mixed-methods study from a low and middle-income country. OBJECTIVE: To assess the effect of COVID-19 vaccination on menstrual patterns and mental health of medical students and to explore the students' perspective regarding this effect. MATERIALS AND METHODS: This mixed-method study was conducted on the medical and dental students of the private and public sector institutions of Peshawar from September 2021 to March 2022. A Menstrual symptom questionnaire (MSQ) and hospital anxiety and depression scale (HADS) were used. This was followed by qualitative interviews with the students who faced problems in their menstruation after the COVID-19 vaccination. RESULTS: A total of 953 students were included, with a mean age of 20.67Â±1. 56 years. More than half (n = 512, 53.7%) experienced menstrual cycle abnormalities post-vaccination. The majority having disturbances in their menstrual cycle had significantly higher levels of anxiety (p = 0.000). Results on the menstrual symptom questionnaire, anxiety, and depression subtype of HADS showed a negative and statistically significant relationship with changes after COVID-19 vaccination (p<0.05). In the qualitative interviews, 10 (58.8%) students each had problems with frequency and flow, followed by 7 (41.2%) students, who had dysmenorrhea. Seven (41.2%) consulted a gynecologist for management. The majority (n = 14, 82.4%) stated that these issues had an adverse impact on their mental health and almost half (n = 8, 47.1%) suggested consulting a gynecologist while facing such situations. CONCLUSION: This study showed the impact of the COVID-19 vaccine on women`s menstrual patterns and subsequent mental health status. Although the majority of the students experienced menstrual cycle abnormalities and subsequent mental health adversities post COVID-19 vaccination but these were temporary and self-limiting and were attributed to the psychological impact of the vaccination. Therefore, it is imperative to alert health care professionals about possible side effects and prior counseling is expected to play an important role in this context.

COVID-19-Associated Hospitalizations Among U.S. Infants Aged <6 Months - COVID-NET, 13 States, June 2021-August 2022. COVID-19-associated hospitalization rates are highest among adults aged â‰¥65 years (1); however, COVID-19 can and does cause severe and fatal outcomes in children, including infants (2,3). After the emergence of the SARS-CoV-2 B.1.1.529 (Omicron) BA.1 variant in December 2021, hospitalizations among children aged <5 years, who were ineligible for vaccination, increased more rapidly than did those in other age groups (4). On June 18, 2022, CDC recommended COVID-19 vaccination for infants and children aged â‰¥6 months (5). Data from the Coronavirus Disease 2019-Associated Hospitalization Surveillance Network (COVID-NET)* were analyzed to describe changes in the age distribution of COVID-19-associated hospitalizations since the Delta-predominant period (June 20-December 18, 2021)(â€) with a focus on U.S. infants aged <6 months. During the Omicron BA.2/BA.5-predominant periods (December 19, 2021â€“August 31, 2022), weekly hospitalizations per 100,000 infants aged <6 months increased from a nadir of 2.2 (week ending April 9, 2022) to a peak of 26.0 (week ending July 23, 2022), and the average weekly hospitalization rate among these infants (13.7) was similar to that among adults aged 65-74 years (13.8). However, the prevalence of indicators of severe disease(Â§) among hospitalized infants did not increase since the B.1.617.2 (Delta)-predominant period. To help protect infants too young to be vaccinated, prevention should focus on nonpharmaceutical interventions and vaccination of pregnant women, which might provide protection through transplacental transfer of antibodies (6).

Acute multifocal placoid pigment epitheliopathy following administration of the first dose of the BNT162B2 COVID-19 vaccine.

Low incidence of neurological recurrent side-effects following COVID-19 reimmunization. BACKGROUND: Individuals who suffered a neurological adverse event after the Coronavirus disease (COVID-19) vaccine could hesitate and defer reimmunization. AIM: We examine the risk of recurrence following reimmunization among patients who developed a neurological event after the first dose of the COVID-19 mRNA vaccine. DESIGN: Observational study. METHODS: Individuals who developed an adjudicated neurological adverse event (based on Brighton Collaboration criteria) within 6â€‰weeks of the first dose of the COVID-19 vaccine requiring hospitalization were enrolled into a multicenter national registry in Singapore. Neurological recurrence, defined by the development of another neurological event within 6â€‰weeks of the second vaccine dose, was reviewed. Clinical characteristics were compared between patients who chose to proceed or withhold further vaccination, and between those who received timely (3-6â€‰weeks) or delayed (>6â€‰weeks) reimmunization. RESULTS: From 235 patients (median age, 67â€‰years; 63% men) who developed an adjudicated neurological event after their first dose of mRNA vaccine between 30 December 2020 and 20 April 2021, 181 (77%) chose to undergo reimmunization. Those who decided against reimmunization were older (median age, 74 vs. 66â€‰years) and had greater physical disability following their primary neurological event (46% vs. 20%, Pâ€‰<â€‰0.001). Patients who suffered greater physical disability were three times more likely to delay their reimmunization (odds ratio 3.36, 95% confidence interval: 1.76-6.40). Neurological recurrence was observed in only four individuals (three with seizures and one with myasthenia gravis exacerbation). CONCLUSIONS: A prior neurological event should not necessarily preclude reimmunization and the decision to proceed with reimmunization should consider the overwhelming benefits conferred by vaccination toward ending this pandemic.

[Evaluation of the COVID-19 vaccination after broad implementation-an interim conclusion for Germany in JulyÂ 2022]. Vaccines against COVID-19 have been available in Germany since December 2020. At the Robert Koch Institute (RKI), the Immunization Unit is responsible for monitoring vaccination coverage and assessment of vaccine effectiveness. This article provides an overview of the respective reporting structures, vaccination databases, and epidemiological studies established by the Immunization Unit during the COVID-19 pandemic. We describe the COVID-19 Digital Vaccination Coverage Monitoring (DIM), which provides daily updates on vaccination coverage by age group. We next describe how, based on the DIM data and COVID-19 case data, the assessment of vaccine effectiveness against different clinical endpoints (hospitalization, intensive care, death) is performed. While this method is used for aÂ preliminary estimate of vaccine efficacy, population-based nonrandomized studies are able to provide more precise and detailed estimates under "real-world" conditions. In this context, we describe the hospital-based case-control study COViK, which is being conducted in collaboration with the Paul Ehrlich Institute (PEI). We discuss strengths and limitations of the abovementioned structures and tools. Finally, we provide an outlook on future challenges that may arise during the ongoing pandemic and during the transition phase into an endemic situation.

Vasculitic flare in a patient with anti-myelin-associated glycoprotein (MAG) antibody following mRNA-1273 SARS-CoV-2 vaccine.

Approaches to pretransplant vaccination. PURPOSE OF REVIEW: The aim of this study was to summarize new data and perspectives in pretransplant vaccination, with a particular focus on COVID-19 vaccination and vaccination requirements. RECENT FINDINGS: Pretransplant vaccination produces superior markers of immunity and is expected to have greater clinical benefit, compared with posttransplant vaccination. As such, efforts are underway to identify and characterize barriers to pretransplant vaccination, with a particular focus on COVID-19 vaccine hesitancy. Unfortunately, vaccine hesitancy is common in transplant patients, often motivated by individual side effect and

safety concerns. COVID-19 vaccination requirements have been implemented in some centres, informed by ethical principles, including beneficence, utility and justice. SUMMARY: Barriers to pretransplant vaccination can be understood in three categories: hard stops, including issues of vaccine availability, eligibility, safety and feasibility; soft stops, including issues of convenience, prioritization and care coordination; and volitional stops related to vaccine hesitancy and refusal. All of these barriers present opportunities for improvement based on recent data.

Safety of coronavirus disease 2019 vaccines in 213 adult patients with sickle cell disease. Given the lack of information about safety of the COVID-19 vaccines for sickle cell disease (SCD) patients, we sought to determine whether COVID-19 vaccine was associated with subsequent hospital admission for vaso-occlusive events (VOEs). We included 402 patients with SCD, including 88 regularly transfused. As of July 31, 2021, 213 (53.0%) of them had received a least one dose of COVID vaccine (Pfizer 93.0%). We showed similar risk of hospital admission for a VOE among vaccinated patients (whether transfused or not) and among a control group of non-vaccinated patients matched for age, sex and genotype.

In-silico evaluation of adenoviral COVID-19 vaccination protocols: Assessment of immunological memory up to 6 months after the third dose. BACKGROUND: The immune response to adenoviral COVID-19 vaccines is affected by the interval between doses. The optimal interval is unknown. AIM: We aim to explore in-silico the effect of the interval between vaccine administrations on immunogenicity and to analyze the contribution of pre-existing levels of antibodies, plasma cells, and memory B and T lymphocytes. METHODS: We used a stochastic agent-based immune simulation platform to simulate two-dose and three-dose vaccination protocols with an adenoviral vaccine. We identified the model's parameters fitting anti-Spike antibody levels from individuals immunized with the COVID-19 vaccine AstraZeneca (ChAdOx1-S, Vaxzevria). We used several statistical methods, such as principal component analysis and binary classification, to analyze the correlation between pre-existing levels of antibodies, plasma cells, and memory B and T cells to the magnitude of the antibody response following a booster dose. RESULTS AND CONCLUSIONS: We find that the magnitude of the antibody response to a booster depends on the number of pre-existing memory B cells, which, in turn, is highly correlated to the number of T helper cells and plasma cells, and the antibody titers. Pre-existing memory T cytotoxic cells and antibodies directly influence antigen availability hence limiting the magnitude of the immune response. The optimal immunogenicity of the third dose is achieved over a large time window, spanning from 6 to 16 months after the second dose. Interestingly, after any vaccine dose, individuals can be classified into two groups, sustainers and decayers, that differ in the kinetics of decline of their antibody titers due to differences in long-lived plasma cells. This suggests that the decayers may benefit from a tailored boosting schedule with a shorter interval to avoid the temporary loss of serological immunity.

Short-term safety and immunogenicity of inactivated and peptide-based SARS-CoV-2 vaccines in patients with endocrine-related cancer. BACKGROUND: The aim of this study was to explore the short-term safety and immunogenicity of inactivated and peptide-based SARS-CoV-2 vaccines in patients with endocrine-related cancer (ER). METHODS: Eighty-eight patients with ER cancer and 82 healthy controls who had completed a full course of inactivated or peptide-based SARS-CoV-2 vaccines were recruited. Adverse events (AEs) were recorded. Responses to receptor-binding domain IgG antibody (anti-RBD-IgG), neutralizing antibodies (NAbs) and RBD+ memory B cells (MBCs) were evaluated. RESULTS: Approximately 26.14% (23/88) of patients with ER cancer reported AEs within 7 days, which was comparable to that reported by healthy controls (24.39%, 20/82). Both the overall seroprevalence of anti-RBD-IgG and NAbs was obviously lower in the cancer group (70.45% vs. 86.59%, $P < 0.05$; 69.32% vs. 82.93%, $P < 0.05$, respectively). Anti-RBD-IgG and NAbs titers exhibited similar results, and dropped gradually over time. Patients with ongoing treatment had an attenuated

immune response, especially in patients receiving active chemotherapy. The frequency of overall RBD+ MBCs was similar between the two groups, but the percentage of active MBCs was remarkably reduced in patients with ER cancer. Unlike antibody titers, MBCs responses were relatively constant over time. CONCLUSION: Inactivated and peptide-based COVID-19 vaccines were well tolerated, but with lower immunogenicity for ER cancer patients. More intensive antibody monitoring and timely booster immunization is recommended for patients with ER cancer presenting disordered subpopulations of RBD+ MBCs.

Vaccine-induced immune thrombotic thrombocytopenia: Updates in pathobiology and diagnosis. Coronavirus disease 2019 (COVID-19) is a viral respiratory infection caused by the severe acute respiratory syndrome virus (SARS-CoV-2). Vaccines that protect against SARS-CoV-2 infection have been widely employed to reduce the incidence of symptomatic and severe disease. However, adenovirus-based SARS-CoV-2 vaccines can cause a rare, thrombotic disorder termed vaccine-induced immune thrombotic thrombocytopenia (VITT). VITT often develops in the first 5 to 30 days following vaccination and is characterized by thrombocytopenia and thrombosis in unusual locations (e.g., cerebral venous sinus thrombosis). The diagnosis is confirmed by testing for anti-PF4 antibodies, as these antibodies are capable of platelet activation without any cofactor. It can be clinically challenging to differentiate VITT from a similar disorder called heparin-induced thrombocytopenia (HIT), since heparin is commonly used in hospitalized patients. VITT and HIT have similar pathobiology and clinical manifestations but important differences in testing including the need for PF4-enhanced functional assays and the poor reliability of rapid immunoassays for the detection of anti-platelet factor 4 (PF4) antibodies. In this review we summarize the epidemiology of VITT; highlight similarities and differences between HIT and VITT; and provide an update on the clinical diagnosis of VITT.

COVID-19 Vaccine-Associated Lymphadenopathy Mimicking Regrowth of Axillary Lymph Node Metastasis of Lung Adenocarcinoma. We encountered a woman with re-enlarged axillary lymph nodes during a computed tomography (CT) scan for surveillance of lung adenocarcinoma with axillary lymph node metastasis at the initial diagnosis that had shrunk with standard chemotherapy. We first suspected cancer recurrence and considered a change in the chemotherapeutic regimen. However, after careful history taking regarding the timing of her Coronavirus Disease 2019 (COVID-19) vaccination, and subsequent careful, close follow-up, radiological shrinkage suggested a strictly benign cause. Especially in lung cancer with a medical history of axillary lymph node involvement, cliniciansshould be aware that vaccine-associated lymphadenopathy can mimic cancer recurrence and sometimesprompt serious misjudgment regarding a current treatment course and strategy.

COVID-19 vaccines associated with vasovagal malaise: A retrospective study in two mass vaccination centers and analysis of the WHO pharmacovigilance database. The association between COVID-19 vaccines and vasovagal malaise (VVM) has recently been reported in the literature. Our study aimed to describe COVID-19 vaccines associated VVM cases and to identify risk factors of COVID-19 vaccines associated VVM. To this end, we performed a descriptive study of VVM reports associated with COVID-19 vaccines from two French mass COVID-19 vaccination centers. We also extracted reports of VVM associated with all-COVID-19 vaccines in VigiBaseÂ®, the World Health Organization (WHO) pharmacovigilance database to analyze demographic data. In the two French mass vaccination center database, 408 entries reported VVM after the standard administration of tozinameran - PfizerÂ® (1.63/1,000 vaccinated persons). Of these cases, 213 (52.2%) occurred in women, and 193 (47.3%) occurred in the 18-29 year-old (yo) age group. In 232 cases (56.8%), patients had a history of anxiety related to needles or medical visits, 213 (52.2%) reported a fear of COVID-19 vaccination in particular, and 233 (57.1%) had a history of VVM. In VigiBaseÂ®, 336,291 notifications of COVID-19 vaccines associated with VVM were identified in the adult population during the period of analysis. The most reported age class was 18-44Â years (52.4%), and women represented 71.7% of the reports.

Reporting widely differed depending on the country. This study, performed in real-life conditions, highlights that VVM is associated with all-COVID-19 vaccines. Young age and history of anxiety related in young adults could be a triggering factor of vaccines-associated VVM. Further studies are needed to confirm our results.
First-Time Diagnosis of Spinal Cord Multiple Sclerosis after COVID-19 Booster Vaccination.
Humoral and cellular responses after a third dose of SARS-CoV-2 mRNA vaccine in patients with glomerular disease.
Hypoglossal nerve palsy after SARS-CoV-2 vaccination - report of two cases. BACKGROUND: SARS-CoV-2 vaccination is associated with an increased risk for Bell's palsy and some other neurological disorders assumed to be of autoimmune origin. While facial nerve palsy is frequent and usually idiopathic, hypoglossal nerve palsy is rare, and a specific cause is almost always found. We firstly report two patients who developed isolated hypoglossal nerve palsy shortly after SARS-CoV-2 vaccination. CASE PRESENTATION: Two otherwise healthy patients, a 49-year-old man and a 39-year-old woman, developed unilateral hypoglossal nerve palsy 10 and 7Â days after the second SARS-CoV-2-vaccination (AstraZeneca and BioNTech/Pfizer), respectively. In both subjects, needle electromyography showed denervation and rarefication of motor units. CT, MRI, examination of blood and CSF as well as ENT exam were unremarkable. In both subjects symptoms gradually improved. CONCLUSION: Due to close temporal relationship, the absence of other etiologies, and spontaneous improvement we suspect the vaccination as the cause for hypoglossal nerve palsy in both patients. This is further supported by the rarity of isolated hypoglossal nerve palsies, especially in idiopathic cases. We suggest the addition of hypoglossal nerve palsy to the list of neurological injuries potentially caused by SARS-CoV-2 vaccination.
Understanding thrombosis with thrombocytopenia syndrome after COVID-19 vaccination. Safety and efficacy of vaccines against the SARS-CoV-2 coronavirus has been demonstrated in clinical trials and next by their real world use through the course of the ongoing COVID-19 pandemic. However, very rare adverse events have been detected post-authorization in certain parts of the world. This meeting report summarizes an EMA workshopâ€™s discussion on the epidemiology, clinical presentation and biology of thrombosis with thrombocytopenia syndrome after adenovirus vector COVID-19 vaccination. General agreement was reached by international regulators, scientists and developers on the steps needed to fill the gaps in the characterization of this new syndrome. In particular, actions should be taken to improve the post-vaccination surveillance activities in low and middle income countries and investigate potential genetic predisposition factors.
Reactions following Pfizer-BioNTech COVID-19 mRNA vaccination and related healthcare encounters among 7,077 children aged 5-11 years within an integrated healthcare system. BACKGROUND: Studies combining data from digital surveys and electronic health records (EHR) can be used to conduct comprehensive assessments on COVID-19 vaccine safety. METHODS: We conducted an observational study using data from a digital survey and EHR of children aged 5-11Â years vaccinated with Pfizer-BioNTech COVID-19 mRNA vaccine across Kaiser Permanente Southern California during November 4, 2021-February 28, 2022. Parents/guardians who enrolled their children were sent a 14-day survey on reactions. Survey results were combined with EHR, and medical encounters were described for children whose parents or guardians indicated seeking medical care for vaccine-related symptoms. This study describes self-reported reactions (local and systemic) and additional symptoms (chest pain, tachycardia, and pre-syncope). RESULTS: The study recruited 7,077 participants aged 5-11Â years who received the Pfizer-BioNTech COVID-19 mRNA vaccine. Of 6,247 participants with survey responses after dose 1, 2,176 (35Â %) reported at least one systemic reaction, and 1,076 (32Â %) of 3,401 respondents following dose 2 reported at least one systemic reaction. Local reactions were reported less frequently following dose 2 (1,113, 33Â %) than dose 1 (3,140, 50Â %).

The most frequently reported reactions after dose 1 were pain at the injection site (48Â %), fatigue (20Â %), headache (12Â %), myalgia (9Â %) and fever (5Â %). The most frequently reported symptoms after dose 2 were also pain at the injection site (30Â %), fatigue (19Â %), headache (13Â %), myalgia (10Â %) and fever (9Â %). Post-vaccination reactions occurred most frequently-one day following vaccination. Chest pain or tachycardia were reported infrequently (1Â %). EHR demonstrated that parents rarely sought care for post-vaccination symptoms, and among those seeking care, the most common symptoms documented in EHR were fever and nausea, comprising <0.5Â % of children. No encounters were related to myocarditis. CONCLUSION: While post-vaccination reactions to the Pfizer-BioNTech COVID-19 mRNA vaccine were common in children aged 5-11Â years, our data showed that in most cases they were transient and did not require medical care.

Fatal Cerebral Venous Thrombosis in a Pregnant Woman with Inherited Antithrombin Deficiency after BNT162b2 mRNA COVID-19 Vaccination. Antithrombin deficiency is a high-risk factor for venous thromboembolism during pregnancy, whereas cerebral venous thrombosis is rare. Cerebral venous thrombosis related to coronavirus disease 2019 (COVID-19) vaccines has been reported; however, there are a few reports of cerebral venous thrombosis after a messenger RNA (mRNA) vaccination. A 25-year-old female in her sixth week of pregnancy presented with headache 24 days after BNT162b2 mRNA COVID-19 vaccination. The following day, she presented with altered sensorium and was diagnosed with severe cerebral venous thrombosis. She demonstrated heparin resistance and was found to have an inherited antithrombin deficiency. A heterozygous missense variant in SERPINC1 (c.379T>C, p.Cys127Arg, 'AT Morioka') was detected by DNA analysis. Despite intensive care with unfractionated heparin, antithrombin concentrate, and repeated endovascular treatments, she died on the sixth day of hospitalization. Cerebral venous thrombosis in pregnant women with an antithrombin deficiency can follow a rapid and fatal course. Treatment with unfractionated heparin and antithrombin concentrate may be ineffective in severe cerebral venous thrombosis cases with antithrombin deficiency. Early recognition of antithrombin deficiency and an immediate switch to other anticoagulants may be required. Although the association between cerebral venous thrombosis and the vaccine is uncertain, COVID-19 vaccinations may require careful evaluation for patients with prothrombic factors.

New-onset Adult-onset Still's Disease Following COVID-19 Vaccination: Three Case Reports and a Literature Review. Since December 2020, coronavirus disease 2019 (COVID-19) vaccines have been distributed in most countries to prevent the onset and aggravation of COVID-19. There is little information regarding the long-term safety of the vaccines. We report three cases and a literature review of new-onset adult-onset Still's disease (AOSD) that occurred following COVID-19 vaccination. Our cases include moderate to severe AOSD, and two were complicated with macrophage activation syndrome. Seventeen cases of new-onset or relapse of AOSD following COVID-19 vaccination, including 14 identified in the literature review and our 3 patients, were all treated successfully with glucocorticoid therapy, immunosuppressive drugs, or biologic agents.

Australasian Institute of Digital Health Summit 2022-Automated Social Media Surveillance for Detection of Vaccine Safety Signals: A Validation Study. BACKGROUND: Social media platforms have emerged as a valuable data source for public health research and surveillance. Monitoring of social media and user-generated data on the Web enables timely and inexpensive collection of information, overcoming time lag and cost of traditional health reporting systems. OBJECTIVES: This article identifies personally experienced coronavirus disease 2019 (COVID-19) vaccine reactions expressed on Twitter and validate the findings against an established vaccine reactions reporting system. METHODS: We collected around 3 million tweets from 1.4 million users between February 1, 2021, to January 31, 2022, using COVID-19 vaccines and vaccine reactions keyword lists. We performed topic modeling on a sample of the data and applied a modified F1 scoring technique to

identify a topic that best differentiated vaccine-related personal health mentions. We then manually annotated 4,000 of the records from this topic, which were used to train a transformer-based classifier to identify likely personally experienced vaccine reactions. Applying the trained classifier to the entire data set allowed us to select records we could use to quantify potential vaccine side effects. Adverse events following immunization (AEFI) referred to in these records were compared with those reported to the state of Victoria's spontaneous vaccine safety surveillance system, SAEFVIC (Surveillance of Adverse Events Following Vaccination In the Community). RESULTS: The most frequently mentioned potential vaccine reactions generally aligned with SAEFVIC data. Notable exceptions were increased Twitter reporting of bleeding-related AEFI and allergic reactions, and more frequent SAEFVIC reporting of cardiac AEFI. CONCLUSION: Social media conversations are a potentially valuable supplementary data source for detecting vaccine adverse event mentions. Monitoring of online observations about new vaccine-related personal health experiences has the capacity to provide early warnings about emerging vaccine safety issues.

Cases of severe acute liver injury following inactivated SARS-CoV-2 vaccination.

Association of health literacy, COVID-19 threat, and vaccination intention among Brazilian adolescents. OBJECTIVE: investigate the influence of health literacy on the assessment of COVID-19 threat to health and the intention not to be vaccinated among Brazilian adolescents. METHOD: cross-sectional study with 526 Brazilian adolescents aged 14 to 19 years. Socioeconomic aspects, health-disease profile, health literacy, health threat by COVID-19 and intention not to be vaccinated were analyzed by bivariate association and multiple linear regression with Poisson response. RESULTS: higher health literacy score (p=0.010), cardiovascular disease (p=0.006), lower income (p=0.000), and living in the North region (p=0.007) were factors that contributed to feeling more threatened by COVID-19. Health literacy did not influence the intention not to be vaccinated (p=0.091), whose prevalence was lower among adolescents in the Southeast region when compared to those in the North region (p=0.010), among those who attended higher education (p=0,049) and those with higher income (p=0.000). CONCLUSION: health literacy influenced the perception of COVID-19 threat, but not the intention not to be vaccinated. Assessment of COVID-19 threat to health and prevalence of the intention not to be vaccinated were influenced by the region of residence, income, and education, which reinforces the importance of social determinants of health in this context. KEYPOINTS: (1) Average health literacy (HL) score of Brazilian adolescents: 25.3 (p-HLAT-8). (2) Adolescents in the Southeast region felt less threatened by COVID-19. (3) Higher HL score indicated adolescents felt more threatened by COVID-19. (4) Intention not to be vaccinated was observed among adolescents with higher income and education. (5) About 87% of Brazilian adolescents want to be vaccinated against COVID-19.

Simultaneous unilateral central retinal vein occlusion and branch retinal artery occlusion after Coronavirus Disease 2019 (COVID-19) mRNA vaccine. A 51-year-old non-obese woman presented with a one-week history of progressive blurry vision within the inferior visual field of her left eye. Her only relevant past medical history was long-standing hypothyroidism and recent vaccination against Coronavirus Disease 2019 (COVID-19) with an mRNA vaccine 12 days before the onset of symptoms. At examination, the anterior segment was unremarkable, but the retinal fundus revealed a central retinal vein occlusion associated with a branch retinal artery occlusion of the superior temporal branch in her left eye. Ancillary tests to rule out thrombophilia, hyperviscosity, hypercoagulability, or inflammation were negative. Ultrasound tests were also negative for a cardiac or carotid origin of the branch retinal artery occlusion. At two-month follow-up, no new retinal vascular occlusive events were observed. Although the best-corrected visual acuity at presentation was 8/10 in the left eye, the final best-corrected visual acuity remained 3/10.

Comparison of Maternal and Neonatal Antibody Levels After COVID-19 Vaccination vs SARS-CoV-2 Infection. IMPORTANCE: Pregnant persons are at an increased risk of severe COVID-19 from SARS-CoV-2 infection, and COVID-19 vaccination is currently recommended during pregnancy. OBJECTIVE: To ascertain the association of vaccine type, time from vaccination, gestational age at delivery, and pregnancy complications with placental transfer of antibodies to SARS-CoV-2. DESIGN, SETTING, AND PARTICIPANTS: This cohort study was conducted in Pennsylvania Hospital in Philadelphia, Pennsylvania, and included births at the study site between August 9, 2020, and April 25, 2021. Maternal and cord blood serum samples were available for antibody level measurements for maternal-neonatal dyads. EXPOSURES: SARS-CoV-2 infection vs COVID-19 vaccination. MAIN OUTCOMES AND MEASURES: IgG antibodies to the receptor-binding domain of the SARS-CoV-2 spike protein were measured by quantitative enzyme-linked immunosorbent assay. Antibody concentrations and transplacental transfer ratios were measured after SARS-CoV-2 infection or receipt of COVID-19 vaccines. RESULTS: A total of 585 maternal-newborn dyads (median [IQR] maternal age, 31 [26-35] years; median [IQR] gestational age, 39 [38-40] weeks) with maternal IgG antibodies to SARS-CoV-2 detected at the time of delivery were included. IgG was detected in cord blood from 557 of 585 newborns (95.2%). Among 169 vaccinated persons without SARS-CoV-2 infection, the interval from first dose of vaccine to delivery ranged from 12 to 122 days. The geometric mean IgG level among 169 vaccine recipients was significantly higher than that measured in 408 persons after infection (33.88 [95% CI, 27.64-41.53] arbitrary U/mL vs 2.80 [95% CI, 2.50-3.13] arbitrary U/mL). Geometric mean IgG levels were higher after vaccination with the mRNA-1273 (Moderna) vaccine compared with the BNT162b2 (Pfizer/BioNTech) vaccine (53.74 [95% CI, 40.49-71.33] arbitrary U/mL vs 25.45 [95% CI, 19.17-33.79] arbitrary U/mL; Pâ€‰<â€‰.001). Placental transfer ratios were lower after vaccination compared with after infection (0.80 [95% CI, 0.68-0.93] vs 1.06 [95% CI, 0.98-1.14]; Pâ€‰<â€‰.001) but were similar between the mRNA vaccines (mRNA-1273: 0.70 [95% CI, 0.55-0.90]; BNT162b2: 0.85 [95% CI, 0.69-1.06]; Pâ€‰=â€‰.25). Time from infection or vaccination to delivery was associated with transfer ratio in models that included gestational age at delivery and maternal hypertensive disorders, diabetes, and obesity. Placental antibody transfer was detectable as early as 26 weeks' gestation. Transfer ratio that was higher than 1.0 was present for 48 of 51 (94.1%) births at 36 weeks' gestation or later by 8 weeks after vaccination. CONCLUSIONS AND RELEVANCE: This study found that maternal and cord blood IgG antibody levels were higher after COVID-19 vaccination compared with after SARS-CoV-2 infection, with slightly lower placental transfer ratios after vaccination than after infection. The findings suggest that time from infection or vaccination to delivery was the most important factor in transfer efficiency.

Optimizing Safety Surveillance for COVID-19 Vaccines at the National Pharmacovigilance Centre Lareb: One Year of COVID-19 Vaccine Experience. INTRODUCTION: Due to the COVID-19 vaccination campaign, national pharmacovigilance (PV) centres had to deal with high volumes of Individual Case Safety Reports (ICSRs) that needed to be processed and assessed in a short time span. This necessitated the development of a dedicated system to enable near real-time vaccine safety monitoring at the Dutch PV Centre Lareb. OBJECTIVES: To describe infrastructure, processes and Adverse Events Following Immunisation (AEFIs) reported for vaccine safety monitoring of COVID-19 vaccines during a large-scale vaccination campaign in the Netherlands. METHODS: A COVID-19 tailored vaccine web-based reporting form collected information on the vaccine administered, AEFIs and other (medical) information. A fully automated process for ICSRs enabled the handling of the majority of common and known reported AEFIs. All other ICSRs were triaged daily and processed separately. There were daily signal detection meetings and weekly reports for batch analysis. RESULTS: In 2021, Lareb received 184,411 ICSRs, a reporting rate of 0.67% for vaccines given in the

Netherlands. 887,954 AEFIs were reported, mostly well-known, nonserious AEFIs; 2.4% were serious and 0.3% were fatal. 33.1% of all ICSRs were processed fully automatically. Based on the daily triage, 4.2% were flagged as 'high priority'; 62.7% as 'low-priority'. Twenty-seven signals and news stories about the COVID-19 vaccines were disseminated. CONCLUSIONS: Due to automatic processing of well-known AEFIs, daily triage and signal detection meetings, 99.9% of the ICSRs were processed within the compliance timeframe to Eudravigilance, and signal detection was performed during a large-scale vaccination campaign. These experiences may serve as a blueprint for future mass vaccination programs.

Filling the gap in epidemiology, management and clinical course of COVID-19 vaccination-related pericarditis.

IgA quantification as a good predictor of the neutralizing antibodies levels after vaccination against SARS-CoV-2. BACKGROUND: Vaccination against COVID-19 was implemented very quickly, but the emergence of new variants that can evade the previous acquired immunological protection highlights the importance of understanding the mechanisms involved in the immune response generated after SARS-CoV-2 infection or vaccination. OBJECTIVES: Since most of our knowledge on the humoral immunity generated against SARS-CoV-2 has been obtained from studies with infected patients before vaccination, our goal here was to evaluate seroconversion and its correlation with the titers of neutralizing antibodies (NAbs) in individuals who received the complete initial recommended vaccination schedule with three different vaccines. STUDY DESIGN: We analyzed serum IgG, IgA and total NAbs against the trimeric SARS-CoV-2 Spike (S) protein or its receptor binding domain (RBD) in blood samples collected from 118 healthy individuals without known previous infection, before and after receiving the first and the second dose of CoronaVac (nÂ =Â 18), ChAdOx-1 (nÂ =Â 68) or BNT162b2 (nÂ =Â 32) vaccines. RESULTS: We found that although IgG titers were high in all sera collected after the two doses of these vaccines, NAbs amounts varies among the groups. In contrast, serum NAbs concentrations were much more comparable to the IgA levels, indicating that these antibodies would have a major neutralizing capacity against SARS-CoV-2. CONCLUSIONS: Altogether our data suggest that quantification of serum anti-S or anti-RBD IgA, rather than IgG, may be a valuable tool to screen NAbs and may be considered for surveillance of vaccine coverage.

Breakthrough infections, hospital admissions, and mortality after major COVID-19 vaccination profiles: A prospective cohort study. BACKGROUND: Several COVID-19 vaccination rollout strategies are implemented. Real-world data from the large-scale, government-mandated Central Vaccination Center (CVC), Thailand, could be used for comparing the breakthrough infection, across all available COVID-19 vaccination profiles. METHODS: This prospective cohort study combined the vaccine profiles from the CVC registry with three nationally validated outcome datasets to assess the breakthrough COVID-19 infection, hospitalization, and death among Thais individuals who received at least one dose of the COVID-19 vaccine. The outcomes were analyzed by comparing vaccine profiles to investigate the shot effect and homologous effect. FINDINGS: Of 2,407,315 Thais who had at least one dose of COVID-19 vaccine, 63,469 (2.75%) had breakthrough infection, 42,001 (1.79%) had been hospitalized, and 431 (0.02%) died. Per one vaccination shot added, there was an 18% risk reduction of breakthrough infection (adjusted hazard ratio [HR] 0.82, 95% confidence interval [CI] 0.80-0.82), a 25% risk reduction of hospitalization (HR 0.75, 95% CI 0.73-0.76), and a 96% risk reduction of mortality (HR 0.04, 95% CI 0.03-0.06). The heterologous two-shot vaccine profiles had a higher protective effect against infection, hospitalization, and mortality compared to the homologous counterparts. INTERPRETATION: COVID-19 breakthrough infection, hospitalization, and death differ across vaccination profiles that had a different number of shots and types of vaccines. FUNDING: This study did not involve any funding.

Response to the Letter to the Editor: "COVID-19 Infection Risk, Elective Arthroplasty and Surgical Complications, and COVID-19 Vaccination: Correspondence".

COVID-19 Infection Risk, Elective Arthroplasty and Surgical Complications, and COVID-19 Vaccination: Correspondence.

Menstrual Changes after COVID-19 Infection and COVID-19 Vaccination. BACKGROUND: Several factors such as stress, depression, infection, and vaccination influenced the menstrual cycle in women during the coronavirus disease 2019 (COVID-19) pandemic. We investigated whether there were changes in the menstrual cycle in women after COVID-19 vaccination or infection and, if so, the nature of the change. METHODS: This study was designed as a descriptive, cross-sectional study. A face-to-face survey was conducted among menstruating women aged 18-50 years from May 31 to July 31, 2022. Women were inquired about their first three menstrual cycles that occurred after COVID-19 infection or vaccination. RESULTS: Of 241 women with COVID-19 infection, 86 (35.7%) mentioned that they experienced various changes in their menstrual patterns in the first three cycles after infection. Of 537 participants who received various COVID-19 vaccines, 82 (15.1%) stated that they experienced changes in their menstrual patterns after vaccination. The incidence of postvaccination menstrual change was higher in women who received Pfizer-BioNTech and Sinovac (CoronaVac) vaccines. Only 10.9% of women who reported a change in their menstrual pattern after vaccination or infection consulted a physician. CONCLUSION: COVID-19 infection and vaccination can affect the menstrual cycle in women. It is important to be aware of the menstrual changes after COVID-19 infection and vaccination and to warn and inform women about this issue.

SARS-CoV-2 Vaccination as a Trigger for Perinuclear Antineutrophil Cytoplasmic Antibodies (p-ANCA) Associated With Rapidly Progressive Glomerulonephritis. The coronavirus disease 2019 (COVID-19) pandemic was devastating worldwide. The introduction of severe acute respiratory syndrome coronavirus 2 vaccination has reduced transmission, hospitalizations, and deaths, with infrequent major side effects. We present the case of a 51-year-old woman with rapidly progressive glomerulonephritis following COVID-19 vaccination with ChAdOx1 (AstraZeneca). Workup and histopathologic examination demonstrated active extracapillary proliferative lesions in cellular and fibrocellular crescents with extensive fibrinoid necrosis and karyorrhexis with diffuse glomerulonephritis, as well as positive perinuclear antineutrophil cytoplasmic antibodies. Treatment with cyclophosphamide and steroids was initiated with the improvement of renal function. Similar cases were seen with influenza vaccination, potentially describing vaccination as a possible trigger for anti-myeloperoxidase rapidly progressive glomerulonephritis.

Prurigo Nodularis Eruption Triggered by SARS-CoV-2 Vaccine. We discuss a case of a 63-year-old male who presented with generalized itchy papulonodular rash a few weeks after receiving a vaccination against SARS-CoV-2. The patientÂ had a negative medical history for atopic dermatitis and other pruritic skin conditions, and clinical presentation was consistent with prurigo nodularis, which was confirmed later by tissue biopsy and microscopic analysis. The pathophysiology of this skin condition is thoughtÂ to be due to an overlap between the immune and nervous systems. Due to the hypothesized involvement of the immune system in this disease, it. is presumed that the patient had a dysregulated immune response caused by his recentÂ SARS-CoV-2 vaccination.

Factors associated with COVID-19 vaccine intention in Benin in 2021: A cross-sectional study. INTRODUCTION: The development of COVID-19 vaccines has brought considerable hope for the control of the pandemic. With a view to promoting good vaccine coverage, this study aimed to measure vaccine intention against COVID-19 and to understand the factors that promote it. METHOD: In April 2021, we conducted a cross-sectional and analytical study at the national level through a telephone survey of Beninese aged 18Â years or older. We used a marginal quota sampling method (nÂ =Â 865) according to age, gender, and department. We constructed the questionnaire using a

theoretical framework of health intention. We determined the factors associated with intention to vaccinate against COVID-19 in Benin using a multinomial logistic regression at the 5Â % significance level. RESULTS: The intention to vaccinate was 64.7Â %; 10.9Â % of the population were hesitant, and 24.4Â % did not want to vaccinate. Thinking that it was important to get vaccinated (AORÂ =Â 0.274; CIÂ =Â 0.118-0.638) or that getting vaccinated will help protect loved ones from the virus (AORÂ =Â 0.399; CIÂ =Â 0.205-0.775) increased the intention to vaccinate. Having a high level of education (AORÂ =Â 1.988; CIÂ =Â 1.134-3.484), thinking that the vaccine could put one's health at risk (AORÂ =Â 2.259; CIÂ =Â 1.114-4.578), and hearing something negative about the vaccine (AORÂ =Â 1.765; CIÂ =Â 1.059-2.941) reduced intention to vaccinate. In addition, believing that the creators of the vaccine had ensured its safety (AORÂ =Â 0.209; CIÂ =Â 0.101-0.430), and believing that it was unlikely to be infected after vaccination (AORÂ =Â 0.359; CIÂ =Â 0.183-0.703) decreased hesitancy in favour of the intention to vaccinate. CONCLUSION: In April 2021, vaccine intention was high, but maintaining this high rate requires building confidence in the vaccine and combating misinformation about the vaccine.

A case of anti-melanoma differentiation-associated gene 5 antibody-positive dermatomyositis-associated rapidly progressive interstitial lung diseases developed after administration of COVID-19 vaccine and subsequent pneumococcal vaccine. Five cases of anti-melanoma differentiation-associated gene 5 antibody-positive dermatomyositis-associated rapidly progressive interstitial lung diseases (anti-MDA5-positive DM-RPILD) following COVID-19 vaccination have been reported previously. We present the first case of the disease that developed following the sequence of COVID-19 infection, COVID-19 vaccination, and 23-valent pneumococcal polysaccharide vaccine (PPSV23) administration. A 75-year-old-Japanese man received the third dose of Pfizer COVID-19 vaccine 4â€‰weeks after he had a mild COVID-19 infection. Eleven weeks after vaccination, he received PPSV23 for the first time. He developed fever, malaise, and anorexia the day after the PPSV23, rash a week later, and shortness of breath 2â€‰weeks later. He was then admitted to a local hospital and treated with antibiotics, but his condition worsened. He was transferred to our hospital 4â€‰weeks after the PPSV23 and was diagnosed with anti-MDA5-positive DM-RPILD. Despite intensive treatment, the patient died on the 10th hospital day.

Adverse reactions of different COVID-19 vaccines among healthcare professionals: A qualitative study in Mosul, Iraq. BACKGROUND: COVID-19 disease was highly infectious causing a declaration of a global pandemic and the scientists believed that developing a safe and effective vaccine was the solution. Various vaccine candidates were announced by different health authorities. Many factors affect the acceptance of vaccines. This study aims to explore the perceptions, attitudes, and expectations of healthcare professionals (HCPs) toward COVID-19 vaccines. METHOD: A qualitative study approach was conducted by using face-to-face semi-structured interviews with HCPs in Mosul city, Iraq. RESULTS: Twenty-five HCPs participated in the interviews. After qualitative analysis four main themes emerged: perception of vaccines; participants believed that vaccines were vital inventions, motivations to take the vaccine; most HCPs were motivated based on the scientific evidence regarding COVID-19 vaccines, expectations about the safety and efficacy of COVID-19 vaccines; participants had different opinions based on the type of the vaccine and the available data, side effects experienced; severe side effects were expected but only mild adverse reactions were experienced by the majority. CONCLUSION: HCPs had good knowledge about COVID-19 vaccines which was not affected by rumors and misinformation. In contrast to their expectations, the experienced side effects of the first and the second doses were mild to moderate in severity. The majority of HCPs based their choice of the vaccine on the efficacy and safety profile of the available options.

Maternal Antibody Response and Transplacental Transfer Following Severe Acute Respiratory Syndrome Coronavirus 2 Infection or Vaccination in Pregnancy. BACKGROUND: Pregnant persons are at increased risk of severe coronavirus disease 2019 (COVID-19) and adverse obstetric outcomes. Understanding maternal antibody response, duration, and transplacental transfer after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and COVID-19 vaccination is important to inform public health recommendations. METHODS: This prospective observational cohort study included 351 pregnant people who had SARS-CoV-2 infection or COVID-19 vaccination during pregnancy. Immunoglobulin (Ig) G and IgM to SARS-CoV-2 S1 receptor binding domain were measured in maternal and cord blood. Antibody levels and transplacental transfer ratios were compared across (1) disease severity for those with SARS-CoV-2 infection and (2) infection versus vaccination. RESULTS: There were 252 individuals with SARS-CoV-2 infection and 99 who received COVID-19 vaccination during pregnancy. Birthing people with more severe SARS-CoV-2 infection had higher maternal and cord blood IgG levels (P = .0001, P = .0001). Median IgG transfer ratio was 0.87-1.2. Maternal and cord blood IgG were higher after vaccination than infection (P = .001, P = .001). Transfer ratio was higher after 90 days in the vaccinated group (P < .001). Modeling showed higher amplitude and half-life of maternal IgG following vaccination (P < .0001). There were no significant differences by fetal sex. CONCLUSIONS: COVID-19 vaccination in pregnancy leads to higher and longer lasting maternal IgG levels, higher cord blood IgG, and higher transfer ratio after 90 days compared with SARS-CoV-2 infection. Greater infection severity leads to higher maternal and cord blood antibodies. Maternal IgG decreases over time following both vaccination and infection, reinforcing the importance of vaccination, even after infection, and vaccine boosters for pregnant patients.

Antigen specific T cells in people with obesity at five months following ChAdOx1 COVID-19 vaccination. BACKGROUND/OBJECTIVES: People with obesity (PWO) face an increased risk of severe outcomes from COVID-19, including hospitalisation, ICU admission and death. Obesity has been seen to impair immune memory following vaccination against influenza, hepatitis B, tetanus, and rabies. Little is known regarding immune memory in PWO following COVID-19 adenovirus vector vaccination. SUBJECTS/METHODS: We investigated SARS-CoV-2 specific T cell responses in 50 subjects, five months following a two-dose primary course of ChAdOx1 nCoV-19 (AZD1222) vaccination. We further divided our cohort into PWO (nâ€‰=â€‰30) and matched controls (nâ€‰=â€‰20). T cell (CD4(+), CD8(+)) cytokine responses (IFNÎ³, TNFÎ±) to SARS-CoV-2 spike peptide pools were determined using multicolour flow cytometry. RESULTS: Circulating T cells specific for SARS-CoV-2 were readily detected across our cohort, with robust responses to spike peptide stimulation across both T cell lines. PWO and controls had comparable levels of both CD4(+) and CD8(+) SARS-CoV-2 spike specific T cells. Polyfunctional T cells - associated with enhanced protection against viral infection - were detected at similar frequencies in both PWO and controls. CONCLUSIONS: These data indicate that PWO who have completed a primary course of ChAdOx1 COVID-19 vaccination have robust, durable, and functional antigen specific T cell immunity that is comparable to that seen in people without obesity.

Clinically suspected lethal viral myocarditis combined with encephalitis: a COVID-19 vaccine complication. This case study aimed to identify rare viral myocarditis combined with encephalitis as a COVID-19 vaccine complication. A 59-year-old male patient with a 2Â day history of headache and rapidly progressive cognitive decline, who had received the third dose of COVID-19 vaccine 12Â days before, was admitted to our hospital. The patient had no underlying systemic conditions, no prior medical history, and no prior history of COVID-19 infection. The patient was diagnosed with viral myocarditis and encephalitis by two neurologists and two cardiologists after laboratory examination, head computed tomography, and magnetic resonance imaging evaluation. The patient experienced cardiogenic shock and developed severe arrhythmia, resulting in his death 10Â h after admission.

Clinically suspected lethal viral myocarditis combined with encephalitis in the patient could be related to COVID-19 vaccination. Adverse effects of the Chinese COVID-19 vaccine, especially serious complications, have been uncommon. This case study highlights a rare complication after COVID-19 vaccination that needs high attention.

Reporting complete heart block in a patient with polyarteritis nodosa after COVID-19 vaccination. Complete heart block (CHB) is a serious health condition, and polyarteritis nodosa (PAN) is an important autoimmune disease. In the COVID-19 pandemy, several vaccines were developed for the COVID-19 disease that shown several side effects, and some of these complications are still unknown. This is the first report of CHB in a patient with history of PAN after COVID-19 vaccination. A 68-year-old man with a history of PAN referred to our hospital, complaining of presyncope episodes and dizziness after receiving a COVID-19 vaccine. Physical examination, laboratory tests, and transthoracic echocardiography were normal. In his electrocardiogram, a narrow QRS complex, AV dissociation, and junctional escape rhythm were seen. Coronary angiography showed a mild coronary artery disease. The patient, suffering from PAN for years, was hypothesized due to CHB a few days after COVID-19 vaccination. This case report suggests that COVID-19 vaccines may interrupt the conduction system of the heart and the fact that underlying PAN may predispose to CHB following COVID-19 vaccination. Further studies are needed to accurately assess a possible association between PAN, CHB, and COVID-19 vaccines.

Factors associated with COVID-19 breakthrough infection among vaccinated patients with rheumatic diseases: A cohort study. OBJECTIVE: Rheumatic disease patients on certain immunomodulators are at increased risk of impaired humoral response to SARS-CoV-2 vaccines. We aimed to identify factors associated with breakthrough infection among patients with rheumatic diseases. METHODS: We identified patients with rheumatic diseases being treated with immunomodulators in a large healthcare system who received at least two doses of either the mRNA-1273 (Moderna) or BNT162b2 (Pfizer-BioNTech) vaccines or one dose of the Johnson & Johnson-Janssen (J&J) vaccine. We followed patients until SARS-CoV-2 infection, death, or December 15, 2021, when the Omicron variant became dominant in our region. We estimated the association of baseline characteristics with the risk of breakthrough infection using multivariable Cox regression. RESULTS: We analyzed 11,468 patients (75% female, mean age 60 years). Compared to antimalarial monotherapy, multiple immunomodulators were associated with higher risk of infection: anti-CD20 monoclonal antibodies (aHR 5.20, 95% CI: 2.85, 9.48), CTLA-4 Ig (aHR 3.52, 95% CI: 1.90, 6.51), mycophenolate (aHR 2.31, 95% CI: 1.25, 4.27), IL-6 inhibitors (aHR 2.15, 95% CI: 1.09, 4.24), JAK inhibitors (aHR 2.02, 95% CI: 1.01, 4.06), and TNF inhibitors (aHR 1.70, 95% CI: 1.09, 2.66). mRNA-1273 recipients had a lower risk of breakthrough infection compared to BNT162b2 recipients (aHR 0.66, 95% CI: 0.50, 0.86). There was no association of sex, body mass index, smoking status, race, or ethnicity with risk of breakthrough infection. CONCLUSION: Among patients with rheumatic diseases, multiple immunomodulators were associated with increased risk of breakthrough infection. These results highlight the need for additional mitigation strategies in this vulnerable population.

An autopsy case report of aortic dissection after mRNA COVID-19 vaccination: correspondence.

Thrombosis and bleeding after COVID-19 vaccination: do differences in sex matter? Gender medicine deals with differences in approach to diagnostic work-up and management according to gender. Although the issue is relevant in every field of medicine, it is often neglected. However, the recent SARS-CoV-2 pandemic has made consideration of gender even more urgent. In fact, available literature has suggested a higher number of deaths among infected men than in women and more side effects in women than in male recipients of certain anti-COVID-19 vaccines. This review examines sex-disaggregated data on thrombotic and bleeding events associated with vaccination against COVID-19. Thrombotic complications are by far more frequently reported than bleeding events after

vaccination and are mostly observed in young women receiving viral-vectored vaccines. However, detailed data that could help better stratify the risk according to sex/gender are generally lacking. Likewise, overall bleeding complications and those associated with a specific vaccine are mainly reported as aggregated data, including thrombocytopenia that is reported to occur in the presence or absence of thrombotic complications. Such information is important as it underlines the need to differentiate between thrombocytopenia with and without thrombosis because management and prognosis differ according to the association of thrombotic events. Here, we highlight how the lack of disaggregated data has led to the publication of conflicting information about adverse events by sex in recipients of viral-vectored vaccines. Lastly, we examine the possible mechanisms underlying vaccine-associated thrombotic and bleeding complications according to sex/gender.

Post-SARS-CoV-2 vaccination COVID toes and fingers correspondence.

Models of determinants of COVID-19 vaccine hesitancy in non-pregnant and pregnant population: Review of current literature". Vaccination has proven to be the most effective tool in controlling the COVID-19 pandemic. While pregnant individuals are considered to be a high-risk population and are more likely to experience adverse effects from COVID-19, vaccination rates among pregnant individuals are significantly lower than in the general population. The Health Belief Model (HBM), Theory of Planned Behavior (TPB), 3C model, 5C model, and 5A model have been used to assess vaccination hesitancy behaviors. In this paper, we review the use of each of these models to address vaccine hesitancy, with a focus on the pregnant population and the COVID-19 vaccine. The HBM, TPB, 3C model, and 5C model have demonstrated great versatility in their ability to evaluate, explain, and modify vaccine hesitancy and behavior. Up to date, the HBM and 3C models appear to be the most effective models to study and address vaccination hesitancy within the pregnant persons.

Willingness to Accept COVID-19 Vaccine and Associated Factors Among Adult Household Members in Dire Dawa City Administration, East Ethiopia. BACKGROUND: COVID-19 vaccine is a vital strategy to prevent and control this pandemic. This will depend principally on people's acceptance of COVID-19 vaccine. We aimed to determine the willingness to accept COVID vaccine among adult household members of Dire Dawa city administration. METHODS: A community-based cross-sectional study was conducted among randomly selected 634 adult household members in the Dire Dawa city administration during January 16-31/2022. Data were collected using face-to-face interview. Extent of willingness was estimated using participants' self-report. Bivariate and multivariate logistic regression models were fitted, and statistical significance was set at p-value <0.05. RESULTS: The estimated willingness to accept COVID-19 vaccine was 28.4% (95% CI 25.1, 31.5) in the study setting. The odds of willingness to accept COVID-19 vaccine was higher for household members living without at least one chronic disease (AOR 1.7, 95% CI 1.10, 2.70), who had good knowledge score (AOR 2.3, 95% CI 1.31, 2.18) and positive attitude score (AOR 5.5, 95% CI 2.1, 14.5) compared to their counterparts, respectively. The estimated willingness to accept COVID-19 vaccine among household members with good knowledge score was 47.4 (95% CI 42.1, 52.7) and 15.5 (95% CI 8.7, 22.2) among those with poor knowledge. Nearly, 90% of the study participants had limited knowledge about COVID 19 vaccine. CONCLUSION: The estimated willingness to accept COVID-19 vaccine in the study setting is very low and far from the set target to be reached by the end of 2022. Being free from chronic disease, and having good knowledge and positive attitude about COVID-19 vaccine were the main drivers for willingness. Public awareness directed to increase knowledge about COVID-19 vaccine and attitude change strategies should be scaled up to increase the COVID-19 vaccine uptake. Moreover, those individuals with chronic diseases need special attention.

Antibody status following booster vaccination against SARS-CoV-2 virus in patients with haematologic malignancies. Antibody titres in 462 patients with haematological malignancies after the second (D2) and third (D3) SARS-CoV-2 vaccine were compared with those of healthy controls (HCs).

Significant decay of antibody titre was observed pre D3, but titre surged post D3. The number of seronegative patients decreased from 79 (17.1%) to 44 (9.5%) from post D2 to post D3, and patients with adequate antibody titre increased from 204 (44.2%) to 358 (77.5%). Of the patients who received B-cell-targeted therapy, 80% were seronegative and 71% remained seronegative after D3. CD19+, CD4+, CD8+ cell counts, and immunoglobulin G (IgG) levels were identified as independent predictors for adequate serologic response.

Letter to the Editor: Rule Out Alternative Mechanisms Before Attributing Elevated Hemidiaphragm to Parsonage Turner Syndrome and SARS-CoV-2 Vaccination.

Reports of New and Recurrent Keratitis following mRNA-based COVID-19 Vaccination. PURPOSE: As ophthalmic side effects of messenger RNA (mRNA)-based COVID-19 vaccination are not well understood, it is crucial to document and report such instances should they occur. METHODS: In this observational case series, we report nine patients (55.6% male, mean age 58.9) who received either the BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna) COVID-19 vaccinations from January to June of 2021, and presented with symptoms of keratitis within 14Â days. All patients underwent slit-lamp examination and histories were taken. RESULTS: Most subjects (66.7%) had a history of corneal inflammatory diseases and resolved under antiviral and/or steroidal treatment. Patients who reported symptoms after their second vaccine dose presented earlier than those who reported symptoms after the first dose (mean 4.4Â days vs 10.5Â days, respectively). CONCLUSIONS: The immunological reaction following mRNA-based COVID-19 vaccinations may trigger new-onset or reactivation of keratitis, though causality cannot be proven. Despite its rarity, clinicians should be aware of this possible complication and be prepared to treat.

Association between treatment failure and hospitalization after receipt of neutralizing monoclonal antibody treatment for COVID-19 outpatients. BACKGROUND: Neutralizing monoclonal antibodies (mAbs) are highly effective in reducing hospitalization and mortality among early symptomatic COVID-19 patients in clinical trials and real-world data. While resistance to some mAbs has since emerged among new variants, characteristics associated with treatment failure of mAbs remain unknown. METHODS: This multicenter, observational cohort study included patients with COVID-19 who received mAb treatment between November 20, 2020, and December 9, 2021. We utilized electronic health records from a statewide health system plus state-level vaccine and mortality data. The primary outcome was mAb treatment failure, defined as hospitalization or death within 28Â days of a positive SARS-CoV-2 test. RESULTS: COVID-19 mAb was administered to 7406 patients. Hospitalization within 28Â days of positive SARS-CoV-2 test occurred in 258 (3.5%) of all patients who received mAb treatment. Ten patients (0.1%) died within 28Â days, and all but one were hospitalized prior to death. Characteristics associated with treatment failure included having two or more comorbidities excluding obesity and immunocompromised status (adjusted odds ratio [OR] 3.71, 95% confidence interval [CI] 2.52-5.56), lack of SARS-CoV-2 vaccination (OR 2.73, 95% CI 2.01-3.77), non-Hispanic black race/ethnicity (OR 2.21, 95% CI 1.20-3.82), obesity (OR 1.79, 95% CI 1.36-2.34), one comorbidity (OR 1.68, 95% CI 1.11-2.57), ageâ€‰â‰¥â€‰65Â years (OR 1.62, 95% CI 1.13-2.35), and male sex (OR 1.56, 95% CI 1.21-2.02). Immunocompromised status (none, mild, or moderate/severe), pandemic phase, and type of mAb received were not associated with treatment failure (all pâ€‰>â€‰0.05). CONCLUSIONS: Comorbidities, lack of prior SARS-CoV-2 vaccination, non-Hispanic black race/ethnicity, obesity, ageâ€‰â‰¥â€‰65Â years, and male sex are associated with treatment failure of mAbs.

Humoral immunity after second dose of BNT162b2 vaccine in Japanese communities: an observational cross-sectional study, Fukushima Vaccination Community Survey. To reveal waning humoral immunity after second dose BNT162b2 vaccinations in a rural Japanese community and determine factors affecting antibody titers. We aimed to report Immunoglobulin G (IgG) antibody

against the SARS-CoV-2 spike (S1) protein levels and neutralizing activity in a large scale community based cohort. METHODS: Participants in the observational cross-sectional study received a second dose of vaccination with BNT162b2 (Pfizer/BioNTech) and were not previously infected with COVID-19. Questionnaire-collected data on sex, age, adverse vaccine reactions, and medical history was obtained. RESULTS: Data from 2496 participants revealed that older age groups reached a low antibody titer 90-120Â days after the second vaccination. Neutralizing activity decreased with age; 35 (13.3%) of those agedâ€‰â‰¥â€‰80Â years had neutralizing activity under the cut-off value. Neutralizing activityâ€‰>â€‰179Â days from the second vaccination was 11.6% compared to that atâ€‰<â€‰60Â days from the second vaccination. Significantly lower IgG antibody titers and neutralizing activity were associated with age, male sex, increased time from second vaccination, smoking, steroids, immunosuppression, and comorbidities. CONCLUSIONS: Antibody titer decreased substantially over time. Susceptible populations, older people, men, smokers, steroid users, immunosuppression users, and people with three or more comorbidities may require a special protection strategy.

Association of malnutrition with SARS-CoV-2 vaccine response in patients undergoing hemodialysis. BACKGROUND & AIMS: Patients undergoing dialysis are less likely to develop immune responses to SARS-CoV-2 vaccine. Malnutrition is common in the dialysis population. However, whether malnutrition contributes to the impaired immunogenicity remains unknown. The aim of this study was to assess the association between nutritional status and SARS-CoV-2 vaccine response in patients receiving maintenance hemodialysis. METHODS: A total of 206 hemodialysis patients (mean age, 67Â Â±Â 13 years) without prior SARS-CoV-2 infection were examined for the primary outcome of seroconversion, defined as the detection of IgG antibodies (â‰¥50 AU/mL) to the receptor-binding domain of the S1 spike protein of SARS-CoV-2 one month after a priming dose of ChAdOx1 nCoV-19, an adenovirus-vectored vaccine. Nutritional status was assessed by using the Controlling Nutritional Status (CONUT) score, an objective indicator of nutrition incorporating serum albumin, total cholesterol, and total lymphocyte count, as well as the subjective global assessment (SGA). RESULTS: Overall, 16.5% of patients were classified as malnourished, and 64.1% of patients were at risk for malnutrition based on the CONUT score. Anti-SARS-CoV-2 IgG were the highest in patients with normal nutrition. In multivariate logistic regression analyses adjusted for age, sex, comorbidities, and use of immunosuppressants, patients with malnutrition remained less likely to develop an antibody response than those with normal nutrition (odds ratio 0.23, 95% CI, 0.07-0.76). SGA was a significant predictor of anti-SARS-CoV-2 IgG seroconversion in univariate but not multivariate analyses. CONCLUSIONS: Malnutrition according to CONUT score is associated with impaired humoral responses to SARS-CoV-2 vaccination in patients undergoing hemodialysis. Our results highlight the importance of incorporating nutritional assessment into routine dialysis care to identify patients at risk for suboptimal immune responses after SARS-CoV-2 vaccination. Further research is needed to determine whether nutritional intervention can improve immune responses in these vulnerable patients.

Impact of disruptions to routine vaccination programs, quantifying burden of measles, and mapping targeted supplementary immunization activities. Measles is a highly transmissible disease that requires high levels of vaccination coverage for control and elimination. Areas that are unable to achieve and maintain high coverage levels are at risk for measles outbreaks resulting in increased morbidity and mortality. Public health emergencies, such as the current COVID-19 pandemic, pose a threat to the functioning of health systems by disrupting immunization services which can derail measles vaccination efforts. Efforts to bridge coverage gaps in immunization include the rapid return to fully functioning services as well as deploying supplementary immunization activities (SIAs), which are additional vaccination campaigns intended to catch-up children who have missed routine

services. However, SIAs, which to date tend to be national efforts, can be difficult to mobilize quickly, resource-intensive, and even more challenging to deploy during a public health crisis. By mapping expected burden of measles, more effective SIAs that are setting-specific and resource-efficient can be planned and mobilized. Using a spatial transmission model of measles dynamics, we projected and estimated the expected burden of national and local measles outbreaks in Zambia with the current COVID-19 pandemic as a framework to inform disruptions to routine vaccination. We characterize the impact of disruptions to routine immunization services on measles incidence, map expected case burden, and explore SIA strategies to mitigate measles outbreaks. We find that disruptions lasting six months or longer as well as having low MCV1 coverage prior to disruptions resulted in an observable increase of measles cases across provinces. Targeting provinces at higher risk of measles outbreaks for SIAs is an effective strategy to curb measles virus incidence following disruptions to routine immunization services.

Letter to the editor regarding article "Hlaca N, Zagar T, Kastelan M, Peternel S, Brajac I, Prpic-Massari L. New-onset lichen planus and lichen planus flare in elderly women after COVID-19 vaccination. J Cosmet Dermatol. 2022;10.1111/jocd.15185".

Human type I IFN deficiency does not impair B cell response to SARS-CoV-2 mRNA vaccination. Inborn and acquired deficits of type I interferon (IFN) immunity predispose to life-threatening COVID-19 pneumonia. We longitudinally profiled the B cell response to mRNA vaccination in SARS-CoV-2 naive patients with inherited TLR7, IRF7, or IFNAR1 deficiency, as well as young patients with autoantibodies neutralizing type I IFNs due to autoimmune polyendocrine syndrome type-1 (APS-1) and older individuals with age-associated autoantibodies to type I IFNs. The receptor-binding domain spike protein (RBD)-specific memory B cell response in all patients was quantitatively and qualitatively similar to healthy donors. Sustained germinal center responses led to accumulation of somatic hypermutations in immunoglobulin heavy chain genes. The amplitude and duration of, and viral neutralization by, RBD-specific IgG serological response were also largely unaffected by TLR7, IRF7, or IFNAR1 deficiencies up to 7 mo after vaccination in all patients. These results suggest that induction of type I IFN is not required for efficient generation of a humoral response against SARS-CoV-2 by mRNA vaccines.

Acute Reactions After Vaccination Against COVID-19 and Long-Term Antibody Levels.

Atypical Hemolytic Uremic Syndrome Occurring After Receipt of mRNA-1273 COVID-19 Vaccine Booster: A Case Report. Atypical hemolytic uremic syndrome (aHUS) is a subtype of thrombotic microangiopathy (TMA) characterized by a dysregulation of the alternative complement pathway. Here, we report a previously healthy 38-year-old woman in whom aHUS developed after a COVID-19 vaccine booster. One day after receipt of a booster dose of mRNA-1273 vaccine, she felt ill. Because of persistent headache, nausea, and general malaise, she went to her general practitioner, who referred her to the hospital after detecting hypertension and acute kidney injury. A diagnosis of TMA was made. Her treatment consisted of blood pressure control, hemodialysis, plasma exchange, and respiratory support. Kidney biopsy confirmed the diagnosis of acute TMA. The patient was referred for treatment with eculizumab, and kidney function improved after initiation of this therapy. Genetic analysis revealed a pathogenic C3 variant. SARS-CoV-2 infection as a trigger for complement activation and development of aHUS has been described previously. In addition, there is one reported case of aHUS occurring after receipt of the adenovirus-based COVID-19 vaccine ChAdOx1 nCoV-19, but, to our knowledge, this is the first case of aHUS occurring after a booster dose of an mRNA COVID-19 vaccine in a patient with an underlying pathogenic variant in complement C3. Given the time frame, we hypothesize that the vaccine probably was the trigger for development of aHUS in this patient.

Humoral and Cellular Immune Responses against SARS-CoV-2 after Third Dose BNT162b2 following Double-Dose Vaccination with BNT162b2 versus ChAdOx1 in Patients with Cancer. PURPOSE: Patients with cancer display reduced humoral responses after double-dose COVID-19 vaccination, whereas their cellular response is more comparable with that in healthy individuals. Recent studies demonstrated that a third vaccination dose boosts these immune responses, both in healthy people and patients with cancer. Because of the availability of many different COVID-19 vaccines, many people have been boosted with a different vaccine from the one used for double-dose vaccination. Data on such alternative vaccination schedules are scarce. This prospective study compares a third dose of BNT162b2 after double-dose BNT162b2 (homologous) versus ChAdOx1 (heterologous) vaccination in patients with cancer. EXPERIMENTAL DESIGN: A total of 442 subjects (315 patients and 127 healthy) received a third dose of BNT162b2 (230 homologous vs. 212 heterologous). Vaccine-induced adverse events (AE) were captured up to 7 days after vaccination. Humoral immunity was assessed by SARS-CoV-2 anti-S1 IgG antibody levels and SARS-CoV-2 50% neutralization titers (NT50) against Wuhan and BA.1 Omicron strains. Cellular immunity was examined by analyzing CD4+ and CD8+ T-cell responses against SARS-CoV-2-specific S1 and S2 peptides. RESULTS: Local AEs were more common after heterologous boosting. SARS-CoV-2 anti-S1 IgG antibody levels did not differ significantly between homologous and heterologous boosted subjects [GMT 1,755.90 BAU/mL (95% CI, 1,276.95-2,414.48) vs. 1,495.82 BAU/mL (95% CI, 1,131.48-1,977.46)]. However, homologous-boosted subjects show significantly higher NT50 values against BA.1 Omicron. Subjects receiving heterologous boosting demonstrated increased spike-specific CD8+ T cells, including higher IFNÎ³ and TNFÎ± levels. CONCLUSIONS: In patients with cancer who received double-dose ChAdOx1, a third heterologous dose of BNT162b2 was able to close the gap in antibody response.

Reactive infectious mucocutaneous eruption following COVID-19 infection in vaccinated patients.

Cutaneous lupus erythematosus flare with vitiligo-like depigmentation following the AstraZeneca COVID vaccine.

Spontaneous Adverse Event Reporting by COVID-19 Vaccinated Healthcare Professionals Through an Electronic Form Implemented by the Hospital Pharmacy. Aim: Implementation of a web-form based pharmacovigilance plan for the spontaneous notification of adverse events to the ComirnatyÂ® COVID-19 vaccine during its administration to hospital healthcare professionals. Methods: An electronic pharmacovigilance form was developed containing 8 pre-defined event options, an open answer option for the description of other events and/or symptoms, and a question about the overall intensity of symptoms. The adverse events reports were standardized according to physiological and pathological condition. Results: A total of 4119 adverse events notifications were obtained with a 45% rate of electronic notification. The most clinically relevant events reported were:tachycardia (nâ€‰=â€‰19), dyspnea (nâ€‰=â€‰7), chest pain (nâ€‰=â€‰6), facial/labial edema (nâ€‰=â€‰6), lipothymia (nâ€‰=â€‰5), bronchospasm (nâ€‰=â€‰2), herpetic infection (nâ€‰=â€‰2), vasculitis (nâ€‰=â€‰2), arrhythmia (nâ€‰=â€‰1), difficult to control arterial hypertension (nâ€‰=â€‰1), gastritis (nâ€‰=â€‰1), and spontaneous abortion (nâ€‰=â€‰1). Regarding the intensity of symptoms (nâ€‰=â€‰2928), 70.0% were reported as mild, 25.8% as moderate, and 4.27% as severe, with higher intensity in the second dose compared to first dose. The highest frequency of severe events were reported in the groups from 40 to 59â€‰years in both vaccination periods. During the vaccination process, no hospitalizations and no deaths were notified and/or recorded. Conclusion: In this real world study, comparing with Comirnaty clinical trials program, it was observed a higher frequency of adenomegaly and gastrointestinal disorders. Noteworthy, the notification of a case of miscarriage. The use of hospital pharmacy pharmacovigilance electronic forms, seemed to be relevant to notification adherence and to obtain a greater and faster knowledge of COVID-19 vaccine safety profile.

A Patient Develops Bullous Rash After Receiving the Second Dose of COVID-19 Vaccine. Our knowledge about the clinical spectrum of COVID-19 has continued to evolve. The clinical features of the infection and vaccine are continuously updated. We present a case of bullous pemphigoidÂ after receiving a second dose of the COVID-19 vaccine. This case highlights autoimmune skin findings seen in a patient after COVID-19 vaccination. A 70-year-old male presented with the chief complaint of blistering skin rash. He received his second dose of Pfizer COVID-19 vaccine two days before developing a painful pruritic maculopapular rash that started on his hands and extended proximally to his trunk. Physical exam was remarkable for tense bullae with negative Nikolsky sign. Biopsy and direct immunofluorescence lead to the diagnosis of bullous pemphigoid. The lesions improved significantly with steroids. Various cutaneous eruptions have been reported with Moderna and Pfizer COVID-19 vaccines, including the new onset of bullous pemphigoid.Â Based on our case, we suggest thatÂ bullous pemphigoidÂ after COVID-19 vaccination is responsive to steroids and the prognosis is excellent. Understanding the clinical course and prognosis of bullous pemphigoidÂ from the COVID-19 vaccine is of significant importance as we strive to keep our patients and communities safe. More data is needed to better guide recommendations, but so far looking at the example from our case, the benefits of COVID-19 vaccination seem to outweigh the risks. Therefore, patients should be advised to continue with future vaccinations.

Inflammatory myopathy following coronavirus disease 2019 vaccination: A systematic review. INTRODUCTION: Reports of unexpected side effects have accompanied the vaccination of larger proportions of the population against coronavirus disease 2019 (COVID-19), including a few cases of inflammatory myopathy (IM). In a bid to improve understanding of the clinical course of vaccine complications, a systematic review of reported cases of IM following COVID-19 vaccination has been conducted. METHODS: The PRISMA guideline 2020 was followed. Two independent investigators systematically searched PubMed and Embase to identify relevant studies published up to July 2022, using the following keywords: COVID-19 Vaccine, inflammatory myositis. The Joanna Briggs Institute critical appraisal tools were used for the risk of bias. RESULTS: A total of 24 articles presenting clinical features of 37 patients with IM following COVID-19 vaccine were identified. Female patients composed 59.5% of cases and 82.4% had been vaccinated with BNT162b2 or ChAdOx1. Onset of symptoms occurred within 2 weeks of the first or second vaccine dose in 29 (85.3%) patients and included muscular weakness in 54.1% and skin rash in 71.4% of patients. Myositis specific autoantibodies (MSAs) and myositis associated autoantibodies (MAAs) were reported in 28 patients. Specific clinical subtypes of myositis, reported in 27 patients, included 22 (81.5%) cases of dermatomyositis (DM) and 3 (11.1%) cases of immune-mediated necrotizing myopathy (IMNM). Following treatment, 32 (86.5%) patients showed improvement on follow-up. CONCLUSION: COVID-19 vaccine may induce various clinical myositis subtypes and related antibodies. Muscular weakness was the most common presenting symptom. Clinicians should be aware of this unexpected adverse event following COVID-19 vaccination and arrange for appropriate management. SYSTEMATIC REVIEW REGISTRATION: INPLASY https://inplasy.com/inplasy-2022-9-0084/ [INPLASY202290084].

Relationship of political ideology of US federal and state elected officials and key COVID pandemic outcomes following vaccine rollout to adults: April 2021-March 2022. BACKGROUND: Scant research, including in the United States, has quantified relationships between the political ideologies of elected representatives and COVID-19 outcomes among their constituents. METHODS: We analyzed observational cross-sectional data on COVID-19 mortality rates (age-standardized) and stress on hospital intensive care unit (ICU) capacity for all 435 US Congressional Districts (CDs) in a period of adult vaccine availability (April 2021-March 2022). Political metrics comprised: (1) ideological scores based on each US Representative's and Senator's concurrent overall voting record and their specific COVID-19 votes, and (2) state trifectas (Governor, State House, and State Senate

under the same political party control). Analyses controlled for CD social metrics, population density, vaccination rates, the prevalence of diabetes and obesity, and voter political lean. FINDINGS: During the study period, the higher the exposure to conservatism across several political metrics, the higher the COVID-19 age-standardized mortality rates, even after taking into account the CD's social characteristics; similar patterns occurred for stress on hospital ICU capacity for Republican trifectas and US Senator political ideology scores. For example, in models mutually adjusting for CD political and social metrics and vaccination rates, Republican trifecta and conservative voter political lean independently remained significantly associated with an 11%-26% higher COVID-19 mortality rate. INTERPRETATION: Associations between the political ideologies of US federal elected officials and state concentrations of political party power with population health warrant greater consideration in public health analyses and monitoring dashboards. FUNDING: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Acute perimyocarditis following heterologous vaccination of CoronaVac and BNT162b2 SARS-CoV-2 vaccine in an elderly woman.

COVID-19 vaccine booster significantly decreases the risk of intensive care unit hospitalization in heart failure patients during the Omicron variant wave: A population-based study. BACKGROUND: Heart failure (HF) patients are at higher risk of severe coronavirus disease 2019 (COVID-19). The Omicron variant has many novel mutations including those in the spike protein, leading to questions about vaccine effectiveness. The aim of this analysis was to evaluate the effectiveness of the COVID-19 vaccine with or without a booster (i.e., after the third dose) during the Omicron variant wave. METHODS: Chronic heart failure patients in the Czech Republic were included in the analysis. COVID-19 infection was monitored from January 1st 2022 to March 31st 2022. The analysis was conducted on data collected in the National Health Information System. Vaccine effectiveness of vaccinated (with or without booster) vs. unvaccinated patients was analyzed for incidence of COVID-19, COVID-19-related hospitalizations, COVID-19 related intensive care unit admissions, and COVID-19 related mechanical ventilation/extracorporeal membrane oxygenation treatment. FINDINGS: From a total 165,453 HF patients in the Czech Republic, 9,728 contracted COVID-19 (22.9% of them not vaccinated, 23.2% vaccinated and 53.8% vaccinated and boosted). Risk of intensive care unit (ICU) hospitalization was 7.6% in the unvaccinated group, 4.8% in the vaccinated group and 2.9% in the boosted group. The calculated effectiveness of the COVID-19 vaccine in prevention of ICU hospitalization in the vaccinated group was 41.9 and 76.6% in the boosted group. INTERPRETATION: The results demonstrated moderate vaccine effectiveness in the prevention of severe COVID-19 in vaccinated but not boosted HF patients. Much stronger effectiveness was found in those who were vaccinated and boosted.

A third dose SARSâ€‘CoVâ€‘2 BNT162b2 mRNA vaccine results in improved immune response in hemodialysis patients. BACKGROUND: The hemodialysis (HD) population has been a vulnerable group during the coronavirus disease 2019 (COVID-19) pandemic. Advanced chronic kidney disease with uremia is associated with weaker immune response to infections and an attenuated response to vaccines. The aim of this study was to study the humoral and cellular response to the second and third doses of Severe Acute Respiratory Syndrome Coronavirus 2 (SARSâ€‘CoVâ€‘2) BNT162b2 mRNA vaccine in HD patients and to follow the response over time. METHODS: The patients received their first two vaccine doses from 28 December 2020 within a 4-week interval and the third dose in September 2021 and were followed-up for humoral and cellular immune response at 1) 7-15 weeks and 2) 6-8 months after dose two (no t-cell reactivity measured), and 3) 3 weeks and 4) 3 months after dose three. Fifty patients were initially enrolled, and 40 patients were followed during the entire study. Levels of COVID-19 (SARS-CoV-2) IgG antibody against the Spike antigen (anti-S) and T-cell reactivity testing against the Spike protein using Enzyme-Linked ImmunoSpot (ELISPOT) technology

were evaluated. RESULTS: IgG antibodies to anti-S were detected in 35 (88%) of the 40 patients 7-15 weeks after vaccine dose two, 31 (78%) were positive, and 4 (10%) borderline. The median anti-S titer was 606 Abbott Units/milliliter (AU/mL) (interquartile range [IQR] 134-1,712). Three months after the third dose, anti-S was detected in 38 (95%) of 40 patients ($P < 0.01$ compared to after dose two), and the median anti-S titer was 9,910 AU/mL (IQR 2,325-26,975). Cellular reactivity was detected in 22 (55%), 34 (85%), and 28 (71%) of the 40 patients, and the median T-cell response was 9.5 (IQR 3.5-80), 51.5 (14.8-132), and 19.5 (8.8-54.2) units, respectively, for 6-8 months after dose two, 3 weeks, and 3 months after dose three. CONCLUSIONS: Our data show that a third dose of SARSâ€‘CoVâ€‘2 BNT162b2 mRNA vaccine gives a robust and improved immunological response in HD patients, but a few patients did not develop any anti-S response during the entire study, indicating the importance to monitor the vaccine response since those who do not respond could now be given monoclonal antibodies if they contract a COVID-19 infection or in the future antivirals.

[Association of SARS-CoV-2 infection and administration of COVID-19 vaccines with alterations in the menstrual cycle. Literature review]. A number of factors can affect a woman's menstrual cycle, including diseases or drugs, such as COVID-19 disease and vaccinations. The aim of this review is to explore the studies published to date that have studied the presence of alterations that may be related to COVID-19 or vaccination against the SARS-CoV-2 virus.We conducted a review in the PubMed database, selecting 10 articles in which the menstrual cycle of adult women of childbearing age was studied, 3 of them in which the participants had been diagnosed with COVID-19 and 7 in which the participants had been vaccinated against the SARS-CoV-2 virus.Regarding COVID-19-related disturbances, 16%-47.2% of the participants presented a prolongation of their cycle, which was more frequent in those who reported more COVID-19 symptoms, and which normalised after 1-2 cycles.Regarding the alterations described after SARS-CoV-2 vaccination, 45%-78% of participants reported menstrual cycle alterations, with disparate results for the different parameters analysed, except that the alterations resolved in about 2 months.Both COVID-19 disease and vaccination appear to be associated with the occurrence of menstrual disturbances, which are limited in time and not severe. However, studies are scarce to date, and it is important to continue to develop studies that provide scientific evidence.

Acute hepatitis following mRNA BNT162b2 COVID-19 vaccination. BACKGROUND: Widespread administration of COVID-19 vaccinations have led to reports of rare but potentially serious side effects. METHODS: We present two cases of acute hepatitis following mRNA BNT162b2 (Comirnaty, Pï¬•zer-BioNTech) vaccination. RESULTS: A 25-year-old male presented to hospital with progressive jaundice 5 days following his second dose of Comirnaty. Initial bloodwork revealed severe hepatocellular enzyme elevation and conjugated hyperbilirubinemia with preserved INR. Extensive serologic workup was negative, with normal imaging. Percutaneous liver biopsy was performed and revealed acute cholestatic hepatitis possibly related to drug-induced liver injury. He was started on prednisone 40 mg daily with good initial response but had a second flare; a biopsy was repeated which showed near-identical findings. Steroids were discontinued given non-response and the patient had gradual near complete resolution of liver enzymes and hyperbilirubinemia. A 32-year-old male presented with a 4-week history of nausea followed by progressive choluria, jaundice, and pruritis. He received his second dose of Comirnaty vaccination two weeks prior to presentation. Initial bloodwork showed mixed enzyme elevation with hyperbilirubinemia. Serological workup and imaging were unrevealing. He underwent liver biopsy which showed severe intrahepatic cholestasis, with drug-induced liver injury being suggested as most likely cause. His course was self-limited with resolution of serological abnormalities and symptoms. CONCLUSIONS: While overwhelmingly safe on a population level, our case series illustrate two cases of acute icteric hepatitis following mRNA

BNT162b2 vaccination. Clinicians should be aware of this association with hepatic inflammation and consider vaccine history an important component of evaluating patients with acute liver injury.

Axillary adenopathy detected on breast MRI following COVID-19 vaccination: outcomes and follow-up recommendations. This retrospective study presents 110 patients with suspected COVID-19 vaccine-related axillary adenopathy on breast MRI. Our study aimed to assess the outcomes of axillary adenopathy detected on breast MRI performed within one year after COVID-19 vaccination. The median time between the COVID-19 vaccine and breast MRI was shorter in patients with detected adenopathy compared to patients without detected adenopathy (6Â weeks [2-17] versus 15 [7-24] weeks, pÂ <Â 0.001). Unilateral axillary adenopathy detected on breast MRI had a low malignancy rate (3.3%), and no cases of malignant axillary adenopathy were diagnosed without a known breast cancer in the ipsilateral breast. Our findings suggest that unilateral axillary adenopathy identified on breast MRI ipsilateral to a recent COVID-19 vaccination can be considered benign in the absence of a suspicious breast finding or known breast cancer. Regardless of vaccine status and timing, unilateral axillary adenopathy detected on MRI evaluation with a known malignancy or suspicious breast finding should be considered suspicious. This will avoid unnecessary scheduling constraints, patient anxiety, and cost, without delaying diagnosis of metastatic breast cancer.

Pearls and pitfalls: Adverse cutaneous reactions after COVID-19 vaccination. Background: Rashes after coronavirus disease of 2019 (COVID-19) mRNA vaccinations occur with typical and atypical presentations. Objective: The goal of this article is to increase awareness and review the various diagnosis and management of cutaneous adverse reactions associated with COVID-19 vaccinations for allergy/immunology fellows, residents, general physicians, and general practitioners. Methods: Pertinent information was included from the patient's case. A review of the available literature using the works cited in the most up-to-date reviews was completed. Results: A case of a patient with cutaneous adverse reaction after COVID-19 vaccination as presented, followed by a review of cutaneous reactions after COVID-19 vaccinations. Conclusion: Providers should be aware of the different rashes after COVID-19 vaccinations. Pearls and pitfalls of the diagnosis and management are provided.

Positive perception of COVID-19 vaccination in HAE: No significant impact of vaccination on disease course. Background: There are some adverse effects with coronavirus disease 2019 (COVID-19) vaccines, but the impact of COVID-19 vaccination on attacks in hereditary angioedema (HAE) is not well defined. Objective: We aimed to investigate the influence of COVID-19 vaccination on the course of HAE. Method: The COVID-19 vaccination status was determined in 140 adult patients with HAE. The number and severity of attacks recorded from patients' diaries were evaluated at four different periods, comprising 1 month before the first dose, the period between the first and the second doses of COVID-19 vaccine in all the patients, the period between the second dose and the third doses in those who received three doses, and 1 month after the last vaccination dose. The disease and attack severities were assessed with the disease severity score (DSS) and 10-point visual analog scale, respectively. The patients were divided into two main groups as group 1 (those who had at least two doses of COVID-19 vaccines [n = 114]) and group 2 (those who had no vaccination [n = 26]). Only Sinovac and Biontech, which were only approved in Turkey. Results: The mean Â± standard deviation DSS was significantly higher in the patients who experienced an attack after vaccination within 48 hours (6.61 Â± 1.88 versus 4.14 Â± 1.69; p < 0.001). Long-term prophylaxis was less common in the patients with an increased number of attacks (n = 5 (27.8%) versus n = 54 (56.3%); p = 0.027). The number of patients with less than a high school education was higher in group 2 (n = 23 [88.5%]) than in group 1 (n = 26 [3.1%]) (p < 0.001). The number of patients who had concerns about the triggering of a vaccine-induced HAE attack or about the possible vaccine adverse effects was higher in group 2 (n = 26 [100%]) than in group 1 (n = 74 [64.9%]). Conclusion: It seems that COVID-19 vaccination does

not increase HAE attacks regardless of the type of the vaccines. We recommend that HAE activity should be under control before COVID-19 vaccination, and the patients should be well informed about the safety of the vaccines.

Longitudinal antibody response kinetics following SARS-CoV-2 messenger RNA vaccination in pregnant and nonpregnant persons. BACKGROUND: For some vaccine-preventable diseases, the immunologic response to vaccination is altered by a pregnant state. The effect of pregnancy on SARS-CoV-2 vaccine response remains unclear. OBJECTIVE: We sought to characterize the peak and longitudinal anti-S immunoglobulin G, immunoglobulin M, and immunoglobulin A responses to messenger RNA-based SARS-CoV-2 vaccination in pregnant persons and compare them with those in nonpregnant, reproductive-aged persons. STUDY DESIGN: We conducted 2 parallel prospective cohort studies among pregnant and nonpregnant persons who received SARS-CoV-2 messenger RNA vaccinations. Blood was collected at the time of first and second vaccine doses, 2 weeks post second dosage, and with serial longitudinal follow-up up to 41.7 weeks post vaccination initiation. Anti-S immunoglobulin M, immunoglobulin G, and immunoglobulin A were analyzed by enzyme-linked immunosorbent assay. We excluded those with previous evidence of SARS-CoV-2 infection by history or presence of antinucleocapsid antibodies. In addition, for this study, we did not include individuals who received a third or booster vaccine dosage during the study period. We also excluded pregnant persons who were not fully vaccinated (14 days post receipt of the second vaccine dosage) by time of delivery and nonpregnant persons who became pregnant through the course of the study. We studied the effect of gestational age at vaccination on the anti-S response using Spearman correlation. We compared the peak anti-S antibody responses between pregnant and nonpregnant persons using a Mann-Whitney U test. We visualized and studied the longitudinal anti-S antibody response using locally weighted scatterplot smoothing, Mann-Whitney U test, and mixed analysis of variance test. RESULTS: Data from 53 pregnant and 21 nonpregnant persons were included in this analysis. The median (interquartile range) age of the pregnant and nonpregnant participants was 35.0 (33.3-37.8) years and 36.0 (33.0-41.0) years, respectively. Six (11.3%) participants initiated vaccination in the first trimester, 23 (43.3%) in the second trimester, and 24 (45.3%) in the third trimester, with a median gestational age at delivery of 39.6 (39.0-40.0) weeks. The median (interquartile range) follow-up time from vaccine initiation to the last blood sample collected was 25.9 (11.9) weeks and 28.9 (12.9) weeks in the pregnant and nonpregnant cohort, respectively. Among pregnant persons, anti-S immunoglobulin G, immunoglobulin A, and immunoglobulin M responses were not associated with gestational age at vaccine initiation (all P>.05). The anti-S immunoglobulin G response at 2 weeks post second dosage was not statistically different between pregnant and nonpregnant persons (P>.05). However, the anti-S immunoglobulin M and immunoglobulin A responses at 2 weeks post second dosage were significantly higher in nonpregnant persons (P<.001 for both). The anti-S immunoglobulin G and immunoglobulin M levels 6 to 8 months after vaccine initiation fell to comparable proportions of the peak 2 weeks post second dosage antibody levels between pregnant and nonpregnant persons (immunoglobulin G P=.77;Â immunoglobulin M P=.51). In contrast, immunoglobulin A levels 6 to 8 months after vaccine initiation fell to statistically significantly higher proportions of peak 2 weeks post second dosage antibody levels in pregnant compared with nonpregnant persons (P=.002). Maternal anti-S immunoglobulin G levels were strongly correlated with umbilical cord anti-S immunoglobulin G levels (R=0.8, P<.001). CONCLUSION: The anti-S immunoglobulin A, immunoglobulin M, and immunoglobulin G response to SARS-CoV-2 vaccination in pregnancy is independent of gestational age of vaccine initiation. Maintenance of the immunoglobulin G response is comparable between pregnant and nonpregnant persons. The differential peak response of immunoglobulin M and

immunoglobulin A and the differential decline of anti-S immunoglobulin A between pregnant and nonpregnant persons requires further investigation.
[Myocarditis and pericarditis after COVID-19 mRNA vaccination].
mRNA COVID-19 Vaccines and Their Risk to Induce a Relapse of Glomerular Diseases.
A Population-Based Analysis of the Risk of Glomerular Disease Relapse after COVID-19 Vaccination. BACKGROUND: Although case reports have described relapses of glomerular disease after COVID-19 vaccination, evidence of a true association is lacking. In this population-level analysis, we sought to determine relative and absolute risks of glomerular disease relapse after COVID-19 vaccination. METHODS: In this retrospective population-level cohort study, we used a centralized clinical and pathology registry (2000-2020) to identify 1105 adult patients in British Columbia, Canada, with biopsy-proven glomerular disease that was stable on December 14, 2020 (when COVID-19 vaccines first became available). The primary outcome was disease relapse, on the basis of changes in kidney function, proteinuria, or both. Vaccination was modeled as a 30-day time-varying exposure in extended Cox regression models, stratified on disease type. RESULTS: During 281 days of follow-up, 134 (12.1%) patients experienced a relapse. Although a first vaccine dose was not associated with relapse risk (hazard ratio [HR]=0.67; 95% confidence interval [95% CI], 0.33 to 1.36), exposure to a second or third dose was associated with a two-fold risk of relapse (HR=2.23; 95% CI, 1.06 to 4.71). The pattern of relative risk was similar across glomerular diseases. The absolute increase in 30-day relapse risk associated with a second or third vaccine dose varied from 1%-2% in ANCA-related glomerulonephritis, minimal change disease, membranous nephropathy, or FSGS to 3%-5% in IgA nephropathy or lupus nephritis. Among 24 patients experiencing a vaccine-associated relapse, 4 (17%) had a change in immunosuppression, and none required a biopsy. CONCLUSIONS: In a population-level cohort of patients with glomerular disease, a second or third dose of COVID-19 vaccine was associated with higher relative risk but low absolute increased risk of relapse.
COVID-19 vaccination is associated with reduced non-COVID in-hospital mortality. We retrieved data on a cohort of medical patients at a regional Israeli hospital. The dependent variable was non-COVID-19 hospital mortality; the independent variables were vaccination status, age, and laboratory data. Serum sodium, age, serum creatinine, and COVID-19 vaccination status were the main independent variables associated with non-COVID-19 mortality. The odds ratio for in-hospital deaths of non-vaccinated patients was 2.01 (1.65-2.44) (unadjusted) and 1.61 (1.29-2.03) after adjustment for the independent variables. This "healthy adherer effect" may confound observational assessments of the clinical efficacy of COVID-19 vaccines.
Aquaporin-4 IgG neuromyelitis optica spectrum disorder onset after Covid-19 vaccination: Systematic review. Neuromyelitis optica spectrum disorder (NMOSD) is rarely reported following Coronavirus disease 2019 (COVID-19) vaccination. We identified 16 cases of new onset NMOSD with positive aquaporin-4 IgG (AQP4-IgG) following COVID-19 vaccination. Transverse myelitis was the most common clinical presentation (75%). Most patients received high dose steroids for acute treatment and maintenance therapy was started in 12 patients (75%). Twelve patients (75%) had improvement of their symptoms at the time of discharge or follow-up. The included cases share similar epidemiology and natural course to non-vaccine related cases. Clinicians should be aware of possible post-vaccination NMOSD to help with earlier diagnosis and treatment.
Immune responses following COVID-19 infection in multiple sclerosis patients using immunomodulatory therapy. Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus type-2 (SARS-CoV-2), has quickly become a global pandemic. Most multiple sclerosis (MS) patients use disease-modifying treatments (DMTs), such as immunomodulators or immunosuppressants. By targeting different types of immune cells, DMTs affect cellular and/or humoral immunity. The potential effects of DMTs on the long-term immune

response to COVID-19 is not fully known. Between 16.04.2020 and 15.07.2020, a total of 34 people, 17 of whom were diagnosed with MS according to the 2010 McDonald diagnostic criteria and a control group of 17 individuals who did not have a known systemic disease who were matched according to age, gender, and COVID-19 disease severity, where all received COVID-19 diagnosis with SARS-CoV-2 PCR positivity in nasopharyngeal swab test and immune responses were measured (SARS-CoV-2 IgM and IgG antibody levels COVID 19 ELISA kit), were included in our study. Demographic data of MS patients and the control group, SARS-CoV-2 immune responses, antibody titers and disease year of MS patients, EDSS scores, disease type, and disease duration were determined. All patients were symptomatic for COVID-19. COVID-19 disease severity was divided into three groups as mild, moderate, and severe according to the clinical condition of the patient. Demographic data of MS patients and the control group, SARS-CoV-2 immune responses, antibody titers and disease year of MS patients, EDSS scores, disease type, and disease duration were determined. All patients were symptomatic for COVID-19. COVID-19 disease severity was divided into three groups as mild, moderate, and severe according to the clinical condition of the patient. According to our study results, IgG-type long-term immune responses were lower in MS patients using DMTs than in the healthy population. We hope that our study will provide insight into the COVID-19 vaccine immune responses.

Cardiac adverse reactions of COVID-19 vaccination: cardiac MRI findings. BACKGROUND: The rapid development of COVID-19 vaccines in the wake of the COVID-19 pandemic has led to an equally expediently deployed vaccination campaign with more than 12Â billion vaccinations administered worldwide. Reports of vaccine-associated adverse reactions (VAARs) have ranged from headaches and pain at the injection site to potentially life-threatening events such as cerebral venous sinus thrombosis. The heart has also not been spared of VAARs, as vaccine-associated myocardial infarction and more commonly, albeit still rare, myocarditis and perimyocarditis have been reported in predominantly young male recipients. METHODOLOGICAL INNOVATIONS: Cardiac magnetic resonance imaging findings of vaccine-associated myocarditis such as prolonged T1 and T2 relaxation times, increased T2 signal intensity ratio, and subepicardial late gadolinium enhancement have been demonstrated to be similar to those in virus-induced myocarditis, enabling the use of the modified 2018 Lake Louise Criteria for diagnostic purposes to confirm vaccination-associated myocardial inflammation. Other reported cardiac findings such as cardiomyopathies and arrhythmias were confined to case reports. The incidence of myocardial infarction was not noted to be higher than in the overall population. CONCLUSION: The overall preliminary prognosis of vaccine- associated myocarditis seems to be good as suggested by initial reports, but long-term follow-up is needed to sufficiently assess possible sequelae and consequences.

Lichen planus following SARS-CoV-2 infection and vaccination? A systematic review.

Expert review of global real-world data on COVID-19 vaccine booster effectiveness and safety during the omicron-dominant phase of the pandemic. INTRODUCTION: COVID-19 vaccines have been highly effective in reducing morbidity and mortality during the pandemic. However, the emergence of the Omicron variant and subvariants as the globally dominant strains have raised doubts about the effectiveness of currently available vaccines and prompted debate about potential future vaccination strategies. AREAS COVERED: Using the publicly available IVAC VIEW-hub platform, we reviewed 52 studies on vaccine effectiveness (VE) after booster vaccinations. VE were reported for SARS-CoV-2 symptomatic infection, severe disease and death and stratified by vaccine schedule and age. In addition, a non-systematic literature review of safety was performed to identify single or multi-country studies investigating adverse event rates for at least two of the currently available COVID-19 vaccines. EXPERT OPINION: Booster shots of the current COVID-19 vaccines provide consistently high protection against Omicron-related severe disease and death. Additionally, this protection appears to

be conserved for at least 3Â months, with a small but significant waning after that. The positive risk-benefit ratio of these vaccines is well established, giving us confidence to administer additional doses as required. Future vaccination strategies will likely include a combination of schedules based on risk profile, as overly frequent boosting may be neither beneficial nor sustainable for the general population.

Omicron BA.2.75 variant is efficiently neutralised following BA.1 and BA.5 breakthrough infection in vaccinated individuals, Israel, June to September 2022. We evaluated neutralising antibody titres against wild type (WT) SARS-CoV-2 and four Omicron variants (BA.1, BA.2, BA.5 and BA.2.75) in fully vaccinated (three doses of Comirnaty vaccine) healthcare workers (HCW) in Israel who had breakthrough BA.1/BA5 infections. Omicron breakthrough infections in vaccinated individuals resulted in increased neutralising antibodies against the WT and Omicron variants compared with vaccinated uninfected HCW. HCW who recovered from BA.1 or BA.5 infections showed similar neutralising antibodies levels against BA.2.75.

COVID-19 Vaccines and Solid Organ Transplantation: More Doses, More Protection.

Immunogenicity and safety of a three-dose SARS-CoV-2 vaccination strategy in patients with immune-mediated inflammatory diseases on immunosuppressive therapy. OBJECTIVES: Humoral vaccine responses to SARS-CoV-2 vaccines are impaired and short lasting in patients with immune-mediated inflammatory diseases (IMID) following two vaccine doses. To protect these vulnerable patients against severe COVID-19 disease, a three-dose primary vaccination strategy has been implemented in many countries. The aim of this study was to evaluate humoral response and safety of primary vaccination with three doses in patients with IMID. METHODS: Patients with IMID on immunosuppressive therapy and healthy controls receiving three-dose and two-dose primary SARS-CoV-2 vaccination, respectively, were included in this prospective observational cohort study. Anti-Spike antibodies were assessed 2-4 weeks, and 12 weeks following each dose. The main outcome was anti-Spike antibody levels 2-4 weeks following three doses in patients with IMID and two doses in controls. Additional outcomes were the antibody decline rate and adverse events. RESULTS: 1100 patients and 303 controls were included. Following three-dose vaccination, patients achieved median (IQR) antibody levels of 5720 BAU/mL (2138-8732) compared with 4495 (1591-6639) in controls receiving two doses, p=0.27. Anti-Spike antibody levels increased with median 1932 BAU/mL (IQR 150-4978) after the third dose. The interval between the vaccine doses and vaccination with mRNA-1273 or a combination of vaccines were associated with antibody levels following the third dose. Antibody levels had a slower decline-rate following the third than the second vaccine dose, p<0.001. Adverse events were reported by 464 (47%) patients and by 196 (78%) controls. Disease flares were reported by 70 (7%) patients. CONCLUSIONS: This study shows that additional vaccine doses to patients with IMID contribute to strong and sustained immune-responses comparable to healthy persons vaccinated twice, and supports repeated vaccination of patients with IMID. TRIAL REGISTRATION NUMBER: NCT04798625.

Adverse events of the Pfizer-BioNTech COVID-19 vaccine in Korean children and adolescents aged 5 to 17 years. OBJECTIVES: This study aimed to identify potential safety signals and adverse events following the primary Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccination series among children and adolescents aged 5 to 17 years in the Republic of Korea. METHODS: Adverse events reported through the COVID-19 vaccination management system (CVMS, a web-based passive vaccine safety surveillance system) and adverse events and health conditions collected from a text message-based survey were analyzed. RESULTS: A total of 14,786 adverse events among 5 to 17-year-old children and adolescents were reported in the CVMS; 14,334 (96.9%) were non-serious and 452 (3.1%) were serious, including 125 suspected cases of acute cardiovascular injury and 101 suspected cases of anaphylaxis. The overall reporting rate was lower in 5 to 11-year-old children (64.5 per

100,000 doses) than in 12 to 17-year-old adolescents (300.5 per 100,000 doses). The text message survey identified that local and systemic adverse events after either dose were reported less frequently in 5 to 11-year-old children than in 12 to 17-year-old adolescents (p<0.001). The most commonly reported adverse events were pain at the injection site, myalgia, headache, and fatigue/tiredness. CONCLUSION: The overall results are consistent with the results of controlled trials; serious adverse events were extremely rare among 5 to 17-year-old children and adolescents following Pfizer-BioNTech COVID-19 vaccination. Adverse events were less frequent in children aged 5 to 11 years than in adolescents aged 12 to 17 years.

Relapses of Immune Thrombocytopenia after the Second and Booster Doses of BNT162b2 Vaccine. We present here a 65-year-old male patient known for immune thrombocytopenic purpura (ITP) and fluctuating platelet count who experienced a severe exacerbation of thrombocytopenia following BNT162b2 COVID-19 vaccination. One month after the second dose, he presented petechiae and asthenia with isolated thrombocytopenia (platelet count: 3 Ã— 109/L). He recovered after a 4-day course of intravenous corticosteroid treatment and intravenous immunoglobulin therapy. Eight months later, his platelet count was within the normal range, and he received a booster dose of vaccine after premedication with prednisone. Eight days later, his platelet count dropped to 29 Ã— 109/L, but he remained asymptomatic. He received a rescue treatment with prednisone followed by rituximab over 4 weeks, allowing progressive improvement. Our case suggests a strong association between COVID-19 vaccination and the exacerbation of ITP.

Hospitalization among vaccines for SARS-CoV-2 breakthrough infection after dose sparing strategies in Libya: A cohort study. SARS-CoV-2 infection is widely spread over people, from youth to the elderly. Vaccination against SARS-CoV-2 is an essential preventive measure to help end the SARS-CoV-2 pandemic. A multi-center retrospective cohort study was conducted on patients in Libya who had received single-dose licensed three different types of vaccines (Oxford/AstraZeneca, CoronaVac, or Sputnik-V) and were admitted to healthcare centers with SARS-CoV-2 infection from 30th April to 15th July 2021. In this study, the number of people infected with SARS-COV-2 and the mortality rate from daily reports issued by the National Centers for Disease Control of Libya (NCDC) were collected. Approximately 445000 single doses of the SARS-COV-2 vaccine were administered in Libya from April to July 2021. In corresponding, 39996 people were infected during this period. It has been found that among the people who did not receive any vaccine, the number of patients infected by SARS-COV-2 and admitted to the healthcare centers, and died was (N = 3176 patients (7.94%), and 266 (7.10%) respectively). Compared to 43 (0.10%) of those admitted to healthcare centers who had taken a single dose from one of the licensed vaccines, of which 8 patients (0.02%) died during this period. The documented 23 patients were those who admitted to healthcare centers and got vaccinated with the CoronaVac (Sinovac) vaccine. Fourteen patients received Oxford/AstraZeneca. Only 2 patients received the Sputnik V vaccine. Of the breakthrough infection cases reviewed, 8 patients died. No deaths due to breakthrough infection among Sputnik V vaccinated patients were reported. In conclusion, a single dose of the three different types of the vaccine has significantly reduced virus interpersonal transmission and also showed a decrease in the mortality rate until the tenth week in Libya. The present study demonstrates the extent of the remarkable success of the early rollout of the coronavirus national vaccination campaign.

Factors associated with willingness to take COVID-19 vaccine among pregnant women at Gondar town, Northwest Ethiopia: A multicenter institution-based cross-sectional study. BACKGROUND: Coronavirus disease has spread worldwide since late 2019. Vaccination is critical in controlling this pandemic. However, vaccine acceptance among pregnant women is not well-studied. Therefore, this study aimed to assess the COVID-19 vaccine acceptance and associated factors among pregnant women attending antenatal care clinics in Gondar town, Northwest Ethiopia. METHODS: An

institution-based cross-sectional study was conducted among pregnant women attending antenatal care clinics at Gondar town, Northwest Ethiopia, 2021. About 510 study subjects were selected using a systematic random sampling technique from August 25 to September 10/2021. Data collection was done by using an interviewer-administered, structured questionnaire. Epi-info 7.2 was used to enter data and then exported to SPSS version 25 software for analysis. Bivariable and multivariable binary logistic regression models were used to identify factors associated with the outcome variable. Variables with a p-value < 0.2 in the bivariable analysis were entered into the multivariable analysis to control for possible confounders. Statistical significance is determined using an adjusted odds ratio and 95% confidence interval (CI) at a p-value of < 0.05. RESULTS: Of 510 participants, 211 (41.4%) were willing to take COVID-19 vaccines. Maternal age â‰¥ 35 years (AOR: 5.678, 95% CI: 1.775-18.166), having contact history with COVID-19 diagnosed people (AOR: 7.724, 95% CI: 2.183, 27.329), having a pre-existing chronic disease (AOR: 3.131, 95% CI: 1.700-5.766), good knowledge about COVID-19 vaccine (AOR: 2.391, 95% CI: 1.144, 4.998) and good attitude towards COVID-19 vaccine (AOR: 2.128, 95% CI: 1.348) were significantly associated with the outcome variable. CONCLUSIONS: The willingness to take COVID-19 vaccine among pregnant mothers was low. Age, contact history with COVID-19 diagnosed people, chronic disease, knowledge, and attitude towards COVID-19 vaccine were factors associated with COVID-19 vaccine willingness. To enhance the COVID-19 vaccine acceptance, the government with different stakeholders should strengthen public education about the importance of getting COVID-19 vaccine.
Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Persons Aged â‰¥12 Years - United States, August 31-October 23, 2022. On August 31, 2022, the Food and Drug Administration (FDA) authorized bivalent formulations of BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) COVID-19 vaccines; these vaccines include mRNA encoding the spike protein from the original (ancestral) strain of SARS-CoV-2 (the virus that causes COVID-19) and from the B.1.1.529 (Omicron) variants BA.4 and BA.5 (BA.4/BA.5). These bivalent mRNA vaccines were authorized for use as a single booster dose â‰¥2 months after completion of primary series or monovalent booster vaccination; Pfizer-BioNTech bivalent booster was authorized for persons aged â‰¥12 years and Moderna for adults aged â‰¥18 years.*(,)(â€) On September 1, 2022, the Advisory Committee on Immunization Practices (ACIP) recommended that all persons aged â‰¥12 years receive an age-appropriate bivalent mRNA booster dose.(Â§) To characterize the safety of bivalent mRNA booster doses, CDC reviewed adverse events and health impacts reported after receipt of bivalent Pfizer-BioNTech and Moderna booster doses during August 31-October 23, 2022, to v-safe,(Â¶) a voluntary smartphone-based U.S. safety surveillance system established by CDC to monitor adverse events after COVID-19 vaccination, and the Vaccine Adverse Event Reporting System (VAERS),** a U.S. passive vaccine safety surveillance system managed by CDC and FDA (1). During August 31-October 23, 2022, approximately 14.4 million persons aged â‰¥12 years received a bivalent Pfizer-BioNTech booster dose, and 8.2 million adults aged â‰¥18 years received a bivalent Moderna booster dose.(â€ â€) Among the 211,959 registrants aged â‰¥12 years who reported receiving a bivalent booster dose to v-safe, injection site and systemic reactions were frequently reported in the week after vaccination (60.8% and 54.8%, respectively); fewer than 1% of v-safe registrants reported receiving medical care. VAERS received 5,542 reports of adverse events after bivalent booster vaccination among persons aged â‰¥12 years; 95.5% of reports were nonserious and 4.5% were serious events. Health care providers and patients can be reassured that adverse events reported after a bivalent booster dose are consistent with those reported after monovalent doses. Health impacts after COVID-19 vaccination are less frequent and less severe than those associated with COVID-19 illness (2).
Spinal cord ischemia complicating BNT162b2 mRNA COVID-19 vaccination.

Prevalence, clinical course and outcomes of COVID-19 in peritoneal dialysis (PD) patients: a single-center experience. INTRODUCTION: There are limited data on the effects of COVID-19 on peritoneal dialysis (PD) patients. This study aimed to describe the impact of COVID-19 on the PD population. METHODS: A monocentric retrospective observational study was conducted on 146 consecutive PDÂ patients followed from January 2020 to March 2022 at the University Hospital of Modena, Italy. RESULTS: Twenty-seven (18.4%) PD patients experienced 29 episodes of SARS-CoV-2 infection, corresponding to an incidence rate of 0.16 episodes/patient-year. Median age of COVID-19 patients was 60.4 (interquartile range [IQR] 50.2-66.5) years. In unvaccinated patients (n. 9), COVID-19 was always symptomatic and manifested with fever (100%) and cough (77.7%). COVID-19 caused hospital admission of three (33.3%) patients and two (22.2%) died of septic shock. COVID-19 was symptomatic in 83.3% of vaccinatedÂ subjects (n.18) and manifested with fever (61.1%) and cough (55.6%). Hospital admission occurred in 27.8% of the subjects but all were discharged home. Median SARS-CoV-2 shedding was 32 and 26Â days in the unvaccinated and vaccinated groups, respectively. At the end of the follow-up, COVID-19 triggered the shift from PD to HD in two subjects without affecting the residual renal function of the remaining patients. Overall, COVID-19 caused an excess death of 22.2%. COVID-19 vaccination refusal accounted for only 1.6%Â in this cohort of patients. CONCLUSION: COVID-19 incident rate was 0.16 episodes/patient-year in the PD population. About one-third of the patients were hospitalized for severe infection. Fatal outcome occurred in two (7.4%)Â unvaccinated patients. A low vaccination refusal rate was observed in this population.

Humoral response after aÂ third and fourth dose of mRNA-based SARS-CoV-2 vaccine in previously seronegative kidney transplant recipients. Growing evidence shows diminished response to mRNA-based SARS-CoVâ€‘2 vaccination in kidney transplant recipients. We aimed to investigate the seroconversion rate after aÂ 3rd and 4th dose of mRNA vaccination in kidney transplant recipients without prior antibody response to two or three vaccination doses.This retrospective study included 324 prevalent kidney transplant recipients of aÂ single tertiary transplantation center of which 157 remained seronegative, defined as anti-spike-RBD-IgG antibody titer <â€¯7.1 BAU/ml, after two doses of mRNA-based SARS-CoVâ€‘2 vaccination. Maintenance immunosuppression was not changed. The median patient age was 60.6 years (IQR 51.4-68.1 years), 66.9% were male. Positivity for anti-spike-RBD-IgG (â‰¥â€¯7.1 BAU/ml) was measured 4-5Â weeks after administration of aÂ 3rd and 4th vaccine dose.Seroconversion rates were 63.9% after aÂ 3rd dose and 29.3% after aÂ 4th dose of vaccine. Cumulative prevalence of seropositivity was 51.5% after 2 doses, 80.5% after 3 doses and 84.2% after 4 doses.In conclusion, seroconversion can be achieved in the majority of the kidney transplant recipients by administrating three or four doses of mRNA vaccine without changing maintenance immunosuppression.

Adverse events reported after first dose of SARS-CoV-2 vaccine in the Northern Region of Ghana. AIM: The study examined the associated adverse events following SARS-CoV-2 vaccination among healthcare workers during the first dose of the vaccine in the Northern Region of Ghana. DESIGN: The study was a cross-sectional survey involving 463 healthcare workers. METHOD: The data were collected using a structured questionnaire. The data were analysed descriptively, and binary logistics was performed using SPSS version 25. RESULTS: The mean age was 33.4â€‰Â±â€‰9.7â€‰years, the majority (43.6%) being â‰¤30â€‰years and males (57.2%). The self-reported prevalence of SARS-CoV-2 vaccine adverse events was 75.5%. Common systemic adverse events comprised headache (47.5%), dizziness (18.4%) and local adverse events included generalized body pains (44.0%) and abscess around the injection sites (11.2%). The study found a high prevalence of self-reported SARS-CoV-2 vaccine adverse events involving both systemic and local adverse events. Our study gives useful information that can be used for public health-targeted interventions to boost public confidence in SARS-CoV-2 vaccines.

COVID-19 Vaccination-Induced Ventricular Fibrillation in an Afebrile Patient With Brugada Syndrome. A 43-year-old man presented with cardiac arrest 2 days after the second coronavirus disease 2019 (COVID-19) vaccination with an mRNA vaccine. Electrocardiograms showed ventricular fibrillation and type 1 Brugada pattern ST segment elevation. The patient reported having no symptoms, including febrile sensation. There were no known underlying cardiac diseases to explain such electrocardiographic abnormalities. ST segment elevation completely disappeared in two weeks. Although there were no genetic mutations or personal or family history typical of Brugada syndrome, flecainide administration induced type 1 Brugada pattern ST segment elevation. This case suggests that COVID-19 vaccination may induce cardiac ion channel dysfunction and cause life threatening ventricular arrhythmias in specific patients with Brugada syndrome.

mRNA Vaccination Decreases COVID-19-Associated Morbidity and Mortality Among Organ Transplant Recipients: A Contemporary Cohort Study. BACKGROUND: Organ transplant recipients (OTRs) are less protected from vaccination than immunocompetent hosts. Additional vaccine doses have shown increased immunogenicity. Few studies have assessed their clinical efficacy, particularly against Omicron variants, as most included patients from earlier phases of the pandemic, with higher base mortality rates. METHODS: We studied adult OTRs who had coronavirus disease 2019 (COVID-19) between 12/15/21 and 5/25/22. We compared clinical outcomes between those who had received 2 or â‰¥3 doses of an mRNA vaccine and concurrent unvaccinated controls. RESULTS: Among 103 OTRs, vaccination was associated with lower 90-day mortality (unvaccinated vs 2 vs â‰¥3 doses: 25% vs 7% vs 3%; P = .003), hospital (unvaccinated vs 2 vs â‰¥3 doses: 56% vs 37% vs 27%; P = .018) and intensive care unit (ICU; unvaccinated vs 2 vs â‰¥3 doses: 25% vs 15% vs 3%; P = .001) admission rates, and peak O(2) requirements (ordinal scale Kendall's tau b = -0.309 [lower scores, ie, O(2) requirements with more vaccine doses]; P = .003). Age (age >60â€…years: adjusted hazard ratio [aHR], 7.73; P = .016; administration of antispike monoclonal antibody: aHR, 0.17; P = .042) and vaccination, especially with â‰¥3 doses (aHR, 0.105; P = .01), were independently associated with 90-day mortality. Black (P = .021) and Hispanic (P = .016) OTRs were underrepresented among the vaccinated, especially in the â‰¥3-dose group. CONCLUSIONS: Despite lower mRNA vaccine efficacy in OTRs and against Omicron variants, vaccination protects this vulnerable patient population from severe COVID-19 and death. Ethnic and racial disparities in health care have been exacerbated by the COVID-19 pandemic and warrant better community outreach efforts.

Efficacy and safety of four COVID-19 vaccines in preventing SARS-CoV-2 infection: A rapid review. INTRODUCTION: Since the emergence of the SARS-CoV-2, there have been efforts to develop vaccines to control the COVID-19 pandemic. OBJECTIVE: The present study assessed the efficacy and safety of the BNT162b2, mRNA-1273, ChAdOx1/AZD1222 and Gam-COVID-Vac rAd26-S/rAd5-S vaccines against the SARS-CoV-2. MATERIALS AND METHODS: We searched PubMed/MEDLINE, Google Scholar, Cochrane, and the WHO International Clinical Trials Registry Platform on March 15, 2021. The search terms used were: "vaccine" OR "vaccination" AND "covid19" OR "coronavirus" OR "sarscov2" AND "bnt162b2" OR "chadox1-S" OR "azd1222" OR "sputnik" OR "Gam-COVID-Vac" OR "mrna" OR "mRNA-1273" . We measured the risk of bias of the studies and the quality of the evidence using GRADE profiles. A qualitative and quantitative analysis of the results of clinical trials is presented. RESULTS: Of the 74 identified studies, 4 were finally included in this review. The efficacies of the BNT162b2, mRNA-1273, ChAdOx1/AZD1222 and Gam-COVID-VacrAd26-S/rAd5-S vaccines against symptomatic COVID-19 were 95,0% (CI95% 90,3-97,6), 94,1% (CI95% 89,3-96,8), 66,7% (CI95% 57,4-74,0), and 91,1% (CI95% 83,8-95,1), respectively. There was moderate certainty of the evidence due to serious indirectness, when we measured the risk of bias of the studies and the quality of the evidence using GRADE profile. The safety profiles were acceptable, and data on serious adverse events (summary RR=0,93; CI95% 0,77-1,12; p=0,16) and deaths from all causes (summary RR=0,70;

CI95% 0,33-1,50; p=0,90) showed no significant differences. CONCLUSION: The results of this review support the level of evidence for the efficacy and safety of the COVID-19 vaccines analysed.

Factors associated with timely COVID-19 vaccination in a population-based cohort of patients with cancer. BACKGROUND: In many jurisdictions, cancer patients were prioritized for COVID-19 vaccination because of increased risk of infection and death. To understand sociodemographic disparities that affected timely receipt of COVID-19 vaccination among cancer patients, we undertook a population-based study in Ontario, Canada. METHODS: Patients older than 18â€‰years and diagnosed with cancer January 2010 to September 2020 were identified using administrative data; vaccination administration was captured between approval (December 2020) up to February 2022. Factors associated with time to vaccination were evaluated using multivariable Cox proportional hazards regression. RESULTS: The cohort consisted of 356â€Š535 patients, the majority of whom had solid tumor cancers (85.9%) and were not on active treatment (74.1%); 86.8% had received at least 2 doses. The rate of vaccination was 25% lower in recent (hazard ratio [HR] = 0.74, 95% confidence interval [CI] = 0.72 to 0.76) and nonrecent immigrants (HR = 0.80, 95% CI = 0.79 to 0.81). A greater proportion of unvaccinated patients were from neighborhoods with a high concentration of new immigrants or self-reported members of racialized groups (26.0% vs 21.3%, standardized difference = 0.111, Pâ€‰<â€‰.001), residential instability (27.1% vs 23.0%, standardized difference = 0.094, Pâ€‰<â€‰.001), or material deprivation (22.1% vs 16.8%, standardized difference = 0.134, Pâ€‰<â€‰.001) and low socioeconomic status (20.9% vs 16.0%, standardized difference = 0.041, Pâ€‰<â€‰.001). The rate of vaccination was 20% lower in patients from neighborhoods with the lowest socioeconomic status (HR = 0.82, 95% CI = 0.81 to 0.84) and highest material deprivation (HR = 0.80, 95% CI = 0.78 to 0.81) relative to those in more advantaged neighborhoods. CONCLUSIONS: Despite funding of vaccines and prioritization of high-risk populations, marginalized patients were less likely to be vaccinated. Differences are likely due to the interplay between systemic barriers to access and cultural or social influences affecting uptake.

Impact of Biologic Agents on the Immune Response Induced by the Additional Dose of SARS-CoV-2 Vaccine in Inflammatory Bowel Disease Patients. The immusne response to the vaccine against SARS-CoV-2 is altered in patients with inflammatory bowel disease using biological agents, and so we should ensure effective immunization in these patients by prioritizing those receiving anti-tumor necrosis factor agents in the indication of new doses or booster doses of the vaccine.

Diagnostic accuracy of vaccine and vaccine excipient testing in the setting of allergic reactions to COVID-19 vaccines: AÂ systematic review and meta-analysis. For persons with immediate allergic reactions to mRNA COVID-19 vaccines, skin testing (ST) to the vaccine/excipients (polyethylene glycol[PEG] and polysorbate 80 [PS]) has been recommended, but has unknown accuracy. To assess vaccine/excipient ST accuracy in predicting all-severity immediate allergic reactions upon re-vaccination, systematic review was performed searching Medline, EMBASE, Web of Science, and the WHO global coronavirus database (inception-Oct 4, 2021) for studies addressing immediate (â‰¤4Â h post-vaccination) all-severity allergic reactions to 2nd mRNA COVID-19 vaccination in persons with 1st dose immediate allergic reactions. Cases evaluating delayed reactions, change of vaccine platform, or revaccination without vaccine/excipient ST were excluded. Meta-analysis of diagnostic testing accuracy was performed using Bayesian methods. The GRADE approach evaluated certainty of the evidence, and QUADAS-2 assessed risk of bias. Among 20 studies of mRNA COVID-19 first dose vaccine reactions, 317 individuals underwent 578 ST to any one or combination of vaccine, PEG, or PS, and were re-vaccinated with the same vaccine. Test sensitivity for either mRNA vaccine was 0.2 (95%CrI 0.01-0.52) and specificity 0.97 (95%CrI 0.9-1). PEG test sensitivity was 0.02 (95%CrI 0.00-0.07) and specificity 0.99 (95%CrI 0.96-1). PS test sensitivity was 0.03 (95%CrI 0.00-0.0.11) and specificity 0.97 (95%CrI 0.91-1). Combined for use of any of the 3 testing agents, sensitivity was 0.03

(95%CrI 0.00-0.08) and specificity was 0.98 (95%CrI 0.95-1.00). Certainty of evidence was moderate. ST has low sensitivity but high specificity in predicting all-severity repeat immediate allergic reactions to the same agent, among persons with 1st dose immediate allergic reactions to mRNA COVID-19 vaccines. mRNA COVID-19 vaccine or excipient ST has limited risk assessment utility.

Communication is crucial: Lessons from COVID-19 vaccination and pregnancy. The morbidity and mortality from COVID-19 infection are higher in pregnant women compared to their nonpregnant counterparts. As real-world evidence accumulates demonstrating there is no increased risk of adverse maternal and neonatal outcomes associated with COVID-19 vaccination during pregnancy, guidelines have evolved from a case-by-case benefit-risk decision through to clear recommendation in April 2021 for COVID-19 vaccination in pregnancy. However, vaccine hesitancy is a barrier to uptake, especially among the younger population and individuals of ethnic minority backgrounds; pregnant women have additional concerns. Trust in the importance and effectiveness of the vaccine, trust in public health agencies and science, together with good communication methods regarding the safety of COVID-19 vaccines are strong factors for vaccination acceptance in pregnancy. Lack of trust in the health system was worsened by initial knowledge gaps in the information provided about COVID-19 infection and the safety and immunogenicity of COVID-19 vaccines. This was exacerbated by access to incorrect information and misinformation to fill in those knowledge gaps, especially with the increased use of social media. To provide advice and reassurance on COVID-19 vaccine safety to pregnant women, healthcare professionals involved in their care should have the knowledge and skills to provide risk-benefit communication and would benefit from access to training in science communication. Clinical pharmacologists have the expertise to appraise and synthesize emerging pharmacovigilance data, which can inform and support risk-benefit communication by other clinicians. Information should be strategically directed at individual audiences, taking their perspectives and foundational belief systems into consideration.

Vaccination against COVID-19 does not lead to exacerbation in patients with myasthenia gravis. Seeâ€‰articleâ€‰onâ€‰pagesâ€‰558â€•561â€‰inâ€‰volumeâ€‰66,â€‰Issueâ€‰5,â€‰Novemberâ€‰issue.

A Case Series on the COVID-19 Vaccines and Possible Immune-Related Adverse Events: A New Challenge for the Rheumatologists. The COVID-19 pandemic has been a prime health issue since December 2019. Consequently, there has been an urgent need to prevent severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) infection and its associated morbidity and mortality. The currently available vaccines are designed to prevent infection. Their efficacy and safety have been demonstrated in clinical trials. Yet, given the short duration of the trials and the urgency to start vaccination, adverse events have been reported worldwide in real-life data format. Immune-mediated disease flares or new-onset inflammatory diseases following vaccine administration have recently been reported worldwide. Here, we present three cases of inflammatory arthritis (IA) caused by the BNT162b2 COVID vaccination, including two new-onset cases and one case of a flareÂ of existing disease. The first case is new-onset IA, the second case is new-onset rheumatoid arthritis, and the third case is a flare of existing rheumatoid arthritis. Given the timeline of when our patients developed either a flare of their existing rheumatoid arthritis or new-onset IA or polymyalgia rheumatica (PMR) (a few days after receiving the COVID-19 vaccine), in addition to the currently available evidence of documented similar cases post administration of mRNA vaccines, as well as the link between their mechanism of action and the pathogenesis of those diseases, we can speculate a causal relationship between the vaccine and the triggering of these disease entities. In the future, it is important to consider that autoimmune diseases might be triggered or flared by the administration of vaccines, which appears to be associated with the COVID vaccine as well.Â Further evaluation of its incidence will provide additional clarity, though the rarity of this occurrence in the setting of more

than half of the US population becoming vaccinated indicates that the benefit of the vaccine in terms of protection from COVID morbidity and mortality far outweighs this risk.

Withholding methotrexate after vaccination with ChAdOx1 nCov19 in patients with rheumatoid or psoriatic arthritis in India (MIVAC I and II): results of two, parallel, assessor-masked, randomised controlled trials. BACKGROUND: There is a necessity for an optimal COVID-19 vaccination strategy for vulnerable population groups, including people with autoimmune inflammatory arthritis on immunosuppressants such as methotrexate, which inhibit vaccine-induced immunity against SARS-CoV-2. Thus, we aimed to assess the effects of withholding methotrexate for 2 weeks after each dose of ChAdOx1 nCov-19 (Oxford-AstraZeneca) vaccine (MIVAC I) or only after the second dose of vaccine (MIVAC II) compared with continuation of methotrexate, in terms of post-vaccination antibody titres and disease flare rates. METHODS: MIVAC I and II were two parallel, independent, assessor-masked, randomised trials. The trials were done at a single centre (Dr Shenoy's Centre for Arthritis and Rheumatism Excellence; Kochi, India) in people with either rheumatoid arthritis or psoriatic arthritis with stable disease activity, who had been on a fixed dose of methotrexate for the preceding 6 weeks. Those with previous COVID-19 or who were positive for anti-SARS-CoV-2 nucleocapsid antibodies were excluded from the trials. People on high-dose corticosteroids and rituximab were also excluded, whereas other disease-modifying antirheumatic drugs were allowed. In MIVAC I, participants were randomly assigned (1:1) to stop methotrexate treatment for 2 weeks after each vaccine dose or to continue methotrexate treatment. In MIVAC II, participants who had continued methotrexate during the first dose of vaccine were randomly assigned (1:1) to withhold methotrexate for 2 weeks after the second dose of vaccine or to continue to take methotrexate. The treating physician was masked to the group assignments. The primary outcome for both MIVAC I and MIVAC II was the titre (absolute value) of anti-receptor binding domain (RBD) antibody measured 4 weeks after the second dose of vaccine. All analyses were done per protocol. The trials were registered with the Clinical Trials Registry- India, number CTRI/2021/07/034639 (MIVAC I) and CTRI/2021/07/035307 (MIVAC II). FINDINGS: Between July 6 and Dec 15, 2021, participants were recruited to the trials. In MIVAC I, 250 participants were randomly assigned and 158 completed the study as per the protocol (80 in the methotrexate hold group and 78 in the control group; 148 [94%] were women and 10 [6%] were men). The median post-vaccination antibody titres in the methotrexate hold group were significantly higher compared with the control group (2484Â·0 IU/mL, IQR 1050Â·0-4388Â·8 vs 1147Â·5 IU/mL, 433Â·5-2360Â·3; p=0Â·0014). In MIVAC II, 178 participants were randomly assigned and 157 completed the study per protocol (76 in the methotrexate hold group and 81 in the control group; 135 [86%] were women and 22 [14%] were men). The methotrexate hold group had higher post-vaccination antibody titres compared with the control group (2553Â·5 IU/ml, IQR 1792Â·5-4823Â·8 vs 990Â·5, 356Â·1-2252Â·5; p<0Â·0001). There were no reports of any serious adverse events during the trial period. INTERPRETATION: Withholding methotrexate after both ChAdOx1 nCov-19 vaccine doses and after only the second dose led to higher anti-RBD antibody titres compared with continuation of methotrexate. However, withholding methotrexate only after the second vaccine dose resulted in a similar humoral response to holding methotrexate after both vaccine doses, without an increased risk of arthritis flares. Hence, interruption of methotrexate during the second dose of ChAdOx1 nCov-19 vaccine appears to be a safe and effective strategy to improve the antibody response in patients with rheumatoid or psoriatic arthritis. FUNDING: Indian Rheumatology Association.

Successful Treatment of Subacute Thyroiditis After Recombinant COVID-19 Vaccination Using Traditional Chinese Medicine: A Case Report. Subacute thyroiditis (SAT) is a thyroid inflammatory disease, which can beÂ triggered by viral infection. The severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) is considered to be a potent SAT-triggering factorÂ in this COVID-19

pandemic. However, SAT occurring after SARS-CoV-2 vaccination is rarely reported. Despite the high availability of diagnostic tools, the recurrence and steroid dependence as well as delayed diagnosis of SAT remain. This paper reports a rare case where a patient was diagnosed with SAT post receiving a recombinant novel coronavirus vaccine (Anhui Zhifei Longcom Biopharmaceutical Co.Ltd., China), and efficiently treated with traditional Chinese medicine rather than prednisone. We hope that this case report not only contributes to raising awareness of SAT related to the COVID-19 vaccine but also provides an effective remedy in addition toÂ glucocorticoid (GC).

Kinetics of immune responses elicited after three mRNA COVID-19 vaccine doses in predominantly antibody-deficient individuals. Mass vaccination campaigns reduced COVID-19 incidence and severity. Here, we evaluated the immune responses developed in SARS-CoV-2-uninfected patients with predominantly antibody-deficiencies (PAD) after three mRNA-1273 vaccine doses. PAD patients were classified based on their immunodeficiency: unclassified primary antibody-deficiency (unPAD, nÂ = 9), common variable immunodeficiency (CVID, nÂ = 12), combined immunodeficiency (CID, nÂ = 1), and thymoma with immunodeficiency (TID, nÂ = 1). unPAD patients and healthy controls (HCs, nÂ = 10) developed similar vaccine-induced humoral responses after two doses. However, CVID patients showed reduced binding and neutralizing titers compared to HCs. Of interest, these PAD groups showed lower levels of Spike-specific IFN-Î³-producing cells. CVID individuals also presented diminished CD8(+)T cells. CID and TID patients developed cellular but not humoral responses. Although the third vaccine dose boosted humoral responses in most PAD patients, it had limited effect on expanding cellular immunity. Vaccine-induced immune responses in PAD individuals are heterogeneous, and should be immunomonitored to define a personalized therapeutic strategies.

Immunogenicity, Reactogenicity, and Reinfection After 2 Doses of the Inactivated Whole-virion CoronaVac Vaccine in Kidney Transplant Recipients Convalescents From COVID-19.

Cross neutralization of SARS-CoV-2 omicron subvariants after repeated doses of COVID-19 mRNA vaccines. We have measured the humoral response to messenger RNA (mRNA) vaccines in COVID-19 naÃ¯ve and convalescent individuals. Third doses of mRNA COVID-19 vaccines induced a significant increase in potency and breadth of neutralization against SARS-CoV-2 variants of concern (VoC) including Omicron subvariants BA.1, BA.2, and BA.2.12.1, that were cross-neutralized at comparable levels and less for BA.4/5. This booster effect was especially important in naÃ¯ve individuals that only after the third dose achieved a level that was comparable with that of vaccinated COVID-19 convalescents except for BA.4/5. Avidity of RBD-binding antibodies was also significantly increased in naÃ¯ve individuals after the third dose, indicating an association between affinity maturation and cross neutralization of VoC. These results suggest that at least three antigenic stimuli by infection or vaccination with ancestral SARS-CoV-2 sequences are required to induce high avidity cross-neutralizing antibodies. Nevertheless, the circulation of new subvariants such as BA.4/5 with partial resistance to neutralization will have to be closely monitored and eventually consider for future vaccine developments.

The association of three doses of the BNT162b2 mRNA vaccine with abnormal bleeding and an irregular menstrual cycle among premenopausal females: A single institute observation study. BACKGROUND: The COVID-19 vaccine is effective in preventing severe cases of COVID-19. For women, gynecological adverse events, such as menstrual irregularities and irregular bleeding, could be a concern after COVID-19 vaccination. In this study, we investigated gynecological adverse events in the vaccinated Japanese female population. METHODS: We conducted a survey-based study with health-care workers, including medical doctors and nurses, medical coworkers, and medical university faculty, staff, and students, at a single medical school and affiliated hospital in Japan. We used McNemar's test and network analysis. RESULTS: Overall, we obtained 819 responses, and 424 were from females. After the exclusion of contradictory answers, 309 surveys were finally considered

appropriate for the analysis. The frequencies of abnormal bleeding were 0.6%, 1.0%, and 3.0% for the first, second, and third doses, respectively. An irregular menstrual cycle was more common than abnormal bleeding: 1.9%, 4.9%, and 6.6% for the first, second, and third doses, respectively. Network analysis revealed that abnormal bleeding and an irregular menstrual cycle were not associated with other adverse reactions. CONCLUSION: The present study showed that the effects of COVID-19 vaccination on menstruation seem limited.

IgA Vasculitis Following COVID-19 Vaccination: A French Multicenter Case Series Including 12 Patients. OBJECTIVE: The worldwide coronavirus disease 2019 (COVID-19) vaccination campaign triggered several autoimmune diseases. We hereby aimed to describe IgA vasculitis (IgAV) following COVID-19 vaccination. METHODS: We conducted a national, multicenter, retrospective study in France of new-onset adult IgAV diagnosis following COVID-19 vaccination. RESULTS: In total, 12 patients with new-onset IgAV were included. Of these, 5 (41.7%) were women, and the median age was 52.5 (IQR 30.75-60.5) years. Of the 12 patients, 10 had received an mRNA vaccine and 2 had received a viral vector vaccine. The median time from vaccination to onset of symptoms was 11.5 (IQR 4.25-21.25) days. Vasculitis occurred after the first vaccine dose in most patients (n = 8). All patients had skin involvement, with skin necrosis in 4 patients. In total, 7 patients had joint involvement and 2 had arthritis. A total of 4 patients had nonsevere gastrointestinal involvement and 2 had nonsevere renal involvement. The median C-reactive protein level was 26 (IQR 10-66.75) mg/L, the median creatininemia level was 72 (IQR 65-81) Î¼mol/L, and 1 patient had an estimated glomerular filtration rate of less than 60 mL/min at management. All patients received treatment, including 9 patients (75%) who received glucocorticoids. In total, 5 patients received a vaccine dose after developing IgAV, 1 of whom experienced a minor cutaneous relapse. CONCLUSION: The baseline presentation of IgAV following COVID-19 vaccination was mild to moderate, and outcomes were favorable. Thus, a complete COVID-19 vaccination regimen should be completed in this population. Of note, a fortuitous link cannot be ruled out, requiring a worldwide pharmacovigilance search to confirm these findings.

Bullous pilomatricoma arising at a COVID-19 vaccination site.

Durable spike-specific T cell responses after different COVID-19 vaccination regimens are not further enhanced by booster vaccination. Several COVID-19 vaccines are approved to prevent severe disease outcome after SARS-CoV-2 infection. Whereas induction and functionality of antiviral antibody response are largely studied, the induction of T cells upon vaccination with the different approved COVID-19 vaccines is less studied. Here, we report on T cell immunity 4 weeks and 6 months after different vaccination regimens and 4 weeks after an additional booster vaccination in comparison with SARS-CoV-2Â T cell responses in convalescents and prepandemic donors using interferon-gamma ELISpot assays and flow cytometry. Increased T cell responses and cross-recognition of B.1.1.529 Omicron variant-specific mutations were observed ex vivo in mRNA- and heterologous-vaccinated donors compared with vector-vaccinated donors. Nevertheless, potent expandability of T cells targeting the spike protein was observed for all vaccination regimens, with frequency, diversity, and the ability to produce several cytokines of vaccine-induced T cell responses comparable with those in convalescent donors. T cell responses for all vaccinated donors significantly exceeded preexisting cross-reactive T cell responses in prepandemic donors. Booster vaccination led to a significant increase in anti-spike IgG responses, which showed a marked decline 6Â months after complete vaccination. In contrast, T cell responses remained stable over time after complete vaccination with no significant effect of booster vaccination on T cell responses and cross-recognition of Omicron BA.1 and BA.2 mutations. This suggested that booster vaccination is of particular relevance for the amelioration of antibody response. Together, our work shows that different

vaccination regimens induce broad and long-lasting spike-specific CD4(+) and CD8(+) T cell immunity to SARS-CoV-2.

Evaluation of SARS-CoV-2 Antibody Response Post Third Dose COVID-19 mRNA Vaccination at Universitas Indonesia Hospital. OBJECTIVE: The longevity of vaccine effectiveness and antibody titer after the Moderna mRNA COVID-19 vaccination booster in healthcare workers in Indonesia is not known. MATERIALS AND METHODS: We performed a prospective observational study of healthcare workers at the Universitas Indonesia Hospital after Moderna mRNA COVID-19 booster vaccination. An Immunology Analyzer with Chemiluminescence Immunoassay (CLIA) test was used to examine Anti SARS-CoV-2 S-RBD levels. Antibody levels were classified into two systems (3 categories, and 2 categories). RESULTS: There were 31 male subjects (75.6%), 33 subjects (80.5%) aged 25-39 years, 17 subjects (41.5%) with overweight BMI, 35 subjects (85.4%) without comorbidities, and 29 subjects without previous history of COVID-19 infection (70.7%) who had antibody titer >1000 AU/ml. There were 27 subjects (65.9%) who had a booster shot â‰¥6 months after the second vaccination with antibody titer >1000 AU/ml. In this study, there was no significant correlation between antibody titer with factors such as gender, age, BMI, comorbidities, history of COVID-19 infection and time between the 2nd vaccination and booster vaccination. CONCLUSION: There is no significant correlation between antibody titer with factors such as gender, age, BMI, comorbidities, history of COVID-19 infection and time between the 2nd vaccination and booster vaccination.

Effects of COVID-19 vaccination on platelet counts and bleeding in children, adolescents, and young adults with immune thrombocytopenia. Coronavirus disease 2019 (COVID-19) vaccines rarely cause de novo immune thrombocytopenia (ITP) but may worsen preexisting ITP in adults. Whether severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines impact platelet counts and bleeding in children, adolescents, and young adults (C-AYA) with preexisting ITP is unknown. We report here the very limited effect of COVID-19 vaccination on platelet counts and bleeding in a single-center series of 2 C-AYA with ITP. No patient experienced worsening bleeding and only one child had a significant decrease in platelet count which improved spontaneously to her baseline without intervention. SARS-CoV2 vaccination was safe in C-AYA with ITP in this small cohort.

Managing adult asthma during the COVID-19 pandemic: A 2022 review and current recommendations. INTRODUCTION: This review aims to examine asthma management during the COVID-19 pandemic. METHOD: Relevant recommendations and articles were identified by respiratory professional societies and PubMed search using the terms "asthma" and "COVID-19", and examined for relevance and inclusion in this study. RESULTS: Recommendations for the management of asthma have remained similar but are now supported by new evidence between the years 2020 and 2022. Patients with well-controlled, mild-to-moderate asthma are unlikely to be at increased risk of acquiring COVID-19 or having worse outcomes from COVID-19. All asthma patients should receive COVID-19 vaccination. Spirometry can be performed with the usual strict infection control procedures unless there is a suspicion of COVID-19. Mask-wearing and other health measures remain important for asthma patients. CONCLUSION: While previous recommendations were largely based on expert opinion, the tremendous amount of literature published since the pandemic first emerged 2 years ago has helped guide respiratory professional bodies to update their recommendations. This study provides a timely review of the various recommendations and can be used to guide healthcare professionals in managing asthma patients, as the world prepares for a future with COVID-19 becoming endemic. The long-term consequences of COVID-19 infection in asthma patients and the ripple effects of COVID-19 remain uncertain and deserve ongoing study.

Evaluation of immunoprotection against coronavirus disease 2019: Novel variants, vaccine inoculation, and complications. The strikingly rapidly mutating nature of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) genome has been a constant challenge during the

coronavirus disease 2019 (COVID-19) pandemic. In this study, various techniques, including reverse transcription-quantitative polymerase chain reaction, antigen-detection rapid diagnostic tests, and high-throughput sequencing were analyzed under different scenarios and spectra for the etiological diagnosis of COVID-19 at the population scale. This study aimed to summarize the latest research progress and provide up-to-date understanding of the methodology used for the evaluation of the immunoprotection conditions against future variants of SARS-CoV-2. Our novel work reviewed the current methods for the evaluation of the immunoprotection status of a specific population (endogenous antibodies) before and after vaccine inoculation (administered with biopharmaceutical antibody products). The present knowledge of the immunoprotection status regarding the COVID-19 complications was also discussed. Knowledge on the immunoprotection status of specific populations can help guide the design of pharmaceutical antibody products, inform practice guidelines, and develop national regulations with respect to the timing of and need for extra rounds of vaccine boosters.

A case of hemophagocytic lymphohistiocytosis after BNT162b2 COVID-19 (ComirnatyÂ®) vaccination. RATIONALE: Coronavirus disease (COVID-19), an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 virus, was reported in Wuhan of China in December 2019. The world is still in a state of pandemic owing to COVID-19. COVID-19 vaccines help our bodies develop immunity against the virus that causes COVID-19 without having to get the illness. Herein, we describe a rare case of a critical disorder, hemophagocytic lymphohistiocytosis (HLH), in a patient with nephritic sclerosis associated with hypertension, following mRNA COVID-19 vaccination. HLH is a life-threatening hyperinflammatory syndrome caused by aberrantly activated macrophages and cytotoxic T cells that may rapidly progress to terminal multiple organ failure. PATIENT CONCERNS: An 85-year-old Japanese woman with chronic renal failure and hypertension was included in this study. Routine laboratory investigations provided the following results: white blood cell (WBC) count, 4.6â€…Ã—â€…109/L; hemoglobin (Hb), 8.1â€‰g/dL; platelet count, 27â€…Ã—â€…109/L; blood urea nitrogen 48.9â€‰mg/dL, and serum creatinine 3.95â€‰mg/dL. The patient developed malaise, vomiting, and persistent high fever (up to 39.7Â°C) on the 12th day after receiving the second dose of the vaccine. Initial evaluation revealed neutropenia. The total WBC count was 0.40â€…Ã—â€…109/L (Neutrophils 0, Lymphocytes 240/Î¼, blast 0%); Hb 9.0â€‰g/dL, platelet count 27â€…Ã—â€…109/L; and, C Reactive Protein 9.64â€‰mg/dL. DIAGNOSIS: Further tests showed hyperferritinemia (serum ferritin 2284.4 Î¼g/L). Bone marrow examination revealed haemophagocytosis. A provisional diagnosis of HLH associated with the ComirnatyÂ® vaccination was made based on the HLH-2004 diagnostic criteria. INTERVENTIONS: The patient was treated with granulocyte colony-stimulating factor and 500â€‰mg methylprednisolone. OUTCOMES: A significant improvement was observed in the patient's condition; the abnormal laboratory results resolved gradually, and the patient was discharged. LESSONS: This case serves to create awareness among clinicians that HLH is a rare complication of COVID-19 vaccination and should be considered, especially in patients with a history of chronic renal failure and hypertension.

Posterior ocular manifestations following BNT162b2 mRNA COVID-19 vaccine: a case series. PURPOSE: To report the occurrence of posterior ocular adverse events following the administration of the BNT162b2 mRNA vaccine against SARS-CoV-2. METHODS: A retrospective consecutive case series, in which the medical files of patients presenting with ocular adverse events within 30Â days of the vaccine inoculation, were analyzed. RESULTS: Four patients (2 females) were included in the study. The diagnoses included: posterior scleritis, paracentral acute middle maculopathy, herpes panuveitis, and Vogt-Koyanagi-Harada (VKH)-like uveitis. Three of the patients had no relevant ocular history, but the patient who developed scleritis was in remission without medical therapy for four years, until the flare-up, which occurred one day after the vaccine. All patients improved with treatment.

CONCLUSION: Though a causal relationship cannot be definitively established, the temporal relationship suggests a possible link between the COVID-19 vaccine and the posterior ocular complications. The benefits of vaccination clearly outweigh the potential adverse effects; however, ophthalmologists should be aware of the potential for vaccine-associated uveitis.

Good tolerance of hyaluronic acid filler injections during the COVID-19 pandemic. BACKGROUND: The aim of our study was to identify and evaluate the complications related to hyaluronic acid during the COVID-19 pandemic. METHOD: Twelve dermatologists participated in this study. A cohort and a non-cohort follow-up were ensured. RESULTS: (1) Cohort follow-up: 1041 patients. 8% had a COVID-19 infection, 27% had received COVID-19 vaccination. 2% had immediate side effects (edema, erythema, bruising). 0.5% had delayed side effects (two inflammatory nodules, one nodule without inflammation, one edema). None of these side effects occurred in the context of infection or COVID-19 vaccinations. (2) Non-cohort follow-up: 7900 syringes used. Two early side effects (inflammatory edema) were reported, of which one occurred 15â€‰days after vaccination. Two cases of delayed side effects such as inflammation on the injected area and inflammatory nodules occurred of which one was in the context of vaccination and one during COVID-19 infection. We estimate the frequency of complications possibly attributable to the disease or to the COVID vaccination to be 0.06% in our population. DISCUSSION: Complications of HA injections in the context of COVID-19 disease or vaccination appear to be very rare but the frequency could be underestimated because of the low rate of vaccination/infection in our population. Our study shows a very good tolerance of hyaluronic acid injections during the COVID-19 pandemic.

Miller-Fisher syndrome and Guillain-Barre syndrome overlap syndrome following inactivated COVID-19 vaccine: Case report and scope review. Miller-Fisher syndrome (MFS) is a rare variant of Guillain-BarrÃ© syndrome (GBS) manifesting as the triad of ataxia, areflexia, and ophthalmoplegia. With the extensive 2019 coronavirus disease (COVID-19) immunization program, cases of GBS or MFS following vaccination are increasingly being reported. A 64-y-old Chinese man presented with new-onset paresthesia of the extremities, bilateral abduction limitation, right facial palsy, areflexia of bilateral lower limbs, and left-dominant limb ataxia 12â€‰d after the second dose of inactivated vaccine against COVID-19. Cerebrospinal fluid analysis indicated albumin-cytological dissociation and was positive for anti-GQ1b IgG and anti-GT1b IgG. Nerve conduction studies of limbs showed evidence of axonal neuropathy with reduced sensory amplitudes. Based on the clinical presentations, temporal progression of symptoms, and laboratory findings, the diagnosis of MFS-GBS overlap syndrome was made. The patient was treated with intravenous immunoglobulin and acupuncture and made a complete recovery 54â€‰d after the onset of his initial neurological signs. To the best of our knowledge, we report the first case of MFS-GBS overlap syndrome following the inactivated COVID-19 vaccination. However, a coincidental relationship with this inactivated vaccine cannot be excluded. Although the benefits of COVID-19 vaccination largely outweigh its risk and the prognosis of MFS is generally favorable, a close surveillance of neurological complications post-COVID-19 vaccination is always necessary, considering its potentially disabling and lethal effects on vaccinated populations.

COVID-19 vaccination in autoimmune diseases (COVAD) study: vaccine safety and tolerance in rheumatoid arthritis. OBJECTIVES: The COVID-19 vaccination in autoimmune diseases (COVAD) study aimed to assess short-term COVID-19 vaccination-related adverse events (AEs) in RA patients. METHODS: An online self-reported questionnaire (March-December 2021) was used to capture data related to COVID-19 vaccination-related AEs in RA, other autoimmune rheumatic diseases (AIRDs) (excluding RA and inflammatory myositis), non-rheumatic autoimmune diseases (nrAIDs) and healthy controls (HCs). Descriptive and multivariable regression analyses were performed. RESULTS: Of the 9462 complete respondents, 14.2% (nâ€‰=â€‰1347) had been diagnosed with RA; they had a mean

(s.d.) age of 50.7 (13.7) years, 74.2% were women and 49.3% were Caucasian. In total, 76.9% and 4.2% of patients with RA reported minor and major AEs, respectively. Patients with active and inactive RA had similar AE and hospitalization frequencies. Overall, AEs were reported more frequently by BNT162b2 and mRNA-1273 recipients and less frequently by BBV152 recipients compared with the rest. Major AE and hospitalization frequencies were similar across recipients of different vaccines. Patients receiving methotrexate and hydroxychloroquine reported fewer minor AEs than those patients not on them. Compared with HCs and patients with other AIRDs, patients with RA reported similar total AEs, overall minor AEs, and hospitalizations. Compared with nrAIDs, patients with RA reported lower frequencies of overall AEs, minor AEs (both odds ratio [OR]â€‰=â€‰0.7; 95% CI: 0.5, 0.9), and injection site pain (ORâ€‰=â€‰0.6; 95% CI: 0.5, 0.8) with similar major AE and hospitalization frequencies. CONCLUSION: Despite the differences in AE frequency across different COVID-19 vaccines, all were well tolerated in patients with RA and were comparable to HCs, providing reassurance as to the safety of COVID-19 vaccination.

First Booster of SARS-COV-2 mRNA Vaccine Is Not Associated With Alloimmunization and Subclinical Injury of Kidney Allograft.

Very severe immune aplastic anemia after mRNA vaccination against COVID-19 responds well to immunosuppressive therapy: clinical characteristics and comparison to previous reports. OBJECTIVE: Various hematologic side effects of the Coronavirus Disease 2019 (COVID-19) vaccination has been reported, and most of them are thought to be related to autoimmune pathways. To the best of our knowledge, only few cases of post-COVID-19 vaccination aplastic anemia (AA) have been reported and there is no reported Korean case of COVID-19 vaccine-induced AA yet. We present a case of severe immune-mediated AA that developed after the administration of a messenger ribonucleic acid (mRNA) gene-based spike protein vaccine against COVID-19, which responded well to immunosuppressive therapy, and discuss the probable pathogenesis of AA and the implication of vaccination along with a comparison of previous cases reported. METHODS: A 53-year-old Korean man developed sudden pancytopenia three months after COVID-19 vaccination. To evaluate the cause of pancytopenia, a bone marrow study was performed. RESULTS: A diagnosis of AA was made through the bone marrow study and he received triple immunosuppressive therapy (IST). After triple IST for five months, his blood cell count was improved and maintained without transfusion and his follow-up bone marrow examination showed improved cellularity. CONCLUSION: COVID-19 vaccine might be associated with the development of immune-mediated AA. Prompt hematologic evaluation should be performed when there are symptoms or signs suggestive of cytopenia after COVID-19 vaccination. Although the clinical outcome of post-vaccination AA varies, a good prognosis can be possible for patients with COVID-19 vaccination-induced AA.

Impact of Sex and Age on mRNA COVID-19 Vaccine-Related Side Effects in Japan. mRNA COVID-19 vaccination was initiated worldwide in late 2020, and its efficacy has been well reported. However, studies about vaccine-related side effects are sparse. A total of 262 health care workers who received mRNA COVID-19 vaccine BNT162b2 were recruited, and their vaccine-related side effects were investigated. Impact of sex and age on the side effects was statistically analyzed. A higher number of vaccine-related side effects among females versus males was identified (median 3 versus 2, Pâ€‰<â€‰0.05, after the first dose, and 5 versus 2.5, Pâ€‰<â€‰0.01, after the second dose). General fatigue, headache, chills, and fever were the culprit adverse symptoms. In multivariate analysis, females had an increasing number of side effects after receiving their first (Bâ€‰=â€‰0.7; 95% confidence interval [CI], 0.2 to 1.2) and second (Bâ€‰=â€‰1.5; 95% CI, 0.7 to 2.2) vaccine doses compared to that of males. In age analysis, the older group (â‰¥60â€‰years old) had a lower number of side effects than the younger group (B = -0.5 with a 95% CI of -1.1 to -0.02 after the first vaccine dose, and B = -2.1 with a 95% CI of -2.9 to -1.2 after the second vaccine dose). Additionally,

prolonged time to recovery was found among females (Pâ€‰=â€‰0.003 after the first dose; Pâ€‰=â€‰0.008 after the second dose). Specifically, symptoms of general fatigue, headache, itching, swelling at the injection site, and dizziness were the culprit symptoms affecting recovery time. Several cutaneous and membranous symptoms, including "COVID arm," were identified among females. These results highlight the impact of sex and age on side effects from mRNA COVID-19 vaccine and will aid in creating a safer vaccine. IMPORTANCE We demonstrate sex- and age-related impact on mRNA COVID-19 vaccine-related side effects, with a higher number and frequency of side effects and prolonged time to recovery in females compared to males and negative correlation between age and vaccine-related side effects. Identification of unique age- and sex-specific adverse symptoms will provide the opportunity to better understand the nature of sex- and age-associated immunological differences and develop safer and more efficacious vaccines.

Suspected Delayed Inflammatory Cutaneous Reaction due to ChAdOx1/nCoV-19 Vaccine Sited in Preexisting Morphea Lesions.

A Histologic Timeline of a Delayed Hypersensitivity Reaction after the COVID-19 Pfizer Booster. A 54-year-old man presented with worsening bilateral rashes on legs and arms 7 days after receiving his BNT162b2 mRNA COVID-19 (Pfizer) vaccine booster. He developed burning on his palms about 5 days after receiving the booster. On day 6, he observed significant edema on his fingers and palms in addition to thin erythematous papules on his forearms. On day 7, he developed edema on his bilateral dorsal feet, and thin erythematous plaques on his shins. He stated that the rashes were pruritic. He had no rashes following the first two doses of the Pfizer vaccine. He denied having any history of skin disease, autoimmune disease, or allergies. Physical examination revealed multiple thin erythematous papules coalescing into thin plaques on his flexor forearms, and thin erythematous plaques on his dorsal feet (Figure 1). Three 4-mm punch biopsies were performed on his left flexor forearm. The biopsies were carried out at papules present for different lengths of time. Papules at biopsy sites "A," "B," and "C" were present for approximately 24-36 hours, 12-18 hours, and 3-6 hours, respectively (Figure 1).

Waning immunity to SARS-CoV-2 following vaccination or infection. We use survival analysis to analyze the decay in the protection induced by eight SARS-CoV-2 vaccines using data from 33,418 fully anonymized patients from the IMSS public health system in Mexico, including only previously vaccinated, confirmed SARS-CoV-2 positive with a PCR test. We analyze the waning effect in those with complete vs. incomplete dose fitting a Weibull distribution. We compare these results with an estimate of the waning effect due to active infection. In two-dose vaccines, we found that the average protection time of a complete dose increases 2.6 times compared to that of an incomplete dose. All analyzed vaccines provided a protection that lasted longer than the protection due to active infection, except in those patients that did not fulfilled the complete dose. The average protection of a full dose is 2.2 times larger than that provided by active infection. The average protection of active infection is about the same as the average protection of an incomplete dose. All evaluated vaccines had lost most of their protective effect between 8 and 11 months of application of first shot. Our results highly correlate with NT(50) and other estimates of vaccine efficacy. We found that on average, vaccination increases Age(50), the age at which there is a 50% probability of severe disease if infected, in 15 years. We also found that Age(50) increases with mean protection time.

Variation of Total Anti-SARS-CoV-2 Antibodies After Primary BNT162b2 Vaccination and Homologous Booster. BACKGROUND: In this serosurveillance study, we investigated the variation of total anti-SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) antibodies in healthcare workers receiving primary BNT162b2 vaccination and homologous booster. METHODS: A total number of 524 subjects (median age, 46 years; 65.3% females), were studied. All received primary BNT162b2 vaccination (two doses) and homologous booster (one dose) >8 months after completing the primary

cycle. Blood samples were collected before the first and second vaccine doses, at 1, 3 and 6 months after the second dose, as well as before and 1 month after booster. Total anti-SARS-CoV-2 neutralizing antibodies were assayed with Roche Elecsys Anti-SARS-CoV-2 S chemiluminescent immunoassay. RESULTS: Overall, 65.1% subjects were baseline (i.e., pre-vaccination) SARS-CoV-2 seronegative and always tested SARS-CoV-2 negative ("N/N"), 16.2% were baseline SARS-CoV-2 seronegative but tested SARS-CoV-2 positive after receiving the vaccine booster dose ("N/P"), whilst 18.7% were baseline SARS-CoV-2 seropositive and always tested SARS-CoV-2 negative afterwards ("P/N"). All groups displayed a similar trend of total anti-SARS-CoV-2 S antibodies throughout the study period, though the P/N cohort exhibited higher values compared to the other two groups until receiving the booster, after which the levels become similar in all cohorts. Significant differences in total anti-SARS-CoV-2 S antibodies values were not found between N/N and N/P groups, neither 1 month after booster. The rate of subjects with protective antibodies values become 100% in all groups after booster. CONCLUSIONS: Although baseline seropositivity is associated with more pronounced humoral immune response following primary vaccination compared to never infected subjects, SARS-CoV-2 infection after booster does not significantly foster antibody titers.

Acute pancreatitis as an adverse effect of COVID-19 vaccination. While vaccination against COVID-19 has significantly improved the morbidity and mortality of the disease, with the increase in the administration of COVID-19 vaccines, it is more likely to observe their rare side effects in the clinical settings. Herein, we report a case of an 82-year-old man with history of coronary artery disease, prostate cancer in remission, gastroesophageal reflux disease, and hypothyroidism, who presented with acute pancreatitis few hours after receiving the third dose of Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine, without other identified etiology. His symptoms were mild and he was discharged in a stable condition after improvement in his condition with supportive care.

Nephrotic Syndrome in Adult Patients With COVID-19 Infection or Post COVID-19 Vaccine: A Systematic Review. Nephrotic syndrome is a condition characterized by damage to podocytes that results in significant proteinuria, edema, hyperlipidemia, and hypercoagulability. Infections and malignancies are frequently associated with nephrotic syndrome. The COVID-19 virus has been associated with several atypical presentations of upper respiratory infections and acute kidney injury. Considering that COVID-19 causes systemic inflammatory changes, it seems plausible that it may also lead to nephrotic syndrome. This study aimed to investigate if an association between COVID-19 and the different types of nephrotic syndromes exists. Data were extracted into a spreadsheet. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS, IBM Corp., Armonk, NY, USA). We performed a systematic search of PubMed/Medline and Embase databases using both medical subject headings (MeSH) and regular keywords associated with COVID-19 and nephrotic syndrome, including different types of nephrotic syndromes. The search was performed on 17th December 2021. We included case reports and case series about adult patients who developed findings suggestive of nephrotic syndrome shortly after infection or vaccination. We excluded cases involving children, pregnant women, articles written in languages other than English, and those that were not retrievable. The relevance and quality of identified articles were assessed. We included 32 articles in the study, primarily case reports and case series. In our study, COVID-19 and the COVID-19 vaccine have been associated with the development of nephrotic syndrome, primarily a collapsing form of focal segmental glomerulosclerosis, although other forms have been observed as well. There was little consistency in patient histories, clinical presentations, clinical courses, or treatment regimens, although it appeared that most cases eventually resolved. More cases need to be reported and analyzed before more definitive conclusions can be reached. In conclusion, nephrotic syndrome is a possible complication of both COVID-19 infection and the COVD-19 vaccine and should be considered in patients exhibiting sudden onset edemas or deterioration in kidney function. While the

majority of cases respond to standard treatment, clearer guidelines will need to be developed once more data is available.

Comparison of the Immune Response After an Extended Primary Series of COVID-19 Vaccination in Kidney Transplant Recipients Receiving Standard Versus Mycophenolic Acid-sparing Immunosuppressive Regimen. Two doses of coronavirus disease 2019 vaccination provide suboptimal immune response in transplant patients. Mycophenolic acid (MPA) is one of the most important factors that blunts the immune response. We studied the immune response to the extended primary series of 2 doses of AZD1222 and a single dose of BNT162b2 in kidney transplant patients who were on the standard immunosuppressive regimen compared to those on the MPA-sparing regimen. METHODS: The kidney transplant recipients who were enrolled into the study were divided into 2 groups based on their immunosuppressive regimen. Those on the standard immunosuppressive regimen received tacrolimus (TAC), MPA, and prednisolone (standard group). The patients in the MPA-sparing group received mammalian target of rapamycin inhibitors (mTORi) with low dose TAC plus prednisolone (MPA-sparing group). The vaccination consisted of 2 doses of AZD1222 and a single dose of BNT162b2. RESULTS: A total of 115 patients completed the study. There were 76 (66.08%) patients in the standard group and 39 (33.91%) patients in the MPA-sparing group. The overall median anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) S antibody level at 4 wk after vaccine completion was 676.64 (interquartile range = 6.02-3644.03) BAU/mL with an 80% seroconversion rate. The MPA-sparing group achieved higher anti-SARS-CoV-2 S antibody level compared to the standard group (3060.69 and 113.91 BAU/mL, $P < 0.001$). The seroconversion rate of MPA-sparing and standard groups were 97.4% and 71.1%, respectively ($P < 0.001$). The anti-HLA antibodies did not significantly increase after vaccination. CONCLUSIONS: The extended primary series of 2 doses of AZD1222 and a single dose of BNT162b2 provided significant humoral immune response. The MPA-sparing regimen with mTORi and low dose TAC had a higher ant-SARS-CoV-2 S antibody level and seroconversion rate compared to the participants in the standard regimen.

Factors influencing the SARS-CoV-2 infection and vaccination induced immune response in rheumatoid arthritis. BACKGROUND: To investigate the factors that have significant impact on the Severe Acute Respiratory Syndrome Corona Virus 2 (SARS-CoV-2) infection and vaccination induced immune response in rheumatoid arthritis (RA). METHODS: Serological response was measured by quantifying anti-SARS-CoV-2 specific antibodies, while the cell-mediated response was measured by a whole-blood test quantifying the interferon (IFN)-Î³ response to different SARS-CoV-2-specific domains. RESULTS: We prospectively enrolled 109 RA patients and 43 healthy controls. The median time (IQR) between the confirmed infection or the last vaccination dose and the day when samples were taken ("sampling interval") was 3.67 (2.03, 5.50) months in the RA group. Anti-Spike (anti-S) specific antibodies were detected in 94% of RA patients. Among the investigated patient related variables, age ($p<0.004$), sampling interval ($p<0.001$), the brand of the vaccine ($p<0.001$) and targeted RA therapy (TNF-inhibitor, IL-6 inhibitor, anti-CD20 therapy) had significant effect on the anti-S levels. After covariate adjustment TNF-inhibitor therapy decreased the anti-S antibody concentrations by 80% ($p<0.001$). The same figures for IL-6 inhibitor and anti-CD20 therapy were 74% ($p=0.049$) and 97% ($p=0.002$), respectively. Compared to subjects who were infected but were not vaccinated, the RNA COVID-19 vaccines increased the anti-S antibody levels to 71.1 (mRNA-1273) and 36.0 (BNT162b2) fold ($p<0.001$). The corresponding figure for the ChAdOx1s vaccine is 18.1($p=0.037$). Anti-CCP (anti-cyclic citrullinated peptides) positive patients had 6.28 times ($p= 0.00165$) higher anti-S levels, than the anti-CCP negative patients. Positive T-cell response was observed in 87% of the healthy volunteer group and in 52% of the RA patient group. Following vaccination or infection it declined significantly ($p= 0.044$) but more slowly than that of anti-S titer (6%/month versus 25%). Specific T-cell responses were decreased by 65% in patients treated with anti-CD20 therapy

(p=0.055). CONCLUSION: Our study showed that the SARS-CoV-2-specific antibody levels were substantially reduced in RA patients treated with TNF-Î±-inhibitors (N=51) and IL-6-inhibitor (N=15). In addition, anti-CD20 therapy (N=4) inhibited both SARS-CoV-2-induced humoral and cellular immune responses. Furthermore, the magnitude of humoral and cellular immune response was dependent on the age and decreased over time. The RNA vaccines and ChAdOx1s vaccine effectively increased the level of anti-S antibodies.

Analyses of reported severe adverse events after immunization with SARS-CoV-2 vaccines in the United States: One year on. OBJECTIVE: To analyze rates of reported severe adverse events after immunization (sAEFI) attributed to SARS-CoV-2 vaccines in the United States (US) using safety surveillance data. METHODS: Observational study of sAEFI reported to the vaccine adverse events reporting system (VAERS) between December 13, 2020, to December 13, 2021, and attributed to SARS-CoV-2 vaccination programs across all US states and territories. All sAEFI in conjunction with mRNA (BNT-162b2 or mRNA-1273) or adenovector (Ad26.COV2.S) vaccines were included. The 28-day crude cumulative rates for reported emergency department (ED) visits and sAEFI viz. hospitalizations, life-threatening events and deaths following SARS-CoV-2 vaccination were calculated. Incidence rate ratios (IRRs) of reported sAEFI were compared between mRNA and adenovector vaccines using generalized Poisson regression models. RESULTS: During the study period, 485 million SARS-CoV-2 vaccines doses were administered nationwide, and 88,626 sAEFI reported in VAERS. The 28-day crude cumulative reporting rates per 100,000 doses were 14.97 (95% confidence interval, 14.86-18.38) for ED visits, 5.32 (5.26-5.39) for hospitalizations, 1.72 (1.68-1.76) for life-threatening events, and 1.08 (1.05-1.11) for deaths. Females had two-fold rates for any reported AEFI compared to males, but lower adjusted IRRs for sAEFI. Cumulative rates per dose for reported sAEFI attributed to adenovector vaccine were 2-3-fold higher, and adjusted IRRs 1.5-fold higher than mRNA vaccines. CONCLUSIONS: Overall cumulative rates for reported sAEFI following SARS-CoV-2 vaccination in the US over 1 year were very low; single-dose adenovector vaccine had 1.5-fold higher adjusted rates for reported sAEFI, which may however equate with multiple-doses mRNA vaccine regimens. These data indicate absence of high risks of sAEFI following SARS-CoV-2 vaccines and support safety equipoise between mRNA and adenovector vaccines. Public health messaging of these data is critical to overcome heuristic biases. Furthermore, these data may support ongoing adenovector vaccine use, especially in low- and middle-income countries due to affordability, logistical and cold chain challenges.

Failure to mount a humoral response to COVID-19 vaccination identifies individuals with previously undiagnosed severe antibody deficiency state: preliminary data from the COVID-19 ENLIST study.

Adverse Events Following Immunization With mRNA and Viral Vector Vaccines in Individuals With Previous Severe Acute Respiratory Syndrome Coronavirus 2 Infection From the Canadian National Vaccine Safety Network. BACKGROUND: Adults previously infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) develop short-term immunity and may have increased reactogenicity to coronavirus disease 2019 (COVID-19) vaccines. This prospective, multicenter, active-surveillance cohort study examined the short-term safety of COVID-19 vaccines in adults with a prior history of SARS-CoV-2. METHODS: Canadian adults vaccinated between 22 December 2020 and 27 November 2021 were sent an electronic questionnaire 7 days post-dose 1, dose 2, and dose 3 vaccination. The main outcome was health events occurring in the first 7 days after each vaccination that prevented daily activities, resulted in work absenteeism, or required a medical consultation, including hospitalization. RESULTS: Among 684 998 vaccinated individuals, 2.6% (18 127/684 998) reported a prior history of SARS-CoV-2 infection a median of 4 (interquartile range: 2-6) months previously. After dose 1, individuals with moderate (bedridden) to severe (hospitalized) COVID-19 who received BNT162b2, mRNA-1273, or ChAdox1-S vaccines had higher odds of a health event

preventing daily activities, resulting in work absenteeism or requiring medical consultation (adjusted odds ratio [95% confidence interval]: 3.96 [3.67-4.28] for BNT162b2, 5.01 [4.57-5.50] for mRNA-1273, and 1.84 [1.54-2.20] for ChAdox1-S compared with no infection). Following dose 2 and 3, the greater risk associated with previous infection was also present but was attenuated compared with dose 1. For all doses, the association was lower or absent after mild or asymptomatic infection. CONCLUSIONS: Adults with moderate or severe previous SARS-CoV-2 infection were more likely to have a health event sufficient to impact routine activities or require medical assessment in the week following each vaccine dose.

Post-COVID-19 vaccination arm pain diagnosed as complex regional pain syndrome: A case report. As the vaccination efforts against the coronavirus disease-2019 (COVID-19) continue, more patients are likely to present with complications related to COVID-19 vaccination. We describe the first reported case of complex regional pain syndrome (CRPS), involving the upper extremities, that occurred after COVID-19 vaccination. The patient presented with acute-onset severe arm pain and swelling following vaccine administration. Based on the clinical, electrodiagnostic, and radionuclide three-phase bone scan findings, the patient was diagnosed with postvaccination CRPS. The COVID-19 vaccine possibly elicited an immune-mediated inflammatory response to the injected antigen in the patient, who was predisposed to CRPS due to inflammatory immunity. The COVID-19 vaccine elicited an immune-mediated inflammatory response to the injected antigen, resulting in CRPS following COVID-19 vaccination.

Female genital mucosal lesions associated with COVID-19 vaccination: A brief review of the literature.

Risks of Myocarditis and Pericarditis Following Vaccination with SARS-CoV-2 mRNA Vaccines in Japan: An Analysis of Spontaneous Reports of Suspected Adverse Events. OBJECTIVE: To identify the risks of myocarditis or pericarditis after vaccination with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccines in Japan. METHODS: We conducted an observed-to-expected analysis (OE analysis) of spontaneous reports of suspected adverse events from pharmaceutical companies, calculating rate ratios with myocarditis and pericarditis after the vaccination of the mRNA vaccines Comirnaty (BNT162b2) and Spikevax (mRNA-1273) and expected rate of myocarditis and pericarditis in the population before the COVID-19 pandemic. These reports dated from 17/2/2021 to 14/11/2021 and from 22/5/2021 to 14/11/2021 for Comirnaty and Spikevax, respectively. The observed-to-expected ratios (OE ratios) for each vaccine were estimated by age groups and sex. RESULTS: We identified 281 and 195 cases of myocarditis or pericarditis for Comirnaty and Spikevax, respectively, which were administrated 163,059,502 and 31,768,352 doses for Comirnaty and Spikevax until the 14th of November 2021, respectively. The OE ratios were statistically significantly higher in adolescent and young adult males in their age of teens and twenties after the second dose in a two-dose series [Comirnaty in teens male: 6.15 (95% CI, 2.26-21.98), Comirnaty in twenties male: 2.86 (95% CI, 1.13-8.38), Spikevax in teens male: 41.59 (95% CI, 5.64-43,281.94), Spikevax in twenties male: 16.84 (95%CI, 6.77-57.49)]. CONCLUSIONS: Risks of myocarditis and pericarditis following SARS-CoV-2 mRNA vaccines in Japan seems to be significantly elevated for adolescent and young adult males.

Adverse Reactions and Attitudes Toward the BNT162b2 COVID-19 Vaccine in Children 5 to 11 Years of Age in Japan.

Factors Associated With COVID-19 Non-vaccination in Adolescents Hospitalized Without COVID-19. BACKGROUND: Pfizer-BioNTech COVID-19 vaccine received emergency use authorization for personsâ€…â‰¥â€…16 years in December 2020 and for adolescents 12-15 years in May 2021. Despite the clear benefits and favorable safety profile, vaccine uptake in adolescents has been suboptimal. We sought to assess factors associated with COVID-19 non-vaccination in adolescents 12-18 years of age. METHODS: Between June 1, 2021 and April 29, 2022, we assessed factors associated

with COVID-19 non-vaccination in hospitalized adolescents ages 12-18 years enrolled in the Overcoming COVID-19 vaccine effectiveness network. Demographic characteristics and clinical information were captured through parent interviews and/or electronic medical record abstraction; COVID-19 vaccination was assessed through documented sources. We assessed associations between receipt of the COVID-19 vaccine and demographic and clinical factors using univariate and multivariable logistic regression and estimated adjusted odds ratios (aOR) for each factor associated with non-vaccination. RESULTS: Among 1665 hospitalized adolescents without COVID-19, 56% were unvaccinated. Unvaccinated adolescents were younger (median age 15.1 years vs. 15.4 years, pâ€…<â€….01) and resided in areas with higher social vulnerability index (SVI) scores (median 0.6 vs 0.5, pâ€…<â€….001) than vaccinated adolescents. Residence in the Midwest [aOR 2.60 (95% CI: 1.80, 3.79)] or South [aOR 2.49 (95% CI: 1.77, 3.54)] US census regions, rarely or never receiving influenza vaccine [aOR 5.31 (95% CI: 3.81, 7.47)], and rarely or never taking precautions against COVID-19 [aOR 3.17 (95% CI: 1.94, 5.31)] were associated with non-vaccination against COVID-19. CONCLUSIONS: Efforts to increase COVID-19 vaccination of adolescents should focus on persons with geographic, socioeconomic, and medical risk factors associated with non-vaccination.

High degree atrio-ventricular block following COVID-19 vaccination. The coronavirus disease 2019 (COVID-19) pandemic has resulted in more than four million deaths globally. In addition to the lower respiratory system, a wide range of major organ injuries have been reported among patients infected with COVID-19. These injuries include cardiac involvement. The spectrum of cardiac manifestations includes cardiac injury, heart failure, cardiogenic shock, acute coronary syndrome, myocarditis, tachyarrhythmias, and bradyarrhythmia [1]. Different degrees of atrioventricular blocks have been reported [2]. The pathogenesis of these complications is not fully understood. Different mechanisms are proposed, including direct myocyte injury, interstitial inflammation and fibrosis, cytokine storm, plaque destabilization, and and/or hypoxia [3]. Many countries have worked toward mass vaccination using the Pfizer BioNTech (BNT162b2) COVID-19 vaccine, including Israel. We report a case of high degree atrioventricular block (AVB) following vaccination with the COVID-19 BNT162b2 vaccine.

Chronic cold agglutinin disease after a third COVID-19 mRNA vaccination. COVID-19 mRNA vaccines manufactured by Pfizer-BioNTech and Moderna have been approved in many countries, and have been administered since 2020. Recent reports of mRNA vaccination exacerbating autoimmune hematologic disorders, such as immune thrombocytopenia or autoimmune hemolytic anemia, have caught the attention of the general public, resulting in alarm over the risks of serious consequences. Meanwhile, in very rare cases, vaccination was reported to trigger new onset of hemolytic anemia. However, it remains unknown whether this was a transient reaction or a persistent event, because all cases reported to date were immediately treated with corticosteroids or rituximab. Here, we present a case of newly diagnosed cold agglutinin disease after a third COVID-19 mRNA vaccination. The patient was followed for 4Â months without treatment and continued to exhibit high levels of cold agglutinin and aggregation of red blood cells. The present case indicates that the disease can become chronic, and provides insights into the pathogenesis and treatment strategies.

The Incidence and Effect of Adverse Events Due to COVID-19 Vaccines on Breakthrough Infections: Decentralized Observational Study With Underrepresented Groups. BACKGROUND: Despite continuing efforts to improve the inclusion of underserved groups in clinical research, gaps in diversity remain. Participation of special populations is especially important when facing problems of unprecedented complexity such as the COVID-19 pandemic. A better understanding of factors associated with the immune response in diverse populations would advance future preventive and curative approaches. OBJECTIVE: The objective of this study was to investigate the factors potentially responsible for adverse events following COVID-19 immunization. The study population included

adults from rural areas, transitional countries, and those with medically understudied conditions, across a broad age range. METHODS: The study evolved from peer support networks developed during the COVID-19 pandemic. Participants were recruited digitally through online neighborhood and health communities. Some of the participants volunteered as study investigators assisting with offline recruitment and safety monitoring. Individuals who consented to participate were asked to share their vaccination experiences either using constantly evolving web-based surveys or via one-on-one communication. Inferential statistical analysis to estimate differences between study groups was performed using parametric and nonparametric tests. RESULTS: Of 1430 participants who shared their vaccination experiences, 648 had outcome measures at their 1.5-year follow-up. Significant differences were found between age groups, types of vaccine adverse events (VAEs), incidences of breakthrough infections, and health conditions linked to the microbiome. Pairwise comparisons showed that VAEs interfering with daily activities were significantly higher in both younger (18-59 years) and older age groups (80-100 years, P<.001) than in the 60-79-year age group. Short-term VAEs were associated with lower incidence of breakthrough COVID-19 infections relative to those who reported either minimal or long-term adverse events (P<.001). A genetic origin was suggested for some adverse reactions. CONCLUSIONS: The findings of this study demonstrate that vaccine adverse reactions in older individuals are being overlooked, and the incidence of VAEs impairing immunity may be higher than previously perceived. Better preventive measures are needed for all those at risk for life-threatening and long-term adverse events due to vaccination. Supportive community-based studies focusing on these populations could add important data to the current body of knowledge. Further and more comprehensive studies should follow. TRIAL REGISTRATION: ClinicalTrials.gov NCT04832932; https://clinicaltrials.gov/ct2/show/NCT04832932. INTERNATIONAL REGISTERED REPORT IDENTIFIER (IRRID): RR2-10.1101/2021.06.28.21256779.

COVID-19 mRNA vaccine-associated cerebral venous thrombosis: Rare adverse event or coincidence?

Amphiphile-CpG vaccination induces potent lymph node activation and COVID-19 immunity in mice and non-human primates. Despite the success of currently authorized vaccines for the reduction of severe COVID-19 disease risk, rapidly emerging viral variants continue to drive pandemic waves of infection, resulting in numerous global public health challenges. Progress will depend on future advances in prophylactic vaccine activity, including advancement of candidates capable of generating more potent induction of cross-reactive T cells and durable cross-reactive antibody responses. Here we evaluated an Amphiphile (AMP) adjuvant, AMP-CpG, admixed with SARS-CoV-2 Spike receptor binding domain (RBD) immunogen, as a lymph node-targeted protein subunit vaccine (ELI-005) in mice and non-human primates (NHPs). AMP-mediated targeting of CpG DNA to draining lymph nodes resulted in comprehensive local immune activation characterized by extensive transcriptional reprogramming, inflammatory proteomic milieu, and activation of innate immune cells as key orchestrators of antigen-directed adaptive immunity. Prime-boost immunization with AMP-CpG in mice induced potent and durable T cell responses in multiple anatomical sites critical for prophylactic efficacy and prevention of severe disease. Long-lived memory responses were rapidly expanded upon re-exposure to antigen. In parallel, RBD-specific antibodies were long-lived, and exhibited cross-reactive recognition of variant RBD. AMP-CpG-adjuvanted prime-boost immunization in NHPs was safe and well tolerated, while promoting multi-cytokine-producing circulating T cell responses cross-reactive across variants of concern (VOC). Expansion of RBD-specific germinal center (GC) B cells in lymph nodes correlated to rapid seroconversion with variant-specific neutralizing antibody responses exceeding those measured in convalescent human plasma. These results demonstrate the promise of lymph-node adjuvant-targeting to coordinate innate immunity and generate robust adaptive responses critical for vaccine efficacy.

Ocular Adverse Events after Coronavirus Disease 2019 mRNA Vaccination: Matched Cohort and Self-Controlled Case Series Studies Using a Large Database. PURPOSE: To investigate the risk of ocular adverse events after Coronavirus Disease 2019 (COVID-19) mRNA vaccination. DESIGN: Matched cohort and self-controlled case series (SCCS) studies. PARTICIPANTS: We used a population-based database of medical claims and vaccination records in a large Japanese city. In the matched cohort study, we identified individuals who received COVID-19 vaccination (BNT162b2) from February 2021 to September 2021. One control was selected from nonvaccinated individuals by matching time, date of birth, sex, Charlson comorbidity index, and the enrollment period for health insurance. In the SCCS study, we analyzed individuals who developed ocular adverse events. METHODS: In the matched cohort study, we applied the Kaplan-Meier estimator to estimate the cumulative incidence of ocular adverse events over 21 days after the first dose and 84 days after the second dose. In the SCCS method, we used conditional Poisson regression to estimate the incidence rate ratio (IRR) of ocular adverse events during the risk periods (0-21 days after the first dose and 0-84 days after the second dose) compared with the remaining periods. MAIN OUTCOME MEASURES: Composite outcome of uveitis, scleritis, retinal vein occlusion (RVO), and optic neuritis. RESULTS: There were 99 718 pairs eligible for the matched cohort study after the first dose (mean age, 69.3 years; male, 44%). The vaccinated and control groups developed 29 and 21 events, respectively, over 21 days after the first dose, and 79 and 28 events, respectively, over 84 days after the second dose. The differences in cumulative incidence (reference, the control group) were 2.9 (95% confidence interval, -14.5 to 19.1) events/100 000 persons and 51.3 (16.2-84.3) events/100 000 persons, respectively, for the first and second doses. The SCCS study showed the IRRs of 0.89 (0.62-1.28) and 0.89 (0.71-1.11) for the first and second doses, respectively. CONCLUSIONS: The matched cohort analysis found an increased risk for the composite outcome after the second dose; however, the SCCS analysis showed no increased risk. Considering that the SCCS can cancel out time-invariant confounders, the current results suggest that COVID-19 vaccination is unlikely to causally increase the risk of ocular adverse events. FINANCIAL DISCLOSURE(S): Proprietary or commercial disclosure may be found after the references.

A Case of Neuroretinitis Following COVID-19 Vaccination. PURPOSE: To present a case of neuroretinitis following an mRNA COVID-19 vaccination. CASE REPORT: A 78-year-old healthy woman was presented with blurry vision in her left eye 1 day after receiving the third dose of the Pfizer-BioNTech COVID-19 vaccine. The ocular examination revealed an optic disc swelling and retinal thickening of the macula with subretinal fluid in the left eye. The fluorescein angiography revealed hyperfluorescence of the left optic disc. The neuroretinitis resolved gradually after taking azithromycin and prednisolone orally. CONCLUSIONS: This is the first report of unilateral neuroretinitis following COVID-19 vaccination, implying a potential association between the mRNA vaccine and neuroretinitis.

A Curious Case of Occlusive Retinal Vasculitis in a Young Individual Associated with COVID-19 Vaccination. A 23-year-old man presented with the blurring of vision in the left eye for 4Â days. Best-corrected visual acuity was 6/6 N6 in both eyes. Examination revealed an unremarkable right eye while the left eye showed occlusive retinal vasculitis with no retinitis, choroiditis, or macular involvement. Fundus fluorescein angiography confirmed the same. History revealed the patient had received 2nd dose of Covishield vaccination 4Â weeks before the onset of symptoms. Blood investigations were negative for infectious or any systemic autoimmune disease. Serum homocysteine and serum CMV IgG levels were grossly increased while tests for antiphospholipid syndrome were weakly positive. He responded well to a combination of intravitreal and oral antivirals, oral steroids for vasculitis and tablets Clopilet and Homin. This case is extremely intriguing in terms of the involvement of the adenoviral vector vaccine either as a causative factor or being just a coincidental finding.

Response to: There is not enough evidence to support the claim that Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count.
Experiences from COVID-19 vaccination in patients with epilepsy. OBJECTIVE: This study aimed to investigate the safety of coronavirus disease 2019 (COVID-19) vaccination in patients with epilepsy (PWE) and their willingness to undergo vaccination. METHODS: This study was a survey the survey questionnaire, which included general, epilepsy-specific, and COVID-specific questions, was completed by patients of the outpatient clinic and hospital ward at The Third Xiangya Hospital in 2021. RESULTS: A total of 120 valid questionnaires were returned. Eighty-nine of 120 responders (74.2%) were not vaccinated, and 31 (25.8%) were vaccinated against COVID-19. Of the 31 vaccinated PWE, one (3.2%) had worsening of seizures and four (12.9%) had adverse reactions that were characteristic of the COVID-19 vaccine. The other 26 patients (83.9%) reported no adverse reactions, Moreover, there was no significant difference between the 18 PWE with well-controlled seizures and the 13 PWE with poorly-controlled seizures. Of the 89 unvaccinated PWE, 69.7% (62/89) were willing to receive the COVID-19 vaccine, 28.1% (25/89) were unsure, and 2.2% (2/89) declined to be vaccinated. SIGNIFICANCE: Among PWE, few adverse reactions occurred following the COVID-19 vaccination. Most PWE were willing to receive the COVID-19 vaccine. COVID-19 vaccination is safe for PWE.
Possible case of polyarteritis nodosa with epididymitis following COVID-19 vaccination: A case report and review of the literature. The global outbreak of coronavirus disease (COVID-19) caused by severe acute respiratory syndrome coronavirus type 2 has prompted the rapid spread and development of vaccines to prevent the spread of the disease. COVID-19 vaccine has demonstrated excellent efficacy in reducing morbidity and severity of the disease, and most adverse reactions are very minor. However, some patients have been reported to develop autoimmune diseases, such as rheumatoid arthritis, myocarditis, Guillain-Barre syndrome, and vasculitis, following COVID-19 vaccination. Herein, we present a case of polyarteritis nodosa with epididymitis, following COVID-19 mRNA vaccination. The patient's initial symptoms were fever and testicular pain, and magnetic resonance imaging showed epididymitis. He was diagnosed as having polyarteritis nodosa with epididymitis and was treated with high-dose prednisolone, with a good clinical outcome.
There is not enough evidence to support the claim that Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count.
COVID-19 vaccine side effects in patients with and without atopic dermatitis.
Systemic Allergic Contact Dermatitis Post Inactivated COVID-19 Vaccine.
Multisystem inflammatory syndrome following COVID-19 vaccination. Multiple extrapulmonary symptoms have been described in individuals with elevated inflammatory markers after COVID infection, which have been grouped and classified as a new inflammatory syndrome, called multisystem inflammatory syndrome in adults (MIS-A). However, little is known about MIS-A, including its prevalence, predisposing conditions, or patient outcomes. We report a case of severe postvaccination symptoms that occurred after administration of the Moderna vaccine in an individual with no prior history of COVID infection. We also review a case series that fulfills the criteria for MIS-A reported in the literature and summarize the characteristics of patients developing MIS-A after COVID-19 vaccination.
Erythema multiforme after third COVID-19 vaccination (Pfizer-BioNTech). We present a case of erythema multiforme (EM) associated with a third (booster) dose of COVID-19 vaccination in a patient who had no cutaneous reactions to previous doses. To our knowledge, this is the first documented case of vaccine-associated EM occurring after a third/booster vaccination. Furthermore, our case emphasizes the need to remain vigilant for vaccine-associated EM in any patient recently

vaccinated, regardless of whether previous vaccinations were administered without cutaneous reactions.

A singular case of hyposmia and transient audiovestibular post-vaccine disorders: case report and literature review. INTRODUCTION: Rare and mild adverse effects on cranial nerves have been reported after vaccination. Here, we report a singular case of smell and taste disorder associated with tinnitus that occurred after Oxford-AstraZeneca vaccination together with a review of the available literature. CASE PRESENTATION: A 76-year-old patient experienced smell disorder, ear fullness and tinnitus 2â€‰days after the first dose of Oxford-AstraZeneca vaccine. The patient then underwent a complete audiological and Ear, Nose and Throat evaluation, nasal endoscopy, Sniffin'Sticks battery, audiometric test battery, and cerebral magnetic resonance imaging (MRI). The exams revealed hyposmia and bilateral reduction of the volume of the olfactory bulbs (OB). At the follow-up, tinnitus was completely resolved while olfactory dysfunction only partially reduced. REVIEW OF THE LITERATURE: A PubMed search was conducted on olfactory and gustatory dysfunctions after COVID-19 vaccination resulting in four case reports with a total of 10 patients. The main symptoms were hyposmia, parosmia, and dysgeusia developed after 1-9â€‰days from vaccination with complete resolution occurring within 1â€‰month. Notably, none of the considered articles reported reduction of OB volumes at cerebral MRI. DISCUSSION: So far, no definitive cause-effect relationship has been established between anti-COVID19 vaccination and otolaryngologic adverse reactions. The persistence of hyposmia in our patient could possibly be explained by the reduction in OB volume, even though also the advanced age of the patient needs to be taken into account. This is a first indication of a cause-effect relation between hyposmia and Covid19 vaccination, even though a more robust study is needed to confirm the autoimmunological mechanisms responsible for these rare adverse reactions. However, it is worth highlighting that benefits of the anti-COVID-19 vaccination clearly outweigh the risk of rare adverse events.

Sars-Cov2 world pandemic recurrent waves controlled by variants evolution and vaccination campaign. While understanding the time evolution of Covid-19 pandemic is needed to plan economics and tune sanitary policies, a quantitative information of the recurrent epidemic waves is elusive. This work describes a statistical physics study of the subsequent waves in the epidemic spreading of Covid-19 and disclose the frequency components of the epidemic waves pattern over two years in United States, United Kingdom and Japan. These countries have been taken as representative cases of different containment policies such as "Mitigation" (USA and UK) and "Zero Covid" (Japan) policies. The supercritical phases in spreading have been identified by intervals with RIC-indexâ€‰>â€‰0. We have used the wavelet transform of infection and fatality waves to get the spectral analysis showing a dominant component around 130Â days. Data of the world dynamic clearly indicates also the crossover to a different phase due to the enforcement of vaccination campaign. In Japan and United Kingdom, we observed the emergence in the infection waves of a long period component (~â€‰170Â days) during vaccination campaign. These results indicate slowing down of the epidemic spreading dynamics due to the vaccination campaign. Finally, we find an intrinsic difference between infection and fatality waves pointing to a non-trivial variation of the lethality due to different gene variants.

Severe cutaneous reaction to the messenger RNA (mRNA) BNT162b2 (Pfizer-BioNTech) vaccine. The pathway out of the COVID-19 pandemic has been reliant on uptake of vaccination. In New Zealand, we have access to the messenger RNA (mRNA) BNT162b2 (Pfizer-BioNTech) vaccine. In this case report we discuss a patient who presented to an acute general medical service with a severe cutaneous adverse reaction (SCAR) after the vaccine with features of both Stevens-Johnson syndrome and acute generalised pustulosis. Early recognition and management of SCARs is required to prevent morbidity and mortality.

Comparative risk of cerebral venous sinus thrombosis (CVST) following COVID-19 vaccination or infection: A national cohort study using linked electronic health records. To inform the public and policy makers, we investigated and compared the risk of cerebral venous sinus thrombosis (CVST) after SARS-Cov-2 vaccination or infection using a national cohort of 2,643,699 individuals aged 17â€‰y and above, alive, and resident in Wales on 1 January 2020 followed up through multiple linked data sources until 28 March 2021. Exposures were first dose of Oxford-ChAdOx1 or Pfizer-BioNTech vaccine or polymerase chain reaction (PCR)-confirmed SARS-Cov-2 infection. The outcome was an incident record of CVST. Hazard ratios (HR) were calculated using multivariable Cox regression, adjusted for confounders. HR from SARS-Cov-2 infection was compared with that for SARS-Cov-2 vaccination. We identified 910,556 (34.4%) records of first SARS-Cov-2 vaccination and 165,862 (6.3%) of SARS-Cov-2 infection. A total of 1,372 CVST events were recorded during the study period, of which 52 (3.8%) and 48 (3.5%) occurred within 28â€‰d after vaccination and infection, respectively. We observed slight non-significant risk of CVST within 28â€‰d of vaccination [aHR: 1.34, 95% CI: 0.95-1.90], which remained after stratifying by vaccine [BNT162b2, aHR: 1.18 (95% CI: 0.63-2.21); ChAdOx1, aHR: 1.40 (95% CI: 0.95-2.05)]. Three times the number of CVST events is observed within 28â€‰d of a positive SARS-Cov-2 test [aHR: 3.02 (95% CI: 2.17-4.21)]. The risk of CVST following SARS-Cov-2 infection is 2.3 times that following SARS-Cov-2 vaccine. This is important information both for those designing COVID-19 vaccination programs and for individuals making their own informed decisions on the risk-benefit of vaccination. This record-linkage approach will be useful in monitoring the safety of future vaccine programs.

Ipsilateral Upper-Limb Lymphedema After COVID-19 Vaccine Booster. Recent data suggest that protective immunity from COVID-19 vaccine may wane after a period, with booster doses becoming increasingly deployed in many countries. An 84-year-old woman presents with a 6-month history of left upper-limb swelling; the only history of note was an intramuscular Pfizer-BioNTech mRNA vaccine booster in the ipsilateral deltoid just 1 week before the onset of the swelling. Upper-extremity lymphoscintigraphy after the administration of 99m Tc-nanocolloid into the interstitial space of the hands showed left upper-limb lymphatic dysfunction.

Longitudinal serologic and viral testing post-SARS-CoV-2 infection and post-receipt of mRNA COVID-19 vaccine in a nursing home cohort-Georgia, October 2020â€’April 2021. There are limited data describing SARS-CoV-2-specific immune responses and their durability following infection and vaccination in nursing home residents. We conducted a prospective longitudinal evaluation of 11 consenting SARS-CoV-2-positive nursing home residents to evaluate the quantitative titers and durability of binding antibodies detected after SARS-CoV-2 infection and subsequent COVID-19 vaccination. The evaluation included nine visits over 150 days from October 25, 2020, through April 1, 2021. Visits included questionnaire administration, blood collection for serology, and paired anterior nasal specimen collection for testing by BinaxNOWâ„¢ COVID-19 Ag Card (BinaxNOW), reverse transcription polymerase chain reaction (RT-PCR), and viral culture. We evaluated quantitative titers of binding SARS-CoV-2 antibodies post-infection and post-vaccination (beginning after the first dose of the primary series). The median age among participants was 74 years; one participant was immunocompromised. Of 10 participants with post-infection serology results, 9 (90%) had detectable Pan-Ig, IgG, and IgA antibodies, and 8 (80%) had detectable IgM antibodies. At first antibody detection post-infection, two-thirds (6/9, 67%) of participants were RT-PCR-positive, but none were culture- positive. Ten participants received vaccination; all had detectable Pan-Ig, IgG, and IgA antibodies through their final observation â‰¤90 days post-first dose. Post-vaccination geometric means of IgG titers were 10-200-fold higher than post-infection. Nursing home residents in this cohort mounted robust immune responses to SARS-CoV-2 post-infection and post-vaccination. The

augmented antibody responses post-vaccination are potential indicators of enhanced protection that vaccination may confer on previously infected nursing home residents.

Case Report of COVID-19 mRNA Vaccine-Associated Myocarditis. INTRODUCTION: We present a case report highlighting a single patient out of 3 who developed myocarditis within days after receiving Pfizer and Moderna COVID-19 mRNA vaccines. CASE PRESENTATION: A 19-year-old male was admitted to our hospitalist service with substernal chest pain that was sharp, constant, and varied with position. He had received his second dose of the Pfizer-BioNTech COVID-19 vaccine (Pfizer vaccine) 2 days prior. Electrocardiogram was consistent with pericarditis. He had persistently elevated troponins and globally reduced systolic function by echocardiogram, which was consistent with myocarditis. He received colchicine, ibuprofen, and proton pump inhibitors with a resolution of symptoms. After 32 days, follow-up echocardiogram had returned to normal, and his symptoms had resolved completely. DISCUSSION: Given the onset of symptoms after the second dose of vaccine and our review of similar cases in the literature, it seems likely the patient's myopericarditis was caused by the vaccine. Rare complications of new vaccines given to millions of people are rapidly identified by the Vaccine Adverse Event Reporting System. CONCLUSIONS: The identification of myopericarditis as a complication of mRNA vaccines will need further study to understand the pathophysiology, incidence, and prevalence in specific age groups and biological sexes.

Acute Worsening of Atypical Parkinson's Syndrome After Receiving Second Dose of Moderna COVID-19 Vaccine. INTRODUCTION: Atypical Parkinson's syndromes are a rare set of neurodegenerative conditions in which a patient experiences the typical symptoms of Parkinson's disease, in addition to various other unrelated issues. CASE PRESENTATION: We present the case of a 71-year-old White man with a 1-year history of weakness and upper extremity tremors that, per patient report, rapidly worsened after receiving the second dose of the Moderna COVID-19 vaccine. His symptoms were consistent with an asymmetric atypical Parkinson's disease, with electromyogram results indicating chronic motor neuron involvement. DISCUSSION: There have been multiple reports of deterioration in patients with Parkinson's disease and atypical Parkinson's syndromes in response to contracting COVID-19. However, there are few, if any, case reports that describe an acute change in Parkinson-related symptoms in association with the COVID-19 vaccines. CONCLUSIONS: As the pandemic continues, we must continue to remain vigilant as we learn more about the long-lasting effects of the virus and vaccines.

Association of COVID-19 Vaccinations With Intensive Care Unit Admissions and Outcome of Critically Ill Patients With COVID-19 Pneumonia in Lombardy, Italy. IMPORTANCE: Data on the association of COVID-19 vaccination with intensive care unit (ICU) admission and outcomes of patients with SARS-CoV-2-related pneumonia are scarce. OBJECTIVE: To evaluate whether COVID-19 vaccination is associated with preventing ICU admission for COVID-19 pneumonia and to compare baseline characteristics and outcomes of vaccinated and unvaccinated patients admitted to an ICU. DESIGN, SETTING, AND PARTICIPANTS: This retrospective cohort study on regional data sets reports: (1) daily number of administered vaccines and (2) data of all consecutive patients admitted to an ICU in Lombardy, Italy, from August 1 to December 15, 2021 (Delta variant predominant). Vaccinated patients received either mRNA vaccines (BNT162b2 or mRNA-1273) or adenoviral vector vaccines (ChAdOx1-S or Ad26.COV2). Incident rate ratios (IRRs) were computed from August 1, 2021, to January 31, 2022; ICU and baseline characteristics and outcomes of vaccinated and unvaccinated patients admitted to an ICU were analyzed from August 1 to December 15, 2021. EXPOSURES: COVID-19 vaccination status (no vaccination, mRNA vaccine, adenoviral vector vaccine). MAIN OUTCOMES AND MEASURES: The incidence IRR of ICU admission was evaluated, comparing vaccinated people with unvaccinated, adjusted for age and sex. The baseline characteristics at ICU admission of vaccinated and unvaccinated patients were investigated. The association between vaccination status

at ICU admission and mortality at ICU and hospital discharge were also studied, adjusting for possible confounders. RESULTS: Among the 10â€¯107â€¯674 inhabitants of Lombardy, Italy, at the time of this study, the median [IQR] age was 48 [28-64] years and 5â€¯154â€¯914 (51.0%) were female. Of the 7â€¯863â€¯417 individuals who were vaccinated (median [IQR] age: 53 [33-68] years; 4â€¯010â€¯343 [51.4%] female), 6â€¯251â€¯417 (79.5%) received an mRNA vaccine, 550â€¯439 (7.0%) received an adenoviral vector vaccine, and 1â€¯061â€¯561 (13.5%) received a mix of vaccines and 4â€¯497â€¯875 (57.2%) were boosted. Compared with unvaccinated people, IRR of individuals who received an mRNA vaccine within 120 days from the last dose was 0.03 (95% CI, 0.03-0.04; Pâ€‰<â€‰.001), whereas IRR of individuals who received an adenoviral vector vaccine after 120 days was 0.21 (95% CI, 0.19-0.24; Pâ€‰<â€‰.001). There were 553 patients admitted to an ICU for COVID-19 pneumonia during the study period: 139 patients (25.1%) were vaccinated and 414 (74.9%) were unvaccinated. Compared with unvaccinated patients, vaccinated patients were older (median [IQR]: 72 [66-76] vs 60 [51-69] years; Pâ€‰<â€‰.001), primarily male individuals (110 patients [79.1%] vs 252 patients [60.9%]; Pâ€‰<â€‰.001), with more comorbidities (median [IQR]: 2 [1-3] vs 0 [0-1] comorbidities; Pâ€‰<â€‰.001) and had higher ratio of arterial partial pressure of oxygen (Pao2) and fraction of inspiratory oxygen (FiO2) at ICU admission (median [IQR]: 138 [100-180] vs 120 [90-158] mm Hg; Pâ€‰=â€‰.007). Factors associated with ICU and hospital mortality were higher age, premorbid heart disease, lower Pao2/FiO2 at ICU admission, and female sex (this factor only for ICU mortality). ICU and hospital mortality were similar between vaccinated and unvaccinated patients. CONCLUSIONS AND RELEVANCE: In this cohort study, mRNA and adenoviral vector vaccines were associated with significantly lower risk of ICU admission for COVID-19 pneumonia. ICU and hospital mortality were not associated with vaccinated status. These findings suggest a substantial reduction of the risk of developing COVID-19-related severe acute respiratory failure requiring ICU admission among vaccinated people.

Torquetenovirus viral load is associated with anti-spike antibody response in SARS-CoV-2 mRNA BNT162b2 vaccinated kidney transplant patients. INTRODUCTION: Kidney transplant patients (KT) are at high risk for severe COVID-19 and presented attenuated antibody responses to vaccination when compared to immunocompetent individuals. Torquetenovirus (TTV) has recently gained attention as a potential surrogate marker of the net state of immunosuppression. We evaluated the association between pre-vaccination TTV viral load and anti-spike total antibody response to SARS-CoV-2 vaccination in KT. MATERIAL AND METHODS: The 114 adult KT recipients enrolled in this prospective single-center cohort study received two doses of SARS-CoV-2 mRNA BNT162b2 vaccine. Serum samples were collected immediately before vaccination at the days when patients received both the first (T0) and the second dose (T1) and 16-45 days after the second dose (T2). Primary endpoint was the development of anti-spike total antibodies after vaccination. Demographic, clinical, and laboratorial parameters were compared between patients with and without detectable SARS-CoV-2 antibodies at T2. RESULTS: Ninety-nine patients (86.8%) were naÃ¯ve for SARS-CoV-2 before vaccination. Fifty-six (56.6%) patients developed anti-spike total antibodies at T2. The use of mTOR inhibitors was associated with a favorable response (pÂ =Â .005); conversely, mycophenolic acid (MPA) was associated with a negative response (pÂ =Â .006). In a multivariable model, the presence of TTV at T0Â â‰¥Â 3.36 log(10) cp/ml was associated with unfavorable vaccine response (OR: 5.40; 95% CI: 1.47-19.80; pÂ =Â .011), after adjusting for age and eGFR at T0. CONCLUSIONS: Higher TTV viral loads before vaccination are associated with reduced anti-spike total antibody response in SARS-CoV-2 mRNA BNT162b2 vaccinated KT patients. The association between TTV viral load and vaccine response may be an added-value in the optimization of vaccination regimens in KT.

Allergists and COVID-vaccine: which is the actual risk of reactions in allergic patients?

Do we miss rare adverse events induced by COVID-19 vaccination? Although severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection has caused many complications, the invention of coronavirus disease 2019 (COVID-19) vaccines has also brought about several adverse events, from common side effects to unexpected and rare ones. Common vaccine-related adverse reactions manifest locally or systematically following any vaccine, including COVID-19 vaccines. Specific side effects, known as adverse events of particular interest (AESI), are unusual and need more evaluation. Here, we discuss some of the most critical rare adverse events of COVID-19 vaccines.

A Rare Case of Longitudinally Extensive Transverse Myelitis Following Pfizer-BioNTech COVID-19 Vaccination with a Favourable Outcome. INTRODUCTION: mRNA COVID-19 vaccines are very safe, but rare adverse events such as transverse myelitis have been reported after COVID-19 vaccination. CASE DESCRIPTION: We report the case of 50-year-old man who presented with progressive lower extremity weakness, back pain and urinary retention after his second dose of the Pfizer COVID-19 vaccine. MRI of the spine revealed longitudinally extensive transverse myelitis (LETM). He recovered completely after treatment with intravenous methylprednisone and physical therapy. DISCUSSION: This case highlights the rare association between LETM and COVID-19 vaccines and encourages clinicians to maintain a high index of suspicion for prompt diagnosis and treatment. LEARNING POINTS: Longitudinally extensive transverse myelitis (LETM) is rare adverse events after mRNA COVID-19 vaccination.Clinicians should maintain a high index of suspicion for prompt diagnosis of vaccine-induced transverse myelitis.Vaccine-induced LETM should show marked clinical improvement after appropriate treatment.

Immunity induced by vaccination with recombinant influenza B virus neuraminidase protein breaks viral transmission chains in guinea pigs in an exposure intensity-dependent manner. Mucosal vaccines and vaccines that block pathogen transmission are under-appreciated in vaccine development. However, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has shown that blocking viral transmission is an important attribute of efficient vaccines. Here, we investigated if recombinant influenza virus neuraminidase (NA) vaccines delivered at a mucosal site could protect from onward transmission of influenza B viruses in the guinea pig model. We tested four different scenarios in which sequential transmission was investigated in chains of four guinea pigs. The variables tested included a low and a high viral inoculum (10(4) vs 10(5) plaque forming units) in the initial donor guinea pig and variation of exposure/cohousing time (1 day vs 6 days). In three out of four scenarios - low inoculum-long exposure, low inoculum-short exposure and high inoculum-short exposure - transmission chains were efficiently blocked. Based on this data we believe an intranasal recombinant NA vaccine could be used to efficiently curtail influenza virus spread in the human population during influenza epidemics.

Immune Response after the Fourth Dose of SARS-CoV-2 mRNA Vaccine Compared to Natural Infection in Three Doses' Vaccinated Solid Organ Transplant Recipients. Solid organ transplant recipients (SOTRs) show higher rates of COVID-19 breakthrough infection than the general population, and nowadays, vaccination is the key preventative strategy. Nonetheless, SOTRs show lower vaccine efficacy for the prevention of severe COVID-19. Moreover, the emergence of new SARS-CoV-2 variants of concern has highlighted the need to improve vaccine-induced immune responses by the administration of repeated booster doses. In this study, we analyzed the humoral and cellular responses in a cohort of 25 SOTRs, including 15 never-infected SOTRs who received the fourth dose of the mRNA vaccine and 10 SOTRs who contracted SARS-CoV-2 infection after the third dose. We analyzed the serum IgG and IgA levels through CLIA or ELISA, respectively, and the Spike-specific T cells by ELISpot assay. We report a significant increase in anti-Spike IgG and no differences in IgA secretion in both groups of patients before and after the booster dose or the natural infection. Still,

we show higher IgA levels in recovered SOTRs compared to the fourth dose recipients. Conversely, we show the maintenance of a positive Spike-specific T-cell response in SOTRs who received the fourth dose, which, instead, was significantly increased in SOTRs who contracted the infection. Our results suggest that the booster, either through the fourth dose or natural infection, in vulnerable poor responder SOTRs, improves both humoral and cellular-specific immune responses against SARS-CoV-2.

Susceptibility to Resurgent COVID-19 Outbreaks Following Vaccine Rollouts: A Modeling Study. Using the recently proposed Susceptible-Asymptomatic-Infected-Vaccinated-Removed (SAIVR) model, we study the impact of key factors affecting COVID-19 vaccine rollout effectiveness and the susceptibility to resurgent epidemics. The SAIVR model expands the widely used Susceptible-Infectious-Removed (SIR) model for describing epidemics by adding compartments to include the asymptomatic infected (A) and the vaccinated (V) populations. We solve the model numerically to make predictions on the susceptibility to resurgent COVID-19 epidemics depending on initial vaccination coverage, importation loads, continuing vaccination, and more contagious SARS-CoV-2 variants, under persistent immunity and immunity waning conditions. The parameters of the model represent reported epidemiological characteristics of the SARS-CoV-2 virus such as the disease spread in countries with high levels of vaccination coverage. Our findings help explain how the combined effects of different vaccination coverage levels and waning immunity lead to distinct patterns of resurgent COVID-19 epidemics (either surges or endemic), which are observed in countries that implemented different COVID-19 health policies and achieved different vaccinated population plateaus after the vaccine rollouts in the first half of 2021.

Immunogenicity, Safety, and Anti-Viral Efficacy of a Subunit SARS-CoV-2 Vaccine Candidate in Captive Black-Footed Ferrets (Mustela nigripes) and Their Susceptibility to Viral Challenge. A preliminary vaccination trial against the emergent pathogen, SARS-CoV-2, was completed in captive black-footed ferrets (Mustela nigripes; BFF) to assess safety, immunogenicity, and anti-viral efficacy. Vaccination and boosting of 15 BFF with purified SARS-CoV-2 S1 subunit protein produced a nearly 150-fold increase in mean antibody titers compared to pre-vaccination titers. Serum antibody responses were highest in young animals, but in all vaccinees, antibody response declined rapidly. Anti-viral activity from vaccinated and unvaccinated BFF was determined in vitro, as well as in vivo with a passive serum transfer study in mice. Transgenic mice that received BFF serum transfers and were subsequently challenged with SARS-CoV-2 had lung viral loads that negatively correlated ($p < 0.05$) with the BFF serum titer received. Lastly, an experimental challenge study in a small group of BFF was completed to test susceptibility to SARS-CoV-2. Despite viral replication and shedding in the upper respiratory tract for up to 7 days post-challenge, no clinical disease was observed in either vaccinated or naive animals. The lack of morbidity or mortality observed indicates SARS-CoV-2 is unlikely to affect wild BFF populations, but infected captive animals pose a potential risk, albeit low, for humans and other animals.

New-Onset and Relapsed Membranous Nephropathy post SARS-CoV-2 and COVID-19 Vaccination. Since the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) outbreak and COVID-19 vaccination, new-onset and relapsed clinical cases of membranous nephropathy (MN) have been reported. However, their clinical characteristics and pathogenesis remained unclear. In this article, we collected five cases of MN associated with SARS-CoV-2 infection and 37 related to COVID-19 vaccination. Of these five cases, four (4/5, 80%) had acute kidney injury (AKI) at disease onset. Phospholipase A2 receptor (PLA2R) in kidney tissue was negative in three (3/5, 60%) patients, and no deposition of virus particles was measured among all patients. Conventional immunosuppressive drugs could induce disease remission. The underlying pathogenesis included the subepithelial deposition of viral antigens and aberrant immune response. New-onset and relapsed MN after

COVID-19 vaccination generally occurred within two weeks after the second dose of vaccine. Almost 27% of patients (10/37) suffered from AKI. In total, 11 of 14 cases showed positive for PLA2R, and 20 of 26 (76.9%) presented with an elevated serum phospholipase A2 receptor antibody (PLA2R-Ab), in which 8 cases exceeded 50 RU/mL. Conventional immunosuppressive medications combined with rituximab were found more beneficial to disease remission for relapsed patients. In contrast, new-onset patients responded to conservative treatment. Overall, most patients (24/37, 64.9%) had a favorable prognosis. Cross immunity and enhanced immune response might contribute to explaining the mechanisms of MN post COVID-19 vaccination.

Autoimmune Rheumatic Disease Flares with Myocarditis Following COVID-19 mRNA Vaccination: A Case-Based Review. Since the introduction of coronavirus disease 2019 (COVID-19) messenger ribonucleic acid (mRNA) vaccines, there have been multiple reports of post-vaccination myocarditis (mainly affecting young healthy males). We report on four patients with active autoimmune rheumatic diseases (ARDs) and probable or confirmed myocarditis following COVID-19 mRNA vaccination managed at a tertiary hospital in Singapore; we reviewed the literature on post-COVID-19 mRNA vaccination-related myocarditis and ARD flares. Three patients had existing ARD flares (two had systemic lupus erythematosus (SLE), one had eosinophilic granulomatosis polyangiitis (EGPA)), and one had new-onset EGPA. All patients recovered well after receiving immunosuppressants comprising high-dose glucocorticoids, cyclophosphamide, and rituximab. Thus far, only one case of active SLE with myocarditis has been reported post-COVID-19 mRNA vaccination in the literature. In contrast to isolated post-COVID-19 mRNA vaccination myocarditis, our older-aged patients had myocarditis associated with ARD flares post-COVID-19 vaccination (that occurred after one dose of an mRNA vaccine), associated with other features of ARD flares, and required increased immunosuppression to achieve myocarditis resolution. This case series serves to highlight the differences in clinical and therapeutic aspects in ARD patients, heighten the vigilance of rheumatologists for this development, and encourage the adoption of risk reduction strategies in this vulnerable population.

COVID-19 Vaccination Trends and Side Effects among Egyptian Hemodialysis Patients: A Multicenter Survey Study. (1) Background: Vaccination may be a key intervention to prevent infection in chronic hemodialysis (CHD) patients. This study aimed to determine the COVID-19 vaccination status in Egyptian CHD patients and to analyze the safety and detailed side effect profile of the COVID-19 vaccine among these patients. (2) Methods: This survey-based study was conducted on 670 end-stage renal disease (ESRD) patients on CHD from 3 December 2021 to 5 February 2022. Subjects were asked about sociodemographic characteristics, clinical and therapeutic data, in addition to their COVID-19 vaccination status. If the subject had been vaccinated, we inquired about the type of vaccine and the side effects that occurred within a few days after administration of the first and second dose of the COVID-19 vaccine. Additionally, subjects were asked about the onset of side effects (days from vaccination), timing of maximum symptoms, intensity of symptoms and their effect on activity and need for medical attention. (3) Results: The study included 670 CHD patients with a mean age of 50.79 years; 58.1% were females. The vast majority (614; 91.6%) of the studied patients received two doses of the vaccine. Side effects were more commonly reported after the first dose than the second dose. The main side effects reported were generalized weakness/fatigue (56%), headache (43.8%) and fever (40.4%), and sore arm/pain was also reported (29.3%). Adverse events mostly occurred within one day after vaccination and the maximum symptoms usually happened on the second day. The median duration of symptoms was 3 days with a maximum duration up to 5 days. The univariate logistic regression analysis showed that male gender (OR 1.848; (95% CI, 1.242âˆ’2.749), p = 0.002), age (OR 0.981; (95% CI, 0.969âˆ’0.993), p = 0.003), smoking (OR 6.067; (95% CI, 3.514âˆ’10.475), p < 0.001), duration since starting HD (OR 0.998; (95% CI, 0.998âˆ’0.999), p < 0.001), associated

comorbidities (OR 2.202; (95% CI, 1.478â^'3.281), p < 0.001) and prior COVID-19 infection (OR 3.318; (95% CI, 1.952â^'5.642), p < 0.001) were the main determinants of adverse events related to COVID-19 vaccination. (4) Conclusions: our preliminary findings support the favorable short-term safety profile of the COVID-19 vaccine among CHD patients, and hence can reassure both clinicians and patients, as well as further promote COVID-19 vaccine administration among these patients.

COVID-19 Vaccine-Associated Optic Neuropathy: A Systematic Review of 45 Patients. We provide a systematic review of published cases of optic neuropathy following COVID-19 vaccination. We used Ovid MEDLINE, PubMed, and Google Scholar. Search terms included: â€œCOVID-19 vaccinationâ€•, â€œoptic neuropathyâ€•, â€œoptic neuritisâ€•, and â€œischemic optic neuropathyâ€•. The titles and abstracts were screened, then the full texts were reviewed. Sixty eyes from forty-five patients (28 females) were included. Eighteen eyes from fourteen patients (31.1%) were diagnosed with anterior ischemic optic neuropathy (AION), while 34 eyes from 26 patients (57.8%) were diagnosed with optic neuritis (ON). Other conditions included autoimmune optic neuropathy and Leber hereditary optic neuropathy. Fifteen patients (33.3%) had bilateral involvement. The mean age of all patients was 47.4 Â± 17.1 years. The mean age of AION patients was 62.9 Â± 12.2 years and of ON patients was 39.7 Â± 12.8 years (p < 0.001). The mean time from vaccination to ophthalmic symptoms was 9.6 Â± 8.7 days. The mean presenting visual acuity (VA) was logMAR 0.990 Â± 0.924. For 41 eyes with available follow-up, the mean presenting VA was logMAR 0.842 Â± 0.885, which improved to logMAR 0.523 Â± 0.860 at final follow-up (p < 0.001). COVID-19 vaccination may be associated with different forms of optic neuropathy. Patients diagnosed with ON were more likely to be younger and to experience visual improvement. More studies are needed to further characterize optic neuropathies associated with COVID-19 vaccination.

Post-Vaccination Neutralization Responses to Omicron Sub-Variants. BACKGROUND: The emergence of the Omicron variant (B.1.1.529), which correlated with dramatic losses in cross-neutralization capacity of post-vaccination sera, raised concerns about the effectiveness of COVID-19 vaccines against infection and disease. Several clinically relevant sub-variants subsequently emerged rapidly. METHODS: We evaluated published and pre-print studies reporting sub-variant specific reductions in cross-neutralization compared to the prototype strain of SARS-CoV-2 and between sub-variants. Median fold-reduction across studies was calculated by sub-variant and vaccine platform. RESULTS: Among 178 studies with post-vaccination data, after primary vaccination the sub-variant specific fold-reduction in neutralization capacity compared to the prototype antigen varied widely, from median 4.2-fold for BA.3 to 40.1-fold for BA.2.75; in boosted participants fold-reduction was similar for most sub-variants (5.3-fold to 7.0-fold); however, a more pronounced fold-change was observed for sub-variants related to BA.4 and BA.5 (10.4-fold to 14.2-fold). Relative to BA.1, the other Omicron sub-variants had similar neutralization capacity post-primary vaccination (range median 0.8-fold to 1.1-fold) and post-booster (0.9-fold to 1.4-fold) except for BA.4/5-related sub-variants which was higher (2.1-fold to 2.7-fold). Omicron sub-variant-specific responder rates were low post-primary vaccination (range median 28.0% to 65.9%) compared to the prototype (median 100%) but improved post-booster (range median 73.3% to 100%). CONCLUSIONS: Fold-reductions in neutralization titers were comparable post-booster except for sub-variants related to BA.4 and BA.5, which had higher fold-reduction. Assessment after primary vaccination was not possible because of overall poor neutralization responses causing extreme heterogeneity. Considering large fold-decreases in neutralization titers relative to the parental strain for all Omicron sub-variants, vaccine effectiveness is very likely to be reduced against all Omicron sub-variants, and probably more so against variants related to BA.4 or BA.5.

Identifying Modifiable Predictors of COVID-19 Vaccine Side Effects: A Machine Learning Approach. Side effects of COVID-19 or other vaccinations may affect an individual's safety, ability to work or care

for self or others, and/or willingness to be vaccinated. Identifying modifiable factors that influence these side effects may increase the number of people vaccinated. In this observational study, data were from individuals who received an mRNA COVID-19 vaccine between December 2020 and April 2021 and responded to at least one post-vaccination symptoms survey that was sent daily for three days after each vaccination. We excluded those with a COVID-19 diagnosis or positive SARS-CoV2 test within one week after their vaccination because of the overlap of symptoms. We used machine learning techniques to analyze the data after the first vaccination. Data from 50,484 individuals (73% female, 18 to 95 years old) were included in the primary analysis. Demographics, history of an epinephrine autoinjector prescription, allergy history category (e.g., food, vaccine, medication, insect sting, seasonal), prior COVID-19 diagnosis or positive test, and vaccine manufacturer were identified as factors associated with allergic and non-allergic side effects; vaccination time 6:00-10:59 was associated with more non-allergic side effects. Randomized controlled trials should be conducted to quantify the relative effect of modifiable factors, such as time of vaccination.

Third BNT162b2 Vaccine Booster Dose against SARS-CoV-2-Induced Antibody Response among Healthcare Workers. This study assessed humoral response to the third BNT162b2 dose among healthcare workers (HCW). This prospective cohort study of HCW tested for anti-spike antibodies (LIAISON SARS-CoV-2 S1/S2 IgG assay) at 1, 3, 6, 9, and 12 months after receiving the second BNT162b2 vaccine dose (tests 1, 2, 3, 4, and 5, respectively). A third (booster) vaccination dose was introduced before test 4. Linear regression model was used to determine the humoral response following vaccine doses. For each serology test, changes in log-transformed antibody concentrations over time, adjusted for age, sex, underlying diseases, steroid treatment, and smoking were described using the general linear mix model. Serology tests were performed at 3, 6, 9, and 12 months after the second vaccine dose in 1113, 1058, 986, and 939 participants, respectively. The third dose was received by 964 participants before the 9-month tests, 797 of whom participated in the 9- and 12-month serology tests. A significant inverse correlation was noted between time from third dose and antibody concentrations (Spearman correlation âˆ’0.395; $p < 0.001$). Age ($p < 0.0001$; CI 95% âˆ’0.005âˆ’âˆ’0.004), heart disease ($p < 0.0001$; CI 95% âˆ’0.177âˆ’âˆ’0.052), immunodeficiency ($p < 0.0001$; CI 95% 0.251âˆ’âˆ’0.106), and smoking ($p < 0.0001$; CI 95% âˆ’0.122âˆ’âˆ’0.040) were significantly associated with decreased antibody concentrations. Female sex ($p = 0.03$; CI 95% 0.013âˆ’0.066) was associated with increased antibody concentrations. The third booster dose had a better effect on immunogenicity, with higher antibody concentrations among tested HCW. Heart disease, smoking, and other known risk factors were associated with decreased antibody concentrations.

Impact of Media Use on Chinese Public Behavior towards Vaccination with the COVID-19 Vaccine: A Latent Profile Analysis. (1) Background: research on vaccines has received extensive attention during epidemics. However, few studies have focused on the impact of media use on vaccination behavior and the factors influencing vaccination in groups with different media use degrees; (2) Method: Based on seven items related to media use, a total of 11,031 respondents were categorized by the frequency of media use by using latent profile analysis (LPA). Binary regression analysis was used to study the factors that influence the vaccination behaviors of people with different media use frequencies; (3) Results: All respondents were classified into the following three groups: media use low frequency (9.7%), media use general (67.1%), and media use high frequency (23.2%). Media use low frequency ($Î² = âˆ’0.608$, $p < 0.001$) was negatively associated with COVID-19 vaccination behavior. In the media use low frequency, analysis showed that â€œaged 41 years or olderâ€• ($Î² = 1.784$, $p < 0.001$), had religious belief ($Î² = 0.075$, $p < 0.05$), were ethnic minorities ($Î² = 0.936$, $p < 0.01$) and had friends support ($Î² = 0.923$, $p < 0.05$) were associated with a preference to accept the COVID-19 vaccine. In the media use general, those who aged 41 years old and older ($Î² = 1.682$, $p < 0.001$),

had major depression (Î² = 0.951, p < 0.05), had friends support (Î² = 0.048, p < 0.001) would be more likely to receive COVID-19 vaccination. However, respondents who live in towns (Î² = â^'0.300, p < 0.01) had lower behaviors to receive vaccination for COVID-19. In the media use high frequency, the respondents who aged 41 or older (Î² = 1.010, p < 0.001), were ethnic minorities (Î² = 0.741, p < 0.001), had moderate depression (Î² = 1.003, p < 0.05) would receive the vaccination for COVID-19 positively; (4) Conclusions: The more occluded the media use is, the less likely the respondents are to get vaccinated against COVID-19. Vaccination behavior is influenced by different factors in groups with different frequencies of media use. Therefore, the government and appropriate departments should make individualized and targeted strategies about COVID-19 vaccination and disseminate the vaccination information to different media use groups.

Idiopathic Multicentric Castleman Disease Occurring Shortly after mRNA SARS-CoV-2 Vaccine. Idiopathic Multicentric Castleman Disease (iMCD) is a potentially life-threatening systemic disease whose complex symptomatology is due to cytokine dysregulation. We, herein, present a case of severe iMCD occurring in a previously healthy young man shortly after mRNA SARS-CoV-2 vaccination, responding to interleukin-6 blockade with siltuximab. Six months after the completion of siltuximab, the patient remained without any signs of iMCD or inflammation, indicating a temporal trigger of the disease. This case not only adds to the potential pathogenetic spectrum of MCD, but also extends the clinical picture of potential but rare adverse events following COVID-19 immunization.

Exploring the Association between Negative Emotions and COVID-19 Vaccine Acceptance: A Cross-Sectional Analysis of Unvaccinated Adults in Sweden. The coronavirus disease 2019 (COVID-19) pandemic has had a significant impact on individuals' mental health. This study aimed to investigate how negative emotions toward the COVID-19 pandemic, including feeling anxious, depressed, upset, and stressed, were associated with COVID-19 vaccine acceptance in Sweden. The study is a cross-sectional online survey conducted between 21-28 May 2021, using three nested hierarchical logistic regression models to assess the association. The study included 965 unvaccinated individuals, 51.2% (n = 494) of whom reported their intention to get vaccinated. We observed graded positive associations between reported negative emotions and vaccine acceptance. Individuals who experienced economic stress had lower odds of vaccine acceptance while having a positive opinion of the government's response to COVID-19 was associated with higher odds of being vaccine-acceptant. In conclusion, unvaccinated individuals experiencing negative emotions about the pandemic were more willing to get the vaccine. On the contrary, those with a negative opinion about the government's response, and those that had experienced economic stress were less likely to accept the immunization.

Recurrent and De Novo Toxoplasmosis Retinochoroiditis following Coronavirus Disease 2019 Infection or Vaccination. This study reports three cases of toxoplasmosis retinochoroiditis following coronavirus disease 2019 (COVID-19) infection or vaccination from the national Canadian COVID-19 Eye Registry between December 2020 and September 2021. A 56-year-old male presented 15 days after a positive COVID-19 test with toxoplasmosis retinochoroiditis. He later relapsed 8 days following a first Pfizer-BioNTech vaccine dose. Two patients presented with toxoplasmosis retinochoroiditis following COVID-19 vaccination: A 58-year-old female presenting 4 days following a first Pfizer-BioNTech vaccine dose with anterior uveitis and a posterior pole lesion discovered 3 months later and a 39-year-old female presenting 17 days after a first Moderna vaccine dose. Resolution was achieved with oral clindamycin, oral trimethoprim/sulfamethoxazole, and topical prednisolone acetate 1%. Patients were offered prophylactic trimethoprim/sulfamethoxazole for subsequent doses without relapse. Following COVID-19 infection or vaccination, patients may be at risk for toxoplasmosis

retinochoroiditis. Prophylactic antibiotics for future doses may be offered to patients with known ocular toxoplasmosis to prevent recurrence.

The Effect of a Booster Dose mRNA Vaccine on COVID-19 Infection in Kidney Transplant Recipients after Inactivated or Viral Vector Vaccine Immunization. The mortality rate after novel coronavirus infection, which causes severe acute respiratory distress syndrome (SARS-CoV-2), is much higher in kidney transplant recipients (KTRs) compared to the general population. Seroconversion after vaccination is also lower, and breakthrough infection is much higher. Many studies reported seroconversion rate after a booster (third) dose of vaccine but clinical outcomes received less attention. Here, we reported the impact of an mRNA vaccine booster dose on clinical outcomes of KTRs with SARS-CoV-2 infection. A total of 183 KTRs with SARS-CoV-2 infection were identified. Of 183 KTRs, 146 KTRs had sufficient data for analysis and were included in this study. Forty-eight patients (32.9%) received zero to 1 doses of vaccine (Group 1), thirty-one (21.2%) received two doses (Group 2), and sixty-seven (45.9%) received a booster dose (Group 3). Pneumonia developed in 50%, 23%, and 10% in Group 1, 2, and 3 ($p < 0.001$). Hospital admission requirement was 81%, 48%, and 12% ($p < 0.001$). Mortality rate was 26%, 3%, and 3% ($p = 0.001$). A multivariate analysis showed that only diabetes adversely affects mortality while the booster dose of the vaccine significantly reduced mortality. The booster dose of the vaccine is strongly recommended in all KTRs especially those with diabetes. Our study also suggested the timing of the booster dose vaccine to be administered within 4 months after the second dose.

Adult-Onset Still's Disease following Coronavirus 2 (SARS-CoV-2) Vaccination: A Case Report. In recent years, during the ravages of COVID-19, a variety of vaccines have been developed and are now on the market. However, although these new vaccines have undergone various trials, there are still many unknown side effects. We report a case of a 30-year-old woman who presented with general weakness, sore throat, generalized skin rashes, symmetrical arthralgia, and persistent fever of up to 40 Â°C with onset 16 days after receiving the Moderna COVID-19 vaccine. Adult-onset Still's disease (AOSD) was diagnosed according to Yamaguchi's criteria after excluding the feasibility of infectious diseases, autoimmune diseases, and malignancies. In particular, her responses to glucocorticoids and naproxen were significant and inversely proportional to her use of empirical antibiotics in the initial stage of treatment. We studied some similar cases of AOSD, which also considered the adverse effects of COVID-19 vaccination and suggested the immunogenicity and possibility of inflammatory responses related to COVID-19 vaccination.

Dysautonomia in Children with Post-Acute Sequelae of Coronavirus 2019 Disease and/or Vaccination. Long-term health problems such as fatigue, palpitations, syncope, and dizziness are well-known in patients after COVID-19 (post-acute sequelae of coronavirus (PASC)). More recently, comparable problems have been noticed after the SARS-CoV-2 vaccination (post-VAC). The pathophysiology of these problems is not well-understood. METHODS: In 38 children and young adults, we tested if these health problems were related to dysautonomia in an active standing test (Group 1: 19 patients after COVID-19; Group 2: 12 patients with a breakthrough infection despite a vaccination; and Group 3: 7 patients after a vaccination without COVID-19). The data were compared with a control group of 47 healthy age-matched patients, as recently published. RESULTS: All patients had a normal left ventricular function as measured by echocardiography. Significantly elevated diastolic blood pressure in all patient groups indicated a regulatory cardiovascular problem. Compared with the healthy control group, the patient groups showed significantly elevated heart rates whilst lying and standing, with significantly higher heart rate increases. The stress index was significantly enhanced in all patient groups whilst lying and standing. Significantly decreased pNN20 values, mostly whilst standing, indicated a lower vagus activity in all patient groups. The respiratory rates were significantly elevated in Groups 1 and 2. CONCLUSION: The uniform increase in the heart rates and stress indices, together

with low pNN20 values, indicated dysautonomia in children with health problems after COVID-19 disease and/or vaccination. A total of 8 patients fulfilled the criteria of postural orthostatic tachycardia syndrome and 9 patients of an inappropriate sinus tachycardia, who were successfully treated with omega-3 fatty acid supplementation and pharmacotherapy.

Benefits of Switching Mycophenolic Acid to Sirolimus on Serological Response after a SARS-CoV-2 Booster Dose among Kidney Transplant Recipients: A Pilot Study. Kidney transplant recipients (KTRs) have a suboptimal immune response to COVID-19 vaccination due to the effects of immunosuppression, mostly mycophenolic acid (MPA). This study investigated the benefits of switching from the standard immunosuppressive regimen (tacrolimus (TAC), MPA, and prednisolone) to a regimen of mammalian target of rapamycin inhibitor (mTORi), TAC and prednisolone two weeks pre- and two weeks post-BNT162b2 booster vaccination. A single-center, opened-label pilot study was conducted in KTRs, who received two doses of ChAdOx-1 and a single dose of BNT162b2. The participants were randomly assigned to continue the standard regimen (control group, n = 14) or switched to a sirolimus (an mTORi), TAC, and prednisolone (switching group, n = 14) regimen two weeks before and two weeks after receiving a booster dose of BNT162b2. The anti-SARS-CoV-2 S antibody level after vaccination in the switching group was significantly greater than the control group (4051.0 [IQR 3142.0-6466.0] BAU/mL vs. 2081.0 [IQR 1077.0-3960.0] BAU/mL, respectively; p = 0.01). One participant who was initially seronegative in the control group remained seronegative after the booster dose. These findings suggest humoral immune response benefits of switching the standard immunosuppressive regimen to the regimen of mTORi, TAC, and prednisolone in KTRs during vaccination.

There Is No Evidence That Inactivated COVID-19 Vaccines Increase Risks of Uveitis Flare. This is a retrospective study to investigate the impact of inactivated Coronavirus disease-2019 (COVID-19) vaccination on uveitis flare in patients with uveitis. Sixty patients that were regularly followed up for uveitis for at least two months after the last dose of inactivated COVID-19 vaccines were included in the vaccination group. Sixty patients with comparable characteristics of uveitis who had not received the COVID-19 vaccines were included in the control group. Uveitis flare within 30 days and 60 days after the vaccination in the vaccination group, or after a randomly selected date in the control group, were statistically compared. The flare rate was 16.7% (30 days) and 23.3% (60 days) in the vaccination group, while it was 13.3% (30 days) and 25% (15/60) in the control group. There was no statistical difference in the flare rate of uveitis between the two groups (p = 0.471 for 30 days, p = 0.347 for 60 days). Inactivated COVID-19 vaccination appeared not to increase the flare rate in patients with uveitis. Ophthalmologists should give proper and individualized recommendations based on the overall conditions of patients.

Comparison of SARS-CoV-2 Antibody Levels after a Third Heterologous and Homologous BNT162b2 Booster Dose. This study aimed to determine the anti-S (receptor binding protein) RBD IgG antibody titers formed against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV2) and the neutralizing antibody inhibition percentages (nAb IH%) in blood samples taken after two doses of inactive or mRNA-based vaccine and a booster dose. Volunteers with two doses of inactivated CoronaVac (heterologous group; n = 75) and BioNTech (BNT)162b2 mRNA vaccine (homologous group; n = 75) were included in this study. All participants preferred the BNT162b2 vaccine as a booster dose. First, peripheral blood samples were taken 3 months after the second vaccine dose. Second, peripheral blood samples were taken 1 month after the booster dose. Anti-S-RBD IgG titers were determined by CMIA (SARS-CoV-2 IgG II Quant). Neutralizing antibodies were detected by a surrogate neutralization assay (SARS-CoV-2 NeutraLISA, Euroimmun, LÃ¼beck, Germany). The median age of the volunteers was 40 (IQR 29-47) years old. After the heterologous booster dose, anti-S-RBD IgG levels and neutralizing antibodies increased approximately 50-fold and 9-fold, respectively. Anti-

S-RBD IgG titers increased by 9 and 57 times, respectively, while nAb IH% increased by 1.5 and 16 times, respectively, among those with heterologous reminder doses and those with and without a prior history of coronavirus disease (COVID-19). This study showed that after the administration of a heterologous booster dose with BNT162b2 to those whose primary vaccination was with inactivated CoronaVac, the binding and neutralizing antibody levels were similar to those who received a homologous BNT162b2 booster dose. It was observed that the administration of heterologous and homologous booster doses resulted in the development of similar levels of neutralizing antibodies, independently from a prior history of COVID-19.

Estimated Infection and Vaccine Induced SARS-CoV-2 Seroprevalence in Israel among Adults, January 2020-July 2021. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) emerged in Israel in February 2020 and spread from then. In December 2020, the FDA approved an emergency use authorization of the Pfizer-BioNTech vaccine, and on 20 December, an immunization campaign began among adults in Israel. We characterized seropositivity for IgG anti-spike antibodies against SARS-CoV-2 between January 2020 and July 2021, before and after the introduction of the vaccine in Israel among adults. We tested 9520 serum samples, collected between January 2020 and July 2021. Between January and August 2020, seropositivity rates were lower than 5.0%; this rate increased from September 2020 (6.3%) to April 2021 (84.9%) and reached 79.1% in July 2021. Between January and December 2020, low socio-economic rank was an independent, significant correlate for seropositivity. Between January and July 2021, the 40.00-64.99-year-old age group, Jews and others, and residents of the Northern district were significantly more likely to be seropositive. Our findings indicate a slow, non-significant increase in the seropositivity rate to SARS-CoV-2 between January and December 2020. Following the introduction of the Pfizer-BioNTech vaccine in Israel, a significant increase in seropositivity was observed from January until April 2021, with stable rates thereafter, up to July 2021.

Temporal Association between Hampton's Hump Pulmonary Embolism and First-Dose ChAdOx1 nCov-19 Vaccine in a Patient with Activated Protein C Resistance. A 58-year-old man presented to his practitioner with right-sided pleuritic chest pain, dyspnea, and fatigue 18 days following the first dose of the ChAdOx1 nCov-19 vaccine. Chest radiography showed a basal wedge-shaped consolidation indicative of a Hamptonâ€™s hump in the right lower lobe, which was confirmed by subsequent computed tomography pulmonary angiography. The major laboratory abnormalities were a markedly elevated D-dimer level of 7.53 Âµg/mL (normal range < 0.5 Âµg/mL), a CRP level of 62.8 mg/L (normal range < 5 mg/L), and a previously unknown activated protein C resistance of 1.3 (normal range â‰¥ 1.8). Genetic analysis identified the patient to be heterozygous for the FVLeiden mutation. Neither other errors of hemostasis nor antibodies against platelet factor 4-polyanion complexes could be observed. Moreover, we failed to demonstrate Severe Acute Respiratory Syndrome Coronavirus-2 infection. The patient fully recovered with no sequelae but is being continued on long-term anticoagulation given his risk of recurrent venous thromboembolism. Here we report on the temporal association between the first dose of the ChAdOx1 nCov-19 vaccine and extensive pulmonary embolism in an otherwise healthy patient with activated protein C resistance, however, further investigation is needed to prove causality.

A Vaccine with Multiple Receptor-Binding Domain Subunit Mutations Induces Broad-Spectrum Immune Response against SARS-CoV-2 Variants of Concern. With the emergence of more variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the immune evasion of these variants from existing vaccines, the development of broad-spectrum vaccines is urgently needed. In this study, we designed a novel SARS-CoV-2 receptor-binding domain (RBD) subunit (RBD5m) by integrating five important mutations from SARS-CoV-2 variants of concern (VOCs). The neutralization activities of antibodies induced by the RBD5m candidate vaccine are more balanced

and effective for neutralizing different SARS-CoV-2 VOCs in comparison with those induced by the SARS-CoV-2 prototype strain RBD. Our results suggest that the RBD5m vaccine is a good broad-spectrum vaccine candidate able to prevent disease from several different SARS-CoV-2 VOCs.

A Case Report: Multifocal Necrotizing Encephalitis and Myocarditis after BNT162b2 mRNA Vaccination against COVID-19. The current report presents the case of a 76-year-old man with Parkinson's disease (PD) who died three weeks after receiving his third COVID-19 vaccination. The patient was first vaccinated in May 2021 with the ChAdOx1 nCov-19 vector vaccine, followed by two doses of the BNT162b2 mRNA vaccine in July and December 2021. The family of the deceased requested an autopsy due to ambiguous clinical signs before death. PD was confirmed by post-mortem examinations. Furthermore, signs of aspiration pneumonia and systemic arteriosclerosis were evident. However, histopathological analyses of the brain uncovered previously unsuspected findings, including acute vasculitis (predominantly lymphocytic) as well as multifocal necrotizing encephalitis of unknown etiology with pronounced inflammation including glial and lymphocytic reaction. In the heart, signs of chronic cardiomyopathy as well as mild acute lympho-histiocytic myocarditis and vasculitis were present. Although there was no history of COVID-19 for this patient, immunohistochemistry for SARS-CoV-2 antigens (spike and nucleocapsid proteins) was performed. Surprisingly, only spike protein but no nucleocapsid protein could be detected within the foci of inflammation in both the brain and the heart, particularly in the endothelial cells of small blood vessels. Since no nucleocapsid protein could be detected, the presence of spike protein must be ascribed to vaccination rather than to viral infection. The findings corroborate previous reports of encephalitis and myocarditis caused by gene-based COVID-19 vaccines.

Vitiligo-like Lesions and COVID-19: Case Report and Review of Vaccination- and Infection-Associated Vitiligo. Several cutaneous manifestations in patients undergoing COVID-19 vaccination have been described in the literature. Herein, we presented a case of new-onset vitiligo that occurred after the second dose of the Comirnaty vaccine. An updated literature search revealed the occurrence of a total of 16 cases, including new-onset or worsening of preexisting vitiligo. Given the autoimmune pathogenesis of the disease, we reviewed and discussed the potential role of the vaccine prophylaxis as a trigger for the development of such hypopigmented skin lesions.

An Update on Complications Associated with SARS-CoV-2 Infection and COVID-19 Vaccination. Over the past two years, SARS-CoV-2 has dramatically spread worldwide and emerged as a major pandemic which has left an unprecedented mark on healthcare systems and economies worldwide. As our understanding of the virus and its epidemiology continues to grow, the acute phase clinical symptoms and long-term and vaccine-related complications are becoming more apparent. With heterogeneity in presentations, comparisons may be drawn between COVID-19-related sequelae and vaccination related adverse events. The present review article aims to address the currently available literature on the SARS-CoV-2 virus, immune responses, the pathophysiology of clinical presentations, and available vaccinations with its adverse events for the appraisal of its potential impact on the COVID-19 management system.

The Antibody Response to the BNT162b2 mRNA COVID-19 Booster in Healthcare Workers: Association between the IgG Antibody Titers and Anthropometric and Body Composition Parameters. BACKGROUND: Research shows that in most people, two-dose vaccination helps to shape the humoral response to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Further studies are required to learn about the vaccine's effectiveness after boosting. METHODS: We conducted a prospective study among 103 healthcare workers (HCWs) from a regional multi-specialty hospital vaccinated with three doses of the BNT162b2 vaccine. We compared their immunoglobulin G (IgG) titers 14 days after the second dose with those 21 days after the booster. We also compared their anthropometric and body composition parameters with IgG concentrations at the same time points.

RESULTS: Twenty-one days after the booster, all study participants were seropositive. Their mean IgG antibody titers were significantly lower than 14 days after the second dose (158.94 AU/mL Â± 90.34 AU/mL vs. 505.79 AU/mL Â± 367.16 AU/mL). Post-booster Spearman's correlation analysis showed a significantly weak correlation between the IgG antibody titer and parameters related to muscle tissue and adipose tissue (including body fat mass). CONCLUSIONS: The BNT162b2 booster stimulates the humoral response to a lesser extent than the two-dose BNT162b2 primary vaccination. The adipose and muscle tissue parameters show a weak positive correlation with the SARS-CoV-2 IgG antibody titers.

Glaucoma Cases Following SARS-CoV-2 Vaccination: A VAERS Database Analysis. Background: To counter the rapidly spreading severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), global vaccination efforts were initiated in December 2020. We assess the risk of glaucoma following SARS-CoV-2 vaccination and evaluate its onset interval and clinical presentations in patients. Methods: We performed a retrospective analysis of the glaucoma cases reported to the Vaccine Adverse Event Reporting System (VAERS) database between 16 December 2020, and 30 April 2022. We assessed the crude reporting rate of glaucoma, clinical presentations, onset duration, and associated risk factors. Results: During this period, 161 glaucoma cases were reported, with crude reporting rates (per million doses) of 0.09, 0.06, and 0.07 for BNT162b2, mRNA-1273, and Ad26.COV2.S, respectively. The mean age of the patients was 60.41 Â± 17.56 years, and 67.7% were women. More than half (56.6%) of the cases were reported within the first week of vaccination. The cumulative-incidence analysis showed a higher risk of glaucoma in patients who received the BNT162b2 vaccines compared with mRNA-1273 ($p = 0.05$). Conclusions: The incidence of glaucoma following vaccination with BNT162b2, mRNA-1273, or Ad26.COV2.S is extremely rare. Amongst the patients diagnosed with glaucoma, the onset interval of adverse events was shorter among those who received the BNT162b2 and rAd26.COV2.S vaccines compared with mRNA-1273. Most glaucoma cases were reported within the first week following vaccination in female patients and from the fifth to seventh decade. This study provides insights into the possible temporal association between reported glaucoma events and SARS-CoV-2 vaccines; however, further investigations are required to identify the potential causality link and pathological mechanisms.

Allergic Reactions to COVID-19 Vaccination in High-Risk Allergic Patients: The Experience of Trieste University Hospital (North-Eastern Italy). Background. Allergic patients may develop reactions following COVID-19 vaccination more frequently than non-allergic individuals. The aim of our study was to assess the risk of reactions in high-risk allergic patients vaccinated for COVID-19 at the University Health Agency Giuliano-Isontina (ASUGI) of Trieste (northeastern Italy). Methods. Patients were considered at high risk for allergic reactions in case of: prior anaphylactic reaction to any drug/vaccine; multiple drug allergy; intolerance to polyethylene glycol (PEG) or polysorbate 80 (PS80) containing drugs; and mast cell disorders. High-risk allergic patients were immunized in hospital by a dedicated allergy team supported by resuscitation staff. Patients were interviewed over the phone one month after vaccination to complete a structured questionnaire investigating signs and symptoms developed after immunization. Results. From March 2021 to February 2022, 269 patients with a history of severe allergic reactions were assessed, of whom 208 (77.3%) eventually received COVID-19 vaccination, 50 (18.6%) refused to be immunized, 10 (3.7%) were deferred for medical reasons and one was declared exempted due to testing positive for PS80. Mild reactions (urticaria, angioedema, rhinitis, erythema) to COVID-19 vaccines were reported by 30.3% of patients, 8.7% within 4 h and 21.6% > 4 h after immunization. No anaphylactic events were observed. Although they were 80 times (3.8%) more prevalent than in COVID-19 vaccinees from the general population (0.047%), vaccine allergic reactions in high-risk patients were mainly mild and late, more likely affecting women (OR = 3.05; 95% CI 1.22â^'7.65). Conclusions. High-risk allergic patients with

urticaria and angioedema may experience mild flare-ups of mast cell activation-like symptoms following COVID-19 vaccination, supporting antihistamine premedication before vaccination and to be continued for one week afterwards.

Dynamics of B-Cell Responses after SARS-CoV-2 Vaccination in Spain. The high mortality rate due to COVID-19 has necessitated the mass vaccination against SARS-CoV-2 to induce protective humoral and cellular immunity. (1) Objective: To study the dynamics of SARS-CoV-2-specific B cells after two doses of the Pfizer-BioNTech SARS-CoV-2 vaccine. (2) Methods: Immunophenotyping and cellular cultures were used to determine the kinetics of B-cell subpopulations and vaccine responses in volunteers before and seven days, three months and seven months after the second dose in Spain (n = 19). (3) Results: Seven days after immunisation, memory B cells and plasmablasts expressing receptors for factors implicated in the maturation of plasma cells were augmented in blood. Three months after vaccination, SARS-CoV-2 spike-specific plasmablasts disappeared from circulation while spike-specific memory-B cells circulated, with heterogeneous dynamics among individuals. (4) Conclusion: After vaccination, specific plasmablasts equipped with receptors for maturation factors were quickly generated and disappeared rapidly from the blood, while specific memory B cells circulated for at least seven months.

Association between Adverse Reactions and Humoral Immune Response No Longer Detectable after BNT162b2 Booster Vaccination. In a previous study, we described a highly significant association between reactogenicity and SARS-CoV-2 RBD IgG titers and wild-type neutralization capacity in males after basic vaccination with BNT162b2. The objective of this study was to assess whether this benefit was long lasting and also evident after BNT162b2 booster vaccination. Reactogenicity was classified into three groups: no or minor injection site symptoms, moderate (not further classified) and severe adverse reactions (defined as any symptom(s) resulting in sick leave). We initially compared 76 non-immunocompromised individuals who reported either no or minor injection site symptoms or severe adverse reactions after second vaccination. In total, 65 of them took part in another blood sampling and 47 were evaluated after booster vaccination. 26 weeks after second vaccination, men who reported severe adverse reactions after second vaccination had 1.7-fold higher SARS-CoV-2 RBD IgG titers ($p = 0.025$) and a 2.5-fold better neutralization capacity ($p = 0.006$) than men with no or only minor injection site symptoms. Again, no association was found in women. Reactogenicity of BNT162b2 booster vaccination was different from second vaccination according to our classification and was no longer associated with SARS-CoV-2 RBD IgG titers or wild-type neutralization capacity. To conclude, after BNT162b2 basic vaccination, the association between reactogenicity and humoral immune response in men persisted over time but was no longer detectable after BNT162b2 booster vaccination.

Quantitative Analysis of SARS-CoV-2 Serological Responses Post Three Doses of Immunization and Prior to Breakthrough COVID-19 Infections. BACKGROUND: Vaccine mediated SARS-CoV-2 antibody responses should be carefully evaluated. With regular follow-up in healthy individuals, we aimed to determine SARS-CoV-2 serological responses post three doses of immunization and prior to breakthrough infections in the Canadian population. METHODS: In a prospective cohort study, we enrolled 140 healthy participants post COVID-19 vaccination in Kingston, Ontario, Canada. IgG antibodies against the SARS-CoV-2 spike receptor-binding domain were quantified by immunoassay post three doses of immunization. With COVID-19 rapid antigen test, polymerase chain reaction, and whole genome sequencing, 27 breakthrough infections were identified. RESULTS: Following SARS-CoV-2 vaccine (including BNT162b2, AZD1222, and mRNA-1273), the median serum anti-spike protein antibody level was 143.6 BAU/mL (binding antibody unit, interquartile range 79.0-266.6) post the first dose of immunization, 1046.4 BAU/mL (423.9-1738.2) post the second dose, and 1604.7 BAU/mL (700.1-3764.0) post the third dose. Observed differences were significant (p â‰¤ 0.001). The median

antibody level of 1604.7 BAU/mL post third dose is 45.6 times that of the seroconversion level (35.2 BAU/mL). This indicates that most vaccines approved are effective in producing robust antibody responses. In seven breakthrough cases characterized by whole genome sequencing, prior to infection, antibody concentrations of breakthrough cases were at 3249.4 (Delta), 2748.4 (Delta), 4893.9 (Omicron), 209.1 (Omicron), and 231.5 (Omicron), 725.7 (Omicron), and 2346.6 (Omicron) BAU/mL. Compared with the average antibody concentration of 2057.7 BAU/mL (58 times that of the seroconversion concentration) from above seven cases, 37.2% of triple vaccinated, 19.0% of double vaccinated, and 1.5% single dosed individuals have higher SARS-CoV-2 antibody levels. CONCLUSIONS: Most vaccines are effective in producing robust antibody responses when more than one dose is given, and the more doses the higher the serological response. Likely due to the highly contagious nature of SARS-CoV-2 variants, a significant number of participants have SARS-CoV-2 antibody responses lower than the average antibody concentration prior to the known breakthrough infections. Additional vaccination is likely required to ensure immunity against infection by SARS-CoV-2.

The Longitudinal Analysis on the Anti-SARS-CoV-2 Antibodies among Healthcare Workers in Poland-Before and after BNT126b2 mRNA COVID-19 Vaccination. One of the groups most vulnerable to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection is healthcare workers (HCWs) who have direct contact with suspected and confirmed coronavirus diseases 2019 (COVID-19) patients. Therefore, this study aimed to (i) conduct a longitudinal analysis of the seroprevalence of SARS-CoV-2 infection among HCWs working in two healthcare units (HCUs) in Poland and (ii) identify anti-SARS-CoV-2 IgG antibody (Ab) response factors following infection and anti-COVID-19 vaccination. The overall seroprevalence increased from 0% at baseline in September 2020 to 37.8% in December 2020. It reached 100% in February 2021 after BNT126b2 (Pfizer New York, NY, USA/BioNTech Mainz, Germany) full vaccination and declined to 94.3% in September 2021. We observed significant differences in seroprevalence between the tested high- and low-risk infection HCUs, with the highest seropositivity among the midwives and nurses at the Gynecology and Obstetrics Ward, who usually have contact with non-infectious patients and may not have the proper training, practice and personal protective equipment to deal with pandemic infections, such as SARS-CoV-2. We also found that anti-SARS-CoV-2 Ab levels after coronavirus infection were correlated with disease outcomes. The lowest Ab levels were found among HCWs with asymptomatic coronavirus infections, and the highest were found among HCWs with severe COVID-19. Similarly, antibody response after vaccination depended on previous SARS-CoV-2 infection and its course: the highest anti-SARS-CoV-2 Ab levels were found in vaccinated HCWs after severe COVID-19. Finally, we observed an approximately 90-95% decrease in anti-SARS-CoV-2 Ab levels within seven months after vaccination. Our findings show that HCWs have the highest risk of SARS-CoV-2 infection, and due to antibody depletion, extra protective measures should be undertaken. In addition, in the context of the emergence of new pathogens with pandemic potential, our results highlight the necessity for better infectious disease training and regular updates for the low infection risk HCUs, where the HCWs have only occasional contact with infectious patients.

A Case of Atypical Unilateral Optic Neuritis Following BNT162b2 mRNA COVID-19 Vaccination. BACKGROUND: We report a case of atypical unilateral optic neuritis after receiving the BNT162b2 mRNA-based COVID-19 vaccine. CASE PRESENTATION: An 86-year-old man complained of blurred vision and decreased visual acuity in his right eye 8 days after receiving the second BNT162b2 mRNA-based COVID-19 vaccine and was referred to our hospital. He also had pain with eye movement. Best corrected visual acuity (BCVA) in the right eye was 20/200 and critical flicker frequency dropped to 16 Hz. Relative afferent pupillary defect was positive and central scotomas were observed on visual field analysis. Fundus examination and SD-OCT revealed optic disc swelling and apparent thickening of the

retinal nerve fiber layer around the optic disc in the right eye. Although either an increase in CRP or ESR on laboratory tests, demyelinating lesion on MRI, or positive of anti-MOG antibodies or anti-AQP4 antibodies were not observed, fluorescein angiography presented only hyperfluorescence of the optic disc in the right eye, but there were no findings such as papillary deficiency and choroidal delay that would suggest ischemic optic neuropathy. We diagnosed atypical optic neuritis developed after the SARS-CoV-2 mRNA-based vaccination and initiated oral corticosteroid therapy. One month later, the optic disc swelling disappeared and BCVA improved to 20/100; however, the central scotoma remained and no further improvement in visual function OD was obtained. CONCLUSIONS: An atypical acute idiopathic optic neuritis can occur after receiving the second vaccination with BNT162b2, which may present a limited response to corticosteroid therapy.

SARS-CoV-2 and Influenza Vaccines in People with Excessive Body Mass-A Narrative Review. In the face of a growing number of overweight people and two widely known viral diseases, SARS-CoV-2 and influenza, it is crucial to be aware of the impact of excess body weight on immunisation against these diseases. The aim of this review is to show the effectiveness of SARS-CoV-2 and influenza vaccines in overweight and obese patients. Excessive adipose tissue releases cytokines and maintains local hypoxia, which causes persistent low-grade inflammation. These factors make excess body mass patients' immune systems weaker. Under such conditions, the humoral response becomes less efficient, leading to a weakened ability to fight against infection and an increased risk of developing lower antibody titres. Vaccines help to reduce morbidity both in normal-weight and excess body mass people, although most studies show that patients with higher BMI tend to lose the antibodies produced more quickly. It is shown that the most effective vaccines (in terms of preventing the infection and potential post-illness complications) are the BNT162b2 vaccine against SARS-CoV-2 and the inactivated influenza vaccine against influenza among both obese and non-obese subjects.

Machine Learning Analyses Revealed Distinct Arterial Pulse Variability According to Side Effects of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2). Various adverse events and complications have been attributed to COVID-19 (coronavirus disease 2019) vaccinations, which can affect the cardiovascular system, with conditions such as myocarditis, thrombosis, and ischemia. The aim of this study was to combine noninvasive pulse measurements and frequency domain analysis to determine if the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) vaccination and its accompanying cardiovascular side effects will induce changes in arterial pulse transmission and waveform. Radial blood pressure waveform and photoplethysmography signals were measured noninvasively for 1 min in 112 subjects who visited Shuang-Ho Hospital for a BNT162b2 vaccination. Based on side effects, each subject was assigned to Group N (no side effects), Group CV (cardiac or vascular side effects), Group C (cardiac side effects only), or Group V (vascular side effects only). Two classification methods were used: (1) machine-learning (ML) analysis using 40 harmonic pulse indices (amplitude proportions, phase angles, and their variability indices) as features, and (2) a pulse-variability score analysis developed in the present study. Significant effects on the pulse harmonic indices were noted in Group V following vaccination. ML and pulse-variability score analyses provided acceptable AUCs (0.67 and 0.80, respectively) and hence can aid discriminations among subjects with cardiovascular side effects. When excluding ambiguous data points, the AUC of the score analysis further improved to 0.94 (with an adopted proportion of around 64.1%) for vascular side effects. The present findings may help to facilitate a time-saving and easy-to-use method for detecting changes in the vascular properties associated with the cardiovascular side effects following BNT162b2 vaccination.

SARS-CoV-2 Vaccines and Adverse Effects in Gynecology and Obstetrics: The First Italian Retrospective Study. The most common effects reported by the Italian Medicine Agency following administration of SARS-CoV-2 vaccine are myalgia, soreness to the arm of inoculation, fever, and asthenia. To date, there are no specific and official reports registered by the Italian Medicine

Agency on possible alterations of the menstrual cycle, or of the female reproductive system, following the vaccine. Actually, clinical experience showed a spread of transient adverse drug reactions of the menstrual cycle, following the administration of all COVID-19 vaccine types, both mRNA and Adenovirus vectored ones. In this work, we conducted the first retrospective study on Italian patients vaccinated for SARS-CoV-2 in the period between April 2021 and April 2022, to report the onset of menstrual changes after the vaccine in order to understand: etiology, duration of possible adverse effects, and the extent of the phenomenon. We recruited 100 women aged 18-45, vaccinated for SARS-CoV-2, who were asked to complete a questionnaire consisting of 12 multiple choice questions about the effects of the vaccine on the reproductive system. Thirty-seven of them received three doses of the vaccine, while the remaining 63 received two doses. Symptoms such as delayed menstruation and abnormal uterine bleeding (metrorrhagia, menometrorrhagia, and menorrhagia) were generally reported within the first three weeks of vaccination, especially after the second dose, with a percentage of 23% and 77%, respectively. These preliminary data suggest that this problem may be broader and deserving of further investigation in the future.

Intrinsic Kidney Pathology in Children and Adolescents Following COVID-19 Vaccination: A Systematic Review. Global COVID-19 vaccination programs for children and adolescents have been developed with international clinical trial data confirming COVID-19 mRNA vaccine safety and efficacy for the pediatric population. The impact of COVID-19 vaccination in the kidneys is thought to be explained by a complex immune-mediated relationship between the two, although the pathophysiological mechanisms of how COVID-19 vaccination potentially induces kidney pathology are not presently well known. Whilst intrinsic kidney pathologies following COVID-19 vaccination have been reported in adults, such cases are only being recently reported with greater frequency in children and adolescents. Conforming to the PRISMA checklist, we conducted a systematic review of the current literature to provide an overview on the range of intrinsic kidney pathologies that have been reported following COVID-19 vaccination in children and adolescents. All English language research articles published on or before 30 June 2022 reporting new-onset or relapsed intrinsic kidney pathology in children or adolescents (â‰¤18 years) following COVID-19 vaccination were selected for qualitative analysis. Out of 18 cases from the 13 published articles selected, there were 10 cases of IgA nephropathy (1 case of rapidly progressive glomerulonephritis requiring acute hemodialysis), 5 cases of minimal change disease (MCD), 1 case of concurrent MCD/tubulointerstitial nephritis (TIN) and 2 cases of TIN. There is no indication currently to avoid vaccination, unless specific circumstances exist, as the benefits of COVID-19 vaccination far outweigh its risks. Concluding the findings from our systematic review based on preliminary evidence, potential adverse effects to the kidney from COVID-19 vaccination affects a small number of children and adolescents among the many who have been vaccinated. There remains good reason at present to support vaccination of children and adolescents with a greater morbidity status, such as those living with preexisting chronic kidney disease. Close observation of all children and adolescents receiving COVID-19 vaccination is recommended, particularly in those with preceding intrinsic kidney pathology to identify risks of relapsed disease.

Quantitative Analysis of SARS-CoV-2 Antibody Levels in Cancer Patients Post Three Doses of Immunization and Prior to Breakthrough COVID-19 Infections. (1) Background: COVID-19 vaccine effectiveness should be carefully evaluated and explicitly defined. To our knowledge, this is the first report to quantitatively evaluate humoral responses post 3 doses of SARS-CoV-2 immunization and prior to breakthrough COVID-19 infection in Canadian cancer patients. (2) Methods: In a prospective cohort study, we enrolled 185 cancer participants post COVID-19 vaccination in Kingston, Ontario, Canada. IgG antibodies against the SARS-CoV-2 spike receptor-binding domain were quantified by immunoassay post three doses of immunization. With the COVID-19 rapid antigen test and

polymerase chain reaction (PCR), 16 breakthrough infections were identified. Results: Following SARS-CoV-2 vaccination (including BNT162b2, AZD1222, and mRNA-1273), the mean serum anti-spike protein antibody level was 197.2 BAU/mL (binding antibody unit, SD Â± 393.9), 1335.9 BAU/mL (Â±3337.8), and 3164.8 BAU/mL (Â±6500.9) post the first, second, and third dose of vaccination. Observed differences were significant (p â‰¤ 0.001). The average antibody level of 3164.8 BAU/mL post the third dose was 89.9 times that of the seroconversion level (35.2 BAU/mL). This indicates that most vaccines approved are effective in producing robust antibody responses. In 11 breakthrough cases confirmed by PCR, prior to infection, the average antibody concentration was 3675.6 BAU/mL with the highest concentration being 9107.4 BAU/mL. Compared with this average antibody concentration of 3675.6 BAU/mL (104.4 times that of the seroconversion concentration), 0% of single dosed, 9.6% of double vaccinated, and 29.5% of triple vaccinated cancer patients had higher SARS-CoV-2 antibody levels. When patients were split into hematological and solid cancer, the hematological cancer group demonstrated lower serological responses than the solid cancer group in the first and second doses (first dose, average concentration 11.1 vs. 201.4 BAU/mL, respectively, $p < 0.05$; second dose, average concentration 441.5 vs. 1725.9 BAU/mL, respectively, $p < 0.05$). There was no difference in the third dose level (1756.3 vs. 2548.0 BAU/mL, $p = 0.21$). (4) Conclusions: Most vaccines were effective in producing robust antibody responses when more than one dose was given, and the more doses the higher the serological response. Likely due to the highly contagious nature of SARS-CoV-2 variants, a significant number of participants had SARS-CoV-2 antibody responses lower than the average antibody concentration prior to the known breakthrough infections. Additional vaccination is likely required to ensure immunity against infection by SARS-CoV-2.

COVID-19 vaccination coverage among patients with psychiatric disorders in China during the pandemic: a cross-sectional study. BACKGROUND: To investigate the Coronavirus Disease 2019 (COVID-19) vaccination coverage and the influential factors of vaccination among patients with mental disorders, we conducted a cross-sectional study in China. METHOD: The anonymous questionnaires including demographic data, vaccination status, intention to be vaccinated and its reasons were collected in the Second Xiangya Hospital, one of the biggest four psychiatric centers in China. Mental health of these participants were measured by the Patient Health Questionnaire (PHQ-9) and the Generalized Anxiety Disorder-7 items (GAD-7). The influential factors associated with vaccination status were analyzed by Fisher exact tests and binary logistical analysis. RESULT: 1328 patients and 922 family members completed the survey. The vaccination rate of patients included was 69.4%, whereas 85.5% patients were willing to be vaccinated. Being hospitalized (aOR 0.41, 95% CI:0.27-0.60), suffering from schizophrenia (aOR 0.38, 95% CI: 0.19-0.75) and secondary school educational background (aOR 0.58, 95% CI: 0.37-0.93) were significantly associated with less likelihood to get vaccinated. Uptaking vaccines could reduce depressive (aOR 0.63, 95% CI: 0.41-0.98) or anxious symptoms (aOR 0.40, 95% CI: 0.25-0.63) in these patients for a short period. CONCLUSION: Further COVID-19 immunization programme should prioritize hospitalized psychiatric patients and schizophrenic patients since their demands for vaccination had been partly ignored during the current inoculation.

Efficacy and safety of the SARS-CoV-2 mRNA vaccine in lung transplant recipients: a possible trigger of rejection. OBJECTIVE: Solid organ transplant recipients have an increased risk of developing severe coronavirus disease 2019 (COVID-19). Although SARS-CoV-2 mRNA vaccination has been strongly recommended for solid organ transplant recipients, its efficacy and safety have remained unknown. METHODS: We performed an observational prospective cohort study in 18 lung transplant recipients who received two doses of SARS-CoV-2 mRNA vaccine, including BNT162b2 (nâ€‰=â€‰17) or mRNA-1273 (nâ€‰=â€‰1), between June and October 2021. The titers of IgG antibodies against the SARS-CoV-2 spike protein (S-IgG) were measured in serum samples collected

before the prime dose, three weeks after the prime dose, and four weeks after the booster dose. Reactogenicity and adverse events were evaluated after vaccination. RESULTS: There were no recipients with previous SARS-CoV-2 infection prior to vaccination. S-IgG levels were elevated in 2/18 (11.1%) recipients after the prime dose and in 5/18 recipients (27.8%) after the booster dose (31.7â€‰Â±â€‰30.6 U/ml). The time from transplantation to vaccination tended to be longer in the seropositive group than the seronegative group [7.5 (3.9-10.2) vs 2.8 (1.9-4.0) years, pâ€‰=â€‰0.059]. Maintenance dose of mycophenolate mofetil tended to be lower in the seropositive group than in the seronegative group [500 (250-500) vs 1000 (1000-1000) mg/day, pâ€‰=â€‰0.088]. Regarding the adverse events after vaccination, the development of chronic lung allograft dysfunction (CLAD) or antibody-mediated rejection (AMR) were observed in two seropositive patients. CONCLUSIONS: The antibody response to the SARS-CoV-2 mRNA vaccine was quite poor in lung transplant recipients. We experienced cases that developed clinical CLAD or AMR that was likely related to SARS-CoV-2 vaccination.

First manifestation of AQP4-IgG-positive neuromyelitis optica spectrum disorder following the COVID-19 mRNA vaccine BNT162b2. BNT162b2 is one of the effective COVID-19 vaccines. However, some researchers have also reported some neurological adverse events after the vaccination. Here, we present a case of a 52-year-old female who developed aquaporin (AQP) 4-IgG-positive neuromyelitis optica spectrum disorder (NMOSD) 14Â days after the first dose of BNT162b2. She experienced the neck pain, weakness of the left arm and leg, numbness of the left hand, and impaired temperature sensation of the right leg. MRI showed T2WI hyperintense lesions in the area postrema and cervical spinal cord ranging from C1 to C6 level and Gd-enhanced lesions from C3 to C5 level; especially left lateral column was predominantly enhanced. Cell-based assays showed anti-AQP4 antibody (AQP4Ab) was positive. We diagnosed AQP4-IgG-positive NMOSD. After high-dose glucocorticoid therapy, she is showing improved symptoms. The present case was characterized by the findings that a Gd-enhanced lesion in the cervical cord localized dominantly at the left lateral column, consistent with the side of the shoulder where the vaccine was injected. Many studies suggested that AQP4-IgG-positive NMOSD development has multistep mechanisms following the blood-brain barrier (BBB) breakdown. We suspected that immune responses following vaccination lead to BBB disruptions. Through the limitedly damaged BBB, the plasma cells producing AQP4Abs might be recruited to CNS, and AQP4Abs might bind to the cervical cord and the area postrema. A population-based study revealed that neurological events following COVID-19 vaccination were less likely to be observed than COVID-19 infectious symptoms. Considering rare adverse events, clinicians need to observe any changes in patient condition.

Central retinal vein occlusion post ChAdOx1 nCoV-19 vaccination - can it be explained by the two-hit hypothesis? PURPOSE: To report a case of central retinal vein occlusion (CRVO) seven days following the first dose of ChAdOx1 nCoV-19 vaccine and propose a hypothesis for the possible underlying pathogenesis. OBSERVATION: A 31-year-old male presented with CRVO with cystoid macular edema, one week after receiving his first ChAdOx1 nCoV-19 vaccine dose. Apart from mild hyperhomocysteinemia, no major thrombophilic or systemic risk factors were found. Anti-platelet factor 4 antibodies, specific for vaccine-induced immune thrombotic thrombocytopenia, were also negative. However, he tested strongly positive (>â€‰250 U/mL) for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG spike antibodies, 2Â weeks post the first dose - suggestive of a prior subclinical infection. CONCLUSION: COVID-19 is known to be associated with an altered host one-carbon metabolism resulting in hyperhomocysteinemia. We hypothesize that a prior subclinical infection with COVID-19, the first hit, may have led to hyperhomocysteinemia in our patient and vaccination must have been the second hit that triggered the thrombotic event. Further

studies, including correlation of thrombotic complications with IgG antibody titres post-vaccination, are essential in order to better understand the pathogenesis of such events.
Postmortem PF4 antibodies confirm a rare case of thrombosis thrombocytopenia syndrome associated with ChAdOx1 nCoV-19 anti-COVID vaccination. We report a case of cerebral venous sinus thrombosis, bilateral adrenal hemorrhage, and thrombocytopenia in a 70-year-old man found dead. He had previously received the ChAdOx1 nCoV-19 vaccine (VaxzevriaÂ®, AstraZeneca) 18Â days before, and had since developed unspecific and undiagnosed characteristics of what proved to be a rare case of vaccine-associated thrombocytopenia with thrombosis syndrome (TTS). He was found dead 1Â week after the beginning of symptoms (day 25 post-vaccine). Autopsy yielded venous hemorrhagic infarction with the presence of thrombi within dural venous sinuses, and extensive hemorrhagic necrosis of the central part of the adrenal glands. Antibodies against platelet factor 4 (PF4) were strongly positive in postmortem fluids, as measured with an enzyme-linked immunosorbent assay (ELISA). This difficult diagnosis is usually made during the patient's lifetime. After eliminating differential diagnoses, we concluded on a fatal case of vaccine-induced immune TTS with positive anti-PF4 antibodies in cadaveric blood, 3Â weeks after ChAdOx1 nCoV-19 vaccination. Specific search for anti-PF4 antibodies in cadaveric blood appears therefore paramount to assess postmortem cases of TTS associated with anti-COVID vaccines.
Influence of vaccination and immunosuppressive treatments on the coronavirus disease 2019 outcomes in patients with systemic autoimmune diseases.
Comparative risk of thrombosis with thrombocytopenia syndrome or thromboembolic events associated with different covid-19 vaccines: international network cohort study from five European countries and the US. OBJECTIVE: To quantify the comparative risk of thrombosis with thrombocytopenia syndrome or thromboembolic events associated with use of adenovirus based covid-19 vaccines versus mRNA based covid-19 vaccines. DESIGN: International network cohort study. SETTING: Routinely collected health data from contributing datasets in France, Germany, the Netherlands, Spain, the UK, and the US. PARTICIPANTS: Adults (age â‰¥18 years) registered at any contributing database and who received at least one dose of a covid-19 vaccine (ChAdOx1-S (Oxford-AstraZeneca), BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), or Ad26.COV2.S (Janssen/Johnson & Johnson)), from December 2020 to mid-2021. MAIN OUTCOME MEASURES: Thrombosis with thrombocytopenia syndrome or venous or arterial thromboembolic events within the 28 days after covid-19 vaccination. Incidence rate ratios were estimated after propensity scores matching and were calibrated using negative control outcomes. Estimates specific to the database were pooled by use of random effects meta-analyses. RESULTS: Overall, 1â€‰332â€‰719 of 3â€‰829â€‰822 first dose ChAdOx1-S recipients were matched to 2â€‰124â€‰339 of 2â€‰149â€‰679 BNT162b2 recipients from Germany and the UK. Additionally, 762â€‰517 of 772â€‰678 people receiving Ad26.COV2.S were matched to 2â€‰851â€‰976 of 7â€‰606â€‰693 receiving BNT162b2 in Germany, Spain, and the US. All 628â€‰164 Ad26.COV2.S recipients from the US were matched to 2â€‰230â€‰157 of 3â€‰923â€‰371 mRNA-1273 recipients. A total of 862 thrombocytopenia events were observed in the matched first dose ChAdOx1-S recipients from Germany and the UK, and 520 events after a first dose of BNT162b2. Comparing ChAdOx1-S with a first dose of BNT162b2 revealed an increased risk of thrombocytopenia (pooled calibrated incidence rate ratio 1.33 (95% confidence interval 1.18 to 1.50) and calibrated incidence rate difference of 1.18 (0.57 to 1.8) per 1000 person years). Additionally, a pooled calibrated incidence rate ratio of 2.26 (0.93 to 5.52) for venous thrombosis with thrombocytopenia syndrome was seen with Ad26.COV2.S compared with BNT162b2. CONCLUSIONS: In this multinational study, a pooled 30% increased risk of thrombocytopenia after a first dose of the ChAdOx1-S vaccine was observed, as was a trend towards an increased risk of venous thrombosis

with thrombocytopenia syndrome after Ad26.COV2.S compared with BNT162b2. Although rare, the observed risks after adenovirus based vaccines should be considered when planning further immunisation campaigns and future vaccine development.

Neurological manifestations associated with COVID-19 vaccine. INTRODUCTION: Coronavirus disease 2019 (COVID-19) has spread rapidly, giving rise to a pandemic, causing significant morbidity and mortality. In this context, many vaccines have emerged to try to deal with this disease. OBJECTIVE: To review the reported cases of neurological manifestations after the application of COVID-19 vaccines, describing clinical, analytical and neuroimaging findings and health outcomes. METHODS: We carried out a review through bibliographic searches in PubMed. RESULTS: We found 86 articles, including 13Â 809 patients with a wide spectrum of neurological manifestations temporally associated with COVID-19 vaccination. Most occurred in women (63.89%), with a median age of 50 years. The most frequently reported adverse events were Bell's palsy 4936/13Â 809 (35.7%), headache (4067/13Â 809), cerebrovascular events 2412/13Â 809 (17.47%), Guillain-BarrÃ© syndrome 868/13Â 809 (6.28%), central nervous system demyelination 258/13Â 809 (1.86%) and functional neurological disorder 398/13Â 809 (2.88%). Most of the published cases occurred in temporal association with the Pfizer vaccine (BNT162b2), followed by the AstraZeneca vaccine (ChAdOX1-S). CONCLUSIONS: It is not possible to establish a causal relationship between these adverse events and COVID-19 vaccines with the currently existing data, nor to calculate the frequency of appearance of these disorders. However, it is necessary for health professionals to be familiar with these events, facilitating their early diagnosis and treatment. Large controlled epidemiological studies are necessary to establish a possible causal relationship between vaccination against COVID-19 and neurological adverse events.

Multiple evanescent white dot syndrome following COVID-19 vaccines.

SARS-CoV-2 Seroprevalence Following a Large-Scale Vaccination Campaign in Portugal: Results of the National Serological Survey, September - November 2021. INTRODUCTION: Following a COVID-19 mass vaccination campaign, it is important to evaluate the population level of SARS-CoV-2 antibodies. The aim of this study was to estimate the seroprevalence rate of SARS-CoV-2 specific antibodies acquired due to infection or vaccination in the Portuguese population. MATERIAL AND METHODS: The National Serological Survey (third wave - ISN3COVID-19) is a cross-sectional nationwide epidemiological study developed on a sample of 4545 Portuguese residents aged one year or older, between the 28th September 2021 and the 19th November 2021. The SARS-CoV-2 anti-nucleoprotein and anti-spike IgG antibody levels were determined in serum samples using Abbott Chemiluminescent Microparticle Immunoassays. Seroprevalence estimates were stratified by age group, sex, administrative region and self-reported chronic conditions. Medians and respective 95% confidence intervals were used to describe the distribution of SARS-CoV-2 specific antibodies in specific population subgroups. RESULTS: The total seroprevalence rate of SARS-CoV-2 was 86.4% (95% CI: 85.2% to 87.6%). A higher seroprevalence rate was estimated for women (88.3%), 50 to 59 years-old (96.5%) and in those with two or more self-reported chronic conditions (90.8%). A higher IgG (anti-Spike) concentration was observed in individuals vaccinated with the booster dose (median = 1 2601.3 AU/mL; 95% CI: 4127.5 to 19 089.1). CONCLUSION: There was a significant increase in SARS-CoV-2 seroprevalence following the mass vaccination campaign in Portugal. It is important to continue to monitor the distribution of specific SARS-COV-2 antibody at the population level to further inform public health policies.

Infection with SARS-CoV-2 is associated with menstrual irregularities among women of reproductive age. BACKGROUND: Biological and psychological mechanisms may be responsible for menstrual irregularities occurring among women during the COVID-19 pandemic. STUDY DESIGN: From January 2019 to September 2021, women (18- to 45-years-old and not using hormonal contraception) were

recruited in Miami-Dade County, Florida. Cross-sectional, self-report surveys collected data on menstrual irregularities, COVID-19 vaccination, stress, depression, and loneliness. A EUA approved rapid test assay using whole blood measured SARS-CoV-2 IgG antibodies. Chi-square and Fisher's exact tests described menstrual irregularities among women recruited before versus after the start of the COVID-19 pandemic and with detectable versus undetectable SARS-CoV-2 IgG antibodies. A logistic regression examined the relationship between the presence of SARS-CoV-2 IgG antibodies and menstrual irregularities controlling for age, stress, depression, and loneliness. RESULTS: Among 182 women enrolled, 73 were enrolled after pandemic onset, and 36 provided vaccination data. Having detectable SARS-CoV-2 IgG antibodies was associated with a higher percentage of menstrual irregularities among unvaccinated women (0% vs. 39%, p = .026) and among all women regardless of vaccination status (31% vs. 5%; p = .005). Adjusting for age and psychological variables, the odds of menstrual irregularities were 7.03 times (95% CI [1.39, 35.60]; p = .019) higher among women with detectable antibodies compared to women without detectable antibodies. Neither enrollment date, age, nor psychological factors were associated to menstrual irregularities. CONCLUSIONS: Biological mechanisms related to SARS-CoV-2 infection may be responsible for irregular menstruation and should be further examined to mitigate the impact of the COVID-19 pandemic on women's health.

Adverse reactions to inactivated COVID-19 vaccination in patients with chronic liver disease: The effect of anxiety. Studies have shown that patients with chronic liver disease are at a higher risk of contracting novel coronavirus pneumonia than healthy individuals, and many guidelines state that patients with chronic liver disease should be prioritized for COVID-19 vaccination, but there are a few studies on its safety in CLD patients. We aimed to evaluate the safety of the inactivated COVID-19 vaccine in patients with chronic liver disease, and the effect of anxiety on adverse reactions. A questionnaire survey for self-administered post-vaccination adverse reaction monitoring was conducted from June 17, 2021, to August 11, 2021, in patients with chronic liver disease attending a tertiary care hospital in Taizhou, China. We analyzed the data from of a total of 160 participants who scanned the QR code on social media to respond to the questionnaire. The overall incidence of adverse reactions after COVID-19 vaccination in patients with chronic liver disease was 44.4% (71/160), and the most common adverse reaction was local injection site reaction, accounting for 80.3% of adverse reactions (57/71). No serious adverse reactions were reported. Approximately 53.1% of the patients had anxiety about vaccination, and 51.8% of those who felt anxious reported adverse reactions. The safety of COVID-19 vaccination in patients with chronic liver disease is good, and there is a strong association between adverse reactions and vaccine anxiety. Pre-vaccination education for patients with vaccine anxiety and psychological counseling may reduce reports of adverse reactions and improve patients' confidence in the vaccine.

Vulnerability to SARS-CoV-2 infection and disease: ripping the curl after the storm. SARS-CoV-2 infection now seems to have entered the announced endemic phase. The population's immunity is increasingly more robust, thanks to successive vaccination and booster campaigns, and the almost inevitable exposure and re-exposure to the virus itself, which has truly served as a natural immunizing mechanism. On the other hand, the genetic drift of the virus is leading it to become another catarrhal agent, as are the other endemic human coronaviruses. However, it should not be lost sight of that there are still segments of the population with susceptibility to severe COVID, who will be candidates to continue receiving vaccine boosters or antiviral drugs in the initial stages of infection.

Myocarditis After COVID-19 Vaccination in Pediatrics: A Proposed Pathway for Triage and Treatment.

Vaccine-Triggered Acute Autoimmune Myocarditis: Defining, Detecting, and Managing an Apparently Novel Condition.

SARS-CoV-2 Spike-specific IFN-Î³ T-cell Response After COVID-19 Vaccination in Patients With Chronic Kidney Disease, on Dialysis, or Living With a Kidney Transplant. Studies have shown that

coronavirus disease 2019 (COVID-19) vaccination is associated with a lower humoral response in vulnerable kidney patients. Here, we investigated the T-cell response following COVID-19 vaccination in kidney patients compared with controls. METHODS: Patients with chronic kidney disease (CKD) stage G4/5 [estimated glomerular filtration rate <30â€‰mL/min/1.73 m2], on dialysis, or living with a kidney transplant and controls received 2 doses of the mRNA-1273 COVID-19 vaccine. Peripheral blood mononuclear cells were isolated at baseline and 28 d after the second vaccination. In 398 participants (50% of entire cohort; controls n = 95, CKD G4/5â€‰n = 81, dialysis n = 78, kidney transplant recipients [KTRs] n = 144)' SARS-CoV-2-specific T cells were measured using an IFN-Î³ enzyme-linked immune absorbent spot assay. RESULTS: A significantly lower SARS-CoV-2-specific T-cell response was observed after vaccination of patients on dialysis (54.5%) and KTRs (42.6%) in contrast to CDK G4/5 (70%) compared with controls (76%). The use of calcineurin inhibitors was associated with a low T-cell response in KTRs. In a subset of 20 KTRs, we observed waning of the cellular response 6 mo after the second vaccination, which was boosted to some extent after a third vaccination, although T-cell levels remained low. CONCLUSION: Our data suggest that vaccination is less effective in these patient groups, with humoral nonresponders also failing to mount an adequate cellular response, even after the third vaccination. Given the important role of T cells in protection against disease and cross-reactivity to SARS-CoV-2 variants, alternative vaccination strategies are urgently needed in these high-risk patient groups.

Immunogenicity, efficacy, and safety of SARS-CoV-2 vaccine dose fractionation: a systematic review and meta-analysis. BACKGROUND: Dose fractionation of a coronavirus disease 2019 (COVID-19) vaccine could effectively accelerate global vaccine coverage, while supporting evidence of efficacy, immunogenicity, and safety are unavailable, especially with emerging variants. METHODS: We systematically reviewed clinical trials that reported dose-finding results and estimated the dose-response relationship of neutralizing antibodies (nAbs) of COVID-19 vaccines using a generalized additive model. We predicted the vaccine efficacy against both ancestral and variants, using previously reported correlates of protection and cross-reactivity. We also reviewed and compared seroconversion to nAbs, T cell responses, and safety profiles between fractional and standard dose groups. RESULTS: We found that dose fractionation of mRNA and protein subunit vaccines could induce SARS-CoV-2-specific nAbs and T cells that confer a reasonable level of protection (i.e., vaccine efficacy > 50%) against ancestral strains and variants up to Omicron. Safety profiles of fractional doses were non-inferior to the standard dose. CONCLUSIONS: Dose fractionation of mRNA and protein subunit vaccines may be safe and effective, which would also vary depending on the characteristics of emerging variants and updated vaccine formulations.

Phenotypic and functional changes of T cell subsets after CoronaVac vaccination. BACKGROUND: The pandemic coronavirus disease 2019 (COVID-19) is a major global public health concern and several protective vaccines, or preventive/therapeutic approaches have been developed. Sinovac-CoronaVac, an inactivated whole virus vaccine, can protect against severe COVID-19 disease and hospitalization, but less is known whether it elicits long-term T cell responses and provides prolonged protection. METHODS: This is a longitudinal surveillance study of SARS-CoV-2 receptor binding domain (RBD)-specific IgG levels, neutralizing antibody levels (NAb), T cell subsets and activation, and memory B cells of 335 participants who received two doses of CoronaVac. SARS-CoV-2 RBD-specific IgG levels were measured by enzyme-linked immunosorbent assay (ELISA), while NAb were measured against two strains of SARS-CoV-2, the Wuhan and Delta variants. Activated T cells and subsets were identified by flow cytometry. Memory B and T cells were evaluated by enzyme-linked immune absorbent spot (ELISpot). FINDINGS: Two doses of CoronaVac elicited serum anti-RBD antibody response, elevated B cells with NAb capacity and CD4(+) T cell-, but not CD8(+) T cell-responses. Among the CD4(+) T cells, CoronaVac activated mainly Th2 (CD4(+) T) cells. Serum antibody levels

significantly declined three months after the second dose. INTERPRETATION: CoronaVac mainly activated B cells but T cells, especially Th1 cells, were poorly activated. Activated T cells were mainly Th2 biased, demonstrating development of effector B cells but not long-lasting memory plasma cells. Taken together, these results suggest that protection with CoronaVac is short-lived and that a third booster dose of vaccine may improve protection.

Two pediatric cases of multisystem inflammatory-like syndrome following COVID-19 vaccination. Multisystem inflammatory syndrome in children (MIS-C) is a novel post-infectious disease occurring in the context of SARS-CoV2 infection. COVID-19 vaccines have been authorized since December 2020, and adverse events including myocarditis have been reported following vaccination. We describe the cases of two pediatric patients presenting with clinical and laboratory features suggestive of MIS-C a few days after receiving their first dose of the Pfizer BNT162b2 vaccine. The outcome was favorable for both patients (after corticosteroid and immunoglobulin administration for one patient). These cases suggest an association between the COVID-19 vaccine and the occurrence of MIS-C.

FDA urged to publish follow-up studies on covid-19 vaccine safety signals.

Neutralizing antibodies and T-cell responses to inactivated SARS-CoV-2 vaccine in COVID-19 convalescents one and a half years after infection. Vaccines have been considered the most promising solution for ending the coronavirus disease 2019 (COVID-19) pandemic. Information regarding neutralizing antibodies (NAbs) and T-cell immune response in inactivated SARS-CoV-2 vaccine-immunized COVID-19 convalescent patients were either only available for a short time after illness recovered or not available at all (T-cell immunity). We evaluated SARS-CoV-2 NAbs and cellular immune responses to the SARS-CoV-2 inactivated vaccine in convalescent patients who recovered from infection for about one and a half years. We found that compared to before vaccination, SARS-CoV-2 NAbs and specific T-cell responses were significantly boosted by the inactivated vaccine in convalescent patients, which confirmed the pre-existing adaptive immunity in SARS-CoV-2 infected people. We observed that NAbs and IFN-Î³-secreting T-cell response elicited by a single vaccine dose in subjects with prior COVID-19 infection were higher than after two doses of vaccine in SARS-CoV-2 naÃ¯ve subjects. Both humoral and cellular immune responses elicited by one and two doses of inactivated vaccine were comparable in COVID-19-recovered persons. In conclusion, inactivated COVID-19 vaccine induced robust NAbs and T-cell responses to SARS-CoV-2 in COVID-19 convalescent patients and immune responses after one dose were equal to that after receiving two doses, which highlighted that robust humoral and cellular immune response can be reactivated by the inactivated vaccine in SARS-CoV-2 convalescent patients.

Audiological and vestibular symptoms following SARS-CoV-2 infection and COVID-19 vaccination in children aged 5-11Â years. PURPOSE: The present study assessed the prevalence of audio-vestibular symptoms following SARS-COV-2 infection or COVID-19 vaccination among children, comparing the two groups. A further aim was to evaluate whether children with pre-existing unilateral hearing loss were more prone to adverse events. MATERIALS AND METHODS: This retrospective study included children aged 5-11Â years with normal hearing or a proven history of unilateral hearing loss who contracted SARS-CoV-2 or received two doses of COVID-19 vaccine. Tinnitus, hyperacusis, aural fullness, otalgia, otorrhea, new-onset hearing loss, vertigo and dizziness were investigated as possible complications of SARS-CoV-2 infection or the COVID-19 vaccine. RESULTS: This study included 272 children (143 boys, 129 girls), with a mean age of 7.8Â Â±Â 2.3Â years. Among these, 120 were affected by pre-existing unilateral hearing loss. The most common audio-vestibular symptoms reported by children following SARS-CoV-2 infection and COVID-19 vaccination were aural fullness (33/132, 25Â %) and dizziness (5/140, 3.6Â %), respectively. All symptoms following COVID-19 vaccination resolved within 24Â h. Compared to children who received the COVID-19 vaccine, those infected with SARS-CoV-2 had a higher prevalence of tinnitus

(pÂ =Â 0.009), hyperacusis (pÂ =Â 0.003), aural fullness (pÂ <Â 0.001), otalgia (pÂ <Â 0.001), otorrhea (pÂ <Â 0.001), and vertigo (pÂ =Â 0.006). Two girls also experienced new-onset unilateral sensorineural hearing loss following SARS-CoV-2 infection. Children with a known history of unilateral hearing loss did not have a higher prevalence of audio-vestibular symptoms than children with normal hearing. CONCLUSIONS: Our results suggest that the COVID-19 vaccine is safe and can be recommended for children with unilateral hearing loss without fear of possible audio-vestibular sequelae.

Immune-mediated inflammatory diseases after anti-SARS-CoV-2 vaccines: new diagnoses and disease flares. OBJECTIVE: New-onset immune-mediated inflammatory diseases (IMIDs) and flares of pre-existing IMIDs have been reported following anti- SARS-CoV2 vaccination. Our study aimed at describing a retrospective cohort of patients developing new-onset IMIDs or flares of known IMIDs within 30 days after any anti-SARS-CoV2 vaccine dose. METHODS: We evaluated clinical records of all inpatients and outpatients referring to our institution between February 2021 and February 2022 with any clinical manifestations. We then selected those having received any anti-SARS-CoV2 vaccine dose within the prior 30 days and classified them as having or not a previous IMID according to predefined criteria. We recorded new-onset IMIDs or flares of known IMIDs and investigated any relationship with demographic, clinical and serological variables. RESULTS: 153 patients that received any anti-SARS-CoV2 vaccine dose within the previous 30 days were included of which 45 (29%) already had a diagnosis of IMID while 108 (71%) had no previously diagnosed IMID. 33 (30%) of the 108 patients, were diagnosed with a new-onset IMID. Pericarditis, polymyalgia rheumatica and vasculitis were the most frequent conditions. Among the 45 patients that already had an IMID, disease flare was the reason for referral in 69% of patients. Patients with an IMID flare had a lower number of comorbidities and tended to be younger compared with those who developed other conditions after anti-SARS-CoV2 vaccination. CONCLUSION: We provided a retrospective overview of a cohort of patients who developed new-onset IMIDs or flares of known IMIDs within 30 days after any dose of anti-SARS-CoV2 vaccine. While vaccination campaigns proceed, postvaccination surveillance programmes are ongoing and hopefully will soon clarify whether a causal relationship between vaccines and new-onset/flares of IMIDs exists.

Erythema nodosum at COVID-19 vaccine injection site.

Consecutive BNT162b2 mRNA vaccination induces short-term epigenetic memory in innate immune cells. Consecutive mRNA vaccinations against SARS-CoV-2 reinforced both innate and adaptive immune responses. However, it remains unclear whether the enhanced innate immune responses are mediated by epigenetic regulation and, if so, whether these effects persist. Using mass cytometry, RNA-Seq, and ATAC-Seq, we show that BNT162b2 mRNA vaccination upregulated antiviral and IFN-stimulated gene expression in monocytes with greater effects after the second vaccination than those after the first vaccination. Transcription factor-binding motif analysis also revealed enriched IFN regulatory factors and PU.1 motifs in accessible chromatin regions. Importantly, although consecutive BNT162b2 mRNA vaccinations boosted innate immune responses and caused epigenetic changes in isolated monocytes, we show that these effects occurred only transiently and disappeared 4 weeks after the second vaccination. Furthermore, single-cell RNA-Seq analysis revealed that a similar gene signature was impaired in the monocytes of unvaccinated patients with COVID-19 with acute respiratory distress syndrome. These results reinforce the importance of the innate immune response in the determination of COVID-19 severity but indicate that, unlike adaptive immunity, innate immunity is not unexpectedly sustained even after consecutive vaccination. This study, which focuses on innate immune memory, may provide novel insights into the vaccine development against infectious diseases.

Trained immunity is induced in humans after immunization with an adenoviral vector COVID-19 vaccine. BackgroundHeterologous effects of vaccines are mediated by "trained immunity," whereby myeloid cells are metabolically and epigenetically reprogrammed, resulting in heightened responses to subsequent insults. Adenovirus vaccine vector has been reported to induce trained immunity in mice. Therefore, we sought to determine whether the ChAdOx1 nCoV-19 vaccine (AZD1222), which uses an adenoviral vector, could induce trained immunity in vivo in humans.MethodsTen healthy volunteers donated blood on the day before receiving the ChAdOx1 nCoV-19 vaccine and on days 14, 56, and 83 after vaccination. Monocytes were purified from PBMCs, cell phenotype was determined by flow cytometry, expression of metabolic enzymes was quantified by RT-qPCR, and production of cytokines and chemokines in response to stimulation ex vivo was analyzed by multiplex ELISA.ResultsMonocyte frequency and count were increased in peripheral blood up to 3 months after vaccination compared with their own prevaccine controls. Expression of HLA-DR, CD40, and CD80 was enhanced on monocytes for up to 3 months following vaccination. Moreover, monocytes had increased expression of glycolysis-associated enzymes 2 months after vaccination. Upon stimulation ex vivo with unrelated antigens, monocytes produced increased IL-1Î², IL-6, IL-10, CXCL1, and MIP-1Î± and decreased TNF, compared with prevaccine controls. Resting monocytes produced more IFN-Î³, IL-18, and MCP-1 up to 3 months after vaccination compared with prevaccine controls.ConclusionThese data provide evidence for the induction of trained immunity following a single dose of the ChAdOx1 nCoV-19 vaccine.FundingThis work was funded by the Health Research Board (EIA-2019-010) and Science Foundation Ireland Strategic Partnership Programme (proposal ID 20/SPP/3685).

Inactivated SARS-CoV-2 vaccine does not increase the risk of relapse in patients with clinically inactive adult-onset Still's disease. OBJECTIVE: A succession of cases have reported flares of adult-onset Still's disease (AOSD) after vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), raising concerns. We aimed to investigate the impact of inactivated SARS-CoV-2 vaccines on disease activity in patients with AOSD. METHODS: We prospectively enrolled clinically inactive AOSD patients visiting the outpatient clinics of our department. The patients received SARS-CoV-2 vaccines (BBIBP-CorV, Sinopharm, Beijing, China) voluntarily. The occurrence of relapse in the participants was recorded during the follow-up period, and a propensity score matching (PSM) method was used to compare the relapse rates between vaccinated and unvaccinated patients. Localized and systemic symptoms were assessed in the vaccinated patients. RESULTS: A total of 122 patients with inactive AOSD were included, of which 49.2% (nâ€‰=â€‰60) voluntarily received the inactivated SARS-CoV-2 vaccine. The relapse rate did not increase significantly in vaccinated patients in comparison with unvaccinated patients (after PSM: 6.8% vs 6.8%), and no relapse occurred within 1â€‰month after vaccination. No obvious adverse reactions were reported in 75.0% of the participants, and none of the patients reported severe reactions. CONCLUSION: Increased disease activity or relapse following vaccination with inactivated SARS-CoV-2 was rare in patients with inactive AOSD. Local and systemic adverse reactions were found to be mild and self-limiting. These safety profiles of inactivated SARS-CoV-2 vaccines in patients with AOSD may assist in eliminating vaccine hesitancy and increase the vaccination rate against SARS-CoV-2.

Higher risk of short term COVID-19 vaccine adverse events in myositis patients with autoimmune comorbidities: results from the COVAD study.

Immunogenicity and safety of the CoronaVac and BNT162b2 Covid-19 vaccine in patients with inflammatory rheumatic diseases and healthy adults: comparison of different vaccines. OBJECTIVES: To determine the seroconversion (SC) rate after CoronaVac and BNT162b2 vaccines in adults with inflammatory rheumatic disease (IRD). METHODS: Patients who were followed up with IRD and who received two doses of either CoronaVac or BNT162b2 vaccines were included in this

prospective observational single-center study. Subjects with two doses of CoronaVac or BNT162b2 without known IRD were included in the healthy controls. The blood samples were taken at a minimum of two and a maximum of 12Â weeks after the second dose of vaccine. RESULTS: A total of 81 patients with IRD (61 CoronaVac, 20 BNT162b2) and 100 healthy controls (70 CoronaVac, 30 BNT162b2) were included. The SC rate was slightly lower among patients with IRD versus controls (84 vs 97%, pâ€‰=â€‰0.002). The SC rate was 100% in all participants who received BNT162b2 both in the patient and control group. The IgG antibody level after CoronaVac in the patient group was significantly lower than both the BNT162b2 (pâ€‰=â€‰0.031) and the healthy group (pâ€‰<â€‰0.001). Among patients with IRD, those on rituximab (RTX) (12/81,14.8%) had significantly less SC rate (5/12, 41.7%). The median neutralizing antibody titers were significantly higher in patients with BNT162b2 compared with CoronaVac (1.97 vs. 16.34, pâ€‰<â€‰0.001). CONCLUSIONS: This study showed that all patients with BNT162b2 vaccine developed immunogenicity in patients with IRD, while there was a decreased antibody response with CoronaVac vaccine compared to that of BNT162b2. In particular, RTX significantly reduces the SC rate.

Immunogenicity of COVID-19 mRNA vaccines in patients with acute myeloid leukemia and myelodysplastic syndrome. Immunocompromised patients are susceptible to complications from severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). The mRNA vaccines BNT162b2 and mRNA-1273 are effective in immunocompetent adults, but have diminished activity in immunocompromised patients. We measured anti-spike SARS-CoV-2 antibody (anti-S) response, avidity, and surrogate neutralizing antibody activity in COVID-19 vaccinated patients with acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). Anti-S was induced in 89% of AML and 88% of MDS patients, but median levels were significantly lower than in healthy controls. SARS-CoV-2 antibody avidity and neutralizing activity from AML patients were significantly lower than controls. Antibody avidity was significantly greater in patients after mRNA-1273 versus BNT162b2; there were trends toward higher anti-S levels and greater neutralizing antibody activity after mRNA-1273 vaccination. Patients with AML and MDS are likely to respond to COVID-19 mRNA vaccination, but differences in anti-S levels, avidity, and neutralizing antibody activity may affect clinical outcomes and require further study.

Corneal Graft Rejection after Vaccination against COVID-19: A Case Report.

Multisystem Inflammatory Syndrome in an Adult Following COVID-19 mRNA Vaccination: Successful Treatment With Medium-Dose Steroids and Colchicine. Multisystem inflammatory syndrome in children and adults (MIS-C/A) was rarely reported as a complication of coronavirus disease 2019 (COVID-19) and potential adverse events following COVID-19 vaccination. Recently, the case definition of MIS-C/A was developed by the Brighton Collaboration Network. However, only a limited number of adult patients with MIS-A following immunization have been reported, and there is still little evidence for adequate treatment. A 57-year-old man presented with fever, headache, vomiting, and hypotension 24 days after receiving the second COVID-19 vaccination with the Pfizer-BioNTech vaccine. According to the Brighton Collaboration Case Definition, the patient met a definitive case of MIS-A after vaccination (level 1 of diagnostic certainty). After administration of medium-dose prednisolone (20 mg/d) with colchicine (1.2 mg/d), all symptoms and signs improved rapidly. The dose of prednisolone was gradually tapered from the third week, and the patient confirmed a full recovery without medication after 8 weeks. This is the first report showing that low-dose steroids in combination with colchicine may be an effective treatment option for MIS-A after vaccination.

Myocardial Injury and Altered Gene Expression Associated With SARS-CoV-2 Infection or mRNA Vaccination. SARS CoV-2 enters host cells via its Spike protein moiety binding to the essential cardiac enzyme angiotensin-converting enzyme (ACE) 2, followed by internalization. COVID-19 mRNA vaccines are RNA sequences that are translated into Spike protein, which follows the same ACE2-

binding route as the intact virion. In model systems, isolated Spike protein can produce cell damage and altered gene expression, and myocardial injuryÂ or myocarditis can occur during COVID-19 or after mRNA vaccination. We investigated 7 COVID-19 andÂ 6 post-mRNA vaccination patients with myocardial injury and found nearly identical alterations in geneÂ expression that would predispose to inflammation, coagulopathy, and myocardial dysfunction.
Myocarditis following administration of COVID-19 Vaccine: Should we be worried?
Impact of Age, Gender, post infection and post vaccination status on antibody response in COVID 19 patients. OBJECTIVE: To evaluate severe acute respiratory syndrome coronavirus-2 spike protein antibodies against coronavirus disease-2019 in post-infection and post-vaccinated individuals. METHODS: The cross-sectional study was conducted from June, 1 to July 31, 2021 at the Rehman Medical Institute, Peshawar, Pakistan, and comprised subjects of either gender in whom immunogenicity was checked 35 days post-vaccination and 90 days post-infection. Correlation with age and gender was checked. Specimens were collected and investigated for severe acute respiratory syndrome coronavirus-2 spike protein antibodies by consuming electro-chemiluminescence immunoassay. Data was analysed using SPSS 23. RESULTS: Of the total 256 patients enrolled, 70(27.34%) were included; 49(69%) males and 21(29.6%) females. The overall mean age was 44Â±7.75 years. Among 30(42.8%) patients with positive polymerase chain reaction test, the mean time between the positive test and antibody screening was 90Â±30 days. Among the 40(57.2%) vaccinated individuals, the time between vaccination and antibody screening was 35Â±9.74 days. Overall, 68(97%) patients revealed robust positive findings to severe acute respiratory syndrome coronavirus-2 spike proteins antibodies >50IU/mL. Male subjects had significantly higher immunogenic response compared to females (p=0.001), and immunogenicity decreased with advancing age (p<0.001). Also, post-vaccinated patients' antibody response was significant compared to post-infection patients' response (p=0.001). CONCLUSION: Majority of the patients had significantly higher antibody titers against severe acute respiratory syndrome coronavirus-2 post-infection and post-vaccination. Males and younger individuals developed a significant humoral immunity compared to females and the elderly.
Safety and Adverse Effects of Inactive SARS-Cov-2 Vaccine (CoronaVac) in Health Care Professionals. OBJECTIVE: To assess adverse effects post-vaccination in healthcare professionals in the first vaccinated group against coronavirus disease-2019. METHODS: The retrospective study was conducted at the Indus Hospital, Badin, The prospective study was conducted at the vaccination unit of a university hospital in Tekirdag, Turkey, from January to February 2021, and comprised healthcare professionals who came for receiving the second dose of the coronavirus disease-2019 inactivated severe acute respiratory syndrome coronavirus 2 vaccine 28 days after the first dose. Data was analysed using SPSS 18. RESULTS: Of the 1088 subjects, 714(65.6%) were female with mean age 29.85Â±9.2 years and 374(34.4%) were male with mean age 29.57Â±9.85 years. Overall, local pain in the vaccinated area 495(45.5%), fatigue 266(24.4%), headache 261(23.9%) and muscle pain 197(18.1%) were very common adverse effects. CONCLUSIONS: Inactivated severe acute respiratory syndrome coronavirus 2 vaccine was found to be safe.
COVID-19 vaccine related menstrual irregularities: A cause of vaccine hesitation?
COVID-19 vaccination-related intraocular inflammation in Japanese patients.
Graded-dosing immunization in adults at risk for immediate-type reactions to mRNA SARS-CoV-2 vaccines.
Central diabetes insipidus revealing a hypophysitis induced by SARS-CoV-2 vaccine.
Myocarditis associated with COVID-19 and its vaccines - a systematic review. Since the beginning of the COVID-19 (Coronavirus Disease of 2019) pandemic, myocarditis has received much attention and controversy as one of the more worrisome cardiovascular complications. After the availability of

highly effective COVID-19 mRNA vaccines in late 2020, myocarditis was also appreciated as an important vaccine-related adverse event. Though the overall frequency of clinically evident viral myocarditis is rare in the general population, young males show a higher predilection for COVID vaccine-induced myocarditis. The severity of COVID-19 viral myocarditis is variable, ranging from very mild to severe, while vaccine-induced myocarditis is usually mild, and rarely a severe or fatal disease. The diagnosis of either COVID-19 or vaccine-induced myocarditis is based on typical clinical features, laboratory investigations, and imaging, preferably with cardiac magnetic resonance. The management of COVID-19 myocarditis is supportive care for mild or moderate disease. For the rare patient who develops severe disease, advanced heart failure therapies such as mechanical circulatory support devices may have to be employed and can be lifesaving. Avoidance of strenuous exercise during the bout of myocarditis and its recovery phase is important. Despite the small but finite risk of vaccine-induced myocarditis, the benefits of protection against COVID-19 disease and its attendant complications far outweigh the risks.

NVX-CoV2373-induced cellular and humoral immunity towards parental SARS-CoV-2 and VOCs compared to BNT162b2 and mRNA-1273-regimens. BACKGROUND: The NVX-CoV2373-vaccine has recently been licensed, although knowledge on vaccine-induced humoral and cellular immunity towards the parental strain and variants of concern (VOCs) in comparison to mRNA-regimens is limited. METHODS: In this observational study, 66 individuals were recruited to compare immunogenicity and reactogenicity of NVX-CoV2373 with BNT162b2 or mRNA-1273. Vaccine-induced antibodies were analyzed using ELISA and neutralization assays, specific CD4 and CD8 T-cells were characterized based on intracellular cytokine staining using flow-cytometry after antigen-specific stimulation with parental spike or VOCs. RESULTS: Two doses of NVX-CoV2373 strongly induced anti-spike IgG, although IgG-levels were lower than after vaccination with BNT162b2 or mRNA-1273 (pÂ =Â 0.006). Regardless of the vaccine and despite different IgG-levels, neutralizing activity towards VOCs was highest for Delta, followed by BA.2 and BA.1. The protein-based vaccine failed to induce any spike-specific CD8 T-cells which were detectable in 3/22 (14%) individuals only. In contrast, spike-specific CD4 T-cells were induced in 18/22 (82%) individuals, although their levels were lower ($p<0.001$), had lower CTLA-4 expression ($p<0.0001$) and comprised less multifunctional cells co-expressing IFNÎ³, TNFÎ± and IL-2 (pÂ =Â 0.0007). Unlike neutralizing antibodies, NVX-CoV2373-induced CD4 T-cells equally recognized all tested VOCs from Alpha to Omicron. In individuals with a history of infection, one dose of NVX-CoV2373 had similar immunogenicity as two doses in non-infected individuals. The vaccine was overall well tolerated. CONCLUSION: NVX-CoV2373 strongly induced spike-specific antibodies and CD4 T-cells, albeit at lower levels as mRNA-regimens. Cross-reactivity of CD4 T-cells towards the parental strain and all tested VOCs may hold promise to protect from severe disease.

COVID-19 infection and vaccination against SARS-CoV-2 in myasthenia gravis. INTRODUCTION: Myasthenia gravis (MG) is an autoimmune disease of the neuromuscular junction which is typically presented with muscle weakness and excessive fatigability. Majority of MG patients require long-term immune suppression. Our aim was to analyze the frequency and severity of COVID-19 infection in MG patients, as well as the frequency of vaccinated MG patients against SARS-CoV-2. METHODS: We included 125 MG patients from the central Belgrade municipalities-60% females, age at MG onset 50.1â€‰Â±â€‰19.7Â years, age at testing 61.7â€‰Â±â€‰16.8Â years, anti-acetylcholine receptor (anti-AChR) positive 78% and muscle specific tyrosine kinase (MuSK) positive 8.6%. RESULTS: One-third of our MG patients had a COVID-19 infection and they were younger compared to those without verified COVID-19. Severe COVID-19 infection was registered in 28% of MG patients, mostly in elder subjects with comorbidities such as cardiac diseases and malignancies. MG worsening was noted in 21% of patients during/after COVID-19 and 42% had COVID-19 sequelae. Majority of MG patients

were vaccinated against SARS-CoV-2 (almost 70%). Vaccination was more common among MG patients with diabetes and in those with a milder form of MG. The most common types of vaccines were Sinopharm (42%) and Pfizer-BioNTech (25.6%). Adverse events were observed in 36% of vaccinated patients, with flu-like symptoms (77%) and local reactions (13%) being the most common ones. MG worsening was noticed in 5 (5.8%) patients after vaccination. CONCLUSION: COVID-19 has placed a significant new burden for MG patients. Elder MG patients and patients with comorbidities are in higher risk of having adverse outcome following SARS-CoV-2 infection. Percentage of vaccinated MG patients was higher than in general Serbian population.

Myopericarditis in a Male Adolescent Following the Second Shot of COVID-19 Pfizer m-RNA Vaccine: Typical Example and Analysis of 110 Single Case Reports. One of the most powerful weapons against COVID-19 is vaccines. After the worldwide spread of the disease, m-RNA vaccines were authorized not only in adult patients, but also in children and adolescents aged 12-18. Since then, alarming reports of cases of myocarditis and/or pericarditis have been noted, primarily involving males after the second vaccine shot. A typical example of myopericarditis occurring in an adolescent a few days after the second shot of an m-RNA vaccine is described here. An in-depth review of all 110 single case reports published up to July 2022 with related features and outcomes is also presented. This is the first extensive analysis focused solely on a significant number of single case reports, which have usually been excluded from systematic reviews and meta-analyses carried out in the field. The analysis presented here confirms that most cases occurred in males after the second injection of an m-RNA vaccine. Cases were mild and responsive to the usual medical treatment. What is newly reported is that not only adolescents, but also older people, especially females, were affected by this adverse event.

First Diagnosis of Immunoglobulin A Nephropathy Following SARS-CoV-2 mRNA Vaccination in Japan.

Myocarditis following COVID-19 vaccination in adolescents: Cardiac magnetic resonance imaging study. INTRODUCTION: Vaccination-associated myocarditis was reported following COVID-19 vaccine initially among persons aged 16 or older and recently among adolescents aged 12-15. OBJECTIVES: To describe the clinical and cardiac magnetic resonance (CMR) characteristics of adolescents aged 12-15 with myocarditis following the administration of the BNT162b2 mRNA COVID-19 vaccine. METHODS: CMR of adolescents (age 12-15) with a clinical diagnosis of myocarditis within 42 days following the first COVID-19 vaccine were analyzed. RESULTS: A total of 182,605 adolescent were vaccinated, out of which 9 were diagnosed with clinically adjudicated myocarditis while CMR was performed in 5/9 patients (56%). Median age was 15 years (range 13-15), 4/5 (80%) males. All the patients we previously healthy. The ECG upon presentation was abnormal in 3/5 (60%) of patients. All cases were classified as clinically mild and no patient required inotropes or mechanical circulatory support treatment. The median follow-up time, for the 5-included patients, was 206 (IQR 192-229, range 179-233) days. During the follow-up, no re-admissions, deaths, or any other cardiac events have occurred.The median time between the diagnosis to the CMR was 104 days (range 27-149). The median left ventricular ejection fraction was within normal range 65% (range 62-69). Native T1 was available in four patients, the local T1 value was increased in three of them. T2 values were available in two patients and were all within normal range. The median late gadolinium enhancement (LGE) was 2% (range 0-6%) with inferolateral wall being the most common location (3/5). The patterns of the LGE were as following: (i) mid-wall in 3 patients; (ii) epicardial in 1-patient. LGE in the pericardium was present in 2/5 patients with pericardial effusion present in 4/5 patients with a median diameter of 4 mm (range 3-5 mm) at end-systole. CONCLUSIONS: CMR findings and clinical course of adolescents with COVID-19 vaccination associated myocarditis, are similar to those of older patients, being relatively mild and potentially implying favorable outcomes.

Evaluation of Short-Term Symptoms Associated With COVID-19 Vaccines Used Among Adolescents in Saudi Arabia. OBJECTIVES: Several government-sponsored reporting systems have stated mild to moderate side effects of COVID-19 vaccines. However, patient-reported data on COVID-19 vaccine-associated adverse effects in adolescents are lacking. Our objective was to assess the short-term side effects of Pfizer-BioNTech BNT162b2 or Moderna mRNA-1273 vaccinations among teenagers in Saudi Arabia. METHODS: A retrospective, cross-sectional studyÂ wasÂ conducted amongÂ individualsÂ aged 12-18 years oldÂ who receivedÂ one of the two mentionedÂ vaccines between July 2021Â andÂ March 2022 in Riyadh, Saudi Arabia. RESULTS: The most common short-term side effects reported for COVID-19 vaccines among teenagers in our study were fatigue, pain at the site of injection, fever, chills, headache, nausea, and vomiting. Female participants, individuals who had a history of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, and those who received two doses of the vaccine are at higher risk to develop side effects after getting the vaccine. Importantly, asthmatic participants have a higher incidence of COVID-19 vaccine side effects when compared to those with no history of chronic diseases. CONCLUSION: Our findings might enhanceÂ public trust in the COVID-19 vaccine, which could speed up the immunization procedure.

Erratum to "COVID-19 vaccine-associated granulomatous mass mimicking a sarcoma: A case report" [Radiology Case Reports 17 (2022) 2775-2778]. [This corrects the article DOI: 10.1016/j.radcr.2022.05.035.].

Spot the adenoma after pituitary apoplexy following a SARS-CoV-2 vaccination. Pituitary apoplexy often manifests with a severe headache and is often caused by bleeding in a pituitary adenoma, which is common and often undiagnosed. The pituitary gland is damaged when the tumour suddenly enlarges due to bleeding. Bleeding into the pituitary can block blood supply to the pituitary gland. The larger the tumour, the higher the risk of a future pituitary apoplexy. Since only few cases have been reported, the SARS-CoV-2 vaccine is unlikely to cause pituitary apoplexy. Patients with new-type headache require neurological evaluation and may require cerebral imaging to rule out bleeding, ischemia, venous sinus thrombosis, meningitis, encephalitis, pituitary apoplexy, reversible cerebral vasoconstriction syndrome, dissection, or migraine.

ANCA-associated vasculitis following Oxford-AstraZeneca COVID-19 vaccine in Brazil: Is there a causal relationship? A case report. This article presents a case of rapidly progressive glomerulonephritis following the Oxford-AstraZeneca COVID-19 vaccine in a female patient 58 years old. After 5 days, she presented fatigue, paleness, arthralgia on hands, knees, ankles, foamy urine, and elevated blood pressure. Exams showed serum creatinine of 2.2 mg/dL (baseline creatinine of 1.0 mg/dL). Urinalysis revealed hematuria, and her 24-h urinary protein excretion was 4.4 g. Additional exams showed hypercholesterolemia, severe anemia, and normal serum albumin. Testing of antineutrophil cytoplasmic antibodies anti-myeloperoxidase was positive at a titer of 1/80. Serum and urine protein electrophoresis and other exams showed no alterations. She was started on steroid pulse therapy after worsening kidney function, reaching serum creatinine of 3.3 mg/dL. A kidney biopsy revealed crescentic glomerulonephritis with glomerular sclerosis, fibrous crescents, interstitial fibrosis, and tubular atrophy. Induction therapy was given with intravenous cyclophosphamide 0.5 g/m(2) for 6-monthly pulses, followed by maintenance therapy with oral azathioprine at 2 mg/kg and prednisone tapering. The patient did not develop any complications during the induction therapy, and is currently on maintenance therapy with a serum creatinine of 1.87 mg/dL.

Changes in the urinary proteome before and after quadrivalent influenza vaccine and COVID-19 vaccination. The proteome of urine samples from quadrivalent influenza vaccine cohort were analyzed with self-contrasted method. Significantly changed urine protein at 24 hours after vaccination was enriched in immune-related pathways, although each person's specific pathways varied. We speculate that this may be because different people have different immunological

backgrounds associated with influenza. Then, urine samples were collected from several uninfected SARS-CoV-2 young people before and after the first, second, and third doses of the COVID-19 vaccine. The differential proteins compared between after the second dose (24h) and before the second dose were enriched in pathways involving in multicellular organismal process, regulated exocytosis and immune-related pathways, indicating no first exposure to antigen. Surprisingly, the pathways enriched by the differential urinary protein before and after the first dose were similar to those before and after the second dose. It is inferred that although the volunteers were not infected with SARS-CoV-2, they might have been exposed to other coimmunogenic coronaviruses. Two to four hours after the third vaccination, the differentially expressed protein were also enriched in multicellular organismal process, regulated exocytosis and immune-related pathways, indicating that the immune response has been triggered in a short time after vaccination. Multicellular organismal process and regulated exocytosis after vaccination may be a new indicator to evaluate the immune effect of vaccines. Urinary proteome is a terrific window to monitor the changes in human immune function.

Divergent SARS-CoV-2-specific T cell responses in intensive care unit workers following mRNA COVID-19 vaccination. The cellular immune response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in response to full mRNA COVID-19 vaccination could be variable among healthy individuals. Studies based only in specific antibody levels could show an erroneous immune protection at long times. For that, we analyze the antibody levels specific to the S protein and the presence of SARS-CoV-2-specific T cells by ELISpot and AIM assays in intensive care unit (ICU) workers with no antecedents of COVID-19 and vaccinated with two doses of mRNA COVID-19 vaccines. All individuals were seronegative for the SARS-CoV-2 protein S before vaccination (Pre-v), but 34.1% (14/41) of them showed pre-existing T lymphocytes specific for some viral proteins (S, M and N). One month after receiving two doses of COVID-19 mRNA vaccine (Post-v1), all cases showed seroconversion with high levels of total and neutralizing antibodies to the spike protein, but six of them (14.6%) had no T cells reactive to the S protein. Specifically, they lack of specific CD8(+) T cells, but maintain the contribution of CD4(+) T cells. Analysis of the immune response against SARS-CoV-2 at 10 months after full vaccination (Post-v10), exhibited a significant reduction in the antibody levels ($p<0.0001$) and protein S-reactive T cells ($p=0.0073$) in all analyzed individuals, although none of the individuals become seronegative and 77% of them maintained a competent immune response. Thus, we can suggest that the immune response to SARS-CoV-2 elicited by the mRNA vaccines was highly variable among ICU workers. A non-negligible proportion of individuals did not develop a specific T cell response mediated by CD8(+) T cells after vaccination, that may condition the susceptibility to further viral infections with SARS-CoV-2. By contrast, around 77% of individuals developed strong humoral and cellular immune responses to SARS-CoV-2 that persisted even after 10 months. Analysis of the cellular immune response is highly recommended for providing exact information about immune protection against SARS-CoV-2.

Longitudinal cellular and humoral immune responses after triple BNT162b2 and fourth full-dose mRNA-1273 vaccination in haemodialysis patients. Haemodialysis patients respond poorly to vaccination and continue to be at-risk for severe COVID-19. Therefore, dialysis patients were among the first for which a fourth COVID-19 vaccination was recommended. However, targeted information on how to best maintain immune protection after SARS-CoV-2 vaccinations in at-risk groups for severe COVID-19 remains limited. We provide, to the best of our knowledge, for the first time longitudinal vaccination response data in dialysis patients and controls after a triple BNT162b2 vaccination and in the latter after a subsequent fourth full-dose of mRNA-1273. We analysed systemic and mucosal humoral IgG responses against the receptor-binding domain (RBD) and ACE2-binding inhibition towards variants of concern including Omicron and Delta with multiplex-based

immunoassays. In addition, we assessed Spike S1-specific T-cell responses by interferon Î³ release assay. After triple BNT162b2 vaccination, anti-RBD B.1 IgG and ACE2 binding inhibition reached peak levels in dialysis patients, but remained inferior compared to controls. Whilst we detected B.1-specific ACE2 binding inhibition in 84% of dialysis patients after three BNT162b2 doses, binding inhibition towards the Omicron variant was only detectable in 38% of samples and declining to 16% before the fourth vaccination. By using mRNA-1273 as fourth dose, humoral immunity against all SARS-CoV-2 variants tested was strongly augmented with 80% of dialysis patients having Omicron-specific ACE2 binding inhibition. Modest declines in T-cell responses in dialysis patients and controls after the second vaccination were restored by the third BNT162b2 dose and significantly increased by the fourth vaccination. Our data support current advice for a four-dose COVID-19 immunisation scheme for at-risk individuals such as haemodialysis patients. We conclude that administration of a fourth full-dose of mRNA-1273 as part of a mixed mRNA vaccination scheme to boost immunity and to prevent severe COVID-19 could also be beneficial in other immune impaired individuals. Additionally, strategic application of such mixed vaccine regimens may be an immediate response against SARS-CoV-2 variants with increased immune evasion potential.

Tissue resident memory T cells- A new benchmark for the induction of vaccine-induced mucosal immunity. Historically, the gold-standard benchmark for vaccine immunogenicity has been the induction of neutralizing antibodies detectable in the serum of peripheral blood. However, in recent years there has been a new appreciation for the mucosa as an important site for vaccine induced immunity. As a point of first contact, the mucosal tissue represents a major site of immune based detection and restriction of pathogen entry and dissemination. Tissue resident memory T cells (T(rm)) are one of the critical cell types involved in this early detection and restriction of mucosal pathogens. Following tissue-specific infection or vaccination, T(rm) lodge themselves within tissues and can perform rapid sensing and alarm functions to control local re-infections, in an effort that has been defined as important for restriction of a number of respiratory pathogens including influenza and respiratory syncytial virus. Despite this characterized importance, only minor attention has been paid to the importance of T(rm) as a benchmark for vaccine immunogenicity. The purpose of this review is to highlight the functions of T(rm) with particular emphasis on respiratory infections, and to suggest the inclusion of T(rm) elicitation as a benchmark for vaccine immunogenicity in animal models, and where possible, human samples.

Coronavirus disease 2019 vaccination uptake and hesitancy among Polish patients with inborn errors of immunity, autoinflammatory syndromes, and rheumatic diseases: A multicenter survey. Data regarding the willingness of patients affected by inborn errors of immunity to accept vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection are limited. Therefore, this study assessed SARS-CoV-2 vaccination coverage and hesitancy in immunodeficient patients by surveying adults with primary immune deficiencies and autoinflammatory and rheumatic diseases on biologic therapy. The study was conducted from September 20, 2021, to January 22, 2022, when the primary coronavirus disease 2019 (COVID-19) vaccinations were available to all adults in Poland. We included 207 participants consecutively recruited from five referral centers (57% female; median age: 42.6 [range: 18-76, standard deviation Â± 14.70] years). Overall, 55% (n = 114), 17% (n = 36), and 28% (n = 57) of the patients had primary immune deficiencies, autoinflammatory diseases, and rheumatic diseases, respectively. Among the entire cohort, 168 patients (81%) were vaccinated, and 82% were willing to receive a booster dose. Patients with autoinflammatory diseases had the highest vaccination rate (94.4%). A strong conviction that it was the correct decision (72%), fear of getting COVID-19 (38%), and expert opinions (34%) influenced the decision to vaccinate. Among the unvaccinated patients, 33.3% had primary or vocational education ($p < 0.001$). Furthermore, only 33% believed they were at risk of a severe course of COVID-19 ($p = 0.014$), and

10% believed in vaccine efficacy (p <0.001). They also doubted the safety of the vaccine (p <0.001) and feared a post-vaccination flare of their disease (p <0.001). Half of the unvaccinated respondents declared that they would consider changing their decision. Vaccination coverage in immunodeficient patients was higher than in the general Polish population. However, the hesitant patients doubted the vaccine's safety, feared a post-vaccination disease flare, and had primary or vocational education. Therefore, vaccination promotion activities should stress personal safety and the low risk of disease flares due to vaccination. Furthermore, all evidence must be communicated in patient-friendly terms.

Atypical hemolytic uremic syndrome triggered by mRNA vaccination against SARS-CoV-2: Case report. Atypical hemolytic uremic syndrome (aHUS), also called complement-mediated hemolytic uremic syndrome (CM-HUS), is a rare disease caused by dysregulation in the alternative complement activation pathway. It is a life-threatening condition causing ischemia of a number of organs, and it typically causes acute kidney injury. This disorder may be triggered by various factors including viral or bacterial infections, pregnancy, surgery, and injuries. In about 60% of cases, the genetic origin of the disease can be identified-commonly mutations affecting complementary factor H and MCP protein. Eculizumab, a monoclonal antibody to the C5 component of the complement, represents the current effective treatment.We describe a case of a young woman with a previous history of polyvalent allergies, who developed atypical hemolytic uremic syndrome after vaccination with mRNA vaccine against SARS-CoV-2. The disease manifested by scleral bleeding, acute renal insufficiency, anemia, and thrombocytopenia. The patient was treated with plasma exchanges without sufficient effect; remission occurred only after starting treatment with eculizumab. Genetic examination showed that the patient is a carrier of multiple inherited risk factors (a rare pathogenic variant in CFH, MCPggaac haplotype of the CD46 gene, and the risk haplotype CFH H3). The patient is currently in hematological remission with persistent mild renal insufficiency, continuing treatment with eculizumab/ravulizumab. By this case report, we meant to point out the need for careful monitoring of people after vaccination, as it may trigger immune-mediated diseases, especially in those with predisposing factors.

Association between immunosuppressants and poor antibody responses to SARS-CoV-2 vaccines in patients with autoimmune liver diseases. The antibody and B cell responses after inactivated SARS-CoV-2 vaccination have not been well documented in patients with autoimmune liver disease (AILD). Therefore, we conducted a prospective observational study that included AILD patients and healthy participants as controls between July 1, 2021, and September 30, 2021, at the Second Affiliated Hospital of Chongqing Medical University. All adverse events (AEs) after the COVID-19 vaccination were recorded and graded. Immunoglobulin (Ig)-G antibodies against the receptor-binding domain (RBD) of the SARS-CoV-2 spike protein (anti-RBD-IgG) and neutralizicadng antibodies (NAbs) were tested following full-course vaccination (BBIBP-CorV or CoronaVac). In addition, SARS-CoV-2-specific B cells were detected by flow cytometry. In total, 76 AILD patients and 136 healthy controls (HCs) were included. All AEs were mild and self-limiting, and the incidences were similar between the AILD and HCs. The seropositivity rates of anti-RBD-IgG and NAbs in AILD were 97.4% (100% in HCs, p = 0.13) and 63.2% (84.6% in HCs, p < 0.001), respectively. The titers of anti-RBD-IgG and NAbs were significantly lower in AILD patients than those in HCs. After adjusting for confounders, immunosuppressive therapy was an independent risk factor for low-level anti-RBD-IgG (adjusted odds ratio [aOR]: 4.7; 95% confidence interval [CI], 1.5-15.2; p = 0.01) and a reduced probability of NAbs seropositivity (aOR, 3.0; 95% CI, 1.0-8.9; p = 0.04) in AILD patients. However, regardless of immunosuppressants, the SARS-CoV-2-specific memory B cells responses were comparable between the AILD and HC groups. Our results suggest that inactivated SARS-CoV-2 vaccines (BBIBP-CorV and CoronaVac) are safe, but their immunogenicity is compromised in patients with AILD. Moreover, immunosuppressants are significantly associated with poor antibody responses to the SARS-CoV-2

vaccines. These results could inform physicians and policymakers about decisions on screening the populations at higher risk of poor antibody responses to SARS-CoV-2 vaccines and providing additional vaccinations in patients with AILD.

Association between COVID-19 vaccination and bullous pemphigoid - a case series and literature review. Bullous pemphigoid is an acquired autoimmune blistering dermatosis that is commonly associated with high morbidity and mortality. New-onset bullous pemphigoid following vaccinations has rarely been reported in the literature. We report two cases of new-onset bullous pemphigoid after COVID-19 vaccination followed by a brief literature review. Twenty-six cases were included in our analysis. Our cases support that new-onset bullous pemphigoid may develop following COVID-19 vaccinations. Entering a period of clinical remission before subsequent COVID-19 vaccinations in addition to close follow-up should be considered to lessen the risk of recurrences or exacerbations.

Durability of antibodies post vaccination with two doses of inactivated BBIBP-CorV vaccine. BACKGROUND: Breakthrough infections post-COVID-19 vaccination occur with the emerging variants of the SARS-CoV virus which might be either due to the newer variants escaping immune response or the waning of antibodies over time. However, there is lack of long-term follow-up evidence on the waning of immune response following inactivated COVID-19 vaccine. METHODS: A retrospective, observational study was conducted on serum samples of individuals who had received two doses of BBIBP-CorV vaccine. Individual's antibody responses were evaluated based on IgG anti-S and neutralizing antibodies measurements. Antibody samples were categorized into four groups, defined by the time interval from the individual's receipt of the BBIBP-CorV vaccine: <30â€‰days, 30-90â€‰days, 91-180â€‰days and >180â€‰days. RESULTS: A total of 6668 serum samples from inactivated BBIBP-CorV vaccine recipients were analyzed for IgG anti-S and neutralizing antibodies. 571 (8.6%) samples were tested during the first 29â€‰days interval post vaccination, 3642 (54.6%) were tested during 30-90â€‰days interval, 2173 (32.6%) samples were tested during 91 to 180â€‰days interval and 282(4.2%) were tested at >180â€‰days interval post vaccination. We found that more than 50% of the individuals had antibody titers below the average cut-off range at the 91-180â€‰days interval post vaccination. Older age (>60â€‰years), male gender, chronic kidney disease, hypertension, immunodeficiencies and increased interval post vaccination emerged as independent risk factors associated with lower immune response. CONCLUSION: Inactivated BBIBP-CorV vaccine recipients, based on age, gender and associated comorbid conditions might need booster doses at an earlier interval than the currently followed six months interval.

COVID-19 mRNA Vaccines: A Retrospective Observational Pharmacovigilance Study. BACKGROUND AND OBJECTIVE: Coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus has caused millions of deaths worldwide. The mRNA vaccines prevented the figure from being more severe. The objective of this retrospective study is to evaluate the safety of COVID-19 vaccines by analyzing the adverse events following immunization (AEFIs). METHODS: A retrospective observational pharmacovigilance study was conducted, based on the collection of reports of suspected AEFIs reported between 1 January 2021 and 31 December 2021 at the Naples 3 local health authority. AEFIs were stratified and described according to mRNA vaccine, demographics, clinical status, description of AEFI, and degree of severity. In 2021, local health authority Asl Naples 3 South received 1164 reports of suspected adverse events that occurred following the administration of mRNA vaccines. RESULTS: During the reporting period, 746 reports were related to the Comirnaty vaccine (64.1%), 281 to the Vaxzevria vaccine (24.1%), 107 to the Spikevax vaccine (9.2%), and 30 to the Jcovden vaccine (2.6%); 89.3% of the reports were classified as not serious (NÂ =Â 1039 reports), the remaining 10.7% as serious (NÂ =Â 125 reports). CONCLUSIONS: This retrospective pharmacovigilance study demonstrates thatÂ COVID-19 mRNA vaccines are safe in all population groups.

 Pharmacovigilance is an activity that ensures the safety of health care treatments.

The COVID-19 pandemic has accelerated the administration of vaccines whose efficacy and safety is to be evaluated. In the year 2021, an analysis of all reported adverse events following immunization (AEFIs) to the vaccine was conducted on a sample of about 1 million people with the aim of understanding efficacy and safety. All adverse events were divided by age, sex, type of reaction, and severity. Serious reactions were divided into subcategories to report the most common critical issues. At the conclusion of the work, it can be seen that COVID-19 mRNA vaccines are safe but can give serious cardiovascular (12% of the total number of serious reports) and neurological (one serious case that led to the development of Guillain BarrÃ© syndrome) side effects that need to be monitored by medical personnel.

Humoral Response After SARS-CoV-2 Vaccination in Kidney Transplant Recipients: Role of Immunosuppression Therapy. BACKGROUND: Messenger RNA vaccination against COVID-19 has been shown to produce an immune response with sufficient efficacy to prevent natural infection in immunocompetent recipients. However, the response in kidney transplant recipients is low. We aimed to evaluate the specific humoral response to SARS-CoV-2 after vaccination in a population of kidney transplant recipients and assess the main factors associated with a lack of response. METHODS: We undertook a prospective study of 105 kidney transplant recipients and 11 recipients of a combined kidney-pancreas transplant. We analyzed immunoglobulin G and immunoglobulin M antibodies after the patients received their second and third doses of the messenger RNA 1273 (Moderna) or BNT162b1 (BionTECH-Pfizer) vaccinations between February and November 2021. RESULTS: Mean (SD) age of the 116 patients was 50 (16) years, and 65% were men. They had their transplants for 40 months (IQR, 15-123 months), with 14% undergoing retransplant and 11% sensitized. The maintenance immunosuppression regimen was steroidsÂ + tacrolimusÂ + mycophenolate (MMF) in 68% of the patients and any combination with mammalian target of rapamycin inhibitor (mTORi) in 28%. A humoral response developed in 40% of the patients 6 weeks (IQR, 4-10 weeks) after receiving the second dose of the vaccine. Of the 67 patients with no response to the second dose, 51 had an analysis of the humoral response after the third dose, which was positive in 16 (31%). A total of 80% received the Moderna vaccine and 20% the BionTECH-Pfizer. No patient experienced major adverse effects after the vaccination. Factors associated with a lack of humoral response to the vaccine were recipient age (odds ratio [OR], 1.02; 95% CI, 1.001-1.05; PÂ =Â .04), diabetes (OR, 2.8; 95% CI, 1.2-6.9; PÂ =Â .02), and treatment with MMF (OR, 2.6; 95% CI, 1.08-6.8; PÂ =Â .03). Treatment with mTORi was associated with a better response to vaccination (OR, 0.3; 95% CI, 0.1-0.9; PÂ =Â .04). CONCLUSIONS: The humoral response to the COVID-19 vaccine in kidney transplant recipients is poor. Factors related with this lack of immunity are recipient age and diabetes, plus MMF therapy, whereas mTORi therapy was associated with a better response to vaccination.

COVID-19 Vaccines and the Virus: Impact on Drug Metabolism and Pharmacokinetics. This article reports on an American Society of Pharmacology and Therapeutics, Division of Drug Metabolism and Disposition symposium held at Experimental Biology on April 2, 2022, in Philadelphia. As of July 2022, over 500 million people have been infected with SARS-CoV-2 (the virus causing COVID-19) and over 12 billion vaccine doses have been administered. Clinically significant interactions between viral infections and hepatic drug metabolism were first recognized over 40 years ago during a cluster of pediatric theophylline toxicity cases attributed to reduced hepatic drug metabolism amid an influenza B outbreak. Today, a substantive body of research supports that the activated innate immune response generally decreases hepatic cytochrome P450 activity. The interactions extend to drug transporters and other organs and have the potential to impact drug absorption, distribution, metabolism, and excretion (ADME). Based on this knowledge, altered ADME is predicted with SARS-CoV-2 infection or vaccination. The report begins with a clinical case exploring the possibility of SARS-

CoV-2 vaccination increasing clozapine levels. This is followed by discussions of how SARS-CoV-2 infection or vaccines alter the metabolism and disposition of complex drugs, such as nanoparticles and biologics and small molecule therapies. The review concludes with a discussion of the effects of viral infections on placental amino acid transport and their potential to impact fetal development. The session improved our understanding of the impact of emerging viral infections and vaccine technologies on drug metabolism and disposition, which will help mitigate drug toxicity and improve drug and vaccine safety and effectiveness. SIGNIFICANCE STATEMENT: Altered pharmacokinetics of small molecule and complex molecule drugs and fetal brain distribution of amino acids following SARS-CoV-2 infection or immunization are possible. The proposed mechanisms involve decreased liver cytochrome P450 metabolism of small molecules, enhanced innate immune system metabolism of complex molecules, and altered placental and fetal blood-brain barrier amino acid transport, respectively. Future research is needed to understand the effects of these interactions on adverse drug responses, drug and vaccine safety, and effectiveness and fetal neurodevelopment.

Durability of ChAdOx1 nCoV-19 (AZD1222) vaccine and hybrid humoral immunity against variants including omicron BA.1 and BA.4 6 months after vaccination (COV005): a post-hoc analysis of a randomised, phase 1b-2a trial. BACKGROUND: COVID-19 vaccine rollout is lagging in Africa, where there has been a high rate of SARS-CoV-2 infection. We aimed to evaluate the effect of SARS-CoV-2 infection before vaccination with the ChAdOx-nCoV19 (AZD1222) vaccine on antibody responses through to 180 days. METHODS: We did an unmasked post-hoc immunogenicity analysis after the first and second doses of AZD1222 in a randomised, placebo-controlled, phase 1b-2a study done in seven locations in South Africa. AZD1222 recipients who were HIV-uninfected, were stratified into baseline seropositive or seronegative groups using the serum anti-nucleocapsid (anti-N) immunoglobulin G (IgG) electroluminescence immunoassay to establish SARS-CoV-2 infection before the first dose of AZD1222. Binding IgG to spike (anti-S) and receptor binding domain (anti-RBD) were measured before the first dose (day 0), second dose (day 28), day 42, and day 180. Neutralising antibody (NAb) against SARS-CoV-2 variants D614G, beta, delta, gamma, and A.VOI.V2, and omicron BA1 and BA.4 variants, were measured by pseudovirus assay (day 28, day 42, and day 180). This trial is registered with ClinicalTrials.gov, NCT04444674, and the Pan African Clinicals Trials Registry, PACTR202006922165132. FINDINGS: Of 185 individuals who were randomly assigned to AZD1222, we included 91 individuals who were baseline seropositive and 58 who were baseline seronegative, in the final analysis. In the seropositive group, there was little change of anti-S IgG (and anti-RBD IgG) or neutralising antibody (NAb) titres at day 42 compared with at day 28. Anti-S (and anti-RBD) IgG geometric mean concentrations (GMCs) were higher throughout in the seropositive compared with the seronegative group, including at day 180 (GMCs 517Â·8 [95% CI 411Â·3-651Â·9] vs 82Â·1 [55Â·2-122Â·3] BAU/mL). Also D614G NAb geometric mean titres (GMTs) were higher in the seropositive group than the seronegative group, as was the percentage with titres of at least 185 (80% putative risk reduction threshold [PRRT] against wild-type-alpha COVID-19), including at day 180 (92Â·0% [74Â·0-99Â·0] vs 18Â·2% [2Â·3-51Â·8). Similar findings were observed for beta, A.VOI.V2, and gamma. For delta, BA.1, and BA.4, NAb GMTs and the proportion with titres above the PRRT were substantially higher in the seropositive compared with seronegative group at day 28 and day 42, but no longer differed between the groups by day 180. INTERPRETATION: A single dose of AZD1222 in the general African population, where COVID-19 vaccine coverage is low and SARS-CoV-2 seropositivity is 90%, could enhance the magnitude and quality of antibody responses to SARS-CoV-2. FUNDING: The Bill & Melinda Gates Foundation, the South African Medical Research Council, the UK Research and Innovation, the UK National Institute for Health Research, and the South African Medical Research Council. TRANSLATION: For the Zulu translation of the abstract see Supplementary Materials section.

Predictors of shorter- and longer-term mortality after COVID-19 presentation among dialysis patients: parallel use of machine learning models in Latin and North American countries. BACKGROUND: We developed machine learning models to understand the predictors of shorter-, intermediate-, and longer-term mortality among hemodialysis (HD) patients affected by COVID-19 in four countries in the Americas. METHODS: We used data from adult HD patients treated at regional institutions of a global provider in Latin America (LatAm) and North America who contracted COVID-19 in 2020 before SARS-CoV-2 vaccines were available. Using 93 commonly captured variables, we developed machine learning models that predicted the likelihood of death overall, as well as during 0-14, 15-30,â€‰>â€‰30Â days after COVID-19 presentation and identified the importance of predictors. XGBoost models were built in parallel using the same programming with a 60%:20%:20% random split for training, validation, & testing data for the datasets from LatAm (Argentina, Columbia, Ecuador) and North America (United States) countries. RESULTS: Among HD patients with COVID-19, 28.8% (1,001/3,473) died in LatAm and 20.5% (4,426/21,624) died in North America. Mortality occurred earlier in LatAm versus North America; 15.0% and 7.3% of patients died within 0-14Â days, 7.9% and 4.6% of patients died within 15-30Â days, and 5.9% and 8.6% of patients diedâ€‰>â€‰30Â days after COVID-19 presentation, respectively. Area under curve ranged from 0.73 to 0.83 across prediction models in both regions. Top predictors of death after COVID-19 consistently included older age, longer vintage, markers of poor nutrition and more inflammation in both regions at all timepoints. Unique patient attributes (higher BMI, male sex) were top predictors of mortality during 0-14 and 15-30Â days after COVID-19, yet not mortalityâ€‰>â€‰30Â days after presentation. CONCLUSIONS: Findings showed distinct profiles of mortality in COVID-19 in LatAm and North America throughout 2020. Mortality rate was higher within 0-14 and 15-30Â days after COVID-19 in LatAm, while mortality rate was higher in North Americaâ€‰>â€‰30Â days after presentation. Nonetheless, a remarkable proportion of HD patients diedâ€‰>â€‰30Â days after COVID-19 presentation in both regions. We were able to develop a series of suitable prognostic prediction models and establish the top predictors of death in COVID-19 during shorter-, intermediate-, and longer-term follow up periods.

Comment on "Neuromuscular complications after COVID-19 vaccination: a series of eight patients" by Leemans et al.

Corrigendum: The Association Between Previous Influenza Vaccination and COVID-19 Infection Risk and Severity: A Systematic Review and Meta-analysis. Su W, Wang H, Sun C, et al. Am J Prev Med. 2022;63(1):121-130.

Correction to: New-onset IgA nephropathy following COVID-19 vaccination.

Encephalitis, myocarditis, and thrombocytopenia after COVID-19 mRNA vaccination: Clinical and pathophysiological considerations.

COVID-19 vaccination in systemic lupus erythematosus: a systematic review of its effectiveness, immunogenicity, flares and acceptance. OBJECTIVES: COVID-19 infection is associated with significant morbidity in systemic lupus erythematosus but is potentially preventable by vaccination, although the impact of the myriad vaccines among SLE patients is not established. We aimed to assess the effectiveness, efficacy, acceptance and safety of COVID-19 vaccination in SLE. METHODS: We performed a systematic review of PubMed, EMBASE, CENTRAL, and Scopus publications until 8 June 2022 without language, publication year or publication status restrictions. Reports with fewer than 5 patients or incomplete information on study outcomes were excluded. Risk of bias was assessed, and results reported according to the PRISMA 2020 guidelines. RESULTS: We identified 32 studies (34 reports) comprising 8269 individuals with SLE. Post-vaccine COVID-19 infections ranged from 0 to 17% in 6 studies (5065 patients), while humoral and cellular immunogenicity was evaluated in 17 studies (976 patients) and 5 studies (112 patients), respectively. The pooled seropositivity rate

was 81.1% (95% CI: 72.6, 88.5%, I2â€‰=â€‰85%, Pâ€‰<â€‰0.01), with significant heterogeneity and higher rates for mRNA vaccines compared with non-mRNA vaccines. Adverse events and specifically lupus flares were examined in 20 studies (3853 patients) and 13 studies (2989 patients), respectively. Severe adverse events and moderate to severe lupus flares were infrequent. The pooled vaccine acceptance rate was 67.0% (95% CI: 45.2, 85.6%, I2=98%, Pâ€‰<â€‰0.01) from 8 studies (1348 patients), with greater acceptance in older patients. CONCLUSION: Among SLE patients, post-vaccine COVID-19 infections, severe flares, and adverse events were infrequent, while pooled seropositivity and acceptance were high, with significant heterogeneity. These results may inform shared decision-making on vaccination during the ongoing COVID-19 pandemic. TRIAL REGISTRATION: PROSPERO, https://www.crd.york.ac.uk/PROSPERO/, CRD42021233366.

IL-13 determines specific IgE responses and SARS-CoV-2 immunity after mild COVID-19 and novel mRNA vaccination. After recovery, mild and severe COVID-19 diseases are associated with long-term effects on the host immune system, such as prolonged T-cell activation or accumulation of autoantibodies. In this study, we show that mild SARS-CoV-2 infections, but not SARS-CoV-2 spike mRNA vaccinations, cause durable atopic risk factors such as a systemic Th2- and Th17-type environment as well as activation of B cells responsive of IgE against aeroallergens from house dust mite and mold. At an average of 100 days post mild SARS-CoV-2 infections, anti-mold responses were associated with low IL-13 levels and increased pro-inflammatory IL-6 titers. Acutely severely ill COVID-19 patients instead showed no evidence of atopic reactions. Considering convalescents of mild COVID-19 courses and mRNA-vaccinated individuals together, IL-13 was the predominant significantly upregulated factor, likely shaping SARS-CoV-2 immunity. Application of multiple regression analysis revealed that the IL-13 levels of both groups were determined by the Th17-type cytokines IL-17A and IL-22. Taken together, these results implicate a critical role for IL-13 in the aftermath of SARS-CoV-2 mild infections and mRNA vaccinations, conferring protection against airway directed, atopic side reactions that occur in mildly experienced COVID-19.

Moderate to severe SARS-CoV-2 infection primes vaccine-induced immunity more effectively than asymptomatic or mild infection. Hybrid immunity induced by vaccination following recovery from SARS-CoV-2 infection is more robust than immunity induced by either infection or vaccination alone. To investigate how infection severity influenced the strength and character of subsequent vaccine-induced humoral or cellular immune responses against SARS-CoV-2, we assessed humoral and cellular immune responses against SARS-CoV-2 following recovery from infection, vaccine dose 1 and vaccine dose 2 in 35 persons recovered from COVID-19. Persons with polymerase chain reaction or serologically confirmed SARS-CoV-2 infection were recruited into a study of immunity against SARS-CoV-2. Self-reported symptoms categorized them as experiencing asymptomatic, mild, moderate or severe infection based on duration, intensity and need for hospitalization. Whole blood was obtained before vaccination and after first and second doses. Humoral immunity was assessed by ELISA and cellular immunity by ELISpot and intracellular flow cytometry. Responses were compared between groups recovered from either asymptomatic/mild (nâ€‰=â€‰14) or moderate/severe (nâ€‰=â€‰21) infection. Most subjects experienced robust increases in humoral and cellular immunity against SARS-CoV-2 spike (S) protein following 1 vaccination. Quantitative responses to second vaccination were marginal when measured 2.5 months afterwards and moderate or severe infection maintained stronger responses. Polyfunctional CD8(+) T cell responses were largely restricted to subjects recovered from moderate or severe infection. One vaccine dose triggered stronger immune responses than in a comparable group never infected with SARS-CoV-2, while the second dose produced only minor lasting increases in humoral or cellular responses. Infection history should be considered in planning COVID-19 vaccine administration.

Web and social media searches highlight menstrual irregularities as a global concern in COVID-19 vaccinations. Delineation of public concerns that prevent vaccine compliance is a major step in generating assurances and enhancing the success of COVID-19 prevention programs. We therefore sought to identify public concerns associated with COVID-19 vaccines, as reflected by web and social media searches, with a focus on menstrual irregularities. We used trajectory analyses of web and social media search data in combination with global COVID-19 data to reveal time-dependent correlations between vaccination rates and the relative volume of vaccine and period related searches. A surge of period and vaccine related Google searches followed the introduction of Covid vaccines around the world, and the commencement of vaccination programs in English speaking countries and across the United States. The relative volume of searches such as "Covid vaccine menstrual irregularities", "Covid vaccine menstrual period", "Pfizer vaccine menstruation", and "Moderna vaccine menstruation" was each significantly correlated with vaccination rates (Spearman râ€‰=â€‰0.42-0.88, Pâ€‰=â€‰4.33â€‰Ã—â€‰10(-34)-1.55â€‰Ã—â€‰10(-5)), and significantly different before and after the introduction of Covid vaccines (Mann-Whitney Pâ€‰=â€‰2.00â€‰Ã—â€‰10(-21)-7.10â€‰Ã—â€‰10(-20)). TikTok users were more engaged in period problems in 2021 than ever before. International, national, and state-level correlations between COVID-19 vaccinations and online activity demonstrate a global major concern of vaccine-related menstrual irregularities. Whether it is a potential side effect or an unfounded worry, monitoring of web and social media activity could reveal the public perception of COVID-19 prevention efforts, which could then be directly addressed and translated into insightful public health strategies.

COVID-19 vaccination status and associated factors among lactating women during the COVID-19 outbreak: a cross-sectional study in southern China. OBJECTIVES: Different countries and institutions around the world have debated whether lactating women should receive the COVID-19 vaccine during the COVID-19 pandemic. In China, lactating is not a contraindication to vaccination, but many women are still hesitant to get vaccinated. The purpose of this study was to investigate the current status of COVID-19 vaccination among lactating women and the related factors affecting vaccination. METHODS: An online cross-sectional survey involving 506 lactating women was conducted in southern China. We explored the related factors affecting COVID-19 vaccination of lactating women from three aspects: general information, knowledge-attitude-behaviour towards COVID-19 and its vaccine, and postpartum psychological state. RESULTS: A total of 432 lactating women completed the questionnaire, 198 of whom had received the COVID-19 vaccine. On the knowledge-attitude-behaviour questionnaire on COVID-19 and its vaccines, the vaccinated group scored higher than the unvaccinated group on both the three subdimensions of the questionnaire and the total score ($p<0.01$). The results of binary logistics regression analysis showed that mixed feeding (OR=2.68, 95% CI: 1.82 to 3.96), longer breastfeeding duration (OR=1.31, 95% CI: 1.16 to 1.49), better physical condition (OR=5.28, 95% CI: 1.82 to 15.32), higher attitude score of COVID-19 and its vaccine (OR=1.18, 95% CI: 1.10 to 1.27), and having a travel history in medium high-risk areas (OR=3.49, 95% CI: 1.46 to 8.37) were significantly associated with COVID-19 vaccination in lactating women. Having a master's degree or above (OR=0.03, 95% CI: 0.01 to 0.30), and having higher anxiety score (OR=0.66, 95% CI: 0.54 to 0.81) and depression score (OR=0.84, 95% CI: 0.75 to 0.93) were inversely associated with COVID-19 vaccination in lactating women. CONCLUSION: 45.8% of lactating women were vaccinated against COVID-19. Education level, feeding methods, duration of breast feeding, travel history in medium high-risk areas, physical condition, attitude score of COVID-19 and its vaccine, anxiety symptom and depressive symptom score were associated with vaccination of lactating women. More interventions based on these factors were needed to reduce concerns for lactating women and increase their vaccination rates.

Infliximab and Tofacitinib Attenuate Neutralizing Antibody Responses Against SARS-CoV-2 Ancestral and Omicron Variants in Inflammatory Bowel Disease Patients After 3 Doses of COVID-19 Vaccine.
Association of Symptoms After COVID-19 Vaccination With Anti-SARS-CoV-2 Antibody Response in the Framingham Heart Study. This cohort study examines the association of self-reported postvaccination symptoms with antiâ€“SARS-CoV-2 antibody response among Framingham Heart Study participants contributing to the Collaborative Cohort of Cohorts for COVID-19 Research study.
Severe bullous pemphigoid following Covid-19 vaccination resistant to rituximab and successfully treated with dupilumab.
Clinical profile of patients with type 2 diabetes after COVID-19 vaccination: A prospective study. The purpose of this study was to characterize the clinical profile of patients with type 2 diabetes after COVID-19 vaccination. This prospective study has involved 100 adult diabetic patients followed in the primary health care. SARS-CoV-2 infection after COVID-19 vaccination was the outcome indicator.
Safety and immunogenicity of intradermal administration of fractional dose CoronaVac(Â®), ChAdOx1 nCoV-19 and BNT162b2 as primary series vaccination. There is a limited supply of COVID-19 vaccines, with less than 20% of eligible populations in low-income countries having received one dose. Intradermal delivery of fractional dose vaccines is one way to improve global vaccine access, but no studies have reported data on intradermal delivery of COVID-19 primary series vaccination. We conducted a pilot study to examine the safety and immunogenicity of three intradermal primary series regimens - heterologous regimen of CoronaVac and ChAdOx1 (CoronaVac-ChAdOx1), homologous regimen of ChAdOx1 (ChAdOx1-ChAdOx1), and homologous regimen of BNT162b2 (BNT162b2-BNT162b2). Each dose was 1/5(th) or 1/6(th) of the standard dose. Two additional exploratory arms of intradermal vaccination for the second dose following an intramuscular first dose of ChAdOx1 and BNT162b2 were included. Intradermal vaccination was found to be immunogenic and safe. The antibody responses generated by the intradermal primary series were highest in the BNT162b2 arms. The anti-receptor binding domain (anti-RBD) IgG concentration following fractional dose intradermal vaccination was similar to that of standard dose intramuscular vaccination of the same regimen for all study arms except for BNT162b2. The BNT162b2 intradermal series generated a lower antibody concentration than the reference intramuscular series, despite generating the highest antibody concentration of all three intradermal primary series regimens. Neutralizing antibody responses against the SARS-CoV-2 ancestral strain were consistent with what was observed for anti-RBD IgG, with lower titers for SARS-CoV-2 variants. Neutralizing titers were lowest against the omicron variant, being undetectable in about a quarter of study participants. T-cell responses against spike- and nucleocapsid-membrane-open reading frame proteins were also detected following intradermal vaccination. Adverse effects following intradermal vaccination were generally comparable with post-intramuscular vaccination effects. Taken together, our data suggest that intradermal vaccination using 1/5(th) or 1/6(th) of standard COVID-19 intramuscular vaccination dosing were immunogenic with tendency of lower systemic adverse reactions than intramuscular vaccination. Our findings have implications in settings where COVID-19 vaccines are in shortage.
Case report: Vaccine-induced immune thrombotic thrombocytopenia complicated by acute cerebral venous thrombosis and hemorrhage after AstraZeneca vaccines followed by Moderna COVID-19 vaccine booster and surgery. Vaccine-induced thrombotic thrombocytopenia (VITT) is a well-known complication of adenoviral vector COVID-19 vaccines including ChAdOx1 nCoV-19 (AstraZeneca) and Ad26. COV2.S (Janssen, Johnson & Johnson). To date, only a few cases of mRNA COVID-19 vaccine such as mRNA-1273 (Moderna) or BNT162b2 (Pfizer-BioNTech)-induced VITT have been reported. We report a case of VITT with acute cerebral venous thrombosis and hemorrhage after a booster of mRNA-1273 (Moderna) vaccine in a patient previously vaccinated with two doses of the AstraZeneca vaccine. A 42-year-old woman presented with sudden onset of weakness of the right

upper limb with focal seizure. She had received two doses of AstraZeneca vaccines and a booster with Moderna vaccine 32 days before presentation. She had also undergone a laparoscopic myomectomy 12 days previously. Laboratory examinations revealed anemia (9.5 g/dl), thrombocytopenia (31 Ã— 10(3)/Î¼l), and markedly elevated d-dimer (>20.0 mg/L; reference value < 0.5 mg/L). The initial brain computed tomography (CT) was normal, but a repeated scan 10 h later revealed hemorrhage at the left cerebrum. Before the results of the blood smear were received, on suspicion of thrombotic microangiopathy with thrombocytopenia and thrombosis, plasmapheresis and pulse steroid therapy were initiated, followed by intravenous immunoglobulin (1 g/kg/day for two consecutive days) due to refractory thrombocytopenia. VITT was confirmed by positive anti-PF4 antibody and both heparin-induced and PF4-induced platelet activation testing. Clinicians should be aware that mRNA-1273 Moderna, an mRNA-based vaccine, may be associated with VITT with catastrophic complications. Additionally, prior exposure to the AstraZeneca vaccine and surgical procedure could also have precipitated or aggravated autoimmune heparin-induced thrombocytopenia/VITT-like presentation.

New-onset atypical fulminant type 1 diabetes after COVID-19 vaccination: A case report. Adverse reactions, including the onset of diabetes, after coronavirus disease 2019 (COVID-19) vaccination have been reported. Herein, we report a case of a man who developed anti-glutamic acid decarboxylase (GAD) antibody-positive fulminant type 1 diabetes 15â€‰weeks after COVID-19 vaccination, atypical of the previously reported anti-GAD antibody-negative cases.

Associations of race/ethnicity and socioeconomic factors with vaccination among US adults during the COVID-19 pandemic, January to March 2021. To date, there has been limited data available to understand the associations between race/ethnicity and socioeconomic and related characteristics with novel coronavirus disease (COVID-19) vaccination in the United States. I leveraged the large, nationally-representative cross-sectional surveys of the U.S. Household Pulse Survey between January and March 2021 with relatively complete race/ethnicity and socioeconomic data to examine national trends in levels of COVID-19 vaccine initiation and intention in adults aged 18-85Â years. I further estimated the multivariable associations between race/ethnicity, education, income, and financial hardship with the adjusted prevalence odds ratios of: 1) receipt ofÂ â‰¥1 COVID-19 vaccine dose; and 2) among those unvaccinated, the definite intention to receive a vaccine. I observed persistent disparities in vaccine initiation for non-Hispanic Blacks, Hispanics, and non-Hispanic multiracial/other race persons, and vaccine intention for Blacks and multiracial/other race persons, compared to non-Hispanic Whites and Asians. In late March 2021, the prevalence estimates of Hispanics and Blacks receiving a vaccine were 12-percentage points and 8-percentage points lower than for Whites, respectively. Education and income exhibited dose-response relationships with vaccine initiation (P for trendÂ â‰¤0.01 andÂ <0.001, respectively). Substantial financial hardship was linked to 35-44% lower adjusted odds of vaccination (P<.001). In this large, nationally-representative study, I found persistent racial/ethnic and socioeconomic disparities in vaccine initiation and intention, more than three months after COVID-19 vaccines first became available. Addressing these persistent racial/ethnic and socioeconomic inequities in vaccination is essential to mitigate the pandemic's higher risks of infection and adverse health outcomes in Hispanic, Black, and socioeconomically-disadvantaged communities.

Acute panuveitis after COVID-19 mRNA booster vaccination following cataract surgery. PURPOSE: To report a case of presumed COVID-19 Pfizer third dose (booster) vaccination leading to severe panuveitis mimicking acute endophthalmitis in the early postoperative period following routine cataract extraction and intraocular lens implantation. OBSERVATIONS: A 68-year-old female with mild refractive error who previously received 2 doses of the BNT162b2 vaccine underwent routine cataract extraction and intraocular lens implantation in the right eye. On postoperative day (POD) 2 the patient received her BNT162b2 booster vaccination. On POD 3 the patient's vision was hand motion

at face with photophobia. Anterior segment examination was significant for 2+ conjunctival injection, mild stromal edema, 4+ cell and flare with trace hypopyon, and 4+ anterior vitreous cell without any wound leak. Subsequent Gram staining, culture for aerobic and anaerobic bacteria, KOH preparation, and PCR testing for infectious organisms were also obtained, all of which were found to be negative. ESR and CRP values were also negative. The patient was started on intravitreal injections of vancomycin and ceftazidime, as well as oral moxifloxacin, fortified vancomycin and tobramycin drops, prednisolone acetate 1%, and atropine 1%. On POD 5 the patient reported significant improvement of her vision and was found to have 20/80 vision. On POD 12 her vision improved to 20/25, and improved further on POD 19 to 20/20 vision with a completely normal examination. Cultures remained negative throughout the entire course. CONCLUSIONS AND IMPORTANCE: This is the first report to suggest a possible association between the BNT162b2 booster vaccination and development of acute panuveitis in the postoperative period after routine cataract extraction and intraocular lens implantation. This condition may mimic acute bacterial postoperative endophthalmitis and may portend a more favorable prognosis, but the authors believe such cases should nonetheless be treated aggressively as presumed infection.

New mycosis fungoides-like lymphomatoid reaction following COVID-19 vaccination: A case report. Numerous cutaneous side effects arising from COVID-19 vaccination have been reported. Mycosis fungoides (MF) is a rare indolent form of cutaneous t-cell lymphoma. While the pathogenesis of MF is not well understood, it is thought to involve immune dysregulation. There have been reports of COVID-19 vaccination induced flares and recurrences of cutaneous lymphomas and lymphomatoid reactions. We present the first reported case of COVID-19 vaccine induced MF-like lymphomatoid reaction.

Successful Treatment of Delayed Localized Necrotizing Inflammatory Myositis After Severe Acute Respiratory Syndrome Coronavirus 2 mRNA-1273 Vaccine: A Case Report. Reported adverse reactions to the mRNA-1273 vaccine (Spikevax, Moderna Inc) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) range from mild, local delayed cutaneous reactions to rarer, more serious reactions such as myocarditis. Here, we describe the presentation and successful treatment of delayed, localized necrotizing inflammatory myositis following a third dose of the mRNA-1273 SARS-CoV-2 vaccine. To our knowledge, this is the first report of biopsy-confirmed, delayed inflammatory myositis after administration of an mRNA-1273 SARS-CoV-2 vaccine booster.

Skin reaction to COVID-19 vaccine: A report of 4 cases. Since the beginning of the covid-vaccine campaign, a lot of local and systemic dermatologic reactions happening after the administration of Coronavirus disease 2019 (COVID-19) vaccines have been described, even if their exact biological mechanism is still debated. In this paper we report 4 cases of cutaneous manifestations arose within ten days after the first dose of messenger RNA (mRNA)-based COVID-19 vaccination: one case of giant urticaria, one case of head and neck redness and two cases of Erythema Multiforme (EM). In our experience these reactions were mild, transient and all of them resolved, not recurring after the second dose, so these manifestations shouldn't be considered as an absolute contraindication to the second dose of vaccine, that to date is fundamental.

Spike-specific humoral and cellular immune responses after COVID-19 mRNA vaccination in patients with cirrhosis: A prospective single center study. BACKGROUND AND AIMS: COVID-19 mRNA vaccines were approved to prevent severe forms of the disease, but their immunogenicity and safety in cirrhosis is poorly known. METHOD: In this prospective single-center study enrolling patients with cirrhosis undergoing COVID-19 vaccination (BNT162b2 and mRNA-1273), we assessed humoral and cellular responses vs healthy controls, the incidence of breakthrough infections and adverse events (AEs). Antibodies against spike- and nucleocapsid-protein (anti-S and anti-N) and Spike-specific T-cells responses were quantified at baseline, 21 days after the first and second doses and during follow-up.

RESULTS: 182 cirrhotics (85% SARS-CoV-2-naÃ¯ve) and 38 controls were enrolled. After 2 doses of vaccine, anti-S titres were significantly lower in cirrhotics vs controls [1,751 (0.4-25,000) U/mL vs 4,523 (259-25,000) U/mL, p=0.012] and in SARS-CoV-2-naÃ¯ve vs previously infected cirrhotics [999 (0.4-17,329) U/mL vs 7,500 (12.5-25,000) U/mL, (p<0.001)]. T-cell responses in cirrhotics were similar to controls, although with different kinetics. In SARS-CoV-2-naÃ¯ve cirrhotics, HCC, Child-Pugh B/C and BNT162b2 were independent predictors of low response. Neither unexpected nor severe AEs emerged. During follow-up, 2% turned SARS-CoV-2 positive, all asymptomatic. CONCLUSION: Humoral response to COVID-19 vaccines appeared suboptimal in patients with cirrhosis, particularly in SARS-CoV-2-naÃ¯ve decompensated cirrhotics, although cellular response appeared preserved, and low breakthrough infections rate was registered.

A Systematic Review and Meta-analysis of the Association Between SARS-CoV-2 Vaccination and Myocarditis or Pericarditis. INTRODUCTION: There have been reports of potential negative cardiovascular effects from the COVID-19 vaccine, such as myocarditis or pericarditis. This study sought to ascertain the risk of myocarditis/pericarditis after COVID-19 vaccination by conducting an extensive meta-analysis of published cases. METHODS: A systematic literature search was conducted in 7 online databases by March 31, 2022. Heterogeneity was tested by I(2) index. RR and 95% CI were pooled through either random-effect or fixed-effect models. Sensitivity analysis and publication bias were also conducted. RESULTS: A total of 11 studies with 58,620,611 subjects were included. COVID-19 vaccination correlated with an increased risk of myocarditis or pericarditis (RR=2.04; 95% CI=1.33, 3.14). In addition, an increased risk of myocarditis or pericarditis in people who received the second dose of COVID-19 vaccine compared with that in those who received only the first dose of COVID-19 vaccine was also found (RR=4.06; 95% CI=2.08, 7.92). An increased incidence of pericarditis or myocarditis was noted predominantly in those who received BNT162b2 and mRNA-1273 vaccines (RR=2.19; 95% CI=1.46, 3.29 and RR=4.15; 95% CI=1.87, 9.22, respectively). DISCUSSION: Study results indicate that a higher incidence of myocarditis or pericarditis was found after COVID-19 vaccination. In addition, the risk of developing myocarditis or pericarditis was greater after the second dose than after the first dose. Nevertheless, the risks of myocarditis and pericarditis in COVID-19 vaccine recipients are still significantly lower than the health risks observed in patients with COVID-19. Therefore, the benefits and harms must be carefully assessed to determine the best management option for patients who are in the high-risk group of myocarditis or pericarditis.

Antibody response and safety of COVID-19 vaccine in peritoneal dialysis patients.

Allergy Workup in the Diagnosis of COVID-19 Vaccines-Induced Hypersensitivity Reactions and Its Impact on Vaccination. INTRODUCTION: Immediate and delayed hypersensitivity reactions (HSR) to COVID-19 vaccines are rare adverse events that need to be prevented, diagnosed, and managed in order to guarantee adherence to the vaccination campaign. The aims of our study were to stratify the risk of HSR to COVID-19 vaccines and propose alternative strategies to complete the vaccination. METHODS: 1,640 subjects were screened for vaccinal eligibility, according to national and international recommendations. Among them, we enrolled for allergy workup 152 subjects, 43 with HSR to COVID-19 vaccines and 109 at high risk of HSR to the first dose. In vivo skin tests with drugs and/or vaccines containing PEG/polysorbates were performed in all of them, using skin prick test and, when negative, intradermal tests. In a subgroup of patients resulted negative to the in vivo skin tests, the programmed dose of COVID-19 vaccine (Pfizer/BioNTech) was administered in graded doses regimen, and detection of neutralizing anti-spike antibodies was performed in these patients after 4 weeks from the vaccination, using the SPIA method. RESULTS: Skin tests for PEG/polysorbates resulted positive in only 3% (5/152) of patients, including 2 with previous HSR to COVID-19 vaccines and 3 at high risk of HSR to the first dose. Among the 147 patients with negative skin tests, 97% (143/147) were eligible for vaccination and 87% (124/143) of them received safely the programmed

COVID-19 vaccine dose. Administration of graded doses of Pfizer/BioNTech vaccine were well tolerated in 17 out of 18 patients evaluated; only 1 developed an HSR during the vaccination, less severe than the previous one, and all developed neutralizing anti-spike antibodies after 4 weeks with values comparable to those subjects who received the vaccine in unfractionated dose. CONCLUSION: On the whole, the usefulness of the skin tests for PEG/polysorbates seems limited in the diagnosis of HSR to COVID-19 vaccines. Graded doses regimen (Pfizer/BioNTech) is a safe and effective alternative strategy to complete the vaccinal course.

Vaccine-associated thrombocytopenia. Vaccination is the most cost-effective means of preventing and even eliminating infectious diseases. However, adverse reactions after vaccination are inevitable. In addition to common vaccine-related adverse reactions, some rare but serious adverse reactions have been reported, including secondary immune thrombocytopenia (ITP). The measles-mumps-rubella (MMR) vaccine is currently the only vaccine for which a cause-effect relationship with immune thrombocytopenia has been demonstrated with an incidence of approximately 0.087-4 per 100,000 doses, and the complication is mostly observed in children. In addition, thrombocytopenia can be induced by coronavirus disease 2019 (COVID-19) vaccines following COVID-19 vaccination primarily occurs within a few weeks post-vaccination. The condition mostly occurs in elderly individuals with no sex differences. Its incidence is approximately 0.80 to 11.3 per million doses. Some patients have previously suffered from chronic ITP likely to develop exacerbation of ITP after COVID-19 vaccines, especially those who have undergone splenectomy or are being treated with >5 medications. Based on clinical practice, first-line treatments for vaccine-associated thrombocytopenia are essentially limited to those used for primary ITP, including glucocorticoids and intravenous immunoglobulin (IVIg).

The Risk of Hospitalization and Mortality After Breakthrough SARS-CoV-2 Infection by Vaccine Type: Observational Study of Medical Claims Data. BACKGROUND: Several risk factors have been identified for severe COVID-19 disease by the scientific community. In this paper, we focus on understanding the risks for severe COVID-19 infections after vaccination (ie, in breakthrough SARS-CoV-2 infections). Studying these risks by vaccine type, age, sex, comorbidities, and any prior SARS-CoV-2 infection is important to policy makers planning further vaccination efforts. OBJECTIVE: We performed a comparative study of the risks of hospitalization (n=1140) and mortality (n=159) in a SARS-CoV-2 positive cohort of 19,815 patients who were all fully vaccinated with the Pfizer, Moderna, or Janssen vaccines. METHODS: We performed Cox regression analysis to calculate the risk factors for developing a severe breakthrough SARS-CoV-2 infection in the study cohort by controlling for vaccine type, age, sex, comorbidities, and a prior SARS-CoV-2 infection. RESULTS: We found lower hazard ratios for those receiving the Moderna vaccine (P<.001) and Pfizer vaccine (P<.001), with the lowest hazard rates being for Moderna, as compared to those who received the Janssen vaccine, independent of age, sex, comorbidities, vaccine type, and prior SARS-CoV-2 infection. Further, individuals who had a SARS-CoV-2 infection prior to vaccination had some increased protection over and above the protection already provided by the vaccines, from hospitalization (P=.001) and death (P=.04), independent of age, sex, comorbidities, and vaccine type. We found that the top statistically significant risk factors for severe breakthrough SARS-CoV-2 infections were age of >50, male gender, moderate and severe renal failure, severe liver disease, leukemia, chronic lung disease, coagulopathy, and alcohol abuse. CONCLUSIONS: Among individuals who were fully vaccinated, the risk of severe breakthrough SARS-CoV-2 infection was lower for recipients of the Moderna or Pfizer vaccines and higher for recipients of the Janssen vaccine. These results from our analysis at a population level will be helpful to public health policy makers. Our result on the influence of a previous SARS-CoV-2 infection necessitates further research into the impact of multiple exposures on the risk of developing severe COVID-19.

[Post-vaccination antibodies against SARS-CoV-2 in a cohort of workers of a general hospital]. INTRODUCTION: The aim was to estimate the evolution of the levels of anti-SARS-CoV-2 antibodies, the associated factors, and the incidence of new infections during the follow-up period.Â Method: Prospective cohort study of a representative sample of workers at the General University Hospital of Castellon 8 months after receiving the second dose of Pfizer-BioNTech vaccine against SARS-CoV-2, by determining IgG-S, IgG-NP, follow-up and response to a questionnaire. The results were compared with those at the start of the cohort in February 2021. Multivariate linear regression and Poisson regression were used.Â Results: A total of 253 workers participated out of the 275 in the start of the cohort. All had detectable levels of IgG-S, median 691% AU/ml, decreasing by 93.3% compared with the first study. The decline of IgG-S increased with age and obesity; and decreased with a COVID-19 previous history, regular exercise, and in smokers. IgG-NP was positively associated with a history of COVID-19, taking vitamin D, and decreased from 4.4% to 1.2%. There were 4 new cases of COVID-19 in the cohort, with and incidence rate of 1.7%. One death occurred in a participant with immunosuppressive treatment, only one case was asymptomatic and no reinfections occurred. CONCLUSIONS: A general decrease of IgG-S and IgG-NP antibodies after the second dose of Pfizer-BioNTech vaccine was observed in the cohort, as well as with new SARS-CoV-2 infections. Booster doses, maintaining protective measures and further determination of the protection threshold of vaccination are recommended.

Risk of SARS-CoV-2 infection following initial COVID-19 vaccination: Population-based cohort study. BACKGROUND: Anecdotally there are reports of newly diagnosed SARS-CoV-2 infection shortly after vaccination. This has led some to speculate that vaccination itself might inadvertently increase the short-term risk of COVID potentially due to airborne spread at mass vaccination clinics or relaxation of precautions following vaccination. We explored whether receipt of vaccination was associated with a short-term increase in the risk of being diagnosed with COVID-19 and if differences exist between vaccination settings. METHODS: We conducted a cohort study in Ontario, Canada to compare the risk of SARS-CoV-2 infection within 21 days of receiving a first vaccination, according to the setting in which vaccines were administered between March 1, 2021 and May 6, 2021. We used linked population-wide vaccination, laboratory testing, and health administrative databases. We created a 1:1 matched comparison group of unexposed individuals. We reported the overall risk of infection calculated at 3, 7, 10, 14, 18, and 21 days. This was completed overall and by setting of vaccine receipt. RESULTS: We identified 4,798,430 Ontario residents who received their first dose of a COVID-19 vaccine. In the primary analysis, the rate of SARS-CoV-2 infection was significantly lower among vaccine recipients vs non-recipients at all the post-vaccination time points. Analysis stratified by vaccination setting found that mass vaccination clinics, pharmacies, and physician offices were consistent with the main findings. Individuals who received their first vaccine dose in congregate residential settings had a higher rate of SARS-CoV-2 infection at 7 days (HR 1.35, 95% CI 1.00-1.83) and 10 days (HR 1.49, 95% CI 1.03-2.15). CONCLUSION: In this population-based cohort study, we found that there was no increased risk of SARS-CoV2 infection after vaccination suggesting no broad transmission of disease at time of vaccination. Some evidence of increased risk among those vaccinated in congregate settings, highlighting the need to consider opportunities for supporting safe vaccine administration in these settings. Given ongoing and future immunization programs, the results support the need for continued vigilance during any mass vaccination processes and education regarding the delayed nature of protection following vaccination.

Factors Associated With Severe COVID-19 Among Vaccinated Adults Treated in US Veterans Affairs Hospitals. IMPORTANCE: With a large proportion of the US adult population vaccinated against SARS-CoV-2, it is important to identify who remains at risk of severe infection despite vaccination. OBJECTIVE: To characterize risk factors for severe COVID-19 disease in a vaccinated population.

DESIGN, SETTING, AND PARTICIPANTS: This nationwide, retrospective cohort study included US veterans who received a SARS-CoV-2 vaccination series and later developed laboratory-confirmed SARS-CoV-2 infection and were treated at US Department of Veterans Affairs (VA) hospitals. Data were collected from December 15, 2020, through February 28, 2022. EXPOSURES: Demographic characteristics, comorbidities, immunocompromised status, and vaccination-related variables. MAIN OUTCOMES AND MEASURES: Development of severe vs nonsevere SARS-CoV-2 infection. Severe disease was defined as hospitalization within 14 days of a positive SARS-CoV-2 diagnostic test and either blood oxygen level of less than 94%, receipt of supplemental oxygen or dexamethasone, mechanical ventilation, or death within 28 days. Association between severe disease and exposures was estimated using logistic regression models. RESULTS: Among 110â€¯760 patients with infections following vaccination (97â€¯614 [88.1%] men, mean [SD] age at vaccination, 60.8 [15.3] years; 26â€¯953 [24.3%] Black, 11â€¯259 [10.2%] Hispanic, and 71â€¯665 [64.7%] White), 10â€¯612 (9.6%) had severe COVID-19. The strongest association with risk of severe disease after vaccination was age, which increased among patients aged 50 years or older with an adjusted odds ratio (aOR) of 1.42 (CI, 1.40-1.44) per 5-year increase in age, such that patients aged 80 years or older had an aOR of 16.58 (CI, 13.49-20.37) relative to patients aged 45 to 50 years. Immunocompromising conditions, including receipt of different classes of immunosuppressive medications (eg, leukocyte inhibitor: aOR, 2.80; 95% CI, 2.39-3.28) or cytotoxic chemotherapy (aOR, 2.71; CI, 2.27-3.24) prior to breakthrough infection, or leukemias or lymphomas (aOR, 1.87; CI, 1.61-2.17) and chronic conditions associated with end-organ disease, such as heart failure (aOR, 1.74; CI, 1.61-1.88), dementia (aOR, 2.01; CI, 1.83-2.20), and chronic kidney disease (aOR, 1.59; CI, 1.49-1.69), were also associated with increased risk. Receipt of an additional (ie, booster) dose of vaccine was associated with reduced odds of severe disease (aOR, 0.50; CI, 0.44-0.57). CONCLUSIONS AND RELEVANCE: In this nationwide, retrospective cohort of predominantly male US Veterans, we identified risk factors associated with severe disease despite vaccination. Findings could be used to inform outreach efforts for booster vaccinations and to inform clinical decision-making about patients most likely to benefit from preexposure prophylaxis and antiviral therapy.

Significance of biopsy in SARS-CoV-2 mRNA vaccine-associated myocarditis: Paving the way toward precision vaccinology.

Response to commentary: Reactive synovitis of the knee joint and COVID-19 vaccination.

Reactive synovitis of the knee joint and COVID-19 vaccination: Commentary.

Guillain-Barre Syndrome Following SARS-CoV-2 Vaccination: A Case Report. After more than a year of Coronavirus disease 2019 pandemic, in 2021 Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccination have been made possible and vaccine was distributed globally. Since then, there have been reports of symptoms following SARS-CoV-2 vaccination, including neurological symptoms of ascending paralysis known as Guillain-Barre syndrome. In this report, we describe the first case of Guillain-Barre syndrome following vaccination in Indonesia. Symptoms of ascending paralysis were of late onset after the first dose, however, were full blown after receiving the second dose followed by left-sided facial paralysis.

Maternal, fetal and neonatal outcomes among pregnant women receiving COVID-19 vaccination: The preg-co-vax study. INTRODUCTION: Although the European Medicines Agency (EMA) encourage coronavirus disease 2019 (COVID-19) vaccination in pregnant women, the scientific evidence supporting the use of COVID-19 vaccines during pregnancy is still limited. AIM: We aimed to investigate adverse events following immunization (AEFI) with COVID-19 vaccines during pregnancy. METHODS: We retrieved Individual Case Safety Reports (ICSRs) related to the use of COVID-19 vaccines during pregnancy from the EudraVigilance database for the year 2021. We analyzed AEFI related to the mother and fetus/newborn. The reporting odds ratio (ROR) was computed to compare

the reporting probability of spontaneous abortion between COVID-19 vaccines. RESULTS: During the study period, among 1,315,315 ICSRs related to COVID-19 vaccines, we retrieved 3,252 (0.25%) reports related to the use in pregnancy. More than half (58.24%) of ICSRs were submitted by non-healthcare professionals. Although the majority (87.82%) of ICSRs concerned serious AEFI, their outcomes were mostly favorable. In this study, 85.0% of total ICSRs referred to pregnant women (n = 2,764), while 7.9% referred to fetuses/newborns (n = 258). We identified 16,569 AEFI. Moreover, 55.16% were AEFI not related to pregnancy (mostly headache, pyrexia, and fatigue), while 17.92% were pregnancy-, newborn-, or fetus-related AEFI. Among pregnancy-related AEFI, the most reported was spontaneous abortion. Messenger RNA (mRNA) vaccines had a lower reporting probability of spontaneous abortion than viral vector-based vaccines (ROR 0.80, 95% CI 0.69-0.93). Moderna and Oxford-AstraZeneca vaccines had a higher reporting probability of spontaneous abortion (ROR 1.2, 95% CI 1.05-1.38 and ROR 1.26, 95% CI 1.08-1.47, respectively), while a lower reporting probability was found for Pfizer-BioNTech vaccine compared with all other COVID-19 vaccines (ROR 0.73, 95% CI 0.64-0.84). In addition, 5.8% of ICSRs reported a fatal outcome. CONCLUSIONS: No strong insight of unknown AEFI associated with COVID-19 vaccination in pregnant women was observed. Considering the high risk associated with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, our analysis suggests that the benefits of COVID-19 vaccines during pregnancy outweigh the possible risks. However, it is important to continue monitoring the safety profile of COVID-19 vaccines in this subpopulation.

Recurrence of Thrombotic Thrombocytopenic Purpura After Vaccination with mRNA-1273 COVID-19 vaccine. Thrombotic thrombocytopenic purpura (TTP) is a rare disease characterized by thrombocytopenia, microangiopathic hemolytic anemia, and ischemic organ damage. Several cases of TTP associated with administration of COVID-19 vaccines have been reported. We report a case of a 63-year-old woman with a past medical history of hypertension, diabetes mellitus, chronic kidney disease, HIV infection, and remote history of TTP who presented with several days of shortness of breath on exertion, chest tightness, low-grade fever, and bruising thirty-three days after receiving the second dose of the mRNA-1273 COVID-19 vaccine. Thrombocytopenia and hemolytic anemia with schistocytes were noted on testing, and ADAMTS13 activity was <5%. Temporizing treatment with fresh frozen plasma was started immediately on presentation, and treatment was continued with daily therapeutic plasma exchange and corticosteroids. TTP should be considered in patients who present with thrombocytopenia after COVID-19 vaccination, especially if there is a past history of TTP.

A Case of Adult Multisystem Inflammatory Syndrome Following COVID-19 Vaccine. Multisystem inflammatory syndrome is a life-threatening condition associated with elevated inflammatory markers and multiple organ injury. A diagnosis of exclusion, it has been reported after severe acute respiratory syndrome coronavirus 2 infection (SARS-CoV-2) in children and adults; recently it has been described in some post-COVID-19 vaccinated individuals. The prognosis with supportive care and immunomodulatory therapy is good, although some individuals may require treatment in the intensive care unit (ICU). Here we report a case of a 58-year-old man who developed multi-organ failure after receiving the second dose of the Moderna mRNA-1273 COVID-19 vaccine. He required critical organ support in the ICU. An extensive workup was done to rule out alternative infectious and inflammatory processes. Following a period of gradual in-hospital convalescence, our patient made a full recovery. To our knowledge, this is the first comprehensively described case of multisystem inflammatory syndrome associated with Moderna mRNA-1273 COVID-19 vaccine in an adult over 50 years of age.

Healthcare Workers and Nonhealthcare Workers Pro-Vaccination Attitude and Its Associated Factors towards COVID-19 Vaccine Globally: A Systematic Review and Meta-Analysis. INTRODUCTION: Coronavirus disease 2019 (COVID-19) pandemic has not been managed and controlled globally. The

aim of this systematic review and meta-analysis were to determine the global pro-vaccination attitude and associated factors towards COVID-19 vaccine among healthcare workers (HCWs) and nonhealthcare workers (non-HCWs). METHODS: Different databases such as PubMed, Scopus, EMBASE, and Google Scholar were used. Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) 2020 flowchart diagram and PRISMA checklist were used for study screening, selection, and inclusion into this systematic review and meta-analysis. Newcastle-Ottawa Scale (NOS) quality assessment criteria for cross-sectional studies were used to assess the included articles. RESULTS: A total of 51 studies were included into this systematic review and meta-analysis. The meta-analysis revealed that the global pooled prevalence of pro-vaccination attitude towards COVID-19 vaccine among both HCWs and non-HCWs was 61.30% (95%CI: 56.12, 66.47, I (2)â€‰=â€‰99.8%: p=0.000). Subgroup analysis showed that the global pooled prevalence of pro-vaccination attitude towards COVID-19 vaccine was the lowest (59.77%, 95%CI (51.56, 67.98); I (2)â€‰=â€‰99.6%, p=0.000) among the HCWs participants and the highest (62.53%, 95%CI (55.39, 69.67); I (2)â€‰=â€‰99.8%, p=0.000) among the non-HCWs participants and the lowest (54.31%, 95%CI (43, 65.63); I (2)â€‰=â€‰99.5%, p=0.000) for sample size <700 and the highest (66.49%, 95%CI (60.01, 72.98); I (2)â€‰=â€‰99.8%, p=0.000) for sample size >700; the lowest (60.70%, 95%CI (54.08, 67.44); I (2)â€‰=â€‰93.0%, p=0.000) for studies published in 2020 year and the highest (61.31%, 95%CI (55.93, 66.70); I (2)â€‰=â€‰99.8%, p=0.000) for the studies published after 2020 years. From this systematic review, factors significantly associated with pro-vaccination attitude towards COVID-19 vaccine among HCWs were such as age, gender, race, work experience, home location, having no fear of injections, being a non-smoker, profession, presence of chronic illnesses, allergies, confidence in pharmaceutical companies, history of taking influenza vaccine, vaccine recommendation, perceived risk of new vaccines, perceived utility of vaccine, receiving a seasonal flu vaccination in the last 5 years, working in a private hospital, a high perceived pandemic risk index, low vaccine harm index, high pro-socialness index, being in close contact with a high-risk group, knowledge about the virus, confidence in and expectations about personal protective equipment, and behaviors. The level of positive attitude towards COVID-19 vaccine among non-HCWs ranged from 21.40% to 91.99%. Factors associated with the attitude towards COVID-19 vaccine among non-HCWs were such as age, gender, educational level, occupation, marital status, residency, income, ethnicity, risk for severe course of COVID-19, direct contact with COVID-19 at work, being a health profession, being vaccinated against seasonal flu, perceived benefits, cues to actions, having previous history of vaccination, fear of passing on the disease to relatives, and the year of medical study, studying health-related courses, COVID-19 concern, adherence level to social distancing guidelines, history of chronic disease, being pregnant, perceived vaccine safety, having more information about vaccine effectiveness, mandatory vaccination, being recommended to be vaccinated, lack of confidence in the healthcare system to control epidemic, and belief in COVID-19 vaccines protection from COVID-19 infection. CONCLUSION: This meta-analysis revealed that the global estimated pooled prevalence of pro-vaccination attitude towards COVID-19 vaccine among both HCWs and non-HCWs was unsatisfactory. Globally, there is a need for a call for action to cease the crisis of this pandemic.

Neutrophilic Pustular Eruption with Behcet's Like Illness Post Covid-19 Vaccination. The COVID-19 pandemic has deeply impacted the lives of many. In such unprecedent times, mass vaccination has been the cornerstone in decreasing morbidity and mortality. However, various adverse events (AEs) to COVID-19 vaccines including cutaneous AEs have been reported worldwide. We report a case of neutrophilic pustular eruption with a Behcet's disease-like illness following COVID-19 vaccination with no history of known allergies or prior severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) infection.

A Chronic Obstructive Pulmonary Disease Exacerbation Following the Administration of a COVID 19-Booster Vaccine: A Case Report. We present a case of a patient who presented to the emergency department with symptoms suggestive of a chronic obstructive pulmonary disease (COPD) exacerbation one day after receiving the BNT162b2 COVID-19 booster vaccine. Laboratory studies indicated she was in a state of inflammation, but not infection. Other potential triggers, including cardiac and viral etiologies, were ruled out. To our knowledge, this is the first documented case of a COPD exacerbation following the administration of the BNT162b2 COVID-19 vaccine.

Comparison of vaccine-induced antibody neutralization against SARS-CoV-2 variants of concern following primary and booster doses of COVID-19 vaccines. The SARS-CoV-2 pandemic has, as of July 2022, infected more than 550 million people and caused over 6 million deaths across the world. COVID-19 vaccines were quickly developed to protect against severe disease, hospitalization and death. In the present study, we performed a direct comparative analysis of four COVID-19 vaccines: BNT162b2 (Pfizer/BioNTech), mRNA-1273 (Moderna), ChAdOx1 (Oxford/AstraZeneca) and Ad26.COV2.S (Johnson & Johnson/Janssen), following primary and booster vaccination. We focused on the vaccine-induced antibody-mediated immune response against multiple SARS-CoV-2 variants: wildtype, B.1.1.7 (Alpha), B.1.351 (Beta), B.1.617.2 (Delta) and B.1.1.529 (Omicron). The analysis included the quantification of total IgG levels against SARS-CoV-2 Spike, as well as the quantification of antibody neutralization titers. Furthermore, the study assessed the high-throughput ACE2 competition assay as a surrogate for the traditional pseudovirus neutralization assay. The results demonstrated marked differences in antibody-mediated immune responses. The lowest Spike-specific IgG levels and antibody neutralization titers were induced by one dose of the Ad26.COV2.S vaccine, intermediate levels by two doses of the BNT162b2 vaccine, and the highest levels by two doses of the mRNA-1273 vaccine or heterologous vaccination of one dose of the ChAdOx1 vaccine and a subsequent mRNA vaccine. The study also demonstrated that accumulation of SARS-CoV-2 Spike protein mutations was accompanied by a marked decline in antibody neutralization capacity, especially for B.1.1.529. Administration of a booster dose was shown to significantly increase Spike-specific IgG levels and antibody neutralization titers, erasing the differences between the vaccine-induced antibody-mediated immune response between the four vaccines. The findings of this study highlight the importance of booster vaccines and the potential inclusion of future heterologous vaccination strategies for broad protection against current and emerging SARS-CoV-2 variants.

Association of COVID-19 vaccination before conception with maternal thyroid function during early pregnancy: A single-center study in China. Despite the high vaccination coverage, potential COVID-19 vaccine-induced adverse effects, especially in pregnant women, have not been fully characterized. We examined the association between COVID-19 vaccination before conception and maternal thyroid function during early pregnancy. We conducted a retrospective cohort study in Shanghai, China. A total of 6979 pregnant women were included. Vaccine administration was obtained from electronic vaccination records. Serum levels of thyroid hormone were measured by fluorescence and chemiluminescence immunoassays. Among the 6979 included pregnant women, 3470 (49.7%) received at least two doses of an inactivated vaccine. COVID-19 vaccination had a statistically significant association with both maternal serum levels of free thyroxine (FT4) and thyroid stimulating hormone (TSH). Compared with unvaccinated pregnant women, the mean FT4 levels were lower in pregnant women who had been vaccinated within 3 months before the date of conception by 0.27â€‰pmol/L (Î²â€‰=â€‰-0.27, 95% confidence interval [CI], -0.42, -0.12), and the mean TSH levels were higher by 0.08 mIU/L (Î²â€‰=â€‰0.08, 95% CI, 0.00, 0.15). However, when the interval from vaccination to conception was prolonged to more than 3 months, COVID-19 vaccination was not associated with serum FT4 or TSH levels. Moreover, we found that COVID-19 vaccination did not significantly associate with maternal hypothyroidism. Our study suggested that vaccination with

inactivated COVID-19 vaccines before conception might result in a small change in maternal thyroid function, but this did not reach clinically significant levels.
Newly-diagnosed immunoglobulin A nephropathy with increased plasma galactose-deficient-IgA(1) antibody associated with mRNA COVID-19 vaccination: a case report. Newly-diagnosed or relapses of immunoglobulin A nephropathy (IgAN) have been associated with COVID-19 vaccination in the literature. Most reported cases were mild clinical diseases characterized by microscopic haematuria and do not require dialysis treatment. This current case report describes a 55-year-old male patient that presented to the emergency department with acute kidney injury after receiving the first dose of the mRNA-1273 COVID-19 vaccine. After admission, his renal function deteriorated rapidly, and then he developed uraemic encephalopathy. He underwent emergency haemodialysis with a rapid improvement in his mental status. Renal biopsy showed newly-diagnosed IgA nephropathy along with markedly elevated plasma level of galactose-deficient-IgA(1) (Gd-IgA(1)) antibody. The patient did not receive immunosuppressive treatment and is now dialysis-free. Immune activation is considered an essential factor in developing or exacerbating IgAN following COVID-19 vaccination. This current case report demonstrates that elevated Gd-IgA(1) antibody may be the potential mechanistic link between COVID-19 vaccination and IgAN.
The value of public-private collaborative real-world evidence platforms to monitor vaccine performance post authorization: DRIVE - a European initiative. INTRODUCTION: Fighting pandemics requires an established infrastructure for pandemic preparedness, with existing, sustainable platforms ready to be activated. This includes platforms for disease surveillance, virus circulation, and vaccine performance monitoring based on Real-World data, to complement clinical trial evidence. AREAS COVERED: Because of its complexity, this can best be done by combining efforts between public and private sectors, developing a multi-stakeholder approach. Public-Private-Partnerships increasingly play a critical role in combating infectious diseases but are still looked at with hesitancy. The Development of Robust and Innovative Vaccine Effectiveness (DRIVE) project, which established a platform for measuring brand-specific influenza vaccine effectiveness in Europe, exemplifies how to build a collaborative platform with transparent governance, state-of-the-art methodology, and a large network of participating sites. Lessons learned from DRIVE have been cardinal to set up COVIDRIVE, a platform for brand-specific COVID-19 vaccine effectiveness monitoring. EXPERT OPINION: The DRIVE partners propose that a debate on the benefits of Public-Private-Partnership-generated real-world evidence for vaccine effectiveness monitoring should be pursued to clarify roles and responsibilities, set up expectations, and decide the future environment for vaccine monitoring in Europe. In parallel, the driving factors behind PPP hesitancy should be studied.
Cases of Rapid Hepatitis B Surface Antigen Reduction after COVID-19 Vaccination. Objective One of the therapeutic goals for chronic infection with hepatitis B virus is the clearance of hepatitis B surface antigen (HBsAg) from the blood, as a high load of HBsAg has been proposed to induce antigen-specific immunotolerance. To achieve HBsAg reduction, Pegylated interferon and nucleos (t) ide analogs are used to treat chronic hepatitis B. Following the coronavirus disease 2019 (COVID-19) outbreak, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection has rapidly spread worldwide, and vaccination with mRNA COVID-19 vaccines has been conducted since 2021 in Japan. We experienced three clinical cases in which HBsAg levels rapidly decreased after injection of the COVID-19 vaccine without any incentive. Method To examine whether the vaccine administration was involved in the HBsAg reduction, the number of patients with chronic hepatitis B showing a change in the HBsAg levels during the period before the commencement of the COVID-19 vaccination program in Japan (i.e. until the end of 2020; pre-vaccination-program period) was compared to the number of those who showed a change in HBsAg levels after the initiation of the program (i.e. 2021

onwards; post-vaccination-program period). Results The number of patients whose HBsAg levels was reduced by >50% per year was prominent after the initiation of the vaccination program. Although the involvement of vaccination in HBsAg reduction was not statistically proven (p=0.0532), the result suggests that the administration of COVID-19 vaccines may have been involved in HBsAg reduction in patients with chronic hepatitis B. Conclusion COVID-19 vaccines may be involved in HBsAg reduction.

COVID-19 Vaccination-associated Thoracic Outlet Syndrome.

Evaluation of the T cell and B cell response following the administration of COVID-19 vaccines in Korea. BACKGROUND: The coronavirus disease (COVID-19) has been a worldwide concern since 2019. Vaccines are predicted to be crucial in preventing further outbreaks. The development and kinetics of immune responses determine the efficacy of COVID-19 vaccines. METHODS: We measured interferon-gamma (IFN-Î³) levels upon administering homologous adenovirus vector-based (ChAdOx1-S [AZ], Ad26.COV2.S [JAN]), mRNA-based (BNT162b2 [PF]; mRNA-1273 [MO]), and heterologous (AZ/PF) vaccines in healthy Korean individuals using two IFN-Î³ release assays: the Covi-FERON ELISA and T-SPOT Discovery SARS-CoV-2 assay. B cell responses were evaluated by assessing the production of neutralizing antibodies by surrogate virus neutralization assay. The immune response among the vaccine groups was compared after adjusting the vaccination dose and interactions between each group. RESULTS: AZ triggered the highest T cell response after the first dose but showed instability after the second. PF and MO yielded stable and higher increments of T and B cell responses compared to AZ. MO yielded a higher immune response than PF. JAN yielded T and B cell responses at lower levels than the other vaccines. The booster dose triggered significant increases in the T and B cell responses and is therefore needed to protect against SARS-CoV-2 given the possibility of waning immune responses. CONCLUSION: Administering two doses of mRNA vaccines provides the most effective results among the administered vaccines in triggering the immune response specific to SARS-CoV-2 in healthy Korean individuals. Administration of booster doses demonstrated a significant increase in the immune response and may provide longer protection against SARS-CoV-2.

Liver injury with autoimmune features after vaccination against SARS-CoV-2: The verdict is still open.

Evaluation of mRNA-1273 Vaccine in Children 6 Months to 5 Years of Age. BACKGROUND: The safety, reactogenicity, immunogenicity, and efficacy of the mRNA-1273 coronavirus disease 2019 (Covid-19) vaccine in young children are unknown. METHODS: Part 1 of this ongoing phase 2-3 trial was open label for dose selection; part 2 was an observer-blinded, placebo-controlled evaluation of the selected dose. In part 2, we randomly assigned young children (6 months to 5 years of age) in a 3:1 ratio to receive two 25-Î¼g injections of mRNA-1273 or placebo, administered 28 days apart. The primary objectives were to evaluate the safety and reactogenicity of the vaccine and to determine whether the immune response in these children was noninferior to that in young adults (18 to 25 years of age) in a related phase 3 trial. Secondary objectives were to determine the incidences of Covid-19 and severe acute respiratory syndrome coronavirus 2 infection after administration of mRNA-1273 or placebo. RESULTS: On the basis of safety and immunogenicity results in part 1 of the trial, the 25-Î¼g dose was evaluated in part 2. In part 2, 3040 children 2 to 5 years of age and 1762 children 6 to 23 months of age were randomly assigned to receive two 25-Î¼g injections of mRNA-1273; 1008 children 2 to 5 years of age and 593 children 6 to 23 months of age were randomly assigned to receive placebo. The median duration of follow-up after the second injection was 71 days in the 2-to-5-year-old cohort and 68 days in the 6-to-23-month-old cohort. Adverse events were mainly low-grade and transient, and no new safety concerns were identified. At day 57, neutralizing antibody geometric mean concentrations were 1410 (95% confidence interval [CI], 1272 to 1563) among 2-to-5-year-olds and 1781 (95% CI, 1616 to 1962) among 6-to-23-month-olds, as compared with 1391 (95% CI, 1263 to 1531) among young adults, who had received 100-Î¼g injections of mRNA-1273, findings that met the noninferiority criteria for immune responses for both age cohorts. The

estimated vaccine efficacy against Covid-19 was 36.8% (95% CI, 12.5 to 54.0) among 2-to-5-year-olds and 50.6% (95% CI, 21.4 to 68.6) among 6-to-23-month-olds, at a time when B.1.1.529 (omicron) was the predominant circulating variant. CONCLUSIONS: Two 25-Î¼g doses of the mRNA-1273 vaccine were found to be safe in children 6 months to 5 years of age and elicited immune responses that were noninferior to those in young adults. (Funded by the Biomedical Advanced Research and Development Authority and National Institute of Allergy and Infectious Diseases; KidCOVE ClinicalTrials.gov number, NCT04796896.).
Myocarditis after BNT162b2 Vaccination in Israeli Adolescents.
Predictors of impaired antibody response after SARS-CoV-2 mRNA vaccination in hematopoietic cell transplant recipients: A Japanese multicenter observational study. HCT recipients reportedly have a high mortality rate after developing COVID-19. SARS-CoV-2 vaccination is generally useful to prevent COVID-19. However, its safety and efficacy among HCT recipients remain elusive. This large-scale prospective observational study including 543 HCT recipients with 37-months interval from transplant demonstrated high safety profiles of mRNA vaccine: only 0.9% of patients avoided the second dose due to adverse event or GVHD aggravation following the first dose. Regarding the efficacy, serological response with a clinically relevant titer (â‰¥250 BAU/mL) was obtained in 397 (73.1%) patients. We classified the remaining 146 patients as impaired responders and compared the clinical and immunological parameters between two groups. In allogeneic HCT recipients, multivariable analysis revealed the risk factors for impaired serological response as follows: age (â‰¥60, 1 points), HLA-mismatched donor (1 points), use of systemic steroids (1 points), absolute lymphocyte counts (<1000/Î¼L, 1 points), absolute B-cell counts (<100/Î¼L, 1 points), and serum IgG level (<500â€‰mg/dL, 2 points). Notably, the incidence of impaired serological response increased along with the risk scores: patients with 0, 1-3, and 4-7 points were 3.9%, 21.8%, and 74.6%, respectively. In autologous HCT recipients, a shorter interval from transplant to vaccination was the only risk factor for impaired serological response. Our findings indicate that two doses of SARS-CoV-2 vaccine are safe but insufficient for a part of HCT recipients with higher risk scores. To improve this situation, we should consider additional treatment options, including booster vaccination and prophylactic neutralizing antibodies during the SARS-CoV-2 pandemic.
Herpes zoster after COVID-19 vaccination in an adolescent.
A new eruption of bullous pemphigoid following mRNA COVID-19 vaccination. The rapid development and implementation of COVID-19 vaccines throughout the global population has given rise to unique, rare, adverse skin reactions. This case report describes an elderly man with new-onset bullous pemphigoid following the second dose of the Pfizer-BioNTech (mRNA) COVID-19 vaccine.
Severe bullous drug reaction after COVID-19 mRNA vaccination.
Hypoglossal Nerve Palsy Following COVID-19 Vaccination in a Young Adult Complicated by Various Medicines. Mononeuritis multiplex is a rare form of cerebral nerve palsy caused by various factors. Coronavirus disease 2019 (COVID-19) vaccination could be an etiology of mononeuritis multiplex, which can affect various nerves. Post-COVID-19 and vaccination-related neurological impairments involve cranial nerves such as the facial, trigeminal, and vagal nerves. We report our experience with a 34-year-old man who developed hypoglossal nerve palsy following COVID-19 vaccination, complicated by progressive mononeuritis multiplex. Hypoglossal nerve palsy may occur following COVID-19 vaccination. The symptoms vary and may progress without treatment. Physicians should consider the possibility of mononeuritis multiplex after COVID-19 vaccination and provide prompt treatment for acute symptom progression.
COVID-19 Vaccine as a Potential Triggering Factor for Anti-Glomerular Basement Membrane (GBM) Disease: A Case Report and Literature Review. Coronavirus 2019 (COVID-19) is considered one of the most significant medical pandemics ofÂ this century, with high morbidity and mortality associated

with the pandemic. The virus was recognized initially as a cause of pneumonia, but subsequent studies showed significant association with gastrointestinal, neurological, and autoimmune diseases.Â By 2020, several vaccines became available for use, significantly reducing the infection rate. A good safety profile supported most of the studies related to vaccines. However, this area is still under study, and some reports linked the COVID-19 vaccine to the development of thrombocytopenia, thrombosis, Guillain-Barre syndrome, autoimmune diseases, and myocarditis. These side effects need to be reported to VAERS (Vaccine Adverse Event Reporting System). The exact etiology of anti-glomerular basementÂ (Anti-GBM) disease remains unknown, but the disease is thought to be triggered by environmental factors in genetically predisposed individuals. It is considered one of the serious diseases that could lead to permanent kidney impairment if not treated early and adequately. That's why a great effort is being made by health care practitioners to figure out and avoid the risk and triggering factors. Few previously published papers linked the COVID-19 vaccine and the development of anti-GBM disease, which raised concerns about digging more into this area. Herein, we are reporting a case of a patient who developed rapidly progressive glomerulonephritis (RPGN) due to anti-glomerular basement membrane (GBM) antibody disease two days after receiving the second dose of the COVID-19 vaccine.
COVID-19 Vaccination-Induced Cholangiopathy and Autoimmune Hepatitis: A Series of Two Cases. The coronavirus disease 2019 (COVID-19) pandemic has been associated with significant morbidity and mortality. Following the introduction of vaccines, various side effects have been reported. Whilst those reported may be attributed to the vaccine itself, at times, it may simply incite an immunological phenomenon. We present a case series of two patients who presented with symptoms of yellowing of the eyes and the skin along with fatigue, and tiredness, following vaccination for COVID-19. The diagnosis of post COVID-19-vaccination related hepatitis is one of the fewer, less understood, yetÂ reported side effects associated with significant morbidity. The diagnosis of COVID-19 vaccination-related cholangitis is an outcome reported here for the first time to the best of our knowledge. It was alarming that both patients did not haveÂ any significant past history of medical ailments. A prompt assessment followed by investigations including liver biopsy assisted in a timely understanding of the phenomenon with complete resolution of the symptoms.
Autoimmune seronegative limbic encephalitis following ChAdOx1-S/nCoV-19 vaccination in a patient with ankylosing spondylitis.
Immunity After Vaccination Against SARS-CoV-2 in Lung Transplant? BACKGROUND: SARS-CoV2 infection causes high morbidity and mortality in lung transplant (LT) recipients. Vaccination with messenger RNA vaccines has been shown to play a key role in controlling the severity of infection in the general population. The aim of our study is to analyze whether vaccination with 2 doses of SARS-Cov2 provides immunity in LT recipients. METHODS: Retrospective descriptive and analytical study of LT recipients vaccinated with 2 doses of SARS-CoV2. We analyzed the vaccine received, if they had COVID-19, antibody levels (antispike and antinucleoprotein), anticalcineurin levels, infections in the last year, and presence of neoplasias. RESULTS: The most commonly administered vaccine was from Moderna, with 27% of patients showing immunity with a median antibody levels of 4.81 binding antibody units/mL, far from the values considered protective (> 34 binding antibody units/mL). Thirteen patients were infected with SARS-CoV2, 7 post vaccination (5 of them were antispike-positive). No relationship was demonstrated between generation of immunity and age and level of immunosuppression. CONCLUSIONS: Vaccination against SARS-CoV2 in LT recipients generates limited and ineffective immunity with only 2 doses.
Drug induced hepatitis and SARS-CoV-2 vaccination: Correspondence.
A comparative characterization of SARS-CoV-2-specific TÂ cells induced by mRNA or inactive virus COVID-19 vaccines. Unlike mRNA vaccines based only on the spike protein, inactivated severe

acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccines should induce a diversified TÂ cell response recognizing distinct structural proteins. Here, we perform a comparative analysis of SARS-CoV-2-specific TÂ cells in healthy individuals following vaccination with inactivated SARS-CoV-2 or mRNA vaccines. Relative to spike mRNA vaccination, inactivated vaccines elicit a lower magnitude of spike-specific TÂ cells, but the combination of membrane, nucleoprotein, and spike-specific TÂ cell response is quantitatively comparable with the sole spike TÂ cell response induced by mRNA vaccine, and they efficiently tolerate the mutations characterizing the Omicron lineage. However, this multi-protein-specific TÂ cell response is not mediated by a coordinated CD4 and CD8 TÂ cell expansion but by selective priming of CD4 TÂ cells. These findings can help in understanding the role of CD4 and CD8 TÂ cells in the efficacy of the different vaccines to control severe COVID-19 after Omicron infection.

A systematic review of current status and challenges of vaccinating children against SARS-CoV-2. The coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has inflicted immense damage to countries, economies and societies worldwide. Authorized COVID-19 vaccines based on different platforms have been widely inoculated in adults, showing up to 100% immunogenicity with significant efficacy in preventing SARS-CoV-2 infections and the occurrence of severe COVID-19. It has also greatly slowed the evolution of SARS-CoV-2 variants, as shown in clinical trials and real-world evidence. However, the total dosage of COVID-19 vaccines for children is much smaller than that for adults due to limitations from parental concern of vaccine safety, presenting a potential obstacle in ending the COVID-19 pandemic. SARS-CoV-2 not only increases the risk of severe multisystem inflammatory syndrome (MIS-C) in children, but also negatively affects children's psychology and academics, indirectly hindering the maintenance and progress of normal social order. Therefore, this article examines the clinical manifestations of children infected with SARS-CoV-2, the status of vaccination against COVID-19 in children, vaccination-related adverse events, and the unique immune mechanisms of children. In particular, the necessity and challenges of vaccinating children against SARS-CoV-2 were highlighted from the perspectives of society and family. In summary, parental hesitancy is unnecessary as adverse events after COVID-19 vaccination have been proven to be infrequent, comprise of mild symptoms, and have a good prognosis.

Psychosis Following COVID-19 Vaccination - A Case Series: Correspondence.

Bilateral Atypical Optic Neuritis following ChAdOx1_nCoV-19 Vaccination: A Putative Plausibility. PURPOSE: In this case report, we describe the clinical features and treatment outcomes of bilateral optic neuritis developing after the administration of the first dose ChAdOx1_nCoV-19 (Covishield) vaccine in a previously healthy young immunocompetent male. STUDY DESIGN: Case report. RESULTS: A 35-year-old healthy male, presented with sudden decrease in vision which was progressive in nature. The symptoms developed two days following the first dose of the Covid ChAdOx1_nCoV-19 vaccine. A possible diagnosis of vaccine associated optic neuritis was based on the temporal association between the administration of vaccine and the development of ocular symptoms and ruling out other immune or infectious etiologies. The patient showed good response to pulse systemic steroids followed by a short course of oral steroids. CONCLUSION: Bilateral optic nerve involvement with disc edema may represent a rare adverse event of covid 19 vaccine which responds well to a short course of steroids.

Comparative Safety of the BNT162b2 Messenger RNA COVID-19 Vaccine vs Other Approved Vaccines in Children Younger Than 5 Years. IMPORTANCE: SARS-CoV-2 vaccines are authorized for use in most age groups. The safety of SARS-CoV-2 vaccines is unknown in children younger than 5 years. OBJECTIVE: To retrospectively evaluate the safety of the BNT162b2 vaccine used off-label in children younger than 5 years compared with the safety of non-SARS-CoV-2 vaccines in the same sample. DESIGN, SETTING, AND PARTICIPANTS: This investigator-initiated retrospective cohort study included

parents or caregivers who registered children for SARS-CoV-2 vaccination in outpatient care facilities in Germany. The study was performed as an authenticated online survey. A total of 19â€¯000 email addresses were contacted from vaccination registration databases between April 14 and May 9, 2022. Inclusion criteria were child age younger than 5 years at the first BNT162b2 vaccination and use of a correct authentication code to prove invitation. EXPOSURES: Off-label BNT162b2 vaccination and on-label non-SARS-CoV-2 vaccinations. MAIN OUTCOMES AND MEASURES: Reported short-term safety data of 1 to 3 doses of 3 to 10 Î¼g BNT162b2 in children from birth to younger than 60 months are presented. Coprimary outcomes were the frequencies of 11 categories of symptoms after vaccination with bivariate analyses and regression models adjusting for age, sex, weight, and height. RESULTS: The study included 7806 children (median age, 3 years [IQR, 2-4 years]; 3824 [49.0%] female) who were followed up of for a mean (SD) of 91.4 (38.8) days since first BNT162b2 vaccination (survey response rate, 41.1%). A 10-Î¼g dosage was more frequently associated with local injection-site symptoms compared with lower dosages. In the active-comparator analysis, the probability of any symptoms (odds ratio [OR], 1.62; 95% CI, 1.43-1.84), local symptoms (OR, 1.68; 95% CI, 1.38-2.05), musculoskeletal symptoms (OR, 2.55; 95% CI, 1.32-4.94), dermatologic symptoms (OR, 2.18; 95% CI, 10.7-4.45), or otolaryngologic symptoms (OR, 6.37; 95% CI, 1.50-27.09) were modestly elevated after BNT162b2 compared with non-SARS-CoV-2 vaccines, whereas the probabilities of general symptoms (OR, 0.77; 95% CI, 0.63-0.95) and fever (OR, 0.42; 95% CI, 0.32-0.55) were lower after BNT162b2. Symptoms requiring hospitalization (nâ€‰=â€‰10) were reported only at BNT162b2 dosages above 3 Î¼g. CONCLUSIONS AND RELEVANCE: In this cohort study, the symptoms reported after BNT162b2 administration were comparable overall to those for on-label non-SARS-CoV-2 vaccines in this cohort of children younger than 5 years. The present data may be used together with prospective licensure studies of BNT162b2 efficacy and safety and could help guide expert recommendations about BNT162b2 vaccinations in this age group.

Case series of chronic spontaneous urticaria following COVID-19 vaccines: an unusual skin manifestation. BACKGROUND: Urticaria following the COVID-19 vaccine was rarely reported and had a short self-limited resolution. However, there has been relatively little literature published on CSU induced by COVID-19 vaccines. PURPOSE: We describe a case series of patients who experienced CSU after SARS-CoV-2 vaccination. METHODS: A retrospective case series of 10 patients referred to the Department of Clinical Pharmacology of the University of Monastir (January 2021-January 2022) and included for evaluation of urticaria after COVID-19 vaccination. RESULTS: The median age was 31Â years and patients were mostly female. Atopy was presented in 3 patients and urticaria was accompanied by angioedema in 6 patients. The median time interval between vaccination and the onset of urticaria was 28.5Â h. The offended dose was the first one in 8 patients. The resolution of the eruption was observed at least 2Â months later, despite the regular use of a full dose of antihistamine in nine patients. Polynuclear leucocytosis was identified in 5 patients. Anti-TPOAb was positive in one patient after receiving the BNT162b2 vaccine. Total serum IgE was elevated in 4 patients. Skin tests for the suspected vaccine as well as the vaccine excipient were negative. CONCLUSION: We add to the medical literature ten new cases of chronic spontaneous urticarial reactions following COVID-19 vaccines uncontrolled with high-dose first-generation H1 antihistamines.

Association of mRNA Vaccination With Clinical and Virologic Features of COVID-19 Among US Essential and Frontline Workers. IMPORTANCE: Data on the epidemiology of mild to moderately severe COVID-19 are needed to inform public health guidance. OBJECTIVE: To evaluate associations between 2 or 3 doses of mRNA COVID-19 vaccine and attenuation of symptoms and viral RNA load across SARS-CoV-2 viral lineages. DESIGN, SETTING, AND PARTICIPANTS: A prospective cohort study of essential and frontline workers in Arizona, Florida, Minnesota, Oregon, Texas, and Utah with

COVID-19 infection confirmed by reverse transcriptase-polymerase chain reaction testing and lineage classified by whole genome sequencing of specimens self-collected weekly and at COVID-19 illness symptom onset. This analysis was conducted among 1199 participants with SARS-CoV-2 from December 14, 2020, to April 19, 2022, with follow-up until May 9, 2022, reported. EXPOSURES: SARS-CoV-2 lineage (origin strain, Delta variant, Omicron variant) and COVID-19 vaccination status. MAIN OUTCOMES AND MEASURES: Clinical outcomes included presence of symptoms, specific symptoms (including fever or chills), illness duration, and medical care seeking. Virologic outcomes included viral load by quantitative reverse transcriptase-polymerase chain reaction testing along with viral viability. RESULTS: Among 1199 participants with COVID-19 infection (714 [59.5%] women; median age, 41 years), 14.0% were infected with the origin strain, 24.0% with the Delta variant, and 62.0% with the Omicron variant. Participants vaccinated with the second vaccine dose 14 to 149 days before Delta infection were significantly less likely to be symptomatic compared with unvaccinated participants (21/27 [77.8%] vs 74/77 [96.1%]; OR, 0.13 [95% CI, 0-0.6]) and, when symptomatic, those vaccinated with the third dose 7 to 149 days before infection were significantly less likely to report fever or chills (5/13 [38.5%] vs 62/73 [84.9%]; OR, 0.07 [95% CI, 0.0-0.3]) and reported significantly fewer days of symptoms (10.2 vs 16.4; difference, -6.1 [95% CI, -11.8 to -0.4] days). Among those with Omicron infection, the risk of symptomatic infection did not differ significantly for the 2-dose vaccination status vs unvaccinated status and was significantly higher for the 3-dose recipients vs those who were unvaccinated (327/370 [88.4%] vs 85/107 [79.4%]; OR, 2.0 [95% CI, 1.1-3.5]). Among symptomatic Omicron infections, those vaccinated with the third dose 7 to 149 days before infection compared with those who were unvaccinated were significantly less likely to report fever or chills (160/311 [51.5%] vs 64/81 [79.0%]; OR, 0.25 [95% CI, 0.1-0.5]) or seek medical care (45/308 [14.6%] vs 20/81 [24.7%]; OR, 0.45 [95% CI, 0.2-0.9]). Participants with Delta and Omicron infections who received the second dose 14 to 149 days before infection had a significantly lower mean viral load compared with unvaccinated participants (3 vs 4.1 log10 copies/Î¼L; difference, -1.0 [95% CI, -1.7 to -0.2] for Delta and 2.8 vs 3.5 log10 copies/Î¼L, difference, -1.0 [95% CI, -1.7 to -0.3] for Omicron). CONCLUSIONS AND RELEVANCE: In a cohort of US essential and frontline workers with SARS-CoV-2 infections, recent vaccination with 2 or 3 mRNA vaccine doses less than 150 days before infection with Delta or Omicron variants, compared with being unvaccinated, was associated with attenuated symptoms, duration of illness, medical care seeking, or viral load for some comparisons, although the precision and statistical significance of specific estimates varied.

Serological response after anti-SARS-CoV-2 BNT162b2 vaccine in IBD patients on biological therapy: a monocentric case-control study. BACKGROUND: Inflammatory bowel disease (IBD) patients on biological therapy are receiving vaccines against severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2). However, it is unclear if IBD therapy could influence the response to this vaccine. In a case-control study, we assessed the antibody profiling after anti-SARS-CoV-2 BNT162b2 vaccine in IBD patients on biological therapy. METHODS: We analyzed seroprevalence and antibody titer, after 14 weeks from the first BNT162b2 vaccine dose, in IBD patients on biological therapy and health care workers (HCWs). In IBD patients, medical history and disease data were recorded. RESULTS: Eighty-two subjects were enrolled in this study. Among them, 40 were IBD patients on biological therapy and 42 were HCWs. All subjects developed an IgG anti-Spike antibody titer above the cut-off. IBD patients on biological therapy developed a lower antibody titer than HCWs (P<0.00001). No differences were reported in patients who received at least one dose of the vaccine within a period of 7 days from the last biological drug administration, compared to all other IBD patients. A difference was found between patients who were on concomitant immunosuppressive therapy and patients on sole biological therapy (P=0.0287). Patients with presence of any sign of disease activity (clinical, endoscopic or laboratory) showed a higher development of antibody titer compared to those in

complete disease remission (P=0.0468). CONCLUSIONS: Our data indicate that in IBD patients, treatment with biological therapies do not affect the seroprevalence but leads to a lower antibody titer development after anti-SARS-CoV-2 BNT162b2 vaccine.

Coronavirus disease 2019 vaccination-induced acute exacerbation in idiopathic pulmonary fibrosis. We report a rare case of acute exacerbation (AE) of idiopathic pulmonary fibrosis (IPF) after coronavirus disease 2019 (COVID-19) vaccination. Clinicians should be aware of this COVID-19 vaccination-induced AE in IPF.

Guillain-BarrÃ© syndrome following COVID-19 vaccine: AÂ case report. Coronavirus disease is a viral infection affecting different organs with various morbidities and mortality. Vaccines are used to control the disease. COVID-19 vaccines have brought many benefits but their adverse effects should not be ignored. Here, we report a case of Guillain-BarrÃ© Syndrome Following Sinopharm COVID-19 Vaccine.

Silent progressive bilateral papillitis after COVID-19 vaccination: A case report. RATIONALE: We report the case of a patient who developed asymptomatic bilateral papillitis after coronavirus disease 2019 (COVID-19) vaccination. PATIENT CONCERNS: A 61-year-old man presented to our tertiary clinic with bilateral optic disc edema, which was incidentally detected during his visit to a primary ophthalmology clinic. He had received an adenovirus-vectored COVID-19 vaccine 2 weeks before the optic disc edema was detected and had experienced no ocular discomfort, except for a floater in his right eye. Although his visual acuity was normal and he had no color vision deficiencies or marked visual field defects, the optic disc edema worsened over several days. Orbital magnetic resonance imaging showed no optic tract enhancement, and lumbar puncture revealed normal cerebrospinal fluid pressure. The patient tested negative for aquaporin-4 and myelin oligodendrocyte glycoprotein antibodies and Leber hereditary optic neuropathy-associated gene mutations. DIAGNOSIS: The patient was diagnosed with bilateral papillitis, possibly induced by the COVID-19 vaccination. INTERVENTIONS: The patient received steroid pulse therapy with methylprednisolone (500â€‰mg/day) for 3 days followed by an oral prednisolone taper for 3 weeks. OUTCOMES: The patient's papillitis started to subside 3 weeks after he received systemic steroid therapy and completely resolved without any sequelae 2 months later. A year after the diagnosis, the fundus remained stable without disease recurrence or optic disc atrophy. LESSONS: Healthy individuals receiving COVID-19 vaccines may present with various manifestations of optic neuritis. In the present case, the patient presented with asymptomatic progressive bilateral optic disc edema and had a favorable long-term course after receiving steroid therapy.

A population-based matched cohort study of early pregnancy outcomes following COVID-19 vaccination and SARS-CoV-2 infection. Data on the safety of COVID-19 vaccines in early pregnancy are limited. We conducted a national, population-based, matched cohort study assessing associations between COVID-19 vaccination and miscarriage prior to 20 weeks gestation and, separately, ectopic pregnancy. We identified women in Scotland vaccinated between 6 weeks preconception and 19 weeks 6 days gestation (for miscarriage; nâ€‰=â€‰18,780) or 2 weeks 6 days gestation (for ectopic; nâ€‰=â€‰10,570). Matched, unvaccinated women from the pre-pandemic and, separately, pandemic periods were used as controls. Here we show no association between vaccination and miscarriage (adjusted Odds RatioÂ [aOR], pre-pandemic controlsâ€‰=â€‰1.02, 95% Confidence Interval [CI]â€‰=â€‰0.96-1.09) or ectopic pregnancy (aORâ€‰=â€‰1.13, 95% CIâ€‰=â€‰0.92-1.38). We undertook additional analyses examining confirmed SARS-CoV-2 infection as the exposure and similarly found no association with miscarriage or ectopic pregnancy. Our findings support current recommendations that vaccination remains the safest way for pregnant women to protect themselves and their babies from COVID-19.

One-month humoral response following two or three doses of messenger RNA coronavirus disease 2019 vaccines as primary vaccination in specific populations in France: first results from the Agence Nationale Recherche contre le Sida (ANRS)0001S COV-POPART cohort. OBJECTIVES: We aimed to investigate the 1-month humoral response to two or three doses of a messenger RNA coronavirus disease 2019 (COVID-19) vaccine as a primary vaccination regimen in specific populations compared with that in healthy adults. METHODS: Agence Nationale Recherche contre le Sida (ANRS)0001S-COV-POPART (NCT04824651) is a French nation-wide, multi-centre, prospective, observational cohort study assessing the immune response to COVID-19 vaccines routinely administered to 11 sub-groups of patients with chronic conditions and two control groups. Patients and controls who received at least two vaccine doses and whose results 1Â month after the second dose were available were included. The humoral response was assessed 1Â month after the first, second and third doses (if applicable) based on the percentage of responders (positive for anti-Spike severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] IgG antibodies), geometric means of anti-Spike SARS-CoV-2 IgG antibodies (enzyme-linked immunosorbent assay) and proportion of participants with anti-SARS-CoV-2-specific neutralizing antibodies (inÂ vitro neutralization assay for the original SARS-CoV-2 strain). All analyses were centralized. RESULTS: We included 4091 participants in this analysis: 2979 participants from specific sub-populations and 1112 controls. Only 522 (17.5%) participants from the specific populations received three doses as a primary vaccination regimen. Patients living with human immunodeficiency virus, cancer and diabetes had high percentages of responders after two doses, whereas patients with solid organ transplants, allogeneic hematopoietic stem cell transplants and hypogammaglobulinaemia had the lowest percentage of responders (35.9% [95% CI, 29.2-43.0], 57.4% [95% CI, 48.1-66.3] and 77.1% [95% CI, 65.6-86.3], respectively). In those who received the third dose, the percentage of responders reached 54.2% (95% CI, 42.9-65.2) (vs. 32.3% [95% CI, 16.7-51.4] after 2 doses) among those with solid organ transplants and 73.9% (95% CI, 58.9-85.7) (vs. 56.1% [95% CI, 46.2-65.7] after 2 doses) among those with hematopoietic stem cell transplants. Similar results were found with anti-SARS-CoV-2-specific neutralizing antibodies. CONCLUSIONS: A lower humoral response to COVID-19 vaccines was observed in the specific populations compared with that in the controls. The third dose of this vaccine in the primary regimen had a positive effect on the percentages of patients who developed anti-Spike IgG antibodies and specific neutralizing antibodies.

BNT162b2-induced neutralizing and non-neutralizing antibody functions against SARS-CoV-2 diminish with age. Each severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variant renews concerns about decreased vaccine neutralization weakening efficacy. However, while prevention of infection varies, protection from disease remains and implicates immunity beyond neutralization in vaccine efficacy. Polyclonal antibodies function through Fab domains that neutralize virus and Fc domains that induce non-neutralizing responses via engagement of Fc receptors on immune cells. To understand how vaccines promote protection, we leverage sera from 51 SARS-CoV-2 uninfected individuals after two doses of the BNT162b2 mRNA vaccine. We show that neutralizing activities against clinical isolates of wild-type and five SARS-CoV-2 variants, including Omicron BA.2, link to Fcî³RIIIa/CD16 non-neutralizing effector functions. This is associated with post-translational afucosylation and sialylation of vaccine-specific antibodies. Further, polyfunctional neutralizing and non-neutralizing breadth, magnitude, and coordination diminish with age. Thus, studying Fc functions in addition to Fab-mediated neutralization provides greater insight into vaccine efficacy for vulnerable populations, such as the elderly, against SARS-CoV-2 and novel variants.

Comparing public knowledge around value of hand and respiratory hygiene, vaccination, and pre- and post-national COVID-19 lockdown in England. OBJECTIVES: The COVID-19 pandemic spotlighted the importance of infection prevention and control (IPC) measures. Existing literature focuses on

healthcare professionals, whereas this article explores changes in public knowledge of IPC, where knowledge is comparably sparse. STUDY DESIGN: National surveys were conducted before (March 2020) and after (March 2021) the COVID-19 lockdown across England. METHODS: A telephone survey of 1676 adults (2021) and a face-to-face survey of 2202 adults (2020) across England were conducted. Key demographics were representative of the population. Weighted logistic regression with composite Wald P-values was used to investigate knowledge change from 2020 to 2021. RESULTS: Compared with 2020, significantly more respondents correctly stated that infections can spread by shaking hands (86% post vs 79% pre; PÂ <Â .001) and that microbes are transferred through touching surfaces (90% vs 80%; PÂ <Â .001). More knew that hand gel is effective at removing microbes if water and soap are unavailable (94% vs 92%; PÂ =Â .015); that when you cough, you may infect other people near you in a room (90% vs 80%; PÂ <Â .001). Knowledge that vaccination protects others from infection also increased (63% post vs 50% pre; PÂ <Â .001). There was also significant increase in those confident in their answers. CONCLUSION: Knowledge of IPC measures was higher in 2021 than before the pandemic. Future public health hygiene campaigns should capitalise on this and emphasise that continuing hygiene behaviours, and vaccination can help prevent acquisition and illnesses with other non-COVID-19 infections, thus reducing the strain on the national health service.

New Onset or Deterioration of Thyroid Eye Disease After mRNA SARS-CoV-2 Vaccines: Report of 2 Cases and Literature Review. CONTEXT: Occurrence of Graves' disease (GD) has been reported following SARS-CoV-2 vaccine administration, but little is known about thyroid eye disease (TED) after SARS-CoV-2 vaccination. OBJECTIVE: We describe 2 cases of TED activation following mRNA SARS-CoV-2 vaccination and review additional cases reported in the literature. METHODS: We report 2 cases of TED activation following SARS-CoV-2 vaccination: 1 case of TED worsening in a patient with GD, and 1 of de novo active TED progressing to dysthyroid optic neuropathy in a patient with a history of Hashimoto hypothyroidism. Our literature search revealed 8 additional reported TED cases associated with SARS-CoV-2 vaccination until June 2022. We review the characteristics, duration, and management of TED following SARS-CoV-2 vaccination in these cases. RESULTS: Of all 10 reported TED cases following SARS-CoV-2 vaccination, 4 developed new-onset TED and 6 previously stable TED cases experienced significant deterioration. Six patients had known GD and 2 patients had Hashimoto thyroiditis. Two cases progressed to dysthyroid optic neuropathy, 6 had moderate/severe active disease, and 2 had mild disease that did not require treatment. Seven TED cases received teprotumumab and had a favorable response, 2 of whom had prior limited response to initial prednisone or methylprednisolone and tocilizumab therapy. CONCLUSION: New diagnosis or deterioration of TED after mRNA SARS-CoV-2 vaccination can occur, with most cases described in patients with underlying autoimmune thyroid disease. Our report raises awareness to this potential complication to promote early recognition and prompt management of TED associated with mRNA SARS-CoV-2 vaccines. Further studies are needed to explore the mechanism, risk factors, prevention, and treatment of TED following mRNA SARS-CoV-2 vaccination.

Cellular interferon-gamma and interleukin-2 responses to SARS-CoV-2 structural proteins are broader and higher in those vaccinated after SARS-CoV-2 infection compared to vaccinees without prior SARS-CoV-2 infection. Class I- and Class II-restricted epitopes have been identified across the SARS-CoV-2 structural proteome. Vaccine-induced and post-infection SARS-CoV-2 T-cell responses are associated with COVID-19 recovery and protection, but the precise role of T-cell responses remains unclear, and how post-infection vaccination ('hybrid immunity') further augments this immunity To accomplish these goals, we studied healthy adult healthcare workers who were (a) uninfected and unvaccinated (n = 12), (b) uninfected and vaccinated with Pfizer-BioNTech BNT162b2 vaccine (2 doses n = 177, one dose n = 1) or Moderna mRNA-1273 vaccine (one dose, n = 1), and (c) previously infected with SARS-CoV-2 and vaccinated (BNT162b2, two doses, n = 6, one dose n = 1; mRNA-1273 two doses,

n = 1). Infection status was determined by repeated PCR testing of participants. We used FluoroSpot Interferon-gamma (IFN-Î³) and Interleukin-2 (IL-2) assays, using subpools of 15-mer peptides covering the S (10 subpools), N (4 subpools) and M (2 subpools) proteins. Responses were expressed as frequencies (percent positive responders) and magnitudes (spot forming cells/106 cytokine-producing peripheral blood mononuclear cells [PBMCs]). Almost all vaccinated participants with no prior infection exhibited IFN-Î³, IL-2 and IFN-Î³+IL2 responses to S glycoprotein subpools (89%, 93% and 27%, respectively) mainly directed to the S2 subunit and were more robust than responses to the N or M subpools. However, in previously infected and vaccinated participants IFN-Î³, IL-2 and IFN-Î³+IL2 responses to S subpools (100%, 100%, 88%) were substantially higher than vaccinated participants with no prior infection and were broader and directed against nine of the 10 S glycoprotein subpools spanning the S1 and S2 subunits, and all the N and M subpools. 50% of uninfected and unvaccinated individuals had IFN-Î³ but not IL2 or IFN-Î³+IL2 responses against one S and one M subpools that were not increased after vaccination of uninfected or SARS-CoV-2-infected participants. Summed IFN-Î³, IL-2, and IFN-Î³+IL2 responses to S correlated with IgG responses to the S glycoprotein. These studies demonstrated that vaccinations with BNT162b2 or mRNA-1273 results in T cell-specific responses primarily against epitopes in the S2 subunit of the S glycoprotein, and that individuals that are vaccinated after SARS-CoV-2 infection develop broader and greater T cell responses to S1 and S2 subunits as well as the N and M proteins.

Immunogenicity and reactogenicity of a third dose of BNT162b2 vaccine for COVID-19 after a primary regimen with BBIBP-CorV or BNT162b2 vaccines in Lima, Peru. BACKGROUND: The administration of a third (booster) dose of COVID-19 vaccines in Peru initially employed the BNT162b2 (Pfizer) mRNA vaccine. The national vaccination program started with healthcare workers (HCW) who received BBIBP-CorV (Sinopharm) vaccine as primary regimen and elderly people previously immunized with BNT162b2. This study evaluated the reactogenicity and immunogenicity of the "booster" dose in these two groups in Lima, Peru. METHODS: We conducted a prospective cohort study, recruiting participants from November to December of 2021 in Lima, Peru. We evaluated immunogenicity and reactogenicity in HCW and elderly patients previously vaccinated with either two doses of BBIBP-CorV (heterologous regimen) or BTN162b2 (homologous regimen). Immunogenicity was measured by anti-SARS-CoV-2 IgG antibody levels immediately before boosting dose and 14 days later. IgG geometric means (GM) and medians were obtained, and modeled using ANCOVA and quantile regressions. RESULTS: The GM of IgG levels increased significantly after boosting: from 28.5Â±5.0 AU/mL up to 486.6Â±1.2 AU/mL (p<0.001) which corresponds to a 17-fold increase. The heterologous vaccine regimen produced higher GM of post-booster anti-SARS-CoV-2 IgG levels, eliciting a 13% increase in the geometric mean ratio (95%CI: 1.02-1.27) and a median difference of 92.3 AU/ml (95%CI: 24.9-159.7). Both vaccine regimens were safe and well tolerated. Previous COVID-19 infection was also associated with higher pre and post-booster IgG GM levels. CONCLUSION: Although both boosting regimens were highly immunogenic, two doses of BBIBP-CorV boosted with BTN162b2 produced a stronger IgG antibody response than the homologous BNT162b2 regimen in the Peruvian population. Additionally, both regimens were mildly reactogenic and well-tolerated.

Humoral and cellular immunity in patients with rare autoimmune rheumatic diseases following SARS-CoV-2 vaccination. OBJECTIVES: Coronavirus 2019 vaccine responses in rare autoimmune rheumatic diseases (RAIRDs) remain poorly understood; in particular there is little known about whether people develop effective T cell responses. We conducted an observational study to evaluate the short-term humoral and cell-mediated T cell response after the second severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination in RAIRD patients compared with healthy controls (HCs). METHODS: Blood samples were collected after the second dose and anti-spike, anti-nucleocapsid antibody levels and SARS-CoV-2-specific T cell responses were measured and compared

with those of HCs. Activation-induced marker and deep phenotyping assays were used to identify differences in T cells between high and no/low antibody groups, followed by multidimensional clustering. RESULTS: A total of 50 patients with RAIRDs were included (31 with AAV, 4 with other systemic vasculitis, 9 with SLE and 6 with myositis). The median anti-spike levels were significantly lower in RAIRD patients compared with HCs (Pâ€‰<â€‰0.0001). Fifteen (33%) patients had undetectable levels and 26 (57%) had levels lower than the lowest HC. Rituximab in the last 12â€‰months (Pâ€‰=â€‰0.003) was associated with reduced immunogenicity compared with a longer pre-vaccination period. There was a significant difference in B cell percentages (Pâ€‰=â€‰0.03) and spike-specific CD4+ T cells (Pâ€‰=â€‰0.02) between no/low antibody vs high antibody groups. Patients in the no/low antibody group had a higher percentage of terminally differentiated (exhausted) T cells. CONCLUSIONS: Following two doses, most RAIRD patients have lower antibody levels than the lowest HC and lower anti-spike T cells. RAIRD patients with no/low antibodies have diminished numbers and poor quality of memory T cells that lack proliferative and functional capacities.

Observational study of antibody levels after second and third SARS-CoV-2 vaccinations in medical workers. BACKGROUND: Countries around the world are actively promoting vaccination against COVID-19. We observed the changes in serum neutralizing antibody titers in medical workers vaccinated with inactivated COVID-19 vaccine, in order to explore the necessity of a third dose of vaccination. METHODS: A total of 62 medical workers in our hospital were observed. Novel coronavirus neutralizing antibody titers in serum were detected by ELISA (enzyme-linked immunoassay). Neutralizing antibody tests followed in four batches according to the different time periods after three vaccinations. Sixty-two observers participated in the first batch of testing for neutralizing antibody, and 18 of them participated in all four batches. Fasting venous blood was taken from all the participants in the morning to detect serum neutralizing antibody titers. RESULTS: Sixty-two medical workers were divided into age groups of 21-30, 31-40, and >40â€‰years, and the antibody titer in the oldest group was significantly lower than that in youngest group (pÂ =Â 0.0137). There was a gradual decrease in antibody titers over time at around 1, 3, and 6â€‰months after the second dose of vaccine (pâ€‰<â€‰0.0001). The antibody positive rate also decreased gradually (pÂ =Â 0.0003). The neutralizing antibody titer around 1â€‰month after the third dose was significantly increased (pâ€‰<â€‰0.0001). Unexpectedly, three participants with negative neutralizing antibody after the first and second dose produced neutralizing antibody with a measurable titer after the third dose. CONCLUSIONS: The neutralizing antibody titer in serum increased significantly after the third dose of vaccine. A third immunization even produced neutralizing antibody in previously negative individuals.

Immunological imprint on peripheral blood in kidney transplant recipients after two doses of SARS-CoV-2 mRNA vaccination in Japan. The immunological imprint after two doses of severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) mRNA vaccination for patients after kidney transplantation (KTx) remain unclear. This study included KTx recipients and volunteer healthy controls (HCs) who received two doses of SARS-CoV-2 mRNA vaccine (Pfizer BioNTech) from January 2021 to December 2021. We analyzed safety within 21 days after each vaccination dose and compared the immune response in peripheral blood mononuclear cells (PBMCs) between the two groups. No graft rejection was observed throughout this study. Adverse events were generally observed within 5 days. The KTx group exhibited a significantly lower degree of symptoms between doses 1 and 2 ($P < 0.001$). Increases in activated subsets of T and B cells expressing human leukocyte antigen (HLA)-DR and/or CD38 were observed in the HC group after dose 2 (both $P < 0.001$), with the greatest increases in HLA-DR(+)CD8(+) T cells and CD38(+)CD19(+) B cells ($P = 0.042$ and $P = 0.031$, respectively). In addition, PD1(+)CD8(+) T cells-but not PD1(+)CD4(+) T cells-increased significantly in

the HC group (P = 0.027). In the KTx group, however, activated HLA-DR(+), CD38(+), and PD1(+) cells remained at baseline levels. Immunoglobulin (Ig)G against SARS-CoV-2 was detected in only four KTx recipients (13.3%) after dose 2 (P < 0.001). Multivariate logistic regression analyses revealed that Î”HLA-DR(+)CD8(+) T cells and Î”CD38(+)CD19(+) B cells were significantly associated with IgG formation (both P = 0.02). SARS-CoV-2 mRNA vaccine generates impaired cellular and humoral immunity for KTx recipients. Results indicate the need for modified vaccination strategies in immunocompromised KTx recipients.

A Case of Recurrent Myocarditis After COVID-19 Vaccination, Due to Acute Myeloid Leukemia. A 25-year-old man presented with chest pain and an elevated troponin level following COVID-19 vaccination. Despite initial response to nonsteroidal anti-inflammatory drugs, he developed a recurrent and relapsing course requiring multiple readmissions. Cardiac magnetic resonance imaging confirmed myocarditis. Due to progressing macrocytic anemia, he was eventually diagnosed with acute myeloid leukemia, thought to be the underlying driver of his recurrent and persistent myocarditis.

Post-COVID-19 Vaccine Limbic Encephalitis: A Case Report. Limbic encephalitis (LE) diagnosis can be challenging due to its broad spectrum of clinical presentation and variety of causes. The most commonly known causes include paraneoplastic and autoimmune, but they can also occur post-vaccine. Since 2020, many people worldwide have received the coronavirus disease 2019 (COVID-19) vaccine after FDA approval. Mild self-limited neurological adverse reactions, including headache and dizziness, were reported post-vaccine. However, emerging few neurological severe events, including encephalitis, have also been reported. Herein, we present a case of a middle-aged female who presented with seizures after two days of receiving the second dose of the Moderna COVID-19 vaccine. A diagnosis of limbic encephalitis was made based on headÂ MRI findings. It was treated with immunosuppressive agents and responded well with no additional neurological sequelae. This caseÂ is unique as it highlights a possible association between limbic encephalitis and the COVID-19 vaccine.

Case report: Bilateral panuveitis resembling Vogt-Koyanagi-Harada disease after second dose of BNT162b2 mRNA COVID-19 vaccine. Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) remains a serious pandemic. COVID-19 vaccination is urgent needed for limiting SARS-CoV-2 outbreaks by herd immunity. Simultaneously, post-marketing surveillance to assess vaccine safety is important, and collection of vaccine-related adverse events has been in progress. Vision-threatening ophthalmic adverse events of COVID-19 vaccines are rare but are a matter of concern. We report a 45-year-old Japanese male with positive for HLA-DR4/HLA-DRB1*0405, who developed bilateral panuveitis resembling Vogt-Koyanagi-Harada (VKH) disease after the second dose of Pfizer-BioNTech COVID-19 mRNA (BNT162b2) vaccine. Glucocorticosteroid (GC) therapy combined with cyclosporine A (CsA) readily improved the panuveitis. The immune profile at the time of onset was analyzed using CyTOF technology, which revealed activations of innate immunity mainly consisting of natural killer cells, and acquired immunity predominantly composed of B cells and CD8(+) T cells. On the other hand, the immune profile in the remission phase was altered by GC therapy with CsA to a profile composed primarily of CD4(+) cells, which was considerably similar to that of the healthy control before the vaccination. Our results indicate that BNT162b2 vaccine may trigger an accidental immune cross-reactivity to melanocyte epitopes in the choroid, resulting in the onset of panuveitis resembling VKH disease.

Early immunological responses to the mRNA SARS-CoV-2 vaccine in patients with neuromuscular disorders. BACKGROUNDS: Intramuscular injection of the SARS-CoV-2 vaccine has raised concerns about its use in patients with neuromuscular disorders (NMDs). We evaluated the response of patients with NMDs to the BNT162b2 vaccine. METHODS: Healthy subjects, patients with spinal

muscular atrophy (SMA), and patients with Duchenne muscular dystrophy (DMD) were included. All participants received two BNT162b2 doses. SARS-CoV-2 antibody titers at baseline and 2 weeks after each vaccination were compared between groups. Residual muscle volume was evaluated in NMDs group. A questionnaire documented adverse reactions. RESULTS: Eleven patients with NMDs (9 with SMA, 2 with DMD; 7 males; aged 32.7 Â± 19.3 years) and 346 healthy subjects (60 males, aged 40.0 Â± 12.4 years) were included. Antibody titers (U/mL) were similar between groups (baseline: <0.40 vs. <0.40, first vaccination, 145 Â± 258 vs. 103 Â± 1192, and second vaccination, 1528 Â± 1265 vs. 1429 Â± 944; p = 1.000, 0.909, and 0.736, respectively). A negative correlation was found between antibody titers and residual muscle volume but was not significant (Mercuri scale, r = -0.429, p = 0.249; fat infiltration rate, r = -0.194, p = 0.618). The adverse reactions were comparable between groups. CONCLUSION: The BNT162b2 vaccine is safe and effective in patients with NMDs.

Humoral and cellular immune response in patients with hematological disorders after two doses of BNT162b2 mRNA COVID-19 vaccine: A single-center prospective observational study (NCT05074706). Hematological patients at higher risk of severe COVID-19 were excluded from the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine trials. In this single-center observational prospective study (NCT05074706), we evaluate immune response in the hematological patients followed at the Hematological Division of San Gerardo Hospital, Monza (Italy) deemed to be severely immunosuppressed after vaccination with two doses of the BNT162b2 vaccine. Anti-SARS-CoV-2 immunoglobulin G titers above the cutoff value of 33.8 BAU/ml were detected in 303 (80.2%) out of the 378 patients enrolled. Patients with lymphoproliferative disorders had a significant lower probability of immunization (43.2% vs. 88.4%, pÂ <Â 0.001). Patients treated with anti-CD20 showed a significantly lower probability of immunization compared to all other treatments (21.4%, pÂ <Â 0.0001). Among 69 patients who failed seroconversion, 15 patients (22.7%) showed a positive T-cell response. Patients previously treated with anti-CD20 were 2.4 times more likely to test positive for T-cell responses (pÂ =Â 0.014). Within a follow-up of 9 months from the second COVID-19 vaccination, symptomatic SARS-CoV-2 infections were reported by 20 patients (5.3%) and four of them required hospitalization. Successful serological or T-cell-mediated immunization conferred protection from symptomatic COVID-19. Patients treated with anti-CD20 who were not seroconverted after vaccination might still be protected from COVID-19 due to the T-cell immune response.

Cytokine release syndrome in a patient with non-small cell lung cancer on ipilimumab and nivolumab maintenance therapy after vaccination with the mRNA-1273 vaccine: a case report. BACKGROUND: Cytokine release syndrome (CRS) is caused by the release of inflammatory cytokines that appear during or immediately after administration of a therapeutic antibody and can cause a variety of symptoms. COVID-19 vaccination is effective in cancer patients and prevents breakthrough infections. The safety of vaccines during immune checkpoint inhibitor (ICI) therapy has been reported; however, multiple vaccinations have been developed in recent years, and it is unclear whether repeated vaccinations play a role in the development of CRS in patients receiving ICI. CASE DESCRIPTION: A 55-year-old man with stage IV non-small cell lung cancer received ipilimumab and nivolumab maintenance therapy; adverse reactions during the first and second COVID-19 vaccinations (BNT162b2) included injection site pain and slight fever; however, the day after the third COVID-19 vaccination (mRNA-1273), he developed a high fever and lost consciousness. Brain MRI showed parietal meningitis. Cytokine levels (IL-6, sIL-2R, IL-10, IFN-Î³) were elevated and Grade 2 liver and renal dysfunction were also observed. As various tests ruled out infection and a PCR test for SARS-CoV-2 was negative, a diagnosis of CRS due to COVID-19 vaccination was made. After steroid therapy, his symptoms improved dramatically. CONCLUSIONS: In this case, there was a close association between the time course after vaccination and clinical symptoms of high fever and lost

consciousness. Clinicians should be aware of the possibility of vaccine-induced adverse effects such as CRS.

A case of aseptic bilateral cavernous sinus thrombosis following a recent inactivated SARS-CoV-2 vaccination. This case report aims to describe the first report of bilateral aseptic cavernous sinus thrombosis (CST) with a recent history of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. A 50-year-old woman presented with bilateral proptosis, decreased vision, and ophthalmoplegia 16 days following CoronaVac(Â®) vaccine. The visual acuity of the left eye was 20/150, while the right eye was no light perception with a hyperemic optic nerve head. She had a history of hyperthyroidism and currently on warfarin consumption. Laboratory results depicted elevated free T4, free T3, international normalized ratio, and low protein S and C. Magnetic resonance imaging showed bilateral CST, and high-dose methylprednisolone along with fondaparinux was given. The symptoms were significantly resolved, with the visual acuity of the left eye being improved to 20/20 but not the right eye. Bilateral CST has not been previously reported following inactivated SARS-CoV-2 vaccination. The underlying systemic conditions should be taken into consideration for the possibility of the inactivated SARS-CoV-2 vaccine-related event.

Case report: Sudden cardiorespiratory collapse in a healthy male after coronavirus disease 2019 vaccination at a vaccination center. Since 2020, new vaccines were developed to fight the coronavirus disease 2019 (COVID-19). Vaccination is important in preventing mortality and achieving herd immunity. However, due to vast vaccination, fatal adverse events could be seen. We report a case of a previously healthy, young male who had a cardiopulmonary arrest 2 min after receiving the Oxford- AstraZeneca (ChAdOx1 nCoV-19) COVID-19 vaccination. After targeted temperature management, a coronary angiogram was performed after neurological recovery and showed severe stenosis at the proximal left anterior descending artery. Stenting was done and he was discharge. No similar case of sudden cardiorespiratory collapse immediately after COVID-19 vaccination has been reported. Our patient did not have any effort-related angina or dyspnea on exertion before this event. The sudden cardiorespiratory collapse was probably related to underlying coronary artery disease, complicated with a vasovagal event. We stress the importance of coronary angiography in out of hospital cardiac arrest patients after neurological recovery. In the era of COVID-19 vaccination, even though fatal adverse events following immunization are rare, heightened awareness of severe side effects needing medical attention is very important.

New diagnosis of systemic lupus erythematosus after COVID-19 vaccination: AÂ case report and review of literature.

Humoral and Cellular Immune Responses After a 3-dose Course of mRNA-1273 COVID-19 Vaccine in Kidney Transplant Recipients: A Prospective Cohort Study. In kidney transplant recipients, there is discordance between the development of cellular and humoral response after vaccination against SARS-CoV-2. We sought to determine the interplay between the 2 arms of adaptive immunity in a 3-dose course of mRNA-1273 100 Î¼g vaccine. METHODS: Humoral (IgG/IgM) and cellular (N- and S-ELISpot) responses were studied in 117 kidney and 12 kidney-pancreas transplant recipients at the following time points: before the first dose, 14 d after the second dose' and before and after the third dose, with a median of 203 and 232 d after the start of the vaccination cycle, respectively. RESULTS: After the second dose, 26.7% of naive cases experienced seroconversion. Before the third dose and in the absence of COVID-19, this percentage increased to 61.9%. After the third dose, seroconversion occurred in 80.0% of patients. Naive patients who had at any time point a detectable positivity for S-ELISpot were 75.2% of the population, whereas patients who maintained S-ELISpot positivity throughout the study were 34.3%. S-ELISpot positivity at 42 d was associated with final seroconversion (odds ratio' 3.14; 95% confidence interval' 1.10-8.96; Pâ€‰=â€‰0.032). Final IgG titer was significantly higher in patients with constant S-ELISpot positivity (Pâ€‰<â€‰0.001).

CONCLUSIONS: A substantial proportion of kidney transplant recipients developed late seroconversion after 2 doses. Cellular immunity was associated with the development of a stronger humoral response.

Acute myocardial infarction immediately after second vaccination for coronavirus disease 2019. We present a serious and rare case of acute myocardial infarction soon after the administration of second vaccination for coronavirus disease 2019. Patient's culprit lesion in the right coronary artery was identified and appropriately treated using intravascular imaging. Postvaccination monitoring of patients who are at high risk of cardiovascular diseases is critical. Rare but severe cases of acute myocardial infarction following vaccination for coronavirus disease 2019 have been reported. Physicians should consider this rare side effect as a possible differential diagnosis and appropriately manage such patients.

Successful fractionated undiluted doses of COVID-19 vaccine in five cases of suspected allergic reactions to the first dose. After a suspected allergic reaction to first dose of mRNA COVID-19 vaccine, given the PEG skin tests negativity and tolerance in vivo to PEG containing drugs, five patients were vaccinated with the second dose of Pfizer-Biontech undergoing a fractional protocol, with antihistamine premedication, without presenting immediate or delayed reactions.

Increased PD-L1 surface expression on peripheral blood granulocytes and monocytes after vaccination with SARS-CoV2 mRNA or vector vaccine.

Isolated abducens nerve palsy following Covid-19 vaccine.

Esophagitis and SARS-CoV-2 vaccine: Correspondence.

Severe COVID-19 outcomes after full vaccination of primary schedule and initial boosters: pooled analysis of national prospective cohort studies of 30 million individuals in England, Northern Ireland, Scotland, and Wales. BACKGROUND: Current UK vaccination policy is to offer future COVID-19 booster doses to individuals at high risk of serious illness from COVID-19, but it is still uncertain which groups of the population could benefit most. In response to an urgent request from the UK Joint Committee on Vaccination and Immunisation, we aimed to identify risk factors for severe COVID-19 outcomes (ie, COVID-19-related hospitalisation or death) in individuals who had completed their primary COVID-19 vaccination schedule and had received the first booster vaccine. METHODS: We constructed prospective cohorts across all four UK nations through linkages of primary care, RT-PCR testing, vaccination, hospitalisation, and mortality data on 30 million people. We included individuals who received primary vaccine doses of BNT162b2 (tozinameran; Pfizer-BioNTech) or ChAdOx1 nCoV-19 (Oxford-AstraZeneca) vaccines in our initial analyses. We then restricted analyses to those given a BNT162b2 or mRNA-1273 (elasomeran; Moderna) booster and had a severe COVID-19 outcome between Dec 20, 2021, and Feb 28, 2022 (when the omicron (B.1.1.529) variant was dominant). We fitted time-dependent Poisson regression models and calculated adjusted rate ratios (aRRs) and 95% CIs for the associations between risk factors and COVID-19-related hospitalisation or death. We adjusted for a range of potential covariates, including age, sex, comorbidities, and previous SARS-CoV-2 infection. Stratified analyses were conducted by vaccine type. We then did pooled analyses across UK nations using fixed-effect meta-analyses. FINDINGS: Between Dec 8, 2020, and Feb 28, 2022, 16â€ˆ208â€ˆ600 individuals completed their primary vaccine schedule and 13â€ˆ836â€ˆ390 individuals received a booster dose. Between Dec 20, 2021, and Feb 28, 2022, 59â€ˆ510 (0Â·4%) of the primary vaccine group and 26â€ˆ100 (0Â·2%) of those who received their booster had severe COVID-19 outcomes. The risk of severe COVID-19 outcomes reduced after receiving the booster (rate change: 8Â·8 events per 1000 person-years to 7Â·6 events per 1000 person-years). Older adults (â‰¥80 years vs 18-49 years; aRR 3Â·60 [95% CI 3Â·45-3Â·75]), those with comorbidities (â‰¥5 comorbidities vs none; 9Â·51 [9Â·07-9Â·97]), being male (male vs female; 1Â·23 [1Â·20-1Â·26]), and those with certain underlying health conditions-in particular, individuals receiving

immunosuppressants (yes vs no; 5Â·80 [5Â·53-6Â·09])-and those with chronic kidney disease (stage 5 vs no; 3Â·71 [2Â·90-4Â·74]) remained at high risk despite the initial booster. Individuals with a history of COVID-19 infection were at reduced risk (infected â‰¥9 months before booster dose vs no previous infection; aRR 0Â·41 [95% CI 0Â·29-0Â·58]). INTERPRETATION: Older people, those with multimorbidity, and those with specific underlying health conditions remain at increased risk of COVID-19 hospitalisation and death after the initial vaccine booster and should, therefore, be prioritised for additional boosters, including novel optimised versions, and the increasing array of COVID-19 therapeutics. FUNDING: National Core Studies-Immunity, UK Research and Innovation (Medical Research Council), Health Data Research UK, the Scottish Government, and the University of Edinburgh.

Safety of COVID-19 vaccine in patients with epilepsy: a meta-analysis.

COVID-19 vaccine update: vaccine effectiveness, SARS-CoV-2 variants, boosters, adverse effects, and immune correlates of protection. Coronavirus Disease 2019 (COVID-19) has been the most severe public health challenge in this century. Two years after its emergence, the rapid development and deployment of effective COVID-19 vaccines have successfully controlled this pandemic and greatly reduced the risk of severe illness and death associated with COVID-19. However, due to its ability to rapidly evolve, the SARS-CoV-2 virus may never be eradicated, and there are many important new topics to work on if we need to live with this virus for a long time. To this end, we hope to provide essential knowledge for researchers who work on the improvement of future COVID-19 vaccines. In this review, we provided an up-to-date summary for current COVID-19 vaccines, discussed the biological basis and clinical impact of SARS-CoV-2 variants and subvariants, and analyzed the effectiveness of various vaccine booster regimens against different SARS-CoV-2 strains. Additionally, we reviewed potential mechanisms of vaccine-induced severe adverse events, summarized current studies regarding immune correlates of protection, and finally, discussed the development of next-generation vaccines.

Acquired Angioedema Acute Attack After Administration of the Moderna COVID-19 (mRNA-1273) Vaccine.

Immunoglobulin A Vasculitis Following COVID-19: A French Multicenter Case Series. OBJECTIVE: Immunoglobulin A vasculitis (IgAV) usually occurs following viral respiratory tract infection. In the context of the global coronavirus disease 2019 (COVID-19) pandemic, we describe a case series of patients who developed IgAV following SARS-CoV-2 infection. METHODS: This national multicenter retrospective study included patients with IgAV following SARS-CoV-2 infection from January 1, 2020, to January 1, 2022. Patients had histologically proven IgAV and reverse transcription PCR (RT-PCR)-proven SARS-CoV-2 infection. The interval between infection and vasculitis onset had to be < 4 weeks. RESULTS: We included 5 patients, 4 of whom were women with a mean age of 45 years. Four patients had paucisymptomatic infections and 1 required a 48-hour low-flow oxygen treatment. All 5 patients had purpuric skin involvement. Arthritis was observed in 2 patients, 3 had IgA glomerulonephritis, and 2 had digestive involvement. Three renal biopsies were performed and showed mesangial IgA deposits without any extracapillary proliferation. Median C-reactive protein was 180 (range 15.1-225) mg/L, median serum creatinine level was 65 (range 41-169) Âµmol/L, and 2 patients had a glomerular filtration rate < 60 mL/min. Four patients received first-line treatment with glucocorticoids. All patients had a favorable progression and 2 patients experienced minor skin relapses, one after COVID-19 vaccination. CONCLUSION: This series describes the emergence of IgAV closely following COVID-19; we were not able to eliminate an incidental link between these events. Their disease outcomes were favorable. In most of our patients, the SARS-CoV-2 infection was paucisymptomatic, and we recommend RT-PCR tests to look for COVID-19 in patients without any evident triggers for IgAV.

Enhanced SARS-CoV-2 IgG durability following COVID-19 mRNA booster vaccination and comparison of BNT162b2 with mRNA-1273. BACKGROUND: BNT162b2 (Pfizer/BioNTech, Comirnaty) and mRNA-1273 (Moderna, Spikevax) are messenger RNA (mRNA) vaccines that elicit antibodies against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike receptor-binding domain (S-RBD) and have been approved by the US Food and Drug Administration to combat the coronavirus disease 2019 (COVID-19) pandemic. Because vaccine efficacy and antibody levels waned over time after the 2-shot primary series, the US Food and Drug Administration authorized a booster (third) dose for both mRNA vaccines to adults in the fall of 2021. OBJECTIVE: To evaluate the magnitude and durability of S-RBD immunoglobulin (Ig)G after the booster mRNA vaccine dose in comparison to the primary series. We also compared S-RBD IgG levels after BNT162b2 and mRNA-1273 boosters and explored effects of age and prior infection. METHODS: Surrounding receipt of the second and third homologous mRNA vaccine doses, adults in an employee-based cohort provided serum and completed questionnaires, including information about previous COVID-19 infection. The IgG to S-RBD was measured using an ImmunoCAP-based system. A subset of samples were assayed for IgG to SARS-CoV-2 nucleocapsid by commercial assay. RESULTS: There were 228 subjects who had samples collected between 7 and 150 days after their primary series vaccine and 117 subjects who had samples collected in the same time frame after their boost. Antibody levels from 7 to 31 days after the primary series and booster were similar, but S-RBD IgG was more durable over time after the boost, regardless of prior infection status. In addition, mRNA-1273 post-boost antibody levels exceeded BNT162b2 out to 5 months. CONCLUSION: The COVID-19 mRNA vaccine boosters increase antibody durability, suggesting enhanced long-term clinical protection from SARS-CoV-2 infection compared with the 2-shot regimen.

Hashimoto encephalopathy after vaccination against SARS-CoV-2.

Immune-Related Adverse Events Among COVID-19-Vaccinated Patients With Cancer Receiving Immune Checkpoint Blockade. BACKGROUND: Whether COVID-19 vaccination and the associated immune response increases susceptibility to immune-related adverse events (irAEs) among patients treated with immune checkpoint inhibition (ICI) remains unknown. Short-term follow-up can assess the safety of concurrent administration of the vaccine and ICI treatment. METHODS: We conducted an electronic health record analysis of a cohort of 408 patients with cancer receiving ICI therapy and who were vaccinated for COVID-19 between January 16 and March 27, 2021. Patients were seen in follow-up for 90 days from the day of the first dose in this single-institution tertiary care center. We evaluated the incidence of irAEs and the frequency of each event type and grade among patients who experienced an irAE. We also evaluated the incidence of irAEs in patients who began a new immunotherapy agent after vaccination. RESULTS: Among 408 patients with cancer receiving ICI therapy (median age, 71 years; 217 [53%] male), administration of a COVID-19 mRNA vaccine within 90 days of ICI treatment was not associated with an increased incidence of irAEs. A total of 27 (7%) patients experienced a new irAE within the observation period. Among patients with previous irAEs from ICIs (n=54), 3 (6%) experienced a recurrent irAE, and of those initiating a new immunotherapy (n=52), 9 (17%) experienced an irAE. No excess risk of COVID-19 diagnosis was seen in this subset of patients receiving ICI therapy, and no breakthrough COVID-19 cases were seen after full COVID-19 vaccination. CONCLUSIONS: These findings should reassure providers that COVID-19 vaccination during ICI therapy is safe and efficacious.

Functional immune responses against SARS-CoV-2 variants of concern after fourth COVID-19 vaccine dose or infection in patients with blood cancer. Patients with blood cancer continue to have a greater risk of inadequate immune responses following three COVID-19 vaccine doses and risk of severe COVID-19 disease. In the context of the CAPTURE study (NCT03226886), we report immune responses in 80 patients with blood cancer who received a fourth dose of BNT162b2. We measured

neutralizing antibody titers (NAbTs) using a live virus microneutralization assay against wild-type (WT), Delta, and Omicron BA.1 and BA.2 and TÂ cell responses against WT and Omicron BA.1 using an activation-induced marker (AIM) assay. The proportion of patients with detectable NAb titers and TÂ cell responses after the fourth vaccine dose increased compared with that after the third vaccine dose. Patients who received B cell-depleting therapies within the 12Â months before vaccination have the greatest risk of not having detectable NAbT. In addition, we report immune responses in 57 patients with breakthrough infections after vaccination.

In Vitro Fertilization Outcomes After Inactivated COVID-19 Vaccine.

Association Between Time Interval from COVID-19 Vaccination to In Vitro Fertilization and Pregnancy Rate After Fresh Embryo Transfer. IMPORTANCE: There is a lack of information regarding the need to postpone conception after COVID-19 vaccination. OBJECTIVE: To investigate the time interval between the first dose of inactivated COVID-19 vaccine and in vitro fertilization (IVF) treatment as well as the rate of pregnancy after a fresh embryo transfer. DESIGN, SETTING, AND PARTICIPANTS: This cohort study was conducted at a single public IVF center in China. Female patients aged 20 to 47 years and undergoing IVF treatment were consecutively registered from May 1 to December 22, 2021, with follow-up until March 31, 2022. Patients with SARS-CoV-2 infection before or during IVF treatment and those who underwent 2 or more IVF treatments, received the noninactivated or unknown COVID-19 vaccine, or did not have a fresh embryo transfer were excluded from this study. EXPOSURES: The vaccinated group (subdivided into 4 subgroups of time interval from first vaccination to fertilization treatment: â‰¤30 days, 31-60 days, 61-90 days, and â‰¥91 days) and nonvaccinated group. MAIN OUTCOMES AND MEASURES: Risk ratios (RRs) for the association between the time interval and ongoing pregnancy (pregnancy continued at least 12 weeks). RESULTS: A total of 3052 female patients (mean [SD] age, 31.45 [3.96] years) undergoing IVF treatment were analyzed in this study. There were 667 vaccinated patients receiving IVF (35 were vaccinated â‰¤30 days, 58 were vaccinated 31-60 days, 105 were vaccinated 61-90 days, and 469 were vaccinated â‰¥91 days before fertilization treatment), and 2385 unvaccinated patients receiving treatment. The ovarian stimulation and laboratory parameters were similar among all groups. Ongoing pregnancy was significantly lower in the 30 days or less subgroup (34.3% [12 of 35]; adjusted RR [aRR], 0.61; 95% CI, 0.33-0.91) and the 31 to 60 days' subgroup (36.2% [21 of 58]; aRR, 0.63; 95% CI, 0.42-0.85). A slightly but not statistically lower rate was found in the 61 to 90 days' subgroup, and no reduced risk for ongoing pregnancy in the 91 days or more subgroup was observed (56.3% [264 of 469]; aRR, 0.96; 95% CI, 0.88-1.04) compared with the unvaccinated group (60.3% [1439 of 2385], as reference). CONCLUSIONS AND RELEVANCE: Findings of this study suggest that receipt of the first inactivated COVID-19 vaccine dose 60 days or less before fertilization treatment is associated with a reduced rate of pregnancy. In patients undergoing IVF treatment with a fresh embryo transfer, the procedure may need to be delayed until at least 61 days after COVID-19 vaccination.

Perceptions of COVID-19 Vaccination in Patients with Genitourinary Cancers: A Survey Study.
Since the approval of the COVID-19 vaccines, their safety and efficacy has been widely demonstrated in patients with cancer. However, there remain patients with reservations regarding vaccination. We aimed to assess genitourinary cancer patients' perceptions of the vaccines as well as barriers and influencers of decision-making through the completion of a questionnaire. While vaccine-associated concerns were observed, most patients with genitourinary cancers were willing to receive the vaccine. Moving forward, differing strategies could be considered to enhance patient education on the utility of vaccination in the setting of cancer and beyond.

Booster vaccination is required to elicit and maintain COVID-19 vaccine-induced immunity in SIV-infected macaques. ABSTRACTProlonged infection and possible evolution of SARS-CoV-2 in patients living with uncontrolled HIV-1 infection highlight the importance of an effective vaccination

regimen, yet the immunogenicity of COVID-19 vaccines and predictive immune biomarkers have not been well investigated. Herein, we report that the magnitude and persistence of antibody and cell-mediated immunity (CMI) elicited by an Ad5-vectored COVID-19 vaccine are impaired in SIV-infected macaques with high viral loads (> 10(5) genome copies per ml plasma, SIV(hi)) but not in macaques with low viral loads (< 10(5), SIV(low)). After a second vaccination, the immune responses are robustly enhanced in all uninfected and SIV(low) macaques. These responses also show a moderate increase in 70% SIV(hi) macaques but decline sharply soon after. Further analysis reveals that decreased antibody and CMI responses are associated with reduced circulating follicular helper T cell (TFH) counts and aberrant CD4/CD8 ratios, respectively, indicating that dysregulation of CD4(+) T cells by SIV infection impairs the COVID-19 vaccine-induced immunity. Ad5-vectored COVID-19 vaccine shows no impact on SIV loads or SIV-specific CMI responses. Our study underscores the necessity of frequent booster vaccinations in HIV-infected patients and provides indicative biomarkers for predicting vaccination effectiveness in these patients.
New onset of palmoplantar keratosis triggered by COVID-19 vaccination.
Herpes zoster and alopecia areata following mRNA BNT162b2 COVID-19 vaccine: Controversial immune effects.
Tolerance for three commonly administered COVID-19 vaccines by healthcare professionals. IMPORTANCE: Most healthcare institutions require employees to be vaccinated against SARS-CoV-2 and many also require at least one booster. OBJECTIVE: We determine the impact of vaccine type, demographics, and health conditions on COVID-19 vaccine side effects in healthcare professionals. DESIGN: A COVID-19 immunity study was performed at the 2021 American Association for Clinical Chemistry Annual Scientific meeting. As part of this study, a REDCap survey with cascading questions was administered from September 9, 2021 to October 20, 2021. General questions included participant demographics, past and present health conditions, smoking, exercise, and medications. COVID-19 specific questions asked about SARS-CoV-2 vaccine status and type, vaccine-associated side effects after each dose including any boosters, previous infection with COVID-19, diagnostic testing performed, and type and severity symptoms of COVID-19. RESULTS: There were 975 participants (47.1% male, median age of 50 years) who completed the survey. Pfizer was the most commonly administered vaccine (56.4%) followed by Moderna (32.0%) and Johnson & Johnson (7.1%). There were no significant differences in vaccine type received by age, health conditions, smoking, exercise, or type or number of prescription medications. Side effects were reported more frequently after second dose (e.g., Moderna or Pfizer) (54.1%) or single/only dose of Johnson & Johnson (47.8%). Males were significantly more likely to report no side effects ($p < 0.001$), while females were significantly more likely to report injection site reactions ($p < 0.001$), fatigue ($p < 0.001$), headache ($p < 0.001$), muscle pain ($p < 0.001$), chills ($p = 0.001$), fever ($p = 0.007$), and nausea ($p < 0.001$). There was a significant upward trend in participants reporting no side effects with increasing age ($p < 0.001$). There were no significant trends in side effects among different races, ethnicities, health conditions, medications, smoking status or exercise. In multivariate logistic regressions analyses, the second dose of Moderna was associated with a significantly higher risk of side effects than both the second dose of Pfizer and the single dose of Johnson & Johnson. CONCLUSIONS AND RELEVANCE: Younger people, females, and those receiving the second dose of Moderna had more COVID-19 vaccine side effects that per self-report led to moderate to severe limitations. As reported in other studies, the increase in side effects from Moderna may be explained by higher viral mRNA concentrations but be associated with additional protective immunity.
Herpetic endotheliitis and stromal keratitis following inactivated COVID-19 vaccination. Given the scarcity of data regarding ocular complications following COVID-19 vaccination, the approach toward patients with suggestive symptoms and established clinical practice is lacking. Herein, we report the

first case of herpetic endotheliithis and secondary stromal keratitis following inactivated COVID-19 vaccination who experienced a relapse due to poor adherence.

Graves' disease following vaccination against SARS-CoV-2: A systematic review of the reported cases. The newly developed COVID-19 vaccines have established a safe profile, yet some individuals experience a wide range of adverse events. Recently, thyroid dysfunction, including Graves' disease, has been observed after administration of different COVID-19 vaccines, although causality remains a matter of debate. The aim of this systematic review was to examine the available literature and provide an overview of reported cases of Graves' disease following COVID-19 vaccination. We identified 21 eligible articles which included 57 patients with Graves' disease following COVID-19 vaccination. Fourteen participants were males (25%, 14/57) and 43 (75%, 44/57) were females with a mean age of 44.3 years. The most common presenting symptom was palpitations (63%, 27/43) followed by weight loss (35%, 15/43). The majority of patients received thionamides (47%, 25/53). The clinical status after treatment was provided for 37 patients and it was improved in the majority of them (84%, 31/37). Graves' disease is possibly a condition clinicians may expect to encounter in patients receiving COVID-19 vaccines. While the above adverse event is rare, considering the scarcity of available data in scientific literature, and causality is not yet confirmed, the increased awareness of clinicians and the early recognition of the disorder are important for the optimal management of these patients.

Retinal microvascular abnormalities, cotton wool-like lesions, and macular edema following COVID-19 in a patient previously vaccinated with AstraZeneca and idiopathic myopathy. In this case study, the authors describe peculiar bilateral cotton wool-like retinal lesions associated with macular edema in a patient with COVID-19 who was vaccinated with a single dose of AstraZeneca one month earlier. This patient had no pulmonary or systemic cardiovascular complications from COVID-19, as reported in other papers that found retinal lesions. However, the patient was diagnosed with idiopathic myopathy when discovering the SARS-CoV-2 infection. The patient was a 22-year-old white female with no previous history of morbidity, complaining of blurred vision in both eyes seven days after testing positive for SARS-CoV-2 by PCR (using nasal and oral swab) and confirmed through ELISA blood test (IgM positive). There was no ancillary test revealing diabetes mellitus. The patient presented with scattered whitish cotton wool-like lesions and a few hemorrhages on the posterior pole in fundus examination. On spectral domain optical coherence tomography (SD-OCT), there were hyperreflective lesions in the nerve fiber layer, ganglion cell layer, inner nuclear layer, and inner and outer plexiform layers at the site corresponding to the whitish cotton wool-like lesions in the posterior fundus photos. Moreover, the macula of both eyes had intraretinal and subretinal fluid, reversible with corticosteroid therapy. In conclusion, COVID-19 has been associated with capillary disorders at different target sites such as retina, lungs, and central nervous system. Similarly, vaccination against SARS-CoV-2 has been linked to retinal complications in the literature; however, cotton wool-like lesions have not yet been reported. There are many questions yet to be answered about the implications of COVID-19 infection and its vaccines.

COVID-19 Vaccines Adverse Reactions Reported to the Pharmacovigilance Unit of Beira Interior in Portugal. Coronavirus disease 2019 is an acute respiratory disease caused by the severe acute respiratory syndrome coronavirus 2. As the virus spreads rapidly, it has become a major public health emergency, which has led to rapid vaccines development. However, vaccines can present harmful and unintended responses, which must be notified to the National Pharmacovigilance System. The aim of this study is to characterize the adverse drug reactions (ADRs) of these vaccines notified in the region covered by the Regional Pharmacovigilance Unit (RPU) of Beira Interior, in Portugal, between 1 and 31 December 2020. During this period, 4 vaccines were administered: Comirnaty(Â®), Spikevax(Â®), Vaxzevria(Â®) and Jcovden(Â®). The RPU of Beira Interior received 2134 notifications

corresponding to 5685 ADRs, of which 20.34% (n = 434) of the notifications were considered serious reactions. Of these, 9.52% (n = 42) resulted in hospitalization and 0.45% (n = 2) resulted in death. Among the ADRs notified, reactions at or around the injection site, myalgia, headaches and pyrexia were the most commonly notified. Most ADRs were resolved within a few hours or days without sequelae. These ADRs are in accordance with clinical trials, the summary of product characteristics (SmPC) of each vaccine and ADR notifications from other countries. However, further studies are needed to confirm these results.

Two Cases of Autoimmune Thyroid Disorders after COVID Vaccination in Dialysis Patients. SARS-CoV-2 infection and vaccination have been associated with autoimmune thyroid dysfunctions. Autoimmune/inflammatory syndrome induced by adjuvants (ASIA) and molecular mimicry have been referred to as potential causes. Such a case has not been reported in immunocompromised end-stage renal disease (ESRD) patients. Herein we present two dialysis patients with no previous history of thyroid disease who developed immune mediated thyroid disorders after BNT162b mRNA vaccine against SARS-CoV-2. The first patient is a 29-year-old man on hemodialysis diagnosed with Grave's disease four months post-vaccination and the second one is a 67-year-old female on peritoneal dialysis who developed Hashimoto's thyroiditis two months post-vaccination. Grave's disease is uncommon in dialysis patients, whereas Hashimoto's thyroiditis has a higher incidence in this population. Time proximity in both cases suggests potential causality. To our knowledge, this is the first report of de novo immune-mediated thyroid disorders in dialysis patients following vaccination against SARS-CoV-2.

The Receptor Binding Domain of SARS-CoV-2 Lambda Variant Has a Better Chance Than the Delta Variant in Evading BNT162b2 COVID-19 mRNA Vaccine-Induced Humoral Immunity. The SARS-CoV-2 Delta and Lambda variants had been named variants of concern (VOC) and variants of interest (VOI), respectively, by the World Health Organization (WHO). Both variants have two mutations in the spike receptor binding domain (RBD) region, with L452R and T478K mutations in the Delta variant, and L452Q and F490S mutations in the Lambda variant. We used surface plasmon resonance (SPR)-based technology to evaluate the effect of these mutations on human angiotensin-converting enzyme 2 (ACE2) and Bamlanivimab binding. The affinity for the RBD ligand, ACE2, of the Delta RBD is approximately twice as strong as that of the wild type RBD, an increase that accounts for the increased infectivity of the Delta variant. On the other hand, in spite of its amino acid changes, the Lambda RBD has similar affinity to ACE2 as the wild type RBD. The protective anti-wild type RBD antibody Bamlanivimab binds very poorly to the Delta RBD and not at all to the Lambda RBD. Nevertheless, serum antibodies from individuals immunized with the BNT162b2 vaccine were found to bind well to the Delta RBD, but less efficiently to the Lambda RBD in contrast. As a result, the blocking ability of ACE2 binding by serum antibodies was decreased more by the Lambda than the Delta RBD. Titers of sera from BNT162b2 mRNA vaccinated individuals dropped 3-fold within six months of vaccination regardless of whether the target RBD was wild type, Delta or Lambda. This may account partially for the fall off with time in the protective effect of vaccines against any variant.

Life-Space Mobility and Objectively Measured Movement Behavior in Older Adults with Hypertension after Receiving COVID-19 Vaccination. This study examined the changes in life-space (LS) mobility and objectively measured movement behavior in older adults with hypertension after receiving the COVID-19 vaccine and their associations with housing type. A total of 32 participants were included in this exploratory longitudinal study with a 1-year follow-up. LS mobility and accelerometer-based physical activity (PA) and sedentary behavior (SB) were assessed before and ~2 months after receiving COVID-19 vaccination. Participants residing in apartment/row housing showed an increase in LS mobility composite score ($\hat{I}^2 = 14$, $p < 0.05$). In addition, they showed an increase in light PA on weekdays and the weekend ($\hat{I}^2 = 3.5\%$; $\hat{I}^2 = 6.5\%$; $p < 0.05$) and a decrease in SB on weekdays and the

weekend (Î² = -3.7%; Î² = -6.6%; p < 0.05). Furthermore, changes in SB pattern were found (less time spent in bouts of â‰¥10 and 30 min, more breaks/day and breaks/hour). Significant associations were found between changes in LS mobility composite score and PA (positive association) and SB (negative association) in older adults residing in apartment/row housing (p < 0.05). Older adults with hypertension, particularly those who resided in houses with limited outdoor space (apartment/row housing), showed positive changes in LS mobility and objectively measured movement behavior in a period after receiving the COVID-19 vaccine and characterized by social distancing policies without mobility restrictions when compared with the period of social distancing policies with high mobility restrictions and without vaccine.

COVID-19 Vaccine in Inherited Metabolic Disorders Patients: A Cross-Sectional Study on Rate of Acceptance, Safety Profile and Effect on Disease. BACKGROUND: Vaccines for COVID-19 have had a significant impact on the spread of COVID-19 infection, reducing the incidence and mortality of the infection in several countries. However, hesitancy toward this vaccine is a global health issue for the general population The Vaccine acceptance rate among patients affected with inherited metabolic disorders (IMD), as well as safety profile, has not been described. METHODS: We conducted a cross-sectional study, based on a telephone survey, investigating the COVID-19 vaccination rate, the incidence and type of adverse effects (AEs), the reasons for vaccine refusal and the effects on the underlying disease in a cohort of IMD patients followed at a single center and invited directly to vaccination by specialistic team. RESULTS: Seventy-four patients were included in the study, the median age was 23.4 years (min 12.1-max 61.7), 47% (n = 85) were females and 61% (107) were affected from impaired metabolism of phenylalanine. By October 2021, 94% (n = 163) of them had received at least one dose of the vaccine, which was, in 98% of cases, mRNA-based vaccine, given at the referral hospital in 65% of cases. Overall, 72% of patients with IMD reported AE to the vaccine: 60% after the first dose, 81% after the second. The highest rate of adverse events at the first dose was reported in patients with amino acids related disorders other than impaired phenylalanine metabolism (PKU/HPA) (88%). For the second dose, the PKU/HPA group reported the highest rate of AEs (89% of cases). There was no effect on the underlying disease or acute decompensation after the vaccine. Eleven patients (6%) were not vaccinated because they considered it dangerous. CONCLUSION: Among individuals with IMD, the vaccination rate was high, the incidence and severity of AEs were comparable to those in the general population with no effects on the disease. Direct contact with the specialist medical team, has proven to reassure patients and effectively contrast hesitancy.

Strong SARS-CoV-2 T-Cell Responses after One or Two COVID-19 Vaccine Boosters in Allogeneic Hematopoietic Stem Cell Recipients. A full exploration of immune responses is deserved after anti-SARS-CoV-2 vaccination and boosters, especially in the context of allogeneic hematopoietic stem cell transplantation (allo-HSCT). Although several reports indicate successful humoral responses in such patients, the literature is scarce on cellular specific immunity. Here, both B- (antibodies) and T-cell responses were explored after one (V3 n = 40) or two (V4 n = 12) BNT162b2 mRNA vaccine boosters in 52 allo-HSCT recipients at a median of 755 days post-transplant (<1 year n = 9). Results were compared with those of 12 controls who had received only one booster (BNT162b2 n = 6; mRNA-1273 n = 6). All controls developed protective antibody levels (>250 BAU/mL) and anti-spike T-cell responses. Similarly, 81% of the patients developed protective antibody levels, without difference between V3 and V4 (82.5% vs. 75%, p = 0.63), and 85% displayed T-cell responses. The median frequency of anti-spike T cells did not differ either between controls or the whole cohort of patients, although it was significantly lower for V3 (but not V4) patients. COVID-19 infections were solely observed in individuals having received only one booster. These results indicate that four vaccine

injections help to achieve a satisfactory level of both humoral and cellular immune protection in allo-HSCT patients.

Risk of thyroid dysfunction associated with mRNA and inactivated COVID-19 vaccines: a population-based study of 2.3 million vaccine recipients. BACKGROUND: In view of accumulating case reports of thyroid dysfunction following COVID-19 vaccination, we evaluated the risks of incident thyroid dysfunction following inactivated (CoronaVac) and mRNA (BNT162b2) COVID-19 vaccines using a population-based dataset. METHODS: We identified people who received COVID-19 vaccination between 23 February and 30 September 2021 from a population-based electronic health database in Hong Kong, linked to vaccination records. Thyroid dysfunction encompassed anti-thyroid drug (ATD)/levothyroxine (LT4) initiation, biochemical picture of hyperthyroidism/hypothyroidism, incident Graves' disease (GD), and thyroiditis. A self-controlled case series design was used to estimate the incidence rate ratio (IRR) of thyroid dysfunction in a 56-day post-vaccination period compared to the baseline period (non-exposure period) using conditional Poisson regression. RESULTS: A total of 2,288,239 people received at least one dose of COVID-19 vaccination (57.8% BNT162b2 recipients and 42.2% CoronaVac recipients). 94.3% of BNT162b2 recipients and 92.2% of CoronaVac recipients received the second dose. Following the first dose of COVID-19 vaccination, there was no increase in the risks of ATD initiation (BNT162b2: IRR 0.864, 95% CI 0.670-1.114; CoronaVac: IRR 0.707, 95% CI 0.549-0.912), LT4 initiation (BNT162b2: IRR 0.911, 95% CI 0.716-1.159; CoronaVac: IRR 0.778, 95% CI 0.618-0.981), biochemical picture of hyperthyroidism (BNT162b2: IRR 0.872, 95% CI 0.744-1.023; CoronaVac: IRR 0.830, 95% CI 0.713-0.967) or hypothyroidism (BNT162b2: IRR 1.002, 95% CI 0.838-1.199; CoronaVac: IRR 0.963, 95% CI 0.807-1.149), GD, and thyroiditis. Similarly, following the second dose of COVID-19 vaccination, there was no increase in the risks of ATD initiation (BNT162b2: IRR 0.972, 95% CI 0.770-1.227; CoronaVac: IRR 0.879, 95%CI 0.693-1.116), LT4 initiation (BNT162b2: IRR 1.019, 95% CI 0.833-1.246; CoronaVac: IRR 0.768, 95% CI 0.613-0.962), hyperthyroidism (BNT162b2: IRR 1.039, 95% CI 0.899-1.201; CoronaVac: IRR 0.911, 95% CI 0.786-1.055), hypothyroidism (BNT162b2: IRR 0.935, 95% CI 0.794-1.102; CoronaVac: IRR 0.945, 95% CI 0.799-1.119), GD, and thyroiditis. Age- and sex-specific subgroup and sensitivity analyses showed consistent neutral associations between thyroid dysfunction and both types of COVID-19 vaccines. CONCLUSIONS: Our population-based study showed no evidence of vaccine-related increase in incident hyperthyroidism or hypothyroidism with both BNT162b2 and CoronaVac.

New-onset and relapsed liver diseases following COVID-19 vaccination: a systematic review. BACKGROUND: Liver diseases post-COVID-19 vaccination is extremely rare but can occur. A growing body of evidence has indicated that portal vein thrombosis, autoimmune hepatitis, raised liver enzymes and liver injuries, etc., may be potential consequence of COVID-19 vaccines. OBJECTIVES: To describe the results of a systematic review for new-onset and relapsed liver disease following COVID-19 vaccination. METHODS: For this systematic review, we searched Proquest, Medline, Embase, PubMed, CINAHL, Wiley online library, Scopus and Nature through the Preferred Reporting Items for Systematic Reviews and Meta Analyses PRISMA guideline for studies on the incidence of new onset or relapsed liver diseases post-COVID-19 vaccination, published from December 1, 2020 to July 31, 2022, with English language restriction. RESULTS: Two hundred seventy-five cases from one hundred and eighteen articles were included in the qualitative synthesis of this systematic review. Autoimmune hepatitis (138 cases) was the most frequent pathology observed post-COVID-19 vaccination, followed by portal vein thrombosis (52 cases), raised liver enzymes (26 cases) and liver injury (21 cases). Other cases include splanchnic vein thrombosis, acute cellular rejection of the liver, jaundice, hepatomegaly, acute hepatic failure and hepatic porphyria. Mortality was reported in any of the included cases for acute hepatic failure (nâ€‰=â€‰4, 50%), portal vein thrombosis (nâ€‰=â€‰25, 48.1%), splanchnic vein thrombosis (nâ€‰=â€‰6, 42.8%), jaundice (nâ€‰=â€‰1, 12.5%), raised

liver enzymes (nâ€‰=â€‰2, 7.7%), and autoimmune hepatitis (nâ€‰=â€‰3, 2.2%). Most patients were easily treated without any serious complications, recovered and did not require long-term hepatic therapy. CONCLUSION: Reported evidence of liver diseases post-COIVD-19 vaccination should not discourage vaccination against this worldwide pandemic. The number of reported cases is relatively very small in relation to the hundreds of millions of vaccinations that have occurred and the protective benefits offered by COVID-19 vaccination far outweigh the risks.

Comparison of the safety and immunogenicity of the BNT-162b2 vaccine and the ChAdOx1 vaccine for solid organ transplant recipients: a prospective study. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and its resulting disease, coronavirus disease 2019 (COVID-19), has spread to millions of people worldwide. Preliminary data from organ transplant recipients have shown reduced seroconversion rates after the administration of different SARS-CoV-2 vaccination platforms. However, it is unknown whether different vaccination platforms provide different levels of protection against SARS-CoV-2. To answer this question, we prospectively studied 431 kidney and liver transplant recipients (kidney: nâ€‰=â€‰230; liver: nâ€‰=â€‰201) who received either the ChAdOx1 vaccine (nâ€‰=â€‰148) or the BNT-162b2 vaccine (nâ€‰=â€‰283) and underwent an assessment of immunoglobulin M/immunoglobulin G spike antibody levels. The primary objective of the study is to directly compare the efficacy of two different vaccine platforms in solid organ transplant recipients by measuring of immunoglobulin G (IgG) antibodies against the RBD of the spike protein (anti-RBD) two weeks after first and second doses. Our secondary endpoints were solicited specific local or systemic adverse events within 7Â days after the receipt of each dose of the vaccine. There was no difference in the primary outcome between the two vaccine platforms in patients who received two vaccine doses. Unresponsiveness was mainly linked to diabetes. The rate of response after the first dose among younger older patients was significantly larger; however, after the second dose this difference did not persist (pâ€‰=â€‰0.079). Side effects were similar to those that were observed during the pivotal trials.

Tolerability and immunogenicity of an intranasally-administered adenovirus-vectored COVID-19 vaccine: An open-label partially-randomised ascending dose phase I trial. BACKGROUND: Intranasal vaccination may induce protective local and systemic immune responses against respiratory pathogens. A number of intranasal SARS-CoV-2 vaccine candidates have achieved protection in pre-clinical challenge models, including ChAdOx1 nCoV-19 (AZD1222, University of Oxford / AstraZeneca). METHODS: We performed a single-centre open-label Phase I clinical trial of intranasal vaccination with ChAdOx1 nCoV-19 in healthy adults, using the existing formulation produced for intramuscular administration. Thirty SARS-CoV-2 vaccine-naÃ¯ve participants were allocated to receive 5Â Ã—Â 10(9) viral particles (VP, n=6), 2Â Ã—Â 10(10) VP (n=12), or 5Â Ã—Â 10(10) VP (n=12). Fourteen received second intranasal doses 28 days later. A further 12 received non-study intramuscular mRNA SARS-CoV-2 vaccination between study days 22 and 46. To investigate intranasal ChAdOx1 nCoV-19 as a booster, six participants who had previously received two intramuscular doses of ChAdOx1 nCoV-19 and six who had received two intramuscular doses of BNT162b2 (Pfizer / BioNTech) were given a single intranasal dose of 5Â Ã—Â 10(10) VP of ChAdOx1 nCoV-19. Objectives were to assess safety (primary) and mucosal antibody responses (secondary). FINDINGS: Reactogenicity was mild or moderate. Antigen-specific mucosal antibody responses to intranasal vaccination were detectable in a minority of participants, rarely exceeding levels seen after SARS-CoV-2 infection. Systemic responses to intranasal vaccination were typically weaker than after intramuscular vaccination with ChAdOx1 nCoV-19. Antigen-specific mucosal antibody was detectable in participants who received an intramuscular mRNA vaccine after intranasal vaccination. Seven participants developed symptomatic SARS-CoV-2 infection. INTERPRETATION: This formulation of

intranasal ChAdOx1 nCoV-19 showed an acceptable tolerability profile but induced neither a consistent mucosal antibody response nor a strong systemic response. FUNDING: AstraZeneca.

Induction of cross-reactive, mucosal anti-SARS-CoV-2 antibody responses in rheumatoid arthritis patients after 3rd dose of COVID-19 vaccination. Systemic vaccination against SARS-CoV-2 elicited high titers of specific antibodies in the blood and in the oral cavity. Preexisting autoimmune diseases, such as rheumatoid arthritis, and biological treatments, like B cell depletion, are known to exhibit higher risk of severe COVID-19 manifestation and increased frequency of breakthrough infections after vaccination. We hypothesized that such increased risk is associated with an aberrant induction of secreted antibodies in the oral cavity. Here we evaluated the levels of secreted antibodies in the oral cavity against the SARS-CoV-2 Spike protein during the course of vaccination in RA patients with or without B cell depletion. We found that total salivary IgG levels were correlated with number of B cells in the blood. Anti-Spike IgG responses 7 days after second vaccination were induced in the oral cavity of all healthy individuals, while only 6 out 23 RA patients exhibited anti-Spike IgG in their saliva regardless of B cell depleting therapy. Importantly, both salivary and serologic anti-Spike IgG and IgA responses towards WT and omicron Spike variants were efficiently induced by third vaccination in RA patients with or without B cell depletion to the levels that were similar to healthy individuals. Altogether, these data advocate for the necessity of three dose vaccination for RA patients to mount anti-Spike antibody responses at the mucosal surfaces and annotate the reduction of secreted salivary IgG by B cell depletion.

Real-world Evidence of COVID-19 Vaccines Effectiveness in Solid-organ Transplant Recipient Population in Colombia: A Study Nested in the Esperanza Cohort. BACKGROUND: Solid-organ transplant recipients (SOTRs) have a higher risk of coronavirus disease 2019 (COVID-19) complications and death and a less powerful and lasting response to vaccines and to natural infection. In Colombia, this population was prioritized in the National Vaccination Plan against COVID-19 and received vaccines from different platforms. The aim of this study was to estimate the effectiveness of the complete vaccination schedule and of the vaccine booster for COVID-19 administered to SOTRs in Colombia. METHODS: A nested-cohort was assembled within the population-based ESPERANZA cohort and included the subset of 16 y and older SOTRs (n = 6963); the follow-up period spanned March 11, 2021, to May 11, 2022. The vaccine effectiveness was estimated with Cox proportional-hazards models so that the overall effectiveness of the complete vaccination schedule, the vaccine booster, each used vaccine, and the homologous and heterologous schedules were estimated, adjusting by the main confounders. RESULTS: The overall effectiveness of being fully vaccinated was 73.7% (95% confidence interval [CI], 68.9%-77.0%) to prevent COVID-19 infection, 83.7% (95% CI, 78.7%-87.5%) to prevent hospitalization, and 92.1% (95% CI, 88.8%-94.4%) to prevent death due to COVID-19. Similarly, the effectiveness of the vaccine booster was 76.7% (95% CI, 70.6%-81.5%), 86.9% (95% CI, 79.4%-91.6%), and 94.5% (95% CI, 89.8%-97.1%) to prevent confirmed COVID-19 infection, hospitalization, and death due to COVID-19, respectively. In both cases, there were no statistically significant differences across age groups. CONCLUSIONS: Findings from this work show a high protection of vaccination against infection, hospitalization, and death due to COVID-19 in SOTRs, which increases with the vaccine booster.

Case Report: Retinal Vasculitis in Two Adolescents After COVID-19 Vaccination. PURPOSE: To report two cases of bilateral retinal vasculitis in adolescents following COVID-19 vaccination. STUDY DESIGN: Case report. RESULTS: Â We report the first two cases of retinal vasculitis in adolescents following COVID-19 vaccinations. Both patients received recent second-dose COVID-19 vaccinations (7 weeks and 4 weeks respectively), and presented with bilateral retinal vasculitis and vitritis. Investigations did not reveal other causes of retinal vasculitis. Both patients' retinal vasculitis settled with a short course of oral prednisolone. CONCLUSION: Although rare, the temporal association

between vaccination, bilateral eye involvement, and the absence of alternative infective or inflammatory causes, makes this a plausible etiology. mRNA vaccinations may cause an autoimmune reaction via host antigenic mimicry, and systemic vasculitis has previously been described. We believe that a short interval between COVID-19 vaccination doses might be a risk factor for the development of retinal vasculitis in adolescents, and clinicians should be aware to elicit vaccination history.

Multiple Evanescent White Dot Syndrome Following COVID-19 mRNA Vaccination. PURPOSE: To report two cases of multiple evanescent white dot syndrome (MEWDS) following COVID-19 vaccination with the BNT162b2 mRNA vaccine. METHODS: Two case reports. Case-1: A 40-yo Caucasian male, complained of blurred and decrease of vision in his left eye (OS) one week after the first dose of the BNT162b2 mRNA SARS-CoV-2 vaccine. Funduscopic examination OS showed multiple granular white dots with an aspect of foveal granularity. Case-2: A 23-yo woman also presented with defective and decrease of vision OS. She received her first dose of the BNT162b2 mRNA SARS-CoV-2 vaccine ten days before. Dilated fundus examination OS showed altered macular reflex with an aspect of foveal granularity. RESULTS: Multimodal imaging showed features of MEWDS in both cases. The anomalies found resolved spontaneously after 6Â weeks. CONCLUSION: Inflammation and immune dysregulation induced by COVID-19 mRNA vaccine or its adjuvants could be involved in ocular adverse effects.

Omicron infections profile and vaccination status among 1881 liver transplant recipients: a multi-centre retrospective cohort. ABSTRACTA wave of Omicron infections rapidly emerged in China in 2022, but large-scale data concerning the safety profile of vaccines and Coronavirus disease 2019 (COVID-19) infection features in liver transplant (LT) recipients have not been collected. Therefore, the aim of this study was to assess the protectiveness and safety profile of the inactivated vaccines in LT patients against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron variant infections. A multi-centre retrospective study was conducted in a cohort with a history of liver transplantation. A total of 1881 participants (487 vaccinated and 1394 unvaccinated patients) were enrolled from seven centres in China. Fourteen of the participants were infected by Omicron, and 50% patients had over 14 days of viral shedding duration. The protection rate of COVID-19 vaccinations to Omicron was 2.59%. The three breakthrough infections occurred more than 6 months after fully vaccinated. A total of 96 (19.7%) vaccinated patients had adverse events, including fatigue, myalgia, liver dysfunction, swelling, and scleroma. There were more Grade 3 adverse events in the preoperative vaccination group than those in the postoperative vaccination group. Inactivated whole-virion SARS-CoV-2 vaccines are safe in patients with post-liver transplantation. The efficacy of inactivated vaccines decreases after 6 months of vaccination, it is recommended that liver transplant patients get boosted vaccinations as early as possible even when they are fully vaccinated. Although clinical manifestations of Omicron infections were mild in LT patients, unvaccinated patients might have a higher risk of liver dysfunction during infections.

Ocular Complications Following COVID-19 Vaccination - Coincidence, Correlation, or Causation?

Analysis of Severe Illness After Postvaccination COVID-19 Breakthrough Among Adults With and Without HIV in the US. IMPORTANCE: Understanding the severity of postvaccination SARS-CoV-2 (ie, COVID-19) breakthrough illness among people with HIV (PWH) can inform vaccine guidelines and risk-reduction recommendations. OBJECTIVE: To estimate the rate and risk of severe breakthrough illness among vaccinated PWH and people without HIV (PWoH) who experience a breakthrough infection. DESIGN, SETTING, AND PARTICIPANTS: In this cohort study, the Corona-Infectious-Virus Epidemiology Team (CIVET-II) collaboration included adults (aged â‰¥18 years) with HIV who were receiving care and were fully vaccinated by June 30, 2021, along with PWoH matched according to date fully vaccinated, age group, race, ethnicity, and sex from 4 US integrated health systems and academic centers. Those with postvaccination COVID-19 breakthrough before December 31, 2021,

were eligible. EXPOSURES: HIV infection. MAIN OUTCOMES AND MEASURES: The main outcome was severe COVID-19 breakthrough illness, defined as hospitalization within 28 days after a breakthrough SARS-CoV-2 infection with a primary or secondary COVID-19 discharge diagnosis. Discrete time proportional hazards models estimated adjusted hazard ratios (aHRs) and 95% CIs of severe breakthrough illness within 28 days of breakthrough COVID-19 by HIV status adjusting for demographic variables, COVID-19 vaccine type, and clinical factors. The proportion of patients who received mechanical ventilation or died was compared by HIV status. RESULTS: Among 3649 patients with breakthrough COVID-19 (1241 PWH and 2408 PWoH), most were aged 55 years or older (2182 patients [59.8%]) and male (3244 patients [88.9%]). The cumulative incidence of severe illness in the first 28 days was low and comparable between PWoH and PWH (7.3% vs 6.7%; risk difference,â€‰-0.67%; 95% CI, -2.58% to 1.23%). The risk of severe breakthrough illness was 59% higher in PWH with CD4 cell counts less than 350 cells/Î¼L compared with PWoH (aHR, 1.59; 95% CI, 0.99 to 2.46; Pâ€‰=â€‰.049). In multivariable analyses among PWH, being female, older, having a cancer diagnosis, and lower CD4 cell count were associated with increased risk of severe breakthrough illness, whereas previous COVID-19 was associated with reduced risk. Among 249 hospitalized patients, 24 (9.6%) were mechanically ventilated and 20 (8.0%) died, with no difference by HIV status. CONCLUSIONS AND RELEVANCE: In this cohort study, the risk of severe COVID-19 breakthrough illness within 28 days of a breakthrough infection was low among vaccinated PWH and PWoH. PWH with moderate or severe immune suppression had a higher risk of severe breakthrough infection and should be included in groups prioritized for additional vaccine doses and risk-reduction strategies.

Reply to 'A case of pityriasis lichenoides et varioliformis acuta developed after first dose of Oxford-AstraZeneca COVID-19 vaccine'.

Association between the risk of seizure and COVID-19 vaccinations: A self-controlled case-series study. OBJECTIVE: The risk of seizure following BNT162b2 and CoronaVac vaccinations has been sparsely investigated. This study aimed to evaluate this association. METHOD: Patients who had their first seizure-related hospitalization between February 23, 2021 and January 31, 2022, were identified in Hong Kong. All seizure episodes happening on the day of vaccination (day 0) were excluded, since clinicians validated that most of the cases on day 0 were syncopal episodes. Within-individual comparison using a modified self-controlled case series analysis was applied to estimate the incidence rate ratio (IRR) with 95% confidence intervals (CIs) of seizure using conditional Poisson regression. RESULTS: We identified 1656 individuals who had their first seizure-related hospitalization (BNT162b2: 426; CoronaVac: 263; unvaccinated: 967) within the observation period. The incidence of seizure was 1.04 (95% CI .80-1.33) and 1.11 (95% CI .80-1.50) per 100â€‰000 doses of BNT162b2 and CoronaVac administered, respectively. Sixteen and 17 individuals, respectively, received a second dose after having a first seizure within 28â€‰days after the first dose of BNT162b2 and CoronaVac vaccinations. None had recurrent seizures after the second dose. There was no increased risk during day 1-6 after the first (BNT162b2: IRRÂ =Â 1.39, 95% CIÂ =Â .75-2.58; CoronaVac: IRRÂ =Â 1.19, 95% CIÂ =Â .50-2.83) and second doses (BNT162b2: IRRÂ =Â 1.36, 95% CIÂ =Â .72-2.57; CoronaVac: IRRÂ =Â .71, 95% CIÂ =Â .22-2.30) of vaccinations. During 7-13, 14-20, and 21-27â€‰days post-vaccination, no association was observed for either vaccine. SIGNIFICANCE: The findings demonstrated no increased risk of seizure following BNT162b2 and CoronaVac vaccinations. Future studies will be warranted to evaluate the risk of seizure following COVID-19 vaccinations in different populations, with subsequent doses to ensure the generalizability.

Case report: Clinical features of COVID-19 vaccine-induced exacerbation of psoriasis-A case series and mini review. Recently, COVID-19 vaccination-induced exacerbation or new-onset of psoriasis have been reported. Underlying immune pathogenesis is unclear and different mechanisms are assumed. Further, clinical- and vaccine-related features and characteristics are partly inconsistent and

remain to be elucidated. To add to the understanding of COVID-19 vaccination-triggered psoriasis, we report five cases with exacerbation or new-onset of psoriasis. In our cohort, one patient experienced the new onset of psoriasis, while four had an exacerbation following COVID-19 vaccination. In most patients, exacerbation or new onset occurred after the 2nd or 3rd vaccination. The mean latency from the day of vaccination was 7.2 (1.8) days (SD). The clinical impact with a mean PASI increase following COVID-19 vaccination of 7.2 (5.6) was considered relevant. In most cases, psoriatic lesions almost cleared after applying topical steroids in addition to current treatment, while one patient with psoriatic arthritis required systemic treatment. New onset and exacerbation of psoriasis have also been noted following COVID-19 infections. Hence, the underlying inflammatory response is most likely the culprit agent triggering psoriasis. This underscores that the benefits of COVID-19 vaccination far outweigh the risks, as also in patients with psoriasis.
Ventricular tachycardia because of myocardial infarction after COVID-19 vaccination.
A racing heart post-Pfizer/BioNTech BNT162b2. Palpitations is one of the most common side effects experienced post-messenger-RNA COVID-19 vaccines. However, some patients experience significant symptoms and further workup needs to be considered. We present an interesting case of inappropriate sinus tachycardia in a fit gentleman who presented with worsening palpitations and elevated heart rate post-first and -second dose of the Pfizer/BioNTech vaccine.
Single-cell sequencing of PBMC characterizes the altered transcriptomic landscape of classical monocytes in BNT162b2-induced myocarditis. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been the most dangerous threat to public health worldwide for the last few years, which led to the development of the novel mRNA vaccine (BNT162b2). However, BNT162b2 vaccination is known to be associated with myocarditis. Here, as an attempt to determine the pathogenesis of the disease and to develop biomarkers to determine whether subjects likely proceed to myocarditis after vaccination, we conducted a time series analysis of peripheral blood mononuclear cells of a patient with BNT162b2-induced myocarditis. Single-cell RNA sequence analysis identified monocytes as the cell clusters with the most dynamic changes. To identify distinct gene expression signatures, we compared monocytes of BNT162b2-induced myocarditis with monocytes under various conditions, including SARS-CoV-2 infection, BNT162b2 vaccination, and Kawasaki disease, a disease similar to myocarditis. Representative changes in the transcriptomic profile of classical monocytes include the upregulation of genes related to fatty acid metabolism and downregulation of transcription factor AP-1 activity. This study provides, for the first time, the importance of classical monocytes in the pathogenesis of myocarditis following BNT162b2 vaccination and presents the possibility that vaccination affects monocytes, further inducing their differentiation and infiltration into the heart.
Humoral response and neutralising capacity at 6 months post-vaccination against COVID-19 among institutionalised older adults in Argentina. The COVID-19 pandemic has particularly affected older adults residing in nursing homes, resulting in high rates of hospitalisation and death. Here, we evaluated the longitudinal humoral response and neutralising capacity in plasma samples of volunteers vaccinated with different platforms (Sputnik V, BBIBP-CorV, and AZD1222). A cohort of 851 participants, mean age 83 (60-103 years), from the province of Buenos Aires, Argentina were included. Sequential plasma samples were taken at different time points after vaccination. After completing the vaccination schedule, infection-naÃ¯ve volunteers who received either Sputnik V or AZD1222 exhibited significantly higher specific anti-Spike IgG titers than those who received BBIBP-CorV. Strong correlation between anti-Spike IgG titers and neutralising activity levels was evidenced at all times studied (rho=0.7 a 0.9). Previous exposure to SARS-CoV-2 and age <80 years were both associated with higher specific antibody levels. No differences in neutralising capacity were observed for the infection-naÃ¯ve participants in either gender or age group. Similar to anti-Spike IgG titers,

neutralising capacity decreased 3 to 9-fold at 6 months after initial vaccination for all platforms. Neutralising capacity against Omicron was between 10-58 fold lower compared to ancestral B.1 for all vaccine platforms at 21 days post dose 2 and 180 days post dose 1. This work provides evidence about the humoral response and neutralising capacity elicited by vaccination of a vulnerable elderly population. This data could be useful for pandemic management in defining public health policies, highlighting the need to apply reinforcements after a complete vaccination schedule.

COVID-19 Vaccine-Induced Rapid Progression of Prediabetes to Ketosis-Prone Diabetes Mellitus in an Elderly Male. Studies show a low progression rate of prediabetes to Type 2 diabetes mellitus (DM) that we commonly seek to reverse, but we don't associate prediabetes as a lead-up to the first presentation of ketosis. We present a prediabetic who, in less than a year, converted to GAD65 antibody-positive diabetes mellitus with a diabetic ketoacidosis presentation. A 69-year-old male presented with three weeks of fatigue, polyuria, polydipsia, abdominal pain, and weight loss. Vital signs and physical exam were normal except for abdominal tenderness and dry oral mucosa. Complete blood count (CBC) was normal; blood glucose was severely elevated with mild corrected hyponatremia; elevated anion gap metabolic acidosis with glucosuria and ketonuria. He received an insulin drip, normal saline, and potassium in the intensive care unit. His anion gap closed overnight and was switched to basal-bolus insulin. Hemoglobin A1c (HbA1c) came out to be higher than expected as compared to last year of low prediabetic value, decreased c-peptide levels, and positive anti-GAD65 antibody. His first abnormal HbA1c was 5.8% a year ago and no autoimmune marker was checked before. He was vaccinated with the messenger ribonucleic acid (mRNA) coronavirus disease 2019 (COVID-19) vaccine a year ago with an mRNA vaccine booster two months earlier. He was not COVID-19 infected. We discharged him with a basal-bolus insulin regimen. Type I DM passes from autoimmunity-positive normoglycemia to dysglycemia to the symptomatic stage, typically progressing more rapidly in children than in older adults. A new Type I or dysglycemia in Type II DM is increasingly reported after COVID-19 vaccines/infection. Mechanisms could be cytokine-mediated beta-cell damage or autoimmunity after mRNA vaccines or as a part of autoimmune syndrome induced by vaccine adjuvants. This case reports the rapid progression of prediabetes to Type 1 rather than Type 2 DM and highlights the possibility of dysglycemia after COVID-19 vaccines and calls for measures to prevent or early management of these side effects.

Acute Myopericarditis After the Third Vaccination of BNT162b2 in a Middle-Aged Man. Messenger ribonucleic acid (mRNA) vaccines againstÂ coronavirus disease 2019 (COVID-19) are highly effective in preventing and decreasing disease severity, but the duration of the effect is attenuated over time and repeated vaccination is required. A 41-year-old Japanese male presented to our hospital with chest pain three days after receiving the third dose of the BNT162b2 mRNA vaccine. After various examinations, such as endomyocardial biopsy and viral polymerase chain reaction (PCR) testing of endomyocardial biopsy tissue, we made the diagnosis of acute myopericarditis associated with booster vaccination. Here, we report a rare case of myopericarditis after booster mRNA vaccination.

Long COVID following Omicron wave in Eastern India-A retrospective cohort study. Long coronavirus disease (COVID) or postacute sequelae of coronavirus disease of 2019 (COVID-19) is widely reported but the data of long COVID after infection with the Omicron variant is limited. This study was conducted to estimate the incidence, characteristics of symptoms, and predictors of long COVID among COVID-19 patients diagnosed during the Omicron wave in Eastern India. The cohort of COVID-19 patients included were adults (â‰¥18 years) diagnosed asÂ severe acute respiratory syndrome coronavirus 2 positive with Reverse Transcription Polymerase Chain Reaction. After 28 days of diagnosis; participants were followed up with a telephonic interview to capture data on sociodemographic, clinical history, anthropometry, substance use, COVID-19 vaccination status, acute

COVID-19 symptoms, and long COVID symptoms. The long COVID symptoms were self-reported by the participants. Logistic regression was used to determine the predictors of long COVID. The median follow-up of participants was 73 days (Interquartile range; 67-83). The final analysis had 524 participants' data; among them 8.2% (95% Confidence Interval [CI]: 6%-10.9%) self-reported long COVID symptoms. Fatigue (34.9%) was the most common reported symptom followed by cough (27.9%). In multivariable logistic regression only two predictors were statistically significant-number of acute COVID-19 symptomsâ€‰â‰¥â€‰five (Adjusted odds ratio (aOR)â€‰=â€‰2.95, 95% CI: 1.30-6.71) and past history of COVID-19 (aORâ€‰=â€‰2.66, 95% CI: 1.14-6.22). The proportion of self-reported long COVID is considerably low among COVID-19 patients diagnosed during the Omicron wave in Eastern India when compared with estimates during Delta wave in the same setting.

Time course of adverse reactions following BNT162b2 vaccination in healthy and allergic disease individuals aged 5-11Â years and comparison with individuals aged 12-15Â years: an observational and historical cohort study. We aimed to investigate the type and frequency of adverse events over 7Â days following the first and second BNT162b2 vaccination. This observational and historical cohort study included patients aged 5-11Â years who received two doses of BNT162b2 and provided consent along with their guardians. We collected data on sex, age, height, weight, blood type, history of Bacille Calmette-Guerin vaccination, allergic disease, medication, history of coronavirus disease 2019 (COVID-19), and adverse reactions 7Â days following the first and second BNT162b2 vaccination using a questionnaire. Our results were compared with previously reported results for individuals aged 12-15Â years. A total of 421 participants were eligible for this study. Among the 216 patients with allergic disease, 48 (22.2%) had experienced worsening of their chronic diseases, and the frequency of fatigue and dizziness after the second dose was higher than that of healthy individuals. The experience of systemic adverse reactions was associated with asthma. The frequency of headache, diarrhea, fatigue, muscle/joint pain, and fever after the second BNT162b2 vaccination was lower in individuals aged 5-11Â years than in those aged 12-15Â years. Fever was the only systemic adverse reaction that lasted longer than 5Â days (1.0% of participants). CONCLUSIONS: Individuals with allergic diseases, who are potentially susceptible to COVID-19, may experience worsening of their chronic diseases and more frequent adverse reactions after BNT162b2 vaccination than healthy individuals. To ensure that children with allergic diseases receive the vaccine safely, further information needs to be collected. WHAT IS KNOWN: â€¢ Adverse reactions after BNT162b2 vaccination among individuals aged 5-11 years are generally nonserious, more common after second vaccination, and substantially less common compared to those observed among individuals aged 12-15 years. WHAT IS NEW: â€¢ Individuals with allergic diseases experienced worsening of their chronic diseases and more frequent adverse reactions after BNT162b2 vaccination than healthy individuals. â€¢Â Systemic adverse reactions were associated with asthma. Fever was the only systemic adverse reaction that lasted longer than 5 days.

Antibody response to a third booster dose of SARS-CoV-2 vaccination in adults with haematological and solid cancer: a systematic review. BACKGROUND: Patients living with cancer are at a significantly increased risk of morbidity and mortality after infection with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). This systematic review aims to investigate the current available evidence about the immunogenicity of SARS-CoV-2 booster vaccines in patients living with cancer. METHODS: A systematic search was undertaken for studies published until March 1, 2022. A systematic narrative review was undertaken to include all studies that evaluated the efficacy of booster vaccines against SARS-CoV-2 in patients with cancer. RESULTS: Fifteen studies encompassing 1205 patients with cancer were included. We found that a booster vaccine dose induced a higher response in patients with solid cancer as compared to haematological malignancies. Recent systemic anticancer therapy does not appear to affect seroconversion in solid organ malignancies, however,

there is an association between B-cell depleting therapies and poor seroconversion in haematological patients. CONCLUSIONS: Third booster vaccination induces an improved antibody response to SARS-CoV-2 in adults with haematological and solid cancer, relative to patients who only receive two doses. Access to vaccination boosters should be made available to patients at risk of poor immunological responses, and the provision of fourth doses may be of benefit to this vulnerable population. REGISTRATION: PROSPERO number CRD42021270420.

No correlation of neutralizing antibody titers against the Omicron variant after a booster dose of COVID-19 vaccines with subsequent breakthrough Omicron infections among healthcare workers.

Side effects of the Pfizer BioNTech vaccine in health workers of a hospital in the southeast of Mexico. INTRODUCTION: The goal of this study was to evaluate the side effects of application of the Pfizer BioNTech vaccine on the workers at a Mexican hospital. METHODOLOGY: A cross-sectional study was carried out, in which 1351 workers from a tertiary care center in the Mexican southeast were included. Sociodemographic data, comorbidities, and side effects after the Pfizer BioNTech vaccine were obtained through an online survey. The variables were analyzed through descriptive statistics. The presence or absence of side effects was analyzed through the Chi-square test or t-test, as appropriate. The result was considered statistically significant at $p < 0.05$. RESULTS: A total of 1351 health workers participated in the online survey. The mean age was 37.8 Â± 10.9 years and 56.4% were women. Among them, 8.2% suffered from high blood pressure. In addition, 76.7% manifested pain in the application area. The presence of side effects was associated with the female gender ($p < 0.01$). Side effects were more prevalent in younger age (37.2 Â± 10.7) than older age (41.5 Â± 10.8) ($p < 0.01$). There was no association with the presence of comorbidities ($p > 0.05$). CONCLUSIONS: The data suggest that pain in the application area is the most frequent side effect among workers in a Mexican hospital who received the Pfizer BioNTech vaccine against COVID-19. In addition, we observed sialorrhea as a side effect in the studied population and this had not previously been reported. The highest number of adverse events occurred between 24 to 72 hours after application.

Characteristics Associated With a Previous COVID-19 Diagnosis, Vaccine Uptake, and Intention to Be Vaccinated Among Essential Workers in the US Household Pulse Survey. Objectives. To explore previous COVID-19 diagnosis and COVID-19 vaccination status among US essential worker groups. Methods. We analyzed the US Census Household Pulse Survey (May 26-July 5, 2021), a nationally representative sample of adults aged 18 years and older. We compared currently employed essential workers working outside the home with those working at home using adjusted prevalence ratios. We calculated proportion vaccinated and intention to be vaccinated, stratifying by essential worker and demographic groups for those who worked or volunteered outside the home since January 1, 2021. Results. The proportion of workers with previous COVID-19 diagnosis was highest among first responders (24.9%) working outside the home compared with workers who did not (13.3%). Workers in agriculture, forestry, fishing, and hunting had the lowest vaccination rates (67.5%) compared with all workers (77.8%). Those without health insurance were much less likely to be vaccinated across all worker groups. Conclusions. This study underscores the importance of improving surveillance to monitor COVID-19 and other infectious diseases among workers and identify and implement tailored risk mitigation strategies, including vaccination campaigns, for workplaces. (Am J Public Health. 2022;112(11):1599-1610. https://doi.org/10.2105/AJPH.2022.307010).

SARS-CoV-2 Vaccines: Types, Working Principle, and Its Impact on Thrombosis and Gastrointestinal Disorders. In the current scenario of the coronavirus pandemic caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), considerable efforts have been made to control the pandemic by the development of a strong immune system through massive vaccination. Just after the discovery of the genetic sequences of SARS-CoV-2, the development of vaccines became the prime focus of scientists around the globe. About 200 SARS-CoV-2 candidate vaccines have already

been entered into preclinical and clinical trials. Various traditional and novel approaches are being utilized as a broad range of platforms. Viral vector (replicating and non-replicating), nucleic acid (DNA and RNA), recombinant protein, virus-like particle, peptide, live attenuated virus, an inactivated virus approaches are the prominent attributes of the vaccine development. This review article includes the current knowledge about the platforms used for the development of different vaccines, their working principles, their efficacy, and the impacts of COVID-19 vaccines on thrombosis. We provide a detailed description of the vaccines that are already approved by administrative authorities. Moreover, various strategies utilized in the development of emerging vaccines that are in the trial phases along with their mode of delivery have been discussed along with their effect on thrombosis and gastrointestinal disorders.
New onset of Susac syndrome after mRNA COVID-19 vaccine: a case report.
A case of Anti-MDA5-Positive dermatomyositis after inactivated COVID-19 vaccine.
COVID-19 vaccine-related eruption of papules and plaques-A case report.
A web-based survey of SARS-CoV-2 vaccination and its adverse effects in Chinese postoperative patients with breast cancer: a cross-sectional study. BACKGROUND: Vaccination against SARS-CoV-2 has been the most important strategy for preventing infection and controlling pandemics of coronavirus disease 2019 (COVID-19). Cancer patients have a significantly higher risk of infection with COVID-19 because of their impaired immunity. Breast cancer is the most common female malignant tumor in the world. However, studies on COVID-19 vaccination in breast cancer patients are scarce, so that more information is needed to guide vaccination in these. METHODS: We conducted a web-based questionnaire survey on SARS-CoV-2 vaccination in breast cancer patient. Questionnaires completed by non-postoperative patients will be considered invalid. The main variables in the questionnaire including vaccination status, willingness to get the vaccines, candidate factors, and measures of adverse events in vaccinated individuals were used for analysis. Univariate and multivariate logistic regression was used to estimate the associations. RESULTS: Among 947 valid online questionnaires, 341 (36.0%) accepted SARS-CoV-2 vaccination, while 606 (64.0%) did not. There were significant differences in age, current treatment, time since surgery, and symptoms of anxiety and depression between the two groups. Compared to vaccinated patients, we identified current treatment [odds ratio (OR) =0.51 for endocrine therapy; 95% confidence interval (CI): 0.29-0.89], time since surgery (OR =22.49 for 1-2 years; 95% CI: 12.31-41.10; OR =8.49 for 2-5 years; 95% CI: 4.98-14.46; OR =1.79 for >5 years; 95% CI: 1.11-2.89), and symptoms of depression (OR =2.48; 95% CI: 1.19-5.15) as significant factors for being unvaccinated. The overall incidence of adverse reactions was 43.1%, and the most common local and systemic adverse reactions were pain (28.4%) and fatigue (8.8%). However, about 76.6% of the unvaccinated participants were willing to be vaccinated. CONCLUSIONS: Compared to the general population, postoperative patients with breast cancer had a lower rate of vaccination for SARS-CoV-2. Receiving treatment, a shorter time since surgery, and symptoms of depression were associated with being unvaccinated. However, about 76.6% of the unvaccinated participants were willing to be vaccinated. Although our study showed that there were adverse effects of SARS-CoV-2 vaccines, such as pain, fatigue, they are common adverse effects of routine vaccination. We believe that vaccination against COVID-19 is safe in postoperative patients with breast cancer.
Seroconversion among rituximab-treated patients following SARS-CoV-2 vaccine supplemental dose. Rituximab (RTX) is a very effective treatment for autoimmune rheumatic diseases (AIRD), but it increases infection risk and impairs vaccine responses. Herein we evaluated the antibody response of RTX-treated patients to the supplemental COVID-19 vaccine. After the supplemental dose, 53.1% of patients had detectable antibody titers. Only 36% of patients who did not mount an antibody response after the original vaccine series did have detectable antibodies after the supplemental dose

(seroconversion). Patients with undetectable CD20(+) cell levels did not seroconvert while hypogammaglobulinemia was associated with a 15-times decrease in the likelihood of seroconversion. Although we noted 11 COVID-19 infections after the supplemental dose, no patients who received monoclonal antibodies pre-exposure prophylaxis had COVID-19 afterwards. We propose that patients receiving RTX should continue to be prioritized for prophylaxis measures and that vaccination should be timed after B cell recovery wherever possible.
An unusual case of superior vena cava syndrome.
Pfizer COVID-19 vaccine-induced peritonitis.
Transverse Leukonychia and Beau Lines Following COVID-19 Vaccination.
Can mRNA COVID-19 vaccines induce flares of chronic urticaria?
Atypical presentation of Sweet syndrome with nodular erythema and oral ulcerations provoked by Ad26.COV2.S SARS-CoV-2 vaccination and review of literature. The aim of this article is to present the case of acute febrile neutrophilic dermatosis (Sweet syndrome-SS) after Ad26.COV2.S vaccination against SARS-CoV-2. To the best of our knowledge, this is the second case of SS provoked by this specific vaccine. What is more, the mildly symptomatic beginning of the disease, later followed by typical SS manifestation with a variety of symptoms including nodular erythema of the feet and oral ulcerations, made it very challenging to establish the diagnosis. The article focuses on the current literature on the acute febrile neutrophilic dermatosis, along with the coexistence with other neutrophilic dermatoses and anti-SARS-CoV-2 vaccinations as provoking factors. It emphasizes the necessity for sharing the knowledge and experience on the subject of SS's clinical manifestations and underlying causes to facilitate prompt diagnosis and introduction of appropriate treatment.
Comparison of renal histopathology in three patients with gross hematuria after SARS-CoV-2 vaccination. We present three cases of IgA nephropathy with gross hematuria following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) messenger RNA (mRNA) vaccination. Case 1 was a 60-year-old woman who has previously experienced transient proteinuria. Case 2 was a 22-year-old woman with no history of urinary abnormality. Finally, case 3 was a 66-year-old woman who has had microscopic hematuria since she was in her 50s. They were all diagnosed as IgA nephropathy with little histological active lesion. Their renal function and proteinuria improved without the use of corticosteroids. There were differences in the findings of vascular endothelial damage based on the time between the appearance of gross hematuria and renal biopsy. Glomerular endocapillary damage could be a part of the mechanism triggered by mRNA vaccination. When a patient presents with gross hematuria following vaccination, a comprehensive approach including renal biopsy should be considered.
Features and follow-up of patients affected by noninflammatory myocarditis after coronavirus disease 2019 vaccination.
Evaluation of Seropositivity After Standard Doses of Vaccination Against SARS-CoV-2 in Patients With Early Breast Cancer Receiving Adjuvant Treatment. BACKGROUND: Coronavirus disease 2019 (COVID-19) pandemic affected millions of individuals, and patients with cancer are known to be more susceptible. Vaccines against SARS-CoV-2 have been developed and used for patients with cancer, but scarce data are available on their efficacy in patients under active anti-cancer therapies. MATERIALS AND METHODS: In this study, we semi-quantitatively measured the titers of the immunoglobulin G against the anti-spike protein subunit 1 of SARS-CoV-2 after vaccination of patients with early breast cancer undergoing concurrent chemotherapy, endocrinal or targeted non-cytotoxic treatments, and no treatments. RESULTS: Standard doses of COVID-19 vaccines provided sufficient immune responses in patients with early breast cancer, regardless of the type of anticancer therapies. However, the post-vaccination serum anti-spike antibody titers were significantly lower in the patients under

cytotoxic chemotherapy. CONCLUSION: Our study emphasizes the importance of the personalized risk stratification and consideration for booster doses in more vulnerable populations.

[Guillain-Barre syndrome and thrombocytopenia after SARS-CoV-2 vaccination with Moderna. A case report]. INTRODUCTION: The massive vaccination against the SARS-CoV-2 virus has demonstrated to be one of the major measures for the reduction of the morbidity and mortality that this virus causes. However, during the last months the administration of the vaccine has been also associated with some rare, but life-threatening, adverse effects. CASE REPORT: In this article we describe the case of a patient that developed a Guillain-Barre syndrome and an Idiopathic thrombocytopenic purpura nine days after the vaccination with the third dose for the SARS-CoV-2 virus (Moderna). He had received previously two doses of the AstraZeneca vaccine. Moreover, the patient was positive for auto-antibodies anti-SSA/Ro60 and auto-antibodies IgG anti-GM1 and IgG anti-GM3. DISCUSSION: Even though it is not possible to stablish a clear relation of causality between the administration of the vaccine booster for SARS-CoV-2 and the diseases developed by the patient, the association of two concomitant autoimmune processes is remarkable. As well as the positivity for the auto-antibodies anti-SSA/Ro60, which have been described in the bibliography in cases of SARS-CoV-2 infection.

SARS-CoV-2 vaccination associated venous sinus thrombosis in three patients. INTRODUCTION: There is increasing evidence that vaccinations against the severe acquired respiratory syndrome coronavirus type-2 (SARS-CoV-2) virus can be followed by venous sinus thrombosis (VST). Here we report on three patients who developed VST shortly after SARS-CoV-2 vaccinations. CASE SERIES: An 80-year-old male, a 58-year-old male, and a 34-year-old female developed VST 14 to 24 days after the first dose of an mRNA-based SARS-CoV-2 vaccine. All three patients profited from analgesics, heparinisation, and oral anticoagulation, but made only an incomplete recovery at the time of discharge. Arguments for a causal relationship are: VST was time-linked to vaccination in the three patients; VST was previously reported after SARS-CoV-2 vaccination; SARS-CoV-2 infections can be complicated by VST; and SARS-CoV-2 can be associated with hypercoagulability. The fact that no hypercoagulability occurred in a pilot study after SARS-CoV-2 vaccination and that there has been no evidence of an increased prevalence/incidence of VST after vaccination since the introduction of the SARS-CoV-2 vaccination speak against a causal relationship. CONCLUSIONS: SARS-CoV-2 vaccinations can occasionally be followed by a VST. There are more arguments for than against a causal relationship.

Assessment of COVID-19 vaccine booster dose acceptance, reluctance and concerns among elderly diabetes patients in Pakistan. People around the globe rumored so many things about the safety and efficacy of initial two doses and booster dose of Covid-19 vaccine, which eventually affected the acceptance of the only tool available against the fight between humans and virus. The aim of current study is to evaluate the acceptance and reluctance level among the population specifically elderly diabetes patients. The cross-sectional study was conducted during a time period of 3 months i.e. from July 2021 until September 2021. A 16-item questionnaire was used to assess the acceptance, reluctance and concerns of the Covid-19 vaccine booster dose among elderly diabetes patients. A 16-item questionnaire was used to assess the acceptance, reluctance and concerns of the Covid-19 vaccine booster dose among elderly diabetes patients. A total of 497 responses were collected and analyzed. Approximately 32% of respondents believed that they need additional information about the Covid-19 vaccine booster dose will be ineffective due to not enough information about the potential side effects of the vaccine dose, while around 80% of respondents showed concerns about safety, efficacy, newness and not enough information about vaccine contents. Around 47.1% of respondents expressed robust concerns about possible side effects of the Covid-19 vaccine booster dose.

Fulminant Myocarditis After SARS-CoV-2 mRNA Vaccine Successfully Managed With Biventricular Impella Support: Multimodality Imaging Follow-Up.

Delayed nonlocal cutaneous reactions after inactive COVID-19 vaccinations.

Adverse events after administration of the first and second doses of messenger RNA-based COVID-19 vaccines in Japanese subjects aged 12-18 years. OBJECTIVE: Using a prospective observational design, we assessed adverse events (AEs) after COVID-19 vaccination in Japanese patients. METHODS: Two doses of the mRNA-1273 (SPIKEVAXÂ®) or BNT162b2 (COMIRNATYÂ®) vaccine were administered to participants aged 12 to 18 years, and AEs after each dose were recorded for 14 days. Data on the duration and nature (local vs. systemic) of AEs were collected using a questionnaire. Sex-based differences in AE frequency were also analyzed. RESULTS: After the first and second doses, 152 and 135 vaccinees were enrolled, respectively. After the first dose, fever (>37.1Â°C) occurred in 38.9% of males and 50.0% of females, whereas local pain occurred in 89.8% and 97.7% of males and females, respectively (only SPIKEVAXÂ® was used as the first dose). After the second dose, fever (>37.1Â°C) occurred in 77.8% and 82.6% of males vaccinated with COMIRNATYÂ® and SPIKEVAXÂ®, respectively, and 82.6% of females (all received SPIKEVAXÂ®). The local pain rates in these groups were 80.6%, 76.3%, and 100%, respectively. After the second dose, local pain, fever (>38.1Â°C) and headache were significantly more common in female participants, and the median symptom duration was 3 days. CONCLUSIONS: AEs were more frequent after the second dose and in females.

Increased heart rate response to exercise following Pfizer COVID-19 vaccination with no change in cardiac output or stroke volume?

Pregnancy outcomes after SARS-CoV-2 infection in periods dominated by delta and omicron variants in Scotland: a population-based cohort study. BACKGROUND: Evidence suggests that the SARS-CoV-2 omicron (B.1Â·1.529) is associated with lower risks of adverse outcomes than the delta (B.1.617.2) variant among the general population. However, little is known about outcomes after omicron infection in pregnancy. We aimed to assess and compare short-term pregnancy outcomes after SARS-CoV-2 delta and omicron infection in pregnancy. METHODS: We did a national population-based cohort study of women who had SARS-CoV-2 infection in pregnancy between May 17, 2021, and Jan 31, 2022. The primary maternal outcome was admission to critical care within 21 days of infection or death within 28 days of date of infection. Pregnancy outcomes were preterm birth and stillbirth within 28 days of infection. Neonatal outcomes were death within 28 days of birth, and low Apgar score (<7 of 10, for babies born at term) or neonatal SARS-CoV-2 infection in births occurring within 28 days of maternal infection. We used periods when variants were dominant in the general Scottish population, based on 50% or more of cases being S-gene positive (delta variant, from May 17 to Dec 14, 2021) or S-gene negative (omicron variant, from Dec 15, 2021, to Jan 31, 2022) as surrogates for variant infections. Analyses used logistic regression, adjusting for maternal age, deprivation quintile, ethnicity, weeks of gestation, and vaccination status. Sensitivity analyses included restricting the analysis to those with first confirmed SARS-CoV-2 infection and using periods when delta or omicron had 90% or more predominance. FINDINGS: Between May 17, 2021, and Jan 31, 2022, there were 9923 SARS-CoV-2 infections in 9823 pregnancies, in 9817 women in Scotland. Compared with infections in the delta-dominant period, SARS-CoV-2 infections in pregnancy in the omicron-dominant period were associated with lower maternal critical care admission risk (0Â·3% [13 of 4968] vs 1Â·8% [89 of 4955]; adjusted odds ratio 0Â·25, 95% CI 0Â·14-0Â·44) and lower preterm birth within 28 days of infection (1Â·8% [37 of 2048] vs 4Â·2% [98 of 2338]; 0Â·57, 95% CI 0Â·38-0Â·87). There were no maternal deaths within 28 days of infection. Estimates of low Apgar scores were imprecise due to low numbers (5 [1Â·2%] of 423 with omicron vs 11 [2Â·1%] of 528 with delta, adjusted odds ratio 0Â·72, 0Â·23-2Â·32). There were fewer stillbirths in the omicron-dominant period than in the delta-dominant period (4Â·3 [2 of 462] per 1000 births vs 20Â·3 [13 of 639] per 1000) and

no neonatal deaths during the omicron-dominant period (0 [0 of 460] per 1000 births vs 6Â·3 [4 of 626] per 1000 births), thus numbers were too small to support adjusted analyses. Rates of neonatal infection were low in births within 28 days of maternal SARS-CoV-2 infection, with 11 cases of neonatal SARS-CoV-2 in the delta-dominant period, and 1 case in the omicron-dominant period. Of the 15 stillbirths, 12 occurred in women who had not received two or more doses of COVID-19 vaccination at the time of SARS-CoV-2 infection in pregnancy. All 12 cases of neonatal SARS-CoV-2 infection occurred in women who had not received two or more doses of vaccine at the time of maternal infection. Findings in sensitivity analyses were similar to those in the main analyses. INTERPRETATION: Pregnant women infected with SARS-CoV-2 were substantially less likely to have a preterm birth or maternal critical care admission during the omicron-dominant period than during the delta-dominant period. FUNDING: Wellcome Trust, Tommy's charity, Medical Research Council, UK Research and Innovation, Health Data Research UK, National Core Studies-Data and Connectivity, Public Health Scotland, Scottish Government Health and Social Care, Scottish Government Chief Scientist Office, National Research Scotland.

COVID vaccine recommendations in dermatologic patients on immunosuppressive agents: Lessons learned from pandemic. BACKGROUND: Since SARS-CoV2 vaccines were approved without enough long-term monitoring due to emergent situations, some issues have been raised about timing and protocol of receiving them by patients treated by different immunosuppressive agents. AIM AND METHOD: Here, we present different aspects of SARS-CoV-2 vaccination in such patients in the field of dermatology. RESULT: In brief, SARS-CoV-2 vaccination is recommended in all dermatologic patients, regardless of their disorders and therapeutic regimens. Nevertheless, special considerations should be given to the immunosuppressive therapy and its association with vaccination timing due to the decreased immunogenicity of vaccines in this setting. CONCLUSION: Novel biologic immunotherapies are advantageous over conventional systemic therapies not only in their safety and selective functions but also in this aspect that many of them do not affect vaccines immunogenicity.

How Media Literacy, Trust of Experts and Flu Vaccine Behaviors Associated with COVID-19 Vaccine Intentions. PURPOSE: To assess how previous experiences and new information contributed to COVID-19 vaccine intentions. DESIGN: Online survey (N = 1264) with quality checks. SETTING: Cross-sectional U.S. survey fielded June 22-July 18, 2020. SAMPLE: U.S. residents 18+; quotas reflecting U.S. Census, limited to English speakers participating in internet panels. MEASURES: Media literacy for news content and sources, COVID-19 knowledge; perceived usefulness of health experts; if received flu vaccine in past 12 months; vaccine willingness scale; demographics. ANALYSIS: Structural equation modelling. RESULTS: Perceived usefulness of health experts (b = .422, P < .001) and media literacy (b = .162, P < .003) predicted most variance in vaccine intentions (R-squared=31.5%). A significant interaction (b = .163, P < .001) between knowledge (b = -.132, P = .052) and getting flu shot (b = .185, P < .001) predicted additional 3.5% of the variance in future vaccine intentions. An increase in knowledge of COVID-19 associated with a decrease in vaccine intention among those declining the flu shot. CONCLUSION: The interaction result suggests COVID-19 knowledge had a positive association with vaccine intention for flu shot recipients but a counter-productive association for those declining it. Media literacy and trust in health experts provided strong counterbalancing influences. Survey-based findings are correlational; thus, predictions are based on theory. Future research should study these relationships with panel data or experimental designs.

Associations of neuralgic amyotrophy with COVID-19 vaccination: Disproportionality analysis using the World Health Organization pharmacovigilance database. INTRODUCTION/AIMS: There are limited studies on the association of COVID-19 vaccination with neuralgic amyotrophy (NA). Therefore, we evaluated the association between COVID-19 vaccination and the occurrence of NA. METHODS: We explored unexpected safety signals for NA related to COVID-19 vaccination through

disproportionality analysis using VigiBase, the World Health Organization's pharmacovigilance database. RESULTS: On October 15, 2021, 335 cases of NA were identified in the database. The median time to onset of NA after vaccination was around 2â€‰weeks. A significant signal of disproportionality of NA was observed for the ChAdOx1 nCoV-19 vaccine (AstraZeneca) (information component [IC](025) Â =Â 0.33, reporting odds ratio [ROR](025) Â =Â 1.30) and two mRNA-based COVID-19 vaccines (BNT162b2 [Pfizer and BioNTech] and mRNA-1273 [Moderna]) (IC(025) Â =Â 1.74, ROR(025) Â =Â 3.82) compared with the entire database. However, when compared with influenza vaccines, we did not detect any signal of disproportionality of NA for both the ChAdOx1 nCoV-19 vaccine (IC(025) Â =Â -2.71, ROR(025) Â =Â 0.05) and mRNA-based COVID-19 vaccines (IC(025) Â =Â -1.38, ROR(025) Â =Â 0.13). DISCUSSION: A weak association was observed between NA and COVID-19 vaccines. However, the risk did not surpass that of influenza vaccines.

Letter by Kounis et al Regarding Article, "Biopsy-Proven Giant Cell Myocarditis Following the COVID-19 Vaccine".

Safety and adverse events following COVID-19 vaccination among people with epilepsy: A cross-sectional study. OBJECTIVE: Epilepsy is a non-communicable disease costing a massive burden globally. It is known that there is increased prevalence of morbidity and mortality following COVID-19 infection among people with epilepsy (PWE). However, there is limited information about the adverse events following COVID-19 immunization among PWE. Hence, this study aimed to assess the safety and adverse events following immunization (AEFI) of various COVID-19 vaccines among PWE fromÂ our centre, focusing on neurological AEFI. METHODS: This cross-sectional study recruited 120 adult PWE from the Neurology Clinic of the Universiti Kebangsaan Malaysia Medical Centre (UKMMC). Consent-taking was conducted via synchronous or asynchronous approaches, followed by a phone call interview session. The interview collected socio-demographic information, epilepsy-related variables, and vaccination-related variables. Univariate analysis and multiple logistic regression analysis were done to confirm factors associated with the AEFI of COVID-19 vaccination. RESULTS: Among all types of COVID-19 vaccines, most of the PWE received the CominartyÂ® COVID-19 vaccination (52.5%). Overall, local AEFI was the quickest to develop, with an average onset within a day. PWE with normal body mass index (BMI) had a higher risk of developing both local and systemic AEFI compared to those underweight and obese PWE (OR: 15.09, 95% CI 1.70-134.28, PÂ =Â 0.02). SIGNIFICANCE: COVID-19 vaccines are safe for PWE. AEFI among PWE are similar to those of the general population following COVID-19 vaccination. Therefore, clinicians should encourage PWE to take COVID-19 vaccines.

Undetermined Fatal Complications of SARS-CoV-2 Vaccinations Require Clarification by Autopsy. How to cite this article: Finsterer J. Undetermined Fatal Complications of SARS-CoV-2 Vaccinations Require Clarification by Autopsy. Indian J Crit Care Med 2022;26(9):1060-1061.

Commentary: Case report: Associated ocular adverse reactions with inactivated COVID-19 vaccine in China.

Pituitary apoplexy after COVID-19 vaccination: Correspondence.

Neurofilament light chain and vaccination status associate with clinical outcomes in severe COVID-19. Blood neurofilament light chain (NFL) is proposed to serve as an estimate of disease severity in hospitalized patients with coronavirus disease 2019 (COVID-19). We show that NFL concentrations in plasma collected from 880 patients with COVID-19 within 5Â days of hospital admission were elevated compared to controls. Higher plasma NFL associated with worse clinical outcomes including the need for mechanical ventilation, intensive care, prolonged hospitalization, and greater functional disability at discharge. No difference in the studied clinical outcomes between black/African American and white patients was found. Finally, vaccination associated with less disability at time of hospital discharge. In aggregate, our findings support the utility of measuring NFL shortly after hospital

admission to estimate disease severity and show that race does not influence clinical outcomes caused by COVID-19 assuming equivalent access to care, and that vaccination may lessen the degree of COVID-19-caused disability.

COVID-19 Vaccination Associated Bilateral Pulmonary Embolism: Cause or Coincidence. BACKGROUND: Acute pulmonary embolism (APE) is a common cause of morbidity and mortality all over the world. Sudden onset dyspnea and chest pain are characteristic. Prior to our index case, only two previous cases of bilateral pulmonary thromboembolism were reported in black Africans and the first to be associated with COVID-19 vaccination. These cases were seen and described in middle-aged men. Case Summary. A 59-year-old man presented with a 2 week history of sudden onset dyspnea and a week history of productive cough. No associated chest pain or hemoptysis. No preceding history suggestive of leg pain/swelling. The patient had the booster dose of moderna (mRNA) COVID-19 vaccine a month before the onset of symptoms. There was associated anorexia, generalized body pain, joint pain, and weakness. He had reduced oxygen saturation at presentation with tachycardia. CTPA showed nearly occlusive right and left pulmonary arteries. CONCLUSION: Bilateral acute pulmonary embolism is rare all over the world. Its association with COVID-19 vaccine administration is even rarer. However, the clinical presentations and investigation findings are similar to the descriptions available in the literature for unilateral APE.

A Single-Centre Experience of Post-COVID-19 Vaccine-Related Immune-Mediated Complications. The significant impact of the COVID-19 pandemic has resulted in a worldwide effort to develop effective vaccines. In the United Kingdom, the COVID-19 vaccine development and roll-out has been overwhelmingly successful in reducing infections and deaths. However, case reports have emerged of a rare syndrome of vaccine-induced immune thrombocytopenia and thrombosis (VITT), as well as cases of immune thrombocytopenia (ITP). This has necessitated a better understanding of these conditions. However, as both VITT and "vaccine-associated ITP" are emerging conditions, evidence on the clinical features, epidemiology, and management is still evolving. Subsequently, with the initiation of the COVID-19 vaccine booster program, it has become increasingly important to continue to collect accurate data on post-COVID-19 vaccine complications to aid with their prompt recognition and management. In this case series, we report on the presentations and management of seven cases of post-COVID-19 vaccine-related immune-mediated complications which occurred at our center between the months of March and July 2021.

Development of facial palsy following COVID-19 vaccination: A systematic review. OBJECTIVE: Reports of facial palsy occurring after the receipt of COVID-19 vaccines have raised concerns but are rare. The purpose of this study is to systematically assess the association between COVID-19 vaccination and facial palsy. METHODS: Our systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) checklist and compiled all the reported cases of facial palsy post-COVID-19 vaccination. We discussed the probable pathophysiology behind facial palsy as a consequence of COVID-19 vaccination and measures to be taken for future reference. Furthermore, we conducted a detailed assessment of characteristics, clinical courses, treatment, and recovery of patients with facial palsy after receiving a COVID-19 vaccine. RESULTS: We included 37 studies providing data on 58 individuals in our review. Over half (51.72%) of the patients complained of facial paralysis following the Oxford-AstraZeneca vaccination. Out of 51 cases, most (88.24%) occurred after the 1st dose. The majority (53.45%) of cases had bilateral facial palsy. Intravenous immunoglobin (IVIg), corticosteroids, and plasmapheresis were the first line of treatment with 75.93% of patients partially recovered, including those undergoing treatment or a lack of follow-up till the end while 22.22% had complete symptomatic recovery. CONCLUSIONS: Our review shows that Bell's palsy can be a plausible non-serious adverse effect of COVID-19 vaccination. However, the association observed between COVID-19 vaccination and Bell's palsy is less threatening than the

COVID-19 infection. Hence, vaccination should be encouraged because facial palsy, if it occurs, has shown favourable outcomes with treatment.

Thrombocytopenia and pneumonitis associated with BNT16B2b2 mRNA COVID-19 vaccine: A case report. An 80-year-old Japanese male patient with BehÃ§et's disease presented with a seven-day history of fever, cough, and progressive shortness of breath after receiving a second dose of the BNT16B2b2 mRNA COVID-19 vaccine (Pfizer-BioNTech). The initial diagnosis was community-acquired pneumonia, and antibiotic treatment was started but proved ineffective. Twenty days after onset, his platelet count was significantly decreased. We suspected vaccine-induced pneumonitis and thrombocytopenia. After administration of prednisolone and intravenous immunoglobulin, and platelet transfusions, his platelet count normalized. The pneumonia symptoms improved three weeks after onset. Herein, we also summarize previous reports of cases of pneumonitis and thrombocytopenia associated with SARS-CoV-2 vaccination.

Thrombosis after SARS-CoV2 infection or COVID-19 vaccination: will a nonpathologic anti-PF4 antibody be a solution?-A narrative review. The coronavirus disease 2019 (COVID-19) pandemic was triggered by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a previously unknown strain of coronavirus. To fully understand the consequences and complications of SARS-CoV-2 infections, we have reviewed current literature on coagulation dysfunctions that are related to the disease and vaccination. While COVID-19 is more commonly considered as a respiratory illness, studies indicate that, in addition to respiratory illness, a coagulation dysfunction may develop in individuals after the initial infection, placing them at the risk of developing thrombotic events. Patients who died of COVID-19 had higher levels of D-dimer, a biomarker for blood clot formation and breakdown. Effective treatments for coagulation dysfunctions are critically needed to improve patient survival. On the other hand, antibodies against platelet factor 4 (PF4)/heparin may be found in patients with rare instances of vaccine-induced immunological thrombotic thrombocytopenia (VITT) following vaccination with adenovirus-based vaccines. VITT is characterized by atypical thrombosis and thrombocytopenia, similar to immune-mediated heparin-induced thrombocytopenia (HIT), but with no need for heparin to trigger the immune response. Although both adenovirus-based and mRNA-based vaccines express the Spike protein of SARS-CoV-2, VITT is exclusively related to adenovirus-based vaccines. Due to the resemblance with HIT, the use of heparin is highly discouraged against treating patients with thrombotic thrombocytopenia after SARS-CoV-2 infection or with VITT after vaccination. Intravenous immunoglobulin therapy coupled with anticoagulation is recommended instead. The well-studied anti-PF4 monoclonal antibody RTO, which does not induce pathologic immune complexes in the presence of heparin and has been humanized for a potential treatment modality for HIT, may provide a nonanticoagulant HIT-specific solution to the problem of increased blood coagulation after SARS-CoV-2 infection or the VITT after immunization.

Bilateral upper extremity myositis after COVID-19 vaccination. Vaccination adverse reactions are common and usually are represented by transitory pain and edema. We present a case of bilateral muscle edema involving shoulders and arms due to myositis following COVID-19 vaccination, and focus on the imaging findings to differentiate with other diagnosis such as infection and tumors.

Reaction of SARS-CoV-2 antibodies with other pathogens, vaccines, and food antigens. It has been shown that SARS-CoV-2 shares homology and cross-reacts with vaccines, other viruses, common bacteria and many human tissues. We were inspired by these findings, firstly, to investigate the reaction of SARS-CoV-2 monoclonal antibody with different pathogens and vaccines, particularly DTaP. Additionally, since our earlier studies have shown immune reactivity by antibodies made against pathogens and autoantigens towards different food antigens, we also studied cross-reaction between SARS-CoV-2 and common foods. For this, we reacted monoclonal and polyclonal antibodies against SARS-CoV-2 spike protein and nucleoprotein with 15 different bacterial and viral antigens and

2 different vaccines, BCG and DTaP, as well as with 180 different food peptides and proteins. The strongest reaction by SARS-CoV-2 antibodies were with DTaP vaccine antigen, E. faecalis, roasted almond, broccoli, soy, cashew, Î±+Î² casein and milk, pork, rice endochitinase, pineapple bromelain, and lentil lectin. Because the immune system tends to form immune responses towards the original version of an antigen that it has encountered, this cross-reactivity may have its advantages with regards to immunity against SARS-CoV-2, where the SARS-CoV-2 virus may elicit a "remembered" immune response because of its structural similarity to a pathogen or food antigen to which the immune system was previously exposed. Our findings indicate that cross-reactivity elicited by DTaP vaccines in combination with common herpesviruses, bacteria that are part of our normal flora such as E. faecalis, and foods that we consume on a daily basis should be investigated for possible cross-protection against COVID-19. Additional experiments would be needed to clarify whether or not this cross-protection is due to cross-reactive antibodies or long-term memory T and B cells in the blood.

Paracentral Acute Middle Maculopathy Associated With Cilioretinal Artery Insufficiency Following COVID-19 Vaccination in a Young Patient. We aim toÂ present a unique case of unilateral paracentral acute middle maculopathy (PAMM) associated with cilioretinal artery insufficiency following the coronavirus disease 2019 (COVID-19) vaccination.Â A 28-year-old male complained of a sudden blurring of vision in his left eye 40 days after receiving the second dose of COVID-19 immunization. The optical coherence tomography revealed a diffuse paracentral area of hyper-reflective change in the inner plexiform layerÂ and an increase in the inner nuclear layer volume, consistent with PAMMÂ along the course of the cilioretinal artery. PAMM has beenÂ connectedÂ to an assortmentÂ of retinal vasculatureÂ anomalies. Considering COVID-19 vaccination, we hypothesize that the immunogenic cascade following vaccination dysregulated coagulation and led to retinal vascular thrombosis. However, the link between COVID-19 vaccination and retinal vascular occlusion disease remains unknown.

Inspiration to mRNA-based COVID-19 vaccination: Serious adverse case reports with hepatitis B vaccine in real-world. OBJECTIVES: The hepatitis B vaccine comprises hepatitis B surface antigen (HBsAg) produced by transgenic yeast cells. There are few serious adverse events (SAE) reports after Hepatitis B vaccination. METHODS: The authors searched the Chinese legal documents database for all SAE with Hepatitis B vaccination from January 2010 to January 2022. RESULTS: All seven patients received yeast-derived recombinant hepatitis B vaccine. Three cases of myocarditis (death), 2 cases of interstitial pneumonia (death), and 2 cases of encephalitis. The mean time of onset of SAE was 8.3 Â± 4.3 h after vaccination. CONCLUSION: The mechanism of vaccine-induced myocarditis may come from immune protein reactions. Based on the experience of Hepatitis B vaccine adverse events, we present new insights into the mechanism of myocarditis caused by the COVID-19 vaccine.

Long-term humoral immunity decline in hemodialysis patients following severe acute respiratory syndrome coronavirus 2 vaccination: A cohort study. BACKGROUND AND AIMS: Dialysis patients are extremely vulnerable to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection with high rates of hospitalization and mortality rates. In JanuaryÂ 2021, the University of Virginia Dialysis Program initiated a program-wide vaccination campaign to administer the Pfizer BioNTech messenger RNA SARS-CoV-2 (BNT162b2) vaccine. The aim of this study was to characterize the long-term time-dependent decline in humoral immunity in hemodialysis patients. METHODS: A prospective cohort study measuring serial monthly semiquantitative IgG antibody levels to the SARS-CoV-2 spike protein receptor binding domain in fully vaccinated in-center hemodialysis patients. Samples were collected monthly and tested for anti-SARS-CoV-2 antibodies against the anti-spike S1 domain for 2-6 months post full vaccination. Results were presented as internationally harmonized binding antibody units (BAU/ml). To analyze the change in antibody levels over time, a linear mixed model with random intercept and random slope was used for longitudinal antibody levels. A

multivariable model was used to estimate the slope of antibody levels by adjusting for selected patient characteristics. Based on the estimated intercepts and slopes for each subject from the unadjusted model, 10-month antibody levels were projected. RESULTS: The mean baseline antibody level was 647.59â€‰BAU/ml and 87.88% (29/33) of patients were considered qualitatively positive. Two patients were negative at baseline and an additional two had borderline results. Patient antibody levels declined at an adjusted average rate of 31% per month. At 6 months postvaccination, 40% of patients remaining in the cohort possessed either negative or borderline IgG antibody levels. Projecting future antibody levels suggests that 65% of the cohort will progress to borderline or negative antibody levels at 10 months post full vaccination. CONCLUSION: The long-term vaccine response following vaccination with the BNT162b2 in hemodialysis patients was characterized. Our data addÂ to the limited pool of data in this patient population and emphasizeÂ the critical need for vaccine boosters.

Severe treatment-refractory antibody positive autoimmune autonomic ganglionopathy after mRNA COVID19 vaccination. BACKGROUND: COVID-19 vaccine-associated peripheral and central neuroimmunological disorders have been well described. We present the case of a 56Â year old male who developed Î±3-ganglionic AChR antibody positive Autoimmune Autonomic Ganglionopathy (AAG) after completion of a two-dose course of mRNA (Comirnaty) vaccination for COVID19. RESULTS: A previously hypertensive 56Â year old male presented with the subacute onset of severe constipation, urinary retention, erectile dysfunction, sudomotor failure, sicca symptoms, non-reactive pupils and severe orthostatic hypotension shortly after receiving the second dose of an mRNA vaccine against COVID19. Autonomic testing revealed severe cardiovagal, adrenergic and sudomotor impairment, and tonic 'half-mast' pupils with evidence of sympathetic and parasympathetic denervation. Pathological Î±3-ganglionic ACHR antibodies were positive in serum as detected by a new flow cytometric immunomodulation assay. Malignancy was excluded. The patient was diagnosed with severe, treatment-refractory acute AAG. CONCLUSIONS: While autonomic dysfunction has been previously reported post-COVID19 vaccination, to our knowledge this is the first reported case of antibody-positive AAG in this setting. The severity of this case is in marked contrast to the existing literature on idiopathic antibody-positive autoimmune pandysautonomia.

Safety and Efficacy of the NVX-CoV2373 Coronavirus Disease 2019 Vaccine at Completion of the Placebo-Controlled Phase of a Randomized Controlled Trial. BACKGROUND: The recombinant protein-based vaccine, NVX-CoV2373, demonstrated 89.7% efficacy against coronavirus disease 2019 (COVID-19) in a phase 3, randomized, observer-blinded, placebo-controlled trial in the United Kingdom. The protocol was amended to include a blinded crossover. Data to the end of the placebo-controlled phase are reported. METHODS: Adults aged 18-84 years received 2 doses of NVX-CoV2373 or placebo (1:1) and were monitored for virologically confirmed mild, moderate, or severe COVID-19 (onset from 7 days after second vaccination). Participants who developed immunoglobulin G (IgG) against nucleocapsid protein but did not show symptomatic COVID-19 were considered asymptomatic. Secondary outcomes included anti-spike (S) IgG responses, wild-type virus neutralization, and T-cell responses. RESULTS: Of 15 185 participants, 13 989 remained in the per-protocol efficacy population (6989 NVX-CoV2373, 7000 placebo). At a maximum of 7.5 months (median, 4.5) postvaccination, there were 24 cases of COVID-19 among NVX-CoV2373 recipients and 134 cases among placebo recipients, a vaccine efficacy of 82.7% (95% confidence interval [CI], 73.3%-88.8%). Vaccine efficacy was 100% (95% CI, 17.9%-100.0%) against severe disease and 76.3% (95% CI, 57.4%-86.8%) against asymptomatic disease. High anti-S and neutralization responses to vaccination were evident, together with S-protein-specific induction of interferon-Î³ secretion in peripheral blood T cells. Incidence of serious adverse events and adverse events of special interest were similar between groups. CONCLUSIONS: A 2-dose regimen of NVX-CoV2373 conferred a high level of ongoing

protection against asymptomatic, symptomatic, and severe COVID-19 through >6 months postvaccination. A gradual decrease of protection suggests that a booster may be indicated. CLINICAL TRIALS REGISTRATION: EudraCT, 2020-004123-16.

Fixed drug eruptions - the common and novel culprits since 2000. A fixed drug eruption (FDE) is a common cutaneous adverse drug reaction which occurs following administration of an offending drug. The aim of this review is to provide an update on the list of drugs causing FDE, with a focus on emerging drug culprits reported since the start of the century. Across published literature, triggers for FDE are widely varied. The most frequently implicated drugs include analgesics (nonsteroidal anti-inflammatory drugs [NSAIDs] and paracetamol) and antibiotics. Co-trimoxazole is perhaps the most well described single agent. Since the start of the century there have been over 200 drugs named in case reports on FDE. Newer, novel agents of note include cyclooxygenase-2 specific inhibitors, fluconazole, and phosphodiesteraseÂ 5 inhibitors. Other implicated drugs include vaccines, such as various SARS-CoV-2 vaccines. Drugs incriminated in FDE vary based on the geographical region studied and prescribing patterns at a given time. Newer drugs continue to enter the market and are playing an increasing role in the field of FDE. Awareness of rarer culprits and emerging novel agents can help identify a trigger, allowing for prompt withdrawal of the causative agent, preventing recurrence.

Risk for uveitis relapse after COVID-19 vaccination. OBJECTIVES: Several studies suggested that coronavirus disease 2019 (COVID-19) vaccination may lead to uveitis, a vision-threatening condition often associated with a variety of autoimmune or autoinflammatory diseases. This study aims to explore factors that influence the risk of uveitis relapse after COVID-19 vaccination to guide the prevention of disease. METHODS: Uveitis relapse was evidenced by worsening activity of intraocular inflammation (e.g. anterior chamber cells, vitreous haze) as defined by the Standardization of Uveitis Nomenclature Working Group. Time to uveitis relapse since the administration of each dose of COVID-19 vaccine was compared across participants with modifiable variables. RESULTS: The primary analysis included 438 non-COVID-19 participants with 857 doses of COVID-19 vaccine administered in total. The median age was 41 years (interquartile range, 30 to 51), and 57.3% were female. A total of 39 episodes of uveitis relapse events occurred in 34 patients after the receipt of a dose of COVID-19 vaccine within 30 days. The median time to relapse after vaccination was 5 days (interquartile range, 1 to 14). Concomitant use of systemic glucocorticoids at the time of vaccination was independently associated with a decrease in risk of relapse after vaccination (HR, 0.23 [95% CI, 0.07-0.74]; P valueÂ =Â 0.014). There was a trend in attenuating the risk of relapse with increasing prednisone dose from none to less than 20Â mg per day and then to 20Â mg per day or greater (P value for trendÂ =Â 0.029). CONCLUSIONS: Concomitant treatment with systemic glucocorticoids for uveitis at the time of COVID-19 vaccination was associated with a dose-dependent lower risk of uveitis relapse after vaccination.

Sweet syndrome after the first dose of SARS-CoV-2 vaccine (Pfizer-BioNTech).

A multinational, phase 2, randomised, adaptive protocol to evaluate immunogenicity and reactogenicity of different COVID-19 vaccines in adults â‰¥75 already vaccinated against SARS-CoV-2 (EU-COVAT-1-AGED): a trial conducted within the VACCELERATE network. BACKGROUND: In the ongoing COVID-19 pandemic, advanced age is a risk factor for a severe clinical course of SARS-CoV-2 infection. Thus, older people may benefit in particular from booster doses with potent vaccines and research should focus on optimal vaccination schedules. In addition to each individual's medical history, immunosenescence warrants further research in this population. This study investigates vaccine-induced immune response over 1 year. METHODS/DESIGN: EU-COVAT-1-AGED is a randomised controlled, adaptive, multicentre phase II protocol evaluating different booster strategies in individuals aged â‰¥75 years (n=600) already vaccinated against SARS-CoV-2. The initial protocol

foresaw a 3rd vaccination (1st booster) as study intervention. The present modified Part B of this trial foresees testing of mRNA-1273 (SpikevaxÂ®) vs. BNT162b2 (ComirnatyÂ®) as 4th vaccination dose (2nd booster) for comparative assessment of their immunogenicity and safety against SARS-CoV-2 wild-type and variants. The primary endpoint of the trial is to assess the rate of 2-fold antibody titre increase 14 days after vaccination measured by quantitative enzyme-linked immunosorbent assay (Anti-RBD-ELISA) against wild-type virus. Secondary endpoints include the changes in neutralising antibody titres (Virus Neutralisation Assay) against wild-type as well as against Variants of Concern (VOC) at 14 days and up to 12 months. T cell response measured by qPCR will be performed in subgroups at 14 days as exploratory endpoint. Biobanking samples are being collected for neutralising antibody titres against potential future VOC. Furthermore, potential correlates between humoral immune response, T cell response and neutralising capacity will be assessed. The primary endpoint analysis will be triggered as soon as for all patients the primary endpoint (14 days after the 4th vaccination dose) has been observed. DISCUSSION: The EU-COVAT-1-AGED trial Part B compares immunogenicity and safety of mRNA-1273 (SpikevaxÂ®) and BNT162b2 (ComirnatyÂ®) as 4th SARS-CoV-2 vaccine dose in adults â‰¥75 years of age. The findings of this trial have the potential to optimise the COVID-19 vaccination strategy for this at-risk population. TRIAL REGISTRATION: ClinicalTrials.gov NCT05160766 . Registered on 16 December 2021. PROTOCOL VERSION: V06_0: 27 July 2022.

Development and exacerbation of autoimmune hemolytic anemia following COVID-19 vaccination: A systematic review. Autoimmune hemolytic anemia (AIHA) is caused by the production of autoantibodies against RBCs. COVID-19 vaccines can reduce the risk of severe disease, however, various adverse effects such as AIHA were observed following vaccination. This review aimed to assess the relationship of AIHA and COVID-19 vaccination using the PRISMA guidelines. Among 18 cases included in this review, new post-vaccination AIHA development was reported in 11 patients (7 women and 4 men) with a median age of 67.0â€‰years. In 7 of 11 and 3 of 11 cases, the onset of symptoms occurred after first and second vaccine dose with median times of 7 and 14â€‰days, respectively. In 1 of 11 cases, the AIHA occurred on Day 17 after booster vaccination. Ten of 11 and 1 of 11 AIHA patients received mRNA- and vector-based vaccine, respectively. After vaccination, 9 of 11, 1 of 11, and 1 of 11 AIHA patients developed warm IgG, cold IgM, and mixed autoantibodies against RBCs, respectively. Significant AIHA exacerbation was reported in seven patients (four women and three men) with a median age of 73.0â€‰years. In 4 of 7 and 2 of 7 exacerbated AIHA cases, the onset of symptoms occurred after first and second vaccine dose with median times of 7 and 3â€‰days, respectively. In 1 of 7 exacerbated AIHA cases, the onset of symptoms was observed on Day 2 after booster vaccination. All exacerbated AIHA cases received mRNA-based vaccines; 3 of 7 and 4 of 7 exacerbated AIHA cases developed IgG and IgM against RBCs, respectively. This review provides a comprehensive explanation regarding the AIHA development and exacerbation after COVID-19 vaccination.

Decoding the Human Genetic and Immunological Basis of COVID-19 mRNA Vaccine-Induced Myocarditis.

Response to R.Â Mungmumpuntipanip and V.Â Wiwantikit : Correspondence to "Post-SARS-CoV-2 vaccination COVID toes and fingers".

COVID-19 vaccine triggered autoimmune hepatitis: case report. Autoimmune hepatitis (AIH) is a non-contagious, chronic, inflammatory autoimmune disease in which one's own immune system attacks healthy, normal hepatic cells. The exact cause of AIH is unknown; however, the combination of genetic, environmental (eg, drugs and natural infection) and immunological factors may lead to AIH. AIH may also be potentiated with the use of vaccines: this case reports one such event following immunisation, along with 1â€‰year of follow-up. A female patient in her late 20s presented to the

hospital with yellowish discolouration of eyes, urine and stools. Her medical history revealed that she had been vaccinated with the first dose of a COVID-19 vaccine 10 days earlier. She had a history of asymptomatic COVID-19 infection 3 months ago and a history of chronic analgesic consumption for migraine. She was diagnosed as having AIH through extensive clinical and laboratory workup. This case may be an immediate enhancement of a hidden autoimmune disorder triggered by the vaccination. This adverse event following immunisation has an adequate temporal relationship with her COVID-19 vaccine. The causality can be categorised as 'indeterminate' and may be considered as a potential signal following COVID-19 vaccination.

Association Between Vaccination Status and Mortality Among Intubated Patients With COVID-19-Related Acute Respiratory Distress Syndrome. IMPORTANCE: Although vaccination substantially reduces the risk of severe COVID-19, it is yet unknown whether vaccinated patients who develop COVID-19 and require invasive mechanical ventilation have lower mortality than controls. OBJECTIVE: To examine the association between COVID-19 vaccination status and mortality among critically ill patients who require invasive mechanical ventilation owing to acute respiratory distress syndrome (ARDS) related to COVID-19. DESIGN, SETTING, AND PARTICIPANTS: This multicenter cohort study was performed between June 7, 2021, and February 1, 2022, among 265 consecutive adult patients with COVID-19 in academic intensive care units who underwent invasive mechanical ventilation owing to ARDS. EXPOSURES: Patients in the full vaccination group had completed the primary COVID-19 vaccination series more than 14 days but less than 5 months prior to intubation. This time threshold was chosen because guidelines from the US Centers for Disease Control and Prevention recommend a booster dose beyond that time. The remaining patients (ie, those who were unvaccinated, partially vaccinated, or fully vaccinated <14 days or >5 months before intubation) comprised the control group. MAIN OUTCOMES AND MEASURES: The primary outcome was time from intubation to all-cause intensive care unit mortality. A Cox proportional hazards regression model including vaccination status, age, comorbid conditions, and baseline Sequential Organ Failure Assessment score on the day of intubation was used. RESULTS: A total of 265 intubated patients (170 men [64.2%]; median age, 66.0 years [IQR, 58.0-76.0 years]; 26 [9.8%] in the full vaccination group) were included in the study. A total of 20 patients (76.9%) in the full vaccination group received the BNT162b2 vaccine, and the remaining 6 (23.1%) received the ChAdOx1 nCoV-19 vaccine. Patients in the full vaccination group were older (median age, 72.5 years [IQR, 62.8-80.0 years] vs 66.0 years [IQR, 57.0-75.0 years]) and more likely to have comorbid conditions (24 of 26 [92.3%] vs 160 of 239 [66.9%]), including malignant neoplasm (6 of 26 [23.1%] vs 18 of 239 [7.5%]), than those in the control group. Full vaccination status was significantly associated with lower mortality compared with controls (16 of 26 patients [61.5%] died in the full vaccination group vs 163 of 239 [68.2%] in the control group; hazard ratio, 0.55 [95% CI, 0.32-0.94]; Pâ€‰=â€‰.03). CONCLUSIONS AND RELEVANCE: In this cohort study, full vaccination status was associated with lower mortality compared with controls, which suggests that vaccination might be beneficial even among patients who were intubated owing to COVID-19-related ARDS. These results may inform discussions with families about prognosis.

SARS-CoV-2 spike IgG titres up to 137â€‰days following Comirnaty mRNA COVID-19 vaccination, Israel, February to May 2021. BackgroundData regarding the long-term protection afforded by vaccination for the SARS-CoV-2 infection are essential for allocation of scarce vaccination resources worldwide.MethodsWe conducted a retrospective cohort study aimed at studying the kinetics of IgG antibodies against SARS-CoV-2 in COVID-19-naÃ¯ve patients fully vaccinated with two doses of Comirnaty mRNA COVID-19 vaccine. Geometric mean concentrations (GMCs) of antibody levels were reported. Linear models were used to assess antibody levels after full vaccination and their decline over time.ResultsThe study included 4,740 patients and 5,719 serological tests. Unadjusted GMCs peaked 28-41â€‰days after the first dose at 10,174â€‰AU/mL (95%â€‰CI:â€‰9,211-11,237) and

gradually decreased but remained well above the positivity cut-off. After adjusting for baseline characteristics and repeated measurements, the antibodies half-life time was 34.1â€‰days (95%â€‰CI:â€‰33.1-35.2), and females aged 16-39â€‰years with no comorbidities had antibody levels of 20,613â€‰AU/mL (95%â€‰CI:â€‰18,526-22,934) on dayâ€‰28 post-first-dose. Antibody levels were lower among males (0.736 of the level measured in females; 95%â€‰CI:â€‰0.672-0.806), people aged 40-59 (0.729; 95%â€‰CI:â€‰0.649-0.818) and â‰¥â€‰60â€‰years (0.452;â€‰95%â€‰CI:â€‰0.398-0.513), and patients having haematological (0.241;â€‰95%â€‰CI:â€‰0.190-0.306) or solid malignancies (0.757;â€‰95%â€‰CI:â€‰0.650-0.881), chronic kidney disease with glomerular filtration rate (GFR)â€‰â‰¥â€‰30 (0.434;â€‰95%â€‰CI:â€‰0.354-0.532) or with GFRâ€‰<â€‰30â€‰mL/min (0.176;â€‰95%â€‰CI:â€‰0.109-0.287), and immunosuppression (0.273;â€‰95%â€‰CI:â€‰0.235-0.317). Body mass index, cardiovascular disease, congestive heart failure, chronic obstructive pulmonary disease, diabetes and inflammatory bowel diseases were not associated with antibody levels.ConclusionsVaccination with two doses resulted in persistently high levels of antibodies (â‰¥â€‰cut-off of 50â€‰AU/mL) up to 137â€‰days post-first-dose. Risk factors for lower antibody levels were identified.

Bipolar I Disorder Exacerbation Following COVID-19 Vaccination. We present the cases of a 60-year-old female patient and 40-year-old male patient who experienced exacerbations of previously well-controlled symptoms of bipolar I disorder (BD1) after receiving COVID-19 vaccines, despite being stable for years on the same medications. The first patient experienced worsened depression, mania, and psychosis that improved with an increase in risperidone. The second patient experienced depression, mania, psychosis, and suicidal ideation that resulted in hospitalization. Prior to hospitalization, he took lamotrigine and bupropion, the latter of which was changed to aripiprazole in hospital. We reviewed current literature on inflammation in mental disorders, vaccination-related inflammatory changes, and the type of inflammation induced by COVID-19 vaccines. Inflammation is a component of psychiatric disorders, and the inflammatory response induced by vaccines might potentiate acute mental health exacerbations, necessitating treatment changes. However, this case series should not be used to justify recommendations against vaccination without larger, well-designed studies. At this time, the known benefits of vaccination outweigh these unknown risks, especially because individuals with serious mental illness are more likely to die from COVID-19 than the general population.

Safety and immunogenicity of 3 doses of BNT162b2 and CoronaVac in children and adults with inborn errors of immunity. Our study (NCT04800133) aimed to determine the safety and immunogenicity in patients with IEIs receiving a 3-dose primary series of mRNA vaccine BNT162b2 (age 12+) or inactivated whole-virion vaccine CoronaVac (age 3+) in Hong Kong, including Omicron BA.1 neutralization, in a nonrandomized manner. Intradermal vaccination was also studied. Thirty-nine patients were vaccinated, including 16 with homologous intramuscular 0.3ml BNT162b2 and 17 with homologous intramuscular 0.5ml CoronaVac. Two patients received 3 doses of intradermal 0.5ml CoronaVac, and 4 patients received 2 doses of intramuscular BNT162b2 and the third dose with intradermal BNT162b2. No safety concerns were identified. Inadequate S-RBD IgG and surrogate virus neutralization responses were found after 2 doses in patients with humoral immunodeficiencies and especially so against BA.1. Dose 3 of either vaccine increased S-RBD IgG response. T cell responses against SARS-CoV-2 antigens were detected in vaccinated IEI patients by intracellular cytokine staining on flow cytometry. Intradermal third dose vaccine led to high antibody response in 4 patients. The primary vaccination series of BNT162b2 and CoronaVac in adults and children with IEIs should include 3 doses for optimal immunogenicity.

Spike-specific T cells are enriched in breastmilk following SARS-CoV-2 mRNA vaccination. Human breastmilk is rich in T cells; however, their specificity and function are largely unknown. We compared the phenotype, diversity, and antigen specificity of T cells in the breastmilk and peripheral blood of lactating individuals who received SARS-CoV-2 mRNA vaccination. Relative to blood, breastmilk contained higher frequencies of T effector and central memory populations that expressed mucosal-homing markers. T cell receptor (TCR) sequence overlap was limited between blood and breastmilk. Overabundan t breastmilk clones were observed in all individuals, were diverse, and contained CDR3 sequences with known epitope specificity including to SARS-CoV-2 Spike. Spike-specific TCRs were more frequent in breastmilk compared to blood and expanded in breastmilk following a third mRNA vaccine dose. Our observations indicate that the lactating breast contains a distinct T cell population that can be modulated by maternal vaccination with potential implications for infant passive protection. ONE-SENTENCE SUMMARY: The breastmilk T cell repertoire is distinct and enriched for SARS-CoV-2 Spike-specificity after maternal mRNA vaccination.

Quality of life and sexual function analysis in a group of Italian postmenopausal women after COVID-19 vaccination. AIM: The aim of the study was to evaluate the impact of SARS-CoV-2 vaccination on quality of life, psychological aspect and sexual life in a group of Italian postmenopausal women during the COVID-19 pandemic. METHODS: The study was a prospective, observational analysis of postmenopausal women before and after the COVID-19 vaccination. The population previously answered different questionnaires, such as the Female Sexual Function Index (FSFI), the Female Sexual Distress Scale (FSDS), the 36-Item Short Form Survey (SF-36) and the Hospital Anxiety and Depression Scale (HADS). Twelve weeks after the end of the vaccine cycle, these women were invited to complete the same questionnaires by e-mail to evaluate if vaccination coverage could positively impact the quality of life of postmenopausal women. The Patient Impression of Global Improvement (PGI-I) after three months of treatment was also calculated. RESULTS: A total of 114 patients were reported. The median age was 60.96 (52-66) years. Mean sexual intercourses/month increased from 1.28â€‰Â±â€‰1.23 to 4.21â€‰Â±â€‰1.80 (pâ€‰=â€‰0.001). The FSFI increased (19.22â€‰Â±â€‰3.31 vs 29.24â€‰Â±â€‰4.21, pâ€‰<â€‰0.0001) and the FSDS decreased significantly (20.12â€‰Â±â€‰5.23 vs 9.32â€‰Â±â€‰5.55, pâ€‰<â€‰0.0001) 12â€‰weeks after vaccination coverage. The SF-36 increased from 64.23â€‰Â±â€‰11.76 to 82.21â€‰Â±â€‰10.24 (p < .0001) and the HADS questionnaire improved significantly from 9.3â€‰Â±â€‰2.73 to 5.1â€‰Â±â€‰1.34 after the COVID-19 vaccine execution (p<.0001). CONCLUSIONS: The spread of COVID-19 vaccine coverage positively influenced sexual function, quality of life and psychological aspect in postmenopausal women.

Histopathologically TMA-like distribution of multiple organ thromboses following the initial dose of the BNT162b2 mRNA vaccine (Comirnaty, Pfizer/BioNTech): an autopsy case report. BACKGROUND: Coronavirus disease 2019 (COVID-19) has spread worldwide. Vaccination is now recommended as one of the effective countermeasures to control the pandemic or prevent the worsening of symptoms. However, its adverse effects have been attracting attention. Here, we report an autopsy case of multiple thromboses after receiving the first dose of the BNT162b2 mRNA vaccine (Comirnaty, Pfizer/BioNTech) in an elderly woman. CASE PRESENTATION: A 72-year-old woman with a history of diffuse large B-cell lymphoma in the stomach and hyperthyroidism received the first dose of the BNT162b2 mRNA vaccine and died 2 days later. The autopsy revealed multiple microthrombi in the heart, brain, liver, kidneys, and adrenal glands. The thrombi were CD61 and CD42b positive and were located in the blood vessels primarily in the pericardial aspect of the myocardium and subcapsular region of the adrenal glands; their diameters were approximately 5-40Â Î¼m. Macroscopically, a characteristic myocardial haemorrhage was observed, and the histopathology of the characteristic thrombus distribution, which differed from that of haemolytic uraemic syndrome

and disseminated intravascular coagulation, suggested that the underlying pathophysiology may have been similar to that of thrombotic microangiopathy (TMA). CONCLUSION: This is the first report on a post-mortem case of multiple thromboses after the BNT162b2 mRNA vaccine. The component thrombus and characteristic distribution of the thrombi were similar to those of TMA, which differs completely from haemolytic uraemic syndrome or disseminated intravascular coagulation, after vaccination. Although rare, it is important to consider that fatal adverse reactions may occur after vaccination and that it is vital to conduct careful follow-up.

Safety, immunogenicity and antibody persistence of a bivalent Beta-containing booster vaccine against COVID-19: a phase 2/3 trial. Updated immunization strategies are needed to address multiple severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants. Here we report interim results from an ongoing, open-label phase 2/3 trial evaluating the safety and immunogenicity of the bivalent Coronavirus Disease 2019 (COVID-19) vaccine candidate mRNA-1273.211, which contains equal mRNA amounts encoding the ancestral SARS-CoV-2 and Beta variant spike proteins, as 50-Âµg (nâ€‰=â€‰300) and 100-Âµg (nâ€‰=â€‰595) first booster doses administered approximately 8.7-9.7â€‰months after the mRNA-1273 primary vaccine series (NCT04927065). The primary objectives were to evaluate the safety and reactogenicity of mRNA-1273.211 and to demonstrate non-inferior antibody responses compared to the mRNA-1273 100-Âµg primary series. Additionally, a pre-specified immunogenicity objective was to demonstrate superior antibody responses compared to the previously authorized mRNA-1273 50-Âµg booster. The mRNA-1273.211 booster doses (50-Âµg or 100-Âµg) 28â€‰days after immunization elicited higher neutralizing antibody responses against the ancestral SARS-CoV-2 and Beta variant than those elicited 28â€‰days after the second mRNAâ€‘1273 dose of the primary series (NCT04470427). Antibody responses 28â€‰days and 180â€‰days after the 50-Âµg mRNA-1273.211 booster dose were also higher than those after a 50-Âµg mRNA-1273 booster dose (NCT04405076) against the ancestral SARS-CoV-2 and Beta, Omicron BA.1 and Delta variants, and all pre-specified immunogenicity objectives were met. The safety and reactogenicity profile of the bivalent mRNA-1273.211 booster (50-Âµg) was similar to the booster dose of mRNA-1273 (50-Âµg). Immunization with the primary series does not set a ceiling to the neutralizing antibody response, and a booster dose of the bivalent vaccine elicits a robust response with titers that are likely to be protective against COVID-19. These results indicate that bivalent booster vaccines can induce potent, durable and broad antibody responses against multiple variants, providing a new tool in response to emerging variants.

Immune response after COVID-19 vaccination among patients with chronic kidney disease and kidney transplant. BACKGROUND: Vaccination of patients with chronic kidney disease (CKD) and kidney transplants (KTs) may achieve a less robust immune response. Understanding such immune responses is crucial for guiding current and future vaccine dosing strategies. METHODS: This prospective, observational study estimated the immunogenicity of humoral and cellular responses of two SARS-CoV-2 vaccines in different patient groups with CKD compared with controls. Secondary outcomes included adverse events after vaccination and the incidence of COVID-19 breakthrough infection, including illness severity. RESULTS: In total, 212 patients received ChAdOx1 nCoV-19 (89.62Â %) or inactivated vaccines (10.38Â %).The antibody response against the S protein was analyzed at T0 (before the first injection), T1 (before the second injection), and T2 (12Â weeks after the second injection). Seroconversion occurred in 92.31Â % of controls at T2 and in 100Â % of patients with CKD, 42.86Â % undergoing KT, 80.18Â % of hemodialysis (HD), and 0Â % of patients undergoing continuous ambulatory peritoneal dialysis (CAPD) at T2 of the ChAdOx1 nCoV-19 vaccine. Neutralizing antibody levels by surrogate virus neutralization test were above the protective level at T2 in each group. The KT group exhibited the lowest neutralizing antibody and T cell response. Blood groups O and vaccine type were associated with good immunological responses. After the first dose,

14 individuals (6.6 out of the total population experienced COVID-19 breakthrough infection. CONCLUSION: Immunity among patients with CKD and HD after vaccination was strong and comparable with that of healthy controls. Our study suggested that a single dose of the vaccine is not efficacious and delays may result in breakthrough infection. Some blood groups and types of vaccine can affect the immune response.

Cardiac Magnetic Resonance Imaging Midterm Follow Up of COVID-19 Vaccine-Associated Myocarditis.

A mathematical model of the within-host kinetics of SARS-CoV-2 neutralizing antibodies following COVID-19 vaccination. Compelling evidence continues to build to support the idea that SARS-CoV-2 Neutralizing Antibody (NAb) levels in an individual can serve as an important indicator of the strength of protective immunity against infection. It is not well understood why NAb levels in some individuals remain high over time, while in others levels decline rapidly. In this work, we present a two-state mathematical model of within-host NAb dynamics in response to vaccination. By fitting only four host-specific parameters, the model is able to capture individual-specific NAb levels over time as measured by the AditxtScoreâ„¢ for NAbs. The model can serve as a foundation for predicting NAb levels in the long-term, understanding connections between NAb levels, protective immunity, and breakthrough infections, and potentially guiding decisions about whether and when a booster vaccination may be warranted.

Effect of the COVID-19 vaccine on facial aesthetic injectables and suspension threads among patients treated by the Philippine Dermatological Society (PDS) dermatologists.

Inactivated Covid-19 vaccine did not undermine live birth and neonatal outcomes of women with frozen-thawed embryo transfer. STUDY QUESTION: Does inoculation with inactivated vaccines against coronavirus disease 2019 (Covid-19) before frozen-thawed embryo transfer (FET) affect live birth and neonatal outcomes? SUMMARY ANSWER: Inactivated Covid-19 vaccines did not undermine live birth and neonatal outcomes of women planning for FET. WHAT IS KNOWN ALREADY: Accumulating reports are now available indicating the safe use of mRNA vaccines against Covid-19 in pregnant and lactating women, and a few reports indicate that they are not associated with adverse effects on ovarian stimulation or early pregnancy outcomes following IVF. Evidence about the safety of inactivated Covid-19 vaccines is very limited. STUDY DESIGN, SIZE, DURATION: This is a retrospective cohort analysis from Reproductive Medical Center of a tertiary teaching hospital. Clinical records and vaccination record of 2574 couples with embryos transferred between 1 March 2021 and 30 September 2021 were screened for eligibility of this study. PARTICIPANTS/MATERIALS, SETTING, METHODS: Clinical and vaccination data of infertile couples planning for FET were screened for eligibility of the study. The reproductive and neonatal outcomes of FET women inoculated with inactivated Covid-19 vaccines or not were compared. The primary outcomes were live birth rate per embryo transfer cycle and newborns' birth height and weight. Secondary outcomes included rates of ongoing pregnancy, clinical pregnancy, biochemical pregnancy and spontaneous miscarriage. Multivariate logistical regression and propensity score matching (PSM) analyses were performed to minimize the influence of confounding factors. Subgroup analyses, including single dose versus double dose of the vaccines and the time intervals between the first vaccination and embryo transfer, were also performed. MAIN RESULTS AND THE ROLE OF CHANCE: Vaccinated women have comparable live birth rates (43.6% versus 45.0% before PSM, Pâ€‰=â€‰0.590; and 42.9% versus 43.9% after PSM, Pâ€‰=â€‰0.688), ongoing pregnancy rates (48.2% versus 48.1% before PSM, Pâ€‰=â€‰0.980; and 52.2% versus 52.7% after PSM, Pâ€‰=â€‰0.875) and clinical pregnancy rate (55.0% versus 54.8% before PSM, Pâ€‰=â€‰0.928; and 54.7% versus 54.2% after PSM, Pâ€‰=â€‰0.868) when compared with unvaccinated counterparts. The newborns' birth length (50.0â€‰Â±â€‰1.6 versus 49.0â€‰Â±â€‰2.9â€‰cm before PSM, Pâ€‰=â€‰0.116; and

49.9â€‰Â±â€‰1.7 versus 49.3â€‰Â±â€‰2.6â€‰cm after PSM, Pâ€‰=â€‰0.141) and birth weight (3111.2â€‰Â±â€‰349.9 versus 3030.3â€‰Â±â€‰588.5â€‰g before PSM, Pâ€‰=â€‰0.544; and 3053.8â€‰Â±â€‰372.5 versus 3039.2â€‰Â±â€‰496.8â€‰g after PSM, Pâ€‰=â€‰0.347) were all similar between the two groups. Neither single dose nor double dose of vaccines, as well as different intervals between vaccination and embryo transfer showed any significant impacts on reproductive and neonatal outcomes. LIMITATIONS, REASONS FOR CAUTION: The main findings might be limited by retrospective design. Besides, inoculations of triple dose of Covid-19 vaccines were not available by the time of data collection, thus the results cannot reflect the safe use of triple dose of inactivated Covid-19 vaccines. Finally, history of Covid-19 infection was based on patients' self-report rather than objective laboratory tests. WIDER IMPLICATIONS OF THE FINDINGS: Eligible individuals of inactivated vaccines against Covid-19 should not postpone vaccination plan because of their embryo transfer schedule, or vice versa. STUDY FUNDING/COMPETING INTEREST(S): This study was supported by the Medical Key Discipline of Guangzhou (2021-2023). All authors had nothing to disclose. TRIAL REGISTRATION NUMBER: N/A.

Psoriasis exacerbation after COVID-19 vaccines: A brief report of the reported cases. Despite the significant reduction of both morbidity and mortality after the introduction of many vaccines against COVID-19, recent reports indicated a worsening skin conditions in particular patients with psoriasis. We extracted the data of 51 patients from 19 papers. The mean age was 56.9 (SDÂ =Â 16.2) years, with a male prevalence 45%. Of the 51 cases, vaccine types at which psoriasis flare occurred were as the following: Pfizer vaccine (30), AstraZeneca (9), Moderna (8), Coronavac (2) Covishield (1), and Covaxin (1). Exacerbation was common in the second dose of Pfizer, AstraZeneca, Moderna, and Covishield vaccines. Moreover, the onset of psoriasis exacerbation was shorter after the second dose of Pfizer (meanÂ =Â 12.8 [SDÂ =Â 15.2]) and AstraZeneca (meanÂ =Â 7.4 [SDÂ =Â 3.6]) rather than the first dose of both vaccines, respectively (meanÂ =Â 19.2 [SDÂ =Â 21.3]) and (meanÂ =Â 18.5 [SDÂ =Â 10.7]).

Isolated popliteal artery lesion due to giant cell vasculitis post COVID-19 mRNA vaccine and COVID-19 asymptomatic infection. OBJECTIVE: Giant cell arteritis (GCA) is a rare granulomatous vasculitis, affecting medium and large vessels, usually in old patients. The incidence of GCA has been higher during current COVID-19 pandemia and COVID-19 is recognized for its immune dysregulation. Lower limbs involvement is uncommon but can be limb threatening, resulting in limb loss. METHOD: A 43-year-old man presented with a sudden pain in his right calf and foot associated with pallor and hypothermia, and there was objective evidence of ischemia. Symptoms began few days after he received the first dose of a COVID-19 mRNA vaccine and COVID-19 asymptomatic infection 20 days after vaccination. He had no history of any signs of claudication pre-COVID or limb trauma and was very fit.Enhanced computed tomography and magnetic resonance imaging (MRI)suggest diagnosis of popliteal artery cystic adventitial disease. We resected the affected popliteal artery with interposition using a right great saphenous vein graft, through a posterior approach. On the fourth postoperative day, he was discharged.Histopathological examination revealed patchy intramural inflammatory infiltrates composed of lymphocytes and rare multinucleated giant cells at the internal lamina and adventitia consistent with a diagnosis of GCA. CONCLUSION AND RESULT: Our case represents the first reported case of isolated popliteal GCA following vaccination with a COVID-19 mRNA vaccine and COVID-19 infection. We propose that the upregulated immune response to the vaccine acted as a trigger for GCA in this patient with predisposing risk factors and recurrent and repetitive microtrauma in popliteal fossa (the patient is a professional runner). Our case suggests the need for further studies about real world incidence of GCA associated vaccination and COVID-19 infection. Currently, data is limited regarding this relationship. We continue to encourage COVID-19 vaccination, even in elderly

patients because the benefits of vaccination far outweigh any theoretical risk of immune dysregulation following administration.
Immune response after mRNA COVID-19 vaccination in heart transplant recipients: long-term follow-up and evaluation of a third vaccination.
Vaccines and variants: an update on cardiopulmonary assessment prior to return to high-hazard occupations following COVID-19.
Limited Humoral and Specific T-Cell Responses After SARS-CoV-2 Vaccination in PWH With Poor Immune Reconstitution. BACKGROUND: We analyzed humoral and cellular immune responses induced by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) messenger RNA (mRNA) vaccines in people with human immunodeficiency virus (HIV; PWH) who had CD4+ T-cell counts <200/ÂµL (HIV<200 group). METHODS: This prospective cohort study included 58 PWH in the HIV<200 group, 36 with CD4+ T-cell counts >500/ÂµL (HIV>500 group), and 33 HIV-1-negative controls (control group). Antibodies against the SARS-CoV-2 spike protein (anti-S immunoglobulin [Ig] G) and the receptor-binding domain (anti-RBD IgG) were quantified before and 4â€…weeks after the first and the second doses of BNT162b2 or mRNA-1273 (at week 8). Viral neutralization activity and T-cell responses were also determined. RESULTS: At week 8, anti-S/anti-RBD IgG responses increased in all groups (P < .001). Median (interquartile range) anti-S and anti-RBD IgG levels at week 8 were 153.6 (26.4-654.9) and 171.9 (61.8-425.8) binding antibody units (BAU)/mL, respectively, in the HIV<200 group, compared with 245.6 (145-824) and 555.8 (166.4-1751) BAU/mL in the HIV>500 group and 274.7 (193.7-680.4) and 281.6 (181-831.8) BAU/mL in controls (P < .05). Neutralizing capacity and specific T-cell immune responses were absent or reduced in 33% of those in the HIV<200 group, compared with 3.7% in the HIV>500 group (P < .01). CONCLUSIONS: One-third of PWH with CD4+ T-cell counts <200/ÂµL show low anti-S/anti-RBD IgG levels, reduced in vitro neutralization activity against SARS-CoV-2, and no vaccine-induced T cells after receiving coronavirus disease 2019 mRNA vaccines.
A Case Series and Literature Review of the Association of COVID-19 Vaccination With Autoimmune Diseases: Causality or Chance? The coronavirus disease 2019 (COVID-19) pandemic has been a challenging time for the whole world. Ever since the start of the pandemic, vaccine development has been underway and now there are several approved COVID-19 vaccines bringing hope for the end of the pandemic. However, there have been been a few individuals who have been affected in some other ways by the COVID-19 vaccinations. Here in this case series, we present 16 cases of autoimmune diseases with a strong temporal relation with the COVID-19 vaccine. We would like to emphasize that COVID-19 vaccines are essential to alter the course of the pandemic and save lives and the temporal relation is not by any means proof of causation. However, we must be vigilant for the occurrence of these conditions.
The persistence of anti-Spike antibodies following two SARS-CoV-2 vaccine doses in patients on immunosuppressive therapy compared to healthy controls-a prospective cohort study. BACKGROUND: The durability of vaccine-induced humoral immunity against SARS-CoV-2 in patients with immune-mediated inflammatory diseases (IMIDs) on immunosuppressive therapy is not known. The aim of this study was to compare the persistence of anti-Spike antibodies following two-dose SARS-CoV-2 vaccination between IMID patients and healthy controls and to identify factors associated with antibody decline. METHODS: IMID patients on immunosuppressive medication enrolled in the prospective observational Nor-vaC study were included. Participants received two-dose SARS-CoV-2 vaccination. Serum collected at two time points following vaccination (first assessment within 6-48 days, second within 49-123 days) were analyzed for antibodies binding the receptor-binding domain (RBD) of the SARS-CoV-2 Spike protein. Multivariable regression models estimated percent reduction in anti-RBD over 30 days and factors associated with reduction.

RESULTS: A total of 1108 patients (403 rheumatoid arthritis, 195 psoriatic arthritis, 195 spondyloarthritis, 124 ulcerative colitis, 191 Crohn's disease) and 134 controls provided blood samples within the defined intervals (median 19 days [IQR 15-24] and 97 days [87-105] after second vaccine dose). Antibody levels were lower in patients compared to controls at both time points, with median anti-RBD 2806 BAU/ml [IQR 1018-6068] in patients and 6187 BAU/ml [4105-7496] in controls ($p<0.001$) at first assessment, and 608 BAU/ml [IQR 58-1053] in patients and 1520 BAU/ml [979-3766] in controls ($p<0.001$) at second assessment. At second assessment, low anti-RBD antibody levels (defined as <200 BAU/ml) were found in 449 (41%) patients, and 6 (5%) controls ($p<0.001$). The change was - 83% in patients and - 66% in controls ($p<0.001$). Patients had a greater estimated 30 days percent reduction in anti-RBD levels compared to controls - 4.9 (95% CI - 7.4 to - 2.4), ($p<0.05$). Among therapies, mono- or combination treatment with tumor necrosis factor inhibitors was associated with the greatest decline. CONCLUSIONS: Within 4 months after vaccination, antibody levels declined considerably in both IMID patients and controls. Patients had lower initial antibody levels and a more pronounced decline compared to healthy controls and were therefore more likely to decline to low antibody levels. These results support that IMID patients need additional vaccine doses at an earlier stage than healthy individuals.

Omicron neutralizing antibody response following booster vaccination compared with breakthrough infection. BACKGROUND: The spread of the vaccine-resistant Omicron severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants threatens unvaccinated and fully vaccinated individuals, and accelerated booster vaccination campaigns are underway to mitigate the ongoing wave of Omicron cases. The immunity provided by standard vaccine regimens, boosted regimens, and immune responses elicited by vaccination plus natural infection remain incompletely understood. The magnitude, quality, and durability of serological responses, and the likelihood of protection against future SARS-CoV-2 variants following these modes of exposure, are poorly characterized but are critical to the future trajectory of the coronavirus disease 2019 (COVID-19) pandemic. METHODS: Ninety-nine individuals were semi-randomly selected from a larger vaccination cohort following vaccination and, in some cases, breakthrough infection. We analyzed spike receptor-binding domain-specific immunoglobulin G (IgG), IgA, and IgM by enzyme-linked immunosorbent assay, neutralizing antibody titers against live SARS-CoV-2 variants, and antibody-dependent cell-mediated phagocytosis. FINDINGS: In 99 vaccinated adults, compared with responses after two doses of an mRNA regimen, the immune responses 3Â months after a third vaccine dose and 1Â month after breakthrough infection due to prior variants show dramatic increases in magnitude, potency, and breadth, including increased antibody-dependent cellular phagocytosis and robust neutralization of the currently circulating Omicron BA.2 variant. CONCLUSIONS: Boosters and natural infection substantially boost immune responses. As the number of Omicron sub-variant cases rise and as global vaccination and booster campaigns continue, an increasing proportion of the world's population will acquire potent immune responses that may be protective against future SARS-CoV-2 variants. FUNDING: This work was funded by the M. J. Murdock Charitable Trust, the OHSU Foundation, the NIH (T32HL083808), and OHSU Innovative IDEA.

Dermatopathology of COVID-19 infection and vaccination. BACKGROUND: Many peculiar skin changes have been described in relation to both coronavirus diseaseÂ 2019 (COVID-19) infection and vaccination. OBJECTIVE: This paper provides an overview of these dermatologic manifestations, focusing on their dermatopathological appearances. RESULTS: Most COVID-19Â patients develop variegated maculopapular eruptions with aÂ combination of histological patterns commonly including keratinocyte apoptosis and eosinophilia. Urticaria-like lesions often show aÂ combination of spongiotic and lichenoid patterns and are more frequent in individuals with severe disease. Vesicular lesions can be disseminated; in some cases, they become pustular and in others show dyskeratosis

and aÂ peculiar form of ballooning. Some patients develop vesicular Grover disease on the trunk. Young patients with aÂ strong immunological response can eliminate the virus easily but may develop chilblains as aÂ consequence of the high interferon response. Conversely, older individuals with immunosenescence and aÂ tendency toward hypercoagulability can present livedoid and ischemic areas. Regarding COVID-19 vaccination, hypersensitivity reactions are most frequent, including "COVID-arm." Nonetheless, aÂ combination of local and systemic cutaneous manifestations (reactogenicity) is commonly seen. Histopathologically, lichenoid and spongiotic changes and aÂ variable number of eosinophils are typical of rashes characterized by papules and plaques. Other dermatological side effects of COVID-19 vaccination include lesions mimicking well-defined dermatoses such as lichen planus or bullous pemphigoid and triggering of collagenous diseases. CONCLUSION: Well-characterized skin manifestations of coronavirus diseaseÂ 2019 (COVID-19) include chilblains, livedo necrotic lesions, vesicular eruptions, urticarial lesions, and maculopapular eruptions. Hypersensitivity reactions are common after SARS-CoVâ€‘2 mRNA vaccination. Vaccine reactions may also mimic other dermatosis such as bullous pemphigoid or lichen planus, stimulate herpes reactivation, or trigger the development of autoimmune diseases.

Adverse events following immunization of elderly with COVID-19 inactivated virus vaccine (CoronaVac) in Southeastern Brazil: an active surveillance study. Healthcare workers, the elderly and other vulnerable populations were the first to receive COVID-19 vaccines in public health programs. There were few vaccine safety data available on the elderly. This observational study aimed to evaluate the inactivated vaccine (CoronaVac) safety in the elderly, at the beginning of the vaccination program, in Sao Paulo city, Brazil. The elderly people that received CoronaVac at the Reference Center for Special Immunobiologicals (CRIE) or at home, administered by the Interdisciplinary Home Care Team (NADI) of the Hospital das Clinicas were invited to participate in this phase 4 observational study. The vaccination schedule included two CoronaVac doses 28 days apart. The information on solicited and unsolicited adverse events following immunization were collected by phone calls on days 4 and 8 after each vaccine dose. We enrolled 158 adults aged 65 to 101 years (mean of 84.1 years); 63.9% were females and 95.6% had chronic conditions, 21.5% had moderate or severe impairment in daily living activities; 34.2% were pre-frail and 19.6% were frail. We were able to contact 95.6% and 91.6% of the vaccinated people, after the first and second doses, respectively; 31.8% and 23.4% of the contacted participants reported some adverse events (AE) following the first and second doses, respectively. Pain at the injection site, fatigue, myalgia and headaches were the most frequent solicited AE. Most AE were mild to moderate. There were eight severe adverse events, but none of them were considered related to the vaccine. The CoronaVac was safe and well tolerated by these adults of advanced age with frailty and comorbidities.

The consequences of COVID-19 and its vaccine on pregnant and lactating mothers. The single-stranded RNA virus (coronavirus 2019) pandemic has represented a massive influence on health care professionals and communities around the world. This virus is accompanied by a range of respiratory disorders. Morbidity and mortality are in elevation among pregnant mothers. COVID-19 vaccine is considered safe for the majority of the population. Safety concerns were raised toward pregnant mothers and the COVID-19 vaccine. In the present study, data were taken out from relevant manuscripts; from 20th April 2021 to 25th December 2021. In this study, literature reviews from the most comprehensive health database on 100 papers published during 2020 and 2021 were used. This review article aimed to assess the present evidence available in the literature about the possible effect of COVID-19 on pregnant mothers and their fetuses and, to address considerations for maternal COVID-19 vaccine based on the review of existing data to aid in spreading the awareness about the benefits of vaccine that could save lives. In general, COVID-19 vaccines resulted in reducing the ability of virus transmission and patients' hospitalization. COVID-19 vaccines will never cause

infection of corona virus. Evidence showed that COVID-19 vaccines from any brand will reduce the mortality and morbidity. However, available data indicated that possible deterioration of the clinical conditions of pregnant mothers infected with COVID-19 cannot be excluded. Primary outcomes did not show clear safety signs among pregnant mothers who received COVID-19 vaccines. This is because pregnant and lactating mothers were excluded from COVID-19 vaccine studies. Thus, data to lead vaccine decision-making are inadequate. More longitudinal follow up studies are necessary to reinforce the safety of the vaccine.

Booster Vaccination Against SARS-CoV-2 Induces Potent Immune Responses in People With Human Immunodeficiency Virus. BACKGROUND: People with human immunodeficiency virus (HIV) on antiretroviral therapy (ART) with good CD4 T-cell counts make effective immune responses following vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). There are few data on longer term responses and the impact of a booster dose. METHODS: Adults with HIV were enrolled into a single arm open label study. Two doses of ChAdOx1 nCoV-19 were followed 12 months later by a third heterologous vaccine dose. Participants had undetectable viraemia on ART and CD4 counts >350 cells/ÂµL. Immune responses to the ancestral strain and variants of concern were measured by anti-spike immunoglobulin G (IgG) enzyme-linked immunosorbent assay (ELISA), MesoScale Discovery (MSD) anti-spike platform, ACE-2 inhibition, activation induced marker (AIM) assay, and T-cell proliferation. FINDINGS: In total, 54 participants received 2 doses of ChAdOx1 nCoV-19. 43 received a third dose (42 with BNT162b2; 1 with mRNA-1273) 1 year after the first dose. After the third dose, total anti-SARS-CoV-2 spike IgG titers (MSD), ACE-2 inhibition, and IgG ELISA results were significantly higher compared to Day 182 titers ($P < .0001$ for all 3). SARS-CoV-2 specific CD4+ T-cell responses measured by AIM against SARS-CoV-2 S1 and S2 peptide pools were significantly increased after a third vaccine compared to 6 months after a first dose, with significant increases in proliferative CD4+ and CD8+ T-cell responses to SARS-CoV-2 S1 and S2 after boosting. Responses to Alpha, Beta, Gamma, and Delta variants were boosted, although to a lesser extent for Omicron. CONCLUSIONS: In PWH receiving a third vaccine dose, there were significant increases in B- and T-cell immunity, including to known variants of concern (VOCs).

Body Weight is Inversely Associated with Anti-SARS-CoV-2 Antibody Levels after BNT162b2 mRNA Vaccination in Young and Middle Aged Adults. BACKGROUND: This study aimed to determine factors affecting serum levels of anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibodies 2 months after coronavirus disease 2019 (COVID-19) vaccination in young and middle aged healthy adults. MATERIALS AND METHODS: Healthcare workers who have no history of SARS-CoV-2 infection, were enrolled at 2 months after second shot of BNT162b2 mRNA COVID-19 vaccine. Antibody immunoglobulin G against the spike protein subunit of SARS-CoV-2 was semi-quantitatively measured using 4 commercial enzyme-linked immunosorbent assay kits. Factors affecting anti-SARS-CoV-2 antibodies levels were investigated. RESULTS: Fifty-one persons (22 - 54 years, male sex; 19.6%) were enrolled and all participants acquired anti-SARS-CoV-2 antibodies in four diagnostic kits. Anti-SARS-CoV-2 antibodies were strongly correlated between diagnostic kits; SG Medical and Genscript ($r = 0.942$), SG Medical and HB Healthcare ($r = 0.903$), and HB Healthcare and Genscript ($r = 0.868$). We investigated factors affecting antibody level using SG medical kit. The median inhibition was 93.1%, and 84.0% of participants showed >90.0% inhibition. Systemic adverse event severity had no association with the anti-SARS-CoV-2 antibodies level. Antibody level was inversely correlated with weight (-0.312, $P = 0.027$), body mass index (BMI) ($r = -0.303$, $P = 0.032$), and body surface area ($r = -0.285$, $P = 0.044$). In multivariate analysis, the upper 50% of anti-SARS-CoV-2 antibodies (â‰¥93.1%) was inversely associated with weight (odds ratio [OR]: 0.19; 95% confidence interval [CI]: 0.04 - 0.83 in weight â‰¥55kg) and BMI (OR: 0.12; 95% CI: 0.03 - 0.61 in BMI â‰¥22 kg/mÂ²). CONCLUSION: Anti-SARS-CoV-2 antibody was inversely correlated with weight and BMI, which may be used as a

marker to predict immune response of BNT162b2 mRNA vaccination in young and middle aged adults. TRIAL REGISTRATION: ClinicalTrials.gov Identifier: NCT05083026.
Purpuric dermatosis and lymphocytic vasculopathy following SARS-CoV-2 vaccination: Report of two patients.
Study of the Side Effects of Pfizer and Oxford COVID-19 Vaccines in the Eastern Province of Saudi Arabia. BACKGROUND & OBJECTIVE: The COVID-19 pandemic imposed global concern and became one of the deadliest pandemics of the twenty-first century. Several vaccines were developed against SARS-CoV-2 to counteract the effects of this virus. This study aims to determine the post-vaccination side effects of the most common COVID-19 vaccines used in the Eastern province of Saudi Arabia. METHODS: This is a cross-sectional study using an online questionnaire distributed randomly through social media. Frequencies were calculated to determine participants' demographic information, vaccination details, and post-vaccination side effects. Univariate and multiple regression analysis were applied to test the association between individuals' willingness to receive a booster dose and different categorical variables. RESULTS: A total of 1004 participants were included in the survey, of which 0.6%, 85.3% and 14.1% completed either one, two or three doses of the Pfizer mRNA vaccine and Oxford AstraZeneca vaccines, respectively. The similar common side effects between the first and the second doses were significantly associated with the type of vaccine received; these included fatigue (Pfizer 54.4%, Oxford 73.2%; $p < 0.001$), headache (Pfizer 33.2%, Oxford 44.7%; $p = 0.002$), and fever (Pfizer 25.1%, Oxford 57.6%; $p < 0.001$). Additionally, unusual side effects were also reported (palpitations and menstrual abnormalities). Getting SARS-CoV2 infection after vaccination was significantly associated with the type of vaccine received at the first dose (Chi-Square=5.496, $p = 0.019$). A statistically significant association was found between the individuals' willingness to receive a booster dose and their gender (Chi-Square = 39.493, $p < 0.001$), age (Chi-Square = 11.668, $p = 0.02$), presence of allergies (Chi-Square = 5.602, $p = 0.018$), and previous COVID-19 infection (Chi-Square = 9.495, $p = 0.002$). CONCLUSION: Despite the described side effects, further studies should be done to investigate the unusual and rare side effects to assess COVID-19 vaccines effectiveness and safety over longer period of time within a more diverse population.
A Randomized Trial of Behavioral Nudges Delivered Through Text Messages to Increase Influenza Vaccination Among Patients With an Upcoming Primary Care Visit. PURPOSE: To evaluate if nudges delivered by text message prior to an upcoming primary care visit can increase influenza vaccination rates. DESIGN: Randomized, controlled trial. SETTING: Two health systems in the Northeastern US between September 2020 and March 2021. SUBJECTS: 74,811 adults. INTERVENTIONS: Patients in the 19 intervention arms received 1-2 text messages in the 3 days preceding their appointment that varied in their format, interactivity, and content. MEASURES: Influenza vaccination. ANALYSIS: Intention-to-treat. RESULTS: Participants had a mean (SD) age of 50.7 (16.2) years; 55.8% (41,771) were female, 70.6% (52,826) were White, and 19.0% (14,222) were Black. Among the interventions, 5 of 19 (26.3%) had a significantly greater vaccination rate than control. On average, the 19 interventions increased vaccination relative to control by 1.8 percentage points or 6.1% ($P = .005$). The top performing text message described the vaccine to the patient as "reserved for you" and led to a 3.1 percentage point increase (95% CI, 1.3 to 4.9; $P < .001$) in vaccination relative to control. Three of the top five performing messages described the vaccine as "reserved for you." None of the interventions performed worse than control. CONCLUSIONS: Text messages encouraging vaccination and delivered prior to an upcoming appointment significantly increased influenza vaccination rates and could be a scalable approach to increase vaccination more broadly.
COVID-19 vaccine and menstrual conditions in female: data analysis of the Vaccine Adverse Event Reporting System (VAERS). BACKGROUND: In reports of adverse reactions following vaccination

with the coronavirus disease 2019(COVID-19) vaccines, there have been fewer reports of concern for menstrual disorders in female. OBJECTIVE: Our study employed Vaccine Adverse Event Reporting System (VAERS) to investigate and analyze the relationship between COVID-19 Vaccines and menstrual disorders in female. METHODS: We collected reports of menstrual disorders in VAERS from July 2, 1990 to November 12, 2021, and performed a stratified analysis. The potential relationship between COVID-19 vaccine and reports of menstrual disorders was evaluated using the Reporting Odds Ratio (ROR) method. RESULTS: A total of 14,431 reports of menstrual disorders were included in the study, and 13,118 were associated with COVID-19 vaccine. The ROR was 7.83 (95% confidence interval [95%CI]: 7.39-8.28). The most commonly reported event was Menstruation irregular (4998 reports), and a higher percentage of female aged 30-49Â years reported menstrual disorders (42.55%) after exposure to COVID-19 Vaccines. Both for all reports of menstrual disorders (RORâ€‰=â€‰5.82; 95%CI: 4.93-6.95) and excluding reports of unknown age (RORâ€‰=â€‰13.02; 95%CI: 10.89-15.56),suggest that female age may be associated with menstrual disorders after vaccination with the COVID-19 Vaccines. CONCLUSION: There is a potential safety signal when the COVID-19 vaccine is administered to young adult female (30-49Â years old), resulting in menstrual disorders in. However, due to the well-known limitations of spontaneous reporting data, it is challenging to explicity classify menstrual disorders as an adverse event of the COVID-19 Vaccines, and reports of adverse reactions to COVID-19 Vaccines in this age group should continue to be tracked.

Treatment, outcome and re-vaccination of patients with SARS-CoV-2 vaccine-associated immune thrombocytopenia. PURPOSE: Following the emergency use authorization of BNT162b2 by the Food and Drug administration (FDA) in early December 2020, mRNA- and vector-based vaccines became an important means of reducing the spread and mortality of the COVID-19 pandemic. The European Medicines Agency labelled immune thrombocytopenia (ITP) as a rare adverse reaction of unknown frequency after vector-, but not mRNA-vaccination. Here, we report on the long-term outcome of 6 patients who were diagnosed with de-novo, vaccine-associated ITP (VA-ITP), and on the outcome of subsequent SARS-CoV-2 re-vaccinations. METHODS: Patients were included after presenting to our emergency department. Therapy was applied according to ITP guidelines. Follow-up data were obtained from outpatient departments. Both mRNA- or vector-based vaccines were each used in 3 cases, respectively. RESULTS: In all patients, the onset of symptoms occurred after the 1st dose of vaccine was applied. 5 patients required treatment, 3 of them 2nd line therapy. All patients showed a complete response eventually. After up to 359Â days of follow-up, 2 patients were still under 2nd line therapy with thrombopoietin receptor agonists. 5 patients have been re-vaccinated with up to 3 consecutive doses of SARS-CoV-2 vaccines, 4 of them showing stable platelet counts hereafter. CONCLUSION: Thrombocytopenia after COVID-19 vaccination should trigger a diagnostic workup to exclude vaccine-induced immune thrombotic thrombocytopenia (VITT) and, if confirmed, VA-ITP should be treated according to current ITP guidelines. Re-vaccination of patients seems feasible under close monitoring of blood counts and using a vaccine that differs from the one triggering the initial episode of VA-ITP.

Near real-time surveillance of safety outcomes in US COVID-19 vaccine recipients aged 12 to 64Â years. BACKGROUND: Active monitoring of safety outcomes following COVID-19 vaccination is critical to understand vaccine safety and can provide early detection of rare outcomes not identified in pre-licensure trials. We present findings from an early warning rapid surveillance system in three large commercial insurance databases including more than 16 million vaccinated individuals. METHODS: We evaluated 17 outcomes of interest following COVID-19 vaccination among individuals aged 12-64Â years in Optum, HealthCore, and CVS Health databases from December 11, 2020, through January 22, 2022, January 7, 2022, and December 31, 2021, respectively. We conducted

biweekly or monthly sequential testing and generated rate ratios (RR) of observed outcome rates compared to historical (or expected) rates prior to COVID-19 vaccination. FINDINGS: Among 17 outcomes evaluated, 15 did not meet the threshold for statistical signal in any of the three databases. Myocarditis/pericarditis met the statistical threshold for a signal following BNT162b2 in two of three databases (RRs: 1.83-2.47). Anaphylaxis met the statistical threshold for a signal in all three databases following BNT162b2 vaccination (RRs: 4.48-10.86) and mRNA-1273 vaccination (RRs: 7.64-12.40). DISCUSSION: Consistent with published literature, our near-real time monitoring of 17 adverse outcomes following COVID-19 vaccinations identified signals for myocarditis/pericarditis and anaphylaxis following mRNA COVID-19 vaccinations. The method is intended for early detection of safety signals, and results do not imply a causal effect. Results of this study should be interpreted in the context of the method's utility and limitations, and the validity of detected signals must be evaluated in fully adjusted epidemiologic studies.
Sociodemographic predictors of COVID-19 vaccine hesitancy and leading concerns with COVID-19 vaccines among pregnant women at a South Texas clinic. OBJECTIVE: COVID-19 vaccination rates among pregnant women remain low, despite increased risk of COVID-19-related illness and death and demonstrated vaccine safety and efficacy in this population. The objective of this study is to identify sociodemographic predictors of COVID-19 vaccine hesitancy and elucidate important concerns among the pregnant population in light of evolving conversations regarding COVID-19. METHODS: A prospective survey of pregnant women at a single urban clinic in South Texas was conducted August to September 2021 to identify predictors of COVID-19 vaccine hesitancy among the pregnant population. Collected variables included demographics, COVID-19 beliefs, tetanus-diphtheria-pertussis (Tdap)/influenza vaccine hesitancy, and primary vaccine concerns. Statistical analyses included Fisher's exact test, asymptotic two-sample Brown-Mood median test, and multinomial logistic regression. RESULTS: One hundred and nine participants completed the survey, 35 vaccinated and 74 unvaccinated, with a response rate of 91.6%. Women who were COVID-19 vaccine hesitant were more likely to be younger (28.0 vs. 31.0Â years, pâ€‰<â€‰.004) and further along in pregnancy (30.0 vs. 20.0Â weeks, pâ€‰=â€‰.001). They were also more likely to report influenza (odds ratio (OR) 6.3; 95% confidence interval (CI) 2.5-17.1) and Tdap (OR 4.1; 95% CI 1.75-10.7) vaccine hesitancy. Furthermore, women who were vaccine hesitant were more likely to believe they did not have enough information to confidently make their decision (OR 4.0; 95% CI 1.4-11.4). Primary concerns with COVID-19 vaccines included: short- and long-term side effects on the pregnancy, personal long-term side effects, and harmful ingredients. CONCLUSIONS: COVID-19 vaccine hesitant pregnant women were more likely to be younger, hesitant toward other vaccines, and concerned with pregnancy impact and harmful ingredients. Personal knowledge of other vaccinated pregnant women was associated with significantly higher vaccine acceptance rates. Access to vaccines and concerns about quality control were not cited as reasons for vaccine hesitancy, in contrast to earlier studies on this topic.
Drug-induced hepatitis (DIH) after SARS-CoV-2 vaccination.
Assessing beneficial or side effects of COVID-vaccinations requires personal rather than electronic investigations.
Reactivation of pustular psoriasis following mRNA vaccination versus COVID-19 infection: An overlap?: Reply to "Generalized pustular psoriasis following COVID-19" by Dadras MS et al.: Reply to "Generalized pustular psoriasis following COVID-19" by Dadras MS et al.
Diaphragmatic Dysfunction due to Neuralgic Amyotrophy After SARS-CoV-2 Vaccination: A Case Report. Neuralgic amyotrophy is an idiopathic neuropathy characterized by acute-onset pain, typically in the upper extremity or shoulder, followed by weakness of the associated muscles. Phrenic nerve involvement is rare. We report a 63-year-old man who presented with dyspnea and right

shoulder pain after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. His chest radiograph showed an elevated right hemidiaphragm that was absent before vaccination. A pulmonary function test showed a restrictive pattern with a significant reduction (40%) in forced vital capacity in the supine position. Diaphragm ultrasonography revealed a reduction in both diaphragmatic excursion and a thickening fraction of the right hemidiaphragm. Electrophysiological studies suggested a right upper brachial plexopathy. Considering the temporal relationship between the vaccination and absence of other causes, SARS-CoV-2 vaccination was thought to be the reason for neuralgic amyotrophy with diaphragmatic dysfunction. As there was no evidence of hypoventilation or sleep disturbance that may require noninvasive ventilation, the patient was followed with conservative treatment with analgesics. During 8 months of follow-up, his shoulder pain was relieved significantly but dyspnea improved only slightly. Neuralgic amyotrophy is an under-diagnosed etiology of diaphragmatic dysfunction and should be considered in patients with dyspnea and shoulder pain.

Misinformation about vaccine safety and uptake of COVID-19 vaccines among adults and 5-11-year-olds in the United States. Despite increasing rates of vaccination for COVID-19 in the US, hesitancy continues to be a barrier to the full immunization of the eligible population. Hesitancy appears to be particularly pronounced among adults deciding whether to recommend that children be vaccinated against COVID-19. In this research, we tested whether embrace of misinformation about the safety of vaccination is associated with hesitancy to vaccinate oneself and to recommend vaccination of a 5-11-year-old child for COVID-19. In a national probability panel created in April 2021, we assessed belief in both general vaccination misinformation and misinformation about COVID-19 vaccines, in particular. As hypothesized, belief in general vaccination misinformation predicted the uptake in reported vaccination among adults through September 2021, and likelihood to recommend COVID-19 vaccination of children aged 5-11 in January 2022, three months after the approval of that vaccine. In addition, misinformation about COVID-19 vaccines that arose over time correlated highly with more general vaccination misinformation. For both outcomes, general vaccine misinformation predicted vaccination hesitancy beyond concerns about the health risks of contracting COVID-19 for one's family and children ages 5-11. The findings indicate that continued efforts are needed to bolster beliefs about the safety of authorized and approved vaccines of many types and not just those for COVID-19. Some strategies to achieve this objective are suggested.

An autopsy case report of aortic dissection complicated with histiolymphocytic pericarditis and aortic inflammation after mRNA COVID-19 vaccination. A male in his 90Â s consulted a doctor because he experienced several days of general fatigue and dyspnea. He was diagnosed with heart failure, and diuretic medications taken for 3Â days relieved his symptoms. However, he was found dead on the morning of the fourth day after consultation. He had received a third dose of coronavirus disease 2019 (COVID-19) vaccine approximately 2Â weeks before death. An autopsy revealed dissection of the ascending aorta and pericardial hemotamponade. The heart showed a white villous surface, and the pericardium was fibrously thick. Microscopic examination revealed pericarditis with predominantly macrophage and lymphocyte infiltration. These histological findings were compatible with those of post-vaccination myocarditis. To the best of our knowledge, histopathologically proven pericarditis after COVID-19 vaccination has not been reported. In the present case, extended inflammation of the aortic adventitia was a possible cause of aortic wall fragility followed by dissection.

Peripartum Outcomes Associated With COVID-19 Vaccination During Pregnancy: A Systematic Review and Meta-analysis. IMPORTANCE: The risk and benefits of COVID-19 vaccination during pregnancy are under investigation. Pooled evidence regarding neonatal and maternal outcomes in association with COVID-19 vaccination during pregnancy is scarce. OBJECTIVE: To evaluate the

association between COVID-19 vaccination during pregnancy and peripartum outcomes. DATA SOURCES: PubMed and EMBASE databases were searched on April 5, 2022. Language restrictions were not applied. STUDY SELECTION: Prospective trials and observational studies comparing the individuals who received at least 1 COVID-19 vaccination during pregnancy with those who did not and reporting the neonatal outcomes, including preterm birth, small for gestational age, low Apgar score, neonatal intensive care units (NICU) admission, and intrauterine fetal death (IFD). DATA EXTRACTION AND SYNTHESIS: Two independent investigators extracted relevant data from each study. Odds ratios (ORs) were calculated using a random-effects model. This study followed the Preferred Reporting Items for Systematic Reviews and Meta-analysis guidelines. MAIN OUTCOMES AND MEASURES: The primary outcomes were the neonatal outcomes, including preterm birth, small for gestational age, low Apgar score, NICU admission, and IFD. The secondary outcomes were maternal outcomes, including maternal SARS-CoV-2 infection, cesarean delivery, postpartum hemorrhage, and chorioamnionitis. RESULTS: Nine observational studies involving 81â€¯349 vaccinated (mean age, 32-35 years) and 255â€¯346 unvaccinated individuals during pregnancy (mean age, 29.5-33 years) were included. COVID-19 vaccination during pregnancy was associated with lower risk of NICU admission (OR, 0.88; 95% CI, 0.80-0.97) and IFD (OR, 0.73; 95% CI, 0.57-0.94), whereas there was no statistically significant association with preterm birth (OR, 0.89; 95% CI, 0.76-1.04), small for gestational age (OR, 0.99; 95% CI, 0.94-1.04), and low Apgar score (OR, 0.94; 95% CI, 0.87-1.02). COVID-19 vaccination during pregnancy was associated with a lower risk of maternal SARS-CoV-2 infection (OR, 0.46; 95% CI, 0.22-0.93), whereas it was not associated with increased risk of cesarean delivery (OR, 1.05; 95% CI, 0.93-1.20), postpartum hemorrhage (OR, 0.95; 95% CI, 0.83-1.07), and chorioamnionitis (OR, 0.95; 95% CI, 0.83-1.07). CONCLUSIONS AND RELEVANCE: COVID-19 vaccination during pregnancy was not associated with an increase in the risk of peripartum outcomes, was associated with a decreased risk of NICU admission, IFD, and maternal SARS-CoV-2 infection. Thus, COVID-19 vaccination should be encouraged for pregnant individuals.

Neutralizing SARS-CoV-2 Spike Antibodies against Omicron in Paired Samples after Two or Three Doses of mRNA Vaccine. SARS-CoV-2 antibody levels wane following two-doses of mRNA vaccination. An mRNA booster dose provides increased protection against hospitalization and death. We demonstrated that a booster dose provides a significant increase in the neutralization of the Beta, Delta and Omicron variants in addition to an increased neutralization of the vaccine strain. The total spike IgG measurements, obtained by using commercial kits that target the spike protein from the vaccine strain, may not reflect serum neutralization against variants of concern. IMPORTANCE This study found little to no neutralizing capability following a 2-dose mRNA vaccine series against the omicron variant, and neutralizing capacity to any variant strain tested was lost by 8-months post 2-dose series. However, the mRNA booster dose eliminated the immune escape observed by the Omicron variant, following the 2-dose series. Even more, the neutralizing titers were significantly higher for all variants post-boost, compared to the titers from the post-two-dose series. Our data are unique, using paired samples that eliminate potential confounders that may impact vaccine response. Notably, as seen after the primary two-dose vaccine series, total antibody levels did not correlate perfectly with variant neutralization activity, suggesting that simply testing titers as a measure of protection may not be a long-term solution. Therefore, it is important to reassess the utility of SARS-CoV-2 antibody testing, as current vaccine strain-based testing may not reliably detect reactive antibodies to Omicron or other variants of concern.

Comparison of the Antibody Responses Following Vaccination with AstraZeneca and Sinopharm. BACKGROUND: Vaccines are the most effective way to prevent Coronavirus 2 severe acute respiratory syndrome (SARS-CoV-2). OBJECTIVES: To compare the antibody response of healthy individuals vaccinated with either the AstraZeneca (ChAdOx1 nCoV-19) or the Sinopharm (BBIBP-

CorV) vaccine, in those who had no prior infection with SARS-CoV-2. METHODS: Thirty seven participants were included, of which 17 were administered the AstraZeneca (ChAdOx1 nCoV-19) vaccine, while 20 were given the Sinopharm (BBIBP-CorV) vaccine. SARS-CoV-2 neutralizing antibody and anti-receptor-binding domain (RBD) IgG levels were checked 4 weeks after giving the first and the second dose of either vaccine using the enzyme-linked immunosorbent assay (ELISA) technique. RESULTS: The AstraZeneca (ChAdOx1 nCoV-19) vaccine exhibited a higher levels of anti-(RBD) IgG compared with the Sinopharm (BBIBP-CorV) in both the first (14.51 Î¼g/ml vs. 1.160 Î¼g/ml) and the second (46.68 Î¼g/ml vs. 11.43 Î¼g/ml) doses. About neutralizing Abs, the titer of the antibody was higher in the AstraZeneca (ChAdOx1 nCoV-19) recipients than in the Sinopharm (BBIBP-CorV) subjects after the first (7.77 Î¼g/ml vs. 1.79 Î¼g/ml, $p < 0.0001$) and the second dose (10. 36 Î¼g/ml vs. 4.88 Î¼g/ml, $p < 0.0001$). CONCLUSIONS: Recipients vaccinated with two doses of the AstraZeneca (ChAdOx1 nCoV-19) had superior quantitative antibody levels than Sinopharm (BBIBP-CorV)-vaccinated subjects. These data suggest that a booster dose may be needed for the Sinopharm (BBIBP-CorV) recipients, to control the COVID-19 pandemic.

Post COVID-19 vaccination: AusVaxSafety survey participation and adverse events - a community-based regional Queensland study. OBJECTIVE: To describe adverse events following COVID-19 immunisation (AEFI) and participation in AusVaxSafety surveillance in a Queensland regional community. METHODS: Participants presenting for second dose COVID-19 vaccine at the Hervey Bay Wide Bay Hospital and Health Service (WBHHS) vaccine clinic in July 2021 completed a survey pertaining to their first COVID-19 vaccine. Data collected included participation in AusVaxSafety surveillance, vaccine type (BNT162b2 (Pfizer/BioNTech) or ChAdOx1-S(Oxford/AstraZeneca), AEFI experienced and impact on work/routine activities. Multivariable logistic regression related demographic factors to odds of surveillance participation and AEFI occurrence. RESULTS: Of 1,148 participants, 37.6% participated in AusVaxSafety surveillance and 44.8% reported an AEFI. Participation in surveillance was higher in older (â‰¥50 vs <50 years: OR 1.36, 95%CI:1.04-1.78) and less-educated participants (university vs. high school/below: OR 0.68, 95%CI:0.48-0.95). Reporting an AEFI was higher in younger (â‰¥50 years vs. <50 years: BNT162b2: OR 0.69, 95%CI:0.51-0.93; ChAdOx1-S: OR 0.42, 95%CI:0.10-1.89), female (female vs. male: BNT162b2: OR 2.28, 95%CI:1.67-3.12; ChAdOx1-S: OR 1.85, 95%CI:1.17-2.94) and more educated participants (university vs. high school/below: BNT162b2:OR 1.63, 95%CI: 1.08-2.45; ChAdOx1-S: OR 3.98, 95%CI:2.03-7.79). Of participants with an AEFI, 15% reported missing work/routine activities. CONCLUSIONS: Participation in surveillance was modest in this regional population, despite AEFI being frequent, and impacts of absenteeism in this setting warrants further research. IMPLICATIONS FOR PUBLIC HEALTH: The findings can inform strategies to improve surveillance participation and inform workforce planning in regional areas.

Comments on: After the Storm: Ophthalmic Manifestations of COVID-19 Vaccines.

A rare case of cortical blindness following vaccination against SARS-CoV-2. A 61-year-old male presented with sudden loss of vision in both the eyes about 8 days after the first shot of coronavirus disease 2019 (COVID-19) vaccine (Covishield). On examination, the visual acuity was no perception of light in both the eyes. Contrast-enhanced magnetic resonance imaging (MRI) with diffusion-weighted imaging showed acute cerebral infarcts involving bilateral parieto-occipital region. Considering the temporal correlation with the vaccine shot and absence of any other precipitating factor, we hypothesized that this was probably an immunologic response to the vaccine.

Central retinal artery occlusion after vaccination with whole virion inactivated SARSCoV- 2 vaccine Covaxin. Coronavirus disease 2019 (COVID-19) vaccinations have been associated with a higher risk of thromboembolic events. There have been no reports of central retinal artery occlusion (CRAO) after vaccination with the indigenously developed Covaxin, and worldwide, there has been only one

such isolated case after administration of the AstraZeneca vaccine. We report a case of a 44-year-old healthy man who presented with sudden painless vision loss in his left eye 10 days after receiving Covaxin. His best-corrected visual acuity was minimal perception of light, with a relative afferent pupillary defect. Fundus examination revealed arterial attenuation and macular cherry red spot, suggesting an acute CRAO. Optical coherence tomography showed macular swelling and disorganization of the inner layers due to ischemic sequelae. Blood work was normal and cardiovascular examination was unremarkable. The patient was kept on follow-up. To our knowledge, this is the first case of an isolated CRAO after Covaxin administration, but further studies are needed to evaluate this potential association.

Retinal venous occlusion in a child following Corbevax COVID-19 vaccination. A 13-year-old boy developed painless diminution of vision in left eye 15 days after taking first dose of coronavirus disease 2019 (COVID-19) vaccine (Corbevax). Fundus and fluorescein angiography revealed central retinal vein occlusion in the left eye. Blood investigations were noncontributory. He was administered three doses of pulse corticosteroids followed by a tapering dose of oral corticosteroids. Retinal vascular occlusion can occur following COVID-19 vaccination in children, and early and aggressive systemic anti-inflammatory therapy can be helpful.

Clinical observation and analysis of skin reactions caused by COVID-19 vaccination. The novel coronavirus disease 2019 (COVID-19) vaccination is now an essential strategy for controlling the COVID-19 epidemic. This study included 132 cases of adverse skin reactions after the injection of COVID-19 vaccination from January 2021 to January 2022. The rate of adverse skin reactions after the 1st, 2nd, and 3rd doses of the COVID-19 vaccine were 52%, 40%, and 8% of total adverse skin reactions, respectively. The Urticaria-like rash was the most common manifestation of all adverse skin reactions, accounting for 40.15% of all adverse reactions. The Eczema-like rash was 27.27%. The rates of adverse skin reactions after vaccination with the COVID-19 vaccine in patients with a previous skin disease was 12.12%. Other rare skin adverse reactions after COVID-19 vaccination included herpes zoster, pityriasis rosea, erythema multiforme, chickenpox, herpes simplex, psoriasis, erythrodermatitis, arthus reaction, lichen planus recurrence, measles-like rash, frostbite rash, seborrhea, and vitiligo. There were 23 cases of adverse skin reactions in the same individual after two doses of COVID-19 vaccine. There were three cases of adverse skin reactions in the same person after three doses of the vaccine. Treatment measures are mostly mild regimens, such as oral antihistamines, compounded glycopyrrolate and topical weak to moderately potent corticosteroid creams. The total duration of these skin adverse reactions ranged from 2â€‰weeks to 1â€‰month.

Immunogenicity and safety of two-dose SARS-CoV-2 vaccination via different platforms in kidney transplantation recipients. After kidney transplantation, patients exhibit a poor response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. However, the efficacy and adverse effects of vaccines based on different platforms in these patients remain unclear. We prospectively analyzed both anti-spike protein antibody and cellular responses 1 month after the first and second doses of SARS-CoV-2 vaccines in 171 kidney transplant patients. Four vaccines, including one viral vector (ChAdOx1 nCov-19, n = 30), two mRNA (mRNA1273, n = 81 and BNT162b2, n = 38), and one protein subunit (MVC-COV1901, n = 22) vaccines were administered. Among the four vaccines, mRNA1273 elicited the strongest humoral response and induced the highest interferon-Î³ levels in patients with a positive cellular response against the spike protein. Antiproliferative agents were negatively associated with both the antibody and cellular responses. A transient elevation in creatinine levels was noted in approximately half of the patients after the first dose of mRNA1273 or ChadOx1, and only one of them presented with borderline cellular rejection without definite causality to vaccination. In conclusion, mRNA1273 had better immunogenicity than the other vaccines.

Further, renal function needs to be carefully monitored after vaccination, and vaccination strategies should be tailored according to the transplant status and vaccine characteristics.

Reactogenicity and immunogenicity of the second COVID-19 vaccination in patients with inborn errors of immunity or mannan-binding lectin deficiency. BACKGROUND: Patients with inborn errors of immunity (IEI) are at increased risk for severe courses of SARS-CoV-2 infection. COVID-19 vaccination provides effective protection in healthy individuals. However, it remains unclear whether vaccination is efficient and safe in patients with constitutional dysfunctions of the immune system. Thus, we analyzed the humoral response, adverse reactions and assessed the disease activity of the underlying disease after COVID-19 vaccination in a cohort of patients suffering from IEIs or mannan-binding lectin deficiency (MBLdef). METHODS: Vaccination response was assessed after basic immunization using the Elecsys anti-SARS-CoV-2 S immunoassay and via Vero E6 cell based assay to detect neutralization capabilities. Phenotyping of lymphocytes was performed by flow cytometry. Patient charts were reviewed for disease activity, autoimmune phenomena as well as immunization status and reactogenicity of the vaccination. Activity of the underlying disease was assessed using a patient global numeric rating scale (NRS). RESULTS: Our cohort included 11 individuals with common variable immunodeficiency (CVID), one patient with warts hypogammaglobulinemia immunodeficiency myelokathexis (WHIM) syndrome, two patients with X-linked agammaglobulinemia (XLA), one patient with Muckle Wells syndrome, two patients with cryopyrin-associated periodic syndrome, one patient with Interferon-gamma (IFN-gamma) receptor defect, one patient with selective deficiency in pneumococcal antibody response combined with a low MBL level and seven patients with severe MBL deficiency. COVID-19 vaccination was generally well tolerated with little to no triggering of autoimmune phenomena. 20 out of 26 patients developed an adequate humoral vaccine response. 9 out of 11 patients developed a T cell response comparable to healthy control subjects. Tested immunoglobulin replacement therapy (IgRT) preparations contained Anti-SARS-CoV-2 S antibodies implicating additional protection through IgRT. SUMMARY: In summary the data support the efficacy and safety of a COVID-19 vaccination in patients with IEIs/MBLdef. We recommend evaluation of the humoral immune response and testing for virus neutralization after vaccination in this cohort.

Evidence of premature lymphocyte aging in people with low anti-spike antibody levels after BNT162b2 vaccination. SARS-CoV-2 vaccines have unquestionably blunted the overall impact of the COVID-19 pandemic, but host factors such as age, sex, obesity, and other co-morbidities can affect vaccine efficacy. We identified individuals in a relatively healthy population of healthcare workers (CORALE study cohort) who had unexpectedly low peak anti-spike receptor binding domain (S-RBD) antibody levels after receiving the BNT162b2 vaccine. Compared to matched controls, "low responders" had fewer spike-specific antibody-producing B cells after the second and third/booster doses. Moreover, their spike-specific TÂ cell receptor (TCR) repertoire had less depth and their CD4(+) and CD8(+)T cell responses to spike peptide stimulation were less robust. Single cell transcriptomic evaluation of peripheral blood mononuclear cells revealed activation of aging pathways in low responder B and CD4(+)T cells that could underlie their attenuated anti-S-RBD antibody production. Premature lymphocyte aging may therefore contribute to a less effective humoral response and could reduce vaccination efficacy.

IgG4 related pleural disease: Recurrent pleural effusion after COVID-19 vaccination. IgG4-related disease is characterized by a systemic fibroinflammatory process associated with substantial infiltration by plasma cells with IgG4 in the organs. Our patient presented with pleural effusion, and was diagnosed with IgG4-related lung disease (IgG4-RLD) after he received two doses of the Pfizer COVID-19 vaccine. The patient developed dyspnea and hypoxia 2â€‰weeks after receiving the second dose of the Pfizer COVID-19 vaccine. CT scan revealed left pleural effusion which was drained.

However, the effusion recurred requiring thoracoscopic drainage, placement of an indwelling catheter, and decortication with biopsy. IgG4 serum level was 268â€‰mg/dl and pathology revealed pleural fibrosis, lymphoplasmacytic infiltrates, and increased IgG4-positive plasma cells with no malignant cells leading to a diagnosis of IgG4-RLD. Although COVID vaccine-related IgG4-RLD is a novel finding, having a high degree of suspicion following vaccination is always important for early diagnosis and effective treatment.

Immunological response and temporal associations in myocarditis after COVID-19 vaccination using cardiac magnetic resonance imaging: An amplified T-cell response at the heart of it? INTRODUCTION: Although myocarditis after anti-SARS-CoV-2 vaccination is increasingly recognized, we have little data regarding the course of the disease and, consequently, the imaging findings, including the tissue-specific features. The purpose of this study is to describe the clinical, immunological, and cardiac magnetic resonance (CMR) features of myocarditis after COVID-19 immunization in the acute phase and during follow-up. We aimed to compare the trajectory of the disease to myocarditis cases unrelated to COVID-19. METHODS: We assembled a CMR-based registry of potentially COVID-19 vaccination-related myocarditis cases. All patients who experienced new-onset chest pain and troponin elevation after COVID-19 vaccination and imaging confirming the clinical suspicion of acute myocarditis were enrolled in our study. Participants underwent routine laboratory testing and testing of their humoral and cellular immune response to COVID-19 vaccination. Clinical and CMR follow-up was performed after 3-6 months. We included two separate, sex- and age-matched control groups: (1) individuals with myocarditis unrelated to COVID-19 infection or vaccination confirmed by CMR and (2) volunteers with similar immunological exposure to SARS-CoV-2 compared to our group of interest (no difference in the number of doses, types and the time since anti-SARS-CoV-2 vaccination and no difference in anti-nucleocapsid levels). RESULTS: We report 16 CMR-confirmed cases of myocarditis presenting (mean Â± SD) 4 Â± 2 days after administration of the anti-SARS-CoV-2 vaccine (male patients, 22 Â± 7 years), frequently with predisposing factors such as immune-mediated disease and previous myocarditis. We found that 75% received mRNA vaccines, and 25% received vector vaccines. During follow-up, CMR metrics depicting myocardial injury, including oedema and necrosis, decreased or completely disappeared. There was no difference regarding the CMR metrics between myocarditis after immunization and myocarditis unrelated to COVID-19. We found an increased T-cell response among myocarditis patients compared to matched controls ($p < 0.01$), while there was no difference in the humoral immune response. CONCLUSION: In our cohort, myocarditis occurred after both mRNA and vector anti-SARS-CoV-2 vaccination, frequently in individuals with predisposing factors. Upon follow-up, the myocardial injury had healed. Notably, an amplified cellular immune response was found in acute myocarditis cases occurring 4 days after COVID-19 vaccination.

Transient ischemic attack after mRNA-based COVID-19 vaccination during pregnancy: A case report. BACKGROUND: Thrombocytopenia with thrombosis syndrome has been reported after vaccination against severe acute respiratory syndrome coronavirus 2 with two mRNA vaccines. The syndrome is characterized by thrombosis, especially cerebral venous sinus thrombosis, and may lead to stroke. Pregnant women with stroke show higher rates of pregnancy loss and experience serious pregnancy complications. We present the case of a 24-year-old pregnant woman with a transient ischemic attack (TIA) that developed after vaccination with the Moderna mRNA-1273 vaccine (at 37 2/7 wk). CASE SUMMARY: TIA occurred 13 d following the coronavirus disease vaccination. At 39 1/7 wk of pregnancy, the patient presented with sudden onset of right eye blurred vision with headache, dizziness with nausea, right-hand weakness, anomia, and alexia. The symptoms lasted 3 h; TIA was diagnosed. Blood test results revealed elevated D-dimer, cholesterol, and triglyceride levels. Brain magnetic resonance imaging showed no acute hemorrhagic or ischemic stroke. At pregnancy 37 6/7

wk, she was admitted for cesarean delivery to reduce subsequent risk of stroke during labor. Body mass index on admission was 19.8 kg/m(2). Magnetic resonance angiography and transesophageal echocardiography showed no abnormalities. The next day, a mature female baby weighing 2895 g and measuring 50 cm was delivered. Apgar scores were 8 and 9 in the first and fifth minutes. D-dimer levels decreased on postoperative day 4. After discharge, the autoimmune panel was within normal limits, including antinuclear and antiphospholipid antibodies. CONCLUSION: TIA might be developed after the mRNA vaccines in pregnant women.

SARS-CoV-2 vaccine booster in solid organ transplant recipients previously immunised with inactivated versus mRNA vaccines: A prospective cohort study. BACKGROUND: Solid-organ transplant (SOT) recipients have worse COVID-19 outcomes than general population and effective immunisation in these patients is essential but more difficult to reach. We aimed to determine the immunogenicity of an mRNA SARS-CoV-2 vaccine booster in SOT recipients previously immunised with either inactivated or homologous SARS-CoV-2 mRNA vaccine. METHODS: Prospective cohort study of SOT recipients under medical care at Red de Salud UC-CHRISTUS, Chile, previously vaccinated with either CoronaVac or BNT162b2. All participants received a BNT162b2 vaccine booster. The primary study end point was anti-SARS-CoV-2 total IgG antibodies (TAb) seropositivity at 8-12 weeks (56-84 days) post booster. Secondary end points included neutralising antibodies (NAb) and specific T-cell responses. FINDINGS: A total of 140 (50% kidney, 38% liver, 6% heart) SOT recipients (mean age 54 [13.6] years; 64 [46%] women) were included. Of them, 62 had homologous (three doses of BNT162b2) and 78 heterologous vaccine schedules (two doses of CoronaVac followed by BNT162b2 booster). Boosters were received at a median of 21.3 weeks after primary vaccination. The proportion achieving TAb seropositivity (82.3% vs 65.4%, PÂ =Â 0.035) and NAb positivity (77.4% vs 55.1%, PÂ =Â 0.007) were higher for the homologous versus the heterologous group. On the other hand, the number of IFN-Î³ and IL-2 secreting SARS-CoV-2-specific T-cells did not differ significantly between groups. INTERPRETATION: This cohort study shows that homologous mRNA vaccine priming plus boosting in SOT recipients, reaches a significantly higher humoral immune response than inactivated SARS-CoV-2 vaccine priming followed by heterologous mRNA booster. FUNDING: School of Medicine, UC-Chile and ANID.ClinicalTrials.gov ID: NCT05124509.

Thrombotic Thrombocytopenic Purpura After Ad6.COV2.S Vaccination. Thrombotic thrombocytopenic purpura (TTP) is caused by the deficiency of ADAMTS13, a von Willebrand factor cleaving protease, which results in thrombotic microangiopathy. It is characterized by microangiopathic hemolytic anemia, thrombocytopenia, and microvascular thrombosis leading to organ damage. It has an extremely high mortality rate if left untreated, making early diagnosis and treatment of the utmost importance. We report a case of TTP that developed after vaccination with Ad26.COV2.S COVID vaccine. We present a case of a 50-year-old African American female who presentedÂ with dyspnea one week after receiving the first dose of Ad26.COV2.S vaccine. Initial labs showed anemia, thrombocytopenia, and markers of intravascular hemolysis. The suspicion for thrombotic thrombocytopenic syndromes (TTS), vaccine-induced thrombotic thrombocytopenia (VITT), TTP, and Immune thrombocytopenic purpura (ITP) was high based on the history and laboratory results. Computed tomography (CT) of the chest and ultrasound of bilateral lower extremities did not show any evidence of thrombosis. The absence of thrombosis in the presence of a high PLASMIC score increased the suspicion of TTP over the other differentials. Diagnosis of TTP was confirmed when the ADAMTS13 level was low with an elevated autoantibody inhibitor level. The patient underwent treatment with corticosteroids, plasmapheresis, and rituximab with improvement in symptoms and platelet count. TTP and VITT are the possible differential diagnosis for a patient presenting with anemia, thrombocytopenia, and signs of hemolysis after vaccination with

Ad26.COV2.S. It is necessary to differentiate these two clinical entities as the management varies based on the diagnosis.

COVID-19 Vaccine-Induced Thrombotic Thrombocytopaenia With Venous and Arterial Thrombosis: A Case Report. Coronavirus disease 19 pandemic has put tremendous pressure on health systems and has caused significant morbidity and mortality throughout the world. Vaccination program against COVID-19 has been effective despite repeated outbreaks across the globe. It was however reported that COVID-19 vaccines in particular, the Oxford-AstraZeneca COVID-19 vaccine (AZD1222) was temporarily suspended by some European countries due to risk of thrombosis. COVID-19 is a prothrombotic condition and is associated with venous thromboembolism mainly. The condition can be challenging to diagnose due to its diagnostic variation. Cases of vaccine-induced thrombotic thrombocytopaenia has been reported in several countries. COVID-19 can also cause vaccine-induced thrombosis without thrombocytopaenia. The thrombotic events can affect different parts of the body including brain, heart, and peripheral vessels. We present a case of 54-year-old patient who presented with chest and abdominal pain for 12 hours and evidence of infero-lateral ST segment elevation on electrocardiogram. Patient received COVID-19 AstraZeneca vaccine 10 days prior to admission. Coronary angiography (CAG) showed occlusion of the proximal to mid part of the right coronary artery (RCA) distal to a large Right Ventricular branch with high thrombotic burden and multiple attempts at aspiration of the thrombus resulted in partial restoration of the flow to right coronary artery.

Relapse of Palmoplantar Pustulosis Following COVID-19 Vaccination. Palmoplantar pustulosis (PPP) is a rare chronic pustular condition that affects the palms and soles. Smoking and focal infections and dental metal allergies are risk factors for PPP development. Here we report a case of a 60-year-old woman who experienced a relapse of PPPÂ after receiving the COMIRNATY vaccine against COVID-19. The patient relapsed after being in remission for seven years. This article shows the possible implications of COVID-19 vaccination related to the relapse of previous diseases and stresses the importance of careful observation of post-vaccination occurrences of skin eruptions, especially in patients having a history of PPP.

Neuro-Ophthalmologic Symptoms Associated With the Moderna mRNA COVID-19 Vaccine: A Case Report. Multiple neuro-ophthalmological symptoms, such as visual field defects, optic neuritis, and eye movement abnormalities, have been reported with coronavirus disease 2019 (COVID-19) infection. It is unknown whether the COVID-19 vaccine can result in similar neuro-ophthalmological symptoms post-vaccination. Here, we describe a case of optic neuritis after the administration of the mRNA COVID-19 Moderna vaccine. A 47-year-old female presentedÂ eight days after receiving the first dose of the Moderna COVID-19 vaccineÂ with impaired vision in the left eye and symptoms consistent with optic neuritis. The patient underwent a workup for infectious etiology, autoimmune diseases, and allergies, which was negative. The patient was treated with a high dose of steroids resulting in the complete resolution of her symptoms. The patient was recommended against the second dose of the mRNA COVID-19 vaccine. Early detection and treatment of optic neuritis are important to prevent the long-term sequelae of neuritis with impaired vision.

COVID-19 Infection Risk Following Elective Arthroplasty and Surgical Complications in COVID-19-vaccinated Patients: A Multicenter Comparative Cohort Study. BACKGROUND: We aimed to determine symptomatic Coronavirus disease 2019 (COVID-19) rates within 1Â month of elective arthroplasty for vaccinated individuals and to determine whether vaccination guarantees protection against COVID-19 after arthroplasty (primary outcome). In addition, the 90-day surgical complications were compared to those of an unvaccinated group (secondary outcome). METHODS: A prospective cohort study was conducted on elective joint arthroplasty patients at 3 tertiary hospitals in 2 major cities (Tehran and Isfahan) in our country (Iran). The outcomes of the COVID-19-vaccinated group

were assessed between October 2021 and March 2022. Ninety-day surgical complications were compared with a historical cohort of unvaccinated patients treated earlier in the pandemic (April 2020-March 2021). RESULTS: The study included 1717 consecutive patients: 962 vaccinated and 755 unvaccinated. In the vaccinated group, 38 patients (3.9%) contracted COVID-19, 4 (10.5%) were hospitalized again, and none required intensive care unit admission. The multivariate logistic regression analysis revealed that COVID-19-positive cases are more likely to be female (odds ratio [OR]Â = 12.5), to have visitors to their home (ORÂ = 4.7), and to stay longer in the hospital (ORÂ = 1.2) than COVID-19-negative cases. Compared toÂ unvaccinated patients, the postoperative COVID-19 rate was not significantly different (3.9% vs 2.4%, PÂ = .07). The incidence of surgical complications was similar between the 2 groups (P > .05). CONCLUSIONS: The vaccination does not provide a guarantee that a patient will not contract COVID-19 following their arthroplasty surgery, especially in a region with a high rate of COVID-19. We believe reasonable perioperative COVID-19 precautions may be warranted even in vaccinated patients.

Seroprevalence of SARS-CoV-2 in Mexican Health Care Workers after Two Years of the Pandemic: The Picture of an Ophthalmic Medical Centre. OBJECTIVE: In this study, we investigated the impact of the SARS-CoV-2 vaccination on seroprevalence in a cohort of healthcare workers (HCW) at an ophthalmic medical center. METHODS: IgG antibodies against the N, S1, and S2 antigens of SARS-CoV-2 as well as their serum neutralizing activity were determined. RESULTS: In the present study, we observed that 98.4% of HCW were seropositive for S1/S2 proteins of SARS-CoV-2 due to the national vaccination program. Interestingly, 78.4% of the participants had anti-N protein antibodies, suggesting previous COVID-19 infection. We also evaluated the neutralizing antibodies and found that the mean value was high (90.7%). CONCLUSION: These results indicate that our HCWs cohort presented a robust hybrid humoral response owing to the massive national vaccination program and natural infections.

mRNA (BNT162b2) and Inactivated (CoronaVac) COVID-19 Vaccination and Risk of Adverse Events and Acute Diabetic Complications in Patients with Type 2 Diabetes Mellitus: A Population-Based Study. INTRODUCTION: In Hong Kong, CoronaVac and BNT162b2 have been approved for emergency use owing to the coronavirus disease 2019 (COVID-19) pandemic. Reactions towards the vaccine and the risk of post-vaccination adverse events may be different between recipients with and without type 2 diabetes mellitus (T2DM). OBJECTIVE: The aim of this study was to evaluate the risk of adverse events of special interest (AESI) and acute diabetic complications in the T2DM population after COVID-19 vaccination in Hong Kong. RESEARCH DESIGN AND METHODS: Self-controlled case-series analysis was conducted. Patients with T2DM who received at least one dose of BNT162b2 or CoronaVac between 23 February 2021 and 31 January 2022 from electronic health records in Hong Kong were included. The incidence rates of 29 AESIs and acute diabetic complications (any of severe hypoglycemia, diabetic ketoacidosis or hyperosmolar hyperglycemic syndrome) requiring hospitalization within 21 days after the first or second dose of vaccination were reported. The risks of these outcomes were evaluated using conditional Poisson regression. RESULTS: Among 141,224 BNT162b2 recipients and 209,739 CoronaVac recipients with T2DM, the incidence per 100,000 doses and incidence per 100,000 person-years of individual AESIs and acute diabetic complications ranged from 0 to 24.4 and 0 to 438.6 in BNT162b2 group, and 0 to 19.5 and 0 to 351.6 in CoronaVac group. We did not observe any significantly increased risk of individual AESIs or acute diabetic complications after first or second doses of BNT162b2 or CoronaVac vaccine. Subgroup analysis based on HbA1c < 7% and â‰¥ 7% also did not show significantly excess risk after vaccination. CONCLUSIONS: Patients with T2DM do not appear to have higher risks of AESI and acute diabetic complications after BNT162b2 or CoronaVac vaccination. Moreover, given the low incidence of AESIs and acute diabetic complications after vaccination, the absolute risk increment was likely minimal.

Self-reported adverse events within the seven days following the SpikevaxÂ® (Moderna) vaccination. OBJECTIVE: Continuous monitoring of COVID-19 vaccines safety mayÂ provideÂ additional information to health care professionals and the generalÂ population.Â The aim of the present study was to analyze the localÂ and systemic adverseÂ events following the administration of the SpikevaxÂ®Â (Moderna) vaccine, andÂ to identify the factors related to greater reactogenicity. METHOD: Using a telephone survey, we interviewed 331 recipient ofÂ theÂ SpikevaxÂ® vaccine (50.2% men; Meanage = 46.4). ParticipantsÂ haracteristics,Â prior COVID-19 infection and local and systemic adverseÂ eventsÂ within seven days following the first and second vaccine dosesÂ were asked.Â Results: Injection site pain, fatigue and headache were the most commonÂ adverse events. The prevalence and intensity of local events wasÂ higher after the first dose, while systemic events were higher in theÂ secondÂ one. Most adverse events were mild/moderate; 1.2% of participantsÂ neededÂ hospitalization or emergency room visit. Women and participantsÂ agedÂ 18-55 years were more likely to experience greater reactogenicity,Â participantsÂ with prior COVID-19 infection had more systemicÂ events afterÂ the first dose, and participants with chronic diseases other thanÂ hypertensionÂ reported fewer systemic adverse events following the secondÂ dose. CONCLUSIONS: Our results are consistent with previous studies, identifyingÂ women, people aged 18-55 years and those with previous COVID-19Â infection as those who experienced the greatest reactogenicity to theÂ vaccine.Â A relationship was also found between reactogenicity and sufferingÂ from a chronic disease other than hypertension.

Lichen planus pigmentosus post COVID-19-vaccination: A case report with literature review. Lichen planus (LP) is a T cellâ€•mediated chronic inflammatory disorder. Several clinical variants based on lesion morphology and localization are reported. LPP remains uncommon with an unknown etiology. Besides, some precipitating factors have been suggested in the literature including hepatitis C infection; restrictive underwear, localized friction, and sun exposure.((1, 2)) Herein, we present a case of newâ€•onset of LPP following the ChAdOx1 nCoVâ€•19 (Oxfordâ€•AstraZeneca) vaccine. A literature review was also conducted to summarize the various cases of LP induced and/or trigged by Covidâ€•19 vaccine.

Coronavirus (COVID-19) Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). Coronavirus disease 2019 (COVID-19), the illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), continues to cause significant morbidity and mortality worldwide, with manyÂ nations enduring multiple outbreaks of this viral illness. Besides the importance of infection control measures to prevent or decrease the transmission of SARS-CoV-2, the most crucial step to contain this global pandemic is to vaccinate individuals to prevent SARS-CoV-2 infection in communities across the world. Many vaccines have been developed at an unprecedented speed using distinctive technologies to prevent COVID-19. Vaccination triggers the immune system resulting in the production of neutralizing antibodies against SARS-CoV-2. Four vaccines, namely the BNT162b2, mRNA-1273, Ad26.COV2.S, and ChAdOx1 nCoV-19 have been approved to prevent COVID-19 in many nationsÂ worldwide, including the United States. TheÂ BNT162b2, mRNA-1273 have been approved by the U.S. FDA and theÂ Ad26.COV2.S has received Emergency Use Authorization. One exception is the ChAdOx1 nCoV-19 vaccine, which has not yet received a EUA or approval from the U.S. Food and Drug Administration (FDA) for use in the U.S. The BNT162b2 and mRNA-1273 vaccines are both mRNA-based, while the Ad26.COV2. S and ChAdOx1 nCoV-19 vaccines incorporate replication-incompetent adenoviral vectors in them. In late February 2021, a new clinical syndrome characterized by thrombosis at atypical sites combined with thrombocytopenia was observed in multiple patients days after vaccination with the ChAdOx1 nCoV-19 vaccine.Â In April 2021, similar clinical sequelae were reported in patients after vaccination with the Ad26.COV2. S vaccine. Preceding the approval of

these vaccines, the clinical constellation of this new syndrome was not observed in clinical trials of the ChAdOx1 nCoV-19 vaccine, and a single case was observed in the Ad26.COV2. S vaccine trial recipient.Â Furthermore, the incidence of major adverse effects has remained exceptionally low following the vaccination of more than 400 million people worldwide.Â This novel clinical syndrome demonstrated striking similarities to heparin-induced thrombocytopenia; however, in the absence of prior heparin exposure was named vaccine-induced immune thrombotic thrombocytopenia (VITT).Â It is also known asÂ vaccine-induced prothrombotic immune thrombocytopenia (VIPIT) in some EuropeanÂ nations and Canada.Â Conversely, in millions of doses of BNT162b2 or mRNA-1273 vaccines administered so far, this clinical syndrome has not been reported.Â Due to the concern of VITT associated with the Ad26.COV2. S vaccine, the FDA modified the EUA and recommends limiting the use of this vaccine only to individuals > 18 years of age who are otherwise ineligible to receive any other FDA-approved vaccines due to anaphylaxis to mRNA vaccines or its components or are unable/unwilling to receive any other vaccine. Per the American Society of Hematology, vaccine-induced immune thrombotic thrombocytopenia (VITT) is defined as a clinical syndrome characterized by all of the below described abnormal laboratory and radiologic abnormalities occurring in individuals 4 to 42 days after vaccination with Ad26.COV2. S or ChAdOx1 nCoV-19 vaccines. Development of thrombosis at uncommon sites includes cerebral venous sinus thrombosis (CSVT)/splanchnic venous thrombosis. Mild to severe thrombocytopenia. However, a normal platelet count does not exclude the possibility of this syndrome in its early stages. Positive antibodies against platelet factor 4(PF4) identified by enzyme-linked immunosorbent assay (ELISA) assay. Significantly elevated D-dimer (> 4 times ULN). This review article aims to describe the etiology, epidemiology, pathophysiology, clinical features, diagnosis, and management of COVID-19 vaccine-induced thrombotic immune thrombocytopenia based on the latest available published literature.

Molecular mimicry, hyperactive immune system, and SARS-COV-2 are three prerequisites of the autoimmune disease triangle following COVID-19 infection. SARS-CoV-2 infection can produce a variety of clinical manifestations, which are either directly related to viral tissue damage or indirectly induced by the antiviral immune response. Molecular mimicry enables this virus to undermine self-tolerance in a host's immune system also immune system's attempts to eliminate SARS-COV-2 may trigger autoimmunity by hyper-activating the innate and adaptive immune systems. Auto immune diseases include Systemic lupus erythematosus, autoimmune thyroid diseases, Guillain-Barre syndrome, Immune thrombocytopenic purpura, and the detection of autoantibodies are the cues to the discovery of the potential of COVID-19 in inducing autoimmunity. As COVID-19 and autoimmune diseases share a common pathogenesis, autoimmune drugs may be an effective treatment option. Susceptible patients must be monitored for autoimmune symptoms after contracting CVID-19. In light of the SARS-COV-2 virus' ability to induce autoimmunity in susceptible patients, will the various COVID-19 vaccines that are the only way to end the pandemic induce autoimmunity?

Enhanced antibody responses in fully vaccinated individuals against pan-SARS-CoV-2 variants following Omicron breakthrough infection. Omicron has become the globally dominant severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variant, creating additional challenges due to its ability to evade neutralization. Here, we report that neutralizing antibodies against Omicron variants are undetected following COVID-19 infection with ancestral or past SARS-CoV-2 variant viruses or after two-dose mRNA vaccination. Compared with two-dose vaccination, a three-dose vaccination course induces broad neutralizing antibody responses with improved durability against different SARS-CoV-2 variants, although neutralizing antibody titers against Omicron remain low. Intriguingly, among individuals with three-dose vaccination, Omicron breakthrough infection substantially augments serum neutralizing activity against a broad spectrum of SARS-CoV-2 variants, including Omicron variants BA.1, BA.2, and BA.5. Additionally, after Omicron breakthrough infection,

memory TÂ cells respond to the spike proteins of both ancestral and Omicron SARS-CoV-2 by producing cytokines with polyfunctionality. These results suggest that Omicron breakthrough infection following three-dose mRNA vaccination induces pan-SARS-CoV-2 immunity that may protect against emerging SARS-CoV-2 variants of concern.

Evaluation of SARS-CoV-2 Serum Level in Patients Vaccinated With Sinopharm/BBIBP-CorV With Kidney Transplantation. BACKGROUND: Every year, a large number of people undergo kidney transplants because of various reasons leading to renal failure. These patients usually have low immunoglobulin levels due to the use of immunosuppressive drugs. In recent years, the COVID-19 pandemic has been a major global health risk. Patients who are immunocompromised or who have diabetes are especially at risk. METHODS: In this study, we enrolled 156 patients who had undergone kidney transplant and had received 2 doses of Sinopharm/BIBP-CorV. The serum antibody levels against COVID-19 spike glycoprotein (immunoglobulin [Ig] G and IgM) were measured using a sandwich enzyme-linked immunosorbent assay kit to evaluate whether different immunosuppressive drugs could affect the body's response to the said vaccine. RESULTS: We found that only patients receiving Rapamune had increased IgM secondary to COVID-19 vaccine. None of the immunosuppressive drugs in this study have shown a positive correlation with increased IgG levels. The only factor that showed a significant effect on both IgM and IgG was a positive history of COVID-19, which was correlated with increased levels of serum IgG/M. CONCLUSIONS: Only patients treated with Rapamune showed an acute immune reaction to the vaccine in the form of positive serum IgM levels, and no rise of serum IgM antibody was observed in COVID-19-naive patients. Patients who had a previous history of COVID-19 infection showed an elevated serum IgM and IgG level, suggesting that vaccines in general and Sinopharm/BIBP-CorV in particular are not enough to ensure immunity against COVID-19 in transplant recipients. We recommend further studies using different types of vaccines and immunosuppressive drugs.

Does the BNT162b2 Vaccine Trigger Antimelanoma Differentiation-Associated Gene 5 Antibody-Positive Interstitial Lung Disease?

Immune Response to SARS-CoV-2 Third Vaccine in Patients With Rheumatoid Arthritis Who Had No Seroconversion After Primary 2-Dose Regimen With Inactivated or Vector-Based Vaccines. OBJECTIVE: The aim of this study was to assess the immune response after a third dose of SARS-CoV-2 vaccine in patients with rheumatoid arthritis (RA) with undetectable antibody titers after the primary regimen of 2 doses. METHODS: Patients with RA with no seroconversion after 2 doses of SARS-CoV-2 vaccine and who received a third dose of either an mRNA or vector-based vaccine were included. Anti-SARS-CoV-2 IgG antibodies, neutralizing activity, and T cell responses were assessed after the third dose. RESULTS: A total of 21 nonresponder patients were included. At the time of vaccination, 29% were receiving glucocorticoids and 85% biologic disease-modifying antirheumatic drugs (including 6 taking abatacept [ABA] and 4 taking rituximab [RTX]). The majority (95%) received the BNT162b2 vaccine and only one of them received the ChAdOx1 nCoV-19 vaccine. After the third dose, 91% of the patients presented detectable anti-SARS-CoV-2 IgG and 76% showed neutralizing activity. Compared to other treatments, ABA and RTX were associated with the absence of neutralizing activity in 4 out of 5 (80%) patients and lower titers of neutralizing antibodies (median 3, IQR 0-20 vs 8, IQR 4-128; P = 0.20). Specific T cell response was detected in 41% of all patients after the second dose, increasing to 71% after the third dose. The use of ABA was associated with a lower frequency of T cell response (33% vs 87%, P = 0.03). CONCLUSION: In this RA cohort, 91% of patients who failed to seroconvert after 2 doses of SARS-CoV-2 vaccine presented detectable anti-SARS-CoV-2 IgG after a third dose. The use of ABA was associated with a lower frequency of specific T cell response.

Third dose of COVID-19 mRNA vaccine appears to overcome vaccine hyporesponsiveness in patients with cirrhosis. BACKGROUND & AIMS: Cirrhosis is associated with immune dysregulation and

hyporesponsiveness to several vaccines including those against COVID-19. Our aim was to compare outcomes between patients with cirrhosis who received 3 doses of either the Pfizer BNT162b2 mRNA or Moderna mRNA-1273 vaccines to a propensity-matched control group of patients at similar risk of infection who received 2 doses. METHODS: This was a retrospective cohort study of patients with cirrhosis who received 2 or 3 doses of a COVID-19 mRNA vaccine at the Veterans Health Administration. Participants who received 3 doses of the vaccine (nÂ = 13,041) were propensity score matched with 13,041 controls who received 2 doses, and studied between July 18, 2021 and February 11, 2022, when B.1.617.2 (delta) and B.1.1.529 (omicron) were the predominant variants. Outcomes were aggregated as all cases with COVID-19, symptomatic COVD-19, with at least moderate COVID-19, or severe or critical COVID-19. RESULTS: Receipt of the third dose of a COVID-19 mRNA vaccine was associated with an 80.7% reduction in COVID-19 (95% CI 39.2-89.1, p <0.001), an 80.4% reduction in symptomatic COVID-19, an 80% reduction in moderate, severe or critical COVID-19, (95% CI 34.5-87.6%, pÂ = 0.005), a 100% reduction in severe or critical COVID-19 (95% CI 99.2-100.0, pÂ = 0.01), and a 100% reduction in COVID-19-related death (95% CI 99.8-100.0, pÂ = 0.007). The magnitude of reduction in COVID-19 was greater with the third dose of BNT 162b2 than mRNA-1273 and among participants with compensated rather than decompensated cirrhosis. CONCLUSIONS: Administration of a third dose of a COVID-19 mRNA vaccine was associated with a more significant reduction in COVID-19 in patients with cirrhosis than in the general population, suggesting that the third dose can overcome vaccine hyporesponsiveness in this population. LAY SUMMARY: Cirrhosis is associated with decreased responsiveness to several vaccines, including those against COVID-19. In this study of 26,082 participants with cirrhosis during the delta and omicron surge, receipt of the third dose of the vaccine was associated with an 80% reduction in COVID-19, a 100% reduction in severe/critical COVID-19, and a 100% reduction in COVID-19-related death. These findings support the importance of a third dose of mRNA vaccine among patients with cirrhosis.

Reply to "A case of symmetrical drug-related intertriginous and flexural exanthema-like eruption associated with Pfizer COVID-19 vaccination" by Manaa et al.

COVID-19 vaccines and filler reactions: Should it be considered as a concern? BACKGROUND: Any implant or external material used in the body tissues can potentially be followed by autoimmune or inflammatory reactions. With the global vaccination program against COVID-19, the reports of tissue filler reactions would be increasingly demonstrated. AIM: To summarize the data regarding COVID vaccination and filler reactions. METHOD: We reviewed the existing data in this regard through searching on PubMed, Google Scholar and Scopus. All of the relevant papers published until March 2022, which we could access to their fulltexts were included. RESULTS: Here, we summarized the data regarding COVID-19 vaccination and filler reactions and discussed its etiopathogenesis, management, and importance. CONCLUSION: Although the end of pandemic was announced, the necessity of continuing COVI-
D19Â vaccinationÂ inÂ futureÂ mandatesÂ gatheringÂ dataÂ regardingÂ safetyÂ ofÂ vaccines.

A case report of possible concurrent vasculitis in vertebral bodies and partial transverse myelitis following COVID-19 vaccination. INTRODUCTION: Cases with organ-specific and systemic vasculitis associated with corona virus disease 2019 (COVID-19) vaccination have been reported. However, acute partial transverse myelitis (APTM) is rare adverse events following received COVID-19 vaccines. To the best of our knowledge, there is no report on vaccine-associated APTM accompanied by possible concurrent vasculitis. Herein we present a case with possible concurrent spinal vasculitis and APTM following the second dose of inactivated COVID-19 vaccine. CASE SUMMARY: A 33-year-old man presented with weakness of left lower limb and aberrant sensation of his left lower trunk and limb (from T9 level to toes) for 2 days following receipt of an inactivated COVID-19 vaccine. Remarkable demyelinating lesion at T7 spinal cord was showed by 3.0T magnetic resonance imaging

(MRI) scan. Moreover, vertebral bodies of T3-T7 also presented high signal in T-2 weighted imaging (T2WI) accompanied by multiple sites of flowing void effect indicating possible vasculitis. Oligoclonal band was positive in cerebrospinal fluid (CSF) while it was negative in sera. Intravenous methylprednisolone (1â€‰g/d) was administrated for 5 days followed by subsequent dose-tapering prednisone. His limb weakness and aberrant sensation both improved and he was able to walk unaided after treatment. The MRI recheck also showed remarkable improvement on the lesions in spinal cord and vertebral bodies. CONCLUSION: this case illustrates the concurrence of possible vasculitis in vertebral bodies and acute transverse myelitis (ATM) following COVID-19 vaccination.

BNT162b2 coronavirus disease-2019 vaccination accelerated rheumatoid arthritis disease activity in chronic eosinophilic pneumonia: A case report. RATIONALE: The relationship between rheumatoid arthritis (RA) and eosinophilic inflammation is unclear. According to recent studies, it has been suggested that T helper 2 cell responses play a role in the inhibition of RA. It is unclear how the immunological response after coronavirus disease-2019 (COVID-19) vaccination affects T cell immune reactions. PATIENT CONCERNS AND DIAGNOSES: Here, we report the case of an 88-year-old woman diagnosed with RA and chronic eosinophilic pneumonia (CEP). She was diagnosed with CEP about 20 years ago, and, through steroid treatment, she improved and had no relapse for 16 years. At the time of diagnosis of CEP, the rheumatoid factor (RF) was increased; however, there were no joint symptoms. After receiving the COVID-19 vaccine, joint and respiratory symptoms gradually worsened. Laboratory examinations showed increased RF, anti-cyclin citrullinated peptide antibody, and peripheral absolute eosinophil count. Musculoskeletal ultrasonography showed synovitis. INTERVENTION AND OUTCOME: Methylprednisolone pulse therapy improved respiratory and joint symptoms immediately; RA and CEP stabilized with no relapses. LESSONS: Eosinophilic and rheumatoid reactions following COVID-19 vaccination were an-reported adverse events. Eosinophilic inflammation might be reflected on an anti-inflammatory reaction in initial phase of RA.

Influenza and SARS-CoV-2 vaccinations adherence after liver transplantation during the second year of the COVID-19 pandemic (results of a patients' survey).

Optimizing methotrexate withdrawal during COVID vaccination. Results from two parallel trials suggest that withholding methotrexate only after the second dose of a COVID vaccine is safe and effective in patients with rheumatoid arthritis or psoriatic arthritis.

Risk of thrombocytopenic, haemorrhagic and thromboembolic disorders following COVID-19 vaccination and positive test: a self-controlled case series analysis in Wales. There is a need for better understanding of the risk of thrombocytopenic, haemorrhagic, thromboembolic disorders following first, second and booster vaccination doses and testing positive for SARS-CoV-2. Self-controlled cases series analysis of 2.1 million linked patient records in Wales between 7th December 2020 and 31st December 2021. Outcomes were the first diagnosis of thrombocytopenic, haemorrhagic and thromboembolic events in primary or secondary care datasets, exposure was defined as 0-28Â days post-vaccination or a positive reverse transcription polymerase chain reaction test for SARS-CoV-2. 36,136 individuals experienced either a thrombocytopenic, haemorrhagic or thromboembolic event during the study period. Relative to baseline, our observations show greater risk of outcomes in the periods post-first dose of BNT162b2 for haemorrhagic (IRR 1.47, 95%CI: 1.04-2.08) and idiopathic thrombocytopenic purpura (IRR 2.80, 95%CI: 1.21-6.49) events; post-second dose of ChAdOx1 for arterial thrombosis (IRR 1.14, 95%CI: 1.01-1.29); post-booster greater risk of venous thromboembolic (VTE) (IRR-Moderna 3.62, 95%CI: 0.99-13.17) (IRR-BNT162b2 1.39, 95%CI: 1.04-1.87) and arterial thrombosis (IRR-Moderna 3.14, 95%CI: 1.14-8.64) (IRR-BNT162b2 1.34, 95%CI: 1.15-1.58). Similarly, post SARS-CoV-2 infection the risk was increased for haemorrhagic (IRR 1.49, 95%CI: 1.15-1.92), VTE (IRR 5.63, 95%CI: 4.91, 6.4), arterial thrombosis (IRR 2.46, 95%CI: 2.22-2.71). We found that

there was a measurable risk of thrombocytopenic, haemorrhagic, thromboembolic events after COVID-19 vaccination and infection.
Development of chemiluminescent lab-on-fiber immunosensors for rapid point-of-care testing of anti-SARS-CoV-2 antibodies and evaluation of longitudinal immune response kinetics following three-dose inactivation virus vaccination. Developing reliable, rapid, and quantitative point-of-care testing (POCT) technology of SARS-CoV-2-specific antibodies and understanding longitudinal vaccination response kinetics are highly required to restrain the ongoing coronavirus disease 2019 (COVID-19) pandemic. We demonstrate a novel portable, sensitive, and rapid chemiluminescent lab-on-fiber detection platform for detection of anti-SARS-CoV-2 antibodies: the chemiluminescent lab-on-fiber immunosensor (c-LOFI). Using SARS-CoV-2 Spike S1 RBD protein functionalized fiber bio-probe, the c-LOFI can detect anti-SARS-CoV-2 immunoglobulin G (IgG) and immunoglobulin M (IgM) antibodies with high sensitivity based on their respective horseradish peroxidase-labeled secondary antibodies. The limits of detection of anti-SARS-CoV-2 IgG and IgM antibodies were 0.6 and 0.3â€‰ng/ml, respectively. The c-LOFI was successfully applied for direct detection of anti-SARS-CoV-2 antibodies in whole blood samples with simple dilution, which can serve as a finger prick test to rapidly detect antibodies. Furthermore, the longitudinal immune response (>12 months) kinetics following three-dose inactivated virus vaccines was evaluated based on anti-SARS-CoV-2 IgG detection results, which can provide important significance for understanding the immune mechanism against COVID-19 and identify individuals who may benefit from the vaccination and booster vaccination. The c-LOFI has great potential to become a sensitive, low-cost, rapid, high-frequency POCT tool for the detection of both SARS-CoV-2-specific antibodies and other biomarkers.
Side Effects of COVID-19 Vaccines in Patients with Inflammatory Bowel Disease in Japan. BACKGROUND: Patients with inflammatory bowel disease (IBD) are recommended to receive the coronavirus disease 2019 (COVID-19) vaccine. However, a recent survey showed that patients with IBD are more hesitant to receive the vaccine than the general population. Detailed information on the side effects of the COVID-19 vaccine is necessary to encourage vaccination among patients with IBD. AIM: To investigate the frequency of side effects following COVID-19 vaccination in patients with IBD in Japan. STUDY DESIGN: a cross-sectional survey was conducted using a questionnaire administered to adult patients with IBD in a tertiary medical facility. RESULTS: Among the participants who answered the questionnaire, 92.6%, 91.5%, and 41.5% of the participants had received their first, second, and third doses of the COVID-19 vaccine, respectively. Of the vaccinated participants, 88.3%, 86.3%, and 89.0% experienced side effects after receiving the first, second, and third doses of the vaccine, respectively. The incidences of fever, chills, and headaches were significantly higher among female participants than among male participants (pâ€‰<â€‰0.05). However, the frequencies of most side effects were comparable between the BNT162b2 mRNA and mRNA-1273 vaccines. CONCLUSION: The findings of our survey can help encourage patients with IBD to receive the COVID-19 vaccine.
Gianotti-crosti syndrome after COVID-19 vaccination.
Reply to the letter "cutaneous adverse events following the inactivated and mRNA COVID-19 vaccines: Correspondence".
Acute liver injury and IgG4-related autoimmune pancreatitis following mRNA-based COVID-19 vaccination. IgG4-related disease (IgG4-RD) is a fibro-inflammatory disease that can affect multiple organs. Autoimmune pancreatitis type 1 is a manifestation of IgG4-RD and can often mimic tumor-like masses. Autoimmune phenomena following COVID-19 mRNA vaccination are being increasingly reported. Currently, there are no cases in which IgG4-RD involving the hepatobiliary system has been reported following the COVID-19 vaccination. We present the first case of IgG4-RD and AIP type 1 to be associated with the mRNA-based COVID-19 vaccination.

Capillary leak syndrome following COVID-19 vaccination: Data from the European pharmacovigilance database Eudravigilance. Capillary leak syndrome (CLS) emerged as new adverse event after immunization (AEFI) associated to COVID-19 vaccination. CLS is a rare condition characterized by increased capillary permeability, resulting in hypoalbuminemia, hypotension, and edema mainly in the upper and lower limbs. Our pharmacovigilance study aims to evaluate the CLS onset following receipt of COVID-19 mRNA vaccines (mRNA-1273 and BNT162b2) compared to viral vector vaccines (Ad26.COV2-S and ChAdOx1-SARS-COV-2). We carried a cross-sectional study using all Individual Case Safety Reports (ICSRs) reporting a COVID-19 vaccine as suspected drug and CLS as AEFI, which were collected in the pharmacovigilance database EudraVigilance from January 1st, 2021, to January 14th, 2022. We applied the Reporting Odds Ratio (ROR) 95% CI for the disproportionality analysis. During our study period, CLS was described as AEFI in 84 out of 1,357,962 ICRs reporting a vaccine COVID-19 as suspected drug and collected in the EV database. Overall, the ICSR reported by CLS were mainly related to the viral vector COVID-19(ChAdOx1-SARS-COV-2 = 36; Ad26.COV2-S = 9). The mRNA COVID-19 vaccines were reported in 39 ICSRs (BNT162b2 =33; mRNA-1273 =6). Majority of ICSRs were reported by healthcare professionals (71.4%). Majority of the patients were adult (58.3%) and the female gender accounted in more than 65% of ICSRs referred both to classes vaccines. In particular, women were more represented in ICSRs referred to mRNA-1273 (83.3%) and to ChAdOx1-SARS-COV-2 (72.2%). The CLS outcome was more frequently favorable in mRNA ICSRs (33,3%) than the viral vector ones (13.3%). Among the ICSRs reporting CLS with unfavorable outcome, we found also 9 fatal cases (BNT162b2 = 1; ChAdOx1-SARS-COV-2 = 4; Ad26.COV2-S = 4). From disproportionality analysis emerged a lower CLS reporting probability after vaccination with mRNA vaccines compared to viral vector-based ones (ROR 0.5, 95% CI 0.3-0.7; p <0.001).Our findings, even if subject to the limitations of spontaneous reporting systems, suggest a small but statistically significant safety concern for CLS following receipt of COVID-19 viral vector vaccines, in particular with Ad26.COV2-S. Cytokine-release following T-cell activation could be involved in CLS occurrence, but a precise mechanism has been not yet identified. COVID-19 vaccines remain attentive as possible triggers of CLS.

Efficacy, immunogenicity and safety of COVID-19 vaccines in older adults: a systematic review and meta-analysis. BACKGROUND: Older adults are more susceptible to severe health outcomes for coronavirus disease 2019 (COVID-19). Universal vaccination has become a trend, but there are still doubts and research gaps regarding the COVID-19 vaccination in the elderly. This study aimed to investigate the efficacy, immunogenicity, and safety of COVID-19 vaccines in older people aged â‰¥ 55 years and their influencing factors. METHODS: Randomized controlled trials from inception to April 9, 2022, were systematically searched in PubMed, EMBASE, the Cochrane Library, and Web of Science. We estimated summary relative risk (RR), rates, or standardized mean difference (SMD) with 95% confidence interval (CI) using random-effects meta-analysis. This study was registered with PROSPERO (CRD42022314456). RESULTS: Of the 32 eligible studies, 9, 21, and 25 were analyzed for efficacy, immunogenicity, and safety, respectively. In older adults, vaccination was efficacious against COVID-19 (79.49%, 95% CI: 60.55-89.34), with excellent seroconversion rate (92.64%, 95% CI: 86.77-96.91) and geometric mean titer (GMT) (SMD 3.56, 95% CI: 2.80-4.31) of neutralizing antibodies, and provided a significant protection rate against severe disease (87.01%, 50.80-96.57). Subgroup and meta-regression analyses consistently found vaccine types and the number of doses to be primary influencing factors for efficacy and immunogenicity. Specifically, mRNA vaccines showed the best efficacy (90.72%, 95% CI: 86.82-93.46), consistent with its highest seroconversion rate (98.52%, 95% CI: 93.45-99.98) and GMT (SMD 6.20, 95% CI: 2.02-10.39). Compared to the control groups, vaccination significantly increased the incidence of total adverse events (AEs) (RR 1.59, 95% CI: 1.38-1.83), including most local and systemic AEs, such as pain, fever, chill, etc. For inactivated and DNA vaccines, the incidence of any AEs was similar between vaccination and control groups (p > 0.1), while

mRNA vaccines had the highest risk of most AEs (RR range from 1.74 to 7.22). CONCLUSION: COVID-19 vaccines showed acceptable efficacy, immunogenicity and safety in older people, especially providing a high protection rate against severe disease. The mRNA vaccine was the most efficacious, but it is worth surveillance for some AEs it caused. Increased booster coverage in older adults is warranted, and additional studies are urgently required for longer follow-up periods and variant strains.

A comprehensive review of BBV152 vaccine development, effectiveness, safety, challenges, and prospects. The world has responded to the COVID-19 pandemic with unprecedented speed and vigor in the mass vaccination campaigns, targeted to reduce COVID-19 severity and mortality, reduce the pressure on the healthcare system, re-open society, and reduction in disease mortality and morbidity. Here we review the preclinical and clinical development of BBV152, a whole virus inactivated vaccine and an important tool in the fight to control this pandemic. BBV152, formulated with a TLR7/8 agonist adjuvant generates a Th1-biased immune response that induces high neutralization efficacy against different SARS-CoV-2 variants of concern and robust long-term memory B- and T-cell responses. With seroconversion rates as high as 98.3% in vaccinated individuals, BBV152 shows 77.8% and 93.4% protection from symptomatic COVID-19 disease and severe symptomatic COVID-19 disease respectively. Studies in pediatric populations show superior immunogenicity (geometric mean titer ratio of 1.76 compared to an adult) with a seroconversion rate of >95%. The reactogenicity and safety profiles were comparable across all pediatric age groups between 2-18 yrs. as in adults. Like most approved vaccines, the BBV152 booster given 6 months after full vaccination, reverses a waning immunity, restores the neutralization efficacy, and shows synergy in a heterologous prime-boost study with about 3-fold or 300% increase in neutralization titers against multiple SARS-CoV-2 variants of concern. Based on the interim Phase III data, BBV152 received full authorization for adults and emergency use authorization for children from ages 6 to 18 years in India. It is also licensed for emergency use in 14 countries globally. Over 313 million vaccine doses have already been administered in India alone by April 18(th), 2022.

Isolated breast parenchymal changes following COVID-19 vaccine booster. Ipsilateral transient axillary lymphadenopathy is well-documented following COVID-19 mRNA vaccine administration. Recently, rare mammographic findings of breast tissue changes with co-existing lymphadenopathy have been documented. Current literature on isolated ipsilateral true breast parenchymal changes on diagnostic mammography in symptomatic patients following COVID-19 mRNA vaccine administration is limited. This is one of the first case reports that demonstrates isolated ipsilateral focal asymmetry 5 days after administration of COVID-19 mRNA vaccine followed by complete resolution of symptoms and focal asymmetry confirmed on follow up magnetic resonance imaging. These findings warrant the development of guidelines to reduce unnecessary invasive procedures as part of the workup for possible malignancy.

COVID-19-Induced Myocarditis and mRNA Vaccine-Related Pericarditis: A Case Report. Acute inflammatory cardiac disease is an increasing cause of COVID-19 vaccine-induced complications. We report a case of acute pericarditis following the second dose of the COVID-19 vaccine (BNT162b2) in a 49-year-old woman with previous COVID-19-induced myocarditis and heart failure. A clinical presentation compatible with acute decompensated heart failure elevated troponin levels and a cardiac-MRI showing myocardial fibrosis and inflammatory pericardial effusion led to the diagnosis of perimyocarditis. She was treated with non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine. Her condition improved in eight days. Physicians should be aware of the possible diagnosis of pericarditis and/or a myocardial injury after COVID-19 infection and vaccination.

Decrease in COVID-19 adverse outcomes in adults during the Delta and Omicron SARS-CoV-2 waves, after vaccination in Mexico. Mexico, one of the countries severely affected by COVID-19,

accumulated more than 5. 1 all-cause excess deaths/1,000 inhabitants and 2.5 COVID-19 confirmed deaths/1,000 inhabitants, in 2 years. In this scenario of high SARS-CoV-2 circulation, we analyzed the effectiveness of the country's vaccination strategy that used 7 different vaccines from around the world, and focused on vaccinating the oldest population first. We analyzed the national dataset published by Mexican health authorities, as a retrospective cohort, separating cases, hospitalizations, deaths and excess deaths by wave and age group. We explored if the vaccination strategy was effective to limit severe COVID-19 during the active outbreaks caused by Delta and Omicron variants. Vaccination of the eldest third of the population reduced COVID-19 hospitalizations, deaths and excess deaths by 46-55% in the third wave driven by Delta SARS-CoV-2. These adverse outcomes dropped 74-85% by the fourth wave driven by Omicron, when all adults had access to vaccines. Vaccine access for the pregnant resulted in 85-90% decrease in COVID-19 fatalities in pregnant individuals and 80% decrease in infants 0 years old by the Omicron wave. In contrast, in the rest of the pediatric population that did not access vaccination before the period analyzed, COVID-19 hospitalizations increased >40% during the Delta and Omicron waves. Our analysis suggests that the vaccination strategy in Mexico has been successful to limit population mortality and decrease severe COVID-19, but children in Mexico still need access to SARS-CoV-2 vaccines to limit severe COVID-19, in particular those 1-4 years old.

Similarity between cutaneous reactions due to SARS-CoV-2 and its vaccinations.

Autoimmune myasthenia gravis after COVID-19 in a triple vaccinated patient. Despite a well characterized mechanism, myasthenia gravis (MG) remains a dilemma in terms of etiology. Several case reports and series of cases suggest a potential cause-effect relation between SARS-CoV-2 infection or vaccination and MG. We present the case of an autoimmune MG occurring post Covid-19 in an elderly male, vaccinated with three doses of the BNT162b2/Pfizer-BioNTech vaccine. The 78-year-old male was admitted in the Neurology Clinic in early November 2021 with double vision, bilateral ptosis, dysphonia and dysphagia, 16 days after receiving a third dose of the BNT162b2/Pfizer-BioNTech SARS-CoV-2 vaccine and 12 days after testing positive for SARS-CoV-2 infection. The symptoms began to emerge at 9 days after COVID-19 diagnosis. Clinical neurological examination included ice-pack test and intramuscular neostigmine, both with positive results. Myasthenia gravis positive diagnosis was confirmed by slow repetitive nerve stimulation and abnormally increased serum levels of antibodies against acetylcholine receptors. Due to patient's refusal of further hospitalization, he was discharged with therapy recommendations. Under treatment with oral pyridostigmine, but no oral corticosteroid due to therapeutic noncompliance, the patient was readmitted two months later with aggravated symptoms. The myasthenic crisis was successfully treated with intravenous immunoglobulins, corticosteroid therapy and oral pyridostigmine. The novelty of the current case resides in the fact that, to the best of our knowledge, appears to be the first case of MG clinically manifested after COVID-19 infection in a fully vaccinated patient.

Acquired hemophilia following COVID-19 vaccination: Case report and review of literature. BACKGROUND: Acquired hemophilia A (AHA) is a rare bleeding disorder that can lead to spontaneous hemorrhage or bleeding induced by invasive procedures or trauma. We describe a patient who presented with multiple hematomas and a relapse of bullous pemphigoid shortly after his first dose of Vaxzevria ChAdOx1-S COVID-19 vaccination. We reviewed literature for cases of AHA following COVID-19 vaccination. KEY CLINICAL QUESTION: Can COVID-19 vaccines induce (a recurrence of) AHA? CLINICAL APPROACH AND CONCLUSIONS: The diagnosis of AHA with a relapse of bullous pemphigoid was made. The patient was treated with recombinant activated factor VII, emicizumab, rituximab, and methylprednisolone. There were no further bleeding events. However, the patient deteriorated because of sepsis and died on the fifteenth day of admission. CONCLUSION: Vaccines

may trigger autoimmune events such as AHA. However, proof of causality is not possible and in this case the relapse of bullous pemphigoid before vaccination challenges this even more.

Changes in Behavior After Vaccination and Opinions Toward Mask Wearing: Thoracic Oncology Patient-Reported Experiences During the COVID-19 Pandemic. BACKGROUND: The COVID-19 vaccines, face masks, and social distancing are effective interventions to prevent SARS-CoV-2 infections. In this study, we aimed to determine lung cancer patients' attitudes toward vaccination, changes in behavior after vaccination, and willingness to continue mask wearing after the pandemic. METHODS: We sent out questionnaires to 220 thoracic oncology patients treated at our lung cancer center in May 2021. The questionnaire focused on patients' vaccination status, self-reported experiences surrounding vaccination, and assessed changes in behaviors before and after vaccination as well as opinions toward mask wearing after the pandemic. Results are presented as absolute and relative frequencies and means with standard deviation and compared using t test, paired t test, and analysis of variance test as well as chi(2) test, and Fisher exact text. RESULTS: About 91.0% of patients reported having received at least 1 vaccination. About 73.3% of patients reported having at least 1 reaction to the vaccination. The most common reactions were pain at the injection site, fatigue, and headache. After vaccination, patients increased contact with family and friends, use of public transport, and grocery shopping. Overall, the level of willingness to wear masks beyond the end of the pandemic differed according to vaccination status. CONCLUSIONS: Acceptance of the COVID-19 vaccination among thoracic oncology patients in Germany was high. Overall, patients with thoracic malignancies tolerated the COVID-19 vaccination well. Rate of adverse reaction was not higher compared with the general population. After the vaccination, patients increased social contacts and usage of public transport. These changes suggest positive psychological effects on quality of life. While reducing social distancing can increase the risk of infection, our results indicate that an extension of mask mandates after the pandemic would likely be accepted by a majority of thoracic oncology patients, suggesting that our cohort was still aware and in support of other measure of protection.

Acute pancreatitis in pregnancy following COVID-19 vaccine: a case report. BACKGROUND: Since the approval of the Pfizer-BioNTech (BNT162b2) mRNA vaccine for COVID-19 infection, a few adverse effects have been reported. Acute pancreatitis has been reported in a few patients. However, there is currently no research showing a direct relationship between the vaccine and acute pancreatitis. Here, we report a case of acute pancreatitis following Pfizer vaccination in a young healthy pregnant woman without any known risk factors. To our knowledge, this is the first case report of possible vaccine-induced pancreatitis in a pregnant woman. CASE PRESENTATION: The patient, a 24-year-old South-AsianÂ female, at 31Â weeks of gestation, presented with severe epigastric pain radiating to the back and worsening on lying supine, associated with nausea and vomiting. She was diagnosed with acute pancreatitis with a serum lipase level of 4376Â U/L and an ultrasound showing features of pancreatitis. The patient received her first dose of the Pfizer vaccine 1Â week prior to these symptoms. Detailed evaluation did not show any etiological cause of pancreatitis. The patient had a spontaneous vaginal delivery and the baby was shifted to the neonatal intensive care unit in a stable condition. A computed tomography scan postpartum (day 2) demonstrated acute interstitial edematous pancreatitis. The patient was managed conservatively in the intensive care unit and discharged home in a stable condition. CONCLUSION: This report highlights the importance of a detailed history and evaluation, and the close monitoring of any patient presenting with abdominal pain after vaccination. Acute pancreatitis can be fatal if not picked up early.

Seroepidemiological study of factors affecting anti-spike IgG antibody titers after a two-dose mRNA COVID-19 vaccination in 3744 healthy Japanese volunteers. Several factors related to anti-spike(S) IgG antibody titers after mRNA COVID-19 vaccination have been elucidated, but the

magnitude of the effects of each factor has not been fully understood. This cross-sectional study assessed anti-S and anti-nucleocapsid (N) antibody titers on 3744 healthy volunteers (median age, 36Â years; IQR, 24-49Â years; females, 59.0%) who received two doses of mRNA-1273 or BNT162b2 vaccine and completed a survey questionnaire. Multiple regression was conducted to identify factors associated with antibody titers. All but one participant tested positive for anti-S antibodies (99.97%). The following factors were independently and significantly associated with high antibody titer:â€‰<â€‰3Â months from vaccination (ratio of means 4.41); mRNA-1273 vaccine (1.90, vs BNT162b2); anti-N antibody positivity (1.62); age (10's: 1.50, 20's: 1.37, 30's: 1.26, 40's: 1.16, 50's: 1.15, vs â‰§60's); female (1.07); immunosuppressive therapy (0.54); current smoking (0.85); and current drinking (0.96). The largest impact on anti-S IgG antibody titers was found in elapsed time after vaccination, followed by vaccine brand, immunosuppressants, previous SARS-CoV-2 infection (anti-N antibody positive), and age. Although the influence of adverse reactions after the vaccine, gender, smoking, and drinking was relatively small, they were independently related factors.
Cutaneous Rosai-Dorfman disease after Covid 19 vaccination treated with thalidomide.
Dosing of intravenous immunoglobulin in COVID-19 vaccine-induced immune thrombocytopenia and thrombosis.
Coronavirus disease 2019 vaccination and live birth outcome after fresh embryo transfer.
Clinical advances and ongoing trials on mRNA vaccines for cancer treatment. Years of research exploring mRNA vaccines for cancer treatment in preclinical and clinical trials have set the stage for the rapid development of mRNA vaccines during the COVID-19 pandemic. Therapeutic cancer vaccines based on mRNA are well tolerated, and the inherent advantage in ease of production, which rivals the best available conventional vaccine manufacture methods, renders mRNA vaccines a promising option for cancer immunotherapy. Technological advances have optimised mRNA-based vaccine stability, structure, and delivery methods, and multiple clinical trials investigating mRNA vaccine therapy are now enrolling patients with various cancer diagnoses. Although therapeutic mRNA-based cancer vaccines have not yet been approved for standard treatment, encouraging results from early clinical trials with mRNA vaccines as monotherapy and in combination with checkpoint inhibitors have been obtained. This Review summarises the latest clinical advances in mRNA-based vaccines for cancer treatment and reflects on future perspectives and challenges for this new and promising treatment approach.
[Polyethylengylcole - Friend or Foe?]. Anaphylactic reactions following vaccination are rare. However, anaphylactic reactions towards the Pfizer-BioNTech Covid-19 vaccine were first reported in two patients in the UK and another 19 in the USA. Pegylation with polyethylene glycol (PEG) was thought to be the possible culprit. Pegylation is a common process in the manufacture of vaccines in order to prevent early degradation by the immune system. PEG is a polyether like e. g. Laureth-9, polidocanol, thesit and macrogol and is found in foodstuffs, cosmetics and personal care products as well as in liposomes and nanoparticles, as drug-delivery-system and as osmotic laxans for gastroscopies/coloscopies. Given the widespread use of PEG, reactions to vaccinations are rare and therefore no reason to exclude allergic patients in principle or indeed those who know the exact cause of a former anaphylaxis. In Germany, medical doctors are obliged to report any severe adverse reactions following vaccination; it is hoped that this procedure will help to resolve any remaining questions.
Dystonia as a complication of COVID-19 vaccinations is not as rare as portrayed.
Need For Focused Pharmacovigilance in the Face of Rapid COVID-19 Vaccine Development.
Antibody response after vaccination against SARS-CoV-2 in adults with hematological malignancies: a systematic review and meta-analysis.

Booster dose of COVID-19 mRNA vaccine does not increase risks of myocarditis and pericarditis compared with primary vaccination: New insights from the vaccine adverse event reporting system. BACKGROUND: Despite the likely association between coronavirus 2019 (COVID-19) mRNA vaccines and cases of myocarditis/pericarditis, the benefit-risk assessment by the Centers for Disease Control (CDC) still showed a favorable balance for the primary series of COVID-19 mRNA vaccinations. Since August 2021, a full-scale booster vaccination in certain recipients has been recommended. Great concerns about whether the COVID-19 mRNA booster vaccination could increase the risks of myocarditis/pericarditis have been raised since then. The present study aimed to compare the incidence rates and risks of myocarditis/pericarditis between booster and primary vaccination programs. METHODS: The CDC COVID Data Tracker and the Vaccines Adverse Event Reporting System (VAERS) were queried between December 11, 2020 and March 15, 2022. Incidence rates were calculated by cases of myocarditis/pericarditis divided by the number of vaccinated people or the total doses of COVID-19 mRNA vaccines. Disproportionality patterns for myocarditis/pericarditis of different COVID-19 mRNA vaccinations were accessed based on the reporting odds and proportional reporting ratios (ROR and PRR, respectively). RESULTS: A total of 2,588 reports of myocarditis/pericarditis were identified after administration of primary-series COVID-19 mRNA vaccination and 269 after the booster dose program during the study period. The incidence of myocarditis/pericarditis following booster COVID-19 mRNA vaccination was lower than that of primary series. The results showed significantly high reporting of myocarditis/pericarditis following the administration of primary COVID-19 mRNA vaccination, whereas the disproportional level was lower in the booster-dose vaccination. CONCLUSION: This study found that the booster dose of COVID-19 mRNA vaccination when compared with primary series course did not lead to an increase in the risks of myocarditis/pericarditis.

Ventricular tachycardia triggered by the first dose of an adenoviral vector-based COVID-19 vaccine in an adult patient with congenital heart disease. A unique adverse event of adenoviral COVID-19 vaccine in an adult patient with congenital heart disease is reported.

Comprehensive analysis of immune responses in CLL patients after heterologous COVID-19 vaccination. Patients with chronic lymphocytic leukemia (CLL) treated with B-cell pathway inhibitors and anti-CD20 antibodies exhibit low humoral response rate (RR) following SARS-CoV-2 vaccination. To investigate the relationship between the initial transcriptional response to vaccination with ensuing B and T cell immune responses, we performed a comprehensive immune transcriptome analysis flanked by antibody and T cell assays in peripheral blood prospectively collected from 15 CLL/SLL patients vaccinated with heterologous BNT162b2/ChAdOx1 with follow up at a single institution. The two-dose antibody RR was 40% increasing to 53% after booster. Patients on BTKi, venetoclax Â± anti-CD20 antibody within 12 months of vaccination responded less well than those under BTKi alone. The two-dose T cell RR was 80% increasing to 93% after booster. Transcriptome studies revealed that seven patients showed interferon-mediated signaling activation within 2 days and one at 7 days after vaccination. Increasing counts of COVID-19 specific IGHV genes correlated with B-cell reconstitution and improved humoral RR. T cell responses in CLL patients appeared after vaccination regardless of treatment status. A higher humoral RR was associated with BTKi treatment and B-cell reconstitution. Boosting was particularly effective when intrinsic immune status was improved by CLL-treatment.

SARS-CoV-2 Omicron boosting induces de novo B cell response in humans. The primary two-dose SARS-CoV-2 mRNA vaccine series are strongly immunogenic in humans, but the emergence of highly infectious variants necessitated additional doses of these vaccines and the development of new variant-derived ones (1-4) . SARS-CoV-2 booster immunizations in humans primarily recruit pre-existing memory B cells (MBCs) (5-9) . It remains unclear, however, whether the additional doses

induce germinal centre (GC) reactions where reengaged B cells can further mature and whether variant-derived vaccines can elicit responses to novel epitopes specific to such variants. Here, we show that boosting with the original SARS- CoV-2 spike vaccine (mRNA-1273) or a B.1.351/B.1.617.2 (Beta/Delta) bivalent vaccine (mRNA-1273.213) induces robust spike-specific GC B cell responses in humans. The GC response persisted for at least eight weeks, leading to significantly more mutated antigen-specific MBC and bone marrow plasma cell compartments. Interrogation of MBC-derived spike-binding monoclonal antibodies (mAbs) isolated from individuals boosted with either mRNA-1273, mRNA-1273.213, or a monovalent Omicron BA.1-based vaccine (mRNA-1273.529) revealed a striking imprinting effect by the primary vaccination series, with all mAbs (n=769) recognizing the original SARS-CoV-2 spike protein. Nonetheless, using a more targeted approach, we isolated mAbs that recognized the spike protein of the SARS-CoV-2 Omicron (BA.1) but not the original SARS-CoV-2 spike from the mRNA-1273.529 boosted individuals. The latter mAbs were less mutated and recognized novel epitopes within the spike protein, suggesting a naÃ¯ve B cell origin. Thus, SARS-CoV-2 boosting in humans induce robust GC B cell responses, and immunization with an antigenically distant spike can overcome the antigenic imprinting by the primary vaccination series.

Relapses after SARS-CoV-2 vaccination in patients with neuromyelitis optica spectrum disorder and multiple sclerosis. BACKGROUND: The COVID-19 pandemic outbreak raises the question of whether immunization is recommended for patients with CNS demyelinating diseases. On the one hand, existing studies suggested that SARS-CoV-2 vaccinations are not associated with increased risk of relapse activity. On the other hand, case reports with acute CNS demyelinating disease post vaccination were emerging and raising clinicians' attention. METHODS: In this longitudinal observational study, we included 556 patients with neuromyelitis optica spectrum disorder (NMOSD) and 280 patients with relapsing-remitting multiple sclerosis (RRMS). Each vaccinated patient was matched to two unvaccinated patients according to age, gender, ARR and immunotherapy status, based on propensity score matching model (PSM). The primary outcome is the short- and medium-term risk of relapse, which were evaluated by Kaplan-Meier analysis between groups. RESULTS: In our cohort, 649 patients (77.6%) have not yet been vaccinated, mainly due to their concerns about relapse. After PSM, 109 vaccinated patients with NMOSD, 218 PS-matched unvaccinated patients with NMOSD, 78 vaccinated patients with RRMS, and 156 PS-matched unvaccinated patients with RRMS were included in the survival analysis to explore the safety of vaccines, with a median of 9-month follow-up. Following the first vaccination dose, 10 patients with NMOSD (9.2%) and four with RRMS (5.1%) experienced an acute relapse. Meanwhile, in the PS-matched unvaccinated group, 15 patients with NMOSD (6.9%) and 12 patients with RRMS (7.7%) presented with an acute relapse. There was no significant difference between the two curves in both NMOSD and RRMS groups over the course of the observation period. There were no significant differences in demographic characteristics, clinical characteristics, and symptoms of relapses between the vaccinated and PS-matched unvaccinated groups. Post vaccination adverse events (ADE) were reported in 39 individuals (20.9%). CONCLUSION: Our results indicate that inactivated SARS-CoV-2 vaccines appear safe for patients with CNS demyelinating diseases.

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: First Described Complication after Gam-COVID-Vac Vaccine. BACKGROUND: Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is a severe, debilitating chronic disease characterized by marked tiredness and fatigue, cognitive dysfunction, sleep disturbances, pain, and autonomic, immunological, and metabolic dysfunctions, in which all symptoms are usually exacerbated by physical and/or psychological stress. SUBJECTS AND METHODS: We report a case of ME/CFS with severe myalgia and severe locomotor disorders in a 25-year-old female after Gam-COVID-Vac vaccine (Sputnik V) ten days before the

manifestation of the symptoms. RESULTS: This is the first report of such a complication from the Gam-COVID-Vac vaccine.
First Episode Psychosis Following COVID-19 Vaccination: a Case Report. Vaccines are crucial to ending the COVID-19 pandemic. An mRNA-based COVID-19 vaccine can cause mild to moderate side effects. A number of cases of cardiac, gastrointestinal, and psychiatric side effects have been reported as rare side effects associated with the COVID-19 vaccine. This article presents a patient, who after the second injection of the mRNA-based COVID-19 vaccine, immediately developed anxiety, nonspecific fear, and insomnia as the prodromal phase of psychosis. Starting from the second week, the patient manifested delusions of persecution, delusions of influence, thoughts insertion, and delusional behaviour, culminating in the suicide attempt. The duration of psychosis was eight weeks, and symptom reduction was observed only after the gradual administration of antipsychotics over four weeks. The investigations of the patient did not support any structural changes of the brain, any severe medical conditions, a neurological abnormality, a confusion or a state of unconsciousness or alterations in laboratory tests. Psychosis due to the use of alcohol or psychoactive substances was excluded. The psychological assessment of the patient demonstrated the endogenous type of thinking, and the patient had schizoid and paranoid personality traits strongly associated with schizophrenia. This case indicates a strong causal relationship between the mRNA-based COVID-19 vaccine injection and the onset of psychosis. We intend to follow up this case for possible development of schizophrenia and understand that the COVID-19 vaccine could possible play a trigger role in the development of primary psychosis. Longer-term supporting evidence is needed to estimate the prevalence of psychosis following vaccination with the mRNA-based COVID-19 vaccine.
Waning natural and vaccine-induced immunity leading to reinfection with SARS-CoV-2 Omicron variant. We have investigated six COVID-19 recovered cases with two doses of Covishield vaccination followed by reinfection. The primary SARS-CoV-2 infection found to occur with B.1 and reinfection with Omicron BA.1 and BA.2 variants. The genomic characterization and duration between two infections confirms these cases as SARS-CoV-2 reinfection. The immune response determined at different time intervals demonstrated boost post two dose vaccination, decline in pre-reinfection sera post 7 months and rise post reinfection. In conclusion, it was observed that these cases got SARS-CoV-2 reinfection with declined hybrid immunity acquired from primary infection and two dose covishield vaccination. This findings suggests the need to protect the community through booster dose of vaccination and prevent further infections following personal hygiene and non-pharmaceutical interventions.
Association of Influenza Vaccination With SARS-CoV-2 Infection and Associated Hospitalization and Mortality Among Patients Aged 66 Years or Older. IMPORTANCE: Vaccine effectiveness studies have rarely implemented strategies to reduce the healthy vaccinee bias arising from differences in health care-seeking behavior between vaccinated and unvaccinated individuals. Although previous observational studies suggest that influenza vaccination is associated with a reduced risk of SARS-CoV-2-associated outcomes, the healthy vaccinee bias may have led to overestimating the vaccination effect. OBJECTIVE: To estimate the association between influenza vaccination and SARS-CoV-2-associated outcomes. DESIGN, SETTING, AND PARTICIPANTS: This cohort study was conducted over 2 consecutive influenza vaccination campaigns (2019-2020 and 2020-2021), owing to the substantial COVID-19 burden and the greater validity of influenza vaccination data in the studied age group. The study population included community-dwelling adults aged 66 years or older in Ontario, Canada. EXPOSURE: Influenza vaccination for a given season. MAIN OUTCOMES AND MEASURES: The outcomes of interest included SARS-CoV-2 infection, SARS-CoV-2-associated hospitalization, SARS-CoV-2-associated death, and a composite of SARS-CoV-2-associated hospitalization or death. Cox proportional hazards models were used to measure the association between influenza vaccination

and SARS-CoV-2-associated outcomes, censoring individuals who moved into long-term care, received COVID-19 vaccines, or died before the observation period end date. Primary care periodic health examinations (PHEs) were explored as a negative tracer exposure (ie, no association expected with SARS-CoV-2 outcomes) and as an effect modifier of the association between influenza vaccination and SARS-CoV-2 outcomes. RESULTS: Of 2â€¯922â€¯449 individuals aged 66 years or older (54.2% female) living in Ontario, 2 279 805 were included in the study. Among these, 1 234 647 (54.2%) were female and 1 045 158 (45.8%) were male; their mean (SD) age was 75.08 (7.21) years. Those who had received influenza vaccination exhibited a lower incidence of SARS-CoV-2 infection than unvaccinated individuals for the 2019-2020 cohort (adjusted hazards ratio [aHR],â€‰0.78; 95% CI, 0.73-0.84) and the 2020-2021 cohort (aHR, 0.76; 95% CI, 0.74-0.78). This association was also observed for SARS-CoV-2-associated hospitalization or death (2019-2020: aHR, 0.83; 95% CI, 0.74-0.92; 2020-2021: aHR, 0.66; 95% CI, 0.63-0.70). Similarly, undergoing a PHE was also associated with a lower incidence of SARS-CoV-2 infection (aHR,â€‰0.85; 95% CI, 0.78-0.91) and SARS-CoV-2-associated hospitalization or death (aHR,â€‰0.80; 95% CI, 0.70-0.90), and modified the association between influenza vaccination and SARS-CoV-2 infection for vaccinated individuals who underwent PHE (aHR,â€‰0.62; 95% CI, 0.52-0.74) and for vaccinated individuals who did not undergo PHE (aHR,â€‰0.81; 95% CI, 0.76-0.87), and also SARS-CoV-2-associated hospitalization or death in vaccinated individuals who underwent PHE (aHR,â€‰0.66; 95% CI, 0.49-0.88) and vaccinated individuals who did not undergo PHE (aHR,â€‰0.85, 95% CI, 0.76-0.95). CONCLUSIONS AND RELEVANCE: The findings of this cohort study suggest that undergoing a PHE may at least partially modify the association between influenza vaccination and SARS-CoV-2-associated outcomes in individuals aged 66 years or older, providing evidence of the healthy vaccinee bias that may affect vaccine effectiveness studies.

mRNA-1273 SARS-CoV-2 vaccine safety and COVID-19 risk perception in recently transplanted allogeneic hematopoietic stem cell transplant recipients. PURPOSE: This study aims to describe the incidence and severity of adverse events (AEs) following the mRNA-1273 SARS-CoV-2 vaccine and explore the risk perception of COVID-19 in allogeneic hematopoietic stem cell transplant (HCT) recipients. METHODS: We performed a single-center prospective study including recently transplanted (<â€‰2Â years post-infusion) allogeneic HCT recipients. AEs were assessed through phone calls and graded from 0 to 4, while COVID-19 risk perception was measured using the Brief Illness Perception Questionnaire (BIP-Q5). RESULTS: Fifty-four HCT recipients were evaluated. Incidence and grades of AE (94.4% and 85.2% after the first and second dose, respectively) were similar to those described in the general population. The most common AE was pain at the site of injection. Three patients (5.6%) developed a gradeâ€‰â‰¥â€‰3 AE. Vaccine-related cytopenias and graft-versus-host disease flares were not observed. Female sex (OR 3.94, 95% CI 1.14-13.58, pâ€‰=â€‰0.03) and time since HCT (per month since HCT: OR 1.09, 95% CI 1.01-1.18, pâ€‰=â€‰0.04) were associated with the occurrence of any AE. The patients' risk perception level of COVID-19 decreased over time (pâ€‰<â€‰0.05). CONCLUSION: Our study confirms that the mRNA-1273 SARS-CoV-2 vaccine is safe in recent HCT recipients and suggests that the perceived risk of COVID-19 decreases over time.

Fatal intracerebral haemorrhage associated with thrombosis with thrombocytopenia syndrome after ChAdOx1-S vaccine. INTRODUCTION: The COVID-19 pandemic has had a devastating impact on health, society and economics worldwide. Therefore, vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have recently emerged as an important measure to fight the pandemic. ChAdOx1-S (Oxford-AstraZeneca) is an adenovirus-vectored vaccine that expresses the SARS-CoV-2 spike protein. It shows an acceptable safety profile. Nevertheless, several cases of unusual thrombosis and thrombocytopenia have been reported after initial vaccination with ChAdOx1-S mimicking autoimmune heparin-induced thrombocytopenia. This condition has been

called thrombosis with thrombocytopenia syndrome (TTS) and complications such as intracerebral haemorrhage have been described. CASE REPORT: We present a case of intracerebral haemorrhage after ChAdOx1-S vaccination. Middle-aged patient with no prior medical history was seen in the emergency room 16 days after the first dose of ChAdOx1-S vaccine with sudden onset left hemiplegia and severe holocranial oppressive headache. She did not receive heparin treatment in the previous 100 days. Blood test showed moderate thrombocytopenia and a right frontal lobar haemorrhage was seen on computed tomography scan, computed tomography venography was negative for thrombosis. The presence of antibodies against platelet factor 4 was confirmed. The patient's neurological condition progressively worsened. She developed a treatment resistant intracranial hypertension syndrome and she died three weeks later. CONCLUSIONS: TTS is a rare adverse effect of ChAdOx1-S vaccine, defined by the presence of thrombosis in uncommon locations. In our case we report an spontaneous intracerebral haemorrhage probable due to the thrombocytopenia related to probable TTS. It represents a rare clinical presentation of TTS.

Seroconversion after COVID-19 vaccination and heart transplant recipients: Correspondence.

COVID-19 Vaccination in Solid-Organ Transplant: A Real-World Multicenter Experience. OBJECTIVES: India ranks third globally in organ procurement and transplant and has the second highest COVID-19 incidence rate, but data regarding COVID-19 vaccination in solid-organ transplant patients are scarce. MATERIALS AND METHODS: We created a cross-sectional, anonymous, online questionnaire and sentinvitations to several transplant centers in India. We surveyed vaccine mandates, immunization coverage and side effects, administration timing, infection severity among solid-organ transplant recipients, and booster dosage recommendations. RESULTS: The survey results showedthat vaccinepolicy is heterogeneous among centers; vaccination is voluntary at some centers (44.7%), but some centers have established COVID-19 vaccination as a requirement for transplant candidates (44.6%). CoviShield was the most common vaccine administered (89.3%), and more than 50% of transplant recipients and donors were fully vaccinated. Survey results showed that the pretransplant wait time after full vaccination (both doses) is 2 to 4 weeks (48.9%), and the optimal time for vaccination after transplant is 3 to 6 months (59.3%). For vaccinated transplant patients, 89.4% of respondents reported an incidence rate for posttransplant breakthrough infection of less than 25%. For unvaccinated patients, 38.3% ofrespondents reported a 25% to 50% incidence rate of posttransplant COVID- 19 infection. Booster doses are recommended at many transplant centers in India, as reported by 89.4% of survey respondents. CONCLUSIONS: The results of the survey suggested that there are no substantial safety concerns Future targets should include increasing efficacy and increasing booster doses of the COVID-19 vaccine.

Examining the association between vaccine reactogenicity and antibody titer dynamics after the third dose of BNT162b2 vaccine using a mixed-effects model. BACKGROUND: To mitigate the COVID-19 pandemic, many countries have recommended the use of booster vaccinations. The relationship between the degree of adverse vaccine reactions and elevated antibody titers is of interest; however, no studies have investigated the temporal changes in antibody titers based on repeated measurements after a third dose of the BNT162b2 vaccine. METHODS: This prospective longitudinal cohort study was conducted with 62 healthcare workers who received a third dose of the BNT162b2 at Okayama University Hospital, Japan. Venous blood draw and fingertip whole blood test sample collection were conducted at the early (3-13 days) and 1-month time points; only FWT sample collection was conducted at the 2-month time point. Information on adverse reactions within 1 week after vaccination was also obtained. The association between fever of 37.5Â Â°C or higher and antibody titers after the third dose of BNT162b2 was examined using a mixed-effects model and Poisson regression with robust variance. RESULTS: A trend toward higher antibody titers in the early period after vaccination was observed in the febrile individuals, but the differences were not

significant at 1 and 2 months post-vaccination (the partial regression coefficient for fever was 8094.3 [-1910.2, 18,098.8] at 1 month after vaccination, and 1764.1 [-4133.9, 7662.1] at 2 months after vaccination in the adjusted models). CONCLUSION: The findings suggest that the presence of fever after the third vaccine does not predict a sustained elevation in serum antibody titers.
Risk of Long COVID in People Infected With Severe Acute Respiratory Syndrome Coronavirus 2 After 2 Doses of a Coronavirus Disease 2019 Vaccine: Community-Based, Matched Cohort Study. We investigated long COVID incidence by vaccination status in a random sample of UK adults from April 2020 to November 2021. Persistent symptoms were reported by 9.5% of 3090 breakthrough severe acute respiratory syndrome coronavirus 2 infections and 14.6% of unvaccinated controls (adjusted odds ratio, 0.59 [95% confidence interval, .50-.69]), emphasizing the need for public health initiatives to increase population-level vaccine uptake.
Risk factors for SARS-CoV-2 infection after primary vaccination with ChAdOx1 nCoV-19 or BNT162b2 and after booster vaccination with BNT162b2 or mRNA-1273: A population-based cohort study (COVIDENCE UK). BACKGROUND: Little is known about how demographic, behavioural, and vaccine-related factors affect risk of post-vaccination SARS-CoV-2 infection. We aimed to identify risk factors for SARS-CoV-2 infection after primary and booster vaccinations. METHODS: This prospective, population-based, UK study in adults (â‰¥16 years) vaccinated against SARS-CoV-2 assessed risk of breakthrough SARS-CoV-2 infection up to February, 2022, for participants who completed a primary vaccination course (ChAdOx1 nCoV-19 or BNT162b2) and those who received a booster dose (BNT162b2 or mRNA-1273). Cox regression models explored associations between sociodemographic, behavioural, clinical, pharmacological, and nutritional factors and test-positive breakthrough infection, adjusted for local weekly SARS-CoV-2 incidence. FINDINGS: 1051 (7Â·1%) of 14â€‰713 post-primary participants and 1009 (9Â·5%) of 10â€‰665 post-booster participants reported breakthrough infection, over a median follow-up of 203 days (IQR 195-216) and 85 days (66-103), respectively. Primary vaccination with ChAdOx1 (vs BNT162b2) was associated with higher risk of infection in both post-primary analysis (adjusted hazard ratio 1Â·63, 95% CI 1Â·41-1Â·88) and after an mRNA-1273 booster (1Â·26 [1Â·00-1Â·57] vs BNT162b2 primary and booster). Lower risk of infection was associated with older age (post-primary: 0Â·97 [0Â·96-0Â·97] per year; post-booster: 0Â·97 [0Â·97-0Â·98]), whereas higher risk of infection was associated with lower educational attainment (post-primary: 1Â·78 [1Â·44-2Â·20] for primary/secondary vs postgraduate; post-booster: 1Â·46 [1Â·16-1Â·83]) and at least three weekly visits to indoor public places (post-primary: 1Â·36 [1Â·13-1Â·63] vs none; post-booster: 1Â·29 [1Â·07-1Â·56]). INTERPRETATION: Vaccine type, socioeconomic status, age, and behaviours affect risk of breakthrough infection after primary and booster vaccinations. FUNDING: Barts Charity, UK Research and Innovation Industrial Strategy Challenge Fund.
Asymptomatic or symptomatic SARS-CoV-2 infection plus vaccination confers increased adaptive immunity to variants of concern. The ongoing evolution of SARS-CoV-2 requires monitoring the capability of immune responses to cross-recognize Variants of Concern (VOC). In this cross-sectional study, we examined serological and cell-mediated immune memory to SARS-CoV-2 variants, including Omicron, among a cohort of 18-21-year-old Marines with a history of either asymptomatic or mild SARS-CoV-2 infection 6 to 14Â months earlier. Among the 210 participants in the study, 169 were unvaccinated while 41 received 2 doses of mRNA-based COVID-19 vaccines. Vaccination of previously infected participants strongly boosted neutralizing and binding activity and memory B and TÂ cell responses including the recognition of Omicron, compared to infected but unvaccinated participants. Additionally, no measurable differences were observed in immune memory in healthy young adults with previous symptomatic or asymptomatic infections, for ancestral or variant strains. These results

provide mechanistic immunological insights into population-based differences observed in immunity against Omicron and other variants among individuals with different clinical histories.

Ipsilateral Radial Neuropathy after COVID-19 mRNA Vaccination in an Immunocompetent Young Man. The global coronavirus disease 2019 (COVID-19) pandemic spurred an urgent need for vaccination and herd immunity. Recently, mRNA vaccines for COVID-19 have been used widely despite reports of several adverse events. Most adverse effects are mild, although a few are associated with neurological complications. Unfortunately, there is a scarcity of information on peripheral nerve complications after COVID-19 mRNA vaccination. We report the case of an immunocompetent young male patient who suffered from ipsilateral wrist drop with multiple lymphadenopathy in the cervical and axillary region after Pfizer-BioNTech vaccination. He experienced unilateral wrist drop, which significantly improved with corticosteroid treatment. Based on knowledge of this adverse effect, careful surveillance and increased awareness are needed for early diagnosis. To the best of our knowledge, this is the first reported case in the English literature of radial neuropathy resulting in wrist drop in a recently vaccinated and young immunocompetent patient.

Bilateral Ischemic Optic Neuropathy From Giant Cell Arteritis Following COVID-19 Vaccination.

Coronavirus disease 2019 vaccination-related pericarditis: a single tertiary-center experience. AIMS: Vaccination represents a cornerstone of prevention in the COVID-19 pandemic. Rare adverse events including acute pericarditis and myopericarditis have been reported. METHODS: All consecutive patients referred to our referral center for pericardial diseases following COVID-19 vaccination from 1 April 2021 to 15 April 2022 were included. Acute pericarditis and myopericarditis were diagnosed according to ESC guidelines. Patients with SARS-CoV-2 infection were excluded from the study. RESULTS: Twenty-four patients (79% men) aged 39.7â€ŠÂ±â€Š19.8â€Šyears were referred to our center with pericarditis after receiving COVID-19 vaccination. Thirteen (54%) patients were diagnosed with myopericarditis. The mean time between vaccination and symptoms onset was 7.0â€ŠÂ±â€Š4.9â€Šdays, and the most frequent symptom was pericarditic chest pain (83%). Respectively, 50 and 33% of patients presented after the second and the third dose of the vaccine. Almost all patients were treated with both nonsteroidal anti-inflammatory drugs and colchicine. Five patients (21%) experienced a recurrence of pericarditis. No patient died or developed constrictive pericarditis. Mean follow-up was 8.0â€ŠÂ±â€Š3.2â€Šmonths. CONCLUSION: COVID-19 vaccine-related pericarditis typically manifest with mild clinical signs, in young male individuals, a few days after the second or third vaccine dose and are commonly characterized by a rapid complete recovery.

Hybrid and vaccine-induced immunity against SAR-CoV-2 in MS patients on different disease-modifying therapies. OBJECTIVE: To compare "hybrid immunity" (prior COVID-19 infection plus vaccination) and post-vaccination immunity to SARS CoV-2 in MS patients on different disease-modifying therapies (DMTs) and to assess the impact of vaccine product and race/ethnicity on post-vaccination immune responses. METHODS: Consecutive MS patients from NYU MS Care Center (New York, NY), aged 18-60, who completed primary COVID-19 vaccination series â‰¥6â€‰weeks previously were evaluated for SARS CoV-2-specific antibody responses with electro-chemiluminescence and multiepitope bead-based immunoassays and, in a subset, live virus immunofluorescence-based microneutralization assay. SARS CoV-2-specific cellular responses were assessed with cellular stimulation TruCulture IFNÎ³ and IL-2 assay and, in a subset, with IFNÎ³ and IL-2 ELISpot assays. Multivariate analyses examined associations between immunologic responses and prior COVID-19 infection while controlling for age, sex, DMT at vaccination, time-to-vaccine, and vaccine product. RESULTS: Between 6/01/2021 and 11/11/2021, 370 MS patients were recruited (mean age 40.6â€‰years; 76% female; 53% non-White; 22% with prior infection; common DMT classes: ocrelizumab 40%; natalizumab 15%, sphingosine-1-phosphate receptor modulators 13%; and no DMT 8%). Vaccine-to-collection time was 18.7 (Â±7.7) weeks and 95% of patients received mRNA

vaccines. In multivariate analyses, patients with laboratory-confirmed prior COVID-19 infection had significantly increased antibody and cellular post-vaccination responses compared to those without prior infection. Vaccine product and DMT class were independent predictors of antibody and cellular responses, while race/ethnicity was not. INTERPRETATION: Prior COVID-19 infection is associated with enhanced antibody and cellular post-vaccine responses independent of DMT class and vaccine type. There were no differences in immune responses across race/ethnic groups.

Is Myasthenia Gravis a Real Complication of the COVID-19 Vaccine? A Case Report-Based Systematic Review. BACKGROUND: Myasthenia gravis (MG) is a neuromuscular, autoimmune disease that causes weakness by impairing neuromuscular transmission. According to reports, vaccines can lead to autoimmunity in different ways, and COVID-19 vaccines are suggested to trigger MG. We conducted this systematic review to assess MG patients after the COVID-19 vaccination. METHODS: We collected 231 studies from four databases from inception to 26 March 2022. RESULTS: 4 case studies were selected from 231 research studies, and data were extracted based on inclusion criteria. In all cases, MG was reported following COVID-19 vaccination. Symptoms such as muscle weakness, numbness, and ptosis were common. The MG was confirmed through RNST, MRC, NCS, and AchR-binding antibody titer tests. CONCLUSION: Although all cases of MG were diagnosed following appropriate tests, the sample size was small; therefore, further investigation is required to demonstrate the possible association between MG and COVID-19 vaccination.

New-Onset Lichen Planus Induced by the Pfizer COVID-19 Vaccine. OBJECTIVE: Coronavirus disease 2019 (COVID-19) vaccine distribution continues to expand; however, increased cutaneous reactions have been reported. Several recent studies suggest a link between COVID-19 vaccination and the development of various cutaneous complications. Lichen planus is a chronic, immune-mediated, inflammatory dermatological illness with an unclear etiology. In this case report, we assessed the relationship between COVID-19 vaccination (Pfizer) and lichen planus diagnosis and evaluated the link between additional doses of the vaccine and disease progression. METHODS: Complete clinical, laboratory, and histopathological assessment of a patient was performed with ethical and privacy considerations. Written informed consent for all clinical data, images, and publication was obtained from the patient. RESULTS: New-onset lichen planus appeared 48 hours after the first dose of the Pfizer vaccine. The symptoms worsened following the second dose. The patient responded gradually to topical corticosteroids, and lichen planus was controlled within 21 days. CONCLUSION: Our case significantly contributes to the literature by highlighting that additional doses of the Pfizer vaccine can contribute to disease progression. Therefore, reporting the patient's condition associated with COVID-19 vaccination should be considered. Future studies should be performed to investigate the combined onset of lichen planus and multisystem COVID-19 vaccine-related complications.

Uptake and Equity in Influenza Vaccination Among Veterans with VA Coverage, Veterans Without VA Coverage, and Non-Veterans in the USA, 2019-2020. BACKGROUND: Vaccination is a primary method of reducing the burden of influenza, yet uptake is neither optimal nor equitable. Single-tier, primary care-oriented health systems may have an advantage in the efficiency and equity of vaccination. OBJECTIVE: To assess the association of Veterans' Health Administration (VA) coverage with influenza vaccine uptake and disparities. DESIGN: Cross-sectional. PARTICIPANTS: Adult respondents to the 2019-2020 National Health Interview Survey. MAIN MEASURES: We examined influenza vaccination rates, and racial/ethnic and income-based vaccination disparities, among veterans with VA coverage, veterans without VA coverage, and adult non-veterans. We performed multivariable logistic regressions adjusted for demographics and self-reported health, with interaction terms to examine differential effects by race/ethnicity and income. KEY RESULTS: Our sample included n=2,277 veterans with VA coverage, n=2,821 veterans without VA coverage, and

n=46,456 non-veterans. Veterans were more often White and male; among veterans, those with VA coverage had worse health and lower incomes. Veterans with VA coverage had a higher unadjusted vaccination rate (63.0%) than veterans without VA coverage (59.1%) and non-veterans (46.5%) ($p<0.05$ for each comparison). In our adjusted model, non-veterans were 11.4 percentage points (95% CI -14.3, -8.5) less likely than veterans with VA coverage to be vaccinated, and veterans without VA coverage were 6.7 percentage points (95% CI -10.3, -3.0) less likely to be vaccinated than those with VA coverage. VA coverage, compared with non-veteran status, was also associated with reduced racial/ethnic and income disparities in vaccination. CONCLUSIONS: VA coverage is associated with higher and more equitable influenza vaccination rates. A single-tier health system that emphasizes primary care may improve the uptake and equity of vaccination for influenza, and possibly other pathogens, like SARS-CoV2.

Significance of PPD Test for the Relationship Between BCG Vaccine and COVID-19 in Patients on Kidney Transplant Waiting List. BACKGROUND: The aim of this study was to determine the relationship between purified protein derivative of tuberculin (PPD) values, an indicator of BCG protection, and COVID-19 disease in patients with end-stage renal disease (ESRD) on the kidney transplant waiting list. METHODS: Age, sex, dialysis type, ERSD etiologies, and PPD values of patients on the renal transplant waiting list were recorded. SARS-CoV-2 PCR data, whether the patients were previously infected with the virus, and, if infected, the severity of the disease were noted. Data were statistically compared. RESULTS: PCR of 87 (47.02%) of 185 patients were studied; 107 of the patients were male and 78 were female, with a mean age of 52.8 years. The test result was positive for 28 patients. Of the patients for whom PCR was studied, 41 had a negative PPD result, while 46 had a positive PPD result. There was no correlation with SARS-CoV-2 PCR positivity in patients with a PPD â‰¤ 5 mm and > 5 mm. However, patients with pneumonic infiltration who required hospitalization had a significantly higher PPD value. CONCLUSIONS: The PPD measurement, which is an indicator of BCG protection, might be a significant parameter for predicting the course of the disease in SARS-CoV-2 pneumonia.

A case report of unilateral cervical lymphadenopathy and multiple cranial neuropathies following mRNA-COVID-19 vaccination. BACKGROUND: We report a rare case of ipsilateral multiple cranial neuropathy and ipsilateral lymphadenopathy following mRNA-COVID-19 vaccination. CASE PRESENTATION: A 41-year-old male visited our emergency room complaining of dysphagia and hoarseness that started a week after receiving COVID19 mRNA vaccination (in his right arm). During his hospitalization, he also complained of right side hearing loss and diplopia. Neurological examination depicted a right IV nerve palsy, ipsilateral facial paresthesia and peripheral facial paresis. Otorinolaryngological examination revealed right vocal cord paralysis. A brain magnetic resonance imaging showed enhancement of the right VII and VIII cranial nerves in the auditory canal. The lumbar puncture revealed increased protein concentration and lymphocytic pleocytosis in the cerebrospinal fluid (CSF). Additionally, a neck computed tomography (CT) scan showed a swollen right supraclavicular lymph node. We hypothesize that the ipsilateral cranial neuropathies of IV, VI, VII, VIII and X, associated with cervical lymphadenopathy, was possible caused by a post-vaccination immune-mediated reaction. The patient was treated with a 5-day course of intravenous methylprednisolone (1000Â mg/day), and a gradual improvement was observed. CONCLUSIONS: Similarly, to other vaccines, it is possibly that also mRNA vaccines may act as triggers of non-specific autoimmune neurological syndromes.

A systemic review and recommendation for an autopsy approach to death followed the COVID 19 vaccination. The outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) started in December 2019. An immediate prevention approach for the outbreak is the development of a vaccination program. Despite a growing number of publications showing the effectiveness of

vaccination in preventing SARS-CoV-2 outbreak and reducing the mortality rate, substantial fatal adverse effects were reported after vaccination. Confirmation of the causal relationship of death is required to reimburse under the national vaccination program and could provide a reference for the selection of vaccination. However, a lack of guidelines in the laboratory study and autopsy approach hampered the investigation of post-vaccination death. In this paper, we performed a systematic electronic search on scientific articles related to severe Covid-19 vaccination adverse effects and approaches in identifying the severe side effects using PubMed and Cochrane libraries. A summary on the onset, biochemistry changes and histopathological analyzes of major lethally side effects post-vaccination were discussed. Ultimately, a checklist is suggested to improve the quality of investigation.

Leukocytoclastic vasculitis and COVID-19 vaccination.

Seroconversion rate after COVID-19 vaccination in patients with solid cancer: A systematic review and meta-analysis. Patients with solid cancer have an increased risk of severe coronavirus disease 2019 (COVID-19) and associated mortality than the general population. This meta-analysis aimed to investigate the currently available evidence about the efficacy of COVID-19 vaccines in patients with solid cancer. We included prospective studies comparing the immunogenicity and efficacy of COVID-19 vaccines between patients with solid cancer and healthy individuals. Relative risks of seroconversion after the first and second dose of a COVID-19 vaccine were separately pooled with the use of random effects meta-analysis. Thirty studies with 11,245 subjects met the inclusion criteria. After first vaccine dose, the pooled RR of seroconversion in patients with solid cancer vs healthy individuals was 0.54 (95% CI 0.38-0.78, I(2)â€‰=â€‰94%). After a second dose, the pooled RR of seroconversion in patients with solid cancer vs healthy controls was 0.87 (0.86-0.88, I(2)â€‰=â€‰87%). Our review suggests that, compared with healthy individuals, COVID-19 vaccines show favorable immunogenicity and efficacy in patients with solid cancer. A second dose is associated with significantly improved seroconversion, although it is slightly lower in patients with solid cancer compared with healthy individuals.

COVID-19 vaccine-associated myocarditis. Myocarditis is now recognized as a rare complication of coronavirus disease 2019 (COVID-19) mRNA vaccination, particularly in adolescent and young adult males. Since the authorization of the Pfizer-BioNTechâ„¢ and Modernaâ„¢ mRNA vaccines targeting the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) spike protein, the Centers for Disease Control and Prevention (CDC) has reported 1175 confirmed cases of myocarditis after COVID-19 vaccination in individuals ages 30 years and younger as of January 2022. According to CDC data in June 2021, the incidence of vaccine-mediated myocarditis in males ages 12-29 years old was estimated to be 40.6 cases per million second doses of COVID-19 mRNA vaccination administered. Individuals with cases of COVID-19 vaccine-mediated myocarditis typically present with acute chest pain and elevated serum troponin levels, often within one week of receiving the second dose of mRNA COVID-19 vaccination. Most cases follow a benign clinical course with prompt resolution of symptoms. Proposed mechanisms of COVID-19 vaccine myocarditis include molecular mimicry between SARS-CoV-2 spike protein and self-antigens and the triggering of preexisting dysregulated immune pathways in predisposed individuals. The higher incidence of COVID-19 vaccine myocarditis in young males may be explained by testosterone and its role in modulating the immune response in myocarditis. There is limited data on long-term outcomes in these cases given the recency of their occurrence. The CDC continues to recommend COVID-19 vaccination for everyone 5 years of age and older given the greater risk of serious complications related to natural COVID-19 infection including hospitalization, multisystem organ dysfunction, and death. Further study is needed to better understand the immunopathology and long-term outcomes behind COVID-19 mRNA vaccine-mediated myocarditis.

Septic arthritis of shoulder joint following a COVID-19 vaccination: A case report.
INTRODUCTION: Septic arthritis of the shoulder joint is a serious condition which requires early diagnosis and treatment. This condition usually presents with shoulder pain, limited range of motion and/or fever, and is diagnosed by shoulder arthrocentesis with significant synovial fluid leukocytosis or positive synovial fluid gram stain or culture. There are some risk factors for septic arthritis, notably bacteremia, pre-existing joint pathology and an immunocompromised host such as poorly controlled type II diabetes mellitus. CASE PRESENTATION: A 45-year-old Thai female developed left shoulder septic arthritis after an Astra-Zeneca COVID-19 vaccine administration. The clinical symptoms were left shoulder pain, limited range of motion and fever. The probable risk factors were underlying diabetes mellitus type II and vaccine administration technique. The joint fluid culture showed Staphylococcus aureus. This patient was treated with combined arthroscopic debridement and an intravenous antibiotic for 1Â week which was then switched to an oral antibiotic for 5Â weeks. Her clinical symptoms gradually improved over the 2Â weeks following the initiation of treatment. CONCLUSION: Septic arthritis is a rare complication after a vaccination. Doctors should be especially careful with immunocompromised patients, and always use a correct injection technique.

Presumably Corneal Graft Rejection after COVID-19 Vaccination. We report two cases of corneal graft rejection following immunization with COVID-19-inactivated vaccine Sinopharm and describe the practical implications of this phenomenon in the clinical setting. A 36-year-old woman with a history of unilateral repeated PKP received the first dose of inactivated Sinopharm vaccine. Seven days later, she presented with symptoms and signs of unilateral corneal graft rejection on slit-lamp examination. A 54-year-old woman with a history of unilateral PKP secondary to herpes simplex keratitis (HSK) developed signs of unilateral corneal graft rejection just a week after injection of the first dose of the similar vaccine. Rejection in both patients was treated successfully with topical steroids. To the best of our knowledge, this is the first report of corneal graft rejection following the COVID-19-inactivated Sinopharm vaccine which occurred through the short period after the injection. We hypothesized that the rejection is the result of an allogenic reaction and the immunogenic role of aluminum hydroxide as an adjuvant of this type of vaccine. However, as the second case had a history of rejection following the HSK, a reactivation could not be definitely ruled out. Ophthalmologists should consider these types of adverse reactions after COVID-19 immunization and also monitor a close follow-up of graft health postimmunization. Patients should be informed about the signs and symptoms of rejection, urgent referral, and treatment.

Bilateral Optic Neuritis after COVID-19 mRNA Vaccination. We report the case of a healthy man who was diagnosed with bilateral optic neuritis after COVID-19 vaccination. A 63-year-old man presented with acute painful blurred vision in his left eye and temporal pain. Eleven days before the appearance of his symptoms, he received the first dose of COVID-19 mRNA vaccination. On examination, his best corrected visual acuity was 20/20 in his right eye and counting fingers in the left eye. Funduscopic examination showed bilateral optic disc swelling, and postcontrast magnetic resonance imaging showed left optic nerve sheath enhancement, consistent with left optic perineuritis and right optic papillitis. After steroid pulse therapy, his visual function and headache showed significant improvement. A few cases of optic neuritis as a side effect of COVID-19 mRNA vaccination were reported. This report provides important information about side effects assumed to be related to the COVID-19 mRNA vaccine.

Multiple Evanescent White Dot Syndrome Developing Three Days following Administration of mRNA-1273 Booster Vaccine: Case Report. Little is known about the potential ocular adverse events following mRNA-1273 vaccine. We aimed to report a case of multiple evanescent white dot syndrome (MEWDS) developing 3 days following the administration of mRNA-1273 vaccine booster. A 71-year-old white myopic female presented with complaints of seeing "pulsating light" and scotoma with her

left eye that started about 3 days following mRNA-1273 vaccine booster administration. The patient was found to have multiple scattered white-yellow outer retinal lesions on dilated fundus exam of the left eye. Visual symptoms and exam findings continued to improve without any intervention confirming a short-lived and self-limiting disease course. Clinical presentation was consistent with a clinical diagnosis of MEWDS. Ophthalmologists need to take detailed vaccination history in patients presenting with MEWDS.

Factors associated with neutralizing antibody levels induced by two inactivated COVID-19 vaccines for 12 months after primary series vaccination. BACKGROUND: BBIBP-CorV and CoronaVac inactivated COVID-19 vaccines are widely-used, World Health Organization-emergency-listed vaccines. Understanding antibody level changes over time after vaccination is important for booster dose policies. We evaluated neutralizing antibody (nAb) titers and associated factors for the first 12 months after primary-series vaccination with BBIBP-CorV and CoronaVac. METHODS: Our study consisted of a set of cross-sectional sero-surveys in Zhejiang and Shanxi provinces, China. In 2021, we enrolled 1,527 consenting 18-59-year-olds who received two doses of BBIBP-CorV or CoronaVac 1, 3, 6, 9, or 12 months earlier and obtained blood samples and demographic and medical data. We obtained 6-month convalescent sera from 62 individuals in Hebei province. Serum nAb titers were measured by standard micro-neutralization cytopathic effect assay in Vero cells with ancestral SARS-CoV-2 strain HB01. We used the first WHO International Standard (IS) for anti-SARS-CoV-2 immunoglobulin (NIBSC code 20/136) to standardized geometric mean concentrations (IU/mL) derived from the nAb geometric mean titers (GMT over 1:4 was considered seropositive). We analyzed nAb titer trends using Chi-square and factors related to nAb titers with logistic regression and linear models. RESULTS: Numbers of subjects in each of the five month-groupings ranged from 100 to 200 for each vaccine and met group-specific target sample sizes. Seropositivity rates from BBIBP-CorV were 98.0% at 1 month and 53.5% at 12 months, and GMTs were 25.0 and 4.0. Respective seropositivity rates from CoronaVac were 90.0% and 62.5%, and GMTs were 20.2 and 4.1. One-, three-, six-, nine-, and twelve-month GMCs were 217.2, 84.1, 85.7, 44.6, and 10.9 IU/mL in BBIBP-CorV recipients and 195.7, 94.6, 51.7, 27.6, and 13.4 IU/mL in CoronaVac recipients. Six-month convalescent seropositivity was 95.2%; GMC was 108.9 IU/mL. Seropositivity and GMCs were associated with age, sex, and time since vaccination. CONCLUSIONS: Neutralizing Ab levels against ancestral SARS-CoV-2 from BBIBP-CorV or CoronaVac vaccination were similar and decreased with increasing time since vaccination; over half of 12-month post-vaccination subjects were seropositive. Seropositivity and GMCs from BBIBP-CorV and CoronaVac six and nine months after vaccination were similar to or slightly lower than in six-month convalescent sera. These real-world data suggest necessity of six-month booster doses.

Breakthrough infections with the omicron and delta variants of SARS-CoV-2 result in similar re-activation of vaccine-induced immunity. BACKGROUND: Results showing that sera from double vaccinated individuals have minimal neutralizing activity against Omicron have been interpreted as indicating the need for a third vaccine dose for protection. However, there is little information about early immune responses to Omicron infection in double vaccinated individuals. METHODS: We measured inflammatory mediators, antibodies to the SARS-CoV-2 spike and nucleocapsid proteins, and spike peptide-induced release of interferon gamma in whole blood in 51 double-vaccinated individuals infected with Omicron, in 14 infected with Delta, and in 18 healthy controls. The median time points for the first and second samples were 7 and 14 days after symptom onset, respectively. FINDINGS: Infection with Omicron or Delta led to a rapid and similar increase in antibodies to the receptor-binding domain (RBD) of Omicron protein and spike peptide-induced interferon gamma in whole blood. Both the Omicron- and the Delta-infected patients had a mild and transient increase in inflammatory parameters. INTERPRETATION: The results suggest that two vaccine doses are sufficient

to mount a rapid and potent immune response upon infection in healthy individuals of with the Omicron variant. FUNDING: The study was funded by the Oslo University Hospital, and by grants from The Coalition for Epidemic Preparedness Innovations, Research Council of Norway (no 312780, 324272), South-Eastern Norway Regional Health Authority (no 2019067, 2021071, 10357, 2021047, 33612, 2021087, 2017092), EU Horizon 2020 grant no 848099, a philantropic donation from Vivaldi Invest A/S, and The European Virus Archive Global.

Delayed inflammatory response evoked in nasal alloplastic implants after COVID-19 vaccination: A case report. BACKGROUND: Delayed inflammatory reactions (DIRs) in alloplast rhinoplasty are a rare complication that may occur several months to years after surgery. The exact causes and mechanisms are unclear, but several triggering factors, including infections, trauma, dental procedures, and vaccination, have been reported. CASE SUMMARY: A 39-year-old male patient who had undergone augmentation rhinoplasty 8 years ago had DIRs after the administration of the first dose of the mRNA Pfizer coronavirus disease 2019 (COVID-19) vaccine. He suddenly had tender, erythematous swelling on his face 6 d after vaccination. As there was no improvement in the patient's condition after the conservative treatment, surgical removal of an alloplastic nasal implant was performed. Immediately after the surgery, the DIRs and accompanying symptoms ameliorated rapidly. A histological study conducted during surgery was fibrosis and small fragments of the hyaline cartilage. CONCLUSION: The correlation between DIRs and COVID-19 vaccination has not been reported yet and the exact mechanism is unclear. Because the uncontrolled inflammatory reactions on the nose leave serious sequelae, surgeons should be conscious of the correlation between COVID-19 vaccines and DIRs associated with nasal alloplastic implants. And further histological or microbiological studies should be performed to determine the cause of DIRs.

Rapid progressive vaccine-induced immune thrombotic thrombocytopenia with cerebral venous thrombosis after ChAdOx1 nCoV-19 (AZD1222) vaccination: A case report. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare and potentially life-threatening condition after receiving coronavirus disease vaccines. It is characterized by symptom onset at 5 to 30 d postvaccination, thrombocytopenia, thrombosis, high D-dimer level, and antiplatelet factor 4 (anti-PF4) antibody positivity. VITT can progress very fast, requiring urgent management. Only few studies have described its detailed clinical course and imaging changes. We report a typical VITT case in a patient who underwent regular repeated brain imaging examinations. CASE SUMMARY: A young woman presented with headaches at 7 d after the ChAdOx1 nCoV-19 vaccine (AZD1222) injection. She then showed progressive symptoms of left upper limb clumsiness. Brain computed tomography revealed venous infarction at the right parietal lobe with a hyperacute thrombus in the cortical vein. Two hours later, brain magnetic resonance imaging revealed hemorrhage at the same area. Magnetic resonance venography showed an irregular contour of the right transverse sinus. Laboratory examination revealed a high D-dimer level, thrombocytopenia, and a high titer for anti-PF4 antibodies. She was treated with anticoagulants, intravenous immunoglobulin, and steroids and analgesic agents were administered for pain control. She had a marked improvement on headaches and clumsiness after treatment along with radiological thrombus resolution. During follow-up at the outpatient department, her modified Rankin scale at 90 d was 1. CONCLUSION: Clinicians should be alerted whenever patients present with persistent and progressive headaches or focal motor/sensory deficits postvaccination.

Seroprevalence of SARS-CoV-2 infection in the Tyrolean district of Schwaz at the time of the rapid mass vaccination in March 2021 following B.1.351-variant outbreak. In order to curb the rapid dissemination of the B.1.351 variant of SARS-CoV-2 in the district of Schwaz and beyond, the EU allocated additional vaccine doses at the beginning of March 2021 to implement a rapid mass vaccination of the population (16+). The aim of our study was to determine the seroprevalence of

SARS-CoV-2 among the adult population in the district of Schwaz at the time of the implementation. Data on previous history of infections, symptoms and immunization status were collected using a structured questionnaire. Blood samples were used to determine SARS-CoV-2 specific anti-spike, anti-nucleocapsid and neutralizing antibodies. We recruited 2,474 individuals with a median age (IQR) of 42 (31-54) years. Using the official data on distribution of age and sex, we found a standardized prevalence of undocumented infections at 15.0% (95% CI: 13.2-16.7). Taken together with the officially documented infections, we estimated that 24.0% (95% CI: 22.5-25.6) of the adult population had prior SARS-CoV-2 infection. Hence, the proportion of undocumented infections identified by our study was 55.8% (95% CI: 52.7-58.5). With a vaccination coverage of 10% among the adults population at that time, we imply that a minimum of two-thirds of the target popuation was susceptible to the circulating threat when this unique campaign started.

Case report: Myocarditis following COVID-19 protein subunit vaccination. We report findings in a 34-year-old female patient who presented with fulminant myocarditis 8 days after receiving the first dose of the ZF2001 RBD-subunit vaccine against coronavirus disease 2019 (COVID-19). Autopsy showed severe interstitial myocarditis, including multiple patchy infiltrations of lymphocytes and monocytes in the myocardium of the left and right ventricular walls associated with myocyte degeneration and necrosis. This report highlights the details of clinical presentations and autopsy findings of myocarditis after ZF2001 (RBD-subunit vaccine) vaccination. The correlation between vaccination and death due to myocarditis is discussed.

Ear, nose, and throat manifestations of COVID-19 and its vaccines. Coronavirus disease 2019 (COVID-19) is a highly infectious disease and was designated a pandemic by the World Health Organization (WHO) on March 11, 2020. There are no classical manifestations of the disease. The most prevalent symptoms include fever, cough, dyspnea, myalgia and headache. The main route of transmission of the severe acute respiratory syndrome coronavirus-2 is through the upper respiratory tract. Therefore, it is not strange to find different ear, nose and throat (ENT) symptoms in individuals infected with this virus. Olfactory dysfunction is a common feature of COVID-19; either it is the only presenting symptom or it accompanies other manifestations of the disease. Other otolaryngological features such as sudden sensorineural hearing loss (SSNHL), dysphonia, nasal obstruction, sore throat, etc. are less frequent manifestations of COVID-19. These features, in addition, to being presented early in the disease process, certain long-standing symptoms like parosmia, dysphonia, and persistent deafness, are other characteristics of the disease. Geographical variation in otorhinolaryngological prevalence is another problem with this debilitating disease. Local and systemic adverse effects (local site injection pain, fever, myalgia, headache, and others) of the COVID-19 vaccines are more frequent than otolaryngological side effects (anosmia, hyposmia, Bell's palsy, SSNHL, etc.). We aimed in this review to summarize the early and persistent ENT symptoms of COVID-19 or after the various COVID-19 vaccines.

COVID-19 vaccination and inflammatory skin diseases.

Incidence of Severe COVID-19 Illness Following Vaccination and Booster With BNT162b2, mRNA-1273, and Ad26.COV2.S Vaccines. IMPORTANCE: Evidence describing the incidence of severe COVID-19 illness following vaccination and booster with BNT162b2, mRNA-1273, and Ad26.COV2.S vaccines is needed, particularly for high-risk populations. OBJECTIVE: To describe the incidence of severe COVID-19 illness among a cohort that received vaccination plus a booster vaccine dose. DESIGN, SETTING, AND PARTICIPANTS: Retrospective cohort study of adults receiving care at Veterans Health Administration facilities across the US who received a vaccination series plus 1 booster against SARS-CoV-2, conducted from July 1, 2021, to May 30, 2022. Patients were eligible if they had received a primary care visit in the prior 2 years and had documented receipt of all US Food and Drug Administration-authorized doses of the initial mRNA vaccine or viral vector vaccination series after

December 11, 2020, and a subsequent documented booster dose between July 1, 2021, and April 29, 2022. The analytic cohort consisted of 1â€¯610â€¯719 participants. EXPOSURES: Receipt of any combination of mRNA-1273 (Moderna), BNT162b2 (Pfizer-BioNTech), and Ad26.COV2.S (Janssen/Johnson & Johnson) primary vaccination series and a booster dose. MAIN OUTCOMES AND MEASURES: Outcomes were breakthrough COVID-19 (symptomatic infection), hospitalization with COVID-19 pneumonia and/or death, and hospitalization with severe COVID-19 pneumonia and/or death. A subgroup analysis of nonoverlapping populations included those aged 65 years or older, those with high-risk comorbid conditions, and those with immunocompromising conditions. RESULTS: Of 1â€¯610â€¯719 participants, 1â€¯100â€¯280 (68.4%) were aged 65 years or older and 132â€¯243 (8.2%) were female; 1â€¯133â€¯785 (70.4%) had high-risk comorbid conditions, 155â€¯995 (9.6%) had immunocompromising conditions, and 1â€¯467â€¯879 (91.1%) received the same type of mRNA vaccine (initial series and booster). Over 24 weeks, 125.0 (95% CI, 123.3-126.8) per 10â€¯000 persons had breakthrough COVID-19, 8.9 (95% CI, 8.5-9.4) per 10â€¯000 persons were hospitalized with COVID-19 pneumonia or died, and 3.4 (95% CI, 3.1-3.7) per 10â€¯000 persons were hospitalized with severe pneumonia or died. For high-risk populations, incidence of hospitalization with COVID-19 pneumonia or death was as follows: aged 65 years or older, 1.9 (95% CI, 1.4-2.6) per 10â€¯000 persons; high-risk comorbid conditions, 6.7 (95% CI, 6.2-7.2) per 10â€¯000 persons; and immunocompromising conditions, 39.6 (95% CI, 36.6-42.9) per 10â€¯000 persons. Subgroup analyses of patients hospitalized with COVID-19 pneumonia or death by time after booster demonstrated similar incidence estimates among those aged 65 years or older and with high-risk comorbid conditions but not among those with immunocompromising conditions. CONCLUSIONS AND RELEVANCE: In a US cohort of patients receiving care at Veterans Health Administration facilities during a period of Delta and Omicron variant predominance, there was a low incidence of hospitalization with COVID-19 pneumonia or death following vaccination and booster with any of BNT162b2, mRNA-1273, or Ad26.COV2.S vaccines.

HLA-DR4 and DRB4 and COVID-19 vaccination-related ANCA-associated vasculitis: Correspondence.

Relapse or worsening of chronic spontaneous urticaria during SARS-CoV-2 infection and vaccination in children: A telemedicine follow-up. BACKGROUND: Chronic urticaria (CU), characterized by daily wheals and/or angioedema lasting more than 6 weeks, is a common skin disease. CU is classified as spontaneous or inducible. Because of Coronavirus Disease-19 (COVID-19) pandemic, face-to-face visits were reduced, and many centers started remote consultations to minimize hospital admissions and risk for viral diffusion. Telemedicine became a valuable tool for evaluating and monitoring patients with chronic diseases, such as CU. This study aims to evaluate the effectiveness of telemedicine as a means for the follow-up of patients with chronic spontaneous urticaria (CSU) during the COVID-19 pandemic. In particular, we collected data related to CSU evolution and treatment by remote consultation. Moreover, we specifically investigated the impact of SARS-CoV-2 infection or vaccination on CSU in relapsing or worsening of such a disease. METHODS: The electronic charts were reviewed for patients diagnosed with CSU, who were referred to the allergy unit of Meyer Children's Hospital, Florence. For each patient, a review of demographic characteristics, diagnostic workup, efficacy, and tolerability of the treatment was performed. Patients with a physical agent triggering CU were excluded from the study. Disease activity was monitored using the Urticaria Activity Score (UAS7). In addition, when the COVID-19 pandemic started, follow-up continued through telemedicine after an initial face-to-face visit when possible. Approximately 1 year after the diagnosis of CSU, patients were recontacted to investigate whether they had experienced a relapse or worsening of urticaria during a possible COVID-19 or immediately after receiving a COVID-19 vaccine. RESULTS: From January 2020 to March 2021, 84 cases of CSU were identified, with 71 (84.5%) of these being evaluated via televisit (remote consultation). During the remote follow-up period, 38/71 (53.5%)

patients who were evaluated via televisit recovered completely from CSU, while 24 (33.8%) made therapy adjustments, and 9 (12.7%) had to discontinue follow-up through remote visits and return to face-to-face visits. In February 2022, we recontacted the 71 patients with CSU, and 50 (70.4%) of them answered by phone call interview. Four (19.2%) of the 26 patients who had COVID-19 showed CSU relapse, while 1 (3.8%) had a CSU worsening. Instead, 1 (3.8%) patient of the 26 who were vaccinated had a relapse of CSU, and 1 (3.8%) had a worsening of CSU, both after the first dose. CONCLUSION: Our data showed that telemedicine can be an effective tool for the follow-up of patients with CSU. Moreover, COVID-19, as well as COVID-19 vaccination, may trigger CSU relapse or worsening, but both are unspecific triggers, and urticaria shows a very short duration in most cases.

Association of Primary and Booster Vaccination and Prior Infection With SARS-CoV-2 Infection and Severe COVID-19 Outcomes. IMPORTANCE: Data about the association of COVID-19 vaccination and prior SARS-CoV-2 infection with risk of SARS-CoV-2 infection and severe COVID-19 outcomes may guide prevention strategies. OBJECTIVE: To estimate the time-varying association of primary and booster COVID-19 vaccination and prior SARS-CoV-2 infection with subsequent SARS-CoV-2 infection, hospitalization, and death. DESIGN, SETTING, AND PARTICIPANTS: Cohort study of 10.6 million residents in North Carolina from March 2, 2020, through June 3, 2022. EXPOSURES: COVID-19 primary vaccine series and boosters and prior SARS-CoV-2 infection. MAIN OUTCOMES AND MEASURES: Rate ratio (RR) of SARS-CoV-2 infection and hazard ratio (HR) of COVID-19-related hospitalization and death. RESULTS: The median age among the 10.6 million participants was 39 years; 51.3% were female, 71.5% were White, and 9.9% were Hispanic. As of June 3, 2022, 67% of participants had been vaccinated. There were 2â€¯771â€¯364 SARS-CoV-2 infections, with a hospitalization rate of 6.3% and mortality rate of 1.4%. The adjusted RR of the primary vaccine series compared with being unvaccinated against infection became 0.53 (95% CI, 0.52-0.53) for BNT162b2, 0.52 (95% CI, 0.51-0.53) for mRNA-1273, and 0.51 (95% CI, 0.50-0.53) for Ad26.COV2.S 10 months after the first dose, but the adjusted HR for hospitalization remained at 0.29 (95% CI, 0.24-0.35) for BNT162b2, 0.27 (95% CI, 0.23-0.32) for mRNA-1273, and 0.35 (95% CI, 0.29-0.42) for Ad26.COV2.S and the adjusted HR of death remained at 0.23 (95% CI, 0.17-0.29) for BNT162b2, 0.15 (95% CI, 0.11-0.20) for mRNA-1273, and 0.24 (95% CI, 0.19-0.31) for Ad26.COV2.S. For the BNT162b2 primary series, boosting in December 2021 with BNT162b2 had the adjusted RR relative to primary series of 0.39 (95% CI, 0.38-0.40) and boosting with mRNA-1273 had the adjusted RR of 0.32 (95% CI, 0.30-0.34) against infection after 1 month and boosting with BNT162b2 had the adjusted RR of 0.84 (95% CI, 0.82-0.86) and boosting with mRNA-1273 had the adjusted RR of 0.60 (95% CI, 0.57-0.62) after 3 months. Among all participants, the adjusted RR of Omicron infection compared with no prior infection was estimated at 0.23 (95% CI, 0.22-0.24) against infection, and the adjusted HRs were 0.10 (95% CI, 0.07-0.14) against hospitalization and 0.11 (95% CI, 0.08-0.15) against death after 4 months. CONCLUSIONS AND RELEVANCE: Receipt of primary COVID-19 vaccine series compared with being unvaccinated, receipt of boosters compared with primary vaccination, and prior infection compared with no prior infection were all significantly associated with lower risk of SARS-CoV-2 infection (including Omicron) and resulting hospitalization and death. The associated protection waned over time, especially against infection.

Acute-type acquired hemophilia A after COVID-19 mRNA vaccine administration: A new disease entity? Acquired hemophilia A (AHA) is a rare autoimmune bleeding disorder. Various autoimmune diseases, including AHA, have been reported to occur after the administration of mRNA COVID-19 vaccines. However, the characteristics of these AHA cases remain unclear. We report a case in which AHA arose in a young patient after the administration of an mRNA COVID-19 vaccine, but improved rapidly. The patient's factor VIII (FVIII) inhibitor titer spontaneously decreased to less than half of that seen at diagnosis. One week after the initial immunosuppressive therapy, the FVIII

inhibitor had disappeared. Our case suggests that AHA that arises in young patients after COVID-19 vaccination may resolve spontaneously, and the levels of FVIII inhibitors may decrease more rapidly in such cases than in idiopathic AHA. Unlike for immune thrombocytopenic purpura (ITP), no acute type of AHA has been recognized. This case suggests that just as there is an acute type of ITP that develops in children/after vaccination, there may be an acute type of AHA that arises in young patients that receive mRNA COVID-19 vaccines.

[Herpes Zoster Ophthalmicus after Pfizer BNT162b2 and Moderna mRNA-1273 vaccination in two young and immunocompetent patients]. Coronavirus disease 19 (COVID-19) was first observed in Wuhan, China. The disease is caused by a virus (SARS-CoV-2), which spread around the world within a matter of weeks, leading to a large number of deaths. While the health crisis was managed on the ground, the scientific community focused on finding a means to stop it. Vaccine candidates such as the mRNA vaccines (Pfizer BTN162b2 and Moderna mRNA-1273), started to emerge. As these treatments came on the market recently, there is still concern about potential side effects, among them, Herpes Zoster Ophthalmicus (HZO).

Time of Day of Vaccination Does Not Associate With SARS-CoV-2 Antibody Titer Following First Dose of mRNA COVID-19 Vaccine. The immune system exhibits circadian rhythms, and its response to viral infection is influenced by the circadian clock system. Previous studies have reported associations between the time of day of vaccination against COVID-19 and production of anti-SARS-CoV-2 antibody titer. We examined the effect of vaccination time of day on anti-SARS-CoV-2 antibody titer after the first dose of vaccination with the mRNA-1273 (Moderna) COVID-19 vaccine in an adult population. A total of 332 Japanese adults participated in the present study. All participants were not infected with SARS-CoV-2 and had already received the first dose of mRNA-1273 2 to 4 weeks prior to participating in the study. The participants were asked to provide basic demographic characteristics (age, sex, medical history, allergy, medication, and mean sleep duration), the number of days after the first dose of vaccination, and the time of day of vaccination. Blood was collected from the participants, and SARS-CoV-2 antibody titers were measured. Ordinary least square regression was used for assessing the relationship between basic demographic characteristics, number of days after vaccination, time of day of vaccination, and the log(10)-transformed normalized antibody titer. The least square mean of antibody titers was not associated with the vaccination time and sleep durations. The least square means of antibody titers was associated with age; the antibody titers decreased in people aged 50 to 59 years and 60 to 64 years. The present findings demonstrate that the vaccination time with mRNA-1273 was not associated with the SARS-CoV-2 antibody titer in an adult population, suggesting that these results do not support restricting vaccination to a particular time of day. The present findings may be useful in optimizing SARS-CoV-2 vaccination strategies.

Development of donor specific antibodies after SARS-CoV-2 vaccination in kidney and heart transplant recipients. This study examined the development of new or changes in donor specific antibodies (DSA) mean-fluorescence intensity (MFI) after SARS-CoV-2 vaccination in 100 kidney and 50 heart transplant recipients. The study was performed when the Center for Disease Control and Prevention (CDC) recommended two doses of Pfizer/BioNTech [BNT162b2] and Moderna [mRNA-1273 SARS-CoV-2] vaccine or 1 dose Johnson & Johnson/Janssen [Ad26.COV2Â·S] vaccines for full vaccination in transplant recipients. A novel assay bead-based platform for detecting antibodies against 4 domains of the SARS-CoV-2 spike protein to determine vaccine response (SA) and one nucleocapsid protein (NC) to determine prior SARS-CoV-2 infection was utilized. These assays were performed on the multiplex, bead-based platform utilized to assay DSA levels. 61/150 patients (40.7%) had successful vaccination. 18 patients had confirmed SARS-CoV-2 infection based on positive NC assay or previous Covid-19 oropharyngeal swab. 138 patients had no DSA prior to vaccination but 3 heart recipients developed new DSA's. Among 12 patients with known DSA prior to vaccination, 4

developed new DSA's or increased MFI. All 7 patients with new or increased DSA had stable graft function without rejection and had no changes in immunosuppression. All 8 patients with stable post vaccine DSA had stable graft function and immunosuppression was not changed. The presence of DSA before vaccination was associated with subsequent development of increased MFI or new DSA's (pÂ =Â 0.001). There was no association between pre-vaccine DSA and positive vaccine response (NS). There was no association with successful vaccination or prior SARS-CoV-2 infection and DSA changes (NS).

Safety of and antibody response to the BNT162b2 COVID-19 vaccine in adolescents and young adults with underlying disease. BACKGROUND: Data are limited regarding the safety of and antibody response to the BNT162b2 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) messenger ribonucleic acid vaccine in adolescents and young adults with underlying disease. METHODS: This prospective observational study enrolled patients age 12-25 years with chronic underlying disease who received 2 doses of BNT162b2. A 18-item questionnaire was used to assess adverse events within 7 days post-vaccination, and data regarding severe adverse events were collected from electronic medical records. An antibody titer for the receptor-binding domain of the spike protein in SARS-CoV-2 was used to assess antibody response after the second vaccine dose. RESULTS: Study participants were 429 patients (241 [56.2%] age 12-15 years; 188 [43.8%] age 16-25 years). The most common underlying diseases were genetic or chromosomal abnormalities and/or congenital anomalies, followed by endocrine or metabolic diseases; 32% of participants were immunocompromised. Severe adverse events were observed after the second dose in 1 (0.4%) patient age 12-15 years and in 2 (1.1%) patients age 16-25 years; all patients recovered. Seropositivity after the second vaccine dose was 99.0%. The geometric mean antibody titer was higher in patients age 12-15 years versus 16-25 years (1603.3 [1321.8-1944.7] U/mL vs. 949.4 [744.2-1211.0] U/mL). Compared with immunocompetent patients, immunocompromised patients had a lower antibody titer (2106.8 [1917.5-2314.7] U/mL vs. 467.9 [324.4-674.8] U/mL). CONCLUSIONS: Vaccination with BNT162b2 was acceptably safe and immunogenic for adolescents and young adults with underlying disease.

Pharmacovigilance for COVID-19 vaccines: A 1-year experience in France. As of February 2022, more than 130 million Covid vaccine doses had been distributed in France. During the first year of relevant vaccination, 128,766 adverse events (AE) were reported and analysed, as compared to an average of 40,000 per year for all drugs combined in the pre-pandemic years. A weekly monitoring committee was set up. Through enhanced pharmacovigilance, by February 2022, 49 safety signals had been identified nationwide and submitted to the EMA. For example, very few cases of myocarditis and pericarditis were reported. In children, 9 multisystem inflammatory syndromes were reported.

Outcomes at least 90 days since onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study. BACKGROUND: Data on medium-term outcomes in indivduals with myocarditis after mRNA COVID-19 vaccination are scarce. We aimed to assess clinical outcomes and quality of life at least 90 days since onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults. METHODS: In this follow-up surveillance study, we conducted surveys in US individuals aged 12-29 years with myocarditis after mRNA COVID-19 vaccination, for whom a report had been filed to the Vaccine Adverse Event Reporting System between Jan 12 and Nov 5, 2021. A two-component survey was administered, one component to patients (or parents or guardians) and one component to health-care providers, to assess patient outcomes at least 90 days since myocarditis onset. Data collected were recovery status, cardiac testing, and functional status, and EuroQol health-related quality-of-life measures (dichotomised as no problems or any problems), and a weighted quality-of-life measure, ranging from 0 to 1 (full health). The EuroQol results were compared with published results in US populations (aged

18-24 years) from before and early on in the COVID-19 pandemic. FINDINGS: Between Aug 24, 2021, and Jan 12, 2022, we collected data for 519 (62%) of 836 eligible patients who were at least 90 days post-myocarditis onset: 126 patients via patient survey only, 162 patients via health-care provider survey only, and 231 patients via both surveys. Median patient age was 17 years (IQR 15-22); 457 (88%) patients were male and 61 (12%) were female. 320 (81%) of 393 patients with a health-care provider assessment were considered recovered from myocarditis by their health-care provider, although at the last health-care provider follow-up, 104 (26%) of 393 patients were prescribed daily medication related to myocarditis. Of 249 individuals who completed the quality-of-life portion of the patient survey, four (2%) reported problems with self-care, 13 (5%) with mobility, 49 (20%) with performing usual activities, 74 (30%) with pain, and 114 (46%) with depression. Mean weighted quality-of-life measure (0Â·91 [SD 0Â·13]) was similar to a pre-pandemic US population value (0Â·92 [0Â·13]) and significantly higher than an early pandemic US population value (0Â·75 [0Â·28]; p<0Â·0001). Most patients had improvements in cardiac diagnostic marker and testing data at follow-up, including normal or back-to-baseline troponin concentrations (181 [91%] of 200 patients with available data), echocardiograms (262 [94%] of 279 patients), electrocardiograms (240 [77%] of 311 patients), exercise stress testing (94 [90%] of 104 patients), and ambulatory rhythm monitoring (86 [90%] of 96 patients). An abnormality was noted among 81 (54%) of 151 patients with follow-up cardiac MRI; however, evidence of myocarditis suggested by the presence of both late gadolinium enhancement and oedema on cardiac MRI was uncommon (20 [13%] of 151 patients). At follow-up, most patients were cleared for all physical activity (268 [68%] of 393 patients). INTERPRETATION: After at least 90 days since onset of myocarditis after mRNA COVID-19 vaccination, most individuals in our cohort were considered recovered by health-care providers, and quality of life measures were comparable to those in pre-pandemic and early pandemic populations of a similar age. These findings might not be generalisable given the small sample size and further follow-up is needed for the subset of patients with atypical test results or not considered recovered. FUNDING: US Centers for Disease Control and Prevention.

Recovery from mRNA COVID-19 vaccine-related myocarditis.

Acquired hemophilia A following COVID-19 vaccination - The importance of prompt diagnosis: A case report. Acquired hemophilia A (AHA) is a rare coagulopathy characterized by hemorrhagic manifestations. It has been linked to various conditions, including autoimmune disorders, drugs, tumors, lymphoproliferative disorders, and infections. We present a case of AHA in a 71-year-old male patient with cutaneous hematoma occurring 8 days after vaccination for COVID-19. This report aims to highlight the risk of FVIII inhibitor development following an immune stimulus, thus improving our knowledge regarding possible vaccination-related adverse events. Furthermore, we underline how the potential risk of not recognizing disease manifestations promptly, together with specific coagulation alterations, could significantly affect the patient's outcome. Adequate management plans and the diffusion of shared guidelines are of fundamental importance in order to prevent the development of life-threatening complications and initiate appropriate treatment as soon as possible. DATA AVAILABILITY: All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

Bilateral retinal vein occlusion after two doses of SARS-CoV-2 adenovirus vector-based vaccine.

Association between a low response to rubella vaccination and reduced anti-severe acute respiratory syndrome coronavirus 2 immune response after vaccination with BNT162b2: a cross-sectional study. OBJECTIVES: Some vaccinated individuals fail to acquire an adequate immune response against infection. We aimed to determine whether mRNA severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination could induce a sufficient immune response against SARS-CoV-2 in low responders to other vaccinations. METHODS: Using data from health-care workers who received two

doses of the BNT162b2 vaccine (BioNTech/Pfizer), we conducted a single-centre, cross-sectional study to determine whether low responders to measles, rubella, and hepatitis B virus (HBV) vaccinations could acquire sufficient antibodies after SARS-CoV-2 vaccination. From May 2021 to June 2021, participants were tested for anti-SARS-CoV-2 spike (anti-S) IgG antibodies at least 2Â weeks after the second dose of BNT162b2. The association between a low response to measles, rubella, and HBV vaccinations and the post-vaccination anti-S IgG titre was evaluated using the multivariable linear regression analysis. RESULTS: All 714 participants were positive for the anti-S IgG titre (â‰¥50.0 AU/mL) after two doses of BNT162b2 (median, 7126.8 AU/mL; interquartile range, 4496.2-11 296.8). There were 323 (45.2%), 131 (18.3%), and 43 (6.0%) low responders to measles, rubella, and HBV vaccinations, respectively. In the multivariable linear regression analysis, low responders to rubella vaccination had significantly low acquisition of the anti-S IgG titre after two doses of the BNT162b2 vaccine (standardized coefficient Î²,Â -0.110; 95% CI,Â -0.175 toÂ -0.044). CONCLUSIONS: A low response to rubella vaccination is a potential predictor of a reduced response to SARS-CoV-2 vaccination. Further studies are needed to determine whether a low response to rubella vaccination is associated with the durability of SARS-CoV-2 vaccination-induced immune response.
COVID 19 vaccination and people with disability: Australian perspective.
Shot in the dark. A 43-year-old woman presented with decreased vision in the right eye associated with painful eye movements 10 days after receiving her first dose of Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine (Pfizer Inc, New York, NY). Two days later she developed painful loss of vision in the left eye. Clinical presentation and magnetic resonance imaging findings were consistent with bilateral optic perineuritis transitioning to optic neuritis. Extensive evaluation including aquaporin-4 immunoglobin G (IgG), myelin oligodendrocyte glycoprotein IgG, and lumbar puncture was unrevealing. Visual acuity at nadir was counting fingers in both eyes, but after receiving intravenous steroids and plasma exchange vision eventually improved to 20/20 in each eye, although she was left with inferior visual field defects and bilateral optic disc pallor. This case highlights the diagnostic challenge in the evaluation of atypical optic neuritis with a review of post-COVID-19 vaccination-associated optic neuritis.
Hybrid immunity in immunocompromised patients with CLL after SARS-CoV-2 infection followed by booster mRNA vaccination.
Abducens and Trochlear Nerve Palsies After COVID-19 Vaccination: Report of Two Cases. The authors report two cases of an abducens palsy and a trochlear nerve palsy, respectively, in two patients who received a coronavirus disease 2019 (COVID-19) vaccine 2 weeks previously. Given the lack of other symptoms, normal test results, and spontaneous resolution of the diplopia, a likely association with the COVID-19 vaccine was suggested. [J Pediatr Ophthalmol Strabismus. 2022;59(5):e50-e53.].
Medium-term outcomes of myocarditis and pericarditis following BNT162b2 vaccination among adolescents in Hong Kong. In this study, we examined the clinical and electrophysiological outcomes of adolescents in Hong Kong who developed myocarditis or pericarditis following BNT162b2 vaccination for COVID-19, and followed-up for 60-180 days after their initial diagnosis. Clinical assessments included electrocardiogram (ECG) and echocardiogram at the initial admission and follow-up were compared. Treadmill testing was also performed in some cases. Between 14 June 2021 and 16 February 2022, 53 subjects were approached to participate in this follow-up study, of which 28 patients were followed up for >60 days with a median follow-up period of 100 days (range, 61-178 days) and were included in this study. On admission, 23 patients had ECG abnormalities but no high-grade atrioventricular block. Six patients had echocardiogram abnormalities, including reduced contractility, small rim pericardial effusions, and hyperechoic ventricular walls. All patients achieved complete recovery on follow-up. After discharge, 10 patients (35.7%) reported symptoms,

including occasional chest pain, shortness of breath, reduced exercise tolerance, and recurrent vasovagal near-syncope. At follow-up, assessments, including ECGs, were almost all normal. Among the three patients with possible ECG abnormalities, all their echocardiograms or treadmill testings were normal. Sixteen patients (57.1%) underwent treadmill testing at a median of 117 days post-admission, which were also normal. However, at follow-up, there was a significant mean bodyweight increase of 1.81â€…kg (95%CI 0.47-3.1â€…kg, pâ€‰=â€‰0.01), possibly due to exercise restriction. In conclusion, most adolescents experiencing myocarditis and pericarditis following BNT162b2 vaccination achieved complete recovery. Some patients developed non-specific persistent symptoms, and bodyweight changes shall be monitored.
Is the second jab of an anti-SARS-CoV-2 vaccine reasonable after guillain-Barre syndrome following the first dose?
Humoral and cellular immunity after mRNA COVID-19 vaccine in psoriatic patients on biological or immunosuppressive therapy: a real-life experience.
Regression of common viral warts in an immunocompetent child and an immunosuppressed adult relative after mRNA BNT162b2 COVID-19 vaccine.
Serial infection with SARS-CoV-2 Omicron BA.1 and BA.2 following three-dose COVID-19 vaccination. SARS-CoV-2 Omicron infections are common among individuals who are vaccinated or have recovered from prior variant infection, but few reports have immunologically assessed serial Omicron infections. We characterized SARS-CoV-2 humoral responses in an individual who acquired laboratory-confirmed Omicron BA.1.15 ten weeks after a third dose of BNT162b2, and BA.2 thirteen weeks later. Responses were compared to 124 COVID-19-naive vaccinees. One month post-second and -third vaccine doses, the participant's wild-type and BA.1-specific IgG, ACE2-displacement and virus neutralization activities were average for a COVID-19-naive triple-vaccinated individual. BA.1 infection boosted the participant's responses to the cohortÂ â‰¥95th percentile, but even this strong "hybrid" immunity failed to protect against BA.2. Reinfection increased BA.1 and BA.2-specific responses only modestly. Though vaccines clearly protect against severe disease, results highlight the continued importance of maintaining additional protective measures to counteract the immune-evasive Omicron variant, particularly as vaccine-induced immune responses naturally decline over time.
Anti-Spike antibodies 3 months after SARS-CoV-2 mRNA vaccine booster dose in patients on hemodialysis: the prospective SENCOVAC study. BACKGROUND: Patients on hemodialysis are at high-risk for complications derived from coronavirus disease 2019 (COVID-19). The present analysis evaluated the impact of a booster vaccine dose and breakthrough severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections on humoral immunity 3Â months after the booster dose. METHODS: This is a multicentric and prospective study assessing immunoglobulin G anti-Spike antibodies 6 and 9Â months after initial SARS-CoV-2 vaccination in patients on hemodialysis that had also received a booster dose before the 6-month assessment (early booster) or between the 6- and 9-month assessments (late booster). The impact of breakthrough infections, type of vaccine, time from the booster and clinical variables were assessed. RESULTS: A total of 711 patients [67% male, median age (range) 67 (20-89) years] were included. Of these, 545 (77%) received an early booster and the rest a late booster. At 6Â months, 64 (9%) patients had negative anti-Spike antibody titers (3% of early booster and 29% of late booster patients, PÂ =Â .001). At 9 months, 91% of patients with 6-month negative response had seroconverted and there were no differences in residual prevalence of negative humoral response between early and late booster patients (0.9% vs 0.6%, PÂ =Â .693). During follow-up, 35 patients (5%) developed breakthrough SARS-CoV-2 infection. Antibody titers at 9Â months were independently associated with mRNA-1273 booster (PÂ =Â .001), lower time from booster (PÂ =Â .043) and past breakthrough SARS-CoV-2 infection (PÂ <Â .001). CONCLUSIONS: In

hemodialysis patients, higher titers of anti-Spike antibodies at 9 months were associated with mRNA-1273 booster, lower time from booster and past breakthrough SARS-CoV-2 infection.

Vaccination Decreases the Infectious Viral Load of Delta Variant SARS-CoV-2 in Asymptomatic Patients. The Delta variant of SARS-CoV-2 has caused many breakthrough infections in fully vaccinated individuals. While vaccine status did not generally impact the number of viral RNA genome copies in nasopharyngeal swabs of breakthrough patients, as measured by Ct values, it has been previously found to decrease the infectious viral load in symptomatic patients. We quantified the viral RNA, infectious virus, and anti-spike IgA in nasopharyngeal swabs collected from individuals asymptomatically infected with the Delta variant of SARS-CoV-2. Vaccination decreased the infectious viral load, but not the amount of viral RNA. Furthermore, vaccinees with asymptomatic infections had significantly higher levels of anti-spike IgA in their nasal secretions compared to unvaccinated individuals with asymptomatic infections. Thus, vaccination may decrease the transmission risk of Delta, and perhaps other variants, despite not affecting the amount of viral RNA measured in nasopharyngeal swabs.

SARS-CoV-2 RBD-Specific Antibodies Induced Early in the Pandemic by Natural Infection and Vaccination Display Cross-Variant Binding and Inhibition. The development of vaccine candidates for COVID-19 has been rapid, and those that are currently approved display high efficacy against the original circulating strains. However, recently, new variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have emerged with increased transmission rates and less susceptibility to vaccine induced immunity. A greater understanding of protection mechanisms, including antibody longevity and cross-reactivity towards the variants of concern (VoCs), is needed. In this study, samples collected in Denmark early in the pandemic from paucisymptomatic subjects (n = 165) and symptomatic subjects (n = 57) infected with SARS-CoV-2 were used to assess IgG binding and inhibition in the form of angiotensin-converting enzyme 2 receptor (ACE2) competition against the wild-type and four SARS-CoV-2 VoCs (Alpha, Beta, Gamma, and Omicron). Antibodies induced early in the pandemic via natural infection were cross-reactive and inhibited ACE2 binding of the VoC, with reduced inhibition observed for the Omicron variant. When examined longitudinally, sustained cross-reactive inhibitory responses were found to exist in naturally infected paucisymptomatic subjects. After vaccination, receptor binding domain (RBD)-specific IgG binding increased by at least 3.5-fold and inhibition of ACE2 increased by at least 2-fold. When vaccination regimens were compared (two doses of Pfizer-BioNTech BNT162b2 (n = 50), or one dose of Oxford-AstraZeneca ChAdOx1 nCoV-19 followed by Pfizer-BioNTech BNT162b2 (ChAd/BNT) (n = 15)), higher levels of IgG binding and inhibition were associated with mix and match (ChAd/BNT) prime-boosting and time since vaccination. These results are particularly relevant for countries where vaccination levels are low.

Lymphocyte Subpopulations Associated with Neutralizing Antibody Levels of SARS-CoV-2 for COVID-19 Vaccination. The comprehensive knowledge regarding the immune response during coronavirus disease 2019 (COVID-19) vaccination is limited. The aim of this study was to longitudinally investigate not only the dynamic changes of peripheral lymphocyte subpopulations and cytokine levels but parallel changes of antibody levels against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Blood samples of 20 healthcare workers with two doses of COVID-19 vaccine were prospectively collected. The percentages of lymphocyte subpopulations from peripheral blood and cytokine production in lymphocytes with in vitro stimulation were assessed using eight-color flow cytometry. SARS-CoV-2 spike antibodies (anti-S Abs) and functional neutralizing antibodies (nAbs) were also measured. The relation between pre- and post-vaccination immunity was analyzed. There are 7 men and 13 women with a median age of 44.0 years (range: 25.7âˆ’59.5 years). The individuals had an increased percentage of lymphocytes at post-vaccination with statistical significance post first dose ($p = 0.031$). The levels of transitional cells ($p = 0.001$), such as plasmablasts ($p < 0.001$) and

plasma cells (p = 0.031), were increased compared with pre-vaccination. Recent thymic emigrants of CD4+ T cells subsets were significantly higher at post-vaccination than those at pre-vaccination (p = 0.029). Intracellular levels of tumor necrosis factor-alpha, interferon-Î³, interleukin (IL)-2, IL-21, transforming growth factor-beta and IL-17 produced by CD4+ T, CD8+ T, and natural killer cells were increased. All individual samples showed reactivity to anti-S Abs and the levels of nAbs were elevated after vaccination. The magnitude of adaptive immunity was associated with vaccine types and doses. Alterations of total memory B cells (p < 0.001), non-switched memory B cells (p = 0.016), and memory Treg cells (p < 0.001) were independent predictors for nAb levels. These findings might be helpful in elucidating the immune response of COVID-19 vaccination and in developing new strategies for immunization.

Despite Vaccination: A Real-Life Experience of Severe and Life-Threatening COVID-19 in Vaccinated and Unvaccinated Patients. Some vaccinated individuals still develop severe COVID-19, and the underlying causes are not entirely understood. We aimed at identifying demographic, clinical, and coinfection characteristics of vaccinated patients who were hospitalized. We also hypothesized that coinfections might play a role in disease severity and mortality. We retrospectively collected data from our COVID-19 registry for whom vaccination data were available. Patients were split into groups based on the number of administered doses (zero, one, two, or three). Data were assessed with Chi-square and Kruskalâ€'Wallis tests and multiple logistic regression analysis. We collected data from 1686 patients and found that intra-hospital mortality was not associated to the vaccination status (e.g., p = 0.2 with three doses), while older age, sepsis, and non-viral pneumonia were (p < 0.001). Unvaccinated patients needed mechanical ventilation more often (8.5%) than vaccinated patients, in whom the probability of mechanical ventilation decreased with increasing doses (8.7%, 2.8%, 0%). We did not find more coinfections in vaccinated people. We concluded that there is a lack of real-life data to adequately characterize the pathophysiology and risk factors of patients who develop severe COVID-19, but coinfections do not appear to play a role in disease severity.

Factors Associated with Vaccination Intention against the COVID-19 Pandemic: A Global Population-Based Study. Several vaccines have been developed for COVID-19 since the pandemic began. This study aimed to evaluate the factors associated with COVID-19 vaccination intention. A global survey was conducted across 26 countries from October, 2020 to December, 2021 using an online self-administered questionnaire. Demographic information, socio-economic status, and clinical information were collected. A logistic regression examined the associations between vaccine intention and factors such as perceptions and the presence of chronic physical and mental conditions. The sample included 2459 participants, with 384 participants (15.7%) expressing lower COVID-19 vaccination intent. Individuals who identified as female; belonged to an older age group; had a higher level of education; were students; had full health insurance coverage; or had a previous history of influenza vaccination were more willing to receive vaccination. Conversely, those who were working part-time, were self-employed, or were receiving social welfare were less likely to report an intention to get vaccinated. Participants with mental or physical health conditions were more unwilling to receive vaccination, especially those with sickle cell disease, cancer history within the past five years, or mental illness. Stronger vaccination intent was associated with recommendations from the government or family doctors. The presence of chronic conditions was associated with lower vaccine intention. Individuals with health conditions are especially vulnerable to health complications and may experience an increased severity of COVID-19 symptoms. Future research should evaluate the effectiveness of interventions targeting the vaccine perceptions and behaviours of at-risk groups. As such, public awareness campaigns conducted by the government and proactive endorsement from health physicians may help improve COVID-19 vaccination intention.

The Post-Vaccination Quantitative Total Immunoglobulin Levels against SARS-CoV-2 in Healthcare Workers: A Multi-Centric Cohort Study in India. Healthcare workers (HCWs) in India received the AZD1222 and BBV152 vaccines from January 2021 onwards. The objective of this study was to compare the immune response (seropositivity rate and geometric mean titer (GMT), and 95% confidence interval (CI)] against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in HCWs who received these vaccines, after the first and second doses. Therefore, the total immunoglobulin (Ig) levels specific to SARS-CoV-2 were measured using quantitative enzyme-linked immunosorbent assay (ELISA). The study population of 133 HCWs consisted of two groups in which the immune response was measured for the AZD1222 and BBV152 vaccines. Data collection was performed from 6 February to 20 August 2021. Four weeks after the first and second dose, the odds ratio of seroconversion for AZD1222 and BBV152 vaccine was 10.3 times (95% CI: 4.5-23.7) and 15.9 times (95% CI: 6.3-39.9), respectively. The GMT was 6392.93 and 6398.82 U/mL for AZD1222 and 1480.47 and 990.38 U/mL for BBV152 after the first and second doses, respectively. Both vaccines elicited an immune response, but the seroconversion rate and GMT after each dose were significantly higher for AZD1222 than those for the BBV152 vaccine in this study.

Human Fc-Conjugated Receptor Binding Domain-Based Recombinant Subunit Vaccines with Short Linker Induce Potent Neutralizing Antibodies against Multiple SARS-CoV-2 Variants. The coronavirus disease-19 (COVID-19) pandemic has been ongoing since December 2019, with more than 6.3 million deaths reported globally as of August 2022. Despite the success of several SARS-CoV-2 vaccines, the rise in variants, some of which are resistant to the effects of vaccination, highlights the need for a so-called pan-coronavirus (universal) vaccine. Here, we performed an immunogenicity comparison of prototype vaccines containing spike protein receptor-binding domain (RBD) residues 319-541, or spike protein regions S1, S2 and S fused to a histidine-tagged or human IgG1 Fc (hFC) fragment with either a longer (six residues) or shorter (three residues) linker. While all recombinant protein vaccines developed were effective in eliciting humoral immunity, the RBD-hFc vaccine was able to generate a potent neutralizing antibody response as well as a cellular immune response. We then compared the effects of recombinant protein length and linker size on immunogenicity in vivo. We found that a longer recombinant RBD protein (residues 319-583; RBD-Plus-hFc) containing a small alanine linker (AAA) was able to trigger long-lasting, high-titer neutralizing antibodies in mice. Finally, we evaluated cross-neutralization of wild-type and mutant RBD-Plus-hFc vaccines against wild-type, Alpha, Beta, Delta and Omicron SARS-CoV-2 variants. Significantly, at the same antigen dose, wild-type RBD-Plus-hFc immune sera induced broadly neutralizing antibodies against wild-type, Alpha, Beta, Delta and Omicron variants. Taken together, our findings provide valuable information for the continued development of recombinant protein-based SARS-CoV-2 vaccines and a basic foundation for booster vaccinations to avoid reinfection with SARS-CoV-2 variants.

T-Cell Responses Induced by an Intradermal BNT162b2 mRNA Vaccine Booster Following Primary Vaccination with Inactivated SARS-CoV-2 Vaccine. A practical booster vaccine is urgently needed to control the coronavirus disease (COVID-19) pandemic. We have previously reported the safety and immunogenicity of a fractional intradermal booster, using the BNT162b2 mRNA vaccine in healthy volunteers who had completed two doses of inactivated SARS-CoV-2 vaccine. In this study, an intramuscular booster at full dosage was used as a control, and a half-dose vaccination was included for reciprocal comparison. Detailed T-cell studies are essential to understand cellular responses to vaccination. T-cell immunity was examined using S1 peptide restimulation and flow cytometry. The fractional dose (1:5) of the BNT162b2 mRNA vaccine enhanced antigen-specific effector T-cells, but the responses were less remarkable compared to the intramuscular booster at full dosage. However, the intradermal regimen was not inferior to the intramuscular booster a month after boosting. An intradermal booster using only one-fifth of the standard dosage could provide comparable T-cell

responses with the fractional intramuscular booster. This work confirms the efficacy of intradermal and fractional vaccination in terms of T-cell immunogenicity in previously immunised populations.

Reduced Antibody Acquisition with Increasing Age following Vaccination with BNT162b2: Results from Two Longitudinal Cohort Studies in The Netherlands. Vaccine-induced protection against severe COVID-19, hospitalization, and death is of the utmost importance, especially in the elderly. However, limited data are available on humoral immune responses following COVID-19 vaccination in the general population across a broad age range. We performed an integrated analysis of the effect of age, sex, and prior SARS-CoV-2 infection on Spike S1-specific (S1) IgG concentrations up to three months post-BNT162b2 (Pfizer/BioNTech; Comirnaty) vaccination. In total, 1735 persons, eligible for COVID-19 vaccination through the national program, were recruited from the general population (12 to 92 years old). Sixty percent were female, and the median vaccination interval was 35 days (interquartile range, IQR: 35â^'35). All participants had seroconverted to S1 one month after two vaccine doses. S1 IgG was higher in participants with a history of SARS-CoV-2 infection (median: 4535 BAU/mL, IQR: 2341â^'7205) compared to infection-naive persons (1842 BAU/mL, 1019â^'3116), $p < 0.001$. In infection-naive persons, linear mixed effects regression showed a strong negative association between age and S1 IgG ($p < 0.001$) across the entire age range. Females had higher S1 IgG than males ($p < 0.001$). In persons with an infection history, age nor sex was associated with S1 IgG concentrations. The lower magnitude of S1 antibodies in older persons following COVID-19 vaccination will affect long-term protection.

Cutaneous Adverse Reactions to SARS-CoV-2 Vaccines: A Systematic Review and Meta-Analysis. Background: An increasing number of cutaneous adverse reactions (CARs) to SARS-CoV-2 vaccines have been reported, but their incidence is debated. Objective: To estimate the pooled incidence of CARs to SARS-CoV-2 vaccines in the general adult population. Methods: A systematic review and meta-analysis of original articles published on MEDLINE via PubMed and Web Of Science from 1 January 2020 to 18 July 2022 was undertaken. Studies reporting the incidence proportion of CARs (defined as number of new cases of CARs on the total of vaccinated people) were included. All types of SARS-CoV-2 vaccine were included. People receiving at least one dose were considered eligible. Local cutaneous reactions were excluded. Results: A total of 970 records were identified and screened by title and abstract; 22 observational studies were included with aggregate data on 93,165 participants. The pooled incidence of overall CARs was 5% (95%CI 4â^'6%; $I2 = 99\%$; $p < 0.001$), ranging from <0.01 to 19.00%. Most CARs were new onset dermatitis including rash, urticaria and vascular lesions; one case of Stevenâ^'Johnson syndrome and six cases of erythema multiforme were reported. In the sensitivity analysis we found that the incidence of CARs after the first and second dose was similar, i.e., 3% (95%CI 2â^'3%; $I2 = 96\%$; $p < 0.001$) and 3% (95%CI 2â^'4%; $I2 = 97\%$; $p < 0.001$), respectively. The magnitude of incidence of CARs remained unchanged independently of vaccine platform and in the general population versus healthcare workers. Conclusions: CARs associated with SARS-CoV-2 vaccines are frequent but mild and self-remitting, whereas severe CARs are rare.

Alopecia Areata Occurring after COVID-19 Vaccination: A Single-Center, Cross-Sectional Study. Limited data concerning the development of autoimmune skin diseases after COVID-19 vaccination are currently available. Recently, a few reports described the development, worsening or recurrence of alopecia areata after the administration of COVID-19 vaccines. High variability in terms of disease onset following vaccination as well as the heterogeneous topical and/or systemic treatment approaches have been described. Methods: All patient-related data and images were obtained as part of clinical routine. Diagnosis of alopecia areata was established according to clinical and trichoscopic findings, along with the exclusion of common differential diagnoses. Results. Twenty-four patients, 20 females (83.3%) and four males (16.7%), with a mean age of 39.1 years (age range:

14-66 years), were examined for the occurrence of alopecia areata within 16 weeks after COVID-19 vaccination. Out of 24, 14 patients (58.3%) experienced a patchy alopecia areata, while an extensive disease occurred in 10/24 patients (41.7%): six patients with whole scalp involvement (alopecia areata totalis) and four patients with the whole body affected (alopecia areata universalis). Twelve patients reported a history of autoimmune disease (50%). Treatment with topical corticosteroid was performed in almost all patients with patchy alopecia areata, whilst it was associated with systemic drugs (corticosteroids, minoxidil, cyclosporin) in the case of generalized alopecia areata and alopecia areata universalis. Mean baseline values of Severity of Alopecia Tool (SALT) score decreased from 43.4 to 36.6 after 12 weeks of treatment, with evidence of hair regrowth in 16/21 patients. Conclusion. This study described the occurrence of alopecia areata after COVID-19 vaccination and its management that implicates the use of both topical and systemic therapies.

Sinopharm's BBIBP-CorV Vaccine and ChAdOx1 nCoV-19 Vaccine Are Associated with a Comparable Immune Response against SARS-CoV-2. Coronavirus disease 2019 (COVID-19) has affected millions of people worldwide. During the early stages of vaccination in Egypt, the ChAdOx1 nCoV-19 and BBIBP-CorV vaccines were the most distributed. The aim of this study was to compare the immune responses and short-term efficacies of these two vaccines. We recruited adults who received two doses of either vaccine. Samples were collected after the first dose of ChAdOx1 nCoV-1 and after the second dose of both vaccines. Antibodies against SARS-CoV-2 antigens were measured using LABScreenâ„¢ COVID Plus kits, and cell-mediated immune responses were assessed using flow cytometry. Of the 109 recruited subjects, 60 (55%) received the ChAdOx1 nCoV-19 vaccine, and the remainder received the BBIBP-CorV vaccine. The total antibody level did not significantly differ between the two groups. The level of the anti-spike subunit 2 (S2) antibody was significantly higher in the ChAdOx1 nCoV-19 group. The percentages of both total T cells and B cells were unaffected by the type of vaccination. However, the ChAdOx1 nCoV-1 vaccine was significantly associated with a higher percentage of CD8+ cells. The vaccines did not significantly differ in the number or severity of infections postvaccination. None of the participants were admitted to the hospital or died of COVID-19 infection. In conclusion, the BBIBP-CorV vaccine is associated with an immune response and protection against infection that is comparable to that of the ChAdOx1 nCoV-1 vaccine. Follow-up is needed to study the long-term protective effects of both vaccines. Inactivated vaccines are easier to manufacture in developing countries and their limited side effects may lead to better economic benefits by limiting the number of absences from work.

Antibody Response and Adverse Events of AZD1222 COVID-19 Vaccination in Patients Undergoing Dialysis: A Prospective Cohort Study. This study observed the antibody response and adverse events of AZD1222 (Oxford/AstraZeneca) vaccination in dialysis patients. A prospective cohort study was conducted in E-Da Healthcare Group hospitals between 1 July and 30 November 2021. Patients receiving hemodialysis (HD, n = 204) or peritoneal dialysis (PD, n = 116) were enrolled alongside healthy subjects (control, n = 34). Anti-SARS-CoV-2 S1 RBD IgG antibodies were measured before the first vaccination (T0), four to six weeks afterwards (T1), one week before the second dose (T2), and four to six weeks afterwards (T3). Adverse events were recorded one week after each dose. The positive IgG rates in the HD (T1: 72%; T2: 62%) and PD (T1: 69%; T2: 70%) groups were lower than the control group (T1: 97%; T2: 91%), with lower median antibody titers. At T3, the positive antibody response rates (HD: 94%; PD: 93%; control: 100%) and titers were similar. Titers were higher after the second dose in all groups. Adverse events were more severe after the first dose and less common with HD than PD or controls. Dialysis patients exhibited lower antibody responses than controls after the first dose of the AZD1222 vaccine but achieved similar responses after consecutive vaccination. Age, health status, two vaccine doses, and alcohol consumption may influence antibody levels.

Longitudinal Comparison of Neutralizing Antibody Responses to COVID-19 mRNA Vaccines after Second and Third Doses. COVID-19 mRNA vaccines protect against severe disease and hospitalization. Neutralizing antibodies (NAbs) are a first-line defense mechanism, but protective NAb responses are variable. Currently, NAb testing is not widely available. This study employed a lateral flow assay for monitoring NAb levels postvaccination and natural infection, using a finger-stick drop of blood. We report longitudinal NAb data from BNT162b2 (Pfizer) and mRNA-1273 (Moderna) recipients after second and third doses. Results demonstrate a third dose of mRNA vaccine elicits higher and more durable NAb titers than the second dose, independent of manufacturer, sex, and age. Our analyses also revealed that vaccinated individuals could be categorized as strong, moderate, and poorly neutralizing responders. After the second dose, 34% of subjects were classified as strong responders, compared to 79% after the third dose. The final months of this study coincided with the emergence of the SARS-CoV-2 Omicron variant and symptomatic breakthrough infections within our study population. Lastly, we show that NAb levels sufficient for protection from symptomatic infection with early SARS-CoV-2 variants were not protective against Omicron infection and disease. This work highlights the need for accessible vaccine response monitoring for use in healthcare, such that individuals, particularly those in vulnerable populations, can make informed vaccination decisions.

Parental Willingness and Associated Factors of Pediatric Vaccination in the Era of COVID-19 Pandemic: A Systematic Review and Meta-Analysis. A significant decline in pediatric vaccination uptake due to the COVID-19 pandemic has been documented. Little is known about the parental willingness and associated factors of pediatric vaccination during the COVID-19 pandemic. An extensive literature search in the databases of PubMed, Scopus, Web of Science, and EBSCOhost were conducted. A total of 20 eligible studies published from 2020-2022 were included for systematic summary by a thematic analysis, among which 12 studies were included in a meta-analysis conducted with R-4.2.1. The prevalence of parental willingness to childhood/routine vaccination and seasonal influenza vaccination was 58.6% (95%CI 2.8-98.6%) and 47.3% (95%CI 25.3-70.5%). Moreover, there is no sufficient evidence of significant change in parental willingness to childhood/routine vaccination, human papillomavirus vaccination, or pneumococcal conjugate vaccination during the pandemic. However, a significant increase in parental willingness to vaccinate their children against seasonal influenza was found. In addition to the factors of parental vaccination willingness/hesitancy that are well-studied in literature, children/parents' history of COVID-19 and children's perceived vulnerability to COVID-19 were associated with parental willingness. Developing synergetic strategies to promote COVID-19 vaccination together with other pediatric vaccination is warranted during the pandemic. This may help to improve and/or catch up the vaccine uptake of children during and/or after the COVID-19 pandemic.

Analysis of Adverse Effects of COVID-19 Vaccines Experienced by Healthcare Workers at Guizhou Provincial Staff Hospital, China. Objective: A retrospective survey was conducted of adverse events following immunization (AEFI) experienced by health care workers (HCWs) in a relatively remote ethnic region in southwest China (Guizhou Province) who received COVID-19 vaccines. Methods: From 18 January 2021 to 21 January 2022, all HCWs of Guizhou Provincial Staff Hospital, China, who received at least one dose of inactivated COVID-19 vaccine (Vero cell), recombinant novel coronavirus vaccine (CHO cell), or one dose of adenovirus type-5 (Ad5) vectored COVID-19 vaccine were asked to complete a self-report questionnaire to provide information on any adverse events that may have occurred in the first 3 days after injection. The frequency of AEFI corresponding to the three types of vaccines were compared and the potential risks of AEFI due to the three different vaccines were predicted by multivariate logistic regression analysis. Results: Of the 904 HCWs who completed the survey, the rates of AEFI were 10.1% (80/794) due to Vero cell, 16.3% (13/80) due to

CHO cell, and 46.67% (14/30) due to Ad5 vectored vaccines, and the rates were significantly different (Ï‡2 = 38.7, p < 001) between the three vaccines. Multivariate logistic regression models predict that (1) compared to the Ad 5 vectored group, the risk of AEFI occurrence in the Vero cell group was reduced by about 85.9% (OR = 0.141, 95% CI: 0.065â^'0.306, p < 0.001) and in the CHO cell group by about 72.1% (OR = 0.279, 95% CI: 0.107â^'0.723, p = 0.009), (2) the odds for women experiencing AEFI were about 2.1 (OR = 2.093, 95% CI: 1.171â^'3.742, p = 0.013) times as high as those of men, and (3) the risk of AEFI for HCWs with a Bachelorâ€™s degree or above was about 2.2 (OR = 2.237, 95% CI: 1.434â^'3.489, p = 0.001) times higher than in HCWs who do not have a Bachelorâ€™s degree. Conclusions: 1. The inactivated COVID-19 vaccine (Vero cell), recombinant novel coronavirus vaccine (CHO cell), and adenovirus type-5 (Ad5) vectored COVID-19 vaccine made in China are safe and relatively broad-spectrum. 2. The prevalence of AEFI is more common in women healthcare workers. 3. The risk of AEFI was higher in those with a Bachelorâ€™s degree or above and may be related to the psychological and social effects triggered by the global COVID-19 pandemic.

Graves' Disease Following SARS-CoV-2 Vaccination: A Systematic Review. (1) Background: Autoimmune diseases, including autoimmune endocrine diseases (AIED), are thought to develop following environmental exposure in patients with genetic predisposition. The vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) could represent a new environmental trigger for AIED, including Graves' disease (GD). (2) Methods: We performed a literature search of MEDLINE/PubMed databases regarding thyroid dysfunction after SARS-CoV-2 vaccination since 1 January 2020 to 31 July 2022, considering only cases of thyrotoxicosis that meet the 2016 American Thyroid Association guidelines criteria for the diagnosis of GD and arising after administration of the anti-SARS-CoV-2 vaccine, regardless of the number of doses. (3) Results: A total of 27 articles were identified, consisting of case reports or case series, of which 24 describe the appearance of 48 new diagnoses of GD and 12 GD recurrences arising after the administration of the anti-SARS-CoV-2 vaccine, and 3 papers that instead report only 3 cases of GD relapse following vaccination. (4) Conclusions: physicians should be aware of the possibility of developing GD and other autoimmune sequelae following SARS-CoV-2 vaccination. Regardless of the underlying pathogenetic mechanisms (autoimmune/inflammatory syndrome induced by adjuvants (ASIA syndrome), cytokines induction, molecular mimicry, and cross-reactivity), an individual predisposition seems to be decisive for their development.

A Systematic Review of Reported Cases of Immune Thrombocytopenia after COVID-19 Vaccination. With the recent outbreak of the COVID-19 pandemic and emergency use authorization of anti-SARS-CoV-2 vaccines, reports of post-vaccine immune thrombocytopenia (ITP) have gained attention. With this systematic review, we aim to analyze the clinical characteristics, therapeutic strategies, and outcomes of patients presenting with ITP after receiving COVID-19 vaccination. Medline, Embase, and Ebsco databases were systematically explored from inception until 1 June 2022. Case reports and case series investigating the association between the anti-SARS-CoV-2 vaccine and ITP were included. We found a total of 66 patients. The mean age of presentation was 63 years with a female preponderance (60.6%). Sixteen patients had pre-existing ITP. The mean time from vaccine administration to symptom onset was 8.4 days. More ITP events were triggered by mRNA vaccines (BNT162b2 (n = 29) > mRNA-1273 (n = 13)) than with adenoviral vaccines (ChAdOx1-S AstraZeneca (n = 15) > Ad26.COV2-S (n = 9)). Most of the patients were treated with steroids or IVIG, or both. The overall outcome was promising, with no reported deaths. Our review attempts to increase awareness among physicians while evaluating patients presenting with thrombocytopenia after receiving the vaccine. In our solicited opinion, the rarity of these events and excellent outcomes for patients should not change views regarding the benefits provided by immunization.

Assessment of Predictors for SARS-CoV-2 Antibodies Decline Rate in Health Care Workers after BNT162b2 Vaccination-Results from a Serological Survey. Background: SARS-CoV-2 is a novel human pathogen causing Coronavirus Disease 2019 that has caused widespread global mortality and morbidity. Since health workers in Israel were among the first to be vaccinated, we had a unique opportunity to investigate the post-vaccination level of IgG anti-S levels antibodies (Abs) and their dynamics by demographic and professional factors. Methods: Prospective Serological Survey during December 2020â^'August 2021 at Barzilai Medical Center among 458 health care workers (HCW) followed for 6 months after the second BNT162b2 vaccine dose. Results: Antibody levels before the second dose, and 30, 90 and 180 days after were 57.1 Â± 29.2, 223 Â± 70.2, 172.8 Â± 73.3 and 166.4 Â± 100.7 AU/mL, respectively. From GEE analysis, females had higher Abs levels (Î² = 26.37 AU/mL, p = 0.002). Age was negatively associated with Abs, with a 1.17 AU/mL decrease for each additional year ($p < 0.001$). Direct contact with patients was associated with lower Abs by 25.02 AU/mL ($p = 0.009$) compared to working with no such contact. The average decline rate overall for the study period was 3.0 Â± 2.9 AU/mL per week without differences by demographic parameters and was faster during the first 3 months after vaccination than in the subsequent 3 months. Conclusions: All demographic groups experienced a decline in Abs over time, faster during the first 3 months. Findings of overall Abs lower in males, workers with direct contact with patients, and older workers, should be considered for policy-making about choosing priority populations for additional vaccine doses in hospital settings.

Adult-Onset Familial Hemophagocytic Lymphohistiocytosis Presenting with Annular Erythema following COVID-19 Vaccination. Familial hemophagocytic lymphohistiocytosis (HLH) is a rare genetic and life-threatening immunodeficiency disease. Here, we present a 38-year-old male who initially developed multiple annular to irregular erythema accompanied by a fever after COVID-19 vaccination. He was diagnosed with HLH with evidence of leukocytopenia in a full blood test, elevations of ferritin and sCD25, decreased NK cell function, and hemophagocytosis of a bone marrow biopsy specimen. A genetic examination revealed two probable disease-causing heterozygous mutations on UNC13D associated with type 3 familial HLH. A review of the case reports relevant to HLH following COVID-19 vaccination and the cutaneous manifestations of HLH with genetic defects suggests the necessity that individuals with preexisting immune dysregulation or diseases not classified should be cautious about COVID-19 vaccination and reminds clinicians that various recalcitrant skin lesions may be a sign of HLH.

Factors Associated with the COVID-19 Vaccination Status of Higher Education Students: Results of an Online Cross-Sectional Survey at Six Universities in Southwestern Germany. This cross-sectional study explored factors associated with the corona virus disease 2019 (COVID-19) vaccination acceptance among higher education students in southwestern Germany. We conducted a cross-sectional online survey at six state-approved higher education institutions (HEIs) between July and November 2021. In addition to descriptive analyses, univariate as well as multivariate binary logistic regression analyses were conducted. A total of 6556 higher education students aged 18 years and older participated in our survey; 91.4% of participating students had been vaccinated against COVID-19 at least once. The factors that significantly contributed to the explanation of higher education students' vaccination status in the multivariate analysis (area under curve-AUC = 0.94) were variables on the perception of the virus SARS-CoV-2 (affective risk perception: Adjusted odds ratio-aOR = 1.2; perception of the outbreak as a media-hype: aOR = 0.8), attitudes towards personal (aOR = 0.7) and study-related (aOR = 0.8) health and safety measures to prevent transmission of SARS-CoV-2, and attitudes towards COVID-19 vaccination (preservation of own health: aOR = 1.3; confidence in vaccine safety: aOR = 1.7; supporting higher education through vaccination: aOR = 1.2; own contribution to

the containment of the pandemic: aOR = 1.7). The findings target assisting HEIs in returning to face-to-face teaching after previous semesters of online teaching.

Vaccination Status and Number of Vaccine Doses Are Independently Associated with the PaO(2)/FiO(2) Ratio on Admission in Hospitalized COVID-19 Patients. INTRODUCTION: Coronavirus Disease-19 (COVID-19) vaccines reduce the risk of severe disease and mortality. However, the association between vaccination status and number of doses and the PaO(2)/FiO(2) ratio, a clinical measure of hypoxemia associated with an increased risk of intensive care treatment and mortality, has not been investigated. METHODS: We retrospectively assessed a consecutive series of 116 patients admitted to hospital with a primary diagnosis of COVID-19 between January and April 2022. Demographic, clinical, and laboratory data were collected within 24 h from admission. RESULTS: There was a significant positive relationship between the number of vaccine doses and the PaO(2)/FiO(2) ratio ($r = 0.223$, $p = 0.012$). This association remained significant after adjusting for confounders. Vaccinated patients had significantly higher PaO(2)/FiO(2) ratios than the unvaccinated (median: 250; IQR: 195-309 vs. 200; IQR: 156-257, $p = 0.013$). CONCLUSION: These results highlight the importance of the number of vaccine doses received in reducing the degree of hypoxia on admission in hospitalized COVID-19 patients.

Associations between Public Fear of COVID-19 and Number of COVID-19 Vaccinations: A County-Level Longitudinal Analysis. BACKGROUND AND PURPOSE: A large number of COVID-19 infections and deaths and the ensuing socioeconomic problems created widespread public fear around COVID-19. Fear around COVID-19 greatly influences people's attitudes towards receiving the COVID-19 vaccines. The purpose of this study is examining (a) the impact of the public fear of COVID-19 (PFC) on the number of COVID-19 vaccinations at the county level; (b) the interaction effect between the PFC and per capita income, unemployment rates, and COVID-19 vaccines incentive policies, on the number of COVID-19 vaccinations at the county level. METHOD: This is a longitudinal analysis across states in the U.S. by using county-level data of 2856 counties from 1 February to 1 July. Random-effects models were adopted to analyze the associations between the PFC and the number of COVID-19 vaccinations. RESULT: the PFC was positively associated with the number of COVID-19 vaccinations at county-level, as PFC increases from 0 to 300, the predicted vaccination number increases from 10,000 to 230,000. However, the associations were divergent when the PFC interacts with county-level per capita income, unemployment rates, and incentive policies. CONCLUSION: public fear is an important indicator for the county-level vaccination numbers of COVID-19. However, it is critical to consider public fear and socioeconomic factors when making policies that aim to increase COVID-19 vaccination rates.

Cytomegalovirus Proctitis Developed after COVID-19 Vaccine: A Case Report and Literature Review. (1) Background: We describe a case of a 58-year-old Chinese woman, without obvious cause of immunosuppression, who developed cytomegalovirus (CMV) proctitis three days after a second COVID-19 vaccination. Electronic colonoscopy revealed a new lesion that was circumferential at the anorectal junction, with an uneven surface and ulceration, which mimicked rectal carcinoma. This is the first case of CMV proctitis following vaccination since the invention of the COVID-19 vaccine, suggesting that the COVID-19 vaccine may cause disorders of immune homeostasis, including not only immune hyperactivity but also immune deficiency. We report this case to increase readers' awareness of the risks after COVID-19 vaccination and to provide new ideas for the diagnosis and treatment of similar cases. (2) Methods: In this case, we used laboratory biochemical examinations, colonoscopy, immunohistochemistry, and a biochemical index to confirm the existence of CMV proctitis. (3) Results: In this case, the vaccine-induced CMV proctitis had a similar endoscopic appearance to rectal neoplastic lesions, which could be confirmed by biopsy and quickly relieved by ganciclovir treatment. Ganciclovir was used to treat the patient, and a good effect was observed. (4)

Conclusions: COVID-19 vaccination may cause immune disorders, not just immune hyperactivity as previously reported, but also immune deficiency, such as CMV proctitis in this case. The clinical course of CMV proctitis secondary to COVID-19 vaccination was favorable with ganciclovir therapy.

Delayed Skin Reactions to COVID-19 mRNA-1273 Vaccine: Case Report and Literature Review. BACKGROUND: The COVID-19 mRNA vaccine was granted emergency use authorization (EUA) on December 18, 2020. Some patients experienced a transient, pruritic rash at the injection site, which was referred to as "COVID arm". It is considered a delayed-type hypersensitivity reaction and occurs mostly in individuals after vaccination with the Moderna vaccine but rarely with other mRNA vaccines. CASE SUMMARY: A healthy 33-year-old woman with no history of disease or long-term medication presented with fever and rash on the left upper arm three days after her first vaccination with the mRNA-1273 vaccine (Moderna). RESULTS: After treatment with antihistamines, all lesions gradually resolved over the following 4 to 5 days. CONCLUSION: We report a case of "COVID arm": a localized erythematous rash surrounding the injection site that arose three days after the first dose of the Moderna COVID-19 vaccine. Delayed injection site reactions occurred in approximately 0.8% of vaccinated people after the first dose and in approximately 0.2% after the second dose. The lesions persisted for several days and then resolved without treatment. Health care providers were not prepared to address these delayed local reactions to the mRNA-1273 vaccine. Given the scale-up of mass vaccination campaigns worldwide, these skin reactions may likely generate concerns among patients and requests for evaluation. Although these skin reactions have not been consistently recognized, guidance regarding the second dose of the vaccine has varied, and many patients have unnecessarily received antibiotic agents.

Tyrosine Kinase Inhibitors Do Not Promote a Decrease in SARS-CoV-2 Anti-Spike IgG after BNT162b2 Vaccination in Chronic Myeloid Leukemia: A Prospective Observational Study. We performed a prospective observational study of chronic myeloid leukemia (CML) patients after anti-SARS-CoV-2 BNT162b2 vaccination (VC). In total, 32 CML patients with tyrosine kinase inhibitor (TKI) therapy, 10 CML patients with treatment-free remission, and 16 healthy subjects participated in the study. From April 2021 to September 2021, all cases (median age = 58 years) were vaccinated twice. Immunoglobulin G for SARS-CoV-2 spike protein (S-IgG) was measured at three timepoints (before the first VC, 1â^'5 weeks after the second VC (T1), and approximately 6 months after the second VC (T2)). S-IgG was not observed before the first VC in any participant. At T1, all cases had acquired S-IgG. There were no significant differences in S-IgG levels among groups. A paired sample comparison of median S-IgG titers between T1 and T2 in all groups showed a significant reduction in T2 S-IgG titers. There were no significant differences in S-IgG levels among groups. When all patients were analyzed, those aged â‰¥58 years had significantly lower S-IgG levels than those aged <58 years at T1. The BNT162b2 vaccine was highly effective in CML patients with or without TKIs, and S-IgG levels were as persistent as those in healthy individuals.

Analysis of Adverse Effects of COVID-19 Vaccines in Spain following Booster Dose. The present study evaluates the adverse effects of three vaccines: AstraZeneca (Vaxzevria), Pfizer/BioNTech (Comirnaty) and Moderna (Spikevax) according to the dose. From 733 participants collected, the vaccine schedule was as follows: 330 (45%) received a double dose of the AstraZeneca vaccine, 382 (52.1%) received a double dose of Pfizer, 18 (2.5%) received a heterologous prime boost and 3 (0.4%) received a single dose. Pfizer and Moderna vaccines were administered as a third dose in 70 and 121 individuals, respectively. Local and systemic reactions observed in the three vaccines were mild to moderate in severity. Only one AstraZeneca recipient (0.3%) presented a serious adverse effect: blurred vision. Adverse events were more frequent after the first dose of AstraZeneca and after the second dose of Pfizer. As the third dose, Moderna causes more adverse effects than Pfizer regardless of the type of vaccine previously administered, whereas the reactogenicity of a third dose of Pfizer is

slightly higher in the group previously vaccinated with Pfizer than in that group with AstraZeneca. In short, secondary effects of the third dose of COVID-19 vaccines were similar to those after dose 2, but their frequency depends on the type of vaccine and the combinations of vaccines.

High Stress Levels and Trust toward the Government Are Associated with More Positive Attitudes toward COVID-19 Vaccines among French Students: A Pilot Study. Mistrust in COVID-19 vaccines may hinder vaccination campaigns. We looked at cognitive determinants of vaccination intentions against COVID-19. We were interested in (i) the effects of stress and (ii) the effects of self-protection systems on attitudes and intentions to get COVID-19 vaccines. We conducted an online observational pilot study with 203 participants and used self-report questionnaires to assess perceived stress and vulnerability to disease, beliefs about a dangerous world, pandemic-related stressors, living conditions, attitudes and intentions toward the vaccines and trust in government management of the COVID-19 pandemic. The participants reporting high levels of trust in government and high levels of stress were more likely to have positive attitudes toward COVID-19 vaccines, although these two effects are at least partially independent of each other. We discuss how to improve the communication around COVID-19 vaccine policies.

Epidemiological and Serological Analysis of a SARS-CoV-2 Outbreak in a Nursing Home: Impact of SARS-CoV-2 Vaccination and Enhanced Neutralizing Immunity Following Breakthrough Infection. Background: Despite a vaccination rate of 82.0% (n = 123/150), a SARS-CoV-2 (Alpha) outbreak with 64.7% (n = 97/150) confirmed infections occurred in a nursing home in Bavaria, Germany. Objective: the aim of this retrospective cohort study was to examine the effects of the Corminaty vaccine in a real-life outbreak situation and to obtain insights into the antibody response to both vaccination and breakthrough infection. Methods: the antibody status of 106 fully vaccinated individuals (54/106 breakthrough infections) and epidemiological data on all 150 residents and facility staff were evaluated. Results: SARS-CoV-2 infections (positive RT-qPCR) were detected in 56.9% (n = 70/123) of fully vaccinated, compared to 100% (n = 27/27) of incompletely or non-vaccinated individuals. The proportion of hospitalized and deceased was 4.1% (n = 5/123) among fully vaccinated and therewith lower compared to 18.5% (n = 5/27) hospitalized and 11.1% (n = 3/27) deceased among incompletely or non-vaccinated. Ct values were significantly lower in incompletely or non-vaccinated ($p = 0.02$). Neutralizing antibodies were detected in 99.1% (n = 105/106) of serum samples with significantly higher values ($p < 0.001$) being measured post-breakthrough infection. Î±-N-antibodies were detected in 37.7% of PCR positive but not in PCR negative individuals. Conclusion: Altogether, our data indicate that SARS-CoV-2 vaccination does provide protection against infection, severe disease progression and death with regards to the Alpha variant. Nonetheless, it also shows that infection and transmission are possible despite full vaccination. It further indicates that breakthrough infections can significantly enhance Î±-S- and neutralizing antibody responses, indicating a possible benefit from booster vaccinations.

Immune Checkpoint Inhibitor-Induced Myocarditis vs. COVID-19 Vaccine-Induced Myocarditis-Same or Different? Immune checkpoint inhibitor (ICI) and coronavirus disease 2019 (COVID-19) vaccine-induced myocarditis possibly share common mechanisms secondary to overactivation of the immune system. We aimed to compare the presenting characteristics of ICIs and COVID-19 vaccine-induced myocarditis. We performed a retrospective analysis of characteristics of patients diagnosed with either ICIs or COVID-19 vaccine-induced myocarditis and compared the results to a control group of patients diagnosed with acute viral myocarditis. Eighteen patients diagnosed with ICIs (ICI group) or COVID-19 vaccine (COVID-19 vaccine group)-induced myocarditis, and 20 patients with acute viral myocarditis (Viral group) were included. The ICI group presented mainly with dyspnea vs. chest pain and fever among the COVID-19 vaccine and Viral groups. Peak median high sensitivity Troponin I was markedly lower in the ICI group (median 619 vs. 15,527 and 7388 ng/L, $p = 0.004$). While the median

left ventricular (LV) ejection fraction was 60% among all groups, the ICI group had a lower absolute mean LV global longitudinal strain (13%) and left atrial conduit strain (17%), compared to the COVID-19 vaccine (17% and 30%) and Viral groups (18% and 37%), p = 0.016 and p = 0.001, respectively. Despite a probable similar mechanism, ICI-induced myocarditis's presenting characteristics differed from COVID-19 vaccine-induced myocarditis.

Easy Scheme Outlining the Various Morphological and Vascular Abnormalities of the Lymph Node Structure Associated with Recent COVID-19 Vaccination, Each with a Different Clinical/Diagnostic Management. Throughout this recent ongoing SARS-CoV-2 pandemic, the European Society of Breast Imaging have surely contributed in improving the management of unilateral axillary adenopathy appearance homolaterally to the side of vaccine inoculation. After considering the patient's COVID-19 history of vaccination, our group produced a day-to-day scheme that evaluates meticulously the probability of mammary malignancy, according to the lymph node characteristics including vascular abnormalities. It comprises of a UN (ultrasound node) score ranging from 2 to 5, that increases with the suspicion of malignancy. In this setting and in view of the additional incoming COVID-19 boost-dose vaccinations, we believe our model could be of great utility to radiologist when assessing patients whom do not have a straight forward diagnosis, in order to reduce breast cancer missed diagnosis, avoid delaying vaccinations, reduce rescheduling of breast imaging examinations and lastly avoid unnecessary lymph node biopsies.

The Limited Effect of a History of COVID-19 on Antibody Titers and Adverse Reactions Following BNT162b2 Vaccination: A Single-Center Prospective Study. Background and Objectives: The need for, and ideal frequency of, the vaccination against coronavirus disease 2019 (COVID-19) of previously infected individuals have not yet been sufficiently evaluated. The aim of this study was to examine the anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody status and adverse reactions after vaccination among medical staff with or without a history of COVID-19. Materials and Methods: A single-center prospective study was performed at Fukuoka University Chikushi Hospital. We investigated the presence of the anti-SARS-CoV-2 antibody titer among medical staff before and after mRNA vaccination with the BNT162b2. The levels of immunoglobulin G antibody were quantitatively measured at six points-before vaccination, after the first vaccination, at three points after the second vaccination, and finally, after the third vaccination-and the levels were then compared based on the COVID-19 infection history. Results: The previously infected (before the first vaccination) subjects (n = 17) showed a marked increase in antibody titers two weeks after the first vaccination and four weeks after the second vaccination. Although they were able to maintain a certain level of antibody titers until 30 weeks after the second vaccination, the titers fell in the same way as observed in the non-infected subjects. The subjects who did not receive the third vaccination due to adverse reactions to previous vaccines (n = 1) or who were positive for COVID-19 prior to the third vaccination (n = 2) were excluded from the subsequent analyses. Among non-infected subjects (n = 36), smokers had lower peak antibody titers than the others. The previously infected subjects had a significantly higher incidence of adverse reactions after the first vaccination but had a similar incidence of adverse reactions after the second and third vaccinations compared to the non-infected subjects. Conclusions: A history of COVID-19 may influence only the initial increase in anti-SARS-CoV-2 antibody titers and the occurrence of adverse reactions after the first vaccination.

Metabolic and Proteomic Profiles Associated with Immune Responses Induced by Different Inactivated SARS-CoV-2 Vaccine Candidates. Since the emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in late 2019, the virus has been mutating continuously, resulting in the continuous emergence of variants and creating challenges for epidemic prevention and control. Here, we immunized mice with different vaccine candidates, revealing the immune, protein, and metabolomic changes that take place in vaccines composed of different variants. We

found that the prototype strain and Delta- and Omicron-variant inactivated vaccine candidates could all induce a high level of neutralizing antibodies and cellular immunity responses in mice. Next, we found that the metabolic and protein profiles were changed, showing a positive association with immune responses, and the level of the change was distinct in different inactivated vaccines, indicating that amino acid variations could affect metabolomics and proteomics. Our findings reveal differences between vaccines at the metabolomic and proteomic levels. These insights provide a novel direction for the immune evaluation of vaccines and could be used to guide novel strategies for vaccine design.

Two-Dose Vaccination Significantly Prolongs the Duration from Symptom Onset to Death: A Retrospective Study Based on 173,894 SARS-CoV-2 Cases in Khyber Pakhtunkhwa, Pakistan. This research was carried out to quantify the duration from symptom onset to recovery/death (SOR/SOD) during the first four waves and the Alpha/Delta period of the epidemic in Khyber Pakhtunkhwa, Pakistan, and identify the associated factors. A total of 173,894 COVID-19 cases were admitted between 16 March 2020 and 30 November 2021, including 458 intensive care unit (ICU) cases. The results showed that the case fatality rate (CFR) increased with age, and females had a higher CFR. The median SOR of ICU cases was longer than that of non-ICU cases (27.6 vs. 17.0 days), while the median SOD was much shorter (6.9 vs. 8.4 days). The SOR and SOD in the Delta period were slightly shortened than the Alpha period. Age, cardiovascular diseases, chronic lung disease, diabetes, fever, breathing issues, and ICU admission were risk factors that were significantly associated with SOD ($p < 0.001$). A control measure, in-home quarantine, was found to be significantly associated with longer SOD (odds ratio = 9.49, $p < 0.001$). Infected vaccinated individuals had longer SOD than unvaccinated individuals, especially for cases that had received two vaccine doses ($p < 0.001$). Finally, an advice on getting full-dose vaccination is given specifically to individuals aged 20-59 years.

Coronavirus Vaccination: Spike Antibody Levels in Health Workers after Six Months-A Cross-Sectional Study. Healthcare workers bear a high risk of infection during epidemics and pandemics such as the current SARS-CoV-2 pandemic. Various new vaccines have been approved. We investigated the influence of the time elapsed since vaccination, as well as of vaccination schema, on health workers' spike antibody levels following their second vaccination. Blood samples were obtained from employees working at a German hospital between August 2021 and December 2021 on average half a year (range 130-280 days) after their second vaccination. Levels of SARS-CoV-2-IgG antibodies (spike and nucleocapsid protein) were qualitatively detected via chemiluminescent immunoassays (CLIAs). A previous infection with SARS-CoV-2 was an exclusion criterion. In total, 545 persons were included in this cross-sectional study. Most participants (97.8%) showed elevated anti-spike concentrations. Anti-spike levels differed significantly among vaccination schemas. Repeated vector vaccinations resulted in lower protective antibody levels. Higher age levels, immunosuppression and a longer time period since the second vaccination resulted in lower anti-spike levels. Women's antibody levels were higher, but not significantly. Since anti-spike levels drop after vaccination, further boosters are required to increase immunoreactivity. If two vector vaccines have been administered, it is possible that an mRNA booster might increase the anti-spike level.

T Cell and Antibody Response Following Double Dose of BNT162b2 mRNA Vaccine in SARS-CoV-2 NaÃ¯ve Heart Transplant Recipients. Introduction: Preliminary studies have suggested a low post-vaccination antibody response against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in heart transplant(HTx)recipients. Although many studies have focused on the role of antibodies in vaccine-induced protection against SARS-CoV-2, the role of T cell immunity is less well characterized. To date, data regarding seroconversion and T cell response after mRNA SARS-CoV-2 vaccination in patients undergoing HTx are scarce. Therefore, the present study aimed to assess the specific memory humoral and cellular responses after two doses of the BNT162b2 vaccine in HTx recipients.

Methods: Blood was drawn from heart transplant (HTx) recipients at two pre-specified time points after the first and second vaccine doses to measure both the anti-SARS-CoV-2 antibody response against the spike protein and the SARS-CoV-2-reactive T cell response. Results: Our study included 34 SARS-CoV-2 naÃ¯ve HTx recipients (mean age, 61 Â± 11 years). The mean time from transplantation to the first vaccine dose is 10 Â± 10 years. Subgroup analysis (n = 21) demonstrated that after the first vaccine dose, only 14% had antibodies and 19% had a SARS-CoV-2-reactive T-cell response, which increased to 41% and 53%, respectively, after the second dose. Interestingly, 20% of patients with no antibodies after the second dose still had a positive SARS-CoV-2-reactive T cell response. The percentage of patients with positive S-IgG antibody titers was significantly higher 5 years after transplantation (18% 0-5 years post-TX vs. 65% 5 years post-TX, p = 0.013). Similarly, 5 years after heart transplantation, the percentage of patients with a T cell response was significantly higher (35% 0-5 years post-TX vs. 71% 5 years post-TX, p = 0.030). Conclusions: In SARS-CoV-2 naÃ¯ve HTx recipients, post-vaccination antibody titers but also SARS-CoV-2 specific T cell response are low. Therefore, the protection from SARS-CoV-2 that is generally attributed to vaccination should be regarded with caution in HTx recipients.

Sudden Sensorineural Hearing Loss after Third Dose Booster of COVID-19 Vaccine Administration. Coronavirus disease 2019 (COVID-19) was declared a pandemic due to its rapid spread worldwide, and its vaccination campaign is considered one of the most historic public hygiene measures in modern medicine. Sudden sensorineural hearing loss (SSHL) is a common emergency that affects patient's quality of life and requires rapid treatment with steroids. The etiology could be viral or vascular even though in most cases it remains unknown (idiopathic SSHL). During the SARS-CoV-2 vaccination campaign, several rare but serious adverse events have been reported including thrombosis with thrombocytopenia syndrome, myocarditis, and Guillain-BarrÃ© Syndrome. ENT adverse events after vaccination were reported too, including cases of sudden sensorineural hearing loss (SSHL), vestibular neuronitis and audio vestibular disorders (such as tinnitus, dizziness, and vertigo). For the first time here, we reported two cases of SSHL after third administration of COVID-19 mRNA vaccine. Even if there is not clear evidence of an association between SSHL and vaccination, adverse effects should be kept in mind since viral infection could be the etiology of SSHL.

Immune Profiling Uncovers Memory T-Cell Responses with a Th17 Signature in Cancer Patients with Previous SARS-CoV-2 Infection Followed by mRNA Vaccination. It is unclear whether patients with cancer present inherently impaired responses to COVID-19 and vaccination due to their treatments, neoplastic diseases or both. To address this question, immune profiling was performed in three cohorts of healthy donors and oncologic patients: infected with SARS-CoV-2, BNT162b2-vaccinated, and with previous COVID-19 disease and subsequently vaccinated. Cancer patients showed good antibody responses to vaccination, but poor induction of T-cell responses towards the S protein when compared to infection. Following natural infection, the major targets for T-cells were the SARS-CoV-2 structural proteins M and S, but not the N protein. Similar to antibody titers, the T-cell responses quickly decayed after six months post-vaccination. Significant memory T-cell expansion was observed in vaccinated donors only if previously diagnosed with COVID-19 before undergoing vaccination. Oncologic patients with previous COVID-19 followed by vaccination exhibited potent IL-17+ CD4 and CD8 T-cell responses and elevated numbers of circulating neutrophils in peripheral blood.

Antibody response 6 months after the booster dose of Pfizer in previous recipients of CoronaVac. The most widely used vaccines were messenger RNA (mRNA), viral vector, and inactivated virus with two-dose schedules. In Brazil, the CoronaVac (Sinovac) was the first vaccine approved for emergency use, and the third dose was administered, preferably, with the BNT162b2 vaccine. We evaluated antibody levels after 6 months of the booster dose with BNT162B2 in previous recipients of

CoronaVac and whether a subsequent severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) infection enhances the antibody response. We analyze the humoral responseÂ (spike [S] IgM for the SARS-CoV-2Â and IgG for the SÂ and nucleocapsid [N] proteins) in samples collected before the third dose and 6 months after the third dose. The presence of antibodies was measured by using Abbott Architect i2000SR. The IgM and IgG antispikes were stimulated mainly 30 days after the third dose (30d/3D),Â with a decline over time. The IgG anti-N was stimulated predominantly in 90d/3D and 180d/3D. The N IgG levels were 50 and 35 times higher in the positive polymerase chain reaction (PCR) group in 90d/3D and 180d/3D, respectively. The S IgG titers were 1.5 times elevated in the positive PCR group, in 180d/3D. The BNT162b2 boosted the S IgG levels, decreasing after 60 days. The booster shot induced IgM and IgG antibodies against spike protein. Infection after vaccination increased antibodies against protein N.

The impact of COVID-19 vaccines on fertility-A systematic review and meta-analysis. BACKGROUND: Despite literature's evidence about COVID-19 vaccines' safety, concerns have arisen regarding adverse events, including the possible impact on fertility, accentuated by misinformation and anti-vaccine campaigns. The present study aims to answer the question: Is there any impact of COVID-19 vaccines on the fertility of men and women of reproductive age? METHODS: PubMed, Scopus, Web of Science, Cochrane and Embase databases were searched for eligible studies until June 8th, 2022. The search was restricted to articles regarding humans, published in any languages, without additional restrictions. Studies' quality was assessed by the Newcastle-Ottawa and the Before and After Quality Assessment scales for cohort and pre-post studies, respectively. Random-effect meta-analyses were performed for parameters considered inÂ â‰¥Â 2 studies, calculating means, p-values and 95Â % Confidence Intervals (CIs). RESULTS: Out of 1406 studies screened, 29 were included in the systematic review. These studies, conducted in Israel (34.5Â %), USA (24.1Â %), Russia (20.7Â %) China (10.3Â %), Italy (3.5Â %), North America (3.5%) and Turkey (3.5Â %) were of poor (34.5Â %), moderate (58.6Â %) and good (6.9Â %) quality. Meta-analyses were performed for pre- and post-vaccination sperm progressive motility (44Â %, 95Â % CI 42Â %-62Â % vs 43Â %, 95Â % CI 31Â %-59Â % pÂ =Â 0.07) and concentration (50.6 mln/ml, 95Â % CI 35.1-72.8 vs 55.4 mln/ml, 95Â % CI 37.4-82.2pÂ =Â 0.12). Biochemical (0.51, 95Â % CI 0.40-0.66 vs 0.60, 95Â % CI 0.53-0.68pÂ =Â 0.45) and clinical (0.45, 95Â % CI 0.37-0.54 vs 0.47, 95Â % CI 0.40-0.55 pÂ =Â 0.31) pregnancy rate did not differ among vaccinated and not vaccinated groups. Subgroup meta-analyses based on the type of vaccine showed no significant difference: between vaccinated with mRNA vaccines and non-vaccinated regarding biochemical pregnancy rates; pre- and post-vaccination with Gam-COVID-Vac regarding testosterone, FSH and LH levels; pre- and post-vaccination with BNT162b2 vaccines regarding sperm volumes. CONCLUSION: Based on the studies published so far, there is no scientific proof of any association between COVID-19 vaccines and fertility impairment in men or women.

Psychological and situational factors associated with COVID-19 vaccine intention among postpartum women in Pakistan: a cross-sectional study. OBJECTIVES: Contributing factors to COVID-19 vaccination intention in low-income and middle-income countries have received little attention. This study examined COVID-19-related anxiety and obsessive thoughts and situational factors associated with Pakistani postpartum women's intention to get COVID-19 vaccination. DESIGN: Cross-sectional study administering a survey by a telephone interview format between 15 July and 10 September 2020. SETTING: Four centres of Aga Khan Hospital for Women and Children-Garden, Kharadar, Karimabad and Hyderabad-in Sindh Province, Pakistan. PARTICIPANTS: Women who were enrolled in our longitudinal Pakistani cohort study were approached (n=1395), and 990â€‰women (71%) participated in the survey, of which 941â€‰women who were in their postpartum period were included in the final analysis. PRIMARY OUTCOME MEASURE AND FACTORS: COVID-19 vaccine intention, sociodemographic and COVID-19-related factors, Coronavirus anxiety, obsession with

COVID-19 and work and social adjustment were assessed. Multiple multinomial logistic regression analysis was used to identify factors associated with women's intentions. RESULTS: Most women would accept a COVID-19 vaccine for themselves (66.7%). Only 24.4% of women were undecided about vaccination against COVID-19, and a small number of women rejected the COVID-19 vaccine (8.8%). Women with primary education were less likely to take a COVID-19 vaccine willingly than those with higher education. COVID-19 vaccine uncertainty and refusal were predicted by having no experience of COVID-19 infection, childbirth during the pandemic, having no symptoms of Coronavirus anxiety and obsession with COVID-19. Predictors for women's intention to vaccinate themselves and their children against COVID-19 were similar. CONCLUSION: Understanding the factors shaping women's intention to vaccinate themselves or their children would enable evidence-based strategies by healthcare providers to enhance the uptake of the COVID-19 vaccine and achieve herd immunity against Coronavirus.

Livedoid skin reaction to 2nd dose of mRNA Covid-19 vaccine. Skin often represents a target organ for adverse drug reactions and this also applies to the mRNA vaccines against Sars-CoV-2. Here we present a case of extensive livedoid reaction after 2nd dose of BNT162b-2 vaccine with massive blood skin extravasation and no systemic symptoms apart from anemization. The 30-year-old woman developed progressively enlarging livedoid lesions on limbs and abdomen. Histology showed a near-normal epidermis and a very mild interstitial mixed inflammatory infiltrate with extensive blood extravasation in mid- and deep dermis. Diagnosis was adverse reaction to vaccine with skin capillary hyperpermeability and anaemization with lower than diagnostic features of cutaneous small vessel vasculitis. To date, no cases of a livedoid skin reaction associated to Covid-19 vaccine have been reported, and this case illustrates that massive livedoid reaction can be another kind of skin reaction to mRNA Covid-19 vaccine.

Increased FluoroDeoxyGlucose (FDG) Avidity Following COVID-19 Vaccination. A 65-year-old woman presented to the Pulmonary Clinic for evaluation after Positron Emission Tomography/Computed Tomography (PET/CT), which was obtained for assessment of a 12 mm right middle lobe solitary pulmonary nodule [...].

Inhibition of SARS-CoV-2 Omicron BA.1 and BA.4 Variants After Fourth Vaccination or Tixagevimab and Cilgavimab Administration in Patients With Cancer. This cohort study assesses the capacity of passive immunization and tixagevimab and cilgavimab to inhibit interaction between receptor-binding domains and angiotensin-converting enzyme 2 in patients with hemato-oncologic diseases.

Reactogenicity, safety and disease flares following BNT162b2 mRNA COVID-19 vaccine in patients with chronic immune-inflammatory arthritis treated with biological and targeted synthetic disease-modifying anti-rheumatic drugs. OBJECTIVES: The safety of COVID-19 vaccination in rheumatic patients treated with biological (b) and targeted synthetic (ts) disease-modifying anti-rheumatic drugs (DMARDs) remains poorly explored. METHODS: Reactogenicity, safety and disease flares following each of the two doses of the BNT162b2 mRNA vaccine was evaluated in 186 patients with rheumatoid arthritis, psoriatic arthritis and spondyloarthritis treated with b/tsDMARDs, who discontinued anti-rheumatic treatments around vaccination. A group of 53 healthy controls was used for comparison. RESULTS: The frequency and severity of systemic events was similar to that reported in the general population, and no particular safety concerns emerged. The use of methotrexate reduced systemic reactogenicity (adjORs [95% CI] 0.49 [0.25-0.94] and 0.63 [0.32-0.99] after each vaccine dose), whilst no specific effects of different b/tsDMARDs were seen. Flares around vaccination were reported by 24.5% of the patients. Factors associated with flares were active disease (adjORs [95% CI] 2.8 [1.01-8.09] and 1.86 [0.99-6.03] after each vaccine dose) and use of JAKi (adjORs [95% CI] 3.96 [1.39-11.27] and 3.10 [0.99-7.85]). The percentage of cases requiring change or increase in DMARD therapy due to persistent worsening of disease activity at follow-up visits was low

(3.2%). CONCLUSIONS: The safety of mRNA COVID-19 vaccination in arthritis patients on treatment with b/tsDMARDs is reassuring. In a regimen of peri-vaccine drug interruption, transient flares of the disease more commonly occur in association with active arthritis and use of shorter half-life drugs. Most flares do not require treatment escalation or change.

Restoration of Neutralization Activity Against Omicron BA.2 and BA.5 in Older Adults and Individuals With Risk Factors Following the Fourth Dose of Severe Acute Respiratory Syndrome Coronavirus 2 BNT162b2 Vaccine.

Neutralizing Immunity Induced Against the Omicron BA.1 and BA.2 Variants in Vaccine Breakthrough Infections. BACKGROUND: As of early 2022, the Omicron variants are the predominant circulating lineages globally. Understanding neutralizing antibody responses against Omicron BA.1 and BA.2 after vaccine breakthrough infections will provide insights into BA.2 infectivity and susceptibility to subsequent reinfection. METHODS: Live virus neutralization assays were used to study immunity against Delta and Omicron BA.1 and BA.2 variants in samples from 86 individuals, 24 unvaccinated (27.9%) and 62 vaccinated (72.1%), who were infected with Delta (n = 42, 48.8%) or BA.1 (n = 44, 51.2%). Among the 62 vaccinated individuals, 39 were unboosted (62.9%), whereas 23 were boosted (37.1%). RESULTS: In unvaccinated infections, neutralizing antibodies (nAbs) against the three variants were weak or undetectable, except against Delta for Delta-infected individuals. Both Delta and BA.1 breakthrough infections resulted in strong nAb responses against ancestral wild-type and Delta lineages, but moderate nAb responses against BA.1 and BA.2, with similar titers between unboosted and boosted individuals. Antibody titers against BA.2 were generally higher than those against BA.1 in breakthrough infections. CONCLUSIONS: These results underscore the decreased immunogenicity of BA.1 compared to BA.2, insufficient neutralizing immunity against BA.2 in unvaccinated individuals, and moderate to strong neutralizing immunity induced against BA.2 in Delta and BA.1 breakthrough infections.

De Novo Diagnosis of Lymphocytic Colitis After SARS-CoV-2 Vaccination. SARS-CoV-2 mRNA vaccines are safe and effective for most patients. Gastrointestinal complications reported after vaccination have included gastroparesis and inflammatory bowel disease flares. In this study, we present a unique case of lymphocytic colitis that occurred in a healthy middle-aged man after Moderna SARS-CoV-2 mRNA vaccination. This reveals an unexpected complication of a mRNA vaccine that presented as worsening diarrhea after vaccination in a dose-dependent pattern. Caregivers should be aware of lymphocytic colitis as a possible complication of the Moderna vaccine and monitor those patients closely for symptom resolution.

Safety monitoring in inactivated COVID-19 vaccines by clinical pharmacists from a single center in China. Given that vaccine-induced adverse effects were mostly based on previous laboratory research and clinical trials, real-world data on the safety of coronavirus disease 2019 (COVID-19) vaccination were lacking. This study reported the adverse events (AEs) among inactivated COVID-19 vaccine recipients. Data were collected from a total of 2,808 hospital employees and their family members in Wuhan, China, with all of them receiving the first dose of inactivated COVID-19 vaccines from two pharmaceutical companies. The first dose was given between 29th April and 13th May 2021.Â A total of 2,732 vaccinees received the second dose between 27th May and 8th July 2021. The whole process of receiving the vaccine was monitored by clinical pharmacists, and the information on AEs including demographics, occurrence, types, and severity was recorded through an online questionnaire and telephone follow-up. Most of the common AEs were mild and tolerable, and the overall incidence of AEs was lower than the data from the safety profile in clinical trials. Moreover, the incidence of AEs in the first dose (21.30%, 598) was higher than that in the second dose (16.07%, 439). Furthermore, the first injection had more severe AEs (4, 0.14%) than the second injection (2, 0.07%). The AEs involved the skin, muscle, respiratory tract, gastrointestinal tract, cardiovascular

system, and other tissues and systems. The most common AE was pain at the injection site (first dose: 10.19%, second dose: 12.55%). All the vaccinees with AEs for both doses recovered fully in the end. It was noted that some AEs might cause blood coagulation disorder and bleeding risk. Therefore, ongoing monitoring of AEs after COVID-19 vaccination is essential in evaluating the benefits and risks of each vaccine.

Vaccine-induced binding and neutralizing antibodies against Omicron 6 months after a homologous BNT162b2 booster. Evidence about the long-term persistence of the booster-mediated immunity against Omicron is mandatory for pandemic management and deployment of vaccination strategies. A total of 155 healthcare professionals (104 COVID-19 naive and 51 with a history of SARS-CoV-2 infection) received a homologous BNT162b2 booster. Binding antibodies against the spike protein and neutralizing antibodies against Omicron were measured at several time points before and up to 6 months after the booster. Geometric mean titers of measured antibodies were correlated to vaccine efficacy (VE) against symptomatic disease. Compared to the highest response, a significant 10.2- and 11.5-fold decrease in neutralizing titers was observed after 6 months in participants with and without history of SARS-CoV-2 infection. A corresponding 2.5- and 2.9-fold decrease in binding antibodies was observed. The estimated T(1/2) of neutralizing antibodies in participants with and without history of SARS-CoV-2 infection was 42 (95% confidence interval [CI]: 25-137) and 36 days (95% CI: 25-65). Estimated T(1/2) were longer for binding antibodies: 168 (95% CI: 116-303) and 139 days (95% CI: 113-180), respectively. Both binding and neutralizing antibodies were strongly correlated to VE (râ€‰=â€‰0.83 and 0.89). However, binding and neutralizing antibodies were modestly correlated, and a high proportion of subjects (36.7%) with high binding antibody titers (i.e., >8434â€‰BAU/ml) did not have neutralizing activity. A considerable decay of the humoral response was observed 6 months after the booster, and was strongly correlated with VE. Our study also shows that commercial assays available in clinical laboratories might require adaptation to better predict neutralization in the Omicron era.

SARS-CoV-2 vaccination and new-onset myasthenia gravis: A report of 7 cases and review of the literature. Myasthenia gravis (MG) is an antibody-mediated immune disorder of the neuromuscular junction. SARS-CoV-2 is now recognised as a trigger factor for autoimmune diseases and to cause immune-mediated dysregulation, likely due to molecular mimicry induced by viral antigens. SARS-CoV-2 vaccination, similarly, results in exposure to viral antigen. Here we report 7 cases of new-onset myasthenia gravis in timely association with SARS-CoV-2 vaccination, including the first paediatric case identified to date. We also reviewed the literature for other new-onset MG cases reported within 4 weeks of SARS-CoV-2 vaccination and discuss our findings in the context of altered (auto)immunity following SARS-CoV-2 vaccination and/or infection.

Distinct Clinical Features of Post-COVID-19 Vaccination Early-onset Graves' Disease. CONTEXT: Several case reports of Graves' disease (GD) occurrence after COVID-19 vaccination that are possibly related to the autoimmune syndrome induced by adjuvants (ASIA) were published recently. OBJECTIVE: The aim of our study was to evaluate possible distinctive features in the presentation and clinical course of patients with GD occurring early (within 4 weeks) after COVID-19 vaccination who attended our Endocrine Unit in 2021. METHODS: Patients with a first episode of GD attending a tertiary endocrine center between January 1, 2021, and December 31, 2021, were included. RESULTS: Sixty-four patients with a first episode of GD were seen in 2021: 20 (31.2%) of them had onset within 4 weeks following vaccine administration. Compared with the other 44 patients, the 20 patients with postvaccine early-onset (PoVEO) GD were older (median age 51 years vs 35 years, P = .003) and more likely to be male (40.0% vs 13.6%, P = .018). At diagnosis, the biochemical and immune profiles were similar between the 2 groups. However, at 3 months after starting methimazole, patients with PoVEO GD had significantly lower thyrotropin receptor antibody titer and were taking lower doses of

methimazole than the other patients with GD. None in the PoVEO group had sustained free triiodothyronine elevation. CONCLUSION: This relatively large series suggests that in 2021 PoVEO GD may be a new nosologic entity representing one-third of patients evaluated for new-onset GD in our center. Distinctive features included older age at onset, higher male prevalence, and a better initial biochemical and immunologic response to treatment. Further studies are warranted to clinically and biochemically differentiate these cases from sporadically occurring GD.

Associations of Immunogenicity and Reactogenicity After Severe Acute Respiratory Syndrome Coronavirus 2 mRNA-1273 Vaccine in the COVE and TeenCOVE Trials. BACKGROUND: The reactogenicity and immunogenicity of coronavirus disease 2019 (COVID-19) vaccines are well studied. Little is known regarding the relationship between immunogenicity and reactogenicity of COVID-19 vaccines. METHODS: This study assessed the association between immunogenicity and reactogenicity after 2 mRNA-1273 (100 Âµg) injections in 1671 total adolescent and adult participants (â‰¥12 years) from the primary immunogenicity sets of the blinded periods of the Coronavirus Efficacy (COVE) and TeenCOVE trials. Associations between immunogenicity through day 57 and solicited adverse reactions (ARs) after the first and second injections of mRNA-1273 were evaluated among participants with and without solicited ARs using linear mixed-effects models. RESULTS: mRNA-1273 reactogenicity in this combined analysis set was similar to that reported for these trials. The vaccine elicited high neutralizing antibody (nAb) geometric mean titers (GMTs) in evaluable participants. GMTs at day 57 were significantly higher in participants who experienced solicited systemic ARs after the second injection (1227.2 [1164.4-1293.5]) than those who did not (980.1 [886.8-1083.2], P = .001) and were associated with fever, chills, headache, fatigue, myalgia, and arthralgia. Significant associations with local ARs were not found. CONCLUSIONS: These data show an association of systemic ARs with increased nAb titers following a second mRNA-1273 injection. While these data indicate systemic ARs are associated with increased antibody titers, high nAb titers were observed in participants after both injections, consistent with the immunogenicity and efficacy in these trials. These results add to the body of evidence regarding the relationship of immunogenicity and reactogenicity and can contribute toward the design of future mRNA vaccines.

IL-1RA Antibodies in Myocarditis after SARS-CoV-2 Vaccination.

External Supports Are Associated With the COVID-19 Vaccination in Chinese Breast Cancer Patients: A Cross-Sectional Survey. BACKGROUND: Coronavirus disease 2019 (COVID-19) is a global pandemic. Breast cancer is the most commonly diagnosed malignant cancer in China. Considering the specific national conditions, no evidence is available for factors associated with COVID-19 vaccination in patients with breast cancer. METHODS: This was a cross-sectional survey, fielded from June 21 through June 27, 2021. A total of 944 nationally representative samples of Chinese breast cancer patients participating in the survey were included. Participant surveys included questions addressing who finished COVID-19 vaccination with the question "Have you taken the COVID-19 vaccine?", and response options were "Yes" and "No". RESULTS: Overall, 730 (77.33%) women with breast cancer were unvaccinated, and only 214 (22.67%) were vaccinated with the COVID-19 vaccine. After adjusting for potential confounders, including both sociodemographic and clinical characteristics, we found that external support, including positive doctor suggestions (odds ratio (OR): 5.52; 95% confidence interval (CI): 3.50 - 8.71; P < 0.0001), positive support from surrounding people (OR: 11.65; 95% CI: 7.57 - 17.91; P < 0.0001), and negative initiative from the community (OR: 0.15; 95% CI: 0.06 - 0.35; P < 0.0001), was associated with COVID-19 vaccination rates among breast cancer patients. These results remain stable in subgroup analyses. We found that most participants (82.52%) understood the necessity of COVID-19 vaccinations in China was strong; however, the recognition regarding the COVID-19 vaccine showed different patterns between vaccinated and unvaccinated participants. CONCLUSIONS: Our findings suggest external support, including vaccination suggestions

from surgeons or oncologists, vaccination suggestions from associated people, and residents' committee mandated vaccinations, was associated with the COVID-19 vaccination rates. Interventions regarding these factors and improving publicity as well as education regarding COVID-19 vaccines among breast cancer patients are warranted.

Serial Changes in Troponin I in COVID-19 Vaccine-Associated Myocarditis. A 63-year-old woman presented with atypical chest pain after a third dose of the coronavirus disease 2019 (COVID-19) messenger ribonucleic acid (mRNA) vaccine. Serial cardiac troponin measurements were performed to evaluate the trajectory of her time-concentration curve which showed a typical myocarditis curve with rapid normalization. The diagnosis of myocarditis was confirmed by cardiac magnetic resonance imaging and follow-up imaging showed resolution. All symptoms resolved with weeks.

Ad26.COV2.S Vaccine-Induced Thrombocytopenia Leading to Dural Sinus Thrombosis and Intracranial Hemorrhage Requiring Hemicraniectomy: A Case Report and Systematic Review. The coronavirus disease 2019 (COVID-19) pandemic has claimed nearly 5.5 million lives worldwide. Adenovirus-based vaccines are safe and effective, but they are rarely associated with vaccine-induced thrombosis and thrombocytopenia (VITT) as well as cerebral venous sinus thrombosis (CVST). We conducted a systematic literature search of intracerebral hemorrhage (ICH) secondary to CVST associated with VITT from the Ad26.COV2.S vaccine, and we present the first case of this pathology in the reviewed literature of a patient who required neurosurgical decompression. The systematic literature review was completed on December 19, 2021, by searching PubMed and Ovid for articles with primary data on CVST associated with VITT following the Ad26.COV2.S vaccine. We also specifically searched for cases that required neurosurgical intervention. Articles were independently screened by two authors, and both secondary and tertiary searches were done as well. Descriptive statistics were collected and presented in table form.Â Nine studies were identified that met inclusion criteria. There were no cases identified of patients who underwent neurosurgical decompression after developing this pathology. We thus present the first case in the reviewed literature of a patient who developed ICH after receiving the Ad26.COV2.S vaccine and underwent decompressive hemicraniectomy.Â Despite severe thrombocytopenia and prolonged intensive care, the patient was discharged to neurorehabilitation.Â There is a much greater risk of CVST and ICH during COVID-19 infections than from the vaccines. However, as booster vaccines are approved and widely distributed, it is critical to make prompt, accurate diagnoses of this vaccine-related complication and consider neurosurgical decompression.

Bilateral Axillary Nodal Uptake on 99m Tc-White Blood Cell Study Secondary to COVID-19 mRNA Vaccination. A 77-year-old man with a history of chronic lower back pain, and prior spinal fusion surgery X2 was referred for 99m Tc-WBC Study for evaluation of worsening back pain and cervical radiculopathy to rule out any signs of infection. The patients white blood cells were tagged with 99m Tc-HMPAO (hexamethylpropylene amine oxime), and planar and SPECT/CT imaging was performed at 4 and 24 hours. 99m Tc-WBC Study showed no abnormal isotope localization in the spine; however, there was an incidental finding of bilateral increased soft tissue uptake in axillary lymph nodes. Medical history revealed intramuscular injection of second and third dose of Moderna mRNA COVID-19 vaccine in bilateral deltoids approximately 11 and 5 months before scan.

Humoral immunity induced by mRNA COVID-19 vaccines in Nursing Home Residents previously infected with SARS-CoV-2. BACKGROUND: Nursing home (NH) residents suffered the greatest impact of the COVID-19 pandemic. Limited data are available on vaccine-induced immunity and on the protection ensured by a prior infection in this population. AIMS: The present study aims to monitor antibody levels and their persistence over a 6-month period in NH residents according to the history of prior SARS-CoV-2 infection. METHODS: We measured anti-trimeric Spike IgG antibody levels in a sample of 395 residents from 25 NHs in 6 Italian Regions at study enrolment (prior to the first

dose of vaccine, T0) and then after 2 (T1) and 6Â months (T2) following the first vaccine dose. All participants received mRNA vaccines (BNT162b2 or mRNA-1273). Analyses were performed using log-transformed values of antibody concentrations and geometric means (GM) were calculated. RESULTS: Superior humoral immunity was induced in NH residents with previous SARS-CoV-2 infection. (T0: GM 186.6 vs. 6.1 BAU/ml, pâ€‰<â€‰0.001; T1: GM 5264.1 vs. 944.4 BAU/ml, pâ€‰<â€‰0.001; T2: GM 1473.6 vs. 128.7 BAU/ml, pâ€‰<â€‰0.001). Residents with prior SARS-CoV-2 infection receiving two vaccine doses presented significantly higher antibody concentration at T1 and T2. A longer interval between previous infection and vaccination was associated with a better antibody response over time. DISCUSSION: In a frail sample of NH residents, prior SARS-CoV-2 infection was associated with a higher humoral response to vaccination. Number of vaccine doses and the interval between infection and vaccination are relevant parameters in determining humoral immunity. CONCLUSIONS: These findings provide important information to plan future immunization policies and disease prevention strategies in a highly vulnerable population.

Ad5-nCoV booster and Omicron variant breakthrough infection following two doses of inactivated vaccine elicit comparable antibody levels against Omicron variants. Little information is available for antibody levels against SARS-CoV-2 variants of concern induced by Omicron breakthrough infection and a third booster with an inactivated vaccine (InV) or Ad5-nCoV in people with completion of two InV doses. Plasma was collected from InV pre-vaccinated Omicron-infected patients (OIPs), unvaccinated OIPs between 0 and 22 days, and healthy donors (HDs) 14 days or 6 months after the second doses of an InV and 14 days after a homogenous booster or heterologous booster of Ad5-nCoV. Anti-Wuhan-, Anti-Delta-, and Anti-Omicron-receptor binding domain (RBD)-IgG titers were detected using enzyme-linked immunosorbent assay. InV pre-vaccinated OIPs had higher anti-Wuhan-, anti-Delta-, and anti-Omicron-RBD-IgG titers compared to unvaccinated OIPs. Anti-Wuhan-RBD-IgG titers sharply increased in InV pre-vaccinated OIPs 0-5 days postinfection (DPI), while the geometric mean titers (GMTs) of anti-Delta- and anti-Omicron-RBD-IgG were 3.3-fold and 12.0-fold lower. Then, the GMT of anti-Delta- and anti-Omicron-RBD-IgG increased to 35 112 and 28 186 during 11-22 DPI, about 2.6-fold and 3.2-fold lower, respectively, than the anti-Wuhan-RBD-IgG titer. The anti-Wuhan-, anti-Delta-, and anti-Omicron-RBD-IgG titers declined over time in HDs after two doses of an InV, with 25.2-fold, 5.6-fold, and 4.5-fold declination, respectively, at 6 months relative to the titers at 14 days after the second vaccination. Anti-Wuhan-, anti-Delta-, and anti-Omicron-RBD-IgG titers elicited by a heterologous Ad5-nCoV booster were significantly higher than those elicited by an InV booster, comparable to those in InV pre-vaccinated OIPs. InV and Ad5-nCoV boosters could improve humoral immunity against Omicron variants. Of these, the Ad5-nCoV booster is a better alternative.

COVID vaccine-induced immune thrombotic thrombocytopenia: Rare but relevant.

Change in COVID19 outbreak pattern following vaccination in long-term care facilities in Flanders, Belgium. INTRODUCTION: Long term care facilities for elderly (LTCFs) in Europe encountered a high disease burden at the start of the COVID-19 pandemic. Therefore, these facilities were the first to receive COVID-19 vaccines in many European countries. A limited COVID-19 vaccine supply early 2021 resulted in a majority of residents and healthcare workers (HCWs) in LTCFs being vaccinated compared to a minority in the general population. This study exploits this imbalance to assess the efficiency of COVID-19 vaccination in containing outbreaks in LTCFs. METHODS: Exploratory statistics were performed using data from a COVID-19 surveillance system covering all 842 LTCFs in Flanders (the northern region of Belgium). The number and size of COVID-19 outbreaks in LTCFs were compared (1) before and after introducing vaccines and (2) with the status of the pandemic in the general population. Based on individual data from 15 LTCFs, the infection rate and symptoms of vaccinated and unvaccinated residents and HCWs were compared during a COVID-19 outbreak.

RESULTS: 95.8% of the residents and 90.9% of the HCWs in Flemish LTCFs were vaccinated before May 30, 2021. Before vaccine introduction, residents in LTCFs were 10 times more likely to test positive for COVID-19 than the general population of Flanders. This ratio reversed after vaccination. Furthermore, after vaccination fewer and shorter outbreaks were observed involving fewer residents. During these outbreaks, vaccinated and unvaccinated residents were equally likely to test positive, but positive vaccinated residents were less likely to develop severe symptoms. In contrast, unvaccinated HCWs were more likely to test positive. CONCLUSION: In the first half of 2021, two-dose vaccination was highly efficient in preventing and containing outbreaks in LTCFs, reducing COVID-19 hospitalizations and deaths. The high likelihood of unvaccinated HCWs to be involved in COVID-19 outbreaks in vaccinated LTCFs emphasizes the importance of vaccinating HCWs.

Immunogenicity and safety of third-dose mRNA COVID-19 vaccines in healthy adults previously vaccinated with two doses of the ChAdOx1 vaccine. BACKGROUND/PURPOSE: The efficacy and safety of coronavirus disease 2019 (COVID-19) booster vaccines remain limited. We investigated the immunogenicity and adverse events of the third dose of mRNA vaccines in healthy adults. METHODS: Volunteers vaccinated with two doses of the adenoviral vaccine (ChAdOx1) 12 weeks before were administered with an mRNA COVID-19 vaccine. These were divided into three groups, full-dose mRNA-1273 (group 1); half-dose mRNA-1273 (group 2); and full-dose BNT-162b2 (group 3). Primary outcomes included serum anti-SARS-CoV-2 spike immunoglobulin G (IgG) titers and neutralizing antibody titers against B.1.1.7 (alpha), B.1.617.2 (delta), and B.1.1.529 (omicron) variants. Secondary outcomes included the evaluation of humoral and cellular immunity and vaccine-associated adverse events after the boost. RESULTS: Totally 300 participants were recruited, and 298 participants were enrolled. For all three groups, an increase in anti-SARS-CoV-2 spike IgG geometric mean titers (30.12- to 71.80-fold) and neutralizing antibody titers against the alpha variant (69.80- to 173.23-folds), delta variant (132.69- to 324.63-folds), and omicron variant (135.36- to 222.37-folds) were observed on day 28. All groups showed robust T- and B-cell responses after boosting. Adverse events were overall mild and transient but with higher prevalence and severity in group 1 participants than in other groups. CONCLUSION: Third dose mRNA COVID-19 vaccines markedly enhanced cellular and humoral responses and were safe. Immunological responses and adverse events were higher in individuals receiving the full-dose mRNA-1273 vaccine, followed by a half-dose mRNA-1273 vaccine and BNT-162b2 vaccine.

SARS-CoV-2 Vaccination Safety in Guillain-BarrÃ© Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy, and Multifocal Motor Neuropathy. BACKGROUND AND OBJECTIVES: There are concerns on the safety of SARS-CoV-2 vaccination in patients with a history of Guillain-BarrÃ© syndrome (GBS), chronic inflammatory demyelinating polyneuropathy (CIDP), and multifocal motor neuropathy (MMN). The aim of this study was to determine the risk of recurrence of GBS and exacerbations of CIDP or MMN after SARS-CoV-2 vaccination. METHODS: We conducted a prospective, multicenter cohort study from January 2021 to August 2021. Patients known in 1 of 3 Dutch University Medical Centers with research focus on immune-mediated neuropathy and members of the Dutch Patient Association for Neuromuscular Diseases were invited to participate if they were 18 years or older and diagnosed with GBS, CIDP, or MMN. Participants completed a series of questionnaires at 4 different time points: study baseline (1), within 48 hours before any SARS-CoV-2 vaccination (2 and 3, if applicable), and 6 weeks after their last vaccination (4). Participants unwilling to get vaccinated completed the last questionnaire (4) 4 months after study baseline. We assessed recurrences of GBS, any worsening of CIDP or MMN-related symptoms, treatment alterations, and hospitalization. RESULTS: Of 1,152 individuals to whom we sent the questionnaires, 674 (59%) signed informed consent. We excluded 153 individuals, most often because they had already received a SARS-CoV-2 vaccination or had had the infection (84%) before study baseline. Of

521 participants included in analyses, 403 (81%) completed the last questionnaire (time point 4). None of 162 participants with a history of GBS had a recurrence after vaccination. Of 188 participants with CIDP, 10 participants (5%) reported a worsening of symptoms within 6 weeks after vaccination. In 5 (3%) of these patients, maintenance treatment was modified. Two of 53 participants with MMN (4%) reported a worsening of symptoms, and treatment modification was reported by 1 participant. DISCUSSION: We found no increased risk of GBS recurrence and a low to negligible risk of worsening of CIDP or MMN-related symptoms after SARS-CoV-2 vaccination. Based on our data, SARS-CoV-2 vaccination in patients with these immune-mediated neuropathies seems to be safe.

Clinical onset of CNS demyelinating disease after COVID-19 vaccination: denovo disease? BACKGROUND: Clinical onset of multiple sclerosis (MS(postvacc)) and myelin-oligodendrocyte-glycoprotein-antibody-associated disease (MOGAD(postvacc)) has been reported in association with SARS-CoV-2-vaccination. There is uncertainty as to whether this is causality (denovoÂ disease) or temporal coincidence (manifestation of a preexisting, subclinical neuroinflammation). OBJECTIVES: Comparing the clinical characteristics of MS(postvacc)-patients versus patients with MS (PwMS) whose clinical onset occurred independently of vaccination (MS(reference)). METHODS: Consecutive patients with clinical onset â‰¤30 days after SARS-CoV-2-vaccination were included. Clinical data, cerebrospinal fluid (CSF) parameters and magnetic resonance imaging (MRI) as well as optical coherence tomography (OCT) data were compared to an age- and sex-matched MS(reference)-cohort. RESULTS: We identified 5 MS(postvacc)Â and 1 MOGAD(postvacc)Â patients who developed their clinical onset â‰¤ 30 days after SARS-CoV-2-vaccination. Clinical characteristics, CSF, MRI and OCT parameters from MS(postvacc)Â patients were comparable to the MS(reference)Â cohort and showed evidence of preexisting subclinical CNS disease. The single case with MOGAD(postvacc)Â clearly differed from PwMS in higher CSF cell counts, remission of MRI lesions during follow-up, and absence of oligoclonal bands. CONCLUSIONS: Our case series indicates that MS(postvacc)Â patients showed a rather typical initial manifestation in temporal association with SARS-CoV-2-vaccination and harbored preexisting subclinical neuroinflammation. This argues against theÂ denovoÂ development of MS in this cohort.

Trend of hand, foot, and mouth disease from 2010 to 2021 and estimation of the reduction in enterovirus 71 infection after vaccine use in Zhejiang Province, China. BACKGROUND: Zhejiang, ranked in the top three in HFMD (hand, foot, and mouth disease) incidence, is located in the Yangtze River Delta region of southeast China. Since 2016, the EV71 vaccine has been promoted in Zhejiang Province. This study aimed to investigate the trend and seasonal variation characteristics of HFMD from 2010 to 2021 and estimate the reduction in enterovirus 71 infection after vaccine use. METHODS: The data on HFMD cases in Zhejiang Province from January 2010 to December 2021 were obtained from this network system. Individual information on cases and deaths was imported, and surveillance information, including demographic characteristics and temporal distributions, was computed by the system. The Joinpoint regression model was used to describe continuous changes in the incidence trend. The BSTS (Bayesian structural time-series models) model was used to estimate the monthly number of cases from 2017 to 2021 based on the observed monthly incidence during 2010-2016 by accounting for seasonality and long-term trends. The seasonal variation characteristics of HFMD pathogens were detected by wavelet analysis. RESULTS: From 2010 to 2021, the annual incidence rate fluctuated between 98.81 cases per 100,000 in 2020 and 435.63 cases per 100,000 in 2018, and 1711 severe HFMD cases and 106 fatal cases were reported in Zhejiang Province, China. The annual percent change (APC) in EV71 cases was -30.72% (95% CI: -45.10 to -12.50) from 2016 to 2021. The wavelet transform of total incidence and number of cases of the three pathogens all showed significant periodicity on the 1-year scale. The average 2-year scale periodicity was significant for the total incidence, EV71 cases and Cox A16 cases, but the other enterovirus cases showed

significant periodicity on the 30-month scale. The 6-month scale periodicity was significant for the total incidence, EV71 case and Cox A16 case but not for the other enteroviruses case. The relative error percentage of the performance of the BSTS model was 0.3%. The estimated number of cases from 2017 to 2021 after the EV-A71 vaccines were used was 9422, and the reduction in the number of cases infected with the EV71 virus was 73.43% compared to 70.80% when the impact of the COVID-19 epidemic in 2020 was excluded. CONCLUSIONS: Since 2010, the incidence of EV71 infections has shown an obvious downward trend. All types of viruses showed significant periodicity on the 1-year scale. The periodicity of the biennial peak is mainly related to EV71 and Cox A16 before 2017 and other enteroviruses since 2018. The half-year peak cycle of HFMD was mainly caused by EV71 and Cox A6 infection. The expected incidence will be 2.76 times(include the cases of 2020) and 2.43 times(exclude the cases of 2020) higher than the actual value assuming that the measures of vaccination are not taken. EV71 vaccines are very effective and should be administered in the age window between 5 months and 5 years.

A narrative review of anti-SARS-CoV-2 vaccines and immune thrombocytopenia: be aware, but reassured. The COVID-19 pandemic gave rise to rapid development of anti-SARS-CoV-2 vaccines using established and new technologies. Immune thrombocytopenia (ITP) is a bleeding disorder that has been associated with COVID-19 vaccine products that are currently in use. We reviewed the available evidence regarding the most commonly used vaccines against SARS-CoV-2 in North America and Europe and their association with ITP. We found that population-based studies suggested a small increase in the incidence of ITP in persons receiving the ChAdOx1 nCoV-19 vaccine from Oxford-AstraZeneca, on the order of 6 cases per million doses administered. Severe bleeding was an even rarer event. Both messenger RNA-based and adenovirus-based vaccines have been associated with exacerbation of preexisting ITP in 6% to 20% of patients. ITP exacerbation is readily treatable with standard approaches when needed. Severe bleeding events are rare both in the general population and in persons with preexisting ITP, and overall, the benefits of vaccination outweigh the risks. Further identification of persons at the highest risk for complications (including those with ITP, vaccine-induced immune thrombotic thrombocytopenia, and myocarditis) and clear communication of both risks and benefits of immunization will continue to be paramount in the global campaign against COVID-19.

Disproportionate rate of female referrals for suspected COVID-19 vaccine allergies.

Portal vein thrombosis after second Pfizer/BioNTech coronavirus disease 2019 vaccine. We have reviewed a case of portomesenteric venous thrombosis that occurred shortly after the administration of the second Pfizer/BioNTech coronavirus disease 2019 (COVID-19) vaccine and discussed the literature surrounding the subject. Our report was generated after reviewing the patient's medical records and clinical images with his written informed consent. The literature review was conducted using PubMed and Google Scholar. Portomesenteric venous thrombosis after the Pfizer/BioNTech COVID-19 vaccine has previously been reported, although infrequently. We did not find enough information, given the paucity of the reported data, to assert a causative relationship between the Pfizer/BioNTech COVID-19 vaccine and the occurrence of portomesenteric thrombosis.

Does potential antibody-dependent enhancement occur during SARS-CoV-2 infection after natural infection or vaccination? A meta-analysis. Coronavirus disease 2019 (COVID-19) continues to constitute an international public health emergency. Vaccination is a prospective approach to control this pandemic. However, apprehension about the safety of vaccines is a major obstacle to vaccination. Amongst health professionals, one evident concern is the risk of antibody-dependent enhancement (ADE), which may increase the severity of COVID-19. To explore whether ADE occurs in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections and increase confidence in the safety of vaccination, we conducted a meta-analysis to investigate the relationship between post-

immune infection and disease severity from a population perspective. Databases, including PubMed, EMBASE, Chinese National Knowledge Infrastructure, SinoMed, Scopus, Science Direct, and Cochrane Library, were searched for articles on SARS-CoV-2 reinfection published until 25 October 2021. The papers were reviewed for methodological quality, and a random effects model was used to analyse the results. Heterogeneity was assessed using the I(2) statistic. Publication bias was evaluated using a funnel plot and Egger's test. Eleven studies were included in the final meta-analysis. The pooled results indicated that initial infection and vaccination were protective factors against severe COVID-19 during post-immune infection (ORâ€‰=â€‰0.55, 95%Clâ€‰=â€‰0.31-0.98). A subgroup (post-immune infection after natural infection or vaccination) analysis showed similar results. Primary SARS-CoV-2 infection and vaccination provide adequate protection against severe clinical symptoms after post-immune infection. This finding demonstrates that SARS-CoV-2 may not trigger ADE at the population level.
Antibody dynamics post-Comirnaty and CoronaVac vaccination in Malaysia. Several vaccines have been fast-tracked through clinical trials to mitigate the progression of the SARSâ€‘CoVâ€‘2 pandemic. We analyzed sequential blood samples from 314 recipients of Comirnaty and CoronaVac in East Malaysia for the spike-binding IgG (IgG-S), nucleocapsid-binding IgG (IgG-N), spike-binding IgM (IgM-S) and serum vitamin D (VitD). A subset of samples was analyzed for the neutralizing antibodies (Ig-RBD). Results showed that IgG-S due to Comirnaty was significantly higher than CoronaVac. IgM-S was detected in 80.0% Comirnaty and 69.5% CoronaVac recipients, while IgG-N was detected in 58.1% CoronaVac but not in Comirnaty recipients. All IgG-S-positive vaccines possessed detectable Ig-RBD after the second dose but with a weak to moderate correlation. The serum VitD levels did not influence the antibody magnitude in both vaccines. In essence, SARS-CoV-2 vaccination is an IgG-S-dominant event, Comirnaty was more effective than CoronaVac in mounting IgG-S and Ig-RBD responses, independent of the patient's VitD level.
Acute asthma exacerbation due to the SARS-CoV-2 vaccine (Pfizer-BioNTech BNT162b2 messenger RNA COVID-19 vaccine [Comirnaty(â“‡)]). The messenger RNA vaccine against SARS-CoV-2 is effective at preventing COVID-19-associated hospitalization, and the Centers for Disease Control and Prevention has recommended vaccination for all eligible individuals. We demonstrate a case involving a patient who developed a life-threatening acute asthma exacerbation after receiving their third dose of the BNT16b2 vaccine. Because eosinophilia was observed after the second inoculation, it was considered likely that the patient had been sensitized to the BNT16b2 vaccine. Theoretically, the SARS-CoV-2 vaccine could trigger the exacerbation of asthma. It should be recognized that repeated SARS-CoV-2 vaccination may be a risk factor for the acute exacerbation of asthma.
A review post-vaccination SARS-CoV-2 serological test: Method and antibody titer response. The development of the Coronavirus disease 2019 (COVID-19) vaccine is one of the most important efforts in controlling the pandemic. Serological tests are used to identify highly reactive human donors for convalescent plasma therapy, measuring vaccine efficacy and durability. This review article presents a review of serology tests and how antibody titers in response to vaccines have been developed. Some of the serological test methods discussed are Plaque Reduction Neutralization Test (PRNT), Enzyme-Linked Immunosorbent Assay (ELISA), Lateral flow immunoassay (LFIA), chemiluminescent immunoassay (CLIA), and Chemiluminescent Micro-particle Immunoassay (CMIA). This review can provide an understanding of the application of the body's immune response to vaccines to get some new strategies for vaccines.
[Myopericarditis after administration of the ComirnatyÂ© vaccine against SARS-CoV-2].
Association of COVID-19 With Major Arterial and Venous Thrombotic Diseases: A Population-Wide Cohort Study of 48 Million Adults in England and Wales. BACKGROUND: Infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) induces a prothrombotic state, but long-term

effects of COVID-19 on incidence of vascular diseases are unclear. METHODS: We studied vascular diseases after COVID-19 diagnosis in population-wide anonymized linked English and Welsh electronic health records from January 1 to December 7, 2020. We estimated adjusted hazard ratios comparing the incidence of arterial thromboses and venous thromboembolic events (VTEs) after diagnosis of COVID-19 with the incidence in people without a COVID-19 diagnosis. We conducted subgroup analyses by COVID-19 severity, demographic characteristics, and previous history. RESULTS: Among 48 million adults, 125â€‰985 were hospitalized and 1â€‰319â€‰789 were not hospitalized within 28 days of COVID-19 diagnosis. In England, there were 260â€‰279 first arterial thromboses and 59â€‰421 first VTEs during 41.6 million person-years of follow-up. Adjusted hazard ratios for first arterial thrombosis after COVID-19 diagnosis compared with no COVID-19 diagnosis declined from 21.7 (95% CI, 21.0-22.4) in week 1 after COVID-19 diagnosis to 1.34 (95% CI, 1.21-1.48) during weeks 27 to 49. Adjusted hazard ratios for first VTE after COVID-19 diagnosis declined from 33.2 (95% CI, 31.3-35.2) in week 1 to 1.80 (95% CI, 1.50-2.17) during weeks 27 to 49. Adjusted hazard ratios were higher, for longer after diagnosis, after hospitalized versus nonhospitalized COVID-19, among Black or Asian versus White people, and among people without versus with a previous event. The estimated whole-population increases in risk of arterial thromboses and VTEs 49 weeks after COVID-19 diagnosis were 0.5% and 0.25%, respectively, corresponding to 7200 and 3500 additional events, respectively, after 1.4 million COVID-19 diagnoses. CONCLUSIONS: High relative incidence of vascular events soon after COVID-19 diagnosis declines more rapidly for arterial thromboses than VTEs. However, incidence remains elevated up to 49 weeks after COVID-19 diagnosis. These results support policies to prevent severe COVID-19 by means of COVID-19 vaccines, early review after discharge, risk factor control, and use of secondary preventive agents in high-risk patients.

Longitudinal Serological Surveillance for COVID-19 Antibodies after Infection and Vaccination.
The impact of COVID-19 is still felt around the world, and more information is needed regarding infection risk, vaccination responses, and the timing of booster vaccinations. We aimed to evaluate the association of vaccination with closely followed, longitudinal antibody titers and COVID-19 infection events. We conducted a natural history study in a convenience cohort in an ambulatory research unit. We measured anti-nucleocapsid and anti-spike antibody levels every 3â€‰months for 1â€‰year and captured weekly reports of medically confirmed COVID-19 infections. We analyzed the association of antibody titers with infection events as well as the association of the decision to receive vaccination with social, medical, and behavioral characteristics. 629 subjects were followed for 1â€‰year, and 82.8% of them were vaccinated. 90 cases of medically confirmed COVID-19 infection were reported. Notable findings from our study include: an association of vaccination choice with social distancing, a qualitatively different anti-spike response in participants receiving the Ad26.COV2.S vaccine compared to those receiving mRNA vaccines, a muted anti-nucleocapsid response in breakthrough infections compared to unvaccinated infections, and the identification of a low antibody titer threshold associated with the risk of breakthrough infections. We conclude that, in a real-life setting, vaccination and social distancing behavior are positively correlated. The observed effect of vaccination in preventing COVID-19 may include both vaccine-mediated protection and the associated more cautious behavior exhibited by vaccinated individuals. In addition, we identified an antibody threshold associated with breakthrough infections in mRNA vaccinees, and this threshold may be used in medical decision-making regarding the timing of booster vaccinations. Therefore, our data may aid in the refinement of vaccination strategies during the COVID-19 pandemic.
IMPORTANCE The COVID-19 pandemic continues to impact societies and health care systems worldwide and is continuously evolving. Immunity via vaccination or prior infection is the first and most important line of defense against COVID-19. We still do not have complete information on how vaccination-induced or infection-induced antibody titers change with time or on how this information

can be used to guide decisions regarding booster vaccination. In a longitudinal observational study of a cohort of 629 subjects, 82% of breakthrough infections in vaccinees occurred when their anti-spike antibody titers were below 3,000â€‰AU/mL. Our findings suggest that there may be an antibody threshold associated with breakthrough infections and that this threshold could possibly be used to aid decision-making regarding booster vaccinations. In addition, the use of anti-nucleocapsid antibody tiers may significantly underestimate the prevalence of breakthrough infections in vaccinated individuals.

[Inflammation of BCG Inoculation Site Scar after the First Dose of an Anti-SARS-CoV-2 mRNA Vaccine]. Inflammatory reactions in the Bacillus Calmette-GuÃ©rin (BCG) inoculation scar site have been previously described, in association with viral infections. The inflammation of the scar in association with other vaccines has been described with the flu vaccine and, more recently, after the second dose of mRNA anti-SARS-CoV-2 vaccines (mRNA-1273 e BNT162b2), in two healthcare workers. We present the case of a 27-year-old female, without a relevant past medical history, including no previous SARS-CoV-2 infection, and with inflammation of the BCG scar eight days after the first dose of the mRNA anti-SARS-CoV-2 vaccine. Pharmacovigilance and the notification of adverse events should be encouraged, as a way of warding off hesitation in this process.

Parsonage-Turner Syndrome Following Covishield (AstraZeneca ChAdOx1 nCoV-19) Vaccination: A Case Report. Parsonage-Turner Syndrome (PTS) is a rare neurological disorder involving brachial plexus and periscapular muscles following viral infection, surgery, and vaccination. We hereby describe the first case of PTS from India following Covishield (AstraZenecaÂ ChAdOx1 nCoV-19) COVID-19 vaccination. A 21-year-old healthy male presented to us with complaints of pain and weakness in the right shoulder five weeks after Covishield vaccination on the contralateral deltoid. There was no history of injury or constitutional symptoms. On examination, hyperalgesia over the area innervated by the axillary nerve and wasting of the deltoid, supra, and infraspinatus muscles were noted. An MRI scan of the shoulder,Â cervical spine, and brachial plexus neurogram were normal. Decreased motor amplitude in right axillary and musculocutaneous nerve was recorded in the nerve conduction study (NCS). High titers of SARS-COV-2 IgG neutralizing antibodies were noted after a single dose of vaccination and SARS CoV-2 IgM antibodies were negative. Having been diagnosed with post-vaccination PTS, the right shoulder was splinted and an intravenous injection of 1g methylprednisolone was administered for three days followed by oral steroids for three weeks. NCS and electromyography at 10 weeks showed insignificant differences between the two sides suggesting early neurological recovery. Currently, the patient is being followed up regularly for complete neurological recovery. PTS is a known side effect of vaccination. We report the index case of PTS following the administration of Covishield vaccination from India to aid in early diagnosis and management, further evaluation, and public health safety.

COVID-19 vaccine type-dependent differences in immunogenicity and inflammatory response: BNT162b2 and ChAdOx1 nCoV-19. Evaluation of the safety and immunogenicity of new vaccine platforms is needed to increase public acceptance of coronavirus disease 2019 (COVID-19) vaccines. Here, we evaluated the association between reactogenicity and immunogenicity in healthy adults following vaccination by analyzing blood samples before and after sequential two-dose vaccinations of BNT162b2 and ChAdOx1 nCoV-19. Outcomes included anti-S IgG antibody and neutralizing antibody responses, adverse events, and proinflammatory cytokine responses. A total of 59 and 57 participants vaccinated with BNT162b2 and ChAdOx1 nCoV-19, respectively, were enrolled. Systemic adverse events were more common after the first ChAdOx1 nCoV-19 dose than after the second. An opposite trend was observed in BNT162b2 recipients. Although the first ChAdOx1 nCoV-19 dose significantly elevated the median proinflammatory cytokine levels, the second dose did not, and neither did either dose of BNT162b2. Grades of systemic adverse events in ChAdOx1 nCoV-19

recipients were significantly associated with IL-6 and IL-1Î² levels. Anti-S IgG and neutralizing antibody titers resulting from the second BNT162b2 dose were significantly associated with fever. In conclusion, systemic adverse events resulting from the first ChAdOx1 nCoV-19 dose may be associated with proinflammatory cytokine responses rather than humoral immune responses. Febrile reactions after second BNT162b2 dose were positively correlated with vaccine-induced immune responses rather than with inflammatory responses.

SARS-CoV-2 vaccination in androgen sensitive phenotypes - A study on associated factors for SARS-CoV-2 vaccination and its adverse effects among androgenetic alopecia and benign prostate hyperplasia patients. BACKGROUND: Androgen sensitivity, which was established as the leading etiology of androgenetic alopecia (AGA) and benign prostatic hyperplasia (BPH), plays an important role in SARS-CoV-2 infection. Vaccination is essential for AGA and BPH patients in view of the high risk from SARS-CoV-2 infection. PURPOSE: We aimed to investigate the associated factors for SARS-CoV-2 vaccination and its side effects in populations with AGA and BPH. METHOD: We collected the data on SARS-CoV-2 vaccination and adverse reactions of male AGA and BPH patients visited the outpatient of Xiangya hospital by telephone and web-based questionnaires. Vaccination rate and adverse reactions were compared by different vaccine types and use of anti-androgen therapy. RESULT: A total of 457 AGA patients and 397 BPH patients were recruited in this study. Among which, 92.8% AGA patients and 61.0% BPH patients had at least the first dose of SARS-CoV-2 vaccination ($p < 0.001$). Having comorbidities and use of anti-androgen therapy increased the risk of un-vaccination among AGA by 2.875 and 3.729 times, respectively ($p < 0.001$). Around 31.1% AGA patients and 9.5% BPH patients presented adverse reactions, which were mostly mild. Anti-androgen therapy increased the inclination of injection site pain after vaccination (18.7% vs 11.9%; OR: 1.708, 95% CI: 1.088-2.683, $p = 0.019$). CONCLUSION: Co-existence of other systemic diseases and anti-androgen therapy were the limiting factors for SARS-CoV-2 unvaccination, especially in AGA patients. The importance of SARS-CoV-2 vaccines should be strengthened and popularized in androgen sensitive phenotypes.

Immune response in ofatumumab treated multiple sclerosis patients after SARS-CoV-2 vaccination. OBJECTIVE: The pandemic induced by SARS-CoV-2 has huge implications for patients with immunosuppression that is caused by disorders or specific treatments. Especially approaches targeting B cells via anti-CD20 therapy are associated with impaired humoral immune response but sustained cellular immunity. Ofatumumab is a human anti-CD20 directed antibody applied in low dosages subcutaneously, recently licensed for Multiple Sclerosis (MS). Effects of early ofatumumab treatment on alterations of immune cell composition and immune response towards SARS-CoV-2 are incompletely understood. METHODS: We here investigated immune cell alterations in early ofatumumab (Ofa) treated patients and effects on humoral (titer, neutralization capacity against wild type, Delta and Omicron) and cellular immune responses in Ofa treated MS patients following a third vaccination against SARS-CoV-2 compared to healthy controls. RESULTS: We show that a mean treatment duration of three months in the Ofa group led to near complete B cell depletion in line with altered composition of certain CD4(+) T cell subpopulations such as enhanced frequencies of naive and a decrease of non-suppressive regulatory T cells (Tregs). Titer and neutralization capacity against SARS-CoV-2 variants was impaired while cellular immune response was sustained, characterized by a strong T helper 1 profile (Th1). INTERPRETATION: In summary, low dosage ofatumumab treatment elicits sustained depletion of B cells in line with alterations of immune cells, mainly Tregs. This is associated with impaired humoral immune response towards SARS-CoV-2 vaccination but preserved, Th1 driven cellular immunity adding crucial information regarding early effects of low dosage anti-CD20 therapy on humoral and cellular immunity.

Adipokines, and not vitamin D, associate with antibody immune responses following dual BNT162b2 vaccination within individuals younger than 60 years. Severe acute respiratory syndrome

coronavirus-2 (SARS-CoV-2) led to a global health outbreak known as the COVID-19 pandemic which has been lasting since March 2020. Vaccine became accessible to people only at the beginning of 2021 which greatly helped reducing the mortality rate and severity of COVID-19 infection afterwards. The efficacy of vaccines was not fully known and studies documenting the immune responses following vaccination are continuing to emerge. Recent evidence indicate that natural infection prior vaccination may improve the antibody and cellular immune responses, while little is known about the factors influencing those processes. Here we investigated the antibody responses following BNT162b2 vaccination in relation to previous-infection status and age, and searched for possible biomarkers associated with the observed changes in immune responses. We found that the previous-infection status caused at least 8-times increase in the antibody titres, effect that was weaker in people over 60 years old and unaltered by the vitamin D serum levels. Furthermore, we identified adiponectin to positively associate with antibody responses and negatively correlate with pro-inflammatory molecules (MCP-1, factor D, CRP, PAI-1), especially in previously-infected individuals.

Renal Complications in Kidney Transplant Recipients After Whole-virus Inactivated COVID-19 Vaccination.

Vaccine-induced seroconversion in participants in the North Carolina COVID-19 community Research Partnership. Well-regulated clinical trials have shown FDA-approved COVID-19 vaccines to be immunogenic and highly efficacious. We evaluated seroconversion rates in adults reportingÂ â‰¥Â 1 dose of an mRNA COVID-19 vaccine in a cohort study of nearly 8000 adults residing in North Carolina to validate immunogenicity using a novel approach: at-home, participant administered point-of-care testing. Overall, 91.4% had documented seroconversion within 75Â days of first vaccination (median: 31Â days). Participants who were older and male participants were less likely to seroconvert (adults aged 41-65: adjusted hazard ratio [aHR] 0.69 [95% confidence interval (CI): 0.64, 0.73], adults aged 66-95: aHR 0.55 [95% CI: 0.50, 0.60], compared to those 18-40; males: aHR 0.92 [95% CI: 0.87, 0.98], compared to females). Participants with evidence of prior infection were more likely to seroconvert than those without (aHR 1.50 [95% CI: 1.19, 1.88]) and those receiving BNT162b2 were less likely to seroconvert compared to those receiving mRNA-1273 (aHR 0.84 [95% CI: 0.79, 0.90]). Reporting at least one new symptom after first vaccination did not affect time to seroconversion, but participants reporting at least one new symptom after second vaccination were more likely to seroconvert (aHR 1.11 [95% CI: 1.05, 1.17]). This data demonstrates the high community-level immunogenicity of COVID-19 vaccines, albeit with notable differences in older adults, and feasibility of using at-home, participant administered point-of-care testing for community cohort monitoring. Trial registration: ClinicalTrials.gov NCT04342884.

COVID-19 vaccination and myelin oligodendrocyte glycoprotein associated disorder: Correspondence.

In situ detection of vaccine mRNA in the cytoplasm of hepatocytes during COVID-19 vaccine-related hepatitis.

Depressive symptoms predict antibody titers after a second dose of the SARS-CoV-2 BNT162b2 vaccine among hospital workers in Japan. BACKGROUND: Although factors associated with the antibody response to the BNT162b2 mRNA COVID-19 vaccine have been reported, psychological factors have not been examined. Depression or anxiety may affect vaccine reactions because these factors influence immune responses. This study aimed to determine whether psychological status at the time of vaccination predicts antibody responses. METHODS: A prospective observational study of the BNT162b2 mRNA COVID-19 vaccine response was carried out among individuals attending for an annual health check-up. Participants included 78 volunteers out of 80 hospital workers in Nagoya, Japan. No participants had been infected with COVID-19 and all gave written informed consent to participate in the study. Blood samples were obtained approximately 28Â days after the second dose of the vaccine, and antibody titers of the SARS-CoV-2 spike protein were determined using the SARS-

CoV-2 IgG II Quant assay. Participants completed the Japanese version of the hospital anxiety and depression scale (HADS) questionnaire, one day before both vaccinations. Participants also recorded any adverse reactions, such as body temperature and other side effects, every day for two weeks after each dose. The relationships between antibody titers and the predictive factors were analyzed using multiple linear regression analysis, with the antibody titers as the dependent variables, followed by univariate analysis. RESULTS: Multiple linear regression analysis revealed that no or excessive alcohol intake (pÂ =Â 0.039), poor results from a health check-up (pÂ =Â 0.011), a longer duration between the second dose and blood collection (pÂ =Â 0.039), and increased degree of depressive symptoms (pÂ =Â 0.041) were significant negative predictors of antibody titers, while body temperature one day after the second dose as a significant positive predictor of antibody titers (pÂ <Â 0.0005). CONCLUSION: We identified that depressive symptoms just before the second dose of the BNT162b2 mRNA COVID-19 were an independent negative predictor of antibody responses, in addition to other factors. Our results highlight the importance of mental health at the time of vaccination to achieve the higher antibody responses necessary to acquire humoral immunity.

T cell receptor sequencing reveals reduced clonal breadth of T-cell responses against SARS-CoV-2 after natural infection and vaccination in allogeneic hematopoietic stem cell transplant recipients.

Vaccination of multiple sclerosis patients during the COVID-19 era: Novel insights into vaccine safety and immunogenicity. Multiple sclerosis (MS) is an incurable autoimmune disease known to cause widespread demyelinating lesions in the central nervous system (CNS) and a host of debilitating symptoms in patients. The development of MS is believed to be driven by the breakdown of the blood brain barrier, subsequent infiltration by CD4(+) and CD8(+) T cells, and widespread CNS inflammation and demyelination. Disease modifying therapies (DMTs) profoundly disrupt these processes and therefore compose an essential component of disease management. However, the effects of these therapeutic agents on vaccine safety and immunogenicity in individuals with MS are not yet fully understood. As such, the primary objective of this review article was to summarize the findings of recently conducted studies on vaccine safety and immunogenicity in MS patients treated with DMTs, particularly in the context of the ongoing coronavirus disease 2019 (COVID-19) pandemic. Discussed in this review are vaccinations against influenza, yellow fever, human papillomavirus, measles, mumps, rubella, Streptococcus pneumoniae, hepatitis B, and COVID-19. This article additionally reviews our current understanding of COVID-19 severity and incidence in this patient population, the risks and benefits of vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and vaccination guidelines set forth by MS societies and organizations.

Corrigendum to 'Thrombosis patterns and clinical outcome of COVID-19 vaccine-induced immune thrombotic thrombocytopenia: A Systematic Review and Meta-Analysis' International Journal of Infectious Diseases, Volume 119, June 2022, Page 130-139.

COVID-19 Vaccine Hesitancy in a Medically-Challenged Context: A Cross-Sectional Study of Drivers, Dangers and Corrective Measures for Vaccine Hesitancy and Potential Penalties for Declining Vaccination among Adults in South-Eastern Nigeria. BACKGROUND: COVID-19 vaccine hesitancy is a global public health problem. It is a complex and context-specific phenomenon that varies within and across nations. Despite COVID-19 vaccine programmes in Nigeria, there are possibilities that vaccine uptake and coverage among adult citizens will suffer setbacks amidst various interventions by the Federal Government of Nigeria. AIM: The study aimed to determine the drivers, dangers, and corrective measures for COVID-19 vaccine hesitancy and potential penalties for declining vaccination among adults in South-eastern Nigeria. METHODS: A descriptive study was carried out from March to April, 2021 on a cross section of 400 adults in South-eastern Nigeria. Data collection was done using a structured, pretested, and interviewer administered questionnaire. The questionnaire elicited information on drivers, dangers and corrective measures for COVID-19 vaccine hesitancy and

potential penalties for declining vaccination. RESULTS: The study participants were aged 18-86 (51Â±14.2) years. There were 227(56.8%) females. The most common driver of refusal of COVID-19 vaccination was the safety of COVID-19 vaccines(100.0%). The most perceived dangers of refusing the COVID-19 vaccine were the risks of contracting COVID-19 infection(100.0%) and dying from its complications(100.0%). The most common corrective measure for refusal of the COVID-19 vaccine was public health information and education on vaccine safety(100.0%). The predominant potential penalty for declining the COVID-19 vaccine was restricting access to air travel (100.0%). CONCLUSION: This study has shown that the most common driver of vaccine hesitancy was vaccine safety while the most commonly perceived dangers were risks of contracting COVID-19 infection and dying from its complications. The most common corrective measure for refusal of the COVID-19 vaccine was public health information and education on vaccine safety. The most preeminent penalty for declining the COVID-19 vaccine was restricting access to air travel. There is a need to address these context-specific drivers and dangers that promote vaccine hesitancy. Public health information and education strategies to reduce vaccine hesitancy should be the focus of intervention to improve uptake of COVID-19 vaccination and safeguard the health of Nigerians.

mRNA-1273 but not BNT162b2 induces antibodies against polyethylene glycol (PEG) contained in mRNA-based vaccine formulations. Two messenger RNA (mRNA)-based vaccines are widely used globally to prevent coronavirus disease 2019 (COVID-19). Both vaccine formulations contain PEGylated lipids in their composition, in the form of polyethylene glycol [PEG] 2000 dimyristoyl glycerol for mRNA-1273, and 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide for BNT162b2. It is known that some PEGylated drugs and products for human use which contain PEG are capable of eliciting immune responses that lead to to detectable PEG-specific antibodies in serum. In this study, we determined if any of the components of mRNA-1273 or BNT162b2 formulations elicited PEG-specific antibody responses in serum by enzyme linked immunosorbent assay (ELISA). We detected an increase in the reactivity to mRNA vaccine formulations in mRNA-1273 but not BNT162b2 vaccinees' sera in a prime-boost dependent manner. Furthermore, we observed the same pattern of reactivity against irrelevant lipid nanoparticles from an influenza virus mRNA formulation and found that the reactivity of such antibodies correlated well with antibody levels against high and low molecular weight PEG. Using sera from participants selected based on the vaccine-associated side effects experienced after vaccination, including delayed onset, injection site or severe allergic reactions, we found no obvious association between PEG antibodies and adverse reactions. Overall, our data shows a differential induction of anti-PEG antibodies by mRNA-1273 and BNT162b2. The clinical relevance of PEG reactive antibodies induced by administration of the mRNA-1273 vaccine, and the potential interaction of these antibodies with other PEGylated drugs remains to be explored.

Influenza vaccine and subsequent development of zoster. BACKGROUND: Herpes zoster (HZ), which is caused by reactivation of the latent varicella zoster virus, was not listed as a side effect of any vaccines until the introduction of coronavirus disease 2019 (COVID-19) vaccine. This study used a nationwide population database to examine whether the HZ risk is increased after receiving the influenza vaccination. METHODS: This population-based retrospective self-controlled case series evaluated the association between influenza vaccine exposure and HZ risk. Data were collected from Taiwan's National Health Insurance Research Database between 2015 and 2017. Patients with HZ diagnosed within 6â€‰months before and after receiving the influenza vaccination were included. After receiving the influenza vaccine, the first 15 and 30â€‰days were defined as risk intervals, whileÂ the other periods were defined as control intervals. Poisson regression was used to compare the incidence rate ratio (IRR) for HZ during the risk interval vs. the control interval. RESULTS: In total, 13,728 patients were diagnosed with HZ before and after receiving the influenza vaccine. The IRR for days 1-15 was significantly higher (IRRâ€‰=â€‰1.11; 95% confidence interval [CI], 1.02-1.20), but

insignificant for days 1-30 (IRRâ€‰=â€‰1.04; 95% CI, 0.98-1.10). In a subgroup analysis, the IRRs were significantly higher in participants, including 50-64â€‰years old (1.16; 95% CI, 1.02-1.33), males (1.14; 95% CI, 1.01-1.28), and healthier individuals (i.e., no history of cancer or autoimmune diseases). CONCLUSIONS: There was a slight increase in risk of HZ in people receiving influenza vaccine in the first 1-15â€‰days after vaccination.

Humoral Immune Response and Safety of SARS-CoV-2 Vaccination in Pediatric Inflammatory Bowel Disease. INTRODUCTION: Children with inflammatory bowel disease (IBD) may respond differently to COVID-19 immunization as compared with healthy children or adults with IBD. Those younger than 12 years receive a lower vaccine dose than adults. We sought to describe the safety and humoral immune response to COVID-19 vaccine in children with IBD. METHODS: We recruited children with IBD, ages 5-17 years, who received â‰¥ 2 doses of the BNT162b2 vaccine by a direct-to-patient outreach and at select sites. Patient demographics, IBD characteristics, medication use, and vaccine adverse events were collected. A subset of participants had quantitative measurement of anti-receptor binding domain IgG antibodies after 2-part immunization. RESULTS: Our study population included 280 participants. Only 1 participant required an ED visit or hospitalization because of an adverse event. Of 99 participants who underwent anti-receptor binding domain IgG antibody measurement, 98 had a detectable antibody, with a mean antibody level of 43.0 Î¼g/mL (SD 67) and a median of 22 Î¼g/mL (interquartile range 12-38). In adjusted analyses, older age (P = 0.028) and antitumor necrosis factor monotherapy compared with immunomodulators alone (P = 0.005) were associated with a decreased antibody level. Antibody response in patients treated with antitumor necrosis factor combination vs monotherapy was numerically lower but not significant. DISCUSSION: Humoral immune response to COVID-19 immunization in children with IBD was robust, despite a high proportion of this pediatric cohort being treated with immunosuppressive agents. Severe vaccine-related AEs were rare. Overall, these findings provide a high level of reassurance that pediatric patients with IBD respond well and safely to SARS-CoV-2 vaccination.

COVID-19 mRNA vaccine-induced adverse effects: unwinding the unknowns.

The spike hypothesis in vaccine-induced adverse effects: questions and answers. Trougakos and colleagues recently discussed the role of coronavirus disease 2019 (COVID-19) mRNA vaccine-induced spike (S) protein in adverse effects following vaccination [1]. We would like hereafter to answer one of their outstanding questions requiring response to improve efficacy and safety of COVID-19 vaccines, and to propose an additional question along with its possible answer.

Incidence of acute exacerbation in patients with interstitial lung disease after COVID-19 vaccination. Acute exacerbations due to COVID-19 vaccination in patients with interstitial lung disease (ILD) have been reported, but their incidence is unknown. We investigated the incidence of exacerbations of ILD and respiratory symptoms due to the mRNA COVID-19 vaccines. A questionnaire survey was conducted on adverse reactions to the mRNA COVID-19 vaccination in 545 patients with ILD attending our hospital and retrospectively examined whether the eligible patients actually developed acute exacerbations of ILD induced by the vaccine. Of the 545 patients, 17 (3.1%) patients were aware of the exacerbation of respiratory symptoms, and four (0.7%) patients developed an acute ILD exacerbation after vaccination. Of the four patients who experienced exacerbations, two had collagen vascular disease-associated ILD, one had nonspecific interstitial pneumonia, another had unclassifiable idiopathic pneumonia, and none had idiopathic pulmonary fibrosis. Four patients were treated using steroid pulse therapy with a steroid taper, and two of the four also received intravenous cyclophosphamide pulse therapy. Tacrolimus was started in one patient with myositis-associated interstitial lung disease. Eventually, all patients exhibited improvement with immunosuppressive treatment and were discharged. COVID-19 vaccination for patients with ILD

should be noted for developing acute exacerbations of ILD with low incidence, although manageable with early diagnosis and treatment.

Risk of Death in Nursing Home Residents After COVID-19 Vaccination. OBJECTIVES: In the first months of 2021, the Dutch COVID-19 vaccination campaign was disturbed by reports of death in Norwegian nursing homes (NHs) after vaccination. Reports predominantly concerned persons >65Â years of age with 1 or more comorbidities. Also, in the Netherlands adverse events were reported after COVID-19 vaccination in this vulnerable group. Yet, it was unclear whether a causal link between vaccination and death existed. Therefore, we investigated the risk of death after COVID-19 vaccination in Dutch NH residents compared with the risk of death in NH residents prior to the COVID-19 pandemic. DESIGN: Population-based longitudinal cohort study with electronic health record data. SETTING AND PARTICIPANTS: We studied Dutch NH residents from 73 NHs who received 1 or 2 COVID-19 vaccination(s) between January 13 and April 16, 2021 (nÂ = 21,762). As a historical comparison group, we included Dutch NH residents who were registered in the same period in 2019 (nÂ = 27,591). METHODS: Data on vaccination status, age, gender, type of care, comorbidities, and date of NH entry and (if applicable) discharge or date of death were extracted from electronic health records. Risk of death after 30Â days was evaluated and compared between vaccinated residents and historical comparison residents with Kaplan-Meier and Cox regression analyses. Regression analyses were adjusted for age, gender, comorbidities, and length of stay. RESULTS: Risk of death in NH residents after one COVID-19 vaccination (regardless of whether a second vaccination was given) was decreased compared with historical comparison residents from 2019 (adjusted HR 0.77, 95% CI 0.69-0.86). The risk of death further decreased after 2 vaccinations compared with the historical comparison group (adjusted HR 0.57, 95% CI 0.50-0.64). CONCLUSIONS AND IMPLICATIONS: We found no indication that risk of death in NH residents is increased after COVID-19 vaccination. These results indicate that COVID-19 vaccination in NH residents is safe and could reduce fear and resistance toward vaccination.

Efficacy, safety, and immunogenicity of a booster regimen of Ad26.COV2.S vaccine against COVID-19 (ENSEMBLE2): results of a randomised, double-blind, placebo-controlled, phase 3 trial. BACKGROUND: Despite the availability of effective vaccines against COVID-19, booster vaccinations are needed to maintain vaccine-induced protection against variant strains and breakthrough infections. This study aimed to investigate the efficacy, safety, and immunogenicity of the Ad26.COV2.S vaccine (Janssen) as primary vaccination plus a booster dose. METHODS: ENSEMBLE2 is a randomised, double-blind, placebo-controlled, phase 3 trial including crossover vaccination after emergency authorisation of COVID-19 vaccines. Adults aged at least 18 years without previous COVID-19 vaccination at public and private medical practices and hospitals in Belgium, Brazil, Colombia, France, Germany, the Philippines, South Africa, Spain, the UK, and the USA were randomly assigned 1:1 via a computer algorithm to receive intramuscularly administered Ad26.COV2.S as a primary dose plus a booster dose at 2 months or two placebo injections 2 months apart. The primary endpoint was vaccine efficacy against the first occurrence of molecularly confirmed moderate to severe-critical COVID-19 with onset at least 14 days after booster vaccination, which was assessed in participants who received two doses of vaccine or placebo, were negative for SARS-CoV-2 by PCR at baseline and on serology at baseline and day 71, had no major protocol deviations, and were at risk of COVID-19 (ie, had no PCR-positive result or discontinued the study before day 71). Safety was assessed in all participants; reactogenicity, in terms of solicited local and systemic adverse events, was assessed as a secondary endpoint in a safety subset (approximately 6000 randomly selected participants). The trial is registered with ClinicalTrials.gov, NCT04614948, and is ongoing. FINDINGS: Enrolment began on Nov 16, 2020, and the primary analysis data cutoff was June 25, 2021. From 34â€ˆ571 participants screened, the double-blind phase enrolled 31â€ˆ300 participants, 14â€ˆ492 of

whom received two doses (7484 in the Ad26.COV2.S group and 7008 in the placebo group) and 11â€ˆ639 of whom were eligible for inclusion in the assessment of the primary endpoint (6024 in the Ad26.COV2.S group and 5615 in the placebo group). The median (IQR) follow-up post-booster vaccination was 36Â·0 (15Â·0-62Â·0) days. Vaccine efficacy was 75Â·2% (adjusted 95% CI 54Â·6-87Â·3) against moderate to severe-critical COVID-19 (14 cases in the Ad26.COV2.S group and 52 cases in the placebo group). Most cases were due to the variants alpha (B.1.1.7) and mu (B.1.621); endpoints for the primary analysis accrued from Nov 16, 2020, to June 25, 2021, before the global dominance of delta (B.1.617.2) or omicron (B.1.1.529). The booster vaccine exhibited an acceptable safety profile. The overall frequencies of solicited local and systemic adverse events (evaluated in the safety subset, n=6067) were higher among vaccine recipients than placebo recipients after the primary and booster doses. The frequency of solicited adverse events in the Ad26.COV2.S group were similar following the primary and booster vaccinations (local adverse events, 1676 [55Â·6%] of 3015 vs 896 [57Â·5%] of 1559, respectively; systemic adverse events, 1764 [58Â·5%] of 3015 vs 821 [52Â·7%] of 1559, respectively). Solicited adverse events were transient and mostly grade 1-2 in severity. INTERPRETATION: A homologous Ad26.COV2.S booster administered 2 months after primary single-dose vaccination in adults had an acceptable safety profile and was efficacious against moderate to severe-critical COVID-19. Studies assessing efficacy against newer variants and with longer follow-up are needed. FUNDING: Janssen Research & Development.

Joint Recommendations From The Latin American Association of Cardiac and Endovascular Surgery (LACES) and The Cardiovascular Anesthesia Committee of The Latin American Confederation of Anesthesia Societies (CLASA) on the Timing for Cardiac Surgery After COVID-19 Infection. INTRODUCTION: Since the coronavirus disease 2019 (COVID-19) pandemic, cardiac surgeries in patients with previous infection by COVID-19 were suspended or postponed, which led to surgeries performed in patients with an advanced stage of their disease and an increase in the waiting list. There is a heterogeneous attitude in Latin America on the optimal timing to cardiac surgery in patients with previous COVID-19 infection due to scarce data on its outcome. Two Latin American associations joined to establish common suggestions on the optimal timing of surgery in patients with previous COVID-19 infection. METHODS: Data collection was performed using a pre-established form, which included year of publication, objective, type of study (prospective/retrospective, descriptive/analytical), number of patients, year of study, waiting time between infection and surgery, type of surgery, morbidity, mortality, and conclusions regarding the association between mortality and morbidity. Final recommendations were approved by the board of directors of Latin American Association of Cardiac and Endovascular Surgery (LACES) and Latin American Confederation of Anesthesia Societies (CLASA). RESULTS: Of the initial 1,016 articles, 11 comprised the final selection. Only six of them included patients who underwent cardiac surgery. According to the analyzed literature, optimal timing for cardiac surgery needs to consider the following aspects: deferable surgery, symptomatic COVID-19 infection, completeness of COVID-19 vaccination. CONCLUSION: These recommendations derive from the analysis of the scarce literature published at present on outcomes after cardiac surgery in patients with previous COVID-19 infection. These are to be taken as a dynamic recommendation in which Latin American reality was taken into consideration.

Lymphadenopathy after COVID-19 vaccination in patients with endocrine cancer: two case reports. SUMMARY: The Covid-19 vaccination has been rapidly implemented among patients with cancer. We present two cases of patients with endocrine tumours who developed lymphadenopathy following a Covid-19 vaccination. In the case of a patient with multiple endocrine neoplasia (MEN) 1 syndrome, an 18-fluorodeoxyglucose (18FDG)-PET/CT showed positive axillary lymph nodes. Further work-up with fine needle aspiration showed a reactive pattern following a Covid-19 vaccination in the ipsilateral arm shortly before the 18FDG-PET/CT. A second patient, in follow-up for thyroid cancer,

developed clinical supraclavicular lymphadenopathy after a Covid-19 vaccination. Follow-up ultrasound proved the lesion to be transient. These cases demonstrate lymphadenopathy in response to a Covid-19 vaccination in two patients susceptible to endocrine tumours and metastatic disease. With growing evidence about the pattern and occurrence of lymphadenopathy after mRNA Covid-19 vaccination, recommendations for scheduling and interpretation of imaging among cancer patients should be implemented to reduce equivocal findings, overdiagnosis, and overtreatment, while maintaining a good standard of care in oncological follow-up. LEARNING POINTS: Reactive lymphadenopathy is very common after an mRNA vaccination against Covid-19 and should be part of the differential diagnosis in patients with endocrine tumours who recently received a Covid-19 mRNA vaccination and present with an ipsilateral lymphadenopathy. A good vaccine history is essential in assessing the risk for lymphadenopathy and if possible, screening imaging in patients with endocrine tumours should be postponed at least 6 weeks after the previous vaccination. For now, a multidisciplinary care approach is recommended to determine the necessary steps in the diagnostic evaluation of lymphadenopathy in the proximity of a Covid-19 vaccination.

Two cases with new onset of pemphigus foliaceus after SARS-CoV-2 vaccination.

Genetic risk and incident venous thromboembolism in middle-aged and older adults following COVID-19 vaccination. BACKGROUND: COVID-19 vaccination has been associated with increased venous thromboembolism (VTE) risk. However, it is unknown whether genetic predisposition to VTE is associated with an increased risk of thrombosis following vaccination. METHODS: Using data from the UK Biobank, which contains in-depth genotyping and linked vaccination and health outcomes information, we generated a polygenic risk score (PRS) using 299 genetic variants. We prospectively assessed associations between PRS and incident VTE immediately after first- and the second-dose vaccination and among historical unvaccinated cohorts during the pre- and early pandemic. We estimated hazard ratios (HR) for PRS-VTE associations using Cox models. RESULTS: Of 359â€‰310 individuals receiving one dose of a COVID-19 vaccine, 160â€‰327 (44.6%) were males, and the mean age at the vaccination date was 69.05 (standard deviation [SD] 8.04) years. After 28- and 90-days' follow-up, 88 and 299 individuals developed VTE, respectively, equivalent to an incidence rate of 0.88 (95% confidence interval [CI] 0.70-1.08) and 0.92 (0.82-1.04) per 100â€‰000 person-days. The PRS was significantly associated with a higher risk of VTE (HR per 1 SD increase in PRS, 1.41 (1.15-1.73) in 28â€‰days and 1.36 (1.22-1.52) in 90â€‰days). Similar associations were found in the historical unvaccinated cohorts. CONCLUSIONS: The strength of genetic susceptibility with post-COVID-19-vaccination VTE is similar to that seen in historical data. Additionally, the observed PRS-VTE associations were equivalent for adenovirus- and mRNA-based vaccines. These findings suggest that, at the population level, the VTE that occurred after the COVID-19 vaccination has a similar genetic etiology to the conventional VTE.

Incessant pericarditis following the second dose of SARS-CoV-2 mRNA vaccine successfully treated with anakinra: a case report. BACKGROUND: The SARS-CoV-2 pandemic has led to the development of the first mRNA vaccines used in humans. These vaccines are well tolerated, safe, and highly effective; however, post-marketing surveillance is revealing potential rare adverse effects. We report a case of incessant pericarditis following administration of the second dose of mRNA-1273 SARS-CoV-2 vaccine, unresponsive to conventional therapy, and successfully treated with anakinra. CASE SUMMARY: A 30-year-old man presented to the Emergency Department for incessant pericarditis unresponsive to evacuative pericardiocentesis and conventional first-line anti-inflammatory therapy. Given the typical 'inflammatory phenotype' clinically characterized by fever, C-reactive protein (CRP) elevation, and leucocytosis, we decided, in agreement with the rheumatologist team, to avoid glucocorticoid and to administer anakinra. A sudden clinical and echocardiographic improvement was observed, with complete resolution of the symptoms and of the pericardial

effusion; similarly, CRP values progressively decreased. The patient was discharged at home; no recurrences of pericarditis were described at clinical and instrumental follow-up made 3 months later. DISCUSSION: Several cases of pericarditis have been described in patients who received the COVID-19 vaccination, especially with the mRNA vaccine that can induce a non-adaptive immunity response against the viral spike protein, triggering cardiac damage for a molecular mimicry mechanism; however, defined pathogenesis of pericarditis associated with mRNA vaccine is still missing. The clinical scenario described is characterized by the typical 'inflammatory phenotype', triggered by a disproportionate and uncontrolled activation of the inflammasome based on an interleukin-1 (IL-1) overproduction. We administered anakinra, an IL-1 blocking drug, with a sharp clinical, echocardiographic and laboratoristic improvement. The complete response observed in this case suggests that vaccine-related pericarditis could be triggered by an auto-inflammatory pathway based on IL-1 overproduction. Further research is, therefore, warranted to determine the mechanisms by which the mRNA vaccine may cause pericarditis in order to choose the most targeted therapy.

Factors Associated with the Acceptance of COVID-19 Vaccines in Citizens of Northern Peru: Cross-Sectional Study. PURPOSE: The presence of the COVID-19 coronavirus in Peru, and especially in northern Peru, was very fast and caused many deaths. As a result, vaccination proved to be the most immediate option to control it. However, a sector of the population was reluctant to vaccination. Therefore, this study aimed to analyze the factors associated with the acceptance of COVID-19 vaccines by citizens of northern Peru. PATIENTS AND METHODS: The study was observational, descriptive-correlational and the sample was stratified and consisted of 516 citizens from eight departments of northern Peru, who answered an online questionnaire regarding sociodemographic, cultural and health aspects. The data were analyzed using statistical tests of association and a logistic model was estimated to identify factors predicting vaccine acceptance. RESULTS: Among the factors associated with vaccine acceptance, sociodemographic factors such as age and family income, cultural factors such as level of knowledge, and health factors such as having another chronic disease and a vaccine with a higher confidence ($p<0.05$) were found. In addition, 12% of the population do not trust them, 10% are afraid that they may cause thrombosis, 13% disagree with vaccination for children, 7% think that a chip will be implanted and 8% believe that their DNA will be changed. However, most people accept vaccination and consider it necessary. A multivariate analysis was also performed for the acceptance of vaccines, which presented a percentage of 80.2% correct in the prognosis. CONCLUSION: The multivariate analysis allowed a conclusion that the predictor variables for vaccine acceptance are household income of less than 1000 Peruvian soles per month, low or medium levels of knowledge, and having another chronic disease.

A Review of Humoral and Cellular Immune Responses to SARS-CoV-2 Vaccination Following Solid Organ Transplantation. The introduction of vaccines preventing a severe course of COVID-19 disease is particularly important in immunocompromised patients, among whom organ recipients and patients awaiting transplantation constitute a large group. The article is a critical review of 68 recent publications on the impact of the SARS-CoV-2 pandemic on transplantology worldwide. The study discusses research results concerning various aspects of SARS-CoV-2 vaccination in transplant patients; it also lists important factors influencing vaccination effectiveness. A suboptimal immune response to 2 doses of vaccine in this group of patients is a major challenge prompting further research. Therefore, this review aims to provide an update on the humoral and cellular immune responses to SARS-CoV-2 vaccination following solid organ transplantation.

Reports of acute adverse events in mRNA COVID-19 vaccine recipients after the first and second doses in Japan. Mass vaccination against coronavirus disease 2019 (COVID-19) is ongoing in many countries worldwide. This study reports the occurrence of acute adverse events among vaccine

recipients at a mass vaccination center in Japan. Between August and November 2021, approximately 130,000 individuals received two mRNA vaccine doses (mRNA-1273; Moderna) at the vaccination center. Acute adverse events at the site were observed in 1.1% of the recipients after the first dose and in 0.4% of the recipients after the second dose. The most common event was vasovagal syncope/presyncope, followed by acute allergic reactions. The occurrence rate of vasovagal syncope/presyncope was highest in the young population of those aged 16-29Â years, but such age-dependency was not apparent in acute allergic reactions. Both symptoms were more prevalent in women than in men. Vasovagal syncope/presyncope occurred mainly within 20Â min of the injection, whereas nearly half of the episodes of acute allergic reactions occurred after 20Â min. The vaccine being injected while the recipient was in the supine position effectively reduced the occurrence of vasovagal syncope/presyncope. In summary, the suggested risk factors for vasovagal syncope/presyncope included a young age and female sex. The vaccine being injected while the recipient was in the supine position would reduce the risk of vasovagal syncope/presyncope.

Urticaria relapse after mRNA COVID-19 vaccines in patients affected by chronic spontaneous urticaria and treated with antihistamines plus omalizumab: A single-center experience. Urticaria is a disease characterized by wheals and/or angioedema. Chronic spontaneous urticaria (CSU) occurs for longer than 6â€‰weeks and appears independently of any identifiable exogenous stimulus. During the vaccination campaign for Coronavirus disease 2019 (COVID-19) pandemic, several cutaneous adverse events have been described, among which urticaria lasting less than 6â€‰weeks (acute urticaria, AU). AU due to vaccines can be IgE or non-IgE mediated; the former typically develop within 4Â h of drug exposure, the latter occurs later and the mechanism is unclear. In this retrospective study we analyzed the frequency and clinical characteristics of urticaria occurring after COVID-19 vaccine (post-vaccination urticaria relapse) in adult CSU patients treated with antihistamine and omalizumab, and in clinical remission.

Safety and immunogenicity of a third COVID-19 vaccination in patients with immune-mediated inflammatory diseases compared with healthy controls. OBJECTIVES: A third COVID-19 vaccination is recommended for immunosuppressed patients. However, data on immunogenicity and safety of a third COVID-19 vaccination in patients with immune-mediated inflammatory diseases (IMIDs) are sparse and therefore addressed within this clinical trial. METHODS: 60 immunosuppressed patients and 48 healthy controls (HCs) received a third vaccination with an mRNA vaccine. The primary endpoint was defined as the presence of antibody levels against the receptor-binding domain (RBD)>1500 BAU/mL in patients with IMIDs versus HCs. Further endpoints included differences in neutralising antibodies and cellular immune responses after the third vaccination. Reactogenicity was recorded for 7â€‰days, and safety was evaluated until week 4. RESULTS: Rate of individuals with anti-RBD antibodies>1500 BAU/mL was not significantly different after the third vaccination between patients with IMIDs and HCs (91% vs 100% p=0.101). Anti-RBD and neutralising antibody levels were significantly lower in patients with IMIDs after the third vaccination than in HCs (p=0.002â€‰and p=0.016, respectively). In contrast, fold increase in antibody levels between week 0 and 4 was higher in patients with IMIDs. Treatment with biological (b) disease-modifying anti-rheumatic drugs (DMARD) or combination of bDMARDs and conventional synthetic DMARDs was associated with reduced antibody levels. Enhanced cellular immune response to wild type and Omicron peptide stimulation was observed after the third vaccination. No serious adverse event was attributed to the third vaccination. CONCLUSION: Our clinical trial data support the immunogenicity and safety of a third COVID-19 vaccination in patients with IMIDs. However, effects of DMARD therapy on immunogenicity should be considered. TRIAL REGISTRATION NUMBER: EudraCT No: 2021-002693-10.

Heterologous prime boost COVID 19 vaccination. Heterologous prime boost vaccination is a primary vaccination with different vaccines, most often from different vaccine platforms. It combines

the immunological properties of the different vaccines and thereby induces humoral, cellular and, in some cases, mucosal response. For Covid prevention, it has been used in primary vaccination, due to safety issues and in boosters. We have evaluated some articles reporting on the results of this type of vaccine, and demonstrating its usefulness.
Clinical Phenotypes of Immediate First-Dose Reactions to mRNA COVID-19: A Multicenter Latent Class Analysis. BACKGROUND: Although immediate potentially allergic reactions have been reported after dose 1 of mRNA coronavirus disease 2019 (COVID-19) vaccines, comprehensively defined subtypes have not been clearly distinguished. OBJECTIVE: To define distinct clinical phenotypes of immediate reactions after dose 1 of mRNA COVID-19 vaccination, and to assess the relation of clinical phenotype to mRNA COVID-19 vaccine second dose tolerance. METHODS: This retrospective study included patients with 1 or more potentially allergic symptoms or signs within 4 hours of receiving dose 1 of an mRNA COVID-19 vaccine and assessed by allergy/immunology specialists from 5 U.S. academic medical centers (January-June 2021). We used latent class analysis-an unbiased, machine-learning modeling method-to define novel clinical phenotypes. We assessed demographic, clinical, and reaction characteristics associated with phenotype membership. Using log-binomial regression, we assessed the relation between phenotype membership and second dose tolerance, defined as either no symptoms or mild, self-limited symptoms resolving with antihistamines alone. A sensitivity analysis considered second dose tolerance as objective signs only. RESULTS: We identified 265 patients with dose-1 immediate reactions with 3 phenotype clusters: (1) Limited or Predominantly Cutaneous, (2) Sensory, and (3) Systemic. A total of 223 patients (84%) received a second dose and 200 (90%) tolerated their second dose. Sensory cluster (all patients had the symptom of numbness or tingling) was associated with a higher likelihood of second dose intolerance, but this finding did not persist when accounting for objective signs. CONCLUSIONS: Three novel clinical phenotypes of immediate-onset reactions after dose 1 of mRNA COVID-19 vaccines were identified using latent class analysis: (1) Limited or Predominantly Cutaneous, (2) Sensory, and (3) Systemic. Whereas these clinical phenotypes may indicate differential mechanistic etiologies or associations with subsequent dose tolerance, most individuals proceeding to their second dose tolerated it.
Slow Waning of Antibodies Following BNT162b2 as a Third Dose in Adults Who Had Previously Received 2 Doses of Inactivated Vaccine. We administered BNT162b2 as a third dose to 314 adults aged â‰¥30 years who had previously received 2 doses of inactivated vaccine. We collected blood samples before the third dose and again after 1 month and 6 months, and found robust antibody responses to the ancestral strain at 6 months after receipt of BNT162b2. Antibody responses to Omicron BA.2 by live virus neutralization were weaker after the third dose and had declined to a low level by 6 months.
Severe refractory warm autoimmune haemolytic anaemia after the SARS-CoV-2 Pfizer-BioNTech vaccine (BNT162b2 mRNA) managed with emergency splenectomy and complement inhibition with eculizumab. A male in his teens with a history of liver transplant for biliary atresia (aged 2 years) and autoimmune haemolytic anaemia (AIHA, aged 6 years) presented with jaundice, dark urine, fatigue and chest discomfort that began 48 hours after the first dose of SARS-CoV-2 Pfizer-BioNTech vaccine (BNT162b2 mRNA). Investigations revealed a warm AIHA picture. Over 4 weeks the patient developed life-threatening anaemia culminating in haemoglobin of 35â€‰g/L (after transfusion), lactate dehydrogenase of 1293â€‰units/L and bilirubin of 228â€‰Âµmol/L, refractory to standard treatment with corticosteroids and rituximab. An emergency splenectomy was performed that slowed haemolysis but did not completely ameliorate it. Eculizumab, a terminal complement pathway inhibitor, was initiated to arrest intravascular haemolysis and showed a favourable response. AIHA is rare but described after the SARS-CoV-2 Pfizer-BioNTech vaccine. This case highlights the rare

complication of AIHA, the use of emergency splenectomy for disease control, and the use of eculizumab.

Assessment of immunological anti-platelet factor 4 antibodies for vaccine-induced thrombotic thrombocytopenia (VITT) in a large Australian cohort: A multicenter study comprising 1284 patients. BACKGROUND: Vaccine-induced thrombotic thrombocytopenia (VITT) is a rare complication of adenovirus-based vaccines aimed to prevent and minimize COVID-19 and related pathophysiology. OBJECTIVES: To describe patterns of testing for anti-platelet factor 4 (PF4) antibodies using various ELISA assays in a large Australian cohort and comparative functional platelet activation assays in a subset. PATIENTS/METHODS: Asserachrom HPIA IgG ELISA was performed in 1284 patients over a period of 12â€‰months, supplemented in select cohorts by comparative ELISA using three other methods (nÂ =â€‰78-179), three different functional assays (flow cytometry, serotonin release assay, and/or Multiplate; nÂ =â€‰476), and rapid immunological chemiluminescence anti-PF4 assay (nÂ =â€‰460), in a multicenter study. RESULTS: For first episode presentations, 190/1284 (14.8%) ELISA tests were positive. Conversely, most (445/460; 96.7%) chemiluminescence anti-PF4 test results were negative. All functional assays showed associations of higher median ELISA optical density with functional positivity and with high rates of ELISA positivity (64.0% to 85.2%). Data also identified functional positivity in 14.8%-36.0% of ELISA negative samples, suggesting false negative VITT by HPIA IgG ELISA in upward of one third of assessable cases. CONCLUSION: To our knowledge, this is the largest multicenter evaluation of anti-PF4 testing for investigation of VITT. Discrepancies in test results (ELISA vs. ELISA or ELISA vs. functional assay) in some patients highlighted limitations in relying on single methods (ELISA and functional) for PF4 antibody detection in VITT, and also highlights the variability in phenotypic test presentation and pathomechanism of VITT.

Durability of Immune Response After COVID-19 Booster Vaccination and Association With COVID-19 Omicron Infection. IMPORTANCE: The BNT162b2 two-dose vaccine (BioNTech/Pfizer) has high effectiveness that wanes within several months. The third dose is effective in mounting a significant immune response, but its durability is unknown. OBJECTIVE: To compare antibody waning after second and third doses and estimate the association of antibody kinetics with susceptibility to infection with the Omicron variant of SARS-CoV-2. DESIGN, SETTING, AND PARTICIPANTS: In a prospective longitudinal cohort study in a tertiary medical center in Israel, health care workers who received the BNT162b2 vaccine were followed up monthly for IgG and neutralizing antibody levels. Linear mixed models were used to compare antibody titer waning of second and third doses and to assess whether antibody dynamics were associated with Omicron transmission. Avidity, T cell activation, and microneutralization of sera against different variants of concern were assessed for a subgroup. EXPOSURE: Vaccination with a booster dose of the BNT162b2 vaccine. MAIN OUTCOMES AND MEASURES: The primary outcome was the rate of antibody titer change over time, and the secondary outcome was SARS-CoV-2 Omicron variant infection, as confirmed by reverse transcriptase-polymerase chain reaction. RESULTS: Overall, 4868 health care workers (mean [SD] age, 46.9 [13.7] years; 3558 [73.1%] women) and 3972 health care workers (mean [SD] age, 48.5 [14.1] years; 996 [74.9%] women) were followed up for 5 months after their second and third vaccine doses, respectively. Waning of IgG levels was slower after the third compared with the second dose (1.32%/d [95% CI, 1,29%/d to 1.36%/d] vs 2.26% [95% CI, 2.13%/d 2.38%/d]), as was waning of neutralizing antibody levels (1.32%/d [95% CI, 1.21%/d to 1.43%/d] vs 3.34%/d [95% CI, 3.11%/d to 3.58%/d]). Among 2865 health care workers assessed for Omicron incidence during an additional 2 months of follow-up, lower IgG peak (ratio of means 0.86 [95% CI, 0.80-0.91]) was associated with Omicron infection, and among participants aged 65 years and older, faster waning of IgG and neutralizing antibodies (ratio of mean rates, 1.40; [95% CI, 1.13-1.68] and 3.58 [95% CI, 1.92-6.67], respectively) were associated with Omicron infection. No waning in IgG avidity was observed 112

days after the third dose. Live neutralization of Omicron was lower compared with previous strains, with a geometric mean titer at the peak of 111 (95% CI, 75-166), compared with 942 (95% CI, 585-1518) for WT, 410 (95% CI, 266-634) for Delta; it demonstrated similar waning to 26 (95% CI, 16-42) within 4 months. Among 77 participants tested for T cell activity, mean (SD) T cell activity decreased from 98 (5.4) T cells/106 peripheral blood mononuclear cells to 59 (9.3) T cells/106 peripheral blood mononuclear cells. CONCLUSIONS AND RELEVANCE: This study found that the third vaccine dose was associated with greater durability than the second dose; however, Omicron was associated with greater resistance to neutralization than wild type and Delta variants of concern. Humoral response dynamics were associated with susceptibility to Omicron infection.
Atrophic lichen planus post-COVID vaccination in a hepatitis C positive individual.
Durability of protection and immunogenicity of AZD1222 (ChAdOx1 nCoV-19) COVID-19 vaccine over 6 months. BackgroundWe report updated safety, efficacy, and immunogenicity of AZD1222 (ChAdOx1 nCoV-19) from an ongoing phase 3 trial.MethodsAdults at increased risk of SARS-CoV-2 infection were randomized (2:1), stratified by age, to receive 2 doses of AZD1222 or placebo. The primary efficacy end point was confirmed SARS-CoV-2 reverse-transcriptase PCR-positive (RT-PCR-positive) symptomatic COVID-19 at 15 or more days after a second dose in baseline SARS-CoV-2-seronegative participants. The 21,634 and 10,816 participants were randomized to AZD1222 and placebo, respectively.FindingsData cutoff for this analysis was July 30, 2021; median follow-up from second dose was 78 and 71 days for the double-blind period (censoring at unblinding or nonstudy COVID-19 vaccination) and 201 and 82 days for the period to nonstudy COVID-19 vaccination (regardless of unblinding) in the AZD1222 and placebo groups, respectively. For the primary efficacy end point in the double-blind period (141 and 184 events; incidence rates: 39.2 and 118.8 per 1,000 person years), vaccine efficacy was 67.0% ($P < 0.001$). In the period to nonstudy COVID-19 vaccination, incidence of events remained consistently low and stable through 6 months in the AZD1222 group; for the primary efficacy end point (328 and 219 events; incidence rates: 36.4, 108.4) and severe/critical disease (5 and 13 events; incidence rates: 0.6, 6.4), respective vaccine efficacy estimates were 65.1% and 92.1%. AZD1222 elicited humoral immune responses over time, with waning at day 180. No emergent safety issues were seen.ConclusionAZD1222 is safe and well tolerated, demonstrating durable protection and immunogenicity with median follow-up (AZD1222 group) of 6 months.Trial registrationClinicalTrials.gov NCT04516746.FundingAstraZeneca; US government.
Lessons from a large-scale COVID-19 vaccine trial. Global vaccination coverage remains indispensable in combatting the ongoing SARS-CoV-2 pandemic. Safety, efficacy, and durability of immune protection are the key parameters of randomized controlled trials (RCTs) and are essential for vaccine approvals, global distribution, and comprehensive population-vaccination programs. Immune protection from either vaccination or natural infection decreases over time, further challenged by rapid viral evolution. In this issue of the JCI, Sobieszczyk and colleagues report an update on the safety, efficacy, and durability of immune protection of AZD12222 in a large-scale, multinational, Phase III RCT. They report that protection lasted through 6 months, with immunity waning after 180 days. The study also highlights challenges facing vaccine trials, including the need for early unblinding for vulnerable participants, which may affect outcome measurements. Another challenge is to ensure fair representation of marginalized and minority ethnic groups in vaccine safety and efficacy studies worldwide.
Immune responses following 3rd and 4th doses of heterologous and homologous COVID-19 vaccines in kidney transplant recipients. BACKGROUND: Solid organ transplant recipients have attenuated immune responses to SARS-CoV-2 vaccines. In this study, we report on immune responses to 3rd- (V3) and 4th- (V4) doses of heterologous and homologous vaccines in a kidney transplant population.

METHODS: We undertook a single centre cohort study of 724 kidney transplant recipients prospectively screened for serological responses following 3 primary doses of a SARS-CoV2 vaccine. 322 patients were sampled post-V4 for anti-spike (anti-S), with 69 undergoing assessment of SARS-CoV-2 T-cell responses. All vaccine doses were received post-transplant, only mRNA vaccines were used for V3 and V4 dosing. All participants had serological testing performed post-V2 and at least once prior to their first dose of vaccine. FINDINGS: 586/724 (80.9%) patients were infection-naÃ¯ve post-V3; 141/2586 (24.1%) remained seronegative at 31 (21-51) days post-V3. Timing of vaccination in relation to transplantation, OR: 0.28 (0.15-0.54), p=0.0001; immunosuppression burden, OR: 0.22 (0.13-0.37), p<0.0001, and a diagnosis of diabetes, OR: 0.49 (0.32-0.75), p=0.001, remained independent risk factors for non-seroconversion. Seropositive patients post-V3 had greater anti-S if primed with BNT162b2 compared with ChAdOx1, p=0.001.Post-V4, 45/239 (18.8%) infection-naÃ¯ve patients remained seronegative. De novo seroconversion post-V4 occurred in 15/60 (25.0%) patients. There was no difference in anti-S post-V4 by vaccine combination, p=0.50. T-cell responses were poor, with only 11/54 (20.4%) infection-naive patients having detectable T-cell responses post-V4, with no difference seen by vaccine type. INTERPRETATION: A significant proportion of transplant recipients remain seronegative following 3- and 4- doses of SARS-CoV-2 vaccines, with poor T-cell responses, and are likely to have inadequate protection against infection. As such alternative strategies are required to provide protection to this vulnerable group. FUNDING: MW/PK received study support from Oxford Immunotec.

Effectiveness, safety, and immunogenicity of half dose ChAdOx1 nCoV-19 COVID-19 Vaccine: Viana project. Fractional dose is an important strategy to increase access to vaccines. This study evaluated the effectiveness, safety, and immunogenicity of half dose of ChAdOx1 nCoV-19 vaccine. A non-inferiority non-randomized controlled trial compared a half dose of ChAdOx1 nCoV-19 with the full dose, with an interval of 8 to 10 weeks, in individuals aged 18-49 years. The primary endpoints were the incidence rate of new cases/1,000 person-year at 90 days after 14 days of the second dose, confirmed by RT-PCR and new cases registered at SUS National Health Surveillance Database (e-SUS VS). The anti-SARS-CoV-2 spike (S) protein receptor binding domain (RBD) by chemiluminescence and the neutralizing antibodies by plaque reduction neutralization test (PRNT) were titrated. The soluble biomarkers were quantified with a multiplex immunoassay. Follow-up was 90 days after 14 days of the second dose. A total of 29,598 individuals were vaccinated. After exclusion, 16,570 individuals who received half a dose and 6,402 who received full doses were analyzed. The incidence of new cases confirmed by RT-PCR of half dose was non-inferior to full dose (23.7 vs. 25.7 cases per 1,000 persons-year [coefficient group -0.09 CI95%(-0.49 to 0.31)], even after adjusting for age and sex. There were no deaths or hospitalization after immunization of either group. Immunogenicity was evaluated in a subsample (N=558) compared to 154 healthcare workers who received a full dose. The seroconversion rate in seronegative individuals at baseline half dose was 99.8%, similar to that of the full dose (100%). Geometric mean concentration (95% CI; BAU/mL) were half dose = 188 (163-217) and full dose = 529 (423-663) ($p < 0.001$). In seropositive subjects at baseline (pre-immune individuals), the first dose induced very high and similar IgG-S in half dose 1,359 (1,245-1,483) and full dose 1,354 (1,048-1,749) BAU/mL. A half dose induced a high increase in plasma chemokines, pro-inflammatory/regulatory cytokines, and growth factors. The frequency of adverse events was similar. No serious adverse events or deaths were reported. A half dose of ChAdOx1 nCoV-19 is as effective, safe, and immunogenic as the full dose. The immune response in pre-immune (seropositive in the baseline) individuals indicates that the half dose may be a booster dose schedule.

Atypical acute disseminated encephalomyelitis with systemic inflammation after a first dose of AztraZaneca COVID-19 vaccine. A case report. BACKGROUND: Only a few cases of acute disseminated encephalomyelitis (ADEM) following coronavirus disease 19 (COVID-19) vaccination

have been described since the beginning of the vaccination campaign. RESULTS: Here we report the first case of central nervous system (CNS) demyelination with systemic inflammatory findings on whole body 19-fluorodeoxyglucose positron emission tomography with computed tomography (FDG-PET/CT) following the ChAdOx1 nCoV-19 vaccine. CONCLUSIONS: Clinicians should stay aware of potential new adverse events after immunization.

Higher benefit-risk ratio of COVID-19 vaccination in patients with schizophrenia and major depressive disorder versus patients with bipolar disorder when compared to controls. Patients with major psychiatric disorders (MPD) that include schizophrenia (SCH), bipolar disorder (BP), and major depressive disorder (MDD) are at increased risk for coronavirus disease 2019 (COVID-19). However, the safety and efficacy of COVID-19 vaccines in MPD patients have not been fully evaluated. This study aimed to investigate adverse events (AEs)/side effects and efficacy of COVID-19 vaccines in MPD patients. This retrospective study included 2034 patients with SCH, BP, or MDD who voluntarily received either BBIBP-CorV or Sinovac COVID-19 vaccines, and 2034 matched healthy controls. The incidence of AEs/side effects and the efficacy of COIVD-19 vaccinations among the two groups were compared. The risk ratio (RR) of side effects in patients with MPD was 0.60 (95% confidence interval [CI]: 0.53-0.68) after the first dose and 0.80 (95% CI: 0.65-0.99) following the second dose, suggesting a significantly lower risk in the MPD group versus healthy controls. The RRs of AEs did not differ between patients and controls. Notably, fully vaccinated patients exhibited a decreased risk of influenza with or without fever compared with controls (RR=0.38, 95% CI: 0.31-0.46; RR=0.23, 95% CI: 0.17-0.30; respectively). Further subgroup comparisons revealed a significantly lower risk of influenza with fever in MDD (RR=0.13, 95% CI: 0.08-0.21) and SCH (RR=0.24, 95% CI: 0.17-0.34) than BP (RR=0.85, 95% CI: 0.69-1.06) compared to controls. We conclude that the benefit-risk ratio of COVID-19 vaccination was more favorable in SCH or MDD versus BP when compared with controls. These data indicate that COVID-19 vaccines are safe and protective in patients with MPD from COVID-19.

Survey of glucocorticoid dose escalation in patients with adrenal insufficiency during the peri-COVID-19 vaccination period. There is uncertainty regarding the need for COVID-19 peri-vaccination glucocorticoid coverage in patients with adrenal insufficiency. In this survey conducted in a single tertiary medical institution, 167 consecutive outpatients taking physiological glucocorticoids because of adrenal insufficiency were included. The patients declared if they developed an adrenal crisis after vaccination, and the amount and duration of an increase in their glucocorticoid dosage, if any. None of the patients without preventive glucocorticoid increase suffered an adrenal crisis after COVID-19 vaccination. Only 8.3% (14 cases) and 27.5% (46 cases) of the patients needed to escalate the dose of glucocorticoids when systemic symptoms appeared after the first and second injections, respectively. Glucocorticoids were increased in patients <60 years of age more than in patients â‰¥60 years of age at the time of both the first ($p = 0.026$) and second injections ($p = 0.005$). Sex and the causes of adrenal insufficiency were not associated with the frequency of the patients who needed glucocorticoid dose escalation. In the cases with increased glucocorticoids, the median dosage for escalation was 10 mg (hydrocortisone equivalent). In conclusion, even without prophylactic glucocorticoid administration, adrenal crisis did not occur during the peri-COVID-19 vaccination period. The dose escalation of steroid was more frequent in younger patients following the second vaccination. Careful monitoring of adverse effects and the appropriate management of glucocorticoids when necessary are essential following COVID-19 vaccinations.

Anti-signal Recognition Particle Antibody-positive Immune-mediated Myopathy after mRNA-1273 SARS-CoV-2 Vaccination. A 26-year-old Japanese woman developed a fever, myalgia and gait disturbance one day after receiving the second dose of the mRNA-1273 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. A neurological examination revealed symmetrical weakness and myalgia in proximal lower limbs, and a blood examination showed prominent elevation

of creatinine kinase. Magnetic resonance imaging (MRI) revealed a high signal intensity in the thigh muscles on short-tau inversion recovery images, and antibody testing revealed positive findings for anti-signal recognition particle (SRP) antibody. Thus, anti-SRP antibody-positive immune-mediated myopathy was diagnosed. We initiated immunotherapy, and she was ultimately able to walk stably.

Different humoral but similar cellular responses of patients with autoimmune inflammatory rheumatic diseases under disease-modifying antirheumatic drugs after COVID-19 vaccination. OBJECTIVES: The effect of different modes of immunosuppressive therapy in autoimmune inflammatory rheumatic diseases (AIRDs) remains unclear. We investigated the impact of immunosuppressive therapies on humoral and cellular responses after two-dose vaccination. METHODS: Patients with rheumatoid arthritis, axial spondyloarthritis or psoriatic arthritis treated with TNFi, IL-17i (biological disease-modifying antirheumatic drugs, b-DMARDs), Janus-kinase inhibitors (JAKi) (targeted synthetic, ts-DMARD) or methotrexate (MTX) (conventional synthetic DMARD, csDMARD) alone or in combination were included. Almost all patients received mRNA-based vaccine, four patients had a heterologous scheme. Neutralising capacity and levels of IgG against SARS-CoV-2 spike-protein were evaluated together with quantification of activation markers on T-cells and their production of key cytokines 4 weeks after first and second vaccination. RESULTS: 92 patients were included, median age 50 years, 50% female, 33.7% receiving TNFi, 26.1% IL-17i, 26.1% JAKi (all alone or in combination with MTX), 14.1% received MTX only. Although after first vaccination only 37.8% patients presented neutralising antibodies, the majority (94.5%) developed these after the second vaccination. Patients on IL17i developed the highest titres compared with the other modes of action. Co-administration of MTX led to lower, even if not significant, titres compared with b/tsDMARD monotherapy. Neutralising antibodies correlated well with IgG titres against SARS-CoV-2 spike-protein. T-cell immunity revealed similar frequencies of activated T-cells and cytokine profiles across therapies. CONCLUSIONS: Even after insufficient seroconversion for neutralising antibodies and IgG against SARS-CoV-2 spike-protein in patients with AIRDs on different medications, a second vaccination covered almost all patients regardless of DMARDs therapy, with better outcomes in those on IL-17i. However, no difference of bDMARD/tsDMARD or csDMARD therapy was found on the cellular immune response.

Vaccine-Induced Immune Thrombocytopenia and Thrombosis after the Sputnik V Vaccine.

A randomized, double-blind, placebo-controlled phase 1 and phase 2 clinical trial to evaluate efficacy and safety of a SARS-CoV-2 vaccine SCoK in adults. BACKGROUND: To determine an appropriate dose of, and immunization schedule for, a vaccine SCoK against COVID-19 for an efficacy study; herein, we conducted randomized controlled trials to assess the immunogenicity and safety of this vaccine in adults. METHODS: These randomized, double-blind, placebo-controlled phase 1 and 2 trials of vaccine SCoK were conducted in Binhai District, Yan City, Jiangsu Province, China. Younger and older adult participants in phase 1 and 2 trials were sequentially recruited into different groups to be intramuscularly administered 20 or 40Â Î¼g vaccine SCoK or placebo. Participants were enrolled into our phase 1 and 2 studies to receive vaccine or placebo. RESULTS: No serious vaccine-related adverse events were observed in either trial. In both trials, local and systemic adverse reactions were absent or mild in most participants. In our phase 1 and 2 studies, the vaccine induced significantly increased neutralizing antibody responses to pseudovirus and live SARS-CoV-2. The vaccine induced significant neutralizing antibody responses to live SARS-CoV-2 on day 14 after the last immunization, with NT50s of 80.45 and 92.46 in participants receiving 20 and 40Â Î¼g doses, respectively; the seroconversion rates were 95.83% and 100%. The vaccine SCoK showed a similar safety and immunogenicity profiles in both younger participants and older participants. The vaccine showed better immunogenicity in phase 2 than in phase 1 clinical trial. Additionally, the incidence of adverse reactions decreased significantly in phase 2 clinical trial. The vaccine SCoK was well tolerated and immunogenic.

Higher Cell-Mediated Immune Responses in Patients With Inflammatory Bowel Disease on Anti-TNF Therapy After COVID-19 Vaccination. BACKGROUND: Some patients with inflammatory bowel disease (IBD) on immunosuppressive therapies may have a blunted response to certain vaccines, including the messenger RNA (mRNA) coronavirus disease 2019 (COVID-19) vaccines. However, few studies have evaluated the cell-mediated immune response (CMIR), which is critical to host defense after COVID-19 infection. The aim of this study was to evaluate the humoral immune response and CMIR after mRNA COVID-19 vaccination in patients with IBD. METHODS: This prospective study (HERCULES [HumoRal and CellULar initial and Sustained immunogenicity in patients with IBD] study) evaluated humoral immune response and CMIR after completion of 2 doses of mRNA COVID-19 vaccines in 158 IBD patients and 20 healthy control (HC) subjects. The primary outcome was the CMIR to mRNA COVID-19 vaccines in patients with IBD. The secondary outcomes were a comparison of (1) the CMIR in patients with IBD and HC subjects, (2) CMIR and humoral immune response in all participants, and (3) correlation between CMIR and humoral immune response. RESULTS: The majority (89%) of patients with IBD developed a CMIR, which was not different vs HC subjects (94%) (Pâ€…=â€….6667). There was no significant difference (Pâ€…=â€….5488) in CMIR between immunocompetent (median 255 [interquartile range, 146-958] spike T cells per million peripheral blood mononuclear cells) and immunosuppressed patients (median 377 [interquartile range, 123-1440]). There was no correlation between humoral and cell-mediated immunity after vaccination (Pâ€…=â€….5215). In univariable analysis, anti-tumor necrosis factor therapy was associated with a higher CMIRs (Pâ€…=â€….02) and confirmed in a multivariable model (Pâ€…=â€….02). No other variables were associated with CMIR. CONCLUSIONS: Most patients with IBD achieved CMIR to a COVID-19 vaccine. Future studies are needed evaluating sustained CMIR and clinical outcomes.

 Antibody and T cell responses to coronavirus disease 2019 vaccines in patients with inflammatory bowel disease do not correlate. Most patients with inflammatory bowel disease mount a T cell response despite being on biologic therapies, those on anti-tumor necrosis factor may have a higher T cell response. Anti-tumor necrosis factor therapy has been associated with a lower antibody response to coronavirus disease 2019 vaccines, but the T cell response is augmented.

A Suspected Case of Multisystem Inflammatory Disease in Children Following COVID-19 Vaccination: A Case Report and Systematic Literature Review. Multisystem inflammatory syndrome in children (MIS-C) is rare but can be a potentially serious complication following SARS-CoV-2 infection in children. 1 Introduction of coronavirus disease 2019 (COVID-19) vaccines are effective in lowering the burden due to SARS-CoV-2. However, there have been reports of MIS occurrence following COVID-19 vaccination in adults. 2 The potential public health implication of MIS-C following COVID-19 vaccination is not clear in children. Our objective is to describe the spectrum of clinical disease, therapy, and outcomes of MIS-C following COVID-19 vaccination in children.

Health and Vaccination Status of Unaccompanied Minors After Arrival in a European Border Country: A Cross-sectional Study (2017-2020). BACKGROUND: Unaccompanied and separated children (UASC) are a high-risk group for infectious diseases and information on their vaccination status is scarce. Different approaches are used to screen newly arrived minors in Europe. The aim of this study was to describe the health status and serological protection against different vaccine-preventable diseases among UASC to inform public health decision-making. METHODS: Retrospective study of all UASC seen at an international health reference center in Barcelona (Spain) between January 2017 and February 2020. Screening results were analyzed using binary logistic regression with adjustment for symptoms, geographic origin, and time since arrival. RESULTS: We studied 289 UASC (88.9% males; median age, 17 years). At least one infection was diagnosed in 136 minors (47.1%). There was a high prevalence of intestinal parasites (22.8%), latent tuberculosis infection (22.5%), and hepatitis B (5.2%), even in asymptomatic individuals, and especially among UASC from sub-Saharan Africa (odds

ratio, 2.5; 95% confidence interval, 1.5-4.0, P < 0.001). We did not observe a significant association between clinical symptoms and the presence of infection or differences in the prevalence of different infections according to number of months since arrival. Protection against hepatitis B virus (36%), measles (80%), and varicella (83%) was suboptimal. CONCLUSIONS: Our results highlight the importance of screening and vaccination programs for UASC arriving in Europe, especially border countries. Protocols should be adjusted according to geographic origin. Absence of symptoms does not necessarily rule out infection, highlighting the importance of screening in asymptomatic minors. These programs are a public health priority and should not be neglected during the current COVID-19 pandemic.

Disseminated cutaneous herpes simplex infection after COVID-19 vaccination in a rheumatoid arthritis patient: a case report and review. Since COVID-19 vaccination started in December 2020, different side effects were reported. This case report describes the possibility of developing disseminated herpes simplex infection after COVID-19 vaccine in a patient with rheumatoid arthritis. In this case report, we describe a 63-year-old Iranian female. She was a known case of seronegative rheumatoid arthritis and presented with generalized papulo-pustular itchy and painful skin lesions which appeared about seven days after the second dose of Sinopharm BIBP COVID-19 vaccine (BIBP-CorV). A biopsy of the skin lesions revealed acantholysis, neutrophils, and enlarged keratinocytes with eosinophilic intra-nuclear inclusions. Findings were consistent with herpes simplex infection. She was successfully treated by acyclovir. Disseminated cutaneous herpes simplex infection may have been triggered by COVID-19 vaccination. Reactivation of herpes virus after COVID-19 vaccines was reported in both rheumatic patients and other individuals. Whether having an underlying autoimmune inflammatory disorder could be an additional risk factor is still unknown.

Prevalence of rheumatoid arthritis following COVID-19 vaccine: An autoimmune disorder.

COVID-19 vaccine acceptance and associated factors among people living with HIV in the Middle East and North Africa region. BACKGROUND: Identifying coronavirus disease 2019 (COVID-19) vaccine acceptance and associated factors among people living with HIV (PLHIV) in the Middle East and North Africa region is important to meet the need for broad-scale vaccination against COVID-19. OBJECTIVES: To investigate the COVID-19 vaccine acceptance rate and factors among PLHIV in the Middle East and North Africa region. METHOD: An online cross-sectional survey was conducted among PLHIV currently living in Egypt, Tunisia and Saudi Arabia between March 2021 and August 2021. RESULTS: Of the 540 respondents, 19.3% reported already being vaccinated against COVID-19 (n = 104), 32.0% responded 'definitely yes' (n = 173), and 13.3% responded 'probably yes' (n = 72) for intention to receive a COVID-19 vaccine, with an overall COVID-19 vaccine acceptance rate of 64.6% among PLHIV in the region. The most significant predictors of COVID-19 vaccine acceptance included feeling less worried about COVID-19 transmission post-vaccination (221.0% higher odds), and believing the disease is vaccine-preventable (160.0% higher odds). Reported barriers to COVID-19 vaccine acceptance include concerns about vaccine effectiveness and belief that HIV medications protect against COVID-19 transmission, living in a rural area and reporting less-frequent engagement with HIV care. Nine out of 10 participants reported that the chances of them getting COVID-19 vaccine would increase if given adequate information and if their doctor recommended it. CONCLUSION: Findings of the study can help researchers, health officials, and other health system actors understand the predictors and barriers to COVID-19 vaccine acceptance reported by PLHIV. This understanding could inform the future planning of interventions tailored to PLHIV.

Myocarditis as a manifestation of the disease COVID-19 and after vaccination against this disease. Although the involvement of the heart muscle in the coronavirus disease 2019 (COVID-19) is relatively common (5-10%), myocarditis is a complication with a much lower incidence, depending, however, on the diagnostic methods used. The pathophysiological mechanisms have been described, but there

are significant gaps in current knowledge. Myocarditis in connection with vaccination against the disease COVID-19 is a separate nosological unit. Even here, the pathophysiological processes are not explored in detail. The incidence of this complication is estimated in the low tens per million vaccinated.

Comparative analysis of humoral responses to BNT162b2 vaccine among patients with hematologic disorders and organ transplant recipients. Vaccination against SARS-COV-2 is considered the most promising approach to curbing the pandemic. Patients with an immunocompromised state, such as those with hematological malignancies and organ transplantation recipients, are considered more susceptible to infection, but these at-risk patients were underrepresented in early clinical trials for vaccination. Although a growing body of studies suggests that the humoral response to COVID-19 vaccination in each of these at-risk groups of patients may be suboptimal in comparison to healthy controls, a clinical and strategic information for the further comparative analysis among these groups is not fully described. The humoral responses after two doses of BNT162b2 vaccination were evaluated in a total of 187 patients either with allogeneic hematopoietic transplantation, with renal transplantation, with anti-CD20 antibody therapy, or with anti-CD38 antibody therapy, and in 66 healthy controls. The early response at one to three months after vaccination was significantly inferior among patients with renal transplantation, patients with anti-CD20 antibody therapy, and patients with anti-CD38 antibody therapy in comparison to healthy control. But the patients with allogeneic hematopoietic transplantation showed early humoral response comparable to healthy control. The late response at 6Â months after vaccination was still suboptimal among patients with renal transplantation and patients with anti-CD20 therapy. Among our patient group, renal transplant recipients had the lowest antibody titers after vaccination regardless of timing of vaccination. Patients who had received allogeneic hematopoietic transplantation attained a comparable serological response to the control group especially if they are vaccinated >300Â days after transplantation, but the response was suboptimal if the vaccination was within 300Â days after transplantation. Our results may provide policy makers with critical information for the further stratification of at-risk groups, helping contribute to a better allocation of resources, including additional booster vaccination.

Guillain-BarrÃ© syndrome in association with COVID-19 vaccination: a systematic review. Since the beginning of worldwide vaccination against coronavirus disease 2019 (COVID-19), studies have reported a possible association between vaccination and Guillain-BarrÃ© syndrome (GBS). In this regard, we conducted a systematic review assessing different demographic, clinical, and neurophysiological aspects of patients with GBS following immunization with COVID-19 vaccines. A comprehensive search of PubMed, Web of Science, Scopus, and Google Scholar was performed. Articles in English between January 2020 and November 2021 were included. Data on demographics, clinical characteristics, vaccines information, treatment approaches, and outcomes were extracted. The data of a total of 88 patients out of 41 studies was included. The mean age of patients was 58.7â€‰Â±â€‰16.6Â years and 55 cases (62.5%) were male. AstraZeneca was the most-reported vaccine associated with GBS with 52 cases (59.1%) followed by Pfizer with 20 cases (22.7%). GBS occurred after the first dose of vaccination in 70 cases (79.5%). The mean time interval between vaccination and symptom onset was 13.9â€‰Â±â€‰7.4Â days. Limb weakness (47.7%), sensory disturbance (38.6%), and facial weakness (27.3%) were the most common reported symptoms, respectively. Albuminocytologic dissociation was seen in 65% of patients who underwent lumbar puncture (nâ€‰=â€‰65). Acute inflammatory demyelinating polyradiculopathy was the most common GBS subtype, which was reported in 38 patients (43.2%). While one-fifth of patients underwent intubation (nâ€‰=â€‰17), a favorable outcome was achieved in the majority of subjects

(nâ€‰=â€‰46, 63%). Overall, a small rise in GBS incidence, following various COVID-19 vaccines, was observed. Notably, 85% of affected individuals experienced at least a partial recovery.

Letter to the editor: A case of functional isolated tongue tremor-like dyskinesia after COVID-19 vaccine.

The effect of SARS-CoV-2 BNT162b2 vaccine on the symptoms of women with endometriosis. PURPOSE: As the use of the messenger RNA (mRNA) BNT162b2 (Pfizer-BioNTech) Coronavirus disease 2019 vaccine has grown, reports on menstrual changes have arisen. We aimed to examine menstrual bleeding patterns and endometriosis-associated symptoms after receiving the mRNA BNT162b2 SARS-CoV-2 vaccine in women with endometriosis, as compared to the control group. METHODS: This is a questionnaire-based cross-sectional study including a total of 174 women. The study group included 86 women with a confirmed diagnosis of endometriosis and the control group included 88 women with no diagnosis or suspected diagnosis of endometriosis. Each woman completed a questionnaire on menstrual bleeding patterns and endometriosis-associated symptoms before and after receiving two doses of the BNT162b2 vaccine. Primary outcomes were changes in amount or length of menstrual bleeding, rates of intermenstrual bleeding and worsening in dysmenorrhea in the endometriosis patient group, as compared to the control group. Secondary outcomes included changes in all endometriosis-associated symptoms. RESULTS: In our cohort, women with endometriosis were more likely to experience changes in bleeding patterns (women with endometriosis: 39.5%, control group: 31.0%, pâ€‰=â€‰0.02), and a significant worsening in endometriosis-associated symptoms with an almost 4.3-fold worsening in dysmenorrhea [95% CI 1.9-9.9, pâ€‰<â€‰0.01] and 5.5-fold odds for any worsening in symptoms in endometriosis patients, as compared to the control group [95% CI 2.7-11.1, pâ€‰<â€‰0.01]. CONCLUSION: In our cohort, endometriosis was shown to be a significant risk factor for worsening of menstrual symptoms, after receiving the SARS-CoV-2 BNT162b2 mRNA vaccine. Further research is needed to confirm these findings.

Atypical follicular hyperplasia with light chain-restricted germinal centers after COVID-19 booster: a diagnostic pitfall. There has been a surge in COVID-19 vaccine-associated lymphadenopathy (LAD), including after the booster dose of vaccine. This can create diagnostic dilemmas in oncology patients as the relatively sudden LAD can mimic metastasis or cancer recurrence, at a risk of leading to additional but unnecessary anti-neoplastic therapy. Here we report the histopathologic features in a case of persistent LAD occurring in a patient with history of breast invasive ductal carcinoma which followed a COVID-19 vaccine booster. A needle core and then excisional biopsy showed atypical follicular hyperplasia with features that histologically and phenotypically could mimic follicular lymphoma, but the findings were ultimately interpreted to be reactive in nature and related temporally to COVID-19 vaccine. To our knowledge, this is the first case of an atypical lymphoproliferative lesion with features potentially mimicking lymphoma associated with COVID-19 vaccine.

New-onset systemic lupus erythematosus following BNT162b2 mRNA COVID-19 vaccine: a case series and literature review. Emerging data evaluated the possible link between the Coronavirus 19 (COVID-19) vaccine and acute flares of rheumatic autoimmune diseases. However, the association between the COVID-19 vaccine and the development of de-novo rheumatic autoimmune diseases remained unclear. We report the first case series of three male patients who developed new-onset systemic lupus erythematosus following receiving Pfizer BNT162b2 mRNA vaccination. The clinical characteristics share some similarities with drug-induced lupus. More patients with SLE following COVID-19 may be diagnosed in the future. Additional studies will provide more significant insights into the possible immunogenic influence of the COVID-19 vaccine.

Axillary Lymphadenopathy after Pfizer-BioNTech and Moderna COVID-19 Vaccination: MRI Evaluation. Background COVID-19 vaccination-related axillary lymphadenopathy has become an important problem in cancer imaging. Data are needed to update or support imaging guidelines for conducting appropriate follow-up. Purpose To investigate the prevalence, predisposing factors, and MRI characteristics of COVID-19 vaccination-related axillary lymphadenopathy. Materials and Methods Prospectively collected prevaccination and postvaccination chest MRI scans were secondarily analyzed. Participants who underwent two doses of either the Pfizer-BioNTech or Moderna COVID-19 vaccine and chest MRI from June to October 2021 were included. Enlarged axillary lymph nodes were identified on postvaccination MRI scans compared with prevaccination scans. The lymph node diameter, signal intensity with T2-weighted imaging, and apparent diffusion coefficient (ADC) of the largest enlarged lymph nodes were measured. These values were compared between prevaccination and postvaccination MRI by using the Wilcoxon signed-rank test. Results Overall, 433 participants (mean age, 65 years Â± 11 [SD]; 300 men and 133 women) were included. The prevalence of axillary lymphadenopathy in participants 1-14 days after vaccination was 65% (30 of 46). Participants with lymphadenopathy were younger than those without lymphadenopathy (P < .001). Female sex and the Moderna vaccine were predisposing factors (P = .005 and P = .003, respectively). Five or more enlarged lymph nodes were noted in 2% (eight of 433) of participants. Enlarged lymph nodes greater than or equal to 10 mm in the short axis were noted in 1% (four of 433) of participants. The median signal intensity relative to the muscle on T2-weighted images was 4.0; enlarged lymph nodes demonstrated a higher signal intensity (P = .002). The median ADC of enlarged lymph nodes after vaccination in 90 participants was 1.1 Ã— 10(-3) mm(2)/sec (range, 0.6-2.0 Ã— 10(-3) mm(2)/sec), thus ADC values remained normal. Conclusion Axillary lymphadenopathy after the second dose of the Pfizer-BioNTech or Moderna COVID-19 vaccines was frequent within 2 weeks after vaccination, was typically less than 10 mm in size, and had a normal apparent diffusion coefficient. Â© RSNA, 2022.

Prevalence of New-Onset Tinnitus after COVID-19 Vaccination with Comparison to Other Vaccinations. OBJECTIVE: To investigate how often patients are diagnosed with new-onset tinnitus within 21â€‰days after COVID-19 vaccination in comparison to after three other common vaccinations: influenza, Tdap (tetanus, diphtheria, and acellular pertussis), and polysaccharide pneumococcus. METHODS: The TriNetX Analytics Network, a federated health research network that aggregates the de-identified electronic health record (EHR) data of over 78â€‰million patients, was queried for patients receiving each vaccination. Instances of new-onset tinnitus within 21â€‰days of vaccination were recorded and reported. RESULTS: Out of 2,575,235 patients receiving a first dose of the mRNA COVID-19 vaccine without any prior tinnitus diagnosis, 0.038% (95% CI: 0.036%-0.041%) of patients had a new diagnosis of tinnitus within 21â€‰days. There was a higher risk of a new tinnitus diagnosis after the influenza vaccine (RR: 1.95, 95% CI: 1.72-2.21), Tdap vaccine (RR: 2.36, 95% CI: 1.93-2.89), and pneumococcal vaccine (RR: 1.97, 95% CI: 1.48-2.64) than after the first dose of the COVID-19 vaccine. There was a lower risk of a new tinnitus diagnosis after the second dose of COVID-19 than after the first dose (RR: 0.80, 95% CI: 0.71-0.91). CONCLUSION: The rate of newly diagnosed tinnitus acutely after the first dose of the COVID-19 vaccine is very low. There was a higher risk of newly diagnosed tinnitus after influenza, Tdap, and pneumococcal vaccinations than after the COVID-19 vaccine. The present findings can help to address COVID-19 vaccine hesitancy during the ongoing pandemic. LEVEL OF EVIDENCE: Level 3 Laryngoscope, 133:1722-1725, 2023.

Combined central retinal artery occlusion and vein occlusion with exudative retinal detachment following COVID-19 vaccination.

RE: Regional Lymphadenopathy Following COVID-19 Vaccination in Patients with or Suspicious of Breast Cancer: A Quick Summary of Current Key Facts and Recommendations.

Adverse cutaneous reactions reported post COVID-19 vaccination in Al Buraimi governorate, Sultanate of Oman. On March 11, 2020, the World Health Organization (WHO) declared the novel coronavirus (COVID-19) a global pandemic. This has led to the rapid development and emergency approval of vaccines to overcome the alarming spread of the virus. Data on the cutaneous side effects related to the COVID-19 vaccine remains limited. In this prospective observational study, which was conducted from June 20 to September 20, 2021, we evaluated the incidence and various patterns of cutaneous side effects reported post COVID-19 vaccination in Al Buraimi Governorate in Oman. All vaccinated individuals aged 12â€‰years and older, who had a skin reaction within 4â€‰weeks following any dose of the COVID-19 vaccine, were enrolled in the study. The demographic data, medical history, vaccine-related information of all the patients were documented and the analysis was performed using the SPSS version 23 software. In total, 67 cutaneous reactions were reported by 55 patients accounting for 0.11% of all vaccinated individuals. The mean age of the patients was 33.3â€‰years, 80.6% were females, 61.2% of the reactions were reported after the first vaccine dose, and 38.8% were reported after the second dose. We observed a wide range of cutaneous reactions and categorized them into three major patterns: local injection site reaction (2%), new onset rash (81.6%), and flare up of pre-existing dermatological conditions (16.4%). Notably, urticaria was the most common reaction overall, followed by generalized pruritus and maculopapular rash. In general, we reported a diversity of cutaneous side effects that healthcare workers should be aware of as some reactions may be overlooked and not linked to the COVID-19 vaccination.

A prospective study on myocardial injury after BNT162b2 mRNA COVID-19 fourth dose vaccination in healthy persons. AIMS: To prospectively evaluate the incidence of myocardial injury after the administration of the fourth dose BNT162b2 mRNA vaccine (Pfizer-BioNTech) against COVID-19. METHODS AND RESULTS: Health care workers who received the BNT162b2 vaccine during the fourth dose campaign had blood samples collected for high-sensitivity cardiac troponin (hs-cTn) during vaccine administration and 2-4â€‰days afterward. Vaccine-related myocardial injury was defined as hs-cTn elevation above the 99th percentile upper reference limit and >50% increase from baseline measurement. Participants with evidence of myocardial injury underwent assessment for possible myocarditis. Of 324 participants, 192 (59.2%) were female and the mean age was 51.8Â Â±â€‰15.0â€‰years. Twenty-one (6.5%) participants had prior COVID-19 infection, the mean number of prior vaccine doses was 2.9Â Â±â€‰0.4, and the median time from the last dose was 147 (142-157) days. Reported vaccine-related adverse reactions included local pain at injection site in 57 (17.59%), fatigue in 39 (12.04%), myalgia in 32 (9.88%), sore throat in 21 (6.48%), headache in 18 (5.5%), fever â‰¥38Â°C in 16 (4.94%), chest pain in 12 (3.7%), palpitations in 7 (2.16%), and shortness of breath in one (0.3%) participant. Vaccine-related myocardial injury was demonstrated in two (0.62%) participants, one had mild symptoms and one was asymptomatic; both had a normal electrocardiogram and echocardiography. CONCLUSION: In a prospective investigation, an increase in serum troponin levels was documented among 0.62% of healthy health care workers receiving the fourth dose BNT162b2 vaccine. The two cases had mild or no symptoms and no clinical sequela. CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov Identifier: NCT05308680.

Re: COVID-19 vaccine associated cervical lymphadenopathy: correspondence.

Heterologous vector versus homologous mRNA COVID-19 booster vaccination in non-seroconverted immunosuppressed patients: a randomized controlled trial. Impaired response to COVID-19 vaccination is of particular concern in immunosuppressed patients. To determine the best vaccination strategy for this vulnerable group we performed a single center, 1:1 randomized blinded clinical trial. Patients who failed to seroconvert upon two mRNA vaccinations (BNT162b2 or mRNA-1273) are randomized to receive either a third dose of the same mRNA or the vector vaccine ChAdOx1 nCoV-19. Primary endpoint is the difference in SARS-CoV-2 spike antibody seroconversion rate between vector

and mRNA vaccinated patients four weeks after the third dose. Secondary outcomes include cellular immune responses. Seroconversion rates at week four are significantly higher in the mRNA (homologous vaccination, 15/24, 63%) as compared to the vector vaccine group (heterologous vaccination, 4/22, 18%). SARS-CoV-2-specific T-cell responses are reduced but could be increased after a third dose of either vector or mRNA vaccine. In a multivariable logistic regression analysis, patient age and vaccine type are associated with seroconversion. No serious adverse event is attributed to COVID-19 booster vaccination. Efficacy and safety data underline the importance of a booster vaccination and support the use of a homologous mRNA booster vaccination in immunosuppressed patients.Trial registration: EudraCT No.: 2021-002693-10.
Humoral response to mRNA-based COVID-19 vaccine in patients with de novo and pre-existing immune thrombocytopenia with exacerbation of thrombocytopenia after vaccination.
Reduced T-cell response following a third dose of SARS-CoV-2 vaccine in infection-naÃ¯ve people living with HIV.
Incidence of new onset glomerulonephritis after SARS-CoV-2 mRNA vaccination is not increased. Numerous cases of glomerulonephritis manifesting shortly after SARS-CoV-2 vaccination have been reported, but causality remains unproven. Here, we studied the association between mRNA-based SARS-CoV-2 vaccination and new-onset glomerulonephritis using a nationwide retrospective cohort and a case-cohort design. Data from all Swiss pathology institutes processing native kidney biopsies served to calculate incidence of IgA nephropathy, pauci-immune necrotizing glomerulonephritis, minimal change disease, and membranous nephropathy in the adult Swiss population. The observed incidence during the vaccination campaign (January to August 2021) was not different from the expected incidence calculated using a Bayesian model based on the years 2015 to 2019 (incidence rate ratio 0.86, 95% credible interval 0.73-1.02) and did not cross the upper boundary of the 95% credible interval for any month. Among 111 patients 18 years and older with newly diagnosed glomerulonephritis between January and August 2021, 38.7% had received at least one vaccine dose before biopsy, compared to 39.5% of the general Swiss population matched for age and calendar-time. The estimated risk ratio for the development of new-onset biopsy-proven glomerulonephritis was not significant at 0.97 (95% confidence interval 0.66-1.42) in vaccinated vs. unvaccinated individuals. Patients with glomerulonephritis manifesting within four weeks after vaccination did not differ clinically from those manifesting temporally unrelated to vaccination. Thus, vaccination against SARS-CoV-2 was not associated with new-onset glomerulonephritis in these two complementary studies with most temporal associations between SARS-CoV-2 vaccination and glomerulonephritis likely coincidental.
A Case of Hemophagocytic Lymphohistiocytosis following Second Dose of COVID-19 Vaccination. Hemophagocytic lymphohistiocytosis (HLH) is a rare, severe hyperinflammatory disease characterized by overproduction of cytokines and hemophagocytosis of hematopoietic cells, resulting in multiorgan failure. Prompt treatment initiation is essential for patient survival. The coronavirus disease 2019 (COVID-19) pandemic has led to the rapid development of several vaccines, including BNT162b2 by Pfizer-BioNTech. Few cases of immune-mediated complications of COVID-19 and its vaccines have been reported, characterized by persistent stimulation of the immune system, resembling HLH. We report the case of a 21-year-old man with secondary HLH following a second dose of the BNT162b2 vaccine. The patient did not have primary HLH or other contributors to secondary HLH and met the HLH-2004 diagnostic criteria. He was safely treated with steroid pulse therapy alone, without etoposide, cyclosporin, or immunoglobulins, which are recommended for pediatric patients. Physicians need to be aware of such severe complications following a second dose of the COVID-19 vaccine.

Infectious viral shedding of SARS-CoV-2 Delta following vaccination: A longitudinal cohort study. The impact of vaccination on SARS-CoV-2 infectiousness is not well understood. We compared longitudinal viral shedding dynamics in unvaccinated and fully vaccinated adults. SARS-CoV-2-infected adults were enrolled within 5 days of symptom onset and nasal specimens were self-collected daily for two weeks and intermittently for an additional two weeks. SARS-CoV-2 RNA load and infectious virus were analyzed relative to symptom onset stratified by vaccination status. We tested 1080 nasal specimens from 52 unvaccinated adults enrolled in the pre-Delta period and 32 fully vaccinated adults with predominantly Delta infections. While we observed no differences by vaccination status in maximum RNA levels, maximum infectious titers and the median duration of viral RNA shedding, the rate of decay from the maximum RNA load was faster among vaccinated; maximum infectious titers and maximum RNA levels were highly correlated. Furthermore, amongst participants with infectious virus, median duration of infectious virus detection was reduced from 7.5 days (IQR: 6.0-9.0) in unvaccinated participants to 6 days (IQR: 5.0-8.0) in those vaccinated (P = 0.02). Accordingly, the odds of shedding infectious virus from days 6 to 12 post-onset were lower among vaccinated participants than unvaccinated participants (OR 0.42 95% CI 0.19-0.89). These results indicate that vaccination had reduced the probability of shedding infectious virus after 5 days from symptom onset.

New onset of pemphigus foliaceus following BBIBP COVID-19 vaccine.

A case of BNT162b2 COVID-19 vaccine-associated fulminant myocarditis in a very elderly woman. Coronavirus disease 2019 (COVID-19) vaccination is reportedly safe and effective. The histologic features of post-COVID-19 vaccination myocarditis are unknown. We present a case of a 77-year-old Japanese woman diagnosed with eosinophilic myocarditis using endomyocardial biopsy, 7â€‰days after the second dose of BNT162b2 COVID-19 vaccine. Steroid pulse therapy was effective.

Antibody Avidity and Neutralizing Response against SARS-CoV-2 Omicron Variant after Infection or Vaccination. BACKGROUND: The recently emerged SARS-CoV-2 Omicron variant exhibits several mutations on the spike protein, enabling it to escape the immunity elicited by natural infection or vaccines. Avidity is the strength of binding between an antibody and its specific epitope. The SARS-CoV-2 spike protein binds to its cellular receptor with high affinity and is the primary target of neutralizing antibodies. Therefore, protective antibodies should show high avidity. This study aimed at investigating the avidity of receptor-binding domain (RBD) binding antibodies and their neutralizing activity against the Omicron variant in SARS-CoV-2 infected patients and vaccinees. METHODS: Samples were collected from 42 SARS-CoV-2 infected patients during the first pandemic wave, 50 subjects who received 2 doses of mRNA vaccine before the Omicron wave, 44 subjects who received 3 doses of mRNA vaccine, and 35 subjects who received heterologous vaccination (2 doses of adenovirus-based vaccine plus mRNA vaccine) during the Omicron wave. Samples were tested for the avidity of RBD-binding IgG and neutralizing antibodies against the wild-type SARS-CoV-2 virus and the Omicron variant. RESULTS: In patients, RBD-binding IgG titers against the wild-type virus increased with time, but remained low. High neutralizing titers against the wild-type virus were not matched by high avidity or neutralizing activity against the Omicron variant. Vaccinees showed higher avidity than patients. Two vaccine doses elicited the production of neutralizing antibodies, but low avidity for the wild-type virus; antibody levels against the Omicron variant were even lower. Conversely, 3 doses of vaccine elicited high avidity and high neutralizing antibodies against both the wild-type virus and the Omicron variant. CONCLUSIONS: Repeated vaccination increases antibody avidity against the spike protein of the Omicron variant, suggesting that antibodies with high avidity and high neutralizing potential increase cross-protection against variants that carry several mutations on the RBD.

Interleukin-1/6 Blockade for the Treatment of Severe Steroid-Refractory BNT162b2 Vaccine-Induced Adult-Onset Still's Disease. INTRODUCTION: Several immune-mediated side effects have been reported with COVID-19 vaccines, including myocarditis. CASE DESCRIPTION: A 27-year-old woman

with a past medical history of mild COVID-19, developed adult-onset Still's disease (AOSD) with salmon-pink flagellate erythema, polyarthritis, a sore throat, myocarditis and haemophagocytic lymphohistiocytosis after receiving two doses of the BNT162b2 vaccine (Pfizer(Â®), BioNTech(Â®)). Despite the initial efficacy of high-dose pulses of methylprednisolone, inflammatory markers rose as soon as de-escalation of corticosteroids was attempted, warranting initiation of biologics targeting the interleukin (IL)-1/6 axis, which allowed sustained remission of the disease despite withdrawal of corticosteroids. DISCUSSION: To our knowledge, this is the first case of AOSD with both haemophagocytic lymphohistiocytosis and cardiac magnetic resonance imaging-proven myocarditis triggered by COVID-19 vaccination, successfully treated with steroids and biologics targeting the IL-1/IL-6 axis. The pathophysiological process by which COVID-19 vaccination can lead to AOSD is still unknown, although it has been reported that the spike protein may act as a pathogen-associated molecular pattern and thus induce an overproduction of pro-inflammatory cytokines of the innate immune system (e.g., IL-1, IL-6 or IL-18). CONCLUSION: Targeting the IL-1/6 axis is effective for the treatment of severe steroid-refractory BNT162b2 vaccine-induced adult-onset Still's disease. At a population level, the favourable benefit/risk ratio of COVID-19 vaccination remains indisputable. LEARNING POINTS: Adult-onset Still's disease can be triggered by the BNT162b2 COVID-19 vaccine.Biologics targeting the interleukin-1/6 axis should be considered early in the course of vaccine-induced adult-onset Still's disease, especially when steroids do not effectively curb the disease.

Description of Hospitalizations due to the Severe Acute Respiratory Syndrome Coronavirus 2 Omicron Variant Based on Vaccination Status. BACKGROUND: Limited descriptive data exist regarding the clinical characteristics of hospitalizations due to the severe acute respiratory syndrome coronavirus 2 Omicron variant based on vaccination status. METHODS: This was a retrospective cohort study of all patients hospitalized with a diagnosis of coronavirus disease 2019 (COVID-19) between 15 January 2022 and 15 February 2022 across 9 hospitals in a large health network. Data were extracted by manual records review. RESULTS: A total of 351 of 452 (77.7%) unvaccinated, 209 of 331 (63.1%) fully vaccinated, and 107 of 163 (65.6%) boosted patients hospitalized with a COVID-19 diagnosis were determined to be admitted specifically due to COVID-19 (Pâ€‰<â€‰.001). Most (85%) boosted patients admitted due to COVID-19 were at least 65 years old and/or had severe immunosuppression, compared to 72.2% of fully vaccinated and 60.7% of unvaccinated patients (Pâ€‰<â€‰.001). Significantly more unvaccinated patients (34.2%) required >6â€…L/minute of supplemental oxygen compared to fully vaccinated (24.4%) and boosted (25.2%) patients (Pâ€‰=â€‰.027). The age-adjusted vaccine effectiveness (VE) against hospitalization due to COVID-19 was estimated to be 81.1% and 94.1% for full vaccination and boosted status, respectively, whereas VE against mortality related to COVID-19 was estimated to be 84.7% and 94.8%, respectively. CONCLUSIONS: During the Omicron BA.1 sublineage wave, unvaccinated patients hospitalized with a COVID-19 diagnosis were more likely than vaccinated patients to be admitted specifically due to COVID-19. Despite being younger with fewer comorbidities, unvaccinated patients required higher levels of care. Vaccination with a booster provides the greatest protection against hospitalization and death from COVID-19.

Anti-SARS-COV-2 specific immunity in HIV immunological non-responders after mRNA-based COVID-19 vaccination. Individuals infected with the human immunodeficiency virus type 1 (HIV-1) belong to the group of people most vulnerable to SARS-CoV-2 infections and the associated disease COVID-19. Here we describe SARS-CoV-2-specific antibody and cellular immune responses in a small cohort of immunological non-responder HIV-1 patients (HIV-INRs) after receiving the COVID-19 mRNA-based BioNTech/Pfizer vaccine. Compared to the control group of vaccinated healthy individuals that all developed a virus-specific immune response, 5 of 10 vaccinated HIV-1 patients showed insufficient immune responses. The lack of response was not directly correlated with patients

CD4 cell counts. Three of the five non-responders that agreed to receive a booster vaccination subsequently generated a virus-specific response. Thus, even HIV-INRs can be efficiently vaccinated against COVID-19 but may require a follow-up by virus-specific immune monitoring to guarantee clinical vaccine benefits.

Vaccination counseling with and without excipient skin testing in patients with suspected allergic reactions to mRNA COVID-19 vaccines and patients with atopy. BACKGROUND: Allergic reactions have been reported with mRNA vaccines for COVID-19 prevention. Patients perceived to be at higher risk for a reaction may be referred to an allergist, although evaluation strategies may differ between allergists. OBJECTIVE: Our aim was to determine outcomes of COVID-19 vaccinations in patients evaluated by an allergist using different approaches. METHODS: We conducted a retrospective case series evaluation of 98 patients seen at the University of Michigan Allergy Clinic for concerns regarding COVID-19 vaccination. Of these 98 patients, 34 underwent skin testing with polyethylene glycol (PEG) 2000 with or without PEG 3350/polysorbate 80 testing. RESULTS: Of the 34 patients on whom skin testing was performed, 16 underwent testing before vaccination and 18 underwent testing after a reported vaccine-related event. One patient had a positive skin testing result in response to PEG 3350 following a vaccination reaction and natural infection and was advised against a second dose. One patient with a significant history concerning of anaphylaxis in response to PEG had positive results of testing to identify allergy to PEG 2000, PEG 3350, and polysorbate 80 and was advised against vaccination. Of the 98 patients, 63 (64%) tolerated COVID-19 vaccination without complication after evaluation by an allergist. CONCLUSION: No significant differences were found between vaccination counseling with and without skin testing to excipients. Patients who presented before the first dose of vaccination were more likely to proceed with COVID-19 vaccination and tolerate vaccination without complication.

SARS-CoV-2 vaccination in patients with multiple sclerosis in Germany and the United Kingdom: Gender-specific results from a longitudinal observational study. BACKGROUND: Vaccines offer people with multiple sclerosis (PwMS) an effective protection against severe COVID-19 disease courses. However, representative real-world data on the tolerability of SARS-CoV-2 vaccines in PwMS are limited. We aimed at analysing vaccination reactions (VRs) and MS deterioration following SARS-CoV-2 vaccinations in German and United Kingdom (UK) PwMS, especially regarding gender-specific differences. METHODS: The German Multiple Sclerosis Society and the UK MS Registry acquired health data via an online system following the first (X(1)) and second SARS-CoV-2 vaccination (X(2)), respectively: sociodemographic and clinical data, vaccines used, VRs, MS deterioration (worsened or new MS symptoms, Germany only) and relapses (Germany only). The frequencies of VRs and MS deterioration were analysed stratified by gender. FINDINGS: Following X(1) (X(2)), 2346 (1835) German PwMS and 3796 (683) UK PwMS participated in the study. The most frequent vaccination scheme was two-dose tozinameran for Germany (77Â·1%, 1424/1847) and two-dose AZD1222 for the UK (61Â·3%, 419/683). The most common VRs were fatigue, headache and pain (at the injection site) and occurred more often in women compared with men. German PwMS reported VRs more frequently after X(2) vs. X(1) (65Â·4% [1201/1835] vs. 61Â·2% [1435/2346]), while for UK patients it was the opposite (X(1) vs. X(2): 48Â·7% [1849/3796] vs. 30Â·0% [205/683]). MS deterioration occurred in 19Â·0% (445/2346) of the German PwMS without resulting in gender-specific differences. Fatigue and gait impairment were the most frequent deteriorated MS symptoms. INTERPRETATION: Female PwMS reported experiencing VRs more often than men. Longitudinal data are needed to enable valid statements regarding long-term MS deterioration and long-lasting VRs. FUNDING: German Multiple Sclerosis Society (DMSG Bundesverband e.V.), Biogen, Bristol Myers Squibb, Merck Serono, Mylan, Novartis, Roche and Sanofi.

COVID-19 infection, vaccine status, and avoidance behaviors in adults with attention deficit and hyperactivity disorder: A cross-sectional study. OBJECTIVE: We aim to examine infection risk and vaccine status of COVID-19 in attention deficit and hyperactivity disorder and evaluate the impact of demographic, clinical, and COVID-19-related factors on the infection status and behavioral avoidance of COVID-19. METHODS: This cross-sectional study assessed adults with attention deficit and hyperactivity disorder recruited from an outpatient psychiatry clinic. Patients and healthy controls completed a survey on sociodemographic data, COVID-19 infection status, and vaccine status. COVID-19 Disease Perception Scale, COVID-19 Avoidance Attitudes Scale, Attitudes toward COVID-19 Vaccine Scale, Adult Attention Deficit and Hyperactivity Disorder Self-report Screening Scale for DSM-5, Adult Attention Deficit and Hyperactivity Disorder Self-Report Scale Symptoms Checklist, Patient Health Questionnaire-9, and State-Trait Anxiety Inventory were applied. RESULTS: Ninety patients and 40 healthy controls participated. Patients did not differ from controls in COVID-19 infection and vaccine status, and behavioral avoidance of COVID-19. No demographic and clinical factor significantly affected the COVID-19 infection status. Patients scored higher than controls in the perception of COVID-19 as contagious ($p = 0.038$), cognitive avoidance of COVID-19 ($p = 0.008$), and positive attitudes toward the COVID-19 vaccine ($p = 0.024$). After adjustment of possible factors, a positive perception of the COVID-19 vaccine and a perception of COVID-19 as dangerous were the two factors significantly affecting behavioral avoidance of COVID-19 [$R (2) = 0. 17$, $F(2) = 13.189$, $p < 0.0001$]. CONCLUSION: Infection and vaccine status of COVID-19 in patients did not significantly differ from controls. No demographic and clinical factor significantly affected the COVID-19 infection status. Approximately four-fifths of the patients were fully vaccinated as recommended by national and global health organizations. This has increased the knowledge base showing that the COVID-19 vaccine is acceptable and receiving the vaccine is endorsed by ADHD patients. Attention deficit and hyperactivity disorder itself may provoke no kind of mental disturbance in sense of perception of the danger of this disease. Our findings have increased the knowledge base showing that the COVID-19 vaccine is acceptable and the actual practice of receiving the vaccine is endorsed in this population. Our message for practice would be to take into account not only the core symptoms and the comorbidities of the disorder but also the perception of the disease while exploring its link with COVID-19.

Hearing disorder following COVID-19 vaccination: A pharmacovigilance analysis using the Vaccine Adverse Event Reporting System. WHAT IS KNOWN AND OBJECTIVE: Evidence on whether the coronavirus disease 2019 (COVID-19) vaccination could cause hearing-related adverse events is still conflicting. This study aims to access the association between COVID-19 vaccine and hearing disorder. METHODS: The Vaccine Adverse Event Reporting System (VAERS) was queried between January 2020 to November 2021. The disproportionality pattern for hearing impairment of COVID-19 vaccine was accessed by calculating the reporting odds ratio (ROR) and proportional reporting ratio (PRR). A further subgroup analysis based on the type of COVID-19 vaccine and the doses administered was performed. In addition, the disproportionalities for hearing dysfunction between COVID-19 and influenza vaccines were compared. RESULTS AND DISCUSSION: A total of 14,956 reports of hearing-related adverse events were identified with COVID-19 vaccination and 151 with influenza vaccine during the analytic period in VAERS. The incidence of hearing disorder following COVID-19 vaccination was 6.66 per 100,000. The results of disproportionality analysis revealed that the adverse events of hearing impairment, after administration of COVID-19 vaccine, was significantly highly reported (ROR 2.38, 95% confidence interval [CI] 2.20-2.56; PRR: 2.35, Ï‡(2) 537.58), for both mRNA (ROR 2.37, 95% CI 2.20-2.55; PRR 2.34, Ï‡(2) 529.75) and virus vector vaccines (ROR 2.50, 95% CI 2.28-2.73; PRR 2.56, Ï‡(2) 418.57). While the disproportional level for hearing dysfunction was quite lower in influenza vaccine (ROR 0.36, 95% CI 0.30-0.42; PRR 0.36, Ï‡(2) 172.24). WHAT IS NEW AND CONCLUSION: This

study identified increased risk for hearing disorder following administration of both mRNA and virus vector COVID-19 vaccines compared to influenza vaccination in real-world settings.
Differential vaccine-induced kinetics of humoral and cellular immune responses in SARS-CoV-2 naive and convalescent health care workers. Effective vaccination is a key element in the exit strategy from the current severe acute respiratory syndrome-CoV coronavirus-2 (SARS-CoV-2) pandemic, and may also offer protection against severe disease from future variants of concern. Here, we prospectively monitored T-cell responses over time, using ELISpot interferon-Î³ (INF-y) release assays, and B-cell responses, using serological tests, after vaccination and booster with BioNTech/Pfizer mRNA (Pfizer) and Janssen vector (Janssen/Johnson & Johnson) vaccines in hospital health care workers. Vaccine recipients were divided into seropositive and seronegative individuals at baseline, in order to determine the effect of natural immunity on vaccine-induced immune kinetics. We found that convalescent individuals mounted higher spike-specific INF-y-secreting T-cell responses and B-cell-mediated IgG responses, after receiving the Janssen vaccine or the first dose of the Pfizer vaccine. IgG levels corresponded to the virus neutralization capacity as measured by VNT assay. At 8 months postvaccination, spike-specific cellular immunity waned to low levels in individuals with or without prior natural immunity, whereas waning of humoral immunity occurred predominantly in naive individuals. The booster shot effectively reinduced both cellular and humoral immune responses. To conclude, our data supports the implemented single-dose mRNA booster strategy employed in the Netherlands. Furthermore, the level of pre-existing natural immunity may be factored into determining the optimal time window between future booster vaccines.
Serological response after COVID-19 mRNA-1273 booster dose in immunocompromised patients, Taiwan, July to August 2021. BACKGROUND: Whether immunocompromising conditions affect the immunogenicity of COVID-19 booster vaccination remains a concern, which impedes the vaccination campaign in people most vulnerable to COVID-19-associated morbidity and mortality. We aimed to evaluate the effect of immune dysfunction on immunogenicity of homologous and heterologous prime-boost COVID-19 vaccination. METHODS: Between July and August, 2021, 399 participants were randomized to receive ChAdOx1/ChAdOx1 8 weeks apart, ChAdOx1/mRNA-1273 8 weeks apart, ChAdOx1/mRNA-1273 4 weeks apart, and mRNA-1273/mRNA-1273 4 weeks apart. The anti-SARS-CoV-2 spike IgG antibody titers on the day before booster vaccination and 4 weeks after booster vaccination were compared between participants with and without immunocompromising conditions. RESULTS: Among ChAdOx1-primed participants, a trend of lower anti-SARS-CoV-2 spike IgG titers before booster vaccination were found in participants with autoimmune diseases (geometric means, 34.76 vs. 84.25 binding antibody units [BAU]/mL, PÂ =Â 0.173), compared to those without. Participants receiving immunosuppressants and/or immunomodulators had significant lower anti-SARS-CoV-2 spike IgG titers before booster vaccination than those without (geometric means, 36.39 vs. 83.84Â BAU/mL; PÂ =Â 0.001). Among mRNA-1273-boosted participants, anti-SARS-CoV-2 spike IgG titers 4 weeks after booster vaccination were similar across all the strata. Participants with autoimmune diseases and receiving immunosuppressants and/or immunomodulators, had numerically lower anti-SARS-CoV-2 spike IgG titers 4 weeks after booster vaccination compared to those without (geometric means, 1474.34 vs. 1923.23 and 1590.61 vs. 1918.38Â BAU/mL; PÂ >Â 0.05). CONCLUSION: The immunogenicity of prime vaccination with ChAdOx1 decreased by immune dysfunction, but enhanced after receiving boost vaccination with mRNA-1273. Our study results support the efficacy of mRNA-1273 booster dose among immunocompromised hosts.
Screening for antibodies to HLA class I in apheresis donors following Covid-19 or SARS-CoV-2 vaccination. Transfusion of HLA-specific antibodies may play a role in induction of TRALI, the transfusion complication responsible for most transfusion-related deaths. In Oslo, we screen our apheresis donors and defer HLA-immunized donors from donation of plasma-rich blood components.

During the second year of the Covid-19 pandemic and following the first months of SARS-CoV-2 vaccination, both the virus itself and the vaccines were suspected of inducing de novo production of antibodies to HLA class I in patients. For the blood center, the possibility of finding HLA-antibodies in an increased number of blood donors has serious implications. We therefore conducted a study to map the extent of de novo HLA-specific antibodies in representative donor groups. 106 apheresis donors were screened for antibodies to HLA class I/II following Covid-19 or vaccination with either mRNA or adenovirus-vector vaccines, and the findings were compared to pre-Covid blood samples from the same donors. In addition, we analyzed pre-Covid samples from 11 HLA-antibody-positive donors of Covid convalescence plasma. Only three established thrombapheresis donors were deferred due to vaccine-induced HLA-antibodies. In short, our findings did not support the hypothesis that SARS-CoV-2 virus or vaccination cause de novo HLA immunization in healthy blood donors. However, some donors with pre-existing antibodies showed increased antibody expression, confirming a general boost of the immune response following infection or vaccination.

Management of patients with immediate reactions to COVID-19 vaccines.

COVID-19 vaccine-induced antibody and T-cell responses in immunosuppressed patients with inflammatory bowel disease after the third vaccine dose (VIP): a multicentre, prospective, case-control study. BACKGROUND: COVID-19 vaccine-induced antibody responses are reduced in patients with inflammatory bowel disease (IBD) taking anti-TNF or tofacitinib after two vaccine doses. We sought to assess whether immunosuppressive treatments were associated with reduced antibody and T-cell responses in patients with IBD after a third vaccine dose. METHODS: VIP was a multicentre, prospective, case-control study done in nine centres in the UK. We recruited immunosuppressed patients with IBD and non-immunosuppressed healthy individuals. All participants were aged 18 years or older. The healthy control group had no diagnosis of IBD and no current treatment with systemic immunosuppressive therapy for any other indication. The immunosuppressed patients with IBD had an established diagnosis of Crohn's disease, ulcerative colitis, or unclassified IBD using standard definitions of IBD, and were receiving established treatment with one of six immunosuppressive regimens for at least 12 weeks at the time of first dose of SARS-CoV-2 vaccination. All participants had to have received three doses of an approved COVID-19 vaccine. SARS-CoV-2 spike antibody binding and T-cell responses were measured in all participant groups. The primary outcome was anti-SARS-CoV-2 spike (S1 receptor binding domain [RBD]) antibody concentration 28-49 days after the third vaccine dose, adjusted by age, homologous versus heterologous vaccine schedule, and previous SARS-CoV-2 infection. The primary outcome was assessed in all participants with available data. FINDINGS: Between Oct 18, 2021, and March 29, 2022, 352 participants were included in the study (thiopurine n=65, infliximab n=46, thiopurine plus infliximab combination therapy n=49, ustekinumab n=44, vedolizumab n=50, tofacitinib n=26, and healthy controls n=72). Geometric mean anti-SARS-CoV-2 S1 RBD antibody concentrations increased in all groups following a third vaccine dose, but were significantly lower in patients treated with infliximab (2736Â·8 U/mL [geometric SD 4Â·3]; p<0Â·0001), infliximab plus thiopurine (1818Â·3 U/mL [6Â·7]; p<0Â·0001), and tofacitinib (8071Â·5 U/mL [3Â·1]; p=0Â·0018) compared with the healthy control group (16â€‰774Â·2 U/mL [2Â·6]). There were no significant differences in anti-SARS-CoV-2 S1 RBD antibody concentrations between the healthy control group and patients treated with thiopurine (12â€‰019Â·7 U/mL [2Â·2]; p=0Â·099), ustekinumab (11â€‰089Â·3 U/mL [2Â·8]; p=0Â·060), or vedolizumab (13â€‰564Â·9 U/mL [2Â·4]; p=0Â·27). In multivariable modelling, lower anti-SARS-CoV-2 S1 RBD antibody concentrations were independently associated with infliximab (geometric mean ratio 0Â·15 [95% CI 0Â·11-0Â·21]; p<0Â·0001), tofacitinib (0Â·52 [CI 0Â·31-0Â·87]; p=0Â·012), and thiopurine (0Â·69 [0Â·51-0Â·95]; p=0Â·021), but not with ustekinumab (0Â·64 [0Â·39-1Â·06]; p=0Â·083), or vedolizumab (0Â·84 [0Â·54-1Â·30]; p=0Â·43). Previous SARS-CoV-2 infection (1Â·58 [1Â·22-2Â·05];

p=0Â·0006) was independently associated with higher anti-SARS-CoV-2 S1 RBD antibody concentrations and older age (0Â·88 [0Â·80-0Â·97]; p=0Â·0073) was independently associated with lower anti-SARS-CoV-2 S1 RBD antibody concentrations. Antigen-specific T-cell responses were similar in all groups, except for recipients of tofacitinib without evidence of previous infection, where T-cell responses were significantly reduced relative to healthy controls (p=0Â·021). INTERPRETATION: A third dose of COVID-19 vaccine induced a boost in antibody binding in immunosuppressed patients with IBD, but these responses were reduced in patients taking infliximab, infliximab plus thiopurine, and tofacitinib. Tofacitinib was also associated with reduced T-cell responses. These findings support continued prioritisation of immunosuppressed groups for further vaccine booster dosing, particularly patients on anti-TNF and JAK inhibitors. FUNDING: Pfizer.

SARS-CoV-2 vaccination and risk of severe COVID-19 outcomes in patients with autoimmune hepatitis. BACKGROUND: Data regarding outcome of Coronavirus disease 2019 (COVID-19) in vaccinated patients with autoimmune hepatitis (AIH) are lacking. We evaluated the outcome of COVID-19 in AIH patients who received at least one dose of Pfizer- BioNTech (BNT162b2), Moderna (mRNA-1273) or AstraZeneca (ChAdOx1-S) vaccine. PATIENTS AND METHODS: We performed a retrospective study on AIH patients with COVID-19. The outcomes of AIH patients who had acute respiratory syndrome coronavirus 2 (SARS-CoV-2) breakthrough infection after at least one dose of COVID-19 vaccine were compared to unvaccinated patients with AIH. COVID-19 outcome was classified according to clinical state during the disease course as: (i) no hospitalization, (ii) hospitalization without oxygen supplementation, (iii) hospitalization with oxygen supplementation by nasal cannula or mask, (iv) intensive care unit (ICU) admission with non-invasive mechanical ventilation, (v) ICU admission with invasive mechanical ventilation or (vi) death, and data was analyzed using ordinal logistic regression. RESULTS: We included 413 (258 unvaccinated and 155 vaccinated) patients (81%, female) with a median age of 52 (range: 17-85) years at COVID-19 diagnosis. The rates of hospitalization were (36.4% vs. 14.2%), need for any supplemental oxygen (29.5% vs. 9%) and mortality (7% vs. 0.6%) in unvaccinated and vaccinated AIH patients with COVID-19. Having received at least one dose of SARS-CoV-2 vaccine was associated with a significantly lower risk of worse COVID-19 severity, after adjusting for age, sex, comorbidities and presence of cirrhosis (adjusted odds ratio [aOR] 0.18, 95% confidence interval [CI], 0.10-0.31). Overall, vaccination against SARS-CoV-2 was associated with a significantly lower risk of mortality from COVID-19 (aOR 0.20, 95% CI 0.11-0.35). CONCLUSIONS: SARS-CoV-2 vaccination significantly reduced the risk of COVID-19 severity and mortality in patients with AIH.

Covid-19 vaccines and neurological complications: a systematic review. The COVID-19 mainly causes respiratory disorders with high infection and severe morbidity and mortality. Neurologists have concerns about potential neurological side effects, profits, and timing of COVID-19 vaccines. ThisÂ study aimed to review systematically research for theÂ COVID-19 vaccine and neurological complications. Data was searched in Scopus, ISI web of knowledge, Medline, PubMed, Wiley, Embase, International Clinical Trials Registry Platform and Clinical Trials, Cochrane Library, and Google Scholar. Two reviewer authors individually searched and assessed the titles and abstracts of all articles. The third reviewer resolved disagreement between them. Data were documented regarding study location, study design, type ofÂ complications, number of patients, various types of COVID-19 vaccine, and type of neurological complications. Six studies in COVID-19 vaccine and neurological complications include two studies about neurological manifestations after the mRNA vaccines, four records about side effects of vector-based vaccine were included in the study. The main neurological complication associated mRNA vaccines were body aches, paresthesia, and difficulty walking, erythema migrans lesion, fatigue, myalgia, and pain in the left lateral deltoid region. The major neurological complication related to vector-based vaccines were urinary retention difficulty, feeding

and ambulating, arm soreness, mild fatigue, chills, left-sided facial droop, headaches, a generalized epileptic seizure, hemianopia, and mild aphasia, acute somnolence and right-hand hemiparesis, acute transverse myelitis, deep vein thrombosis in her left leg, a vigilance disorder and a twitching, a severe immobilizing opsoclonus myoclonus syndrome, and encephalitis. A large spectrum of severe neurological unfavorable has been reported. These complications could occur as a result ofÂ molecular stimulation and later neuronal damage. Generally, the advantages of COVID-19 vaccination are dominant on the risks of a neurological complication at both individual and population levels. Future investigations will be required to find any relationship between neurological complications and COVID-19 vaccines principally as new strains of the virus and new vaccines are technologically advanced against them.

Lichen planus pigmentosus inversus with nail involvement following COVID-19 vaccination: A case report.

Higher sensitivity monitoring of reactions to COVID-19 vaccination using smartwatches. More than 12 billion COVID-19 vaccination shots have been administered as of August 2022, but information from active surveillance about vaccine safety is limited. Surveillance is generally based on self-reporting, making the monitoring process subjective. We study participants in Israel who received their second or third Pfizer BioNTech COVID-19 vaccination. All participants wore a Garmin Vivosmart 4 smartwatch and completed a daily questionnaire via smartphone. We compare post-vaccination smartwatch heart rate data and a Garmin-computed stress measure based on heart rate variability with data from the patient questionnaires. Using a mixed effects panel regression to remove participant-level fixed and random effects, we identify considerable changes in smartwatch measures in the 72â€‰h post-vaccination even among participants who reported no side effects in the questionnaire. Wearable devices were more sensitive than questionnaires in determining when participants returned to baseline levels. We conclude that wearable devices can detect physiological responses following vaccination that may not be captured by patient self-reporting. More broadly, the ubiquity of smartwatches provides an opportunity to gather improved data on patient health, including active surveillance of vaccine safety.

Hesitancy for SARS-CoV-2 vaccines and post-vaccination flares in patients with systemic lupus erythematosus. OBJECTIVES: To study the rate of SARS-CoV-2 vaccination and post-vaccination disease flares in patients with systemic lupus erythematosus (SLE). METHODS: Patients who fulfilledÂ â‰¥Â 4 of the ACR criteria for SLE were identified and their SARS-CoV-2 vaccination status was traced. Flares of SLE at 6-week post-vaccination were reviewed retrospectively. Clinical characteristics of patients with and without vaccination, and those who did or did not experience post-vaccination flares were compared by statistical analyses. RESULTS: 914 adult patients with SLE were studied (92.5Â % women, age 48.6Â Â±Â 14.0Â years; SLE duration 14.5Â Â±Â 8.6Â years). Two doses of the SARS-Cov-2 vaccines (61.5Â % BioNTech; 38.5Â % CoronaVac) were received by 449 (49.1Â %) patients. The vaccination rate in SLE was significantly lower than that of the adult general population (77.8Â %; pÂ <Â 0.001) at the time of data analysis. Patients who were hesitant for vaccination were more likely to be hypertensive, have a history of neuromuscular manifestations, and a significantly higher organ damage score (1.10Â Â±Â 1.45 vs 0.74Â Â±Â 1.15; pÂ <Â 0.001). However, none of these factors were significantly associated with vaccine hesitancy on multivariate analysis. Among 449 vaccinated patients, 37(8.2Â %) experienced SLE flares: mild/moderate in 34; severe in 3. In an equal number of unvaccinated SLE controls randomly matched for the post-vaccination observation period, 28(6.2Â %) had SLE flares: mild/moderate in 17; severe in 11 (odds ratio [OR] for flare in vaccinated patients 1.40[0.81-2.43]; pÂ =Â 0.23, adjusted for age, sex, active serology, SLE duration and prednisolone use). In vaccinated patients, logistic regression revealed that active lupus serology before vaccination (OR 2.63[1.05-6.62]; pÂ =Â 0.04) and a history of arthritis

(OR 2.71[1.05-7.00]; pÂ =Â 0.04) or discoid skin lesion (OR 4.73[1.90-11.8]; pÂ =Â 0.001) were associated with SLE flares following vaccination, adjusted for confounders. CONCLUSION: Hesitancy for COVID-19 vaccination is common in SLE patients. Vaccination against SARS-CoV-2 is not significantly associated with increased SLE flares. Patients with active SLE serology or a history of arthritis/discoid lesion are more likely to flare after vaccination.

Methodology to estimate natural- and vaccine-induced antibodies to SARS-CoV-2 in a large geographic region. Accurate estimates of natural and/or vaccine-induced antibodies to SARS-CoV-2 are difficult to obtain. Although model-based estimates of seroprevalence have been proposed, they require inputting unknown parameters including viral reproduction number, longevity of immune response, and other dynamic factors. In contrast to a model-based approach, the current study presents a data-driven detailed statistical procedure for estimating total seroprevalence (defined as antibodies from natural infection or from full vaccination) in a region using prospectively collected serological data and state-level vaccination data. Specifically, we conducted a longitudinal statewide serological survey with 88,605 participants 5 years or older with 3 prospective blood draws beginning September 30, 2020. Along with state vaccination data, as of October 31, 2021, the estimated percentage of those 5 years or older with naturally occurring antibodies to SARS-CoV-2 in Texas is 35.0% (95% CI = (33.1%, 36.9%)). This is 3Ã— higher than, state-confirmed COVID-19 cases (11.83%) for all ages. The percentage with naturally occurring or vaccine-induced antibodies (total seroprevalence) is 77.42%. This methodology is integral to pandemic preparedness as accurate estimates of seroprevalence can inform policy-making decisions relevant to SARS-CoV-2.

Safety of ChAdOx1 nCoV-19 vaccination in patients with end-stage renal disease on hemodialysis. BACKGROUND: COVID-19 vaccination is essential. However, no study has reported adverse events (AEs) after ChAdOx1 nCoV-19 vaccination in patients with end-stage renal disease (ESRD) on hemodialysis (HD). This study investigated the AEs within 30-days after the first dose of ChAdOx1 nCoV19 (Oxford-AstraZeneca) in ESRD patients on HD. METHODS AND FINDINGS: A total of 270 ESRD patients on HD were enrolled in this study. To determine the significance of vascular access thrombosis (VAT) post vaccination, we performed a self-controlled case study (SCCS) analysis. Of these patients, 38.5% had local AEs; local pain (29.6%), tenderness (28.9%), and induration (15.6%) were the most common. Further, 62.2% had systemic AEs; fatigue (41.1%), feverishness (20%), and lethargy (19.9%) were the most common. In addition, post-vaccination thirst affected 18.9% of the participants with female predominance. Younger age, female sex, and diabetes mellitus were risk factors for AEs. Five patients had severe AEs, including fever (n = 1), herpes zoster (HZ) reactivation (n = 1), and acute VAT (n = 3). However, the SCCS analysis revealed no association between vaccination and VAT; the incidence rate ratio (IRR)-person ratio was 0.56 (95% CI 0.13-2.33) and 0.78 (95% CI 0.20-2.93) [IRR-event ratio 0.78 (95% CI 0.15-4.10) and 1.00 (95% CI 0.20-4.93)] in the 0-3 months and 3-6 months period prior to vaccination, respectively. CONCLUSIONS: Though some ESRD patients on HD had local and systemic AEs after first-dose vaccination, the clinical significance of these symptoms was minor. Our study confirmed the safety profile of ChAdOx1 nCoV-19 in HD patients and presented a new viewpoint on vaccine-related AEs. The SCCS analysis did not find an elevated risk of VAT at 1 month following vaccination. Apart from VAT, other vaccine-related AEs, irrespective of local or systemic symptoms, had minor clinical significance on safety issues. Nonetheless, further coordinated, multi-center, or registry-based studies are needed to establish the causality.

COVID-19 symptom relationship to antibody response and ACE2 neutralization in recovered health systems employees before and after mRNA BNT162b2 COVID-19 vaccine. BACKGROUND: The humoral response to SARS-CoV-2 can provide immunity and prevent reinfection. However, less is known about how the diversity, magnitude, and length of the antibody response after a primary infection is associated with symptoms, post-infection immunity, and post-vaccinated immunity.

METHODS: Cook County Health employees provided blood samples and completed an online survey 8-10 weeks after a PCR-confirmed positive SARS-CoV-2 test (pre-vaccinated, N = 41) and again, 1-4 weeks after completion of a 2-dose series mRNA BNT162b2 COVID-19 vaccine (post-vaccinated, N = 27). Associations were evaluated between SARS-CoV-2 antibody titers, participant demographics, and clinical characteristics. Antibody titers and angiotensin-converting enzyme 2 (ACE2) neutralization were compared before and after the mRNA BNT162b2 COVID-19 vaccine. RESULTS: Antibody titers to the spike protein (ST4), receptor binding domain (RBD), and RBD mutant D614G were significantly associated with anosmia and ageusia, cough, and fever. Spike protein antibody titers and ACE2 neutralization were significantly higher in participants that presented with these symptoms. Antibody titers to the spike protein N-terminal domain (NTD), RBD, and ST4, and ACE2 IC50 were significantly higher in all post-vaccinated participant samples compared to pre-vaccinated participant sample, and not dependent on previously reported symptoms. CONCLUSIONS: Spike protein antibody titers and ACE2 neutralization are associated with the presentation of anosmia and ageusia, cough, and fever after SARS-CoV-2 infection. Symptom response to previous SARS-CoV-2 infection did not influence the antibody response from subsequent vaccination. These results suggest a relationship between infection severity and the magnitude of the immune response and provide meaningful insights into COVID-19 immunity according to discrete symptom presentation.

Pemphigus vulgaris and COVID-19 vaccination: Management and treatment.

Third-dose SARS-CoV-2 mRNA vaccine increases Omicron variant neutralization in patients with chronic myeloid disorders.

Triggers for Acceptance of COVID-19 Vaccination: A Community- Based Study. BACKGROUND: COVID- 19 vaccines have been released, giving a major hope of getting rid of the dark pandemic crisis. The availability of vaccines does not necessarily mean that the mass vaccination program is a success. We aimed to investigate COVID-19 vaccination knowledge level, acceptance rate, and perception state among Egyptians. METHODS: An analytical cross-sectional online survey was carried out utilizing a selfadministered adult questionnaire that assesses vaccination acceptance with related sociodemographic factors and perceptions based on health belief model perspectives. Predictors of vaccination acceptance were based on logistic regression analysis. RESULTS: We analyzed data for 957 participants, aged 18-78 years, 55.7% were females, and 66.9% were healthcare workers (HCWs). About one-fourth had a history of confirmed COVID-19 infection and 56.5% would accept to have one of the COVID-19 vaccines, where "Pfizer" was the preferable one (37.8%), while "AstraZeneca" was the most rejected vaccine (26.8%). The 1st vaccine dose was received by 273 (28.5%) of which 260 were intended to receive the 2nd dose. Vaccine efficacy, side effects, protection time, and administration route were essentially among the factors that may influence their decision to accept COVID-19 vaccines. About 83.1% had good knowledge about vaccination which was significantly higher with increased age, among graduates/professionals, governmental workers, HCWs in addition to those able to save/invest money, had a history of confirmed COVID-19 infection and intending to have COVID-19 vaccine. Perceptions that vaccination decreases the chance of getting COVID-19 or its complications (OR = 9.28; CI: 5.03-17.12), vaccination makes less worry about catching COVID-19 (OR = 6.76; CI: 3.88-11.76), and being afraid of getting COVID-19 (OR = 2.04; CI: 1.26-3.31) were strong significant predictors for vaccine acceptance. CONCLUSION: Vaccine campaigns should emphasize vaccine benefits and highlight the severity of infection while addressing barriers to vaccination in order to improve vaccine coverage among populations.

Outcomes of Cerebral Venous Thrombosis due to Vaccine-Induced Immune Thrombotic Thrombocytopenia After the Acute Phase. BACKGROUND: Cerebral venous thrombosis (CVT) due to vaccine-induced immune thrombotic thrombocytopenia (VITT) is a severe condition, with high in-hospital mortality rates. Here, we report clinical outcomes of patients with CVT-VITT after SARS-CoV-2

(severe acute respiratory syndrome coronavirus 2) vaccination who survived initial hospitalization. METHODS: We used data from an international registry of patients who developed CVT within 28 days of SARS-CoV-2 vaccination, collected until February 10, 2022. VITT diagnosis was classified based on the Pavord criteria. Outcomes were mortality, functional independence (modified Rankin Scale score 0-2), VITT relapse, new thrombosis, and bleeding events (all after discharge from initial hospitalization). RESULTS: Of 107 CVT-VITT cases, 43 (40%) died during initial hospitalization. Of the remaining 64 patients, follow-up data were available for 60 (94%) patients (37 definite VITT, 9 probable VITT, and 14 possible VITT). Median age was 40 years and 45/60 (75%) patients were women. Median follow-up time was 150 days (interquartile range, 94-194). Two patients died during follow-up (3% [95% CI, 1%-11%). Functional independence was achieved by 53/60 (88% [95% CI, 78%-94%]) patients. No new venous or arterial thrombotic events were reported. One patient developed a major bleeding during follow-up (fatal intracerebral bleed). CONCLUSIONS: In contrast to the high mortality of CVT-VITT in the acute phase, mortality among patients who survived the initial hospitalization was low, new thrombotic events did not occur, and bleeding events were rare. Approximately 9 out of 10 CVT-VITT patients who survived the acute phase were functionally independent at follow-up.

Gout and Excess Risk of Severe SARS-CoV-2 Infection Among Vaccinated Individuals: A General Population Study. OBJECTIVE: Gout patients often have multiple comorbidities, making them susceptible to SARS-CoV-2 infection and poor outcomes. This study was undertaken to examine the association between gout and the risk of SARS-CoV-2 infection and severe outcomes, especially in patients who have received a SARS-CoV-2 vaccine. METHODS: We conducted 2 cohort studies using The Health Improvement Network in the UK. Individuals with gout and those without gout from the general population were followed up from December 8, 2020 to October 31, 2021. We estimated the rate difference (RD) and hazard ratio (HR) of SARS-CoV-2 infection and severe outcomes (i.e., hospitalization and death within 30â€‰days after SARS-CoV-2 infection) for individuals with gout versus those without gout using a Cox proportional hazards model according to SARS-CoV-2 vaccination status. We adjusted for potential confounders by using overlap weighting of exposure scores. RESULTS: Among the vaccinated cohort, 1,955 cases of breakthrough COVID-19 infection occurred in 54,576 individuals with gout (4.68 cases per 1,000 person-months), and 52,468 cases occurred in 1,336,377 individuals without gout (3.76 cases per 1,000 person-months). The partially adjusted RD of breakthrough infection was 0.91 cases per 1,000 person-months (95% confidence interval [95% CI] 0.62-1.20 cases per 1,000 person-months), and the partially adjusted HR was 1.24 (95% CI 1.19-1.30). Gout was also associated with an increased risk of hospitalization (adjusted HR 1.30 [95% CI 1.10-1.53]) and death (adjusted HR 1.36 [95% CI 0.87-2.13]). Women with gout had an increased risk of hospitalization (adjusted HR 1.55 [95% CI 1.15-2.10]) and death (adjusted HR 2.46 [95% CI 1.12-5.41]). Similar associations with gout were observed in the unvaccinated cohort. CONCLUSION: These general population data suggest that individuals with gout, especially women, have higher risks of SARS-CoV-2 infection and severe outcomes, even when vaccinated.

Cardiovascular magnetic resonance imaging patterns of acute COVID-19 mRNA vaccine-associated myocarditis in young male patients: A first single-center experience. BACKGROUND: The risk of myocarditis after mRNA vaccination against COVID-19 has emerged recently. Current evidence suggests that young male patients are predominantly affected. In the majority of the cases, only mild symptoms were observed. However, little is known about cardiac magnetic resonance (CMR) imaging patterns in mRNA-related myocarditis and their differences when compared to classical viral myocarditis in the acute phase of inflammation. METHODS AND RESULTS: In total, 10 mRNA vaccination-associated patients with myocarditis were retrospectively enrolled in this study and compared to 10 patients suffering from viral myocarditis, who were matched for age, sex,

comorbidities, and laboratory markers. All patients (n = 20) were hospitalized and underwent a standardized clinical examination, as well as an echocardiography and a CMR. Both, clinical and imaging findings and, in particular, functional and volumetric CMR assessments, as well as detailed tissue characterization using late gadolinium enhancement and T1 + T2-weighted sequences, were compared between both groups. The median age of the overall cohort was 26 years (group 1: 25.5; group 2: 27.5; p = 0.57). All patients described chest pain as the leading reason for their initial presentation. CMR volumetric and functional parameters did not differ significantly between both groups. In all cases, the lateral left ventricular wall showed late gadolinium enhancement without significant differences in terms of the localization or in-depth tissue characterization (late gadolinium enhancement [LGE] enlargement: group 1: 5.4%; group 2: 6.5%; p = 0.14; T2 global/maximum value: group 1: 38.9/52 ms; group 2: 37.8/54.5 ms; p = 0.79 and p = 0.80). CONCLUSION: This study yielded the first evidence that COVID-19 mRNA vaccine-associated myocarditis does not show specific CMR patterns during the very acute stage in the most affected patient group of young male patients. The observed imaging markers were closely related to regular viral myocarditis in our cohort. Additionally, we could not find any markers implying adverse outcomes in this relatively little number of patients; however, this has to be confirmed by future studies that will include larger sample sizes.

Willingness to Receive COVID-19 Vaccination Among Adult Diabetes Patients in Woldia Comprehensive Specialized Hospital, North Ethiopia; A Cross-Sectional Study. BACKGROUND: According to recently published data, individuals infected with COVID-19 having concomitant diabetes may experience disease worsening or even death. The purpose of this study was to determine diabetes patients' willingness to get the COVID-19 vaccine as well as its magnitude and determinants. METHODS: Three hundred eighty six diabetes patients who visited Woldia Comprehensive Specialized Hospital during February and March 2022 participated in this institution-based cross-sectional study. Descriptive statistics were used to demonstrate frequencies and percentages, while logistic regression was used to identify the relevant determinants of vaccination readiness. Age, gender, income, place of residence, COVID-19 exposure, length of diabetes, awareness of and attitudes toward the COVID-19 immunization were all evaluated as associated factors. RESULTS: Out of 386 study participants, 268 (69.43%) were male and 146 (37.82) completed their secondary schooling. From 386 study participants 82.6% (95% CI; 78.5-86.3%) were willing to get vaccinated. The uptake of the COVID-19 vaccination among diabetes patients was independently influenced by sex (Adjusted Odd Ratio [AOR] = 6.84 (2.98, 15.68)), exposure to the illness (AOR 8.98 (3.22, 25.04)), attitude (AOR = 2.63 (1.2, 5.77)), and length of the disease (AOR = 0.62 (0.51, 0.76)). CONCLUSION: Most of the study participants were willing to get the COVID-19 immunization. The relevant agency should make the immunization available in order to enhance disease control and reduce infection-related complications with special consideration of diabetes patients.

Clinical outcomes of COVID-19 in patients with multiple sclerosis treated with ocrelizumab in the pre- and post-SARS-CoV-2 vaccination periods: Insights from Israel. The coronavirus disease 2019 (COVID-19) pandemic caused challenges in the management of patients living with multiple sclerosis (PLwMS). We investigated the occurrence and severity of COVID-19 infection post-vaccination among PLwMS treated with ocrelizumab and enrolled in the Maccabi Health Services (MHS) (nÂ =Â 289) or followed at the Hadassah Medical Center (HMC) (nÂ =Â 80) in Israel. Most patients were fully vaccinated (MHS nÂ =Â 218; HMC nÂ =Â 76) and confirmed infection post-vaccination was low (3.7% and 2.6%, respectively). MHS: infection was more severe (hospitalization/intensive care unit/death) in non-vaccinated (33.3%) vs vaccinated patients (25%). HMC: one vaccinated patient required hospitalization with COVID-19Â vs two unvaccinated patients. These data from two Israel cohorts suggest that occurrence of COVID-19 after mRNA vaccination is low and limited in severity.

Retinal Vascular Occlusion after COVID-19 Vaccination: More Coincidence than Causal Relationship? Data from a Retrospective Multicentre Study. BACKGROUND: To investigate whether vaccination against SARS-CoV-2 is associated with the onset of retinal vascular occlusive disease (RVOD). METHODS: In this multicentre study, data from patients with central and branch retinal vein occlusion (CRVO and BRVO), central and branch retinal artery occlusion (CRAO and BRAO), and anterior ischaemic optic neuropathy (AION) were retrospectively collected during a 2-month index period (1 June-31 July 2021) according to a defined protocol. The relation to any previous vaccination was documented for the consecutive case series. Numbers of RVOD and COVID-19 vaccination were investigated in a case-by-case analysis. A case-control study using age- and sex-matched controls from the general population (study participants from the Gutenberg Health Study) and an adjusted conditional logistic regression analysis was conducted. RESULTS: Four hundred and twenty-one subjects presenting during the index period (61 days) were enrolled: one hundred and twenty-one patients with CRVO, seventy-five with BRVO, fifty-six with CRAO, sixty-five with BRAO, and one hundred and four with AION. Three hundred and thirty-two (78.9%) patients had been vaccinated before the onset of RVOD. The vaccines given were BNT162b2/BioNTech/Pfizer (n = 221), followed by ChadOx1/AstraZeneca (n = 57), mRNA-1273/Moderna (n = 21), and Ad26.COV2.S/Johnson & Johnson (n = 11; unknown n = 22). Our case-control analysis integrating population-based data from the GHS yielded no evidence of an increased risk after COVID-19 vaccination (OR = 0.93; 95% CI: 0.60-1.45, p = 0.75) in connection with a vaccination within a 4-week window. CONCLUSIONS: To date, there has been no evidence of any association between SARS-CoV-2 vaccination and a higher RVOD risk.

Serum Proteome Signatures of Anti-SARS-CoV-2 Vaccinated Healthcare Workers in Greece Associated with Their Prior Infection Status. Over the course of the pandemic, proteomics, being in the frontline of anti-COVID-19 research, has massively contributed to the investigation of molecular pathogenic properties of the virus. However, data on the proteome on anti-SARS-CoV-2 vaccinated individuals remain scarce. This study aimed to identify the serum proteome characteristics of anti-SARS-CoV-2 vaccinated individuals who had previously contracted the virus and comparatively assess them against those of virus-naÃ¯ve vaccine recipients. Blood samples of n = 252 individuals, out of whom n = 35 had been previously infected, were collected in the "G. Gennimatas" General Hospital of Thessaloniki, from 4 January 2021 to 31 August 2021. All participants received the BNT162b2 mRNA COVID-19 vaccine (Pfizer/BioNTech). A label-free quantitative proteomics LC-MS/MS approach was undertaken, and the identified proteins were analyzed using the GO (Gene Ontology) and KEGG (Kyoto Encyclopedia of Genes) databases as well as processed by bioinformatics tools. Titers of total RBD-specific IgGs against SARS-CoV-2 were also determined using the SARS-CoV-2 IgG II Quant assay. A total of 47 proteins were significantly differentially expressed, the majority of which were down-regulated in sera of previously infected patients compared to virus-naÃ¯ve controls. Several pathways were affected supporting the crucial role of the humoral immune response in the protection against SARS-CoV-2 infection provided by COVID-19 vaccination. Overall, our comprehensive proteome profiling analysis contributes novel knowledge of the mechanisms of immune response induced by anti-SARS-CoV-2 vaccination and identified protein signatures reflecting the immune status of vaccine recipients.

Tumefactive Lesions Following a SARS-CoV-2 Vaccination Require Diagnostic Assignment.

Case Report: Adult Onset Still's Disease after vaccination against Covid-19. Vaccination against the virus responsible for COVID-19 has become key in preventing mortality and morbidity related to the infection. Studies have shown that the benefits of vaccination outweigh the risks. However, there are concerns regarding serious adverse events of some vaccines, although they are fortunately rare. Here, we report a case of a 47-year-old female from Kathmandu who presented with high grade fever, dry cough and erythematous rash a week after exposure to the Oxford-AstraZeneca vaccine.

She had hepatosplenomegaly, persistent leucocytosis, anaemia and thrombocytosis along with markedly raised inflammatory markers. Her tests for infectious causes and haematological malignancies were negative and she showed no response to multiple antibiotics. Finally, she had a dramatic response to steroids with disappearance of fever and normalization of other laboratory parameters. Hence, she was diagnosed with Adult-onset Still's Disease (AOSD). She was under methotrexate and prednisolone tapering dose and doing well as of the time of writing. The trigger for the disease was hypothesized to be the vaccine because of the strong temporal association.

Clinical cardiovascular emergencies and the cellular basis of COVID-19 vaccination: from dream to reality? OBJECTIVES: SARS-CoV-2 is responsible for the global COVID-19 pandemic, with little prevention or treatment options. More than 600 million mortalities have been documented from SARS-CoV-2 infection, with the majority of fatalities occurring among elderly patients (aged >65 years). A number of vaccines have been developed in an effort to restrain the rapid spread of SARS-CoV-2. Considering the widespread administration of these vaccines, substantial side or undesired effects in multiple organ systems have emerged, necessitating essential critical care. Herein, we tabulate the adverse cardiovascular responses resulting from COVID-19 vaccines. DESIGN OR METHODS: We searched PubMed for articles published through April, 2022, with the terms "SARS-CoV-2", "COVID-19", "cardiovascular", "SARS-CoV-2 vaccines", "COVID-19 vaccines", "myocarditis", "pericarditis", "thrombosis", "thrombocytopenia", "vaccine-induced thrombotic thrombocytopenia", "acute coronary syndrome", "myocardial infarction", "hypertension", "arrythmia", "postural orthostatic tachycardia syndrome", "Takotsubo cardiomyopathy", "cardiac arrest" and "death". We mainly selected publications from the past 3 years, but did not exclude widely referenced and highly regarded older publications. Besides, we searched the reference lists of articles identified by above search method and chose those we considered relevant. RESULTS: COVID-19 vaccines evoke rare but fatal thrombotic events, whereas messenger RNA\055based vaccines appear to be associated with risks of pericarditis/myocarditis, with the latter being more predominant in young adults following the second dose. Reports of other cardiovascular responses, including hypertension, arrhythmia, acute coronary syndrome, and cardiac arrest, have also been indicated. CONCLUSION: The undesired cardiovascular complications remain infrequent, giveng the large number of vaccinations inoculated to general population. And lower mortality takes precedence over the undesired cardiovascular complications.

Risk factors associated with mortality in hospitalized patients with laboratory confirmed SARS-CoV-2 infection during the period of omicron (B.1.1.529) variant predominance. BACKGROUND: SARS-CoV-2 Omicron variant has a high transmission rate. In December 2021, Omicron became the dominant variant and quickly accounted for majority of infections in the United States. Drug shortages have led to prioritization of patients for COVID-19 treatment based on risk factors for severe disease. METHODS: A retrospective analysis of hospitalized patients with COVID-19 infection at Veteran Affairs Healthcare System across the United States. The primary outcome was 14-day all-cause mortality after the first documented positive SARS-CoV-2 laboratory test. Odds ratios were generated from a multivariate logistic regression of significant factors. RESULTS: This study included 12,936 COVID-19 inpatients during a period of Omicron predominance. Age â‰¥ 65 years is a predictor of 14-day mortality among the vaccinated and unvaccinated population (OR 4.05, CI 3.06-5.45, P â‰¤ .0001). Triple vaccinated patients demonstrated a 52% decreased risk of death with COVID-19 infection (OR 0.48, CI 0.37-0.61, P â‰¤ .0001). Patients who were double vaccinated had a 39% decreased risk of death with COVID-19 infection (OR 0.61, CI 0.46-0.80, PÂ =Â .003). CONCLUSION: Advanced age â‰¥ 65 is the greatest risk factor for mortality in hospitalized COVID-19 patients. COVID-19 vaccination, especially booster doses, was associated with a decreased risk of 14-day mortality compared to double vaccinated or non-vaccinated patients. Results of this study

suggest that advanced age should be considered first for prioritization of COVID-19 treatments for Omicron.
Immunogenicity and safety of an inactivated whole-virus COVID-19 vaccine (VLA2001) compared with the adenoviral vector vaccine ChAdOx1-S in adults in the UK (COV-COMPARE): interim analysis of a randomised, controlled, phase 3, immunobridging trial. BACKGROUND: The Valneva COVID-19 vaccine (VLA2001; Valneva Austria, Vienna, Austria) is an inactivated whole-virus, adjuvanted SARS-CoV-2 vaccine. We aimed to assess the safety and immunogenicity of primary vaccination with VLA2001 versus the ChAdOx1-S (Oxford-AstraZeneca) adenoviral-vectored vaccine. METHODS: In this immunobridging phase 3 trial (COV-COMPARE), participants aged 18 years and older who were medically stable (as determined by an investigator) were enrolled at 26 sites in the UK. In the double-blind, randomised, controlled arm of the trial, participants aged 30 years and older were randomly assigned (2:1) to receive two doses of VLA2001 (0Â·5 mL; with 33 antigen units [AU] per dose) or ChAdOx1-S (0Â·5 mL; with 2Â·5â€‰Ã—â€‰10(8) infectious units per dose) on days 1 and 29. In another arm, participants aged 18-29 years received two doses of VLA2001 (same dose) open label on days 1 and 29. The primary immunogenicity outcome was the immune response of a two-dose schedule of VLA2001 on day 43, in adults aged 30 years and older, versus two doses of ChAdOx1-S via superiority of geometric mean titres (GMTs) of neutralising antibodies (GMT ratio of >1 at a two-sided significance level of 5%) and non-inferiority of the seroconversion rate (non-inferiority margin of -10% for the lower limit of the 95% CI for the difference between groups). The primary safety outcome was the frequency and severity of any adverse events in all participants up to day 43. Safety was assessed in all participants who received at least one dose of vaccine. GMTs were assessed in a subset of participants aged 30 years and older who were seronegative at baseline, had at least one evaluable antibody titre measurement after vaccination, and had no confirmed COVID-19 during the study (immunogenicity population); and seroconversion was assessed in the per-protocol population, which comprised the immunogenicity population but excluding any participants with major protocol violations. For each timepoint, only participants with available data were included in the analysis. This study is registered with ClinicalTrials.gov, NCT04864561, and is ongoing. FINDINGS: Between April 28 and June 3, 2021, 4181 individuals were screened and 4017 enrolled, of whom 2975 (74%) were aged 30 years or older and randomly assigned to receive VLA2001 (n=1978) or ChAdOx1-S (n=997), and 1042 (26%) were aged 18-29 years (all received open-label VLA2001). 4012 participants received at least one dose of vaccine (1040 in the open-label VLA2001 group, 1977 in the randomised VLA2001 group, and 995 in the ChAdOx1-S group). The immunogenicity population comprised 492 participants in the randomised VLA2001 group and 498 in the ChAdOx1-S group; three participants in the VLA2001 group were excluded from the per-protocol population. VLA2001 induced higher neutralising GMTs than did ChAdOx1-S (803Â·5 [95% CI 748Â·5-862Â·6] vs 576Â·6 [543Â·6-611Â·7]; GMT ratio 1Â·39 [95% CI 1Â·25-1Â·56]; p<0Â·0001), and non-inferior seroconversion rates (444 [97Â·4%] of 456 participants vs 444 [98Â·9%] of 449; difference -1Â·5% [95% CI -3Â·3 to 0Â·2]. Any adverse event was reported in 963 (92Â·6%) participants in the open-label VLA2001 group, 1755 (88Â·8%) in the randomised VLA2001 group, and 976 (98Â·1%) in the ChAdOx1-S group. Most adverse events reported were mild or moderate in severity. INTERPRETATION: VLA2001 has a favourable tolerability profile and met superiority criteria for neutralising antibodies and non-inferiority criterion for seroconversion rates compared with ChAdOx1-S. The data presented here formed the basis of successful marketing approval for use of VLA2001 in primary vaccination in the EU, the UK, Bahrain, and United Arab Emirates. FUNDING: UK Department of Health and Social Care and Valneva Austria.
HLA-DR4 and DRB4: Potential risk alleles for COVID-19 vaccination-related ANCA-associated vasculitis.
Analysis of Vaccine Reactions After COVID-19 Vaccine Booster Doses Among Pregnant and Lactating Individuals. IMPORTANCE: COVID-19 vaccine boosters or third doses are recommended for

adolescents and adults who completed their initial COVID-19 vaccine course more than 5 months prior. Minimal data are available on COVID-19 vaccine booster or third dose reactogenicity among pregnant and lactating individuals. OBJECTIVE: To describe the reactions to the booster or third dose of the COVID-19 vaccine and vaccine experiences among pregnant and lactating individuals. DESIGN, SETTING, AND PARTICIPANTS: Beginning in October 2021, a follow-up Research Electronic Data Capture (REDCap) survey regarding a COVID-19 vaccine booster or third dose was sent to 17â€¯504 participants in an ongoing online prospective cohort study on COVID-19 vaccines among pregnant and lactating individuals. A convenience sample of adults enrolled in the online prospective study who were pregnant, lactating, or neither pregnant nor lactating at the time of their booster or third dose was eligible for this follow-up survey; 17â€¯014 (97.2%) completed the follow-up survey. EXPOSURE: Receipt of a booster or third dose of the COVID-19 vaccine. MAIN OUTCOMES AND MEASURES: Self-reported vaccine reactions less than 24 hours after the dose. RESULTS: As of April 4, 2022, 17â€¯014 eligible participants (mean [SD] age, 33.3 [3.5] years) responded to the booster or third dose survey; of these, 2009 (11.8%) were pregnant at the time of their booster or third dose, 10â€¯279 (60.4%) were lactating, and 4726 (27.8%) were neither pregnant nor lactating. After a COVID-19 booster or third dose, most individuals (14â€¯074 of 17â€¯005 [82.8%]) reported a local reaction, and 11â€¯542 of 17â€¯005 (67.9%) reported at least 1 systemic symptom. Compared with individuals who were neither pregnant nor lactating, pregnant participants were more likely to report any local reaction to a COVID-19 booster or third dose (adjusted odds ratio [aOR], 1.2; 95% CI, 1.0-1.4; Pâ€‰=â€‰.01) but less likely to report any systemic reaction (aOR, 0.7; 95% CI, 0.6-0.8; Pâ€‰<â€‰.001). Most pregnant (1961 of 2009 [97.6%]) and lactating (9866 of 10â€¯277 [96.0%]) individuals reported no obstetric or lactation concerns after vaccination. CONCLUSIONS AND RELEVANCE: This study suggests that COVID-19 vaccine boosters or third doses were well tolerated among pregnant and lactating individuals. Data to evaluate tolerability of boosters or additional doses among pregnant and lactating individuals will be important as they are considered for these populations.

Induction of neutralizing antibodies in CLL patients after SARS-CoV-2 mRNA vaccination: a monocentric experience. Vaccination represents the best strategy to fight COVID-19 pandemics, especially in immune compromised subjects. In chronic lymphatic leukemia patients, a marked impairment of the immune response to mRNA SARS-CoV-2 vaccine was observed. In this report, we analyzed anti-RBD and neutralizing antibodies in CLL patients after two doses of mRNA SARS CoV 2 vaccine and evaluated the impact of Bruton kinase inhibitory agents. Twenty-seven CLL patients vaccinated with mRNA vaccines against SARS CoV-2 were recruited. Serum IgG, IgM and IgA anti-RBD antibodies and neutralizing antibodies were detected, and antibody avidity was measured. Peripheral blood leukocytes subsets were evaluated by flow cytometry. After two vaccine doses anti-RBD IgG were produced in 11/27 (40.5%) of patients and levels of IgG and IgA anti RBD in CLL patients were sensibly lower than in controls. Neutralizing antibodies were detectable in 12/27 (44.5%) of the patients and their level was lower than that observed in controls. Disease burden and treatment with Bruton kinases inhibitors markedly impaired vaccine induced antibody response. However, in responder patients, antibody avidity was comparable to normal subjects, indicating that the process of clonal selection and affinity maturation takes place as expected. Taken together, these data confirm the impact of disease burden and therapy on production of anti-RBD and neutralizing antibodies and support the current policy of vaccinating CLL patients.

Acceptance of Seasonal Influenza Vaccine Following COVID-19 Vaccination: A Survey among Israel Defense Forces Soldiers. Data regarding the contribution of COVID-19 vaccine rollouts to real-world uptake of influenza vaccination remains unclear. This cross-sectional survey-based study among Israel Defense Forces (IDF) soldiers aimed to assess the impact of the COVID-19 pandemic and

specifically, previous COVID-19 vaccines uptake, on the intention to vaccinate for influenza during 2021-2022 season. Participants engaged in an online survey addressing vaccination history and current vaccine-related preferences. The survey was delivered prior to the initiation of the IDF's annual influenza immunization campaign. A multinomial logistic regression model was applied to analyze factors correlated with unwillingness to receive influenza vaccine. Overall, 825 invitations to participate in the survey were distributed and the overall response rate was 78.5%. Among the 648 participants who replied (61.6% males, median age of 20â€‰years), 51.9% were willing to receive the upcoming influenza vaccine. Factors associated with vaccine reluctance included being female, not receiving the previous season's influenza vaccine, not having a previous diagnosis of COVID-19, and having decreased uptake of COVID-19 vaccines. Among participants not intending to receive an influenza vaccine, 50.3% stated that they are healthy and have no need for the vaccine and 36.2% stated they received too many vaccines over the previous year. The results of this study may suggest that influenza vaccination rates in the post-COVID-19 vaccine era may be reduced due to a perceived "vaccine saturation" phenomenon, owing to the density of COVID-19 vaccine administration. Future interventions such as campaigns related to maximizing influenza vaccination coverage should address repeated doses of COVID-19 vaccine administration.

No need of glucocorticoid dose adjustment in patients with adrenal insufficiency before COVID-19 vaccine. OBJECTIVE: Coronavirus disease-2019 (COVID-19) causes acute respiratory distress syndrome. Patients with adrenal insufficiency (AI) may develop severe complications due to this infection and should undergo COVID-19 vaccination; however, there is no consensus about the management of their replacement therapy. The aim of our study was to evaluate the tolerability and need for glucocorticoid dose adjustment related to COVID-19 mRNA vaccines in a cohort of patients with AI. DESIGN AND METHODS: We prospectively administered to 88 patients (51 M/37 F; mean age: 62.3 Â± 16 years), with AI (28 primary and 60 secondary AI), a questionnaire about the occurrence, severity and duration of the side effects and the need for glucocorticoid dose adjustment within 1 week after the first and the second dose of COVID-19 mRNA vaccines (Pfizer-BioNTech and Moderna). RESULTS: Side effects of mild to moderate severity occurred in about 70% of patients after both vaccine doses. The most common adverse events were pain at the injection site, fatigue, fever and flu-like symptoms. The occurrence and severity of the side effects were not correlated to gender, type of AI and mRNA vaccine, but their total number was higher after the second vaccine dose. Doubling the oral glucocorticoid dose was needed in up to 8% of patients, especially after the second vaccine dose, but no parenteral administration was required. CONCLUSIONS: COVID-19 mRNA vaccines were well tolerated in patients with AI. Side effects were similar to those observed in the general population, and increasing glucocorticoid replacement therapy before vaccine administration was not needed.

COVID-19 vaccination not associated with increased risk of erectile dysfunction. Although mRNA COVID-19 vaccines have proven to be safe and effective against SARS-CoV-2, vaccination rates have slowed, with some individuals citing impotence as a concern. Therefore, we conducted a survey of the US males to evaluate the impact of COVID-19 vaccination on erectile function. We hypothesized that vaccinated men would not have a higher risk of ED compared to unvaccinated men. Amazon Mechanical Turk (MTurk) was utilized to survey the US adult male population between August 26 and September 2, 2021. Survey participation was open to 1000 males over the age of 18 and currently living in the United States regardless of vaccination status or the past medical history of COVID-19. Selection criteria included respondents â‰¥45â€‰years old, no history of physician-diagnosed ED, biologically born, and identify as male. Participants completed an anonymous 16-question survey that included a multidimensional scale used to evaluate ED, the International Index of Erectile Function (IIEF-5). Among vaccinated men, the median IIEF-5 score was 20 [16-24] compared to 22 [17.5-25] in

the unvaccinated group (pÂ =â€‰0.195). The multivariable-adjusted analysis demonstrated that vaccination against COVID-19 was not associated with increased risk of ED. Overall, this cross-sectional survey showed that COVID-19 vaccination was not associated with an increased risk of erectile dysfunction in males 45â€‰years and older.

Coexistence of Pemphigus Vulgaris and Lichen Planus following COVID-19 Vaccination. SARS-CoV-2 vaccines were approved without long-term monitoring due to emergent situation and might have several side effects. Herein, we describe the first case with development of both LP and PV following COVID-19 vaccination. Immunological alteration due to COVID-19 vaccination and its potential role in triggering autoimmune disorders were also dealt with.

SARS CoV- 2 vaccination induces antibodies against cardiolipin. OBJECTIVE: Cases of thrombosis have been reported after administration of SARS-CoV-2 vaccines, with controversial results relating to Oxford-AstraZeneca's ChAdOx1-S. Despite such cases being rare, they still raised concerns for their involvement in coagulopathies. Anti-cardiolipin (aCL) IgG antibodies have been linked to venous and arterial thrombosis. The aim was to evaluate the concentration of aCL IgG antibodies in vaccinated and COVID-19 positive individuals using indirect ELISA and commercial sourced calibrators. RESULTS: The concentration of aCL IgG antibodies was measured in the serum of COVID-19 positive (nâ€‰=â€‰37), ChAdOx1-S vaccinated (nâ€‰=â€‰37) and BioNTech Pfizer BNT162b2 vaccinated (nâ€‰=â€‰42) individuals. Samples from COVID-19 negative, unvaccinated individuals (nâ€‰=â€‰41) served as controls. The highest percentage of positivity was in the COVID-19 positive group (18.9%). Concerning vaccination, BNT162b2 had the highest percentage of positivity (11.9%) (pâ€‰=â€‰0.0037). Additionally, aCL concentrations were evaluated at different time points in both vaccinated groups (before, 3Â weeks after and 3Â months after the second dose). A significant difference in the levels of aCL IgG antibodies over time (pâ€‰=â€‰0.0391) was observed only in ChAdOx1-S individuals. Our study concluded that levels of aCL, after vaccination with either of the vaccines or following SARS-CoV-2 infection, were not clinically pathogenic for the risk of thrombosis.

Vaccination willingness in association with personality traits in patients with multiple sclerosis in the course of SARS-CoV-2 pandemic. Vaccination is a key strategy for controlling the SARS-CoV-2 pandemic. Acceptance of SARS-CoV-2 vaccines by chronically ill patients, such as multiple sclerosis (MS) patients, plays an important role in prevention of complicated disease course. This longitudinal, prospective, multi-centre-study of German MS-patients aimed to detect socio-demographic, clinical, or psychological determinants of attitudes towards standard vaccines, SARS-CoV-2 vaccines, and governmental measures before/during the pandemic. Exactly 404 MS-patients were investigated by standardized questionnaires and structured interviews on socio-demographic, clinical-neurological, and psychological characteristics, vaccination status, and vaccination from June 2019. Data on SARS-CoV-2 vaccination willingness were collected in two follow-up assessments (1st: June to July 2020, before SARS-CoV-2 vaccine availability, Nâ€‰=â€‰200; 2nd: March to May 2021, after SARS-CoV-2 vaccine availability, Nâ€‰=â€‰157). Age, sex, MS course type, depression, and personality characteristics (Extraversion, Novelty seeking, Self-directedness, and Cooperativeness) were significantly associated with vaccination willingness. Although the majority of MS-patients showed SARS-CoV-2 vaccination willingness at both follow-ups (1st: 60%, 2nd: 61%), a substantial proportion had concerns and were undecided or opposed to vaccination. Socio-demographic variables like age and sex, psychopathological status, and various personality characteristics might influence vaccination willingness and should be considered when discussing with MS-patients about SARS-CoV-2 vaccination.

Medium-vessel Vasculitis Presenting with Myalgia Following COVID-19 Moderna Vaccination. Coronavirus disease 2019 (COVID-19) vaccines have been delivered worldwide to prevent the spread of the disease, and almost all Japanese have received the mRNA vaccines "BNT162b2" (Pfizer-

BioNTech) or "mRNA-1273" (Moderna). These vaccines have shown efficacy and safety with only minor adverse drug reactions. However, some patients develop severe adverse drug reactions, including autoimmune reactions. In addition, systemic vasculitis, mainly small-vessel vasculitis, following COVID-19 vaccination, has been reported. However, only a few investigators have reported medium-vessel vasculitis following vaccination. We herein report a case of medium-vessel vasculitis presenting with myalgia as the initial clinical manifestation following COVID-19 Moderna vaccination.

New-onset Seropositive Rheumatoid Arthritis Following COVID-19 Vaccination in a Patient with Seronegative Status. Coronavirus disease 2019 (COVID-19) has spread worldwide since 2019, and mRNA vaccines for the disease have been rapidly delivered to limit the severity of infection. However, while these vaccines are effective in reducing the morbidity and severity of the disease, some patients develop severe adverse drug reactions and new-onset autoimmune phenomena, such as myocarditis, thrombosis with thrombocytopenia, and vasculitis. In addition, some patients develop arthritis following vaccination, including rheumatoid arthritis (RA). We herein report a case of new-onset seropositive RA following COVID-19 mRNA vaccination. Although tests for rheumatoid factor and anti-cyclic citrullinated peptide antibody had been negative three years before vaccination, the patient developed seropositive RA following COVID-19 mRNA vaccination.

Should I stay or should I go? Observation post-vaccination during the COVID-19 pandemic and the law of unintended consequences. BACKGROUND: Standard practice after all vaccinations in Australia is to observe patients for 15min. During the coronavirus disease 2019 (COVID-19) pandemic, could the risk of contracting and dying from COVID-19 acquired in the waiting room be greater than the risk of dying from post-vaccine anaphylaxis when leaving immediately? METHODS: The risks are modelled for a patient aged 70+years attending for annual influenza vaccination in a typical Australian general practice clinic. The risk of death from anaphylaxis is estimated based on known rates of anaphylaxis shortly after influenza vaccination. The risk of acquiring COVID-19 during a 15-min wait and then dying from that infection is estimated using the COVID-19 Aerosol Transmission Estimator and COVID-19 Risk Calculator. RESULTS: Other than at times of extremely low COVID-19 prevalence, the risk of death from anaphylaxis for a patient aged 70+years leaving immediately after influenza vaccine is less than the risk of death from COVID-19 acquired via aerosol transmission during a 15-min wait. The risk of death from COVID-19 is greatest for the unimmunised and when masks are not worn. CONCLUSIONS: A more nuanced approach to advice post-vaccination is recommended that considers current COVID-19 prevalence and virulence, the characteristics of the waiting room, the risk of anaphylaxis, and the patient's susceptibility to death from COVID-19. There are many circumstances where it would be safer for a patient to leave immediately after vaccination.

Temporary reduction of immunosuppression enhances production of anti-S antibody against severe acute respiratory syndrome coronavirus 2 after vaccination in kidney transplant recipients. OBJECTIVES: The study identified factors affecting anti-S immunoglobulin G production after vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in kidney transplant recipients. METHODS: Serum samples were prospectively collected from kidney transplant recipients, live kidney donors, and healthy volunteers 1â€‰month after receiving the second dose of SARS-CoV-2 vaccine, and anti-S immunoglobulin G titers were measured. The mycophenolate mofetil dose was reduced before vaccination in some immunologically low-risk recipients. RESULTS: A total of 151 kidney transplant recipients, 74 live kidney donors, and 50 healthy volunteers were included. Kidney transplant recipients had significantly lower titers of anti-S immunoglobulin G than donors and healthy volunteers (1377â€‰Â±â€‰246, 8310â€‰Â±â€‰932, and 9908â€‰Â±â€‰1040â€‰AU/ml, respectively). Only 67.3% of kidney transplant recipients, compared to 100% of donors and healthy volunteers, were positive for anti-S immunoglobulin G. Among the kidney transplant recipients, the anti-S titer was higher in younger recipients, those with

higher peripheral blood lymphocyte counts and glomerular filtration rates, those without a history of antithymocyte globulin use, and those who had discontinued or received a reduced dose of mycophenolate mofetil. Younger age, higher lymphocyte count, glomerular filtration rate, and mycophenolate reduction were significantly associated with anti-S immunoglobulin Gâ€‰>â€‰1000â€‰AU/ml in nominal logistic regression analysis. There were no rejection episodes after mycophenolate modification in kidney transplant recipients. CONCLUSIONS: Anti-S immunoglobulin G production after vaccination was attenuated in kidney transplant recipients. Mycophenolate mofetil cessation or reduction is a modifiable means to enhance anti-S immunoglobulin G production in immunosuppressed kidney transplant recipients.

Clinical characteristics in immune thrombocytopenia patients after COVID-19 vaccination. It is well documented that COVID-19 vaccines greatly reduce the severity and complications of SARS-CoV-2 infection. However, it has been reported that COVID-19 related vaccines may induce or exacerbate autoimmune hematological disorders, for example, a decrease in platelet numbers characteristic of immune thrombocytopenia (ITP). To investigate this, we retrospectively reported, for the first time, the clinical characteristics of 42 ITP patients after COVID-19 vaccination in southwest China. Of the 42 patients, 28 patients were historically diagnosed ITP, and their platelet counts (PC) decrease mainly occurred after the first-dose vaccinations. The average PC after vaccination was 39.5â€‰Ã—â€‰10(9)/L and recovered to an average of 80.6â€‰Ã—â€‰10(9)/L after treatment. Efficacy of treatment was 90%, and only 10% maintained low PC at the third month of treatment. More interestingly, of the 42 patients, 14 were newly diagnosed ITP following vaccination. Of these 14 patients, 6 patients (43%) were found PC deterioration after the first vaccine dose, and 7 patients (50%) after the second dose. Fortunately, the peripheral PC of all 14 patients recovered significantly after treatment, and the average PC was 139.4â€‰Ã—â€‰10(9)/L, including 8 CRs (complete response) and 6 PRs (partial response). Notably, 9 of the 14 cases were found to have abnormal immune indices when thrombocytopenia diagnosed. No severe organ hemorrhage was found in either subgroup. These results are reassuring the vaccine safety for ITP patients, in that the risks of aggravating thrombocytopenia by COVID-19 vaccination do exist, but it was transient and can be effectively controlled through intensive clinical monitoring and management.

Cardiomyopathy following COVID-19 vaccination in a patient with systemic lupus erythematosus. There are an increasing number of reports of myocarditis associated with mRNA-based COVID-19 vaccination. We describe the case of a female patient with underlying systemic lupus erythematosus, who developed heart failure symptoms following a second dose of the BNT162b2 vaccine. Despite her history of refractory systemic lupus erythematosus, the disease remained stable after she began rituximab treatment. She underwent serial transthoracic echocardiogram and cardiac magnetic resonance imaging for the evaluation of cardiomyopathy. She showed improvement in cardiac function after treatment with glucocorticoids and intravenous immunoglobulin therapy.

Guillain-BarrÃ© syndrome in an era of global infections and 21st century vaccination. PURPOSE OF REVIEW: Guillain-Barre syndrome is sometimes a severe and disabling postinfectious neuromuscular paralysis that is causally associated with a number of well defined infections, and occasionally with immunization. The severe acute respiratory syndrome coronavirus 2 (Sars-CoV-2) pandemic and the worldwide immunization programme provoked fears of an epidemic of coronavirus disease 2019 (COVID-19) related disease. As we emerge from the pandemic this review summarises some of the huge volume of publications about Guillain-Barre syndrome (GBS), COVID-19 and immunisation against it. RECENT FINDINGS: In the early months of COVID-19, there were concerns of significant numbers of cases of GBS resulting from SARS-CoV-2 infection. Large epidemiological studies have provided reassurance that the association of GBS with COVID-19 is small or absent. Despite considerable efforts, plausible pathogenic mechanisms aligned with our understanding of

GBS causation have not been identified. Reliable data from national surveillance of COVID-19 vaccinations have shown GBS to occur at about 5.8 cases per million first doses of adenovirus vectored COVID-19 vaccines, otherwise not distinguishable from incident naturally occurring cases. However, this risk is far outweighed by the protective benefits of vaccination in the at-risk older deciles of age. SUMMARY: With no obvious link of GBS to COVID-19 epitopes, in particular the spike (S-)protein, but a clearly demonstrable causation in some susceptible individuals from the global rollout of novel adenovirus vectored vaccine technologies, adenoviruses are of significant interest in the pathogenesis of GBS as well as vectors in their many expanding pharmaceutical applications.

Widespread cutaneous eruption following COVID-19 vaccine in the setting of immunotherapy.

A Case of Segmental Arterial Mediolysis of Multiple Visceral Arteries Following Anti-COVID-19 Vaccination: Late Complication or Rare Coincidence? BACKGROUND Segmental arterial mediolysis (SAM) is a rare noninflammatory, nonatherosclerotic vascular disorder characterized by arterial media disruption. In conjunction with the SARS-CoV-2 infection or anti-COVID-19 vaccination, vascular disorders have been recognized as organ-specific immune-mediated complications, and the number of reported cases is gradually increasing. CASE REPORT A 68-year-old man presented with severe upper abdominal pain and nausea 58 days after a third injection of Pfizer-BioNTech anti-COVID-19 mRNA vaccination. An abdominal dynamic computed tomography angiography showed stenosis and dilatation of multiple visceral arteries, including the middle and right colic arteries. In the omental arteries, spindle-shaped dilatation and stenosis were identified. The left epiploic artery was not visualized, suggesting the development of occlusion due to arterial dissection. Based on these findings, SAM of multiple visceral arteries was diagnosed. Because the patient's vital condition was stable, treatment by observation, with restriction of daily living, was chosen. Seventy-five days later, the pathological lesions in the affected vessels spontaneously resolved. CONCLUSIONS While coincidence could not be completely excluded in this case, anti-COVID-19 mRNA vaccination should be noted for its potential association with SAM as a possible late complication.

Vasovagal reactions after COVID-19 vaccination in Japan. Coronavirus disease 2019 (COVID-19) vaccine administration started in February 2021 in Japan. As of December 2021, approximately 75% of the population aged â‰¥12Â years had received two doses of vaccine. We conducted a study to investigate vasovagal reactions (VVR) after COVID-19 vaccination using data on adverse events following immunization. The crude reporting rate of VVR (cases/1,000,000 doses) after vaccination was 9.6 in all age groups combined, and was more frequent in the younger age groups: 28.6 and 37.2 in individuals aged 10-19Â years and 20-29Â years, respectively. In individuals aged 10-29Â years, the rate was similar in males and females (33.0 and 34.2, respectively, pÂ =Â 0.53); but was higher after dose 1 than after dose 2 (57.4 and 8.8, respectively, pÂ <Â 0.001). Based on these results, caution needs to be exercised when vaccinating adolescents and young adults, especially with dose 1 of COVID-19 vaccines.

Side effects during the week after first dose vaccination with four Covid-19 vaccines. Results of the ProVaVac Survey Study with 13,837 people in Spain. BACKGROUND: In 2021, four vaccines against Covid-19 (BNT162b2, mRNA-1273, ChAdOx1nCoV-19, and JNJ-78436735) were employed in the region of Valencia, Spain. We conducted a survey to identify real-world, self-reported frequency and severity of side effects during the week after vaccination. METHODS: Survey data was obtained from April 19, 2021, to October 6, 2021, at three different moments in time: day one, day three and day seven after vaccination. Answers were linked to individual-level, personal and clinical information. Respondents were stratified by the vaccine they received and reported effects were presented over time and stratified by severity. We compared our results per vaccine with the frequencies stated in each Summary of Product Characteristics (SmPC). We used binomial logistic models to identify associations between respondent characteristics and side effects. RESULTS: No

symptoms were reported by 1,986 respondents (14.35Â %), 6,254 informed exclusively mild symptoms (45.20Â %), 3,444 up to moderate symptoms (24.89Â %), and 2,153 people (15.56Â %) notified also severe symptoms. Among the latter, the more frequent were extreme tiredness (7.0Â %), and nausea or vomiting (7.1Â %). The reported frequency of facial paralysis (0.4Â %) was much higher than reflected in SmPCs. Female sex, younger age, previous positive Active Infection Diagnostic Test, chronicity, and vaccination with other than the BNT162b2 vaccine were associated to an increased risk of side effects (pÂ <Â 0.001). CONCLUSIONS: Side effects after vaccination are common in the real-world. However, they are principally mild, and their frequency declines after a few days. Providing patients with dependable, beforehand information about side effects may improve outcomes and reinforce vaccination programs.

Antibody titers and neutralizing activity in cases of COVID-19 after a single dose of vaccination. Vaccines for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have shown high efficacy in preventing the onset of disease. However, the immune response to infection immediately after the first vaccination remains unknown. We examined the anti-SARS-CoV-2-binding-antibody titers and neutralizing activity in patients who developed coronavirus disease 2019 after the first vaccination. The amount of anti-SARS-CoV-2-binding antibodies and neutralizing activity drastically increased from the first to the second collection. Our results may provide important data on the course of immune response following vaccination.

Adverse Events Related to COVID-19 Vaccines Reported in Pregnant Women in Brazil. Regulations for the vaccination of pregnant women in Brazil occurred in March 2021. Despite the absence of robust data in the literature on the coronavirus disease 2019 (COVID-19) vaccinations in pregnant women, it is understood that the benefit-risk ratio tends to be favorable when considering the pandemic and the high burden of the disease. However, it is still important to monitor for Events Supposedly Attributable to Vaccination or Immunization (ESAVI) and to draw safety profiles of the different platforms used in pregnant and postpartum women. The present study aims to describe the main characteristics of ESAVIs related to COVID-19 vaccines occurring in pregnant women in the first months of the vaccination campaign in Brazil. During the evaluation period, 1,674 notifications of ESAVIs in pregnant women were recorded, and 582 notifications were included for the analysis. Of the 582 ESAVIs identified, 481 (82%) were classified as non-serious adverse events and 101 (17%) as serious adverse events. Ten deaths were identified, including one death which was considered to be causally related to the vaccine. The other nine maternal deaths had causality C, that is, without causal relationship with the vaccine, and most were due to complications inherent to pregnancy, such as pregnancy-specific hypertensive disorder (PSHD) in 4 cases and 3 due to COVID-19. Despite some limitations in our study, we believe it brings new insights into COVID-19 vaccines in this group and will add to the available evidence.

COVID-19 Vaccines for Children with Developmental Disabilities: Survey of New York State Parents' Willingness and Concerns. OBJECTIVE: While 1 in 6 US children have a developmental disability (DD), and such children are disproportionately affected by COVID-19, little is known about their vaccination status. We surveyed New York State parents of children with DDs to ascertain willingness and concerns regarding COVID-19 vaccines. METHODS: An online survey was distributed to statewide DD networks from June to September 2021 (vaccines were authorized for adolescents in May 2021). We report associations between vaccine willingness and concerns and race/ethnicity, child age, in-person schooling, routine/flu vaccinations, and DD diagnoses. Willingness was categorized as "got/will get ASAP" (high), "wait and see/only if required," or "definitely not." RESULTS: A total of 352 parents (49.1% White) responded. Willingness differed by age ($p < 0.001$). High willingness was reported for 73.9%, 50.0%, and 36.0% of children aged 12 to 17, 6 to 11, and 0 to 5 years, respectively. Willingness differed by autism diagnosis ($p < 0.01$) and routine and flu vaccination

status (p < 0.001). Predominant concerns included side effects (89%) and children with disabilities not being in trials (80%). Less common concerns were COVID not serious enough in children to warrant vaccine (23%) and misinformation (e.g., microchips, 5G, DNA changes) (24%). Concerns about vaccine safety differed by age (p < 0.01) and were highest for older and then the youngest children. In age-stratified adjusted models, attention-deficit/hyperactivity disorder was negatively associated with high willingness for age 5 or younger (OR = 0.02, 95% confidence interval, <0.001-0.622). CONCLUSION: Parents of children with DD in New York seemed highly willing for them to receive COVID-19 vaccines. Although few factors predicted willingness to vaccinate, addressing safety and developmental concerns regarding young children is warranted. Given their increased vulnerability, improved COVID-19 surveillance for children with DD is warranted.

Combination treatment of COVID-19 associated herpes zoster scar with 1540 nm and 755 nm picosecond lasers: a case report. A 33-year-old female, Fitzpatrick IV phototype, developed varicella zoster eruption over the ophthalmic dermatome of the right trigeminal nerve, confirmed through Polymerase Chain Reaction, 4Â weeks after recovering from COVID-19 disease. After the resolution of the acute manifestations, she developed significant atrophic scars on the forehead, about 2 mm deep, with marked post-inflammatory hyperpigmentation. She came to our clinic looking for treatment, as the scars caused significant psychological distress. We decided for a combination treatment with Erbium:glass 1540Â nm non-ablative laser and 755Â nm Alexandrite picosecond laser. After 16Â weeks of starting treatment, significant improvement was observed, with complete resolution of the hyperpigmentation and overall improvement in the atrophic scar. No complications occurred during the treatment period. This strategy may be an effective and safe option to treat these lesions, which may be increasingly found in young individuals after COVID-19 disease or SARS-CoV-2 vaccination, even in darker skin phototypes.

Adverse events after SARS-CoV-2 vaccination in solid organ transplant recipients: A systematic review.

The complexity of immunology: a rare adverse event following a Pfizer-BioNTech vaccine booster shot. OBJECTIVE: Several mRNA vaccines have been developed to tackle the global pandemic. Despite their remarkable clinical efficacy, they are not devoid of severe short- and long-term adverse events. CASE PRESENTATION: In this paper, we describe a rare delayed adverse event (arterial and venous renal thrombosis with myocardial injury) in an otherwise healthy adult female, which occurred three months after she received a booster shot of Pfizer COVID-19 vaccine. Â The patient was successfully treated for subacute renal ischemia with intra-arterial urokinase, and her myocardial injury was diagnosed with imaging (contrast-enhanced thoracic CT and cardiac magnetic resonance) and percutaneous coronary intervention. Deferred post-vaccine myocarditis was diagnosed and resolved with steroid therapy. CONCLUSIONS: In this paper, we report a useful clinical case for the pharmacovigilance database. Although scientific evidence confirms that the benefits of vaccination far outweigh the risk of adverse events, we would like to point out how important watchful observation is in the medium and long term, especially when the subject belongs to a specific risk category.

Myocarditis following COVID-19 vaccine: incidence, presentation, diagnosis, pathophysiology, therapy, and outcomes put into perspective. A clinical consensus document supported by the Heart Failure Association of the European Society of Cardiology (ESC) and the ESC Working Group on Myocardial and Pericardial Diseases. Over 10 million doses of COVID-19 vaccines based on RNA technology, viral vectors, recombinant protein, and inactivated virus have been administered worldwide. Although generally very safe, post-vaccine myocarditis can result from adaptive humoral and cellular, cardiac-specific inflammation within days and weeks of vaccination. Rates of vaccine-associated myocarditis vary by age and sex with the highest rates in males between 12 and

39â€‰years. The clinical course is generally mild with rare cases of left ventricular dysfunction, heart failure and arrhythmias. Mild cases are likely underdiagnosed as cardiac magnetic resonance imaging (CMR) is not commonly performed even in suspected cases and not at all in asymptomatic and mildly symptomatic patients. Hospitalization of symptomatic patients with electrocardiographic changes and increased plasma troponin levels is considered necessary in the acute phase to monitor for arrhythmias and potential decline in left ventricular function. In addition to evaluation for symptoms, electrocardiographic changes and elevated troponin levels, CMR is the best non-invasive diagnostic tool with endomyocardial biopsy being restricted to severe cases with heart failure and/or arrhythmias. The management beyond guideline-directed treatment of heart failure and arrhythmias includes non-specific measures to control pain. Anti-inflammatory drugs such as non-steroidal anti-inflammatory drugs, and corticosteroids have been used in more severe cases, with only anecdotal evidence for their effectiveness. In all age groups studied, the overall risks of SARS-CoV-2 infection-related hospitalization and death are hugely greater than the risks from post-vaccine myocarditis. This consensus statement serves as a practical resource for physicians in their clinical practice, to understand, diagnose, and manage affected patients. Furthermore, it is intended to stimulate research in this area.

Protocol for isolation and characterization of lung tissue resident memory TÂ cells and airway trained innate immunity after intranasal vaccination in mice. Vaccination route dictates the quality and localization of immune responses within tissues. Intranasal vaccination seeds tissue-resident adaptive immunity, alongside trained innate responses within the lung/airways, critical for superior protection against SARS-CoV-2. This protocol encompasses intranasal vaccination in mice, step-by-step bronchoalveolar lavage for both cellular and acellular airway components, lung mononuclear cell isolation, and detailed flow cytometric characterization of lung tissue-resident memory TÂ cell responses, and airway macrophage-trained innate immunity. For complete details on the use and execution of this protocol, please refer to Afkhami etÂ al. (2022).

Salivary and serum IgA and IgG responses to SARS-CoV-2-spike protein following SARS-CoV-2 infection and after immunization with COVID-19 vaccines. Background: Secretory immunoglobulin A (sIgA) plays an important role in antiviral protective immunity. Although salivary testing has been used for many viral infections, including severe acute respiratory syndrome (SARS) and Middle East Respiratory Syndrome (MERS), its use has not yet been well established with the SARS coronavirus 2 (SARS-CoV-2). Quantification of salivary IgA and IgG antibodies can elucidate mucosal and systemic immune responses after natural infection or vaccination. Here, we report the development and validation of a rapid enzyme-linked immunosorbent assay (ELISA) for anti-SARS-CoV-2 salivary IgA and serum IgG antibodies, and present quantitative results for immunized subjects both prior to or following COVID-19 infections. Objective: Total and serum SARS-CoV-2 spike-specific IgG responses were compared with salivary spike-specific IgA and IgG responses in samples obtained from patients recently infected with SARS-CoV-2 and from subjects recently immunized with COVID-19 vaccines. Methods: A total of 52 paired saliva and serum samples were collected from 26 study participants: 7 subjects after COVID-19 infection and 19 subjects who were uninfected. The ELISA results from these samples were compared with five prepandemic control serum samples. Total IgG and SARS-CoV-2 spike-specific IgG in the serum samples from the subjects who were infected and vaccinated were also measured in a commercial laboratory with an enzyme immunoassay. Results: A wide variation in antibody responses was seen in salivary and serum samples measured by both methods. Three groups of serum total and IgG spike-specific SARS-CoV-2 antibody responses were observed: (1) low, (2) intermediate, and (3) high antibody responders. A correlational analysis of salivary IgA (sIgA) responses with serum IgG concentrations showed a statistical correlation in the low and intermediate antibody responder groups but not in the high group (which we believe was a result of saturation).

Conclusion: These preliminary findings suggest measuring salivary and serum IgG and IgA merit further investigation as markers of current or recent SARS-CoV-2 infections.

Efficacy and safety of an e-consult program for COVID-19 vaccine allergy concerns. Background: Although severe allergic reactions to coronavirus disease 2019 (COVID-19) vaccines are rare, fear of allergic reactions remains a major source of vaccine hesitancy. For concerned patients and providers alike, allergist consultation is recommended for further guidance on the risk of vaccination. The electronic consultation (e-consult) medium has the potential to make this guidance more widely accessible, thereby supporting vaccination efforts. Objective: To determine the safety and efficacy of an e-consult program for COVID-19 vaccine allergy concerns. Methods: We performed a retrospective analysis of a single-center COVID-19 vaccine allergy e-consult program. Data on demographics, allergy history, and outcomes after recommendations were gathered via review of the electronic medical record (EMR). Patients without EMR data available following the e-consult were called to inquire about vaccination status. Results: Our study included 64 patients, most of whom (51.6% [33/64]) had e-consults placed for second-dose concerns. E-consults were completed within 2 days for all patients. The most common recommendation was that patients receive any COVID-19 vaccination available (62.5%, [40/64]). Forty-one patients (64.1%) were vaccinated after receiving recommendations from an allergist, 11 of whom (26.8%) reported a vaccine reaction. Most of these reactions were nonallergic (9/11 [81.2%]). No anaphylactic events were reported. Conclusion: Results of our study suggest that e-consults were a safe and effective method of providing guidance with regard to COVID-19 vaccine risk in patients with concerns about allergic reactions. The efficiency of this medium, highlighted by the 2-day turnaround time in our study, has the potential to expand access to vaccine risk evaluations by board-certified allergist/immunologists.

Thromboembolic events after Ad.26.COV2.S COVID-19 vaccine: Reports to the Vaccine Adverse Event Reporting System. PURPOSE: The Food and Drug Administration (FDA) has identified a potential safety concern for thromboembolic events (TEEs) after Ad.26.COV2.S COVID-19 Vaccine. We sought to characterize the frequency, severity, type, and anatomic location of TEEs reported to the Vaccine Adverse Event Reporting System (VAERS) following Ad.26.COV2.S. METHODS: Reports of TEEs after Ad.26.COV2.S were identified in VAERS, and demographics, clinical characteristics, and relevant medical history were summarized. For a subset of reports, physicians reviewed available medical records and evaluated clinical presentation, diagnostic evaluation, risk factors, and treatment. The crude reporting rate of TEEs was estimated based on case counts in VAERS and vaccine administration data. RESULTS: Through February 28, 2022, FDA identified 3790 reports of TEEs after Ad.26.COV2.S. Median age was 56â€‰years, and 1938 individuals (51.1%) were female. Most reports, 2892 (76.3%), were serious, including 421 deaths. Median time to onset was 12â€‰days post-vaccination. Obesity and ischemia were among the most commonly documented risk factors. Thrombocytopenia (platelet count less than 150â€‰000/Î¼l) was documented in 63 records (11.5%) and anti-platelet 4 antibodies in 25 (4.6%). Medical review identified cases of severe clot burden (e.g., bilateral, saddle, or other massive pulmonary embolism with or without cor pulmonale; lower extremity thrombus involving the external iliac, common femoral, popliteal, posterior tibial, peroneal, and gastrocnemius veins). The crude reporting rate was ~20.7 cases of TEE per 100â€‰000 doses of Ad.26.COV2.S administered. CONCLUSIONS: Life-threatening or fatal TEEs have been reported after Ad.26.COV2.S, including bilateral massive pulmonary embolism or other severe clot burden.

NETosis and thrombosis in vaccine-induced immune thrombotic thrombocytopenia. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare yet serious adverse effect of the adenoviral vector vaccines ChAdOx1 nCoV-19 (AstraZeneca) and Ad26.COV2.S (Janssen) against COVID-19. The mechanisms involved in clot formation and thrombocytopenia in VITT are yet to be fully determined. Here we show neutrophils undergoing NETosis and confirm expression markers of

NETs in VITT patients. VITT antibodies directly stimulate neutrophils to release NETs and induce thrombus formation containing abundant platelets, neutrophils, fibrin, extracellular DNA and citrullinated histone H3 in a flow microfluidics system and in vivo. Inhibition of NETosis prevents VITT-induced thrombosis in mice but not thrombocytopenia. In contrast, in vivo blockage of FcÎ³RIIa abrogates both thrombosis and thrombocytopenia suggesting these are distinct processes. Our findings indicate that anti-PF4 antibodies activate blood cells via FcÎ³RIIa and are responsible for thrombosis and thrombocytopenia in VITT. Future development of NETosis and FcÎ³RIIa inhibitors are needed to treat VITT and similar immune thrombotic thrombocytopenia conditions more effectively, leading to better patient outcomes.

Attitude toward COVID-19 vaccines and its association with depressive symptoms in 386,924 Chinese primary school students during COVID-19 epidemic normalization. AIM: Before Chinese primary school students were generally vaccinated against the COVID-19 vaccine, this study evaluated the willingness of this population and its influencing factors before vaccination, and evaluate its association between attitudes toward the vaccine and depressive symptoms. METHODS: A cross-sectional study involved 386,924 primary school students using a cluster sampling method during May 21-27, 2021. The Chinese version of the Children Depression Inventory (CDI) was used to assess depressive symptoms. Multiple logistic regression analysis models were used to estimate the relationship between attitudes toward COVID-19 vaccines and depressive symptoms. RESULTS: Among the participants, the prevalence of depressive symptoms was higher in higher grades. The prevalence was higher in fifth and sixth grade students than third and fourth grade students and first and second grades (10.22% vs. 6.07% vs. 3.04%). In addition, 20.79% of students do not know whether the vaccine can protect him from the COVID-19 infection, and 40.60% of students do not know whether the vaccine is safe. Of note, in terms of attitudes toward COVID-19 vaccines, students with more positive attitudes have a lower risk of depressive symptoms (adjusted odds ratio (aOR)Â =Â 0.151; 95% confidence interval (CI): 0.140-0.164). CONCLUSION: Based on these findings, it is necessary for the government and schools to promote vaccine safety and reliability information in a timely manner to increase vaccination uptake.

Immunisation with Coronavirus-2 vaccines induces potent antibody responses and does not aggravate the lymphocyte compartment of primary SjÃ¶gren's syndrome patients. OBJECTIVES: The peripheral lymphocyte compartment of patients with primary SjÃ¶gren's syndrome (pSS) differs strongly from healthy individuals. Whether this altered lymphocyte composition also changes abnormally during immune reactions, especially by novel CoV-2-vaccines, is unknown. METHODS: Peripheral blood mononuclear cells (PBMC) from 26 pSS patients and 6 healthy controls were compared before Coronavirus-2 (CoV-2) vaccination (Pfizer/BNT162b2, Moderna/mRNA-1273, AstraZeneca/AZD122 ChAdOx1 nCoV-19) and 7 days after secondary vaccination. Spike 1 (S1)-receptor binding domain (RBD)-specific IgG antibodies were measured in serum samples. Among PBMCs, B and T cell subpopulations were phenotypically analysed and RBD-specific B and plasma cells were evaluated. RESULTS: Immunisation induced CoV-2 specific serum antibodies in all pSS patients and healthy participants. When analysing pSS patients and controls together, frequencies of circulating IgG+ RBD-specific antibody-secreting cells (ASC) and anti-RBD serum titres correlated (r=0.42, p=0.022). Previously described alterations of peripheral B cells in pSS patients (e.g. reduced memory B cells, increased naive and transitional B cells and higher maturity of ASCs) remained stable during vaccination. The subset distribution of CD4+ and CD8+ T cells also stayed largely unchanged. However, frequencies of CD4+CXCR5-PD-1+ circulating peripheral helper T (cTPH)-like cells increased in pSS patients comparing pre- and post-vaccination (p=0.020), while circulating CD4+CXCR5+PD-1+ follicular helper T (cTFH)-like cells declined (p=0.024). CONCLUSIONS: An immune reaction induced by vaccination with the novel CoV-2 vaccines yields adequate antibody production and vaccine specific

lymphocytes in pSS patients and controls. Aberrant lymphocyte subset distribution in pSS patients persisted after vaccination and no major changes were induced despite small changes in cTPH and cTFH cells.

COVID-19 Vaccine-Related Adverse Events in Solid Cancer Patients Treated with Immunotherapy. Little data are available regarding the effects of COVID-19 vaccine in cancer patients undergoing immunotherapy. Thereby, COVID-19 vaccine-related adverse events were monitored through a short questionnaire in solid cancer patients receiving immunotherapy. A total of 95 patients were included in this study. Two doses of vaccines were administered to cancer patients which mainly received Pembrolizumab (51.1%). Respectively 78.2% and 62.2% of patients reported no adverse events after the first and the second dose regardless of the type of vaccine used. Considering the high mortality rate due to COVID-19 among cancer patients, this study demonstrated the good tolerance of COVID-19 vaccine.

Orbital myositis and scleritis after anti-SARS-CoV-2 mRNA vaccines: A report of three cases. PURPOSE: To report three cases of ocular myositis and scleritis, bilateral scleritis and unilateral single muscle myositis after mRNA COVID-19 vaccination. METHODS: Case series of three patients who presented to the Orbit Outpatient Service of Fondazione Policlinico Universitario A. Gemelli with a history of unilateral proptosis, diplopia and pain, bilateral red eye and pain during eye movements and unilateral proptosis and inconstant diplopia respectively with onset 5-10 days after m-RNA COVID-19 vaccine. A thorough hematologic work up and orbital contrast enhanced magnetic resonance imaging (MRI) in patients with proptosis was performed. RESULTS: Patients were females, 64, 58 and 45 years old respectively. MRI showed enlargement of all right rectus muscles, with both muscle belly and insertion involvement in the first case associated to right scleritis. A bilateral scleritis was diagnosed in the second patient and a single muscle myositis in the third patient. Serological tests excluded thyroid diseases. The first and second patient were treated respectively with oral and topical glucorticoids with a complete clinical response. Two 2 cycles of oral non-steroidal anti-inflammatory drugs were administered to the third patient with a partial response. CONCLUSION: As far as we know these are the first report of orbital myositis and scleritis presenting after mRNA BNT162b2 vaccine (Pfizer/BioNTech) and mRNA-1273-(Moderna) vaccine, an uncommon effect of a likely autoimmune reaction triggered by the virus antigen.

Branch retinal vein occlusion following ChAdOx1 nCoV-19 (Oxford-AstraZeneca) vaccine. PURPOSE: To present a case of branch retinal vein occlusion (BRVO) following ChAdOx1 nCoV-19 (Oxford-AstraZeneca) Vaccine. METHODS: Case report. RESULTS: A 60-year old otherwise healthy Caucasian male, presented to the ophthalmology emergency clinic complaining of sudden, painless vision loss in his right eye of 24 h'' duration. The patient had received Vaxveria seven days prior. The clinical and fundus examination of the right eye established the diagnosis of BRVO. CONCLUSION: The present case descibes the occurrence of BRVO soon after the vaccination with the Oxford-AstraZeneca vaccine. The close temporal relationship between the BRVO incidence and the vaccination is reinforced by the lack of othe subjective cause to justify the episode.

A case of recurrent fixed drug eruption following the administration of 2 different coronavirus disease 2019 vaccines verified using intradermal and patch tests.

A microarray patch SARS-CoV-2 vaccine induces sustained antibody responses and polyfunctional cellular immunity. Sustainable global immunization campaigns against COVID-19 and other emerging infectious diseases require effective, broadly deployable vaccines. Here, we report a dissolvable microarray patch (MAP) SARS-CoV-2 vaccine that targets the immunoresponsive skin microenvironment, enabling efficacious needle-free immunization. Multicomponent MAPs delivering both SARS-CoV-2 S1 subunit antigen and the TLR3 agonist Poly(I:C) induce robust antibody and cellular immune responses systemically and in the respiratory mucosa. MAP vaccine-induced

antibodies bind S1 and the SARS-CoV-2 receptor-binding domain, efficiently neutralize the virus, and persist at high levels for more than a year. The MAP platform reduces systemic toxicity of the delivered adjuvant and maintains vaccine stability without refrigeration. When applied to human skin, MAP vaccines activate skin-derived migratory antigen-presenting cells, supporting the feasibility of human translation. Ultimately, this shelf-stable MAP vaccine improves immunogenicity and safety compared to traditional intramuscular vaccines and offers an attractive alternative for global immunization efforts against a range of infectious pathogens.

Association Between COVID-19 Vaccination Coverage and Case Fatality Ratio: a Comparative Study - Hong Kong SAR, China and Singapore, December 2021-March 2022. WHAT IS ALREADY KNOWN ABOUT THIS TOPIC? Hong Kong Special Administrative Region (SAR), China and Singapore are both facing considerable Omicron variant epidemic. However, the overwhelmed medical system and high case fatality ratio (CFR) just occurred in Hong Kong SAR, China but not in Singapore. WHAT IS ADDED BY THIS REPORT? The low vaccination coverage in Hong Kong SAR, China, especially among the older adults, is shown to be a primary reason of its recent high CFR. WHAT ARE THE IMPLICATIONS FOR PUBLIC HEALTH PRACTICE? Facing the potential epidemic risk, non-vaccinated, non-fully-vaccinated, and non-booster-vaccinated people in China, especially the elderly, should get any type of accessible vaccine, which could save lives when the infection unfortunately befalls.

Case report: Case series of isolated acute pericarditis after SARS-CoV-2 vaccinations. During the worldwide ongoing immunization campaign against SARS-CoV-2, growing data on very rare but potentially harmful side effects of such vaccines arise since approval trials have not been adequately powered to detect those events. Besides the already reported vaccine-related myocarditis, which primarily occurs in young male individuals, our attention was recently drawn to a series of older male and female patients, who were referred to our institutions with isolated acute pericarditis without myocardial damage, shortly after SARS-CoV-2 vaccination. We describe a series of five adult patients presenting with chest pain, shortness of breath and isolated pericarditis with and without pericardial effusion after SARS-CoV-2 vaccination. All patients underwent echocardiography and cardiac magnetic resonance, and the corresponding findings, including late gadolinium enhancement (LGE) and T1 and T2 mapping are reported herein. To our knowledge, such cases have not been systematically reported in the current literature so far.

Case report: Five patients with myocarditis after mRNA COVID-19 vaccination. OBJECTIVES: To describe clinical features and laboratory data of myocarditis after the mRNA COVID-19 vaccine in children. METHODS: We reviewed patients younger than 18 years of age, who visited our hospital because of myocarditis within 1 week after BNT162b2 from June 2021 to January 2022. RESULTS: We identified five male patients aged 12-16 years who presented to our hospital with myocarditis within 2-3 days after the second dose of BNT162b2 COVID-19 vaccination between June 2021 and January 2022. All patients experienced chest pain, and fever, pain other than chest pain, and shortness of breath were present in two, three, and two patients, respectively. The serum troponin I level was increased in all patients except one, and electrocardiogram (ECG) showed ST elevation in all patients. Echocardiography revealed pericardial effusion and decreased ejection fraction in three and one patients, respectively. In accordance with the Japanese guidelines for myocarditis, the patients were treated with colchicine and aspirin. Chest pain improved within a few days with no hemodynamic instability. The patients were discharged with no sequelae. CONCLUSIONS: ST changes on ECG and elevated troponin I levels may aid the diagnosis of myocarditis after mRNA COVID-19 vaccination.

Patients with post-COVID-19 vaccination facial palsy: To boost or not to boost? A possible association between Bell's palsy and COVID-19 vaccination has been suggested. While it is likely that COVID-19 vaccine recipients from the general population do have a slightly increased risk of developing Bell's palsy, there are little data regarding this risk in individuals with a history of disease.

Gaining a better understanding of this association is particularly important for informing evidence-based recommendations regarding future booster shots in subjects who developed Bell's palsy as a side effect of vaccination, or as a result of SARS-CoV-2 infection. We previously described the first case of COVID-19 vaccine-related Bell's palsy; here we report an 18-month clinical and electromyographic follow-up and discuss the implications of receiving further vaccine doses in patients with positive disease history.

Acute Macular Neuroretinopathy Following COVID-19 mRNA Vaccination. A 21-year-old female developed bilateral acute-onset paracentral scotomas three days after receiving the second dose of her Moderna COVID-19 vaccination. A clinical diagnosis of acute macular neuroretinopathy (AMN) was confirmed after classic findings were demonstrated on near-infrared reflectance imaging, spectral-domain optical coherence tomography, and colored fundus photography. The patient presented with visual acuity of 20/100-1 OD and 20/20 OS. After treatment with brimonidine and difluprednate, at a two-week follow-up, her visual acuity was 20/100-2 OD and 20/25-2 OS. There have been reported cases of AMN following flu-like illnesses as well as after receiving vaccines. However, this is the first report of AMN following vaccination with a Moderna COVID-19 vaccine.

Hypertensive emergency and intracranial bleed following vaccination against SARS-COV-2 virus.

Prevalence, severity, and risk factor of breakthrough infection after vaccination with either the Covaxin or the Covishield among healthcare workers: A nationwide cross-sectional study. BACKGROUND AND AIMS: The coronavirus disease-2019 (COVID-19) pandemic has grappled the entire globe since the beginning of 2020. In India, two vaccines were released in January 2021, the CovaxinÂ® and the Covishieldâ„¢. However, despite vaccination, many breakthrough infections were reported during the second wave in India. The present cross-sectional study aimed to find out prevalence, severity, and associated risk factors of breakthrough infection among healthcare workers (HCWs) vaccinated against COVID-19. MATERIAL AND METHODS: After ethical approval and CTRI registration, a validated questionnaire was circulated as Google form-based survey to HCWs across the nation through e-mail over 3 weeks. Biweekly reminders were sent to nonresponders till the desired sample size was attained, after which the survey was closed, and responses were charted. Data obtained from the responses were collated and analyzed. RESULTS: A total of 1096 HCWs responded to the survey (54.8% response rate) and 23.36% had breakthrough infection. The severity of infection was more in the 30-50 years age group (P = 0.0170) and doctors belonging to clinical branches (P = 0.0005). The point estimate for effectiveness in preventing infection was significantly better with Covishieldâ„¢ (78.5% vs. 72.4%) (P = 0.0260). Nearly all those who were infected after vaccination thought that vaccination decreased disease severity. CONCLUSION: Breakthrough COVID-19 infection still occurred after vaccination though the prevalence of severe infection was low. Covishieldâ„¢ performed significantly better than CovaxinÂ® in terms of preventing the disease. Clinical branches of medicine were found at a higher risk and younger HCWs or those with comorbidities had a higher severity of the disease.

Humoral response to SARS-CoV-2 mRNA vaccination in previous non-responder kidney transplant recipients after short-term withdrawal of mycophenolic acid. Seroconversion rates after COVID-19 vaccination are significantly lower in kidney transplant recipients compared to healthy cohorts. Adaptive immunization strategies are needed to protect these patients from COVID-19. In this prospective observational cohort study, we enrolled 76 kidney transplant recipients with no seroresponse after at least three COVID-19 vaccinations to receive an additional mRNA-1273 vaccination (full dose, 100 Î¼g). Mycophenolic acid was withdrawn in 43 selected patients 5-7 days prior to vaccination and remained paused for 4 additional weeks after vaccination. SARS-CoV-2-specific antibodies and neutralization of the delta and omicron variants were determined using a live-virus assay 4 weeks after vaccination. In patients with temporary mycophenolic acid withdrawal,

donor-specific anti-HLA antibodies and donor-derived cell-free DNA were monitored before withdrawal and at follow-up. SARS-CoV-2 specific antibodies significantly increased in kidney transplant recipients after additional COVID-19 vaccination. The effect was most pronounced in individuals in whom mycophenolic acid was withdrawn during vaccination. Higher SARS-CoV-2 specific antibody titers were associated with better neutralization of SARS-CoV-2 delta and omicron variants. In patients with short-term withdrawal of mycophenolic acid, graft function and donor-derived cell-free DNA remained stable. No acute rejection episode occurred during short-term follow-up. However, resurgence of prior anti-HLA donor-specific antibodies was detected in 7 patients.
Adverse events associated with Covishield vaccination among healthcare workers in a tertiary hospital in South India. BACKGROUND: Vaccination is the most important prophylactic measure taken to curb COVID-19 pandemics. This study was undertaken to throw light on the safety of Covishield vaccine among health care workers (HCWs) and to assess the co-variates associated with incidence of adverse events. METHODS: This prospective observational study was conducted in a tertiary care center in South India as part of the HCW vaccination drive. All consenting HCWs who received the first dose of Covishield vaccine and developed ADRs were included in this study. After vaccination, all beneficiaries were monitored for AEFI for a period of half an hour and later followed up through telephone and google survey forms on day 2 and day 7 of vaccination. The data was subsequently collated into spreadsheet format and analyzed. RESULTS: The study included 1264 consenting healthcare workers who were predominantly youth, aged 15-24Â years (nÂ =Â 583, 46Â %) and with a female preponderance of 76Â % (nÂ =Â 960). Past history of COVID-19 infections was reported among 4.6Â % (58) of the study population. Postvaccination symptoms were majorly reported during the first (40Â %) and second day (44Â %) after vaccination with a high prevalence of both local (nÂ =Â 1083, 85Â %) and systemic symptoms (nÂ =Â 1065, 84Â %). The mean duration of symptoms was observed to be 1.4Â Â±Â 0.81Â days post vaccination. Symptoms were observed significantly high among females (76.7Â %, pÂ =Â 0.013). The prevalence of systemic (88Â % vs 80Â %) (pÂ <Â 0.001) and allergic symptoms (7Â % vs 3Â %; pÂ =Â 0.03) were observed to be significantly high among respondents with <25Â years of age. The systemic and allergic symptoms following vaccination were reported to be low among healthcare workers who had a previous history of COVID-19 infection. CONCLUSION: COVID vaccination has been observed to be safe and well tolerated with more systemic symptoms reported among younger age group and females.
Cross-sectional analysis of the humoral response after SARS-CoV-2 vaccination in Sardinian multiple sclerosis patients, a follow-up study. Monitoring immune responses to SARS-CoV-2 vaccination and its clinical efficacy over time in Multiple Sclerosis (MS) patients treated with disease-modifying therapies (DMTs) help to establish the optimal strategies to ensure adequate COVID-19 protection without compromising disease control offered by DMTs. Following our previous observations on the humoral response one month after two doses of BNT162b2 vaccine (T1) in MS patients differently treated, here we present a cross-sectional and longitudinal follow-up analysis six months following vaccination (T2, n=662) and one month following the first booster (T3, n=185). Consistent with results at T1, humoral responses were decreased in MS patients treated with fingolimod and anti-CD20 therapies compared with untreated patients also at the time points considered here (T2 and T3). Interestingly, a strong upregulation one month after the booster was observed in patients under every DMTs analyzed, including those treated with fingolimod and anti-CD20 therapies. Although patients taking these latter therapies had a higher rate of COVID-19 infection five months after the first booster, only mild symptoms that did not require hospitalization were reported for all the DMTs analyzed here. Based on these findings we anticipate that additional vaccine booster shots will likely further improve immune responses and COVID-19 protection in MS patients treated with any DMT.

Cellular and humoral immune responses and breakthrough infections after three SARS-CoV-2 mRNA vaccine doses. BACKGROUND: SARS-CoV-2 vaccination has proven the most effective measure to control the COVID-19 pandemic. Booster doses are being administered with limited knowledge on their need and effect on immunity. OBJECTIVE: To determine the duration of specific T cells, antibodies and neutralization after 2-dose vaccination, to assess the effect of a third dose on adaptive immunity and to explore correlates of protection against breakthrough infection. METHODS: 12-month longitudinal assessment of SARS-CoV-2-specific T cells, IgG and neutralizing antibodies triggered by 2 BNT162b2 doses followed by a third mRNA-1273 dose in a cohort of 77 healthcare workers: 17 with SARS-CoV-2 infection prior to vaccination (recovered) and 60 naÃ¯ve. RESULTS: Peak levels of cellular and humoral response were achieved 2 weeks after the second dose. Antibodies declined thereafter while T cells reached a plateau 3 months after vaccination. The decline in neutralization was specially marked in naÃ¯ve individuals and it was this group who benefited most from the third dose, which resulted in a 20.9-fold increase in neutralization. Overall, recovered individuals maintained higher levels of T cells, antibodies and neutralization 1 to 6 months post-vaccination than naÃ¯ve. Seventeen asymptomatic or mild SARS-CoV-2 breakthrough infections were reported during follow-up, only in naÃ¯ve individuals. This viral exposure boosted adaptive immunity. High peak levels of T cells and neutralizing antibodies 15 days post-vaccination associated with protection from breakthrough infections. CONCLUSION: Booster vaccination in naÃ¯ve individuals and the inclusion of viral antigens other than spike in future vaccine formulations could be useful strategies to prevent SARS-CoV-2 breakthrough infections.

Does SARS-CoV2 vaccine exposure trigger acute-onset polyradiculopathy characterized by more common facial paralysis?

Curbing the Delta Surge: Clinical Outcomes After Treatment With Bamlanivimab-Etesevimab, Casirivimab-Imdevimab, or Sotrovimab for Mild to Moderate Coronavirus Disease 2019. OBJECTIVE: To describe and compare the clinical outcomes of bamlanivimab-etesevimab, casirivimab-imdevimab, and sotrovimab treatment of mild to moderate coronavirus disease 2019 (COVID-19) during the severe acute respiratory coronavirus 2 (SARS-CoV-2) B.1.617.2 Delta surge. METHODS: This is a retrospective study of high-risk patients who received bamlanivimab-etesevimab, casirivimab-imdevimab, and sotrovimab for mild to moderate COVID-19 between August 1, 2021, and December 1, 2021. Rates of severe disease, hospitalization, intensive care unit admission, and death were assessed. RESULTS: Among 10,775 high-risk patients who received bamlanivimab-etesevimab, casirivimab-imdevimab, or sotrovimab for mild to moderate COVID-19 during the Delta surge, 287 patients (2.7%) developed severe disease that led to hospitalization, oxygen supplementation, or death within 30 days after treatment. The rates of severe disease were low among patients treated with bamlanivimab-etesevimab (1.2%), casirivimab-imdevimab (2.9%), and sotrovimab (1.6%; P<.01). The higher rate of severe outcomes among patients treated with casirivimab-imdevimab may be related to a significantly lower COVID-19 vaccination rate in that cohort. Intensive care unit admission was comparable among patients treated bamlanivimab-etesevimab, casirivimab-imdevimab, or sotrovimab (1.0%, 1.0%, and 0.4%, respectively). CONCLUSION: This real-world study of a large cohort of high-risk patients shows low rates of severe disease, hospitalization, intensive care unit admission, and mortality after treatment with bamlanivimab-etesevimab, casirivimab-imdevimab, and sotrovimab for mild to moderate COVID-19 during the SARS-CoV-2 Delta surge.

Humoral and Cellular Immune Response to Covid-19 Vaccination in Patients with Chronic Graft-versus-Host Disease on Immunosuppression. Chronic graft-versus-host disease (cGVHD) and its management with immunosuppressive therapies increase the susceptibility to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, as well as progression to severe Coronavirus 19 disease (COVID-19). Vaccination against COVID-19 is strongly recommended, but

efficacy data are limited in this patient population. In this study, responses to COVID-19 vaccination were measured at 3 time points-after the initial vaccine series, before the third dose, and after the third dose-in adults with cGVHD receiving immunosuppressive therapy. Humoral response was measured by quantitative anti-spike antibody and neutralizing antibody levels. Anti-nucleocapsid antibody levels were measured to detect natural infection. T cell response was evaluated by a novel immunosequencing technique combined with immune repertoire profiling from cryopreserved peripheral blood mononuclear cell samples. Present or absent T cell responses were determined by the relative proportion of unique SARS-CoV-2-associated T cell receptor sequences ("breadth") plus clonal expansion of the response ("depth") compared with those in a reference population. Based on both neutralizing antibody and T cell responses, patients were categorized as vaccine responders (both detected), nonresponders (neither detected), or mixed (one but not both detected). Thirty-two patients were enrolled for the initial series, including 17 (53%) positive responders, 7 (22%) mixed responders, and 8 (25%) nonresponders. All but one patient categorized as mixed responders had humoral responses while lacking T cell responses. No statistical differences were observed in patient characteristics among the 3 groups of patients categorized by immune response, although sample sizes were limited. Significant positive correlations were observed between the robustness of cellular and humoral responses after the initial series. Among the 20 patients with paired samples (pre- and post-third dose), a third vaccination resulted in increased neutralizing antibody titers. cGVHD worsened in 10 patients (26%; 6 after the initial series and 4 after the third dose), necessitating escalation of immunosuppressive doses in 5 patients, although 4 had been tapering immunosuppression and 5 had already worsening cGVHD at the time of vaccination, and a clear association between COVID-19 vaccination and cGVHD could not be drawn. Among the patients with cGVHD on immunosuppressive therapy, 72% demonstrated a neutralizing antibody response after a 2-dose primary COVID-19 vaccination, two-thirds of whom also developed a T cell response; 25% had neither a humoral nor a T cell response. A third dose further amplified the antibody response.

Erythema multiforme following vaccination for SARS-CoV-2: Report of a case and review of the literature - Secondary Publication.

Severe acute respiratory syndrome coronavirus 2 spike antibody level decline is more pronounced after the second vaccination, but response to the third vaccination is similar in people with type 1 and type 2 diabetes compared with healthy controls: The prospective COVAC-DM cohort study.

Case reports of management of aplastic anemia after COVID-19 vaccination: a single institute experience in Taiwan. Global vaccination against the coronavirus disease 2019 (COVID-19) is thought to be the most effective way to end or at least contain the COVID-19 pandemic. However, despite the good safety profiles and effectiveness of the available COVID-19 vaccines, rare but serious hematological complications have emerged, including thromboembolic outcomes with thrombocytopenia following the ChAdOx1 nCoV-19 (Oxford-AstraZeneca) and Ad26.COV.2.S (Johnson & Johnson/Janssen) vaccines. Moreover, COVID-19 vaccination may be linked to the development of aplastic anemia (AA). We discuss four cases of AA that arose after COVID-19 vaccination in our hospital and two other such cases identified in our literature review.

Measuring concerns about the COVID-19 vaccine among Japanese internet users through search queries. With the increasing availability of the COVID-19 vaccines, vaccination has been rapidly promoted globally as a countermeasure against the spread of COVID-19. In Japan, vaccination was first introduced in February 2021. However, the amount of concern towards vaccination differs between individuals, and topics of concern include adverse reactions and side effects. This study investigated attitudes toward vaccines or vaccination during the COVID-19 pandemic across different Japanese prefectures, using Yahoo! JAPAN search queries. We first defined a vaccine concern index (VCI) by aggregating the search counts of vaccine-related queries from Yahoo! JAPAN users before

examining VCI across all Japanese prefectures, accounting for gender and age. Our results demonstrated that VCI tended to be lower in more populated areas, and VCI was higher in their 20s to 40s than older people, especially in female users. Furthermore, there was a significant positive correlation (Spearman's Rank correlation coefficient [Formula: see text] = 0.60, [Formula: see text]) between VCI and prefectural vaccination rate, suggesting that web searching of adverse vaccine reactions may precede actual vaccination. This could reflect the information-seeking behavior of individuals who are accepting of vaccinations.

Incidence of COVID-19 after vaccination in people with multiple sclerosis in Argentina: Data from the nationwide registry RelevarEM. The objective of the study was to evaluate the incidence of COVID-19 after complete vaccination in people with multiple sclerosis (PwMS) included in the Argentinean MS and NMOSD registry (RelevarEM, NCT03375177). METHODS: cohort study conducted between May 2021 and December 2021. The primary outcome was the appearance of infection during the follow-up time (at least three months after complete vaccination (second dose)). Data was collected through the contact between the treating physician and the patient. Specific information was requested (date, symptoms, need for hospitalization, ventilatory assistance, treatment, and evolution). The contact was made every 30 days during the period of 3 months after the full dose vaccination. A positive COVID-19 case was defined according to the definition established by the Ministry of Health in Argentina. Cumulative incidence was reported by Kaplan Meier survival curves as well as incidence density. RESULTS: A total of 576 PwMS were included, mean age 45.2Â Â±Â 13 years, 432 (75%) RRMS, 403 (70%) were female. The mean and median time of follow-up after the second dose was 91Â Â±Â 17 and 94Â Â±Â 21 days respectively. Most frequent first and second dose received was Astra-Zeneca vaccine, followed by Sputnik V vaccine. During follow-up a total of twenty COVID-19 cases were observed for a total exposure time of 39,557 days. The overall cumulative incidence for the observed period was 3.4% (SE 0.4%) with an overall incidence density of 5Â Ã—Â 10.000 patients/day (95%CI 0.7-12). We observed more cases in woman than men with an incidence density of 6Â Ã—Â 10.000 patients/day (95%CI 0.9-9) vs. 3Â Ã—Â 10.000 patients/day (95%CI 0.2-6) respectively, but not significantly different (IRR 1.7 95% CI 0.56-7.37 pÂ =Â 0.15). CONCLUSION: we found an incidence density of breakthrough COVID-19 infection of 5Â Ã—Â 10.000 patients/day (95%CI 0.7-12) after vaccination in Argentina.

Correction to: Assessing Case Fatality on Cases of Thrombosis with Concurrent Thrombocytopenia Following COVID-19 Vaccine AstraZeneca (Vaxzevria) in the United Kingdom: A Review of Spontaneously Reported Data.

Semi-selective plasma filtration applied to the treatment of acquired thrombotic thrombocytopenic purpura following bnt162b2 administration. Following the widespread use of anti SARS-CoV-2 vaccines, there have been reports of thrombocytopenia developing after the administration ofÂ different types of vaccine. We report a case of a 63-year-old male who developed neurological symptoms after receiving the second dose of the bnt162b2 vaccine. Blood tests performed upon admission to the Emergency Department revealed severe thrombocytopenia and microangiopathic hemolytic anemia. ADAMTS13 activity wasÂ undetectable and antibody titer was high. Due to the rapid neurological deterioration, steroid therapy with prednisone was started at an initial dose of 1Â mg/kg/day. Rituximab therapy was started to prevent the formation of new antibodies. Given the slow response to this therapy, we added Caplacizumab, (aÂ monoclonal antibody anti-Von Willebrand factor) in order to inhibit platelet hyperaggregation, combined with standard plasma exchange. The patient experienced repeated episodes of intolerance to fresh frozen plasma (FFP). Switching fromÂ plasma exchange toÂ plasma filtration, remission was attainedÂ in this unusual case of vaccine-related thrombocytopenia with microangiopathic hemolytic anemia.

Vestibular syndromes after COVID-19 vaccination: A prospective cohort study. BACKGROUND AND PURPOSE: Dizziness and vertigo are common symptoms after COVID-19-vaccination. We aimed to prospectively evaluate objective central or peripheral vestibular function in patients with dizziness, vertigo, and postural symptoms that started or worsened after COVID-19-vaccination. METHODS: Of 4137 patients who presented between January 2021 and April 2022 at the German Center for Vertigo and Balance Disorders, Ludwig Maximilian University of Munich, we identified 72 patients (mean ageÂ =Â 47â€‰years) with enduring vestibular symptoms following COVID-19 vaccination. All underwent medical history-taking, and neurological and neuro-otological workup with bithermal caloric test, video head-impulse test, orthoptics, and audiometry. Diagnoses were based on international criteria. The distribution of diagnoses was compared to a cohort of 39,964 patients seen before the COVID-19 pandemic. RESULTS: Symptom onset was within the first 4â€‰weeks postvaccination. The most prevalent diagnoses were somatoform vestibular disorders (34.7%), vestibular migraine (19.4%), and overlap syndromes of both (18.1%). These disorders were significantly overrepresented compared to the prepandemic control cohort. Thirty-six percent of patients with somatoform complaints reported a positive history of depressive or anxiety disorders. Nine patients presented with benign paroxysmal positional vertigo, three with acute unilateral vestibulopathy, and seven with different entities (vestibular paroxysmia, MÃ©niÃ¨re disease, polyneuropathy, ocular muscular paresis). Causally related central vestibular deficits were lacking. Novel peripheral vestibular deficits were found in four patients. CONCLUSIONS: Newly induced persistent vestibular deficits following COVID-19 vaccination were rare. The predominant causes of prolonged vestibular complaints were somatoform vestibular disorders and vestibular migraine, possibly triggered or aggravated by stress-related circumstances due to the COVID-19 pandemic or vaccination. An increase of other central or peripheral vestibular syndromes after COVID-19 vaccination was not observed.

COVID-19 Mass Vaccination and Flu Season: Concern for Decreased Public Health Measures and Worsening the Influenza Situation. Reports show that other ordinary childhood infections like measles or influenza are likely to reemerge. The re-emergence of infectious diseases may happen due to the direct impact of the pandemic on the community because of decreased access to health and medical services, interrupted transport systems, weaknesses in the supply chain, flight restrictions, closings of the border, and international trade problems. The most prevalent cause (60.9%) for low vaccine uptake and coverage during the current pandemic was fear of exposure to the COVID-19 virus outside the home. The expectation and hope that the pattern of reduction in transmission and number of influenza cases will continue over the next flu season depend on continued adherence to nonpharmaceutical interventions and their long-term application. But there is always the fear and threat of increasing the spread of influenza by reducing the movement restrictions and low adherence to protective health measures due to vaccination. So far, not much information has been published about the interaction between different infectious diseases in the background of the coronavirus pandemic and related interventions. The purpose of this article is to examine the general effects of the COVID-19 vaccination on the spread of influenza in the coming seasons.

Henoch-SchÃ¶nlein purpura following COVID-19 vaccine in a child: a case report. BACKGROUND: Henoch-SchÃ¶nlein purpura (HSP) is an IgA-mediated small vessel vasculitis, typical of childhood. It's a self-limiting disease and it affects different systems. HSP is characterized by dermatological, abdominal, joint and renal clinical manifestations. This condition usually occurs upon infections, mainly upper respiratory tract ones, medications, vaccinations and malignancies. CASE PRESENTATION: We describe the case of a 11Â year-old girl who developed a urticarial rash 12Â days after the first dose of Pfizer-BioNTech BNT16B2b2 mRNA vaccine and a clear picture of Henoch SchÃ¶nlein purpura 5Â days after administration of the second dose of the same vaccine.

CONCLUSION: To our knowledge, this is the first description of a pediatric patient with Henoch-SchÃ¶nlein purpura occurring in association with vaccination against COVID-19.

Spike-based adenovirus vectored COVID-19 vaccine does not aggravate heart damage after ischemic injury in mice. An unprecedented number of COVID-19 vaccination campaign are under way worldwide. The spike protein of SARS-CoV-2, which majorly binds to the host receptor angiotensin converting enzyme 2 (ACE2) for cell entry, is used by most of the vaccine as antigen. ACE2 is highly expressed in the heart and has been reported to be protective in multiple organs. Interaction of spike with ACE2 is known to reduce ACE2 expression and affect ACE2-mediated signal transduction. However, whether a spike-encoding vaccine will aggravate myocardial damage after a heart attack via affecting ACE2 remains unclear. Here, we demonstrate that cardiac ACE2 is up-regulated and protective after myocardial ischemia/reperfusion (I/R). Infecting human cardiac cells or engineered heart tissues with a spike-based adenovirus type-5 vectored COVID-19 vaccine (AdSpike) does not affect their survival and function, whether subjected to hypoxia-reoxygenation injury or not. Furthermore, AdSpike vaccination does not aggravate heart damage in wild-type or humanized ACE2 mice after I/R injury, even at a dose that is ten-fold higher as used in human. This study represents the first systematic evaluation of the safety of a leading COVID-19 vaccine under a disease context and may provide important information to ensure maximal protection from COVID-19 in patients with or at risk of heart diseases.

Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. INTRODUCTION: In 2020, prior to COVID-19 vaccine rollout, the Brighton Collaboration created a priority list, endorsed by the World Health Organization, of potential adverse events relevant to COVID-19 vaccines. We adapted the Brighton Collaboration list to evaluate serious adverse events of special interest observed in mRNA COVID-19 vaccine trials. METHODS: Secondary analysis of serious adverse events reported in the placebo-controlled, phase III randomized clinical trials of Pfizer and Moderna mRNA COVID-19 vaccines in adults (NCT04368728 and NCT04470427), focusing analysis on Brighton Collaboration adverse events of special interest. RESULTS: Pfizer and Moderna mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events of special interest of 10.1 and 15.1 per 10,000 vaccinated over placebo baselines of 17.6 and 42.2 (95Â % CI -0.4 to 20.6 and -3.6 to 33.8), respectively. Combined, the mRNA vaccines were associated with an excess risk of serious adverse events of special interest of 12.5 per 10,000 vaccinated (95Â % CI 2.1 to 22.9); risk ratio 1.43 (95Â % CI 1.07 to 1.92). The Pfizer trial exhibited a 36Â % higher risk of serious adverse events in the vaccine group; risk difference 18.0 per 10,000 vaccinated (95Â % CI 1.2 to 34.9); risk ratio 1.36 (95Â % CI 1.02 to 1.83). The Moderna trial exhibited a 6Â % higher risk of serious adverse events in the vaccine group: risk difference 7.1 per 10,000 (95Â % CI -23.2 to 37.4); risk ratio 1.06 (95Â % CI 0.84 to 1.33). Combined, there was a 16Â % higher risk of serious adverse events in mRNA vaccine recipients: risk difference 13.2 (95Â % CI -3.2 to 29.6); risk ratio 1.16 (95Â % CI 0.97 to 1.39). DISCUSSION: The excess risk of serious adverse events found in our study points to the need for formal harm-benefit analyses, particularly those that are stratified according to risk of serious COVID-19 outcomes. These analyses will require public release of participant level datasets.

Safety of the Fiocruz ChAdOx COVID-19 vaccine used in a mass vaccination campaign in Botucatu, Brazil. INTRODUCTION: Brazil has been at the core of the COVID-19 pandemic, with the second-highest death toll worldwide. A mass vaccination campaign was initiated on May 16th, 2021, in Botucatu, Brazil, where two doses of ChadOx1-nCoV19 were offered 12Â weeks apart to all 18-60-year-olds. This context offers a unique opportunity to study the vaccine safety during a mass campaign. METHODS: The first and second doses of the vaccine were administered in May and August 2021, respectively. Emergency room (ER) and hospitalization records were obtained from the Hospital das ClÃ-nicas da Faculdade de Medicina de Botucatu for six weeks before and six weeks after

the first and second doses, from 4 April to 19 September 2021. Diagnoses with COVID-19-related ICD codes were excluded to distinguish any trends resulting from the COVID-19 pandemic. ER and hospital visits during the two time periods were compared, including an ICD code comparison, to identify any changes in disease distributions. Data were scanned for a defined list of Adverse Events of Special Interest (AESIs), as presented by the Safety Platform for Emergency Vaccines. RESULTS AND DISCUSSION: A total of 77,683 and 74,051 subjects received dose 1 and dose 2 of ChadOx1-nCoV19, respectively. Vaccination was well tolerated and not associated with any major safety concerns. Increases in ER visits 1Â week following both doses were primarily seen in ICD codes related to non-serious side effects of the vaccine, including vaccination site pain and other local events. The neurological AESIs identified (2 of 3 cases of multiple sclerosis) were relapses of a pre-existing condition. One potentially serious hospitalization event for Bell's palsy had onset before vaccination with dose 1, in a patient who also had a viral infection of the central nervous system. There was no myocarditis, pericarditis cases, or vaccine-related increases in thromboembolic events.

No significant increase in Guillain-BarrÃ© syndrome after COVID-19 vaccination in adults: A vaccine adverse event reporting system study. OBJECTIVE: To investigate the association between Guillain-BarrÃ© syndrome (GBS) and COVID-19 vaccination. BACKGROUND: On July 13, 2021, the US Food and Drug Administration (FDA) released a new warning that Johnson & Johnson COVID-19 vaccine could increase the risk of developing GBS. METHODS: The reporting rate of adult GBS after COVID-19 vaccination, ascertained with Brighton criteria, was compared with the reporting rate after other vaccinations during the same time period, and also compared with the reporting rate during control periods. Statistical methods such as proportion tests, and Pearson's chi-squared test were utilized to identify significant relationships. Self-controlled and case centered analyses were conducted. A machine learning model was utilized to identify the factors associated with a worse outcome defined as emergency room (ER) or doctor visits, hospitalizations, and deaths. RESULTS: The reporting rate of GBS after COVID-19 vaccination was significantly higher than after influenza and other vaccinations (49.7, 0.19, 0.16 per 10 million, pÂ <Â 0.0001). However, the reporting rate was within the incidence range of GBS in the general population. Using self-controlled and case centered analyses, there was a significant difference in the reporting rate of GBS after COVID-19 vaccination between the risk period and control period (pÂ <Â 0.0001). There was an estimated 0.7-1.7 per million excess reports of GBS within 6Â weeks of COVID-19 vaccination. Machine learning model demonstrated that female gender and age between 18 and 44 are associated with worse outcome. No association was found between the onset interval of GBS and its prognosis. CONCLUSIONS: Although the reporting rate of GBS after COVID-19 vaccination was not statistically different than that of the general population, the increased reporting of GBS within the first 6Â weeks after COVID-19 vaccination, more so than with other vaccinations, suggests that some cases of GBS are temporally associated with COVID-19 vaccination. However, there is a reduction in the reporting rate of GBS after other vaccines, compared to reporting rates pre-COVID-19, highlighting limitations inherent in any passive surveillance system. These findings warrant continuous analysis of GBS after COVID-19 vaccination. Further improvement of the machine learning model is needed for clinical use.

Vaccine-Associated Uveitis after COVID-19 Vaccination: Vaccine Adverse Event Reporting System Database Analysis. PURPOSE: To assess the risk of vaccine-associated uveitis (VAU) after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination and evaluate uveitis onset interval and clinical presentations in the patients. DESIGN: A retrospective study from December 11, 2020, to May 9, 2022, using the Centers for Disease Control and Prevention Vaccine Adverse Event Reporting System. PARTICIPANTS: Patients diagnosed with VAU after administration of BNT162b2 (Pfizer-BioNTech, Pfizer Inc/BioNTech SE), mRNA-1273 (Moderna, Moderna Therapeutics Inc), and Ad26.COV2.S (Janssen, Janssen Pharmaceuticals) vaccine worldwide. METHODS: A descriptive

analysis of the demographics, clinical history, and presentation was performed. We evaluated the correlation among the 3 vaccines and continuous and categorical variables. A post hoc analysis was performed between uveitis onset interval after vaccination and age, dose, and vaccine type. Finally, a 30-day risk analysis for VAU onset postvaccination was performed. MAIN OUTCOME MEASURES: The estimated global crude reporting rate, observed to expected ratio of VAU in the United States, associated ocular and systemic presentations, and onset duration. RESULTS: A total of 1094 cases of VAU were reported from 40 countries with an estimated crude reporting rate (per million doses) of 0.57, 0.44, and 0.35 for BNT162b2, mRNA-1273, and Ad26.COV2.S, respectively. The observed to expected ratio of VAU was comparable for BNT162b2 (0.023), mRNA-1273 (0.025), and Ad26.COV2.S (0.027). Most cases of VAU were reported in patients who received BNT162b2 (nÂ = 853, 77.97%). The mean age of patients with VAU was 46.24 Â± 16.93 years, and 68.65% (nÂ = 751) were women. Most cases were reported after the first dose (nÂ = 452, 41.32%) and within the first week (nÂ = 591, 54.02%) of the vaccination. The onset interval for VAU was significantly longer in patients who received mRNA-1273 (21.22 Â± 42.74 days) compared with BNT162b2 (11.42 Â± 23.16 days) and rAd26.COV2.S (12.69 Â± 16.02 days) vaccines (P < 0.0001). The post hoc analysis revealed a significantly shorter interval of onset for the BNT162b2 compared with the mRNA 1273 vaccine (P < 0.0001). The 30-day risk analysis showed a significant difference among the 3 vaccines (P < 0.0001). CONCLUSIONS: The low crude reporting rate and observed to expected ratio suggest a low safety concern for VAU. This study provides insights into a possible temporal association between reported VAU events and SARS-CoV-2 vaccines; however, further investigations are required to delineate the associated immunological mechanisms.

Investigating a Signal of Acquired Hemophilia Associated with COVID-19 Vaccination: A Systematic Case Review. Acquired hemophilia A (AHA), a rare but life-threatening disorder, most commonly occurs in older people and during pregnancy. During the coronavirus disease 2019 (COVID-19) vaccination campaign, an unexpected number of newly diagnosed AHA patients have been identified in clinical practice that were temporally related to COVID-19 vaccination. We present the result of a signal detection analysis aimed at exploring a possible association between COVID-19 immunization and occurrence of AHA. A disproportionality analysis on the World Health Organization (WHO) database was performed to investigate the presence of a signal of risk for AHA associated with COVID-19 vaccines. Reports of AHA associated with any COVID-19 vaccine included in the WHO database were then integrated with those available on the Food and Drug Administration Vaccine Adverse Events Reporting System and those published in the medical literature. The WHO database included 146 reports of AHA. The information component (IC) was significant for the association of AHA with all COVID-19 vaccines (IC025: 1.1) and with the vaccine product BNT162b2 (IC025: 1.6). After duplicate exclusion, 96 unique cases of AHA following COVID-19 vaccines have been reviewed. Median time to diagnosis was 18 days and 40% of cases documented the occurrence after the second dose. Overall, in 57% of the investigated cases, a preexisting condition predisposing to AHA was excluded. About 22% of cases occurred in subjects with age â‰¤65 years and there was no case associated with pregnancy. Mortality was 11%. Although we cannot exclude that the unexpected frequency of AHA diagnosis can be explained by a detection bias, the signal for COVID-19 vaccine-related AHA is robust and deserves further investigations.

The correlation between COVID-19 vaccination and cardiac surgery: When is safe to vaccinate?

Transverse Myelitis Following SARS-CoV-2 Vaccination: A Pharmacoepidemiological Study in the World Health Organization's Database. BACKGROUND: Transverse myelitis (TM) has recently been associated by health authorities with Ad26.COV2.S (Janssen/Johnson & Johnson), one of the 5 US Food and Drug Administration (FDA) or European Medicines Agency (EMA) labeled severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) vaccines. It is unknown whether a similar

association exists for the other FDA or EMA labeled SARS-CoV-2 vaccines (BNT162b2 [Pfizer/BioNTech], mRNA-1273 [Moderna], ChAdOx1nCov-19 [Oxford-AstraZeneca], and NVX-CoV2373 [Novavax]). This study aimed to evaluate the association between SARS-CoV-2 vaccine class and TM. METHODS: This observational, cross-sectional, pharmacovigilance cohort study examined individual case safety reports from VigiBase, the World Health Organization's pharmacovigilance database. We first conducted a disproportionality analysis with the information component (IC) using the reports of TM that occurred within 28â€‰days following exposure to the FDA or EMA labeled SARS-CoV-2 vaccines, from December 1, 2020 (first adverse event related to a SARS-CoV-2 vaccine) to March 27, 2022. Second, we analyzed the clinical features of SARS-CoV-2 vaccine-associated TM cases reported in VigiBase. RESULTS: TM was significantly associated both with the messenger ribonucleic acid (mRNA)-based (nÂ =Â 364; IC(025) Â =Â 0.62) and vector-based (nÂ =Â 136; IC(025) Â =Â 0.52) SARS-CoV-2 vaccines that are authorized by the FDA or the EMA. CONCLUSIONS: Findings from this observational, cross-sectional pharmacovigilance study showed that mRNA-based and vector-based FDA/EMA labeled SARS-CoV-2 vaccines can be associated with TM. However, because TM remains a rare event, with a previously reported rate of 0.28 cases per 1 million vaccine doses, the risk-benefit ratio in favor of vaccination against SARS-CoV-2 virus remains unchallenged. Rather, this study suggests that clinicians should consider the diagnosis of TM in patients presenting with early signs of spinal cord dysfunction after SARS-CoV-2 vaccination. ANN NEUROL 2022;92:1080-1089.

Efficacy and safety of SARS-CoV-2 vaccination in patients with inflammatory bowel disease on immunosuppressive and biological therapy: Prospective observational study. BACKGROUND AND AIMS: SARS-CoV-2 is a worldwide serious health problem and vaccination seems to have a crucial role in managing the COVID-19 pandemic. The aim of this prospective observational study was to monitor the trend of antibodies against SARS-CoV-2 after vaccination with BNT162b2 (COMIRNATY) in patients with inflammatory bowel disease treated by immunosuppressive and/or biological therapy, demonstrate whether any type of this therapy is associated with poorer production of antibodies against COVID-19 and evaluate the safety of vaccination against COVID-19 in these patients. METHODS: Eighty-seven eligible patients from one tertiary gastroenterological center with inflammatory bowel disease (60 with CD, 27 with UC) treated by immunosuppressive and/or biological therapy from the antiTNFÎ± group were indicated to vaccination against SARS-CoV-2. Effectiveness of vaccination was evaluated by the values of antibodies before and 4 weeks after 2nd dose of vaccine. Additional goal was to evaluate adverse events of vaccination. RESULTS: Before the 2nd dose of vaccine, geometric mean of SARS-CoV-2 IgG antibodies were 40.7 U/ml in the biological therapy group, 34.8 U/ml in the azathioprine group and 44.8 U/ml in the combination therapy group of patients. The geometric means were 676.5.7 U/ml in the biological therapy group, 614.4 U/ml in the azathioprine group and 500.1 U/ml in the combination therapy group of patients four weeks after 2nd dose. Statistically significant differences between these groups were not proved. Several non-severe local and general adverse events were present in our patients with a majority of these events on the day of vaccine administration and the day after, no anaphylactic reactions were present. CONCLUSIONS: Our measurements proved the efficacy and safety of vaccination against SARS-CoV-2 in patients with inflammatory bowel disease treated by immunosuppressive and/or biological therapy. Statistically significant differences between our groups of patients were not proved.

Postvaccinal GABA-B receptor antibody encephalitis after ChAdOx1 nCoV-19 vaccination. Several cases of autoimmune encephalitis have been reported after ChAdOx1 nCoV-19 (AZD1222) vaccination. We encountered a male patient who presented with generalized tonic-clonic seizures, cognitive decline, and gait disturbance that occurred suddenly after the second dose of the ChAdOx1 nCoV-19 vaccine. Clinical presentation and magnetic resonance imaging (MRI) and cerebrospinal fluid (CSF) test results were compatible with limbic encephalitis. Synaptic autoantibody tests confirmed

serum and CSF GABA B receptor antibodies were present. The patient was treated with immunotherapy with intravenous immunoglobulin and rituximab. This GABA-B receptor antibody encephalitis case occurred presumably due to transient autoantibody production following vaccine administration.

COVID-19 infection and vaccination in patients with skeletal muscle channelopathies. INTRODUCTION/AIMS: Although we have gained insight into coronavirus disease-2019 (COVID-19) caused by severe acute respiratory syndrome-coronavirus 2 since the beginning of the pandemic, our understanding of the consequences for patients with neuromuscular disorders is evolving. In this study we aimed to study the impact of COVID-19 and COVID-19 vaccination on skeletal muscle channelopathies. METHODS: We conducted a survey of patients with genetically confirmed skeletal muscle channelopathies seen at the UK Nationally Commissioned Channelopathy Service. RESULTS: Thirty-eight patient responses were received. Six patients had COVID-19 infection leading to exacerbation of their underlying muscle channelopathy. No major complications were reported. Thirty-six patients had received one or two COVID-19 vaccinations and the majority (68%) had no worsening of their underlying channelopathy. Thirty-two percent reported worsening of their usual symptoms of their muscle channelopathy, but all reported recovery to baseline levels. No serious adverse events were reported. DISCUSSION: The overall rates of COVID-19 infection were low in our study and COVID-19 vaccine uptake rates were high. Our results have been useful to inform patients that a subset of patients have reversible worsening of their channelopathy post-COVID-19 vaccination. Our study provides information for giving advice to patients with skeletal muscle channelopathies regarding COVID-19 infection and vaccination.

Acute Idiopathic Maculopathy Following SARS-CoV-2 Vaccination. A 49-year-old man presented with acute unilateral blurred vision one week after SARS-CoV-2 vaccination. A unilateral serous detachment of the macula, intraretinal hemorrhages, vitritis, and anterior chamber cell was found. Diagnostic testing was negative for infectious and inflammatory causes, and a diagnosis of acute idiopathic maculopathy (AIM) was made. Symptoms and serous detachment resolved over 12Â weeks, with residual retinal pigment epithelial changes consistent with the disease course. AIM is a rare diagnosis that presented in close proximity to SARS-CoV-2 vaccination without evidence of coxsackievirus infection. Further research is necessary to clarify an association between this vaccine and uveitis.

Subacute thyroiditis post viral vector vaccine for COVID-19. SUMMARY: Subacute thyroiditis is an inflammatory disorder of the thyroid gland that has previously been described following viral illnesses and occasionally post vaccination such as influenza vaccine. 2021 was a revolutionary year for the development of SARS-CoV-2 vaccinations with multiple different vaccines now available. There are increasing numbers of case reports of thyroiditis following these vaccinations. We report a case of a 50-year-old female who developed subacute thyroiditis 6 days post ChAdOx1 nCoV-19 vaccine (AZD1222 produced by AstraZeneca Vaxzevria). The initial thyrotoxic phase was followed by overt hypothyroidism. This resolved spontaneously within 5 months without levothyroxine replacement. We hope that our case will add to the growing literature of cases of thyroiditis occurring after multiple different types of SARS-CoV-2 vaccination and create awareness of this rare but treatable adverse effect. We also review the literature on the proposed mechanisms behind this adverse effect. LEARNING POINTS: Subacute thyroiditis is an inflammatory disorder of the thyroid gland that can occur after a viral illness or vaccination against certain infections. Subacute thyroiditis is a rare adverse effect that has been reported to occur after different types of SARS-CoV-2 vaccinations. Subacute thyroiditis post vaccination is relatively straightforward to manage, with some patients requiring non-steroidal anti-inflammatory drugs and beta-blockers, while more severe cases may require corticosteroid therapy. This adverse effect should not dissuade vaccination use at a

population level. There are many postulated mechanisms for the development of subacute thyroiditis following vaccination including the presence of the ACE-2 receptor for SARS-CoV-2 on the thyroid gland, an inflammatory/immune response as is seen in COVID-19 infection itself and molecular mimicry between SARS-CoV-2 spike protein and healthy thyroid antigen.
Comment on 'Morphoea following COVID-19 vaccination'.
Surrogate neutralization responses following SARS-CoV-2 vaccination in people with HIV.
De novo podocytopathy following moderna COVID-19 vaccine: A case report and racial disproportionality in adverse effect reports. In this study, we report a case of de novo minimal change disease shortly after the second dose of the Moderna COVID-19 vaccine. A previously healthy 51-year-old Asian man presented with lower-limb edema and foamy urine 3 days after receiving the second dose of the vaccine. Laboratory data revealed the following: serum creatinine, 0.65 mg/dl; serum albumin, 1.3 g/dl; urine protein-to-creatinine ratio, 15.3 g. A renal biopsy was performed, and minimal change in the disease was confirmed. The patient achieved complete remission in the tenth week after starting treatment with prednisolone (1 mg/kg/day). Ethnic differences may influence the adverse effects of drugs and vaccines. However, there is very limited data to address the influence of ethnic diversity on disease prevalence, clinical presentation, and treatment outcomes in COVID-19 vaccine-associated glomerulonephritis.
Transient Pneumonitis as a Possible Adverse Reaction to the BNT162b2 COVID-19 mRNA Vaccine in a Patient with Rheumatoid Arthritis: A Case Report and Review of the Literature. The coronavirus disease (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 has led to rapid progress in vaccine development to prevent the spread of the disease. Although COVID-19 vaccines have excellent effectiveness in reducing morbidity and disease severity with minor adverse reactions, some patients develop late hypersensitivity events as autoimmune reactions such as rheumatoid arthritis, lupus nephritis, and vasculitis following COVID-19 vaccination. Herein, we describe a case of pneumonitis following COVID-19 mRNA vaccination in a patient with rheumatoid arthritis, which resolved spontaneously.
COVID-19 Vaccine-Induced Myocarditis: A Systemic Review and Literature Search. Myocarditis is one of the complications reported with COVID-19 vaccines, particularly both Pfizer-BioNTech and Moderna vaccines. Most of the published data about this association come from case reports and series. Integrating the geographical data, clinical manifestations, and outcomes is therefore important in patients with myocarditis to better understand the disease. A thorough literature search was conducted in Cochrane library, PubMed, ScienceDirect, and Google Scholar for published literature till 30 March 2022. We identified 26 patients eligible from 29 studies; the data were pooled from these qualifying case reports and case series. Around 94% of patients were male in this study, the median age for onset of myocarditis was 22 years and 85% developed symptoms after the second dose. The median time of admission for patients to hospitals post-vaccination was three days and chest pain was the most common presenting symptom in these patients. Most patients had elevated troponin on admission and about 90% of patients had cardiac magnetic resonance imaging (CMR) that showed late gadolinium enhancement. All patients admitted with myocarditis were discharged home after a median stay of four days. Results from this current analysis show that post-mRNA vaccination myocarditis is mainly seen in young males after the second dose of vaccination. The pathophysiology of vaccine-induced myocarditis is not entirely clear and late gadolinium enhancement is a common finding on CMR in these patients that may indicate myocardial fibrosis or necrosis. Prognosis remains good and all patients recovered from myocarditis, however further studies are advisable to assess long-term prognosis of myocarditis.
The Adverse Reactions of Pfizer BioNTech COVID-19 Vaccine Booster Dose are Mild and Similar to the Second Dose Responses: A Retrospective Cross-Sectional Study. BACKGROUND: Like other

vaccines, Pfizer BioNTech's COVID-19 vaccine efficacy against SARS-CoV-2 virus infections begins to decline within a few months after the 2(nd) dose. On August 12, 2021, the FDA allowed additional Pfizer BioNTch's COVID-19 vaccine dose (3(rd) or booster dose) for individuals with weakened immunity. This study aimed to evaluate the short-term adverse reactions (ADRs) of the 2(nd) and the 3(rd) doses of the Pfizer BioNTech COVID-19 vaccine. METHODS: Information for this study was collected by Google Form questionnaire (online survey). The results included responses from 442 people, the majority from Saudi Arabia. RESULTS: The most common local ADRs following the 3(rd) dose were injection site pain, injection site hypersensitivity, and axillary lymph node swelling. The most common systemic ADRs were fatigue, muscle pain, bone pain, headache, and fever less than 38ÂºC. Less common systemic ADRs were shivering, fever more than 38ÂºC, nasal congestion and rhinorrhea, arrhythmia, cough, abdominal pain, chest tightness, nausea, diarrhea, vomiting, and tachypnea. Rare systemic ADRs were constipation, dizziness and vertigo, lack of concentration, sore throat, excessive hair loss, dysmenorrhea and heavy menstruation, and Bell's palsy. Severe allergic reactions were reported by 2.6% of participants after the 2(nd) dose, compared with none after the 3(rd) dose. Nasal congestion and runny nose are more frequent after the 3(rd) dose. The ADRs of the 2(nd) and 3(rd) doses were significantly more prevalent in females. 12% of participants reported ADRs lasting more than one week after the 3(rd) dose compared to 5% after the 2(nd) dose. People â‰¤ 60 years were more affected by the vaccine ADRs. CONCLUSION: Most of the ADRs reported after the 3(rd) vaccine dose were consistent with the Pfizer vaccine information sheet and similar to the 2(nd) dose ADRs.

Impact of COVID-19 vaccination on the risk of developing long-COVID and on existing long-COVID symptoms: A systematic review. BACKGROUND: Although COVID-19 vaccination decreases the risk of severe illness, it is unclear whether vaccine administration may impact the prevalence of long-COVID. The aim of this systematic review is to investigate the association between COVID-19 vaccination and long-COVID symptomatology. METHODS: MEDLINE, CINAHL, PubMed, EMBASE, and Web of Science databases, as well as medRxiv and bioRxiv preprint servers were searched up to June 20, 2022. Peer-reviewed studies or preprints monitoring multiple symptoms appearing after acute SARS-CoV-2 infection either before or after COVID-19 vaccination collected by personal, telephone or electronic interviews were included. The methodological quality of the studies was assessed using the Newcastle-Ottawa Scale. FINDINGS: From 2584 studies identified, 11 peer-reviewed studies and six preprints were included. The methodological quality of 82% (n=14/17) studies was high. Six studies (n=17,256,654 individuals) investigated the impact of vaccines before acute SARS-CoV-2 infection (vaccine-infection-long-COVID design). Overall, vaccination was associated with reduced risks or odds of long-COVID, with preliminary evidence suggesting that two doses are more effective than one dose. Eleven studies (n=36,736 COVID-19 survivors) investigated changes in long-COVID symptoms after vaccination (infection-long-COVID-vaccine design). Seven articles showed an improvement in long-COVID symptoms at least one dose post-vaccination, while four studies reported no change or worsening in long-COVID symptoms after vaccination. INTERPRETATION: Low level of evidence (grade III, case-controls, cohort studies) suggests that vaccination before SARS-CoV-2 infection could reduce the risk of subsequent long-COVID. The impact of vaccination in people with existing long-COVID symptoms is still controversial, with some data showing changes in symptoms and others did not. These assumptions are limited to those vaccines used in the studies. FUNDING: The LONG-COVID-EXP-CM study supported by a grant of Comunidad de Madrid.

New-onset refractory status epilepticus due to autoimmune encephalitis after vaccination against SARS-CoV-2: First case report. BACKGROUND: Vaccination against SARS-CoV-2 has been conducted frequently to limit the pandemic but may rarely be associated with postvaccinal autoimmune reactions or disorders. CASE PRESENTATION: We present a 35-year-old woman who

developed fever, skin rash, and headache 2 days after the second SARS-CoV-2 vaccination with BNT162b2 (Pfizer/Biontech). Eight days later, she developed behavioral changes and severe recurrent seizures that led to sedation and intubation. Cerebral magnetic resonance imaging showed swelling in the (para-) hippocampal region predominantly on the left hemisphere and bilateral subcortical subinsular FLAIR hyperintensities. Cerebrospinal fluid analysis revealed a lymphocytic pleocytosis of 7 cells/Î¼l and normal protein and immunoglobulin parameters. Common causes of encephalitis or encephalopathy such as viral infections, autoimmune encephalitis with well-characterized autoantibodies, paraneoplastic diseases, and intoxications were ruled out. We made a diagnosis of new-onset refractory status epilepticus (NORSE) due to seronegative autoimmune encephalitis. The neurological deficits improved after combined antiepileptic therapy and immunomodulatory treatment including high-dose methylprednisolone and plasma exchange. CONCLUSIONS: Although a causal relationship cannot be established, the onset of symptoms shortly after receiving the SARS-CoV-2 vaccine suggests a potential association between the vaccination and NORSE due to antibody-negative autoimmune encephalitis. After ruling out other etiologies, early immunomodulatory treatment may be considered in such cases.

Myasthenia Gravis Presenting after Administration of the mRNA-1273 Vaccine. The mRNA-1273 SARS-CoV-2 vaccine received emergency use authorization in December 2021. We present a case of myasthenia gravis (MG) which became clinically apparent following vaccination against SARS-CoV-2. A 30-year-old man developed acute onset diplopia, 2 days after receiving his first mRNA-1273 vaccination against SARS-CoV-2. He reported blurred vision with horizontally displaced images, which worsened with increased eye strain. Diplopia resolved when one eye was covered. He also had fatigable arm weakness, but denied dysphagia, dysarthria, dysphonia or dyspnoea. On examination, he had left-sided ptosis and esotropia at rest which worsened with sustained upward gaze and prolonged focus. He also had fatigable weakness of neck flexion and extension (4+/5), and generalized, fatigable weakness (4/5). His single-breath count was 38. Cranial nerves, sensory examination and deep tendon reflexes were normal. A 2-min ice-pack test and neostigmine test temporarily improved his diplopia and ptosis. The acetylcholine receptor (AChR) antibody was borderline high and muscle-specific tyrosine kinase (MuSK) antibody was negative. Chest CT and brain MRI with contrast were unremarkable. The patient was diagnosed with MG and oral pyridostigmine and prednisone therapy were initiated. We present a case of newly diagnosed MG after administration of mRNA-1273 vaccination against SARS-CoV-2. Although there has been long-standing discussion regarding the potential for vaccines to exacerbate autoimmune conditions, data remain sparse and consensus has not been reached. Consequently, this case is important to make providers aware of potential side effects of a novel vaccine, and may also help guide the selection of vaccination candidates and monitoring parameters. LEARNING POINTS: We present a case of newly diagnosed myasthenia gravis after administration of the mRNA-1273 SARS-CoV-2 vaccine.mRNA-1273 vaccination against SARS-CoV-2 may exacerbate subclinical cases of myasthenia gravis.Recognition of new vaccine side effects may guide the selection of vulnerable patients.

Duration of immunity following full vaccination against SARS-CoV-2: a systematic review. BACKGROUND: As vaccine roll-out continues across the globe as part of the efforts to protect humanity against SARS-CoV-2, concerns are increasingly shifting to the duration of vaccine-induced immunity. Responses to these concerns are critical in determining if, when, and who will need booster doses following full vaccination against SARS-CoV-2. However, synthesised studies about the durability of vaccine-induced immunityÂ against SARS-CoV-2 are scarce. This systematic review synthesised available global evidence on the duration of immunity following full vaccination against SARS-CoV-2. METHODS: We searched through Psych Info, Web of Science, Scopus, Google Scholar, PubMed, and WHO COVID-19 databases for relevant studies published before December 2021. Five

eligibility criteria were used in scrutinising studies for inclusion. The quality of the included studies was assessed based on Joana Briggs Institute's (JBI) Critical Appraisal tool and Cochrane's Risk of Bias tool-version 2 (RoB 2), while the reporting of the results was guided by the Synthesis Without Meta-analysis (SWiM) guidelines. RESULTS: Twenty-seven out of the 666 identified studies met the inclusion criteria. The findings showed that vaccine-induced protection against SARS-CoV-2 infections builds rapidly after the first dose of vaccines and peaks within 4 to 42Â days after the second dose, before waning begins in subsequent months, typically from 3 to 24Â weeks. Vaccine-induced antibody response levels varied across different demographic and population characteristics and were higher in peopleÂ whoÂ reported no underlying health conditions compared to those with immunosuppressed conditions. CONCLUSIONS: Waning of immunityÂ against SARS-CoV-2 begins as early as the first month after full vaccination and this decline continues till the sixth month when the level of immunity may not be able to provide adequate protection against SARS-CoV-2. While the evidence synthesised in this review could effectively inform and shape vaccine policies regarding the administration of booster doses, more evidence, especially clinical trials, are still needed to ascertain, with greater precision, the exact duration of immunity offered by differentÂ vaccine types, across diverse population characteristics, andÂ in different vulnerability parameters. REGISTRATION: The protocol for this review was pre-registered with the International Prospective Register of Systematic Reviews [PROSPERO] (Registration ID: CRD420212818).

Evaluating risk factors associated with COVID-19 infections among vaccinated people early in the U.S. vaccination campaign: an observational study of five states, January-March 2021. BACKGROUND: COVID-19 vaccines are an effective tool to prevent illness due to SARS-CoV-2 infection. However, infection after vaccination still occurs. We evaluated all infections identified among recipients of either the Pfizer-BioNTech or Moderna COVID-19 vaccine in five U.S. states during January-March 2021. METHODS: Using observational data reported to CDC, we compared the incidence of SARS-CoV-2 infection among vaccinated and unvaccinated persons, and the sex, age, and vaccine product received for individuals with vaccine breakthrough infections to those of the vaccinatedÂ population using Poisson regression models. We also compared the proportion of vaccine breakthrough cases due to a SARS-CoV-2 variant of concern to data reported to CDC's national genomic surveillance program. RESULTS: The age-adjusted incidence of reported SARS-CoV-2 infection was 97% lower among vaccinated as compared to unvaccinated persons aged â‰¥â€‰16Â years (68 vs 2252 cases per 100,000 people). Vaccinated adults aged â‰¥â€‰85Â years were 1.6 times (95% CI 1.3-1.9) as likely to become infected with SARS-CoV-2 than vaccinated adults aged <â€‰65Â years. Pfizer-BioNTech COVID-19 vaccine recipients were 1.4 times (95% CI 1.3-1.6) as likely to experience infection compared to Moderna COVID-19 recipients. The proportion of infections among vaccinated persons caused by SARS-CoV-2 variants of concern was similar to the proportion of circulating viruses identified as variants of concern in the five states during the same time. CONCLUSIONS: Vaccinated persons had a substantially lower incidence of SARS-CoV-2 infection compared to unvaccinated persons. Adults aged â‰¥â€‰85Â years and Pfizer-BioNTech vaccine recipients had a higher risk of infection following vaccination. We provide an analytic framework for ongoing evaluation of patterns associated with SARS-CoV-2 infection among vaccinated persons using observational surveillance and immunization data. Our findings reinforce the effectiveness of COVID-19 vaccines in preventing infection in real-world settings.

Immunogenicity and safety of the mRNA-based BNT162b2 vaccine in systemic autoimmune rheumatic diseases patients. BACKGROUND: The COVID-19 outbreak has led to the rapid development and administration of the COVID-19 vaccines worldwide. Data about the immunogenicity and adverse effects of the vaccine on patients with systemic autoimmune rheumatic diseases (SARDs) is emerging. AIM: To evaluate Pfizer/BioNTech (BNT162b2) mRNA-based vaccine

second-dose immunogenicity and safety, and the relation between them, in patients with SARDs. METHODS: A total of one hundred forty tow adults who received two doses of the BNT162b2 vaccine were included in the study. The SARDs group included Ninety-nine patients and the control group (forty-three participants) comprised a mixture of healthy participants and patients who were seen at the rheumatology clinic for non-SARDs. Anti-SARS-CoV-2 IgG antibodies against the Spike protein were evaluated using a SARS-CoV-2 IgG immunoassay. A level ofâ€‰>â€‰150 AU/mL was considered positive. An adverse effects questionnaire was given to the participants upon their first visit to the clinic after their BNT162b2 vaccination. RESULTS: Of the 142 participants, 116 were seropositive (81.7%) and 26 (18.3%) were seronegative. Of the seronegative participants, 96.2% were SARDs patients. The proportion of seropositivity in the SARDs patients treated with any immunosuppressant was significantly lower (69.9%) compared to the control group and SARDs patients not receiving immunosuppressants (96.8%). A significant negative correlation between seronegativity and treatment with rituximab, mycophenolate mofetil (MMF), and prednisone was found in the SARDs group (pâ€‰=â€‰0.004, 0.044, 0.007 respectively). No fever was observed following the BNT162b2 vaccine in seronegative patients, and the frequency of musculoskeletal adverse effects upon the second dose of the BNT162b2 vaccine was significantly higher in seropositive compared to seronegative patients and in the control group compared to the SARDs patients (pâ€‰=â€‰0.045, pâ€‰=â€‰0.02 respectively). CONCLUSION: A decline in the immunogenicity to the second dose of BNT162b2 mRNA is seen in patients with SARDs, especially in patients treated with rituximab, MMF, and prednisone. Adverse effects of the vaccine including fever and musculoskeletal symptoms might be a signal for the acquisition of immunity in those patients. KEY POINTS: â€¢ BNT162b2 mRNA vaccine is less immunogenic in SARDs patients compared to the control group. â€¢ Rituximab, prednisone, and mycophenolate mofetil significantly reduced immunogenicity to the vaccine. â€¢ There is a correlation between immunogenicity and adverse effects of the vaccine.

SARS-CoV-2 vaccination induces mucosal antibody responses in previously infected individuals. Immune responses at the respiratory mucosal interface are critical to prevent respiratory infections but it is unclear to what extent antigen specific mucosal secretory IgA (SIgA) antibodies are induced by mRNA vaccination in humans. Here we analyze paired serum and saliva samples from patients with and without prior coronavirus disease 2019 (COVID-19) at multiple time points pre and post severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccination. Our results suggest mucosal SIgA responses induced by mRNA vaccination are impacted by pre-existing immunity. Indeed, vaccination induced a minimal mucosal SIgA response in individuals without pre-exposure to SARS-CoV-2 while SIgA induction after vaccination was more efficient in patients with a history of COVID-19.

Safety and immunogenicity of MVC-COV1901 vaccine in older adults: Phase 2 randomized dose-comparison trial. INTRODUCTION: Older adults are subject to higher COVID-19 infection and mortality rates. Safety and immunogenicity of MVC-COV1901, a protein subunit vaccine have been demonstrated in phase 2 clinical trial for the general population, and negative correlations have been observed between immune responses and age, however, older adults were under-represented. METHODS: A double-blind, randomized, multi-center study compared safety and immunogenicity of high-dose (25 mcg) to mid-dose (15 mcg) of MVC-COV1901 administered 2 times 28 days apart in 420 participants of 65 years and older. The results have been stratified by the comorbidity status. RESULTS: Both high and mid-dose regimens elicited mostly mild adverse events and robust immune responses when measured as neutralizing and binding antibodies titers. High doses elicited better immune responses in the group without comorbidities. CONCLUSION: Given the general population-associated safety and immunogenicity of MVC-COV1901, we recommend high dose for immunization

of elder adults with MVC-COV1901. The clinical trial was registered at https://clinicaltrials.gov/ (NCT04822025).

Is vaccination against COVID-19 associated with autoimmune rheumatic disease flare? A self-controlled case series analysis. OBJECTIVES: To investigate the association between vaccination against coronavirus disease 2019 (COVID-19) and autoimmune rheumatic disease (AIRD) flare. MATERIAL AND METHODS: Patients with AIRDs vaccinated against COVID-19 who consulted for disease flare between 1 December 2020 and 31 December 2021 were ascertained in Clinical Practice Research Datalink (Aurum). AIRD flare was defined as consultation for AIRD with CS prescription on the same day or the next day. Vaccination was defined using date of vaccination and product code. The observation period was partitioned into vaccine-exposed (21 days after vaccination), pre-vaccination (7 days before vaccination) and remaining vaccine-unexposed periods. Participants contributed data with multiple vaccinations and outcomes. Season adjusted incidence rate ratios (aIRR) and 95% CI were calculated using self-controlled case series analysis. RESULTS: Data for 3554 AIRD cases, 72% female, mean age 65â€‰years and 68.3% with RA, were included. COVID-19 vaccination was associated with significantly fewer AIRD flares in the 21-day vaccine-exposed period when all vaccinations were considered [aIRR (95% CI) 0.89 (0.80, 0.98)]. Using dose-stratified analyses there was a statistically significant negative association in the 21 days after first COVID-19 vaccination but no association after the second or third COVID-19 vaccinations [aIRR (95% CI) 0.76 (0.66, 0.89), 0.94 (0.79, 1.11) and 1.01 (0.85, 1.20), respectively]. On AIRD-type stratified analyses, vaccination was not associated with disease flares. Vaccination without or after severe acute respiratory syndrome coronavirus 2 infection, and with vectored DNA or mRNA vaccines, associated with comparable reduced risk of AIRD flares in the vaccine-exposed period after first COVID-19 vaccination. CONCLUSIONS: Vaccination against COVID-19 was not associated with increased AIRD flares regardless of prior COVID-19, AIRD type, and whether mRNA or DNA vaccination technology were used.

COVID-19 mRNA Vaccine Safety Among Children Aged 6 Months-5 Years - United States, June 18, 2022-August 21, 2022.

Batch-to-batch consistency trial of an adenovirus type-5 vector-based COVID-19 vaccine in adults aged 18 years and above. BACKGROUND: The demonstration of batch-to-batch consistency is indispensable for quality control of vaccines. METHODS: We conducted a randomized, double-blind, parallel-controlled trial to evaluate the immunogenicity consistency of a single shot of Ad5-nCoV in healthy adults who had not previously received any COVID-19 vaccine. All eligible participants were randomly assigned equally to receive one of the three consecutive batches of Ad5-nCoV (5Â Ã— Â 10(10) viral particles/vial, 0.5 mL). The primary endpoint was geometric mean titers (GMTs) of serum SARS-CoV-2 receptor-binding domain (RBD)-specific IgG on day 28 post-vaccination. RESULTS: One thousand fifty participants were enrolled, with 350 (33%) participants per group. On day 28 post-vaccination, GMTs in three groups were 78.3 binding antibody units (BAU)/mL (95% CI 70.3-87.3), 82.9 BAU/mL (73.9-92.9), and 78.8 BAU/mL (70.2-88.4), respectively. The two-sided 95% CIs for the GMT ratios between each pair of batches were all between 0.67 and 1.5. The highest incidence of solicited adverse reactions within 7Â days post-vaccination was reported by batch 3 recipients (23.1% versus 15.1% in batch 1 recipients and 14.6% in bath 2 recipients; p =Â 0.0039). None of the serious adverse events were related to vaccination. CONCLUSIONS: Immunogenicity consistency between consecutive batches of Ad5-nCoV was well established in adults. CLINICAL TRIAL REGISTRATION: This trial was registered with ClinicalTrials.gov (NCT05313646).

New Onset and Exacerbations of Psoriasis Following COVID-19 Vaccines: A Systematic Review. BACKGROUND: Vaccination has been promoted to control viral transmission in response to the coronavirus disease 2019 (COVID-19) pandemic. Cases of new-onset or exacerbation of psoriasis, an

immune-mediated inflammatory disease, were reported following COVID-19 vaccination. However, a comprehensive review examining the association between COVID-19 vaccination and the occurrence or exacerbation of psoriasis has yet to be performed. OBJECTIVE: The aim of this systematic review isÂ to investigate the demographics, clinical variables, and outcomes associated with psoriasis following COVID-19 vaccination. METHODS: A systematic literature search was conducted using the PubMed, Embase, Web of Science, and Cochrane databases from database inception to April 25, 2022. The review included studies with relevant terms, including 'psoriasis,' 'psoriasis vulgaris,' 'guttate psoriasis,' 'pustular psoriasis,' 'palmoplantar pustulosis,' 'psoriatic erythroderma,' 'psoriatic arthritis,' 'COVID-19,' and 'vaccine.' We included all studies reporting at least one patient who developed new-onset psoriasis or experienced a psoriasis flare following at least one dose of any COVID-19 vaccine. A flare was defined as the worsening of disease conditions after vaccinationÂ according to the study by Gregoire et al. The appraisal tool described by Murad et al. was used to assess the quality of case reports and series, whereas the National Institute of Health quality assessment tool was used to assess observational studies. RESULTS: The initial search yielded 367 results, including 7 studies reporting new-onset psoriasis, 32 studies reporting psoriasis flares, and 4 studies reporting both. The most commonly observed psoriasis subtype was plaque-type psoriasis. mRNA vaccines, including those produced by Moderna and BioNTech/Pfizer, were frequently associated with subsequent psoriasis episodes. First, second, and third vaccine doses were associated with psoriasis incidents, with the second dose most frequently associated with psoriasis flares. Delayed onset was observed, ranging from 2 to 21 days in the new-onset group and from 1 to 90 days in the flare group. Most patients experienced favorable outcomes, with improvement or resolution occurring within 3 days to 4 months. CONCLUSIONS: Both new-onset psoriasis and psoriasis flares were reported as cutaneous adverse events following COVID-19 vaccination. Psoriatic patients may require regular follow-up before and after COVID-19 vaccination. TRIAL REGISTRATION: Review registration number PROSPERO database: CRD42022304157.

Failure to seroconvert after three doses of inactivated COVID-19 vaccines in a patient co-infected with HBV and HIV: A case report. In the global context of the COVID-19 pandemic, the overall benefits of getting any COVID-19 vaccine approved by the World Health Organization for emergency use outweigh the potential risks, even in people with weakened immune systems, including people living with HIV (PLWH). At present, there are no reports of HIV/hepatitis B virus (HBV) co-infected patients receiving a booster dose of the inactivated COVID-19 vaccine. Here, we describe a patient with HIV/HBV co-infection who did not seroconvert to three doses of the inactivated COVID-19 vaccine.

Taxanes hypersensitivity is not a risk factor for severe reactions to SARS-CoV-2 vaccines. Background. Hypersensitivity reactions (HSR) to taxanes have been related to a complement activation by their excipients, polyoxyethylated castor oil and Polysorbate 80, structurally related to those of SARS-CoV-2 vaccines. The aim of this study was to verify the presence of a higher risk of HSR to SARS-CoV-2 vaccines in patients with history of HSR to taxanes. Methods. Patients with history of HSR to taxanes were evaluated before the vaccination in our center and underwent skin tests for PEG and Polysorbate 80 (PandP). Some patients completed the vaccination course in other centers without prior PandP skin tests because they had not manifested taxanes hypersensitivity before vaccination, or because those tests were not available. Results. 50 patients were evaluated. 100% of patients with history of hypersensitivity to taxanes completed the vaccine course with no cases of anaphylaxis. 33 underwent skin tests for PandP before the vaccination and no correlation was found between the positivity of PandP and taxanes skin tests ($p = 0.538$). 7 patients developed mild symptoms during skin tests and vaccination, similar but weaker than those suffered at the time of the taxane infusion, independently from the results of skin tests. Conclusions. In our cohort patients with

history of reaction to taxanes were not at higher risk to develop anaphylaxis to SARS-CoV-2 vaccines. However, a common non-IgE mediated mechanism behind those HSRs cannot be completely excluded. This can only account for mild and harmless symptoms in case of SARS-CoV-2 vaccines. However, prudence is still recommended in these patients.

SARS-CoV-2 vaccines: A double-edged sword throughout rapid evolution of COVID-19. After more than 2 years of the coronavirus disease 2019 pandemic caused by severe acute respiratory syndrome coronavirus 2, several questions have remained unanswered that affected our daily lives. Although substantial vaccine development could resist this challenge, emerging new variants in different countries could be considered as potent concerns regarding the adverse effects of reinfection or postvaccination. Precisely, these concerns address some significant and probable outcomes in vaccinated or reinfected models, followed by some virus challenges, such as antibody-dependent enhancement and cytokine storm. Therefore, the importance of evaluating the effectiveness of neutralizing antibodies (nAbs) elicited by vaccination and the rise of new variants must be addressed.

Transition of Antibody Titers after SARS-CoV-2 mRNA Vaccination in Japanese Healthcare Workers. Since February 2021, healthcare workers in Japan have been preferentially vaccinated with a messenger RNA vaccine (BNT162b2; Pfizer/BioNTech) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). While many studies have confirmed that this vaccine is highly effective in reducing hospitalization and deaths from coronavirus disease 2019 (COVID-19), antibody titers tend to decline at 3 months after vaccination, leading to a risk of breakthrough infections. Thus, information is needed to support the decision regarding the 3rd vaccination. In this study, we investigated the transition of anti-SARS-CoV-2 spike protein receptor-binding domain (RBD) IgG and neutralizing antibody titers in 37 vaccinated Japanese healthcare workers. Samples were collected 6 times starting before vaccination until 6 months after the second vaccination. The levels of anti-SARS-CoV-2 RBD IgG peaked 1 week after the 2nd vaccination, then declined over time and decreased to < 10% at 6 months after the 2nd vaccination. Additionally, approximately one-third of the healthcare workers were seronegative for the Omicron variant 6 months after the 2nd vaccination. Workers with low anti-SARS-CoV-2 RBD IgG levels also had low neutralizing antibody titers. These data support booster dose administration for healthcare workers, especially those with low anti-SARS-CoV-2 RBD IgG levels.

Immune-mediated diseases after coronavirus disease 2019 vaccination: rare but important complication. Since the beginning of mass vaccination against coronavirus disease 2019 (COVID-19), vaccine-linked immune-mediated diseases have been increasingly reported. The development of these diseases after COVID-19 vaccination may be attributed to the mechanisms of molecular mimicry and cross-reactivity between the viral spike protein and self-antigens. The most frequent vaccine-linked glomerular disease is immunoglobulin A nephropathy (IgAN). Cutaneous vasculitis has also been reported after COVID-19 vaccination. In both diseases, deposition of immune complexes activates the inflammatory response with end-organ damage. We report on a case of de novo IgAN in a young man and a case of severe cutaneous vasculitis in a 68-year-old woman, both after the second dose of Pfizer-BioNTech COVID-19 vaccine. Neither of the patients had a history of autoimmunity or adverse reactions to vaccines. The temporal association between vaccination and disease development in the absence of other possible intercurrent inciting events suggests a causal mechanism, although coincidental co-occurrence cannot be excluded. In both cases, immunosuppressive treatment was warranted to stop disease progression and to partially or completely resolve the disease. A timely reaction is needed if new-onset signs of an immune-mediated disease appear after vaccination.

Acute Adverse Effects of Vaccines Against SARS-COV-2. Introduction The global struggle against the impact of severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) on physical and mental

health and on economic and social aspects of human life continues even after two and a half years have passed since the emergence of this virus. The development of vaccines was a milestone. By June 2022, billions of people have been vaccinated against the deadly virus. However, like any other vaccine, the various vaccines against coronavirus disease 2019 (COVID-19) also cause a variety of adverse effects. Therefore this study aimed to determine the different acute side effects experienced after receiving the vaccines and correlating them with some socio-demographic and biomedical factors.Â Methodology This cross-sectional study has a sample size of 467. Study participants were recruited after fulfilling inclusion and exclusion criteria. After gaining approval from the Ethical Review Board (ERB) of CMH Lahore Medical College and Institute of Dentistry, Lahore, Pakistan,Â an onlineÂ questionnaire was distributed via social media. The survey questionnaire had a series of questions regarding the socio-demographic and biomedical characteristics of the participants, as well as the type of vaccine they got, followed by questions about the development of adverse effects after each dose (first and second). Data were statistically analyzed using IBM SPSS Statistics for Windows, Version 25.0 (Released 2017; IBM Corp., Armonk, New York, United States). The analysis was carried out in a confidence range of 95%, and a p-value<0.05 was considered statistically significant.Â Results Sinopharm (76.0%) was the most frequently received vaccine. Adverse events were reported more after the first dose (79.7%) than in the second (67.2%) (p value 0.001). The reported adverse events after either dose were of mild intensity (p<0.05). None of the individuals reported serious adverse events or hospitalization after getting the shots. Females, younger age groups, and individuals with BMI in the underweight category were more prone to developing symptoms and experiencing difficulty doing routine work after getting the doses. The associations were statistically significant (p<0.05). Blood group (A,B,0,AB), past COVID-19 history, and smoking status were not positively associated with the appearance of symptoms after either dose or with inconvenience doing daily work post-vaccination. Conclusion The vaccines developed against COVID-19 offer benefits that outweigh the few mild adverse effects experienced. None of these symptoms is severe enough to stop an individual from doing routine work or result in morbidity or mortality. Therefore, people should avoid any hesitancy towards getting vaccinated to get past this pandemic.

Heterologous immunity induced by 1(st) generation COVID-19 vaccines and its role in developing a pan-coronavirus vaccine. Severe acute respiratory syndrome virus-2 (SARS-CoV-2), the causative infectious agent of the COVID-19 pandemic, has led to multiple (4-6) waves of infections worldwide during the past two years. The development of vaccines against SARS-CoV-2 has led to successful mass immunizations worldwide, mitigating the worldwide mortality due the pandemic to a great extent. Yet the evolution of new variants highlights a need to develop a universal vaccine which can prevent infections from all virulent SARS-CoV-2. Most of the current first generation COVID-19 vaccines are based on the Spike protein from the original Wuhan-hu-1 virus strain. It is encouraging that they still protect from serious illnesses, hospitalizations and mortality against a number of mutated viral strains, to varying degrees. Understanding the mechanisms by which these vaccines provide heterologous protection against multiple highly mutated variants can reveal strategies to develop a universal vaccine. In addition, many unexposed individuals have been found to harbor T cells that are cross-reactive against SARS-CoV-2 antigens, with a possible protective role. In this review, we will discuss various aspects of natural or vaccine-induced heterologous (cross-reactive) adaptive immunity against SARS-CoV-2 and other coronaviruses, and their role in achieving the concept of a pan-coronavirus vaccine.

Four cases of cytokine storm after COVID-19 vaccination: Case report. The global coronavirus disease 2019 (COVID-19) pandemic has led to the rapid development of vaccines against this disease. Despite the success of the international vaccination program, adverse events following vaccination, and the mechanisms behind them, remain poorly understood. Here we present four cases of death

following receipt of a second dose of COVID-19 vaccine, with no obvious cause identified at autopsy. Using RNA sequencing, we identified genes that were differentially expressed between our post-vaccination cases and a control group that died of blood loss and strangulation. Three hundred and ninety genes were found to be upregulated and 115 genes were downregulated in post-vaccination cases compared with controls. Importantly, genes involved in neutrophil degranulation and cytokine signaling were upregulated. Our results suggest that immune dysregulation occurred following vaccination. Careful observation and care may be necessary if an abnormally high fever exceeding 40Â°C occurs after vaccination, even with antipyretic drugs.

Oral lesions after COVID-19 vaccination: Immune mechanisms and clinical approach. COVID-19 vaccination, although is a promising tool to overcome the pandemic, has side effects. There are increasing reports of oral lesions after COVID-19 vaccination. The aim of this review is to identify the occurrence of some oral lesions after COVID-19 vaccination, and highlight the underlying immune mechanisms involved. A narrative literature review was performed by searching electronic databases including PubMed, Scopus and Web of Science to investigate the oral lesions after COVID-19 vaccination. The inclusion criteria were original studies, including the case reports, case series, letter to the editor, and cross-sectional studies. The exclusion criteria included the studies which examined the oral lesions caused by COVID-19 infection. The information, including the number of participant(s) receiving vaccine, type of vaccine, dose number, side effect(s), time of onset following vaccination, healing time, treatment strategies for the existing lesions, and related mechanisms were then summarized in a data extraction sheet. The results of this review showed that some vaccines had side effects with oral involvement such as pemphigus vulgaris, bullous pemphigoid, herpes zoster, lichen planus, Stevens-Johnson syndrome and BehÃ§et's disease. Future research needs to elucidate the physiopathology of oral manifestations after the COVID-19 vaccination, and better understand the risk factors associated with such responses. Sometimes vaccine's side effects may be due to the nocebo effect, which means that the person expects some adverse events to occur following the vaccine administration.

Disproportionality analysis of adverse neurological and psychiatric reactions with the ChAdOx1 (Oxford-AstraZeneca) and BNT162b2 (Pfizer-BioNTech) COVID-19 vaccines in the United Kingdom. BACKGROUND: Information on neurological and psychiatric adverse events following immunization (AEFIs) with COVID-19 vaccines is limited. RESEARCH DESIGN & METHODS: We examined and compared neurological and psychiatric AEFIS reports related to BNT162b2 (Pfizer-BioNTech) and ChAdOx1 (Oxford-AstraZeneca) COVID-19 vaccines and recorded in the United Kingdom Medicines and Healthcare products Regulatory Agency between 9 December 2020 and 30 June 2021. RESULTS: As of 30 June 2021, 46.1 million doses of ChAdOx1 and 30.3 million doses of BNT162b2 had been administered. The most frequently reported AEFI was headache with 1,686 and 575 cases per million doses of ChAdOx1 and BNT162b2, respectively. AEFIs more frequently reported after CHAdOx1 compared with BNT162b2 vaccination were Guillain-BarrÃ© syndrome (OR, 95% CIÂ =Â 2.53, 1.82-3.51), freezing (6.66, 3.12-14.22), cluster headache (1.53, 1.28-1.84), migraine (1.23,1.17-1.30), postural dizziness (1.24,1.13-1.37), tremor (2.86, 2.68-3.05), headache (1.40, 1.38-1.43), paresthesia (1.11, 1.06-1.16), delirium (1.85, 1.45-2.36), hallucination (2.20, 1.82-2.66), poor quality sleep (1.53, 1.26-1.85), and nervousness (1.54, 1.26-1.89) Reactions less frequently reported with ChAdOx1 than with BNT162b2 were Bell's palsy (0.47, 0.41-0.55), anosmia (0.58, 0.47-0.71), facial paralysis (0.35, 0.29-0.41), dysgeusia (0.68, 0.62-0.73), presyncope (0.48, 0.42-0.55), syncope (0.63, 0.58-0.67), and anxiety (0.75 (0.67-0.85). CONCLUSION: Neurological and psychiatric AEFIs were relatively infrequent, but each vaccine was associated with a distinctive toxic profile.

 We examined reports on adverse neurological and psychiatric effects following immunization with BNT162b2 (Pfizer-BioNTech) and ChAdOx1 (Oxford-AstraZeneca) for COVID-19 to the United Kingdom Medicines and Healthcare

products Regulatory Agency between 9 December 2020 and 30 June 2021. Adverse effects following immunization (AEFIs) were relatively infrequent. Compared to BNT162b2, Guillain-BarrÃ© syndrome, freezing phenomenon, cluster headache, migraine, postural dizziness, tremor, headache, paresthesia, delirium, hallucination, poor quality sleep, and nervousness were more frequently reported for ChAdOx1. Reactions less frequently reported for ChAdOx1 than for BNT162b2 were Bellâ€™s palsy, anosmia, facial paralysis, dysgeusia, presyncope, syncope, and anxiety.

Induced Depressive Disorder Following the First Dose of COVID-19 Vaccine. INTRODUCTION: Several COVID-19 vaccines have been implemented. However, some side effects of the vaccine have been reported, which are sometimes very harmful. Reported cases and data are still very limited regarding the psychiatric side effects of the COVID-19 vaccine. To our knowledge, only one case has been reported. In this paper, we report the case of a patient who presented an acute depressive episode 24 hours after receiving his first dose of the BNT162b2mRNA vaccine. CASE REPORT: The case was a 26-year-old man with a history of Down syndrome with moderately good autonomy for daily routine tasks. The patient, who presented hypothyroidism at 10 years old and schizophrenia at 15 years old, was doing well before the vaccination and received his first dose of the BNT162b2mRNA vaccine. Twenty-four hours later, he presented depressive symptoms that resolved spontaneously after one week. Then, fifteen days later, the symptoms reappeared, and the episode lasted for 5 weeks. The patient received 10 mg/day of escitalopram besides his usual treatment. The depressive symptoms improved considerably by the second day of treatment. DISCUSSION: The presented case illustrated significant diagnostic challenges, especially when taking into account the sequential relationship between the COVID-19 vaccine and the occurrence of depressive symptoms. A single case of depression has been reported after the administration of the COVID-19 vaccine. Scientific evidence suggests the important role of the immune system in the pathophysiology of various psychiatric disorders, including depression. CONCLUSION: Health professionals must take into consideration the potential psychiatric side effects even being rare so far, especially in vulnerable subjects. Further studies are required to establish the causal effects of depressive symptoms occurring during the weeks following the COVID-19 vaccine bolus injection.

Prediction and reasons for COVID-19 second dose vaccine hesitation: a cross-sectional study in a municipality of Brazil. BACKGROUND: Hesitation and refusal to take a second dose of the vaccine for coronavirus disease 19 (COVID-19) are prevalent. OBJECTIVES: We aimed to identify predictive factors for hesitation or refusal and describe groups with higher rates of vaccine hesitancy. DESIGN AND SETTING: A cross-sectional study in Assis City, Brazil. METHODS: The study included adults who passed the due date for taking the COVID-19 second dose vaccine. Participants were recruited in December 2021 using a mobile-based text message. Sociodemographic and clinical data and reasons for hesitance were collected. The outcome was the attitude towards completing the recommended second dose of the vaccine. Bivariate and multivariate Poisson analyses were performed to determine the adjusted predictors. RESULTS: Participants between 30-44 years of age had a 2.41 times higher prevalence of hesitation than those aged 18-29 years. In addition, people who had adverse events or previously had COVID-19 had 4.7 and 5.4 times higher prevalences of hesitation, respectively (P value < 0.05). CONCLUSION: We found a significant group of adults aged between 30-44 years who refused the second dose of the COVID-19 vaccine. Furthermore, those who reported adverse effects after the first dose and those who had COVID-19 previously were a significant group for refusal.

Primary and Secondary Attack Rates by Vaccination Status after a SARS-CoV-2 B.1.617.2 (Delta) Variant Outbreak at a Youth Summer Camp-Texas, June 2021. Children are capable of initiating COVID-19 transmission into households, but many questions remain about the impact of vaccination on transmission. Data from a COVID-19 Delta variant outbreak at an overnight camp in Texas during June 23-27, 2021, were analyzed. The camp had 451 attendees, including 364 youths aged

â€…<â€…18 years and 87 adults. Detailed interviews were conducted with 92 (20.4%) of consenting attendees and 117 household members of interviewed attendees with COVID-19. Among 450 attendees with known case status, the attack rate was 41%, including 42% among youths; attack rates were lower among vaccinated (13%) than among unvaccinated youths (48%). The secondary attack rate was 51% among 115 household contacts of 55 interviewed index patients. Secondary infections occurred in 67% of unvaccinated household members and 33% of fully or partially vaccinated household members. Analyses suggested that household member vaccination and camp attendee masking at home protected against household transmission.

Association of Homologous and Heterologous Vaccine Boosters With SARS-CoV-2 Infection in BBIBP-CorV Vaccinated Healthcare Personnel. Vaccines against severe acute respiratory syndromeÂ coronavirus 2 (SARS-CoV-2) have played a crucial role in mitigating the coronavirus disease 2019 (COVID-19) pandemic. However, few studies have addressed the optimal booster vaccine type in recipients of the primary series of BBIBP-CorV (an inactivated virus vaccine developed by Sinopharm). This study aimed to estimate the association between the heterologous or homologous COVID-19 vaccination and SARS-CoV-2 infection. The study enrolled healthcare personnel (HCP) who had completed two doses of BBIBP-CorV between November 2020 and September 2021. The associations between SARS-CoV-2 infection and boosters were measured using multivariable logistic regression, comparing the odds of a positive COVID-19 test result between the no booster group and booster groups (BNT162b2 {Pfizer-BioNTechÂ COVID-19 vaccine} group and BBIBP-CorV group, respectively). A total of 495 HCP comprising 326 (65.9%) in the BNT162b2 group, 121 (24.4%) in the no booster group, and 48 (9.7%) in the BBIBP-CorV group enrolled. One hundred thirty-six cases (27.5%) tested positive for COVID-19. The odds ratios for testing positive after booster dose were 0.401 (95% CI: 0.187-0.860, p = 0.019) and 0.446 (95% CI: 0.170-1.167, p = 0.100) for BNT162b2 and BBIBP-CorV group, respectively. The BNT162b2 booster in HCP after a second dose of BBIBP-CorV, relative to no booster, and the BBIBP-CorV booster, was associated with protection against laboratory-confirmed COVID-19.

COVID-19 Vaccine-associated Thrombosis (Disseminated Intravascular Thrombosis) with Rare Cutaneous Involvement. Many COVID-19 vaccines have been used on the population all over the world. Not much is known about the vaccines and their adverse effects. A middle-aged lady got fever, body ache, and cutaneous lesions suggestive of disseminated intravascular thrombosis (DIC) almost immediately after COVID vaccination with very high D-dimer level in blood. She was successfully managed with timely initiation of treatment with steroids, anticoagulation, and antibiotics. HOW TO CITE THIS ARTICLE: Sinha S, Tripathy S. COVID-19 Vaccine-associated Thrombosis (Disseminated Intravascular Thrombosis) with Rare Cutaneous Involvement. Indian J Crit Care Med 2022;26(8):963-965.

Higher mortality associated with the SARS-CoV-2 Delta variant in the Western Cape, South Africa, using RdRp target delay as a proxy: a cross-sectional study. Background: The SARS-CoV-2 Delta variant (B.1.617.2) has been associated with more severe disease, particularly when compared to the Alpha variant. Most of this data, however, is from high income countries and less is understood about the variant's disease severity in other settings, particularly in an African context, and when compared to the Beta variant. Methods: A novel proxy marker, RNA-dependent RNA polymerase (RdRp) target delay in the Seegene Allplex (TM) 2019-nCoV (polymerase chain reaction) PCR assay, was used to identify suspected Delta variant infection in routine laboratory data. All cases diagnosed on this assay in the public sector in the Western Cape, South Africa, from 1 April to 31 July 2021, were included in the dataset provided by the Western Cape Provincial Health Data Centre (PHDC). The PHDC collates information on all COVID-19 related laboratory tests, hospital admissions and deaths for the province. Odds ratios for the association between the proxy marker and death were calculated, adjusted for

prior diagnosed infection and vaccination status. Results: A total of 11,355 cases with 700 deaths were included in this study. RdRp target delay (suspected Delta variant) was associated with higher mortality (adjusted odds ratio [aOR] 1.45; 95% confidence interval [CI]: 1.13-1.86), compared to presumptive Beta infection. Prior diagnosed infection during the previous COVID-19 wave, which was driven by the Beta variant, was protective (aOR 0.32; 95%CI: 0.11-0.92) as was vaccination (aOR [95%CI] 0.15 [0.03-0.62] for complete vaccination [â‰¥28 days post a single dose of Ad26.COV2.S or â‰¥14 days post second BNT162b2 dose]). Conclusion: RdRp target delay, a proxy for infection with the Delta variant, is associated with an increased risk of mortality amongst those who were tested for COVID-19 in our setting.

Recurrent, non-traumatic, non-exertional rhabdomyolysis after immunologic stimuli in a healthy adolescent female: a case report. BACKGROUND: Dysferlinopathy refers to a heterogenous group of autosomal recessive disorders that affect a skeletal muscle protein called dysferlin. These mutations are associated with limb-girdle muscular dystrophy type 2B, Miyoshi myopathy, asymptomatic hyperCKemia, and distal myopathy with anterior tibial onset. CASE PRESENTATION: A 16Â year old female presented with myalgia, weakness and dark urine one week after her second BNT162b2 mRNA (Pfizer) vaccine. Initial serum creatine kinase (CK) was measured at 153,000Â IU/L, eventually up-trending to over 200,000Â IU/L. However, stable renal function precluded hemodialysis allowing discharge after 10Â days of intravenous (IV) hydration and alkaline diuresis. Just two years prior to the current presentation, the patient was hospitalized following Group A Streptococcal pharyngitis infection complicated by rhabdomyolysis. She presented with fatigue, lower extremity weakness, and dark oliguria with CK measuring 984,800Â IU/L. IV hydration was attempted however hemodialysis was ultimately required throughout her 24-day hospital stay. Her episode was presumed to be idiopathic and no further work-up was performed at that time. During the patient's current hospitalization, she reported similar symptomology (myalgias and weakness) following her first quadrivalent Gardasil vaccine at age 11. No hospitalization was required at that time. A comprehensive workup was now initiated while the patient was being treated for her suspected second or third non-exertional, non-traumatic rhabdomyolysis. Rheumatologic, metabolic, infectious, and endocrinologic workup were all unremarkable. Patient eventually had whole exome sequencing performed which revealed a heterozygous pathogenic variant in the DYSFÂ gene (DYSFÂ c.2643â€‰+â€‰1Gâ€‰>â€‰A) encoding dysferlin. No clinically significant sequelae occurred thus far. CONCLUSIONS: While there have been reports of symptomatic heterozygote carriers of dysferlinopathies, to our knowledge none have been associated with recurrent rhabdomyolysis after immunogenic stimuli. This unique case presentation highlights the importance of a multi-disciplinary care team, the utility of modern whole-exome gene sequencing, and the future challenges of balancing vaccine risk vs benefit.

Glucocorticoids' treatment impairs the medium-term immunogenic response to SARS-CoV-2 mRNA vaccines in Systemic Lupus Erythematosus patients. Limited data exists on SARS-CoV-2 sustained-response to vaccine in patients with rheumatic diseases. This study aims to evaluate neutralizing antibodies (nAB) induced by SARS-CoV-2 vaccine after 3 to 6Â months from administration in Systemic Lupus Erythematosus (SLE) patients, as a surrogate of sustained-immunological response. This cross-sectional study compared nAB titre of 39 SLE patients and 37 Healthy individuals with no previous SARS-CoV-2 infection, who had all received a complete regimen of a mRNA SARS-CoV-2 vaccine within the last 3 to 6Â months. We included four lines of SLE treatment including Not-treated, Hydroxychloroquine, immunosuppressive drugs and biological therapy. Glucocorticoids were allowed in all groups. Healthy and Not-treated individuals showed the highest levels of nAB. Treated patients presented lower nAB titres compared to Healthy: a 73% decrease for First-Line patients, 56% for Second-Line treatment and 72% for Third-Line. A multivariate analysis pointed to Glucocorticoids as

the most associated factor with declining nAB levels (75% decrease) in treated SLE. Furthermore, a significant reduction in nAB titres was observed for Rituximab-users compared to Healthy subjects (89% decrease). Medium-term response of SLE patients to SARS-CoV-2 mRNA vaccines is negatively impacted in Glucocorticoids and Rituximab users. These findings might help to inform recommendations in vaccination protocols for SLE patients.

Examining Pregnant Veterans' Acceptance and Beliefs Regarding the COVID-19 Vaccine. BACKGROUND: Pregnant persons have received mixed messages regarding whether or not to receive COVID-19 vaccines as limited data are available regarding vaccine safety for pregnant and lactating persons and breastfeeding infants. OBJECTIVE: The aims of this study were to examine pregnant Veteran's acceptance of COVID-19 vaccines, along with perceptions and beliefs regarding vaccine safety and vaccine conspiracy beliefs. DESIGN AND PARTICIPANTS: We conducted a cross-sectional survey of pregnant Veterans enrolled in VA care who were taking part in an ongoing cohort study at 15 VA medical centers between January and May 2021. MAIN MEASURES: Pregnant Veterans were asked whether they had been offered the COVID-19 vaccine during pregnancy, and whether they chose to accept or refuse it. Additional questions focused on perceptions of COVID-19 vaccine safety and endorsements of vaccine knowledge and conspiracy beliefs. Logistic regression was utilized to examine predictors of acceptance of a vaccine during pregnancy. KEY RESULTS: Overall, 72 pregnant Veterans were offered a COVID-19 vaccine during pregnancy; over two-thirds (69%) opted not to receive a vaccine. Reasons for not receiving a vaccine included potential effects on the baby (64%), side effects for oneself (30%), and immunity from a past COVID-19 infection (12%). Those who received a vaccine had significantly greater vaccine knowledge and less belief in vaccine conspiracy theories. Greater knowledge of vaccines in general (aOR: 1.78; 95% CI: 1.2-2.6) and lower beliefs in vaccine conspiracies (aOR: 0.76; 95% CI: 0.6-0.9) were the strongest predictors of acceptance of a COVID-19 vaccine during pregnancy. CONCLUSIONS: Our study provides important insights regarding pregnant Veterans' decisions to accept the COVID-19 vaccine, and reasons why they may choose not to accept the vaccine. Given the high endorsement of vaccine conspiracy beliefs, trusted healthcare providers should have ongoing, open discussions about vaccine conspiracy beliefs and provide additional information to dispel these beliefs.

Antibody levels after BNT162b2 vaccine booster and SARS-CoV-2 Omicron infection. In the present study, immunogenicity data in 61 vaccinated healthcare workers (HCWs) either infection naÃ¯ve (naÃ¯ve HCWs) or with infection of Delta and/or Omicron COVID-19 (experienced HCWs) were evaluated up to 270Â days after the second dose of BNT162b2 vaccine and up to 90Â days after a booster dose. A decrease in antibody levels at 270Â days following administration of the second dose (pÂ =Â 0.0335) was observed, although values did not fall below the positivity threshold (33.8 BAU/ml). After booster vaccination, antibody levels increased after 30Â days (pÂ =Â 0.0486), with much higher values than after first and second vaccination. Antibody levels then decreased at 60 and 90Â days after the booster dose. A comparison between mean antibody levels of naÃ¯ve and experienced HCWs revealed higher values in experienced HCWs, resulting from both natural and vaccination-induced immunity. A total of 14.7% of HCWs contracted the Omicron virus variant after the vaccine booster, although none showed severe symptoms. These results support that a booster dose results in a marked increase in antibody response that subsequently decreases over time.

Antibody and T-cell responses by ultra-deep T-cell receptor immunosequencing after COVID-19 vaccination in patients with plasma cell dyscrasias. We investigated antibody and coronavirus disease 2019 (COVID-19)-specific T-cell mediated responses via ultra-deep immunosequencing of the T-cell receptor (TCR) repertoire in patients with plasma cell dyscrasias (PCD). We identified 364 patients with PCD who underwent spike antibody testing using commercially available spike-receptor binding domain immunoglobulin G antibodies â‰¥2â€‰weeks after completion of the initial two

doses of mRNA vaccines or one dose of JNJ-78436735. A total of 56 patients underwent TCR immunosequencing after vaccination. Overall, 86% tested within 6â€‰months of vaccination had detectable spike antibodies. Increasing age, use of anti-CD38 or anti-B-cell maturation antigen therapy, and receipt of BNT162b2 (vs. mRNA-1273) were associated with lower antibody titres. We observed an increased proportion of TCRs associated with surface glycoprotein regions of the COVID-19 genome after vaccination, consistent with spike-specific T-cell responses. The median spike-specific T-cell breadth was 3.11â€‰Ã—â€‰10(-5) , comparable to those in healthy populations after vaccination. Although spike-specific T-cell breadth correlated with antibody titres, patients without antibody responses also demonstrated spike-specific T-cell responses. Patients receiving mRNA-1273 had higher median spike-specific T-cell breadth than those receiving BNT162b2 (pÂ =Â 0.01). Although patients with PCD are often immunocompromised due to underlying disease and treatments, COVID-19 vaccination can still elicit humoral and T-cell responses and remain an important intervention in this patient population.
Autoimmune and autoinflammatory conditions after COVID-19 vaccination. New case reports and updated literature review. Autoimmunity linked to COVID-19 immunization has been recorded throughout the pandemic. Herein we present six new patients who experienced relapses of previous autoimmune disease (AD) or developed a new autoimmune or autoinflammatory condition following vaccination. In addition, we documented additional cases through a systematic review of the literature up to August 1st, 2022, in which 464 studies (928 cases) were included. The majority of patients (53.6%) were women, with a median age of 48 years (IQR: 34 to 66). The median period between immunization and the start of symptoms was eight days (IQR: 3 to 14). New-onset conditions were observed in 81.5% (n: 756) of the cases. The most common diseases associated with new-onset events following vaccination were immune thrombocytopenia, myocarditis, and Guillain-BarrÃ© syndrome. In contrast, immune thrombocytopenia, psoriasis, IgA nephropathy, and systemic lupus erythematosus were the most common illnesses associated with relapsing episodes (18.5%, n: 172). The first dosage was linked with new-onset events (69.8% vs. 59.3%, PÂ =Â 0.0100), whereas the second dose was related to relapsing disease (29.5% vs. 59.3%, PÂ =Â 0.0159). New-onset conditions and relapsing diseases were more common in women (51.5% and 62.9%, respectively; PÂ =Â 0.0081). The groups were evenly balanced in age. No deaths were recorded after the disease relapsed, while 4.7% of patients with new-onset conditions died (PÂ =Â 0.0013). In conclusion, there may be an association between COVID-19 vaccination and autoimmune and inflammatory diseases. Some ADs seem to be more common than others. Vaccines and SARS-CoV-2 may induce autoimmunity through similar mechanisms. Large, well-controlled studies are warranted to validate this relationship and assess additional variables such as genetic and other environmental factors.
[Myocarditis following mRNA vaccine]. This article presents the case of aÂ 15-year-old adolescent presenting with myocarditis 4Â days after receiving the 2nd dose of BNT162b2 mRNA vaccine (ComirnatyÂ®) with no other identifiable cause. The main clinical symptom at presentation was chest pain. We found an elevated level of Troponinâ€‘I with preserved left ventricular systolic function. The cardiac MRI showed aÂ clear pathologic result. With symptomatic therapy and strict bed rest, the symptoms resolved quickly and revealed aÂ mild course.
Myocarditis After Vaccination.
COVID-19 vaccine-associated optic neuritis.
An autopsy case of fulminant myocarditis after severe acute respiratory syndrome coronavirus 2 vaccine inoculation. A 61-year-old woman without significant medical history developed fever 3 days after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination and went into shock the next day. She was negative for SARS-CoV-2 mRNA in real-time polymerase chain reaction (PCR). Finally, she died 10 days after vaccination. At autopsy, the heart showed moderate dilatation

of both ventricles, and the myocardium showed an uneven color change and decreased elasticity. Histologically, severe myocarditis with extensive myocytolysis was observed. The myocarditis showed severe inflammatory cell infiltration with T-lymphocyte and macrophage predominance, and in addition to the inflammatory cells described above, vast nuclear dust accompanying neutrophilic infiltration was observed. In the bone marrow and lymph nodes, hemophagocytosis was observed. In postmortem examination, nucleic acids of any cardiotropic viruses including SARS-CoV-2 were not detected using multivirus real-time PCR system. We discussed the relationship between the possible immune reaction after vaccination and the myocarditis observed in this case from immunopathological viewpoints. This mRNA vaccine is the first applied nucleic acid vaccine for humans, and its mechanism of efficacy and immune acquisition remain unclear. We hope the accumulation of more detailed analyses of the similar cases to reveal the mechanism of this kind of adverse reaction.
High rate of seroconversion after COVID-19 vaccination during the long term follow-up of heart transplant recipients.
Impaired immunity and high attack rates caused by SARS-CoV-2 variants among vaccinated long-term care facility residents. INTRODUCTION: Long-term care facilities (LTCF) residents are at high risk for severe coronavirus disease 2019 (COVID-19), and therefore, COVID-19 vaccinations were prioritized for residents and personnel in Finland at the beginning of 2021. METHODS: We investigated COVID-19 outbreaks in two LTCFs, where residents were once or twice vaccinated. After the outbreaks we measured immunoglobulin G (IgG) antibodies to severe acute respiratory syndrome coronavirus 2 spike glycoprotein, neutralizing antibody (NAb) titers, and cell-mediated immunity markers from residents and healthcare workers (HCWs). RESULTS: In LTFC-1, the outbreak was caused by an Alpha variant (B.1.1.7) and the attack rate (AR) among once vaccinated residents was 23%. In LTCF-2 the outbreak was caused by a Beta variant (B.1.351). Its AR was 47% although all residents had received their second dose 1 month before the outbreak. We observed that vaccination had induced lower IgG concentrations, NAb titers and cell-mediated immune responses in residents compared to HCWs. Only 1/8 residents had NAb to the Beta variant after two vaccine doses. CONCLUSIONS: The vaccinated elderly remain susceptible to breakthrough infections caused by Alpha and Beta variants. The weaker vaccine response in the elderly needs to be addressed in vaccination protocols, while new variants capable of evading vaccine-induced immunity continue to emerge.
COVID-19 vaccine and oral lesions: Putative pathogenic mechanisms.
A Case of COVID-19 Vaccine-Induced Thrombotic Thrombocytopenia. This report discusses a case of a 37-year-old female who developed vaccine-induced thrombotic thrombocytopenia (VITT) after receiving the Johnson and Johnson COVID-19 vaccination. The patient first presented to the ED with complaints of a worsening headache. Labs were significant for thrombocytopenia with a platelet count of 22,000, and the patient was admitted to the inpatient unit for monitoring. The day after admission, the patient was found to have a right common femoral artery embolus, left distal popliteal trifurcation embolism, a small pulmonary embolism in the right lower lobe, and a mural thrombus of the infrarenal abdominal aorta. Following these findings, the patient underwent emergent thrombectomy of the common and superficial femoral arteries. Over the hospital course of six days, the patient received steroids and IV immunoglobulin (IVIG), which led to the resolution of the thrombocytopenia. The patient was given argatroban followed by apixaban for anticoagulation. She was instructed to follow up with hematology within one to two weeks post-discharge for monitoring of anticoagulation and thrombus surveillance. This case report outlines the clinical course, diagnosis, and treatment of a case of VITT, which will assist physicians in early recognition and adequate treatment of this condition as the COVID-19 pandemic continues.

Side Effects of COVID-19 Vaccines (Pfizer, AstraZeneca) in Saudi Arabia, Eastern Province. BACKGROUND: The coronavirus disease 2019 (COVID-19) virus has wreaked havoc on the planet, causing death and illness. Effective vaccination to eradicate the virus is the best approach to safeguarding the globe from it. Our study is considered one of the earliest studies conducted to determine the side effects of COVID-19 vaccines. We started data collection from May 2021 till September 2021, which was the beginning period of vaccine distribution in Saudi Arabia. This study aims to look at potential side effects and factors that contribute to their occurrence. METHODS: The optimal study design for achieving our goals was survey-based. Following Institutional Review Board approval, we created an online self-administered questionnaire using the Google survey webpage (Google LLC, Mountain View, California, United States). We disseminated the survey to 2293 individuals from May 2021 till September 2021 in the eastern province of Saudi Arabia, to males and females above the age of 18 who have been vaccinated by either Pfizer or AstraZeneca in one dose or two doses. RESULTS: The most prevalent side effect was pain at the injection site (60.7%), followed by general fatigue (23.8%) and swelling at the injection site (16.7%), with shortness of breath being the least common (0.9%). When the prevalence of COVID-19 vaccine side effects was compared to the socio-demographic characteristics of participants, we discovered that those without associated comorbidity (p=0.025) and non-smoking participants (p=0.009) showed more side effects. On the other hand, those who received Pfizer vaccine (p0.001) and those who exercised regularly (p0.001) had lower rates of COVID-19 vaccine side effects. Also, obesity was shown to be the most commonly related disease in terms of comorbidities (8.5%), followed by allergy (4.9%) and asthma (4.6%). CONCLUSION: We find that vaccination against COVID-19 has only minor adverse effects. Therefore we anticipate that this study will assist in dispelling rumors about dangerous side effects of the COVID-19 vaccine.

A Case Report for Acute Myopericarditis After NVX-CoV2373 (Novavax(Â®)) COVID-19 Vaccination. Post-vaccination myocarditis after administration of the NVX-CoV2373 coronavirus disease 2019 (COVID-19) vaccine has been reported in a limited population. We report the first biopsy-proven case of myopericarditis after administration of second dose of NVX-CoV2373 COVID-19 vaccine (NovavaxÂ®) in Korea. A 30-year-old man was referred to emergency department with complaints of chest pain and mild febrile sense for two days. He received the second dose vaccine 17 days ago. Acute myopericarditis by the vaccination was diagnosed by cardiac endomyocardial biopsy. He was treated with corticosteroid 1 mg/kg/day for 5 days and tapered for one week. He successfully recovered and was discharged on the 12th day of hospitalization. The present case suggests acute myopericarditis as a vaccination complication by NovavaxÂ® in Korea.

Prevalence and factors associated with COVID-19 vaccine acceptance among the general population in Asadabad, Iran: a cross-sectional study. BACKGROUND: Vaccination can be an essential protective measure against Coronavirus disease 2019 (COVID-19) if well received by the public. Various factors affect the acceptance or refusal of vaccines. Several waves of COVID-19 caused much death in Iran. This study aimed to evaluate the acceptance of the COVID-19 vaccine in the general population of Asadabad in 2021. METHODS: In this cross-sectional study, 650 people from the general population of Asadabad with a mean age of 34.6 (SDâ€‰=â€‰15.1) years were selected and included. In addition to socio-economic and demographic data, data were collected using the COVID-19 fear scale. Univariate and multiple logistic regression models were used to investigate the relationship between the tendency to get the COVID-19 vaccine (the dependent variable) and other variables. RESULTS: About 42.3% of participants were reluctant to receive the available COVID-19 vaccines. After adjusting for several covariates, there was a significant relationship between willingness to get vaccinated and family history of COVID-19 infection (ORâ€‰=â€‰1.86, 95% CI 1.06-3.27, pâ€‰=â€‰0.032), trust in healthcare workers (ORâ€‰=â€‰2.07, 95% CI 1.13-3.79,

pâ€‰=â€‰0.019), trust in existing vaccines (AORâ€‰=â€‰3.94, 95% CI 2.15-7.23, pâ€‰<â€‰0.001), encouraging family members to get vaccinated (AORâ€‰=â€‰7.6, 95% CI 4.12-14.01, pâ€‰<â€‰0.0001). Also, people infected with COVID-19 are less likely to accept vaccination (AORâ€‰=â€‰0.55, 95% CI 0.33-0.93, pâ€‰=â€‰0.025). Also, a unit increase in the score of fear of getting the COVID-19 virus increased the odds of getting the COVID-19 vaccine by 6% (AORâ€‰=â€‰1.06, 95% CI 1.02-1.10, pâ€‰=â€‰0.002). CONCLUSION: The culture and context of different societies can affect the acceptance or refusal of the COVID-19 vaccine. Based on these characteristics and providing extensive education to the people, the health authorities in each community should build trust and better communicate all health information to clear any fear and remove all obstacles to increase willingness to get COVID-19 vaccination.

Differential persistence of neutralizing antibody against SARS-CoV-2 in post immunized Bangladeshi population. Development of effective vaccines have been immensely welcomed by the world to prevent the transmission of SARS-CoV-2. However, the duration and clinical implications of antibody-mediated natural immunity in SARS-CoV-2 have not been adequately elucidated alongside some other immune system transforming factors. In a cohort study, we measured NAb titer following the 2nd immunization dosage of the CoviShield (AZD1222) vaccine. The enzyme-linked immunoassay was used to look for SARS-CoV-2-specific NAb. We measured NAb at 30Â days after the 2nd dosage of immunization andâ€‰>â€‰96% titer was detected in 42.9% of subjects, but only 5.1% of subjects retained the same level after 180Â days. The median NAb titer dropped significantly, from 92% at 30Â days to 58% at 180Â days (pâ€‰<â€‰0.001). Besides, there were significant differences observed in NAb titer after 180Â days by age, sex, COVID-19 infection, tobacco use, and asthma patients. However, SARS-CoV-2 infection along with two dosages of immunization upheld NAb titer (pâ€‰<â€‰0.001) even at the end of the study period.

COVID-19 vaccination and male fertility issues: Myth busted. Is taking COVID-19 vaccine the best choice for semen protection and male fertility from risky infection hazards? The emerging coronavirus illness (COVID-19) pandemic is posing a global health hazard, with men being at a larger risk than women. There have been few publications on the andrological consequences of COVID-19 and its vaccines so far. To assuage vaccine fear stemming from concerns about fertility, the effect of inactivated whole-virus and viral vector vaccines on semen quality was investigated in 100 Egyptian men. The safety of COVID-19 vaccines on semen parameters was validated with no significant change in pre- and post-vaccination semen analyses in either type of vaccine. Following COVID-19 vaccination, we can declare male semen parameters as unaffected.

Short-term mortality following COVID-19 vaccination in Bologna, Italy: a one-year study. The main objective of the study is to assess whether there is an increased risk of mortality in the days following the administration of COVID-19 vaccines in Bologna Health Authority in the first year of COVID-19 vaccination campaign. A secondary objective was to describe causes of deaths occurred in the days after vaccination. We conducted a retrospective observational study on all residents of Bologna Health Authority who received at least one COVID-19 vaccination dose from December 27, 2020 to December 31, 2021 and compared mortality in the 3, 7, 14 30Â days after vaccination (risk interval) with the mortality in the period of the same length (3, 7, 14 and 30Â days) beyond the 30th day after the last dose of vaccination (control interval). The cohort included 717,538 people. The mortality rate was 2.24 per 100 person-years during the 30Â days risk interval vs 2.72 in the control interval with an adjusted incidence rate ratio equal to 0.76 (95% CI: 0.70-0.83, pÂ <Â 0.001). The risk of mortality is significantly lower (pÂ <Â 0.001) also in the 3, 7, 14Â days risk intervals than in the control intervals. This study shows that there is no increase in mortality in the short-term period after COVID-19 vaccines.

Vaccines and Bell's palsy: A narrative review. The association between vaccines and peripheral facial palsy (PFP), an issue that has been the subject of debate for many years, has been raised again following results of clinical trials assessing mRNA based COVID-19 vaccines. To review the available literature on this topic, PubMed was searched from inception until February 25, 2022. Inclusion criteria were case reports with documented rechallenge and comparative epidemiological studies. Cases of COVID-19 vaccine-induced PFP with available data on vaccine rechallenge were also identified from Vigibase until December 31, 2021. Of the 347 articles retrieved, 32 comparative epidemiological studies, 1 meta-analysis and 4 case reports met our criteria, of which 13 involved COVID-19 vaccines. Eight studies found an association between at least one vaccine and the occurrence of PFP, whereas 24 did not. Positive studies involved seasonal or pandemic H1N1 influenza vaccines administered parenterally (4 studies) or intranasally (1 study with a toxin-adjuvanted vaccine), BNT162b2, a mRNA COVID-19 vaccine (1 disproportionality analysis and 1 observed-to-expected analysis) and an inactivated virus COVID-19 vaccine (CoronaVacÂ®) (1 study combining a case-control and an observed-to-expected approach). Strong evidence was found only for the intranasal influenza vaccine while other positive studies detected only a marginal association between PFP and vaccination. Of the four case reports with documented rechallenge, only two were positive and involved an influenza vaccine and tozinameran in one case each. In Vigibase, rechallenge was documented in 49 reports with 29 (59.2%) cases being negative and 20 (40.8%) positive. The available data did not confirm an excess risk of PFP after vaccination in most studies. Moreover, of the eight epidemiological studies suggesting a possible excess risk of PFP after any vaccine, three were disproportionality analyses and two observed-to excepted analyses, suggesting great caution should be taken when interpreting these results.

Onset of various CNS inflammatory demyelination diseases following COVID-19 vaccinations. BACKGROUND: Since the start of COVID-19 vaccination worldwide, there have been several reports of inflammatory demyelinating diseases of the central nervous system (CNS-IDDs) following vaccination. METHODS: We prospectively collected cases of new-onset CNS-IDDs with a temporal relationship between disease onset and COVID-19 vaccination and investigated their proportion among newly registered cases of CNS-IDD over the past year. RESULTS: Among 117 cases, 10 (8.5%) had their first disease manifestation within one month following COVID-19 vaccination: 2 multiple sclerosis, 2 neuromyelitis optica spectrum disorder, 3 MOG antibody-associated disease, and 3 unclassified CNS-IDDs. CONCLUSION: This observation suggests that COVID-19 vaccination may trigger the onset of various CNS-IDDs in susceptible individuals.

Autopsy findings of post-COVID-19 vaccination deaths in Tokyo Metropolis, Japan, 2021. BACKGROUND: COVID-19 vaccines have been used across Japan since 17 February 2021, and as of 17 April 2022, 1690 deaths potentially caused by vaccine-related adverse effects have been reported to the Ministry of Health, Labour and Welfare. However, the causal relationship between vaccination and death could not be fully evaluated because of a lack of sufficient information. METHODS: Autopsy cases in which deaths occurred within seven days after COVID-19 vaccination in Tokyo Metropolis and were handled by medical examiners were selected (nÂ =Â 54). Age, sex, vaccine-related information, cause of death, and possible causal relationship between vaccination and death were examined. RESULTS: The mean age of the deceased individuals was 68.1Â years, and the study sample consisted of 34 males (63.9%) and 20 females (37.0%). Thirty-seven and six individuals received Comirnaty and Spikevax, respectively (68.5% and 11.1% respectively). The manner of death included natural (nÂ =Â 43), non-natural (nÂ =Â 8), and undetermined (nÂ =Â 3). The most frequent cause of death was ischemic heart disease (nÂ =Â 16). Regarding causal relationships, 46 cases (85.2%) did not show a causal relationship to vaccination, except for myocarditis (nÂ =Â 3), thrombosis-related death (nÂ =Â 4), and others (nÂ =Â 1). CONCLUSION: Although many cases of deaths after COVID-19

vaccination in this study showed no definite causal relationship between the vaccination and deaths, some cases showed possible adverse events such as myocarditis. Autopsies are essential for detecting vaccine-related deaths, and the Japanese death investigation system needs to be reinforced from this viewpoint.

Preexisting anti-PF4 antibodies are not further triggered upon vaccination with SARS-CoV-2 vector vaccines in a cohort of 400 health care workers.

Parents' and guardians' acceptability of COVID-19 vaccination for children in Ghana: An online survey. Few studies have examined the intentions of parents and guardians to vaccinate their children younger than 18 years against COVID-19 in Ghana. Parents are the decision makers for children younger than 18 years; therefore, we examined parents' and guardians' intentions to accept the COVID-19 vaccines for their children. An online survey was conducted among 415 parents and guardians in Ghana. The Statistical Package for Social Sciences version 25 was used to analyse the data. We found that 73.3% of parents/guardians would allow their children to be vaccinated against COVID-19. The binary logistic regression analysis shows that parents/guardians with Senior High School education, those who believed COVID-19 could not be cured, and those who agreed and those who neither agreed nor disagreed with the statement "once the vaccine is available and approved, it would be safe" were less likely to accept COVID-19 vaccine for their children. Also, parents/guardians who neither agreed nor disagreed that "the best way to avoid the complications of COVID-19 is by being vaccinated", those who agreed that "I am of the notion that physiological/natural community is better compared to vaccine-induced immunity" and "I believe the vaccine programming may be likened to the new world order" were less likely to accept COVID-19 vaccine for their children. There is a need for public health practitioners to intensify education on the benefits and side effects of COVID-19 vaccines, as well as provide regular and up-to-date information about vaccines' safety to parents and guardians.

Changes in Health and Quality of Life in US Skilled Nursing Facilities by COVID-19 Exposure Status in 2020. IMPORTANCE: During the COVID-19 pandemic, the US federal government required that skilled nursing facilities (SNFs) close to visitors and eliminate communal activities. Although these policies were intended to protect residents, they may have had unintended negative effects. OBJECTIVE: To assess health outcomes among SNFs with and without known COVID-19 cases. DESIGN, SETTING, AND PARTICIPANTS: This retrospective observational study used US Medicare claims and Minimum Data Set 3.0 for January through November in each year beginning in 2018 and ending in 2020 including 15â€¯477 US SNFs with 2â€¯985â€¯864 resident-years. EXPOSURES: January through November of calendar years 2018, 2019, and 2020. COVID-19 diagnoses were used to assign SNFs into 2 mutually exclusive groups with varying membership by month in 2020: active COVID-19 (â‰¥1 COVID-19 diagnosis in the current or past month) or no-known COVID-19 (no observed diagnosis by that month). MAIN OUTCOMES AND MEASURES: Monthly rates of mortality, hospitalization, emergency department (ED) visits, and monthly changes in activities of daily living (ADLs), body weight, and depressive symptoms. Each SNF in 2018 and 2019 served as its own control for 2020. RESULTS: In 2018-2019, mean monthly mortality was 2.2%, hospitalization 3.0%, and ED visit rate 2.9% overall. In 2020, among active COVID-19 SNFs compared with their own 2018-2019 baseline, mortality increased by 1.60% (95% CI, 1.58% to 1.62%), hospitalizations decreased by 0.10% (95% CI, -0.12% to -0.09%), and ED visit rates decreased by 0.57% (95% CI, -0.59% to -0.55%). Among no-known COVID-19 SNFs, mortality decreased by 0.15% (95% CI, -0.16% to -0.13%), hospitalizations by 0.83% (95% CI, -0.85% to -0.81%), and ED visits by 0.79% (95% CI, -0.81% to -0.77%). All changes were statistically significant. In 2018-2019, across all SNFs, residents required assistance with an additional 0.89 ADLs between January and November, and lost 1.9 lb; 27.1% had worsened depressive symptoms. In 2020, residents in active COVID-19 SNFs required assistance with an

additional 0.36 ADLs (95% CI, 0.34 to 0.38), lost 3.1 lb (95% CI, -3.2 to -3.0 lb) more weight, and were 4.4% (95% CI, 4.1% to 4.7%) more likely to have worsened depressive symptoms, all statistically significant changes. In 2020, residents in no-known COVID-19 SNFs had no significant change in ADLs (-0.06 [95% CI, -0.12 to 0.01]), but lost 1.8 lb (95% CI, -2.1 to -1.5 lb) more weight and were 3.2% more likely (95% CI, 2.3% to 4.1%) to have worsened depressive symptoms, both statistically significant changes. CONCLUSIONS AND RELEVANCE: Among skilled nursing facilities in the US during the first year of the COVID-19 pandemic and prior to the availability of COVID-19 vaccination, mortality and functional decline significantly increased at facilities with active COVID-19 cases compared with the prepandemic period, while a modest statistically significant decrease in mortality was observed at facilities that had never had a known COVID-19 case. Weight loss and depressive symptoms significantly increased in skilled nursing facilities in the first year of the pandemic, regardless of COVID-19 status.

Sever erythema multiforme post-COVID-19 moderna vaccine: Case report and literature review. INTRODUCTION: Although the COVID-19 Vaccine usually causes a few non-serious side effects, serious ones such as Erythema multiforme recently has been linked to it. CASE PRESENTATION: Our patient presented with severe skin reaction one day post-Covid-19 Moderna vaccine diagnosed as erythema multiforme proven by skin biopsy that responded well to steroids. DISCUSSION: Erythema multiform major, an immune-mediated cutaneous reaction to infections or drugs involving the oral cavity, should be considered a possible adverse effect of numerous vaccinations, including SARSCoV2. Correct patient history gathering enables early detection and successful medical therapy with oral corticosteroids.Furthermore, the disease's rarity makes establishing a causative link difficult. However, because we are still learning about the innovative antiSARSCoV2 vaccines, it is crucial to be cautious of the potential cutaneous adverse responses. CONCLUSION: Despite being rare, life-threatening adverse reactions can occur post-COVID-19 Vaccination.

COVID-19 vaccination related exacerbations of hair loss in patients with moderate-to-severe alopecia areata on systemic therapy.

Humoral immune responses against SARS-CoV-2 Spike variants after mRNA vaccination in solid organ transplant recipients. Although SARS-CoV-2 mRNA vaccination has been shown to be safe and effective in the general population, immunocompromised solid organ transplant recipients (SOTRs) were reported to have impaired immune responses after one or two doses of vaccine. In this study, we examined humoral responses induced after the second and the third dose of mRNA vaccine in different SOTR (kidney, liver, lung, and heart). Compared to a cohort of SARS-CoV-2 naÃ¯ve immunocompetent health care workers (HCWs), the second dose induced weak humoral responses in SOTRs, except for the liver recipients. The third dose boosted these responses but they did not reach the same level as in HCW. Interestingly, although the neutralizing activity against Delta and Omicron variants remained very low after the third dose, Fc-mediated effector functions in SOTR reached similar levels as in the HCW cohort. Whether these responses will suffice to protect SOTR from severe outcome remains to be determined.

New-Onset Ocular Myasthenia Gravis After Booster Dose of COVID-19 Vaccine. Coronavirus disease 2019 (COVID-19) vaccines have been reported as possible triggers of the production of antibodies pathogenic to the peripheral nerve and neuromuscular junction.Â We report on a patient who experienced vertical diplopia three weeks after the booster dose of the Pfizer-BioNTech vaccine (ComirnatyÂ®). The diagnosis ofÂ myasthenia gravis (MG) was established based on highly positive antibodies to the nicotinic acetylcholine receptor (nAChR). Treatment with pyridostigmine and prednisone was started with gradually raising doses. On a follow-up exam two months after treatment initiation, clinical improvement was noted with an almost normal bulbomotor

examination.Â The occurrence of diplopia following COVID-19 vaccination should raise suspicion of new-onset ocular MG and testing for anti-nAChR antibodies is advised.

Disruptions to routine childhood vaccinations in low- and middle-income countries during the COVID-19 pandemic: A systematic review. BACKGROUND: The COVID-19 pandemic has disrupted routine childhood vaccinations worldwide with low- and middle-income countries (LMICs) most affected. This study aims to quantify levels of disruption to routine vaccinations in LMICs. METHODS: A systematic review (PROSPERO CRD42021286386) was conducted of MEDLINE, Embase, Global Health, CINAHL, Scopus and MedRxiv, on the 11th of February 2022. Primary research studies published from January 2020 onwards were included if they reported levels of routine pediatrics vaccinations before and after March 2020. Study appraisal was performed using NHLBI tool for cross-sectional studies. Levels of disruption were summarized using medians and interquartile ranges. RESULTS: A total of 39 cross-sectional studies were identified. These showed an overall relative median decline of -10.8% [interquartile range (IQR) -27.6%, -1.4%] across all vaccines. Upper-middle-income countries (upper-MICs) (-14.3%; IQR -24.3%, -2.4%) and lower-MICs (-18.0%; IQR -48.6%, -4.1%) showed greater declines than low-income countries (-3.1%; IQR -12.8%, 2.9%), as did vaccines administered at birth (-11.8%; IQR -27.7%, -3.5%) compared to those given after birth (-8.0%; IQR -28.6%, -0.4%). Declines during the first 3 months of the pandemic (-8.1%; IQR -35.1%, -1.4%) were greater than during the remainder of 2020 (-3.9%; IQR -13.0%, 11.4%) compared to baseline. CONCLUSION: There has been a decline in routine pediatric vaccination, greatest in MICs and for vaccines administered at birth. Nations must prioritize catch-up programs alongside public health messaging to encourage vaccine uptake. SYSTEMATIC REVIEW REGISTRATION: Identifier: CRD42021286386.

Vaccine-associated enhanced disease in humans and animal models: Lessons and challenges for vaccine development. The fight against infectious diseases calls for the development of safe and effective vaccines that generate long-lasting protective immunity. In a few situations, vaccine-mediated immune responses may have led to exacerbated pathology upon subsequent infection with the pathogen targeted by the vaccine. Such vaccine-associated enhanced disease (VAED) has been reported, or at least suspected, in animal models, and in a few instances in humans, for vaccine candidates against the respiratory syncytial virus (RSV), measles virus (MV), dengue virus (DENV), HIV-1, simian immunodeficiency virus (SIV), feline immunodeficiency virus (FIV), severe acute respiratory syndrome coronavirus 1 (SARS-CoV-1), and the Middle East respiratory syndrome coronavirus (MERS-CoV). Although alleviated by clinical and epidemiological evidence, a number of concerns were also initially raised concerning the short- and long-term safety of vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which is causing the ongoing COVID-19 pandemic. Although the mechanisms leading to this phenomenon are not yet completely understood, the individual and/or collective role of antibody-dependent enhancement (ADE), complement-dependent enhancement, and cell-dependent enhancement have been highlighted. Here, we review mechanisms that may be associated with the risk of VAED, which are important to take into consideration, both in the assessment of vaccine safety and in finding ways to define models and immunization strategies that can alleviate such concerns.

BNT162b2 induced neutralizing and non-neutralizing antibody functions against SARSCoV-2 diminish with age. Each novel SARS-CoV-2 variant renews concerns about decreased vaccine efficacy caused by evasion of vaccine induced neutralizing antibodies. However, accumulating epidemiological data show that while vaccine prevention of infection varies, protection from severe disease and death remains high. Thus, immune responses beyond neutralization could contribute to vaccine efficacy. Polyclonal antibodies function through their Fab domains that neutralize virus directly, and Fc domains that induce non-neutralizing host responses via engagement of Fc receptors on immune cells. To understand how vaccine induced neutralizing and non-neutralizing activities synergize to

promote protection, we leverage sera from 51 SARS-CoV-2 uninfected health-care workers after two doses of the BNT162b2 mRNA vaccine. We show that BNT162b2 elicits antibodies that neutralize clinical isolates of wildtype and five variants of SARS-CoV-2, including Omicron BA.2, and, critically, induce Fc effector functions. FcÎ³RIIIa/CD16 activity is linked to neutralizing activity and associated with post-translational afucosylation and sialylation of vaccine specific antibodies. Further, neutralizing and non-neutralizing functions diminish with age, with limited polyfunctional breadth, magnitude and coordination observed in those â‰¥65 years old compared to <65. Thus, studying Fc functions in addition to Fab mediated neutralization provides greater insight into vaccine efficacy for vulnerable populations such as the elderly against SARS-CoV-2 and novel variants.

Myocarditis After the Third Dose of mRNA-1273 Coronavirus Disease 2019 (COVID-19) Vaccine.

Psychological effects and associated factors among vaccinated and unvaccinated general population against COVID-19 infection in Bangladesh. BACKGROUND: The global effort to develop herd immunity in the general public against the COVID-19 pandemic is currently ongoing. However, to the best of our knowledge, there have been no studies on how the COVID-19 vaccine affects mental health in the context of the COVID-19 pandemic in Bangladesh. The present study investigated the psychological effects and associated factors among vaccinated and unvaccinated general populations against COVID-19 infection in Bangladesh. METHODS: A nationwide online cross-sectional survey was conducted in Bangladesh from June 23 to December 25, 2021. The frequency of symptoms of psychological distress, depression, anxiety, stress, post-traumatic stress disorder (PTSD), insomnia, and fear was assessed using the Bangla versions of the GHQ-12, PHQ-2, GAD-2, PSS-4, PC-PTSD-5, ISI, and FCV-19S scales, respectively. RESULTS: The study included 3,013 persons from all eight divisions of Bangladesh, with 1,272 (42.2%) being vaccinated and 1,741 (57.8%) being unvaccinated. Compared with unvaccinated populations, vaccinated populations had significantly lower prevalence rates of psychological distress (36.4 vs. 51.5%), depression (21.1 vs. 37.9%), anxiety (25.1 vs. 44.9%), stress (19.4 vs. 30.4%), PTSD (29.4 vs. 38.3%), insomnia (18.7 vs. 39.4%), and fear symptoms (16.1 vs. 27.5%). Among vaccinated populations, respondents who lived in nuclear families were significantly associated with higher risk of psychological distress (AOR, 1.38; 95% CI, 1.09-1.78), depression (AOR, 1.49; 95% CI, 1.11-1.98), anxiety (AOR, 1.77; 95% CI, 1.21-1.98), and fear (AOR, 1.43; 95% CI, 1.11-1.83) symptoms. Participants who lost family members, friends, or colleagues due to the COVID-19 pandemic had significantly higher risk of symptoms of psychological distress (AOR, 1.35; 95% CI, 1.02-1.79), anxiety (AOR, 1.41; 95% CI, 1.11-1.87), and PTSD (AOR, 1.76; 95% CI, 1.24-2.19). On the other hand, unvaccinated populations who lived in the Dhaka division were significantly associated with an increased risk of depression (AOR, 2.06; 95% CI, 1.40-2.52), anxiety (AOR, 1.86; 95% CI, 1.15-2.47), stress (AOR, 1.92; 95% CI, 1.12-2.88), and insomnia (AOR, 1.88; 95% CI, 1.20-2.94) symptoms. Except for PTSD and fear symptoms, unemployed participants had considerably higher rates of psychological distress, depression, anxiety, stress, and insomnia symptoms (e.g., psychological distress: AOR, 1.83; 95% CI, 1.10-2.62; depression: AOR, 1.74; 95% CI, 1.37-2.19). CONCLUSIONS: This study recommends immunizing unvaccinated populations as soon as possible to prevent infection and boost mental health. Vulnerable people needed special care, health-related education, and psychological assistance.

Case report: A pediatric case of Bickerstaff brainstem encephalitis after COVID-19 vaccination and Mycoplasma pneumoniae infection: Looking for the culprit. Bickerstaff brainstem encephalitis (BBE) is a rare, immune-mediated disease characterized by the acute onset of external ophthalmoplegia, ataxia, and consciousness disturbance. It has a complex multifactorial etiology, and a preceding infectious illness is seen in the majority of cases. Immune-mediated neurological syndromes following COVID-19 vaccination have been increasingly described. Here we report the case of a child developing BBE 2 weeks after COVID-19 vaccination. Despite nerve conduction studies

and CSF analysis showing normal results, BBE was diagnosed on clinical ground and immunotherapy was started early with a complete recovery. Later, diagnosis was confirmed by positive anti-GQ1b IgG in serum. Even if there was a close temporal relationship between disease onset and COVID-19 vaccination, our patient also had evidence of a recent Mycoplasma pneumoniae infection that is associated with BBE. Indeed, the similarity between bacterial glycolipids and human myelin glycolipids, including gangliosides, could lead to an aberrantly immune activation against self-antigens (i.e., molecular mimicry). We considered the recent Mycoplasma pneumoniae infection a more plausible explanation of the disease onset. Our case report suggests that suspect cases of side effects related to COVID-19 vaccines need a careful evaluation in order to rule out well-known associated factors before claiming for a causal relationship.

Persistent but atypical germinal center reaction among 3(rd) SARS-CoV-2 vaccination after rituximab exposure. BACKGROUND: Durable vaccine-mediated immunity relies on the generation of long-lived plasma cells and memory B cells (MBCs), differentiating upon germinal center (GC) reactions. SARS-CoV-2 mRNA vaccination induces a strong GC response in healthy volunteers (HC), but limited data is available about response longevity upon rituximab treatment. METHODS: We evaluated humoral and cellular responses upon 3rd vaccination in seven patients with rheumatoid arthritis (RA) who initially mounted anti-spike SARS-CoV-2 IgG antibodies after primary 2x vaccination and got re-exposed to rituximab (RTX) 1-2 months after the second vaccination. Ten patients with RA on other therapies and ten HC represented the control groups. As control for known long-lived induced immunity, we analyzed humoral and cellular tetanus toxoid (TT) immune responses in steady-state. RESULTS: After 3(rd) vaccination, 5/7 seroconverted RTX patients revealed lower anti-SARS-CoV-2 IgG levels but similar neutralizing capacity compared with HC. Antibody levels after 3rd vaccination correlated with values after 2nd vaccination. Despite significant reduction of circulating total and antigen-specific B cells in RTX re-exposed patients, we observed the induction of IgG+ MBCs upon 3(rd) vaccination. Notably, only RTX treated patients revealed a high amount of IgA+ MBCs before and IgA+ plasmablasts after 3(rd) vaccination. IgA+ B cells were not part of the steady state TT+ B cell pool. TNF-secretion and generation of effector memory CD4 spike-specific T cells were significantly boosted upon 3(rd) vaccination. SUMMARY: On the basis of pre-existing affinity matured MBCs within primary immunisation, RTX re-exposed patients revealed a persistent but atypical GC immune response accompanied by boosted spike-specific memory CD4 T cells upon SARS-CoV-2 recall vaccination.

Safety, immunogenicity, and immune persistence of two inactivated COVID-19 vaccines replacement vaccination in China: An observational cohort study. BACKGROUND: To mitigate a national shortage of WIBP-CorV COVID-19 vaccine, China's regulator approved administering BBIBP-CorV after WIBP-CorV for completion of a primary series. In a pragmatic observational study, we compared immunogenicity and safety of a primary series of WIBP-CorV followed by BBIBP-CorV with a primary series of two doses of BBIBP-CorV. METHODS: We invited healthy 18-59-years-old adults who had already received either WIBP-CorV or BBIBP-CorV as their first dose in a primary series to participate in this observational cohort study. Subjects who had received WIBP-CorV as their first dose became the observation group; subjects who had received BBIBP-CorV as their first dose became the control group. All participants received BBIBP-CorV as their second dose. We obtained sera 1, 2, and 6Â months after second doses for nAb titer measurement by micro-neutralization cytopathic effect assay with SARS-CoV-2 strain HB01, standardized with WHO International Standard for anti-SARS-CoV-2 immunoglobulin. Safety was assessed for the 7Â days after administration of second doses. RESULTS: Between March and December 2021, 275 subjects were included in the observation group and 133 in the control group. Neutralizing seropositivity (â‰¥1:4) rates were 98.91Â % and 99.25Â % at 1Â month and 53.16Â % and 70.69Â % at 6Â months. One-month geometric mean titers (GMTs)

were 21.33 and 22.45; one-month geometric mean concentrations (GMCs) were 227.71Â IU/mL and 273.27Â IU/mL. One to two months after vaccination, observation group seropositivity rates and titers were not significantly different to the control group's. Adverse reaction rates were 11.27Â % and 18.80Â %, all mild or moderate in severity. CONCLUSIONS: Both primary series were immunogenic; immunogenicity of WIBP-CorV followed by BBIBP-CorV was not different than immunogenicity following two doses of BBIBP-CorV for two months after vaccination; safety profiles were acceptable for both regimens. BBIBP-CorV can be used to complete a primary series that started with WIBP-CorV.

Comparison of the reactogenicity and immunogenicity of a reduced and standard booster dose of the mRNA COVID-19 vaccine in healthy adults after two doses of inactivated vaccine. The coronavirus disease 2019 (COVID-19) pandemic has been a serious healthcare problem worldwide since December 2019. The third dose of heterologous vaccine was recently approved by World Health Organization. The present study compared the reactogenicity and immunogenicity of the reduced and standard third booster dose of the BNT162b2 and mRNA-1273 vaccine in adults who previously received the two-dose CoronaVac vaccine. Results showed that headache, joint pain, and diarrhea were more frequent in the 15Â Î¼g- than the 30Â Î¼g-BNT162b2 groups, whereas joint pain and chilling were more frequent in the 100Â Î¼g- than the 50Â Î¼g-mRNA-1273 groups. No significant differences in immunogenicity were detected. These findings demonstrate that the reduced dose of the mRNA vaccines elicited antibody responses against the SARS-CoV-2 delta and omicron variants that were comparable to the standard dose. The reduced dose could be used to increase vaccine coverage in situations of limited global vaccine supply.

Association Between Fever and Antibody Titer Trends After a Third Dose of the mRNA-1273 Vaccine.

COVID-19 vaccine uptake and attitudes among pregnant and postpartum parents. BACKGROUND: Pregnancy poses increased risks from COVID-19, including hospitalization and premature delivery. Yet pregnant individuals are less likely to have received a COVID-19 vaccine. OBJECTIVE: This study aimed to investigate COVID-19 vaccine uptake and reasons for delay or refusal among perinatal parents. STUDY DESIGN: A total of 1542 eligible parents who delivered between 2019 and 2021 were surveyed through the Ovia parenting app, which has a nationally representative user base. Adjusted and nationally weighted means were calculated. Multivariate logistic regression and survival models were used to examine uptake. RESULTS: At least 1 dose of the COVID-19 vaccine was received by 70% of the parents. Those with a bachelor's or graduate degree were significantly more likely to have received a vaccine relative to those with some college or less (adjusted odds ratio for bachelor's degree, 1.854; 95% confidence interval, 1.19-2.90; adjusted odds ratio for graduate degree, 2.833; 95% confidence interval, 1.69-4.75). Parents living in rural areas were significantly less likely to have received a vaccine relative to those living in urban areas (adjusted odds ratio for small city, 0.62; 95% confidence interval, 0.45-0.86; adjusted odds ratio for rural area, 0.56; 95% confidence interval, 0.35-0.89); 56% (281/502) of unvaccinated parents considered that the vaccine "was too new." Among those pregnant in 2021, 44% (258/576) received at least 1 dose, and 34% (195/576) reported that pregnancy had "no impact" on their vaccine decision. CONCLUSION: There was significant heterogeneity in vaccine uptake and attitudes toward vaccines during pregnancy by sociodemographics and over time. Public health experts need to consider and test more tailored approaches to reduce vaccine hesitancy in this population.

The associations between COVID-19 vaccination and psychological disorders among healthcare workers in China. INTRODUCTION: COVID-19 has caused an unprecedented psychological affection that might impact the nationwide vaccination program in China. This study was to explore the association between COVID-19 vaccination and psychological disorders among healthcare workers. METHODS: The study included 1571 healthcare workers from an anonymous online survey.

Participants' sociodemographic characteristics, uptake data for the COVID-19 vaccine, and scores of the Depression, Anxiety, and Stress Scale (DASS-21) were collected. Nonparametric tests were conducted to compare the mean scores of DASS-21 between different subgroups. The potential factors related to psychological disorders of healthcare workers were analyzed using logistic regression. RESULTS: The vaccination rate was 69.6Â %, the incidence of vaccine-related adverse events was 35.13Â %, and the prevalence of depression, anxiety, and stress were 24.8Â %, 32Â %, and 33.4Â % in this study, respectively. Compared to vaccinated participants (single-dose and double-dose vaccines), unvaccinated participants got significantly higher mean scores of DASS-21 (pÂ <Â 0.05 for all). Vaccinated participants who suffered no adverse events scored significantly lower than those who suffered 1-2 or â‰¥3 adverse events (pÂ <Â 0.05 for all). Vaccination was negatively associated with higher depression, anxiety, and stress, however, the number of vaccine-related adverse events was positively associated with them. LIMITATIONS: As this is a cross-sectional study, we could only speculate on the causality. CONCLUSIONS: An obvious impact of the psychological disorders on the COVID-19 vaccine coverage and related adverse events was detected in this study. Public health agencies should attach great importance to the psychological states of our citizens before getting vaccinated.

COVID-19: Vaccine-induced immune thrombotic thrombocytopenia. In late February 2021, a prothrombotic syndrome was encountered for the first time in some of the recipients of ChAdOx1 CoV-19 vaccine (AstraZeneca, University of Oxford, and Serum Institute of India). Since the hallmark of this syndrome is the development of thrombocytopenia and/or thrombosis between 4 and 42â€‰days after receiving a COVID-19 vaccine, it was named vaccine-induced immune thrombotic thrombocytopenia (VITT). Other names include "vaccine-induced prothrombotic immune thrombocytopenia" and "thrombosis with thrombocytopenia syndrome" by the Centers for Disease Control and the Food and Drug Administration (FDA). VITT appears similar to heparin-induced thrombocytopenia in that "platelet activating" autoantibodies are produced in both these conditions due to prior exposure of COVID-19 vaccine and heparin respectively, in turn causing thrombotic complications and consumptive thrombocytopenia. In this article, recent advances in the understanding of pathobiology, clinical features, investigative work-up, and management of VITT are reviewed.

A Prospective Observational Study on BBV152 Coronavirus Vaccine Use in Adolescents and Comparison with Adults: Interim Results of the First Real-World Safety Analysis. INTRODUCTION: The BBV152 coronavirus disease 2019 (COVID-19) vaccine (COVAXIN) has recently been approved for adolescents. OBJECTIVE: We provide the first real-world safety data of COVAXIN use in adolescents and compare with adults. METHODS: A prospective observational study was initiated in January 2022. Enrolled adolescents and adults were contacted by telephone after 14Â days of receiving the BBV152 vaccine. The primary outcome was vaccine safety assessed as rate of adverse events following immunization (AEFIs). Severity grading of AEFIs was done using the Food and Drug Administration (FDA) scale. Interim results are presented. RESULTS: A total of 698 adolescents and 326 adults were enrolled. AEFIs after the first dose developed in 243 out of 670 adolescents (36.3%), with 21% reporting only local AEFIs and 15.2% reporting systemic AEFIs. Among 340 adolescents who had received the second dose of vaccine, 129 (37.9%) developed AEFIs, with only local involvement in 20.3% and systemic involvement in 17.6%. Injection site pain and fever were the common AEFIs. The majority of AEFIs were mild-moderate. Nearly 0.9% of adolescents receiving the first dose reported severe AEFIs. Atypical AEFIs were observed in 0.6-0.9% of adolescents. The majority of the AEFIs resolved in 1-2Â days. AEFIs were persistent in >â€‰2% of adolescents at day 14 after the second dose, and also in 3.7% of adults overall at follow-up. No difference was observed in AEFI incidence and patterns between adolescents and adults. Regression analysis showed females and those with a

history of allergy to be, respectively, at 1.6 times and 3 times increased risk of AEFIs among adolescents. CONCLUSIONS: COVAXIN carries an overall favorable short-term safety profile in adolescents. The observed AEFI rates in adolescents are much lower than that reported with mRNA vaccines, but head-head comparisons in the same population are required to generate relative vaccine safety data. Female adolescents and those with a history of allergy need watchfulness for severe and persistent AEFIs. With some AEFIs persisting at 14 days, a longer follow-up is recommended to strengthen the safety data of COVAXIN.

Antibody titers among healthcare workers for coronavirus disease 2019 at 6Â months after BNT162b2 vaccination. BACKGROUND: Antibody levels decrease substantially at 6Â months after the BNT162b2 vaccine. The factors influencing titer of antibodies against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) among healthcare workers for coronavirus disease 2019 (COVID-19) is unclear. METHODS: We conducted a 6-month longitudinal prospective study in Japanese healthcare workers in a tertiary care hospital for COVID-19. Participants in the study were tested for the presence of anti-spike protein (SP) IgG antibodies before and at 1 and 6Â months after the last vaccination dose. RESULTS: Among 1076 healthcare workers, 794 received the vaccine, and 469 entered the study. Five were infected with SARS-CoV-2 (none among COVID-19 section workers) by the end of the study and 451 participants were finally analyzed (mean age, 42.5Â years; 27.3Â % male; 18.8Â % COVID-19 section workers). Median SP IgG index values were 0.0, 44.4, and 5.5 before and at 1 and 6Â months after the last dose, respectively. Regression analysis revealed a negative correlation of SP IgG antibody levels with age (PÂ <Â 0.0001), and higher levels in COVID-19 section workers (PÂ =Â 0.0185) and in females (PÂ =Â 0.0201). CONCLUSION: In healthcare workers at a COVID-19 hospital, IgG antibody titer was substantially lower at 6Â months after receipt of the last dose of the BNT162b2 vaccine compared with that 1Â month after the last dose, but was better preserved among younger participants, COVID-19 section workers and females.

Immune thrombocytopenic purpura and COVID-19 vaccination.

Multiple sclerosis relapse after COVID-19 vaccination: A case report-based systematic review. BACKGROUND: Concerns about vaccination increased among patients with multiple sclerosis (MS) regarding side effects, efficacy, and disease exacerbation. Recently there were reports of MS relapses after the COVID-19 vaccination, which emerged the safety concerns. Therefore, we aimed to perform a systematic review of case reports and case series studies to investigate the MS relapses after COVID-19 vaccination with most details. METHODS: We systematically searched three databases, including PubMed, Scopus, and Web of Science, in February 2022. Case reports and case series which reported relapse after COVID-19 vaccination in MS patients were eligible to include in our study. RESULTS: Seven studies were included in our systematic review after the abstract and full-text screening with a total of 29 cases. The mean duration between COVID-19 vaccination and relapse appearance was 9.48Â Â±Â 7.29Â days. Among patients, 22 cases experienced relapse after their first dosage of the COVID-19 vaccine, one after the second dose, and five after the booster dose. The type of vaccine was unknown for one patient. The most common symptoms of relapses were sensory deficits (paresthesia, numbness, dysesthesia, and hypoesthesia) and weakness. CONCLUSION: Overall, the COVID-19 vaccination may trigger relapses in some MS patients, but as the infection itself can stimulate relapse, the benefit of vaccination outweighs its risk in this population, and mass vaccination against COVID-19, especially in MS patients, should be continued and encouraged.

COVID-19 mRNA vaccine BNT162b2 induces autoantibodies against type I interferons in a healthy woman. Coronavirus disease (COVID-19) caused by SARS-CoV-2 virus is associated with a wide range of clinical manifestations, including autoimmune features and autoantibody production in a small subset of patients. Pre-exiting neutralizing autoantibodies against type I interferons (IFNs) are associated with COVID-19 disease severity. In this case report, plasma levels of IgG against type I

interferons (IFNs) were increased specifically among the 103 autoantibodies tested following the second shot of COVID-19 vaccine BNT162b2 compared to pre-vaccination and further increased following the third shot of BNT162b2 in a healthy woman. Unlike COVID-19 mediated autoimmune responses, vaccination in this healthy woman did not induce autoantibodies against autoantigens associated with autoimmune diseases. Importantly, IFN-Î±-2a-induced STAT1 responses in human PBMCs in vitro were suppressed by adding plasma samples from the study subject post- but not pre-vaccination. After the second dose of vaccine, the study subject exhibited severe dermatitis for about six months and responded to treatments with Betamethasone Dipropionate Ointment and antihistamines for about one month. Immune responses to type I IFN can be double-edged swords in enhancing vaccine efficacy and immune responses to infectious diseases, as well as accelerating chronic disease pathogenesis (e.g., chronic viral infections and autoimmune diseases). This case highlights the BNT162b2-induced neutralizing anti-type I IFN autoantibody production, which may affect immune functions in a small subset of general population and patients with some chronic diseases.

Assessing Age-Specific Vaccination Strategies and Post-vaccination Reopening Policies for COVID-19 Control Using SEIR Modeling Approach. As the availability of COVID-19 vaccines, it is badly needed to develop vaccination guidelines to prioritize the vaccination delivery in order to effectively stop COVID-19 epidemic and minimize the loss. We evaluated the effect of age-specific vaccination strategies on the number of infections and deaths using an SEIR model, considering the age structure and social contact patterns for different age groups for each of different countries. In general, the vaccination priority should be given to those younger people who are active in social contacts to minimize the number of infections, while the vaccination priority should be given to the elderly to minimize the number of deaths. But this principle may not always apply when the interaction of age structure and age-specific social contact patterns is complicated. Partially reopening schools, workplaces or households, the vaccination priority may need to be adjusted accordingly. Prematurely reopening social contacts could initiate a new outbreak or even a new pandemic out of control if the vaccination rate and the detection rate are not high enough. Our result suggests that it requires at least nine months of vaccination (with a high vaccination rate >â€‰0.1%) for Italy and India before fully reopening social contacts in order to avoid a new pandemic.

Safety of mRNA COVID-19 vaccines in patients with well-controlled myasthenia gravis. INTRODUCTION/AIMS: Data on safety and tolerability of the vaccines against severe acute respiratory virus coronavirus-2 (SARS-CoV-2, or coronavirus disease-2019 [COVID-19]) in patients with myasthenia gravis (MG) are currently limited. In this study we investigated the safety of mRNA-based two-dose vaccination in a cohort of patients with MG. METHODS: This investigation was a prospective observational study of messenger RNA (mRNA)-based vaccines administered to patients with MG with stable disease. Local and systemic reactogenicity after injection was monitored for each dose administered. The patients were categorized and clinically assessed following the recommendations of the Myasthenia Gravis Foundation of America. RESULTS: Thirty-six males and 55 females (mean age at first vaccine dose, 58.8â€‰years; standard deviation,Â =â€‰17.1â€‰years) received vaccines. Seventy-two patients (79.1%) were taking one or more immunosuppressant(s). The most frequent adverse effects were injection-site pain, fatigue, myalgia, chills, fever, and headache. Local and systemic reactions were transient; 58.2% of the patients developed one or more reaction(s). There were no anaphylactic reactions. None of the patients had a myasthenic crisis, and two developed a mild deterioration compared with their Quantitative Myasthenia Gravis baseline score. The clinical outcome scores showed no exacerbation of MG symptoms. Patients over 65â€‰years of age developed fewer adverse effects. COVID-19 vaccination did not induce clinical exacerbation in stable patients with MG, regardless of their age, sex, history of myasthenic crisis, or whether they

were taking immunosuppressants. DISCUSSION: Our data are consistent with the mRNA COVID-19 vaccine being well tolerated in patients with well-controlled MG. The findings may contribute to decisions in vaccination campaigns in the future.

Autoimmune rheumatic disease after SARS-CoV-2 vaccination.

Comparison of Side Effects of COVID-19 Vaccines: Sinopharm, AstraZeneca, Sputnik V, and Covaxin in Women in Terms of Menstruation Disturbances, Hirsutism, and Metrorrhagia: A Descriptive-Analytical Cross-Sectional Study. Present study assessed whether Sinopharm, AstraZeneca, Sputnik V, and Covaxin's vaccinated women
reveal a distinct incidence of menstruation disturbances, hirsutism, and metrorrhagia.
Materials and Methods: Data collection was performed from June to August 2021, and 427 women working in seven
selected hospitals in Tehran were studied in this descriptive-analytical cross-sectional study. All of these women had
received one or both doses of the vaccines with one of the assessed vaccines. Required data was collected via questionnaire
and imported to SPSS 16 for further assessment and analysis. Fisher's Exact Test and Chi-Squared test were
main statistical tests used to understand whether any significant relation exists or not.
Results: The participant's mean age and body mass index (BMI) were 29.78 Â± 10.55 and 23.27 Â± 3.82, respectively.
Three hundred ninety-five cases (92.4%) had received both doses of the vaccines. Also, 154 cases (36.1%) had a history
of COVID-19. A total of 38 cases (8.8%) of menstruation disturbances, 20 cases (4.6%) of metrorrhagia, and 7
cases (1.6%) of hirsutism were reported after receiving the vaccines. There was a significant difference among the
vaccinated groups with the vaccines as mentioned earlier in terms of menstruation disturbances (hypermenorrhea,
dysmenorrhea, Amenorrhea) (P=0.01). The highest and the lowest incidence of menstruation disturbances were recorded
in the group vaccinated with Covaxin (17.6%) and Sputnik V (5%), respectively. There was also no significant
difference amongst the vaccinated groups with the four vaccines regarding the incidence of metrorrhagia and
hirsutism (P=0.10 and P=0.12, respectively). There was no significant relationship between all three complications
incidence with the previous infection concerning all vaccines (coefficient=0.46, 1.27, -0.15 respectively for menstruation
disturbances, metrorrhagia, and, hirsutism).
Conclusion: Seemingly, Covaxin revealed the most side effects in terms of menstruation disturbances. As a result, professionals
must carry out several studies with reasonable samples to recommend the vaccine to those women confidently.

Pityriasis rubra pilaris following booster dose of mRNA (Pfizer-BioNTech) COVID-19 vaccine.

Acute dizziness and mental alteration associated with Moderna COVID-19 vaccine: a case report. BACKGROUND: Due to a rising number of COVID-19 cases, the Indonesian government implemented public health programs to lower the rate. Since January 2021, one of the government's primary policies has been the COVID-19 immunization program. Recently, the Moderna messenger ribonucleic acid (mRNA) vaccine is one of the COVID-19 vaccines used in Indonesia. Based on some research, Moderna has possible side effects throughout the body, including neurological symptoms. CASE PRESENTATION: We describe a 39-year-old female with uncontrolled hypertension who showed behavioral change, communication difficulty, social withdrawal, and a confused state within 7â€‰days from getting her first dose of the Moderna vaccine. The patient had a history of febrile convulsion in childhood. An increase of neutrophil-to-lymphocyte ratio (16.9) and C-reactive protein level (31.75â€‰mg/L) indicates ongoing inflammation. Head CT scan shows no abnormalities. She received ceftriaxone, citicoline, and methylprednisolone. The patient was discharged on the seventh day and completely recovered 1 week later. This study is the first case report of encephalopathy following the administration of the Moderna COVID-19 vaccine reported in Indonesia up to our knowledge. CONCLUSION: Encephalopathy related to the Moderna COVID-19 vaccine should be acknowledged as an adverse effect of the Moderna COVID-19 vaccine.

Age- and sex-based changes in spike protein antibody status after SARS-CoV-2 vaccination and effect of past-infection in healthcare workers in Osaka. OBJECTIVE: We aimed to compare the changes in SARS-CoV-2 spike protein antibody titres based on age group and sex using paired blood sampling after vaccination in association with the presence of nucleocapsid protein antibody. METHODS: All participants were healthcare workers at Yao Municipal Hospital in Osaka who voluntarily provided peripheral blood samples (nâ€‰=â€‰636, men/women 151/485, mean age 45Â years). We investigated the serial changes in SARS-CoV-2 spike protein antibody titres at 1 and 7Â months after the second vaccination regarding their relationship with sex and age group. At 7Â months, we also examined anti-nucleocapsid assays. Antibody titres were shown as logarithmic values and the differences were assessed using a paired or unpaired student's t-test as appropriate. RESULTS: Among participants younger than 30Â years, the antibody titres of spike protein were significantly higher in women one (pâ€‰=â€‰0.005) and seven (pâ€‰=â€‰0.038) months after vaccination. However, among those aged 30-49Â years, the antibody titres were not different between the sexes at either follow-up time point. In contrast, among those aged 50-59Â years, between-sex differences in antibody titres were observed only at 7Â months, which was associated with a significant reduction in men. A significant negative correlation was observed between the antibody titres for spike protein at both time points in participants with positive nucleocapsid protein antibody at 7Â months (râ€‰=â€‰-Â 0.467, pâ€‰=â€‰0.043), although a significant positive correlation was observed in those with negative results (râ€‰=â€‰0.645, pâ€‰<â€‰0.001), CONCLUSIONS: Between-sex differences in SARS-CoV-2 spike protein antibody titres by paired blood sampling at different time points after vaccination depended on age group. The presence of nucleocapsid protein antibody was associated with changes in spike protein antibody titres after vaccination.

Association between BNT162b2 vaccination and reported incidence of post-COVID-19 symptoms: cross-sectional study 2020-21, Israel. The effectiveness of Coronavirus disease 2019 (COVID-19) vaccines against the long-term COVID-19 symptoms expressed by a substantial proportion of patients is not well understood. We determined whether vaccination with the BNT162b2 mRNA vaccine was associated with incidence of reporting long-term symptoms post-SARS-CoV-2 infection. We invited individuals PCR-tested for SARS-CoV-2 infection at participating hospitals between March 2020 and November 2021 to fill an online questionnaire that included information about demographics, acute COVID-19 episode and symptoms they were currently experiencing. Using binomial regression, we compared vaccinated individuals with those unvaccinated and those uninfected, in terms of post-acute self-reported symptoms. Of the 951 infected, 637(67%) were vaccinated. In the study population, the most prevalent symptoms were: fatigue (22%), headache (20%), weakness of limbs (13%), and persistent muscle pain (10%). After adjusting for age, time from beginning of symptoms to responding to the survey, and baseline symptoms, those who received two vaccine doses were less likely than unvaccinated individuals to report any of these symptoms (fatigue, headache, weakness of limbs, persistent muscle pain) by 62%, 50%, 62%, and 66% respectively, (Risk ratios 0.38, 0.50, 0.38, 0.34, pâ€‰<â€‰0.04 in the listed sequence). Compared to the 2447 included individuals who never reported SARS-CoV-2 infection, double-vaccinated participants were no more likely to report any of the mentioned symptoms. Vaccination with 2+ doses of BNT162b2 was associated with a reduced risk of reporting most of the common post-acute COVID-19 symptoms. Our results suggest that BNT162b2 vaccination may have a protective effect against longer term COVID-19 symptoms.

Kinetics of anti-SARS-CoV-2 antibody titer in healthy adults up to 6Â months after BNT162b2 vaccination measured by two immunoassays: A prospective cohort study in Japan. BACKGROUND: Although several assays are used to measure anti-receptor-binding domain (RBD) antibodies induced after severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccination, the assays are not fully comparable in practice. This study evaluated the immunogenicity of the

BNT162b2 mRNA vaccine in healthy adults using two immunoassays. METHODS: This prospective cohort study included SARS-CoV-2-naÃ¯ve adults, predominantly healthcare workers, aged 20-64Â years, who received two BNT162b2 vaccine doses between March and May 2021. Blood samples were collected before the first vaccination (S0), before the second vaccination (S1), 4Â weeks after the second vaccination (S2), and 6Â months after the second vaccination (S3). anti-RBD antibodies were measured using the Architect SARS-CoV-2 IgG II Quant (Abbott Laboratory) and Elecsys anti-SARS-CoV-2 S (Roche Diagnostics) assays. RESULTS: Among the 385 participants, the geometric mean antibody titers (GMTs) on the Architect assay (AU/mL) were 7.5, 693, 7007, and 1030 for S0, S1, S2, and S3, respectively. The corresponding GMTs on the Elecsys assay (U/mL) were 0.40, 24, 928, and 659, respectively. The GMT ratio (S3/S2) was 0.15 on the Architect and 0.71 on the Elecsys assay. The correlation between antibody titers measured with the two assays were strong at all time points after vaccination (Spearman's correlation coefficient: 0.74 to 0.86, PÂ <Â 0.01 for all). GMT was significantly lower in the older age group after vaccination (PÂ <Â 0.01), with no significant differences according to sex. Seroprotection (â‰¥5458 AU/mL on the Architect assay andÂ â‰¥Â 753 U/mL on the Elecsys) at each time point was 0Â %, 1Â %, 67Â %, and 1Â % on the Architect assay and 0Â %, 1Â %, 62Â %, and 43Â % on the Elecsys, respectively. CONCLUSIONS: Two BNT162b2 vaccine doses resulted in adequate anti-RBD antibody response, which varied by age. As the two assays showed different kinetics, the results of single immunoassays should be interpreted with caution.

Longitudinal T-Cell Responses After a Third SARS-CoV-2 Vaccination in Patients With Multiple Sclerosis on Ocrelizumab or Fingolimod.

Reactivation of adult-onset Still's disease after use of the COVID-19 ChAdOx1-S vaccine. A woman in her 60s with a history of adult-onset Still's disease (AOSD) in remission for 14 years received the ChAdOx1-S vaccine as a booster to her initial vaccination schedule (two doses of CoronaVac vaccine 6 months apart). Two weeks later, she consulted for symptoms suggestive of AOSD reactivation. This was confirmed during hospitalisation, where renal and cardiac involvement were also observed. Despite using high-dose corticosteroids, troponin T and N-terminal pro hormone B-type natriuretic peptide (NT-proBNP) were persistently elevated. Tocilizumab was used, with which the patient achieved complete remission of her symptoms and normalised her laboratory tests.

Taking cognizance of the risks associated with COVID-19, vaccine, and treatment in liver transplant recipients - A commentary on "The urgency of the Covid-19 vaccine in liver transplantation patients: What, how, and when?" [Int. J. Surg. 100 (Suppl) (2022) 106492)].

A personal COVID-19 dendritic cell vaccine made at point-of-care: Feasibility, safety, and antigen-specific cellular immune responses. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has caused a world-wide pandemic. Internationally, because of availability, accessibility, and distribution issues, there is a need for additional vaccines. This study aimed to: establish the feasibility of personal dendritic cell vaccines to the SARS-CoV-2 spike protein, establish the safety of a single subcutaneous vaccine injection, and determine the antigen-specific immune response following vaccination. In Phase 1, 31 subjects were assigned to one of nine formulations of autologous dendritic cells and lymphocytes (DCL) incubated with 0.10, 0.33, or 1.0â€‰Âµg of recombinant SARS-CoV-2 spike protein, and admixed with saline or 250 or 500â€‰Âµg of granulocyte-macrophage colony-stimulating factor (GM-CSF) prior to injection, then assessed for safety and humoral response. In Phase 2, 145 subjects were randomized to one of three formulations defined by incubation with the same three quantities of spike protein without GM-CSF, then assessed for safety and cellular response. Vaccines were successfully manufactured for every subject at point-of-care. Approximately 46.4% of subjects had a grade 1 adverse event (AE); 6.5% had a grade 2 AE. Among 169 evaluable subjects, there were no acute allergic, grade 3 or 4, or serious AE. In Phase 1,

anti-receptor binding domain antibodies were increased in 70% of subjects on day-28. In Phase 2, in the 127 subjects who did not have high levels of gamma interferon-producing cells at baseline, 94.4% had increased by day 14 and 96.8% by day 28. Point-of-care personal vaccine manufacturing was feasible. Further development of such subject-specific vaccines is warranted.

Bilateral multifocal choroiditis with disc edema in a 15-year-old girl following COVID-19 vaccination. A few cases of posterior uveitis following COVID-19 vaccination have been reported but none in the pediatric age group. A 15-year-old girl presented with history of headache and bilateral blurred vision of five days duration. The symptoms developed five days after vaccination with the first dose of Covaxin (inactivated SARS-CoV-2 vaccine). Her anterior segment was normal in both eyes (BE), whereas the posterior segment showed mild vitritis with disc edema and multiple yellowish lesions at the level of choroid clustered at the macula and associated with multiple serous detachments. BE uveitis resolved, and the vision was completely recovered three weeks after treatment with steroids. Hence, ophthalmologists should be aware of uveitis following vaccination-a condition that is usually benign, transient, and results in excellent outcomes with timely diagnosis and early treatment with steroids.

Cutaneous reactions following booster dose of COVID-19 mRNA vaccination: What we should know?

The Actual Status of Hospitals as COVID-19 Vaccination Clinics in China and Safety Monitoring of Inactivated Vaccine: A Cross-Sectional Study. BACKGROUND: The outbreak has had a devastating impact, and efforts are underway to speed up vaccination. The study's objective was to describe the clinical characteristics of the coronavirus disease 2019 (COVID-19) vaccination clinic in the Second People's Hospital of Fujian Province, China. Meanwhile, we monitored all the vaccine recipients to evaluate adverse reactions. METHODS: A cross-sectional study was done at the COVID-19 Vaccination Clinic, the Second People's Hospital of Fujian Province, China. We systematically collected Clinical data from the COVID-19 vaccination clinic between March 11 and November 11, 2021, including the type of vaccine, number of doses, gender, age, educational level, occupational category, adverse reactions, etc. Investigators will contact vaccine recipients by means of phone call or WeChat message to record the negative responses. Last, this report covers data through 8 mo, so it will be better to Evaluate the Safety of 2 inactivated COVID-19 vaccines from China (BBIBP-CorV [Beijing Institute of Biological Products, Beijing, China] and CoronaVac [Sinovac Life Sciences, Beijing, China]). RESULTS: The results indicated that the Second People's Hospital of Fujian Province received a total of 64,602 COVID-19 vaccines from March 11 to November 11, 2021, including 34,331 (53.14%) first doses, 29,245 (45.27%) second doses, and 1026 (1.59%) third doses. This study found the highest proportion in other personnel (38.69% at the first dose, 38.75% at the second dose, and 2.44% at the third dose), who were mainly retirees. People with higher levels of education are more likely to be vaccinated against COVID-19 during the early stages of vaccine rollout. In terms of age stratification, the highest proportion was found among people aged 18-49 (BBIBP-CorV: first dose 61%, second dose 62.6%, and third dose 76.8%; CoronaVac: first dose 66.1%, double dose 63.6%, and third dose 75.5%), followed by those over 60. The common adverse reactions were mainly local and systemic, and there were some differences between the 2 inactivated vaccines ($P < 0.05$). CONCLUSIONS: This is the first study to analyze the actual status of hospitals as COVID-19 vaccination clinics in China. The hospital has focused on vaccinating citizens and the initial rollout of vaccines to ensure any safety issues are identified. More citizens are willing to vaccinate in hospitals because of the uncertain safety of the available vaccines and adverse reactions. The good news is that vaccine-related severe adverse events have not been found in the hospital vaccination clinic. The Safety of BBIBP-CorV and CoronaVac is relatively high.

Adverse Events following Immunization with COVID-19 Vaccines: A Narrative Review. Numerous COVID-19 vaccines are being administered to people around the world. Adverse events following

immunization (AEFI) with COVID-19 vaccines have been reported by health care workers as well as surveillance bodies. A wealth of information on the efficacy and safety of vaccines exists in the literature, and the knowledge in this sector is growing exponentially. A narrative literature review was conducted on sources accessed from PubMed, Google Scholar, and Cochrane Review from March 2021 to July 2021. This review is aimed at describing AEFI associated with currently available COVID-19 vaccines, with an emphasis on narrating probable AEFI, and at assisting in a better understanding of the COVID-19 vaccines.
The association of COVID-19 vaccine availability with mental health among adults in the United States. OBJECTIVE: To assess whether COVID-19 vaccine approval and availability was associated with reduction in the prevalence of depression and anxiety among adults in the United States. METHODS: We adopted cross sectional and quasi-experimental design with mental health measurements before vaccine availability (June 2020, N = 68,009) and after vaccine availability (March 2021, N = 63,932) using data from Census Pulse Survey. Depression and anxiety were derived from PHQ-2 and GAD-2 questionnaires. We compared rates of depression and anxiety between June 2020 and March 2021. Unadjusted and adjusted analysis with replicate weights were conducted. RESULTS: Depression prevalence was 25.0% in June 2020 and 24.6% in March 2021; anxiety prevalence was 31.7% in June 2020 and 30.0% in March 2021 in the sample. In adjusted analysis, there were no significant differences in likelihood of depression and anxiety between June 2020 and March 2021. CONCLUSION: Depression and anxiety were not significantly different between June 2020 and March 2021, which suggests that the pandemic effect continues to persist even with widespread availability of vaccines.
Inactivated vaccine Covaxin/BBV152: A systematic review. We systematically reviewed and summarized studies focusing on Bharat Biotech's Whole Virion Inactivated Corona Virus Antigen BBV152 (Covaxin), which is India's indigenous response to fighting the SARS-CoV-2 pandemic. Studies were searched for data on the efficacy, immunogenicity, and safety profile of BBV152. All relevant studies published up to March 22, 2022, were screened from major databases, and 25 studies were eventually inducted into the systematic review. The studies focused on the virus antigen (6 Î¼g) adjuvanted with aluminium hydroxide gel and/or Imidazo quinolin gallamide (IMDG), aTLR7/8 agonist. Pre-clinical, phase I, and II clinical trials showed appreciable immunogenicity. Both neutralizing and binding antibody titers were significant and T cell responses were Th1-biased. Phase III trials on the 6 Î¼g +Algel-IMDG formulation showed a 93.4% efficacy against severe COVID-19. Data from the trials revealed an acceptable safety profile with mostly mild-moderate local and systemic adverse events. No serious adverse events or fatalities were seen, and most studies reported milder and lesser adverse events with Covaxin when compared with other vaccines, especially Oxford-Astra Zeneca's AZD1222 (Covishield). The immunogenicity performance of Covaxin, which provided significant protection only after the second dose, was mediocre and it was consistently surpassed by Covishield. One study reported adjusted effectiveness against symptomatic infection to be just 50% at 2 weeks after the second dose. Nonetheless, appreciable results were seen in previously infected individuals administered both doses. There was some evidence of coverage against the Alpha, Beta, and Delta variants. However, neither Covaxin nor Covishield showed sufficient protection against the Omicron variant. Two studies reported super-additive results on mixing Covaxin with Covishield. Further exploration of heterologous prime-boost vaccination with a combination of an inactivated vaccine and an adenoviral vector-based vaccine for tackling future variants may be beneficial.
Heterologous booster vaccination with CoronaVac following prime vaccination with mRNA vaccine. OBJECTIVE: Despite the high vaccine efficacy of mRNA COVID-19 vaccines, there are individuals who developed excessive reactogenic and/or allergic responses after the first mRNA dose and were considered ineligible for further mRNA doses. CoronaVac, an inactivated SARS-CoV-2 vaccine, is

recommended in Singapore as an alternative. METHODS: Individuals, ineligible for further mRNA vaccines (BNT162b2 or mRNA-1273) because of excessive reactive responses to prime mRNA vaccination, were recruited and offered two doses of CoronaVac as booster vaccination 38-224â€‰days post their mRNA vaccine dose. Individuals who did not develop any excessive reactive responses after the prime mRNA vaccination were also recruited and given another mRNA vaccine as booster vaccination. Blood samples were collected at days 0, 21 and 90 post first CoronaVac dose and mRNA dose, respectively, for analysis. RESULTS: We showed that two CoronaVac booster doses induced specific immunity in these mRNA vaccine-primed individuals. Although the spike-specific antibody response was lower, their memory B cell response against the receptor-binding domain (RBD) of the spike protein was similar, compared with individuals who received two BNT162b2 injections. The spike-specific memory T cell response also increased following CoronaVac booster doses. However, specific immunity against the Omicron variant was low, similar to individuals with two BNT162b2 doses. CONCLUSION: Our findings showed that while mRNA vaccine-primed individuals can opt for two subsequent doses of CoronaVac, an additional dose may be necessary to achieve protection, especially against newly emerging immune escape variants such as Omicron.

Surveillance of adverse events associated with 145 000 doses of COVID-19 vaccines in a Brazilian municipality. There is a lack of real-world surveillance studies on reports of adverse events associated with COVID-19 vaccination, as well as comparative analyses of adverse events from vaccines with different platforms. This observational, descriptive, retrospective study based on secondary data describes the adverse events following immunization (AEFIs) related to the first 145 000 doses of COVID-19 vaccines delivered in Aracaju municipality, Sergipe state, northeast Brazil. Records of AEFIs were collected using the e-SUS Notifica database for January 19 to April 30, 2021. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated for AEFIs and the type of COVID-19 vaccine, either CoronaVac (Sinovac-Butantan) or Oxford-AstraZeneca (Fiocruz). A total of 474 AEFIs (32.7 events/10 000 doses) from 254 individuals were reported and analyzed, and all of them were classified as non-serious. There was an association between the use of the CoronaVac vaccine and headache (OR = 2.1; 95% CI: 1.4-3.2), pain at the injection site (OR = 9.6; 95% CI: 3.9-23.8), lethargy (OR = 5.2; 95% CI: 1.8-14.8), fatigue (OR = 10.1; 95% CI: 2.4-42.3), diarrhea (OR = 4.4; 95% CI: 1.5-12.5) and cold-like symptoms (OR = 8.0; 95% CI: 1.9-34.0). However, the proportion of individuals reporting fever was higher among those who received the Oxford-AstraZeneca vaccine (OR = 3.1; 95% CI 1.5-6.4). This population-based observational study strengthens the evidence for the safety and tolerability of the CoronaVac and Oxford-AstraZeneca vaccines used against COVID-19.

Profile of Brazilian inpatients with COVID-19 vaccine breakthrough infection and risk factors for unfavorable outcome. OBJECTIVE: To characterize the epidemiological and clinical profile of individuals more likely to become infected with SARS-CoV-2 after the fully vaccination schedule in order to profile priority groups to receive a booster dose in situations of vaccine doses shortage as well as for maintenance of personal protective care. METHODS: This cross-sectional study used data from hospitalized COVID-19 patients aged â‰¥18 years, who had been fully vaccinated and had a SARS-CoV-2 infection positive diagnosis collected from the SIVEP-Gripe database (Influenza Epidemiological Surveillance Information System) from January 18, 2021 to September 15, 2021. Demographic data, clinical symptoms and preexisting medical conditions (comorbidities) were analyzed. The primary outcome was in-hospital death. RESULTS: The majority of hospitalized patients with vaccine breakthrough infection were â‰¥60 years old, male, with critical or severe COVID-19. The fatality rate was extremely high (50.27%) and more pronounced in elderly groups. The most prevalent symptoms were cough, dyspnea, respiratory distress, and low blood oxygen saturation. The most frequent comorbidities were heart disease and diabetes. High fatality rates were observed among patients admitted to the intensive care units (72.88%) and those who required invasive

mechanical ventilation (87.82%). The main risk factors for an unfavorable outcome were older age, respiratory compromise, inactivated virus vaccine immunization, and preexisting medical conditions. CONCLUSIONS: We characterized the profile of hospitalized Brazilian patients with COVID-19 vaccine breakthrough infection and the risk factors for an unfavorable outcome. These data allow to identify priority groups to receive a booster dose and to continue using personal protection.

Dynamicity and persistence of severe acute respiratory syndrome coronavirus-2 antibody response after double dose and the third dose with BBV-152 and AZD1222 vaccines: A prospective, longitudinal cohort study. INTRODUCTION: Vaccines are available worldwide to combat coronavirus disease-19 (COVID-19). However, the long-term kinetics of the vaccine-induced antibodies against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) have not been sufficiently evaluated. This study was performed to investigate the persistence and dynamicity of BBV-152 (Covaxin)- and AZD1222 (Covishield)-induced immunoglobulin-G (IgG) antibodies over the year and neutralizing antibodies' status after 1-month of booster dose. MATERIALS AND METHODS: This 52-week longitudinal cohort study documented antibody persistence and neutralizing antibodies status among 304 healthcare workers (HCWs) from six hospitals and research facilities in Odisha, enrolled during January 2021 and continued till March 2022. IgG antibodies against spike receptor-binding domain (RBD) of SARS-CoV-2 were quantified in an automated chemiluminescence immune assay-based (CLIA) platform and a surrogate virus neutralization test (sVNT) was performed by enzyme-linked immunosorbent assay (ELISA). RESULTS: Among these 304 HCWs vaccinated with double doses, 154 HCWs (50.66%) were Covaxin recipients and the remaining 150 (49.34%) were Covishield recipients. During the follow-ups for seven times, a total of 114 participants were identified as vaccine breakthrough cases. In 190 non-infected HCWs, the median antibody titer was significantly waned from DD2 to DD10, both for Covaxin (231.8 vs. 42.7 AU/ml) and Covishield (1,884.6 vs. 369.2 AU/ml). No statistically significant differences in antibody titers were observed based on age, gender, comorbidities, and blood groups. The median inhibition activity of sVNT increased from 23.8 to 91.3% for Covaxin booster recipients and from 41.2 to 96.0% for Covishield booster recipients. Among 146 booster dose recipients, 48 were breakthrough cases after booster and all were contracted by the omicron variant. CONCLUSION: This year-long follow-up study found a 7- and 5-fold antibody waning in Covaxin and Covishield recipients, respectively, without any breakthrough infection history. However, individuals with booster breakthrough had mild symptoms and did not require hospital admission. The data also indicate the possible escape of omicron variants despite the presence of vaccine-induced neutralizing antibodies.

A Systematic Review and Meta-Analysis of Serologic Response following Coronavirus Disease 2019 (COVID-19) Vaccination in Solid Organ Transplant Recipients. Solid organ transplant (SOT) recipients are at greater risk of coronavirus disease 2019 (COVID-19) and have attenuated response to vaccinations. In the present meta-analysis, we aimed to evaluate the serologic response to the COVID-19 vaccine in SOT recipients. A search of electronic databases was conducted to identify SOT studies that reported the serologic response to COVID-19 vaccination. We analyzed 44 observational studies including 6158 SOT recipients. Most studies were on mRNA vaccination (mRNA-1273 or BNT162b2). After a single and two doses of vaccine, serologic response rates were 8.6% (95% CI 6.8-11.0) and 34.2% (95% CI 30.1-38.7), respectively. Compared to controls, response rates were lower after a single and two doses of vaccine (OR 0.0049 [95% CI 0.0021-0.012] and 0.0057 [95% CI 0.0030-0.011], respectively). A third dose improved the rate to 65.6% (95% CI 60.4-70.2), but in a subset of patients who had not achieved a response after two doses, it remained low at 35.7% (95% CI 21.2-53.3). In summary, only a small proportion of SOT recipients achieved serologic response to the COVID-19 mRNA vaccine, and that even the third dose had an insufficient response. Alternative strategies for prophylaxis in SOT patients need to be developed. Key Contribution: In this meta-

analysis that included 6158 solid organ transplant recipients, the serologic response to the COVID-19 vaccine was extremely low after one (8.6%) and two doses (34.2%). The third dose of the vaccine improved the rate only to 66%, and in the subset of patients who had not achieved a response after two doses, it remained low at 36%. The results of our study suggest that a significant proportion of solid organ transplant recipients are unable to achieve a sufficient serologic response after completing not only the two series of vaccination but also the third booster dose. There is an urgent need to develop strategies for prophylaxis including modified vaccine schedules or the use of monoclonal antibodies in this vulnerable patient population.

Ongoing Mycophenolate Treatment Impairs Anti-SARS-CoV-2 Vaccination Response in Patients Affected by Chronic Inflammatory Autoimmune Diseases or Liver Transplantation Recipients: Results of the RIVALSA Prospective Cohort. Vaccines are the most effective means to prevent the potentially deadly effects of SARS-CoV-2 infection, but not all vaccinated individuals gain the same degree of protection. Patients undergoing chronic immunosuppressive therapy due to autoimmune diseases or liver transplants, for example, may show impaired anti-SARS-CoV-2 antibody response after vaccination. We performed a prospective observational study with parallel arms, aiming to (a) evaluate seroconversion after anti-SARS-CoV-2 mRNA vaccine administration in different subgroups of patients receiving immunosuppressive treatment for rheumatological or autoimmune diseases or to prevent organ rejection after liver transplantation and (b) identify negative predictors of IgG anti-SARS-CoV-2 development. Out of 437 eligible patients, 183 individuals were enrolled at the Rheumatology and Hepatology Tertiary Units of â€œMaggiore della CaritÃ â€• University Hospital in Novara: of those, 52 were healthy subjects, while among the remaining 131 patients, 30 had a diagnosis of spondyloarthritis, 25 had autoimmune hepatitis, 10 were liver transplantation recipients, 23 suffered from connective tissue diseases (including 10 cases that overlapped with other diseases), 40 were treated for rheumatoid arthritis, and 5 had vasculitis. Moreover, all patients were receiving chronic immunosuppressive therapy. The immunogenicity of mRNA COVID-19 vaccines was evaluated by measuring IgG anti-SARS-CoV-2 antibody titers before vaccination and after 10, 30, and 90 days since the first dose administration. Of the selected cohort of patients, 24.0% did not develop any detectable anti-SARS-CoV-2 IgG after a complete mRNA-based two doses primary vaccination cycle. At univariate analysis, independent predictors of an absent antibody response to vaccine were a history of liver transplantation (OR 11.5, 95% CI 2.5â^'53.7, p = 0.0018), the presence of a comorbid active neoplasia (OR 26.4, 95% CI 2.8â^'252.4, p = 0.0045), and an ongoing immunosuppressive treatment with mycophenolate (MMF) (OR 14.0, 95% CI 3.6â^'54.9, p = 0.0002) or with calcineurin inhibitors (OR 17.5, 95% CI 3.1â^'99.0, p = 0.0012). At multivariate analysis, only treatment with MMF (OR 24.8, 95% CI 5.9â^'103.2, p < 0.0001) and active neoplasia (OR 33.2, 95% CI 5.4â^'204.1, p = 0.0002) were independent predictors of seroconversion failure. These findings suggest that MMF dose reduction or suspension may be required to optimize vaccine response in these patients.

SARS-CoV-2 Omicron Variant Neutralization after Third Dose Vaccination in PLWH. The aim was to measure neutralizing antibody levels against the SARS-CoV-2 Omicron (BA.1) variant in serum samples obtained from vaccinated PLWH and healthcare workers (HCW) and compare them with those against the Wuhan-D614G (W-D614G) strain, before and after the third dose of a mRNA vaccine. We included 106 PLWH and 28 HCWs, for a total of 134 participants. Before the third dose, the proportion of participants with undetectable nAbsT against BA.1 was 88% in the PLWH low CD4 nadir group, 80% in the high nadir group and 100% in the HCW. Before the third dose, the proportion of participants with detectable nAbsT against BA.1 was 12% in the PLWH low nadir group, 20% in the high nadir group and 0% in HCW, respectively. After 2 weeks from the third dose, 89% of the PLWH in the low nadir group, 100% in the high nadir group and 96% of HCW elicited detectable nAbsT against BA.1. After the third dose, the mean log2 nAbsT against BA.1 in the HCW and PLWH with a high nadir

group was lower than that seen against W-D614G (6.1 log2 (Â±1.8) vs. 7.9 (Â±1.1) and 6.4 (Â±1.3) vs. 8.6 (Â±0.8)), respectively. We found no evidence of a different level of nAbsT neutralization by BA.1 vs. W-D614G between PLWH with a high CD4 nadir and HCW (0.40 (âˆ’1.64, 2.43); p = 0.703). Interestingly, in PLWH with a low CD4 nadir, the mean log2 difference between nAbsT against BA.1 and W-D614G was smaller in those with current CD4 counts 201âˆ’500 vs. those with CD4 counts < 200 cells/mm3 (âˆ’0.80 (âˆ’1.52, âˆ’0.08); p = 0.029), suggesting that in this target population with a low CD4 nadir, current CD4 count might play a role in diversifying the level of SARS-CoV-2 neutralization.

Long-Term Outcomes after Vaccine-Induced Thrombotic Thrombocytopenia. Vaccine-induced thrombotic thrombocytopenia (VITT), or thrombosis with thrombocytopenia syndrome (TTS), is a rare but serious complication of adenovirus-based vaccines against severe respiratory syndrome coronavirus 2 (SARS-CoV-2). Observation of long-term outcomes is important to guide treatment of affected patients. This single-center consecutive cohort study included all patients diagnosed based on (1) vaccination 4 to 21 days before symptom onset, (2) signs or symptoms of venous or arterial thrombosis, (3) thrombocytopenia < 150/nL, (4) positive anti-platelet factor 4 (PF4) antibody, and (5) elevated D-Dimer > 4 times the upper limit of normal. Nine patients were enrolled. Acute management consisted of parenteral anticoagulants, corticosteroids, intravenous immunoglobulin (IVIG), and/or eculizumab. Eculizumab was successfully used in two patients with recurrent thromboembolic events after IVIG. Direct oral anticoagulants were given after hospital discharge. Median follow-up duration was 300 days (range 153 to 380). All patients survived the acute phase of the disease and were discharged from hospital. One patient died from long-term neurological sequelae of cerebral venous sinus thrombosis 335 days after diagnosis. Eight out of nine patients were alive at last follow-up, and seven had fully recovered. Anti-PF4 antibodies remained detectable for at least 12 weeks after diagnosis, and D-Dimer remained elevated in some patients despite oral anticoagulation. No recurrent thromboembolic events, other signs of VITT relapse, or bleeding complications occurred after discharge. In conclusion, VITT appears to be a highly prothrombotic condition. IVIG is not always successful, and eculizumab may be considered a rescue agent. Long-term management with direct oral anticoagulants appears to be safe and effective.

Prognostic Value of Mid-Region Proadrenomedullin and In Vitro Interferon Gamma Production for In-Hospital Mortality in Patients with COVID-19 Pneumonia and Respiratory Failure: An Observational Prospective Study. Coagulopathy and immune dysregulation have been identified as important causes of adverse outcomes in coronavirus disease (COVID-19). Mid-region proadrenomedullin (MR-proADM) is associated with endothelial damage and has recently been proposed as a prognostic factor in COVID-19. In non-COVID-19 immunocompromised patients, low in vitro interferon gamma (IFNÎ³) production correlates with infection risk and mortality. This prospective, monocentric, observational study included adult patients consecutively admitted with radiologic evidence of COVID-19 pneumonia and respiratory failure. MR-proADM and in vitro IFNÎ³ production were measured at T0 (day 1 from admission) and T1 (day 7 from enrollment). One hundred patients were enrolled. Thirty-six percent were females, median age 65 (Q1âˆ’Q3 54.5âˆ’75) years, and 58% had â‰¥1 comorbidity. Only 16 patients had received COVID-19 vaccination before hospitalization. At admission, the median PaO2:FiO2 ratio was 241 (157âˆ’309) mmHg. In-hospital mortality was 13%. MR-proADM levels differed significantly between deceased and survivors both at T0 (1.41 (1.12âˆ’1.77) nmol/L vs. 0.79 (0.63âˆ’1.03) nmol/L, p < 0.001) and T1 (1.67 (1.08âˆ’1.96) nmol/L vs. 0.66 (0.53âˆ’0.95) nmol/L, p < 0.001). In vitro IFNÎ³ production at T0 and T1 did not vary between groups. When only the subset of non-vaccinated patients was considered, both biomarkers at T1 resulted significantly associated with in-hospital mortality. AUROC for MR-proADM at T0 to predict in-hospital mortality was 0.87 (95%CI 0.79âˆ’0.94), with the best cut-off point at 1.04 nmol/L (92%

sensitivity, 75% specificity and 98% negative predictive value). In patients with COVID-19 pneumonia and different degrees of respiratory failure, MR-proADM at admission and during hospitalization resulted strongly associated with in-hospital mortality. Low in vitro IFNÎ³ production after the first week of hospitalization was associated with mortality in non-vaccinated patients possibly identifying the subgroup characterized by a higher degree of immune suppression.

Myocardial Infarction Following COVID-19 Vaccine Administration: Post Hoc, Ergo Propter Hoc? Vaccination against coronavirus disease 2019 (COVID-19) is the safest and most effective strategy for controlling the pandemic. However, some cases of acute cardiac events following vaccine administration have been reported, including myocarditis and myocardial infarction (MI). While post-vaccine myocarditis has been widely discussed, information about post-vaccine MI is scarce and heterogenous, often lacking in histopathological and pathophysiological details. We hereby present five cases (four men, mean age 64 years, range 50-76) of sudden death secondary to MI and tightly temporally related to COVID-19 vaccination. In each case, comprehensive macro- and microscopic pathological analyses were performed, including post-mortem cardiac magnetic resonance, to ascertain the cause of death. To investigate the pathophysiological determinants of MI, toxicological and tryptase analyses were performed, yielding negative results, while the absence of anti-platelet factor 4 antibodies ruled out vaccine-induced thrombotic thrombocytopenia. Finally, genetic testing disclosed that all subjects were carriers of at least one pro-thrombotic mutation. Although the presented cases do not allow us to establish any causative relation, they should foster further research to investigate the possible link between COVID-19 vaccination, pro-thrombotic genotypes, and acute cardiovascular events.

Six-Month Follow-Up of Immune Responses after a Rapid Mass Vaccination against SARS-CoV-2 with BNT162b2 in the District of Schwaz/Austria. In response to a large outbreak of the SARS-CoV-2 Beta (B.1.351) variant in the district Schwaz, Austria, a rapid mass vaccination campaign with BNT162b2 was carried out in spring 2021, immunizing more than 70% of the adult population within one week. Subsequent analysis revealed that the mass vaccination was associated with a significant reduction in new SARS-CoV-2 infections compared to control districts. Here, we aimed to evaluate both SARS-CoV-2-specific T- and B-cell responses at 35 Â± 8 and 215 Â± 7 days after the second dose in 600 study subjects who participated at both time points. Overall, a robust antibody and T-cell response was measured at day 35, which waned over time. Nevertheless, all persons preserved seropositivity and T cell response could still be detected in about half of the participants at day 215. Further, antibody response correlated negatively with age; however, in persons who experienced SARS-CoV-2 infection prior to study enrolment, the serum levels of both S- and N-specific antibodies surprisingly increased with age. In contrast, there was no correlation of T cell response with age. We could not detect any sex-related difference in the immune responses. SARS-CoV-2 infections prior to study enrolment or incident infections before day 215 resulted in higher antibody levels and T cell responses at day 215 compared to study participants with no history of infection. Collectively, our data support that vaccination with BNT162b2 against COVID-19 provides a durable immune response and emphasize the usefulness of vaccination even after a natural infection.

Pre-Existing Comorbidities Diminish the Likelihood of Seropositivity after SARS-CoV-2 Vaccination. BACKGROUND: The impact of chronic health conditions (CHCs) on serostatus post-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination is unknown. METHODS: We assessed serostatus post-SARS-CoV-2 vaccination among fully vaccinated adult residents of Jefferson County, Kentucky, USA, from April 2021 to August 2021. Serostatus was determined by qualitative analysis of SARS-CoV-2-specific Spike IgG antibodies via enzyme-linked immunoassay (ELISA) in peripheral blood samples. RESULTS: Of the 5178 fully vaccinated participants, 51 were seronegative and 5127 were seropositive. Chronic kidney disease (CKD) and autoimmune disease showed the highest association

with negative serostatus in fully vaccinated individuals. The absence of any CHC was strongly associated with positive serostatus. The risk of negative serostatus increased as the total number of pre-existing CHCs increased. Similarly, the use of two or more CHC-related medications was associated with seronegative status. CONCLUSIONS: The presence of any CHC, especially CKD or autoimmune disease, increased the likelihood of seronegative status among individuals who were fully vaccinated to SAR-CoV-2. This risk increased with a concurrent increase in number of comorbidities, especially with multiple medications. The absence of any CHC was protective and increased the likelihood of a positive serological response. These results will help develop appropriate guidelines for booster doses and targeted vaccination programs.

Young Age, Female Sex, and No Comorbidities Are Risk Factors for Adverse Reactions after the Third Dose of BNT162b2 COVID-19 Vaccine against SARS-CoV-2: A Prospective Cohort Study in Japan. BACKGROUND: This study compared the adverse events (AEs) of the second and third doses of BNT162b2, as well as investigated the impact of vaccine recipients' background and vaccination interval on the AEs of the third dose. METHODS: We conducted a questionnaire survey of AEs among health care workers at Osaka University Dental Hospital. Chi-square tests were performed to compare AEs to the administration of second and third vaccine doses. Logistic regression analyses were conducted to identify factors influencing the presence of AEs using age, sex, comorbidities, and the vaccination interval. Spearman's rank correlation coefficient was calculated to investigate the correlation between age, vaccination interval, and severity of each AE. RESULTS: The third dose of BNT162b2 was associated with significantly more frequent or milder AEs than the second dose. Logistic regression analyses detected significant differences in six items of AEs by age, three by sex, two by comorbidities, and zero by vaccination interval. Consistently, the risk of AEs was greater among younger persons, females, and those without comorbidities. Significant negative correlations were detected between age and vaccination interval, and between age and the severity of most AEs. CONCLUSIONS: Young, female, and having no comorbidities are risk factors for AEs after the third dose of BNT162b2, while vaccination interval is not.

Time-Varying Effect of Hybrid Immunity on the Risk of Breakthrough Infection after Booster Dose of mRNA COVID-19 Vaccine: The MOSAICO Study. This longitudinal observational study investigated the risk of breakthrough SARS-CoV-2 infection up to 6 months after a booster dose of an mRNA COVID-19 vaccine in infection-naÃ¯ve vs. previously infected healthcare workers (HCWs), and whether this difference varied over time. A Cox proportional hazard regression model with Aalen's additive analysis was fitted to examine the association between the risk of infections and predictor variables. Overall, we observed an incidence rate of 2.5 cases per 1000 person-days (95% confidence interval [CI] 2.0-3.0), which dropped at 0.8 per 1000 person-days (95% CI 0.3-2.0) in recipients with prior SARS-CoV-2 infection. The fitted analysis indicated an adjusted hazard ratio of 0.32 (95% CI 0.13-0.80; p-value = 0.01) for those with hybrid immunity with a slope that became steeply negative roughly starting from day 90. No difference was seen according to participants' smoking habits. Characteristics of infected HCWs were also described. Our study quantifies the time-varying effects of vaccine-induced and hybrid immunity after the booster dose (during the Omicron variant predominance in Italy) and observed that the protection waned more rapidly in infection-naÃ¯ve recipients starting from the third month. The results add important evidence that can be used to inform COVID-19 vaccination strategies.

Anti-Spike and Neutralizing Antibodies after Two Doses of COVID-19 Sinopharm/BIBP Vaccine. Host response to COVID-19 vaccines is partially evaluated through the estimation of antibody response, specifically the binding anti-spike (anti-S) and the neutralizing antibodies (nAbs) against SARS-CoV-2. Vaccine-induced humoral response affects decisions on the choice of vaccine type, vaccine acceptance, and the need for boosting. Identification of risk factors for poor antibody

response helps to stratify individuals who might potentially require booster doses. The primary objective of this cross-sectional study was to investigate the antibody response after receiving two Sinopharm vaccine doses. Factors affecting antibody response were additionally studied. Moreover, a predictive cutoff for anti-S was generated to predict positivity of nAbs. Blood samples were collected from 92 adults and relevant data were recorded. Antibody levels (anti-S and nAbs) against SARS-CoV-2 were tested one month following the second dose of Sinopharm vaccine using two commercial ELISA tests. Among the 92 participants, 88 tested positive for anti-S (95.7%), with a median level of 52.15 RU/mL (equivalent to 166.88 BAU/mL). Fewer participants (67.4%) were positive for nAbs, with a median percentage of inhibition (%IH) of 50.62% (24.05â^'84.36). A significant positive correlation existed between the titers of both antibodies (correlation coefficient = 0.875, $p < 0.001$). When the anti-S titer was greater than 40 RU/mL (128 BAU/mL), nAbs were also positive with a sensitivity of 80.6% and a specificity of 90%. Positive nAbs results were associated with a higher anti-S titers (62.1 RU/mL) compared to negative nAbs (mean anti-S titer of 18.6 RU/mL). History of COVID-19 infection was significantly associated with higher titers of anti-S ($p = 0.043$) and higher IH% of nAbs ($p = 0.048$). Hypertensive participants were found to have significantly higher median titers of anti-S (101.18 RU/mL) compared with non-hypertensive ones (42.15 RU/mL), $p = 0.034$. Post-vaccination headache was significantly higher among those with higher anti-S than those with relatively lower titers (98.82 versus 43.69 RU/mL, $p = 0.048$). It can be concluded that the Sinopharm vaccine produced high levels of binding antibodies but with low neutralizing abilities. Also, levels of anti-S titer greater than 40 RU/mL could adequately predict positivity of nAbs without need for their testing.

Improved SARS-CoV-2 Neutralization of Delta and Omicron BA.1 Variants of Concern after Fourth Vaccination in Hemodialysis Patients. Hemodialysis patients are exposed to a markedly increased risk when infected with SARS-CoV-2. To date, it is unclear if hemodialysis patients benefit from four vaccinations. A total of 142 hemodialysis patients received four COVID-19 vaccinations until March 2022. RDB binding antibody titers were determined in a competitive surrogate neutralization assay. Vero-E6 cells were infected with SARS-CoV-2 variants of concern (VoC), Delta (B.1.617.2), or Omicron (B.1.1.529, sub-lineage BA.1) to determine serum infection neutralization capacity. Four weeks after the fourth vaccination, serum infection neutralization capacity significantly increased from a 50% inhibitory concentration (IC50, serum dilution factor 1:x) of 247.0 (46.3â^'1560.8) to 2560.0 (1174.0â^'2560.0) for the Delta VoC, and from 37.5 (20.0â^'198.8) to 668.5 (182.2â^'2560.0) for the Omicron VoC (each $p < 0.001$) compared to four months after the third vaccination. A significant increase in the neutralization capacity was even observed for patients with high antibody titers after three vaccinations ($p < 0.001$). Ten patients with SARS-CoV-2 breakthrough infection after the first blood sampling had by trend lower prior neutralization capacity for Omicron ($p = 0.051$). Our findings suggest that hemodialysis patients benefit from a fourth vaccination in particular in the light of the highly infectious SARS-CoV-2 Omicron-variants. A routinely applied four-time vaccination seems to broaden immunity against variants and would be recommended in hemodialysis patients.

Short-Term Adverse Effects Immediately after the Start of COVID-19 Booster Vaccination in Vietnam. Background: Risk communication is necessary to improve the booster vaccination rate, but Vietnam does not have a system to collect and disclose such information. Therefore, the purpose of this study was to clarify adverse reactions and their frequency in the early period after booster vaccination, and to obtain primary data for improving the booster vaccination rate. Methods: A cross-sectional survey was conducted among adults aged â‰¥18 years. Clinical data were collected 14 days after booster vaccination by using a standard questionnaire. Results: A total of 1322 participants were included with median age = 23 and sex ratio (Male/Female) = 0.53. AstraZeneca was the most commonly used vaccine for the first and second doses, while Pfizer was the most commonly used vaccine for booster shots. Injection site pain, fatigue, and myalgia were the most common side effect reported (71.9%,

28.1%, and 21.8%, respectively). Compared to previous COVID-19 vaccine injections, 81.9% of participants reported that their symptoms were similar or milder after receiving the booster dose. They were more likely to present injection site pain (OR = 1.43, $p < 0.0001$) and lymphadenopathy (OR = 4.76, $p < 0.0001$) after receiving the booster shot. Fever (OR = 0.33, $p < 0.0001$) and fatigue (OR = 0.77, $p = 0.002$) were less often reported after booster shots compared to the first and second injections. The severity of symptoms occurring after booster dose versus first and second doses increased significantly with each additional year of age and among participants receiving the Pfizer and Moderna vaccines. Conclusion: Adverse reactions to booster vaccination are minor and their incidence is the same as for the first or the second vaccination. Multicenter studies with larger sample sizes on the side effects and safety of COVID-19 vaccine booster shots need to be conducted to make the population less worried, in order to increase the vaccination rate, to protect individualsâ€™ and communitiesâ€™ health.

Myocarditis or Pericarditis Following the COVID-19 Vaccination in Adolescents: A Systematic Review. Background: By 16 May 2022, 12,186,798,032 people had been vaccinated with COVID-19 vaccines. Our study found that myocarditis/pericarditis may occur in adolescents after COVID-19 vaccination. Methods: In this regard, we conducted a meta-analysis of seven groups of adolescents aged 12-19 years to compare the incidence of myocarditis/pericarditis after vaccination and compare the relative risk incidence after the first and second doses of a COVID-19 vaccine, and between males and females for risk incidence. Results: We analyzed 22,020,997 subjects from seven studies, including 130 cases of confirmed myocarditis/pericarditis. The overall mean incidence rate was 1.69 cases per 100,000 person-years. Of these, 19 of the 12,122,244 people who received a first dose of a COVID-19 vaccine had myocarditis/pericarditis, an incidence rate of 0.0022% (95% CI 0.0001-0.0034), and 111 of the 1,008,753 people who received a second dose had myocarditis/pericarditis, an incidence rate of 0.0107% (95% CI 0.0059-0.0155). The prevalence relative ratio (RR) after the first and second doses was RR = 5.53 (95% CI: 3.01-10.16), with a higher prevalence after the second dose than after the first dose of a COVID-19 vaccine. After a second dose of a COVID-19 vaccine, the RR for males relative to females was RR = 13.91 (95% CI: 4.30-44.95), with a more pronounced risk of disease in males than in females. Conclusions: Our study showed that myocarditis/pericarditis occurred after vaccination with the BNT162b2 or Comirnaty vaccine, especially after the second vaccination in male adolescents, but the incidence of myocarditis/pericarditis after vaccination with the above vaccines was very rare (0.0022%). Therefore, it is recommended that adolescents should be vaccinated with the COVID-19 universal vaccine as soon as possible and closely monitored for subsequent adverse reactions, which can be treated promptly.

Inefficient Induction of Neutralizing Antibodies against SARS-CoV-2 Variants in Patients with Inflammatory Bowel Disease on Anti-Tumor Necrosis Factor Therapy after Receiving a Third mRNA Vaccine Dose. Management of inflammatory bowel disease (IBD) often relies on biological and immunomodulatory agents for remission through immunosuppression, raising concerns regarding the SARS-CoV-2 vaccine's effectiveness. The emergent variants have hindered the vaccine neutralization capacity, and whether the third vaccine dose can neutralize SARS-CoV-2 variants in this population remains unknown. This study aims to evaluate the humoral response of SARS-CoV-2 variants in patients with IBD 60 days after the third vaccine dose [BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna)]. Fifty-six subjects with IBD and 12 healthy subjects were recruited. Ninety percent of patients with IBD (49/56) received biologics and/or immunomodulatory therapy. Twenty-four subjects with IBD did not develop effective neutralizing capability against the Omicron variant. Seventy percent (17/24) of those subjects received anti-tumor necrosis factor therapy [10 = adalimumab, 7 = infliximab], two of which had a history of COVID-19 infection, and one subject did not develop immune neutralization against three other variants: Gamma, Epsilon, and Kappa. All

subjects in the control group developed detectable antibodies and effective neutralization against all seven SARS-CoV-2 variants. Our study shows that patients with IBD might not be protected against SARS-CoV-2 variants, and more extensive studies are needed to evaluate optimal immunity.

Psychological and Psychiatric Events Following Immunization with Five Different Vaccines against SARS-CoV-2. BACKGROUND: Despite the high number of vaccines administered against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) worldwide, the information on the psychological/psychiatric adverse events following immunization (AEFI) with these newly developed vaccines remains scarce. OBJECTIVE: To describe the frequency of psychological/psychiatric symptoms among recipients of five different anti-SARS-CoV-2 vaccines and to explore the factors associated with their development reported in the nationwide Mexican registry of AEFI against SARS-CoV-2. METHODS: Descriptive study of all the psychological/psychiatric symptoms, including anxiety, panic attacks, insomnia, and agitation reported to the Mexican Epidemiological Surveillance System from 21 December 2020 to 27 April 2021, among adult (â‰¥18 years old) recipients of 7,812,845 doses of BNT162b2, ChAdOx1 nCov-19, rAd26-rAd5, Ad5-nCoV, or CoronaVac. The factors associated with their development are determined by multivariate regression analysis. RESULTS: There were 19,163 AEFI reports during the study period; amongst them, 191 (1%) patients had psychological/psychiatric symptoms (median age of 41 years, interquartile range of 32-54; 149 [78%] women) for an observed incidence of 2.44 cases per 100,000 administered doses (95% confidence interval [CI] 2.12-2.82), 72.8% of psychiatric AEFIs were reported among recipients of BNT162b2. The median time from vaccination to symptom onset was 35 min (interquartile range: 10-720). Overall, the most common psychological/psychiatric symptoms were anxiety in 129 (67.5%) patients, panic attacks in 30 (15.7%), insomnia in 25 (13%), and agitation in 11 (5.7%). After adjusting for the confounding factors, the odds for developing psychological/psychiatric symptoms were higher for those concurrently reporting syncope (odds ratio [OR]: 4.73, 95% CI: 1.68-13.33); palpitations (OR: 2.47, 95% CI: 1.65-3.70), and dizziness (OR: 1.59, 95% CI: 1.10-2.28). CONCLUSION: In our population, psychological/psychiatric symptoms were extremely infrequent AEFIs. No severe psychiatric AEFIs were reported. Immunization stress-related responses might explain most of the detected cases.

Solid Organ Rejection following SARS-CoV-2 Vaccination or COVID-19 Infection: A Systematic Review and Meta-Analysis. BACKGROUND: Solid organ rejection post-SARS-CoV-2 vaccination or COVID-19 infection is extremely rare but can occur. T-cell recognition of antigen is the primary and central event that leads to the cascade of events that result in rejection of a transplanted organ. OBJECTIVES: To describe the results of a systematic review for solid organ rejections following SARS-CoV-2 vaccination or COVID-19 infection. METHODS: For this systematic review and meta-analysis, we searched Proquest, Medline, Embase, Pubmed, CINAHL, Wiley online library, Scopus and Nature through the Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) guidelines for studies on the incidence of solid organ rejection post-SARS-CoV-2 vaccination or COVID-19 infection, published from 1 December 2019 to 31 May 2022, with English language restriction. RESULTS: One hundred thirty-six cases from fifty-two articles were included in the qualitative synthesis of this systematic review (56 solid organs rejected post-SARS-CoV-2 vaccination and 40 solid organs rejected following COVID-19 infection). Cornea rejection (44 cases) was the most frequent organ observed post-SARS-CoV-2 vaccination and following COVID-19 infection, followed by kidney rejection (36 cases), liver rejection (12 cases), lung rejection (2 cases), heart rejection (1 case) and pancreas rejection (1 case). The median or mean patient age ranged from 23 to 94 years across the studies. The majority of the patients were male (n = 51, 53.1%) and were of White (Caucasian) (n = 51, 53.7%) and Hispanic (n = 15, 15.8%) ethnicity. A total of fifty-six solid organ rejections were reported post-SARS-CoV-2 vaccination [Pfizer-BioNTech (n = 31), Moderna (n = 14), Oxford Uni-AstraZeneca (n = 10) and Sinovac-CoronaVac (n = 1)]. The median time from SARS-CoV-2 vaccination

to organ rejection was 13.5 h (IQR, 3.2-17.2), while the median time from COVID-19 infection to organ rejection was 14 h (IQR, 5-21). Most patients were easily treated without any serious complications, recovered and did not require long-term allograft rejection therapy [graft success (n = 70, 85.4%), graft failure (n = 12, 14.6%), survived (n = 90, 95.7%) and died (n = 4, 4.3%)]. CONCLUSION: The reported evidence of solid organ rejections post-SARS-CoV-2 vaccination or COIVD-19 infection should not discourage vaccination against this worldwide pandemic. The number of reported cases is relatively small in relation to the hundreds of millions of vaccinations that have occurred, and the protective benefits offered by SARS-CoV-2 vaccination far outweigh the risks.

Acute Polyserositis with Cardiac Tamponade and Bilateral Refractory Pleural Effusion after ChAdOx1 nCoV-19 Vaccination. The association of SARS-CoV-2 messenger ribonucleic acid vaccines with pericarditis in young adults has been reported. However, data regarding other types of vaccines are extremely limited. We presented a 94-year-old man with rapidly progressive dyspnea and fatigue six days after his first ChAdOx1 nCoV-19 vaccination. Impending cardiac tamponade and bilateral pleural effusion were found. Hence, massive yellowish pericardial and pleural effusion were drained. However, the pleural effusion persisted and pigtail catheters were inserted bilaterally. After serial studies including surgical pleural biopsy, acute polyserositis (pericarditis and pleurisy) was diagnosed. Anti-inflammatory treatment with colchicine and prednisolone was administered. All effusions resolved accordingly. This rare case sheds light on the presentation of ChAdOx1 nCoV-19 vaccine-related acute polyserositis. In conclusion, awareness of this potential adverse event may facilitate the diagnosis for unexplained pericardial or pleural effusion after vaccination.

Cervical Staphylococcus aureus Infection after Receiving the Third Dose of COVID-19 Vaccination: A Case Report. INTRODUCTION: Vaccination is one of the most effective ways to control the COVID-19 pandemic. However, as the number of people vaccinated against COVID-19 continues to increase, there are more reports on the safety of vaccines. So far, there have been no reported cases of spinal infection associated with COVID-19 vaccination. Recently, we admitted a patient who developed cervical Staphylococcus aureus infection resulting in high paraplegia after receiving the third dose of COVID-19 vaccine when the symptoms of cold did not completely disappear. CASE PRESENTATION: The patient was a 70-year-old man who received the third injection of COVID-19 vaccine when the cold symptoms were not completely gone. On the day after the injection, the patient developed severe neck and shoulder pain, accompanied by numbness and fatigue in the limbs. MRI examination of the cervical spine on day 6 after vaccination showed no obvious signs of infection. The patient had progressive weakness in the extremities. On the ninth day after vaccination, the patient developed paralysis of both lower limbs and significant sensory loss. Cervical abscess and cervical spinal cord injury were considered for cervical CT and MRI examination on the 15th day after vaccination. We used an anterior approach to remove as much of the lesion as possible. Staphylococcus aureus was detected and antibiotic treatment was continued after surgery. The patient's pain symptoms were significantly relieved, which prevented the abscess from further pressing the spinal cord and provided possible conditions for the recovery of neurological function in the later stage. CONCLUSION: This case is the first reported cervical Staphylococcus aureus infection resulting in high paraplegia after receiving the third dose of COVID-19 vaccine with low immunity. This case raises awareness of this rare but potentially life-threatening adverse reaction, and reminds people to hold off when their immune system is weakened.

Intensity of Humoral Immune Responses, Adverse Reactions, and Post-Vaccination Morbidity after Adenovirus Vector-Based and mRNA Anti-COVID-19 Vaccines. The aim of the study was to compare mRNA vaccine BNT162b2 with adenovirus vector- based vaccines in terms of presence of adverse reactions, immunogenicity, and protection against COVID-19. A total of 270 individuals were enrolled, of which 135 were vaccinated with adenovirus vector-based vaccines and compared with

135 age- and sex-matched participants who received the BNT162b2 mRNA vaccine. Serum sampling was performed on all participants on days 21, 42, 90, and 180 following the first dose, to evaluate anti-spike IgG and IgA responses. Antibodies were quantified by chemiluminescent microplate and ELISA assays. We demonstrate that both mRNA and adenovirus vector-based vaccines caused mild side-effects and were effective in inducing adequate antibody responses against SARS-CoV-2, although BNT162b2 was superior concerning the intensity of antibody responses and protection against severe COVID-19. Moreover, we identify that IgG and IgA responses depended primarily on both history of previous COVID-19 infection and vaccination platform used, with individuals immunized with a single-dose vaccine having lower antibody titers over time. Lastly, all vaccine platforms had limited side-effects, with the most frequent pain at the injection site. Our results provide useful information regarding antibody responses after vaccination with different vaccine platforms, which can be useful for public health vaccination strategies.

Elevated NETs and Calprotectin Levels after ChAdOx1 nCoV-19 Vaccination Correlate with the Severity of Side Effects. ChAdOx1 nCoV-19 vaccination has been associated with the rare side effect; vaccine-induced immune thrombotic thrombocytopenia (VITT). The mechanism of thrombosis in VITT is associated with high levels of neutrophil extracellular traps (NETs). The present study examines whether key markers for NETosis, such as H3-NETs and calprotectin, as well as syndecan-1 for endotheliopathy, can be used as prognostic factors to predict the severity of complications associated with ChAdOx1 vaccination. Five patients with VITT, 10 with prolonged symptoms and cutaneous hemorrhages but without VITT, and 15 with only brief and mild symptoms after the vaccination were examined. Levels of H3-NETs and calprotectin in the vaccinated individuals were markedly increased in VITT patients compared to vaccinees with milder vaccination-associated symptoms, and a strong correlation (r â‰¥ 0.745, $p < 0.001$) was found with severity of vaccination side effects. Syndecan-1 levels were also positively correlated ($r = 0.590$, $p < 0.001$) in vaccinees to side effects after ChAdOx1 nCoV-19 vaccination. We hypothesize that the inflammatory markers NETs and calprotectin may be used as confirmatory tests in diagnosing VITT.

COVID-19 Vaccine Coverage and Sociodemographic, Behavioural and Housing Factors Associated with Vaccination among People Experiencing Homelessness in Toronto, Canada: A Cross-Sectional Study. People experiencing homelessness were prioritized for COVID-19 vaccination in Toronto, Canada, due to the high risk of infection and associated complications relative to the general population. We aimed to ascertain COVID-19 vaccine coverage in this population and explore factors associated with the receipt of at least one dose. We collected survey and blood sample data from individuals ages 16+ recruited by random selection at 62 shelters, hotels and encampment sites between 16 June 2021 and 9 September 2021. We report vaccine coverage by dose number and explored sociodemographic, behavioral, health and housing factors associated with vaccination using multivariable modified Poisson regression. In total, 80.4% (95% CI 77.3-83.1%) received at least one vaccine dose, and 63.6% (CI 60.0-67.0%) received two or more doses. Vaccination was positively associated with age (every 10 years adjusted rate ratio (aRR) 1.05 [95% CI 1.03-1.08]), and receipt of influenza vaccination (aRR 1.19 [95% CI 1.11-1.27]). Factors negatively associated with vaccination included female gender (aRR 0.92 [95% CI 0.85-1.0]), Black racial self-identification (aRR 0.89 [95% CI 0.80-0.99]) and low frequencies of masking in public places (aRR 0.83 [95% CI 0.72-0.95]). COVID-19 vaccine coverage is very high among people experiencing homelessness in Toronto, suggesting advocacy and outreach efforts may have been effective.

Immune Response of a Heterologous mRNA-1273 Second-Dose Immunization after a First Dose of ChadOx1 against SARS-CoV-2: A Cross-Sectional Study. Heterologous vaccination regimens could contribute to broadening vaccination coverage. To date, there is little evidence on the effectiveness of a combination of adenoviral COVID-19 vaccines with a second dose of mRNA vaccines. This study

aims to evaluate the antibody response to the SARS-CoV-2 spike protein 25 weeks after vaccination with mRNA-1273 after a first dose of ChAdOx1. A cross-sectional study was conducted collecting sociodemographic data, clinical characteristics, and serological data from among the general population. Antibody levels were expressed as binding antibody units (BAU) per mL (cutoff = 33.8 BAU/mL). Linear regression models were used to assess the relationship between the subjects' characteristics and anti-SARS-CoV-2 antibody levels. A total of 229 participants were followed up after a median time of 173 days. The overall anti-SARS-CoV-2 IgG antibody titer was 729.0 BAU/mL. The multivariable analysis showed that the only factor associated with anti-SARS-CoV-2 IgG levels was the BMI ($p = 0.007$), with decreases within the healthy range weight and increases in under- or overweight people. Our results support the use of heterologous COVID-19 vaccination regimens, as they can guarantee a sustained immune antibody response. More studies are needed to understand the link between BMI and body composition and the immune response to COVID-19 vaccinations.

Increased Mild Vaccine-Related Side Effects and Higher Specific Antibody Titers in Health Care Workers with Previous SARS-CoV-2 Infection after the mRNA BNT162b2 Vaccine. Background: to evaluate whether prior SARS-CoV-2 infection affects side effects and specific antibody production after vaccination with BNT162b2. Methods: We included 1106 health care workers vaccinated with BNT162b2. We assessed whether prior SARS-CoV-2 infection affects the number and type of side effects and performed a nested caseâˆ’control analysis comparing plasma levels of specific IgG titers between SARS-CoV-2-naÃ¯ve and previously infected subjects after the first and the second vaccine doses. Results: After the first dose, SARS-CoV-2-naÃ¯ve subjects experienced side effects more often than SARS-CoV-2 naÃ¯ve subjects. Individuals with prior SARS-CoV-2 infection more often reported pain at the injection site, weakness, and fever than SARS-CoV-2-naÃ¯ve subjects. After the second dose, the frequency of side effects was similar in the two groups. All subjects with prior SARS-CoV-2 infection developed either a high (>100 AU/mL) or intermediate (10âˆ’100 AU/mL) antibody titer. Among SARS-CoV-2-naÃ¯ve subjects, the majority developed an intermediate titer. After the second dose, a high (>2000 AU/mL) antibody titer was more common among subjects with prior SARS-CoV-2 infection. Conclusions: vaccine-related side effects and a higher anti-SARS-CoV-2-RBD IgG titer were more common in subjects with previous infection than in SARS-CoV-2-naÃ¯ve after the first, but not after the second dose of the BNT162b2 vaccine.

Association between Adverse Reactions to the First and Second Doses of COVID-19 Vaccine. This study investigated the frequency of adverse reactions to COVID-19 vaccines in Japan and the impact of first-dose adverse reactions on second-dose adverse reactions. Individuals who received an mRNA COVID-19 vaccine at our center in March or April 2021 were included. Data were collected using questionnaires. The main factors were age (<40, 40âˆ’59, and >60 years), sex, underlying disease, and first-dose adverse reaction. The primary outcomes were incidence of local and systemic adverse reactions (ARs) attributable to the vaccine. Logistic regression was used to calculate odds ratios (ORs) and 95% confidence intervals (CIs). Among 671 participants, 90% experienced local or systemic ARs. An AR to the first dose was associated with a significantly increased risk of an AR to the second dose (OR: 49.63, 95% CI: 21.96âˆ’112.16). ARs were less common among men than among women (OR: 0.36, 95% CI: 0.17âˆ’0.76). Local ARs were less common among those aged 60 years or older (OR: 0.35, 95% CI: 0.18âˆ’0.66), whereas systemic ARs were more common among those aged under 40 years. Information on ARs to the first dose is important for healthcare providers and recipients when making vaccination decisions.

Clinical Manifestation, Management, and Outcomes in Patients with COVID-19 Vaccine-Induced Acute Encephalitis: Two Case Reports and a Literature Review. INTRODUCTION: Vaccination is one of the best strategies to control coronavirus disease 2019 (COVID-19), and multiple vaccines have been introduced. A variety of neurological adverse effects have been noted after the implementation of

large-scale vaccination programs. METHODS: We reported two rare cases of possible mRNA-1273 vaccine-induced acute encephalitis, including clinical manifestations, laboratory characteristics, and management. RESULTS: The clinical manifestations might be related to hyperproduction of systemic and cerebrospinal fluid (CSF) cytokines. mRNA vaccines are comprised of nucleoside-modified severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA, which is translated into SARS-CoV-2 spike protein by the host's ribosomes, activating the adaptive immune response. Exposed mRNA or vaccine components may also be detected as antigens, further resulting in aberrant proinflammatory cytokine cascades and activation of immune signaling pathways. Both patients exhibited significant clinical improvement after a course of steroid therapy. CONCLUSIONS: The use of COVID-19 vaccines to prevent and control SARS-CoV-2 infections and complications is the most practicable policy worldwide. However, inaccurate diagnosis or other diagnostic delays in cases of vaccine-induced acute encephalitis may have devastating and potentially life-threatening consequences for patients. Early diagnosis and timely treatment can result in a favorable prognosis.

Association of COVID-19 Vaccines ChAdOx1-S and BNT162b2 with Circulating Levels of Coagulation Factors and Antithrombin. BACKGROUND: Severe coronavirus disease 2019 (COVID-19) is associated with increased risk of thrombosis and thromboembolism. Exposure to COVID-19 vaccines is also associated with immune thrombotic thrombocytopenia, ischemic stroke, intracerebral haemorrhage, and cerebral venous thrombosis, and it is linked with systemic activation of coagulation. METHODS: We assess the circulating levels of coagulation factors (factors XI, XII, XIII, and prothrombin) and antithrombin in individuals who completed two doses of either ChAdOx1-S or BNT162b2 COVID-19 vaccine, within the timeframe of two months, who had no previous history of COVID-19. RESULTS: Elevated levels of factors XI, XII, XIII, prothrombin, and antithrombin were seen compared to unvaccinated controls. Levels of coagulation factors, antithrombin, and prothrombin to antithrombin ratio were higher with BNT162b2 compared to ChAdOx1-S vaccine. CONCLUSIONS: The clinical significance of such coagulation homeostasis disruption remains to be elucidated but it is worthy of global scientific follow-up effort.

Cross-Sectional Survey on BNT162b2 mRNA COVID-19 Vaccine Serious Adverse Events in Children 5 to 11 Years of Age: A Monocentric Experience. OBJECTIVE: Our aim was to evaluate the safety of COVID-19 vaccine in children resident in the Latina Local Health Authority. METHODS: We conducted a telephone survey among children aged 5-11 years receiving BNT162b2 mRNA COVID-19 vaccine between December 15 and 21. The main outcomes included the presence of allergic reactions or anaphylaxis, adverse events after 24-48 h, 7 and 20 days of taking the first and second doses of medications, and documented SARS-CoV-2 infection after vaccination. The information obtained was automatically linked to a spreadsheet and analyzed. RESULTS: 569 children were enrolled. The mean age was 114 Â± 4.24 months; there were 251 males in the study. The vaccine showed a favorable safety profile; no anaphylaxis or serious adverse events were reported. The most common symptoms both after the first and second dose were injection site reactions, asthenia, and headache. Injection site reactions were more frequent after the first dose ($p = 0.01$), while systemic symptoms were more frequent after the second dose ($p = 0.022$). These symptoms were more frequent in patients with comorbidities ($p = 0.0159$). CONCLUSION: Our findings confirm the safety of COVID-19 vaccine in children younger 11 years and could be useful to promote its diffusion in pediatric ages in order to achieve "herd immunity" and prevent the virus's circulation.

Lymphedema of the Arm after COVID-19 Vaccination in a Patient with Hidden Breast Cancer and Paraneoplastic Dermatomyositis. The pandemic outbreak of Coronavirus Disease 2019 (COVID-19) led to the development of mRNA vaccines. With the extensive vaccination campaign performed worldwide, many adverse reactions to these drugs have been reported in the literature. Although most of them are mild and self-limiting, they may sometimes cause psychological stress and require

efforts to make a differential diagnosis with other conditions. This is the case of lymphadenopathies and lymphedema in patients with a history of cancer. Herein we present a case of lymphedema of the arm developed ten days after a VAXZEVRIA COVID-19 vaccine shot in a patient who had concomitant signs and symptoms compatible with a diagnosis of dermatomyositis. It was later classified as paraneoplastic as instrumental investigation revealed a breast carcinoma contralateral to the site of vaccine injection. With this report we ponder an adverse reaction to COVID-19 vaccination with the aim of bringing new data for clinicians who face similar clinical presentations, particularly controversial for radiologists and oncologists.

Case Series of Myocarditis Following mRNA COVID Vaccine Compared to Pediatric Multisystem Inflammatory Syndrome: Multicenter Retrospective Study. INTRODUCTION: Since the development of COVID-19 vaccines, more than 4.8 billion people have been immunized worldwide. Soon after vaccinations were initiated, reports on cases of myocarditis following the second vaccine dose emerged. This study aimed to report our experience with adolescent and young adults who developed post-COVID-19 vaccine myocarditis and to compare these patients to a cohort of patients who acquired pediatric inflammatory multisystem syndrome (PIMS/PIMS-TS) post-COVID-19 infection. METHODS: We collected reported cases of patients who developed myocarditis following COVID-19 vaccination (Pfizer mRNA BNT162b2) from all pediatric rheumatology centers in Israel and compared them to a cohort of patients with PIMS. RESULTS: Nine patients with post-vaccination myocarditis were identified and compared to 78 patients diagnosed with PIMS. All patients with post-vaccination myocarditis were males who developed symptoms following their second dose of the vaccine. Patients with post-vaccination myocarditis had a shorter duration of stay in the hospital (mean 4.4 Â± 1.9 vs. 8.7 Â± 4.7 days) and less myocardial dysfunction (11.1% vs. 61.5%), and all had excellent outcomes as compared to the chronic changes among 9.2% of the patients with PIMS. CONCLUSION: The clinical course of vaccine-associated myocarditis appears favorable, with resolution of the symptoms in all the patients in our cohort.

Sociodemographic and Occupational Factors Associated with Low Early Uptake of COVID-19 Vaccine in Hospital-Based Healthcare Workers, Georgia, March-July 2021. In Georgia, an upper-middle income European country, the COVID-19 vaccine rollout began on 15 March 2021 with health workers (HWs), a priority group for vaccination. We assessed the factors associated with COVID-19 vaccination among HWs at six large hospitals in the early stages of the vaccine rollout (Marchâˆ’July 2021). Among 1533 HWs, 274 (17.9%) had received one dose of the COVID-19 vaccine. Strong independent predictors of early vaccine uptake were age > 40 years, especially 50âˆ’59 years old (aOR 2.40, 95% CI 1.50âˆ’3.88), considering the vaccine as â€œsomewhat effectiveâ€• or â€œvery effectiveâ€• rather than â€œnot effectiveâ€• (aOR 6.33, 95% CI 2.29âˆ’26.3 and aOR 10.9, 95% CI 3.88âˆ’45.70, respectively), and previous vaccination against seasonal influenza (aOR 2.98, 95% CI 2.19âˆ’4.08). Previous SARS-CoV-2 infection was negatively associated with receiving the vaccine (aOR 0.6, 95% CI 0.40âˆ’0.80). Compared to physicians, nurses/midwives (aOR 0.22, 95% CI 0.15âˆ’0.32), administrative staff (aOR 0.36, 95% CI 0.22âˆ’0.56), and ancillary staff (aOR 0.07, 95% CI 0.04âˆ’0.15) were less likely to have received the COVID-19 vaccine. Tailoring the COVID-19 vaccine communications campaign to younger and non-physician HWs, and emphasizing the benefits of the COVID-19 vaccine, could help further increase vaccine coverage among HWs in Georgia.

Report of Adverse Effects Following Population-Wide COVID-19 Vaccination: A Comparative Study between Six Different Vaccines in Baja-California, Mexico. After emergency authorization, different COVID-19 vaccines were administered across Mexico in 2021, including mRNA, viral vector, and inactivated platform vaccines. In the state of Baja-California, 3,516,394 doses were administered, and 2285 adverse events (AE) were registered in the epidemiological surveillance system in 2021. Incidence rates per 100,000 doses were calculated for total, mild (local and systemic), and severe AE

for each vaccine. Symptoms were compared between mRNA and viral vector/inactivated virus vaccines. The overall incidence rate for all AE was 64.98 per 100,000 administered doses; 79.05 AE per 100,000 doses for mRNA vaccines; and 56.9 AE per 100,000 doses for viral vector/inactivated virus vaccine platforms. AE were at least five times higher in recipients of the AstraZeneca vaccine from the Serum Institute of India (AZ from SII). Local injection site symptoms were more common in mRNA vaccines while systemic were more prevalent in viral vector/inactivated virus vaccines. Severe AE rates were similar across all administered vaccines (0.72-1.61 AE per 100,000 doses), except for AZ from SII, which documented 12.6 AE per 100,000 doses. Among 32 hospitalized severe cases, 28 (87.5%) were discharged. Guillain-BarrÃ© Syndrome was the most common serious AE reported (n = 7). Adverse events rates differed among vaccine manufacturers but were consistent with clinical trials and population-based reports in the literature.

Survival of Vaccine-Induced Human Milk SARS-CoV-2 IgG, IgA and SIgA Immunoglobulins across Simulated Human Infant Gastrointestinal Digestion. Breastfeeding can be a vital way of acquiring passive immunity via the transfer of antibodies from the mother to the breastfeeding infant. Recent evidence points to the fact that human milk contains immunoglobulins (Ig) against the SARS-CoV-2 virus, either after natural infection or vaccination, but whether these antibodies can resist enzymatic degradation during digestion in the infant gastrointestinal (GI) tract or indeed protect the consumers remains inconclusive. Herein, we evaluated the levels of IgG, IgA, and secretory IgA (SIgA) antibodies against the spike protein of SARS-CoV-2 in 43 lactating mothers who received at least two doses of either an mRNA-based vaccine (Pfizer/BioNTech, Moderna; n = 34) or an adenovirus-based vaccine (AstraZeneca; n = 9). We also accessed the potential persistence of SARS-CoV-2 IgA, IgG, and secretory IgA (SIgA) antibodies from vaccinated women in the GI tract of the infants by means of a static in vitro digestion protocol. Our data depict that, although slightly reduced, the IgA antibodies produced after vaccination resist both the gastric and intestinal phases of infant digestion, whereas the IgGs are more prone to degradation in both phases of digestion. Additionally, SIgA antibodies were found to greatly resist the gastric phase of digestion albeit showing some reduction during the intestinal phase. The evaluation of the vaccine induced Ig profile of breastmilk, and the extent to which these antibodies can resist digestion in the infant GI tract provide important information about the potential protective role of this form of passive immunity that could help decision making during the COVID-19 pandemic and beyond.

SARS-CoV-2 Vaccination Coverage and Factors Associated with Low Uptake in a Cohort of People Living with HIV. People living with HIV (PLWH) are prioritised for SARS-CoV-2 vaccination due to their vulnerability to severe COVID-19. Therefore, the epidemiological surveillance of vaccination coverage and the timely identification of suboptimally vaccinated PLWH is vital. We assessed SARS-CoV-2 vaccination coverage and factors associated with under-vaccination among PLWH in Catalonia, Spain. As of 11.12.2021, 9945/14942 PLWH (66.6%) had received â‰¥1 dose of a SARS-CoV-2 vaccine. Non-Spanish origin (adjusted odds ratio (aOR) 0.64, 95% CI 0.59â^'0.70), CD4 count of 200â^'349 cells/Î¼L (aOR 0.74, 95% CI 0.64â^'0.86) or 350â^'499 cells/Î¼L (aOR 0.79, 95% CI 0.70â^'0.88), detectable plasma HIV-RNA (aOR 0.61 95% CI 0.53â^'0.70), and previous SARS-CoV-2 diagnosis (aOR 0.58 95% CI 0.51â^'0.65) were associated with under-vaccination. SARS-CoV-2 diagnosis (437 [9.5%] vs. 323 [3.5%], p < 0.001), associated hospitalisations (10 [2.3%] vs. 0 [0%], p < 0.001), intensive care unit admissions (6 [1.4%] vs. 0 [0%], p < 0.001), and deaths (10 [2.3%] vs. 0 [0%], p < 0.001) were higher among unvaccinated PLWH. Vaccination coverage was lower among PLWH with a CD4 count >200 cells/Î¼L, detectable plasma HIV-RNA, previous SARS-CoV-2 diagnosis, and migrants. SARS-CoV-2 diagnosis, associated hospitalisations, and deaths among PLWH were lower among the vaccinated compared with the unvaccinated. SARS-CoV-2 vaccination prioritisation

has not completely reached vulnerable PLWH with poorer prognosis. This information can be used to inform public health strategies.

Early Adverse Events and Immune Response Following Second and Third COVID-19 Vaccination in Pregnancy. (1) Background: The adverse-effect profile and short-term obstetric and neonatal outcomes among pregnant women who were vaccinated with the BNT162b2 vaccine at any stage of pregnancy do not indicate any safety concerns. The vaccine is effective in generating a humoral immune response in pregnant women. (2) Objective: To determine the vaccine-induced immunity and adverse events associated with the third (booster) dose of the BNT162b2 vaccine compared to the first and second dose of the vaccine among pregnant women. (3) Study design: A prospective cohort study in a tertiary referral center comparing pregnant women who were vaccinated by the first and second dose of the BNT162b2 (Pfizer/BioNTech) vaccine to pregnant women vaccinated by a third (booster) dose, between January and November 2021. A digital questionnaire regarding adverse events was filled by both groups 2â^'4 weeks after vaccination. Blood samples were collected and tested for SARS-COV-2 IgG antibodies 28â^'32 days after the administration of the second or third BNT162b2 dose. (4) Results: Seventy-eight pregnant women who received the first and second doses of the vaccine were compared to eighty-four pregnant women who received the third dose of the vaccine. In terms of adverse events following vaccination, local rash/pain/swelling (93.6% vs. 72.6%, $p < 0.001$) was significantly less common after the third vaccination compared to after the second vaccination. Other adverse events, including early obstetric complications, did not differ between the two groups. SARS-CoV-2 IgG serum levels 28â^'32 days after the vaccination were significantly higher after the third vaccination compared to the second vaccination (1333.75 vs. 2177.93, respectively, $p < 0.001$). (5) Conclusion: This study confirms the safety regarding early adverse events and immunogenicity, and the lack of early obstetric complications of the BNT162b2 second- and third-dose vaccine in pregnant women. The third (booster) dose is effective in generating a stronger humoral immune response in pregnant women compared with the second dose.

Monitoring Anti-PEG Antibodies Level upon Repeated Lipid Nanoparticle-Based COVID-19 Vaccine Administration. PEGylated lipids are one of the four constituents of lipid nanoparticle mRNA COVID-19 vaccines. Therefore, various concerns have been raised on the generation of anti-PEG antibodies and their potential role in inducing hypersensitivity reactions following vaccination or in reducing vaccine efficacy due to anti-carrier immunity. Here, we assess the prevalence of anti-PEG antibodies, in a cohort of vaccinated individuals, and give an overview of their time evolution after repeated vaccine administrations. Results indicate that, in our cohort, the presence of PEG in the formulation did not influence the level of anti-Spike antibodies generated upon vaccination and was not related to any reported, serious adverse effects. The time-course analysis of anti-PEG IgG showed no significant booster effect after each dose, whereas for IgM a significant increase in antibody levels was detected after the first and third dose. Data suggest that the presence of PEG in the formulation does not affect safety or efficacy of lipid-nanoparticle-based COVID-19 vaccines.

Oral Lesions Following Anti-SARS-CoV-2 Vaccination: A Systematic Review. Increasing evidence relate anti-SARS-CoV-2 vaccinations to orofacial adverse reactions, therefore, the present systematic review aimed to evaluate primary oral lesions diagnosed in adult subjects, following the WHO Emergency Use Listing approved and EMA authorized vaccines, also in relation to cases' age, gender, comorbidities, and history of COVID-19, and in relation to vaccine type and doses. The study protocol, registered on PROSPERO (CRD42022339032) and compliant with the PRISMA statement, included an electronic search across Scopus, MEDLINE/PubMed, BioMed Central databases, and PROSPERO, ended on 18 June 2022 and succeeded by a manual search, an independent data extraction, and arisk of bias evaluation through ROBINS-I tool. Qualitatively synthesized data from the 13studies included showed an overall low prevalence (16 cases), though higher in females (68.8%), of oral lesions, mainly

erosions and ulcers (34.5%). Nine cases were diagnosed following Pfizer-BioNTech, two Moderna, and one AstraZeneca, Serum Institute of India, Sinopharm, and Johnson&Johnson vaccines, respectively; specifically, eight after the first dose and seven after the second. In one case, vaccine type and dose were not specified. Considering newly developing vaccines, presented findings may be updated and further studies needed to highlight factors affecting oral lesion occurrence and specific macro-microscopic phenotypes in relation to cases' and vaccines' characteristics.

Understanding, Trusting, and Applying Scientific Insights to Improve Your Health: A Latent Profile Analysis Approach. Various leading causes of death can be prevented or delayed through informed decision-making and lifestyle changes. Previous work has, to some extent, linked such health-promoting behavior (HPB) with variables capturing individuals' understanding of science, trust in science, and capacity to apply evidence-based information in the health context. However, empirical research on the relationship between scientific knowledge, trust in science, health literacy, and HPB is scarce. Additionally, no study has investigated whether these characteristics interact to form homogeneous, high-risk subgroups of the population. The present online study (N = 705) revealed that trust in science and health literacy were positively related to a wide array of HPBs (e.g., healthy nutrition, physical activity, stress management), while scientific knowledge was only positively associated with COVID-19 vaccination intention. Furthermore, the results of latent profile analyses yielded four subgroups (i.e., low, moderate, and high levels of all three variables and a varied profile exhibiting very low trust in science, low health literacy, and moderate scientific knowledge). The identified subgroups differ significantly in HPB and variables determining profile membership (e.g., political conservatism). Hence, the present study offers some guidance on which groups may be targeted with public health campaigns and how they may be designed.

Analysis of Factors Affecting Neutralizing Antibody Production after COVID-19 Vaccination Using Newly Developed Rapid Point-of-Care Test. (1) Objective: To investigate the factors that affect rates of neutralizing antibody production and duration after vaccination using the newly developed SARS-CoV-2 POCT. (2) Methods: The production of immunoglobulin and neutralizing antibody in clinical subjects who completed various vaccines was analyzed using the POCT, the semi-quantitative was interpreted by measurement application, and the quantified neutralizing antibody titers were using the ELISA. (3) Results: According to the clinical performance analysis of the POCT, the clinical sensitivity and the specificity were 96.8% (90/93) and 97.7% (167/171), respectively, for the S1 RBD IgG antibody. The clinical sensitivity was 92.22% (83/90), and the clinical specificity was 100.00% (174/174) for neutralizing antibodies. Factors influencing antibody production were analyzed using the whole blood of the five types of second-completed vaccinators (N = 736, 20â˜’80 years old). General and neutralizing antibody and showed significant differences in age ($p < 0.0001$), vaccine type ($p < 0.0001$), inoculation interval ($p < 0.0001$), pain score ($p < 0.0001$), diabetes ($p < 0.0001$), and hypertension ($p = 0.002$). The gender ($p = 0.021$) and chronic fatigue ($p = 0.02$) did not show the significance. (4) Conclusions: An acquisition of immunoglobulin and neutralizing antibody varies according to vaccine type, age, days after vaccination, pain degree after vaccination, and underlying diseases. The POCT used in this study will be utilized for clinical recommendations such as deciding whether to receive additional vaccines through the immediate rapid determination of neutralizing antibody generation in the clinical site.

Association between Vitamin D Serum Levels and Immune Response to the BNT162b2 Vaccine for SARS-CoV-2. The use of micronutrients such as vitamin D could improve the response to viral vaccines, particularly in immunosuppressed and immunosenescent subjects. Here, we analysed the association between serum 25-hydroxyvitamin D (25OHD) levels and the immune response elicited by the BNT162b2 vaccine in a cohort of 101 healthcare workers naÃ¯ve for SARS-CoV-2 infection. We observed no significant differences in anti-spike (S) IgG and T-cell responses according to the 25OHD

status at baseline. However, significant correlations between the 25OHD concentration at baseline and (i) the anti-S response ($p < 0.020$) and (ii) the neutralizing antibody (NT) titre ($p = 0.040$) at six months after the second dose were detected. We concluded that adequate levels of vitamin D may improve the immune response to mRNA vaccines such as BNT162b2, and that further larger studies are warranted in order to confirm these preliminary observations.

Bilateral Facial Weakness with Distal Paresthesia Following COVID-19 Vaccination: A Scoping Review for an Atypical Variant of Guillain-BarrÃ© Syndrome. Background and Purpose: Recent population-based studies from the US and UK have identified an increase in the occurrence of Guillain-BarrÃ© syndrome (GBS) following coronavirus disease 2019 (COVID-19) vaccination. However, the localized variant of GBS might be underestimated due to its rarity and atypical features. We aimed to identify and characterize bilateral facial weakness with distal paresthesia (BFWdp) as a GBS variant following COVID-19 vaccination. Materials and Methods: Relevant studies published during the COVID-19 pandemic were searched and identified in the MEDLINE, Embase, and other databases. Results: This review found that 18 BFWdp cases presented characteristics similar to previous BFWdp cases as defined in the literature: male dominance, frequent albuminocytological dissociation, and acute inflammatory demyelinating neuropathy pattern. In contrast, facial nerve enhancement on brain MRI and antiganglioside antibody positivity were often observed in BFWdp following COVID-19 vaccination. Conclusions: The mechanism of BFWdp following COVID-19 vaccination appears to be somewhat different from that of sporadic BFWdp. Neurological syndromes with rare incidence and difficulty in diagnosis should be considered adverse events of COVID-19 vaccination.

Myocarditis in 13-Year-Old Monochorionic Diamniotic Twins After COVID-19 Vaccination.

Humoral response after SARS-CoV-2 mRNA vaccination in patients with prostate cancer using steroids. OBJECTIVES: The effect of concomitant steroid use on the antibody response to a SARS-CoV-2 vaccine in patients with prostate cancer (PC) remains unknown. We aimed to evaluate the rates of antispike immunoglobulin G (IgG) antibody response to the BNT162b2 mRNA vaccine in patients with PC using steroids. METHODS: This cross-sectional study conducted from June 21, 2021 to January 5, 2022 included 215 patients with PC who received the second dose of the BNT162b2 mRNA vaccine at least 7 days before the measurement of titers of IgG antibodies against the receptor-binding domain of SARS-CoV-2 spike (S) protein. We compared the rate of anti-SARS-CoV-2 S IgG â‰¥15 U/mL between patients with or without concomitant steroid use. RESULTS: Of 215, we identified 33 patients who had concomitant steroid use. Of these, 12 and 21 patients were metastatic castration-sensitive PC and castration-resistant PC (CRPC), respectively. Patients with concomitant steroid use had a significantly lower rate of antibody titer â‰¥15 U/mL than those without steroid use (82% vs. 95%, Pâ€¯=â€¯0.021). Patients with CRPC with concomitant steroid use (n =21) also had a lower rate of antibody titer â‰¥15 U/mL (71%) than those without steroid use (93%, Pâ€¯=â€¯0.051), although this was not statistically different. Increased number of systemic treatments administered after diagnosis of CRPC (3 lines or more) were significantly associated with antibody titers <15 U/mL (97% vs. 77%, P <0.001). CONCLUSION: The humoral response to the BNT162b2 mRNA vaccine was significantly lower in patients with concomitant steroid use. Anti-SARS-CoV-2 S antibody titers were affected by CRPC status, the accumulation of post-CRPC treatments, and steroid use.

Neutralizing antibody responses in healthcare personnel after three doses of mRNA BNT162b2 vaccine and association with baseline characteristics and past SARS-CoV-2 infection. AIM: To estimate neutralizing antibody (NAb) immunity against SARS-CoV-2 in 739 healthcare personnel (HCP) vaccinated with three doses of BNT162b2 mRNA vaccine. METHODS: Serum samples were collected at 3, 6, and 9Â months after the second vaccine dose and at 7-55Â days after the third dose. Samples

were tested for NAbs against SARS-CoV-2 receptor binding domain. RESULTS: The mean inhibition rates at 3, 6, and 9Â months after the second dose were 86.33%, 73.38%, and 61.18%, and increased to 95.57% after the booster dose. Younger HCP and HCP with past SARS-CoV-2 infection had higher inhibition rates while there was an inverse correlation between NAb levels and comorbidities or tobacco use (p-valuesÂ <Â 0.001). Increased NAb titers were also noticed in women (p-valueÂ =Â 0.033), especially at the end of the 9-month study period. CONCLUSION: NAb levels increased considerably after a booster mRNA vaccine dose. Host factors and past SARS-CoV-2 infection influence NAb titers.

Is it safe and effective to administer COVID-19 vaccines during pregnancy? A systematic review and meta-analysis. OBJECTIVE: To evaluate the safety and efficacy of COVID-19 vaccines in pregnant women performing an updated meta-analysis. METHODS: We searched PubMed, Cochrane Central, and SCOPUS from inception to March 2022. Outcomes of interest were incidence of adverse maternal, fetal and neonatal consequences pertaining to safety of the vaccines. Secondarily, we analyzed the number of SARS-CoV-2 infections, hospitalization for COVID-19, and admission to the I.C.U. for COVID-19 assessing the effectiveness of vaccines. Results were pooled using a random effects model. RESULTS: Ten observational studies (n=326,499) analyzing pregnant women were included. Our results suggest that COVID-19 vaccination prevents infection (OR: 0.56, 95% CI: 0.47, 0.67; PÂ =Â <0.00001) and related hospitalizations (OR: 0.50, 95% CI: 0.31, 0.82; PÂ =Â 0.006) effectively. It was also observed that vaccination does not change adverse outcomes in pregnancy, namely preeclampsia or eclampsia, stroke (four weeks of delivery), meconium-stained amniotic fluid, spontaneous vaginal delivery, operative vaginal delivery, cesarean delivery, postpartum hemorrhage, and blood transfusions. Furthermore, the vaccine was observed to be protective against neonatal COVID-19 I.C.U. admissions (OR: 0.85; 95% CI: 0.81, 0.90; PÂ =Â <0.00001). CONCLUSION: Our pooled analysis suggests that the COVID-19 vaccination in pregnant women prevents infection effectively and has no adverse outcomes. Future large-scale trials in a randomized fashion are needed to confirm our results.

Good recovery of immunization stress-related responses presenting as a cluster of stroke-like events following CoronaVac and ChAdOx1 vaccinations. BACKGROUND: Immunization stress-related responses presenting as stroke-like symptoms could develop following COVID-19 vaccination. Therefore, this study aimed to describe the clinical characteristics of immunization stress-related responses causing stroke-like events following COVID-19 vaccination in Thailand. METHODS: We conducted a retrospective study of the secondary data of reported adverse events after COVID-19 immunization that presented with neurologic manifestations. Between March 1 and July 31, 2021, we collected and analyzed the medical records of 221 patients diagnosed with stroke-like symptoms following immunization. Two majority types of vaccines were used at the beginning of the vaccination campaign, including CoronaVac (Sinovac) or ChAdOx1 (AstraZeneca). Demographic and medical data included sex, age, vaccine type, sequence dose, time to event, laboratory data, and recovery status as defined by the modified Rankin score. The affected side was evaluated for associations with the injection site. RESULTS: Overall, 221 patients were diagnosed with immunization stress-related responses (stroke-like symptoms) following CoronaVac (Sinovac) or ChAdOx1 (AstraZeneca) vaccinations. Most patients (83.7%) were women. The median (interquartile range) age of onset was 34 (28-42) years in patients receiving CoronaVac and 46 (33.5-60) years in those receiving ChAdOx1. The median interval between vaccination and symptom onset for each vaccine type was 60 (16-960) min and 30 (8.8-750) min, respectively. Sensory symptoms were the most common symptomology. Most patients (68.9%) developed symptoms on the left side of the body; 99.5% of the patients receiving CoronaVac and 100% of those receiving ChAdOx1 had a good outcome (modified Rankin scores â‰¤2, indicating slight or no disability). CONCLUSIONS: Immunization stress-related responses

presenting as stroke-like symptoms can develop after COVID-19 vaccination. Symptoms more likely to occur on the injection side are transient (i.e., without permanent pathological deficits). Public education and preparedness are important for administering successful COVID-19 vaccination programs.
Cardiovascular Manifestation of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents. This study focuses on cardiovascular manifestation, particularly myocarditis and pericarditis events, after BNT162b2 mRNA COVID-19 vaccine injection in Thai adolescents. This prospective cohort study enrolled students aged 13-18 years from two schools, who received the second dose of the BNT162b2 mRNA COVID-19 vaccine. Data including demographics, symptoms, vital signs, ECG, echocardiography, and cardiac enzymes were collected at baseline, Day 3, Day 7, and Day 14 (optional) using case record forms. We enrolled 314 participants; of these, 13 participants were lost to follow-up, leaving 301 participants for analysis. The most common cardiovascular signs and symptoms were tachycardia (7.64%), shortness of breath (6.64%), palpitation (4.32%), chest pain (4.32%), and hypertension (3.99%). One participant could have more than one sign and/or symptom. Seven participants (2.33%) exhibited at least one elevated cardiac biomarker or positive lab assessments. Cardiovascular manifestations were found in 29.24% of patients, ranging from tachycardia or palpitation to myopericarditis. Myopericarditis was confirmed in one patient after vaccination. Two patients had suspected pericarditis and four patients had suspected subclinical myocarditis. In conclusion, Cardiovascular manifestation in adolescents after BNT162b2 mRNA COVID-19 vaccination included tachycardia, palpitation, and myopericarditis. The clinical presentation of myopericarditis after vaccination was usually mild and temporary, with all cases fully recovering within 14 days. Hence, adolescents receiving mRNA vaccines should be monitored for cardiovascular side effects. Clinical Trial Registration: NCT05288231.
Myocarditis Following COVID-19 Vaccination: Cardiac Imaging Findings in 118 Studies. We reviewed the reported imaging findings of myocarditis in the literature following COVID-19 vaccination on cardiac imaging by a literature search in online databases, including Scopus, Medline (PubMed), Web of Science, Embase (Elsevier), and Google Scholar. In total, 532 cases of myocarditis after COVID-19 vaccination were reported (462, 86.8% men and 70, 13.2% women, age range 12 to 80) with the following distribution: Pfizer-BioNTech: 367 (69%), Moderna: 137 (25.8%), AstraZeneca: 12 (2.3%), Janssen/Johnson & Johnson: 6 (1.1%), COVAXIN: 1 (0.1%), and unknown mRNA vaccine: 9 (1.7%). The distribution of patients receiving vaccine dosage was investigated. On cardiac MR Imaging, late intravenous gadolinium enhancement (LGE) was observed mainly in the epicardial/subepicardial segments (90.8%, 318 of 350 enhancing segments), with the dominance of inferolateral segment and inferior walls. Pericardial effusion was reported in 13.1% of cases. The vast majority of patients (94%, 500 of 532) were discharged from the hospital except for 4 (0.7%) cases. Post-COVID-19 myocarditis was most commonly reported in symptomatic men after the second or third dose, with CMRI findings including LGE in 90.8% of inferior and inferolateral epicardial/subepicardial segments. Most cases were self-limited.
Rare Heterogeneous Adverse Events Associated with mRNA-Based COVID-19 Vaccines: A Systematic Review. Background: Since the successful development, approval, and administration of vaccines against SARS-CoV-2, the causative agent of COVID-19, there have been reports in the published literature, passive surveillance systems, and other pharmacovigilance platforms of a broad spectrum of adverse events following COVID-19 vaccination. A comprehensive review of the more serious adverse events associated with the Pfizer-BioNTech and Moderna mRNA vaccines is warranted, given the massive number of vaccine doses administered worldwide and the novel mechanism of action of these mRNA vaccines in the healthcare industry. Methods: A systematic review of the literature was conducted to identify relevant studies that have reported mRNA COVID-19 vaccine-related adverse

events. Results: Serious and severe adverse events following mRNA COVID-19 vaccinations are rare. While a definitive causal relationship was not established in most cases, important adverse events associated with post-vaccination included rare and non-fatal myocarditis and pericarditis in younger vaccine recipients, thrombocytopenia, neurological effects such as seizures and orofacial events, skin reactions, and allergic hypersensitivities. Conclusions: As a relatively new set of vaccines already administered to billions of people, COVID-19 mRNA-based vaccines are generally safe and efficacious. Further studies on long-term adverse events and other unpredictable reactions in close proximity to mRNA vaccination are required.

Epidemiological aspects of headache after different types of COVID-19 vaccines: An online survey. BACKGROUND: Coronavirus disease 2019 (COVID-19) vaccine-related side effects are a key concern with the emergence of various types of vaccines in the market. We aimed to assess the frequency and characteristics of headache following different types of COVID-19 vaccines. METHODS: Fully vaccinated people were recruited by a convenience sample through an online survey from September 1 to December 1, 2021. Detailed analysis of headache following vaccination was investigated. Participants with a history of pre-existing headaches were telephone interviewed by a neurologist to ascertain the type of headache. RESULTS: A total of 1372 participants participated (mean age 32.9â€‰Â±â€‰11.1). The highest frequency of headache was reported with the adenoviral vector type (302/563, 53.6%), followed by mRNA vaccines (129/269, 48%) and then the inactivated type (188/540, 34.8%). Recipients of the adenoviral vector type had a significantly longer latency between vaccination and the headache onset (median 8Â h [5:12]) than recipients of the inactivated type (median 4Â h [2:8], pâ€‰<â€‰0.001). Headache intensity was significantly higher with the adenoviral vector type (median 6 [5:8]) than with the inactivated type (median 5 [4:7], pâ€‰<â€‰0.001). Adenoviral vector vaccines would increase the likelihood of headache by 2.38 times more than inactivated vaccines (odds ratio [OR] 2.38, 95% confidence interval [CI] 1.83-3.04, pâ€‰<â€‰0.001). Female sex and thyroid disease were significantly associated with headache related to COVID-19 vaccines (OR 1.52, 95% CI 1.16-1.99; OR 3.97, 95% CI 1.55-10.2, respectively). CONCLUSION: Recipients of the COVID-19 vaccine should be counseled that they may experience headaches, especially after the adenoviral vector type. However, the intensity of such headache is mild to moderate and can resolve within a few days. Based on the current study design and the potential recall bias, these results may not be generalizable and should be preliminary.

A Preliminary Study about the Role of Reactive Oxygen Species and Inflammatory Process after COVID-19 Vaccination and COVID-19 Disease. During the last couple of critical years, worldwide, there have been more than 550 million confirmed cases of COVID-19, including more than 6 million deaths (reported by the WHO); with respect to these cases, several vaccines, mainly mRNA vaccines, seem to prevent and protect from SARS-CoV-2 infection. We hypothesize that oxidative stress is one of the key factors playing an important role in both the generation and development of various kinds of disease, as well as antibody generation, as many biological paths can generate reactive oxygen species (ROS), and cellular activities can be modulated when ROS/antioxidant balance is interrupted. A pilot study was conducted in two stages during the COVID-19 pandemic in 2021 involving 222 participants between the ages of 26 and 66 years. ROS levels were measured before an after vaccination in the blood samples of 20 individuals who were vaccinated with two doses of mRNA vaccine, and an increase in ROS levels was observed after the first dose, with no modifications observed until the day before the second vaccination dose. A statistically significant difference ($p < 0.001$) was observed between time points 3 and 4 (before and after second dose), when participants were vaccinated for the second time, and ROS levels decreased from 21,758 to 17,580 a.u. In the second stage, blood was collected from 28 participants 45 days after COVID-19 infection (Group A), from 131 participants 45 days after receiving two doses of mRNA vaccine against COVID-19 (Group B),

and from 13 healthy individuals as a control group (Group C). Additionally, antibodies levels were measured in all groups to investigate a possible correlation with ROS levels. A strong negative correlation was found between free radicals and disease antibodies in Group A (r = âˆ’0.45, p = 0.001), especially in the male subgroup (r = âˆ’0.88, p = 0.001), as well as in the female subgroup (r = âˆ’0.24, p < 0.001). Furthermore, no significant correlation (only a negative trend) was found with antibodies derived from vaccination in Group B (r = âˆ’0.01), and a negative trend was observed in the female subgroup, whereas a positive trend was observed in the male subgroup.

A Rapid and Sensitive Microfluidics-Based Tool for Seroprevalence Immunity Assessment of COVID-19 and Vaccination-Induced Humoral Antibody Response at the Point of Care. As of 8 August 2022, SARS-CoV-2, the causative agent of COVID-19, has infected over 585 million people and resulted in more than 6.42 million deaths worldwide. While approved SARS-CoV-2 spike (S) protein-based vaccines induce robust seroconversion in most individuals, dramatically reducing disease severity and the risk of hospitalization, poorer responses are observed in aged, immunocompromised individuals and patients with certain pre-existing health conditions. Further, it is difficult to predict the protection conferred through vaccination or previous infection against new viral variants of concern (VoC) as they emerge. In this context, a rapid quantitative point-of-care (POC) serological assay able to quantify circulating anti-SARS-CoV-2 antibodies would allow clinicians to make informed decisions on the timing of booster shots, permit researchers to measure the level of cross-reactive antibody against new VoC in a previously immunized and/or infected individual, and help assess appropriate convalescent plasma donors, among other applications. Utilizing a lab-on-a-chip ecosystem, we present proof of concept, optimization, and validation of a POC strategy to quantitate COVID-19 humoral protection. This platform covers the entire diagnostic timeline of the disease, seroconversion, and vaccination response spanning multiple doses of immunization in a single POC test. Our results demonstrate that this platform is rapid (~15 min) and quantitative for SARS-CoV-2-specific IgG detection.

Measurements of Anti-SARS-CoV-2 Antibody Levels after Vaccination Using a SH-SAW Biosensor. To prevent the COVID-19 pandemic that threatens human health, vaccination has become a useful and necessary tool in the response to the pandemic. The vaccine not only induces antibodies in the body, but may also cause adverse effects such as fatigue, muscle pain, blood clots, and myocarditis, especially in patients with chronic disease. To reduce unnecessary vaccinations, it is becoming increasingly important to monitor the amount of anti-SARS-CoV-2 S protein antibodies prior to vaccination. A novel SH-SAW biosensor, coated with SARS-CoV-2 spike protein, can help quantify the amount of anti-SARS-CoV-2 S protein antibodies with 5 Î¼L of finger blood within 40 s. The LoD of the spike-protein-coated SAW biosensor was determined to be 41.91 BAU/mL, and the cut-off point was determined to be 50 BAU/mL (Youdenâ€™s J statistic = 0.94733). By using the SH-SAW biosensor, we found that the total anti-SARS-CoV-2 S protein antibody concentrations spiked 10âˆ’14 days after the first vaccination (p = 0.0002) and 7âˆ’9 days after the second vaccination (p = 0.0116). Furthermore, mRNA vaccines, such as Moderna or BNT, could achieve higher concentrations of total anti-SARS-CoV-2 S protein antibodies compared with adenovirus vaccine, AZ (p < 0.0001). SH-SAW sensors in vitro diagnostic systems are a simple and powerful technology to investigate the local prevalence of COVID-19.

A mosaic-type trimeric RBD-based COVID-19 vaccine candidate induces potent neutralization against Omicron and other SARS-CoV-2 variants. Large-scale populations in the world have been vaccinated with COVID-19 vaccines, however, breakthrough infections of SARS-CoV-2 are still growing rapidly due to the emergence of immune-evasive variants, especially Omicron. It is urgent to develop effective broad-spectrum vaccines to better control the pandemic of these variants. Here, we present a mosaic-type trimeric form of spike receptor-binding domain (mos-tri-RBD) as a broad-spectrum

vaccine candidate, which carries the key mutations from Omicron and other circulating variants. Tests in rats showed that the designed mos-tri-RBD, whether used alone or as a booster shot, elicited potent cross-neutralizing antibodies against not only Omicron but also other immune-evasive variants. Neutralizing antibody ID50 titers induced by mos-tri-RBD were substantially higher than those elicited by homo-tri-RBD (containing homologous RBDs from prototype strain) or the BIBP inactivated COVID-19 vaccine (BBIBP-CorV). Our study indicates that mos-tri-RBD is highly immunogenic, which may serve as a broad-spectrum vaccine candidate in combating SARS-CoV-2 variants including Omicron.

 The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic continues to pose a serious threat to public health and has so far resulted in over six million deaths worldwide. Mass vaccination programs have reduced the risk of serious illness and death in many people, but the virus continues to persist and circulate in communities across the globe. Furthermore, the current vaccines may be less effective against the new variants of the virus, such as Omicron and Delta, which are continually emerging and evolving. Therefore, it is urgent to develop effective vaccines that can provide broad protection against existing and future forms of SARS-CoV-2. There are several different types of SARS-CoV-2 vaccine, but they all work in a similar way. They contain molecules that induce immune responses in individuals to help the body recognize and more effectively fight SARS-CoV-2 if they happen to encounter it in the future. These immune responses may be so specific that new variants of a virus may not be recognized by them. Therefore, a commonly used strategy for producing vaccines with broad protection is to make multiple vaccines that each targets different variants and then mix them together before administering to patients. Here, Zhang et al. took a different approach by designing a new vaccine candidate against SARS-CoV2 that contained three different versions of part of a SARS-CoV2 protein â€“ the so-called spike protein â€“ all linked together as one molecule. The different versions of the spike protein fragment were designed to include key features of the fragments found in Omicron and several other SARS-CoV-2 variants. The experiments found that this candidate vaccine elicited a much higher immune response against Omicron and other SARS-CoV-2 variants in rats than an existing SARS-CoV-2 vaccine. It was also effective as a booster shot after a first vaccination with the existing SARS-CoV-2 vaccine. These findings demonstrate that the molecule developed by Zhang et al. induces potent and broad immune responses against different variants of SARS-CoV-2 including Omicron in rats. The next steps following on from this work are to evaluate the safety and immunogenicity of this vaccine candidate in clinical trials. In the future, it may be possible to use a similar approach to develop new broad-spectrum vaccines against other viruses.

Decompressive craniectomy for intracranial hypertension in vaccine-induced immune thrombotic thrombocytopaenia: a case series. BACKGROUND: Vaccines have been key in preventing COVID-19 infections and the AstraZeneca (AZ) vaccine has been widely used. However, increased rates of thromboembolic events were identified in recipients and, subsequently, a syndrome of vaccine-induced immune thrombotic thrombocytopaenia (VITT) was described whereby recipients presented with venous sinus thromboses, haemorrhagic infarctions, and - consequently - raised intracranial pressure. National guidance recommended decompressive craniectomies for refractory intracranial hypertension. We describe our neurosurgical experience in managing a cohort of patients with VITT. CLINICAL PRESENTATION: Four patients were included (three females and one male); median age was 46 years. All patients presented with a constellation of headache, focal neurological deficit(s), altered consciousness, and/or seizure at a median 11 d post-vaccine. Pre-operatively, median GCS was 7 and the median platelet count was 28â€‰Ã—â€‰10(9)/L. Mean craniectomy size was 13â€‰cm Ã—â€‰10â€‰cm. All four cases tested positive for anti-PF4 antibodies. Median length of stay was 9 d (range: 2-25). Of the four who were operated upon, two survived to hospital discharge, and one of these subsequently died at a peripheral hospital. CONCLUSIONS: VITT-related sinus thromboses and

associated infarcts are rare complications of the AZ vaccine. Neurosurgical management involves treating intracranial hypertension however survival outcomes in our cohort were poor. In our series, decompression was performed in deteriorating patients however prophylactic decompression, in the presence of extensive venous sinus thrombosis, should be considered on a case-by-case basis. As vaccination programmes accelerate across the world, neurosurgeons are likely to be increasingly involved in managing intracranial hypertension in patients with VITT-related sinus thromboses.

Pityriasis Rosea Following Pfizer-BioNTech Vaccination in an Adolescent Girl. Pityriasis rosea (PR) is an acute self-limiting exanthematous skin disorder characterized by the presence of a primary solitary lesion called a herald patch and the subsequent development of diffuse papulosquamous lesions within 1 to 2 weeks. This is a case of COVID-19 vaccine-induced PR in the age group (12-18 years) that was recently approved for vaccination. We report a case of a 15-year-old otherwise healthy female with a history of 2 weeks of single oval primary plaque appearing on the right wrist 2 days after receiving the second dose of Pfizer-BioNTech vaccine, followed by diffuse and mild itchy skin eruptions spreading over the abdomen, back, chest, and extremities. The patient had no other symptoms and no PR risk factors. The patient was placed on 800 mg acyclovir five times a day and improved markedly after 1 week. As vaccine-induced PR/PR-like eruptions (PR-LE) is an uncommon phenomenon, we recommend further studies to determine the association between PR/PR-LE and COVID-19 vaccination.

Renal outcomes in immunoglobulin A nephropathy following COVID-19 vaccination: a retrospective cohort study.

Emotional profiling and cognitive networks unravel how mainstream and alternative press framed AstraZeneca, Pfizer and COVID-19 vaccination campaigns. COVID-19 vaccines have been largely debated by the press. To understand how mainstream and alternative media debated vaccines, we introduce a paradigm reconstructing time-evolving narrative frames via cognitive networks and natural language processing. We study Italian news articles massively re-shared on Facebook/Twitter (up to 5 million times), covering 5745 vaccine-related news from 17 news outlets over 8 months. We find consistently high trust/anticipation and low disgust in the way mainstream sources framed "vaccine/vaccino". These emotions were crucially missing in alternative outlets. News titles from alternative sources framed "AstraZeneca" with sadness, absent in mainstream titles. Initially, mainstream news linked mostly "Pfizer" with side effects (e.g. "allergy", "reaction", "fever"). With the temporary suspension of "AstraZeneca", negative associations shifted: Mainstream titles prominently linked "AstraZeneca" with side effects, while "Pfizer" underwent a positive valence shift, linked to its higher efficacy. Simultaneously, thrombosis and fearful conceptual associations entered the frame of vaccines, while death changed context, i.e. rather than hopefully preventing deaths, vaccines could be reported as potential causes of death, increasing fear. Our findings expose crucial aspects of the emotional narratives around COVID-19 vaccines adopted by the press, highlighting the need to understand how alternative and mainstream media report vaccination news.

Acute Arterial Ischemic Stroke Following COVID-19 Vaccination: A Systematic Review and Meta-analysis. BACKGROUND AND OBJECTIVES: Acute arterial ischemic stroke (AIS) has been reported as a rare adverse event following coronavirus disease 2019 (COVID-19) vaccination with messenger RNA (mRNA) or viral vector vaccines. However, data are sparse regarding the risk of postvaccination AIS and its potential association with thrombotic-thrombocytopenia syndrome (TTS). METHODS: A systematic review and meta-analysis of randomized controlled clinical trials (RCTs), pharmacovigilance registries, registry-based studies, observational cohorts, and case-series was performed with the aim to calculate the following: (1) the pooled proportion of patients presenting with AIS following COVID-19 vaccination; (2) the prevalence of AIS after mRNA and vector-based vaccination; and (3) the proportion of TTS among postvaccination AIS cases. Patient characteristics

were assessed as secondary outcomes. RESULTS: Two RCTs, 3 cohort studies, and 11 registry-based studies comprising 17,481 AIS cases among 782,989,363 COVID-19 vaccinations were included in the meta-analysis. The pooled proportion of AIS following exposure to any COVID-19 vaccine type was 4.7 cases per 100,000 vaccinations (95% CI 2.2-8.1; I (2) = 99.9%). The pooled proportion of AIS following mRNA vaccination (9.2 cases per 100,000 vaccinations; 95% CI 2.5-19.3; I (2) = 99.9%) did not differ compared with adenovirus-based vaccination (2.9 cases per 100,000 vaccinations; 95% CI 0.3-7.8; I (2) = 99.9%). No differences regarding demographics were disclosed between patients with AIS following mRNA-based or vector-based vaccination. The pooled proportion of TTS among postvaccination AIS cases was 3.1% (95% CI 0.7%-7.2%; I (2) = 78.8%). DISCUSSION: The pooled proportion of AIS following COVID-19 vaccination is comparable with the prevalence of AIS in the general population and much lower than the AIS prevalence among severe acute respiratory syndrome coronavirus 2-infected patients. TTS is very uncommonly reported in patients with AIS following COVID-19 vaccination.

Acute Perimyocarditis in an Adolescent Japanese Male after a Booster Dose of the BNT162b2 COVID-19 Vaccine. Perimyocarditis is a rare and serious cardiac complication following COVID-19 vaccination. Young males are most at risk after the second dose. With the introduction of the booster (third) dose, some reports have focused on the risk of perimyocarditis after a booster dose. However, no currently available report in Japan has comprehensively described this phenomenon. A healthy 14-year-old Japanese male, who had completed a two-dose primary series of the BNT162b2 (Pfizer-BioNTech) vaccine six months prior, developed fever and chest pain within 24 hours after a homologous booster dose. He was transferred to our institute because of worsening chest pain. A multiplex PCR test showed no evidence of active viral infections, including SARS-CoV-2. Electrocardiography revealed ST-segment elevation in almost all leads, suggesting pericarditis. Echocardiography showed normal systolic function. Laboratory data demonstrated C-reactive protein levels of 8.8 mg/dL and elevated cardiac damage markers (troponin T, 1.9 ng/mL; creatine phosphokinase, 1527 U/L; MB isoenzyme, 120 U/L), suggesting myocarditis. He was diagnosed with perimyocarditis associated with the booster dose, which was confirmed by cardiac magnetic resonance imaging four days after initial symptoms. Chest pain improved spontaneously along with a resolution of electrocardiographic findings and laboratory data within several days. He was discharged eight days after admission. Perimyocarditis is less frequent after a booster dose than after primary doses. In this case, the patient with booster-dose-associated perimyocarditis showed favorable clinical course without severe sequelae. The patient's clinical course was consistent with findings on previous large-scale reports on primary-dose-associated perimyocarditis and case series on booster-dose-associated perimyocarditis.

Cutaneous manifestations following SARS-CoV-2 vaccination.

Hyperbaric oxygen for COVID-19 patients with severe hypoxia prior to vaccine availability. INTRODUCTION: Few treatments have demonstrated mortality benefits among hospitalized hypoxic COVID-19 patients. We evaluated the use of hyperbaric oxygen (HBO2) therapy as a therapeutic intervention among hospitalized patients with a high oxygen requirement prior to vaccine approval. METHODS: We extracted data on patients with COVID-19 hypoxia who required oxygen supplementation ranging from a 6L nasal cannula up to a high-flow nasal cannula at 100% FiO2 at 60L/minute with a 100% non-rebreather mask at 15 L/minute and were eligible for off-label HBO2 therapy from October 2020 to February 2021. We followed the Monitored Emergency use of Unregistered and Investigational Interventions or (MEURI) in conjunction with the consistent re-evaluation of the protocol using the Plan-Do-Study-Act (PDSA) tool [1]. We compared patient characteristics and used Fisher's exact test and a survival analysis to assess the primary endpoint of inpatient death. RESULTS: HBO2 therapy was offered to 36 patients, of which 24 received treatment

and 12 did not receive treatment. Patients who did not receive treatment were significantly older (p â‰º 0.01) and had worse baseline hypoxia (p = 0.06). Three of the 24 (13%) patients who received treatment died compared to six of 12 (50%) patients who did not receive treatment (RR ratio: 0.25, p = 0.04, 95% CI: 0.08 to 0.83). In the survival analysis, there was a statistically significant reduction in inpatient mortality in the treatment group (HR: 0.19, p = 0.02, 95% CI: 0.05-0.74). However, after adjusting for age and baseline hypoxia, there was no difference in inpatient mortality (hazard ratio: 0.48, p = 0.42, 95% CI: 0.08-2.86). CONCLUSION: The survival benefit of HBO2 therapy observed in our unadjusted analysis suggests that there may be therapeutic benefits of HBO2 in treating COVID-19 hypoxia as an adjunct to standard care.

Immune response induced in rodents by anti-CoVid19 plasmid DNA vaccine via pyro-drive jet injector inoculation. There is an urgent need to stop the coronavirus disease 2019 (COVID-19) pandemic through the development of efficient and safe vaccination methods. Over the short term, plasmid DNA vaccines can be developed as they are molecularly stable, thus facilitating easy transport and storage. pVAX1-SARS-CoV2-co was designed for the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) S protein. The antibodies produced led to immunoreactions against the S protein, an anti-receptor-binding-domain, and a neutralizing action of the pVAX1-SARS-CoV2-co, as previously confirmed. To promote the efficacy of the pVAX1-SARS-CoV2-co vaccine a pyro-drive jet injector (PJI) was used. An intradermally adjusted PJI demonstrated that the pVAX1-SARS-CoV2-co vaccine injection caused a high production of anti-S protein antibodies, triggered immunoreactions, and neutralized the actions against SARS-CoV-2. A high-dose pVAX1-SARS-CoV2-co intradermal injection using PJI did not cause any serious disorders in the rat model. A viral challenge confirmed that intradermally immunized mice were potently protected from COVID-19. A pVAX1-SARS-CoV2-co intradermal injection using PJI is a safe and promising vaccination method for overcoming the COVID-19 pandemic.

Toxic epidermal necrolysis after first dose of Pfizer-BioNTech (BNT162b2) vaccination with pharmacogenomic testing. Toxic epidermal necrolysis (TEN) is a rare and acute life-threatening condition and one of the severe cutaneous adverse drug reactions. There are limited data on TEN from the COVID-19 vaccine regarding its pathogenesis, treatment, and prognosis, particularly in children. We report a case of COVID-19 vaccine-induced TEN and the patient's human leukocyte antigen pharmacogenomic profile.

Comment on "Toxic epidermal necrolysis (TEN) after first dose of Pfizer (BNT162b2) vaccination and pharmacogenomic-based-point-care support: First case report in pediatric and review of literature".

Seroconversion after a third COVID-19 vaccine is affected by rituximab dose but persistence is not in patients with rheumatoid arthritis. OBJECTIVES: In patients with RA treated with (ultra-)low-dose rituximab (RTX), we investigated the association of dosing and timing of RTX on seroconversion after a third coronavirus disease 2019 (COVID-19) vaccination and the persistence of humoral response after a two-dose vaccination. MATERIAL AND METHODS: In this monocentre observational study, patients from the COVAC cohort were included in the third vaccine analysis if humoral response was obtained 2-6â€‰weeks after a third vaccination in previous non-responders and in the persistence analysis if a follow-up humoral response was obtained before a third vaccination in previous responders. Dichotomization between positive and negative response was based on the assay cut-off. The association between the latest RTX dose before first vaccination, timing between the latest RTX dose and vaccination and response was analysed with univariable logistic regression. RESULTS: Of the 196 patients in the cohort, 98 were included in the third vaccine analysis and 23 in the persistence analysis. Third vaccination response was 19/98 (19%) and was higher for 200â€‰mg RTX users [5/13 (38%)] than for 500 and 1000â€‰mg users [7/37 (19%) and 7/48 (15%), respectively]. Non-significant trends were seen for higher response with lower dosing [200 vs 1000â€‰mg: odds ratio (OR) 3.66

(95% CI 0.93, 14.0)] and later timing [per month since infusion: OR 1.16 (95% CI 0.97, 1.35)]. Humoral response persisted in 96% (22/23) and 89% (8/9) of patients who received RTX between the two measurements. CONCLUSIONS: Repeated vaccination as late as possible after the lowest RTX dose possible seems the best vaccination strategy. A once positive humoral response after COVID-19 vaccination persists irrespective of intercurrent RTX infusion. Study registration. Netherlands Trial Registry (https://www.trialregister.nl/), NL9342.

Hybrid Immunity Shifts the Fc-Effector Quality of SARS-CoV-2 mRNA Vaccine-Induced Immunity. Despite the robust immunogenicity of SARS-CoV-2 mRNA vaccines, emerging data have revealed enhanced neutralizing antibody and T cell cross-reactivity among individuals that previously experienced COVID-19, pointing to a hybrid immune advantage with infection-associated immune priming. Beyond neutralizing antibodies and T cell immunity, mounting data point to a potential role for additional antibody effector functions, including opsinophagocytic activity, in the resolution of symptomatic COVID-19. Whether hybrid immunity modifies the Fc-effector profile of the mRNA vaccine-induced immune response remains incompletely understood. Thus, here we profiled the SARS-CoV-2 specific humoral immune response in a group of individuals with and without prior COVID-19. As expected, hybrid Spike-specific antibody titers were enhanced following the primary dose of the mRNA vaccine but were similar to those achieved by naive vaccinees after the second mRNA vaccine dose. Conversely, Spike-specific vaccine-induced Fc-receptor binding antibody levels were higher after the primary immunization in individuals with prior COVID-19 and remained higher following the second dose compared to those in naive individuals, suggestive of a selective improvement in the quality, rather than the quantity, of the hybrid humoral immune response. Thus, while the magnitude of antibody titers alone may suggest that any two antigen exposures-either hybrid immunity or two doses of vaccine alone-represent a comparable prime/boost immunologic education, we find that hybrid immunity offers a qualitatively improved antibody response able to better leverage Fc-effector functions against conserved regions of the virus. IMPORTANCE Recent data indicates improved immunity to SARS-CoV-2 in individuals who experience a combination of two mRNA vaccine doses and infection, "hybrid immunity," compared to individuals who receive vaccination or experience infection alone. While previous infection accelerates the vaccine-induced immune response following the first dose of mRNA vaccination, subsequent doses demonstrate negligible increases in antibody titers or T cell immunity. Here, using systems serology, we observed a unique antibody profile induced by hybrid immunity, marked by the unique induction of robust Fc-recruiting antibodies directed at the conserved region of the viral Spike antigen, the S2-domain, induced at lower levels in individuals who only received mRNA vaccination. Thus, hybrid immunity clearly redirects vaccine-induced immunodominance, resulting in the induction of a robust functional humoral immune response to the most highly conserved region of the SARS-CoV-2 Spike antigen, which may be key to protection against existing and emerging variants of concern. Thus, next-generation vaccines able to mimic hybrid immunity and drive a balanced response to conserved regions of the Spike antigen may confer enhanced protection against disease.

Acute near-fatal multisystem inflammatory syndrome and fulminant myocarditis post ChAdOx1 nCoV-19 vaccination in a SARS-CoV-2 naÃ¯ve individual.

Polymyositis and raised troponin after mRNA COVID-19 vaccination.

Patients with previous immediate hypersensitivity reactions to polyethylene glycol can safely receive the BNT162b2 mRNA COVID-19 vaccine. Previous anaphylaxis or immediate allergic reaction to polyethylene glycol (PEG; also known as macrogol) is considered a contraindication to the BNT162b2 mRNA COVID-19 vaccine, which contains 50â€‰ug of PEG at a molecular weight of 2000, and this component is thought to account for the higher rate of anaphylaxis seen with this vaccine (4.7 per million doses) than with other non-mRNA vaccines. However, there is evidence that both anaphylaxis

to PEG and anaphylaxis to the Pfizer COVID-19 reaction may not be IgE-mediated, with patients with anaphylaxis to first dose of the Pfizer COVID-19 vaccine receiving their second dose of vaccine without no or milder reactions in a high-risk clinic setting. In New Zealand, non-PEG-containing COVID-19 vaccines were not available until late 2021. Therefore, we offered patients with known or suspected PEG anaphylaxis their first dose of Pfizer COVID-19 vaccine in a high-risk hospital clinic. Eleven patients with previous hypersensitivity to PEG (including eight with anaphylaxis) successfully received their first dose with mild or no reactions; all have now had their second doses in the community without significant reaction. Record review also showed that most patients with previous hypersensitivity reactions to pegylated asparaginase have also been successfully vaccinated. This demonstrates that previous PEG hypersensitivity, including anaphylaxis, does not exclude immunisation with the Pfizer COVID-19 vaccine.

De novo PLA2R positive membranous nephropathy following BNT162b2 mRNA COVID-19 vaccine.

Association of COVID-19 vaccination before conception with maternal liver function during early pregnancy: a cohort study of 7745 Chinese pregnant women. ABSTRACTMulticenter case series has reported patients with hepatic injury following COVID-19 vaccination, which raised concern for the possibility of vaccine-induced liver dysfunction. We aimed to assess the impact of COVID-19 vaccination on liver function of pregnant women, who may be uniquely susceptible to vaccine-induced liver dysfunction. We conducted a retrospective cohort study at a tertiary hospital in Shanghai, China. Vaccine administration was obtained from the electronic vaccination record. Serum levels of alanine transaminase (ALT), aspartate transaminase (AST), total bile acid (TBA) and total bilirubin (TBIL) in early pregnancy were determined by enzymatic methods. Among the 7745 included pregnant women, 3832 (49.5%) received at least two doses of an inactivated vaccine. COVID-19 vaccination was significantly associated with higher levels of maternal serum TBA. Compared with unvaccinated pregnant women, the mean TBA levels increased by 0.17 Î¼mol/L (Î²â€‰=â€‰0.17, 95% CI, 0.04, 0.31) for women who had been vaccinated within 3 months before the date of conception. Moreover, COVID-19 vaccination was significantly associated with an increased risk of maternal hyperbileacidemia. The risk of hyperbileacidemia increased by 113% (RRâ€‰=â€‰2.13; 95% CI, 1.17-3.87) for pregnant women who had been vaccinated within 3 months before conception compared with unvaccinated pregnant women. However, when the interval from complete vaccination to conception was prolonged to more than 3 months, COVID-19 vaccination was not associated with serum TBA levels or maternal hyperbileacidemia. Our findings suggest that vaccination with inactivated COVID-19 vaccines more than 3 months before conception have no detrimental effects on maternal liver function in early pregnancy.

Efficacy and safety of COVID-19 vaccines: A network meta-analysis. OBJECTIVE: Several vaccines showed a good safety profile and significant efficacy against COVID-19. Moreover, in the absence of direct head to head comparison between COVID-19 vaccines, a network meta-analysis that indirectly compares between them is needed. METHODS: Databases PubMed, CENTRAL, medRxiv, and clinicaltrials.gov were searched. Studies were included if they were placebo-controlled clinical trials and reported the safety profile and/or effectiveness of COVID-19 vaccines. The quality of the included studies was assessed using the Revised Cochrane risk-of-bias tool for randomized trials and the Revised Cochrane risk-of-bias tool for nonrandomized trials. RESULTS: Forty-nine clinical trials that included 421,173 participants and assessed 28 vaccines were included in this network meta-analysis. The network meta-analysis showed that Pfizer is the most effective in preventing COVID-19 infection whereas the Sputnik Vaccine was the most effective in preventing severe COVID-19 infection. In terms of the local and systemic side, the Sinopharm and V-01 vaccines were the safest. CONCLUSION: We found that almost all of the vaccines included in this study crossed the threshold of 50% efficacy. However, some of them did not reach the previously mentioned threshold against the B.1.351 variant

while the remainder have not yet investigated vaccine efficacy against this variant. Since each vaccine has its own strong and weak points, we strongly advocate continued vaccination efforts in individualized manner that recommend the best vaccine for each group in the community which is abundantly required to save lives and to avert the emergence of future variants.

Axillary Lymphadenopathy Associated With COVID-19 Vaccination: Updates and Recommendations. Lymphadenopathy (LAD) associated with vaccination has been documented as complicating the evaluation of metastatic malignancy. In the past this was a limited finding, primarily documented in association with smallpox and H1N1 vaccination.The advent of the novel mRNA vaccine for COVID-19 in December of 2021, and subsequent large scale vaccination effort, has resulted in a marked increase in the identification of LAD associated with vaccination. Because axillary LAD is a concerning sign of metastatic disease in breast cancer, identifying the difference between benign inflammatory reaction and concerning LAD and avoiding unnecessary additional imaging and biopsy is an essential skill. This article describes the current literature, recommendations for follow-up, and interventions to improve diagnostics.

Isolated abducens nerve palsy following AstraZeneca vaccine: A case report. The corona virus disease 2019 (COVID-19) pandemic was triggered by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). SARS-CoV-2 infected millions of individuals globally. Despite the recent clearance of several medications, effective and safe COVID-19 vaccinations are still urgently needed, not only to prevent the disease from spreading but also to restore social and economic activity through mass vaccination. We present a case of a 72-year-old female who presented with sudden right abducens nerve palsy after receiving the 2nd dose of booster vaccine following the AstraZeneca COVID-19 vaccine. Because of the temporal association between vaccination and abducens nerve palsy, they assumed her vaccine caused it. The onset of symptoms, the absence of any prior medical conditions, and normal magnetic resonance imaging. This case highlights the importance of determining whether a COVID-19 vaccine could generate neurologic side effects similar to those found with the virus and previous vaccinations.

Changes in thrombosis-related parameters after AstraZeneca COVID-19 vaccination in a male volunteer: a case report. BACKGROUND: We speculated that subclinical thrombosis may occur frequently through crosstalk between immune/inflammatory reactions and hemostasis after corona virus disease-2019 (COVID-19) vaccination. To test this hypothesis, we measured thrombosis-related parameters after COVID-19 vaccination in a volunteer for 21 days. CASE PRESENTATION: The following parameters were measured in a 72-year-old Korean man at 1 day before vaccination and on days 1, 3, 7, 14, and 21 post vaccination (AstraZeneca COVID-19 vaccine: ChAdOx1-S/nCoV-19, CTMAV563): complete blood count, platelet indices, thrombin receptor-activating peptide-induced platelet aggregation, prothrombin time, activated partial thromboplastin time, D-dimer, thrombin-antithrombin III complex (TAT), plasmin-Î±2 antiplasmin complex (PAP), von Willebrand factor (vWF) antigen and activity, plasminogen activator inhibitor-1 (PAI-1), protein C and protein S antigen and activity, lupus anticoagulant, fibrinogen degradation product, and plasminogen. We found that the TAT had significantly increased from 0.7 ng/mL (baseline) to 21.7 ng/mL (day 1). There was a transient increase in the PAI-1 level from 7.2 ng/mL (baseline) to 10.9 ng/mL (day 3), followed by a decrease in PAP level from 0.9 ng/mL (baseline) to 0.3 Î¼g/mL (day 7), suggesting that plasmin generation is suppressed by PAI-1. CONCLUSIONS: Increased thrombotic factors (such as decreased protein S) and decreased fibrinolytic activity due to increased PAI-1 were potential factors causing thrombogenesis after COVID-19 vaccination. Sequential measurement of platelet indices, TAT, PAP, protein C, protein S, vWF, D-dimer, and PAI-1 following COVID-19 vaccination was informative.

Active Safety Surveillance of Four Types of COVID-19 Vaccines: A National Study from Jordan. BACKGROUND: Although the Pfizer-BioNTech (BNT162b2), Oxford-AstraZeneca (ChAdOx1 nCoV-19),

Sinopharm (BBIBP-CorV), and Sputnik V coronavirus disease 2019 (COVID-19) vaccines have been granted emergency approval in many nations, their safety has never been studied and compared in one community-based study. This study aimed to investigate and compare the incidence, nature, severity, and predictors of adverse events following immunization (AEFIs) with COVID-19 vaccines. METHOD: This was a prospective observational study conducted in Jordan between 1 January and 21 September 2021. A team of pharmacists and nurses (nÂ =Â 407) collected the local and systemic AEFIs of four COVID-19 vaccines by prospectively contacting participants registered in the national vaccination program platform. A red-flag technology was inserted to classify and track rare and serious AEFIs. RESULTS: This study included 658,428 participants who were vaccinated with 1,032,430 doses; 610,591, 279,606, 140,843, and 1390 participants received the first and second doses of the BNT162b2, BBIBP-CorV, ChAdOx1 nCoV-19, and Sputnik V vaccines, respectively. The overall incidence of AEFIs was 28.8%, and the overall rates of systemic, local, and immediate hypersensitivity AEFIs were 22.2%, 18.8%, and 0.5%, respectively. The highest proportions of immediate hypersensitivity AEFIs and systemic AEFIs were reported after administration of the Sputnik V vaccine and ChAdOx1 nCoV-19 first dose, respectively. The most severe AEFIs were reported after ChAdOx1 nCoV-19 first dose and BNT162b2 second dose. The hospitalization and mortality rates after vaccination were 20 in 10,000 and 1 in 10,000, respectively. Based on red-flag tracking, the top three outcome events were lymphadenopathy (157.9/100,000), anxiety disorders (136.6/100,000), and lower respiratory tract infection (100.9/100,000), with Guillain-BarrÃ© syndrome (1.8/100,000), vasculitis (3.0/100,000), and myopericarditis (4.8/100,000) being the least common. CONCLUSION: The incidence rates of local, systemic, and immediate hypersensitivity AEFIs of four COVID-19 vaccines occur frequently. High incidence rates of rare and serious AEFIs were reported in this study. Younger participants, females, those who had previously had COVID-19, and smokers were more likely to encounter AEFIs.

Vaccination in patients with kidney failure: lessons from COVID-19. Infection is the second leading cause of death in patients with chronic kidney disease (CKD). Adequate humoral (antibody) and cellular (T cell-driven) immunity are required to minimize pathogen entry and promote pathogen clearance to enable infection control. Vaccination can generate cellular and humoral immunity against specific pathogens and is used to prevent many life-threatening infectious diseases. However, vaccination efficacy is diminished in patients with CKD. Premature ageing of the immune system and chronic systemic low-grade inflammation are the main causes of immune alteration in these patients. In the case of SARS-CoV-2 infection, COVID-19 can have considerable detrimental effects in patients with CKD, especially in those with kidney failure. COVID-19 prevention through successful vaccination is therefore paramount in this vulnerable population. Although patients receiving dialysis have seroconversion rates comparable to those of patients with normal kidney function, most kidney transplant recipients could not generate humoral immunity after two doses of the COVID-19 vaccine. Importantly, some patients who were not able to produce antibodies still had a detectable vaccine-specific T cell response, which might be sufficient to prevent severe COVID-19. Correlates of protection against SARS-CoV-2 have not been established for patients with kidney failure, but they are urgently needed to enable personalized vaccination regimens.

Postvaccination Symptoms After a Third Dose of mRNA SARS-CoV-2 Vaccination in Patients With Inflammatory Bowel Disease: Results From CORALE-IBD. BACKGROUND: The safety of a third dose of SARS-CoV-2 mRNA vaccination in patients with inflammatory bowel disease is unknown. METHODS: We compared symptoms following a third SARS-CoV-2 mRNA vaccine dose with symptoms after the second dose in IBD. RESULTS: The study group included 594 patients (70% female, 58% BNT162b2). Overall, 41% reported symptoms after a third dose. Symptom frequency and severity were lower after the third dose relative to the second dose for every organ system, except

for gastrointestinal symptoms which were marginally worse. CONCLUSION: The frequency and severity of symptoms after a third mRNA vaccine dose are generally similar or milder than after a second dose for most organ systems.

 The postvaccination symptom profile in patients with IBD is unknown after a third mRNA COVID vaccine dose. In a cohort of 594 subjects with IBD, we demonstrated that 41% experienced any symptoms after a third dose, the vast majority of which were mild and lasted less than 2 days. Symptoms after third dose were less frequently reported than after the second dose.

Response to: Before blaming SARS-CoV-2 vaccinations for rhabdomyolysis, other potential triggers should be considered.

A case of Miller Fisher syndrome with delayed onset peripheral facial nerve palsy after COVID-19 vaccination: a case report. BACKGROUND: To prevent the spread of the novel coronavirus disease 2019 (COVID-19) infection, various vaccines have been developed and used in a large number of people worldwide. One of the most commonly used vaccines is the mRNA vaccine developed by Moderna. Although several studies have shown this vaccine to be safe, the full extent of its side effects has not yet been known. Miller-Fisher syndrome (MFS) is a rare condition that manifests ophthalmoplegia, ataxia, and loss of tendon reflexes. It is a subtype of Guillain-BarrÃ© syndrome and an immune-mediated disease related to serum IgG anti-GQ1b antibodies. Several vaccines including those for COVID-19 have been reported to induce MFS. However, there have been no reports of MFS following Moderna COVID-19 vaccine administration. CASE PRESENTATION: A 70-year-old man was referred to our hospital due to diplopia that manifested 1 week after receiving the second Moderna vaccine dose. The patient presented with restricted abduction of both eyes, mild ataxia, and loss of tendon reflexes. He was diagnosed with MFS based on his neurological findings and detection of serum anti-GQ1b antibodies. The patient was administered intravenous immunoglobulin, and his symptoms gradually improved. Five days after admission, the patient showed peripheral facial paralysis on the right side. This symptom was suggested to be a delayed onset of peripheral facial nerve palsy following MFS that gradually improved by administration of steroids and antiviral drugs. CONCLUSION: There have been no previous reports of MFS after Moderna COVID-19 vaccination. This case may provide new information about the possible neurological side effects of COVID-19 vaccines.

Factors related to the serious adverse events in patients visiting the emergency department after ChAdOx1 and mRNA COVID-19 vaccination. INTRODUCTION: We investigated the clinical characteristics, outcomes and factors related to the serious adverse events (AEs) of patients visiting the emergency department (ED) with various AEs after ChAdOx1 and mRNA COVID-19 vaccination. METHODS: Patients with AEs who visited the ED between March 2021 and September 2021 were selected from three EDs. The clinical data of these patients were collected by retrospectively reviewing medical records. Serious adverse events (AEs) were defined as any adverse medical events that led to hospital admission. RESULTS: A total of 3572 patients visited the ED with AEs; 69.6% were administered mRNA vaccines, and the median (IQR) age was 48 (31-63) years. Regarding chief complaints, chest pain/discomfort (43.7%) was most common in the mRNA vaccines group, while fever (15.8%) was more commonly presented in the ChAdOx1 group. Most patients (93.9%) were discharged from the ED. In multivariate analysis, age â‰¥70 years, days from vaccination to ED visit â‰¥8 days, fever and dyspnea as chief complaints were higher independent risk factors for serious AEs (OR 27.94, OR 2.55, OR 1.95 and OR 2.18: pÂ <Â 0.001, pÂ <Â 0.001, pÂ =Â 0.003 and pÂ =Â 0.003, respectively). CONCLUSION: Most patients who visited the ED with AEs after vaccination were discharged from the ED regardless of the type of vaccine. Emergency physicians need to differentiate serious AEs and consider factors that may require admission to the ED.

Risk for Myocardial Infarction, Stroke, and Pulmonary Embolism Following COVID-19 Vaccines in Adults Younger Than 75 Years in France. BACKGROUND: The BNT162b2 (Pfizer-BioNTech) vaccine

has been shown to be safe with regard to risk for severe cardiovascular events (such as myocardial infarction [MI], pulmonary embolism [PE], and stroke) in persons aged 75 years or older. Less is known about the safety of other COVID-19 vaccines or outcomes in younger populations. OBJECTIVE: To assess short-term risk for severe cardiovascular events (excluding myocarditis and pericarditis) after COVID-19 vaccination in France's 46.5 million adults younger than 75 years. DESIGN: Self-controlled case series method adapted to event-dependent exposure and high event-related mortality. SETTING: France, 27 December 2020 to 20 July 2021. PATIENTS: All adults younger than 75 years hospitalized for PE, acute MI, hemorrhagic stroke, or ischemic stroke (nÂ =Â 73Â 325 total events). MEASUREMENTS: Linkage between the French National Health Data System and COVID-19 vaccine databases enabled identification of hospitalizations for cardiovascular events (MI, PE, or stroke) and receipt of a first or second dose of the Pfizer-BioNTech, mRNA-1273 (Moderna), Ad26.COV2.S (Janssen), or ChAdOx1 nCoV-19 (Oxford-AstraZeneca) vaccine. The relative incidence (RI) of each cardiovascular event was estimated in the 3 weeks after vaccination compared with other periods, with adjustment for temporality (7-day periods). RESULTS: No association was found between the Pfizer-BioNTech or Moderna vaccine and severe cardiovascular events. The first dose of the Oxford-AstraZeneca vaccine was associated with acute MI and PE in the second week after vaccination (RI, 1.29 [95% CI, 1.11 to 1.51] and 1.41 [CI, 1.13 to 1.75], respectively). An association with MI in the second week after a single dose of the Janssen vaccine could not be ruled out (RI, 1.75 [CI, 1.16 to 2.62]). LIMITATIONS: It was not possible to ascertain the relative timing of injection and cardiovascular events on the day of vaccination. Outpatient deaths related to cardiovascular events were not included. CONCLUSION: In persons aged 18 to 74 years, adenoviral-based vaccines may be associated with increased incidence of MI and PE. No association between mRNA-based vaccines and the cardiovascular events studied was observed. PRIMARY FUNDING SOURCE: None.

An Insight Into Pathophysiology, Epidemiology, and Management of Cardiovascular Complications of SARS-CoV-2 Infection, Post-acute COVID Syndrome, and COVID Vaccine. Coronavirus disease 2019 (COVID-19), the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was declared a pandemic health emergency in March 2020. Elderly patients and those with pre-existing medical conditions including cardiovascular disease are at increased risk of developing severe disease. Not only is the viral infection with SARS-CoV-2 associated with higher mortality in patients with underlying cardiovascular disease, but development of cardiovascular complications is also common in patients with COVID-19. Even after recovery from the acute illness, post-acute COVID syndrome with cardiopulmonary manifestations can occur in some patients. Additionally, there are rare but increasingly recognized adverse events, including cardiovascular side effects, reported with currently available COVID-19 vaccines. In this review, we discuss the most common cardiovascular complications of SARS-CoV-2 and COVID-19 vaccines, cardiopulmonary manifestations of post-acute COVID syndrome and the current evidence-based guidance on the management of such complications.

Axillary Adenopathy after COVID-19 Vaccine: No Reason to Delay Screening Mammogram.

COVID-19 Disease Severity in Persons Infected With Omicron BA.1 and BA.2 Sublineages and Association With Vaccination Status. This retrospective study compares the severity of SARS-CoV-2 infection among persons infected with BA.1 and BA.2 sublineages by vaccination status.

Risk of Myocarditis After Sequential Doses of COVID-19 Vaccine and SARS-CoV-2 Infection by Age and Sex. BACKGROUND: Myocarditis is more common after severe acute respiratory syndrome coronavirus 2 infection than after COVID-19 vaccination, but the risks in younger people and after sequential vaccine doses are less certain. METHODS: A self-controlled case series study of people ages 13 years or older vaccinated for COVID-19 in England between December 1, 2020, and December 15, 2021, evaluated the association between vaccination and myocarditis, stratified by age

and sex. The incidence rate ratio and excess number of hospital admissions or deaths from myocarditis per million people were estimated for the 1 to 28 days after sequential doses of adenovirus (ChAdOx1) or mRNA-based (BNT162b2, mRNA-1273) vaccines, or after a positive SARS-CoV-2 test. RESULTS: In 42 842 345 people receiving at least 1 dose of vaccine, 21 242 629 received 3 doses, and 5 934 153 had SARS-CoV-2 infection before or after vaccination. Myocarditis occurred in 2861 (0.007%) people, with 617 events 1 to 28 days after vaccination. Risk of myocarditis was increased in the 1 to 28 days after a first dose of ChAdOx1 (incidence rate ratio, 1.33 [95% CI, 1.09-1.62]) and a first, second, and booster dose of BNT162b2 (1.52 [95% CI, 1.24-1.85]; 1.57 [95% CI, 1.28-1.92], and 1.72 [95% CI, 1.33-2.22], respectively) but was lower than the risks after a positive SARS-CoV-2 test before or after vaccination (11.14 [95% CI, 8.64-14.36] and 5.97 [95% CI, 4.54-7.87], respectively). The risk of myocarditis was higher 1 to 28 days after a second dose of mRNA-1273 (11.76 [95% CI, 7.25-19.08]) and persisted after a booster dose (2.64 [95% CI, 1.25-5.58]). Associations were stronger in men younger than 40 years for all vaccines. In men younger than 40 years old, the number of excess myocarditis events per million people was higher after a second dose of mRNA-1273 than after a positive SARS-CoV-2 test (97 [95% CI, 91-99] versus 16 [95% CI, 12-18]). In women younger than 40 years, the number of excess events per million was similar after a second dose of mRNA-1273 and a positive test (7 [95% CI, 1-9] versus 8 [95% CI, 6-8]). CONCLUSIONS: Overall, the risk of myocarditis is greater after SARS-CoV-2 infection than after COVID-19 vaccination and remains modest after sequential doses including a booster dose of BNT162b2 mRNA vaccine. However, the risk of myocarditis after vaccination is higher in younger men, particularly after a second dose of the mRNA-1273 vaccine.

SARS-CoV2 mRNA Vaccine-Specific B-, T- and Humoral Responses in Adolescents After Kidney Transplantation. Protection of adult kidney transplant recipients against SARS-CoV2 was shown to be strongly impaired owing to low reactogenicity of available vaccines. So far, data on vaccination outcomes in adolescents are scarce due to later vaccination approval for this age group. We therefore comprehensively analyzed vaccination-specific humoral-, T- and B-cell responses in kidney transplanted adolescents aged 12-18Â years in comparison to healthy controls 6Â weeks after standard two-dose BNT162b2 ("Comirnaty"; Pfizer/BioNTech) vaccination. Importantly, 90% (18/20) of transplanted adolescents showed IgG seroconversion with 75% (15/20) developing neutralizing titers. Still, both features were significantly diminished in magnitude compared to controls. Correspondingly, spike-specific B cells were quantitatively reduced and enriched for non-isotype-class-switched IgD(+)27(+) memory cells in patients. Whereas spike specific CD4(+) T cell frequencies were similar in both groups, cytokine production and memory differentiation were significantly impaired in transplant recipients. Although our data identify limitations in all arms of vaccine-specific immunity, the majority of our adolescent patients showed robust humoral responses despite antimetabolite-based treatment being associated with poor vaccination outcomes in adults.

COVID-19 vaccine-induced Recurrence of the Radiation Recall Phenomenon in the Laryngeal Mucosa Due to a VEGF Inhibitor. PURPOSE: The radiation recall phenomenon (RRP) is a rare and unexpected late complication of radiation therapy (RT). Although predominantly in the skin, RRP of the upper respiratory tract has also been reported. In general, RRP is caused by anticancer agents, and the COVID-19 vaccine has also been reported to cause RRP in recent years. METHODS AND MATERIALS: A 50-year-old woman who had received RT around the larynx 3 years prior and was receiving a docetaxelÂ +Â ramucirumab (RAM) regimen experienced recurrent sore throat. The administration of RAM was discontinued after a gastroscopic examination revealed mucosal bleeding from around the larynx, which was thought to be RRP caused by RAM, a vascular endothelial growth factor inhibitor. RESULTS: After the remission of the RRP, the patient received a COVID-19 vaccine (Pfizer-BioNTech). Five days later, the appearance of cough and recurrence of sore throat worsened

with time, and marked stridor was observed. The patient was admitted, and steroid pulse therapy was administered for 3 days starting on day 18 after vaccination. On day 50 after vaccination, edema of the vocal cords improved. CONCLUSIONS: When administering COVID-19 vaccines, considering that these vaccines may cause RRP is important, because RRP can be fatal in patients with a history of RT in the laryngeal region and treated with vascular endothelial growth factor inhibitors.

Global reports of takotsubo (stress) cardiomyopathy following COVID-19 vaccination: A systematic review and meta-analysis. Concerns have been raised recently about takotsubo cardiomyopathy (TCM) after receiving COVID-19 vaccines, particularly the messenger RNA (mRNA) vaccines. The goal of this study was to compile case reports to provide a comprehensive overview of takotsubo cardiomyopathy (TCM) associated with COVID-19 vaccines. A systematic literature search was conducted in PubMed, Scopus, Embase, Web of Science, and Google Scholar between 2020 and June 1, 2022. The study included individuals who developed cardiac takotsubo cardiomyopathy from receiving COVID-19 vaccinations. Ten studies, including 10 cases, participated in the current systematic review. The mean age was 61.8â€¯years; 90â€¯% were female, while 10â€¯% were male. 80â€¯% of the patients received the mRNA COVID-19 vaccine, while 20â€¯% received other types. In addition, takotsubo cardiomyopathy (TCM) occurred in 50â€¯% of patients receiving the first dose and another 40â€¯% after the second dose of COVID-19 vaccines. Moreover, the mean number of days to the onset of symptoms was 2.62â€¯days. All cases had an elevated troponin test and abnormal ECG findings. The left ventricular ejection fraction (LVEF) was lower than 50â€¯% in 90â€¯% of patients. In terms of the average length of hospital stay, 50â€¯% stayed for 10.2â€¯days, and all cases recovered from their symptoms. In conclusion, takotsubo (stress) cardiomyopathy (TCM) complications associated with COVID-19 vaccination are rare but can be life-threatening. Chest pain should be considered an alarming symptom, especially in those who have received the first and second doses of the COVID-19 vaccine.

Sweet syndrome following Moderna COVID-19 vaccine: A case report. With the COVID-19 pandemic, vaccines have been administered all around the world probably more than ever. Even though they are considered safe, with such a huge quantity of doses used, many adverse effects including cutaneous ones were reported. We report here the case of a male adult with a history of monoclonal gammopathy of undetermined significance who presented with an extensive cutaneous eruption of indurated erythematous papules and plaques 2 days after receiving his first dose of Moderna COVID-19 vaccine (mRNA-1273 SARS-CoV-2 vaccine). Histopathology was compatible with a histiocytoid Sweet syndrome and history suggested that the vaccine contributed to the eruption.

Case report: subacute thyroiditis after receiving SARS-CoV-2 vaccine, maybe not only adjuvants. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) induced the new coronavirus disease 2019 (COVID-19) pandemic worldwide. SARS-CoV-2 vaccines are designed to control the transmission of the disease. However, post-vaccination subacute thyroiditis (SAT) also appears with increase vaccination rate. Three cases of SAT after SARS-CoV-2 vaccines are described in this study. We have reported the patients' clinical symptoms, laboratory tests, and thyroid imaging. Tests for COVID-19 were all negative, and the patients did not report thyroid-related diseases, autoimmune diseases, or preceding upper respiratory system infections in their medical history. Three female patients showed neck pain on physical examination. The laboratory test results and imaging findings were consistent with the diagnostic criteria of SAT. The patients were carried out a standardized treatment according to their symptoms, and we closely followed up their response to the treatment. Clinicians must be aware of the possibility of SAT after receiving the vaccines and make timely therapy.

Clinical presentation and cardiac imaging findings in patient cases of perimyocarditis and pericarditis with a temporal association to SARS-CoV-2 vaccination. AIMS: We aimed to investigate and present cases of perimyocarditis and pericarditis verified by cardiovascular resonance (CMR) imaging

in patients with a strong temporal association to SARS-CoV-2 vaccination. We sought to describe the clinical presentation including coronary artery angiography, CMR, transthoracic echocardiography, blood samples, electrocardiography, and symptoms. METHODS: We included 10 patients admitted with chest pain shortly after vaccination for SARS-CoV-2, who were diagnosed with pericarditis or perimyocarditis by CMR. We reviewed the CMR, echocardiography, electrocardiography, blood samples, coronary artery angiography, vital signs and medical history. The updated Lake Louise Criteria were used to determine the diagnosis by CMR. RESULTS: Eight patients had perimyocarditis and two patients had pericarditis. The mean age was 22 Â± 5 years (range 16 to 31 years), 90% were male. The median time from vaccination to hospital admission was 4 days (range 2 to 28 days). Admissions were seen after vaccination with three different SARS-CoV-2 vaccine manufacturers. Nine Patients had ST-elevation on the initial electrocardiography. Peak troponins varied from 357 to 23,547 ng/l, with a median of 4,304 ng/l. Two patients had an LVEF <50% on echocardiography and four patients had left ventricular global longitudinal strain values <18%. CMR revealed preserved left ventricular ejection fraction (LVEF), although one patient had decreased LVEF on CMR. The T1 and T2 mapping values were increased in all patients. Of the 8 patients with perimyocarditis, all patients had signs of myocardial injury in the lateral segments of the left ventricle. CONCLUSIONS: This case series of 10 patients supports the emerging evidence of an association between vaccination for SARS-CoV-2 and perimyocarditis and pericarditis, especially in young males. The temporal association was seen after vaccines from three different manufacturers. Imaging data from echocardiography and CMR displayed normal to mildly impaired cardiac function, usually with a mild disease course.

Safety of inactivated SARS-CoV-2 vaccines in myasthenia gravis: A survey-based study. BACKGROUND: Vaccination remains the most effective measure to prevent SARS-CoV-2 infection and worse outcomes. However, many myasthenia gravis (MG) patients are hesitant to receive vaccine due to fear of worsening. METHODS: MG patients were consecutively enrolled in two MG centers in North China. The "worsening" after vaccination was self-reported by MG patients, and severity was measured with a single simple question. The general characteristics and disease status immediately prior to the first dose were compared between the worsening and non-worsening groups. Independent factors associated with worsening were explored with multivariate regression analysis. RESULTS: One hundred and seven patients were included. Eleven patients (10.3%) reported worsening after vaccination, including eight patients with mild or moderate worsening and three patients with severe worsening. Only one of them (0.9%) needed an escalation of immunosuppressive treatments. There were significant differences between the worsening and non-worsening groups in terms of Myasthenia Gravis Foundation of America classes immediately before the first dose and intervals since the last aggravation. Precipitating factors might contribute to the worsening in some patients. Logistic regression revealed that only interval since the last aggravation â‰¤6 months was associated with worsening after SARS-CoV-2 vaccination (P = 0.01, OR = 8.62, 95% CI: 1.93-38.46). CONCLUSION: SARS-CoV-2 vaccines (an overwhelming majority were inactivated vaccines) were found safe in milder Chinese MG patients who finished two doses. Worsening after vaccination was more frequently seen in patients who were presumed as potentially unstable (intervals since last aggravation â‰¤6 months). However, mild worsening did occur in patients who were presumed to be stable. Precipitating factors should still be sought and treated for better outcome.

Post-vaccination T cell immunity to omicron. In late 2021, the omicron variant of SARS Coronavirus 2 (SARS-CoV-2) emerged and replaced the previously dominant delta strain. Effectiveness of COVID-19 vaccines against omicron has been challenging to estimate in clinical studies or is not available for all vaccines or populations of interest. T cell function can be predictive of vaccine longevity and effectiveness against disease, likely in a more robust way than antibody neutralization. In this mini review, we summarize the evidence on T cell immunity against omicron including effects

of boosters, homologous versus heterologous regimens, hybrid immunity, memory responses and vaccine product. Overall, T cell reactivity in post-vaccine specimens is largely preserved against omicron, indicating that vaccines utilizing the parental antigen continue to be protective against disease caused by the omicron variant.

COVID-19 Vaccine Acceptance and Associated Factors Among College Students in Dessie City, Northeastern Ethiopia. BACKGROUND: The COVID-19 vaccine is regarded as an effective measure for reducing the pandemic's impact. But, COVID-19 disease burden reduction efforts are being affected by the rising vaccine resistance. OBJECTIVE: To assess the COVID-19 vaccine acceptance and associated factors among college students in Dessie city, Northeastern Ethiopia. METHODS: An institutional-based cross-sectional study was carried out among college students in Dessie town from July 1-20, 2021. The association between independent and dependent variables was assessed by binary logistic regression analysis using crude odds ratio and adjusted odds ratio. Variables having p values of less than 0.05 at the 95% confidence interval were regarded as potential determinants of COVID-19 vaccine acceptance. RESULTS: A total of 422 college students participated in the study with a response rate of 95.6%. More than half 226 (56.2%) of the participants had willingness to accept COVID-19 vaccine. Respondents who had history of chronic medical illness (AOR: 4.340, 95% CI: 1.166, 16.149), training on COVID-19 vaccine (AOR: 4.755, 95% CI: 2.606, 6.674), history of regular vaccine uptake (AOR: 2.534, 95% CI: 1.412, 4.549), perception of COVID-19 severity (AOR: 4.109, 95% CI: 2.190, 7.710), perception that COVID-19 can be prevented by vaccine (AOR: 2.420, 95% CI: 1.160, 5.049), and development of herd immunity against COVID-19 vaccines (AOR: 2.566, 95% CI: 1.431, 4.599) were factors significantly associated with COVID-19 vaccine acceptance. CONCLUSION: The acceptance of COVID-19 vaccine among college students was low. The history of chronic medical illness, training on COVID-19 vaccine, history of vaccine uptake, perception that COVID-19 can be prevented by vaccine, perception of herd immunity development against COVID-19, and severity of COVID 19 infection were factors significantly associated with the acceptance of COVID-19 vaccine. Hence, it is necessary to promote COVID-19 vaccination among college students through health education and vaccine outreach.

Mental health outcomes and associated factors among vaccinated and unvaccinated teachers against COVID-19 infection in Bangladesh. BACKGROUND: Vaccination of teachers is recommended during the COVID-19 pandemic to reduce the risk of infection for themselves and their students, as well as to encourage their parents to get immunized. The present study investigated the mental health outcomes and associated factors among vaccinated and unvaccinated teachers against COVID-19 infection in Bangladesh. METHODS: A cross-sectional survey was conducted in Bangladesh from March 4 to September 9, 2021. The frequency of symptoms of psychological distress, depression, anxiety, stress, post-traumatic stress disorder (PTSD), insomnia, and fear was assessed using the Bangla versions of the GHQ-12, PHQ-2, GAD-2, PSS-4, PC-PTSD-5, ISI, and FCV-19S scales, respectively. RESULTS: A total of 1,527 Bangladeshi teachers completed the questionnaire, with 678 (44.4%) being vaccinated and 849 (55.6%) being unvaccinated. Compared with unvaccinated teachers, vaccinated teachers had a statistically significant lower prevalence of psychological distress (35.8 vs. 42.9%), depression (37.6 vs. 46.4%), anxiety (31.9 vs. 45.1%), stress (18.3 vs. 32.0%), PTSD (33.0 vs. 43.8%), insomnia (25.2 vs. 36.9%), and fear symptoms (23.3 vs. 29.6%). Among vaccinated teachers, participants with master's or lower degree levels had significantly higher symptoms of depression, stress, and fear than other education levels. Respondents with children had a significantly higher risk of depression, anxiety, stress, and fear symptoms than those who did not have children. Participants who lost family members, friends, or colleagues due to the COVID-19 pandemic had a significantly higher chance of experiencing symptoms of anxiety, PTSD, and fear than those who did not. On the other hand, unvaccinated male teachers were significantly associated with a higher risk of all mental

health outcomes except psychological distress and PTSD symptoms compared to female teachers. Participants who were smokers had a significantly higher chance of anxiety, stress, and fear symptoms than non-smokers. Compared to participants with strong social support, those with poor social support had a higher risk of all mental health outcomes except PTSD symptoms. CONCLUSION: This study suggests emphasizing the vaccinated to unvaccinated teachers as soon as possible to control the infection and improve mental health outcomes. Vulnerable teachers also required special attention, health-related education, and psychological support.

Myelin Oligodendrocyte Glycoprotein Antibody Disease After COVID-19 Vaccination - Causal or Incidental? A variety of neurological complications of COVID-19 vaccinations are reported with each passing day. We report a rare case of a patientÂ who developed brain stem and spinal cord lesions 20 days after the first dose of the ChAdOx1 nCoV-19 coronavirus vaccine. On further investigation, anti-myelin oligodendrocyte glycoprotein (anti-MOG) antibodies were strongly positive, and a diagnosis of myelin oligodendrocyte glycoprotein antibody disease (MOGAD) was made. This case report aims to add a rare entity to the possible complications of COVID-19 vaccines and discuss symptoms, MRI findings, and the differential diagnosis of MOGAD. We also suggest that these patients undergo follow-up serological tests to recognize recurrences quickly.

Reply to 'Nail psoriasis: A rare mRNA COVID-19 vaccine reaction' by Lamberti A et al.

Association of Systemic Adverse Reactions and Serum SARS-CoV-2 Spike Protein Antibody Levels after Administration of BNT162b2 mRNA COVID-19 Vaccine. Objectives The influential factors for anti-severe acute respiratory syndrome coronavirus 2 spike protein antibody (S-ab) levels were assessed after the administration of BNT162b2 mRNA coronavirus disease-2019 (COVID-19) vaccine at short and medium terms. Methods A total of 470 healthcare workers (118 males, mean age 41.0Â±11.9 years) underwent serum S-ab level measurement at 3 and 8 months after two inoculations of BNT162b2 vaccine given 3 weeks apart, who had no history of COVID-19 were enrolled in this study. The changes and differences after vaccination due to gender and adverse reactions of S-ab were analyzed. Results Systemic adverse reactions incidence (48%) was significantly higher after the second dose than after the first dose (8%). S-ab levels decreased as the age increased (from the 20s to 60s) in both measurements. S-ab level 8 months after the second inoculation [median 476.3 (interquartile range (IQR) 322.4-750.6) U/mL] was significantly lower than that after 3 months [977.5 (637.2-1,409.0) U/mL; p<0.001]. The median decrease rate of S-ab levels in 5 months was 50.3% (IQR 40.3-62.6) and those differences were not observed among all generations. Gender-associated differences in S-ab levels were not observed; however, a significant relationship between higher S-ab levels and the systemic adverse reactions was observed at both measurements. Conclusions The systemic adverse reaction is an independent factor for higher S-ab levels at short and medium terms after BNT162b2 vaccination as demonstrated in our data.

COVID-19 vaccination-related attendance at a pediatric emergency department in Singapore among 12- to 18-year old adolescents. BACKGROUND: Singapore was one of the first countries to begin COVID-19 vaccination with the BNT162b2 vaccine for adolescents aged 12-18 years. This study evaluates the incidence of COVID-19 vaccine related attendances to a Pediatric Emergency Department (PED) to understand post-vaccination health behaviors among adolescents. METHODS: This was a retrospective review of electronic medical records over a 4 month period, from the start of the adolescent vaccination drive to when more than 85% of this group had been fully vaccinated. RESULTS: The incidence of COVID-19 vaccination-related presentations to our PED was 3.1% over 4 months (291 of 9387Â PED attendances), with a peak daily incidence of 15.4% (14 of 91 attendances). Presentations were characterized by severity into: severe (3.4%), moderate (7.9%) or mild (88.7%) based on predefined criteria. The most common presenting complaints were chest pain (58.8%), dyspnea (28.2%) and palpitations (22.6%). Hospitalization was required in only 6.2% of attendances.

Patients with moderate-severe presentations were 0.7 years older (pÂ =Â 0.030), more likely to have underlying drug allergies (pÂ =Â 0.048) and had higher rates of hospitalization (pÂ <Â 0.005) compared to mild presentations. Despite concerns of cardiac inflammation, chest pain related attendances were less likely to be severe (pÂ <Â 0.005) with reduced hospitalization need (pÂ =Â 0.043) compared to other presentations. Investigations beyond clinical assessment comprised 91% of attendances, but abnormalities were only found in 6.4% cases. CONCLUSION: Our study supports current evidence that COVID-19 vaccination is safe amongst adolescents. We highlight the health behaviors among adolescents post-vaccination, which is partly driven by media reports on vaccine side effects and an element of anxiety. While most of the presentations were mild, these can have implications on health resource utilization, particularly in an ongoing pandemic. As healthcare workers, we have an ongoing role to ensure accurate information on vaccine safety is communicated effectively to the public.

Thrombosis with thrombocytopenia after AZD1222 (ChAdOx1 nCov-19) vaccination: Case characteristics and associations. BACKGROUND: Post-marketing surveillance for COVID-19 vaccines during the pandemic identified an extremely rare thrombosis with thrombocytopenia syndrome (TTS) reported post-vaccination, requiring further characterisation to improve diagnosis and management. METHODS: We searched the AstraZeneca Global Safety Database (through April 26, 2021) for cases with co-reported thrombocytopenia and thrombosis (using standardised MedDRA queries/high-level terms) following AZD1222 (ChAdOx1 nCoV-19). Cases were adjudicated by experts as 'typical','possible', 'no' or 'unknown' according to available TTS criteria. Additional confirmatory datasets (May 20-June 20, October 1-December 28) were evaluated. FINDINGS: We identified 573 reports, including 273 (47.6Â %) 'typical' and 171 (29.8Â %) 'possible' TTS cases. Of these 444 cases, 275 (61.9Â %) were female, median age was 50.0Â years (IQR: 38.0-60.0). Cerebral venous sinus thrombosis was reported in 196 (44.1Â %) cases, splanchnic venous thrombosis in 65 (14.6Â %) and thromboses at multiple sites in 119 (26.8Â %). Median time to onset was 12.0Â days (IQR: 9.0-15.0). Comparison with a pre-pandemic reference population indicated higher rates of autoimmune disorders (13.8Â %, 4.4Â %), previous heparin therapy (7.4Â %, 1.2Â %), history of thrombosis (5.5Â %, 1.4Â %), and immune thrombocytopenia (6.1Â %, 0.2Â %). Fatality rate was 22.2Â % (127/573) overall and 23.6Â % (105/444) in 'typical'/'possible' TTS, which decreased from 39.0Â % (60/154) in February/March to 15.5Â % (45/290) in April. Overall patterns were similar in confirmatory datasets. CONCLUSIONS: The reporting rate of 'typical'/'possible' TTS post first-dose vaccination in this dataset is 7.5 per million vaccinated persons; few cases were reported after subsequent doses, including booster doses. Peak reporting coincided with media-driven attention. Medical history differences versus a reference population indicate potentially unidentified risk factors. The decreasing fatality rate correlates with increasing awareness and publication of diagnostic/treatment guidelines. Adjudication was hindered by unreported parameters, and an algorithm was developed to classify potential TTS cases; comprehensive reporting could help further improve definition and management of this extremely rare syndrome.

Severe autoimmune haemolytic anaemia following SARS-CoV-2 vaccination in patients with treatment naÃ¯ve B-cell neoplasms: a case series.

Multiple Evanescent White Dot Syndrome with Submacular Fluid in Dome-shaped Macula Following COVID-19 Vaccination: A Case Report.

Clinical characteristics of patients with COVID-19 vaccine-related pneumonitis: a case series and literature review. BACKGROUND/AIMS: Pulmonary toxicities of coronavirus disease 2019 (COVID-19) vaccination are exceedingly rare. However, there are a few reported cases after mRNA vaccination, especially from Asian countries. The purpose of this study was to report the clinical characteristics of patients with COVID-19 vaccine-related pneumonitis (CV-P) and to review cases

reported in the literature. METHODS: We performed a prospective, observational case series analysis. RESULTS: Eleven patients with a median age of 80 years were enrolled. Ten patients developed CV-P after BNT162b2-mRNA vaccination and one after ChAdOx1 nCoV-19 vaccination. We identified various patterns of CV-P, including transient infiltration, life-threatening acute respiratory distress syndrome, and aggravation of underlying interstitial lung disease. Most patients showed favorable outcomes with good responses to corticosteroid therapy. CONCLUSION: Identifying the mechanism of CV-P requires further investigation; however, radiological and laboratory findings in our case series support inflammatory dysregulation in the lung parenchyma after vaccination. Clinicians should consider CV-P in patients with atypical lung infiltration, no specific etiologies, and recent COVID-19 vaccination.

Antibody response to coronavirus disease 2019 vaccines after allergic reaction to first dose: Correspondence.

Quantitative and qualitative features of acute phase-adverse events following SARS-CoV-2 vaccination in a large sample of people with multiple sclerosis. INTRODUCTION: Few data are available on adverse events (AE) associated to vaccines in persons with multiple sclerosis (pwMS). AIMS: to study the incidence of acute phase AE (AP-AE) related to SARS-CoV-2 mRNA vaccines in pwMS compared to a control group, and to analyze the association between AP-AE and disease modifying treatments (DMT). METHODS: This was a cross-sectional study on 438 PwMS and 481 age- and sex-matched subjects not affected by dysimmune diseases that underwent two doses of SARS-CoV-2 mRNA BNT162b2Â vaccine (Pfizer/BioNtech). RESULTS: Two hundred and twenty five (51.4%) pwMS complained of â‰¥1 AP-AE after the first dose, 269 (61.4%) after the second dose. A logistic regression analysis revealed that only pwMS on Fingolimod and Ocrelizumab did not show a higher risk of developing AP-AE. The likelihood to present with â‰¥1 AP-AE, after correcting for age and sex, was significantly higher in pwMS than controls. CONCLUSIONS: This study reports qualitative and quantitative features of AP-AE associated with the first and second doses of SARS-CoV-2 vaccine in a large sample of pwMS. The only risk factor identified for developing AP-AE is female gender. AntiCD-20 monoclonal antibodies and S1P inhibitors are associated with a lower risk of AP-AE occurrence.

Are corticosteroids useful in the treatment of brain edema associated with venous cerebral thrombosis (CVT) in patients with COVID-19 vaccine-related CVT? A controversial topic.

Parents' views on the acceptability of a COVID-19 vaccine for their children: A cross-sectional study in Abu Dhabi-United Arab Emirates. BACKGROUND: The United Arab Emirates had approved the COVID-19 vaccine for children. Assessing parents' acceptance of the vaccine for their children will influence decision-making in the COVID-19 vaccine roll-out. METHOD: Parents registered inthe AbuDhabiDepartmentofEducation (12,000 families) were invitedtocompleteanonlinequestionnaire from 8th September 2021 to 17th October 2021. Out of the 12,000 families, 2510 (21%) participants answered the survey. The questionnaire investigated the parents' attitudes and beliefs regarding the COVID-19 vaccine. RESULTS: The vaccination rate among this group of respondents was high, with 2255 (89.9%) having received two doses and 1002 (45.5%) having already received a booster dose. Acceptance of the respondents to vaccinate their children was high, (75.1%) said they would vaccinate their children, with 64.4% reporting that they would immediately vaccinate their children if the vaccine were made available. Determinants of COVID-19 child vaccination acceptance included the respondent's vaccination status-i.e., if the respondent is already vaccinated (OR 4.96 [2.89-8.53]) or has taken the third dose (OR 2.37 [1.4-4.01])-their children's age (OR 1.11 [1.30-1.18] for older children), and their trust in the following information sources: the government (OR 2.53 [1.61-3.98]), health care providers (OR 1.98 [1.2-3.24]), or social media (OR 2.17 [1.22-3.88]). Increased level of education had a negative impact on the acceptance of giving the vaccine to children (OR 0.63 [0.52-0.77]); fear of side effects OR 0.000164 (0.000039-0.001) was another determinant. The main factor

that encouraged parents to give their children the vaccine was to protect their child's health as reported by 1537 (55.5%) participants. CONCLUSION: The Abu Dhabi community is highly accepting of the vaccine for their children. Future studies of how this vaccine acceptance can influence the pandemic are needed.
Comparison the effects and side effects of Covid-19 vaccination in patients with inflammatory bowel disease (IBD): a systematic scoping review. Covid-19 is a pandemic disease that is more severe and mortal in people with immunodeficiency, such as those with inflammatory bowel disease (IBD). On the other hand, no definitive treatment has been identified for it and the best way to control it is wide spread vaccination. The aim of this study was to evaluate the benefits and side effects of different vaccines in patients with IBD. Three Electronic databases [Medline (accessed from PubMed), Scopus, Science Direct, and Cochrane] were searched systematically without time limit, using MESH terms and the related keywords in English language. We focused on the research studies on the effect and side effects of Covid-19 vaccination in patients with IBD. Articles were excluded if they were not relevant, or were performed on other patients excerpt patients with IBD. Considering the titles and abstracts, unrelated studies were excluded. The full texts of the remained studies were evaluated by authors, independently. Then, the studies' findings were assessed and reported. Finally, after reading the full text of the remained articles, 15 ones included in data extraction. All included studied were research study, and most of them (12/15) had prospective design. Totally, 8/15 studies were performed in single-center settings. In 8/15 studies, patients with IBD were compared with a control group. The results were summarized the in two categories: (1) the effect of vaccination, and (2) side effects. The effect of vaccination were assessed in 13/15 studies. Side effects of Covid-19 vaccination in patients with IBD were reported in 7/15 studies. Patients with IBD can be advised that vaccination may have limited minor side effects, but it can protect them from the serious complications of Covid-19 and its resulting mortality with a high success rate. They should be also mentioned in booster doses.
Response to "A commentary on "post-SARS-CoV-2-vaccine shoulder pain: Is it relevant to the vaccine injection? - Correspondence" (Int J Surg 2022;100:106603)".
SARS-CoV-2 vaccine-induced antibody and TÂ cell response in SARS-CoV-1 survivors. Preexisting immunity cross-reactive to severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) in SARS-CoV-1 survivors suggests that a coronavirus disease 2019 vaccine may boost such preexisting cross-reactive memory TÂ cells. We measure SARS-CoV-2 and SARS-CoV-1 spike-specific neutralizing antibody and TÂ cell responses in a single dose of Ad5-nCoV-immunized SARS-CoV-1 survivors 6Â months after vaccination. Compared with Ad5-nCoV-immunized naive healthy individuals (NHIs), vaccination of Ad5-nCoV in SARS-CoV-1 survivors boosts the antibody response against SARS-CoV-1 but induces a limited neutralizing antibody that is capable of neutralizing SARS-CoV-2 variants of concern, and nearly all serum samples lose neutralization to Omicron subvariants. Immunized SARS-CoV-1 survivors produce a TÂ cell response to SARS-CoV-2 comparable with that of Ad5-nCoV-immunized NHIs. However, a robust cross-reactive TÂ cell response to SARS-CoV-1 is identified in immunized SARS-CoV-1 survivors compared with Ad5-nCoV-immunized NHIs. These findings suggest that vaccination with Ad5-nCoV elicits a stronger neutralizing antibody and cross-reactive TÂ cell responses against SARS-CoV-1 in SARS-CoV-1 survivors.
Fatal neuromyelitis optica after COVID-19 vaccination.
Secondary Syphilis Presentation and Urticarial Eruption After Moderna COVID-19 Vaccination Response to the Letter to the Editor.
Evaluation of humoral immune responses induced by different SARS-CoV-2 spike trimers from wild-type and emerging variants with individual, sequential, and combinational delivered strategies. The spike trimer of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is an effective

target for inducing neutralizing antibodies by coronavirus disease 2019 (COVID-19) vaccines. However, the diversity of spike protein from emerging SASR-CoV-2 variants has become the major challenge for development of a universal vaccine. To investigate the immunogenicity of spike proteins from various circulating strains including wild type, Delta, and Omicron variants, we produced various natural spike trimers and designed three vaccination strategies, that is, individual, sequential, and bivalent regimens to assess autologous and heterogenous antibody responses in a mouse model. The results indicated that monovalent vaccine strategy with individual spike trimer could only induce binding and neutralizing antibodies against homologous viruses. However, sequential and bivalent immunization with Delta and Omicron spike trimers could induce significantly broader neutralizing antibody responses against heterogenous SARS-CoV-2. Interestingly, the spike trimer from Omicron variant showed superior immunogenicity in inducing antibody response against recently emerging XE variant. Taken together, our data supported the development of novel vaccination strategies or multivalent vaccine against emerging variants.

Unusual Case of Painful Glossitis and Xerostomia Following Vaccination with Pfizer-BioNTech SARS-CoV-2 (BNT162b2). BACKGROUND Adverse events following immunization (AEFIs) remain under recognized, particularly when the symptoms experienced are uncommon and mimic natural disease. In the context of the worldwide effort to provide protection against SARS-CoV-2 using multiple doses of vaccination and with the availability of multiple vaccines, the early recognition and prompt treatment of AEFIs has increased importance, as does the ability to carefully select an alternative after an AEFI occurs. CASE REPORT A 60-year-old woman presented for clinical immunology review with a 9-month history of glossitis and xerostomia. Onset of symptoms occurred following her first vaccination with a COVID-19 vaccine (BNT162b2). After partial interval improvement, her symptoms progressively worsened after a second vaccination and third booster vaccination with BNT162b2. While undergoing reviews from multiple specialists for possible underlying connective tissue disease, and with other causes of her symptoms being excluded, the patient's symptoms progressed, with worsening tongue swelling with new fissuring and xerostomia. The patient experienced an unintentional weight loss of 8 kg due to oral discomfort. It was only after this time that an AEFI was considered the cause of her presentation, after all other diagnostic considerations were considered unlikely. Targeted, symptomatic, localized treatment with topical oral corticosteroids was initiated, followed by a gradual tapering regimen, with excellent response. CONCLUSIONS This case highlights the need to consider AEFIs early in the differential diagnosis of unusual presentations and the importance of considering a trial of targeted symptomatic treatment for patients, even if diagnostic uncertainty remains.

SARS-CoV-2 RNA load in nasopharyngeal specimens from outpatients with breakthrough COVID-19 due to Omicron BA.1 and BA.2. This retrospective observational study compared severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA load in nasopharyngeal specimens (NPs) from patients with breakthrough coronavirus disease 2019 (COVID-19) caused by the Omicron BA.1 or BA.2 sublineages. The convenience sample was composed of 277 outpatients (176 female/112 male; median age, 48 years; range, 12-97) with breakthrough COVID-19 (nâ€‰=â€‰130 due to BA.1 and nâ€‰=â€‰147 due to BA.2). All participants had completed a full vaccination schedule and 56% had received a booster vaccine dose at the time of COVID-19 breakthrough microbiological diagnosis. NPs were collected within 7 days (median 2 days) after symptom onset. The TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific) was used to estimate viral loads in NPs. Overall, viral RNA loads in NPs were comparable (pâ€‰=â€‰0.31) for BA.1 (median, 7.1 log(10) copies/ml; range, 2.7-10.6) and BA.2 (median, 7.5 log(10) copies/ml; range, 2.7-10.6), yet peak viral load appeared to be reached sooner for BA.2 than for BA.1 (Day 1 vs. Days 3-5; pâ€‰=â€‰0.002). Time elapsed since last vaccine dose had no significant impact on SARS-CoV-2 RNA loads in the upper respiratory tract (URT) for either

BA.1 or BA.2. The data presented do not support that the transmissibility advantage of BA.2 over BA.1 is related to generation of higher viral loads in the URT early after infection.

Major severe acute respiratory coronavirus-2 (SARS-CoV-2) vaccine-associated adverse effects; benefits outweigh the risks. INTRODUCTION: Since its emergence, there have been huge efforts to design vaccines against coronavirus disease 2019 (COVID-19) to inhibit its interpersonal spread. Global vaccine development is the most promising cost-effective method for overcoming the epidemic. However, following reports of post-vaccination thromboembolic adverse effects, there have been raising concerns about the safety profile of the COVID-19 vaccine. AREAS COVERED: We aimed to review the recent Food and Drug Administration (FDA)-approved vaccines and identify the organ-based major complications of COVID-19 vaccines based on reliable published studies. To find high-quality and large-scale observational, clinical trial, and cohort studies, PubMED, Scholar, Embase, and Web of Science were searched using keywords: COVID-19, SARS-CoV-2, vaccine, Pfizer (BNT162b2), Johnson and Johnson (Ad26.COV2), Moderna (mRNA-1273), Oxford AstraZeneca (ChAdOx1nCoV19), Coronavac (Sinovac), BBIBP-CorV (Sinopharm), adverse effect, and complication. To include all relevant articles, backward searching was also done on similar article citations. Case reports, studies including less than 10 participants, and biased articles were excluded. EXPERT OPINION: Based on data from high-quality and population-based studies, major adverse effects are divided into four major organ-specific groups, including cardiovascular, neurologic, hematologic, and immune-allergic side effects. The incidence of most of these side effects is not different between vaccinated and normal populations, and currently, the benefits of vaccination against COVID-19 are greater than the mortality and morbidity risks of COVID-19 infection. However, further studies, specifically systematic review and meta-analysis, are still indicated to investigate further unknown side effects of these vaccines and the existence of causality between the vaccine and reported adverse events.

Abnormal Uterine Bleeding Among COVID-19 Vaccinated and Recovered Women: a National Survey. The objective of this researchÂ wasÂ to characterize menstrual changes including amount, duration, and frequency among COVID-19 vaccinated and infected women. We conducted an online nationwide questionnaire survey on premenopausal, non-pregnant women over 18Â years of age in Israel, querying about any changes in their menstrual patterns after COVID-19 vaccination or infection. In total, 10,319 women responded, of which 7904 met the inclusion criteria. Changes in menstrual patterns following COVID-19 vaccination or infection were reported in 3689/7476 (49.3%) women compared with 202/428 (47.2%) women, respectively, (Pâ€‰=â€‰.387). The most commonly described menstrual disturbance was excessive bleeding (heavy, prolonged, or intermenstrual) in both the vaccinated and infected groups, (80.6% versus 81.4%, respectively, Pâ€‰=â€‰.720). Among women who experienced abnormal uterine bleeding (AUB), in most cases (61.1%), it occurred between the vaccination and the ensuing menstrual period. Menstrual disturbances were similar in type among the vaccinated and infected women. In conclusion, AUB emerged as a side effect of the BNT162b2 vaccine and a symptom of the COVID-19 infection and was characterized mainly by excessive bleeding. Although the precise incidence could not be determined in this study, the type of bleeding disorder as well as the characterization of risk factors including increasing age and a baseline menstrual pattern of prolonged, frequent, and heavy menses are well defined. The incidence and the long-term consequences of the BNT162b2 vaccine on uterine bleeding warrant further investigation.

SARS CoV-2 mRNA vaccination exposes latent HIV to Nef-specific CD8(+) T-cells. Efforts to cure HIV have focused on reactivating latent proviruses to enable elimination by CD8(+) cytotoxic T-cells. Clinical studies of latency reversing agents (LRA) in antiretroviral therapy (ART)-treated individuals have shown increases in HIV transcription, but without reductions in virologic measures, or evidence

that HIV-specific CD8(+) T-cells were productively engaged. Here, we show that the SARS-CoV-2 mRNA vaccine BNT162b2 activates the RIG-I/TLR - TNF - NFÎºb axis, resulting in transcription of HIV proviruses with minimal perturbations of T-cell activation and host transcription. T-cells specific for the early gene-product HIV-Nef uniquely increased in frequency and acquired effector function (granzyme-B) in ART-treated individuals following SARS-CoV-2 mRNA vaccination. These parameters of CD8(+) T-cell induction correlated with significant decreases in cell-associated HIV mRNA, suggesting killing or suppression of cells transcribing HIV. Thus, we report the observation of an intervention-induced reduction in a measure of HIV persistence, accompanied by precise immune correlates, in ART-suppressed individuals. However, we did not observe significant depletions of intact proviruses, underscoring challenges to achieving (or measuring) HIV reservoir reductions. Overall, our results support prioritizing the measurement of granzyme-B-producing Nef-specific responses in latency reversal studies and add impetus to developing HIV-targeted mRNA therapeutic vaccines that leverage built-in LRA activity.
Vaccine effectiveness of BNT162b2 and CoronaVac against SARS-CoV-2 Omicron BA.2 infection, hospitalisation, severe complications, cardiovascular disease and mortality in patients with diabetes mellitus: A case control study.
Autoimmune hepatitis following COVID-19 vaccination.
Comment on D'Addio et al. Immunogenicity and Safety of SARS-CoV-2 mRNA Vaccines in a Cohort of Patients With Type 1 Diabetes. Diabetes 2022;71:1800-1806.
Response to Comment on D'Addio et al. Immunogenicity and Safety of SARS-CoV-2 mRNA Vaccines in a Cohort of Patients With Type 1 Diabetes. Diabetes 2022;71:1800-1806.
Type 1 diabetes mellitus following SARS-CoV-2 mRNA vaccination.
New-onset crescent IgA nephropathy following the CoronaVac vaccine: A case report. RATIONALE: Although coronavirus disease 2019 (COVID-19) remains a global threat, administering effective and safe vaccines is currently the most promising strategy to curb the ongoing pandemic and decrease the number of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections. However, there remains some uncertainty regarding the safety of vaccines for patients with kidney disease. PATIENT CONCERNS: A 58-year-old man presented at our institution with gross hematuria 48 hours after receiving his first dose of the CoronaVac (Sinovac) vaccine. DIAGNOSES: Analysis of a renal biopsy sample led to the diagnosis of crescentic immunoglobulin A nephropathy (IgAN), which we considered an adverse event of receiving the CoronaVac vaccine in China. INTERVENTIONS: The patient's serum creatinine and albumin levels were 1.20â€‰mg/dL and 31.3â€‰g/L, respectively; as such, he was administered a diuretic. His serum creatinine level had risen to 7.45â€‰mg/dL 1 month later, and he developed high blood pressure. The patient then received conventional doses of hormone therapy but developed recurrent fever, which led to the suspicion of active tuberculosis (which he had a history of) and suspension of the hormone therapy. OUTCOMES: The patient's renal function deteriorated further, and he ultimately underwent dialysis. LESSONS: The patient's course of events of apparent IgAN exacerbation should prompt nephrologists to closely follow patients with glomerular disease after they receive a COVID-19 vaccine, especially if persistent gross hematuria occurs.
Acute Myopericarditis after the Second Dose of mRNA COVID-19 Vaccine Mimicking Acute Coronary Syndrome. Myocarditis is a rare adverse event of vaccination. Recently, mRNA vaccines for COVID-19 have been reported to correlate with myocarditis, specifically in adolescents and young men. We report a rare case of a 50-year-old man who presented with symptoms of myocardial infarction 3 days after the second dose of vaccination for COVID-19. Cardiac magnetic resonance (CMR) imaging revealed acute myopericarditis. Clinicians should be aware of that rare side effect of

mRNA vaccines for COVID-19 that can affect not only younger recipients but also middle-aged patients presenting with symptoms mimicking acute coronary syndrome.
[Assessment of quality of systematic reviews and Meta-analyses on efficacy and safety of COVID-19 vaccines]. Objective: To evaluate the methodology of the published systematic reviews and Meta-analyses (SR/MA) on efficacy and safety of coronavirus disease 2019 (COVID-19) vaccines. Methods: We conducted a retrieval for literatures published as of December 10, 2021 in English databases (Medline, Embase, Cochrane Library, Web of science) and Chinese databases (CNKI, Wanfang data, VIP, Sinomed). Two reviewers independently screened literatures and extracted data. The methodology of included SR/MA papers was assessed by A MeaSurement Tool to Assess systematic Review-2 (AMSTAR-2) tool in 16 items. Results: A total 22 SR/MA papers were included, in which 3 (13.6%) had low quality and 19 (86.4%) had very low quality. The main problems of these SR/MA included having no definite PICO (Participants, intervention, control and outcome), providing no preliminary research protocol, no list of excluded studies and justify the exclusions, making no evaluation and explanation or discussion of the risk of bias of original studies, no adequate evaluation of publication bias and discuss its likely impact on the results, etc. Conclusion: SR/MA for the efficacy and safety of COVID-19 vaccines had varied methodological deficiencies, further improvements are needed.
[Progress in epidemiological research of 2019-nCoV infection and COVID-19 vaccination in pregnancy]. Coronavirus disease 2019 (COVID-19) is an acute respiratory infectious disease caused by 2019-nCoV. Due to the physiological change in pregnancy, pregnant women are susceptible to COVID-19 and are at increased risk for adverse pregnancy outcomes, especially in the context of spread of novel variants. At present, less evidences have been obtained from randomized controlled trials on the effectiveness and safety of COVID-19 vaccine use in pregnant women, and the recommendations of COVID-19 vaccination for pregnant women vary with countries, posing challenge to the prevention and control of COVID-19 in pregnant women. This paper summarizes the progress in major research of 2019-nCoV infection in pregnancy conducted both at home and abroad, describes the harm of COVID-19 in pregnancy to pregnant women, fetuses and infants and introduces the effectiveness and safety of COVID-19 vaccination in pregnancy revealed by real world studies in order to provide reference for the related research and development of COVID-19 prevention and control strategies in pregnant women.
A neutralizing epitope on the SD1 domain of SARS-CoV-2 spike targeted following infection and vaccination. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike is the target for neutralizing antibodies elicited following both infection and vaccination. While extensive research has shown that the receptor binding domain (RBD) and, to a lesser extent, the N-terminal domain (NTD) are the predominant targets for neutralizing antibodies, identification of neutralizing epitopes beyond these regions is important for informing vaccine development and understanding antibody-mediated immune escape. Here, we identify a class of broadly neutralizing antibodies that bind an epitope on the spike subdomain 1 (SD1) and that have arisen from infection or vaccination. Using cryo-electron microscopy (cryo-EM) and hydrogen-deuterium exchange coupled to mass spectrometry (HDX-MS), we show that SD1-specific antibody P008_60 binds an epitope that is not accessible within the canonical prefusion states of the SARS-CoV-2 spike, suggesting a transient conformation of the viral glycoprotein that is vulnerable to neutralization.
Assessment of COVID-19 vaccination-related medical waste management practices in Bangladesh. The COVID-19 pandemic forces people to be vaccinated as early as possible. The COVID-19 vaccination program certainly raised the medical waste volume all over the world, including in Bangladesh. Numerous recent reports showed a fragile medical waste management system in Bangladesh; during the pandemic, the situation became worse. In addition, the nation-wide ongoing

COVID-19 vaccination processes have been posing an extra burden to the existing biomedical waste management in the country. Failing to proper management of this waste might be a threat to human and environmental health. Therefore, the study investigated the current COVID-19 vaccine waste management practices in Bangladesh and made a comparison to the proposed standard operating procedures of international organizations and vaccine waste management practices of two other countries (USA and India). The study was carried out through a mixed methodological approach such as qualitative and quantitative, including a questionnaire survey in 15 Upazila of 4 Districts (Dhaka, Narayanganj, Manikganj, and Gazipur) of Bangladesh. The article focused on a nation-wide legitimate COVID-19 vaccination waste estimation, strength, weakness, opportunity, and threat (SWOT) analysis and drivers, pressure, state, impact, and response (DPSIR) framework analysis to identify the present state of medical waste management in the study area. The study found an excellent segregation system (100%) but very poor waste handling (35.5%) along with very poor syringes and sharps disposal method (open burning without buried 46.6%) and poor vials disposal method (without disinfection/open dump 52%) of vaccine waste. It is estimated that about 58 and 257.85 tonnes of syringes (with needles and packaging) and vaccine vials (Sinopharm 2 doses) waste have been generated since the mass-vaccination program started. Upon SWOT analysis, good separation techniques, poor waste management (ex-situ), enough space for management, and environmental and human health concerns were mostly identified as a strength, weakness, opportunity, and threat, respectively. Finally, a DPSIR framework was prepared for vaccine waste generation and its consequences in the studied area. This study will be useful to prepare a suitable vaccination waste management system in Bangladesh.

Safety Monitoring of Pfizer-BioNTech COVID-19 Vaccine Booster Doses Among Children Aged 5-11 Years - United States, May 17-July 31, 2022. On May 17, 2022, the Food and Drug Administration (FDA) amended the Emergency Use Authorization (EUA) for BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine to authorize a homologous* booster dose for children aged 5-11 years â‰¥5 months after receipt of the second primary series dose(â€) (1) based on findings from a clinical trial conducted among 401 children aged 5-11 years (2). To further characterize the safety of booster vaccination in this age group, CDC reviewed adverse events and health impact assessments after receipt of a Pfizer-BioNTech third dose reported to v-safe, a voluntary smartphone-based safety surveillance system for adverse events occurring after COVID-19 vaccination, and adverse events reported to the Vaccine Adverse Event Reporting System (VAERS), a passive vaccine safety surveillance system comanaged by CDC and FDA. During May 17-July 31, 2022, approximately 657,302 U.S. children aged 5-11 years received a third Pfizer-BioNTech dose (either a third primary series dose administered to immunocompromised children or a booster dose administered to immunocompetent children)(Â§); 3,249 Pfizer-BioNTech third doses were reported to v-safe for children in this age group. Local and systemic reactions were reported to v-safe after a second dose and a third dose with similar frequency; some reactions (e.g., pain) were reported to be moderate or severe more frequently after a third dose. VAERS received 581 reports of adverse events after receipt of a Pfizer-BioNTech third dose by children aged 5-11 years; 578 (99.5%) reports were considered nonserious, and the most common events reported were vaccine administration errors. Three (0.5%) reports were considered serious; no reports of myocarditis or death were received. Local and systemic reactions were common among children after Pfizer-BioNTech third dose vaccination, but reports of serious adverse events were rare. Initial safety findings are consistent with those of the clinical trial (2).

Variables Associated With COVID-19 Vaccination Among Israeli Adolescents and the Need for Targeted Interventions. BACKGROUND: We aimed to elucidate variables associated with coronavirus disease 2019 (COVID-19) vaccine compliance in adolescents and devise targeted interventions. Our secondary aim was to compare the rates of severe acute respiratory syndrome

coronavirus 2 infection, hospitalizations and deaths between vaccinated and unvaccinated adolescents. METHODS: A retrospective review of electronic medical records was performed on all adolescents 12-17 years of age registered at Clalit Health District in Israel during January 1, 2021, to November 18, 2021, with characterization by vaccination status against COVID-19. Univariate and multivariable analyses were employed to identify predictors of vaccination. RESULTS: Of the 43,919 subjects included in the study, 28,207 (64.2%) were vaccinated. Non-ultraorthodox Jewish adolescents had a higher vaccination rate than the minorities Arabs or ultraorthodox Jews (72.5%, 66.2% and 40.5%, respectively, P < 0.001). Adolescents of high socioeconomic status had nearly 2-fold higher vaccination rates than those of low socioeconomic status (80.4% vs 42.3%; P < 0.0001). Adolescents 16-17 years old had a higher rate of COVID-19 vaccination than those 12-15 years old (72.5% vs 60.6%, P < 0.001), as were girls versus boys (64.7% vs 63.8%, P = 0.047). Multivariate analysis identified 3 independent variables that were significantly (P < 0.001) associated with low vaccination: ultraorthodox sector, Arab population, and underlying obesity (hazard rations 0.42, 0.72 and 0.84, respectively). Vaccination was significantly associated with reduced severe acute respiratory syndrome coronavirus 2 infection, hospitalization and death (P < 0.001). CONCLUSION: This study highlights several pediatric populations with low COVID-19 vaccine compliance. Targeted interventions aimed at these populations are suggested with consideration of their special cultural, social and societal characteristics.

Consider multisystem inflammatory syndrome in children with kidney failure after SARS-CoV-2 vaccination.

Predictors of COVID-19 Vaccination Among EMS Personnel. INTRODUCTION: Unvaccinated emergency medical services (EMS) personnel are at increased risk of contracting coronavirus disease 2019 (COVID-19) and potentially transmitting the virus to their families, coworkers, and patients. Effective vaccines for the severe acute respiratory syndrome coronavirus 2 virus exist; however, vaccination rates among EMS professionals remain largely unknown. Consequently, we sought to document vaccination rates of EMS professionals and identify predictors of vaccination uptake. METHODS: We conducted a cross-sectional survey of North Carolina EMS professionals after the COVID-19 vaccines were widely available. The survey assessed vaccination status as well as beliefs regarding COVID-19 illness and vaccine effectiveness. Prediction of vaccine uptake was modeled using logistic regression. RESULTS: A total of 860 EMS professionals completed the survey, of whom 74.7% reported receiving the COVID-19 vaccination. Most respondents believed that COVID-19 is a serious threat to the population, that they are personally at higher risk of infection, that vaccine side effects are outweighed by illness prevention, and the vaccine is safe and effective. Despite this, only 18.7% supported mandatory vaccination for EMS professionals. Statistically significant differences were observed between the vaccinated and unvaccinated groups regarding vaccine safety and effectiveness, recall of employer vaccine recommendation, perceived risk of infection, degree of threat to the population, and trust in government to take actions to limit the spread of disease. Unvaccinated respondents cited reasons such as belief in personal health and natural immunity as protectors against infection, concerns about vaccine safety and effectiveness, inadequate vaccine knowledge, and lack of an employer mandate for declining the vaccine. Predictors of vaccination included belief in vaccine safety (odds ratio [OR] 5.5, P=<0.001) and effectiveness (OR 4.6, P=<0.001); importance of vaccination to protect patients (OR 15.5, P=<0.001); perceived personal risk of infection (OR 1.8, P=0.04); previous receipt of influenza vaccine (OR 2.5, P=0.003); and sufficient knowledge to make an informed decision about vaccination (OR 2.4, P=0.024). CONCLUSION: In this survey of EMS professionals, over a quarter remained unvaccinated for COVID-19. Given the identified predictors of vaccine acceptance, EMS systems should focus on countering misinformation

through employee educational campaigns as well as on developing policies regarding workforce immunization requirements.

De Novo Vasculitis after COVID-19 Vaccination. BACKGROUND: The coronavirus disease 2019 (COVID-19) pandemic continues to spread around the world. Vaccinations have been administered globally and have been proven to be safe and effective. However, vasculitis has been reported as an adverse event occurring after COVID-19 vaccination. METHODS: In this review, we analyzed the literature to identify original articles that reported on patients who developed vasculitis following COVID-19 vaccination and summarized their clinical manifestations. PubMed and Web of Knowledge were searched to identify relevant studies. RESULTS: A total of 27 patients who developed vasculitis following COVID-19 vaccination were identified from 21 studies. The involved organs included the skin and kidney. The main clinical features of patients whose skin was affected were papules, maculopapular rashes, and plaques. Most of the patients exhibited small vessel vasculitis and single-organ vasculitis; these were resolved within one month. Patients whose kidneys were affected exhibited vasculitis, including anti-neutrophil cytoplasmic antibody glomerulonephritis and IgA nephritis. Most patients were treated with corticosteroid, rituximab, and cyclophosphamide, and one patient needed hemodialysis. The renal function of most patients was improved or recovered, but one patient needed maintenance dialysis. CONCLUSION: Vasculitis was rarely reported after COVID-19 vaccine administration. It often manifested as cutaneous small-vessel vasculitis or glomerulonephritis. Notably, when a patient demonstrates hematuria, proteinuria, and acute kidney injury after COVID-19 vaccination, there is a possibility that the patient could have developed vasculitis. Skin-related problems were quickly resolved, while kidney-related problems may progress to chronic kidney disease.

Multisystem Inflammatory Syndrome in Adults (MIS-A) After COVID-19 Infection and Recent Vaccination with Recombinant Adenoviral Vector Encoding the Spike Protein Antigen of SARS-CoV-2 (ChAdOx1 nCoV-19, Vaxzevria). The clinical spectrum of Coronavirus 2019 (COVID-19) includes acute COVID-19, long covid and multisystem inflammatory syndrome in children and adults (MISC/A). The rapid roll-out of COVID-19 vaccination has the potential to affect the clinical presentation of COVID-19 and case reports document rare occurrences of MIS-A after COVID-19 infection and recent vaccination with m-RNA vaccines. We describe 2 cases of MIS-A after COVID-19 infection and recent vaccination with ChAdOx1 nCoV-19.

Four cases of Graves' disease following viral vector severe acute respiratory syndrome corona virus-2 (SARS-CoV-2) vaccine. Mass immunization has led to a decrease in the transmission of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) worldwide. At the same time, awareness regarding possible adverse effects of newly developed vaccines is critical. The present study was undertaken to report the cases of Graves' disease occurring after administration of viral vector vaccine (ChAdox1nCoV-19) and describe the clinical profile, response to treatment, and effect of administration of a second dose in patients developing Graves' disease. Four cases of Graves' disease after administration of the vaccine were noted. Two of these had a mild thyroid eye disease. Three cases were female and had a family/self-history of autoimmune disease. All cases responded well to treatment and became euthyroid within two to four months. Two patients exhibited worsening thyrotoxicosis after receiving a second dose of the vaccine. We propose that the temporal relationship between administration of the vaccine and the onset of symptoms establishes Graves' disease as an adverse event after the SARS-CoV-2 viral vector vaccine. Close follow-up is advisable in individuals developing Graves' disease after SARS-CoV-2 vaccination.

Rapid progression of marginal zone B-cell lymphoma after COVID-19 vaccination (BNT162b2): A case report. B-cell lymphomas are neoplastic diseases occasionally associated with chronic inflammation. mRNA vaccines for coronavirus disease 2019 (COVID-19) induce inflammatory

responses, which often lead to fever and lymphadenopathies indistinguishable from lymphomas. Although both lymphadenopathies and lymphomas can be influential, the correlation between them is unclear. Herein, we present the first case of marginal zone B-cell lymphoma following mRNA COVID-19 vaccination. An 80-year-old Japanese woman presented with a right temporal mass that appeared the morning after she was administered her first mRNA COVID-19 vaccination (BNT162b2). The mass gradually decreased in size but persisted over 6 weeks after her first vaccination (3 weeks after her second vaccination). At her first visit to our hospital, ultrasound revealed the size of the mass to be 28.5 Ã— 5.7 mm, and computed tomography revealed multiple lymphadenopathies in the right parotid, submandibular, jugular, and supraclavicular regions. Initially, we suspected head-and-neck benign lymphadenopathy as a side effect of vaccination. Nine weeks later, the number of swollen submandibular and parotid glands increased, and the lymph nodes further enlarged. Finally, the right temporal mass was diagnosed as marginal zone B-cell lymphoma based on immunohistochemical and flow cytometry findings of biopsy specimens. Our findings suggest that although 4-6 weeks of observation for lymph node inflammation after the second vaccination is recommended, malignancy should also be considered in the differential diagnosis of lymphadenopathy following vaccination.

Idiopathic nephrotic syndrome relapse following COVID-19 vaccination: a series of 25 cases. BACKGROUND: Several cases of idiopathic nephrotic syndrome (INS) relapse following the administration of coronavirus disease 2019 (COVID-19) vaccines have recently been reported, raising questions about the potential relationship between the immune response to COVID-19 vaccination and INS pathogenesis. METHODS: We performed a retrospective multicentre survey describing the clinical and biological characteristics of patients presenting a relapse of INS after COVID-19 vaccination, with an assessment of outcome under treatment. RESULTS: We identified 25 patients (16 men and 9 women) presenting a relapse within 1 month of a COVID-19 vaccine injection. The glomerular disease was of childhood onset in half of the patients and most patients (21/25) had received at least one immunosuppressive drug in addition to steroids for frequently relapsing or steroid-dependent nephrotic syndrome (NS). All patients were in a stable condition at the time of injection and 11 had no specific treatment. In five patients, the last relapse was reported >5 years before vaccine injection. The Pfizer-BioNTech (BNT162b2) vaccine was used in 80% of the patients. In 18 cases, INS relapse occurred after the first injection, a mean of 17.5 days after vaccination. A second injection was nevertheless administered in 14 of these patients. Five relapses occurred after administration of the second dose and two relapses after the administration of the third dose. All but one of the patients received steroids as first-line treatment, with an additional immunosuppressive agent in nine cases. During follow-up, complete remission was achieved in 21 patients, within 1 month in 17 cases. Only one patient had not achieved at least partial remission after 3 months of follow-up. CONCLUSIONS: This case series suggests that, in rare patients, COVID-19 vaccination may trigger INS relapse that is generally easy to control. These findings should encourage physicians to persuade their patients to complete the COVID-19 vaccination schedule.

Autoimmune inflammatory rheumatic diseases post-COVID-19 vaccination. Vaccination against COVID-19 is one of the critical tools to provide herd immunity, reduce mortality, and control the pandemic worldwide. Despite the safety of vaccination against SARS-CoV-2 in the healthy population, a minority of people may develop rare post-vaccine adverse reactions such as autoimmune syndromes. The current study aimed to identify and present a series of patients with de-novo autoimmune rheumatic diseases (ARDs) associated with COVID-19 vaccines. Inclusion criteria were the onset of ARDs symptoms at âˆ¼3-4Â weeks post-vaccination, ageÂ â‰¥Â 16, no previous history of ARDs, meeting the classification criteria for one of the ARDs, and staying in the follow-up. The most commonly used vaccines in patients were Sinopharm [7 cases (50%)] and AstraZeneca [6 cases

(42.9%)]. ARDs were significantly more common in subjects who received the AstraZeneca vaccine than in those who received other vaccines. Based on the results, patients were diagnosed with rheumatoid arthritis or one of its subtypes (5 cases), vasculitis (4 cases), systemic lupus erythematosus (3 cases), and peripheral seronegative spondyloarthritis (2 cases). Except for one patient with self-limitation of ARD, others were treated with disease-modifying antirheumatic drugs, and one case developed irreversible neurological complications. Indeed, our data can warn physicians about the possibility of ARDs post-vaccination, lead to faster diagnosis, prevent loss of window of opportunity for treatment, and prevent irreversible organ damage. Based on the published literature, autoimmune phenomena post-COVID-19 vaccination may be related to the overstimulation of mediators and cytokines due to complicated antigen-specific/non-specific immunological responses and mechanisms.

Trends in COVID-19 hospital outcomes in England before and after vaccine introduction, a cohort study. Widespread vaccination campaigns have changed the landscape for COVID-19, vastly altering symptoms and reducing morbidity and mortality. We estimate trends in mortality by month of admission and vaccination status among those hospitalised with COVID-19 in England between March 2020 to September 2021, controlling for demographic factors and hospital load. Among 259,727 hospitalised COVID-19 cases, 51,948 (20.0%) experienced mortality in hospital. Hospitalised fatality risk ranged from 40.3% (95% confidence interval 39.4-41.3%) in March 2020 to 8.1% (7.2-9.0%) in June 2021. Older individuals and those with multiple co-morbidities were more likely to die or else experienced longer stays prior to discharge. Compared to unvaccinated people, the hazard of hospitalised mortality was 0.71 (0.67-0.77) with a first vaccine dose, and 0.56 (0.52-0.61) with a second vaccine dose. Compared to hospital load at 0-20% of the busiest week, the hazard of hospitalised mortality during periods of peak load (90-100%), was 1.23 (1.12-1.34). The prognosis for people hospitalised with COVID-19 in England has varied substantially throughout the pandemic and according to case-mix, vaccination, and hospital load. Our estimates provide an indication for demands on hospital resources, and the relationship between hospital burden and outcomes.

Safety and antibody response of recipients who unexpectedly received undiluted prime dose of BNT162b2 COVID-19 vaccine in Taiwan. We reported 25 recipients (14 females and 11 males) aged from 18 to 65 years who unexpectedly received a primary dose of undiluted BNT162b2 vaccine (180Â Î¼g). The most common adverse reactions included injection site pain (nÂ =Â 22), followed by fever (9), fatigue (8), chest tightness (6), and dizziness (6). The most common laboratory abnormalities were anemia (nÂ =Â 4) and elevated liver transaminase level (4), followed by abnormal leukocyte counts (3) and elevated D-dimer level (3). The adverse reactions and laboratory abnormalities of these recipients were mild and spontaneously recovered within a few weeks. Significant elevations of anti-SARS-CoV-2 spike IgG titers after a booster dose of the BNT162b2 were found. Similar to reports of BNT162b2 clinical trials, the adverse reactions and laboratory abnormalities of these recipients were mild, and they spontaneously recovered within a few weeks. These results provide clinical and immunological effects of undiluted BNT162b2 vaccine inoculation.

Letter to the Editor Regarding: "Myocarditis and Cardiac Complications Associated With COVID-19 and mRNA Vaccination" by Holland et al., Heart Lung Circ. 2022;31(7):924-33.

Immunogenicity and safety of a fourth COVID-19 vaccination in rituximab-treated patients: an open-label extension study. OBJECTIVES: Patients under rituximab therapy are at high risk for a severe COVID-19 disease course. Humoral immune responses to SARS-CoV-2 vaccination are vastly diminished in B-cell-depleted patients, even after a third vaccine dose. However, it remains unclear whether these patients benefit from a fourth vaccination and whether continued rituximab therapy affects antibody development. METHODS: In this open-label extension trial, 37 rituximab-treated patients who received a third dose with either a vector or mRNA-based vaccine were vaccinated a

fourth time with an mRNA-based vaccine (mRNA-1273 or BNT162b2). Key endpoints included the humoral and cellular immune response as well as safety after a fourth vaccination. RESULTS: The number of patients who seroconverted increased from 12/36 (33%) to 21/36 (58%) following the fourth COVID-19 vaccination. In patients with detectable antibodies to the spike protein's receptor-binding domain (median: 8.0 binding antibody units (BAU)/mL (quartiles: 0.4; 13.8)), elevated levels were observed after the fourth vaccination (134.0 BAU/mL (quartiles: 25.5; 1026.0)). Seroconversion and antibody increase were strongly diminished in patients who received rituximab treatment between the third and the fourth vaccination. The cellular immune response declined 12 weeks after the third vaccination, but could only be slightly enhanced by a fourth vaccination. No unexpected safety signals were detected, one serious adverse event not related to vaccination occurred. CONCLUSIONS: A fourth vaccine dose is immunogenic in a fraction of rituximab-treated patients. Continuation of rituximab treatment reduced humoral immune response, suggesting that rituximab affects a second booster vaccination. It might therefore be considered to postpone rituximab treatment in clinically stable patients. TRIAL REGISTRATION NUMBER: 2021-002348-57.

Association between COVID-19 vaccination rates and the Australian 'Million Dollar Vax' competition: an observational study. OBJECTIVE: To examine the association between financial incentives from entry into a vaccine competition with the probability of vaccination for COVID-19. DESIGN: A cross-sectional study with adjustment for covariates using logistic regression. SETTING: October and November 2021, Australia. PARTICIPANTS: 2375 respondents of the Taking the Pulse of the Nation survey. PRIMARY AND SECONDARY OUTCOME MEASURES: The proportion of respondents who had any vaccination, a first dose only, or second dose after the competition opened. RESULTS: Those who entered the competition were 2.27 (95% CI 1.73 to 2.99) times more likely to be vaccinated after the competition opened on 1 October than those who did not enter-an increase in the probability of having any dose of 0.16 (95 % CI 0.10 to 0.21)â€‰percentage points. This increase was mostly driven by those receiving second doses. Entrants were 2.39 (95% CI 1.80 to 3.17) times more likely to receive their second dose after the competition opened. CONCLUSIONS: Those who entered the Million Dollar Vax competition were more likely to have a vaccination after the competition opened compared with those who did not enter the competition, with this effect dominated by those receiving second doses.

Risk of preterm birth, small for gestational age at birth, and stillbirth after covid-19 vaccination during pregnancy: population based retrospective cohort study. OBJECTIVE: To assess the risk of preterm birth, small for gestational age at birth, and stillbirth after covid-19 vaccination during pregnancy. DESIGN: Population based retrospective cohort study. SETTING: Ontario, Canada, 1 May to 31 December 2021. PARTICIPANTS: All liveborn and stillborn infants from pregnancies conceived at least 42 weeks before the end of the study period and with gestational age â‰¥20 weeks or birth weight â‰¥500 g. MAIN OUTCOME MEASURES: Using Cox regression, hazard ratios and 95% confidence intervals were estimated for preterm birth before 37 weeks (overall and spontaneous preterm birth), very preterm birth (<32 weeks), small for gestational age at birth (<10th centile), and stillbirth. Vaccination against covid-19 was treated as a time varying exposure in the outcome specific risk window, and propensity score weighting was used to adjust hazard ratios for potential confounding. RESULTS: Among 85â€‰162 births, 43â€‰099 (50.6%) occurred in individuals who received one dose or more of a covid-19 vaccine during pregnancy-42â€‰979 (99.7%) received an mRNA vaccine. Vaccination during pregnancy was not associated with any increased risk of overall preterm birth (6.5% among vaccinated v 6.9% among unvaccinated; adjusted hazard ratio 1.02, 95% confidence interval 0.96 to 1.08), spontaneous preterm birth (3.7% v 4.4%; 0.96, 0.90 to 1.03), or very preterm birth (0.59% v 0.89%; 0.80, 0.67 to 0.95). No increase was found in risk of small for gestational age at birth (9.1% v 9.2%; 0.98, 0.93 to 1.03) or stillbirth (0.25% v 0.44%; 0.65, 0.51 to

0.84). Findings were similar by trimester of vaccination, mRNA vaccine product, and number of doses received during pregnancy. CONCLUSION: The findings suggest that vaccination against covid-19 during pregnancy is not associated with a higher risk of preterm birth, small for gestational age at birth, or stillbirth.
Two Cases of Erythema Annulare Centrifigum Triggered by COVID-19 Vaccination.
Immunogenicity evaluation of ChAdox1 nCov-19 (AZD1222) vaccine in solid cancer patients in Chulabhorn Hospital. INTRODUCTION: Cancer patients are more vulnerable to coronavirus disease 2019 (COVID-19) owing to their compromised immune status. However, data regarding COVID-19 vaccine safety and immune response in cancer patients are scarce. METHOD: This prospective, age- and sex-matched, single-center cohort study included 61 cancer patients and 122 healthy control participants. Seropositivity was defined as anti-S IgG titer >0.8 units/ml. Primary end point was seroconversion rate of immunoglobulin (Ig)G antibodies against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike (S) protein (anti-S IgG) in cancer patients vs. healthy control participants following the second dose of COVID-19 vaccine ChAdOx1 nCoV-19 (AZD1222). RESULTS: After the second-dose vaccination, there was no difference in seropositivity rate between groups (57 [93.44%] patients with cancer vs. 121 [99.18%] control participants; geometric mean ratio [GMR]: 0.39; 95%CI: 0.01-10.46; p-valueâ€‰=â€‰0.571). In contrast, after the first-dose vaccination, the seropositivity rate was significantly lower in the cancer patients than in the control participants (50/61 [81.97%] vs. 121/122 [99.18%]; GMR: 0.07; 95%CI: 0.01-0.71; pâ€‰=â€‰0.025). The median anti-S IgG titer after the first-and second dose vaccination were not significantly different between groups. Female sex was significantly associated with a higher anti-S IgG titer. 5FU- and taxane-based chemotherapy regimens were associated with a lower IgG titer. Side effects of vaccination were tolerable. CONCLUSIONS: The anti-S IgG seropositivity rate after completing the second vaccine dose did not differ between the cancer patients and control participants. However, the anti-S IgG seropositivity rate after the first-dose vaccination was lower in cancer patients.
Pemphigus foliaceus triggered after inactivated SARS-CoV-2 vaccine: Coincidence or causal link?
Anaphylaxis to SARS-CoV-2 Vaccines in the Setting of a Nationwide Passive Epidemiological Surveillance Program. BACKGROUND: Information on anaphylaxis among recipients of vaccines against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) remains scarce. OBJECTIVE: To identify the observed incidence of anaphylaxis in recipients of different anti-SARS-CoV-2 vaccines. METHODS: A nationwide observational study among recipients of 61,414,803 doses of seven different anti-SARS-CoV-2 vaccines, describing the incidence and characteristics of adult patients (ageâ€‰â‰¥â€‰18Â years) who developed anaphylaxis as an adverse event following immunization (AEFI) against SARS-CoV-2 vaccines between December 24, 2020, and October 15, 2021, in Mexico. RESULTS: Sixty-six patients developed anaphylaxis as an AEFI, for an overall observed incidence of 1.07 cases per 1,000,000 (95% CI 0.84-1.37) administered doses. Eighty-six percent of the patients were female, consistent with previous reports of AEFI to COVID-19 vaccines. mRNA-based vaccine recipients had the highest frequency of anaphylaxis, followed by adenovirus-vectored vaccines and inactivated virus recipients, with an observed incidence of 2.5, 0.7, and 0.2 cases per 1,000,000 doses administered, respectively. Only 46% of the patients received correct treatment with epinephrine as the first-line treatment through the appropriate route and dose. We detected one case of anaphylactic reaction-related death occurring 5Â min following immunization with ChAdOx1 nCov-19 for a mortality rate of 1.5% among those who developed this AEFI. CONCLUSIONS: In our population, anaphylactic reactions were infrequent. Our study provides further evidence supporting the security of these newly developed vaccines.
[COVID-19 mortality in Brazil in different age groups: differentials between extreme rates in 2021 and 2022]. This ecological study evaluated the trajectory of COVID-19 mortality rates in Brazil and

compared the extreme rates of 2022 and 2021, in different age groups. Data on deaths due to severe acute respiratory syndrome by COVID-19 were obtained from the Influenza Epidemiological Surveillance Information System. Deaths were evaluated from January 10, 2021 to February 12, 2022, grouped into Epidemiological Weeks (EW). Data analysis was conducted in the R software, using Poisson models to estimate mortality rates. Statistical significance level was set at 5%. A total of 408,180 deaths were evaluated, 0.34% of whom were under 18 years old, and 64.6% of whom were 60 years old and over. On the one hand, in the 0-1, 2-4 and 5-11 age groups, higher mortality rates were observed in EW 4-6/2022, compared to the higher ones in 2021. On the other, in the 12-17 age group, a lower rate was estimated in the EW 4-6/2022 group compared to the EW 11-13 group in 2021, with a mortality ratio of 0.60 (95%CI: 0.38-0.94). Opposing patterns were detected in COVID-19 mortality in Brazil among children and individuals included in the national vaccination campaign. Among the former, mortality rates equal to or worse than in previous phases of the epidemic were observed, contrasting with the consistent and strong decline registered in the latter, reinforcing the effectiveness of COVID-19 vaccines.

Herpes Zoster after mRNA COVID-19 Vaccination: A Case Series. We present seven immunocompetent patients devoid of any comorbidities and risk factors, who developed for the first time in their life varicella-zoster virus (VZV) reactivation shortly after 1st (four patients) and 2nd dose (three patients) of mRNA COVID-19 vaccines.All four patients who exhibited herpes zoster after the 1st dose of vaccine received the 2nd dose without any adverse reactions or complications. Oral treatment prescribed to all patients with valacyclovir (Valtrex 1 mg tds/day) for 5-7 days led to a complete resolution of symptoms, and rashes disappeared within 9-14 days. Presently, All patients have completed a 3-4Â½-month follow-up without any evidence of complications and/or recurrence of herpes zoster. (SKINmed. 2022;20:284-288).

Five cases of new-onset pemphigus following vaccinations against coronavirus disease 2019. Pemphigus is a group of blistering disorders characterized by the formation of intraepithelial blisters in skin and mucous membranes induced by the binding of circulating autoantibodies to intercellular adhesion molecules. The pathogenesis is complex and not fully understood; however, genetic predisposition and various triggers are widely accepted as key factors in pemphigus development. A few cases of new-onset pemphigus following coronavirus disease 2019 (COVID-19) vaccination have already been published. The present paper reports a total of two cases of pemphigus foliaceous and three cases of pemphigus vulgaris that occurred following vaccinations against COVID-19, with anamnestic, clinical, and diagnostic data collection suggesting assumptions over a possible causal correlation.

Longitudinally extensive transverse myelitis following ChAdOx1 nCoV-19 vaccine. Transverse myelitis (TM) has been reported in association with various vaccinations. Herein we describe a case of longitudinally extensive transverse myelitis (LETM) associated with vaccination with ChAdOx1 nCoV-19 (COVISHIELD) vaccine. A 59-year-old woman with no prior co-morbidities presented with lower extremity numbness, weakness, acute urinary retention, and constipation. Numbness gradually extended up to the lower costal margin with band like sensation. She had received the vaccine 5 days prior to the onset of the symptoms. Extensive diagnostic evaluation effectively ruled out causes other than vaccination-associated transverse myelitis. Following treatment with intravenous methylprednisolone, the patient made a significant recovery. TM may be associated with vaccination against the novel ChAdOx1 nCoV-19 vaccine and we believe this to be the first report from India of LETM associated with this vaccine.

A Comprehensive Analysis of Myocarditis in Formerly Healthy Individuals Following SARS-CoV-2 Vaccination (COVID-19 Immunization). Due to the rapid development of the coronavirus disease 2019 (COVID-19) pandemic, the Food and Drug Administration (FDA) expedited the authorization of

immunizations to counteract life-threatening COVID-19 effects. COVID-19 immunization was seen as an essential component of surviving endemically with COVID-19. Although there were no major adverse eventÂ reports that mandated an early authorization of the mass vaccination approval in initial studies, a few significant adverse events were reported after real-world usage. The most prevalent adverse events are regional reactions, such as discomfort at the injection site. Anaphylactic shock and acute responses were quite infrequent. Current evidence stronglyÂ convince the community that the advantages of immunization outweigh the risks. The review investigates the potential adverse reaction in the form ofÂ myocarditis caused by the COVID-19 vaccine.Â Age, sexuality, vaccination type, clinical manifestations, and diagnostic modalities were among the confounding factors associated with vaccine-induced myocarditis. This picture depicts COVID-19 immunization-inducedÂ myocarditis and the treatment options available to practitioners. Further evaluation is needed to establish the underlying cause of this association. We compiled the most recent data on SARS-CoV-2 vaccine-induced myocarditis after reviewing available research. Information sources including PubMed and Google Scholar were evaluated retrospectively.

COVID-19 Vaccine-Associated Lymphadenopathy in Breast Imaging Recipients: A Review of Literature. TheÂ unpredictability of the coronavirus disease 2019 (COVID-19) pandemic has created an ongoing global healthcare crisis. Implementation of a mass vaccination program to accelerate disease controlÂ remainsÂ in progress. Although injection site soreness, fatigue, and fever are the most common adverse reactions reported after a COVID-19 vaccination, ipsilateral lymph node enlargement has increasingly been observed.Â In patients undergoing routine screening and surveillance for breast cancer, interpreting lymphadenopathy (LAP) is challenging in the setting of a recent COVID-19 vaccination.Â With a growing proportion of the population receiving the vaccine, a multifaceted approach is necessary to avoid unnecessary and costly workup. In this comprehensive review, we summarize the existing literature on COVID-19 vaccine-associated LAP in breast imaging patients.

Bullous pemphigoid and COVID-19 vaccination: Management and treatment reply to 'Bullous pemphigoid in a young male after COVID-19 mRNA vaccine: A report and brief literature review' by Pauluzzi et al.

Decreased daily exercise since the COVID-19 pandemic and the deterioration of health-related quality of life in the elderly population: a population-based cross-sectional study. BACKGROUNDS: The current prolonging state of the coronavirus disease (COVID-19), could affect many aspects of people's lives, especially the elderly population who experience a decrease in regular exercise. However, whether this decrease in regular exercise affects health-related quality of life (HRQOL) of the elderly population, remains unclear. METHODS: The current population-based cross-sectional survey aimed to identify the relationship between the decrease in regular exercise since the COVID-19 pandemic and any changes in the HRQOL in the general elderly Japanese population. This study was conducted as a part of the COVID-19 vaccination program in Habikino city in Japan, between June and July 2021 using printed questionnaires. The participants included residents of the city who were agedâ€‰â‰¥â€‰65Â years, and were being vaccinated for COVID-19 at the city's center. The EuroQoL 5-dimension 5-level (EQ-5D-5L) was assessed at two different time points (pre-pandemic and current). Data on lifestyle changes, including their regular exercise routine since the pandemic, were collected. RESULTS: Finally, 14,494 participants (45.3% of the city's total elderly residents) were enrolled. Among them, 4321 participants (29.8%) had experienced a decrease in regular exercise since the pandemic. These participants showed a significantly higher rate of deterioration in all the EQ-5D-5L domains than the participants who did not experience a decrease in regular exercise. In the multivariate logistic regression analysis, participants with a decrease in regular exercise were significantly related to the EQ-5D-5L index deterioration compared to those with an unchanged

regular exercise routine (pâ€‰<â€‰0.001, adjusted odds ratioâ€‰=â€‰5.60) independent of age, sex, body mass index (BMI), and the existence of back pain, joint pain, and/or numbness of extremities. CONCLUSION: The current survey that included 45% of the elderly people living in a city revealed that up to 30% of them had experienced a decrease in the regular exercise since the COVID-19 pandemic. This decrease was significantly related to HRQOL deterioration independent of age, sex, BMI, baseline activities of daily living status, and musculoskeletal symptoms. Our data could be useful for understanding the current problem and provide a strong basis for the creation of exercise guidelines for the post-COVID-19 era.

Assessment of Immediate Allergic Reactions After Immunization With the Pfizer BNT162b2 Vaccine Using Intradermal Skin Testing With the COVID-19 Vaccines. BACKGROUND: Allergic reactions to the coronavirus disease 2019 (COVID-19) vaccines have raised concerns, particularly as repeated doses are required. Skin tests with the vaccines excipient were found to be of low value, whereas the utility of skin tests with the whole vaccine is yet to be determined. OBJECTIVE: To evaluate a panel of skin tests and the outcomes of subsequent doses of immunization among subjects who suffered an immediate allergic reaction to the BioNTech (BNT162b2) COVID-19 vaccine. METHODS: Between March and December 2021, patients who experienced symptoms consistent with immediate allergic reactions to the BNT162b2 vaccine and were referred to the Sheba Medical Center underwent skin testing with polyethylene glyol (PEG)-containing medicines, Pfizer-BNT162b2, and Oxford-AstraZeneca vaccine (AZD1222). Further immunization was performed accordingly and under medical observation. RESULTS: A total of 51 patients underwent skin testing for suspected allergy to the COVID vaccines, of which 38 of 51 (74.5%) were nonreactive, 7 of 51(13.7%) had no skin sensitization but suffered a clinical reaction during skin testing (mainly cough), and 6 of 51 (11.7%) exhibited immediate skin sensitization. Both skin sensitization and cough during testing were related to a higher use of adrenaline following immunization (PÂ = .08 and PÂ = .024, respectively). Further immunization with the BNT162b2 vaccine was recommended unless sensitization or severe reaction to previous immunization was evident. The latter were referred to be tested/receive the alternative AZD1222 vaccine. Ten patients underwent skin testing with AZD1222: 2 of 10 (20%) demonstrated skin sensitization to both vaccines; thus, 8 of 10 were immunized with the AZD1222, of which 2 of 8 (25%) had allergic reactions. CONCLUSIONS: Immediate allergic reactions to COVID-19 vaccines are rare but can be severe and reoccur. Intradermal testing with the whole vaccine may discriminate sensitized subjects, detect cross-sensitization between vaccines, and enable estimation of patients at higher risk.

Skin reaction after SARS-CoV-2 vaccines Reply to 'cutaneous adverse reactions following SARS-CoV-2 vaccine booster dose: A real-life multicentre experience'.

Frequency and safety of COVID-19 vaccination in children with multisystem inflammatory syndrome: a telephonic interview-based analysis.

Re: COVID-19 Vaccine-Induced Multisystem Inflammatory Syndrome With Polyserositis Detected by FDG PET/CT.

Association of COVID-19 vs Influenza With Risk of Arterial and Venous Thrombotic Events Among Hospitalized Patients. IMPORTANCE: The incidence of arterial thromboembolism and venous thromboembolism in persons with COVID-19 remains unclear. OBJECTIVE: To measure the 90-day risk of arterial thromboembolism and venous thromboembolism in patients hospitalized with COVID-19 before or during COVID-19 vaccine availability vs patients hospitalized with influenza. DESIGN, SETTING, AND PARTICIPANTS: Retrospective cohort study of 41â€¯443 patients hospitalized with COVID-19 before vaccine availability (April-November 2020), 44â€¯194 patients hospitalized with COVID-19 during vaccine availability (December 2020-May 2021), and 8269 patients hospitalized with influenza (October 2018-April 2019) in the US Food and Drug Administration Sentinel System (data

from 2 national health insurers and 4 regional integrated health systems). EXPOSURES: COVID-19 or influenza (identified by hospital diagnosis or nucleic acid test). MAIN OUTCOMES AND MEASURES: Hospital diagnosis of arterial thromboembolism (acute myocardial infarction or ischemic stroke) and venous thromboembolism (deep vein thrombosis or pulmonary embolism) within 90 days. Outcomes were ascertained through July 2019 for patients with influenza and through August 2021 for patients with COVID-19. Propensity scores with fine stratification were developed to account for differences between the influenza and COVID-19 cohorts. Weighted Cox regression was used to estimate the adjusted hazard ratios (HRs) for outcomes during each COVID-19 vaccine availability period vs the influenza period. RESULTS: A total of 85â€¯637 patients with COVID-19 (mean age, 72 [SD, 13.0] years; 50.5% were male) and 8269 with influenza (mean age, 72 [SD, 13.3] years; 45.0% were male) were included. The 90-day absolute risk of arterial thromboembolism was 14.4% (95% CI, 13.6%-15.2%) in patients with influenza vs 15.8% (95% CI, 15.5%-16.2%) in patients with COVID-19 before vaccine availability (risk difference, 1.4% [95% CI, 1.0%-2.3%]) and 16.3% (95% CI, 16.0%-16.6%) in patients with COVID-19 during vaccine availability (risk difference, 1.9% [95% CI, 1.1%-2.7%]). Compared with patients with influenza, the risk of arterial thromboembolism was not significantly higher among patients with COVID-19 before vaccine availability (adjusted HR, 1.04 [95% CI, 0.97-1.11]) or during vaccine availability (adjusted HR, 1.07 [95% CI, 1.00-1.14]). The 90-day absolute risk of venous thromboembolism was 5.3% (95% CI, 4.9%-5.8%) in patients with influenza vs 9.5% (95% CI, 9.2%-9.7%) in patients with COVID-19 before vaccine availability (risk difference, 4.1% [95% CI, 3.6%-4.7%]) and 10.9% (95% CI, 10.6%-11.1%) in patients with COVID-19 during vaccine availability (risk difference, 5.5% [95% CI, 5.0%-6.1%]). Compared with patients with influenza, the risk of venous thromboembolism was significantly higher among patients with COVID-19 before vaccine availability (adjusted HR, 1.60 [95% CI, 1.43-1.79]) and during vaccine availability (adjusted HR, 1.89 [95% CI, 1.68-2.12]). CONCLUSIONS AND RELEVANCE: Based on data from a US public health surveillance system, hospitalization with COVID-19 before and during vaccine availability, vs hospitalization with influenza in 2018-2019, was significantly associated with a higher risk of venous thromboembolism within 90 days, but there was no significant difference in the risk of arterial thromboembolism within 90 days.

SARS-CoV-2 breakthrough infection in vaccinees induces virus-specific nasal-resident CD8+ and CD4+ T cells of broad specificity. Rapid recognition of SARS-CoV-2-infected cells by resident T cells in the upper airway might provide an important layer of protection against COVID-19. Whether parenteral SARS-CoV-2 vaccination or infection induces nasal-resident T cells specific for distinct SARS-CoV-2 proteins is unknown. We isolated T cells from the nasal mucosa of COVID-19 vaccinees who either experienced SARS-CoV-2 infection after vaccination (n = 34) or not (n = 16) and analyzed their phenotype, SARS-CoV-2 specificity, function, and persistence. Nasal-resident SARS-CoV-2-specific CD8+ and CD4+ T cells were detected almost exclusively in vaccinees who experienced SARS-CoV-2 breakthrough infection. Importantly, the Spike-specific T cells primed by vaccination did not suppress the induction of T cells specific for other SARS-CoV-2 proteins. The nasal-resident T cell responses persisted for â‰¥140 d, with minimal sign of waning. These data highlight the importance of viral nasal challenge in the formation of SARS-CoV-2-specific antiviral immunity at the site of primary infection and further define the immunological features of SARS-CoV-2 hybrid immunity.

Self-Reported Reactogenicity After Different COVID-19 Vaccination Regimens. BACKGROUND: In Rhineland-Palatinate, most COVID-19 vaccinations are centrally registered by the Rhineland-Palatinate Division of Vaccine Documentation, which includes self-reported vaccination reactions (SRVR) and their level of perceived intensity. We analyzed the occurrence of SRVR reported between 12/2020 and 12/2021 in relation to the different vaccination regimens involving BioNTech/Pfizer (BNT) and Moderna (m1273) mRNA vaccines and AstraZeneca (ChAd) and Johnson & Johnson (Ad26)

viral vector vaccines. METHODS: Using sex-specific logistic regression models, we analyzed the occurrence of all local and systemic SRVR, as well as the occurrence of local and systemic SRVR that were self-rated as "severe" by the vaccinated persons, in relation to the vaccine of the first vaccination and the vaccination regimen of the second vaccination (BNT/BNT, ChAd/ChAd, m1273/m1273, ChAd/ BNT, ChAd/m1273). Vaccination with BNT or the BNT/BNT regimen formed the reference category for the estimated odds ratios (OR) with respective 95% confidence intervals. RESULTS: Of all those vaccinated, 40.7% provided valid information on SRVR after the first vaccination and 33.8% after the second vaccination. As a result, 887 052 individuals were included in the analyses. Their median age was 60 years, and 58% were women. The most common vaccination regimen was BNT/BNT (67.3%). The most common SRVR were pain at the injection site and fatigue. Self-reported reactogenicity after the first vaccination was lowest for BNT. Self-reported systemic reactogenicity was notably higher after vaccination with a vector vaccine. After the second vaccination, self-reported reactogenicity was lowest after a ChAd/ChAd regimen and highest after an m1273 second vaccination. CONCLUSION: With overall acceptable tolerability, differences in self-reported reactogenicity were evident depending on the particular COVID-19 vaccines and vaccination regimens in question.

Belimumab is not associated with COVID-19 mRNA vaccination failure in systemic lupus erythematosus.

New-onset vitiligo after COVID-19 mRNA vaccination: A causal association?

mRNA-carrying lipid nanoparticles that induce lysosomal rupture activate NLRP3 inflammasome and reduce mRNA transfection efficiency. In the last several years, countless developments have been made to engineer more efficient and potent mRNA lipid nanoparticle vaccines, culminating in the rapid development of effective mRNA vaccines against COVID-19. However, despite these advancements and materials approaches, there is still a lack of understanding of the resultant immunogenicity of mRNA lipid nanoparticles. Therefore, a more mechanistic, design-driven approach needs to be taken to determine which biophysical characteristics, especially related to changes in lipid compositions, drive nanoparticle immunogenicity. Here, we synthesized a panel of six mRNA lipid nanoparticle formulations, varying the concentrations of different lipid components and systematically studied their effect on NLRP3 inflammasome activation; a key intracellular protein complex that controls various inflammatory responses. Initial experiments aimed to determine differences in nanoparticle activation of NLRP3 inflammasomes by IL-1Î² ELISA, which unveiled that nanoparticles with high concentrations of ionizable lipid DLin-MC3-DMA in tandem with high cationic lipid DPTAP and low cholesterol concentration induced the greatest activation of the NLRP3 inflammasome. These results were further corroborated by the measurement of ASC specks indicative of NLRP3 complex assembly, as well as cleaved gasdermin-D and caspase-1 expression indicating complex activation. We also uncovered these activation profiles to be mechanistically correlated primarily with lysosomal rupturing caused by the delayed membrane disruption capabilities of ionizable lipids until the lysosomal stage, as well as by mitochondrial reactive oxygen species (ROS) production and calcium influx for some of the particles. Therefore, we report that the specific, combined effects of each lipid type, most notably ionizable, cationic lipids, and cholesterol, is a crucial mRNA lipid nanoparticle characteristic that varies the endo/lysosomal rupture capabilities of the formulation and activate NLRP3 inflammasomes in a lysosomal rupture dependent manner. These results provide a more concrete understanding of mRNA lipid Nanoparticle-Associated Molecular Patterns for the activation of molecular-level immune responses and provide new lipid composition design considerations for future mRNA-delivery approaches.

Successful mRNA COVID-19 Vaccination and Colonoscopy After Oral Desensitization in a Patient With Polyethylene Glycol Allergy. Anaphylaxis to polyethylene glycol (PEG) is rare and mainly occurs

with the use of laxatives containing PEG. Recently, an increasing number of PEG allergies have been reported, particularly those related to coronavirus disease 2019 (COVID-19) vaccines. mRNA COVID-19 vaccines, such as the BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) vaccines, contain PEG2000 as an excipient and are contraindicated when allergy to a vaccine component exist. We report a 55-year-old woman's history as a case of successful mRNA COVID-19 vaccination and colonoscopy after oral desensitization to PEG in a patient with PEG allergy who required both COVID-19 vaccination and colon evaluation. Allergy to PEG was diagnosed based on clinical history, skin test results, and basophil histamine release testing. Oral desensitization effectively suppressed histamine release from basophils in response to PEG stimulation, suggesting that oral desensitization using PEG-based laxatives may be an effective treatment option for patients with allergy to the substance.

Effects of side-effect risk framing strategies on COVID-19 vaccine intentions: a randomized controlled trial. BACKGROUND: Fear over side-effects is one of the main drivers of COVID-19 vaccine hesitancy. A large literature in the behavioral and communication sciences finds that how risks are framed and presented to individuals affects their judgments of its severity. However, it remains unknown whether such framing changes can affect COVID-19 vaccine behavior and be deployed as policy solutions to reduce hesitancy. METHODS: We conducted a pre-registered randomized controlled trial among 8998 participants in the United States and the United Kingdom to examine the effects of different ways of framing and presenting vaccine side-effects on individuals' willingness to get vaccinated and their perceptions of vaccine safety. RESULTS: Adding a descriptive risk label ('very low risk') next to the numerical side-effect and providing a comparison to motor-vehicle mortality increased participants' willingness to take the COVID-19 vaccine by 3.0 percentage points (p=0.003) and 2.4 percentage points (p=0.049), respectively. These effects were independent and additive and combining both framing strategies increased willingness to receive the vaccine by 6.1 percentage points (p<0.001). Mechanistically, we find evidence that these framing effects operate by increasing individuals' perceptions of how safe the vaccine is. CONCLUSIONS: Low-cost side-effect framing strategies can meaningfully affect vaccine intentions at a population level. FUNDING: Heidelberg Institute of Global Health. CLINICAL TRIAL NUMBER: German Clinical Trials Registry (#DRKS00025551).

 Vaccination is one of the main strategies for controlling the COVID-19 pandemic. But vaccination rates have slowed and are below target levels in countries like the United States and the United Kingdom. While there are many causes of vaccine hesitancy, several studies have found that fear of side effects is the one of the most important. Although COVID-19 vaccine side-effects are rare, how the media presents these risks may amplify concerns. Addressing public concerns over vaccine side effects is key to improving the uptake of vaccines and booster doses, which has been even lower than primary vaccine series uptake. Studies show that how risk is presented affects peopleâ€™s risk perceptions and behavior. To learn more about how COVID-19 vaccine risk framing affects risk perception, Sudharsanan et al. enrolled 8,998 people from the United States and the United Kingdom in an online randomized controlled trial. Participants received information about a hypothetical new COVID-19 vaccine, including its side effect rate, and reported their perception of safety and whether they would take the vaccine. The experiments showed that adding the label â€œvery low riskâ€• when describing vaccine side effect rates increased the number of people who said they would take the vaccine by three percentage points. Comparing the risks of the hypothetical vaccine to the much higher chances of motor vehicle deaths increased an individualâ€™s willingness to take the vaccine by 2.4 percentage points. Combining both framing strategies increased peopleâ€™s desire to get vaccinated by 6.1 percentage points. Deploying these two strategies in vaccine risk communications may help increase primary and booster vaccinations against COVID-19. A next step would be to measure both vaccination intentions and vaccination rates to confirm these strategies.

Evaluation of Prevalence of Side-Effects Associated with Booster Dose of mRNA-Based COVID-19 Vaccine Among Healthcare Workers in Eastern Province, Saudi Arabia: A Descriptive Cross-Sectional Study. BACKGROUND: The purpose of this study was to examine the mild and moderate side-effects experienced by the healthcare workers (HCWs) in the Eastern Province of Saudi Arabia after receiving the booster dose of the Pfizer-BioNTech/BNT162b2 COVID-19 vaccine. METHODS: We directed a descriptive cross-sectional study among adults living in the Eastern Province of Saudi Arabia. A survey link was distributed through WhatsApp, SMS, or e-mail to HCWs. Participants' general and demographic information were also collected, as well as information about any local and systemic side-effects reported following vaccination. RESULTS: The results of this study showed that 81.84% (401/490) of the HCWs who contributed to this study reported the minimum COVID-19 post-vaccination side-effect. Body pain (89%) and pain at the site of injection (88.73%) were the most frequent frequently reported side-effects, followed by headache (28.68%), joint or bone pain (27.18%), muscle pain (26.43%), nausea or vomiting (21.2%), fever (18.95%), skin rashes (10.22%). History of chronic diseases had a 0.44-fold increased risk of side-effects compared to no history of chronic diseases HCWs (adjusted odds ratio (aOR) = 0.44; 95% CI = 0.224, 0.880), and significant association of occupation with side-effects was also 1.61-fold increased risk compared to nonmedical ((aOR) = 1.61; 95% CI = 1.037, 2.513). CONCLUSION: According to this study, the Pfizer-BioNTech/BNT162b2 COVID-19 vaccine was safe when given to Saudi Arabian HCWs. All reported side-effects were mild to moderate. The outcomes indicated that most participants had body pain and pain at the site of injection and fatigue is among the least reported side-effect post-booster dose. Healthcare was highly connected with more reporting of side-effects.

Catecholamines Are the Key Trigger of COVID-19 mRNA Vaccine-Induced Myocarditis: A Compelling Hypothesis Supported by Epidemiological, Anatomopathological, Molecular, and Physiological Findings. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine-induced myocarditis is a rare but well-documented complication in young males. The increased incidence of sudden death among athletes following vaccination has been reported and requires further investigation. Whether the risk of myocarditis, a known major cause of sudden death in young male athletes, also increases after coronavirus disease 2019 (COVID-19) infection is unknown. The severity and implications of these critical adverse effects require a thorough analysis to elucidate their key triggering mechanisms. The present review aimed to evaluate whether there is a justification to hypothesize that catecholamines in a "hypercatecholaminergic" state are the key trigger of SARS-CoV-2 mRNA vaccine-induced myocarditis and related outcomes and whether similar risks are also present following COVID-19 infection. A thorough, structured scoping review of the literature was performed to build the hypothesis through three pillars: detection of myocarditis risk, potential alterations and abnormalities identified after SARS-CoV-2 mRNA vaccination or COVID-19 infection and consequent events, and physiological characteristics of the most affected population. The following terms were searched in indexed and non-indexed peer review articles and recent preprints (<12 months): agent, "SARS-CoV-2" or "COVID-19"; event, "myocarditis" or "sudden death(s)" or "myocarditis+sudden death(s)" or "cardiac event(s)";Â underlying cause, "mRNA" or "spike protein" or "infection"Â or "vaccine"; proposed trigger, "catecholamine(s)" or "adrenaline" or "epinephrine" or "noradrenaline" or "norepinephrine" or "testosterone"; and affected population, "young male(s)" or "athlete(s)."Â The rationale and data that supported the hypothesis were as follows: SARS-CoV-2 mRNA vaccine-induced myocarditis primarily affected young males, while the risk was not observed following COVID-19 infection; independent autopsies or biopsies of patients who presented post-SARS-CoV-2 mRNA vaccine myocarditis in different geographical regions enabled the conclusion that a primary hypercatecholaminergic state was the key trigger of these events; SARS-CoV-2 mRNA was densely present, and SARS-CoV-2 spike protein was progressively produced in adrenal medulla

chromaffin cells, which are responsible for catecholamine production; the dihydroxyphenylalanine decarboxylase enzyme that converts dopamine into noradrenaline was overexpressed in the presence of SARS-CoV-2 mRNA, leading to enhanced noradrenaline activity; catecholamine responses were physiologically higher in young adults and males than in other populations; catecholamine responses and resting catecholamine production were higher in male athletes than in non-athletes; catecholamine responses to stress and its sensitivity were enhanced in the presence of androgens; and catecholamine expressions in young male athletes were already high at baseline, were higher following vaccination, and were higher than those in non-vaccinated athletes. The epidemiological, autopsy, molecular, and physiological findings unanimously and strongly suggest that a hypercatecholaminergic state is the critical trigger of the rare cases of myocarditis due to components from SARS-CoV-2, potentially increasing sudden deaths among elite male athletes.
Second-dose ChAdOx1 and BNT162b2 COVID-19 vaccines and thrombocytopenic, thromboembolic and hemorrhagic events in Scotland. We investigated thrombocytopenic, thromboembolic and hemorrhagic events following a second dose of ChAdOx1 and BNT162b2 using a self-controlled case series analysis. We used a national prospective cohort with 2.0 million(m) adults vaccinated with two doses of ChAdOx or 1.6â€‰m with BNT162b2. The incidence rate ratio (IRR) for idiopathic thrombocytopenic purpura (ITP) 14-20 days post-ChAdOx1 second dose was 2.14, 95% confidence interval (CI) 0.90-5.08. The incidence of ITP post-second dose ChAdOx1 was 0.59 (0.37-0.89) per 100,000 doses. No evidence of an increased risk of CVST was found for the 0-27 day risk period (IRR 0.83, 95% CI 0.16 to 4.26). However, few (â‰¤5) events arose within this risk period. It is perhaps noteworthy that these events all clustered in the 7-13 day period (IRR 4.06, 95% CI 0.94 to 17.51). No other associations were found for second dose ChAdOx1, or any association for second dose BNT162b2 vaccination. Second dose ChAdOx1 vaccination was associated with increased borderline risks of ITP and CVST events. However, these events were rare thus providing reassurance about the safety of these vaccines. Further analyses including more cases are required to determine more precisely the risk profile for ITP and CVST after a second dose of ChAdOx1 vaccine.
Functional neurologic disorder associated with SARS-CoV-2 vaccination.
Adult-Onset Still Disease After ChAdOx1 nCOV-19 Vaccination.
Evaluation of safety and immunogenicity of receptor-binding domain-based COVID-19 vaccine (Corbevax) to select the optimum formulation in open-label, multicentre, and randomised phase-1/2 and phase-2 clinical trials. BACKGROUND: We assessed the efficacy of a receptor-binding domain (RBD)-based protein subunit COVID-19 vaccine. METHODS: A randomised Phase-1/2 trial followed by a Phase-2 trial were conducted to assess the safety and immunogenicity of the COVID-19 vaccine Corbevax and select to an optimum formulation. Healthy adults (n=460) without COVID-19 vaccination or SARS-CoV-2 infection in the Phase-1/2 study were randomly divided into four vaccine formulation groups. FINDINGS: A low incidence of adverse events was reported post-vaccination. All formulations showed similar profiles of humoral and cellular immune responses that were associated with the content of CpG1018 adjuvant in the vaccine. In the Phase-2 study, 750 Âµg of CpG1018 showed significant improvement (> 4-fold increase from baseline) in immune responses, including the titres of anti-RBD IgG and neutralising antibody (nAb), and cellular immune responses, while maintaining the safety profile. Antibodies persisted consistently for 12 months after the second dose of vaccine. INTERPRETATIONS: Corbevax (two-dose schedule with 28 days of interval between doses) was well tolerated with no observed safety concerns. Previous observations from efficacy studies by Moderna and AstraZeneca and the correlation between nAb titres post-vaccination and a human convalescent serum panel showed that Corbevax induced significantly high nAb titres. These studies were prospectively registered with the Clinical Trial Registry of India (CTRI/2021/06/034014 and CTRI/2020/11/029032). FUNDING: Bill & Melinda Gates Foundation, BIRAC-Division of Department of

Biotechnology, Govt of India, and the Coalition for Epidemic Preparedness Innovations funded this study.

One-year results from the vaccination campaign against COVID-19 infection in 47 million individuals with severe mental disorders and other chronic diseases. Severe mental disorders have been associated with increased COVID-19 mortality. The aim of this study was to evaluate the results of the vaccination campaign against COVID-19 after 1 year using exhaustive population-based data. In this nationwide population-based study, we used data from the French national medico-administrative database (SNDS) and the COVID Vaccine teleservice from January 4, 2021 (date of activation of the teleservice) to January 30th, 2022. As of January 30th, 2022, the rate of first injection in France was 80.2% (54 million people) and the rate of booster vaccination was 78.3% (52.7 million people). Except for opioid use disorder, all individuals with chronic illnesses or risk factors for poor COVID-19 outcome (e.g., smoking and obesity) had higher rates of vaccination than the general population (from 83.4 to 94.5% vs. 78.3%). However, the four diseases ranking last for both initial and booster vaccinations were mental disorders: alcohol use disorders (86 and 84.3%), neurodevelopmental psychiatric disorders (85.3 and 83.7%), schizophrenia-spectrum disorder (85 and 83.4%) and opioid use disorders (72.9 and 69.4%). Except for opioid disorders, all patients with mental disorders had higher rates of vaccination compared to the general population. However, these rates were lower than other chronic diseases at risk of severe COVID-19 outcomes. Vaccination campaigns must redouble their efforts to improve vaccination penetration in patients with mental disorders.

Invited Commentary: Vaccines and Fertility-Why Worry? In a recent issue of the Journal, Wesselink et al. (Am J Epidemiol. 2022;191(8):1383-1395) presented findings that indicate that the coronavirus disease 2019 (COVID-19) vaccine does not cause any reduction in fertility in either men or women, while COVID-19 infection may reduce fertility temporarily among men. These are reassuring findings for those seeking pregnancy, as well as for clinicians and the public. There was no scientific reason to be concerned about effects of the COVID-19 vaccine on fertility, so some of the psychological, ethical, and historical reasons for concern are discussed. These include perceptions of risk around "unnatural," unusual, or dreaded outcomes; vaccine resistance as part of a social and political identity; and the tendency for moral panics to occur around women's reproductive capacity. On this and other topics, there is a broad need for reproductive health to be better incorporated into clinical trials, and for fertility research to advance in measurement and include a more diverse and global population.

Leukocytoclastic Vasculitis following the First Dose of the Elasomeran COVID-19 Vaccination. Our case highlights leukocytoclastic vasculitis as a potential side effect of the elasomeran COVID-19 vaccine. As the elasomeran vaccine becomes more widely available to the public, cutaneous reactions should be noted and looked for as potential side effects of the vaccine. Our patient had a history of immune thrombocytopenic purpura, making this a potential predisposing condition to the development of vasculitis following elasomeran administration. The case of vasculitis in our patient, although diffuse in distribution, was self-resolving. Our patient was counseled of the potential risk of worsening reaction to the second dose of the vaccine and instructed to proceed at their own risk. He elected to receive the second vaccination dose without any further reaction or side effects. Primary teaching points from this case include the potential of developing leukocytoclastic vasculitis following the elasomeran vaccination. Patients who develop LCV following the first dose should be counseled of the risks associated with receiving the second dose, including progression to systemic organ involvement.

Factors associated to acceptance and willingness to pay for COVID vaccine in Nepal. INTRODUCTION: Corona virus disease (COVID-19) remains pandemic globally. Vaccination is considered one of the best means to control both morbidity and mortality of COVID-19. The study

aims to find out the people's acceptance and willingness to pay for it. METHODS: The study used cross-sectional survey design. Data were collected using a survey questionnaire from 1072 respondents (age 20-60 years) from 14 districts of Nepal. Socio-demographic characteristics of the respondents were independent and acceptance of vaccine was the dependent variable. RESULTS: The study found that 84% of the respondents accepted the COVID vaccine. Only one out of six did not accept the COVID vaccine while 16% of the respondents stated that they would like to pay for the COVID vaccination. The average willingness to pay (WTP) for vaccination was NRs. 1053 (US$ 9) while median and mode remained the same NRs. 500. The middle age groups (30-49 years), respondents belonged to Madhesi, business people in terms of occupation and the respondents who had completed school level education had a higher acceptance rate than other categories. It was observed that place of residence in terms of provinces or districts, age group, caste/ethnicity, and educational level of the respondents were significantly associated with the acceptance of the COVID vaccine. Moreover, respondents residing from Lumbini Province, age group of 30-39 years, and having secondary or higher education were noticed as more likely to accept the COVID vaccine than the respective compared groups. CONCLUSION: Appropriate information, education and communication needs to disseminate to minimize the misinformation about the COVID and lack of trust in vaccine that may lead to low acceptance and poor WTP for vaccine. These findings could be considered while making COVID and the COVID vaccine-related interventions.

Post Covishield (ChAdOx1 nCoV-19) Vaccination: New Onset Focal Segmental Glomerulosclerosis Resistant to Steroid and Calcineurin Inhibitor. With the ongoing mass COVID vaccination program, various case reports link the COVID-19 vaccines with heightened off-target immune responses leading to de novo development or relapse of various glomerular diseases. Very few glomerular diseases (totally nine published cases to date) have been reported post ChAdOx1 nCoV-19 (Oxford-AstraZeneca) vaccination compared to more potent m RNA vaccine. In this case report, we present a case of de novo focal segmental glomerulosclerosis (FSGS) post ChAdOx1 nCoV-19 vaccination resistant to steroid and calcineurin inhibitor treatment. To our knowledge, this is the first case of FSGS tip variant reported after the ChAdOx1 nCoV-19 vaccination and the second de novo FSGS case post COVID vaccination (any types of COVID vaccines). We may expect more such types of cases resistant to conventional therapy as the global penetration of vaccination programs will improve.

Antibody response following the third and fourth SARS-CoV-2 vaccine dose in individuals with common variable immunodeficiency. BACKGROUND: The antibody response after vaccination is impaired in common variable immunodeficiency (CVID). OBJECTIVE: We aimed to study the spike receptor-binding domain IgG antibody (anti-S-RBD) levels during a four-dose SARS-CoV-2 vaccination strategy and after monoclonal antibody (mAB) treatment in CVID. Moreover, we assessed the anti-S-RBD levels in immunoglobulin replacement therapy (IgRT) products. METHODS: In an observational study, we examined anti-S-RBD levels after the second, third, and fourth dose of mRNA SARS-CoV-2 vaccines. Moreover, we measured anti-S-RBD after treatment with mAB. Finally, anti-S-RBD was assessed in common IgRT products. Antibody non-responders (anti-S-RBD < 7.1) were compared by McNemar's test and anti-S-RBD levels were compared with paired and non-paired Wilcoxon signed rank tests as well as Kruskal-Wallis tests. RESULTS: Among 33 individuals with CVID, anti-S-RBD levels increased after the third vaccine dose (165 BAU/ml [95% confidence interval: 85; 2280 BAU/ml], p = 0.006) and tended to increase after the fourth dose (193 BAU/ml, [-22; 569 BAU/ml], p = 0.080) compared to the previous dose. With increasing number of vaccinations, the proportion of patients who seroconverted (anti-S-RBD â‰¥ 7.1) increased non-significantly. mAB treatment resulted in a large increase in anti-S-RBD and a higher median level than gained after the fourth dose of vaccine (p = 0.009). IgRT products had varying concentrations of anti-S-RBD (p < 0.001), but none of the

products seemed to affect the overall antibody levels (p = 0.460). CONCLUSION: Multiple SARS-CoV-2 vaccine doses in CVID seem to provide additional protection, as antibody levels increased after the third and fourth vaccine dose. However, anti-S-RBD levels from mAB outperform the levels mounted after vaccination. CLINICAL IMPLICATIONS: Boosting with SARS-CoV-2 vaccines seems to improve the antibody response in CVID patients. CAPSULE SUMMARY: The third and possibly also the fourth dose of mRNA SARS-CoV-2 vaccine in CVID improve the antibody response as well as stimulate seroconversion in most non-responders.

Analysis of immunization time, amplitude, and adverse events of seven different vaccines against SARS-CoV-2 across four different countries. BACKGROUND: Scarce information exists in relation to the comparison of seroconversion and adverse events following immunization (AEFI) with different SARS-CoV-2 vaccines. Our aim was to correlate the magnitude of the antibody response to vaccination with previous clinical conditions and AEFI. METHODS: A multicentric comparative study where SARS-CoV-2 spike 1-2 IgG antibodies IgG titers were measured at baseline, 21-28 days after the first and second dose (when applicable) of the following vaccines: BNT162b2 mRNA, mRNA-1273, Gam-COVID-Vac, Coronavac, ChAdOx1-S, Ad5-nCoV and Ad26.COV2. Mixed model and Poisson generalized linear models were performed. RESULTS: We recruited 1867 individuals [52 (SD 16.8) years old, 52% men]. All vaccines enhanced anti-S1 and anti-S2 IgG antibodies over time (p<0.01). The highest increase after the first and second dose was observed in mRNA-1273 (p<0.001). There was an effect of previous SARS-CoV-2 infection; and an interaction of age with previous SARS-CoV-2 infection, Gam-COVID-Vac and ChAdOx1-S (p<0.01). There was a negative correlation of Severe or Systemic AEFI (AEs) of naÃ¯ve SARS-CoV-2 subjects with age and sex (p<0.001); a positive interaction between the delta of antibodies with Gam-COVID-Vac (p=0.002). Coronavac, Gam-COVID-Vac and ChAdOx1-S had less AEs compared to BNT162b (p<0.01). mRNA-1273 had the highest number of AEFIs. The delta of the antibodies showed an association with AEFIs in previously infected individuals (p<0.001). CONCLUSIONS: The magnitude of seroconversion is predicted by age, vaccine type and SARS-CoV-2 exposure. AEs are correlated with age, sex, and vaccine type. The delta of the antibody response only correlates with AEs in patients previously exposed to SARS-CoV-2. REGISTRATION NUMBER: ClinicalTrials.gov, identifier NCT05228912.

Correction to "Hyper inflammatory syndrome following COVID-19 mRNA vaccine in children: A national post-authorization pharmacovigilance study". [This corrects the article DOI: 10.1016/j.lanepe.2022.100393.].

Serial negative response after standard and third (Booster) dose of COVID-19 inactivated vaccine is associated with low vitamin D levels in patients with solid cancers. INTRODUCTION: The response is poorly understood to the third dose in patients with cancer who failed the standard dose of inactivated SARS-CoV-2 vaccines (CoronaVac). We aim to assess the immune response to the third dose and identify whether vitamin D deficiency is associated with serial serologic failure in patients with cancer. METHODS: Solid cancer patients (SCP-N) and healthy controls (HCs) who were seronegative after the standard-dose vaccines in our previous study were prospectively recruited, from October 2021 to February 2022, to receive the third dose vaccines and anti-SARS-CoV-2S antibodies were measured. SCP-N who failed the third dose (serial seronegative group, SSG) were matched by propensity scores with the historical standard-dose positive cancer patient group (robust response group, RRG). An exploratory analysis was carried out to validate the role of vitamin D on the serology response. RESULTS: The multi-center study recruited 97 SCP-N with 279 positive controls as RRG and 82 negative controls as HC group. The seroconversion rate after third-dose vaccination was higher in SCP-N than in HC (70.6% vs. 29.4%, p < 0.01). The matched comparison showed that patients in SSG had a significantly lower level of vitamin D and consumption rate than RRG or RRG-B (RRG with third-dose positive) (all p < 0.01). None had serious (over grade II) adverse events after the

third dose. CONCLUSION: Solid cancer patients with second-dose vaccine failure may have a relatively poor humoral response to the third dose of COVID-19 vaccines as compared with the seronegative HC group. The consecutively poor humoral response could be associated with poor vitamin D levels and intake. Vitamin D status and cancer-related immune compromise may jointly affect the humoral response following booster vaccination.

Allergic reaction to anisakis-contaminated fish after the first administration of BNT162b2 mRNA vaccine: a case report.

Population-wide persistent hemostatic changes after vaccination with ChAdOx1-S. Various vaccines were developed to reduce the spread of the Severe Acute Respiratory Syndrome Cov-2 (SARS-CoV-2) virus. Quickly after the start of vaccination, reports emerged that anti-SARS-CoV-2 vaccines, including ChAdOx1-S, could be associated with an increased risk of thrombosis. We investigated the hemostatic changes after ChAdOx1-S vaccination in 631 health care workers. Blood samples were collected 32 days on average after the second ChAdOx1-S vaccination, to evaluate hemostatic markers such as D-dimer, fibrinogen, Î±2-macroglobulin, FVIII and thrombin generation. Endothelial function was assessed by measuring Von Willebrand Factor (VWF) and active VWF. IL-6 and IL-10 were measured to study the activation of the immune system. Additionally, SARS-CoV-2 anti-nucleoside and anti-spike protein antibody titers were determined. Prothrombin and fibrinogen levels were significantly reduced after vaccination (-7.5% and -16.9%, $p < 0.0001$). Significantly more vaccinated subjects were outside the normal range compared to controls for prothrombin (42.1% vs. 26.4%, $p = 0.026$) and antithrombin (23.9% vs. 3.6%, $p = 0.0010$). Thrombin generation indicated a more procoagulant profile, characterized by a significantly shortened lag time (-11.3%, $p < 0.0001$) and time-to-peak (-13.0% and $p < 0.0001$) and an increased peak height (32.6%, $p = 0.0015$) in vaccinated subjects compared to unvaccinated controls. Increased VWF (+39.5%, $p < 0.0001$) and active VWF levels (+24.1 %, $p < 0.0001$) pointed toward endothelial activation, and IL-10 levels were significantly increased (9.29 pg/mL vs. 2.43 pg/mL, $p = 0.032$). The persistent increase of IL-10 indicates that the immune system remains active after ChAdOx1-S vaccination. This could trigger a pathophysiological mechanism causing an increased thrombin generation profile and vascular endothelial activation, which could subsequently result in and increased risk of thrombotic events.

Erythrodermic psoriasis after COVID-19 vaccination.

Subcutaneous panniculitis-like T-cell lymphoma after COVID-19 vaccination.

Endovascular mechanical thrombectomy for cerebral venous sinus thrombosis after mRNA-based SIRS-CoV-2 vaccination. BACKGROUND: As vaccinations against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) continue worldwide, increased rates of venous thrombotic events, mainly as cerebral venous sinus thrombosis (CVST), have been reported following adenovirus vector-based SARS-CoV-2 vaccination. However, few reports have described the occurrence of venous thrombosis after messenger RNA (mRNA)-based vaccination. Here, we describe a case of CVST after a first dose of mRNA-based vaccination that was treated with emergent endovascular mechanical thrombectomy and systemic heparinization.Case Description.A 43-year-old, previously healthy man suffered severe headache and partial seizures affecting the left arm 4Â days after receiving the first dose of an mRNA-based SARS-CoV-2 vaccination (FC3661; Pfizer/BioNTech). Computed tomography showed intraparenchymal hemorrhage. Seven days after vaccination, symptoms worsened and he was transferred to our tertiary hospital. Magnetic resonance venography revealed CVST with occlusion of the superior sagittal sinus (SSS) and right transverse sinus (TS). Since no findings suggested thrombosis with thrombocytopenia syndrome, the patient underwent systemic heparinization and emergent mechanical thrombectomy with balloon transluminal angioplasty, a stent retriever and an aspiration catheter. Complete SSS and right TS recanalization were achieved and the patient was discharged without neurological deficits. CONCLUSION: Clinicians should be

aware that apparently healthy individuals with no risk factors can develop CVST after receiving an mRNA-based vaccine and appropriate treatment including EMT need to be performed immediately.(228 words).
Delayed urticaria after BNT162b2 booster vaccination at previous intradermal test site with severe acute respiratory syndrome-coronavirus-2 spike protein. Urticaria is a common cutaneous adverse event from coronavirus disease 2019 vaccination. Previous studies hypothesized that excipients as polyethylene glycol in BNT162b2 vaccine and polysorbate in ChAdOx1 nCoV-19 vaccine are allergens. A 28-year-old woman had urticaria after a booster vaccination with BNT162b2 at the site of previous intradermal injection with severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) spike protein. This reaction emphasized that delayed urticaria may not be an allergic reaction to excipient but rather to the immunogen as such as SARS-CoV-2 spike protein.
Kinetics of anti-SARS-CoV-2 responses post complete vaccination with coronavac: A prospective study in 50 health workers. BACKGROUND: COVID-19 pandemic causes severe acute respiratory syndrome and requires rapid action. The development of effective safe vaccines become a global priority for achieving herd immunity. Vaccination is expected to form specific antibodies against the SARS-CoV-2 spike protein which can neutralize the virus, preventing the virus from binding with ACE 2 receptors. OBJECTIVE: Evaluating and to know if there any differences of kinetics antibody levels from recipient's anti-IgG S-RBD and NAb with complete second dose CoronaVac Vaccine, to determine the antibody response in preventing SARS-CoV-2. METHOD: A prospective-cohort study using observational analytics was conducted from January-April 2021 at Dr. Soetomo Hospital, Surabaya. A total of 50 subjects are healthcare workers who received two doses of CoronaVac. The IgG S-RBD and NAb levels were measured on Maglumi 800 device (SNIBE, China). Differences in IgG S-RBD and NAb levels before vaccination and after second dose CoronaVac vaccination on 14th day, on 28th day, ware tested using Friedman and Wilcoxon tests. RESULT: Mean values of IgG S-RBD and NAb have fluctuated. There was a significant difference between IgG S-RBD and NAb levels on day-0 (0.090 vs 18.630; pâ€‰<â€‰0.001) and day-28 (141.266 vs 116.640; pâ€‰=â€‰0.037). The median value showed the IgG S-RBD level on day-28 was much better than NAb value (141,266 v 116,640). CONCLUSION: CoronaVac will form persistent antibodies. Despite antibody development, the acquired humoral immunity decreased at 28â€‰days after full CoronaVac immunization. Kinetics of antibody NAb decreased more rapidly than IgG S-RBD.
A case of COVID-19 vaccination during radiotherapy for breast cancer. BACKGROUND: The coronavirus disease 19 (COVID-19) vaccination has been progressing. The safety of vaccination during radiotherapy is not clear. CASE PRESENTATION: We experienced a patient who received a COVID-19 vaccine during radiotherapy. A 60-year-old woman with breast cancer underwent postoperative radiotherapy. She received two vaccine doses and she suffered from severe vertigo. Her radiotherapy was suspended for several days and the radiotherapy schedule needed to be changed. CONCLUSIONS: The association between vertigo and vaccination during radiotherapy is not clear. However, if the general condition of patients worsens, suspension of treatment might be necessary. Therefore, attention should be given to COVID-19 vaccination during radiotherapy.
Anaphylaxis after COVID-19 vaccination: A registry-based study.
The effectiveness and safety of mRNA (BNT162b2) and inactivated (CoronaVac) COVID-19 vaccines among individuals with chronic kidney diseases. [Figure: see text]
Safety of mRNA COVID-19 vaccines during pregnancy.
Safety of COVID-19 vaccines in pregnancy: a Canadian National Vaccine Safety (CANVAS) network cohort study. BACKGROUND: Pregnant individuals have been receiving COVID-19 vaccines following pre-authorisation clinical trials in non-pregnant people. This study aimed to determine the frequency and nature of significant health events among pregnant females after COVID-19

vaccination, compared with unvaccinated pregnant controls and vaccinated non-pregnant individuals. METHODS: We did an observational cohort study, set in seven Canadian provinces and territories including Ontario, Quebec, British Columbia, Alberta, Nova Scotia, Yukon, and Prince Edward Island. Eligibility criteria for vaccinated individuals were a first dose of a COVID-19 vaccine within the previous 7 days; an active email address and telephone number; ability to communicate in English or French; and residence in the aforementioned provinces or territories. Study participants were pregnant and non-pregnant females aged 15-49 years. Individuals were able to participate as controls if they were unvaccinated and fulfilled the other criteria. Data were collected primarily by self-reported survey after both vaccine doses, with telephone follow-up for those reporting any medically attended event. Participants reported significant health events (new or worsening of a health event sufficient to cause work or school absenteeism, medical consultation, or prevent daily activities) occurring within 7 days of vaccination or within the past 7 days for unvaccinated individuals. We employed multivariable logistic regression to examine significant health events associated with mRNA vaccines, adjusting for age group, previous SARS-CoV-2 infection, and trimester, as appropriate. FINDINGS: As of Nov 4, 2021, 191â€ˆ360 women aged 15-49 years with known pregnancy status had completed the first vaccine dose survey and 94â€ˆ937 had completed the second dose survey. 180â€ˆ388 received one dose and 94â€ˆ262 received a second dose of an mRNA vaccine, with 5597 pregnant participants receiving dose one and 3108 receiving dose two, and 174â€ˆ765 non-pregnant participants receiving dose one and 91â€ˆ131 receiving dose two. Of 6179 included unvaccinated control participants, 339 were pregnant and 5840 were not pregnant. Overall, 226 (4Â·0%) of 5597 vaccinated pregnant females reported a significant health event after dose one of an mRNA vaccine, and 227 (7Â·3%) of 3108 after dose two, compared with 11 (3Â·2%) of 339 pregnant unvaccinated females. Pregnant vaccinated females had an increased odds of a significant health event within 7 days of the vaccine after dose two of mRNA-1273 (adjusted odds ratio [aOR] 4Â·4 [95% CI 2Â·4-8Â·3]) compared with pregnant unvaccinated controls within the past 7 days, but not after dose one of mRNA-1273 or any dose of BNT162b2. Pregnant vaccinated females had decreased odds of a significant health event compared with non-pregnant vaccinated females after both dose one (aOR 0Â·63 [95% CI 0Â·55-0Â·72]) and dose two (aOR 0Â·62 [0Â·54-0Â·71]) of any mRNA vaccination. There were no significant differences in any analyses when restricted to events which led to medical attention. INTERPRETATION: COVID-19 mRNA vaccines have a good safety profile in pregnancy. These data can be used to appropriately inform pregnant people regarding reactogenicity of COVID-19 vaccines during pregnancy, and should be considered alongside effectiveness and immunogenicity data to make appropriate recommendations about best use of COVID-19 vaccines in pregnancy. FUNDING: Canadian Institutes of Health Research, Public Health Agency of Canada.

Association of interstitial granulomatous dermatitis with messenger Rna-1273 Sars-Cov-2 vaccine.

New onset pemphigus foliaceus following AstraZeneca COVID-19 vaccination.

COVAD survey 2 long-term outcomes: unmet need and protocol. Vaccine hesitancy is considered a major barrier to achieving herd immunity against COVID-19. While multiple alternative and synergistic approaches including heterologous vaccination, booster doses, andÂ antiviral drugs have been developed, equitable vaccine uptake remains the foremost strategy to manage pandemic. Although none of the currently approved vaccines are live-attenuated, several reports of disease flares, waning protection, and acute-onset syndromes have emerged as short-term adverse events after vaccination. Hence, scientific literature falls short when discussing potential long-term effects in vulnerable cohorts. The COVAD-2 survey follows on from the baseline COVAD-1 survey with the aimÂ to collect patient-reported data on the long-term safety and tolerability of COVID-19 vaccines in immune modulation. The e-survey has been extensively pilot-tested and validated with translations

into multiple languages. Anticipated results will help improve vaccination efforts and reduce the imminent risks of COVID-19Â infection, especially in understudiedÂ vulnerable groups.

Immunogenicity, effectiveness, safety and psychological impact of COVID-19 mRNA vaccines. In December 2019, a new single-stranded RNA coronavirus, SARS-CoV-2, appeared in China and quickly spread around the world leading to a pandemic. Infection with SARS-CoV-2 generates symptoms ranging from asymptomatic to severe, occasionally requiring hospitalization in intensive care units, and, in more severe cases, leading to death. Scientists and researchers around the world have made a real race against time to develop various vaccines to slow down and stop the spread of the virus. In addition to conventional viral vector vaccines, new generation mRNA vaccines, BNT152b2 (Comirnaty) and mRNA-1273 (Spikevax), have been developed respectively by Pfizer/BioNTech and Moderna. These vaccines act on immune cells to induce an immune response with the production of specific antibodies against Spike protein of SARS-CoV-2, and to stimulate the differentiation of T and B memory cells. The objective of this review is to provide a detailed picture of the validity of these new vaccines and the safety of vaccination. Not only was the immunogenic effect of mRNA vaccines evaluated, but also the psychosocial impact they had on the population. The data collected show that this type of vaccine can also be an excellent candidate for future treatment and eradication of possible new pathologies with viral and non-viral etiology.

Influenza and pneumococcal vaccination and COVID-19 in kidney transplant patients. BACKGROUND: This study aims to investigate the effect of recent influenza and pneumococcal vaccines' administration on the development of COVID-19 infection in kidney transplant recipients during the pandemic. METHODS: The effect of influenza and pneumococcal vaccines on the clinical course of the disease in COVID-positive (COVID group, n: 105) and COVID-negative (control group, n: 127) recipients has been examined. The control group included patients with negative rRT-PCR test results. At the time of the study, no patient was vaccinated with COVID-19 vaccine. The patients' influenza and/or pneumococcal vaccination rates in 2019 and 2020 were determined. In 2019 and 2020, 32 and 33 people in the COVID-positive group and 61 and 54 people in the COVID-negative group had received influenza and/or pneumococcal vaccines, respectively. The median study follow-up times of the COVID-negative and COVID-positive groups were 13.04 and 8.31Â months, respectively. RESULTS: Compared with the COVID-negative group, the patients in the COVID-positive group were younger and had a longer post-transplant time. In addition, the rate of transplantation from a living donor and the rate of COVID positivity in family members were also higher. The influenza vaccination rates in the COVID negative group were significantly higher than the COVID-positive group in 2020 (23.8% vs 37%, pÂ =Â 0.031). Multivariate logistic regression analysis revealed that the presence of COVID-19 in family members and lack of pneumococcal vaccination in 2020 increased the risk of being positive for COVID-19. There was no significant difference in the hospitalization rates, the need for dialysis and intensive care, the hospital stay, and the graft dysfunction in the COVID-positive patients with and without influenza and pneumococcal vaccines. CONCLUSION: The observations made throughout this study suggest that influenza and pneumococcal vaccination in transplant patients may reduce the risk of COVID-19 disease and provide additional benefits during the pandemic period.

Durability of Immunity Is Low Against Severe Acute Respiratory Syndrome Coronavirus 2 Omicron BA.1, BA.2, and BA.3 Variants After Second and Third Vaccinations in Children and Young Adults With Inflammatory Bowel Disease Receiving Biologics.

Safety and immunogenicity following a homologous booster dose of a SARS-CoV-2 recombinant spike protein vaccine (NVX-CoV2373): a secondary analysis of a randomised, placebo-controlled, phase 2 trial. BACKGROUND: Emerging SARS-CoV-2 variants and evidence of waning vaccine efficacy present substantial obstacles towards controlling the COVID-19 pandemic. Booster doses of SARS-

CoV-2 vaccines might address these concerns by amplifying and broadening the immune responses seen with initial vaccination regimens. We aimed to assess the immunogenicity and safety of a homologous booster dose of a SARS-CoV-2 recombinant spike protein vaccine (NVX-CoV2373). METHODS: This secondary analysis of a phase 2, randomised study assessed a single booster dose of a SARS-CoV-2 recombinant spike protein vaccine with Matrix-M adjuvant (NVX-CoV2373) in healthy adults aged 18-84 years, recruited from 17 clinical centres in the USA and Australia. Eligible participants had a BMI of 17-35 kg/m(2) and, for women, were heterosexually inactive or using contraception. Participants who had a history of SARS-CoV or SARS-CoV-2, confirmed diagnosis of COVID-19, serious chronic medical conditions, or were pregnant or breastfeeding were excluded. Approximately 6 months following their primary two-dose vaccination series (administered day 0 and day 21), participants who received placebo for their primary vaccination series received a placebo booster (group A) and participants who received NVX-CoV2373 for their primary vaccination series (group B) were randomly assigned (1:1) again, via centralised interactive response technology system, to receive either placebo (group B1) or a single booster dose of NVX-CoV2373 (5 Î¼g SARS-CoV-2 rS with 50 Î¼g Matrix-M adjuvant; group B2) via intramuscular injection; randomisation was stratified by age and study site. Vaccinations were administered by designated site personnel who were masked to treatment assignment, and participants and other site staff were also masked. Administration personnel also assessed the outcome. The primary endpoints are safety (unsolicited adverse events) and reactogenicity (solicited local and systemic) events and immunogenicity (serum IgG antibody concentrations for the SARS-CoV-2 rS protein antigen) assessed 14 days after the primary vaccination series (day 35) and 28 days following booster (day 217). Safety was analysed in all participants in groups A, B1, and B2, according to the treatment received; immunogenicity was analysed in the per-protocol population (ie, participants in groups A, B1, and B2) who received all assigned doses and who did not test SARS-CoV-2-positive or received an authorised vaccine, analysed according to treatment assignment). This trial is registered with ClinicalTrials.gov, NCT04368988. FINDINGS: 1610 participants were screened from Aug 24, 2020, to Sept 25, 2020. 1282 participants were enrolled, of whom 173 were assigned again to placebo (group A), 106 were re-randomised to NVX-CoV2373-placebo (group B1), and 104 were re-randomised to NVX-CoV2373-NVX-CoV2373 (group B2); after accounting for exclusions and incorrect administration, 172 participants in group A, 102 in group B1, and 105 in group B2 were analysed for safety. Following the active booster, the proportion of participants with available data reporting local (80 [82%] of 97 participants had any adverse event; 13 [13%] had a grade â‰¥3 event) and systemic (75 [77%] of 98 participants had any adverse event; 15 [15%] had a grade â‰¥3 event) reactions was higher than after primary vaccination (175 [70%] of 250 participants had any local adverse event, 13 [5%] had a grade â‰¥3 event; 132 [53%] of 250 had any systemic adverse event, 14 [6%] had a grade â‰¥3 event). Local and systemic events were transient in nature (median duration 1Â·0-2Â·5 days). In the per-protocol immunogenicity population at day 217 (167 participants in group A, 101 participants in group B1, 101 participants in group B2), IgG geometric mean titres (GMT) had increased by 4Â·7-fold and MN(50) GMT by 4Â·1-fold for the ancestral SARS-CoV-2 strain compared with the day 35 titres. INTERPRETATION: Administration of a booster dose of NVX-CoV2373 resulted in an incremental increase in reactogenicity. For both the prototype strain and all variants evaluated, immune responses following the booster were similar to or higher than those associated with high levels of efficacy in phase 3 studies of the vaccine. These data support the use of NVX-CoV2373 in booster programmes. FUNDING: Novavax and the Coalition for Epidemic Preparedness Innovations.

Association between household composition and severe COVID-19 outcomes in older people by ethnicity: an observational cohort study using the OpenSAFELY platform. BACKGROUND: Ethnic differences in the risk of severe COVID-19 may be linked to household composition. We quantified

the association between household composition and risk of severe COVID-19 by ethnicity for older individuals. METHODS: With the approval of NHS England, we analysed ethnic differences in the association between household composition and severe COVID-19 in people aged 67 or over in England. We defined households by number of age-based generations living together, and used multivariable Cox regression stratified by location and wave of the pandemic and accounted for age, sex, comorbidities, smoking, obesity, housing density and deprivation. We included 2â€Š692â€Š223 people over 67â€‰years in Wave 1 (1 February 2020-31 August 2020) and 2 731 427 in Wave 2 (1 September 2020-31 January 2021). RESULTS: Multigenerational living was associated with increased risk of severe COVID-19 for White and South Asian older people in both waves [e.g. Wave 2, 67+ living with three other generations vs 67+-year-olds only: White hazard ratio (HR) 1.61 95% CI 1.38-1.87, South Asian HR 1.76 95% CI 1.48-2.10], with a trend for increased risks of severe COVID-19 with increasing generations in Wave 2. There was also an increased risk of severe COVID-19 in Wave 1 associated with living alone for White (HR 1.35 95% CI 1.30-1.41), South Asian (HR 1.47 95% CI 1.18-1.84) and Other (HR 1.72 95% CI 0.99-2.97) ethnicities, an effect that persisted for White older people in Wave 2. CONCLUSIONS: Both multigenerational living and living alone were associated with severe COVID-19 in older adults. Older South Asian people are over-represented within multigenerational households in England, especially in the most deprived settings, whereas a substantial proportion of White older people live alone. The number of generations in a household, number of occupants, ethnicity and deprivation status are important considerations in the continued roll-out of COVID-19 vaccination and targeting of interventions for future pandemics.

Clinical and immunological data from chronic urticaria onset after mRNA SARS-CoV-2 vaccines.

Acute Cellular Rejection in A Kidney Transplant Recipient Following Vaccination with Inactivated SARS-CoV-2 Vaccine. SARS-CoV-2 vaccines are being administered worldwide. Most of the reported side effects are mild and self-limiting with few reported cases of severe adverse reactions. Here we report a case of acute cellular rejection in a kidney transplant recipient following vaccination with an inactivated SARS-CoV-2 vaccine. fifty- one years old man with autosomal dominant polycystic kidney disease, who had received a kidney transplantation from a living related donor, 3 years ago, presented with an impaired kidney function seven days after receiving the first dose of Sinovac's COVID-19 vaccine. Kidney transplant biopsy revealed acute cellular rejection. The allograft function completely recovered after treatment with steroids. The analysis and investigation of the complications and adverse reactions induced by anti-COVID-19 vaccines, could increase our understanding of the underlying pathogenesis. Â DOI: 10.52547/ijkd.6915.

Efficacy of SinopharmÂ® COVID-19 Vaccine in Hemodialysis Patients: A Preliminary Report. INTRODUCTION: SARS-CoV-2 infection have been reported to have a greater mortality rate in adults receiving dialysis, as compared to general population. Hence, vaccination is very important in this vulnerable population group, in order to achieve an acceptable level of immunity. The aim of this study was to compare the level of anti-SARS-CoV-2 anti-spike protein receptor-binding domain IgG neutralizing antibody before and after vaccination with two doses of SinopharmÂ® vaccine, in patients undergoing hemodialysis. METHODS: Ninety patients on maintenance in-center hemodialysis received two doses of SinopharmÂ® COVID-19 vaccine with an interval of about 28 days. Anti-SARS-CoV-2 anti-spike protein receptor-binding domain IgG (Anti-RBD) neutralizing antibody was measured with an ELISA kit. All statistical analyses were performed by SPSS-26 software. RESULTS: The absolute mean (Â± SE) change in antibody titer following full-scheduled vaccination was 8.98 Â± 1.49 Âµg/mL. The rate of seroconversion was 31.1% after two doses of vaccine. In addition, the rate of seroconversion was higher in those with a history of COVID-19 than in those without a history of COVID-19. CONCLUSION: The administration of booster doses, doubling of the dose in each episode

of vaccination schedule as well as combination of different vaccine platforms are recommended to increase COVID-19 vaccine efficacy in hemodialysis patients. Â DOI: 10.52547/ijkd.7024.

Acute small fiber neuropathy after Oxford-AstraZeneca ChAdOx1-S vaccination: A report of three cases and review of the literature. Small fiber neuropathy usually presents with gradual and progressive chronic length-dependent pain. Acute small fiber neuropathy is rarely reported. Three patients with acute onset neuropathic pain after Oxford-AstraZeneca ChAdOx1-S vaccination are described. Two patients were identified at the Oxford University NHS Foundation Trust, Oxford, UK and one patient in Red de Salud UC Christus, Santiago, Chile. All patients underwent a clinical assessment that included a detailed neurological examination, laboratory investigations, nerve conduction studies, thermal threshold testing, and skin biopsy for intra-epidermal nerve fiber density. Patients seen in Oxford underwent MRI of the brain and spinal cord. Cerebrospinal analysis was not performed. Neuropathic symptoms (burning pain, dysaesthesias) developed in the hands and feet within 2â€‰weeks of vaccination. On clinical examination, there was pinprick and thermal hyposensitivity in the area of neuropathic pain. Laboratory investigation, nerve conduction tests, sympathetic skin responses, and MRI showed no relevant abnormalities. Thermal thresholds were abnormal and intra-epidermal nerve fiber density in the lower leg was reduced. In two cases symptoms persist after several months. Three cases of definite acute small fiber neuropathy after Oxford-AstraZeneca ChAdOx1-S vaccination are described. At follow up, neuropathic pain was present in two of the patients.

Erythema multiforme-like reaction following COVID-19 vaccination.

Medium-term impact of the SARS-CoV-2 mRNA vaccine against disease activity in patients with systemic lupus erythematosus. OBJECTIVES: Numerous case reports have referred to new onset or flare of SLE after SARS-CoV-2 messenger RNA (mRNA) vaccines. Several observational studies showed that the short-term flare rate of SLE after SARS-CoV-2 vaccination is low. However, well-controlled clinical surveys are unavailable and the medium-term impact of the SARS-CoV-2 mRNA vaccines against the flare of SLE is uncertain. Therefore, we aimed to analyse the association between vaccination and medium-term subjective and objective disease activities of SLE and flares using matched pair methods. METHODS: Altogether, 150 patients with SLE from the Kyoto Lupus Cohort were included. Patients who received two doses of the SARS-CoV-2 mRNA vaccines were 1:1 matched with unvaccinated patients based on the first vaccination date. The outcome measures were the SLE Disease Activity Index-2000 (SLEDAI-2K), the Japanese version of the SLE Symptom Checklist Questionnaire (SSC-J) and the Safety of Estrogens in Lupus Erythematosus National Assessment-SLEDAI flare index at 30, 60 and 90 days after vaccination. RESULTS: SLEDAI-2K levels were not significantly different in vaccinated and unvaccinated patients with SLE at 30, 60 and 90 days after the second vaccination (adjusted estimate (95% CI): 30 days: -0.46 (-1.48 to 0.56), p=0.39; 60 days: 0.38 (-0.64 to 1.40), p=0.47; 90 days: 0.40 (-0.54 to 1.34), p=0.41). Similar results were observed in the SSC-J score (adjusted estimate (95% CI), 30 days: 0.05 (-1.46 to 1.56), p=0.95; 60 days: -0.63 (-2.08 to 0.82), p=0.40; 90 days: 0.27 (-1.04 to 1.58), p=0.69) and flare index (adjusted OR (95% CI), 30 days: 0.81 (0.36 to 1.85), p=0.62; 60 days: 1.13 (0.50 to 2.54), p=0.77; 90 days: 0.85 (0.32 to 2.26), p=0.74). CONCLUSION: SARS-CoV-2 vaccination did not significantly influence the medium-term subjective and objective disease activities or flares of SLE until 90 days after the second vaccination.

Prevalence and factors associated with not receiving the booster dose of the COVID-19 vaccine in adults in Latin America and the Caribbean. BACKGROUND: Booster doses have been described as effective in reducing hospitalizations and deaths from the new variants. However, its coverage is heterogeneous in Latin America and the Caribbean (LAC), one of the regions most affected by the pandemic. We aimed to assess the factors associated with not receiving a coronavirus disease 2019 (COVID-19) vaccine booster dose in adults from LAC. METHODS: We analyzed a secondary database

compiled by the University of Maryland and Facebook assessing the global impact of COVID-19. We included Facebook users over 18 years of age who resided in LAC and responded to the survey between February 13, 2022, and March 14, 2022. We evaluated sociodemographic characteristics, comorbidities, food, and economic insecurity, mental health, and vaccination-related practices. We calculated crude (cPR) and adjusted (aPR) prevalence ratios with their respective 95% confidence intervals (95%CI). RESULTS: The sample included 154,841 adults from 20 LAC countries. 33.7% (nÂ =Â 46,459) reported not receiving the COVID-19 booster vaccine. Being under 75 years old, having a college, high school, pre-university, primary, or lower education, having no or 1 to 2 comorbidities, living in a town, having food insecurity, depressive symptoms, and having had COVID-19, were associated with a higher prevalence of not receiving the booster dose. In contrast, being female or non-binary and having anxiety symptoms were associated with a lower prevalence of not receiving the booster dose. CONCLUSIONS: Approximately three out of 10 adults surveyed in LAC reported not having received the booster vaccine. Authorities must design campaigns that promote receiving a booster dose considering the factors found.

Incidence and Clinical Characteristics of Severe Acute Respiratory Syndrome Coronavirus 2 Infection After Vaccination in Children. The objective of this single-center cohort study was to characterize the frequency, clinical characteristics, and molecular epidemiology of pediatric severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection after vaccination. Between May 15, 2021, and January 1, 2022, 171 children experienced SARS-CoV-2 infection postvaccination, 146 (86%) following the Omicron variant predominance. Outcomes were generally mild and comparable before and after Omicron predominance.

COVID-19 vaccination in people with multiple sclerosis, real-life experience. BACKGROUND: Vaccination against the severe acute respiratory syndrome coronavirus type-2 (SARS-CoV-2) virus is recommended in multiple sclerosis (MS) to reduce the risk of complications from Coronavirus disease 2019 (COVID-19) infection. These vaccines were not investigated in people with MS (PWMS). OBJECTIVE: This study aimed to report the short-term safety of the COVID-19 vaccines among PWMS. METHODS: Pfizer-BioNTech mRNA (BNT162b2) vaccine and Oxford-Astra Zenecaa chimpanzee adenovirus-vectored (ChAdOx1 nCoV-19) vaccine have been approved to be used in Kuwait since December 2021. PWMS registered in Kuwait national registry were contacted by phone, WhatsApp, or through face-to-face interviews and were invited to complete our questionnaire. Demographic, clinical data, symptoms following the vaccine, worsening of pre-existing MS symptoms, and occurrence of relapse were recorded. RESULTS: Of the 820 PWMS, 647 completed the questionnaire. Between January 2021 and 31 August 2021, 383 (59.28%) PWMS received at least one dose of the approved vaccinations versus 63.4% of the general population on the same date. Their mean age was 36.82Â +Â 8.80, and most of them, 247 (64.3%), were females. A total of 356 vaccinated cohorts (92.6%) were treated with disease-modifying therapies. Adverse events were reported by 261 (68.15%) subjects. One case of COVID-19 infection was encountered after the first dose of the BNT162b2 vaccine. Twenty-one (5.48%) cases reported worsening of pre-existing MS symptoms after the vaccine. Five patients (1.31%) reported relapse after the COVID-19 vaccine. The most common adverse events of the COVID-19 vaccine were pain at the injection site, fatigue, low-grade fever, and body ache; and resolved within one week. There was no significant association between use of disease modifying therapy (DMT) and COVID-19 vaccine adverse events. CONCLUSION: BNT162b2 and ChAdOx1 nCoV-19 are safe for PWMS. No increased risk of relapse activity or worsening of pre-existing MS symptoms.

Secondary Syphilis, Urticarial Eruption, and COVID-19 Vaccination.

Evaluation and comparison of post-vaccination adverse effects among Janssen and Oxford-AstraZeneca vaccinated adult individuals in Debre Tabor Town: A cross- sectional survey in Northwest

Ethiopia. COVID 19 vaccination has recently been launched globally to halt the pandemic. But COVID 19 vaccines have some adverse effects that raise concerns in the global community. This study aimed to evaluate and compare the adverse effects of Janssen and Oxford-AstraZeneca vaccinated adults. A community-based cross-sectional study was conducted from March 15 to 30, 2022 among 421 (211 Janssen and 210 Astra Zeneca vaccinated) adults recruited by a convenience sampling technique in Debre Tabor Town, Northwest Ethiopia. Data were collected via face-to-face interviews and by reviewing the immunization card. Chi-square test, independent t-test, and Mann-Whitney test were used to compare the adverse symptoms and related parameters between the two vaccines. A linear regression model was also used to identify predictors of the number of post-vaccination symptoms. The majority (75.8%) of participants reported at least one side effect after vaccination. Adverse symptoms had a significantly greater occurrence (pâ€‰<â€‰.05) among recipients of the AstraZeneca vaccine (84.8%) than receivers of the Janssen vaccine (66.8%). The main adverse symptoms were injection site pain, fever, fatigue, arthralgia, and myalgia in both vaccines. Significant variations (pâ€‰<â€‰.05) between the receipts of the two vaccines were shown in injection site pain, fever, and arthralgia. The total number of symptoms was significantly higher (pâ€‰<â€‰.05) in participants with female sex, younger age, BMI <25â€‰kg/m2, no prior COVID 19, and those who had received AstraZeneca vaccine. Thus, the authors advise that they should receive vaccines with no hesitation, while continuous tracking of vaccine safety is kept in place.

Safety and immunogenicity of the first Kazakh inactivated vaccine for COVID-19. This article describes the results of a preclinical safety and immunogenicity study of QazCovid-inÂ®, the first COVID-19 vaccine developed in Kazakhstan, on BALB/c mice, rats, ferrets, Syrian hamsters and rhesus macaques (Macaca mulatta). The study's safety data suggests that this immunobiological preparation can be technically considered a Class 5 nontoxic vaccine. The series of injections that were made did not produce any adverse effect or any change in the general condition of the model animals' health, while macroscopy and histology studies identified no changes in the internal organs of the BALB/c mice and rats. This study has demonstrated that a double immunization enhances the growth of antibody titers as assessed by the microneutralization assay (MNA) and the enzyme-linked immunosorbent assay (ELISA) in a pre-clinical immunogenicity test on animal models. The best GMT results were assessed in MNA and ELISA 7â€‰days after re-vaccination; however, we noted that GMT antibody results in ELISA were lower than in MNA. A comparative GMT assessment after the first immunization and the re-immunization identified significant differences between model animal groups and a growth of GMT antibodies in all of them; also, differences between the gender groups were statistically significant. Moreover, the most marked MNA immune response to the QazCovid-inÂ® vaccine was seen in the Syrian hamsters, while their SARS-CoV-2-specific antibody activity as assessed with ELISA was the lowest.

Tolerability of COVID-19 Infection and Messenger RNA Vaccination Among Patients With a History of Kawasaki Disease. IMPORTANCE: Kawasaki disease (KD) symptoms significantly overlap with multisystem inflammatory syndrome in children due to COVID-19. Patients with KD may be at risk for adverse outcomes from exposure to SARS-CoV-2 infection or vaccination. OBJECTIVE: To describe the outcomes of patients with KD to SARS-CoV-2 infection or vaccination. DESIGN, SETTING, AND PARTICIPANTS: This case series evaluated 2 cohorts using an existing KD database and reviewed individual electronic medical records for the period spanning January 1, 2020, through January 31, 2022, via electronic medical records that include Washington state immunization records. Vaccine cohort inclusion criteria consisted of being 21 years or younger at immunization and receiving 1 or more BNT162b2 (Pfizer-BioNTech) or messenger RNA (mRNA)-1273 (Moderna) vaccine doses. The COVID-19 cohort included patients 21 years or younger with positive polymerase chain reaction or nuclear capsid IgG findings for SARS-CoV-2. Participants included 826 patients from a preexisting KD

database. One hundred fifty-three patients received at least 1 BNT162b2 or mRNA-1273 vaccine dose and were included in the mRNA vaccine cohort. Thirty-seven patients had positive test results for SARS-CoV-2 and were included in the COVID-19 cohort. EXPOSURES: SARS-CoV-2 vaccination and/or infection. MAIN OUTCOMES AND MEASURES: Adverse events after mRNA vaccination and/or COVID-19, including clinician visits, emergency department encounters, or hospitalizations. RESULTS: Among the 153 patients included in the mRNA vaccination cohort (mean [SD] age, 13.0 [4.3] years; 94 male [61.4%]), the BNT162b2 vaccine was provided for 143 (93.5%), and the remaining 10 (6.5%) received mRNA-1273 or a combination of both. Among patients in the vaccine cohort, 129 (84.3%) were fully vaccinated or received a third-dose booster. No clinically severe adverse events occurred, and there were no reports of vaccine-related hospitalizations or outpatient visits. The COVID-19 cohort included 37 patients (mean [SD] age, 11.0 [5.5] years; 22 male [59.5%]). No patients required hospitalization due to COVID-19. The most common symptoms included low-grade fever, fatigue, cough, and myalgia with resolution within a few days. Two patients, aged 9 and 19 years, had extended cough and fatigue for 3 to 4 weeks. One patient developed COVID-19 within 6 weeks of receiving intravenous immunoglobulin for KD. CONCLUSIONS AND RELEVANCE: These findings suggest that the mRNA vaccines may be safe and COVID-19 may not be severe for patients with a history of KD.

Pemphigus vulgaris following second dose of mRNA-(Pfizer-BioNTech) COVID-19 vaccine.

[Investigation of Humoral and Cellular Immunity in TOBB ETÃœ Hospital Workers After Three Doses of CoronaVac Vaccination and after One Dose of Comirnaty Vaccination Following Two Doses of CoronaVac]. The Coronavirus disease 2019 (COVID-19) pandemic still continues around the world by making peaks with different variants. In the fight against COVID-19, vaccination is currently the only protective measure. In Turkey, vaccination started firstly in healthcare workers on 13 January 2021 with the CoronaVac (Sinovac Biotech, Chinese) vaccine, and booster doses were administered with the CoronaVac and Comirnaty vaccines in July 2021. In this cross-sectional study, it was aimed to determine the humoral and cellular immunity levels of the employees of the TOBB ETU Hospital 2.5-3.5 months after three doses of vaccination and identify the effective factors. With the power analysis that was conducted with the G*Power software, it was determined to be suitable to include 40 TOBB ETU Hospital workers who had their third dose with the CoronaVac vaccine and 60 workers of the same hospital who had their third dose with the Comirnaty (Pfizer Biontech, Germany) vaccine, and age- and sex-matching was considered by selecting 60 workers randomly from among 223 workers who had Comirnaty as their third dose. The study excluded individuals who had a previous COVID-19 infection or had a positive PCR test result. After collecting blood samples on 18-22 October 2021, severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) immunoglobulin G levels were studied with the chemiluminescence immunoassay method using a Beckman-Access device (Beckman Coulter Inc., CA, USA) for humoral immunity, and T-SPOT test (T-SPOT. COVID SARS-CoV-2 test-Oxford Immunotec, Singapur) was carried out for cellular immunity. Additionally, demographic data, habits, personal information such as weight and height, reasons for choosing the vaccine and post-vaccine side effects were obtained through the data collection form. Data collection was completed on 29 November 2021. As a result, among the healthcare workers who had received their third dose of vaccine with Comirnaty and CoronaVac; while 25% of those who received three doses of CoronaVac had humoral immunity, 93.3% humoral immunity was determined in the heterogeneous vaccine group with two doses of CoronaVac and one dose of Comirnaty vaccine ($p<0.05$). Cellular immunity was found to be higher (88.3%, 70%) in those who received the heterologous vaccine than those who completed three doses of the same vaccine ($p<0.05$). In the heterogeneous vaccination group consisting of the healthcare workers who had their third vaccine dose with Comirnaty and those who had it with CoronaVac, humoral and cellular immunity levels were found high. Among the participants whose humoral immunity was found negative, cellular immunity was present in 75% of those who

had Comirnaty as their third dose and 63.3% of those who had CoronaVac. While no significant relationship was found between immunity levels and age, sex or body mass index (BMI), the levels of both forms of immunity were lower in those who had chronic diseases. Among the participants, physicians preferred the third dose of Comirnaty vaccine at a rate of 71.4% and laboratory workers preferred this vaccine at a rate of 80% according to the workplace. In the third dose vaccine preference reasons, it was stated that 55% would continue with the same vaccine, experience fewer side effects, 44% provide more immunity and 9% do not prevent going abroad. The incidence of side effects after the third dose of vaccine was 53% higher in those who received the Comirnaty vaccine than in those who received CoronaVac (35%). Based on these data, it was concluded that heterologous vaccination should be preferred in vaccination strategies, and knowing cellular immunity levels is important for the decision. There is a need for more comprehensive and follow-up studies on how long humoral and especially cellular immunity lasts.

Impact of Seasonal Coronavirus Antibodies on Severe Acute Respiratory Syndrome Coronavirus 2 Vaccine Responses in Solid Organ Transplant Recipients. Antibody responses to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination are reduced in solid organ transplant recipients (SOTRs). We report that increased levels of preexisting antibodies to seasonal coronaviruses are associated with decreased antibody response to SARS-CoV-2 vaccination in SOTRs, supporting that antigenic imprinting modulates vaccine responses in SOTRs.

De novo posttransplant membranous nephropathy following BNT162b2 mRNA COVID-19 vaccine in a kidney transplant recipient.

A prospective multicenter study on cutaneous reactions reported after Sinopharm COVID-19 vaccination. BACKGROUND: The new coronavirus COVID-19 pandemic has had an unprecedented impact on global health and economic growth. A widely used vaccine is the weakened inactivated severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) virus (Sinopharm). Following major SARS-CoV-2 vaccination campaigns, cutaneous symptoms are on the rise. METHODS: This study is a prospective observational study evaluating cutaneous reactions and time of recovery after Sinopharm vaccination. The cases involved were over the age of 18. The data were anonymized. On the registry's vaccine section, we tracked vaccination dates, skin reactions, and recovery times. All respondents who reported only a cutaneous reaction to the first vaccination dose received a follow-up contact asking about a second vaccination dose cutaneous reaction. RESULTS: The study included 4560 cases. The mean age of all studied cases was 41.2â€‰Â±â€‰6.1â€‰years. There were dermatologic complications in 1190 patients (26.1%). There was induration at the injection site in 495 patients (10.9%), urticaria in 210 patients (4.6%), morbilliform eruption in 375 patients (8.2%), flare of skin site in 105 patients (2.3%), and angioedema in 105 patients (2.3%). The mean recovery days in all studied patients were 2.92â€‰Â±â€‰0.94â€‰days with a minimum recovery period of 2â€‰days and a maximum of 7â€‰days. CONCLUSIONS: Because Sinopharm's cutaneous reactions are frequently mild and self-limiting, vaccination should not be discouraged based on these findings. If the first vaccine dose creates a cutaneous reaction, there is no need to skip the second dose.

COVID-19 Vaccine-Related Arthritis: A Descriptive Study of Case Reports on a Rare Complication. Large-scale coronavirus disease 2019 (COVID-19) vaccination programs have been rolled out worldwide. Vaccines that are widely used globally include mRNA vaccines, adenoviral vector vaccines, and inactivated whole-virus vaccines. COVID-19 vaccines can lead to varying side effects. Among the most common of these adverse effects are pain at the injection site, fatigue, and headaches. Some side effects, however, are not very well documented, and these include joint-related adverse effects. In this review, we assess the epidemiology and clinical features of post-COVID-19 vaccination joint-related adverse effects based on the analysis of 16 patient case reports. Based on our analysis, we found that females formed the majority of the cases, accounting for 62.5% of patients, while 37.5% of

the cases wereÂ males. The mean age of presentation among the patients was 54.8 years, with a standard deviation (SD) of 17.49 years. In 37.5% of the cases, patients received the Sinovac vaccine. The proportion of patients who received other vaccines was as follows: the Pfizer vaccine: 31.25%; Sputnik V:Â 12.5%; Moderna, AstraZeneca, and Covaxin: 6.25% each. The characteristics ofÂ joint-related adverse effects following COVID-19 vaccination were analyzed in this study. We identified several key findings related to factors such as age, gender, type of vaccine, clinical features, and diagnosis modality. Our analysis showed that more cases were reported among individuals who received the Sinovac vaccine, as compared to the others. Further research is required to examine the underlying cause of this association.

Optimal health and economic impact of non-pharmaceutical intervention measures prior and post vaccination in England: a mathematical modelling study. Background. Even with good progress on vaccination, SARS-CoV-2 infections in the UK may continue to impose a high burden of disease and therefore pose substantial challenges for health policy decision makers. Stringent government-mandated physical distancing measures (lockdown) have been demonstrated to be epidemiologically effective, but can have both positive and negative economic consequences. The duration and frequency of any intervention policy could, in theory, be optimized to maximize economic benefits while achieving substantial reductions in disease. Methods. Here, we use a pre-existing SARS-CoV-2 transmission model to assess the health and economic implications of different strengths of control through time in order to identify optimal approaches to non-pharmaceutical intervention stringency in the UK, considering the role of vaccination in reducing the need for future physical distancing measures. The model is calibrated to the COVID-19 epidemic in England and we carry out retrospective analysis of the optimal timing of precautionary breaks in 2020 and the optimal relaxation policy from the January 2021 lockdown, considering the willingness to pay (WTP) for health improvement. Results. We find that the precise timing and intensity of interventions is highly dependent upon the objective of control. As intervention measures are relaxed, we predict a resurgence in cases, but the optimal intervention policy can be established dependent upon the WTP per quality adjusted life year loss avoided. Our results show that establishing an optimal level of control can result in a reduction in net monetary loss of billions of pounds, dependent upon the precise WTP value. Conclusion. It is vital, as the UK emerges from lockdown, but continues to face an on-going pandemic, to accurately establish the overall health and economic costs when making policy decisions. We demonstrate how some of these can be quantified, employing mechanistic infectious disease transmission models to establish optimal levels of control for the ongoing COVID-19 pandemic.

Menstrual irregularities following COVID-19 vaccination: A global cross-sectional survey. INTRODUCTION: The coronavirus disease 2019 (COVID-19) vaccination generates protective immunity against SARS-CoV-2 infection. There is no clear evidence of COVID-19 vaccine-induced menstrual irregularities. OBJECTIVE: To identify potential menstrual irregularities following COVID-19 vaccine among females. METHODS: A worldwide cross-sectional survey study was conducted from June 10, 2021, to July 10, 2021 using online mediums. The survey consisted of 15 questions divided into baseline characteristics, vaccination status and dosage, menstruation and relate factors, and thoughts and knowledge about menstrual irregularities. Non-probability convenience sampling method was used including 510 responses. The results were tabulated, with bivariate analysis and chi-square test results. The sensitivity and specificity test of factors associated to knowledge about menstrual irregularities post COVID-19 vaccination were analyzed by receiver operating characteristic analysis. RESULTS: The associations between healthcare worker (HCW) status and perceptions (Ï‡2â€¯=â€¯10.422; pâ€¯=â€¯0.064), and knowledge about menstrual irregularities post-vaccination (Ï‡2â€¯=â€¯1.966; pâ€¯=â€¯0.161) were found. Vaccinated compared to non-vaccinated women had

a higher risk of change in inter-cycle length between periods (ORâ€¯=â€¯3.172; 95% Câ€¯=â€¯0.470-21.431). Of 314 HCW vs. 196 non-HCW, 60 (19.1%) vs. 28 (14.3%) were knowledgeable about menstrual irregularities (ORâ€¯=â€¯1.338, 95% Câ€¯=â€¯0.886-2.019 vs. ORâ€¯=â€¯0.944; 95% Câ€¯=â€¯0.873-1.021). On asking the HCW vs. non-HCW about perceptions of COVID-19 vaccine-induced menstrual irregularities, 24 (7.6%) vs. 9 (4.6%) agreed, 139 (44.3%) vs. 67 (34.2%) disagreed, and 151 (48.1%) vs. 120 (61.2%) did not know or chose not applicable. CONCLUSION: There is a gap in the current understanding of menstrual irregularities, even if temporary, following COVID-19 vaccination that requires further exploration. Misinformation may also be the culprit for the observed proportion of women that noticed changes in their menstrual periods after COVID-19 vaccination.

Optic neuritis following COVID-19 vaccination: Do autoimmune diseases play a role? PURPOSE AND CONTEXT: We report two cases of optic neuritis following Pfizer-BioNTech COVID-19 vaccination in patients with autoimmune diseases. Post-vaccine optic neuritis, although rare, is reported in the literature and an autoimmune mechanism seems to be involved, especially in genetically predisposed subjects. METHOD: Report of two cases of optic neuritis following COVID-19 vaccination in patients with autoimmune diseases. KEY RESULTS: He novelty of this article is the fact that the two patients had a medical history of autoimmune diseases (Hashimoto thyroiditis and ankylosing spondylitis), a point of interest for research because it is not yet clear whether this could constitute a risk factor for adverse events after vaccination. CONCLUSIONS: The reactogenicity of COVID-19 mRNA vaccine in individuals suffering from immune-mediated diseases is yet to be elucidated and it is being increasingly investigated. Our paper supports the hypothesis that patients who are already affected or predisposed to autoimmune or autoinflammatory disorders should be carefully evaluated for the benefits and risks of COVID-19 mRNA vaccination.

Clinical Characteristics of Patients with Myocarditis following COVID-19 mRNA Vaccination: A Systematic Review and Meta-Analysis. COVID-19 mRNA vaccinations have recently been implicated in causing myocarditis. Therefore, the primary aim of this systematic review and meta-analysis was to investigate the clinical characteristics of patients with myocarditis following mRNA vaccination. The secondary aims were to report common imaging and laboratory findings, as well as treatment regimes, in these patients. A literature search was performed from December 2019 to June 2022. Eligible studies reported patients older than 18 years vaccinated with mRNA, a diagnosis of myocarditis, and subsequent outcomes. Pooled mean or proportion were analyzed using a random-effects model. Seventy-five unique studies (patient n = 188, 89.4% male, mean age 18-67 years) were included. Eighty-six patients had Moderna vaccines while one hundred and two patients had Pfizer-BioNTech vaccines. The most common presenting symptoms were chest pain (34.5%), fever (17.1%), myalgia (12.4%), and chills (12.1%). The most common radiologic findings were ST-related changes on an electrocardiogram (58.7%) and hypokinesia on cardiac magnetic resonance imaging or echocardiography (50.7%). Laboratory findings included elevated Troponin I levels (81.7%) and elevated C-reactive protein (71.5%). Seven patients were admitted to the intensive care unit. The most common treatment modality was non-steroid anti-inflammatory drugs (36.6%) followed by colchicine (28.5%). This meta-analysis presents novel evidence to suggest possible myocarditis post mRNA vaccination in certain individuals, especially young male patients. Clinical practice must therefore take appropriate pre-cautionary measures when administrating COVID-19 mRNA vaccinations.

Characteristics and Clinical Ocular Manifestations in Patients with Acute Corneal Graft Rejection after Receiving the COVID-19 Vaccine: A Systematic Review. This study aimed to determine the characteristics and clinical ocular manifestations of acute corneal graft rejection after coronavirus disease 2019 (COVID-19) vaccination. We conducted an online search of the PubMed and EMBASE databases. Data on recipients' characteristics, corneal transplantation types, interval between

vaccination and allograft rejection, clinical manifestations, and graft rejection medication were extracted. Thirteen articles on 21 patients (23 eyes) with acute corneal graft rejection after COVID-19 vaccination, published between April and December 2021, were included. The median (interquartile range) age at the onset of rejection was 68 (27-83) years. Types of transplantation included penetrating keratoplasty (12 eyes), Descemet membrane endothelial keratoplasty (six eyes), Descemet stripping automated endothelial keratoplasty (four eyes), and living-related conjunctival-limbal allograft (one eye). The interval between vaccination and rejection ranged from 1 day to 6 weeks. Corneal edema was the leading clinical manifestation (20 eyes), followed by keratic precipitates (14 eyes) and conjunctival or ciliary injection (14 eyes). Medications included frequently applied topical corticosteroids (12 eyes), followed by a combination of topical and oral corticosteroids (four eyes). In addition, the clinical characteristics of corneal allograft rejection after COVID-19 vaccination were identified. Corneal transplant recipients may require further vaccination, necessitating appropriate management and treatment.

Focus on High School: Factors Associated with Creating Harmony between the Educational Transition and Adolescents' Well-Being. The transition from online to on-site education was difficult due to a lack of standardized school guidance for school reopening. Even though schools have reopened, uncertainty about the COVID-19 situation and the capacity of the school to maintain safe school operations to mitigate risks may increase hesitancy among students and parents to participate in on-site studying. Rapid-response surveys of students and parents can provide information to stakeholders on how learning and well-being can best be supported during the educational transition in each context. The aim of this study was to explore the hesitancy of high-school students and the factors that influenced their hesitancy to return to school on site. An online cross-sectional survey was distributed to high-school students in an urban district of Chiang Mai, Thailand, during the fourth wave of the pandemic from 17 November to 13 December 2021. A multivariable logistic regression was performed to explore factors related to the students' hesitancy to attend on-site education. With a response rate of 10.2% of the targeted study population, the 1266 participants revealed that 15.9% of them had very-high- and extremely high-level hesitancy to study on site, which was associated with less negative moods while studying online (aOR, 1.69; p, 0.016) and a greater fear of infection after returning to school (aOR, 2.95; p, 0.001). Increased readiness to return to school on site (aOR, 0.28; p, 0.001) and discussing COVID-19 prevention with family or friends (aOR, 0.71; p, 0.016) were also associated with a lower hesitancy of students. Only 5.6% of the students reported being hesitant to receive the COVID-19 vaccination. However, no significant associations were found between schooling hesitancy and their willingness to get vaccinated, nor the frequency of students' outside activities. High-school students who experience negative moods during online studying should be monitored and receive additional support if the reopening is postponed. More opportunities to discuss COVID-19 prevention with family or friends, as well as a higher level of readiness, may increase the willingness to return to school on site. Local authorities and schools need to strengthen communication and coordination mechanisms to reduce parents' and students' schooling hesitancy by providing explicit information about the COVID-19 situation and risk-mitigation measures, along with normalizing messages about fear and anxiety.

Clinical Post-SARS-CoV-2 Infection Scenarios in Vaccinated and Non-Vaccinated Cancer Patients in Three German Cancer Centers: A Retrospective Analysis. COVID-19 vaccines have become an integral element in the protection of cancer patients against SARS-CoV-2. To date, there are no direct comparisons of the course of COVID-19 infection in cancer patients between the pre- and post-vaccine era. We analyzed SARS-CoV-2 infections and their impact on cancer in COVID-19 vaccinated and non-vaccinated patients from three German cancer centers. Overall, 133 patients with SARS-CoV-2 were enrolled in pre- and post-vaccine eras: 84 non-vaccinated and 49 vaccinated, respectively. A

mild course of COVID-19 was documented more frequently in vaccinated patients (49% vs. 29%), while the frequency of severe and critical courses occurred in approximately one-half of the non-vaccinated patients (22% vs. 42%, p = 0.023). Particularly, patients with hematologic neoplasms benefited from vaccination in this context (p = 0.031). Admissions to intermediate- and intensive-care units and the necessity of non-invasive and invasive respiratory support were reduced by 71% and 50% among vaccinated patients, respectively. The median length of admission was 11 days for non-vaccinated and 5 days for vaccinated patients (p = 0.002). COVID-19 mortality was reduced by 83% in vaccinated patients (p = 0.046). Finally, the median time from SARS-CoV-2 infection to restarting cancer therapy was 12 and 26 days among vaccinated and non-vaccinated groups, respectively (p = 0.002). Although this study does not have enough power to perform multivariate analyses to account for confounders, it provides data on COVID-19 in non-vaccinated and vaccinated cancer patients and illustrates the potential benefits of COVID-19 vaccines for these patients.

SARS-CoV-2 vaccine safe for young patients.

Pfizer SARS-CoV-2 BNT162b2 mRNA vaccination (BNT162b2) has no adverse effect on elective oocyte cryopreservation outcomes. RESEARCH QUESTION: Do elective oocyte cryopreservation outcomes in women 1-13 months after SARS-CoV-2 vaccination alter compared with unvaccinated women and do different time intervals between vaccination and ovarian stimulation impact these outcomes? DESIGN: This retrospective cohort study, conducted in a university-affiliated IVF centre, included 232 elective oocyte cryopreservation cycles of vaccinated and unvaccinated patients, without previous infection with the SARS-CoV-2 virus, between December 2020 and January 2022. Two control groups - pre-pandemic (January 2019 to February 2020) and intra-pandemic (December 2020 to January 2022) unvaccinated groups - were compared with the vaccinated group, further divided into four subgroups (under 3, 3-6, 6-9 and 9-13 months). The primary outcome was the elective oocyte cryopreservation cycle outcomes - number of retrieved and number of mature oocytes. RESULTS: The vaccinated group demonstrated comparable outcomes with regards to number of retrieved and mature oocytes compared with the pre-pandemic and intra-pandemic unvaccinated groups (12.6Â Â±Â 8.0 versus 13.0Â Â±Â 8.2 and 12.5Â Â±Â 7.4 retrieved and 10.1Â Â±Â 6.9 versus 9.5Â Â±Â 6.4 and 10.1Â Â±Â 6.3 mature oocytes, respectively; not significant for both). Similar results were noted in a comparison between the intra-pandemic unvaccinated group and the four vaccinated subgroups. No correlation was found between the parameter of days from vaccination and cycle outcomes. Similarly, analysis of covariance showed no association between vaccination status and timing and number of mature oocytes. CONCLUSIONS: The SARS-CoV-2 vaccination does not alter the outcomes of elective oocyte cryopreservation procedures. This is true even in a relatively long time interval of 9 to 13 months from vaccination.

Potential mechanisms of vaccine-induced thrombosis. Vaccine-induced immune thrombocytopenia and thrombosis (VITT) is a rare syndrome characterized by high-titer anti-platelet factor 4 (PF4) antibodies, thrombocytopenia and arterial and venous thrombosis in unusual sites, as cerebral venous sinuses and splanchnic veins. VITT has been described to occur almost exclusively after administration of ChAdOx1 nCoV-19 and Ad26.COV2.S adenovirus vector- based COVID-19 vaccines. Clinical and laboratory features of VITT resemble those of heparin-induced thrombocytopenia (HIT). It has been hypothesized that negatively charged polyadenylated hexone proteins of the AdV vectors could act as heparin to induce the conformational changes of PF4 molecule that lead to the formation of anti-PF4/polyanion antibodies. The anti-PF4 immune response in VITT is fostered by the presence of a proinflammatory milieu, elicited by some impurities found in ChAdOx1 nCoV-19 vaccine, as well as by soluble spike protein resulting from alternative splice events. Anti-PF4 antibodies bind PF4, forming immune complexes which activate platelets, monocytes and granulocytes, resulting in the VITT's immunothrombosis. The reason why only a tiny minority of

patents receiving AdV-based COVID-19 vaccines develop VITT is still unknown. It has been hypothesized that individual intrinsic factors, either acquired (i.e., pre-priming of B cells to produce anti-PF4 antibodies by previous contacts with bacteria or viruses) or inherited (i.e., differences in platelet T-cell ubiquitin ligand-2 [TULA-2] expression) can predispose a few subjects to develop VITT. A better knowledge of the mechanistic basis of VITT is essential to improve the safety and the effectiveness of future vaccines and gene therapies using adenovirus vectors.

Incidence and Risk Factors of Immediate Hypersensitivity Reactions and Immunization Stress-Related Responses With COVID-19 mRNA Vaccine. BACKGROUND: With the implementation of mass vaccination campaigns against COVID-19, the safety of vaccine needs to be evaluated. OBJECTIVE: We aimed to assess the incidence and risk factors for immediate hypersensitivity reactions (IHSR) and immunization stress-related responses (ISRR) with the Moderna COVID-19 vaccine. METHODS: This nested case-control study included recipients who received the Moderna vaccine at a mass vaccination center, Japan. Recipients with IHSR and ISRR were designated as cases 1 and 2, respectively. Controls 1 and 2 were selected from recipients without IHSR or ISRR and matched (1 case: 4 controls) with cases 1 and cases 2, respectively. Conditional logistic regression analysis was used to identify risk factors associated with IHSR and ISRR. RESULTS: Of the 614,151 vaccine recipients who received 1,201,688 vaccine doses, 306 recipients (cases 1) and 2478 recipients (cases 2) showed 318 events of IHSR and 2558 events of ISRR, respectively. The incidence rates per million doses were estimated as IHSR: 266 cases, ISRR: 2129 cases, anaphylaxis: 2 cases, and vasovagal syncope: 72 cases. Risk factors associated with IHSR included female, asthma, atopic dermatitis, thyroid diseases, and a history of allergy; for ISRR, the risk factors were younger age, female, asthma, thyroid diseases, mental disorders, and a history of allergy and vasovagal reflex. CONCLUSION: In the mass vaccination settings, the Moderna vaccine can be used safely owing to the low incidence rates of IHSR and anaphylaxis. However, providers should be aware of the occurrence of ISRR. Although recipients with risk factors are associated with slightly increased risks of IHSR and ISRR, this is not of sufficient magnitude to warrant special measures regarding their vaccination.

Vaccine-associated enhanced respiratory pathology in COVID-19 hamsters after T(H)2-biased immunization. Vaccine-associated enhanced respiratory disease (VAERD) is a severe complication for some respiratory infections. To investigate the potential for VAERD induction in coronavirus disease 2019 (COVID-19), we evaluate two vaccine leads utilizing a severe hamster infection model: a T helper type 1 (T(H)1)-biased measles vaccine-derived candidate and a T(H)2-biased alum-adjuvanted, non-stabilized spike protein. The measles virus (MeV)-derived vaccine protects the animals, but the protein lead induces VAERD, which can be alleviated by dexamethasone treatment. Bulk transcriptomic analysis reveals that our protein vaccine prepares enhanced host gene dysregulation in the lung, exclusively up-regulating mRNAs encoding the eosinophil attractant CCL-11, T(H)2-driving interleukin (IL)-19, or T(H)2 cytokines IL-4, IL-5, and IL-13. Single-cell RNA sequencing (scRNA-seq) identifies lung macrophages or lymphoid cells as sources, respectively. Our findings imply that VAERD is caused by the concerted action of hyperstimulated macrophages and T(H)2 cytokine-secreting lymphoid cells and potentially links VAERD to antibody-dependent enhancement (ADE). In summary, we identify the cytokine drivers and cellular contributors that mediate VAERD after T(H)2-biased vaccination.

Alopecia areata after COVID-19 infection and vaccination: A cross-sectional analysis.

Appearance of anti-MDA5 antibody-positive dermatomyositis after COVID-19 vaccination. The direct causes of dermatomyositis, a common autoimmune disease, have not yet been accurately identified, but several studies have linked this condition to various patient-associated and environmental factors, such as viral infections and area of residence. In the present report, we describe our experience with a patient presenting with anti-melanoma differentiation-associated

gene 5 (MDA5) antibody-positive dermatomyositis, which developed after vaccination against coronavirus disease 2019 (COVID-19). This patient was simultaneously diagnosed with anti-glutamic acid decarboxylase antibody-positive slowly progressive insulin-dependent diabetes (SPIDDM); her human leucocyte antigen test revealed that she expressed the DRB1*04:05 allele. This is important as this genotype is known to increase susceptibility to both anti-MDA5 antibody-positive dermatomyositis and type I diabetes. To the best of our knowledge, this is the first case of dermatomyositis complicated by SPIDDM identified after COVID-19 vaccination against COVID-19 and presenting with an underlying susceptible genotype. The patient's genetic predisposition may also be important for the development of autoimmune disease after COVID-19 vaccination.

Constrictive pericarditis following inactivated virus COVID-19 vaccine: a case report with review of the literature. Cardiac adverse effects of the COVID-19 vaccine are very rare, myocarditis and pericarditis are the most common amid them, and constrictive pericarditis (CP) is reported to be restricted to a few cases following mRNA COVID-19 vaccines. We report a case of a 72-year-old male patient who developed symptoms of right-sided heart failure, which started after 8 days of receiving the third dose of inactivated virus COVID-19 vaccine and his diagnostic tests comprising transthoracic echocardiography, chest CT scan, cardiac magnetic resonance were in favor of CP. Ultimately, invasive cardiac catheterization confirmed the diagnosis of CP. Due to the lack of satisfactory response to corticosteroid therapy, pericardiectomy was performed, which gave rise to symptom relief progressively and substantially. Considering the temporal course of the patient's symptoms and exclusion of other possible etiologies based on the patient's medical history and diagnostic evaluation, immunization with the COVID-19 vaccine was recognized as a culprit for developing CP. Despite being a scarce phenomenon, the COVID-19 vaccine could have a tendency to provoke pericardial inflammation in so far as causing CP. Hence, physicians should have a high index of suspicion in these circumstances and accelerate the diagnostic investigation.

Adverse reactions to mRNA coronavirus disease 2019 (COVID-19) vaccine for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in 576 medical staff. OBJECTIVES: Various measures have been taken to curb the COVID-19 epidemic, but their effect has been limited. Vaccines are expected to make a definite improvement. In Japan, vaccination began in February 2021. However, there are very few reports of adverse reactions to mRNA vaccines for the new coronavirus (SARS-CoV-2) in Japanese people. Therefore, adverse reactions in 576 vaccinated medical staff at the author's hospital were investigated. METHODS: The subjects were 576 medical staff who wished to receive the new coronavirus (SARS-CoV-2) vaccine. The first vaccination was performed with Pfizer's new coronavirus mRNA vaccine (commercial name: Comirnaty intramuscular injection) from March 8 to March 15, 2021. The second vaccination was performed from March 29 to April 5, 2021, at an interval of more than 21 days from the first vaccination. RESULTS: Adverse reactions were seen in six subjects in the first vaccination. There was dyspnea in one subject, arthralgia in one subject, fever/malaise in three subjects, and left axillary pain and lymphadenopathy in one subject. One subject had a reaction at the vaccination site that needed to be addressed. At the second vaccination, adverse reactions were observed in 64 subjects. There was fever in 58 subjects, malaise in 21 subjects, arthralgia in 12 subjects, aching pain in 11 subjects, headache in six subjects, chills in six subjects, nausea in three subjects, redness in two subjects, dizziness in two subjects, hives in two subjects, swelling in two subjects, cough in one subject, and itching in one subject (some had multiple adverse reactions). Fever was observed in the range of body temperature from 37.4 to 38.9 degrees. CONCLUSIONS: Most of the adverse reactions to the COVID-19 vaccine were mild, and no serious anaphylaxis was observed. Vaccination was considered perfectly feasible if attention is paid to adverse reactions.

Unprovoked Submassive Saddle Pulmonary Embolism in an Adult Male After Pfizer COVID-19 Vaccination. Pulmonary emboli (PEs) occur when the pulmonary artery is blocked by foreign

material. In one such instance, this foreign material can beÂ a blood clot that may occur fromÂ patient risk factors inducing a prothrombotic state. The relationship between COVID-19 vaccines and a prothrombotic state is novel and changing as our understanding of the relationship between the two evolves. The patient in this case study presented with unrelenting and progressive dyspnea, tachycardia, and unilateral lower extremity swelling two days after receiving the second dose of the Pfizer COVID-19 vaccine. After diagnostic testing, the patient was found to have a submassive saddle pulmonary embolism with subsequent right heart strain. This patient was treated with appropriate anticoagulation therapies, including heparin and apixaban, as well as thrombectomy, and made a complete recovery. The possible relationship between COVID-19 vaccines and thrombotic events supports the need for increased awareness of a potential new risk factor behind the development of PE. It is our hope that this case report will help raiseÂ awareness of an association despite the lack of incident data at this time.

Immune thrombocytopenic purpura induced by the COVID-19 vaccine after the second dose in a 78-year-old patient: A case report. Coronavirus disease 2019 (COVID-19) has become a global pandemic, but treatment options remain limited. Up to now, vaccination has been the main strategy to prevent transmission and reduce disease severity. However, with follow-up observations after massive vaccination, immune thrombocytopenic purpura (ITP) induced by COVID-19 vaccines has attracted the attention of investigators. The present study reported the case of a 78-year-old elderly female who presented with 'oral bleeding for 2 days and scattered bleeding spots on the extremities for 1 day' after vaccination with the COVID-19 vaccine (Vero Cells), and blood routine analysis indicated a white blood cell count of 6.27x10(9)/l, hemoglobin levels of 144 g/l and a low platelet (PLT) count of 1x10(9)/l. Bone marrow cytomorphology showed thrombocytopenia, while no platelet-producing megakaryocytes were observed. The patient was diagnosed with ITP and given symptomatic and supportive treatment, such as prednisone acetate 1 mg/kg, recombinant human thrombopoietin, intravenous injection of human immunoglobulin 0.4 g/kg and prevention of bleeding. At 1 week after the treatment started, the patient's PLT count began to increase, and 9 days later, it returned to normal levels. The aim of the present study was to raise the awareness of medical staff regarding this disease and to increase the vigilance of the general public. At the same time, the present study also provided an effective method to manage this type of adverse reaction to the COVID-19 vaccine.

Modular capsid decoration boosts adenovirus vaccine-induced humoral immunity against SARS-CoV-2. Adenovirus vector vaccines have been widely and successfully deployed in response to coronavirus disease 2019 (COVID-19). However, despite inducing potent TÂ cell immunity, improvement of vaccine-specific antibody responses upon homologous boosting is modest compared with other technologies. Here, we describe a system enabling modular decoration of adenovirus capsid surfaces with antigens and demonstrate potent induction of humoral immunity against these displayed antigens. Ligand attachment via a covalent bond was achieved using a protein superglue, DogTag/DogCatcher (similar to SpyTag/SpyCatcher), in a rapid and spontaneous reaction requiring only co-incubation of ligand and vector components. DogTag was inserted into surface-exposed loops in the adenovirus hexon protein to allow attachment of DogCatcher-fused ligands on virus particles. Efficient coverage of the capsid surface was achieved using various ligands, with vector infectivity retained in each case. Capsid decoration shielded particles from vector neutralizing antibodies. In prime-boost regimens, adenovirus vectors decorated with the receptor-binding domain of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) spike induced >10-fold higher SARS-CoV-2 neutralization titers compared with an undecorated vector encoding spike. Importantly, decorated vectors achieved equivalent or superior TÂ cell immunogenicity against encoded antigens compared

with undecorated vectors. We propose capsid decoration using protein superglues as a novel strategy to improve efficacy and boostability of adenovirus-based vaccines and therapeutics.
Outcome of Post-Covid Vaccination Myocarditis in an Adolescent Male.
Autoimmune hepatitis triggered by COVID-19 vaccination: correspondence.
Covid-19 vaccination in pregnancy. Pregnancy is an independent risk factor for severe covid-19. Vaccination is the best way to reduce the risk for SARS-CoV-2 infection and limit its morbidity and mortality. The current recommendations from the World Health Organization, Centers for Disease Control and Prevention, and professional organizations are for pregnant, postpartum, and lactating women to receive covid-19 vaccination. Pregnancy specific considerations involve potential effects of vaccination on fetal development, placental transfer of antibodies, and safety of maternal vaccination. Although pregnancy was an exclusion criterion in initial clinical trials of covid-19 vaccines, observational data have been rapidly accumulating and thus far confirm that the benefits of vaccination outweigh the potential risks. This review examines the evidence supporting the effectiveness, immunogenicity, placental transfer, side effects, and perinatal outcomes of maternal covid-19 vaccination. Additionally, it describes factors associated with vaccine hesitancy in pregnancy. Overall, studies monitoring people who have received covid-19 vaccines during pregnancy have not identified any pregnancy specific safety concerns. Additional information on non-mRNA vaccines, vaccination early in pregnancy, and longer term outcomes in infants are needed. To collect this information, vaccination during pregnancy must be prioritized in vaccine research.
Adverse events following immunization with ChAdOx1 nCoV-19 and BBIBP-CorV vaccine: A comparative study among healthcare professionals of Nepal. BACKGROUND: Adverse events following immunization (AEFI) against SARS-CoV-2 are common as reported by clinical trials and contemporary evidence. The objective of the present study was to evaluate the local and systemic adverse events following vaccination with ChAdOx1 nCoV-19 and BBIBP-CorV among the healthcare professionals (HCPs) of Nepal. METHODS: This cross-sectional study was conducted among 606 vaccinated HCPs of Kathmandu, Nepal. Data was collected from June 15 to 30, 2021 using a self-administered online survey tool. Multiple binary logistic regression models were used to predict the adverse events according to the vaccine types and doses after adjusting for age, sex, comorbidity and previous SARS-CoV-2 infection. RESULTS: The mean (SD) age of the participants was 35.6 (13.2) years and 52% of them were female. Almost 59% of participants were vaccinated with two doses and around 54% of total of them took the ChAdOx1 nCoV-19 vaccine. At least one local and systemic adverse event was reported by 54% and 62% of participants after the first dose and 37% and 49% after the second dose of ChAdOx1 nCoV-19 and by 37% and 43% after the first dose and 42% and 36% after the second dose of BBIBP-CorV vaccine respectively. Injection site pain, swelling and tenderness at the injection site were the most frequently reported local AEFI while, fatigue, headache, fever and myalgia were the most frequently reported systemic AEFI. The logistic model demonstrated that the risk of both local and systemic adverse events was higher among the ChAdOx1 nCoV-19 vaccine recipients compared to the BBIBP-CorV vaccine. Almost 10% of individuals reported a post-vaccination SARS-CoV-2 infection and most of them occurred after taking the first dose of vaccine. CONCLUSIONS: Recipients of both the ChAdOx1 nCoV-19 and BBIBP-CorV vaccine among the HCPs of Nepal reported only mild and constitutional symptoms including injection site pain and tenderness, headache, fever, fatigue, etc. after vaccination.
Reply to the Letter to Editor regarding "Autoimmune hepatitis with history of HCV treatment triggered by COVIDâ€‘19 vaccination: case report and literature review".
Adverse events following immunization associated with coronavirus disease 2019 (COVID-19) vaccines: A descriptive analysis from VigiAccess. This study assessed adverse events following immunizations (AEFIs) reported on COVID-19 vaccines in VigiAccess and determined the reporting

trends across all continents of the world. The study was cross-sectional quantitative in design. VigiAccess was searched on 10 November 10 2021 for reported adverse events following the introduction of COVID-19 vaccines. After entering the search term, "COVID-19 vaccines" in VigiAccess, AEFIs associated with nine approved brands of COVID-19 vaccines had been documented in the database. Data were captured among age groups, sex, and continents of the world and analyzed using Statistical Package for Social Sciences (SPSS) version 25. Overall, 2,457,386 AEFIs had been reported in VigiAccess at the time of the search. No causal associations could be established between the vaccines and the AEFIs. The public accessing VigiAccess data should therefore be made aware of this in order to not falsely attribute AEFIs to COVID-19 vaccines when assessing the database.

Lupus anticoagulant activity and thrombosis post COVID-19 vaccination. Some reports have discussed the development of a new entity called vaccine-induced immune thrombotic thrombocytopenia after COVID-19 vaccination. In this case series, we are describing four patients who have developed lupus anticoagulant-associated venous thromboembolism after Pfizer mRNA COVID-19 vaccination. All were COVID-19 negative on admission. Three had developed thrombosis after the first dose and one after the second dose of vaccination. All of them had venous thrombosis. Three patients developed thrombosis 2 weeks after vaccination and the fourth patient had developed thrombosis after 3 weeks of vaccination. None of the patients had thrombocytopenia on or during admission as seen in the case of vaccine-induced immune thrombotic thrombocytopenia. All patients had positive lupus anticoagulant and negative anticardiolipin antibodies and antibeta2 glycoprotein I. All of them were stable on discharge and were treated with low molecular weight heparin followed by warfarin. We suggest the presence of a possible link between the development of antiphospholipid antibodies and COVID-19 vaccine that requires further assessment.

A Clinical Case of COVID-19 Vaccine-Associated Guillain-BarrÃ© Syndrome. BACKGROUND Guillain-Barre syndrome (GBS) is an autoimmune condition that presents as weakness, numbness, paresthesia, and areflexia. GBS may occur following infection or vaccination. The pathogenesis of GBS is characterized by inflammatory infiltrates and segmental demyelination. The mechanism of GBS following COVID-19 vaccination is hypothesized to arise from an autoimmune-mediated mechanism leading to an increase in inflammatory cytokines. While there were no reported cases of GBS during the mRNA COVID-19 vaccination clinical trials, there have been a few case reports of GBS following COVID-19 vaccination. CASE REPORT We report a case of symmetric weakness and paresthesia that began 3 days after the patient received his first dose of the Moderna COVID-19 vaccine. Cerebrospinal fluid (CSF) studies demonstrated albuminocytologic dissociation. The combination of the patient's CSF findings and clinical symptoms was concerning for Guillain-Barre syndrome. Given the clinical findings 3 days following COVID-19 vaccination, there was a high concern for COVID-19 vaccine-induced GBS. The patient was treated with IVIG followed by plasmapheresis but failed to show significant improvement from either treatment. CONCLUSIONS Our case report demonstrates occurrence of GBS soon after the patient received the COVID-19 Moderna vaccine. Although rare, there is some evidence to support an association between COVID-19 vaccination and GBS, but this is generally limited to case reports and case series. Clinicians, however, should remain vigilant to mitigate potential risks, such as autonomic dysfunction, respiratory failure, permanent disability, and death in patients who develop GBS after vaccination.

The long term vaccine-induced anti-SARS-CoV-2 immune response is impaired in quantity and quality under TNFÎ± blockade. The humoral immune response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination in patients with chronic inflammatory disease (CID) declines more rapidly with tumor necrosis factor-Î± (TNF-Î±) inhibition. Furthermore, the efficacy of current vaccines against Omicron variants of concern (VOC) including BA.2 is limited. Alterations within immune cell populations, changes in IgG affinity, and the ability to neutralize a pre-VOC strain and the

BA.2 virus were investigated in these at-risk patients. Serum levels of anti-SARS-CoV-2 IgG, IgG avidity, and neutralizing antibodies (NA) were determined in anti-TNF-Î± patients (nâ€‰=â€‰10) and controls (nâ€‰=â€‰24 healthy individuals; nâ€‰=â€‰12 patients under other disease-modifying antirheumatic drugs, oDMARD) before and after the second and third vaccination by ELISA, immunoblot and live virus neutralization assay. SARS-CoV-2-specific B- and T cell subsets were analysed by multicolor flow cytometry. Six months after the second vaccination, anti-SARS-CoV-2 IgG levels, IgG avidity and anti-pre-VOC NA titres were significantly reduced in anti-TNF-Î± recipients compared to controls (healthy individuals: avidity: pâ€‰â‰¤â€‰0.0001; NA: pâ€‰=â€‰0.0347; oDMARDs: avidity: pâ€‰=â€‰0.0012; NA: pâ€‰=â€‰0.0293). The number of plasma cells was increased in anti-TNF-Î± patients (Healthy individuals: pâ€‰=â€‰0.0344; oDMARDs: pâ€‰=â€‰0.0254), while the absolute number of SARS-CoV-2-specific plasma cells 7 days after 2nd vaccination were comparable. Even after a third vaccination, these patients had lower anti-BA.2 NA titres compared to both other groups. We show a reduced SARS-CoV-2 neutralizing capacity in patients under TNF-Î± blockade. In this cohort, the plasma cell response appears to be less specific and shows stronger bystander activation. While these effects were observable after the first two vaccinations and with older VOC, the differences in responses to BA.2 were enhanced.

Not Feeling Swell: Superior Vena Cava (SVC) Syndrome Falsely Attributed to COVID-19 Vaccine Reaction. BACKGROUND: The mass immunization campaign against Coronavirus disease 2019 (COVID-19) has resulted in more patients presenting to the emergency department (ED) with concern for a vaccine reaction. CASE REPORT: A 68-year-old man presented to the ED reporting an allergic reaction to the COVID-19 vaccine. He initially noted swelling of his face, neck, and right arm after receiving the first dose of the vaccine. After his second dose of the vaccine, the swelling became more pronounced and prompted him to seek care. On examination, he had fullness of the neck and engorgement of the left external jugular vein, which were exacerbated when the patient raised his arms above his head, consistent with Pemberton's sign. Apart from the swelling of the head and neck, there were no other findings consistent with an allergic reaction. The presence of Pemberton's sign prompted a computed tomography scan of the chest with contrast, which revealed a paratracheal mass measuring 4.5Â Ã—Â 2.0 cm with marked narrowing of the superior vena cava (SVC). The patient was admitted to the hospital for SVC syndrome, and further workup revealed a non-small cell lung cancer. WHY SHOULD AN EMERGENCY PHYSICIAN BE AWARE OF THIS?: Patients may misattribute their symptoms to a COVID vaccine reaction when they are, in fact, experiencing a more serious underlying disease. This case highlights the importance of a thorough physical examination and maintaining a broad differential diagnosis. In this case, the presence of Pemberton's sign raised suspicion for SVC syndrome, and prompted further workup.

A Novel Development of Sarcoidosis Following COVID-19 Vaccination and a Literature Review. BNT162b2 (Pfizer/BioNTech) is a coronavirus disease 2019 (COVID-19) vaccine containing nucleoside-modified messenger RNA encoding the severe acute respiratory syndrome coronavirus 2 spike glycoprotein. Recently, ocular complications of mRNA vaccines have been reported increasingly frequently. However, immunological adverse events due to mRNA vaccines in real-world settings are not fully known. We herein report the novel development of sarcoidosis manifested as uveitis, bilateral hilar lymphadenopathy, angiotensin-converting enzyme elevation, and epithelioid and giant cell granuloma formation in the lung soon after the first BNT162b2 injection and review the current literature, including three reported cases of sarcoid-like reaction following COVID-19 vaccination.

Decrease in CD8(+)CD45(+)CCR7(+)CD62L(+) T cells in individuals vaccinated with Sinovac-CoronaVac following COVID-19 infection. Vaccines induce antibodies, but T cell responses are also important for protection against Coronavirus disease 2019. Here, we analyzed the frequency of memory T cells

in infected and/or vaccinated individuals and observed a decrease in central memory T cells in individuals who were vaccinated following COVID-19 infection.

Natural History of Myocardial Injury After COVID-19 Vaccine-Associated Myocarditis. BACKGROUND: Acute myocarditis is a rare complication of mRNA-based COVID-19 vaccination. Little is known about the natural history of this complication. METHODS: Baseline and convalescent (â‰¥ 90 days) cardiac magnetic resonance (CMR) imaging assessments were performed in 20 consecutive patients meeting Updated Lake Louise Criteria for acute myocarditis within 10 days of mRNA-based vaccination. CMR-based changes in left ventricular volumes, mass, ejection fraction (LVEF), markers of tissue inflammation (native T1 and T2 mapping), and fibrosis (late gadolinium enhancement [LGE] and extracellular volume [ECV]) were assessed between baseline and convalescence. Cardiac symptoms and clinical outcomes were captured. RESULTS: Median age was 23.1 years (range 18-39 years), and 17 (85%) were male. Convalescent evaluations were performed at a median (IQR) 3.7 (3.3-6.2) months. The LVEF showed a mean 3% absolute improvement, accompanied by a 7% reduction in LV end-diastolic volume and 5% reduction in LV mass (all P < 0.015). Global LGE burden was reduced by 66% (P < 0.001). Absolute reductions in global T2, native T1, and ECV of 2.1 ms, 58 ms, and 2.9%, repectively, were documented (all P â‰¤ 0.001). Of 5 patients demonstrating LVEF â‰¤ 50% at baseline, all recovered to above this threshold in convalescence. A total of 18 (90%) patients showed persistence of abnormal LGE although mean fibrosis burden was < 5% of LV mass in 85% of cases. No patient experienced major clinical outcomes. CONCLUSIONS: COVID-19 mRNA vaccine-associated myocarditis showed rapid improvements in CMR-based markers of edema, contractile function, and global LGE burden beyond 3 months of recovery in this young patient cohort. However, regional fibrosis following edema resolution was commonly observed, justifying need for ongoing surveillance.

Unusual accumulation of 177Lu-DOTATATE at the injection site of a COVID-19 vaccination.

Adherence to and early adverse events of COVID-19 vaccine in a cohort of 600 Italian breastfeeding and pregnant physicians. Pregnant and breastfeeding women (PBW) have been excluded from COVID-19 vaccine registry and the majority of post-marketing trials, despite the recognized increased risk of severe infections and complications. The lack of efficacy and safety data prevented the formulation of specific indications/guidelines for vaccination and could have also contributed to increased vaccine hesitancy (VH) in PBW. The aim of this cross-sectional study is to assess the rate and predictors of VH, and early adverse events (AEFI) following COVID-19 vaccine in PBW with a cross-sectional study. In January 2021, a purposely designed questionnaire was administered to 600 PBW part of a Facebook group of physicians, immunized with two doses of ComirnatyÂ®. Thirty-eight (29%) pregnant women and 13 (2.8%) breastfeeders were hesitant. The only statistically significant negative predictor of COVID-19 VH appeared to be having had the flu shot in 2020/2021 (OR: 0.35; 95% CI: 0.13-0.97; pâ€‰=â€‰.044). Approximately 27% of PBW reported hesitancy toward the 2020/2021 season influenza vaccine. Among the vaccinated subjects, 51.6% of pregnant and 75.2% of breastfeeding women reported at least one symptom after the first, and 82.4% and 81.6%, respectively, after the second dose. Nausea/vomiting, fatigue, headache and arthralgia/myalgia were the most common symptoms; dizziness, shivering, syncope and limb paresthesia were rarely reported. Among infants of breastfeeding mothers, six experienced fever, five rash and four moderate and self-limiting diarrhea. Preliminary data on mRNA COVID-19 vaccine in PBW and in their infants are reassuring since AEFI, although frequent, are typically mild and similar to those occurring in the general population, and in PBW after other vaccines. Larger studies with longer follow-up after vaccination are strongly recommended to develop recommendations in these patients.

Global burden of SARS-CoV-2 infection, hospitalization and case fatality rate among COVID-19 vaccinated individuals and its associated factors: A systematic review and meta-analysis protocol. BACKGROUND: COVID-19 has been the most important public health concern worldwide since 2020.

Several vaccines are now available to help in controlling COVID-19 associated morbidity and mortality. This study will aim to provide the global and regional prevalence of SARS-CoV-2 infection as well as an estimate of disease severity among COVID-19 vaccinated individuals. MATERIALS AND METHODS: In order to determine the global burden of SARS-CoV-2 infection among vaccinated individuals, we will systematically extract and review papers from PubMed/MEDLINE, Excerpta Medica database (EMBASE), Cochrane Central Register of Controlled Trials (CENTRAL), Science direct and Cumulative Index to Nursing and Allied Health Literature (CINAHL). All the studies describing the prevalence and/or disease severity (hospitalization and case fatality rate) data of COVID-19 among individuals who received a partial or complete dose of WHO-approved COVID-19 vaccines will be eligible. A random effect model will be used to calculate the pooled prevalence and to estimate the disease severity. Subgroup analysis will be performed to explore the association between the number of vaccine doses received and the COVID-19 burdens. DISCUSSION: This systematic review and meta-analysis will provide the global estimate data on pooled prevalence, hospitalization and case fatality rates of COVID-19 among vaccinated individuals. Moreover, the factors associated with reinfection and disease severity will be equally investigated in the meta-analysis. The results of this study will contribute in the understanding and estimation of the global burden of COVID-19 among vaccinated individuals. Findings will provide meaningful information for the success of the current global rollout of COVID-19 vaccination strategies and pave the way for future interventions. SYSTEMATIC REVIEW REGISTRATION: CRD42021273074.

Risk factors of SARS-CoV-2 infection in cancer patients pre- and post-vaccination. BACKGROUND: Severe complications from COVID-19 and poor responses to SARS-CoV-2 vaccination were commonly reported in cancer patients compared to those without cancer. Therefore, the identification of predisposing factors to SARS-CoV-2 infection in cancer patients would assist in the prevention of COVID-19 and improve vaccination strategies. The literature lacks reports on this topic from the Kingdom of Saudi Arabia (KSA). Therefore, we studied clinical and laboratory data of 139 cancer patients from King Abdulaziz Medical City, Riyadh, KSA. METHODS: The cancer patients fall into three categories; (i) uninfected with SARS-CoV-2 pre-vaccination and remained uninfected post-vaccination (control group; n = 114; 81%), (ii) pre-vaccination infected group (n = 16; 11%), or (iii) post-vaccination infected group (n = 9; 6%). Next, the clinical and lab data of the three groups of patients were investigated. RESULTS: Comorbidity factors like diabetes and hemodialysis were associated with the risk of infection in cancer patients before the vaccination ($p<0.05$). In contrast to breast cancer, papillary thyroid cancer was more prevalent in the infected patients pre- and post-vaccination ($p<0.05$). Pre-vaccination infected group had earlier cancer stages compared with the control group ($p = 0.01$). On the other hand, combined therapy was less commonly administrated to the infected groups versus the control group ($p<0.05$). Neutrophil to lymphocyte ratio was lower in the post-vaccination infected group compared to the control group ($p = 0.01$). CONCLUSION: Collectively, this is the first study from KSA to report potential risk factors of SARS-CoV-2 infection in cancer patients pre- and post-vaccination. Further investigations on these risk factors in a larger cohort are worthwhile to draw a definitive conclusion about their roles in predisposing cancer patients to the infection.

Rural-Urban Differences in the Associations Between Aging and Disability Services and COVID-19 Vaccination Rates Among Older Adults. Aging services were poised to play an important role in supporting the COVID-19 vaccination rollout for older adults. In this study, we use ordinary least squares regression models of county-level data (N = 3086) to examine if density of aging and disability services is associated with COVID-19 vaccination rates for older adults in rural and urban areas of the United States. We find that net of compositional characteristics, county-level density of aging and disability services is associated with higher older adult vaccination rates. However, in the rural-urban

stratified models, this only remained consistently true for rural counties. Given higher risk of COVID-19 mortality for older adults and larger relative shares of older adults in rural areas, rural counties with low vaccination rates should invest in supporting and/or expanding older adult services to facilitate vaccination.

Seizures following COVID-19 vaccination in Mexico: AÂ nationwide observational study. The COVID-19 pandemic led to the development and emergency approval of an array of effective vaccines against SARS-CoV-2. Given the relatively small number of patients included in vaccine trials, postapproval epidemiological surveillance is crucial to detect infrequent vaccine-related adverse events. We conducted a nationwide retrospective descriptive study evaluating the incidence of seizures among recipients of SARS-CoV-2 vaccines in Mexico from December 24, 2020 (date of administration of first doses nationwide) to October 29, 2021. Among 81â€‰916â€‰351 doses of any vaccine that were administered, we documented seizures in 53 patients, of which 31 (60%) were new onset seizures. The incidence rate of seizures per million doses was highest for mRNA-1273 (Moderna) with 2.73 per million, followed by BNT162b2 (Pfizer-BioNTech) with 1.02 per million, and Ad5-nCoV (CanSino) with 1.01 per million. Thus, we found that seizures following SARS-CoV-2 vaccination are exceedingly rare events.

Immune defects associated with lower SARS-CoV-2 BNT162b2 mRNA vaccine response in aged people. The immune factors associated with impaired SARS-CoV-2 vaccine response in elderly people are mostly unknown. We studied individuals older than 60 and younger than 60 years, who had been vaccinated with SARS-CoV-2 BNT162b2 mRNA, before and after the first and second dose. Aging was associated with a lower anti-RBD IgG levels and a decreased magnitude and polyfunctionality of SARS-CoV-2-specific T cell response. The dramatic decrease in thymic function in people > 60 years, which fueled alteration in T cell homeostasis, and their lower CD161+ T cell levels were associated with decreased T cell response 2 months after vaccination. Additionally, deficient DC homing, activation, and TLR-mediated function, along with a proinflammatory functional profile in monocytes, were observed in the > 60-year-old group, which was also related to lower specific T cell response after vaccination. These findings might be relevant for the improvement of the current vaccination strategies and for the development of new vaccine prototypes.

Factors associated with severe or fatal clinical manifestations of SARS-CoV-2 infection after receiving the third dose of vaccine. BACKGROUND: Little is known about vulnerability to severe COVID-19 illness after vaccination completion with three doses of vaccine against COVID-19. OBJECTIVES: To identify individual features associated with increased risk of severe clinical manifestation of SARS-CoV-2 infections after receiving the third dose of vaccine against COVID-19. METHODS: We performed a nested case-control study based on 3,360,116 citizens from Lombardy, Italy, aged 12 years or older who received the third dose of vaccine against COVID-19 from 20 September through 31 December 2021. Individuals were followed from 14 days after vaccination completion until the occurrence of severe COVID-19 illness, death unrelated to COVID-19, emigration or 15 March 2022. For each case, controls were randomly selected to be 1:10 matched for the date of vaccination completion and municipality of residence. The association between candidate predictors and outcome was assessed through multivariable conditional logistic regression models. RESULTS: During 12,538,330 person-months of follow-up, 5171 cases of severe illness occurred. As age increased, a trend towards increasing odds of severe illness was observed. Male gender was a significant risk factor. As the number of contacts with the Regional Health Service increased, a trend towards increasing odds of severe illness was observed. Having had a previous SARS-CoV-2 infection was a significant protective factor. Having received the Moderna vaccine significantly decreased the odds of severe illness. Significant higher odds were associated with 42 diseases/conditions. Odds ratios ranged from 1.23 (diseases of the musculoskeletal system) to 5.00 (autoimmune disease).

CONCLUSIONS: This study provides useful insights for establishing priority in fourth-dose vaccination programs.

Severe Acute Respiratory Syndrome Coronavirus 2 Vaccine Boosters: An Influenza Vaccine Perspective. Changes to severe acute respiratory syndrome 2 (SARS-CoV-2) vaccine guidance since their initial authorization may lead to confusion and hesitancy. Suggested recommendations for an annual SARS-CoV-2 vaccine naturally draw comparisons with the influenza vaccine program. Considering viral and vaccine characteristics between these pathogens provides an important perspective that can help increase vaccine confidence with SARS-CoV-2 vaccines.

Immunity after COVID-19 vaccination in people with higher risk of compromised immune status: a scoping review. BACKGROUND: High efficacy in terms of protection from severe COVID-19 has been demonstrated for several SARS-CoV-2 vaccines. However, patients with compromised immune status develop a weaker and less stable immune response to vaccination. Strong immune response may not always translate into clinical benefit, therefore it is important to synthesise evidence on modified schemes and types of vaccinationÂ in these population subgroups for guiding health decisions. As the literature on COVID-19 vaccines continues to expand, we aimed to scope the literature on multiple subgroups to subsequently decide on the most relevant research questions to be answered by systematic reviews. OBJECTIVES: To provide an overview of the availability of existing literature on immune response and long-term clinical outcomes after COVID-19 vaccination, and to map this evidence according to the examined populations, specific vaccines, immunity parameters, and their way of determining relevant long-term outcomes and the availability of mapping between immune reactivity and relevant outcomes. SEARCH METHODS: We searched the Cochrane COVID-19 Study Register, the Web of Science Core Collection, and the World Health Organization COVID-19 Global literature on coronavirus disease on 6 December 2021.Â SELECTION CRITERIA: We included studies that published results on immunity outcomes after vaccination with BNT162b2, mRNA-1273, AZD1222, Ad26.COV2.S, Sputnik V or Sputnik Light, BBIBP-CorV, or CoronaVac on predefined vulnerable subgroups such as people with malignancies, transplant recipients, people undergoing renal replacement therapy, and people with immune disorders, as well as pregnant and breastfeeding women, and children. We included studies if they had at least 100 participants (not considering healthy control groups); we excluded case studies and case series. DATA COLLECTION AND ANALYSIS: We extracted data independently and in duplicate onto an online data extraction form. Data were represented as tables and as online maps to show the frequency of studies for each item. We mapped the data according to study design, country of participant origin, patient comorbidity subgroup, intervention, outcome domains (clinical, safety, immunogenicity), and outcomes.Â MAIN RESULTS: Out of 25,452 identified records, 318 studies with a total of more than 5 million participants met our eligibility criteria and were included in the review. Participants were recruited mainly from high-income countries between January 2020 and 31 October 2021 (282/318); the majority of studies included adult participants (297/318).Â Haematological malignancies were the most commonly examined comorbidity group (N = 54), followed by solid tumours (N = 47), dialysis (N = 48), kidney transplant (N = 43), and rheumatic diseases (N = 28, 17, and 15 for mixed diseases, multiple sclerosis, and inflammatory bowel disease, respectively). Thirty-one studies included pregnant or breastfeeding women. The most commonly administered vaccine was BNT162b2 (N = 283), followed by mRNA-1273 (N = 153), AZD1222 (N = 66), Ad26.COV2.S (N = 42), BBIBP-CorV (N = 15), CoronaVac (N = 14), and Sputnik V (N = 5; no studies were identified for Sputnik Light). Most studies reported outcomes after regular vaccination scheme.Â The majority of studies focused on immunogenicity outcomes, especially seroconversion based on binding antibody measurements and immunoglobulin G (IgG) titres (N = 179 and 175, respectively). Adverse events and serious adverse events were reported in 126 and 54 studies, whilst SARS-CoV-2 infection irrespective of severity was reported in 80 studies.

Mortality due to SARS-CoV-2 infection was reported in 36 studies. Please refer to our evidence gap maps for more detailed information. AUTHORS' CONCLUSIONS: Up to 6 December 2021, the majority of studies examined data on mRNA vaccines administered as standard vaccination schemes (two doses approximately four to eight weeks apart) that report on immunogenicity parameters or adverse events. Clinical outcomes were less commonly reported, and if so, were often reported as a secondary outcome observed in seroconversion or immunoglobulin titre studies. As informed by this scoping review, two effectiveness reviews (on haematological malignancies and kidney transplant recipients) are currently being conducted.

COVID vaccine-associated myocarditis in an 8-year-old patient - ERRATUM.

Pituitary apoplexy after COVID-19 vaccination: A case report. BACKGROUND: Pituitary apoplexy is a rare endocrine emergency, which commonly presents with headache and is occasionally associated with visual disturbances. Prompt diagnosis and treatment can be both life and vision saving. In the emergence of novel coronavirus and global pandemic, rapid development of new vaccines have shown to reduce morbidity and mortality associated with Covid-19. Recognition of rare potential adverse effects of these vaccines including pituitary apoplexy are yet to be reported. A causal link between pituitary apoplexy and COVID-19 vaccination has not been established. CASE PRESENTATION: We report a case of a 24-year-old woman who presented with progressively worsening headache soon after completing her COVID-19 vaccination. Imaging showed pituitary apoplexy with an underlying pituitary mass. In view of the age and the typical presentation of severe headache, pituitary hypophysitis was considered, despite the absence of the almost pathognomonic feature of a thickened pituitary stalk in the initial imaging. In the context that the headache had started shortly after the administration of the second dose of COVID-19 vaccine, this potentially could have been the trigger for the occurrence of pituitary apoplexy. CONCLUSION: Although the pathophysiology is not entirely clear and no direct link could be ascertained, our patient may have developed an exaggerated immunological response after the vaccine, with a possible pituitary hypophysitis leading to a pituitary apoplexy.

Case reports: Persistent hiccup as an atypical presentation of COVID-19 infection in a vaccinated subject. INTRODUCTION: and Importance: COVID-19 have wide array of clinical manifestation involving both respiratory and non-respiratory symptoms including neurological symptoms. Hiccups is the involuntary and spasmodic movement of the diaphragm and the intercoastal muscle that leads to the closure of the glottis and limitation of breathing in air. CASE PRESENTATION: We present a case of a 72-year old SARS COV-2 positive male with hypertension who have persistent hiccup. The patient is a vaccinated subject with 2 dose of Vero cells. CLINICAL FINDINGS AND INVESTIGATIONS: Vitals were stable.Mild dehydration was present.Bilateral Diffuse wheeze was present on Respiratory examination. No other abnormalities were detected during systemic examination.Imaging of his chest revealed bilateral mid-lung opacities and air bronchogram. INTERVENTIONS AND OUTCOME: Perisitent hiccup was treated with metoclopramide. The hiccups reduced as the patient required less oxygen supplementation and inflammatory indicators decreased. RELEVANCE AND IMPACT: This case report tends to provide information and awareness among physicians regarding this atypical presentation of the disease.

Adult paroxysmal cold hemoglobinuria following mRNA COVID-19 vaccination. Paroxysmal cold hemoglobinuria (PCH) is an extremely rare subtype of autoimmune hemolytic anemia (AIHA) in adults. PCH is caused by the biphasic Donath-Landsteiner (DL) antibody which fixes complement to red blood cells at low temperatures and dissociates at warmer temperatures, leading to complement-mediated intravascular hemolysis. Autoimmune hematological disorders including AIHA and immune thrombocytopenia have been reported to develop following the mRNA COVID-19 vaccination. However, PCH developing subsequent to mRNA vaccination has never been reported. We report a 59-

year-old male who developed PCH approximately a month after his second mRNA COVID-19 vaccination.

Severe aplastic anaemia after serial vaccinations for SARS-CoV-2, pneumococcus and seasonal influenza. We present a 67-year-old woman who developed progressive pancytopenia over 10 months, concomitant with administration of severe adult respiratory syndrome coronavirus-2 (SARS-CoV-2), pneumococcal and influenza vaccines. She developed mild leukopenia â^¼2Â weeks after the SARS-CoV-2 mRNA vaccine sequence, with progressive symptoms after subsequent vaccines, eventually developing severe aplastic anaemia (SAA). While there have been several reports of vaccine-related SAA, at time of submission, our case is the first reported to develop after the Moderna mRNA SARS-CoV-2 vaccine, as well as the first to document the gradual development of SAA over the course of many vaccine exposures. Physicians should be cognizant of vaccine-associated SAA, considering current widespread coronavirus disease 2019 vaccination efforts.

New Onset of Severe Plaque Psoriasis Following COVID-19 Vaccination: A Case Report. A case of new onset of severe plaque psoriasis following COVID-19 vaccination was reported. A 63-year-old woman presented with multiple plaques for 2 months after the second dose of COVID-19 vaccination. Dermatological examination revealed diffuse erythematous papules and plaques on trunk and limbs. Her lesions responded well to the treatment of secukinumab 150 mg per week. In this case, we presented the potential association between COVID-19 vaccination and the onset of psoriasis. It is essential to recognize the possible adverse events as vaccination against COVID-19 continues worldwide.

Humoral responses after inactivated COVID-19 vaccination in individuals with and without prior SARS-CoV-2 infection: A prospective cohort study. We evaluated and compared humoral immune responses after inactivated coronavirus disease 2019 (COVID-19) vaccination among naÃ¯ve individuals, asymptomatically infected individuals, and recovered patients with varying severity. In this multicenter, prospective cohort study, blood samples from 666 participants were collected before and after 2 doses of inactivated COVID-19 vaccination. Among 392 severe acute respiratory syndrome coronavirus 2-naÃ¯ve individuals, the seroconversion rate increased significantly from 51.8% (median antispike protein pan-immunoglobulins [S-Igs] titer: 0.8â€‰U/ml) after the first dose to 96% (median S-Igs titer: 79.5â€‰U/ml) after the second dose. Thirty-two percent of naÃ¯ve individuals had detectable neutralizing antibodies (NAbs) against the original strain but all of them lost neutralizing activity against the Omicron variant. In 274 individuals with natural infection, humoral immunity was significantly improved after a single vaccine dose, with median S-Igs titers of 596.7, 1176, 1086.5, and 1828â€‰U/ml for asymptomatic infections, mild cases, moderate cases, and severe/critical cases, respectively. NAb titers also improved significantly. However, the second dose did not substantially increase antibody levels. Although a booster dose is needed for those without infection, our findings indicate that recovered patients should receive only a single dose of the vaccine, regardless of the clinical severity, until there is sufficient evidence to confirm the benefits of a second dose.

[A Patient Developing Guillain-BarrÃ© Syndrome After Receiving the BNT162b2 COVID-19 mRNA Vaccine]. We report a 71-year-old woman who presented with paresthesia, progressive weakness, difficulty walking, diarrhea, and bladder dysfunction one week after she received the BNT162b2 COVID-19 vaccine. Her neurological signs and symptoms gradually worsened up to 27 days after onset, after which her weakness slowly improved without immunotherapy. Analysis of serial cerebrospinal fluid specimens showed gradually increasing protein levels. Results of a nerve conduction study suggested functional axonal disturbance. The clinical findings together with the monophasic clinical course were consistent with Guillain-BarrÃ© syndrome. Her previous history was negative for symptomatic infection. Serological and bacterial tests, including the presence of anti-

glycolipid antibodies, were negative for prior infection. Few cases have been reported on the development of Guillain-BarrÃ© syndrome after the BNT162b2 vaccine. Our patient's syndrome was characterized by atypical proximal weakness of the dominant lower limb. (Received January 28, 2022; Accepted April 4, 2022; Published August 1, 2022).

Seroconversion following the first, second, and third dose of SARS-CoV-2 vaccines in immunocompromised population: a systematic review and meta-analysis. BACKGROUND: Immunocompromised (IC) patients are at higher risk of more severe COVID-19 infections than the general population. Special considerations should be dedicated to such patients. We aimed to investigate the efficacy of COVID-19 vaccines based on the vaccine type and etiology as well as the necessity of booster dose in this high-risk population. MATERIALS AND METHODS: We searched PubMed, Web of Science, and Scopus databases for observational studies published between June 1st, 2020, and September 1st, 2021, which investigated the seroconversion after COVID-19 vaccine administration in adult patients with IC conditions. For investigation of sources of heterogeneity, subgroup analysis and sensitivity analysis were conducted. Statistical analysis was performed using R software. RESULTS: According to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses, we included 81 articles in the meta-analysis. The overall crude prevalence of seroconversion after the first (n: 7460), second (n: 13,181), and third (n: 909, all population were transplant patients with mRNA vaccine administration) dose administration was 26.17% (95% CI 19.01%, 33.99%, I(2)â€‰=â€‰97.1%), 57.11% (95% CI: 49.22%, 64.83%, I(2)â€‰=â€‰98.4%), and 48.65% (95% CI: 34.63%, 62.79%, I(2)â€‰=â€‰94.4%). Despite the relatively same immunogenicity of mRNA and vector-based vaccines after the first dose, the mRNA vaccines induced higher immunity after the second dose. Regarding the etiologic factor, transplant patients were less likely to develop immunity after both first and second dose rather than patients with malignancy (17.0% vs 37.0% after first dose, Pâ€‰=â€‰0.02; 38.3% vs 72.1% after second dose, Pâ€‰<â€‰0.001) or autoimmune disease (17.0% vs 36.4%, Pâ€‰=â€‰0.04; 38.3% vs 80.2%, Pâ€‰<â€‰0.001). To evaluate the efficacy of the third dose, we observed an increasing trend in transplant patients after the first (17.0%), second (38.3%), and third (48.6%) dose. CONCLUSION: The rising pattern of seroconversion after boosting tends to be promising. In this case, more attention should be devoted to transplant patients who possess the lowest response rate.

COVID-19 mRNA booster vaccine induces transient CD8+ T effector cell responses while conserving the memory pool for subsequent reactivation. Immunization with two mRNA vaccine doses elicits robust spike-specific CD8(+) T cell responses, but reports of waning immunity after COVID-19 vaccination prompt the introduction of booster vaccination campaigns. However, the effect of mRNA booster vaccination on the spike-specific CD8(+) T cell response remains unclear. Here we show that spike-specific CD8(+) T cells are activated and expanded in all analyzed individuals receiving the 3(rd) and 4(th) mRNA vaccine shots. This CD8(+) T cell boost response is followed by a contraction phase and lasts only for about 30-60 days. The spike-specific CD8(+) T memory stem cell pool is not affected by the 3(rd) vaccination. Both 4(th) vaccination and breakthrough infections with Delta and Omicron rapidly reactivate CD8(+) T memory cells. In contrast, neutralizing antibody responses display little boost effect towards Omicron. Thus, COVID-19 mRNA booster vaccination elicits a transient T effector cell response while long-term spike-specific CD8(+) T cell immunity is conserved to mount robust memory recall targeting emerging variants of concern.

COVID-19 vaccine compliance in adolescents with attention-deficit/hyperactivity disorder. OBJECTIVE: To compare the rate of the administration of the Pfizer-BioNTech COVID-19 vaccinations between adolescents diagnosed with attention-deficit/hyperactivity disorder (ADHD) and non-ADHD subjects. METHOD: A retrospective chart review was performed on all adolescents aged 12-17Â years registered at a central district in Israel from January 1(st) 2021 to October 31(st) 2021. RESULTS: Of

the 46,544 subjects included in the study, 8241 (17.7%) were diagnosed with ADHD. Of them, 3% were PCR-COVID-19 positive. Among the patients with ADHD, the older adolescents were more likely to be vaccinated: 48.8% of those aged 12-15Â years were vaccinated versus 59.6% of patients aged 16-17Â years. The ultra-orthodox Jewish and Arab adolescents in the ADHD group were far less likely to be vaccinated (22.9% and 34.6%, respectively), compared to the adolescents with ADHD in the general population (60.5%). Girls were also somewhat more likely to be vaccinated. CONCLUSIONS: Adolescents diagnosed with ADHD had a higher COVID-19 vaccination rate compared to their non-ADHD counterparts. The vaccine uptake was lower amongst Arab and ultra-orthodox Jewish populations.

Cerebral Venous Sinus Thrombosis Following COVID-19 and Otogenic Infection: A Diagnostic and Therapeutic Dilemma Followed by mRNA COVID-19 Vaccination. IntroductionCerebral venous sinus thrombosis (CVST) is a rare neurovascular emergency that has been observed following COVID-19 infection, as well as following the use of non-mRNA COVID-19 vaccines. Case PresentationThe authors report a case of CVST in a 67-year-old woman, unvaccinated for COVID-19, who presented with acute otitis externa. It remains unclear whether the CVST was a following COVID-19 infection complication, otogenic CVST, or a combination of both. ConclusionThis case demonstrates the diagnostic and therapeutic dilemmas in managing this patient's challenging anticoagulation and antibiotic duration, as well as subsequent COVID-19 vaccination recommendations.

Immunogenicity After a Heterologous BNT262b2 Versus Homologous Booster in Kidney Transplant Recipients Receiving 2 Doses of CoronaVac Vaccine: A Prospective Cohort Study. BACKGROUND: Comparative studies of third heterologous doses following the CoronaVac vaccine against coronavirus disease 2019 (COVID-19) in kidney transplant recipients are lacking. METHODS: This prospective, single-center cohort study included kidney transplant recipients without previous COVID-19. Patients received a third heterologous (BNT162b2 mRNA) or homologous dose at least 4 wk after 2 doses of the CoronaVac vaccine. Immunoglobulin G antibody response and seroprevalence for neutralizing anti-severe acute respiratory syndrome coronavirus 2 antibodies immediately before and 28 d after third doses were compared between the groups. RESULTS: There were 307 patients in the heterologous group and 777 in the homologous group. Patients in the heterologous group were older (54 versus 50 y; $P < 0.0001$), with a longer time since transplant (11 versus 6 y; $P < 0.0001$). Immediately before the third dose, immunoglobulin G seroprevalence (36% versus 34%; $P = 0.597$) and antibody titers (246 versus 268 AU/mL; $P = 0.279$) were similar. After booster, seroconversion was higher in the heterologous group (49% versus 32%; $P < 0.0001$), resulting in a higher seroprevalence (67% versus 55%; $P = 0.0003$); however, 42% of all patients remained seronegative. Antibody titers after booster in seropositive patients were higher in the heterologous group (7771 versus 599 AU/mL; $P < 0.0001$). These results persisted after adjusting for confounding variables. Lastly, a similar proportion of patients became seropositive for neutralizing antibodies (98% versus 94%; $P = 0.098$). CONCLUSIONS: In kidney transplant recipients fully vaccinated with CoronaVac, a third dose with an mRNA vaccine produced a higher seroconversion rate and antibody titers than a third homologous dose. However, both boosters achieved equivalent seroprevalence for neutralizing antibodies. The high proportion of still seronegative patients indicates the need for alternative strategies of protection.

New onset of acute uveitis following COVID-19 vaccination. PURPOSE: This study reported 11 cases of new-onset acute uveitis following coronavirus disease 2019 (COVID-19) vaccination. METHODS: This retrospective observational case study included 11 eyes of 11 patients with acute uveitis after the COVID-19 vaccination. We only included patients with new-onset uveitis. The medical records of the patients from January 2021 to January 2022 were reviewed. RESULTS: The mean age of the participants was 51.81Â years, and all patients demonstrated anterior chamber reaction with

keratic precipitates in the affected eye. The mean duration between vaccination and uveitis was 8.27Â days. Seven patients developed uveitis after receiving the second dose of vaccination, and four developed uveitis after receiving the third dose of vaccination. Five patients showed posterior synechiae, and three patients showed hypopyon. After treatment with topical 1% prednisolone acetate eye drops and systemic prednisolone, inflammation was adequately controlled and quickly resolved. CONCLUSIONS: COVID-19 vaccination with messenger RNA and viral vector vaccines may cause acute anterior uveitis. Although initially severe, uveitis responded well to steroid therapy with no visual impairment.

New-onset dermatomyositis following SARS-CoV-2 infection and vaccination: a case-based review. Dermatomyositis is a rare, type I interferon-driven autoimmune disease, which can affect muscle, skin and internal organs (especially the pulmonary system). In 2021, we have noted an increase in new-onset dermatomyositis compared to the years before the SARS-CoV-2 pandemic in our center. We present four cases of new-onset NXP2 and/or MDA5 positive dermatomyositis shortly after SARS-CoV-2 infection or vaccination. Three cases occurred within days after vaccination with Comirnaty and one case after SARS-CoV-2 infection. All patients required intensive immunosuppressive treatment. MDA5 antibodies could be detected in three patients and NXP2 antibodies were found in two patients (one patient was positive for both antibodies). In this case-based systematic review, we further analyze and discuss the literature on SARS-CoV-2 and associated dermatomyositis. In the literature, sixteen reports (with a total of seventeen patients) of new-onset dermatomyositis in association with a SARS-CoV-2 infection or vaccination were identified. Ten cases occurred after infection and seven after vaccination. All vaccination-associated cases were seen in mRNA vaccines. The reported antibodies included for instance MDA5, NXP2, Mi-2 and TIF1Î³. The reviewed literature and our cases suggest that SARS-CoV-2 infection and vaccination may be considered as a potential trigger of interferon-pathway. Consequently, this might serve as a stimulus for the production of dermatomyositis-specific autoantibodies like MDA5 and NXP2 which are closely related to viral defense or viral RNA interaction supporting the concept of infection and vaccination associated dermatomyositis.

Hypersensitivity Lymphohistiocytic Myocarditis After Moderna mRNA-1273 Vaccine.

Long-term effects of Pfizer-BioNTech COVID-19 vaccinations on platelets. There is a global concern about the safety of COVID-19 vaccines associated with platelet function. However, their long-term effects on overall platelet activity remain poorly understood. Here we address this problem by image-based single-cell profiling and temporal monitoring of circulating platelet aggregates in the blood of healthy human subjects, before and after they received multiple Pfizer-BioNTech (BNT162b2) vaccine doses over a time span of nearly 1Â year. Results show no significant or persisting platelet aggregation trends following the vaccine doses, indicating that any effects of vaccinations on platelet turnover, platelet activation, platelet aggregation, and platelet-leukocyte interaction was insignificant.

Miller Fisher syndrome following COVID-19 vaccines: A scoping review. BACKGROUND AND PURPOSE: Miller Fisher syndrome (MFS), a variant of Guillain-BarrÃ© Syndrome (GBS), could be underestimated in evaluations of its adverse events (AEs) following COVID-19 vaccination. We aimed to identify and characterize MFS following COVID-19 vaccination. MATERIALS AND METHODS: Relevant studies reported on during the COVID-19 pandemic were identified in the MEDLINE, Embase, and other databases. RESULTS: Nine cases of MFS following COVID-19 vaccination from various regions were included. Unlike MFS following COVID-19 infection, patients with MFS following COVID-19 vaccination frequently presented with anti-GQ1b antibody positivity (44%, 4/9). Unlike GBS following COVID-19 vaccination, only two of nine (22%) cases of MFS following COVID-19 vaccination had developed after viral-vector-related vaccine administration. CONCLUSIONS: Miller Fisher

syndrome following COVID-19 vaccination seems to have a different pathophysiology from MFS following COVID-19 infection and GBS following COVID-19 vaccination. This neurological syndrome with a rare incidence and difficulty in diagnosis should be considered an AE of COVID-19 vaccination.
Increased induction of de novo serum ANCA and ANCA-associated vasculitis after mass vaccination against SARS-CoV-2. Different immune-mediated diseases have been described after SARS-CoV-2 vaccination, with antineutrophil cytoplasmic antibodies (ANCA)-associated vasculitis (AAV) being one of the possible side effects. In this study, a total of 35 patients presented ANCA for the first time during 2021, with the number during 2019 being 15. Twenty-seven out of thirty-five patients developed ANCA after vaccination. Two of them developed these antibodies after receiving the first dose (7.4%), and 25 patients developed ANCA after the second dose of the vaccine (92.6%), with BNT162b2 being the main vaccine received by these patients. In 97.1% of the patients who developed ANCA during 2021, the positivity of ANCA was accompanied by systemic involvement, with renal and respiratory tracts being the main organs affected. Therefore, an increase in the development of AAV has been observed during 2021 in comparison with 2019, which could be due to the administration of SARS-CoV-2 vaccine.
A study of SARS-CoV-2 delta variant breakthrough infections and side effects of the Oxford-AstraZeneca vaccine. OBJECTIVE: This study aimed to investigate the breakthrough infection rate and safety profile of the AstraZeneca vaccine. METHODS: The breakthrough COVID-19 infection rate was defined as a positive polymerase chain reaction test 14 days after the vaccine dose. Safety was assessed as local reactions and systemic events that occurred within 14 days of receiving vaccine doses. RESULTS: The average age of the 265 participants was 43.85 years and 169 (63.77%) were male. . After the second dose, 18 (6.71%) participants contracted the infection. The SARS-CoV-2 delta variant was responsible for all infections but no participants required hospitalisation. We found significant correlations between post-vaccination IgG levels and post-vaccination infection (PÂ =Â 0.001; odds ratio [OR]Â =Â 0.959; 95% Confidence interval [CI]: 0.944-0.974), and between a history of previous infection and post-vaccination infection rates (PÂ =Â 0.005; ORÂ =Â 0.1; 95%CI:0.009-0.6). IgG levels were significantly higher in women than in men (PÂ =Â 0.006) and in patients who developed side effects after vaccination than in those without side effects (PÂ =Â 0.04). A significant association was found between a history of COVID-19 infection prior to vaccination and IgG levels (PÂ =Â 0.001). CONCLUSIONS: The vaccine is effective in preventing severe disease, with few side effects.
Bullous pemphigoid following COVID-19 vaccine: An autoimmune disorder.
Systematic lupus erythematous patients following COVID-19 vaccination: Its flares up and precautions. Systemic lupus erythematosus (SLE) is an autoimmune disease that can cause both direct and indirect inflammatory damage to multiple organs. Clinical symptoms in the skin, joints, kidneys, and central nervous system, as well as serological indicators such as antinuclear antibodies (ANA), notable antibodies to dsDNA, are used to diagnose SLE. mRNA SARS-CoV-2 vaccines have been shown to trigger SLE flares and the development of new rheumatic diseases. SARS-CoV-2 mRNA vaccinations increase type I interferon (INF), which is not only known to have a role in the antiviral response but is also a crucial cytokine in the pathophysiology of SLE. Furthermore, both the mRNA and adenovirus vaccines boost the production of type 1 interferons, which are required for the spread of SARS-CoV-2. The danger of not administering the COVID-19 vaccination to SLE patients is significantly larger than the likelihood of its adverse effects, which are most likely caused by intrinsic immune failure, demographic disease activity, medications, linked organ damage, and comorbidities. The adverse effects of COVID-19 vaccination in SLE patients are common (about 50%), although they do not interfere with daily functioning in the majority of cases. Several precautions can be taken to avoid the complications associated with COVID-19 vaccinations.

COVID-19 Vaccine Booster-Induced Dermatographism. The urgent requirement for a preventative vaccination became more pressing due to the severe repercussions that the SARS-CoV-2 (COVID-19) virus had on society and the economy. The deployment of the COVID-19 vaccination program had to be expedited. As with all vaccinations, adverse events have been recorded with the COVID-19 vaccine. Some patients may experience cutaneous reactions such as rashes, itching, hives, and swelling after receiving the COVID-19 vaccine, but it is unclear how common these events are or how frequently they recur. This article discusses an unusual case of a young man who got chronic severe dermatographism after receiving a booster shot of the Moderna vaccine (Moderna, Inc., Cambridge, Massachusetts).

Evans Syndrome Presenting as an Atypical Complication of SARS-CoV-2 Vaccination. The coronavirus disease 2019 (COVID-19) pandemic, caused by severe acute respiratory syndromeÂ coronavirus 2Â (SARS-CoV-2), has drastically affected our daily lives, causing millions of deaths worldwide. The early and late complications of this infection are being increasingly revealed on a regular basis; however, an important brake on the spread and especially the lethality of the disease has been guaranteed by the introduction of mRNA-based and viral vector-based COVID-19 Vaccines. Also, an increasing numberÂ of adverse effects of the vaccination have been reported to specific pharmacovigilance boards, most of them totally non-serious events that are resolved within one to three days after the administration of the vaccine. In this report, we present a case of Evans syndrome (ES) secondary to SARS-CoV-2 vaccination in an 85-year-old male patient. To the best of our knowledge, this is the first case of ES caused by the COVID-19 vaccination to be reported in the literature.

Long-term evaluation of sperm parameters after coronavirus disease 2019 messenger ribonucleic acid vaccination. OBJECTIVE: To determine whether the COVID-19 mRNA vaccines can negatively impact the semen parameters of young healthy men in the long-term. DESIGN: We conducted semen analyses on 12 men before, 3 and 9 months after achieving fully vaccinated status. Individuals who admitted a history of infertility or previous azoospermia were excluded from study participation. SUBJECTS: Healthy male volunteers between the ages of 18-50 years old were recruited between September 2021 - March 2022. MAIN OUTCOME MEASURES: Semen analyses were performed and evaluated volume, sperm concentration, total motility, and total motile sperm count (TMSC). The primary outcome was median change in the TMSC at baseline, 3 months, and at least 9 months following vaccination. RESULTS: A total of 12 men volunteered in our study (median age 26 [25 - 30] years). Subjects provided follow-up semen samples at a median of 10 months following the second vaccine dose. There were no significant changes in any semen parameters between baseline, 3 months, and 10 months following vaccination. Baseline samples demonstrated median sperm concentrations and TMSC of 29.5Â million/cc [9.3 - 49] and 31 million [4-51.3], respectively. At 9-month follow-up, sperm concentration and TMSC were 43 [20.5 - 63.5] (P=.351) and 37.5 [8.5 - 117.8] (P=.519), respectively. Of note, there were no significant changes in semen volume nor total motility (%) for participants at follow-up. CONCLUSION: COVID-19 mRNA vaccines and the booster dose does not appear to negatively impact the semen parameters of healthy males up to 10 months following vaccination.

Local and Systemic Immunity Are Impaired in End-Stage-Renal-Disease Patients Treated With Hemodialysis, Peritoneal Dialysis and Kidney Transplant Recipients Immunized With BNT162b2 Pfizer-BioNTech SARS-CoV-2 Vaccine. Vaccination against COVID-19 in patients with end-stage renal disease (ESRD) on replacement therapy and kidney transplant recipients (KTRs) is particularly important due to the high mortality rate. Here, we tested the local and systemic immunity to the novel Pfizer BioNTech (BNT162b2) messenger RNA (mRNA) in ESRD, KTR patients, and healthy individuals (150 subjects). The ESRD group was divided into: hemodialysis (HD) and peritoneal dialysis

(PD). We investigated the local and systemic immunity based on anti-N (nucleoprotein) and anti-S (spike1/2) Immunoglobulin A (IgA) and Immunoglobulin G (IgG) antibodies, respectively. Additionally, we performed an Interferon gamma (IFN-Î³) release test Interferon-gamma release assay (IGRA) to monitor the cellular component of vaccine response. The control group had the highest level of anti-S IgG antibodies (153/2,080 binding antibody units (BAU)/ml) among all analyzed patients after the 1st and 2nd dose, respectively. The HD group (48/926 BAU/ml) had a diminished antibody level compared to PD (93/1,607 BAU/ml). Moreover, the seroconversion rate after the 1st dose was lower in HD than PD (56% vs. 86%). KTRs had extremely low seroconversion (33%). IgA-mediated immunity was the most effective in the control group, while other patients had diminished IgA production. We observed a lower percentage of vaccine responders based on the IFN-Î³ level in all research participants (100% vs. 85% in control, 100% vs. 80% in PD, 97% vs. 64% in HD). 63% of seropositive KTRs had a positive IGRA, while 28% of seronegative patients produced IFN-Î³. Collectively, PD patients had the strongest response among ESRD patients. Two doses of the Pfizer vaccine are ineffective, especially in HD and KTRs. A closer investigation of ESRD and KTRs is required to set the COVID-19 vaccine clinical guidance. CLINICAL TRIAL REGISTRATION NUMBER: www.ClinicalTrials.gov, identifier: NCT04 905 862.

Case Report: Subacute thyroiditis after receiving inactivated SARS-CoV-2 vaccine (BBIBP-CorV). BACKGROUND: Subacute thyroiditis, an inflammatory disease, has been reported caused by vaccines in rare cases. In the context of the coronavirus disease 19 pandemic, various SARS-CoV-2 vaccines have been developed and may be potential triggers for subacute thyroiditis. CASE PRESENTATION: We report a case of subacute thyroiditis 3 days after receiving the second dose of inactivated SARS-CoV-2 vaccine (BBIBP-CorV). The patient did not report a previous history of thyroid disease, upper respiratory tract infection, or COVID-19. Physical examination, laboratory testing, ultrasonography, and radioactive iodine uptake were consistent with subacute thyroiditis. During follow-up, the patient recovered from symptoms and signs, and imaging changes except for hypothyroidism, requiring an ongoing thyroxine replacement. CONCLUSIONS: Inactivated SARS-CoV-2 vaccine may be a causal trigger leading to subacute thyroiditis. Clinicians should be aware of subacute thyroiditis as a possible thyroid-related side effect of an inactivated SARS-CoV-2 vaccine.

Morphoea and COVID-19 vaccination.

Post-COVID-19 vaccine small-fiber neuropathy and tinnitus treated with plasma exchange.

Genetic basis of sudden death after COVID-19 vaccination in Thailand. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 vaccination reduces morbidity and mortality associated with coronavirus disease 2019 (COVID-19); unfortunately, it is associated with serious adverse events, including sudden unexplained death (SUD). OBJECTIVE: We aimed to study the genetic basis of SUD after COVID-19 vaccination in Thailand. METHODS: From April to December 2021, cases with natural but unexplained death within 7 days of COVID-19 vaccination were enrolled for whole exome sequencing. RESULTS: Thirteen were recruited, aged between 23 and 72 years; 10 (77%) were men, 12 were Thai; and 1 was Australian. Eight (61%) died after receiving the first dose of vaccine, and 7 (54%) died after receiving ChAdOx1 nCoV-19; however, there were no significant correlations between SUD and either the number or the type of vaccine. Fever was self-reported in 3 cases. Ten (77%) and 11 (85%) died within 24 hours and 3 days of vaccination, respectively. Whole exome sequencing analysis revealed that 5 cases harbored SCN5A variants that had previously been identified in patients with Brugada syndrome, giving an SCN5A variant frequency of 38% (5 of 13). This is a significantly higher rate than that observed in Thai SUD cases occurring 8-30 days after COVID-19 vaccination during the same period (10% [1 of 10]), in a Thai SUD cohort studied before the COVID-19 pandemic (12% [3 of 25]), and in our in-house exome database (12% [386 of 3231]). CONCLUSION: These findings suggest that SCN5A variants may be associated with SUD within 7 days

of COVID-19 vaccination, regardless of vaccine type, number of vaccine dose, and presence of underlying diseases or postvaccine fever.
Management of oral lesions following COVID-19 vaccination.
Outcome after single dose of ChAdOx1 vaccine against SARS-CoV-2 infection at 16 weeks post-vaccination among healthy adults in Saudi Arabia. BACKGROUND: The rate of severe acute respiratory syndrome coronavirus 2 (SARS CoV-2) infection and immunogenicity of a single dose of ChAdOx1 vaccine at 16 weeks post-vaccination among young and healthy participants remains unclear in Saudi Arabia. OBJECTIVES: Assess the rate of subsequent infection and immunogenicity of a single dose of ChAdOx1 vaccine at 16 weeks post-vaccination in a sample of healthy and young participants. DESIGN: Cross-sectional study SETTING: Academic teaching hospital in Riyadh, Saudi Arabia SUBJECTS AND METHODS: Healthy participants 18-50 years of age, who received one dose of ChAdOx1 vaccine and had no history of SARS CoV-2 infection were recruited, and blood samples were obtained 16 weeks after vaccination to assess immunogenicity using a commercially available kit. MAIN OUTCOME MEASURES: The rate of SARS-CoV-2 infection within 16 weeks post-vaccination. SAMPLE SIZE: 385 participants with median (IQR) age of 34 (29-38) years. RESULTS: Eleven (2.8%) participants acquired polymerase chain reaction (PCR)-confirmed infection within 16 weeks after a single dose of ChAdOx1 vaccine (mean [SD] 42.5 [28] days post-vaccination). No hospital or intensive care unit admissions occurred among the subjects in this sample. Females were significantly over-represented in PCR-confirmed cases of SARS-CoV-2 infection, with 10 of 11 infections occurring in females (P=.006). Antibody response against anti-spike IgG were detectable in 92.7% of subjects at 16 weeks' post-vaccination. The median anti-spike IgG level after vaccination was 273.1 (IQR 107-1052 AU/mL). However, the anti-nucleocapsid IgG antibody demonstrated a sensitivity of only 20%. CONCLUSION: A single dose of ChAdOx1 vaccine in healthy and young individuals was associated with a low, single-digit rate of PCR-confirmed infection, most of which were mild. LIMITATIONS: Small sample size and single-center. CONFLICT OF INTEREST: None.
Immunity to a third BNT162B2 COVID-19 vaccine after heart transplantation: Bridging the knowledge gap to end the pandemic for organ transplant recipients.
Immunogenicity and safety of a SARS-CoV-2 inactivated vaccine (CoronaVac) co-administered with an inactivated quadrivalent influenza vaccine: A randomized, open-label, controlled study in healthy adults aged 18 to 59Â years in China. BACKGROUND: Studies are needed for evidence of inactivated COVID-19 vaccine co-administered with influenza vaccine. METHODS: A randomized, open-label, controlled study was conducted in Zhejiang Province, China. Eligible healthy adults aged 18-59Â years underwent randomization at a ratio of 1:1:2 to receive inactivated quadrivalent influenza vaccine (IIV4) either concomitantly with the first (C1 subgroup) or the second (C2 subgroup) dose of CoronaVac, or 14Â days after the first dose of CoronaVac (S group). The primary purpose of the study was to prove the non-inferiority in seroconversion rate of antibody against SARS-CoV-2. RESULTS: Overall, 480 participants were enrolled, with 120, 120, and 240 randomly assigned to the C1, C2, and S groups, respectively. As lower bound of the two-sided 95% confidence interval (CI) of the difference for the seroconversion rate of antibodies against SARS-CoV-2 was over -10%, the immune response for CoronaVac in the C group (93.1% [89.0, 96.0]) was non-inferior to that in the S group (95.2% [91.5, 97.6]) in the per-protocol set. A lower GMT of antibody against SARS-CoV-2 was observed in the C group as compared to the S group (27.5 vs. 38.1, PÂ =Â 0.0001). Decrease of immune response to CoronaVac was mainly observed in participants received IIV4 concomitantly with their second dose of CoronaVac (C2 subgroup), with a seroconversion rate of 89.7% (95CI: 82.6%-94.5%) and a GMT of 23.3. The occurrences of vaccine related adverse reactions were no more than 20% and comparable among different groups. Most of the adverse reactions were mild and moderate. CONCLUSION: Co-administration of inactivated COVID-19 vaccine and seasonal influenza

vaccine, especially the administration regimen that the seasonal influenza vaccine co-administered with the first dose of the inactivated COVID-19 vaccine, would be feasible.

Reply to Letter to the Editor Regarding: "Myocarditis and Cardiac Complications Associated With COVID-19 and mRNA Vaccination".

SARS-CoV-2 mRNA Vaccination-induced Autoimmune Polyarthritis-like Rheumatoid Arthritis.

Neuropsychiatric sequelae of COVID-19 after vaccination: A gathering storm?

Curbing COVID-19 Vaccine Hesitancy from a Dermatological Standpoint: Analysis of Cutaneous Reactions in the Vaccine Adverse Event Reporting System (VAERS) Database. OBJECTIVES: Adverse reactions to the COVID-19 vaccines have been of interest since their emergency authorization. Cutaneous manifestations of the vaccines are not well studied. We aimed to characterize cutaneous reactions to the Moderna (mRNA-1273) and the Pfizer-BioNTech (BNT162b2) COVID-19 vaccines on a large, national scale. METHODS: The Vaccine Adverse Event Reporting System was filtered for cutaneous and hair and nail reactions to the COVID-19 vaccines. Patient demographics and past medical histories, vaccine manufacturer and dosing, symptom timing, reaction location, and patient outcomes were extracted from each report. RESULTS: As of December 24, 2021, there were 67,273 cutaneous reactions to all COVID-19 vaccines, with most patients receiving the Moderna (mRNA-1273) or Pfizer-BioNTech (BNT162b2) vaccines. The most common reactions overall were injection-site reaction, urticaria, and papular rash, with injection-site reaction more common after the Moderna (mRNA-1273) vaccine, and all other cutaneous reactions more common after the Pfizer-BioNTech (BNT162b2) vaccine. Patients with past histories of psoriasis, urticaria, and local site reactions to a vaccine were more likely to report these same symptoms after the COVID-19 vaccine. CONCLUSION: Patients should be counseled about these potential dermatologic reactions to the COVID-19 vaccines. Most occur within the first few days after vaccination, and are mild and self-limiting. Patients should therefore be encouraged that it is safe to receive the COVID-19 vaccine from a dermatological perspective.

Immunogenicity and safety of an inactivated SARS-CoV-2 vaccine (Sinopharm BBIBP-CorV) coadministered with quadrivalent split-virion inactivated influenza vaccine and 23-valent pneumococcal polysaccharide vaccine in China: A multicentre, non-inferiority, open-label, randomised, controlled, phase 4 trial. BACKGROUND: The safety and immunogenicity of the coadministration of an inactivated SARS-CoV-2 vaccine (Sinopharm BBIBP-CorV), quadrivalent split-virion inactivated influenza vaccine (IIV4), and 23-valent pneumococcal polysaccharide vaccine (PPV23) in adults in China is unknown. METHODS: In this open-label, non-inferiority, randomised controlled trial, participants agedÂ â‰¥Â 18Â years were recruited from the community. Individuals were eligible if they had no history of SARS-CoV-2 vaccine or any pneumonia vaccine and had not received an influenza vaccine during the 2020-21 influenza season. Eligible participants were randomly assigned (1:1:1), using block randomization stratified, to either: SARS-CoV-2 vaccine and IIV4 followed by SARS-CoV-2 vaccine and PPV23 (SARS-CoV-2Â +Â IIV4/PPV23 group); two doses of SARS-CoV-2 vaccine (SARS-CoV-2 vaccine group); or IIV4 followed by PPV23 (IIV4/PPV23 group). Vaccines were administered 28Â days apart, with blood samples taken on day 0 and day 28 before vaccination, and on day 56. RESULTS: Between March 10 and March 15, 2021, 1152 participants were recruited and randomly assigned to three groups (384 per group). 1132 participants were included in the per-protocol population (375 in the SARS-CoV-2Â +Â IIV4/PPV23 group, 380 in the SARS-CoV-2 vaccine group, and 377 in the IIV4/PPV23 group). The seroconversion rate (100Â % vs 100Â %) and GMT (159.13 vs 173.20; GMT ratio of 0.92 [95Â % CI 0.83 to 1.02]) of SARS-CoV-2 neutralising antibodies in the SARS-CoV-2Â +Â IIV4/PPV23 group was not inferior to those in the SARS-CoV-2 vaccine group. The SARS-CoV-2Â +Â IIV4/PPV23 group was not inferior to the IIV4/PPV23 group in terms of seroconversion rates and GMT of influenza virus antibodies for all strains except for the

seroconversion rate for the B/Yamagata strain. The SARS-CoV-2Â +Â IIV4/PPV23 group was not inferior to the IIV4/PPV23 group regarding seroconversion rates and GMC of Streptococcus pneumoniae IgG antibodies specific to all serotypes. All vaccines were well tolerated. CONCLUSIONS: The coadministration of the inactivated SARS-CoV-2 vaccine and IIV4/PPV23 is safe with satisfactory immunogenicity. This study is registered with ClinicalTrials.gov, NCT04790851.

Longitudinal determination of BNT162b2 vaccine induced strongly binding SARS-CoV-2 IgG antibodies in a cohort of Romanian healthcare workers. Mass vaccination against the disease caused by the novel coronavirus (COVID-19) was a crucial step in slowing the spread of SARS-CoV-2 in 2021. Even in the face of new variants, it still remains extremely important for reducing hospitalizations and COVID-19 deaths. In order to better understand the short- and long-term dynamics of humoral immune response, we present a longitudinal analysis of post-vaccination IgG levels in a cohort of 166 Romanian healthcare workers vaccinated with BNT162b2 with weekly follow-up until 35Â days past the first dose and monthly follow-up up to 6Â months post-vaccination. A subset of the patients continued with follow-up after 6Â months and either received a booster dose or got infected during the Delta wave in Romania. Tests were carried out on 1694 samples using a CE-marked IgG ELISA assay developed in-house, containing S1 and N antigens of the wild type virus. Participants infected with SARS-CoV-2 before vaccination mount a quick immune response, reaching peak IgG levels two weeks after the first dose, while IgG levels of previously uninfected participants mount gradually, increasing abruptly after the second dose. Overall higher IgG levels are maintained for the previously infected group throughout the six month primary observation period (e.g. 36-65Â days after the first dose, the median value in the previously infected group is 5.29 AU/ml, versus 3.58 AU/ml in the infection naÃ¯ve group, pÂ less thanÂ 0.001). The decrease of IgG levels is gradual, with lower median values in the infection naÃ¯ve cohort even 7-8Â months after vaccination, compared to the previously infected cohort (0.7 AU/ml versus 1.29 AU/ml, pÂ =Â 0.006). Administration of a booster dose yielded higher median IgG antibody levels than post second dose in the infection naÃ¯ve group and comparable levels in the previously infected group.

Varicella-Zoster virus reactivation following severe acute respiratory syndrome coronavirus 2Â vaccination or infection: New insights. INTRODUCTION: Varicella zoster virus (VZV) reactivation has been reported following vaccination for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), but the real extent remains unknown. METHODS: We conducted a systematic review to summarize evidence of VZV reactivation or infection following SARS-CoV-2 vaccination. Episodes after coronavirus disease-2019 (COVID-19) were also identified. Related articles were identified in PubMed and EMBASE databases till December 31, 2021 using the terms "varicella zoster" and "COVID-19â€³. PROSPERO Register Number: CRD42021289399. RESULTS: The search revealed 314 articles, of which 55 met the inclusion criteria. VZV manifestations were documented in 179 (82.1%) subjects following SARS-CoV-2 vaccination and in 39 (17.9%) patients with COVID-19. Among the vaccinated, median (IQR) age was 56.5 (42-70) years, and 56.8% were female. Twenty-one (16.8%) were immunosuppressed. The median (IQR) latency time after vaccination was 6 (3-10) days, and 84.4% received mRNA vaccines. VZV reactivation occurred following a first dose (68.2%), a second dose (12.8%) or a booster (0.6%). The most important VZV manifestation was dermatome herpes zoster rash, which accounted for 86.4% of events in vaccinated subjects. Twenty patients (11.3%) presented serious VZV events after vaccination, with Herpes Zoster ophthalmicus (5.6%) and post-herpetic neuralgia (3.4%) predominating. No VZV pneumonia or deaths were recorded. Antiviral prescriptions were made in 96.2% of vaccinated subjects. No significant differences between vaccinated and infected subjects were found. CONCLUSION: This study indicates that the occurrence of VZV reactivation is clinically relevant. However, our findings suggest that COVID-19 vaccination is safe, and remains strongly recommended.

Mortality Due to COVID-19 in Renal Transplant Recipients, Related to Variants of SARS-CoV-2 and Vaccination in Mexico. BACKGROUND: SARS-CoV-2 infection in transplant patients has shown greater lethality and vaccination in this group of patients has shown less information. The objective of this study is to show the statistics in Mexico of lethality in kidney recipients infected with COVID-19 in relation to vaccination and variants of the coronavirus. METHODS: This is a bibliographic search of kidney transplant recipient patients since the start of the pandemic in Mexico to determine lethality after SARS-CoV-2 compared to the general population and in relation to patients, the 4 most important infectious peaks in the country due to identified variants, and also before and after vaccination. RESULTS: The global lethality is 26.91% from the beginning of the pandemic to April 9, 2022 in kidney recipients in Mexico (130 deaths of 483 infected kidney transplant recipients) compared to the national lethality of 5.60%. Variant B. 1.1.220 represented the highest lethality with 30.43% and the lowest lethality was Omicron with 16.41%. The lethality prior to vaccination was 30.94% and 23.46% after it. CONCLUSION: Both some variants and vaccination have influenced a lower lethality due to COVID-19 in Mexico in kidney transplant patients; It is important to consider global recommendations, such as a third or fourth dose, a combination of mRNA vaccines and vectors in order to reduce lethality in this group of patients.

New-Onset Myasthenia Gravis Confirmed by Electrodiagnostic Studies After a Third Dose of SARS-CoV-2 mRNA-1273 Vaccine. Coronavirus disease 2019 vaccine-related pathology is a rare occurrence with few reported cases. We report on a case of a 60-yr-old man experiencing symptoms of dysphagia, dysarthria, diplopia, and weakness with onset 6 days after receiving a third full dose of SARS-CoV-2 vaccine (mRNA-1273 vaccine) in August 2021, which he received outside of the Center for Disease Control recommended guidelines, at 4 mos after his second dose of the Moderna vaccination course in March 2021. The Food and Drug Administration Emergency Use Authorization for mRNA-1273 booster was established in October 2021.Over the next month, the patient's symptoms progressed including his inability to swallow, requiring hospitalization due to dehydration and malnutrition. Evaluation including laboratory prompted referral for electrodiagnostic studies consisting of repetitive nerve stimulation studies and needle electromyography, confirming a case of new onset bulbar myasthenia gravis.

Hesitancy and reactogenicity to mRNA-based COVID-19 vaccines-Early experience with vaccine rollout in a multi-site healthcare system. BACKGROUND: Hesitancy and incomplete vaccination against coronavirus disease 2019 (COVID-19) remains an obstacle to achieving herd immunity. Because of fear of vaccine reactions, patients with medical and allergic co-morbidities express heightened hesitancy. Limited information is available to guide these patients. We sought to identify factors associated with mRNA-based COVID-19 vaccines hesitancy and reactogenicity. METHODS: We surveyed employees of a multi-site health system in central Pennsylvania who were offered the COVID-19 vaccine (N = 18,740) inquiring about their experience with the Moderna and Pfizer-BioNTech mRNA-based vaccines. The survey was administered online using the REDCap platform. We used multivariable regression analysis to determine whether a particular factor(s) (e.g., demographics, selected co-morbid allergic and medical conditions, vaccine brand, and prior COVID-19) were associated with vaccine reactogenicity including the occurrence and severity of local and systemic reactions. We also explored factors and reasons associated with vaccine hesitancy. RESULTS: Of the 5709 who completed the survey (response rate, 30.4%), 369 (6.5%) did not receive the vaccine. Black race and allergy to other vaccines were associated with vaccine hesitancy. Reaction intensity following the first vaccine dose and allergic co-morbidities were associated with incomplete vaccination. Older individuals (>60 years) experienced less reactogenicity. Females had higher odds of local and systemic reactions and reported more severe reactions. Asians reported more severe reactions. As compared to Pfizer-BioNTech, the Moderna vaccine was associated with higher odds of

vaccine reactions of higher severity. Prior COVID-19 resulted in more severe reactions following the first dose, but less severe reactions following the second dose. CONCLUSIONS: Targeted campaigns to enhance vaccination acceptance should focus on Black individuals, females, and those with allergic co-morbidities. Prior COVID-19 caused more severe reactions after the first but not the second vaccine dose. Moderna vaccine caused more vaccine reactions. Lessons learned from the early rollout of COVID-19 vaccine may serve to inform future novel vaccine experiences.

Adherence to Covid-19 mitigation measures and its associated factors among health care workers at referral hospitals in Amhara regional state of Ethiopia. INTRODUCTION: With fragile health care systems, sub-Saharan Africa countries like Ethiopia are facing a complex epidemic, and become difficult to control the noble coronavirus. The use of COVID-19 preventive measures is strongly recommended. This study aimed to assess the adherence of COVID-19 mitigation measures and associated factors among health care workers. METHODS: A facility-based cross-sectional study was conducted among health care workers at referral hospitals in the Amhara regional state of Ethiopia from May 15 to June 10; 2021. It was a web-based study using an online questionnaire. STATA 14.2 was used for data analysis. Variables with a p-value<0.05 at 95% confidence level in multivariable analysis were declared as statistically significant using binary logistic regression. RESULT: Adherence to COVID-19 mitigation measures was 50.24% in the current study. The odd of adherence of participants with a monthly income of â‰¥12801birr was 15% whereas the odds of adherence of participants who hesitate to take the COVID 19 vaccine were 10% as compared to those who don't hesitate. Participants who had undergone COVID-19 tests adhered 6.64 times more than their counterparts. Those who believe adequate measurements are taken by the government adhered 4.6 times more than those who believe not adequate. Participants who believe as no risk of severe disease adhered 16% compared to those with fear of severe disease. Presence of households aged >60years adhered about 7.9 times more than with no households aged>60. Participants suspected of COVID-19 diagnosis adhered 5.7 times more than those not suspected. CONCLUSION: In this study, a significant proportion of healthcare workers did not adhere to COVID-19 mitigation measures. Hence, giving special attention to healthcare workers with a monthly income of â‰¥12801 birr, being hesitant towards COVID-19 vaccine, being aged 26-30, and perceiving no risk of developing a severe infection is crucial to reduce non-adherence.

Communicating about COVID-19 vaccine development and safety. PURPOSE: Beliefs that the risks from a COVID-19 vaccine outweigh the risks from getting COVID-19 and concerns that the vaccine development process was rushed and lacking rigor have been identified as important drivers of hesitancy and refusal to get a COVID-19 vaccine. We tested whether messages designed to address these beliefs and concerns might promote intentions to get a COVID-19 vaccine. METHOD: We conducted an online survey fielded between March 8-23, 2021 with US Veteran (n = 688) and non-Veteran (n = 387) respondents. In a between-subjects experiment, respondents were randomly assigned to a control group (with no message) or to read one of two intervention messages: 1. a fact-box styled message comparing the risks of getting COVID-19 compared to the vaccine, and 2. a timeline styled message describing the development process of the COVID-19 mRNA vaccines. RESULTS: Most respondents (60%) wanted a COVID-19 vaccine. However, 17% expressed hesitancy and 23% did not want to get a COVID-19 vaccine. The fact-box styled message and the timeline message did not significantly improve vaccination intentions, $F(2,358) = 0.86$, $p = .425$, [Formula: see text] = .005, or reduce the time respondents wanted to wait before getting vaccinated, $F(2,306) = 0.79$, $p = .453$, [Formula: see text] = .005, compared to no messages. DISCUSSION: In this experimental study, we did not find that providing messages about vaccine risks and the development process had an impact on respondents' vaccine intentions. Further research is needed

to identify how to effectively address concerns about the risks associated with COVID-19 vaccines and the development process and to understand additional factors that influence vaccine intentions.

New onset and flare of rheumatic diseases following COVID-19 vaccination are mild and respond well to treatment: 9-month follow-up data from a single centre cohort. OBJECTIVES: Anti-COVID-19 vaccines have proved to be effective and well tolerated. Great attention is now being paid to the characterisation of possible adverse events associated to their administration. We report a case series of suspected rheumatic diseases (RDs) following anti-COVID-19 vaccination. METHODS: We included patients evaluated at first-aid rheumatologic consultancy and at rheumatologic outpatient and inpatient clinic at Padova University Hospital between May and September 2021 presenting with a RD within 30 days after an anti-COVID-19 vaccine dose. Our selection was in accordance with the World Health Organisation guidelines for adverse event following immunisation (AEFI) surveillance. Patients were regularly re-evaluated by telemedicine or face-to-face visit. RESULTS: We identified 30 cases of RD following vaccination: 24 (80.0%) new onsets and 6 (20.0%) flares. Most of patients (76.6%) received the BNT162b2 vaccine. The mean time to RD onset/flare was 12Â±9 days. The most common manifestations were inflammatory arthritis (40.0%), rheumatic polymyalgia (33.3%) and adult-onset Still's disease (13.3%). At the last FU visit (9.6Â±2.2 months), 83.3% of patients showed complete response to first- or second-line therapy, 13.3% a partial response and one patient (3.3%) was still experiencing an active disease. CONCLUSIONS: Considering the amount of vaccine doses administered during the evaluation period we overall detected a limited number of cases. We noted a clear prevalence of autoinflammatory conditions and seronegative manifestations. The great majority of patients had mild features and showed a good response to therapy.

Vulvar Aphthous Ulcers in an Adolescent After Coronavirus Disease 2019 (COVID-19) Vaccination. BACKGROUND: Nonsexually acquired genital ulcers have been described among girls who are prepubertal after various viral illnesses due to mucosal inflammation from an immunologic response. Until recently, nonsexually acquired genital ulcers have only been associated with viral infections. CASE: We present a case of an adolescent girl developing nonsexually acquired genital ulcers after both her first and second coronavirus disease 2019 (COVID-19) vaccine doses. Her course followed an expected timeline for severity and resolution of ulcers. CONCLUSIONS: Aphthous ulcers may arise from inflammatory effects of COVID-19 vaccination. Clinical monitoring after COVID-19 vaccination from all formulations should include assessment for nonsexually acquired genital ulcers if vaginal pain is reported.

Adverse events after COVID-19 vaccination self-reported by healthcare workers are reliable.

Use of biologics during the COVID-19 pandemic: lessons learned from psoriasis. INTRODUCTION: Given the increased infectious risk associated with biologics, particularly with TNFÎ± inhibitors, concerns were raised over the safety of these agents in relation to SARS-CoV-2 infection. Furthermore, the impact of biologics on SARS-CoV-2 vaccination was questioned. AREAS COVERED: In this review, studies conducted on patients with moderate to severe plaque psoriasis treated with biologics during the COVID-19 pandemic have been analyzed, including 1) the safety of biologics in psoriatic patients in terms of increased risk and/or worse outcome of SARS-CoV-2 infection; and 2) whether biologic agents could affect the safety and response to SARS-CoV-2 vaccines in psoriatic patients. EXPERT OPINION: Current evidence indicates that the use of biologics in psoriatic patients does not seem to be associated with an increased COVID-19 infection risk or worse outcome, with TNFÎ± inhibitors being even protective of severe COVID-19 relative to other treatments or no treatment at all. Furthermore, biologic treatment does not seem to have a significant impact on the response and safety of vaccines in patients with psoriasis treated with biologics. However, uncertainty remains given the limitations of current studies which are often of short duration, limited sample sizes and do not stratify on specific biologic classes.

COVID-19 Outcomes and Risk Factors Among People Living with HIV. PURPOSE OF REVIEW: In this review, we examine the intersection of the HIV and COVID-19 epidemics with focus on COVID-19-related health outcomes and risk factors for SARS-CoV-2 among people living with HIV (PLWH). RECENT FINDINGS: Evidence to date do not suggest a higher incidence of SARS-CoV-2 infection among PLWH compared to the general population, although-once exposed-PLWH are at greater risk of severe COVID-19 outcomes. Key risk factors for severe COVID-19 include non-HIV comorbidities known to be associated with severe disease, as well as HIV-specific risk factors such as low CD4â€‰+â€‰T-cell count, unsuppressed viral load, and tuberculosis co-infection. The disproportionate impact of the SARS-CoV-2 pandemic among Black, Latinx, and Native American/Alaskan Native PLWH could worsen pre-existing disparities in health outcomes among PLWH. Data on SARS-CoV-2 vaccine protection among PLWH needs additional study, although some studies suggest decreased humoral responses among those with low CD4â€‰+â€‰T-cell counts, while there is a signal of increased vaccine breakthrough rates among PLWH in two large observational cohorts. Data on post-acute sequelae of SARS-CoV-2 (PASC) among PLWH is also limited. PLWH do not have a higher susceptibility to SARS-CoV-2, but once exposed, they are at higher risk of severe COVID-19 outcomes. Additional resources will need to be dedicated to the development of interventions to improve health outcomes and address disparities among PLWH impacted by the COVID-19 pandemic.

The COVID-19 pandemic and children with PANS/PANDAS: an evaluation of symptom severity, telehealth, and vaccination hesitancy. The current study assessed the impact of the COVID-19 pandemic on children with PANS/PANDAS, a condition characterized by sudden-onset obsessive-compulsive, tic, or restrictive eating symptoms following infection. We conducted an anonymous survey between February and June 2021 of 254 self-reported caregivers of minors with PANS/PANDAS. Caregivers answered questions regarding PANS/PANDAS symptoms, telehealth care, and intention to vaccinate their child against COVID-19. PANS/PANDAS symptoms during COVID-19 infections were assessed when applicable. Children's OCD symptoms and coercive behaviors towards caregivers, along with the caregivers' mental health, relationship satisfaction, and burden, were assessed using standardized questionnaires. A majority of respondents endorsed a negative impact on their child's friendships, relationships with extended family, hobbies, and academic skills due to the pandemic. Children with suspected or diagnosed COVID-19 experienced new or worsened psychiatric symptoms, particularly mood lability, OCD, and anxiety. Telehealth care was the preferred treatment modality if the child had mild symptoms of PANS/PANDAS. A majority of caregivers reported high levels of relationship dissatisfaction and caregiver burden. As expected, these data suggest an overall negative impact of the COVID-19Â pandemic on children with PANS/PANDAS and their caregivers.

Acute Kidney Injury after First Dose of AstraZeneca COVID-19 Vaccine Managed in a Nigerian Hospital. INTRODUCTION: The association of kidney disease and COVID-19 vaccination has been reported with minimal change disease being a common presentation. CASE REPORT: Index patient is a 54-year-old female who presented with a history of reduction in urine output within 3 weeks of receiving the Oxford-AztraZeneca COVID-19 vaccine. Her serum creatinine on admission was 1,057 Âµmol/L with a premorbid serum creatinine of 78 Âµmol/L. Her vital signs were stable. She was on antihypertensive and antidiabetic medications for hypertension and diabetes mellitus, respectively. Renal biopsy was precluded by her morbid obesity and she was commenced on oral prednisolone. She had 5 sessions of hemodialysis and her serum creatinine gradually reduced to 106 Âµmol/L, and she is being followed up on an outpatient basis. CONCLUSION: We report a case of a female patient with acute kidney injury following COVID-19 Oxford-AztraZeneca vaccination. Further studies are required to better understand the pathogenesis of the renal affectation post-vaccination.

Reactive synovitis of the knee joint after COVID-19 vaccination: The first ultrastructural analysis of synovial fluid. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and the resulting coronavirus 2019 disease (COVID-19) have spread all around the world since 2019 and have affected millions of people. The development of COVID-19 vaccines helped to decelerate the spread of the virus. However, as in the case of vaccines against other infectious diseases, adverse events can also present with COVID-19 vaccines. CASE PRESENTATION: We report here a rare case of a 53-year-old man with knee-joint synovitis, after the first dose of messenger RNA vaccine, with no fever and a negative COVID-19 reverse transcription polymerase chain reaction test. During a clinical examination the suspicion of pyogenic arthritis was excluded by blood tests and by a complex joint effusion examination, including a microbiological and cytological-energy analysis of the synovial fluid. The treatment received by our patient consisted of 3 doses of dexamethasone administered intravenously over a period of 3â€‰days. All the symptoms improved after this therapy, and in the 3-week follow-up period we recorded full recovery with no consequences. CONCLUSION: Case reports on patients undergoing COVID-19 vaccination should be examined in order to detect rare and long-term side-effects. This is the first report to present the outcomes of an ultrastructural analysis of post-vaccination synovitis.

Self-reported side effects of the Oxford AstraZeneca COVID-19 vaccine among healthcare workers in Ethiopia, Africa: A cross-sectional study. INTRODUCTION: Ethiopia is the second most populous country in Africa. Ethiopia received most of its COVID-19 vaccines through donations. The Oxford AstraZeneca vaccine is the first to be donated to Ethiopia by the COVAX facility. Healthcare workers were the priority population that received the Oxford AstraZeneca COVID-19 vaccine. However, there was no nationwide study on the safety of the vaccine in Ethiopia. This study aimed to measure the prevalence and predictors of self-reported side effects of the Oxford AstraZeneca vaccine. MATERIALS AND METHODS: The study employed a cross-sectional design. A sample of healthcare workers who took Oxford AstraZeneca COVID-19 vaccine was drawn from four regions of Ethiopia; namely, Amhara, Oromia, Somali, and Southwest. Data were collected on sociodemographic characteristics, medical anamnesis, COVID-19 related anamnesis, and COVID-19 vaccine anamnesis via telephone interview. Descriptive and inferential analyses were done. The software, IBM SPSS Statistics v21.0, was used for analyses of data. RESULTS: Out of 384 people, 346 responded (response rate: 90.1%). Female accounted for 34.1% of the respondents. The mean age of the respondents was 31.0 years (Standard Deviation (SD) = 7.4). Nurses accounted for 43.7% of the respondents. The prevalence of at least one local- and systemic-side effect was 50.6 and 44.5%, respectively. The most frequent local- and systemic- side effect were injection site pain and headache, respectively. Both types of side effects mostly subsided in the first 3 days. A third of healthcare workers with side effects took at least one medication. Paracetamol followed by diclofenac sodium were taken by healthcare workers to overcome side effects. There was no independent predictor of local side effect. After controlling for age and chronic diseases, the odds of healthcare workers with COVID-19 like symptoms to experience systemic side effects was 1.38 (Confidence Interval (CI): 1.04-1.82) times more than that of healthcare workers without COVID-19 like symptoms. CONCLUSIONS: The prevalence of local- and systemic-side effects of the Oxford AstraZeneca COVID-19 vaccine was modest. As the symptoms were mostly common in the first 3 days, it is preferable to monitor healthcare workers at least in the first 3 days following the administration of the vaccine.

Exacerbation of Autoimmune Bullous Diseases After Severe Acute Respiratory Syndrome Coronavirus 2 Vaccination: Is There Any Association? BACKGROUND AND AIM: There have been concerns regarding the potential exacerbation of autoimmune bullous diseases (AIBDs) following vaccination against COVID-19 during the pandemic. In the current study, vaccine safety was evaluated in patients with AIBDs. METHODS: In this study, patients with AIBDs were contacted via face-to-face visits or

phone calls. Patient demographics, vaccine-related information, pre- and post-vaccine disease status, and complications were recorded. The exacerbation was considered either relapse in the remission/controlled phase of the disease or disease worsening in the active phase. The univariate and multivariate logistic regression tests were employed to determine the potential risk factors of disease exacerbation. RESULTS: Of the patients contacted, 446 (74.3%) reported receiving at least one dose of vaccine injection (54.7% female). Post-vaccine exacerbation occurred in 66 (14.8%) patients. Besides, there were 5 (1.1%) patients with AIBD diagnosis after vaccination. According to the analysis, for every three patients who received vaccines during the active phase of the disease one experienced disease exacerbation. The rate of disease exacerbation increased by three percent with every passing month from the last rituximab infusion. Active disease in the past year was another risk factor with a number needed to harm of 10. CONCLUSION: Risk of AIBD exacerbation after the COVID-19 vaccine is not high enough to prevent vaccination. This unwanted side effect, can be reduced if the disease is controlled at the time of vaccination.

Efficacy of Sinopharm Vaccine Among Stem Cell Transplant Recipients During Two Peaks of Delta and Omicron variants of COVID-19. BACKGROUND: Considering the dearth of research on the complications of Sinopharm coronavirus disease 2019 (COVID-19) vaccine in immunocompromised individuals and the lack of available data on COVID-19 vaccination from Iran. OBJECTIVE: This study aimed to investigate the efficacy of vaccine of Sinopharm COVID-19 vaccine and its complications in bone marrow transplant (BMT) recipients. METHODS: This was a retrospective cross-sectional study conducted on 250 patients with BMT who were referred to Montaserieh Hospital, Mashhad, Iran. Among them, 53 cases who received at least two doses of Sinopharm COVID-19 vaccine from March to January 2021 were entered in this study. The data were extracted from a student dissertation (Code:4000370). RESULTS: Sinopharm vaccine side effects were reported only in 7.7% of the patients, and shingles was the only serious side effect of the Sinopharm vaccine, which was observed only in one case. The results also revealed that Sinopharm COVID-19 vaccine side effects were not related to age or gender. Infection with the Delta variant of COVID-19 was reported in 7.5% (n=4) and no mortality was reported among them. Vaccine failure was reported in 39.6% of the cases; however, no mortality was reported among patients infected with the Omicron variant of COVID-19. CONCLUSION: In summary, it seems that Sinopharm COVID-19 vaccine adverse effects were not serious among stem cell transplant recipients. However, it may lead to some severe complications in the population. Vaccine failure against the Delta and Omicron variants of COVID-19 has been reported among more than one-third of BMT patients; however, no mortality was observed among BMT patients infected with the new variants of COVID-19.

Surveillance on Adverse Events Following COVISHIELD (ChAdOx1 nCoV-19) vaccination in Goa, India: An Observational Study. BACKGROUND: COVISHIELD, ChAdOx1 nCoV- 19 Corona Virus Vaccine was granted emergency use authorization (EUA) as the first vaccine in India in January 2021. Knowing what to anticipate after vaccination will reduce vaccine hesitancy in the public. This study aimed to identify and measure the adverse events following COVID-19 vaccination. MATERIALS AND METHODS: A cross-sectional observational study was conducted at Goa Medical College, starting on February 21 till May 23, 2021. A total of 418 people were enrolled. We collected the data using the Microsoft Form and analyzed using Microsoft Excel and R-program. RESULTS: Of the 418 vaccine recipients, the incidence rate of AEFI (Adverse Events Following Immunization) was 54.31%. Fever, fatigue, and headache were the most commonly reported systemic AEFIs. Among these, 54.7% of AEFI were mild, 42.38% were of the moderate category, and only 2.96% were of grade 3 severity. None of the AEFIs were severe enough for hospitalization. Most of them developed symptoms within 24 hours of the first dose. Complete recovery from AEFIs took a median time of 24 hours. CONCLUSION: Most of our study findings were consistent with the phase 1, 2/3 trials findings of

Oxford-AstraZeneca's ChAdOx1 vaccine. The AEFI symptoms were considered immune reactions to the vaccine. The AEFIs were more common among younger individuals and females. The chance of missing a serious adverse event like a thromboembolic phenomenon cannot be ruled out. We observed low AEFI rates with COVISHIELD in the Indian population compared to Oxford-AstraZeneca's ChAdOx1 vaccine in the UK-based population, which can be explained by preexisting immunity against adenovirus in the Indian population. However, based on the study findings, we may interpret that the COVISHIELD, Serum Institute of India, carries a good safety profile overall.

Protection against MIS-C outweighs the risk of myocarditis after Covid-19 vaccination in children. From March 2020 to July 2022, in Liguria region (North-West Italy) incidence of MIS-C among pediatric patients infected by SARS-CoV-2 was 38.7/100.000, which is higher than that of myocarditis after COVID-19 vaccination. In our opinion severity of MIS-C-related cardiac disease outweigh the risk of myocarditis after COVID-19 vaccine.

Assessing Case Fatality on Cases of Thrombosis with Concurrent Thrombocytopenia Following COVID-19 Vaccine AstraZeneca (Vaxzevria) in the United Kingdom: A Review of Spontaneously Reported Data. INTRODUCTION: Thrombotic thrombocytopenia syndrome (TTS) events were reported very rarely following the coronavirus disease 2019 (COVID-19) vaccine AstraZeneca (Vaxzevria). Clinical and demographic characteristics of the affected people, including the outcomes of TTS events, need to be examined using available information to better understand aspects of this association. OBJECTIVE: To analyse clinical and demographic information of TTS events, including calculating the case fatality of reported cases of TTS by age and sex, using spontaneously reported data from the UK's Yellow Card spontaneous reporting system of suspected adverse drug reactions. METHODS: TTS events reported to the Yellow Card scheme were extracted at weekly time points between 12 May 2021 and 25 May 2022. Cumulative numbers of TTS cases and deaths were recorded for each weekly interval, overall and stratified by age, sex, and vaccine dose. RESULTS: To 25 May 2022, 443 cases (81 fatal, 18.28%) had been reported in the UK. Events more frequently occurred following the first vaccine dose. No trends were observed for case fatality overall, or by age or sex. CONCLUSION: In the UK, case fatality of TTS events reported to the Medicines and Health products Regulatory Agency (MHRA) following Vaxzevria has been approximately 17-18% since May 2021. There were no statistical differences in fatality based on age or sex. Most reports followed the first vaccine dose; none have been reported following a third dose to date, although Vaxzervia was not recommended for a third dose of COVID-19 vaccine in the UK. TTS remains very rare, and benefits of vaccination outweigh the risks.

IgA vasculitis with transient glomerular hematuria, diarrhea, and pericarditis following COVID-19 mRNA vaccination in a young patient with possible pre-existing ulcerative colitis. Exacerbations or de novo autoimmune/autoinflammatory disease have been reported after COVID-19 vaccination. A young male presented with cutaneous IgA vasculitis with glomerular hematuria, diarrhea and pericarditis following his second COVID-19 mRNA vaccination. He also showed positivity for proteinase 3 anti-neutrophil cytoplasmic antibody (PR3-ANCA) and anti-cardiolipin antibody. Skin biopsy was compatible to IgA vasculitis. His purpura subsided and hematuria spontaneously disappeared. Treatment with anti-inflammatory medications and prednisolone resolved the pericarditis. He had a history of persistent diarrhea, and colonic biopsies showed possible ulcerative colitis without vasculitis. Kidney biopsy after prednisolone therapy revealed minor glomerular abnormalities without any immune reactants and did not show vasculitis. After prednisolone treatment, PR3-ANCA decreased in a medium degree despite of improvement of symptoms and inflammatory data, suggesting that his PR3-ANCA may be associated with ulcerative colitis. The cause of the transient glomerular hematuria was unclear, however, it might be caused by focal glomerular active lesions (glomerular vasculitis) due to vaccine-induced IgA vasculitis with nephritis. This case

highlights that COVID-19 mRNA vaccination can activate multiple autoimmune/autoinflammatory systems. The conditions might help us better understand the mutual mechanisms of the relevant disorders.

Retrospective review COVID-19 vaccine induced thrombotic thrombocytopenia and cerebral venous thrombosis-what can we learn from the immune response. INTRODUCTION: Cerebral Venous Thrombosis (CVT), prior to the COVID pandemic, was rare representing 0.5 of all strokes, with the diagnosis made by MRI or CT venography.(1-,3) COVID-19 patients compared to general populations have a 30-60 times greater risk of CVT compared to non-affected populations, and up to a third of severe COVID patients may have thrombotic complications.(4-8) Currently, vaccines are the best way to prevent severe COVID-19. In February 2021, reports of CVT and Vaccine-induced immune thrombotic thrombocytopenia (VITT) related to adenovirus viral vector vaccines including the Oxford-AstraZeneca vaccine (AZD1222 (ChAdOx1)) and Johnson & Johnson COVID-19 vaccine (JNJ-78436735 (Ad26.COV2Â·S)), were noted, with a 1/583,000 incidence from Johnson and Johnson vaccine in the United States.(11, 12) This study retrospectively analyzed CVT and cross-sectional venography at an Eastern Medical Center from 2018 to 2021, and presents radiographic examples of CVT and what is learned from the immune response. METHODS: After IRB approval, a retrospective review of cross-sectional CTV and MRVs from January 1st 2018 to April 30th 2021, at a single health system was performed. Indications, vaccine status, patient age, sex, and positive finding incidence were specifically assessed during March and April for each year. A multivariable-adjusted trends analysis using Poisson regression estimated venogram frequencies and multivariable logistic regression compared sex, age, indications and vaccination status. RESULTS AND DISCUSSION: From January 1, 2018 to April 30, 2021, (Fig. 1), a total of nÂ =Â 2206 in patient and emergency room cross-sectional venograms were obtained, with 322 CTVs and 1884 MRVs. In 2018, 2019, 2020, respective totals of cross-sectional venograms were 568, 657, 660, compared to 321 cross-sectional venograms in the first four months of 2021. CTV in 2018, 2019, 2020, respective totals were 51, 86, 97, MRV totals were 517, 571, 563, compared to the 2021 first four month totals of 88 CTVs and 233 MRVs. March, April 2018, 2019, 2020, CTVs respectively were 6, 17, 11, compared to the 2021 first four months of 59 CTVs, comprising 63% of the total 93 CTVs, respective MRVs were 79, 97, 52, compared to 143 MRVs in the first four months of 2021 for 39% of the total 371 MRVs. In March, April 2020 during the pandemic onset, cross-sectional imaging at the East Coast Medical Center decreased, as priorities were on maintaining patient ventilation, high level of care and limiting spread of disease. In March/April 2021, reports of VITT and CVT likely contributed to increased CTVs and MRVs, of 39.65% [1.20-1.63] increase (PÂ <Â 0.001) from prior. In March, April 2021 of 202 venograms obtained, 158 (78.2.%) were unvaccinated patients, 16 positive for CVT (10.1%), 44 were on vaccinated patients (21.7%), 8 specifically ordered with vaccination as a clinical indication, 2 positive for CVT (4.5%), (odds ratioÂ =Â 0.52 [0.12-2.38], pÂ =Â 0.200). CONCLUSION: CTV prior to the COVID pandemic, was rare, responsible for 0.5 of all strokes, at the onset of the pandemic in the East Coast, overall cross-sectional imaging volumes declined due to maintaining ventilation, high levels of care and limiting disease spread, although COVID-19 patients have a 30-60 times greater risk of CVT compared to the general population, and vaccination is currently the best option to mitigate severe disease. In early 2021, reports of adenoviral vector COVID vaccines causing CTV and VITT, led to at 39.65% increase in cross-sectional venography, however, in this study unvaccinated patients in 2021 had higher incidence of CVT (10.1%), compared to the vaccinated patients (4.5%). Clinicians should be aware that VITT CVT may present with a headache 5-30Â days post-vaccination with thrombosis best diagnosed on CTV or MRV. If thrombosis is present with thrombocytopenia, platelets <150Â Ã—Â 10(9), elevated D-Dimer >4000 FEU, and positive anti-PF4 ELISA assay, the diagnosis is definitive.(13) VITT CVT resembles spontaneous autoimmune heparin induced thrombocytopenia (HIT), and is postulated

to occur from platelet factor 4 (PF4) binding to vaccine adenoviral vectors forming a novel antigen, anti-PF4 memory B-cells and anti-PF4 (VITT) antibodies.(14-17).
Exploring the Trends of Acute Appendicitis Following Recovery or Vaccination From COVID-19. INTRODUCTION: The relationship that vaccination against corona virus disease 19 (COVID-19) or recovery from the acute form of the illness may have with the incidence or severity of acute appendicitis (AA) has not been explored. The aim of this study was to evaluate this relationship. METHODS: A single centre retrospective study of all consecutive adult patients presenting with AA in the 6Â mo after the initiation of a national vaccination program was performed. The presenting characteristics and pathological data of patients who had either been vaccinated against or recovered from COVID-19 were compared with those who had not. In addition, historical data from the equivalent period 12 and 24Â mo beforehand was also extracted. The incidence of AA was compared between each of these time-frames. RESULTS: Of the 258 patients initially identified, 255 were included in the analysis of which 156 had either been vaccinated and/or recovered from COVID-19 (61.2%) whilst 99 (38.8%) patients had not. When comparing these two groups, there were no significant differences in the presenting characteristics, operative findings or postoperative courses. There was also no significant change in the incidence of AA when comparing the study dates with historical data (median weekly incidence of AA 8.0 versus 8.0 versus 8.0 respectively, PÂ =Â 0.672). CONCLUSIONS: Based on the data presented here, we failed to find a relationship between a national vaccination program and both the nature and incidence of AA presenting to a busy urban hospital.
Safety of Booster Doses of Coronavirus Disease 2019 (COVID-19) Vaccine in Pregnancy in the Vaccine Adverse Event Reporting System. OBJECTIVE: To evaluate and summarize reports to the Vaccine Adverse Event Reporting System (VAERS), a national spontaneous reporting system, in pregnant people who received a booster dose of mRNA coronavirus disease 2019 (COVID-19) vaccine. METHODS: We searched VAERS for U.S. reports of adverse events in pregnant people who received a booster dose of an mRNA COVID-19 vaccine from September 22, 2021, to March 24, 2022. Clinicians reviewed reports and available medical records. RESULTS: The Vaccine Adverse Event Reporting System received 323 reports of adverse events in pregnant people who received a booster dose of COVID-19 vaccine; 178 (55.1%) after BNT162b2 from Pfizer-BioNTech and 145 (44.9%) after mRNA-1273 from Moderna. Seventy-two (22.3%) reports were coded as serious. One neonatal death was reported, but no maternal deaths occurred. Pregnancy-specific outcomes included 56 (17.3%) spontaneous abortions (before 20 weeks of gestation), eight (2.5%) episodes of vaginal bleeding, five (1.5%) stillbirths (at or after 20 weeks of gestation), four (1.2%) episodes of preeclampsia, and two (0.6%) preterm deliveries. Reporting rates for stillbirth and preterm delivery were below background rates. Ten instances of adverse events in neonates were reported, which included two reports of birth defects. Non-pregnancy-specific adverse events (n=207; 64.1%) were mostly systemic (eg, headache, fatigue) and local reactions and occurred in proportions comparable with those seen in pregnant people who received the primary COVID-19 vaccination series and reported to VAERS during the same period. CONCLUSION: Review of reports after a booster dose of mRNA COVID-19 vaccine in pregnant people in VAERS found their safety profile was comparable with that of published reports after primary COVID-19 vaccination in pregnant people.
Kidney transplantation from deceased donors with vaccine-induced thrombosis and thrombocytopenia (VITT): Definitely feasible and safe?
Safety of COVID-19 vaccine challenge in patients with immediate adverse reactions to prior doses: A multi-centre cohort study.
Reply to fever, Covid-19 vaccination, and Brugada syndrome-Incidence and management: Correspondence.

Effects of boosted mRNA and adenoviral-vectored vaccines on immune responses to omicron BA.1 and BA.2 following the heterologous CoronaVac/AZD1222 vaccination. The coronavirus 2019 omicron variant has surged rapidly and raises concerns about immune evasion even in individuals with complete vaccination, because it harbors mutations. Here we examine the capability of booster vaccination following CoronaVac/AZD1222 prime to induce neutralizing antibodies (NAbs) against omicron (BA.1 and BA.2) and T-cell responses. A total of 167 participants primed with heterologous CoronaVac/AZD1222 for 4-5 months were enrolled, to receive AZD1222, BNT162b2, or mRNA-1273 as a third dose. Reactogenicity was recorded. Immunogenicity analyses of severe acute respiratory syndrome coronavirus 2-binding antibodies were measured using enzyme-linked immunosorbent assay. The NAb titers against omicron BA.1 and BA.2 were determined using the focus reduction neutralization test (FRNT50) and total interferon-Î³ responses were measured to observe the T-cell activation. A substantial loss in neutralizing potency to omicron variant was found at 4-5 months after receiving the heterologous CoronaVac/AZD1222. Following booster vaccination, a significant increase in binding antibodies and neutralizing activities toward delta and omicron variants was observed. Neutralization to omicron BA.1 and BA.2 were comparable, showing the highest titers after boosted mRNA-1273 followed by BNT162b2 and AZD1222. In addition, individuals boosted with messenger RNA (mRNA) vaccines develop a T-cell response to spike protein, whereas those boosted with AZD1222 did not. Reactogenicity was mild to moderate without serious adverse events. Our findings demonstrated that mRNA booster vaccination is able to overcome waning immunity to provide antibodies that neutralize omicron BA.1 and BA.2, as well as a T-cell response.

Fever, COVID-19 vaccination, and Brugada syndrome: Incidence and management-Correspondence.

Severity of Illness Caused by Severe Acute Respiratory Syndrome Coronavirus 2 Variants of Concern in Children: A Single-Center Retrospective Cohort Study. BACKGROUND: Recent COVID-19 surges are attributed to emergence of more transmissible SARS-CoV-2 variants of concern (VOCs). The relative severity of VOCs in children is unknown. METHODS: We performed a single-center retrospective cohort study of children â‰¤18 years old diagnosed with COVID-19 from October 2020-February 2022 and whose SARS-CoV-2 isolate underwent Illumina sequencing. We measured the frequency of five markers of COVID-19 severity. Logistic regression models were fitted to estimate the odds of each severity marker with each VOC. RESULTS: Among 714 children, 471 (66.0%) were infected with a VOC: 96 (13.4%) alpha, 38 (5.3%) gamma, 119 (16.7%) delta, and 215 (30.1%) omicron. High-risk medical conditions and increasing age were independently associated with COVID-19 severity. After adjusting for age, race, ethnicity, high-risk medical conditions, and COVID-19 community incidence, neither alpha, delta, nor omicron was associated with severe COVID-19. Gamma was independently associated with hospitalization (OR 6.7, 95% CI 2.0-22.1); pharmacologic treatment (OR 5.7, 95% CI 1.2-26.8); respiratory support (OR 11.9, 95% CI 2.7-62.4); and severe disease per the WHO Clinical Progression Scale (OR 11.7, 95% CI 2.1-90.5). Upon subgroup analyses, omicron was independently associated with ICU admission and severe disease per the WHO Clinical Progression Scale in children without SARS-CoV-2 immunization or prior COVID-19 infection. CONCLUSIONS: Compared to non-VOC COVID-19, the gamma VOC was independently associated with increased COVID-19 severity, as was omicron in children without SARS-CoV-2 immunization or prior COVID-19 infection. SARS-CoV-2 vaccination and prior COVID-19 prevented severe outcomes during the omicron surge.

BNT162b2 mRNA Vaccination Against Coronavirus Disease 2019 is Associated With a Decreased Likelihood of Multisystem Inflammatory Syndrome in Children Aged 5-18 Years-United States, July 2021 - April 2022. BACKGROUND: Multisystem inflammatory syndrome in children (MIS-C), linked to antecedent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, is associated with considerable morbidity. Prevention of SARS-CoV-2 infection or coronavirus disease 2019 (COVID-

19) by vaccination might also decrease MIS-C likelihood. METHODS: In a multicenter, case-control, public health investigation of children ages 5-18 years hospitalized from 1 July 2021 to 7 April 2022, we compared the odds of being fully vaccinated (2 doses of BNT162b2 vaccine â‰¥28 days before hospital admission) between MIS-C case-patients and hospital-based controls who tested negative for SARS-CoV-2. These associations were examined by age group, timing of vaccination, and periods of Delta and Omicron variant predominance using multivariable logistic regression. RESULTS: We compared 304 MIS-C case-patients (280 [92%] unvaccinated) with 502 controls (346 [69%] unvaccinated). MIS-C was associated with decreased likelihood of vaccination (adjusted OR [aOR]: .16; 95% CI: .10-.26), including among children ages 5-11 years (aOR: .22; 95% CI: .10-.52), ages 12-18 years (aOR: .10; 95% CI: .05-.19), and during the Delta (aOR: .06; 95% CI: .02-.15) and Omicron (aOR: .22; 95% CI: .11-.42) variant-predominant periods. This association persisted beyond 120 days after the second dose (aOR: .08; 95% CI: .03-.22) in 12-18-year-olds. Among all MIS-C case-patients, 187 (62%) required intensive care unit admission and 280 (92%) vaccine-eligible case-patients were unvaccinated. CONCLUSIONS: Vaccination with 2 doses of BNT162b2 is associated with reduced likelihood of MIS-C in children ages 5-18 years. Most vaccine-eligible hospitalized patients with MIS-C were unvaccinated.

Case Report: Post-COVID-19 Vaccine Recurrence of Guillain-BarrÃ© Syndrome Following an Antecedent Parainfectious COVID-19-Related GBS. Guillain-BarrÃ© syndrome (GBS) is an autoimmune neurological disorder often preceded by viral illnesses or, more rarely, vaccinations. We report on a unique combination of postcoronavirus disease 2019 (COVID-19) vaccine GBS that occurred months after a parainfectious COVID-19-related GBS. Shortly after manifesting COVID-19 symptoms, a 57-year-old man developed diplopia, right-side facial weakness, and gait instability that, together with electrophysiology and cerebrospinal fluid examinations, led to a diagnosis of post-COVID-19 GBS. The involvement of cranial nerves and IgM seropositivity for ganglioside GD1b were noteworthy. COVID-19 pneumonia, flaccid tetraparesis, and autonomic dysfunction prompted his admission to ICU. He recovered after therapy with intravenous immunoglobulins (IVIg). Six months later, GBS recurred shortly after the first dose of the Pfizer/BioNTech vaccine. Again, the GBS diagnosis was confirmed by cerebrospinal fluid and electrophysiology studies. IgM seropositivity extended to multiple gangliosides, namely for GM3/4, GD1a/b, and GT1b IgM. An IVIg course prompted complete recovery. This case adds to other previously reported observations suggesting a possible causal link between SARS-CoV-2 and GBS. Molecular mimicry and anti-idiotype antibodies might be the underlying mechanisms. Future COVID-19 vaccinations/revaccinations in patients with previous para-/post-COVID-19 GBS deserve a reappraisal, especially if they are seropositive for ganglioside antibodies.

MRI Findings in Case of Post-COVID-19 Vaccination Rhabdomyolysis: A Rare Postvaccination Adverse Effect. In the era of this pandemic, without any proper and efficacious availability of antiviral agents against the novel coronavirus disease 2019 (COVID-19), vaccines have come as a hope for humankind. Although adverse reactions are common after getting the COVID-19 vaccine, serious or life-threatening side effects are very uncommon in these new emergency-approved vaccines. In this case report, we describe an unusual case of adverse reaction in a patient who received the COVID-19 vaccination. The patient who received the COVID-19 vaccination presented with progressive right lower limb pain and swelling, which further progressed to bilateral shoulder pain and swelling. Ultrasonography, Doppler, and magnetic resonance imaging of right lower limb were done for the patient.

Immune Thrombocytopenia in Previously Healthy Individuals Following SARS-CoV-2 Vaccination (COVID-19 Immunization): A Descriptive Research of 70 Instances With a Focus on Biomarkers, Predictive Outcomes, and Consequences. The coronavirus disease-2019 (COVID-19) pandemic is

exacerbating the worldwide healthcare crisis. The pandemic has had an impact on nearly every system of our body. The Food and Drug Administration (FDA) gave immediate authorization of several vaccines to avoid critical COVID-19 outcomes following the rapid spread of the COVID-19. There have only been a few cases of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination-induced immune thrombocytopenia (ITP) so far. There should be enough information to identify whether some vaccination adverse effects, such as ITP, are caused by the vaccine. This study aims to determine how common ITPÂ occurs after receiving the SARS-CoV-2 vaccine, as well as gender, age, symptoms, biomarkers, predicted outcomes, and sequelae. We looked at a number of research and compiled the best evidence of SARS-CoV-2 vaccine-induced thrombocytopenia currently available. To find the recommended reporting items, the search technique included keywords like "Immune thrombocytopenia,"Â "COVID-19,"Â "SARS-CoV-2," and "Vaccination."Â The search results were grouped using Boolean operators ("OR," "AND").

COVID-19 cases, hospitalizations and deaths after vaccination: a cohort event monitoring study, Islamic Republic of Iran. OBJECTIVE: To investigate the incidence of coronavirus disease 2019 (COVID-19) cases, hospitalizations and deaths in Iranians vaccinated with either AZD1222 Vaxzevria, CovIranÂ® vaccine, SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) or Sputnik V. METHODS: We enrolled individuals 18 years or older receiving their first COVID-19 vaccine dose between April 2021 and January 2022 in seven Iranian cities. Participants completed weekly follow-up surveys for 17 weeks (25 weeks for AZD1222) to report their COVID-19 status and hospitalization. We used Cox regression models to assess risk factors for contracting COVID-19, hospitalization and death. FINDINGS: Of 89â€‰783 participants enrolled, incidence rates per 1â€‰000â€‰000 person-days were: 528.2 (95% confidence interval, CI: 514.0-542.7) for contracting COVID-19; 55.8 (95% CI: 51.4-60.5) for hospitalization; and 4.1 (95% CI: 3.0-5.5) for death. Compared with SARS-CoV-2 Vaccine (Vero Cell), hazard ratios (HR) for contracting COVID-19 were: 0.70 (95% CI: 0.61-0.80) with AZD1222; 0.73 (95% CI: 0.62-0.86) with Sputnik V; and 0.73 (95% CI: 0.63-0.86) with CovIranÂ®. For hospitalization and death, all vaccines provided similar protection 14 days after the second dose. History of COVID-19 protected against contracting COVID-19 again (HR: 0.76; 95% CI: 0.69-0.84). Diabetes and respiratory, cardiac and renal disease were associated with higher risks of contracting COVID-19 after vaccination. CONCLUSION: The rates of contracting COVID-19 after vaccination were relatively high. SARS-CoV-2 Vaccine (Vero Cell) provided lower protection against COVID-19 than other vaccines. People with comorbidities had higher risks of contracting COVID-19 and hospitalization and should be prioritized for preventive interventions.

Eosinophil-rich linear IgA bullous dermatosis induced by mRNA COVID-19 booster vaccine. We present a case of eosinophil-rich linear IgA bullous disease (LABD) following the administration of a messenger RNA COVID-19 booster vaccine. A 66-year-old man presented to the emergency department with a 3-week history of a pruritic blistering rash characterized by fluid-filled bullae and multiple annular and polycyclic plaques. He was initially diagnosed with bullous pemphigoid based on a biopsy showing a subepidermal blister with numerous eosinophils. However, direct immunofluorescence studies showed linear IgA and IgM deposition along the basement membrane zone with no immunoreactivity for C3 or IgG. Additionally, indirect immunofluorescence was positive for IgA basement membrane zone antibody. The patient was subsequently diagnosed with LABD and initiated on dapsone therapy with resolution of his lesions at 3-month follow-up. This case illustrates the growing number of autoimmune blistering adverse cutaneous reactions from vaccination. Dermatopathologists should be aware that features of autoimmune blistering diseases can overlap and may not be distinguishable based on these histopathological findings alone. Confirmation with direct immunofluorescence and/or serological studies may be necessary for accurate diagnosis.

Chronic glucocorticoid maintenance treatment is associated with the risk of SARS-CoV-2 infection in patients with systemic lupus erythematosus who received vaccination.
Increasing COVID-19 vaccination in the United States: projected impact on cases, hospitalizations, and deaths by age and racial group. OBJECTIVES: Minority populations in the United States face a disproportionate burden of illness from COVID-19 infection and have lower vaccination rates compared with other groups. This study estimated the equity implications of increased COVID-19 vaccination in the United States, with a focus on the number of cases, hospitalizations, and deaths avoided. STUDY DESIGN: This was an observational real-world modeling study. METHODS: Data from the Centers for Disease Control and Prevention (CDC) were used to identify the remaining unvaccinated US population by county, age, and race as of October 22, 2021. The number of COVID-19 cases, hospitalizations, and deaths avoided were calculated based on case incidence and death data from the CDC, along with data on race- and age-specific hospitalization multipliers, under a scenario in which half of the remaining unvaccinated population per county, race, and age group obtained a full vaccine regimen. RESULTS: Vaccinating half of the remaining unvaccinated population in each age and race subgroup within counties would result in an estimated 22.09 million COVID-19 cases avoided, 1.38 million hospitalizations avoided, and 150,000 deaths avoided over 12 months. Some minority groups, particularly Black and Hispanic/Latino populations, were projected to experience substantial benefits from increased vaccination rates as they face both lower vaccination rates and worse outcomes if infected with COVID-19. CONCLUSIONS: Increasing COVID-19 vaccination in the United States not only benefits the population as a whole but also serves as a potentially useful lever to reduce the disproportionate burden of COVID-19 illness among minority populations.
Carotid free-floating thrombus during COVID-19 vaccine era: causality or not? Carotid free-floating thrombus (FFT) is very rarely diagnosed in patients with acute ischemic stroke. It is a real clinical emergency due to the significant risk of death associated with thromboembolic complications. Herein, we present three patients with ischemic stroke caused by carotid FFT after less than 20Â days from administration of mRNA vaccine BNT162b1 (Pfizer/BioNTech) for Severe Acute Respiratory Syndrome-CoronaVirus 2 (SARS-CoV-2). To our knowledge, these are the first cases reporting carotid FTT following SARS-CoV-2 vaccination.
New-onset IgA nephropathy following COVID-19 vaccination. Coronavirus disease 2019 (COVID-19) pandemic, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has caused significant economic and health damage worldwide. Rapid vaccination is one of the key strategies to curb severe illness and death due to SARS-CoV-2 infection. Hundreds of millions of people worldwide have received various COVID-19 vaccines, including mRNA vaccines, inactivated vaccines and adenovirus-vectored vaccines, but the side effects and efficacy of most vaccines have not been extensively studied. Recently, there have been increasing reports of immunoglobulin A nephropathy (IgAN) after COVID-19 vaccination, however, whether their relationship is causal or coincidental remains to be verified. Here, we summarize the latest clinical evidence of IgAN diagnosed by renal biopsy associated with the COVID-19 vaccine published by 10 July 2022 with the largest sample size, and propose a hypothesis for the pathogenesis between them. At the same time, the new opportunity presented by COVID-19 vaccine allows us to explore the mechanism of IgAN recurrence for the first time. Indeed, we recognize that large-scale COVID-19 vaccination has enormous benefits in preventing COVID-19 morbidity and mortality. The purpose of this review is to help guide the clinical assessment and management of IgA nephropathy post-COVID-19 vaccination and to enrich the 'multi-hit' theory of IgA nephropathy.
Impaired physical function in patients with idiopathic inflammatory myopathies: results from the multicentre COVAD patient-reported e-survey. OBJECTIVES: The assessment of physical function is fundamental in the management of patients with idiopathic inflammatory myopathies (IIMs). We

aimed to investigate the physical function of patients with IIMs compared with those with non-IIM autoimmune rheumatic diseases (AIRDs) utilizing Patient-Reported Outcome Measurement Information System (PROMIS) Physical Function (PF) data obtained in the COVAD study, an international self-reported e-survey assessing the safety of COVID-19 vaccines in AIRDs. METHODS: Demographics, AIRD diagnosis, disease activity, and PROMIS PF short form-10a data were extracted from the COVAD database. PROMIS PF-10a scores were compared between disease categories and stratified by disease activity. Factors affecting PROMIS PF-10a scores other than disease activity were identified by multivariable regression analysis in patients with inactive disease. RESULTS: A total of 1057 IIM patients, 3635 non-IIM AIRD patients and 3981 healthy controls (HCs) responded to the COVAD e-survey from April to August 2021. Using a binomial regression model, the predicted mean of PROMIS PF-10a scores was significantly lower in IIM patients compared with non-IIM AIRD patients or HCs [36.3 (95% CI 35.5, 37.1) vs 41.3 (95% CI 40.2, 42.5) vs 46.2 (95% CI 45.8, 46.6), Pâ€‰<â€‰0.001], irrespective of disease activity. The independent factors for lower PROMIS PF-10a scores in patients with inactive disease were older age, female, longer disease duration, and a diagnosis of inclusion body myositis or polymyositis. CONCLUSION: Physical function is significantly impaired in IIMs compared with non-IIM AIRDs or HCs, even in patients with inactive disease. Our study highlights a critical need for better strategies to minimize functional disability in patients with IIMs.

Vascular retinal findings after coronavirus disease 2019 vaccination: a correspondence.

Predictors of hospitalization and severe disease due to breakthrough SARS-CoV-2 infection in fully vaccinated individuals. OBJECTIVE: We aimed to identify risk factors for hospital admission and severe disease among fully vaccinated (FV) individuals with COVID-19. Further, we investigated if risk factors for hospitalization and severe disease are similar between unvaccinated (UV) and vaccinated individuals. METHODS: This was a multicenter, observational cohort analysis from a large regional healthcare system in metro Detroit using electronic health record data to evaluate risk factors for hospitalization and severe COVID-19 disease. Vaccination data were retrieved using electronic medical records linked to our statewide immunization database. Consecutive adult FV and UV patients with a primary admission diagnosis of COVID-19 were included in the comparative analysis. Partially vaccinated patients and patients who had received a booster dose were excluded. The primary outcome of this study was hospital admission and severe disease inclusive of intensive care unit (ICU) admission, mechanical ventilation, or death. RESULTS: Between December 15, 2020 and December 19, 2021, 20,584 emergency department visits met our inclusion criteria. Among these, 2005 (9.7%) visits consisted of FV individuals, 18,579 (90.3%) were UV, and 40.3% of UV and 52.7% of FV required hospitalization with similar (12.7% and 12.6%, respectively) rates of severe disease. Hospitalized UV patients with severe disease were younger than their FV counterparts (49.5% <65 years vs. 13.5% p < 0.001). Risk factors for severe disease on UV and FV included age â‰¥65 years (UV: adjusted odds ratio [aOR] 1.49, 95% confidence interval [CI] 1.28-1.73, p < 0.001 and FV: aOR 2.50, 95% CI 1.44-4.36 p = 0.001) and weighted Elixhauser score >10 (UV: aOR 9.11, 95% CI 6.92-12.00, p < 0.001 and FV: aOR 6.04, 95% CI 2.68-13.26, p < 0.001). However, only on UV status, body mass index (BMI) â‰¥30 kg/m(2) was associated with increased odds of severe disease (aOR 2.59, 95% CI 2.09-3.22, p < 0.001). CONCLUSIONS: FV patients with breakthrough SARS-CoV-2 infection who require hospitalization and have severe disease are older and have more medical comorbidities compared to UV patients. When comparing risk factors for severe disease between UV and FV individuals, FV status is particularly associated with reduced risk among patients with a BMI â‰¥30 kg/m(2) and a moderate number of medical comorbidities, regardless of age, highlighting the importance of vaccination in these particularly vulnerable groups.

COVID-19 vaccine humoral response in frequent platelet donors with plateletpheresis-associated lymphopenia. BACKGROUND: Plateletpheresis involves platelet separation and collection from whole blood while other blood cells are returned to the donor. Because platelets are replaced faster than red blood cells, as many as 24 donations can be done annually. However, some frequent apheresis platelet donors (>20 donations annually) display severe plateletpheresis-associated lymphopenia; in particular, CD4(+) T but not B cell numbers are decreased. COVID-19 vaccination thereby provides a model to assess whether lymphopenic platelet donors present compromised humoral immune responses. STUDY DESIGN AND METHODS: We assessed vaccine responses following 2 doses of COVID-19 vaccination in a cohort of 43 plateletpheresis donors with a range of pre-vaccination CD4(+) T cell counts (76-1537 cells/Î¼l). In addition to baseline T cell measurements, antibody binding assays to full-length Spike and the Receptor Binding Domain (RBD) were performed pre- and post-vaccination. Furthermore, pseudo-particle neutralization and antibody-dependent cellular cytotoxicity assays were conducted to measure antibody functionality. RESULTS: Participants were stratified into two groups: <400 CD4/Î¼l (nÂ =Â 27) andâ€‰â‰¥â€‰400 CD4/Î¼l (nÂ =Â 16). Following the first dose, 79% seroconverted within the <400 CD4/Î¼l group compared to 87% in the â‰¥400 CD4/Î¼l group; all donors were seropositive post-second dose with significant increases in antibody levels. Importantly differences in CD4(+) T cell levels minimally impacted neutralization, Spike recognition, and IgG Fc-mediated effector functions. DISCUSSION: Overall, our results indicate that lymphopenic plateletpheresis donors do not exhibit significant immune dysfunction; they have retained the T and B cell functionality necessary for potent antibody responses after vaccination.

Keratoplasty rejection after messenger RNA vaccine (BNT162b2) for COVID-19. This report shows a case of corneal transplant rejection after vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), short after receiving the BNT162b2 vaccine, in a patient who had undergone keratoplasty more than 20 years ago, with no previous episodes of rejection and no other factor that could lead to the findings on his examinations. After treatment with high doses of topic, oral, and sub-conjunctival corticoids, the patient had a favorable therapeutic response. The signs of corneal transplant rejection must be oriented to the patients and the causing factors actively searched by ophthalmologists so that treatment is rapidly initiated and sequels are avoided. This report raises the question if these events are correlated and whether the patient should receive the second dose of the vaccine against SARS-CoV-2 or not.

Hypogammaglobulinemia is associated with reduced antibody response after anti-SARS-CoV-2 vaccination in MS patients treated with antiCD20 therapies. BACKGROUND: COVID-19 vaccination is highly recommended to multiple sclerosis (MS) patients. Little is known about the role of patients' clinical and demographic characteristics in determining antibody response. METHODS: We evaluated safety and efficacy of anti-SARS-CoV-2 vaccines on 143 included MS patients. Then, we analyzed antibody titer in a subgroup, assessing clinical and demographic variables associated with protection and antibody titer. RESULTS: After completing the vaccination cycle, the rate of local adverse events was similar after the first and second dose. A higher proportion of systemic AEs was reported after the second dose (65.7% vs 24.5% after the first dose). Antibody response was evaluated in 97 patients. Higher EDSS (OR 0.6, 95% CI 0.4-0.9, pâ€‰=â€‰0.006) and treatment with antiCD20 (OR 0.02, 95% CI 0.003-0.098, p 0.001) were associated with a lower chance of having an efficacious response. Higher weight was associated with higher Ab titer (Î²â€‰=â€‰15.2, 95% CI 2.8-27.6, pâ€‰=â€‰0.017), while treatment with antiCD20 with lower titers (Î²â€‰=â€‰â€‰-â€‰1092.3, 95% CIâ€‰-â€‰1477.4 toâ€‰-â€‰702.2, pâ€‰<â€‰0.001). In patients treated with antiCD20, hypogammaglobulinemia (Î²â€‰-â€‰543, 95% CIâ€‰-â€‰1047.6 toâ€‰-â€‰39.1, pâ€‰=â€‰0.036) and treatment duration (Î²â€‰-â€‰182, 95% CIâ€‰-â€‰341.4 toâ€‰-â€‰24.3, pâ€‰=â€‰0.027) were associated with lower Ab titer. CONCLUSION: Our study confirms

that COVID-19 vaccination in MS patient is safe and effective in preventing symptomatic COVID-19 and should be recommended to all patients. Moreover, we suggest a possible role of hypogammaglobulinemia in reducing Ab response in patients treated with antiCD20 therapies.

Quality Measures for Patients at Risk of Adverse Outcomes in the Veterans Health Administration: Expert Panel Recommendations. IMPORTANCE: Despite longstanding efforts to improve health care quality for patients with complex needs who are at highest risk for hospitalization or death, to our knowledge, no guidance exists on what constitutes measurable high-quality care for this heterogeneous population. Identifying quality measures that are cross-cutting (ie, relevant to multiple chronic conditions and disease states) may enable health care professionals and health care systems to better design and report on quality improvement efforts for this patient population. OBJECTIVE: To identify quality measures of care and prioritize quality-of-care concepts in the ambulatory primary care setting for patients in the Veterans Health Administration (VHA) who have complex care needs and are at high risk for adverse outcomes, such as hospitalization or death. EVIDENCE REVIEW: In this expert panel assessment and prioritization, relevant measure concepts for future quality measure development in 3 care categories (assessment, management, and other features of health care) were extracted from a systematic review, conducted from June 2020 to June 2021, of published studies that suggested, evaluated, or used indicators of quality care for patients at high risk of adverse outcomes. Measure concepts associated with single conditions, surgical or other specialty care settings, and inpatient care were excluded. A panel of 14 experts (10 VHA leaders and staff, 2 non-VHA physician investigators, and 2 veterans) discussed and rated the importance of the remaining set of potentially relevant measure concepts using a modified RAND/UCLA Appropriateness Method on January 15, 2021. Measure concepts were rated on a scale of 1 to 9, with 9 being the highest priority. A median rating of 7.5 or greater was used as the cutoff to identify the highest-priority items. FINDINGS: The systematic review identified 519 measure concepts, from which 15 domains and 49 measure concepts were proposed for expert panel consideration. After panel discussions and changes to measure concepts, the expert panel rated 63 measure concepts in 13 domains. The measure concepts with the highest median ratings focused on caregiver availability and support, COVID-19 vaccination, and pneumonia vaccination (all rated 9.0); housing instability (rated 8.5); and physical function, depression symptoms, cognitive impairment, prescription regimen, primary care follow-up after an emergency department visit or hospitalization, and timely transmission of discharge information to primary care (all rated 8.0). Recommendations to improve care included timely assessment of housing instability, caregiver support, physical function, depression symptoms, and cognitive impairment; annual prescription regimen review; coordinated transitions in care; and preventive care including vaccinations. CONCLUSIONS AND RELEVANCE: The expert panelists identified a parsimonious set of high-priority, evidence-based, cross-cutting quality measure concepts for improving care of patients at high risk for adverse health outcomes in the VHA. These quality measures may inform both future research for patients at high risk and health care system quality improvement.

Association of Receiving a Fourth Dose of the BNT162b Vaccine With SARS-CoV-2 Infection Among Health Care Workers in Israel. IMPORTANCE: Despite the high 3-dose vaccination rate among health care workers (HCWs) in Israel, a high rate of SARS-CoV-2 breakthrough infections in this group was observed during the Omicron wave. As a result, the Israeli Ministry of Health decided to recommend a fourth vaccine dose to medical staff. OBJECTIVE: To evaluate the benefit of a fourth BNT162b2 vaccine dose on the breakthrough infection rate among HCWs. DESIGN, SETTING, AND PARTICIPANTS: This multicenter cohort study was performed in January 2022, the first month of the 4-dose vaccination campaign, during a surge of the Omicron variant wave. All health care workers at 11 general hospitals in Israel who had been vaccinated with 3 doses up to September 30, 2021, and

had not contracted COVID-19 before the vaccination campaign were included. EXPOSURES: Vaccination with a fourth dose of the BNT162b2 vaccine during January 2022. MAIN OUTCOMES AND MEASURES: Breakthrough COVID-19 infections in 4-dose recipients vs 3-dose recipients measured by a polymerase chain reaction test result positive for SARS-CoV-2. Health care workers were tested based on symptoms or exposure. RESULTS: A total of 29â€¯611 Israeli HCWs (19â€¯381 [65%] female; mean [SD] age, 44 [12] years) had received 3 vaccine doses between August and September 2021; of these, 5331 (18%) received the fourth dose in January 2022 and were not infected by the first week after vaccination. Overall breakthrough infection rates were 368 of 5331 (7%) in the 4-dose group and 4802 of 24280 (20%) in the 3-dose group (relative risk, 0.35; 95% CI, 0.32-0.39). Similar reductions were found in a matched analysis by the exact day of receiving the third vaccine (relative risk, 0.61; 95% CI, 0.54-0.71) and in a time-dependent Cox proportional hazards regression model (adjusted hazard ratio, 0.56; 95% CI, 0.50-0.63). In both groups, no severe disease or death occurred. CONCLUSIONS AND RELEVANCE: In this cohort study, the fourth BNT162b2 vaccine dose resulted in a reduced breakthrough infection rate among hospital staff. This reduction was lower than that observed after the third dose; nevertheless, considering the high infectivity of the Omicron variant, which led to critical medical staff shortages, a fourth vaccine dose should be considered to mitigate the infection rate among HCWs.

Eyelid edema following the first Pfizer-BioNTech COVID-19 vaccination: is it a coincidence? OBJECTIVE: This report describes an ocular allergic reaction manifested as eyelid edema after Pfizer-BioNTech COVID-19 vaccination. CASE DESCRIPTION: A 28-year-old female had the first Pfizer-BioNTech COVID-19 vaccine dose and was discharged following a 20-minute post-vaccination observation for potential adverse complications. She came to the emergency department after her left eyelid swelled unexpectedly two hours later, accompanied by itching and redness. Aside from left eyelid edema and redness, there were no other remarkable bilateral ocular findings. The lack of recent history of any cause of eyelid edema suggested a vaccine-induced ocular allergy. Immediate administration of systemic and topical anti-allergic medications resulted in a significant clinical improvement within 4-6 hours. CONCLUSIONS: Reporting any adverse reactions to vaccines, especially recently approved ones, is extremely critical. Local ocular allergy, as opposed to systemic allergy, could be considered one of the COVID 19 vaccine's rare and mild side effects.

COVID-19 and tinnitus: an initiative to improve tinnitus care. OBJECTIVE: To investigate the effects of COVID-19 on individuals with tinnitus and their views to guide future tinnitus care. DESIGN: A mixed-methods cross-sectional research design. STUDY SAMPLE: An online survey was completed by 365 individuals with tinnitus from Australia and other countries. RESULTS: Tinnitus was reported to be more bothersome during the pandemic by 36% of respondents, whereas 59% reported no change and 5% reported less bothersome tinnitus. Nearly half of the respondents had received COVID-19 vaccination(s) and 12% of them reported more bothersome tinnitus while 2% developed tinnitus post-vaccination. Australian respondents spent less time in self-isolation or quarantine and saw fewer change in in-person social contact than respondents from other countries. More than 70% of respondents thought that tinnitus care services were insufficient both before and during the pandemic. Regarding their opinions on how to improve tinnitus care in the future, five themes including alleviation of condition, government policies, reduced barriers, self- and public-awareness, and hearing devices were identified. CONCLUSIONS: A majority of respondents did not perceive any change in tinnitus perception and one-third of respondents had worsened tinnitus during the pandemic. To improve tinnitus care, better awareness and more accessible resources and management are crucial.

Myocarditis After Clozapine Initiation and mRNA SARS-CoV-2 Vaccination.

Adverse events after anti-COVID-19 vaccine administration: a six-month experience.

mRNA COVID-19 Vaccine-Associated Subserosal Eosinophilic Gastroenteritis: A Case Report. The World Health Organization declared coronavirus disease 2019 (COVID-19) a global pandemic in March 2020. Several vaccines have been developed to overcome the COVID-19 pandemic, and messenger RNA vaccines, commonly known as mRNA vaccines, were the first COVID-19 vaccines to be authorized in Korea. With the worldwide increase in vaccinations, reports of adverse reactions are increasing. However, to the best of our knowledge, there have been no reports of eosinophilic gastroenteritis (EGE) following mRNA vaccination. Here, we present the first case of EGE in a patient who received a second dose of the mRNA vaccine, BNT162b2 (Pfizer-BioNTech). A previously healthy 34-year-old woman presented to the emergency department with generalized abdominal pain for the preceding 2 weeks. She had received a second dose of the mRNA COVID-19 vaccine 2 weeks prior. Subserosal EGE was diagnosed, oral prednisolone was administered, and she recovered completely.

COVID-19 and vaccination during pregnancy: a systematic analysis using Korea National Health Insurance claims data. OBJECTIVE: This study systematically analyzed coronavirus disease 2019 (COVID-19) and vaccination details during pregnancy by using the national health insurance claims data. METHODS: Population-based retrospective cohort data of 12,399,065 women aged 15-49 years were obtained from the Korea National Health Insurance Service claims database between 2019 and 2021. Univariate analysis was performed to compare the obstetric outcomes of pregnant women (ICD-10 O00-O94) and their newborns (ICD-10 P00-P96) with and without COVID-19. Univariate analysis was also performed to compare the age and obstetric outcomes of pregnant women receiving different types of vaccines. RESULTS: The percentage of pregnant women with COVID-19 during pregnancy was 0.11%. Some obstetric outcomes of pregnant women with COVID-19, including the rates of preterm birth or cesarean delivery, were significantly better than those of pregnant women without COVID-19. The rate of miscarriage was higher in pregnant women with COVID-19 than without COVID-19. However, the outcomes of newborns of women with and without COVID-19 were not significantly different. Regarding vaccination type, obstetric outcomes of pregnant women appeared to be worse with the viral vector vaccine than with the mRNA vaccine. CONCLUSION: To the best of our knowledge, this is the first study to systematically analyze COVID-19 and vaccination details during pregnancy using the national health insurance claims data in Korea. The obstetric outcomes in pregnant women with and without COVID-19 and their newborns were similar.

mRNA vaccines induce rapid antibody responses in mice. mRNA vaccines can be developed and produced quickly, making them prime candidates for immediate outbreak responses. Furthermore, clinical trials have demonstrated rapid protection following mRNA vaccination. Thus, we sought to investigate how quickly mRNA vaccines elicit antibody responses compared to other vaccine modalities. We first compared the immune kinetics of mRNA and DNA vaccines expressing SARS-CoV-2 spike in mice. We observed rapid induction of antigen-specific binding and neutralizing antibodies by day 5 following mRNA (4â€‰Âµg/mouse), but not DNA (50â€‰Âµg/mouse), immunization. Comparing innate responses hours post immunization, the mRNA vaccine induced increased levels of IL-5, IL-6, and MCP-1 cytokines which maybe promoting humoral responses downstream. We then evaluated the immune kinetics of an HIV-1 mRNA vaccine in comparison to DNA, protein, and rhesus adenovirus 52 (RhAd52) vaccines of the same HIV-1 envelope antigen in mice. Again, induction of envelope-specific antibodies was observed by day 5 following mRNA vaccination, whereas antibodies were detected by day 7-14 following DNA, protein, and RhAd52 vaccination. Thus, eliciting rapid humoral immunity may be a unique and advantageous property of mRNA vaccines for controlling infectious disease outbreaks.

Chilblains After SARS-CoV-2 Vaccination: Coincidence or Real Association?

Infection with SARS-CoV-2 Omicron Variant 24 Days after Non-Omicron Infection, Pennsylvania, USA. A 42-year-old man, with up-to-date COVID-19 vaccination, experienced symptomatic SARS-CoV-2

infection in December 2021. Mutation tests suggested a non-Omicron variant. After his recovery, and 24 days after the first positive SARS-CoV-2 test, he had onset of symptomatic infection with the BA.1.1 (Omicron) variant, which was confirmed by whole-genome sequencing.
Acute Rejection Following COVID-19 Vaccination in Penetrating Keratoplasty in a Young Male - A Case Report and Review of Literature. PURPOSE: To report a case of a boy with acute keratoplasty rejection manifesting 12Â days after receiving BNT162b2 messenger RNA (mRNA) vaccine for COVID-19. STUDY DESIGN: A case report. RESULTS: A 15-year-old boy with a history of penetrating keratoplasty due to acanthamoeba keratitis developed corneal decompensation 12Â days after BNT162b2 messenger RNA vaccine for COVID-19 disease. One-week treatment with topical Dexamethasone 2% eye drops resulted in a complete resolution of corneal edema. CONCLUSIONS: This case suggests that BNT162b2 messenger RNA (mRNA) vaccine can be associated with acute keratoplasty rejection in children, which responds completely to topical steroids. Ophthalmologists should be aware of this risk of cornea decompensation after COVID-19 vaccine in children who received a cornea transplant.
Herpetic Eye Disease Following the SARS-CoV-2 Vaccinations. PURPOSE: To describe herpetic ocular infections following SARS-CoV-2 vaccinations. METHODS: A retrospective study of herpetic ocular infections after BNT162b2mRNA vaccination and a literature review. RESULTS: A cohort of five patients: three varicella zoster virus (VZV) and two herpes simplex virus (HSV) cases, as well as 19 literature cases: 9 cases of VZV and 10 cases of HSV post BNT162b2mRNA, AZD1222, mRNA-1273, and CoronaVac vaccinations. All cases presented within 28Â days post vaccination. Most VZV and HSV cases (15/19) reported in the literature presented post first vaccine dose, while in our cohort 2 VZV cases presented post second dose and both HSV cases and one VZV case post third dose. The most common presentations were HZO with ocular involvement and HSV keratitis. All eyes had complete resolution; however, one had retinal detachment and three corneal scars. CONCLUSION: Herpetic ocular infections may develop shortly after SARS-CoV-2 vaccinations. Overall, the outcome is good.
Orbital Inflammatory Pseudotumor following mRNA COVID-19 Vaccination. The authors present a case of orbital pseudotumor after mRNA COVID-19 vaccination. A 40-year-old otherwise healthy woman was referred to our oculoplastics unit because of left blepharoptosis of 2Â months duration starting 1 week after she received her first Pfizer-BioNTech mRNA vaccination. On presentation, her best-corrected visual acuity was 20/20 in each eye. The external examination revealed left blepharoptosis and mild upper eyelid swelling. Orbital magnetic resonance imaging revealed left lacrimal gland enlargement with homogeneous contrast enhancement and diffuse mild enlargement of the left lateral and superior rectus muscles. The results of the extended workup for autoimmune and infectious etiologies and the systemic examination findings were normal. Systemic corticosteroids were started for the orbital pseudotumor. The presented case of orbital pseudotumor development after the mRNA vaccine may be considered to be an immunological process targeting the orbital tissue following immunization, although the cause-effect relationship remains uncertain.
Possible COVID-19 MRNA Vaccine-Induced Case of Unilateral Central Retinal Vein Occlusion. PURPOSE: To report a case of a patient with central retinal vein occlusion (CRVO), 2Â weeks after the first dose of a COVID-19 mRNA vaccine. RESULTS: A 35-year-old man presented with decreased vision on his right eye, 2Â weeks after receiving the first dose of COVID-19 mRNA vaccine. During examination, signs of right CRVO were found. We started general checkup of the patient, extended with laboratory tests specific for VIPIT. No exact cause of the thromboembolic episode could be documented. With the applied therapy, symptoms resolved completely. CONCLUSION: CRVO after COVID-19 mRNA vaccination is reported only in one case in the literature. In our case, the young age of the patient, the close onset of the symptoms to the vaccination and the negative systemic, immunologic and hematologic tests are suggesting a vaccine-induced thrombotic mechanism. We

propose further investigation of vaccine-induced thrombotic mechanisms and also close follow of the reported cases.

Bilateral Acute Macular Neuroretinopathy after COVID-19 Vaccination and Infection. PURPOSE: To describe a case of acute macular neuroretinopathy (AMN) in a patient with recent COVID-19 vaccination and infection who demonstrated atypical features on presentation. OBSERVATIONS: A 64-year-old woman presented with central vision loss in both eyes (OU). She had recently received the Moderna COVID-19 vaccine and rapidly developed systemic symptoms. Testing revealed COVID-19 infection. Visual acuities were 20/200 OU and near-infrared reflectance revealed hypo-reflective lesions in the maculae OU, optical coherence tomography (OCT) showed outer nuclear layer thinning and ellipsoid zone disruption OU, and OCT-angiography showed flow voids in the deep capillary plexus and choriocapillaris OU, all consistent with AMN. She was treated with oral prednisone with subsequent mild vision improvement and persistent scotomas. DISCUSSION: COVID-19 associated AMN can present with a more severe clinical presentation than classically seen in AMN. Ischemic and inflammatory changes due to COVID-19 infection may contribute to this more advanced presentation.

Possible Association between Vogt-Koyanagi-Harada Disease and Coronavirus Disease Vaccine: A Report of Four Cases. Vogt-Koyanagi-Harada (VKH) syndrome is an autoimmune, multisystemic disease characterized by severe bilateral granulomatous posterior, which can occur due to viral infection or vaccination. We report four cases that had a likely association between VKH disease and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. Two patients had VKH symptoms within 1 and 2Â weeks after receiving the ChAdOx1 nCoV-19 vaccine. One patient presented with VKH symptoms 5Â days after receiving the BNT162b2 vaccine, and one patient had symptoms within 4Â weeks after receiving the CoronaVac vaccine. Early diagnosis and treatment of VKH disease are essential for the visual prognosis of this aggressive disease. Further in-depth studies are necessary to investigate this likely association to enable ophthalmologists to identify new assumed correlations between the diseases described in this study.

mRNA COVID-19 vaccines were linked to myocarditis at 28 d (0.15 to 10 excess events/100Â 000 vaccinated persons). Karlstad Ã˜, Hovi P, Husby A, et al. SARS-CoV-2 vaccination and myocarditis in a Nordic cohort study of 23 million residents. JAMA Cardiol. 2022;7:600-12. 35442390.

Trends in reporting embolic and thrombotic events after COVID-19 vaccination: A retrospective, pharmacovigilance study. With the progression of global vaccination against coronavirus disease 2019 (COVID-19), embolic and thrombotic events (ETEs) following COVID-19 vaccination continue to be reported. To date, most reports on the type of COVID-19 vaccine and ETEs have been based on clinical trials, and other reports include a small number of cases. Further, the relationship between the type of COVID-19 vaccine and ETEs has not been clarified. It is important to elucidate trends in the development of ETEs after vaccination, which is a crucial concern for both prospective patients and healthcare providers. In this retrospective, pharmacovigilance study, we analyzed the Vaccine Adverse Event Reporting System (VAERS) reports from January 1, 2020 to June 18, 2021, and performed signal detection and time-to-onset analysis of adverse events by calculating the reported odds ratio (ROR) to understand ETE trends after COVID-19 vaccination based on the vaccine type. Using VAERS, we could collect data about several ETEs associated with COVID-19 vaccination. Nine adverse events associated with ETEs were reported following the administration of viral vector vaccines. The median time to ETE onset was 6 (interquartile range: 2-17) days for mRNA vaccines and 11 (interquartile range: 4-21) days for viral vector vaccines. This study suggests that VAERS aids in disequilibrium analysis to examine the association between vaccine type and ETEs after COVID-19 vaccination. Additionally, the tendency to develop ETEs and the number of days taken to develop ETEs varied depending on the type of the COVID-19 vaccine. Thus, vaccinators and healthcare providers should consider the primary diseases associated with ETEs while selecting vaccines for

administration and carefully monitor patients following vaccination for potential ETEs based on the characteristics of vaccine type-specific onset period.

Immunogenicity and safety of SARS-CoV-2 mRNA vaccine in patients with nephrotic syndrome receiving immunosuppressive agents. BACKGROUND: As there are no large-scale reports of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) mRNA vaccination in patients with nephrotic syndrome using immunosuppressive agents, we conducted the prospective study. METHODS: SARS-CoV-2 mRNA vaccines were administered to patients with nephrotic syndrome receiving immunosuppressive agents. The titers of SARS-CoV-2 spike protein receptor-binding domain antibodies were measured before and after vaccination. We evaluated factors associated with antibody titers after vaccination and analyzed adverse events. RESULTS: We enrolled 40 patients and evaluated vaccine immunogenicity in 35 of them. Seroconversion (>â€‰0.8 U/mL) was achieved in all patients, and the median antibody titer was 598 U/mL (interquartile range, 89-1380 U/mL). Patients using mycophenolate mofetil (MMF) showed lower antibody titers than those who were not (median: 272 U/mL vs. 2660 U/mL, pâ€‰=â€‰0.0002), and serum immunoglobulin G (IgG) levels showed a weak linear relationship with antibody titers (R(2)â€‰=â€‰0.16). No breakthrough infections were noted. Three patients (7.5%) suffered from a relapse of nephrotic syndrome (2 and 3Â days, respectively, after the first dose and 8Â days after the second dose), two of whom had a history of relapse within 6Â months before the vaccination. CONCLUSIONS: The SARS-CoV-2 mRNA vaccine was immunogenic in patients with nephrotic syndrome using immunosuppressive agents, although the use of MMF and low levels of serum IgG were associated with lower antibody titers after vaccination. Patients with high disease activity may experience a relapse of nephrotic syndrome after vaccination. A higher resolution version of the Graphical abstract is available as Supplementary information.

Drug hypersensitivity, in vitro tools, biomarkers, and burden with COVID-19 vaccines. Hypersensitivity reactions to drugs are increasing worldwide. They display a large degree of variability in the immunological mechanisms involved, which impacts both disease severity and the optimal diagnostic procedure. Therefore, drug hypersensitivity diagnosis relies on both in vitro and in vivo assessments, although most of the methods are not well standardized. Moreover, several biomarkers can be used as valuable parameters for precision medicine that provide information on the endotypes, diagnosis, prognosis, and prediction of drug hypersensitivity development, as well on the identification of therapeutic targets and treatment efficacy monitoring. Furthermore, in the last 2â€‰years, the SARS-CoV-2 (severe acute respiratory syndrome-coronavirus) pandemic has had an important impact on health system, leading us to update approaches on how to manage hypersensitivity reactions to drugs used for its treatment and on COVID-19 (Coronavirus disease) vaccines used for its prevention. This article reviews recent advances in these 3 areas regarding drug hypersensitivity: in vitro tools for drug hypersensitivity diagnosis, recently identified biomarkers that could guide clinical decision making and management of hypersensitivity reactions to drugs and vaccines used for COVID-19.

Anti-Phospholipid Antibodies and Coronavirus Disease 2019: Vaccination Does Not Trigger Early Autoantibody Production in Healthcare Workers. A molecular mimicry between severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and human proteins supports the possibility that autoimmunity takes place during coronavirus disease 2019 (COVID-19) contributing to tissue damage. For example, anti-phospholipid antibodies (aPL) have been reported in COVID-19 as a result of such mimicry and thought to contribute to the immunothrombosis characteristic of the disease. Consistently, active immunization with the virus spike protein may elicit the production of cross-reactive autoantibodies, including aPL. We prospectively looked at the aPL production in healthcare workers vaccinated with RNA- (BNT162b2, n. 100) or adenovirus-based vaccines (ChAdOx1, n. 50). Anti-cardiolipin, anti-beta2 glycoprotein I, anti-phosphatidylserine/prothrombin immunoglobulin G

(IgG), IgA, and IgM before and after vaccination were investigated. Anti-platelet factor 4 immunoglobulins were also investigated as autoantibodies associated with COVID-19 vaccination. Additional organ (anti-thyroid) and non-organ (anti-nuclear) autoantibodies and IgG against human proteome were tested as further post-vaccination autoimmunity markers. The antibodies were tested one or three months after the first injection of ChAdOx1 and BNT162b2, respectively; a 12-month clinical follow-up was also performed. Vaccination occasionally induced low titers of aPL and other autoantibodies but did not affect the titer of pre-existing autoantibodies. No significant reactivities against a microarray of approximately 20,000 human proteins were found in a subgroup of ChAdOx1-vaccinees. Consistently, we did not record any clinical manifestation theoretically associated with an underlying autoimmune disorder. The data obtained after the vaccination (two doses for the RNA-based and one dose for the adenovirus-based vaccines), and the clinical follow-up are not supporting the occurrence of an early autoimmune response in this cohort of healthcare workers.

A Complementary Union of SARS-CoV2 Natural and Vaccine Induced Immune Responses. Our understanding of the immune responses that follow SARS-CoV-2 infection and vaccination has progressed considerably since the COVID-19 pandemic was first declared on the 11(th) of March in 2020. Recovery from infection is associated with the development of protective immune responses, although over time these become less effective against new emerging SARS-CoV-2 variants. Consequently, reinfection with SARS-CoV-2 variants is not infrequent and has contributed to the ongoing pandemic. COVID-19 vaccines have had a tremendous impact on reducing infection and particularly the number of deaths associated with SARS-CoV-2 infection. However, waning of vaccine induced immunity plus the emergence of new variants has necessitated the use of boosters to maintain the benefits of vaccination in reducing COVID-19 associated deaths. Boosting is also beneficial for individuals who have recovered from COVID-19 and developed natural immunity, also enhancing responses immune responses to SARS-CoV-2 variants. This review summarizes our understanding of the immune responses that follow SARS-CoV-2 infection and vaccination, the risks of reinfection with emerging variants and the very important protective role vaccine boosting plays in both vaccinated and previously infected individuals.

Different Impacts on the Heart After COVID-19 Infection and Vaccination: Insights From Cardiovascular Magnetic Resonance. INTRODUCTION: Myocarditis-like findings after COVID-19 (coronavirus disease 2019) infection and vaccination were reported by applying cardiovascular magnetic resonance (CMR). These results are very heterogenous and dependent on several factors such as hospital admission or outpatient treatment, timing of CMR, and symptomatic load. This retrospective study aimed to identify differences in myocardial damage in patients with persistent symptoms both after COVID-19 infection and vaccine by applying CMR. MATERIALS AND METHODS: This study entails a retrospective analysis of consecutive patients referred for CMR between August 2020 and November 2021 with persistent symptoms after COVID-19 infection or vaccination. Patients were compared to healthy controls (HC). All patients underwent a CMR examination in a 1.5-T scanner with a scan protocol including: cine imaging for biventricular function and strain assessment using feature tracking, T2 mapping for the quantification of edema, and T1 mapping for diffuse fibrosis and late gadolinium enhancement (LGE) for the detection and quantification of focal fibrosis. Patients were divided into a subacute COVID-19 (sCov) group with symptoms lasting < 12 weeks, post-COVID-19 (pCov) group with symptoms > 12 weeks, and patients after COVID-19 vaccination (CovVac). RESULTS: A total of 162 patients were recruited of whom 141 were included for analysis. The median age in years (interquartile range (IQR)) of the entire cohort was 45 (37-56) which included 83 women and 58 men. Subgroups were as follows (total patients per subgroup, median age in years (IQR), main gender): 34 sCov, 43 (37-52), 19 women; 63 pCov, 52 (39-58), 43 women; 44 CovVac, 43 (32-56), 23 men; 44 HC (41 (28-52), 24 women). The biventricular function was preserved and

revealed no differences between the groups. No active inflammation was detected by T2 mapping. Global T1 values were higher in pCov in comparison with HC (median (IQR) in ms: pCov 1002ms (981-1023) vs. HC 987ms (963-1009; p = 0.005) with other parings revealing no differences. In 49/141 (34.6%) of patients, focal fibrosis was detectable with the majority having a non-ischemic pattern (43/141; 30.4%; patients) with the subgroups after infection having more often a subepicardial pattern compared with CovVac (total (% of group): sCov: 7/34(21%); pCov 13/63(21%); CovVac 2/44(5%); p = 0.04). CONCLUSION: Patients after COVID-19 infection showed more focal fibrosis in comparison with patients after COVID-19 vaccination without alterations in the biventricular function.

Severe Thrombocytopenia Two Weeks Following Immunization with the Janssen Ad26.CoV2.S Vaccine. Immune thrombocytopenia (ITP) has been associated with immunizations with various proposed mechanisms, including overactivation of the immune system and production of antibodies against circulating platelets. ITP has also been associated with several viral infections, including HCV, HIV, and most recently, active SARS-CoV-2 infection. Here, we present a case of a 52-year-old male with no past medical history who sought evaluation with his primary care physician for upper and lower extremity ecchymosis of one week duration. Outpatient laboratory studies were notable for severe isolated thrombocytopenia with platelet count of 8â€‰Ã—â€‰10(^)9/L. Interestingly, he received the Johnson and Johnson COVID-19 vaccine 16 days prior to his presentation. Clinical work up and laboratory investigations led to the diagnosis of ITP.

COVID-19 Vaccination is Associated With Favorable Outcomes Among Lung Transplant Patients With Breakthrough Infections. BACKGROUND: There are limited data regarding the clinical efficacy of COVID-19 vaccines among lung transplant (LT) patients. METHODS: We included all LT patients diagnosed with COVID-19 between March 1, 2020, and December 10, 2021 (nÂ =Â 84; median age 55, range, 20-73 years; males 65.5%). The study group was divided into 3 groups based on the vaccination status (patients who did not complete the primary series for any of the vaccines: nÂ =Â 58; those with 2 doses of messenger RNA (mRNA) or 1 dose of the adenoviral vector vaccine, vaccinated group: nÂ =Â 16; those with at least 1 additional dose beyond the primary series, boosted group: nÂ =Â 10). RESULTS: Pulmonary parenchymal involvement on chest computed tomography scan was less common among the boosted group (PÂ =Â .009). The proportion of patients with new or worsening respiratory failure was significantly lower among the vaccinated and boosted groups and these patients were significantly more likely to achieve the composite endpoint of oxygen-dependence free survival (PÂ =Â .02). On multivariate logistic regression analysis, higher body mass index, restrictive lung disease as the transplant indication, and preinfection chronic lung allograft dysfunction were independently associated with acute or acute on chronic respiratory failure while being on therapeutic dose anticoagulation and having received the booster dose had a protective effect. CONCLUSION: COVID-19 vaccines appear to have several favorable effects among LT patients with breakthrough infections including lower likelihood of allograft involvement on imaging (among boosted patients), need of hospitalization, and complications such as new or worsening respiratory failure.

[Erythema nodosum associated with Tozinameran vaccine: Report of 2Â cases and review of the literature].

SARS-CoV-2 vaccine safety in adolescents with inflammatory rheumatic and musculoskeletal diseases and adults with juvenile idiopathic arthritis: data from the EULAR COVAX physician-reported registry. BACKGROUND: There is a lack of data on SARS-CoV-2 vaccination safety in children and young people (CYP) with rheumatic and musculoskeletal diseases (RMDs). Current vaccination guidance is based on data from adults with RMDs or CYP without RMDs. OBJECTIVES: To describe the safety of SARS-COV-2 vaccination in adolescents with inflammatory RMDs and adults with juvenile idiopathic arthritis (JIA). METHODS: We described patient characteristics, flares and adverse events (AEs) in adolescent cases

under 18 with inflammatory RMDs and adult cases aged 18 or above with JIA submitted to the European Alliance of Associations for Rheumatology COVAX registry. RESULTS: A total of 110 cases were reported to the registry. Thirty-six adolescent cases were reported from four countries, most with JIA (42%). Over half (56%) reported early reactogenic-like AEs. One mild polyarthralgia flare and one serious AE of special interest (malaise) were reported. No CYP reported SARS-CoV-2 infection postvaccination.Seventy-four adult JIA cases were reported from 11 countries. Almost two-thirds (62%) reported early reactogenic-like AEs and two flares were reported (mild polyarthralgia and moderate uveitis). No serious AEs of special interest were reported among adults with JIA. Three female patients aged 20-30â€‰years were diagnosed with SARS-CoV-2 postvaccination; all fully recovered. CONCLUSIONS: This is an important contribution to research on SARS-CoV-2 vaccine safety in adolescents with RMDs and adults with JIA. It is important to note the low frequency of disease flares, serious AEs and SARS-CoV-2 reinfection seen in both populations, although the dataset is limited by its size.

The winding 12-month journey of the AstraZeneca COVID-19 vaccine since its first administration to humans. The deficiently designed and conducted initial clinical development plan and the occurrence of thrombotic thrombocytopenia cases, have marked the first 12-month journey of the AstraZeneca coronavirus disease 2019 (COVID-19) vaccine after it was first administered to humans. When it was authorized, there were no available efficacy data in the elderly. However, this age group was included in the product labelling based on immunogenicity data. The lack of safety and efficacy data in the elderly that was acknowledged in the product information, triggered most European Union (EU) countries to limit the administration of this vaccine to certain age groups. In February-March/2021, after the results of observational studies supported the vaccine effectiveness in the elderly, several countries broadened its use to this age group. When trust on the vaccine was ramping up, unusual blood clot cases were described in Europe, which led 24 countries around the world to temporarily halt its administration. These cases were first described as thrombotic thrombocytopenia in late March. In mid-April, the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) updated the product information and confirmed the positive benefit/risk ratio of the vaccine, recommending its use with no age restrictions. The World Health Organization (WHO) coincided with this approach. However, several countries decided to limit its use to certain age groups. The EMA listed thrombotic thrombocytopenia as a "very rare" adverse reaction. Although, the AstraZeneca vaccine was conceived in early 2020 to be a worldwide leader in the fight against COVID-19, its use was abandoned by the African Union, Denmark, and Israel. However, this vaccine has shown its usefulness in many settings across the world.

BNT162b2 mRNA COVID-19 vaccine three-dose safety and risk of COVID-19 in patients with myasthenia gravis during the alpha, delta, and omicron waves. COVID-19 affects the respiratory parenchyma and may potentially contribute to the tendency of myasthenia gravis (MG) patients to develop respiratory failure. It is, therefore, important to study the safety of vaccines against SARS-CoV-2 and to assess the risk of COVID-19 in MG patients. The safety of the three-dose BNT162b2 mRNA vaccine and outcomes of COVID-19 during the alpha, delta, and omicron waves were studied in MG patients as well as the rate of exacerbations and safety for a period of up to 6Â weeks from each vaccine dose and patient morbidity and mortality during COVID-19 compared to the general population. 430 vaccine doses were administered across 150 patients. Thirteen patients (8.7%) complained of exacerbation within 6Â weeks of each vaccine dose. Both MG onset rate and exacerbation rate were similar to previous years. MG exacerbation rate among fifteen patients who had COVID-19 was significantly higher (40%) compared to the rate following vaccination. During the alpha and delta waves, COVID-19 mortality and severe disease were significantly higher (26.7%) compared to the general population (0.96%). All of them were unvaccinated and had generalized MG.

During the omicron wave, all the MG patients who contracted COVID-19 were vaccinated and had mild disease. We concluded that COVID-19 is hazardous for generalized MG patients, while the vaccination did not raise the risk for either exacerbation or new onset of MG and was associated with a reduced risk for severe COVID-19. Hence, it is recommended for generalized MG patients to get vaccinated.
Vaccine-induced dermatomyositis following COVID-19 vaccination.
Pemphigus vulgaris with advanced hypopharyngeal and gastric cancer following SARS-CoV-2 vaccination.
Overlapping acute generalized exanthematous pustulosis drug reaction with eosinophilia and systemic symptoms induced by a second dose of the Moderna COVID-19 vaccine.
COVID-19 vaccination and carditis in children and adolescents: a systematic review and meta-analysis. BACKGROUND: Coronavirus Disease-2019 (COVID-19) vaccination has been associated with the development of carditis, especially in children and adolescent males. However, the rates of these events in the global setting have not been explored in a systematic manner. The aim of this systematic review and meta-analysis is to investigate the rates of carditis in children and adolescents receiving COVID-19 vaccines. METHODS: PubMed, Embase and several Latin American databases were searched for studies. The number of events, and where available, at-risk populations were extracted. Rate ratios were calculated and expressed as a rate per million doses received. Subgroup analysis based on the dose administered was performed. Subjectsâ€‰â‰¤â€‰19Â years old who developed pericarditis or myocarditis following COVID-19 vaccination were included. RESULTS: A total of 369 entries were retrieved. After screening, 39 articles were included. Our meta-analysis found that 343 patients developed carditis after the administration of 12,602,625 COVID-19 vaccination doses (pooled rate per million: 37.76; 95% confidence interval [CI] 23.57, 59.19). The rate of carditis was higher amongst male patients (pooled rate ratio: 5.04; 95% CI 1.40, 18.19) and after the second vaccination dose (pooled rate ratio: 5.60; 95% CI 1.97, 15.89). In 301 cases of carditis (281 male; mean age: 15.90 (standard deviation [SD] 1.52) years old) reported amongst the case series/reports, 261 patients were reported to have received treatment. 97.34% of the patients presented with chest pain. The common findings include ST elevation and T wave abnormalities on electrocardiography. Oedema and late gadolinium enhancement in the myocardium were frequently observed in cardiac magnetic resonance imaging (CMR). The mean length of hospital stay was 3.91Â days (SD 1.75). In 298 out of 299 patients (99.67%) the carditis resolved with or without treatment. CONCLUSIONS: Carditis is a rare complication after COVID-19 vaccination across the globe, but the vast majority of episodes are self-limiting with rapid resolution of symptoms within days. Central illustration. Balancing the benefits of vaccines on COVID-19-caused carditis and post-vaccination carditis.
When do persuasive messages on vaccine safety steer COVID-19 vaccine acceptance and recommendations? Behavioural insights from a randomised controlled experiment in Malaysia. INTRODUCTION: Vaccine safety is a primary concern among vaccine-hesitant individuals. We examined how seven persuasive messages with different frames, all focusing on vaccine safety, influenced Malaysians to accept the COVID-19 vaccine, and recommend it to individuals with different health and age profiles; that is, healthy adults, the elderly, and people with pre-existing health conditions. METHODS: A randomised controlled experiment was conducted from 29 April to 7 June 2021, which coincided with the early phases of the national vaccination programme when vaccine uptake data were largely unavailable. 5784 Malaysians were randomly allocated into 14 experimental arms and exposed to one or two messages that promoted COVID-19 vaccination. Interventional messages were applied alone or in combination and compared against a control message. Outcome measures were assessed as intent to both take the vaccine and recommend it to healthy adults, the elderly, and people with pre-existing health conditions, before and after message

exposure. Changes in intent were modelled and we estimated the average marginal effects based on changes in the predicted probability of responding with a positive intent for each of the four outcomes. RESULTS: We found that persuasive communication via several of the experimented messages improved recommendation intentions to people with pre-existing health conditions, with improvements ranging from 4 to 8â€‰percentage points. In contrast, none of the messages neither significantly improved vaccination intentions, nor recommendations to healthy adults and the elderly. Instead, we found evidence suggestive of backfiring among certain outcomes with messages using negative attribute frames, risky choice frames, and priming descriptive norms. CONCLUSION: Message frames that briefly communicate verbatim facts and stimulate rational thinking regarding vaccine safety may be ineffective at positively influencing vaccine-hesitant individuals. Messages intended to promote recommendations of novel health interventions to people with pre-existing health conditions should incorporate safety dimensions. TRIAL REGISTRATION NUMBER: NCT05244356.

Morphoea following COVID-19 vaccination. We present a case of generalized morphoea developing after recent COVID-19 mRNA vaccination and suggest the plausible pathomechanisms.

Incidence of immediate allergic reactions to mRNA COVID-19 vaccines in adults with drug allergies and other allergic disorders. Concerns have been raised about allergic reactions to messenger ribonucleic acid (mRNA) coronavirus disease 2019 (COVID-19) vaccines. A history of allergic reactions, including anaphylaxis to drugs, has been frequently reported in individuals with anaphylaxis to mRNA vaccines. To estimate the rate of immediate allergic reactions in patients with a history of drug allergy or other allergic disorders. We included adult patients who had received at least 1 dose of an mRNA COVID-19 vaccine at the Special Hospital for Pulmonary Diseases between March 1, 2021, and October 1, 2021, and who reported a history of drug allergy or other allergic diseases (asthma, allergic rhinitis, atopic dermatitis, food or insect venom allergy, mastocytosis, idiopathic anaphylaxis, acute or chronic urticaria, and/or angioedema). Immediate allergic reactions, including anaphylaxis, occurring within 4 hours of vaccination were recorded. Six immediate allergic reactions were noted in the cohort of 1679 patients (0.36%). One patient experienced anaphylaxis (0.06%), which resolved after epinephrine administration, and the other reactions were mild and easily treatable. Most patients with a history of allergies can safely receive an mRNA COVID-19 vaccine, providing adequate observation periods and preparedness to recognize and treat anaphylaxis.

Acute pericarditis in patients receiving coronavirus disease 2019 vaccines: a case series from the community. BACKGROUND: International agencies reported that cases of pericarditis occur very rarely following the administration of coronavirus disease 2019 (COVID-19) vaccines. Herewith, we described a series of patients from the community diagnosed with acute pericarditis after vaccination. METHODS: We retrospectively included 28 patients (median age 51â€Šyears, 79% female) with or without a positive history of acute respiratory syndrome coronavirus 2 recovered infection who were diagnosed with acute pericarditis following the administration of COVID-19 vaccine. We excluded specific identifiable causes of pericarditis, including infectious, autoimmune, neoplastic and metabolic disease. Patients were referred for a complete cardiovascular evaluation. Transthoracic echocardiography (TTE) was performed and diagnosis of acute pericarditis was achieved according to current guidelines. RESULTS: There were 16 patients administered with Pfizer-BioNTech/Comirnaty vaccine, 8 with Moderna/Spikevax vaccine and 4 with Astra Zeneca/Vaxzevria vaccine. Nine patients had been previously diagnosed with COVID-19, while the others had no prior history of COVID-19. Eleven patients had no comorbidity while the others had between one and four comorbidities. Ten patients had a history of rheumatic or autoimmune diseases. Chest pain was present in 24 patients. Minor ECG abnormalities were detected in 10 patients, T-wave inversion in 6, and 7 patients had concave ST elevation. The majority of patients showed mild pericardial effusions

at TTE. Only two patients exhibited large pericardial effusions. CONCLUSION: This case series shows a higher incidence of acute pericarditis in patients administered with COVID-19 vaccines than previously estimated, probably because of a more comprehensive assessment of clinical as well as echocardiographic parameters.
A report on short-term follow-up cardiac imaging and clinical outcomes of myocarditis after coronavirus disease 2019 vaccination.
Safety and Acceptance of COVID-19 Vaccination After Multisystem Inflammatory Syndrome in Children (MIS-C) in Spain. In this cohort of 42 adolescents with a previous multisystem inflammatory syndrome (MIS-C) diagnosis, 32 (76.2%) were vaccinated with COVID-19 vaccines, with a low incidence of relevant adverse events. More importantly, no new MIS-C or myocarditis occurred after a median of 10 weeks (range 5.3-19.7) post-vaccination.
COVID-19 vaccination and BA.1 breakthrough infection induce neutralising antibodies which are less efficient against BA.4 and BA.5 Omicron variants, Israel, March to June 2022. This work evaluated neutralising antibody titres against wild type (WT) SARS-CoV-2 and four Omicron variants (BA.1, BA.2, BA.4 and BA.5) in healthcare workers who had breakthrough BA.1 infection. Omicron breakthrough infection in individuals vaccinated three or four times before infection resulted in increased neutralising antibodies against the WT virus. The fourth vaccine dose did not further improve the neutralising efficiency over the third dose against all Omicron variants, especially BA.4 and BA.5. An Omicron-specific vaccine may be indicated.
The Peripheral Immune Landscape in a Patient with Myocarditis after the Administration of BNT162b2 mRNA Vaccine. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has posed a serious threat to global public health. A novel vaccine made from messenger RNA (mRNA) has been developed and approved for use at an unprecedented pace. However, an increased risk of myocarditis has been reported after BNT162b2 mRNA vaccination due to unknown causes. In this study, we used single-cell RNA sequencing and single-cell T cell receptor sequencing analyses of peripheral blood mononuclear cells (PBMCs) to describe, for the first time, changes in the peripheral immune landscape of a patient who underwent myocarditis after BNT162b2 vaccination. The greatest changes were observed in the transcriptomic profile of monocytes in terms of the number of differentially expressed genes. When compared to the transcriptome of PBMCs from vaccinated individuals without complications, increased expression levels of IL7R were detected in multiple cell clusters. Overall, results from this study can help advance research into the pathogenesis of BNT162b2-induced myocarditis.
Association between infections, the microbiome, vaccination, and neuromyelitis optica spectrum disorder. Neuromyelitis optica spectrum disorder (NMOSD) is a devastating antibody-mediated condition of the central nervous system. As in other autoimmune diseases, there is considerable evidence to suggest that NMOSD arises from complex interactions between genetic susceptibility and environmental factors. However, whether factors like aquaporin-4-Antibody production initiate NMOSD attacks, currently remains unclear, and requires further investigation. Infectious diseases have also been proposed as possible environmental factors associated with NMOSD onset or relapses, some of which are more common in Asia and Latin America than in Europe and North America, in parallel with the higher incidence of NMOSD in these geographic locations. In this review, we examine current evidence on specific infections and vaccines associated with NMOSD onset and/or attacks, as well as the most recent data on gut microbiome composition and SARS-CoV-2 infection in NMOSD patients.
Heterologous adenovirus-vector/messenger RNA regimen is associated with improved severe acute respiratory syndrome coronavirus 2 humoral response in liver transplant recipients. Knowledge of the immunogenicity of vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-

CoV-2) in liver transplant recipients (LTRs) is mainly limited to messenger RNA (mRNA)-based types. We aimed to evaluate the humoral response in LTRs and to address the use of different doses of mycophenolate (MMF) on the probability of developing anti-spike immunoglobulin G (IgG). In this prospective cohort study, SARS-CoV-2 anti-spike IgG, neutralizing antibodies (NAs), and nucleocapsid protein (N) were evaluated in LTRs and healthy volunteers 21-90â€‰days after receiving the second vaccine dose of either ChAdOx1 (AstraZeneca), rAd26-rAd5 (Sputnik V), inactivated BBIBP-CorV (Sinopharm), or the heterologous combination rAd26/mRNA-1273 (Sputnik V/Moderna). We collected information regarding clinical data and vaccine side effects. After excluding three LTRs due to a positive N test, 120 LTRs and 27 controls were analyzed. No significant differences were found among groups. Overall, 24 (89%) controls and 74 (62%) LTRs were positive for anti-spike IgG (pÂ =Â 0.007). Among LTRs, those immunized with rAd26/mRNA-1273 presented significantly higher positive serology and NAs when compared with the homologous regimens (91% vs. 55%, pÂ =Â 0.001; and 1182â€‰IU/ml vs. 446â€‰IU/ml, pÂ =Â 0.002; respectively). In the multivariate analysis, humoral response was significantly reduced in LTRs who received higher doses of MMF (odds ratio [OR], 0.1; 95% confidence interval [CI], 0.03-0.3; pâ€‰<â€‰0.001) and with increased BMI (OR, 0.4; 95% CI, 0.2-0.7; pÂ =Â 0.005); and it was significantly higher in those immunized with rAd26/mRNA-1273 (OR, 13.1; 95% CI, 2.3-72.9; pÂ =Â 0.003). In LTRs anti-spike IgG concentrations showed a very good correlation with NA titers (R(2) =â€‰0.949; 95% CI, 0.919-0.967; pâ€‰<â€‰0.001). No serious adverse events were reported in either group. Conclusion: In LTRs, rAd26/mRNA-1273 was independently associated with higher antibody response. Future studies are necessary to evaluate whether combining different vaccine platforms and MMF reduction may lead to a better booster response.

Humoral Response Following Triple Dose of mRNA Vaccines Against SARS-CoV-2 in Hemodialysis Patients: Results After 1 Year of Follow-Up. INTRODUCTION: COVID-19 is associated with an increased mortality in hemodialysis patients. Therefore, achieving a long-lasting effective immune response to SARS-CoV-2 vaccines is essential. This study describes the humoral immune response in hemodialysis patients following three doses of mRNA vaccines against SARS-CoV-2, and explores the factors associated with a sustained immune response. MATERIALS AND METHODS: We analyzed the monthly serological evolution of SARS-CoV-2 anti-S(RBD) antibodies for 1 year in 178 chronic hemodialysis patients who received three doses of SARS-CoV-2 mRNA vaccines. The primary outcome was sustained effective humoral response defined as anti-S(RBD) levels > 1,000 AU/ml after 4 months from the third dose. Multivariate logistic regression analyses were used to identify features associated with a sustained humoral immune response. RESULTS: After the initial two SARS-CoV-2 mRNA vaccine doses, 77.8% of patients showed an immediate effective humoral response, decreasing to 52.5% after 4 months. Antibody levels were significantly higher in COVID-exposed patients and HBV vaccine responders. After the third dose, 97% of patients showed an effective humoral response, and remained in 91.7% after 4 months. The mean monthly rate of antibody titer decline decreased from 33 Â± 14.5 to 25 Â± 16.7%. Multivariate regression analysis showed that previous exposure to COVID-19 and response to HBV vaccines were associated with an effective sustained humoral immune response. CONCLUSION: Immunization with SARS-CoV-2 mRNA vaccines elicits an effective immediate humoral immune response in hemodialysis patients, with a progressive waning in antibody levels. A third booster dose enhances the immune response with significantly higher antibody levels and more sustained humoral immune response. COVID-naÃ¯ve patients and patients without previous response to HBV vaccines are likely to benefit from receiving more booster doses to maintain an effective immune response.

Bimodal antibody-titer decline following BNT162b2 mRNA anti-SARS-CoV-2 vaccination in healthcare workers of the INT - IRCCS "Fondazione Pascale" Cancer Center (Naples, Italy). BACKGROUND:

Both SARS-CoV-2 mRNA-based vaccines [BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna)] have shown high efficacy, with very modest side effects in limiting transmission of SARS-CoV-2 and in preventing the severe COVID-19 disease, characterized by a worrying high occupation of intensive care units (ICU), high frequency of intubation and ultimately high mortality rate. At the INT, in Naples, only the BNT162b2/Pfizer vaccine has been administered to cancer patients and healthcare professionals aged 16 and over. In the present study, the antibody response levels and their decline were monitored in an interval of 6-9Â months after vaccine administration in the two different cohorts of workers of the INT - IRCCS "Fondazione Pascale" Cancer Center (Naples, Italy): the group of individuals previously infected with SARS-CoV-2 and vaccinated with a single dose; and that of individuals negative for previous exposure to SARS-CoV-2 vaccinated with two doses 21Â days apart. METHODS: Specific anti-RBD (receptor-binding domain) titers against trimeric spike glycoprotein (S) of SARS-CoV-2 by Roche Elecsys Anti-SARS-CoV-2â€‰S ECLIA immunoassay were determined in serum samples of 27 healthcare workers with a previously documented history of SARS-CoV-2 infection and 123 healthcare workers without, during antibody titers' monitoring. Moreover, geometric mean titers (GMT) and relative fold changes (FC) were calculated. RESULTS: Bimodal titer decline was observed in both previously infected and uninfected SARS-CoV-2 subjects. A first rapid decline was followed by a progressive slow decline in the 6/9Â month-period before the further vaccine boost. The trend was explained by 2 different mathematical models, exponential and power function, the latter revealing as predictive of antibody titer decline either in infected or in not previously infected ones. The value of the prolonged lower vaccine titer was about 1 log below in the 6/9-month interval after the single dose for previously infected individuals with SARS-CoV-2 and the two doses for those not previously infected. The titer change, after the boost dose administration, on the other hand, wasâ€‰â‰¥â€‰1.5 FC higher than the titers at the 6/9-month time-points in both cohorts. A similar quantitative immune titer was observed in both cohorts 8Â days after the last boost dose. The subsequent immunoresponse trend remains to be verified. DISCUSSION: The results show that a very rapid first decline, from the highest antibody peak, was followed by a very slow decline which ensured immune protection lasting more than 6 months. The apparent absence of adverse effects of the rapid decline on the vaccine's immune protective role has been related to a large majority of low avidity antibodies induced by current vaccines. High avidity antibodies with prolonged anti-transmission efficacy show a longer half-life and are lost over a longer interval period. The cellular immunity, capable of preventing severe clinical diseases, lasts much longer. The unbalanced dual activity (cellular vs humoral) while effective in limiting ICU pressure and overall mortality, does not protect against transmission of SARS-CoV-2, resulting in high circulation of the virus among unvaccinated subjects, including the younger population, and the continuous production of variants characterized by changes in transmissibility and pathogenicity. The high mutation rate, peculiar to the RNA virus, can however lead to a dual opposite results: selection of defective and less efficient viruses up to extinction; risk of more efficiently transmitted variants as the current omicron pandemic. CONCLUSIONS: In conclusion the current bimodal antibody-titer decline, following BNT162b2 mRNA anti-SARS-CoV-2 vaccination, needs a further extended analysis to verify the protective borderline levels of immunity and the optimal administration schedule of vaccine boosters. Our current results can contribute to such goal, besides a direct comparison of other FDA-approved and candidate vaccines.

Response to: Factors Associated With COVID-19 Breakthrough Infections: Correspondence.

Factors Associated With COVID-19 Breakthrough Infections: Correspondence.

Risk of myocarditis and pericarditis following BNT162b2 and mRNA-1273 COVID-19 vaccination. BACKGROUND: Evidence indicates that mRNA COVID-19 vaccination is associated with risk of myocarditis and possibly pericarditis, especially in young males. It is not clear if risk differs between

mRNA-1273 versus BNT162b2. We assessed if risk differs using comprehensive health records on a diverse population. METHODS: Members 18-39Â years of age at eight integrated healthcare-delivery systems were monitored using data updated weekly and supplemented with medical record review of myocarditis and pericarditis cases. Incidence of myocarditis and pericarditis events that occurred among vaccine recipients 0 to 7Â days after either dose 1 or 2 of a messenger RNA (mRNA) vaccine was compared with that of vaccinated concurrent comparators who, on the same calendar day, had received their most recent dose 22 to 42Â days earlier. Rate ratios (RRs) were estimated by conditional Poisson regression, adjusted for age, sex, race and ethnicity, health plan, and calendar day. Head-to-head comparison directly assessed risk following mRNA-1273 versus BNT162b2 during 0-7Â days post-vaccination. RESULTS: From December 14, 2020 - January 15, 2022 there were 41 cases after 2,891,498 doses of BNT162b2 and 38 cases after 1,803,267 doses of mRNA-1273. Cases had similar demographic and clinical characteristics. Most were hospitalized for â‰¤1Â day; none required intensive care. During days 0-7 after dose 2 of BNT162b2, the incidence was 14.3 (CI: 6.5-34.9) times higher than the comparison interval, amounting to 22.4 excess cases per million doses; after mRNA-1273 the incidence was 18.8 (CI: 6.7-64.9) times higher than the comparison interval, amounting to 31.2 excess cases per million doses. In head-to-head comparisons 0-7Â days after either dose, risk was moderately higher after mRNA-1273 than after BNT162b2 (RR: 1.61, CI 1.02-2.54). CONCLUSIONS: Both vaccines were associated with increased risk of myocarditis and pericarditis in 18-39-year-olds. Risk estimates were modestly higher after mRNA-1273 than after BNT162b2.

Relapse of immune thrombotic thrombocytopenic purpura (iTTP) possibly triggered by COVID-19 vaccination and/or concurrent COVID-19 infection. Thrombotic thrombocytopenic purpura (TTP) is a life-threatening disease that may be triggered by inflammation, including infection or vaccination. Since the start of the COVID-19 pandemic, several case reports were published on de novo or relapsed immune TTP (iTTP) in COVID-19-infected patients. Case reports of iTTP episodes following vaccination against COVID-19 are also emerging. We report a case of relapsed iTTP in a patient who received Moderna mRNA-1273 SARS-CoV-2 vaccine and developed concurrent severe COVID-19 infection. The patient's iTTP was successfully managed with caplacizumab, therapeutic plasma exchange and high-dose steroids. We summarise published cases of iTTP associated with COVID-19 infection or vaccination.

Postmarketing active surveillance of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines in persons aged 12 to 39 years in Italy: A multi-database, self-controlled case series study. BACKGROUND: Myocarditis and pericarditis following the Coronavirus Disease 2019 (COVID-19) mRNA vaccines administration have been reported, but their frequency is still uncertain in the younger population. This study investigated the association between Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) mRNA vaccines, BNT162b2, and mRNA-1273 and myocarditis/pericarditis in the population of vaccinated persons aged 12 to 39 years in Italy. METHODS AND FINDINGS: We conducted a self-controlled case series study (SCCS) using national data on COVID-19 vaccination linked to emergency care/hospital discharge databases. The outcome was the first diagnosis of myocarditis/pericarditis between 27 December 2020 and 30 September 2021. Exposure risk period (0 to 21 days from the vaccination day, subdivided in 3 equal intervals) for first and second dose was compared with baseline period. The SCCS model, adapted to event-dependent exposures, was fitted using unbiased estimating equations to estimate relative incidences (RIs) and excess of cases (EC) per 100,000 vaccinated by dose, age, sex, and vaccine product. Calendar period was included as time-varying confounder in the model. During the study period 2,861,809 persons aged 12 to 39 years received mRNA vaccines (2,405,759 BNT162b2; 456,050 mRNA-1273); 441 participants developed myocarditis/pericarditis (346 BNT162b2; 95 mRNA-1273). Within the 21-day risk interval, 114 myocarditis/pericarditis events occurred, the RI was 1.99 (1.30 to 3.05) after

second dose of BNT162b2 and 2.22 (1.00 to 4.91) and 2.63 (1.21 to 5.71) after first and second dose of mRNA-1273. During the [0 to 7) days risk period, an increased risk of myocarditis/pericarditis was observed after first dose of mRNA-1273, with RI of 6.55 (2.73 to 15.72), and after second dose of BNT162b2 and mRNA-1273, with RIs of 3.39 (2.02 to 5.68) and 7.59 (3.26 to 17.65). The number of EC for second dose of mRNA-1273 was 5.5 per 100,000 vaccinated (3.0 to 7.9). The highest risk was observed in males, at [0 to 7) days after first and second dose of mRNA-1273 with RI of 12.28 (4.09 to 36.83) and RI of 11.91 (3.88 to 36.53); the number of EC after the second dose of mRNA-1273 was 8.8 (4.9 to 12.9). Among those aged 12 to 17 years, the RI was of 5.74 (1.52 to 21.72) after second dose of BNT162b2; for this age group, the number of events was insufficient for estimating RIs after mRNA-1273. Among those aged 18 to 29 years, the RIs were 7.58 (2.62 to 21.94) after first dose of mRNA-1273 and 4.02 (1.81 to 8.91) and 9.58 (3.32 to 27.58) after second dose of BNT162b2 and mRNA-1273; the numbers of EC were 3.4 (1.1 to 6.0) and 8.6 (4.4 to 12.6) after first and second dose of mRNA-1273. The main study limitations were that the outcome was not validated through review of clinical records, and there was an absence of information on the length of hospitalization and, thus, the severity of the outcome. CONCLUSIONS: This population-based study of about 3 millions of residents in Italy suggested that mRNA vaccines were associated with myocarditis/pericarditis in the population younger than 40 years. According to our results, increased risk of myocarditis/pericarditis was associated with the second dose of BNT162b2 and both doses of mRNA-1273. The highest risks were observed in males of 12 to 39 years and in males and females 18 to 29 years vaccinated with mRNA-1273. The public health implication of these findings should be considered in the light of the proven mRNA vaccine effectiveness in preventing serious COVID-19 disease and death.

Safety Monitoring of COVID-19 mRNA Vaccine Second Booster Doses Among Adults Aged â‰¥50 Years - United States, March 29, 2022-July 10, 2022. The Advisory Committee on Immunization Practices (ACIP) recommends that all persons aged â‰¥5 years receive 1 booster dose of a COVID-19 vaccine after completion of their primary series.* On March 29, 2022, the Food and Drug Administration (FDA) authorized a second mRNA booster dose â‰¥4 months after receipt of a first booster dose for adults aged â‰¥50 years and persons aged â‰¥12 years with moderate to severe immunocompromise (1,2). To characterize the safety of a second mRNA booster dose among persons aged â‰¥50 years, CDC reviewed adverse events and health impact assessments reported to v-safe and the Vaccine Adverse Event Reporting System (VAERS) after receipt of a second mRNA booster dose during March 29-July 10, 2022. V-safe is a voluntary smartphone-based U.S. active surveillance system that monitors adverse events occurring after COVID-19 vaccination. VAERS is a U.S. passive surveillance system for monitoring adverse events after vaccination, managed by CDC and FDA (3). During March 29-July 10, 2022, approximately 16.8 million persons in the United States aged â‰¥50 years received a fourth dose.(â€) Among 286,380 v-safe registrants aged â‰¥50 years who reported receiving a second booster of an mRNA vaccine, 86.9% received vaccines from the same manufacturer for all 4 doses (i.e., homologous vaccination). Among registrants who reported homologous vaccination, injection site and systemic reactions were less frequent after the second booster dose than after the first booster dose. VAERS received 8,515 reports of adverse events after second mRNA booster doses among adults aged â‰¥50 years, including 8,073 (94.8%) nonserious and 442 (5.1%) serious events. CDC recommends that health care providers and patients be advised that local and systemic reactions are expected after a second booster dose, and that serious adverse events are uncommon.

New-onset Graves' disease following SARS-CoV-2 vaccination: a case report. A 22-year-old male with a history of ulcerative colitis and nephrotic syndrome treated with immunomodulatory agents including vedolizumab and mycophenolic acid developed hyperthyroidism 2 weeks following the first administration of BNT162b2 vaccine (Pfizer-BioNTech COVID-19 vaccine). Graves' disease (GD) was

diagnosed based on the elevated thyrotropin-receptor antibody, thyroid scintigraphy and ultrasound. To this day, four cases of new-onset GD following SARS-CoV-2 vaccine were reported in patients with no previous history of thyroid disease. Two cases of recurrence of GD following SARS-CoV-2 vaccine were also reported. Although the underlying mechanisms of vaccine-induced autoimmunity remain to be clarified, there is a rationale for the association between SARS-CoV-2 vaccination and the development of Th1-mediated diseases, at least in predisposed individuals. The BNT162b2 vaccine could be a trigger for GD in some patients. However, the benefit/risk ratio remains by far in favour of SARS-CoV-2 vaccination considering the potentially higher risk of severe infection in these patients.

Author reply to Comment on "Herpes zoster in the era of COVID 19: A prospective observational study to probe the association of herpes zoster with COVID 19 infection and vaccination".

Acute kidney injury after Pfizer COVID-19 vaccine due to crescentic fibrillary glomerulonephritis. Fibrillary glomerulonephritis (FGN) is a rare glomerular disease manifesting with proteinuria, renal impairment, hematuria, hypertension, and in a very small proportion can be associated with rapidly progressive glomerulonephritis and, rarely, crescent formation. The main modality for diagnosis is kidney biopsy, which ultrastructurally demonstrates randomly arranged non-branching mesangial and glomerular basement membrane (GBM) fibrils and positive staining for the biomarker DNAJB9. The pathogenesis is largely unknown. It was previously hypothesized to represent an immune-complex-type glomerulonephritis, as most cases show IgG4 restriction. We present the first case of crescentic FGN after mRNA Pfizer vaccine for COVID-19. A strong temporal association between vaccination, elevated creatinine, and diffuse crescentic fibrillary process was found. Immunological, neoplastic, and infectious causes were ruled out. We hypothesized that the vaccine stimulated an immune response that triggered crescentic FGN, however, further investigations will be needed to elucidate the direct role of COVID-19 vaccination in crescentic glomerular disease.

Inactivated COVID-19 vaccines: durability of Covaxin/BBV152 induced immunity against variants of concern. BACKGROUND: Covaxin/BBV152 is one of the most widely used vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and one of the few vaccines used extensively in low- and middle-income countries (LMIC). METHODS: We investigated the effect of Covaxin on the SARS-CoV-2 specific IgG and IgA and neutralizing antibody (NAb) levels at baseline (M0) and at Months 1 (M1), 2 (M2), 3 (M3), 4 (M4), 6 (M6) and 12 (M12) following vaccination in healthcare workers. In addition, we also examined the NAb levels against variant lineages of B.1.617.2 (Delta, India), B.1.617.2.1 (Delta Plus, India), B.1.351 (Beta, SA), B.1.1.7 (Alpha, UK) and B.1.1.529 (Omicron). RESULTS: Covaxin induces enhanced SARS-CoV-2 binding antibodies of IgG and IgA responses against both spike (S) and nucleocapsid (N) antigens at M1, M2, M3, M4, M6 and M12 in comparison with M0. Our data also reveal that NAb levels against the ancestral strain (Wuhan, wild type) are elevated and sustained at M1, M2, M3, M4, M6 and M12 in comparison with M0 and against variant lineages of B.1.617.2 (Delta, India), B.1.617.2.1 (Delta Plus, India), B.1.351 (Beta, SA) and B.1.1.7 (Alpha, UK) are elevated at M3, M6 and M12 in comparison with M0. However, NAb levels against B.1.1.529 (Omicron) was consistently below the limit of detection except at M12. CONCLUSION: Thus, Covaxin induces an enhanced humoral immune response, with persistence till at least 12 months post-vaccination against most SARS-CoV-2 variants.

Comment on "Herpes zoster in the era of COVID-19: A prospective observational study to probe the association of herpes zoster with COVID-19 infection and vaccination".

Comparative global B cell receptor repertoire difference induced by SARS-CoV-2 infection or vaccination via single-cell V(D)J sequencing. Dynamic changes of the paired heavy and light chain B cell receptor (BCR) repertoire provide an essential insight into understanding the humoral immune response post-SARS-CoV-2 infection and vaccination. However, differences between the endogenous paired BCR repertoire kinetics in SARS-CoV-2 infection and previously recovered/naÃ¯ve subjects

treated with the inactivated vaccine remain largely unknown. We performed single-cell V(D)J sequencing of B cells from six healthy donors with three shots of inactivated SARS-CoV-2 vaccine (BBIBP-CorV), five people who received the BBIBP-CorV vaccine after having recovered from COVID-19, five unvaccinated COVID-19 recovered patients and then integrated with public data of B cells from four SARS-CoV-2-infected subjects. We discovered that BCR variable (V) genes were more prominently used in the SARS-CoV-2 exposed groups (both in the group with active infection and in the group that had recovered) than in the vaccinated groups. The VH gene that expanded the most after SARS-CoV-2 infection was IGHV3-33, while IGHV3-23 in the vaccinated groups. SARS-CoV-2-infected group enhanced more BCR clonal expansion and somatic hypermutation than the vaccinated healthy group. A small proportion of public clonotypes were shared between the SARS-CoV-2 infected, vaccinated healthy, and recovered groups. Moreover, several public antibodies had been identified against SARS-CoV-2 spike protein. We comprehensively characterize the paired heavy and light chain BCR repertoire from SARS-CoV-2 infection to vaccination, providing further guidance for the development of the next-generation precision vaccine.

Oral Adverse Events Following COVID-19 Vaccination: Analysis of VAERS Reports. BACKGROUND: Oral adverse events (AEs) following COVID-19 vaccination have been sporadically reported during the previous months, warranting further investigation for their prevalence and suspected relationship with vaccine-elicited immune response. METHODS: A retrospective analysis using the Vaccine Adverse Event Reporting System (VAERS) data was conducted to evaluate AEs within the oral cavity (mucosa, tongue, lips, palate, dentition, salivary glands) and AEs involving taste and other sensations. Oral AEs reported after receiving COVID-19 vaccination (test group) and seasonal influenza vaccination (control group) were extracted and cross-tabulated to assess their relative prevalence. RESULTS: Among the 128 solicited (suspected) oral AEs, oral paresthesia (0.872%) was most reported after receiving COVID-19 vaccines, followed by the swelling of lips (0.844%), ageusia (0.722%), oral hypoesthesia (0.648%), swollen tongue (0.628%), and dysgeusia (0.617%). The reported prevalence of oral AEs was higher in the COVID-19 vaccine group than in the seasonal influenza group. The distribution pattern of the most reported oral AEs was similar for both COVID-19 and seasonal influenza vaccines. Female sex, older age (>39 years old), primer doses, and mRNA-based COVID-19 vaccines exhibited a higher reported prevalence of oral AEs. CONCLUSION: Within the limitations of this study, COVID-19 vaccines were found to be associated with rare oral AEs that are predominantly similar to those emerging following seasonal influenza vaccines. The most commonly reported oral AEs were oral paraesthesia (mouth-tingling), lip swelling, and ageusia, representing various pathophysiologic pathways that remain unclear. Taste-related AEs should be acknowledged in the context of the COVID-19 pandemic and the public should be adequately informed about a potential taste dysfunction after receiving the COVID-19 vaccination. Dentists and dental teams need to be aware of the prevalence, severity, and prognosis of oral AEs to inform their patients and increase public confidence in vaccines.

Neutralizing Activity Against SARS-CoV-2 Delta and Omicron Variants Following a Third BNT162b2 Booster Dose According to Three Homologous or Heterologous COVID-19 Vaccination Schedules. With the emergence and rapid spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Delta and Omicron variants, escaping vaccine-induced immunity is a concern. Three vaccination schedules, homologous or heterologous, have been initially applied due to an insufficient supply of vaccines in Korea. We investigated neutralizing activities against Omicron and Delta variants in each schedule. Three schedules using three doses of the BNT162b2 (BNT) or the ChAdOx1 (ChAd) vaccines include ChAd-ChAd-BNT, ChAd-BNT-BNT, and BNT-BNT-BNT. Neutralizing activities were evaluated using plaque-reduction neutralization test (PRNT) against wild type (WT) SARS-CoV-2, Delta variant, and Omicron variant. A total of 170 sera from 75 participants were tested, and the baseline

characteristics of participants were not significantly different between groups. After the 2nd vaccine dose, geometric mean titers of PRNT ND(50) against WT, Delta, and Omicron were highest after ChAd-BNT vaccination (2,463, 1,097, and 107) followed by BNT-BNT (2,364, 674, and 38) and ChAd-ChAd (449, 163, and 25). After the 3rd dose of BNT, the increase of PRNT ND(50) against WT, Delta, and Omicron was most robust in ChAd-ChAd-BNT (4,632, 988, and 260), while the BNT-BNT-BNT group showed the most augmented neutralizing activity against Delta and Omicron variants (2,315 and 628). ChAd-BNT-BNT showed a slight increase of PRNT ND(50) against WT, Delta, and Omicron (2,757, 1,279, and 230) compared to the 2nd dose. The results suggest that a 3rd BNT booster dose induced strengthened neutralizing activity against Delta and Omicron variants. The waning of cross-reactive neutralizing antibodies after the 3rd dose and the need for additional boosting should be further investigated.

Acute necrotic disorder of the small intestine post-coronavirus disease-2019 vaccination. The Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine is extensively used worldwide, and its safety has been proven. Herein, we report a case of an acute necrotic disorder in the small intestine post-COVID-19 vaccination. The patient developed severe abdominal pain the day after the first vaccination. Contrast-enhanced computed tomography showed extensive ileum wall thickening and ascites. Colonoscopy revealed a ring-shaped ulcer and stricture in the terminal ileum. Ileocecal resection was performed, and the patient did not have further episodes of a necrotic disorder in the small intestine. Although it is unknown if this event is associated with vaccination, and this occurrence also does not outweigh the efficacy and safety of the Pfizer-BioNTech COVID-19 vaccine, gastroenterologists need to be aware of this rare case, given its noteworthy timing.

Suggested risk factor for oral lichen planus arising after mRNA COVID-19 vaccination. A single dose of BNT162b2 vaccine is suggested for COVID-19-infected individuals to reduce side effects due to release of inflammatory mediators such as oral lichen planus (OLP).

Leukocytoclastic Vasculitis Following COVID-19 Vaccination: A Case Report. Background: Hypersensitivity or Leukocytoclastic vasculitis (LCV) following the COVID-19 vaccination has been reported rarely all over the world. LCV can be induced by certain factors such as infections, autoimmune disorders, malignancy, or some classes of drugs. Case presentation: A 32-year-old man, who was a known case of seizure disorder from his childhood presented to the department of dermatology with itchy red lesions on extremities and abdomen for the past 1â€‰month. He explains a history of COVID-19 vaccination 1-month back and experienced itching on his lower limbs on the same day at night. A gradual worsening of the condition was observed day by day. He was hospitalized and diagnosed as LCV through clinical and laboratory findings. Conclusion: This case highlights a temporal association with the event of vaccination. The causality assessment showed an indeterminate causal association to LCV with COVID-19 Vaccination.

Usefulness of Vaccine Adverse Event Reporting System for Machine-Learning Based Vaccine Research: A Case Study for COVID-19 Vaccines. Usefulness of Vaccine-Adverse Event-Reporting System (VAERS) data and protocols required for statistical analyses were pinpointed with a set of recommendations for the application of machine learning modeling or exploratory analyses on VAERS data with a case study of COVID-19 vaccines (Pfizer-BioNTech, Moderna, Janssen). A total of 262,454 duplicate reports (29%) from 905,976 reports were identified, which were merged into a total of 643,522 distinct reports. A customized online survey was also conducted providing 211 reports. A total of 20 highest reported adverse events were first identified. Differences in results after applying various machine learning algorithms (association rule mining, self-organizing maps, hierarchical clustering, bipartite graphs) on VAERS data were noticed. Moderna reports showed injection-site-related AEs of higher frequencies by 15.2%, consistent with the online survey (12% higher reporting rate for pain in the muscle for Moderna compared to Pfizer-BioNTech). AEs {headache, pyrexia,

fatigue, chills, pain, dizziness} constituted >50% of the total reports. Chest pain in male children reports was 295% higher than in female children reports. Penicillin and sulfa were of the highest frequencies (22%, and 19%, respectively). Analysis of uncleaned VAERS data demonstrated major differences from the above (7% variations). Spelling/grammatical mistakes in allergies were discovered (e.g., ~14% reports with incorrect spellings for penicillin).
Macrotroponin Complex as a Cause for Cardiac Troponin Increase after COVID-19 Vaccination and Infection.
Commentary on Macrotroponin Complex as a Cause for Cardiac Troponin Increase after COVID-19 Vaccination and Infection.
Cerebral venous sinus thrombosis after COVID-19 vaccination and congenital deficiency of coagulation factors: Is there a correlation? In January 2020, SARS-COV-2 infection spread worldwide and was declared "pandemic" by WHO. Because of the high contagiousness of the virus and devastating effects of the epidemic on public health, numerous efforts have been made to develop suitable vaccines to prevent the infection. Among the side effects developed by patients who undergone vaccination, there are common symptoms but also more serious reactions such as the thrombosis syndromes. This paper presents two cases of thrombosis temporally associated with live-vectored Covid vaccination similar to vaccine-induced thrombocytopenia (VITT) in patients with inherited thrombophilia (respectively, the deficiency of protein S and a Factor II mutation). The clinical manifestation caused by VITT is characterized by widespread thrombosis especially affecting intracranial venous sinus, which may cause massive bleeding and intracranial hemorrhage. Although this condition is widely described in literature, there is no evident correlation between this side effect and inherited condition of thrombophilia. The authors suggest that the presence of inherited thrombophilia should be better investigated and, if necessary, screened during the anamnestic data collection before the vaccine administration, leading the healthcare professional to choose the appropriate vaccine to the patient.
[Bilateral Parsonage-Turner syndrome after COVID-19 vaccination. A case report and review of the literature]. Parsonage---Turner syndrome (PTS; neuralgic amyotrophy) is a generally unilateral neuritis with sudden onset, severe shoulder or upper arm pain. Although the intense pain is usually self-limiting, two-thirds of patients experience pro-gressive motor weakness, narrowed range of motion, reflex changes, dysesthesias and chronic neuropathic pain in the shoulder girdle musculature and proximal upper limb muscles. The aetiology is unclear, in addition to some idiopath-ic cases the most common triggers of PTS are surgery, trauma, infection or vaccination. It is reported after SARS-CoV-2 infection, and unilateral PTS has been described in some cases following different types of COVID-19 vaccines. We are currently presenting the case of a middle-aged woman who developed partial neuralgic amyotrophy on the right shoulder one month after receiving the second dose of the BNT162b2 COVID-19 mRNA vaccine (Pfizer-BioNTech), and seven months later the symptoms appeared in the contralateral upper limb. The diagnosis of PTS was also confirmed by magnetic resonance and electrodiagnostic examination. The PTS is not an uncommon condi-tion, but in the absence of knowledge it is rarely thought of. The purpose of this report is to draw attention to the possibility of PTS in shoulder or upper arm pain following both SARS-CoV-2 infection and COVID-19 vaccination, as early diagnosis and adequate therapy may help to shorten the course of the disease.
Enhanced Humoral Immune Response After COVID-19 Vaccination in Elderly Kidney Transplant Recipients on Everolimus Versus Mycophenolate Mofetil-containing Immunosuppressive Regimens: Erratum.
Cutaneous adverse events following the inactivated and mRNA COVID-19 vaccines: Correspondence.
Serological findings following the second and third SARS-CoV-2 vaccines in lung transplant recipients. INTRODUCTION: Lung transplant recipients (LuTX) represent a vulnerable population for severe acute

respiratory syndrome coronavirus 2 (SARS-CoV-2). Even though many vaccines are already developed, more clinical data need to support effective immunological response in immunocompromised patients. METHODS: Stable LuTX recipients with no medical history of coronavirus disease (COVID-19) were enrolled. Currently available messenger RNA (mRNA) (BNT162b2-mRNA, mRNA-1273) and non-mRNA (ChAdOx1, BBIBP-CorV) vaccines were given according to availability, boosters were all mRNA-based. SARS-CoV-2 Spike1 immunoglobulin G (IgG) antibody titer was evaluated before and 2 weeks after second and third dose. Difference between mRNA versus non-mRNA vaccines was assessed. RESULTS: Forty-one patients (49% men, age 48.4â€‰Â±â€‰13.8 years) received two doses of SARS-CoV-2 vaccines: 23 of mRNA, 18 of non-mRNA, and 24/41 (58%) received a third dose. Median 92 months passed since transplantation, and serum level of tacrolimus was median 5.5â€‰ng/ml. Positive serology was found in 37% of all patients after the second dose, 86% had mRNA vaccine. After the third dose, 29% became positive who had no antibody before. Significantly higher level of antibody was found after the second mRNA than non-mRNA vaccines (2.2 vs. 1568.8â€‰U/ml, respectively, pâ€‰=â€‰.002). 6/23 (26%) patients received two doses of mRNA vaccine developed COVID-19 after the second injection in an average of 178 days, half of them recovered, half of them died in intensive care unit (ICU). 3/6 (50%) patients with two doses mRNA and recovered from COVID-19 had significantly higher level of antibody (average 20847.3â€‰U/ml) than without infection. After the booster vaccine, 1/24 (4%) developed infection. CONCLUSION: Immunosuppression therapy may induce a weaker SARS-CoV-2 response in LuTX recipients; therefore, third dose is a priority in transplanted patients. The highest antibody level was measured recovering from COVID after two doses. Our data confirm that booster mRNA vaccine could increase antibody levels, even if immunization was started with non-mRNA vaccine.

[Clinical features of children with coronavirus disease 2019 Delta variant infection after vaccination with inactivated SARS-CoV-2 vaccine]. OBJECTIVES: To study the clinical features of children with coronavirus disease 2019 (COVID-19) Delta variant infection vaccinated or not vaccinated with inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. METHODS: A total of 11 children with COVID-19 Delta variant infection who were vaccinated with inactivated SARS-CoV-2 vaccine and were hospitalized in the designated hospital in Henan Province, China, from November 3 to December 17, 2021 were enrolled as the vaccinated group. Thirty-one children with COVID-19 Delta variant infection who were not vaccinated and were hospitalized during the same period were enrolled as the unvaccinated group. A retrospective analysis was performed on their epidemiological data, clinical features, and laboratory examination results. RESULTS: There was no significant difference in gender composition and disease classification between the two groups (P>0.05), and there was also no significant difference in the incidence rates of the clinical symptoms such as cough, expectoration, and fever between the two groups (P>0.05). No significant difference was found between the two groups in leukocyte count, lymphocyte percentage, alanine aminotransferase, and serum creatinine (P>0.05). Compared with the unvaccinated group, the vaccinated group had significantly lower levels of aspartate aminotransferase, lactate dehydrogenase, and creatine kinase-MB (P<0.05). There was no significant difference between the two groups in the proportion of children with elevated C-reactive protein or procalcitonin and the levels of peripheral blood cytokines (P>0.05). The vaccinated group had significantly lower counts of B lymphocytes and total T lymphocytes (CD3(+)) than the unvaccinated group (P<0.05). Compared with the unvaccinated group, the vaccinated group had a significantly higher positive rate of IgG on admission and at week 2 of the course of disease (P<0.05), as well as a significantly higher Ct value of nucleic acid at weeks 1 and 2 of the course of disease (P<0.05). CONCLUSIONS: Vaccination with inactivated SARS-CoV-2 vaccine may reduce myocardial injury caused by SARS-CoV-2 Delta variant. For children with SARS-CoV-2 Delta variant infection after the vaccination, more attention should be paid to their immune function.

COVID-19 vaccination rate and safety profile in a multicentre Italian population affected by mixed cryoglobulinaemic vasculitis. OBJECTIVES: Mixed cryoglobulinaemic vasculitis (MCV) is an immune-complex-mediated systemic vasculitis characterised by heterogeneous clinical manifestations mainly involving lymphatic system, skin, kidney and peripheral nervous system. Although MCV patients have been included in priority programs for vaccination against SARS-CoV-2 in Italy, limited information is available for these patients. The aims of this multicentre Italian study were to investigate SARS-CoV-2 vaccination rate in MCV patients and its safety profile. METHODS: All MCV patients referring to participating centres were assessed with an interview-based survey about vaccination, reasons for not getting vaccinated, adverse events (AE), and disease flares within a month after vaccination. RESULTS: A total of 416 patients were included in the study. Among participants, 7.7% did not get vaccinated, mainly for fear related to vaccine side-effects (50%) or medical decision (18.8%). They were more frequently treated with chronic glucocorticoids or rituximab (p=0.049 and p=0.043, respectively). Mild and self-limiting AE were recorded in 31.7% of cases, while post-vaccination vasculitis flares were observed in 5.3% of subjects. Disease relapses were mainly observed in patients with peripheral neuropathy or skin vasculitis (40% and 25%, respectively). CONCLUSIONS: Vaccination against SARS-CoV-2 has been performed in a high percentage of MCV patients with encouraging safety profile. Vasculitis flares rate was in line with that observed for other autoimmune diseases, despite patients with purpura or peripheral neuropathy seem to be at risk for symptoms' exacerbation. Patients' hesitancy, rituximab and glucocorticoids treatment were the main reasons for delaying vaccination.

Immunogenicity and risk of disease flare after a three-dose regimen with SARS-CoV-2 vaccination in patients with systemic lupus erythematosus: results from the prospective cohort study COVAC-SLE. OBJECTIVES: To investigate the humoral immune response and risk of disease flare in systemic lupus erythematosus (SLE) patients following three-doses of SARS-CoV-2 vaccines. METHODS: In adult patients with SLE, we measured SARS-CoV-2 spike IgG in blood samples drawn three weeks after the 1st dose (baseline), four and eight weeks after the 2nd dose and after the 3rd dose. A sufficient antibody response was â‰¥54BAU/mL. SLEDAI-2K, SLAQ and SDI were assessed at baseline and eight weeks after the 2nd dose along with adverse events. Demographic and treatment data were collected from hospital records. RESULTS: Of 123 patients, 115 (93.5%) received the BNT162b2 vaccine, the remaining received the 1st dose of ChAdOx-1 followed by a 2nd and 3rd dose of mRNA-1273. After the 2nd dose 102 (83%) patients had a sufficient antibody response (median 559.2, IQR 288.8-1180.5 BAU/mL), increasing to 115 (93.5%) (median 2416.9, IQR 1289-4603.8 BAU/mL) patients after the 3rd dose. Eight weeks after the 2nd dose patients treated with high dose prednisolone (p=0.034) and DMARDs (p<0.001) had significantly lower antibodies; however, this difference was not significant following the 3rd dose. Disease activity and damage were stable during the study period. Adverse events were more frequent in patients with a sufficient response. Breakthrough infections were reported in 39 (31.7%) patients; all with mild symptoms. CONCLUSIONS: A 3rd dose improved the humoral response to SARS-CoV-2 vaccines in patients with SLE to the level of healthy individuals. Vaccination did not affect SLE disease activity. Subsequent breakthrough infections were mild and did not require hospitalisation.

Anti-TNFÎ± Treatment Impairs Long-Term Immune Responses to COVID-19 mRNA Vaccine in Patients with Inflammatory Bowel Diseases. Patients with inflammatory bowel disease (IBD) treated with anti-tumor-necrosis factor-alpha (TNFÎ±) exhibited lower serologic responses one-month following the second dose of the COVID-19 BNT162b2 vaccine compared to those not treated with anti-TNFÎ± (non-anti-TNFÎ±) or to healthy controls (HCs). We comprehensively analyzed long-term humoral responses, including anti-spike (S) antibodies, serum inhibition, neutralization, cross-reactivity and circulating B cell six months post BNT162b2, in patients with IBD stratified by therapy compared to

HCs. Subjects enrolled in a prospective, controlled, multi-center Israeli study received two BNT162b2 doses. Anti-S levels, functional activity, specific B cells, antigen cross-reactivity, anti-nucleocapsid levels, adverse events and IBD disease score were detected longitudinally. In total, 240 subjects, 151 with IBD (94 not treated with anti-TNFÎ± and 57 treated with anti-TNFÎ±) and 89 HCs participated. Six months after vaccination, patients with IBD treated with anti-TNFÎ± had significantly impaired BNT162b2 responses, specifically, more seronegativity, decreased specific circulating B cells and cross-reactivity compared to patients untreated with anti-TNFÎ±. Importantly, all seronegative subjects were patients with IBD; of those, >90% were treated with anti-TNFÎ±. Finally, IBD activity was unaffected by BNT162b2. Altogether these data support the earlier booster dose administration in these patients.

A Large Cluster of New Onset Autoimmune Myositis in the Yorkshire Region Following SARS-CoV-2 Vaccination. BACKGROUND: The novel SARS-CoV-2 vaccines partially exploit intrinsic DNA or RNA adjuvanticity, with dysregulation in the metabolism of both these nucleic acids independently linked to triggering experimental autoimmune diseases, including lupus and myositis. METHODS: Herein, we present 15 new onset autoimmune myositis temporally associated with SARS-CoV-2 RNA or DNA-based vaccines that occurred between February 2021 and April 2022. Musculoskeletal, pulmonary, cutaneous and cardiac manifestations, laboratory and imaging data were collected. RESULTS: In total, 15 cases of new onset myositis (11 polymyositis/necrotizing/overlap myositis; 4 dermatomyositis) were identified in the Yorkshire region of approximately 5.6 million people, between February 2021 and April 2022 (10 females/5 men; mean age was 66.1 years; range 37-83). New onset disease occurred after first vaccination (5 cases), second vaccination (7 cases) or after the third dose (3 cases), which was often a different vaccine. Of the cases, 6 had systemic complications including skin (3 cases), lung (3 cases), heart (2 cases) and 10/15 had myositis associated autoantibodies. All but 1 case had good therapy responses. Adverse event following immunization (AEFI) could not be explained based on the underlying disease/co-morbidities. CONCLUSION: Compared with our usual regional Rheumatology clinical experience, a surprisingly large number of new onset myositis cases presented during the period of observation. Given that antigen release inevitably follows muscle injury and given the role of nucleic acid adjuvanticity in autoimmunity and muscle disease, further longitudinal studies are required to explore potential links between novel coronavirus vaccines and myositis in comparison with more traditional vaccine methods.

Factors Associated with Not Receiving a Booster Dose of COVID-19 Vaccine in Peru. To determine the factors associated with not receiving the booster dose for COVID-19 in Peru, a cross-sectional study by secondary analysis of a University of Maryland and Facebook survey database assessing the global impact of COVID-19 was conducted. Data of Peruvian users of this social network over 18 years of age who answered the survey between 13 February 2022 and 14 April 2022 were analyzed. We evaluated the association between sociodemographic characteristics, comorbidities, and history of COVID-19 with having received a booster dose for COVID-19. Crude (cPR) and adjusted (aPR) prevalence ratios with their respective 95% confidence intervals (95%CI) were calculated. A sample of 20,814 adults, 21.5% of whom reported not receiving the booster dose, was analyzed. People under 75 years of age had a higher prevalence of not having received the booster dose. Likewise, having a university education (aPR = 1.03; 95%CI: 1.02-1.05), secondary, or pre-university education (aPR = 1.07; 95%CI: 1.05-1.09), or having a primary level or less (aPR = 1.11; 95%CI: 1.05-1.18), were associated with a higher prevalence of not receiving the booster, compared to individuals with a postgraduate education. Being employed (aPR = 1.01; 95%CI: 1.00-1.02), having had COVID-19 (aPR = 1.03; 95%CI: 1.01-1.04) and living in a town (aPR = 1.05; 95%CI: 1.02-1.07) or in a rural area (aPR = 1.06; 95%CI: 1.03-1.10), compared to living in the city, had a similar association. On the contrary, the female gender was associated with a lower prevalence of not receiving the booster (aPR = 0.97;

95%CI: 0.96-0.99). Sociodemographic characteristics and a history of having had COVID-19 were associated with the probability of not having received the booster dose for COVID-19 in the Peruvian population.

DNA-Vaccine-Induced Immune Response Correlates with Lower Viral SARS-CoV-2 Titers in a Ferret Model. The COVID-19 pandemic is entering a new era with the approval of many SARS-CoV-2 vaccines. In spite of the restoration of an almost normal way of life thanks to the immune protection elicited by these innovative vaccines, we are still facing high viral circulation, with a significant number of deaths. To further explore alternative vaccination platforms, we developed COVID-eVax-a genetic vaccine based on plasmid DNA encoding the RBD domain of the SARS-CoV-2 spike protein. Here, we describe the correlation between immune responses and the evolution of viral infection in ferrets infected with the live virus. We demonstrate COVID-eVax immunogenicity as means of antibody response and, above all, a significant T-cell response, thus proving the critical role of T-cell immunity, in addition to the neutralizing antibody activity, in controlling viral spread.

COVID vaccine-associated myocarditis in an 8-year-old patient. COVID vaccine-associated myocarditis was first identified in March 2021. There have been numerous case reports that detail the clinical course of paediatric patients older than age 12 with COVID vaccine-associated myocarditis. There are still very few reports of children between the ages of 5 and 11 with COVID vaccine-associated myocarditis. We present an 8 year- old with COVID vaccine-associated myocarditis after his second vaccination against SARS-CoV-2.

Humoral response after SARS-CoV-2 booster vaccination in haemodialysis patients with and without prior infection.

Neutralising antibody responses to SARS-CoV-2 omicron among elderly nursing home residents following a booster dose of BNT162b2 vaccine: A community-based, prospective, longitudinal cohort study. BACKGROUND: The protective immunity against omicron following a BNT162b2 Pfizer booster dose among elderly individuals (ie, those aged >65 years) is not well characterised. METHODS: In a community-based, prospective, longitudinal cohort study taking place in France in which 75 residents from three nursing homes were enrolled, we selected 38 residents who had received a two-dose regimen of mRNA vaccine and a booster dose of Pfizer BNT162b2 vaccine. We excluded individuals that did not receive three vaccine doses or did not have available sera samples. We measured anti-S IgG antibodies and neutralisation capacity in sera taken 56 (28-68) and 55 (48-64) days (median (range)) after the 2(nd) and 3(rd) vaccine doses, respectively. Antibodies targeting the SARS-CoV-2 Spike protein were measured with the S-Flow assay as binding antibody units per milliliter (BAU/mL). Neutralising activities in sera were measured as effective dilution 50% (ED50) with the S-Fuse assay using authentic isolates of delta and omicron BA.1. FINDINGS: Among the 38 elderly individuals recruited to the cohort study between November 23(rd), 2020 and April 29(th), 2021, with median age of 88 (range 72-101) years, 30 (78.95%) had been previously infected with SARS-CoV-2. After three vaccine doses, serum neutralising activity was lower against omicron BA.1 (median ED50 of 774.5, range 15.0-34660.0) than the delta variant (median ED50 of 4972.0, range 213.7-66340.0), and higher among previously infected (ie, convalescent; median ED50 against omicron: 1088.0, range 32.6-34660.0) compared with infection-naive residents (median ED50 against omicron: 188.4, range 15.0-8918.0). During the French omicron wave in December 2021-January 2022, 75% (6/8) of naive residents were infected, compared to 25% (7/30) of convalescent residents (P=0.0114). Anti-Spike antibody levels and neutralising activity against omicron BA.1 after a third BNT162b2 booster dose were lower in those with breakthrough BA.1 infection (n=13) compared with those without (n=25), with a median of 1429.9 (range 670.9-3818.3) BAU/mL vs 2528.3 (range 695.4-8832.0) BAU/mL (P=0.029) and a median ED50 of 281.1 (range 15.0-2136.0) vs 1376.0 (range 32.6-34660.0) (P=0.0013), respectively. INTERPRETATION: This study shows that elderly individuals who received

three vaccine doses elicit neutralising antibodies against the omicron BA.1 variant of SARS-CoV-2. Elderly individuals who had also been previously infected showed higher neutralising activity compared with naive individuals. Yet, breakthrough infections with omicron occurred. Individuals with breakthrough infections had significantly lower neutralising titers compared to individuals without breakthrough infection. Thus, a fourth dose of vaccine may be useful in the elderly population to increase the level of neutralising antibodies and compensate for waning immunity. FUNDING: Institut Pasteur, Fondation pour la Recherche MÃ©dicale (FRM), European Health Emergency Preparedness and Response Authority (HERA), Agence nationale de recherches sur le sida et les hÃ©patites virales - Maladies Infectieuses Emergentes (ANRS-MIE), Agence nationale de la recherche (ANR), Assistance Publique des HÃ´pitaux de Paris (AP-HP) and Fondation de France.

Think like a Virus: Toward Improving Nanovaccine Development against SARS-CoV-2. There is no doubt that infectious diseases present global impact on the economy, society, health, mental state, and even political aspects, causing a long-lasting dent, and the situation will surely worsen if and when the viral spread becomes out of control, as seen during the still ongoing coronavirus disease 2019 (COVID-19) pandemic. Despite the considerable achievements made in viral prevention and treatment, there are still significant challenges that can be overcome through careful understanding of the viral mechanism of action to establish common ground for innovating new preventative and treatment strategies. Viruses can be regarded as devil nanomachines, and one innovative approach to face and stop the spread of viral infections is the development of nanoparticles that can act similar to them as drug/vaccine carriers. Moreover, we can use the properties that different viruses have in designing nanoparticles that reassemble the virus conformational structures but that do not present the detrimental threats to human health that native viruses possess. This review discusses the current preventative strategies (i.e., vaccination) used in facing viral infections and the associated limitations, highlighting the importance of innovating new approaches to face viral infectious diseases and discussing the current nanoapplications in vaccine development and the challenges that still face the nanovaccine field.

Kinetics of the SARS-CoV-2 Antibody Avidity Response Following Infection and Vaccination. Serological assays capable of measuring antibody responses induced by previous infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been critical tools in the response to the COVID-19 pandemic. In this study, we use bead-based multiplex assays to measure IgG and IgA antibodies and IgG avidity to five SARS-CoV-2 antigens (Spike (S), receptor-binding domain (RBD), Nucleocapsid (N), S subunit 2, and Membrane-Envelope fusion (ME)). These assays were performed in several cohorts of healthcare workers and nursing home residents, who were followed for up to eleven months after SARS-CoV-2 infection or up to six months after vaccination. Our results show distinct kinetic patterns of antibody quantity (IgG and IgA) and avidity. While IgG and IgA antibody levels waned over time, with IgA antibody levels waning more rapidly, avidity increased with time after infection or vaccination. These contrasting kinetic patterns allow for the estimation of time since previous SARS-CoV-2 infection. Including avidity measurements in addition to antibody levels in a classification algorithm for estimating time since infection led to a substantial improvement in accuracy, from 62% to 78%. The inclusion of antibody avidity in panels of serological assays can yield valuable information for improving serosurveillance during SARS-CoV-2 epidemics.

Characterization of the Antibody and Interferon-Gamma Release Response after a Second COVID-19 Booster Vaccination. The emergence of SARS-CoV-2 Omicron subvariants prompted countries to call for accelerated booster vaccinations to limit disease and transmission. Here, we characterized correlates of protection over time after the second booster or after Omicron BA.1 infection comparing variants of concern (VOCs). Sera from subjects before and two and seven weeks after the second booster or after Omicron infection were examined for the level of Spike receptor-binding-

domain (RBD)-specific antibodies. Furthermore, neutralizing antibodies (nABs) were characterized in in vitro neutralization assays comparing the variants of concern Alpha, Beta, Delta, and Omicron BA.1 and BA.2 against the ancestral strain B.1. Here, the second booster resulted in an increase in anti-RBD-IgG-antibodies, remaining nearly constant over time, accompanied by an increase in nABs against B.1 and the VOCs Alpha, Beta, Delta, and Omicron BA.1 and BA.2. However, compared to B.1, the neutralizing capacity against the Omicron subvariants remained low and was limited after the second booster vaccination. This indicates that antibody-mediated protection against infection with this VOC is unlikely, as evidenced by the fact that three individuals of our study cohort became infected with Omicron BA.1 after the second booster. T cell activation was measured by interferon-gamma release assays in a subgroup of subjects and was increased in all subjects tested after the second booster vaccination, correlating with the amount of Spike-specific antibodies. In subjects with Omicron BA.1 breakthrough infection, a significant increase in nABs to all VOCs studied was observed independently of booster vaccinations. Taken together, our data indicate that a second booster or Omicron BA.1 infection mediate a substantial increase in anti-Spike IgG antibodies; however, infection with Omicron BA.1 induced a stronger increase in neutralizing antibodies against the different VOCs.

COVID-19 Vaccine for Children: Vaccination Willingness of Parents and Its Associated Factors-A Network Analysis. Different COVID-19 vaccines have been approved for underage children, so parents and caregivers currently face the decision of whether to vaccinate their children against COVID-19 or not. Due to the rather moderate vaccine acceptance among parents across different countries, the objective of the present study was to investigate the relationship between different psychological, demographic, and behavioral factors related to the acceptance of the COVID-19 vaccine for underage children among parents. In particular, vaccination attitudes, whether parents have been vaccinated against COVID-19 themselves, COVID-19 fear, attitude towards COVID-19 policy measures, governmental trust, subjective level of information, perceived risk of disease progression, and perceived risk of vaccine side effects were the variables of interest. The study adopted a cross-sectional study design, and the sample consisted of 2405 participants. A network analysis was conducted to investigate the associations and interconnection among these variables. The results showed that, in particular, compliance, confidence in the safety of vaccines, whether parents have been vaccinated against COVID-19 themselves, trust in the governmental system, fear of COVID-19, and the parents' age were directly related to the acceptance of the COVID-19 vaccine for children. To increase compliance and confidence in the vaccines' safety among parents, promotion campaigns should provide more information concerning the vaccines' safety, particularly for younger parents who are not vaccinated against COVID-19 themselves.

Quantitative Analysis of Anti-N and Anti-S Antibody Titers of SARS-CoV-2 Infection after the Third Dose of COVID-19 Vaccination. We quantitatively analyzed SARS-CoV-2 antibody levels in patients after two doses of the ChAdOx1 nCoV-19 vaccine and the third BNT162b2 booster. We obtained 255 serum samples from 149 healthcare workers 1 and 4 months after the third dose. Of the 149 participants, 58 (38.9%) experienced COVID-19 infection during the 4-month study period, with infection occurring 7âˆ’62 days before the second blood draw. Total antibody titers against the anti-spike (anti-S) and anti-nucleocapsid (anti-N) proteins of SARS-CoV-2 were measured using Elecsys Anti-SARS-CoV-2 S and Elecsys Anti-SARS-CoV-2 assays (Roche), respectively. The median anti-S antibody titer in the non-infected groups at 4 months after the third dose was significantly decreased compared to that at 1 month after the third dose (from 17,777 to 3673 U/mL, $p < 0.001$). The infected group showed higher median anti-S antibody titers at 4 months (19,539 U/mL) than the non-infected group (3673 U/mL). The median anti-N antibody titer in the infected group at 4 months after the third dose was a 5.07 cut-off index (79.3% positivity). Anti-N antibody titers in the infected group were

correlated with the number of days after SARS-CoV-2 infection. These data provide useful information for determining quarantine strategies and fourth vaccination requirements.

Clinical and Molecular Characterization of a Rare Case of BNT162b2 mRNA COVID-19 Vaccine-Associated Myositis. Initial clinical trials and surveillance data have shown that the most commonly administered BNT162b2 COVID-19 mRNA vaccine is effective and safe. However, several cases of mRNA vaccine-induced mild to moderate adverse events were recently reported. Here, we report a rare case of myositis after injection of the first dose of BNT162b2 COVID-19 mRNA vaccine into the left deltoid muscle of a 34-year-old, previously healthy woman who presented progressive proximal muscle weakness, progressive dysphagia, and dyspnea with respiratory failure. One month after vaccination, BNT162b2 vaccine mRNA expression was detected in a tissue biopsy of the right deltoid and quadriceps muscles. We propose this case as a rare example of COVID-19 mRNA vaccine-induced myositis. This study comprehensively characterizes the clinical and molecular features of BNT162b2 mRNA vaccine-associated myositis in which the patient was severely affected.

HPV Vaccination during the COVID-19 Pandemic in Italy: Opportunity Loss or Incremental Cost. OBJECTIVES: Italy was the first European country to introduce universal vaccination of adolescents, for both males and females, against Human Papilloma Virus (HPV) starting in 2017 with the NIP 2017-2019's release. However, vaccine coverage rates (VCRs) among adolescents have shown a precarious take-off since the NIP's release, and this situation worsened due to the impact of the COVID-19 pandemic in 2020. The aim of this work is to estimate the epidemiological and economic impact of drops in VCRs due to the pandemic on those generations that missed the vaccination appointment and to discuss alternative scenarios in light of the national data. METHODS: Through an analysis of the official ministerial HPV vaccination reports, a model was developed to estimate the number of 12-year-old males and females who were not vaccinated against HPV during the period 2017-2021. Based on previously published models that estimate the incidence and the economic impact of HPV-related diseases in Italy, a new model was developed to estimate the impact of the aggregated HPV VCRs achieved in Italy between 2017 and 2021. RESULTS: Overall, in 2021, 723,375 girls and 1,011,906 boys born between 2005 and 2009 were not vaccinated against HPV in Italy (42% and 52% of these cohorts, respectively). As compared with the 95% target provided by the Italian NIP, between 505,000 and 634,000 girls will not be protected against a large number of HPV-related diseases. For boys, the number of the unvaccinated population compared to the applicable target is over 615,000 in the 'best case scenario' and over 749,000 in the 'worst case scenario'. Overall, between 1.1 and 1.3 million young adolescents born between 2005 and 2009 will not be protected against HPV-related diseases over their lifetime with expected lifetime costs of non-vaccination that will be over EUR 905 million. If the 95% optimal VCRs were achieved, the model estimates a cost reduction equal to EUR 529 million, the net of the costs incurred to implement the vaccination program. CONCLUSION: Suboptimal vaccination coverage represents a missed opportunity, not only because of the increased burden of HPV-related diseases, but also in terms of economic loss. Thus, reaching national HPV immunization goals is a public health priority.

Immune Response after mRNA COVID-19 Vaccination in Lung Transplant Recipients: A 6-Month Follow-Up. BACKGROUND AND OBJECTIVE: This prospective cohort study analyzed the immune response to COVID-19 mRNA vaccines in lung transplant recipients (LuTRs) compared to healthy controls (HCs) at a 6-month follow-up. METHODS: After the first two doses of either BNT162b2 or mRNA-1273, SARS-CoV-2 antibodies were measured in LuTRs (n = 57) and sex- and age-matched HCs (n = 57). Antibody kinetics during a 6-month follow-up and the effect of a third vaccine dose were evaluated. Humoral responses were assessed using the Elecsys(Â®) Anti-SARS-CoV-2 S immunoassay. In 16 LuTRs, SARS-CoV-2-specific T cell responses were quantified using IFN-Î³ ELISpot assays. RESULTS: Seroconversion rates were 94% and 100% after the first and second vaccine dose,

respectively, in HCs, while only 19% and 56% of LuTRs developed antibodies. Furthermore, 22 of 24 LuTRs who received the third vaccine dose showed seroconversion (five of seven primary non-responders and 17 of 17 primary responders). A T cell response against SARS-CoV-2-spike S1 and/or S2 was detected in 100% (16/16) of HCs and 50% (8/16) of LuTRs. CONCLUSIONS: The data suggest that LuTRs have reduced humoral and cellular immune responses after two doses of COVID-19 mRNA vaccination when compared to HCs. A third dose may be of substantial benefit.

A Rare Adverse Effect of the COVID-19 Vaccine on Autoimmune Encephalitis. Since countries commenced COVID-19 vaccination around the world, many vaccine-related adverse effects have been reported. Among them, short-term memory loss with autoimmune encephalitis (AE) was reported as a rare adverse effect. Since case numbers are limited, this brief report may draw the attention of the medical community to this uncommon adverse effect and serve as a reference for future vaccine improvement. However, given the high risk of adverse outcomes when infected with SARS-CoV-2 and the clearly favorable safety/tolerability profile of existing vaccines, vaccination is still recommended.

Incidence and Characteristics of Adverse Events after COVID-19 Vaccination in a Population-Based Programme. Compliance with vaccination is linked to its safety. In Italy, a plan to identify people who could be at an increased risk of adverse events (AEs) was defined so they could be vaccinated in a protected setting. We conducted an audit to describe the process of AE risk assessment and occurrence in the Reggio Emilia Province in Italy in people who received any of the four COVID-19 vaccines currently used in Italy. Incidence of AEs was calculated by dose and type of vaccine and type of setting (standard vs. protected). After 182,056 first doses were administered, 521 (0.3%) AEs were reported. Most of the AEs were non-serious (91.4%) and non-allergic (92.7%). The percentage of AEs was similar in both settings: 0.3% in the standard setting and 0.2% in the protected setting. However, the incidence of AEs was higher among those who had an allergist visit than among those who did not (IR 666.7 vs. 124.9). All deaths (1.6/100.000) occurred in standard settings and after the Pfizer and Moderna vaccines. The incidence of AEs was lower after the second dose (IR 286.2 vs. 190.3), except for mRNA vaccines, for which it was higher after the second dose (IR 169.8 vs. 251.8). Although vaccination in a protected medical setting could reassure patients with a history of allergies to be vaccinated, allergy history and other anamnestic information is not useful in predicting the risk of COVID-19 vaccine-related AEs in the general population.

Acceptance of Booster COVID-19 Vaccine and Its Association with Components of Vaccination Readiness in the General Population: A Cross-Sectional Survey for Starting Booster Dose in Japan. The Japanese government approved COVID-19 vaccine booster doses in November 2021. However, intentions and readiness for booster vaccines among the general population were unknown. This survey measured the intentions for COVID-19 booster vaccination. Among 6172 participants (53.2% female), 4832 (78.3%) accepted booster doses; 415 (6.7%) hesitated. Vaccination intention was associated with higher age, marital status, having children, underlying diseases, and social norms. To evaluate the readiness for vaccination, the seven component (7C) vaccination readiness scale was employed, comprising â€œConfidenceâ€•, â€œComplacencyâ€•, â€œConstraintsâ€•, â€œCalculationâ€•, â€œCollective responsibilityâ€•, â€œComplianceâ€•, and â€œConspiracyâ€•. Participants with acceptance showed significantly higher 7C scores ($p < 0.001$) than those who hesitated or were unsure. Multivariable logistic regression analysis revealed that the â€œsocial normsâ€• predictor was the strongest predictor of acceptance (adjusted odds ratio (AOR) 4.02, 95% confidence interval (CI): 3.64â^'4.45). â€œConstraintsâ€• (AOR: 2.27, 95% CI: 2.11â^'2.45) and â€œcomplacencyâ€• (AOR: 2.18, 95% CI: 2.03â^'2.34) were also strongly associated with acceptance, but â€œcomplianceâ€• (AOR: 1.24, 95% CI: 1.18â^'1.31) and â€œconspiracyâ€• (AOR: 1.42, 95% CI: 1.33â^'1.52) were weakly associated. The â€œ7C vaccination readiness scaleâ€• is useful for measuring vaccine acceptance in the Japanese population. However, â€œsocial normsâ€• might be

more suitable than â€œcomplianceâ€• and â€œconspiracyâ€• for measuring vaccine acceptance in Japan.

Immunity after COVID-19 Recovery and Vaccination: Similarities and Differences. The coronavirus disease 2019 (COVID-19) pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is associated with a robust immune response. The development of systemic inflammation leads to a hyperinflammatory state due to cytokine release syndrome during severe COVID-19. The emergence of many new SARS-CoV-2 variants across the world deteriorates the protective antiviral immunity induced after infection or vaccination. The innate immune response to SARS-CoV-2 is crucial for determining the fate of COVID-19 symptomatology. T cell-mediated immunity is the main factor of the antiviral immune response; moreover, SARS-CoV-2 infection initiates a rapid B-cell response. In this paper, we present the current state of knowledge on immunity after COVID-19 infection and vaccination. We discuss the mechanisms of immune response to various types of vaccines (nucleoside-modified, adenovirus-vectored, inactivated virus vaccines and recombinant protein adjuvanted formulations). This includes specific aspects of vaccination in selected patient populations with altered immune activity (the elderly, children, pregnant women, solid organ transplant recipients, patients with systemic rheumatic diseases or malignancies). We also present diagnostic and research tools available to study the anti-SARS-CoV-2 cellular and humoral immune responses.

Rare Adverse Events Associated with BNT162b2 mRNA Vaccine (Pfizer-BioNTech): A Review of Large-Scale, Controlled Surveillance Studies. Given the increasing anti-vaccine movements erroneously touting vaccine danger, this review has investigated the rare adverse events potentially associated with BNT162b2 (Pfizer-BioNTech), an mRNA vaccine against the severe acute respiratory distress syndrome coronavirus 2 (SARS-CoV-2). Only real-world surveillance studies with at least 0.1 million BNT162b2-vaccinated participants and one unvaccinated control group were selected for review. A total of 21 studies examining the potential association of BNT162b2 with cardiovascular, herpetic, thrombotic or thrombocytopenic, neurological, mortality, and other miscellaneous rare adverse events were described in this review. Only myocarditis is consistently associated with BNT162b2. An unclear direction of association was seen with stroke (hemorrhagic and ischemic), herpes zoster, and paresthesia from BNT162b2, which may require more studies to resolve. Fortunately, most surveillance studies detected no increased risks of the remaining rare adverse events reviewed herein, further reassuring the safety of BNT162b2. In conclusion, this review has concisely summarized the current rare adverse events related and unrelated to BNT162b2, arguably for the first time in sufficient depth, to better communicate vaccine safety to the public.

Post-Vaccinal Encephalitis with Early Relapse after BNT162b2 (COMIRNATY) COVID-19 Vaccine: A Case Report. We describe the case of a 72-year-old man who received the first dose of the BNT162b2 (COMIRNATY) vaccine against COVID-19 on 18 May 2021, and the second dose on 9 September 2021. One day after receiving the first dose, he cursed with malaise, headache, fever, confusion, aggressiveness, and gait alterations. We performed serum and cerebrospinal fluid (CSF) tests (finding elevated proteins in CSF) with negative results for infectious, systemic, and neoplastic causes. We performed brain nuclear magnetic resonance imaging (MRI), finding circumscribed encephalitis at the anterior frontal and bilateral temporal lobes. We were unable to perform a panel of antineuronal antibodies. The patient was readmitted due to early clinical relapse four days after receiving his second dose. We found sequelae lesions at the frontal level but with new demyelinating lesions at the left temporal level in brain MRI. We indicated methylprednisolone, and he presented a favorable improvement. We report an encephalitis case of probable autoimmune etiology after vaccination with BNT162b2, which presented early clinical relapse after receiving the second dose and presented a favorable response to methylprednisolone.

Durability of Humoral and Cellular Immunity after an Extended Primary Series with Heterologous Inactivated SARS-CoV-2 Prime-Boost and ChAdOx1 nCoV-19 in Dialysis Patients (ICON3). The durability of a three-dose extended primary series of COVID-19 vaccine in dialysis patients remains unknown. Here, we assessed dynamic changes in SARS-CoV-2-specific humoral and cell-mediated immunity at baseline, 3 months, and 6 months after the extended primary series in 29 hemodialyzed (HD), 28 peritoneal dialyzed (PD) patients, and 14 healthy controls. Participants received two doses of inactivated SARS-CoV-2 vaccine followed by a dose of ChAdOx1 nCoV-19 vaccine. At 6 months, median anti-RBD IgG titers (IQR) significantly declined from baseline in the HD (1741 (1136â^'3083) BAU/mL vs. 373 (188â^'607) BAU/mL) and PD (1093 (617â^'1911) BAU/mL vs. 180 (126â^'320) BAU/mL) groups, as did the mean percent inhibition of neutralizing antibodies (HD: 96% vs. 81%; PD: 95% vs. 73%) (all $p < 0.01$). Age and post-vaccination serological response intensity were predictors of early humoral seroprotection loss. In contrast, cell-mediated immunity remained unchanged. In conclusion, humoral immunity declined substantially in dialysis patients, while cell-mediated immunity remained stable 6 months after the extended heterologous primary series of two inactivated SARS-CoV-2/ChAdOx1 nCoV-19 vaccine. A booster dose could be considered in dialysis patients 3 months after this unique regimen, particularly in the elderly or those with a modest initial humoral response.

Uptake of COVID-19 Booster Dose among Saudi Arabian Population. Backgroundand objectives: Although several vaccines have been produced and administered around the world, new SARS-CoV-2 worsened the COVID-19 infection risk and impacted the initial vaccine dosage effectiveness. Based on studies indicating that the third and fourth COVID-19 vaccine doses significantly reduced COVID-19 transmission, Saudi Arabia has been administering COVID-19 booster vaccine doses to its citizens. The purpose of this study was to evaluate the uptake of the COVID-19 vaccine booster in relation to the socio-demographic characteristics and other associated factors among the Saudi population. Materials and Methods: This study was an online analytical cross-sectional study using a self-administered questionnaire. Pearson Chi-square test and multiple logistic regression analyses were used to determine factors associated with the uptake of COVID-19 booster dose vaccines. Results: A total of 2332 responded to our study. Overall, 527 (22.6%) participants had received a booster dose. An age of 55 and above (aOR: 5.415; 95% CI: 2.719-10.783), Eastern region (aOR: 2.513; 95% CI: 1.566-4.033), history of influenza vaccination at annual intervals (aOR: 2.387; 95% CI: 1.730-3.293), the first dose of Moderna vaccine (aOR: 1.324; 95% CI: 1.160-1.510), and cancer (aOR: 2.161; 95% CI: 1.218-3.879) were independent factors most associated with a higher uptake of the COVID-19 vaccine booster dose. In contrast, the second dose of Moderna vaccine (aOR: 0.794; 95% CI: 0.683-0.922), AstraZeneca vaccine (aOR: 0.691; 95% CI: 0.509-0.939), strong symptoms from side effects after the second dose of the COVID-19 vaccine (aOR: 0.615; 95% CI: 0.404-0.935) were independent factors most associated with a lower uptake of the COVID-19 vaccine booster dose. Conclusions: Our findings indicate low COVID-19 vaccine booster uptake. This necessitates the need for strategies to address discouraging factors of the COVID-19 vaccine booster dose uptake and engage the Saudi population to raise awareness about the importance of the booster dose.

Antibody Responses after Two Doses of COVID-19 mRNA Vaccine in Dialysis and Kidney Transplantation Patients Recovered from SARS-CoV-2 Infection. Background and Objectives: Hemodialysis patients (HD) and kidney transplant recipients (KTRs) have been heavily impacted by COVID-19, showing increased risk of infection, worse clinical outcomes, and higher mortality rates than the general population. Although mass vaccination remains the most successful measure in counteracting the pandemic, less evidence is available on vaccine effectiveness in immunodepressed subjects previously infected and recovered from COVID-19. Materials and Methods: This study aimed at investigating the ability to develop an adequate antibody response after vaccination in a 2-dose

series against SARS-CoV-2 in HD patients and KTR that was administered after laboratory and clinical recovery from COVID-19. Results: Comparing SARS-CoV-2 S1/S2 IgG levels measured before and after 2 doses of mRNA vaccine (BNT162b2 vaccine, Comirnaty, Pfizer-BioNTech or mRNA-1273 vaccine, Spikevax, Moderna), highly significant increases of antibody titers were observed. The antibody peak level was reached at 3 months following second dose administration, regardless of the underlying cause of immune depression and the time of pre-vaccine serology assessment after negativization. Conclusions: Our data indicate that HD patients and KTR exhibit a satisfying antibody response to a 2-dose series of mRNA vaccine, even in cases when infection-induced humoral immunity was poor or rapidly fading. Further studies are needed to evaluate the role of booster doses in conferring effective and durable protection in weak patient categories.

ANCA-Associated Vasculitis May Result as a Complication to Both SARS-CoV-2 Infection and Vaccination. In the last two years, our world experienced one of the most devastating and fast-exploding pandemic, due to the wide spread of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). The scientific community managed to develop effective vaccines, the main weapons to shield the immune system and protect people. Nevertheless, both SARS-CoV-2 infection and the vaccination against it have been associated with the stimulation of inflammatory cells such as T and B lymphocytes that results in a cytokine storm, endothelial inflammation and vascular injury, which can lead to different types of vasculitis. We present the first case of de novo MPO-ANCA-associated vasculitis, which developed shortly after SARS-CoV-2 vaccination, adequately responded to treatment, and subsequently relapsed after COVID-19 infection. With this case, we indicate an etiological connection between viral infection and disease development, as well as the possibility of a common immune mechanism between SARS-CoV-2 infection and vaccination, that can stimulate vascular events and lead to vasculitis. There have been several case reports of de novo vasculitis, affecting large, medium, or small vessels, following either infection or vaccination against COVID-19, during the pandemic outbreak. We summarize previous reports and also analyze proposed pathogenic mechanisms between SARS-CoV-2 and vasculitis.

Pre-Omicron Vaccine Breakthrough Infection Induces Superior Cross-Neutralization against SARS-CoV-2 Omicron BA.1 Compared to Infection Alone. SARS-CoV-2 variants raise concern because of their high transmissibility and their ability to evade neutralizing antibodies elicited by prior infection or by vaccination. Here, we compared the neutralizing abilities of sera from 70 unvaccinated COVID-19 patients infected before the emergence of variants of concern (VOCs) and of 16 vaccine breakthrough infection (BTI) cases infected with Gamma or Delta against the ancestral B.1 strain, the Gamma, Delta and Omicron BA.1 VOCs using live virus. We further determined antibody levels against the Nucleocapsid (N) and full Spike proteins, the receptor-binding domain (RBD) and the N-terminal domain (NTD) of the Spike protein. Convalescent sera featured considerable variability in the neutralization of B.1 and in the cross-neutralization of different strains. Their neutralizing capacity moderately correlated with antibody levels against the Spike protein and the RBD. All but one convalescent serum failed to neutralize Omicron BA.1. Overall, convalescent sera from patients with moderate disease had higher antibody levels and displayed a higher neutralizing ability against all strains than patients with mild or severe forms of the disease. The sera from BTI cases fell into one of two categories: half the sera had a high neutralizing activity against the ancestral B.1 strain as well as against the infecting strain, while the other half had no or a very low neutralizing activity against all strains. Although antibody levels against the spike protein and the RBD were lower in BTI sera than in unvaccinated convalescent sera, most neutralizing sera also retained partial neutralizing activity against Omicron BA.1, suggestive of a better cross-neutralization and higher affinity of vaccine-elicited antibodies over virus-induced antibodies. Accordingly, the IC50: antibody level ratios were comparable for BTI and convalescent sera, but remained lower in the neutralizing convalescent sera

from patients with moderate disease than in BTI sera. The neutralizing activity of BTI sera was strongly correlated with antibodies against the Spike protein and the RBD. Together, these findings highlight qualitative differences in antibody responses elicited by infection in vaccinated and unvaccinated individuals. They further indicate that breakthrough infection with a pre-Omicron variant boosts immunity and induces cross-neutralizing antibodies against different strains, including Omicron BA.1.

Cellular and Humoral Responses Follow-up for 8 Months after Vaccination with mRNA-Based Anti-SARS-CoV-2 Vaccines. Vaccination against SARS-CoV-2 has become the main method of reducing mortality and severity of COVID-19. This work aims to study the evolution of the cellular and humoral responses conferred by two mRNA vaccines after two doses against SARS-CoV-2. On days 30 and 240 after the second dose of both vaccines, the anti-S antibodies in plasma were evaluated from 82 volunteers vaccinated with BNT162b2 and 68 vaccinated with mRNA-1273. Peripheral blood was stimulated with peptides encompassing the entire SARS-CoV-2 Spike sequence. IgG Anti-S antibodies (humoral) were quantified on plasma, and inflammatory cytokines (cellular) were measured after stimulation. We observed a higher response (both humoral and cellular) with the mRNA-1273 vaccine. Stratifying by age and gender, differences between vaccines were observed, especially in women under 48 and men over 48 years old. Therefore, this work could help to set up a vaccination strategy that could be applied to confer maximum immunity.

Immune Response in Regard to Hypersensitivity Reactions after COVID-19 Vaccination. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19), is a member of the genus Betacoronavirus. This virus was first detected in December 2019, and the situation quickly escalated to cause a global pandemic within a few months. COVID-19 had caused more than 5.5 million deaths as of January 2022. Hence, the urgency of effective vaccination contributed to the fastest rate of vaccine development seen to date (i.e., within 1.5 years). Despite reports of good vaccine efficacy without severe systemic reactions at the clinical trial stage, hypersensitivity reactions have been reported following worldwide vaccination campaigns. We provide a brief review regarding the structure of SARS-CoV-2. We also review the most acceptable types of vaccines in terms of safety profiles, namely the BNT162b2, mRNA-1273, and AZD1222 vaccines. This review aims to facilitate an understanding of the possible immune mechanisms regarding COVID-19-vaccination-related hypersensitivity reactions, such as thrombosis and thrombocytopenia, cutaneous adverse reactions, myocarditis, and perimyocarditis.

Tolosa-Hunt Syndrome and Hemorrhagic Encephalitis Presenting in a Patient after COVID-19 Vaccination Followed by COVID-19 Infection. The presence of neurological symptoms within the clinical range of COVID-19 disease infection has increased. This paper presents the situation of a 45-year-old man having the medical antecedent diabetes mellitus, who presented to the emergency department with fever, headache, and respiratory symptoms, nine days following vaccination with the Ad26.COV2-S COVID-19 vaccine. The patient tested positive for SARS-CoV-2 based on nasal polymerase chain reaction (RT-PCR). Two weeks after the presentation, he developed Tolosa-Hunt Syndrome, an autoimmune phenomenon, with painful left ophthalmoplegia. Significant improvement was seen in terms of his discomfort; however, ptosis and ocular mobility improved only moderately after treatment with intravenous methylprednisolone, and the patient was discharged on a new insulin regimen. The patient returned after four weeks and the neurological exam results showed significant signs of right hemiparesis, mixed aphasia, incomplete left ophthalmoplegia, severe headache, and agitation; after a few days, the patient experienced a depressed level of consciousness and coma. The patient's clinical condition worsened and, unfortunately, he died. MRI brain images revealed multiple ischemic strokes, meningitis, infectious vasculitis, and hemorrhagic encephalitis, which are all serious complications of COVID-19.

Adenomesenteritis following SARS-CoV-2 Vaccination in Children: A Case Report and Review of The Literature. At present, the vaccine authorized in children aged 5 years and older is the BNT162b2 messenger RNA COVID-19 vaccine. Unlike adults, there is limited data available in the pediatric age describing adverse events after vaccine. We report a case of adenomesenteritis in a young girl following the first dose of vaccine.

Rational development of a combined mRNA vaccine against COVID-19 and influenza. As the world continues to experience the COVID-19 pandemic, seasonal influenza remain a cause of severe morbidity and mortality globally. Worse yet, coinfection with SARS-CoV-2 and influenza A virus (IAV) leads to more severe clinical outcomes. The development of a combined vaccine against both COVID-19 and influenza is thus of high priority. Based on our established lipid nanoparticle (LNP)-encapsulated mRNA vaccine platform, we developed and characterized a novel mRNA vaccine encoding the HA antigen of influenza A (H1N1) virus, termed ARIAV. Then, ARIAV was combined with our COVID-19 mRNA vaccine ARCoV, which encodes the receptor-binding domain (RBD) of the SARS-CoV-2 S protein, to formulate the final combined vaccine, AR-CoV/IAV. Further characterization demonstrated that immunization with two doses of AR-CoV/IAV elicited robust protective antibodies as well as antigen-specific cellular immune responses against SARS-CoV-2 and IAV. More importantly, AR-CoV/IAV immunization protected mice from coinfection with IAV and the SARS-CoV-2 Alpha and Delta variants. Our results highlight the potential of the LNP-mRNA vaccine platform in preventing COVID-19 and influenza, as well as other respiratory diseases.

Menstrual abnormalities post-COVID vaccination: a cross-sectional study on adult Lebanese women. BACKGROUND: In the year 2020, the coronavirus pandemic invaded the world. Since then, specialized companies began to compete, producing many vaccines. Coronavirus vaccines have different adverse events. Menstrual disorders have been noticed as a common complaint post-vaccination. AIM: Our study fills an important gap by evaluating the relationship between coronavirus vaccines and menstrual disorders. METHODS: This is a cross-sectional study between 20 September 2021, and 1 October 2021, using an online survey. The questionnaire consisted of 36 questions divided into 4 sections: demographics, COVID-19 exposure and vaccination, hormonal background, and details about the menstrual cycle. Sample t-test, ANOVA test, chi-square, and McNemar test were used in bivariate analysis. RESULTS: This study includes 505 Lebanese adult women vaccinated against COVID-19. After vaccination, the number of women having heavy bleeding or light bleeding increased (pâ€‰=â€‰0.02 and pâ€‰<â€‰0.001, respectively). The number of women having regular cycles decreased after taking the vaccine (pâ€‰<â€‰0.001). Irregularity in the cycle post-vaccination was associated with worse PMS symptoms (pâ€‰=â€‰0.036). Women using hormonal contraception method or using any hormonal therapy had higher menstrual irregularity rates (pâ€‰=â€‰0.002 and pâ€‰=â€‰0.043, respectively). Concerning vaccine adverse events, those who had headaches had a higher rate of irregularity (pâ€‰=â€‰0.041). Those having PCOS, osteoporosis, or blood coagulation disorders had higher irregularity rate (pâ€‰<â€‰0.001 and pâ€‰=â€‰0.005, respectively). CONCLUSION: Vaccine adverse events may include specific menstrual irregularities. Moreover, some hormonal medications and diseases are associated with the alteration of the menstrual cycle. This study helps in predicting vaccines' menstrual adverse events, especially in a specific population prone to menstrual disorders.

Spontaneus (dumbbell-shaped) coronary artery pseudoaneurysm after COVID-19 vaccination.

Under-awareness and over-diagnosis of COVID-19 vaccine 'allergy'.

Dynamics of SARS-CoV-2-Spike-reactive antibody and T-cell responses in chronic kidney disease patients within 3 months after COVID-19 full vaccination. BACKGROUND: Little is known regarding the dynamics of antibody and T-cell responses in chronic kidney disease (CKD) following coronavirus disease 2019 (COVID-19) vaccination. METHODS: Prospective observational cohort study

including 144 participants on haemodialysis (HD) (n = 52) or peritoneal dialysis (PD) (n = 14), those undergoing kidney transplantation (KT) (n = 30) or those with advanced CKD (ACKD) not on dialysis and healthy controls (n = 18). Anti-Spike (S) antibody and T-cell responses were assessed at 15 days (15D) and 3 months (3M) after complete vaccination schedule. HD, PD and KT patients received mRNA vaccines (mRNA-123 and BNT162b2). Most ACKD patients received BNT162b2 (n = 23), or Ad26.COV.2.S (4). Most controls received BNT162b2 (n = 12), or Ad26.COV.2.S (n = 5). RESULTS: Anti-S antibodies at 15D and 3M were detectable in 95% (48/50)/98% (49/50) of HD patients, 93% (13/14)/100% of PD patients, 67% (17/26)/75% (21/28) of KT patients and 96% (25/26)/100% (24/24) of ACKD patients. Rates for healthy controls were 81% (13/16)/100% (17/17). Previous severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2-S) infection was documented in four (7.7%) HD patients, two (14.3%) PD patients, two (6.7%) KT patients, one (5.55%) healthy control and in no ACKD patient. Antibody levels decreased at 3M in HD (P = .04), PD (P = .008) and ACKD patients (P = .0009). In KT patients, levels increased (P = .04) between 15D and 3M, although they were low at both time points.T-cell responses were detected in HD patients in 37 (80%) at baseline, 35 (70%) at 15D and 41 (91%) at 3M. In PD patients, T-cell responses appeared in 8 (67%) at baseline, 13 (93%) at 15D and 9 (100%) at 3M. In KT patients, T-cell responses were detected in 12 (41%) at baseline, 22 (84%) at 15D and 25 (96%) at 3M. In ACKD patients, T-cell responses were detected in 13 (46%) at baseline, 20 (80%) at 15D and 17 (89%) at 3M. None of healthy controls showed T-cell response at baseline, 10 (67%) at 15D and 8 (89%) at 3M. CONCLUSIONS: Most HD, PD and ACKD patients develop SARS-CoV-2-S antibody responses comparable to that of healthy controls, in contrast to KT recipients. Antibody waning at 3M was faster in HD, PD and ACKD patients. No differences in SARS-CoV-2 T-cell immunity responses were noticed across study groups.
Humoral response and safety of the third booster dose of BNT162b2 mRNA COVID-19 vaccine in patients with multiple sclerosis treated with ocrelizumab or fingolimod. BACKGROUND: The assessment of the safety and the humoral response to a third booster dose of the BNT162b2 mRNA COVID-19 vaccine is relevant in patients with Multiple Sclerosis (pwMS) treated with Ocrelizumab (OCR) or Fingolimod (FNG). METHODS: Serum samples were collected from Healthy controls (HCs) and pwMS treated with OCR or FNG at the following time-points: before the first of two vaccine doses (T0); 8 (T1), 16 (T2), 24 (T3) weeks after the first dose; within 8Â weeks before (T0b) and after (T1b) the booster dose. IgG antibodies to SARS-CoV-2 trimeric spike protein (Anti-TSP IgG) were quantified and expressed as binding antibody units (BAU)/mL. RESULTS: 40 HCs, 28 pwMS on OCR and 19 on FNG were included. At T0b 12 (42.9%) pwMS on OCR and 6 (31.6%) on FNG were still positive while, at T1b 16 (57.14%) pwMS on OCR and 16 (84.2%) on FNG, passed the threshold of positivity. The increase of Anti-TSP IgG levels at T1b was higher for: (i) HCs with respect to OCR (pâ€‰<â€‰0.001) and FNG (pâ€‰=â€‰0.032) groups; (ii) pwMS on FNG compared with pwMS on OCR (pâ€‰<â€‰0.001). No socio-demographic, clinical or laboratory variables were able to predict the anti-TSP IgG increase between T0b and T1b. Neither clinical relapses nor severe adverse events were reported in pwMS after each dose of vaccine. CONCLUSIONS: The third booster dose of BNT162b2 mRNA vaccine to OCR- and FNG-treated pwMS revives the humoral response, independently of any clinical variable, and manifests a good safety and tolerability profile.
No increased risk of acute liver injury after COVID-19 vaccination.
A case of interstitial lung disease following Oxford-AstraZeneca COVID-19 vaccination.
SARS-CoV-2 Omicron escapes mRNA vaccine booster-induced antibody neutralisation in patients with autoimmune rheumatic diseases: an observational cohort study. OBJECTIVES: This study investigates whether COVID-19 vaccines can elicit cross-reactive antibody responses against the Omicron variant in patients with autoimmune rheumatic diseases (ARDs). METHODS: This observational cohort study comprised 149 patients with ARDs and 94 healthcare workers (HCWs).

Blood samples were obtained at enrolment, a median of 15 weeks after the second vaccine dose or 8 weeks after the third dose. The functional cross-neutralisation capacity of sera was measured using the Omicron variant receptor-binding domain-ACE2 binding inhibition assay. We assessed the incidence of breakthrough infections and the potential correlation with neutralising responses in participants after receiving third doses. The association of time-from-vaccine and neutralising responses in sera was predicted using linear regression analysis. RESULTS: The mean cross-neutralising responses against the Omicron variant developed after the second dose was 11.5% in patients with ARDs and 18.1% in HCWs (p=0.007). These responses were significantly lower in patients with ARDs than in HCWs after the third dose (26.8% vs 50.3%, p<0.0001). Only 39.2% of the patient sera showed functional neutralisation capacity to the Omicron variant and cross-neutralising responses were shown to be poorly correlated with anti-spike immunoglobulin G titres. Within 6 weeks of immunological assessments, significantly lower Omicron-neutralising responses were detected in sera from patients with ARDs who developed breakthrough infections compared with those who did not (p=0.018). Additionally, a relative decline was implied in neutralising responses against the Omicron variant as a reference to the wild-type virus during 120 days since the third vaccination, with a predicted decay rate of -0.351%/day (95% CI, -0.559 to -0.144, p=0.001). CONCLUSIONS: Striking antibody evasion manifested by the Omicron variant in patients with ARDs and current vaccine-induced immunity may not confer broad protection from Omicron breakthrough infection, highlighting the need for further research on vaccine effectiveness in patients with immune dysfunctions.

CoronaVac: A review of efficacy, safety, and immunogenicity of the inactivated vaccine against SARS-CoV-2. CoronaVac, also known as the Sinovac inactivated SARS-CoV-2 vaccine, has been widely implemented in combating the COVID-19 pandemic. We summarized the results of clinical trials and real-world studies of CoronaVac in this review. The overall efficacy for the prevention of symptomatic COVID-19 (before the emergence of variants of concern) using two doses of 3â€‰Î¼g CoronaVac was 67.7% (95% CI, 35.9% to 83.7%). Effectiveness in preventing hospitalizations, ICU admissions, and deaths was more prominent than that in preventing COVID-19. A third dose inherited the effectiveness against non-variants of concern and increased effectiveness against severe COVID-19 outcomes caused by omicron variants compared to two doses. Most adverse reactions were mild. Few vaccine-related serious adverse reactions have been reported. Moreover, three-dose regimen significantly increased the seroconversion levels of neutralizing antibodies against omicron as compared to two-dose regimen. This review of CoronaVac may provide a scientific basis for optimizing global immunization strategies.

Safety and immunogenicity of inactivated COVID-19 vaccination in adult rheumatic patients in South China: a prospective study. Patients with rheumatic diseases (RD) are considered to be a high-risk population for infection with the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). The effectiveness of inactivated COVID-19 vaccinations (ICVs) was described as more effective than 95%. Despite this, no data on the immunogenicity and safety of the ICV in Han race stable RD patients in China. In this study, we sought to assess the safety and immunogenicity of the ICVs in RD patients in South China. A total of 80 adult stable RD patients were recruited. Following 14-35â€‰days of immunization, cheiluminescence immunoassays (CLIA) were utilized to detect antibodies titers. An investigation into the relative parameters on the immunogenicity response to vaccination was carried out using logistic regression analysis. Compared to the HC group, the positive response of IgG and Nab in RD patients were lower than those in healthy control (HC) (Pâ€‰=â€‰.040 and Pâ€‰<â€‰.0001, respectively) after two doses of ICV were inoculated. The use of methotrexate (Pâ€‰=â€‰.016) and prednisolone (Pâ€‰=â€‰.018), and the level of red blood cell distribution width-C (RDW-C) (Pâ€‰=â€‰.035) and C-reactive protein (Pâ€‰=â€‰.015) were independently

associated with lower rises in the magnitude of COVID-19 vaccine antibodies. No vaccine-related serious adverse reactions were observed in either group. After receiving two doses of ICVs, the production of protective antibodies in stable RD patients treated with immunosuppressive agents may decrease. It was discovered that ICVs were safe and well tolerated by RD patients.

 What is the context?There are currently no accessible data on the efficacy and safety of inactivated COVID-19 vaccinations in South China RD patients who are receiving immunosuppressive medications.What is new?Inactivated COVID-19 vaccinations were immunogenic in stable RD patients in our investigation. No significant adverse reactions to the vaccination were seen in either group. No disease flares were observed in our study.What is the impact?Inactivated COVID-19 vaccinations are immunogenic and safe in stable RD patients in China, according to the findings of this study. The use of methotrexate or prednisolone, the RDW-C level, and the CRP level may all have an effect on the development of protective antibodies following vaccination.

Post-vaccination antibody evaluation for nosocomial SARS-CoV-2 delta variant breakthrough infection. Waning humoral immunity after mRNA vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a significant problem for public health. Breakthrough infection in hospitals over several months after vaccination has not been fully characterized, especially against the delta (B.1.617.2) variant. Here, we describe an outbreak in our hospital in September of 2021, mainly through serological evaluation of the breakthrough infection. This retrospective observational study was done at an emergency and acute care hospital with 204 beds and 486 staff members where most staff members (92.6%) had had their second BNT162b2 vaccination by May of 2021. The peri-infection anti-spike RBD protein IgG (anti-S IgG) titers (lowest values between 11 days before and 7 days after onset or diagnosis) of serum samples from the breakthrough-infected persons were quantified. We also logarithmically estimated the anti-S IgG titers during the exposure period in September of uninfected staff members from their samples collected in May and December 2021. Whole-genome sequencing was done on obtained samples. In this outbreak, twelve persons (ten inpatients and two staff members) were diagnosed with SARS-CoV-2 infection by Loop-Mediated Isothermal Amplification (LAMP) or RT-PCR, eight of whom had been vaccinated twice. Peri-infection anti-S IgG titers could be determined in seven of the eight breakthrough cases, with a geometric mean titer (GMT) of 1,034 AU/ml (95% confidence interval [CI], 398 to 2,686). Among 289 uninfected staff members with data from the two sampling points, the GMT of the estimated anti-S IgG titers during the exposure period in 51 staff members, who were working at the outbreak ward and potentially exposed but uninfected, and 238 other unexposed staff members were 1,458 AU/ml (95% CI, 1,196 to 1,777) and 1,628 AU/ml (95% CI, 1,500 to 1,766), respectively. All viruses from the eight samples for which whole-genome sequencing was available were identified as delta variants. Of the infected persons, one remained asymptomatic throughout the course of treatment, and eleven had an illness of mild to moderate severity, including ten who received monoclonal antibody cocktail (Casirivimab/imdevimab) therapy. Measurement and estimation of anti-spike antibody levels after SARS-CoV-2 vaccination would be helpful for evaluating the risk of breakthrough infection and for determining the necessity of booster vaccination.

Time-Series Associations between Public Interest in COVID-19 Variants and National Vaccination Rate: A Google Trends Analysis. The emergence of a constantly mutating novel virus has led to considerable public anxiety amid the COVID-19 pandemic. Information seeking is a common strategy to cope with pandemic anxiety. Using Google Trends analysis, this study investigated public interest in COVID-19 variants and its temporal associations with the disease-prevention measure of vaccination during the initial COVID-19 vaccine rollout period (13 December 2020 to 25 September 2021). Public interest was operationalized as the relative search volume of online queries of variant-related terms in the countries first affected by the Alpha, Beta, and Delta variants: the UK, South Africa, and India,

respectively. The results show that public interest in COVID-19 variants was greater during the Delta-variant-predominant period than before this period. The time-series cross-correlation analysis revealed positive temporal associations (i.e., greater such public interest was accompanied by an increase in national vaccination rate) tended to occur more frequently and at earlier time lags than the negative temporal associations. This study yielded new findings regarding the temporal changes in public interest in COVID-19 variants, and the between-country variations in these public interest changes can be explained by differences in the rate and pace of vaccination among the countries of interest.

Linear lichen planus after COVID-19 vaccination.

Acute vestibular neuritis: A rare complication after the adenoviral vector-based COVID-19 vaccine. Vestibular neuritis was first reported in 1952 by Dix and Hallpike, and 30% of patients reporting a flu-like symptom before acquiring the disorder. The most common causes are viral infections, often resulting from systemic viral infections or bacterial labyrinthitis. Here we presented a rare case of acute vestibular neuritis after the adenoviral vector-based COVID-19 vaccination. A 51-year-old male pilot awoke early in the morning with severe vertigo, nausea, and vomiting after receiving the first dose of the ChAdOx1 nCoV-19 vaccine 11Â days ago. Nasopharyngeal SARS-CoV-2 RT-PCR test and chest CT scan were inconclusive for COVID-19 pneumonia. Significant findings were a severe spontaneous and constant true-whirling vertigo which worsened with head movement, horizontal-torsional spontaneous nystagmus, abnormal caloric test, positive bedside head impulse tests, and inability to tolerate head-thrust test. PTA, MRI of the brain and internal auditory canal, and cerebral CT arteriography were normal. According to the clinical, imaging, and laboratory findings, he was admitted to the neurology ward and received treatment for vestibular neuritis. His vertigo increased gradually over 6-8Â h, peaking on the first day, and gradually subsided over 7Â days. Ten days later, the symptoms became tolerable; the patient was discharged with advice for home-based vestibular rehabilitation exercises. Despite the proper treatment and rehabilitation, signs of dynamic vestibular imbalances persisted after 1Â year. Based on the Federal Aviation Administration (FAA) regulations, the Air Medical Council (AMC) suspended him from flight duties until receiving full recovery. Several cases of vestibular neuritis have been reported in the COVID-19 patients and after the COVID-19 vaccination. This is the first case report of acute vestibular neuritis after the ChAdOx1 nCoV-19 vaccination in a healthy pilot without past medical history. However, the authors believe that this is a primary clinical suspicion that must be considered and confirmed after complete investigations.

Functional neurological disorders after COVID-19 vaccination: Case series and literature review.

Author reply to myocarditis after COVID-19 mRNA vaccination: Correspondence.

Both COVID-19 infection and vaccination induce high-affinity cross-clade responses to SARS-CoV-2 variants. The B.1.1.529 (omicron) variant has rapidly supplanted most other SARS-CoV-2 variants. Using microfluidics-based antibody affinity profiling (MAAP), we have characterized affinity and IgG concentration in the plasma of 39 individuals with multiple trajectories of SARS-CoV-2 infection and/or vaccination. Antibody affinity was similar against the wild-type, delta, and omicron variants (K (A) ranges: 122Â Â± 155, 159Â Â± 148, 211Â Â± 307Â Ï¼M(-1), respectively), indicating a surprisingly broad and mature cross-clade immune response. Postinfectious and vaccinated subjects showed different IgG profiles, with IgG3 (p-valueÂ = 0.002) against spike being more prominent in the former group. Lastly, we found that the ELISA titers correlated linearly with measured concentrations (RÂ = 0.72) but not with affinity (RÂ = 0.29). These findings suggest that the wild-type and delta spike induce a polyclonal immune response capable of binding the omicron spike with similar affinity. Changes in titers were primarily driven by antibody concentration, suggesting that B-cell expansion, rather than affinity maturation, dominated the response after infection or vaccination.

Durability of SARS-CoV-2 Specific IgG Antibody Responses Following Two Doses of Match and Mixed COVID-19 Vaccines Regimens in Saudi Population. BACKGROUND: SARS-CoV-2 pandemic continues to threaten the human population with millions of infections and deaths worldwide. Vaccination campaigns undertaken by several countries have resulted in a notable decrease in hospitalization and deaths. However, with the emergence of new virus variants, it is critical to determine the longevity and the protection efficiency provided by the current authorized vaccines. AIM: The aims of this study are to provide data about the magnitude of immune responses in individuals fully vaccinated against COVID-19 in Riyadh province of Saudi Arabia. Also, to evaluate the continuity of specific IgG levels and compare the titers in individuals who have been received two doses of the matched and mixed vaccines, including Pfizer and AstraZeneca against SARS-CoV-2 during the period of three to six months. Moreover, we analyze the current state of immune response in terms of antibody responses in thepopulation postvaccination using homogenous or hetrogenous vaccine regimen. METHODS: A total of 141 healthy volunteers were recruited to our study; blood (n=63) and the saliva samples (n=78) and were collected from fully vaccinated individuals in Riyadh city. We employed a specific ELISA assay in plasma and saliva of fully vaccinated individuals. RESULTS: IgG levels varied with age groups with the highest concentration in the age group 19-29 years, but the age group (â‰¥50) had the lowest IgG concentration. The IgG levels in both serum and saliva were higher after three months and start to wane after six months. Individuals who received mixed types of vaccines had significantly better response than Pfizer vaccine alone. CONCLUSION: The current study investigates the status of humoral responses in different age groups, in terms of antibody measurements. These data will help to evaluate the need for further COVID-19 vaccine doses and to what extent a two-dose regimen will protect vaccinated individuals.

Antibody Response to SARS-CoV-2 Vaccination in Patients With Lymphoproliferative Disorders and Plasma Cell Dyscrasias: Anti-Lymphoma Therapy as a Predictive Biomarker of Response to Vaccination. We retrospectively analyzed SARS-CoV-2 vaccination antibody responses in a cohort of 273 patients with lymphoproliferative disorders or plasma cell dyscrasias who were seen at a single tertiary cancer center. Semi-quantitative anti-spike protein serologic testing was performed with enzyme immunoassay method. We found that the antibody response rate to SARS-CoV-2 vaccination was 74.7% in our patient cohort with no difference based on gender, age or race. The highest response rate was found in patients with Multiple Myeloma (MM) (95.5%). The response rates found in Diffuse Large B-Cell Lymphoma (DLBCL), Chronic Lymphocytic Leukemia (CLL), and Low-Grade Non-Hodgkin Lymphoma (LG-NHL) were 73.2%, 61.5% and 53% respectively. We also evaluated the effects of receiving active chemo-immunotherapy on SARS-CoV-2 vaccination antibody response. We found that the patients on treatment had lower response than the patients off treatment (62.1% versus 84.4% p<0.001). Thirty-four of 58 LG-NHL patients were receiving anti-lymphoma treatment with a lower SARS-CoV-2 vaccination response as compared to the patients who were not on treatment (29.4% v 87.5% p<0.001). We observed a similar pattern in CLL patients receiving treatment (48.1 v 76.0 p:0.049). We found that only disease type and treatment status (on-treatment vs. off-treatment), but not gender, age or race were significant predictors of non-response in the multivariable logistic regression model. The interaction between disease type and treatment status was not statistically significant by multivariate analysis. In conclusion, receiving anti-cancer treatment was found to play a significant role in decreasing the response to COVID-19 vaccination.

COVID-19 Inpatient Deaths and Brought-in-Dead Cases in Malaysia. Coronavirus disease 2019 (COVID-19) deaths can occur in hospitals or otherwise. In Malaysia, COVID-19 deaths occurring outside of the hospital and subsequently brought to the hospital are known as brought-in-dead (BID) cases. To date, the characteristics of BID COVID-19 cases in Malaysia are not clear. The objectives of this study are 2-fold: to explore the characteristics of 29,155 mortality cases in Malaysia and

determine the factors associated with the high probability of BID, using the multilevel logistic regression model. Data on COVID-19 mortality cases from the entire country between March 17, 2020 and November 3, 2021 were retrieved from a national open data source. Of the 29,155 COVID-19 mortality cases, 5,903 (20.2%) were BID. A higher probability of BID ($p < 0.05$) was seen among individuals aged between 18 and 59 years, non-Malaysians, had no comorbidities, did not receive COVID-19 vaccination, and the interval between the date of death and diagnosis. A high prevalence of BID is an alarming public health issue, as this may signal health system failure at one or several levels and, hence, need urgent attention from relevant stakeholders. Based on the findings of this study, increasing the intensity of the vaccination campaign, addressing any issues faced by noncitizens about to COVID-19 management in- and out-of-hospital, increasing the awareness of signs and symptoms of worsening COVID-19 and, hence, the significance of self-monitoring, and determining the potential gaps in the health system may contribute to their increased risk of deaths.

Is there a post-SARS-CoV-2 vaccination dementia?

The clinical course of patients with previous acute and recurrent pericarditis receiving the BNT162b2 vaccine. BACKGROUND: Vaccines against SARS-COV2 have been crucial in efforts against COVID19, yet there have been reports of pericarditis following vaccination with mRNA-based vaccines. METHODS: We questioned consecutive patients with a history of acute pericarditis (AP) evaluated in the pericardial disease clinic during 3-11/2020 in a single tertiary center. Patients with significant myocardial involvement or pericarditis secondary to another systemic disease were excluded. RESULTS: We included 64 patients in the final analysis. Mean age was 53.1 (Â±18), and 26 (41%) were female. At least 1 recurrence of AP was documented in 47 (73%) cases, 32 (50%) hadÂ â‰¥Â 3 recurrences prior to vaccination. AP was considered to be idiopathic\viral in 45 (70%) cases, 20 (31%) cases were post-injury. All patients received at least 2 doses of the vaccine, and 48 patients (75%) received a 3rd dose. Two cases of breakthrough COVID19 infections were documented. Overall, 12 patients (19%) reported any adverse events. Of which, 2 had recurrent pericarditis. There was a trend for a younger age in those patients who had adverse events (median age 45 [IQR 36-61] vs. 60 [38-71], pÂ =Â 0.08). no other significant difference was seen. CONCLUSION: In patients with a history of acute\recurrent pericarditis, the use of BNT162b2 was mostly uneventful, but some mild disease recurrences did occur.

Diagnostics of messenger ribonucleic acid (mRNA) severe acute respiratory syndrome-corona virusâ€‘2 (SARS-CoVâ€‘2) vaccination-associated myocarditis-AÂ systematic review. BACKGROUND: During the recent pandemic with the severe acute respiratory syndrome-corona virusâ€‘2 the first messenger ribonucleic acid (mRNA) vaccines were approved. To facilitate mass vaccination, confidence of the general population in these new vaccines is mandatory, which is in turn strongly dependent on the availability of reliable data on complications. OBJECTIVE: Summary of the current knowledge on mRNA vaccination-associated myocarditis as aÂ potentially fatal side effect. METHODS: Systematic literature review. RESULTS: Diagnostic algorithm for the postmortem diagnosis of mRNA vaccination-associated myocarditis. CONCLUSION: Autopsy series of fatalities following mRNA SARS-CoVâ€‘2 vaccination up to 6Â weeks with subsequent sophisticated and interdisciplinary work-up are necessary to complement clinical data on vaccination-associated myocarditis, especially regarding the incidence of fatal courses. SUPPLEMENTARY INFORMATION: The online version of this article (10.1007/s00194-022-00587-9) includes aÂ PDF file with supplemental clinical features.

A predictive model to estimate fever after receipt of the second dose of Pfizer-BioNTech coronavirus disease 2019 vaccine: An observational cohort study. BACKGROUND AND AIMS: Fever afterÂ coronavirus disease 2019Â (COVID-19) vaccination is generally a mild and benign event, but can cause excessive anxiety in younger adults. This study aimed to find key factors that include

allergic diseases or physique that determine fever after vaccination. METHODS: We conducted an observational cohort study in our hospital to assess post-COVID-19 vaccination fever from April to June 2021. A total of 153 medical personnel aged 22-86â€‰years of age were involved in the study to receive two doses, intramuscularly 21â€‰days apart, of the Pfizer-BioNTech COVID-19 vaccine (30â€‰Î¼g per dose). Vaccination records were taken more than 72â€‰h after vaccination. Clinical and laboratory variables (age, sex, allergy history, weight, height, serum hemoglobin concentration, and these derivatives) were examined by multivariable logistic regression analysis using the peak axillary temperature in the 4-day period after the second vaccination as a dependent variable. RESULTS: No serious safety problems were detected. The incidence of a postsecond vaccination fever of 37.3Â°C or above was 29.4%. Logistic regression analysis found age, history of perennial allergic rhinitis, body surface area, body weight, percent overweight, and serum hemoglobin concentration as independent predictors of postvaccination fever. The characteristics of this individual were incorporated into the numerical model of human thermoregulation. The evaluation of this model had a sensitivity of 66.1% and a specificity of 90.7% in the detection of postvaccination fever. The multiple coefficient of determination (R (2)) was 0.410. CONCLUSION: The COVID-19 vaccine induced higher rates of fever during the 4-day period after the second vaccination. Younger age, part of the allergy history, small and light body, and concentrated blood were associated with postvaccination fever.

Menstrual abnormalities after COVID-19 vaccines: A systematic review. The objective of this systematic review is to give a comprehensive interpretation of menstrual cycle changes after the COVID-19 vaccination. Additionally, it is imperative to assess reports of menstrual changes following vaccination to dispel concerns that COVID-19 vaccines hinder the likelihood of pregnancy in the long run. A literature review was conducted using digital databases to systematically identify the studies reporting any menstrual abnormalities after the COVID-19 vaccine. Detailed patient-level study characteristics including the type of study, sample size, administered vaccines, and menstrual abnormalities were abstracted. A total of 78â€¯138 vaccinated females were included in this review from 14 studies. Of these, 39â€¯759 (52.05%) had some form of a menstrual problem after vaccination. Due to the lack of published research articles, preprints were also included in this review. Menorrhagia, metrorrhagia, and polymenorrhea were the most commonly observed problems and the overall study-level rate of menstrual abnormality ranged from 0.83% to 90.9%. Age, history of pregnancy, systemic side-effects of COVID-19, smoking, and second dose of COVID-19 vaccine were predictors of menstrual problems after vaccination.

COVID-19 Patient-Reported Symptoms Using FLU-PRO Plus in a Cohort Study: Associations With Infecting Genotype, Vaccine History, and Return to Health. BACKGROUND: Patient-reported outcomes of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection are an important measure of the full burden of coronavirus disease (COVID). Here, we examine how (1) infecting genotype and COVID-19 vaccination correlate with inFLUenza Patient-Reported Outcome (FLU-PRO) Plus score, including by symptom domains, and (2) FLU-PRO Plus scores predict return to usual activities and health. METHODS: The epidemiology, immunology, and clinical characteristics of pandemic infectious diseases (EPICC) study was implemented to describe the short- and long-term consequences of SARS-CoV-2 infection in a longitudinal, observational cohort. Multivariable linear regression models were run with FLU-PRO Plus scores as the outcome variable, and multivariable Cox proportional hazards models evaluated effects of FLU-PRO Plus scores on return to usual health or activities. RESULTS: Among the 764 participants included in this analysis, 63% were 18-44 years old, 40% were female, and 51% were White. Being fully vaccinated was associated with lower total scores (Î²â€‰=â€‰-0.39; 95% CI, -0.57 to -0.21). The Delta variant was associated with higher total scores (Î²â€‰=â€‰0.25; 95% CI, 0.05 to 0.45). Participants with higher FLU-PRO Plus scores were less likely to report returning to usual health and activities (health: hazard ratio [HR], 0.46; 95% CI, 0.37 to 0.57;

activities: HR, 0.56; 95% CI, 0.47 to 0.67). Fully vaccinated participants were more likely to report returning to usual activities (HR, 1.24; 95% CI, 1.04 to 1.48). CONCLUSIONS: Full SARS-CoV-2 vaccination is associated with decreased severity of patient-reported symptoms across multiple domains, which in turn is likely to be associated with earlier return to usual activities. In addition, infection with the Delta variant was associated with higher FLU-PRO Plus scores than previous variants, even after controlling for vaccination status.

Vaccination Is Associated With Shorter Time to Target Cycle Threshold Value in Patients With SARS-CoV-2 Omicron Variant. BACKGROUND: Limited data are available on the responses to vaccination for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron variant in the Chinese population. This study aimed to investigate whether vaccination could alter the disease course of SARS-CoV-2 Omicron variant. METHODS: A retrospective cohort included 142 patients who had no or mild symptoms and were admitted to our department for centralized isolation after being locally infected with SARS-CoV-2 Omicron variant from March 4 to 30, 2022, in Shanghai, China. RESULTS: Of the 142 subjects with the mean age of 43.1 years, 53.5% were male and 90.8% had been vaccinated before the infection. Comparing the vaccinated with the unvaccinated patients, there was no difference in patient characteristics, but patients with vaccination had shorter time to target cycle threshold value (TtCT) (vaccinated vs. unvaccinated, 12.6 Â± 3.4 vs. 14.8 Â± 4.7 days, P = 0.039). There was no difference in TtCT between heterogeneous and homologous vaccination. Of subjects with homologous vaccination, 43.1% were vaccinated with CoronaVac (Sinovac Life Science), 47.2% with Sinopharm BBIBP-CorV, 4.9% with Sinopharm WIBP, 3.3% with CanSinoBio, and 1.6% with Zhifei Longcom. No difference in TtCT was observed among different vaccines. Comparing two-dose primary vaccination with three-dose booster vaccination, we found no difference in TtCT either. CONCLUSION: Vaccination is associated with shorter TtCT in patients with SARS-CoV-2 Omicron variant.

Acute Pulmonary Embolism Following Moderna mRNA-1273 SARS-CoV-2 Vaccination - A Case Report and Literature Review.

MMF/MPA Is the Main Mediator of a Delayed Humoral Response With Reduced Antibody Decline in Kidney Transplant Recipients After SARS-CoV-2 mRNA Vaccination. Kidney transplant recipients (KTR) show significantly lower seroconversion rates after SARS-CoV-2 mRNA vaccination compared to dialysis patients (DP). Mycophenolate mofetil or mycophenolic acid (MMF/MPA) in particular has been identified as a risk factor for seroconversion failure. While the majority of all KTR worldwide receive MMF/MPA for immunosuppressive therapy, its impact on antibody decline in seroconverted KTR still remains unclear. In an observational study (NCT04799808), we investigated whether 132 seroconverted KTR (anti-spike S1 IgG or IgA positive after 2 vaccinations) show a more rapid antibody decline with MMF/MPA than those without this medication. A total of 2 months after mRNA vaccination, average anti-spike S1 IgG levels of KTR with MMF/MPA were lower than without (p = 0.001), while no differences between these two groups were observed after 6 months (p = 0.366). Similar results were obtained for anti-RBD IgG antibodies (T2 p = 0.003 and T3 p = 0.135). The probability of severe IgG decline with MMF/MPA was three times lower than without (p = 0.003, OR 0.236, 95% CI 0.091-0.609). In the multivariate analysis, neither immunosuppressants, such as calcineurin inhibitors, mTOR inhibitors (mTOR-I; mechanistic target of rapamycin), glucocorticoids, nor vaccine type, sex, or age showed a significant influence on IgG titer decline between 2 and 6 months. For the decision on additional booster vaccinations, we consider immunosurveillance to be needed as an integral part of renal transplant follow-up after SARS-CoV-2 mRNA vaccination. Not only the lack of seroconversion but also the peak and titer decline of the specific IgG and RBD IgG antibody formation after two mRNA vaccinations is significantly influenced by MMF/MPA.

Reporting of Allergic Reactions During Pfizer-BioNTech BNTT162B2 Vaccination in Israel. BACKGROUND: In December 2020, the Israeli Ministry of Health launched a national vaccination campaign against SARS-CoV-2. Concomitant sporadic reports on anaphylactic responses in other countries raised safety concerns at the outset of this operation. OBJECTIVE: To characterize reports on allergic reactions to coronavirus disease 2019 vaccines. METHODS: Allergy events were reported by health care professionals throughout the country to Israeli Ministry of Health Division of Epidemiology via a Web-based computerized national vaccine registry. The study period was from December 19, 2020 to September 13, 2021, during which 14,475,979 injections were administered. RESULTS: Allergic reactions were reported in 463 subjects, 99.3% of whom received Pfizer-BioNTech BNTT162B2. The reporting rate was 106 per million in December 2020. From January to May 2021, a reduction was observed to 66, 18, 14, eight, and zero per million, and reporting remained low until September. Mean age of subjects was 48.9 Â± 16.7 years (range, 15-96 years) with a female preponderance of 78%. Epinephrine was administered in 34 subjects. Validated immediate allergy was observed in only 37 cases (8%), suggesting 2.5 to 3.3 bona fide reactions per million. In subjects with reactions classified as severe (nÂ = 46), plausible allergy was identified in 36% to 41% of cases. A history of allergy was associated with high false reporting of immediate reactions (83%). Allergic events after the first dose did not compromise adherence to subsequent doses. CONCLUSIONS: Excessive reporting of allergy declined over time and did not affect adherence to vaccination. The existence of previous allergy may affect reporting profiles, but not the occurrence of vaccine allergy.

Donor-directed immunologic safety of COVID-19 vaccination in renal transplant recipients. Infection risk and COVID-19 outcomes make SARS-CoV-2 vaccination essential forsolid-organ transplant recipients. Reports of immune activation after vaccination causing graft failure raise concerns, but data are limited. Here, we document graft function, donor-derived-cell-free-DNA(dd-cfDNA), and donor-specific antibodies (DSA) in solid-organ renal transplant recipients after vaccination. Retrospective demographics, graft function, and immunologic parameters were collected in 96 renal transplant patients one month after their second vaccine dose. For-cause biopsies were performed based on clinician judgment. Similar proportions of subjects experienced increases (39.6Â %) and decreases (44.8Â %) in serum creatinine in the post-vaccination period, pÂ =Â 0.56. Similar proportions of subjects experienced increases (23Â %) and decreases (25Â %) in serum ddcfDNA in the post-vaccination period, pÂ =Â 0.87. Post-vaccination changes in serum creatinine and ddcfDNA (r(95)Â =Â -0.04, pÂ =Â 0.71), serum creatinine and cumulative DSA MFI (r(95)Â =Â 0.07, pÂ =Â 0.56), and ddcfDNA and cumulative DSA MFI(r(95)Â =Â 0.13, pÂ =Â 0.21) were not significantly correlated. Five subjects had increased cumulativeDSA MFI, but there were no de novo cases. Biopsies on three subjects confirmed pre-existing diagnoses. Our study found minimal evidence ofdonor-directed immunologic activity post-vaccination, and all immunologic changesdid not correlate to graft dysfunction. We believe these findings do not amount to evidence ofpost-vaccination deleterious donor-directed activation. SARS-CoV-2 vaccination is immunologically safe and should continue for renal transplant recipients.

Skin-patch delivered subunit vaccine induces broadly neutralising antibodies against SARS-CoV-2 variants of concern. The ongoing SARS-CoV-2 pandemic continues to pose an enormous health challenge globally. The ongoing emergence of variants of concern has resulted in decreased vaccine efficacy necessitating booster immunizations. This was particularly highlighted by the recent emergence of the Omicron variant, which contains over 30 mutations in the spike protein and quickly became the dominant viral strain in global circulation. We previously demonstrated that delivery of a SARS-CoV-2 subunit vaccine via a high-density microarray patch (HD-MAP) induced potent immunity resulting in robust protection from SARS-CoV-2 challenge in mice. Here we show that serum from HD-MAP immunized animals maintained potent neutralisation against all variants tested, including Delta

and Omicron. These findings highlight the advantages of HD-MAP vaccine delivery in inducing high levels of neutralising antibodies and demonstrates its potential at providing protection from emerging viral variants.

A Case of Sequential Development of Polymyalgia Rheumatica and Guillain-BarrÃ© Syndrome Following Administration of the Pfizer-BioNTech COVID-19 Vaccine.

SARS-CoV-2 humoral responses following booster BNT162b2 vaccination in patients with B-cell malignancies. Patients with B-cell malignancies have suboptimal immune responses to SARS-CoV-2 vaccination and are a high-risk population for severe COVID19 disease. We evaluated the effect of a third booster BNT162b2 vaccine on the kinetics of anti- SARS-CoV-2 neutralizing antibody (NAbs) titers in patients with B-cell malignancies. Patients with NHL (nÂ =Â 54) WaldenstrÃ¶m's macroglobulinemia (nÂ =Â 90) and chronic lymphocytic leukemia (nÂ =Â 49) enrolled in the ongoing NCT04743388 study and compared against matched healthy controls. All patient groups had significantly lower NAbs compared to controls at all time points. 1â€‰month post the third dose (M1P3D) NAbs increased significantly compared to previous time points (median NAbs 77.9%, pâ€‰<â€‰.05 for all comparisons) in all patients. NAbsâ€‰â‰¥â€‰50% were seen in 59.1% of patients, 34.5% of patients with suboptimal responses post-second dose, elicited a protective NAb titer â‰¥50%. Active treatment, rituximab, and BTKi treatment were the most important prognostic factors for a poor NAb response at 1MP3D; only 25.8% of patients on active treatment had NAbsâ€‰â‰¥â€‰50%. No significant between-group differences were observed. Patients with B-cell malignancies have inferior humoral responses against SARS-CoV-2 and booster dose enhances the NAb response in a proportion of these patients.

Meralgia paresthetica mimic after Moderna COVIDâ€‘19 vaccine. This report describes the case of a 56-year-old male who developed unilateral right anterior thigh numbness which began 16 hours after receiving his second Moderna COVID-19 vaccine in the left deltoid. The numbness persisted and after one week a circular, raised, painless area with a red border appeared in the center of the anterior thigh which resolved after 2 weeks spontaneously. There was no clinical history or risk factors consistent with meralgia paresthetica. At his 6 month follow up the patient reported that his symptoms spontaneously resolved. While many other non-specific neurologic side effects of COVID-19 vaccines have been documented, this is the first case of meralgia paresthetica documented after a vaccine without any other risk factors for the syndrome. COVID vaccines should be considered as a potential cause of very localized peripheral neuropathy.

Antibody responses and SARS-CoV-2 infection after BNT162b2 mRNA booster vaccination among healthcare workers in Japan. INTRODUCTION: Vaccine effectiveness against SARS-CoV-2 infections decreases due to waning immunity, and booster vaccination was therefore introduced. We estimated the anti-spike antibody (AS-ab) recovery by booster vaccination and analyzed the risk factors for SARS-CoV-2 infections. METHODS: The subjects were health care workers (HCWs) in a Chiba University Hospital vaccination cohort. They had received two doses of vaccine (BNT162b2) and a booster vaccine (BNT162b2). We retrospectively analyzed AS-ab titers and watched out for SARS-CoV-2 infection for 90 days following booster vaccination. RESULTS: AS-ab titer eight months after two-dose vaccinations had decreased to as low as 587 U/mL (median, IQR (interquartile range) 360-896). AS-ab titer had then increased to 22471 U/mL (15761-32622) three weeks after booster vaccination. There were no significant differences among age groups. A total of 1708 HCWs were analyzed for SARS-CoV-2 infection, and 48 of them proved positive. SARS-CoV-2 infections in the booster-vaccinated and non-booster groups were 1.8% and 4.0%, respectively, and were not significant. However, when restricted to those 20-29 years old, SARS-CoV-2 infections in the booster-vaccinated and non-booster groups were 2.9% and 13.6%, respectively (pÂ =Â 0.04). After multivariate logistic regression, COVID-19 wards (adjusted odds ratio (aOR):2.9, 95% confidence

interval (CI) 1.5-5.6) and those aged 20-49 years (aOR:9.7, 95%CI 1.3-71.2) were risk factors for SARS-CoV-2 infection. CONCLUSIONS: Booster vaccination induced the recovery of AS-ab titers. Risk factors for SARS-CoV-2 infection were HCWs of COVID-19 wards and those aged 20-49 years. Increased vaccination coverage, together with implementing infection control, remains the primary means of preventing HCWs from SARS-CoV-2 infection.

Acute myocarditis following a third dose of COVID-19 mRNA vaccination in adults. INTRODUCTION: Myocarditis has been reported following the second dose of COVID-19 mRNA vaccination. Whether administration of additional doses of COVID-19 vaccines further increases the risk of myocarditis is unknown. METHODS: We included individuals who received one to three doses of BNT162b2 or mRNA-1273 mRNA vaccine between 12/14/2020 and 2/18/2022. Myocarditis within 21Â days of vaccine administration was identified using electronic medical records. Incidence rate ratios were calculated by comparing the observed incidence with the expected incidence from the same population during a 365-day baseline period. RESULTS: Of 3,076,660 KPSC members who received at least one dose of COVID-19 mRNA vaccines, 2,916,739 (94.5%) received at least two doses, and 1,146,254 (47.0%) received three doses. The incidence rate ratio for myocarditis was 0.86 (95% CI 0.31-1.93) for the first dose, 4.22 (95% CI 2.63-6.53) for the second dose, and 2.61 (1.13-5.29) for the third dose. Most myocarditis cases following the second and third dose occurred within seven days of vaccination. CONCLUSION: Myocarditis was a rare event observed after the second or third dose of vaccination. Most cases presented within seven days of vaccination. The incidence of myocarditis following the third dose was not significantly higher than that observed after the second dose.

Postural orthostatic tachycardia syndrome after mRNA COVID-19 vaccine.

New-onset myasthenia gravis after mRNA SARS-CoV-2 vaccination: a case series. BACKGROUND: Myasthenia gravis (MG) is an autoimmune disease that targets acetylcholine receptor (AChR) of the neuromuscular junction. New-onset MG after SARS-CoV-2 vaccination has rarely been reported. CASE PRESENTATION: We report about three patients who presented new-onset myasthenia gravis after receiving mRNA SARS-CoV-2 vaccination. The patients were all males and older than 55Â years. All the patients presented with ocular and bulbar symptoms. The interval between vaccine administration and MG onset ranged from 3Â days after the first dose to 10Â days after the second dose. All the patients had elevated serum AChR antibodies and responded to pyridostigmine. Two out of three patients were successfully treated with IVIG or plasma exchange and with long-term immunosuppression. CONCLUSIONS: MG is a rare disease; clinicians should be aware of possible new-onset MG after SARS-CoV-2 vaccination, especially with the current recommendation of booster doses. The hyperstimulation of the innate immune system or the exacerbation of a subclinical pre-existing MG could be possible explanations.

Development of an Effective Immune Response in Adults With Down Syndrome After Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccination. BACKGROUND: Immune dysregulation in individuals with Down syndrome (DS) leads to an increased risk for hospitalization and death due to coronavirus disease 2019 (COVID-19) and may impair the generation of protective immunity after vaccine administration. METHODS: The cellular and humoral responses of 55 individuals with DS who received a complete SARS-CoV-2 vaccination regime at 1 to 3 (visit [V 1]) and 6 (V2) months were characterized. RESULTS: SARS-CoV-2-reactive CD4+ and CD8+ T lymphocytes with a predominant Th1 phenotype were observed at V1 and increased at V2. Likewise, an increase in SARS-CoV-2-specific circulating Tfh (cTfh) cells and CD8+ CXCR5+ PD-1hi lymphocytes was already observed at V1 after vaccine administration. Specific immunoglobulin G (IgG) antibodies against SARS-CoV-2 S protein were detected in 96% and 98% of subjects at V1 and V2, respectively, although

IgG titers decreased significantly between both time points. CONCLUSIONS: Our findings show that DS individuals develop an effective immune response to usual regimes of SARS-CoV-2 vaccination.

Exposure to avian coronavirus vaccines is associated with increased levels of SARS-CoV-2-cross-reactive antibodies. BACKGROUND: Although avian coronavirus infectious bronchitis virus (IBV) and SARS-CoV-2 belong to different genera of the Coronaviridae family, exposure to IBV may result in the development of cross-reactive antibodies to SARS-CoV-2 due to homologous epitopes. We aimed to investigate whether antibody responses to IBV cross-react with SARS-CoV-2 in poultry farm personnel who are occupationally exposed to aerosolized IBV vaccines. METHODS: We analyzed sera from poultry farm personnel, COVID-19 patients, and pre-pandemic controls. IgG levels against the SARS-CoV-2 antigens S1, RBD, S2, and N and peptides corresponding to the SARS-CoV-2 ORF3a, N, and S proteins as well as whole virus antigens of the four major S1-genotypes 4/91, IS/1494/06, M41, and D274 of IBV were investigated by in-house ELISAs. Moreover, live-virus neutralization test (VNT) was performed. RESULTS: A subgroup of poultry farm personnel showed elevated levels of specific IgG for all tested SARS-CoV-2 antigens compared with pre-pandemic controls. Moreover, poultry farm personnel, COVID-19 patients, and pre-pandemic controls showed specific IgG antibodies against IBV strains. These antibody titers were higher in long-term vaccine implementers. We observed a strong correlation between IBV-specific IgG and SARS-CoV-2Â S1-, RBD-, S2-, and N-specific IgG in poultry farm personnel compared with pre-pandemic controls and COVID-19 patients. However, no neutralization was observed for these cross-reactive antibodies from poultry farm personnel using the VNT. CONCLUSION: We report here for the first time the detection of cross-reactive IgG antibodies against SARS-CoV-2 antigens in humans exposed to IBV vaccines. These findings may be useful for further studies on the adaptive immunity against COVID-19.

COVID-19 Vaccination in Autoimmune Diseases (COVAD) study: Vaccine safety in idiopathic inflammatory myopathies. INTRODUCTION/AIMS: In this study we investigated COVID-19 vaccination-related adverse events (ADEs) 7â€‰days postvaccination in patients with idiopathic inflammatory myopathies (IIMs) and other systemic autoimmune and inflammatory disorders (SAIDs). METHODS: Seven-day vaccine ADEs were collected in an international patient self-reported e-survey. Descriptive statistics were obtained and multivariable regression was performed. RESULTS: Ten thousand nine hundred respondents were analyzed (1227 IIM cases, 4640 SAID cases, and 5033 healthy controls [HCs]; median age, 42 [interquartile range, 30-455] years; 74% female; 45% Caucasian; 69% completely vaccinated). Major ADEs were reported by 76.3% of the IIM patients and 4.6% reported major ADEs. Patients with active IIMs reported more frequent major (odds ratio [OR], 2.7; interquartile range [IQR], 1.04-7.3) and minor (OR, 1.5; IQR, 1.1-2.2) ADEs than patients with inactive IIMs. Rashes were more frequent in IIMs (OR, 2.3; IQR, 1.2-4.2) than HCs. ADEs were not impacted by steroid dose, although hydroxychloroquine and intravenous/subcutaneous immunoglobulins were associated with a higher risk of minor ADEs (OR, 1.9; IQR, 1.1-3.3; and OR, 2.2; IQR, 1.1-4.3, respectively). Overall, ADEs were less frequent in inclusion-body myositis (IBM) and BNT162b2 (Pfizer) vaccine recipients. DISCUSSION: Seven-day postvaccination ADEs were comparable in patients with IIMs, SAIDs, and HCs, except for a higher risk of rash in IIMs. Patients with dermatomyositis with active disease may be at higher risk, and IBM patients may be at lower risk of specific ADEs. Overall, the benefit of preventing severe COVID-19 through vaccination likely outweighs the risk of vaccine-related ADEs. Our results may inform future guidelines regarding COVID-19 vaccination in patients with SAIDs, specifically in those with IIMs. Studies to evaluate long-term outcomes and disease flares are needed to shed more light on developing future COVID-19 vaccination guidelines.

Evaluation of the Correlation Between Responders and Non-Responders to the Second Coronavirus Disease Vaccination In Kidney Transplant Recipients: A Retrospective Single-Center Cohort Study.

BACKGROUND: The immune response to COVID-19 vaccination in kidney transplant (KTx) recipients is significantly lower than that in healthy controls. We evaluated immune responses after the COVID-19 vaccine and their possible relationship with other cofactors in KTx recipients. METHODS: This retrospective single-center cohort study included 29 KTx recipients 2-8 weeks after receiving 2 doses of the Pfizer-BioNTech SARS-CoV-2 messenger RNA vaccine. Anti-SARS-CoV-2 spike (S) immunoglobulin (Ig)-G levels were evaluated to define cofactors influencing the immune response between the responder (anti-SARS-CoV-2 IgG level â‰¥0.8 U/mL) (nÂ =Â 16) and nonresponder groups (anti-SARS-CoV-2 IgG level <0.8 U/mL) (nÂ =Â 13). The kinetics of antibodies between 2 and 6 months after the second vaccination was also compared between the groups. RESULTS: KTx recipients with IgG levels â‰¥0.8 U/mL were younger (54 [interquartile range {IQR}, 46.5-61] years vs 65 [IQR, 55-71.5] years; PÂ =Â .01), had been transplanted for a longer median time (1588 [IQR, 1382-4751] days vs 1034 [IQR, 548.5-1833] days; PÂ =Â .02), and were more often treated with a lower mycophenolate mofetil dosage (765.6 Â± 119.6 vs 1077 Â± 76.9 mg; PÂ =Â .04) than KTx recipients with IgG levels <0.8 U/mL. There was no significant difference in antibody titers between time periods after the second dose in the responder group. At the 6-month follow-up, a serologic response against the SARS-CoV-2 S was observed in 44.4% of KTx recipients in the nonresponder group. CONCLUSIONS: More than 50% of KTx recipients developed a higher antibody response after the second dose of COVID-19 vaccination.

The Onset of Sarcoidosis After COVID-19 Vaccination Revealed by the 18 F-FDG PET. Sarcoidosis is a heterogeneous multisystem disease characterized by noncaseating granulomas. We presented 18 F-FDG PET/CT findings of sarcoidosis in a previously healthy 43-year-old man who presented intermittent cough after the third dose of COVID-19 vaccination. 18 F-FDG PET/CT showed high uptake of one solitary nodule in the right middle lobe, mediastinal lymph nodes, bilateral hila, and multiple nodules under the right pleura, mimicking the malignancy. Nevertheless, the biopsy confirmed distinct noncaseating granulomas. This case emphasizes the onset of sarcoidosis revealed by 18 F-FDG PET/CT after COVID-19 vaccination.

COVID-19 susceptibility in endometriosis patients: A case control study. PROBLEM: Starting from November 2019, the world has had to face a devastating pandemic caused by SARS-CoV-2. Various studies have identified potential risk factors facilitating the infection, however it has not been demonstrated whether endometriosis might represent one of them. The purpose of this study was to evaluate if patients with endometriosis had a higher risk of contracting COVID-19 infection and, in such case, whether they developed a more severe infection than the general population. Furthermore, this study evaluated the possible correlation with the stage of endometriosis, based on the r-ASRM score, and the potential worsening of the disease during the SARS-CoV-2 infection. METHOD OF STUDY: A case-control study was conducted from March 2020 to April 2021 at Macedonio Melloni Hospital, in Milan. A total of 401 women were recruited. The cases were 201 women with clinical or surgical diagnosis of endometriosis. The control group consisted of 200 women, without the disease. All women completed a self-administered questionnaire which evaluated their demographic and clinical characteristics, as well as a potential diagnosis of Covid-19. RESULTS: Comparison between the two groups showed that women with endometriosis had a higher frequency of COVID-19 than the control subjects (23%Â vs. 13.5%, PÂ =Â .014), with a greater prevalence of fever (14.4%Â vs. 6%, PÂ =Â .008) and myalgias or arthralgias (11.4%Â vs. 4.5%, PÂ =Â .01). In multivariable logistic regression analyses, women with endometriosis had a higher risk of contracting SARS-CoV-2 infection (ORÂ =Â 2.11, 95% IC: 1.20-3.80), regardless the stage of the disease. CONCLUSION: Endometriosis increases the susceptibility to COVID-19, and women who suffer from it should be considered as fragile patients, worthy of prior access to SARS-CoV-2 vaccination campaign.

A cross-sectional study of COVID-19 vaccination patterns among patients with epilepsy in Hong Kong. OBJECTIVE: As Hong Kong faced the 5th wave of the COVID-19 pandemic, the facilitators and hurdles toward effective vaccination is important for healthcare professionals to understand the vaccination gap among patients with epilepsy. METHODS: A cross-sectional, pragmatic study of COVID-19 vaccination was performed at a tertiary epilepsy center with regards to patterns of vaccination and any unusually high rate of adverse events. Patients having recent visits at the epilepsy center (4â€‰months) had their anonymized electronic linkage records examined 12Â months after the inception of vaccination program for types of vaccines, seizure demographics, and adverse events following immunization (AEFI). RESULTS: A total of 200 patients with epilepsy and their anonymized data were analyzed. The vaccine uptake was approximately 60% of that of the general population. Twice as many patients with epilepsy chose to receive mRNA vaccine as compared with inactivated vaccine. The proportion of patients who kept up-to-date with all available dosing was 7%. Patients with epilepsy with genetic etiology were least likely to receive vaccination (13/38, 34%, PÂ =Â .02). There was no unreasonably high rate of unacceptable side effects after vaccination among patients with epilepsy. Only 3 patients reported worsening of seizures without meeting the criteria for AEFI. Refractory epilepsy, allergy to antiseizure medications and elder age (â‰¥65) did not confer any significant difference in vaccination patterns or adverse effects. SIGNIFICANCE: A vaccination gap exists among epilepsy patients which calls for actionable strategies for improving vaccine uptake, including education and outreach programs.

Association Between Vaccination and Acute Myocardial Infarction and Ischemic Stroke After COVID-19 Infection. This retrospective cohort study examines the incidence of acute myocardial infarction and ischemic stroke after COVID-19 infection among vaccinated vs unvaccinated adults in Korea.

Brown-SÃ©quard syndrome in a patient with spondyloarthritis after COVID-19 vaccine: a challenging differential diagnosis. A 41-year-old woman with pre-radiographic axial and peripheric spondyloarthritis, taking adalimumab since 2010, started motor impairment of the right limbs and numbness of the left leg seven days after the administration of COVID-19 mRNA vaccine. Adalimumab was taken 47 days before clinical onset. A comprehensive study for infectious, autoimmune and neoplastic causes were unremarkable. MRI depicted an acute inflammatory lesion at C2 level with gadolinium enhancement. The patient started methylprednisolone with clinical improvement. Three scenarios should be considered: primary CNS inflammatory disorder or a secondary manifestation of the underlying rheumatologic disease; immune-mediated inflammatory lesion triggered by vaccine; demyelinating event due to adalimumab.

COVID-19 After Vaccination in Lung Transplant Recipients: Real-Life Data. OBJECTIVES: The effectiveness of COVID-19 vaccines in lung transplant recipients is unclear. We retrospectively analyzed lung transplant recipients vaccinated with an inactivated virus vaccine (CoronaVac) and the mRNA vaccine BNT162b2 used against the SARS-CoV-2 virus in Turkey and shared their effects on COVID-19. MATERIALS AND METHODS: Demographic data of lung transplant recipients followed up for >3 months were collected, and vaccination dates and status against the SARS-CoV-2 virus were recorded. Recipients who received at least 3 doses of CoronaVac or 2 doses of BNT162b2, or 1 dose of CoronaVac plus 2 doses of BNT162b2, or 2 doses of CoronaVac plus 1 dose of BNT162b2 were considered fully vaccinated; those who were vaccinated less than this number were considered partially vaccinated. Patients with positive SARS-CoV-2 reverse transcription-polymerase chain reaction tests from respiratory tract samples were accepted as positive for COVID-19. Recipients were classified by number and type of vaccine, and groups were compared for infection, need for intensive care, and death as a result of COVID-19. RESULTS: Of the 53 lung transplant recipients, 51 were vaccinated (7 partially vaccinated, 44 fully vaccinated) and 2 were not vaccinated. Of fully vaccinated

recipients, 13/44 received the inactivated vaccine, 5/44 received the mRNA vaccine, and 26/44 had a combination of the 2 vaccines. During the follow-up period, 13 patients (2/2 not vaccinated, 2/7 [28.5%] partially vaccinated, 9/44 [20.5%] fully vaccinated) were diagnosed with COVID-19. There was no significant difference in protection against infection between the inactivated, the mRNA, and combined vaccine groups. There was no significant association in cycle threshold values that determine the infection load and COVID-19 severity between transplant recipients who died and those who did not. CONCLUSIONS: In lung transplant recipients, 3 doses of inactivated vaccine, 2 doses of mRNA vaccine, or the combined heterologous vaccine provided similar protection. Prevention of exposure is one of the most crucial steps.

Case report of transient corneal edema after immunization with adenovirus-vectored COVID-19 vaccine. RATIONALE: To report a case of bilateral transient corneal edema presumably associated with adenovirus-vectored coronavirus disease 2019 (COVID-19) vaccination that resolved with eye drops treatment. PATIENT CONCERNS: A 55-year-old Asian woman presented with sudden onset of bilateral visual disturbance developed 6 days after immunization with an adenovirus-vectored COVID-19 vaccine (AstraZeneca, London, United Kingdom). She underwent uneventful cataract surgery in right and left eyes 2 months ago and maintained good visual acuity bilaterally. Slit-lamp examination showed bilateral mild corneal edema that was confirmed with anterior segment optical coherent tomography. Anterior chamber and vitreous were clear bilaterally. Both fundi were normal. DIAGNOSES: The patient was diagnosed with corneal edema following adenovirus-vectored COVID-19 vaccination. INTERVENTIONS: She was prescribed with prednisolone acetate 1% eye drops bilaterally. OUTCOMES: Treatment with topical steroid for 2 weeks resulted in resolution of the corneal edema and improvement of the visual acuity bilaterally. LESSONS: This case suggests that transient corneal edema can develop following adenovirus-vectored COVID-19 vaccination. Prompt ophthalmologic evaluation and treatment may improve the corneal edema.

Influence of COVID-19 mRNA vaccination on the efficacy and safety of Botulinum toxin type A injections. BACKGROUND: Concerns have been raised recently regarding the efficacy and safety of Botulinum toxin type A (BTA) injections following COVID-19 vaccination. AIMS: To assess the influence of BNT162b2 mRNA vaccine on the safety and efficacy of BTA injections performed for aesthetic indications. METHODS: A retrospective cohort study followed patients undergoing periodic BTA treatments who completed two doses of BNT162b2 vaccine. The latency between BTA injections before and after getting vaccinated was assessed for all study participants. Efficacy and longevity of BTA was reflected and evaluated by the latency between BTA injections. Patients were longitudinally monitored for the development of adverse events. RESULTS: Forty-five patients were eligible for inclusion in the current study. The mean (standard deviation [SD]) age of patients was 48.3 (8.9) years and 40 (88.9%) patients were females. The mean (SD) number of pre- and post-COVID-19 vaccination BTA injections was 5.1 (2.6) and 3.1 (0.4), respectively. The average (SD) interval between BTA injections after COVID-19 vaccination (96.0 [12.3] days) was significantly shorter than before it (118.6 [22.7]; pÂ <â€‰0.001). No severe BTA-associated adverse events were registered after the administration of BNT162b2 vaccine. CONCLUSIONS: Our findings indicate that BTA might be less effective after COVID-19 vaccination. Further research is required to delineate the pathomechanism underlying this observation.

SARS-CoV-2 vaccine as a potential trigger for narcolepsy.

Fulminant hepatitis following COVID-19 vaccination: AÂ case report. The common side effects of COVID-19 vaccination were mostly self-restricted local reactions that quickly resolved. Nevertheless, rare autoimmune hepatitis cases have been reported in some vaccinated with mRNA COVID-19 vaccines. This article presents a young man who developed fulminant hepatitis a few days after vaccination with the first dose of the AstraZeneca COVID-19 vaccine. A 35-year-old man was admitted

to our hospital with generalized weakness, abdominal pain, and jaundice. He received the first dose of the AstraZeneca COVID-19 vaccine 8â€‰days earlier. He was admitted to the hospital with a chief complaint of abdominal pain. On admission and because of his high D-dimers, low platelet count, and low Fibrinogen level, vaccine-induced immune thrombosis thrombocytopenia was suspected, which was ruled out later. Then, after a surge in his liver function tests, decreasing platelet, and abnormal clotting tests, fulminant hepatitis was considered for this patient. Several bacterial, viral, and autoimmune etiologies were then suspected, with all ruled out. Thus, fulminant hepatitis secondary to his AstraZeneca COVID-19 vaccine was confirmed. Unfortunately, he died 3â€‰days later of disseminated intravascular coagulopathy, after which a liver necropsy was performed, indicating drug/toxin-induced hepatitis.

COVID-19 Vaccination and the Rate of Immune and Autoimmune Adverse Events Following Immunization: Insights From a Narrative Literature Review. Despite their proven efficacy and huge contribution to the health of humankind, vaccines continue to be a source of concern for some individuals around the world. Vaccinations against COVID-19 increased the number of distressed people and intensified their distrust, particularly as the pandemic was still emerging and the populations were encouraged to be vaccinated under various slogans like "back to normal life" and "stop coronavirus", goals which are still to be achieved. As fear of vaccination-related adverse events following immunization (AEFIs) is the main reason for vaccine hesitancy, we reviewed immune and autoimmune AEFIs in particular, though very rare, as the most worrisome aspect of the vaccines. Among others, autoimmune AEFIs of the most commonly administered COVID-19 vaccines include neurological ones such as Guillain-Barre syndrome, transverse myelitis, and Bell's palsy, as well as myocarditis. In addition, the newly introduced notion related to COVID-19 vaccines, "vaccine-induced immune thrombotic thrombocytopenia/vaccine-induced prothrombotic immune thrombotic thrombocytopenia" (VITT/VIPITT)", is of importance as well. Overviewing recent medical literature while focusing on the major immune and autoimmune AEFIs, demonstrating their rate of occurrence, presenting the cases reported, and their link to the specific type of COVID-19 vaccines represented the main aim of our work. In this narrative review, we illustrate the different vaccine types in current use, their associated immune and autoimmune AEFIs, with a focus on the 3 main COVID-19 vaccines (BNT162b2, mRNA-1273, and ChAdOx1). While the rate of AEFIs is extremely low, addressing the issue in this manner, in our opinion, is the best strategy for coping with vaccine hesitancy.

Use of Tumor Necrosis Factor-Î± Antagonists Is Associated With Attenuated IgG Antibody Response Against SARS-CoV-2 in Vaccinated Patients With Inflammatory Bowel Disease. INTRODUCTION: Patients with Inflammatory Bowel Disease (IBD) frequently receive immunomodulating treatment, which may render them at increased risk of an attenuated immune response upon vaccination. In this study, we assessed the effects of different types of commonly prescribed immunosuppressive medications on the serological response after vaccination against SARS-CoV-2 in patients with IBD. METHODS: In this prospective observational cohort study, IgG antibody titers against SARS-CoV-2 were measured 2-10 weeks after completion of standard vaccination regimens in patients with IBD. Clinical characteristics, previous history of SARS-CoV-2 infection, type of vaccine (mRNA- or vector-based) and medication use were recorded at the time of sampling. Subsequently, a chemiluminescent microparticle immunoassay was used for the quantitative determination of IgG antibodies against the receptor-binding domain (RBD) of the S1 subunit of the spike protein of SARS-CoV-2. RESULTS: Three hundred and twelve (312) patients with IBD were included (172 Crohn's disease [CD] and 140 ulcerative colitis [UC]). Seroconversion (defined as titer of >50 AU/ml) was achieved in 98.3% of patients. Antibody concentrations were significantly lower in patients treated with TNF-Î±-antagonists vs. non-users of TNF-Î±-antagonists (geometric mean [95% confidence interval]: 2204 [1655-2935] vs. 5002 [4089-6116] AU/ml, P<0.001). In multivariable models, use of TNF-Î±-antagonists (P<0.001),

vector vaccines (P<0.001), age (>50 years) (P<0.01) and CD (P<0.05) were independently associated with lower anti-SARS-CoV-2 antibody titers. In patients who received mRNA vaccines, users of thiopurines (either prescribed as monotherapy or in combination with biologicals) demonstrated significantly lower antibody titers compared to thiopurine non-users (P<0.05). CONCLUSION: Despite reassuring findings that most patients with IBD have detectable antibodies after anti-SARS-CoV-2 vaccination, TNF-Î±-antagonists were found to be strongly associated with an attenuated IgG antibody response after vaccination against SARS-CoV-2, independent of vaccine type, the time elapsed after vaccination and blood sampling, prior SARS-CoV-2 infection and patient age. Patients treated with thiopurines and receiving mRNA-based vaccines demonstrated lower anti-SARS-CoV-2 antibody titers compared with non-users.

Effect of Inactivated SARS-CoV-2 Vaccine on Thyroid Function and Autoimmunity Within 28 Days After the Second Dose. Background: The safety of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines is widely appreciated. However, there is limited knowledge regarding the potential impact of SARS-CoV-2 vaccines on the thyroid. Methods: We performed two prospective clinical trials between April and June, 2021, enrolling recipients of the inactivated SARS-CoV-2 vaccine (BBIBP-CorV and CoronaVac). Thyroid function, antithyroid antibody levels, and SARS-CoV-2 neutralizing antibody levels were detected for each participant before receiving the first vaccine dose and 28 days after receiving the second vaccine dose. Results: A total of 657 recipients participated in the study. The overall median thyroid function and levels of antithyroid antibodies before and after SARS-CoV-2 vaccination were within the normal range. Among the 564 participants with normal thyroid function at baseline, 36 (6.38% [confidence interval; CI 4.51-8.73]) developed thyroid dysfunction. Of the 545 recipients with negative antithyroid antibodies at baseline, none developed abnormal antibodies after vaccination. Notably, 75.27% (70/93 [CI 65.24-83.63]) of the 93 recipients with thyroid dysfunction returned to normal function after vaccination. The levels of antithyroid peroxidase antibody (96.20% [CI 89.30-99.21]) and antithyroglobulin antibody (TgAb; 88.31% [CI 78.97-94.51]) remained positive after vaccination in most patients with abnormal values at baseline. However, the TgAb levels in more than half of the patients (48/77) decreased. All of 11 abnormal thyrotropin receptor antibody levels at baseline decreased postvaccination. Conclusions: Vaccination with an inactivated SARS-CoV-2 vaccine had no significant adverse impact on thyroid function or antithyroid antibodies within the first 28 days after the second dose. Clinical Trial Registration: ChiCTR2100045109 and ChiCTR2100042222.

Maternal and neonatal safety outcomes after SAR-CoV-2 vaccination during pregnancy: a systematic review and meta-analysis. BACKGROUND AND OBJECTIVE: More than five million individuals died because of problems connected to COVID-19. SARS-Cov-2 poses a particular challenge to expectant mothers, who comprise one of the most vulnerable segments of the population. Our aim is to demonstrate the maternal and neonatal safety of the COVID-19 vaccine during pregnancy. METHODS: We searched PubMed, Cochrane Library, Scopus, Web of Science (WOS), Embase, Ovid, MedRxiv, and BioRxiv databases from inception till December 2021 and then updated it in April 2022. Additionally, we searched ClinicalTrials.gov, Research Square and grey literature. Cohort, case-control studies, and randomized controlled trials detecting the safety of the Covid-19 vaccine during pregnancy were included. We used the Cochrane tool and Newcastle-Ottawa Scale to assess the risk of bias of the included studies and the GRADE scale to assess the quality of evidence. A meta-analysis was conducted using review manager 5.4. RESULTS: We included 13 studies with a total number of 56,428 patients. Our analysis showed no statistically significant difference in the following outcomes: miscarriage (1.56% vs 0.3%. RR 1.23; 95%CI 0.54 to 2.78); length of maternal hospitalization (MD 0.00; 95%CI -0.08 to 0.08); puerperal fever (1.71% vs 1.1%. RR 1.04; 95%CI 0.67 to 1.61); postpartum hemorrhage (4.27% vs 3.52%. RR 0.84; 95%CI 0.65 to 1.09); instrumental or vacuum-assisted delivery

(4.16% vs 4.54%. RR 0.94; 95%CI 0.57 to 1.56); incidence of Apgar scoreâ€‰â‰¤â€‰7 at 5Â min (1.47% vs 1.48%. RR 0.86; 95%CI 0.54 to 1.37); and birthweight (MD -7.14; 95%CI -34.26 to 19.99). CONCLUSION: In pregnancy, the current meta-analysis shows no effect of SAR-CoV-2 vaccination on the risk of miscarriage, length of stay in the hospital, puerperal fever, postpartum hemorrhage, birth weight, or the incidence of an Apgar score ofâ€‰â‰¤â€‰7 at 5Â min.

Immunogenicity and safety of two doses of SARS-CoV-2 mRNA vaccine in kidney transplant recipients with low-dose rituximab. OBJECTIVES: We evaluated whether the treatment history of low-dose rituximab affected safety profiles, and humoral and cellular responses induced by severe acute respiratory syndrome coronavirus 2 messenger ribonucleic acid vaccine in healthy controls and kidney transplant recipients. METHODS: We enrolled 10 healthcare workers as controls, 22 kidney transplant recipients with rituximab, and 36 kidney transplant recipients without rituximab without history of coronavirus disease 2019 who received two doses of vaccine. We assessed anti-severe acute respiratory syndrome coronavirus 2 spike antibody and the antigen-specific T cells using enzyme-linked immunospot against spike protein at baseline and after two doses of vaccine. RESULTS: All controls showed anti-severe acute respiratory syndrome coronavirus 2 antibody seroconversion and enzyme-linked immunospot positivity. Only 19/58 (33%) kidney transplant recipients experienced anti-severe acute respiratory syndrome coronavirus 2 antibody seroconversion and 31/58 (53%) kidney transplant recipients developed enzyme-linked immunospot assay positivity after vaccination. The anti-severe acute respiratory syndrome coronavirus 2 antibody seroconversion rate and enzyme-linked immunospot assay positivity rate after vaccination were not significantly different between kidney transplant recipients with or without rituximab. Multivariate regression analysis demonstrated rituximab was not associated with a lack of humoral and cellular responses to the vaccine. CONCLUSIONS: Low-dose rituximab in kidney transplant recipients did not affect humoral or cellular responses to the severe acute respiratory syndrome coronavirus 2 messenger ribonucleic acid vaccine without severe systemic adverse events including the deterioration of kidney function.

Persistence of immunity against Omicron BA.1 and BA.2 variants following homologous and heterologous COVID-19 booster vaccines in healthy adults after a two-dose AZD1222 vaccination. OBJECTIVES: The SARS-CoV-2 Omicron variant presents numerous mutations potentially able to evade neutralizing antibodies (NAbs) elicited by COVID-19 vaccines. Therefore, this study aimed to provide evidence on a heterologous booster strategy to overcome the waning immunity against Omicron variants. METHODS: Participants who completed the Oxford/AstraZeneca (hereafter AZD1222) vaccine dose for 5-7 months were enrolled. The reactogenicity and persistence of immunogenicity in both humoral and cellular response after a homologous or heterologous booster with the AZD1222 and messenger RNA (mRNA) vaccines (BNT162b2, full, or half-dose mRNA-1273) administered 6 months after primary vaccination were determined. RESULTS: A total of 229 individuals enrolled, and waning of immunity was observed 5-7 months after the AZD1222-primed vaccinations. Total receptor-binding domain (RBD) immunoglobulin (Ig) levels, anti-RBD IgG, and focus reduction neutralization test against Omicron BA.1 and BA.2 variants and T cell response peaked at 14-28 days after booster vaccination. Both the full and half dose of mRNA-1273 induced the highest response, followed by BNT162b2 and AZD1222. At 90 days, the persistence of immunogenicity was observed among all mRNA-boosted individuals. Adverse events were acceptable for all vaccines. CONCLUSION: A heterologous mRNA booster provided a significantly superior boost of binding and NAbs levels against the Omicron variant compared with a homologous booster in individuals with AZD1222-primed vaccinations.

SARS-CoV-2 immunoglobulin G antibody levels in infants following messenger RNA COVID-19 vaccination during pregnancy.

Vaccination status, favipiravir, and micronutrient supplementation roles in post-COVID symptoms: A longitudinal study. INTRODUCTION: Post-COVID symptoms are the new concern in the COVID-19 pandemic, where recovered patients experience residual symptoms affecting their quality of life. Therefore, it is imperative to evaluate the role of complete vaccination, prescribed medication, and micronutrients during COVID episodes in the occurrence of post-COVID symptoms. METHOD: A longitudinal evaluation of Indonesia's recovered COVID-19 patients was performed using the data collected from July 2021 and extracted in mid-February 2022. All participants were confirmed with a Real-Time Polymerase Chain Reaction test (PCR) and/or antigen test. This study collected demography and comorbidities information, symptoms and treatment of COVID-19, and collection of self-reported post-COVID symptoms every 30 days within 90 days after diagnosis/onset. Exposures of interest include vaccination status, Favipiravir administration, Vitamin C, Vitamin D, and Zinc. A Generalized Estimating Equation (GEE) was used to evaluate the longitudinal effect of exposures, presented with adjusted odds ratios and its 95% confidence interval. RESULTS: A total of 923 participants (18.2% fully-vaccinated) were involved in the study, with 79.7% being non-hospitalized. Only 25.7% did not develop any residual symptoms within 90 days. Fatigue was the most reported post-COVID symptom in each measurement time (39.5%, 16.3%, and 7.3%). Full-vaccination was effective against chronic cough (aOR 0.527, 95% CI 0.286-0.971), chronic headache (aOR 0.317, 95% CI 0.163-0.616), and chronic arthritis (aOR 0.285, 95% CI 0.116-0.703). The combination of micronutrient supplementations and Favipiravir gave no significant effect on all post-COVID symptoms. However, early initiation of Favipiravir and delaying vitamin D administration were associated with arthritis. CONCLUSION: Full vaccination of COVID-19 prevents the disease and the development of residual symptoms when infected with SARS-COV-2. Hence, it is crucial to reconsider the prescription of micronutrient supplementation or adjust the dose of Favipiravir in the current guideline.

Hypertension and Excess Risk for Severe COVID-19 Illness Despite Booster Vaccination.

Antibody Titers After a Third and Fourth SARS-CoV-2 BNT162b2 Vaccine Dose in Older Adults. This cohort study evaluates the response to a third and fourth SARS-CoV-2 BNT162b2 vaccine dose among individuals aged 60 years or older by evaluating antispike immunoglobulin G antibody titers before and after each dose.

Safety and Adverse Events Among Long-term Care Residents Receiving a Third COVID-19 mRNA Vaccine Booster Dose in Quebec. This cohort study examines the safety and adverse events associated with receipt of various 3-dose combinations of COVID-19 mRNA vaccines with among long-term care residents in Quebec, Canada.

Cutaneous adverse reactions following COVID-19 vaccinations: A systematic review and meta-analysis. BACKGROUND: COVID-19 vaccines are currently the most effective interventions in controlling and preventing severe disease progression. Dermatologic reactions to COVID-19 vaccinations may be rare among clinical trial participants. However, since global mass vaccination became a reality, these adverse effects may become more widespread, and different skin reactions would arise. OBJECTIVE: To systematically review the cutaneous adverse reactions in cases subject to vaccines for COVID-19. METHODS: We searched the PubMed, SCOPUS, Web of Science, and Embase databases, identifying the relevant records and including the eligible observational ones. After assessing the methodological quality of the included studies, we qualitatively and quantitatively synthesized the data regarding the cutaneous side effects experienced by those in the studies' population. RESULTS: Overall, 36 studies were included in our systematic review, with the majority being cross-sectional. We found that pain, erythema, and swelling were the most common local side effects, while different types of rashes, urticaria, and angioedema were the most non-local. Few cases also reported experiencing flare-ups of their underlying diseases or developing newly-onset diseases

of various etiologies. Our meta-analyses also found that while viral vector-based vaccines are, though insignificantly, safer in injection site complaints, individuals who received mRNA vaccines developed significantly fewer non-local cutaneous adverse events. DISCUSSION: Cutaneous reactions to the COVID-19 vaccines are similar to common cutaneous drug eruptions and COVID-19 cutaneous manifestations. However, we believe that further high-quality research is needed to assess better how and why cutaneous reactions occur in different vaccines.

Association between BNT162b2 vaccination and the development of delayed inflammatory reactions to hyaluronic acid-based dermal fillers-A nationwide survey. BACKGROUND: Delayed inflammatory reactions (DIRs) to hyaluronic acid-based dermal fillers following COVID-19 vaccination has been reported in a few anecdotal reports and small series of cases. AIM: To evaluate the clinical characteristics, incidence, and management options relevant to BNT162b2 vaccination-associated DIR-A nationwide survey was conducted. METHODS: An online self-administered survey was sent to physicians who actively practice tissue filler injections. The data acquired included demographic and clinical characteristics of relevant DIR cases. RESULTS: Out of 262 responders, 20 cases with DIR following the vaccination were reported. 35% and 65% occurred shortly after the first and second vaccination dose, respectively. Overall, 65% of the DIRs appeared â‰¤5â€‰days after vaccine administration and most DIRs resolved within 21â€‰days. The filler's volume (pÂ =â€‰0.016) was associated with higher DIR severity, and the same tendency was noted among some filler types and locations of injection. Medical intervention was provided in 12 (60%) cases. CONCLUSION: DIR associated with BNT162b2 vaccination is rare and tends to resolve spontaneously or with short-term medical intervention.

Implementation of a Military Emergency Department Influenza Vaccination Program: Lessons from Failure. INTRODUCTION: Influenza infection in the United States results in hundreds of thousands of hospitalizations and 12,000 to 60,000 yearly deaths. Influenza season sees a sharp increase in emergency department (ED) patients nationwide, as primary care offices become overwhelmed. Because the ED is unique in its reach of underserved communities, ED vaccination programs can help maximize the number of people protected by vaccination. Influenza vaccination is one of the only vaccines that occurs yearly; therefore, successes with ED distribution of the influenza vaccine can potentially be translated into efforts of vaccinating the U.S. population more efficiently against other viral illnesses, such COVID-19. There has also not been a previous description in the literature of a vaccination program being used in a military setting. The original purpose of this study was to measure the effect of an ED vaccination program on our vaccine penetration and ED length of stay as well as to analyze the impact of provider education on vaccine uptake on vaccine refusal. METHODS: This was an observational, quality improvement project in the Wright-Patterson Medical Center Emergency Department evaluating an influenza vaccination program set to last from October 1, 2020 to April 1, 2021. Patients were to be surveyed to assess prior vaccination status, identify those at high risk for influenza complications, and to measure the effects of point-of-care education on vaccine acceptance. Separate measurements included average ED length of stay and the study's impact on how quickly the base population could be vaccinated. RESULTS: The effort was determined no longer feasible on November 20, 2020 because of the significant barriers. Although no data were gathered, we were able to glean important information that is vital in future efforts to implement ED-based vaccination programs. Reasons for program failure were multi-factorial, but were mainly attributed to rapid implementation, issues with Pyxis ordering and vaccine shipments, and vaccine storage capacity. The program also lacked a multidisciplinary implementation team of nurses and technicians, which could have better anticipated critical barriers. CONCLUSION: Influenza has caused multiple worldwide pandemics, contributed to countless deaths, and continues to be a challenge. ED-based influenza vaccination programs have been trialed to augment the primary care system in their effort

to prevent deaths from influenza. The literature has shown that these programs are cost-effective and efficacious, but significant barriers have stunted their widespread utilization. Examining the rapid implementation and failure of this program highlights the importance of implementation models, process and barrier mapping, and proper operationalization. It is also the first such program that has been trialed in a military treatment facility. In consideration of the recent pandemic, successful ED-based vaccination programs can also offer a model for additional dissemination of other vaccines, such as the COVID-19 vaccine.

[COVID-19 Vaccine-Induced Thrombosis with Thrombocytopenia Syndrome]. Thrombosis with thrombocytopenia syndrome (TTS) induced by the coronavirus disease 2019 vaccine is characterized by thrombocytopenia and thrombosis. Positivity for the anti-platelet factor 4-antibody is related to TTS pathophysiology, similar to heparin-induced thrombocytopenia. Although TTS is very rare, with an incidence of almost 1/100,000 cases, physicians need to keep in mind this adverse reaction that can lead to serious symptoms and death. Prompt treatment should be initiated in cases of suspected TTS.

[COVID-19 Vaccines for Patients with Neuroimmunological Diseases]. More than 2 years have passed since the outbreak of coronavirus disease 2019 (COVID-19), but there is still no sign that the COVID-19 pandemic has ended. Although vaccines have shown high efficacy against severe acute respiratory syndrome coronavirus 2, a risk of adverse reactions and thrombosis has also been reported. Here we review the current knowledge regarding vaccination in patients with neuroimmunological diseases and those receiving immunosuppressive drugs or disease-modifying therapy.

[Ataxia, Involuntary Movement and Paroxysmal Motor Abnormality Associated with COVID-19 Infection]. The new coronavirus SARS-CoV-2 infection (COVID-19) has caused many casualties, mainly respiratory infections. However, it has also caused several neurological disorders including encephalitis/encephalopathy, demyelinating disease, Gullain-BarrÃ© sydrome etc. In addition, it has been clarified that movement disorders develop within a few days to weeks after infection. Vaccination for COVID-19 has progressed, but autoimmune neurological complications have also been reported. Although a causal relationship is suspected over time, this paper describes the pathophysiology of movement disorders such as myoclonus, opsoclonus, parkinsonism, and cerebellar ataxia, which are relatively common in COVID-19 infections, and their relevance to the SARS-CoV-2 vaccine.

Fulminant myocarditis after the first dose of mRNA-1273 vaccination in a patient with previous COVID-19: a case report. BACKGROUND: COVID-19 vaccines have shown success in protecting people worldwide, although serious adverse effects have been reported in very rare cases. CASE SUMMARY: A 32-year-old male with a prior medical history of mild COVID-19 infection developed fulminant myocarditis five days after mRNA-1273 vaccination (first dose), which was confirmed using endomyocardial biopsy. He acutely developed respiratory failure and cardiogenic shock with ventricular tachycardia, but recovered completely with short-term high-dose steroid therapy and mechanical cardiac support, which is the recommended treatment for fulminant lymphocytic myocarditis. DISCUSSION: COVID-19 vaccine-induced myocarditis varies from mild to severe. In the present case, the patient was treated as for fulminant lymphocytic myocarditis and recovered relatively quickly. The mechanism of COVID-19 vaccine-associated myocarditis needs to be urgently investigated.

SARS-CoV-2 Spike- and Nucleoprotein-Specific Antibodies Induced After Vaccination or Infection Promote Classical Complement Activation. Antibodies specific for the spike glycoprotein (S) and nucleocapsid (N) SARS-CoV-2 proteins are typically present during severe COVID-19, and induced to S after vaccination. The binding of viral antigens by antibody can initiate the classical complement

pathway. Since complement could play pathological or protective roles at distinct times during SARS-CoV-2 infection we determined levels of antibody-dependent complement activation along the complement cascade. Here, we used an ELISA assay to assess complement protein binding (C1q) and the deposition of C4b, C3b, and C5b to S and N antigens in the presence of antibodies to SARS-CoV-2 from different test groups: non-infected, single and double vaccinees, non-hospitalised convalescent (NHC) COVID-19 patients and convalescent hospitalised (ITU-CONV) COVID-19 patients. C1q binding correlates strongly with antibody responses, especially IgG1 levels. However, detection of downstream complement components, C4b, C3b and C5b shows some variability associated with the subject group from whom the sera were obtained. In the ITU-CONV, detection of C3b-C5b to S was observed consistently, but this was not the case in the NHC group. This is in contrast to responses to N, where median levels of complement deposition did not differ between the NHC and ITU-CONV groups. Moreover, for S but not N, downstream complement components were only detected in sera with higher IgG1 levels. Therefore, the classical pathway is activated by antibodies to multiple SARS-CoV-2 antigens, but the downstream effects of this activation may differ depending the disease status of the subject and on the specific antigen targeted.

The Flare of Rheumatic Disease After SARS-CoV-2 Vaccination: A Review. As the coronavirus disease 2019 (COVID-19) pandemic continues worldwide, vaccination has been considered an effective measure to protect people from the COVID-19 and end the pandemic. However, for patients with rheumatic diseases (RD), concern for the induction of RD flare may combat the enthusiasm for vaccination. In general, current evidence doesn't support the increased risk of disease flare after COVID-19 vaccination. However, the disease flare of RDs may be triggered by COVID-19 vaccinations, especially for patients with high disease activity. Most of these flares after vaccination are mild and need no treatment escalation. Considering the benefits and risks, RD patients are recommended to receive the COVID-19 vaccination but should be vaccinated when the RDs are in stable states.

Spike Mutation Profiles Associated With SARS-CoV-2 Breakthrough Infections in Delta Emerging and Predominant Time Periods in British Columbia, Canada. BACKGROUND: COVID-19 vaccination is a key public health measure in the pandemic response. The rapid evolution of SARS-CoV-2 variants introduce new groups of spike protein mutations. These new mutations are thought to aid in the evasion of vaccine-induced immunity and render vaccines less effective. However, not all spike mutations contribute equally to vaccine escape. Previous studies associate mutations with vaccine breakthrough infections (BTI), but information at the population level remains scarce. We aimed to identify spike mutations associated with SARS-CoV-2 vaccine BTI in a community setting during the emergence and predominance of the Delta-variant. METHODS: This case-control study used both genomic, and epidemiological data from a provincial COVID-19 surveillance program. Analyses were stratified into two periods approximating the emergence and predominance of the Delta-variant, and restricted to primary SARS-CoV-2 infections from either unvaccinated individuals, or those infected â‰¥14 days after their second vaccination dose in a community setting. Each sample's spike mutations were concatenated into a unique spike mutation profile (SMP). Penalized logistic regression was used to identify spike mutations and SMPs associated with SARS-CoV-2 vaccine BTI in both time periods. RESULTS AND DISCUSSION: This study reports population level relative risk estimates, between 2 and 4-folds, of spike mutation profiles associated with BTI during the emergence and predominance of the Delta-variant, which comprised 19,624 and 17,331 observations, respectively. The identified mutations cover multiple spike domains including the N-terminal domain (NTD), receptor binding domain (RBD), S1/S2 cleavage region, fusion peptide and heptad regions. Mutations in these different regions imply various mechanisms contribute to vaccine escape. Our profiling method identifies naturally occurring spike mutations associated with BTI, and can be applied to emerging SARS-CoV-2 variants with novel groups of spike mutations.

Return to Flying Duties Following a COVID-19 Booster Dose. INTRODUCTION: Israel began vaccinating with the booster dose of the Pfizer-BioNTech vaccine in July 2021, before the Food and Drug Administration (FDA) authorized the vaccine in September 2021. The first and second vaccines were shown to have several side effects that could possibly affect aircrews' fitness to fly. Thus, the Israel Air Force (IAF) decided on a disqualification period of 24 h following the first vaccine, and 48 h following the second vaccine. The aim of this study was to determine the disqualification period following the booster dose of the vaccine.METHODS: A survey was conducted among IAF aviators in the Aeromedical Center (AMC) in order to characterize the side effects and their duration following a Pfizer-BioNTech COVID-19 vaccine booster dose.RESULTS: The most common local side effect was injection site pain. The most common systemic side effects were general weakness, fatigue, and myalgia. Duration of side effects was up to 48 h from vaccine administration among the majority of aircrew members.CONCLUSION: The IAF AMC policy for the Pfizer-BioNTech COVID-19 vaccine booster dose recipients is to disqualify from flight for 48 h following the vaccination.Ekshtein A, Hay G, Shapira S, Ben-Ari O. Return to flying duties following a COVID-19 booster dose. Aerosp Med Hum Perform. 2022; 93(7):593-596.

Predicting a Positive Antibody Response After 2 SARS-CoV-2 mRNA Vaccines in Transplant Recipients: A Machine Learning Approach With External Validation. BACKGROUND: Solid organ transplant recipients (SOTRs) are less likely to mount an antibody response to SARS-CoV-2 mRNA vaccines. Understanding risk factors for impaired vaccine response can guide strategies for antibody testing and additional vaccine dose recommendations. METHODS: Using a nationwide observational cohort of 1031 SOTRs, we created a machine learning model to explore, identify, rank, and quantify the association of 19 clinical factors with antibody responses to 2 doses of SARS-CoV-2 mRNA vaccines. External validation of the model was performed using a cohort of 512 SOTRs at Houston Methodist Hospital. RESULTS: Mycophenolate mofetil use, a shorter time since transplant, and older age were the strongest predictors of a negative antibody response, collectively contributing to 76% of the model's prediction performance. Other clinical factors, including transplanted organ, vaccine type (mRNA-1273 versus BNT162b2), sex, race, and other immunosuppressants, showed comparatively weaker associations with an antibody response. This model showed moderate prediction performance, with an area under the receiver operating characteristic curve of 0.79 in our cohort and 0.67 in the external validation cohort. An online calculator based on our prediction model is available at http://transplantmodels.com/covidvaccine/ . CONCLUSIONS: Our machine learning model helps understand which transplant patients need closer follow-up and additional doses of vaccine to achieve protective immunity. The online calculator based on this model can be incorporated into transplant providers' practice to facilitate patient-centric, precision risk stratification and inform vaccination strategies among SOTRs.

Persistence of MERS-CoV-spike-specific B cells and antibodies after late third immunization with the MVA-MERS-S vaccine. The Middle East respiratory syndrome (MERS) is a respiratory disease caused by MERS coronavirus (MERS-CoV). In follow up to a phase 1 trial, we perform a longitudinal analysis of immune responses following immunization with the modified vaccinia virus Ankara (MVA)-based vaccine MVA-MERS-S encoding the MERS-CoV-spike protein. Three homologous immunizations were administered on days 0 and 28 with a late booster vaccination at 12 Â± 4Â months. Antibody isotypes, subclasses, and neutralization capacity as well as T and B cell responses were monitored over a period of 3 years using standard and bead-based enzyme-linked immunosorbent assay (ELISA), 50% plaque-reduction neutralization test (PRNT50), enzyme-linked immunospot (ELISpot), and flow cytometry. The late booster immunization significantly increases the frequency and persistence of spike-specific B cells, binding immunoglobulin G1 (IgG1) and neutralizing antibodies but not TÂ cell responses. Our data highlight the potential of a late boost to enhance long-term antibody and B cell

immunity against MERS-CoV. Our findings on the MVA-MERS-S vaccine may be of relevance for coronavirus 2019 (COVID-19) vaccination strategies.

Clinical characteristics, radiological features and prognostic factors of transverse myelitis following COVID-19 vaccination: A systematic review. BACKGROUND: Since introducing COVID-19 vaccines, many neurological complications such as acute transverse myelitis have been reported in the literature. This study aims to identify the clinical characteristics, radiological findings, and prognostic factors in patients with COVID-19 vaccine-associated transverse myelitis (TM). METHODS: We systematically reviewed Scopus, Pubmed, Cochrane library, Google Scholar, and preprint databases using appropriate keywords from inception till 8th April 2022. Besides, we manually searched the reference lists of the included studies and relevant previous reviews. RESULTS: We included 28 studies identifying 31 post-COVID-19 vaccination myelitis patients (17 female and 14 male). The mean age of the included patients was 52Â±19 years. ChAdOx1 nCoV-19 vaccine (Oxford-AstraZeneca) was the most common type of vaccine in association with myelitis (12 out of 31), followed by Pfizer (8 out of 31), Moderna (7 out of 31), Sinopharm (3 out of 31), and Janssen vaccine (1 out of 31). The myelitis occurred in 24 and 7 patients after administering the first and second dose of the vaccine, respectively. 21 and 10 patients had good recovery (Modified Rankin Score (MRS) <3 at the follow-up) and poor recovery (MRSâ‰¥3 at the follow-up) from myelitis, respectively. Age (OR 1.09, 95%CI 1.01-1.18, p(value) 0.02), and MRS at admission (OR 17.67, 95%CI 1.46-213.76, p(value) 0.024) were two independent risk factors for poor recovery from myelitis. CONCLUSION: The patients with higher age and MRS at admission had a worse prognosis and needed timely and more aggressive therapeutic strategies.

Fulminant neuromyelitis optica spectrum disorder (NMOSD) following COVID-19 vaccination: A need for reconsideration? During the coronavirus disease 2019 (COVID-19) pandemic, mass vaccination was a beneficial strategy in many countries. Nevertheless, reports of serious complications such as postvaccination neuromyelitis optica spectrum disorder (NMOSD) raised concerns about the safety of vaccines. Anamnart and colleagues explained postvaccination NMOSD following different vaccines, including COVID-19. To emphasize the message of this article, in this letter, we present a unique case of postvaccination NMOSD with a fulminant and fatal course, which may show a plausible relationship between COVID-19 vaccination and triggering anti-aquaporin-4 antibody (AQP4-Ab).

The durability of natural infection and vaccine-induced immunity against future infection by SARS-CoV-2. The durability of vaccine-mediated immunity to SARS-CoV-2, the durations to breakthrough infection, and the optimal timings of booster vaccination are crucial knowledge for pandemic response. Here, we applied comparative evolutionary analyses to estimate the durability of immunity and the likelihood of breakthrough infections over time following vaccination by BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), ChAdOx1 (Oxford-AstraZeneca), and Ad26.COV2.S (Johnson & Johnson/Janssen). We evaluated anti-Spike (S) immunoglobulin G (IgG) antibody levels elicited by each vaccine relative to natural infection. We estimated typical trajectories of waning and corresponding infection probabilities, providing the distribution of times to breakthrough infection for each vaccine under endemic conditions. Peak antibody levels elicited by messenger RNA (mRNA) vaccines mRNA-1273 and BNT1262b2 exceeded that of natural infection and are expected to typically yield more durable protection against breakthrough infections (median 29.6 mo; 5 to 95% quantiles 10.9 mo to 7.9 y) than natural infection (median 21.5 mo; 5 to 95% quantiles 3.5 mo to 7.1 y). Relative to mRNA-1273 and BNT1262b2, viral vector vaccines ChAdOx1 and Ad26.COV2.S exhibit similar peak anti-S IgG antibody responses to that from natural infection and are projected to yield lower, shorter-term protection against breakthrough infection (median 22.4 mo and 5 to 95% quantiles 4.3 mo to 7.2 y; and median 20.5 mo and 5 to 95% quantiles 2.6 mo to 7.0 y; respectively).

These results leverage the tools from evolutionary biology to provide a quantitative basis for otherwise unknown parameters that are fundamental to public health policy decision-making.

Technical performance of a lateral flow immunoassay for detection of anti-SARS-CoV-2 IgG in the outpatient follow-up of non-severe cases and at different times after vaccination: comparison with enzyme and chemiluminescent immunoassays. This study assessed the technical performance of a rapid lateral flow immunochromatographic assay (LFIA) for the detection of anti-SARS-CoV-2 IgG and compared LFIA results with chemiluminescent immunoassay (CLIA) results and an in-house enzyme immunoassay (EIA). To this end, a total of 216 whole blood or serum samples from three groups were analyzed: the first group was composed of 68 true negative cases corresponding to blood bank donors, healthy young volunteers, and eight pediatric patients diagnosed with other coronavirus infections. The serum samples from these participants were obtained and stored in a pre-COVID-19 period, thus they were not expected to have COVID-19. In the second group of true positive cases, we chose to replace natural cases of COVID-19 by 96 participants who were expected to have produced anti-SARS-CoV-2 IgG antibodies 30-60 days after the vaccine booster dose. The serum samples were collected on the same day that LFIA were tested either by EIA or CLIA. The third study group was composed of 52 participants (12 adults and 40 children) who did or did not have anti-SARS-CoV-2 IgG antibodies due to specific clinical scenarios. The 12 adults had been vaccinated more than seven months before LFIA testing, and the 40 children had non-severe COVID-19 diagnosed using RT-PCR during the acute phase of infection. They were referred for outpatient follow-up and during this period the serum samples were collected and tested by CLIA and LFIA. All tests were performed by the same healthcare operator and there was no variation of LFIA results when tests were performed on finger prick whole blood or serum samples, so that results were grouped for analysis. LFIA's sensitivity in detecting anti-SARS-CoV-2 IgG antibodies was 90%, specificity 97.6%, efficiency 93%, PPV 98.3%, NPV 86.6%, and likelihood ratio for a positive or a negative result were 37.5 and 0.01 respectively. There was a good agreement (Kappa index of 0.677) between LFIA results and serological (EIA or CLIA) results. In conclusion, LFIA analyzed in this study showed a good technical performance and agreement with reference serological assays (EIA or CLIA), therefore it can be recommended for use in the outpatient follow-up of non-severe cases of COVID-19 and to assess anti-SARS-CoV-2 IgG antibody production induced by vaccination and the antibodies decrease over time. However, LFIAs should be confirmed by using reference serological assays whenever possible.

Respiratory mucosal immunity against SARS-CoV-2 after mRNA vaccination. SARS-CoV-2 mRNA vaccination induces robust humoral and cellular immunity in the circulation; however, it is currently unknown whether it elicits effective immune responses in the respiratory tract, particularly against variants of concern (VOCs), including Omicron. We compared the SARS-CoV-2 S-specific total and neutralizing antibody responses, and B and T cell immunity, in the bronchoalveolar lavage fluid (BAL) and blood of COVID-19-vaccinated individuals and hospitalized patients. Vaccinated individuals had significantly lower levels of neutralizing antibody against D614G, Delta (B.1.617.2), and Omicron BA.1.1 in the BAL compared with COVID-19 convalescents despite robust S-specific antibody responses in the blood. Furthermore, mRNA vaccination induced circulating S-specific B and T cell immunity, but in contrast to COVID-19 convalescents, these responses were absent in the BAL of vaccinated individuals. Using a mouse immunization model, we demonstrated that systemic mRNA vaccination alone induced weak respiratory mucosal neutralizing antibody responses, especially against SARS-CoV-2 Omicron BA.1.1 in mice; however, a combination of systemic mRNA vaccination plus mucosal adenovirus-S immunization induced strong neutralizing antibody responses not only against the ancestral virus but also the Omicron BA.1.1 variant. Together, our study supports the contention that the current COVID-19 vaccines are highly effective against severe disease development, likely through recruiting circulating B and T cell responses during reinfection, but offer

limited protection against breakthrough infection, especially by the Omicron sublineage. Hence, mucosal booster vaccination is needed to establish robust sterilizing immunity in the respiratory tract against SARS-CoV-2, including infection by the Omicron sublineage and future VOCs.
Investigating trends in those who experience menstrual bleeding changes after SARS-CoV-2 vaccination. Early in 2021, many people began sharing that they experienced unexpected menstrual bleeding after SARS-CoV-2 inoculation. We investigated this emerging phenomenon of changed menstrual bleeding patterns among a convenience sample of currently and formerly menstruating people using a web-based survey. In this sample, 42% of people with regular menstrual cycles bled more heavily than usual, while 44% reported no change after being vaccinated. Among respondents who typically do not menstruate, 71% of people on long-acting reversible contraceptives, 39% of people on gender-affirming hormones, and 66% of postmenopausal people reported breakthrough bleeding. We found that increased/breakthrough bleeding was significantly associated with age, systemic vaccine side effects (fever and/or fatigue), history of pregnancy or birth, and ethnicity. Generally, changes to menstrual bleeding are not uncommon or dangerous, yet attention to these experiences is necessary to build trust in medicine.
Cutaneous T-Cell-Rich Lymphoid Infiltrates After SARS-CoV-2 Vaccination. This case series study describes cutaneous T-cellâ€“rich lymphoid infiltrates characterized by papulonodules on the trunk and/or extremities in 6 patients after receiving the Pfizer/BioNTech COVID-19 mRNA vaccine.
COVID-19 vaccination effectiveness: a review in early vaccine adopters in Asian Countries. COVID-19 vaccines were designed to stimulate an immunological response, producing neutralizing antibodies against the SARS-CoV-2 spike protein. Vaccine variants such as mRNA, viral vector, whole-cell inactivated virus, and protein subunit vaccines, have been reported to be efficacious in phase III trials and have gained emergency use approval in many countries. However, several adverse effects are reported in certain types of vaccines. All vaccines are being expedited by some Asian countries as part of their national immunization programs. This review primarily discussed the selected manufacturers of the COVID-19 vaccines used and their effectiveness in early-adopting Asian countries. The effectiveness in reducing the infection rate and safety of COVID-19 vaccines in Japan, Thailand, Singapore and Malaysia was also analyzed based on the available data. Strategies that can be used to speed up the vaccination rate in reducing the number of COVID-19 cases were also evaluated.
Recombinant protein subunit COVID-19 vaccine-induced Guillain-BarrÃ© Syndrome in an adolescent: A case report. Guillain-BarrÃ© Syndrome (GBS), an autoimmune neurological disease of peripheral nerves, has been causally associated with COVID-19 vaccination in adults. However, no such report has been published so far in children. We describe a 13-year-old female child who presented to the emergency department with complaints of bilateral upper limb, lower limb and truncal weakness over 3â€‰days following first dose of recombinant protein subunit COVID-19 vaccine (Corbevax). Clinical examination and nerve conduction studies showed pure motor axonal polyneuropathy with absent compound muscle action potential (CMAP) in all sampled nerves of upper and lower limbs which was consistent with the diagnosis of GBS after ruling out possible alternative aetiologies. A temporal association between first dose of protein subunit COVID-19 vaccine administered a day prior and symptom onset was noted. The causality assessment using the World Health Organization (WHO) tool for adverse event following immunization (AEFI) assessment indicated vaccine product-related reaction categorized as A1. The patient's clinical condition improved after seven sessions of plasmapheresis. The purpose of this report is to create awareness among health care professionals about COVID-19 vaccine-induced GBS in children as early diagnosis and management can be critical in avoiding complications and improving patient outcomes.

The effect of BNT162b2 SARS-CoV-2 mRNA vaccine on menstrual cycle symptoms in healthy women. OBJECTIVE: To investigate the impact of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA BNT162b2 vaccine on women's menstrual cycle. METHODS: In this questionnaire-based cross-sectional study, we assessed menstrual pattern and changes in women who completed the SARS-CoV-2 mRNA BNT162b2 vaccine 3Â months before and after receiving the vaccine. Included were women aged 18-50â€‰years without known gynecologic comorbidities who regularly monitor their menstruation through electronic calendars. All participants competed a detailed questionnaire on their menstrual symptoms including information on any irregular bleeding. To minimize bias, each woman served as a self-control before and after vaccination. Primary outcome was rate of irregular bleeding following vaccination and secondary outcome was presence of any menstrual change, including irregular bleeding, mood changes, or dysmenorrhea following the vaccine. RESULTS: A total of 219 women met the inclusion critieria. Of them, 51 (23.3%) experienced irregular bleeding following the vaccine. Almost 40% (nÂ =â€‰83) of study participants reported any menstrual change following vaccination. Parity was positively asssociated with irregular bleeding with 26 (50%) of those suffering from irregular bleeding being multiparous compared with only 53 (31.5%) of women with no irregular bleeding (nulliparous 46% vs 60%, multiparous 50% vs 31%, rest 4% vs 8%, PÂ =â€‰0.049). The presence of medical comorbidities was also significantly higher among patients who experienced irregular bleeding (20.0% vs 6.0%, PÂ =â€‰0.003). CONCLUSION: Our study shows relatively high rates of irregular bleeding and menstrual changes after receiving the SARS-CoV-2 mRNA BNT162b2 vaccine. Further research is needed to confirm our findings and to better characterize the magnitude of change and any possible long-term implications.

Breakthrough SARS-CoV-2 infections, morbidity, and seroreactivity following initial COVID-19 vaccination series and additional dose in patients with SLE in New York City.

Guillain-BarrÃ© syndrome following SARS-CoV-2 vaccination in the UK: a prospective surveillance study. OBJECTIVE: To investigate features of Guillain-BarrÃ© syndrome (GBS) following SARS-CoV-2 vaccines and evaluate for a causal link between the two. METHODS: We captured cases of GBS after SARS-CoV-2 vaccination through a national, open-access, online surveillance system. For each case, the certainty of GBS was graded using the Brighton criteria, and the relationship to the vaccine was examined using modified WHO Causality Assessment criteria. We compared age distribution of cases with that of prepandemic GBS cases and clinical features with the International GBS Outcome Study (IGOS). RESULTS: Between 1 January and 30 June 2021, we received 67 reports of GBS following the ChAdOx1 vaccine (65 first doses) and three reports following the BNT162b2 vaccine (all first doses). The causal association with the vaccine was classified as probable for 56 (80%, all ChAdOx1), possible for 12 (17%, 10 ChAdOx1) and unlikely for two (3%, 1 ChAdOx1). A greater proportion of cases occurred in the 50-59 age group in comparison with prepandemic GBS. Most common clinical variants were sensorimotor GBS (n=55; 79%) and facial diplegia with paraesthesias (n=10; 14%). 10% (n=7/69) of patients reported an antecedent infection, compared with 77% (n=502/652) of the IGOS cohort (p<0.00001). Facial weakness (63% (n=44/70) vs 36% (n=220/620); p<0.00001) and sensory dysfunction (93% (n=63/68) vs 69% (n=408/588); p=0.00005) were more common but disease severity and outcomes were similar to the IGOS study. INTERPRETATION: Most reports of GBS followed the first dose of ChAdOx1 vaccine. While our study cannot confirm or refute causation, this observation, together with the absence of alternative aetiologies, different than expected age distribution and the presence of unusual clinical features support a causal link. Clinicians and surveillance bodies should remain vigilant to the possibility of this very rare adverse event and its atypical variants.

Zoster sine herpete following BNT162b2 mRNA COVID-19 vaccination in an immunocompetent patient. As a result of the COVID-19 pandemic, mRNA vaccination has become widespread.

Recently, it has been suggested that instances of herpes zoster increase following mRNA COVID-19 vaccination. Herein, we describe the first case of zoster sine herpete (ZSH) after mRNA vaccination for COVID-19. A 60-year-old Japanese immunocompetent man presented with fever, fatigue, headache, cervical pain, and lumbar pain, which developed after receiving a second dose of BNT162b2 mRNA COVID-19 vaccination. Whereas most symptoms improved with symptomatic treatment, headache and numbness of the right forehead persisted in areas innervated by the trigeminal and second and third cervical nerves. Based on positive results of an enzyme-linked immunosorbent assay examination for anti-VZV IgM, ZSH was diagnosed, and amitriptyline improved the patient's symptoms. Diagnosis of ZSH is challenging due to the lack of a characteristic herpes zoster rash. Physicians should be aware that ZSH can develop after mRNA vaccination.
Lethal Toxic Epidermal Necrolysis probably induced by Sinopharm COVID-19 vaccine.
Potential Association Between COVID-19 Vaccination and Facial Palsy: Three Cases With Neuroimaging Findings. Acute onset Facial palsy was reported in four vaccinated participants in the BNT162b2 (Pfizer-BioNTech) vaccine clinical trials published on December 10, 2020. So far, few cases of Facial palsy among the mRNA vaccine groups have been previously documented in the literature. Facial palsy is cited as medically attended adverse event following immunization on April 12, 2021, after the first dose of the approved Pfizer-BioNTech COVID-19 vaccines for preventive immunization for SARS-CoV-2 is administrated to the population in Turkey. This study is aimed to describe clinical and magnetic resonance imaging features of three patients, who developed acute onset peripheral facial paralysis after administration of the BNT162b2 vaccine, without any previous medical condition. The first patient presented with right sided facial palsy within the same day following the vaccine was administrated, while the second patient presented with left sided facial palsy 2 months after vaccination. The third patient, on the other hand, presented with right sided facial palsy and abducens nerve (CN VI) paralysis two days after vaccine was administrated.
Eruptive halo nevi: A new COVID-19 vaccine-related cutaneous adverse event or a paraneoplastic phenomenon?
Acute coronary syndromes following COVID-19 vaccine application: Kounis syndrome or chance?
Chest Pain in a 15-Year-Old Boy Following Administration of Second COVID-19 Vaccine Dose.
Isolated ACTH deficiency following immunization with the BNT162b2 SARS-CoV-2 vaccine: a case report. BACKGROUND: The global COVID-19 pandemic requires urgent development of new vaccines. Endocrinological adverse effects following the new mRNA vaccine against COVID-19 have been reported in several cases. Specific to the involvement of pituitary function; however, only a single case with hypophysis has been reported. This is the first case of isolated adrenocorticotropic hormone (ACTH) deficiency (IAD) following mRNA vaccination against COVID-19. CASE PRESENTATION: A healthy 31-year-old man received the BNT162b2 SARS-CoV-2 mRNA vaccine. The first injection was uneventful. One day after the second injection, he noticed general fatigue and fever. In the following several days, he additionally developed headaches, nausea, and diarrhea. Four days after the vaccine injection, he visited a hospital with worsening of these symptoms. Physical examination revealed slight disorientation but no other deficits. Laboratory tests revealed hyponatremia, hypoglycemia, and extremely low plasma ACTH and serum cortisol levels (ACTHâ€‰<â€‰1.5Â pg/ml, cortisol 1.6Â Î¼g/dl). He was diagnosed with adrenal crisis and was emergently treated with hydrocortisone. The symptoms responded well and he recovered within a few days. Magnetic resonance images after the replacement with hydrocortisone revealed an atrophic pituitary gland. The patient was referred to our tertiary hospital for further endocrinological examination. Pituitary endocrine load tests revealed isolated adrenocortical response deficiency. After other clinical assessments, he was diagnosed as having isolated ACTH deficiency. After initiation of hydrocortisone replacement, there has been no recurrence of symptoms related to adrenocortical

insufficiency nor involvement of other pituitary functions. CONCLUSION: This is the first reported case of IAD potentially associated with COVID-19 immunization. Recent reports have emphasized the importance of adjuvants in the mRNA vaccine that induce the endocrinological adverse effects through disturbance of the autoimmune system, but details are still unclear. Given the broad and rapid spread of vaccinations against COVID-19, it is clinically important to consider that there could be cases with a rare but emergent adrenal crisis even among those who present common symptoms of adverse effects following inactive SARS-CoV-2 mRNA vaccination.

A child with crescentic glomerulonephritis following SARS-CoV-2 mRNA (Pfizer-BioNTech) vaccination. BACKGROUND: There are few reports on kidney complications after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) messenger RNA (mRNA) vaccination, especially in the pediatric population. We report a pediatric case diagnosed with crescentic glomerulonephritis (CrGN) after the second dose of the SARS-CoV-2 mRNA vaccine. CASE-DIAGNOSIS/TREATMENT: A 16-year-old girl was admitted due to dyspnea and headache approximately 6Â weeks after receiving the second SARS-CoV-2 mRNA vaccine (Pfizer-BioNTech). She had previously experienced fever, nausea, vomiting, and dyspnea after the first vaccination, which persisted for a week. On admission, her blood pressure was 155/89Â mmHg with a 7Â kg weight gain in a month. She had microhematuria and proteinuria. Laboratory findings were as follows: blood urea nitrogen/creatinine, 66/9.57Â mg/dL; and brain natriuretic peptide, 1,167Â pg/mL. Anti-neutrophil cytoplasmic antibody (ANCA), anti-glomerular basement membrane (GBM) antibody, and antinuclear antibody findings were negative. Kidney doppler sonography revealed swelling and increased echogenicity of both kidneys with increased resistive index. Cardiac magnetic resonance imaging results showed early minimal fibrosis of myocarditis. We then started hemodialysis. Kidney biopsy showed diffuse extra capillary proliferative glomerulonephritis with diffuse crescent formation. We treated the patient with methylprednisolone pulse therapy with subsequent oral steroids and mycophenolate mofetil. Although dialysis was terminated, the patient remained in the chronic kidney disease stage. CONCLUSIONS: This is the first case of ANCA-negative CrGN after SARS-CoV-2 mRNA vaccination in the pediatric population. As children are increasingly vaccinated with SARS-CoV-2 mRNA vaccines, monitoring for kidney complications is warranted.

Clinical profile of COVID-19 infection in postvaccination individuals. OBJECTIVES: Covishield and Covaxin vaccines have been introduced after rapid approval in India, the nation that has the second most COVID-19 cases globally. These vaccines have been administered in a 2-dose schedule since January 16, 2021. This study deals with the clinical profile of individuals who developed COVID-19 infection post COVID-19 vaccination. This is the first study of its kind in India. STUDY DESIGN: Descriptive cross-sectional study. METHODS: The study population was composed of individuals who were COVID-19 positive more than 4 weeks post vaccination and were compared with individuals who were COVID-19 positive within the first 4 weeks of vaccination. Data were collected in a digital questionnaire format and analyzed with SPSS version 23 software. Clinical features were profiled in detail. Chi-square analysis was done to find out the association of various demographic features with the severity of the disease. RESULTS: In the study population, fever was the most common symptom (75.1%), followed by anosmia (72.1%) and shortness of breath (16.3%). There was a lower incidence of fever, cough, dyspnea, and requirement of hospitalization in the study population compared with the control group and previous epidemiological data. The time required for complete recovery and disease severity was favorable in our study population. There was a significant correlation in the rate of hospitalization among the study group and the comparative group (Pâ€‰=â€‰.0001) and between the number of doses of COVID-19 vaccine and the lowest oxygen saturation recorded (Pâ€‰=â€‰.001). CONCLUSIONS: The findings of this study should boost the ongoing initiative of

maximizing the vaccinated population countrywide and emphasize the need for 2 doses of vaccination.

In response to comment on "Autoimmune postâ€‘COVID vaccine syndromes: does the spectrum of autoimmune/inflammatory syndrome expand?" by Jara LJ et al.

Decline of humoral immune responses after natural SARS-CoV-2 infection can be efficiently reversed by vaccination. Our aim was to analyze severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-specific antibody level kinetics after coronavirus disease 2019 (COVID-19) infection and determine the efficiency of vaccination on SARS-CoV-2-specific antibody levels. The study included 50 SARS-CoV-2 infected and 70 uninfected cases. Levels of SARS-CoV-2-specific IgG nucleocapsid protein (IgG-NP), IgG spike protein (IgG-SP), IgM nucleocapsid protein (IgM-NP), and IgA spike protein (IgA-SP) antibodies were evaluated by an enzyme-linked immunosorbent assay in sera obtained at baseline, 1st, 3rd, and 6th month follow-up visits for infected cases and at postvaccination visits for all cases. In symptomatic cases (n = 50), IgG-SP levels were decreased in 6 months compared with baseline, while IgA-SP levels were significantly increased. IgG-NP levels were significantly decreased in symptomatic cases at the 6-month visit. After vaccination, IgG-SP levels were increased in symptomatic cases compared with prevaccination levels. Among subjects vaccinated with CoronaVac (the Sinovac COVID-19 vaccine), infected cases had approximately double the IgG-SP level of uninfected cases. SARS-CoV-2-specific antibody levels were higher at the baseline in symptomatic cases. Nevertheless, all infected cases showed significantly reduced IgG-SP levels at the 6th month. Vaccination effectively increased IgG-SP levels.

Maternal and Neonatal Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Immunoglobulin G Levels After the Pfizer-BioNTech Booster Dose for Coronavirus Disease 2019 (COVID-19) Vaccination During the Second Trimester of Pregnancy. OBJECTIVE: To evaluate maternal and neonatal severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) immunoglobulin G (IgG) antibody levels at birth after a third (booster) dose of the Pfizer-BioNTech messenger RNA (Pfizer) coronavirus disease 2019 (COVID-19) vaccine during the second trimester of pregnancy, and compare them with those in women who received two vaccine doses during the second trimester. METHODS: We conducted a prospective cohort study of women admitted to the delivery ward at a single center who received the third Pfizer COVID-19 vaccine dose (booster group) at 17-30 weeks of pregnancy and who did not have previous SARS-CoV-2 infection. Maternal and neonatal antibody levels were measured on admission for delivery and in the umbilical cord blood after birth. Antibody levels for the booster group were compared with those in a historical control group of pregnant women who received their second vaccine dose (two-dose group) within the same gestational age window. RESULTS: Between October 2021 and February 2022, antibody levels were measured in 121 women and 109 neonates at a meanÂ±SD of 15.3Â±3.9 weeks after booster vaccination. Neonatal titers measured two times higher than maternal titers, with inverse correlation between maternal and neonatal titers at birth and time interval from third vaccination. The two-dose group included 121 women and 107 neonates, with antibody levels measured at a meanÂ±SD of 14.6Â±2.6 weeks after the second dose. Median [interquartile range] maternal antibody titers were higher in the booster group (4,485 [2,569-9,702] AU/mL) compared with the two-dose group (1,122 [735-1,872] AU/mL) (P<.001). Furthermore, neonatal antibody titers were higher in the booster group (8,773 [5,143-18,830] AU/mL) compared with the two-dose group (3,280 [2,087-5,754] AU/mL) (P<.001). CONCLUSION: Maternal and neonatal SARS-CoV-2 IgG antibody titers after second-trimester maternal Pfizer COVID-19 vaccination were significantly higher after the booster dose compared with the two-dose vaccination series. Although there is uncertainty as to whether antibody levels correlate with protection, these data support the importance of booster vaccination during pregnancy to restore maternal and neonatal protection against COVID-19.

Effects of anti-SARS-CoV-2 vaccination on safety and disease exacerbation in patients with BehÃ§et syndrome in a monocentric cohort. AIM: Vaccination represents a cornerstone in mastering the coronavirus disease 2019 (COVID-19) pandemic. There is a paucity of data regarding the safety of COVID-19 vaccines in patients with rheumatic diseases such as BehÃ§et syndrome (BS). The present study aimed to investigate the side-effects and post-vaccine disease exacerbation rates of COVID-19 vaccines in a BS cohort. METHODS: We retrospectively evaluated 450 BS patients followed in our clinic who met the criteria of the International Study Group. COVID-19 vaccination status, type of vaccine received (Pfizer-BioNTech vs CoronaVac), post-vaccine side-effects and exacerbations were evaluated by interviewing patients over the phone or face to face. BehÃ§et's Disease Current Activity Form (BDCAF) scores were calculated for BS symptoms before and after vaccination. RESULTS: In all, 287 patients received at least one dose of the COVID-19 vaccine. Of the total number of COVID-19 vaccines (nÂ =Â 639), 379 (59%) were Pfizer-BioNTech vaccines and 257 (41%) were CoronaVac vaccines. The number of side-effects after first, second, third and fourth vaccine doses were 151 (52.6%), 135 (49.4%), 29 (42.6%), and 3 (30%), respectively. BS exacerbation after first, second, third, and fourth vaccine doses were 151 (52.6%), 135 (49.4%), 16 (23.5%), and 3 (30%), respectively. Injection site pain/swelling was the most common side-effect at all vaccine doses followed by fatigue and arthralgia. CONCLUSION: COVID-19 vaccines are well tolerated in patients with BS, and more side-effects develop after mRNA vaccines. Regardless of the vaccine type, exacerbations after the COVID-19 vaccine are common, predominantly mucocutaneous and articular involvement, and exacerbations in the form of other organ involvement are rare.

Comments on: Autoimmune post-COVID vaccine syndromes: does the spectrum of autoimmune/inflammatory syndrome expand? By Jara et al.

Vaccine-Induced Myocarditis in Two Intern Doctors in the Same Night Shift. The coronavirus disease 2019 (COVID-19) pandemic has affected millions of people around the globe and vaccines against the disease have started to develop. Side effects of the vaccine have been reported in the literature, including myocarditis, which has a very low incidence and with a good prognosis. This case report aims to present two medical students' vaccine-induced myocarditis cases after the first doses of BNT162b2.These patients were young males with no previous medical history and both of them had good recovery after the disease. Both of them had their vaccine very recently before the event. These cases show that myocarditis can be seen after the first dose as well.Global vaccination is the most effective prevention method against COVID-19. Considering the fact that morbidities after the disease occur more than the side effects of the vaccine, they are still the best option against the current pandemic.

T cell responses against SARS-CoV-2 and its Omicron variant in a patient with B cell lymphoma after multiple doses of a COVID-19 mRNA vaccine. Anti-SARS-CoV-2 antibodies are crucial for protection from future COVID-19 infections, limiting disease severity, and control of viral transmission. While patients with the most common type of hematologic malignancy, B cell lymphoma, often develop insufficient antibody responses to messenger RNA (mRNA) vaccines, vaccine-induced T cells would have the potential to 'rescue' protective immunity in patients with B cell lymphoma. Here we report the case of a patient with B cell lymphoma with profound B cell depletion after initial chemoimmunotherapy who received a total of six doses of a COVID-19 mRNA vaccine. The patient developed vaccine-induced anti-SARS-CoV-2 antibodies only after the fifth and sixth doses of the vaccine once his B cells had started to recover. Remarkably, even in the context of severe treatment-induced suppression of the humoral immune system, the patient was able to mount virus-specific CD4(+) and CD8(+) responses that were much stronger than what would be expected in healthy subjects after two to three doses of a COVID-19 mRNA vaccine and which were even able to target the Omicron 'immune escape' variant of the SARS-CoV-2 virus. These findings not

only have important implications for anti-COVID-19 vaccination strategies but also for future antitumor vaccines in patients with cancer with profound treatment-induced immunosuppression.

Oral lichen planus arising after BNT162b2 mRNA COVID-19 vaccine: report of 2 cases. The ongoing COVID-19 pandemic required a firm and prompt effort in the development of an effective vaccine. Reports of adverse reactions are increasing. Lichen planus, as well as its oral variant, is a condition that has previously been reported to be associated with vaccines. This is one of the first reports of oral lichen planus (OLP) arising after any COVID-19 vaccine. Here the authors present 2 cases of OLP that occurred after BNT162b2 mRNA COVID-19 vaccination (Comirnaty, Pfizer, New York, NY, USA; BioNTech, Mainz, Germany).

Transient cryoglobulinaemic vasculitis following ChAdOx1 nCoV-19 vaccine. Cryoglobulinaemic vasculitis is an immune-complex-mediated, systemic inflammatory syndrome usually involving small-to-medium vessels due to precipitation of cryoglobulins at <37Â°C. It can involve any organ but most commonly affects the skin. Associated conditions include infections (hepatitis C and HIV), haematological disorders (chronic lymphocytic lymphoma, monoclonal gammopathy of uncertain significance and multiple myeloma), autoimmune conditions (systemic lupus erythematosus and Sjogren syndrome) or as a complication following vaccination (influenza, pneumococcal and hepatitis B vaccines). Biochemical hallmarks include detection of serum cryoglobulin with low C4 levels. We describe a case of previous healthy patient with transient cryoglobulinaemic vasculitis after first dose of ChAdOx1 nCoV-19 vaccine (AstraZeneca/Oxford).

SARS-CoV-2 Vaccination-Induced Thrombotic Thrombocytopenia: A Rare but Serious Immunologic Complication. Billions of individuals worldwide have benefited from the unprecedented large-scale rollout of COVID-19 vaccines. Given the sheer number of people that have received these vaccines, it is not surprising that rare side effects are reported that were not previously detected in the phase III vaccine trials. This review addresses one rare complication called SARS-CoV-2 vaccination-induced thrombotic thrombocytopenia (VITT). It occurs in approximately 1/50,000 to 1/100,000 recipients of the adenovirus vector-based COVID-19 vaccines made by AstraZeneca-Oxford or Johnson & Johnson. Information on VITT syndrome was disseminated quickly via social media and publications after it was first discovered. Initial observations associating VITT with specific patient populations, thrombus locations, and outcomes associated with heparin therapy have since been refined with additional clinical experience. In this review, we discuss what is currently known about the incidence, pathophysiology, diagnosis, and treatment of VITT.

Humoral and Cellular Immune Response After Third and Fourth SARS-CoV-2 mRNA Vaccination in Liver Transplant Recipients. BACKGROUND & AIMS: Liver transplant recipients (LTRs) show a decreased immune response after 2 severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) vaccinations compared with healthy controls (HCs). Here, we investigated the immunogenicity of additional vaccinations. METHODS: In this prospective study, humoral (anti-SARS-CoV-2 receptor-binding domain [anti-S RBD]) and cellular (interferon-gamma release assay) immune responses were determined after mRNA-based SARS-CoV-2 vaccination in 106 LTRs after a third vaccination and in 36 LTRs after a fourth vaccination. Patients with anti-S RBD antibody levels >0.8 arbitrary unit (AU)/mL after vaccination were defined as responders. RESULTS: After 3 vaccinations, 92% (97/106) of LTRs compared with 100% (28/28) of HCs were responders. However, the antibody titer of LTRs was lower compared with HCs (1891.0 vs 21,857.0 AU/mL; P < .001). Between a second and third vaccination (nÂ = 75), the median antibody level increased 67-fold in LTRs. In patients seronegative after 2 vaccinations, a third dose induced seroconversion in 76% (19/25), whereas all HCs were already seropositive after 2 vaccinations. A spike-specific T-cell response was detected in 72% (28/39) after a third vaccination compared with 32% (11/34) after a second vaccination. Independent risk factors for a low antibody response (anti-S RBD <100 AU/mL) were first vaccination within the first

year after liver transplant (odds ratio [OR], 8.00; PÂ = .023), estimated glomular filtration rate <45 mL/min (OR, 4.72; PÂ = .006), and low lymphocyte counts (OR, 5.02; PÂ = .008). A fourth vaccination induced a 9-fold increase in the median antibody level and seroconversion in 60% (3/5) of previous non-responders. CONCLUSIONS: A third and fourth SARS-CoV-2 vaccination effectively increases the humoral and cellular immune response of LTRs, but to a lesser extent than in HCs. A fourth vaccination should be generally considered in LTRs.

ANCA-Associated Vasculitis following the First Dose of Pfizer-BioNTech COVID-19 Vaccine. Coronavirus disease (COVID-19) vaccine can alter the body's immunological balance leading to autoimmune disease in rare cases. Anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis is one of the autoimmune diseases which have been rarely reported to appear post-COVID-19 vaccine. Herein, we report the case of a 47-year-old woman who developed acute renal failure few days after receiving the first dose of the Pfizer-BioNTech COVID-19 vaccine. Corticosteroids along with azathioprine were used for the management.

COVID-19 infection and vaccination against COVID-19: Impact on managing demyelinating CNS disorders in Southern India- experience from a demyelinating disease registry. BACKGROUND AND OBJECTIVE: The impact of COVID-19 infection and the effect of COVID-19 vaccinations on patients with demyelinating central nervous system disease in low middle income countries (LMIC's) have not been reported in detail earlier. We sought to identify risk factors associated with COVID-19 infection and the role of vaccination in order to develop management guidelines relevant to our patients. METHODS: A total of 621 patients from our registry that included 297 MS and 324 non MS disorders (Aquaporin- 4 antibody positive [50], Myelin oligodendrocyte glycoprotein antibody positive [81], seronegative [162] and clinically isolated syndrome [31]) were contacted. COVID-19 infection and vaccination status were queried. Patients who self reported COVID-19 infection based on a positive RT PCR report were compared with non infected patients to identify factors associated with susceptibility for COVID-19 infection. Univariate and multivariate analysis of potential risk factors included demographic and clinical features, body mass index (BMI), presence of comorbidities, absolute lymphocyte count, treatment types and vaccination status. RESULTS: Sixty seven patients with MS and 27 with non MS disorders developed COVID-19 infection. Among them 81 patients had mild infection and remained quarantined at home. All 13 patients who needed hospitalization recovered. Vaccination status was known in 582 patients among whom 69.8% had completed or taken one dose of vaccine at the time of inquiry. Majority of treated patients (61.3%) were on nonspecific immunosuppressants. In univariate analysis, presence of â‰¥1 comorbidity was significantly associated with COVID-19 infection in both MS (p value 0.01, OR-2.28, 95%CI- 1.18-4.4) and non MS patients (p- 0.001, OR-4.4, 95% CI-1.88-10.24). In the latter, BMI â‰¥Â 30 (p-0.04, OR-3.27, 95% CI- 0.98-10.87) and EDSS score â‰¥Â 3 (p-0.02, OR- 2.59,95% CI- 1.08-6.23) were other significant associations. History of prior COVID-19 vaccination was associated with reduced frequency of COVID-19 infection among MS (p- 0.001,OR- 0.24,95% CI- 0.13-0.43) and non MS patients (p-0.0001,OR-0.14, 95% CI- 0.058-0.35). In multivariate analysis presence of comorbidities significantly increased and prior vaccination significantly reduced frequency of COVID-19 infection for both MS and related disorders. Concurrent disease modifying treatments showed a trend for association with infection. In the unvaccinated group, patients on disease modifying treatment were significantly at risk of infection, 81.5% unvaccinated and treated versus 18.5% who were unvaccinated and untreated (p- 0.0001, OR-10.1, 95% CI-0.56-2.11). CONCLUSION: Frequency and severity of COVID-19 infection was low among our patient cohort. Higher rate of infection in the treated group was significantly seen among unvaccinated patients. Our preliminary results suggests that in LMIC's, where "off label therapies" with inexpensive immunosuppressives are the main disease modifying drugs, mRNA vaccinations appear safe and effective against severe COVID-19 infection.

Optic Neuritis Following the BNT162b2 mRNA COVID-19 Vaccine in a Patient with Systemic Lupus Erythematosus Uncovering the Diagnosis of Neuromyelitis Optica Spectrum Disorders. COVID-19 vaccinations have been given worldwide to save the lives of millions. However, several complications following different types of COVID-19 vaccinations were reported previously in the literature. Previous articles have reported multiple ocular complications following different types of COVID-19 vaccinations. In this article, we report a unique case in which the diagnosis of neuromyelitis optica spectrum disorders (NMOSD) was unveiled following vaccination with BNT162b2 mRNA COVID-19 vaccine and manifesting as acute optic neuritis in a patient with systemic lupus erythematosus (SLE). The temporal association of acute optic neuritis after receiving the BNT162b2 mRNA COVID-19 vaccine along with the serological evidence of NMOSD support this theory. The risk of triggering an occult autoimmune disorder in patients with an overactive immune system such as this patient should be studied to calibrate the benefits and risks of vaccination against COVID-19. Screening for aquaporin-4 antibodies in patients with SLE prior to vaccination against COVID-19 may be considered to prevent potentially devastating neurological disability in patients with premorbid occult NMOSD.

Breakthrough haemolysis in paroxysmal nocturnal haemoglobinuria after COVID-19 infection and COVID vaccination: what is worse?

COVID vaccination can be performed in patients with a history of allergic reactions to the vaccines or their components: experience from a specialist clinic in South Australia. BACKGROUND: The development of vaccines against SARS-CoV2 has been a key public health response to the COVID-19 pandemic. However, since their introduction, there have been reports of anaphylactic reactions to vaccines in individuals with history of allergic reactions to other vaccines, excipients or to COVID vaccines. AIM: A dedicated adult COVID vaccine allergy clinic with a standardised allergy testing protocol was set up to investigate safety and suitability of available COVID vaccines in Australia. METHODS: Patients referred to a state-wide COVID-19 vaccine allergy clinic between March and August 2021 with a history of allergy underwent skin-prick testing and intradermal testing to both available vaccine formulations (BNT162b2 and ChAdOx1-S), excipients (polyethylene glycol and polysorbate 80), excipient-containing medications and controls. Basophil activation testing was conducted in few subjects with convincing history of immediate type reactions. RESULTS: Fifty-three patients underwent testing for possible excipient allergy (n = 19), previous non-COVID vaccine reaction (n = 13) or previous reaction to dose 1 of COVID-19 vaccine (n = 21). Patients were predominantly female (n = 43, 81%), aged 18-83 (median 54) years. Forty-four patients tested negative and 42 of these received at least their first dose of a COVID-19 vaccine. Nine patients tested positive to excipients or excipient-containing medication only (n = 3), or vaccines (n = 6). Five patients were positive to just BNT162b2, 3/5 have been vaccinated with ChAdOx1-S. One who was skin test positive to both vaccines, but negative BAT to ChAdOx1-S was successfully vaccinated with ChAdOx1-S. CONCLUSION: Even in a high-risk population, most patients can be vaccinated with available COVID-19 vaccines. This paper reports local experiences using a combined allergy testing protocol with skin testing and BAT during the pandemic.

Long-term observation of antibody titers against SARS-CoV-2 following vaccination. OBJECTIVES: We aimed to understand how SARS-CoV-2 antibody titer decrease following SARS-CoV-2 mRNA vaccination and to estimate the timing of booster vaccination. STUDY DESIGN: Six hundred sixty-two healthcare workers were administered with total of three doses of SARS-CoV-2 mRNA vaccine during the same short period. Of them, three volunteers were enrolled to measure anti-receptor binding domain (RBD) antibody titers (IgG) monthly following the second and the third doses. METHODS: Serum anti-RBD antibody titers were measured monthly and the decay curve of the antibody was analyzed. We estimate the timing of the third and fourth vaccine based on the observed antibody titer decrease and the period of breakthrough infections in the vaccine recipients. RESULTS: Anti-RBD

antibody decreased exponentially following the 2nd dose. Between 108 and 117 days following the second dose, breakthrough infection of SARS-CoV-2 occurred in 11 out of the 662 vaccine recipients. Based on the decrease in anti-RBD antibody and the timing of the breakthrough infections, we estimate that the optimal timing of a third dose would be at earliest 108 days after the second dose, when anti-RBD antibody titers are less than 338 BAU/mL. The anti-RBD antibody titers were sustained relatively higher for 161 days following the third dose (416 days following the second dose). CONCLUSIONS: We estimate that the optimal timing of a third dose would be at earliest 108 days after the second dose, or anti-RBD antibody titers are less than 338 BAU/mL. We suggest that a fourth dose should be administered later than 161 days following the third dose.

Acute Unilateral Peripheral Vestibulopathy After COVID-19 Vaccination: Initial Experience in a Tertiary Neurotology Center. OBJECTIVE: The aim of the present study was to identify patients who developed acute unilateral peripheral vestibulopathy (AUPVP) after COVID-19 vaccination. METHODS: For this single-center, retrospective study, we screened the medical records of our tertiary interdisciplinary neurotology center for patients who had presented with AUPVP within 30 days after COVID-19 vaccination (study period: 1 June-31 December 2021). The initial diagnosis of AUPVP was based on a comprehensive bedside neurotological examination. Laboratory vestibular testing (video head impulse test, cervical and ocular vestibular evoked myogenic potentials, dynamic visual acuity, subjective visual vertical, video-oculography, caloric testing) was performed 1-5 months later. RESULTS: Twenty-six patients were diagnosed with AUPVP within the study period. Of those, n = 8 (31%) had developed acute vestibular symptoms within 30 days after COVID-19 vaccination (mean interval: 11.9 days, SD: 4.8, range: 6-20) and were thus included in the study. The mean age of the patients (two females, six males) was 46 years (SD: 11.7). Seven patients had received the Moderna mRNA vaccine and one the Pfizer/BioNTech mRNA vaccine. All patients displayed a horizontal(-torsional) spontaneous nystagmus toward the unaffected ear and a pathological clinical head impulse test toward the affected ear on initial clinical examination. Receptor-specific laboratory vestibular testing performed 1-5 months later revealed recovery of vestibular function in two patients, and heterogeneous lesion patterns of vestibular endorgans in the remaining six patients. DISCUSSION AND CONCLUSIONS: The present study should raise clinicians' awareness for AUPVP after COVID-19 vaccination. The relatively high fraction of such cases among our AUPVP patients may be due to a certain selection bias at a tertiary neurotology center. Patients presenting with acute vestibular symptoms should be questioned about their vaccination status and the date of the last vaccination dose. Furthermore, cases of AUPVP occurring shortly after a COVID-19 vaccination should be reported to the health authorities to help determining a possible causal relationship.

Deep venous sinus thrombosis with right thalamic infarction in a young patient after COVID-19 vaccination. Cerebral venous thrombosis is a rare illness, it compromises 0.5% of cases of cerebrovascular diseases globally. The condition can be treated if discovered and treated properly and quickly. With many known risk factors and in recent times with invent of the COVID-19 vaccine, there have been reported incidences of vaccination being implicated in cerebral venous sinus thrombosis. We report an unusual case of an adolescent female with imaging findings of deep cerebral venous sinus thrombosis and right thalamic infarction after recent vaccination against COVID-19. Laboratory results revealed microcytic hypochromic anemia. Further imaging was done which included a non-contrast CT head, magnetic resonance imaging, and magnetic resonance venography leading to a diagnosis of thrombosis of deep venous (galenic) system with vasogenic edema in bilateral thalami and left caudate nucleus with areas of infarction in the right thalamus. She was treated with subcutaneous low molecular weight heparin (Enoxaparin) and discharged on the third day under oral dabigatran and oral iron.

New-onset pemphigus vegetans and pemphigus foliaceus after SARS-CoV-2 vaccination: A report of 2 cases.

Physical activity and antibody persistence 6 months after the second dose of CoronaVac in immunocompromised patients. This prospective cohort study within an open-label, single-arm, phase 4 vaccination trial (clinicaltrials.gov #NCT04754698) aimed to investigate the association between physical activity and persistent anti-SARS-CoV-2 antibodies 6Â months after two-dose schedule of CoronaVac in autoimmune rheumatic diseases (ARD) patients (nÂ =Â 748). Persistent immunogenicity 6Â months after the full-course vaccination was assessed using seroconversion rates of total anti-SARS-CoV-2Â S1/S2 IgG, geometric mean titers of anti-S1/S2 IgG (GMT), and frequency of positive neutralizing antibodies (NAb). Physical activity was assessed trough questionnaire. Adjusted point estimates from logistic regression models indicated that physically active patients had greater odds of seroconversion rates (OR: 1.5 [95%CI: 1.1 to 2.1]) and NAb positivity (OR: 1.5 [95%CI: 1.0 to 2.1]), and approximately 43% greater GMT (42.8% [95%CI: 11.9 to 82.2]) than inactive ones. In conclusion, among immunocompromised patients, being physically active was associated with an increment in antibody persistence through 6Â months after a full-course of an inactivated SARS-CoV-2 vaccine.

Subacute thyroiditis after SARS-Cov2 vaccination: A review of the cases being described and personal experience. Objective. The present study evaluates the occurrence of subacute thyroiditis in temporal connection with SARS-Cov2 vaccinations described in the literature last year and confirmed by our clinical routine. Methods. Systematic literature search in Medline for studies reporting diagnosis of subacute thyroiditis in temporal connection with vaccinations against Covid 19. Results. The literature search yielded 24 relevant references out of which 22 were "case reports" and two "Letters to the Editor" and encompassed 37 patient cases, in total. They had received a SARS-Cov2 vaccination shortly before the diagnosis (median interval to vaccination six days). In none of these cases, infection of the upper respiratory tract had previously been identified as a classic trigger of the disease. Newly occurring hyperthyroidism and increased laboratory signs of inflammation were described in 78% and 74% of cases, respectively. Atypical clinical pictures (asymptomatic, euthyroid, no inflammation marks) have been observed in both the literature and our patients suspected of thyroid cancer referred to surgery. Conclusions. In times of pandemics and the resulting vaccination, new rapidly occurring sonographic changes in the thyroid gland should be revaluated after 2-3 weeks, or recommended to undergo a fine-needle biopsy, in order to avoid unnecessary surgical interventions.

Brain dural arteriovenous fistulas in the COVID-19 Era: A warning and rationale for association. OBJECTIVES: Brain dural arteriovenous fistulas(bDAVFs) are anomalous connections between dural arteries and cerebral veins or sinuses. Cerebral venous thrombosis(CVT) often precedes or coincides with bDAVFs and is considered a risk factor for these vascular malformations. Recently, vaccine-induced thrombotic thrombocytopenia causing CVTs has been associated with COVID-19 vaccines. Concurrently with the start of massive vaccination in our region, we have observed a fivefold increase in the average incidence of bDAVFs. Our objective is to raise awareness of the potential involvement of COVID-19 vaccines in the pathogenesis of bDAVF. METHODS: A retrospective review of demographic, clinical, radiological, COVID-19 infection and vaccination data of patients diagnosed with bDAVFs between 2011 and 2021 was conducted. Patients were divided into two cohorts according to their belonging to pre- or post-COVID-19 vaccination times. Cohorts were compared for bDAVFs incidences and demographic and clinical features. RESULTS: Twenty-one bDAVFs were diagnosed between 2011 and 2021, 7 of which in 2021. The mean age was 57.7 years, and 62 % were males. All cases except one were treated; of them, 85 % exclusively managed with surgery. All treated cases were successfully occluded. The incidence in 2021 was significantly higher than that in the

prevaccination period (1.72 vs 0.35/100,000/year;pÂ =Â 0.036; 95 %Confidence Interval=0.09-2.66). Cohorts were not different in age, sex, hemorrhagic presentation, dural sinus thrombosis or presence of prothrombotic or cardiovascular risk factors. CONCLUSION: The significant increase in the incidence of bDAVF following general vaccination policies against COVID-19 observed in our region suggests a potential correlation between these two facts. Our findings need confirmation from larger cohorts and further pathogenic research.

Author's response to the commentary: Neuromyelitis optica complicating COVID vaccinations and additional case reports. Our article Newly diagnosed neuromyelitis optica spectrum disorders following vaccination: Case report and systematic review had instigated a critique that there were more cases of post-COVID-19-vaccination NMOSD. Indeed, after the systematic review was performed in July 2021, many reports have been published, and we have seen two new patients at our center as well. However, Finsterer's question on the subclinical activity of NMOSD prior to vaccination, although an interesting notion, was debatable. NMOSD is a relapsing disease with severe attacks. Investigations in our patients did not reveal robust evidence of prior subclinical attacks so far.

Urticaria and/or angioedema secondary to mRNA COVID-19 vaccines: Updates from a United States case registry.

Antibody response after COVID-19 vaccination in intravenous immunoglobulin-treated immune neuropathies. BACKGROUND AND PURPOSE: This study assessed the prevalence of anti-SARS-CoV-2 antibodies in therapeutic immunoglobulin and their impact on serological response to COVID-19 mRNA vaccine in patients with intravenous immunoglobulin (IVIg)-treated chronic immune neuropathies. METHODS: Forty-six samples of different brands or lots of IVIg or subcutaneous IgG were analyzed for anti-SARS-CoV-2 IgG using enzyme-linked immunosorbent assay and chemiluminescent microparticle immunoassay. Blood sera from 16 patients with immune neuropathies were prospectively analyzed for anti-SARS-CoV-2 IgA, IgG, and IgM before and 1â€‰week after IVIg infusion subsequent to consecutive COVID-19 mRNA vaccine doses and after 12â€‰weeks. These were compared to 42 healthy subjects. RESULTS: Twenty-four (52%) therapeutic immunoglobulin samples contained anti-SARS-CoV-2 IgG. All patients with immune neuropathies (mean ageÂ =Â 65â€‰Â±â€‰16â€‰years, 25% female) were positive for anti-SARS-CoV-2 IgG after COVID-19 vaccination. Anti-SARS-CoV-2 IgA titers significantly decreased 12-14â€‰weeks after vaccination (pÂ =â€‰0.02), whereas IgG titers remained stable (pÂ =â€‰0.2). IVIg did not significantly reduce intraindividual anti-SARS-CoV-2 IgA/IgG serum titers in immune neuropathies (pÂ =â€‰0.69). IVIg-derived anti-SARS-CoV-2 IgG did not alter serum anti-SARS-CoV-2 IgG decrease after IVIg administration (pÂ =â€‰0.67). CONCLUSIONS: Our study indicates that IVIg does not impair the antibody response to COVID-19 mRNA vaccine in a short-term observation, when administered a minimum of 2â€‰weeks after each vaccine dose. The infusion of current IVIg preparations that contain anti-SARS-CoV-2 IgG does not significantly alter serum anti-SARS-CoV-2 IgG titers.

Safety outcomes of SARS-CoV-2 vaccination in pediatric patients with a first dose reaction history or allergy to polyethylene glycol or polysorbate.

Polymyalgia rheumatica and giant cell arteritis with intracranial involvement postvaccination anti-COVID-19.

Central retinal artery occlusion after Moderna mRNA-1273 vaccination.

Is the mRNA COVID-19 Vaccine Safe in Patients With a Prior History of Myocarditis? BACKGROUND: Numerous studies have reported myocarditis resulting from messenger RNA (mRNA) coronavirus disease 2019 (COVID-19) vaccination. However, to date, there have been no reports highlighting the safety of mRNA COVID-19 vaccines in children and adults with a prior history of myocarditis, which was the intent of this study. METHODS AND RESULTS: Children and adults cared for at the Cleveland Clinic were identified through the electronic health records, who had a history of

myocarditis before the COVID-19 pandemic and had subsequently received at least 2 doses of the mRNA COVID-19 vaccines (nâ€¯=â€¯34). Only 1 patient in this series had recurrence of myocarditis confirmed by cardiac magnetic resonance imaging after receiving the second dose. He was a White man who had his first episode of myocarditis at age 20 and was 27 years of age at the time of recurrence. He was hospitalized for 2 days with no need for cardiac support or reported arrhythmias and was stable at outpatient follow-up. CONCLUSIONS: In patients with an old history of non-COVID-19 myocarditis, the risk of recurrent myocarditis after receipt of mRNA COVID-19 vaccination is low, and when it occurs it seems to be self-limiting. Our study will be valuable to clinicians while discussing the risk-benefit ratio of vaccinations in patients with a prior history of myocarditis.

A prospective study of the association between SARS-CoV-2 infection and COVID-19 vaccination with changes in usual menstrual cycle characteristics. BACKGROUND: Despite anecdotal reports, the impacts of SARS-CoV-2 infection or COVID-19 vaccination on menstrual health have not been systemically investigated. OBJECTIVE: This study aimed to examine the associations of SARS-CoV-2 infection and COVID-19 vaccination with menstrual cycle characteristics. STUDY DESIGN: This study prospectively observed 3858 premenopausal women in the Nurses' Health Study 3 living in the United States or Canada who received biannual follow-up questionnaires between January 2011 and December 2021 and completed additional monthly and quarterly surveys related to the COVID-19 pandemic between April 2020 and November 2021. History of positive SARS-CoV-2 test, COVID-19 vaccination status, and vaccine type were self-reported in surveys conducted in 2020 and 2021. Current menstrual cycle length and regularity "before COVID-19" were reported at baseline between 2011 and 2016, and current menstrual cycle length and regularity "after COVID-19" were reported in late 2021. Pre- to post-COVID change in menstrual cycle length and regularity was calculated between reports. Logistic or multinomial logistic regression models were used to assess the associations between SARS-CoV-2 infection and COVID-19 vaccination and change in menstrual cycle characteristics. RESULTS: The median age at baseline and the median age at end of follow-up were 33 years (range, 21-51) and 42 years (range, 27-56), respectively, with a median follow-up time of 9.2 years. This study documented 421 SARS-CoV-2 infections (10.9%) and 3527 vaccinations (91.4%) during follow-up. Vaccinated women had a higher risk of increased cycle length than unvaccinated women (odds ratio, 1.48; 95% confidence interval, 1.00-2.19), after adjusting for sociodemographic and behavioral factors. These associations were similar after in addition accounting for pandemic-related stress. COVID-19 vaccination was only associated with change to longer cycles in the first 6 months after vaccination (0-6 months: odds ratio, 1.67 [95% confidence interval, 1.05-2.64]; 7-9 months: odds ratio, 1.43 [95% confidence interval,Â 0.96-2.14]; >9 months: odds ratio, 1.41 [95% confidence interval, 0.91-2.18]) and among women whose cycles were short, long, or irregular before vaccination (odds ratio, 2.82 [95% confidence interval, 1.51-5.27]; odds ratio, 1.10 [95% confidence interval, 0.68-1.77] for women with normal length, regular cycles before vaccination). Messenger RNA and adenovirus-vectored vaccines were both associated with this change. SARS-CoV-2 infection was not associated with changes in usual menstrual cycle characteristics. CONCLUSION: COVID-19 vaccination may be associated with short-term changes in usual menstrual cycle length, particularly among women whose cycles were short, long, or irregular before vaccination. The results underscored the importance of monitoring menstrual health in vaccine clinical trials. Future work should examine the potential biological mechanisms.

A severe case of papulovesicular exthanthema with rhabdomyolysis after corona virus disease 2019 heterologous booster vaccination.

Pityriasis lichenoides chronica after BNT162b2 Pfizer-BioNTech vaccine: A novel cutaneous reaction after SARS-CoV-2 vaccine.

Incidence of Guillain-BarrÃ© syndrome following SARS-CoV-2 immunization: Analysis of a nationwide registry of recipients of 81 million doses of seven vaccines. BACKGROUND AND PURPOSE: Information on Guillain-BarrÃ© syndrome (GBS) as an adverse event following immunization (AEFI) against SARS-CoV-2 remains scarce. We aimed to report GBS incidence as an AEFI among adult (â‰¥18â€‰years) recipients of 81,842,426 doses of seven anti-SARS-CoV-2 vaccines between December 24, 2020, and October 29, 2021, in Mexico. METHODS: Cases were retrospectively collected through passive epidemiological surveillance. The overall observed incidence was calculated according to the total number of administered doses. Vaccines were analyzed individually and by vector as mRNA-based (mRNA-1273 and BNT162b2), adenovirus-vectored (ChAdOx1 nCov-19, rAd26-rAd5, Ad5-nCoV, and Ad26.COV2-S), and inactivated whole-virion-vectored (CoronaVac) vaccines. RESULTS: We identified 97 patients (52 males [53.6%]; median [interquartile range] age 44 [33-60] years), for an overall observed incidence of 1.19/1,000,000 doses (95% confidence interval [CI] 0.97-1.45), with incidence higher among Ad26.COV2-S (3.86/1,000,000 doses, 95% CI 1.50-9.93) and BNT162b2 recipients (1.92/1,00,000 doses, 95% CI 1.36-2.71). The interval (interquartile range) from vaccination to GBS symptom onset was 10Â (3-17) days. Preceding diarrhea was reported in 21 patients (21.6%) and mild COVID-19 in four more (4.1%). Only 18 patients were tested for Campylobacter jejuni (positive in 16 [88.9%]). Electrophysiological examinations were performed in 76 patients (78.4%; axonal in 46 [60.5%] and demyelinating in 25 [32.8%]); variants were similar across the platforms. On admission, 91.8% had a GBS disability scoreâ€‰â‰¥3. Seventy-five patients (77.3%) received intravenous immunoglobulin, received seven plasma exchange (7.2%), and 15 (15.5%) were treated conservatively. Ten patients (10.3%) died, and 79.1% of survivors were unable to walk independently. CONCLUSIONS: Guillain-BarrÃ© syndrome was an extremely infrequent AEFI against SARS-CoV-2. The protection provided by these vaccines outweighs the risk of developing GBS.

Author Correction: Cytokine release syndrome-like serum responses after COVID-19 vaccination are frequent and clinically inapparent under cancer immunotherapy.

Analysis of the humoral and cellular response after the third COVID-19 vaccination in patients with autoimmune hepatitis. BACKGROUND & AIMS: To explore the humoral and T-cell response to the third COVID-19 vaccination in autoimmune hepatitis (AIH). METHODS: Anti-SARS-CoV-2 antibody titers were prospectively determined in 81 AIH patients and 53 healthy age- and sex-matched controls >7â€‰days (median 35) after the first COVID-19 booster vaccination. The spike-specific T-cell response was assessed using an activation-induced marker assay (AIM) in a subset of patients. RESULTS: Median antibody levels were significantly lower in AIH compared to controls (10Â 908 vs. 25â€‰000Â AU/ml, pÂ <â€‰.001), especially in AIH patients treated with MMF (NÂ =â€‰14, 4542â€‰AU/ml, pÂ =â€‰.004) or steroids (NÂ =â€‰27, 7326â€‰AU/ml, pÂ =â€‰.020). Also, 48% of AIH patients had antibody titers below the 10% percentile of the healthy controls (9194â€‰AU/ml, pÂ <â€‰.001). AIH patients had a high risk of failing to develop a spike-specific T-cell response (15/34 (44%) vs. 2/16 (12%), pÂ =â€‰.05) and showed overall lower frequencies of spike-specific CD4â€‰+â€‰T cells (median: 0.074% vs 0.283; pÂ =â€‰.01) after the booster vaccination compared to healthy individuals. In 34/81 patients, antibody titers before and after booster vaccination were available. In this subgroup, all patients but especially those without detectable/low antibodies titers (<100â€‰AU/ml) after the second vaccination (NÂ =â€‰11/34) showed a strong, 148-fold increase. CONCLUSION: A third COVID-19 vaccination efficiently boosts antibody levels and T-cell responses in AIH patients and even seroconversion in patients with the absent immune response after two vaccinations, but to a lower level compared to controls. Therefore, we suggest routinely assessing antibody levels in AIH patients and offering additional booster vaccinations to those with suboptimal responses.

Authors' Reply to Mungmunpuntipantip et al.'s Comment on "Description of Frequencies of Reported Adverse Events Following Immunization Among Four Different COVID-19 Vaccine Brands".

Comment on "Description of Frequencies of Reported Adverse Events Following Immunization Among Four Different COVID-19 Vaccine Brands".

Reactogenicity and Concomitant Administration of the COVID-19 Booster and Influenza Vaccine.

Reactogenicity of Simultaneous COVID-19 mRNA Booster and Influenza Vaccination in the US. IMPORTANCE: COVID-19 and seasonal influenza vaccines are essential in preventing respiratory infections and their potentially severe complications. Simultaneous administration of vaccines is efficient and may improve coverage with each vaccine. However, the safety of simultaneous administration of COVID-19 and influenza vaccines has not been well described. OBJECTIVE: To evaluate adverse events and health impacts associated with simultaneously administered COVID-19 mRNA booster and seasonal influenza vaccines in the US population. DESIGN, SETTING, AND PARTICIPANTS: In this retrospective cohort study, self-reported vaccine data were collected on days 0 to 7 after vaccination from September 22, 2021, through May 1, 2022, through v-safe, a voluntary smartphone-based monitoring system established by the Centers for Disease Control and Prevention. Participants were persons who voluntarily registered in v-safe following COVID-19 vaccination. EXPOSURE: Receipt of simultaneously administered COVID-19 mRNA booster and seasonal influenza vaccines or COVID-19 mRNA booster alone. MAIN OUTCOMES AND MEASURES: Local injection site and systemic reactions (eg, fatigue, headache, and myalgia) and health impacts reported by v-safe respondents in the week following COVID-19 mRNA booster vaccination. Adjusted odds ratios (aORs) were estimated for simultaneous administration compared with booster dose alone, controlling for sex, age, and week of vaccination. RESULTS: Of a total of 981â€¯099 persons aged 12 years or older registered with v-safe, simultaneous administration of COVID-19 mRNA booster and seasonal influenza vaccines was reported by 92â€¯023 (9.4%) v-safe respondents; of these respondents, 54â€¯926 (59.7%) were female, 36â€¯234 (39.4%) were male, and sex was unknown for 863 (0.9%). In the week following vaccination, any systemic reactions were reported by 36â€¯144 (58.9%) of 61â€¯390 respondents who simultaneously received Pfizer-BioNTech booster and influenza vaccines and 21â€¯027 (68.6%) of 30633 respondents who simultaneously received Moderna booster and influenza vaccines. Respondents who simultaneously received influenza and Pfizer-BioNTech booster vaccines (aOR, 1.08; 95% CI, 1.06-1.10) or influenza and Moderna booster vaccines (aOR, 1.11; 95% CI, 1.08-1.14) were slightly more likely to report any systemic reaction in the week following simultaneous vaccination than respondents who received only a COVID-19 mRNA vaccine booster. CONCLUSIONS AND RELEVANCE: In this study, compared with administration of COVID-19 mRNA booster vaccines alone, simultaneous administration of COVID-19 mRNA booster and seasonal influenza vaccines was associated with significant increases in reports of systemic reactions during days 0 to 7 following vaccination. These results may help better characterize the outcomes associated with simultaneously administered COVID-19 booster and influenza vaccines in the US population.

The influence of SARS-CoV-2 vaccination on post-operative outcomes in microsurgery patients. BACKGROUND: The healthcare industry's efforts to immunize the global community against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) have been unprecedented. Given the fast-tracking of the novel vaccine, its short- and long-term medical implications remain largely to-be-determined in most patient populations. This study aims to analyze 90-day post-operative outcomes in microsurgical patients, who have received or not received SARS-CoV-2-vaccination, using a continuously updated federated electronic medical record network (TriNetX Inc, Cambridge, MA). METHODS: After screening 70 million de-identified records, 16,799 microsurgery patients aged 18-99 meeting medical coding criteria were allocated into two cohorts. Cohort One received SARS-CoV-2-vaccination prior to undergoing microsurgery whereas Cohort Two did not. Two equally sized cohorts,

totaling 818 patients were created after propensity score matching for characteristics including: age, race, ethnicity, smoking, hypertension, heart disease, diabetes, obesity, chronic obstructive pulmonary disease, and history of SARS-CoV-2 exposure. Postoperative outcomes within 30-, 60-, and 90-days of microsurgery were analyzed. RESULTS: Patients who were SARS-CoV-2-immunized experienced significantly lower (pâ€‰<â€‰.01) surgical site infections (Absolute Risk Reduction (ARR)[95%CI])Â =Â (3.79%-5.36% [0.84-8.54]) ICU admission (9.47%-9.82%[5.45-13.88]), generalized infections (7.68%-9.92%[3.15-14.64]), and hospitalizations (28.48%-32.57%[20.99-40.13]) within 30-, 60-, and 90-days of microsurgery. Additionally, SARS-CoV-2-vaccinated patients also experienced significantly less flap failure (2.49%[0.97-4.02]) and death (2.46%[0.96-3.97]) within 30- and 60-days post-operatively. CONCLUSION: Our analysis examines the potential protective effect of SARS-CoV-2-vaccination in microsurgical patients. Limitations include the retrospective nature of this analysis and the inherent reliance on medical coding. Future prospective studies are warranted to better understand if in fact pre-operative SARS-CoV-2-vaccination has the potential to protect against post-operative microsurgery outcomes.

COVID-19 Vaccination and the Timing of Surgery Following COVID-19 Infection. OBJECTIVE: To evaluate whether COVID-19 vaccination status or mode of anesthesia modified the temporal harms associated with surgery following coronavirus disease-2019 (COVID-19) infection. BACKGROUND: Surgery shortly after COVID-19 infection is associated with higher rates of complications, leading to recommendations to delay surgery following COVID-19 infection when possible. However, prior studies were based on populations with low or no prevalence of vaccination. METHODS: A retrospective cohort study of patients who underwent scheduled surgery in a health system from January 1, 2018 to February 28, 2022 (N=228,913) was performed. Patients were grouped by time of surgery relative to COVID-19 test positivity: 0 to 4 weeks after COVID-19 ("early post-COVID-19"), 4 to 8 weeks after COVID-19 ("mid post-COVID-19"), >8 weeks after COVID-19 ("late post-COVID-19"), surgery at least 30 days before subsequent COVID-19 ("pre-COVID-19"), and surgery with no prior or subsequent test positivity for COVID-19. RESULTS: Among patients who were not fully vaccinated at the time of COVID-19 infection, the adjusted rate of perioperative complications for the early post-COVID-19 group was significantly higher than for the pre-COVID-19 group (relative risk: 1.55; P =0.05). No significantly higher risk was identified between these groups for patients who were fully vaccinated (0.66; P =1.00), or for patients who were not fully vaccinated and underwent surgery without general anesthesia (0.52; P =0.83). CONCLUSIONS: Surgery shortly following COVID-19 infection was not associated with higher risks among fully vaccinated patients or among patients who underwent surgery without general anesthesia. Further research will be valuable to understand additional factors that modify perioperative risks associated with prior COVID-19 infection.

SARS-CoV-2 mRNA vaccination is not associated with the induction of anti-HLA or non-HLA antibodies. BACKGROUND: SARS-CoV-2 vaccination is strongly recommended in kidney transplant recipients (KTR) and dialysis patients. Whether these vaccinations may trigger alloantibodies, is still debated. METHODS: In the current study we evaluated the effect of SARS-CoV-2 mRNA vaccines on anti-Human Leukocyte Antigen (HLA) and 60 anti-non-HLA antibody profiles in clinically stable KTR and dialysis patients. In total, we included 28 KTR, 30 patients on haemodialysis, 25 patients on peritoneal dialysis and 31 controls with a positive seroresponse 16-21Â days after the first dose of either the SARS-CoV-2 mRNA BNT162b2 or mRNA-1273 vaccine. Both anti-HLA and anti-non-HLA antibodies were determined prior to vaccination and 21 to 35Â days after the second vaccine dose. RESULTS: Overall, the proportion of patients with detectable anti-HLA antibodies was similar before and after vaccination (class I 14% vs. 16%, pÂ =Â 0.48; class II 25% before and after vaccination). After vaccination, there was no pattern in 1) additionally detected anti-HLA antibodies, or 2) the levels of pre-existing ones. Additional anti-non-HLA antibodies were detected in 30% of the

patients, ranging from 1 to 5 new anti-non-HLA antibodies per patient. However, the clinical significance of anti-non-HLA antibodies is still a matter of debate. To date, only a significant association has been found for anti-non-HLA ARHGDIB antibodies and long-term kidney graft loss. No additionally developed anti-ARHGDIB antibodies or elevated level of existing anti-ARHGDIB antibodies was observed. CONCLUSION: The current data indicate that SARS-CoV-2 mRNA vaccination does not induce anti-HLA or anti-non-HLA antibodies, corroborating the importance of vaccinating KTR and dialysis patients.

Association between vaccination against COVID-19 and postmenopausal bleeding.

Manifestation of a cancer-associated TIF-1 gamma dermatomyositis after COVID-19 vaccine.

The Role of Vitamin D for Modulating the T Helper 1 Immune Response After the Coronavac Vaccination. The purpose of this study was to observe the role of vitamin D levels with T helper 1 (Th1)-type cytokines, such as interferon Î³ (IFN-Î³) and interleukin-12 (IL-12) efficacy, in those who had already received 2 injections of inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) vaccines (CoronaVac). We also observed if these cytokines played any significance in the CoronaVac effectiveness for preventing coronavirus disease 2019 (Covid-19) infection. One hundred ninety-four volunteers were monitored for 8 months upon receiving 2 inactivated SARS-CoV2 vaccination injections (CoronaVac, Sinovac Life Sciences). The rate of confirmed Covid-19 infections was the primary outcome. Six to 7 weeks after the second vaccine injection, and blood samples were obtained to measure the serum vitamin D, IFN-Î³, and IL-12 levels. Low vitamin D level was defined if vitamin D level <30â€‰ng/mL. Subjects with low vitamin D had lower IFN-Î³ and IL-12 levels (Pâ€‰=â€‰0.04 and Pâ€‰=â€‰0.04, respectively). The receiver operating characteristics curve analysis revealed that the area under curve for IFN-Î³ was 0.59, whereas IL-12 was 0.59 for predicting the low vitamin D levels. During follow-up, a higher incidence of Covid-19 infections was observed in subjects with low IFN-Î³ levels (Pâ€‰=â€‰0.03). Kaplan-Meier survival analysis revealed that the cumulative hazard of confirmed Covid-19 cases was increased in subjects with low IFN-Î³ levels (log-rank test, Pâ€‰=â€‰0.03). We concluded that lower vitamin D level was correlated with a lower Th1 immune response, whereas the adequate IFN-Î³ level was required to obtain better CoronaVac effectiveness.

Safety Monitoring of COVID-19 mRNA Vaccine First Booster Doses Among Persons Aged â‰¥12 Years with Presumed Immunocompromise Status - United States, January 12, 2022-March 28, 2022. Persons with moderate to severe immunocompromising conditions are at risk for severe COVID-19, and their immune response to COVID-19 vaccination might not be as robust as the response in persons who are not immunocompromised* (1). The Advisory Committee on Immunization Practices (ACIP) recommends that immunocompromised persons aged â‰¥12 years complete a 3-dose primary mRNA COVID-19 vaccination series followed by a first booster dose (dose 4) â‰¥3 months after dose 3 and a second booster dose (dose 5) â‰¥4 months after dose 4.(â€) To characterize the safety of first booster doses among immunocompromised persons aged â‰¥12 years during January 12, 2022-March 28, 2022, CDC reviewed adverse events and health impact assessments reported to v-safe and the Vaccine Adverse Event Reporting System (VAERS) during the week after receipt of an mRNA COVID-19 first booster dose. V-safe is a voluntary smartphone-based safety surveillance system for adverse events after COVID-19 vaccination. VAERS is a passive surveillance system for all vaccine-associated adverse events co-managed by CDC and the Food and Drug Administration (FDA). A fourth mRNA dose reported to v-safe or VAERS during January 12, 2022-March 28, 2022, was presumed to be an mRNA COVID-19 vaccine booster dose administered to an immunocompromised person because no other population was authorized to receive a fourth dose during that period (2,3). In the United States, during January 12, 2022-March 28, 2022, approximately 518,113 persons aged â‰¥12 years received a fourth dose. Among 4,015 v-safe registrants who received a fourth dose,

local and systemic reactions were less frequently reported than were those following dose 3 of their primary series. VAERS received 145 reports after fourth doses; 128 (88.3%) were nonserious and 17 (11.7%) were serious. Health care providers, immunocompromised persons, and parents of immunocompromised children should be aware that local and systemic reactions are expected after a first booster mRNA COVID-19 vaccine dose, serious adverse events are rare, and safety findings were consistent with those previously described among nonimmunocompromised persons (4,5).
COVID-19 Vaccine Tolerability in a Patient With a Delayed Allergic Reaction to Polyethylene Glycol: AÂ Case Report.
High seroconversion rate after vaccination with mRNA BNT162b2 vaccine against SARS-CoV-2 among people with HIV - but HIV viremia matters?
Decay of coronavirus disease 2019 mRNA vaccine-induced immunity in people with HIV. Current coronavirus disease 2019 (COVID-19) mRNA vaccines induce robust SARS-CoV-2-specific humoral and cellular responses in people with HIV (PWH). However, the rate of decay of effector immune responses has not been studied in these individuals. Here, we report a significant waning of antibody responses but persistent T-cell responses 6 months post vaccination in virally suppressed PWH with high CD4+ T-cell counts. These responses are comparable with those seen in healthy donors.
Antibody Response Post-COVID-19 Vaccination in Patients With Chronic Myeloid Leukemia With Comparison Between Comirnaty and CoronaVac Vaccine.
Study of Adverse Events following COVID-19 Vaccination: A cross-sectional Survey in India.
COVID-19 vaccination-triggered cluster headache episodes with frequent attacks. BACKGROUND: The pathophysiology of cluster headache and how cluster episodes are triggered, are still poorly understood. Recurrent inflammation of the trigeminovascular system has been hypothesized. It was noted that some long-term attack-free cluster headache patients suddenly developed a new cluster episode shortly after COVID-19 vaccination. METHODS: Cases are described from patients with cluster headache who reported a new cluster episode within days after COVID-19 vaccination. All cases were seen in a tertiary university referral center and a general hospital in the Netherlands between March 2021 and December 2021, when the first COVID-19 vaccinations were carried out in The Netherlands. Clinical characteristics of the previous and new cluster episodes, and time between the onset of a new cluster episode and a previous COVID-19 vaccination were reported. RESULTS: We report seven patients with cluster headache, who had been attack-free for a long time, in whom a new cluster episode occurred within a few days after a COVID-19 vaccination. INTERPRETATION: COVID-19 vaccinations may trigger new cluster episodes in patients with cluster headache, possibly by activating a pro-inflammatory state of the trigeminocervical complex. COVID-19 vaccinations may also exacerbate other neuroinflammatory conditions.â€ƒ.
Side Effects Related to BNT162b2 and CoronaVac Vaccine Requiring Emergency Department Visit. Background â€ƒCurrently, the most effective method in the fight against coronavirus disease 2019 (COVID-19) is vaccination against the disease. However, there are hesitations among society concerning the safety and side effects of COVID-19 vaccines. We aimed to determine the observed side effects that require an emergency room visit after taking the BNT162b2 and CoronaVac vaccines. Methods â€ƒThis prospective observational study was conducted with patients who presented to the emergency department due to vaccine-related complications after COVID-19 vaccination. The patients' symptoms at the time of presentation, time from vaccination to the onset of symptoms, and dose of the vaccine administered were determined. In addition, the demographic characteristics of the patients, whether they had a history of COVID-19 infection, and their vital signs at the time of presentation were recorded. The variables were compared according to the type of vaccine administered. Results â€ƒThe study included 182 patients who presented to the emergency department over a 6-month period. It was determined that 166 of these patients (91.2%) had

received the BNT162b2 vaccine and 16 (8.8%) had received the CoronaVac vaccine. The majority of the patients did not have a history of COVID-19 infection (70.3%), and most presented to the hospital with complications after the second dose (61%). The onset of vaccine-related symptoms was mostly within 1 to 12â€‰hours (39%). The majority of patients (97.8%) were discharged from the emergency department. The most common symptoms after vaccination were fatigue (n â€‰=â€‰70), followed by muscle/joint pain (n â€‰=â€‰52), headache (n â€‰=â€‰33), and fever (n â€‰=â€‰32). The rate of dizziness was found to be statistically significantly higher in the CoronaVac vaccine group than in the BNT162b2 vaccine group (p â€‰=â€‰0.008). There was no statistically significant difference between the two vaccine groups in relation to the remaining symptoms (p â€‰>â€‰0.005). Conclusion â€ƒThere were no serious complications related to the BNT162b2 or CoronaVac vaccine. The most common symptom after both vaccines was fatigue; therefore, the BNT162b2 and CoronaVac vaccines can be safely administered.

A Possible Case of COVID-19 Booster Vaccine-Associated Rhabdomyolysis and Acute Kidney Injury. Background: Nearly 10 billion doses of the various messenger ribonucleic acid (mRNA) and viral vector vaccines against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) have been administered worldwide. Adverse drug reactions (ADRs) have been overwhelmingly mild to moderate in nature. Rare side effects have included myocarditis/pericarditis, thrombosis with thrombocytopenia syndrome (TTS), Guillain-BarrÃ© Syndrome (GBS), and death. However, vaccine-related ADR data are still being collected using a variety of reporting systems. Purpose: We will describe a case of suspected mRNA coronavirus disease 2019 (COVID-19) booster-related rhabdomyolysis in a woman who developed signs and symptoms 10 days after administration of the vaccine dose. With a Naranjo ADR probability score of 4, the vaccine was deemed to be a possible cause of our patient's rhabdomyolysis. Methods: A search of the VAERS (Vaccine Adverse Event Reporting System) mined in November 2021 revealed 386 reported cases of COVID-19 vaccine-related rhabdomyolysis. However, system limitations make the utility of the information problematic. Conclusions: It is vitally important that clinicians, scientists, and patients are aware of rhabdomyolysis as a potential side effect of vaccination. Suspected vaccine-related ADRs should be promptly and accurately reported via VAERS or other surveillance systems to support the ongoing effort to ensure vaccine safety.

COVID-19 vaccine side effect: age and gender disparity in adverse effects following the first dose of AstraZeneca COVID-19 vaccine among the vaccinated population in Eastern Ethiopia: a community-based study. OBJECTIVE: The pandemic of coronavirus disease 2019 (COVID-19) is a major threat to community health, and vaccinations are a safe and effective way to reduce disease loads around the world. This study aimed to assess the age and gender disparity in adverse effects following the first dose of the AstraZeneca COVID-19 vaccine among the vaccinated population in Eastern Ethiopia. METHODS: A community-based cross-sectional study design was conducted among 832 randomly selected individuals from December 1st to 20th, 2021, in eastern Ethiopia. Data were collected by face-to-face interviews using a pretested structured questionnaire. Data were analyzed using the SPSS V26. Descriptive summary statistics were done. A chi-square test statistic was computed to assess the difference in adverse effects between age groups and both genders. RESULT: Out of 832 study participants who had taken the first dose of AstraZeneca vaccine, 96.3% of them felt at least one adverse effect. The magnitude of adverse reactions was higher among male participants. The reported adverse reactions were significantly higher in the age group of 50-60â€‰years with comorbidity than those of <50 and >60â€‰years of age. CONCLUSION: Overall, there is a significant age and gender difference in adverse effects following the first dose of the AstraZeneca COVID-19 vaccine. In addition, adverse reactions were higher among people with comorbidity in the age group of 50-60â€‰years. The Harari Regional Health Bureau should provide training for frontline

healthcare workers on early recognition and response to adverse effects of the COVID-19 vaccine. In addition, information and education should be provided to the community as a whole regarding recognition and the appropriate measures to be taken.
ANCA-associated vasculitis following Johnson and Johnson COVID-19 vaccine. INTRODUCTION: Antineutrophil cytoplasmic autoantibodies associated vasculitis (AAV) is characterized by antibodies against antigens in cytoplasmic granules of neutrophils and predominantly affects small vessels. AAV after COVID-19 mRNA vaccination has been reported. CASE PRESENTATION: We report a rare case of AAV in a patient who presented with rapidly progressive glomerulonephritis (RPGN) after Johnson & Johnson COVID-19 vaccine administration. DISCUSSION: The temporal causal association between autoimmune manifestations like AAV and COVID-19 vaccines can be explained by hypothesized mechanisms like molecular mimicry, defective neutrophilic apoptosis, polyclonal activation, and systemic proinflammatory cytokine response. These mechanisms are likely to trigger autoimmune responses in genetically susceptible individuals. Still there are many research going on to fill the research gap on the development of ANCA associated with COVID-19 vaccines. CONCLUSION: Increasing reports of rare adverse effects like AAV following COVID-19 vaccination warrants the further study and evaluation of immune responses induced by those vaccines. Considering the potential severity of COVID-19 and the rarity of the above-mentioned adverse effects, COVID-19 vaccination should not be withheld.
Immune Thrombocytopenia Following COVID-19 Vaccination.
Myocarditis after COVID-19 mRNA vaccination in Australia.
Safety of heterologous primary and booster schedules with ChAdOx1-S and BNT162b2 or mRNA-1273 vaccines: nationwide cohort study. OBJECTIVE: To assess the risk of adverse events associated with heterologous primary (two dose) and booster (three dose) vaccine schedules for covid-19 with Oxford-AstraZeneca's ChAdOx1-S priming followed by mRNA vaccines (Pfizer-BioNTech's BNT162b2 or Moderna's mRNA-1273) as compared with homologous mRNA vaccine schedules for covid-19. DESIGN: Nationwide cohort study. SETTING: Denmark, 1 January 2021 to 26 March 2022. PARTICIPANTS: Adults aged 18-65 years who received a heterologous vaccine schedule of priming with ChAdOx1-S and one or two mRNA booster doses (with either the BNT162b2 or mRNA-1273 vaccine) were compared with adults who received a homologous BNT162b2 or mRNA-1273 vaccine schedule (ie, two dose v two dose, and three dose v three dose schedule). MAIN OUTCOME MEASURES: The incidence of hospital contacts for a range of adverse cardiovascular and haemostatic events within 28 days after the second or third vaccine dose, comparing heterologous versus homologous vaccine schedules. Secondary outcomes included additional prioritised adverse events of special interest. Poisson regression was used to estimate incidence rate ratios with adjustment for selected covariates. RESULTS: Individuals who had had a heterologous primary vaccine (n=137 495) or a homologous vaccine (n=2 688 142) were identified, in addition to those who had had a heterologous booster (n=129 770) or a homologous booster (n=2 197 213). Adjusted incidence rate ratios of adverse cardiovascular and haemostatic events within 28 days for the heterologous primary and booster vaccine schedules in comparison with the homologous mRNA vaccine schedules were 1.22 (95% confidence interval 0.79 to 1.91) and 1.00 (0.58 to 1.72) for ischaemic cardiac events, 0.74 (0.40 to 1.34) and 0.72 (0.37 to 1.42) for cerebrovascular events, 1.12 (0.13 to 9.58) and 4.74 (0.94 to 24.01) for arterial thromboembolisms, 0.79 (0.45 to 1.38) and 1.09 (0.60 to 1.98) for venous thromboembolisms, 0.84 (0.18 to 3.96) and 1.04 (0.60 to 4.55) for myocarditis or pericarditis, 0.97 (0.45 to 2.10) and 0.89 (0.21 to 3.77) for thrombocytopenia and coagulative disorders, and 1.39 (1.01 to 1.91) and 1.02 (0.70 to 1.47) for other bleeding events, respectively. No associations with any of the outcomes were found when restricting to serious adverse events defined as stay in hospital for more than 24 h. CONCLUSION: Heterologous primary and booster covid-19 vaccine schedules of

ChAdOx1-S priming and mRNA booster doses as both second and third doses were not associated with increased risk of serious adverse events compared with homologous mRNA vaccine schedules. These results are reassuring but given the rarity of some of the adverse events, associations cannot be excluded.

Incidence, risk factors, natural history, and hypothesised mechanisms of myocarditis and pericarditis following covid-19 vaccination: living evidence syntheses and review. OBJECTIVES: To synthesise evidence on incidence rates and risk factors for myocarditis and pericarditis after use of mRNA vaccination against covid-19, clinical presentation, short term and longer term outcomes of cases, and proposed mechanisms. DESIGN: Living evidence syntheses and review. DATA SOURCES: Medline, Embase, and the Cochrane Library were searched from 6 October 2020 to 10 January 2022; reference lists and grey literature (to 13 January 2021). One reviewer completed screening and another verified 50% of exclusions, using a machine learning program to prioritise records. A second reviewer verified all exclusions at full text, extracted data, and (for incidence and risk factors) risk of bias assessments using modified Joanna Briggs Institute tools. Team consensus determined certainty of evidence ratings for incidence and risk factors using GRADE (Grading of Recommendations, Assessment, Development and Evaluation). ELIGIBILITY CRITERIA FOR SELECTING STUDIES: Large (>10â€‰000 participants) or population based or multisite observational studies and surveillance data (incidence and risk factors) reporting on confirmed myocarditis or pericarditis after covid-19 mRNA vaccination; case series (nâ‰¥5, presentation, short term clinical course and longer term outcomes); opinions, letters, reviews, and primary studies focused on describing or supporting hypothesised mechanisms. RESULTS: 46 studies were included (14 on incidence, seven on risk factors, 11 on characteristics and short term course, three on longer term outcomes, and 21 on mechanisms). Incidence of myocarditis after mRNA vaccines was highest in male adolescents and male young adults (age 12-17 years, range 50-139 cases per million (low certainty); 18-29 years, 28-147 per million (moderate certainty)). For girls and boys aged 5-11 years and women aged 18-29 years, incidence of myocarditis after vaccination with BNT162b2 (Pfizer/BioNTech) could be fewer than 20 cases per million (low certainty). Incidence after a third dose of an mRNA vaccine had very low certainty evidence. For individuals of 18-29 years, incidence of myocarditis is probably higher after vaccination with mRNA-1273 (Moderna) compared with Pfizer (moderate certainty). Among individuals aged 12-17, 18-29, or 18-39 years, incidence of myocarditis or pericarditis after dose two of an mRNA vaccine for covid-19 might be lower when administered â‰¥31 days compared with â‰¤30 days after dose one (low certainty). Data specific to men aged 18-29 years indicated that the dosing interval might need to increase to â‰¥56 days to substantially drop myocarditis or pericarditis incidence. For clinical course and short term outcomes, only one small case series (n=8) was found for 5-11 year olds. In adolescents and adults, most (>90%) myocarditis cases involved men of a median 20-30 years of age and with symptom onset two to four days after a second dose (71-100%). Most people were admitted to hospital (â‰¥84%) for a short duration (two to four days). For pericarditis, data were limited but more variation than myocarditis has been reported in patient age, sex, onset timing, and rate of admission to hospital. Three case series with longer term (3 months; n=38) follow-up suggested persistent echocardiogram abnormalities, as well as ongoing symptoms or a need for drug treatments or restriction from activities in >50% of patients. Sixteen hypothesised mechanisms were described, with little direct supporting or refuting evidence. CONCLUSIONS: These findings indicate that adolescent and young adult men are at the highest risk of myocarditis after mRNA vaccination. Use of a Pfizer vaccine over a Moderna vaccine and waiting for more than 30 days between doses might be preferred for this population. Incidence of myocarditis in children aged 5-11 years is very rare but certainty was low. Data for clinical risk factors were very limited. A clinical course of mRNA related myocarditis appeared to be benign, although longer term follow-up data were limited.

Prospective studies with appropriate testing (eg, biopsy and tissue morphology) will enhance understanding of mechanism.
Low Rates of Breakthrough COVID-19 Infection After SARS-CoV-2 Vaccination in Patients With Inflammatory Bowel Disease. We demonstrate low rates of breakthrough coronavirus disease 2019 (COVID-19) infection and mild course of illness following severe acute respiratory syndrome coronavirus 2 vaccination in a large cohort of inflammatory bowel disease patients. Residence in southern United States and lower median anti-receptor binding antibody level were associated with development of COVID-19.
SARS-CoV-2 vaccine may trigger thyroid autoimmunity: real-life experience and review of the literature. PURPOSE: SARS-CoV-2 infection can be associated with destructive thyroiditis and triggers thyroid autoimmunity. More recent evidence suggests that SARS-CoV-2 vaccines may also be associated with permanent or transient thyroid dysfunction in susceptible individuals. METHODS: We observed three patients who developed/exacerbated autoimmune thyroid diseases (AITDs) shortly after receiving mRNA-based vaccines against SARS-CoV2. Clinical histories are reported, and relevant literature in the field is summarized. RESULTS: Our case series gives a description of the full spectrum of autoimmune disorders that may occur after SARS-CoV-2 vaccines administration, ranging from a case of new-onset Graves' disease to autoimmune hypothyroidism in two patients with pre-existing AITDs. Our three patients had a personal and/or family history of autoimmune disorders, suggesting that genetic predisposition is an important risk factor for the development of AITDs following vaccination. Moreover, our real-life experience demonstrates that persistent hypothyroidism may occur in the long run and should be overlooked; subjects with a previous AITDs are at risk of developing it. Reviewing the pertinent literature up to date Graves' disease is the most common vaccine-related AITDs with up to 51 cases reported in the literature, occurring mainly in female patients with no personal history of AIDTs, while only a case of autoimmune hypothyroidism has been reported so far. CONCLUSIONS: SARS-CoV-2 vaccines can trigger autoimmune reactions and the present case series contributes to make clinicians aware of full spectrum of AITDs that may occur following vaccination. Thyroid function monitoring is recommended, mainly in subjects with a personal/family history of AITDs.
Pulmonary Embolism and Inferior Vena Cava Thrombosis in a Young Male Patient after mRNA-1273 (Moderna) Immunization: A Case Report.
A disproportionality analysis for the association of central nervous system demyelinating diseases with COVID-19 vaccination using the World Health Organization pharmacovigilance database. BACKGROUND: Limited information is available on associations between COVID-19 vaccines and central nervous system (CNS) demyelinating diseases. OBJECTIVES: We investigated potential safety signals for CNS demyelinating diseases related to COVID-19 vaccines using the World Health Organization pharmacovigilance database. METHODS: Disproportionality analyses of CNS demyelinating disease following COVID-19 vaccination were performed by calculating the information component (IC) or the reporting odds ratio (ROR) compared with those for the entire database and for all other viral vaccines. RESULTS: We identified 715 cases of optic neuritis, 515 of myelitis, 220 of acute disseminated encephalomyelitis (ADEM), and 2840 total CNS demyelinating events adverse drug reactions from July 2020 through February 2022. For mRNA-based and ChAdOx1 nCoV-19 vaccines, there were no potential safety signals of disproportionality for optic neuritis (IC(025)â€‰=â€‰-0.93, ROR(025)â€‰=â€‰0.38; IC(025)â€‰=â€‰-1.76, ROR(025)â€‰=â€‰0.26), myelitis (IC(025)â€‰=â€‰-0.69, ROR(025)â€‰=â€‰0.50; IC(025)â€‰=â€‰-0.63, ROR(025)â€‰=â€‰0.53), ADEM (IC(025)â€‰=â€‰-1.05, ROR(025)â€‰=â€‰0.33; IC(025)â€‰=â€‰-1.76, ROR(025)â€‰=â€‰0.20), or overall CNS demyelinating disease events (IC(025)â€‰=â€‰-0.66, ROR(025)â€‰=â€‰0.52; IC(025)â€‰=â€‰-

1.31, ROR(025)â€‰=â€‰0.34) compared with other viral vaccines. CONCLUSION: As with other viral vaccines, our disproportionality analyses indicate that the risk of COVID-19 vaccine-associated CNS demyelinating disease was low.

Post-vaccination infection rates and modification of COVID-19 symptoms in vaccinated UK school-aged children and adolescents: A prospective longitudinal cohort study. BACKGROUND: We aimed to explore the effectiveness of one-dose BNT162b2 vaccination upon SARS-CoV-2 infection, its effect on COVID-19 presentation, and post-vaccination symptoms in children and adolescents (CA) in the UK during periods of Delta and Omicron variant predominance. METHODS: In this prospective longitudinal cohort study, we analysed data from 115,775 CA aged 12-17 years, proxy-reported through the Covid Symptom Study (CSS) smartphone application. We calculated post-vaccination infection risk after one dose of BNT162b2, and described the illness profile of CA with post-vaccination SARS-CoV-2 infection, compared to unvaccinated CA, and post-vaccination side-effects. FINDINGS: Between August 5, 2021 and February 14, 2022, 25,971 UK CA aged 12-17 years received one dose of BNT162b2 vaccine. The probability of testing positive for infection diverged soon after vaccination, and was lower in CA with prior SARS-CoV-2 infection. Vaccination reduced proxy-reported infection risk (-80Â·4% (95% CI -0Â·82 -0Â·78) and -53Â·7% (95% CI -0Â·62 -0Â·43) at 14-30 days with Delta and Omicron variants respectively, and -61Â·5% (95% CI -0Â·74 -0Â·44) and -63Â·7% (95% CI -0Â·68 -0.59) after 61-90 days). Vaccinated CA who contracted SARS-CoV-2 during the Delta period had milder disease than unvaccinated CA; during the Omicron period this was only evident in children aged 12-15 years. Overall disease profile was similar in both vaccinated and unvaccinated CA. Post-vaccination local side-effects were common, systemic side-effects were uncommon, and both resolved within few days (3 days in most cases). INTERPRETATION: One dose of BNT162b2 vaccine reduced risk of SARS-CoV-2 infection for at least 90 days in CA aged 12-17 years. Vaccine protection varied for SARS-CoV-2 variant type (lower for Omicron than Delta variant), and was enhanced by pre-vaccination SARS-CoV-2 infection. Severity of COVID-19 presentation after vaccination was generally milder, although unvaccinated CA also had generally mild disease. Overall, vaccination was well-tolerated. FUNDING: UK Government Department of Health and Social Care, Chronic Disease Research Foundation, The Wellcome Trust, UK Engineering and Physical Sciences Research Council, UK Research and Innovation London Medical Imaging & Artificial Intelligence Centre for Value Based Healthcare, UK National Institute for Health Research, UK Medical Research Council, British Heart Foundation and Alzheimer's Society, and ZOE Limited.

mRNA-LNP vaccines tuned for systemic immunization induce strong antitumor immunity by engaging splenic immune cells. mRNA vaccines have recently proved to be highly effective against SARS-CoV-2. Key to their success is the lipid-based nanoparticle (LNP), which enables efficient mRNA expression and endows the vaccine with adjuvant properties that drive potent antibody responses. Effective cancer vaccines require long-lived, qualitative CD8 TÂ cell responses instead of antibody responses. Systemic vaccination appears to be the most effective route, but necessitates adaptation of LNP composition to deliver mRNA to antigen-presenting cells. Using a design-of-experiments methodology, we tailored mRNA-LNP compositions to achieve high-magnitude tumor-specific CD8 TÂ cell responses within a single round of optimization. Optimized LNP compositions resulted in enhanced mRNA uptake by multiple splenic immune cell populations. Type I interferon and phagocytes were found to be essential for the TÂ cell response. Surprisingly, we also discovered a yet unidentified role of BÂ cells in stimulating the vaccine-elicited CD8 TÂ cell response. Optimized LNPs displayed a similar, spleen-centered biodistribution profile in non-human primates and did not trigger histopathological changes in liver and spleen, warranting their further assessment in clinical studies. Taken together, our study clarifies the relationship between nanoparticle composition and their

TÂ cell stimulatory capacity and provides novel insights into the underlying mechanisms of effective mRNA-LNP-based antitumor immunotherapy.

Kidney Transplantation From Deceased Donors With Vaccine-induced Immune Thrombocytopenia and Thrombosis: An Updated Analysis of the UK Experience. BACKGROUND: The emergence and attendant mortality of vaccine-induced immune thrombocytopenia and thrombosis (VITT) as a consequence of vaccination against severe acute respiratory syndrome coronavirus 2 have resulted in some patients with VITT being considered as deceased organ donors. Outcomes after kidney transplantation in this context are poorly described. Because the disease seems to be mediated by antiplatelet factor 4 antibodies, there is a theoretical risk of transmission via passenger leukocytes within the allograft. METHODS: We analyzed the experience of kidney transplantation from donors with VITT in the United Kingdom between January and June 2021. We followed-up all recipients of kidney-only transplants from donors with VITT to detect major postoperative complications or features of disease transmission and assess graft survival and function. RESULTS: There were 16 kidney donors and 30 single kidney transplant recipients in our study period. Of 11 preimplantation biopsies, 4 showed widespread glomerular microthrombi. After a median of 5 mo, patient and graft survival were 97% and 90%, respectively. The median 3-mo estimated glomerular filtration rate was 51â€‰mL/min/1.73 m 2 . Two recipients had detectable antiplatelet factor 4 antibodies but no evidence of clinical disease after transplantation. Major hemorrhagic complications occurred in 3 recipients, all of whom had independent risk factors for bleeding, resulting in the loss of 2 grafts. The involvement of VITT could not be completely excluded in one of these cases. CONCLUSIONS: The UK experience to date shows that favorable outcomes are possible after kidney transplantation from donors with VITT but highlights the need for ongoing vigilance for donor-related complications in these patients.

Transjugular intrahepatic portosystemic shunt, local thrombaspiration, and lysis for management of fulminant portomesenteric thrombosis and atraumatic splenic rupture due to vector-vaccine-induced thrombotic thrombocytopenia: a case report. INTRODUCTION: Recombinant adenoviral vector vaccines against severe acute respiratory syndrome coronavirus 2 have been observed to be associated with vaccine-induced immune thrombotic thrombocytopenia. Though vaccine-induced immune thrombotic thrombocytopenia is a rare complication after vaccination with recombinant adenoviral vector vaccines, it can lead to severe complications. In vaccine-induced immune thrombotic thrombocytopenia, the vector vaccine induces heparin-independent production of platelet factor 4 autoantibodies, resulting in platelet activation and aggregation. Therefore, patients suffering from vaccine-induced immune thrombotic thrombocytopenia particularly present with signs of arterial or venous thrombosis, often at atypical sites, but also signs of bleeding due to disseminated intravascular coagulation and severe thrombocytopenia. We describe herein a rare case of fulminant portomesenteric thrombosis and atraumatic splenic rupture due to vaccine-induced immune thrombotic thrombocytopenia. This case report presents the diagnosis and treatment of a healthy 29-year-old male Caucasian patient suffering from an extended portomesenteric thrombosis associated with atraumatic splenic rupture due to vaccine-induced immune thrombotic thrombocytopenia after the first dose of an adenoviral vector vaccine against severe acute respiratory syndrome coronavirus 2 [ChAdOx1 nCoV-19 (AZD1222)]. Therapeutic management of vaccine-induced immune thrombotic thrombocytopenia initially focused on systemic anticoagulation avoiding heparin and the application of steroids and intravenous immune globulins as per the recommendations of international societies of hematology and hemostaseology. Owing to the atraumatic splenic rupture and extended portomesenteric thrombosis, successful management of this case required splenectomy with additional placement of a transjugular intrahepatic portosystemic shunt to perform local thrombaspiration, plus repeated local lysis to reconstitute

hepatopetal blood flow. CONCLUSION: The complexity and wide spectrum of the clinical picture in patients suffering from vaccine-induced immune thrombotic thrombocytopenia demand an early interdisciplinary diagnostic and therapeutic approach. Severe cases of portomesenteric thrombosis in vaccine-induced immune thrombotic thrombocytopenia, refractory to conservative management, may require additional placement of a transjugular intrahepatic portosystemic shunt, thrombaspiration, thrombolysis, and surgical intervention for effective management.

Vaccine-induced immune thrombotic thrombocytopenia presenting as a mimic of heparin-induced thrombocytopenia in a hemodialysis patient receiving ChAdOx1 nCoV-19 vaccine.

Quantitative ultrasound image analysis of axillary lymph nodes to differentiate malignancy from reactive benign changes due to COVID-19 vaccination. PURPOSE: The aim of this study is to assess the potential of quantitative image analysis and machine learning techniques to differentiate between malignant lymph nodes and benign lymph nodes affected by reactive changes due to COVID-19 vaccination. METHOD: In this institutional review board-approved retrospective study, we improved our previously published artificial intelligence model, by retraining it with newly collected images and testing its performance on images containing benign lymph nodes affected by COVID-19 vaccination. All the images were acquired and selected by specialized breast-imaging radiologists and the nature of each node (benign or malignant) was assessed through a strict clinical protocol using ultrasound-guided biopsies. RESULTS: A total of 180 new images from 154 different patients were recruited: 71 images (10 cases and 61 controls) were used to retrain the old model and 109 images (36 cases and 73 controls) were used to evaluate its performance. The achieved accuracy of the proposed method was 92.7% with 77.8% sensitivity and 100% specificity at the optimal cut-off point. In comparison, the visual node inspection made by radiologists from ultrasound images reached 69.7% accuracy with 41.7% sensitivity and 83.6% specificity. CONCLUSIONS: The results obtained in this study show the potential of the proposed techniques to differentiate between malignant lymph nodes and benign nodes affected by reactive changes due to COVID-19 vaccination. These techniques could be useful to non-invasively diagnose lymph node status in patients with suspicious reactive nodes, although larger multicenter studies are needed to confirm and validate the results.

Longitudinally extensive transverse myelitis after covid vaccination: Response to letter.

Willingness to receive COVID-19 vaccine and associated factors among adult chronic patients. A cross-sectional study in Northwest Ethiopia. BACKGROUND: People with pre-existing chronic diseases are more likely to acquire COVID-19 infections, which can be fatal, and die from COVID-19 illness. COVID-19 vaccination will benefit those at a higher risk of developing complications and dying from the disease. This study aimed to determine chronic patients' willingness to receive a COVID-19 vaccine and the factors that influence their willingness. METHOD: An institutional-based cross-sectional study was conducted among 423 adult chronic patients in the University of Gondar specialized hospital outpatient departments. The participants were chosen using systematic random sampling methods with an interval of 5. Face-to-face interviews were used to collect data from eligible respondents. Epi-data version 4.6 and SPSS version 25 were used for the data entry data analysis. Bivariable and multivariable binary logistic regression analyses were used to evaluate the relationship between the dependent and independent factors. An odds ratio with 95 percent confidence intervals and a P-value was used to determine the association's strength and statistical significance. RESULT: Out of 401 respondents, 219 (54.6%) with [95% CI (49.7-59.5%)] of study participants were willing to receive the COVID-19 vaccination. Being a healthcare worker (AOR = 2.94, 95% CI: 1.24-6.96), Lost family members or friends due to COVID-19 (AOR = 2.47, 95% CI: 1.21-5.00), good knowledge about COVID-19 vaccine (AOR = 2.44, 95% CI: 1.37-4.33), favorable attitude towards COVID-19 vaccine (AOR = .8.56 95% CI: 4.76-15.38), perceived suitability of the COVID-19 infection (AOR = 2.94, 95% CI: 1.62-5.33) and perceived benefit of the COVID-19 vaccine (AOR = 1.89, 95% CI:

1.08-3.31), were found to be a significant association with the willingness to receive the COVID-19 vaccine among chronic patients. CONCLUSION: This study confirms that around 55% of adult chronic patients were willing to receive the COVID-19 vaccine. Providing health education for chronic patients to emphasize the knowledge and attitude of the COVID-19 vaccine and raise patients' perceived risk of COVID-19 and the benefit of the COVID-19 vaccine could be recommended to improve their willingness to COVID-19 vaccination.
Ocular Inflammatory Reactions following an Inactivated SARS-CoV-2 Vaccine: A Four Case Series. PURPOSE: To report a four-case series of ocular adverse events post an inactivated COVID-19 vaccination in China. METHODS: The four patients exhibited ocular inflammatory reactions on the same day after receiving an inactivated SARS-CoV-2 vaccine. RESULTS: All patients underwent detailed ophthalmic examinations, with the medical diagnosis of Vogt-Koyanagi-Harada, Ponser-Schlossman, secondary post-inflammatory glaucoma, and iridocyclitis, respectively. No patients had any other underlying medical conditions causing the ocular complications. The ocular inflammatory reactions of these four patients were resolved with the administration of oral or topical corticosteroids. CONCLUSION: Our cases remind the ophthalmologist that adverse ocular events may happen after the administration of SARS-CoV-2 vaccine. Since the ocular complications could be resolved with the corticosteroid treatment, the events were considered to be inflammatory reactions caused by the SARS-CoV-2 vaccine.
Inflammatory myopathy secondary to SARS-CoV-2 vaccination.
Myocarditis after COVID-19 mRNA vaccination: Correspondence.
Giant cell arteritis presenting with chronic cough and headache after BNT162b2 mRNA COVID-19 vaccination.
Symptomatic hyponatremia after ChAdOx1 nCoV-19 coronavirus disease-19 vaccination. Adverse events, particularly severe adverse events, after coronavirus disease vaccination are the primary concern for many patients. We present the first report of symptomatic hyponatremia, a potentially life-threatening condition, after administration of the ChAdOx1 nCoV-19 coronavirus disease-19 vaccine. A 24-year-old man developed altered consciousness and high-grade fever a day after receiving this vaccine. Computed tomography of the brain showed diffuse brain swelling with bilateral descending transtentorial brain herniation. His serum sodium level, urine sodium level, and urine osmolarity were 114Â mEq/L, 77Â mEq/L, and 230Â mOsm/kg, respectively. He was diagnosed with symptomatic hyponatremia due to syndrome of inappropriate antidiuretic hormone. His symptoms rapidly improved after treatment with 3% NaCl. Seven days after admission, his serum sodium level was normal, and no further intervention was required. We believe that the vaccine was the trigger for hyponatremia in this case based on temporal relationship of vaccination and hyponatremia, the rapid improvement of the patient, and the transient nature of the hyponatremia. We postulate that cytokine underlies the pathophysiology of hyponatremia in this case. Recognition of adverse events after coronavirus disease-19 vaccination is essential. Symptomatic hyponatremia should be included in the differential diagnosis in altered-consciousness patients after administration of ChAdOx1 nCoV-19 coronavirus disease-19 vaccine.
Unilateral recurrent central serous chorioretinopathy (CSCR) following COVID-19 vaccination- A multimodal imaging study. Corona virus disease-19 (COVID-19) vaccines have been approved for emergency use. Ocular adverse effects following the vaccines have been reported. PURPOSE: To report an unique case of recurrent central serous chorioretinopathy following both doses of COVID-19 vaccine. OBSERVATIONS: A 40-year-old male presented with blurring of vision in the left eye during 2 days following COVISHIELDâ„¢ (Serum Institute of India). He had a previous history of central serous chorioretinopathy in the right eye 2 years back and was treated with micropulse laser. Ocular examination showed a best corrected visual acuity of 20/20 right eye and 20/60 left eye. Fundus

evaluation of left eye showed central serous chorioretinopathy. Spectral domain optical coherence tomography of the left eye revealed neurosensory detachment. Fundus fluorescein angiography of the left eye showed multiple window defects and ink-blot appearance in the macula. Oral eplerenone 50mg once a day for a month showed significant reduction in the subretinal fluid. Patient developed central serous chorioretinopathy in the left eye 3 days after 2nd dose of COVISHIELDâ„¢. CONCLUSION AND IMPORTANCE: CSCR following vaccination may be a temporal event. In our patient it occurred following the vaccination. This is the first case of a recurrent CSCR after either dose of COVID-19 vaccination. Ocular symptoms after vaccination warrant a thorough eye evaluation.

Cataracts in setting of multisystem inflammation after COVID-19 vaccination. PURPOSE: To describe a unique case of bilateral cataract formation in the setting of multisystem inflammation after the 1st dose of the BNT162b2 mRNA COVID-19 vaccination. OBSERVATIONS: A previously healthy 20-year-old male developed intumescent bilateral cataracts leading to visual decline from 20/20 to 20/300-20/400 in each eye, likely from systemic inflammation after vaccination. CONCLUSION AND IMPORTANCE: This is the first reported case of cataract formation following a COVID-19 vaccine. While ocular adverse effects associated with COVID-19 vaccination are rare, it is important to raise awareness of these entities amongst medical providers as the COVID-19 pandemic continues and vaccinations become widespread.

Severe Acute Respiratory Syndrome Coronavirus 2 Neutralization After Messenger RNA Vaccination and Variant Breakthrough Infection. The emergence of severe acute respiratory syndrome coronavirus 2 variants that have greater transmissibility and resistance to neutralizing antibodies has increased the incidence of breakthrough infections. We show that breakthrough infection increases neutralizing antibody titers to varying degrees depending on the nature of the breakthrough variant and the number of vaccine doses previously administered. Omicron breakthrough infection resulted in neutralizing antibody titers that were the highest across all groups, particularly against Omicron.

Multifocal motor neuropathy after SARS-CoV-2 vaccination: a causal or coincidental association? Multifocal motor neuropathy (MMN) is an immune-mediated and acquired demyelinating motor polyneuropathy. Several cases of polyneuropathy associated with severe acquired respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination have been reported. However, MMN has not been reported as a complication of SARS-CoV-2 vaccination. In this study, we report a case of MMN with progressive muscle weakness following the second dose of the Pfizer-BioNTech mRNA vaccine. It was diagnosed by clinical evaluation and electroneuromyography. SARS-CoV-2 vaccination is increasing rapidly all over the world. Some cases of polyneuropathy, especially Guillain-BarrÃ© syndrome, have been reported after vaccination. This is the first case report of MMN after SARS-CoV-2 vaccination.

Gross hematuria can be an impact of severe acute respiratory syndrome coronavirus 2 vaccination on immunoglobulin A nephropathy: a case report. BACKGROUND: Immunoglobulin A nephropathy is typically accelerated by upper respiratory tract infections and can relapse following vaccination. There have been reports of patients who presented with immunoglobulin A nephropathy flares with or without gross hematuria following coronavirus disease 2019 vaccination. However, this relationship remains to be elucidated. CASE PRESENTATION: Herein, we present the case of a patient with newly diagnosed immunoglobulin A nephropathy who presented with gross hematuria following the second dose of coronavirus disease 2019 vaccine. A 21-year-old Japanese woman presented with fever and new-onset gross hematuria 1Â day after receiving the second dose of the coronavirus disease 2019 vaccine (Pfizer). She had microhematuria without proteinuria for 2Â years at the time of her medical check-up. Gross hematuria resolved 6Â days after the second dose of the coronavirus disease 2019 vaccine; however, microhematuria (>Â 100 per high-power field) and mild proteinuria were observed. She was admitted to our hospital 4Â weeks after the second vaccination because of persistent urinary abnormalities. She was well before the vaccination and did not have any

pulmonary involvement on chest radiography or any symptoms suggestive of coronavirus disease 2019. Renal biopsy revealed an immunoglobulin A nephropathy. The Oxford MEST-C score was M0E0S0T0C0. Our patient's urinary abnormalities implied exacerbation of immunoglobulin A nephropathy after coronavirus disease 2019 vaccination. CONCLUSIONS: In our case, gross hematuria served as a trigger for immunoglobulin A nephropathy diagnosis, suggesting that nephrologists should pay close attention to gross hematuria and urinalysis after coronavirus disease 2019 vaccination.

Shoulder injury related to vaccine administration (SIRVA) after COVID-19 vaccination. OBJECTIVE: The global fight against COVID-19 has required mass vaccination clinics as well as mass recruitment of personnel, including many who may not regularly administer intramuscular deltoid immunizations, potentially increasing the incidence of improper intramuscular injection. Shoulder injury related to vaccine administration (SIRVA) is a well-described, preventable injury resulting from improper injection into anatomic structures adjacent to the deltoid muscle leading to mechanical and chemical trauma augmented by an inflammatory immune response to the vaccine and/or adjuvants. SIRVA is best described in the setting of influenza vaccination, and little is known about it as it pertains to COVID-19 vaccination. This study aims to describe SIRVA in the current pandemic, increase clinician awareness, and offer considerations for prevention. METHODS: To identify clinical characteristics of patients with post-COVID-19-vaccination shoulder injuries, we performed a systematic review of the cases of vaccination-related shoulder injuries reported in the literature and conducted a review of the public Vaccine Adverse Event Reporting System (VAERS). RESULTS: We identified 305 cases of SIRVA in the VAERS database and 28 cases of SIRVA in the setting of COVID-19 vaccination from the literature (nÂ =Â 333). Patients had a mean age of 51.8Â years and a median of 51.5 (range: 19-90) years. Of these, 76.3% were female and 23.7% male. Most patients sought medical evaluation with 54 of the 305 VAERS cases reporting utilizing emergency services. Of patients with imaging-confirmed SIRVA (nÂ =Â 95), the most common diagnoses were adhesive capsulitis and bursitis, and the most common symptoms were pain (97.7%) and limited range of motion (68.1%). Most patients reported requiring treatment with the majority receiving physical therapy (56.3%), followed by cortisone injection (34.4%). Other modalities used were non-steroidal anti-inflammatory drugs, oral steroids, and surgery. Only 5 patients from this group reported recovery while 60 stated they had not yet recovered. Of those, 23.3% reported disability. CONCLUSION: SIRVA should be regarded as an under-reported, significant cause of post-vaccination morbidity. In the setting of COVID-19 mass vaccination, clinicians must be aware of signs and symptoms of SIRVA as well as appropriate diagnostic modalities and treatment options. Additionally, standardization and proper education regarding injection technique and appropriate needle length is imperative to reducing harm.

Correspondence on "Safety of vaccination against SARS-CoV-2 in people with rheumatic and musculoskeletal diseases: results from the EULAR Coronavirus Vaccine (COVAX) physician-reported registry" by Machado et al.

Disease flare in patients with dermatomyositis following COVID-19 vaccination.

Risk of acute liver injury following the mRNA (BNT162b2) and inactivated (CoronaVac) COVID-19 vaccines. BACKGROUND & AIMS: Case reports of severe acute liver injury (ALI) following COVID-19 vaccination have recently been published. We evaluated the risks of ALI following COVID-19 vaccination (BNT162b2 or CoronaVac). METHODS: We conducted a modified self-controlled case series analysis using the vaccination records in Hong Kong with data linkage to electronic medical records from a territory-wide healthcare database. Incidence rate ratios (IRRs) for ALI outcome in the 56-day period following first and second doses of COVID-19 vaccines in comparison to the non-exposure period were estimated and compared to the ALI risk in patients with SARS-CoV-2 infection. RESULTS: Among 2,343,288 COVID-19 vaccine recipients who were at risk, 4,677 patients developed ALI for the first time between 23(rd) February 2021 to 30(th) September 2021. The number of ALI

cases within 56 days after the first and second dose of vaccination were 307 and 521 (335 and 334 per 100,000 person-years) for BNT162b2, and 304 and 474 (358 and 403 per 100,000 person-years) for CoronaVac, respectively, compared to 32,997 ALI cases per 100,000 person-years among patients within 56 days of SARS-CoV-2 infection. Compared to the non-exposure period, no increased risk was observed in the 56-day risk period for first (IRR 0.800; 95% CI 0.680-0.942) and second (IRR 0.944; 95% CI 0.816-1.091) dose of BNT162b2, or first (IRR 0.689; 95% CI 0.588-0.807) and second (IRR 0.905; 95% CI 0.781-1.048) dose of CoronaVac. There were no severe or fatal cases of ALI following COVID-19 vaccination. CONCLUSION: There was no evidence of an increased risk of ALI associated with BNT162b2 or CoronaVac vaccination. Based on all current available evidence from previous studies and our study, the benefit of mass vaccination far outweighs the ALI risk from vaccination. LAY SUMMARY: There have been some recent reports that COVID-19 vaccination could be associated with acute liver injury. In our study, we found no evidence that COVID-19 vaccination increased the risk of acute liver injury, which was much more common after SARS-CoV-2 infection than after vaccination. Hence, our study provides further data indicating that the benefits of mass COVID-19 vaccination outweigh the potential risks.

Immune-mediated liver injury represented as overlap syndrome after SARS-CoV-2 vaccination.

Did it hurt? COVID-19 vaccination experience in people with multiple sclerosis. BACKGROUND: Current guidelines recommend vaccination against SARS-CoV2 for people with multiple sclerosis (pwMS). The long-term review of the safety and effectiveness of COVID-19 vaccines in pwMS is limited. METHODS: Service re-evaluation. PwMS using the MS service at Barts Health National Health Service Trust were sent questionnaires via email to report symptoms following first and second COVID-19 vaccinations (nÂ =Â 570). A retrospective review of electronic health records was conducted for clinical and safety data post-vaccination(s); cut-off was end of September 2021. Separate logistic regressions were carried out for symptoms experienced at each vaccination. Two sets of regressions were fitted with covariates: (i) Disease-modifying therapy type and (ii) patient characteristics for symptoms experienced. RESULTS: 193/570 pwMS responded. 184 pwMS had both vaccinations. 144 received the AZD1222 and 49 the BNT162b2 vaccine. 87% and 75% of pwMS experienced any symptoms at first and second vaccinations, respectively. The majority of symptoms resolved within a short timeframe. No severe adverse effects were reported. Two pwMS subsequently died; one due to COVID-19 and one due to aspiration pneumonia. Males were at a reduced risk of reporting symptoms at first vaccination. There was evidence that pwMS in certain treatment groups were at reduced risk of reporting symptoms at second vaccination only. CONCLUSIONS: Findings are consistent with our preliminary data. Symptoms post-vaccination were similar to the non-MS population and were mostly temporary. It is important to inform the MS community of vaccine safety data.

Radiation recall dermatitis induced by COVID-19 vaccination in breast cancer patients treated with postoperative radiation therapy. BACKGROUND: and purpose: Radiation recall dermatitis is an adverse event predominantly due to systemic therapy administration after a previous radiation therapy course. Few case reports describe radiation recall dermatitis in breast cancer patients treated with postoperative radiation therapy following COVID-19 vaccination. In this study we investigated the incidence and severity of radiation recall dermatitis after COVID-19 vaccination in irradiated breast cancer patients. METHODS: Patients that received at least one COVID-19 vaccination dose during the year after the end of postoperative breast radiation therapy were included in this observational monocentric study. Local symptoms occurring inside the radiation field after vaccination were patient-reported and scored according to the PRO-CTCAE questionnaire. Descriptive data of radiation recall dermatitis incidence and severity, and potential risk factors were evaluated. RESULTS: A cohort of 361 patients with 756 administered COVID-19 vaccinations was analyzed. Breast

symptoms were reported by 7.5% of patients, while radiation recall dermatitis was considered for 5.5%. The incidence of radiation recall dermatitis per single dose of vaccine was 2.6%, with a higher risk for the first dose compared to the second/third (4.4% vs 1%, pÂ =Â 0.003), especially when administered within the first month after the end of irradiation (12.5% vs 2.2%, pÂ =Â 0.0004). Local symptoms were generally self-limited and a few cases required anti-inflammatory drugs. CONCLUSIONS: Radiation recall dermatitis is an uncommon but not rare phenomenon in breast cancer patients that received COVID-19 vaccination within one year after breast irradiation. However, symptoms severity were generally low/mild and reversible. These findings can be useful for patient counseling.

Misinformation About COVID-19 Vaccines on Social Media: Rapid Review. BACKGROUND: The development of COVID-19 vaccines has been crucial in fighting the pandemic. However, misinformation about the COVID-19 pandemic and vaccines is spread on social media platforms at a rate that has made the World Health Organization coin the phrase infodemic. False claims about adverse vaccine side effects, such as vaccines being the cause of autism, were already considered a threat to global health before the outbreak of COVID-19. OBJECTIVE: We aimed to synthesize the existing research on misinformation about COVID-19 vaccines spread on social media platforms and its effects. The secondary aim was to gain insight and gather knowledge about whether misinformation about autism and COVID-19 vaccines is being spread on social media platforms. METHODS: We performed a literature search on September 9, 2021, and searched PubMed, PsycINFO, ERIC, EMBASE, Cochrane Library, and the Cochrane COVID-19 Study Register. We included publications in peer-reviewed journals that fulfilled the following criteria: original empirical studies, studies that assessed social media and misinformation, and studies about COVID-19 vaccines. Thematic analysis was used to identify the patterns (themes) of misinformation. Narrative qualitative synthesis was undertaken with the guidance of the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 Statement and the Synthesis Without Meta-analysis reporting guideline. The risk of bias was assessed using the Joanna Briggs Institute Critical Appraisal tool. Ratings of the certainty of evidence were based on recommendations from the Grading of Recommendations Assessment, Development and Evaluation Working Group. RESULTS: The search yielded 757 records, with 45 articles selected for this review. We identified 3 main themes of misinformation: medical misinformation, vaccine development, and conspiracies. Twitter was the most studied social media platform, followed by Facebook, YouTube, and Instagram. A vast majority of studies were from industrialized Western countries. We identified 19 studies in which the effect of social media misinformation on vaccine hesitancy was measured or discussed. These studies implied that the misinformation spread on social media had a negative effect on vaccine hesitancy and uptake. Only 1 study contained misinformation about autism as a side effect of COVID-19 vaccines. CONCLUSIONS: To prevent these misconceptions from taking hold, health authorities should openly address and discuss these false claims with both cultural and religious awareness in mind. Our review showed that there is a need to examine the effect of social media misinformation on vaccine hesitancy with a more robust experimental design. Furthermore, this review also demonstrated that more studies are needed from the Global South and on social media platforms other than the major platforms such as Twitter and Facebook. TRIAL REGISTRATION: PROSPERO International Prospective Register of Systematic Reviews CRD42021277524; https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021277524. INTERNATIONAL REGISTERED REPORT IDENTIFIER (IRRID): RR2-10.31219/osf.io/tyevj.

SARS-CoV-2 vaccines in children and adolescents: Can immunization prevent hospitalization? The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and its variants of concern can infect people of all ages and can cause severe diseases in children, such as encephalitis, which require

intensive care. Therefore, vaccines are urgently required to prevent severe disease in all age groups. We reviewed the safety and efficacy profiles of mRNA vaccines-BNT162b2 and mRNA-1273-demonstrated by clinical trials or observed in the real world. mRNA-1273 is effective in preventing SARS-CoV-2 infection in preschool children (6 months-6 years old). Both BNT162b2 and mRNA-1273 are effective in preventing SARS-CoV-2 infection in school-aged children and adolescents, thereby preventing post-coronavirus disease (COVID) conditions. The common side effects of vaccination are pain at the injection site, fatigue, and headache. Myocarditis and pericarditis are uncommon. Monitoring post-vaccination troponin levels may help prevent severe cardiac events. The SARS-CoV-2 coronavirus mutates its genome to overcome the herd immunity provided by mass vaccinations; therefore, we may need to develop new generations of vaccines, such as those using viral nucleocapsid proteins as antigens. In conclusion, the mRNA vaccines are generally safe and effective in preventing severe diseases and hospitalization among children and adolescents.

Immunogenicity and reactogenicity against the SARS-CoV-2 variants following heterologous primary series involving CoronaVac, ChAdox1 nCov-19 and BNT162b2 plus BNT162b2 booster vaccination: An open-label randomized study in healthy Thai adults. We evaluated the immunogenicity and reactogenicity of heterologous COVID-19 primary schedules involving BNT162b2 (Pfizer-BioNTech), ChAdOx1 nCoV-19 (AstraZeneca) and CoronaVac (Sinovac) in healthy adults, as well as booster response to BNT162b2 following heterologous CoronaVac and ChAdOx1 nCoV-19 regimens. Participants were randomized to one of seven groups that received two-dose homologous BNT162b2 or heterologous combinations of CoronaVac, ChAdOx1 nCoV-19 and BNT162b2, with 4â€‰weeks interval. A total of 210 participants were enrolled, 30 in each group. Median age of participants was 38 (19-60) years, and 108/210 (51.43%) were female. Overall adverse events after the second dose were mild to moderate. We found that groups that received BNT162b2 as second dose induced the highest anti-receptor binding domain IgG response against the ancestral strain [BNT162b2: geometric mean concentration (GMC) 2133-2249 BAU/mL; ChAdOx1 nCoV-19: 851-1201; CoronaVac: 137-225 BAU/mL], neutralizing antibodies (NAb) against Beta and Delta, and interferon gamma response. All groups induced low to negligible NAb against Omicron after second dose. A BNT162b2 booster (third dose) following heterologous CoronaVac and ChAdOx1 nCoV-19 regimens induced >140-fold increase in NAb titers against Omicron. Our findings indicate that heterologous regimens using BNT162b2 as the second dose may be an alternative schedule to maximize immune response. While heterologous two-dose schedules induced low NAb against Omicron, the use of an mRNA vaccine booster dose substantially increased the Omicron response. These findings are relevant for low-income countries considering heterologous primary and booster COVID-19 vaccine schedules.

Unusual arm vein thrombosis after the Moderna (mRNA-1273) COVID-19 vaccination-a case report. BACKGROUND: Since 2019, all over the world is still suffering from managing never-experienced pandemic era of coronavirus-2019 (COVID-19). Prompt development and administration of vaccines contributed lowering severity of the disease, but adverse events related to vaccination were also reported. Exact association between each adverse conditions and vaccination or COVID-19 infection are being investigated. CASE DESCRIPTION: A 44-year-old Asian male developed right upper arm diffuse swelling 4 days after receiving the third dose of messenger ribonucleic acid (mRNA)-1273 COVID-19 vaccine in his left deltoid muscle. He was previously healthy, but has history of COVID-19 infection 4 months before the third dose vaccination. Venous duplex ultrasound revealed acute thrombosis in the right cephalic arch, axillary vein, and subclavian vein. There were no abnormal laboratory test results. After 3 months of anticoagulation therapy, arm vein thrombosis was completely resolved upon follow-up duplex ultrasonography. CONCLUSIONS: Although, positive COVID-19 polymerase chain reaction (PCR) history might be associated with potential cause of this unusual arm vein thrombosis, we postulate that a possible cause may be secondary to his third dose

of mRNA-1273 vaccine given the onset and no prior medical comorbidities. Since the previous studies was mostly done based on mRNA vaccines of other manufacturers rather than Moderna, exact thrombosis mechanism of this case was not established yet. Contralateral arm vein thrombosis is unique to report, and future comprehensive studies are needed.

Comparative assessment of myocarditis and pericarditis reporting rates related to mRNA COVID-19 vaccines in Europe and the United States. OBJECTIVES: The novel mRNA vaccines proved to be safe and effective in averting severe COVID-19. Vaccine-related complications recorded by pharmacovigilance systems, such as 'EudraVigilance' in Europe and 'VAERS' in the United States (US), rarely include myocarditis and pericarditis. Given the novelty of the platform and the increasing global-scale vaccine production needs, we assessed their reporting rates comparatively across continents. METHODS: Data of myocarditis and pericarditis cases post COVID-19 vaccination reported from week 52/2020 (December 21 to 27, 2020) to week 40/2021 (October 4 to 10, 2021) were collected for mRNA vaccines from EudraVigilance and VAERS. The corresponding administered vaccine doses were used as denominators to estimate reporting rates for comparison purposes. Cross-tabulation analysis was employed to compare the reporting rates of mRNA vaccines-associated myocarditis and pericarditis between EudraVigilance and VAERS. RESULTS: Low reporting rates of myocarditis (7.64/million vaccine doses) and pericarditis (5.32/million) were found, with higher rates of both disorders in EudraVigilance compared to VAERS; these differences were more pronounced post-mRNA-1273 (5-6-fold, p=0.000 for myocarditis and p<0.001 for pericarditis) than post-BNT162b2 vaccination (1.5-2-fold, p<0.001 for both conditions). Most myocarditis cases occurred in males <30Â years. Pericarditis affected predominantly males <40 and both sexes >40Â years. The extremely rare fatalities related to myocarditis (0.102/million) or pericarditis (0.017/million) were also higher in EudraVigilance versus VAERS. CONCLUSIONS: Understanding the underlying causes of the observed differences could provide guidance for the enhanced quality of mRNA vaccines that would also foster vaccine acceptance.

Recurrent Myocarditis Following COVID-19 Infection and the mRNA Vaccine. COVID-19 infection has cardiovascular manifestations such as acute myocarditis, arrhythmia, ischemic cardiomyopathy, heart failure, pericardial effusion, cardiac tamponade, andÂ thromboembolism. The COVID-19 mRNA vaccinesÂ BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and viral vector vaccine Ad26.COV2.S (Johnson & Johnson - Janssen) were initially approved for emergency authorized use by the US-FDA. Cases of myocarditis were reported primarily in adolescents and young adults after administration of COVID-19 mRNA vaccines, with the subsequent emergence of cases of myocarditis after administration of viral vectorÂ vaccine Ad26.COV2.S. A majority of these cases were observed after the second dose of the mRNA vaccine. This case report demonstratesÂ the occurrence of symptomatic myocarditis in a patient during acute COVID-19 infection, followed by recurrence of symptoms after the first dose of mRNA COVID-19 vaccine and subsequent recurrence of cardiac MRI-proven myocarditis after the second dose of mRNA COVID-19 vaccine.Â This case stands out due to the occurrence of symptoms with COVID-19 infection and after vaccination, suggesting possible incomplete interval resolution of infection-related myocarditis.

Correspondence on "paroxysmal supra-ventricular ventricular tachycardia after COVID-19 vaccine injection".

Two cases of acute respiratory failure following SARS-CoV-2 vaccination in post-COVID-19 pneumonia. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination is a very effective method of preventing infection and is recommended for people having recovered from coronavirus disease 2019 (COVID-19). In this novel case report, we describe two patients with post-COVID-19 pneumonia who experienced acute respiratory failure and new bilateral ground-glass opacities several days after receiving SARS-CoV-2 vaccination. Both patients were treated with

methylprednisolone pulse therapy and recovered from the disease successfully. Indeed, post-COVID-19 patients can gain benefits from the vaccine, but vaccination at the early stage of recovery from COVID-19 might be a risk for certain populations. These cases highlight a potential association between vaccination, interstitial lung disease and worsening of post-COVID-19 pneumonia. Further investigation and research examining the relationship between the timing of SARS-CoV-2 vaccination and potential risks in post-COVID-19 patients is recommended.

Esophagitis after administration of the 1273-RNAm SARS-CoV-2 vaccine.

COVID-19 vaccines for the older population: safety and efficacy go hand in hand.

Antibody and cellular immune responses following dual COVID-19 vaccination within infection-naive residents of long-term care facilities: an observational cohort study. BACKGROUND: Older age and frailty are risk factors for poor clinical outcomes following SARS-CoV-2 infection. As such, COVID-19 vaccination has been prioritised for individuals with these factors, but there is concern that immune responses might be impaired due to age-related immune dysregulation and comorbidity. We aimed to study humoral and cellular responses to COVID-19 vaccines in residents of long-term care facilities (LTCFs). METHODS: In this observational cohort study, we assessed antibody and cellular immune responses following COVID-19 vaccination in members of staff and residents at 74 LTCFs across the UK. Staff and residents were eligible for inclusion if it was possible to link them to a pseudo-identifier in the COVID-19 datastore, if they had received two vaccine doses, and if they had given a blood sample 6 days after vaccination at the earliest. There were no comorbidity exclusion criteria. Participants were stratified by age (<65 years or â‰¥65 years) and infection status (previous SARS-CoV-2 infection [infection-primed group] or SARS-CoV-2 naive [infection-naive group]). Anticoagulated edetic acid (EDTA) blood samples were assessed and humoral and cellular responses were quantified. FINDINGS: Between Dec 11, 2020, and June 27, 2021, blood samples were taken from 220 people younger than 65 years (median age 51 years [IQR 39-61]; 103 [47%] had previously had a SARS-CoV-2 infection) and 268 people aged 65 years or older of LTCFs (median age 87 years [80-92]; 144 [43%] had a previous SARS-CoV-2 infection). Samples were taken a median of 82 days (IQR 72-100) after the second vaccination. Antibody responses following dual vaccination were strong and equivalent between participants younger then 65 years and those aged 65 years and older in the infection-primed group (median 125â€ˆ285 Au/mL [1128 BAU/mL] for <65 year olds vs 157â€ˆ979 Au/mL [1423 BAU/mL] for â‰¥65 year olds; p=0Â·47). The antibody response was reduced by 2Â·4-times (467 BAU/mL; pâ‰¤0Â·0001) in infection-naive people younger than 65 years and 8Â·1-times (174 BAU/mL; pâ‰¤0Â·0001) in infection-naive residents compared with their infection-primed counterparts. Antibody response was 2Â·6-times lower in infection-naive residents than in infection-naive people younger than 65 years (p=0Â·0006). Impaired neutralisation of delta (1.617.2) variant spike binding was also apparent in infection-naive people younger than 65 years and in those aged 65 years and older. Spike-specific T-cell responses were also significantly enhanced in the infection-primed group. Infection-naive people aged 65 years and older (203 SFU per million [IQR 89-374]) had a 52% lower T-cell response compared with infection-naive people younger than 65 years (85 SFU per million [30-206]; pâ‰¤0Â·0001). Post-vaccine spike-specific CD4 T-cell responses displayed single or dual production of IFN-Î³ and IL-2 were similar across infection status groups, whereas the infection-primed group had an extended functional profile with TNFÎ± and CXCL10 production. INTERPRETATION: These data reveal suboptimal post-vaccine immune responses within infection-naive residents of LTCFs, and they suggest the need for optimisation of immune protection through the use of booster vaccination. FUNDING: UK Government Department of Health and Social Care.

The Impact of Vaccination Against SARS-CoV-2 Virus on the Outcome of COVID-19 Disease. BACKGROUND: Coronavirus disease 2019 (COVID-19) is a rapidly spreading infection that is on the rise. New variants are continuously appearing with variable degrees of lethality and infectivity. The

extensive work since the start of the pandemic has led to the evolution of COVID-19 vaccines with varying mechanisms. We aim to determine real-world data by looking at the different clinical outcomes associated with COVID-19 vaccination, focusing on the rate of hospitalization, severity, and mortality. METHODOLOGY: A retrospective observational study included 624 patients with COVID-19 infection who were hospitalized at King Fahad Hospital of the University and King Fahad Military Medical City between April and July 2021. The cohort was divided into 3 groups: unvaccinated, partially vaccinated (PV), and fully vaccinated (FV). The severity and outcome of COVID-19 disease were compared among the three groups. Among the vaccinated group, we studied the effect of vaccine type on the severity and outcome of COVID-19 disease. RESULTS: We found that 70.4% of patients with COVID-19 disease who required hospitalization were unvaccinated. Un-vaccination was a significant predictor of critical COVID-19 disease (OR 2.31; P <0.001), whereas full vaccination was associated with significantly milder disease severity (OR 0.36; P 0.01). Moreover, un-vaccination status was an independent predictor of longer hospitalization (OR 3.0; P <0.001), a higher requirement for ICU admission (OR 4.7; P <0.001), mechanical ventilation (OR 3.6; P <0.001), and death (OR 4.8; P <0.001), whereas the FV group had a lower risk of ICU admission (OR 0.49; P 0.045). Unvaccinated patients with comorbidities had worse severity and outcome of COVID-19 infection (P<0.05). Both vaccine types (Pfizer and AstraZeneca) had similar protective effects against the worst outcomes of COVID-19 disease. CONCLUSION: COVID-19 vaccination has been shown to be effective in reducing hospitalization, the severity of COVID-19 infection, and improving outcomes, especially in high-risk group patients. COVID-19 vaccination programs should continue to improve the outcome of such a disease.

An autopsy case report of fulminant myocarditis: Following mRNA COVID-19 vaccination. There have been few case reports on fatal outcomes in patients with acute myocarditis after mRNA coronavirus disease 2019 (COVID-19) vaccination. In most cases of myocarditis after mRNA COVID-19 vaccination, the myocarditis is mild, and the prognosis is good. Here we report an autopsy case of fulminant myocarditis following mRNA COVID-19 vaccination. LEARNING OBJECTIVE: The global distribution of the mRNA coronavirus disease 2019 vaccine requires consideration of appropriate treatment for postvaccination myocarditis. Eosinophil-mediated immunological injury to cardiomyocytes can be involved in the cause of fulminant inflammation from the pathological findings of postvaccination myocarditis.

Seroconversion and outcomes after initial and booster COVID-19 vaccination in adults with hematologic malignancies. BACKGROUND: Patients with hematologic malignancies have impaired humoral immunity secondary to their malignancy and its treatment, placing them at risk of severe coronavirus disease-19 (COVID-19) infection and reduced response to vaccination. METHODS: The authors retrospectively analyzed serologic responses to initial and booster COVID-19 vaccination in 378 patients with hematologic malignancy and subsequently tracked COVID-19-related outcomes. RESULTS: Seroconversion occurred in 181 patients (48%) after initial vaccination; patients who had active malignancy or those who were recently treated with a B-cell-depleting monoclonal antibody had the lowest rates of seroconversion. For initial nonresponders to vaccination, seroconversion after a booster dose occurred in 48 of 85 patients (56%). The seroconversion rate after the booster was similar for patients on (53%) and off (58%) active therapy (pÂ =Â .82). Thirty-three patients (8.8%) developed a COVID-19 infection, and there were three COVID-19-related deaths (0.8%). Although no significant association was observed between postvaccination seroconversion and the incidence of COVID-19 infection, no patient with seroconversion died from COVID-19, and no patient who received tixagevimab/cilgavimab (NÂ =Â 25) was diagnosed with a COVID-19 infection. CONCLUSIONS: Booster vaccinations can promote seroconversion in a significant proportion of patients who are seronegative after the initial vaccination course regardless of the specific vaccine or

on/off treatment status at the time of revaccination. Although postvaccination seroconversion may not be associated with a decrease in any (including asymptomatic) COVID-19 infection, the authors' experience suggested that effective vaccination (including a booster), supplemented by passive immunization using tixagevimab/cilgavimab in case of lack of seroconversion, effectively eliminated the risk of COVID-19 death in the otherwise high-risk population. LAY SUMMARY: Patients with hematologic malignancy, especially lymphoma, have an impaired response to coronavirus disease 2019 (COVID-19) vaccination. In this single-institution review, less than one half of the patients studied made detectable antibodies. For those who did not make detectable antibodies after initial vaccination, over one half (65%) were able to produce antibodies after booster vaccination. By the end of February 2022, 33 of the original 378 patients had a documented COVID-19 infection. The only deaths from COVID-19 were in those who had undetectable antibodies, and no patient who received prophylactic antibody therapy developed a COVID-19 infection.

Postherpetic granulomatous dermatitis and herpes zoster necroticans triggered by Covid-19 vaccination.

Generalized morphea following the COVID vaccine: A series of two patients and a bibliographic review. The appearance of morphea after vaccination has been reported to date as single and deep lesions that appear exactly at the site of the skin puncture. It was therefore postulated that the origin could be the trauma related to the injection. The aim of this article is to review the various hypotheses offered in the published literature about generalized morphea following vaccination. We present two cases of generalized morphea after COVID-19 vaccination and review the published literature on immune-related cutaneous reactions. As previously reported, antigenic cross-reactivity between vaccine spike proteins and human tissues could cause certain immune-mediated diseases, including generalized morphea. Herein we report two cases of generalized morphea probably induced by the COVID-19 vaccine, given the temporal relationship with its administration. In summary, environmental factors such as vaccination against SARS-COV-2 could induce an immune system dysregulation, which would have an important role in the pathogenesis of morphea. We present two cases of generalized morphea probably induced by the COVID-19 vaccine, given the time elapsed between vaccination and the onset of the skin lesions.

Shoulder Injury Related to Vaccine Administration (SIRVA) in 16 Patients Following COVID-19 Vaccination Who Presented to Chiropractic, Orthopedic, and Physiotherapy Clinics in Hong Kong During 2021. BACKGROUND Shoulder injury related to vaccine administration (SIRVA) occurs when an intramuscular deltoid injection is administered into the shoulder joint. This observational study describes clinical features in 16 patients with SIRVA following Coronavirus 2019 (COVID-19) vaccination who presented to chiropractic, orthopedic, and physiotherapy clinics in Hong Kong between January 1, 2021, and January 1, 2022. MATERIAL AND METHODS Adults age â‰¥18 with new-onset shoulder pain and imaging-confirmed shoulder pathology were retrospectively identified from 35 clinics. Patient demographics and clinical and vaccination details were extracted from the electronic medical record. Shoulder injury was determined by correlating clinical and imaging features. RESULTS Of 730 patients with shoulder pain, 16 SIRVA cases (mean age, 49Â±10 years, 75% female) were identified; (12/16, 75%) of patients received the Pfizer-BioNTech vaccine while (4/16, 25%) received Sinovac-CoronaVac. The most common diagnosis was adhesive capsulitis (10/16, 63%), followed by bursitis (3/16, 19%) and supraspinatus tear (3/16, 19%). Mean symptom onset was 3.5Â±2.5 days post-vaccination, and always occurred after the 2nd or 3rd vaccination, involving reduced shoulder range of motion (ROM). Mean baseline pain was 8.1Â±1 (out of 10). All patients received conservative care (eg, exercise, manual therapies). At 3-month follow-up, mean pain reduced to 2.4Â±1.4; all patients had normal shoulder ROM. CONCLUSIONS In the past 2 years, millions of intramuscular COVID-19 vaccinations have been administered. It is important that

clinicians are aware of SIRVA as a cause of new symptoms of shoulder injury and should ask the patient about recent vaccinations, including for COVID-19.

Safety and immunogenicity of COVID-19 vaccination in patients with hepatocellular carcinoma (CHESS-NMCID 2101): A multicenter prospective study. Data on safety and immunogenicity of coronavirus disease 2019 (COVID-19) vaccinations in hepatocellular carcinoma (HCC) patients are limited. In this multicenter prospective study, HCC patients received two doses of inactivated whole-virion COVID-19 vaccines. The safety and neutralizing antibody were monitored. Totally, 74 patients were enrolled from 10 centers in China, and 37 (50.0%), 25 (33.8%), and 12 (16.2%) received the CoronaVac, BBIBP-CorV, and WIBP-CorV, respectively. The vaccines were well tolerated, where pain at the injection site (6.8% [5/74]) and anorexia (2.7% [2/74]) were the most frequentÂ local and systemic adverse events. The median level of neutralizing antibody was 13.5 (interquartile range [IQR]: 6.9-23.2)â€‰AU/ml at 45 (IQR: 19-72) days after the second dose of vaccinations, and 60.8% (45/74) of patients had positive neutralizing antibody. Additionally, lower Î³-glutamyl transpeptidase level was related to positive neutralizing antibody (odds ratioâ€‰=â€‰1.022 [1.003-1.049], pâ€‰=â€‰0.049). In conclusion, this study found that inactivated COVID-19 vaccinations are safe and the immunogenicity is acceptable or hyporesponsive in patients with HCC. Given that the potential benefits may outweigh the risks and the continuing emergences of novel severe acute respiratory syndrome coronavirus 2 variants, we suggest HCC patients to be vaccinated against COVID-19. Future validation studies are warranted.

Neutralizing antibody responses against SARS-CoV-2 in patients with plasma cell disorders who are on active treatment after two doses of mRNA vaccination. Many patients with plasma cell disorder (PCD) on active treatment with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) require hospitalization, with an increased mortality rate over healthy adults. The FDA approved two mRNA vaccines against SARS-CoV-2: BNT162b2 and mRNA-1273. To assess the efficacy of vaccination in patients with PCD, retrospectively, we identified all patients on active treatment. A total of 149 patients were included. Neutralizing antibodies (NAbs) levels against SARS-CoV-2 adequate, intermediate, and no response were observed in 42%, 32%, and 26%, respectively. Low NAbs were seen in patients on daratumumab combinations or anti-BCMA therapy, low lymphocytes, and low IgG levels. Twenty-three (15%) patients have SARS CoV-2, while 8% required hospitalization, majority of these patients had intermediate or no response based on NAbs levels. Therefore, checking NAbs may be clinically helpful in identifying patients' responses. Further prospective studies should ascertain the value of a third vaccine dose in this population.

Variability of eliciting thresholds in PEG allergy limits prediction of tolerance to PEG-containing mRNA COVID vaccines.

Safety and immunogenicity of intramuscular, single-dose V590 (rVSV-SARS-CoV-2 Vaccine) in healthy adults: Results from a phase 1 randomised, double-blind, placebo-controlled, dose-ranging trial. BACKGROUND: Vaccines against COVID-19 are needed to overcome challenges associated with mitigating the global pandemic. We report the safety and immunogenicity of V590, a live recombinant vesicular stomatitis virus-based COVID-19 vaccine candidate. METHODS: In this placebo-controlled, double-blind, three-part phase 1 study, healthy adults were randomised to receive a single intramuscular dose of vaccine or placebo. In Part 1, younger (18-54 years) and, in Part 2, older (â‰¥55 years) adults seronegative for SARS-CoV-2 nucleocapsid received one of four V590 dose levels (5.00Â Ã—Â 10(5); 2.40Â Ã—Â 10(6); 1.15Â Ã—Â 10(7); or 5.55Â Ã—Â 10(7) plaque-forming units [pfu]) or placebo. In Part 3, a single V590 dose level (5.55Â Ã—Â 10â•· pfu) or placebo was administered to younger SARS-CoV-2 seropositive adults. Primary endpoints included adverse events (AEs) and for Parts 1 and 2 anti-SARS-CoV-2 serum neutralising antibody responses measured by 50% plaque reduction neutralisation (PRNT50) assay at Day 28. Registration NCT04569786 [P001-02].

FINDINGS: 232 participants were randomised and 219 completed the study. In seronegative participants, anti-SARS-CoV-2 spike-specific antibody responses to V590 were low and comparable to placebo across the lower dose levels. At the highest dose level (5.55Â Ã—Â 10(7) pfu), anti-SARS-CoV-2 spike-specific PRNT50 was 2.3-fold higher than placebo. The most frequently reported AEs were injection-site pain (38.4%), headache (15.1%) and fatigue (13.4%). INTERPRETATION: V590 was generally well-tolerated. However, Day 28 anti-SARS-Cov-2 spike-specific antibody responses in seronegative participants following a single intramuscular administration of V590 were not sufficient to warrant continued development. FUNDING: The study was funded by Merck Sharp & Dohme LLC., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

Clinical and Immunological Features of SARS-CoV-2 Breakthrough Infections in Vaccinated Individuals Requiring Hospitalization. BACKGROUND AND PURPOSE: Waning immunity and the surge of SARS-CoV-2 variants are responsible for breakthrough infections, i.e., infections in fully vaccinated individuals. Although the majority of vaccinated infected subjects report mild or no symptoms, some others require hospitalization. The clinical and immunological features of vaccinated hospitalized COVID-19 patients are currently unknown. METHODS: Twenty-nine unvaccinated and 36 vaccinated hospitalized COVID-19 patients were prospectively enrolled and clinical and laboratory data were gathered. Immunophenotyping of leukocytes' subsets, T and B cell SARS-CoV-2-specific responses were evaluated via flow cytometry. Anti-IFN-Î± autoantibodies were measured via ELISA. RESULTS: Despite vaccinated patients were older and with more comorbidities, unvaccinated subjects showed higher levels of pro-inflammatory markers, more severe disease, and increased mortality rate. Accordingly, they presented significant alterations in the circulating leukocyte composition, typical of severe COVID-19. Vaccinated patients displayed higher levels of anti-Spike IgGs and Spike-specific B cells. Of all participants, survivors showed higher levels of anti-Spike IgGs and Spike-specific CD4+â€‰T cells than non-survivors. At hospital admission, 6 out of 65 patients (9.2%) displayed high serum concentrations of autoantibodies targeting IFN-Î±. Remarkably, 3 were unvaccinated and eventually died, while the other 3 were vaccinated and survived. CONCLUSION: Despite more severe pre-existing clinical conditions, vaccinated patients have good outcome. A rapid activation of anti-SARS-CoV-2-specific immunity is fundamental for the resolution of the infection. Therefore, prior immunization through vaccination provides a significant contribution to prevention of disease worsening and can even overcome the presence of high-risk factors (i.e., older age, comorbidities, anti-IFN-Î± autoantibodies).

Type 1 diabetes mellitus following SARS-CoV-2 mRNA vaccination. PURPOSE: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccines have been reported to trigger immune side effects. Type 1 diabetes as a manifestation of autoimmune/inflammatory syndrome induced by adjuvants has been reported in a limited number of cases after vaccinations. A few type 1 diabetes cases after SARS-CoV-2 vaccination have been reported. This study aims to report type 1 diabetes cases associated with the mRNA-based SARS-CoV-2 vaccination. METHODS: We report four cases of type 1 diabetes mellitus after mRNA-based SARS-CoV-2 vaccine, BNT162b2 (Pfizer-BioNTech). In the medical history, one subject had autoimmune thyroid disease. All patients had autoantibodies against glutamate decarboxylase. RESULTS: In the presented case series, type 1 diabetes developed a few weeks after BNT162b2 vaccination. After developing type 1 diabetes, the insulin dose requirements of all patients decreased rapidly, and the need for insulin therapy in three patients disappeared during follow-up. Acute deterioration of glucose regulation in a patient followed by BNT162b2 administration may be due to vaccine-induced autoimmune diabetes. CONCLUSION: Vaccination with BNT162b2 may trigger type 1 diabetes.

Kinetics of the humoral response 1-year following vaccination with BNT162b2 SARS-CoV-2 vaccine among maintenance hemodialysis patients.

Seroprevalence study prior and post vaccination in cancer patients in principality of Andorra (COVONCO study). BACKGROUND: COVID-19 serologic response in patients with cancer may be lower than in the general population and may be influenced by the type of tumor or anticancer treatment. This study aims to analyze serological response prior and after vaccination of COVID-19 within the oncological population in Andorra. We set out to identify risk factors for a higher or lower serological response. PATIENTS AND METHODS: Observational, unicentric, prospective cohort study of oncologic patients in Andorra. We calculated the seroprevalence of antibodies against SARS-CoV-2 (May 2020-June 2021) and analyzed the main demographic, oncologic features and factors associated with being seropositive. RESULTS: A total of 373 patients were analyzed, mainly with solid tumours (nâ€‰=â€‰334, 89.5%). At baseline, seroprevalence was 13%, increasing during follow-up to 19%; lower seroprevalence was observed in patients with hematologic malignancies (2.6% vs 14.2%; pâ€‰=â€‰0.041) and patients receiving biological therapies (0% vs 15%, pâ€‰=â€‰0.005). In the overall seroprevalence analysis, women (23% vs 11.9%; pâ€‰=â€‰0.006) and tumour-free patients (pâ€‰=â€‰0.034) showed higher seroprevalence. The multivariable analysis showed that odds of being seropositive were higher among women (OR: 2.44, 95% CI 1.28-4.64), and patients who underwent surgery (OR: 3.35, 95% CI 1.10-10.20). About 80% of the cohort received at least one dose of COVID-19 vaccination, showing a higher seroprevalence of patients who received ChAdOx1-S than those who received BNT162b2 (24.4% vs 6.4%: pâ€‰=â€‰0.001). CONCLUSION: The seroprevalence of antibodies against SARS-COV-2 in oncologic patients in Andorra was higher among females and patients who received hormonal therapy and surgery while patients with hematologic malignancies and biologic therapies showed lower seropositivity without finding differences in the type of tumour or anticancer treatment.

Cytotoxic lesions of the corpus callosum after COVID-19 vaccination. A 23-year-old previously healthy man (Patient 1) and a 33-year-old woman with a past history of depression (Patient 2) developed neurological symptoms approximately 1Â week after receipt of the first COVID-19 mRNA vaccination and deteriorated over the next week. Patient 1 reported nausea, headache, a high fever, and retrograde amnesia. Patient 2 reported visual disturbance, headache, dysarthria, a left forearm tremor, dysesthesia of the mouth and distal limbs, and visual agnosia. PCR test results for SARS-CoV-2 were negative. Complete blood cell count, biochemistry, and antibody test and cerebrospinal fluid test findings were unremarkable. Diffusion-weighted and fluid-attenuated inversion recovery MRI of the brain showed a high signal intensity lesion at the midline of the splenium of the corpus callosum compatible with cytotoxic lesions of the corpus callosum (CLOCCs). High-dose intravenous methylprednisolone improved their symptoms and imaging findings. CLOCCs should be considered in patients with neurological manifestation after COVID-19 vaccination.

COVID-19 mRNA vaccines have no effect on endometrial receptivity after euploid embryo transfer. RESEARCH QUESTION: Does the COVID-19 vaccination affect endometrial receptivity after single euploid embryo transfer, measured by sustained implantation rate? DESIGN: A retrospective cohort study analysing two groups of single euploid embryo transfers using own oocytes: one historical cohort of 3272 transfers 1 year before the pandemic; and one comprising 890 transfers in women previously vaccinated with mRNA vaccines against severe acute respiratory syndrome coronavirus 2. The main outcomes were clinical pregnancy rate (CPR) and sustained implantation rate (SIR) per embryo transfer. These outcomes were compared between non-vaccinated and vaccinated women, and women who had received one and two doses. Lastly, vaccinated women were divided into quartiles according to the time from last dose to embryo transfer. RESULTS: Similar CPR and SIR were found between non-vaccinated and vaccinated women, and the odds ratio for both outcomes was not statistically significant after being controlled for potential confounders (OR 0.937, 95% CI 0.695 to 1.265 and OR 0.910, 95% CI 0.648 to 1.227 respectively). Within the vaccinated group, women who

had received one or two doses also had similar outcomes. In addition, no differences were found according to the time interval from vaccination to embryo transfer. CONCLUSION: The administration of mRNA vaccines against COVID-19 had no effect on endometrial receptivity and embryo implantation, regardless of the number of doses and time interval from vaccination to embryo transfer. The potential negative effect of the vaccine on endometrial receptivity and reproductive outcomes is reassuring for patients in the process of undergoing assisted reproductive treatment.

Efficacy and safety of a single dose of casirivimab and imdevimab for the prevention of COVID-19 over an 8-month period: a randomised, double-blind, placebo-controlled trial. BACKGROUND: There is an unmet need for COVID-19 prevention in patient populations who have not mounted or are not expected to mount an adequate immune response to complete COVID-19 vaccination. We previously reported that a single subcutaneous 1200 mg dose of the monoclonal antibody combination casirivimab and imdevimab (CASâ€‰+â€‰IMD) prevented symptomatic SARS-CoV-2 infections by 81Â·4% in generally healthy household contacts of SARS-CoV-2-infected individuals over a 1-month efficacy assessment period. Here we present additional results, including the 7-month follow-up period (months 2-8), providing additional insights about the potential for efficacy in pre-exposure prophylaxis settings. METHODS: This was a randomised, double-blind, placebo-controlled trial done in the USA, Romania, and Moldova in 2020-2021, before the emergence of omicron (B.1.1.529) and omicron-lineage variants. Uninfected and unvaccinated household contacts of infected individuals, judged by the investigator to be in good health, were randomly assigned (1:1) to receive 1200 mg CASâ€‰+â€‰IMD or placebo by subcutaneous injection according to a central randomisation scheme provided by an interactive web response system; randomisation was stratified per site by the test results of a local diagnostic assay for SARS-CoV-2 and age group at baseline. COVID-19 vaccines were prohibited before randomisation, but participants were allowed to receive COVID-19 vaccination during the follow-up period. Participants who developed COVID-19 symptoms during the follow-up period underwent RT-PCR testing. Prespecified endpoints included the proportion of previously uninfected and baseline-seronegative participants (seronegative-modified full analysis set) who had RT-PCR-confirmed COVID-19 in the follow-up period (post-hoc for the timepoints of months 2-5 and 6-8 only) and underwent seroconversion (ie, became seropositive, considered a proxy for any SARS-CoV-2 infections [symptomatic and asymptomatic]; prespecified up to day 57, post-hoc for all timepoints thereafter). We also assessed the incidence of treatment-emergent adverse events. This study is registered with ClinicalTrials.gov, NCT04452318. FINDINGS: From July 13, 2020, to Oct 4, 2021, 2317 participants who were RT-PCR-negative for SARS-CoV-2 were randomly assigned, of whom 1683 (841 assigned to CASâ€‰+â€‰IMD and 842 assigned to placebo) were seronegative at baseline. During the entirety of the 8-month study, CASâ€‰+â€‰IMD reduced the risk of COVID-19 by 81Â·2% (nominal p<0Â·0001) versus placebo (prespecified analysis). During the 7-month follow-up period, protection was greatest during months 2-5, with a 100% relative risk reduction in COVID-19 (nominal p<0Â·0001; post-hoc analysis). Efficacy waned during months 6-8 (post-hoc analysis). Seroconversion occurred in 38 (4Â·5%) of 841 participants in the CASâ€‰+â€‰IMD group and in 181 (21Â·5%) of 842 in the placebo group during the 8-month study (79Â·0% relative risk reduction vs placebo; nominal p<0Â·0001). Six participants in the placebo group were hospitalised due to COVID-19 versus none who received CASâ€‰+â€‰IMD. Serious treatment-emergent adverse events (including COVID-19) were reported in 24 (1Â·7%) of 1439 participants receiving CASâ€‰+â€‰IMD and in 23 (1Â·6%) of 1428 receiving placebo. Five deaths were reported, none of which were due to COVID-19 or related to the study drugs. INTERPRETATION: CASâ€‰+â€‰IMD is not authorised in any US region as of Jan 24, 2022, because data show that CASâ€‰+â€‰IMD is not active against omicron-lineage variants. In this study, done before the emergence of omicron-lineage variants, a single subcutaneous 1200 mg dose of CASâ€‰+â€‰IMD protected against COVID-19 for up to 5

months of community exposure to susceptible strains of SARS-CoV-2 in the pre-exposure prophylaxis setting, in addition to the post-exposure prophylaxis setting that was previously shown. FUNDING: Regeneron Pharmaceuticals, F Hoffmann-La Roche, US National Institute of Allergy and Infectious Diseases, US National Institutes of Health.

Increased antibody titers and reduced seronegativity following fourth mRNA COVID-19 vaccination in patients with cancer.

To be or not to be vaccinated: The risk of MS or NMOSD relapse after COVID-19 vaccination and infection. BACKGROUND: COVID-19 vaccination and infection are speculated to increase the activity of immune-mediated diseases, including multiple sclerosis (MS) and neuromyelitis optica spectrum disorder (NMOSD). The aim of this study was to evaluate a short-term risk of relapse after COVID-19 vaccination and COVID-19 infection in patients with these demyelinating disorders of the central nervous system and to determine disease exacerbation risk factors. METHODS: Data in this retrospective, observational cohort study was collected via the Czech nationwide registry ReMuS from March 1, 2020, to October 30, 2021. We compared the proportion of patients with at least one clinical relapse in the 90 days following vaccination or infection to the 90-day intervals during the year before. For the evaluation of the risk factors of relapse, a comparison between groups with and without relapses after COVID-19 vaccination or infection was made. RESULTS: We identified 1661 vaccinated (90.11% BNT162b2) patients with MS without a history of COVID-19 and 495 unvaccinated patients with MS who experienced COVID-19. A mild increase in the proportion of patients with at least one clinical relapse (-360 to -270 days: 4.46%; -270 to -180: 4.27%; -180 to -90: 3.85%; -90 to 0: 3.79% vs. 0 to +90 days: 5.30%) after vaccination in patients with MS was observed, as well as a rise in the proportion of patients with at least one clinical relapse after COVID-19. Lower age was associated with MS relapse after vaccination or infection. Although there were only 17 vaccinated and eight post-COVID-19 patients with NMOSD, the results were broadly consistent with those of patients with MS. CONCLUSION: There is a mild increase in the relapse incidence after the COVID-19 vaccination. The risks, however, need to be balanced against the risks of COVID-19 itself, also leading to the rise in relapse rate and particularly to morbidity and mortality.

COVID-19 infection after two doses of SARS-CoV-2 mRNA vaccine in multiple sclerosis, AQP4-antibody NMOSD and MOGAD. BACKGROUND: In pre-vaccinated people with multiple sclerosis (MS), certain disease-modifying therapies (DMTs), particularly the anti-CD20 treatments, appear to be associated with an increased risk of COVID-19 infection and indeed with severe infection. It is still not known if such observations extend to vaccinated individuals and there have been considerably fewer studies in aquaporin-4-antibody neuromyelitis optica spectrum disorder (AQP4-NMOSD) and myelin oligodendrocyte glycoprotein-antibody associated disease (MOGAD) patients. In this study, we investigated the rates of symptomatic COVID-19 infection in adult patients with MS, AQP4-NMOSD and MOGAD who had received 2 doses of SARS-CoV-2 mRNA vaccine. METHODS: This was a prospective observational study conducted at the 2 main neuroimmunology referral centres in Singapore. Only patients on active follow-up were recruited to ensure robust data collection. Data on demographics, disease history, DMTs and SARS-CoV-2 mRNA vaccinations were recorded, and for those infected with COVID-19, data on COVID-19 infection was collected. RESULTS: Nineteen (13 MS, 5 AQP4-NMOSD, 1 MOGAD) out of 365 (231 MS, 106 AQP4-NMOSD, 28 MOGAD) patients had COVID-19 infection despite 2 doses of SARS-CoV-2 mRNA vaccine. Amongst the infected patients, 11 patients were on DMTs (3 rituximab, 2 interferons, 1 azathioprine, 1 mycophenolate, 1 prednisolone, 1 cladribine, 1 alemtuzumab, 1 fingolimod), while 8 patients were untreated. The crude infection rate was calculated using time-at-risk analysis, revealing that rituximab had the highest infection rate amongst all the DMTs. A lower crude infection rate was observed in patients who received a third vaccination. The majority of infections were mild and no patients required oxygen supplementation.

CONCLUSION: Our findings suggest that patients on rituximab are still at risk of COVID-19 infection after 2 vaccinations and the receipt of a third vaccination may help to prevent infection. Future large scale studies will be required to better delineate the infection risk of different DMTs after the second and subsequent vaccinations.

COVID-19 vaccine-related Guillain-BarrÃ© syndrome in the Liguria region of Italy: A multicenter case series. BACKGROUND AND PURPOSE: Guillain-BarrÃ©-Syndrome (GBS) can follow COVID-19 vaccination, with clinical and paraclinical features still to be precisely assessed. We describe a cohort of patients who developed GBS after vaccination with different types of COVID-19 vaccines. METHODS: Patients with post-COVID-19 vaccination GBS, admitted to the six hospitals that cover the whole Liguria Region, Northwestern Italy, from February 1st to October 30th 2021, were included. Clinical, demographic, and paraclinical data were retrospectively collected. RESULTS: Among the 13 patients with post-COVID-19 vaccination GBS (9 males; mean age, 64Â year), 5 were vaccinated with Oxford-AstraZeneca, 7 with Pfizer-BioNTech, and one with Moderna. Mean time between vaccination and GBS onset was 11.5Â days. Ten patients developed GBS after the first vaccination dose, 3 after the second dose. Acute inflammatory demyelinating polyradiculoneuropathy (AIDP) was the predominant GBS variant, mainly characterized by sensory involvement. Bilateral seventh cranial nerve involvement followed AstraZeneca vaccination in two cases. Three patients presented treatment-related fluctuations, and 4 mild symptoms that delayed treatments and negatively affected prognosis. Prognosis was poor (GBS-disability score, â‰¥3) in 5/13 patients, with a disability rate of 3/13. CONCLUSIONS: Our findings confirm that most post-COVID-19 vaccination GBS belong to the AIDP subtype, and occur after the first vaccine dose. Treatment-related fluctuations, and diagnosis-delaying, mild symptoms at onset are clinical features that affect prognosis and deserve particular consideration.

How to counter the anti-vaccine rhetoric: Filling information voids and building resilience. Widely circulating anti-vaccine misinformation online has been constituting a large obstacle for the success of COVID-19 vaccination campaigns and for the well-being of people during the pandemic. In this paper we discuss strategies to mitigate negative effects of online anti-vaccine contents on public health and to prevent hesitant individuals from falling prey of the traps set by anti-vaccine disinformation spreaders. Here we discuss the importance of filling information voids and understanding trends and concerns that shape the vaccine debate, and we highlight the relevance of building resilience to vaccine misinformation by strengthening public health and digital literacy.

Unilateral Acute Idiopathic Blind Spot Enlargement following Second Dose of Covid-19 mRNA Vaccine. Acute idiopathic blind spot enlargement (AIBSE) is a rare condition which is poorly understood. To our knowledge, this is the first report of acute idiopathic blind spot enlargement following covid-19 vaccination. We believe there is educational value for ophthalmologists to recognize the potential association of ocular inflammation and new mRNA vaccines.

Incidence and severity of SARS-CoV-2 infections in liver and kidney transplant recipients in the post-vaccination era: Real-life data from Denmark. Coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 has been associated with a high risk of adverse outcomes in solid organ transplant (SOT) recipients in the pre-vaccination era. In this retrospective cohort study, we examined the incidence and severity of COVID-19 in kidney and liver transplant recipients in Denmark in the post-vaccination era, from December 27, 2020, to December 27, 2021. We included 1428 SOT recipients with 143 cases of first-positive SARS-CoV-2 PCR test. The cumulative incidence of first-positive SARS-CoV-2 PCR test 1â€‰year after initiation of vaccination was 10.4% (95% CI: 8.8-12.0), and the incidence was higher in kidney than in liver transplant recipients (11.6% [95% CI: 9.4-13.8] vs. 7.4% [95% CI: 5.1-9.8], pÂ =â€‰.009). After the first-positive SARS-CoV-2 PCR test, the hospitalization rate was 31.5% (95% CI: 23.9-39.1), and 30-day all-cause mortality was 3.7% (95% CI: 0.5-6.8). Hospitalization was lower in

vaccinated than in unvaccinated SOT recipients (26.4% [95% CI: 18.1-34.6] vs. 48.5% [95% CI: 31.4-65.5], pÂ =â€‰.011), as was mortality (1.8% [95% CI: 0.0-4.3] vs. 9.1% [95% CI: 0.0-18.9], pÂ =â€‰.047). In conclusion, SOT recipients remain at high risk of adverse outcomes after SARS-CoV-2 infections, with a lower risk observed in vaccinated than in unvaccinated SOT recipients.

Outcomes following SARS-CoV-2 infection in individuals with and without solid organ transplantation-A Danish nationwide cohort study. The risk of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, hospitalization and death, and the effects of SARS-CoV-2 vaccines in solid organ transplant recipients (SOTRs) is still debated. We performed a nationwide, population-based, matched cohort study, including all Danish SOTRs (nÂ =Â 5184) and a matched cohort from the general population (nÂ =Â 41â€‰472). Cox regression analyses were used to calculate incidence rate ratios (IRRs). SOTRs had a slightly increased risk of SARS-CoV-2 infection and were vaccinated earlier than the general population. The overall risk of hospital contact with COVID-19, severe COVID-19, need for assisted respiration, and hospitalization followed by death was substantially higher in SOTRs (IRR: 32.8 95%CI [29.0-37.0], 9.2 [6.7-12.7], 12.5 [7.6-20.8], 12.4 [7.9-12.7]). The risk of hospitalization and death after SARS-CoV-2 infection decreased substantially in SOTRs after the emergence of the Omicron variant (IRR: 0.45 [0.37-0.56], 0.17 [0.09-0.30]). Three vaccinations reduced the risk of SARS-CoV-2 infection only marginally compared to two vaccinations, but SOTRs with three vaccinations had a lower risk of death (IRR: 022 [0.16-0.35]). We conclude that SOTRs have a risk of SARS-CoV-2 infection comparable to the general population, but substantially increased the risk of hospitalization and death following SARS-CoV-2 infection. A third vaccination only reduces the risk of SARS-CoV2 infection marginally, but SOTRs vaccinated 3 times have reduced mortality.

Myasthenia gravis with ocular symptoms following a ChAdOx1 nCoV-19 vaccination: A case report. PURPOSE: We report on the case of a 35-year-old man who developed myasthenia gravis with ocular symptoms following a ChAdOx1 nCoV-19 vaccine injection. OBSERVATIONS: A 35-year-old man complained of binocular diplopia one month following ChAdOx1 nCoV-19 vaccination. He had weak infraduction of the left eye. Upper and lower extremity strength was normal on presentation. A serum antiacetylcholine receptor antibody titer was elevated at 1.60 nmol/L. His diplopia improved temporarily following the application of an ice pack for 2Â min. CONCLUSIONS AND IMPORTANCE: This case report describes a rare occurrence of myasthenia gravis with ocular symptoms as a potential complication of ChAdOx1 nCoV-19 vaccination.

Axillary lymphangioma that developed following COVID-19 vaccination: a case report. BACKGROUND: Extensive vaccination programs are being implemented worldwide for coronavirus disease 2019 (COVID-19). With the spread of vaccination, swelling of the lymph nodes after vaccination is frequently seen. We encountered a patient who developed left axillary lymphadenoma following vaccine administration. CASE PRESENTATION: The patient was a Japanese woman in her 80Â s who had previously undergone surgery for right breast cancer. She received two injections of the Pfizer-BioNTech COVID-19 vaccine in her left arm. Approximately 3Â months later, she complained of left axillary swelling, and imaging resulted in a diagnosis of left axillary lymphangioma. In accordance with the patient's wishes, we performed axillary mass resection. The pathological diagnosis was lymphangioma. CONCLUSION: Our examination findings indicated that congestion of the axillary lymph vessels might have been caused by upper-arm injections of the COVID-19 vaccine.

COVID-19 vaccine safety monitoring in low and middle income countries - Time for a bold new approach.

Relationship between double COVID-19 vaccine uptake and trust in effectiveness and safety of vaccination in general in 23 Member states of the European Union: an ecological study. INTRODUCTION: The aim of this study was to assess the relationship between double COVID-19 vaccine uptake and trust in effectiveness and safety of vaccination in general in 23 European Union

(EU) countries. METHODS: Ecological study. Data was retrieved from the Flash Eurobarometer 494 and Our World in Data. We estimated Pearson's correlation coefficients and fitted multiple linear regression models. RESULTS: There is a negative linear correlation between the percentage of people doubly vaccinated and the percentage of low trust in vaccine effectiveness (rÂ =Â -0.48, p-valueÂ =Â 0.021), and the percentage of low trust in vaccine safety (rÂ =Â -0.43, p-valueÂ =Â 0.041). There is a negative adjusted relation between the percentage of low trust in vaccine safety and the percentage of people doubly vaccinated (aÎ²(% low trust in vaccine)(safety):-0.25; 95% CI: -0.49,-0.01, p-valueÂ =Â 0.045). CONCLUSION: An increase in health literacy of people living in certain countries in the EU may be needed to boost COVID-19 vaccine uptake.

Case of reactive sacroiliitis possibly induced by an mRNA coronavirus disease vaccine. A woman in her 30s received a second dose, first booster, Corminaty vaccine against the SARS-CoV-2. Three days later, the patient developed unilateral sacroiliitis. A pelvic scan revealed inflammatory joint edges, bone erosion and a heterogeneous mass of 2.5â€‰cm in the psoas muscle. Joint puncture revealed no microcrystalline deposits, but bone marrow cells, erythroblast were identified. The standard bacterial cultures and culture for mycobacteria were negative. HLA B27 was negative, and no seroconversion was identified for HIV, Epstein-Barr virus, cytomegalovirus, chlamydia or Quantiferon. Two months later, the sacroiliitis resolved.The aetiologic approach of this erosive unilateral acute sacroiliitis in a person naÃ¯ve to rheumatologic pathology was negative for inflammatory or infectious sacroiliitis. Arthralgias after vaccination are expected. Arthritis is less common, and acute sacroiliitis has not yet been described. Acute sacroiliitis may be considered a reactive sacroiliitis to the anti-COVID-19 mRNA vaccine.

Recurrent MRI-documented myocarditis following Pfizer-BioNTech SARS-CoV-2 vaccination.

Factors Associated with Delayed or Missed Second-Dose mRNA COVID-19 Vaccination among Persons >12 Years of Age, United States. To identify demographic factors associated with delaying or not receiving a second dose of the 2-dose primary mRNA COVID-19 vaccine series, we matched 323 million single Pfizer-BioNTech (https://www.pfizer.com) and Moderna (https://www.modernatx.com) COVID-19 vaccine administration records from 2021 and determined whether second doses were delayed or missed. We used 2 sets of logistic regression models to examine associated factors. Overall, 87.3% of recipients received a timely second dose (â‰¤42 days between first and second dose), 3.4% received a delayed second dose (>42 days between first and second dose), and 9.4% missed the second dose. Persons more likely to have delayed or missed the second dose belonged to several racial/ethnic minority groups, were 18-39 years of age, lived in more socially vulnerable areas, and lived in regions other than the northeastern United States. Logistic regression models identified specific subgroups for providing outreach and encouragement to receive subsequent doses on time.

Risk of gout flares after COVID-19 vaccination: A case-crossover study. OBJECTIVE: Routine vaccinations are associated with an increased risk of gout flares. We examined the association between COVID-19 vaccination, an immunization program implemented to a large proportion of population, and the risk of gout flares. METHODS: We conducted a time-stratified case-crossover study among patients with gout who experienced gout flares between December 2020 and September 2021, using data from The Health Improvement Network. We compared the risk of gout flares on each of the seven days on and after the day of COVID-19 vaccination vs. no vaccination during that period using conditional logistic regression. In addition, we performed subgroup analyses stratified by different COVID-19 vaccines (i.e., BNT162b2, hereafter referred to as BNT, and ChAdOx1 nCov-19, hereafter referred to as ChAd). RESULTS: Among 5,904 patients with gout (mean age: 63Â·1 years; 85Â·5% male) who experienced gout flares within one month, the risk of gout flares slightly increased on the second day after COVID-19 vaccination (odds ratio: 1Â·44; 95% CI: 1Â·02 to 2Â·07). The risk of gout flares also slightly increased after receiving COVID-19 vaccine on other remaining

days (ORs ranged from 1Â·03 to 1Â·22); however, none of them was statistically significant. An increased risk of gout flares on the second day after vaccination was mainly observed for the ChAd vaccine (odds ratio: 1Â·44; 95% CI: 1Â·00 to 2Â·05), but not for BNT vaccine (odds ratio: 1Â·18; 95% CI: 0Â·67 to 2Â·02). CONCLUSION: COVID-19 vaccination, mainly ChAd vaccination, slightly increases the risk of gout flares on the second day after vaccination. This finding reassures the safety of COVID-19 vaccination for patients with gout.

Factors Associated with Severe Outcomes Among Immunocompromised Adults Hospitalized for COVID-19 - COVID-NET, 10 States, March 2020-February 2022. Immunocompromised persons are at increased risk for severe COVID-19-related outcomes, including intensive care unit (ICU) admission and death (1). Data on adults aged â‰¥18 years hospitalized with laboratory-confirmed COVID-19 from 10 U.S. states in the COVID-19-Associated Hospitalization Surveillance Network (COVID-NET) were analyzed to assess associations between immunocompromise and ICU admission and in-hospital death during March 1, 2020-February 28, 2022. Associations of COVID-19 vaccination status with ICU admission and in-hospital death were also examined during March 1, 2021-February 28, 2022. During March 1, 2020-February 28, 2022, among a sample of 22,345 adults hospitalized for COVID-19, 12.2% were immunocompromised. Among unvaccinated patients, those with immunocompromise had higher odds of ICU admission (adjusted odds ratio [aOR]Â =Â 1.26; 95% CIÂ =Â 1.08-1.49) and in-hospital death (aORÂ =Â 1.34; 95% CIÂ =Â 1.05-1.70) than did nonimmunocompromised patients. Among vaccinated patients,* those with immunocompromise had higher odds of ICU admission (aORÂ =Â 1.40; 95% CIÂ =Â 1.01-1.92) and in-hospital death (aOR = 1.87; 95% CIÂ =Â 1.28-2.75) than did nonimmunocompromised patients. During March 1, 2021-February 28, 2022, among nonimmunocompromised patients, patients who were vaccinated had lower odds of death (aORÂ =Â 0.58; 95% CIÂ =Â 0.39-0.86) than did unvaccinated patients; among immunocompromised patients, odds of death between vaccinated and unvaccinated patients did not differ. Immunocompromised persons need additional protection from COVID-19 and using multiple known COVID-19 prevention strategies,(â€) including nonpharmaceutical interventions, up-to-date vaccination of immunocompromised persons and their close contacts,(Â§) early testing, and COVID-19 prophylactic (Evusheld) and early antiviral treatment,(Â¶) can help prevent hospitalization and subsequent severe COVID-19 outcomes among immunocompromised persons.

Antibody and T-Cell Responses 6 Months After Coronavirus Disease 2019 Messenger RNA-1273 Vaccination in Patients With Chronic Kidney Disease, on Dialysis, or Living With a Kidney Transplant. BACKGROUND: The immune response to COVID-19 vaccination is inferior in kidney transplant recipients (KTRs) and to a lesser extent in patients on dialysis or with chronic kidney disease (CKD). We assessed the immune response 6 months after mRNA-1273 vaccination in kidney patients and compared this to controls. METHODS: A total of 152 participants with CKD stages G4/5 (eGFR <30 mL/min/1.73 m2), 145 participants on dialysis, 267 KTRs, and 181 controls were included. SARS-CoV-2 Spike S1 specific IgG antibodies were measured using fluorescent bead-based multiplex-immunoassay, neutralizing antibodies to ancestral, Delta, and Omicron (BA.1) variants by plaque reduction, and T-cell responses by interferon-Î³ release assay. RESULTS: At 6 months after vaccination, S1-specific antibodies were detected in 100% of controls, 98.7% of CKD G4/5 patients, 95.1% of dialysis patients, and 56.6% of KTRs. These figures were comparable to the response rates at 28 days, but antibody levels waned significantly. Neutralization of the ancestral and Delta variants was detected in most participants, whereas neutralization of Omicron was mostly absent. S-specific T-cell responses were detected at 6 months in 75.0% of controls, 69.4% of CKD G4/5 patients, 52.6% of dialysis patients, and 12.9% of KTRs. T-cell responses at 6 months were significantly lower than responses at 28 days. CONCLUSIONS: Although seropositivity rates at 6 months were comparable to rates at 28 days after vaccination, significantly decreased antibody levels and T-cell responses were

observed. The combination of low antibody levels, reduced T-cell responses, and absent neutralization of the newly emerging variants indicates the need for additional boosts or alternative vaccination strategies in KTRs. CLINICAL TRIALS REGISTRATION: NCT04741386.

Immunity waning after COVID vaccine booster vs. infection-better than expected. BACKGROUND: Rapid decline in antibody-titres after BNT162b2 mRNA COVID-19 vaccine was reported; thus, a booster dose, and recently a second booster were approved. The study aims to discuss immunogenicity throughout the pandemic, especially after booster dose. METHODS: A prospective study conducted in EMMS-Nazareth hospital, Israel. Anti-SARS-CoV-2 IgG antibody titres were monitored every 5â€‰weeks starting from the vaccine's second dose. To detect symptomatic and asymptomatic infections, nasopharyngeal swabs for COVID-19 PCR were obtained bi-weekly, and on suggestive symptoms. Third dose of the vaccine was suggested for all participants 5â€‰months after the second one. A comparison was made between those who received three doses (booster-group), and those who were infected after having two doses (infection-group) or three doses (booster-infection) group. RESULTS: One-hundred participants were included; 66 finished 14â€‰months of follow-up, out of whom 40 received a third dose, 10 received only two doses-all were infected (mean time for infection 5â€‰Â±â€‰12.15â€‰weeks before the designated booster), and 12 received three doses and were infected. The mean titres of these three groups 7â€‰months after the designated booster dose (regardless of receiving it) were 1756â€‰Â±â€‰2279; 3483â€‰Â±â€‰3016 and 6925â€‰Â±â€‰3720 BAU/mL, respectively. The booster group had high titres 7â€‰months after the booster dose, comparable to two months after the second dose (pâ€‰=â€‰.69); The booster-infected group had even higher titres. CONCLUSION: Immunogenicity decline rate after the booster dose is slower than the second dose. Timing of second booster in general population is still to be determined; neutralizing-antibody titres might be helpful.

Association of BNT162b2 Vaccine Third Dose Receipt With Incidence of SARS-CoV-2 Infection, COVID-19-Related Hospitalization, and Death Among Residents of Long-term Care Facilities, August to October 2021. IMPORTANCE: COVID-19 vaccine might be less immunogenic and effective among residents of long-term care facilities (LTCFs). OBJECTIVE: To examine the association of BNT162b2 third dose (first booster dose) with overall SARS-CoV-2 infection, COVID-19 hospitalizations, and mortality among LTCF residents during a nationwide surge of the Delta variant in Israel. DESIGN, SETTING, AND PARTICIPANTS: This observational cohort study conducted nationwide COVID-19 surveillance in LTCFs in Israel between August and October 2021. Participants were residents of LTCFs aged 60 years or older. EXPOSURES: Vaccination with the third dose of BNT162b2 vaccine vs receipt of 2 doses at least 5 months earlier, based on self-preference and choice. MAIN OUTCOMES AND MEASURES: The cumulative incidences of reverse transcription-polymerase chain reaction (RT-PCR)-confirmed SARS-CoV-2 infection, COVID-19 hospitalizations, and COVID-19-related deaths more than 7 days after vaccination with the third dose were compared between the groups using Kaplan-Meier curves. Hazard ratios (HRs) and 95% CIs were obtained using multivariable Cox regression models. RESULTS: Among 18â€¯611 residents included in the analysis, 12â€¯715 (68.3%) were female, 463 (2.5%) were from the Arab population, 16â€¯976 (91.2%) were from the general Jewish population, and 618 (3.3%) were from the ultraorthodox Jewish population; the mean (SD) age was 81.1 (9.2) years; 16â€¯082 residents received their first booster dose (third dose) and 2529 were vaccinated with 2 doses at least 5 months earlier. The median (IQR) follow-up durations were 66 (60-70) days among 3-dose recipients and 56 (53-62) days among 2-dose-only recipients; 107 residents had SARS-CoV-2 infection after 7 days following vaccination with the booster dose compared with 185 among the 2-dose only group (cumulative incidence: 0.7% vs 7.5%; adjusted HR, 0.11 [95% CI, 0.07-0.15]). The respective adjusted HRs were 0.07 (95% CI, 0.03-0.14) and 0.10 (95% CI, 0.04-0.24) for the associations of vaccination with the third dose with hospitalization for mild-to-moderate COVID-19

and severe illness. Five COVID-19-related deaths occurred among the third dose vaccinees during the follow-up period compared with 22 among the 2-dose-only vaccinees (cumulative rate: 0.04% vs 0.9%; adjusted HR, 0.04 [95% CI, 0.009-0.16]). CONCLUSIONS AND RELEVANCE: This cohort study found significant inverse associations between vaccination with the third dose of the BNT162b2 vaccine with overall SARS-CoV-2 infection, COVID-19 hospitalizations, severe disease, and COVID-19-related deaths among LTCF residents during a massive surge caused by the Delta variant in Israel.

Association Between BNT162b2 Vaccination and Long COVID After Infections Not Requiring Hospitalization in Health Care Workers. This study examines the risk of long COVID following mRNA vaccination, compared with no vaccination, in health care workers in Italy who had COVID-19 infection.

Comparing reactogenicity of COVID-19 vaccines: a systematic review and meta-analysis. OBJECTIVES: A number of vaccines have now been developed against COVID-19. Differences in reactogenicity and safety profiles according to the vaccine technologies employed are becoming apparent from clinical trials. METHODS: Five databases (Medline, EMBASE, Science Citation Index, Cochrane Central Register of Controlled Trials, London School of Hygiene and Tropical Medicine COVID-19 vaccine tracker) were searched for relevant randomized controlled trials between 1 January 2020 and 12 January 2022 according to predetermined criteria with no language limitations. RESULTS: Forty-two datasets were identified, with 20 vaccines using four different technologies (viral vector, inactivated, mRNA and protein sub-unit). Adults and adolescents over 12Â years were included. Control groups used saline placebos, adjuvants, and comparator vaccines. The most consistently reported solicited adverse events were fever, fatigue, headache, pain at injection site, redness, and swelling. Both doses of mRNA vaccines, the second dose of protein subunit and the first dose of adenovirus vectored vaccines were the most reactogenic, while the inactivated vaccines were the least reactogenic. CONCLUSIONS: The different COVID-19 vaccines currently available appear to have distinct reactogenicity profiles, dependent on the vaccine technology employed. Awareness of these differences may allow targeted recommendations for specific populations. Greater standardization of methods for adverse event reporting will aid future research in this field.

Exacerbation of psoriasis following vaccination with the Pfizer-BioNTech BTN162b2 mRNA COVID-19 vaccine during risankizumab treatment.

Immune response and reactogenicity after immunization with two-doses of an experimental COVID-19 vaccine (CVnCOV) followed by a third-fourth shot with a standard mRNA vaccine (BNT162b2): RescueVacs multicenter cohort study. BACKGROUND: There is no evidence to date on immunogenic response among individuals who participated in clinical trials of COVID-19 experimental vaccines redirected to standard national vaccination regimens. METHODS: This multicentre, prospective controlled cohort study included subjects who received a COVID-19 experimental vaccine (CVnCoV)(test group, TG) - and unvaccinated subjects (control group, CG), selected among individuals to be vaccinated according to the Spanish vaccination program. All study subjects received BNT162b2 as a standard national vaccination schedule, except 8 (from CG) who received mRNA-1273 and were excluded from immunogenicity analyses. Anti-RBD antibodies level and neutralising titres (NT50) against G614, Beta, Mu, Delta and Omicron variants were analysed. Reactogenicity was also assessed. FINDINGS: 130 participants (TG:92; CG:38) completed standard vaccination. In TG, median (IQR) of anti-RBD antibodies after first BNT162b2 dose were 10740Â·0 BAU/mL (4466Â·0-12500) compared to 29Â·8 BAU/mL (14Â·5-47Â·8) in CG (p <0Â·0001). Median NT50 (IQR) of G614 was 2674Â·0 (1865Â·0-3997Â·0) in TG and 63Â·0 (16Â·0-123Â·1) in CG (p <0Â·0001). After second BNT162b2 dose, anti-RBD levels increased to â‰¥12500 BAU/mL (11625Â·0-12500) in TG compared to 1859Â·0 BAU/mL (915Â·4-3820Â·0) in CG (p <0Â·0001). NT50 was 2626Â·5 (1756Â·0-5472Â·0) and 850Â·4 (525Â·1-1608Â·0), respectively (p <0Â·0001). Variant-specific (Beta, Mu, Omicron) response was also assessed.

Most frequent adverse reactions were headache, myalgia, and local pain. No severe AEs were reported. INTERPRETATION: Heterologous BNT162b2 as third and fourth doses in previously suboptimal immunized individuals elicit stronger immune response than that obtained with two doses of BNT162b2. This apparent benefit was also observed in variant-specific response. No safety concerns arose. FUNDING: Partly funded by the Institute of Health Carlos-III and COVID-19 Fund, co-financed by the European Regional Development Fund (FEDER) "A way to make Europe".
Anaphylaxis and Related Events Following COVID-19 Vaccination: A Systematic Review. The coronavirus disease 2019 (COVID-19), induced by the severe acute respiratory syndrome coronavirus 2, is responsible for a global pandemic following widespread transmission and death. Several vaccines have been developed to counter this public health crisis using both novel and conventional methods. Following approval based on promising efficacy and safety data, the AstraZeneca, Janssen, Moderna, Pfizer/BioNTech, and Sinovac vaccines have been administered globally among different populations with various reported side effects. Reports of life-threatening anaphylaxis following administration were of particular concern for both health care providers and the public. A systematic literature search using PubMed, Embase, Scopus, Web of Science, Science Direct, MedRxiv, and Lens.org databases identified relevant studies reporting anaphylaxis following vaccine administration. This systematic review includes 41 studies reporting anaphylaxis. A total of 7942 cases, including 43 deaths, were reported across 14 countries. Most cases occurred following the administration of the first dose. Importantly, the benefits of vaccination outweigh the risks of anaphylaxis. Subsequently, as populations continue to get vaccinated, it is important for health care providers to be able to recognize individuals at risk of developing anaphylaxis. Furthermore, they must be familiar with both the clinical hallmarks and treatment of anaphylactic reactions to minimize long-term sequalae and prevent death in vaccinated individuals.
Fourth BNT162b2 vaccination neutralization of omicron infection after heart transplantation. We investigated changes in receptor-binding domain IgG and neutralizing antibodies against the omicron and delta variants, vs the wild-type virus, in response to a fourth BNT162b2 dose in 90 heart transplant (HT) recipients. The fourth dose induced anti-RBD IgG antibodies and a higher neutralization efficiency against the wild-type virus and the variants; however, neutralization efficiency against the omicron variant was lower than that against the delta variant (the latter demonstrating efficacy similar to that against the wild-type virus). Notably, while IgG anti-RBD antibodies were detectable in >80% of the HT recipients, only about half demonstrated neutralization efficiency against the omicron variant. AÂ SARS-CoV-2-specific-T-cell response following the fourth dose was evident in the majority of transplant recipients. Boosting vulnerable groups improves antibody responses (including neutralizing responses) and cellular immunity, but the incomplete immunological response, particularly for omicron, suggests continued preventive measures and optimization of vaccination strategies that elicit strong, and long-lasting immune responses, in this high-risk population, should remain a priority.
Intratympanic steroid treatments rescued recurrent hearing loss following COVID-19 vaccination and detection of an intralabyrinthine schwannoma. It remains unclear how to effectively treat rare cases of sudden and recurrent hearing losses which might coincidently follow vaccination. We report the first case, to our knowledge, of systemic and local steroid administration to successfully treat sudden and recurrent left-ear hearing loss, respectively, following a second dose of the BNT162b2 COVID-19 mRNA vaccination which inflammatory response potentially affected an existing left intralabyrinthine schwannoma in a young male patient. This case highlights the importance and timing of intratympanic steroid treatment strategies to suppress the progressive symptoms and restore hearing to a stable condition, and therefore avoid permanent hearing loss which would

otherwise demand a surgical removal of the schwannoma to improve vertigo and reconstitute artificial hearing.

Antibody responses and risk factors associated with impaired immunological outcomes following two doses of BNT162b2 COVID-19 vaccination in patients with chronic pulmonary diseases. INTRODUCTION: Responses to COVID-19 vaccination in patients with chronic pulmonary diseases are poorly characterised. We aimed to describe humoral responses following two doses of BNT162b2 mRNA COVID-19 vaccine and identify risk factors for impaired responses. METHODS: Prospective cohort study including adults with chronic pulmonary diseases and healthcare personnel as controls (1:1). Blood was sampled at inclusion, 3 weeks, 2 and 6 months after first vaccination. We reported antibody concentrations as geometric means with 95% CI of receptor binding domain (RBD)-IgG and neutralising antibody index of inhibition of ACE-2/RBD interaction (%). A low responder was defined as neutralising index in the lowest quartile (primary outcome) or RBD-IgG <225 AU/mL plus neutralising index <25% (secondary outcome), measured at 2 months. We tested associations using Poisson regression. RESULTS: We included 593 patients and 593 controls, 75% of all had neutralising index â‰¥97% at 2 months. For the primary outcome, 34.7% of patients (n=157/453) and 12.9% of controls (n=46/359) were low responders (p<0.0001). For the secondary outcome, 8.6% of patients (n=39/453) and 1.4% of controls (n=5/359) were low responders (p<0.001). Risk factors associated with low responder included increasing age (per decade, adjusted risk ratio (aRR) 1.17, 95%â€‰CI 1.03 to 1.32), Charlson Comorbidity Index (per point) (aRR 1.15, 95%â€‰CI 1.05 to 1.26), use of prednisolone (aRR 2.08, 95%â€‰CI 1.55 to 2.77) and other immunosuppressives (aRR 2.21, 95%â€‰CI 1.65 to 2.97). DISCUSSION: Patients with chronic pulmonary diseases established functional humoral responses to vaccination, however lower than controls. Age, comorbidities and immunosuppression were associated with poor immunological responses.

Sudden sensorineural hearing loss with intralabyrinthine hemorrhage after COVID-19 vaccination. Otologic symptoms of sudden sensorineural hearing loss (SSNHL) have been reported after Coronavirus disease 2019 (COVID-19) vaccinations. However, the association between SSNHL and COVID-19 vaccination has not been clearly established. SSNHL with vertigo can be induced by intralabyrinthine hemorrhage (ILH). The case of a 61-year-old female who was diagnosed SSNHL with ILH after COVID-19 vaccination is presented here. She visited the emergency department for left sudden hearing loss and vertigo that had occurred the previous day. She had received a third booster COVID-19 mRNA vaccination one day prior to the visit; symptoms occurred 6â€‰hours after vaccination. On pure tone audiometry, her hearing threshold indicated deafness in the left ear. A lesion assumed to be ILH was observed on temporal magnetic resonance imaging. She received an oral steroid followed by salvage treatment with intratympanic steroid injection. Three months after symptom onset, her hearing threshold remained deaf with slight improvement at low frequencies in the left ear. Because the symptoms of and prognosis for SSNHL may be worse and vertigo may occur in patients with SSNHL and ILH, careful treatment is required.

Reactogenicity, immunogenicity, and humoral immune response dynamics after the third dose of heterologous COVID-19 vaccines in participants fully vaccinated with inactivated vaccine. INTRODUCTION: Immunogenicity after the CoronaVac vaccine remains uncertain, especially regarding infections with the coronavirus variants of concern and waning immunity. METHODS: This was a single-center, open-label clinical trial designed to assess the immunogenicity and safety of BBIBP-CorV, AZD1222, or BNT162b2 as the third vaccination. The key eligible criteria were individuals at least 18Â years old who were fully vaccinated with two doses of CoronaVac vaccine for 2-4Â months. The primary endpoint was the ratio of the geometric mean concentration (GMC) of the total anti-receptor binding domain (RBD) antibody post-vaccination compared with that pre-vaccination. The secondary endpoint was reactogenicity within 7Â days. RESULTS: Forty-one participants received

AZD1222, 40 received BBIBP-CorV, and 40 received BNT162b2. The GMC of anti-RBD antibody at 2Â weeks post-vaccination was 31,138.67 binding antibody units (BAU)/mL for BNT162b2, 6,412.10 BAU/mL for AZD1222, and 1,092.7 BAU/mL for BBIBP-CorV. Compared with pre-vaccination, the ratio of anti-RBD concentration was 690.24 for BNT162b2, 130.02 for AZD1222, and 17.79 for BBIBP-CorV. No potentially life-threatening adverse reaction were observed within 7Â days. CONCLUSION: A third vaccination with the heterologous vaccine, BBIBP-CorV, AZD1222, or BNT162b2, can elicit a robust immune response, without serious adverse events in participants fully vaccinated with the CoronaVac vaccine.

The role of treatment with plasma exchange therapy in two pediatric toxic epidermal necrolysis cases related to COVID-19. Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are life-threatening mucocutaneous reactions characterized by necrosis and detachment of the epidermis. Drugs and bacterial or viral infections are the most common causes of SJS/TEN. Although cases of SJS/TEN have been reported after hydroxychloroquine, vaccine (mRNA [Biontech], and inactivated vaccine [Sinovac]) administration and during the clinical course of active Coronavirus disease 2019 (COVID-19), limited data is indicating the COVID-19 disease as a triggering factor. Also, there are no pediatric cases of SJS/TEN associated with COVID-19 in the literature. Herein we reported two pediatric cases with a diagnosis of TEN related to COVID-19. Therapeutic plasma exchange therapy was applied to both of our patients. Although there are a few adult cases in the literature, our article is the first pediatric case report about patients diagnosed with TEN related to COVID-19 and successfully treated with plasma exchange.

Reactogenic sleepiness after COVID-19 vaccination. A hypothesis involving orexinergic system linked to inflammatory signals. Coronavirus disease 2019 (COVID-19) represents a global healthcare crisis that has led to morbidity and mortality on an unprecedented scale. While studies on COVID-19 vaccines are ongoing, the knowledge about the reactogenic symptoms that can occur after vaccination and its generator mechanisms can be critical for healthcare professionals to improve compliance with the future vaccination campaign. Because sleep and immunity are bidirectionally linked, sleepiness or sleep disturbance side effects reported after some of the COVID-19 vaccines advise an academic research line in the context of physiological or pathological neuroimmune interactions. On the recognized basis of inflammatory regulation of hypothalamic neurons in sickness behavior, we hypothesized that IL-1Î², INF-Î³ and TNF-Î± pro-inflammatory cytokines inhibit orexinergic neurons promoting sleepiness after peripheral activation of the innate immune system induced by the novel COVID-19 vaccines. In addition, based on knowledge of previous vaccines and disease manifestations of SARS-CoV-2 infection, it also suggests that narcolepsy must be included as potential adverse events of particular interest to consider in pharmacovigilance studies.

Health Care Workers' Sick Leave due to COVID-19 Vaccination in Context With SARS-CoV-2 Infection and Quarantine-A Multicenter Cross-Sectional Survey. BACKGROUND: Reactogenicity of coronavirus disease 2019 (COVID-19) vaccines can result in inability to work. The object of this study was to evaluate health care workers' sick leave after COVID-19 vaccination and to compare it with sick leave due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and quarantine leave. METHODS: A multicenter cross-sectional survey was conducted at Regensburg University Medical Center and 10 teaching hospitals in South-East Germany from July 28 to October 15, 2021. RESULTS: Of 2662 participants, 2309 (91.8%) were fully vaccinated without a history of SARS-CoV-2 infection. Sick leave after first/second vaccination occurred in 239 (10.4%) and 539 (23.3%) participants. In multivariable logistic regression, the adjusted odds ratio for sick leave after first/second vaccination compared with BNT162b2 was 2.26/3.72 for mRNA-1237 (95% CI, 1.28-4.01/1.99-6.96) and 27.82/0.48 for ChAdOx1-S (95% CI, 19.12-40.48/0.24-0.96). The actual median sick leave (interquartile range [IQR]) was 1 (0-2) day after any vaccination. Two hundred fifty-one

participants (9.4%) reported a history of SARS-CoV-2 infection (median sick leave [IQR] 14 [10-21] days), 353 (13.3%) were quarantined at least once (median quarantine leave [IQR], 14 [10-14] days). Sick leave due to SARS-CoV-2 infection (4642 days) and quarantine leave (4710 days) accounted for 7.7 times more loss of workforce than actual sick leave after first and second vaccination (1216 days) in all fully vaccinated participants. CONCLUSIONS: Sick leave after COVID-19 vaccination is frequent and is associated with the vaccine applied. COVID-19 vaccination should reduce the much higher proportion of loss of workforce due to SARS-CoV-2 infection and quarantine.

Describing the population experiencing COVID-19 vaccine breakthrough following second vaccination in England: a cohort study from OpenSAFELY. BACKGROUND: While the vaccines against COVID-19 are highly effective, COVID-19 vaccine breakthrough is possible despite being fully vaccinated. With SARS-CoV-2 variants still circulating, describing the characteristics of individuals who have experienced COVID-19 vaccine breakthroughs could be hugely important in helping to determine who may be at greatest risk. METHODS: With the approval of NHS England, we conducted a retrospective cohort study using routine clinical data from the OpenSAFELY-TPP database of fully vaccinated individuals, linked to secondary care and death registry data and described the characteristics of those experiencing COVID-19 vaccine breakthroughs. RESULTS: As of 1st November 2021, a total of 15,501,550 individuals were identified as being fully vaccinated against COVID-19, with a median follow-up time of 149 days (IQR: â€‹107-179). From within this population, a total of 579,780 (<4%) individuals reported a positive SARS-CoV-2 test. For every 1000 years of patient follow-up time, the corresponding incidence rate (IR) was 98.06 (95% CI 97.93-98.19). There were 28,580 COVID-19-related hospital admissions, 1980 COVID-19-related critical care admissions and 6435 COVID-19-related deaths; corresponding IRs 4.77 (95% CI 4.74-4.80), 0.33 (95% CI 0.32-0.34) and 1.07 (95% CI 1.06-1.09), respectively. The highest rates of breakthrough COVID-19 were seen in those in care homes and in patients with chronic kidney disease, dialysis, transplant, haematological malignancy or who were immunocompromised. CONCLUSIONS: While the majority of COVID-19 vaccine breakthrough cases in England were mild, some differences in rates of breakthrough cases have been identified in several clinical groups. While it is important to note that these findings are simply descriptive and cannot be used to answer why certain groups have higher rates of COVID-19 breakthrough than others, the emergence of the Omicron variant of COVID-19 coupled with the number of positive SARS-CoV-2 tests still occurring is concerning and as numbers of fully vaccinated (and boosted) individuals increases and as follow-up time lengthens, so too will the number of COVID-19 breakthrough cases. Additional analyses, to assess vaccine waning and rates of breakthrough COVID-19 between different variants, aimed at identifying individuals at higher risk, are needed.

Immune response and safety to inactivated COVID-19 vaccine: a comparison between people living with HIV and HIV-naive individuals. BACKGROUND: Multi-types COVID-19 vaccines have shown safety and efficacy against COVID-19 in adults. Although current guidelines encourage people living with HIV (PLWH) to take COVID-19 vaccines, whether their immune response to COVID-19 vaccines is distinct from HIV-free individuals is still unclear. METHODS: Between March to June 2021, 48 PLWH and 40 HNC, aged 18 to 59â€‰years, were enrolled in the study in Wuchang district of Wuhan city. All of them received inactivated COVID-19 vaccine (Sinopharm, WIBP-CorV, Wuhan Institute of Biological Products Co. Ltd) at day 0 and the second dose at day 28. The primary safety outcome was the combined adverse reactions within 7â€‰days after each injection. The primary immunogenicity outcomes were SARS-CoV-2 neutralizing antibodies (nAbs) responses by chemiluminescence and total specific IgM and IgG antibodies responses by ELISA and colloidal gold at baseline (day 0), day 14, day 28, day 42, and day 70. RESULTS: In total, the study included 46 PLWH and 38 HNC who finished 70â€‰days' follow-up. The frequency of adverse reactions to the first and second dose was not

different between PLWH (30% and 11%) vs. HNC (32% and 24%). NAbs responses among PLWH peaked at day 70, while among HNC peaked at day 42. At day 42, the geometric mean concentration (GMC) and seroconversion rate of nAbs among PLWH were 4.46 binding antibody units (BAU)/mL (95% CI 3.18-5.87) and 26% (95% CI 14-41), which were lower than that among HNC [GMC (18.28 BAU/mL, 95% CI 10.33-32.33), seroconversion rate (63%, 95% CI 44-79)]. IgG responses among both PLWH and HNC peaked at day 70. At day 70, the geometric mean ELISA units (GMEU) and seroconversion rate of IgG among PLWH were 0.193 ELISA units (EU)/mL (95% CI 0.119-0.313) and 51% (95% CI 34-69), which was lower than that among HNC [GMEU (0.379 EU/mL, 95% CI 0.224-0.653), seroconversion rate (86%, 95% CI 64-97)]. There were no serious adverse events. CONCLUSIONS: Early humoral immune response to the inactivated COVID-19 vaccine was weaker and delayed among the PLWH population than that among HNC. This observation remained consistent regardless of a high CD4 count with effective antiretroviral therapy.

Long-term outcome of patients with vaccine-induced immune thrombotic thrombocytopenia and cerebral venous sinus thrombosis. We present the long-term outcomes of 44 patients who developed cerebral venous sinus thrombosis after vaccination with the adenoviral vector ChAdOx1 nCoV-19 COVID-19 vaccine. Assessment of the Extended Glasgow Outcome Scale was performed within 3-6 months after the initial hospital admissions. Patient outcomes ranged from good recovery (13 patients, 29.6%) to moderate disability (11 patients, 25.0%) and severe disability or vegetative state (6 patients, 13.6%). Fatal outcomes were reported in 14 patients (31.8%).

Letter to the Editor: Pre-Existing Neuropathy Favours SARS-CoV-2 Vaccination Associated Guillain-Barre Syndrome.

A Case Report of MPO-ANCA-Associated Vasculitis Following Heterologous mRNA1273 COVID-19 Booster Vaccination. Despite that clinical trials have been examining the safety profile of coronavirus disease 2019 (COVID-19) vaccines, there are concerns about long-term side effects as the number of vaccinations increases. Herein, we report a case of new-onset renal-limited anti-myeloperoxidase (MPO) antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis after booster vaccination with the mRNA 1273 (Moderna) vaccine. A 72-year-old woman with no specific past history, and who had a normal renal function, developed ANCA-associated vasculitis following heterologous booster with mRNA1273 (Moderna) vaccine. After a kidney biopsy, she was diagnosed with ANCA-associated pauci-immune crescentic glomerulonephritis. Her renal function and constitutional symptoms have been improved with treatment with plasmapheresis, intravenous cyclophosphamide and steroid pulse therapy (intravenous 500 mg of methylprednisolone sodium succinate for 3 days) followed by a reduced steroid regimen.

Characteristics associated with the residual risk of severe COVID-19 after a complete vaccination schedule: A cohort study of 28 million people in France. BACKGROUND: Prior to the availability of vaccines, the risk factors for developing severe forms of COVID-19 were mostly older age and various comorbidities such as diabetes, cardiovascular diseases, mental disorders, transplantations, and kidney disease. Although vaccines have been shown to be highly effective in preventing severe forms of COVID-19, a residual risk may persist, despite vaccination, for certain population groups. METHODS: The study was based on data from the national COVID-19 vaccination database (VAC-SI) coupled with the National Health Data System (SNDS), which contains comprehensive reimbursement and hospitalisation data for all of France. All people fully vaccinated by July 31, 2021, with a double-injection vaccine, i.e., the mRNA BNT162b2, mRNA-1273, or ChAdOx1 nCoV-19 vaccines, or a single dose for people with a previous confirmed SARS-CoV-2 infection were included and followed until August 31, 2021. Cox proportional hazard models were performed to estimate adjusted hazard ratios (aHR) for COVID-19-related hospitalisation or in-hospital death associated with age, gender, deprivation index, comorbidities, and immunosuppressive or oral corticosteroid therapy from day 14

after full-vaccination. FINDINGS: In a population of 28,031,641 fully vaccinated individuals with an average follow-up of 80 days, 5,345 (87 hospitalisations per 100,000 person-years) were hospitalised for COVID-19 and 996 (16 in-hospital death per 100,000 person-years) died in hospital. In multivariable analysis, a higher risk was observed with increasing age, male gender, and social deprivation. Most of the 47 chronic conditions considered were positively associated with an increased risk of COVID-19-related hospitalisation and a slight excess risk of death. The risk of hospitalisation and in-hospital death for COVID-19 also increased with the use of immunosuppressants (aHR 3.3 [2.8-3.8] and 2.4 [1.7-3.5], respectively) and oral corticosteroids (aHR 2.8 [2.5-3.1] and 4.1 [3.3-5.1]).Less than 10% (519/5,345) of hospitalised cases and 2% (24/996) of those who died in hospital had no identified comorbidities. There was a strong association between an increasing number of comorbidities and the risk of hospitalisation and in-hospital death (e.g., 5+ versus none, aHR 10.1 95%CI 9.0-11.5 and 17.8 95%CI 11.5-27.4, respectively). INTERPRETATION: Although vaccination has dramatically reduced the occurrence of severe forms of COVID-19, a residual risk remains for the elderly, immunocompromised, and polypathological populations and warrants complementary preventive measures. FUNDING: None.
Blaschkolinear acquired inflammatory skin eruption (blaschkitis) following COVID-19 vaccination.
Intractable alopecia areata following the second dose of COVID-19 vaccination: Report of two cases.
Reply to 'development of severe pemphigus vulgaris following SARS-CoV-2 vaccination with BNT162b2' by Solimani F etâ€‰al.
SARS-CoV-2 infection in multiple sclerosis patients: interaction with treatments, adjuvant therapies, and vaccines against COVID-19. The SARS-CoV-2 pandemic has raised particular concern for people with Multiple Sclerosis, as these people are believed to be at increased risk of infection, especially those being treated with disease-modifying therapies. Therefore, the objective of this review was to describe how COVID-19 affects people who suffer from Multiple Sclerosis, evaluating the risk they have of suffering an infection by this virus, according to the therapy to which they are subjected as well as the immune response of these patients both to infection and vaccines and the neurological consequences that the virus can have in the long term. The results regarding the increased risk of infection due to treatment are contradictory. B-cell depletion therapies may cause patients to have a lower probability of generating a detectable neutralizing antibody titer. However, more studies are needed to help understand how this virus works, paying special attention to long COVID and the neurological symptoms that it causes.
Re: The Impact of COVID-19 Vaccine on Sperm Quality.
HeartWare Thrombosis After mRNA COVID-19 Vaccination.
Use of heated tobacco products, moderate alcohol drinking, and anti-SARS-CoV-2 IgG antibody titers after BNT162b2 vaccination among Japanese healthcare workers. The effect of heated tobacco products (HTPs) use and moderate alcohol drinking on immunogenicity to coronavirus disease (COVID-19) vaccines remain elusive. This study aimed to examine the association of tobacco product use and alcohol consumption with anti-SARS-CoV-2 spike IgG antibody titers after the BNT162b2 vaccine. Participants were 3433 healthcare workers receiving two vaccine doses in the 4 national centers for advanced medical and research in Japan. Smoking status and alcohol consumption were assessed via a questionnaire, and anti-SARS-CoV-2 spike IgG titers were measured with chemiluminescent enzyme immunoassay using serum collected on the median of 64Â days after the second vaccination. Multilevel linear regression models were used to estimate the geometric mean titers (GMT) and the ratios of means (RoM) between groups with adjustment for covariates. Compared with never-smokers (GMTÂ =Â 118), IgG antibody titers were significantly lower among HTPs users (including those who also smoked cigarettes) (GMTÂ =Â 105; RoMÂ =Â 0.89 [95%CI: 0.78-0.99]) and exclusive cigarettes smokers (GMTÂ =Â 98; RoMÂ =Â 0.81 [95%CI: 0.71-0.92]). Compared

with non-drinkers of alcohol (GMTÂ =Â 123), alcohol drinkers consuming <1 go/day (GMTÂ =Â 113; RoMÂ =Â 0.93 [95%CI: 0.88-0.98]), 1-1.9 go/day (GMTÂ =Â 104; RoMÂ =Â 0.85 [95%CI: 0.78-0.93]), andÂ â‰¥Â 2 go/day (GMTÂ =Â 103; RoMÂ =Â 0.84 [95%CI: 0.74-0.96]) had significantly lower antibody titers (P for trend<0.01). Spline analysis showed a large reduction of antibody until around 1 go/day of alcohol consumption, and then they gradually decreased. Results suggest that in addition to conventional cigarette smoking and heavy alcohol drinking, HTPs use and moderate alcohol drinking may be predictors of lower immunological response to COVID-19 vaccine.

Acute lower limb ischemia caused by vaccine-induced immune thrombotic thrombocytopenia: focus on perioperative considerations for 2 cases. BACKGROUND: ChAdOx1 nCoV-19 (AstraZeneca) and Ad26COV2.S (Johnson & Johnson/Janssen) adenoviral vector vaccines have been associated with vaccine-induced immune thrombotic thrombocytopenia (VITT). Arterial thrombosis and acute limb ischemia have been described in a minority of patients with VITT. These patients usually need a revascularization, but they potentially are at a higher risk of complications. Optimal perioperative care of patients undergoing vascular surgery in acute VITT is unknown and important considerations in such context need to be described. CASES PRESENTATIONS: We report 2 cases of VITT presenting with acute limb ischemia who needed vascular surgery and we describe the multidisciplinary team decisions for specific treatment surrounding the interventions. Both patients' platelet counts initially increased after either intravenous immune globulin (IVIG) or therapeutic plasma exchange (TPE). None received platelet transfusion. They both received argatroban as an alternative to heparin for their surgery. Despite persistent positivity of anti-platelet factor 4 (PF4) antibodies and serotonin-release assay with added PF4 (PF4-SRA) in both patients, only one received a repeated dose of IVIG before the intervention. Per- and post-operative courses were both unremarkable. CONCLUSION: In spite of persistent anti-PF4 and PF4-SRA positivityÂ in the setting of VITT, after platelet count improvement using either IVIG or TPE, vascular interventions using argatroban can show favorable courses. Use of repeated IVIG or TPE before such interventions still needs to be defined.

Frail older people and those in deprived areas remain at risk from covid-19, even after vaccination. The studyAntonelli M, Penfold RS, Merino J, et al. Risk factors and disease profile of post-vaccination SARS-CoV-2 infection in UK users of the COVID Symptom Study app: a prospective, community-based, nested, case-control study. Lancet Infect Dis 2022;22:1.To read the full NIHR Alert, go to: https://evidence.nihr.ac.uk/alert/older-people-at-risk-from-covid-even-after-vaccine/.

Case of adult-onset Kawasaki disease and multisystem inflammatory syndrome following SARS-CoV-2 vaccination. Kawasaki disease (KD) and multisystem inflammatory syndrome (MIS) are rare conditions that occur predominately in children. Recent reports document KD and MIS in adult patients following infection with SARS-CoV-2. Rarely, MIS is observed following vaccination against SARS-CoV-2, mostly in patients with prior SARS-CoV-2 infection. We report a case of KD in a man after a second SARS-CoV-2 vaccine dose, in absence of concurrent or prior SARS-CoV-2 infection. This patient also met criteria for probable MIS associated with vaccination. He tested negative for SARS-CoV-2 RNA via reverse transcriptase PCR, negative for SARS-CoV-2 nucleocapsid antibodies and demonstrated high levels SARS-CoV-2 spike protein antibodies, commonly used to assess vaccine response. Symptom improvement followed treatment with intravenous immunoglobulin, including desquamation of the hands and feet. As widespread vaccination against SARS-CoV-2 continues, increased vigilance and prompt intervention is necessary to limit the effects of postvaccination inflammatory syndromes.

Parent Attitudes Towards Childhood Vaccines After the Onset of SARS-CoV-2 in the United States. OBJECTIVE: To understand the influence of a novel infectious disease epidemic on parent general attitudes about childhood vaccines. METHODS: We conducted a natural experiment utilizing cross-sectional survey data from parents of infants in Washington and Colorado participating in a larger

trial that began on September 27, 2019. At enrollment, parents completed the short version of the Parental Attitudes about Childhood Vaccines (PACV-SF), a validated survey scored from 0 to 4, with higher scores representing more negative attitudes. The exposure variable was onset of the SARS-CoV-2 pandemic in the United States, with the before-period defined as September 27, 2019 to February 28, 2020 and the after-period defined as April 1, 2020-December 10, 2020, with the after-period further separated into proximate (April 1, 2020-July 31, 2020) and distant periods (August 1, 2020-December 10, 2020). The outcome variable was parent negative attitudes about childhood vaccines, defined as a score of â‰¥2 on the PACV-SF. We estimated the probability of the outcome after (vs before) the exposure using log-binomial regression with generalized estimating equations adjusted for demographic confounding variables. RESULTS: Among 4562 parents, the risk of negative attitudes was lower immediately after (vs before) SARS-CoV-2 onset (adjusted risk ratio [aRR]Â =Â 0.58; 95% confidence interval [CI], 0.36, 0.94; PÂ =Â .027), but by August-December 2020, the average rate of negative attitudes was 35% higher than during April-July 2020 (aRR: 1.35; 95% CI: 1.13, 1.61; PÂ =Â .0009). CONCLUSIONS: A reduced risk of negative general vaccine attitudes observed immediately after SARS-CoV-2 onset was quickly attenuated.

Methodological Issues in Using a Common Data Model of COVID-19 Vaccine Uptake and Important Adverse Events of Interest: Feasibility Study of Data and Connectivity COVID-19 Vaccines Pharmacovigilance in the United Kingdom. BACKGROUND: The Data and Connectivity COVID-19 Vaccines Pharmacovigilance (DaC-VaP) UK-wide collaboration was created to monitor vaccine uptake and effectiveness and provide pharmacovigilance using routine clinical and administrative data. To monitor these, pooled analyses may be needed. However, variation in terminologies present a barrier as England uses the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), while the rest of the United Kingdom uses the Read v2 terminology in primary care. The availability of data sources is not uniform across the United Kingdom. OBJECTIVE: This study aims to use the concept mappings in the Observational Medical Outcomes Partnership (OMOP) common data model (CDM) to identify common concepts recorded and to report these in a repeated cross-sectional study. We planned to do this for vaccine coverage and 2 adverse events of interest (AEIs), cerebral venous sinus thrombosis (CVST) and anaphylaxis. We identified concept mappings to SNOMED CT, Read v2, the World Health Organization's International Classification of Disease Tenth Revision (ICD-10) terminology, and the UK Dictionary of Medicines and Devices (dm+d). METHODS: Exposures and outcomes of interest to DaC-VaP for pharmacovigilance studies were selected. Mappings of these variables to different terminologies used across the United Kingdom's devolved nations' health services were identified from the Observational Health Data Sciences and Informatics (OHDSI) Automated Terminology Harmonization, Extraction, and Normalization for Analytics (ATHENA) online browser. Lead analysts from each nation then confirmed or added to the mappings identified. These mappings were then used to report AEIs in a common format. We reported rates for windows of 0-2 and 3-28 days postvaccine every 28 days. RESULTS: We listed the mappings between Read v2, SNOMED CT, ICD-10, and dm+d. For vaccine exposure, we found clear mapping from OMOP to our clinical terminologies, though dm+d had codes not listed by OMOP at the time of searching. We found a list of CVST and anaphylaxis codes. For CVST, we had to use a broader cerebral venous thrombosis conceptual approach to include Read v2. We identified 56 SNOMED CT codes, of which we selected 47 (84%), and 15 Read v2 codes. For anaphylaxis, our refined search identified 60 SNOMED CT codes and 9 Read v2 codes, of which we selected 10 (17%) and 4 (44%), respectively, to include in our repeated cross-sectional studies. CONCLUSIONS: This approach enables the use of mappings to different terminologies within the OMOP CDM without the need to catalogue an entire database. However, Read v2 has less granular concepts than some terminologies, such as SNOMED CT. Additionally, the OMOP CDM cannot compensate for limitations in the clinical coding system.

Neither Read v2 nor ICD-10 is sufficiently granular to enable CVST to be specifically flagged. Hence, any pooled analysis will have to be at the less specific level of cerebrovascular venous thrombosis. Overall, the mappings within this CDM are useful, and our method could be used for rapid collaborations where there are only a limited number of concepts to pool.
Retinal artery/vein occlusion complicating SARS-CoV-2 vaccinations.
Safety and immunogenicity of COVID-19 vaccination among liver transplant recipients in China.
COVID-19 diagnosis, but not vaccination, was linked to increased risk for immune-mediated neurologic events. Li X, RaventÃ³s B, Roel E, et al. Association between covid-19 vaccination, SARS-CoV-2 infection, and risk of immune mediated neurological events: population based cohort and self-controlled case series analysis. BMJ. 2022;376:e068373. 35296468.
Pulmonary embolism with junctional tachycardia: A serious complication after COVID-19 vaccination. INTRODUCTION: the association between the development of a thromboembolic event following COVID-19 vaccination is very rare, it represents less than 0.1% of vaccinated cases. Until now this association remains to be discussed. CASE PRESENTATION: A 49-year-old man presented to the Emergency Department a 7-day after receiving her second dose of BNT162b2 mRNA COVID-19 (Pfizer-BioNTech), and he was diagnosed with pulmonary embolism (PE) with junctional tachycardia on ECG. The biological workup showed an increase in CRP with elevated D-dimer, but no abnormalities in cardiac markers, including troponin and BNP, the COVID-19 testing was negative and absence of thrombocytopenia. The patient was put under curative anticoagulation by rivaroxabon. DISCUSSION: Studies have reported the association of venous thrombosis after administration of the COVID-19 vaccine with negative FP4 antibodies and normal platelet count which is similar with our patient. Moreover, spike proteins generated by mRNA vaccines can produce a pro-inflammatory state, a cascade of events guiding to endothelial dysfunction and afterwards to the development of venous thrombosis. CONCLUSION: All the same that some studies association COVID-19 immunizations to the development of VTE, we nevertheless recommend COVID-19 vaccination, due to the rarity of these events, compared to the hypercoagulable effects and other serious complications of COVID-19 infection.
Autoimmune Hepatitis Triggered by COVID-19 Vaccine: The First Case From Inactivated Vaccine. We report a case of a 52-year-old woman without previous underlying liver disease, presenting with progressive jaundice and diagnosed with autoimmune hepatitis after 2 doses of an inactivated coronavirus disease 2019 (CoronaVac) vaccine. All serology and histology were compatible with autoimmune hepatitis. Symptoms were improved and liver function tests were normalized after treatment with steroids and azathioprine.
Acute Severe Ulcerative Colitis After mRNA Coronavirus Disease 2019 Vaccination: Can mRNA Vaccines Unmask Inflammatory Bowel Diseases? BNT162b2 is a messenger RNA vaccine for the prevention of the novel coronavirus disease 2019 caused by severe acute respiratory syndrome coronavirus 2 infection. The widespread use of this vaccination has brought along several adverse events. We present a patient with newly diagnosed ulcerative colitis after BNT162b2 vaccine.
The short term safety of COVID-19 vaccines in Australia: AusVaxSafety active surveillance, February - August 2021. OBJECTIVE: To assess the short term safety of the COVID-19 vaccines Comirnaty (Pfizer-BioNTech BNT162b2) and Vaxzevria (AstraZeneca ChAdOx1) in Australia. DESIGN: Prospective observational cohort study; online surveys by AusVaxSafety, a national active vaccine safety surveillance system, three and eight days after vaccination. SETTING, PARTICIPANTS: People aged 16â€‰years or more who received COVID-19 vaccines at sentinel vaccination hubs, general practices, or Aboriginal Community Controlled Health Organisation clinics, 22 February - 30 August 2021. MAIN OUTCOME MEASURES: Primary outcome: proportion of respondents who reported any adverse event following immunisation (AEFI) 0-3â€‰days after vaccination. SECONDARY OUTCOMES: proportions

of respondents who reported specific adverse events or medical review for AEFI within seven days of vaccination; impact on usual daily activities; recovery. RESULTS: 4â€‰851â€‰480 people received COVID-19 vaccines at participating sentinel sites during the study period (25% of all COVID-19 vaccine doses administered in Australia to 30 August 2021). 3â€‰035â€‰983 people responded to both surveys (response rate, 62.6%); 35.9% of respondents reported one or more AEFI 0-3â€‰days after Comirnaty dose 1, 54.7% after Comirnaty dose 2, 52.8% after Vaxzevria dose 1, and 22.0% after Vaxzevria dose 2. Local pain, fatigue, headache, and myalgia were the most frequently reported symptoms. After adjusting for demographic characteristics, vaccination site type, jurisdiction, and self-reported medical conditions, the odds of reporting any AEFI were higher for women than men (range of adjusted odd ratios [aORs], by vaccine and dose, 1.53-1.84), for people with a history of anaphylaxis (aOR range, 1.28-1.45), and for people reporting certain underlying conditions, including obesity (aOR range, 1.15-1.75), immunodeficiency (aOR range, 1.04-2.24), or chronic inflammatory disease (aOR range, 1.05-1.75). 0.9% of respondents sought medical advice in the three days following vaccination, most frequently after Comirnaty dose 2 (1.4%) and Vaxzevria dose 1 (1.2%). CONCLUSION: AusVaxSafety active surveillance affirms the short term safety profile of Comirnaty and Vaxzevria vaccines in a large population sample during the first six months of the Australian COVID-19 vaccination program.

Acute corneal allograft rejection following SARS-CoV-2 vaccination-A systematic review. All documented cases of acute corneal allograft rejection following SARS-CoV-2 vaccination were examined, to characterize possible risk factors and graft outcomes. Comprehensive search (4 electronic databases: PubMed, CENTRAL, ClinicalTrials.gov, Google Scholar, plus manual search in articles' reference lists) until March 1st 2022 to identify studies reporting acute corneal allograft rejection following SARS-CoV-2 vaccination; study protocol was developed in line with PRISMA statement. We analysed demographics, allograft type, rejection prophylaxis regime at the time of vaccination, transplantation-to-vaccination time (G-Vt), vaccination-to-immune reaction onset time (V-Rt), management, best-corrected visual acuity before and after rejection, and graft survival. Of 169 titles/abstracts screened, 16 studies (n Â =Â 36 eyes) met the inclusion criteria. Fourteen eyes (38.9%) had received >1 graft, and 11.1% of cases had history of immune reactions; 52.9% of cases occurred after the first dose. Median (P25-P75) G-Vt was 48 (10-78) months; median V-Rt was 9 (7-14) days. In eyes with resolved rejection, median time-to-resolution was 3 (1-4) weeks. Four eyes (11.1%) had partial resolution of corneal decompensation, and 5 grafts (13.9%) failed. Acute corneal allograft rejection after SARS-CoV-2 vaccination is a rare event, but may occur any time post-keratoplasty. Early recognition and prompt, aggressive treatment is warranted to optimize vision and graft survival. Well-known risk factors for rejection may be confounding factors, including the high proportion of cases with a history of previous grafts and the rejection prophylaxis regimes at the time of vaccination. Increasing immunosuppressants in the peri-vaccination period may decrease the risk of immune reactions, especially in high-risk cases.

Cutaneous reactions after COVID-19 vaccination in Turkey: A multicenter study. OBJECTIVES: In this study covering all of Turkey, we aimed to define cutaneous and systemic adverse reactions in our patient population after COVID-19 vaccination with the Sinovac/CoronaVac (inactivated SARS-CoV-2) and Pfizer/BioNTech (BNT162b2) vaccines. METHODS: This prospective, cross-sectional study included individuals presenting to the dermatology or emergency outpatient clinics of a total of 19 centers after having been vaccinated with the COVID-19 vaccines. Systemic, local injection site, and non-local cutaneous reactions after vaccination were identified, and their rates were determined. RESULTS: Of the 2290 individuals vaccinated between April 15 and July 15, 2021, 2097 (91.6%) received the CoronaVac vaccine and 183 (8%) BioNTech. Systemic reactions were observed at a rate of 31.0% after the first CoronaVac dose, 31.1% after the second CoronaVac dose, 46.4% after the first

BioNTech dose, and 46.2% after the second BioNTech dose. Local injection site reactions were detected at a rate of 35.6% after the first CoronaVac dose, 35.7% after the second CoronaVac dose, 86.9% after the first BioNTech dose, and 94.1% after the second BioNTech dose. A total of 133 non-local cutaneous reactions were identified after the CoronaVac vaccine (2.9% after the first dose and 3.5% after the second dose), with the most common being urticaria/angioedema, pityriasis rosea, herpes zoster, and maculopapular rash. After BioNTech, 39 non-local cutaneous reactions were observed to have developed (24.8% after the first dose and 5% after the second dose), and the most common were herpes zoster, delayed large local reaction, pityriasis rosea, and urticaria/angioedema in order of frequency. Existing autoimmune diseases were triggered in 2.1% of the patients vaccinated with CoronaVac and 8.2% of those vaccinated with BioNTech. CONCLUSIONS: There are no comprehensive data on cutaneous adverse reactions specific to the CoronaVac vaccine. We determined the frequency of adverse reactions from the dermatologist's point of view after CoronaVac and BioNTech vaccination and identified a wide spectrum of non-local cutaneous reactions. Our data show that CoronaVac is associated with less harmful reactions while BioNTech may result in more serious reactions, such as herpes zoster, anaphylaxis, and triggering of autoimmunity. However, most of these reactions were self-limiting or required little therapeutic intervention.

Applicability of probabilistic graphical models for early detection of SARS-CoV-2 reactive antibodies after SARS-CoV-2 vaccination in hematological patients. Prior studies of antibody response after full SARS-CoV-2 vaccination in hematological patients have confirmed lower antibody levels compared to the general population. Serological response in hematological patients varies widely according to the disease type and its status, and the treatment given and its timing with respect to vaccination. Through probabilistic machine learning graphical models, we estimated the conditional probabilities of having detectable anti-SARS-CoV-2 antibodies at 3-6 weeks after SARS-CoV-2 vaccination in a large cohort of patients with several hematological diseases (n= 1166). Most patients received mRNA-based vaccines (97%), mainly ModernaÂ® mRNA-1273 (74%) followed by Pfizer-BioNTechÂ® BNT162b2 (23%). The overall antibody detection rate at 3 to 6 weeks after full vaccination for the entire cohort was 79%. Variables such as type of disease, timing of anti-CD20 monoclonal antibody therapy, age, corticosteroids therapy, vaccine type, disease status, or prior infection with SARS-CoV-2 are among the most relevant conditions influencing SARS-CoV-2-IgG-reactive antibody detection. A lower probability of having detectable antibodies was observed in patients with B-cell non-Hodgkin's lymphoma treated with anti-CD20 monoclonal antibodies within 6 months before vaccination (29.32%), whereas the highest probability was observed in younger patients with chronic myeloproliferative neoplasms (99.53%). The ModernaÂ® mRNA-1273 compound provided higher probabilities of antibody detection in all scenarios. This study depicts conditional probabilities of having detectable antibodies in the whole cohort and in specific scenarios such as B cell NHL, CLL, MM, and cMPN that may impact humoral responses. These results could be useful to focus on additional preventive and/or monitoring interventions in these highly immunosuppressed hematological patients.

Active monitoring of adverse reactions following COVID-19 and other vaccinations: a feasibility study as part of the CoVaKo project. BACKGROUND: The Corona-Vakzin-Konsortium project (CoVaKo) analyses the efficacy and safety of COVID-19 vaccines in a real-world setting, as well as breakthrough infections in Bavaria, Germany. A subproject of CoVaKo aims to identify adverse reactions of the COVID-19 vaccine and compare these to adverse reactions of other vaccines in an online survey. In a preceding feasibility study, the study materials were tested for comprehensibility, visual design, and motivation to participate, as well as for their ability to be implemented and carried out in primary care practices and vaccination centres. METHODS: We used a mixed-methods research design. First,

three focus groups consisting of general population participants were organised to evaluate the study materials and survey. Second, a test roll-out was conducted in vaccination centres and primary care practices that involved implementing and quantitatively evaluating the online survey. Third, interviews were conducted with participating general practitioners and heads of vaccination centresÂ four weeks after the test roll-out. RESULTS: Parts of the information and registration form proved incomprehensible, specifically regarding the recruitment material and/or online survey. For example, headings were misleading given that, relative to other vaccinations, the COVID-19 vaccination was overemphasised in the title. Participants requested additional information regarding the procedure and completion time. Within 31 days, 2199 participants, who received either a COVID-19 vaccination (99%) or at least one of the control vaccinations (1%), registered for the study. Participants (strongly) agreed that the registration process was easy to understand, that the completion time was reasonable, and that the technical setup was straightforward. Physicians and heads of the vaccination centres perceived the study as easy to integrate into their workflow. The majority expressed willingness to participate in the main study. CONCLUSIONS: Our study indicated that identifying and documenting adverse reactions following vaccinations using an online survey is feasible. Testing materials and surveys provided valuable insight, enabling subsequent improvements. Participation from health professionals proved essential in ensuring the practicality of procedures. Lastly, adapting the study's organisation to external fluctuating structures and requirements confirmed necessary for a successful implementation, especially due to dynamic changes in the nation's COVID-19 vaccination strategies. TRIAL REGISTRATION: The trial was retrospectively registered at the "Deutsches Register Klinischer Studien" (DRKS-ID: DRKS00025881) on Oct 14, 2021.

Vaccine-induced immune thrombotic thrombocytopenia after COVID-19 vaccination: Description of a series of 39 cases in Brazil. OBJECTIVE: Describe a case series of vaccine-induced immune thrombotic thrombocytopenia (VITT) after COVID-19 vaccination in Brazil that included ChAdOx1 nCoV-19, Ad26.COV2.S and BNT162b2 vaccines, describing their clinical and laboratory characteristics. METHODOLOGY: Descriptive case series study using Bio-Manguinhos/Fiocruz/AstraZeneca Brazil and National Immunization Program/Ministry of Health (NIP/MoH) data on COVID-19 AEFI surveillance. We obtained patient-level data from pharmacovigilance for AEFI surveillance and used both the NIP/MoH and Bio-Manguinhos/Fiocruz pharmacovigilance databases to create the study database. Thirty-nine cases of suspect VITT were included, 36 after ChAdOx1 nCoV-19, one after BNT162b2 and two after Ad26.COV2.S vaccine. All cases were based on meeting the Brighton Collaboration criteria for VITT. The primary outcomes were clinical and laboratory features, site of thrombosis, and anti-PF4 ELISA, when available. RESULTS: Thirty-nine cases met the criteria, 38 of which were classified as level 1 and one as level 3 according to Brighton Collaboration. Most cases had the central nervous system (CNS) as the main site of thrombosis (21/39) and happened after the vaccine first dose (34/39). The median age of the cases was 41Â years old (23 to 86 yo). Most of the cases (61.5%) occurred in women. The median interval between vaccination and onset of symptoms was 8Â days (0-37Â days). The platelet count and D-dimer count had median values of 34,000/ÂµL and 19,235Â Âµg FEU/L, respectively. The ELISA anti-PF4 antibody was positive in 18 samples. The overall mortality rate was 51% and was higher in cases of CNS thrombosis with intracerebral bleeding. CONCLUSION: Our case series shows that Brazilian VITT cases have similar clinical and laboratory profiles as demonstrated in the literature. Brazil has administered more than 300 million doses of COVID-19 vaccines (more than 110 million from ChAdOx1 nCoV-19). VITT seems to be a very rare but serious adverse event following COVID-19 immunization, especially adenoviral vector immunization.

An exploratory analysis of the response to ChAdOx1 nCoV-19 (AZD1222) vaccine in males and females. BACKGROUND: There are known differences in vaccine reactogenicity and

immunogenicity by sex. Females have been shown to report greater reactogenicity and generate higher humoral and cellular immune responses than males following vaccination with several different vaccines. Whether this is also the case for COVID-19 vaccines is currently unknown, as COVID-19 vaccine study data disaggregated by sex are not routinely reported. Therefore, we have assessed the influence of sex on reactogenicity, immunogenicity and efficacy of COVID-19 vaccine ChAdOx1 nCoV-19. METHODS: Vaccine efficacy was assessed in 15169 volunteers enrolled into single-blind randomised controlled trials of ChAdOx1 nCoV-19 in Brazil and the UK, with the primary endpoint defined as nucleic acid amplification test (NAAT)-positive symptomatic SARS-CoV-2 infection. All participants were electronically randomised to receive two standard doses of vaccine or the control product. Logistic regression models were fitted to explore the effect of age and sex on reactogenicity, and linear models fitted to log-transformed values for immunogenicity data. Reactogenicity data were taken from self-reported diaries of 788 trial participants. Pseudovirus neutralisation assay data were available from 748 participants and anti-SARS-CoV-2 spike IgG assay data from 1543 participants. FINDINGS: 7619 participants received ChAdOx1 nCoV-19 and 7550 received the control. Vaccine efficacy in participants after two doses of ChAdOx1 nCoV-19 (4243 females and 3376 males) was 66.1% (95% CI 55.9-73.9%) in males and 59.9% (95% CI 49.8-67.9%) in females; with no evidence of a difference in efficacy between the sexes (vaccine by sex interaction term P=0.3359). A small, statistically significant difference in anti-spike IgG was observed (adjusted GMR 1.14; 95% CI 1.04-1.26), with higher titres in females than males, but there were no statistically significant differences in other immunological endpoints. Whilst the majority of individuals reported at least one systemic reaction following a first dose of ChAdOx1 nCoV-19, females were twice as likely as males to report any systemic reaction after a first dose (OR 1.95; 95% CI 1.37-2.77). Measured fever of 38Â°C or above was reported in 5% of females and 1% of males following first doses. Headache and fatigue were the most commonly reported reactions in both sexes. INTERPRETATION: Our results show that there is no evidence of difference in efficacy of the COVID-19 vaccine ChAdOx1 nCoV-19 in males and females. Greater reactogenicity in females was not associated with any difference in vaccine efficacy. FUNDING: Studies were registered with ISRCTN 90906759 (COV002) and ISRCTN 89951424 (COV003) and follow-up is ongoing. Funding was received from the UK Research and Innovation, Engineering and Physical Sciences Research Council, National Institute for Health Research, Coalition for Epidemic Preparedness Innovations, National Institute for Health Research Oxford Biomedical Research Centre, Chinese Academy of Medical Sciences Innovation Fund for Medical Science, Thames Valley and South Midlands NIHR Clinical Research Network, the Lemann Foundation, Rede D'Or, the Brava and Telles Foundation, the Coordenacao de Aperfeicoamento de Pessoal de Nivel Superior, Brazil, and AstraZeneca.

Venous thromboembolism after COVID-19 mRNA vaccination.

Higher antibody responses after mRNA-based vaccine compared to inactivated vaccine against SARS-CoV-2 in Behcet's syndrome. There are limited data about humoral response to vaccine in BehÃ§et's syndrome (BS). We compared SARS-CoV-2 antibody response after two doses of inactivated (Sinovac/CoronaVac) or mRNA (Pfizer/BioNTech) vaccines in patients with BS and healthy controls (HCs). We studied 166 (92M/74F) patients with BS (mean age: 42.9â€‰Â±â€‰9.6Â years) and 165 (75M/90F) healthy controls (mean age: 42.4â€‰Â±â€‰10.4Â years), in a single-center cross-sectional design between April 2021 and October 2021. A total of 80 patients with BS and 89 HCs received two doses of CoronaVac, while 86 patients with BS and 76 HCs were vaccinated with BioNTech. All study subjects had a negative history for COVID-19. Serum samples were collected at least 21Â days after the second dose of the vaccine. Anti-spike IgG antibody titers were measured quantitatively using a commercially available immunoassay method. We found that theÂ great majority in both patient and HC groups had detectable antibodies after either CoronaVac (96.3% vs

100%) or BioNTech (98.8% vs 100%). Among those vaccinated with CoronaVac, BS patients had significantly lower median (IQR) titers compared to HCs [36.5 (12.5-128.5) vs 102 (59-180), pâ€‰<â€‰0.001]. On the other hand, antibody titers did not differ among patients with BS and HCs who were vaccinated with BioNTech [1648.5 (527.0-3693.8) vs 1516.0 (836.3-2599.5), pâ€‰=â€‰0.512). Among different treatment regimen subgroups in both vaccine groups, those who were using anti-TNF-based treatment had the lowest antibody titers. However, the difference was statistically significant only among those vaccinated with CoronaVac. Among patients vaccinated with BioNTech, there was no statistically significant difference between different treatment regimen groups. Compared to inactivated COVID-19 vaccine, mRNA-based vaccine elicited higher antibody titers among BS patients. Only in the CoronaVac group, patients especially those using anti-TNF agents were found to have low titers compared to healthy subjects. BS patients vaccinated with BioNTech were found to have similar seroconversion rates and antibody levels compared to healthy controls. Further studies should assess whether the low antibody titers are associated with diminished protection against COVID-19 in both vaccine groups.

Immunogenicity, efficacy and safety of COVID-19 vaccines: an update of data published by 31 December 2021. The unprecedented coronavirus disease 2019 (COVID-19) pandemic has caused a disaster for public health in the last 2 years, without any sign of an ending. Various vaccines were developed rapidly as soon as the outbreak occurred. Clinical trials demonstrated the reactogenicity, immunogenicity and protection efficacy in humans, and some of the vaccines have been approved for clinical use. However, waves of infections such as the recently circulating Omicron variant still occur. Newly emerging variants, especially the variants of concern, and waning humoral responses pose serious challenges to the control of the COVID-19 pandemic. Previously, we summarized the humoral and cellular immunity, safety profiles and protection efficacy of COVID-19 vaccines with clinical data published by 21 May 2021. In this review, we summarize and update the published clinical data of COVID-19 vaccines and candidates up to 31 December 2021.

Mucocutaneous lichenoid eruptions following COVID-19 vaccination: A keen observation.

Secondary Syphilis Presentation and Urticarial Eruption After Moderna COVID-19 Vaccination.
The diversity of the cutaneous manifestations of syphilis and the ability of the spirochete to evade diagnosis have been well documented by medical literature. However, what triggers the onset of secondary syphilis is not yet clear because of difficulties studying the bacterium. Our case describes the onset of a heterogeneous rash (or coexisting rashes) that presented the day after vaccination with the Moderna mRNA-1273 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. The potential etiologies of the patient's rash: A vaccine reaction, reactivation of chronic spontaneous urticaria, or a physical sign of syphilis itself are then reviewed. The potential for the Moderna coronavirus disease 2019 (COVID-19) vaccine to be the catalyst of this patient's cutaneous manifestations of his immune system responses is also hypothesized.

The role of mild and asymptomatic infections on COVID-19 vaccines performance: A modeling study. INTRODUCTION: Different COVID-19 vaccine efficacies are reported, with remarkable effectiveness against severe disease. The so called sterilizing immunity, occurring when vaccinated individuals cannot transmit the virus, is still being evaluated. It is also unclear to what extent people with no symptoms or mild infection transmit the disease, and estimating their contribution to outbreaks is challenging. OBJECTIVE: With an uneven roll out of vaccination, the purpose of this study is to investigate the role of mild and asymptomatic infections on COVID-19 vaccine performance as vaccine efficacy and vaccine coverage vary. METHODS: We use an epidemiological SHAR (Susceptible-Hospitalized-Asymptomatic-Recovered) model framework to evaluate the effects of vaccination in different epidemiological scenarios of coverage and efficacy. Two vaccination models, the vaccine V(1) protecting against severe disease, and the vaccine V(2), protecting against infection as well as

severe disease, are compared to evaluate the reduction of overall infections and hospitalizations. RESULTS: Vaccine performance is driven by the ability of asymptomatic or mild disease cases transmitting the virus. Vaccines protecting against severe disease but failing to block transmission might not be able to reduce significantly the severe disease burden during the initial stage of a vaccination roll out programme, with an eventual increase on the number of overall infections in a population. CONCLUSION: The different COVID-19 vaccines currently in use have features placing them closer to one or the other of these two extreme cases, V(1) and V(2), and insights on the importance of asymptomatic infection in a vaccinated population are of a major importance for the future planning of vaccination programmes. Our results give insights on how to best combine the use of the available COVID-19 vaccines, optimizing the reduction of hospitalizations.

Systematic review of spontaneous reports of myocarditis and pericarditis in transplant recipients and immunocompromised patients following COVID-19 mRNA vaccination. OBJECTIVES: To determine whether spontaneous reporting rates of myocarditis and pericarditis differed in immunocompromised patients compared with the whole population overall, and in terms of demographics, vaccine dose and time-to-onset. DESIGN: Systematic review of spontaneously reported data from the European Union/European Economic Area (EU/EEA), the USA and the UK. DATA SOURCES: EudraVigilance (EU/EEA), Vaccine Adverse Event Reporting System (VAERS; USA) and the Medicines and Healthcare products Regulatory Agency (UK) spontaneous reporting databases were searched from date of vaccine launch to 1 December 2021. ELIGIBILITY CRITERIA: Publicly available spontaneous reporting data for 'myocarditis' and 'pericarditis' from EU/EEA and USA following COVID-19 messenger RNA vaccines. Reports with comorbidities or concurrent medication indicative of transplantation, HIV infection or cancer ('immunocompromised' population) were compared with each overall database population. DATA EXTRACTION AND SYNTHESIS: Two researchers extracted data. Spontaneously reported events of myocarditis and pericarditis were presented for immunocompromised populations for each data source, stratified by age, sex, dose and time-to-onset (where available). Seriousness of each event was determined according to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guideline E2A definition. Proportional reporting ratio (PRR) was calculated. RESULTS: There were 178 reports of myocarditis and pericarditis among immunocompromised individuals overall. Seriousness was comparable between the immunocompromised and overall populations in both databases. No trends in age or sex were observed among immunocompromised individuals. Most reports followed a second vaccine dose and occurred within 14 days. The frequency of reporting was similar to the wider population (PRR=1.36 (95% CI=0.89 to 1.82) for VAERS population). CONCLUSIONS: Myocarditis and pericarditis following COVID-19 vaccination are very rare, and benefits of COVID-19 vaccination continue to outweigh any perceived risks. Reporting rates of myocarditis and pericarditis were similar in immunocompromised individuals, however defining characteristics differed compared with the whole population; therefore, continued monitoring of adverse events following vaccination remains vital to understand differences between population subgroups.

Dr. Trefond et al reply: Giant Cell Arteritis After SARS-CoV-2 Vaccination-Coincidence or Trigger?

The effect of COVID 19 vaccination on kidney recipients. BACKGROUND: Nearly one year from the onset of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, safe and effective vaccines began distribution around the world. This study aimed to assess the rate of COVID-19 disease among vaccinated kidney transplant patients and the types of symptoms found within them. DESIGN: This cross-sectional study was performed at the transplant ward and Organ Procurement Unit of Sina Hospital, Tehran, Iran. As a sample size, 159 cadavers' kidney recipients received two doses of the Sinopharm SARS-CoV-2 vaccine. The required data were collected using a

checklist via conducting a face-to-face interview. RESULTS: The mean age of the vaccinated participants was 49.44Â Â±Â 13.87Â years old. There were 73 (45.91%) vaccinated cases of SARS-CoV-2 infection during the study period, 18 cases (12.6%) occurred among fully vaccinated individuals, and 53 cases (33.3%) were among individuals who had received only one dose of vaccine. 45% of the fully vaccinated patients (received 2 doses vaccine) contracted SARS-CoV-2 from their families; 35% were infected through participation in social events (35%). There was a significant difference in disease severity levels between the fully vaccinated group and the one-dose vaccinated (pÂ <Â 0.023). The severe disease occurred in 2 patients after vaccination, who were subsequently admitted to the hospital. There was a significant difference between the number of kidney transplant days and infection with SARS-CoV-2 before (PÂ =Â 0.15) and after vaccination (pÂ <Â 0.015). CONCLUSION: Even after vaccination, kidney recipients are still at the risk of contracting SARS-CoV-2. In addition to these results, the efficacy of vaccination in preventing death caused by SARS-CoV-2 was confirmed.

Vaccine-Related adverse events following AZD1222 (ChAdOx1-nCoV-19) Covid-19 vaccine in solid malignancy patients receiving cancer treatment, as compared to age-matched healthy controls. The study aimed to evaluate vaccine-related adverse events (VRAEs) following ChAdOx1-nCoV-19 vaccine in solid cancer patients receiving treatment compared to healthy controls. 399 cancer patients and 90 healthy volunteers were enrolled. In the overall population, the incidence of VRAEs was significantly lower in cancer patients than in healthy volunteers (57% vs 80%, Pâ€‰<â€‰.001). Because the mean age of the cancer patients was higher than the healthy volunteers (59 vs 48â€‰years, Pâ€‰<â€‰.001), we analyzed age-matched comparison and found that there was no significant difference of VRAEs between two groups (74% vs 79%, P .32). Most VRAEs were of mild severity in both groups. The most common local VRAE was pain at the injection site in both groups, and the most common systemic VRAE was fatigue in the cancer cohort, while myalgia was the most common VRAE among the healthy controls. In the cancer cohort, fever was the only VRAE that led to interruption of the cancer treatment (in two cases). Among the cancer treatment types, patients undergoing chemotherapy-containing regimens had a lower likelihood of experiencing VRAEs. In summary, the overall incidence of VRAEs following ChAdOx1-nCoV-19 vaccine in actively treated cancer patients was comparable to healthy controls after adjusting for age. The VRAEs that occurred rarely interfered with the cancer treatment. These findings substantiate that vaccination with AZD1222 is safe in cancer patients undergoing treatment.

Effects of SARS-CoVâ€‘2 infections on inpatient mortality of geriatric patients after proximal femoral fracture surgery. BACKGROUND: The medical challenges caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoVâ€‘2) pose aÂ tremendous burden on the healthcare system. This study aimed to analyze the effects of aÂ SARS-CoVâ€‘2 infections or disease progression on inpatient mortality of geriatric patients after proximal femoral fracture surgery. METHODS: AÂ retrospective analysis was conducted in all patients with aÂ proximal femoral fracture surgically treated in an urban regional trauma center from 01/01/2020 to 01/31/2021. According to PCR test results detecting SARS-CoVâ€‘2, the patients were divided into two groups (SARS-CoVâ€‘2 positive vs. SARS-CoVâ€‘2 negative). Patient data, disease progression data, and treatment-related information were evaluated for all patients. Statistical data analysis was performed using unpaired Student's t test or non-parametric Mann-WhitneyÂ U test. RESULTS: A total of 311Â patients (women: 70.4%, age: 82.0â€¯Â±â€‰11.0Â years) were included in this study. Of these 3.9% (12/311) had aÂ positive test result for SARS-CoVâ€‘2. Significantly more deceased patients were found in the group tested positive for SARS-CoVâ€‘2 (SARS-CoVâ€‘2 positive: 41.7%, SARS-CoVâ€‘2 negative: 5.4%, pâ€¯<â€‰0.001). In addition, the number of proximal femoral fracture associated deaths correlated with the number of positive test results performed in the Clinic. The length of stay of SARS-CoVâ€‘2 COVID-19 survivors tended to be greater than in those who were tested negative (SARS-CoVâ€‘2 COVID-19 positive:

15.6â€¯Â±â€‰13.1â€¯days, SARS-CoVâ€‘2 COVID-19 negative: 11.5â€¯Â±â€‰6.5â€¯days, pâ€¯=â€‰0.683). Furthermore, aÂ significant difference in age was found in SARS-CoVâ€‘2 survivors and SARS-CoVâ€‘2 decedents (deceased: 95.5â€¯Â±â€‰7.5Â years, alive: 83.5â€¯Â±â€‰7.3Â years, pâ€¯=â€‰0.020). CONCLUSION: The study was conducted before the introduction of SARS-CoVâ€‘2 vaccination. The results therefore refer to immune naive (unvaccinated) patients. In our study, more than 40% of all patients with proximal femoral fractures who tested positive for SARS-CoVâ€‘2 died during hospitalization. An additional, critical factor in this respect was the age of the infected patients. Nonetheless, aÂ positive correlation was demonstrated between the mortality rate and the number of positive SARS-CoVâ€‘2 detections. Regarding the greater length of stay of patients tested positive for SARS-CoVâ€‘2, the limited transfer options (further rehabilitation, skilled nursing facility) of the infected ones can be considered as causal. Particularly the vulnerable older patients are increasingly endangered by aÂ combination of proximal femoral fracture and SARS-CoVâ€‘2.

Antibody evolution to SARS-CoV-2 after single-dose Ad26.COV2.S vaccine in humans. The single-dose Ad.26.COV.2 (Janssen) vaccine elicits lower levels of neutralizing antibodies and shows more limited efficacy in protection against infection than either of the two available mRNA vaccines. In addition, Ad.26.COV.2 has been less effective in protection against severe disease during the Omicron surge. Here, we examined the memory B cell response to single-dose Ad.26.COV.2 vaccination. Compared with mRNA vaccines, Ad.26.COV.2 recipients had significantly lower numbers of RBD-specific memory B cells 1.5 or 6 mo after vaccination. Despite the lower numbers, the overall quality of the memory B cell responses appears to be similar, such that memory antibodies elicited by both vaccine types show comparable neutralizing potency against SARS-CoV-2 Wuhan-Hu-1, Delta, and Omicron BA.1 variants. The data help explain why boosting Ad.26.COV.2 vaccine recipients with mRNA vaccines is effective and why the Ad26.COV2.S vaccine can maintain some protective efficacy against severe disease during the Omicron surge.

Cutaneous adverse events following 771 doses of the inactivated and mRNA COVID-19 vaccines: A survey study among health care providers. INTRODUCTION: As Coronavirus disease 19 (COVID-19) still continues to affect humanity worldwide, different types of COVID-19 vaccines are being administered to maintain immunization against COVID-19. As both the inactivated and mRNA vaccines are now being applied prevalently, systemic adverse events along with cutaneous side effects are frequently being reported in the literature. AIM: In our study, we aimed to determine the cutaneous adverse effects of the inactivated (Sinovac-CoronaVac) and mRNA (Pfizer-BioNTech) vaccines in healthcare providers in a tertiary referral hospital. METHODS: A web-based survey consisting of 26 questions related to the systemic and cutaneous side effects of the inactivated and mRNA COVID-19 vaccines, was formed. The online questionnaire was spread among the healthcare professionals working in a tertiary referral hospital via common instant messaging groups and e-mail. FINDINGS: A total number of 234 participants were included in the study. One hundred fifty-seven were female whereas 77 were male. The mean age was 31.51â€‰years. Eighty-nine respondents reported to have at least one cutaneous side effect after COVID-19 vaccination. Most commonly observed cutaneous side effects were local injection site reactions. Pfizer-BioNTech vaccine at the first and second doses, was shown to have statistically significantly higher rates of systemic and cutaneous adverse events compared to the Sinovac-CoronaVac vaccine. RESULTS: Our study shows that both inactivated and mRNA COVID-19 vaccines are associated with transient local injection site reactions, no severe systemic or cutaneous adverse events were observed in our study population.

How to preserve information equity for COVID-19 vaccination among severely immunocompromised populations: Challenges among heart transplant recipients in Japan.

Dermatological adverse reactions after vaccination with BNT162b2 in a cohort of healthcare workers. BACKGROUND: The description of the skin reactions produced by the different vaccines against SARS-

CoV-2 has focused on the symptoms reported by the general population. There are few studies with very different measurement methods focused on healthcare workers. METHODS: A longitudinal observational study was conducted on all the healthcare workers from the Hospital Universitario San Cecilio that received vaccination against COVID-19 with BNT162b2. The recruitment period was from December 2020 to September 2021. The recommended regimen was double, with a minimum interval of 21â€‰days between doses. All dermatological reactions reported as adverse effects of the vaccine were evaluated by the Staff of the Dermatology Unit of our center. RESULTS: A total of 3969 healthcare workers of our center were followed. Only 0.7% of them reported dermatological adverse reactions. The most frequently reported reactions were morbilliform rash and COVID arm. In the multivariate analysis, the vaccination regimen (one dose) and the history of COVID-19 infection remained the main factors associated with the report of dermatological adverse reactions. CONCLUSION: The rate of dermatological adverse reactions after vaccination with BNT162b2 (Pfizer-BioNTech) is extraordinarily low. No patient required hospitalization, which supports the safety of this vaccination in a population of healthcare workers.
Covid-19 vaccination in autoimmune rheumatic diseases: AÂ multi-center survey from southern India. AIM: This survey was conducted to evaluate COVID-19 vaccination status in patients with autoimmune rheumatic diseases (AIRDs). Our objectives were to study vaccine hesitancy, adverse effects, breakthrough infections and flare of underlying disease in this population subgroup. METHODS: This was a multi-center, cross-sectional, interview-based survey done at 6 tertiary care centers across Tamil Nadu, in the southern part of India from September 15, 2021 to October 14, 2021. The survey questionnaire was filled up by AIRD patients attending their clinics. The survey questionnaire comprised a set of 14 questions, distributed between patient characteristics, vaccines taken, their characteristics and COVID-19 infection. RESULTS: There were 2092 participants, with a mean age of 47.5â€‰Â±â€‰13.17â€‰years. Among them, 1293 (61.81%) were vaccinated, of which 837 (64.73%) were fully vaccinated. Two-thirds of our subjects were vaccinated with ChAdOx1 nCov-19 (COVISHIELD) (77.64%) and 21.57% with BBV 152 (COVAXIN). Age, gender, education and comorbidities had no association with vaccine hesitancy. The commonest (421; 52.69%) reason for vaccine hesitancy was fear of side effects. The incidence (nÂ =Â 72) of breakthrough infections was similar in both the vaccine groups, of which 58 (80.55%) were partially vaccinated and 14 (19.44%) were fully vaccinated. Thirty-two patients had a flare of pre-existing rheumatic disease. CONCLUSION: ChAdOx1 nCov-19 and BBV 152 were found to be safe in patients with rheumatic diseases. Fear of side effects was the major cause of vaccine hesitancy. All adverse effects were minor and self-limiting. Breakthrough infections and disease flares occurred only in a small subset of our cohort.
Response to: Possible Associations Between Alopecia Areata and COVID-19 Vaccination and Infection.
Transient ipsilateral breast edema following COVID-19 vaccination. While ipsilateral lymphadenopathy following COVID-19 vaccination is a relatively common finding on mammography and breast ultrasound transient ipsilateral breast edema is rare with only a few published case reports. Radiologists should be aware of this potential imaging appearance of the breast and axilla following COVID-19 vaccination given the imaging features of edema such as trabecular thickening, skin thickening, and increased echogenicity can overlap with benign and malignant breast conditions such as mastitis and inflammatory breast cancer. We describe a case of transient ipsilateral breast edema after COVID-19 vaccination followed by a discussion summarizing the current understanding and management of transient ipsilateral breast edema following COVID-19 vaccination.
First Episode of Psychosis Following the COVID-19 Vaccination - A Case Series.
Sudden Sensorineural Hearing Loss and COVID-19 Vaccination Revisited-An Ongoing Conversation.
Sudden Sensorineural Hearing Loss and COVID-19 Vaccination Revisited-An Ongoing Conversation-Reply.

Immune Persistence and Safety After SARS-CoV-2 BNT162b1 mRNA Vaccination in Chinese Adults: A Randomized, Placebo-Controlled, Double-Blind Phase 1 Trial. INTRODUCTION: BNT162b1 is a lipid nanoparticle-formulated, nucleoside-modified mRNA SARS-CoV-2 vaccine. Here, we report safety and immune persistence data following a primary two-dose vaccination schedule administered 21Â days apart. METHODS: Immune persistence was determined at month 3 in 72 younger participants (aged 18-55Â years) and at month 6 in 70 younger and 69 older participants (aged 65-85Â years). RESULTS: In younger participants, neutralizing antibody (nAb) geometric mean titers (GMTs) for the 10 and 30Â Âµg dose levels declined from 233 and 254 (21Â days after dose 2) to 55 and 87 at month 3, respectively, and to 16 and 27 at monthÂ 6, respectively. In older participants, nAb GMTs declined from 80 and 160 (21Â days after dose 2) to 10 and 21 at monthÂ 6. Overall, higher antibody titers were observed in younger participants, and the 30Â Âµg dose induced higher levels of nAb, which declined more slowly by month 6. No serious adverse events were reported in the vaccine group. CONCLUSION: This study showed BNT162b1 maintains a favorable safety profile in younger and older participants in the 6Â months after vaccination. This study further extends our understanding of immune persistence and the safety of the BNT162b1 vaccine as a candidate vaccine in the BioNTech pipeline. TRIAL REGISTRATION NUMBER: NCT04523571, registered August 21, 2020.
Reactions in leprosy patients triggered by COVID-19 vaccination - a cross-sectional study from a tertiary care centre in India.
Pyoderma gangrenosum after mRNA-based SARS-CoV-2 vaccine.
Cutaneous adverse reactions following SARS-CoV-2 vaccine booster dose: a real-life multicentre experience.
Safe administration of subsequent mRNA COVID-19 vaccine doses following a possible allergic reaction to the first dose.
Delayed urticaria after the third dose of mRNA COVID19 vaccine: A case series.
New-onset systemic lupus erythematosus after ChAdOX1 nCoV-19 and alopecia areata after BNT162b2 vaccination against SARS-CoV-2.
Generalized and persistent skin pigmentation after COVID-19 vaccination.
Thromboembolic events and hemorrhagic stroke after mRNA (BNT162b2) and inactivated (CoronaVac) covid-19 vaccination: A self-controlled case series study. BACKGROUND: This study aims to evaluate the association between thromboembolic events and hemorrhagic stroke following BNT162b2 and CoronaVac vaccination. METHODS: Patients with incident thromboembolic events or hemorrhagic stroke within 28 days of covid-19 vaccination or SARS-CoV-2 positive test during 23 February to 30 September 2021 were included. The incidence per 100,000 covid-19 vaccine doses administered and SARS-CoV-2 test positive cases were estimated. A modified self-controlled case series (SCCS) analysis using theÂ data from the Hong Kong territory-wide electronic health and vaccination records. Seasonal effect was adjusted by month. FINDINGS: A total of 5,526,547 doses of BNT162b2 and 3,146,741 doses of CoronaVac were administered. A total of 334 and 402 thromboembolic events, and 57 and 49 hemorrhagic stroke cases occurred within 28 days after BNT162b2 and CoronaVac vaccination, respectively. The crude incidence of thromboembolic events and hemorrhagic stroke per 100,000 doses administered for both covid-19 vaccines were smaller than that per 100,000 SARS-CoV-2 test positive cases. The modified SCCS detected an increased risk of hemorrhagic stroke in BNT162b2 14-27 days after first dose with adjusted IRR of 2.53 (95% CI 1.48-4.34), and 0-13 days after second dose with adjusted IRR 2.69 (95% CI 1.54-4.69). No statistically significant risk was observed for thromboembolic events for both vaccines. INTERPRETATION: We detected a possible safety signal for hemorrhagic stroke following BNT162b2 vaccination. The incidence of thromboembolic event or hemorrhagic stroke following vaccination is lower than that among SARS-CoV-2 test positive cases; therefore, vaccination against covid-19 remains an important

public health intervention. FUNDING: This study was funded by a research grant from the Food and Health Bureau, The Government of the Hong Kong Special Administrative Region (reference COVID19F01).
Breakthrough SARS-CoV-2 infections after COVID-19 immunization. As no vaccines are 100% effective at preventing illness, COVID-19 vaccine breakthrough cases are expected. We here aim to review the most recent literature on COVID-19 vaccine breakthrough infections. SARS-CoV-2 breakthrough infections are, in general, rare. Age may still be a factor in SARS-CoV-2 infections in immunized individuals.
Resumption of active recommendation of the human papillomavirus vaccine in Japan and future challenges for the National Immunization Program. Japan's immunization program resumed proactively recommending the use of the human papillomavirus (HPV) vaccine nationwide in April 2022, after suspending this recommendation in June 2013. The promotion of catch-up vaccinations is an urgent issue to reduce the increase in cervical cancer and other cancers caused by low vaccination rates. In addition, the National Immunization Program still has issues to be considered, such as the adoption of the 9-valent vaccine, establishment of an appropriate number of vaccinations according to age, and routine immunization of males. There is a history of eliminating the use of the measles, mumps, and rubella vaccine and the mouse brain-derived, purified inactivated Japanese encephalitis vaccine, as well as suspending the HPV vaccine recommendation in Japan. These decisions have led to the current preventable infectious disease burden. In order to make the right policy decisions based on science-based assessments, it is necessary to establish a safety assessment platform to evaluate the causal relationship between vaccines and adverse events following immunization. Information technology, which has been promoted with the coronavirus disease 2019 vaccine in the current pandemic, may assist in providing more detailed vaccine safety evaluations for other vaccines.
Acquired hemophilia A with SARS-CoV-2 mRNA vaccine: first case from Pakistan.
A spectrum of leprosy reactions triggered by Covid-19 vaccination: a series of four cases.
What's Important: The Challenge in Diagnosing Frozen Shoulder After COVID-19 Vaccination.
Response to "Do not miss Bickerstaff encephalitis as a complication of SARS-CoV-2 vaccines".
Tolerability and Reactogenicity Profile of mRNA SARS-Cov-2 Vaccines from a Mass Vaccination Campaign in a Tertiary Hospital: Between-Vaccine and Between-Population Prospective Observational Study (VigilVacCOVID Study). BACKGROUND: The comparative safety profile of SARS-Cov2 vaccines requires further characterization in real-world settings. OBJECTIVES: The aim of the VigilVacCOVID study was to assess the short-term safety of BNT162b2 and mRNA-1273 during the vaccination campaign of healthcare professionals (HCPs) and solid-organ transplant recipients (SOTRs) at a hospital clinic. METHODS: We conducted an observational, prospective, single-center, post-authorization study to characterize short-term adverse reactions (ARs) after vaccination. The primary endpoint was to assess between-vaccine differences (HCPs receiving BNT162b2 or mRNA-1273) and between-population differences (HCPs and SOTRs, both receiving mRNA-1273) in the risk of any ARs. Propensity score and covariate-adjusted multivariate models were used. The key secondary endpoint was to provide a descriptive assessment of the frequencies and intensity distribution of ARs. RESULTS: We included 5088 HCPs and 1289 patients. mRNA-1273 showed greater reactogenicity than BNT162b2, with an odds ratio (OR) for any AR of 3.04 (95% confidence interval (CI) 2.48-3.73; p value: <Â 0.001) and a higher frequency and intensity of reported ARs. Compared with HCPs vaccinated with mRNA-1273, SOTRs showed a lower risk of ARs (OR = 0.36; 95% CI 0.25-0.50), with fewer and less severe ARs. Age, sex, and previous SARS-CoV-2 infection were statistically significant covariates for the risk of any AR. A history of drug allergy was significant in the comparison between vaccines (BNT162b2 vs. mRNA-1273), but not in that between SOTRs and HCPs. CONCLUSIONS: Our study shows that mRNA-1273 had greater reactogenicity than BNT162b2. Overall,

both vaccines had an adequate tolerability profile. mRNA-1273 vaccination caused fewer ARs with milder severity in SOTRs.
Immune Responses after a Third Dose of mRNA Vaccine Differ in Virus-Naive versus SARS-CoV-2-Recovered Dialysis Patients. BACKGROUND AND OBJECTIVES: After two doses of mRNA vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), patients on dialysis show a defective humoral response, but a third dose could increase anti-SARS-CoV-2 spike IgG titers. Responses could be different in virus-naive and SARS-CoV-2-recovered patients on dialysis. However, characterization of memory B cell response after three doses is lacking. DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: We evaluated the dynamics of antireceptor binding domain IgG titers and antireceptor binding domain memory B cells until 6 months after two and three doses (administered within 6 months after the second dose) of mRNA vaccine in SARS-CoV-2-recovered and virus-naive dialysis populations. Results were analyzed by ordinary one-way ANOVA, the Kruskal-Wallis test, or the Wilcoxon matched-pairs test as appropriate. RESULTS: In total, 108 individuals (59 patients on dialysis and 49 controls) were included. In virus-naive patients on dialysis, antireceptor binding domain IgG response was quantitatively lower after two doses compared with healthy controls, but IgG titers increased by three-fold after three doses (P=0.008). In SARS-CoV-2-recovered patients on dialysis, antireceptor binding domain IgG titers after two doses were significantly higher compared with virus-naive patients on dialysis but did not significantly increase after a third dose. Regarding memory B cell response, we detected receptor binding domain-specific memory B cells at similar proportions in virus-naive patients on dialysis and vaccinated controls after two doses. Moreover, a strong receptor binding domain-specific memory B cell expansion was observed after the third dose in virus-naive patients on dialysis (5.5-fold; P<0.001). However, in SARS-CoV-2-recovered patients on dialysis, antireceptor binding domain memory B cells remained unchanged after the third dose. CONCLUSIONS: The third dose of mRNA vaccine given within 6 months after the second dose boosts serologic and memory response in virus-naive patients but not in SARS-CoV-2-recovered patients on dialysis. CLINICAL TRIAL REGISTRY NAME AND REGISTRATION NUMBER: COVID-19: SARS-CoV-2 Specific Memory B and T-CD4+ Cells (MEMO-COV2), NCT04402892.
Watch out for neuromyelitis optica spectrum disorder onset or clinical relapse after COVID-19 vaccination: What neurologists need to know? INTRODUCTION: The ongoing global COVID-19 pandemic has dramatically impacted our lives. We conducted this systematic review to investigate the safety of the COVID-19 vaccines in NMOSD patients. METHODS: We systematically searched PubMed, Scopus, Web of Science, and Embase from the beginning of the COVID-19 vaccination to March 1, 2022. Except for the letters, posters, and reviews, we included all related articles to answer two main questions. Our first question examined the occurrence of NMOSD onset as an adverse effect of the COVID-19 vaccine. Our second question investigated the safety of the COVID-19 vaccines in NMOSD patients. RESULTS: Out of 262 records, nine studies, including five studies for the first question and four studies for the second question, met the inclusion criteria. Out of the six patients with NMOSD onset after COVID-19 vaccination, five (83.3%) were female. The median time to NMOSD onset was 6.5 days, and the frequency of the COVID-19 vaccine type was identical in all patients. The most common presentation was longitudinally extensive transverse myelitis, significantly improved by pulse methylprednisolone with or without plasma exchange. The maintenance therapy was described only in three patients: rituximab (n=2) and azathioprine (n=1). Regarding the second question, out of 67 patients, 77.61% were female, with a mean age of 54.75 years old, a mean EDSS of 2.83, and a mean disease duration of 9.5 years. 77% reported at least one preexisting comorbidity. 88.05% were under treatment, most of which were rituximab and azathioprine. 98.50% received two doses of the COVID-19 vaccine. mRNA vaccines were the most commonly used vaccine(86.56%), which were well tolerated. No significant adverse event was

reported, and local pain was the most frequently reported. 4.67% of the patients experienced a clinical relapse after a mean interval of 49.75 days, which was mainly mild to moderate in severity. Unfortunately, the data on the COVID-19 vaccines were missing. CONCLUSION: The analysis suggests the safety profile of the COVID-19 vaccines. All NMOSD patients are strongly recommended to vaccinate for COVID-19. To maximize the effectiveness of the COVID-19 vaccines, further studies are needed to draw the best practice for vaccination.

Uveitis and Posterior Ophthalmic Manifestations Following the SARS-CoV-2 (COVID-19) Vaccine. PURPOSE: To present four cases of posterior ophthalmic manifestations associated with a temporal relationship to SARS-CoV-2 vaccination. METHODS: Retrospective case series with a review of clinical findings. RESULTS: Four patients presented with various posterior ophthalmic findings including uveitis, maculopathy, and optic neuropathy. Each of their clinical courses varied in terms of ophthalmic imaging and exam findings. CONCLUSION: The coronavirus disease 2019 (COVID-19) pandemic has ushered in a new wave of challenges to healthcare, epidemiological endeavors, and widespread vaccination efforts. Novel vaccines have been developed for the SARS-CoV-2 virus, including both mRNA and viral vector-based platforms. The ocular manifestations and side effects related to the SARS-CoV-2 vaccine is not well established or understood. There may be an association between vaccination and posterior ophthalmic manifestations.

Immunogenicity and safety of BNT162b2 mRNA COVID-19 vaccine in a subject affected by Shapiro's syndrome: A case report. Shapiro's syndrome (SS) is a rare neurological disorder characterized by spontaneous periodic hypothermia and hyperhidrosis without identifiable systemic causes or brain injuries. We present the case of F. a young patient, without agenesis of the corpus callosum and with episodes of recurrent hypothermia, who was successfully immunized against SARS-CoV-2 via vaccination. F. was born on 2012 and started suffering from episodes of hypothermia at the age of three, with body temperature reaching as low as 32.8Â°C Hypothermia episodes were initially associated with ibuprofen intake, but were later defined as symptoms of SS. No SARS-CoV-2 infections had been reported before vaccination. The subject received the first dose of pediatric formulation anti-SARS-CoV-2 Comirnaty vaccine on 11 January 2022 and the second dose on 5 February 2022. A one-week follow-up for adverse events was performed via telephone contact after both administrations. Further contact occurred one month after immunization. Anti-SARS-CoV-2 IgG titers were evaluated fifteen days after administration of the second dose. Following vaccination, slight fluctuations in body temperature and local adverse events were noted. These adverse events were not worrying; the vaccine's safety profile is therefore confirmed. The child also developed an excellent antibody titer (>28x10(3) AU/ml), thus suggesting a good immune response.

Reactogenicity and immunogenicity of BNT162b2 or mRNA-1273 COVID-19 booster vaccinations after two doses of BNT162b2 among healthcare workers in Japan: a prospective observational study. BACKGROUND: This study evaluates the immunogenicity and reactogenicity of BNT162b2 and mRNA-1273 booster doses after the primary two-dose BNT162b2 series in Japan and is the first report from Western Pacific region. RESEARCH DESIGN AND METHODS: Healthcare workers receiving the two-dose BNT162b2 series and eligible for booster vaccination were enrolled. Self-reported adverse reactions were recorded for 8 days. Antibody titer was measured at baseline and on day 28. RESULTS: A total of 2,931 and 890 subjects received BNT162b2 (homologous) and mRNA-1273 (heterologous) booster vaccinations, respectively. The anti-SARS-CoV-2 spike protein IgG titer increased by 50.9- and 64.3-fold in the homologous and heterologous groups, respectively. Immunogenicity was greater with increasing age, regardless of sex. Adverse reactions were mild to moderate and decreased with age. The most common adverse reactions were injection-site pain (92.2%), fatigue (71.8%), headache (58.3%), and fever â‰¥37.5Â°C (46.5%). Two cases of non-severe myocarditis occurred in the heterologous group and resolved without clinical sequelae. CONCLUSION: Homologous booster

schedules had fewer reported adverse reactions; heterologous boosters elicited greater immunogenicity. Among different age groups, subjects aged 60 or over had the lowest immunogenicity before the booster, and both homologous and heterologous boosters restored vaccine immunogenicity level comparable to those of younger age groups.

Autoimmune and inflammatory thyroid diseases following vaccination with SARS-CoV-2 vaccines: from etiopathogenesis to clinical management. Since the Covid-19 pandemic emerged in 2019, several adenoviral-vectored, mRNA-based and inactivated whole-virus vaccines have been developed. A massive vaccination campaign has been undertaken around the world, and an increasing number of SARS-CoV-2 vaccine-induced thyroid diseases have been described in the literature. Subacute thyroiditis has been reported in 52 patients, mean age 45.5â€‰Â±â€‰1.8 years, mainly in women (nâ€‰=â€‰39). Graves' disease is more frequent in women (nâ€‰=â€‰22) than in men (nâ€‰=â€‰10), mean age 46.2â€‰Â±â€‰2.6 years, reported as new onset, recurrent or exacerbation of well-controlled hyperthyroidism. The mean time to symptoms onset is 9.0â€‰Â±â€‰0.8 days in subacute thyroiditis, and 15.1â€‰Â±â€‰2.6 days in Graves' patients. Rare patients (nâ€‰=â€‰6) present silent or painless autoimmune thyroiditis. Thyroid function and autoimmune tests, inflammatory markers, thyroid echography with colour flow Doppler, radio-activity uptake on thyroid scan, medical treatment and follow-up are described and compared in patients with SARS-CoV-2 vaccine-induced thyroid diseases. The underlying pathogenic mechanisms of vaccine-induced thyroid diseases, molecular mimicry (various SARS-CoV-2 proteins sharing a genetic homology with a large heptapeptide human protein) or autoimmune/inflammatory syndrome induced by adjuvants (ASIA) are discussed in the context of predisposition or genetic susceptibility. The benefits of SARS-CoV-2 vaccination far outweigh the potential vaccine-induced adverse effects, but clinicians should be aware of possible autoimmune and inflammatory thyroid diseases, and can advise patients to seek medical assistance when experiencing anterior neck pain, fever or palpitations following SARS-CoV-2 vaccines. Further studies are warranted to investigate the etiopathogenesis and to clarify the factors which predispose patients to SARS-CoV-2 vaccine-induced thyroid diseases.

Unilateral optic neuritis after vaccination against the coronavirus disease: two case reports. BACKGROUND: Due to the emergence of COVID-19, many countries have started mass immunization programs. To date, no cases of optic neuritis following COVID-19 vaccination have been reported in the literature. CASE PRESENTATION: Objective: Here, we report 2 cases of unilateral optic neuritis after vaccination against COVID-19 using the Sinopharm vaccine (Sinopharm Group Co. Ltd, China). DESIGN: The clinical history, examination, and test findings of two individuals with unilateral optic neuritis associated with the timing of COVID-19 vaccination were described and further analyzed. SETTING: Two patients developed optic neuritis after receiving the COVID-19 vaccine. One patient developed optic neuritis 6Â weeks after the first dose and 3Â weeks after the second dose. The other patient developed optic neuritis 3Â weeks after the first dose. PARTICIPANTS: Two female patients, aged 21 and 39Â years. RESULT: The patients were successfully treated with intravenous methylprednisolone pulse therapy. Both patients had typical manifestations of optic neuritis and their visual acuity recovered fully after treatment. The second of these patients was positive for anti-myelin oligodendrocyte glycoprotein antibodies (MOG). CONCLUSION: Optic neuritis is a potential adverse effect after vaccination against the coronavirus disease (COVID-19).

Hand-foot syndrome like eruption following mRNA COVID-19 vaccine.

Vaccine Coverage Associated With Ending a Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Wave: A Retrospective Longitudinal Analysis. BACKGROUND: Two SARS-CoV-2 waves in Israel ended while a substantial number of individuals remained unvaccinated or partially vaccinated. The indirect protective effect of the first BNT162b2 vaccination campaign in Israel was evaluated between 22 December 2020 and 18 May 2021. METHODS: The daily percentage of new polymerase

chain reaction (PCR)-confirmed SARS-CoV-2 cases among unvaccinated individuals was analyzed for trends. Major shifts were identified using piecewise linear regression analysis. At these shifts, the percentage of naturally vaccinated (past SARS-CoV-2 cases) and the percentage of actively vaccinated (by inoculation) individuals were weighted and summed to determine the percentage of natural and active vaccination (NAV). RESULTS: A first decline among unvaccinated individuals occurred during a lockdown period, when the percentage of NAV was 8.16%. The major decline occurred after the end of the lockdown when the percentage of NAV reached 52.05%. SARS-CoV-2 cases ultimately declined among unvaccinated individuals when the percentage of NAV reached 63.55%. During the study period, the Alpha variant was prevalent and the use of nonpharmaceutical interventions, including social distancing, existed to varying degrees. CONCLUSIONS: The vaccination campaign played a major role in the decline of SARS-CoV-2 infection among unvaccinated individuals, leading to the end of the first 2021 SARS-CoV-2 wave (Alpha variant) in Israel. Infection in unvaccinated individuals stopped when two-thirds of the population were naturally or actively vaccinated. Any change in characteristics of the virus or the population can lead to a new outbreak.

IgG-RBD Response Due to Inactivated SARS-CoV-2 Vaccine: Alteration in D-Dimer and Fibrinogen Concentrations, Association with Comorbidities and Adverse Effects. OBJECTIVE: To examine the immunoglobulin G-receptor-binding domain (IgG-RBD) response and changes in fibrinogen and D-dimer concentrations in individuals with a past coronavirus infection and followed by CoronaVac. METHODS: The study consisted of a total of 116 participants. Blood samples were drawn from subjects 21-25 days after they received first and second doses of CoronaVac as well as from individuals with a past infection. Fibrinogen, D-dimer, and IgG-RBD concentrations were measured. RESULTS: The IgG concentrations of the vaccinated subjects were significantly higher ($P < .001$), fibrinogen levels were lower ($P < .001$), and D-dimer levels increased following the second vaccination compared with the first vaccination ($P = .083$). No difference was obtained in IgG-RBD between vaccinated and previously infected individuals ($P = .063$). The differences in fibrinogen and D-dimer were statistically nonsignificant between both groups. CONCLUSION: The CoronaVac vaccine appears to be safe and effective. It is essential for individuals to take personal protective measures, such as using masks and distancing.

Autoimmune hepatitis (AIH) following coronavirus (COVID-19) vaccine-No longer exclusive to mRNA vaccine?

Factors Associated With COVID-19 Vaccine Response in Transplant Recipients: A Systematic Review and Meta-analysis. BACKGROUND: The rapid development and universal access to vaccines represent a milestone in combating the coronavirus disease 2019 (COVID-19) pandemic. However, there are major concerns about vaccine response in immunocompromised populations in particular transplant recipients. In the present study, we aim to comprehensively assess the humoral response to COVID-19 vaccination in both orthotopic organ transplant and allogeneic hematopoietic stem cell transplant recipients. METHODS: We performed a systematic review and meta-analysis of 96 studies that met inclusion criteria. RESULTS: The pooled rates of seroconversion were 49% (95% confidence interval [CI], 43%-55%) in transplant recipients and 99% (95% CI, 99%-99%) in healthy controls after the second dose of vaccine. The pooled rate was 56% (95% CI, 49%-63%) in transplant recipients after the third dose. Immunosuppressive medication is the most prominent risk factor associated with seroconversion failure, but different immunosuppressive regimens are associated with differential outcomes in this respect. Calcineurin inhibitors, steroids, or mycophenolate mofetil/mycophenolic acid are associated with an increased risk of seroconversion failure, whereas azathioprine or mammalian target of rapamycin inhibitors do not. Advanced age, short interval from receiving the vaccine to the time of transplantation, or comorbidities confers a higher risk for seroconversion failure. CONCLUSIONS: Transplant recipients compared with the general population have much lower

rates of seroconversion upon receiving COVID-19 vaccines. Immunosuppressants are the most prominent factors associated with seroconversion, although different types may have differential effects.
An Argentinean cohort of patients with rheumatic and immune-mediated diseases vaccinated for SARS-CoV-2: the SAR-CoVAC Registry-protocol and preliminary data. BACKGROUND/OBJECTIVE: To evaluate the efficacy and safety of SARS-CoV-2 vaccine in patients with rheumatic and immune-mediated inflammatory diseases (IMIDs) in Argentina: the SAR-CoVAC registry. METHODS: SAR-CoVAC is a national, multicenter, and observational registry. Adult patients with rheumatic or IMIDs vaccinated for SARS-CoV-2 were consecutively included between June 1 and September 17, 2021. Sociodemographic data, comorbidities, underlying rheumatic or IMIDs, treatments received, their modification prior to vaccination, and history of SARS-CoV-2 infection were recorded. In addition, date and place of vaccination, type of vaccine applied, scheme, adverse events (AE), disease flares, and new immune-mediated manifestations related to the vaccine were analyzed. RESULTS: A total of 1234 patients were included, 79% were female, with a mean age of 57.8 (SD 14.1) years. The most frequent diseases were rheumatoid arthritis (41.2%), osteoarthritis (14.5%), psoriasis (12.7%), and spondyloarthritis (12.3%). Most of them were in remission (28.5%) or low disease activity (41.4%). At the time of vaccination, 21% were receiving glucocorticoid treatment, 35.7% methotrexate, 29.7% biological (b) disease modifying anti-rheumatic drugs (DMARD), and 5.4% JAK inhibitors. In total, 16.9% had SARS-CoV-2 infection before the first vaccine dose. Most patients (51.1%) received Gam-COVID-Vac as the first vaccine dose, followed by ChAdOx1 nCoV-19 (32.8%) and BBIBP-CorV (14.5%). Half of them (48.8%) were fully vaccinated with 2 doses; 12.5% received combined schemes, being the most frequent Gam-COVID-Vac/mRAN-1273. The median time between doses was 51Â days (IQR 53). After the first dose, 25.9% of the patients reported at least one AE and 15.9% after the second, being flu-like syndrome and local hypersensitivity the most frequent manifestations. There was one case of anaphylaxis. Regarding efficacy, 63 events of SARS-CoV-2 infection were reported after vaccination, 19% occurred during the first 14Â days post-vaccination, 57.1% after the first dose, and 23.8% after the second. Most cases (85.9%) were asymptomatic or mild and 2 died due to COVID-19. CONCLUSIONS: In this national cohort of patients, the most common vaccines used were Gam-COVID-Vac and ChAdOx1 nCoV-19. A quarter of the patients presented an AE and 5.1% presented SARS-CoV-2 infection after vaccination, in most cases mild. STUDY REGISTRATION: This study has been registered in ClinicalTrials.gov under the number: NCT04845997. Key Points â€¢ This study shows real-world data about efficacy and safety of SARS-CoV-2 vaccination in patients with rheumatic and immune-mediated inflammatory diseases. Interestingly, different types of vaccines were used including vector-based, mRNA, and inactivated vaccines, and mixed regimens were enabled. â€¢ A quarter of the patients presented an adverse event. The incidence of adverse events was significantly higher in those receiving mRAN-1273 and ChAdOx1 nCoV-19. â€¢ In this cohort, 5.1% presented SARS-CoV-2 infection after vaccination, in most cases mild.
Three cases of thyroiditis after COVID-19 RNA-vaccine.
Indeterminate mycobacterium tuberculosis QuantiFERON post Moderna mRNA Covid-19 vaccination. We report an interesting case of an indeterminate MTB QuantiFERON for a 26-year-old healthy soldier planned for a routine field exercise to Brunei. Further medical history revealed that the patient had a Moderna mRNA Covid-19 vaccine the day before his MTB QuantiFERON test. The patient was subsequently asked to repeat a T-spot test which was non-reactive, there were no longer any issues with the positive control for the T-spot test. Current Covid-19 research suggests that infection causes a dysregulation of the immune system, perhaps this might also be extrapolated where a Covid-19 vaccine might provoke an immune response which might interfere with some immunological assays. In summary there should be more research invested into the immunological

interactions that the newly developed Covid-19 vaccinations have with our existing immunological tests such as QuantiFERON tests which forms a key cornerstone in our fight against tuberculosis.
Rule out appropriately all differentials before attributing severe rhabdomyolysis to SARS-CoV-2 vaccination.
Severe rhabdomyolysis and SARS-CoV-2 vaccination: a reply to the letter by Dr. Josef Finsterer.: Reply to Letter to the Editor regarding our report to Dr. Finsterer.
Acquired Thrombotic Thrombocytopenic Purpura: A Rare Coincidence after COVID-19 mRNA Vaccine?
Response of COVID-19 vaccination in multiple sclerosis patients following disease-modifying therapies: A meta-analysis. BACKGROUND: COVID-19 vaccination is recommended for patients with multiple sclerosis (pwMS), while disease-modifying therapies (DMTs) may influence the efficacy of SARS-CoV-2 vaccines in this population. Thus, we conducted a meta-analysis to evaluate the impact of DMTs on immune response to COVID-19 vaccines in pwMS. METHODS: Literature search from December 1, 2019 to March 31, 2022 was performed in PubMed, MedRxiv, Embase and Cochrane Library. The risk of impaired response to vaccination in pwMS receiving DMTs was estimated in odds ratios (ORs) using random-effects method. FINDINGS: A total of 48 studies comprising 6860 pwMS were included. Overall, pwMS with anti-CD20 (OR=0.02, 95%â€‰CI:â€‰0.01-0.03) and sphingosine-1-phosphate receptor modulator (S1PRM) (OR=0.03, 95%â€‰CI:â€‰0.01-0.06) treatments had attenuated serologic response after full vaccination compared with those without DMTs. Additionally, pwMS vaccinated within six months since last anti-CD20 therapy were at significantly higher risk of blunted response compared with those receiving anti-CD20 therapy more than six months prior to vaccination (PÂ =Â 0.001). We found no significant associations between other treatments (including IFN-Î², GA, DMF, TERI, NTZ, CLAD, and ALE) and humoral response to SARS-CoV-2 vaccines in pwMS. As for T-cell response, no significant difference was found between pwMS on anti-CD20 and those without DMTs after vaccination, while S1PRM was marginally associated with impaired cellular response (PÂ =Â 0.03). INTERPRETATION: Our findings suggested that routine serological monitoring may be required for pwMS on anti-CD20 and S1PRMs after SARS-CoV-2 vaccination and highlighted the benefits of a booster dose. The effect of cellular response and optimal interval from last anti-CD20 treatment to vaccination should be further addressed. FUNDING: This study was supported by Natural Science Foundation of Shanghai (21ZR1433000).
COVID-19 vaccine counseling and safety assessment in children and teenagers with underlying medical conditions in China: a single center study. Safety concerns about novel vaccines and necessity of COVID-19 vaccination for children, especially with underlying medical conditions, are the obstacle of COVID-19 vaccination program among pediatric population. The study was conducted to investigate the vaccine hesitancy reasons among the parents, and to monitor the adverse events of inactivated COVID-19 vaccines in children and teenagers with underlying medical conditions in China. Children with underlying medical conditions encountered to the Immunization Advisory Clinic for COVID-19 vaccine counseling were enrolled. They were given immunization recommendation and followed up at 72 h and 28â€‰d after immunization to monitor the immunization compliance after consultation and adverse events. A total of 324 children aged 3-17â€‰y were included. The top three primary medical conditions for counseling were allergy (33.6%), neurological diseases (31.2%) and rheumatic diseases (8.3%). COVID-19 vaccination was promptly recommended for 242 (74.7%) children. Seventy-one (65.7%) children who had allergy issues were recommend to take vaccination, which was significantly lower than that of other medical conditions (pâ€‰<â€‰.05). The follow-up record showed that 180 children received 340 doses of inactivated COVID-19 vaccine after consultation. Overall, 39 (21.6%) children reported at least one adverse event within 28â€‰d of either vaccination. No serious adverse reactions were observed. No difference of adverse effects between the first dose and the second dose of vaccination except fever. Parents' hesitancy in COVID-

19 vaccination for children with underling medical conditions are mainly due to the safety concerns. Specialist consultation is helpful to improve the vaccine uptake.

Antibody Response to COVID-19 mRNA Vaccine in Patients With Lung Cancer After Primary Immunization and Booster: Reactivity to the SARS-CoV-2 WT Virus and Omicron Variant. PURPOSE: To examine COVID-19 mRNA vaccine-induced binding and neutralizing antibody responses in patients with non-small-cell lung cancer (NSCLC) to SARS-CoV-2 614D (wild type [WT]) strain and variants of concern after the primary 2-dose and booster vaccination. METHODS: Eighty-two patients with NSCLC and 53 healthy volunteers who received SARS-CoV-2 mRNA vaccines were included in the study. Blood was collected longitudinally, and SARS-CoV-2-specific binding and neutralizing antibody responses were evaluated by Meso Scale Discovery assay and live virus Focus Reduction Neutralization Assay, respectively. RESULTS: A majority of patients with NSCLC generated binding and neutralizing antibody titers comparable with the healthy vaccinees after mRNA vaccination, but a subset of patients with NSCLC (25%) made poor responses, resulting in overall lower (six- to seven-fold) titers compared with the healthy cohort (P = < .0001). Although patients age > 70 years had lower immunoglobulin G titers (P = < .01), patients receiving programmed death-1 monotherapy, chemotherapy, or a combination of both did not have a significant impact on the antibody response. Neutralizing antibody titers to the B.1.617.2 (Delta), B.1.351 (Beta), and in particular, B.1.1.529 (Omicron) variants were significantly lower (P = < .0001) compared with the 614D (WT) strain. Booster vaccination led to a significant increase (P = .0001) in the binding and neutralizing antibody titers to the WT and Omicron variant. However, 2-4 months after the booster, we observed a five- to seven-fold decrease in neutralizing titers to WT and Omicron viruses. CONCLUSION: A subset of patients with NSCLC responded poorly to the SARS-CoV-2 mRNA vaccination and had low neutralizing antibodies to the B.1.1.529 Omicron variant. Booster vaccination increased binding and neutralizing antibody titers to Omicron, but antibody titers declined after 3 months. These data highlight the concern for patients with cancer given the rapid spread of SARS-CoV-2 Omicron variant.

SARS-CoV-2 Infection in Patients with a History of VITT.

Neutralizing Antibody Activity to Severe Acute Respiratory Syndrome Coronavirus 2 Delta (B.1.617.2) and Omicron (B.1.1.529) After 1 or 2 Doses of BNT162b2 Vaccine in Infection-Naive and Previously Infected Individuals. Previous reports demonstrated that severe acute respiratory syndrome coronavirus (SARS-CoV-2) binding immunoglobulin G levels did not increase significantly between the first and second doses of the BNT162b2 vaccine in previously infected individuals. We tested neutralizing antibodies (nAbs) against SARS-CoV-2 Delta and Omicron variants after the first and second doses of this vaccine in infection-naive and previously infected individuals. Delta, but not Omicron, nAb titers significantly increased from the first to the second dose in both groups of individuals. Importantly, we found that Omicron nAb titers were much lower than Delta nAb titers and that even after 2 doses of vaccine, 17 of 29 individuals in the infection-naive group and 2 of 27 in the previously infected group did not have detectable Omicron nAb titers. Infection history alone did not adequately predict whether a second dose resulted in adequate nAb. For future variants of concern, the discussion on the optimal number of vaccine doses should be based on studies testing for nAb against the specific variant.

Serosurveillance after a COVID-19 vaccine campaign in a Swiss police cohort. INTRODUCTION: To assess the risk for COVID-19 of police officers, we are studying the seroprevalence in a cohort. The baseline cross-sectional investigation was performed before a vaccination campaign in January/February 2021, and demonstrated a seroprevalence of 12.9%. Here, we demonstrate serosurveillance results after a vaccination campaign. METHODS: The cohort consists of 1022 study participants. The 3- and 6-month follow-up visits were performed in April/May and September 2021. Data on infection and vaccination rates were obtained via measuring antibodies to the nucleocapsid

protein and spike protein and online questionnaires. RESULTS: The mean age of the population was 41 (SD 8.8) years, 72% were male and 76% had no comorbidity. Seroconversion was identified in 1.05% of the study population at the 3-month visit and in 0.73% at the 6-month visit, resulting in an infection rate of 1.8% over a time period of 6 months. In comparison, the infection rate in the general population over the same time period was higher (3.18%, pâ€‰=â€‰.018). At the 6-month visit, 77.8% of participants reported being vaccinated once and 70.5% twice; 81% had an anti-S antibody titer of >250â€‰U/ml and 87.1% of â‰¥2â€‰U/ml. No significant association between infection and job role within the department, working region, or years of experience in the job was found. Anti-spike antibody titers of vaccinated study participants showed a calculated decreasing trend 150-200 days after the second vaccine dose. CONCLUSION: These data confirm the value of the vaccination campaign in an exposed group other than healthcare professionals.

Short-term side effects of COVID-19 vaccines: A cross-sectional study in Jordan. The rapid manufacturing of vaccines has increased hesitancy toward receiving the COVID-19 vaccines. Clarifying what to expect after vaccination and revealing the possible side effects will lower hesitancy toward receiving the COVID-19 vaccine and increase public awareness. This descriptive cross-sectional survey-based study was conducted in Jordan (August 2021) to collect data on the short-term side effects following the COVID-19 vaccines. An extensive literature review was conducted by the research team to assist in developing the first draft of the survey. The survey was tested for face and content validity and piloted test to improve readability and clarity. The survey was organized into two sections (demographics and perceived COVID-19 vaccines' side effects). Data were analyzed using the Statistical Package for Social Science (SPSS). A total of 1,044 participants were enrolled in the study. The most received vaccine among the participants was Pfizer-BioNTech (51.1%). The most frequently reported side effects were sore arm at the injection site (84.65%), fatigue (84.48%), discomfort (65.43%), muscles/joint pain (61.38%), drowsiness (58.73%), and headache (58.38%). More side effects were significantly associated with being older (pâ€‰=â€‰0.046), having an allergy (pâ€‰=â€‰0.024) or rheumatoid arthritis (pâ€‰=â€‰0.023), and participants who take NSAIDs regularly (pâ€‰=â€‰0.029). Short-term side effects of COVID-19 vaccines seem to be mostly local or transient in nature. Older age and certain comorbidities may increase susceptibility to side effects.

Immunogenicity and safety of SpikoGenÂ®, an adjuvanted recombinant SARS-CoV-2 spike protein vaccine as a homologous and heterologous booster vaccination: A randomized placebo-controlled trial. SpikoGenÂ® is a subunit recombinant spike protein vaccine combined with Advax-CpG55.2â„¢ adjuvant. This COVID-19 vaccine was shown to be safe, immunogenic and efficacious in previous clinical trials. This study aimed to assess the safety and immunogenicity of SpikoGenÂ® vaccine as a homologous and heterologous booster vaccination. This double-blind and randomized placebo-controlled (5:1) trial was performed on 300 already vaccinated participants. SpikoGenÂ® or saline placebo was administered as a booster dose to participants who had received a full two-dose COVID-19 vaccination course. Immunogenicity assessments were done 14â€‰days after the booster dose with the primary immunogenicity outcome seroconversion rate of neutralizing antibodies. Safety outcomes included the incidence of solicited adverse events up to 7â€‰days after the booster dose. SpikoGenÂ® vaccine induced a robust humoral response both as a homologous and heterologous booster, when compared to the placebo. At Day 14, seroconversion of neutralizing antibodies was 76% (95% confidence interval [CI]: 69%-82%) in the SpikoGenÂ® group versus 3% (95% CI: 0%-13%) in the placebo group. The most common local and systemic reported adverse events were injection site pain and fatigue. No serious adverse events were reported. The SpikoGenÂ®-booster induced cross-neutralization of other SARS-CoV-2 variants. Irrespective of the primary vaccine course received, SpikoGenÂ® vaccine showed promising effects as both a homologous and heterologous booster dose. This vaccine also had a good safety profile with no vaccine-associated

serious adverse events. On the basis of these results, SpikoGenÂ® vaccine has been approved as a booster dose.
Pediatric and adolescent COVID-19 vaccination side effects: A retrospective cohort study of the Iranian teenage group in 2021. To determine the safety and efficacy profile of teenager COVID-19 vaccination.Â In this retrospective cohort study, contact numbers of parents of teenagers under 18 years of age referred to a teenager vaccination centers in Tehran-Iran to receive the corona vaccine were collected, and the following information was obtained via the phones: demographic information, type of vaccine, and the number of doses received, as well as additional informationÂ like complications andÂ required treatments.Â Eleven thousand forty-twoÂ subjects aged 10-18 years, mean age 14.55â€‰Â±â€‰1.83 yearâ€‰ including 5374 boys and 5768 girls were investigated. 88.1% received the Sinopharm and 11.9% the Soberana vaccine. General side effects, including fatigue, fever and chills, injection site pain and dizziness, and so forthÂ happened in 2978 cases; 7421 children presented with at least one general or organ-specific side effect following vaccination, including potentially critical side effects, such as vascular injuries, respiratory complication, and so forth.Â 0.1% of the subject needed hospital admission. The breakthrough infection happened in 200 individuals.Â Our study shows that Sinopharm and Soberana (PastoCoVac) COVID-19 vaccinesÂ are generally safe with no serious side effects in less than 18 years old. COVID-19 infection and reinfection can occur after vaccination, but the incidence is actually tolerable and significantly lower than in the unvaccinated group.
Safety and immunogenicity of fifth dose SARS-CoV-2 vaccination in patients with autoimmune disease: a case series.
Alopecia areata after CoronaVac vaccination.
First case of atypical haemolytic uraemic syndrome following COVID-19 vaccination with BNT162b2.
Vitiligo of the arm after COVID-19 vaccination.
Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease and Transverse Myelitis Probably Associated With SARS-CoV-2 mRNA Vaccines: Two Case Reports. Post-vaccination CNS demyelinating syndromes have been reported with a variety of vaccines including the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines. We report a case of myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) probably associated with the mRNA-1273 (by Moderna) SARS-CoV-2 mRNA vaccine, and a case of acute transverse myelitis (ATM) probably associated with the BNT162b2 (by Pfizer-BioNTech) SARS-CoV-2 mRNA vaccine. A 38-year-old man developed left blurry vision, lower extremity weakness/paresthesia, and bowel/bladder dysfunction three days after receiving the Moderna vaccine. He was diagnosed with left optic neuritis and longitudinally extensive transverse myelitis; he tested positive for the myelin oligodendrocyte glycoprotein antibody. A 39-year-old woman presented with progressive lower extremity weakness/numbness 7Â days after receiving the Pfizer vaccine. She was diagnosed with ATM. Both patients improved with intravenous corticosteroids. The association between CNS demyelinating syndromes and vaccination has been reported for many years. We describe two cases of acute CNS demyelinating events probably associated with both mRNA variations of the SARS-CoV-2 vaccines. While the risk of CNS demyelinating events is non-negligible, the incidence is very low and the overall benefits of vaccination outweigh the marginal risk. However, providers should be aware of this potential neurological complication of the SARS-CoV-2 mRNA vaccines.
Facial Diplegia as the Sole Manifestation of Post-Vaccination Guillain-Barre Syndrome: A Case Report and Literature Review. INTRODUCTION: Recently, a large study concluded that certain brands of vaccines may increase the risk of Bell's palsy and Guillain Barre Syndrome (GBS). As to whether vaccination after COVID-19 modify the risk of Bell's palsy or GBS has not yet been studied. CASE: Here we report a 35Â years old COVID-19 survivor whom in less than 2Â weeks after his second dose of

inactivated SARS-CoV2 vaccine, developed bilateral facial nerve paralysis. In addition, he had hyperacusis, dysgeusia and decreased lacrimation without any signs of sensory and motor deficits in the limbs. His limb nerve conduction study (NCS) was unremarkable in contrast to bilaterally abnormal facial NCS and blink reflexes. Although he had negative anti-GM1 IgG and IgM antibodies, he has marked albuminocytologic dissociation, classic of acute inflammatory demyelinating polyneuropathy. CONCLUSION: To date, there were no similar case reports which published the occurrence of facial diplegia as sole manifestation of GBS in a post COVID-19 patient who recently completed vaccination. We believe that molecular mimicry, induced by magnified immune response from both COVID-19 and vaccination may have caused the symptom.

Willingness to be vaccinated against COVID-19 is equal in individuals with affective disorders and healthy controls. Affective disorders such as major depressive disorder and bipolar disorder are associated with higher infection rates and a more severe course of coronavirus disease (COVID-19). In turn, COVID-19 could trigger mental disease relapse. Vaccinations lead to a reduction of infections and the prevention of severe courses. This work aims to survey the willingness of individuals with affective disorders to get vaccinated and concerns about vaccinations. METHODS: An online study (April-May 2021) assessed the current infection and vaccination rate amongst individuals with affective disorder in Austria by surveying attitudes towards the vaccination, the willingness to get vaccinated soon and possible reasons for decision. The analyses included 59 individuals with affective disorders and 59 healthy controls, matched for sex and age. RESULTS: There was an overall high willingness to get vaccinated against COVID-19. Individuals with affective disorders were more skeptical about vaccinations in general but there was no significant difference between the groups in the willingness to get vaccinated against COVID-19. In both groups reasons for waiting were mainly fears of acute and/or long-term side effects and the fast development of the vaccines. LIMITATIONS: It was a cross sectional design. Due to the online design, no objective rating of current psychopathological symptoms was assessed. Willingness to get vaccinated in general and against COVID-19 in particular were self-created variables, whereas item statistics and factor analysis were conducted. DISCUSSION: Because of the higher risk for individuals with affective disorders, preventive strategies like vaccinating should be promoted in this group. It is important to help individuals with AD to overcome barriers such as negative beliefs and concerns about acute and/or long-term side effects.

Long-term antibody response following SPUTNIK V primary vaccination in healthcare workers with and without history of SARS-CoV-2 infection: Prospective cohort study from a hospital in Argentina. BACKGROUND: In December 2020, Sputnik V was incorporated to the National COVID-19 Immunization Plan in Argentina. Studies had shown 98% of antibody response rate. To date, data on immunogenicity and antibody persistence in Argentina are scarce.The objective was to assess humoral immune response after two doses of Sputnik V in Health Care Workers (HCWs) at the Ricardo Gutierrez Children's Hospital (RGCH). METHODS: A prospective, cohort study in HCWs immunized with two doses of Sputnik V between February and March 2021. The following variables were assessed: age, gender, risk factors for severe COVID-19 or mortality, immunosuppressive therapy and history of SARS-CoV-2. Blood samples were drawn on the day of the first dose, 28Â days and 180Â days after the second. Anti-Spike IgG was measured using an ELISA assay. Differences in immune response were evaluated according to study variables. Comparison analyses between groups with or without history of infection were performed, with T-test and ANOVA or Mann-Whitney tests. For each subject, we compared baseline values with 28Â days and 180Â days after the second vaccine.STATA version 14 and R Sofware were used for data analyses. RESULTS: We included 528 individuals, mean age 41.5Â years, 82.9% female, 14.4% (76/528) reported previous SARS-CoV-2 infection.All subjects developed antibodies post-vaccination. At day 28, concentrations were

significantly higher in previously infected than naÃ¯ve subjects (pÂ <Â 0.001) with no differences according to age, gender and comorbidities.At day 180, 17% (95% CI 13.17-21.53) of naÃ¯ve subjects were negative. Antibody concentrations decreased significantly in all subjects except in those who reported SARS-CoV-2 infection after vaccination (nÂ =Â 31). This last group had significantly higher antibody concentrations. CONCLUSION: This study assessed immune response to a new COVID-19 vaccine in real life in a cohort of subjects. Antibody concentrations varied according to history of SARS-COV-2 infection and decreased over time.

A Case of Hypophysitis Associated With SARS-CoV-2 Vaccination. BACKGROUND/OBJECTIVE: Although SARS-CoV-2 vaccines have been developed with multiple novel technologies and rapidly disseminated worldwide, the full profile of adverse effects has not been known. Recently, there are sporadic but increasing reports of endocrinopathy in relation to SARS-CoV-2 vaccination. Here we report a rare case of hypophysitis with acute onset of diabetes insipidus, immediately after SARS-CoV-2 vaccination. CASE REPORT: A 48-year-old female patient had been in her usual state of health until she received the first SARS-CoV-2 vaccine. Two days after vaccination, she started to have flu-like symptoms, including severe headache and myalgia as well as persistent headache, polydipsia, and polyuria. She was diagnosed with diabetes insipidus, and magnetic resonance imaging revealed thickening of the pituitary stalk. Three months after vaccination, her symptoms had somewhat improved, but she still had pituitary stalk thickening on magnetic resonance imaging. DISCUSSION: Given the timing of the occurrence of diabetes insipidus, we believe that the patient's hypophysitis may be associated with SARS-CoV-2 vaccination. We also found 19 cases of endocrinopathy after SARS-CoV-2 vaccination by literature search. The reported endocrine organs were the thyroid, pituitary, and adrenals. Twelve cases of diabetes were also reported. Among 3 pituitary cases, diabetes insipidus was reported only in our case. CONCLUSION: We report a rare case of SARS-CoV-2 vaccine-triggered hypophysitis, which led to diabetes insipidus. SARS-CoV-2 vaccine-related endocrinopathy seems, indeed, possible. Endocrinopathy is associated with infrequent complications; however, it may be underestimated in the post-SARS-CoV-2-vaccinated population. Further studies are warranted to better understand SARS-CoV-2 vaccine-related endocrinopathy.

New-onset lichen planus and lichen planus flare in elderly women after COVID-19 vaccination.

Cutaneous lupus-erythematosus-like reaction arising after COVID-19 vaccination. Multiple adverse cutaneous reactions have been described following vaccination against COVID-19. This case report describes a reaction to the Pfizer-BioNTech (BNT162b2) vaccine that histopathologically resembles cutaneous lupus erythematosus with vacuolar interface alteration, superficial to mid-dermal perivascular and periadnexal lymphocytic infiltrate with clusters of CD123(+) cells, and mildly increased dermal mucin.

Relapses of idiopathic inflammatory myopathies after vaccination against COVID-19: a real-life multicenter Italian study. Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccination plays a crucial role as pivotal strategy to curb the coronavirus disease-19 (COVID-19) pandemic. The present study described the clinical status of patients affected by idiopathic inflammatory myopathies (IIM) after COVID-19 vaccination to assess the number of relapses. We included all patients affected by IIM and followed by Myositis Clinic, Rheumatology and Respiratory Diseases Units, Siena University Hospital, Bari University Hospital, Policlinico Umberto I, Sapienza University, Rome, and Policlinico Paolo Giaccone, Palermo. They underwent a telephone survey. A total of 119 IIM patients (median, IQR 58 (47-66) years; 32males; 50 dermatomyositis, 39 polymyositis and 30 anti-synthetase syndrome) were consecutively enrolled. Except four patients who refused the vaccination, 94 (81.7%) received Comirnaty, 16 (13.9%) Spikevax, 5 (4.4%) Vaxzevria. Seven (6.1%) patients had flare after vaccination. One of them had life-threatening systemic involvement and died two months after second dose of COVID-19 vaccination. From logistic

regression analysis, Chi(2)-log ratioâ€‰=â€‰0.045,the variable that most influences the development of flare was the number of organs involved (pâ€‰=â€‰0.047). Sixty-eight patients received the third dose of COVID-19 vaccination: 51(75%) Comirnaty and 17 (25%) Moderna. No patients had flares after third dose. Our study represents the largest cohort of IIM patients in which the incidence of recurrence after anti-SARS-CoV-2 vaccine was assessed. In line with real-life data from other diseases, we found a clinical non-statistically significant risk of relapse in our patients, which occurred seldom, usually mild and in patients with a more severe and aggressive course of disease.

Commentary on "Risk of venous thromboembolism after COVID-19 vaccination".

Successful management of intracranial hemorrhage in a patient with COVID-19 vaccine-induced immune thrombotic thrombocytopenia and cerebral venous thrombosis.

[A case of polyneuropathy after COVID-19 vaccine]. A 43-year-old-woman developed paresthesia, weakness of limbs, dysphagia and deep sensory impairment 12 days after vaccination of Pfizer COVID-19 vaccine. Her deep tendon reflexes were absent and cerebrospinal fluid showed normal cell counts and protein level. Anti-ganglioside antibodies were negative, and F wave frequency was decreased in nerve conduction studies. We diagnosed her as immune mediated polyneuropathy caused by COVID-19 vaccine, and plasma exchange improved her symptoms. Compared with Guillain-BarrÃ© syndrome and polyneuropathy following COVID-19 infection and COVID-19 vaccination, deep sensory impairment was the most characteristic of this case. We supposed that non-antigen specific mechanism played an important role in the pathogenesis of this case.

Efficacy and safety of sotrovimab for vaccinated or unvaccinated patients with mild-to-moderate COVID-19 in the omicron era. Although sotrovimab, one of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) neutralizing antibodies has been shown to be effective in patients with mild-to-moderate coronavirus disease 2019 (COVID-19) with risk factors, their efficacy in mRNA COVID-19 vaccinated patients in omicron era is unknown. To evaluate the effectiveness of sotrovimab clinical data from both COVID-19 vaccinated and unvaccinated patients who were hospitalized and receiving sotrovimab at the Japanese Red Cross Medical Center were compared. The efficacy and adverse events were evaluated. Of the total 60 patients enrolled in this study, 45 had received the mRNA COVID-19 vaccine and 15 were unvaccinated. The clinical progression with low nasal cannula or face mask was not significantly different between groups (occurring in one patient in each group; p = 0.44), with no further progression in both groups. The duration of hospitalization was eight days for both groups (p = 0.90). Two patients in each group experienced adverse events (7%, p = 0.26). The results suggested that the efficacy and safety of sotrovimab against mild-to-moderate COVID-19 with risk factors in the omicron era might not be different regardless of the vaccination status. The results of the present study are encouraging; however, further randomized clinical studies are needed.

Risk stratification through allergy history: single-centre experience of specialized COVID-19 vaccine clinic. Anaphylaxis is a rare side-effect of COVID-19 vaccines. To (a) provide direct advice and reassurance to certain persons with a history of anaphylaxis/complex allergy, in addition to that available in national guidelines, and (b) to provide a medically supervised vaccination, a specialist regional vaccine allergy clinic was established. The main objective was to determine if risk stratification through history can lead to safe COVID-19 vaccination for maximum population coverage. A focused history was taken to establish contraindications to giving COVID-19 vaccines. People who reported a high-risk allergy history were given a vaccine not containing the excipient thought to have directly caused previous anaphylaxis. All vaccines were monitored for 30 min after administration. A total of 206 people were vaccinated between 6 July 2021 and 31 August 2021; Comirnaty (Pfizer-BioNTech) (n = 34), and Janssen (n = 172). In total, 78% were women. Ninety-two

people (45%) reported a high-risk allergy history. There were no cases of anaphylaxis. Three people developed urticaria and one of these also developed transient tachycardia. One vaccinee developed a pseudoseizure. Two of 208 people (<1%) referred during this time declined vaccination based on personal preference, despite the assessment of low clinical risk. In our experience, all vaccines with high-risk allergy histories were administered Pfizer BioNTech or Janssen Covid-19 vaccines uneventfully following screening based on allergy-focussed history. Our data support that drug allergy is not associated with a higher risk of vaccine-related anaphylaxis but may act to guide the administration of alternate vaccines to people with polyethylene glycol/polysorbate 80/trometamol allergies or anaphylaxis after the first dose.

SARS-CoV-2 vaccine safety and immunogenicity in patients with hematologic malignancies, transplantation, and cellular therapies. Individuals with hematological malignancies and hematopoietic stem cell transplant (HCT) recipients are immunologically heterogenous groups with varying degrees of immunosuppression at increased risk of severe disease and mortality from SARS-CoV-2 infection. SARS-CoV-2 vaccines are key interventions to preventing severe COVID-19 and its complications. While these individuals were excluded from initial vaccine trials, there is now a growing body of acceptable safety and immunogenicity data among these individuals. A consistent signal for new or worsening graft versus host disease in allogeneic HCT recipients has not been demonstrated post-vaccination. Immunogenicity in these populations is variable depending on disease and treatment factors. However, serological responses may not accurately reflect vaccine protection as correlates of protection within these populations are not yet established. Large-scale studies powered to identify rare serious events, resolve differences in vaccine responses between different vaccination strategies, and identify immune correlates of protection within these populations are needed.

Acute ischemic stroke and vaccine-induced immune thrombotic thrombocytopenia post COVID-19 vaccination; a systematic review. INTRODUCTION: One of the rare but potentially serious side effects of COVID-19 vaccination is arterial and venous thrombosis. Acute ischemic stroke (AIS) cases have been reported post COVID-19 vaccination. Herein, we systematically reviewed the reported cases of AIS after COVID-19 vaccination. METHOD: This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline. We searched PubMed and Scopus until April 14, 2022 to find studies that reported AIS post COVID-19 vaccination. RESULTS: We found 447 articles. From those, 140 duplicates were removed. After screening and excluding irrelevant articles, 29 studies (43 patients) were identified to be included. From all cases, 22 patients (51.1%) were diagnosed with AIS associated with Vaccine-induced immune thrombotic thrombocytopenia (VITT). Among AIS associated with VITT group, all received viral vector vaccines except one. The majority of cases with AIS and VITT were female (17 cases, 77.2%) and aged below 60Â years (15 cases, 68%). Fourteen patients (32.5%) had additional thrombosis in other sites. Four of them (0.09%) showed concurrent CVST and ischemic stroke. Hemorrhagic transformation following AIS occurred in 7 patients (16.27%). Among 43 patients with AIS, at least 6 patients (14%) died during hospital admission. CONCLUSION: AIS has been reported as a rare complication within 4Â weeks post COVID-19 vaccination, particularly with viral vector vaccines. Health care providers should be familiar with this rare consequence of COVID-19 vaccination in particular in the context of VITT to make a timely diagnosis and appropriate treatment plan.

SARS-CoV-2 spike protein antibody titers 6Â months after SARS-CoV-2 mRNA vaccination among patients undergoing hemodialysis in Japan. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination is shown to prevent severe illness and death in hemodialysis (HD) patients, but the immune response to vaccines is reduced in this population. This study compared SARS-CoV-2 spike protein antibody titers between HD patients and healthy controls in

Japan for up to 6Â months following vaccination. METHODS: A multi-institutional retrospective study at five clinics in Japan was conducted using 412 HD patients and 156 healthy controls who received two doses of the BNT162b2 (Pfizer-BioNTech) mRNA vaccine. Anti-SARS-CoV-2 spike protein S1 IgG antibody titers were measured at 1, 3, and 6Â months after the second dose. The attenuation speed was calculated as slope (i.e., -Î²) using a linear mixed-effects model toward the log-transformed antibody titers. RESULTS: The HD group had significantly lower month 1 antibody titers (Ab-titer-1) than the controls, and these remained lower through month 6 (95% CI: 2617.1 (1296.7, 5240.8) vs. 7285.4 (4403.9, 11,000.0) AU/mL at Ab-titer-1, and 353.4 (178.4, 656.3) vs. 812.0 (498.3, 1342.7) AU/mL at Ab-titer-6 (pâ€‰<â€‰0.001, respectively)). Lower log Ab-titer-1 levels in the HD group were significantly associated with a lower log Ab-titer-6 (0.90 [0.83, 0.97], pâ€‰<â€‰0.001). The -Î² values in the HD patients and healthy controls were -4.7â€‰Â±â€‰1.1 and -4.7â€‰Â±â€‰1.4 (year(-1)), respectively. CONCLUSION: SARS-CoV-2 spike protein antibody titers were significantly lower in HD patients than in healthy controls at 1 (peak) and 6Â months after the second vaccination. Low peak antibody titers contributed to low 6-month antibody titers.

Anti-LGI1 encephalitis following COVID-19 vaccination: a case series.

Associations of Guillain-BarrÃ© syndrome with coronavirus disease 2019 vaccination: Disproportionality analysis using the World Health Organization pharmacovigilance database. Vaccinations against the severe acute respiratory syndrome coronavirus 2 which causes COVID-19 have been administered worldwide. We aimed to investigate associations of COVID-19 vaccination with the occurrence of Guillain-BarrÃ© syndrome (GBS). We explored potential safety signals regarding the development of GBS using disproportionality analyses to compare COVID-19 vaccination with all adverse drug reaction (ADR) reports and influenza vaccines reported to VigiBase. As of October 15, 2021, a total of 2163 cases (0.13%) of GBS and its variants (including 46 cases of Miller-Fisher syndrome and 13 cases of Bickerstaff's encephalitis) were identified in entire ADR database after vaccination with the ChAdOx1 nCoV-19 (AstraZeneca, Cambridge, UK) or the two messenger RNA-based COVID-19 (BNT162b2; Pfizer and BioNTech) or mRNA-1273; Moderna) vaccines. The median time to onset of GBS after vaccination was around 2â€‰weeks. The ChAdOx1 nCoV-19 and two messenger RNA-based COVID-19 vaccines demonstrated a higher risk for GBS against entire database (information component [IC](025) Â =Â 1.73 reporting odds ratio [ROR](025) Â =Â 3.51; IC(025) Â =Â 1.07, ROR(025) Â =Â 2.22, respectively). When compared with influenza vaccines, neither the ChAdOx1 nCoV-19 nor mRNA-based vaccines were found to be associated with greater risks of GBS (IC(025) Â =Â -1.84, ROR(025) Â =Â 0.11; IC(025) Â =Â -1.86, ROR(025) Â =Â 0.06, respectively). Although potential safety signals associated with GBS COVID-19 vaccines have been identified, the risk of GBS from COVID-19 vaccines were low and did not surpass those of influenza vaccines; however, because of the heterogeneity of the sources of information in the WHO pharmacovigilance database, further epidemiological studies are warranted to confirm these observations.

A Cross-Sectional Study of Untoward Reactions Following Homologous and Heterologous COVID-19 Booster Immunizations in Recipients Seventeen Years of Age and Older. A booster dose after primary COVID-19 vaccination series was considered crucial after the emergence of the B.1.617.2 (Delta) and B.1.1.529 (Omicron) variants. Active surveillance was used to investigate reporting of adverse events post-booster dose of either of the licensed mRNA Comirnaty (Pfizer/BioNTech) or Spikevax (Moderna) vaccines in adult (17Â years and older) recipients in central Italy. Eligible participants were enrolled and interviewed via phone using a structured questionnaire. Primary outcomes related to the occurrence of adverse events post-booster were stratified by vaccine, and frequency of local/systemic, mild/moderate/severe events. Of a total of 622 participants interviewed, 554 (89.1%) reported at least one adverse event (88.2% and 92.9% after the Comirnaty or Spikevax

vaccine, respectively): 63.4% were female, and 78.5% aged 17 to 64Â years, regardless of vaccine. 87.7% and 68.2% of all recipients described at least one local or systemic reaction, respectively: 97.3, 38.6 and 4.7% reported mild, moderate, or severe events, respectively. The most frequent adverse reactions were pain, redness, or swelling at the injection site and fatigue, while malaise and fever significantly occurred after the Comirnaty, and vomiting after the Spikevax booster. Compared to the primary vaccination, lymphadenopathy was more common after the booster (pâ€‰<â€‰0.001), especially after Comirnaty vaccine. The study findings revealed no serious or unexpected adverse events, and are in agreement with data available on booster dose for both mRNA vaccines. The transient, mild to moderate, and common to very common side reactions reported should be used to reassure potential recipients of the lack of safety concerns.

Immunosuppressed non-responders to two doses of mRNA SARS-CoV-2 vaccines achieve an immune response comparable to those of immunocompetent individuals after a third dose. The SARS-CoV-2 vaccines trigger the production of neutralizing antibodies to the SARS-CoV-2 spike (S) protein and induce a T cell-mediated immune response. However, the antibody titers that confer protection against the SARS-CoV-2 virus are currently not well-established. While immunocompetent individuals achieve a high level of immune response after SARS-CoV-2 vaccination, it now appears that a high proportion of immunosuppressed or immunocompromised, patients exhibit low or no response to two doses of the vaccines. Most non-responders are on treatment with either glucocorticoids, mycophenolate-mofetil (MMF), the anti-CD20 monoclonal antibody rituximab, calcineurin inhibitors like cyclosporine and tacrolimus, rapamycin (mTOR) signaling cascade inhibitors (i.e., sirolimus and everolimus), azathioprine, or methotrexate given for a variety of diseases including autoimmune disorders, hematological malignancies, and solid cancers, while recipients of solid organ transplants also fall within this category. Recently, several published reports have suggested that a third dose of these vaccines induces an elevated antibody response against the SARS-CoV-2 S protein.

Myocarditis and/or pericarditis risk after mRNA COVID-19 vaccination: A Canadian head to head comparison of BNT162b2 and mRNA-1273 vaccines. BACKGROUND: Canadian and international data suggest the risk of myocarditis and/or pericarditis is elevated during the week after mRNA COVID-19 vaccination, particularly in younger age groups, in males, and after second doses. OBJECTIVES: This article examines whether there is a product-specific difference in the risk for myocarditis and/or pericarditis between the two mRNA vaccines administered in Canada: BNT162b2 (Pfizer-BioNTech Comirnaty) and mRNA-1273 (Moderna Spikevax). MATERIALS AND METHODS: Reporting rates of myocarditis and/or pericarditis were calculated from reports received by the Canadian Adverse Events Following Immunization Surveillance System from December 2020-March 2022. Excess cases and attributable incidence among individuals aged 18-39 were estimated for each vaccine in comparison with background rates from 2015 to 2019. Head-to-head comparisons used Poisson regression, conditioned on week of vaccine administration, to estimate rate ratios for the week after mRNA-1273 vaccination versus the week after BNT162b2, by age and sex as well as overall. Analyses were restricted to May 30-March 13, 2021, when heightened media awareness was unlikely to have affected reporting rates for the two products differentially. RESULTS: In 18-29Â year-old males who received a second dose of mRNA COVID-19 vaccine, attributable risk of myocarditis and/or pericarditis was found to be 5.69 (95% CI: 4.07 - 7.95; pÂ <Â 0.001) times higher among mRNA-1273 recipients (nÂ =Â 106) as compared to BNT162b2 recipients (nÂ =Â 33). In the same group, Poisson regression modelling estimated that the risk of myocarditis and/or pericarditis was 4.72 (p-value = <0.001) times higher after mRNA-1723 compared to BNT162b2 vaccination. CONCLUSIONS: The risk of myocarditis and/or pericarditis is higher after mRNA-1723 vaccination than BNT162b2 vaccination in those aged 18-39Â years, especially in males aged 18-29Â years, where the risk is several times higher.

Impaired serological response to COVID-19 vaccination following anticancer therapy: A systematic review and meta-analysis. Owing to the high coronavirus disease 2019Â (COVID-19)-related morbidity and fatality rate among patients with cancer, the introduction of COVID-19 vaccines is of profound significance in this fragile population. Accumulating data suggested that oncologic patients, especially those with anticancer therapy have an impaired immune response to COVID-19 vaccination. However, the exact effect of anticancer treatments on postvaccination response has not been elucidated yet. We, therefore, conducted a meta-analysis to evaluate the impact of treatments on response to COVID-19 vaccination in patients with cancer. A total of 39 studies were finally included comprising 11â€‰075 oncologic patients. Overall, we found the humoral response was significantly decreased in patients undergoing anticancer treatments (odds ratio [OR]â€‰=â€‰2.55, 95% confidence interval [CI]: 2.04-3.18) compared with those without active treatment. The seroconversion rates were significantly lower in patients with chemotherapy (ORâ€‰=â€‰3.04, 95%â€‰CI:â€‰2.28-4.05), targeted therapy (ORâ€‰=â€‰4.72, 95%â€‰CI:â€‰3.18-7.01) and steroid usage (ORâ€‰=â€‰2.19, 95%Â CI: 1.57-3.07), while there was no significant association between immunotherapy or hormonal therapy and seroconversion after vaccination. Subgroup analyses showed therapies with anti-CD20 antibody (ORâ€‰=â€‰11.28, 95% CI: 6.40-19.90), B-cell lymphoma 2 inhibitor (ORâ€‰=â€‰5.76, 95% CI: 3.64-9.10), and Bruton tyrosine kinase inhibitor (ORâ€‰=â€‰6.86, 95% CI: 4.23-11.15) were significantly correlated with the risk of negative humoral response to vaccination. In conclusion, our results demonstrated that specific oncologic therapies may significantly affect serological response to COVID-19 vaccines in patients with cancer. Thus, an adapted vaccination strategy taking the influence of active treatment into account is in need, and further research on the effect of the third dose of vaccine and the role of postvaccination cellular response in oncologic patients is also needed.

Improved Durability to SARS-CoV-2 Vaccine Immunity following Coimmunization with Molecular Adjuvant Adenosine Deaminase-1. Although severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines have demonstrated strong immunogenicity and protection against severe disease, concerns about the duration and breadth of these responses remain. In this study, we show that codelivery of plasmid-encoded adenosine deaminase-1 (pADA) with SARS-CoV-2 spike glycoprotein DNA enhances immune memory and durability in vivo. Coimmunized mice displayed increased spike-specific IgG of higher affinity and neutralizing capacity as compared with plasmid-encoded spike-only-immunized animals. Importantly, pADA significantly improved the longevity of these enhanced responses in vivo. This coincided with durable increases in frequencies of plasmablasts, receptor-binding domain-specific memory B cells, and SARS-CoV-2-specific T follicular helper cells. Increased spike-specific T cell polyfunctionality was also observed. Notably, animals coimmunized with pADA had significantly reduced viral loads compared with their nonadjuvanted counterparts in a SARS-CoV-2 infection model. These data suggest that pADA enhances immune memory and durability and supports further translational studies.

Decreased Antibody Response After Severe Acute Respiratory Syndrome Coronavirus 2 Vaccination in Patients With Down Syndrome. The risk of a severe course of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in adults with Down syndrome is increased, resulting in an up to 10-fold increase in mortality, in particular in those >40 years of age. After primary SARS-CoV-2 vaccination, the higher risks remain. In this prospective observational cohort study, SARS-CoV-2 spike S1-specific antibody responses after routine SARS-CoV-2 vaccination (BNT162b2, messenger RNA [mRNA]-1273, or ChAdOx1) in adults with Down syndrome and healthy controls were compared. Adults with Down syndrome showed lower antibody concentrations after 2 mRNA vaccinations or after 2 ChAdOx1 vaccinations. After 2 mRNA vaccinations, lower antibody concentrations were seen with increasing age. CLINICAL TRIALS REGISTRATION: NCT05145348.

Adjuvant-Protein Conjugate Vaccine with Built-In TLR7 Agonist on S1 Induces Potent Immunity against SARS-CoV-2 and Variants of Concern. With the global pandemic of the new coronavirus disease (COVID-19), a safe, effective, and affordable mass-produced vaccine remains the current focus of research. Herein, we designed an adjuvant-protein conjugate vaccine candidate, in which the TLR7 agonist (TLR7a) was conjugated to S1 subunit of SARS-CoV-2 spike protein, and systematically compared the effect of different numbers of built-in TLR7a on the immune activity for the first time. As the number of built-in TLR7a increased, a bell-shaped reaction was observed in three TLR7a-S1 conjugates, with TLR7a(10)-S1 (with around 10 built-in adjuvant molecules on one S1 protein) eliciting a more potent immune response than TLR7a(2)-S1 and TLR7a(18)-S1. This adjuvant-protein conjugate strategy allows the built-in adjuvant to provide cluster effects and prevents systemic toxicity and facilitates the co-delivery of adjuvant and antigen. Vaccination of mice with TLR7a(10)-S1 triggered a potent humoral and cellular immunity and a balanced Th1/Th2 immune response. Meanwhile, the vaccine induces effective neutralizing antibodies against SARS-CoV-2 and all variants of concern (B.1.1.7/alpha, B.1.351/beta, P.1/gamma, B.1.617.2/delta, and B.1.1.529/omicron). It is expected that the adjuvant-protein conjugate strategy has great potential to construct a potent recombinant protein vaccine candidate against various types of diseases.

Case report of acute encephalitis following the AstraZeneca COVID-19 vaccine. Coronavirus disease 2019 (COVID-19) vaccines have proven to be safe, effective and life-saving. However, little information is available on the neurological complications of COVID-19 vaccine. Here, we report a case who developed acute encephalomyelitis 1â€‰week after being vaccinated with AstraZeneca COVID-19 vaccine (AZ vaccine). Autoimmune/inflammatory syndrome induced by adjuvants (ASIA) was also suspected. After intravenous dexamethasone and subcutaneous fondaparinux therapy, he returned to normal life without neurological sequelae. Four months later, he received Moderna COVID-19 vaccine without any sequelae.

Post-vaccination analysis of anti-spike antibody responses in kidney transplant recipients with and without COVID-19 infection in a tertiary care centre, India. BACKGROUND: To investigate the anti-spike antibody response to vaccination in kidney transplant recipients (KTRs) previously infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as compared with KTRs with no history of coronavirus disease 2019 (COVID-19) from India. METHODS: SARS-CoV-2 spike immunoglobulin (Ig) G antibody response was measured in 105 post-COVID-19 KTRs with PCR-confirmed SARS-CoV-2 infection who received either no vaccination (cohort 1), a single dose (cohort 2) or two doses (cohort 3) of vaccine and compared with 103 two-dose vaccinated COVID-19-naÃ¯ve KTRs with no history of COVID-19 (cohort 4). RESULTS: Out of 103 COVID-19-naÃ¯ve two-dose vaccinated KTRs, <50% became seropositive with anti-spike antibody titres >50 arbitrary unit/mL subsequent to complete vaccination, the seroconversion rate being comparable in subjects receiving Covishield(TM) versus Covaxin(TM) vaccines. However, the seropositive KTRs vaccinated with Covishield(TM) had higher anti-spike antibody titres as compared with those who received Covaxin(TM). We observed higher anti-SARS-CoV-2 spike antibody levels in post-COVID-19 KTRs after one dose of vaccine as compared with COVID-19-naÃ¯ve two-dose vaccinated KTRs. Importantly, the second dose in post-COVID-19 KTRs did not significantly increase anti-spike antibody levels compared with the single-dose recipients. CONCLUSIONS: Our data present that in KTRs with previous SARS-CoV-2 infection, a single dose of vaccine (Covishield(TM)) may be effective in mounting an optimal immune response. In contrast, COVID-19-naÃ¯ve two-dose vaccinated KTRs respond poorly (<50%) to the current recommendation of a two-dose regimen in India.

Antibody titers after a third dose of the SARS-CoV-2 BNT162b2 vaccine in immunocompromised adults in Greece: Is a fourth dose necessary? Real-world data suggestÂ that protection against COVID-19 declines a few months after vaccination, particularly in the elderly and

immunocompromised individuals. Our study aimed to analyze the humoral response induced by a third supplemental dose of BNT162b2 vaccine in a mixed group of immunocompromised individuals by determining anti-spike (anti-S) IgG antibody titers at baseline (pre-third vaccine dose) and 4 weeks after the dose. Serum samples were obtained from a total group of 85 immunocompromised individuals (history of cancer: nâ€‰=â€‰20, lymphoma: nâ€‰=â€‰4, leukemia: nâ€‰=â€‰3, transplant recipients: nâ€‰=â€‰4, autoimmune disease: nâ€‰=â€‰42, inflammatory disease: nâ€‰=â€‰6, autoimmune diabetes type 1: nâ€‰=â€‰6) all of whom had previously received a two-dose schedule of the vaccine. The average number of days between second and third dose was 139.6145 (Â±41.39071). The overall IgG GMCs 4 weeks postvaccination were increased by more than 35 times (fold changeâ€‰=â€‰35.30, pâ€‰<â€‰0.001). Fold changes were not significantly correlated with underlying condition, age, sex nor with days between second and third dose. Considering the predominance of omicron variants in the current period and the results of studies showing a decrease in the effectiveness of the third dose after 10 weeks we highly recommend a fourth dose to this vulnerable population group.

Safety and protective capability of an inactivated SARS-CoV-2 vaccine on pregnancy, lactation and the growth of offspring in hACE2 mice. The mass inoculation of a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine to induce herd immunity is one of the most effective measures to fight COVID-19. The vaccination of pregnant women cannot only avoid or reduce the probability of infectious diseases, but also offers the most effective and direct protection for neonates by means of passive immunization. However, there is no randomized clinical data to ascertain whether the inactivated vaccination of pregnant women or women of childbearing age can affect conception and the fetus. We found that human angiotensin-converting enzyme 2 (hACE2) mice that were vaccinated with two doses of CoronaVac (an inactivated SARS-CoV-2 vaccine) before and during pregnancy exhibited normal weight changes and reproductive performance indices; the physical development of their offspring was also normal. Following intranasal inoculation with SARS-CoV-2, pregnant mice in the immunization group all survived; reproductive performance indices and the physical development of offspring were all normal. In contrast, mice in the non-immunization group all died before delivery. Analyses showed that inoculation of CoronaVac was safe and did not exert any significant effects on pregnancy, lactation, or the growth of offspring in hACE2 mice. Vaccination effectively protected the pregnant mice against SARS-CoV-2 infection and had no adverse effects on the growth and development of the offspring, thus suggesting that inoculation with an inactivated SARS-CoV-2 vaccine may be an effective strategy to prevent infection in pregnant women.

Immunogenicity and safety of booster dose of S-268019-b or BNT162b2 in Japanese participants: An interim report of phase 2/3, randomized, observer-blinded, noninferiority study. In this randomized, observer-blinded, phase 2/3 study, S-268019-b (nÂ =Â 101), a recombinant spike protein vaccine, was analyzed for noninferiority versus BNT162b2 (nÂ =Â 103), when given as a booster â‰¥6Â months after 2-dose BNT162b2 regimen in Japanese adults without prior SARS-CoV-2 infection. Interim results showed noninferiority of S-268019-b versus BNT162b2 in co-primary endpoints for neutralizing antibodies on day 29: geometric mean titer (GMT) (124.97 versus 109.70; adjusted-GMT ratio [95% CI], 1.14 [0.94-1.39]; noninferiority P-value, <0.0001) and seroresponse rate (both 100%; noninferiority P-value, 0.0004). Both vaccines elicited anti-spike-protein immunoglobulin G antibodies, and produced T-cell response (nÂ =Â 29/group) and neutralizing antibodies against Delta and Omicron pseudovirus and live virus variants (nÂ =Â 24/group) in subgroups. Most participants reported low-grade reactogenicity on days 1-2, the most frequent being fatigue, fever, myalgia, and injection-site pain. No serious adverse events were reported. In conclusion, S-268019-b was safe and showed robust immunogenicity as a booster, supporting its use as COVID-19 booster vaccine.

Axillary Lymph Node Swelling After COVID-19 Booster Vaccination: Japanese Case Report and Literature Review. BACKGROUND/AIM: COVID-19 has been a global pandemic for more than 2 years, and vaccination against COVID-19 using an mRNA vaccine is widespread. The COVID-19 vaccination can cause specific side-effects, such as axillary lymph node swelling; therefore, breast oncologists should pay attention to such occurrences. Initially, only two COVID-19 vaccinations were planned; however, in some countries third or fourth vaccines have been administered. Here, we present a female case who developed axillary lymph node swelling after her third vaccination. We have also reviewed the literature regarding this side-effect after a third or fourth COVID-19 vaccination. CASE REPORT: A 64-year-old woman who came to our clinic regarding a mammography abnormality in her left breast. She had no palpable mass, but a left breast mass was shown by mammography, and ultrasonography and magnetic resonance imaging indicated a hamartoma. At 2 months after her second COVID-19 vaccination when she underwent these tests, she had no axillary lymph node swelling. We planned a follow-up after 6 months. At her next visit, by chance, she underwent ultrasonography 14 days after she received a third COVID-19 vaccination, and a swollen axillary lymph node was observed. CONCLUSION: Axillary lymph node swelling can occur after a third COVID-19 vaccination. Therefore, breast oncologists will have to consider this side-effect of COVID-19 vaccination when diagnosing breast tumors.

Characteristics associated with serological COVID-19 vaccine response and durability in an older population with significant comorbidity: author's response.

Association of Receipt of the Fourth BNT162b2 Dose With Omicron Infection and COVID-19 Hospitalizations Among Residents of Long-term Care Facilities. IMPORTANCE: The administration of a fourth BNT162b2 COVID-19 vaccine dose was approved in Israel in December 2021 for individuals 60 years or older who were vaccinated with a third dose 4 months previously or earlier to control the substantial surge of the SARS-CoV-2 Omicron variant. Nonetheless, the association between receipt of the fourth dose and protection against infection remains elusive. OBJECTIVE: To determine the association of the fourth BNT162b2 dose with protection against SARS-CoV-2-related infections, hospitalizations, and deaths during the Omicron surge in long-term care facility (LTCF) residents. DESIGN, SETTING, AND PARTICIPANTS: This prospective cohort study was conducted in Israel between January 10 and March 31, 2022 and included LTCF residents 60 years or older. EXPOSURES: Vaccination with the fourth dose of BNT162b2 vs 3 doses that were administered 4 months previously or earlier. MAIN OUTCOMES AND MEASURES: Cumulative incidences of SARS-CoV-2 infections, hospitalizations, and deaths during the Omicron surge. The follow-up was initiated more than 7 days after receipt of the fourth dose, which was matched to the follow-up initiation date of those who had received 3 doses of vaccine in each facility. We obtained hazard ratios and 95% confidence intervals from multivariable Cox regression models. RESULTS: The data of 43â€¯775 residents (mean [SD] age, 80.1 [9.4] years; 29â€¯679 women [67.8%]) were analyzed, of whom 24â€¯088 (55.0%) and 19â€¯687 (45.0%) received the fourth and third dose (4 months previously or earlier), respectively. The median follow-up time was 73 days (4-dose group: IQR, 6 days; 3-dose group: IQR, 56 days). More than 7 days postvaccination with the fourth dose, SARS-CoV-2 infection was detected among 4058 fourth-dose vs 4370 third-dose recipients (cumulative incidence, 17.6% vs 24.9%). The corresponding incidences of hospitalizations for mild-to-moderate COVID-19, severe illness, and mortality were 0.9% and 2.8%, 0.5% and 1.5%, and 0.2% and 0.5%, respectively. The adjusted protections were 34% (95% CI, 30%-37%), 64% (95% CI, 56%-71%), and 67% (95% CI, 57%-75%) against overall infection, hospitalizations for mild-to-moderate illness, and severe illness, respectively, and 72% (95% CI, 57%-83%) against related deaths. CONCLUSIONS AND RELEVANCE: The results of this cohort study suggest that receipt of a fourth BNT162b2 dose conferred high protection against COVID-19 hospitalizations and deaths among LTCF residents during a substantial Omicron

variant surge, but protection was modest against infection. These findings are relevant to the control of COVID-19 pandemic globally, especially among the population of LTCFs.

Signaling COVID-19 Vaccine Adverse Events. INTRODUCTION: Statistical signal detection is a crucial tool for rapidly identifying potential risks associated with pharmaceutical products. The unprecedented environment created by the coronavirus disease 2019 (COVID-19) pandemic for vaccine surveillance predisposes commonly applied signal detection methodologies to a statistical issue called the masking effect, in which signals for a vaccine of interest are hidden by the presence of other reported vaccines. This masking effect may in turn limit or delay our understanding of the risks associated with new and established vaccines. OBJECTIVE: The aim is to investigate the problem of masking in the context of COVID-19 vaccine signal detection, assessing its impact, extent, and root causes. METHODS: Based on data underlying the Vaccine Adverse Event Reporting System, three commonly applied statistical signal detection methodologies, and a more advanced regression-based methodology, we investigate the temporal evolution of signals corresponding to five largely recognized adverse events and two potentially new adverse events. RESULTS: The results demonstrate that signals of adverse events related to COVID-19 vaccines may be undetected or delayed due to masking when generated by methodologies currently utilized by pharmacovigilance organizations, and that a class of advanced methodologies can partially alleviate the problem. The results indicate that while masking is rare relative to all possible statistical associations, it is much more likely to occur in COVID-19 vaccine signaling, and that its extent, direction, impact, and roots are not static, but rather changing in accordance with the changing nature of data. CONCLUSIONS: Masking is an addressable problem that merits careful consideration, especially in situations such as COVID-19 vaccine safety surveillance and other emergency use authorization products.

Post-SARS-CoV-2 vaccination COVID toes and fingers : Two case reports and aÂ short literature review.

MOG encephalomyelitis after vaccination against severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2): case report and comprehensive review of the literature. BACKGROUND: In around 20% of cases, myelin oligodendrocyte glycoprotein (MOG) immunoglobulin (IgG)-associated encephalomyelitis (MOG-EM; also termed MOG antibody-associated disease, MOGAD) first occurs in a postinfectious or postvaccinal setting. OBJECTIVE: To report a case of MOG-EM with onset after vaccination with the PfizerÂ BioNTech COVID-19Â mRNA vaccine BNT162b2 (ComirnatyÂ®) and to provide a comprehensive review of the epidemiological, clinical, radiological, electrophysiological and laboratory features as well as treatment outcomes of all published patients with SARS-CoV-2Â vaccination-associated new-onset MOG-EM. METHODS: Case report and review of the literature. RESULTS: In our patient, MOG-IgG-positive (serum 1:1000, mainly IgG1 and IgG2; CSF 1:2; MOG-specific antibody indexâ€‰<â€‰4) unilateral optic neuritis (ON) occurred 10Â days after booster vaccination with BNT162b2, which had been preceded by two immunizations with the vector-based Oxford AstraZeneca vaccine ChAdOx1-S/ChAdOx1-nCoV-19 (AZD1222). High-dose steroid treatment with oral tapering resulted in complete recovery. Overall, 20 cases of SARS-CoV2Â vaccination-associated MOG-EM were analysed (median age at onset 43.5 years, range 28-68; female to male ratio = 1:1.2). All cases occurred in adults and almost all after immunization with ChAdOx1-S/ChAdOx1 nCoV-19 (median interval 13 days, range 7-32), mostly after the first dose. In 70% of patients, more than one CNS region (spinal cord, brainstem, supratentorial brain, optic nerve) was affected at onset, in contrast to a much lower rate in conventional MOG-EM in adults, in which isolated ON is predominant at onset and ADEM-like phenotypes are rare. The cerebrospinal fluid white cell count (WCC) exceeded 100 cells/Î¼l in 5/14 (36%) patients with available data (median peak WCC 58 cells/Î¼l in those with pleocytosis; range 6-720). Severe disease with tetraparesis, paraplegia, functional blindness, brainstem involvement and/or bladder/bowel dysfunction and a

high lesion load was common, and treatment escalation with plasma exchange (Nâ€‰=â€‰9) and/or prolonged IVMP therapy was required in 50% of cases. Complete or partial recovery was achieved in the majority of patients, but residual symptoms were significant in some. MOG-IgG remained detectable in 7/7 cases after 3 or 6Â months. CONCLUSIONS: MOG-EM with postvaccinal onset was mostly observed after vaccination with ChAdOx1-S/ChAdOx1 nCoV-19. Attack severity was often high at onset. Escalation of immunotherapy was frequently required. MOG-IgG persisted in the long term.
Side effects of SARS-CoV-2 vaccines should be assessed by unbiased professionals on-site.
COVID-19 review shows that benefits of vaccinating children and adolescents appear to outweigh risks of post-vaccination myopericarditis. AIM: Myopericarditis after COVID-19 vaccination were the most serious adverse events reported in children over 5â€‰years of age. We want to summarise these cases, describing their incidence, clinical features, diagnostic pathways, therapeutic strategies and outcome. METHODS: A systematic review of the literature was conducted until 20 March 2022 by bibliographic electronic databases. We included all reports of post-vaccination myopericarditis in children aged between 5 and 18â€‰years. RESULTS: All reported cases had elevated serum Troponin levels, associated with electrocardiogram changes, but often with normal echocardiogram. Cardiac magnetic resonance images always showed typical alterations. The pathogenetic mechanism is still unknown. Myocarditis following post-COVID vaccination is more frequent in boys with an average age of about 15â€‰years. Treatment involves the usage of non-steroidal anti-inflammatory drugs, and the average hospitalisation is about 3â€‰days. The long-term consequences are not yet known, so these patients should be studied in a cardiological follow-up and abstention from physical activity should be recommended. CONCLUSION: The benefits of COVID-19 vaccination in children and adolescents appear to outweigh the risk of developing post-vaccination myopericarditis. We can also speculate a possible approval of vaccination in children under 5â€‰years for the coming winter.
COVID-19 vaccine-induced adverse events predict immunogenicity among recipients of allogeneic hematopoietic stem cell transplantation.
SARS-CoV-2-specific cellular response following third COVID-19 vaccination in patients with chronic lymphocytic leukemia.
Pfizer/BioNTech SARS-CoV-2 vaccine as a potential trigger for the development of narcolepsy: a case report. Narcolepsy is a rare condition in Israel. Currently, the incidence of narcolepsy following SARS-CoV-2 vaccination in Israel is unknown. We are reporting a case report of a 51-year-old woman of Ashkenazi Jewish descent who was evaluated for complaints of excessive daytime sleepiness and relative functional decline that immediately followed receipt of the Pfizer/BioNTech SARS-CoV-2 vaccination. Evaluation of patient-reported data with polysomnography and multiple sleep latency test was consistent with narcolepsy with cataplexy, meeting the criteria for a diagnosis of type 1 narcolepsy. Further investigation included human leukocyte antigen testing. Prior studies have demonstrated genetic, immunological, and environmental factors associated with narcolepsy following other vaccinations. This case is a valuable contribution to the literature as there are no prior reports of type 1 narcolepsy following SARS-CoV-2 vaccination in the State of Israel. CITATION: Mahamid A, Bornstein RJ, Amir H. Pfizer/BioNTech SARS-CoV-2 vaccine as a potential trigger for the development of narcolepsy: a case report. J Clin Sleep Med. 2022;18(10):2503-2506.
Giant cell myocarditis after first dose of BNT162b2 - a case report. Herein we report the case of a young man, admitted to the Department of Cardiology and Angiology at Hannover Medical School with shortness of breath and elevated troponin. Few weeks earlier the patient received the first dose of BioNTech's mRNA vaccine (Comirnaty, BNT162b2). After diagnostic work-up revealed giant cell myocarditis, the patient received immunosuppressive therapy. In the present context of myocarditis

after mRNA vaccination we discuss this rare aetiology and the patient's treatment strategy in the light of current recommendations.
Course of Cardiac Magnetic Resonance Imaging Findings in Acute Myocarditis after COVID-19 mRNA Vaccination. Myocarditis is being increasingly reported as a rare complication of coronavirus disease 2019 (COVID-19) mRNA vaccines. We herein report a case of myocarditis following COVID-19 mRNA vaccination in a man. Cardiac magnetic resonance imaging (CMRI) revealed an area of high signal intensity on short T1 inversion recovery (STIR) and late gadolinium enhancement (LGE), which are characteristic of myocarditis. Follow-up CMRI performed six months later revealed improvement in the myocardial edema and LGE findings. CMRI is a useful non-invasive imaging modality for making an initial diagnosis as well as for follow-up in cases of myocarditis after COVID-19 mRNA vaccination.
Association between BNT162b2 or CoronaVac COVID-19 vaccines and major adverse cardiovascular events among individuals with cardiovascular disease. AIMS: Concern about the cardiovascular safety of coronavirus disease 2019 (COVID-19) vaccines among individuals with cardiovascular disease (CVD) may lead to vaccine hesitancy. We sought to assess the association between two COVID-19 vaccines, BNT162b2 and CoronaVac, and the risk of major adverse cardiovascular events (MACE) in individuals with established CVD. METHODS AND RESULTS: We identified individuals with a history of CVD before 23 February 2021 and a diagnosis of MACE between 23 February 2021 and 31 January 2022 in Hong Kong. MACE was defined as a composite of myocardial infarction, stroke, revascularization, and cardiovascular death. Electronic health records from the Hong Kong Hospital Authority were linked to vaccination records from the Department of Health. A self-controlled case-series method was used to evaluate the risk of MACE for 0-13 and 14-27 days after two doses of COVID-19 vaccine. We estimated incidence rate ratios (IRRs) to compare the risk of MACE between each risk period and the baseline period. A total of 229â€‰235 individuals with CVD were identified, of which 1764 were vaccinated and had a diagnosis of MACE during the observation period (BNT162b2â€‰=â€‰662; CoronaVacâ€‰=â€‰1102). For BNT162b2, IRRs were 0.48 [95% confidence interval (CI) 0.23-1.02] for the first dose and 0.87 (95% CI 0.50-1.52) for the second dose during the 0-13 days risk period, 0.40 (95% CI 0.18-0.93) for the first dose and 1.13 (95% CI 0.70-1.84) for the second dose during the 14-27 days risk period. For CoronaVac, the IRRs were 0.43 (95% CI 0.24-0.75) for the first dose and, 0.73 (95% CI 0.46-1.16) for the second dose during the 0-13 days risk period, 0.54 (95% CI 0.33-0.90) for the first dose and 0.83 (95% CI 0.54-1.29) for the second dose during the 14-27 days risk period. Consistent results were found in subgroup analyses for different sexes, age groups and different underlying cardiovascular conditions. CONCLUSION: Our findings showed no evidence of an increased risk of MACE after vaccination with BNT162b2 or CoronaVac in patients with CVD. Future research is required to monitor the risk after the third dose of each vaccine.
This Month in JAAD International: August 2022: Cutaneous reactions to COVID-19 messenger RNA booster dose vaccination.
Evaluation of Acute Adverse Events after Covid-19 Vaccination during Pregnancy.
Maternal Vaccination and Risk of Hospitalization for Covid-19 among Infants. BACKGROUND: Infants younger than 6 months of age are at high risk for complications of coronavirus disease 2019 (Covid-19) and are not eligible for vaccination. Transplacental transfer of antibodies against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) after maternal Covid-19 vaccination may confer protection against Covid-19 in infants. METHODS: We used a case-control test-negative design to assess the effectiveness of maternal vaccination during pregnancy against hospitalization for Covid-19 among infants younger than 6 months of age. Between July 1, 2021, and March 8, 2022, we enrolled infants hospitalized for Covid-19 (case infants) and infants hospitalized without Covid-19 (control infants) at 30 hospitals in 22 states. We estimated vaccine effectiveness by comparing the

odds of full maternal vaccination (two doses of mRNA vaccine) among case infants and control infants during circulation of the B.1.617.2 (delta) variant (July 1, 2021, to December 18, 2021) and the B.1.1.259 (omicron) variant (December 19, 2021, to March 8, 2022). RESULTS: A total of 537 case infants (181 of whom had been admitted to a hospital during the delta period and 356 during the omicron period; median age, 2 months) and 512 control infants were enrolled and included in the analyses; 16% of the case infants and 29% of the control infants had been born to mothers who had been fully vaccinated against Covid-19 during pregnancy. Among the case infants, 113 (21%) received intensive care (64 [12%] received mechanical ventilation or vasoactive infusions). Two case infants died from Covid-19; neither infant's mother had been vaccinated during pregnancy. The effectiveness of maternal vaccination against hospitalization for Covid-19 among infants was 52% (95% confidence interval [CI], 33 to 65) overall, 80% (95% CI, 60 to 90) during the delta period, and 38% (95% CI, 8 to 58) during the omicron period. Effectiveness was 69% (95% CI, 50 to 80) when maternal vaccination occurred after 20 weeks of pregnancy and 38% (95% CI, 3 to 60) during the first 20 weeks of pregnancy. CONCLUSIONS: Maternal vaccination with two doses of mRNA vaccine was associated with a reduced risk of hospitalization for Covid-19, including for critical illness, among infants younger than 6 months of age. (Funded by the Centers for Disease Control and Prevention.).

Coronavirus disease 2019 and the cardiologist. PURPOSE OF REVIEW: There continues to be extensive clinical and epidemiological data to suggest that coronavirus disease 2019 (COVID-19) infection is associated with numerous different types of cardiac involvement. RECENT FINDINGS: Myocardial injury has been reported in over 25% of patients hospitalized due to COVID-19 infection and is not only associated with a worse prognosis but with higher mortality, approaching 40%. Currently proposed mechanisms of myocardial injury include direct viral infection, cytokine storm, endothelial inflammation, demand ischemia, interferon-mediated response and stress cardiomyopathy. COVID-19 infection is associated with new-onset arrhythmias and heart failure regardless of history of previous cardiovascular disease. Echocardiographic findings can be useful to predict mortality in COVID-19 patients and cardiac MRI is an effective tool to both assess COVID-19 induced myocarditis and to follow-up on cardiac complications of COVID-19 long-term. Although there is an association between COVID-19 vaccination and myocarditis, pericarditis or arrhythmias, the risk appears lower when compared to risk attributable to the natural infection. SUMMARY: Patients with cardiovascular disease are not only more likely to suffer from severe COVID-19 infection but are at increased risk for further complications and higher mortality. Further data compilation on current and emerging treatments of COVID-19 will have additional impact on cardiovascular morbidity and mortality of COVID-19 infection.

Viral keratitis after the second and third doses of inactivated COVID-19 vaccination: A case report. Rare cases of viral keratitis after coronavirus disease 2019 (COVID-19) vaccination have been reported. Furthermore, to our knowledge, cases of viral keratitis after two rounds of COVID-19 vaccination have not yet been reported. We report the case of a 19-year-old man without a history of keratitis, who developed viral keratitis soon after receiving the second and third doses of inactivated COVID-19 vaccines. Each time after the patient received treatment with topical and systemic drugs, his ocular symptoms were gradually relieved, and corrected visual acuity in both eyes returned to normal. COVID-19 vaccination may be associated with rare cases of the development of keratitis in individuals without a medical history of keratitis. Physicians should be aware of the possible relationship between ocular symptoms and adverse reactions to the COVID-19 vaccination. Despite the potential risks of COVID-19 vaccination, the benefits of immunization against the virus far outweigh these risks.

Evaluation of anti-severe acute respiratory syndrome coronavirus 2 antibody levels in coronavirus disease breakthrough infection during immunosuppressive therapy in a patient with connective tissue

disease-related interstitial lung disease. Herein, we report the case of a 67-year-old man with severe coronavirus disease (COVID-19) pneumonia and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine breakthrough infection during immunosuppressive therapy for connective tissue disease-related interstitial lung disease (CTD-ILD). The patient received glucocorticoids combined with tacrolimus as maintenance therapy. His serum anti-SARS-CoV-2-immunoglobulin G (IgG) antibody levels were extremely low at the onset of COVID-19 pneumonia, even after the second dose of SARS-CoV-2 mRNA vaccine (BNT162b2). After treatment for COVID-19 pneumonia, the levels of anti-SARS-CoV-2-IgG antibodies increased. These results indicated a lack of the ability to produce neutralising antibodies from immune cells despite the booster vaccination. Therefore, we suggest that advanced-age patients with CTD-ILD receiving immunosuppressive therapy with polypharmacy require consistent personal protection, vaccination of close caregivers, increased awareness, and booster vaccination. Moreover, we recommend that tacrolimus should be withdrawn for a while after vaccination under controlled conditions.

Deferring Risk: Limitations to the Evidence in Product Labels for Vaccine Use in Pregnancy. Background: The gaps in clinical trial evidence about vaccination in pregnancy have serious implications for health care worker and public misunderstandings. Contradictions between National Immunization Technical Advisory Group (NITAG) recommendations and regulatory product labeling information contribute to misinformation about vaccine safety and effectiveness. Methods: A mixed methods approach that included a stakeholder consensus decision-making workshop and a national survey of Canadian health care providers (HCPs). Results: We identified knowledge gaps and serious limitations concerning the information in vaccine product labels. Stakeholders were troubled that some HCPs rely on regulatory product labels to inform their decisions without knowing their limitations in content. Our survey showed that HCPs were uncertain about the purpose of product labels and the evidence contained in them. Over a third of respondents incorrectly thought that product labels and NITAG recommendations are based on the same evidence and that the information they contain is regularly updated. Conclusions: Applying social risk theories, we show how such gaps in information defer responsibility for decisions about disease risk and vaccine safety from regulatory agencies and vaccine manufacturers onto HCPs and their clients. This may be especially relevant for COVID-19 and other emerging vaccines that are initially authorized for conditional or emergency use, and especially in understudied populations such as pregnant people. More frequent updating and alignment of robust, unbiased, and independently reviewed clinical trial and postmarket safety and effectiveness evidence with NITAG recommendations would allay HCP and public misunderstandings.

Acute kidney injury after COVID-19 vaccines: correspondence.

Comment: Humoral and T-cell Immunities to SARS-CoV-2 Vaccines: Safety, Efficacy, and Challenges in Autoimmune Neurology.

Immune Response and Safety of SARS-CoV-2 mRNA-1273 Vaccine in Patients With Myasthenia Gravis. BACKGROUND AND OBJECTIVES: Evidence regarding the safety and efficacy of messenger RNA (mRNA) vaccines in patients with myasthenia gravis (MG) after immunosuppressive therapies is scarce. Our aim is to determine whether the mRNA-1273 vaccine is safe and able to induce humoral and cellular responses in patients with MG. METHODS: We performed an observational, longitudinal, prospective study including 100 patients with MG of a referral center for MG in our country, conducted from April 2021 to November 2021 during the vaccination campaign. The mRNA-1273 vaccine was scheduled for all participants. Blood samples were collected before vaccination and 3 months after a second dose. Clinical changes in MG were measured using the MG activities of daily life score at baseline and 1 week after the first and second doses. A surveillance of all symptoms of coronavirus disease 2019 (COVID-19) was conducted throughout the study. Humoral and cellular

immune responses after vaccination were assessed using a spike-antibody ELISA and interferon gamma release assay in plasma. The primary outcomes were clinically significant changes in MG symptoms after vaccination, adverse events (AEs), and seroconversion and T-cell immune response rates. RESULTS: Ninety-nine patients completed the full vaccination schedule, and 98 had 2 blood samples taken. A statistically significant worsening of symptoms was identified after the first and second doses of the mRNA-1273 vaccine, but this was not clinically relevant. Mild AEs occurred in 14 patients after the first dose and in 21 patients after the second dose. Eighty-seven patients developed a humoral response and 72 patients showed a T-cell response after vaccination. A combined therapy with prednisone and other immunosuppressive drugs correlated with a lower seroconversion ratio (OR = 5.97, 95% CI 1.46-24.09, p = 0.015) and a lower T-cell response ratio (OR = 2.83, 95% CI 1.13-7.13, p = 0.024). DISCUSSION: Our findings indicate that the mRNA vaccination against COVID-19 is safe in patients with MG and show no negative impact on the disease course. Patients achieved high humoral and cellular immune response levels. CLASSIFICATION OF EVIDENCE: This study provides Class IV evidence that patients with MG receiving the mRNA-1273 vaccine did not show clinical worsening after vaccination and that most of the patients achieved high cellular or immune response levels.
Tixagevimab/cilgavimab pre-exposure prophylaxis is associated with lower breakthrough infection risk in vaccinated solid organ transplant recipients during the omicron wave. The neutralizing monoclonal antibody combination of tixagevimab/cilgavimab has been shown to reduce the risk of SARS-CoV-2 infection in unvaccinated individuals during the Alpha (B.1.1.7) and Delta (B.1.617.2) waves. However, data on the efficacy and safety of tixagevimab/cilgavimab in vaccinated solid organ transplant recipients during the Omicron wave is limited. To address this, we conducted a retrospective cohort study comparing 222 solid organ transplant recipients (SOTRs) who received tixagevimab/cilgavimab for pre-exposure prophylaxis and 222 vaccine-matched solid organ transplant recipients who did not receive tixagevimab/cilgavimab. Breakthrough SARS-CoV-2 infections occurred in 11 (5%) of SOTRs who received tixagevimab/cilgavimab and in 32 (14%) of SOTRs in the control group (pâ€‰<â€‰.001). In the tixagevimab/cilgavimab group, SOTRs who received the 150-150â€‰mg dose had a higher incidence of breakthrough infections compared to those who received the 300-300â€‰mg dose (pÂ =Â .025). Adverse events were uncommon, occurring in 4% of our cohort and most were mild. There was no significant change in serum creatinine or liver chemistries in kidney and liver transplant recipients, respectively. In conclusion, we found that tixagevimab/cilgavimab use is safe and associated with a lower risk of breakthrough SARS-CoV-2 infection in vaccinated solid organ transplant recipients during the Omicron wave.
Relapse of minimal change disease and inactivated SARS-CoV-2 vaccination.
Management of patients with hidradenitis suppurativa during COVID-19 vaccination: an experience from southern Italy. Comment on: 'Evaluating the safety and efficacy of COVID-19 vaccination in patients with hidradenitis suppurativa'.
A Case Report of Concurrent Graves' Disease and Subacute Thyroiditis Following SARS-CoV-2 Vaccination: An Autoimmune/Inflammatory Syndrome (ASIA). BACKGROUND: The response against adjuvants in vaccines is presented as autoimmune/inflammatory syndrome (ASIA). In this case report, we presented both SAT and Graves' disease in a patient as ASIA following the BNT162b2 mRNA COVID-19 vaccination. CASE PRESENTATION: A 31-year-old woman was admitted to the endocrinology outpatient clinic with the complaint of neck pain following the second dose of the BNT162B2 SARS-CoV-2 (Pfizer/BioNTech) vaccine. On physical examination, her thyroid gland was tender on palpation. Her thyroid function tests were compatible with hyperthyroidism, and inflammatory markers were high. In the thyroid ultrasonography (US) examination, we observed bilateral diffuse hypoechoic areas in the thyroid gland and increased vascularity in some parts of the

thyroid. Anti-thyroid stimulating hormone receptor antibodies (TRAB) were positive. Overall, we considered concurrent subacute thyroiditis (SAT) and Graves' disease. CONCLUSION: The present study may be the first report to evaluate SAT and Graves' disease as ASIA following mRNA COVID-19 vaccination. Clinicians should be aware of possible vaccine-related complications.

Human Milk Antibody Response After Combining Two Different COVID-19 Vaccines: Mix-and-Match. BACKGROUND: SARS-CoV-2-specific antibodies are secreted into human milk after women are vaccinated against COVID-19, which might protect the breastfed infant. Due to several reports of severe side-effects of the Oxford-AstraZeneca ChAdOx1 (AZD1222) vaccine against COVID-19, some lactating women followed a heterologous vaccination schedule consisting of the first dose of AZD1222 and a second dose of an mRNA-based vaccine. However, it is unclear whether this generates a significant SARS-CoV-2-specific antibody response in human milk. MAIN ISSUE: To quantify the SARS-CoV-2-specific antibody response in human milk of two lactating women receiving a heterologous vaccination schedules: AZD1222 and mRNA-based vaccine (Pfizer-BioNTech [BNT162b2] and Moderna [mRNA-1273]). MANAGEMENT: Both participants collected 16 samples of human milk longitudinally. SARS-CoV-2-specific Immunoglobulin A was measured using an enzyme-linked immunosorbent assay. CONCLUSION: Based on our results, it could be suggested that heterologous vaccination with AZD1222 and an mRNA-based vaccine can elicit a significant SARS-CoV-2 specific IgA response in human milk.

A case of transient POTS following COVID-19 vaccine.

The effect of SARS-CoV-2 vaccination on post-acute sequelae of COVID-19 (PASC): A prospective cohort study. BACKGROUND: Symptoms of post-acute sequelae of COVID-19 (PASC) may improve following SARS-CoV-2 vaccination. However few prospective data that also explore the underlying biological mechanism are available. We assessed the effect of vaccination on symptomatology of participants with PASC, and compared antibody dynamics between those with and without PASC. METHODS: RECoVERED is a prospective cohort study of adult patients with mild to critical COVID-19, enrolled from illness onset. Among participants with PASC, vaccinated participants were exact-matched 1:1 on age, sex, obesity status and time since illness onset to unvaccinated participants. Between matched pairs, we compared the monthly mean numbers of symptoms over a 3-month follow-up period, and, using exact logistic regression, the proportion of participants who fully recovered from PASC. Finally, we assessed the association between PACS status and rate of decay of spike- and RBD-binding IgG titers up to 9Â months after illness onset using Bayesian hierarchical linear regression. FINDINGS: Of 349 enrolled participants, 316 (90.5%) had â‰¥3Â months of follow-up, of whom 186 (58.9%) developed PASC. Among 36 matched pairs with PASC, the mean number of symptoms reported each month during 3Â months of follow-up were comparable between vaccinated and unvaccinated groups. Odds of full recovery from PASC also did not differ between matched pairs (OR 1.57 [95%CI 0.46-5.84]) within 3Â months after the matched time-point. The median half-life of spike- and RBD-binding IgG levels were, in days (95%CrI), 233 (183-324) and 181 (147-230) among participants with PASC, and 170 (125-252) and 144 (113-196) among those without PASC, respectively. INTERPRETATION: Our study found no strong evidence to suggest that vaccination improves symptoms of PASC. This was corroborated by comparable spike- and RBD-binding IgG waning trajectories between those with and without PASC, refuting any immunological basis for a therapeutic effect of vaccination on PASC.

Predictors of Covid-19 Vaccination Response After In-Vivo T-Cell-Depleted Stem Cell Transplantation. Covid-19 vaccination is recommended in allogeneic transplant recipients, but many questions remain regarding its efficacy. Here we studied serologic responses in 145 patients who had undergone allogeneic transplantation using in vivo T-cell depletion. Median age was 57 (range 21-79) at transplantation and 61 (range 24-80) at vaccination. Sixty-nine percent were Caucasian. One third

each received transplants from HLA-identical related (MRD), adult unrelated (MUD), or haploidentical-cord blood donors. Graft-versus-host disease (GVHD) prophylaxis involved in-vivo T-cell depletion using alemtuzumab for MRD or MUD transplants and anti-thymocyte globulin for haplo-cord transplants. Patients were vaccinated between January 2021 and January 2022, an average of 31 months (range 3-111 months) after transplantation. Sixty-one percent received the BNT162b2 (bioNtech/Pfizer) vaccine, 34% received mRNA-1273 (Moderna), and 5% received JNJ-78436735 (Johnson & Johnson). After the initial vaccinations (2 doses for BNT162b2 and mRNA-1273, 1 dose for JNJ-7843673), 124 of the 145 (85%) patients had a detectable SARS-CoV-2 spike protein (S) antibody, and 21 (15%) did not respond. Ninety-nine (68%) had high-level responses (â‰¥100 binding antibody units [BAU]/mL)m and 25 (17%) had a low-level response (<100 BAU/mL). In multivariable analysis, lymphocyte count less than 1Â Ã—Â 10(9)/ mL, having chronic GVHD, and being vaccinated in the first year after transplantation emerged as independent predictors for poor response. Neither donor source nor prior exposure to rituximab was predictive of antibody response. SARS-CoV-2 vaccination induced generally high response rates in recipients of allogeneic transplants including recipients of umbilical cord blood transplants and after in-vivo T cell depletion. Responses are less robust in those vaccinated in the first year after transplantation, those with low lymphocyte counts, and those with chronic GVHD.

Possible Associations Between Alopecia Areata and COVID-19 Vaccination and Infection.

COVID19 vaccination in adults with sickle cell disease is not associated with increases in rates of pain crisis. ABSTRACTPeople with sickle cell disease (SCD) are more vulnerable to hospitalization, pneumonia, and pain following COVID-19 infection. However, given the association between the inflammatory response and vaso-occlusive crises in SCD and a case report of vaso-occlusive crises following administration of the ChAdOx1 nCov-195-7/AstraZeneca vaccine, there is concern that the administration of COVID-19 vaccines in people with SCD might provoke a vaso-occlusive crisis. To address this critical gap in knowledge, we sought to examine acute care usage for vaso-occlusive crisis and frequency and severity of side effects following COVID-19 vaccination among patients at the Montefiore Sickle Cell Center for Adults. As part of regular care, patients were asked if they had received COVID-19 vaccination and any side effects were noted. Electronic medical records were reviewed for the type of vaccine, dates received, episodes of vaso-occlusive crises within seven days of a dose, and side effects noted. The risk of average hospital utilization per week in 2019 was calculated as a baseline. We found that fewer than 1 in 10 patients presented to the hospital within seven days of vaccination and that the risk of hospital utilization was similar to the average risk in a week in 2019. Of patients who reported side effects, one reported a possible case of sensorineural hearing loss otherwise no other rare side effects, including thrombosis or death, were reported.

Omicron Breakthrough Infection After Heterologous Prime-Boost Vaccination Induces a Vigorous Antibody Response. Infection with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron variant is usually asymptomatic or mild and appears to be poorly immunogenic at least in unvaccinated individuals. Here, we found that health care workers vaccinated with 2 doses of Sputnik V and a booster dose of ChAdOx1 mount a vigorous neutralizing-antibody response after Omicron breakthrough infection.

High Neutralizing Antibody Levels Against Severe Acute Respiratory Syndrome Coronavirus 2 Omicron BA.1 and BA.2 After UB-612 Vaccine Booster. The highly transmissible severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron variant has caused high rates of breakthrough infections in those previously vaccinated with ancestral strain coronavirus disease 2019 (COVID-19) vaccines. Here, we demonstrate that a booster dose of UB-612 vaccine candidate delivered 7-9 months after primary vaccination increased neutralizing antibody levels by 131-, 61-, and 49-fold against ancestral SARS-CoV-2 and the Omicron BA.1 and BA.2 variants, respectively. Based on the

receptor-binding domain protein binding antibody responses, the UB-612 third-dose booster may lead to an estimated approximately 95% efficacy against symptomatic COVID-19 caused by the ancestral strain. Our results support UB-612 as a potential potent booster against current and emerging SARS-CoV-2 variants.
Non-allergic nature of vast majority of cutaneous adverse reactions to mRNA COVID-19 vaccines: implications on treatment and re-vaccination.
Sweet Syndrome following SARS-CoV-2 CoronaVac vaccine.
Reply to 'Cutaneous adverse effects of the available COVID-19 vaccines in India: A questionnaire-based study' by Bawane J etâ€‰al.
Menstrual Cycle Parameters Are Not Significantly Different After COVID-19 Vaccination. Background: Some studies have suggested minor changes in the menstrual cycle after COVID-19 vaccination, but more detailed analyses of the menstrual cycle are needed to evaluate more specific changes in the menstrual cycle that are not affected by survey-based recall bias. Materials and Methods: Using a pretest-post-test quasi-experimental evaluation of menstrual cycle parameters before and after COVID-19 vaccination, we conducted an anonymous online survey of two groups of North American women who prospectively monitor their menstrual cycle parameters daily including bleeding patterns, urinary hormone levels using the ClearBlue Fertility Monitor, or cervical mucus observations. The primary outcome measures were cycle length, length of menses, menstrual volume, estimated day of ovulation (EDO), luteal phase length, and signs of ovulation. Perceived (subjective) menstrual cycle changes and stressors were also evaluated in this study as secondary outcome measures. Results: Of the 279 women who initiated the survey, 76 met the inclusion criteria and provided 588 cycles for analysis (227 pre-vaccine cycles, 145 vaccine cycles, 216 post-vaccine cycles). Although 22% of women subjectively identified changes in their menstrual cycle, there were no significant differences in menstrual cycle parameters (cycle length, length of menses, EOD, and luteal phase length) between the pre-vaccine, vaccine, and post-vaccine cycles. Conclusions: COVID-19 vaccines were not associated with significant changes in menstrual cycle parameters. Perceived changes by an individual woman must be compared with statistical changes to avoid confirmation bias.
Integrating the CARD (Comfort Ask Relax Distract) system in a mass vaccination clinic to improve the experience of individuals during COVID-19 vaccination: a pre-post implementation study. Many people have negative experiences with vaccination due to stress-related reactions including fear and pain. We used a pre-post study design to evaluate the impact of implementing a modified version of the CARD (Comfort-Ask-Relax-Distract) system on stress-related reactions in individuals aged 12â€‰y or older undergoing COVID-19 vaccinations in mass vaccination clinics. Vaccine recipients reported their level of pain, fear and dizziness during vaccination. Clinic staff reported their attitudes about CARD and use of CARD interventions. CARD improved client symptoms across genders and ages with an average reduction in needle pain, fear and dizziness of 75%, 40% and 44%, respectively. CARD was more effective in younger individuals. Clinic staff reported positive attitudes about CARD and uptake of selected CARD interventions. In summary, the modified CARD system reduced stress-related responses in a general population undergoing COVID-19 vaccinations in a mass vaccination clinic, was feasible and acceptable to staff. Future implementation efforts are recommended that include more diverse cultural contexts and incorporate education of individuals about CARD ahead of time.
Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Transmission Associated With an Indoor Music Event That Required Proof of Full Vaccination Against Coronavirus Disease 2019 (COVID-19) Prior to Entry-Seattle, July 2021. In July 2021, Public Health-Seattle & King County investigated a coronavirus disease 2019 (COVID-19) outbreak at an indoor event intended for fully vaccinated individuals, revealing unvaccinated staff, limited masking, poor ventilation, and

overcrowding. Supporting businesses to develop and implement comprehensive COVID-19 prevention plans is essential for reducing spread in these settings.

Management of suspected and confirmed COVID-19 (SARS-CoV-2) vaccine hypersensitivity. BACKGROUND: Systemic allergic reactions to vaccines are very rare. In this study we assessed the management and outcome of suspected SARS-CoV-2 vaccine hypersensitivity. METHODS: Totally, 334 individuals underwent an allergy work up regarding SARS-CoV-2 vaccination (group A: 115 individuals suspected to be at increased risk for vaccine-related reactions before vaccination and group B: 219 patients with reactions after COVID vaccination). The large majority of the SPT/IDT with the vaccines were negative; however, we identified in 14.1% (nÂ =Â 47) a possible sensitization to the SARS-CoV-2 vaccine and/or its ingredients defined as one positive skin test. Of the 219 individuals (group B) who experienced symptoms suspicious for a hypersensitivity reaction after vaccination, 214 were reported after the first vaccination with a mRNA vaccine (157 mRNA (ComirnatyÂ®, 38 SpikevaxÂ®) and 18 with a vector vaccine (VaxzevriaÂ®), 5 cases were after the second vaccination. RESULTS: The symptom profile in group B was as follows: skin symptoms occurred in 115 cases (nÂ =Â 59 angioedema, nÂ =Â 50 generalized urticaria and nÂ =Â 23 erythema/flush. Seventy individuals had cardiovascular, 53 respiratory and 17 gastrointestinal symptoms. Of the overall 334 individuals, 78 patients tolerated (re)-vaccination (out of skin test positive/negative 7/19 from group A and 17/35 from group B). CONCLUSION: Proven IgE-mediated hypersensitivity to SARS-CoV-2 vaccines is extremely rare and not increased in comparison with reported hypersensitivity to other vaccines. The value of skin tests is unclear and nonspecific reactions, in particular when intradermal testing is applied, should be considered.

Adverse events following introduction of the ChAdOx1 nCoV-19 vaccine in Somalia in 2021: findings from a fragile setting and implications for the future. BACKGROUND: Vaccination against coronavirus disease 2019 (COVID-19) began in Somalia on 16 March 2021 with the Covishield (ChAdOx1 nCoV-19) vaccine. However, by the end of 2021, only a small percentage of the population had been fully vaccinated. As side effects play an important role in determining public confidence in vaccines and their uptake, this study aimed to examine reported adverse events following immunization (AEFIs) of vaccine recipients. METHODS: This cross-sectional-survey-based study was conducted between March and October 2021 in Somalia. Vaccine recipients who were eligible to receive the first dose of the Covishield vaccine in the first phase of COVID-19 vaccination were eligible for study inclusion. $P<0.05$ was considered to indicate significance. RESULTS: Of the 149,985 respondents who had received the first dose of the Covishield vaccine, 378 reported side effects. This represented a reported AEFI rate of 2.5 per 1000 population. Amongst those who reported adverse events, males (2.8 per 1000; $P<0.001$), respondents aged 35-49 years (3.3 per 1000; $P=0.001$) and teachers (3.5 per 1000; $P=0.000$) had higher rates of adverse events compared with females, other age groups and other occupations. Amongst population settlement types, a higher rate of AEFIs was observed amongst refugees (23.9 per 1000; $P=0.000$) and internally displaced populations (19 per 1000; $P=0.000$). Nearly half of the vaccine recipients who reported side effects (48%) reported one local symptom, and most symptoms were mild in nature. The probability of having acute and severe side effects was found to be 66% lower among males compared with females [odds ratio (OR) 0.44, 95% confidence interval (CI) 0.26-0.73; $P=0.002$]. Respondents aged >60 years (OR 1.52, 95% CI 0.64-3.62; $P=0.34$) were more likely to develop acute and severe AEFIs. None of the study population reported any severe life-threatening symptoms or death. CONCLUSION: Some variables (sex, profession, age) put recipients at higher odds of acute and severe AEFIs, but the Covishield vaccine generally produced mild side effects in a small proportion of the vaccinated population in Somalia. This study confirms that COVID-19 vaccines are safe, and their benefits clearly outweigh any associated risk.

De novo Vogt-Koyanagi-Harada disease after vaccination for COVID-19, successfully treated with systemic steroid therapy and monitored with laser speckle flowgraphy. PURPOSE: Vogt-Koyanagi-Harada (VKH) disease after vaccination for coronavirus disease 2019 (COVID-19) is rare, and the prognosis for this condition and its effect on ocular blood flow remains unclear. The purpose of this paper is to present the first case of de novo VKH disease after the second vaccination for COVID-19 with an mRNA vaccine that was successfully treated with systemic steroid therapy and monitored with laser speckle flowgraphy (LSFG). OBSERVATIONS: A 30s-year-old Japanese woman reported bilateral decreased visual function 2â€‰weeks after receiving a second dose of the BNT162b2 mRNA vaccine. Best-corrected visual acuity was 20/50 OD and 20/70 OS. Optical coherence tomography revealed bilateral serous retinal detachment over the swollen choroidal layer. LFSG showed decreased blood flow in the peripapillary region of both eyes. This case was diagnosed as complete VKH syndrome, and the patient underwent systemic steroid therapy. After treatment, the retinal detachment disappeared, choroidal thickness decreased, and ocular blood flow increased. Three months later, visual acuity recovered to 20/20 in both eyes. CONCLUSIONS: Caution should be exercised in cases with visual symptoms after COVID-19 vaccination, even after more than one dose and more than one week after vaccination. LSFG may be a useful way to measure the ocular blood flow response to treatment and determine the prognosis for VKH disease after COVID-19 vaccination.

Serum polyethylene glycol-specific IgE and IgG in patients with hypersensitivity to COVID-19 mRNA vaccines. BACKGROUND: The mechanism of allergic reactions to COVID-19 mRNA vaccines has not been clarified. Polyethylene glycol (PEG) is a potential antigen in the components of vaccines. However, there is little evidence that allergy after COVID-19 mRNA vaccination is related to PEG. Furthermore, the role of polysorbate (PS) as an antigen has also not been clarified. The objective of this study was to investigate whether PEG and PS allergies are reasonable causes of allergic symptoms after vaccination by detecting PEG-specific and PS-specific antibodies. METHODS: Fourteen patients who developed immediate allergic reactions to BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna) vaccines and nineteen healthy controls who did not present allergic symptoms were recruited. Serum PEG-specific immunoglobulin E (IgE) and immunoglobulin G (IgG) and PS-specific IgE and IgG were measured by enzyme-linked immunosorbent assay. Skin tests using PEG-2000 and PS-80 were applied to five patients and three controls. RESULTS: Serum levels of PEG-specific IgE and IgG in patients with immediate allergic reactions to the COVID-19 mRNA vaccine were higher than those in the control group. Serum levels of PS-specific IgE in patients with allergy to the vaccine were higher than those in patients of the control group. Intradermal tests using PEG verified the results for PEG-specific IgE and IgG. CONCLUSIONS: The results suggest that PEG is one of the antigens in the allergy to COVID-19 mRNA vaccines. Cross-reactivity between PEG and PS might be crucial for allergy to the vaccines. PEG-specific IgE and IgG may be useful in diagnosing allergy to COVID-19 mRNA vaccines.

A Case of ST Segment Elevation Myocardial Infarction Within 24 h of a Third Dose of COVID-19 mRNA Vaccine. Although coronavirus disease 2019 (COVID-19) vaccination is known to carry a slight risk of myocarditis and pericarditis, it remains unclear whether it has any impact on coronary artery disease. Here we present a case without particular thrombotic diathesis with a diagnosis of ST segment elevation acute myocardial infarction (STEMI) 19 h after a third dose of a COVID-19 mRNA vaccine. A primary percutaneous coronary intervention procedure for occluded right coronary artery with thrombus aspiration alone was successful in this patient. However, the relationship between STEMI and COVID-19 mRNA vaccination is uncertain, and additional studies to validate thrombogenetic effects of COVID-19 mRNA vaccines are needed. This case was helpful in distinguishing STEMI from myocarditis and pericarditis, which are recognized rare cardiac side effects of COVID-19 vaccination. It is important not to hesitate to perform coronary angiography procedures to rule out the possibility of STEMI occurrence, as in this case.

Benefit-risk evaluation of COVID-19 vaccination in special population groups of interest. Several population groups display an increased risk of severe disease and mortality following SARS-CoV-2 infection. These include those who are immunocompromised (IC), have a cancer diagnosis, human immunodeficiency virus (HIV) infection or chronic inflammatory disease including autoimmune disease, primary immunodeficiencies, and those with kidney or liver disease. As such, improved understanding of the course of COVID-19 disease, as well as the efficacy, safety, and benefit-risk profiles of COVID-19 vaccines in these vulnerable groups is paramount in order to inform health policy makers and identify evidence-based vaccination strategies. In this review, we seek to summarize current data, including recommendations by national health authorities, on the impact and benefit-risk profiles of COVID-19 vaccination in these populations. Moving forward, although significant efforts have been made to elucidate and characterize COVID-19 disease course and vaccine responses in these groups, further larger-scale and longer-term evaluation will be instrumental to help further guide management and vaccination strategies, particularly given concerns about waning of vaccine-induced immunity and the recent surge of transmission with SARS-CoV-2 variants of concern.

Dynamics of antibody titers and cellular immunity among Japanese healthcare workers during the 6 months after receiving two doses of BNT162b2 mRNA vaccine. BACKGROUND: The antibody titer is known to wane within months after receiving two doses of the Pfizer-BioNTech BNT162b2 mRNA SARS-CoV-2 vaccine. However, knowledge of the cellular immune response dynamics following vaccination is limited. This study to aimed to determine antibody and cellular immune responses following vaccination, and the incidence and determinants of breakthrough infection. METHODS: This prospective cohort study a 6-month follow-up period was conducted among Japanese healthcare workers. All participants received two doses of BNT162b2 vaccine. Anti-SARS-CoV-2 antibody titers and T-cell immune responses were measured in serum samples collected at several timepoints before and after vaccination. RESULTS: A total of 608 participants were included in the analysis. Antibody titers were elevated 3Â weeks after vaccination and waned over the remainder of the study period. T-cell immune responses showed similar dynamics. Six participants without predisposing medical conditions seroconverted from negative to positive on the IgG assay for nucleocapsid proteins, indicating breakthrough SARS-CoV-2 infection. Five of the six breakthrough infections were asymptomatic. CONCLUSIONS: Both humoral and cellular immunity waned within 6Â months after BNT162b2 vaccination. The incidence of asymptomatic breakthrough infection within 6Â months after vaccination was approximately one percent. UMIN CLINICAL TRIALS REGISTRY ID: UMIN000043340.

Long-term cardiac surveillance and outcomes of COVID-19 patients. Acute cardiac manifestions of COVID-19 have been well described, while chronic cardiac sequelae remain less clear. Various studies have shown conflicting data on the prevalence of new or worsening cardiovascular disease, myocarditis or cardiac dysrhythmias among patients recovered from COVID-19. Data are emerging that show that patients recovering from COVID-19 have an increased incidence of myocarditis and arrhythmias after recovery from COVID-19 compared with the control groups without COVID-19. The incidence of myocarditis after COVID-19 infection is low but is still significantly greater than the incidence of myocarditis from a COVID-19 vaccine. There have been several studies of athletes who underwent a variety of screening protocols prior to being cleared to return to exercise and competition. The data show possible, probable or definite myocarditis or cardiac injury among 0.4-3.0% of the athletes studied. Recent consensus statements suggest that athletes with full recovery and absence of cardiopulmonary symptoms may return to exercise and competition without cardiovascular testing. In conclusion, patients with COVID-19 may be expected to have an increased risk of cardiovascular disease, myocarditis or arrhythmias during the convalescent phase. Fortunately,

the majority of patients, including athletes may return to their normal activity after recovery from COVID 19, in the absence of persisting cardiovascular symptoms.

Immunizing the imperfect immune system: Coronavirus disease 2019 vaccination in patients with inborn errors of immunity. OBJECTIVE: To update clinicians on current evidence regarding the immunogenicity and safety of coronavirus disease 2019 (COVID-19) vaccines in patients with inborn errors of immunity (IEI). DATA SOURCES: Peer-reviewed, published studies in PubMed, clinical trials listed on ClinicalTrials.gov, and professional organization and governmental guidelines. STUDY SELECTIONS: Literature searches on PubMed and ClinicalTrials.gov were performed using a combination of the following keywords: primary immunodeficiency, COVID-19, SARS-CoV-2, and vaccination. RESULTS: A total of 26 studies met the criteria and were included in this review. Overall, antibody responses to COVID-19 vaccination were found in 72% of study subjects, with stronger responses observed after messenger RNA vaccination. Neutralizing antibodies were detected in patients with IEI, though consistently at lower levels than healthy controls. Risk factors for poor antibody responses included diagnosis of common variable immunodeficiency, presence of autoimmune comorbidities, and use of rituximab. T cell responses were detectable in most patients with IEI, with poorer responses often found in patients with common variable immunodeficiency. Safety of COVID-19 vaccines in patients with IEI was acceptable with high rates of reactogenicity but very few serious adverse events, including in patients with immune dysregulation. CONCLUSION: COVID-19 vaccines are safe in patients with IEI and seem to be immunogenic in most individuals, with stronger responses found after messenger RNA vaccinations.

Safety and immunogenicity of the inactivated whole-virus adjuvanted COVID-19 vaccine VLA2001: A randomized, dose escalation, double-blind phase 1/2 clinical trial in healthy adults. OBJECTIVES: We aimed to evaluate the safety and optimal dose of a novel inactivated whole-virus adjuvanted vaccine against SARS-CoV-2: VLA2001. METHODS: We conducted an open-label, dose-escalation study followed by a double-blind randomized trial using low, medium and high doses of VLA2001 (1:1:1). The primary safety outcome was the frequency and severity of solicited local and systemic reactions within 7 days after vaccination. The primary immunogenicity outcome was the geometric mean titre (GMT) of neutralizing antibodies against SARS-CoV-2 two weeks after the second vaccination. The study is registered as NCT04671017. RESULTS: Between December 16, 2020, and June 3, 2021, 153 healthy adults aged 18-55 years were recruited in the UK. Overall, 81.7% of the participants reported a solicited AE, with injection site tenderness (58.2%) and headache (46.4%) being the most frequent. Only 2 participants reported a severe solicited event. Up to day 106, 131 (85.6%) participants had reported any AE. All observed incidents were transient and non-life threatening in nature. Immunogenicity measured at 2 weeks after completion of the two-dose priming schedule, showed significantly higher GMTs of SARS-CoV-2 neutralizing antibody titres in the highest dose group (GMT 545.6; 95% CI: 428.1, 695.4) which were similar to a panel of convalescent sera (GMT 526.9; 95% CI: 336.5, 825.1). Seroconversion rates of neutralizing antibodies were also significantly higher in the high-dose group (>90%) compared to the other dose groups. In the high dose group, antigen-specific IFN-Î³ expressing T-cells reactive against the S, M and N proteins were observed in 76, 36 and 49%, respectively. CONCLUSIONS: VLA2001 was well tolerated in all tested dose groups, and no safety signal of concern was identified. The highest dose group showed statistically significantly stronger immunogenicity with similar tolerability and safety, and was selected for phase 3 clinical development.

SARS-CoV-2 infection in cancer patients on active therapy after the booster dose of mRNA vaccines. INTRODUCTION: The protective role against SARS-CoV-2 infection by the third booster dose of mRNA vaccines in cancer patients with solid malignancies is presently unknown. We prospectively investigated the occurrence of COVID-19 in cancer patients on active therapy after the booster

vaccine dose. METHODS: Cancer patients on treatment at the Center for Immuno-Oncology (CIO) of the University Hospital of Siena, Italy, and health care workers at CIO who had received a booster third dose of mRNA vaccine entered a systematic follow-up monitoring period to prospectively assess their potential risk of SARS-CoV-2 infection. Serological and microneutralization assay were utilized to assess levels of anti-spike IgG, and of neutralizing antibodies to the SARS-CoV-2 Wild Type, Delta and Omicron variants, respectively, after the booster dose and after negativization of the nasopharyngeal swab for those who had developed COVID-19. RESULTS: Ninety cancer patients with solid tumors on active treatment (Cohort 1) and 30 health care workers (Cohort 2) underwent a booster third dose of mRNA vaccine. After the booster dose, the median value of anti-spike IgG was higher ($p = 0.009$) in patients than in healthy subjects. Remarkably, 11/90 (12%) patients and 11/30 (37%) healthy subjects tested positive to SARS-CoV-2 infection during the monitoring period. Similar levels of anti-spike IgG and of neutralizing antibodies against all the investigated variants, with geometric mean titers of neutralizing antibodies against the Omicron being the lowest were detected after the booster dose and after COVID-19 in both Cohorts. CONCLUSIONS: The occurrence of SARS-CoV-2 infection we observed in a sizable proportion of booster-dosed cancer patients and in healthy subjects during the Omicron outbreak indicates that highly specific vaccines against SARS-CoV-2 variants are urgently required.

COVID-19 vaccine concerns of health care providers and ancillary staff. A web-based survey was widely distributed between November 1(st)-December 27(th), 2021, to health care providers and ancillary staff to assess reported COVID-19 vaccination of their children as well as their vaccine concerns. Fewer nurses and laboratory / radiology technicians reported COVID-19 vaccination of their adolescent children and intent to vaccinate their younger children compared to physicians and pharmacists, along with more frequently reported concern about anaphylaxis and infertility. Focused efforts to update ancillary staff as well as all health care providers on emerging COVID-19 vaccine safety information for children is crucial to promote strong COVID-19 vaccine recommendations. IMPACT: Nurses, laboratory technicians and radiology technicians frequently reported concern about anaphylaxis and infertility after COVID-19 vaccination despite reassuring safety data. Education of ancillary staff with emerging safety data is important to strengthen health care provider vaccine recommendations.

Acute macular neuroretinopathy after COVID-19 vaccine.

Re: Characteristics associated with serological COVID-19 vaccine response and durability in an older population with significant comorbidity.

B cell-derived cfDNA after primary BNT162b2 mRNA vaccination anticipates memory B cells and SARS-CoV-2 neutralizing antibodies. BACKGROUND: Much remains unknown regarding the response of the immuneÂ system to severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccination. METHODS: We employed circulating cell-free DNA (cfDNA) to assess the turnover of specific immune cell types following administration of the Pfizer/BioNTech vaccine. FINDINGS: The levels of B cell cfDNA after the primary dose correlated with development of neutralizing antibodies and memory B cells after the booster, revealing a link between early B cell turnover-potentially reflecting affinity maturation-and later development of effective humoral response. We also observed co-elevation of B cell, TÂ cell, and monocyte cfDNA after the booster, underscoring the involvement of innate immune cell turnover in the development of humoral and cellular adaptive immunity. Actual cell counts remained largely stable following vaccination, other than a previously demonstrated temporary reduction in neutrophil and lymphocyte counts. CONCLUSIONS: Immune cfDNA dynamics reveal the crucial role of the primary SARS-CoV-2 vaccine in shaping responses of the immune system following the booster vaccine. FUNDING: This work was supported by a generous gift from Shlomo Kramer. Supported by grants from Human Islet Research Network (HIRN UC4DK116274

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Antibody response following a Comirnaty booster dose in CoronaVac vaccinated individuals. Serum samples from 106 health care workers were analyzed by enzyme-linked immunosorbent assay (ELISA) test 15 days after a booster dose. A total of 99% of the participants showed a significant increase in the anti-S1 IgG index. The significant humoral response was observed 15 days after the heterologous dose of Comirnaty in most the subjects, regardless of having comorbidities. The administration of a third booster dose is suggested 5 months after the second vaccine dose of the initial vaccine.

Immunologic response, Efficacy, and Safety of Vaccines against COVID-19 Infection in Healthy and immunosuppressed Children and Adolescents Aged 2 - 21 years old: A Systematic Review and Meta-analysis. Children and adolescents form a large proportion of societies and play an important role in the transmission of COVID-19. On the other hand, their education, mental and physical wellness, and safety are compromised which makes vaccination a crucial step to return to normal life. In the current systematic review, the COVID-19 vaccination was evaluated in a total of 50,148 children and adolescents in 22 published studies and 5,279 participants in two ongoing clinical trials. The study was registered in the PROSPERO with the ID# CRD42022303615. Data were collected about multiple vaccines including BNT162b2 (Pfizer), mRNA-1273 (Moderna), JNJ-78436735 (Johnson and Johnson), CoronaVac (Sinovac), BBIBP-CorV (Sinopharm), adenovirus type-5-vectored vaccine, ZyCov-D, and BBV152 (COVAXIN). The immune response and efficacy of such vaccines were 96% - 100% in healthy children and adolescents and were also acceptable in those with underlying diseases and suppressed immune systems. The current systematic review revealed favorable safety profiles of employed vaccines in children and adolescents; however, adverse reactions such as myocarditis and myopericarditis were reported which were transient and resolved entirely. Consequently, vaccinating children and adolescents aged 2 - 21 years old is beneficial to abort the COVID-19 pandemic. Moreover, the risk-benefit assessments revealed favorable results for vaccinating children and adolescents, especially those with underlying diseases and immunosuppressed conditions, alongside adults to prevent transmission, severe infection, negative outcomes, and new variants formation. Also, according to the meta-analysis, the efficacy and immune response of vaccines after the first and second doses were 91% and 92%, respectively. Meanwhile, overall immune response for all vaccines was 95% and 91% for Pfizer vaccine.

Autoimmune hepatitis with history of HCV treatment triggered by COVID-19 vaccination: case report and literature review. Although vaccines have been effective against the worldwide pandemic of Coronavirus Disease 19 (COVID-19), some case reports have described autoimmune hepatitis triggered by COVID-19 vaccination. Meanwhile, hepatitis C virus (HCV) is known to be related to autoimmune diseases. Here, we report a case of autoimmune hepatitis with history of HCV treatment triggered by COVID-19 vaccination. An 82-year-old woman was referred to our hospital for severe liver injury. She had received a COVID-19 vaccination 7Â days prior. She had a history of HCV treatment with direct-acting antivirals 7Â years previously. In her blood data, despite HCV antibody positivity, she was negative for HCV RNA by real-time RT-PCR. Anti-nuclear antibody was positive and IgG was elevated. Interface hepatitis and plasma cell infiltration were confirmed pathologically. She was diagnosed as autoimmune hepatitis and her liver injury quickly improved after initiation of

steroid administration. This is a first case report of autoimmune hepatitis with history of HCV treatment triggered by COVID-19 vaccination.

Cutaneous manifestations following COVID-19 vaccination: A report of 25 cases. Various adverse effects particularly cutaneous manifestations associated with different COVID-19 vaccines have been observed in practice. The aim of our study was to evaluate all patients who presented to our tertiary center with skin manifestations following COVID-19 vaccines injection from September to December 2021. All patients with skin manifestation within 30â€‰days or less following COVID-19 vaccination were enrolled in our case-series. All cases included in our study were diagnosed based on clinical and/or histopathological evaluation and all other possible differential diagnoses were ruled out. Twenty-five individuals including 16 (64%) males and 9 (36%) females with the mean age of 47Â Â±â€‰17.62â€‰years (range 18-91) were enrolled in our study. Twenty-two (88%) patients developed lesions after Sinopharm vaccine injection and 3 (12%) cases manifested lesions after the AstraZeneca vaccine. Six (24%) patients developed new-onset lichen planus (LP) and 1 (4%) patient manifested LP flare-up. Two (8%) individuals developed psoriasis and 1 (4%) case showed psoriasis exacerbation. One (4%) patient developed new-onset pemphigus vulgaris (PV) and 1 (4%) case experienced a flare of PV lesions. One (4%) patient manifested pityriasis lichenoides et varioliformis acuta (PLEVA) flare-up. Other new-onset cases were as follows: toxic epidermal necrolysis (TEN) (nÂ =Â 1, 4%), bullous pemphigoid (BP) (nÂ =Â 2, 8%), alopecia areata (AA) (nÂ =Â 2, 8%), pytriasis rosea (nÂ =Â 1, 4%), herpes zoster (nÂ =Â 1, 4%), cutaneous small vessel vasculitis (nÂ =Â 1, 4%), erythema multiform (EM) and urticaria (nÂ =Â 3, 12%), and morphea (nÂ =Â 1, 4%). Physicians should be aware of the possible side effects especially cutaneous manifestations associated with COVID-19 vaccines.

Cytokine release syndrome-like serum responses after COVID-19 vaccination are frequent and clinically inapparent under cancer immunotherapy. Patients with cancer frequently receive immune-checkpoint inhibitors (ICIs), which may modulate immune responses to COVID-19 vaccines. Recently, cytokine release syndrome (CRS) was observed in a patient with cancer who received BTN162b2 vaccination under ICI treatment. Here, we analyzed adverse events and serum cytokines in patients with 23 different tumors undergoing (nâ€‰=â€‰64) or not undergoing (nâ€‰=â€‰26) COVID-19 vaccination under ICI therapy in a prospectively planned German single-center cohort study (nâ€‰=â€‰220). We did not observe clinically relevant CRS (â‰¥grade 2) after vaccination (95% CI 0-5.6%; Common Terminology of Adverse Events v.5.0) in this small cohort. Within 4 weeks after vaccination, serious adverse events occurred in eight patients (12.5% 95% CI 5.6-23%): six patients were hospitalized due to events common under cancer therapy including immune related adverse events and two patients died due to conditions present before vaccination. Despite absence of CRS symptoms, a set of pairwise-correlated CRS-associated cytokines, including CXCL8 and interleukin-6 was >1.5-fold upregulated in 40% (95% CI 23.9-57.9%) of patients after vaccination. Hence, elevated cytokine levels are common and not sufficient to establish CRS diagnosis.

Vaccines based on the replication-deficient simian adenoviral vector ChAdOx1: Standardized template with key considerations for a risk/benefit assessment. Replication-deficient adenoviral vectors have been under investigation as a platform technology for vaccine development for several years and have recently been successfully deployed as an effective COVID-19 counter measure. A replication-deficient adenoviral vector based on the simian adenovirus type Y25 and named ChAdOx1 has been evaluated in several clinical trials since 2012. The Brighton Collaboration Benefit-Risk Assessment of VAccines by TechnolOgy (BRAVATO) was formed to evaluate the safety and other key features of new platform technology vaccines. This manuscript reviews key features of the ChAdOx1-vectored vaccines. The simian adenovirus Y25 was chosen as a strategy to circumvent pre-existing immunity to common human adenovirus serotypes which could impair immune responses induced by

adenoviral vectored vaccines. Deletion of the E1 gene renders the ChAdOx1 vector replication incompetent and further genetic engineering of the E3 and E4 genes allows for increased insertional capability and optimizes vaccine manufacturing processes. ChAdOx1 vectored vaccines can be manufactured in E1 complementing cell lines at scale and are thermostable. The first ChAdOx1 vectored vaccines approved for human use, against SARS-CoV-2, received emergency use authorization in the UK on 30th December 2020, and is now approved in more than 180 countries. Safety data were compiled from phase I-III clinical trials of ChAdOx1 vectored vaccines expressing different antigens (influenza, tuberculosis, malaria, meningococcal B, prostate cancer, MERS-CoV, Chikungunya, Zika and SARS-CoV-2), conducted by the University of Oxford, as well as post marketing surveillance data for the COVID-19 Oxford-AstraZeneca vaccine. Overall, ChAdOx1 vectored vaccines have been well tolerated. Very rarely, thrombosis with thrombocytopenia syndrome (TTS), capillary leak syndrome (CLS), immune thrombocytopenia (ITP), and Guillain-Barre syndrome (GBS) have been reported following mass administration of the COVID-19 Oxford-AstraZeneca vaccine. The benefits of this COVID-19 vaccination have outweighed the risks of serious adverse events in most settings, especially with mitigation of risks when possible. Extensive immunogenicity clinical evaluation of ChAdOx1 vectored vaccines reveal strong, durable humoral and cellular immune responses to date; studies to refine the COVID-19 protection (e.g., via homologous/heterologous booster, fractional dose) are also underway. New prophylactic and therapeutic vaccines based on the ChAdOx1 vector are currently undergoing pre-clinical and clinical assessment, including vaccines against viral hemorrhagic fevers, Nipah virus, HIV, Hepatitis B, amongst others.

Safety of COVID-19 vaccination and acute neurological events: A self-controlled case series in England using the OpenSAFELY platform. INTRODUCTION: We investigated the potential association of COVID-19 vaccination with three acute neurological events: Guillain-BarrÃ© syndrome (GBS), transverse myelitis and Bell's palsy. METHODS: With the approval of NHS England we analysed primary care data from >17 million patients in England linked to emergency care, hospital admission and mortality records in the OpenSAFELY platform. Separately for each vaccine brand, we used a self-controlled case series design to estimate the incidence rate ratio for each outcome in the period following vaccination (4-42Â days for GBS, 4-28Â days for transverse myelitis and Bell's palsy) compared to a within-person baseline, using conditional Poisson regression. RESULTS: Among 7,783,441 ChAdOx1 vaccinees, there was an increased rate of GBS (NÂ =Â 517; incidence rate ratio 2Â·85; 95% CI2Â·33-3Â·47) and Bell's palsy (NÂ =Â 5,350; 1Â·39; 1Â·27-1Â·53) following a first dose of ChAdOx1 vaccine, corresponding to 11.0 additional cases of GBS and 17.9 cases of Bell's palsy per 1 million vaccinees if causal. For GBS this applied to the first, but not the second, dose. There was no clear evidence of an association of ChAdOx1 vaccination with transverse myelitis (NÂ =Â 199; 1Â·51; 0Â·96-2Â·37). Among 5,729,152 BNT162b2 vaccinees, there was no evidence of any association with GBS (NÂ =Â 283; 1Â·09; 0Â·75-1Â·57), transverse myelitis (NÂ =Â 109; 1Â·62; 0Â·86-3Â·03) or Bell's palsy (NÂ =Â 3,609; 0Â·89; 0Â·76-1Â·03). Among 255,446 mRNA-1273 vaccine recipients there was no evidence of an association with Bell's palsy (NÂ =Â 78; 0Â·88, 0Â·32-2Â·42). CONCLUSIONS: COVID-19 vaccines save lives, but it is important to understand rare adverse events. We observed a short-term increased rate of Guillain-BarrÃ© syndrome and Bell's palsy after first dose of ChAdOx1 vaccine. The absolute risk, assuming a causal effect attributable to vaccination, was low.

Vaccination After SARS-CoV-2 Infection Increased Antibody Avidity Against the Omicron Variant Compared to Vaccination Alone. The SARS-CoV-2 Omicron variant has caused infections among individuals vaccinated or with prior COVID-19, suggesting immune escape. Here, we showed a decrease in binding and surrogate neutralizing antibody responses to the Omicron variant after 2 doses of the Pfizer COVID-19 mRNA vaccine. Individuals recovered from infection before vaccination had higher antibody levels and avidity to the Omicron variant compared to individuals vaccinated

without infection. This suggested that COVID-19 infection before vaccination elicited a higher magnitude and affinity antibody response to the Omicron variant, and repeated exposure through infection or vaccine may be required to improve immunity to emerging SARS-CoV-2 variants.

Placing the risk of myopericarditis following COVID-19 vaccination into perspective.

COVID-19 vaccination-related adverse events among autoimmune disease patients: results from the COVAD study. OBJECTIVES: COVID-19 vaccines have been proven to be safe in the healthy population. However, gaps remain in the evidence of their safety in patients with systemic autoimmune and inflammatory disorders (SAIDs). COVID-19 vaccination-related adverse events (AEs) in patients with SAIDs and healthy controls (HC) seven days post-vaccination were assessed in the COVAD study, a patient self-reported cross-sectional survey. METHODS: The survey was circulated in early 2021 by >110 collaborators (94 countries) to collect SAID details, COVID-19 vaccination details and 7-day vaccine AEs, irrespective of respondent vaccination status. Analysis was performed based on data distribution and variable type. RESULTS: Ten thousand nine hundred respondents [median (interquartile range) age 42 (30-55) years, 74% females and 45% Caucasians] were analysed; 5867 patients (54%) with SAIDs were compared with 5033 HCs. Seventy-nine percent had minor and only 3% had major vaccine AEs requiring urgent medical attention (but not hospital admission) overall. Headache [SAIDsâ€‰=â€‰26%, HCsâ€‰=â€‰24%; odds ratio (OR)â€‰=â€‰1.1 (95% CI: 1.03, 1.3); Pâ€‰=â€‰0.014], abdominal pain [SAIDsâ€‰=â€‰2.6%, HCsâ€‰=â€‰1.4%; ORâ€‰=â€‰1.5 (95% CI: 1.1, 2.3); Pâ€‰=â€‰0.011], and dizziness [SAIDsâ€‰=â€‰6%, HCsâ€‰=â€‰4%; ORâ€‰=â€‰1.3 (95% CI: 1.07, 1.6); Pâ€‰=â€‰0.011], were slightly more frequent in SAIDs. Overall, major AEs [SAIDsâ€‰=â€‰4%, HCsâ€‰=â€‰2%; ORâ€‰=â€‰1.9 (95% CI: 1.6, 2.2); Pâ€‰<â€‰0.001] and, specifically, throat closure [SAIDsâ€‰=â€‰0.5%, HCsâ€‰=â€‰0.3%; ORâ€‰=â€‰5.7 (95% CI: 2.9, 11); Pâ€‰=â€‰0.010] were more frequent in SAIDs though absolute risk was small (0-4%). Major AEs and hospitalizations (<2%) were comparable across vaccine types in SAIDs. CONCLUSION: Vaccination against COVID-19 is safe in SAID patients. SAIDs were at a higher risk of major AEs than HCs, though absolute risk was small. There are small differences in minor AEs between vaccine types in SAID patients.

Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count among semen donors. BACKGROUND: The development of covid-19 vaccinations represents a notable scientific achievement. Nevertheless, concerns have been raised regarding their possible detrimental impact on male fertility OBJECTIVE: To investigate the effect of covid-19 BNT162b2 (Pfizer) vaccine on semen parameters among semen donors (SD). METHODS: Thirty-seven SD from three sperm banks that provided 216 samples were included in that retrospective longitudinal multicenter cohort study. BNT162b2 vaccination included two doses, and vaccination completion was scheduledÂ 7 days after the second dose. The study included four phases: T0 - pre-vaccination baseline control, which encompassed 1-2 initial samples per SD; T1, T2 and T3 - short, intermediate, and long terms evaluations, respectively. Each included 1-3 semen samples per donor provided 15-45, 75-125 and over 145 days after vaccination completion, respectively. The primary endpoints were semen parameters. Three statistical analyses were conducted: (1) generalized estimated equation model; (2) first sample and (3) samples' mean of each donor per period were compared to T0. RESULTS: Repetitive measurements revealed -15.4% sperm concentration decrease on T2 (CI -25.5%-3.9%, pÂ =Â 0.01) leading to total motile count 22.1% reduction (CI -35% - -6.6%, pÂ =Â 0.007) compared to T0. Similarly, analysis of first semen sample only and samples' mean per donor resulted in concentration and total motile count (TMC) reductions on T2 compared to T0 - median decline of 12 million/ml and 31.2 million motile spermatozoa, respectively (pÂ =Â 0.02 and 0.002 respectively) on first sample evaluation and median decline of 9.5Â Ã—Â 10(6) and 27.3 million motile spermatozoa (pÂ =Â 0.004 and 0.003, respectively) on samples' mean examination. T3 evaluation

demonstrated overall recovery without. Semen volume and sperm motility were not impaired. DISCUSSION: This longitudinal study focused on SD demonstrates selective temporary sperm concentration and TMC deterioration 3 months after vaccination followed by later recovery verified by diverse statistical analyses. CONCLUSIONS: Systemic immune response after BNT162b2 vaccine is a reasonable cause for transient semen concentration and TMC decline. Long-term prognosis remains good.

A Case Report of Conversion from Hashimoto's Thyroiditis to Graves' Disease in Type 1 Diabetic Patient Following the COVID-19 Vaccination. BACKGROUND: A considerable number of COVID-19 vaccines became available following the outbreak. Yet, various inflammatory and autoimmune complications have been reported following vaccination. We aimed to report the case of a type 1 diabetic patient converting from Hashimoto's thyroiditis to Graves' disease after the fourth dose of COVID-19 vaccine, thought to trigger an autoimmune/inflammatory syndrome induced by adjuvants (ASIA syndrome). CASE PRESENTATION: A thirty-one-year-old female patient with type 1 diabetes and Hashimoto's thyroiditis applied to our clinic with complaints of palpitations, anxiety, and weight loss one month after the fourth dose of COVID-19 vaccine (2 doses of CoronaVac + 2 doses of Pfizer/BioNTech). She was receiving levothyroxine 50 mcg/day. When her thyroid function tests showed thyrotoxicosis, we initially considered thyroxine-related exogenous thyrotoxicosis. However, we considered Graves' disease upon persisting thyrotoxicosis despite thyroxine withdrawal, positive serum TSH receptor antibody titers, and other imaging findings. Therefore, various autoimmune and inflammatory events have been reported after the COVID-19 vaccination. Adjuvants in vaccines can trigger autoimmune events, which lead to ASIA syndrome. COVID-19 vaccines may cause increased TSH receptor antibody levels or change the balance in the activity of blocking and stimulating antibodies, which may cause a conversion from Hashimoto's to Graves' disease. CONCLUSION: This was the first case report where the patient experienced a conversion from Hashimoto's to Graves' disease after COVID-19 vaccination, which may ultimately be related to ASIA syndrome. Yet, more data is needed to elucidate such a relationship, and patients should closely be checked regularly after four doses of vaccination.

Comparison of infection-induced and vaccine-induced immunity against COVID-19 in patients with cirrhosis. BACKGROUND AND AIMS: Immunity to SARS-CoV-2 can be infection or vaccine-induced. Cirrhosis is associated with vaccine hyporesponsiveness, but whether there is decreased immunity after SARS-CoV-2 infection in unvaccinated patients with cirrhosis is unknown.The objective of our study was to compare infection-induced and vaccine-induced immunity against COVID-19 among patients with cirrhosis. METHODS: This was a retrospective cohort study among US Veterans with cirrhosis between November 27, 2020, and November 16, 2021, comparing a vaccine-induced immunity group, defined as participants without a documented SARS-CoV-2 infection but fully vaccinated with two doses of an mRNA vaccine, and infection-associated immunity group, defined as unvaccinated participants who had a positive SARS-CoV-2 polymerase chain reaction (PCR). Both groups were propensity score matched for observed characteristics, including location, and the date of the immunity acquiring event, to control for the community prevalence of COVID-19 variants. The outcome was a positive SARS-CoV-2 PCR more than 60â€‰days after previous infection in the infection-induced, or after full vaccination in the vaccine-induced immunity group. RESULTS: We compared 634 participants in the infection-induced immunity group with 27,131 participants in the vaccine-induced immunity group using inverse propensity of treatment weighting. Vaccine-induced immunity was associated with a reduced odds of developing SARS-CoV-2 infection (adjusted hazard ratio [aHR], 0.18; 95% confidence interval [CI], 0.16-0.20, p <â€‰0.0001). On multivariable logistic regression, vaccine-induced immunity was associated with reduced odds of developing symptomatic (adjusted odds ratio [aOR], 0.36; 95% CI, 0.33-0.41, p <â€‰0.0001), moderate/severe/critical (aOR,

0.27; 95% CI, 0.22-0.31, p <â€‰0.0001), and severe or critical COVID-19 (aOR, 0.20; 95% CI, 0.16-0.26, p <â€‰0.001), compared with infection-induced immunity. CONCLUSIONS: In participants with cirrhosis, vaccine-induced immunity is associated with reduced risk of developing COVID-19, compared with infection-induced immunity.

Superficial thrombophlebitis in ipsilateral breast after COVID-19 vaccination. On December 2020, the US Food and Drug Administration issued the first emergency use authorization for a vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). We report development of superficial thrombophlebitis in the ipsilateral breast of a 43-year-old female 7 days after receiving the first dose of the Pfizer-BioNTech COVID-19 vaccine. Given that this is the first case of superficial thrombophlebitis in the breast shortly after mRNA vaccination for COVID-19 reported to our knowledge, we suggest that this may be a rare vaccine-related event.

Evaluation of the diagnostic features and clinical course of COVID-19 vaccine-associated subacute thyroiditis. OBJECTIVE: This study aimed to identify cases of coronavirus disease 2019 (COVID-19) vaccine-associated subacute thyroiditis (SAT) during the active vaccination period of the pandemic, analyze the characteristics of these cases, and compare them with cases of non-vaccine associated SAT diagnosed in the same period. METHODS: A total of 55 patients diagnosed with SAT in our outpatient clinic between February and October, 2021, were included in this retrospective single-center study. RESULTS: Of the study population, 16 (29.1%) were diagnosed with COVID-19 vaccine-associated SAT (10 with CoronaVacÂ® and six with Pfizer-BioNTechÂ® vaccine), with a median time to onset of symptoms after vaccination of 6.5 (range, 2-20) days. There was no statistically significant difference between the vaccine-associated (VA) and non-vaccine associated (NVA) groups in terms of age, gender, time to diagnosis, thyroid volumes, thyroid function tests, and acute phase reactants. Seven (43.8%) and 25 (64.1%) patients were treated with methylprednisolone in the VA group and NVA group, respectively (pâ€‰=â€‰0.16). Follow-up data of 45 patients (16/16 for VA and 29/39 for NVA) were available. The mean follow-up of these patients was 47.4â€‰Â±â€‰19.4Â days, and the follow-up periods of the VA group and NVA group were comparable (pâ€‰=â€‰0.24). There was no difference between the two groups in terms of the frequency of euthyroidism at the follow-up visit (12/16 vs.14/29, pâ€‰=â€‰0.08). CONCLUSION: With the increase in COVID-19 vaccination rates during the current pandemic, VA SAT cases are seen more frequently. The present study demonstrated that these cases have similar diagnostic features and clinical course to that of classic forms of SAT. In addition, most patients with VA SAT had a mild clinical course that improved with non-steroidal anti-inflammatory drugs.

An optimized machine learning model for identifying socio-economic, demographic and health-related variables associated with low vaccination levels that vary across ZIP codes in California. There is an urgent need for an in-depth and systematic assessment of a wide range of predictive factors related to populations most at risk for delaying and refusing COVID-19 vaccination as cases of the disease surge across the United States. Many studies have assessed a limited number of general sociodemographic and health-related factors related to low vaccination rates. Machine learning methods were used to assess the association of 151 social and health-related risk factors derived from the American Community Survey 2019 and the Centers for Disease Control and Prevention (CDC) BRFSS with the response variables of vaccination rates and unvaccinated counts in 1,555 ZIP Codes in California. The performance of various analytical models was evaluated according to their ability to regress between predictive variables and vaccination levels. Machine learning modeling identified the Gradient Boosting Regressor (GBR) as the predictive model with a higher percentage of the explained variance than the variance identified through linear and generalized regression models. A set of 20 variables explained 72.90% of the variability of unvaccinated counts among ZIP Codes in

California. ZIP Codes were shown to be a more meaningful geo-local unit of analysis than county-level assessments. Modeling vaccination rates was not as effective as modeling unvaccinated counts. The public health utility of this model provides for the analysis of state and local conditions related to COVID-19 vaccination use and future public health problems and pandemics.

Safety and efficacy of COVID-19 vaccines in children and adolescents: A systematic review of randomized controlled trials. To systematically review and synthesize the safety and efficacy of coronavirus disease-2019 (COVID-19) vaccines in children and adolescents. PubMed, EMBASE, Web of Science, Cochrane Library databases, the International Clinical Trials Registry Platform (ICTRP), the Chinese Clinical Trials Registry (ChiCTR), and ClinicalTrials.gov website were searched to collect accessible randomized controlled trials (RCTs) about the safety and efficacy of human COVID-19 vaccines in children and adolescents until May 1, 2022. Three steps, including duplicate removal, title and abstract screening, and full-text review, were used to screen the studies. The Cochrane risk-of-bias tool for RCTs was used to assess the bias risk of the included studies. Microsoft Excel 16.57 (2021) software was used for data extraction and analysis. (PROSPERO Code No: CRD42021295422). COVID-19 vaccines were evaluated in a total of 10â€‰950 children and adolescents in seven published studies and over 49â€‰530 participants in 26 ongoing randomized controlled trials. Descriptive findings of the included published studies were reported stratified by vaccine type. The overall, local, and systemic adverse events following immunization (AEFIs) reported in most trials were similar between the vaccine and placebo groups. Most of the reactions reported were mild to moderate, whereas a few were severe. The common adverse events were injection-site pain, fever, headache, cough, fatigue, and muscle pain. Few clinical trials reported serious adverse events, but most of them were unrelated to vaccination. In terms of efficacy, the investigated messenger RNA (mRNA) vaccine was found to be 90.7%-100% efficacious in preventing COVID-19 among children and adolescents, revealing good efficacy profiles in this age group. Among children and adolescents, the safety of current COVID-19 vaccines is acceptable, and studies have suggested that mRNA vaccines can provide high protection against COVID-19 infection in pediatric age groups.

Antimelanoma Differentiation-Associated Gene 5 Antibody-Positive Interstitial Lung Disease After Vaccination With COVID-19 mRNA Vaccines. OBJECTIVE: Melanoma differentiation-associated gene 5 (MDA5) is a viral RNA sensor induced by SARS-CoV-2. Similarities have been reported between the clinical presentations of coronavirus disease 2019 (COVID-19) pneumonia and anti-MDA5 antibody-positive interstitial lung disease (anti-MDA5-ILD). However, it is unknown whether COVID-19 mRNA vaccines are associated with anti-MDA5-ILD. METHODS: We retrospectively reviewed consecutive patients with anti-MDA5-ILD admitted to our hospital between April 2017 and March 2022. In addition, we investigated the clinical presentations of patients who developed anti-MDA5-ILD after vaccination with COVID-19 mRNA vaccines. We also examined the annual number of anti-MDA5-ILD cases before and after the COVID-19 vaccination campaign. RESULTS: Nine patients with anti-MDA5-ILD were seen during the study period, of whom 4 developed anti-MDA5-ILD between August and October 2021, approximately 6 to 12 weeks after vaccination with a COVID-19 mRNA vaccine and a few months after the rapid mRNA COVID-19 vaccination campaign in Japan. None of the 4 patients had evidence of SARS-CoV-2 infection. The difference in the annual number of anti-MDA5-ILD cases before vs after the COVID-19 vaccination campaign (1.25 Â± 0.96 cases/yr vs 4.0 cases/yr) was not statistically significant (P = 0.08). CONCLUSION: We encountered 4 cases of anti-MDA5-ILD after COVID-19 vaccination. Further large population studies are needed to clarify the relationship between anti-MDA5-ILD and vaccination with COVID-19 mRNA vaccines.

Benefit and cost of repeating a severe acute respiratory coronavirus virus 2 (SARS-CoV-2) polymerase chain reaction (PCR) test after the second day of hospitalization in five hospitals during various community prevalences and vaccination rates. At our hospital, universal severe acute respiratory

coronavirus virus 2 (SARS-CoV-2) polymerase chain reaction (PCR) testing was performed upon admission and again after 2 inpatient days. As community-wide prevalence, admission, and vaccination rates varied, the number needed to benefit fluctuated between 16 and 769 and the cost per additional detection fluctuated between $800 and $29,400. These 2 metrics were negatively associated with new hospital admissions. No other community indicator was associated with the number needed to benefit and cost per additional detection.

Decline in antibody responses to SARS-CoV-2 post-vaccination poses a risk to health care workers.

A Case of de novo Annular-plaque Type Psoriasis Following Oxford- AstraZeneca COVID-19 Vaccination. BACKGROUND: There have been increasing reported cases of new-onset or aggravation of pre-existing dermatoses after the implementation of COVID-19 vaccination. CASE PRESENTATION: An elderly male was presented with multiple annular scaly plaques all over the body two weeks following administration of the first dose of Oxford-AstraZeneca COVID-19 vaccine. The lesions further aggravated after taking the second dose of the vaccine. The clinical and histopathology features were suggestive of annular plaque psoriasis. CONCLUSION: We report this first case of de novo plaque psoriasis following the Oxford- AstraZeneca COVID-19 vaccine, and it signifies a potential side effect of autoimmune reactivation after COVID vaccination.

Mammographic findings of diffuse axillary tail trabecular thickening following immunization with mRNA COVID-19 vaccines: Case series study. Axillary lymphadenopathy has been reported after ipsilateral COVID-19 vaccination and can cause confusion for possible malignancy [1]. Intrinsic findings isolated to the breast has not been previously reported. This is the first case series of ipsilateral reversible changes of diffuse axillary tail trabecular thickening on screening mammography in totally asymptomatic patients in connection with COVID vaccination, 3 of which were isolated findings, confirmed by complete resolution of all imaging findings on follow up. In all instances, imaging was performed within 1 week of the first or third dose of an mRNA COVID-19 vaccine. These findings can be confused with breast cancer. Spontaneous resolution distinguishes vaccine-related findings from breast cancer.

Multimodal imaging findings including high-resolution 3D T2-weighted imaging for COVID-19 vaccine-associated axillary lymphadenopathy in a patient with breast cancer. COVID-19 vaccines have received authorization worldwide. Vaccines are typically administered to the deltoid muscle, and axillary swelling/tenderness at the first dose (11.6%) and the second dose (16%) have been reported as secondary effects. Regional lymphadenopathy in the axilla and supraclavicular region has also been reported with a prevalence of 1.1% and is referred to as COVID-19 vaccine-associated lymphadenopathy (VAL). COVID-19 VAL mimics lymph node (LN) metastases on magnetic resonance imaging, ultrasound, and 18F-fluoro-2-deoxy-Dglucose positron emission tomography. Although several specific findings of VAL on clinical imaging have been reported, the difficulty in differentiating between VAL and LN metastases could lead to false-positive or -negative diagnoses. Here, we report a case of breast cancer with ipsilateral VAL with multimodal imaging including 3D T2-weighted imaging, a new magnetic resonance imaging technique, and discuss the future perspective for differentiating between VAL and LN metastases.

Clinical characteristics and outcome of hospitalized elderly patients with COVID- 19 after vaccine failure. We described clinical characteristics and outcome of 160 patients over 65Â years (01 September to 31 August 2021) who had a first positive SARS-CoV-2 PCR- test more than 14Â days after full vaccination and were hospitalized with COVID-19. Median age of included patients was 84Â years, 61.2% were over 80Â years; 50.6% were male and most (82.5%) has at least one comorbidity. Up to 84% received specific treatment against COVID-19, including 76.9% low-flow oxygen therapy. We found that overall mortality was 25.6% and 30.6% in those older than 80Â years. A higher mortality was significantly associated with older age and treatment with tocilizumab. Our

data showed that although COVID-19 vaccines continue protecting elderly patients against hospitalization and death and might improve the prognosis after hospitalization in patients with breakthrough infections, mortality in this population -especially in those older than 80Â years- remains very high.

COVID-19 and liver disease. Knowledge on SARS-CoV-2 infection and its resultant COVID-19 in liver diseases has rapidly increased during the pandemic. Hereby, we review COVID-19 liver manifestations and pathophysiological aspects related to SARS-CoV-2 infection in patients without liver disease as well as the impact of COVID-19 in patients with chronic liver disease (CLD), particularly cirrhosis and liver transplantation (LT). SARS-CoV-2 infection has been associated with overt proinflammatory cytokine profile, which probably contributes substantially to the observed early and late liver abnormalities. CLD, particularly decompensated cirrhosis, should be regarded as a risk factor for severe COVID-19 and death. LT was impacted during the pandemic, mainly due to concerns regarding donation and infection in recipients. However, LT did not represent a risk factor per se of worse outcome. Even though scarce, data regarding COVID-19 specific therapy in special populations such as LT recipients seem promising. COVID-19 vaccine-induced immunity seems impaired in CLD and LT recipients, advocating for a revised schedule of vaccine administration in this population.

Acute encephalitis after COVID-19 vaccination: A case report and literature review. Vaccine-related immune responses are one of the causes of encephalitis. Vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, COVID-19) have been administered worldwide due to the ongoing global pandemic; cases of SARS-CoV-2 vaccination-related encephalitis were scarcely reported. An 82-year-old female was diagnosed with acute encephalitis following her first dose of vaccination with mRNA-1273 against SARS-CoV-2. The patient presented with fever and headache five days after vaccination, followed by behavior change 17â€‰days after vaccination. Electroencephalographic recordings revealed focal slow waves in the right frontoparietal regions. Brain MRI revealed the signal change in the right middle and posterior temporal lobe. Cerebrospinal fluid analysis showed mildly elevated protein. She responded well to steroid pulse therapy and made a full recovery. The severity of the immune response following COVID-19 vaccination may be alleviated if adequate treatment is achieved. Physicians must be alert for encephalitis after vaccination to help ensure a favorable outcome.

Reactivation of minimal change disease after Pfizer vaccine against COVID-19. This case follows a 54-year-old woman with a medical history of hypertension who experienced reactivation of minimal change disease (MCD) after receiving the Pfizer vaccine against COVID-19. She had her first episode of MCD 15Â days after receiving the influenza vaccine in 2018. She remained in remission for over 3Â years following treatment with steroids. She experienced foamy urine and leg edema after receiving the first dose of the Pfizer vaccine, but she did not consult medical professionals until she received the second dose. She wanted to be fully vaccinated because she worked in healthcare. Her initial diagnosis of MCD in 2018 was made following a kidney biopsy. The diagnosis of reactivation following COVID-19 vaccine was made with labs and presenting symptoms. At presentation, her urine protein was 9,977Â mg/day. She was treated with prednisone 50Â mg/day following her relapse with improvement in her urine protein to 85Â mg/g within 4Â weeks of starting treatment. She is currently undergoing treatment with prednisone with improvement in her presenting symptoms, which included foaming of urine and edema of legs. This case demonstrates the importance of vigilance in patients with a history of MCD when receiving the COVID-19 vaccine, particularly if they have a history of such reactions to other vaccines. Patients should discuss the benefits and risks of receiving the vaccine with their medical professionals and stay cognizant about the possibility of reactivation after receiving the COVID-19 vaccine.

Eosinophilic pustular folliculitis developing at the site of COVID-19 vaccination. We present a rare case of eosinophilic pustular folliculitis due to mRNA-based vaccines for COVID-19. Histology of the biopsy specimen was very interesting.

Thrombus Distribution in Vaccine-induced Immune Thrombotic Thrombocytopenia after ChAdOx1 nCov-19 Vaccination. Vaccination strategies have been at the forefront of controlling the COVID-19 pandemic. An association between vaccine-induced immune thrombotic thrombocytopenia (VITT) and one of these vaccines, the ChAdOx1 nCov-19 vaccine, is now recognized. The purpose of this study was to investigate the frequency and location of thrombosis in each vascular system using CT, MRI, and US to identify additional sites of thrombus in a United Kingdom-wide sample of patients with confirmed VITT. Thirty-two radiology centers identified through the national collaborative Radiology Academic Network for Trainees were invited from the United Kingdom; seven of these contributed to this study. All patients with confirmed VITT Â¬between February 3 and May 12, 2021, who met the inclusion criteria were included. The location and extent of thrombi were evaluated using CT, MRI, and US. A total of 40 patients (median age, 41 years [IQR, 32-52]; 22 [55%] men) with confirmed vaccine-induced immune thrombotic thrombocytopenia after administration of their first ChAdOx1 nCov-19 vaccine were included. Thirty-two patients (80%) developed symptoms within the first 14 days, and eight (20%) developed symptoms within 14-28 days. Twenty-nine patients (72%) experienced neurologic symptoms and were confirmed to have cerebral venous sinus thrombosis, 12 (30%) had clinical deterioration and repeat imaging demonstrated extension of their primary thrombus, and eight (20%) died. Twenty-five of 30 patients (83%) who underwent additional imaging had occult thrombosis. In conclusion, patients with VITT are likely to have multiple sites of thrombosis, with the most frequent being cerebral venous sinus thrombosis in combination with pulmonary embolism and portomesenteric venous thrombosis. Whole-body imaging with contrast-enhanced CT can be used to identify occult thrombosis.

Longitudinal Assessment of SARS-CoV-2-Specific T Cell Cytokine-Producing Responses for 1 Year Reveals Persistence of Multicytokine Proliferative Responses, with Greater Immunity Associated with Disease Severity. Cell-mediated immunity is critical for long-term protection against most viral infections, including coronaviruses. We studied 23 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-infected survivors over a 1-year post-symptom onset (PSO) interval by ex vivo cytokine enzyme-linked immunosorbent spot assay (ELISpot) assay. All subjects demonstrated SARS-CoV-2-specific gamma interferon (IFN-Î³), interleukin 2 (IL-2), and granzyme B (GzmB) T cell responses at presentation, with greater frequencies in severe disease. Cytokines, mainly produced by CD4(+) T cells, targeted all structural proteins (nucleocapsid, membrane, and spike) except envelope, with GzmB and IL-2 greater than IFN-Î³. Mathematical modeling predicted that (i) cytokine responses peaked at 6â€‰days for IFN-Î³, 36â€‰days for IL-2, and 7â€‰days for GzmB, (ii) severe illness was associated with reduced IFN-Î³ and GzmB but increased IL-2 production rates, and (iii) males displayed greater production of IFN-Î³, whereas females produced more GzmB. Ex vivo responses declined over time, with persistence of IL-2 in 86% and of IFN-Î³ and GzmB in 70% of subjects at a median of 336â€‰days PSO. The average half-life of SARS-CoV-2-specific cytokine-producing cells was modeled to be 139â€‰days (~4.6â€‰months). Potent T cell proliferative responses persisted throughout observation, were CD4 dominant, and were capable of producing all 3 cytokines. Several immunodominant CD4 and CD8 epitopes identified in this study were shared by seasonal coronaviruses or SARS-CoV-1 in the nucleocapsid and membrane regions. Both SARS-CoV-2-specific CD4(+) and CD8(+) T cell clones were able to kill target cells, though CD8 tended to be more potent. IMPORTANCE Our findings highlight the relative importance of SARS-CoV-2-specific GzmB-producing T cell responses in SARS-CoV-2 control and shared CD4 and CD8 immunodominant epitopes in seasonal coronaviruses or SARS-CoV-1, and they indicate robust persistence of T cell memory at least

1 year after infection. Our findings should inform future strategies to induce T cell vaccines against SARS-CoV-2 and other coronaviruses.
Six cases of pityriasis rosea following SARS-CoV-2 vaccination with BNT162b2.
The Fourth Dose of CoronaVac Vaccine Results in a Small Increase of Seroconversion and Antibody Values Among Kidney Transplant Recipients.
COVID-19 vaccine-related frequently asked questions (FAQs) by people with epilepsy and carers in Iran; educational video is included. OBJECTIVE: The aim of the current study was to inquire the questions and concerns of people with epilepsy (PWE) about COVID-19 vaccines in order to provide a more realistic list of their frequently asked questions (FAQs). METHODS: We surveyed all the consecutive PWE or their care-givers who were referred to our neurology clinics (Shiraz University of Medical Sciences) during January-February 2022. We collected their questions and concerns in relation to COVID vaccines based on a predesigned brief questionnaire. Informed consent to participate in the study was obtained from the participants. RESULTS: In total, 452 people participated in the study; 291 people (64.4%) did not have any questions or concerns with regard to the COVID-19 vaccination. Having any questions or concerns about COVID-19 vaccination was significantly associated with not being vaccinated. Questions and concerns about the adverse effects of COVID-19 vaccines [seizure worsening, general adverse effects, long-term effects (e.g., infertility, cognitive dysfunction)] were by far the most common questions by people with epilepsy and their carers. CONCLUSION: Our findings may be used by policy-makers to prepare appropriate educational materials to provide the best targeted and tailored information to people with epilepsy and their carers to convince them of the necessity and safety of COVID-19 vaccination. Such an educational material must include enough information on the associated adverse effects of COVID-19 vaccines and should also discuss some other important issues such as indications of these vaccines in special populations and drug-vaccine interactions.
Updated US Infection- and Vaccine-Induced SARS-CoV-2 Seroprevalence Estimates Based on Blood Donations, July 2020-December 2021. This cross-sectional study examines monthly blood donations from individuals aged 16 years and older to estimate the population with antibodies to SARS-CoV-2 from infection or vaccination.
Allergic Reactions to COVID-19 Vaccines: Risk Factors, Frequency, Mechanisms and Management. Conventional vaccines have been widely studied, along with their risk of causing allergic reactions. These generally consist of mild local reactions and only rarely severe anaphylaxis. Although all the current COVID-19 vaccines marketed in Europe have been shown to be safe overall in the general population, early post-marketing evidence has shown that mRNA-based vaccines using novel platforms (i.e., lipid nanoparticles) were associated with an increased risk of severe allergic reactions as compared to conventional vaccines. In this paper we performed an updated literature review on frequency, risk factors, and underlying mechanisms of COVID-19 vaccine-related allergies by searching MEDLINE and Google Scholar databases. We also conducted a qualitative search on VigiBase and EudraVigilance databases to identify reports of "Hypersensitivity" and "Anaphylactic reaction" potentially related to COVID-19 vaccines (Comirnaty, Spikevax, Vaxzevria and COVID-19 Janssen Vaccine), and in EudraVigilance to estimate the reporting rates of "Anaphylactic reaction" and "Anaphylactic shock" after COVID-19 vaccination in theÂ European population. We also summarized the scientific societies' and regulatory agencies' recommendations for prevention and management of COVID-19 vaccine-related allergic reactions, especially in those with a history of allergy.
Receipt of inactivated COVID-19 vaccine had no adverse influence on embryo implantation, clinical pregnancy and miscarriage in early pregnancy.

Fever following Covid-19 vaccination in subjects with Brugada syndrome: Incidence and management. BACKGROUND: Fever is a potential side effect of the Covid-19 vaccination. Patients with Brugada syndrome (BrS) have an increased risk of life-threatening arrhythmias when experiencing fever. Prompt treatment with antipyretic drugs is suggested in these patients. AIM OF THE STUDY: To evaluate the incidence and management of fever within 48â€‰h from Covid-19 vaccination among BrS patients. METHODS: One hundred sixty-three consecutive patients were enrolled in a prospective registry involving five European hospitals with a dedicated inherited disease ambulatory. RESULTS: The mean age was 50â€‰Â±â€‰14 years and 121 (75%) patients were male. Prevalence of Brugada electrocardiogramÂ (ECG) pattern type-1, -2, and -3 was 32%, 44%, and 24%, respectively. Twenty-eight (17%) patients had an implantable cardioverter-defibrillator (ICD). Fever occurred in 32 (19%) BrS patients after 16â€‰Â±â€‰10â€‰h from vaccination, with a peak of body temperature of 37.9Â°â€‰Â±â€‰0.5Â°. Patients with fever were younger (39â€‰Â±â€‰13 vs. 48â€‰Â±â€‰13 years, pâ€‰=â€‰.04). No additional differences in terms of sex and cardiovascular risk factors were found between patients with fever and not.Â Twenty-seven (84%) out of 32 patients experienced mild fever and five (16%) moderate fever. Pharmacological treatment with antipyretic drugs was required in 18 (56%) out of 32 patients and was associated with the resolution of symptoms. No patient required hospital admission and no arrhythmic episode was recorded in patients with ICD within 48â€‰h after vaccination. No induced type 1 BrS ECG pattern and new ECG features were found among patients with moderate fever. CONCLUSION: Fever is a common side effect in BrS patients after the Covid-19 vaccination. Careful evaluation of body temperature and prompt treatment with antipyretic drugs may be needed.

SARS-CoV-2 the ASIA virus (Autoimmune/autoinflammatory Syndrome Induced by Adjuvants), the risk of infertility and vaccine hesitancy. INTRODUCTION: COVID-19 has had a catastrophic impact on the world. The current death toll far exceeds 6 million and large numbers of patients are experiencing long-term medical and psychiatric morbidity from the infection. The immunopathology of severe COVID-19 is now better understood. In severely affected patients, there is a chaotic, destructive immune response triggered by SARS-CoV-2, where autoimmunity features prominently. AREAS COVERED: COVID-19 vaccines ensure a coordinated, balanced immune response to future SARS-CoV-2 infection. The rapid global deployment of effective COVID-19 vaccines has been hindered by financial, logistical and political barriers. Of concern is increasing vaccine hesitancy caused by unfounded conspiracy theories of vaccine adverse effects, often fueled by misinformation and disinformation on social media. EXPERT OPINION: This perspective discusses the potential impact of the so-called Autoimmune/autoinflammatory Syndrome Induced by Adjuvants (ASIA) on COVID-19 vaccine uptake. Proponents of the ASIA syndrome have inappropriately linked infertility to HPV vaccines and have recently suggested antigenic cross-reactivity between SARS-CoV-2 and ovarian follicles. COVID-19 vaccines have also been linked to ASIA and unfounded fear of infertility is a leading cause of vaccine hesitancy. Vaccine hesitancy caused by spurious disorders such as ASIA are likely to harm individuals and delay global vaccination efforts leading to emergence of vaccine and monoclonal antibody-resistant SARS-CoV-2 variants, thereby prolonging the COVID-19 pandemic.

Discrimination between Benign and Malignant Post-SARS-CoV-2 Vaccination Lymphadenopathy is Feasible.

Regional Lymphadenopathy Following COVID-19 Vaccination in Patients with or Suspicious of Breast Cancer: A Quick Summary of Current Key Facts and Recommendations.

Response to Letter; Discrimination between Benign and Malignant Post-SARS-CoV-2 Vaccination Lymphadenopathy is Feasible, to Our Article; Axillary Adenopathy in Patients with Recent COVID-19 Vaccination: A New Diagnostic Dilemma.

Development of hepatitis triggered by SARS-CoV-2 vaccination in patient with cancer during immunotherapy: a case report. Patients with cancer have a higher risk of severe COVID-19, and expert consensus advocates forÂ COVID-19 vaccination in this population. Some cases of autoimmune hepatitis have been described after the administration of COVID-19 vaccine in the people in apparently good health. Immune checkpoint inhibitors (ICIs) are responsible for a wide spectrum of immune-related adverse eventsÂ (irAEs). This article reports a case of hepatitis and colitis in a 52-year-old woman who was undergoing immunotherapy andÂ was HBV positive 10 days after receiving the first Pfizer-BioNTech COVID-19 vaccine dose. Because both ICIs and the COVID-19 vaccines stimulate the immune response, the authorsÂ hypothesize that these vaccines may increase the incidence of irAEs during ICI treatment. There is a complex interplay between the immune-mediated reaction triggered by the vaccination and PD-L1 co-administration.

 Patients with cancer have a higher risk of severe COVID-19, and expert consensus advocates forÂ COVID-19 vaccination in this population. Some reports have described autoimmune hepatitis after the administration of COVID-19 vaccine. It is difficult, however, to establish a causal relationship between COVID-19 vaccination and autoimmune hepatitis. This article reports a case of hepatitis and colitis in a 52-year-old woman with lung cancer who was undergoing immunotherapy and wasÂ was found to beÂ HBV positiveÂ 10 days after her first Pfizer-BioNTech COVID-19 vaccine dose. Because both immunotherapy and COVID-19 vaccines stimulate the immune response, the authorsÂ hypothesize that these vaccines may increase the incidence of immune-related side effects.

Do not miss Bickerstaff encephalitis as a complication of SARS-CoV-2 vaccines.

Safety and immunogenicity of anti-SARS CoV-2 vaccine SOBERANA 02 in homologous or heterologous scheme: Open label phase I and phase IIa clinical trials. BACKGROUND: SOBERANA 02 is a COVID-19 vaccine based on SARS-CoV-2 recombinant RBD conjugated to tetanus toxoid (TT). SOBERANA Plus antigen is dimeric-RBD. Here we report safety and immunogenicity from phase I and IIa clinical trials using two-doses of SOBERANA 02 and three-doses (homologous) or heterologous (with SOBERANA Plus) protocols. METHOD: We performed an open-label, sequential and adaptive phase I to evaluate safety and explore the immunogenicity of SOBERANA 02 in two formulations (15 or 25Â Î¼g RBD-conjugated to 20Â Î¼g of TT) in 40 subjects, 19-59-years-old. Phase IIa was open-label including 100 volunteers 19-80-years, receiving two doses of SOBERANA 02-25Â Î¼g. In both trials, half of volunteers were selected to receive a third dose of the corresponding SOBERANA 02 and half received a heterologous dose of SOBERANA Plus. Primary outcome was safety. The secondary outcome was immunogenicity evaluated by anti-RBD IgG ELISA, molecular neutralization of RBD:hACE2 interaction, live-virus-neutralization and specific T-cells response. RESULTS: The most frequent adverse event (AE) was local pain, other AEs had frequenciesÂ â‰¤Â 5%. No serious related-AEs were reported. Phase IIa confirmed the safety in 60 to 80-years-old subjects. In phase-I SOBERANA 02-25Â Âµg elicited higher immune response than SOBERANA 02-15Â Âµg and progressed to phase IIa. Phase IIa results confirmed the immunogenicity of SOBERANA 02-25Â Âµg even in 60-80-years. Two doses of SOBERANA02-25Â Âµg elicited an immune response similar to that of the Cuban Convalescent Serum Panel and it was higher after the homologous and heterologous third doses. The heterologous scheme showed a higher immunological response. Anti-RBD IgG neutralized the delta variant in molecular assay, with a 2.5-fold reduction compared to D614G neutralization. CONCLUSIONS: SOBERANA 02 was safe and immunogenic in persons aged 19-80Â years, eliciting neutralizing antibodies and specific T-cell response. Highest immune responses were obtained in the heterologous three doses protocol. TRIAL REGISTRY: https://rpcec.sld.cu/trials/RPCEC00000340, https://rpcec.sld.cu/trials/RPCEC00000347.

Seroprevalence of SARS-CoV-2 on health professionals via Bayesian estimation: a Brazilian case study before and after vaccines. The increasing number of COVID-19 infections brought by the current

pandemic has encouraged the scientific community to analyze the seroprevalence in populations to support health policies. In this context, accurate estimations of SARS-CoV-2 antibodies based on antibody tests metrics (e.g., specificity and sensitivity) and the study of population characteristics are essential. Here, we propose a Bayesian analysis using IgA and IgG antibody levels through multiple scenarios regarding data availability from different information sources to estimate the seroprevalence of health professionals in a Northeastern Brazilian city: no data available, data only related to the test performance, data from other regions. The study population comprises 432 subjects with more than 620 collections analyzed via IgA/IgG ELISA tests. We conducted the study in pre- and post-vaccination campaigns started in Brazil. We discuss the importance of aggregating available data from various sources to create informative prior knowledge. Considering prior information from the USA and Europe, the pre-vaccine seroprevalence means are 8.04% and 10.09% for IgG and 7.40% and 9.11% for IgA. For the post-vaccination campaign and considering local informative prior, the median is 84.83% for IgG, which confirms a sharp increase in the seroprevalence after vaccination. Additionally, stratification considering differences in sex, age (younger than 30 years, between 30 and 49 years, and older than 49 years), and presence of comorbidities are provided for all scenarios.

Safety and immunogenicity of the FINLAY-FR-1A vaccine in COVID-19 convalescent participants: an open-label phase 2a and double-blind, randomised, placebo-controlled, phase 2b, seamless, clinical trial. BACKGROUND: A phase 1, clinical trial to evaluate FINLAY-FR-1A vaccine in COVID-19 convalescent individuals was completed. Here, we report results of the phase 2, clinical trial. METHODS: We studied 450 convalescent participants with a history of asymptomatic, mild, or moderate COVID-19 at the National Institute of Hematology and Immunology and the National Centre for Sexual Education in Havana, Cuba. The study included adults aged 19-78 years who had recovered from COVID-19 and had had a negative PCR test at least 2 months before the initiation of the study. Phase 2 was done sequentially in two stages. The first stage to assess safety comprised an open, non-controlled phase 2a study in participants aged 60-78 years who received a single dose of the FINLAY-FR-1A vaccine (50 Î¼g of recombinant dimeric receptor binding domain [RBD]). The second stage comprised the placebo-controlled, double-blind, phase 2b trial in participants aged 19-78 years, where participants were randomly assigned (4:1) into two groups: an experimental group vaccinated with a single dose of the FINLAY-FR-1A vaccine, and a control (placebo) group injected with vaccine excipient. The primary outcomes were safety, evaluated 28 days after vaccination by the occurrence of serious adverse events in all participants, and successful immune response, assessed by neutralising antibody ELISA, and defined as half-maximal surrogate virus neutralisation titres of 250 or more. Secondary endpoints included vaccine immunogenicity assessed by ELISA anti-RBD and live-virus neutralisation test. All randomly assigned participants were included in the safety analysis (safety population), and immunogenicity was evaluated in participants without study interruptions (per-protocol population). The trial is registered with the Cuban Public Registry of Clinical Trials, RPCEC00000366-En and WHO-ICTRP and is complete. FINDINGS: From April 9, 2021, to April 17, 2021, 663 COVID-19 convalescent participants were enrolled in the study; 213 participants did not meet the selection criteria and 450 volunteers were recruited. 20 participants aged 60-78 years were included in the open, single-group, phase 2a study and 430 participants were randomly assigned to the experimental (n=344) or control groups (n=86) in the phase 2b study of participants aged 19-78 years. 19 (95%) of 20 phase 2a volunteers achieved a successful immune response after vaccination. No vaccine-associated serious adverse events were reported in the whole study population. Minor adverse events were found, the most common being pain at the injection site (105 [29%] of 364 in the intervention group; 13 [15%] of 86 in the placebo group). A successful immune response was found in 289 (81%) of 358 participants 28 days after vaccination. The vaccine elicited a greater than

31-times increase in anti-RBD-IgG antibodies compared with prevaccination rates, and the seroconversion rate was 302 (84%) of 358 on day 28 after vaccination; the geometric mean titres of live-virus neutralisation test increased from 15Â·4 (95% CI 10Â·3-23Â·2) to 400Â·3 (272Â·4-588Â·1) and high response was found against alpha, beta, and delta variants of concern. INTERPRETATION: A single dose of the FINLAY-FR-1A vaccine against SARS-CoV-2 strengthened the pre-existing natural immunity, with excellent safety profile. FUNDING: Cuba's Ministry of Science, Technology, and Environment.

Significance of digestive symptoms after COVID-19 vaccination: A retrospective single-center study. OBJECTIVE: There is insufficient research on digestive symptoms and outcomes following coronavirus disease (COVID-19) vaccination. We aimed to investigate digestive symptoms and related complications among South Koreans who were administered COVID-19 vaccines. METHODS: Forty-six patients (men: 22, women: 24) with a median age of 68 years (interquartile range:55.5, 73.8 years) who experienced digestive symptoms following COVID-19 vaccination between March 1 and July 30, 2021, were included. This retrospective single-center study collected information on clinical symptoms, laboratory tests, imaging results, comorbidities, complications, treatment type, and prognosis. RESULTS: Thirty-three (71.7%), nine (19.6%), and three (6.5%) patients were administered AZD1222 (AstraZeneca), BNT162b2 (Pfizer/BioNTech), and JNJ-78436735 (Johnson and Johnson) vaccines, respectively. Patients were classified with mild (25 patients, 54.3%), moderate (five patients, 10.9%), and severe (16 patients, 34.8%) based on disease severity. Digestive symptoms included abdominal pain, diarrhea, dyspepsia, and nausea, which usually developed within 1 day (78.3%) following the first vaccination. In total, 14 (30.4%) patients experienced only gastrointestinal symptoms, whereas 32 (69.6%) experienced non-gastrointestinal symptoms. Complications included enterocolitis (76%), acute kidney injury (9%), anaphylactoid reaction (2%), and duodenal perforation (2%). CONCLUSIONS: COVID-19 vaccines caused digestive symptoms and other complications that ranged from mild to severe. While further validation is required, our results suggest that monitoring digestive symptoms following COVID-19 vaccination can help detect rather severe complications that require medical intervention.

Combined assessment of S- and N-specific IL-2 and IL-13 secretion and CD69 neo-expression for discrimination of post-infection and post-vaccination cellular SARS-CoV-2-specific immune response. BACKGROUND: Antibody-based tests are available for measuring SARS-CoV-2-specific immune responses but fast T-cell assays remain scarce. Robust T cell-based tests are needed to differentiate specific cellular immune responses after infection from those after vaccination. METHODS: One hundred seventeen individuals (COVID-19 convalescent patients: nÂ =â€‰40; SARS-CoV-2 vaccinees: nÂ =â€‰41; healthy controls: nÂ =â€‰36) were evaluated for SARS-CoV-2-specific cellular immune responses (proliferation, Th1, Th2, Th17, and inflammatory cytokines, activation-induced marker [AIM] expression) by incubating purified peripheral blood mononuclear cells (PBMC) or whole blood (WB) with SARS-CoV-2 peptides (S, N, or M), vaccine antigens (tetanus toxoid, tick borne encephalitis virus) or polyclonal stimuli (Staphylococcal enterotoxin, phytohemagglutinin). RESULTS: N-peptide mix stimulation of WB identified the combination of IL-2 and IL-13 secretion as superior to IFN-Î³ secretion to discriminate between COVID-19-convalescent patients and healthy controls (pÂ <â€‰.0001). Comparable results were obtained with M- or S-peptides, the latter almost comparably recalled IL-2, IFN-Î³, and IL-13 responses in WB of vaccinees. Analysis 10Â months as opposed to 10â€‰weeks after COVID-19, but not allergic disease status, positively correlated with IL-13 recall responses. WB cytokine responses correlated with cytokine and proliferation responses of PBMC. Antigen-induced neo-expression of the C-type lectin CD69 on CD4(+) (pÂ <â€‰.0001) and CD8(+) (pÂ =â€‰.0002) T cells informed best about the SARS-CoV-2 exposure status with additional benefit coming from CD25 upregulation. CONCLUSION: Along with N- and S-peptide-induced IL-2 and

CD69 neo-expression, we suggest to include the type 2 cytokine IL-13 as T-cellular recall marker for SARS-CoV-2 specific T-cellular immune responses after infection and vaccination.

A Case of Leukocytoclastic Vasculitis Following SARS-COV-2 Vaccination. BACKGROUND: Although vaccination against coronavirus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been proven generally safe, rare but potentially serious adverse reactions do occur. Leukocytoclastic vasculitis (LCV) is a small-vessel vasculitis that has been associated with other immunizations, but, to our knowledge, has not been previously reported in association with vaccines directed against SARS-CoV-2. CASE REPORT: We report the case of a 22-year-old man with no known past medical history who presented to the Emergency Department with 2 days of migratory arthritis in his ankles and palpable purpura on his bilateral lower extremities, occurring 10 days after receiving the Johnson & Johnson SARS-CoV-2 vaccine. The patient's clinical presentation was suggestive of leukocytoclastic vasculitis, and this diagnosis was confirmed on skin biopsy. Why Should an Emergency Physician Be Aware of This? Recognition of vasculitides is important for timely treatment and prevention of complications. In a patient presenting with palpable purpura after immunization against SARS-CoV-2, LCV should be promptly considered and worked up by the Emergency Physician, though management is most often entirely outpatient and the clinical course is typically mild and self-resolving.

Tolerance of the mRNA COVID-19 vaccines in patients with reported taxane reactions.

Clinical impact and disease evolution of SARS-CoV-2 infection in familial Mediterranean fever. The innate immune system is critically involved in the pathogenesis of familial Mediterranean fever (FMF), characterized by dysregulated inflammasome activity and recurrent inflammatory attacks: this is the most common among monogenic autoinflammatory diseases, which shares some biochemical pathways with the severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) infection. In this short review we explore the overlap in the pathophysiology of FMF and SARS-CoV-2 infection, discussing how to understand better the interaction between the two diseases and optimize management. A poorer outcome of SARS-CoV-2 infection seems not to be present in infected FMF patients in terms of hospitalization time, need for oxygen support, need for intensive care, rate of complications and exitus. Long-term surveillance will confirm the relatively low risk of a worse prognosis observed so far in SARS-CoV-2-infected people with FMF. In these patients COVID-19 vaccines are recommended and their safety profile is expected to be similar to the general population.

Effect of priming interval on reactogenicity, peak immunological response, and waning after homologous and heterologous COVID-19 vaccine schedules: exploratory analyses of Com-COV, a randomised control trial. BACKGROUND: Priming COVID-19 vaccine schedules have been deployed at variable intervals globally, which might influence immune persistence and the relative importance of third-dose booster programmes. Here, we report exploratory analyses from the Com-COV trial, assessing the effect of 4-week versus 12-week priming intervals on reactogenicity and the persistence of immune response up to 6 months after homologous and heterologous priming schedules using the vaccines BNT162b2 (tozinameran, Pfizer/BioNTech) and ChAdOx1 nCoV-19 (AstraZeneca). METHODS: Com-COV was a participant-masked, randomised immunogenicity trial. For these exploratory analyses, we used the trial's general cohort, in which adults aged 50 years or older were randomly assigned to four homologous and four heterologous vaccine schedules using BNT162b2 and ChAdOx1 nCoV-19 with 4-week or 12-week priming intervals (eight groups in total). Immunogenicity analyses were done on the intention-to-treat (ITT) population, comprising participants with no evidence of SARS-CoV-2 infection at baseline or for the trial duration, to assess the effect of priming interval on humoral and cellular immune response 28 days and 6 months post-second dose, in addition to the effects on reactogenicity and safety. The Com-COV trial is registered with the ISRCTN registry, 69254139 (EudraCT 2020-005085-33). FINDINGS: Between Feb 11 and 26,

2021, 730 participants were randomly assigned in the general cohort, with 77-89 per group in the ITT analysis. At 28 days and 6 months post-second dose, the geometric mean concentration of anti-SARS-CoV-2 spike IgG was significantly higher in the 12-week interval groups than in the 4-week groups for homologous schedules. In heterologous schedule groups, we observed a significant difference between intervals only for the BNT162b2-ChAdOx1 nCoV-19 group at 28 days. Pseudotyped virus neutralisation titres were significantly higher in all 12-week interval groups versus 4-week groups, 28 days post-second dose, with geometric mean ratios of 1Â·4 (95% CI 1Â·1-1Â·8) for homologous BNT162b2, 1Â·5 (1Â·2-1Â·9) for ChAdOx1 nCoV-19-BNT162b2, 1Â·6 (1Â·3-2Â·1) for BNT162b2-ChAdOx1 nCoV-19, and 2Â·4 (1Â·7-3Â·2) for homologous ChAdOx1 nCoV-19. At 6 months post-second dose, anti-spike IgG geometric mean concentrations fell to 0Â·17-0Â·24 of the 28-day post-second dose value across all eight study groups, with only homologous BNT162b2 showing a slightly slower decay for the 12-week versus 4-week interval in the adjusted analysis. The rank order of schedules by humoral response was unaffected by interval, with homologous BNT162b2 remaining the most immunogenic by antibody response. T-cell responses were reduced in all 12-week priming intervals compared with their 4-week counterparts. 12-week schedules for homologous BNT162b2 and ChAdOx1 nCoV-19-BNT162b2 were up to 80% less reactogenic than 4-week schedules. INTERPRETATION: These data support flexibility in priming interval in all studied COVID-19 vaccine schedules. Longer priming intervals might result in lower reactogenicity in schedules with BNT162b2 as a second dose and higher humoral immunogenicity in homologous schedules, but overall lower T-cell responses across all schedules. Future vaccines using these novel platforms might benefit from schedules with long intervals. FUNDING: UK Vaccine Taskforce and National Institute for Health and Care Research.

Reply to "SARS-CoV-2 Vaccination Is Complicated by Takotsubo Cardiomyopathy Rather Than Myocarditis".

SARS-CoV-2 Vaccination Is Complicated by Takotsubo Cardiomyopathy Rather Than Myocarditis.

Management of Cerebral Venous Thrombosis Due to Adenoviral COVID-19 Vaccination. OBJECTIVE: Cerebral venous thrombosis (CVT) caused by vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare adverse effect of adenovirus-based severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) vaccines. In March 2021, after autoimmune pathogenesis of VITT was discovered, treatment recommendations were developed. These comprised immunomodulation, non-heparin anticoagulants, and avoidance of platelet transfusion. The aim of this study was to evaluate adherence to these recommendations and its association with mortality. METHODS: We used data from an international prospective registry of patients with CVT after the adenovirus-based SARS-CoV-2 vaccination. We analyzed possible, probable, or definite VITT-CVT cases included until January 18, 2022. Immunomodulation entailed administration of intravenous immunoglobulins and/or plasmapheresis. RESULTS: Ninety-nine patients with VITT-CVT from 71 hospitals in 17 countries were analyzed. Five of 38 (13%), 11 of 24 (46%), and 28 of 37 (76%) of the patients diagnosed in March, April, and from May onward, respectively, were treated in-line with VITT recommendations (pâ€‰<â€‰0.001). Overall, treatment according to recommendations had no statistically significant influence on mortality (14/44 [32%] vs 29/55 [52%], adjusted odds ratio [OR]Â =Â 0.43, 95% confidence interval [CI]Â =Â 0.16-1.19). However, patients who received immunomodulation had lower mortality (19/65 [29%] vs 24/34 [70%], adjusted ORÂ =Â 0.19, 95% CIÂ =Â 0.06-0.58). Treatment with non-heparin anticoagulants instead of heparins was not associated with lower mortality (17/51 [33%] vs 13/35 [37%], adjusted ORÂ =Â 0.70, 95% CIÂ =Â 0.24-2.04). Mortality was also not significantly influenced by platelet transfusion (17/27 [63%] vs 26/72 [36%], adjusted ORÂ =Â 2.19, 95% CIÂ =Â 0.74-6.54). CONCLUSIONS: In patients with VITT-CVT, adherence to

VITT treatment recommendations improved over time. Immunomodulation seems crucial for reducing mortality of VITT-CVT. ANN NEUROL 2022;92:562-573.

Editorial: COVID-19 vaccines are safe and effective in patients with inflammatory bowel disease-but many unanswered questions remain. Authors' reply. This article is linked to Bhurwal et al papers. To view these articles, visit https://doi.org/10.1111/apt.16913 and https://doi.org/10.1111/apt.16935

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Meaningful use of imaging resources to rule out cerebral venous sinus thrombosis after ChAdOx1 COVID-19 vaccination: Evaluation of the AHA diagnostic algorithm with a clinical cohort and a systematic data review. Vaccine-induced immune thrombotic thrombocytopenia (VITT) with cerebral venous thrombosis (CVST) is an improbable (0.0005%), however potentially lethal complication after ChAdOx1 vaccination. On the other hand, headache is among the most frequent side effects of ChAdOx1 (29.3%). In September 2021, the American Heart Association (AHA) suggested a diagnostic workflow to facilitate risk-adapted use of imaging resources for patients with neurological symptoms after ChAdOx1. We aimed to evaluate the AHA workflow in a retrospective patient cohort presenting at four primary care hospitals in Germany for neurological complaints after ChAdOx1. Scientific literature was screened for case reports of VITT with CVST after ChAdOx1, published until September 1st, 2021. One-hundred-thirteen consecutive patients (77 female, mean age 38.7 +/- 11.9Â years) were evaluated at our institutes, including one case of VITT with CVST. Further 228 case reports of VITT with CVST are published in recent literature, which share thrombocytopenia (225/227 reported) and elevated d-dimer levels (100/101 reported). The AHA workflow would have recognized all VITT cases with CVST (100% sensitivity), the number needed to diagnose (NND) was 1:113. Initial evaluation of thrombocytopenia or elevated d-dimer levels would have lowered the NND to 1:68, without cost of sensitivity. Hence, we suggest that in case of normal thrombocyte and d-dimer levels, the access to further diagnostics should be limited by the established clinical considerations regardless of vaccination history.

More data on erythema annulare centrifugum induced by COVID-19 vaccination.

Post-COVID green supply chain management of used products: a study towards awareness for vaccination. In the era of digital media, there is rapid spread of information. During coronavirus (COVID-19) pandemic situation, the government and other administrative bodies were highly dependent on media outlets, as direct contact was not feasible. Visual communication tools are used to spread awareness and encourage people towards vaccination. The circulation of wrong information may lead to confusion, which may cause denying the vaccine. There was a need to know the extent for contribution of visual communication tools for spreading correct information and motivating the society towards vaccination in post COVID times. In the present study, survey questionnaires were framed specific to which media (print or digital) was more effective to deliver the correct information to the targeted audience. The present study objectives to answer the questions through a survey of 312 people of different age groups, and the data was collected about their families. The obtained data was tested through hypothesis, and fact-checked was performed adopting analysis of variance (ANOVA). The results from the study highlighted that different age groups prefer different mediums of communication. The reach and adoption of digital media have tremendously increased, and it helped to achieve the sustainable development goals (SDGs) by efficient green supply chain management (GSCM) of daily plastic and paper wastage during post-pandemic.

Response to letter to the editor regarding "Acute onset ocular myasthenia gravis after vaccination with the Oxford-AstraZeneca COVID-19 vaccine".

Comparison of Waning Neutralizing Antibody Responses Against the Omicron Variant 6 Months After Natural Severe Acute Respiratory Syndrome Coronavirus 2 Infection (With or Without Subsequent Coronavirus Disease 2019 [COVID-19] Vaccination) Versus 2-Dose COVID-19 Vaccination.
Following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, subsequent ChAdOx1 nCoV-19 vaccination induced similar neutralizing antibody levels against the original strain but significantly higher levels against the Omicron variant compared to those who were not vaccinated. Prior SARS-CoV-2 infection exhibited higher neutralization antibody titers than vaccination alone for both original strains and the Omicron variant.

Multiplex Detection of Antibody Landscapes to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)/Influenza/Common Human Coronaviruses Following Vaccination or Infection With SARS-CoV-2 and Influenza. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and influenza viruses continue to co-circulate, representing 2 major public health threats from respiratory infections with similar clinical presentations. SARS-CoV-2 and influenza vaccines can also now be co-administered. However, data on antibody responses to SARS-CoV-2 and influenza coinfection and vaccine co-administration remain limited. METHODS: We developed a 41-plex antibody immunity assay that can simultaneously characterize antibody landscapes to SARS-CoV-2/influenza/common human coronaviruses. We analyzed sera from 840 individuals (11-93 years), including sera from reverse transcription-polymerase chain reaction (RT-PCR)-confirmed SARS-CoV-2-positive (nâ€‰=â€‰218) and -negative (nâ€‰=â€‰120) cases, paired sera from SARS-CoV-2 vaccination (nâ€‰=â€‰29) and infection (nâ€‰=â€‰11), and paired sera from influenza vaccination (nâ€‰=â€‰56) and RT-PCR-confirmed influenza infection (nâ€‰=â€‰158) cases. Last, we analyzed sera collected from 377 individuals who exhibited acute respiratory illness (ARI) in 2020. RESULTS: This 41-plex assay has high sensitivity and specificity in detecting SARS-CoV-2 infections. It differentiated SARS-CoV-2 vaccination (antibody responses only to spike protein) from infection (antibody responses to both spike and nucleoprotein). No cross-reactive antibodies were induced to SARS-CoV-2 from influenza vaccination and infection, and vice versa, suggesting no interaction between SARS-CoV-2 and influenza antibody responses. However, cross-reactive antibodies were detected between spike proteins of SARS-CoV-2 and common human coronaviruses that were removed by serum adsorption. Among 377 individuals who exhibited ARI in 2020, 129 were influenza positive; none had serological evidence of SARS-CoV-2/influenza coinfections. CONCLUSIONS: Multiplex detection of antibody landscapes can provide in-depth analysis of the antibody protective immunity to SARS-CoV-2 in the context of other respiratory viruses, including influenza.

Evaluating clinical effectiveness of SARS-CoV-2 vaccine in solid organ transplant recipients: A propensity score matched analysis. BACKGROUND: Solid organ transplant recipients (SOTRs) are at disproportionate risk for severe Coronavirus Disease 2019 (COVID-19). Vaccination is a key preventative strategy but is associated with decreased humoral responses among SOTR. Whether dampened immune responses correlate with reduced clinical effectiveness is unclear. Our study was designed to evaluate the clinical effectiveness of SARS-CoV-2 vaccination in the early vaccine era. METHODS: We conducted a retrospective cohort study comparing SARS-CoV-2 infection rates between SOTRs who received two doses of mRNA or one dose of Ad26.Cov2.S vaccine and those not fully vaccinated (partially vaccinated and unvaccinated). To evaluate clinical effectiveness of vaccine, cause-specific Cox regression model and modified Poisson regression model were built using the propensity score-matched cohort. Additionally, the clinical outcomes of COVID-19 of fully vaccinated and not fully vaccinated SOTR were compared. RESULTS: Of 2705 SOTRs, 1668 were included in our final matched analysis, which showed a 73% reduction of SARS-CoV-2 infection and 76% reduction of

all-cause-mortality among fully vaccinated patients. Thirty-nine SOTRs developed SARS-CoV-2 infection, including nine fully vaccinated and 30 not fully vaccinated. Among fully vaccinated patients, 22% had severe/critical COVID-19 and 0% mortality versus not fully vaccinated SOTRs, of whom 37% had severe/critical COVID-19 and 6.67% COVID-19-related mortality. CONCLUSION: In SOTRs, completion of primary vaccine series in the early vaccine era was associated with a significant reduction of COVID-19 and was protective against severe/critical disease and death. Further studies are needed to evaluate the clinical effectiveness of current vaccine recommendations for SOTR against emerging new variants.

Advancing the Science of Vaccine Safety During the Coronavirus Disease 2019 (COVID-19) Pandemic and Beyond: Launching an International Network of Special Immunization Services. Within 2 years after the start of the coronavirus disease 2019 (COVID-19) pandemic, novel severe acute respiratory syndrome coronavirus 2 vaccines were developed, rigorously evaluated in large phase 3 trials, and administered to more than 5 billion individuals globally. However, adverse events of special interest (AESIs) have been described post-implementation, including myocarditis after receipt of messenger RNA (mRNA) vaccines and thrombosis with thrombocytopenia syndrome after receipt of adenoviral vector vaccines. AESIs are rare (<1 to 10/100â€‰000 vaccinees) and less frequent than COVID-19 complications, though they have associated morbidity and mortality. The diversity of COVID-19 vaccine platforms (eg, mRNA, viral vector, protein) and rates of AESIs both between and within platforms (eg, higher rate of myocarditis after mRNA-1273 vs BNT162b2 vaccines) present an important opportunity to advance vaccine safety science. The International Network of Special Immunization Services has been formed with experts in vaccine safety, systems biology, and other relevant disciplines to study cases of AESIs and matched controls to uncover the pathogenesis of rare AESIs and inform vaccine development.

Erythema nodosum following SARS-CoV-2 vaccine.

Zoster Meningitis in an Immunocompetent Child after COVID-19 Vaccination, California, USA. Varicella zoster virus reactivation after COVID-19 vaccination has been reported in older or immunocompromised adults. We report zoster meningitis from live-attenuated varicella vaccine reactivation in an immunocompetent child after COVID-19 vaccination. This type of case is rare; COVID-19 and varicella vaccines remain safe and effective for appropriate recipients in the pediatric population.

Association of neutralizing breadth against SARS-CoV-2 with inoculation orders of heterologous prime-boost vaccines. BACKGROUND: Emerging evidence suggests heterologous prime-boost COVID-19 vaccination as a superior strategy than homologous schedules. Animal experiments and clinical observations have shown enhanced antibody response against influenza variants after heterologous vaccination; however, whether the inoculation order of COVID-19 vaccines in a prime-boost schedule affects antibody response against SARS-CoV-2 variants is not clear. METHODS: We conducted immunological analyses in a cohort of health care workers (nÂ = 486) recently vaccinated by three types of inactivated COVID-19 vaccines under homologous or heterologous prime-boost schedules. Antibody response against ancestral SARS-CoV-2 (Wuhan-Hu-1) was assessed by total antibody measurements, surrogate virus neutralization tests, and pseudovirus neutralization assays (PNA). Furthermore, serum neutralization activity against SARS-CoV-2 variants of concern was also measured by PNA. FINDINGS: We observed strongest serum neutralization activity against the widely circulating SARS-CoV-2 variant B.1.617.2 among recipients of heterologous BBIBP-CorV/CoronaVac and WIBP-CorV/CoronaVac. In contrast, recipients of CoronaVac/BBIBP-CorV and CoronaVac/WIBP-CorV showed significantly lower B.1.617.2 neutralization titers than recipients of reverse schedules. Laboratory tests revealed that neutralizing activity against common variants but not the ancestral SARS-CoV-2 was associated with the inoculation order of heterologous prime-boost vaccines.

Multivariable regression analyses confirmed this association after adjusting for known confounders. CONCLUSIONS: Our data provide clinical evidence of inoculation order-dependent expansion of neutralizing breadth against SARS-CoV-2 in recipients of heterologous prime-boost vaccination and call for further studies into its underlying mechanism. FUNDING: National Key R&D Program of China, National Development and Re-form Commission of China, National Natural Science Foundation of China, Shenzhen Science and Technology Innovation Commission, and US Department of Veterans Affairs.

Associations between vaccination and quality of life among Taiwan general population: A comparison between COVID-19 vaccines and flu vaccines. The COVID-19 pandemic has profoundly impacted lives worldwide and has led to global vaccination against COVID-19. However, there are concerns about the adverse effects of such vaccines on individuals' health. Therefore, it is important to investigate the association between vaccination and holistic health outcome (i.e., quality of life [QoL]). The present study analyzed data from the Taiwan Social Change Survey (TSCS), a survey conducted utilizing stratified random sampling. More specifically, data (Nâ€‰=â€‰1425; 47.44% males; mean ageâ€‰=â€‰50.58â€‰y) on their vaccinations (including COVID-19 and flu vaccines) and QoL (using the Short-Form 12) were used. Participants were separated into two age subgroups for analyses (those aged below 50â€‰y, and those 50â€‰y or above). For participants aged below 50â€‰y, those who received COVID-19 vaccine and those who received both COVID-19 and flu vaccines had significantly better physical QoL than those who did not receive any vaccination. Mental QoL was not significantly associated with vaccinations for participants aged below 50â€‰y. Moreover, neither mental nor physical QoL was significantly associated with vaccinations for those aged 50â€‰y or above. The present study showed that not having COVID-19 and flu vaccinations is associated with poor QoL. This finding should be disseminated to the public to help aid vaccination promotion.

Reply to 'Development of severe pemphigus vulgaris following SARS-CoV-2 vaccination with BNT162b2' by Solimani etâ€‰al.

Subacute thyroiditis and COVID-19 vaccines: a case/non-case study. PURPOSE: Some case reports have suggested a possible association between COVID-19 vaccines and subacute thyroiditis (SAT), however, to our knowledge, no study has analyzed this possible relationship. This study aimed to analyze whether a disproportionate number of cases of SAT were reported in the EudraVigilance database for four COVID-19 vaccines (BNT162b2, mRNA-1273 ChAdOx1-S or Ad26.COV2.S). METHODS: A case/non-case study was conducted to assess the association between SAT and COVID-19 vaccines, calculating the reporting odds ratios (RORs) up to December 2, 2021. Cases were selected using the preferred term 'subacute thyroiditis'. First, cases involving COVID-19 vaccines were compared with those involving all other drugs. Secondly, the RORs for COVID-19 vaccines compared with other viral vaccines (overall and influenza vaccines only) were obtained. RESULTS: Until December 2, 2021, of 1,221,582 spontaneous cases of adverse reactions with the four vaccines, we found 162 SAT cases: BNT162b2 (nâ€‰=â€‰103), mRNA-1273 (nâ€‰=â€‰27), ChAdOx1-S (nâ€‰=â€‰31) and Ad26.COV2.S (nâ€‰=â€‰1). SAT cases were found to be reported more frequently in association with BNT162b2, mRNA-1273, and ChAdOx1-S vaccines than with other drugs. Moreover, we found a signal of disproportionate reporting for SAT with BNT162b2 and mRNA-1273 vaccines comparing with other viral vaccines (BNT162b2 ROR 3.58, 95% CI 1.92-6.66; mRNA-1273 ROR 3.44, 95% CI 1.71-6.94). However, this association was absent when these COVID-19 vaccines were compared with influenza vaccines. CONCLUSIONS: In EudraVigilance, SAT is relatively more frequently reported in association with mRNA COVID-19 vaccines than with other viral vaccines. Well designed observational studies are needed to confirm these results.

Heterogeneity assessment of vaccine-induced effects using point-of-care surrogate neutralization test for severe acute respiratory syndrome coronavirus 2. INTRODUCTION: Coronavirus disease (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has become a global pandemic even after vaccination. We aimed to identify immunological heterogeneity over time in vaccinated healthcare workers using neutralization antibodies and neutralizing activity tests. METHODS: Serum samples were collected from 214 healthcare workers before vaccination (pre) and on days 22, 90, and 180 after receiving the first dose of BNT162b2 vaccine (day 0). Neutralization antibody (NAb, SARS-CoV-2â€‰S-RBD IgM/IgG) titers and two kinds of surrogate virus neutralization tests (sVNTs) were analyzed (UMIN000043851). RESULTS: The NAb (SARS-CoV-2â€‰S-RBD IgG) titer peaked on day 90 after vaccination (30,808.0Â Î¼g/mlâ€‰Â±â€‰35,211; pÂ <â€‰0.0001) and declined on day 180 (11,678.0Â Î¼g/mlâ€‰Â±â€‰33,770.0; pÂ <â€‰0.0001). The neutralizing activity also peaked on day 90 and declined with larger individual differences than those of IgG titer on day 180 (88.9%â€‰Â±â€‰15.0%, 64.8%â€‰Â±â€‰23.7%, pÂ <â€‰0.0001). We also found that the results of POCT-sVNT (immunochromatography) were highly correlated with those of conventional sVNT (ELISA). CONCLUSIONS: Neutralizing activity is the gold standard for vaccine efficacy evaluation. Our results using conventional sVNT showed large individual differences in neutralizing activity reduction on day 180 (64.8%â€‰Â±â€‰23.7%), suggesting an association with the difference in vaccine efficacy. POCT-sVNT is rapid and user-friendly; it might be used for triage in homes, isolation facilities, and event venues without restrictions on the medical testing environment.

Solid cancer patients achieve adequate immunogenicity and low rate of severe adverse events after SARS-CoV-2 vaccination. Background: SARS-CoV-2 vaccination in cancer patients is crucial to prevent severe COVID-19 disease course. Methods: This study assessed immunogenicity of cancer patients on active treatment receiving mRNA-based SARS-CoV-2 vaccine by detection of anti-SARS-CoV-2 S1 IgG antibodies in serum, before, after the first and second doses and 3Â months after a complete primary course of vaccination. Results were compared with healthy controls. Results: Of 112 patients, the seroconversion rate was 96%. A significant reduction in antibody levels was observed 3Â months after vaccination in patients receiving immune checkpoint inhibitors versus control participants (pÂ <Â 0.001). Adverse events were mostly mild. Conclusion: Immunogenicity after mRNA-based vaccine in cancer patients is adequate but influenced by the type of anticancer therapy. Antibody levels decline after 3Â months, and thus a third vaccination is warranted.

 Because cancer patients are especially endangered by SARS-CoV-2 infection and have worse disease course and outcomes, it is crucial to protect them from this infection. This study was aimed at assessing protective antibodies after patients received mRNA-based SARS-CoV-2 vaccines. Protective antibodies (e.g., anti-SARS-CoV-2 S1 IgG antibodies) were assessed in patientsâ€™ blood before vaccination, after the first and second doses and 3 months after a complete primary course vaccination. Patientsâ€™ oncological treatment was unaffected by the vaccination received. The results of protective antibodies were also compared with healthy control subjects who were vaccinated in the same manner. More than 110 cancer patients participated and agreed to have their blood samples analyzed. The rate of antibody production was 96% after a complete primary course of vaccination and was similar with that of healthy control subjects. However, there were some differences noted regarding the oncological treatment that the patients were receiving, with patients who were treated with targeted therapy achieving the highest levels of protective antibodies. Adverse events after vaccination were mostly mild and did not interfere with patientsâ€™ general performance. The rate of antibody production for cancer patients after SARS-CoV-2 vaccination is high and similar to that in healthy control subjects but varies with regard to the oncological treatment that patients are receiving. However, antibodies decline substantially after 3 months, and thus a third

vaccination is desirable. There were no new safety concerns after vaccination, and most adverse events were mild and short-lived.

Ulcerative injection site reaction after third COVID-19 vaccine dose with mRNA-1273.

Acute kidney injury after COVID-19 vaccines: a real-world study. BACKGROUND: Acute kidney injury (AKI), a rare adverse event, cannot be ignored as millions of doses of coronavirus disease 2019 (COVID-19) vaccinations. We aimed to investigate the occurrence of post-vaccine AKI reported to the Vaccine Adverse Event Reporting System (VAERS). METHODS: After data mapping from December 2020 to June 2021, we summarized demographic and clinical features and outcomes of reported cases from three vaccines (Pfizer-BNT, MODERNA, and JANSSEN). The Bayesian and nonproportional analyses explored the correlations between COVID-19 vaccines and AKI. RESULTS: We identified 1133 AKI cases. Pfizer-BNT appeared to have a stronger AKI correlation than MODERNA and JANSSEN, based on the highest reporting odds ratio (ROR = 2.15, 95% confidence interval = 1.97, 2.36). We observed the differences in ages, comorbidities, current illnesses, post-vaccine AKI causes, and time to AKI onset (all pï¼œ.05) among three vaccines. Most patients are elderly, with the highest age in MODERNA (68.41â€‰years) and lowest in JANSSEN (59.75â€‰years). Comorbidities were noticed in 58.83% of the cases and active infections in over 20% of cases. The leading cause of post-vaccine AKI was volume depletion (40.78%), followed by sepsis (11.74%). Patients in Pfizer-BNT had the worst outcome with 19.78% deaths, following 17.78% in MODERNA and 12.36% in JANSSEN (pâ€‰=â€‰.217). The proportion of patients on dialysis was higher in JANSSEN than in Pfizer-BNT and MODERNA (14.61% vs. 6.54%, 10.62%, pâ€‰=â€‰.008). CONCLUSION: AKI could occur after the COVID-19 vaccines, predominantly in elderly patients. However, the causality needs further identification.

COVID-19 vaccine-associated ganulomatous mass mimicking a sarcoma: a case report. Several studies have previously documented the development of complications stemming from injection with one of the various COVID-19 vaccines. No study, however, has discussed the spontaneous development of a soft tissue mass shortly after a COVID-19 vaccine injection. We report on 66-year-old female with concerns of a growing shoulder mass, 2 weeks after receiving a COVID-19 vaccine booster. Initial work-up with X-ray and MRI was concerning for a soft tissue neoplasm, specifically a soft tissue sarcoma. Subsequent ultrasound guided biopsy demonstrated a benign granulomatous lesion. No further management was required as the lesion spontaneously resolved during a 3-month follow-up period.

Early diagnosis and treatment of SARS-CoV-2 vaccination associated polyradiculitis improves outcome.

Guillain-BarrÃ© Syndrome Associated with COVID-19 Vaccines: A Perspective From Spontaneous Report Data. BACKGROUND AND OBJECTIVE: The concern surrounding the association between Guillain-BarrÃ© syndrome (GBS) and vaccination has increased with the widespread use of COVID-19 vaccines. The aim of this study was to assess the potential association of GBS with mRNA-based or adenovirus-vectored COVID-19 vaccines. METHODS: Reports of GBS associated with mRNA-based or adenovirus-vectored COVID-19 vaccines were extracted from the WHO pharmacovigilance database, exposure data from the Our World in Data website, and the background rates of GBS from published data. For countries contributing to VigiBase and with available data on COVID-19 vaccine exposure, reporting rates were estimated and observed-to-expected (OE) analyses were performed. RESULTS: A total of 2499 cases were included: 1157 (46.3%) cases with adenovirus-vectored COVID-19 vaccines and 1342 (53.7%) with mRNA-based COVID-19 vaccines. The male-to-female sex ratio was 1.09 and the median (IQR) age was 57 (45-66) years. The reporting rates (95% CI) per 100,000 person-years within the 42-day window were 5.57 (5.13-6.03) for adenovirus-vectored COVID-19 vaccines and 1.39 (1.31-1.47) for mRNA-based COVID-19 vaccines, while the background incidence was 1.2-3.1 per

100,000 person-years. For mRNA-based COVID-19 vaccines, the OE ratio was <1 for both time windows in all European countries and slightly elevated for the 21-day window in the USA. For adenovirus-vectored COVID-19 vaccines, the OE ratio was consistently >Â 2.0 for all countries. Sensitivity analyses minimally altered these results. CONCLUSIONS: These findings suggest both the absence of safety concern for GBS with mRNA-based COVID-19 vaccines and an increased risk with adenovirus-vectored COVID-19 vaccines. Back to top.

Messenger RNA Coronavirus Disease 2019 (COVID-19) Vaccination With BNT162b2 Increased Risk of Bell's Palsy: A Nested Case-Control and Self-Controlled Case Series Study. BACKGROUND: Observable symptoms of Bell's palsy following vaccinations arouse concern over the safety profiles of novel coronavirus disease 2019 (COVID-19) vaccines. However, there are only inconclusive findings on Bell's palsy following messenger (mRNA) COVID-19 vaccination. This study aims to update the previous analyses on the risk of Bell's palsy following mRNA (BNT162b2) COVID-19 vaccination. METHODS: This study included cases aged â‰¥16 years with a new diagnosis of Bell's palsy within 28 days after BNT162b2 vaccinations from the population-based electronic health records in Hong Kong. Nested case-control and self-controlled case series (SCCS) analyses were used, where the association between Bell's palsy and BNT162b2 was evaluated using conditional logistic and Poisson regression, respectively. RESULTS: Totally 54 individuals were newly diagnosed with Bell's palsy after BNT162b2 vaccinations. The incidence of Bell's palsy was 1.58 (95% confidence interval [CI], 1.19-2.07) per 100 000 doses administered. The nested case-control analysis showed significant association between BNT162b2 vaccinations and Bell's palsy (adjusted odds ratio [aOR], 1.543; 95% CI, 1.123-2.121), with up to 1.112 excess events per 100 000 people who received 2 doses of BNT162b2. An increased risk of Bell's palsy was observed during the first 14 days after the second dose of BNT162b2 in both nested case-control (aOR, 2.325; 95% CI, 1.414-3.821) and SCCS analysis (adjusted incidence rate ratio, 2.44; 95% CI, 1.32-4.50). CONCLUSIONS: There was an overall increased risk of Bell's palsy following BNT162b2 vaccination, particularly within the first 14 days after the second dose, but the absolute risk was very low.

COVID-19 Infection With the Omicron SARS-CoV-2 Variant in a Cohort of Kidney and Kidney Pancreas Transplant Recipients: Clinical Features, Risk Factors, and Outcomes. BACKGROUND: Since November 2021, a new variant of concern (VOC), the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) lineage B.1.1.529 (Omicron) has emerged as the dominant coronavirus disease 2019 (COVID-19) infection worldwide. We describe the clinical presentation, risk factors, and outcomes in a cohort of kidney and kidney pancreas transplant recipients with COVID-19 caused by Omicron infection. METHODS: We included all kidney and kidney pancreas transplant recipients diagnosed with SARS-CoV-2 Omicron infections between December 26, 2021, and January 14, 2022, in a single transplant center in Australia. Identification of the VOC Omicron was confirmed using phylogenetic analysis of SARS-CoV-2 sequences. RESULTS: Forty-one patients with kidney (6 living and 33 deceased) and kidney pancreas transplants were diagnosed with the VOC Omicron (lineage B.1.1.529/BA.1) infection during the study period. The mean age (SD) at the time of diagnosis was 52 (11.1) y; 40 (out of 41) (98%) had received at least 2 doses of COVID-19 vaccine. Cough was the most frequent symptom (80.5%), followed by myalgia (70.7%), sore throat (63.4%), and fever (58.5%). After a follow-up time of 30 d, 1 (2.4%) patient died, 2 (4.9%) experienced multiorgan failure, and 5 (12.2%) had respiratory failure; 11 (26.8%) patients developed other superimposed infections. Compared with recipients who did not receive sotrovimab antibody therapy, the odds ratio (95% confidence interval) for hospitalization among patients who received sotrovimab was 0.05 (0.005-0.4). CONCLUSIONS: Despite double or triple dose vaccination, VOC Omicron infections in kidney and kidney pancreas transplant recipients are not necessarily mild. Hospitalization rates remained high (around 56%), and sotrovimab use may prevent hospitalization.

Vaccine-Related Lymph Nodes: The Emerging Pitfalls of 18F-Fluorocholine and 68Ga-PSMA-11 PET/CT in the Era of COVID-19 Vaccination. PURPOSE: Vaccination against coronavirus disease 2019 (COVID-19) is currently under worldwide deployment. The consequences of this vaccination can be seen in radiology and nuclear medicine explorations with visualization of axillary lymph nodes (LNs), as observed on ultrasonography, MRI, or 18F-FDG PET/CT.We aimed to evaluate on PET/CT the incidence of vaccine-related LNs and their characteristics after COVID-19 vaccination, using several radiopharmaceuticals different from 18F-FDG. PATIENTS AND METHODS: Between February and July 2021, all consecutive patients undergoing a whole-body PET/CT for any indication using a different radiopharmaceutical from 18F-FDG were eligible for inclusion if they had received at least 1 dose of the COVID-19 vaccine. The radiopharmaceutical administered and vaccine type were recorded for each patient. The incidence of positive vaccine-related axillary and supraclavicular LNs on PET/CT was our primary finding, along with the nodes characteristics. Statistical analyses were performed for patients with prostate cancer (PCa) to determine certain interaction factors that were associated with the detection of vaccine-related LNs. RESULTS: Of the 226 patients in our cohort study, 120 patients underwent an 18F-fluorocholine PET/CT, 79 a 68Ga-PSMA-11 PET/CT, 6 an 18F-FDOPA PET/CT, and 21 a 68Ga-DOTATOC PET/CT. A total of 67.3% of patients (152/226) received BNT162b2mRNA (Pfizer-BioNTech), 26.5% (60/226) ChAdOx1-S (AstraZeneca), 4.9% (11/226) mRNA-1273 (Moderna), and 1.3% (3/226) Ad26.COV2.S (Janssen). The incidence of positive vaccine-related axillary and supraclavicular LNs was 42.5% (51/120 patients) on PET/CT using 18F-fluorocholine and 12.7% (10/79 patients) with 68Ga-PSMA-11. None of our patients undergoing 18F-FDOPA or 68Ga-DOTATOC PET/CT presented any vaccine-related lymphadenopathy. Vaccine-related LNs were statistically associated with the nature of the radiopharmaceutical ($P < 10\text{-}4$), with the number of vaccine doses received ($P = 0.041$), with a short delay between vaccination and PET/CT realization ($P < 10\text{-}5$), and with a higher prostate-specific antigen level for patients with PCa ($P = 0.032$), but not with age or vaccine type. The vaccine-related nodes appeared in 85% of the cases, in the 30 days after vaccine injection, were limited in size and uptake, and were most often limited to the axilla level 1 area. CONCLUSIONS: Detecting positive LNs after COVID-19 vaccination is not an exclusive 18F-FDG PET/CT pattern but is common on 18F-fluorocholine and possible on 68Ga-PSMA-11 PET/CT. Confronting PET/CT findings with clinical data (such as date and site of injection) seems essential in the current pandemic context, just as it does for the radiopharmaceuticals used in PCa to avoid PET/CT misinterpretation and incorrect patient treatment. For 18F-FDOPA or 68Ga-DOTATOC PET/CT, this seems to have a lesser impact.

Atrial fibrillation after vaccination for COVID-19: analysis of the vaccine adverse event reporting system.

Retrospective study on the safety of COVID-19 vaccination in myasthenia gravis. INTRODUCTION/AIM: Given the lack of information on safety of coronavirus disease 2019 (COVID-19) vaccination in myasthenia gravis (MG) patients, we aimed to review our experience after surveying patients, as part of routine clinical practice, to ensure that advice on safety is accurate. METHODS: We performed a retrospective chart review of MG patients from the Prosserman Family Neuromuscular Clinic at the Toronto General Hospital who received two injections of any COVID-19 vaccine from February to August 2021. Demographic data were abstracted from the patient medical records. We assessed changes in the severity of MG using the virtual Myasthenia Gravis Impairment Index (vMGII), the simple single question (SSQ), and Patient Acceptable Symptom State (PASS). We also assessed adverse effects after vaccination. RESULTS: We included 200 patients with a mean age of 64.3â€‰Â±â€‰13.9Â y, 51.5% were men, and 82% had generalized MG. The vMGII, SSQ, and PASS scores remained stable after each vaccine dose, and at last follow-up. Of the patients, 60% reported an adverse reaction after the first injection, and 56% after the second. The most common

adverse reactions reported were local pain at the injection site, fatigue, headache, and fever. DISCUSSION: COVID-19 vaccinations were well tolerated in MG patients and were not associated with worsening severity of their MG. The prevalence of vaccine-related adverse reactions was the same as in the general population.
Factors Associated With COVID-19 Breakthrough Infections in Large Midwestern Healthcare System: Implications for Vulnerable Healthcare Personnel. OBJECTIVE: The aim of the study is to identify factors associated with breakthrough infection among a cohort of Midwestern healthcare personnel (HCP). METHODS: SARS-CoV-2-positive test results between March 1, 2020, and July 31, 2021, were collected from electronic medical records of HCP to identify breakthrough infections. RESULTS: Healthcare personnel who were younger than 35 years, received the Pfizer vaccine, and worked in COVID clinical units had greater adjusted odds of breakthrough infection. COVID infection before full vaccination was associated with reduced odds of breakthrough infection. CONCLUSIONS: Our study concluded that the most vulnerable HCP are younger, working in COVID-19 clinical units, and received Pfizer-BioNTech primary series vaccines. Healthcare personnel who had COVID before vaccination were at reduced risk of breakthrough infection, indicating that supplemental immunity could better protect at-risk HCP groups.
Bilateral anterior uveitis after BNT162b2 mRNA vaccine: Case report.
Abducense nerve palsy following BBIBP-CorV (Sinopharm) COVID-19 vaccine.
Humoral response to SARS-CoV-2 after vaccination and booster effect in patients undergoing dialysis. OBJECTIVE: The aim of this study was to determine and evaluate the postvaccination variation in immunoglobulin G (IgG) receptor-binding domain (RBD) produced in non-SARS-CoV-2-infected patients with nephropathy and renal replacement therapy. METHODS: This is a follow-up study of the humoral response to the BNT162b2 messenger ribonucleic acid COVID-19 vaccine in patients with nephropathy, comparing it with itself at different times and with the healthy population. RESULTS: In patients with nephropathy, a very striking decrease in IgG RBD was observed compared with the healthy population (P<0.001) at three months after the second dose. In patients with nephropathy, the response rate â‰¥590 binding antibody units/ml (4154 AU/ml) was detected in 45% of patients, 15 days after the second dose, whereas at 3 months, this decreased to 9% (P<0.05)Â and then increased to 86% after the third dose (P<0.001). CONCLUSION: In patients with nephropathy and renal replacement therapy, it is necessary to administer a third-dose vaccination within 3 months after the second dose. It is important to continue monitoring the humoral response to obtain a better SARS-CoV-2 vaccination schedule.
Adverse events following COVID-19 vaccination: A systematic review and meta-analysis. BACKGROUND: High speed of COVID-19 vaccination has raised some concerns about the safety of the new vaccines. It is of a great importance to perform a review of the safety and efficacy of the COVID-19 vaccines. METHODS: Two International electronic databases (PubMed, ISI) were searched for clinical trials reporting efficacy and safety of COVID-19 vaccines compared to control group. Pooled risk ratio (RR) for total, systemic and local adverse events following immunization was calculated for different vaccine modalities. RESULTS: The pooled RRs of total adverse reactions for Inactivated, mRNA, and vector vaccines were 1.46 (95% CI: 1.19-1.78), 2.01 (95% CI: 1.82 - 2.23), and 1.65 (95% CI: 1.31 - 2.32) respectively. The pooled RR for occurrence of systemic adverse reactions following immunization for different vaccine modalities was 1.13 (95% CI: 0.79 - 1.61), 1.53 (95% CI 1.08 - 2.16), 1.58 (95% CI: 1.13 - 1.90), 0.72 (95% CI: 0.34 - 1.55), and 1.62 (95% CI: 1.39 - 1.89) for inactivated vaccine, mRNA, vector, DNA, and protein subunit vaccines respectively. The pooled RR of local adverse event following immunization with inactivated vaccine, mRNA vaccine, vector vaccine, DNA vaccine, and protein subunit vaccine was 2.18 (95% CI: 1.32 - 3.59), 4.96 (95% CI: 4.02 - 6.11), 1.48 (95% CI: 0.88-2.50) 1.04 (95% CI: 0.12-8.75), and 4.09 (95% CI: 2.63-6.35) respectively. CONCLUSION:

mRNA vaccines are associated with greater risk of adverse events following immunization. However, at the present moment the benefits of all types of vaccines approved by WHO, still outweigh the risks of them and vaccination if available, is highly recommended.

Association of sleep duration and quality with immunological response after vaccination against severe acute respiratory syndrome coronavirus-2 infection. Growing evidence suggests that sleep could affect the immunological response after vaccination. The aim of this prospective study was to investigate possible associations between regular sleep disruption and immunity response after vaccination against coronavirus disease 2019 (COVID-19). In total, 592 healthcare workers, with no previous history of COVID-19, from eight major Greek hospitals were enrolled in this study. All subjects underwent two Pfizer-BioNTech messenger ribonucleic acid (mRNA) COVID-19 vaccine BNT162b2 inoculations with an interval of 21â€‰days between the doses. Furthermore, a questionnaire was completed 2â€‰days after each vaccination and clinical characteristics, demographics, sleep duration, and habits were recorded. Blood samples were collected and anti-spike immunoglobulin G antibodies were measured at 20â€‰Â±â€‰1â€‰days after the first dose and 21â€‰Â±â€‰2â€‰days after the second dose. A total of 544 subjects (30% males), with median (interquartile range [IQR]) age of 46 (38-54)Â years and body mass index of 24Â·84Â (22.6-28.51)Â kg/m(2) were eligible for the study. The median (IQR) habitual duration of sleep was 6Â (6-7)Â h/night. In all, 283 participants (52%) had a short daytime nap. In 214 (39.3%) participants the Pittsburgh Sleep Quality Index score was >5, with a higher percentage in women (74Â·3%, pâ€‰<â€‰0.05). Antibody levels were associated with age (rÂ =â€‰-0.178, pâ€‰<â€‰0.001), poor sleep quality (rÂ =â€‰-0.094, pâ€‰<â€‰0.05), insomnia (rÂ =â€‰-0.098, pâ€‰<â€‰0.05), and nap frequency per week (rÂ =â€‰-0.098, pâ€‰<â€‰0.05), but after adjusting for confounders, only insomnia, gender, and age were independent determinants of antibody levels. It is important to emphasise that insomnia is associated with lower antibody levels against COVID-19 after vaccination.

COVID-19 vaccination coverage and associated factors in seasonal fruit workers in Lleida. OBJECTIVES: Seasonal fruit workers are a high-risk group for SARS-COV-2 infection. We aimed to estimate vaccination coverage and factors associated with vaccination in seasonal fruit workers. METHODS: We carried out an anonymous survey of seasonal fruit workers in the 2021 campaign in Baix Segria region and Lleida city (Spain) on vaccination, knowledge and attitudes about the COVID-19 vaccine. Univariate and bivariate descriptive analyses were performed comparing vaccinated versus non-vaccinated. Multivariate analysis was performed using to assess factors associated to vaccination uptake. RESULTS: We included 286 seasonal workers. The prevalence of confirmed COVID-19 background was 39.5% and overall vaccination coverage was 78.7%. Factors associated with vaccination were age (aORâ€¯=â€¯0.96; 95% CI: 0.94-0.99), good knowledge of disease (aORâ€¯=â€¯1.87; 95% Clâ€¯:â€¯1.01-3.47) and having a high-perceived vaccine effectiveness (aORâ€¯=â€¯2.94; 95% Clâ€¯:â€¯1.50-5.73). High vaccination coverage in workers was associated to knowledge (ORâ€¯=â€¯3.69; 95% CI: 1.61-8.48), safe transport (ORâ€¯=â€¯2.84; 95% CI: 1.40-5.76) and appropriate housing (ORâ€¯=â€¯2.62; 95% CI: 1.25-5.46) as important non-pharmacological measures to reduced transmission. CONCLUSION: The study confirms the high prevalence of COVID-19 history and moderate vaccination coverage in seasonal fruit workers. Health education programs to improve knowledge about COVID-19 and its vaccination can help improve vaccination uptake.

Association of disease severity and death outcome with vaccination status of admitted COVID-19 patients in delta period of SARS-COV-2 in mixed variety of vaccine background. To understand the effectual role of COVID-19 vaccination, we must analyze its effectiveness in dampening the disease severity and death outcome in patients who acquire infection and require hospitalization. The goal of this study was to see if there was an association between disease progression in admitted COVID-19 patients and their prior vaccination exposure. A prospective cohort study based on 1640

admitted COVID-19 patients were carried between June 2021 and October 2021. Depending on vaccination exposure they were divided into vaccinated (exposed) and unvaccinated (unexposed) groups, excluding partially vaccinated patients. Disease severity was assessed at admission on severity index scale. Disease progression to mortality or need of mechanical ventilation and survival were taken as outcome. Absolute difference with 95%CI and Risk Ratio were calculated using cross tabulation, Chi square test and multivariable logistic regression analysis. Among 1514 total analyzed cohort (median age, 53Â years [IQR, 17,106]; 43.7% from 46 to 65Â years of age group, 56.2% males,33.4% with no comorbid factor for disease progression) 369(24.4%) were vaccinated breakthrough cases and 1145(75.6%) were unvaccinated controls. 556(36.7%) progressed to death or mechanical ventilation, 958(63.3%) patients survived and were discharged home. Disease progression to death or mechanical ventilation was significantly associated with decreased likelihood of vaccination (24.9% among vaccinated breakthrough vs 40.5% unvaccinated controls, [Absolute difference -15.6% 95%CI (-10.2% to -20.6%); RR 0.615 95%CI (0.509, 0.744); pÂ <.001]). This association was stronger for old age population and for increase time span between second dose of vaccine and onset of symptoms. There was no statistically significant difference among different types of vaccination and occurrence of outcome when compared to unvaccinated controls (RR 0.607(0.482, 0.763); 0.673(0.339, 1.33) and 0.623(0.441, 0.881) for Inactivated virus vaccine, mRNA and Adenovirus vector-based vaccine respectively. The patients who were fully vaccinated against SARS-COV-2 die or shift to mechanical ventilation less frequently than unvaccinated COVID-19 admitted patients.

People With Human Immunodeficiency Virus Receiving Suppressive Antiretroviral Therapy Show Typical Antibody Durability After Dual Coronavirus Disease 2019 Vaccination and Strong Third Dose Responses. BACKGROUND: Longer-term humoral responses to 2-dose coronavirus disease 2019 (COVID-19) vaccines remain incompletely characterized in people living with human immunodeficiency virus (HIV) (PLWH), as do initial responses to a third dose. METHODS: We measured antibodies against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein receptor-binding domain, angiotensin-converting enzyme 2 (ACE2) displacement, and viral neutralization against wild-type and Omicron strains up to 6 months after 2-dose vaccination, and 1 month after the third dose, in 99 PLWH receiving suppressive antiretroviral therapy and 152 controls. RESULTS: Although humoral responses naturally decline after 2-dose vaccination, we found no evidence of lower antibody concentrations or faster rates of antibody decline in PLWH compared with controls after accounting for sociodemographic, health, and vaccine-related factors. We also found no evidence of poorer viral neutralization in PLWH after 2 doses, nor evidence that a low nadir CD4+ T-cell count compromised responses. Post-third-dose humoral responses substantially exceeded post-second-dose levels, though Omicron-specific responses were consistently weaker than responses against wild-type virus. Nevertheless, post-third-dose responses in PLWH were comparable to or higher than controls. An mRNA-1273 third dose was the strongest consistent correlate of higher post-third-dose responses. CONCLUSION: PLWH receiving suppressive antiretroviral therapy mount strong antibody responses after 2- and 3-dose COVID-19 vaccination. Results underscore the immune benefits of third doses in light of Omicron.

Hemolysis induced by SARS-CoV-2 mRNA vaccination in patients with paroxysmal nocturnal hemoglobinuria. Autoimmune and complement-related hematological side effects have been observed with messenger ribonucleic acid (mRNA) vaccines. Here, we report the incidence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine-induced hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH). We reviewed the medical records of seventeen patients with PNH visiting the University of Tsukuba Hospital who had received two doses of the SARS-CoV-2 mRNA vaccine between May 2021 and November 2021. Twelve patients were being treated with

complement inhibitors. The median age of all patients was 62Â years (range 29-89Â years).; six were males and eleven were females. Fourteen patients received the BNT162b2 vaccine (Pfizer/BioNTech) and three received the mRNA-1273 vaccine (Moderna). The median percentages of PNH clones in erythrocytes and granulocytes were 37.61% (range 8.11-85.71%) and 59.73% (range 3.76-97.82%), respectively. Of the twelve patients receiving complement inhibitors, only one had a hemolytic reaction after vaccination, but it did not meet the definition of breakthrough hemolysis. By contrast, hemolytic attacks were observed in two of the five untreated patients with PNH, and one of them required a blood transfusion. Appropriate administration of complement inhibitors to patients with PNH may prevent hemolysis induced by SARS-CoV-2 mRNA vaccination.

Risk of serious adverse events after the BNT162b2, CoronaVac, and ChAdOx1 vaccines in Malaysia: A self-controlled case series study. BACKGROUND: Rapid deployment of COVID-19 vaccines is challenging for safety surveillance, especially on adverse events of special interest (AESIs) that were not identified during the pre-licensure studies. This study evaluated the risk of hospitalisations for predefined diagnoses among the vaccinated population in Malaysia. METHODS: Hospital admissions for selected diagnoses between 1 February 2021 and 30 September 2021 were linked to the national COVID-19 immunisation register. We conducted self-controlled case-series study by identifying individuals who received COVID-19 vaccine and diagnosis of thrombocytopenia, venous thromboembolism, myocardial infarction, myocarditis/pericarditis, arrhythmia, stroke, Bell's Palsy, and convulsion/seizure. The incidence of events was assessed in risk period of 21Â days postvaccination relative to the control period. We used conditional Poisson regression to calculate the incidence rate ratio (IRR) and 95% confidence interval (CI) with adjustment for calendar period. RESULTS: There was no increase in the risk for myocarditis/pericarditis, Bell's Palsy, stroke, and myocardial infarction in the 21Â days following either dose of BNT162b2, CoronaVac, and ChAdOx1 vaccines. A small increased risk of venous thromboembolism (IRR 1.24; 95% CI 1.02, 1.49), arrhythmia (IRR 1.16, 95% CI 1.07, 1.26), and convulsion/seizure (IRR 1.26; 95% CI 1.07, 1.48) was observed among BNT162b2 recipients. No association between CoronaVac vaccine was found with all events except arrhythmia (IRR 1.15; 95% CI 1.01, 1.30). ChAdOx1 vaccine was associated with an increased risk of thrombocytopenia (IRR 2.67; 95% CI 1.21, 5.89) and venous thromboembolism (IRR 2.22; 95% CI 1.17, 4.21). CONCLUSION: This study shows acceptable safety profiles of COVID-19 vaccines among recipients of BNT162b2, CoronaVac, and ChAdOx1 vaccines. This information can be used together with effectiveness data for risk-benefit analysis of the vaccination program. Further surveillance with more data is required to assess AESIs following COVID-19 vaccination in short- and long-term.

Thrombocytopenia after Ad.26.COV2.S COVID-19 vaccine: Reports to the vaccine adverse event reporting system. BACKGROUND: On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization for Ad.26.COV2.S COVID-19 vaccine. As part of post-authorization safety surveillance, the FDA has identified a potential safety concern for thrombocytopenia following receipt of Ad.26.COV2.S COVID-19 vaccine. METHODS: Reports of thrombocytopenia were identified in a passive reporting system (Vaccine Adverse Event Reporting System; VAERS) February-December 2021. Demographics, clinical characteristics, laboratory values, and relevant medical history were reviewed. The reporting rate was analyzed, including calculation of the observed-to-expected ratio based on vaccine administration data and the background rate of thrombocytopenia in the general (unvaccinated) population. RESULTS: As of December 31, 2021, 100 reports of thrombocytopenia were identified in VAERS following vaccination with Ad.26.COV2.S. The median platelet count was 33,000 per ÂµL (interquartile range 8,000-86,000). Fifteen reports (15%) documented a platelet count of 5,000 per ÂµL or lower. The median time to onset of thrombocytopenia was 9Â days (interquartile range 3-18.5), with most cases (69; 69%) beginning within 14Â days after vaccination. A large majority of cases (84; 84%) were serious, including six

deaths. With approximately 16,292,911 doses of Ad.26.COV2.S administered to adults in the US, the crude reporting rate was 0.61 cases of thrombocytopenia per 100,000 doses administered. The overall estimated observed-to-expected rate ratio was 2.43 (95% CI 1.97, 2.95). CONCLUSIONS: These findings suggest an increased risk of thrombocytopenia following receipt of Ad.26.COV2.S.

Comment on "SARS-CoV-2 vaccinations may not only be complicated by GBS but also by distal small fiber neuropathy by J. Finsterer.

Global prevalence and clinical manifestations of cutaneous adverse reactions following COVID-19 vaccination: A systematic review and meta-analysis. Although vaccination is widely accepted as an effective method of preventing and controlling the COVID-19 pandemic, many people are concerned about possible cutaneous side-effects, which can delay or prevent them from being vaccinated. The objectives of this systematic review were to assess the global prevalence and clinical manifestations of cutaneous adverse reactions following COVID-19 vaccination. PubMed and Scopus databases were searched for articles published from 1 January 2019 to 31 December 2021, and reference lists for each selected article were screened. Case reports, case series, observational studies and randomized controlled trials that provided information on cutaneous adverse reactions following COVID-19 vaccines were included. A total of 300 studies were included in a systematic review of which 32 studies with 946â€‰366 participants were included in the meta-analysis. The pooled prevalence of cutaneous manifestations following COVID-19 vaccination was 3.8% (95% CI, 2.7%-5.3%). COVID-19 vaccines based on the mRNA platform had a higher prevalence than other platforms at 6.9% (95% CI, 3.8%-12.3%). Various cutaneous manifestations have been reported from injection site reactions, which were the most common (72.16%) to uncommon adverse reactions such as delayed inflammatory reactions to tissue filler (0.07%) and flares of pre-existing dermatoses (0.07%). Severe cutaneous reactions such as anaphylaxis have also been reported, but in rare cases (0.05%). In conclusion, cutaneous adverse reactions are common, especially in those receiving mRNA vaccines. Most reactions are mild and are not contraindications to subsequent vaccination except for anaphylaxis, which rarely occurs. COVID-19 vaccination may also be associated with flares of pre-existing dermatoses and delayed inflammatory reactions to tissue filler. Patients with a history of allergies, pre-existing skin conditions or scheduled for filler injections should receive additional precounselling and monitoring. A better understanding of potential side-effects may strengthen public confidence in those wary of new vaccine technologies.

SARS-CoV-2 vaccination, Parkinson's disease, and other movement disorders: case series and short literature review. BACKGROUND: Several neurological complications have been reported following SARS-Cov-2 vaccination, without a clear causal relationship ever being verified, including some cases of worsening of Parkinson's disease (PD) symptoms and new onset of movement disorders in non-parkinsonian patients. METHODS: We describe two new cases of PD patients treated with device-aided therapy who developed worsening of parkinsonian symptoms after receiving the third vaccine dose (booster). We also conducted a short review of the cases reported in literature of PD symptoms worsening and new onset of movement disorders in non-parkinsonian patients after SARS-Cov-2 vaccination. RESULTS: The first patient, a 46-year-old man implanted with bilateral Subthalamic Deep Brain Stimulation, experienced temporary motor and non-motor symptoms worsening after mRNA-1273 booster, improved after stimulation settings modification. The second patient, a 55-year-old man implanted with percutaneous endoscopic transgastric jejunostomy (PEG-J) for levodopa-carbidopa intestinal gel (LCIG) infusion experienced severe temporary worsening of dyskinesia and managed through temporary LCIG dose reduction. Other seven cases of vaccine-related movement disorder are currently reported in literature, four describing PD symptoms worsening and three the onset of new movement disorders in otherwise healthy people. CONCLUSION: Both our patients and the cases described so far completely recovered after few days

with parkinsonian therapy modification, symptomatic treatment, or even spontaneously, underlining the transient and benign nature of side effects from vaccine. Patients should be reassured about these complications, manageable through a prompt evaluation by the reference neurologist.

Impact of SARS-CoV-2 Vaccination on Inflammatory Bowel Disease Activity and Development of Vaccine-Related Adverse Events: A Survey From China.

Risks of adverse outcomes in COVID-19 patients and vaccination status in a secondary hospital in Spain. INTRODUCTION: In December 2020, vaccination against SARS-CoV-2 started in Spain. Until March 2022, 91.1% of the target population was vaccinated. The objective of the study is to describe the characteristics of patients with SARS-CoV-2 infection, the risk of serious outcomes and their vaccination status. MATERIAL AND METHODS: Retrospective longitudinal analytical observational study. Demographic characteristics and outcomes of COVID-19 infections and vaccination history from 01/01/2021-08/10/2021 were collected from electronic medical records and the Unified Vaccination Registry. Data analysis was performed with Excel and Stata 16. RESULTS: 4161 COVID-19 cases were detected; of which 185 (4.5%) had received a complete vaccination schedule. The most affected age group was 80-89â€¯years (34.1%). 1697 patients were hospitalized, of whom 78 (4.6%) had been vaccinated against SARS-CoV-2. No patient admitted to the ICU had a history of vaccination. The mean hospitalization time in unvaccinated patients was 11â€¯days (95% CI -41.54-63.54) compared to 8.5â€¯days (95% CI 7.04-9.96) in vaccinated patients. The relative risk of hospitalization in vaccinated patients compared to unvaccinated patients for the age group 40 to 59â€¯years was 0.29 (95% CI 0.11-0.72) and 0.77 (95% CI 0.67-0). 0.90) for people over 60â€¯years of age. CONCLUSIONS: The risk of hospitalization and death was lower in vaccinated patients compared to unvaccinated patients in the age groups 40-59 and older than 60â€¯years. This finding supports current clinical evidence.

Anti-MDA5 dermatomyositis after COVID-19 vaccination: a case-based review. Anti-MDA5 (Melanoma differentiation-associated protein 5) myositis is a rare subtype of dermatomyositis (DM) characterized by distinct ulcerative, erythematous cutaneous lesions and a high risk of rapidly progressive interstitial lung disease (RP-ILD). It has been shown that SARS-CoV-2 (COVID-19) replicates rapidly in lung and skin epithelial cells, which is sensed by the cytosolic RNA-sensor MDA5. MDA5 then triggers type 1 interferon (IFN) production, and thus downstream inflammatory mediators (EMBO J 40(15):e107826, 2021); (J Virol, 2021, https://doi.org/10.1128/JVI.00862-21); (Cell Rep 34(2):108628, 2021); (Sci Rep 11(1):13638, 2021); (Trends Microbiol 27(1):75-85, 2019). It has also been shown that MDA5 is triggered by the mRNA COVID-19 vaccine with resultant activated dendritic cells (Nat Rev Immunol 21(4):195-197, 2021). Our literature review identified one reported case of MDA5-DM from the COVID-19 vaccine (Chest J, 2021, https://doi.org/10.1016/j.chest.2021.07.646). We present six additional cases of MDA5-DM that developed shortly after the administration of different kinds of COVID-19 vaccines. A review of other similar cases of myositis developing from the COVID-19 vaccine was also done. We aim to explore and discuss the evidence around recent speculations of a possible relation of MDA5-DM to COVID-19 infection and vaccine. The importance of vaccination during a worldwide pandemic should be maintained and our findings are not intended to discourage individuals from receiving the COVID-19 vaccine.

Longitudinal dynamics of SARS-CoV-2 anti-receptor binding domain IgG antibodies in a wide population of health care workers after BNT162b2 vaccination. OBJECTIVES: With the availability of vaccines, commercial assays detecting anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibodies evolved toward quantitative assays directed to the spike glycoprotein or its receptor-binding domain (RBD). The objective was to perform a large-scale, longitudinal study involving health care workers (HCWs), with the aim of establishing the kinetics of immune response

throughout the 9-month period after receipt of the second dose of the BNT162b2 vaccine. METHODS: Quantitative determination of immunoglobulin (Ig) G antibodies against the RBD of the S1 subunit of the spike protein of SARS-CoV-2 on the Alinity systems. RESULTS: The highest levels of anti-RBD IgG were measured after 1 month from full vaccination (median: 1432 binding antibody units/ml [BAU/ml]); subsequently, a steep decrease (7.4-fold decrease) in IgG levels was observed at 6 months (median: 194.3 BAU/ml), with a further 2.5-fold decrease at 9 months (median: 79.3 BAU/ml). Furthermore, the same data, when analyzed for sex, showed significant differences between male and female participants at both 1 and 9 months from vaccination, but not at 6 months. CONCLUSION: Our results confirm the tendency of anti-RBD antibodies to decrease over time, also when extending the analysis up to 9 months, and highlight a better ability of the female sex to produce antibodies 1 month and 9 months after vaccination. Overall, these data, obtained in a wide population of HCWs, support the importance of having increased the vaccine doses.
Clinical and virologic factors associated with outcomes of COVID-19 before and after vaccination among Veterans: Retrospective analysis from six New England states. We aimed to characterize clinical and demographic factors affecting clinical outcomes of COVID-19 and describe viral epidemiology among unvaccinated Veterans in New England. Veterans infected with COVID-19 in Veterans Administration healthcare systems in six New England states from April 8, 2020, to September 2, 2021, were correlated with outcomes of 30-day mortality, nonpsychiatric hospitalization, and intensive care unit admission (ICU-care). We sequenced 827 viral genomes. Of 3950 Veterans with COVID-19 before full vaccination, 81% were White, 8% were women, and the mean age was 60 years. Overall, 19% of Veterans required hospitalization, 2.8% required ICU care, and 4.9% died. In this largely male and older cohort, poor outcomes correlated with increasing age. Most New England Veterans (>97%) were infected with B.1 sublineages with the D614G mutation in 2020 and early 2021. B.1.617.2 lineage (68%) predominated after July 2021.
A case of cutaneous arteritis after administration of mRNA coronavirus disease 2019 vaccine.
Immunogenicity and Safety of SARS-CoV-2 Vaccination in Patients With Rheumatic Diseases: A Systematic Review and Meta-analysis. OBJECTIVE: The aim of this study was to conduct a systematic review and meta-analysis examining the immunogenicity and safety of SARS-CoV-2 vaccination in patients with RD. METHODS: We systematically searched PubMed/MEDLINE and Scopus to identify observational studies that examined the immunogenicity and safety of SARS-CoV-2 vaccination in RD patients. Information on disease, immunosuppressant, vaccine type, and proportion of patients with serologic response was obtained from each study. RESULTS: There were 25 eligible studies. The pooled rate of seroconversion was 0.79 (95% confidence interval [CI], 0.72-0.86). Compared with control subjects, the odds of seroconversion were significantly lower (odds ratio, 0.11; 95% CI, 0.05-0.24). Users of rituximab showed the lowest rate of seroconversion (0.39; 95% CI, 0.29-0.51) followed by mycophenolate (0.56; 95% CI, 0.40-71). On the other hand, users of interleukin 17 (0.94; 95% CI, 0.78-0.98) and tumor necrosis factor inhibitors (0.94; 95% CI, 0.84-0.98) showed high seroconversion rate. Regarding safety of COVID-19 vaccine, approximately 2% of patients reported severe adverse events and 7% reported diseases flares following the first or second dose. CONCLUSION: Vaccination against SARS-CoV-2 appears to be safe. Most RD patients developed humoral immune response following vaccination. However, the odds of seroconversion were significantly lower in RD patients compared with controls. This is likely driven by certain immunosuppressants including rituximab and mycophenolate. Future studies need to identify strategies to improve vaccine response in these patients.
Evaluation of antibody titer kinetics and SARS-CoV-2 infections in a large cohort of healthcare professionals ten months after administration of the BNT162b2 vaccine. BACKGROUND: Real-world population studies have shown waning immunity, over time, after receiving the two doses of

the BNT162b2 COVID-19 vaccine. Studies reporting the long-term humoral response are important to drive future vaccination strategies like the introduction of the booster dose. Yet, available literature on long follow-up periods is scarce. Covidiagnostix is a multicenter study aiming to assess the antibody response in >1000 healthcare professionals (HCPs) who received the BNT162b2 vaccine. METHODS: Serum was tested at time-0 (T0), before the first dose and then at T1, T2, T3 and T4, respectively, 21, 42, 177 and 302Â days after T0. Antibodies against the SARS-CoV-2 nucleocapsid-protein were measured to assess SARS-CoV-2 infections, whereas antibodies against the receptor-binding domain of the spike protein were measured to assess vaccine response. RESULTS: The antibody titer observed 10Â months post-vaccination showed a decrease of approximately 80% from the peak measured at T2, yet the median titer of the seronegatives HCPs was still higher than seropositives before vaccination. We identified 12 post-vaccination infected HCPs within 6Â months after receiving the first dose and another 12 post-vaccination infected HCPs between 6 and 10Â months post-vaccination. CONCLUSION: Vaccination induced a humoral response which is well detectable even 10Â months post-vaccination. Yet a high anti-spike serum antibody titer does not guarantee protection from infection. Differences in symptomatology between SARS-CoV-2 infections occurred within the first 6Â months post-vaccination and the following 4Â months, and differences in COVID-19 prevalence and vaccination coverage observed in these two time intervals were consistent with a decrease in vaccine efficacy 6Â months after receiving the first dose.
Venous sinus thrombosis following vaccination with ChAdOx1 nCov-19.
Safety and immunogenicity of the SARS-CoV-2 ARCoV mRNA vaccine.
Two doses of the Pfizer-BioNTech vaccine, two different side effects: Skin and eye. A 47-year-old male patient presented to our clinic with the complaints of eye pain, reduced vision and redness in the right eye three days after administration of the second dose of the Pfizer-BioNTech vaccine. The patient was diagnosed with uveitis associated with the Pfizer-BioNTech vaccine and inflammatory glaucoma due to the uveitis. In addition, an erythematous, morbilliform rash had developed three days after the first dose of the vaccine. This is the first case report in the literature to show both skin and eye side effects after the Pfizer-BioNTech vaccine.
Self-limiting reactive disease mimicking polymyalgia rheumatica following Moderna COVID-19 vaccine.
New-onset guttate psoriasis following coronavirus disease 2019 vaccination: About two cases.
A comparative review on mucocutaneous reactions caused by Covid-19 infection versus Covid-19 vaccination. The prevalence and severity of mucocutaneous manifestations in Covid-19 infection are generally higher than those reported in Covid vaccines. Therefore, comparing the mucocutaneous reactions of the Covid-19 infection and vaccination is necessary to enhance our knowledge about such reactions and guide us to evaluate the risk of infection or vaccination. A thorough literature search was conducted on PubMed, Google Scholar, and EBSCO (LISTA), and 2069 articles were downloaded. After screening, 11 studies remained for the final review. The literature review revealed that the prevalence and severity of postvaccine mucocutaneous adverse reactions have been less common compared to Covid-19 infection. Postvaccine adverse reactions primarily occurred after the first dose administration and such reactions were manageable with antihistamines and corticosteroids administration. This comparative analysis highlights the frequency and potential severity of mucocutaneous reactions due to Covid-19 infection and Covid-19 vaccination. It also affirmed that potentially critical (serious) mucocutaneous reactions are more likely to occur in Covid-19 infection compared to Covid vaccination. Moreover, postvaccine reactions predominantly happened after the first dose and were reported to be non-life-threatening, self-manageable and with a lower incidence of potentially critical events. It was also concluded that the incidence of mucocutaneous reactions decreased in the following doses. Hence, given the low rate of such

reactions following Covid-19 vaccination, vaccines have a lower risk of mucocutaneous reactions occurrence than Covid-19 infection. Further, due to the limited number of studies, we recommend that large-scale trials evaluate such reactions comparing various types of Covid-19 vaccines in healthy individuals and those with autoimmune skin disorders.

Acute Unilateral Central Serous Chorioretinopathy after Immunization with Pfizer-BioNTech COVID-19 Vaccine: A Case Report and Literature Review. INTRODUCTION: A 43-year-old Caucasian male presented to our ophthalmology clinic with blurry vision and metamorphopsia in his right eye, 24Â hours after receiving the first dose of the Pfizer-BioNTech COVID-19 vaccine. METHODS: Clinical examination and imaging tests were consistent with acute unilateral central serous chorioretinopathy (CSCR) that completely resolved after 2Â months without any treatment. He had no significant ophthalmic or medical history. He also lacked the classical risk factors for CSCR such as recent psychosocial stressors, Type-A personality traits, history of exogenous steroid use, connective tissue disorders and obstructive sleep apnea. RESULTS: This appears to be only the second reported case of CSCR, temporally associated with a recombinant COVID-19 mRNA vaccine. We also present a summary of published reports demonstrating intraocular complications associated with the novel recombinant COVID-19 mRNA vaccines. CONCLUSION: Findings in this report should not deter COVID-19 vaccinations given the rarity of aforementioned ocular complications and the greater benefit of protection from COVID-19 infection. Medical practitioners, however, should remain mindful of potential ocular complications, given the greater likelihood of occurrence with increasing vaccination booster rates.

Case of Suspected SARS-CoV-2 Vaccine-induced Immune Thrombotic Thrombocytopenia: Dilemma for Organ Donation. Several vaccines were developed and rolled out at an unprecedented rate in response to the coronavirus disease-2019 (COVID-19) pandemic. Most vaccines approved globally by WHO for emergency use to combat the pandemic were deemed remarkably effective and safe. Despite the safety, rare incidences of vaccine-induced thrombosis and thrombocytopenia (VITT), sometimes known as vaccine-induced prothrombotic thrombocytopenia (VIPIT), have been reported. We report a case of young female with prothrombotic conditions and suspected VITT who developed catastrophic cerebral venous sinus thrombosis (CVST) and progressed to brain death. We highlight hurdles of organ retrieval from a brain-dead patient with suspected SARS-CoV-2 vaccine-induced immune thrombotic thrombocytopenia. There is limited data and lack of substantial evidence regarding transplantation of organs from brain-dead patients with suspected VITT. HOW TO CITE THIS ARTICLE: Tiwari AM, Zirpe KG, Gurav SK, Bhirud LB, Suryawanshi RS, Kulkarni SS. Case of Suspected SARS-CoV-2 Vaccine-induced Immune Thrombotic Thrombocytopenia: Dilemma for Organ Donation. Indian J Crit Care Med 2022;26(4):514-517.

Antibody response after two doses of homologous or heterologous SARS-CoV-2 vaccines in healthcare workers at health promotion centers: A prospective observational study. Assaying of anti-spike-protein receptor-binding domainÂ (S-RBD) antibodies areÂ used to aid evaluations of the immune statuses of individuals. The aim of this study was to determine the antibody response after two doses of homologous or heterologous severe acute respiratory syndrome coronavirus 2Â (SARS-CoV-2) vaccines and to identify the factors affecting this response among healthcare workersÂ (HCWs) at health promotion centers.Â In this prospective observational study, 1095 consenting HCWs were recruited from 16 health checkup centers and were tested at T0 (day of first dose), T1-1 (1 month after first dose), T2-0 (day of second dose), T2-1 (1 month after second dose), and T2-3 (3 months after second dose). SARS-CoV-2 antibodies were measured using a chemiluminescence microparticle immunoassay with SARS-CoV-2 IgG II Quant in the ARCHITECT system (Abbott Diagnostics).Â At T1-1, anti-SARS-CoV-2 S-RBD IgG levels were significantly higher in participants who received messengerÂ RNA (mRNA) vaccines than in those who received viral vector

vaccines (pâ€‰<â€‰0.001). At T2-1, anti-SARS-CoV-2 S-RBD IgG levels were about 10 times higher than at T1-1 in participants who received homologous mRNA vaccines, which decreased to a third of those at T2-3. Anti-SARS-CoV-2 S-RBD IgG levels were highest among those who received homologous mRNA vaccines, followed by heterologous mRNA viral vector vaccines and homologous viral vector vaccines at T2-3 (pâ€‰<â€‰0.001). In a multivariable linear regression analysis, being female, taking at least one mRNA vaccine, and having a history of recovery from coronavirus disease 2019Â (COVID-19) were significantly associated with anti-S-RBD levels.Â Anti-SARS-CoV-2 S-RBD IgG levels were decreased at 3 months after two-dose vaccinations and were associated with sex, vaccine type, and COVID-19 history.

Impaired humoral and cellular response to primary COVID-19 vaccination in patients less than 2â€‰years after allogeneic bone marrow transplant. Allogeneic haematopoietic stem cell transplant (HSCT) recipients remain at high risk of adverse outcomes from coronavirus disease 2019 (COVID-19) and emerging variants. The optimal prophylactic vaccine strategy for this cohort is not defined. T cell-mediated immunity is a critical component of graft-versus-tumour effect and in determining vaccine immunogenicity. Using validated anti-spike (S) immunoglobulin G (IgG) and S-specific interferon-gamma enzyme-linked immunospot (IFNÎ³-ELIspot)Â assays we analysed response to a two-dose vaccination schedule (either BNT162b2 or ChAdOx1) in 33 HSCT recipients at â‰¤2â€‰years from transplant, alongside vaccine-matched healthy controls (HCs). After two vaccines, infection-naÃ¯ve HSCT recipients had a significantly lower rate of seroconversion compared to infection-naÃ¯ve HCs (25/32 HSCT vs. 39/39 HCs no responders) and had lower S-specific T-cell responses. The HSCT recipients who received BNT162b2 had a higher rate of seroconversion compared to ChAdOx1 (89% vs. 74%) and significantly higher anti-S IgG titres (pÂ =Â 0.022). S-specific T-cell responses were seen after one vaccine in HCs and HSCT recipients. However, two vaccines enhanced S-specific T-cell responses in HCs but not in the majority of HSCT recipients. These data demonstrate limited immunogenicity of two-dose vaccination strategies in HSCT recipients, bolstering evidence of the need for additional boosters and/or alternative prophylactic measures in this group.

The potential rationale of COVID-19 vaccine-induced myopericarditis.

Self-Reported and Physiologic Reactions to Third BNT162b2 mRNA COVID-19 (Booster) Vaccine Dose. Despite extensive technological advances in recent years, objective and continuous assessment of physiologic measures after vaccination is rarely performed. We conducted a prospective observational study to evaluate short-term self-reported and physiologic reactions to the booster BNT162b2 mRNA (Pfizer-BioNTech, https://www.pfizer.com) vaccine dose. A total of 1,609 participants were equipped with smartwatches and completed daily questionnaires through a dedicated mobile application. The extent of systemic reactions reported after the booster dose was similar to that of the second dose and considerably greater than that of the first dose. Analyses of objective heart rate and heart rate variability measures recorded by smartwatches further supported this finding. Subjective and objective reactions after the booster dose were more apparent in younger participants and in participants who did not have underlying medical conditions. Our findings further support the safety of the booster dose from subjective and objective perspectives and underscore the need for integrating wearables in clinical trials.

Letter to editor about the articles of "Six-month sequelae of post-vaccination SARS-CoV-2 infection: A retrospective cohort study of 10,024 breakthrough infections".

Third trimester messenger RNA COVID-19 booster vaccination upsurge maternal and neonatal SARS-CoV-2 immunoglobulin G antibody levels at birth. OBJECTIVE: BNT162b2 messenger RNA (mRNA) COVID-19 vaccine administered during pregnancy was found to produce a strong maternal immunoglobulin (IgG) response which crosses the placenta to the newborn. Our aim was to evaluate maternal and neonatal SARS-CoV-2 IgG antibody levels at birth, following a COVID-19 booster vaccine

during the third trimester. STUDY DESIGN: A prospective cohort study including women admitted to delivery ward at least 7Â days after their BNT162b2 (Pfizer/BioNTech) booster vaccination without a prior clinical COVID-19 infection. SARS-CoV-2 IgG antibodies levels were measured in maternal blood upon admission to delivery and in the umbilical blood within 30Â min following delivery. The correlation between antibody titers, feto-maternal characteristics, maternal side effects following vaccination, and time interval from vaccination to delivery were analyzed. RESULTS: Between September to November 2021, high antibody levels were measured in all 102 women and 93 neonatal blood samples, at a meanÂ Â±Â standard deviation duration of 7.0Â Â±Â 2.9Â weeks after the third vaccine. We found positive correlation between maternal and neonatal antibodies (rÂ =Â 0.73, 95% confidence interval [CI] 0.61 to 0.81, pÂ <Â 0.001), with neonatal titers approximately 1.4 times higher compared to maternal titers. In the multivariable analysis maternal antibody levels dropped by -7.2% (95% CI -12.0 to -2.3%, pÂ =Â 0.005) for each week that passed since the receipt of the third vaccine dose. In contrary, systemic side effects after the third vaccine were associated with higher maternal antibody levels of 52.0% (95% CI 4.7 to 120.8%, pÂ =Â 0.028). Also, for each 1 unit increase in maternal body mass index, maternal antibody levels increased by 3.6% (95% CI 0.4 to 6.9%, pÂ =Â 0.025). CONCLUSIONS: BNT162b2 mRNA COVID-19 booster dose during the third trimester of pregnancy was associated with strong maternal and neonatal responses as reflected by maternal and neonatal SARS-CoV-2 IgG antibody levels measured at birth. These findings support the administration of the COVID-19 booster to pregnant women to restore maternal and neonatal protection during the ongoing pandemic.

COVID-19 AdenoviralVector Vaccine and Central Retinal Vein Occlusion. PURPOSE: The purpose of this article is to report a case of sudden onset ischemic retinal central vein occlusion after a second dose of COVID-19 adenoviral vector vaccine. CASE REPORT/OBSERVATIONS: A 54-year-old woman with systemic arterial hypertension developed ischemic central retinal vein occlusion in her right eye on day 2 after the second dose of COVID-19 adenoviral vector vaccine ChAdOx1 nCoV-19/ AZD1222, Oxford-AstraZeneca. CONCLUSION: Adenoviral vector vaccine promotes both cellular and humoral immune responses, increasing the level of inflammatory cytokines. These cytokines are the same implied in the possible pathogenesis of central retinal vein occlusion. Subsequently, we recommend informing patients at risk of possible ocular adverse events, which require urgent evaluation.

Sweet-like syndrome and multiple COVID arm syndrome following COVID-19 vaccines: 'specific' patterns in a series of 192 patients. The two clinico-pathological patterns are 'Sweet-like syndrome' and 'Multiple COVID-Arm'. 'Sweet-like syndrome' presents clinically as erythematous and oedematous papules or plaques, sometimes developing vesiculation or bullae. Histology shows classical Sweet syndrome with a diffuse dermal neutrophilic infiltrate, or an infiltrate of histiocyte-like immature myeloid cells consistent with a histiocytoid Sweet syndrome. 'Multiple COVID-arm' is characterized by multiple large inflammatory plaques with histological analyses showing a perivascular and interstitial inflammatory infiltrate with eosinophils.

SARS-CoV-2-specific antibodies and neutralization capacity in breast milk following infection vs vaccination. Anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)Â antibodies have been found in breast milk following both natural SARS-CoV-2 infection and coronavirus disease 2019 (COVID-19)Â vaccination. This was a prospective study to evaluate the temporal changes in amount and neutralization capacity of anti-SARS-CoV-2 antibodies in breast milk stimulated by natural infection and by vaccination. Serial breast milk samples were collected from postnatal women who were recruited through convenience sampling. We found a rapid increase in neutralizing SARS-CoV-2-specific antibodies in breast milk from both study groups. Amongst the infection group, the median immunoglobulin A (IgA) level was 16.99 (range, 0-86.56)â€‰ng/mL and median binding capacity was 33.65% (range, 0-67.65%), while in the vaccination group these were 30.80 (range, 0-

77.40)â€‰ng/mL and 23.80% (range, 0-42.80%), respectively. In both groups, both binding capacity and IgA levels decreased progressively over time after peaking. Neutralizing activity had become undetectable by about 150â€‰days after the first dose of the vaccine, but a vaccine booster dose restored secretion of neutralizing IgA, albeit with different levels of response in different individuals. This highlights the importance of the vaccine booster dose in sustaining neutralizing antibody levels in breast milk, which may potentially provide protection for very young children, who cannot receive the COVID-19 vaccine. Â© 2022 International Society of Ultrasound in Obstetrics and Gynecology.

Urticarial vasculitis after COVID-19 vaccination: A case report and literature review.

Myocarditis after COVID-19 mRNA vaccination: A systematic review of case reports and case series. BACKGROUND: The coronavirus disease of 2019 (COVID-19) is a global pandemic with over 266 million cases and 5 million deaths worldwide. Anti-COVID-19 vaccinations have had exceptional success in subduing the incidence, prevalence, and disease severity of COVID-19, but rare cases of myocarditis have been reported after COVID-19 vaccinations. HYPOTHESIS: Myocarditis occurring after COVID-19 mRNA vaccinations have distinguishable clinical characteristics. They usually have a favorable prognosis. METHODS: We performed a systematic literature search on PUBMED and MEDLINE database from inception to December 5, 2021. Studies were analyzed based on predetermined eligibility criteria. RESULTS: A total of 57 studies containing 275 cases of COVID-19 vaccine-associated myocarditis were catalogued. Mean age was 26.7 yearsÂ and male to female ratio was 14:1. For 86.9% of patients, myocarditis occurred after the second dose. Average time to onset and length of hospitalization were 3.7Â and 3.9 days, respectively. Prognosis was largely benign, but there was a 1.1% reported mortality. Chest pain (95.2%), elevation of troponin (100%), and ST elevation on electrocardiographyÂ (68.5%) were common. Nonsteroidal anti-inflammatory drugsÂ (81.4%) were the most used medication, followed by colchicine (33.1%). CONCLUSIONS: Patients with COVID-19 vaccine-associated myocarditis are usually younger males presenting with chest pain 3-4 days after receiving their second dose of COVID vaccine. Diagnosis is made by exclusion of all other etiologies. Given significant population benefit from COVID-19 vaccination, physicians should continue to encourage vaccination while remaining vigilant of the very rare occurrence of myocarditis following COVID-19 vaccination.

The use of corticosteroids in patients with COVID-19 vaccine-related cerebral venous thrombosis.

Fulminant Myocarditis 24 Days after Coronavirus Disease Messenger Ribonucleic Acid Vaccination. A 60-year-old Japanese woman was hospitalized for cardiogenic shock 24 days after receiving the second dose of the coronavirus disease 2019 BNT162b2 vaccine. Impella CP left ventricular assist device implantation and venoarterial peripheral extracorporeal membranous oxygenation were immediately initiated along with inotropic support and steroid pulse therapy, as an endomyocardial biopsy specimen showed myocarditis. Three weeks later, her cardiac function had recovered, and she was discharged. An immune response associated with the presence of spike protein in cardiac myocytes may be related to myocarditis in the present case because of positive immunostaining for severe acute respiratory syndrome coronavirus 2 spike protein and C4d in the myocardium.

Schnitzler Syndrome after COVID-19 Vaccination.

Assessment of Delayed Large Local Reactions After the First Dose of the SARS-CoV-2 mRNA-1273 Vaccine in Japan. IMPORTANCE: A delayed large local reaction (DLLR) is a delayed-onset adverse skin reaction that may occur after injection of the mRNA-1273 vaccine against SARS-CoV-2. OBJECTIVE: To examine the associations between sex and age and susceptibility of DLLRs after mRNA-1273 vaccination. DESIGN, SETTING, AND PARTICIPANTS: This retrospective cross-sectional study was conducted at the Self-Defense Forces large-scale vaccination center in Tokyo, Japan, from May 24 to November 30, 2021. Participants were recipients of the second dose of the mRNA-1273 vaccine who had received the first dose 4 to 6 weeks earlier. Five experienced dermatologists interviewed

participants to assess whether they had experienced symptoms of DLLR after administration of the first dose of the vaccine. EXPOSURE: Receipt of the first dose of the mRNA-1273 vaccine. MAIN OUTCOMES AND MEASURES: The primary outcome was the incidence rate of DLLR stratified by sex and age group. Odds ratios (ORs) were calculated to evaluate the differences between groups. Outcomes were tested for significance using the Pearson Ï‡2 test with 95% CIs. RESULTS: Of 5893 participants in the study, 3318 (56.3%) were male (median age, 55 years [IQR, 38-68 years]) and 2575 (43.7%) were female (median age, 50 years [IQR, 34-67 years]). A total of 747 participants (12.7%) experienced DLLR symptoms after the first dose of the mRNA-1273 vaccine. Symptoms were mild and not considered as contraindications to the vaccine. The incidence rate was significantly higher among females (22.4% [577 participants]; OR, 5.30; 95% CI, 4.42-6.34) than among males (5.1% [170 participants]; reference). Moreover, the incidence rate was significantly higher among participants aged 30 to 39 years (14.3% [129 participants]; OR, 1.68; 95% CI, 1.25-2.26), 40 to 49 years (15.8% [136 participants]; OR, 1.89; 95% CI, 1.41-2.53), 50 to 59 years (14.9% [104 participants]; OR, 1.76; 95% CI, 1.29-2.40), and 60 to 69 years (12.6% [182 participants]; OR, 1.45; 95% CI, 1.10-1.91) than among participants aged 18 to 29 years (9.0% [81 participants]; reference). CONCLUSIONS AND RELEVANCE: In this cross-sectional study, the first dose of the SARS-CoV-2 mRNA-1273 vaccine was associated with a higher incidence of DLLR among females and among individuals aged 30 to 69 years. The findings suggest that DLLR may be a type IV allergic skin reaction.

Intention to receive a COVID-19 vaccine booster dose and associated factors in Malaysia. This study aims to provide evidence of hesitancy in receiving the COVID-19 booster vaccine and associated factors in the vaccinated population that have completed a primary vaccination series. An anonymous web-based survey was disseminated to Malaysian adults aged â‰¥18â€‰years via social media platforms. A total of 1010 responses were collected, of which 43.0% (95%CI 39.9-46.0) declared a definite willingness to receive a COVID-19 vaccine booster, 38.2% (95%CI 35.2-44.3) reported being somewhat willing and only 5.7% (95%CI 4.5-7.4) reported being definitely unwilling. Demographically younger participants, those of higher income, Chinese ethnicity and those from the central region reported significantly higher odds of a definite willingness to receive the COVID-19 vaccine booster compared to the reference group (somewhat willing/undecided/somewhat unwilling/definitely unwilling). Having no side effects with past COVID-19 vaccination was associated with a significantly higher odds of definite willingness (ORâ€‰=â€‰2.82, 95% CI 1.33-5.99). A lower (range 6-22) pandemic fatigue score (ORâ€‰=â€‰2.34, 95% CI 1.75-3.22) and higher (range 24-30) preventive practices score (ORâ€‰=â€‰2.45, 95% CI 1.80-3.34) were also associated with higher odds of definite willingness. Regarding attitudes toward COVID-19 booster vaccine, having fewer concerns about the side effects of booster vaccination and the uncertain long-term safety of multiple COVID-19 vaccinations were found to create greater odds of a definite willingness to receive the COVID-19 vaccine booster. Findings from this study provided insights into demographic characteristics and important behavioral and attitudinal factors associated with COVID-19 vaccine booster hesitancy.

4BNT162b2 mRNA COVID-19 vaccine and semen: What do we know? BACKGROUND: The effects of an mRNA COVID-19 vaccine on spermatozoa parameters are not known. The aim of this study was to evaluate the effect of the BNT162b2 mRNA COVID-19 vaccine on human semen, comparing spermatozoa parameters before and after vaccine inoculation. MATERIALS AND METHODS: In this single-center prospective study, voluntary subjects who received mRNA vaccines from February to July 2021 were enrolled. The study population included male subjects aged between 18 and 45 years who completed the BNT162b2 mRNA COVID-19 vaccine cycle. All subjects were evaluated before the first dose of vaccine (T0) and after 3 months (T1) with semen analysis and further analysis of seminal plasma, including colorimetric determination of reactive oxygen metabolites (d-ROM test), electrolytes, and interleukin 6 (IL-6) assessment by enzyme-linked immunosorbent assay technology.

RESULTS: The experimental sample included 47 subjects (age: 29.3 Â± 6.0 years, range 24-32; body mass index: 23.15 Â± 2.5 kg/m(2) , range 19.2-28.0). All the subjects reported no systemic side effects. No significant differences were observed in any spermatozoa parameter between T0 and T1. A subanalysis was performed in oligoazoospermic and asthenozoospermic subjects, confirming the same results. Electrolyte analysis also showed no significant differences before and after vaccine inoculation. Finally, no significant differences were observed in T0, compared to T1 for the d-ROM test and IL-6. DISCUSSION AND CONCLUSION: In this study, no significant differences in spermatozoa parameters before and after vaccine inoculations were found. Furthermore, oxidative stress analysis,, the activity of the cell membrane, and IL-6, as a marker of inflammation, was not affected by the mRNA COVID-19 vaccine. These results suggest that this vaccine is safe for male semen quality.

Bilateral facial palsy with paresthesias, variant of Guillain-BarrÃ© syndrome following COVID-19 vaccine: A case series of 9 patients. Several cases of Guillain-BarrÃ© Syndrome (GBS) associated with COVID-19 vaccination have been reported, including the rare subtype known as Bilateral Facial Palsy with paresthesias (BFP). To date, it is not known whether a causal relationship may exist between the two. We report 9 cases of BFP in patients vaccinated against COVID-19 in the previous month. Nerve conduction studies revealed demyelinating polyneuropathy in 4 patients, and 5 presented bilateral, focal facial nerve involvement, exclusively. Ganglioside antibody panel was positive in 4 patients (anti-GM1=2, anti-GD1a=1 and anti-sulfatide=1). Seven patients received intravenous immunoglobulin treatment, one plasma exchange, and one patient died from sudden cardiac arrest following arrhythmia before treatment could be administered. Rates of BFP following COVID-19 vaccination, did not differ from those reported in previous series. Epidemiological studies are essential to determine whether a causal relationship may exist between this rare form of GBS and COVID-19 vaccination.

Prolonged Diarrhea Following COVID-19 Vaccination: A Case Report and Literature Review. Vaccination against coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is currently underway across countries worldwide. However, the prevalence and characteristics of prolonged adverse events lasting for several months after receiving the vaccine remain largely unknown. We herein report a 46-year-old woman with prolonged diarrhea and vomiting after receiving the BNT162b2 mRNA vaccine for COVID-19. She had no notable medical history, including that of gastrointestinal diseases. She developed vomiting several hours after receiving the first vaccine dose and further developed severe diarrhea after 7 days. Several days after the second vaccine dose, her condition deteriorated, unrelieved by symptomatic therapies, including anti-diarrheal drugs. Abdominal computed tomography (CT) revealed inflammatory changes in the entire segment of the small intestine with wall thickening. The upper and lower gastrointestinal and capsule endoscopies were unremarkable. The patient's symptoms persisted for more than 6 months after the second vaccine dose. A Vaccine Adverse Event Reporting System (VAERS) database search suggested that diarrhea is observed in approximately 3% of all vaccine recipients, but a literature review indicated that prolonged gastrointestinal symptoms lasting for several months is very rare. In summary, a case of prolonged unexplained gastrointestinal symptoms, possibly based on inflammatory changes in the small intestine, is described. A literature search revealed that this type of manifestation is very rare, and further evidence is needed to determine the causality between vaccination and gastrointestinal symptoms.

Association of Severe Acute Respiratory Syndrome Coronavirus 2 Vaccination or a Prior Positive Test Result in Adolescents during the Delta Variant Surge in Kentucky. In a cross-sectional study of 89Â 736 adolescents in Kentucky, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination provided an estimated protection against infection of 81% when the highly transmissible Delta variant was predominant. Vaccination provided added benefit to those with a history of prior

infection. These findings support the recommendation that all adolescents receive SARS-CoV-2 vaccination.

Safety and immunogenicity of a live-attenuated influenza virus vector-based intranasal SARS-CoV-2 vaccine in adults: randomised, double-blind, placebo-controlled, phase 1 and 2 trials.

BACKGROUND: All currently available SARS-CoV-2 vaccines are administered by intramuscular injection. We aimed to evaluate the safety and immunogenicity of a live-attenuated influenza virus vector-based SARS-CoV-2 vaccine (dNS1-RBD) administered by intranasal spray in healthy adults. METHODS: We did double-blind, randomised, placebo-controlled phase 1 and 2 trials, followed by a phase 2 extension trial, at a single centre in Jiangsu, China. Healthy adults (â‰¥18 years) who had negative serum or fingertip blood total antibody tests for SARS-CoV-2 (in phases 1 and 2), with no prevalent SARS-CoV-2 infection or history of infection and no SARS-CoV-2 vaccination history (in all three trials reported here), were enrolled. Participants were randomly allocated (4:1 in phase 1, 2:1 in phase 2, and 1:1 in the extension trial) to receive two intranasal doses of the dNS1-RBD vaccine or placebo on days 0 and 14 or, for half of the participants in phase 2, on days 0 and 21. To avoid cross-contamination during administration, vaccine and placebo recipients were vaccinated in separate rooms in the extension trial. The phase 1 primary outcome was safety (adverse events recorded on days 0-44; serious adverse events recorded from day 0 until 12 months after the second dose). In the phase 2 and extension trials, the primary immunogenicity outcomes were SARS-CoV-2-specific T-cell response in peripheral blood (measured by IFN-Î³ ELISpot), proportion of participants with positive conversion for SARS-CoV-2 receptor-binding domain (RBD)-specific IgG and secretory IgA (s-IgA) antibodies, and concentration of SARS-CoV-2 RBD IgG in serum and SARS-CoV-2 RBD s-IgA in the nasopharynx (measured by ELISA) at 1 month after the second dose in the per-protocol set for immunogenicity. Ï‡(2) test and Fisher's exact test were used to analyse categorical data, and t test and Wilcoxon rank sum test to compare the measurement data between groups. These trials were registered with the Chinese Clinical Trial Registry (ChiCTR2000037782, ChiCTR2000039715, and ChiCTR2100048316). FINDINGS: Between Sept 1, 2020, and July 4, 2021, 63, 724, and 297 participants without a history of SARS-CoV-2 vaccination were enrolled in the phase 1, phase 2, and extension trials, respectively. At least one adverse reaction after vaccination was reported in 133 (19%) of 684 participants in the vaccine groups. Most adverse reactions were mild. No vaccine-related serious adverse event was noted. Specific T-cell immune responses were observed in 211 (46% [95% CI 42-51]) of 455 vaccine recipients in the phase 2 trial, and in 48 (40% [31-49]) of 120 vaccine recipients compared with one (1% [0-5]) of 111 placebo recipients (p<0Â·0001) in the extension trial. Seroconversion for RBD-specific IgG was observed in 48 (10% [95% CI 8-13]) of 466 vaccine recipients in the phase 2 trial (geometric mean titre [GMT] 3Â·8 [95% CI 3Â·4-4Â·3] in responders), and in 31 (22% [15-29]) of 143 vaccine recipients (GMT 4Â·4 [3Â·3-5Â·8]) and zero (0% [0-2]) of 147 placebo recipients (p<0Â·0001) in the extension trial. 57 (12% [95% CI 9-16]) of 466 vaccine recipients had positive conversion for RBD-specific s-IgA (GMT 3Â·8 [95% CI 3Â·5-4Â·1] in responders) in the phase 2 trial, as did 18 (13% [8-19]) of 143 vaccine recipients (GMT 5Â·2 [4Â·0-6Â·8]) and zero (0% [0-2]) of 147 placebo recipients (p<0Â·0001) in the extension trial. INTERPRETATION: dNS1-RBD was well tolerated in adults. Weak T-cell immunity in peripheral blood, as well as weak humoral and mucosal immune responses against SARS-CoV-2, were detected in vaccine recipients. Further studies are warranted to verify the safety and efficacy of intranasal vaccines as a potential supplement to current intramuscular SARS-CoV-2 vaccine pools. Steps should be taken in future studies to reduce the potential for cross-contamination caused by the vaccine strain aerosol during administration. FUNDING: National Key Research and Development Program of China, National Science, Fujian Provincial Science, CAMS Innovation Fund for Medical Sciences, and Beijing Wantai Biological Pharmacy Enterprise.

Multiple Evanescent White Dot Syndrome following BioNTech SARS-CoV2 mRNA vaccination.
Association between Vaccination with the BNT162b2 mRNA Coronavirus Disease 2019 Vaccine and Noninfectious Uveitis: A Population-Based Study. PURPOSE: To assess the association between BNT162b2 mRNA coronavirus disease 2019 (COVID-19) vaccine and the risk of active noninfectious uveitis (NIU). DESIGN: Retrospective, population-based study. PARTICIPANTS: Two million six hundred two thousand five hundred fifty-seven people who received the first vaccine dose between December 20, 2020, and April 30, 2021, and 2 441 719 people who received the second vaccine dose between January 10, 2021, and April 30,Â 2021. METHODS: Events of active NIU were included if they occurred within 21 days after either vaccine dose. Active NIU was defined as newly active or worsening ocular inflammation requiring initiation or increase in local or systemic corticosteroids. Observed cases were compared with the expected number, based on the experience of the population inÂ 2019. MAIN OUTCOME MEASURES: Age- and sex-adjusted standardized incidence ratios (SIRs) and attributable risks after BNT126b2 vaccination. RESULTS: Overall, 100 and 88 events of active NIU were recorded within 21 days after the first and second vaccine doses, respectively. Using the experience of the population in 2019 as a reference, after the first dose, the estimated age- and sex-adjusted SIR was 1.41 (95% confidence interval [CI], 1.15-1.71) along with a 21-day attributable risk of 1.12 cases per 100 000 vaccinees. After the second dose, the SIR was 1.31 (95% CI, 1.05-1.62), with an estimated attributable risk of 0.86 cases per 100 000 vaccinees. Anterior uveitis was the most common site of inflammation, occurring in 90.96% of eyes, and idiopathic uveitis was the most common cause (56.38%). CONCLUSIONS: This study suggests that the BNT162b2 mRNA COVID-19 vaccine may be associated with an increased risk of active NIU. However, considering the small effect size and study limitations, this study does not provide proof for a cause-and-effect relationship. The small estimated attributable risks suggest that the impact on public health is relatively minor.
Editorial Comment: Prolonged Resolution of COVID-19 Vaccine-Related Axillary Lymphadenopathy Necessitates a Long Imaging Follow-Up Interval.
Multisystem Inflammatory Syndrome after Breakthrough SARS-CoV-2 Infection in 2 Immunized Adolescents, United States. Eight weeks after having laboratory-confirmed SARS-CoV-2 breakthrough infections, 2 otherwise healthy, fully immunized adolescent patients in the United States who were experiencing related signs and symptoms were diagnosed with multisystem inflammatory syndrome in children. Our findings indicate that COVID-19 vaccination does not completely protect adolescents against multisystem inflammatory syndrome.
A single-center COVID-19 vaccine experience with CoronaVac and BNT162b2 in familial Mediterranean fever patients. AIM: To determine frequency of adverse events and attacks related to vaccination in recipients of CoronaVac and BNT162b2 in familial Mediterranean fever (FMF) patients, and to search whether history of prior COVID-19 or a booster dose increases occurrence of adverse events/attacks. METHODS: FMF patients were surveyed for administration of any COVID-19 vaccine and vaccine-related adverse events or FMF attacks. Demographic, clinical, vaccine-related data, history of COVID-19 infection before or after vaccination, adherence to FMF treatment during vaccination were collected. RESULTS: A total of 161 vaccinated FMF patients were included. Ninety-three patients out of 161 had reported suffering from an adverse event/attack after a vaccine dose. There were 54.7% of BNT162b2 recipients who reported any adverse event after any vaccine dose in comparison to 29.9% of CoronaVac recipients (Pâ€‰<â€‰.001). There were 22.2% of BNT162b2 recipients who reported suffering from a FMF attack within 1â€‰month after vaccination in comparison to 19.4% of CoronaVac recipients (PÂ =Â .653). When patients with or without adverse event/attack were compared, no significant differences were observed in means of demographics, comorbid diseases, disease duration, total vaccine doses, or treatments adhered to for FMF. Rates of adverse events/attacks were similar between patients with and without prior COVID-

19. In booster recipients, adverse events/attacks were most frequent after the booster dose. CONCLUSIONS: A considerable number of FMF patients suffered from vaccine-related adverse events/attacks, particularly with BNT162b2. No serious events or mortalities due to vaccination were detected. Demographics, clinical characteristics and prior history of vaccination did not significantly affect these results. We observed an increased rate of adverse events/attacks with booster dose administration.

Seropositivity to SARS-CoV-2 in Alberta, Canada in a post-vaccination period (March 2021-July 2021). BACKGROUND: The COVID-19 pandemic has necessitated the need to rapidly make public health decisions. We systematically evaluated SARS-CoV-2 seropositivity to understand local COVID-19 epidemiology and support evidence-based public health decision making. METHODS: Residual blood samples were collected for SARS-CoV-2 receptor binding domain (RBD) IgG testing over a 1-5â€‰day period monthly from 26 February 2021-9 July 2021 from six clinical laboratories across the province of Alberta, Canada. Monthly crude and adjusted (for age and gender) seropositivity were calculated. Results were linked to provincial administrative, laboratory, and vaccine databases. RESULTS: 60,632 individual blood samples were tested. Vaccination data were available for 98.8% of samples. Adjusted RBD IgG positivity rose from 11.9% (95% confidence interval [CI] 11.9-12.0%) in March 2021 to 70.2% (95% CI 70.2-70.3%) in July 2021 (pâ€‰<â€‰.0001). Seropositivity rose from 9.4% (95% CI 9.3-9.4%) in March 2021 to 20.2% (95% CI 20.1-20.2%) in July 2021 in unvaccinated Albertans. Unvaccinated seropositive individuals were from geographic areas with significantly (pâ€‰<â€‰.001) lower median household income, lower proportion of married/common-law relationships, larger average household size and higher proportions of visible minorities compared to seronegative unvaccinated individuals. In July 2021, the age groups with the lowest and highest seropositivity in unvaccinated Albertans were those â‰¥80â€‰years (12.0%, 95% CI 5.3-18.6%) and 20-29â€‰years (24.2%, 95% CI 19.6-28.8%), respectively. Of seropositive unvaccinated individuals, 50.2% (95% CI 45.9-54.5%) had no record of prior SARS-CoV-2 molecular testing. CONCLUSIONS: Longitudinal surveillance of SARS-CoV-2 seropositivity with data linkage is valuable for decision-making during the pandemic.

Neuroretinitis after the second injection of a SARS-CoV-2-vaccine: A case report. PURPOSE: We report the first case of neuroretinitis after administration of a second dose of a messenger RNA vaccine for coronavirus disease-2019 (COVID-19). OBSERVATIONS: An 83-year-old healthy woman presented with subacute, painless, and progressive visual loss in the right eye that started 2 days after the second injection of the COVID-19 vaccine (ComirnatyÂ®) from Pfizer (New York, NY, USA) and BioNTech (Mainz, Germany). Visual acuities were hand motion perception in the right eye and 20/30 in the left eye. There was optic nerve head swelling in the right eye and subretinal fluid and disruption of the photoreceptor layers in both eyes. Magnetic resonance imaging revealed an enhancement of the right optic nerve, consistent with optic neuritis. She was treated with intravenous corticosteroids, and the optic nerve swelling in the right eye resolved promptly. However, the amount of subretinal fluid worsened for 1 month and did not improve until 6 months from onset. Her visual acuity was slightly improved to finger count perception in the right eye and 20/20 in the left eye during an examination 6 months from onset. CONCLUSIONS AND IMPORTANCE: Considering the temporal relation between the second dose of vaccination and the symptom onset in our patient, the ophthalmic symptoms here reported might be considered a rare adverse effect of the ComirnatyÂ® COVID-19 vaccine. Although a causal relationship is not established, to our knowledge, this is the first report of neuroretinitis after vaccination with ComirnatyÂ®, and any further similar cases should be examined in detail.

Alopecia universalis with unusual histopathologic features after vaccination with ChAdOx1 nCoV-19 (AZD1222).

Ongoing Dizziness Following Acute COVID-19 Infection: A Single Center Pediatric Case Series. BACKGROUND: Dizziness is a common concern discussed at adolescent medical visits. In this series, we describe 9 pediatric patients with postacute sequelae of severe acute respiratory syndrome coronavirus disease 2 (SARS-CoV-2) who presented with persistent, debilitating dizziness for weeks to months after their acute infection. METHODS: Among the 9 patients, median age was 14 years (range: 11 to 17), 6 were female, and 8 had not received any SARS-CoV-2 vaccines. Five patients met diagnostic criteria for postural orthostatic tachycardia syndrome (POTS) by active standing testing and benefited from a combination of nonpharmacologic therapy (NPT) and medication. RESULTS: NPT alone did not improve symptoms in any patients. Patients who did not meet conventional criteria for POTS, but continued to have symptoms despite NPT compliance, also demonstrated subjective improvement in dizziness when medications were initiated. The majority of patients experienced improvement in dizziness and quality of life, including returning to sports teams and a regular school schedule. CONCLUSIONS: A review of the postacute sequelae of SARS-CoV-2 literature demonstrates increasing recognition of a subset of patients who develop autonomic dysfunction, including POTS, although the etiology and prognosis are not completely understood. Our case series aims to highlight the phenomenon of dysautonomia after acute SARS-CoV-2 infection and its response to therapy.

Unremarkable antibody responses against various infectious agents after inoculation with the BNT162b2 COVID-19 vaccine.

Risk of systemic vasculitis following mRNA COVID-19 vaccination: a pharmacovigilance study.

Transient Pseudothrombocytopenia Detected 8 Months After COVID-19 Vaccination. Pseudothrombocytopenia is an in vitro phenomenon of platelet aggregation due to conformational changes and exposure of cryptic antigens on the platelet surface caused by anticoagulants, leading to the aggregation of platelets and falsely lower automated platelet counts. Although it has no clinical relevance, it can lead to unnecessary fear, diagnostic errors, or unnecessary tests and interventions when unrecognized. Pseudothrombocytopenia was detected in a 25-year-old woman 8 months after the second dose of mRNA COVID-19 vaccine, BNT162b2. The pseudothrombocytopenia was transient and the duration was shorter than 3 months. As pseudothromobocytopenia is not detected unless blood is drawn for other objectives, it is difficult to determine its true occurrence among recipients of vaccines. This case shows that pseudothrombocytopenia may develop transiently even months after COVID-19 vaccination and should be considered when thrombocytopenia is found in recipients of the vaccine to avoid unnecessary fear, diagnostic errors, or unnecessary tests and interventions.

Predictors of seroconversion after coronavirus disease 2019 vaccination. BACKGROUND: Vaccine nonresponse during the coronavirus disease 2019 (COVID-19) pandemic has considerable individual and societal risks. OBJECTIVE: To investigate the clinical characteristics of patients with lack of seroconversion after vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). METHODS: Demographic and clinical data were collected from 805 patients who had validated antibody assays against the SARS-CoV-2 spike protein at least 14 days after completion of their COVID-19 vaccination. Clinical characteristics from patients with a negative (< 0.4 U/mL) antibody response were assessed and summarized. RESULTS: A total of 622 (77.3%) patients attained seroconversion as defined by a titer of greater than or equal to 0.4 U/mL, whereas 183 out of 805 (22.7%) patients exhibited no seroconversion after vaccination against SARS-CoV-2. Univariately, older age (PÂ =Â .02) and male sex were associated with a lower likelihood of seroconversion (PÂ =Â .003). Therapy with immunosuppressive drugs was noted in 93 (50.8%) of seronegative patients with most (nÂ =Â 83/93, 89.2%) receiving ongoing immunosuppressive therapy at the time of vaccination. Among the 134 (73.2%) seronegative patients with immunodeficiency, 110 (82.1%) had primary immunodeficiency. Cancer (nÂ =Â 128, 69.9%), B cell depletion therapy (nÂ =Â 90/115, 78.3%), and immunosuppressant steroid use (nÂ =Â 71/93 on immunosuppressants, 76.3%) were the

other common characteristics among the vaccine nonresponders. More importantly, our study did not evaluate the actual efficacy of COVID-19 vaccination. CONCLUSION: Vaccine responses vary by age and sex, with men showing lower rates of seroconversion as compared with women. Primary immunodeficiency along with active malignancy and ongoing immunosuppression with steroids or B cell depletion therapy appeared to be the most common characteristics for those with a lack of vaccine seroconversion after COVID-19 vaccination.

Fatal intracranial hemorrhage in patient with thrombocytopenia and positive HIT antibodies after vaccination with ChAdOx1 nCoV-19 - VITT without thrombosis?

Do Side Effects to the Primary COVID-19 Vaccine Reduce Intentions for a COVID-19 Vaccine Booster? BACKGROUND: Vaccines are being administered worldwide to combat the COVID-19 pandemic. Vaccine boosters are essential for maintaining immunity and protecting against virus variants. The side effects of the primary COVID-19 vaccine (e.g., headache, nausea), however, could reduce intentions to repeat the vaccination experience, thereby hindering global inoculation efforts. PURPOSE: The aim of this research was to test whether side effects of a primary COVID-19 vaccine relate to reduced intentions to receive a COVID-19 booster. The secondary aim was to test whether psychological and demographic factors predict booster intentions. METHODS: Secondary data analyses were conducted on a U.S. national sample of 551 individuals recruited through the online platform Prolific. Key measures in the dataset were side effects reported from a primary COVID-19 vaccination and subsequent intentions to receive a booster vaccine. Psychological and demographic variables that predicted primary vaccination intentions in prior studies were also measured. RESULTS: Booster intentions were high. COVID-19 booster vaccine intentions were uncorrelated with the number of side effects, intensity of side effects, or occurrence of an intense side effect from the primary COVID-19 vaccine. Correlational and regression analyses indicated intentions for a booster vaccination increased with positive vaccination attitudes, trust in vaccine development, worry about the COVID-19 pandemic, low concern over vaccine side effects, and democratic political party affiliation. CONCLUSIONS: Side effects of a primary COVID-19 vaccine were not directly associated with lower intentions to receive a booster of the COVID-19 vaccine early in the pandemic. However, many variables that predict primary vaccination intentions also predict booster intentions.

Low incidence and transient elevation of autoantibodies post mRNA COVID-19 vaccination in inflammatory arthritis. OBJECTIVES: Autoantibody seroconversion has been extensively studied in the context of COVID-19 infection but data regarding post-vaccination autoantibody production is lacking. Here we aimed to determine the incidence of common autoantibody formation following mRNA COVID-19 vaccines in patients with inflammatory arthritis (IA) and in healthy controls. METHODS: Autoantibody seroconversion was measured by serum ELISA in a longitudinal cohort of IA participants and healthy controls before and after COVID-19 mRNA-based immunization. RESULTS: Overall, there was a significantly lower incidence of ANA seroconversion in participants who did not contract COVID-19 prior to vaccination compared with those who been previously infected (7.4% vs 24.1%, Pâ€‰=â€‰0.014). Incidence of de novo anti-CCP seroconversion in all participants was low at 4.9%. Autoantibody levels were typically of low titre, transient, and not associated with increase in IA flares. CONCLUSIONS: In both health and inflammatory arthritis, the risk of autoantibody seroconversion is lower following mRNA-based immunization than following natural SARS-CoV-2 infection. Importantly, seroconversion does not correlate with self-reported IA disease flare risk, further supporting the encouragement of mRNA-based COVID-19 immunization in the IA population.

Correspondence on "Immunogenicity of COVID-19 Vaccine Doses in Patients With Inflammatory Bowel Disease".

Strong response after fourth dose of mRNA COVID-19 vaccine in autoimmune rheumatic diseases patients with poor response to inactivated vaccine. OBJECTIVES: To assess immunogenicity of a

heterologous fourth dose of an mRNA (BNT162b2) severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine in autoimmune rheumatic diseases (ARD) patients with poor/non-response to inactivated vaccine (Sinovac-CoronaVac). METHODS: A total of 164 ARD patients who were coronavirus disease 2019 (COVID-19) poor/non-responders (negative anti-SARS-CoV-2 S1/S2 IgG and/or neutralizing antibodies-NAb) to the third dose of Sinovac-CoronaVac received an additional heterologous dose of mRNA (BNT162b2) 3â€‰months after last dose. IgG and NAb were evaluated before and after the fourth dose. RESULTS: Significant increases were observed after the fourth dose in IgG (66.4 vs 95.1%, Pâ€‰<â€‰0.001), NAb positivity (5.5 vs 83.5%, Pâ€‰<â€‰0.001) and geometric mean titre (29.5 vs 215.8â€‰AU/ml, Pâ€‰<â€‰0.001), and 28 (17.1%) remained poor/non-responders. Patients with negative IgG after a fourth dose were more frequently under rituximab (Pâ€‰=â€‰0.001). Negative NAb was associated with older age (Pâ€‰=â€‰0.015), RA (Pâ€‰=â€‰0.002), SSc (Pâ€‰=â€‰0.026), LEF (Pâ€‰=â€‰0.016) and rituximab use (Pâ€‰=â€‰0.007). In multiple logistic regression analysis, prednisone dose â‰¥7.5â€‰mg/day (ORâ€‰=â€‰0.34; Pâ€‰=â€‰0.047), LEF (ORâ€‰=â€‰0.32, Pâ€‰=â€‰0.036) and rituximab use (ORâ€‰=â€‰0.19, Pâ€‰=â€‰0.022) were independently associated with negative NAb after the fourth vaccine dose. CONCLUSIONS: This is the largest study to provide evidence of a remarkable humoral response after the fourth dose of heterologous mRNA SARS-CoV-2 vaccination in ARD patients with poor/non-response to the third dose of an inactivated vaccine. We further identified that treatment, particularly rituximab and prednisone, impaired antibody response to this additional dose. TRIAL REGISTRATION: ClinicalTrials.gov, https://clinicaltrials.gov, CoronavRheum #NCT04754698.

Serum Neutralizing Antibody Titers 12 Months After Coronavirus Disease 2019 Messenger RNA Vaccination: Correlation to Clinical Variables in an Adult, US Population. BACKGROUND: We studied whether comorbid conditions affect strength and duration of immune responses after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) messenger RNA vaccination in a US-based, adult population. METHODS: Sera (before and after BNT162b2 vaccination) were tested serially up to 12 months after 2 doses of vaccine for SARS-CoV-2-anti-Spike neutralizing capacity by pseudotyping assay in 124 individuals; neutralizing titers were correlated to clinical variables with multivariate regression. Postbooster (third dose) effect was measured at 1 and 3 months in 72 and 88 subjects, respectively. RESULTS: After completion of primary vaccine series, neutralizing antibody half maximal inhibitory concentration (IC50) values were high at 1 month (14-fold increase from prevaccination), declined at 6 months (3.3-fold increase), and increased at 1 month postbooster (41.5-fold increase). Three months postbooster, IC50 decreased in coronavirus disease (COVID)-naÃ¯ve individuals (18-fold increase) and increased in prior COVID 2019 (COVID-19+) individuals (132-fold increase). Age >65 years (Î² = -0.94, P = .001) and malignancy (Î² = -0.88, P = .002) reduced strength of response at 1 month. Both neutralization strength and durability at 6 months, respectively, were negatively affected by end-stage renal disease ([Î² = -1.10, P = .004]; [Î² = -0.66, P = .014]), diabetes mellitus ([Î² = -0.57, P = .032]; [Î² = -0.44, P = .028]), and systemic steroid use ([Î² = -0.066, P = .032]; [Î² = -0.55, P = .037]). Postbooster IC50 was robust against WA-1 and B.1.617.2. Postbooster neutralization increased with prior COVID-19 (Î² = 2.9, P < .0001), and malignancy reduced neutralization response (Î² = -0.68, P = .03), regardless of infection status. CONCLUSIONS: Multiple clinical factors affect the strength and duration of neutralization response after primary series vaccination, but not the postbooster dose strength. Malignancy was associated with lower booster-dose response regardless of prior COVID infection, suggesting a need for clinically guided vaccine regimens.

Functional Antibody Responses to Severe Acute Respiratory Syndrome Coronavirus 2 Variants in Children With Coronavirus Disease 2019, Multisystem Inflammatory Syndrome in Children, and After Two Doses of BNT162b2 Vaccination. BACKGROUND: Although neutralizing antibodies to severe

acute respiratory syndrome coronavirus 2 (SARS-CoV-2) correlate with protection against coronavirus disease 2019 (COVID-19), little is known about the neutralizing and antibody-dependent cell-mediated cytotoxicity (ADCC) responses to COVID-19, multisystem inflammatory syndrome in children (MIS-C), and COVID-19 vaccination in children. METHODS: We enrolled children 0-21 years of age with a history of COVID-19 (nâ€‰=â€‰13), MIS-C (nâ€‰=â€‰13), or 2 doses of BNT162b2 vaccination (nâ€‰=â€‰14) into a phlebotomy protocol. We measured pseudovirus neutralizing and functional ADCC antibodies to SARS-CoV-2 variants, including Omicron (B.1.1.529). RESULTS: The primary BNT162b2 vaccination series elicited higher neutralizing and ADCC responses with greater breadth to SARS-CoV-2 variants than COVID-19 or MIS-C, although these were diminished against Omicron. CONCLUSIONS: Serologic responses were significantly reduced against variants, particularly Omicron.
Acute onset ocular myasthenia gravis after COVID-19 vaccination: correspondence.
Systemic lupus erythematosus in the light of the COVID-19 pandemic: infection, vaccination, and impact on disease management. Patients with systemic lupus erythematosus (SLE) form a vulnerable group in terms of the impact of the COVID-19 pandemic on disease management. We conducted this overview by searches through Medline/PubMed, Scopus, and the Directory of Open Access Journals (DOAJ). The prevalence and severity of COVID-19, efficacy of COVID-19 vaccination, impact on the management of SLE, and the attitudes of SLE patients to COVID-19 and vaccination were explored. After screening and due exclusions, 198 studies were included for the final review. Patients with SLE have a greater risk of acquiring COVID-19 (0.6-22%) and related hospitalization (30%), severe disease (13.5%), and death (6.5%) than the general population. Older age, male gender, comorbidities, moderate or high disease activity, and glucocorticoid, rituximab, and cyclophosphamide use are associated with unfavorable outcomes, whereas methotrexate and belimumab use showed no association with outcomes. COVID-19 vaccines are safe in SLE with minimal risk of severe flares (<â€‰2%). Vaccine efficacy is negatively associated with glucocorticoids. The overall attitude of patients towards vaccination is positive (54-90%). The pandemic has negatively affected access to medical care, hospitalizations, procurement of drugs, employment, and the mental health of patients which need to be addressed as part of holistic care in SLE. Key Points â€¢ Lupus patients are at a greater risk of acquiring COVID-19, related hospitalization,Â severeÂ disease, and death than the general population. â€¢ COVID-19 vaccines are relatively safe for lupus patients with minimal risk of severe flares. â€¢ Lupus patients' attitude towards COVID-19 vaccination is predominantly positive.
Frailty, vaccination, and hospitalization following COVID-19 positivity in older veterans.
Tolerance to SARS-CoV-2 mRNA Vaccination in a Patient With Challenge-Confirmed PEG 2000 Allergy.
Chronic spontaneous urticaria after COVID-19 primary vaccine series and boosters.
Autoimmune Acquired Factor XIII/13 Deficiency after SARS-CoV-2 mRNA Vaccination.
Antibody response to SARS-CoV-2 vaccination following typical and three-dose dosing schedules in multiple sclerosis patients treated with disease modifying therapies. BACKGROUND: Immunizations against SARS-CoV-2 virus are now available and recommended, but the effect of additional dosing of the vaccine in immunocompromised MS patients is unknown. METHODS: Part I - A retrospective chart review of MS patients who were vaccinated against SARS-CoV-2 and tested commercially for Sars Covid Spike Protein Antibody between March 1 - June 30, 2021. Part II - Patients on treatment with anti-CD20 infusion medications who received a SARS-CoV-2 third mRNA vaccination dose August 13, 2021 - October 31, 2021 and were subsequently commercially tested for Sars Covid Spike Protein Antibody. RESULTS: Part I - A total of NÂ =Â 208 MS patients, age range 23-76 were tested, with 49% (102/208) demonstrating a humoral response. Stratified by DMT type, patients treated with interferon, teriflunomide, or a remote history of alemtuzumab (>2 years since

last DMT) yielded 100% measurable antibodies; >90% amongst patients treated with natalizumab, fumarates and glatiramer acetate; <50% measurable antibodies following vaccination in S1P modulators and anti-CD20 treated patients. Subsequently, in Part II - NÂ =Â 40 patients on anti-CD20 treatments (33 ocrelizumab, 7 rituximab) who received 3 mRNA vaccinations yielded 20% humoral response. CONCLUSIONS: MS patients are able to mount a humoral vaccine response to SARS-CoV-2, irrespective of the vaccine type administered; patients treated with S1P modulators and anti-CD20 agents are least likely to mount such a response with a typical dosing schedule. Patients treated with ocrelizumab/rituximab show a similar modest humoral immune system benefit following three doses as with standard dosing.

The national COVID-19 vaccination campaign targeting the extremely vulnerable: the Florence Medical Oncology Unit experience in patients with cancer. BACKGROUND: International and national oncology societies had released recommendations in favor of COVID-19 vaccination in cancer patients. In the context of the national vaccination campaign targeting the so called extremely vulnerable, we aimed to assess the safety and efficacy of the mRNA vaccines in a cohort of 623 patients. METHODS: Between March 26Â and April 04, 2021, the Pfizer and BioNTech BNT162b2 mRNA and the Moderna mRNA-1273 vaccines were given as a two-dose prime-boost regimen. Starting on September 25th 2021 a third dose was offered to patients in whom a suboptimal immunogenicity with COVID-19 vaccination could be expected. Safety assessments were performed by phone call 7 days after each dose. Electronic health records were accessed to review demographic information, disease history, treatment detail, and outcome events of participants patients'. FINDINGS: No toxicities were reported in 63.7%, 54%, andÂ in 48.7% patients with cancer after each dose. Mild-to-moderate pain at the injection site was the most commonly adverse event. After the second dose, 46% of the 610 patients reported toxicity, with more systemic side-effects observed. Fever was reported in 45% of patients, with a temperature â‰¥ 38Â Â°C in 21.4% of them. Of the 335 patients receiving a third vaccine dose, 51% reported toxicity, with 13% of patients reporting more than one effect. Logistic regression analysis reported mixed results, with limited variables or categories reporting a significant odd ratio. The type of vaccine reported a significant value at first dose (ORÂ =Â 0.12; CI 0.52, 0.26; pÂ =Â 0.00). Thirty-four cases of COVID-19 infection were reported with only one patient requiring a short-term hospitalization for monitoring. INTERPRETATION: The safety profile of the mRNA vaccines does not raise any specific concerns and support prioritization of vaccination for cancer patients.

Acute appendicitis in a patient immunised with COVID-19 vaccine: A case report with morphological analysis. Although the benefit/risk profile for mRNA COVID-19 vaccines is recognised as extremely favourable, appendicitis is currently considered an adverse event (AE) of special interest. We describe the case of a 58-year-old female who presented with signs and symptoms of appendicitis approximately 48â€‰hours after her first injection of the Pfizer-BioNTech vaccine. Abdominal ultrasound revealed fluid collection in the right iliac fossa and cecal wall thickening. Following the surgical visit, CT scan with contrast showed a distended appendix with thickened walls, suggestive of acute appendicitis. The patient tested negative to upper respiratory COVID-19 reverse transcription-polymerase chain reaction. Clinical trials and observational studies suggest a possible association between appendicitis and COVID-19 vaccines. Th-1 driven granulomatous inflammation reported in our case represents an infrequent nonspecific chronic inflammation of the appendix, especially in the setting of delayed or interval appendectomy. In view of the current paediatric vaccination campaign, we recommend monitoring the safety profile and potential gastrointestinal AEs associated with mRNA COVID-19 vaccines to swiftly manage subjects with gastrointestinal symptoms and prevent potential complications.

Subacute cutaneous lupus erythematosus following ChAdOx1 nCoV-19 vaccination.

A commentary on "post-SARS-CoV-2-vaccine shoulder pain: Is it relevant to the vaccine injection? - Correspondence" (int J surg 2022;100:106603).

Reply to "the significance of investigating clinical, histopathologic and virological features in pityriasis rosea and pityriasis rosea-like eruptions following COVID-19 vaccinations" by Ciccarese G. et al.

The significance of investigating clinical, histopathologic and virological features in pityriasis rosea and pityriasis rosea-like eruptions following COVID-19 vaccinations.

Inflammatory immune-mediated adverse reactions induced by COVID-19 vaccines in previously injected patients with soft tissue fillers: A case series of 20 patients. BACKGROUND: Adverse events (AE) after COVID-19 vaccines, particularly, but not solely, with those messenger RNA (mRNA)-based vaccines, have rarely been reported in patients previously treated with dermal fillers (DF). OBJECTIVE: To evaluate the morphology, clinical characteristics, the timing of presentation, and outcomes of inflammatory AE appeared in patients injected with DF, after anti-COVID-19 vaccination. METHODS: Descriptive study of a case series of 20 consecutive patients collected after the occurrence of AE in previously filled areas post COVID-19 vaccination. RESULTS: From January 2021 to July 2021, we analyzed 20 AE reactions triggered by COVID-19 vaccines in the previously mentioned cohort. They were vaccinated with Pfizer/Biontech (11; 55%), Moderna (5; 25%), Astra-Zeneca (3; 15%), and Sputnik (1; 5%). The most common manifestations were oedema/swelling, angioedema, erythema, skin induration, and granuloma. Less common reactions included myalgia and lymphadenopathy. In 13/20 (65%) cases, the AE appeared after the first dose of vaccine. These inflammatory AE appeared more rapidly after the second dose than after the first one. In 13/20 (65%) cases, the symptomatology subsided with anti-inflammatory/antihistaminic drugs, while spontaneously in 3/20 (15%). The manifestations are ongoing.in the remaining four cases (20%). CONCLUSION: Although probably rare, both RNA-based and adenovirus-based anti-COVID-19 vaccines can cause inflammatory bouts in patients previously treated with DF. In these cases, caution should be paid on subsequent vaccine doses, considering a tailored risk/benefit for any case before next vaccination.

Coronavirus Disease 2019 Outcomes, Patient Vaccination Status, and Cancer-Related Delays During the Omicron Wave: A Brief Report From the TERAVOLT Analysis. INTRODUCTION: The Thoracic Centers International coronavirus disease 2019 (COVID-19) Collaboration (TERAVOLT) registry found approximately 30% mortality in patients with thoracic malignancies during the initial COVID-19 surges. Data from South Africa suggested a decrease in severity and mortality with the Omicron wave. Our objective was to assess mortality of patients with thoracic malignancies with the Omicron-predominant wave and evaluate efficacy of vaccination. METHODS: A prospective, multicenter observational study was conducted. A total of 28 institutions contributed data from January 14, 2022, to February 4, 2022. Inclusion criteria were any thoracic cancer and a COVID-19 diagnosis on or after November 1, 2021. End points included mortality, hospitalization, symptomatic COVID-19 infection, asymptomatic COVID-19 infection, and delay in cancer therapy. Analysis was done through contingency tables and a multivariable logistic model. RESULTS: We enrolled a total of 346 patients. Median age was 65 years, 52.3% were female, 74.2% were current or former smokers, 86% had NSCLC, 72% had stage IV at time of COVID-19 diagnosis, and 66% were receiving cancer therapy. Variant was unknown for 70%; for those known, Omicron represented 82%. Overall mortality was 3.2%. Using multivariate analysis, COVID-19 vaccination with booster compared with no vaccination had a protective effect on hospitalization or death (ORÂ = 0.30, confidence interval: 0.15-0.57, pÂ = 0.0003), whereas vaccination without booster did not (ORÂ = 0.64, confidence interval: 0.33-1.24, pÂ = 0.1864). Cancer care was delayed in 56.4% of the patients. CONCLUSIONS: TERAVOLT found reduced patient mortality with the most recent COVID-19 surge. COVID-19 vaccination with booster improved outcomes of hospitalization or death. Delays in cancer therapy remain an issue, which has the potential to worsen cancer-related mortality.

Acute gastric and non-mesenteric colonic infarction following mRNA COVID-19 vaccination.
A case of pityriasis lichenoides et varioliformis acuta developed after first dose of Oxford-AstraZeneca COVID-19 vaccine.
Fulminant necrotizing eosinophilic myocarditis after COVID-19 vaccination survived with mechanical circulatory support. A 69-year-old man was hospitalized for heart failure 7Â days after coronavirus disease 2019 (COVID-19) mRNA vaccination. Electrocardiography showed ST-segment elevation and echocardiography demonstrated severe left ventricular dysfunction. Venoarterial extracorporeal membrane oxygenation and Impella 5.0 were instituted because of cardiogenic shock and ventricular fibrillation. Endomyocardial biopsy demonstrated necrotizing eosinophilic myocarditis (NEM). Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) PCR test was negative. He had no infection or history of new drug exposure. NEM was likely related to COVID-19 vaccination. He was administered 10Â mg/kg of prednisolone following methylprednisolone pulse treatment (1000Â mg/day for 3Â days). Left ventricular function recovered and he was weaned from mechanical circulatory support (MCS). Follow-up endomyocardial biopsy showed no inflammatory cell infiltration. This is the first report of biopsy-proven NEM after COVID-19 vaccination survived with MCS and immunosuppression therapy. It is a rare condition but early, accurate diagnosis and early aggressive intervention can rescue patients.
Chronic spontaneous urticaria following COVID-19 vaccination.
Editorial for "Cardiac Magnetic Resonance Imaging Findings in COVID-19 Vaccine-Related Myocarditis: A Pooled Analysis of 468 Patients".
Multisystem Inflammatory Syndrome Following SARS-CoV-2 Vaccination in Two Children. This report presents 2 pediatric cases of multisystem inflammatory syndrome in children and adults (MIS-C/A) post severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination (MIS-V). Both children presented with MIS-V within 6 weeks of receiving their first and only dose of Pfizer-BioNTech's SARS-CoV-2 vaccine. The first patient had symptoms of MIS-C/A with peri-myocarditis and shock, and the second 1 had classic Kawasaki disease features. Both responded well to intravenous immunoglobulins and/or systemic corticosteroids. Both children were positive only for SARS-2-CoV antispike (S) (and not for antinucleocapsid [NC]) antibodies consistent with a postvaccine, and not a postinfection, event. Surveillance for rare adverse events following immunization should continue, especially now that SARS-CoV-2 vaccination is approved in the 5 to 11 year age group that has had the highest risk of developing MIS-C post SARS-CoV-2 infection. Our patients did not receive any further SARS-CoV-2 vaccines. Our report highlights the importance of measuring differentiating antibodies (anti-S and anti-NC) that can be used within a specific timeframe to help determine if a patient has MIS-V post vaccine (only anti-S present), or MIS-C/A post SARS-CoV-2 infection (both anti-S and anti-NC present).
Cardiac MRI Findings in COVID-19 Vaccine-Related Myocarditis: A Pooled Analysis of 468 Patients. Understanding the pattern and severity of myocarditis caused by the coronavirus disease 2019 (COVID-19) vaccine is imperative for improving the care of the patients, and cardiac evaluation by MRI plays a key role in this regard. Our systematic review and meta-analysis aimed to summarize cardiac MRI findings in COVID-19 vaccine-related myocarditis. We performed a comprehensive systematic review of literature in PubMed, Scopus, and Google Scholar databases using key terms covering COVID-19 vaccine, myocarditis, and cardiac MRI. Individual-level patient data (IPD) and aggregated-level data (AD) studies were pooled through a two-stage analysis method. For this purpose, all IPD were first gathered into a single data set and reduced to AD, and then this AD (from IPD studies) was pooled with existing AD (from the AD studies) using fixed/random effect models. I(2) was used to assess the degree of heterogeneity, and the prespecified level of statistical significance (P value for heterogeneity) was <0.1. Based on meta-analysis of 102 studies (nÂ =Â 468 patients), 79%

(95% confidence interval [CI]: 54%-97%) of patients fulfilled Lake Louise criteria (LLC) for diagnosis of myocarditis. Cardiac MRI abnormalities included elevated T2 in 72% (95% CI: 50%-90%), myocardial late gadolinium enhancement (LGE) in 93% (95% CI: 83%-99%; nearly all with a subepicardial and/or midwall pattern), impaired left ventricular ejection fraction (LVEF) (<50%) in 4% (95% CI: 1.0%-9.0%). Moreover, elevated T1 and extracellular volume fraction (ECV) (>30), reported only by some IPD studies, were detected in 74.5% (76/102) and 32% (16/50) of patients, respectively. In conclusion, our findings may suggest that over two-thirds of patients with clinically suspected myocarditis following COVID-19 vaccination meet the LLC. COVID-19 vaccine-associated myocarditis may show a similar pattern compared to other acute myocarditis entities. Notably, preserved LVEF is probably a common finding in these patients. EVIDENCE LEVEL: 4 TECHNICAL EFFICACY: Stage 3.

Comments on COVID-19 Vaccination and Exacerbation of Idiopathic Pulmonary Fibrosis.

COVID-19 mRNA Vaccines and Interstitial Lung Disease Exacerbation: Causation or Just a Temporal Association?

Attitudes towards and safety of the SARS-CoV-2 inactivated vaccines in 188 patients with systemic lupus erythematosus: a post-vaccination cross-sectional survey. Vaccination is key in mastering the COVID-19 pandemic. Data on attitudes towards and safety of the SARS-CoV-2 inactivated vaccines in patients with systemic lupus erythematosus (SLE) are limited. A post-vaccination cross-sectional survey was conducted to obtain data on attitudes towards and safety of the SARS-CoV-2 inactivated vaccines in SLE patients compared to healthy controls. A post-vaccination cross-sectional survey was conducted in 188 patients with SLE and in 190 healthy controls who had received at least one dose of SARS-CoV-2 inactivated vaccine to find out post-vaccination adverse event (AE) or SLE flares. A total of 188 patients with SLE and 190 healthy controls vaccinated with the two-dose regimen SARS-CoV-2 inactivated vaccine were enrolled in the study. The two groups were matched in age, sex, medical background, income, and education level. All the SLE patients were in disease remission or with low disease activity with a median age of 35Â years, a sex constituent ratio of 87.4% female, and a median disease duration of 4Â years. SLE patients had much more concerns about vaccination safety (44.7% vs. 15.8%, Pâ€‰<â€‰0.001), and were much less willing to get vaccinated (57.4% vs. 88.4%, Pâ€‰<â€‰0.001). SLE patients had more mild adverse events after the first vaccine dose (43.6% vs. 25.3%, Pâ€‰=â€‰0.008), and less mild adverse events after the second vaccine dose (19.8% vs. 34.9%, Pâ€‰=â€‰0.024), compared with healthy controls. The AEs were minor and there were no serious or major adverse events in both groups. In patients with SLE, the post-vaccination disease activity remained stable. One previously undiagnosed female progressed into symptomatic SLE after one week of vaccination. Although SLE patients had concerns about the safety of the SARS-CoV-2 vaccines, the inactivated vaccination was safe in patients with stable SLE.

Retinal vascular occlusion and SARS-CoV-2 vaccination. PURPOSE: To assess the clinical and retinal imaging features of patients in whom retinal vascular occlusion (VO) had developed in temporal associations with COVID-19 vaccination. METHODS: In this retrospective case series, all consecutive adult patients with new onset VO within 6Â weeks of vaccination against COVID-19 were included in the study between May 1 and October 31, 2021. All patients had a systemic medical health assessment, full ophthalmic evaluation, and complete fundus imaging. RESULTS: Fifteen eyes of VO (14 patients) after COVID-19 vaccinations were identified. The median time between vaccination and symptoms onset was 14Â days (range 7-42Â days). The mean best-corrected visual acuity (BCVA) was 20/55 with a range of 20/20 to 20/200. Eleven of 15 eyes (73.3%) had visual acuity improvement after intravitreal treatment at 60-90Â days (range, 45-105Â days) from the presentation. Four of 5 cases without systemic risk factors for VO had a mean BCVAâ€‰>â€‰20/32 at presentation andâ€‰>â€‰20/25 at the latest evaluation. Between May 1 and October 31, 2021, a temporal association was found between the 15 reported cases and COVID-19 vaccination out of a

total of 29 VO (pâ€‰=â€‰0.05). The incidence of VO was higher in the considered period compared to the equivalent 6-month period in 2019 (1.17% vs 0.52%, respectively; pâ€‰=â€‰0.0134). CONCLUSIONS: Retinal vascular occlusion with different grades of severity are reported in temporal association with COVID-19 vaccination. The exact pathogenic mechanism needs to be further studied. No certain causal relationship can be established from this case series.

Investigate the effect of COVID-19 inactivated vaccine on sperm parameters and embryo quality in in vitro fertilization. Since the reproductive toxicity of COVID-19 vaccines have not been assessed in previous clinical trials, and studies have shown that SARS-CoV-2 is associated with a decrease in sperm parameters. Although it has been reported that the mRNA SARS-CoV-2 vaccines do not adversely affect semen parameters, whether this conclusion applies to inactivated vaccines remains unclear. Here, we conducted a study among patients who accepted in vitro fertilization (IVF) at the reproductive centre between June and August of 2021. In the enrolled cases, men who have completed two doses of COVID-19 inactivated vaccine were included in "vaccine group" (NÂ =Â 105), and those who were not vaccinated were included in "control group" (NÂ =Â 155). In this study, we compare the sperm parameters and embryo quality between these two groups. Our data showed that the sperm parameters were similar in terms of volume, sperm concentration, sperm count, progressive motility, total motility and total motile sperm count between these two groups. Similarly, no significant differences were observed in IVF outcomes. The mean number of 2PN, cleavage-stage embryos, blastocysts, and good-quality blastocysts was 8.59â€‰Â±â€‰4.47, 5.06â€‰Â±â€‰3.17 and 2.08â€‰Â±â€‰1.79 in vaccine group, 7.75â€‰Â±â€‰4.14, 4.34â€‰Â±â€‰3.06 and 1.74â€‰Â±â€‰1.54 in control group, respectively. The high-quality blastocyst rate was 41.05% (218 of 531) in vaccine group and 40.03% (269 of 672) in control group (pâ€‰>â€‰0.05). In addition, no differences were observed in biochemical and clinical pregnancy rates between the two groups. In summary, our results revealed that COVID-19 inactivated vaccine administration exhibited no negative effect on sperm parameters and embryo quality in IVF.

COVID-19 vaccines in pregnancy. COVID-19 caused by SARS-CoV-2 coronavirus has been associated with severe illness in pregnant women. Furthermore, COVID-19 during pregnancy is associated with adverse fetal outcomes including preterm labor. Pregnant women were largely excluded from initial clinical trials investigating the safety and efficacy of COVID-19 vaccines; however, they have since been included as part of the routine roll-out of these vaccines. This narrative review synthesizes the evidence on the safety, immunogenicity, and effectiveness predominantly of the mRNA COVID-19 vaccines which have been most widely used in pregnant women.

COVID-19 vaccination rate and willingness of an additional dose among inflammatory bowel disease patients receiving biologic therapy: Fearless and with desire. Effective vaccines against the SARS-CoV-2 are already available and offer a promising action to control the COVID-19 pandemic. IBD patients on biological agents accept the vaccine as well as an additional dose if recommended. BACKGROUND: Vaccination against COVID-19 prevents its severe forms and associated mortality and offers a promising action to control this pandemic. In September 2021, an additional dose of vaccine was approved in patients with immunosuppression including IBD patients on biologic agents. We evaluated the vaccination rate and additional dose willingness in this group of at risk patients. METHODS: A single-center, cross-sectional study was performed among IBD patients on biologic agents and eligible for an additional dose of the COVID-19 vaccine. IBD clinical characteristics and type of vaccine and date of administration were checked in medical records. Acceptance was evaluated after telephone or face-to-face surveys in IBD patients. RESULTS: Out of a total of 344 patients, 269 patients (46.1% male; mean age 47Â±16 years; Crohn's disease 73.6%) were included. Only 15 (5.6%) patients refused the COVID-19 vaccine mainly (40%) for conviction (COVID-19

pandemic denial). 33.3% would re-consider after discussing with their doctor and/or receiving information on the adverse effects of the vaccine. Previous to the additional dose, the COVID-19 vaccination was present in 94.4% of patients (n=254). Adverse effects occurred in 53.9% of the cases, mainly pain in the arm (40%). Up to 94.1% of the patients agreed to an additional dose and 79.4% had already received the additional dose at the final time of the assessment. CONCLUSIONS: IBD patients on biological agents accept the vaccine as well as an additional dose if recommended. Physicians in charge of IBD units should provide information and confidence in the use of the vaccine in these IBD patients.

Allergic reactions to the coronavirus disease 2019 vaccine (ARCOV) study: The McGill University Health Centre experience. BACKGROUND: Messenger RNA coronavirus disease 2019 (COVID-19) vaccines have been associated with allergic reactions. A history of anaphylaxis has been suggested as a risk factor for such reactions. Polyethylene glycol (PEG) has been proposed as a possible culprit allergen. OBJECTIVE: To investigate possible PEG or polysorbate allergy among patients reporting prior reactions to COVID-19 vaccines or PEG and to report their subsequent tolerance of COVID-19 vaccines. METHODS: From January 1, 2021, to October 31, 2021, adult patients referred to the McGill University Health Centre allergy clinics who were considered at risk of anaphylaxis were prospectively recruited. The entry criteria were any documented history of reaction to a COVID-19 vaccine or reported allergy to PEG or polysorbate. Evaluated patients underwent skin prick testing (SPT) with PEG and polysorbate. After SPT, placebo-controlled vaccine challenges were carried out. RESULTS: Of the 44 patients recruited, 40 (90.1%) had reacted to the first vaccine dose, with 18 (45%) of them had anaphylactic reaction. All patients underwent SPT and 5 (11.3%) had a positive test result. A total of 39 patients (88.6%) underwent COVID-19 vaccine challenge at the allergy clinic. Most tolerated the vaccine, with 18 (40.1%) received a single full dose, 20 (45.4%) 2 split doses, and 6 (13.6%) a graded dosing protocol. Of the 40 patients who reacted to the first dose, 2 had immediate nonsevere allergic reactions to the second dose. CONCLUSION: In this cohort of patients with a history of anaphylaxis and increased risk of allergic reactions to the COVID-19 vaccines, after allergist evaluation, including negative PEG skin testing result, the vaccine was safely administered without any serious adverse events.

The clinical and laboratory diagnosis of vaccine-induced immune thrombotic thrombocytopenia. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare but serious adverse syndrome occurring 5 to 30 days after adenoviral vector COVID-19 vaccination. Therefore, a practical evaluation of clinical assessments and laboratory testing for VITT is needed to prevent significant adverse outcomes as the global use of adenoviral vector vaccines continues. We received the clinical information and blood samples of 156 patients in Canada with a suspected diagnosis of VITT between April and July 2021. The performance characteristics of various diagnostic laboratory tests were evaluated against the platelet factor 4 (PF4)-14C-serotonin release assay (SRA) including a commercial anti-PF4/heparin immunoglobulin G (IgG)/IgA/IgM enzyme immunoassay (EIA, PF4 Enhanced; Immucor), in-house IgG-specific anti-PF4 and anti-PF4/heparin-EIAs, the standard SRA, and the PF4/heparin-SRA. Of those, 43 (27.6%) had serologically confirmed VITT-positive based on a positive PF4-SRA result and 113 (72.4%) were VITT-negative. The commercial anti-PF4/heparin EIA, the in-house anti-PF4-EIA, and anti-PF4/heparin-EIA were positive for all 43 VITT-confirmed samples (100% sensitivity) with a few false-positive results (mean specificity, 95.6%). These immunoassays had specificities of 95.6% (95% confidence interval [CI], 90.0-98.6), 96.5% (95% CI, 91.2-99.0), and 97.4% (95% CI, 92.4-99.5), respectively. Functional tests, including the standard SRA and PF4/heparin-SRA, had high specificities (100%), but poor sensitivities for VITT (16.7% [95% CI, 7.0-31.4]; and 46.2% [95% CI, 26.6-66.6], respectively). These findings suggest EIA assays that can directly detect antibodies to

PF4 or PF4/heparin have excellent performance characteristics and may be useful as a diagnostic test if the F4-SRA is unavailable.

Health professionals' COVID-19 vaccine acceptance and associated factors in Wollega University referral hospital, Western Ethiopia: A cross-sectional study. BACKGROUND: Health professionals' willingness to accept the COVID-19 vaccine is very important, and evidence suggests that only a limited proportion of health-care workers were ready to accept a COVID-19 vaccine, which is very low when compared with the risk of the disease. This study aimed to assess health professionals' acceptability and associated factors in Wollega University referral hospital, Western Ethiopia. METHODS: An institution-based cross-sectional study was conducted among health-care workers in Wollega University referral hospital from March 26-28, 2021. The data were collected by using a self-administered questionnaire. Epi-data version 3.2 was used for data entry, and STATA version 14 was used for data analysis. The binary logistic regression model was employed to determine factors associated with the acceptability of the COVID-19 vaccine. Adjusted Odds Ratio (AOR) with 95% confidence intervals was computed and statistical significance was declared at a 5% level (p-value <.05). RESULTS: A total of 191 health professionals have participated in the study. The study indicates that 65.4% (95% CI: 58.6%, 72.2%) of health professionals had the willingness to receive the COVID-19 vaccine if available. Age of health professionals (AORâ€‰=â€‰3.58, 95% CI: 1.38, 8.38), knowledge of the COVID-19 vaccine (AORâ€‰=â€‰2.98, 95% CI: 1.22, 7.23), and perception of COVID 19 vaccine (AORâ€‰=â€‰5.71, 95% CI: 2.50, 13.00) were significantly associated with vaccine acceptability. CONCLUSIONS AND RECOMMENDATIONS: Nearly, two-thirds of health professionals were willing to accept the COVID-19 vaccine, which is low. In general, continuous communication and health education have to be provided to enhance overall awareness of the COVID-19 vaccine.

Hyperviscosity syndrome in COVID-19 and related vaccines: exploring of uncertainties. Hyperviscosity syndrome (HVS) recently emerged as a complication of coronavirus disease 2019 (COVID-19) and COVID-19 vaccines. Therefore, the objectives of this critical review are to establish the association between COVID-19 and COVID-19 vaccines with the development of HVS. HVS may develop in various viral infections due to impairment of humoral and cellular immunity with elevation of immunoglobulins. COVID-19 can increase blood viscosity (BV) through modulation of fibrinogen, albumin, lipoproteins, and red blood cell (RBC) indices. HVS can cause cardiovascular and neurological complications in COVID-19 like myocardial infarction (MI) and stroke. HVS with or without abnormal RBCs function in COVID-19 participates in the reduction of tissue oxygenation with the development of cardio-metabolic complications and long COVID-19. Besides, HVS may develop in vaccine recipients with previous COVID-19 due to higher underlying Ig concentrations and rarely without previous COVID-19. Similarly, patients with metabolic syndrome are at the highest risk for propagation of HVS after COVID-19 vaccination.Â In conclusion, COVID-19 and related vaccines are linked with the development of HVS, mainly in patients with previous COVID-19 and underlying metabolic derangements. The possible mechanism of HVS in COVID-19 and related vaccines is increasing levels of fibrinogen and immunoglobulins. However, dehydration, oxidative stress, and inflammatory reactions are regarded as additional contributing factors in the pathogenesis of HVS in COVID-19. However, this critical review cannot determine the final causal relationship between COVID-19 and related vaccines and the development of HVS. Prospective and retrospective studies are warranted in this field.

Bullous pemphigoid after inactivated COVID-19 vaccination: Case report.

Atrial fibrillation with aberrant ventricular conduction after receiving Bamlanivimab/Etesevimab: a case report. Coronavirus Disease 2019 (COVID-19) is affecting millions of people globally. Several neutralizing monoclonal antibodies have been developed to limit the progression and complications of the disease. These treatments provide immediate and passive immunity. The combination therapy

with Bamlanivimab plus Etesevimab led to a lower incidence of COVID-19-related hospitalization and death and a faster reduction in the SARS-CoV-2 viral load. No or rare cases of cardiovascular side effects are reported. We present the case of a high-risk 79-years-old woman who developed atrial fibrillation with aberrant ventricular conduction after administration of neutralizing monoclonal-antibodies Bamlanivimab plus Etesevimab. The woman with a history of insulin-dependent diabetes and Grade II follicular Non-Hodgkin Lymphoma previously vaccinated with two doses of Pfizer COVID-19 vaccine, presented with malaise, headache, and SARS-CoV-2 nasal swab reverse transcription-polymerase chain reaction tested positive for the infection. She received a single dose of Bamlanivimab (70â€‰mg) + Etesevimab (1400â€‰mg). After about a week, she developed atrial fibrillation with uncontrolled response to frequent premature ventricular complexes and aberrant ventricular conduction. This case presents a high-risk woman with SARS-CoV-2 infection who developed a serious adverse cardiovascular event some days after receiving neutralizing monoclonal antibodies. Risk factors including sex, age, anxiety related to isolation and infection, and COVID-19 itself may have all contributed to atrial fibrillation. Arrhythmia may rarely occur after monoclonal-antibodies treatment, although recommended timing to monitor patients is from 1 to 24â€‰h after the administration of these antibodies. Appreciation of this potential association is important for evaluating monoclonal-antibody treatments' safety and optimizing patient monitoring and follow-up.

The Third dose of CoronVac vaccination induces broad and potent adaptive immune responses that recognize SARS-CoV-2 Delta and Omicron variants. The waning humoral immunity and emerging contagious severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants resulted in the necessity of the booster vaccination of coronavirus disease 2019 (COVID-19). The inactivated vaccine, CoronaVac, is the most widely supplied COVID-19 vaccine globally. Whether the CoronaVac booster elicited adaptive responses that cross-recognize SARS-CoV-2 variants of concern (VoCs) among 77 healthy subjects receiving the third dose of CoronaVac were explored. After the boost, remarkable elevated spike-specific IgG and IgA responses, as well as boosted neutralization activities, were observed, despite 3.0-fold and 5.9-fold reduced neutralization activities against Delta and Omicron strains compared to that of the ancestral strain. Furthermore, the booster dose induced potent B cells and memory B cells that cross-bound receptor-binding domain (RBD) proteins derived from VoCs, while Delta and Omicron RBD-specific memory B cell recognitions were reduced by 2.7-fold and 4.2-fold compared to that of ancestral strain, respectively. Consistently, spike-specific circulating follicular helper T cells (cTfh) significantly increased and remained stable after the boost, with a predominant expansion towards cTfh17 subpopulations. Moreover, SARS-CoV-2-specific CD4(+) and CD8(+) T cells peaked and sustained after the booster. Notably, CD4(+) and CD8(+) T cell recognition of VoC spike was largely preserved compared to the ancestral strain. Individuals without generating Delta or Omicron neutralization activities had comparable levels of CD4(+) and CD8(+) T cells responses as those with detectable neutralizing activities. Our study demonstrated that the CoronaVac booster induced broad and potent adaptive immune responses that could be effective in controlling SARS-CoV-2 Delta and Omicron variants.

Humoral and T-Cell Immune Response After 3 Doses of Messenger RNA Severe Acute Respiratory Syndrome Coronavirus 2 Vaccines in Fragile Patients: The Italian VAX4FRAIL Study.
BACKGROUND: Patients with solid or hematological tumors or neurological and immune-inflammatory disorders are potentially fragile subjects at increased risk of experiencing severe coronavirus disease 2019 and an inadequate response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. METHODS: We designed a prospective Italian multicenter study to assess humoral and T-cell responses to SARS-CoV-2 vaccination in patients (n = 378) with solid tumors (ST), hematological malignancies (HM), neurological disorders (ND), and immunorheumatological diseases (ID). A group of healthy controls was also included. We analyzed

the immunogenicity of the primary vaccination schedule and booster dose. RESULTS: The overall seroconversion rate in patients after 2 doses was 62.1%. Significantly lower rates were observed in HM (52.4%) and ID (51.9%) than in ST (95.6%) and ND (70.7%); a lower median antibody level was detected in HM and ID versus ST and ND (P < .0001). Similar rates of patients with a positive SARS-CoV-2 T-cell response were found in all disease groups, with a higher level observed in ND. The booster dose improved the humoral response in all disease groups, although to a lesser extent in HM patients, whereas the T-cell response increased similarly in all groups. In the multivariable logistic model, independent predictors of seroconversion were disease subgroup, treatment type, and age. Ongoing treatment known to affect the immune system was associated with the worst humoral response to vaccination (P < .0001) but had no effect on T-cell responses. CONCLUSIONS: Immunosuppressive treatment more than disease type per se is a risk factor for a low humoral response after vaccination. The booster dose can improve both humoral and T-cell responses.

Paving the Way Towards Precision Vaccinology: The Paradigm of Myocarditis After Coronavirus Disease 2019 (COVID-19) Vaccination. Systems vaccinology approaches have introduced novel tools for the evaluation of the safety profile of novel vaccine antigens by developing biomarkers of vaccine reactogenicity associated with potential adverse events. The use of such approaches may prove extremely advantageous in the context of a global pandemic where accelerated approval of new vaccine formulations for all ages is essential for the containment of the epidemic. The spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has had devastating effects on global health, but the emergency authorization of mRNA vaccines significantly reduced SARS-CoV-2-associated morbidity and mortality. Despite their favorable safety profile in adult populations, recent reports have raised concerns about an association of the mRNA-based vaccines with acute myocarditis, predominantly among male adolescents and young adults following the second vaccine dose. Here, we review data on myocarditis epidemiology following SARS-CoV-2 mRNA vaccination and describe potential mechanisms involved that may explain the sex- and age-related differences, focusing on mRNA immune reactivity. The case of vaccine-associated myocarditis highlights the need to incorporate precision vaccinology approaches for the development of safe and effective vaccines for everyone.

Association of Frailty, Age, and Biological Sex With Severe Acute Respiratory Syndrome Coronavirus 2 Messenger RNA Vaccine-Induced Immunity in Older Adults. BACKGROUND: Male sex and old age are risk factors for severe coronavirus disease 2019, but the intersection of sex and aging on antibody responses to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines has not been characterized. METHODS: Plasma samples were collected from older adults (aged 75-98 years) before and after 3 doses of SARS-CoV-2 mRNA vaccination, and from younger adults (aged 18-74 years) post-dose 2, for comparison. Antibody binding to SARS-CoV-2 antigens (spike protein [S], S receptor-binding domain, and nucleocapsid), functional activity against S, and live-virus neutralization were measured against the vaccine virus and the Alpha, Delta, and Omicron variants of concern (VOCs). RESULTS: Vaccination induced greater antibody titers in older females than in older males, with both age and frailty associated with reduced antibody responses in males but not females. Responses declined significantly in the 6 months after the second dose. The third dose restored functional antibody responses and eliminated disparities caused by sex, age, and frailty in older adults. Responses to the VOCs, particularly the Omicron variant, were significantly reduced relative to the vaccine virus, with older males having lower titers to the VOCs than older females. Older adults had lower responses to the vaccine and VOC viruses than younger adults, with greater disparities in males than in females. CONCLUSIONS: Older and frail males may be more vulnerable to breakthrough infections owing to low antibody responses before receipt of a third vaccine dose. Promoting third dose coverage in older adults, especially males, is crucial to protecting this vulnerable population.

Maternal and Neonatal Severe Acute Respiratory Syndrome Coronavirus 2 Omicron Variant Neutralization After Antenatal Messenger RNA Vaccination. We evaluated the neutralization efficiency against SARS-CoV-2 Omicron variant in maternal and cord blood sera after antenatal BNT162b2 vaccination. Neutralizing antibodies against Omicron were lacking at the time of delivery after 2-dose vaccination. A third booster dose was essential in building neutralizing antibody capacity against Omicron among mothers and neonates.

Cutaneous adverse reactions following the Pfizer/BioNTech COVID-19 vaccine. A growing number of cutaneous adverse reactions have been reported following the administration of a COVID-19 vaccine. We describe a series of twenty patients who developed a variety of cutaneous conditions within two weeks of receiving the Pfizer/ BioNTech BNT162b2 vaccine.

Serological response to vaccines against SARS-CoV-2 in patients with inflammatory bowel disease. OBJECTIVE: To study the serological response (SR) and tolerability of COVID-19 vaccine in patients with inflammatory bowel disease (IBD) and its relation with IBD treatment and type of vaccine. METHODS: Observational, cross-sectional study in patients with IBD vaccinated against COVID-19 without known previous infection. SR was analyzed by the determination of IgG antibodies against the S1 subunit. Safety was studied using a questionnaire to identify adverse effects (AE). RESULTS: 280 patients with IBD were included. Type of vaccines: ComirnatyÂ® 68.8%; SpikevaxÂ® 10.8%, VaxzevriaÂ® 18.3%, Ad26.COV2-SÂ® 2.2%. 51.3% had AE, being 100% mild. 65% developed IgG antibodies after vaccination. The SR was higher for vaccines with mRNA technology (100% SpikevaxÂ®, 68.5% ComirnatyÂ®) compared to those based on adenovirus vector (38.0% VaxzevriaÂ®, 33.3% Ad26.COV2-SÂ®) (P<.001). In the multivariate analysis, SR was related to age (<60 years; OR: 3.8, 95% CI 1.9-7.0; P<.001). The SR in patients with aminosalicylates was 65.4%, 61.4% with immunosuppressants, 65.8% with anti-TNF, and 68.7% with non-anti-TNF biologicals (P=.9). CONCLUSIONS: One third of patients with IBD did not develop antibodies with the initial vaccination against SARS-CoV-2. The SR to vaccines based on mRNA technology was higher, and it was related to age (higher in younger patients). Immunosuppressants and biologicals did not decrease SR. More than half of the patients presented AD, being mild in all cases.

 OBJECTIVE: To study the serological response (SR) and tolerability of COVID-19 vaccine in patients with inflammatory bowel disease (IBD) and its relation with IBD treatment and type of vaccine. METHODS: Observational, cross-sectional study in patients with IBD vaccinated against COVID-19 without known previous infection. SR was analyzed by the determination of IgG antibodies against the S1 subunit. Safety was studied using a questionnaire to identify adverse effects (AE). RESULTS: 280 patients with IBD were included. Type of vaccines: ComirnatyÂ® 68.8%; SpikevaxÂ® 10.8%, VaxzevriaÂ® 18.3%, Ad26.COV2-SÂ® 2.2%. 51.3% had AE, being 100% mild. 65% developed IgG antibodies after vaccination. The SR was higher for vaccines with mRNA technology (100% SpikevaxÂ®, 68.5% ComirnatyÂ®) compared to those based on adenovirus vector (38.0% VaxzevriaÂ®, 33.3% Ad26.COV2-SÂ®) (P<.001). In the multivariate analysis, SR was related to age (<60 years; OR: 3.8, 95% CI 1.9â€“7.0; P<.001). The SR in patients with aminosalicylates was 65.4%, 61.4% with immunosuppressants, 65.8% with anti-TNF, and 68.7% with non-anti-TNF biologicals (P=.9). CONCLUSIONS: One third of patients with IBD did not develop antibodies with the initial vaccination against SARS-CoV-2. The SR to vaccines based on mRNA technology was higher, and it was related to age (higher in younger patients). Immunosuppressants and biologicals did not decrease SR. More than half of the patients presented AD, being mild in all cases.

The Role of the Allergist in Coronavirus Disease 2019 Vaccine Allergy Safety: A Pilot Study on a "Hub-and-Spoke" Model for Population-Wide Allergy Service. BACKGROUND: Hong Kong started its coronavirus disease 2019 (COVID-19) vaccination program in February 2021. A territory-wide Vaccine Allergy Safety (VAS) clinic was set up to assess individuals deemed at "higher risk" of COVID-19

vaccine-associated allergies. A novel "hub-and-spoke" model was piloted to tackle the overwhelming demand of services by allowing nonallergists to conduct assessment. OBJECTIVE: To evaluate the outcomes of the VAS hub-and-spoke model for allergy assessment. METHODS: Records of patients attending the VAS hub-and-spoke Clinics between March and August 2021 were reviewed (nÂ =Â 2725). We studied the overall results between the Hub (allergist led) and Spoke (nonallergist led) Clinics. The Hub and the Hong Kong West Cluster Spoke Clinic were selected for subgroup analysis as they saw the largest number of patients (nÂ =Â 1411). RESULTS: A total of 2725 patients were assessed under the VAS hub-and-spoke model. Overall, 2324 patients (85.3%) were recommended to proceed with vaccination. Allergists recommended significantly more patients for vaccination than nonallergists (odds ratioÂ =Â 21.58; P < .001). Subgroup analysis revealed that 881 of 1055 (83.5%) patients received their first dose of COVID-19 vaccination safely after assessment. Among those recommended vaccination, more patients assessed by allergists received their first dose of vaccination (odds ratioÂ =Â 4.18; P < .001). CONCLUSION: The hub-and-spoke model has proven to be successful for the vaccination campaign. This study has illustrated the crucial role of allergists in countering vaccine hesitancy. Results from the study revealed considerable differences in outcomes between allergist-led and nonallergist-led clinics. Precise reasons for these differences warrant further evaluation. We are hopeful that the hub-and-spoke model can be similarly adapted for other allergist-integrative services in the future.

A SARS-CoV-2 outbreak associated with vaccine breakthrough in an acute care hospital. BACKGROUND: We aimed to analyze an outbreak caused by a vaccine breakthrough infection in a hospital with an active infection control program where 91.9% of health care workers were vaccinated. METHODS: We investigated a SARS-CoV-2 outbreak between September 9 and October 2, 2021, in a referral teaching hospital in Korea. We retrospectively collected data on demographics, vaccination history, transmission, and clinical features of confirmed coronavirus disease 2019 (COVID-19) in patients, health care workers, and caregivers. RESULTS: During the outbreak, 94 individuals tested positive for SARS-CoV-2 using reverse transcription-polymerase chain reaction testing. There were infections in 61 health care workers, 18 patients, and 15 caregivers; 74.5% (70/94) were vaccine breakthrough infections. Most transmissions appeared to be caused by three index cases, which accounted for 86.2% (81/94) of transmissions. Forty-seven (58.0%, 47/81) cases were associated with the hospital staff cafeteria and offices located in the basement. Among health care workers and caregivers, only one required oxygen supplementation. In contrast, among patients, there were four fatal cases (22.2%, 4/18), 3 of which were unvaccinated. CONCLUSIONS: Superspreading infection among fully vaccinated individuals occurred in an acute care hospital while the delta variant was dominant. Given the potential for severe complications, as this outbreak demonstrated, preventive measures including adequate ventilation should be emphasized to minimize transmission in hospitals.

Safety and immunogenicity of heterologous boost immunisation with an orally administered aerosolised Ad5-nCoV after two-dose priming with an inactivated SARS-CoV-2 vaccine in Chinese adults: a randomised, open-label, single-centre trial. BACKGROUND: Due to waning immunity and protection against infection with SARS-CoV-2, a third dose of a homologous or heterologous COVID-19 vaccine has been proposed by health agencies for individuals who were previously primed with two doses of an inactivated COVID-19 vaccine. METHODS: We did a randomised, open-label, controlled trial to evaluate the safety and immunogenicity of heterologous boost immunisation with an orally administered aerosolised adenovirus type-5 vector-based COVID-19 vaccine (Ad5-nCoV) in Chinese adults (â‰¥18 years old) who had previously received two doses of an inactivated SARS-CoV-2 vaccine-Sinovac CoronaVac. Eligible participants were randomly assigned (1:1:1) to receive a heterologous booster vaccination with a low dose (1Â·0â€ˆÃ—â€ˆ10(11) viral particles per mL; 0Â·1 mL; low dose group), or a high dose (1Â·0â€ˆÃ—â€ˆ10(11) viral particles per mL; 0Â·2 mL; high dose

group) aerosolised Ad5-nCoV, or a homologous intramuscular vaccination with CoronaVac (0Â·5 mL). Only laboratory staff were masked to group assignment. The primary endpoint for safety was the incidence of adverse reactions within 14 days after the booster dose. The primary endpoint for immunogenicity was the geometric mean titres (GMTs) of serum neutralising antibodies (NAbs) against live SARS-CoV-2 virus 14 days after the booster dose. This study was registered with ClinicalTrials.gov, NCT05043259. FINDINGS: Between Sept 14 and 16, 2021, 420 participants were enrolled: 140 (33%) participants per group. Adverse reactions were reported by 26 (19%) participants in the low dose group and 33 (24%) in the high dose group within 14 days after the booster vaccination, significantly less than the 54 (39%) participants in the CoronaVac group (p<0Â·0001). The low dose group had a serum NAb GMT of 744Â·4 (95% CI 520Â·1-1065Â·6) and the high dose group had a GMT of 714Â·1 (479Â·4-1063Â·7) 14 days after booster dose, significantly higher than the GMT in the CoronaVac group (78Â·5 [60Â·5-101Â·7]; p<0Â·0001). INTERPRETATION: We found that a heterologous booster vaccine with an orally administered aerosolised Ad5-nCoV is safe and highly immunogenic in adults who have previously received two doses of CoronaVac as the primary series vaccination. FUNDING: National Natural Science Foundation of China and Jiangsu Provincial Key Research and Development Program.

Acute cervical dystonia following the BNT162b2 mRNA COVID-19 vaccine. The coronavirus disease of 2019 (COVID-19) pandemic is caused by a novel coronavirus SARS-Cov-2. Four major vaccine types are being used to fight against this deadly pandemic and save precious human lives. All types of vaccines have been associated with a risk of neurological complications ranging from mild to severe. Cervical dystonia occurring after a COVID-19 vaccine was not previously reported in the literature. In this article, we describe a case of acute cervical dystonia occurring after the first dose of the BNT162b2 COVID-19 vaccine. We attribute the occurrence of cervical dystonia to the vaccine due to the temporal relationship. This report adds to the literature a possible rare side effect of a COVID-19 vaccine and contributes to the limited literature on potential neurological side effects of mRNA-based vaccines. The likely mechanism is autoimmune. Further research is needed to probe and study the exact mechanism.

Safety of inactivated COVID-19 vaccine in tuberous sclerosis complex patients with epilepsy treated with rapamycin. PURPOSE: To assess the safety of inactivated coronavirus 2019 disease (COVID-19) vaccine in tuberous sclerosis complex (TSC) patients with epilepsy. METHODS: All patients with epilepsy were selected from Efficacy and Safety of Sirolimus in Pediatric Patients with Tuberous Sclerosis (ESOSPIT) project and younger than 17 years old. The patients were treated with mTOR inhibitors (rapamycin). A total of 44 patients who completed the two-dose inactivated COVID-19 vaccine between July 7, 2021, and January 1, 2022, were enrolled. RESULTS: The median age of seizure onset was 23 months. About two-thirds of patients have focal seizures. Thirty-three patients use antiseizure medications. The mean duration of rapamycin treatment was 55.59Â Â±Â 18.42 months. Adverse reactions within 28 days after injection occurred in 11 patients (25%), all were under 12 years old. Injection site pain was the most reported event (20.45%), which was mild in severity and improved within one day. All patients had no seizure-related changes after vaccination. CONCLUSION: This study shows that the inactivated COVID-19 vaccine was well tolerated and safe in TSC patients with epilepsy, as well as for those treated with mTOR inhibitors.

Increased COVID-19 breakthrough infection risk in patients with plasma cell disorders.

Generalized morphea after COVID-19 vaccines: a case series.

Urticarial vasculitis triggered by SARS-CoV-2 vaccine (mRNA vaccine).

Nail psoriasis: a rare mRNA COVID-19 vaccine reaction.

Anti-PF4 testing for vaccine-induced immune thrombocytopenia and thrombosis (VITT): Results from a NEQAS, ECAT and SSC collaborative exercise in 385 centers worldwide. BACKGROUND: Vaccine-

induced immune thrombocytopenia and thrombosis (VITT) following the administration of the AstraZeneca (AZ) ChAdOx1 nCOV-19 vaccine is a well recognized clinical phenomenon. The associated clinical and laboratory features have included thrombosis at unusual sites, thrombocytopenia, raised D-dimer levels and positivity for immunoglobulin G (IgG) anti-platelet factor 4 (PF4) antibodies. OBJECTIVES: A collaborative external quality assessment (EQA) exercise was carried out by distributing five lyophilized samples from subjects with VITT and one from a healthy subject to 500 centers performing heparin-induced thrombocytopenia (HIT) testing. METHODS: Participating centers employed their locally validated testing methods for HIT assays, with some participants additionally reporting results for VITT modified assays. RESULTS: A total of 385 centers returned results for anti-PF4 immunoassay and functional assays. The ELISA assays used in the detection of anti-PF4 antibodies for the samples distributed had superior sensitivities compared with both the functional assays and the non-ELISA methods. CONCLUSION: ELISA-based methods to detect anti PF4 antibodies have a greater sensitivity in confirmation of VITT compared with functional assays regardless of whether such functional assays were modified to be specific for VITT. Rapid immunoassays should not be employed to detect VITT antibodies.
Complete remission of primary cutaneous follicle centre cell lymphoma associated with COVID-19 vaccine.
Generalized granuloma annulare after COVID-19 vaccination.
Periodic recurrent waves of Covid-19 epidemics and vaccination campaign. While understanding of periodic recurrent waves of Covid-19 epidemics would aid to combat the pandemics, quantitative analysis of data over a two years period from the outbreak, is lacking. The complexity of Covid-19 recurrent waves is related with the concurrent role of i) the containment measures enforced to mitigate the epidemics spreading ii) the rate of viral gene mutations, and iii) the variable immune response of the host implemented by vaccination. This work focuses on the effect of massive vaccination and gene variants on the recurrent waves in a representative case of countries enforcing mitigation and vaccination strategy. The spreading rate is measured by the ratio between the reproductive number R(t)(t) and the doubling time T(d)(t) called RIC-index and the daily fatalities number. The dynamics of the Covid-19 epidemics have been studied by wavelet analysis and represented by a non-linear helicoid vortex in a 3D space where both RIC-index and fatalities change with time. The onset of periodic recurrent waves has been identified by the transition from convergent to divergent trajectories on the helicoid vortex. We report a main period of recurrent waves of 120 days and the elongation of this period after the vaccination campaign.
Adverse reactions of BNT162b2 vaccine booster against COVID-19 in Japan. Female participants had a higher incidence of headache, nausea, myalgia, arthralgia, redness, pruritus, and inoculation site redness and pruritus (p 0.05). Low grade fever, headache, malaise, myalgia, and inoculation site induration and heat were associated with age group (p 0.05).
A case of an elderly female who developed subacute pleuropericarditis following BNT162b2 mRNA COVID-19 vaccination. Despite the established safety of BNT162b2 coronavirus disease 2019 (COVID-19) vaccine, some rare but serious complications have been previously reported. Here, we report a rare case of an elderly female who developed subacute pleuropericarditis after the vaccination. An 88-year-old female experienced weight gain and dyspnea three days after the second dose of BNT162b2 vaccination, and one month later, presented to our hospital due to the exacerbation of the symptoms. Computed tomography showed remarkable pericardial and bilateral pleural effusions, and transthoracic echocardiogram visualized collapse signs of right and left atrium which indicates pre-tamponade. Percutaneous drainages of pericardial and pleural effusions stabilized her vital condition and revealed that all of them were exudative, indicating the presence of pleuropericarditis. Finally, we diagnosed this case as COVID-19 vaccine-associated pleuropericarditis

because there were no signs of bacterial/viral infection or any other relevant causes except for the vaccination. When the pericardial and pleural effusions are concurrently found after COVID-19 vaccination, vaccine-associated pleuropericarditis should be considered as a differential diagnosis. The aggressive drainage of pericardial and pleural effusions could be helpful not only for diagnosis but also for treatment in the clinical management of COVID-19 vaccine-associated pleuropericarditis. LEARNING OBJECTIVE: Although the safety and efficacy of BNT162b2 have been widely accepted, it is clinically important to know the potential risk of side effects. When the pericardial and pleural effusions are concurrently found after the vaccination, coronavirus disease 2019 vaccine-associated pleuropericarditis should be considered as a differential diagnosis.

VAERS-reported new-onset seizures following use of COVID-19 vaccinations as compared to influenza vaccinations. The incidence of new-onset seizures, which we defined as de novo seizures occurring within 4â€‰weeks of receiving any of the US Food and Drug Administration-approved COVID-19 vaccinations as reported in patient-reported data compiled in the US Centers for Disease Control and Prevention Vaccine Adverse Events Reporting System Data (CDC VAERS), has not been explored. The VAERS database contains de-identified patient-reported adverse events following vaccination and represents post-marketing surveillance and analysis of vaccine safety. After adjusting for time at risk, this resulted in estimated incidence rates of 3.19 seizures per 100â€‰000 persons per year for the COVID-19 vaccine and 0.090 seizures per 100â€‰000 persons per year for the influenza vaccines. A data-driven, individualized dataset that is comprehensive and coupled with a longitudinal follow-up in larger numbers of vaccinated individuals is needed to expand on our preliminary findings of vaccine-related seizures.

Cluster headache after COVID-19 vaccination with Comirnaty: A signal in pharmacovigilance database.

Randomized clinical trial of BCG vaccine in patients with convalescent COVID-19: Clinical evolution, adverse events, and humoral immune response. BACKGROUND: The Bacillus Calmette-GuÃ©rin (BCG) vaccine may confer cross-protection against viral diseases in adults. This study evaluated BCG vaccine cross-protection in adults with convalescent coronavirus disease 2019 (COVID-19). METHOD: This was a multicenter, prospective, randomized, placebo-controlled, double-blind phase III study (ClinicalTrials.gov: NCT04369794). SETTING: University Community Health Center and Municipal Outpatient Center in South America. PATIENTS: a total of 378 adult patients with convalescent COVID-19 were included. INTERVENTION: single intradermal BCG vaccine (n = 183) and placebo (n = 195). MEASUREMENTS: the primary outcome was clinical evolution. Other outcomes included adverse events and humoral immune responses for up to 6 months. RESULTS: A significantly higher proportion of BCG patients with anosmia and ageusia recovered at the 6-week follow-up visit than placebo (anosmia: 83.1% vs. 68.7% healed, p = 0.043, number needed to treat [NNT] = 6.9; ageusia: 81.2% vs. 63.4% healed, p = 0.032, NNT = 5.6). BCG also prevented the appearance of ageusia in the following weeks: seven in 113 (6.2%) BCG recipients versus 19 in 126 (15.1%) placebos, p = 0.036, NNT = 11.2. BCG did not induce any severe or systemic adverse effects. The most common and expected adverse effects were local vaccine lesions, erythema (n = 152; 86.4%), and papules (n = 111; 63.1%). Anti-severe acute respiratory syndrome coronavirus 2 humoral response measured by N protein immunoglobulin G titer and seroneutralization by interacting with the angiotensin-converting enzyme 2 receptor suggest that the serum of BCG-injected patients may neutralize the virus at lower specificity; however, the results were not statistically significant. CONCLUSION: BCG vaccine is safe and offers cross-protection against COVID-19 with potential humoral response modulation. LIMITATIONS: No severely ill patients were included.

Efficacy and safety of mRNA SARS-CoV-2 vaccines in lung transplant recipients. BACKGROUND: To date, reports addressing the antibody response following mRNA SARS-CoV-2 vaccination in lung transplant (LTX) recipients are limited. Thus, the aim of this clinical study was to investigate the

efficacy and safety of the vaccines in LTX recipients compared to controls. METHODS: An open-label, nonrandomized prospective study was conducted at Tohoku University Hospital. LTX recipients and controls who received either the BNT162b2 vaccine or the mRNA-1273 vaccine were recruited, and SARS-CoV-2 IgG was measured before and after vaccination. The adverse events were reviewed. Predictors of negative serology after vaccination were evaluated with logistic regression. RESULTS: Forty-one LTX recipients and 24 controls were analyzed. Although all controls had a positive antibody response to a SARS-CoV-2 mRNA vaccine, antibody response was found in 24.4% of LTX recipients (pÂ <Â .0001). The amount of SARS-CoV-2 IgG following the 2nd dose significantly climbed to 6557 AU/mL in controls, whereas the increase in IgG in LTX recipients was 8.3 AU/mL (pÂ <Â .0001). Fewer LTX recipients developed systemic fever than controls (pÂ <Â .0001) despite equivalent overall adverse event percentages in both groups. A higher plasma concentration of mycophenolate was a significant predictor of negative serology (pÂ =Â .032). CONCLUSIONS: An impaired antibody response to mRNA vaccines was significantly found in LTX recipients compared to controls and was associated with the plasma concentration of mycophenolate. While repeating mRNA vaccination may be one of the strategies to improve antibody response given the safety of the vaccines, emerging data on humoral immune responses based on immunosuppression regimens in LTX recipients should be studied (jRCT1021210009).

Outcomes of allergic-type reactions after messenger RNA coronavirus disease 2019 vaccination at 3 military medical centers.

COVID-19 Vaccination and Anti-CD19 CAR T Cell-Induced B Cell Aplasia.

Severe Acute Respiratory Syndrome Coronavirus 2 Vaccination in Children with a History of Multisystem Inflammatory Syndrome in Children: AnÂ International Survey. The optimal severe acute respiratory syndrome coronavirus 2 vaccine strategy for patients with a history of multisystem inflammatory syndrome in children (MIS-C) is unclear. We performed an international survey (32 countries) and found substantial variations in vaccine policies. Respondents did not report relapses of MIS-C or other severe inflammatory side effects after severe acute respiratory syndrome coronavirus 2 vaccination in 273 patients with a history of MIS-C.

Definition of factors associated with negative antibody response after COVID-19 vaccination in patients with hematological diseases. COVID-19 in patients with hematological diseases is associated with a high mortality. Moreover, preventive vaccination demonstrated reduced efficacy and the knowledge on influencing factors is limited. In this single-center study, antibody levels of the SARS-CoV-2 spike protein were measuredâ€‰â‰¥â€‰2Â weeks after 2nd COVID-19 vaccination with a concentrationâ€‰â‰¥â€‰0.8 U/mL considered positive. Between July and October 2021, in a total of 373 patients (median age 64Â years, 44% women) with myeloid neoplasms (nâ€‰=â€‰214, 57%), lymphoid neoplasms (nâ€‰=â€‰124, nâ€‰=â€‰33%), and other diseases (nâ€‰=â€‰35, 10%), vaccination was performed with BNT162b2 (BioNTech), mRNA-1273 (Moderna), ChADOx1 (AstraZeneca), or a combination. A total of 229 patients (61%) were on active therapy within 3Â months prior vaccination and 144 patients (39%) were previously treated or treatment naÃ¯ve. Vaccination-related antibody response was negative in 56/373 patients (15%): in 39/124 patients with lymphoid neoplasms, 13/214 with myeloid neoplasms, and 4/35 with other diseases. Active treatment per se was not correlated with negative response. However, rituximab and BTK inhibitor treatment were correlated significantly with a negative vaccination response, whereas younger age and chronic myeloid leukemia (CML) disease were associated with positive response. In addition, 5 of 6 patients with myeloproliferative neoplasm (MPN) and negative vaccination response were on active treatment with ruxolitinib. In conclusion, a remarkable percentage of patients with hematological diseases had no response after 2nd COVID-19 vaccination. Multivariable analysis

revealed important factors associated with response to vaccination. The results may serve as a guide for better protection and surveillance in this vulnerable patient cohort.
New onset and exacerbation of oral lichenoid mucositis following SARS-CoV-2 infection or vaccination.
Heterologous gam-COVID-vac (sputnik V)/mRNA-1273 (moderna) vaccination induces a stronger humoral response than homologous sputnik V in a real-world data analysis. OBJECTIVES: To compare the homologous prime-boost vaccination scheme of Gam-COVID-Vac (Sputnik V (SpV)) to its heterologous combination with mRNA-1273 (Moderna (Mod)) vaccine. METHODS: SARS-CoV-2 anti-spike (S)-receptor binding domain (RBD) IgG concentration was assessed three to seven weeks after complete vaccination. Reactogenicity was evaluated by declared side events and medical assistance required until day 7 post boost. RESULTS: Of 190 participants enrolled, 105 received homologous SpV/SpV and the remaining heterologous SpV/Mod vaccination scheme, respectively. Median (interquartile range (IQR)) age was 54 (37-63) years, 132 out of 190 (69.5%) were female, and 46 out of 190 (24.2%) individuals had a prior confirmed COVID-19. Anti-S-RBD IgG median (IQR) titers were significantly higher for SpV/Mod (2511 (1476-3992) binding antibody units (BAU)/mL) than for SpV/SpV (582 (209-1609) BAU/mL; pÂ <Â 0.001] vaccination scheme. In a linear model adjusted for age, gender, time to the serological assay, and time between doses, SpV/Mod (4.154 (6.585-615.554); pÂ <Â 0.001] and prior COVID (3.732 (8.641-202.010); pÂ <Â 0.001) were independently associated with higher anti-S-RBD IgG values. A higher frequency of mild and moderate adverse effects was associated with the heterologous scheme (20 of 85 (23.5%) vs. 13 of 105 (12.4%); pÂ =Â 0.043 and 27 of 85 (31.8%) vs. 14 of 105 (13.3%); pÂ =Â 0.002), respectively, although it was well tolerated by all individuals and no medical assistance was required. DISCUSSION: The heterologous SpV/Mod combination against SARS-CoV-2 is well tolerated and significantly increases humoral immune response as compared to the homologous SpV/SpV immunization.
Antibody response to graded dosing of coronavirus disease 2019 messenger RNA vaccines after allergic reaction to first dose.
Immunogenicity, safety, and antiphospholipid antibodies after SARS-CoV-2 vaccine in patients with primary antiphospholipid syndrome. OBJECTIVE: Coronavirus disease 19 (COVID-19) has an increased risk of coagulopathy with high frequency of antiphospholipid antibodies (aPL). Recent reports of thrombosis associated with adenovirus-based vaccines raised concern that SARS-CoV-2 immunization in primary antiphospholipid syndrome (PAPS) patients may trigger clotting complications. Our objectives were to assess immunogenicity, safety, and aPL production in PAPS patients, after vaccinating with Sinovac-CoronaVac, an inactivated virus vaccine against COVID-19. METHODS: This prospective controlled phase-4 study of PAPS patients and a control group (CG) consisted of a two-dose Sinovac-CoronaVac (D0/D28) and blood collection before vaccination (D0), at D28 and 6 weeks after second dose (D69) for immunogenicity/aPL levels. Outcomes were seroconversion (SC) rates of anti-SARS-CoV-2 S1/S2 IgG and/or neutralizing antibodies (NAb) at D28/D69 in naÃ¯ve participants. Safety and aPL production were also assessed. RESULTS: We included 44 PAPS patients (31 naÃ¯ve) and 132 CG (108 naÃ¯ve) with comparable age (p=0.982) and sex (p>0.999). At D69, both groups had high and comparable SC (83.9% vs. 93.5%, p=0.092), as well as NAb positivity (77.4% vs. 78.7%, p=0.440), and NAb-activity (64.3% vs. 60.9%, p=0.689). Thrombotic events up to 6 months or other moderate/severe side effects were not observed. PAPS patients remained with stable aPL levels throughout the study at D0 vs. D28 vs. D69: anticardiolipin (aCL) IgG (p=0.058) and IgM (p=0.091); anti-beta-2 glycoprotein I (aÎ²2GPI) IgG (p=0.513) and IgM (p=0.468). CONCLUSION: We provided novel evidence that Sinovac-CoronaVac has high immunogenicity and safety profile in PAPS. Furthermore, Sinovac-CoronaVac did not trigger thrombosis nor induced changes in aPL production.

High seroconversion rates amongst black and Hispanics with hematologic malignancies after SARS-CoV-2 vaccination.

Acquired aplastic anemia following SARS-CoV-2 vaccination. COVID-19 is a potential life-threatening viral disease caused by SARS-CoV-2 and was declared a pandemic by the WHO in March 2020. mRNA-based SARS-CoV-2 vaccines are routinely recommended in immune-compromised patients, including patients with AA, as these patients are at increased risk of contracting COVID-19 and developing a more severe course of disease. Between March 2021 and November 2021 relapse of AA occurred in four (age [median]: 53â€‰years, range 30-84â€‰years) out of 135 patients currently registered at our department and two de novo cases of AA in temporal context to vaccination against SARS-CoV-2, were documented. Median time after first COVID-19 vaccination and relapse of AA was 77â€‰days. All relapsed patients were vaccinated with the mRNA-based vaccine ComirnatyÂ®. Relapse in two out of the four patients was refractory to CsA/eltrombopag, favoring IST with hATG/CsA or BMT, respectively. Our observations should prompt clinicians to take vaccine-induced relapse of AA or de novo AA after SARS-CoV-2 vaccination into account. Furthermore, careful clinical monitoring and vigilance for signs or symptoms that may indicate relapse of AA (e.g., bleeding complications) are indicated.

Acceptance, efficacy, and safety of COVID-19 vaccination in older patients with cancer. PURPOSE: The COVID-19 vaccination campaign began in December 2020, in France, and primarily targeted the oldest people. Our study aimed to determine the level of acceptance of vaccination in a population of older patients with cancer. METHODS: From January 2021, we offered vaccination with the BNT162b2 COVID-19 vaccine to all patients 70Â years and older referred to our geriatric oncology center in Marseille University Hospital (AP-HM) for geriatric assessment before initiation of an oncological treatment. Objectives were to evaluate acceptance rate of COVID-19 vaccination and to assess vaccine safety, reactogenicity, and efficacy two months after the first dose. RESULTS: Between January 18, 2021 and May 7, 2021, 150 older patients with cancer were offered vaccination after a geriatric assessment. The majority were men (61.3%), with a mean age of 81Â years. The two most frequent primary tumors were digestive (29.4%) and thoracic (18%). The vaccine acceptance rate was 82.6% and the complete vaccination rate (2 doses) reached 75.3%. Among the vaccinated patients, 15.9% reported mild side effects after the first dose and 23.4% after the second dose, mostly arm pain and fatigue. COVID-19 cases were observed in 5.1% of vaccinated patients compared with 16.7% in unvaccinated patients. Of the 22 vaccinated patients who agreed to have their serum tested, 15 had antibodies against the spike protein at day 21 after the first dose. CONCLUSION: Our study showed a high acceptance rate of COVID-19 vaccination, with good tolerance in this frail population. These results highlight the benefits of organizing vaccination campaigns at the very beginning of oncological management in older patients. CLINICAL TRIAL REGISTRATION: This study was registered May 23, 2019 in ClinicalTrials.gov (NCT03960593).

Association between Immunosuppressive Drugs and Coronavirus Disease 2019 Outcomes in Patients with Noninfectious Uveitis in a Large US Claims Database. PURPOSE: To determine the dose-dependent risk of systemic corticosteroids (SCs) and the risk of other immunosuppressive therapies on coronavirus disease 2019 (COVID-19) infection, hospitalization, and death in patients with noninfectious uveitis (NIU). DESIGN: A retrospective cohort study from January 20, 2020, to December 31, 2020 (an era before widespread COVID-19 vaccination), using the Optum Labs Data Warehouse, a US national de-identified claims database. PARTICIPANTS: Patients who had at least 1 NIU diagnosis from January 1,Â 2017. METHODS: Unadjusted and adjusted hazard ratios (HRs) were estimated for each variable and COVID-19 outcome using Cox proportional hazards models, with time-updated dichotomous indicators for outpatient immunosuppressive medication exposure. To assess the dose-dependent effect of SC exposure, the average daily dose of prednisone over the

exposed interval was included in the adjusted models as a continuous variable, in addition to the dichotomous variable. MAIN OUTCOME MEASURES: Incidence rates of COVID-19 infection, COVID-19-related hospitalization, and COVID-19-related in-hospital death. RESULTS: This study included 52 286 NIU patients of whom 12 000 (23.0%) were exposed to immunosuppressive medications during the risk period. In adjusted models, exposure to SCs was associated with increased risk of COVID-19 infection (HR, 2.66; 95% confidence interval [CI], 2.19-3.24; P < 0.001), hospitalization (HR, 3.26; 95% CI, 2.46-4.33; P < 0.001), and in-hospital death (HR, 1.99; 95% CI, 0.93-4.27; PÂ = 0.08). Furthermore, incremental increases in the dosage of SCs were associated with a greater risk for these outcomes. Although tumor necrosis factor-Î± (TNF-Î±) inhibitors were associated with an increased risk of infection (HR, 1.48; 95% CI, 1.08-2.04; PÂ = 0.02), other immunosuppressive treatments did not increase the risk of COVID-19 infection, hospitalization, or death. CONCLUSIONS: This study from an era before widespread COVID-19 vaccination demonstrates that outpatient SC exposure is associated with greater risk of COVID-19 infection and severe outcomes in patients with NIU. Future studies should evaluate the impact of immunosuppression in vaccinated NIU patients. Limiting exposure to SCs and use of alternative therapies may be warranted.

Exacerbation of familial intrahepatic cholestasis in conjunction with COVID-19 vaccination.

Clinical manifestations of COVID-19 breakthrough infections: A systematic review and meta-analysis. To provide a comparative meta-analysis and systematic review of the risk and clinical outcomes of coronavirus 2019Â (COVID-19) infection between fully vaccinated and unvaccinated groups.Â Eighteen studies of COVID-19 infections in fully vaccinated ("breakthrough infections") and unvaccinated individuals were reviewed from Medline/PubMed, Scopus, Embase, and Web of Science databases. The meta-analysis examined the summary effects and between-study heterogeneity regarding differences in the risk of infection, hospitalization, treatments, and mortality between vaccinated and unvaccinated individuals.Â he overall risk of infection was lower for the fully vaccinated compared to that of the unvaccinated (relative risk [RR]Â 0.20, 95% confidence interval [CI]: 0.19-0.21), especially for variants other than Delta (Delta: RR 0.29, 95% CI: 0.13-0.65; other variants: RR 0.06, 95% CI: 0.04-0.08). The risk of asymptomatic infection was not statistically significantly different between fully vaccinated and unvaccinated (RR 0.56, 95% CI: 0.27-1.19). There were neither statistically significant differences in risk of hospitalization (RR 1.06, 95% CI: 0.38-2.93), invasive mechanical ventilation (RR 1.65, 95% CI: 0.90-3.06), or mortality (RR 1.19, 95% CI:Â 0.79-1.78). Conversely, the risk of supplemental oxygen during hospitalization was significantly higher for the unvaccinated (RR 1.40, 95% CI: 1.08-1.82).Â Unvaccinated people were more vulnerable to COVID-19 infection than fully vaccinated for all variants. Once infected, there were no statistically significant differences in the risk of hospitalization, invasive mechanical ventilation, or mortality. Still, unvaccinated showed an increased need for oxygen supplementation. Further prospective analysis, including patients' risk factors, COVID-19 variants, and the utilized treatment strategies, would be warranted.

COVID-19 vaccine associated cervical lymphadenopathy: a case series. BACKGROUND: COVID-19 is an evolving worldwide pandemic causing significant morbidity and mortality. COVID-19 vaccinations have been developed to increase immunity against the virus. In New Zealand, the Pfizer BioNTech mRNA vaccine has been provisionally approved for use. Axillary lymphadenopathy is a recognized side effect of the mRNA vaccine, however cervical lymphadenopathy has also been reported. Due to a wide range of differential diagnoses, the finding of cervical lymphadenopathy requires thorough investigation which can include imaging and invasive diagnostic procedures. METHODS: Five patients were identified by otorhinolaryngology (ORL) consultants at Whangarei Base Hospital and Waikato Hospital between 15/7/2021 and 21/12/2021 after being investigated through high suspicion of cancer triage pathways set by the New Zealand Ministry of Health. Inclusion criteria

were adult patients with cervical lymphadenopathy following vaccination. Exclusion criteria were no history of vaccination or lymphadenopathy present before vaccination. RESULTS: All patients were identified to have cervical lymphadenopathy on radiological imaging and a recent history of COVID-19 vaccination with the Pfizer BioNTech vaccine. Interval vaccination to fine needle aspiration time ranged between 41 and 76â€‰days. All patients had cytological or histological diagnosis showing reactive findings or interval imaging showing resolution of lymphadenopathy. CONCLUSION: With increasing levels of COVID-19 vaccination and booster vaccinations we will continue to see cases of COVID-19 vaccine associated cervical lymphadenopathy. We highlight the importance of taking a COVID-19 vaccination history and including COVID-19 associated cervical lymphadenopathy in the differential diagnosis of presentation with a neck lump.
Regression of sarcoidosis skin lesions after receiving the Moderna anti-coronavirus disease 2019 vaccine.
Cutaneous symptoms of connective tissue diseases after COVID-19 vaccination: a systematic review.
COVID-19 vaccination-related small vessel vasculitis with multiorgan involvement. Since its first outbreak in 2019, coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirusÂ 2, has been ongoing, and the pandemic is not over yet. Vaccines developed against COVID-19 have been approved and widely used since 2020; however, vaccine safety concerns need to be addressed. Autoimmune symptoms have been reported as aÂ side effect of many COVID-19 vaccines. In particular, several cases of COVID-19 vaccine-induced vasculitis have recently been reported. Herein, we report the case of aÂ 77-year-old woman who developed small-vessel vasculitis with multiorgan involvement after receiving the BNT162b2 COVID-19 vaccine (Pfizer and BioNTech, New York City, NY, USA).
Herpes simplex virus retinitis following ChAdOx1 nCoV- 19 (Covishield) vaccination for SARS CoV 2: A case report. PURPOSE: To report a case of herpes simplex virus retinitis following ChadOx1 nCoV-19 (covishield) vaccination. CASE REPORT: A 29 year old immunocompetent male presented with unilateral disc edema with adjacent retinitis two days after receiving the first dose of ChAdOx1 nCoV-19 vaccination. Extensive investigations to rule out infective etiology were negative except for polymerase chain reaction (PCR) of the vitreous specimen which was positive for the herpes simplex virus. A diagnosis of herpes simplex (HSV) retinitis post covid vaccination was made. The patient responded well to oral antivirals and steroids. CONCLUSION: HSV retinitis is a rare complication following the COVID-19 vaccination.
Is polyethylene glycol allergy a real contraindication to COVID-19 mRNA vaccines?
Risk of Myopericarditis After COVID-19 Vaccination in Danish Children Aged 5 to 11 Years.
Combined central and peripheral demyelination after COVID-19 vaccination.
Immunogenicity and safety of an inactivated SARS-CoV-2 vaccine in people living with HIV: A cross-sectional study. We aimed to analyze the efficacy and safety of an inactivated SARS-CoV-2 vaccine in people living with HIV (PLWH). A total of 143 PLWH and 50 healthy individuals were included in this study. A commercially available magnetic chemiluminescence enzyme immunoassay kit was used to detect serum IgG and IgM antibodies against SARS-CoV-2. Serum levels of SARS-CoV-2-specific IgG were significantly higher in the control group than in the PLWH group (pâ€‰=â€‰0.001). Overall, 76% of individuals in the control group were detected with seropositivity IgG against SARS-CoV-2 compared to 58% in the PLWH group (pâ€‰=â€‰0.024). In PLWH with IgG seropositivity, CD4+ T-cell counts before antiretroviral therapy (ART) was higher (pâ€‰=â€‰0.015). Multivariable analysis indicated that CD4+ T cells at IgG detection (odds ratio [OR]â€‰=â€‰1.004, pâ€‰=â€‰0.006) and time after vaccination (ORâ€‰=â€‰0.977, pâ€‰=â€‰0.014) were independently associated with seropositivity IgG against SARS-CoV-2 in PLWH. Neutralizing antibody (nAb) titers in PLWH against wild-type SARS-CoV-2 were similar to those in the control group

(pâ€‰=â€‰0.160). The proportion of seropositive nAbs against wild-type SARS-CoV-2 was also similar (95% in the control group vs. 97% in theÂ PLWH group, pâ€‰=â€‰0.665). Similar results were obtained when nAb was detected against the delta variants with similar titers (pâ€‰=â€‰0.355) and a similar proportion of seropositive nAbs were observed (pâ€‰=â€‰0.588). All the side effects observed in our study were mild and self-limiting. The inactivated COVID-19 vaccine appears to be safe with good immunogenicity in Chinese PLWH.

A Rare Side Effect of COVID-19 Vaccination: Abducens Nerve Palsy.

Lymphomatoid papulosis (LyP) after AZD1222 and BNT162b2 COVID-19 vaccines.

New onset of psoriasis following COVID-19 vaccination. The cutaneous side effects of COVID-19 vaccines are being studied and their immunogenicity is most likely linked to the pathophysiology of psoriasis. Although uncommon, several cases of exacerbation and new onset of psoriasis have been reported globally after vaccination. To contribute to the literature on this intriguing topic, we present three cases of de novo psoriasis in adult patients following COVID-19 vaccination. Our observations and a literature review show that this occurrence is independent of the type and brand of vaccines.

Kikuchi-Fujimoto disease can present as delayed lymphadenopathy after COVID-19 vaccination. Following COVID-19 vaccination, ipsilateral axillary and cervical lymphadenopathy may occur, called vaccine-related hypermetabolic lymphadenopathy, which is considered reactive lymphadenopathy. We report here a case of Kikuchi-Fujimoto disease, which occurred three months after vaccination with COVID-19 vaccine. The patient had cervical and axillary lymph node enlargement and a short-term fever that resolved spontaneously after the first and second vaccines. On the 90th day after the first vaccination, the patient developed a high fever and pathologically diagnosed necrotizing lymphadenitis in the axilla, which was diagnosed as Kikuchi-Fujimoto disease. Gallium scintigraphy showed localized swelling and strong uptake in the ipsilateral axilla. It implies the possibility of Kikuchi-Fujimoto Disease in axillary drainage lymph nodes in association with COVID-19 vaccine. Although only a few cases have been reported so far, this case is novel because of its later onset and diagnosis based on pathological and gallium scintigraphy imaging findings.

Time for Resolution of COVID-19 Vaccine-Related Axillary Lymphadenopathy and Associated Factors. BACKGROUND. The variable clinical course of subclinical lymphadenopathy detected on breast imaging after COVID-19 vaccination creates management challenges and has led to evolving practice recommendations. OBJECTIVE. The purpose of this study was to assess the duration of axillary lymphadenopathy ipsilateral to COVID-19 vaccination detected by breast imaging and to assess factors associated with the time until resolution. METHODS. This retrospective single-center study included 111 patients (mean age, 52 Â± 12 years) with unilateral axillary lymphadenopathy ipsilateral to mRNA COVID-19 vaccine administration performed within the prior 8 weeks that was detected on breast ultrasound performed between January 1, 2021, and October 1, 2021, and who underwent follow-up ultrasound examinations at 4- to 12-week intervals until resolution of the lymphadenopathy. Patient information was extracted from medical records. Cortical thickness of the largest axillary lymph node on ultrasound was retrospectively measured and was considered enlarged when greater than 3 mm. Multivariable linear regression analysis was used to identify independent predictors of time until resolution. RESULTS. The mean cortical thickness at the initial ultrasound examination was 4.7 Â± 1.2 mm. The lymphadenopathy resolved a mean of 97 Â± 44 days after the initial ultrasound examination, 127 Â± 43 days after the first vaccine dose, and 2.4 Â± 0.6 follow-up ultrasound examinations. A significant independent predictor of shorter time to resolution was Pfizer-BioNTech (rather than Moderna) vaccination (Î² = -18.0 [95% CI, -34.3 to -1.7]; p = .03]. Significant independent predictors of longer time to resolution were receipt of the second dose after the initial ultrasound examination (Î² = 19.2 [95% CI, 3.1-35.2]; p = .02) and greater cortical thickness at the initial ultrasound examination (Î² = 8.0 [95% CI, 1.5-14.5]; p = .02). Patient age, history of breast

cancer, and axillary symptoms were not significantly associated with time to resolution (all p > .05). CONCLUSION. Axillary lymphadenopathy detected with breast ultrasound after COVID-19 mRNA vaccination lasts longer than reported in initial vaccine clinical trials. CLINICAL IMPACT. The prolonged time to resolution supports not delaying screening mammography because of recent COVID-19 vaccination. It also supports the professional society recommendation of a follow-up interval of at least 12 weeks when vaccine-related lymphadenopathy is suspected.
Pfizer-BioNTech COVID-19 vaccine-associated tinnitus and treatment with transcranial magnetic stimulation.
Safety of third-dose SARS-CoV-2 vaccination in patients with rheumatic and musculoskeletal disease.
Myocarditis after COVID-19 mRNA vaccination in three young adult males: Significance of biopsy in vaccine-associated myocarditis.
Haematological changes and adverse events associated with BNT162b2 mRNA COVID-19 vaccine in patients receiving clozapine-Findings from an audit.
Safety of COVID-19 Vaccination in United States Children Ages 5 to 11 Years. BACKGROUND AND OBJECTIVES: Limited postauthorization safety data for the Pfizer-BioNTech coronavirus disease 2019 vaccination among children ages 5 to 11 years are available, particularly for the adverse event myocarditis, which has been detected in adolescents and young adults. We describe adverse events observed during the first 4 months of the United States coronavirus disease 2019 vaccination program in this age group. METHODS: We analyzed data from 3 United States safety monitoring systems: v-safe, a voluntary smartphone-based system that monitors reactions and health effects; the Vaccine Adverse Events Reporting System (VAERS), the national spontaneous reporting system comanaged by the Centers for Disease Control and Prevention and Food and Drug Administration; and the Vaccine Safety Datalink, an active surveillance system that monitors electronic health records for prespecified events, including myocarditis. RESULTS: Among 48â€‰795 children ages 5 to 11 years enrolled in v-safe, most reported reactions were mild-to-moderate, most frequently reported the day after vaccination, and were more common after dose 2. VAERS received 7578 adverse event reports; 97% were nonserious. On review of 194 serious VAERS reports, 15 myocarditis cases were verified; 8 occurred in boys after dose 2 (reporting rate 2.2 per million doses). In the Vaccine Safety Datalink, no safety signals were detected in weekly sequential monitoring after administration of 726â€‰820 doses. CONCLUSIONS: Safety findings for Pfizer-BioNTech vaccine from 3 United States monitoring systems in children ages 5 to 11 years show that most reported adverse events were mild and no safety signals were observed in active surveillance. VAERS reporting rates of myocarditis after dose 2 in this age group were substantially lower than those observed among adolescents ages 12 to 15 years.
COVID-19 Vaccines: Safe and Effective in Children Aged 5 to 11 Years.
A Single Dose of BNT162b2 Messenger RNA Vaccine Induces Airway Immunity in Severe Acute Respiratory Syndrome Coronavirus 2 Naive and Recovered Coronavirus Disease 2019 Subjects. BACKGROUND: Mucosal antibodies can prevent virus entry and replication in mucosal epithelial cells and therefore virus shedding. Parenteral booster injection of a vaccine against a mucosal pathogen promotes stronger mucosal immune responses following prior mucosal infection compared with injections of a parenteral vaccine in a mucosally naive subject. We investigated whether this was also the case for the BNT162b2 coronavirus disease 2019 (COVID-19) messenger RNA vaccine. METHODS: Twenty recovered COVID-19 subjects (RCSs) and 23 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-naive subjects were vaccinated with, respectively, 1 and 2 doses of the BNT162b2 COVID-19 vaccine. Nasal epithelial lining fluid (NELF) and plasma were collected before and after vaccination and assessed for immunoglobulin G (IgG) and IgA antibody levels to Spike and for their ability to neutralize binding of Spike to angiotensin-converting enzyme-2 receptor. Blood was

analyzed 1 week after vaccination for the number of Spike-specific antibody-secreting cells (ASCs) with a mucosal tropism. RESULTS: All RCSs had both nasal and blood SARS-CoV-2-specific antibodies at least 90 days after initial diagnosis. In RCSs, a single dose of vaccine amplified preexisting Spike-specific IgG and IgA antibody responses in both NELF and blood against both vaccine homologous and variant strains, including Delta. These responses were associated with Spike-specific IgG and IgA ASCs with a mucosal tropism in blood. Nasal IgA and IgG antibody responses were lower in magnitude in SARS-CoV-2-naive subjects after 2 vaccine doses compared with RCSs after 1 dose. CONCLUSIONS: Mucosal immune response to the SARS-CoV-2 Spike protein is higher in RCSs after a single vaccine dose compared with SARS-CoV-2-naive subjects after 2 doses.

Hyper-Eosinophilic Syndrome with Myocarditis after Inactivated SARSCoV- 2 Vaccination - A Case Study. INTRODUCTION: COVID-19 vaccine-induced serious adverse reactions are rare. Hypereosinophilia syndrome with myocarditis has not been reported earlier following BBV152 vaccine administration. CASE PRESENTATION: A young man without any co-morbidities presented with persistent periorbital swelling along with itchy swelling over fingers, resting tachycardia, and exertional breathlessness following the first dose of an inactivated SARS-CoV-2 vaccine (BBV152, COVAXIN). On investigation, the patient had elevated blood eosinophils (maximum 21.5% with an absolute eosinophil count of 2767/mm(3)) and myocarditis (Lake Louise Criteria). He was successfully treated with steroids and supportive treatment. CONCLUSION: This is the first reported case of hyper-eosinophilia syndrome after COVAXIN administration. Prior history of the allergic disease may be a predisposing factor in this case. Hypereosinophilia can present with variable symptoms. In the current case, myocarditis was present with persistent resting tachycardia and dyspnea. Steroid and antiallergic drugs may be successful for the treatment of vaccine-induced hyper-eosinophilia with myocarditis. Increased vigilance is needed for such adverse events.

Effectiveness of first, second, and third COVID-19 vaccine doses in solid organ transplant recipients: A population-based cohort study from Canada. Limited data exists on the effectiveness of a third COVID-19 vaccine dose in solid organ transplant recipients. We conducted a population-based cohort study using linked healthcare databases from Ontario, Canada to answer this question. We included solid organ transplant recipients (nÂ =â€‰12,842) as of December 14, 2020, with follow-up until November 28, 2021. We used an extended Cox proportional hazards model with vaccination status, including BNT162b2, mRNA-1273, and ChAdOx1 vaccines, modeled as a time-dependent exposure. Individuals started in the unvaccinated category (reference) and could contribute person-time to first, second, and third doses. Over a median follow-up of 349â€‰days, 12.7% (nÂ =â€‰1632) remained unvaccinated, 54.1% (nÂ =â€‰6953) received 3 doses, and 488 (3.8%) tested positive for SARS-CoV-2 (of which 260 [53.3%] had a clinically important outcome [i.e., hospitalization or death]). Adjusted vaccine effectiveness against infection was 31% (95% CI: 2, 51%), 46% (95% CI: 21, 63%), and 72% (95% CI: 43, 86%) for one, two, and three doses. Vaccine effectiveness against clinically important outcomes was 38% (95% CI: 4, 61%), 54% (95% CI: 23, 73%), and 67% (95% CI: 11, 87%). Vaccine effectiveness in solid organ transplant recipients is lower than the general population, however, vaccine effectiveness improved following a third dose.

rVSV-Î”G-SARS-CoV-2-S vaccine: repeated intramuscular (IM) toxicity, local tolerance, immunogenicity and biodistribution study in NZW rabbits. BriLife(Â®), a vector-based vaccine that utilizes the recombinant vesicular stomatitis virus (VSV) platform to express and present the spike antigen of SARS-CoV-2, is undergoing testing in a phase 2 clinical trial in Israel. A nonclinical repeated-dose (GLP) toxicity study in New Zealand white rabbits was performed to evaluate the potential toxicity, local tolerance, immunogenicity and biodistribution of the vaccine. rVSV-Î”G-SARS-CoV-2-S (or vehicle) was administered intramuscularly to two groups of animals (10(6), 10(7) PFU/animal, nâ€‰=â€‰10/sex/group) on three occasions, at 2-week intervals, followed by a 3-week recovery

period. Systemic clinical signs, local reactions, body weight, body temperature, food consumption, ophthalmology, urinalysis, clinical pathology, C-reactive protein, viremia and antibody levels were monitored. Gross pathology was performed, followed by organs/tissues collection for biodistribution and histopathological evaluation. Treatment-related changes were restricted to multifocal minimal myofiber necrosis at the injection sites, and increased lymphocytic cellularity in the iliac and mesenteric lymph nodes and in the spleen. These changes were considered related to the inflammatory reaction elicited, and correlated with a trend for recovery. Detection of rVSV-Î"G-SARS-CoV-2-S vaccine RNA was noted in the regional iliac lymph node in animals assigned to the high-dose group, at both termination time points. A significant increase in binding and neutralizing antibody titers was observed following vaccination at both vaccine doses. In view of the findings, it was concluded that the rVSV-Î"G-SARS-CoV-2-S vaccine is safe. These results supported the initiation of clinical trials.

Adverse events after BNT162b2 mRNA COVID-19 vaccination in health care workers and medical students in Japan. To control the coronavirus disease 2019 (COVID-19) pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the promotion of vaccination is important. However, adverse reactions following vaccination remain a concern. To investigate adverse events in the vaccinated Japanese population, we conducted a survey-based study among health care workers, including medical doctors and nurses; other medical staff; and medical university faculty, staff, and students in a single medical school and affiliated hospital in Japan. In addition, we analyzed the association of different adverse events with individual factors (e.g., age, sex) by performing network analysis. While young age and female sex are often considered risk factors for more severe adverse events, the regression models showed neither age nor sex was associated with local injection-site reactions after the second dose in this study. In contrast to local reactions, systemic adverse events were associated with young age and female sex. However, myalgia was unique in that it was not associated with younger age even though the network analysis showed that myalgia was consistently related to arthralgia and belonged to the group of systemic events after both the first and second vaccine doses. Further study is needed to ensure safe and effective vaccination to aid in controlling the COVID-19 pandemic.

No apparent association between mRNA COVID-19 vaccination and venous thromboembolism. By January 2022 over ten billion doses of COVID-19 vaccines had been administered worldwide. Concerns about COVID-19 vaccine-associated thrombosis arose after the characterization of a rare prothrombotic condition associated with adenoviral vector-based COVID-19 vaccines known as vaccine-induced immune thrombotic thrombocytopenia (VITT). Although mRNA COVID-19 vaccines have not been linked to VITT, concerns about thrombosis after vaccination persist despite safety data from hundreds of millions of recipients of mRNA COVID-19 vaccines. With widespread vaccination some VTE will occur shortly after vaccination by chance alone because VTE is a common condition that affects 1 to 2 in 1000 persons each year. Detailed analysis is required to determine whether these VTE events are coincidental or associated when they occur in close proximity to mRNA vaccine administration. This paper will review what is currently known about rates of VTE after mRNA vaccination in adults, discuss the reasons why uncertainty on this topic persists, and briefly review the implications of these findings for clinical practice and health policy.

Anti-severe acute respiratory syndrome coronavirus-2 adenoviral-vector vaccines trigger subclinical antiplatelet autoimmunity and increase of soluble platelet activation markers. To slow down the coronavirus disease 2019 (COVID-19) pandemic an unequalled vaccination campaign was initiated. Despite proven efficacy and safety, a rare but potentially fatal complication of adenoviral-vector vaccines, called vaccine-induced immune thrombotic thrombocytopenia (VITT), has emerged the pathogenesis of which seems to be related to the development of platelet-activating anti-platelet

factor 4 (PF4) antibodies. While a few studies have evaluated the incidence of anti-PF4 positivity in anti-severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccine recipients, to date no studies have assessed whether an antiplatelet immunological response develops and if this associates with platelet and blood clotting activation. We carried out a prospective study in healthy subjects who received the first dose of ChAdOx1 or Ad26.COV2.S or BNT162b2 vaccines to evaluate platelet-specific and non-specific immune response and in vivo platelet activation and blood clotting activation. Individuals receiving ChAdOx1 and, less so, Ad26.COV2.S developed with high frequency auto- or alloantiplatelet antibodies, increased circulating platelet-derived microvesicles and soluble P-selectin associated with mild blood clotting activation. Our study shows that an immunological reaction involving platelets is not uncommon in individuals receiving anti-SARS-CoV-2 vaccination, especially after ChAdOx1 and Ad26.COV2.S, and that it associates with in vivo platelet and blood clotting activation.
Cardiovascular and Hematologic Complications of COVID-19 Vaccines. COVID-19 is a prothrombotic and cardiac-damaging disease. There are 4 vaccines against COVID-19 currently approved in North America, including the mRNA vaccines by Pfizer and Moderna, and the adenovirus vector vaccines by Johnson and Johnson and AstraZeneca. These vaccines have been proven effective in reducing morbidity and preventing mortality in patients who were exposed to COVID-19 infection, but the vaccines have also been associated with complications. Vaccine-induced thrombotic thrombocytopenia (VITT) has a similar pathogenesis to heparin-induced thrombocytopenia, with an inappropriate immune response leading to platelet activation, consumption of platelets, and thrombosis. It appears to be more common with the adenovirus vector vaccines. Secondary immune thrombocytopenic purpura has been reported with all COVID-19 vaccines and is distinct from VITT because there is no sign of platelet activation or thrombotic events. Myocarditis and pericarditis are often reported in young males following mRNA vaccines and is often associated with a full recovery. The long-term effects of VITT, secondary immune thrombocytopenic purpura, myocarditis, and pericarditis secondary to COVID-19 vaccines have yet to be elucidated. Continued surveillance for these complications after vaccination is crucial for accurate diagnosis and effective management. Patients should consult their physicians regarding repeated vaccine doses after experiencing an adverse effect.
COVID-19 and cardiovascular disease: manifestations, pathophysiology, vaccination, and long-term implication. The coronavirus disease 2019 (COVID-19) pandemic is caused by a new coronavirus family member, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and is linked with many disease manifestations in multiple organ systems on top of pulmonary manifestations. COVID-19 is also accompanied by several cardiovascular pathologies including myocarditis, acute myocardial infarction, stress cardiomyopathy, arterial and venous thromboembolism, pericarditis, and arrhythmias. The pathophysiological mechanisms explaining these clinical symptoms are multifactorial including systemic inflammation (cytokine storm), coagulopathy, direct viral invasion through angiotensin-converting enzyme 2, hypoxemia, electrolyte imbalance, and fever. Several case reports have shown the development of an unusual cardiovascular event after receiving SARS-CoV-2 vaccines. The current article aimed to review cardiovascular involvement in the COVID-19 pandemic with respect to clinical features, pathogenesis, long-term effects, and the adverse effects of treatments and vaccines based on the latest evidence.
Local myofascitis of the deltoid muscle after administration of the AstraZeneca (AZD1222) COVID-19 vaccine: two cases, infectious and inflammatory.
Letter in Reply: Alopecia areata after SARS-CoV-2 vaccination.
Response to Martora etÂ al's "Hidradenitis suppurativa flares following COVID-19 vaccination: a case series".

Delayed Vasovagal Reaction with Reflex Syncope Following COVID-19 Vaccination. Coronavirus disease 2019 (COVID-19) has become a pandemic, and vaccines remain the only effective tools available for ending it. However, their side effects, such as syncope, which mimics sudden cardiac death, are serious concerns. We herein report 6 cases of delayed vasovagal syncope and presyncope (VVR) caused by COVID-19 vaccination among 25,530 COVID-19 patients. The prevalence of delayed VVR due to COVID-19 vaccination was 0.026%. In addition, no delayed VVR was found among 17,386 patients who received the influenza vaccine. Delayed VVR is likely to be overlooked if medical staff are not aware of this symptom. This report provides significant information regarding effects of COVID-19 vaccination.
Pemphigus vulgaris after COVID-19 infection and vaccination.
Proposing a standardized assessment of COVID-19 vaccine-associated cutaneous reactions.
Isolated and Combined Unilateral Central Retinal Artery and Vein Occlusions After Vaccination. A Review of the Literature.
New-onset and relapse of nephrotic syndrome following COVID-19 vaccination: a questionnaire survey in Japan. BACKGROUND: Recent clinical reports indicate a correlation between new-onset and relapse of nephrotic syndrome (NS) following coronavirus 2019 (COVID-19) vaccination in patients with glomerular diseases. However, there are no reports of a nationwide survey on NS following COVID-19 vaccination in Japan. METHODS: We conducted a web-based survey of council members of the Japanese Society of Nephrology (581 members, 382 facilities) to elucidate the relationship between COVID-19 vaccination and new-onset and relapse of NS. RESULTS: Following COVID-19 vaccination, 27 patients (male: 15, 55.6%) with new-onset (nâ€‰=â€‰6) and relapse (nâ€‰=â€‰21) of NS were reported. Of them, 12 (44.4%) patients were diagnosed with minimal change disease at the occurrence of NS. Five patients developed a slight increase in serum creatinine levels; however, none progressed to severe renal dysfunction. CONCLUSION: Our findings clarify the clinical features of new-onset and relapse of NS following COVID-19 vaccination. Although there was no obvious progression to severe renal dysfunction, clinicians and pathologists should be aware that NS is a potential adverse effect of the vaccines.
Long-term serological SARS-CoV-2 IgG kinetics following mRNA COVID-19 vaccine: real-world data from a large cohort of healthcare workers. OBJECTIVES: This study aimed to assess kinetics and predictive variables of humoral immune response to mRNA SARS-CoV-2 vaccine administration. METHODS: We collected blood samples before (T0) and 15, 90, and 180 days after vaccination (T1, T2, and T3, respectively). The Quant SARS-CoV-2 Immunoglobulin (IgG) II Chemiluminescent Microparticle Immunoassay was used to determine anti-spike IgG. RESULTS: In almost 3000 healthcare-collected blood samples at the three time points, we found the following: at 15 days postvaccination, 97.6% of subjects presented a robust IgG anti-spike response (>4160 AU/ml); then, at three and six months, it decreased in median 6.5-fold to 35.0% and 3.0-fold to 3.3%, respectively. A linear mixed-effects model supported that female gender, younger age groups, and being seropositive prevaccination maintained higher antibody titers. Curves became tighter with time progression, although titers from seropositive subjects decrease at a slower rate than seronegative ones. CONCLUSION: These findings strengthen the case for a steep decrease of anti-SARS-CoV-2 antibodies up to six months, suggesting that serological evaluation might guide the need for periodic booster vaccinations in specific groups prone to lower antibody titers.
Thromboembolism after COVID-19 Vaccination: A Systematic Review of Such Events in 286 Patients. BACKGROUND: Development of vaccines with high efficacy against COVID-19 disease has ushered a new ray of hope in the fight against the pandemic. Thromboembolic events have been reported after administration of vaccines. We aim to systematically review thromboembolic events reported after COVID-19 vaccination. METHODS: The available literature was systematically screened for available

data on thromboembolic events after COVID-19 vaccination. Data were extracted from selected studies and analyzed for site of thromboembolism as well as other risk factors. All data were pooled to determine cumulative incidence of thromboembolism at various sites after vaccination. RESULTS: A total of 20 studies were selected for the final analysis. The mean age of the population was 48.5Â Â±Â 15.4Â years (females - 67.4%). The mean time to event after vaccination was 10.8Â Â±Â 7.2Â days. Venous thrombosis (74.8%, nÂ =Â 214/286) was more common than arterial thrombosis (27.9%, nÂ =Â 80/286). Cerebral sinus thrombosis was the most common manifestation (28.3%, nÂ =Â 81/286) of venous thrombosis followed by deep vein thrombosis (19.2%, nÂ =Â 49/254). Myocardial infarction was common (20.1%, nÂ =Â 55/274) in patients with arterial thrombosis followed by ischemic stroke (8.02%, nÂ =Â 22/274). Concurrent thrombosis at multiple sites was noted in 15.4% patients. Majority of patients had thrombocytopenia (49%) and antiplatelet factor 4 antibodies (78.6%). Thromboembolic events were mostly reported after the AstraZeneca vaccine (93.7%). Cerebral sinus thrombosis was the most common among thromboembolic events reported after the AstraZeneca vaccine. Among the reported cases, mortality was noted in 29.9% patients. CONCLUSIONS: Thromboembolic events can occur after COVID-19 vaccination, most commonly after the AstraZeneca vaccine. Cerebral sinus thrombosis is the most common manifestation noted in vaccinated individuals.

COVID-19 vaccination in pregnancy. Despite a recent endorsement from official and professional bodies unequivocally recommending COVID-19 vaccination, vaccine hesitancy among pregnant people remains high. The accumulated evidence demonstrates that pregnant people are a special risk group for COVID-19, with an increased risk of intensive care unit admission, extracorporeal membranous oxygenation requirement, preterm birth, and perinatal death. These risks are further increased with some variants of concern, and vaccination of pregnant people reduces the COVID-19-related increase in maternal or fetal morbidity. Data from more than 180,000 vaccinated persons show that immunization against COVID-19 with an mRNA vaccine is safe for pregnant people. Many observational studies comparing perinatal outcomes between vaccinated and unvaccinated pregnant people have had reassuring findings and did not demonstrate harmful effects on pregnancy or the newborn. Immunization with mRNA vaccines does not increase the risk of miscarriage, preterm delivery, low birthweight, maternal or neonatal intensive care unit admission, fetal death, fetal abnormality, or pulmonary embolism. Moreover, observational data corroborate the findings of randomized trials that mRNA vaccination is highly effective at preventing severe SARS-CoV-2 infection in pregnant people, emphasizing that the potential maternal and fetal benefits of vaccination greatly outweigh the potential risks of vaccination. Ensuring pregnant people have unrestricted access to COVID-19 vaccination should be a priority in every country worldwide.

Thrombosis, cancer, and COVID-19. Cancer and coronavirus disease 2019 (COVID-19) have unusual similarities: they both result in a markedly elevated risk of thrombosis, exceptionally high D-dimer levels, and the failure of anticoagulation therapy in some cases. Cancer patients are more vulnerable to COVID-19 infection and have a higher mortality rate. Science has uncovered much about SARS-CoV-2, and made extraordinary and unprecedented progress on the development of various treatment strategies and COVID-19 vaccines. In this review, we discuss known data on cancer-associated thrombosis (CAT), SARS-CoV-2 infection, and COVID-19 vaccines and discuss considerations for managing CAT in patients with COVID-19. Cancer patients should be given priority for COVID-19 vaccination; however, they may demonstrate a weaker immune response to COVID-19 vaccines than the general population. Currently, the Centers for Disease Control and Prevention recommends an additional dose and booster shot of the COVID-19 vaccine after the primary series in patients undergoing active cancer treatment for solid tumors or hematological cancers, recipients of stem cell transplant within the last 2Â years, those taking immunosuppressive medications, and those

undergoing active treatment with high-dose corticosteroids or other drugs that suppress the immune response. The mainstay of thrombosis treatment in patients with cancer and COVID-19 is anticoagulation therapy.
Liver injury after SARS-CoV-2 vaccination: Features of immune-mediated hepatitis, role of corticosteroid therapy and outcome. BACKGROUND AND AIMS: A few case reports of autoimmune hepatitis-like liver injury have been reported after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. We evaluated clinical features, treatment response and outcomes of liver injury following SARS-CoV-2 vaccination in a large case series. APPROACH AND RESULTS: We collected data from cases in 18 countries. The type of liver injury was assessed with the R-value. The study population was categorized according to features of immune-mediated hepatitis (positive autoantibodies and elevated immunoglobulin G levels) and corticosteroid therapy for the liver injury. We identified 87 patients (63%, female), median age 48 (range: 18-79) years at presentation. Liver injury was diagnosed a median 15 (range: 3-65) days after vaccination. Fifty-one cases (59%) were attributed to the Pfizer-BioNTech (BNT162b2) vaccine, 20 (23%) cases to the Oxford-AstraZeneca (ChAdOX1 nCoV-19) vaccine and 16 (18%) cases to the Moderna (mRNA-1273) vaccine. The liver injury was predominantly hepatocellular (84%) and 57% of patients showed features of immune-mediated hepatitis. Corticosteroids were given to 46 (53%) patients, more often for grade 3-4 liver injury than for grade 1-2 liver injury (88.9% vs. 43.5%, pÂ =Â 0.001) and more often for patients with than without immune-mediated hepatitis (71.1% vs. 38.2%, pÂ =Â 0.003). All patients showed resolution of liver injury except for one man (1.1%) who developed liver failure and underwent liver transplantation. Steroid therapy was withdrawn during the observation period in 12 (26%) patients after complete biochemical resolution. None had a relapse during follow-up. CONCLUSIONS: SARS-CoV-2 vaccination can be associated with liver injury. Corticosteroid therapy may be beneficial in those with immune-mediated features or severe hepatitis. Outcome was generally favorable, but vaccine-associated liver injury led to fulminant liver failure in one patient.
COVID-19 vaccine induced dermatological manifestations in pediatric population.
Marie Antoinette syndrome following COVID-19 vaccination.
T-cell recovery and evidence of persistent immune activation 12â€‰months after severe COVID-19. BACKGROUND: T-cell lymphopenia and functional impairment is a hallmark of severe acute coronavirus disease 2019 (COVID-19). How T-cell numbers and function evolve at later timepoints after clinical recovery remains poorly investigated. METHODS: We prospectively enrolled and longitudinally sampled 173 individuals with asymptomatic to critical COVID-19 and analyzed phenotypic and functional characteristics of T cells using flow cytometry, 40-parameter mass cytometry, targeted proteomics, and functional assays. RESULTS: The extensive T-cell lymphopenia observed particularly in patients with severe COVID-19 during acute infection had recovered 6â€‰months after infection, which was accompanied by a normalization of functional T-cell responses to common viral antigens. We detected persisting CD4(+) and CD8(+) T-cell activation up to 12â€‰months after infection, in patients with mild and severe COVID-19, as measured by increased HLA-DR and CD38 expression on these cells. Persistent T-cell activation after COVID-19 was independent of administration of a COVID-19 vaccine post-infection. Furthermore, we identified a subgroup of patients with severe COVID-19 that presented with persistently low CD8(+) T-cell counts at follow-up and exhibited a distinct phenotype during acute infection consisting of a dysfunctional T-cell response and signs of excessive pro-inflammatory cytokine production. CONCLUSION: Our study suggests that T-cell numbers and function recover in most patients after COVID-19. However, we find evidence of persistent T-cell activation up to 12â€‰months after infection and describe a subgroup of severe COVID-19 patients with persistently low CD8(+) T-cell counts exhibiting a dysregulated immune response during acute infection.

Pyoderma gangrenosum following vaccination against coronavirus disease-2019: a case report.
IgA nephropathy with glomerular capillary IgA deposition following SARS-CoV-2 mRNA vaccination: a report of three cases. IgA nephropathy (IgAN) cases histopathologically showing glomerular capillary IgA deposition represent a rare subtype of primary IgAN. Patients with IgAN categorized to this subtype often exhibit heavy proteinuria, advanced histological findings, and are resistant to therapies. Here, we report three cases of biopsy-proven IgAN with glomerular capillary IgA deposition who presented acute deterioration of urinalysis findings following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccinations. Case 1 was recurrent IgAN. Case 2 and Case 3 were newly diagnosed cases with subclinical microhematuria and proteinuria history. All three cases showed gross hematuria and acute exacerbations of proteinuria following SARS-CoV-2 mRNA vaccinations. In all three cases, kidney biopsy findings showed IgA deposition in glomerular capillary walls in addition to mesangial and para-mesangial areas; acute glomerular lesions, such as intra- and extracapillary proliferations were identified, indicating the possibility of a potentially severe type of IgAN. Therefore, attention should be paid to patients with de novo or relapsing IgAN showing marked capillary IgA deposition following SARS-CoV-2 vaccination.
Ischemic colitis after COVID-19 mRNA vaccine.
COVID-19 mRNA vaccine-associated encephalopathy, myocarditis, and thrombocytopenia with excellent response to methylprednisolone: A case report. INTRODUCTION: Large-scale vaccination is considered one of the most effective strategies to control the pandemic of COVID-19. Since its start, different complications have been described thought to be related to vaccination. Here, we present a rare case where encephalopathy, myocarditis, and thrombocytopenia developed simultaneously following the second dose of Pfizer-BioNTech mRNA vaccine (BNT162b2). CASE PRESENTATION: A 15-years-old female presented with fever, altered consciousness, and convulsions after taking the second shot of the vaccine. Clinical and laboratory workup was notable for the presence of thrombocytopenia and myocarditis. No alternative causes of encephalitis were found. The patient responded significantly to methylprednisolone suggesting underlying immune pathogenesis responsible for the clinical features. The diagnostic criteria for possible autoimmune encephalitis were also fulfilled. CONCLUSION: Although rare, the clinician should be aware of the possible adverse events following COVID-19 vaccination. Further research with large pooled data is needed to get more insight into its pathogenesis and causal relationship.
Safety of intramuscular COVID-19 vaccination in patients with haemophilia. BACKGROUND: Guidelines recommend that patients with haemophilia should preferably receive vaccination subcutaneously. COVID-19 and other vaccines, however, are only licenced for intramuscular application. AIMS: To assess the safety of intramuscular COVID-19 vaccination in patients living with haemophilia. METHODS: Part A of this prospective observational study enrolled consecutive patients with haemophilia A (HA) and B (HB) of all ages and severities and assessed injection site bleeding and other complications within 30 days of vaccination. Part B enrolled patients providing informed consent for detailed data collection including medication and prophylaxis around the time of vaccination. Logistic regression was performed to assess potential risk factors for bleeding. RESULTS: Four hundred and sixty-one patients were enrolled into part A. The primary endpoint injection site bleeding occurred in seven patients (1.5%, 95% confidence interval .7-3.1%). Comprehensive analysis of 214 patients (404 vaccinations, part B) revealed that 97% of patients with severe haemophilia had prophylaxis before vaccination, either as part of their routine prophylaxis or using additional doses. 56% and 30% of patients with moderate and mild haemophilia, respectively, received prophylaxis before vaccination. Among the seven bleeds recorded, three occurred when intramuscular vaccination was done without prophylaxis (odds ratio 12). CONCLUSIONS: This is the first prospective study reporting on the safety of intramuscular vaccination in haemophilia. The rate of injection site

bleeding was low in mild haemophilia, and in moderate and severe haemophilia if patients received factor prophylaxis.
Flare-up of generalized pustular psoriasis following Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine: Two cases without mutations of IL36RN and CARD14 genes.
Safety profile of COVID-19 vaccines, preventive strategies, and patient management. INTRODUCTION: Fast-track approval has led to serious concerns on the perception of COVID-19 vaccines' safety among the public. Common adverse drug reactions (ADRs) of COVID-19 vaccines are minor localized reactions, while systemic ADRs have been reported rarely. The serious ADRs include anaphylaxis, vaccine-induced immune thrombotic thrombocytopenia syndrome (VITTS), and reactions related to the pharmaceutical excipients present in the vaccine. A comprehensive review on the safety of COVID-19 vaccines would help in early identification and better management of ADRs. This literature review was conducted using PubMed, Google Scholar, COVID-19 Vaccine package inserts, and UpToDate. AREAS COVERED: This article provides various aspects of COVID-19 vaccine safety and offers strategies to prevent and clinically manage suspected ADRs related to COVID-19 vaccines. EXPERT OPINION: A careful consideration of contraindications and patient education on early identification of serious ADRs are the cornerstones in tackling safety concerns associated with COVID-19 vaccines. Most of the mild ADR cases are manageable with over-the-counter medications, while the serious ones may require physician oversight and hospitalization. It is also mandatory to report all ADRs to the local pharmacovigilance centers, with a higher priority given to the moe significant ones, in order to improve vaccine safety data.
Post-COVID-19 vaccination inflammatory syndrome: A case report. A previously healthy 24-year-old male patient was referred to our clinic with bilateral lower extremity pain and dark urine, which were developed 2 weeks after receiving the second dose of the BNT162b2 vaccine against severe acute respiratory coronavirus 2. Laboratory tests indicated rhabdomyolysis. Lower extremity magnetic resonance imaging was compatible with myositis. Myositis-related antibodies were negative. Biopsy taken from gastrocnemius muscle revealed muscle necrosis and striking expression of major histocompatibility complex class I antigen. He was successfully treated, and his complaints were resolved. One week later at follow-up, he reported new-onset exertional dyspnoea with palpitations. ST-segment depressions were spotted on electrocardiography. Troponin T was found elevated as 0.595â€‰ng/ml (normal <0.014â€‰ng/ml). Echocardiography showed a hypokinetic left ventricle with an ejection fraction of 40% and pericardial effusion of 2â€‰mm. An appropriate treatment plan was formulated for the diagnosis of myocarditis, eventually, the patient recovered within 10â€‰days. The BNT162b2 messenger ribonucleic acid (mRNA) vaccine was felt to cause the aforementioned condition since no other aetiology could be identified. Although it is known that BNT162b2 may induce myocarditis, myositis concomitant myocarditis appears to be a very rare adverse effect of this vaccine.
Response to: Focal segmental glomerulosclerosis recurrence in a young adult with kidney transplant after mRNA COVID-19 vaccination.
Acute necrotizing eosinophilic myocarditis after COVID-19 vaccination.
Immunogenicity and Safety of SARS-CoV-2 mRNA Vaccines in a Cohort of Patients With Type 1 Diabetes. Patients with type 1 diabetes (T1D) may develop severe outcomes during coronavirus disease 2019 (COVID-19), but their ability to generate an immune response against the SARS-CoV-2 mRNA vaccines remains to be established. We evaluated the safety, immunogenicity, and glycometabolic effects of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccines in patients with T1D. A total of 375 patients (326 with T1D and 49 subjects without diabetes) who received two doses of the SARS-CoV-2 mRNA vaccines (mRNA-1273, BNT162b2) between March and April 2021 at ASST Fatebenefratelli Sacco were included in this monocentric observational study.

Local and systemic adverse events were reported in both groups after SARS-CoV-2 mRNA vaccination, without statistical differences between them. While both patients with T1D and subjects without diabetes exhibited a parallel increase in anti-SARS-CoV-2 spike titers after vaccination, the majority of patients with T1D (70% and 78%, respectively) did not show any increase in the SARS-CoV-2-specific cytotoxic response compared with the robust increase observed in all subjects without diabetes. A reduced secretion of the T-cell-related cytokines interleukin-2 and tumor necrosis factor-Î± in vaccinated patients with T1D was also observed. No glycometabolic alterations were evident in patients with T1D using continuous glucose monitoring during follow-up. Administration of the SARS-CoV-2 mRNA vaccine is associated with an impaired cellular SARS-CoV-2-specific cytotoxic immune response in patients with T1D.

A definite case of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) induced by administration of the Pfizer/BioNTech BNT162b2 vaccine for SARS-CoV2. At the end of December 2020, the anti-SARS-CoV2 vaccination campaign began in Italy. As the number of vaccinated subjects in the general population has increased, several adverse reactions have been observed and reported. Severe cutaneous adverse reactions (SCARs) induced by drugs or vaccines are rare but distinguished by high mortality and include DRESS syndrome or drug induced hypersensitivity syndrome (DiHS), a condition characterized by skin rash, eosinophilia, fever, lymphadenopathy, and involvement of one or more internal organs. Here we present a definite case of DRESS that occured following the administration of Pfizer/BioNTech COVID 19 vaccine. He required hospitalization and was managed with supportive care, antihistamines, and intravenous steroid.

Adverse Events and Safety of SARS-CoV-2 Vaccines: What's New and What's Next. Just over 1 year following rollout of the first vaccines for coronavirus disease 2019, 572 million doses have been administered in the United States. Compared with the number of vaccines administered, adverse effects such as anaphylaxis have been rare, and seemingly, the more serious the effect, the rarer the occurrence. Despite these adverse effects, there are few, if any, true contraindications to coronavirus disease 2019 vaccination and most individuals recover without further sequelae. This review provides guidance for the allergist/immunologist regarding appropriate next steps based on patient's known allergy history or adverse reaction after receipt of coronavirus disease 2019 vaccine to assist in safe global immunization.

Safety, immunogenicity, and reactogenicity of BNT162b2 and mRNA-1273 COVID-19 vaccines given as fourth-dose boosters following two doses of ChAdOx1 nCoV-19 or BNT162b2 and a third dose of BNT162b2 (COV-BOOST): a multicentre, blinded, phase 2, randomised trial. BACKGROUND: Some high-income countries have deployed fourth doses of COVID-19 vaccines, but the clinical need, effectiveness, timing, and dose of a fourth dose remain uncertain. We aimed to investigate the safety, reactogenicity, and immunogenicity of fourth-dose boosters against COVID-19. METHODS: The COV-BOOST trial is a multicentre, blinded, phase 2, randomised controlled trial of seven COVID-19 vaccines given as third-dose boosters at 18 sites in the UK. This sub-study enrolled participants who had received BNT162b2 (Pfizer-BioNTech) as their third dose in COV-BOOST and randomly assigned them (1:1) to receive a fourth dose of either BNT162b2 (30 Î¼g in 0Â·30 mL; full dose) or mRNA-1273 (Moderna; 50 Î¼g in 0Â·25 mL; half dose) via intramuscular injection into the upper arm. The computer-generated randomisation list was created by the study statisticians with random block sizes of two or four. Participants and all study staff not delivering the vaccines were masked to treatment allocation. The coprimary outcomes were safety and reactogenicity, and immunogenicity (anti-spike protein IgG titres by ELISA and cellular immune response by ELISpot). We compared immunogenicity at 28 days after the third dose versus 14 days after the fourth dose and at day 0 versus day 14 relative to the fourth dose. Safety and reactogenicity were assessed in the per-protocol population, which comprised all participants who received a fourth-dose booster regardless of their SARS-CoV-2

serostatus. Immunogenicity was primarily analysed in a modified intention-to-treat population comprising seronegative participants who had received a fourth-dose booster and had available endpoint data. This trial is registered with ISRCTN, 73765130, and is ongoing. FINDINGS: Between Jan 11 and Jan 25, 2022, 166 participants were screened, randomly assigned, and received either full-dose BNT162b2 (n=83) or half-dose mRNA-1273 (n=83) as a fourth dose. The median age of these participants was 70Â·1 years (IQR 51Â·6-77Â·5) and 86 (52%) of 166 participants were female and 80 (48%) were male. The median interval between the third and fourth doses was 208Â·5 days (IQR 203Â·3-214Â·8). Pain was the most common local solicited adverse event and fatigue was the most common systemic solicited adverse event after BNT162b2 or mRNA-1273 booster doses. None of three serious adverse events reported after a fourth dose with BNT162b2 were related to the study vaccine. In the BNT162b2 group, geometric mean anti-spike protein IgG concentration at day 28 after the third dose was 23â€‰325 ELISA laboratory units (ELU)/mL (95% CI 20â€‰030-27â€‰162), which increased to 37â€‰460 ELU/mL (31â€‰996-43â€‰857) at day 14 after the fourth dose, representing a significant fold change (geometric mean 1Â·59, 95% CI 1Â·41-1Â·78). There was a significant increase in geometric mean anti-spike protein IgG concentration from 28 days after the third dose (25â€‰317 ELU/mL, 95% CI 20â€‰996-30â€‰528) to 14 days after a fourth dose of mRNA-1273 (54â€‰936 ELU/mL, 46â€‰826-64â€‰452), with a geometric mean fold change of 2Â·19 (1Â·90-2Â·52). The fold changes in anti-spike protein IgG titres from before (day 0) to after (day 14) the fourth dose were 12Â·19 (95% CI 10Â·37-14Â·32) and 15Â·90 (12Â·92-19Â·58) in the BNT162b2 and mRNA-1273 groups, respectively. T-cell responses were also boosted after the fourth dose (eg, the fold changes for the wild-type variant from before to after the fourth dose were 7Â·32 [95% CI 3Â·24-16Â·54] in the BNT162b2 group and 6Â·22 [3Â·90-9Â·92] in the mRNA-1273 group). INTERPRETATION: Fourth-dose COVID-19 mRNA booster vaccines are well tolerated and boost cellular and humoral immunity. Peak responses after the fourth dose were similar to, and possibly better than, peak responses after the third dose. FUNDING: UK Vaccine Task Force and National Institute for Health Research.

Recall of preexisting cross-reactive B cell memory after Omicron BA.1 breakthrough infection. Understanding immune responses after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) breakthrough infection will facilitate the development of next-generation vaccines. Here, we profiled spike (S)-specific B cell responses after Omicron/BA.1 infection in messenger RNA-vaccinated donors. The acute antibody response was characterized by high levels of somatic hypermutation and a bias toward recognition of ancestral SARS-CoV-2 strains, suggesting the early activation of vaccine-induced memory B cells. BA.1 breakthrough infection induced a shift in B cell immunodominance hierarchy from the S2 subunit, which is highly conserved across SARS-CoV-2 variants of concern (VOCs), and toward the antigenically variable receptor binding domain (RBD). A large proportion of RBD-directed neutralizing antibodies isolated from BA.1 breakthrough infection donors displayed convergent sequence features and broadly recognized SARS-CoV-2 VOCs. Together, these findings provide insights into the role of preexisting immunity in shaping the B cell response to heterologous SARS-CoV-2 variant exposure.

Enhanced Humoral Immune Response After COVID-19 Vaccination in Elderly Kidney Transplant Recipients on Everolimus Versus Mycophenolate Mofetil-containing Immunosuppressive Regimens. BACKGROUND: Elderly kidney transplant recipients (KTRs) represent almost one third of the total kidney transplant population. These patients have a very high coronavirus disease 2019 (COVID-19)-related mortality, whereas their response to COVID-19 vaccination is impaired. Finding ways to improve the COVID-19 vaccination response in this vulnerable population is of uttermost importance. METHODS: In the OPTIMIZE trial, we randomly assign elderly KTRs to an immunosuppressive regimen with standard-exposure calcineurin inhibitor (CNI), mycophenolate mofetil, and prednisolone or an

adapted regimen with low dose CNI, everolimus, and prednisolone. In this substudy, we measured the humoral response after 2 (N = 32) and 3 (N = 22) COVID-19 mRNA vaccinations and the cellular response (N = 15) after 2 vaccinations. RESULTS: . The seroconversion rates of elderly KTRs on a standard immunosuppressive regimen were only 13% and 38% after 2 and 3 vaccinations, respectively, whereas the response rates of KTRs on the everolimus regimen were significantly higher at 56% (P = 0.009) and 100% (P = 0.006). Levels of severe acute respiratory syndrome coronaVirus 2 IgG antibodies were significantly higher at both time points in the everolimus group (P = 0.004 and P < 0.001). There were no differences in cellular response after vaccination. CONCLUSIONS: An immunosuppressive regimen without mycophenolate mofetil, a lower CNI dose, and usage of everolimus is associated with a higher humoral response rate after COVID-19 vaccination in elderly KTRs after transplantation. This encouraging finding should be investigated in larger cohorts, including transplant recipients of all ages.

A case of adenoviral covid-19 vector vaccine possibly linked to severe but reversible interstitial lung injury post-vaccination. BACKGROUND: Several safe and effective vaccines against nCoV-19 have been developed to contain the pandemic with very few severe adverse-reactions reported. Vaccine-induced interstitial lung disease (ILD) is a very rare and difficult to recognise and diagnose adverse-reaction and is mostly associated with Influenza vaccines. METHODS: We report a 55-yr old male who presented with severe respiratory failure that required for several days oxygen supplementation with high flow nasal cannula, and myocardial infarction. Symptoms onset was eighteen days after the first shot of adenoviral AZD1222 vector vaccine. Possible SARS-CoV-2 natural infection post-vaccination was excluded with rigorous laboratory work-up including multiple nasopharengeal rt-qPCR tests for SARS-CoV-2 detection and close monitoring of his serum SARS-CoV-2 antibodies. Other potential infectious agents and alternate diagnoses were thoroughly investigated. RESULTS: Patient responded impressively to high dose steroids. A repeat chest CT nine days after the first one showed a remarkable resolution of the bilateral ground glass opacities. Except for his cardiology medication, no supplemental oxygen neither steroids were prescribed upon his discharge. On one month follow-up, no residual pulmonary dysfunction was noticed with patient preserving a SatO2 of 97-98% on ambient air. CONCLUSION: Vaccine-induced ILD might constitute a rare nCoV-19 post-vaccination adverse-event. According to current restricted data, when post-vaccination ILD is early suspected and recognised, then prompt implementation of steroid treatment reverses significantly the lung lesions without progression to fibrosis.

Supraglottitis as the sole manifestation of COVID-19 in a patient who received two doses of mRNA vaccine.

Seroconversion rate after primary vaccination with two doses of BNT162b2 versus mRNA-1273 in solid organ transplant recipients: a systematic review and meta-analysis. BACKGROUND: In the general population, the seroconversion rate after primary vaccination with two doses of an anti-severe acute respiratory syndrome coronavirus 2 messenger RNA (mRNA) vaccine reaches nearly 100%, with significantly higher antibody titers after mRNA-1273 vaccination compared to BNT162b2 vaccination. Here we performed a systematic review and meta-analysis to compare the antibody response after two-dose mRNA-1273 versus BNT162b2 vaccination in solid organ transplant (SOT) recipients. METHODS: A systematic literature review was performed using PubMed, Web of Science and the Cochrane Library and original research papers were included for a meta-analysis to calculate vaccine-specific seroconversion rates for each of the mRNA vaccines. Next, the pooled relative seroconversion rate was estimated. RESULTS: Eight studies that described the development of antibodies against receptor-binding domain (RBD) and/or spike protein were eligible for meta-analysis. Two of these studies also reported antibody titers. The meta-analysis revealed lower seroconversion rates in SOT recipients vaccinated with two doses of BNT162b2 {44.3% [95%

confidence interval (CI) 34.1-54.7]} as compared with patients vaccinated with two doses of mRNA-1273 [58.4% (95% CI 47.2-69.2)]. The relative seroconversion rate was 0.795 (95% CI 0.732-0.864). CONCLUSIONS: This systematic review and meta-analysis indicates that in SOT recipients, higher seroconversion rates were observed after vaccination with mRNA-1273 compared with BNT162b2.

Neuropsychiatric symptoms in post-COVID-19 long haulers. BACKGROUND: Long haulers have been recently reported after contracting coronavirus disease (COVID-19). In the present study, we aimed to screen for the neuropsychiatric signs detected <1 to >6 months after infection by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and to determine whether vaccination has an effect on them. METHODS: An online survey was conducted among participants who had been diagnosed with laboratory-confirmed SARS-CoV-2 infection. The clinical signs and durations of neuropsychiatric complaints and their correlations to sex, age, severity of COVID-19 signs, and vaccination status were screened. RESULTS: A total of 2218 individuals, including 1358 females and 860 males, with an age range of 12-70 years, submitted their responses. The respondents experienced cognitive dysfunction, mood alteration, depression, tinnitus, sleep disorders, and loss of taste and smell, with prevalence rates ranging from 18.9% (tinnitus) to 63.9% (loss of taste and smell). Of the respondents, 2.2-7.7% confirmed the persistence of symptoms for >6 months. Tinnitus was the least common complaint, and only 2.2% of the study participants had tinnitus for >6 months. Meanwhile, mood alteration persisted for >6 months in 7.6% of the study participants. More respondents who received two doses of BNT162b2 vaccine showed persistent symptoms than those in the other groups. Disease severity and female sex were identified as potential determinants of the development and persistency of such symptoms. CONCLUSION: Post-COVID neuropsychiatric symptoms were present in considerable percentages of the study participants with SARS-CoV-2 infection, persisting for >6 months in up to 7.6% of the participants.

Adverse effects of COVID-19 mRNA vaccines: the spike hypothesis. Vaccination is a major tool for mitigating the coronavirus disease 2019 (COVID-19) pandemic, and mRNA vaccines are central to the ongoing vaccination campaign that is undoubtedly saving thousands of lives. However, adverse effects (AEs) following vaccination have been noted which may relate to a proinflammatory action of the lipid nanoparticles used or the delivered mRNA (i.e., the vaccine formulation), as well as to the unique nature, expression pattern, binding profile, and proinflammatory effects of the produced antigens - spike (S) protein and/or its subunits/peptide fragments - in human tissues or organs. Current knowledge on this topic originates mostly from cell-based assays or from model organisms; further research on the cellular/molecular basis of the mRNA vaccine-induced AEs will therefore promise safety, maintain trust, and direct health policies.

The vaccination status and adverse effects of COVID-19 vaccine among pregnant women in Japan in 2021. To investigate the vaccination status and adverse reactions to the COVID-19 vaccine among pregnant women in Japan, we conducted an online questionnaire survey from October 5 to November 22, 2021. The number of participants in the online survey was 6576. Of the participants, 4840 (73.6%) were vaccinated twice, and 557 (8.5%) were vaccinated once. A total of 1179 (17.9%) responders had never been vaccinated against COVID-19. The most frequent adverse reaction was local pain at the injection site. The incidence of local adverse reactions was almost identical after the first and the second vaccinations, while systemic reactions, such as fever and fatigue/malaise, and adverse reactions outside the vaccination site such as headache and arthralgia, were more frequent after the second vaccination than after the first vaccination. Regarding the obstetrical complications, uterine tension and/or contraction was observed in 1.65% of the pregnant women after the first vaccination and in 2.98% after the second vaccination, and uterine pain appeared in 1.06% of the pregnant women after the second vaccination. However, serious symptoms, such as hemorrhage, decreased fetal movement, edema, increased blood pressure, and amniorrhexis, were seen in less

than 1% of vaccinated women after both the first and second vaccinations. This study clarified the characteristics of vaccination, adverse reactions, and obstetrical symptoms in pregnant women in Japan who had the COVID-19 vaccine up to the second dose. As a booster vaccination is currently underway, further study is needed to improve the management of pregnant women during the current pandemic.
Vaccine-induced T-cell responses against SARS-CoV-2 and its Omicron variant in patients with B cell-depleted lymphoma after CART therapy. Patients receiving CD19 CAR T-cell therapy for relapsed/refractory lymphoma experience prolonged and profound B-cell aplasia and hypogammaglobulinemia, placing them at a higher risk for severe COVID-19. Independently, Oh et al and Atanackovic et al demonstrate that despite attenuated humoral response to mRNA-based vaccines, patients demonstrate normal or heightened functional T-cell responses, including antiviral T-cell activity against SARS-CoV-2 variants including Omicron. Collectively, these data reinforce the importance of COVID-19 vaccination following CD19 CAR T-cell therapy, despite long-term B-cell aplasia.
Erythrodermic pityriasis rubra pilaris after SARS-CoV-2 vaccination with concomitant COVID-19 infection.
Onset of amyopathic dermatomyositis following mRNA-based SARS-CoV-2 vaccination.
Allergic reaction to red cosmetic lip tattoo with possible exacerbations after SARS-CoV-2 vaccination.
Development of delayed dermal hypersensitivity reaction following the second dose of COVID-19 vaccine - A series of 37 cases.
Exacerbation of immune thrombocytopenia following initial and booster vaccination with Pfizer-BioNTech COVID-19 vaccine. As the immune thrombocytopenia exacerbation rate after booster COVID-19 vaccines is unknown, we explore the rates after first, second and booster Pfizer-BioNTech COVID-19 vaccines. A retrospective study of adult ITP patients, receiving 1-3 vaccines was performed. The primary outcome was clinical ITP exacerbation defined as platelet count decrease requiring initiation/escalation of ITP treatment and/or new medical attention due to bleeding, within 3Â months. Secondary outcome was any clinically relevant platelet decrease during the 3Â months post-vaccination. The study included 93 ITP patients receiving 1 (nÂ =Â 2), 2 (nÂ =Â 22) or 3 (nÂ =Â 69) vaccines. ITP exacerbation occurred in 2/93 (2.2%) patients following initial vaccination and in 3/69 (4.3%) following booster dose. Clinically relevant platelet decreases after initial doses occurred in 8/72 (11.1%) patients and in 8/39 (20.5%) after the booster. Clinical ITP exacerbation after booster doses did not follow clinical exacerbation after initial doses. Half of patients with clinically relevant platelet decreases after booster dose also had clinically relevant decreases following initial vaccination. We concluded that clinical ITP exacerbation is infrequent following Pfizer-BioNTech COVID-19 vaccine. Clinical exacerbation after booster doses was not preceded by clinical exacerbation after initial doses. Clinically relevant platelet decreases after booster doses occur frequently in patients with clinically relevant decreases after initial doses.
Safety of COVID-19 vaccines and disease flares after vaccines in children with rheumatic disease. OBJECTIVES: Wide spread availability of safe and effective vaccines for COVID-19 in all countries is the best hope to end the COVID-19 pandemic. However, in developing countries, the hesitancy of the society about vaccination is an important problem in terms of public health. This study aimed to investigate the acceptability and tolerability of COVID-19 vaccines in the pediatric population diagnosed with rheumatic disease, as well as the attitudes toward these vaccines. METHODS: This is an observational, cross sectional, single center study. Pediatric patients with at least one diagnosis of rheumatic disease were included in this study to investigate patient and family acceptability and safety of COVID-19 vaccines. RESULTS: A total of 228 patients with rheumatic disease were included in this study. Ninety nine (43.4%) of the patients were juvenile idiopathic arthritis. One hundred and

five (46%) of the patients were using biological agent treatment for their rheumatic disease, whereas 123 (54%) of the patients were not. No serious adverse effect related to the COVID-19 vaccine were observed in any of the patients. No disease activation was observed in any of them. CONCLUSION: There are only a few studies evaluating of the safety and disease flare of COVID-19 vaccines in children with rheumatic disease. Although this study has some limitations, such as the small sample size of patients with different diagnoses, it appears that there is no increase in COVID-19 vaccination-related harms in the patients with rheumatic disease.
Association between COVID-19 vaccination and autoimmune bullous diseases: a random coincidence or rare event.
Vaccine-induced immune thrombotic thrombocytopenia in a male after Ad26.COV2.S vaccination presenting as cerebral venous sinus thrombosis. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare and life-threatening complication that can occur after COVID-19 vaccination. After the first reports of VITT and CVST in 2021 after Ad26.COV2.S vaccination, the FDA and CDC recommended an emergency pause on 13 April 2021, and after extensive safety reviews, on 23 April 2021, the CDC's Advisory Committee on Immunization Practices (ACIP) reaffirmed its original recommendation for use of the Ad26.COV2.S vaccination. As of 31 August 2021, in the United States, 54 cases of VITT following Ad26.COV2.S vaccination (37 female, 17 male) have been reported out of 14.1 million total shots given, 29 of which had cerebral venous sinus thrombosis (CVST). With more data, on 16 December 2021, the CDC endorsed the ACIP recommendations for individuals to receive an mRNA COVID-19 vaccine in preference over the Ad26.COV2.S vaccination. We report a rare case of a male with confirmed VITT and CVST following Ad26.COV2.S vaccination.
A systematic review on COVID-19 vaccination and cosmetic filler reactions: A focus on case studies and original articles. BACKGROUND: Tissue fillers are among the most popular cosmetic procedures performed and notably, cases of filler reactions after COVID-19 vaccination have been reported. OBJECTIVE: The objective was to determine the characteristics of patients with filler reaction after COVID-19 vaccination and address several considerations that have to be taken into practice. METHODS: A PRISMA compliant systematic search was conducted in Scopus, Web of Science, and PubMed/MEDLINE databases for articles published from inception up to October 21, 2021. RESULTS: Out of 106 initially retrieved articles, four of them were included in our study, and a total number of 13 cases were analyzed. In this study, we found that all of the patients who developed delayed-type reaction (DTR) following COVID-19 vaccination were middle-aged women without any known history of allergy to foods or drugs. All patients had a history of hyaluronic acid (HA) filler injection in their head and neck and demonstrated symptoms particularly swelling, from <1Â day up to 10â€‰days after the first or second doses of vaccines. Lisinopril, hyaluronidase, and corticosteroids seemed to have good results in management. CONCLUSION: Although rare, DTR to fillers after COVID-19 vaccination can happen. Physicians should be aware of the pathogenesis and management of this phenomenon.
Autoimmune Hepatitis-Like Syndrome Following COVID-19 Vaccination: Real or Imagined?
Do not misjudge the neurological nature of psychiatric symptoms following COVID-19 vaccinations.
Immunocompromise and durability of BNT162b2 vaccine against severe outcomes due to omicron and delta variants.
Variant Guillain-Barre Syndrome Following SARS-CoV-2 Vaccination: Case Report and Review of the Literature.
Immune transcriptome and antibody response in adult-onset Still's disease with mild flare following administration of mRNA vaccine BNT162b2.
Pityriasis rosea and pityriasis rosea-like eruptions after COVID-19 vaccines.

Antibody levels in people with diabetes after one dose of the ChAdOx1 nCoV-19 (AZD1222) vaccine. Patients with diabetes and coexistent coronavirus disease 2019 (COVID-19) have a higher risk of COVID-19 complications. Therefore, it is critical that sustained and effective immunogenicity against COVID-19 is achieved in such patients. This study evaluates the antibody response for 56Â days after the first dose of the AZD1222 vaccine in subjects with and without diabetes to assess the potential risk of delaying the second dose. This study included 282 people who received one dose of AZD1222. The geometric mean concentration of antibodies specific for severe acute respiratory syndrome coronavirus 2 IgG at 56Â days was significantly (Pâ€‰<â€‰0.001) lower in people with type 2 diabetes mellitus (T2D; 15.13 BAU/mL, 95% confidence interval [CI]â€‰=â€‰10.7-21.4) than in those without diabetes (40.20 BAU/mL, 95% CIâ€‰=â€‰33.43-48.36), as confirmed by a geometric mean ratio of 0.37 (95% CIâ€‰=â€‰0.25-0.54). Weaker immune responses were also observed in diabetic patientsâ€‰â‰¥â€‰65Â years old (10.09 BAU/mL, 95% CIâ€‰=â€‰6.09-16.71) compared with their younger counterparts (22.31 BAU/mL, 95% CIâ€‰=â€‰13.98-35.59, Pâ€‰=â€‰0.034). People with T2D had weaker antibody responses than those without diabetes after the first dose of AZD1222. Older age was associated with weaker antibody responses in elderly patients with diabetes.

Epidemiology, clinical presentations and outcome of patients presenting to the emergency department after a COVID-19 vaccination: An observational study. OBJECTIVE: The World Health Organization declared the COVID-19 pandemic on 11 March 2020. In 2021, several vaccines were provisionally approved to reduce the risk of transmission and hospitalisation of COVID-19 infection. A surge in COVID-19 vaccination was seen between August and October 2021 in Victoria, Australia. We hypothesised this led to an increase in ED presentations. METHODS: Patients in the present study were adults who presented to the ED within 21â€‰days of receiving a dose of a COVID-19 vaccine between 11 August 2021 and 14 November 2021. All cases underwent chart reviews to extract epidemiological features, clinical presentations, ED assessments, investigations and disposition. RESULTS: Notably, 968 patients were included in the study, comprising 6.1% of all ED presentations during the study period. The median age was 31â€‰years. 82.9% of patients were younger than 45â€‰years. 20.1% of patients arrived by ambulance. Chest pain was the most common presenting complaint (43.6%), followed by headache (10.3%) and palpitations (8.2%). The most common investigations were a full blood examination (73.5%), an ECG (63.8%) and serum troponin (49.1%). 64.8% of patients were directly discharged home and 22.1% were sent home after a short stay admission. Only 2.2% of patients were admitted to the hospital. CONCLUSION: A majority of patients who presented to the ED after their COVID vaccinations were young and discharged home after the initial assessment. These presentations have significantly increased the workload in prehospital settings and EDs, contributing to increased investigation usage, ED treatment space occupancy, and increased costs to the health system.

[Delayed acute urticaria after the third vaccine against SARS-CoV-2].

Incidence and clinical phenotype of multisystem inflammatory syndrome in children after infection with the SARS-CoV-2 delta variant by vaccination status: a Danish nationwide prospective cohort study. BACKGROUND: Multisystem inflammatory syndrome in children (MIS-C) occurs after infection with SARS-CoV-2 and its incidence is likely to depend on multiple factors, including the variant of the preceding SARS-CoV-2 infection and vaccine effectiveness. We aimed to estimate the incidence of MIS-C, and describe the clinical phenotype, following the delta variant of SARS-CoV-2 (B.1.617.2 and sublineages) according to vaccination status. We aimed to compare the incidence and clinical phenotype of MIS-C from our cohort during the pre-delta era. METHODS: This prospective, population-based cohort study included patients aged 0-17 years hospitalised with MIS-C in Denmark, according to the US Centers for Disease Control and Prevention case definition, from Aug 1, 2021, to

Feb 1, 2022, a period dominated by the delta variant. We identified MIS-C cases via a nationwide research collaboration involving real-time data collection from all 18 paediatric departments. Aggregated number of SARS-CoV-2 infections by vaccination status was obtained from the Danish COVID-19 surveillance registries. The incidence of MIS-C was calculated using the estimated number of infected individuals by vaccination status. We calculated the incidence of MIS-C per 1â€‰000â€‰000 vaccinated and unvaccinated person-years, and estimated vaccine effectiveness as 1-incidence rate ratio using Poisson regression. Incidence and phenotype of MIS-C were compared with MIS-C cases from the first year of the pandemic. This study is registered at ClinicalTrials.gov, NCT05186597. FINDINGS: We identified 51 MIS-C cases among unvaccinated individuals and one in a fully vaccinated adolescent. The incidence of MIS-C was one in 3400 unvaccinated individuals (95% CI 2600-4600) with the delta variant and one in 9900 vaccinated individuals (95% CI 1800-390â€‰000) with breakthrough infection. The estimated vaccine effectiveness against MIS-C after the delta variant was 94% (95% CI 55-99; p=0Â·0061) in individuals aged 5-17 years. The clinical phenotype during the delta wave was comparable to the pre-delta era. INTERPRETATION: We found the incidence and phenotype of MIS-C in unvaccinated children during the delta wave to be similar to the incidence during the first year of the pandemic. We found vaccine effectiveness to be high against MIS-C, which we suggest was due to protection from infection and, possibly, a decreased incidence of MIS-C after breakthrough infection. Knowledge of the incidence of MIS-C after different SARS-CoV-2 variants and the effect of vaccination might contribute to the elucidation of the extent to which MIS-C is a vaccine-preventable disease. FUNDING: National Ministry of Higher Education and Science and Innovation Fund Denmark.

Factors Associated With Parental Acceptance of COVID-19 Vaccination: A Multicenter Pediatric Emergency Department Cross-Sectional Analysis. STUDY OBJECTIVE: During the delta surge of the COVID-19 pandemic in 2021, we sought to identify characteristics and beliefs associated with COVID-19 vaccination acceptance in parents of pediatric emergency department (ED) patients. METHODS: We conducted a cross-sectional survey-based study of the parents of children aged 3 to 16 years presenting to 1 of 9 pediatric EDs from June to August 2021 to assess the parental acceptance of COVID-19 vaccines. Using multiple variable regression, we ascertained which factors were associated with parental and pediatric COVID-19 vaccination acceptance. RESULTS: Of 1,491 parents approached, 1,298 (87%) participated, of whom 50% of the parents and 27% of their children aged 12 years or older and older were vaccinated. Characteristics associated with parental COVID-19 vaccination were trust in scientists (adjusted odds ratio [aOR] 5.11, 95% confidence interval [CI] 3.65 to 7.15), recent influenza vaccination (aOR 2.66, 95% CI 1.98 to 3.58), college degree (aOR 1.97, 95% CI 1.36 to 2.85), increasing parental age (aOR 1.80, 95% CI 1.45 to 2.22), a friend or family member hospitalized because of COVID-19 (aOR 1.34, 95% CI 1.05 to 1.72), and higher income (aOR 1.60, 95% CI 1.27 to 2.00). Characteristics associated with pediatric COVID-19 vaccination (children aged â‰¥12 years) or intended COVID-19 pediatric vaccination, once approved for use, (children aged <12 years) were parental trust in scientists (aOR 5.37, 95% CI 3.65 to 7.88), recent influenza vaccination (aOR 1.89, 95% CI 1.29 to 2.77), trust in the media (aOR 1.68, 95% CI 1.19 to 2.37), parental college degree (aOR 1.49, 95% CI 1.01 to 2.20), and increasing parental age (aOR 1.26, 95% CI 1.01 to 1.57). CONCLUSION: Overall COVID-19 vaccination acceptance was low. Trust in scientists had the strongest association with parental COVID-19 vaccine acceptance for both themselves and their children.

Risk of appendicitis after SARS-CoV-2 infection and SARS-CoV-2 vaccination.

Post-genomic platform for development of oligonucleotide vaccines against RNA viruses: diamond cuts diamond. The coronavirus pandemic has starkly demonstrated the need to create highly effective vaccines against various viral diseases. The emerging new platforms for vaccine creation (adenovirus vectors and mRNA vaccines) have shown their worth in the fight against the prevention

of coronavirus infection. However, adenovirus vectors and mRNA vaccines have a serious disadvantage: as a rule, only the S protein of the coronavirus is presented as an antigen. This tactic for preventing infection allows the ever-mutating virus to escape quickly from the immunity protection provided by such vaccines. Today, viral genomic databases are well-developed, which makes it possible to create new vaccines on a fundamentally new post-genomic platform. In addition, the technology for the synthesis of nucleic acids is currently experiencing an upsurge in demand in various fields of molecular biology. The accumulated experience suggests that the unique genomic sequences of viruses can act as antigens that trigger powerful humoral and cellular immunity. To achieve this effect, the following conditions must be created: the structure of the nucleic acid must be single-stranded, have a permanent 3D nanostructure, and have a unique sequence absent in the vaccinated organism. Oligonucleotide vaccines are able to resist the rapidly changing genomic sequences of RNA viruses by using conserved regions of their genomes to generate a long-term immune response, acting according to the adage that a diamond cuts a diamond. In addition, oligonucleotide vaccines will not contribute to antibody-dependent enhanced infection, since the nucleic acid of the coronavirus is inside the viral particle. It is obvious that new epidemics and pandemics caused by RNA viruses will continue to arise periodically in the human population. The creation of new, safe, and effective platforms for the production of vaccines that can flexibly change and adapt to new subtypes of viruses is very urgent and at this moment should be considered as a strategically necessary task.

[Immunosuppressed people's beliefs, expectations, and experiences with COVID-19 vaccinations : Results of a longitudinal study]. BACKGROUND: Immunocompromised people are less likely to be vaccinated, despite an increased benefit of many vaccinations in terms of benefit-risk assessment, including the vaccines against SARS CoV-2 (COVID-19). Attitudes, expectations, and experiences with previous vaccinations influence the decision to get vaccinated. OBJECTIVE: To explore the attitudes of immunocompromised people towards vaccinations in general and COVID-19 vaccination in particular and their experiences with COVID-19 vaccinations. MATERIAL AND METHODS: As part of the CoCo Immune study, immunocompromised participants were surveyed in the spring and summer of 2021 (1Â November 2021-7Â September 2021) using questionnaires. Initially, they were asked about their expectations concerning aÂ COVID-19 vaccination and followed up about their experience after COVID-19 vaccination. In addition, sociodemographic data, general attitudes toward vaccinations and experiences with previous vaccinations were collected. Analysis was performed using descriptive and bivariate statistics. RESULTS: The 243Â participants mostly approved vaccinations and expected the COVID-19 vaccination to be effective and well-tolerated. Women were more concerned about the safety of vaccinations and were more often worried about side effects. Older persons felt better informed than younger persons. Participants who reported subjective side effects of previous vaccinations were more skeptical about vaccinations as well as the government institutions that recommend vaccinations. They less often agreed with the statement "in retrospect, the COVID-19 vaccination has been harmless for me so far". DISCUSSION: The participants mostly expressed aÂ positive attitude and anticipation towards COVID-19 vaccinations; however, the age and sex differences found suggest that there are different information needs which should be addressed when educating individuals about vaccinations or designing vaccination campaigns.

Longitudinal T-Cell Responses After a Third SARS-CoV-2 Vaccination in Patients With Multiple Sclerosis on Ocrelizumab or Fingolimod. OBJECTIVES: To evaluate whether a third vaccination shows an added effect on severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) T-cell responses in patients with multiple sclerosis treated with ocrelizumab or fingolimod. METHODS: This is a substudy of a prospective multicenter study on SARS-CoV-2 vaccination in patients with immune-mediated diseases. Patients with MS treated with ocrelizumab, fingolimod, and no disease-modifying

therapies and healthy controls were included. The number of interferon (IFN)-Î³ secreting SARS-CoV-2-specific T cells at multiple time points before and after 3 SARS-CoV-2 vaccinations were evaluated. RESULTS: In ocrelizumab-treated patients (N = 24), IFN-Î³-producing SARS-CoV-2-specific T-cell responses were induced after 2 vaccinations with median levels comparable to healthy controls (N = 12) and patients with MS without disease-modifying therapies (N = 10). A third vaccination in ocrelizumab-treated patients (N = 8) boosted T-cell responses that had declined after the second vaccination, but did not lead to higher overall T-cell responses as compared to immediately after a second vaccination. In fingolimod-treated patients, no SARS-CoV-2-specific T cells were detected after second (N = 12) and third (N = 9) vaccinations. DISCUSSION: In ocrelizumab-treated patients with MS, a third SARS-CoV-2 vaccination had no additive effect on the maximal T-cell response but did induce a boost response. In fingolimod-treated patients, no T-cell responses could be detected following both a second and third SARS-CoV-2 vaccination.

COVID-19 Vaccinations in Pregnancy: Comparative Evaluation of Acute Side Effects and Self-Reported Impact on Quality of Life between Pregnant and Nonpregnant Women in the United States. OBJECTIVE: The objective of this study was to describe the acute side effects experienced by pregnant women who received a coronavirus disease 2019 (COVID-19) vaccine in the United States and to compare their experience to nonpregnant women of similar age. STUDY DESIGN: Adults who received a COVID-19 vaccine in the United States were invited via social media to enroll in an online, longitudinal, community-based registry (www.helpstopCOVID19.com). Participants self-reported pregnancy status, vaccination dates, manufacturer, acute side effects, impact on work and self-care, medical consultation, and hospitalization. This analysis was restricted to women aged 20 to 39 at the time of vaccination. Side effects reported by pregnant women were compared to those reported by nonpregnant women. RESULTS: This analysis included 946 pregnant women, with 572 (60%) receiving at least one dose of Pfizer, 321 (34%) Moderna, and 53 (6%) J&J, and 1,178 nonpregnant women. Demographic and medical history were similar across manufacturers for both cohorts.Overall, pregnant women reported similar side effects as nonpregnant women, with the most common being injection site reactions (83 vs. 87%), fatigue (72 vs.78%), and headache (45 vs. 59%). Pregnant women reported fewer side effects (median: 3 vs. 4, respectively). In both cohorts, very few reported seeking medical care (<5%) or being hospitalized (<0.3%) after vaccination. Fewer pregnant women reported working less after vaccination than nonpregnant women (32 vs. 40%) or trouble with self-care (32 vs. 46%), respectively. CONCLUSION: Pregnant women reported similar COVID-19 vaccine side effects as nonpregnant women, although fewer total side effects; pregnant women judged these side effects to have less impact on work and self-care. While these results do not address pregnancy outcomes or long-term effects, findings about acute side effects and impact offer reassurance for all three vaccines in terms of tolerability. KEY POINTS: Â· COVID vaccines were well tolerated by pregnant women.. Â· Pregnant women reported fewer total side effects.. Â· Pregnant women reported less impact on work and self-care..

Comparison of two T-cell assays to evaluate T-cell responses to SARS-CoV-2 following vaccination in naÃ¯ve and convalescent healthcare workers. T-cell responses to SARS-CoV-2 following infection and vaccination are less characterized than antibody responses, due to a more complex experimental pathway. We measured T-cell responses in 108 healthcare workers (HCWs) using the commercialized Oxford Immunotec T-SPOT Discovery SARS-CoV-2 assay service (OI T-SPOT) and the PITCH ELISpot protocol established for academic research settings. Both assays detected T-cell responses to SARS-CoV-2 spike, membrane, and nucleocapsid proteins. Responses were significantly lower when reported by OI T-SPOT than by PITCH ELISpot. Four weeks after two doses of either Pfizer/BioNTech BNT162b or ChAdOx1 nCoV-19 AZD1222 vaccine, the responder rate was 63% for OI T-SPOT Panels 1 + 2 (peptides representing SARS-CoV-2 spike protein excluding regions present in seasonal

coronaviruses), 69% for OI T-SPOT Panel 14 (peptides representing the entire SARS-CoV-2 spike), and 94% for the PITCH ELISpot total spike. The two OI T-SPOT panels correlated strongly with each other showing that either readout quantifies spike-specific T-cell responses, although the correlation between the OI T-SPOT panels and the PITCH ELISpot total spike was moderate. The standardization, relative scalability, and longer interval between blood acquisition and processing are advantages of the commercial OI T-SPOT assay. However, the OI T-SPOT assay measures T-cell responses at a significantly lower magnitude compared to the PITCH ELISpot assay, detecting T-cell responses in a lower proportion of vaccinees. This has implications for the reporting of low-level T-cell responses that may be observed in patient populations and for the assessment of T-cell durability after vaccination.

Eosinophilic cellulitis in response to BNT162b2 COVID-19 vaccination. A 12-year-old boy presented with a 2-week history of persistent pruritic edematous plaques oneÂ day after he received the first dose of the BNT162b2 COVID-19 mRNA vaccine. A skin biopsy showed urticarial dermatitis with tissue eosinophilia consistent with a diagnosis of vaccine-associated eosinophilic cellulitis, with polyethylene glycol as a potential trigger.

Reply to: correspondence on "Herpes Zoster and Simplex reactivation following COVID-19 vaccination: new insights from a vaccine adverse event reporting system (VAERS) database analysisâ€‹".

Effects of cardiopulmonary bypass on immunoglobulin G antibody titres after SARS-CoV2 vaccination. OBJECTIVES: Patients with cardiovascular disease are vulnerable to severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) infection. Although SARS-CoV2 vaccination may be effective, its impact on surgical patients is not well studied. We investigated the effects of cardiovascular surgery, especially under cardiopulmonary bypass (CPB), on the antibody titres after SARS-CoV2 vaccination. METHODS: A prospective observational study was designed for patients undergoing surgery between July and November 2021. The immunoglobulin G against the receptor-binding domain was measured and antibody preserved rate (APR) was calculated from perioperative titres comparison. RESULTS: Enrolled 63 study patients were divided into 39 undergoing surgery with CPB (Group CPB) and 24 without CPB (Group None). Preoperative vaccines were BNT162b2 (Pfizer/BioNTech) (nâ€‰=â€‰58, 92%) and mRNA-1273 (Moderna) (nâ€‰=â€‰5, 8%). While immunoglobulin G against the receptor-binding domain titres did not significantly decrease after surgery in Group None, they decreased significantly in Group CPB from 21.80 [11.15, 37.85] to 11.95 [6.80, 18.18] U/ml (Pâ€‰<â€‰0.001) a day after surgery, 11.40 [7.85, 22.65] U/ml (Pâ€‰<â€‰0.001) 14â€‰days after surgery and 7.60 [4.80, 17.60] U/ml (Pâ€‰<â€‰0.001) a month after surgery. The APRs a day after the surgery were significantly lower in Group CPB (0.46 [0.41, 0.60]) than in Group None (0.80 [0.68, 0.87]) (Pâ€‰<â€‰0.001). CONCLUSIONS: The SARS-CoV2 antibody titres significantly decreased with lower APRs immediately after surgery under CPB. Based on our informative results, careful considerations of vaccination schedule might be required for surgery under CPB.

Immunogenicity and safety of different platforms of COVID-19 vaccines given as a third (booster) dose in healthy adults.

Timing of headache after COVID-19 vaccines and its association with cerebrovascular events: An analysis of 41,700 VAERS reports. BACKGROUND: Delayed-onset of headache seems a specific feature of cerebrovascular events after COVID-19 vaccines. METHODS: All consecutive events reported to the United States Vaccine Adverse Reporting System following COVID-19 vaccines (1 January to 24 June 2021), were assessed. The timing of headache onset post-vaccination in subjects with and without concomitant cerebrovascular events, including cerebral venous thrombosis, ischemic stroke, and intracranial haemorrhage was analysed. The diagnostic accuracy in predicting concurrent cerebrovascular events of the guideline- proposed threshold of three-days from

vaccination to headache onset was evaluated. RESULTS: There were 314,610 events following 306,907,697 COVID-19 vaccine doses, including 41,700 headaches, and 178/41,700 (0.4%) cerebrovascular events. The median time between the vaccination and the headache onset was shorter in isolated headache (1 day vs. 4 (in cerebral venous thrombosis), 3 (in ischemic stroke), or 10 (in intracranial hemorrhage) days, all P < 0.001). Delayed onset of headache had an area under the curve of 0.83 (95% CI: 0.75-0.97) for cerebral venous thrombosis, 0.70 (95% CI: 0.63-76) for ischemic stroke and 0.76 (95% CI: 0.67-84) for intracranial hemorrhage, and >99% negative predictive value. CONCLUSION: Headache following COVID-19 vaccination occurs within 1 day and is rarely associated with cerebrovascular events. Delayed onset of headache 3 days post-vaccination was an accurate diagnostic biomarker for the occurrence of a concomitant cerebrovascular events.

Analysis ofÂ olderÂ adultsÂ visiting theÂ emergencyÂ department withÂ fever as aÂ suspected Covid-19Â vaccine-relatedÂ adverseÂ reaction: AÂ retrospectiveÂ multicenterÂ study. INTRODUCTION: After COVID-19 vaccination was initiated, the number of patients visiting the emergency department (ED) with vaccine-related adverse reactions increased. We investigated the clinical features of older adults (aged 65 years and older) visiting the ED with self-reported COVID-19 postvaccination fever. METHODS: We conducted a retrospective observational study at three EDs between March 2021 and September 2021. Patients who reported adverse reactions, fever (â‰¥37.5Â Â°C) and/or febrile sensation or rigors following COVID-19 vaccination were included. The demographic and clinical data of these patients were collected by reviewing their medical records. RESULTS: A total of 562 patients were selected, and 396 (70.5%) were female. The older adult group included 155 (27.6%) patients, and the median age was 75 (69-79 years). The older adults less frequently had a fever (â‰¥37.5Â Â°C) upon ED presentation (75.5% vs. 85.7%, respectively), used more emergency medical services (43.9% vs. 18.7%, respectively), and visited an ED more frequently during early hours (00:00-06:00) (31% vs. 20.1%, respectively) compared to the younger adults (pÂ =Â 0.004, pÂ <Â 0.001 and pÂ =Â 0.036). Fewer older adults visited an ED within 2 days of fever onset (73.5% vs. 84%) (pÂ =Â 0.012), and more older adults were admitted for medical conditions other than vaccine-related adverse reactions (32.9% vs. 4.2%) (pÂ <Â 0.001). Older adults received more thorough testing (laboratory and imaging tests). Among the older adults, the admission rate was associated with age (pÂ =Â 0.003). CONCLUSION: Older adults presenting with fever as an adverse reaction following COVID-19 vaccination less frequently had a fever upon visiting the ED, required more ED testing, and had higher admission rates for non-vaccination-related medical conditions.

Sensitization to trometamol in patients with delayed local reactions after administration of the Moderna mRNA-1273 vaccine against SARS-CoV-2.

Axillary lymph node characteristics in breast cancer patients versus post-COVID-19 vaccination: Overview of current evidence per imaging modality. BACKGROUND: Axillary lymph node characteristics on axillary ultrasound (US), breast MRI and 18F-FDG PET/CT are relevant at breast cancer diagnosis. Axillary lymphadenopathy after COVID-19 vaccination has been frequently reported. This may cause a diagnostic dilemma, particularly in the ipsilateral axilla in women who have a either a recent diagnosis of breast cancer or a history of breast cancer. This review provides an overview of the current evidence regarding axillary lymph node characteristics at breast cancer diagnosis versus "post-COVID-19 vaccination". METHODS: A non-systematic narrative review was performed. Studies describing axillary lymph node characteristics per imaging modality (axillary US, breast MRI and 18F-FDG PET/CT) in breast cancer patients versus post-COVID-19 vaccination were selected and used for the current study. RESULTS: The morphologic characteristics and distribution of abnormal nodes on US may differ from the appearance of metastatic adenopathy since diffuse cortical thickening of the lymph nodes is the most observed characteristic after vaccination, whereas metastases show as most suspicious characteristics focal cortical thickening and effacement of the

fatty hilum. Current evidence on MRI and 18F-FDG on morphologic characteristics of axillary lymphadenopathy is missing, although it was suggested that vaccine related lymphadenopathy is more likely to be present in level 2 and 3 nodes than metastatic nodes. Reported frequencies of lymphadenopathy post-COVID-19 vaccination range from 49% to 85% (US), 29% (breast MRI) and 14.5% to 53.9% (18F-FDG PET/CT). Several factors may impact the presence or extent of lymphadenopathy post-COVID-19 vaccination: injection site, type of vaccine (i.e., mRNA versus vector), time interval (days) between vaccination and imaging, previous history of COVID-19 pneumonia, and first versus second vaccine dose. CONCLUSION: Although lymph node characteristics differ at breast cancer diagnosis versus post-COVID-19 vaccination, clinical information regarding injection site, vaccine type and vaccination date needs to be documented to improve the interpretation and guide treatment towards the next steps of action.

Response to: Reported Breast Implant-Related Reactions After COVID-19 or COVID-19 Vaccination: Correspondence.

Decay rate of antiS1/S2 IgG serum levels after 6 months of BNT162b2 vaccination in a cohort of COVID-19-naive and COVID-19-experienced subjects. Vaccination toward SARS-CoV-2 reduced mortality and 'boosters' are being implemented. We offer scientific contribution about IgG production in the COVID-19 experienced population. From January 2021 to March 2021, 183 residents and staff from the Elderly Nursing Home "San Giuseppe Moscati" who had received two doses of the BNT162b2 vaccine were enrolled. The antibody response was assessed by the DiaSorin LIAISON-CLIA S1/S2Â® IgG solution. Cutoff levels for response (>39 BAU/mL) and neutralizing activity (>208 BAU/mL) were derived from DiaSorin official data. Serology was assessed before and after the first vaccination, and 2 weeks and 6 months after the second vaccination. Anti-S IgG in COVID-19 experienced, baseline IgG producers spiked after the first vaccination to median 5044 BAU/mL and decayed at 6â€‰months to 2467.4 BAU/mL. Anti-S IgG in COVID-19 experienced, baseline IgG non-producers spiked after the second vaccination to median 1701.7 BAU/mL and decayed at 6â€‰months to 904.8 BAU/mL. Anti-S IgG in COVID-19 naÃ¯ve subjects spiked after the second vaccination to median 546 BAU/mL and decayed at 6â€‰months to 319.8 BAU/mL. The differences between sequential timepoint levels in each group were statistically significant (pâ€‰<â€‰.0001). Serology analysis revealed different kinetics between COVID-19 experienced subjects depending on baseline response, possibly predicting different IgG persistence in blood.

Relapse of immune-mediated thrombotic thrombocytopenic purpura following mRNA COVID-19 vaccination: a prospective cohort study. Immune-mediated thrombotic thrombocytopenic purpura (iTTP) is a rare and life-threatening disease. Vaccination has been reported to be a trigger of onset and relapse of autoimmune diseases. We evaluated after mRNA COVID-19 vaccination 32 adult patients previously diagnosed with iTTP by means of weekly monitoring of complete blood count and ADAMTS13 testing. Thirty of 32 patients received at least one dose of Pfizer-BioNTech, the remaining two received Moderna. A total of five patients, all vaccinated with Pfizer-BioNTech, had a biochemical relapse at a median post-vaccination time of 15 days following the second or third vaccine dose, presenting without measurable ADAMTS13 activity and a median anti- ADAMTS13 autoantibody value of 34 U/mL. Four of five cases had concomitant clinical relapse and were treated with corticosteroids alone or daily sessions of plasma exchange and caplacizumab, while one patient was closely monitored with ADAMTS13 with no onset of anemia and thrombocytopenia. Although the benefits of vaccination exceed its potential risks, clinicians should be aware that iTTP relapse might follow COVID-19 vaccination. Therefore, laboratory and clinical monitoring of iTTP patients should be done in the first post-vaccination month, in order to promptly diagnose and treat any relapse.

COVID-19 vaccine associated transverse myelitis-Evusheld as an option when vaccination is not recommended due to severe adverse events. Individuals who experience severe COVID-19-

vaccine-related adverse reactions such as transverse myelitis may be precluded from receiving further vaccination to protect from SARS-CoV-2 infection. Although the mechanism of autoimmune spinal cord inflammation resulting in transverse myelitis is unclear, it may be safe to administer antibody therapy for preventing COVID-19. Recently, Evusheld, tixagevimab with cilgavimab, two spike-protein directed monoclonal antibodies were authorized by the U.S. FDA and U.K. MHRA for administration to individuals when vaccination is not recommended. We report the safe administration of Evusheld to a patient who experienced transverse myelitis 11â€‰months previously as a result of receiving the Moderna mRNA vaccine. This patient has experienced no adverse events to Evusheld. Additional experience and data collection are warranted to determine the safety of this prophylactic therapy.
Antibody response to three SARS-CoV-2 mRNA vaccines in adolescent solid organ transplant recipients.
Refractory immune TTP following Pfizer-BioNTech COVID-19 vaccine successfully salvaged with caplacizumab. Immune thrombotic thrombocytopenic purpura (iTTP) is a life-threatening thrombotic microangiopathy caused by antibodies against ADAMTS13. We report a young, healthy female who developed hematuria, vomiting, and hematemesis 3Â weeks after her first dose of Pfizer Bio-NTech COVID-19 vaccine. Investigations confirmed iTTP with undetectable ADAMTS13 activity and a positive antibody assay. Despite initial response to standard treatment with plasma exchange and corticosteroids, she had an acute deterioration of her TTP with neurological and cardiac involvement. Fortunately, she then had prompt response to rituximab and emergently obtained caplacizumab and is now in remission. Although most cases of iTTP are of unknown etiology, we cannot exclude that her almost fatal iTTP episode was triggered by the Pfizer-BioNTech COVID-19 vaccine. This case also highlights the ability of caplacizumab to quickly halt disseminated thrombus formation in refractory TTP.
Four cases of audio-vestibular disorders related to immunisation with SARS-CoV-2 mRNA vaccines. OBJECTIVE: To gain medical insight into the clinical course and safety of otolaryngologic disorders following immunisation with severe acute respiratory coronavirus (SARS-CoV-2) mRNA-based vaccines. DESIGN: Case description. STUDY SAMPLE: We report four cases of transient audio-vestibular symptoms, which occurred shortly after inoculation of two BNT162b2 (Pfizer-BioNTech(Â®)) and mRNA-1273 (ModernaÂ®) vaccines. RESULTS: Hearing loss was unilateral in all cases and recovered at least partially: it was associated with persistent gait instability in two cases, after 1 and 7Â months. Trigger mechanisms underpinning audio-vestibular impairment remain uncertain. Immune tolerance mechanisms with off-target innate activation of T-lymphocytes may be involved in vestibulocochlear nerve disorders, as for other cranial nerves involvement. CONCLUSIONS: The occurrence of audio-vestibular manifestations following mRNA-based vaccines needs ENT monitoring to support their causality in such rare vaccine-related adverse events. Audio-vestibular disorders appeared of transitory nature, including hearing loss, and should not deter further efforts in large-scale vaccination campaigns against SARS-CoV-2.
New-onset bullous pemphigoid and flare of pre-existing bullous pemphigoid after the third dose of the COVID-19 vaccine.
Transient severe myocarditis and intraventricular thrombus associated with SARS-CoV-2 vaccination.
Safety profile of SARS-CoV-2 vaccination in patients with antibody-mediated CNS disorders. OBJECTIVES: In this retrospective multicenter study, we evaluated the safety of SARS-CoV-2 vaccination in patients harboring autoantibodies targeting neuronal surface and/or synaptic antigens. METHODS: From eight Italian Neurology Units, we included patients with: a) serum and/or CSF positivity for specific neuronal autoantibodies; b) a compatible neurological syndrome; and c) available follow-up â‰¥6 weeks after vaccination with any of the approved SARS-CoV-2 vaccines.

Demographics, clinical data, and information regarding previous SARS-CoV-2 infection and vaccination were collected. Disease relapses were considered "post-infectious" or "post-vaccination" when occurring within 6 weeks from infection/vaccination. RESULTS: We included 66 patients; 7/66 (11%) had a previous history of SARS-CoV-2 infection and 1/7 (14%) had post-infection relapses. BNT162b2-Pfizer-BioNTec was administered in 55 cases (83.3%) and mRNA-1273-Moderna in 11 (16.7%). The median number of doses administered per patient was 2 (1-3) and >50% of patients did not experience side effects. Five patients (8%) had post-vaccination relapses (seizure 3/5); 4/5 improved after immunotherapy, while one did not receive immunotherapy and worsened. Patients with post-vaccination relapses had higher disability scores at vaccination (pÂ =Â 0.025), a trend favoring Leucine-rich glioma-inactivated protein 1 LGI1 glutamic acid decarboxylase 65 (GAD65) antibodies (pÂ =Â Â 0.054) and shorter time from last relapse (pÂ =Â 0.057). DISCUSSION: Our data support the safety of SARS-CoV-2 vaccines in patients with neurological disorders associated with antibodies to neuronal and synaptic antigens.

Immune-mediated liver injury following COVID-19 vaccination: A systematic review. Immune-mediated liver injury (ILI) following coronavirus disease 2019 (COVID-19) vaccination is not well-characterized. Therefore, we systematically reviewed the literature on ILI after COVID-19 vaccination. We searched PubMed, Cochrane, Ovid, Embase, and gray literature to include articles describing ILI following COVID-19 vaccination. Reports without confirmatory evidence from liver biopsy were excluded. Descriptive analysis, and study quality were reported as appropriate. Of the 1,048 articles found, 13 (good/fair quality; 23 patients) were included. Studies were primarily from Europe (nÂ =â€‰8), America (nÂ =â€‰2), Asia (nÂ =â€‰2), or Australia (nÂ =â€‰1). Patients were predominantly females (62.5%) of age 55.3â€‰years (49.1-61.4), with an antecedent exposure to Moderna messenger RNA (mRNA)-1273 (47.8%), Pfizer-BioNTech BNT162b2 mRNA (39.2%), or ChAdOx1 nCoV-19 vaccine (13%). Pre-existing comorbidities (69.6%) were common, including liver disease in 26.1% and thyroid disorders in 13% of patients. About two-thirds of the patients were on concurrent medications (paracetamol, levothyroxine, statins, and non-steroidal anti-inflammatory drugs). Jaundice was the most common symptom (78.3%). Peak bilirubin, alanine aminotransferase, and alkaline phosphatase levels were 10.8 (6.8-14.8) mg/dl, 1,106.5 (757.0-1,702.5) U/L, and 229 (174.6-259.6) U/L, respectively. Histological findings were intense portal lymphoplasmacytic infiltrate with interface hepatitis. Steroids were used in 86.9% of patients, and complete response, recovering course, and death were reported in 56.5%, 39.1%, and 4.3% of patients, respectively. ILI following COVID-19 vaccination is rare. The diagnosis is established on temporal correlation, biochemical findings, and histopathology. Prognosis is excellent with corticosteroids. Causality establishment remains a challenge.

Immunogenicity and Safety of Standard and Third-Dose SARS-CoV-2 Vaccination in Patients Receiving Immunosuppressive Therapy. OBJECTIVE: Immunogenicity and safety following receipt of the standard SARS-CoV-2 vaccination regimen in patients with immune-mediated inflammatory diseases (IMIDs) are poorly characterized, and data after receipt of the third vaccine dose are lacking. The aim of the study was to evaluate serologic responses and adverse events following the standard 2-dose regimen and a third dose of SARS-CoV-2 vaccine in IMID patients receiving immunosuppressive therapy. METHODS: Adult patients receiving immunosuppressive therapy for rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, Crohn's disease, or ulcerative colitis, as well as healthy adult controls, who received the standard 2-dose SARS-CoV-2 vaccination regimen were included in this prospective observational study. Analyses of antibodies to the receptor-binding domain (RBD) of the SARS-CoV-2 spike protein were performed prior to and 2-4â€‰weeks after vaccination. Patients with a weak serologic response, defined as an IgG antibody titer of â‰¤100 arbitrary units per milliliter (AU/ml) against the receptor-binding domain of the full-length SARS-Cov-2 spike protein, were

allotted a third vaccine dose. RESULTS: A total of 1,505 patients (91%) and 1,096 healthy controls (98%) had a serologic response to the standard regimen (Pâ€‰<â€‰0.001). Anti-RBD antibody levels were lower in patients (median 619 AU/ml interquartile range [IQR] 192-4,191) than in controls (median 3,355 AU/ml [IQR 896-7,849]) (Pâ€‰<â€‰0.001). The proportion of responders was lowest among patients receiving tumor necrosis factor inhibitor combination therapy, JAK inhibitors, or abatacept. Younger age and receipt of messenger RNA-1273 vaccine were predictors of serologic response. Of 153 patients who had a weak response to the standard regimen and received a third dose, 129 (84%) became responders. The vaccine safety profile among patients and controls was comparable. CONCLUSION: IMID patients had an attenuated response to the standard vaccination regimen as compared to healthy controls. A third vaccine dose was safe and resulted in serologic response in most patients. These data facilitate identification of patient groups at risk of an attenuated vaccine response, and they support administering a third vaccine dose to IMID patients with a weak serologic response to the standard regimen.

COVID-19 vaccine-induced lymphadenopathies: incidence, course and imaging features from an ultrasound prospective study. AIMS: lymphadenopathy can occur after COVID-19 vaccination and when encountered at ultrasound examinations performed for other reasons might pose a diagnostic challenge. Purpose of the study was to evaluate the incidence, course and ultrasound imaging features of vaccine-induced lymphadenopathy. METHODS: 89 healthy volunteers (median age 30, 76 females) were prospectively enrolled. Vaccine-related clinical side effects (e.g., fever, fatigue, palpable or painful lymphadenopathy) were recorded. Participants underwent bilateral axillary, supraclavicular and cervical lymph node stations ultrasound 1-4Â weeks after the second dose and then again after 4-12Â weeks in those who showed lymphadenopathy at the first ultrasound. B-mode, color-Doppler assessment, and shear-wave elastography (SWE) evaluation were performed. The correlation between lymphadenopathy and vaccine-related side effects was assessed using the Fisher's exact test. RESULTS: Post-vaccine lymphadenopathy were found in 69/89 (78%) participants (37 single and 32 multiple lymphadenopathy). Among them, 60 presented vaccine-related side effects, but no statistically significant difference was observed between post-vaccine side effect and lymphadenopathy. Ultrasound features of vaccine-related lymphadenopathy consisted of absence of fatty hilum, round shape and diffuse or asymmetric cortical thickness (median cortical thickness of 5Â mm). Vascular signal was mainly found to be increased, localized in both central and peripheral regions. SWE showed a soft cortical consistence in all cases (median value 11 Kpa). At follow-up, lymph-node morphology was completely restored in most cases (54/69, 78%) and in no case lymphadenopathy had worsened. CONCLUSION: A high incidence of vaccine-induced lymphadenopathy was found in a population of healthy subjects, with nearly complete regression within 4-12Â weeks.

Acquired hemophilia A following SARS CoV-2 mRNA vaccine: Correspondence.

Absence of active systemic anaphylaxis in guinea pigs upon intramuscular injection of inactivated SARS-CoV-2 vaccine (Vero cells). Background: The safety of novel vaccines against COVID-19 is currently a major focus of preclinical research. As a part of the safety evaluation testing package, 24 healthy guinea pigs were used to determine whether repeated administration of inactivated SARS-CoV-2 vaccine could induce active systemic anaphylaxis (ASA), and to evaluate its degree of severity.Method: According to sex and body weight, the animals were randomly divided into three experimental groups (eight animals per group). The negative control group received 0.9% sodium chloride (priming dose: 0.5â€‰mL/animal; challenge dose: 1â€‰mL/animal); the positive control group received 10% ovalbumin (priming dose: 0.5â€‰mL/animal; challenge dose: 1â€‰mL/animal); and the inactivated SARS-CoV-2 vaccine group received inactivated SARS-CoV-2 vaccines (priming dose: 100â€‰U in 0.5â€‰mL/animal; challenge dose: 200â€‰U in 1â€‰mL/animal). Priming dose

administration was conducted by multi-point injection into the muscles of the hind limbs, three times, once every other day. On days 14 and 21 after the final priming injection, a challenge test was conducted. Half of the animals in each group were injected intravenously with twice the dose and volume of the tested substance used for immunization. During the experimental course, the injection site, general clinical symptoms, body weight, and systemic allergic reaction symptoms were monitored.Result: After intramuscular injection of inactivated SARS-CoV-2 vaccine, there were no abnormal reactions at the injection site, clinical symptoms, or deaths. There was no difference in body weight between the groups, and there were no allergic reactions. Conclusion: Thus, inactivated SARS-CoV-2 vaccine injected intramuscularly in guinea pigs did not produce ASA and had a good safety profile, which can provide actual data on vaccine risks and important reference data for clinical research on this vaccine.
"Vitreous Hemorrhage and Long-Lasting Priapism After COVID-19 m-RNA Based Vaccine: A Case Report". PURPOSE: To report a case of possible multi-district thromboembolic event involving the eye of a patient with several cardiovascular risk factors, following a second inoculation of SARS-CoV-2 m-RNA based vaccine. CASE-REPORT: A 60-year-old man presented with blurred vision in the left eye lasting 1 month but started within 24â€…hours from the 2(nd) dose of BNT162b2 vaccine inoculation. He also reported a long-lasting but self-limiting priapism which started about 4â€…h after the vaccination. Patient's medical history included: acute lymphoblastic leukemia, treated with chemotherapy and HLA-identical sibling donor transplant 18 months earlier; subsequent cytomegalovirus posterior outer retinal necrosis (PORN) resolved with antiviral treatment; type II diabetes and erectile dysfunction. Ocular examination of the affected eye revealed vitreous hemorrhage which limited the observation of details of the fundus. After a 2-week follow-up without any clinical improvement, parsplana vitrectomy (PPV) with cataract extraction was performed. Surgical aspiration of a large preretinal hemorrhage revealed intraretinal flame-shaped hemorrhages and some cotton wool spots. Further intraoperative examination and post-operative fluorescein angiography excluded the rhegmatogenaous and the neovascular origin of the intraocular bleeding. CONCLUSIONS: Due to the several predisposing factors such as diabetes, aspirin assumption, history of blood dyscrasia and infectious retinitis, the relationship between the acute intraocular bleeding and the BNT162b2 inoculation remains difficult to ascertain in this patient. However, the occurrence of lasting priapism and vitreous hemorrhage within 24â€…h from the vaccination is a critical event which deserves to be mentioned.
Fatal myositis, rhabdomyolysis and compartment syndrome after ChAdOx1 nCoV-19 vaccination.
Covid19 vaccination-associated portal vein thrombosis-An interdisciplinary clinical challenge. Despite one of the largest vaccination campaigns in human history, the COVID-19 pandemic has not been yet defeated. More than 10 billion doses of COVID-19 vaccine have been administered worldwide. AstraZeneca's Vaxzevria (ChAdOx1 nCoV-19 / AZD1222) was approved as the first viral vector-based vaccine in the EU on 29 January 2021. Thromboembolic events are a rare complication of vaccination with ChAdOx1 nCoV-19 in the context of, now known as vaccine-induced immune thrombotic thrombocytopenia (VITT), with an incidence of 1.5-3 in 100,000 vaccinations. VITT is clinically as well as pathophysiologically comparable to heparin-induced thrombocytopenia. Illustrated by a fulminant patient case, a multidisciplinary step-by-step guideline was developed for the recognition, diagnosis, and management of patients with severe acute portosplanchic venous thrombosis with mesenteric ischemia due to vaccine-induced immunogenic thrombotic thrombocytopenia.
Difference in safety and humoral response to mRNA SARS-CoV-2 vaccines in patients with autoimmune neurological disorders: the ANCOVAX study. BACKGROUND: Assessing the safety of SARS-CoV-2 mRNA vaccines and the effect of immunotherapies on the seroconversion rate in patients

with autoimmune neurological conditions (ANC) is relevant to clinical practice. Our aim was to assess the antibody response to and safety of SARS-CoV-2 mRNA vaccines in ANC. METHODS: This longitudinal study included ANC patients vaccinated with two doses of BNT162b2 or mRNA-1273 between March and August 2021. Side effects were assessed 2-10Â days after each dose. Neurological status and anti-spike receptor binding domain antibody levels were evaluated before vaccination and 4Â weeks after the second dose. Healthcare-workers served as controls for antibody levels. RESULTS: We included 300 ANC patients (median age 52, IQR 40-65), and 347 healthcare-workers (median age 45, IQR 34-54). mRNA-1273 vaccine was associated with an increased risk of both local (OR 2.52 95% CI 1.45-4.39, pâ€‰=â€‰0.001) and systemic reactions (OR 2.51% CI 1.49-4.23, pâ€‰=â€‰0.001). The incidence of relapse was not different before and after vaccine (Incidence rate ratio 0.72, 95% CI 0.29-1.83). Anti-SARS-CoV-2 IgG were detected in 268 (89.9%) patients and in all controls (pâ€‰<â€‰0.0001). BNT162b2 vaccine (OR 8.84 95% CI 2.32-33.65, pâ€‰=â€‰0.001), anti-CD20 mAb (OR 0.004 95% CI 0.0007-0.026, pâ€‰<â€‰0.0001) and fingolimod (OR 0.036 95% CI 0.002-0.628, pâ€‰=â€‰0Â·023) were associated with an increased risk of not developing anti-SARS-CoV-2 IgG. CONCLUSION: SARS-CoV-2 mRNA vaccines were safe in a large group of ANC patients. Anti-CD20 and fingolimod treatment, as well as vaccination with the BNT162b2 vaccine, led to a reduced humoral response. These findings could inform vaccine policies in ANC patients undergoing immunotherapy.

Vaccines and myasthenia gravis: a comprehensive review and retrospective study of SARS-CoV-2 vaccination in a large cohort of myasthenic patients. INTRODUCTION: Myasthenia gravis (MG) is an autoimmune disease, for which the risk of exacerbation after vaccines is debated. The aim of this study is to review the available literature concerning safety and efficacy of vaccines in MG. In addition, we also conducted a retrospective research of MG exacerbations and new onset MG after anti-SARS-CoV-2 vaccination in a large cohort of patients. METHODS: A study of the available literature regarding vaccines and MG was carried out through research in the online database "Pubmed". We also retrospectively collected data from 80 MG patients, who were followed at the Treviso Hospital and completed an anti-SARS-CoV-2 vaccination cycle. For each patient, we recorded MG exacerbations between first and second doses and within a window period of 1Â day - 6Â weeks after the second dose. RESULTS: We found 26 relevant articles about influenza, SARS-CoV-2 and other vaccines. No clear associations between most vaccines and MG exacerbations were found. Moreover, cases of new onset post-vaccine MG are mostly anecdotal, except for Japanese encephalitis virus vaccine. Concerning our cohort, 4/80 (5%) MG patients experienced an exacerbation within the post-vaccine window period. In addition, we report a case of new onset post-vaccine MG. DISCUSSION: Inactivated and subunit vaccines are safe and effective in MG. Although some of them, such as anti-SARS-CoV-2 vaccine, might uncommonly cause MG exacerbations, data from our review suggest that benefits still outweigh by far the potential risks, thus they should be recommended to these patients. Nevertheless, large prospective studies are needed for further investigations.

Cardiac MRI and Clinical Follow-up in COVID-19 Vaccine-associated Myocarditis.

Impaired SARS-CoV-2-specific T-cell reactivity in patients with cirrhosis following mRNA COVID-19 vaccination. BACKGROUND & AIMS: Cirrhosis entails elevated risk of COVID-19-associated mortality. This study determined T cell-mediated and antibody reactivity against the spike 1 (S1) protein of SARS-CoV-2 among 48 patients with cirrhosis and 39 healthy controls after mRNA COVID-19 vaccination. METHODS: SARS-CoV-2-specific T-cell reactivity was measured by induced level of T cell-derived interferon-Î³ (IFN-Î³) in blood cells stimulated exÂ vivo with multimeric peptides spanning the N-terminal portion of S1. S1-induced IFN-Î³ was quantified before and after the 1(st) and 2(nd) vaccination (BNT162b2, Pfizer-BioNTech or mRNA-1273, Moderna) alongside serum IgG against the receptor-binding domain (RBD) within S1 (anti-RBD-S1 IgG). RESULTS: T-cell reactivity against S1 was

reduced in patients with cirrhosis after the 1(st) (p <0.001 vs. controls) and 2(nd) (p <0.001) vaccination. Sixty-eight percent of patients lacked detectable S1-specific T-cell reactivity after the 1(st) vaccination vs. 19% in controls (odds ratio 0.11, 95% CI 0.03-0.48, pÂ = 0.003) and 36% remained devoid of reactivity after the 2(nd) vaccination vs. 6% in controls (odds ratio 0.12, 95% CI 0.03-0.59, pÂ = 0.009). T-cell reactivity in cirrhosis remained significantly impaired after correction for potential confounders in multivariable analysis. Advanced cirrhosis (Child-Pugh class B) was associated with absent or lower T-cell responses (p <0.05 vs. Child-Pugh class A). The deficiency of T-cell reactivity was paralleled by lower levels of anti-RBD-S1 IgG after the 1(st) (p <0.001 vs. controls) and 2(nd) (p <0.05) vaccination. CONCLUSIONS: Patients with cirrhosis show deficient T-cell reactivity against SARS-CoV-2 antigens along with diminished levels of anti-RBD-S1 IgG after dual COVID-19 vaccination, highlighting the need for vigilance and additional preventative measures. CLINICAL TRIAL REGISTRATION: EudraCT 2021-000349-42. LAY SUMMARY: T cells are a pivotal component in the defence against viruses. We show that patients with cirrhosis have impaired SARS-CoV-2-specific T-cell responses and lower antibody levels after mRNA vaccination against COVID-19 compared with healthy controls. Patients with more advanced liver disease exhibited particularly inferior vaccine responses. These results call for additional preventative measures in these patients.

Impact of COVID-19 vaccine on epilepsy in adult subjects: an Italian multicentric experience. OBJECTIVES: To investigate the safety and tolerability of COVID-19 vaccines in people with epilepsy (PwE). METHODS: In this multicentric observational cohort study, we recruited adult patients (ageâ€‰>â€‰18Â years old) with epilepsy who attended the Outpatient Epilepsy Clinic from 1st July to 30th October 2021. We administered to the patients a structured questionnaire and interview on demographic and epilepsy characteristics, current treatment, previous SARS-CoV-2 infection, vaccine characteristics, post-vaccine seizure relapse, other side effect, variation of sleep habits, caffeine, or alcohol intake. Seizure frequency worsening was defined as a ratio between mean monthly frequency post-vaccination and mean monthly frequency pre-vaccination superior to 1. Patients were categorized in two groups: patients with seizure frequency worsening (WORSE) and patients with seizure stability (STABLE). RESULTS: A total of 358 people participated with a mean age of 47.46â€‰Â±â€‰19.04. Focal seizure (79.1%), generalized epilepsy (20.4%), and unknown types of epilepsy (0.5%) were detected among participants. In total, 31 (8.7%) people expressed that they were not willing to receive a COVID-19 vaccine; 302 patients (92.35%) did not experience an increase in the seizure frequency (STABLE-group) whereas 25 patients (7.65%) had a seizure worsening (WORSE-group). Post-vaccine seizures occurred mainly in the 7Â days following the administration of the vaccine. Patients in the WORSE-group were treated with a mean higher number of anti-seizure medication (ASMs) (pâ€‰=â€‰0.003) and had a higher pre-vaccine seizure frequency (pâ€‰=â€‰0.009) compared with patients in the STABLE-group. Drug-resistant epilepsy was also associated with seizure worsening (pâ€‰=â€‰0.01). One-year pre-vaccination seizure frequency pattern demonstrated that patients in the WORSE-group had a higher frequency pattern (pâ€‰<â€‰0.001). Multivariate analysis of the vaccinated group showed that only the seizure frequency pattern (confidence interval [CI]â€‰=â€‰1.257-2.028; pâ€‰<â€‰0.001) was significantly associated with seizure worsening. CONCLUSION: In our cohort of vaccinated PwE, only a little percentage had a transient short-term increase of seizure frequency. The present study demonstrates that COVID-19 vaccines have a good safety and tolerability profile in the short term in PwE.

Vaccine-induced immune thrombotic thrombocytopenia: why, what, who, and how?

An autopsy case of COVID-19-like acute respiratory distress syndrome after mRNA-1273 SARS-CoV-2 vaccination. We report the first case with COVID-19-like acute respiratory distress syndrome after mRNA-1273 SARS-CoV-2 vaccination. An 88-year-old woman developed dyspnea several hours

after vaccination with the second dose of mRNA-1273. She was hospitalized on day nine due to worsening dyspnea. Chest computed tomography showed bilateral ground-glass opacities and consolidations, mainly in the peripheral lung areas. Repeat polymerase chain reaction tests for SARS-CoV-2 were negative, although the serum level of antibodies against spike protein was extremely elevated. Her condition did not improve with high-dose corticosteroids and high-flow nasal cannula oxygen therapy; she died on day 18. Autopsy findings revealed very early-phase diffuse alveolar damage in the whole lung without other lung diseases. The clinical and pathological findings suggested vaccine-induced acute respiratory distress syndrome. Serological and pathological tests might be useful to differentiate the disease from COVID-19.

Acute onset ocular myasthenia gravis after vaccination with the Oxford-AstraZeneca COVID-19 vaccine. Myasthenia gravis (MG) is an autoimmune disease that results in muscle weakness and fatigability. Extraocular involvement may be the first sign of disease. It may be triggered by infections, stress, or medications. We describe a first reported case of ocular MG induced by the viral vector Oxford-AstraZeneca coronavirus disease (COVID-19) vaccine, detail the pathophysiology of vaccine-induced MG, and explore the impact of COVID-19 on MG patients.

Cutaneous reactions following booster doseÂ administration of COVID-19 mRNA vaccine: A first look from the American Academy of Dermatology/International League of Dermatologic Societies registry.

Cognitive deficits and memory impairments after COVID-19 (Covishield) vaccination. Vaccination is an essential public health strategy to control the 2019 Coronavirus (COVID-19) pandemic. While the benefits of the COVID-19 vaccines far outweigh the risks, side effects continue to be reported in the literature. We report a 65-year-old man who developed cognitive deficits and memory impairments following his first dose of Oxford AstraZeneca vaccine (Covishield). The onset of acute cognitive deficits and memory impairments could be another complication to COVID-19 vaccination that physicians and neurologists need to be warned to. Monitoring the safety of COVID-19 vaccines and describing side effects associated with them is essential to improve safety profiles and enhance public trust.

A 17-year-old male with acute myocarditis following mRNA-1273 vaccination in Japan. Vaccinations are the main tool being used to control the COVID-19 pandemic. When the Japanese Ministry of Health approved the Moderna mRNA-1273 vaccination in May 2021, it was limited to patients over 18â€¯years old; however, using the additional data of efficacy and safety from clinical trials, vaccination was approved for 12- to 17-year-olds in Japan in July 2021. A previous study reported that myocarditis after the mRNA-1273 vaccination was more prevalent in young men; however, no patients under 18â€¯years old with myocarditis diagnosed by cardiovascular magnetic resonance (CMR) findings after mRNA-1273 vaccination have been reported in Japan. In the present case, a 17-year-old healthy male developed arthralgia and had fever on the day of the second mRNA-1273 vaccination for severe acute respiratory syndrome coronavirus 2. Three days after the vaccination, the patient felt severe chest pain with broad ST elevations on electrocardiography and troponin T elevations. Symptoms and findings rapidly improved; however, on CMR, myocarditis remained. Thus, it is necessary to be vigilant of potential acute myocarditis in young men following mRNA-1273 vaccination. LEARNING OBJECTIVE: Although it is very rare, acute myocarditis after mRNA-1273 (Moderna) vaccination developed within 3-5â€¯days following the second dose of the vaccine.Most reported cases were mild or moderate in severity, but there were cases of cardiogenic shock. We need to be vigilant of acute myocarditis in young men following mRNA-1273 vaccination.

Safety, efficacy, and immunogenicity of COVID-19 vaccines; a systematic review. The World Health Organization stated on 11 March 2020 that a coronavirus illness had been discovered in Wuhan, China in December 2019. Effective vaccinations are eagerly awaited as the global outbreak of COVID-19 continues. The aim is to evaluate the safety, effectiveness, and immunogenicity of

Pfizer/AstraZeneca/Modera/Cansino vaccines against COVID-19. An electronic search on different databases yielded 12,907 articles. A total of 20 randomized and non-randomized, published, and ongoing trials were selected. Cochrane RoB version 2.0 was used to assess the authenticity of the studies. Of these 20 trials, three were conducted on Pfizer, three on AstraZeneca, three on Moderna, and two on the Cansino vaccine. These trials have reported promising results for the safety, efficacy, and immunogenicity of the respective vaccines. None of the trials have reported the efficacy and severe adverse outcomes for the Cansino vaccine, hindering its reliability as a safe vaccine against covid-19. Furthermore, the results of these trials have established Pfizer to be the most efficacious vaccine against covid-19, having an efficacy of 94.6%. A few severe adverse events were reported by the included trials. However, further systematic reviews are required to understand the respective vaccine profiles on Immuno-suppressive, organ transplants, and patients with other comorbidities.
Pyostomatitis vegetans following coronavirus disease 2019 vaccination in a patient with ulcerative colitis.
Oral and dermatologic lesions observed in mild COVID-19 patients infected after 3rd vaccine dose.
Adverse reactions to BNT162B2 vaccine in health care workers from an Italian Tertiary Care Hospital.
Recent developments in SARS-CoV-2 vaccines: A systematic review of the current studies. Designing and manufacturing efficient vaccines against coronavirus disease 2019 (COVID-19) is a major objective. In this systematic review, we aimed to evaluate the most important vaccines under construction worldwide, their efficiencies and clinical results in healthy individuals and in those with specific underlying diseases. We conducted a comprehensive search in PubMed, Scopus, EMBASE, and Web of Sciences by 1 December 2021 to identify published research studies. The inclusion criteria were publications that evaluated the immune responses and safety of COVID-19 vaccines in healthy individuals and in those with pre-existing diseases. We also searched the VAERS database to estimate the incidence of adverse events of special interest (AESI) post COVID-19 vaccination. Almost all investigated vaccines were well tolerated and developed good levels of both humoural and cellular responses. A protective and efficient humoural immune response develops after the second or third dose of vaccine and a longer interval (about 28Â days) between the first and second injections of vaccine could induce higher antibody responses. The vaccines were less immunogenic in immunocompromised patients, particularly those with haematological malignancies. In addition, we found that venous and arterial thrombotic events, Bell's palsy, and myocarditis/pericarditis were the most common AESI. The results showed the potency of the SARS-CoV-2 vaccines to protect subjects against disease. The provision of further effective and safe vaccines is necessary in order to reach a high coverage of immunisation programs across the globe and to provide protection against infection itself.
The conundrum of thrombosis with thrombocytopenia syndrome following COVID-19 vaccines.
"Reversible cytotoxic lesion of the corpus callosum following SARS-CoV-2 mRNA vaccine administration: a finding to be aware of". Cytotoxic lesions of the corpus callosum (CLOCCs) are a clinical-radiological spectrum of disorders secondary to several etiopathogeneses. Cytotoxic lesions of the corpus callosum are typically associated with mild clinical symptoms including fever, headache, confusion, and altered mental status. We present a case of a 51-year-old Caucasian woman who developed a reversible lesion of the splenium of the corpus callosum associated with small round-shaped white matter hyperintensities after the first dose of SARS-CoV-2 mRNA vaccine. Magnetic resonance imaging is fundamental for diagnosis and no treatment is generally required.
Thrombocytopenia and splenic platelet-directed immune responses after IV ChAdOx1 nCov-19 administration. Vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are based on a range of novel platforms, with adenovirus-based approaches (like ChAdOx1 nCov-19) being one of them. Recently, a novel complication of SARS-CoV-2-targeted adenovirus vaccines has

emerged: immune thrombocytopenia, either isolated, or accompanied by thrombosis (then termed VITT). This complication is characterized by low platelet counts, and in the case of VITT, also by platelet-activating platelet factor 4 antibodies reminiscent of heparin-induced thrombocytopenia, leading to a prothrombotic state with clot formation at unusual anatomic sites. Here, we detected antiplatelet antibodies targeting platelet glycoprotein receptors in 30% of patients with proven VITT (n = 27) and 42% of patients with isolated thrombocytopenia after ChAdOx1 nCov-19 vaccination (n = 26), indicating broad antiplatelet autoimmunity in these clinical entities. We use inÂ vitro andÂ inÂ vivo models to characterize possible mechanisms of these platelet-targeted autoimmune responses leading to thrombocytopenia. We show that IV but not intramuscular injection of ChAdOx1 nCov-19 triggers platelet-adenovirus aggregate formation and platelet activation in mice. After IV injection, these aggregates are phagocytosed by macrophages in the spleen, and platelet remnants are found in the marginal zone and follicles. This is followed by a pronounced B-cell response with the emergence of circulating antibodies binding to platelets. Our work contributes to the understanding of platelet-associated complications after ChAdOx1 nCov-19 administration and highlights accidental IV injection as a potential mechanism of platelet-targeted autoimmunity. Hence, preventing IV injection when administering adenovirus-based vaccines could be a potential measure against platelet-associated pathologies after vaccination.
Focal segmental glomerulosclerosis recurrence in a young adult with kidney transplant after mRNA COVID-19 vaccination.
Autoimmune Hepatitis-Like Syndrome Following COVID-19 Vaccination: A Systematic Review of the Literature. OBJECTIVES: During the summer of 2021, case reports began to emerge documenting a small number of individuals who developed autoimmune hepatitis (AIH) following COVID-19 vaccination. These cases are rare and novel, and very little is known. In our systematic review, we analyzed every published case of AIH and reviewed their characteristic findings, treatment, and outcomes. METHODS: We searched PubMed, Embase, and Web of Science from December 1, 2019, to November 1, 2021. Two researchers independently extracted information from the articles about vaccine type, patient history, laboratory values, histology results, treatment regimens, and disease course. RESULTS: Thirty-two patients developed AIH-like syndromes after receiving a COVID-19 vaccine. Jaundice was the most frequently reported symptom (81%), and 19% of patients were initially asymptomatic and presented with elevated liver enzymes found during routine bloodwork. Mean alanine transaminase, aspartate transaminase, and total bilirubin were 1231 U/L, 921 U/L, and 14Â mg/dL, respectively. Anti-nuclear antibody was positive in 56%, and anti-smooth muscle antibody in 28% of patients. Steroids were used in 75% of patients. Improvement or complete resolution was seen in 97% of patients. One patient died despite aggressive steroid treatment. CONCLUSION: COVID-19 vaccine-induced AIH is an uncommon association with just 32 documented cases in the literature. Clinicians should be vigilant for AIH in patients who present with liver injury following vaccination. These new findings should under not deter individuals from getting vaccinated, as the benefits of vaccination far outweigh the risks. Fortunately, COVID-19 vaccine-induced AIH appears amendable to corticosteroid therapy and appears to have a favorable outcome.
COVID-19 Vaccine-Induced Multisystem Inflammatory Syndrome With Polyserositis Detected by FDG PET/CT: Reply.
A case of symmetrical drug-related intertriginous and flexural exanthema-like eruption associated with Pfizer COVID-19 vaccination.
Comment on: COVID-19 vaccine (mRNA BNT162b2) and COVID-19 infection-induced thrombotic thrombocytopenic purpura in adolescents.
Successful ABO-incompatible living donor kidney transplantation in a recipient who developed flow cytometry crossmatch-positive donor-specific class I HLA antibodies following COVID-19 vaccination.

The effects of COVID-19 vaccination on alloimmunization and clinical impact in transplant candidates remain largely unknown. In a 61-year-old man who had no donor-specific antibodies (DSA) and was planned to undergo ABO-incompatible kidney transplantation (ABOi KT), DSAs (anti-A24, anti-B51, and anti-Cw14) developed after COVID-19 vaccination. After desensitization therapy, antibody level was further increased, leading to flow cytometric crossmatch-positive status. Donor-specific T cell immunity using interferon-gamma ELISPOT was continuously negative, whereas SARS-CoV-2 specific T cell immunity was intact. After confirming the C1q-negative status of DSA, the patient received ABOi KT. The patient had stable graft function and suppressed alloimmunity up to 2â€‰months after KT. COVID-19 vaccination might relate to alloimmunization in transplant candidates, and desensitization through immune monitoring can help guide transplantation.

The Relationship Between Health Literacy and Quality of Life, Attitudes and Perceptions of Covid-19 and Vaccination Among Patients with Systemic Autoimmune Diseases. This study aimed to evaluate health literacy in patients (n=395) with systemic autoimmune diseases (SAD) and analyze their relationships with health-related quality of life (HRQoL), attitudes and beliefs about Covid-19 and vaccination, and perceptions of changes in medical care during the pandemic. This study was cross-sectional and the majority (81%) of particpants resided in Spain. An anonymous online survey was distributed to an online SAD association. Health literacy was measured using the European Health Literacy Survey Questionnaire (HLS-EU-Q16) and the SF-36 tool was used to assess HRQoL. More than half of patients (57.7%) have inadequate health literacy and the mean health literacy level was 9.63(5.66). Patients with inadequate health literacy levels presented the lowest HRQoL scores in all SF-36 domains (pâ€‰<â€‰.001). Health literacy scores were positively correlated with all SF-36 domains (pâ€‰<â€‰.001). The reservations to get vaccinated against Covid-19 were linked to health literacy level (pâ€‰=â€‰0.024). There are high levels of inadequate health literacy among patients with SAD and it is associated with worse HRQoL and risk attitudes about Covid-19 vaccination and medical care during the pandemic.

An intranasal lentiviral booster reinforces the waning mRNA vaccine-induced SARS-CoV-2 immunity that it targets to lung mucosa. As the coronavirus disease 2019 (COVID-19) pandemic continues and new severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants of concern emerge, the adaptive immunityÂ initially induced by the first-generation COVID-19 vaccines starts waning and needs to be strengthened and broadened in specificity. Vaccination by the nasal route induces mucosal, humoral, and cellular immunity at the entry point of SARS-CoV-2 into the host organism and has been shown to be the most effective for reducing viral transmission. The lentiviral vaccination vector (LV) is particularly suitable for this route of immunization owing to its non-cytopathic, non-replicative, and scarcely inflammatory properties. Here, to set up an optimized cross-protective intranasal booster against COVID-19, we generated an LV encoding stabilized spike of SARS-CoV-2 Beta variant (LV::S(Beta-2P)). mRNA vaccine-primed and -boosted mice, with waning primary humoral immunityÂ at 4Â months after vaccination, were boosted intranasally with LV::S(Beta-2P). A strong boost effect was detected on cross-sero-neutralizing activity and systemic TÂ cell immunity. In addition, mucosal anti-spike IgG and IgA, lung-resident B cells, and effector memory and resident TÂ cells were efficiently induced, correlating with complete pulmonary protection against the SARS-CoV-2 Delta variant, demonstrating the suitability of the LV::S(Beta-2P) vaccine candidate as an intranasal booster against COVID-19. LV::S(Beta-2P) vaccination was also fully protective against Omicron infection of the lungs and centralÂ nervous system, in the highly susceptible B6.K18-hACE2(IP-THV) transgenic mice.

Binocular Horizontal Diplopia Following mRNA-1273 Vaccine.

Acquired Thrombotic Thrombocytopenic Purpura After BNT162b2 COVID-19 Vaccine: Case Report and Literature Review. Thrombotic thrombocytopenic purpura (TTP) is a thrombotic

microangiopathy that is deadly if not treated promptly. The treatment of choice in patients presenting with TTP is plasma exchanges. However, immunosuppressive therapy and caplacizumab have significantly improved outcomes in TTP. This microangiopathy is classically divided into 2 entities: hereditary and acquired TTP (aTTP), caused by an autoantibody against ADAMTS 13. We present a case study of a patient wth TTP occurring after a second dose of the BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine along with a review of the literature. A 55-year-old patient presented with gastrointestinal symptoms, anemia, and severe thrombocytopenia. The blood film revealed the presence of schistocytes. A diagnosis of aTTP was established because the patient had severe ADAMTS 13 deficiency and autoantibodies against ADAMTS 13 were positive. This episode occurred 10 days after the patient received the COVID-19 vaccine. The patient received plasma exchanges, prednisone, rituximab, and caplacizumab and achieved complete remission. Ten patients with aTTP induced by the COVID-19 vaccine have been reported in the literature. Most of these situations occurred after the second dose of COVID-19 vaccine, and 7 patients were noted to have received the BNT162b2 vaccine. Caplacizumab was used in 6 patients, and complete remission was achieved in 8 patients.
Follow-up cardiac magnetic resonance in children with vaccine-associated myocarditis. Myocarditis is a rare complication of the COVID-19 mRNA vaccine. We previously reported a case series of 15 adolescents with vaccine-associated myocarditis, 87% of whom had abnormalities on initial cardiac magnetic resonance (CMR), including late gadolinium enhancement (LGE) in 80%. We performed follow-up CMRs to determine the trajectory of myocardial recovery and better understand the natural history of vaccine-associated myocarditis. Case series of patients ageâ€‰<â€‰19Â years admitted to Boston Children's Hospital with acute vaccine-associated myocarditis following the BNT162b2 vaccine who had abnormal CMR at the time of initial presentation, and underwent follow-up testing. CMR assessment included left ventricular (LV) ejection fraction, T2-weighted myocardial imaging, LV global native T1, LV global T2, extracellular volume (ECV), and late gadolinium enhancement (LGE). Ten patients (9 male, median age 15Â years) with vaccine-associated myocarditis underwent follow-up CMR at a median of 92Â days (range 76-119) after hospital discharge. LGE was persistent in 80% of patients, though improved from prior in all cases. Two patients (20%) had abnormal LV global T1 at presentation, which normalized on follow-up. ECV decreased between acute presentation and follow-up in 6/10 patients; it remained elevated at follow-up in 1 patient and borderline in 3 patients. CONCLUSION: CMR performedâ€‰~3Â months after admission for COVID-19 vaccine-associated myocarditis showed improvement of LGE in all patients, but persistent in the majority. Follow-up CMR 6-12Â months after acute episode should be considered to better understand the long-term cardiac risks. WHAT IS KNOWN: â€¢ Myocarditis is a rare side effect of COVID-19 mRNA vaccine. â€¢Late gadolinium enhancement is present on most cardiac magnetic resonance at the time of acute presentation. WHAT IS NEW: â€¢Late gadolinium enhancement improved on all repeat cardiac magnetic resonance at 3-month follow-up. â€¢Most patients still had a small amount of late gadolinium enhancement, the clinical significance of which is yet to be determined.
New Onset of Vitiligo and Atopic Dermatitis-Like Eczematous Dermatitis After Pfizer BioNTech's BNT162b2 Vaccination.
COVID-19 vaccination rate and side effects in CVID patients over the age of 12.
Hypercoagulability, endotheliopathy, and inflammation approximating 1â€‰year after recovery: Assessing the long-term outcomes in COVID-19 patients. Sustained hypercoagulability and endotheliopathy are present in convalescent COVID-19 patients for up to 4â€‰months from recovery. The hemostatic, endothelial, and inflammatory profiles of 39 recovered COVID-19 patients were evaluated up to 16â€‰months after recovery from COVID-19. These values were compared

with a control group of healthy volunteers (nÂ =Â 124). 39 patients (71.8% males, median age 43â€‰years) were reviewed at a mean of 12.7â€‰Â±â€‰3.6â€‰months following recovery. One patient without cardiovascular risk factors had post COVID-19 acute ischaemic limb. Elevated D-dimer and Factor VIII levels above normal ranges were noted in 17.9% (7/39) and 48.7% (19/39) of patients respectively, with a higher median D-dimer 0.34 FEUâ€‰Î¼g/mL (IQR 0.28, 0.46) (pâ€‰<â€‰.001) and Factor VIII 150% (IQR 171, 203) (pÂ =Â .004), versus controls. Thrombin generation (Thromboscreen) showed a higher median endogenous thrombin potential (ETP) of 1352â€‰nM*min (IQR 1152, 1490) (pÂ =Â .002) and a higher median peak height of 221.4â€‰nM (IQR 170.2, 280.4) (pÂ =Â 0.01) and delayed lag time 2.4â€‰min (1.42-2.97) (pÂ =Â 0.0002) versus controls. Raised vWF:Ag and ICAM-1 levels were observed in 17.9% (7/39) and 7.7% (3/39) of patients respectively, with a higher median VWF:Ag 117% (IQR 86, 154) (pÂ =Â 0.02) and ICAM-1 54.1â€‰ng/mL (IQR 43.8, 64.1) (pÂ =Â .004) than controls. IL-6 was noted to be raised in 35.9% (14/39) of patients, with a higher median IL-6 of 1.5â€‰pg/mL (IQR 0.6, 3.0) (pÂ =Â 0.004) versus controls. Subgroup analysis stratifying patients by COVID-19 severity and COVID-19 vaccination preceding SARS-CoV-2 infection did not show statistically significant differences. Hypercoagulability, endothelial dysfunction, and inflammation are still detectable in some patients approximately 1â€‰year after recovery from COVID-19.

Recent advances in clinical practice: management of inflammatory bowel disease during the COVID-19 pandemic. The COVID-19 pandemic has raised considerable concerns that patients with inflammatory bowel disease (IBD), particularly those treated with immunosuppressive therapies, may have an increased risk of SARS-CoV-2 acquisition, develop worse outcomes following COVID-19, and have suboptimal vaccine response compared with the general population. In this review, we summarise data on the risk of COVID-19 and associated outcomes, and latest guidance on SARS-CoV-2 vaccines in patients with IBD. Emerging evidence suggests that commonly used medications for IBD, such as corticosteroids but not biologicals, were associated with adverse outcomes to COVID-19. There has been no increased risk of de novo, or delayed, IBD diagnoses, however, an overall decrease in endoscopy procedures has led to a rise in the number of missed endoscopic-detected cancers during the pandemic. The impact of IBD medication on vaccine response has been a research priority recently. Data suggest that patients with IBD treated with antitumour necrosis factor (TNF) medications had attenuated humoral responses to SARS-CoV-2 vaccines, and more rapid antibody decay, compared with non-anti-TNF-treated patients. Reassuringly, rates of breakthrough infections and hospitalisations in all patients who received vaccines, irrespective of IBD treatment, remained low. International guidelines recommend that all patients with IBD treated with immunosuppressive therapies should receive, at any point during their treatment cycle, three primary doses of SARS-CoV-2 vaccines with a further booster dose as soon as possible. Future research should focus on our understanding of the rate of antibody decay in biological-treated patients, which patients require additional doses of SARS-CoV-2 vaccine, the long-term risks of COVID-19 on IBD disease course and activity, and the potential risk of long COVID-19 in patients with IBD.

Letter Regarding "Delayed-onset Anaphylaxis After COVID-19 Vaccination".

Impact of COVID-19 vaccinations on emergency department presentations. OBJECTIVE: The aim of the present study was to describe the burden of patients presenting to the ED with symptoms occurring after receiving a COVID-19 vaccination. METHODS: This was a retrospective cohort study performed over a 4-month period across two EDs. Participants were eligible for inclusion if it was documented in the ED triage record that their ED attendance was associated with the receipt of a COVID-19 vaccination. Data regarding the type of vaccine (Comirnaty or ChAdOx1) were subsequently extracted from their electronic medical record. Primary outcome was ED length of stay (LOS) and secondary outcomes included requests for imaging and ED disposition destination. RESULTS: During

the study period of 22 February 2021 to 21 June 2021, 632 patients were identified for inclusion in the present study, of which 543 (85.9%) had received the ChAdOx1 vaccination. The highest proportion of COVID-19 vaccine-related attendances occurred in June 2021 and accounted for 21 (8%) of 262 total daily ED attendances. Patients who had an ED presentation related to ChAdOx1 had a longer median ED LOS (253 vs 180â€‰min, PÂ <â€‰0.001) compared to Comirnaty and a higher proportion had haematology tests and imaging requested in the ED. Most patients (n = 588, 88.8%) were discharged home from the ED. CONCLUSION: There was a notable proportion of ED attendances related to recent COVID-19 vaccination administration, many of which were associated with lengthy ED stays and had multiple investigations. In the majority of cases, the patients were able to be discharged home from the ED.

Vaccines for Covid-19: An insight on their effectiveness and adverse effects. An era of SARS-COVID-19 outbreak with a high contagious percentage around the globe has been the subject of multi-agency research aimed at generating vaccines for active immunization. Scientists across the world are joining hands for advanced tie-ups between medical start-ups and pharmaceutical industries for devices and vaccines development to hinder the progress of this outbreak. Moreover, the questions that need to be answered are how to improve the effectiveness and efficacy of vaccines with reduced side effects and the required doses of vaccines for enhanced surveillance. In this review article, we have discussed the effectiveness and efficacy of different Covid-19 vaccines.

T-cell responses to SARS-CoV-2 Omicron spike epitopes with mutations after the third booster dose of an inactivated vaccine. The rapidly spreading severe acute respiratory syndrome coronavirus 2Â (SARS-CoV-2) Omicron variant contains more than 30 mutations that mediate escape from antibody responses elicited by prior infection or current vaccines. Fortunately, T-cell responses are highly conserved in most individuals, but the impacts of mutations are not clear. Here, we showed that the T-cell responses of individuals who underwent booster vaccination with CoronaVac were largely protective against the SARS-CoV-2 Omicron spike protein. To specifically estimate the impact of Omicron mutations on vaccinated participants, 16 peptides derived from the spike protein of the ancestral virus or Omicron strain with mutations were used to stimulate peripheral blood mononuclear cells (PBMCs) from the volunteers. Compared with the administration of two doses of vaccine, booster vaccination substantially enhanced T-cell activation in response to both the ancestral and Omicron epitopes, although the enhancement was slightly weakened by the Omicron mutations. Then, the peptides derived from these spike proteins were used separately to stimulate PBMCs. Interestingly, compared with the ancestral peptides, only the peptides with the G339D or N440K mutation were detected to significantly destabilize the T-cell response. Although more participants need to be evaluated to confirm this conclusion, our study nonetheless estimates the impacts of mutations on T-cell responses to the SARS-CoV-2 Omicron variant.

Immune Responses to SARS-CoV-2 Vaccination in Young Patients with Anti-CD19 Chimeric Antigen Receptor T Cell-Induced B Cell Aplasia. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines are capable of inducing combined humoral and cellular immunity. Which effect is more relevant for their potent protective effects is unclear, but isolated T cell responses without seroconversion in healthy household members of individuals with Coronavirus disease 19 (COVID-19) suggest that T cell responses effectively protect against clinical infection. Oncologic patients have an outsize risk of unfavorable outcomes after SARS-CoV-2 infection and therefore were prioritized when vaccines first became available, although the quality of their immune response to vaccination was expected to be suboptimal, as has been confirmed in subsequent studies. Inherently, patients with anti-CD19 chimeric antigen receptor (CAR) T cell therapy-mediated B cell aplasia would be incapable of generating humoral responses, so that assessment of the vaccine-induced cellular immunity is all the more important to gauge whether the vaccine can induce meaningful protection. A salient

difference between T cell and humoral responses is the former's relative impassiveness to mutations of the antigen, which is more relevant than ever since the advent of the omicron variant. The objective of this study was to assess the immune cell composition and spike protein-specific T cell responses before and after the first and second doses of SARS-CoV-2 mRNA vaccine in a cohort of juvenile CD19 CAR T cell therapy recipients with enduring B cell aplasia. The prospective study included all patients age >12 years diagnosed with multiply relapsed B cell precursor acute lymphoblastic leukemia and treated with anti-CD19 CAR T cell (CAR-T19) therapy in our center. The primary endpoint was the detection of cell-mediated and humoral responses to vaccine (flow cytometry and anti-S immunoglobulin G, respectively). Secondary endpoints included the incidence of vaccine-related grade 3 or 4 adverse events, exacerbation of graft-versus-host disease (GVHD), relapse, and the influence of the vaccine on CAR T cells and lymphocyte subsets. Even though one-half of the patients exhibited subnormal lymphocyte counts and marginal CD4/CD8 ratios, after 2 vaccinations all showed brisk T-cell responsiveness to spike protein, predominantly in the CD4 compartment, which quantitatively was well within the range of healthy controls. No severe vaccine-related grade 3 or 4 adverse events, GVHD exacerbation, or relapse was observed in our cohort. We posit that SARS-CoV-2 mRNA vaccines induce meaningful cellular immunity in patients with isolated B cell deficiency due to CAR-T19 therapy.

Enhanced BNT162b2 vaccine-induced cellular immunity in anti-CD19 CAR T cell-treated patients. Patients receiving CD19 CAR T-cell therapy for relapsed/refractory lymphoma experience prolonged and profound B-cell aplasia and hypogammaglobulinemia, placing them at a higher risk for severe COVID-19. Independently, Oh et al and Atanackovic et al demonstrate that despite attenuated humoral response to mRNA-based vaccines, patients demonstrate normal or heightened functional T-cell responses, including antiviral T-cell activity against SARS-CoV-2 variants including Omicron. Collectively, these data reinforce the importance of COVID-19 vaccination following CD19 CAR T-cell therapy, despite long-term B-cell aplasia.

Victorian Specialist Immunisation Services (VicSIS) - bolstering adult clinics for COVID-19 vaccines. The Victorian Specialist Immunization Services (VicSIS) was established in Victoria, Australia, in February 2021, aiming to enhance vaccine safety services for Coronavirus disease (COVID-19) vaccines. VicSIS supports practitioners and patients with complex vaccine safety questions, including those who experience adverse events following immunization (AEFI) after COVID-19 vaccines. VicSIS provides individual vaccination recommendations, allergy testing, vaccine challenges, and vaccination under supervision. VicSIS initially comprised of eight adult COVID-19 specialist vaccination clinics, subsequently, expanding to better support pediatric patients as the Australian vaccine roll-out extended to adolescents and children. Since their establishment to September 2021, the inaugural VicSIS clinics received a total of 26,401 referrals and reviewed 6,079 patients. Consults were initially predominantly for pre-vaccination reviews, later predominantly becoming post-vaccination AEFI reviews as the program progressed. Regardless of the type of consult, the most common consult outcome was a recommendation for routine vaccination (73% and 55% of consult outcomes respectively). VicSIS is an integral component of the COVID-19 vaccination program and supports confidence in COVID-19 vaccine safety by providing consistent advice across the state. VicSIS aims to strengthen the health system through the pandemic, bolstering specialist immunization services beyond COVID-19 vaccines, including training the next generation of vaccinology experts.

Correspondence on 'Herpes Zoster and Simplex reactivation following COVID-19 vaccination'.

Follow-up of COVID-19 Vaccine-related Axillary Lymphadenopathy before 12 Weeks Is Unnecessary.

US Evaluation of Axillary Lymphadenopathy Following COVID-19 Vaccination: A Prospective Longitudinal Study. Background Both temporal changes in imaging characteristics of lymphadenopathy on US scans after COVID-19 vaccination and expected duration of radiologically

evident lymphadenopathy remain uncertain. Purpose To longitudinally evaluate COVID-19 vaccine-associated lymphadenopathy on axillary US scans at various time intervals in both messenger (mRNA) and vector vaccine recipients. Materials and Methods This prospective cohort study was conducted between March 2021 and January 2022. The participants were asymptomatic women without breast cancer who had received COVID-19 vaccination. Serial follow-up US was performed in women with lymphadenopathy. The following variables were assessed: cortical thickness, number of lymph nodes, morphologic characteristics, and Doppler signal. Temporal changes in cortical thickness and number of lymph nodes during follow-up were assessed using a linear mixed model. Results Ninety-one women with lymphadenopathy in the vaccinated arm had undergone a total of 215 serial US examinations (mean age, 44 years Â± 13 [SD]). Fifty-one participants had received a vector vaccine (ChAdOx1 nCoV-19 vaccine) and 40 had received an mRNA vaccine (BNT162b2 vaccine [n = 37] and mRNA-1273 vaccine [n = 3]). Three of the 91 women were lost to follow-up; thus, 88 women underwent serial US. Complete resolution of axillary lymphadenopathy was observed at a median of 6 weeks after vaccination (range, 4-7 weeks) in 26% of women (23 of 88). Among 49 women with follow-up US at a median of 12 weeks after vaccination (range, 8-14 weeks), persistent lymphadenopathy was observed in 25 (51%). During the follow-up period, the cortical thickness gradually decreased (P < .001) over time regardless of vaccine type; however, values were higher in recipients of the mRNA vaccine than in recipients of the vector vaccine (P = .02). Conclusion COVID-19 vaccine-associated axillary lymphadenopathy frequently persisted for more than 6 weeks on US scans. Lymphadenopathy should be interpreted considering vaccine type and time elapsed since vaccination. Follow-up US examination at least 12 weeks after vaccination may be reasonable, particularly for recipients of the messenger RNA vaccine. Â© RSNA, 2022 Online supplemental material is available for this article. See also the editorial by Moy and Kim in this issue.

Real-world evidence from over one million COVID-19 vaccinations is consistent with reactivation of the varicella-zoster virus. BACKGROUND: Reactivation of the varicella-zoster virus (VZV), which causes herpes zoster (HZ, synonym: shingles) in humans, can be a rare adverse reaction to vaccines. Recently, reports of cases after COVID-19 vaccination have arisen. OBJECTIVES: The aim of this study was to assess whether the frequency of HZ is found to increase after COVID-19 vaccination in a large cohort, based on real-world data. As a hypothesis, the incidence of HZ was assumed to be significantly higher in subjects who received a COVID-19 vaccine (Cohort I) vs. unvaccinated individuals (Cohort II). METHODS: The initial cohorts of 1â€‰095â€‰086 vaccinated and 16â€‰966â€‰018 unvaccinated patients were retrieved from the TriNetX database and were matched on age and gender in order to mitigate confounder bias. RESULTS: After matching, each cohort accounted for 1â€‰095â€‰086 patients. For the vaccinated group (Cohort I), 2204 subjects developed HZ within 60â€‰days of COVID-19 vaccination, while among Cohort II, 1223 patients were diagnosed with HZ within 60â€‰days after having visited the clinic for any other reason (i.e. not vaccination). The risk of developing shingles was calculated as 0.20% and 0.11% for cohort I and cohort II, respectively. The difference was statistically highly significant (Pâ€‰<â€‰0.0001; log-rank test). The risk ratio and odds ratio were 1.802 (95% confidence interval [CI]â€‰=â€‰1.680; 1.932) and 1.804 (95% CIâ€‰=â€‰1.682; 1.934). CONCLUSIONS: Consistent with the hypothesis, a higher incidence of HZ was statistically detectable post-COVID-19 vaccine. Accordingly, the eruption of HZ may be a rare adverse drug reaction to COVID-19 vaccines. Even though the molecular basis of VZV reactivation remains murky, temporary compromising of VZV-specific T-cell-mediated immunity may play a mechanistic role in post-vaccination pathogenesis of HZ. Note that VZV reactivation is a well-established phenomenon both with infections and with other vaccines (i.e. this adverse event is not COVID-19-specific).

Reported Breast Implant-Related Reactions After COVID-19 or COVID-19 Vaccination: Correspondence.
Fixed drug eruption after Pfizer-BioNTech COVID-19 vaccine: A case report.
Social cohesion and loneliness are associated with the antibody response to COVID-19 vaccination. BACKGROUND: Recent research has suggested that psychosocial factors influence the antibody response to vaccine, including SARS-CoV-2 (COVID-19) vaccines. Here we investigated whether social cohesion and loneliness were predictive of antibody response to a single dose of a COVID-19 vaccine. We also tested if the association between social cohesion and antibody response was mediated by feelings of loneliness. METHODS: Participants (NÂ =Â 676) COVID-19 antibody data were extracted from March 2021 wave of the Understanding Society COVID-19 study from the UK. Relevant socio-demographics, health and lifestyle, loneliness, social cohesion indices were also used in a series of hierarchical linear regression to test our main hypotheses. RESULTS: After controlling for covariates (e.g., age and chronic health conditions), lower social cohesion was associated with a lower antibody response. Further, the association between social cohesion and poorer antibody responses was mediated by loneliness; those reporting lower social cohesion also reported higher loneliness, which in turn was associated with lower antibody response. CONCLUSION: This study confirms that feelings of 'being in it together' relate to the strength of the antibody response to COVID-19 vaccination, emphasising the importance of the social cohesion agenda during the pandemic.
COVID-19 vaccination during pregnancy: coverage and safety, a comment.
COVID-19 vaccine and autoimmune hepatitis. We would like to correspond and share ideas on the publication "SARS-CoV-2 vaccine, a new autoimmune hepatitis trigger?." LÃ³pez Romero-Salazar reported a case of autoimmune hepatitis (AIH) after receiving SARS-COV2 vaccine. LÃ³pez Romero-Salazar et al noted that "vaccination can induce the development of autoimmune pathology in patients at risk." The possibility of a link between AIH and the SARS-CoV2 vaccine is explored. We agree that the COVID-19 vaccination has the potential to create clinical problems. The aberrant immune response could lead to a variety of health issues, including hepatitis. The vaccine recipient in this case had hepatitis, but there is no information about his or her health or liver function prior to inoculation. Other probable causes of hepatitis should be considered.
Safety of BNT162b2 mRNA vaccine booster in the setting of Ad26.COV2.S-associated VITT.
Durability of BNT162b2 vaccine against hospital and emergency department admissions due to the omicron and delta variants in a large health system in the USA: a test-negative case-control study. BACKGROUND: The duration of protection against the omicron (B.1.1.529) variant for current COVID-19 vaccines is not well characterised. Vaccine-specific estimates are especially needed. We aimed to evaluate the effectiveness and durability of two and three doses of the BNT162b2 (Pfizer-BioNTech) mRNA vaccine against hospital and emergency department admissions due to the delta (B.1.617.2) and omicron variants. METHODS: In this case-control study with a test-negative design, we analysed electronic health records of members of Kaiser Permanente Southern California (KPSC), a large integrated health system in California, USA, from Dec 1, 2021, to Feb 6, 2022. Vaccine effectiveness was calculated in KPSC patients aged 18 years and older admitted to hospital or an emergency department (without a subsequent hospital admission) with a diagnosis of acute respiratory infection and tested for SARS-CoV-2 via PCR. Adjusted vaccine effectiveness was estimated with odds ratios from adjusted logistic regression models. This study is registered with ClinicalTrials.gov (NCT04848584). FINDINGS: Analyses were done for 11â€ˆ123 hospital or emergency department admissions. In adjusted analyses, effectiveness of two doses of the BNT162b2 vaccine against the omicron variant was 41% (95% CI 21-55) against hospital admission and 31% (16-43) against emergency department admission at 9 months or longer after the second dose. After three doses, effectiveness of BNT162b2 against hospital admission due to the omicron variant was 85% (95% CI

80-89) at less than 3 months but fell to 55% (28-71) at 3 months or longer, although confidence intervals were wide for the latter estimate. Against emergency department admission, the effectiveness of three doses of BNT162b2 against the omicron variant was 77% (72-81) at less than 3 months but fell to 53% (36-66) at 3 months or longer. Trends in waning against SARS-CoV-2 outcomes due to the delta variant were generally similar, but with higher effectiveness estimates at each timepoint than those seen for the omicron variant. INTERPRETATION: Three doses of BNT162b2 conferred high protection against hospital and emergency department admission due to both the delta and omicron variants in the first 3 months after vaccination. However, 3 months after receipt of a third dose, waning was apparent against SARS-CoV-2 outcomes due to the omicron variant, including hospital admission. Additional doses of current, adapted, or novel COVD-19 vaccines might be needed to maintain high levels of protection against subsequent waves of SARS-CoV-2 caused by the omicron variant or future variants with similar escape potential. FUNDING: Pfizer.

Type 1 Diabetes Mellitus Associated with Nivolumab after Second SARS-CoV-2 Vaccination, Japan. Recently, along with increasing use of immune checkpoint inhibitors such as nivolumab, the incidence of immune-related adverse events, including type 1 diabetes mellitus, has become a serious problem. We report a patient who had immune checkpoint inhibitorâ€'associated type 1 diabetes mellitus that developed after a second mRNA-based SARS-CoV-2 vaccination.

Surrogate neutralization responses following severe acute respiratory syndrome coronavirus 2 vaccination in people with HIV: comparison between inactivated and mRNA vaccine. OBJECTIVE: People with HIV (PWH) co-infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are at higher odds of severe diseases. Whereas the immunogenicity of mRNA vaccine and adenovirus-vectored vaccine was similar between PWH in stable condition and healthy adults, the effects of inactivated vaccines are not known. DESIGN: Prospective longitudinal observational study in real-world setting. METHODS: Adult PWH in care and planning to receive either inactivated (day 0 and day 28) or mRNA-based (day 0 and day 21) vaccine against SARS-CoV-2 were recruited, with blood samples collected over 6â€Šmonths for surrogate virus neutralization test (sVNT). Demographic and clinical data including age, sex, CD4 + cell count, and suppressed viral load (SVL) status were transcribed for analyses, by simple and multivariable linear regression models, and multivariable linear generalized estimating equations (GEE). RESULTS: A total of 611 HIV patients, 91% male patients, were recruited, of whom 423 and 184 have received mRNA-based and inactivated vaccine, respectively. The seroconversion rate was 99% for mRNA-based vs, 86% for inactivated vaccine [odds ratio (OR)â€Š=â€Š21.56, P â€Š=â€Š0.004]. At 6â€Šmonths, mRNA-based vaccine continued to give a higher response (94 vs. 57%, P â€Š<â€Š0.001). The temporal pattern varied between the two vaccines. By GEE, mRNA-based vaccine (B â€Š=â€Š40.59, P â€Š<â€Š0.001) and latest SVL status (B â€Š=â€Š10.76, P â€Š=â€Š0.01) were positively associated with sVNT level, but not latest CD4 + cell count. CONCLUSION: In HIV patients, inactivated vaccine gave a lower peak and shorter duration of sVNT responses compared with mRNA vaccine. The results suggested that different strategies may be needed in boosting the immunity in anticipation of the emergence of variants in the community.

Vaccine-Induced Functional Neurological Disorders in the Covid-19 Era. The large amount of information available to the public regarding vaccines against Covid-19 coupled with pandemic stress and increased somatic attention could potentially precipitate development of functional neurological disorders (FNDs) following vaccination. A growing number of reports indicate that functional symptoms may follow Covid-19 vaccination, similar to those observed with other vaccines previously. We review previously reported cases of FND following vaccination against Covid-19 and present three additional cases. While two patients presented to the Emergency Department with functional movement disorders, one patient presented with protracted limb weakness and sensory dysfunction. The superficial resemblance to Guillain-BarrÃ© syndrome, a known but uncommon complication of

vaccination prompted an extensive workup. Clinicians need to convey the diagnosis of FND in clear and unequivocal terms to facilitate institution of appropriate therapy and rehabilitation, but importantly also to dispel any doubts in the minds of the public regarding the safety of the available vaccines. Given the presence of significant vaccine hesitancy in many countries, this is critical to the success of the global immunisation effort.

Transient Large-vessel Vasculitis after COVID-19 mRNA Vaccination.

Pituitary apoplexy following adenoviral vector-based COVID-19 vaccination. Pituitary apoplexy (PA) may complicate the course of coronavirus disease 2019 (COVID-19), posing a potential threat to life. Among vaccines designed to prevent COVID-19, there are those adenoviral vector-based, such as VaxzevriaÂ® (formerly COVID-19 Vaccine AstraZeneca). The product insert states that it can cause very rare coagulation disorders, in particular thrombosis with thrombocytopenia syndrome in some cases accompanied by bleeding, cerebrovascular venous or sinus thrombosis, and thrombocytopenia, including immune thrombocytopenia, also associated with bleeding. Here, we report the onset of PA after VaxzevriaÂ® in a 28-year-old healthy Caucasian female, who experienced long-lasting tension-type headache, hyperprolactinemia and menstrual changes, without thrombocytopenia or thrombosis.

SARS-CoV-2 vaccination can elicit a CD8 T-cell dominant hepatitis. BACKGROUND & AIMS: Autoimmune hepatitis episodes have been described following SARS-CoV-2 infection and vaccination but their pathophysiology remains unclear. Herein, we report the case of a 52-year-old male, presenting with bimodal episodes of acute hepatitis, each occurring 2-3 weeks after BNT162b2 mRNA vaccination. We sought to identify the underlying immune correlates. The patient received oral budesonide, relapsed, but achieved remission under systemic steroids. METHODS: Imaging mass cytometry for spatial immune profiling was performed on liver biopsy tissue. Flow cytometry was performed to dissect CD8 T-cell phenotypes and identify SARS-CoV-2-specific and EBV-specific T cells longitudinally. Vaccine-induced antibodies were determined by ELISA. Data were correlated with clinical laboratory results. RESULTS: Analysis of the hepatic tissue revealed an immune infiltrate quantitatively dominated by activated cytotoxic CD8 T cells with panlobular distribution. An enrichment of CD4 T cells, B cells, plasma cells and myeloid cells was also observed compared to controls. The intrahepatic infiltrate showed enrichment for CD8 T cells with SARS-CoV-2-specificity compared to the peripheral blood. Notably, hepatitis severity correlated longitudinally with an activated cytotoxic phenotype of peripheral SARS-CoV-2-specific, but not EBV-specific, CD8+ T cells or vaccine-induced immunoglobulins. CONCLUSIONS: COVID-19 vaccination can elicit a distinct T cell-dominant immune-mediated hepatitis with a unique pathomechanism associated with vaccination-induced antigen-specific tissue-resident immunity requiring systemic immunosuppression. LAY SUMMARY: Liver inflammation is observed during SARS-CoV-2 infection but can also occur in some individuals after vaccination and shares some typical features with autoimmune liver disease. In this report, we show that highly activated T cells accumulate and are evenly distributed in the different areas of the liver in a patient with liver inflammation following SARS-CoV-2 vaccination. Moreover, within the population of these liver-infiltrating T cells, we observed an enrichment of T cells that are reactive to SARS-CoV-2, suggesting that these vaccine-induced cells can contribute to liver inflammation in this context.

Post ChAdOx1 nCoV-19 vaccination frontal lobe syndrome.

Peripheral lymphocyte subset counts predict antibody response after SARS-CoV-2 mRNA-BNT162b2 vaccine in cancer patients: Results from the Vax-On-Profile study. BACKGROUND: The adaptive immune response following COVID-19 vaccination is essential for humoral immunogenicity and clinical protection against symptomatic infections. We present the results of circulating lymphocyte profiling and their correlation with antibody response in cancer patients tested serologically six

months after receiving a two-dose schedule of mRNA-BNT162b2 vaccine. METHODS: Absolute counts of lymphocyte subsets were determined using peripheral blood immunophenotyping. We collected samples for flow cytometry analysis alongside quantitative detection of IgG antibodies against the receptor-binding domain (RBD) of the SARS-CoV-2 Spike protein (S1). An IgG titerÂ â‰¥Â 50 AU/mL defined a positive seroconversion response. RESULTS: 311 patients were evaluable for lymphocyte profiling and serologic testing. A preliminary multivariate analysis revealed that cytotoxic chemotherapy was the most consistent factor associated with lower counts of all lymphocyte subpopulations. T helper and B cells were found to be useful in predicting the occurrence of a positive seroconversion response using ROC curve analysis. A significant positive linear correlation was shown when anti-RBD-S1 IgG titers were compared to these lymphocyte subset counts. Univariate analysis indicated that antibody titers and seroconversion rates were significantly improved in the high-level T and B cell subgroups. Multivariate analysis confirmed these significant interactions, as well as the negative predictive value of immunosuppressive corticosteroid therapy. CONCLUSIONS: These findings suggest that simple and widely available peripheral counts of T helper and B cells correlate with humoral response to mRNA-BNT162b2 vaccine in actively treated cancer patients. Upon validation, our results could provide additional insights into the predictive assessment of vaccination efficacy.

Anti-MOG associated disease with intracranial hypertension after COVID-19 vaccination.

Factors Associated With COVID-19 Behavioral Intentions: Findings From an Online Survey. PURPOSE: The COVID-19 pandemic provides a novel context through which to evaluate salient factors for promoting behavioral change. We examined how attitudes, perceived community behaviors, and prior related behaviors predict intentions to (1) receive COVID-19 vaccination and (2) practice social distancing. DESIGN: Cross-sectional online survey administered through Amazon's Mechanical Turk in September 2020. SUBJECTS: A convenience sample of US adults (N = 1804). MEASURES: COVID-19 vaccination and social distancing intentions were measured on a 7-point Likert scale. Predictor variables included general vaccination and social distancing attitudes, perceived community mask-wearing, prior influenza vaccination, prior social distancing, and socio-demographics. ANALYSIS: Descriptive statistics and linear regressions. RESULTS: Thirty percent of respondents reported a strong willingness to receive COVID-19 vaccination, while 67% strongly intended to engage in social distancing. In regression analyses, vaccination intention was predicted by positive vaccine attitudes (b = .84; 95%CI: .78, .90; P < .001), prior influenza vaccination (b = -.47; 95%CI: -.63, -.32; P < .001), and perceived community mask-wearing (b = -.28; 95%CI: -.56, -.01; P=.049). Intention to practice social distancing was predicted by positive attitudes (b = .65; 95%CI: .61, .69; P < .001), prior social distancing (b = -.49; 95%CI: -.59, -.39; P < .001), and perceived community mask-wearing (b = -.28; 95%CI: -.46, -.09; P = .003). CONCLUSION: Findings have implications for health promotion efforts. Messages that are targeted and tailored on pre-existing attitudes may be more effective. Additionally, leveraging prior behaviors and perceived community behavior may improve communication strategies.

Self-Reported adverse events among Chinese healthcare workers immunized with COVID-19 vaccines composed of inactivated SARS-CoV-2. Mass vaccination is critical to control the pandemic of coronavirus disease 2019 (COVID-19). Fear of adverse events (AEs) after COVID-19 vaccination is a main factor associated with vaccination hesitancy. We aimed to analyze AEs in healthcare workers (HCWs) vaccinated with COVID-19 vaccines (Aikewei or CoronaVac) composed of inactivated virus. We used a structured self-administered questionnaire to conduct two surveys on COVID-19 vaccination among HCWs in perinatal medicine and obstetrics/gynecology from April 5 to April 21, 2021. In total, 1392 HCWs who had received at least one vaccine dose were included. Of them, 1264 (90.8%) were females and 1047 (75.2%) received two doses. The overall incidence of any AEs after

the first and second dose was 38.2% (532/1392) and 31.0% (325/1047) respectively (Ï‡2 = 13.506, P = .0002). Female and HCWs aged 18-30 y were more likely to report AEs. The most common AEs were local reaction, accounting for 48.1% and 67.4% of all AEs after the first and second dose respectively. The systemic AEs were mainly neurological (9.8% and 4.8% after the first and second injection respectively) and flu-like symptoms (6.3% and 3.2%). Overall, most of AEs were mild, only 5.1% (after the first dose) and 2.8% (after the second dose) of individuals with AEs received symptomatic treatment or sick leaves, and none of them required hospitalization. Our data added more evidence that inactivated COVID-19 vaccines are highly safe. The data are valuable to overcome vaccine hesitancy associated with concerns about the safety of COVID-19 vaccines.

Myocarditis following COVID-19 vaccination in adolescents and adults: a cumulative experience of 2021. Clinical course and outcomes of myocarditis after COVID-19 vaccination remain variable. We retrospectively collected data on patientsâ€‰>â€‰12Â years old from 01/01/2021 to 12/30/2021 who received COVID-19 messenger RNA (mRNA) vaccination and were diagnosed with myocarditis within 60Â days of vaccination. Myocarditis cases were based on case definitions by authors. We report on 238 patients of whom most were male (nâ€‰=â€‰208; 87.1%). The mean age was 27.4â€‰Â±â€‰16 (range 12-80) years. Females presented at older ages (41.3â€‰Â±â€‰21.5Â years) than men 25.7â€‰Â±â€‰14Â years (pâ€‰=â€‰0.001). In patientsâ€‰>â€‰20Â years of age, the mean duration from vaccination to symptoms was 4.8Â daysâ€‰Â±â€‰5.5Â days, but inâ€‰<â€‰20, it was 3.0â€‰Â±â€‰3.3Â days (pâ€‰=â€‰0.04). Myocarditis occurred most commonly after the Pfizer-BioNTech mRNA vaccine (nâ€‰=â€‰183; 76.45) and after the second dose (nâ€‰=â€‰182; 80%). Symptoms started 3.95â€‰Â±â€‰4.5Â days after vaccination. The commonest symptom was chest pain (nâ€‰=â€‰221; 93%). Patients were treated with non-steroidal anti-inflammatory drugs (nâ€‰=â€‰105; 58.3%), colchicine (nâ€‰=â€‰38; 21.1%), or glucocorticoids (nâ€‰=â€‰23; 12.7%). About 30% of the patients had left ventricular ejection fraction but more than half recovered the on repeat imaging. Abnormal cardiac MRIs were common; 168 patients (96% of 175 patients that had MRI) had late gadolinium enhancement, while 120 patients (68.5%) had myocardial edema. Heart failure guideline-directed medical therapy use was common (nâ€‰=â€‰27; 15%). Eleven patients had cardiogenic shock; and 4 patients required mechanical circulatory support. Five patients (1.7%) died; of these, 3 patients had endomyocardial biopsy/autopsy-confirmed myocarditis. Most cases of COVID-19 vaccine myocarditis are mild. Females presented at older ages than men and duration from vaccination to symptoms was longer in patientsâ€‰>â€‰20Â years. Cardiogenic shock requiring mechanical circulatory support was seen and mortality was low. Future studies are needed to better evaluate risk factors, and long-term outcomes of COVID-19 mRNA vaccine myocarditis.

Six-month sequelae of post-vaccination SARS-CoV-2 infection: A retrospective cohort study of 10,024 breakthrough infections. Vaccination has proven effective against infection with SARS-CoV-2, as well as death and hospitalisation following COVID-19 illness. However, little is known about the effect of vaccination on other acute and post-acute outcomes of COVID-19. Data were obtained from the TriNetX electronic health records network (over 81 million patients mostly in the USA). Using a retrospective cohort study and time-to-event analysis, we compared the incidences of COVID-19 outcomes between individuals who received a COVID-19 vaccine (approved for use in the USA) at least 2Â weeks before SARS-CoV-2 infection and propensity score-matched individuals unvaccinated for COVID-19 but who had received an influenza vaccine. Outcomes were ICD-10 codes representing documented COVID-19 sequelae in the 6Â months after a confirmed SARS-CoV-2 infection (recorded between January 1 and August 31, 2021, i.e. before the emergence of the Omicron variant). Associations with the number of vaccine doses (1 vs. 2) and age (<60 vs.Â â‰¥Â 60Â years-old) were assessed. Among 10,024 vaccinated individuals with SARS-CoV-2 infection, 9479 were matched to

unvaccinated controls. Receiving at least one COVID-19 vaccine dose was associated with a significantly lower risk of respiratory failure, ICU admission, intubation/ventilation, hypoxaemia, oxygen requirement, hypercoagulopathy/venous thromboembolism, seizures, psychotic disorder, and hair loss (each as composite endpoints with death to account for competing risks; HR 0.70-0.83, Bonferroni-corrected pÂ <Â 0.05), but not other outcomes, including long-COVID features, renal disease, mood, anxiety, and sleep disorders. Receiving 2 vaccine doses was associated with lower risks for most outcomes. Associations between prior vaccination and outcomes of SARS-CoV-2 infection were marked in those <60Â years-old, whereas no robust associations were observed in those â‰¥60Â years-old. In summary, COVID-19 vaccination is associated with lower risk of several, but not all, COVID-19 sequelae in those with breakthrough SARS-CoV-2 infection. The findings may inform service planning, contribute to forecasting public health impacts of vaccination programmes, and highlight the need to identify additional interventions for COVID-19 sequelae.

Impact of previous exposure to SARS-CoV-2 and of S-Trimer (SCB-2019) COVID-19 vaccination on the risk of reinfection: a randomised, double-blinded, placebo-controlled, phase 2 and 3 trial. BACKGROUND: We previously reported the efficacy of the adjuvanted-protein COVID-19 vaccine candidate S-Trimer (SCB-2019) in adults who showed no evidence of previous exposure to SARS-CoV-2. In this study, we aimed to investigate the extent of protection afforded by previous exposure to SARS-CoV-2 on subsequent COVID-19 infection, as well as the efficacy, safety, and reactogenicity of SCB-2019 in participants who were enrolled in the Study evaluating Protective-Efficacy and safety of Clover's Trimeric Recombinant protein-based and Adjuvanted COVID-19 vaccine (SPECTRA) trial who had already been exposed to SARS-CoV-2 before vaccination. METHODS: In a phase 2 and 3 multicentre, double-blind, randomised, placebo-controlled trial (SPECTRA) done at 31 sites in five countries, participants were randomly assigned 1:1 using the Cenduit Interactive Response Technology system (IQVIA, Durham, NC, USA), with a block size of six, to receive two doses of either SCB-2019 or placebo 21 days apart. The primary outcomes of the SPECTRA trial were vaccine efficacy, measured by real-time PCR (rtPCR)-confirmed COVID-19 of any severity, with onset from 14 days after the second vaccine dose, as well as the safety and solicited local and systemic adverse events in the phase 2 subset. Here, we present secondary analyses to calculate the protective efficacy due to previous exposure to SARS-CoV-2 against reinfection with COVID-19 according to severity in SPECTRA participants who had evidence of exposure to SARS-CoV-2 at baseline, including efficacy against identified viral variants, as well as efficacy of SCB-2019 vaccination in this population. FINDINGS: We enrolled 30â€‰174 participants between March 24, 2021, and Aug 10, 2021. In the 14 670 participants who were randomly assigned to receive placebo, there were 418 (2Â·8%) confirmed cases of COVID-19; 65 (0Â·9%) of 7339 SARS-CoV-2-exposed participants, and 353 (4Â·8%) of 7331 SARS-CoV-2-naive participants (attack rates of 5Â·5 cases per 100 person-years for SARS-CoV-2-exposed participants and 32Â·4 cases per 100 person-years for SARS-CoV-2-naive participants). Protective efficacy due to previous exposure to SARS-CoV-2 was 83Â·2% (95% CI 78Â·0-87Â·3) against any COVID-19, 92Â·5% (82Â·9-97Â·3) against moderate-to-severe COVID-19, and 100% (59Â·3-100) against severe COVID-19; no SARS-CoV-2-exposed participants had hospitalisation associated with COVID-19. Protective efficacy against variants were 100% for alpha (B.1.1.7) and lambda (C.37) variants, 88Â·6% (14Â·9-99Â·7) for B.1.623, 93Â·6% (80Â·1-98Â·7) for gamma (P.1), and 92Â·4% (81Â·2-97Â·6) for mu (B.1.621) variants, and lowest against beta (B.1.351; 72Â·2% [33Â·1-89Â·9]) and delta (B.1.617.2; 77Â·2% [61Â·3-87Â·2]) variants. In addition, one dose of SCB-2019 had 49Â·9% (1Â·5-75Â·6) efficacy against any symptomatic COVID-19, and two doses had 64Â·2% (26Â·5-83Â·8) efficacy. SCB-2019 was well tolerated in SARS-CoV-2-exposed participants, but was associated with higher rates of injection site pain (89 [33Â·8%] of 263 participants) than placebo (16 [6Â·7%] of 239 participants). Rates of solicited systemic adverse events, severe adverse events, and serious adverse

events were similar between vaccine and placebo groups, and with rates in SARS-CoV-2-naive vaccine recipients. INTERPRETATION: Previous exposure to SARS-CoV-2 decreased the risk and severity of subsequent COVID-19 infection, even against newly emerging variants. Protection is further enhanced by one or two doses of SCB-2019. FUNDING: Clover Biopharmaceuticals, The Coalition for Epidemic Preparedness Innovations (CEPI).

Increased memory B cell potency and breadth after a SARS-CoV-2 mRNA boost. The Omicron variant of SARS-CoV-2 infected many vaccinated and convalescent individuals(1-3). Despite the reduced protection from infection, individuals who received three doses of an mRNA vaccine were highly protected from more serious consequences of infection(4). Here we examine the memory B cell repertoire in a longitudinal cohort of individuals receiving three mRNA vaccine doses(5,6). We find that the third dose is accompanied by an increase in, and evolution of, receptor-binding domain (RBD)-specific memory B cells. The increase is due to expansion of memory B cell clones that were present after the second dose as well as the emergence of new clones. The antibodies encoded by these cells showed significantly increased potency and breadth when compared with antibodies obtained after the second dose. Notably, the increase in potency was especially evident among newly developing clones of memory cells, which differed from persisting clones in targeting more conserved regions of the RBD. Overall, more than 50% of the analysed neutralizing antibodies in the memory compartment after the third mRNA vaccine dose neutralized the Omicron variant. Thus, individuals receiving three doses of an mRNA vaccine have a diverse memory B cell repertoire that can respond rapidly and produce antibodies capable of clearing even diversified variants such as Omicron. These data help to explain why a third dose of a vaccine that was not specifically designed to protect against variants is effective against variant-induced serious disease.

SARS-CoV-2 Delta-variant breakthrough infections in nursing home residents at midterm after ComirnatyÂ® COVID-19 vaccination. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Delta variant breakthrough infections in nursing home residents following vaccination with ComirnatyÂ® COVID-19 vaccine were characterized. In total, 201 participants (median age, 87 years; range, 64-100; 133 female) from two nursing homes in the Valencian community (Spain) were included. SARS-CoV-2-Spike (S) antibody responses were determined by a lateral flow immunocromatography (LFIC) assay and by quantitative electrochemiluminescent assay in LFIC-negative participants. SARS-CoV-2-S-IFNÎ³ T cells were enumerated by flow cytometry in 10 participants. Nasopharyngeal SARS-CoV-2 RNA loads were quantified by real-time polymerase chain reaction assays. Vaccine breakthrough COVID-19 due to the Delta variant occurred in 39 residents (median age, 87 years; range, 69-96; 31 female) at a median of 6.5 months after vaccination (nine requiring hospitalization). Breakthrough infections occurred at a higher rate (pâ€‰<â€‰0.0001) in residents who had not been previously infected with SARS-CoV-2 (naÃ¯ve) (33/108; 18%) than in those with prior diagnosis of SARS-CoV-2 infection (experienced) (6/93; 6.4%), and were more likely (pâ€‰<â€‰0.0001) to develop in residents who tested negative by LFIC (20/49) at 3 months after vaccination as compared to their LFIC-positive counterparts (19/142). Among LFIC-negative residents, a trend towards lower plasma anti-RBD antibody levels was noticed in those developing breakthrough infection (pâ€‰=â€‰0.16). SARS-CoV-2 RNA loads in nasopharyngeal specimens were lower in SARS-CoV-2-experienced residents (pâ€‰<â€‰0.001) and in those testing positive by LFIC (pâ€‰=â€‰0.13). The frequency of SARS-CoV-2-S-reactive T cells at 3 months was similar in LFIC-negative residents with (nâ€‰=â€‰7) or without (nâ€‰=â€‰3) breakthrough infection. Prior history of SARS-CoV-2 infection and detection of S-reactive antibodies by LFIC at 3 months is associated with a lower risk of Delta-variant breakthrough infection in nursing home residents at midterm after ComirnatyÂ® COVID-19 vaccination.

Neutralization of Severe Acute Respiratory Syndrome Coronavirus 2 Omicron and Other Variants in Serum From Children With Vaccination-Induced Myocarditis. Our study demonstrates that children who developed severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination-induced myocarditis and may not receive another vaccination, could be susceptible to infection with Omicron and emerging variants. We observed higher neutralizing antibody titers in myocarditis patients vs. healthy vaccinated children, but significantly lower neutralization titers against Omicron in both groups.

Multiple Evanescent White Dot Syndrome Following Medigen Vaccine Biologics Corporation COVID-19 Vaccination. PURPOSE: To report a case of multiple evanescent white dot syndrome (MEWDS) following severe acute respiratory syndrome coronavirus 2 vaccination. STUDY DESIGN: Case report. RESULTS: A 36-year-old healthy Taiwanese female was presented with flashing lights in the right eye two days after the first dose of Medigen Vaccine Biologics Corporation (MVC) coronavirus disease 19 (COVID-19) vaccine. Examination of the retina revealed multiple white dots in the posterior pole extending to the mid-periphery. Disruption of ellipsoid zone on optical coherence tomography, early hyperfluorescence on fluorescein angiography, late hypo-cyanescence on indocyanine green angiography, and paracentral scotoma on visual field test were consistent with MEWDS. At four-week follow-up, the patient's fundus lesions resolved, and symptoms subsided without treatment. CONCLUSION: Resembling previous post-vaccine MEWDs cases, the symptoms are self-limited, and the visual prognosis is excellent. The presented case demonstrates MEWDS following MVC COVID-19 vaccine and suggests the immune-mediated basis for MEWDS in predisposed patients.

Comments on "Goyal M, Murthy SI and Annum S, Bilateral Multifocal Choroiditis following COVID-19 Vaccination". The fundus photographs provided show deep yellowish lesions, multifocal exudative retinal detachments, and optic disc hyperemia in both eyes. Spectral domain optical coherence tomography scans shown demonstrate bilateral exudative retinal detachments involving the macula in the right eye. The exudative retinal detachment is characterized by the presence of subretinal fibrin and septa. The B-scan ultrasonography provided shows low- to medium-reflective choroidal thickening predominating around optic nerve head, in association with exudative retinal detachment in the right eye. All these findings are highly suggestive of acute Vogt-Koyanagi-Harada (VKH) disease rather than multifocal choroiditis.

Severe de novo liver injury after Moderna vaccination - not always autoimmune hepatitis.

Reply to Letter to the Editor: Atypical Optic Neuritis After COVID-19 Vaccination: Response.

Factors predictive of anti-spike antibody titers after COVID-19 vaccination in hemodialysis patients. BACKGROUND: Hemodialysis (HD) patients have a high prevalence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and mortality, but they may have a weak response to coronavirus disease 2019 (COVID-19) vaccines. OBJECTIVES: This study aimed to evaluate factors predictive of humoral response in HD patients vaccinated against SARS-CoV-2 infection. MATERIAL AND METHODS: This is a 2-center observational study including HD patients who received the BNT162b2 mRNA vaccine followed by serological measurements 20 days and 4 weeks after the 1st and 2nd dose, respectively. Healthy controls were included. Anti-spike antibody was measured using the chemiluminescent immunoassay (CLIA) method. The quantile regression analysis was performed to assess factors associated with anti-spike antibody titers. RESULTS: Seventy-two HD patients and 22 healthy controls were included. Mean age of dialysis patients and controls was 72.5 Â±11.5 years and 45.7 Â±17.4 years, respectively. In the HD group, median levels of anti-spike antibody were 3 (interquartile range (IQR): 0.5-26) UI/mL and 391 (IQR: 55-1642) UI/mL after the 1st and 2nd dose, respectively, with response rates of 62.5% and 96.7%. The median level of the anti-spike antibody after the 1st dose in previously infected patients was 8571 (IQR: 2586-19147) UI/mL. There was a significant correlation between anti-spike antibody levels after the 2nd dose and age and anti-

hepatitis B surface (HBs) antibody and serum albumin levels (Spearman's rho: r = -0.289, p < 0.001; r = 0.357, p = 0.027; r = 0.317; p = 0.026, respectively). The regression analysis showed a significant association of previous infection and anti-Hbs antibody level with anti-spike antibody level after the 1st dose of vaccine (p < 0.001). After a 5-month follow-up, 2 vaccinated patients contracted COVID-19. CONCLUSIONS: This study showed a response rate of 96.7% to 2 doses of BNT162b2 mRNA vaccine in HD patients and 100% to a single dose in previously infected patients. The level of anti-spike antibody can be predicted by age, anti-Hbs antibodies, serum albumin, and previous infection. Despite the immunization of patients, preventive measures should be maintained in all dialysis units.

Safety and immunogenicity of SpikoGenÂ®, an Advax-CpG55.2-adjuvanted SARS-CoV-2 spike protein vaccine: a phase 2 randomized placebo-controlled trial in both seropositive and seronegative populations. OBJECTIVE: We aimed to investigate the immunogenicity and safety of SpikoGenÂ®, a subunit COVID-19 vaccine composed of a recombinant prefusion-stabilized SARS-CoV-2 spike protein combined with the Advax-CpG55.2â„¢ adjuvant, in seronegative and seropositive populations as primary vaccination. METHODS: This randomized, placebo-controlled, double-blind phase 2 trial was conducted on 400 participants randomized 3:1 to receive two doses of 25 Î¼g of SpikoGenÂ® 3Â weeks apart or the placebo. The primary safety outcomes were the incidence of solicited adverse events up to 7Â days after each dose and unsolicited adverse events up to 28Â days after the second dose. The primary immunogenicity outcomes were seroconversion against the S(1) protein and the geometric mean concentration of S(1) antibodies by days 21 and 35. RESULTS: The SpikoGenÂ® vaccine was well tolerated and no serious adverse events were recorded. The most common solicited adverse events were injection site pain and fatigue, largely graded as mild and transient. By day 35 (2Â weeks post second dose), the seroconversion rate against S(1) was 63.55 (95% CI: 57.81-69.01) in the SpikoGenÂ® group versus 7.23 (95% CI: 2.7-15.07) in the placebo group. The geometric mean concentration of S(1) antibodies was 29.12 (95% CI: 24.32-34.87) in the SpikoGenÂ® group versus 5.53 (95% CI: 4.39-6.97) in the placebo group. Previously infected seropositive volunteers showed a large SARS-CoV-2 humoral response after a single SpikoGenÂ® dose. DISCUSSION: SpikoGenÂ® had an acceptable safety profile and induced promising humoral and cellular immune responses against SARS-CoV-2.

Temporal relationship of myocarditis and pericarditis following COVID-19 vaccination: A pragmatic approach. BACKGROUND: Complications following COVID-19 vaccination, particularly with mRNA vaccines, rarely include myocarditis and pericarditis. This work principally aimed at defining a realistic temporal relationship between vaccination and myocarditis/pericarditis development. METHODS: All relevant cases reported from week 52/2020 through week 41/2021 in the VAERS database were retrieved and analyzed for licensed vaccines. These included BNT162b2, mRNA-1273, and AD26.COV2Â·S. Incidence rates were calculated using the corresponding administered vaccine doses as denominators. Additionally, analyzed parameters included demographics, dose series, hospitalization length and outcome. RESULTS: Overall, 2016 myocarditis and 1380 pericarditis cases, (4.96/10(6) and 3.40/10(6) administered vaccine doses, respectively), were recorded. Most myocarditis cases occurred following BNT162b2 (5.60/10(6) doses) in males <30Â years. Pericarditis affected predominantly males <40, both sexes >40Â years, and was most common post AD26.COV2Â·S (4.78/10(6) doses). Hospitalization was required for 40.3% and 27.2% of myocarditis and pericarditis cases, respectively. A bimodal pattern was found for both myocarditis and pericarditis, with two peaks that coincided temporally, but were reversed in intensity. The first peak was recorded 1-3Â days post-vaccination and was more pronounced in myocarditis, while the second was recorded 15-30Â days post-vaccination and was more intense in pericarditis. CONCLUSIONS: Myocarditis/pericarditis after COVID-19 vaccination is rare and depicts a bimodal pattern.

Humoral Responses Against SARS-CoV-2 and Variants of Concern After mRNA Vaccines in Patients With Non-Hodgkin Lymphoma and Chronic Lymphocytic Leukemia. PURPOSE: Patients with non-Hodgkin lymphoma including chronic lymphocytic leukemia (NHL/CLL) are at higher risk of severe SARS-CoV-2 infection. We investigated vaccine-induced antibody responses in patients with NHL/CLL against the original SARS-CoV-2 strain and variants of concern including B.1.167.2 (Delta) and B.1.1.529 (Omicron). MATERIALS AND METHODS: Blood from 121 patients with NHL/CLL receiving two doses of vaccine were collected longitudinally. Antibody binding against the full-length spike protein, the receptor-binding, and N-terminal domains of the original strain and of variants was measured using a multiplex assay. Live-virus neutralization against Delta, Omicron, and the early WA1/2020 strains was measured using a focus reduction neutralization test. B cells were measured by flow cytometry. Correlation between vaccine response and clinical factors was determined. RESULTS: Mean anti-SARS-CoV-2 spike immunoglobulin G-binding titers were 85-fold lower in patients with NHL/CLL compared with healthy controls, with seroconversion occurring in only 67% of patients. Neutralization titers were also lower and correlated with binding titers ($P < .0001$). Treatment with anti-CD20-directed therapies within 1 year resulted in 136-fold lower binding titers. Peripheral blood B-cell count also correlated with vaccine response. At 3 months from last anti-CD20-directed therapy, B-cell count â‰¥ 4.31/Î¼L blood around the time of vaccination predicted response (OR 7.46, $P = .04$). Antibody responses also correlated with age. Importantly, neutralization titers against Delta and Omicron were reduced six- and 42-fold, respectively, with 67% of patients seropositive for WA1/2020 exhibiting seronegativity for Omicron. CONCLUSION: Antibody binding and live-virus neutralization against SARS-CoV-2 and its variants of concern including Delta and Omicron were substantially lower in patients with NHL/CLL compared with healthy vaccinees. Anti-CD20-directed therapy < 1 year before vaccination and number of circulating B cells strongly predict vaccine response.

Overview of Reported Breast Implant-Related Reactions After COVID-19 Infection or Vaccination.

A de novo case of minimal change disease following the first dose of the Moderna mRNA-1273 SARS-CoV-2 vaccine without relapse after the second dose. In recent times, new onset or relapse of nephrotic syndrome following the first dose of SARS-CoV-2 vaccines has been reported. Although the vaccination could trigger nephrotic syndrome, the question of whether the same vaccine should be administered as the second dose remains unanswered. A 25-year-old woman had taken the Moderna mRNA-1273 SARS-CoV-2 vaccine (mRNA-1273) and 26Â days later, she noticed facial and peripheral edema. One week later she was referred and admitted to our hospital, wherein laboratory tests revealed that her serum creatinine level, serum albumin level, and urine protein-creatinine ratio were respectively 0.79Â mg/dL, 2.5Â g/dL, and 7.0Â g/gCr. After a thorough inpatient examination including renal biopsy, she was diagnosed with minimal change disease (MCD) and treatment with steroids was initiated. She achieved complete remission the next day and did not experience a relapse upon receiving the second mRNA-1273 dose 56Â days after the first, under treatment with 35Â mg/day of oral prednisolone. This case report yields insight into determining whether patients who develop de novo MCD after the first mRNA-1273 dose should receive the second dose.

Herpes zoster in the era of COVID 19: A prospective observational study to probe the association of herpes zoster with COVID 19 infection and vaccination. Herpes zoster (HZ) is caused by reactivation of the latent varicella zoster virus (VZV) following decline in cell-mediated immunity. All over the world, in the past couple of years, the Corona Virus 2019 (COVID-19) has emerged as a viral cause of severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) infection. Based on the current limited evidence, co-infection of COVID-19 with VZV or reactivation of VZV after COVID-19 vaccination has been sporadically reported. All patients diagnosed with HZ, in Farwaniya Hospital in Kuwait, from March 2020 to July 2021, having either (A) a positive COVID-19 polymerase chain

reaction (PCR) test, or (B) been vaccinated against SARS-CoV-2 were enrolled in the study. All patients' demographic information, medical history, laboratory findings, and vaccination status was documented. All statistical analyses were performed using SPSS Statistics version 21.0 software. Twelve cases infected with COVID-19 with a positive PCR (group 1) and five cases vaccinated against SARS-CoV-2 (group 2) were documented. Out of the 12 COVID-19 infected patients (group 1), only two patients (16.67%) required hospitalization, while the remaining 10 patients had mild/moderate lymphopenia. Furthermore, amongst the 12 positive COVID-19 cases, four patients with HZ were diagnosed within the first week of COVID-19, while the remaining eight cases were diagnosed within 8â€‰weeks of COVID-19. Thoracic segments were affected in five cases (41.67%), cervical in one case (8.33%), cranial in two cases (16.67%), lumbar in three cases (25%) and sacral in one case (8.33%). In group 2, three patients presented with HZ within 4â€‰weeks of having received the first dose of the vaccine and two patients after the second dose. Blood investigations for all five vaccinated patients did not show any abnormalities. Cervical segments were affected in two patients (40%), and cranial, thoracic, and lumbar segment in the remaining patients respectively (20%). Experts must be aware of the probable increased risk of HZ during the COVID 19 pandemic. We propose appropriate curative and preventive measures against HZ infection, including a systematic follow-up of these patients to ensure that they stick to extreme safety measures till the diagnosis of COVID-19 is omitted.

Erythema nodosum induced by Covid-19 Pfizer-BioNTech mRNA vaccine: A case report and brief literature review. Erythema nodosum (EN), the most common form of panniculitis, is a reactive inflammation of the subcutaneous fat clinically presented with a sudden onset of painful, erythematous, nodular, subcutaneous lesions, typically localized to the pretibial area. EN is commonly caused by numerous infections (especially beta-haemolytic streptococcal infections), autoimmune diseases (sarcoidosis), inflammatory bowel conditions and drugs. EN induced by Covid-19 vaccines is rarely reported. We describe an original clinical observation of a 75-year-old woman who presented with EN after receiving the second dose of BNT162b2, an mRNA vaccine.

SARS-CoV-2 specific antibody responses in healthcare workers after a third booster dose of CoronaVac or BNT162b2 vaccine. The first SARS-CoV-2 vaccination campaign in Turkey has started in mid-January for the healthcare workers (HCWs) with the inactive virus vaccine CoronaVac (Sinovac). After four and a half months, the Turkish Ministry of Health rolled out a booster-dose vaccination campaign for HCWs and all people over 50 years old beginning in July 2021. The individuals eligible were given the choice of either CoronaVac or mRNA vaccine BNT162b2 for the third booster-dose vaccination. This study aimed to evaluate SARS-CoV-2 IgG antibody titers against the S1 subunit of the spike protein as a marker of the humoral response in 179 HCWs who received a third booster dose of either CoronaVac or BNT162b2. A total of 136 HCWs, 71 female (52.2%) and 65 male (47.8%), completed both serum collections on Days 0 and 28. The median SARS-CoV-2 IgG S Protein (SP)Â titer in all participants before the vaccination was 175.7â€‰AU/ml. Of 136 HCWs, 103 (75.73%) chose BNT162b2 vaccine and 33 (24.26%) chose CoronaVac as the third booster dose. There was a significant difference between the BNT162b2 group and the CoronaVac group in terms of SARS-CoV-2 IgG SP titers (pâ€‰<â€‰0.001). The median SARS-CoV-2 IgG SP titers in BNT162b2 group (nâ€‰=â€‰103) and in CoronaVac group (nâ€‰=â€‰33) were 17619.3â€‰AU/ml and 1153.0â€‰AU/ml, respectively. The third booster dose with BNT162b2 and CoronaVac increased antibody titers in each participant a mean of 162-fold and 9-fold, respectively. HCWs in the BNT162b2 group reported more frequent adverse events than HCWs in the CoronaVac group (pâ€‰<â€‰0.001).

Delayed large local reactions to Moderna COVID-19 vaccine: A follow-up report after booster vaccination. [Figure: see text]

Reply to "VAERS Could Miss or Misinterpret Neurological Side Effects of COVID Vaccinations".

Preserved recognition of Omicron spike following COVID-19 messenger RNA vaccination in pregnancy. BACKGROUND: SARS-CoV-2 infection is associated with enhanced disease severity in pregnant women. Despite the potential of COVID-19 vaccines to reduce severe disease, vaccine uptake remained relatively low among pregnant women. Just as coordinated messaging from the Centers for Disease Control and Prevention and leading obstetrics organizations began to increase vaccine confidence in this vulnerable group, the evolution of SARS-CoV-2 variants of concerns, including the Omicron variant, raised new concerns about vaccine efficacy because of their ability to escape vaccine-induced neutralizing antibodies. Early data point to a milder disease course following infection with the Omicron variant in vaccinated individuals. Thus, these data suggest that alternate vaccine-induced immunity beyond neutralization may continue to attenuate Omicron variant-induced disease, such as Fc-mediated antibody activity. OBJECTIVE: This study aimed to test whether vaccine-induced antibodies raised during pregnancy continue to bind to and leverage Fc receptors to protect against variants of concern including the Omicron variant. STUDY DESIGN: The receptor binding domain or whole spike-specific antibody isotype binding titers and Fc gamma receptor binding directed toward variants of concern, including the Omicron variant, were analyzed in pregnant women after receiving the full dose regimen of either the Pfizer/BioNTech BNT62b2 (n=10) or Moderna mRNA-1273 (n=10) vaccination using a multiplexing Luminex assay. RESULTS: Reduced isotype recognition of the Omicron receptor binding domain was observed following administration of either vaccine with relatively preserved, albeit reduced, recognition of the whole Omicron spike by immunoglobulin M and G antibodies. Despite the near complete loss of Fc receptor binding to the Omicron receptor binding domain, Fc receptor binding to the Omicron spike was more variable but largely preserved. CONCLUSION: Reduced binding titers to the Omicron receptor binding domain aligns with the observed loss of neutralizing activity. Despite the loss of neutralization, preserved, albeit reduced, Omicron spike recognition and Fc receptor binding potentially continue to attenuate disease severity in pregnant women.

Boosting maternal and neonatal humoral immunity following SARS-CoV-2 infection using a single messenger RNA vaccine dose. BACKGROUND: Post-COVID-19 vaccine boosting is a potent tool in the ongoing pandemic. Relevant data regarding this approach during pregnancy are lacking, which affects vaccination policy guidance, public acceptance, and vaccine uptake during pregnancy. We aimed to investigate the dynamics of anti-SARS-CoV-2 antibody levels following SARS-CoV-2 infection during pregnancy and to characterize the effect of a single postinfection vaccine booster dose on the anti-SARS-CoV-2 antibody levels in parturients in comparison with the levels in naÃ¯ve vaccinated and convalescent, nonboosted parturients. STUDY DESIGN: Serum samples prospectively collected from parturients and umbilical cords at delivery at our university-affiliated urban medical center in Jerusalem, Israel, from May to October 2021, were selected and analyzed in a case-control manner. Study groups comprised the following participants: a consecutive sample of parturients with a polymerase chain reaction-confirmed history of COVID-19 during any stage of pregnancy; and comparison groups selected according to time of exposure comprising (1) convalescent, nonboosted parturients with polymerase chain reaction-confirmed COVID-19; (2) convalescent parturients with polymerase chain reaction-confirmed COVID-19 who received a single booster dose of the BNT162b2 messenger RNA vaccine; and (3) infection-naÃ¯ve, fully vaccinated parturients who received 2 doses of the BNT162b2 messenger RNA vaccine. Outcomes that were determined included maternal and umbilical cord blood anti-SARS-CoV-2 antibody levels detected at delivery, the reported side effects, and pregnancy outcomes. RESULTS: A total of 228 parturients aged 18 to 45 years were included. Of those, samples from 64 were studied to characterize the titer dynamics following COVID-19 at all stages of pregnancy. The boosting effect was determined by comparing (1) convalescent (n=54), (2)

boosted convalescent (n=60), and (3) naÃ¯ve, fully vaccinated (n=114) parturients. Anti-SARS-CoV-2 antibody levels detected on delivery showed a gradual and significant decline over time from infection to delivery (r=0.4371; P=.0003). Of the gravidae infected during the first trimester, 34.6% (9/26) tested negative at delivery, compared with 9.1% (3/33) of those infected during the second trimester (P=.023). Significantly higher anti-SARS-CoV-2 antibody levels were observed among boosted convalescent than among nonboosted convalescent (17.6-fold; P<.001) and naÃ¯ve vaccinated parturients (3.2-fold; P<.001). Similar patterns were observed in umbilical cord blood. Side effects in convalescent gravidae resembled those in previous reports of mild symptoms following COVID-19 vaccination during pregnancy. CONCLUSION: Postinfection maternal humoral immunity wanes during pregnancy, leading to low or undetectable protective titers for a marked proportion of patients. A single boosting dose of the BNT162b2 messenger RNA vaccine induced a robust increase in protective titers for both the mother and newborn with moderate reported side effects.

Delta Infection After Vaccination Elicits Potent Neutralizing Immunity Against Severe Acute Respiratory Syndrome Coronavirus 2 Omicron. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Omicron (B.1.1.529) variant extensively escape neutralizing antibodies by vaccines or infection. We assessed serum neutralizing activity in sera from Delta infection after vaccination and Delta infection only against SARS-CoV-2 Wuhan-Hu-1 (WA1), Beta, Delta, and Omicron. Sera from Delta infection only could neutralize WA1 and Delta but almost completely lost capacity to neutralize Beta and Omicron. However, Delta infection after vaccination resulted in a significant increase of serum neutralizing activity against WA1, Beta, and Omicron. This study demonstrates that breakthrough infection of Delta substantially induced high potency humoral immune response against the Omicron variant and other emerged variants.

Severe Acute Respiratory Syndrome Coronavirus 2 Anti-Spike Antibody Levels Following Second Dose of ChAdOx1 nCov-19 or BNT162b2 Vaccine in Residents of Long-term Care Facilities in England (VIVALDI). General population studies have shown strong humoral response following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination with subsequent waning of anti-spike antibody levels. Vaccine-induced immune responses are often attenuated in frail and older populations, but published data are scarce. We measured SARS-CoV-2 anti-spike antibody levels in long-term care facility residents and staff following a second vaccination dose with Oxford-AstraZeneca or Pfizer-BioNTech. Vaccination elicited robust antibody responses in older residents, suggesting comparable levels of vaccine-induced immunity to that in the general population. Antibody levels are higher after Pfizer-BioNTech vaccination but fall more rapidly compared to Oxford-AstraZeneca recipients and are enhanced by prior infection in both groups.

Heterologous Ad.26.COV2.S versus homologous BNT162b2/mRNA-1273 as a third dose in solid organ transplant recipients seronegative after two-dose mRNA vaccination. Heterologous vaccination ("mixing platforms") for the third (D3) dose of SARS-CoV-2 vaccine is a potential strategy to improve antibody responses in solid organ transplant recipients (SOTRs), but data are mixed regarding potential differential immunogenicity. We assessed for differences in immunogenicity and tolerability of homologous (BNT162b2 or mRNA-1273; D3-mRNA) versus heterologous (Ad.26.COV2.S; D3-JJ) D3 among 377 SARS-CoV-2-infection naÃ¯ve SOTRs who remained seronegative after two mRNA vaccines. We measured anti-spike titers and used weighted Poisson regression to evaluate seroconversion and development of high-titers, comparing D3-JJ to D3-mRNA, at 1-, 3-, and 6 month post-D3. 1-month post-D3, seroconversion (63% vs. 52%, pÂ =Â .3) and development of high-titers (29% vs. 25%, pÂ =Â .7) were comparable between D3-JJ and D3-mRNA recipients. 3 month post-D3, D3-JJ recipients were 1.4-fold more likely to seroconvert (80% vs. 57%, weighted incidence-rate-ratio: wIRRÂ =Â (1.10) 1.40(1.77) , pÂ =Â .006) but not more likely to develop high-titers (27% vs. 22%, wIRRÂ =Â (0.44) 0.92(1.93) , pÂ =Â .8). 6 month post-D3, D3-JJ recipients were 1.41-fold more likely to

seroconvert (88% vs. 59%, wIRRÂ =Â (1.04) 1.41(1.93) , pÂ =Â .029) and 2.63-fold more likely to develop high-titers (59% vs. 21%, wIRRÂ =Â (1.38) 2.63(5.00) , pÂ =Â .003). There was no differential signal in alloimmune events or reactogenicity between platforms. SOTRs without antibody response after two mRNA vaccines may derive benefit from heterologous Ad.26.COV2.S D3.
Cutaneous adverse effects of the available COVID-19 vaccines in India: a questionnaire-based study.
SARS-CoV-2 mRNA booster vaccine-associated lichenoid drug eruption.
Disseminated herpes zoster in an immune-competent patient after SARS-CoV-2 vaccine (BNT162b2 Comirnaty, Pfizer).
Vaccine Adverse Event Reporting System Could Miss or Misinterpret Neurological Side Effects of COVID-19 Vaccinations.
Post SARS-CoV-2 Vaccine Chilblains-like Lesions.
TAFRO syndrome with a fatal clinical course following BNT162b2 mRNA (Pfizer-BioNTech) COVID-19 vaccination: A case report. TAFRO syndrome is a rare disorder that manifests as thrombocytopenia, anasarca, fever, reticulin myelofibrosis, renal dysfunction, and organomegaly. Although this disease often follows a severe clinical course, the cause remains unknown. The coronavirus disease 2019 (COVID-19) pandemic is a major global problem. Vaccination against COVID-19 has been successful; however, there are concerns about severe adverse events. Herein, we report a rare presentation of TAFRO syndrome triggered by the COVID-19 vaccine with a fatal clinical course. A 42-year-old Japanese man presented to our hospital complaining of fever lasting for 2 weeks that occurred a day after receiving the BNT162b2 mRNA (Pfizer-BioNTech) COVID-19 vaccine. The patient had a low platelet count, ascites, reticulin myelofibrosis, renal failure, and lymphadenopathy and was diagnosed with TAFRO syndrome. Despite administering several immunosuppressive drugs, the condition did not improve. The patient repetitively developed and eventually died of bacteremia caused by multidrug-resistant Klebsiella pneumoniae. We highlight the first reported case of TAFRO syndrome after COVID-19 vaccination.
Acceptance, effects, and tolerability in the vaccination process against SARS-CoV-2 among cancer patients in Bosnia and Herzegovina: A single-center cross-sectional study. The SARS-CoV-2 pandemic has been the main public health issue since the end of 2019. The vaccination campaign in Bosnia and Herzegovina started in April 2021, with several vaccines available. Our study aimed to evaluate the acceptance, effects, and tolerability of vaccines against SARS-COV-2 among cancer patients. We conducted a cross-sectional, observational study between 22 October and 30 November 2021, at the Clinic of Oncology, Clinical Center University of Sarajevo. Patients were enrolled during their regular visit to the Clinic of Oncology by agreeing to completean individual paper questionnaire. The study included 1063 patients with malignant diseases, of whom 681 (64.1%) were adequately vaccinated patients. In the study population, 76.9% of patients reported that they did not experience any side effects due to vaccination, while only 0.5% had side effects, causing a delay in their treatment. Among adequately vaccinated patients, there were 40 patients (3.8%) who were infected with SARS-CoV-2 after the second or booster dose of the vaccine. Five patients (0.5%) were hospitalized due to COVID-19 after being adequately vaccinated. The findings of our study suggest that cancer patients have a higher acceptance of vaccines against SARS-CoV-2 than the general population in Bosnia and Herzegovina. Vaccination side effects are tolerable and do not cause major delays in specific cancer treatment. The protective effects of COVID-19 vaccines in the cancer patients presented in our study are comparable to available results of similar studies, which included the general population.
A Case Series of Patients With Acute Liver Allograft Rejection After Anti-SARS-CoV-2 mRNA Vaccination.
Atypical Optic Neuritis After COVID-19 Vaccination.

New-Onset Myasthenia Gravis After ChAdOx1 nCOV-19 Vaccine Inoculation.

COVID-19 immunization in people with cancer-Is it safe and efficient? What do we know? Prior to the COVID-19 pandemic, vaccination of people with cancer or a recent history of cancer was advisable under specific conditions, depending on the type of vaccine (inactivated or live attenuated virus or bacterium), type of cancer, and whether they had undergone treatment for cancer. Some malignancies, especially hematological malignancies, and cancer treatments such as chemotherapy, radiotherapy, and splenectomy negatively impact the immune response. The clinical trials of currently used vaccines against COVID-19 did not include people with active cancer; thus, there is an important gap in the knowledge of safety and efficiency data for COVID-19 immunization in this population. However, considering the risk of mortality and morbidity due to possible infection with SARS-CoV-2, medical experts recommend immunization on an individual basis. As the worldwide prevalence of malignancies is high, reliable information on COVID-19 vaccination is expected to be revealed in future clinical trials. In this review, we examine the key aspects of cancer that may be affected by COVID-19 and summarize the current literature on COVID-19 immunization.

Factors associated with anti-SARS-CoV-2 spike antibody titers after a second BNT162b2 mRNA COVID-19 vaccination in Japanese hemodialysis patients. BACKGROUND: We investigated factors associated with the anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike antibody titer after the second dose of the BNT162b2 messenger RNA coronavirus disease 2019 (COVID-19) vaccine in Japanese patients undergoing hemodialysis. METHODS: Overall, 75 patients (41 men, 34 women; mean age 71.4â€‰Â±â€‰12.2Â years) with a hemodialysis duration of 5.7â€‰Â±â€‰6.1 [interquartile range, 1.0-8.5] years were enrolled in this single-center, prospective, cross-sectional study. We used multiple linear regression analysis to determine the relationships of the anti-SARS-CoV-2 spike antibody titer with patient demographic and clinical parameters. We also compared the anti-SARS-CoV-2 spike antibody titer between hemodialysis patients and 22 healthcare workers (10 men, 12 women; mean age 48.5â€‰Â±â€‰14.4Â years). RESULTS: Autoimmune disease presence (standard coefficient [Î²]â€‰=â€‰â€‰-â€‰0.290, pâ€‰=â€‰0.018), lymphocyte counts (Î²â€‰=â€‰0.261, pâ€‰=â€‰0.015), hemoglobin levels (Î²â€‰=â€‰0.290, pâ€‰=â€‰0.009), and blood urea nitrogen concentrations (Î²â€‰=â€‰0.254, pâ€‰=â€‰0.033) were significantly and independently correlated with the log-anti-SARS-CoV-2 spike antibody titer. The anti-SARS-CoV-2 spike antibody titer was significantly lower in hemodialysis patients than in healthcare workers (3589â€‰Â±â€‰3921 [813-4468] vs. 12,634â€‰Â±â€‰18,804 [3472-10,257] AU/mL; pâ€‰<â€‰0.002). CONCLUSIONS: Autoimmune disease presence, lymphocyte counts, hemoglobin levels, and blood urea nitrogen concentrations were associated with the anti-SARS-CoV-2 spike antibody titer after the second dose of the BNT162b2 messenger RNA COVID-19 vaccine in Japanese patients undergoing hemodialysis.

Regarding Oculomotor Palsy After the Administration of the Messenger RNA-1273 Vaccine for SARS-CoV-2: Diplopia After the COVID-19 Vaccine.

Myopericarditis after COVID-19 vaccination: unexpected but not unprecedented.

Myopericarditis following COVID-19 vaccination and non-COVID-19 vaccination: a systematic review and meta-analysis. BACKGROUND: Myopericarditis is a rare complication of vaccination. However, there have been increasing reports of myopericarditis following COVID-19 vaccination, especially among adolescents and young adults. We aimed to characterise the incidence of myopericarditis following COVID-19 vaccination, and compare this with non-COVID-19 vaccination. METHODS: We did a systematic review and meta-analysis, searching four international databases from Jan 1, 1947, to Dec 31, 2021, for studies in English reporting on the incidence of myopericarditis following vaccination (the primary outcome). We included studies reporting on people in the general population who had myopericarditis in temporal relation to receiving vaccines, and excluded studies

on a specific subpopulation of patients, non-human studies, and studies in which the number of doses was not reported. Random-effects meta-analyses (DerSimonian and Laird) were conducted, and the intra-study risk of bias (Joanna Briggs Institute checklist) and certainty of evidence (Grading of Recommendations, Assessment, Development and Evaluations approach) were assessed. We analysed the difference in incidence of myopericarditis among subpopulations, stratifying by the type of vaccine (COVID-19 vs non-COVID-19) and age group (adult vs paediatric). Among COVID-19 vaccinations, we examined the effect of the type of vaccine (mRNA or non-mRNA), sex, age, and dose on the incidence of myopericarditis. This study was registered with PROSPERO (CRD42021275477). FINDINGS: The overall incidence of myopericarditis from 22 studies (405â€‰272â€‰721 vaccine doses) was 33Â·3 cases (95% CI 15Â·3-72Â·6) per million vaccine doses, and did not differ significantly between people who received COVID-19 vaccines (18Â·2 [10Â·9-30Â·3], 11 studies [395â€‰361â€‰933 doses], high certainty) and those who received non-COVID-19 vaccines (56Â·0 [10Â·7-293Â·7], 11 studies [9â€‰910â€‰788 doses], moderate certainty, p=0Â·20). Compared with COVID-19 vaccination, the incidence of myopericarditis was significantly higher following smallpox vaccinations (132Â·1 [81Â·3-214Â·6], p<0Â·0001) but was not significantly different after influenza vaccinations (1Â·3 [0Â·0-884Â·1], p=0Â·43) or in studies reporting on various other non-smallpox vaccinations (57Â·0 [1Â·1-3036Â·6], p=0Â·58). Among people who received COVID-19 vaccines, the incidence of myopericarditis was significantly higher in males (vs females), in people younger than 30 years (vs 30 years or older), after receiving an mRNA vaccine (vs non-mRNA vaccine), and after a second dose of vaccine (vs a first or third dose). INTERPRETATION: The overall risk of myopericarditis after receiving a COVID-19 vaccine is low. However, younger males have an increased incidence of myopericarditis, particularly after receiving mRNA vaccines. Nevertheless, the risks of such rare adverse events should be balanced against the risks of COVID-19 infection (including myopericarditis). FUNDING: None.

Increasing hip fracture volume following repeated lockdowns: an Irish multicentre study of periods pre-Covid, during Covid lockdown and following vaccination. BACKGROUND: Older age groups were identified as a high-risk cohort for Covid-19 and thus were a focus of lockdown measures enacted internationally. Resultant decreased social mobility and physical activity levels are associated with sarcopenia, which may lead to increased risk of hip fracture upon resuming social integration and physical activities after easing of lockdown restrictions. AIMS: Our aim was to compare the incidence of hip fractures during the period following vaccination with subsequent relaxation of restrictions, to those prior to and during the Covid pandemic. METHODS: A multicentre retrospective cohort study was performed consisting of all patients presenting with a "hip" fracture to 3 regional trauma units over the relevant time periods in 2019, 2020 and 2021. Tallaght, Galway and Waterford University Hospitals are large academic teaching hospitals with a combined mixed urban and rural catchment of over 1 million people. FINDINGS: Four-hundred-fourteen patients in total were included in the final analysis, with 133 eligible hip fractures observed proceeding to operative treatment across the study period in 2019, 132 in 2020 and 149 in 2021, representing a 12.88% increase. Demographic data revealed similar patient cohorts with respect to age and gender, fracture pattern and treatment. CONCLUSIONS: An increase in hip fracture volume was observed during the period post vaccination with subsequent relaxation of restrictions and increased social mobility, compared to those prior to and during the Covid pandemic. These findings have implications for hospital planning and orthopaedic resourcing as we navigate our way forward past the Covid-19 Pandemic.

The Impact of COVID-19 in Bone Metabolism: Basic and Clinical Aspects. The use of standard procedures for the diagnosis of osteoporosis and assessment of fracture risk significantly decreased during the COVID-19 pandemic, while the incidence of fragility fractures was mostly unaltered. Both COVID-19 per se and its treatments are associated with a negative impact on bone health. Preclinical

models show that mice infected with SARS-CoV2 even without symptoms display loss of trabecular bone mass two weeks post infection, due to increased numbers of osteoclasts. Osteoporosis medications do not aggravate the clinical course of COVID-19, while preclinical data suggests possible beneficial effects of some therapies. While vitamin D deficiency is clearly associated with a worse clinical course of COVID-19, evidence of improved patient outcome with vitamin D supplementation is lacking. Osteoporosis treatment should not be generally discontinued, and recommendations for substituting therapies are available. Osteoporosis therapies do not interfere with the efficacy or side-effect profiles of COVID-19 vaccines and should not be stopped or indefinitely delayed because of vaccination.
SARS-CoV-2 vaccinations complicated by transverse myelitis.
A Fourth Dose of COVID-19 Vaccine Does Not Induce Neutralization of the Omicron Variant Among Solid Organ Transplant Recipients With Suboptimal Vaccine Response. BACKGROUND: Humoral responses to coronavirus disease 2019 (COVID-19) vaccines are attenuated in solid organ transplant recipients (SOTRs), necessitating additional booster vaccinations. The Omicron variant demonstrates substantial immune evasion, and it is unknown whether additional vaccine doses increase neutralizing capacity versus this variant of concern (VOC) among SOTRs. METHODS: Within an observational cohort, 25 SOTRs with low seroresponse underwent anti-severe acute respiratory syndrome coronavirus 2 spike and receptor-binding domain immunoglobulin (Ig)G testing using a commercially available multiplex ELISA before and after a fourth COVID-19 vaccine dose (D4). Surrogate neutralization (percent angiotensin-converting enzyme 2 inhibition [%ACE2i], range 0%-100% with >20% correlating with live virus neutralization) was measured against full-length spike proteins of the vaccine strain and 5 VOCs including Delta and Omicron. Changes in IgG level and %ACE2i were compared using the paired Wilcoxon signed-rank test. RESULTS: Anti-receptor-binding domain and anti-spike seropositivity increased post-D4 from 56% to 84% and 68% to 88%, respectively. Median (interquartile range) anti-spike antibody significantly increased post-D4 from 42.3 (4.9-134.2) to 228.9 (1115.4-655.8) World Health Organization binding antibody units. %ACE2i (median [interquartile range]) also significantly increased against the vaccine strain (5.8% [0%-16.8%] to 20.6% [5.8%-45.9%]) and the Delta variant (9.1% [4.9%-12.8%] to 17.1% [10.3%-31.7%]), yet neutralization versus Omicron was poor, did not increase post-D4 (4.1% [0%-6.9%] to 0.5% [0%-5.7%]), and was significantly lower than boosted healthy controls. CONCLUSIONS: Although a fourth vaccine dose increases anti-spike IgG and neutralizing capacity against many VOCs, some SOTRs may remain at high risk for Omicron infection despite boosting. Thus, additional protective interventions or alternative vaccination strategies should be urgently explored.
Worsening of Graves' ophthalmopathy after SARS-CoV-2 mRNA vaccination. More reports are documenting how vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) could represent new external triggers for autoimmune endocrine diseases (AIED) in patients with individual predisposition. We report two cases of Graves' Ophthalmopathy (GO) recrudescence few days after the administration of BNT162B2 (Pfizer-BioNTech) SARS-CoV-2 vaccine. Even if causality relationship cannot be excluded, the development of these events could be explained through immune mediated mechanism such as the autoimmune/inflammatory syndrome induced by adjuvants (ASIA). While further investigations are necessary to improve our knowledge of the underlying pathogenesis of these phenomena, caution may be warranted when vaccinating individuals with known autoimmune diseases.
Acute Genital Ulceration After Severe Acute Respiratory Syndrome Coronavirus 2 Vaccination and Infection. Reactive, nonsexually related acute genital ulceration, also known as LipschÃ¼tz ulcer, is a nonsexually related ulceration involving the vulva, most commonly affecting girls and adolescent

women in response to infection. Herein, we describe 3 female patients with acute genital ulceration occurring after severe acute respiratory syndrome coronavirus 2 vaccination or natural infection.

Asymptomatic SARS-CoV-2 Infection Is Common Among ART-Treated People With HIV. BACKGROUND: Limited data are available regarding asymptomatic COVID-19 among people with HIV (PWH). Data on a representative subset of PWH enrolled in Randomized Trial to Prevent Vascular Events in HIV, a global clinical trial, are presented here. METHODS: Randomized Trial to Prevent Vascular Events in HIV is an atherosclerotic cardiovascular disease prevention trial among 7770 PWH on antiretroviral therapy. Beginning April 2020, targeted data on coronavirus disease 2019 (COVID-19) diagnosis and symptoms were collected during routine trial visits. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection was defined as either COVID-19 clinical diagnosis or presence of SARS-CoV-2 Immunoglobulin G (IgG) or Immunoglobulin A (IgA) receptor binding domain protein (antispike) antibodies in the absence of prior COVID-19 vaccine. RESULTS: The group (N = 2464) had a median age 53 years, 35% female sex, 47% Black or African American race, median CD4 count 649 c/mm 3 , and 97% with HIV VL <400 cp/m. SARS-CoV-2 infection occurred in 318 persons (13%): 58 with clinical diagnosis and 260 with detectable antibodies. Of these PWH, 304 completed symptom questionnaires: 121 (40%) reported symptoms, but 183 (60%) were asymptomatic. PWH with asymptomatic SARS-CoV-2 infection were more likely to be from low-income or middle-income regions, of Black or African American race, older in age, and with higher atherosclerotic cardiovascular disease risk score. Symptomatic COVID was more common with obesity, metabolic syndrome, and low HDL levels. CD4 counts and HIV viral suppression rates were similar among PWH with symptomatic vs. asymptomatic COVID. CONCLUSIONS: Asymptomatic SARS-CoV-2 infection is common among antiretroviral therapy-treated PWH globally. We determined that 60% of infections in PWH were asymptomatic. HIV clinicians must remain vigilant about COVID-19 testing among PWH to identify asymptomatic cases.

Manifestation of Herpetic Eye Disease after COVID-19 Vaccine: A UK Case Series. PURPOSE: To highlight the potential risk of herpetic eye disease (HED) reactivation following COVID-19 vaccine. METHODS: Retrospective analysis of all patients who presented with HED within 28 days post-first dose COVID-19 vaccination. RESULTS: Eleven eyes (nÂ =Â 10 patients) were included. The mean interval between COVID-19 vaccination and ocular symptoms/signs was 12.3Â Â±Â 10.3Â days. Four (40%) patients presented with HSV keratitis, and six (60%) patients presented with VZV keratitis (five had concurrent other signs of herpes zoster ophthalmicus). Common ocular signs included multiple scattered dendritic/pseudodendritic corneal epitheliopathy (90.9%), anterior uveitis (63.6%), and endothelitis (27.3%). All cases were successfully treated with topical and systemic antiviral treatment and/or topical corticosteroids (mean healing timeÂ =Â 3.9Â Â±Â 1.6Â weeks). CONCLUSIONS: Our case series highlights the potential temporal association between HED and COVID-19 vaccine. Prophylactic antiviral treatment is recommended in patients with a history of HED prior to COVID-19 vaccination.

Explaining COVID-19 postvaccination-related immune thrombotic thrombocytopenia: a hypothesis-generating in-silico approach. Cases that experienced COVID-19 postvaccination-related thrombosis have been reported after the first dose of ChAdOx1 nCov-19 (Vaxzevria, AstraZeneca) or Ad26.COV2.S (Johnson & Johnson/Janssen) vaccine. These rare thrombotic events were observed within the expected vaccine-induced seroconversion period and could be attributed to platelet-activating (auto)antibodies against platelet factor 4 (PF4). Newly, vaccine-induced, cross-reactive anti-PF4 antibodies could explain this observation. An in-silico analysis using the Basic Local Alignment Search Tool was used to identify sequence similarity between PF4 and antigens contained in or encoded by ChAdOx1 nCov-19 or Ad26.COV2.S vaccines. Only one sequence within the signaling peptide of the SARS-CoV-2 spike protein exhibited a high percent identity (85.71%) with PF4. This

sequence overlaps with a proven immunogenic peptide recognized from convalescent COVID-19 sera and could be responsible for the formation of platelet-activating immunocomplexes in susceptible patients. Manipulation of the immunogenicity of this particular sequence within the encoded SARS-CoV-2 spike protein signaling peptide may eliminate this iatrogenic severe adverse effect.
Non-arteritic Anterior Ischemic Optic Neuropathy with Macular Star following COVID-19 Vaccination. PURPOSE: To report a case of non-arteritic anterior ischemic optic neuropathy (NAAION) with macular star after receiving the second dose of SARS-CoV-2 vaccination. METHOD: Case report. OBSERVATION: A 51-year-old male presented with acute visual disturbances one day after the second dose of BNT162b2 mRNA SARS-CoV-2 vaccination. At presentation, best corrected visual acuity (BCVA) was 20/25 right eye (OD) and counting fingers at 3 feet left eye (OS). Anterior segment examination was normal in both eyes. Dilated fundoscopy was unremarkable OD, however, it disclosed optic nerve swelling and subretinal fluid OS. Patient was treated with a gradual tapering dose of oral prednisone over 1 month. At the five-week follow-up visit, optic disc swelling and subretinal fluid resolved with minimal improvement in BCVA to 20/400 OS. CONCLUSION: It is unclear whether COVID-19 vaccination was the triggering agent to the NAAION or just a coincidence, yet ophthalmologists should be aware of such a possible association.
COVID-19 Vaccines in IBD Patients: Particularities and Future Perspectives.
COVID-19 Vaccine in Patients with Exacerbation of Idiopathic Pulmonary Fibrosis.
Reactogenicity of the Messenger RNA SARS-CoV-2 Vaccines Associated With Immunogenicity in Patients With Autoimmune and Inflammatory Disease. OBJECTIVE: Little is known regarding the reactogenicity and related SARS-CoV-2 vaccine response in patients with chronic inflammatory disease (CID). Our objective was to characterize the adverse event profile of CID patients following SARS-CoV-2 vaccination and understand the relationship between reactogenicity and immunogenicity of SARS-CoV-2 vaccines. METHODS: CID patients and healthy controls eligible to receive messenger RNA (mRNA) SARS-CoV-2 vaccines participated in 3 study visits (pre-vaccine, after dose 1, and after dose 2) in which blood and clinical data were collected. Assessment of adverse events were solicited within 7â€‰days of receiving each dose. Serum anti-SARS-CoV-2 spike IgGâ€‰Â±â€‰antibody titers were quantified following vaccination. Statistical analysis was performed utilizing mixed models and tobit regressions, with adjustment for covariates. RESULTS: The present study included 441 participants (322 CID patients and 119 control subjects). Compared to controls, CID patients reported greater symptom severity after dose 1 (PÂ =Â 0.0001), including more myalgia and fatigue (Pâ€‰<â€‰0.05). For immunogenicity, a higher symptom severity after dose 1 and a higher number of symptoms after dose 2 was associated with higher antibody titers (Pâ€‰â‰¤â€‰0.05). Each increase of 1 symptom was associated with a 15.1% increase in antibody titer. Symptom association was strongest with site pain after dose 1 (105%; PÂ =Â 0.03) and fatigue after dose 2 (113%; PÂ =Â 0.004). CONCLUSION: Patients with CID have a distinct reactogenicity profile following SARS-CoV-2 vaccination compared to controls. Furthermore, there is an association between increased reactogenicity and increased vaccine response. This finding may speak to the more variable immunogenicity in CID patients and may be an important indicator of vaccine response to the novel SARS-CoV-2 vaccines.
The Association Between Previous Influenza Vaccination and COVID-19 Infection Risk and Severity: A Systematic Review and Meta-analysis. INTRODUCTION: The association between influenza vaccination and COVID-19 remains controversial. This meta-analysis aimed to investigate whether influenza vaccination reduces the susceptibility and severity of SARS-CoV-2 infection. METHODS: A systematic literature search of PubMed, Web of Science, the Cochrane Library, Embase, China National Knowledge Infrastructure, SinoMed, Wanfang Data Knowledge Service Platform, and China Science and Technology Journal VIP Database was conducted from database inception to August

2021. The pooled RR with 95% CI was used to estimate the effect of influenza vaccination on COVID-19. The I(2) value was used to assess heterogeneity. If I(2)>50%, the random-effects model was used as the pooling method. RESULTS: A total of 23 published articles with 1,037,445 participants were identified. This meta-analysis showed that influenza vaccination was associated with reduced risk of COVID-19 infection (RR=0.83, 95% CI=0.76, 0.90) and hospitalization (RR=0.71, 95% CI=0.59, 0.84), although not significantly associated with intensive care unit admission and death (risk of intensive care unit admission: RR=0.93, 95% CI=0.64, 1.36; risk of death: RR=0.83, 95% CI=0.68, 1.01). Further analysis suggested that the tetravalent influenza vaccine may be associated with a reduced risk of COVID-19 infection (RR=0.74, 95% CI=0.65, 0.84). DISCUSSION: The results suggest that influenza vaccination is associated with reduced susceptibility to or disease severity of COVID-19 and that influenza vaccination may reduce the risk of COVID-19 and improve clinical outcomes.

COVID-19 vaccine waning and effectiveness and side-effects of boosters: a prospective community study from the ZOE COVID Study. BACKGROUND: With the surge of new SARS-CoV-2 variants, countries have begun offering COVID-19 vaccine booster doses to high-risk groups and, more recently, to the adult population in general. However, uncertainty remains over how long primary vaccination series remain effective, the ideal timing for booster doses, and the safety of heterologous booster regimens. We aimed to investigate COVID-19 primary vaccine series effectiveness and its waning, and the safety and effectiveness of booster doses, in a UK community setting. METHODS: We used SARS-CoV-2 positivity rates in individuals from a longitudinal, prospective, community-based study (ZOE COVID Study), in which data were self-reported through an app, to assess the effectiveness of three COVID-19 vaccines (ChAdOx1 nCov19 [Oxford-AstraZeneca], BNT162b2 [Pfizer-BioNtech], and mRNA1273 [Moderna]) against infection in the 8 months after completion of primary vaccination series. In individuals receiving boosters, we investigated vaccine effectiveness and reactogenicity, by assessing 16 self-reported systemic and localised side-effects. We used multivariate Poisson regression models adjusting for confounders to estimate vaccine effectiveness. FINDINGS: We included 620â€‰793 participants who received two vaccine doses (204â€‰731 [33Â·0%] received BNT162b2, 405â€‰239 [65Â·3%] received ChAdOx1 nCoV-19, and 10â€‰823 [1Â·7%] received mRNA-1273) and subsequently had a SARS-CoV-2 test result between May 23 (chosen to exclude the period of alpha [B.1.1.7] variant dominance) and Nov 23, 2021. 62â€‰172 (10Â·0%) vaccinated individuals tested positive for SARS-CoV-2 and were compared with 40â€‰345 unvaccinated controls (6726 [16Â·7%] of whom tested positive). Vaccine effectiveness waned after the second dose: at 5 months, BNT162b2 effectiveness was 82Â·1% (95% CI 81Â·3-82Â·9), ChAdOx1 nCoV-19 effectiveness was 75Â·7% (74Â·9-76Â·4), and mRNA-1273 effectiveness was 84Â·3% (81Â·2-86Â·9). Vaccine effectiveness decreased more among individuals aged 55 years or older and among those with comorbidities. 135â€‰932 individuals aged 55 years or older received a booster (2123 [1Â·6%] of whom tested positive). Vaccine effectiveness for booster doses in 0-3 months after BNT162b2 primary vaccination was higher than 92Â·5%, and effectiveness for heterologous boosters after ChAdOx1 nCoV-19 was at least 88Â·8%. For the booster reactogenicity analysis, in 317â€‰011 participants, the most common systemic symptom was fatigue (in 31â€‰881 [10Â·1%] participants) and the most common local symptom was tenderness (in 187â€‰767 [59Â·2%]). Systemic side-effects were more common for heterologous schedules (32â€‰632 [17Â·9%] of 182â€‰374) than for homologous schedules (17â€‰707 [13Â·2%] of 134â€‰637; odds ratio 1Â·5, 95% CI 1Â·5-1Â·6, p<0Â·0001). INTERPRETATION: After 5 months, vaccine effectiveness remained high among individuals younger than 55 years. Booster doses restore vaccine effectiveness. Adverse reactions after booster doses were similar to those after the second dose. Homologous booster schedules had fewer reported systemic side-effects than heterologous boosters. FUNDING: Wellcome Trust, ZOE,

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COVID-19 Vaccination and Uveitis: Epidemiology, Clinical Features and Visual Prognosis.
PURPOSE: To study the epidemiological and clinical features of uveitis post-COVID-19 vaccination. PATIENTS AND METHODS: Retrospective chart review of patients presenting with uveitis after COVID-19 vaccination in tertiary uveitis services. RESULTS: In total, 25 patients, 76% females, mean age 43.2 years, were included. Uveitis occurred after Pfizer, Moderna, Astra-Zeneca and Covaxin vaccination. Anterior uveitis was the most frequent type of uveitis (56%). History of uveitis was found in 19 cases (76%), among whom 90.9% of the tested patients developed anti-Sars-CoV-2 spike antibodies after vaccination. In a mean follow-up of 5 months, one-line decrease in visual acuity was found in 12% of patients. During post-vaccine uveitis, 15.8% of cases needed an increase in their systemic therapy. According to Naranjo score, new-onset uveitis had a higher probability of being associated with vaccination ($p < .01$). CONCLUSION: COVID-19 vaccination can cause uveitis but has no significant impact on the visual prognosis after resolution.

Vogt-Koyanagi-Harada Disease following mRNA-1273 (Moderna) COVID-19 Vaccination.
PURPOSE: To report a case of Vogt-Koyanagi-Harada (VKH) disease following mRNA-1273 (Moderna) COVID-19 vaccination. METHODS: Retrospective case report. RESULTS: A 50-year-old Korean woman developed bilateral serous retinal detachment 35 days after the first dose of COVID-19 mRNA vaccination (mRNA-1273, Moderna). She experienced adverse effects such as erythema and pain at the injection site, headache, myalgia, and allergy symptoms prior to ocular manifestation. She was diagnosed with Vogt-Koyanagi-Harada (VKH) disease. After treatment with oral prednisolone, the serous retinal detachment resolved and vision improved. CONCLUSION: COVID-19 vaccination might be associated with VKH disease development, and the ingredients of the mRNA vaccine or viral peptide encoded by mRNA may have activated the immunological process and induced VKH disease.

A Case of Transient Visual Field Defect following Administration of Pfizer-BioNTech COVID-19 Vaccine.
PURPOSE: To report a case of transient visual field (VF) defect after coronavirus disease-19 (COVID-19) vaccination. CASE REPORT: A 38-year-old Caucasian, otherwise healthy female patient, presented with a complaint of vision loss in the outer quadrant in her left eye after the second dose of PfizerÂ®-BioNTechâ„¢ COVID-19 vaccine. The Snellen visual acuity was 20/20 in both eyes. She did not have relative afferent pupillary defect nor disturbance of color vision. Her intraocular pressures, slit lamp and fundus examinations were normal. In the VF test, a temporal hemifield defect in the left eye and a nasal peripheral VF defect in the right eye were detected. Other imaging characteristics and neurological examination were normal. She was followed without any treatment. One week later, the patient was re-evaluated and complete resolution of the VF defect was observed. CONCLUSION: Clinicians should be aware that patients can experience transient visual symptoms following COVID-19 vaccination.

Herpes Simplex Virus 1 Anterior Uveitis following Coronavirus Disease 2019 (COVID-19) Vaccination in an Asian Indian Female. PURPOSE: To describe a case of herpes simplex virus 1 (HSV 1) infection following coronavirus disease 2019 (COVID-19) vaccination in an Asian Indian female. METHODS: Retrospective case report. RESULT: A 40-year-old female presented with decreased vision, pain, and photophobia of 2 weeks duration. She reported receiving the second dose of COVISHIELD(TM) (ChAdOx1-S [recombinant]) 1 week prior to the onset of ocular symptoms. Left eye examination revealed granulomatous anterior uveitis. Aqueous sample from the left eye tested positive for HSV1 by polymerase chain reaction(PCR) method. She was managed with oral antiviral therapy, topical steroids, and cycloplegic agent and showed significant improvement of inflammation within 1 week and resolved within 3 weeks. CONCLUSION: This report demonstrates a potential association of HSV 1 anterior uveitis with COVID-19 vaccination. A high index of suspicion of viral etiology is warranted

when uveitis presents with reduced corneal sensations and pigmented keratic precipitates, following a recent history of COVID-19 vaccination.

Bilateral Cystoid Macular Edema and Corneal Endothelial Graft Rejection following Influenza and Varicella-Zoster Vaccinations. PURPOSE: Multiple cases of corneal graft rejection after various vaccinations have been reported over the past decades. Here we described a case of bilateral cystoid macular edema (CME) and endothelial rejection in a DSAEK patient following influenza and varicella vaccines. CASE REPORT: A 72-year-old woman with bilateral Fuch's endothelial dystrophy received bilateral DSAEK surgeries. She received an influenza vaccination and her left visual acuity (VA) decreased due to CME. Half a year later, the patient received a varicella-zoster virus vaccine. 11 days later, she was found to have signs of endothelial graft rejection in both eyes. Unfortunately, her vision further deteriorated despite intensive topical steroid treatment. CONCLUSIONS: In view of the current worldwide efforts on mass vaccination against the COVID-19 pandemic, we suggest an increased use of topical corticosteroids both before and after vaccination may be helpful in reducing this risk.

Risk of myopericarditis following COVID-19 mRNA vaccination in a large integrated health system: A comparison of completeness and timeliness of two methods. PURPOSE: How completely do hospital discharge diagnoses identify cases of myopericarditis after an mRNA vaccine? METHODS: We assembled a cohort 12-39â€‰year-old patients, insured by Kaiser Permanente Northwest, who received at least one dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) between December 2020 and October 2021. We followed them for up to 30â€‰days after their second dose of an mRNA vaccine to identify encounters for myocarditis, pericarditis or myopericarditis. We compared two identification methods: A method that searched all encounter diagnoses using a brief text description (e.g., ICD-10-CM code I40.9 is defined as 'acute myocarditis, unspecified'). We searched the text description of all inpatient or outpatient encounter diagnoses (in any position) for "myocarditis" or "pericarditis." The other method was developed by the Centers for Disease Control and Prevention's Vaccine Safety Datalink (VSD), which searched for emergency department visits or hospitalizations with a select set of discharge ICD-10-CM diagnosis codes. For both methods, two physicians independently reviewed the identified patient records and classified them as confirmed, probable or not cases using the CDC's case definition. RESULTS: The encounter methodology identified 14 distinct patients who met the confirmed or probable CDC case definition for acute myocarditis or pericarditis with an onset within 21â€‰days of receipt of COVID-19 vaccination. When we extended the search for relevant diagnoses to 30â€‰days since vaccination, we identified two additional patients (for a total of 16 patients) who met the case definition for acute myocarditis or pericarditis, but those patients had been misdiagnosed at the time of their original presentation. Three of these patients had an ICD-10-CM code of I51.4 "Myocarditis, Unspecified;" that code was omitted by the VSD algorithm (in the late fall of 2021). The VSD methodology identified 11 patients who met the CDC case definition for acute myocarditis or pericarditis. Seven (64%) of the 11 patients had initial care for myopericarditis outside of a KPNW facility and their diagnosis could not be ascertained by the VSD methodology until claims were submitted (median delay of 33â€‰days; range of 12-195â€‰days). Among those who received a second dose of vaccine (nÂ =Â 146â€‰785), we estimated a risk as 95.4 cases of myopericarditis per million second doses administered (95% CI, 52.1-160.0). CONCLUSION: We identified additional valid cases of myopericarditis following an mRNA vaccination that would be missed by the VSD's search algorithm, which depends on select hospital discharge diagnosis codes. The true incidence of myopericarditis is markedly higher than the incidence reported to US advisory committees in the fall of 2021. The VSD should validate its search algorithm to improve its sensitivity for myopericarditis.

Constrictive pericarditis following mRNA COVID-19 vaccination in a patient with systemic sclerosis. A 59-year-old man with systemic sclerosis and interstitial pneumonia was referred to our department because he developed dyspnea and leg edema after receiving a first shot of coronavirus disease 2019 (COVID-19) vaccine. Transthoracic echocardiography showed moderate pericardial effusion with conspicuous fibrin deposition. Prednisolone was increased from 6â€¯mg/day for systemic sclerosis to 20â€¯mg/day. Thereafter, pericardial effusion gradually decreased. However, his symptoms continued. Transthoracic echocardiography showed disappearance of pericardial effusion and thickened pericardium. Pulsed-wave and tissue Doppler echocardiography revealed that the patient suffered from newly developed constrictive pericarditis. COVID-19 vaccination might have contributed to acute pericarditis and subsequent constrictive pericarditis in the present case of systemic sclerosis and pulmonary fibrosis. LEARNING OBJECTIVE: Incidence of adverse effects after coronavirus disease 2019 vaccination is rare. The present case suggests the risk of pericarditis that may lead to constrictive pericarditis.

Risk of venous thromboembolism after COVID-19 vaccination. BACKGROUND: COVID-19 vaccinations in the United States are effective in preventing illness and hospitalization yet concern over post-vaccination venous thromboembolism (VTE) risk has led to vaccine hesitancy. METHODS: The aim of this study was to compare VTE rates before and after COVID-19 vaccination. COVID-19 vaccinated patients â‰¥18Â years between November 1, 2020 through November 1, 2021 were analyzed using electronic medical records across the Mayo Clinic enterprise. The primary outcome was imaging confirmed acute VTE (upper or lower deep vein thrombosis or pulmonary embolism) occurring 90 days before and after the date of first vaccine dose. RESULTS: A total of 792Â 010 patients with at least one COVID-19 vaccination were identified (Pfizer, nÂ =Â 452Â 950, Moderna, nÂ =Â 290Â 607, and Janssen [Johnson & Johnson], nÂ =Â 48Â 453). A total of 1565Â VTE events occurred in the 90 days before (nÂ =Â 772) and after (nÂ =Â 793) COVID-19 vaccination. VTE post-vaccination occurred in 326 patients receiving Moderna (0.11%, incidence rate [IR] 4.58 per 1000p-years), 425 patients receiving Pfizer (0.09%, IR 3.84 per 1000p-years), and 42 receiving Janssen (0.09%, IR 3.56 per 1000p-years). Compared to the pre-vaccination timeframe, the adjusted hazard ratio (aHR) for VTE after the Janssen vaccination was 0.97 (95% confidence interval [CI] 0.63-1.50), aHR 1.02 (95% CI 0.87-1.19) for Moderna, and aHR 1.00 (95% CI 0.87-1.15) for Pfizer. CONCLUSION: In this large cohort of COVID-19 vaccinated patients, no increased risk for acute VTE post-vaccination was identified for the authorized vaccines in the United States.

Haemorrhagic bullous pyoderma gangrenosum following COVID-19 vaccination.

Two cases of axillary lymphadenopathy diagnosed as diffuse large B-cell lymphoma developed shortly after BNT162b2 COVID-19 vaccination.

Stevens-Johnson syndrome precipitated by Moderna Inc. COVID-19 vaccine: a case-based review of literature comparing vaccine and drug-induced Stevens-Johnson syndrome/toxic epidermal necrolysis. The Moderna COVID-19 vaccination was approved for use in the United States in December of 2020(1) and since that time massive public health efforts have been made to vaccinate patients against the COVID-19 infection. Adverse reactions from the vaccination are well-reported and include both local skin reactions, such as pain, swelling, and erythema at the injection site, as well as systemic reactions including fever, malaise, headache, muscle aches, drowsiness, nausea, and vomiting. While severe serious cutaneous adverse reactions, such as Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN), remain rare; two cases of SJS/TEN related to COVID-19 vaccination have been reported. We herein review the two previously reported cases of SJS/TEN and report the first case of SJS precipitated by the Moderna Inc., MRNA 1273 COVID-19 vaccination in the United States. Although we review potential adverse reactions to vaccination, the benefits of COVID-19 vaccination outweigh the risks based on current data. Cases should be reported to the Vaccine

Adverse Event Reporting System (https://vaers.hhs.gov/) to help public health officials recognize and track these severe but rare adverse events.

Safety of third SARS-CoV-2 vaccine (booster dose) during pregnancy. BACKGROUND: COVID-19 during pregnancy is associated with adverse outcomes for both the mother and fetus. SARS-CoV-2 vaccination has significantly reduced the risk for symptomatic disease. Several studies have reported on the safety of SARS-CoV-2 vaccination during pregnancy, with no adverse effects on the obstetrical outcomes. However, data regarding the obstetrical outcomes following a booster dose of the SARS CoV-2 vaccination during pregnancy have not yet to be published. OBJECTIVE: This study aimed to examine the association between the booster dose of the SARS CoV-2 vaccination during pregnancy and obstetrical outcomes. STUDY DESIGN: This was a retrospective cohort study of women who delivered between July and October 2021 at a large tertiary medical center. We compared women who received the booster vaccination dose during pregnancy with women who were not vaccinated and with those who only received 2 vaccination doses. Primary outcomes were the incidence of preterm labor and of small for gestational age neonates. Secondary outcomes were other maternal and neonatal complications. A secondary analysis investigating the association between the time from vaccination to delivery and the outcomes was also performed. Multivariable logistic regression models were used to adjust for potential confounders. RESULTS: There were 6507 women who met the inclusion criteria: 294 women received 3 doses of the vaccination, 2845 women received only 2 doses, and 3368 were unvaccinated. Patients receiving 3 doses of the vaccine were older and more likely to smoke than unvaccinated patients. No differences were noted among the triple-vaccinated, twice-vaccinated, and unvaccinated groups with regards to preterm birth and the incidence of small for gestational age neonates. Regarding the secondary outcomes, women in the triple-vaccinated group had higher rates of postpartum hemorrhage (9.5% vs 3.21%; P<.001) and gestational diabetes mellitus (12.2% vs 8.3%; P=.02) and were less likely to have hypertensive disorders of pregnancy (0% vs 1.4%; P=.041) than the unvaccinated group. Compared with the twice-vaccinated patients, patients with 3 doses of the vaccine were more likely to experience postpartum hemorrhage (9.5% vs 3.5%; P<.001) and were less likely to have a low umbilical artery pH (0.7% vs 6.1%; P<.001). In the sensitivity analysis comparing patients who delivered within 2 weeks of the third vaccination dose (n=53) with those who delivered at least 6 weeks after vaccination (n=96), there were no differences in the rates of small for gestational age neonates, preterm birth, postpartum hemorrhage, or cesarean delivery. CONCLUSION: Receiving the booster dose of the SARS-CoV-2 vaccination during pregnancy was not associated with adverse obstetrical outcomes when compared with unvaccinated or twice-vaccinated women. However, higher rates of postpartum hemorrhage were observed. Further studies on a larger scale are needed to confirm these findings.

Rapid progress in our understanding of COVID-19 vaccine allergy: AÂ cause for optimism, not hesitancy. Anaphylaxis is a life-threatening condition and when associated with vaccination, leads to vaccine hesitancy. The concerns around vaccine-related anaphylaxis have become even more important during the coronavirus disease 2019 (COVID-19) pandemic where the COVID-19 vaccines remain one of our most important tools. Although rates of anaphylaxis to COVID-19 vaccines are not significantly different from those to other vaccines, Centers for Disease Control and Prevention guidance recommends avoidance of the same COVID-19 vaccine in individuals who had an allergic reaction or are allergic to a COVID-19 vaccine component. Fortunately, our understanding of COVID-19 vaccine allergic reactions has improved dramatically in the past year in large part due to important research efforts from individuals in the allergy community. Initially, researchers published algorithmic approaches using risk stratification and excipient skin testing. However, as our experience and knowledge improved with ongoing research, we have better data showing safety of repeat vaccination despite an initial reaction. We review our progress starting in December 2020 when the

Food and Drug Administration approved the first COVID-19 vaccine in the United States through early 2022, highlighting our success in understanding COVID-19 vaccine reactions.
Myocarditis and Cardiac Complications Associated With COVID-19 and mRNA Vaccination: A Pragmatic Narrative Review to Guide Clinical Practice. Coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus is likely to remain endemic globally despite widespread vaccination. There is increasing concern for myocardial involvement and ensuing cardiac complications due to COVID-19, however, the available evidence suggests these risks are low. Pandemic publishing has resulted in rapid manuscript availability though pre-print servers. Subsequent article retractions, a lack of standardised definitions, over-reliance on isolated troponin elevation and the heterogeneity of studied patient groups (i.e. severe vs. symptomatic vs all infections) resulted in early concern for high rates of myocarditis in patients with and recovering from COVID-19. The estimated incidence of myocarditis in COVID-19 infection is 11 cases per 100,000 infections compared with an estimated 2.7 cases per 100,000 persons following mRNA vaccination.Â For substantiated cases, the clinical course of myocarditis related to COVID-19 or mRNA vaccination appears mild and self-limiting, with reports of severe/fulminant myocarditis being rare. There is limited data available on the management of myocarditis in these settings. Clinical guidance for appropriate use of cardiac investigations and monitoring in COVID-19 is needed for effective risk stratification and efficient use of cardiac resources in Australia. An amalgamation of national and international position statements and guidelines is helpful for guiding clinical practice. This paper reviews the current available evidence and guidelines and provides a summary of the risks and potential use of cardiac investigations and monitoring for patients with COVID-19.
Severely impaired humoral response against SARS-CoV-2 variants of concern following two doses of BNT162b2 vaccine in patients with systemic lupus erythematosus (SLE).
Autopsy Histopathologic Cardiac Findings in 2 Adolescents Following the Second COVID-19 Vaccine Dose: Cytokine Storm, Hypersensitivity, or Something Else.
Autopsy Histopathologic Cardiac Findings in 2 Adolescents Following the Second COVID-19 Vaccine Dose.
Recurrent Anterior Non-necrotizing Scleritis as an Adverse Event of ChAdOx1 nCoV-19 (Vaxzevria) Vaccine. PURPOSE: To describe a case of anterior scleritis related to SARS-CoV-2 vaccine. SARS-CoV-2 vaccines appear safe; however vaccination has triggered thromboembolic events in predisposed patients. METHODS: A retrospective case report of anterior scleritis in a woman following administration of both ChAdOx1nCoV-19 vaccine doses was studied by complete ophthalmologic examination and complementary tests. RESULTS: The patient has overcome SARS-CoV-2 infection a year prior. Ancillary tests including autoimmune and infectious diseases were negative. The chronology between ChAdOx1nCoV-19 vaccine and the sequential episodes of scleritis may have a cause-and-effect relationship. CONCLUSION: Ophthalmologists may be aware of scleritis as an ocular manifestation following ChAdOx1nCoV-19 vaccine, in otherwise healthy patients.
Reply to Response to "'A Case of Ulcerative Colitis Relapse Characterized by Systemic Type I Interferon Responses After COVID-19 Vaccination'" by Mungmunpuntipantip and Wiwanitkiton.
Patients With Inflammatory Bowel Diseases Have Impaired Antibody Production After Anti-SARS-CoV-2 Vaccination: Results From a Panhellenic Registry. BACKGROUND: Four EMA-approved vaccines against SARS-CoV-2 are currently available. Data regarding antibody responses to initial vaccination regimens in patients with inflammatory bowel diseases (IBD) are limited. METHODS: We conducted a prospective, controlled, multicenter study in tertiary Greek IBD centers. Participating patients had completed the initial vaccination regimens (1 or 2 doses, depending on the type of COVID-19 vaccine) at least 2 weeks before study enrolment. Anti-S1 IgG antibody levels were measured. Demographic and adverse events data were collected. RESULTS: We tested 403 patients (Crohn's disease, 58.9%;

male, 53.4%; median age, 45 years) and 124 healthy controls (HCs). Following full vaccination, 98% of patients seroconverted, with mRNA vaccines inducing higher seroconversion rates than viral vector vaccines (P = .021). In total, IBD patients had lower anti-S1 levels than HCs (P < .001). In the multivariate analysis, viral vector vaccines (P < .001), longer time to antibody testing (P < .001), anti-TNFÎ± treatment (P = .013), and age (P = .016) were independently associated with lower anti-S1 titers. Vedolizumab monotherapy was associated with higher antibody levels than anti-TNFÎ± or anti-interleukin-12/IL-23 monotherapy (P = .023 and P = .032). All anti- SARS-CoV-2 vaccines were safe. CONCLUSIONS: Patients with IBD have impaired antibody responses to anti-SARS-CoV-2 vaccination, particularly those receiving viral vector vaccines and those on anti-TNFÎ± treatment. Older age also hampers antibody production after vaccination. For those low-response groups, administration of accelerated or prioritized booster vaccination may be considered.

 Thisis a multicenter study on IBD patients after COVID-19 vaccination and anti-S1 IgG antibody levels measurement. Patients with IBD have lower antibody responses than healthy controls, particularly those receiving viral vector vaccines and those on anti-TNFÎ± or combination treatment.

Ulcerative Colitis Relapse After COVID-19 Vaccination: Correspondence.

The impact of pausing the Oxford-AstraZeneca COVID-19 vaccine on uptake in Europe: a difference-in-differences analysis. BACKGROUND: Several countries paused their rollouts of the Oxford-AstraZeneca coronavirus disease-19 (COVID-19) vaccine in mid-March 2021 due to concerns about vaccine-induced thrombosis and thrombocytopenia. Many warned that this risked damaging public confidence during a critical period of pandemic response. This study investigated whether the pause in the use of the Oxford-AstraZeneca vaccine had an impact on subsequent vaccine uptake in European countries. METHODS: We used a difference-in-differences approach capitalizing on the fact that some countries halted their rollouts whilst others did not. A longitudinal panel was constructed for European Economic Area countries spanning 15â€‰weeks in early 2021. Media reports were used to identify countries that paused the Oxford-AstraZeneca vaccine and the timing of this. Data on vaccine uptake were available through the European Centre for Disease Control and Prevention COVID-19 Vaccine Tracker. Difference-in-differences linear regression models controlled for key confounders that could influence vaccine uptake, and country and week fixed effects. Further models and robustness checks were performed. RESULTS: The panel included 28 countries, with 19 in the intervention group and 9 in the control group. Pausing the Oxford-AstraZeneca vaccine was associated with a 0.52% decrease in uptake for the first dose of a COVID-19 vaccine and a 1.49% decrease in the uptake for both doses, comparing countries that paused to those that did not. These estimates are not statistically significant (Pâ€‰=â€‰0.86 and 0.39, respectively). For the Oxford-AstraZeneca vaccine only, the pause was associated with a 0.56% increase in uptake for the first dose and a 0.07% decrease in uptake for both doses. These estimates are also not statistically significant (Pâ€‰=â€‰0.56 and 0.51, respectively). All our findings are robust to sensitivity analyses. CONCLUSIONS: As new COVID-19 vaccines emerge, regulators should be cautious to deviate from usual protocols if further investigation on clinical or epidemiological grounds is warranted.

Cerebral venous sinus thrombosis in the setting of COVID-19 vaccination: a systematic review and meta-analysis. BACKGROUND AND PURPOSE: Cerebral venous sinus thrombosis (CVST) has been reported as a rare adverse event in association with thrombosis-thrombocytopenia syndrome (TTS) following COVID-19 vaccination. METHODS: Â We performed a systematic review and meta-analysis of investigator-initiated registries including confirmed CVST cases, with the aim to calculate (1) the odds ratio of TTS-CVST versus non-TTS-CVST after vector-based vaccines and (2) after non-vector-based vaccines, (3) the in-hospital mortality ratio of TTS-CVST compared to non-TTS-CVST; and (4) the dependency or death at discharge among TTS-CVST compared to non-TTS-CVST cases. RESULTS: Two eligible studies were included in the meta-analysis, comprising a total of 211 patients with CVST

associated with COVID-19 vaccination. Vector-based COVID-19 vaccination was associated with a higher likelihood of TTS-associated CVST than with non-TTS-CVST (OR: 52.34, 95% CI 9.58-285.98). TTS-CVST was also associated with higher likelihood of in-hospital mortality (OR: 13.29; 95% CI 3.96-44.60) and death or dependency at discharge compared to non-TTS-CVST (OR: 6.70; 95% CI 3.15-14.26). TTS-CVST was recorded with a shorter interval between vaccination and symptom onset [Mean Difference (MD):-6.54Â days; 95% CI -Â 12.64 to -Â 0.45], affecting younger patients (MD:-9.00Â years; 95% CI -Â 14.02 to -Â 3.99) without risk factors for thromboses (OR:2.34; 95% CI 1.26-4.33), and was complicated more frequently with intracerebral hemorrhage (OR:3.60; 95% CI 1.31-9.87) and concomitant thromboses in other sites (OR:11.85; 95% CI 3.51-39.98) compared to non-TTS-CVST cases. CONCLUSIONS: TTS-CVST following COVID-19 vaccination has distinct risk factor profile, clinical phenotype and prognosis compared to non-TTS-CVST. Further epidemiological data are required to evaluate the impact of different treatment strategies on outcome of TTS-CVST cases following COVID-19 vaccination.

COVID-19 and autoimmune phenomena: Vitiligo after Astrazeneca vaccine.

Durability of anti-spike antibodies after vaccination with mRNA SARS-CoV-2 vaccine is longer in subjects with previous infection: could the booster dose be delayed? PURPOSE: The long-term effectiveness of BNT162b2/Pfizer vaccine remains undetermined. This observational prospective study was designed to verify durability of antibodies against the viral receptor-binding domain (RBD) spike (S)-protein (RBD S-Protein IgG) after the second-dose administration of the vaccine among Health Care Workers (HCWs). METHODS: In all HCWs at the Poliambulanza Foundation Hospital Brescia (Italy) were quantified the levels of RBD S-Protein IgG (Abbott Diagnostics) at 45 and 240Â days after the second-dose vaccine. Previous infection was defined as antibodies against SARS-CoV-2 nucleocapsid positivity (Abbott Diagnostics) before vaccination. The Mann-Whitney U test was used to compare mean levels of RBD S-Protein IgG among previously infected and uninfected HCWs. RESULTS: The mean level of the RBD S-protein IgG detected 45Â days after the second dose of the vaccine was 30,041 AU/mL (95% CI 145-80,000) for the 250 previously infected HCWs and it was significantly higher (pâ€‰<â€‰0.001) than that observed in the 1121 previously uninfected subject with the mean level of 10,604 AU/mL (95% CI 165-62,241). Similarly, at 240Â days in previously infected subjects the antibody titer was of 8145 AU/mL (95% CI 347-80,000) and significantly higher (pâ€‰<â€‰0.001) than that observed in the 1121 previously uninfected HCWs with a mean antibody level of 1271 AU/mL (95% CI 50-80,000). When comparing the change in mean antibody levels overtime, the previously infected HCWs presented a 72.9% reduction in RBD S-protein IgG while in the previously uninfected HCWs the reduction was 88.0%. In addition, in the HCWs group without previous infection we reported 53 new SARS-CoV-2 infections and they had a mean level of RBD S-protein IgG antibodies of 1039 AU/mL (95% CI 157-4237) at 240Â days. No new infections were found in previously SARS-CoV-2 infected subjects. CONCLUSIONS: We report that the mean level of post vaccinal RBD S-protein IgG was significantly higher in the previously infected HCWs than in previously uninfected subjects at 45 and 240Â days after the second-dose vaccine. Moreover, our data suggest that the risk of a new SARS-CoV-2 infection was higher in the previously uninfected HCWs than in those who had already contracted natural viral infection. The limitations of this study prevent us to draw definitive conclusions on the antibody titers and on the role of a previous SARS-CoV-2 infection in influencing the levels of post-vaccine RBD S-protein IgG. The booster dose of the vaccine could be delayed after the second dose in previously naturally infected subject and it could have an important strategic impact on the organization of the future COVID-19 vaccination campaign.

What have we learned about the allergenicity and adverse reactions associated with the severe acute respiratory syndrome coronavirus 2 vaccines: One year later. OBJECTIVE: The coronavirus disease 2019 (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-

CoV-2) has led to the most rapid response and scale-up in vaccine and therapeutic development in history. We highlight the history of these amazing achievements with a focus on the description of the classification and mechanisms of allergic reactions and adverse events relevant to the allergist and immunologist that have been associated with the SARS-CoV-2 vaccines. Finally, we offer a detailed management approach in the context of a possible allergic reaction. DATA SOURCES: Using defined search strategy, we identified peer-reviewed articles within PubMed that were published between January 1, 2019, and December 4, 2021. STUDY SELECTIONS: All recent articles on COVID-19 published in English were reviewed with focus on the immunogenicity and allergenicity of the current existing COVID-19 vaccines. RESULTS: Following a detailed literature review, we discuss the evolution and development of the new vaccines for SARS-CoV-2. Furthermore, we provide evidence regarding the significance and mechanisms of allergic reactions associated with the vaccines and offer a management approach for those with an increased risk of presenting an allergic or other relevant vaccine reaction. CONCLUSION: The international rollout of COVID-19 vaccination started with reports of immediate allergic reactions. Although we still need to understand the mechanisms of these reactions, we can be reassured that patients with underlying allergic disease will not need to avoid SARS-CoV-2 vaccination. In addition, the vast majority of those with a first-dose reaction will tolerate subsequent doses.

Commentary on "Potential risk factors for Varicella-zoster virus reactivation after COVID-19 vaccination".

Safety and tolerability of SARS-Cov-2 vaccination in patients with myasthenia gravis: A multicenter experience. BACKGROUND AND PURPOSE: During the COVID-19 pandemic, myasthenia gravis (MG) patients have been identified as subjects at high risk of developing severe COVID-19, and thus were offered vaccination with priority. The lack of direct data on the safety and tolerability of SARS-CoV-2 vaccines in MG have contributed to vaccine hesitancy. To address this issue, the safety and tolerability of SARS-CoV-2 vaccines were assessed in a large cohort of MG patients from two referral centers. METHODS: Patients with confirmed MG diagnosis, consecutively seen between October and December 2021 at two MG centers, were enrolled. Demographics, clinical characteristics, and information regarding SARS-CoV-2 infection/vaccination were extracted from medical reports and/or collected throughout telephonic or in-person interviews. RESULTS: Ninety-eight (94.2%) of 104 patients included were administered at least two vaccine doses 4Â weeks before the interview or earlier, and among them, 63 of 98 (64.2%) have already received the "booster" dose. The most frequently used vaccines were BNT162b2-Pfizer-BioNTech and mRNA-1273-Moderna. Overall, only minor side effects were reported, most commonly local pain and fever. MG worsening after vaccination was observed in eight of 104 (7.7%) cases. The frequency of worsening among muscle-specific tyrosine kinase MG cases (3/9, 33.3%) was significantly higher compared to other serological subgroups. Spontaneous symptom regression was observed in six of eight cases. Twelve of 104 (11.5%) patients had SARS-CoV-2 infection, and none of the SARS-CoV-2-infected MG patients worsened after vaccination. CONCLUSIONS: Our data support the safety and tolerability of mRNA COVID-19 vaccines, which should be strongly recommended in MG patients, who could be at higher risk of complications if exposed to SARS-CoV-2 infection.

Acute haemolysis following COVID-19 vaccination in a thalassaemic patient with G6PD deficiency.

SARS-CoV-2-specific T cells are generated in less than half of allogeneic HSCT recipients failing to seroconvert after COVID-19 vaccination. Little is known about the cellular immune response to SARS-CoV-2 vaccination in patients after HSCT and B-NHL with iatrogenic B-cell aplasia. In nonseroconverted HSCT patients, induction of specific T-cell responses was assessed. The majority of allogeneic HSCT patients not showing humoral responses to vaccination also fail to mount antigen-specific T-cell responses.

Correspondence to: hemophagocytic lymphohistiocytosis after SARS-CoV-2 vaccination.

FDG PET/CT radiomics as a tool to differentiate between reactive axillary lymphadenopathy following COVID-19 vaccination and metastatic breast cancer axillary lymphadenopathy: a pilot study. OBJECTIVES: To evaluate if radiomics with machine learning can differentiate between F-18-fluorodeoxyglucose (FDG)-avid breast cancer metastatic lymphadenopathy and FDG-avid COVID-19 mRNA vaccine-related axillary lymphadenopathy. MATERIALS AND METHODS: We retrospectively analyzed FDG-positive, pathology-proven, metastatic axillary lymph nodes in 53 breast cancer patients who had PET/CT for follow-up or staging, and FDG-positive axillary lymph nodes in 46 patients who were vaccinated with the COVID-19 mRNA vaccine. Radiomics features (110 features classified into 7 groups) were extracted from all segmented lymph nodes. Analysis was performed on PET, CT, and combined PET/CT inputs. Lymph nodes were randomly assigned to a training (n = 132) and validation cohort (n = 33) by 5-fold cross-validation. K-nearest neighbors (KNN) and random forest (RF) machine learning models were used. Performance was evaluated using an area under the receiver-operator characteristic curve (AUC-ROC) score. RESULTS: Axillary lymph nodes from breast cancer patients (n = 85) and COVID-19-vaccinated individuals (n = 80) were analyzed. Analysis of first-order features showed statistically significant differences ($p < 0.05$) in all combined PET/CT features, most PET features, and half of the CT features. The KNN model showed the best performance score for combined PET/CT and PET input with 0.98 (Â± 0.03) and 0.88 (Â± 0.07) validation AUC, and 96% (Â± 4%) and 85% (Â± 9%) validation accuracy, respectively. The RF model showed the best result for CT input with 0.96 (Â± 0.04) validation AUC and 90% (Â± 6%) validation accuracy. CONCLUSION: Radiomics features can differentiate between FDG-avid breast cancer metastatic and FDG-avid COVID-19 vaccine-related axillary lymphadenopathy. Such a model may have a role in differentiating benign nodes from malignant ones. KEY POINTS: â€¢ Patients who were vaccinated with the COVID-19 mRNA vaccine have shown FDG-avid reactive axillary lymph nodes in PET-CT scans. â€¢ We evaluated if radiomics and machine learning can distinguish between FDG-avid metastatic axillary lymphadenopathy in breast cancer patients and FDG-avid reactive axillary lymph nodes. â€¢ Combined PET and CT radiomics data showed good test AUC (0.98) for distinguishing between metastatic axillary lymphadenopathy and post-COVID-19 vaccine-associated axillary lymphadenopathy. Therefore, the use of radiomics may have a role in differentiating between benign from malignant FDG-avid nodes.

The deglycosylated form of 1E12 inhibits platelet activation and prothrombotic effects induced by VITT antibodies. In order to improve the safety of COVID-19 vaccines, there is an urgent need to unravel the pathogenesis of vaccineinduced immune thrombotic thrombocytopenia (VITT), a severe complication of recombinant adenoviral vector vaccines used to prevent COVID-19, and likely due to anti-platelet factor 4 (PF4) IgG antibodies. In this study, we demonstrated that 1E12, a chimeric anti-PF4 antibody with a human Fc fragment, fully mimics the effects of human VITT antibodies, as it activates platelets to a similar level in the presence of platelet factor 4 (PF4). Incubated with neutrophils, platelets and PF4, 1E12 also strongly induces NETosis, and in a microfluidic model of whole blood thrombosis, it triggers the formation of large platelet/leukocyte thrombi containing fibrin(ogen). In addition, a deglycosylated form of 1E12 (DG-1E12), which still binds PF4 but no longer interacts with FcÎ³ receptors, inhibits platelet, granulocyte and clotting activation induced by human anti-PF4 VITT antibodies. This strongly supports that 1E12 and VITT antibodies recognize overlapping epitopes on PF4. In conclusion, 1E12 is a potentially important tool to study the pathophysiology of VITT, and for establishing mouse models. On the other hand, DG-1E12 may help the development of a new drug that specifically neutralizes the pathogenic effect of autoimmune anti-PF4 antibodies, such as those associated with VITT.

Two adolescent cases of acute tubulointerstitial nephritis after second dose of COVID-19 mRNA vaccine. The Food and Drug Administration (FDA) expanded the emergency use authorization for the BNT162b2 messenger RNA (mRNA) vaccine (Pfizer-BioNTech) for children aged 12-15â€‰years on 10 May 2021. To date, less than a year has passed since vaccination against COVID-19 has been used in children and adolescents, and the overall effects and safety of these vaccines are still being assessed. The BNT162b2 vaccine originally had a favorable profile in 12-17-year-old recipients compared with older ages, and no serious adverse events had previously been reported. Despite various adverse events, the benefit of reducing the infection rate or the frequency of severe COVID-19 has been evaluated to outweigh the harm caused by COVID-19 vaccination. Additionally, several cases of sudden development of new-onset or relapsing glomerular diseases, including acute kidney injury (AKI), have been reported in adults following the BNT162b2 SARS-CoV-2 mRNA vaccine. Herein, we present two cases of adolescents who developed AKI following the second administration of the BNT162b2. These are the first pediatric cases of acute tubulointerstitial nephritis temporarily linked to SARS-CoV-2 vaccination.

Breakthrough Infections Following mRNA SARS-CoV-2 Vaccination in Kidney Transplant Recipients. BACKGROUND: The clinical effectiveness of coronavirus disease 2019 (COVID-19) vaccination in kidney transplant (KT) recipients is lower than in the general population. METHODS: From April to October 2021, 481 KT recipients with COVID-19, included in the Spanish Society of Nephrology COVID-19 Registry, were analyzed. Data regarding vaccination status and vaccine type were collected, and outcomes of unvaccinated or partially vaccinated patients (n = 130) were compared with fully vaccinated patients (n = 351). RESULTS: Clinical picture was similar and survival analysis showed no differences between groups: 21.7% of fully vaccinated patients and 20.8% of unvaccinated or partially vaccinated died (P = 0.776). In multivariable analysis, age and pneumonia were independent risk factors for death, whereas vaccination status was not related to mortality. These results remained similar when we excluded patients with partial vaccination, as well as when we analyzed exclusively hospitalized patients. Patients vaccinated with mRNA-1273 (n = 213) showed a significantly lower mortality than those who received the BNT162b2 vaccine (n = 121) (hazard ratio: 0.52; 95% confidence interval, 0.31-0.85; P = 0.010). CONCLUSIONS: COVID-19 severity in KT patients has remained high and has not improved despite receiving 2 doses of the mRNA vaccine. The mRNA-1273 vaccine shows higher clinical effectiveness than BNT162b2 in KT recipients with breakthrough infections. Confirmation of these data will require further research taking into account the new variants and the administration of successive vaccine doses.

Bilateral Avid Axillary Nodes on FDG PET/CT Due to Concurrent Booster COVID-19 Immunization and Seasonal Influenza Vaccination. In an attempt to protect the high-risk demographic and reduce burden on health care systems, concomitant administration of COVID-19 and influenza vaccines has been recommended by health bodies. The ComFluCOV trial indicates this is well tolerated with no reduction in immune response to either vaccine. A 48-year-old woman with right oropharyngeal squamous cell carcinoma underwent postradiotherapy FDG PET/CT, which demonstrated complete metabolic response. Incidental avid bilateral axillary lymphadenopathy of benign configuration was noted and concluded to be reactive in response to recent Pfizer-BioNTech booster and influenza vaccination. This is expected to be seen more frequently over the coming months.

Neutralizing antibody response against the B.1.617.2 (delta) and the B.1.1.529 (omicron) variants after a third mRNA SARS-CoV-2 vaccine dose in kidney transplant recipients. Seroconversion after COVID-19 vaccination is impaired in kidney transplant recipients. Emerging variants of concern such as the B.1.617.2 (delta) and the B.1.1.529 (omicron) variants pose an increasing threat to these patients. In this observational cohort study, we measured anti-S1 IgG, surrogate neutralizing, and anti-receptor-binding domain antibodies three weeks after a third mRNA vaccine dose in 49Â kidney

transplant recipients and compared results to 25 age-matched healthy controls. In addition, vaccine-induced neutralization of SARS-CoV-2 wild-type, the B.1.617.2 (delta), and the B.1.1.529 (omicron) variants was assessed using a live-virus assay. After a third vaccine dose, anti-S1 IgG, surrogate neutralizing, and anti-receptor-binding domain antibodies were significantly lower in kidney transplant recipients compared to healthy controls. Only 29/49 (59%) sera of kidney transplant recipients contained neutralizing antibodies against the SARS-CoV-2 wild-type or the B.1.617.2 (delta) variant and neutralization titers were significantly reduced compared to healthy controls (pÂ <Â 0.001). Vaccine-induced cross-neutralization of the B.1.1.529 (omicron) variants was detectable in 15/35 (43%) kidney transplant recipients with seropositivity for anti-S1 IgG, surrogate neutralizing, and/or anti-RBD antibodies. Neutralization of the B.1.1.529 (omicron) variants was significantly reduced compared to neutralization of SARS-CoV-2 wild-type or the B.1.617.2 (delta) variant for both, kidney transplant recipients and healthy controls (pÂ <Â .001 for all).

COVID-19 vaccine in patients with Dravet syndrome: Observations and real-world experiences. OBJECTIVE: Vaccination against the SARS-CoV-2 virus is a primary tool to combat the COVID-19 pandemic. However, vaccination is a common seizure trigger in individuals with Dravet syndrome (DS). Information surrounding COVID-19 vaccine side effects in patients with DS would aid caregivers and providers in decisions for and management of COVID-19 vaccination. METHODS: A survey was emailed to the Dravet Syndrome Foundation's Family Network and posted to the Dravet Parent & Caregiver Support Group on Facebook between May and August 2021. Deidentified information obtained included demographics and vaccination status for individuals with DS. Vaccine type, side effects, preventative measures, and changes in seizure activity following COVID-19 vaccination were recorded. For unvaccinated individuals, caregivers were asked about intent to vaccinate and reasons for their decision. RESULTS: Of 278Â survey responses, 120 represented vaccinated individuals with DS (median age = 19.5Â years), with 50% reporting no side effects from COVID-19 vaccination. Increased seizures following COVID-19 vaccination were reported in 16 individuals, but none had status epilepticus. Of the 158 individuals who had not received a COVID-19 vaccination, 37 were older than 12 years (i.e., eligible at time of study), and only six of these caregivers indicated intent to seek vaccination. The remaining 121 responses were caregivers to children younger than 12 years, 60 of whom indicated they would not seek COVID-19 vaccination when their child with DS became eligible. Reasons for vaccine hesitancy were fear of increased seizure activity and concerns about vaccine safety. SIGNIFICANCE: These results indicate COVID-19 vaccination is well tolerated by individuals with DS. One main reason for vaccine hesitancy was fear of increased seizure activity, which occurred in only 13% of vaccinated individuals, and none had status epilepticus. This study provides critical and reassuring insights for caregivers and health care providers making decisions about the safety of COVID-19 vaccinations for individuals with DS.

Reversible neurological and brain MRI changes following COVID-19 vaccination: A case report. BACKGROUND: Various neurological sequalae have been described following COVID-19 vaccination. Here we describe the first case of untreated post COVID-19 vaccine encephalitis with spontaneous resolution of contrast enhancing hyperintensities on MRI concomitant with clinical improvement. CASE PRESENTATION: A 59-year-old woman presented with a two-day history of unsteady gait, incoordination, visual symptoms, and lethargy. She had received AZD1222 (AstraZeneca) and mRNA-1273 (Moderna) COVID-19 vaccines at 3 months and 12 days, respectively, before presentation. Brain MRI showed no abnormality on the non-enhanced sequences, but numerous enhancing lesions in the cerebral cortex, deep grey matter, brainstem, and cerebellum. Treatment was expectant, the patient improved clinically over 10 days, and repeat MRI showed near complete resolution of the imaging abnormality. CONCLUSIONS: We describe neurological deterioration 12 days after a second dose of COVID-19 vaccine. There was no evidence of edema or demyelinating lesions in the brain on MRI, but

there was extensive contrast-enhancement indicating loss of blood-brain barrier (BBB) integrity. This provides a potential in vivo, clinical-imaging correlate of the post-mortem evidence that SARS-CoV-2 spike protein may induce loss of BBB permeability. While this adds to the list of rare adverse neurological reactions to COVID-19 vaccination, the benefits of receiving the vaccine far outweigh these risks.
Minimal change glomerulonephritis following the second dose of the Moderna COVID-19 vaccine.
Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Naturally Acquired Immunity versus Vaccine-induced Immunity, Reinfections versus Breakthrough Infections: A Retrospective Cohort Study. BACKGROUND: Waning of protection against infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) conferred by 2 doses of the BNT162b2 vaccine begins shortly after inoculation and becomes substantial within 4 months. With that, the impact of prior infection on incident SARS-CoV-2 reinfection is unclear. Therefore, we examined the long-term protection of naturally acquired immunity (protection conferred by previous infection) compared to vaccine-induced immunity. METHODS: A retrospective observational study of 124 500 persons, compared 2 groups: (1) SARS-CoV-2-naive individuals who received a 2-dose regimen of the BioNTech/Pfizer mRNA BNT162b2 vaccine, and (2) previously infected individuals who have not been vaccinated. Two multivariate logistic regression models were applied, evaluating four SARS-CoV-2-related outcomes-infection, symptomatic disease (coronavirus disease 2019 [COVID-19]), hospitalization, and death-between 1 June and 14 August 2021, when the Delta variant was dominant in Israel. RESULTS: SARS-CoV-2-naive vaccinees had a 13.06-fold (95% confidence interval [CI], 8.08-21.11) increased risk for breakthrough infection with the Delta variant compared to unvaccinated-previously-infected individuals, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant for symptomatic disease as well. When allowing the infection to occur at any time between March 2020 and February 2021, evidence of waning naturally acquired immunity was demonstrated, although SARS-CoV-2 naive vaccinees still had a 5.96-fold (95% CI: 4.85-7.33) increased risk for breakthrough infection and a 7.13-fold (95% CI: 5.51-9.21) increased risk for symptomatic disease. CONCLUSIONS: Naturally acquired immunity confers stronger protection against infection and symptomatic disease caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 2-dose vaccine-indued immunity.
Alopecia areata following ChAdOx1 nCoV-19 vaccination (Oxford/AstraZeneca).
Association of COVID-19 Vaccination During Early Pregnancy With Risk of Congenital Fetal Anomalies. This cohort study evaluates the association of COVID-19 vaccination during early pregnancy with risk of major fetal structural anomalies identified on ultrasonography.
Influence of social media on the public perspectives of the safety of COVID-19 vaccines.
CMR Imaging After Myocarditis Associated with mRNA COVID-19 Vaccine: Correspondence.
SARS-CoV-2 vaccine, a new autoimmune hepatitis trigger? SARS-CoV2 infection and vaccination against this virus have been related to the development of autoimmune diseases. We report a case of autoimmune hepatitis (AIH) after SARS-COV2 vaccine. Male, 76 years old, with a history of hepatic cirrhosis secondary to primary biliary cholangitis (PBC), compensated, treated with ursodeoxycholic acid and obeticholic acid. The patient received the third dose of the SARS-CoV2 vaccine (BioNTech/Pfizer) in December 2021. In subsequent analytical control, the patient presented altered liver test, with elevation of ALT and AST. Ultrasound was performed, without alterations, and viral causes were ruled out. IgG elevation and positive antinuclear antibodies were observed. A liver biopsy was performed, with findings of intense interface and lobular hepatitis and areas of centrilobular necrosis. The inflammation was predominantly lymphoplasmacytic. The patient was diagnosed with AIH and initiated therapy with steroids and azathioprine, currently with an adequate response. AIH is an immune-mediated disease of uncertain etiology. Cases of AIH with SARS-CoV2

vaccination as a possible trigger have recently been published, with characteristics similar to ours. Some of them had a history of autoimmune pathology, such as this case (PBC). Therefore, it is suggested that vaccination can induce the development of autoimmune pathology in patients at risk. Our reported case reinforces the hypothesis of an association between AIH and the SARS-CoV2 vaccine.

Histopathological analysis of skin reactions after coronavirus disease 2019 vaccination: Increment in number of infiltrated plasmacytoid dendritic cell. Skin disorders are frequent adverse events after coronavirus disease 2019 (COVID-19) vaccination. However, the pathogenesis of these disorders is not fully understood. Here, we report a case series of cutaneous adverse events following COVID-19 vaccination, and the results of our investigation reveal the underlying mechanism. Case 1: a 47-year-old female developed a wheal, confined to the COVID-19 vaccination site, 2â€‰days after her first injection. She was treated with topical steroids and oral antihistamines. Case 2: a 51-year-old female showed generalized petechial erythema accompanied by fever, genital bleeding, thrombocytopenia, liver dysfunction, and disseminated intravascular coagulation, 2â€‰days after her second injection. She was diagnosed with vaccine-induced macrophage activation syndrome and treated with anti-inflammatory therapy. Immunohistological analysis of the skin eruption, in both these cases, showed infiltration of CD123(+) BDCA2(+) plasmacytoid dendritic cells (p-DC). Despite the distinctive clinical features in these two cases, this finding suggests that p-DC might be involved in different cutaneous adverse events after COVID-19 vaccination.

Safety and immunogenicity of inactivated SARS-CoV-2 vaccines in people living with HIV. It is important to know the safety and efficacy of vaccination in immunocompromised people living with HIV (PLWH), but currently, there is limited data on the inactivated SARS-CoV-2 vaccines' safety and immune responses in PLWH. In this prospective observational study, 139 PLWH and 120 healthy controls were enrolled and monitored for 21-105 days after a two-dose vaccination. The safety, anti-receptor binding domain IgG (anti-RBD-IgG) and anti-spike-IgG responses, and RBD-specific memory B cell (MBC) responses were evaluated. The overall adverse events within seven days were reported in 12.9% (18/139) of PLWH and 13.3% (16/120) of healthy controls. No serious adverse events occurred in both groups. Overall, the seroprevalence of anti-RBD-IgG in PLWH was significantly decreased (87.1% vs. 99.2%; $p<0.001$). The geometric mean end-point titer (GMT) of anti-RBD-IgG in PLWH was also reduced, especially in patients with CD4 counts <200 cells/ÂµL, regardless of age, gender, or HIV viral load. GMTs of anti-RBD-IgG in both PLWH and healthy controls declined gradually over time. Similar results were also observed in the anti-spike-IgG response. The frequency of RBD-specific MBCs in PLWH decreased ($p<0.05$), and then remained stable over time. Lastly, through multivariate analysis, we found the factors that predicted a less robust response to inactivated vaccines in PLWH were a low CD4 count and long time interval after vaccination. In conclusion, inactivated vaccines are well-tolerated in PLWH but with low immunogenicity. Therefore, SARS-CoV-2 vaccines and booster doses should be given priority in PLWH, especially in patients with low CD4 counts.Trial registration: ClinicalTrials.gov identifier: NCT05043129..

A case report of longitudinal extensive transverse myelitis: immunotherapy related adverse effect vs. COVID-19 related immunization complications. Background: Transverse myelitis (TM) is a rare, acquired neuro-immunological spinal cord disorder that occurs with rapid onset of motor weakness, sensory deficits with bowel and bladder dysfunction. Patients being treated with immune checkpoint inhibitors (ICIs) for advanced malignancy have a known higher propensity of developing neuro immune complications. With the advent of COVID-19 pandemic there have been reported cases of TM with COVID-19 immunization. The reported infrequency of TM with both of the aforementioned causes makes delineation of the etiology challenging.Methods: We present a patient with metastatic small cell lung cancer (SCLC) on maintenance Atezolizumab immunotherapy who developed

longitudinal extensive transverse myelitis (LETM) after administration of second dose of COVID-19 mRNA vaccine one day prior to presenting symptoms of acute paralysis of the lower extremity, sensory loss from chest down with overflow incontinence. A clinical diagnosis of myelopathy was supported by MRI of the spine illustrating enhancing lesions from C7-T7 concerning for LETM.Results: A 5-day course of pulsed methylprednisolone followed by therapeutic plasma exchange for 3â€‰days resulted in only minimal improvement in the neurologic exam with increased strength in his lower extremities while the sensory level remained unchanged.Conclusions: This case demonstrates the complication and symptomatology of TM in the setting of anti-PD-L1 monoclonal antibody with coincidental COVID-19 mRNA vaccine administration. The causal relationship between the vaccine and LETM is difficult to establish. However, the presence of a known inciting factor hints at a possible exaggeration of the existing neuro-inflammatory process.

COVID-19 vaccine side effects among nursing home residents and staff.

Bilateral facial palsy after COVID-19 vaccination. Guillain-BarrÃ¨ syndrome (GBS) is an acute immune-mediated neuropathy, possibly triggered by a recent infection or vaccination, and driven by an immune attack targeting the peripheral nervous system. GBS typically leads to ascending limb weakness, often with sensory and cranial nerve involvement 1-2Â weeks after immune stimulation, but emergency and neurology physicians should be aware of its important clinical heterogeneity. In rare cases, bilateral facial nerve palsy can be the main clinical manifestation, as the case of the variant formerly known as bilateral facial weakness with paresthesias. An increasing number of case reports of GBS in patients receiving COVID-19 vaccination have been reported both during the pre-clinical phase and after large-scale authorities' approval. We report two cases of bifacial palsy with paresthesias, a rare variant of GBS, both occurring after the first dose of COVID-19 vaccine Vaxzevriaâ„¢ (formerly COVID-19 vaccine AstraZeneca), showing a favorable outcome after high-dose immunoglobulin therapy, and discuss the literature of GBS post-COVID-19 vaccination.

Factors Associated With Severity of COVID-19 Disease in a Multicenter Cohort of People With HIV in the United States, March-December 2020. BACKGROUND: Understanding the spectrum of COVID-19 in people with HIV (PWH) is critical to provide clinical guidance and risk reduction strategies. SETTING: Centers for AIDS Research Network of Integrated Clinic System, a US multisite clinical cohort of PWH in care. METHODS: We identified COVID-19 cases and severity (hospitalization, intensive care, and death) in a large, diverse HIV cohort during March 1, 2020-December 31, 2020. We determined predictors and relative risks of hospitalization among PWH with COVID-19, adjusted for disease risk scores. RESULTS: Of 16,056 PWH in care, 649 were diagnosed with COVID-19 between March and December 2020. Case fatality was 2%; 106 (16.3%) were hospitalized, and 12 died. PWH with current CD4 count <350 cells/mm 3 [aRR 2.68; 95% confidence interval (CI): 1.93 to 3.71; P < 0.001] or lowest recorded CD4 count <200 cells/mm 3 (aRR 1.67; 95% CI: 1.18 to 2.36; P < 0.005) had greater risks of hospitalization. HIV viral load and antiretroviral therapy status were not associated with hospitalization, although most of the PWH were suppressed (86%). Black PWH were 51% more likely to be hospitalized with COVID-19 compared with other racial/ethnic groups (aRR 1.51; 95% CI: 1.04 to 2.19; P = 0.03). Chronic kidney disease, chronic obstructive pulmonary disease, diabetes, hypertension, obesity, and increased cardiovascular and hepatic fibrosis risk scores were associated with higher hospitalization risk. PWH who were older, not on antiretroviral therapy, and with current CD4 count <350 cells/mm 3 , diabetes, and chronic kidney disease were overrepresented among PWH who required intubation or died. CONCLUSIONS: PWH with CD4 count <350 cells/mm 3 , and a history of CD4 count <200 cells/mm 3 , have a clear excess risk of severe COVID-19, accounting for comorbidities associated with severe outcomes. PWH with these risk factors should be prioritized for COVID-19 vaccination and early treatment and monitored closely for worsening illness.

Absence of SARS-CoV-2 Spike glycoprotein expression in placentas from individuals after mRNA SARS-CoV-2 vaccination. Current public health initiatives to contain the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) global pandemic focus on expanding vaccination efforts to include vulnerable populations such as pregnant people. Vaccines using messenger ribonucleic acid (mRNA) technology rely on translation by immune cells, primarily at the injection site. Hesitancy remains among the general population regarding the safety of mRNA vaccines during gestation, and it remains unknown whether the SARS-CoV-2 Spike protein (the product of mRNA vaccines available) accumulates in the placenta after vaccination. Objective: To determine whether Spike protein translation and accumulation occurs in placental tissue in the context of recent mRNA SARC-CoV-2 vaccination during pregnancy. We identified 48 patients receiving one or two doses of mRNA SARS-CoV-2 vaccine during gestation and used immunohistochemistry against SARS-CoV-2 Spike protein in formalin-fixed, paraffin-embedded placental tissue. One placenta, positive for SARS-CoV-2 RNA by in situ hybridization (ISH) was used as positive control. Seven term placentas collected prior to the emergence of SARS-CoV-2 served as negative controls. Eighty one percent of patients in the study group underwent third-trimester delivery; remaining had a first-trimester spontaneous abortion or elective second-trimester termination. Patients received two (52%) or one (48%) vaccine doses during pregnancy, with a median interval between latest dose and delivery of 13 days (range 2-79 days). Most (63%) cases had their latest dose within 15 days prior to delivery. All the placentas in the study and negative control groups were negative for SARS-CoV-2 immunohistochemistry. Six study cases with short vaccine-delivery intervals (2-7 days) were subjected to SARS-CoV-2 ISH and were negative. Our findings suggest that mRNA vaccines do not reach significant concentrations in the placenta given the absence of definitive SARS-CoV-2 Spike protein accumulation in placental tissue. This observation provides evidence supporting the safety of mRNA vaccines to the placental-fetal unit.

Adverse reactions to the first and second doses of Pfizer-BioNTech COVID-19 vaccine among healthcare workers. INTRODUCTION: In the current coronavirus infection 2019 (COVID-19) pandemic, the messenger RNA vaccines have been shown to help protect high-risk groups from COVID-19. Among healthcare workers vaccinated with Pfizer-BioNTech COVID-19 vaccine, a survey was conducted to analyze the relationship between the incidence and severity of adverse reactions after vaccination. METHODS: We conducted a prospective self-reported survey of adverse reactions among healthcare workers vaccinated with the Pfizer-BioNTech COVID-19 vaccine (ComirnatyÂ®) in Japan. After the first and second dose of vaccine, local and systemic reactions for 8 days after vaccination were reported by volunteer participants using a website. After receiving vaccination, 374 respondents participated in this matched-pair study. RESULTS: Both the incidence and severity of adverse reactions tended to be higher after the second vaccine dose than after the first dose. However, the incidence and numeric rating scale (NRS) score of muscle and skin pain were nearly the same after the first and second doses. In a comparison by sex, women had significantly higher incidence and NRS scores for adverse reactions such as headache, skin pain, erythema, and itching. The results also showed that younger age groups had higher incidence rates and NRS scores for all adverse reactions investigated, except for muscle pain, compared with older age groups. CONCLUSION: Some adverse reactions to the Pfizer-BioNTech ComirnatyÂ® COVID-19 vaccine showed gender and age differences. However, generally speaking, all side reactions disappear within a week. Therefore, these side reactions are not a significant concern in recommending vaccination.

Reply letter to the editor concerning the article 'Safety of Sars-Cov-2 vaccines administration for adult patients with hereditary fructose intolerance'. According to the current European medicines legislation, on the labeling is mandatory a warning contraindicating for hereditary fructose intolerance (HFI) patients medicines with oral or parenteral fructose and sorbitol, and oral sucrose, invert sugar, isomaltitol, lactitol and maltitol, but parenteral sucrose is not mentioned. Intravenous

administration of sucrose does not increase blood glucose concentrations, because sucrose is poorly oxidized to CO(2) and mainly excreted in the urine as a disaccharide; absence of enzimatic activity outside the gut explains why there is not a warning for parenteral sucrose presentations. For this reason, parenteral drugs with sucrose are allowed in HFI patients. Nevertheless, due to interindividual variability and the fact that not all parenterally administered sucrose is recovered in urine, HFI patients need to be closely monitored after parenteral administration of sucrose-containing drugs, especially when the amount exceeds the maximum permissible thresholds.

Vaccine based on folded receptor binding domain-PreS fusion protein with potential to induce sterilizing immunity to SARS-CoV-2 variants. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is responsible for the ongoing global COVID-19 pandemic. One possibility to control the pandemic is to induce sterilizing immunity through the induction and maintenance of neutralizing antibodies preventing SARS-CoV-2 from entering human cells to replicate in. METHODS: We report the construction and in vitro and in vivo characterization of a SARS-CoV-2Â subunit vaccine (PreS-RBD) based on a structurally folded recombinant fusion protein consisting of two SARS-CoV-2 Spike protein receptor-binding domains (RBD) fused to the N- and C-terminus of hepatitis B virus (HBV) surface antigen PreS to enable the two unrelated proteins serving as immunologic carriers for each other. RESULTS: PreS-RBD, but not RBD alone, induced a robust and uniform RBD-specific IgG response in rabbits. Currently available genetic SARS-CoV-2 vaccines induce mainly transient IgG(1) responses in vaccinated subjects whereas the PreS-RBD vaccine induced RBD-specific IgG antibodies consisting of an early IgG(1) and sustained IgG(4) antibody response in a SARS-CoV-2 naive subject. PreS-RBD-specific IgG antibodies were detected in serum and mucosal secretions, reacted with SARS-CoV-2 variants, including the omicron variant of concern and the HBV receptor-binding sites on PreS of currently known HBV genotypes. PreS-RBD-specific antibodies of the immunized subject more potently inhibited the interaction of RBD with its human receptor ACE2 and their virus-neutralizing titers (VNTs) were higher than median VNTs in a random sample of healthy subjects fully immunized with registered SARS-CoV-2 vaccines or in COVID-19 convalescent subjects. CONCLUSION: The PreS-RBD vaccine has the potential to serve as a combination vaccine for inducing sterilizing immunity against SARS-CoV-2 and HBV by stopping viral replication through the inhibition of cellular virus entry.

Extensive cutaneous leukocytoclastic vasculitis after Sinopharm vaccine: Case report and review of the literature. Cutaneous leukocytoclastic vasculitis (LCV) has been reported as a rare form of cutaneous reaction to different SARS-Cov-2 vaccines. Herein, we present the first case of cutaneous LCV following BBIBP-CorV (Sinopharm) vaccine that occurred in a female patient with no prior comorbidities. A literature review about similar cases following different COVID-19 vaccines is discussed.

Analysis of clinical enquiries received by five COVID-19 vaccination centres in the UK. The aim of this study was to explore the nature of clinical enquiries received by UK vaccination centres during the early stages in the roll-out of the COVID-19 vaccination programme. Four centres were situated in acute hospitals and one centre was in a designated public site. Data were collected for eight consecutive weeks between January and February 2021. The hospital centres administered a total of 28â€‰995 doses of the Pfizer BioNTech vaccine, receiving 806 enquiries (1 enquiry per 36 vaccinations, 2.7%). The public centre administered 29â€‰167 doses of AstraZeneca vaccine, receiving 439 enquiries (1 enquiry per 66 vaccinations, 1.5%). Combined enquiry rate was 2.1%. The most common enquiries were related to allergies (44%), compatibility with other medicine (22%) and immunosuppression (16%). These were the topics of clinical guidance that were subject to regular change. Public health programmes implementing novel therapies should ensure the provision of sufficient enquiry answering capacity.

Oncologist counseling practice and COVID-19 vaccination outcomes for patients with history of PEG-asparaginase hypersensitivity. Vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is an effective strategy to prevent serious coronavirus disease 2019 (COVID-19) and is important for oncology patients. mRNA-based COVID-19 vaccines are contraindicated in those with a history of severe or immediate allergy to any vaccine component, including polyethylene glycol (PEG)2000. Patients with acute lymphoblastic leukemia/lymphoma receive asparaginase conjugated to PEG5000 (PEG-ASNase) and those with PEG-ASNase-associated hypersensitivity may be unnecessarily excluded from receiving mRNA COVID-19 vaccines. We, therefore, surveyed oncologists on COVID-19 vaccine counseling practice and vaccination outcomes in COVID-19 vaccination-eligible patients and show safe receipt of mRNA vaccines despite PEG-ASNase hypersensitivity.
Survival study and factors associated with mortality in Chilean patients on peritoneal dialysis infected with SARS-CoV-2. The Covid-19 pandemic has been responsible for millions of deaths worldwide. Patients with comorbidities- such as those on peritoneal dialysis (PD)- present higher morbidity and mortality than the general population. We prospectively evaluated all Chilean patients on PD (48 centres) and followed those who had Covid-19 from the beginning of the Covid-19 pandemic in Chile (March 2020) to January 2021 (start of vaccination campaign). We described demographic history, comorbidities, factors related to infection, need for hospitalisation and death due to Covid-19. During the study period, 106 adults on PD were infected by SARS-CoV-2, with a mean age of 53.1 (Â±16.3) and of which 53.9% were female. From that group, 54.8% required hospitalisation and 24.5% (n = 26) died due to Covid-19. Most of the patients (63.4%) were infected at home and 22.8% during hospitalisation for other reasons. There was a significant association for Covid-19 mortality with: being â‰¥60 years old, diabetes, time on PD â‰¥5 years, need for hospitalisation and hospital-acquired infection. At 90 days of follow-up, all deaths associated to Covid-19 occurred before 40 days. We conclude that patients on PD without Covid-19 vaccination have a high mortality and need for hospitalisation associated to Covid-19. To avoid this negative outcome, it is necessary to intensify strategies to avoid contagion, especially in those â‰¥60 years old, with diabetes and/or â‰¥5 years spent on PD.
Commentary on 'Psoriasis flare-up associated with second dose of Pfizer-BioNTech BNT16B2b2 COVID-19 mRNA vaccine'.
Refractory hypereosinophilia associated with newly diagnosed rheumatoid arthritis following inactivated BBV152 COVID-19 vaccine.
IgA nephropathy following COVID-19 vaccination: challenges and perspectives.
Two patients presenting IgA nephropathy after COVID-19 vaccination during a follow-up for asymptomatic hematuria.
Rare cutaneous reactions after ChAdOx1 (Oxford-AstraZeneca) vaccine: 12 case series from Brazil.
De novo annular pustular psoriasis following mRNA COVID-19 vaccine.
Long-term antibody response following COVID-19 vaccination in patients receiving peritoneal dialysis.
Thyroid dysfunction following vaccination with COVID-19 vaccines: a basic review of the preliminary evidence. PURPOSE: The safety and efficacy of the several types of COVID-19 vaccines, including mRNA-based, viral vector-based, and inactivated vaccines, have been approved by WHO. The vaccines can confer protection against severe SARS-CoV-2 infection through induction of the anti-spike protein neutralizing antibodies. However, SARS-CoV-2 vaccines have been associated with very rare complications, such as thyroid disorders. This review was conducted to highlight main features of thyroid abnormalities following COVID-19 vaccination. METHODS: A comprehensive search within electronic databases was performed to collect reports of thyroid disorders after vaccination with COVID-19 vaccines. RESULTS: Among 83 reported cases including in this review, the most cases of

thyroid abnormalities were observed after vaccination with mRNA-based vaccines (68.7%), followed by viral vector vaccines (15.7%) and 14.5% cases following inactivated vaccines. Subacute thyroiditis (SAT) was the most common COVID-19 vaccination-related thyroid disease, accounting for 60.2% of all cases, followed by Graves' disease (GD) with 25.3%. Moreover, some cases with focal painful thyroiditis (3.6%), silent thyroiditis (3.6%), concurrent GD and SAT (2.4%), thyroid eye disease (1.2%), overt hypothyroidism (1.2%), atypical subacute thyroiditis (1.2%), and painless thyroiditis with TPP (1.2%) were also reported. Overall, in 58.0% of SAT cases and in 61.9% of GD cases, the onset of the symptoms occurred following the first vaccine dose with a median of 10.0 days (ranged: 3-21 days) and 10.0 days (ranged: 1-60 days) after vaccination, respectively. Moreover, 40.0% of SAT patients and 38.1% of GD patients developed the symptoms after the second dose with a median of 10.5 days (ranged: 0.5-37 days) and 14.0 days (ranged: 2-35 days) after vaccination, respectively. CONCLUSION: Fortunately, almost all cases with COVID-19 vaccination-associated thyroid dysfunctions had a favorable outcome following therapy. The benefits of COVID-19 vaccinations in terms of terminating the pandemic and/or reducing mortality rates can exceed any risk of infrequent complications such as a transient thyroid malfunction.

Humoral Response to the Third Dose of Sars-Cov-2 Vaccine in Kidney Transplant Recipients. BACKGROUND: Most solid organ transplant recipients did not develop an appreciable serologic response after 2 doses of the mRNA SARS-CoV-2 vaccine. METHODS: We analyzed the humoral response after a third dose of the BNT162b2 vaccine in 130 kidney transplant recipients, compared to 48 health care workers, and associated factors, including prevaccine cellular immune response, by evaluating intracellular cytokine production after stimulation of donor's peripheral blood mononuclear cells. RESULTS: After 2 doses, most of the controls (47 out of 48, 98%) and only 40% of kidney recipients (52 of 130) kidney recipients were seropositive ($P < .001$). Most seronegative recipients developed a serologic response after the booster (47 out 78, 60%), thus bringing the total number of seropositive recipients to 99 out of 130 (76%). After the third dose, there was a significant increase in antibodies titers in both groups. Decreased humoral response was significantly associated with an older age, lower lymphocyte count, and a lower level of antibodies before booster administration. CD4(+)TNFÎ±(+) and CD4(+)INFÎ³(+) were correlated with mean increase in antibody titers. CONCLUSIONS: A third dose of the BNT162b2 mRNA vaccine in kidney recipients is safe and effectively results in increased IgG anti-S levels, including in individuals who were seronegative after 2 doses. Long-term studies of the length of the immune response and protection are required.

An Electronic Evaluation of Symptoms in People of India Post-COVID-19 Vaccination. BACKGROUND: Remarkable and groundbreaking performances of scientists all over the globe have led to the evolution of COVID-19 vaccines, which are extensively viewed as means to control the epidemic. The primary purpose of this research work was to discover the major side effects of the vaccines, mainly in Homo sapiens. METHODS: An online survey was conducted in various cities of Haryana, India, using a trial version of QualtricsCoreXM software to prototype 20 questionnaires. RESULTS: In the survey, 200 candidates participated, among which 83.5% had received Covishield and 16.5% had been vaccinated with Covaxin. Overall 65% of respondents have reported side effects. The major side effects reported were fever, tiredness, myalgia, diarrhea, headache, etc. Conclusion: Succeeding the survey related to the effects of COVID-19 vaccine on non-identical Homo sapiens, generally with respect to their perspective regarding the symptoms of vaccine, both the vaccines were found to have mild side effects which could be easily managed.

A Case of Systemic Capillary Leak Syndrome With Severe Cardiac Dysfunction After mRNA Vaccination for COVID-19. A 53-year-old woman with no significant medical history developed cardiogenic shock 4 days after receiving the second dose of the COVID-19 mRNA vaccine (BNT162b2, Pfizer/BioNtech). The patient required extracorporeal membrane oxygenation and an Impella device.

Based on significant hemoconcentration, decreased plasma protein levels, and pathologic findings in myocardial specimens, the patient was diagnosed with vaccination-induced fulminant systemic capillary leak syndrome (SCLS) with severe cardiac dysfunction. This case highlights that SCLS can occur after COVID-19 mRNA vaccination and may be associated with cardiac dysfunction. In patients with cardiogenic shock, hemoconcentration, and hypoalbuminemia after vaccination, SCLS should be considered.
The prevalence of inverse health consequences of COVID-19 vaccines: A post-vaccination study. BACKGROUND: COVID-19 vaccinations are intended to help produce neutralizing antibodies which target surface spike protein to combat the SARS-Cov-2 virus. Similarly, COVID-19 recovered patients exhibit high levels of SARS-CoV-2 neutralizing antibodies, which predominantly target the surface spike protein and are associated with the occurrence of health consequences in survivors. OBJECTIVE: The aim of the study is to explore the long-term health consequences of the COVID-19 vaccines. METHODOLOGY: A prospective, exploratory observational study conducted both online and offline using various questionnaires with all immunized individuals who had been inoculated for at least a month following their last COVID-19 vaccine either AZD1222Â® or BBV152Â® vaccines. RESULTS: We evaluated 258 individuals who had taken the COVID vaccine and found that females made up the majority (54.3%) and that the mean age was 24â€¯years. Post-vaccination long-term health issues were reported by 36.05% (93) of the participants, with 37.86% (53) of females and 33.9% (40) of males (pâ€¯=â€¯0.292). Myalgia was reported by 20.15% (52), fatigue was 13.95% (36), paresthesia was 1.16% (3), ageusia was 0.77% (2), sadness/irritability was 2.31% (6), and lack of concentration/excessive worry was 3.1% (8). CONCLUSIONS: Myalgia, fatigue, paresthesia, ageusia, coughs and colds, dyspnea, sadness/irritability, and lack of concentration/excessive worry are health consequences related to the COVID-19 vaccination which follow a similar pattern of post-COVID syndrome.
Symmetrical drug-related intertriginous and flexural exanthema-like eruption after COVID-19 vaccine.
Antibody response to the messenger RNA-1273 vaccine (Moderna) in liver transplant recipients. Different reports have shown the clinical and serologic response to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) messenger RNA (mRNA) vaccines in preventing coronavirus disease 2019 (COVID-19) in the general population, but few studies have examined these responses in transplant recipients. We assessed the vaccine immunogenicity of two doses (100 Î¼g) of the mRNA-1273 vaccine (Moderna) administered with a 28-day interval in liver transplant recipients (LTRs) at follow-up at the Marques de Valdecilla University Hospital. LTRs without a history of COVID-19 infection were tested for SARS-CoV-2 immunoglobulin G (IgG) antibodies directed against the spike protein (S) a median of 43 days after receiving the second Moderna vaccine dose. Clinical data, including immunosuppressive regimen and routine laboratory data, were obtained from the medical record of each patient up to 3 months before the date of the first vaccination. Factors associated with serologic response were evaluated through logistic regression. In total, 129 LTRs who had anti-S results were included. Most patients were men (n = 99; 76.7%) with a median age of 63 years (interquartile range, 56-68). Alcohol (43.4%) and chronic hepatitis C (18.6%) were the most frequent causes of liver transplantation. A positive anti-S IgG response was observed in 113 LTRs (87.6%; 95% confidence interval [CI], 80.8-92.2). A strong inverse relationship between mycophenolate mofetil use and serologic response was found (odds ratio, 0.07; 95% CI, 0.02-0.26; p = 0.001). Conclusion: Most LTRs develop an immunological response to the Moderna SARS-CoV-2 mRNA-based vaccine. An immunosuppressive regimen that includes mycophenolate predicts a weak serologic response.
Advanced cardiac MRI to detect myocarditis after COVID-19 vaccination in a 22-year-old man.
Post-COVID-19 syndrome and humoral response association after 1Â year in vaccinated and unvaccinated patients. OBJECTIVES: This study aimed to describe the impact of vaccination and

the role of humoral responses on post-COVID-19 syndrome 1Â year after the onset of SARS coronavirus type 2 (CoV-2). METHODS: This prospective study was conducted through interviews to investigate post-COVID-19 syndrome 6 and 12Â months after disease onset in all adult in- and outpatients with COVID-19 at Udine Hospital (March-May 2020). Vaccination status and two different serological assays to distinguish between response to vaccination (receptor-binding domain (RBD) SARS-CoV-2 IgG) and/or natural infection (non-RBD-SARS-CoV-2 IgG) were also assessed. RESULTS: A total of 479 patients (52.6% female; mean age: 53Â years) were interviewed 13.5Â months (standard deviation: 0.6Â months) after acute infection. Post-COVID-19 syndrome was observed in 47.2% of patients (nÂ =Â 226) after 1Â year. There were no significant differences in the worsening of post-COVID-19 symptoms (22.7% vs. 15.8%; pÂ =Â 0.209) among vaccinated (nÂ =Â 132) and unvaccinated (nÂ =Â 347) patients. The presence of non-RBD SARS-CoV-2 IgG induced by natural infection showed a significant association with post-COVID-19 syndrome (OR: 1.35; 95% CI, 1.11-1.64; pÂ =Â 0.003), and median non-RBD SARS-CoV-2 IgG titres were significantly higher in long haulers than in patients without symptoms (22 kAU/L (interquartile range, 9.7-37.2 kAU/L) vs. 14.1 kAU/L (interquartile range, 5.4-31.3 kAU/L); pÂ =Â 0.009) after 1Â year. In contrast, the presence of RBD SARS-CoV-2 IgG was not associated with the occurrence of post-COVID-19 syndrome (>2500 U/mL vs. 0.9-2500 U/mL; OR: 1.36; 95% CI, 0.62-3.00; pÂ =Â 0.441), and RBD SARS-CoV-2 IgG titres were similar in long haulers as in patients without symptoms (50% valuesÂ >Â 2500 U/mL vs. 55.6% valuesÂ >Â 2500 U/mL; pÂ =Â 0.451). DISCUSSION: The SARS-CoV-2 vaccination is not associated with the emergence of post-COVID-19 symptoms more than 1Â year after acute infection. The persistence of high serological titre response induced by natural infection, but not vaccination, may play a role in long-haul COVID-19.

Disparities in co-payments for influenza vaccine among the elderly, during the COVID-19 pandemic in Japan. INTRODUCTION: Seasonal influenza vaccination for the elderly is highly recommended during the COVID-19 pandemic. In Japan, the amount of subsidy for influenza differs among municipalities. Thus, we investigated the amount of and variation in subsidy for influenza vaccination for the elderly in 2020. METHODS: This was an ecological study of 1,922 municipalities in Japan. The amount of subsidy for influenza vaccines for the elderly in each municipality was surveyed through websites or via telephone. Geographic and financial data for municipalities and prefectures were obtained from the open data. The amount of co-payment for the influenza vaccine and the geographical and financial status of each municipality were compared, according to the aging rate. Univariate logistic regression analysis was performed to explore factors related to the free influenza vaccine. RESULTS: Municipalities with higher aging rates tended to have higher median co-payments for vaccines in 2020. (0 yen vs 1000 yen, pÂ <Â 0.001) In addition, they tended to have worse financial conditions and lower per capita incomes. A similar trend was observed in the analysis by prefecture, i.e., a higher influenza mortality rate in prefectures with a higher aging rate. Despite having lower incomes, municipalities and prefectures with higher aging populations had higher mortality rates from influenza and higher co-payments for influenza vaccination. CONCLUSIONS: In Japan, there is a disparity among elderly people; areas with an aging population have higher co-payments for influenza vaccines despite lower incomes, suggesting that the government needs to implement corrective measures to reduce this disparity.

Antibody response after a booster dose of SARS-CoV-2 vaccine in liver transplant recipients and those with chronic liver diseases. INTRODUCTION AND OBJECTIVES: Lower antibody (Ab) responses after SARS-CoV-2 vaccination have been reported in liver transplant (LT) recipients and those with chronic liver diseases (CLD). The role of a booster dose in those with poor responses to initial vaccination is not well defined. METHODS: In this prospective study, we determined antibody (Ab) response to spike protein after a booster dose in LT recipients and those with chronic liver diseases (CLD) with and without cirrhosis after they had a poor response to an initial standard regimen.

RESULTS: Of the 80 patients enrolled, 45 had LT, and 35 had CLD (18 with cirrhosis). A booster dose was given at a median of 138.5 days after the completion of the standard regimen. After the booster dose, 58 (73%, 31 LT, 27 CLD) had good response (â‰¥250 U/mL), and 22 (28%, 14 LT, and 8 CLD) had poor response (7 undetectable and 15 with low Ab levels). No patient had any serious adverse events. The antibody responses were lower in those who had undetectable Ab (80 U/mL) than those who had low levels of Ab (0.80-249 U/mL) after the standard vaccination regimen (42% vs. 87%, p=0.0001). The antibody responses after homologous and heterologous booster doses were similar. CONCLUSIONS: We have shown that a booster dose will enhance Ab responses in LT recipients and those with CLD who had poor responses after an initial vaccine regimen.

Concurrent outbreaks of circulating vaccine-derived poliovirus types 1 and 2 affecting the Republic of the Philippines and Malaysia, 2019-2021. Concurrent outbreaks of circulating vaccine-derived poliovirus serotypes 1 and 2 (cVDPV1, cVDPV2) were confirmed in the Republic of the Philippines in September 2019 and were subsequently confirmed in Malaysia by early 2020. There is continuous population subgroup movement in specific geographies between the two countries. Outbreak response efforts focused on sequential supplemental immunization activities with monovalent Sabin strain oral poliovirus vaccine type 2 (mOPV2) and bivalent oral poliovirus vaccines (bOPV, containing Sabin strain types 1 and 3) as well as activities to enhance poliovirus surveillance sensitivity to detect virus circulation. A total of six cVDPV1 cases, 13 cVDPV2 cases, and one immunodeficiency-associated vaccine-derived poliovirus type 2 case were detected, and there were 35 cVDPV1 and 31 cVDPV2 isolates from environmental surveillance sewage collection sites. No further cVDPV1 or cVDPV2 have been detected in either country since March 2020. Response efforts in both countries encountered challenges, particularly those caused by the global COVID-19 pandemic. Important lessons were identified and could be useful for other countries that experience outbreaks of concurrent cVDPV serotypes.

Neurological and neuropsychological adverse effects of SARS-CoV-2 vaccinesÂ - where do we stand? The devastating characteristic of COVID-19 pandemic calls for immediate and effective solutions to tackle it. Vaccines seem to be the only promising and effective way to fight against the novel coronavirusÂ - even against new mutated variants. Because of the rapid development and distribution of numerous COVID-19 vaccines in different platforms, meticulous evaluation of vaccines' safety is more critical than everÂ - especially given the fact that most of the candidates have not completed the clinical phase. Therefore, to optimize the vaccines' safety and efficacy, it is highly important to carefully report and scientifically discuss the serious adverse effects following vaccination. In this respect, we discuss different neurological and neuropsychological adverse effects of COVID-19 vaccines including demyelinating diseases, Bell's palsy (BP), cerebrovascular complications, seizures, functional neurological disorders (FNDs), and some other rare adverse events, and hypothetical mechanisms which can lead to the reported side effects. Given the fact that the incidence of such events are rare and most of them are treatable, the current review aims to shed light on how much the relationship between COVID-19 vaccines and these complications can be reliable and provide an insight for future studies with much more meticulous methodologies to discuss the possible correlational or causal relationship between these complications and COVID-19 vaccines and elucidate whether or not the neurological side effects of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines can count as a considerable threat to public health.

Comparisons of the risk of myopericarditis between COVID-19 patients and individuals receiving COVID-19 vaccines: a population-based study. BACKGROUND: Both COVID-19 infection and COVID-19 vaccines have been associated with the development of myopericarditis. The objective of this study is to (1) analyse the rates of myopericarditis after COVID-19 infection and COVID-19 vaccination in Hong Kong, (2) compared to the background rates, and (3) compare the rates of

myopericarditis after COVID-19 vaccination to those reported in other countries. METHODS: This was a population-based cohort study from Hong Kong, China. Patients with positive RT-PCR test for COVID-19 between 1st January 2020 and 30th June 2021 or individuals who received COVID-19 vaccination until 31st August were included. The main exposures were COVID-19 positivity or COVID-19 vaccination. The primary outcome was myopericarditis. RESULTS: This study included 11,441 COVID-19 patients from Hong Kong, four of whom suffered from myopericarditis (rate per million: 326; 95% confidence interval [CI] 127-838). The rate was higher than the pre-COVID-19 background rate in 2019 (rate per million: 5.5, 95% CI 4.1-7.4) with a rate ratio of 55.0 (95% CI 21.4-141). Compared to the background rate, the rate of myopericarditis among vaccinated subjects in Hong Kong was similar (rate per million: 5.5; 95% CI 4.1-7.4) with a rate ratio of 0.93 (95% CI 0.69-1.26). The rates of myocarditis after vaccination in Hong Kong were comparable to those vaccinated in the United States, Israel, and the United Kingdom. CONCLUSIONS: COVID-19 infection was associated with significantly higher rate of myopericarditis compared to the vaccine-associated myopericarditis.

The association between adverse reactions and immune response against SARS-CoV-2 spike protein after vaccination with BNT162b2 among healthcare workers in a single healthcare system: a prospective observational cohort study. Adverse reactions after vaccination with COVID-19 mRNA vaccines are common; however, the association between adverse reactions and humoral responses is uncertain. To determine whether humoral immune responses after BNT162b2 vaccine administration were associated with local and systemic adverse reactions, we conducted a prospective observational cohort study in a single tertiary referral center. Healthcare workers who received the first dose of BNT162b2 vaccine were recruited. SARS-CoV-2 anti-spike IgG antibody titers were measured three weeks after the second dose and information about adverse reactions after vaccination was collected. Among the 887 participants, 641 (72.3%) were women. The median age was 38 (range, 22-74) years. All but one showed anti-spike IgG levels well above the cutoff, with a median level of 13,600 arbitrary units/mL. Overall, 800 (92.2%) participants reported some reactions after the first dose and 822 (96.3%) after the second dose. Significantly more participants reported systemic reactions after the second dose than after the first dose (Pâ€‰<â€‰.01), and 625 (73.6%) reported that reactions were stronger after the second dose. Factors positively associated with elevation of anti-spike IgG levels were history of asthma (24% higher if present, Pâ€‰=â€‰.01) and stronger reactions after the second dose (19% higher if experienced, Pâ€‰=â€‰.02). The majority of participants showed good humoral responses and reported some adverse reactions after vaccination. Anti-spike IgG levels were significantly higher if adverse reactions after the second dose were stronger than those after the first dose. These findings may help inform current and future vaccine recipients.

Differential Severe Acute Respiratory Syndrome Coronavirus 2 Antibody Profiles After Allergic Reactions to Messenger RNA Coronavirus Disease 2019 Vaccine. Allergic symptoms after messenger RNA (mRNA) coronavirus disease 2019 (COVID-19) vaccines occur in up to 2% of recipients. Compared to nonallergic controls (nâ€…=â€…18), individuals with immediate allergic reactions to mRNA COVID-19 vaccines (nâ€…=â€…8) mounted lower immunoglobulin G1 (IgG1) to multiple antigenic targets in severe acute respiratory syndrome coronavirus 2 spike following vaccination, with significantly lower IgG1 to full-length spike (P = .04). Individuals with immediate allergic reactions to mRNA COVID-19 vaccines bound FcÎ³ receptors similarly to nonallergic controls. Although there was a trend toward an overall reduction in opsonophagocytic function in individuals with immediate allergic reactions compared to nonallergic controls, allergic patients produced functional antibodies exhibiting a high ratio of opsonophagocytic function to IgG1 titer.

Immune Response After a Third Dose of the mRNA-1273 SARS-CoV-2 Vaccine in Liver Transplant Recipients.

Clozapine and COVID-19 Vaccination: Effects on blood levels and leukocytes. An observational cohort study. OBJECTIVE: To investigate the safety of COVID-19 vaccination in patients on clozapine as regards plasma clozapine concentration and haematological parameters. METHODS: We conducted a multicentre observational cohort study from 22 February 2021 to 2 September 2021. Primary outcomes were clinically relevant increase in clozapine blood levels (>100Â Î¼g/L increase compared to baseline) and clozapine alert levels (>1000Â Î¼g/L). Secondary outcomes were granulocytopenia, leukocytopenia and lymphocytopenia. Outcomes were measured approximately 5Â days after the first and (where applicable) second dose of COVID-19 vaccine. RESULTS: This study included 139 patients. Compared to baseline, clozapine blood levels increased significantly (ESÂ =Â 0.28, pÂ =Â 0.003) after the second vaccination. Clinically relevant increases in clozapine blood levels occurred in 20/92 patients (22%) and in 16/56 patients (29%) during the first and second phases, respectively. Clozapine alert levels developed in one patient (1%) following the first dose and in three patients (5%) after the second dose. In both phases, changes in white blood cells (WBC) were limited to mild granulocytopenia (3% and 5%), moderate granulocytopenia (1% and 0%) and leukocytopenia (2% and 3%) without cause for extra monitoring according to the guideline. CONCLUSION: In general, as regards WBC counts COVID-19 vaccination seems to be safe in patients with SMI. Changes in WBC had no clinical implications. Psychoeducation on the symptoms of clozapine intoxication is recommended, especially in patients with clozapine blood levels approaching the upper limit of the therapeutic range. Increase in the C-reactive protein (CRP) level can signal inflammation rapidly and help to prevent clozapine intoxication following vaccination.

A case of acquired hemophilia A and bullous pemphigoid following SARS-CoV-2 mRNA vaccination. Acquired hemophilia is a rare disease resulting from autoantibodies against endogenous factor VIII (FVIII), which associates with bleeding and a high mortality rate. The pathophysiology is still unclear. Recent studies suggest genetic and environmental factors trigger the breakdown of immune tolerance. We report a 77-year-old Taiwanese man presented with multiple ecchymoses and some hemorrhagic blisters three weeks after SARS-CoV-2 mRNA (Moderna) vaccination. Isolated activated partial thromboplastin time (aPTT) prolongation was found. Acquired hemophilia A (AHA) was confirmed by low factor VIII (FVIII) activity and high titer of FVIII inhibitor. The pathohistology of skin biopsy further supported the concomitant diagnosis of bullous pemphigoid. To date, 6 cases of acquired hemophilia A following SARS-CoV-2 mRNA vaccination were reported worldwide. We reviewed and summarized the characteristics of these cases. We also discussed the rare finding of concomitant acquired hemophilia A and bullous pemphigoid. Bullous pemphigoid results from autoantibody against epithelial basement membrane zone of skin. In this article, we proposed possibility of SARS-CoV-2 mRNA vaccine associated autoimmunity against FVIII and epithelial basement membrane zone.

To aspirate or not to aspirate? Considerations for the COVID-19 vaccines. Syringe aspiration when vaccinating intramuscularly was not recommended before the pandemic due to the lack of conclusive evidence that it provides any benefit. However, in vivo evidence suggests that intravenous injection of mRNA vaccine canÂ potentially lead to myocarditis, while introducing adenoviral vector to bloodstream can possiblyÂ result in thrombocytopenia and coagulopathy. These rare reactions were recorded in humans following the administration of the COVID-19 vaccines. Although the syringe aspiration may increase the level of pain at the injection site, it represents a simple technique to decrease the risk of vaccine introduction into the vascular system and potentially decrease the risk of severe reactions to mRNA and adenoviral vaccines. We are of the opinion that this cannot be disregarded if one considers that the COVID-19 vaccines will continue to be administrated globally in the form of initial and booster doses. Therefore, the aspiration when giving mRNA and adenoviral vaccines appears to be fully in line with the precautionary principle.

CMR Imaging 6 Months After Myocarditis Associated with the BNT162b2 mRNA COVID-19 Vaccine. Temporal association between BNT162b2 mRNA COVID-19 vaccine and myocarditis (PCVM) has been reported. We herein present early and 6-month clinical follow-up and cardiac magnetic resonance imaging (CMR) of patients with PVCM. A retrospective collection of data from 15 patients with PCVM and abnormal CMR was performed. Clinical manifestation, laboratory data, hospitalizations, treatment protocols, and imaging studies were collected early (up to 2Â months) and later. In nine patients, an additional CMR evaluation was performed 6Â months after diagnosis. PCVM was diagnosed in 15 patients, mean age 17â€‰Â±â€‰1 (median 17.2, range 14.9-19 years) years, predominantly in males. Mean time from vaccination to onset of symptoms was 4.4â€‰Â±â€‰6.7 (median 3, range 0-28) days. All patients had CMR post diagnosis at 4â€‰Â±â€‰3 (median 3, range 1-9) weeks, 4/5 patients had hyper enhancement on the T2 sequences representing edemaQuery, and 12 pathological Late glandolinium enhancement. A repeat scan performed after 5-6Â months was positive for scar formation in 7/9 patients. PCVM is a rare complication, affecting predominantly males and appearing usually within the first week after administration of the second dose of the vaccine. It usually is a mild disease, with clinical resolution with anti-inflammatory treatment. Late CMR follow up demonstrated resolution of the edema in all patients, while some had evidence of residual myocardial scarring.

Subacute Thyroiditis Following SARS-CoV-2 Vaccines: Six Cases Report and Review of the Literature. Subacute thyroiditis (SAT) is an inflammatory disease of the thyroid that develops following viral upper respiratory tract infections. SARS-CoV-2 virus, the cause of COVID-19, binds to the Angiotensin-Converting Enzyme-2 (ACE2) molecule expressed on the target cell surface. Thyroid gland shows high levels of ACE2 expression. The cases of SARS-CoV-2-related subacute thyroiditis and Graves' disease have been reported. It has recently been noted that vaccines for SARS-CoV-2 also induce autoimmune and inflammatory reactions. We present six (4 male, 2 female) cases of SAT that developed after mRNA and inactivated SARS-CoV-2 vaccines. And we have reviewed the literature. SAT was seen in 5 patients after mRNA vaccine, in one after inactivated vaccine. Their clinic and laboratory findings suggested to SAT. They were treated with nonsteroid anti-inflamatory drugs and/or methylprednisolone.They recovered within few weeks. Out patients did not have permanent hypothyroidism after SAT. The history of SARS-CoV-2 vaccination should be questioned in patients with subacute thyroiditis in pandemic days.

Anti-SARS-Cov2 vaccination at the time of the COVID-19 pandemic: suspected adverse events reporting is the milestone of post-marketing surveillance.

Frozen shoulder after COVID-19 vaccination. BACKGROUND: The data on frozen shoulder and shoulder injury related to vaccine administration (SIRVA) after coronavirus disease 2019 (COVID-19) vaccination are absent from the literature. Hence, the purpose of this case series was to describe the clinical presentation and short-term follow-up of patients who developed frozen shoulder after COVID-19 vaccination. METHODS: In the present study, 10 patients (9 women and 1 man) with a mean age of 53Â Â±Â 8 years (range, 43-68 years) who presented to the shoulder surgeon's practice center with painful stiffness of the shoulder after COVID-19 vaccination between June 1 and September 30, 2021, were retrospectively evaluated. RESULTS: All 10 patients had normal radiographs and were diagnosed as frozen shoulder. Eight patients (80%) had a comorbidity during presentation (4 patients with hypothyroidism, 3 patients with diabetes mellitus, and 1 patient with prediabetes/hyperglycemia). Symptoms developed immediately after the vaccination in 6 patients (60%), at 48 hours in 1 patient (10%), and at 10 days in 3 patients (30%). The mean pain visual analog scale score was 6.5Â Â±Â 1.9 (range, 2.5-8), and both active and passive range of motion were limited in all the patients at the time of presentation. CONCLUSION: The musculoskeletal specialists who will

see such patients with painful shoulder stiffness should be aware of the frozen shoulder diagnosis, which can occur after COVID-19 vaccination, so that such patients can be identified and treated early.
Severe Acute Respiratory Syndrome Coronavirus 2 Adaptive Immunity in Nursing Home Residents Following a Third Dose of the Comirnaty Coronavirus Disease 2019 Vaccine. A third Comirnaty vaccine dose increased severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) receptor-binding domain antibody levels (median, 93-fold) and neutralizing antibody titers against Wuhan-Hu-1 (median, 57-fold), Beta (me 22-fold), Delta, (median, 43-fold), and Omicron (median, 8-fold) variants, but had less impact on S-reactive T-cell immunity in nursing home residents.
[Survey of spike-specific immunoglobulin G antibodies at approximately 3 months and 9 months after vaccination against coronavirus disease 2019 (severe acute respiratory syndrome coronavirus-2 [SARS-CoV-2]) in health care workers]. OBJECTIVE: We investigated the antibody titer of spike-specific immunoglobulin G (IgG) antibodies after receiving coronavirus repair uridine ribonucleic acid (RNA) vaccine (BNT162b2, Pfizer) in health care workers. METHODS: At one hospital, health care workers received the vaccination between February and May 2021. A survey using questionnaires and spike-specific IgG antibody tests (Abbott) was conducted in 293 participants who had been vaccinated at least once and consented to this study at the time of medical checkups between April and May 2021. We calculated the antibody titer in each age group and days post-vaccination. We examined whether antibody titers of 4,000 AU/mL or higher (probability of high titer: approximately 95%, Abbott) were associated with adverse reactions after vaccination. In addition (1), the antibody titers at approximately 100 days after the second vaccination in 11 participants were remeasured. Furthermore (2), the antibody titers at approximately 260 days after the second vaccination in 13 participants were remeasured and compared with the initial measurements. RESULTS: Of the participants, 276 were post-2 doses (A), 14 were post-1 dose (B), and 3 discontinued the second vaccination (C) at the time of health checkup. The median antibody titer was 11,045.8 AU/mL (50.7-40,000) in group A, 122.7 AU/mL (2.6-1,127.0) in group B, 27,099.3 AU/mL in one of group C who had recovered from coronavirus disease 2019 (COVID-19), and 574.2 AU/mL (283.3 and 865.1) in the other two of group C. The median antibody titer was the highest in those in their 20s, and there was a significant difference between those under and above 40 years of age. The median titer was the highest in 2 weeks to 1 month after the second vaccination. After the second dose, fatigue (â‰¥ moderate) was associated with antibody titers of 4,000 AU/mL or higher. The antibody titers of 11 and 13 participants at approximately 100 and 260 days after the second vaccination were significantly lower than those at the first measurement, with median values of 2,838.0 AU/mL (832.9-5,698.6) and 512.0 AU/mL (154.0-1,220.0), respectively. CONCLUSIONS: Antibody titers were higher in participants under 40 years of age than those 40 years or older. In addition, the percentage of high antibody titer (â‰§ 4,000 AU/mL) was higher in those who had severe fatigue after the second vaccination. The peak of antibody titer after the second dose was approximately 1 month, and the titer may decline gradually.
Acute corneal graft rejection and COVID-19 vaccination: Correspondence.
Acute cellular rejection in liver transplantation recipients following coronavirus disease 2019 vaccination.
Acute entire colitis and vein thrombosis after COVID-19 mRNA-1273 vaccination.
Correction to: A case of severe interstitial lung disease after COVID-19 vaccination.
Recurrence of tubercular choroiditis following anti-SARS-CoV-2 vaccination. PURPOSE: To report recurrence of tubercular choroiditis following anti-SARS-CoV-2 vaccination in two patients with quiescent disease activity for more than a year. METHODS: Retrospective observational case reports. RESULTS: Two patients (one female and one male) under follow-up for posterior uveitis having stable course with absence of ocular inflammation for more than a year presented with recurrence of

choroiditis lesions 2-6 weeks following anti-SARS-CoV-2 vaccination. Both the patients were managed with intravitreal dexamethasone implant (OzurdexÂ®, Allergan, Inc., Irvine, CA, USA) and showed resolution of choroiditis lesions upon follow-up. CONCLUSIONS: Acute onset recurrence of inflammation, in absence of any change in health status or treatment suggests the potential role of vaccination being the trigger of this reactivation. Given large-scale vaccination against novel coronavirus- SARS-CoV-2, careful vigilance is warranted to pick up the disease recurrence in patients with posterior uveitis.
Ventricular tachycardia from myocarditis following COVID-19 vaccination with tozinameran (BNT162b2, Pfizer-BioNTech). To combat the coronavirus disease 2019 (COVID-19) pandemic, many countries have started population vaccination programs using messenger ribonucleic acid (mRNA) vaccines. With the widespread use of such vaccines, reports are emerging worldwide, of the vaccine's association with the development of myocarditis. Younger men are more likely to develop postvaccine myocarditis, which usually presents as self-limiting chest pain within a week after the second dose. We present a case of myocarditis following vaccination with tozinameran (BNT162b2, Pfizer-BioNTech), which presented late, with ventricular tachycardia (VT) reduced left ventricular ejection fraction (LVEF).
Inactivated SARS-CoV-2 vaccine in primary SjÃ¶gren's syndrome: humoral response, safety, and effects on disease activity. INTRODUCTION: There is no study specifically focused on SARS-CoV-2 vaccine in primary SjÃ¶gren's syndrome (pSS). OBJECTIVES: To assess the immunogenicity, safety, possible effects on disease activity, and autoantibody profile of the Sinovac-CoronaVac vaccine in pSS. METHODS: Fifty-one pSS patients and 102 sex- and age-balanced controls without autoimmune diseases were included in a prospective phase 4 trial of the Sinovac-CoronaVac vaccine (two doses 28Â days apart, D0/D28). Participants were assessed in three face-to-face visits (D0/D28 and six weeks after the 2nd dose (D69)) regarding adverse effects; clinical EULAR SjÃ¶gren's Syndrome Disease Activity Index (clinESSDAI); anti-SARS-CoV-2 S1/S2 IgG (seroconversion (SC) and geometric mean titers (GMT)); neutralizing antibodies (NAb); and pSS autoantibody profile. RESULTS: Patients and controls had comparable female sex frequency (98.0% vs. 98.0%, pâ€‰=â€‰1.000) and mean age (53.5â€‰Â±â€‰11.7 vs. 53.4â€‰Â±â€‰11.4Â years, pâ€‰=â€‰0.924), respectively. On D69, pSS patients presented moderate SC (67.5% vs. 93.0%, pâ€‰<â€‰0.001) and GMT (22.5 (95% CI 14.6-34.5) vs. 59.6 (95% CI 51.1-69.4) AU/mL, pâ€‰<â€‰0.001) of anti-SARS-CoV-2 S1/S2 IgG but lower than controls, and also, moderate NAb frequency (52.5% vs. 73.3%, pâ€‰=â€‰0.021) but lower than controls. Median neutralizing activity on D69 was comparable in pSS (58.6% (IQR 43.7-63.6)) and controls (64% (IQR 46.4-81.1)) (pâ€‰=â€‰0.219). Adverse events were mild. clinESSDAI and anti-Ro(SS-A)/anti-La(SS-B) levels were stable throughout the study (pâ€‰>â€‰0.05). CONCLUSION: Sinovac-CoronaVac vaccine is safe in pSS, without a deleterious impact on disease activity, and has a moderate short-term humoral response, though lower than controls. Thus, a booster dose needs to be studied in these patients. TRIAL REGISTRATION: ClinicalTrials.gov Identifier: NCT04754698. Key Points â€¢ Sinovac-CoronaVac vaccine is safe in pSS, without a detrimental effect on systemic disease activity, and has a moderate short-term humoral response â€¢ A booster dose should be considered in these patients.
Pituitary apoplexy and COVID-19 vaccination.
Transient inflammation in surgical scars following Covid-19 mRNA vaccination.
Covid-19 and Covid-19 vaccine can slide along sides: a report of two cases of unilateral periflexural exanthema.
Current perspectives regarding SARS-CoV-2 vaccination inÂ chronic lymphocytic leukemia. In immunocompetent people, the mRNA vaccines BNT162b2 and mRNA-1273 have been shown to be safe and effective against coronavirus disease of 2019 (COVID-19). However, results of cohort studies

and meta-analyses have indicated that the degree of humoral response to SARS-CoV-2 vaccines in patients with chronic lymphocytic leukemia (CLL) appears to be lower than that observed in the general population. These inadequate responses are mainly related to the disease itself and to the immunosuppressive effect of therapies administered. In the specific context of CLL, enrolling patients with sub-optimal vaccine-response in pivotal vaccine trials could be considered as an appropriate approach to improve response to the COVID-19 vaccine. These clinical trials should also address the issues of regularity and timing of vaccine booster doses or re-vaccinations, especially in patients undergoing therapy with pathway-targeting agents and anti-CD20 monoclonal antibodies. However, since hypogammaglobulinemia is a serious consequence of CLL, patients who do not have a detectable antibody response should be natural candidates for preventive antibody therapy.
Breakthrough SARS-CoV-2 infections after vaccination: a critical review. At the beginning of the current pandemic, it was believed that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection would induce lifelong immunity and that reinfections would be unlikely. However, after several cases of reinfection were documented in previously infected patients, this was understood to be a false assumption, and this waning humoral immunity has raised significant concerns. Accordingly, long-term and durable vaccine-induced antibody protection against infection have also become a challenge, as several breakthroughs of COVID-19 infection have been identified in individuals who were fully vaccinated. This review discusses the current evidence on breakthrough COVID-19 infections occurring after vaccination.
Macroscopic hematuria in two children with IgA nephropathy remission following Pfizer COVID-19 vaccination.
Nerve block therapy for subacute thyroiditis following COVID-19 vaccination: The first case report.
Early Efficacy and Safety of the Third Dose Inactivated COVID-19 Vaccine Among People Living With HIV.
Acute Bilateral Orbital Myositis Following Covid 19 Vaccination. The authors present a case of acute bilateral orbital myositis occurring 24Â hours after the administration of the mRNA1273 vaccination for COVID 19. The patient was presented with right proptosis, with orbital imaging demonstrating bilateral enlargement of all the extraocular muscles. Serological investigation did not reveal a precipitating cause or underlying disease process. The presenting features resolved entirely following treatment with methylprednisolone and the patient remains asymptomatic.
[Pityriasis rubra pilaris after COVID-19 vaccination: causal relationship or coincidence?]. Numerous cutaneous side effects associated with COVID-19 vaccines have been described since their clinical approval. These include, among others, injection site reactions, urticarial, maculopapular and pityriasiform rashes or temporary exacerbations of aÂ pre-existing chronic inflammatory skin disease. Herein we report about three cases of pityriasis rubra pilaris that occurred for the first time in close temporal relationship with the administration of aÂ COVID-19 vaccine.
Ultrasound Features to Differentiate COVID-19 Vaccine-Induced Benign Adenopathy from Breast Cancer Related Malignant Adenopathy. RATIONALE AND OBJECTIVE: To identify nodal features used to distinguish coronavirus disease 2019 (COVID-19) vaccine-Induced benign reactive adenopathy from malignant adenopathy. MATERIALS AND METHODS: This IRB-approved, single-institution, retrospective study compared features of 77 consecutive patients with benign adenopathy secondary to a messenger RNA COVID-19 vaccine with 76 patients with biopsy-proven malignant adenopathy from breast cancer. Patient demographics and nodal features were compared between the two groups using univariate and multivariate logistic regression models. A receiver operating characteristic analysis with the maximum value of Youden's index was performed for the cutoff value of cortical thickness for predicting nodal status. RESULTS: The mean cortical thickness was 5.1 mm Â± 2.8 mm among benign nodes and 8.9 mm Â± 4.5 mm among malignant nodes ($p < 0.001$). A cortical

thickness â‰¥3.0 mm had a sensitivity of 100% and a specificity of 21% (area under the curve [AUC]Â =Â 0.60, 95% confidence interval [CI]: 0.52-0.68). When the cutoff for cortical thickness was increased to â‰¥5.4 mm, the sensitivity decreased to 74%, while the specificity increased to 69% (AUCÂ =Â 0.77, 95% CI: 0.70-0.84).Cortical thickness correlated with nodal morphology type (r(2)Â =Â 0.57). An axillary node with generalized lobulated cortical thickening had a 7.5 odds ratio and a node with focal cortical lobulation had a 123.0 odds ratio compared to one with diffuse, uniform cortical thickening only ($p < 0.001$). CONCLUSION: Cortical thickness and morphology are predictive of malignancy. Cortical thickness cutoff of â‰¥5.4 mm demonstrates higher specificity and improved accuracy for detecting malignant adenopathy than a cutoff of â‰¥3.0 mm.

The precautionary principle in the COVID-19 vaccination campaign: The complicated relationship between the scientific community, medicines regulatory agencies and citizens.

Breast Inflammatory Change Is Transient Following COVID-19 Vaccination.

Expert Perspective: Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. The antineutrophil cytoplasmic antibody (ANCA)-associated vasculitides (AAV) comprise a major subset of diseases that cause destructive inflammation of small and medium-sized blood vessels. Although these conditions have a predilection for pulmonary and renal involvement, they are in fact protean diseases that can involve essentially any organ system. AAV is among the most difficult rheumatic diseases to diagnose and treat. Therapy for AAV has evolved over the past two decades. Rituximab, an anti-CD20 monoclonal antibody, is now the preferred agent for remission induction in conjunction with a reduced-dose glucocorticoid taper. Rituximab is also often a key therapy for remission maintenance. Glucocorticoid toxicity reduction has become a major priority for treatment regimens. Avacopan, an important new adjunct to remission induction therapy, may reduce glucocorticoid use and its resulting toxicity. The role of avacopan as a remission maintenance agent requires further study. The duration of immunosuppression following remission is guided by a number of factors, including the patient's overall clinical state, the degree of damage from previous disease activity, the tolerability of remission maintenance medications, and SARS-CoV-2 vaccination and immunity status. Certain features, including history of previous relapse, the presence of ANCA directed against proteinase 3, and a diagnosis of granulomatosis with polyangiitis, favor prolonged remission maintenance therapy. The interval between rituximab doses can usually be lengthened over time during the maintenance phase.

Editorial commentary: COVID-19 and COVID-19 vaccination: Observations on thrombosis and thrombocytopenia.

Coronavirus disease 2019 vaccine administration in patients with reported reactions to polyethylene glycol- and polysorbate-containing therapeutics. BACKGROUND: Polyethylene glycol (PEG) and polysorbate reactions were initially implicated as a likely risk factor for reacting to coronavirus disease 2019 (COVID-19) vaccines and remain a source of vaccine hesitancy despite increasing evidence that they do not pose an increased risk for COVID-19 vaccine reactions. OBJECTIVE: To investigate COVID-19 vaccine safety outcomes in patients with reported reactions to PEG- and polysorbate-containing medications and vaccines. METHODS: COVID-19 vaccine safety was reviewed in patients with PEG or polysorbate reactions documented in their electronic medical records at a tertiary academic medical center (cohort 1) and patients referred to Allergy and Immunology with reported PEG or polysorbate reactions (cohort 2). COVID-19 vaccine safety was also reviewed following reported symptoms (onset â‰¤ 12 hours) to first-dose PEG-containing messenger RNA (mRNA) COVID-19 vaccine (cohort 3). RESULTS: Of 252 patients in cohort 1 (nÂ =Â 202) and cohort 2 (nÂ =Â 50), 236 (94%) received mRNA COVID-19 vaccines (106 Pfizer, 130 Moderna); 235 received both doses. Only 3 patients from cohort 2 developed mild rash following vaccination. None of the 44 patients in cohort 3 with acute symptoms following first-dose mRNA COVID-19 vaccine (27 Pfizer, 17

Moderna) had previously reported PEG or polysorbate reactions. Of these 44 patients, 43 received the second dose and all 3 who developed symptoms following the second dose (1 required epinephrine) had negative PEG skin testing. CONCLUSION: Patients with reported reactions to PEG and polysorbate safely received COVID-19 vaccines. PEG and polysorbate skin testing did not identify patients at risk for first dose or recurrent reactions to COVID-19 vaccines. Screening for PEG and polysorbate allergy may only increase vaccine hesitancy without identifying patients at risk for COVID-19 vaccine reactions.

Lymphohistiocytic Myocarditis Possibly Due to Moderna mRNA-1273 Vaccine. OBJECTIVES: Despite the clear benefits of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination in mitigating the impact of the coronavirus disease 2019 pandemic, there are emerging reports of postvaccination myocarditis, the majority of which are diagnosed based on the clinical and radiologic findings without biopsy confirmation. We report a case of biopsy-confirmed lymphohistiocytic myocarditis after Moderna mRNA-1273 vaccination. METHODS: We describe a case of a previously healthy 45-year-old woman who had palpitations, exercise intolerance, and syncope 1 week after her first mRNA-1273 vaccine dose. Laboratory tests and cardiac imaging were compatible with myocarditis. Given her unusual clinical presentation, an endomyocardial biopsy was performed to exclude other potential etiologies. RESULTS: The endomyocardial biopsy specimen showed patchy endocardial and intramyocardial lymphohistiocytic infiltrates with scattered eosinophils and focal myocyte injury. CD3 and CD68 immunostains confirmed the lymphocytic and histiocytic nature of the infiltrate, respectively. A focal histiocytic collection suggestive of an ill-defined granuloma was present. The histologic and immunohistochemical findings of a lymphohistiocytic myocarditis were highly suggestive of a postvaccination hypersensitivity reaction. CONCLUSIONS: Myocarditis following SARS-CoV-2 vaccination is a rare adverse event. The findings of a lymphohistiocytic myocarditis with scattered eosinophils and a possible ill-defined granuloma are highly suggestive of a hypersensitivity reaction. The mechanism by which this inflammation occurs remains uncertain. Despite our findings, the benefits of SARS-CoV-2 vaccination far outweigh the risks.

An Analysis of Serological Response and Infection Outcomes Following Oxford-AstraZeneca (AZD1222) and Pfizer-BioNTech (mRNA BNT162b2) SARS-CoV-2 Vaccines in Kidney and Kidney-pancreas Transplants. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 is associated with high mortality among transplant recipients. Comparative data that define humoral responses to the Oxford-AstraZeneca (AZ) and BNT162b2 (Pfizer-BioNTech) vaccines are limited. METHODS: We recruited 920 kidney transplant patients receiving at least 1 dose of severe acute respiratory syndrome coronavirus 2 vaccine, excluding patients with virus pre-exposure. Serological status was determined with the COVID-SeroKlir ELISA (Kantaro-EKF Diagnostics). Patients with a corrected antibody level of <0.7 AU/mL were considered seronegative. RESULTS: Four hundred ninety-five AZ and 141 Pfizer patients had a sample analyzed after first dose and 593 after second dose (346 AZ versus 247 Pfizer). After first dose, 25.7% of patients seroconverted (26.6% AZ, 22.8% Pfizer). After second dose, 148 (42.8%) of AZ seroconverted compared with 130 (52.6%) of Pfizer (Pâ€‰=â€‰0.02; hazard ratio, 1.48; 95% confidence interval, 1.07-2.06). When negative responders were excluded, Pfizer patients were shown to have significantly higher response than AZ patients (median 2.6 versus 1.78 AU/mL, Pâ€‰=â€‰0.005).Patients on mycophenolate had a reduced seroconversion rate (42.2% versus 61.4%; P < 0.001; hazard ratio, 2.17) and reduced antibody levels (0.47 versus 1.22 AU/mL, Pâ€‰=â€‰0.001), and this effect was dose dependent (Pâ€‰=â€‰0.05). Prednisolone reduced the seroconversion from 58.2% to 43.6% (Pâ€‰=â€‰0.03) among Pfizer but not AZ recipients. Regression analysis showed that antibody levels were reduced by older age (Pâ€‰=â€‰0.002), mycophenolate (P < 0.001), AZ vaccine (versus Pfizer, Pâ€‰=â€‰0.001), and male gender (Pâ€‰=â€‰0.02). Sixteen of 17 serious postvaccine infections occurred to patients who

did not seroconvert. CONCLUSIONS: Both seroconversion and antibody levels are lower in AZ compared with Pfizer vaccinated recipients following 2 vaccine doses. Mycophenolate was associated with lower antibody responses in a dose-dependent manner. Serious postvaccine infections occurred among seronegative recipients.

COVID-19 vaccination among pregnant people in the United States: a systematic review. OBJECTIVE: Pregnant peopleÂ are at increasedÂ riskÂ of COVID-19-related morbidity and mortality, and vaccination presents an important strategy for preventing negative outcomes. However, pregnant people were not included in vaccine trials, and there are limited data on COVID-19 vaccines during pregnancy. The objectives of this systematic review were to identify the safety, immunogenicity, effectiveness, and acceptance of COVID-19 vaccination among pregnant people in the United States. DATA SOURCES: Four databases (PubMed, Web of Science, CINAHL, and Google Scholar) were used to identify eligible studies published from January 1, 2020 through February 6, 2022. STUDY ELIGIBILITY CRITERIA: Inclusion criteria were peer-reviewed empirical research conducted in the United States, publications in English, and research addressing 1 of the following topics: safety, immunogenicity, effectiveness, and acceptance of COVID-19 vaccination among pregnant people. METHODS: A narrative synthesis approach was used to synthesize findings. Critical appraisal was done using the JBI (formerly Joanna Briggs Institute) tool. RESULTS: Thirty-two studies were identified. Most studies (n=24) reported the use of Pfizer and Moderna COVID-19 vaccines among pregnant people; only 6 reported the Janssen vaccine. Of the 32 studies, 11 examined COVID-19 vaccine safety, 10 investigated immunogenicity and effectiveness, and 11 assessed vaccine acceptance among pregnant people. Injection-site pain and fatigue were the most common adverse events. One case study reported immune thrombocytopenia. COVID-19 vaccination did not increase the risk of adverse pregnancy or neonatal outcomes compared with unvaccinated pregnant people. After COVID-19 vaccination, pregnant people had a robust immune response, and vaccinations conferred protective immunityÂ to newborns through breast milk and placental transfer. COVID-19Â vaccine acceptance was low among pregnant peopleÂ in the United States. African American race, Hispanic ethnicity, younger age, low education, previous refusal of the influenza vaccine, and lack of provider counseling were associated with low vaccine acceptance. CONCLUSION: Peer-reviewed studies support COVID-19 vaccine safety and protective effects on pregnant people and their newborns. Future studies that use rigorous methodologies and include diverse populations are needed to confirm current findings. In addition, targeted and tailored strategies are needed to improve vaccine acceptance, especially among minorities.

Characteristics associated with serological COVID-19 vaccine response and durability in an older population with significant comorbidity: the Danish Nationwide ENFORCE Study. OBJECTIVES: To identify individual characteristics associated with serological COVID-19 vaccine responsiveness and the durability of vaccine-induced antibodies. METHODS: Adults without history of SARS-CoV-2 infection from the Danish population scheduled for SARS-CoV-2 vaccination were enrolled in this parallel group, phase 4 study. SARS-CoV-2 Spike IgG and Spike-ACE2-receptor-blocking antibodies were measured at days 0, 21, 90, and 180. Vaccine responsiveness was categorized according to Spike IgG and Spike-ACE2-receptor-blocking levels at day 90 after first vaccination. Nondurable vaccine response was defined as day-90 responders who no longer had significant responses by day 180. RESULTS: Of 6544 participants completing two vaccine doses (median age 64Â years; interquartile range: 54-75), 3654 (55.8%) received BTN162b2, 2472 (37.8%) mRNA-1273, and 418 (6.4%) ChAdOx1 followed by an mRNA vaccine. Levels of both types of antibodies increased from baseline to day 90 and then decreased to day 180. The decrease was more pronounced for levels of Spike-ACE2-receptor-blocking antibodies than for Spike IgG. Proportions with vaccine hyporesponsiveness and lack of durable response were 5.0% and 12.1% for Spike IgG and 12.7% and 39.6% for Spike-ACE2-

receptor-blocking antibody levels, respectively. Male sex, vaccine type, and number of comorbidities were associated with all four outcomes. Additionally, age â‰¥75Â years was associated with hyporesponsiveness for Spike-ACE2-receptor-blocking antibodies (adjusted odds ratio: 1.59; 95% confidence interval: 1.25-2.01) but not for Spike IgG. DISCUSSION: Comorbidity, male sex, and vaccine type were risk factors for hyporesponsiveness and nondurable response to COVID-19 vaccination. The functional activity of vaccine-induced antibodies declined with increasing age and had waned to pre-second-vaccination levels for most individuals after 6Â months.
Unexplained liver test elevations after SARS-CoV-2 vaccination.
Autoimmune hepatitis and COVID-19: No increased risk for AIH after vaccination but reduced care.
Evaluating risk of bullous pemphigoid after mRNA COVID-19 vaccination.
Could the development of COVID-19 vaccine-induced type 1 diabetes be explained by a simple mechanism?
Case of lichen planus pigmentosus-inversus after Oxford-AstraZeneca COVID-19 vaccine: cause or coincidence?
Short and mid-term SARS-CoV-2 antibody response after inactivated COVID-19 vaccine in hemodialysis and kidney transplant patients. The efficacy of the inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine has not been fully elucidated across the whole spectrum of patients on kidney replacement therapy. We aimed to characterize the long-term antibody response of inactivated SARS-CoV-2 vaccine administered in kidney transplant recipients (KTRs) and hemodialysis (HD) patients. We performed this prospective observational study in 50 HD, 64 KTR, and 41 healthy control groups (HG) given two doses of CoronaVac. We measured anti-Spike antibodies after 28 days of every vaccine dose, 3rd and 6th months after the first dose, and compared them between cohorts. After two doses, an anti-spike immunoglobulin G of â‰¥50â€‰AU/ml was present in HD, KTR, and HG as 44%, 7.2%, and 58.5%, respectively (pâ€‰<â€‰0.001). Furthermore, the proportion of antibody titers peaked at 86.5%, 23%, and 97.6% (pâ€‰<â€‰0.001) at the 3rd month and decreased significantly at the 6th month in most HD and HG participants, whereas this effect was not observed in KTRs from basal until the 6th month (pâ€‰<â€‰0.001). During the follow-up, the incidence of coronavirus disease 2019 disease was higher (pâ€‰<â€‰0.003) in KTRs compared to the other groups, but there was no requirement for an intensive care unit and no death was recorded. We found a negative correlation between antibody seroconversion and age (pâ€‰<â€‰0.016). The antibody response following inactivated vaccine in dialysis patients is almost comparable to controls for 6 months. In contrast, kidney transplant patients have a poor response. These findings reinforce the need to discuss the vaccination strategy in immunocompromised patients, including the third dose with homologous or heterologous vaccines.
[Retinal arteriovenous vascular occlusion after COVID vaccination with VaxzevriaÂ® (AstraZeneca)-A complication of vaccination or not?].
Colchicine prophylaxis is associated with fewer gout flares after COVID-19 vaccination. OBJECTIVES: COVID-19 vaccination often triggers a constellation of transitory inflammatory symptoms. Gout is associated with several comorbidities linked to poor outcomes in COVID-19, and gout flares can be triggered by some vaccinations. We analysed the risk of gout flares in the first 3 months after COVID-19 vaccination with inactivated virus, and whether colchicine can prevent gout flares following post-COVID-19 vaccination. METHODS: A clinical delivery population-based cross-sectional study was conducted in the Gout Clinic at the Affiliated Hospital of Qingdao University between February and October 2021. Study participants were selected using a systematic random sampling technique among follow-up patients with gout. We collected data, including vaccinations and potential risk factors, using a combination of interviews, health QR codes and medical records. Logistic regression was used to adjust for covariates. RESULTS: We enrolled 549 gout participants

(median age 39 years, 84.2% vaccinated). For the 462 patients who received COVID-19 vaccine, 203 (43.9%) developed at least one gout flare in the 3 months after vaccination. Most of these flares were experienced within 1â€‰month after the first (99/119 (83.2%)) or second (70/115 (60.9%)) dose of vaccine. Compared with unvaccinated participants, COVID-19 vaccination was associated with higher odds of gout flare within 3 months (adjusted OR 6.02; 95%â€‰CI 3.00 to 12.08). Colchicine use was associated with 47% less likelihood of postvaccine gout flare. CONCLUSION: COVID-19 vaccination was associated with increased odds of gout flare, which developed mainly in month 1 after each vaccine dose, and was negatively associated with colchicine prophylaxis.
Acute myocarditis after a third dose of the BNT162b2 COVID-19 vaccine.
Development of IgA vasculitis with severe glomerulonephritis after COVID-19 vaccination: a case report and literature review. With the worldwide spread of the COVID-19 vaccine program during the COVID-19 pandemic, the numbers of reported cases with new-onset or relapsed kidney disease/vasculitis such as minimal change nephrotic syndrome, immunoglobulinA (IgA) nephropathy, and IgA vasculitis (IgAV) that developed after COVID-19 vaccination are increasing. We present the case of a 67-year-old Japanese woman who developed IgAV with purpura on her extremities and trunk in the evening of the day that she received the second dose of the Pfizer-BioNTech COVID-19 vaccine. She subsequently presented with acute kidney injury and nephrotic syndrome, and a kidney biopsy performed 14Â days after the second vaccination showed diffuse mesangial and endocapillary glomerulonephritis with necrotizing crescent formation, accompanied by IgA deposition. One steroid pulse plus four administrations of a monthly intravenous cyclophosphamide injection were applied, followed by oral azathioprine during oral steroid tapering. Her response to this treatment was unsatisfactory and intractable for some time. Eventually, her renal function improved and nephrotic syndrome was resolved, while microscopic hematuria and proteinuria atâ€‰~â€‰1Â g/gCr remained at 6Â months post-vaccination. Unlike the previous milder renal-involved IgAV cases following COVID-19 vaccination, our patient's case presented severe glomerulonephritis and took a long time to recover despite intensive initial immunosuppressive treatment.
Erythema gyratum repens after COVID vaccination.
Erythema multiforme in COVID-19 patients and following COVID-19 vaccination: manifestations, associations and outcomes.
Two cases of anti-TIF1-Î³ antibody positive dermatomyositis with manifested symptoms after SARS-CoV-19 vaccination.
Another case of generalized bullous fixed drug eruption following an adenoviral vector-based COVID-19 vaccine (ChAdOx1 nCov-19).
Cardiac MRI in Suspected Acute Myocarditis After COVID-19 mRNA Vaccination. PURPOSE: To evaluate cardiac MRI characteristics in patients with suspected hypersensitivity myocarditis following mRNA COVID-19 vaccination. MATERIALS AND METHODS: Patients clinically suspected of acute myocarditis after COVID-19 vaccination were retrospectively analyzed and compared against a healthy control group.â€ŠCardiac MRI protocol included parameters such as T1 and T2 relaxation times, extracellular volume (ECV), T2 signal intensity ratio, and late gadolinium enhancement (LGE). Lymph node size was assessed in the patient group on the injection side. Student t-test, analyses of variance (ANOVA) with Tukey post-hoc test, and Ï‡(2) test were used for statistical analysis. RESULTS: 20 patients with clinically suspected post-vaccine myocarditis (28â€ŠÂ±â€Š12 years; 12 men) and 40 controls (31â€ŠÂ±â€Š11Â years; 25 men) were evaluated. According to the 2018 Lake Louise criteria (LLC), patients with clinically suspected myocarditis were further subdivided into an LLC-positive group (nâ€Š=â€Š9) and an LLC-negative group (nâ€Š=â€Š11). The mean time of symptom onset after vaccination was 1.1â€ŠÂ±â€Š1.2 days (LLC-positive) and 6.5â€ŠÂ±â€Š9.2 days (LLC-negative). Group differences in inflammatory variables between myocarditis patients and control subjects were more

pronounced in the LLC-positive group (e.â€Šg., T1 relaxation time: 1041â€ŠÂ±â€Š61â€Šms [LLC positive] vs. 1008â€ŠÂ±â€Š79â€Šms [LLC-negative] vs. 970â€ŠÂ±â€Š25â€Šms [control]; pâ€Š<.001; or T2 signal intensity ratio 2.0â€ŠÂ±â€Š0.3 vs. 1.6â€ŠÂ±â€Š0.3 [LLC-negative] and vs. 1.6â€ŠÂ±â€Š0.3 [control], pâ€Š=â€Š.012). LLC-positive patients were significantly faster in receiving an MRI after initial symptom onset (8.8â€ŠÂ±â€Š6.1 days vs. 52.7â€ŠÂ±â€Š33.4 days; pâ€Š=â€Š.001) and had higher troponin T levels (3938â€ŠÂ±â€Š5850â€Šng/l vs. 9â€ŠÂ±â€Š11â€Šng/l; pâ€Š<.001). LGE lesions were predominantly located at the subepicardium of the lateral wall. Axillary lymphadenopathy was more frequent in the LLC-positive group compared to the LLC-negative group (8/9 [89â€Š%] vs. 0/11 [0â€Š%], pâ€Š<â€Š0.001). CONCLUSION: Vaccine-induced myocarditis should be considered in patients with acute symptom onset after mRNA vaccination, especially if elevated serum troponin T is observed. Imaging findings of vaccine-induced myocarditis are similar to virus-induced myocarditis, allowing for the use of the Lake Louise Criteria for diagnostic purposes. KEY POINTS: Â· Vaccine-induced hypersensitivity myocarditis can be confirmed with cardiac MRI. Â· Especially patients with sudden onset of symptoms and elevated serum troponin T had positive cardiac MRI findings. Â· Cardiac MRI characteristics of vaccine-induced myocarditis are similar to those in virus-induced myocarditis. CITATION FORMAT: Â· Kravchenko D, Isaak A, Mesropyan N etâ€Šal. Cardiac MRI in Suspected Acute Myocarditis After COVID-19 mRNA Vaccination. Fortschr RÃ¶ntgenstr 2022; 194: 1003â€Š-â€Š1011.

Neutralizing Activities Against the Omicron Variant After a Heterologous Booster in Healthy Adults Receiving Two Doses of CoronaVac Vaccination. BACKGROUND: The use of an inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine (CoronaVac) against SARS-CoV-2 is implemented worldwide. However, waning immunity and breakthrough infections have been observed. Therefore, we hypothesized that the heterologous booster might improve the protection against the delta and omicron variants. METHODS: A total of 224 individuals who completed the 2-dose CoronaVac for 6 months were included. We studied reactogenicity and immunogenicity after a heterologous booster with the inactivated vaccine (BBIBP), the viral vector vaccine (AZD1222), and the messenger ribonucleic acid (mRNA) vaccine (both BNT162B2 and mRNA-1273). We also determined immunogenicity at 3- and 6-month boosting intervals. RESULTS: The solicited adverse events were mild to moderate and well tolerated. Total receptor binding domain (RBD) immunoglobulin (Ig), anti-RBD IgG, focus reduction neutralization test (FRNT50) against delta and omicron variants, and T-cell response were highest in the mRNA-1273 group followed by the BNT162b2, AZD1222, and BBIBP groups, respectively. We also witnessed a higher total Ig anti-RBD in the long-interval than in the short-interval group. CONCLUSIONS: All 4 booster vaccines significantly increased binding and neutralizing antibodies in individuals immunized with 2 doses of CoronaVac. The present evidence may benefit vaccine strategies to thwart variants of concern, including the omicron variant.

Neutralization against Omicron variant in transplant recipients after three doses of mRNA vaccine. The SARS-CoV-2 virus Omicron variant has now supplanted wild-type virus as the dominant circulating strain globally. Three doses of mRNA COVID-19 vaccine are recommended for transplant recipients as their primary vaccine series. However, the immunogenicity of mRNA vaccines as they specifically relate to the Omicron variant are not well studied. We analyzed Omicron-specific neutralization in transplant recipients after three-doses of mRNA-1273 vaccine. Neutralization was determined using a SARS-CoV-2 spike pseudotyped lentivirus assay with constructs for Omicron and Delta variants. A total of 60 transplant patients (kidney, kidney-pancreas, lung, heart, liver) were analyzed 1 month and 3 months after completion of three doses of mRNA-1273. At 1 month, 11/60 (18.3%) patients had detectable neutralizing antibody responses to Omicron (log(10) ID50 of 2.38 [range 1.34-3.57]). At 3 months, 8/51 (15.7%) were positive (median log(10) ID50 [1.68; range 1.12-3.61; approximate

fivefold reduction over time]). The proportion of positive patients was lower for Omicron versus wild-type, and Omicron vs. Delta (pÂ <Â .001). No demographic variables were found to be significantly associated with Omicron response. Many patients with a positive anti-RBD response still had undetectable Omicron-specific neutralizing antibody. In conclusion, three doses of mRNA vaccine results in poor neutralizing responses against the Omicron variant in transplant patients.

Do basophil activation tests help elucidate allergic reactions to the ingredients in COVID-19 vaccines? The worldwide use of COVID-19 vaccines has shown that immediate allergic reactions to the ingredients are rare but should be clarified by means of an allergological work-up. This review aims to highlight the current state of knowledge and possible pathogenesis based on the literature published to date. In addition to recording a detailed history and performing skin tests, cellular tests (basophil activation or basophil histamine release test) by using the vaccines or modified compounds containing polyethylene glycol (PEG), rather than unmodified PEGs, have proven to be particularly helpful. Negative results with vaccines seem to indicate tolerance. Details of the performance of these cellular tests with different vaccines, PEGs of different molecular weights, other ingredients of the vaccines, as well as other PEGylated drugs, and the results in the context of COVID-19 vaccination of various working groups worldwide are summarized.

Subacute thyroiditis with liver dysfunction following coronavirus disease 2019 (COVID-19) vaccination: report of two cases and a literature review. Subacute thyroiditis is a transient inflammatory thyroid disease characterized by neck pain, fever, and typical symptoms associated with thyrotoxicosis. The incidence of subacute thyroiditis is higher in female than in male, and susceptibility is prominent in the 30-50-year age range. The variety of case reports on subacute thyroiditis associated with coronavirus disease 2019 (COVID-19) appears to be increasing, and subacute thyroiditis following COVID-19 vaccination has recently been reported. Herein, we report two cases of subacute thyroiditis that developed after receiving the COVID-19 mRNA vaccine, one of which exhibited remarkable liver dysfunction. The mechanism underlying the development of post-vaccination subacute thyroiditis remains unknown; however, one theory suggests that adjuvants contained in vaccines may play a role in triggering diverse autoimmune and inflammatory responses. Another possibility is the potential cross-reactivity between the coronavirus spike protein target produced by the mRNA vaccine and thyroid cell antigens. Common side effects of the COVID-19 vaccine include pain at the injection site, fever, fatigue, headache, muscle pain, chills, and nausea. These symptoms are usually resolved within a few days. Subacute thyroiditis may present symptoms similar to those of short-term vaccination side effects or exhibit non-specific symptoms, potentially leading to misdiagnosis or underdiagnosis. Therefore, clinicians should be aware of the possible development of subacute thyroiditis after COVID-19 vaccination.

Oral lichen planus following mRNA COVID-19 vaccination.

mRNA COVID-19 vaccine and oral lichen planus: A case report.

Adverse events and breakthrough infections associated with COVID-19 vaccination in the Indian population. Vaccines against COVID-19 provide immunity to deter severe morbidities associated with the infection. However, it does not prevent infection altogether in all exposed individuals. Furthermore, emerging variants of SARS-CoV-2 impose a threat concerning the competency of the vaccines in combating the infection. This study aims to determine the variability in adverse events and the extent of breakthrough infections in the Indian population. A retrospective study was conducted using a pre-validated questionnaire encompassing social, demographic, general health, the status of SARS-CoV-2 infection, vaccination, associated adverse events, and breakthrough infections in the Indian population. Informed consent and ethical approval were obtained as per Indian Council of Medical Research (ICMR) guidelines. Participants, who provided the complete information,Â were Indian citizens, above 18 years, and if vaccinated, administered with either Covishield or Covaxin,

wereÂ considered for the study. Data have been compiled in Microsoft Excel and analyzed for statistical differences using STATA 11. The responses from 2051 individuals fulfilling the inclusion criteria were analyzed. Among 2051, 1119 respondents were vaccinatedÂ and 932 respondents were non-vaccinated. Among 1119 vaccinated respondents, 7 were excluded because of missing data. Therefore, out of 1112 vaccinated, 413 experienced adverse events with a major fraction of younger individuals, age 18-40 years, getting affected (74.82%; 309/413). Furthermore, considerably more females than males encountered adverse consequences to vaccination (pâ€‰<â€‰0.05). Among vaccinated participants, breakthrough infections were observed in 7.91% (88/1112; 57.96% males and 42.04% females) with the older age group, 61 years and above (odds ratio, 3.25 [1.32-8.03]; pâ€‰=â€‰0.011), and males were found to be at higher risk. Further research is needed to findÂ the age and sex-related factors in determining vaccine effectiveness and adverse events.

Subacute thyroiditis following COVID-19 vaccination: Case report and Society for Endocrinology survey.

Determinants of Neutralizing Antibody Response After SARS CoV-2 Vaccination in Patients With Myeloma. PURPOSE: Vaccine-induced neutralizing antibodies (nAbs) play a critical role in protection from SARS CoV-2. Patients with B-cell malignancies including myeloma are at increased risk of COVID-19-related mortality and exhibit variable serologic response to the vaccine. The capacity of vaccine-induced antibodies in these patients to neutralize SARS CoV-2 or its variants is not known. METHODS: Sera from 238 patients with multiple myeloma (MM) undergoing SARS CoV-2 vaccination were analyzed. Antibodies against the SARS CoV-2 spike receptor-binding domain (RBD) and viral nucleocapsid were measured to detect serologic response to vaccine and environmental exposure to the virus. The capacity of antibodies to neutralize virus was quantified using pseudovirus neutralization assay and live virus neutralization against the initial SARS CoV-2 strain and the B1.617.2 (Delta) variant. RESULTS: Vaccine-induced nAbs are detectable at much lower rates (54%) than estimated in previous seroconversion studies in MM, which did not monitor viral neutralization. In 33% of patients, vaccine-induced antispike RBD antibodies lack detectable neutralizing capacity, including against the B1.617.2 variant. Induction of nAbs is affected by race, disease, and treatment-related factors. Patients receiving mRNA1273 vaccine (Moderna) achieved significantly greater induction of nAbs compared with those receiving BNT162b2 (Pfizer; 67% v 48%, P = .006). CONCLUSION: These data show that vaccine-induced antibodies in several patients with MM lack detectable virus-neutralizing activity. Vaccine-mediated induction of nAbs is affected by race, disease, vaccine, and treatment characteristics. These data have several implications for the emerging application of booster vaccines in immunocompromised hosts.

Localized lipoatrophy and inadvertent subcutaneous administration of a COVID-19 vaccine. A 60-year-old woman presented with a depressed lesion at the site of her first COVID-19 (Astra Zeneca) vaccine injection. The lesion was diagnosed as a case of injection related localized lipoatrophy as markers of autoimmune disease were negative and biopsy differentiated it from localized involutional lipoatrophy. This case of localized lipoatrophy was likely due to inadvertent subcutaneous injection of the COVID-19 vaccine with a 16â€‰mm long needle.

SARS-CoV-2 mRNA Vaccination Causes Prolonged Increased Cortical Thickening and Vascularity in Ipsilateral Axillary Lymph Nodes. OBJECTIVES: To describe the serial grey-scale and color Doppler appearance of ipsilateral axillary lymphadenopathy in response to the Pfizer-BioNTech Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) messenger RNA (mRNA) vaccine over 24 to 28â€‰weeks. METHODS: The data for this study were collected during an observational study to determine whether mRNA vaccination induced a germinal center B cell reaction in blood and draining axillary lymph nodes. The current study evaluated the serial color Doppler and grey-scale sonographic appearance of these lymph nodes. Ten participants who each underwent 6 sonograms and FNAs over

24 to 28â€‰weeks were included in the study. A total of 11 lateral lymph nodes were identified. Cortical thickness was measured and absence or presence of color Doppler flow in the hilum and lymph node cortex was graded (scale: 0-2). RESULTS: Eleven lateral axillary lymph nodes were biopsied over 24 to 28â€‰weeks. Mean thickness varied through time (Pâ€‰<â€‰.001) and was greater weeks 2 to 7 compared to weeks 24 to 28 (mean differences of 2.6 to 1.3; Pâ€‰<â€‰.006), but weeks 14 to 17 mean thickness was not different from weeks 24 to 28 (0.57; PÂ =Â .15). Cortical vascularity was increased in all 11 lymph nodes by week 5. Mean vascularity varied through time (Pâ€‰<â€‰.001) and was greater weeks 2 to 14 compared to weeks 24 to 28; mean differences ranged from 1.7 to 0.83 (Pâ€‰<â€‰.001). CONCLUSIONS: Serial grey-scale and color Doppler appearance of ipsilateral axillary lymph nodes after mRNA vaccination manifest as increased and prolonged cortical thickening and vascularity that diminishes and approaches normal by 24 to 28â€‰weeks.

Surgical acute abdomen and COVID-19 vaccination. In response to the publication "Acute appendicitis, foreign bodies and COVID-19 vaccination: correspondence", we reviewed the association between acute surgical abdomen and COVID-19 vaccination.

Humoral immune response of BBIBP COVID-19 vaccination before and after the booster immunization. BACKGROUND: The inactivated Sinopharm/BBIBP COVID-19 vaccine has been widely used in the world and has joined the COVAX vaccine supply program for developing countries. It is also well adapted for usage in low- and middle-income nations due to their low storage requirements. OBJECTIVE: This study aims to report on the kinetics, durability, and neutralizing ability of the induced immunity of the BBIBP vaccine, and the intensified antibody response elicited by the booster. METHODS: A total of 353Â healthy adult participants, aged 20-74Â years, were recruited in this multicenter study. A standard dose of the BBIBP vaccine was administered (Month 0), followed by a second standard dose (Month 1), and a booster dose (after Month 7). Vaccine-induced virus-specific antibody levels (SARS-CoV-2-IgA/IgM/IgG), conventional virus neutralization test (cVNT), pseudovirus neutralization test (pVNT), and surrogate virus neutralization test (sVNT) were monitored over multiple time points. RESULTS: Neutralizing titers induced by the two doses of inactivated vaccine for COVID-19 peaked at Month 2 and declined to 33.89% at Month 6. Following the booster dose, elevated levels of antibodies were induced for IgA, IgG, and neutralizing antibodies, with neutralizing titer reaching 13.2 times that of before the booster. CONCLUSION: By monitoring the antibody titer levels postvaccination, this study has shown that serum antibody levels will decrease over time, but a notable spike in antibody levels postbooster highlights the anamnestic immune response. This signifies that the protection capability has increased following the injection of booster immunization.

Adverse events of special interest following the use of BNT162b2 in adolescents: a population-based retrospective cohort study. Accruing evidence suggests an increased risk of myocarditis in adolescents from messenger RNA COVID-19 vaccines. However, other potential adverse events remain under-researched. We conducted a retrospective cohort study of adolescents aged 12-18 with a territory-wide electronic healthcare database of the Hong Kong population linked with population-based vaccination records and supplemented with age- and sex-specific population numbers. Two age- and sex-matched retrospective cohorts were formed to observe 28 days following the first and second doses of BNT162b2 and estimate the age- and sex-adjusted incidence rate ratios between the vaccinated and unvaccinated. Thirty AESIs adapted from the World Health Organization's Global Advisory Committee on Vaccine Safety were examined. Eventually, the first-dose cohort comprised 274,881 adolescents (50.25% received the first dose) and the second-dose cohort 237,964 (50.29% received the second dose). Ninety-four (34.2 per 100,000 persons) adolescents in the first-dose cohort and 130 (54.6 per 100,000 persons) in the second-dose cohort experienced â‰¥1 AESIs. There

were no statistically significant differences in the risk of any AESI associated with BNT162b2 except myocarditis [first-dose cohort: incidence rate ratio (IRR)â€‰=â€‰9.15, 95% confidence interval (CI) 1.14-73.16; second-dose cohort: IRRâ€‰=â€‰29.61, 95% CI 4.04-217.07] and sleeping disturbances/disorders after the second dose (IRRâ€‰=â€‰2.06, 95% CI 1.01-4.24). Sensitivity analysis showed that, with myocarditis excluded as AESIs, no significantly elevated risk of AESIs as a composite outcome associated with vaccination was observed (Pâ€‰=â€‰0.195). To conclude, the overall absolute risk of AESIs was low with no evidence of an increased risk of AESIs except myocarditis and sleeping disturbances/disorders.

VITT with inactivated SARS-CoV-2 vaccine - index case. We report a case of vaccine-induced immune thrombotic thrombocytopenia (VITT) in a 73-year-old gentleman who presented with pulmonary embolism and thrombocytopenia, two weeks after receiving inactivated COVID-19 vaccine. He responded well to nonheparin anticoagulation with complete resolution of symptoms and platelet count.

IgA vasculitis following COVID-19 vaccination. Immunoglobulin A (IgA) vasculitis is generally triggered by infectious causes, but it has also been reported after immunisation with various vaccines. Herein, we report two cases of IgA vasculitis after receiving the first or second dose of the Pfizer-BioNTech BNT16B2b2 mRNA vaccine. Two men, aged 22 and 30â€‰years, developed palpable purpura on the extremities and arthritis. One patient also complained of fever and gastrointestinal symptoms. Laboratory findings revealed mild leucocytosis and slightly elevated C-reactive protein levels, although the platelet count and coagulation profile were within normal levels in both cases. Proteinuria and microhaematuria were seen in one patient. Skin biopsies were performed in both patients and revealed leucocytoclastic vasculitis. The deposits of IgA and C3 were shown in immunofluorescence studies in one patient. Both patients were diagnosed with IgA vasculitis and treated with prednisolone, and their symptoms resolved within 1â€‰week after initiation of treatment. The coronavirus disease 2019 mRNA vaccine could trigger IgA vasculitis; however, a coincidence cannot be ruled out.

Assessing Clinically Meaningful Hypercoagulability after COVID-19 Vaccination: A Longitudinal Study. A large number of daily requests to exclude possible prothrombotic risk factors for coronavirus disease 2019 (COVID-19) vaccines were received. Our aim was to longitudinally evaluate coagulation profiles in a series of healthy subjects who received COVID-19 vaccination and assess hypercoagulability thereafter. Volunteers awaiting a first or second dose of either the ChAdOx1 or BNT162b2 vaccine were enrolled. Venous samples were obtained at baseline (before the vaccine) and longitudinally 3â€‰Â±â€‰2 days (T1) and 10â€‰Â±â€‰2 days after the vaccine (T2). Global coagulation monitoring was assessed via platelet count, whole blood thromboelastometry and impedance aggregometry, plasma thrombin generation, and anti-platelet factor 4 (PF4)/heparin immunoglobulin G antibodies. One hundred and twenty-two subjects were enrolled (61 [50%] ChAdOx1 and 61 BNT162b2). The ChAdOx1 cohort showed a slight but transient increase in thrombin generation (mainly endogenous thrombin potential [ETP] with thrombomodulin and ETP ratio) at T1, which promptly decreased at T2. In addition, the second dose of either vaccine was associated with increased thrombin peak, ETP with thrombomodulin, and ETP ratio. At baseline, 3.2% of the ChAdOx1 cohort and 1.6% BNT162b2 cohort were positive for PF4/heparin antibodies with a stable titer through T1 and T2. No relevant differences were detected in platelet count and aggregation, or thromboelastometry parameters. No thrombotic or hemorrhagic events occurred. We can confirm that no clinically meaningful hypercoagulability occurred after either vaccine, albeit keeping in mind that thrombin generation may increase in the first days after the second dose of either vaccine and after the first dose of the ChAdOx1 vaccine.

Complications and Efficacy of Sinopharm Vaccine among Liver and Kidney Transplantation. BACKGROUND: There are various vaccines against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, vaccination may lead to some complications. OBJECTIVE: This study aimed to investigate the complications of transplant recipients who received the Sinopharm COVID-19 vaccine. METHODS: This was a retrospective cross-sectional study conducted among 667 transplant recipients (211 liver transplant recipients and 456 kidney transplant recipients) who received the Sinopharm COVID-19 vaccine from March to August 2021 and had medical records in Montaserieh Hospital, affiliated to Mashhad University of Medical Sciences, Mashhad, Iran. The demographic and clinical information, as well as patient's symptoms after each dose of the vaccine, were recorded. RESULTS: Only 16.8% and 13.7% of the patients experienced some symptoms following the first and second doses of the Sinopharm vaccine, respectively. No significant difference was observed between patients younger than 50 years and those aged 50 years and over in terms of the complication rate of the Sinopharm vaccine (P>0.005). Vaccine failure was reported in 10% of the cases; however, the mortality rate due to infection with the Delta variant of COVID-19 in this population was reported to be 0.7%. CONCLUSION: Based on the obtained results, adverse reactions of the Sinopharm COVID-19 vaccine are generally mild, predictable, and non-life-threatening both in the first and second doses. Vaccine failure was reported in 10% of the cases; however, mortality due to infection with the Delta variant of COVID-19 was reported in less than 1% of the cases.

Multisystem inflammatory syndrome with erythema multiforme-like rash in an adult after mRNA COVID-19 vaccination.

Real-World Incidence of Breakthrough Coronavirus Disease 2019 Hospitalization After Vaccination vs Natural Infection in a Large, Local, Empaneled Primary Care Population Using Time-to-Event Analysis. We followed 106â€…349 primary care patients for 22â€…385 3099 person-days across 21 calendar months and documented 69 breakthrough coronavirus disease 2019 (COVID-19) hospitalizations: 65/102,613 (0.06%) among those fully vaccinated, 3/11â€…047 (0.03%) among those previously infected, and 1/7,313 (0.01%) among those with both statuses. These data give providers real-world context regarding breakthrough COVID-19 hospitalization risk.

Frequency and outcomes of MRI-detected axillary adenopathy following COVID-19 vaccination. OBJECTIVES: To assess the frequency of ipsilateral axillary adenopathy on breast MRI after COVID-19 vaccination. To investigate the duration, outcomes, and associated variables of vaccine-related adenopathy. METHODS: In this retrospective cohort study, our database was queried for patients who underwent breast MRI following COVID-19 vaccination from January 22, 2021, to March 21, 2021. The frequency of ipsilateral axillary adenopathy and possible associated variables were evaluated, including age, personal history of ipsilateral breast cancer, clinical indication for breast MRI, type of vaccine, side of vaccination, number of doses, and number of days between the vaccine and the MRI exam. The outcomes of the adenopathy were investigated, including the duration of adenopathy and biopsy results. RESULTS: A total of 357 patients were included. The frequency of adenopathy on breast MRI was 29% (104/357 patients). Younger patients and shorter time intervals from the second dose of the vaccine were significantly associated with the development of adenopathy (p = 0.002 for both). Most adenopathy resolved or decreased on follow-up, with 11% of patients presenting persistence of adenopathy up to 64 days after the second dose of the vaccine. Metastatic axillary carcinoma was diagnosed in three patients; all three had a current ipsilateral breast cancer diagnosis. CONCLUSIONS: Vaccine-related adenopathy is a frequent event after COVID-19 vaccination; short-term follow-up is an appropriate clinical approach, except in patients with current ipsilateral breast cancer. Adenopathy may often persist 4-8 weeks after the second dose of the vaccine, thus favoring longer follow-up periods. KEY POINTS: â€¢ MRI-detected ipsilateral axillary adenopathy is a frequent benign finding after mRNA COVID-19 vaccination. â€¢ Axillary adenopathy

following COVID-19 vaccination often persists > 4 weeks after vaccination, favoring longer follow-up periods. â€¢ In patients with concurrent ipsilateral breast cancer, axillary adenopathy can represent metastatic carcinoma and follow-up is not appropriate.

Granulomatosis with polyangiitis following Pfizer-BioNTech COVID-19 vaccination. We report the first case of proteinase 3-antineutrophil cytoplasmic antibody-positive granulomatosis with polyangiitis (GPA) with predominant ears, nose, and throat manifestations following coronavirus disease 2019 (COVID-19) vaccination. A 63-year-old woman presented with aural fullness 3 days after vaccination. She presented with progressive rhinosinusitis and otitis media leading to profound hearing loss within 3 weeks. Clinical imaging revealed soft-tissue shadows in the paranasal sinuses with multiple pulmonary nodules, and histopathology was consistent with a diagnosis of GPA. It is crucial to be wary of the possibility of GPA in patients who received COVID-19 vaccines due to its rapid disease progression.

Systemic lupus erythematosus and antiphospholipid syndrome after COVID-19 vaccination. A case report. Coronavirus disease 2019 (COVID-19) vaccines have some adverse effects, mostly mild. However, by presenting an immunological challenge to the individual, they could infrequently trigger immune-mediated diseases (IMDs). We report the case of a 42-year-old woman, with no previous medical history, who received the first dose of vaccine against COVID-19 and developed inflammatory arthralgias, associated with sudden-onset dyspnoea and hypoxemia. Pulmonary thromboembolism was documented, and the diagnosis of systemic lupus erythematosus (SLE) and secondary antiphospholipid syndrome (APS) was suspected. Autoantibodies were measured confirming this suspicion. After a few days, she presented a massive pericardial effusion with cardiac tamponade that required surgical management. Treatment with azathioprine, hydroxychloroquine, corticosteroids, and anticoagulation was indicated with improvement of all her symptoms. There is controversy regarding the potential of COVID-19 vaccines to induce autoimmunity. Studies addressing the safety of using these vaccines have reported the occurrence of mild local and systemic reactions, most frequently in young adults. So far, there are few reports of patients who have developed autoimmune or autoinflammatory diseases after getting vaccinated with any of the COVID-19 vaccines. To the best of our knowledge, to date, this is one of the first cases of new-onset SLE and secondary APS after COVID-19 vaccination.

A comparative analysis on the safety and efficacy of Covaxin versus other vaccines against COVID-19: a review. Since the identification of the genomic sequence of SARS-CoV-2, an unprecedented effort is being made until this date for the development of a safe and effective vaccine by pharma companies and laboratories worldwide. To attain herd immunity and quite possibly recover from this pandemic, which has claimed the life of about 4.23 million people, an exceptional effort has been made by the scientific community for the development of a vaccine. Various vaccines have been developed based on different platforms and each of them seems to possess its own merits and demerits based on its safety, immunogenicity, the durability of immunity, dosing schedule, technological platform, and ease of manufacture and transport. Based on these parameters this review aims to critically assess the efficacy of Covaxin and compare it with other vaccines in the WHO EUL list and perform a comparative analysis of COVID-19 vaccines which are in phase 3 and phase 4 of clinical trials. This will help us determine where COVAXIN stands against other vaccines and vaccine candidates based on these parameters which will ultimately help us determine the best vaccine that could potentially eradicate the COVID-19 pandemic.

Perspective on COVID-19 vaccination in patients with immune-mediated kidney diseases: consensus statements from the ERA-IWG and EUVAS. Patients with immune-mediated kidney diseases are at increased risk of severe coronavirus disease 2019 (COVID-19). The international rollout of COVID-19 vaccines has provided varying degrees of protection and enabled the understanding of vaccine

efficacy and safety. The immune response to COVID-19 vaccines is lower in most patients with immune-mediated kidney diseases; either related to immunosuppression or comorbidities and complications caused by the underlying disease. Humoral vaccine response, measured by the presence of antibodies, is impaired or absent in patients receiving rituximab, mycophenolate mofetil (MMF), higher doses of glucocorticoids and likely other immunosuppressants, such as cyclophosphamide. The timing between the use of these agents and administration of vaccines is associated with the level of immune response: with rituximab, vaccine response can only be expected once B cells start to recover and patients with transient discontinuation of MMF mount a humoral response more frequently. The emergence of new COVID-19 variants and waning of vaccine-induced immunity highlight the value of a booster dose and the need to develop mutant-proof vaccines. COVID-19 vaccines are safe, exhibiting a very low risk of de novo or relapsing immune-mediated kidney disease. Population-based studies will determine whether this is causal or coincidental. Such cases respond to standard management, including the use of immunosuppression. The Immunonephrology Working Group and European Vasculitis Society recommend that patients with immune-mediated kidney diseases follow national guidance on vaccination. Booster doses based on antibody measurements could be considered.

Varicella zoster virus reactivation following COVID-19 vaccination: a report of 3 cases. BACKGROUND: The advent of vaccination against COVID-19 brought great expectations for the control of the pandemic. As novel vaccines, much of the associated side effects were unknown. Currently, an increasing number of reports from side effects of COVID-19 vaccines have been published, namely on cutaneous reactions. These are of utmost importance to increase our knowledge about possible undesirable effects and its prevention. METHODS: We describe a series of 3 cases who presented with varicella zoster virus (VZV) reactivation following the first dose of 3 different COVID-19 vaccines. RESULTS: Three patients sought their Family Doctor after developing typical lesions of VZV reactivation, following a period of 3-13 days after COVID-19 vaccination. None was under immunosuppressive therapy. The 3 patients recovered in a few weeks and the subsequent doses of the vaccines were administered, without recurrence of the symptoms. CONCLUSIONS: These cases highlight the possibility of VZV reactivation after the first dose of COVID-19 vaccines. Family Doctors should be aware of this event and play an important role informing and reassuring local communities for this possible vaccine reaction.

Acute cellular rejection in liver transplantation recipients following vaccination against coronavirus disease 2019: A case series.

Symmetric drug-related intertriginous and flexural exanthema-like eruption related to coronavirus disease 2019 vaccine.

Persistence of immunogenicity, contributing factors of an immune response, and reactogenicities after a single dose of the ChAdOx1 (AZD1222) COVID-19 vaccine in the Thai population. INTRODUCTION: Due to the vaccine's short supply and the efficacy of a single dose of the ChAdOx1 (AZD1222) vaccine, many governments delayed the interval between prime and boost dose from 4 to 8-12Â weeks. However, the waning of immune response in this period is a concern. This study evaluated the durability, contributing factors of anti-RBD antibody concentration, and reactogenicities after the single dose of AZD1222 vaccine in the Thai population. METHODS: This was a single-center, prospective cohort study at Chulabhorn Hospital, Bangkok, Thailand. Individuals 18Â years or older who were negative for anti-SARS-CoV-2 antibody were eligible. Anti- receptor-binding domain antibody concentrations were tested at least three weeks after the first vaccination and immediately before the second dose of vaccine. Information on reactogenicities was obtained via a questionnaire sent by a short message service. RESULTS: Anti-RBD Antibody concentration at 2 and 3Â months post-vaccination were significantly higher than at 1Â months post-vaccination (20.14

BAU/mL (95%CI; 16.37, 24.77) at 1Â month, 48.08 BAU/mL (95%CI; 42.76, 54.08) at 2Â month, and 65.01 BAU/mL (95%CI; 58.88,71.61) at 3Â month). Adverse events occurred in approximately 60% of participants. Factors influencing vaccine immunogenicity include age, sex, the time elapsed from the first dose of vaccine, and underlying disease with diabetes and hematologic disease. CONCLUSION: A single dose of AZD1222 could elicit immune responses that did not decline within three months in Thai individuals. These data support the public health strategy of a delay between the prime and boost dose of AZD1222 of 4 to 12Â weeks.

Long-term adverse events of three COVID-19 vaccines as reported by vaccinated physicians and dentists, a study from Jordan and Saudi Arabia. Assessment of safety of COVID-19 vaccines is an ongoing process. This study aims to explore long-term adverse events reported by physicians and dentists who received at least two COVID-19 vaccine doses. A group of physicians and dentists were invited to complete a validated questionnaire that was composed of items on: socio-demographics, medical history, administered vaccines, and long-term adverse events (LTAE). Data of a total of 498 practitioners were included. Age ranged from 22 to 71â€‰years (mean age= 35.75â€‰Â±â€‰11.74) with a female majority (Nâ€‰=â€‰348, 69.9%). The most frequently administered vaccines were Pfizer-BioNtech, Sinopharm and AstraZeneca vaccines. A total of 80 (16.0%) participants reported LTAEs which were mainly fatigue, menstrual disturbances, myalgia, arthralgia, dizziness, and headache (Nâ€‰=â€‰32, 15, 8, 6, 4, and 4, respectively). There was no statistically significant association between LTAEs and: age, gender, or medical history (Pâ€‰>â€‰.05). The collective symptoms of fatigue, myalgia, arthralgia, dizziness, and headache were significantly associated with Sinopharm vaccine (Pâ€‰=â€‰.04). This was further confirmed by general linear multivariate model analysis. Less than 20% of COVID-19 vaccine recipients may complain of LTAEs that are mostly fatigue-related. It seems that factors such as age, gender, and medical status play a negligible role in development of these AEs. On the other hand, Sinopharm vaccine showed the highest significant association with these AEs followed by AstraZeneca vaccine.

Longitudinally extensive transverse myelitis after Covid-19 vaccination: case report and review of literature. Mass vaccination has been the main policy to overcome the Covid-19 pandemic. Several vaccines have been approved by the World Health Organization. With growing vaccination, safety concerns and adverse events that need prompt evaluation are also emerging. Herein, we report a case of a healthy woman with longitudinally extensive transverse myelitis after vaccination with the AstraZeneca vaccine. The patient was successfully treated after ruling out all the possible causes.

Post COVID-19 vaccination Guillain-Barre syndrome: three cases. Guillain-BarrÃ© syndrome (GBS) is an acute inflammatory polyradiculoneuropathy. In two-thirds of patients, it is preceded by an upper respiratory or gastrointestinal tract infection. Temporally associated cases of GBS following COVID-19 vaccination have been described with different COVID-19 vaccines. In this study, we report three cases of GBS patients following COVID-19 vaccine. Two of the studied patients received the Sinopharm vaccine and one patient received the AstraZeneca vaccine. All patients were diagnosed with acute motor axonal neuropathy (AMAN) type of GBS, on nerve conduction studies. All three patients responded well to treatment with intravenous immunoglobulin (IVIg). The association between COVID-19 vaccination and GBS is not well understood and more studies are needed to establish whether it is merely an association or a causal relationship.

Detection of anti-NMDA receptor antibodies following BBIBP-CorV COVID-19 vaccination in a rituximab-treated person with multiple sclerosis presenting with manifestations of an acute relapse. Anti-N-methyl-D-aspartate receptor (NMDAR) encephalitis is a relatively unknown autoimmune entity. Scant reports of post-infection/vaccination anti-NMDAR encephalitis exist. We, hereby, reviewed the relevant cases and added to the literature a possible case of anti-NMDAR encephalitis

following COVID-19 vaccination with BBIBP-CorV (Sinopharm). A 50-year-old Persian woman with previously known rituximab-treated MS presented complaining of worsening neurological symptoms all gradually starting and worsening after receiving the second dose of BBVIP-CorV 2 weeks before. Notable findings in her physical examination included ataxic gait and Babinski sign. Considering an acute MS relapse, corticosteroid pulse therapy was initiated, and she was referred for MRI, which revealed multiple new plaques. Her serum sample interestingly tested positive for anti-NMDAR antibodies. CSF analysis was unfortunately not performed. She responded well to the corticosteroid pulse therapy and showed substantial resolution of the symptoms. Considering its relatively low cost of workup and the benefits of correct early diagnosis, clinicians are advised to consider autoimmune encephalitis encountering patients with progressive neurological symptoms after the administration of vaccines, including the ones for COVID-19 which are currently being used extensively.

Myocarditis post-SARS-CoV-2 vaccination: a systematic review. Variable clinical criteria taken by medical professionals across the world for myocarditis following coronavirus disease 2019 (COVID-19) vaccination along with wide variation in treatment necessitates understanding and reviewing the same. A systematic review was conducted to elucidate the clinical findings, laboratory parameters, treatment and outcomes of individuals with myocarditis after COVID-19 vaccination after registering with PROSPERO. Electronic databases including MEDLINE, EMBASE, PubMed, LitCovid, Scopus, ScienceDirect, Cochrane Library, Google Scholar and Web of Science were searched. A total of 85 articles encompassing 2184 patients were analysed. It was a predominantly male (73.4%) and young population (mean age: 25.5â€‰Â±â€‰14.2â€‰years) with most having taken an mRNA-based vaccine (99.4%). The mean duration from vaccination to symptom onset was 4.01â€‰Â±â€‰6.99â€‰days. Chest pain (90.1%), dyspnoea (25.7%) and fever (11.9%) were the most common symptoms. Only 2.3% had comorbidities. CRP was elevated in 83.3% and cardiac troponin in 97.6% patients. An abnormal ECG was reported in 979/1313 (74.6%) patients with ST-segment elevation being most common (34.9%). Echocardiographic data were available for 1243 patients (56.9%), of whom 288 (23.2%) had reduced left ventricular ejection fraction. Non-steroidal antiinflammatory drugs (76.5%), steroids (14.1%) followed by colchicine (7.3%) were used for treatment. Only 6 patients died among 1317 of whom data were available. Myocarditis following COVID-19 vaccination is often mild, seen more commonly in young healthy males and is followed by rapid recovery with conservative treatment. The emergence of this adverse event calls for harmonizing case definitions and definite treatment guidelines, which require wider research.

Relationship between changes in symptoms and antibody titers after a single vaccination in patients with Long COVID. Coronavirus disease 2019 (COVID-19) is spreading worldwide; there is a need to address its sequelae known as Long COVID. This study evaluated postvaccination changes in symptoms and antibody titers in patients with Long COVID. Patients visiting the outpatient department specializing in Long COVID at our hospital were enrolled. Changes in symptoms were evaluated before and 14-21 days after first vaccination. Antibody titers were measured using ARCHITECT SARS-CoV-2 IgG II Quant at the same time. This study included 42 patients (median age: 45 years; 17 [40.5%] men). Median pre- and postvaccination antibody titers were 456Â and 28,963â€‰AU/ml, respectively. Postvaccination symptoms (fatigue, joint pain, and taste and olfactory abnormalities) were relieved, worsened, and unchanged in 7 (16.7%), 9 (21.4%), and 26 (61.9%) patients, respectively. Ratios of pre- and postvaccination antibody titers were 53, 40, and 174 in the unchanged, relief, and worsened groups, respectively. The worsened group had the significantly highest antibody titer ratio (pâ€‰=â€‰0.02). The higher increased rate of the antibody titer in the worsened group than in the nonworsened group suggests an excessive immune response to vaccination associated with worsening of sequelae. Although patients with Long COVID should be vaccinated, additional concerns should be addressed.

Letter to the Editor: The possible role of lymphadenopathy after vaccination in posttraumatic stress disorder in cancer survivors during COVID-19.

Antibody Response in Immunocompromised Patients After the Administration of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine BNT162b2 or mRNA-1273: A Randomized Controlled Trial. BACKGROUND: BNT162b2 by Pfizer-BioNTech and mRNA-1273 by Moderna are the most commonly used vaccines to prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections. Head-to-head comparison of the efficacy of these vaccines in immunocompromised patients is lacking. METHODS: Parallel, 2-arm (allocation 1:1), open-label, noninferiority randomized clinical trial nested into the Swiss HIV Cohort Study and the Swiss Transplant Cohort Study. People living with human immunodeficiency virus (PLWH) or solid organ transplant recipients (SOTR; ie, lung and kidney) from these cohorts were randomized to mRNA-1273 or BNT162b2. The primary endpoint was antibody response to SARS-CoV-2 spike (S1) protein receptor binding domain (Elecsys Anti-SARS-CoV-2 immunoassay, Roche; cutoffâ€…â‰¥0.8 units/mL) 12 weeks after first vaccination (ie, 8 weeks after second vaccination). In addition, antibody response was measured with the Antibody Coronavirus Assay 2 (ABCORA 2). RESULTS: A total of 430 patients were randomized and 412 were included in the intention-to-treat analysis (341 PLWH and 71 SOTR). The percentage of patients showing an immune response was 92.1% (95% confidence interval [CI]: 88.4-95.8; 186/202) for mRNA-1273 and 94.3% (95% CI: 91.2-97.4; 198/210) for BNT162b2 (difference: -2.2%; 95% CI: -7.1 to 2.7), fulfilling noninferiority of mRNA-1273. With the ABCORA 2 test, 89.1% had an immune response to mRNA-1273 (95% CI: 84.8-93.4; 180/202) and 89.5% to BNT162b2 (95% CI: 85.4-93.7; 188/210). Based on the Elecsys test, all PLWH had an antibody response (100.0%; 341/341), whereas for SOTR, only 60.6% (95% CI: 49.2-71.9; 43/71) had titers above the cutoff level. CONCLUSIONS: In immunocompromised patients, the antibody response of mRNA-1273 was noninferior to BNT162b2. PLWH had in general an antibody response, whereas a high proportion of SOTR had no antibody response.

Myelin Oligodendrocyte Glycoprotein Antibody-Mediated Optic Neuritis Following COVID-19 Vaccination.

COVID-19 in pregnancy-what study designs can we use to assess the risk of congenital anomalies in relation to COVID-19 disease, treatment and vaccination? BACKGROUND: The COVID-19 pandemic has accelerated pregnancy outcome research, but little attention has been given specifically to the risk of congenital anomalies (CA) and first trimester exposures. OBJECTIVES: We reviewed the main data sources and study designs used internationally, particularly in Europe, for CA research, and their strengths and limitations for investigating COVID-19 disease, medications and vaccines. POPULATION: We classify research designs based on four data sources: a) spontaneous adverse event reporting, where study subjects are positive for both exposure and outcome, b) pregnancy exposure registries, where study subjects are positive for exposure, c) congenital anomaly registries, where study subjects are positive for outcome and d) population healthcare data where the entire population of births is included, irrespective of exposure and outcome. STUDY DESIGN: Each data source allows different study designs, including case series, exposed pregnancy cohorts (with external comparator), ecological studies, case-control studies and population cohort studies (with internal comparator). METHODS: The quality of data sources for CA studies is reviewed in relation to criteria including diagnostic accuracy of CA data, size of study population, inclusion of terminations of pregnancy for foetal anomaly, inclusion of first trimester COVID-19-related exposures and use of an internal comparator group. Multinational collaboration models are reviewed. RESULTS: Pregnancy exposure registries have been the main design for COVID-19 pregnancy studies, but lack detail regarding first trimester exposures relevant to CA, or a suitable comparator group. CA registries present opportunities for improving diagnostic accuracy in COVID-19 research, especially when linked

to other data sources. Availability of inpatient hospital medication use in population healthcare data is limited. More use of ongoing mother-baby linkage systems would improve research efficiency. Multinational collaboration delivers statistical power. CONCLUSIONS: Challenges and opportunities exist to improve research on CA in relation to the COVID-19 pandemic and future pandemics.

Cardiac magnetic resonance imaging of myocarditis and pericarditis following COVID-19 vaccination: a multicenter collection of 27 cases. OBJECTIVES: To assess clinical and cardiac magnetic resonance (CMR) imaging features of patients with peri-myocarditis following Coronavirus Disease 2019 (COVID-19) vaccination. METHODS: We retrospectively collected a case series of 27 patients who underwent CMR in the clinical suspect of heart inflammation following COVID-19 vaccination, from 16 large tertiary centers. Our patient's cohort was relatively young (36.6 Â± 16.8 years), predominately included males (n = 25/27) with few comorbidities and covered a catchment area of approximately 8 million vaccinated patients. RESULTS: CMR revealed typical mid-subepicardial non-ischemic late gadolinium enhancement (LGE) in 23 cases and matched positively with CMR T2 criteria of myocarditis. In 7 cases, typical hallmarks of acute pericarditis were present. Short-term follow-up (median = 20 days) from presentation was uneventful for 25/27 patients and unavailable in two cases. CONCLUSIONS: While establishing a causal relationship between peri-myocardial inflammation and vaccine administration can be challenging, our clinical experience suggests that CMR should be performed for diagnosis confirmation and to drive clinical decision-making and follow-up. KEY POINTS: â€¢ Acute onset of dyspnea, palpitations, or acute and persisting chest pain after COVID-19 vaccination should raise the suspicion of possible myocarditis or pericarditis, and patients should seek immediate medical attention and treatment to help recovery and avoid complications. â€¢ In case of elevated troponin levels and/or relevant ECG changes, cardiac magnetic resonance should be considered as the best non-invasive diagnostic option to confirm the diagnosis of myocarditis or pericarditis and to drive clinical decision-making and follow-up.

Characterization of the significant decline in humoral immune response six months post-SARS-CoV-2 mRNA vaccination: A systematic review. Accumulating evidence shows a progressive decline in the efficacy of coronavirus disease 2019 (COVID-19) (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]) messenger RNA (mRNA) vaccines such as Pfizer-BioNTech (mRNA BNT161b2) and Moderna (mRNA-1273) in preventing breakthrough infections due to diminishing humoral immunity over time. Thus, this review characterizes the kinetics of anti-SARS-CoV-2 antibodies after the second dose of a primary cycle of COVID-19 mRNA vaccination. A systematic search of the literature was performed and a total of 18 articles (Nâ€‰=â€‰15â€‰980 participants) were identified and reviewed. The percent difference of means of reported antibody titers was then calculated to determine the decline in humoral response after the peak levels postvaccination. Findings revealed that the peak humoral response was reached at 21-28 days after the second dose, after which serum levels progressively diminished at 4-6-month postvaccination. Additionally, results showed that regardless of age, sex, serostatus, and presence of comorbidities, longitudinal data reporting antibody measurement exhibited a decline of both anti-receptor binding domain immunoglobulin G (IgG) and anti-spike IgG, ranging from 94% to 95% at 90-180 days and 55%-85% at 140-160 days, respectively, after the peak antibody response. This suggests that the rate of antibody decline may be independent of patient-related factors and peak antibody titers but mainly a function of time and antibody class/molecular target. Hence, this study highlights the necessity of more efficient vaccination strategies to provide booster administration in attenuating the effects of waning immunity, especially in the appearance of new variants of concerns.

COVID-19 Vaccination and The Eye. PURPOSE: To summarize the current evidence on COVID-19 vaccine-associated ocular adverse events. DESIGN: Narrative literature review. METHODS: The literature search was conducted in August 2021 using 4 electronic databases: MEDLINE, EMBASE,

PubMed, and the Cochrane Database of Systematic Reviews. Population-based pharmacovigilance surveillance data were retrieved from all governmental agencies participating in the World Health Organization (WHO) Programme for International Drug Monitoring with publicly available online adverse event databases in English. RESULTS: A small number of case reports have documented uveitis flares and acute corneal graft rejection occurring within the first 3 weeks following immunization, while isolated cases of optic neuropathies, retinal conditions, scleritis, and herpetic eye disease have also been highlighted. However, data from population-based pharmacovigilance surveillance systems suggest that the prevalence of vaccination-associated ocular adverse events are very rare. CONCLUSIONS: Vaccination-associated ocular adverse events are rare, and there is currently no substantive evidence to counterweigh the overwhelming benefits of COVID-19 immunization in patients with pre-existing ophthalmic conditions.
Posterior Scleritis Following COVID-19 Vaccination: A Case Report. PURPOSE: To report a case of posterior scleritis following COVID-19 vaccination. STUDY DESIGN: Case report. RESULTS: A 78-year-old female presented with headache and right-sided visual loss 10 days after the second dose of COVID-19 vaccine. 'Examination showed disc oedema and a serous retinal detachment. B-scan ultrasound showed thickening of the posterior sclera with retroscleral fluid. CT head with venogram excluded venous sinus thrombosis. The patient's condition improved rapidly with oral corticosteroids with restoration of vision and resolution of disc swelling and serous detachment by 4 weeks. CONCLUSIONS: Posterior scleritis should be considered in patients presenting with headaches and blurred vision following vaccination. Timely diagnosis and treatment with corticosteroids can prevent permanent visual loss.
Bilateral Panuveitis with Occlusive Vasculitis following Coronavirus Disease 2019 Vaccination. PURPOSE: To report a case of bilateral panuveitis and occlusive vasculitis following COVID-19 vaccination. STUDY DESIGN: Case report. RESULTS: A 41-year-old otherwise healthy male presented with progressive vision loss and floaters starting 48Â hours after a first dose of COVID-19 vaccine. Examination initially showed bilateral anterior uveitis, but this evolved into bilateral panuveitis with occlusive vasculitis despite topical corticosteroids over two weeks. The patient underwent extensive testing for other etiologies which were excluded. He was successfully treated with a gradual taper of topical and systemic corticosteroids leading to improvement of signs and symptoms. Follow-up is maintained for observation of avascular zones with possible neovascularization which could require laser as needed. CONCLUSIONS: The temporal association between vaccine and presentation makes this a plausible etiology. This remains a rare adverse event, but clinicians should be aware of this possibility to include it in their differential diagnosis when confronted with idiosyncratic ocular presentations.
Anterior Uveitis following COVID Vaccination: A Summary of Cases from Global Reporting Systems. PURPOSE: COVID-19 vaccines are currently undergoing long-term safety monitoring, including for ocular side effects. Uveitis following vaccination has been described previously with other vaccines and warrants evaluation for COVID-19 vaccines, especially given their widespread use. CASE REPORTS: We present two cases of patients who developed anterior uveitis following the Moderna COVID-19 vaccine, as reported to the National Registry for Drug-Induced Ocular Side Effects. We also summarize reports of anterior uveitis following COVID-19 vaccination as reported to the World Health Organization global database of individual case safety reports. CONCLUSIONS: Based on the temporal pattern of ocular inflammation following vaccine delivery in these cases, an association may be present between uveitis and COVID-19 vaccination. Further investigation to explore this association is warranted to guide patient care.
Erythema nodosum leprosum post-COVID-19 vaccination: endemic while pandemic.
[Facial Vitiligo After SARS-CoV-2 Vaccination].

Effects of age, sex, serostatus, and underlying comorbidities on humoral response post-SARS-CoV-2 Pfizer-BioNTech mRNA vaccination: a systematic review. With the advent of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) pandemic, several vaccines have been developed to mitigate its spread and prevent adverse consequences of the Coronavirus Disease 2019 (COVID-19). The mRNA technology is an unprecedented vaccine, usually given in two doses to prevent SARS-CoV-2 infections. Despite effectiveness and safety, inter-individual immune response heterogeneity has been observed in recipients of mRNA-based vaccines. As a novel disease, the specific immune response mechanism responsible for warding off COVID-19 remains unclear at this point. However, significant evidence suggests that humoral response plays a crucial role in affording immunoprotection and preventing debilitating sequelae from COVID-19. As such, this paper focused on the possible effects of age, sex, serostatus, and comorbidities on humoral response (i.e. total antibodies, IgG, and/or IgA) of different populations post-mRNA-based Pfizer-BioNTech vaccination. A systematic search of literature was performed through PubMed, Cochrane CENTRAL, Google Scholar, Science Direct, medRxiv, and Research Square. Studies were included if they reported humoral response to COVID-19 mRNA vaccines. A total of 32 studies were identified and reviewed, and the percent differences of means of reported antibody levels were calculated for comparison. Findings revealed that older individuals, male sex, seronegativity, and those with more comorbidities mounted less humoral immune response. Given these findings, several recommendations were proposed regarding the current vaccination practices. These include giving additional doses of vaccination for immunocompromised and elderly populations. Another recommendation is conducting clinical trials in giving a combined scheme of mRNA vaccines, protein vaccines, and vector-based vaccines.

Type 1 diabetes mellitus following COVID-19 RNA-based vaccine. The epidemic of coronavirus disease-2019 (COVID-19) is the major public health issue in the world. COVID-19 vaccines are one of the most effective strategies against COVID-19. Here we report a 36-year-old female patient who had thirst, polydipsia, polyuria, palpitations, loss of appetite, and fatigue 3â€‰days after the first dose of COVID-19 RNA-based vaccines without a prior history of diabetes. Ten days after vaccination, she visited our hospital with diabetic ketoacidosis and was diagnosed with type 1 diabetes. Hyperglycemia (501â€‰mg/dL), anion gap metabolic acidosis and ketonuria were observed. The glycated hemoglobin level was 7.0%. Islet-related autoantibodies were all negative. The glucagon tolerance test revealed attenuated secretion of insulin. Human leukocyte antigen was haplotype DRB1*0405-DQB1*0401, which was associated with type 1 diabetes in Japan. The present case suggests that COVID-19 RNA-based vaccines might trigger the onset of type 1 diabetes, even in subjects without prior histories of diabetes.

Hemophagocytic lymphohistiocytosis after SARS-CoV-2 vaccination. PURPOSE: The coronavirus disease 2019 (COVID-19) pandemic has led to the approval of novel vaccines with different mechanisms of action. Until now, more than 4.7 billion persons have been vaccinated around the world, and adverse effects not observed in pre-authorization trials are being reported at low frequency. METHODS: We report a case of severe hemophagocytic lymphohistiocytosis (HLH) after SARS-CoV-2 immunization and performed a literature search for all reported cases of COVID-19 vaccine-associated HLH. RESULTS: A 24-year-old female developed HLH after immunization with the mRNA COVID-19 vaccine Comirnaty. Diagnosis was made according to HLH-2004 criteria; the HScore was 259 (>â€‰99% HLH probability) with maximum ferritin of 138.244Â Âµg/L. The patient was initially treated with intravenous immunoglobulins (IVIGs) and dexamethasone without response. The addition of the human interleukin 1 receptor antagonist Anakinra resulted in full recovery within 6Â weeks after vaccination. A literature search revealed 15 additional cases of HLH after SARS-CoV-2 vaccination, the majority after immunization with Comirnaty (nâ€‰=â€‰7) or the viral vector vaccine Vaxzevria (nâ€‰=â€‰6). Treatment modalities included corticosteroids (nâ€‰=â€‰13),

Anakinra (nâ€‰=â€‰5), IVIGs (nâ€‰=â€‰5), and etoposide (nâ€‰=â€‰2). Eight patients underwent combination treatment. Three of 16 patients died. CONCLUSION: COVID-19 vaccines may occasionally trigger HLH, and Anakinra may be an efficacious treatment option for this condition.
A Case of Ulcerative Colitis Relapse Characterized by Systemic Type I Interferon Responses after COVID-19 Vaccination.
Impact of disease-modifying therapies on humoral and cellular immune-responses following SARS-CoV-2 vaccination in MS patients. The impact of distinct disease-modifying therapies (DMTs) on severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) vaccination efficacy in patients with multiple sclerosis (MS) is still enigmatic. In this prospective comparative study, we investigated humoral and cellular immune-responses in patients with MS receiving interferon beta, natalizumab, and ocrelizumab pre-vaccination and 6Â weeks post second SARS-CoV-2 vaccination. Healthy individuals and interferon beta-treated patients generated robust humoral and cellular immune-responses. Although humoral immune responses were diminished in ocrelizumab-treated patients, cellular immune-responses were reduced in natalizumab-treated patients. Thus, both humoral and cellular immune responses should be closely monitored in patients on DMTs. Whereas patients with a poor cellular immune-response may benefit from additional vaccination cycles, patients with a diminished humoral immune-response may benefit from a treatment with SARS-CoV-2 antibodies in case of an infection.
Peripheral Ulcerative Keratitis Secondary to the Inactive COVID-19 Vaccine-CoronaVac. PURPOSE: To report a case of peripheral ulcerative keratitis (PUK) secondary to the inactive Covid-19 vaccine. METHODS: The case of a 67-year-old man who presented with unilateral progressive vision-threatening PUK with nodular scleritis was reported. The results of clinical examinations with surgical and medical treatments were noted. RESULTS: The extended workup for autoimmune and infectious etiologies for PUK that all returned negative. The patient was treated with oral steroids, azathioprine, and topical cyclosporine with topical dexamethasone for his PUK and underlying possible immunopathology. Corneal amniotic membrane grafting was also performed 4 times and finally, the patient underwent penetrant keratoplasty for visual rehabilitation. CONCLUSIONS: To our knowledge, we report the first case of PUK that is possible to secondary to an inactive vaccine for SARS-CoV-2. The inactive covid vaccine should be considered as an etiological agent in PUK cases where the standard workup is negative.
Eosinophilic pneumonia following Sinovac/CoronaVac vaccination. Comment on "Hypersensitivity reactions to COVID-19 vaccines: a case of eosinophilic pneumonia following Sinovac/CoronaVac vaccination".
Safety and immunogenicity of heterologous and homologous inactivated and adenoviral-vectored COVID-19 vaccine regimens in healthy adults: a prospective cohort study. In light of intermittent supply shortages of individual vaccines and evidence of rare but serious adverse events after vaccination, heterologous regimens for COVID-19 vaccines have gained significant interest. This study aims to assess the reactogenicity and immunogenicity of the heterologous adenoviral vector (ChAdOx1-S, AstraZeneca; hereafter referred to as AZ) and the inactivated vaccine regimen (CoronaVac; hereafter referred to as CV) in healthy Thai adults immunized between June and September 2021. Our study showed that adverse events following homologous CV-CV and AZ-AZ, and heterologous CV-AZ and AZ-CV combinations, were mild and well tolerated overall. Receptor-binding domain (RBD)-specific antibody responses and neutralizing activities against wild-type and variants of concern after two-dose vaccination were higher in the heterologous CV-AZ and homologous AZ-AZ groups compared to the CV-CV and AZ-CV groups. Conversely, the spike-specific IgA response was detected only in the CV-AZ group after two doses of vaccination. The total interferon gamma response was detected in both the CV-AZ and AZ-CV groups after the two-dose vaccination. Given the

shorter completion time of two doses, heterologous CoronaVac followed by ChAdOx1-S can be considered as an alternative regimen to homologous efficacy-proven ChAdOx1-S in countries with circulating variants. Additional studies on the efficacy and durability of immune responses induced by heterologous vaccine regimens are warranted.

Thrombosis and thrombocytopenia in COVID-19 and after COVID-19 vaccination. Thrombosis that occurs in coronavirus disease 19 (COVID-19) is a serious complication and a critical aspect of pathogenesis in the disease progression. Although thrombocytopenia is uncommon in the initial presentation, it may also reflect disease severity due to the ability of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to activate platelets. This occurs directly through the spike protein-angiotensin converting enzyme 2 (ACE2) interaction and indirectly by coagulation and inflammation activation. Dysregulation in both innate and adaptive immune systems is another critical factor that causes thrombosis and thrombocytopenia in COVID-19. Vaccination is the most potent and effective tool to mitigate COVID-19; however, rare side effects, namely vaccine-induced immune thrombotic thrombocytopenia (VITT)/thrombosis with thrombocytopenia syndrome (TTS) can occur following adenovirus-vectored vaccine administration. VITT/TTS is rare, and thrombocytopenia can be the clue to detect this serious complication. It is important to consider that thrombocytopenia and/or thromboembolism are not events limited to post-vaccination with vectored vaccine, but are also seen rarely after vaccination with other vaccines. Various conditions mimic VITT/TTS, and it is vital to achieving the correct diagnosis at an earlier stage. Antiplatelet factor 4 (PF4) antibody detection by the enzyme-linked immunosorbent assay (ELISA) is used for diagnosing VITT/TTS. However, false-positive rates also occur in vaccinated people, who do not show any thrombosis or thrombocytopenia. Vaccinated people with messenger RNA vaccine can show positive but low density and non-functional in terms of platelet aggregation, it is vital to check the optical density. If anti-PF4 ELISA is not available, discriminating other conditions such as antiphospholipid syndrome, thrombotic thrombocytopenic purpura, immune thrombocytopenic purpura, systemic lupus erythematosus, and hemophagocytic syndrome/hemophagocytic lymphohistiocytosis is critical when the patients show thrombosis with thrombocytopenia after COVID-19 vaccination.

Self-Reported safety of the BBIBP-CorV (Sinopharm) COVID-19 vaccine among Iranian people with multiple sclerosis. To affirm the short-term safety of the BBIBP-CorV (Sinopharm) COVID-19 vaccine among people with multiple sclerosis (pwMS), 517 vaccinated and 174 unvaccinated pwMS were interviewed. 16.2% of the vaccinated pwMS reported at least one neurological symptom in their respective vaccine-related at-risk periods (ARP) - a period from the first dose until two weeks after the second dose of the vaccine. In a multivariable logistic regression model, the presence of comorbidities (Pâ€‰=â€‰0.01), use of natalizumab (Pâ€‰=â€‰0.03), and experiencing post-vaccination myalgia (Pâ€‰<â€‰0.01) predicted the development of post-vaccination neurological symptoms. One MS relapse, one COVID-19 contraction, and one ulcerative colitis flare after the first dose, and four MS relapses after the second dose of the vaccine were the only reported serious adverse events during the ARPs. To show if the vaccine provoked MS relapses, we compared the relapse rate of vaccinated pwMS in the vaccine-related ARP with the annualized relapse rate of unvaccinated pwMS in the prior year-a measure of baseline MS relapsing activity in the respective time-using a multivariable Poisson regression model accounting for possible confounders, which failed to show any statistically significant increase (Pâ€‰=â€‰0.78). Hence, subject to replication-as the vaccinated and unvaccinated pwMS differed in baseline characteristics-the BBIBP-CorV vaccine does not seem to affect short-term MS activity. Furthermore, as 83.33% of the unvaccinated pwMS reported fear of possible adverse events to be the reason of their vaccination hesitancy, provision of evidence-based consultations to pwMS is encouraged. Limitations of our study briefly included lack of

data for self-controlled analysis of relapse rates, possible presence of recall bias, and lack of on-site validations regarding the clinical outcomes due to the remote nature.
Multiple Evanescent White Dot Syndrome following COVID-19 mRNA Vaccination in Two Patients. PURPOSE: To describe two cases of multiple evanescent white dot syndrome (MEWDS) occurring after administration of COVID-19 vaccine. STUDY DESIGN: Case Report. RESULTS: Two patients presented soon after receiving their second-dose of the BNT162b2 Pfizer-BioNTech COVID-19 vaccine with findings consistent with MEWDS. Due to the significant reduction in vision, patients were treated with a short dose of oral corticosteroids. Both had complete resolution of their symptoms, visual acuity and retinal findings. CONCLUSIONS: The onset of inflammatory ocular adverse events following COVID-19 vaccinations suggest a maladaptive inflammatory response triggered by the vaccine. Onset of symptoms after COVID-19 vaccinations should prompt the ophthalmologist to assess for these rare adverse events. Despite the extremely rare occurrences of ocular adverse events, we unequivocally recommend that patients receive the full vaccine due to the vast benefit for both individuals and society that far outweighs the inconsiderable risk of harm.
Vogt-Koyanagi-Harada Relapse after COVID-19 Vaccination. PURPOSE: To report a relapse of Vogt-Koyanagi-Harada (VKH) disease in a patient after COVID-19 vaccination. CASE REPORT: A VKH disease patient, well controlled on azathioprine therapy, presented a uveitis relapse eleven days after the first vaccination for COVID-19. She received an induction high-dose intravenous corticosteroid therapy, followed by oral therapy, which led to a complete recovery from the uveitis in two weeks. No relapses occurred in the following five months of follow-up. Despite high-dose corticosteroid therapy and azathioprine, and one dose only of vaccination, the patient resulted positive for anti-RBD spike COV19 antibody. CONCLUSION: Relapse of VKH disease can occur after COVID-19 vaccination, despite an appropriate immunosuppressive therapy is ongoing. It responds to the classic therapy for VKH, and a serological response to an incomplete COVID-19 vaccination can also be found.
Persistent pruritus following COVID-19 vaccination.
A single dose of COVID-19 vaccine induces a strong T cell and B cell response in healthcare professionals recovered from SARS-CoV-2 infection. A broad understanding on how SARS-CoV-2 infection and vaccination mobilize the immune system is necessary to find the best predictors of long-term protection and identify individuals that would benefit from additional vaccine doses. This study aims to understand the effect of a single dose of Pfizer-BioNTech BNT162b2 COVID-19 vaccine, in individuals recovered from SARS-CoV-2 infection, on circulating CD4(+) T follicular helper (Tfh)-cells, Spike-specific T-cells and IgG/IgA antibodies. For that, peripheral blood samples from 50 healthcare professionals, recovered from SARS-CoV-2 infection, collected immediately before (T1) and 15Â days after (T2) vaccine administration, were used to analyze the frequency and numbers of Tfh-cells and their subsets, serum titers of SARS-CoV-2-specific antibodies, and SARS-CoV-2-specific T-cells. Six months after infection (T1), 96% of recovered participants presented either IgG or T-cells specific for Spike, however, Spike-specific T-cells were missing in 16% of them. These individuals presented lower levels of Spike-specific IgG (T1 and T2), IgA (T1), and Spike-specific T-cells (T2). Vaccination increased the percentage of participants reactive for Spike-specific T-cells (from 64 to 98%), IgG (from 90 to 100%) and IgA (from 48 to 98%). It also mobilized circulating Tfh-cells, increasing their frequency and activation, and promoting Tfh17 polarization, restoring the decreased numbers of Tfh-cells (especially Tfh17) observed in recovered participants. Interestingly, Tfh percentage correlated with Spike-specific IgG levels. Our data showed that a single dose of vaccine efficiently restored Spike-specific T-cells, and IgG and IgA antibodies. Mobilization of Tfh-cells, and their correlation with IgG levels, suggest that vaccination induced a functional Tfh cell response.
A case of encephalitis following COVID-19 vaccine. We describe the first case of encephalitis following coronavirus disease 2019 (COVID-19) vaccination. Our patient was a 46-year-old Japanese

woman who presented with acute onset diplopia. Subsequent magnetic resonance imaging revealed brain stem encephalitis that was rapidly responsive to high dosage steroid therapy and completely improved. Although the occurrence of encephalitis after vaccination could have just been a casual temporal association, her symptoms were temporally correlated with two vaccinations. Our case suggests caution and indicates treatment and prognosis, despite no evidence of a causal relationship. Nonetheless, this report emphasizes the enormous benefits of vaccination, which should not be undermined.
Vocal fold palsy after vaccination against SARS-CoV-2.
Flu vaccination in multiple sclerosis patients: a monocentric prospective vaccine-vigilance study. BACKGROUND: In 2020, the Italian Medicines Agency recommended to bring forward the flu vaccination campaign, whose importance was also emphasized for patients with Multiple Sclerosis (MS). We aimed to assess the safety profile of flu vaccines in terms of occurrence of short-term and long-term Adverse Events Following Immunization (AEFIs). METHODS: This is an observational study that enrolled MS patients who were eligible for any of the flu vaccines recommended by the Italian medicines Agency. RESULTS: 194 patients were enrolled. Out of 133 patients who accepted to be vaccinated, 45 experienced not serious short-term AEFIs (pain at the injection site, headache, flu-like symptoms, fatigue). Long-term AEs were detected in 12 vaccinated patients (flu-like symptoms, COVID-19 and MS relapse). No statistically significant differences in terms of infections or MS relapse were found between vaccinated and unvaccinated groups. Using Kaplan-Meier analysis we observed no differences in the cumulative survival rate in both groups. CONCLUSION: Flu vaccines were well tolerated in MS patients, who mainly experienced not serious short term AEFIs. Considering that COVID-19 vaccines campaign is still ongoing among MS patients, our results might bring new knowledge concerning the safety profile of vaccines in this frail population.
A case of myocarditis following ChAdOx1 nCov-19 vaccination. Introduction: Myocarditis is an inflammatory disease of the myocardium, that might lead to reduced cardiac function and in the most severe cases to mortality. Although uncommon, it is a known adverse event after vaccination with coronavirus disease 2019 (COVID-19) mRNA vaccines. Here, we report the case of myocarditis following vaccination with a viral vector vaccine, ChAdOX1 nCoV-19.Case presentation: A 50-year-old male presented at the emergency department with shortness of breath, general malaise and fever, 5â€‰days after receiving a second dose of the ChAdOx1 vaccine. Biochemical analysis revealed elevated serum CRP and troponin levels. Two weeks after initial presentation, a cardiac MRI showed belated contrast capitation in the left ventricle, confirming the diagnosis of myocarditis.Conclusions: To our knowledge, this is the first report of myocarditis following ChAdOx1 vaccination. Except for some case of myocarditis upon the Ad26COVS1 vaccine, no other cases were reported upon vaccination with the ChAdOX1 viral vector vaccines. With this report we would like to raise awareness about myocarditis as an adverse event following ChAdOx1 vaccination.
[Acute Central Serous Chorioretinopathy Following Immunisation with SARS-CoV-2 mRNA Vaccine?].
Not only toes and fingers: COVID vaccine-induced chilblain-like lesions of the knees.
Trends in Rotavirus Laboratory Detections and Internet Search Volume Before and After Rotavirus Vaccine Introduction and in the Context of the Coronavirus Disease 2019 Pandemic-United States, 2000-2021. BACKGROUND: Since rotavirus vaccines became available in the United States in 2006, there have been reductions in rotavirus hospitalizations, changes in seasonality, and the emergence of a biennial trend of rotavirus activity. Reductions in other pathogens have been associated with coronavirus disease 2019 (COVID-19) mitigation measures. We assessed ongoing rotavirus disease trends during the COVID-19 pandemic. METHODS: We report a 3-week moving average of the number of rotavirus tests, positive tests, and the percent positivity from laboratories reporting to the National Respiratory and Enteric Virus Surveillance System (NREVSS) from July 2000

through June 2021. To complement NREVSS data, we analyzed Google internet search interest in "rotavirus" from July 2004 to June 2021. RESULTS: Declines in rotavirus activity following vaccine introduction and the biennial trend are evident through the 2018-2019 surveillance year. In 2019-2021, rotavirus test positivity was below the historic ranges during the months of typically high rotavirus activity, and precipitous declines were noted in March 2020. CONCLUSIONS: In the 15 years since rotavirus vaccine was introduced, the number of laboratory-detected rotavirus infections has been consistently lower than during the prevaccine era. During the COVID-19 pandemic, rotavirus activity was suppressed. There may be many rotavirus-susceptible children during the 2021-2022 rotavirus season.

SARS-CoV-2 vaccine-associated subacute thyroiditis. PURPOSE: With coronavirus disease 2019 (COVID-19), subacute thyroiditis (SAT) cases are on the rise all over the world. COVID-19 vaccine-associated SAT cases have also been reported. In this article, we present our data on 11 vaccine-associated SAT cases. METHODS: Eleven patients were included in the study. Type of the vaccines patients received, time to the occurrence of SAT after vaccination, symptoms and laboratory findings, treatment given, and response to treatment were evaluated. RESULTS: The age of patients ranged from 26 to 73. Four of the patients were males, and seven were females. Symptoms of six patients were seen after BNT162b2 Pfizer/BioNTech COVID-19 mRNA vaccineÂ®, and four of them after Coronavac inactivated SARS-CoV-2 vaccineÂ®. In one patient, SAT developed after the first dose of BNT162b2, administered after two doses of Coronavac. The average time to the onset of symptoms was 22Â days (15-37) after vaccination. CONCLUSIONS: The fact that both whole virus containing and genetic material containing vaccines cause SAT suggests that the trigger may be viral proteins rather than the whole viral particle. Although corticosteroids are commonly preferred in published vaccine-associated SAT cases, we preferred nonsteroidal anti-inflammatory therapy in our patients for sufficient vaccine antibody response. There is not enough information about whether patients who develop SAT can be revaccinated safely considering the ongoing pandemic. Further research is needed for a conclusion in the treatment and revaccination of these patients.

COVID-19 vaccination and Guillain-BarrÃ© syndrome: analyses using the National Immunoglobulin Database. Vaccination against viruses has rarely been associated with Guillain-BarrÃ© syndrome (GBS), and an association with the COVID-19 vaccine is unknown. We performed a population-based study of National Health Service data in England and a multicentre surveillance study from UK hospitals to investigate the relationship between COVID-19 vaccination and GBS. Firstly, case dates of GBS identified retrospectively in the National Immunoglobulin Database from 8 December 2021 to 8 July 2021 were linked to receipt dates of COVID-19 vaccines using data from the National Immunisation Management System in England. For the linked dataset, GBS cases temporally associated with vaccination within a 6-week risk window of any COVID-19 vaccine were identified. Secondly, we prospectively collected incident UK-wide (four nations) GBS cases from 1 January 2021 to 7 November 2021 in a separate UK multicentre surveillance database. For this multicentre UK-wide surveillance dataset, we explored phenotypes of reported GBS cases to identify features of COVID-19 vaccine-associated GBS. Nine hundred and ninety-six GBS cases were recorded in the National Immunoglobulin Database from January to October 2021. A spike of GBS cases above the 2016-2020 average occurred in March-April 2021. One hundred and ninety-eight GBS cases occurred within 6 weeks of the first-dose COVID-19 vaccination in England [0.618 cases per 100,000 vaccinations; 176 ChAdOx1 nCoV-19 (AstraZeneca), 21 tozinameran (Pfizer) and one mRNA-1273 (Moderna)]. The 6-week excess of GBS (compared to the baseline rate of GBS cases 6-12 weeks after vaccination) occurred with a peak at 24 days post-vaccination; first-doses of ChAdOx1 nCoV-19 accounted for the excess. No excess was seen for second-dose vaccination. The absolute number of excess GBS cases from January-July 2021 was between 98-140 cases for first-dose ChAdOx1 nCoV-19 vaccination. First-

dose tozinameran and second-dose of any vaccination showed no excess GBS risk. Detailed clinical data from 121 GBS patients were reported in the separate multicentre surveillance dataset during this timeframe. No phenotypic or demographic differences identified between vaccine-associated and non-vaccinated GBS cases occurring in the same timeframe. Analysis of the linked NID/NIMS dataset suggested that first-dose ChAdOx1 nCoV-19 vaccination is associated with an excess GBS risk of 0.576 (95% confidence interval 0.481-0.691) cases per 100 000 doses. However, examination of a multicentre surveillance dataset suggested that no specific clinical features, including facial weakness, are associated with vaccination-related GBS compared to non-vaccinated cases. The pathogenic cause of the ChAdOx1 nCoV-19 specific first dose link warrants further study.
Cerebral venous thrombosis after COVID-19 vaccination: the role for endovascular treatment.
Three doses of an inactivation-based COVID-19 vaccine induces cross-neutralizing immunity against the SARS CoV-2 Omicron variant. The immunity potency upon natural infection or vaccination is the main concern for the vaccine strategy of severe acute respiratory syndrome coronavirus 2 (SARS COV-2 variant), especially the recently reported Omicron variant (B.1.1.529). In this study, 200 recipients immunized with three doses of a COVID-19-inactivated vaccine were enrolled, whose serum samples were collected within 2 months after the third immunization. The neutralizing activity of sera against the pseudotyped Omicron variant, prototype, and Delta variant was determined. Our results demonstrated that the positive neutralization activity was 95.5% for the Omicron variant, 99.5% for the prototype, and 98.5% for the Delta variant. The geometric mean titers (GMT) for the Omicron variant was 49 and maintained sustained immune levels for 2 months, which decreased by 4.9-fold and 3.0-fold compared with the prototype (GMT, 239) and Delta variant (GMT, 148), respectively. In summary, our study demonstrated that three doses of a COVID-19-inactivated vaccine effectively yielded potent cross-neutralizing activity against the Omicron variant at 2 months after the third vaccination.
Acute Cardiac Events After ChAdOx1 nCoV-19 Corona Virus Vaccine: Report of Three Cases.
COVID-19 Vaccine Hesitancy Among Patients with Inflammatory Bowel Diseases at a Diverse Safety Net Hospital. BACKGROUND AND AIMS: Patients with inflammatory bowel disease (IBD) and underrepresented minorities (URMs) historically have below average vaccination rates. URMs have increased morbidity and mortality from COVID-19. We surveyed IBD patients to assess COVID vaccination attitudes, particularly among URMs. METHODS: In May and June 2021, all 822 adult patients with IBD, medically homed at a tertiary IBD referral center and safety net hospital, and with access to the electronic patient portal, were sent an electronic survey assessing their attitudes regarding COVID-19 vaccination. An additional 115 without access to the patient portal were contacted by phone. Demographic and clinical data were recorded. The primary outcome was vaccination hesitancy, defined as: likely will become vaccinated later this year, but not immediately; unsure if they will get the vaccine; or do not want the vaccine. Multivariable logistic regression was used to calculate adjusted odds ratios (aOR) of factors associated with vaccination intent. RESULTS: The mean age was 46.6Â years (SD 15.1). 210/1029 patients responded to the survey: 150/822 (18.2%) electronically and 60/115 (52.2%) by phone. Overall vaccine hesitancy rate was 11.9%, significantly higher in younger (aOR for 10-year increments, 0.64; 95% confidence interval [CI], 0.46-0.90, pâ€‰=â€‰0.011), Hispanic (aOR, 7.67; 95% CI, 2.99-21.3, pâ€‰<â€‰0.0002), and Black patients (aOR, 3.52; 95% CI 1.11-11.1, pâ€‰=â€‰0.050). Safety concerns were the most cited reasons for vaccine hesitancy. CONCLUSIONS: URM patients were more vaccine hesitant. Future studies should further explore factors leading to lower vaccination rates among these groups and strategies to improve COVID-19 vaccination rates.
Association study between herpes zoster reporting and mRNA COVID-19 vaccines (BNT162b2 and mRNA-1273). Several cases of herpes zoster (HZ) following mRNA COVID-19 vaccination

(BNT162b2 and mRNA-1273) have been reported, and the first epidemiological evidence suggests an increased risk. We used the worldwide pharmacovigilance database VigiBase to describe HZ cases following mRNA COVID-19 vaccination. We performed disproportionality analyses (case/non-case statistical approach) to assess the relative risk of HZ reporting in mRNA COVID-19 vaccine recipients compared to influenza vaccine recipients and according to patient age. To 30 June 2021, of 716â€‰928 reports with mRNA COVID-19 vaccines, we found 7728 HZ cases. When compared to influenza vaccines, mRNA COVID-19 vaccines were associated with a significantly higher reporting of HZ (reporting odds ratio 1.9, 95% CI 1.8-2.1). Furthermore, we found a reduced risk of reporting HZ among under 40-year-old persons compared to older persons (reporting odds ratio 0.39, 95% CI 0.36-0.41). Mild and infrequent HZ reactions may occur shortly after mRNA COVID-19 vaccination, at higher frequency than reported with influenza vaccination, especially in patients over 40â€‰years old. Further analyses are needed to confirm this risk.
Significant Reduction in Vaccine-Induced Antibody Levels and Neutralization Activity Among Healthcare Workers and Nursing Home Residents 6 Months Following Coronavirus Disease 2019 BNT162b2 mRNA Vaccination. Antibody decline occurred from 2 weeks to 6 months post-BNT162b2 mRNA vaccination in nursing home (NH) residents and healthcare workers. Antispike, receptor-binding domain, and neutralization levels dropped >81% irrespective of prior infection. Notably, 69% of infection-naive NH residents had neutralizing antibodies at or below the assay's limit of detection.
Vaccine-induced immune thrombotic thrombocytopenia: a possible pathogenic role of ChAdOx1 nCoV-19 vaccine-encoded soluble SARS-CoV-2 spike protein.
Cardiac magnetic resonance findings in acute myocarditis after mRNA COVID-19 vaccination. There is increasing evidence for myocarditis as a complication of the mRNA coronavirus disease 2019 (COVID-19) vaccination. We report the case of a 20-year-old previously healthy man who presented with fever and chest pain 2 days after the second dose of mRNA-1273 vaccine. Electrocardiogram and laboratory studies showed extensive ST-segment elevation accompanied by elevated cardiac biomarkers. Cardiac magnetic resonance (CMR) revealed late gadolinium enhancement (LGE) characteristics of myocarditis. The patient rapidly improved with conservative management and was discharged on hospital day 6. As an advantage over previous reports, we performed a 1-month follow-up CMR. It showed improvement in myocardial edema but persistence of LGE which may indicate irreversible fibrosis. CMR may be useful not only for diagnosis but also for prognostic evaluation of myocarditis after COVID-19 mRNA vaccination. <Learning objective: With the expansion of coronavirus disease 2019 (COVID-19) vaccine administration, the number of cases of myocarditis as a complication has been increasing. Cardiac magnetic resonance imaging can be useful for the diagnosis and follow-up of patients with myocarditis after mRNA COVID-19 vaccination. Persistent late gadolinium enhancement may indicate irreversible myocardial fibrosis, and it is also associated with poor prognosis, similar to previously reported cases of other acute myocarditis.>.
Rheumatoid arthritis disease activity assessed by patient-reported outcomes and flow cytometry before and after an additional dose of COVID-19 vaccine.
New-onset fulminant typeâ€‰1 diabetes after severe acute respiratory syndrome coronavirusâ€‰2 vaccination: A case report. Fulminant typeâ€‰1 diabetes is characterized by a rapid progression of insulin deficiency triggered by viral infection. Here, we report a case of a 45-year-old Japanese woman with fulminant typeâ€‰1 diabetes that developed 8â€‰days after receiving messenger ribonucleic acid vaccine against severe acute respiratory syndrome coronavirusâ€‰2. She had been healthy and had no symptoms suggestive of viral infection before the vaccination. Laboratory tests showed exhaustion of insulin secretion and negative results for islet autoantibodies. Human leukocyte antigen genotype analysis showed the DRB1*04:05 and DQB1*04:01 alleles. This is the first

case report of new-onset fulminant typeâ€‰1 diabetes after severe acute respiratory syndrome coronavirusâ€‰2 vaccination, and suggests that a severe acute respiratory syndrome coronavirusâ€‰2 vaccine might trigger the onset of fulminant typeâ€‰1 diabetes in susceptible individuals. However, a causal relationship remains to be identified, and further studies are required to determine the incidence of such cases.

Myocardial Injury Pattern at MRI in COVID-19 Vaccine-Associated Myocarditis. Background There are limited data on the pattern and severity of myocardial injury in patients with COVID-19 vaccination-associated myocarditis. Purpose To describe myocardial injury following COVID-19 vaccination and to compare these findings to other causes of myocarditis. Materials and Methods In this retrospective cohort study, consecutive adult patients with myocarditis with at least one T1-based and at least one T2-based abnormality at cardiac MRI performed at a tertiary referral hospital from December 2019 to November 2021 were included. Patients were classified into one of three groups: myocarditis following COVID-19 vaccination, myocarditis following COVID-19 illness, and other myocarditis not associated with COVID-19 vaccination or illness. Results Of the 92 included patients, 21 (23%) had myocarditis following COVID-19 vaccination (mean age, 31 years Â± 14 [SD]; 17 men; messenger RNA-1273 in 12 [57%] and BNT162b2 in nine [43%]). Ten of 92 (11%) patients had myocarditis following COVID-19 illness (mean age, 51 years Â± 14; three men) and 61 of 92 (66%) patients had other myocarditis (mean age, 44 years Â± 18; 36 men). MRI findings in the 21 patients with vaccine-associated myocarditis included late gadolinium enhancement (LGE) in 17 patients (81%) and left ventricular dysfunction in six (29%). Compared with other causes of myocarditis, patients with vaccine-associated myocarditis had a higher left ventricular ejection fraction and less extensive LGE, even after controlling for age, sex, and time from symptom onset to MRI. The most frequent location of LGE in all groups was subepicardial at the basal inferolateral wall, although septal involvement was less common in vaccine-associated myocarditis. At short-term follow-up (median, 22 days [IQR, 7-48 days]), all patients with vaccine-associated myocarditis were asymptomatic with no adverse events. Conclusion Cardiac MRI demonstrated a similar pattern of myocardial injury in vaccine-associated myocarditis compared with other causes, although abnormalities were less severe, with less frequent septal involvement and no adverse events over the short-term follow-up. Â© RSNA, 2022 Online supplemental material is available for this article. See also the editorial by Raman and Neubauer in this issue.

Autopsy Histopathologic Cardiac Findings in 2 Adolescents Following the Second COVID-19 Vaccine Dose. CONTEXT.â€”: Myocarditis in adolescents has been diagnosed clinically following the administration of the second dose of an mRNA vaccine for coronavirus disease 2019 (COVID-19). OBJECTIVE.â€”: To examine the autopsy microscopic cardiac findings in adolescent deaths that occurred shortly following administration of the second Pfizer-BioNTech COVID-19 dose to determine if the myocarditis described in these instances has the typical histopathology of myocarditis. DESIGN.â€”: Clinical and autopsy investigation of 2 teenage boys who died shortly following administration of the second Pfizer-BioNTech COVID-19 dose. RESULTS.â€”: The microscopic examination revealed features resembling a catecholamine-induced injury, not typical myocarditis pathology. CONCLUSIONS.â€”: The myocardial injury seen in these postvaccine hearts is different from typical myocarditis and has an appearance most closely resembling a catecholamine-mediated stress (toxic) cardiomyopathy. Understanding that these instances are different from typical myocarditis and that cytokine storm has a known feedback loop with catecholamines may help guide screening and therapy.

Hypersensitivity reactions to COVID-19 vaccines: a case of Eosinophilic pneumonia following Sinovac/CoronaVac vaccination. Hypersensitivity reactions has been reported with COVID-19 vaccines. Acute eosinophilic pneumonia has not been reported yet after Sinovac/CoronaVac vaccine.

A 73-year-old woman presented with maculopapular rash, cough and dyspnea following Sinovac/CoronaVac injection. The complete blood count (CBC) indicated eosinophilia and further evaluation of the eosinophilia with CT and bronchoscopy confirmed a diagnosis of acute eosinophilic pneumonia. After methylprednisolone therapy, her rash resolved with marked improvement of the dyspnea. She is still on treatment and on the follow up period, we plan to continue steroid treatment at least 3 months.

Response to Berry etÂ al's "Cutaneous small-vessel vasculitis following single-dose Janssen Ad26.COV2.S vaccination".

The Association of COVID-19 Infection and Vaccination Rates in Florida. OBJECTIVE: This study investigates the association of COVID-19 infection and vaccination rates with 2020 presidential election voting preference in Florida counties and the moderating role of age, race, ethnicity, and other community characteristics. METHODS: Florida county COVID-19 infection and vaccination counts through September 2021 were supplemented with socioeconomic characteristics and 2020 presidential election results. Poisson regression measured the association of infection and vaccination rates with county political preferences, race, ethnicity, and other county demographic and economic characteristics. For models of April through September 2021 infection rates, the same county characteristics were assessed alongside county vaccination levels. RESULTS: Each 1% increase in county full vaccination rates was associated with 82.47 fewer infections per 100 000 during the span of April to September 2021. Vaccination rate was the largest and most statistically significant determinant of vaccine era infections. Each 1% increase in the county share of votes for the 2020 Republican presidential candidate was associated with 109.7 more COVID-19 infections per 100 000 through March 2021 and a 0.546% decrease in county vaccination rates through September 2021. CONCLUSIONS: At the county level, COVID-19 vaccination rates are associated with infection rates, with a higher county population proportion of fully vaccinated associated with fewer infections per 100 000. County political preference in the 2020 presidential election is significantly associated with county-level COVID-19 infection and vaccination rates.

Hypertensive Crisis Following COVID-19 Vaccination.

SARS-CoV-2 vaccine-related cutaneous manifestations: aâ€‰systematic review. To date, over 250 million people have been reportedly infected by COVID-19 disease, which has spread across the globe and led to approximately 5.1 million fatalities. To prevent both COVID-19 and viral transmission, DNA-based/RNA-based vaccines, non-replicating viral vector vaccines, and inactivated vaccines have been recently developed. However, a precise clinical and histological characterization of SARS-CoV-2 vaccine-related dermatological manifestations is still lacking. A systematic review of 229 articles was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, in order to provide an extensive overview of SARS-CoV-2 vaccine-related skin manifestations. Data on demographics, number of reported cases with cutaneous involvement, vaccine, and rash type (morphology) were extracted from articles and summarized. A total of 5941 SARS-CoV-2 vaccine-related dermatological manifestations were gathered. Local injection-site reactions were the most frequently observed, followed by rash/unspecified cutaneous eruption, urticarial rashes, angioedema, herpes zoster, morbilliform/maculopapular/erythematous macular eruption, pityriasis rosea and pityriasis rosea-like eruptions, and other less common dermatological manifestations. Flares of pre-existing dermatological conditions were also reported. Cutaneous adverse reactions following SARS-CoV-2 vaccine administration seem to be heterogeneous, rather infrequent, and not life-threatening. Vaccinated patients should be monitored for skin manifestations, and dermatological evaluation should be offered, when needed.

Distinct Homologous and Variant-Specific Memory B-Cell and Antibody Response Over Time After Severe Acute Respiratory Syndrome Coronavirus 2 Messenger RNA Vaccination. The durability of

protective humoral immunity after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination and infection is largely dependent on the generation and persistence of antigen-specific isotype-switched memory B cells (MBCs) and long-lived plasma cells that reside in the bone marrow and secrete high-affinity neutralizing antibodies. The reactivity of vaccine-induced MBCs to emerging clinically significant SARS-CoV-2 variants of concern (VoCs) is largely unknown. In a longitudinal cohort study (up to 6 months following coronavirus disease 2019 messenger RNA vaccination), we measured MBCs in concert with other functional antibody measures. We found statistically significant differences between the frequencies of MBCs responding to homologous and VoC (Beta, Gamma, and Delta) receptor-binding domains after vaccination that persisted over time. In concert with a waning antibody response, the reduced MBC response to VoCs could translate to a weaker subsequent recall immune response and increased susceptibility to the emerging SARS-CoV-2 variant strains after vaccination.

Lack of inflammatory bowel disease flare-up following two-dose BNT162b2 vaccine: a population-based cohort study.

Rare acute hypersensitivity myocardial infarction (Kounis syndrome) and hypersensitivity myocarditis following COVID-19 vaccination.

Reply to 'Letter to the Editor: Acute hypersensitivity myocardial infarction (Kounis syndrome) and hypersensitivity myocarditis following COVID-19 vaccine vaccination'.

Calcific tendinitis of the shoulder induced by an mRNA vaccine for COVID-19: A case report. Coronavirus disease 2019 (COVID-19) vaccines have been widely used and have been shown to be effective in combating the pandemic. However, various side effects have been reported following vaccination. For instance, a condition called 'shoulder injury related to vaccine administration' (SIRVA) is characterized by shoulder pain and limited range of motion after intramuscular injection of a vaccine into the deltoid muscle of the shoulder. Despite an increase in SIRVA cases, the exact incidence of the disease is unclear, and there are a few reports of SIRVA about the COVID-19 vaccine. Here, we report a rare case of an 83-year-old woman who was diagnosed with calcification in her left shoulder 1 year ago and developed calcific tendinitis after receiving an mRNA vaccine for COVID-19 (Pfizer-BioNTech). Radiographs showed calcification of the supraspinatus tendon, and magnetic resonance images showed continuous inflammatory findings from the subdeltoid bursa to the subacromial bursa. We treated the patient with celecoxib and acetaminophen, and she recovered after about 2 months. In order to prevent SIRVA, the presence of shoulder joint disease should be carefully asked during a pre-vaccination assessment. The puncture point should be chosen with the median point of the deltoid muscle or the anterior-posterior axillary line as landmarks because the more cephalad the puncture position, the greater the chance of causing SIRVA.

Adenovirus-Based Vaccines and Thrombosis in Pregnancy: A Systematic Review and Meta-analysis. BACKGROUND: Rare cases of thrombosis and thrombocytopenia (thrombosis with thrombocytopenia syndrome [TTS]) have been associated with 2 coronavirus disease 2019 adenovirus vector vaccines: the ChAdOx1 nCoV-19 Vaxzevria vaccine (Oxford/AstraZeneca) and the JNJ-7836735 Johnson & Johnson vaccine (Janssen). It is unknown if TTS is a class-mediated effect of adenovirus-based vaccines or if it could worsen known hypercoagulable states. Since most cases of TTS happen in women of childbearing age, pregnancy is a crucial risk factor to assess. Understanding these risks is important for advising vaccine recipients and future adenovirus vector vaccine development. METHODS: To explore the potential associations of adenovirus-based vaccine components with symptoms of TTS in the general clinical trial population and in pregnant women in clinical trials, we conducted a systematic review and meta-analysis of adenovirus-based vector vaccines to document cases of thrombocytopenia, coagulopathy, and or pregnancy from 1 January 1966 to 9 August 2021. RESULTS: We found 167 articles from 159 studies of adenovirus vector-based vaccines, 123 of which

targeted infectious diseases. In the general population, 20 studies reported an event of thrombocytopenia and 20 studies indicated some coagulopathy. Among pregnant women, of the 28 studies that reported a total of 1731 pregnant women, thrombocytopenia or coagulopathy were not reported. CONCLUSIONS: In this systematic review and meta-analysis, there was no class-wide effect of adenovirus vector vaccines toward thrombocytopenia or coagulopathy events in the general population or in pregnant women.
Validation of ISARIC 4C Mortality and Deterioration Scores in a Mixed Vaccination Status Cohort of Hospitalized Coronavirus Disease 2019 (COVID-19) Patients in Singapore. In this cross-sectional study, we studied performance of the International Severe Acute Respiratory and Emerging Infections Consortium mortality and deterioration scores in a cohort of 410 hospitalized patients (51.2% fully vaccinated). area under the receiver operating characteristic curves were 0.778 and 0.764, respectively, comparable to originally published validation cohorts. Subgroup analysis showed equally good performance in vaccinated and partially or unvaccinated patients.
Varicella Zoster Reactivation Causing Acute Retinal Necrosis following mRNA COVID-19 Vaccination in a Young Immunocompetent Man. BACKGROUND: Varicella zoster reactivation is an increasingly recognised event following mRNA COVID-19 vaccination. In addition, various ocular inflammatory and infectious adverse events following COVID-19 vaccination have been described in the literature. This case report describes acute retinal necrosis (ARN) secondary to varicella zoster virus (VZV) reactivation following COVID-19 mRNA vaccination. CASE DESCRIPTION: A 42-year-old immunocompetent man developed left ARN 12Â days following first dose of Pfizer BioNTech mRNA COVID-19 vaccination. Aqueous and vitreous tap polymerase chain reaction testing was positive for VZV. Good visual outcome was achieved with combination therapy, including intravitreal foscarnet, oral valaciclovir and prednisolone, topical dexamethasone and atropine, and barrier retinal laser. Second dose of the vaccine is planned under cover of high-dose oral valaciclovir therapy. CONCLUSION: This case illustrates the possible association between COVID-19 vaccination and potentially blinding VZV reactivation. Therefore, prompt ophthalmic assessment is recommended in patients with visual disturbance following COVID-19 vaccination.
Treatment for Immune Thrombocytopenia in Coronavirus Disease 2019 (COVID-19) Infection after COVID-19 Vaccination: A Case Report. Thrombocytopenia is one of the rare signs of both the coronavirus disease 2019 (COVID-19) and COVID-19 vaccination. An 85-year-old man was diagnosed with immune thrombocytopenia and COVID-19, 7 days after COVID-19 vaccination. The patient was successfully treated with a short course of intravenous immunoglobulin and oral corticosteroids.
COVID-19 Vaccine-Associated Pericarditis.
Incidence and severity of COVID-19 infection post-vaccination: a survey among Indian doctors. PURPOSE: The rollout of COVID-19 vaccines began in India in January 2021, with healthcare professionals being the first to receive vaccination. The purpose of this research was to study the incidence and severity of COVID-19 infections among Indian doctors, following vaccination with ChAdOx1 nCoV-19 or BBV152. METHODS: We conducted an online voluntary survey among Indian doctors who received one or two doses of ChAdOx1 nCoV-19 or BBV152. Questions pertaining to the incidence and severity of COVID-19 infection following vaccination were asked. Data thus obtained were analysed. RESULTS: 9146 doctors were included in this study. 8301 of these received ChAdOx1 nCoV-19, while 845 received BBV152. 2842 (31.07%) respondents reported having a COVID-19 infection following vaccination. Presence of pre-existing medical comorbidities was associated with a higher incidence, while prior COVID-19 infection and two doses of either vaccine were associated with a lower incidence of COVID-19 infection post-vaccination. Exposure to COVID-19 patients on a daily basis did not increase the incidence of COVID-19 infection among doctors who were vaccinated. Increasing age, male gender, presence of pre-existing medical comorbidities, and daily exposure to

COVID-19 patients were associated with increased severity of COVID-19 infection after vaccination. Two doses of either vaccine resulted in less severity of disease compared to one dose. CONCLUSION: ChAdOx1 nCoV-19 and BBV152 confer immunity against severe forms of COVID-19 infections. COVID-19 infections prior to vaccination result in a lower incidence of breakthrough infection. Presence of pre-existing medical comorbidities is associated with increased incidence and severity of breakthrough infections.

SARS-CoV-2 Vaccination Associated Ophthalmic Adverse Effects.

Neutralizing antibody activity against the B.1.617.2 (delta) variant 8Â months after two-dose vaccination with BNT162b2 in health care workers. OBJECTIVES: Humoral immunity wanes over time after two-dose BNT162b2 vaccination. Emerging variants of concern, such as the B.1.617.2 (delta) variant, are increasingly responsible for breakthrough infections owing to their higher transmissibility and partial immune escape. Longitudinal data on neutralization against the B.1.617.2 (delta) variant are urgently needed to guide vaccination strategies. METHODS: In this prospective longitudinal observational study, anti-S1 IgG and surrogate neutralizing antibodies were measured in 234 collected samples from 60 health care workers after two-dose vaccination with BNT162b2 at five different time points over an 8-month period. In addition, antibodies against various severe acute respiratory syndrome coronavirus 2 epitopes, neutralization against wild-type, and cross-neutralization against the B.1.617.2 (delta) variant using a live virus assay were measured 6Â weeks (second time point) and 8Â months (last time point) after first vaccine dose. RESULTS: Median (interquartile range) anti-S1 IgG, surrogate neutralizing, and receptor-binding domain antibodies decreased significantly from a maximum level of 147 (102-298), 97 (96-98), and 20Â 159 (19Â 023-21 628) to 8 (4-13), 92 (80-96), and 15Â 324 (13Â 055-17 288) at the 8-month follow-up, respectively (pÂ <Â 0.001 for all). Neutralization against the B.1.617.2 (delta) variant was detectable in all 36 (100%) participants at 6Â weeks and in 50 of 53 (94%) participants 8Â months after first vaccine dose. Median (interquartile) ID(50) as determined by a live virus assay decreased from 160 (80-320) to 40 (20-40) (pÂ <Â 0.001). DISCUSSION: Although humoral immunity wanes over time after two-dose BNT162b2 vaccination in healthy individuals, most individuals still had detectable neutralizing activity against the B.1.617.2 (delta) variant after 8Â months.

An adolescent girl diagnosed with IgA nephropathy following the first dose of the COVID-19 vaccine. There has been growing interest in reported cases of IgA nephropathy (IgAN) flare-up following administration of the coronavirus disease 2019 (COVID-19) vaccine. Our patient is a previously healthy 17-year-old girl who presented with a 10-year history of microscopic hematuria. Because there were no abnormal findings in blood examination or ultrasonography, we followed her up twice per year as asymptomatic hematuria. Although she never developed gross hematuria when she had upper respiratory infections or received an influenza vaccine, she presented with gross hematuria and proteinuria within a few days after receiving the first dose of the Pfizer vaccine. We performed renal biopsy 2Â weeks after the first vaccination. It revealed minor glomerular abnormalities with diffuse mesangial IgA deposits, and we diagnosed her with mild IgAN. Gross hematuria was detected after both the first and second doses, although it changed to microscopic hematuria within 1Â week. Additionally, her proteinuria resolved spontaneously approximately 10Â days after the second dose of the vaccine. Therefore, we opted to observe her without administering medication. The causation between COVID-19 vaccination and IgAN flare-up remains unclear. Several reports showed IgAN patients presenting gross hematuria following the second dose of the Pfizer or Moderna vaccines. However, our patient developed gross hematuria and proteinuria even after the first dose and without known severe acute respiratory syndrome coronavirus 2 exposure. Nephrologists should inform both patients with IgAN and those with asymptomatic hematuria that this side effect can occur even after the first vaccination.

Bilateral Panuveitis Mimicking Vogt-Koyanagi-Harada Disease following the First Dose of ChAdOx1 nCoV-19 Vaccine. METHOD: We report a case of bilateral panuveitis and its resolution based on multimodal retinal images after she was administered the first dose of a viral vector-based vaccine against SARS-CoV-2. CASE REPORT: A 72-year-old woman complained of bilateral blurred vision with headache, neck stiffness, and tinnitus 3 days after receiving the first dose of the ChAdOx1 nCoV-19 vaccine. Initial examination revealed anterior chamber reactions, left optic disc hyperemia, and bilateral chorioretinal folds with choroidal thickening. Fluorescein and indocyanine green angiography revealed bilateral choroiditis and papillitis. Systemic steroid therapy dramatically alleviated panuveitis and meningeal signs. No recurrence was noted until 3 months after discontinuation of steroids. CONCLUSIONS: Bilateral panuveitis mimicking Vogt-Koyanagi-Harada disease can develop shortly after the first dose of the ChAdOx1 nCoV-19 vaccine. Ophthalmologists should consider bilateral panuveitis as a presumed post-vaccination adverse event. Systemic steroid therapy may be effective for the nCoV-19 vaccine-associated panuveitis.

De Novo Vogt-Koyanagi-Harada Disease following Covid-19 Vaccine: A Case Report and Literature Overview. PURPOSE: To describe a case of Vogt-Koyanagi-Harada (VKH) disease after a Covid-19 mRNA vaccine (tozinameran) and to present the results of a pharmacovigilance disproportionality study. METHODS: A retrospective chart review and a pharmacovigilance disproportionality study using the WHO global individual case safety reports database (VigiBase). RESULTS: A 57-year-old female with no medical history developed a VKH disease 3 weeks after Covid-19 mRNA vaccine. Symptoms at onset were headaches and blurred vision associated with aseptic meningitis and bilateral diffuse granulomatous panuveitis with serous retinal detachment. One month from diagnosis and glucocorticoids treatment, the patient recovered. Five similar cases have been reported in VigiBase. VKH disease is disproportionately reported with tozinameran and other vaccines. CONCLUSION: VKH disease is disproportionately reported with tozinameran, suggesting a possible safety signal. Cases after vaccination support the screening for any possible immune triggers such as vaccines when assessing patients with VKH disease.

SARS-CoV-2-related and Covid-19 vaccine-induced thromboembolic events: A comparative review. Since the start of the pandemic, thrombotic events have been a well-known and severe complication associated with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Nevertheless, the initiation of vaccination programs brought another rare yet highly fatal thrombotic event, vaccine-induced immune thrombotic thrombocytopaenia, which has caused extensive debate regarding the safety of vaccines. This review defines the thromboembolic events following infection and vaccination, identifies their risk factors, describes their pathophysiology, and discusses their management, treatment, and prevention.

Allergies and COVID-19 vaccines: An ENDA/EAACI Position paper. BACKGROUND: Anaphylaxis, which is rare, has been reported after COVID-19 vaccination, but its management is not standardized. METHOD: Members of the European Network for Drug Allergy and the European Academy of Allergy and Clinical Immunology interested in drug allergy participated in an online questionnaire on pre-vaccination screening and management of allergic reactions to COVID-19 vaccines, and literature was analysed. RESULTS: No death due to anaphylaxis to COVID-19 vaccines has been confirmed in scientific literature. Potential allergens, polyethylene glycol (PEG), polysorbate and tromethamine are excipients. The authors propose allergy evaluation of persons with the following histories: 1-anaphylaxis to injectable drug or vaccine containing PEG or derivatives; 2-anaphylaxis to oral/topical PEG containing products; 3-recurrent anaphylaxis of unknown cause; 4-suspected or confirmed allergy to any mRNA vaccine; and 5-confirmed allergy to PEG or derivatives. We recommend a prick-to-prick skin test with the left-over solution in the suspected vaccine vial to avoid waste. Prick test panel should include PEG 4000 or 3500, PEG 2000 and polysorbate 80. The value of in vitro test is

arguable. CONCLUSIONS: These recommendations will lead to a better knowledge of the management and mechanisms involved in anaphylaxis to COVID-19 vaccines and enable more people with history of allergy to be vaccinated.
A public health perspective on the responsibility of mass media for the outcome of the anti-COVID-19 vaccination campaign: the AstraZeneca case. On February 9, 2021, the Italian Ministry of Health made the "Covid-19 vaccine AstraZeneca" (now "Vaxzevria") available for use in the anti-COVID-19 vaccination campaign. However, in early March, the media reported that five people died a few days after receiving the vaccine. The reaction among both those already vaccinated and the vaccine candidates was one of near panic. The subsequent events have had long-lasting consequences, as 10-20% of vaccine candidates have since refused vaccination with the AstraZeneca vac-cine, so in addition to the delay in vaccination, ~200,000 doses of it were not administered. The goal of the vaccination campaign in Italy, when operating at full capacity, was to administer 500,000 doses per day, for a total of 3,500,000 doses per week. In this large amount of people, it is statistically certain that a certain number of subjects will develop non-vaccine related health problems or even die from causes unrelated to having been vaccinated. At this time in history, press reports must be inspired by a strong sense of responsibility and awareness of the potential consequences of misinformation; this is particularly true, especially because also the social media get inevitably involved.
Combined Central and Peripheral Demyelination with Anti-Neurofascin155 IgG Following COVID-19 Vaccination.
Acute myocarditis following COVID-19 mRNA vaccination: a paediatric case. Myocarditis is an inflammation of the heart muscle. In this case, a previously healthy, 17-year-old adolescent with myocarditis after BNT162b2 mRNA vaccination was reported. He was admitted to the hospital with severe chest pain, changes in electrocardiography, and elevation in serum troponin level after fourth day of receiving first dose of vaccine. There was no coronary arterial disease in coronary angiogram. A diagnosis of vaccine-induced myocarditis was made, and supportive treatment was initiated.
SARS-CoV-2 Infectivity and Antibody Titer Reduction for 6 Months After Second Dose of BNT162b2 mRNA Vaccine in Health Care Workers: A Prospective Cohort Study. Several studies reported that severe acute respiratory syndrome coronavirus-2 antibody levels change over 6 months in participants receiving the vaccination. From the enrolled 272 health care workers (HCWs), blood samples were obtained at 2, 16, and 24 weeks after the second vaccination dose. In the 267 noninfected HCWs, the neutralizing antibodies decreased by 23.9%, and the anti-spike/receptor binding domain antibody decreased by 53.8% at 24 weeks. We observed no significant difference in antibody reduction between the sexes; however, in younger individuals, there was higher antibody formation and lower reduction rates of the neutralizing antibody. In 3 HCWs with breakthrough infections, the antibody levels were relatively low just before the coronavirus disease 2019 infection. In conclusion, as antibody titers decrease over time after the second vaccination dose and HCWs with low antibody titers tend to have a high probability of breakthrough infection, an additional dose should be considered after several months. Blood samples were obtained from health care workers at 2, 16, and 24 weeks after a second vaccination dose. Antibody titers decreased over time and the participants with low antibody titers tended to have a high probability of breakthrough infection.
High antibody response in relation to immunosuppressive blood levels in liver transplant recipients after SARS-CoV-2 vaccination: an observational, cohort study.
The adverse reactions to vaccines practice parameter 10 years on-what have we learned? OBJECTIVE: To provide updated information on the evaluation and management of adverse reactions to vaccines. DATA SOURCES: PubMed (MEDLINE) search since publication of a practice parameter in 2012. STUDY SELECTIONS: Original articles and guidelines on adverse reactions to vaccines, including vaccines against severe acute respiratory syndrome coronavirus 2 or coronavirus disease 2019

(COVID-19). RESULTS: Current guidelines conclude that patients with egg allergy are not at increased risk for reaction to egg-based influenza vaccines. Except for gelatin, most patients with allergy to vaccine constituents tolerate vaccines containing them. Most patients who have immediate reactions after receiving COVID-19 vaccines go on to receive a subsequent dose uneventfully. CONCLUSION: The risk of reactions to vaccination should be weighed against the risk of having a vaccine-preventable disease if the vaccine is withheld. There is no need to ask about egg allergy before the administration of influenza vaccines, including on screening forms. In most cases, an allergy to a vaccine constituent is not a contraindication to the vaccine containing it. Patients who have had possible anaphylactic reactions to vaccines should be evaluated by an allergist rather than simply being labeled allergic, because most can go on to receive subsequent doses. Most immediate reactions to COVID-19 vaccines are not allergic, and care should be taken to not label such reactions as anaphylactic. The role, if any, of polyethylene glycol in these reactions has yet to be revealed.
Erythema multiforme reactions after Pfizer/BioNTech (BNT162b2) and Moderna (mRNA-1273) COVID-19 vaccination: A case series.
Pityriasis rosea, pityriasis rosea-like eruptions, and herpes zoster in the setting of COVID-19 and COVID-19 vaccination. Pityriasis rosea (PR), PR-like eruptions (PR-LE), and herpes zoster have been frequently reported during the COVID-19 pandemic and following COVID-19 vaccination. PR is a self-limiting exanthematous disease and herpes zoster is a treatable condition; therefore, their occurrence does not require discontinuation of the vaccination schedule. PR-LE is a hypersensitivity reaction and is, therefore, less predictable in its course. In the case of a booster dose, the clinical manifestation may not recur, may be different from PR-LE, or may present with systemic symptoms; however, in the case of PR-LE, the possibility of mild and predominantly cutaneous adverse events should not discourage all eligible candidates from receiving and completing the COVID-19 vaccination program, as such adverse reactions represent a small risk considering the possible severe and fatal outcome of COVID-19. We emphasize the relevance of looking for any viral reactivation in patients infected with SARS-CoV-2 who have skin eruptions. The search for viral reactivations could be useful not only for distinguishing between PR and PR-LE but also because viral reactivations may contribute to a patient's systemic inflammation and influence the course of the disease.
Systemic syndromes of rheumatological interest with onset after COVID-19 vaccine administration: a report of 30 cases.
Limiting Screening Mammography Recalls for Vaccine-Induced Adenopathy, a Single Institution Experience. RATIONALE AND OBJECTIVES: Reported incidence of vaccine-induced adenopathy varies widely, with higher estimates in early reports and small series. Objective was to evaluate a large sample of vaccinated patients undergoing screening mammography, to determine callback rates associated with vaccine-induced adenopathy and their outcomes. MATERIALS AND METHODS: Single-institution retrospective review of patients who received at least 1 dose of a COVID-19 vaccine prior to presentation for screening mammography from January 15 through May 31, 2021. Patient-related vaccination information (dose, brand, arm, date) was obtained by mammography technologists and available for interpreting radiologists. Patients recalled for axillary adenopathy were included; other causes for recall were excluded. Follow-up imaging and outcomes were tracked. Wilcoxon rank-sum test, Fisher exact test, multivariable logistic regression modeling, and receiver operating characteristic curve analyses were utilized. All tests were two-sided; $p < 0.05$ considered statistically significant. RESULTS: Total of 2304 vaccinated patients underwent screening mammography; 24 (1.0%) recalled for ipsilateral adenopathy. There was no significant difference in presence of adenopathy associated with patient age, dose, or brand of vaccine. Presence of adenopathy significantly decreased as days from vaccination increased ($p < 0.001$). Receiver operating characteristic curve suggested 28.5 days as the best cutoff point to distinguish presence or absence of adenopathy on mammogram. Of 24

callbacks, 13 (54.2%) had benign results, 2 (8.3%) are still undergoing surveillance, and 9 (37.5%) are overdue for subsequent follow-ups. No cases resulted in biopsy or malignancy. CONCLUSION: Low recall rates related to vaccine-induced adenopathy are achievable and can limit unnecessary workups, improve access, and promote flexible timing of vaccinations and screening exams.

Response to: The diagnosis of central retinal artery occlusion after mRNA-SARS-CoV-2 vaccination.

The diagnosis of central retinal artery occlusion after mRNA-SARS-CoV-2 vaccination.

Acquired Hemophilia A following Pfizer-BioNTech SARS CoV-2 mRNA vaccine, successfully treated with prednisolone and rituximab. INTRODUCTION: Acquired haemophilia A (AHA) is a rare bleeding disorder, characterised by the presence of autoantibodies to clotting factor VIII (FVIII). AHA can be idiopathic or occur in the context of malignancy, autoimmune disease, drugs, or pregnancy. Recently, cases of AHA following both COVID-19 infection and vaccination have been reported. CASE REPORT: We report the case of a 95-year-old female who was immunised with the Pfizer-BioNTech SARS CoV-2 mRNA vaccine, with doses given three weeks apart. Spontaneous bruising over her extremities appeared one week after the initial dose, with hospital admission occurring three weeks after the second. Examination revealed a large haematoma on the dorsum of the right hand with resultant bleeding and widespread ecchymoses. Investigations confirmed a diagnosis of AHA. MANAGEMENT AND OUTCOME: Initial management included high dose prednisolone, recombinant Factor VIII and tranexamic acid. There was no significant clinical improvement after three days, so intravenous rituximab 100 mg weekly for four weeks was commenced. The activated partial thromboplastin time (aPTT) normalised after two doses and Factor VIII level reached 0.68U/ml on dayâ€‰+â€‰22. The patient was successfully discharged from hospital after 37 days. DISCUSSION: Four cases of AHA following administration of COVID mRNA vaccines (Pfizer and Moderna) have been documented. AHA should be a differential in patients presenting with bleeding following COVID-19 vaccination, in the presence of a normal platelet count. Rapid recognition, prompt initiation of immunosuppressive treatment and rigorous supportive cares are required to minimise morbidity and mortality.

Leave no one behind: inclusion of alpha-1 antitrypsin deficiency patients in COVID-19 vaccine trials. The coronavirus disease of 2019 (COVID-19) pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections, continues to present an unprecedented challenge worldwide. Emerging evidence suggests that Î±-1 antitrypsin (A1AT), a circulating protein with protective effects on the lung and other vital organs, plays a critical role in preventing SARS-CoV-2 infection and may be a promising therapeutic option for patients with COVID-19. A1AT deficiency (AATD) is characterized by dysfunctional or insufficient levels of A1AT. Recently, we have proposed that AATD patients are a vulnerable population for COVID-19. Patients with AATD may derive limited benefit from the current COVID-19 vaccines and continue to rely on conventional medical therapy and behavioral adaptations to mitigate the risk of infection. Unfortunately, this population has not been included in the COVID-19 vaccine clinical trials and studies have yet to characterize the safety, immunogenicity, and ultimately, the efficacy of COVID-19 vaccines for AATD patients. Re-evaluation of the COVID-19 vaccine safety and immunogenicity will further promote informed decision-making for vaccination in AATD individuals and contribute to reduce morbidity and mortality from COVID-19 infection.

Examining the risk of breakthrough infection and COVID-19 vaccination safety in patients with atopic dermatitis.

COVID-19 vaccination outcomes among patients with dermatomyositis: a multicentered analysis.

Reply to: Real-world Coronavirus disease-19 vaccine hesitancy in systemic sclerosis.

Real-world Coronavirus disease-19 vaccine hesitancy in systemic sclerosis.

Omicron variant susceptibility to neutralizing antibodies induced in children by natural SARS-CoV-2 infection or COVID-19 vaccine. The novel SARS-CoV-2 Omicron variant may increase the risk of

re-infection and vaccine breakthrough infections as it possesses key mutations in the spike protein that affect neutralizing antibody response. Most studies on neutralization susceptibility were conducted using specimens from adult COVID-19 patients or vaccine recipients. However, since the paediatric population has an antibody response to SARS-CoV-2 infection that is distinct from the adult population, it is critical to assess the neutralization susceptibility of pediatric serum specimens. This study compared the neutralization susceptibility of serum specimens collected from 49 individuals of <18 years old, including 34 adolescent BNT162b2 (Pfizer-BioNTech) vaccine recipients, and 15 recovered COVID-19 patients aged between 2 and 17. We demonstrated that only 38.2% of BNT162b2 vaccine recipients and 26.7% of recovered COVID-19 patients had their serum neutralization titre at or above the detection threshold in our live virus microneutralization assay. Furthermore, the neutralizing antibody titer against the Omicron variant was substantially lower than those against the ancestral virus or the Beta variant. Our results suggest that vaccine recipients and COVID-19 patients in the pediatric age group will likely be more susceptible to vaccine breakthrough infections or reinfections due to the Omicron variant than previous variants.
Reported ocular adverse events with three COVID-19 vaccines.
Delayed-onset anaphylaxis after first dose of Pfizer-BioNTech COVID-19 vaccine.
SARS-CoV-2 Infection After Vaccination: Kidney Transplant Recipient Profile and Disease Evolution in a Single Center. BACKGROUND: SARS-CoV-2 infection has had a major impact on kidney transplant patients. Recent evidence suggests that solid organ transplant recipients who received mRNA vaccines reach low immunization rates. There are only few reports about the risk factors and severity of COVID-19 in these patients. Our single center experience describes the patient profile and disease evolution observed in this vulnerable group after inoculation. MATERIAL AND METHODS: Retrospective cohort study with kidney transplant patients who received a COVID-19 vaccine before testing positive for SARS-CoV-19 using polymerase chain reaction. Demographic characteristics and clinical information are described and compared with our previous series of patients who were infected before the initiation of the vaccination rollout. RESULTS: Sixteen kidney transplant recipients diagnosed with COVID-19 after being vaccinated were included and compared with our previous series of 76 unvaccinated patients who were positive for COVID-19. No differences were found among risk factors such as age, time after transplant, hypertension, and obesity between groups (P value > .05). After COVID-19 diagnosis among inoculated patients, 10 patients were hospitalized, and 4 of who met the criteria for admission to the intensive care unit. Three patients died of COVID-19 complications. Despite this, the incidence of infections has decreased after vaccination rollout (P value < .05). CONCLUSIONS: Patients' risk profiles remain constant among recipients who were positive for COVID-19 between waves. We did not find significant differences in hospitalization and severity rates in this reduced group of patients. However, the overall incidence in our kidney transplant population has decreased.
A paediatric case of myopericarditis post-COVID-19 mRNA vaccine. Myopericarditis is a condition, which primarily involves the pericardium, with minimal myocardial involvement. In myopericarditis, chest pain, elevated cardiac enzymes, and electrocardiographic changes occur. Although COVID-19 mRNA vaccines significantly contribute to preventing the COVID-19 disease, rarely myocarditis and/or pericarditis may develop due to these vaccines. We present a previously healthy 14-year-old male patient who developed myopericarditis after receiving the second dose of the COVID-19 mRNA vaccine.
New-onset kidney biopsy-proven IgA vasculitis after receiving mRNA-1273 COVID-19 vaccine: case report. As mRNA COVID-19 vaccines have become widely available, cases of new-onset glomerular disease after receiving COVID-19 vaccination have been reported. Here, we present a case of kidney biopsy-proven new-onset IgA vasculitis after receiving the mRNA-1273 (Moderna) COVID-19

vaccination. A 47-year-old man with a 10-year medical history of hypertension and hyperuricemia visited our hospital 19Â days after receiving an initial mRNA-1273 COVID-19 vaccine injection for purpuric eruption on the legs and dorsal regions of the feet. Although the eruptions spontaneously improved within 5Â days, they developed again at 15Â days after the second injection. A histopathological examination of skin biopsy specimens was reminiscent of leukocytoclastic vasculitis, though direct immunofluorescence did not indicate IgA deposition within small vessel walls. Urinalysis indicated severe proteinuria (3â€‰+) and occult blood (3â€‰+). Thus, a kidney biopsy was performed and light microscopy revealed mild mesangial expansion, hypercellularity, and endocapillary hypercellularity, with cellular and fibrocellular crescents observed in three and one, respectively, of a total of 15 glomeruli. Immunofluorescence also showed diffuse granular mesangial staining (3â€‰+) for IgA. Histopathological features were consistent with IgA vasculitis. Intravenous methylprednisolone at 1000Â mg for 3Â days was initiated, followed by oral prednisolone (0.6Â mg/kg/day). Over the following 2-week period, serum creatinine level improved from 1.24 to 1.06Â mg/dL and proteinuria decreased from 2.98 to 0.36Â g/g Cr, though occult blood persisted. Findings in the present case indicate that new-onset IgA vasculitis after receiving mRNA-1273 COVID-19 vaccine can be treated with corticosteroid therapy.

[Leukocytoclastic vasculitis and acute renal failure following inactivated SARS-CoV-2 vaccine]. SARS-CoV-2 vaccines are being administered worldwide. Most side effects are mild and self-limiting with few reported cases of severe reactions. We report a case of leukocytoclastic vasculitis with acute kidney failure following aninactivated SARS-CoV-2 vaccine, unique for its dramatic visual presentation and its rapid response to treatment. This is the case of a 58years-old man presenting with fever, arthralgias and vascular purpura on his limbs associated with acute kidney failure requiring hemodialysis nine days after anti-COVID-19 vaccination. Skin biopsy revealed a leukocytoclastic vasculitis and a renal biopsy showed an acute tubulointerstitial nephritis. The vascular purpura resolved 7days after initiating treatment with prednisone but the patient remains in chronic renal failure. The analysis and investigation of the complications and adverse events induced by anti-COVID-19 vaccines could increase our understanding of the underlying pathogenesis.

Does the Message Frame Promote People's Willingness to Vaccinate when they Worry about Side Effects from the COVID-19 Vaccine? Evidence from an Online Survey Experiment in China. Vaccination is an effective strategy for controlling the coronavirus disease 2019 (COVID-19) pandemic. However, worrying about side effects (WSE) from the COVID-19 vaccine is the leading concern making people hesitant to get vaccinated. Regrettably, there are few studies on alleviating the negative impacts of WSE on COVID-19 vaccination. This study aimed to assess whether message framing (gain- and loss-framed) can moderate the impacts of WSE on the willingness to vaccinate. We conducted an online self-administered survey experiment with three groups: control group (non-framed group), gain-framed groups, and loss-framed groups. In total, 981 participants were randomly assigned to one of the three groups, and their willingness to vaccinate themselves, their children, and elderly members was recorded. People with a higher level of WSE exhibited a lower willingness to vaccinate against COVID-19. However, the gain- and loss-framed messages increased people's willingness to vaccinate themselves, their children, and the elderly. Compared to the gain-framed messages, the loss-framed messages had a greater impact on enhancing people's willingness to self-vaccinate, but not on vaccinating their children and the elderly. Although the gain- and loss-framed messages weakened the negative impacts of WSE on the willingness to be vaccinated, their buffer effect was non-significantly different. The findings in this study suggest that a loss-framed messaging strategy could be a valuable tool in disseminating information on vaccination against COVID-19.

Two Cases of Acute Macular Neuroretinopathy Associated with the Adenovirus-based COVID-19 Vaccine Vaxzevria (Astrazeneca). PURPOSE: To report two cases of acute macular

neuroretinopathy (AMN) in young female patients following the administration of the adenovirus-based coronavirus disease 2019 (COVID-19) vaccine Vaxzevria (AstraZeneca). METHODS: Spectral-domain optical coherence tomography and infrared imaging were used to confirm the diagnosis of AMN. RESULTS: Both patients showed a parafoveal hyperreflective band in the outer nuclear layer, disruption of the ellipsoid and interdigitation zones of the photoreceptor layers, and correlating hyporeflective areas on the near-infrared images. Both patients presented with flu-like fever and sudden onset of fortifications within 48Â hours of vaccination. One patient showed altered flow in the deep capillary plexus and highly elevated thrombotic parameters. CONCLUSION: We report a possible association between immune-mediated AMN and the administration of adenovirus-based COVID-19 vaccine Vaxzevria.
Bilateral Sequential Acute Macular Neuroretinopathy in an Asian Indian Female with Î² Thalassemia Trait following (Corona Virus Disease) COVID-19 Vaccination and Probable Recent COVID Infection - Multimodal Imaging Study. INTRODUCTION: Corona virus disease (COVID-19) has been associated with a variety of ophthalmic manifestations including acute macular neuroretinopathy and paracentral middle maculopathy. Posterior segment manifestations after post COVID-19 vaccinations have been reported. CASE REPORT: A 25- year-old Asian Indian female developed sequential bilateral AMN following a single dose of COVISHIELDâ„¢ vaccine. On investigations she was found to have a Î² thalassemia trait. Presentation started unilaterally and progressed to the other eye after a month. On clinical examination, the fundus was apparently normal in both eyes. Significant changes suggestive of AMN were seen on multimodal imaging of the posterior segment of the respective eye at the time of involvement which resolved spontaneously in due course. CONCLUSION: We report a temporal association of COVID-19 vaccination and AMN.
Modeled impact of the COVID-19 pandemic and associated reduction in adult vaccinations on herpes zoster in the United States. Due to COVID-19, vaccinations dropped in 2020 and 2021. We estimated the impact of reduced recombinant zoster vaccine (RZV) use on herpes zoster (HZ) cases, complications, and quality-adjusted life-year (QALY) losses among older adults. Various scenarios were compared with Markov models using data from national sources, clinical trials, and literature. Missed series initiations were calculated based on RZV distributed doses. In 2020, 3.9 million RZV series initiations were missed, resulting in 31,945Â HZ cases, 2,714 postherpetic neuralgia cases, and 610 lost QALYs. Scenarios further projected disease burden increases if individuals remain unvaccinated in 2021 or the same number of initiations are missed in 2021. Health professionals should emphasize the importance of vaccination against all preventable diseases during the COVID-19 era.
Dermatomyositis-like rash and inflammatory myopathy after mRNA-1273 vaccination.
B cell receptor signatures associated with strong and poor SARS-CoV-2 vaccine responses. Breakthrough infection of SARS-CoV-2 is a serious challenge, as increased infections were documented in fully-vaccinated individuals. Recipients with poor antibody response are highly vulnerable to reinfection, whereas those with strong antibody responses achieve sterilizing immunity. Thus far, biomarkers associated with levels of vaccine-elicited antibody response are still lacking. Here, we studied the antibody response of age- and gender-controlled healthy cohort, who received inactivated SARS-CoV-2 vaccines and profiled the B cell receptor repertoires in longitudinally consecutive samples. Upon vaccination, all vaccinated individuals displayed a convergent antibody response with shared common antibody clones and public neutralizing antibodies. Strikingly, poor vaccine-responders are distinguishable from strong vaccine-responders by a biased V-usage before vaccination and IgG to IgM mRNA ratio. These findings reveal molecular signatures associated with the different levels of vaccine-induced antibody response, which could be further developed into biomarkers for the design of vaccination strategies.

Safety-Related Outcomes of Novel mRNA COVID-19 Vaccines in Pregnancy. OBJECTIVE: The objective of this study was to describe the safety profile and demographic data for a cohort of pregnant individuals who received an mRNA coronavirus disease 2019 (COVID-19) vaccine. STUDY DESIGN: Prospective cohort study (with exposure matching) of individuals with active pregnancy who underwent immunization with a novel mRNA COVID-19 vaccine matched 1:2 with vaccinated age-matched female nonregnant controls was carried out. The primary outcome was defined as any vaccine-related complaints as defined in the original safety data. Secondary outcomes included specific complaints, COVID-19 screening test, and positive COVID-19 test. RESULTS: Eighty-three vaccinated pregnant persons were age-matched with 166 female controls, all of whom were vaccinated between December 2020 and January, 2021. There was no difference in race or ethnicity between the groups. The mean body mass index of pregnant patients was lower than that of controls (26.1 vs. 29.2, pâ€‰=â€‰0.002). The frequency of complaints following vaccine administration was not different between pregnant and nonpregnant patients (18.1 vs. 16.9%, pâ€‰=â€‰0.201). Pregnant individuals were more likely to report fever (4.8 vs. 0.6%, pâ€‰=â€‰0.044) and gastrointestinal symptoms (4.8 vs. 0%, pâ€‰=â€‰0.012). CONCLUSIONS: Side effect profiles of COVID-19 vaccine administration at our institution were relatively similar between pregnant and nonpregnant individuals and no serious complications occurred in either group. As COVID-19 infection in pregnancy can have significant morbidity, our data support the continued use of the vaccine for pregnant patients. KEY POINTS: Â· Pregnant and nonpregnant women had a similar frequency of complaints.. Â· No serious adverse outcomes were observed in either group.. Â· Pregnant women were more likely to report fever and gastrointestinal side effects which may reflect gestationally mediated physiological responses to immunization..

COVID-19 vaccination rates, intent, and hesitancy in patients with solid organ and blood cancers: A multicenter study. INTRODUCTION: People with cancer are at higher risk of serious illness and death from COVID-19 infection. We investigated COVID-19 vaccine uptake among patients with solid organ and blood cancers and explored factors related to hesitancy. METHODS: Cross-sectional online survey of adults with a history of cancer at three health services across metropolitan and regional Victoria. Vaccine hesitancy was measured by the validated Oxford COVID-19 vaccine hesitancy scale. RESULTS: There were 1073 respondents: 56% female; median age 62 years (range 23 - 91). Commonest tumor types included breast 29%, gastrointestinal 19%, hematological 15%, genitourinary 15%, and lung 8%. Thirty-six percent had metastatic disease, and 54% were receiving active anticancer treatment. Eighty-four percent of respondents indicated positive intent toward COVID-19 vaccination, 10% were undecided, and 6% indicated negative attitudes. At least one vaccine dose had been received by 65% of respondents, leaving 35% unvaccinated. Fifty-eight percent of unvaccinated patients answered that they would "definitely" or "probably" take a vaccine. Higher vaccine uptake was significantly associated with older age, male gender, English as first language, longer time since cancer diagnosis, and not being on current anticancer treatment. Concerns regarding vaccine side effects, particularly thrombosis, and the desire for clear medical advice were prominent among unvaccinated respondents. CONCLUSION: Despite being eligible for COVID-19 vaccination since March 2021, a substantial minority of patients with cancer remained unvaccinated as of August 2021. Targeted communication and educational resources addressing vaccine safety in the context of cancer are key to promoting vaccine uptake in this vulnerable population.

Postvaccinal Encephalopathy Presenting with Amnesia and Seizure After ChAdOx1 nCov-19 Vaccination: A Case Report. PURPOSE: Because of the COVID-19 pandemic and resulting widespread vaccination, many related neurological disorders, including autoimmune encephalopathy, have emerged. The pathophysiological mechanism underlying the COVID-19 vaccination and autoimmune encephalopathy remains unclear; more case reports and further investigation are

required. CASE REPORT: We report a clinical case of a 38-year-old woman who presented with acute-onset amnesia, language disturbance, and seizure. We suspected autoimmune encephalopathy triggered by the ChAdOx1 nCoV-19 vaccine. Brain magnetic resonance imaging revealed a subacute infarction at the right internal capsule and irregular vascular contour, which indicated a vasculopathy, such as vasculitis. Cerebrospinal fluid analysis revealed inflammation without pleocytosis, and electroencephalography detected diffuse background slowing with sharp transients at the right temporal region. Although autoantibody tests were negative, we initiated steroid pulse therapy. The patient's symptoms improved rapidly. The patient was discharged without neurological deficit or sequelae. CONCLUSION: Clinicians should be mindful of postvaccinal encephalopathy and suspect this condition in patients with acute onset of psychosis or mental change, higher cortical dysfunction, and seizure within 2 weeks of vaccination. Early diagnosis is key, and immune treatment, such as steroid pulse therapy or immunosuppressants, may dramatically improve patients'symptoms.
Response to: Adrenal haemorrhage and COVID-19 vaccine-induced immune thrombotic thrombocytopenia: correspondence.
Skin reactions to mRNA-1273 SARS-CoV-2 vaccine.
Response to: Skin reactions to mRNA-1273 SARS-CoV-2 vaccine.
Adrenal haemorrhage and COVID-19 vaccine-induced immune thrombotic thrombocytopenia: correspondence.
Implementation and Short-term Adverse Events of Anti-SARS-CoV-2 Vaccines in Inflammatory Bowel Disease Patients: An International Web-based Survey. INTRODUCTION: Anti-SARS-CoV-2 vaccine clinical trials did not include patients with immune-mediated conditions such as inflammatory bowel disease [IBD]. We aimed to describe the implementation of anti-SARS-CoV-2 vaccination among IBD patients, patients' concerns, and the side effect profile of the anti-SARS-CoV-2 vaccines, using real-world data. METHODS: An anonymous web-based self-completed survey was distributed in 36 European countries between June and July 2021. The results of the patient characteristics, concerns, vaccination status, and side effect profile were analysed. RESULTS: In all 3272 IBD patients completed the survey, 79.6% had received at least one dose of anti-SARS-CoV-2 vaccine, and 71.7% had completed the vaccination process. Patients over 60 years old had a significantly higher rate of vaccination [pâ€…<â€…0.001]. Patients' main concerns before vaccination were the possibility of having worse vaccine-related adverse events due to their IBD [24.6%], an IBD flare after vaccination [21.1%], and reduced vaccine efficacy due to IBD or associated immunosuppression [17.6%]. After the first dose of the vaccine, 72.4% had local symptoms and 51.4% had systemic symptoms [five patients had non-specified thrombosis]. Adverse events were less frequent after the second dose of the vaccine and in older patients. Only a minority of the patients were hospitalised [0.3%], needed a consultation [3.6%], or had to change IBD therapy [13.4%] after anti-SARS-CoV-2 vaccination. CONCLUSIONS: Although IBD patients raised concerns about the safety and efficacy of anti-SARS-CoV-2 vaccines, the implementation of vaccination in those responding to our survey was high and the adverse events were comparable to the general population, with minimal impact on their IBD.
Willingness to Pay for a Coronavirus Vaccine and Its Associated Determinants in Lebanon. OBJECTIVES: This study aimed to investigate the willingness to pay (WTP) for a hypothetical vaccine and its associated determinants among the Lebanese general population during one of the peak episodes during the coronavirus disease 2019 (COVID-19) pandemic in Lebanon. METHODS: An online survey was developed and delivered to the Lebanese general population. The questionnaire included the participants' sociodemographic characteristics, financial situation, attitude toward vaccination, and WTP for the hypothetical vaccine. The study was based on the contingent valuation method. RESULTS: Among 500 individuals solicited, 352 individuals agreed to participate (participation rateÂ = 70.4%); among them, 66% were between 18 and 45 years old, and 54% were women. Notably, 78.1%

of the respondents were ready to pay for this hypothetical vaccine even if the vaccine will not be covered. The maximum WTP of the Lebanese population was approximately $60 Â± $66 (range $3-$500) after excluding extreme values in the sensitivity analysis and ranged between $3 and $500. WTP was associated with the severity of COVID-19 (P<.001), the education level (P=.001), and the place to live during the lockdown (P=.045). There was an association between family income and WTP (P=.004) with a weak correlation. CONCLUSIONS: The WTP was comparable with other studies and highly associated with the level of education, the household income, living in the city during the lockdown, and the perceived severity of COVID-19. These findings can help in understanding COVID-19 vaccination acceptance and WTP in Lebanon.

CENTRAL RETINAL VEIN OCCLUSION FOLLOWING BNT162B2 (PFIZER-BIONTECH) COVID-19 MESSENGER RNA VACCINE. PURPOSE: Coronavirus disease 2019 has had a wide-ranging public health impact, contributing to at least five million deaths globally at the time of this report. Although thromboembolic events following coronavirus disease 2019 vaccination have been an ongoing concern, only a limited number of ophthalmic manifestations have been reported to date. METHODS: A detailed history, hypercoagulable workup, best-corrected visual acuity (BCVA), Humphrey visual field, dilated fundus examination, and multimodal imaging including optical coherence tomography, fundus fluorescein angiography, and fundus photography were obtained. RESULTS: A 27-year-old woman was diagnosed with central retinal vein occlusion a few days after her first dose of the BNT162b2 (Pfizer-BioNTech) coronavirus disease 2019 vaccine. Detailed elicitation of her history and a full hypercoagulable workup did not reveal any primary risk factors that could have explained her disease process. After the patient received the second dose, her symptoms deteriorated significantly and worsening peripapillary hemorrhage were seen on dilated fundus examination. The patient was treated with intravitreal injections of ranibizumab and followed closely, which showed improvement in her central retinal vein occlusion. CONCLUSION: Given the chronology of the patient's condition, it is believed that the central retinal vein occlusion that occurred as a result of the first dose was exacerbated by an intense immunological reaction after the second dose. The severity of this complication, despite its rarity, must be emphasized and weighed in but should not preclude the extensive benefits of vaccination.

Postvaccination COVID-19 infection is associated with reduced mortality in patients with cirrhosis. BACKGROUND AND AIMS: Patients develop breakthrough COVID-19 infection despite vaccination. The aim of this study was to identify outcomes in patients with cirrhosis who developed postvaccination COVID-19. METHODS: We performed a retrospective cohort study among US veterans with cirrhosis and postvaccination or unvaccinated COVID-19. Patients were consideredÂ fully vaccinatedÂ if COVID-19 was diagnosed 14 days after the second dose of either the Pfizer BNT162b2, the Moderna 1273-mRNA, or the single-dose Janssen Ad.26.COV2.S vaccines and partially vaccinatedÂ if COVID-19 was diagnosed 7 days after the first dose of any vaccine but prior to full vaccination. We investigated the association of postvaccination COVID-19 with mortality. RESULTS: We identified 3242 unvaccinated and 254 postvaccination COVID-19 patients with cirrhosis (82 after full and 172 after partial vaccination). In a multivariable analysis of a 1:2 propensity-matched cohort including vaccinated (nÂ =Â 254) and unvaccinated (nÂ =Â 508) participants, postvaccination COVID-19 was associated with reduced risk of death (adjusted HR [aHR], 0.21; 95% CI, 0.11-0.42). The reduction was observed after both full (aHR, 0.22; 95% CI, 0.08-0.63) and partial (aHR, 0.19; 95% CI, 0.07-0.54) vaccination, following the 1273-mRNA (aHR, 0.12; 95% CI 0.04-0.37) and BNT162b2 (aHR, 0.27; 95% CI, 0.10-0.71) vaccines and among patients with compensated (aHR, 0.19; 95% CI, 0.08-0.45) and decompensated (aHR, 0.27; 95% CI, 0.08-0.90) cirrhosis. Findings were consistent in a sensitivity analysis restricted to participants who developed COVID-19 after vaccine availability.

CONCLUSIONS: Though patients with cirrhosis can develop breakthrough COVID-19 after full or partial vaccination, these infections are associated with reduced mortality.

Post BNT162b2 mRNA COVID-19 vaccination Henoch-SchÓ§nlein Pupura.

Case Series: Atypical Optic Neuritis After COVID-19 Vaccination.

Kounis syndrome must be considered in the differential diagnosis of myocardial infarction following COVID-19 vaccination.

Incidence of Positive Severe Acute Respiratory Syndrome Coronavirus Polymerase Chain Reaction After Coronavirus Disease 2019 Vaccination With up to 8 Months of Follow-up: Real-life Data From the Capital Region of Denmark. BACKGROUND: Coronavirus disease 2019 (COVID-19) vaccines are implemented worldwide in efforts to curb the pandemic. This study investigates the risk of a positive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reverse transcriptase polymerase chain reaction (RT-PCR) test following BNT162b2 vaccination in a large real-life population in Denmark. METHODS: Vaccination status and positive SARS-CoV-2 RT-PCR results from adults in the Capital Region of Denmark (nâ€…=â€…1â€…549â€…488) were obtained from national registries. PCR testing was free and widely available. The number of positive PCR tests per individual at risk was calculated as weekly rates. Time to positive PCR test was modelled using Kaplan-Meier methods and hazard ratios (HRs) were calculated using Cox regression. RESULTS: A total of 1â€…119â€…574 individuals received the first dose of BNT162b2 and 1â€…088â€…879 received a second dose of BNT162b2. Individuals were followed up to 8.7 months after first dose (median: 5.5 months; interquartile ratio: 4.1-8.7). Rates of PCR-confirmed SARS-CoV-2 infection 2-4 months after the second dose were 0.21, 0.33, and 0.36 per 1000 individuals per week at risk for July, August, and September, respectively. Four or more months after the second dose, the rates were 0.56, 0.76, and 0.53 per 1000 individuals per week at risk for July, August, and September, respectively. HR of SARS-CoV-2 infection after the second dose was 0.2 (95% confidence interval, .05-.48; Pâ€…=â€….001) for individuals with 8 months' follow-up. CONCLUSIONS: Individuals who received 2 doses of the BNT162b2 COVID-19 vaccine had a low risk of breakthrough infection after up to 8 months of follow-up. However, there was a tendency toward higher rates with longer follow-up.

Antibody responses after two doses of CoronaVac of the participants with or without the diagnosis of COVID-19. BACKGROUND: CoronaVac, an inactivated whole-virion vaccine against COVID-19, has been shown to be safe with acceptable antibody responses by various clinical trials. AIMS: The objective was to investigate the post-vaccination antibody levels of both symptomatic and asymptomatic healthcare workers with or without the diagnosis of COVID-19 in an emergency department (ED) of a hospital serving as a pandemic hospital. METHODS: This single-centred, prospective study was conducted on 86 participants who were working as nurse or doctor in the ED. The volunteers were older than 18Â years and either positive or negative for either computed tomography (CT), real-time reverse transcription polymerase chain reaction (qRT-PCR), or both. Thirty days after the second dose of CoronaVac (3Â Âµg), the antibody levels were chemiluminescent microparticle immunoassay. RESULTS: Mean age of all participants were 33.1â€‰Â±â€‰9.1Â years. The antibody levels in the qRT-PCR(â€‰+) and CT(â€‰+) groups were significantly higher than the qRT-PCR(â€‰-) and CT(â€‰-) groups, respectively (pâ€‰<â€‰0.05). In the CT(â€‰+)/qRT-PCR(â€‰+) group, the antibody level was significantly higher than the CT(â€‰-)/qRT-PCR(â€‰-) and CT(â€‰-)/qRT-PCR(â€‰+) or CT(â€‰+)/qRT-PCR(â€‰-) group (pâ€‰<â€‰0.05). On the other hand, antibody levels in the hospitalized group were significantly higher than in the non-hospitalized group (pâ€‰<â€‰0.05). A significant positive correlation was observed between the time elapsed after vaccination and antibody levels of the participants (râ€‰=â€‰0.343; pâ€‰=â€‰0.000). CONCLUSION: In conclusion, antibody responses of recovered patients COVID-19 diagnosed by both CT and qRT-PCR were much robust than the patients diagnosed by either one of the techniques or

undiagnosed/disease-free participants suggesting that severity of the disease likely contributes to the antibody responses after vaccination with CoronaVac.
Antibody Response Six Months after SARS-CoV-2 mRNA Vaccination in Patients with Inflammatory Bowel Disease. Patients with inflammatory bowel disease (IBD) are recommended to receive vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), regardless of their immunosuppression status. Immunosuppressive medications represent a mainstay of therapy in moderate to severe IBD; however, their impact on the SARS-CoV-2 vaccine response remains unclear. Studies thus far have shown that patients with IBD on various therapies had detectable antibody responses after standard vaccinations.(1-5) To date, one study has examined the kinetics of antibody response at 3 months after vaccination in patients with IBD, but data beyond this time point are not yet available.(6) The aim of this study was to assess anti-spike antibody response 6 months after completion of standard SARS-CoV-2 vaccination in patients with IBD. Secondarily, we observed antibody kinetics over 6 months in a subset of patients post-vaccination.
Age-associated SARS-CoV-2 breakthrough infection and changes in immune response in a mouse model. Older individuals are at higher risk of SARS-CoV-2 infection and severe outcomes, but the underlying mechanisms are incompletely understood. In addition, how age modulates SARS-CoV-2 re-infection and vaccine breakthrough infections remain largely unexplored. Here, we investigated age-associated SARS-CoV-2 pathogenesis, immune responses, and the occurrence of re-infection and vaccine breakthrough infection utilizing a wild-type C57BL/6N mouse model. We demonstrated that interferon and adaptive antibody response upon SARS-CoV-2 challenge are significantly impaired in aged mice compared to young mice, which results in more effective virus replications and severe disease manifestations in the respiratory tract. Aged mice also showed increased susceptibility to re-infection due to insufficient immune protection acquired during the primary infection. Importantly, two-dose COVID-19 mRNA vaccination conferred limited adaptive immune response among the aged mice, making them susceptible to SARS-CoV-2 infection. Collectively, our findings call for tailored and optimized treatments and prevention strategies against SARS-CoV-2 among older individuals.
Abrupt worsening of occult IgA nephropathy after the first dose of SARS-CoV-2 vaccination. Here, we report a case of abrupt onset of gross hematuria and nephrotic range proteinuria after the first dose of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination, which led to a diagnosis of immunoglobulin A nephropathy (IgAN). A Japanese woman in their forties with a significant medical history of occult blood by urine dipstick test (over the past 3Â years) presented with fever, chills, shivering, marked thrombocytopenia, and gross hematuria 9Â days after the first dose of the BNT162b2 mRNA vaccine (Pfizer) against SARS-CoV-2 infection. Although thrombotic microangiopathy (TMA) was first suspected as the cause of the severe thrombocytopenia, TMA was clinically excluded after two sessions of plasma exchange were performed. Renal biopsy was performed as the patient's platelet count improved. We made a diagnosis of acute worsening IgAN, triggered by the first dose of SARS-CoV-2 vaccination. In this case, we speculated that vaccine-induced immune activation may be involved in the exacerbation of occult IgAN, leading to the definite diagnosis. We should pay more attention to the development/worsening of clinically significant kidney disease after SARS-CoV-2 vaccination not only in those with known glomerular disease but also in those with only mild urinary abnormality.
Ramsay Hunt syndrome following COVID-19 vaccination.
Low Response to the COVID-19 Vaccine Among the Arab Population in Israel: Is It a Cultural Background, or a Systemic Failure, or Maybe Both? INTRODUCTION: A low response to COVID-19 vaccination was observed among the Arab population in Israel. Efforts to improve this achieved moderate results. OBJECTIVES: The aim of this study was to examine the extent to which demographic and cultural factors, the media, trust, perceptions, and government policies influence

the willingness of Arabs to be vaccinated against COVID-19. METHODS: A cross-sectional survey was conducted among Israeli Arabs (558 respondents). The questionnaire was distributed through social networks between January 16 and 26, 2021. The t-tests, Chi-square tests, Z tests, which were used to evaluate the significance of variables, and Pearson correlations calculated for the study variables were used for statistical analysis. Hierarchical logistic regression was calculated to assess the extent of background influence on the odds for vaccination, and mediation was examined using the Process procedure. RESULTS: Moderate means were found for attitudes towards vaccination, vulnerability, vaccine effectiveness, and pandemic fatigue. A lower score was found for accessibility to medical services, social norms, and emotional barriers. Trust was highest in health-related authorities, whereas trust in government and the media was the lowest. Higher pandemic fatigue was associated with lower trust and lower odds for vaccination. DISCUSSION: Lack of awareness of the specific needs of the Arab minority in Israel, lack of vaccination campaigns in Arabic language, long neglect of Arabs in the Israeli health system, mistrust of governmental authorities by the Arabs, and low socioeconomic background of Israeli Arabs might have led to lower trust levels and incompliance with governmental policies among Arabs. Addressing these issues may benefit the entire population. The authors believe that "A chain (in population health) is only as strong as its weakest link."

Coronavirus Disease 2019 Messenger RNA Vaccines Associated With Delayed Onset of Breakthrough Infections and Fewer Radiographic Abnormalities. This retrospective study of incoming travelers with coronavirus disease 2019 showed that individuals immunized by messenger RNA vaccines had significantly longer postvaccination intervals (median, 30.5 days) to breakthrough infection, lower white blood cell counts and lactate dehydrogenase levels on admission, and fewer radiographic abnormalities than those immunized by inactivated virus vaccine, who paradoxically had lower respiratory viral load.

A young adult with nephrotic syndrome following COVID-19 vaccination.

Omicron: a drug developer's perspective. We performed an annotation of 35 mutations in the spike protein of the SARS-CoV-2 Omicron variant. Our analysis of the mutations indicates that Omicron has gained prominent immune evasion and potential for enhanced transmissibility. Previous modeling study has revealed that continued evolution in both immune evasion and enhanced transmissibility by SARS-CoV-2 would compromise vaccines as tools for the pandemic control. To combat the future variants of SARS-CoV-2, the world needs novel antiviral drugs that are effective at curb viral spreading without introducing additional selective pressure towards resistant variants.

A new testing platform using fingerstick blood for quantitative antibody response evaluation after SARS-CoV-2 vaccination. Testing and vaccination have been major components of the strategy for combating the ongoing COVID-19 pandemic. In this study, we have developed a quantitative anti-SARS-CoV-2 spike (S1) IgG antibody assay using a fingerstick dried blood sample. We evaluated the feasibility of using this high-throughput and quantitative anti-SARS-CoV-2 spike (S1) IgG antibody testing assay in vaccinated individuals. Fingerstick blood samples were collected and analyzed from 137 volunteers before and after receiving the Moderna or Pfizer mRNA vaccine. Anti-SARS-CoV-2 S1 IgG antibody could not be detected within the first 7 days after receiving the first vaccine dose, however, the assay reliably detected antibodies from day 14 onwards. In addition, no anti-SARS-CoV-2 nucleocapsid (N) protein IgG antibody was detected in any of the vaccinated or healthy participants, indicating that the anti-SARS-CoV-2 S1 IgG assay is specific for the mRNA vaccine-induced antibodies. The S1 IgG levels detected in fingerstick samples correlated with the levels found in venous blood plasma samples and with the efficacy of venous blood plasma samples in the plaque reduction neutralization test (PRNT). The assay displayed a limit of quantification (LOQ) of 0.59â€…Î¼g/mL and was found to be linear in the range of 0.51-1000â€…Î¼g/mL. Finally, its clinical performance displayed a Positive Percent Agreement (PPA) of 100% (95% CI: 0.89-1.00) and a Negative Percent Agreement

(NPA) of 100% (95% CI: 0.93-1.00). In summary, the assay described here represents a sensitive, precise, accurate, and simple method for the quantitative detection and monitoring of post-vaccination anti-SARS-CoV-2 spike IgG responses.

Coronavirus Disease 2019 (COVID-19) Breakthrough Infection and Post-Vaccination Neutralizing Antibodies Among Healthcare Workers in a Referral Hospital in Tokyo: A Case-Control Matching Study. BACKGROUND: While increasing coverage of effective vaccines against coronavirus disease 2019 (COVID-19), emergent variants raise concerns about breakthrough infection. Data are limited, however, whether breakthrough infection during the epidemic of the variant is ascribed to insufficient vaccine-induced immunogenicity. METHODS: We describe incident COVID-19 in relation to the vaccination program among workers of a referral hospital in Tokyo. During the predominantly Delta epidemic, we followed 2415 fully vaccinated staff (BNT162b2) for breakthrough infection and selected 3 matched controls. We measured post-vaccination neutralizing antibodies against the wild-type, Alpha (B.1.1.7), and Delta (B.1.617.2) strains using live viruses and anti-spike antibodies using quantitative assays, and compared them using the generalized estimating equation model between the 2 groups. RESULTS: No COVID-19 cases occurred 1-2 months after the vaccination program during the fourth epidemic wave in Japan, dominated by the Alpha variant, while 22 cases emerged 2-4 months after the vaccination program during the fifth wave, dominated by the Delta variant. In the vaccinated cohort, all 17 cases of breakthrough infection were mild or asymptomatic and participants had returned to work early. There was no measurable difference between cases and controls in post-vaccination neutralizing antibody titers against the wild-type, Alpha, Delta, and anti-spike antibody titers, while neutralizing titers against the variants were considerably lower than those against the wild-type. CONCLUSIONS: Post-vaccination neutralizing antibody titers were not decreased among patients with breakthrough infection relative to their controls under the Delta variant outbreak. The result points to the importance of infection-control measures in the post-vaccination era, irrespective of immunogenicity profile.

Safety and Immunogenicity of SARS-CoV-2 Vaccines in Patients With Chronic Liver Diseases (CHESS-NMCID 2101): AÂ Multicenter Study. BACKGROUND & AIMS: We aimed to assess the safety and immunogenicity of inactivated whole-virion severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines in patients with chronic liver diseases (CLD) in this study. METHODS: This was a prospective, multi-center, open-label study. Participants aged over 18 years with confirmed CLD and healthy volunteers were enrolled. All participants received 2 doses of inactivated whole-virion SARS-CoV-2 vaccines. Adverse reactions were recorded within 14 days after any dose of SARS-CoV-2 vaccine, laboratory testing results were collected after the second dose, and serum samples of enrolled subjects were collected and tested for SARS-CoV-2 neutralizing antibodies at least 14 days after the second dose. RESULTS: A total of 581 participants (437 patients with CLD and 144 healthy volunteers) were enrolled from 15 sites in China. Most adverse reactions were mild and transient, and injection site pain (nÂ = 36; 8.2%) was the most frequently reported adverse event. Three participants had grade 3 aminopherase elevation (defined as alanine aminopherase >5 upper limits of normal) after the second dose of inactivated whole-virion SARS-CoV-2 vaccination, and only 1 of them was judged as severe adverse event potentially related to SARS-CoV-2 vaccination. The positive rates of SARS-CoV-2 neutralizing antibodies were 76.8% in the noncirrhotic CLD group, 78.9% in the compensated cirrhotic group, 76.7% in the decompensated cirrhotic group (PÂ = .894 among CLD subgroups), and 90.3% in healthy controls (PÂ = .008 vs CLD group). CONCLUSION: Inactivated whole-virion SARS-CoV-2 vaccines are safe in patients with CLD. Patients with CLD had lower immunologic response to SARS-CoV-2 vaccines than healthy population. The immunogenicity is similarly low in noncirrhotic CLD, compensated cirrhosis, and decompensated cirrhosis.

Immune-related adverse events of COVID-19 vaccination in skin cancer patients receiving immune-checkpoint inhibitor treatment. To date, few data are available regarding Adverse events (AEs) in cancer patients who are vaccinated for coronavirus disease 2019 (COVID-19) while being actively treated with Immune-checkpoint inhibitors (ICIs). We aimed to assess the safety of COVID-19 vaccines approved in Germany. Specifically, we investigated the frequency of general side effects and immune-related AEs of COVID-19 vaccination. A triage survey was used to collect the following information for patients with metastatic skin cancer: vaccine type, date of receipt of each dose of vaccine, and self-reported side effects. Clinical data were retrieved from the patients' medical records. Of 130 patients with metastatic skin cancer, 89 patients were on immunotherapy and received COVID-19 vaccination. Of these 89 patients (median age: 64Â years; 57 [64%] men), 89% had melanoma, and 71% received ICI therapy with a PD-1 antibody. Eighty-eight percent received an mRNA-based COVID-19 vaccination. The median follow-up time was 125Â days after the first vaccination, and 84Â days after the second. The most common observed side effects were mild to moderate pain at the injection site (40%), followed by fatigue (24%). Grade 3 irAEs were reported in eight patients, seven of whom were on nivolumab plus ipilimumab combination treatment. Of the 19 patients vaccinated within 72Â h before/after ICI, five developed irAEs within 17Â days (1-17Â days). This small cohort study suggests that approved COVID-19 vaccinations are safe for use in cancer patients receiving ICIs. However, some precautions should be taken, especially regarding the timing of vaccination and ICI treatment.

Multisystem inflammatory syndrome following COVID-19 vaccination: ignored and underdiagnosed.

Omicron variant showed lower neutralizing sensitivity than other SARS-CoV-2 variants to immune sera elicited by vaccines after boost. ABSTRACTThe emerging new VOC B.1.1.529 (Omicron) variant has raised serious concerns due to multiple mutations, reported significant immune escape, and unprecedented rapid spreading speed. Currently, studies describing the neutralization ability of different homologous and heterologous booster vaccination against Omicron are still lacking. In this study, we explored the immunogenicity of COVID-19 breakthrough patients, BBIBP-CorV homologous booster group and BBIBP-CorV/ZF2001 heterologous booster group against SARS-CoV-2 pseudotypes corresponding to the prototype, Beta, Delta, and the emergent Omicron variant.Notably, at 14 days post two-dose inactivated vaccines, pVNT titre increased to 67.4 GMTs against prototype, 8.85 against Beta and 35.07 against Delta, while neutralization activity against Omicron was below the lower limit of quantitation in 80% of the samples. At day 14 post BBIBP-CorV homologous booster vaccination, GMTs of pVNT significantly increased to 285.6, 215.7, 250.8, 48.73 against prototype, Beta, Delta, and Omicron, while at day 14 post ZF2001 heterologous booster vaccination, GMTs of pVNT significantly increased to 1436.00, 789.6, 1501.00, 95.86, respectively. Post booster vaccination, 100% samples showed positive neutralization activity against Omicron, albeit illustrated a significant reduction (5.86- to 14.98-fold) of pVNT against Omicron compared to prototype at 14 days after the homologous or heterologous vaccine boosters.Overall, our study demonstrates that vaccine-induced immune protection might more likely be escaped by Omicron compared to prototypes and other VOCs. After two doses of inactivated whole-virion vaccines as the "priming" shot, a third heterologous protein subunit vaccine and a homologous inactivated vaccine booster could improve neutralization against Omicron.

Balancing benefits and potential risks of vaccination: the precautionary principle and the law of unintended consequences. Vaccination is a life-saving endeavour, yet risk and uncertainty are unavoidable in science and medicine. Vaccination remains contentious in the public mind, and vaccine hesitancy is a serious public health issue. This has recently been reignited in the discussion over potential side effects of COVID-19 vaccines, and the decision by several countries to suspend measures such as the AstraZeneca vaccine. In these instances, the precautionary principle has often been invoked as a rationale, yet such heuristics do not adequately weigh potential harms against real

benefits. How we analyse, communicate and react to potential harms is absolutely paramount to ensure the best decisions and outcomes for societal health, and maintaining public confidence. While balancing benefits and risks is an essential undertaking, it cannot be achieved without due consideration of several other pertinent factors, especially in the context of vaccination, where misguided or exaggerated fears have in the past imperilled public health. While well meaning, over reactions to potential hazards of vaccination and other health interventions can have unintended consequences, and cause lingering damage to public trust. In this analysis, we explore the challenges of assessing risk and benefit, and the limitations of the precautionary principle in these endeavours. When risk is unclear, cautious vigilance might be a more pragmatic and useful policy than reactionary suspensions.

Nonarteritic Anterior Ischemic Optic Neuropathy Associated With COVID-19 Vaccination.

Hypersensitivity to the Moderna COVID-19 Vaccine Caused by Tromethamine: PEG Is Not Always the Culprit Excipient.

COVID-19 Associated Collapsing FSGS in an APOL1 Homozygous Transplant Recipient After Successful COVID Vaccination: A Case Report. Organ transplant recipients exhibit lower rates of immune response to coronavirus disease 2019 (COVID-19) vaccination. Even when they do mount a demonstrable antibody response, it is unclear what degree of protection is conferred against the myriad potential complications of COVID-19 infection. We present here a case of a kidney transplant recipient who was homozygous for APOL1 risk alleles on low-dose immunosuppression who developed an antibody response to COVID-19 vaccination and subsequently acquired COVID-19 infection. Although she experienced relatively minor effects in other organ systems, she developed severe collapsing focal segmental glomerulosclerosis that left her dependent on hemodialysis on hospital discharge. This suggests that COVID-19 vaccination may not provide protection from infection-associated focal segmental glomerulosclerosis in patients with APOL1 risk alleles.

Infection With the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Delta Variant Is Associated With Higher Recovery of Infectious Virus Compared to the Alpha Variant in Both Unvaccinated and Vaccinated Individuals. BACKGROUND: The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variant of concern (VOC) B.1.617.2 (Delta) displaced B.1.1.7 (Alpha) and is associated with increases in coronavirus disease 2019 (COVID-19) cases, greater transmissibility, and higher viral RNA loads, but data are lacking regarding the infectious virus load and antiviral antibody levels in the nasal tract. METHODS: Whole genome sequencing, cycle threshold (Ct) values, infectious virus, anti-SARS-CoV-2 immunoglobulin G (IgG) levels, and clinical chart reviews were combined to characterize SARS-CoV-2 lineages circulating in the National Capital Region between January and September 2021 and differentiate infections in vaccinated and unvaccinated individuals by the Delta, Alpha, and B.1.2 (the predominant lineage prior to Alpha) variants. RESULTS: The Delta variant displaced the Alpha variant to constitute 99% of the circulating lineages in the National Capital Region by August 2021. In Delta infections, 28.5% were breakthrough cases in fully vaccinated individuals compared to 4% in the Alpha infected cohort. Breakthrough infections in both cohorts were associated with comorbidities, but only Delta infections were associated with a significant increase in the median days after vaccination. More than 74% of Delta samples had infectious virus compared to <30% from the Alpha cohort. The recovery of infectious virus with both variants was associated with low levels of local SARS-CoV-2 IgG. CONCLUSIONS: Infection with the Delta variant was associated with more frequent recovery of infectious virus in vaccinated and unvaccinated individuals compared to the Alpha variant but was not associated with an increase in disease severity in fully vaccinated individuals. Infectious virus was correlated with the presence of low amounts of antiviral IgG in the nasal specimens.

Cardiac complications following mRNA COVID-19 vaccines: A systematic review of case reports and case series. There have been several local and systemic adverse events associated with mRNA COVID-19 vaccines. Pericarditis, myocarditis and myocardial infarction are examples of cardiac complications related to these vaccines. In this article, we conducted a systematic review of case reports and case series to identify the clinical profile, investigations, and management of reported cardiac complications post-mRNA COVID-19 vaccines. We systematically searched PubMed, Scopus, Web of Science, and Google Scholar, as well as the medRxiv preprint server, with terms including: 'SARS-CoV-2', 'COVID-19', 'messenger RNA vaccine*', 'mRNA-1273 vaccine', 'BNT162 vaccine', 'myocarditis', 'pericarditis', 'stroke' and 'Myocardial Ischemia' up to 25 September 2021. Studies were excluded if they were not case reports or case series, or reported cases from non-mRNA vaccines. Case reports and case series were included that investigated the potential cardiac complications associated with mRNA COVID-19 vaccines. The JBI checklist was used to assess quality and data synthesis was conducted using a qualitative methodology called narrative synthesis. Sixty-nine studies, including 43 case reports and 26 case series, were included. Myocarditis/myopericarditis and pericarditis were the most common adverse events among the 243 reported cardiac complications, post mRNA COVID-19 vaccination. Males with a median age of 21Â years had the highest frequency of myocarditis. Almost three quarters (74.4%) of cases with myocarditis had received the BNT162b2 vaccine and 87.7% had received the second dose of the vaccine. Chest pain (96.1%) and fever (38.2%) were the most common presentations. CK-MB, troponin, and NT-proBNP were elevated in 100%, 99.5% and 78.3% of subjects, respectively. ST-segment abnormality was the most common electrocardiogram feature. Cardiac magnetic resonance imaging, which is the gold-standard approach for diagnosing myocarditis, was abnormal in all patients diagnosed with myocarditis. Non-steroidal anti-inflammatory drugs were the most prescribed medication for the management of myocarditis. Apart from inflammatory conditions, some rare cases of Takotsubo cardiomyopathy, myocardial infarction, myocardial infarction with non-obstructive coronary arteries, and isolated tachycardia were also reported following immunisation with mRNA COVID-19 vaccines. We acknowledge that only reviewing case reports and case series studies is one potential limitation of our study. We found that myocarditis was the most commonly reported adverse cardiac event associated with mRNA COVID-19 vaccines, which presented as chest pain with a rise in cardiac biomarkers. Further large-scale observational studies are recommended.

Response to: Vaccine-induced immune thrombocytopenia and thrombosis should be considered in those presenting following the ChAdOx1 nCoV-19 vaccine with tachycardia, tachypnoea and a raised D-dimer.

Vaccine-induced immune thrombocytopenia and thrombosis should be considered in those presenting following the ChAdOx1 nCoV-19 vaccine with tachycardia, tachypnoea and a raised D-dimer.

Vaccine-Induced Thrombotic Thrombocytopenia Due to Coronavirus Disease 2019 Vaccine From a Deceased Donor: A Case Report. With the rapid and massive vaccination campaign against coronavirus disease 2019 (COVID-19) taking place across the globe, there are increasing reports of thrombotic complications with various COVID-19 vaccines such as the Pfizer-BioNTech mRNA, Moderna mRNA, AstraZeneca Oxford (serum institute), and Johnson & Johnson/Janssen vaccines. We report a case of successful organ donation from an 18-year-old woman who presented with cerebral venous thrombosis caused by vaccine-induced thrombotic thrombocytopenia following the first dose of the COVID-19 vaccine (AstraZeneca, University of Oxford, and Serum Institute of India), which caused brain death. Four recipients received 5 organs, kidneys (2), liver (1), and combined heart and lung (1). All 4 recipients had normal graft function without any thrombotic complications after 16 weeks of transplantation. This is first such case being reported from Asian countries.

Optic neuropathy after COVID-19 vaccination: a report of two cases. PURPOSE: We report two cases of optic nerve pathology after the administration of the Pfizer-BioNTech and AstraZeneca-Oxford COVID-19 vaccines, respectively, and describe the implications for management of post-vaccination central nervous system (CNS) inflammation. CASE REPORTS: A 69-year-old woman presented with bilateral optic nerve head oedema, 16â€‰days after the second dose of the Pfizer-BioNTech vaccine. She was diagnosed with post-vaccination CNS inflammatory syndrome and was treated for five days with intravenous methylprednisolone at a dose of 1 gram per day. Her optic disc swelling improved, and her vision stabilised. A 32-year-old woman presented six days after her first dose of the AstraZeneca-Oxford vaccine with two days of sudden onset of progressive blurring of vision in her left eye. Posterior segment examination revealed left optic disc swelling, and an MRI of the brain, orbit, and cervical spine was significant for left optic nerve enhancement. The patient was diagnosed with a unilateral post-vaccination optic neuritis. She was treated with a three-day course of intravenous methylprednisolone followed by oral prednisone. Her optic disc swelling and visual field improved, and she recovered 6/6 vision. CONCLUSIONS: Clinicians and patients should be aware of the potential for post-vaccination CNS inflammatory syndromes associated with COVID-19 vaccine administration. Neuroimaging and cerebrospinal fluid analysis may aid in the diagnosis of the cause of vision loss. Further studies are needed to evaluate the spectrum and frequency of optic nerve involvement associated with COVID-19 vaccination.

Immunogenicity of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection and Ad26.CoV2.S Vaccination in People Living With Human Immunodeficiency Virus (HIV). BACKGROUND: People living with HIV (PLWH) have been reported to have a higher risk of more severe COVID-19 disease and death. We assessed the ability of the Ad26.CoV2.S vaccine to elicit neutralizing activity against the Delta variant in PLWH relative to HIV-negative individuals. We also examined effects of HIV status and suppression on Delta neutralization response in SARS-CoV-2-infected unvaccinated participants. METHODS: We enrolled participants who were vaccinated through the SISONKE South African clinical trial of the Ad26.CoV2.S vaccine in healthcare workers (HCWs). PLWH in this group had well-controlled HIV infection. We also enrolled unvaccinated participants previously infected with SARS-CoV-2. Neutralization capacity was assessed by a live virus neutralization assay of the Delta variant. RESULTS: Most Ad26.CoV2.S vaccinated HCWs were previously infected with SARS-CoV-2. In this group, Delta variant neutralization was 9-fold higher compared with the infected-only group and 26-fold higher relative to the vaccinated-only group. No decrease in Delta variant neutralization was observed in PLWH relative to HIV-negative participants. In contrast, SARS-CoV-2-infected, unvaccinated PLWH showed 7-fold lower neutralization and a higher frequency of nonresponders, with the highest frequency of nonresponders in people with HIV viremia. Vaccinated-only participants showed low neutralization capacity. CONCLUSIONS: The neutralization response of the Delta variant following Ad26.CoV2.S vaccination in PLWH with well-controlled HIV was not inferior to HIV-negative participants, irrespective of past SARS-CoV-2 infection. In SARS-CoV-2-infected and nonvaccinated participants, HIV infection reduced the neutralization response to SARS-CoV-2, with the strongest reduction in HIV viremic individuals.

Hyperinflammatory Syndromes After Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Messenger RNA vaccination in Individuals With Underlying Immune Dysregulation. The development of effective severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) messenger RNA (mRNA) vaccines has been a significant accomplishment. Adverse events are extremely rare, but continued surveillance is important, especially in at-risk populations. In 5 patients with preexisting immune dysregulation, hyperinflammatory syndromes, including hemophagocytic lymphohistiocytosis, developed after SARS-CoV-2 mRNA vaccination. Early recognition of this rare condition is essential.

Clinical Performance of a Standardized Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Interferon-Î³ Release Assay for Simple Detection of T-Cell Responses After Infection or Vaccination. BACKGROUND: We evaluated a standardized interferon-Î³ (IFN-Î³) release assay (IGRA) for detection of T-cell immune response after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection or vaccination. METHODS: This prospective study included patients with coronavirus disease 2019 (COVID-19) with different severity of illness and follow-up (FU), vaccinated subjects, and healthy unvaccinated persons. SARS-CoV-2 T-cell response was measured using a specific quantitative IGRA in whole blood (Euroimmun, Germany) and TrimericS-IgG and neutralizing antibodies with validated serological platforms. Positivity of reverse transcription-polymerase chain reaction or vaccination was considered as the reference standard. RESULTS: A total of 239 individuals were included (152 convalescent, 54 vaccinated, and 33 uninfected unvaccinated). Overall sensitivity, specificity, and positive- and negative-predictive values (95% confidence interval) of the IGRA were 81.1% (74.9-86%), 90.9% (74.5-97.6%), 98.2% (94.5-99.5%), and 43.5% (31.8-55.9%), respectively. All vaccinated SARS-CoV-2-naive subjects had positive IGRA at 3 months. In convalescent subjects the magnitude of IFN-Î³ responses and IGRA accuracy varied according to disease severity and duration of FU, with the best performance in patients with severe COVID-19 at 3 months and the worst in those with mild disease at 12 months. The greatest contribution of IGRA to serological tests was observed in patients with mild disease and long-term FU (incremental difference, 30.4%). CONCLUSIONS: The IGRA was a reliable method of quantifying T-cell response after SARS-COV-2 infection or vaccination. In convalescent patients, the sensitivity is largely dependent on disease severity and time since primary infection. The assay is more likely to add clinical value to serology in patients with mild infections.

Aortic thrombosis and acute limb ischemia after ChAdOx1 nCov-19 (Oxford-AstraZeneca) vaccination: a case of vaccine-induced thrombocytopenia and thrombosis (VITT). INTRODUCTION: Vaccine-induced thrombocytopenia and thrombosis (VITT) is a rare but devastating adverse event associated with the ChAdOx1 nCoV-19 (Oxford-AstraZeneca) adenoviral vaccine against the Severe Acute Respiratory Syndrome CoronaVirus-2 (SARS-CoV-2). METHODS: A 49-year-old man presented to the emergency department with acute right limb ischemia (Rutherford IIB) nine days after his ChAdOx1 nCoV-19 (Oxford-AstraZeneca) vaccination. CT angiography revealed significant aortic thrombosis and right femoral artery occlusion. Severe thrombocytopenia (platelet count of 23â€‰Ã—â€‰10(3)/ÂµL), promptly elevated D-dimers (37937â€‰ng/mL) and a reduced fibrinogen level (176â€‰mg/dL) were remarkable. ELISA testing for anti-PF4 antibodies confirmed the diagnosis of VITT. RESULTS: An emergency revascularization of the right leg was provided via thrombectomy. High-dose intravenous immunoglobulins were administered whereafter the platelet count restored gradually. Therapeutic anticoagulation was progressively started. The postoperative course was uneventful and follow-up imaging after four weeks showed an almost complete resolution of the significant aortic thrombosis. CONCLUSION: Early recognition and appropriate counseling of VITT is advocated to pursue a good clinical outcome. Our patient presenting with severe aortic thrombosis and acute limb ischemia was successfully treated by a vascular thrombectomy along with intravenous immunoglobulins and anticoagulation therapy as the mainstay therapy.

Read science news critically and look for original studies: An example of misleading headlines related to COVID-19 vaccines in mainstream media.

Aseptic meningitis after SARS-CoV-2 Pfizer/BioNTech vaccination. OBJECTIVE: Aseptic meningitis is a rare, but possible severe side effect after SARS-CoV-2 Pfizer/BioNTech vaccination. CASE PRESENTATION: Recently, a first case of aseptic meningitis after the first shot of mRNA-BNT162b2 SARS-CoV-2 (Pfizer/BioNTech) vaccine was reported. We present the first case of a 34-year-old woman without relevant medical history developing aseptic meningitis after her 2(nd) Pfizer/BioNTech vaccination. She was admitted with severe headache and fever for 5Â days prior to

her presentation at the emergency department. An extensive work-up of the clinical problem could narrow the differential diagnosis. Symptoms resolved after methylprednisolone therapy. CONCLUSION: This case highlights a rare but important side effect after vaccination that primary physicians and neurologists should be aware of in order to identify and efficiently manage these patients.

Impact of SARS-CoV-2 Vaccination on Inflammatory Bowel Disease Activity and Development of Vaccine-Related Adverse Events: Results From PREVENT-COVID. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 vaccination is recommended for all individuals with inflammatory bowel disease (IBD), including those on immunosuppressive therapies; however, little is known about vaccine safety and efficacy in these patients or the impact of vaccination on IBD disease course. METHODS: We evaluated coronavirus disease 2019 (COVID-19) vaccine-related adverse events (AEs) and the effect of vaccination on IBD disease course among participants in the PREVENT-COVID (Partnership to Report Effectiveness of Vaccination in populations Excluded from iNitial Trials of COVID) study, a prospective, observational cohort study. Localized and systemic reactions were assessed via questionnaire. Disease flare was defined by worsening IBD symptoms and change in IBD medications. Outcomes were stratified by vaccine type and IBD medication classes. RESULTS: A total of 3316 individuals with IBD received at least 1 COVID-19 vaccine. Injection site tenderness (68%) and fatigue (46% dose 1, 68% dose 2) were the most commonly reported localized and systemic AEs after vaccination. Severe localized and systemic vaccine-related AEs were rare. The mRNA-1273 vaccine was associated with significantly greater severe AEs at dose 2 (localized 4% vs 2%, systemic 15% vs 10%; P < .001 for both). Prior COVID-19 infection, female sex, and vaccine type were associated with severe systemic reactions to dose 1, while age <50 years, female sex, vaccine type, and antitumor necrosis factor and vedolizumab use were associated with severe systemic reactions to dose 2. Overall rates (2%) of IBD flare were low following vaccination. CONCLUSIONS: Our findings provide reassurance that the severe acute respiratory syndrome coronavirus 2 vaccine is safe and well tolerated among individuals with IBD, which may help to combat vaccine hesitancy and increase vaccine confidence.

 The severe acute respiratory syndrome coronavirus 2 vaccine is safe and well tolerated among individuals with inflammatory bowel disease (IBD). Severe localized and systemic vaccine-related adverse events were rare, and rates of IBD flare were low (2%) following severe acute respiratory syndrome coronavirus 2 vaccination in a cohort of 3316 participants with IBD.

Chest Pain with New Abnormal Electrocardiogram Development after Injection of COVID-19 Vaccine Manufactured by Moderna.

Differences in Post-mRNA Vaccination Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Immunoglobulin G (IgG) Concentrations and Surrogate Virus Neutralization Test Response by Human Immunodeficiency Virus (HIV) Status and Type of Vaccine: A Matched Case-Control Observational Study. Following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccination, people living with human immunodeficiency virus (HIV, PLWH) had lower surrogate virus neutralization test response (PÂ =Â .03) and a trend toward lower immunoglobulin G (IgG) response (PÂ =Â .08), particularly among those with lower CD4+ T-cell counts and who received the BNT162b2 vaccine. Study of the impact of supplemental vaccine doses among PLWH is needed.

Long-term trajectories of SARS-CoV-2 neutralizing antibodies and predictive value of first dose vaccination-induced IgG-antibodies in hemodialysis patients. PURPOSE: The predictive value of antibody titers after the first SARS-CoV-2 vaccination and long-term trajectories of antibody titers in hemodialysis patients are unknown. METHODS: SARS-CoV-2 IgG antibodies and their neutralizing effect six weeks after the first and second vaccination were analysed in 30 hemodialysis patients. IgG titers served to classify participants as responders or non-responders and to calculate sensitivity,

specificity, and accuracy. Associations between potential risk factors and post-vaccine non-response were analysed by Mann-Whitney-U test and Chi-Squared test. Long-term follow-up analysis (ANOVA) on the evolution of neutralizing IgG-titers was performed in 24 participants 94 and 135Â days after the second immunization. RESULTS: IgG antibodiesâ€‰â‰¥â€‰1Â AU/L (mean 9â€‰Â±â€‰20Â AU/L) after the first dose were found in 20 patients (66.7%). After the second dose only two participants (6.7%) remained sero-negative and 16.6% showed neutralizing levels below 30%, whereas 25 patients showed IgG antibodies with the high neutralizing activity of 86â€‰Â±â€‰18%. Positive IgG antibodies 6Â weeks after the first vaccination predicted vaccination effectiveness after two cycles with a specificity of 100%, sensitivity of 76%, and accuracy of 87%. Even low-dose immunosuppressive therapy increased the relative risk for non-response after the first and second dose 1.9 (95% CI 0.8-4.6) and 4.9 (95% CI 1.0-23.8) times, respectively. Over a period of about 4.5Â months IgG titers slowly declined by 51% from baseline or by 0.45Â AU/mL per day, respectively. CONCLUSION: Two cycles of SARS-CoV-2 vaccination-induced high seroconversion rates comparable to the general population. Immunosuppressive medication is a major risk factor for vaccination non-response. Mounted IgG antibodies showed a high neutralizing capacity as evidence of protective effectiveness. IgG antibodies after the first dose may serve to predict later vaccination outcome. Patients on dialysis display a more rapid decline in antibody titers on long-term follow-up compared to healthy controls.

Absolute Lymphocyte Count After COVID-19 Vaccination Is Associated with Vaccine-Induced Hypermetabolic Lymph Nodes on (18)F-FDG PET/CT: A Focus in Breast Cancer Care. We aimed to predict the presence of vaccine-induced hypermetabolic lymph nodes (v-HLNs) on (18)F-FDG PET/CT after coronavirus disease 2019 (COVID-19) vaccination and determine their association with lymphocyte counts. Methods: In this retrospective single-center study, we included consecutive patients who underwent (18)F-FDG PET/CT imaging after messenger RNA- or viral vector-based COVID-19 vaccination between early March and late April 2021. Demographics, clinical parameters, and absolute lymphocyte count (ALC) were collected, and their association with the presence of v-HLNs in the draining territory was studied by logistic regression. Results: In total, 260 patients were eligible, including 209 (80%) women and 145 (56%) with breast cancer. The median age was 50 y (range, 23-96 y). The messenger RNA vaccine had been given to 233 (90%). Ninety (35%) patients had v-HLNs, with a median SUV(max) of 3.7 (range, 2.0-26.3), and 74 (44%) displayed lymphopenia, with a median ALC of 1.4 Ã— 10(9)/L (range, 0.3-18.3 Ã— 10(9)/L). An age of no more than 50 y (odds ratio [OR], 2.2; 95% CI, 1.0-4.5), the absence of lymphopenia (OR, 2.2; 95% CI, 1.1-4.3), and less than a 30-d interval from the last vaccine injection to the (18)F-FDG PET/CT (OR, 2.6; 95% CI, 1.3-5.6) were independent factors for v-HLNs on multivariate analysis. In breast cancer patients, the absence of lymphopenia was the only independent factor significantly associated with v-HLNs (OR, 2.9; 95% CI, 1.2-7.4). Conclusion: Patients with a normal ALC after COVID-19 vaccination were more likely to have v-HLNs on (18)F-FDG PET/CT, both of which might be associated with a stronger immune response to vaccination.

Acute Retinal Necrosis from Reactivation of Varicella Zoster Virus following BNT162b2 mRNA COVID-19 Vaccination. PURPOSE: To report a case of acute retinal necrosis (ARN) due to varicella zoster virus (VZV) after COVID-19 vaccine administration. DESIGN/METHODS: Observational case report. RESULT: A 62-year-old immunocompetent African American male presented with left eye redness, decreased vision, and floaters after receiving a COVID-19 vaccine seven days prior. Slit-lamp examination revealed diffuse fine endothelial keratic precipitates. Funduscopic examination was notable for vitreous cells, occlusive retinal vasculitis, large retinal hemorrhages, and three quadrants of peripheral areas of retinal whitening. Quantitative polymerase chain reaction testing was positive for varicella zoster virus in the vitreous humor. Treatment with intravitreal and intravenous antiviral

therapy resulted in symptomatic improvement. CONCLUSION: COVID-19 mRNA vaccination may cause an immunomodulatory response that leads to reactivation of dormant VZV. Early recognition and treatment can improve visual outcomes.
Acute Multifocal Placoid Pigment Epitheliopathy-like Presentation following the First Dose of BNT162B2 COVID-19 Vaccination. PURPOSE: To report a case with acute posterior multifocal placoid pigment epitheliopathy (APMPPE)-like presentation following the first dose of BNT162b2 COVID-19 vaccination. CASE REPORT: An otherwise healthy 45-year-old woman presented with a headache and blurred vision in her right eye 7 days after the administration of first dose of mRNA (BNT162b2) COVID-19 vaccine. Fundus examination of the right eye revealed multiple discrete yellow-white placoid lesions at the level of deep retinal layers throughout the posterior pole, while left fundus was unremarkable at that time. Swept source-optical coherence tomography (SS-OCT) showed subretinal fluid together with an appearance of bacillary layer detachment at the right macula. A detailed systemic evaluation was carried out without any positive finding. Two weeks after the initial eye examination, similar multiple placoid lesions were observed in her left eye. Fundus lesions almost totally resolved without any treatment bilaterally 5 weeks after the onset of initial symptoms. CONCLUSION: To the best of our knowledge, this is the first report of APMPPE-like presentation described after the BNT162b2 COVID-19 vaccination. Previous COVID-19 vaccination should be kept in mind in the differential diagnosis of APMPPE disease spectrum.
Response to: Multisystem inflammatory syndrome following COVID-19 vaccination: ignored and underdiagnosed.
Multisystem Inflammatory Syndrome in Adults After Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection and Coronavirus Disease 2019 (COVID-19) Vaccination. BACKGROUND: Multisystem inflammatory syndrome in adults (MIS-A) was reported in association with the coronavirus disease 2019 (COVID-19) pandemic. MIS-A was included in the list of adverse events to be monitored as part of the emergency use authorizations issued for COVID-19 vaccines. METHODS: Reports of MIS-A patients received by the Centers for Disease Control and Prevention (CDC) after COVID-19 vaccines became available were assessed. Data collected on the patients included clinical and demographic characteristics and their vaccine status. The Vaccine Adverse Events Reporting System (VAERS) was also reviewed for possible cases of MIS-A. RESULTS: From 14 December 2020 to 30 April 2021, 20 patients who met the case definition for MIS-A were reported to CDC. Their median age was 35 years (range, 21-66 years), and 13 (65%) were male. Overall, 16 (80%) patients had a preceding COVID-19-like illness a median of 26 days (range 11-78 days) before MIS-A onset. All 20 patients had laboratory evidence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Seven MIS-A patients (35%) received COVID-19 vaccine a median of 10 days (range, 6-45 days) before MIS-A onset; 3 patients received a second dose of COVID-19 vaccine 4, 17, and 22 days before MIS-A onset. Patients with MIS-A predominantly had gastrointestinal and cardiac manifestations and hypotension or shock. CONCLUSIONS: Although 7 patients were reported to have received COVID-19 vaccine, all had evidence of prior SARS-CoV-2 infection. Given the widespread use of COVID-19 vaccines, the lack of reporting of MIS-A associated with vaccination alone, without evidence of underlying SARS-CoV-2 infection, is reassuring.
Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination. BACKGROUND: Age-specific incidence of acute myocarditis/pericarditis in adolescents following Comirnaty vaccination in Asia is lacking. This study aimed to study the clinical characteristics and incidence of acute myocarditis/pericarditis among Hong Kong adolescents following Comirnaty vaccination. METHODS: This is a population cohort study in Hong Kong that monitored adverse events following immunization through a pharmacovigilance system for coronavirus disease 2019 (COVID-19) vaccines. All adolescents aged between 12 and 17 years

following Comirnaty vaccination were monitored under the COVID-19 vaccine adverse event response and evaluation program. The clinical characteristics and overall incidence of acute myocarditis/pericarditis in adolescents following Comirnaty vaccination were analyzed. RESULTS: Between 14 June 2021 and 4 September 2021, 33 Chinese adolescents who developed acute myocarditis/pericarditis following Comirnaty vaccination were identified. In total, 29 (87.88%) were male and 4 (12.12%) were female, with a median age of 15.25 years. And 27 (81.82%) and 6 (18.18%) cases developed acute myocarditis/pericarditis after receiving the second and first dose, respectively. All cases are mild and required only conservative management. The overall incidence of acute myocarditis/pericarditis was 18.52 (95% confidence interval [CI], 11.67-29.01) per 100Â 000 persons vaccinated. The incidence after the first and second doses were 3.37 (95% CI, 1.12-9.51) and 21.22 (95% CI, 13.78-32.28 per 100Â 000 persons vaccinated, respectively. Among male adolescents, the incidence after the first and second doses were 5.57 (95% CI, 2.38-12.53) and 37.32 (95% CI, 26.98-51.25) per 100Â 000 persons vaccinated. CONCLUSIONS: There is a significant increase in the risk of acute myocarditis/pericarditis following Comirnaty vaccination among Chinese male adolescents, especially after the second dose.

Acute Myopericarditis Post-Intravenous Injection of Coronavirus Disease 2019 (COVID-19) mRNA Vaccine Differs From Viral Myocarditis.

Rheumatoid arthritis patients treated with Janus kinase inhibitors show reduced humoral immune responses following BNT162b2 vaccination. OBJECTIVES: The mRNA-based COVID-19 vaccines are now employed globally and have shown high efficacy in preventing SARS-CoV-2 infection. However, less is known about the vaccine efficacy in immune-suppressed individuals. This study sought to explore whether humoral immunity to the COVID-19 vaccine BNT162b2 is altered in RA patients treated with Janus kinase inhibitors by analysing their antibodies titre, neutralization activity and B cell responses. METHODS: We collected plasma samples from 12 RA patients who were treated with Janus kinase inhibitors and received two doses of the BNT162b2 vaccine, as well as 26 healthy individuals who were vaccinated with the same vaccine. We analysed the quantity of the anti-spike IgG and IgA antibodies that were elicited following the BNT162b2 vaccination, the plasma neutralization capacity and the responsiveness of the B-lymphocytes. We used ELISA to quantify the antibody titres, and a plasma neutralization assay was used to determine the virus neutralization capacity. Alteration in expression of the genes that are associated with B cell activation and the germinal centre response were analysed by quantitative PCR. RESULTS: Reduced levels of anti-spike IgG antibodies and neutralization capacity were seen in the RA patients who were treated with JAK inhibitors in comparison with healthy individuals. Furthermore, B cell responsiveness to the SARS-CoV-2 spike protein was reduced in the RA patients. CONCLUSION: RA patients who are treated with JAK inhibitors show a suppressed humoral response following BNT162b2 vaccination, as revealed by the quantity and quality of the anti-spike antibodies.

Clozapine, mRNA COVID-19 vaccination and drug-induced myocarditis.

Risk of herpes zoster reactivation after messenger RNA COVID-19 vaccination: A cohort study.

Development of pemphigus vulgaris after the second dose of the mRNA-1273 SARS-Cov-2 vaccine.

COVID-19 Vaccine Hesitancy and Early Adverse Events Reported in a Cohort of 7,881 Italian Physicians. BACKGROUND: The COVID-19 vaccination campaign began in Italy at the end of December 2020, with the primary aim of immunizing healthcare professionals, using the EMA approved mRNA vaccines (ComirnatyÂ® by Pfizer/BioNTech; mRNA-1273 by Moderna) and recombinant adenoviral vaccine (VaxzevriaÂ® by AstraZeneca). The study aimed at evaluating the prevalence and motivations underlying Vaccine Hesitancy, as well as the incidence and type of adverse events associated with COVID-19 vaccination. METHODS: Cross-sectional study. Data were collected January 1st to 28th 2021 using a purposely created online self-administered questionnaire

from a selected cohort of Italian physicians. RESULTS: Overall, 7,881 questionnaires were analyzed: 6,612 physicians had received one dose, and 1,670 two doses of ComirnatyÂ®; 30 had received one dose of mRNA-1273. Vaccine Hesitancy rate was 3.6%; it correlated with prior SARS-CoV-2 infection, diabetes, Adverse Eventss at previous vaccinations and refusal of 2020 flu vaccine, and was mainly motivated by concerns about vaccine Adverse Events. Typical Adverse Events were pain/itching/paresthesia at the inoculation site, followed by headache, fever, fatigue and myalgia/arthralgia occurring more frequently after the second dose (77.8 vs 66.9%; p<0.001), and in subjects with a prior SARS-CoV-2 infection. CONCLUSION: Adherence to COVID-19 vaccination is high among physicians. Adverse Events are typically mild and more frequent in people with a prior SARS-CoV-2 infection.

Risk of adverse events and reported clinical relapse after COVID-19 vaccination in patients with IBD.

Reduced sensitivity of the SARS-CoV-2 Lambda variant to monoclonal antibodies and neutralizing antibodies induced by infection and vaccination. Severe acute respiratory syndrome coronavirus 2 variants have continued to emerge in diverse geographic locations with a temporal distribution. The Lambda variant containing multiple mutations in the spike protein, has thus far appeared mainly in South America. The variant harbours two mutations in the receptor binding domain, L452Q and F490S, which may change its infectivity and antigenicity to neutralizing antibodies. In this study, we constructed 10 pseudoviruses to study the Lambda variant and each individual amino acid mutation's effect on viral function, and used eight cell lines to study variant infectivity. In total, 12 monoclonal antibodies, 14 convalescent sera, and 23 immunized sera induced by mRNA vaccines, inactivated vaccine, and adenovirus type 5 vector vaccine were used to study the antigenicity of the Lambda variant. We found that compared with the D614G reference strain, Lambda demonstrated enhanced infectivity of Calu-3 and LLC-MK2 cells by 3.3-fold and 1.6-fold, respectively. Notably, the sensitivity of the Lambda variant to 5 of 12 neutralizing monoclonal antibodies, 9G11, AM180, R126, X593, and AbG3, was substantially diminished. Furthermore, convalescent- and vaccine-immunized sera showed on average 1.3-2.5-fold lower neutralizing titres against the Lambda variant. Single mutation analysis revealed that this reduction in neutralization was caused by L452Q and F490S mutations. Collectively, the reduced neutralization ability of the Lambda variant suggests that the efficacy of monoclonal antibodies and vaccines may be compromised during the current pandemic.

A review of COVID-19 vaccination and the reported cardiac manifestations. In Singapore, 9.03 million doses of the mRNA COVID-19 vaccines by Pfizer-BioNTech and Moderna have been administered, and 4.46 million people are fully vaccinated. An additional 87,000 people have been vaccinated with vaccines in World Health Organization's Emergency Use Listing. The aim of this review is to explore the reported cardiac adverse events associated with different types of COVID-19 vaccines. A total of 42 studies that reported cardiac side effects after COVID-19 vaccination were included in this study. Reported COVID-19 vaccine-associated cardiac adverse events were mainly myocarditis and pericarditis, most commonly seen in adolescent and young adult male individuals after mRNA vaccination. Reports of other events such as acute myocardial infarction, arrhythmia and stress cardiomyopathy were rare. Outcomes of post-vaccine myocarditis and pericarditis were good. Given the good vaccine efficacy and the high number of cases of infection, hospitalisation and death that could potentially be prevented, COVID-19 vaccine remains of overall benefit, based on the current available data.

Experience with polyethylene glycol allergy-guided risk management for COVID-19 vaccine anaphylaxis. BACKGROUND: Polyethylene glycol (PEG) may elicit anaphylaxis to COVID-19 mRNA vaccines, and guidance for patients at risk is needed. METHODS: In retrospective patients with PEG allergy collected from 2006 till 2019, clinical, skin, and basophil activation test (BAT) characteristics discriminative for PEG allergy were analyzed and compared with the literature. In 421 prospective

real-life patients asking for allergy workup for COVID-19 vaccine hypersensitivity in 2020/2021, risk assessment was performed and tolerance of the recommended vaccination approach was assessed. RESULTS: Ten patients with PEG allergy were found in the retrospective cohort. Patients reacted with immediate anaphylaxis (100%) not only to PEG-based laxatives/bowel preparations or injections, but also to cold medication, antiseptics, analgetics, or antibiotics. Skin testsÂ Â±Â BAT with PEGÂ Â±Â elicitors were positive in 10/10. Provocation tests were positive in 7/9 patients. From the prospective cohort, 370/421 patients self-reporting increased risk for vaccine allergy lacked criteria necessitating allergy workup and were recommended for routine vaccination. A total of 51/421 patients were tested, and three (6%) with PEG allergy were identified, whereas 48 patients remained negative in skin tests. Vaccination was recommended in all those patients. No hypersensitivity reactions were reported to vaccination including six PEG-allergic patients tolerating COVID-19 vaccination. CONCLUSIONS: Taking a detailed history excluded PEG allergy in most referred patients and enabled direct safe vaccination. Immediate urticaria/anaphylaxis to typical elicitors identified patients requiring PEG allergy workup. Skin testsÂ Â±Â BAT identified PEG allergy and helped to select the vaccine and the vaccination approach. Even PEG-allergic patients can tolerate COVID-19 vaccines.

A Case of Acute Retinal Necrosis Associated with Reactivation of Varicella Zoster Virus after COVID-19 Vaccination. PURPOSE: To report a case of acute retinal necrosis (ARN) after receiving COVID-19 vaccination. METHODS: A case report. RESULTS: A 78-year-old man complained of blurred vision and floaters in the right eye 2Â days after receiving BNT162b2 mRNA-based COVID-19 vaccine and was referred to our hospital with worsening visual acuity after 7Â days. He had no systemic symptoms and no history of systemic diseases. Ophthalmic examination revealed white-yellowish placoid lesions spreading to the entire circumference of the retina, and temporal and upper lesions extending to the posterior pole, although anterior inflammation and vitreous opacity were mild. Diagnostic and therapeutic vitrectomy was performed, and VZV-DNA was detected by comprehensive PCR using a vitreous fluid sample. The ocular inflammation subsided by systemic administration of antivirals and corticosteroids. However, total retinal detachment requiring repeat vitrectomy using silicone oil occurred after the second vaccination. CONCLUSION: ARN associated with VZV reactivation may develop after SARS-CoV-2 mRNA vaccination.

Multimodal Imaging of Acute Foveolitis following COVID-19 Vaccination. PURPOSE: To report a case of unilateral acute foveolitis following COVID-19 vaccination. METHODS: A case report. RESULTS: A 24-year-old woman developed a sudden blurring of vision in the left eye (LE) 5Â days after receiving the first dose of COVID-19 vaccine. Examination of the LE showed a visual acuity at 20/40, 2+Â cells in the vitreous, and a small yellow-orange foveal subretinal lesion. Late-phase fluorescein angiography showed a mild diffuse retinal vascular leakage and a faint foveal hyperfluorescence. ICG angiography showed in the late-phase hypofluorescence of the centrofoveal lesion. OCT B-scan demonstrated a conical hyperreflective subfoveal lesion on the retinal pigment epithelium associated with disruption of the outer retinal layers. En-face OCT revealed granular hyperreflective specks mainly in the inner nuclear layer. Work-up results were unremarkable. The patient received oral prednisolone with subsequent full functional and anatomic recovery. CONCLUSION: Foveolitis may rarely occur as a complication of COVID-19 vaccination.

Response to: Note the distinction between myocarditis, novel coronavirus myocarditis and COVID-19 vaccine-associated myocarditis.

Note the distinction between myocarditis, novel coronavirus myocarditis and COVID-19 vaccine-associated myocarditis.

Safety and immediate humoral response of COVID-19 vaccines in chronic kidney disease patients: the SENCOVAC study. BACKGROUND: Chronic kidney disease (CKD) patients are at high-risk for severe coronavirus disease 2019 (COVID-19). The multicentric, observational and prospective

SENCOVAC study aims to describe the humoral response and safety of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines in CKD patients. Safety and immediate humoral response results are reported here. METHODS: Four cohorts of patients were included: kidney transplant (KT) recipients, and haemodialysis (HD), peritoneal dialysis (PD) and non-dialysis CKD patients from 50 Spanish centres. Adverse events after vaccine doses were recorded. At baseline and on Day 28 after the last vaccine dose, anti-Spike antibodies were measured and compared between cohorts. Factors associated with development of anti-Spike antibodies were analysed. RESULTS: A total of 1746 participants were recruited: 1116 HD, 171 PD, 176 non-dialysis CKD patients and 283 KT recipients. Most patients (98%) received mRNA vaccines. At least one vaccine reaction developed after the first dose in 763 (53.5%) and after the second dose in 741 (54.5%) of patients. Anti-Spike antibodies were measured in the first 301 patients. At 28 days, 95% of patients had developed antibodies: 79% of KT, 98% of HD, 99% of PD and 100% of non-dialysis CKD patients (PÂ <Â 0.001). In a multivariate adjusted analysis, absence of an antibody response was independently associated with KT (odds ratio 20.56, PÂ =Â 0.001) and with BNT162b2 vaccine (odds ratio 6.03, PÂ =Â 0.023). CONCLUSION: The rate of anti-Spike antibody development after vaccination in KT patients was low but in other CKD patients it approached 100%, suggesting that KT patients require persistent isolation measures and booster doses of a COVID-19 vaccine. Potential differences between COVID-19 vaccines should be explored in prospective controlled studies.

Endovascular treatment for vaccine-induced cerebral venous sinus thrombosis and thrombocytopenia following ChAdOx1 nCoV-19 vaccination: a report of three cases. BACKGROUND: Vaccine-induced thrombosis and thrombocytopenia (VITT) is a rare complication following ChAdOx1 nCoV-19 vaccination. Cerebral venous sinus thrombosis (CVST) is overrepresented in VITT and is often associated with multifocal venous thromboses, concomitant hemorrhage and poor outcomes. Hitherto, endovascular treatments have not been reviewed in VITT-related CVST. METHODS: Patient records from a tertiary neurosciences center were reviewed to identify patients who had endovascular treatment for CVST in VITT. RESULTS: Patient records from 1 January 2021 to 20 July 2021 identified three patients who underwent endovascular treatment for CVST in the context of VITT. All were female and the median age was 52 years. The location of the CVST was highly variable. Two-thirds of the patients had multifocal dural sinus thromboses (sigmoid, transverse, straight and superior sagittal) as well as internal jugular vein thromboses. Intracerebral hemorrhage occurred in all patients; subarachnoid blood was noted in two of them, and intraparenchymal hemorrhage occurred in all. There was one periprocedural parenchymal extravasation which abated on temporary cessation of anticoagulation. Outcome data revealed a 90-day modified Rankin Scale (mRS) score of 2 in all cases. CONCLUSIONS: We demonstrate that endovascular treatment for VITT-associated CVST is feasible and can be safe in cases that deteriorate despite medical therapy. Extensive clot burden, concomitant hemorrhage, rapid clinical progression and persistent rises in intracranial pressure should initiate multidisciplinary team discussion for endovascular treatment in appropriate cases.

Red urine and a red herring - diagnosing rare diseases in the light of the COVID-19 pandemic. BACKGROUND: The COVID-19 pandemic has occupied the time and resources of health care professionals for more than 1 year. The risk of missed diagnoses has been discussed in the medical literature, mainly for common diseases such as cancer and cardiovascular events. However, rare diseases also need appropriate attention in times of a pandemic. CASE REPORT: We report a 34-year-old woman with fever, pinprick sensation in her chest and thoracic spine, and dizziness after receiving the first dose of ChAdOx1 nCoV-19 vaccination. The patient's condition worsened with abdominal pain, red urine, and hyponatremia, needing intensive care admission. Syndrome of inappropriate antidiuretic hormone secretion (SIADH) was diagnosed. Vaccine-induced thrombocytopenia and thrombosis were ruled out. Acute hepatic porphyria was finally diagnosed, and the patient recovered

completely after treatment with hemin. CONCLUSION: Currently, the focus of physicians is on COVID-19 and associated medical problems, such as vaccine side effects. However, it is important to be vigilant for other uncommon medical emergencies in medically exceptional situations that may shift our perception.
Guillain-BarrÃ¨ syndrome following COVID-19 vaccine mRNA-1273: a case report.
Covid-19 vaccines and variants of concern: A review. Since the outbreak of coronavirus disease 2019 (Covid-19) in December 2019, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the number of confirmed infections has risen to more than 242 million worldwide, with nearly 5 million deaths. Currently, nine Covid-19 vaccine candidates based on the original Wuhan-Hu-1 strain are at the forefront of vaccine research. All nine had an efficacy over 50% against symptomatic Covid-19 disease: NVX-CoV2373 (âˆ¼96%), BNT162b2 (âˆ¼95%), mRNA-1273 (âˆ¼94%), Sputnik V (âˆ¼92%), AZD1222 (âˆ¼81%), BBIBP-CorV (âˆ¼79%), Covaxin (âˆ¼78%), Ad26.CoV.S (âˆ¼66%) and CoronaVac (âˆ¼51%). However, vaccine efficacy (VE) can be jeopardised by the rapid emergence and spread of SARS-CoV-2 variants of concern (VOCs) that could escape from neutralising antibodies and/or cell-mediated immunity. Rare adverse events have also been reported soon after administration of viral vector and mRNA vaccines. Although many Covid-19 vaccines have been developed, additional effective vaccines are still needed to meet the global demand. Promising Covid-19 vaccines such as WIBP-CorV, AD5-nCOV, ZyCoV-D, CVnCoV, EpiVacCorona and ZF2001 have advanced to clinical studies. This review describes the most relevant mutations in the SARS-CoV-2 spike protein, discusses VE against VOCs, presents rare adverse events after Covid-19 vaccination and introduces some promising Covid-19 vaccine candidates.
Failure of desensitization with Pfizer-BioNTech COVID-19 vaccine in two asthmatic patients. Since December 2020, in various countries of the world, many cases of severe allergic reactions after administration of PfizerBioNTech COVID-19 vaccine, were reported. A great concern has arisen among the doctors who administer the vaccine and the allergic patients who undergo vaccinations. In Italy guidelines were published in order to stratify the risk in the allergic population. In mRNA vaccines, the component currently suspected of causing allergic reactions is the polyethylene glycol excipient (PEG or macrogol). In patients who have shown an immediate allergic reaction to vaccine and who are negative to skin tests for PEG, desensitization with the same vaccine is proposed. In this paper we describe two cases of asthma after the first COVID vaccine administration in which desensitization has failed.
Determinants of healthcare workers perceptions, acceptance and choice of COVID-19 vaccines: a cross-sectional study from the United Arab Emirates. Acceptance of COVID-19 vaccine among health-care workers (HCWs) is crucial for controlling the pandemic and ensuring HCW and patient safety. Information on the acceptance of different COVID-19 vaccines is lacking. Despite the United Arab Emirates (UAE) having vaccinated most of its population, vaccine acceptance still raises concerns. This study explores COVID-19 vaccine acceptance, vaccine choice, and associated factors among HCWs in the UAE. An online national cross-sectional study was conducted among 517 HCWs. Acceptance and choice of COVID-19 vaccines were assessed, and logistic regression analysis identified predictors for vaccine acceptance. More than half (58%) of HCWs were willing to take the vaccine and give it to their family. Reasons for taking the vaccine were concerns for families contracting COVID-19 (67%) and social responsibility (64%). Reasons for refusals included concerns with side-effects (61%). Most HCWs knew of the Pfizer (79%) and Sinopharm (57%) vaccines; however, acceptance was higher for Pfizer (35%) and AstraZeneca (21%) vaccines. Being male and being influenza vaccinated predicted willingness to take the vaccine (aOR: 2.34; 95% CI:1.34-4.08; p â‰¤Â 0.001) and (aOR: 2.13; 95% CI: 1.29-3.51; p â‰¤Â 0.001), respectively. HCWs who expressed concerns with inadequate safety data were less likely to take the vaccine (aOR: 0.17; 95% CI: 0.10-0.30; p â‰¤Â 0.001). Additionally, side

effects, perception of risk, and level of trust of company and country of manufacture predicted acceptance and choice of vaccines. Effective vaccine policy campaigns to improve acceptance should target HCW's knowledge and awareness of perceived risks of COVID-19, safety data, social responsibility, and individual preferences for vaccine choice.
Evaluation of antibody response to BNT162b2 mRNA COVID-19 vaccine in patients affected by immune-mediated inflammatory diseases up to 5Â months after vaccination. SARS-CoV-2 vaccination with mRNA product BNT162b2 elicited high immunogenicity in healthy subjects in trials. This study aims to better understand the factors that influence the humoral immune response to vaccination against SARS-CoV-2 in patients with immune-mediated inflammatory diseases (IMIDs). We enrolled patients and healthy healthcare workers control group (HCW) that underwent mRNA BNT162b2 vaccination and measured the serum IgG anti-S-RBD response at booster dose (T1), one month after booster dose (T2) and up to 5Â months (T3). Demographic, disease-specific and vaccination data were recorded. Vaccination response of 551 participants naÃ¯ve to SARS-CoV-2 infection were included in HCW and 102 in the IMID group, analyzing separately those on anti-CD20. At T2 all naÃ¯ve HCW developed anti-S-RBD-IgG, while 94% of IMID responded (pâ€‰<â€‰0.001). IMID patients had a significantly different level of IgG than HCW at both T1 (pâ€‰=â€‰0.031), T2 (pâ€‰<â€‰0.001), while there was no significant difference at T3. There were no statistically significant differences according to the IMID type or to ongoing treatment with immunosuppressants, corticosteroids or biological drugs other than anti-CD20. The proportion and magnitude of response was significantly lower in IMID treated with anti-CD20 drugs. There was a correlation with age at T1 and at T2 but not at T3, stronger in patients than in HCW. Immune response close after BNT162b2 vaccination is reduced in patients with IMID, but there is no significant difference at 5Â months. The measured reduction is related to age and the disease itself rather than treatments, with the exception of anti-CD20 drugs.
Myocarditis following COVID-19 vaccination: magnetic resonance imaging study. AIMS: To describe the cardiac magnetic resonance (CMR) imaging findings of patients who developed myocarditis following messenger RNA (mRNA) coronavirus disease 2019 (COVID-19) vaccination. METHODS AND RESULTS: The present study retrospectively evaluated patients with clinically adjudicated myocarditis within 42 days of the first Pfizer-BNT162b2 mRNA COVID-19 vaccination, between 20 December 2020 and 24 May 2021 who underwent CMR. A total of 15 out 54 patients (28%) with myocarditis underwent a CMR and were included, 100% males, median age of 32 years (interquartile range = 22.5-40). Most patients presented with chest pain (87%) and had an abnormal electrocardiogram (79%). The severity of the disease was mild in 67% and intermediate in 33%. All patients survived and one patient was readmitted during the study period. CMR was performed at a median of 65 days (range 3-130 days) following diagnosis. Median ejection fraction was 58% (range 51-74%) global- and regional wall motion abnormalities were present in one and three patients, respectively. Native T1 was available in 13/15 patients (2/3 in 3 T and 11/12 in the 1.5 T), with increased values among 6/13. Late gadolinium enhancement (LGE) was found among 13/15 patients with a median of 2% (range 0-15%) with inferolateral wall being the most common location (8/13). The patterns of the LGE were: mid-wall in six patients; epicardial in five patients; and mid-wall and epicardial in two patients. CONCLUSIONS: Among patients who were diagnosed with post-vaccination clinical myocarditis, CMR imaging findings are mild and consistent with 'classical myocarditis'. The short-term clinical course and outcomes were favourable.
A new look on politicized reticence to vaccination: populism and COVID-19 vaccine refusal.
Myocarditis Following Coronavirus Disease 2019 mRNA Vaccine: A Case Series and Incidence Rate Determination. BACKGROUND: Myocarditis following coronavirus disease 2019 (COVID-19) mRNA vaccines (Pfizer-BioNTech and Moderna) has been increasingly reported. Incidence rates in the

general population are lacking, with pericarditis rather than myocarditis diagnostic codes being used to estimate background rates. This comparison is critical for balancing the risk of vaccination with the risk of no vaccination. METHODS: A retrospective case series was performed using the Mayo Clinic COVID-19 Vaccine Registry. We measured the incidence rate ratio (IRR) for myocarditis temporally related to COVID-19 mRNA vaccination compared with myocarditis in a comparable population from 2016 through 2020. Clinical characteristics and outcomes of the affected patients were collected. A total of 21 individuals were identified, but ultimately 7 patients met the inclusion criteria for vaccine-associated myocarditis. RESULTS: The overall IRR of COVID-19-related myocarditis was 4.18 (95% confidence interval [CI], 1.63-8.98), which was entirely attributable to an increased IRR among adult males (IRR, 6.69; 95% CI, 2.35-15.52) compared with females (IRR 1.41; 95% CI, .03-8.45). All cases occurred within 2 weeks of a dose of the COVID-19 mRNA vaccine, with the majority occurring within 3 days (range, 1-13) following the second dose (6 of 7 patients, 86%). Overall, cases were mild, and all patients survived. CONCLUSIONS: Myocarditis is a rare adverse event associated with COVID-19 mRNA vaccines. It occurs in adult males with significantly higher incidence than in the background population. Recurrence of myocarditis after a subsequent mRNA vaccine dose is not known at this time.

Organizational design: the case of SARS-CoV-2 vaccination in a healthcare centre. BACKGROUND: Only recently Anti-Covid-19 strategies have been applied through specific vaccines, that are a decisive support to modify the evolution of the disease and to reduce the contagion curve. Along vaccination campaigns, the necessity to guarantee rapidity and effectiveness is a critical challenge for all health organizations; their operative capability is applied to carry out govern plans, to ensure safety of the procedures, to adopt good clinical practices, to help with adhesion to vaccine administration and to monitor adverse effects. STUDY DESIGN: The "Centro Clinico Morgagni" is a private accredited diagnosis and treatment Centre with high specialty departments and several hospital beds. The challenge for its administration was to complete the vaccination of all the staff, so a COVID19 crisis unit was established to assure the control of all activities in the center throughout the pandemic. The goal was to complete the vaccination plan following the guidelines with no risks or harm. METHODS: An original organizational model, based on different planning methodologies was developed, its task was to define a standard procedure and to give operational instructions based on ISO 9001 for monitoring the entire vaccination process. Also, the model had to define every responsibility role and it had to follow Joint Commission International's methodologies as far as error barriers, drug conservation risks, drug transport and drug administration were concerned.Furthermore, in agreement with the HACCP system, critical control points were highlighted during all the process. The results have been processed in the form of quick references and illustrative panels based on relevant process aspects, which were given to the staff involved in the operations as reference tools for prompt consultation. RESULTS: The vaccination operations at the Centro Clinico Morgagni took place quickly in only four days: 800 staff units were vaccinated - first and second doses with Covid19 mRNA BNT162b2 (Cominraty) - in three different vaccination centers without highlighting significant events that did not comply with the guidelines, nor deviations from the established goals. More precisely, starting from 277 bottles corresponding to six doses each, only 0.2% was wasted, while ADR monitoring reported a prevalence of adverse effects in females (78%) compared to males (22%). Adhesion for vaccination of qualified personnel, thanks to the activities of the Medical College set up for this purpose, reached 100% of the candidate staff through repeated personalized interviews with only one opposition, compared to the 30 communicated at the beginning. CONCLUSIONS: It was necessary to ensure the efficiency of the entire process and the model was tested positively. This model can also provide a security control of all the vaccinated personnel; its schematization allows an

easy application and flexibility, thus making it an organizational tool that could be reproduced and transferred to other contexts.
Symptom monitoring after coronavirus disease 2019 (COVID-19) vaccination in a large integrated healthcare system: Separating symptoms from severe acute respiratory coronavirus virus 2 (SARS-CoV-2) infection. OBJECTIVE: To describe the incidence of systemic overlap and typical coronavirus disease 2019 (COVID-19) symptoms in healthcare personnel (HCP) following COVID-19 vaccination and association of reported symptoms with diagnosis of severe acute respiratory coronavirus virus 2 (SARS-CoV-2) infection in the context of public health recommendations regarding work exclusion. DESIGN: This prospective cohort study was conducted between December 16, 2020, and March 14, 2021, with HCP who had received at least 1 dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccine. SETTING: Large healthcare system in New England. INTERVENTIONS: HCP were prompted to complete a symptom survey for 3 days after each vaccination. Reported symptoms generated automated guidance regarding symptom management, SARS-CoV-2 testing requirements, and work restrictions. Overlap symptoms (ie, fever, fatigue, myalgias, arthralgias, or headache) were categorized as either lower or higher severity. Typical COVID-19 symptoms included sore throat, cough, nasal congestion or rhinorrhea, shortness of breath, ageusia and anosmia. RESULTS: Among 64,187 HCP, a postvaccination electronic survey had response rates of 83% after dose 1 and 77% after dose 2. Report of â‰¥3 lower-severity overlap symptoms, â‰¥1 higher-severity overlap symptoms, or at least 1 typical COVID-19 symptom after dose 1 was associated with increased likelihood of testing positive. HCP with prior COVID-19 infection were significantly more likely to report severe overlap symptoms after dose 1. CONCLUSIONS: Reported overlap symptoms were common; however, only report of â‰¥3 low-severity overlap symptoms, at least 1 higher-severity overlap symptom, or any typical COVID-19 symptom were associated with infection. Work-related restrictions for overlap symptoms should be reconsidered.
Short-term immune response after inactivated SARS-CoV-2 (CoronaVacÂ®, Sinovac) and ChAdOx1 nCoV-19 (VaxzevriaÂ®, Oxford-AstraZeneca) vaccinations in health care workers. BACKGROUND: Inactivated SARS-CoV-2 (CoronaVacÂ®, Sinovac, or SV) and ChAdOx1 nCoV-19 (VaxzevriaÂ®, Oxford-Astra Zeneca, or AZ) vaccines have been administered to the health care workers (HCWs). OBJECTIVE: To determine the short-term immune response after the SV and AZ vaccinations in HCWs. METHODS: In this prospective cohort study, HCWs who completed a 2-dose regimen of the SV or AZ were included. Immune response was evaluated by surrogate viral neutralization test (sVNT) and anti-SARS-CoV-2 total antibody. Blood samples were analyzed at 4 and 12 weeks after the complete vaccination. The primary outcome was the seroconversion rate at 4-weeks after complete immunization. RESULTS: Overall, 185 HCWs with a median (IQR) age of 40.5 (30.3-55.8) years (94 HCWs in the SV group and 91 in the AZ group) were included. At 4 weeks after completing the SV vaccination, 60.6% (95%CI: 50.0-70.6%) had seroconversion evaluated by sVNT (â‰¥ 68% inhibition), comparable to the patients recovered from mild COVID-19 infection (69.0%), with a rapid reduction to 12.2% (95%CI: 6.3-20.8) at 12 weeks. In contrast, 85.7% (95%CI: 76.8-92.2%) HCWs who completed two doses of the AZ for 4 weeks had seroconversion, comparable to the COVID-19 pneumonia patients (92.5%), with a reduction to 39.2% (95%CI: 28.4-50.9%) at 12 weeks. When using the anti-SARS-CoV-2 total antibody level (â‰¥ 132 U/ml) criteria, only 71.3% HCWs in the SV group had seroconversion, compared to 100% in the AZ group at 4 weeks. CONCLUSIONS: A rapid decline of short-term immune response in the HCWs after the SV vaccination indicates the need for a vaccine booster, particularly during the ongoing spreading of the SARS-CoV-2 variants of concern.
Potential Effects of Iodine Supplementation on Inflammatory Processes and Toxin Removal Following COVID-19 Vaccination.

Comment on "Oral lichen planus following the administration of vector based COVID-19 vaccine (Ad26.COV2.S)". Authors' reply.

A Case Report of Posttransplant Lymphoproliferative Disorder After AstraZeneca Coronavirus Disease 2019 Vaccine in a Heart Transplant Recipient. We report a case of a heart transplant recipient who presented with a rapidly growing Epstein-Barr virus (EBV)-positive, diffuse large B-cell lymphoma 7 days after receiving the first dose of the ChAdOx1 nCoV-19 vaccine. Because of the atypical radiologic presentation, the initial tentative diagnosis was a mediastinal abscess. This observation indicates a potential risk of EBV reactivation after coronavirus disease 2019 (COVID-19) vaccination, which might lead to or aggravate the presentation of posttransplant lymphoproliferative disorder in transplantation patients. Transplant surgeons should be aware of the potential immunomodulatory effects of the COVID-19 vaccination.

Update on Coronavirus 2019 Vaccine Guidelines for Transplant Recipients. The coronavirus disease 2019 (COVID-19) vaccine and its utility in solid organ transplantation need to be timely revised and updated. These guidelines have been formalized by the experts-the apex technical committee members of the National Organ and Tissue Transplant Organization and the heads of transplant societies-for the guidance of transplant communities. We recommend that all personnel involved in organ transplantation should be vaccinated as early as possible and continue COVID-19-appropriate behavior despite a full course of vaccination. For specific guidelines of recipients, we suggest completing the full schedule before transplantation whenever the clinical condition permits. We also suggest a single dose, rather than proceeding unvaccinated for transplant, in case a complete course is not feasible. If vaccination is planned before surgery, we recommend a gap of at least 2 weeks between the last dose of vaccine and surgery. For those not vaccinated before transplant, we suggest waiting 4 to 12 weeks after transplant. For the potential living donors, we recommend the complete vaccination schedule before transplant. However, if this is not feasible, we suggest receiving at least a single dose of the vaccine 2 weeks before donation. We suggest that suitable transplant patients and those on the waiting list should accept a third dose of the vaccine when one is offered to them. We recommend that organs from a deceased donor with suspected/proven vaccine-induced thrombotic thrombocytopenia should be avoided and are justified only in cases of emergency situations with informed consent and counseling.

The value of the basophil activation test in the evaluation of patients reporting allergic reactions to the BNT162b2 mRNA COVID-19 vaccine. BACKGROUND: mRNA-based COVID-19 vaccines have been reported to induce hypersensitivity reactions (HSR) in a small number of individuals. We aimed to evaluate the real-world incidence of the BNT162b2Â mRNA COVID-19 vaccine HSR and to determine the value of the basophil activation test (BAT) in the allergological workup of patients reporting these reactions. METHODS: We prospectively enrolled patients with a clinical history indicative of HSR to the BNT162b2Â mRNA COVID-19 vaccine. The allergological workup included skin testing (STs) and BAT with polyethylene glycol (PEG) and the vaccine. In those with negative allergy assessments, the administration of the second dose of the BNT162b2Â mRNA COVID-19 vaccine was offered. RESULTS: Seventeen adults were included. Eleven cases (64.7%) tested negative in the allergological workup and tolerated the re-administration of the second dose of the vaccine and considered non-allergic. Six cases (35.3%) were considered allergic and classified into three groups: 2Â subjects displayed positive STs and/or BAT to PEG (Group A), two individuals displayed positive BAT to the vaccine (Group B), and in 2 patients with moderate or severe reactions, the culprit was not identified, tested negative to STs and BAT to both PEG and vaccine (Group C). We further evaluated the value of BAT when the results were positive to the vaccine and negative to PEG by performing BAT in controls groups, finding positive BAT results in 50% of controls, all of them recovered from COVID-19 infection. In contrast, BAT was negative in patients who had not suffered from COVID-19

disease. CONCLUSIONS: BAT can be used as a potential diagnostic tool for confirming allergy to PEG excipient but not to the vaccine as a positive result in BAT may indicate a past COVID-19 infection instead of an allergy.

Systemic autoimmune myopathies: a prospective phase 4 controlled trial of an inactivated virus vaccine against SARS-CoV-2. OBJECTIVES: To evaluate immunogenicity and safety of an inactivated SARS-CoV-2 vaccine in systemic autoimmune myopathies (SAMs) and the possible influence of baseline disease parameters, comorbidities and therapy on immune response. METHODS: This prospective controlled study included 53 patients with SAMs and 106 non-immunocompromised control group (CTRL). All participants received two doses of the Sinovac-CoronaVac vaccine (28-day interval). Immunogenicity was assessed by anti-SARS-CoV-2 S1/S2 IgG seroconversion (SC), anti-S1/S2 IgG geometric mean titre (GMT), factor increase GMT (FI-GMT), neutralizing antibodies (NAb) positivity, and median neutralizing activity after each vaccine dose (D0 and D28) and six weeks after the second dose (D69). Participants with pre-vaccination positive IgG serology and/or NAb and those with RT-PCR confirmed COVID-19 during the protocol were excluded from immunogenicity analysis. RESULTS: Patients and CTRL had comparable sex (P>0.99) and age (P=0.90). Immunogenicity of 37 patients and 79 CTRL-naÃ¯ve participants revealed at D69, a moderate but significantly lower SC (64.9% vs 91.1%, P<0.001), GMT [7.9 (95%CI 4.7-13.2) vs 24.7 (95%CI 30.0-30.5) UA/ml, P<0.001] and frequency of NAb (51.4% vs 77.2%, P<0.001) in SAMs compared with CTRL. Median neutralizing activity was comparable in both groups [57.2% (interquartile range (IQR) 43.4-83.4) vs 63.0% (IQR 40.3-80.7), P=0.808]. Immunosuppressives were less frequently used among NAb+ patients vs NAb- patients (73.7% vs 100%, P=0.046). Type of SAMs, disease status, other drugs or comorbidities did not influence immunogenicity. Vaccine-related adverse events were mild with similar frequencies in patients and CTRL (P>0.05). CONCLUSION: Sinovac-CoronaVac is safe and has a moderate short-term immunogenicity in SAMs, but reduced compared with CTRL. We further identified that immunosuppression is associated with diminished NAb positivity. TRIAL REGISTRATION: COVID-19 CoronaVac in Patients With Autoimmune Rheumatic Diseases and HIV/AIDS (CoronavRheum), http://clinicaltrials.gov/ct2/show/NCT04754698.

COVID-19 vaccine - can it affect fertility? Headlines have appeared across multiple social media platforms questioning the effects of newly authorised COVID-19 vaccines on fertility. Although the effects on future fertility were not studied in the initial trials, at present, there is no evidence that the COVID-19 vaccine has any effect of future fertility. It is well known that pregnant women are at a higher risk of complications associated with COVID-19 such as ICU admission and death, and there is a rare but tragic increase in placentitis and stillbirth, highlighting the importance for those planning a pregnancy any time in the future to be vaccinated. Here we summarise international consensus from multiple organisations advising on fertility and the COVID-19 vaccine. Preliminary studies all suggest that there is neither link, nor indeed any theoretical reason why any of the COVID-19 vaccines might affect fertility. Dissemination of misinformation regarding the impact of the vaccine on future fertility needs to be controlled in order to avoid any hesitancy amongst young women attending for vaccination. It is also vital that the medical profession counteract this information, and, in order to do that, healthcare providers must be well informed on the latest recommendations and research.

Reported COVID-19 vaccines side effects among Jordanian population: a cross sectional study. Concerns about the safety and side effects of coronavirus SARS CoV2 vaccines have been raised among many communities worldwide. The aim of this study was to describe the side effects reported by vaccinated individuals in Jordan. A cross-sectional survey was used to recruit responses from participants who were vaccinated with either one dose or both doses of any of the administered vaccines in Jordan (AstraZeneca, Pfizer, Sinopharm). A total of 1,086 participants were enrolled in the study. Most of participants have not been infected with SARS CoV2 before receiving the vaccine

(77.2%). Larger proportion of the study population received Pfizer vaccine (40.6%) followed by the AstraZeneca vaccine (33.0%), and Sinopharm vaccine (26.4%). Side effects after receiving the first dose of the vaccine were reported by most participants (89.9%) and included pain at the injection site (78.4%), fatigue (51.8%), myalgia (37.6%), headache (33.1%), and chills (32.3%). To a lesser extent, there were gastrointestinal side effects such as nausea (15.1%), loss of appetite (9.4%), and diarrhea (6.4%). More side effects were significantly associated with AstraZeneca vaccine (P <Â .001). Only one case for each of second dose of Pfizer and Sinopharm vaccines reported that their side effects required hospitalization. In this study, we found that people in Jordan experienced more side effects with AstraZeneca vaccine followed by Pfizer vaccine and the least one is Sinopharm vaccine. Our study showed that these side effects are not severe and should not be an obstacle against the successful control of the pandemic in Jordan.

Acute myocardial infarction and myocarditis following COVID-19 vaccination. Emerging reports raise concerns on the potential association between the COVID-19 vaccines and cardiac manifestations. We sought to evaluate cardiac complications associated with COVID-19 vaccination in a pooled analysis from our institution's cohort study and systematic review. Consecutive patients admitted to a tertiary hospital in Singapore between 1 January 2021 and 31 March 2021, with the onset of cardiac manifestations within 14â€‰days following COVID-19 vaccination, were studied. Furthermore, a systematic review was performed, with PubMed, Embase, Research Square, MedRxiv and LitCovid databases accessed from inception up to 29 June 2021. Relevant manuscripts reporting individual patient data on cardiac complications following COVID-19 vaccination were included. Thirty patients were included in the study cohort, with 29 diagnosed with acute myocardial infarction (AMI) and 1 with myocarditis. Five patients developed heart failure, two had cardiogenic shock, three intubated, and one had cardiovascular-related mortality. In the systematic review, 16 studies were included with 41 myocarditis and 6 AMI cases. In the pooled analysis of the study cohort and the systematic review, 35 patients had AMI and 42 had myocarditis. Majority were men, and myocarditis patients were younger than AMI patients. Myocarditis patients tended to present 72â€‰h postvaccination, while AMI patients were older and typically presented 24â€‰h postvaccination. Majority with AMI or myocarditis developed symptoms after the first and second vaccination dose, respectively. This pooled analysis of patients presenting with cardiac manifestations following COVID-19 vaccination highlights the differences between myocarditis and AMI presentations in temporal association with the vaccination.

Comment on: 'Acute macular neuroretinopathy following COVID-19 vaccination'.

Oral pemphigus after COVID-19 vaccination.

Changes in COVID-19-Associated Deaths During a Year Among Blacks and Hispanics Compared to Whites in the State of Connecticut. BACKGROUND: With recent COVID-19 vaccination rates relatively high in the USA, the USA still maintains the most documented cases globally,[1] even though COVID-19 cases, hospitalization, and mortality have been declining. However, the health burden has been largely felt in communities involving racial and ethnic minorities. Thus, in order to provide a clearer picture of what is happening in Black, Indigenous, and people of color communities, we examined the racial/ethnic differences of monthly COVID-19 deaths in Connecticut. METHODS: This is an epidemiological study analyzing mortality data from March 1, 2020, to February 28, 2021, obtained from the Connecticut State Department of Public Health. The data include cause of death (COVID-19 death identified by ICD-10 code U071), race/ethnicity (non-Hispanic White (White), non-Hispanic Black (Black), and Hispanic), sex, and age. Both crude and age-adjusted rates were reported by racial/ethnic groups. To compare age-adjusted rates between racial groups, with estimated age-adjusted death counts as outcomes, between-racial group rate ratios, 95% confidence intervals, and p values significant atâ€‰<â€‰0.05 were derived from the Poisson regression model. RESULTS:

From March 2020 to May 2020 (wave 1) of COVID-19 cases, the COVID-19-related mortality rates were the highest for all three race groups (Whites, Blacks, and Hispanics) with statistical group differences (pâ€‰<â€‰0.05). Blacks had the highest rates of deaths followed by Hispanics and then Whites. Further, more Whites died in a nursing home when compared to Blacks and Hispanics. From June 2010 to October 2020 (wave 2), COVID-19 mortality declined significantly for all three race groups with no statistical differences between groups. COVID-19 deaths in nursing homes declined for all three racial/ethnic groups. From November 2020 to February 2021 (wave 3), COVID-19 mortality rates were significantly higher compared to wave 2 but lower than wave 1 for all three race groups. The mortality rates for Blacks and Hispanics were higher than Whites. Hispanics had the highest rates of deaths, followed by Blacks, and then Whites (pâ€‰<â€‰0.05). Whites showed the lowest mortality rates among all three racial/ethnic groups. CONCLUSIONS: In summary, COVID-19 health disparities among Black and Hispanic populations were evident in this study. Blacks and Hispanics had significantly higher mortality rates when compared to Whites. Blacks had the highest mortality rates during wave 1, and in wave 3, Hispanics has the highest mortality rates. Our data are important because they show monthly COVID-19 deaths data by race. Data reported this way gives a better and more accurate understanding of what is really happening in Black, Indigenous, and people of color populations.

Post-vaccination COVID Toes (Chilblains) Exacerbated by Rituximab Infusion Suggests Interferon Activation as Mechanism. Coronavirus disease (COVID) toes are pernio-like skin lesions associated with severe acute respiratory syndrome coronavirus 2. We observed pernio-like skin findings presenting after a Pfizer BioNTech vaccine, which significantly worsened after an infusion of rituximab. This suggests that the mechanism for COVID toes is interferon activation. Military providers may avoid unnecessary referrals for this self-limiting condition by anticipating this adverse effect.

Safety and Immunogenicity of a Recombinant Adenovirus Type-5-Vectored Coronavirus Disease 2019 (COVID-19) Vaccine With a Homologous Prime-Boost Regimen in Healthy Participants Aged â‰¥6 Years: A Randomized, Double-Blind, Placebo-Controlled, Phase 2b Trial. BACKGROUND: We assessed the safety and immunogenicity of a recombinant adenovirus type-5 (Ad5)-vectored coronavirus disease 2019 (COVID-19) vaccine with homologous prime-boost regimens in healthy participants aged â‰¥6 years. METHODS: In this randomized, double-blind, placebo-controlled trial, participants received vaccine or placebo 56 days apart. Enzyme-linked immunosorbent assay (ELISA) antibodies to the receptor binding domain (RBD) and pseudovirus neutralizing antibodies were detected. Adverse events were monitored for 28 days following each vaccination. RESULTS: A total of 430 participants were enrolled in the study, with 30 participants aged 18-55 years (MID cohort), 250 aged â‰¥56 years (OLD cohort), and 150 aged 6-17 years (MIN cohort). Ad5-vectored COVID-19 vaccine induced significant RBD-specific ELISA antibodies that decreased with increasing age, with geometric mean titers (GMTs) of 1037.5 in the MIN cohort, 647.2 in the MID cohort, and 338.0 in the OLD cohort receiving 5 Ã— 1010 viral particles on day 28 following boost vaccination. Pseudovirus neutralizing antibodies showed a similar pattern, with GMTs of 168.0 in the MIN cohort, 76.8 in the MID cohort, and 79.7 in the OLD cohort. A single dose in children and adolescents induced higher antibody responses than that elicited by 2 doses in adults, with GMTs of 1091.6 and 96.6 for ELISA antibody and neutralizing antibody, respectively. Homologous prime-boost vaccination was safe and tolerable. CONCLUSIONS: Ad5-vectored COVID-19 vaccine with a single dose was safe and induced robust immune responses in children and adolescents aged 6-17 years. A prime-boost regimen needs further exploration for Ad5-vectored COVID-19 vaccine.Ad5-vectored COVID-19 vaccine with a single dose was safe and tolerated, and induced robust immune responses in children and adolescents aged

6-17 years. The boosting effect on immune responses of the homologous prime-boost regime given 56 days apart was limited. CLINICAL TRIALS REGISTRATION: NCT04566770.
The Impact of Prior Infection and Age on Antibody Persistence After Severe Acute Respiratory Syndrome Coronavirus 2 Messenger RNA Vaccine. Determining the duration of immunity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines is critical for informing the timing of booster immunization. Many genetic and environmental factors could influence both the magnitude and persistence of the antibody response. Here, we showed that SARS-CoV-2 infection before vaccination and age affected the decay of antibody responses to the SARS-CoV-2 messenger RNA vaccine.
Oral lichen planus following the administration of vector-based COVID-19 vaccine (Ad26.COV2.S).
Reactivation of varicella zoster infection presenting as acute retinal necrosis post COVID 19 vaccination in an Asian Indian male. PURPOSE: To present the clinical features of a rare case of varicella zoster infection following one dose of Coronavirus Disease 2019 (COVID-19) vaccination in an elderly Asian Indian male. METHODS: Retrospective observational case report. RESULTS: A 71-year-old gentleman presented to us with complaints of reduced vision associated with redness and pain in his right eye for 1â€‰week. On examination he revealed a right eye pan uveitis picture with circumcorneal congestion, multiple fine keratic precipitates, anterior chamber cells and flare, vitritis and widespread areas of acute retinal necrosis. His left eye was within normal limits. Ten days prior to the presentation he had received the first dose of COVID-19 vaccine following which he had developed fever for 2â€‰days that preceded the red eye. The patient's aqueous sample tested positive for varicella zoster virus (VZV) by nested polymerase chain reaction (PCR) method. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in reverse transcriptase polymerase chain reaction (RT-PCR) assay from the aqueous and also from the nasopharyngeal swab was negative. CONCLUSION AND SIGNIFICANCE: To the best of our knowledge this is the earliest description of a case that has a viral reactivation following COVID-19 vaccination. Elderly people with pre-existing comorbidities, may be at a risk of both primary coronavirus infection and unconceivable risk of aberrant immune reactions leading to a different virus infection or reactivation need to be kept in mind. We present a possible link between SARS-CoV-2 virus vaccination and varicella zoster reactivation in this patient.
Safety and Immunogenicity of an Inactivated Severe Acute Respiratory Syndrome Coronavirus 2 Vaccine in a Subgroup of Healthy Adults in Chile. BACKGROUND: The development of effective vaccines against coronavirus disease 2019 is a global priority. CoronaVac is an inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine with promising safety and immunogenicity profiles. This article reports safety and immunogenicity results obtained for healthy Chilean adults aged â‰¥18 years in a phase 3 clinical trial. METHODS: Volunteers randomly received 2 doses of CoronaVac or placebo, separated by 2 weeks. A total of 434 volunteers were enrolled, 397 aged 18-59 years and 37 aged â‰¥60 years. Solicited and unsolicited adverse reactions were registered from all volunteers. Blood samples were obtained from a subset of volunteers and analyzed for humoral and cellular measures of immunogenicity. RESULTS: The primary adverse reaction in the 434 volunteers was pain at the injection site, with a higher incidence in the vaccine than in the placebo arm. Adverse reactions observed were mostly mild and local. No severe adverse events were reported. The humoral evaluation was performed on 81 volunteers. Seroconversion rates for specific anti-S1-receptor binding domain (RBD) immunoglobulin G (IgG) were 82.22% and 84.44% in the 18-59 year age group and 62.69% and 70.37% in the â‰¥60 year age group, 2 and 4 weeks after the second dose, respectively. A significant increase in circulating neutralizing antibodies was detected 2 and 4 weeks after the second dose. The cellular evaluation was performed on 47 volunteers. We detected a significant induction of T-cell responses characterized by the secretion of

interferon-Î³ (IFN-Î³) upon stimulation with Mega Pools of peptides from SARS-CoV-2. CONCLUSIONS: Immunization with CoronaVac in a 0-14 schedule in Chilean adults aged â‰¥18 years is safe, induces anti-S1-RBD IgG with neutralizing capacity, activates T cells, and promotes the secretion of IFN-Î³ upon stimulation with SARS-CoV-2 antigens.

Antibody Responses to SARS-CoV-2 After Infection or Vaccination in Children and Young Adults With Inflammatory Bowel Disease. BACKGROUND: Characterization of neutralization antibodies to SARS-CoV-2 infection or vaccination in children and young adults with inflammatory bowel disease (IBD) receiving biologic therapies is crucial. METHODS: We performed a prospective longitudinal cohort study evaluating SARS-CoV-2 spike protein receptor binding domain (S-RBD) IgG positivity along with consistent clinical symptoms in patients with IBD receiving infliximab or vedolizumab. Serum was also obtained following immunization with approved vaccines. The IgG antibody to the spike protein binding domain of SARS-CoV-2 was assayed with a fluorescent bead-based immunoassay that takes advantage of the high dynamic range of fluorescent molecules using flow cytometry. A sensitive and high-throughput neutralization assay that incorporates SARS-CoV-2 spike protein onto a lentivirus and measures pseudoviral entry into ACE2-angiotensin converting enzyme 2 (ACE2) expressing human embryonic kidney 293 (HEK-293) cells was used. RESULTS: There were 436 patients enrolled (mean age, 17 years, range 2-26 years; 58% male; 71% Crohn's disease, 29% ulcerative colitis, IBD-unspecified). Forty-four (10%) of enrolled subjects had SARS-CoV-2 S-RBD IgG antibodies. Compared to non-IBD adults (ambulatory) and hospitalized pediatric patients with PCR documented SARS-CoV-2 infection, S-RBD IgG antibody levels were significantly lower in the IBD cohort and by 6 months post infection most patients lacked neutralizing antibody. Following vaccination (nâ€…=â€…33), patients had a 15-fold higher S-RBD antibody response in comparison with natural infection, and all developed neutralizing antibodies to both wild type and variant SARS-CoV-2. CONCLUSIONS: The lower and less durable SARS-CoV-2 S-RBD IgG response to natural infection in IBD patients receiving biologics puts them at risk of reinfection. The robust response to immunization is likely protective.

Antibody response and self-reported adverse reactions following vaccination with Comirnaty: a pilot study from a Croatian university hospital. This study aimed to determine antibody responses against SARS-CoV-2 spike (S) after both BioNTech-Pfizer Comirnaty vaccine doses and study the correlation with self-perceived adverse reactions. Antibodies determination with Elecsys anti-SARS-CoV-2 S assay was performed a day prior to or just before administration of the second dose and 8-13â€‰days after the second dose. Participants selected from a predefined list of the experienced local (injection site reactions) and/or systemic (fatigue, headache, myalgia, arthralgia, chills and fever) post-vaccination adverse reactions. An average 100-fold increase in antibody titre in naive vaccinees was observed between the two time points (median 67â€‰U/mL vs 2841â€‰U/mL, p<0.001). Participants aged below 50 had higher antibody titres (median 99 U/mL vs 26â€‰U/mL, p=0.003 after the first dose; median 3617 U/mL vs 2556â€‰U/mL, p=0.026 after the second dose). All reported adverse reactions were mild-to-moderate, with more participants declaring systemic reactions after the second dose (p=0.001), without a clear correlation with antibody titre.

A case of multisystem inflammatory syndrome (MIS-A) in an adult woman 18 days after COVID-19 vaccination. We discuss a case of a young woman, presenting a constellation of clinical and biochemical features meeting the current case definition of multisystem inflammatory syndrome in adults (MIS-A), 18Â days after receiving her first dose of the Oxford/AstraZeneca vaccine. Therapy by means of intravenous immunoglobulins was initiated, leading to clinical and biochemical recovery. Although a relationship between MIS-A and the preceding vaccination cannot be confirmed, it can also not be excluded, given the temporal association and the fact that there were no indicators of a preceding SARS-CoV-2 infection.

Coronavirus disease 2019 (COVID-19) infection of healthcare personnel after complete COVID-19 vaccination.
Healthcare Personnel (HCP) Attitudes About Coronavirus Disease 2019 (COVID-19) Vaccination After Emergency Use Authorization. BACKGROUND: We previously reported on coronavirus disease 2019 (COVID-19) vaccination intent among healthcare personnel (HCP) before emergency use authorization. We found widespread hesitancy and a substantial proportion of HCP did not intend to vaccinate. METHODS: We conducted a cross-sectional survey of HCP, including clinical and nonclinical staff, researchers, and trainees between 21 February and 19 March 2021. The survey evaluated vaccine attitudes, beliefs, intent, and acceptance. RESULTS: Overall, 3981 (87.7%) of respondents had already received a COVID-19 vaccine or planned to get vaccinated. There were significant differences in vaccine acceptance by gender, age, race, and hospital role. Males (93.7%) were more likely than females (89.8%) to report vaccine acceptance ($P < .001$). Mean age was higher among those reporting vaccine acceptance ($P < .001$). Physicians and scientists showed the highest acceptance rate (97.3%), whereas staff in ancillary services showed the lowest acceptance rate (79.9%). Unvaccinated respondents were more likely to be females, to have refused vaccines in the past due to reasons other than illness or allergy, to care for COVID-19 patients, or to rely on themselves when making vaccination decision. Vaccine acceptance was more than twice previous intent among Black respondents, an increase from 30.8% to 73.8%, and across all hospital roles with all > 80% vaccine acceptance. CONCLUSIONS: The majority of HCP were vaccinated, much higher than reporting intent before vaccine was available. However, many HCP-particularly ancillary services-are still hesitant. Feasible and effective interventions to address the hesitant, including individually-tailored education strategies are needed, or vaccine can be mandated.
Reply to 'Letter to the editor: Myocarditis should be considered in those with a troponin rise and unobstructed coronary arteries following PfizerBioNTech COVID-19 vaccination'.
Myocarditis should be considered in those with a troponin rise and unobstructed coronary arteries following Pfizer-BioNTech COVID-19 vaccination.
[Vaccination against COVID-19 in pharmacies in the Auvergne-RhÃ´ne-Alpes region. Study conducted three months after the start of vaccination]. INTRODUCTION: The development of vaccines against SARS-Cov-2 has enabled the deployment of vaccination, particularly through dispensing pharmacists, who are already authorised to administer influenza vaccines in France. METHODS: We surveyed pharmacists in the Auvergne-RhÃ´ne-Alpes region to assess the current status of SARS-Cov-19 vaccination in the region. A questionnaire was sent to them; the analysis was carried out jointly with the URPS-Pharmacists. RESULTS: 739 pharmacies took part in our survey, and gave us their impressions of the organisation of the anti-COVID-19 vaccination and the information to be transmitted to patients. CONCLUSIONS: The commitment of pharmacists to the anti-COVID-19 vaccination testifies to the attachment of pharmacists to their patients, and their privileged place in prevention in France. The extension of their competences to the general vaccination of the population expects legitimacy from the decision-making authorities.
Post-Vaccination Coronavirus Disease 2019: A Case-Control Study and Genomic Analysis of 119 Breakthrough Infections in Partially Vaccinated Individuals. BACKGROUND: Post-vaccination infections challenge the control of the coronavirus disease 2019 (COVID-19) pandemic. METHODS: We matched 119 cases of post-vaccination severe acute respiratory syndrome coronavirus 2 infection with BNT162b2 mRNA or ChAdOx1 nCOV-19 to 476 unvaccinated patients with COVID-19 (September 2020-March 2021) according to age and sex. Differences in 60-day all-cause mortality, hospital admission, and hospital length of stay were evaluated. Phylogenetic, single-nucleotide polymorphism (SNP), and minority variant allele (MVA) full-genome sequencing analysis was performed. RESULTS: Overall, 116 of 119 cases developed COVID-19 post-first vaccination dose (median, 14 days). Thirteen

of 119 (10.9%) cases and 158 of 476 (33.2%) controls died (Pâ€…<â€….001), corresponding to the 4.5 number needed to treat (NNT). Multivariably, vaccination was associated with a 69.3% (95% confidence interval [CI]: 45.8 to 82.6) relative risk (RR) reduction in mortality. Similar results were seen in subgroup analysis for patients with infection onset â‰¥14 days after first vaccination and across vaccine subgroups. Hospital admissions (odds ratio, 0.80; 95% CI: .51 to 1.28) and length of stay (-1.89 days; 95% CI: -4.57 to 0.78) were lower for cases, while cycle threshold values were higher (30.8 vs 28.8, Pâ€…=â€….053). B.1.1.7 was the predominant lineage in cases (100 of 108, 92.6%) and controls (341 of 446, 76.5%). Genomic analysis identified 1 post-vaccination case that harbored the E484K vaccine-escape mutation (B.1.525 lineage). CONCLUSIONS: Previous vaccination reduces mortality when B.1.1.7 is the predominant lineage. No significant lineage-specific genomic changes during phylogenetic, SNP, and MVA analysis were detected.

Analysis of School-Day Disruption of Administering School-Located Vaccination to Children in Three Local Areas, 2012-2013 School Year. The purpose of this study was to determine the amount of time elementary and middle-school students spend away from the classroom and clinic time required to administer vaccines in school-located vaccination (SLV) clinics. We conducted a time study and estimated average time away from class and time to administer vaccine by health department (HD), student grade level, vaccine type, and vaccination process for SLV clinics during the 2012-2013 school year. Average time away from classroom was 10â€…min (sample: 688 students, 15 schools, three participating HD districts). Overall, time to administer intranasally administered influenza vaccine was nearly half the time to administer injected vaccine (52.5 vs. 101.7â€…s) (sample: 330 students, two HDs). SLV administration requires minimal time outside of class for elementary and middle-school students. SLV clinics may be an efficient way to administer catch-up vaccines to children who missed routine vaccinations during the coronavirus disease-2019 pandemic.

Platelet Surface Protein Expression and Reactivity upon TRAP Stimulation after BNT162b2 Vaccination. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection induces a coagulopathy characterized by platelet activation and a hypercoagulable state with an increased incidence of cardiovascular events. The viral spike protein S has been reported to enhance thrombosis formation, stimulate platelets to release procoagulant factors, and promote the formation of platelet-leukocyte aggregates even in absence of the virus. Although SARS-CoV-2 vaccines induce spike protein overexpression to trigger SARS-CoV-2-specific immune protection, thrombocyte activity has not been investigated in this context. Here, we provide the first phenotypic platelet characterization of healthy human subjects undergoing BNT162b2 vaccination. Using mass cytometry, we analyzed the expression of constitutive transmembrane receptors, adhesion proteins, and platelet activation markers in 12 healthy donors before and at five different time points within 4 weeks after the first BNT162b2 administration. We measured platelet reactivity by stimulating thrombocyte activation with thrombin receptor-activating peptide. Activation marker expression (P-selectin, LAMP-3, LAMP-1, CD40L, and PAC-1) did not change after vaccination. All investigated constitutive transmembrane proteins showed similar expressions over time. Platelet reactivity was not altered after BNT162b2 administration. Activation marker expression was significantly lower compared with an independent cohort of mild symptomatic COVID-19 patients analyzed with the same platform. This study reveals that BNT162b2 administration does not alter platelet protein expression and reactivity.

Acute attack in a patient with multiple sclerosis 2 days after COVID vaccination: a case report.

Transient Oculomotor Palsy Following the Administration of the Messenger RNA-1273 Vaccine for SARS-CoV-2 Diplopia Following the COVID-19 Vaccine.

ChAdOx1 SARS-CoV-2 vaccination: A putative precipitant of adrenal crises. BACKGROUND: Patients with adrenal insufficiency (AI) have excess mortality, in part due to the occurrence of life-

threatening adrenal crises. Infective processes, including that of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), are recognised as the major precipitant of adrenal crises. Adverse reactions to the ChAdOx1 SARS-CoV-2 vaccine occur in a significant proportion of individuals, however, are mild-moderate in the majority of cases. DESIGN: Case series. PATIENTS & RESULTS: We describe five cases where more severe adverse reactions to the ChAdOx1 SARS-CoV-2 vaccine led to actual or incipient adrenal crises requiring parenteral hydrocortisone within 24â€‰h of receiving the first ChAdOx1 SARS-CoV-2 vaccination. CONCLUSION: In individuals with adrenal insufficiency, adverse reactions to the initial dose of the ChAdOx1 SARS-CoV-2 vaccination can precipitate adrenal crises. We recommend that patients with AI should immediately increase their maintenance glucocorticoid dosage 2-3 fold on experiencing any symptoms in the initial 24â€‰h following vaccination.

Healthcare-associated transmission of severe acute respiratory coronavirus virus 2 (SARS-CoV-2) among Thai healthcare personnel who receive 2 doses of a coronavirus disease 2019 (COVID-19) vaccine: A call for considering a booster dose.

COVID-19 in South Korea: Proper Timing for Easing Mask Mandates After COVID-19 Vaccination. OBJECTIVE: As of July 25, 2021, the Korea Disease Control and Prevention Agency reported 1,422 new coronavirus disease 2019 (COVID-19) cases, 188,848 total cases, and 2,073 total deaths (1.10% fatality rates). Since the first severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) case was reported, efforts to find a treatment and vaccine against COVID-19 have been widespread. METHODS: Four vaccines are on the World Health Organization's (WHO's) emergency use listing and are approved of their usage; BNT162b2, mRNA-1273, AZD1222, and Ad26.COV2.S. Vaccines against SARS-CoV-2 need at least 14 d to achieve effectiveness. Thus, people should abide by prevention and control measures, including wearing masks, washing hands, and social distancing. RESULTS: However, a lot of new cases were reported after vaccinations, as many people did not follow the prevention control measures before the end of the 14-d period. There is no doubt we need to break free from mask mandates. CONCLUSIONS: But let us not decide the timing in haste. Even if the mask mandates are eased, they should be changed depending on the number of reported cases, vaccinations, as well as prevention and control measures on how circumstances are changing under the influence of mutant coronavirus.

COVID-19 vaccine hesitancy: misinformation and perceptions of vaccine safety. Despite COVID-19's devastating toll, many Americans remain unwilling to receive the COVID-19 vaccine. The authors conducted a US national survey to understand the health literacy of adults regarding the vaccine, as well as their COVID-19 beliefs and experiences. People who believed the COVID-19 vaccine was unsafe were less willing to receive the vaccine, knew less about the virus and were more likely to believe COVID-19 vaccine myths. On average, they were less educated, lower income, and more rural than people who believed the vaccine is safe. The results highlight the importance of developing clear health communications accessible to individuals from varied socioeconomic and educational backgrounds.

Prosociality and Social Responsibility Were Associated With Intention of COVID-19 Vaccination Among University Students in China. BACKGROUND: Coronavirus disease 2019 (COVID-19) vaccination is expected to end the pandemic; a high coverage rate is required to meet this end. This study aimed to investigate the prevalence of behavioral intention of free/self-paid COVID-19 vaccination and its associations with prosociality and social responsibility among university students in China. METHODS: An anonymous online cross-sectional survey was conducted among 6922 university students in five provinces in China during November 1-28, 2020. With informed consent, participants filled out an online survey link distributed to them via WeChat study groups. The response rate was 72.3%. RESULTS: The prevalence of behavioral intentions of free COVID-19

vaccination was 78.1%, but it dropped to 57.7% if the COVID-19 vaccination involved self-payment (400 RMB; around 42 USD). After adjusting for background factors, prosociality (free vaccination: adjusted odds ratio [ORa] = 1.10, 95% CI: 1.09-1.12; self-paid vaccination: ORa = 1.08, 95% CI: 1.07-1.09) and social responsibility (free vaccination: ORa = 1.17, 95% CI: 1.14-1.19; self-paid vaccination: ORa = 1.13, 95% CI: 1.11-1.14) were positively associated with the two variables of COVID-19 vaccination intention. CONCLUSION: The present study demonstrated the positive effects of prosociality and social responsibility on the intention of COVID-19 vaccination. Accordingly, modification of prosociality and social responsibility can potentially improve COVID-19 vaccination. Future longitudinal and intervention studies are warranted to confirm such associations across populations and countries.

Adverse events and humoral response after two doses of severe acute respiratory coronavirus virus 2 (SARS-CoV-2) mRNA vaccine in the hospital personnel of a cardiopulmonary tertiary-care center.

COVID-19 vaccination and the right to take risks. The rare but severe cerebral venous thrombosis occurring in some AstraZeneca vaccine recipients has prompted some governments to suspend part of their COVID-19 vaccination programmes. Such suspensions have faced various challenges from both scientific and ethical angles. Most of the criticisms against such suspensions follow a consequentialist approach, arguing that the suspension will lead to more harm than benefits. In this paper, I propose a rights-based argument against the suspension of the vaccine rollouts amid this highly time-sensitive combat of COVID-19. I argue that by suspending a vaccine rollout, a government infringes people's right to take the risks they deem worth taking for their health. I also consider four potential objections to my argument and explain why none of them undermines my argument.

Vaccine-induced thrombosis and thrombocytopenia with bilateral adrenal haemorrhage.

Otolaryngology-Specific Symptoms May Be Highly Observed in Patients With a History of Covid-19 Infection After Inactivated Coronavirus Vaccination. OBJECTIVE: To evaluate the otolaryngology-specific symptoms that occur after receiving the Covid-19 vaccine and its possible side effects in patients who had Covid-19 infection in the last 6 months before the vaccination. PATIENTS AND METHODS: The study comprised 3383 health care workers who were vaccinated against Covid 19. After excluding, the study was conducted with 1710 (51%) participants who agreed to answer the study questions. The participants were divided into 2 groups according to the history of Covid-19 positivity in the last 6 months before vaccination. The presence of symptoms related to otolaryngology practice, including cough, nasal congestion, rhinorrhea, sore throat, hearing loss, dizziness, loss of smell, loss of taste, ear pressure, and facial paralysis was recorded. RESULTS: The mean age of the study population was 35.79 Â± 10.2 (19-71) years and 1454 (85%) of the patients had a history of Covid-19 infection in the last 6 months. Regarding otolaryngology-related symptoms, the most common complaints were rhinorrhea (4.4%), sore throat (3.2%), and nasal congestion (2.9%). The presence of smell and taste loss, nasal congestion, rhinorrhea, sore throat, and hearing loss was significantly more common in patients with a history of Covid-19 infection. CONCLUSIONS: The patients with a history of Covid-19 disease might have otolaryngology-specific symptoms more commonly than those without a history of Covid-19 disease in the last 6 months before vaccination.

The use of antibody tests to determine level of immunity against coronavirus disease 2019 (COVID-19) after vaccination: A recent trend in India.

COVID-19 vaccination in pregnancy and postpartum. Pregnant women were excluded from the initial phase 3 clinical trials of COVID-19 vaccines resulting in limited data on their efficacy and safety during pregnancy and postpartum. As a result, since December 2020, there has been conflicting advice from public health, governmental, and professional authorities on this matter. From the end of 2020 up to now, some consensus guidance has been published with a prevalent precautionary approach on the administration of vaccines in pregnant women, in breastfeeding ones, or for those

who are planning a pregnancy (either spontaneously or with assisted technologies). After the first few months of vaccine administration in some countries, more permissiveness seems to prevail, although with inconsistencies. Some little indicative advice, their inconsistency around the world and their changes in a short time have probably disoriented both women and their health care providers and placed the burden of decision making upon women and their health care providers without information to assist in making an informed choice. We reviewed the COVID-19 vaccination guidance for pregnant and breastfeeding women published to date and evidence from cases of unplanned pregnancy during the course of vaccine trials, preclinical experimental and observational clinical studies, and discuss their implications. In this way, we have tried to identify the safety of COVID-19 vaccines for pregnant or breastfeeding women, and their offspring.

Perceptions and Concerns Regarding COVID-19 Vaccination in a Military Base Population. INTRODUCTION: Safe and effective vaccines against severe acute respiratory syndrome-associated coronavirus 2 are essential tools in the fight against the coronavirus disease 2019Â (COVID-19) pandemic. However, hesitancy to vaccination is a major barrier to achieving herd immunity, particularly among a population working on a military base. To better understand the perceptions and concerns of these individuals, a voluntary survey was conducted. MATERIALS AND METHODS: An interactive, online survey was constructed and disseminated to individuals associated with Wright-Patterson Air Force Base (WPAFB) in Dayton, OH. Survey participation was voluntary with responses collected over the initial weeks in which WPAFB began to distribute COVID-19 vaccines in a series of phases. Although initially designed to collect demographic data and identify reasons for potential vaccine hesitancy among WPAFB 88th Medical Group personnel, the study population was expanded to include all WPAFB-affiliated personnel at the direction of base leadership. The chi-squared test was used to examine the relationships between categorical variables, while multivariable logistic regression was used to assess age and occupation as independent risk factors for vaccine hesitancy. RESULTS: A total of 816 individuals completed the survey, of whom 22.7% (nâ€‰=â€‰185) self-identified as vaccine hesitant (VH). The VH group had a lower mean age than the not vaccine hesitant (NVH) group (39.3â€‰Â±â€‰14.2 vs. 45.9â€‰Â±â€‰13.4, Pâ€‰<â€‰.001). Respondents whose occupation was medical were more likely to be VH than their non-medical colleagues (49% vs. 18%, Pâ€‰<â€‰.001). The VH group was more concerned about short-term side effects (43% vs. 26%, Pâ€‰<â€‰.001), long-term side effects (82% vs. 50%, Pâ€‰<â€‰0.001), vaccine effectiveness (23% vs. 5%, Pâ€‰<â€‰.001), vaccine making them feel sick (22% vs. 13%, Pâ€‰=â€‰.002), being infected with COVID-19 from the vaccine (10% vs. 5%, Pâ€‰=â€‰0.008), and worry about misinformation/political agenda (43% vs. 31%, Pâ€‰=â€‰0.003). Younger respondents and medical personnel were more likely to be concerned about long-term side effects and vaccine effectiveness, and the younger group was also more likely to be concerned about pregnancy/breastfeeding issues and worry about misinformation/political agenda. Age (younger vs. older, odds ratio 2.15) and occupation (medical vs. non-medical, odds ratio 3.74) were independent risk factors for vaccine hesitancy. The NVH group was more likely to recommend the COVID-19 vaccine to a friend or family member than the VH group (93% vs. 20%, Pâ€‰<â€‰.001) as were the older age group (79% vs. 67%, Pâ€‰=â€‰.001) and non-medical personnel (81% vs. 52%, Pâ€‰<â€‰.001). CONCLUSIONS: Younger age and medical occupation were independent risk factors for vaccine hesitancy and these individuals were less likely to recommend vaccination to a friend or family member. We also identified several key concerns related to vaccination hesitancy, in particular those related to short- and long-term side effects, and the spread of misinformation. Among military personnel, these findings carry important implications that may negatively impact mission readiness, a matter that merits further investigation. Our COVID-19 vaccination hesitancy findings can be used to guide targeted interventions at future vaccination campaigns in a military population.

Do coronavirus vaccine challenge trials have a distinctive generalisability problem? Notwithstanding the success of conventional field trials for vaccines against COVID-19, human challenge trials (HCTs) that could obtain more information about these and about other vaccines and further strategies against it are about to start in the UK. One critique of COVID-19 HCTs is their distinct paucity of information on crucial population groups. For safety reasons, these HCTs will exclude candidate participants of advanced age or with comorbidities that worsen COVID-19, yet a vaccine should (perhaps especially) protect such populations. We turn this clichÃ© on its head. The truth is that either an HCT or a field trial has intrinsic generalisability limitations, that an HCT can expedite protection of high-risk participants even without challenging them with the virus, and that an important route to obtaining results generalisable to high-risk groups under either strategy is facilitated by HCTs.
Petechial skin rash associated with CoronaVac vaccination: first cutaneous side effect report before phase 3 results.
COVID-19 vaccination in pregnancy and postpartum. AIM: To identify whether COVID-19 vaccines should be administered in pregnant and breastfeeding women by reviewing the guidance and other evidence. METHODS: We reviewed the COVID-19 vaccination guidance for pregnant and breastfeeding women published to date and evidence from preclinical experimental and observational clinical studies, and discuss their implications. RESULTS: Pregnant women were excluded from the initial phase 3 clinical trials of COVID-19 vaccines resulting in limited data on their efficacy and safety during pregnancy and postpartum. As a result, since December 2020, there has been conflicting advice from public health, governmental, and professional authorities on this matter. From the end of 2020 up to now, some consensus guidance has been published with a prevalent precautionary approach on the administration of vaccines in pregnant women, in breastfeeding ones, or for those who are planning a pregnancy (either spontaneously or with assisted technologies). After the first few months of vaccine administration in some countries, more permissiveness seems to prevail, although with inconsistencies. At the moment, the results obtained by preclinical experimental and observational clinical studies suggest that the risks of the maternal COVID-19 outweigh the undocumented and hypothetical risks of the COVID-19 vaccines in pregnancy. Also, until two viral vector COVID-19 vaccines were associated with very rare thromboembolic events, all guidance had agreed that all approved COVID-19 vaccines could be administered in pregnancy. Actually, some concern has been expressed. CONCLUSION: COVID-19 vaccines administered in pregnancy can reduce the risk of severe COVID-19 and their serious consequences for mothers and their offspring. However, many aspects remain to be clarified.
Painless idiopathic neuralgic amyotrophy after COVID-19 vaccination: A case report.
Anaphylaxis After the Covid-19 Vaccine in a Patient With Cholinergic Urticaria. Cholinergic urticaria is a common disorder that has been associated with anaphylaxis. We report the events, workup, and eventual second dose vaccination of a patient at the Walter Reed National Military Medical Center, who had immediate anaphylaxis after administration of the first Pfizer-BioNTech Covid-19 (BNT162b2) vaccine dose. During the initial evaluation after anaphylaxis, the patient described a history of symptoms suspicious for cholinergic urticaria but had never had this condition confirmed with standardized testing. After the episode of anaphylaxis, we performed several studies including immediate hypersensitivity skin testing, which did not demonstrate vaccine or component sensitization. We then performed an exercise provocation challenge and confirmed the diagnosis of cholinergic urticaria. These results, combined with the patient history, suggested that the episode of anaphylaxis was most likely driven by a severe flare of cholinergic urticaria. After obtaining the patient's consent, she received and tolerated her second dose without any objective findings of anaphylaxis. We conclude that patients with mast cell disorders or anaphylaxis after their first Covid-

19 immunization will benefit from referral to an allergist since receipt of their second Covid-19 immunization may be possible.

Digital tools, multidisciplinarity and innovation for communicating vaccine safety in the COVID-19 era. The research on the anti-SARS-CoV-2 vaccines and their commercialization is an opportunity to test and consolidate the current knowledge along with the diverse available tools related to vaccine communication.In this paper we explore the value of a multidisciplinary approach in this field: vaccine communication activities can be combined with insights from data science, risk communication, behavior change, design thinking and digital marketing. Methodologies derived from innovation and human-centered design can contribute to the development and testing of vaccine promotion campaigns, speeding up processes and streamlining the production of evidence in this area. The multiple activities involving the anti-SARS-CoV-2 vaccine could be the fertile ground in which to develop, test and refine effective frameworks to transfer data acquired through listening strategies into effective vaccine promotion campaigns. The World Health Organization's Vaccine Safety Net is an interesting example of trusted information sources that aim toward using digital tools and innovative methodologies for communicating science-based information on vaccine safety at the global level.

Association of Pneumococcal and Influenza Vaccination With Patient-Physician Communication in Older Adults: A Nationwide Cross-sectional Study From the JAGES 2016. BACKGROUND: Increasing the coverage of vaccinations recommended by the World Health Organization in the older adult population is an urgent issue, especially in the context of avoiding co-epidemics during the current coronavirus disease 2019 crisis. The aim of this study was to examine factors associated with the quality of perceived patient-physician communication and whether this variable was associated with increased odds of vaccination. METHODS: We used cross-sectional data from the Japan Gerontological Evaluation Study conducted from October 2016 to January 2017. The participants were 22,253 physically and cognitively independent individuals aged 65 or older living in 39 municipalities in Japan. Multilevel logit models were used to estimate the odds of vaccination. RESULTS: Among the participants, 40.0% and 58.8% had received pneumococcal and influenza vaccinations as per the recommended schedule, respectively. People with low educational levels were more likely to have a family physician but rate their experience in asking questions lower than those with higher educational levels. Having a family physician and high rating for physicians' listening attitude were positively associated with increased odds of pneumococcal and influenza vaccinations. High rating for patients' questioning attitude and shared decision-making, compared to an ambiguous attitude toward medical decision-making, were positively associated with increased odds of pneumococcal vaccination. CONCLUSION: The results suggest that promotion of having a family physician, better patient-physician communication, and shared decision-making may encourage older adults to undergo recommended vaccinations.

The comparison of SARS-CoV-2 antibody levels in medical personnel induced by different types of vaccines compared to the natural infection. INTRODUCTION: During the last two and a half years, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection has spread around the world. Most of the SARS-CoV-2 vaccines are designed to produce anti-SARS-CoV-2 immunoglobulin G (IgG) against the viral S-glycoprotein. The aim of this study was to measure the anti-S antibody titres among the medical personnel who had been fully vaccinated with different types of vaccines, and to compare them with those who were COVID-19 convalescents. MATERIAL AND METHODS: In this study serum was collected from 261 healthcare workers, of whom 227 were vaccinated, while 34 were recovered participants who were not immunised. Serum samples were collected 21 days after the first dose and 60 and 180 days after the second dose of the vaccines and tested with a commercial ELISA kit. RESULTS: The highest antibody level (12 AU/ml) was measured in the Pfizer-BioNTech group, followed by Sinopharm (9.3 AU/ml), Sputnik V (5.9 AU/ml), Sinovac (4.6 AU/ml) and

Oxford/Astra- Zeneca vaccine (2.5 AU/ml) 60 days after the second dose of the vaccines (90 days after the first dose). The seropositivity rate for mRNA vaccine was 88.5%, for vector vaccines 86.2% and for inactivated vaccines 71.4%. When comparing these antibody levels with COVID-19 convalescents, higher antibody titres were found in vaccinated participants (5.76 AU/ml vs 7.06 AU/ml), but the difference was not significant (p = 0.08). CONCLUSIONS: Individuals vaccinated with mRNA and vector vaccines had a higher seroconversion rate compared to the group vaccinated with inactivated vaccines, or convalescents.

Trigeminal neuralgia occurring after the third dose of Pfizer BioNTech COVID-19 vaccine. Complication or coincidence? An illustrative case report and literature review. The coronavirus disease 2019 pandemic is an ongoing concern for medical care worldwide. Since its emergence, multiple COVID-19 vaccines have been designed, allowing for more effective control of the pandemic. COVID-19 vaccines, like any other form of medical intervention, may cause adverse and unforeseen side effects, varying in frequency and severity. Determining a correlation between the occurring symptoms and the vaccination is often a challenging task, requiring multiple data sources and reported cases. So far, there have been multiple reports of trigeminal neuralgia developing after COVID-19 vaccination. A 36-year-old woman was admitted to the Emergency Ward due to chronic pain attacks in the left side of her face. The pain appeared two months ago, on the day following the vaccination using the third dose of the Pfizer BioNTech COVID-19 vaccine. At the Neurology Department she was diagnosed with trigeminal neuralgia. Based on the lack of any obvious causes, relation to the vaccination, and other similar reports, we assumed that the trigeminal neuralgia was a complication of the vaccination. Hospital treatment consisted of oxcarbazepine, dexamethasone and pregabalin. Treatment was successful, with transient episodes of exacerbation. Six months after the onset of the disorder the patient remains without pain. We believe that the presented case supports the possibility of trigeminal neuralgia occurring in relation to the Pfizer BioNTech COVID-19 vaccine administration. Additional reports may further contribute to establishing a certain link.

Unilateral Axillary Lymphadenopathy After COVID-19 Vaccine Causing Medial Cord Plexopathy: A Case Report. CASE: The global reach of coronavirus disease 2019 has led to the rollout of new generation messenger ribonucleic acid (mRNA) vaccines. As populations are vaccinated, some side effects will become more apparent. We present a case of unilateral lymphadenopathy resulting in a transient plexopathy presenting as neuralgic pain, paresthesia, and numbness in the hand. CONCLUSION: Multiple image modalities and electrodiagnostic studies were used to infer the diagnosis. This condition was expectantly managed, and the patient's symptoms resolved within weeks.

Acute immune thrombocytopenic purpura post first dose of COVID-19 vaccination.

Multisystem inflammatory syndrome after SARS-CoV-2 vaccination (MIS-V), to interpret with caution.

Accounting for Potential Unmeasured Confounding in the Association between Influenza vaccination and COVID-19 Hospitalization: Sensitivity Analysis Using E-value Method. BACKGROUND: Unmeasured confounding is the primary obstacle to causal inference in observational research. We aimed to illuminate the association between exposure to influenza vaccination (IV) within six months before contracting the coronavirus disease (COVID-19) and COVID-19 hospitalization in relation to unmeasured confounding using the E-value method. MATERIALS AND METHODS: Information about 367 patients, 103 of whom (28.07 %) had received IV, and confounders included sex, age, occupation, cigarette smoking, opium, and comorbidities were collected. We estimated the interest association using the inverse probability weighted (IPW) method. There was no information on some potential unmeasured confounders, such as socioeconomic status. Therefore, we computed E-value as a sensitivity analysis, which is the minimum strength of unmeasured confounding to explain away an exposure-outcome association beyond the measured confounders completely. RESULTS: IPW

denoted 1.12 (95% CI: 0.71 to 1.29) times greater risk of COVID-19 hospitalization in patients exposed to IV than in unexposed individuals. Sensitivity analysis demonstrated that an E-value (95% CI) of 1.49 (1.90 to 2.15) is required to shift the RR and the corresponding confidence Interval (CI) lower and upper limits toward the null. Moreover, if they had been omitted, the most computed E-values for measured confounders were relatively larger than for unmeasured confounders. CONCLUSION: According to the context of the measured confounders, if they had been omitted, an E-value of 1.16 to 1.76, a weaker confounding could fully explain away the reported association, suggesting that no relationship exists between IV and COVID-19 hospitalization.

What vaccination rate(s) minimize total societal costs after 'opening up' to COVID-19? Age-structured SIRM results for the Delta variant in Australia (New South Wales, Victoria and Western Australia). Using three age-structured, stochastic SIRM models, calibrated to Australian data post July 2021 with community transmission of the Delta variant, we projected possible public health outcomes (daily cases, hospitalisations, ICU beds, ventilators and fatalities) and economy costs for three states: New South Wales (NSW), Victoria (VIC) and Western Australia (WA). NSW and VIC have had on-going community transmission from July 2021 and were in 'lockdown' to suppress transmission. WA did not have on-going community transmission nor was it in lockdown at the model start date (October 11th 2021) but did maintain strict state border controls. We projected the public health outcomes and the economic costs of 'opening up' (relaxation of lockdowns in NSW and VIC or fully opening the state border for WA) at alternative vaccination rates (70%, 80% and 90%), compared peak patient demand for ICU beds and ventilators to staffed state-level bed capacity, and calculated a 'preferred' vaccination rate that minimizes societal costs and that varies by state. We found that the preferred vaccination rate for all states is at least 80% and that the preferred population vaccination rate is increasing with: (1) the effectiveness (infection, hospitalization and fatality) of the vaccine; (2) the lower is the daily lockdown cost; (3) the larger are the public health costs from COVID-19; (4) the higher is the rate of community transmission before opening up; and (5) the less effective are the public health measures after opening up.

[Skin reactions to the Pfizer-BioNTech vaccine for COVID-19. An Ecuadorian experience]. OBJETIVE: To assess cutaneous reactions after Pfizer-BioNTech COVID-19 vaccine administration. METHODS: A cross-sectional observational study was carried out in health workers belonging to the city of Guayaquil-Ecuador, from March to May 2021. The participants were contacted through a local registry established by the Universidad EspÃ-ritu Santo. Frequencies and percentages were used to represent the proportions of nominal variables, while the mean and standard deviation were used for continuous data, given a normal sample distribution. RESULTS: Local skin reactions were the most frequent, and included redness, edema, and itching. On the other hand, delayed large local skin reactions (generalized rash and pruritus, angioedema, urticaria, eczema, petechiae) were rare and occurred in less than 1.4% of participants, (95% CI = 0.69-1.00). Finally, we did not find cases of anaphylaxis or other life-threatening reactions requiring urgent attention after vaccination. CONCLUSIONS: Our findings suggest that local skin reactions occur in a minority of recipients and are often mild and self-limited.

Adverse drug reactions to the three doses of the severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) mRNA-1273 vaccine in a cohort of cancer patients under active treatment of a tertiary hospital in Madrid, Spain. Background: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines efficacy and safety have been tested in phase 3 studies in which cancer patients were not included or were underrepresented. Methods: The objective of this study is to evaluate the safety profile of the mRNA-1273 vaccine across cancer patients and its relationship to patients' demographics. We selected from our records all 18-years or older solid cancer patients under active treatment vaccinated with the complete three-dose schedule mRNA-1273 vaccine whose adverse

drug reactions (ADRs) Â after each dose were recorded. Medical records were reviewed retrospectively to collect data between April 19, 2021, and December 31, 2021. Patients with documented previous infection by SARS-Cov-2 were excluded. Results: A total of 93 patients met the inclusion criteria. Local ADRs were reported more frequently after the first and second dose than after the third (41.9%, 43% and 31.1% of the patients respectively), while systemic ADRs followed the opposite pattern (16.1%, 34.4% and 52.6% of the patients respectively). We found a statistically significant association between sex and systemic adverse reactions after the third dose, $p < 0.001$ and between systemic adverse reactions after the second dose and systemic adverse reactions after the third dose, $p = 0.001$ A significant linear trend, $p = 0.012$, with a higher Eastern Cooperative Oncology Group (ECOG) score associated with a lower proportion of patients suffering from systemic side effects was found. Women had 5.79 times higher odds to exhibit systemic ADRs after the third dose ($p=0.01$) compared to males. Increasing age was associated with a decreased likelihood of exhibiting ADRs ($p=0.016$). Conclusion:Â The mRNA-1273 vaccine shows a tolerable safety profile. The likelihood of ADRs appears to be associated with gender and age. Its association with ECOG scores is less evident. Further studies are needed to elucidate this data in cancer patients.

COVID-19 post-vaccination depression in older Israeli adults: the role of negative world assumptions. BACKGROUND: With the outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, the aging population has been shown to be highly vulnerable. As a result, policy makers and the media urged older adults to restrict social interactions, placing them at greater risk of mental health problems, such as depression. However, there has been a little previous attempt to examine coronavirus disease-2019 (COVID-19) vaccine-related risk factors and depressive symptoms amongst older adults. METHODS: Participants (938 older adults, Mage = 68.99, s.d. = 3.41, range 65-85) answered an online questionnaire at the start of the COVID-19 vaccination program in Israel. Participants completed measures of background characteristics, world assumptions, COVID-19 vaccine-related variables, and symptoms of depression. RESULTS: Univariate logistic regression revealed that more negative world assumptions were linked with clinical depression levels. CONCLUSIONS: Older adults in our sample were susceptible to unique factors associated with clinical depression influenced by their world assumptions during their COVID-19 vaccination. The high level of depression following vaccination indicates that it may take time to recover from depression associated with pandemic distress. Cognitive interventions that focus on world assumptions are recommended.

Parental concerns about COVID-19 vaccine safety and hesitancy in Korea: implications for vaccine communication. OBJECTIVES: Vaccination is one of the most important strategies to contain the spread of coronavirus disease 2019 (COVID-19). Vaccination in children is dependent on their parents, making it important to understand parents' awareness and attitudes toward vaccines in order to devise strategies to raise vaccination rates in children. METHODS: A web-based nationwide survey was conducted among Korean parents of 7-year-old to 18-year-old children in August 2021 to estimate parents' intention to vaccinate their children against COVID-19 and identify key factors affecting parental acceptance and hesitancy through regression analysis. RESULTS: Approximately 56.4% (575/1,019) were willing to vaccinate their children against COVID-19. Contributing factors to COVID-19 vaccine hesitancy were being a mother (adjusted odds ratio [aOR], 0.36; 95% confidence interval [CI], 0.25 to 0.52), a lower education level (aOR, 0.83; 95% CI, 0.70 to 0.97), hesitancy to other childhood vaccines (aOR, 0.78; 95% CI, 0.64 to 0.96), and refusal to vaccinate themselves (aOR, 0.08; 95% CI, 0.02 to 0.20). Having older children (aOR, 1.20; 95% CI, 1.13 to 1.28), trusting the child's doctor (aOR, 1.19; 95% CI, 1.07 to 1.32), positive perceptions of the COVID-19 vaccine's effectiveness (aOR, 2.60; 95% CI, 1.90 to 3.57) and perceiving the COVID-19 vaccine as low-risk (aOR, 1.68; 95% CI, 1.27 to 2.24) were associated with COVID-19 vaccine acceptance. Concerns about adverse reactions

were the most common cause of hesitancy. CONCLUSIONS: Providing parents with accurate and reliable information on vaccine effectiveness and safety is important to increase COVID-19 vaccine uptake in children. Differential or targeted approaches to parents according to gender, age, and their children's age are necessary for effective communication about vaccination in children.

Myocarditis in children after COVID-19 vaccine. Three healthy adolescents presented with myocarditis confirmed on cardiac magnetic resonance imaging after receiving Pfizer-BioNTech COVID-19 vaccine. All patients were hemodynamically stable and had good short-term outcomes. Long-term outcomes are yet to be determined. Larger studies are needed to determine whether an association between Pfizer-BioNTech COVID-19 vaccine and myocarditis exists.

Multiple sites of thrombosis without thrombocytopenia and COVID-19 vaccine: Correspondence. Background: An adverse effect of COVID-19 vaccine is possible and it is necessary to monitor it. Methods and results: This is a correspondence on the published article on multiple sites of thrombosis without thrombocytopenia and COVID-19 vaccine. Conclusion: Confounding factors regarding thrombosis without thrombocytopenia and COVID-19 vaccine are discussed.

[Relapse of lupus nephritis in temporal association with anti SARS-CoV-2 vaccination]. During the past two years we have witness a tremendous worldwide health crisis imposed by the coronavirus disease (COVID-19). This situation led to the urgent development and implementation of vaccines in an attempt to decrease not only the SARS-CoV-2 transmissibility but also the severe forms of COVID-19. Although these vaccines were approved based on an adequate benefit-risk ratio, at the moment of their implementation in 2021 we did not have sub-studies in special populations; patients with systemic lupus erythematosus (SLE) among them. We describe two cases of lupus nephritis flare following the immunization against SARS-CoV-2 with the first component of Sputnik V and Sinopharm. Both patients were in complete remission on maintenance therapy with mycophenolate and without glucocorticoids. The flare presented with an increased protein/creatinine ratio in urine and positive anti-DNA antibodies without other relevant accompanying findings. After treatment with prednisone (20 y 10 mg/day in case 1 and 2, respectively) and an increased dose of mycophenolate (from 1.5 g/day to 2.0 g/dayand 1.08 to 1.44 g/dÃ-a of sodic mycophenolate in case 1 y 2, respectively) both patients regained renal remission. These cases are of relevance as they introduce a possible association between the different anti-SARS-CoV-2 vaccine platforms and SLE flares; at the same time to suggest the need for close control in the post vaccination period in this population of patients.

Guillain-BarrÃ© Syndrome and Unilateral Optic Neuritis Following Vaccination for COVID-19: A Case Report and Literature Review. A 71-year-old woman presented 2Â weeks after vaccination with the first dose of Vaxzevria (AstraZeneca, Oxford) for COVID-19 with a left lower motor neuron facial nerve palsy, which progressed to bilateral involvement. This was accompanied by bilateral proximal leg weakness. She was diagnosed with the 'facial diplegia with paraesthesia' variant of Guillain-BarrÃ© syndrome. Seven weeks post vaccination she developed painless loss of vision in the right eye. The visual acuity in that eye was light perception only with a right relative afferent pupillary defect and right optic disc swelling. A diagnosis of optic neuritis was made and she received pulsed intravenous methylprednisolone for 3Â days, followed by oral prednisolone. The optic neuritis recurred following initial cessation of steroids requiring an extended course of steroids. Despite this, she made a good visual recovery to 6/6 in the affected eye. We present this case and a review of the literature surrounding vaccination and the development of these conditions.

Guillain-BarrÃ© syndrome following different COVID-19 vaccines: a case series. BACKGROUND: The COVID-19 vaccine-related Guillain-BarrÃ© syndrome (GBS) has been described for both messenger-RNA vaccine and adenovirus-vectored types in a few cases with great public concern and the necessity to inform physicians about the variations of its presentations given its life-threatening

consequences. CASE PRESENTATION: This case series highlighted the presentation with GBS following different COVID-19 vaccinations in seven cases with ages ranging from 29 to 59Â years. Three patients received the AstraZeneca vaccine, two received the Pfizer vaccine, one received Sinopharm, and one received the Janssen vaccine. Latency ranged from 5 to 60Â days and cases achieved either partial or complete improvement after treatment trials. Patients responded to plasmaphereses, but not pulse steroid therapy. CONCLUSION: This case series highlights the variable presentations and outcomes of GBS following different COVID-19 vaccination from one center. The early identification and appropriate management of such cases can lead to better outcomes.

Potential POTS association with COVID-19 vaccination weaker than with COVID-19 infection. Postural orthostatic tachycardia syndrome (POTS) has been observed following SARS-CoV-2 infection. In this study, we observed occurences of POTS following COVID-19 vaccination, albeit at a lower rate than following COVID-19 infection.

Factors Associated with Vaccine Breakthrough Incidence among Health Care Workers Vaccinated with Inactivated SARS-CoV2 Vaccine (CoronaVac). BACKGROUND: Healthcare workers (HCWs) run a high risk of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The HCWs are prone to the SARS-CoV-2 infection in the hospital despite being fully vaccinated. The present study aimed to address the factors associated with the coronavirus disease 2019 (COVID-19) vaccine breakthrough among HCWs. STUDY DESIGN: A prospective cohort study. METHODS: Participants were 184 HCWs receiving two doses of inactivated SARS-CoV-2 vaccine (CoronaVac, Sinovac Life Science). All participants were followed for six months. Confirmed COVID-19 was defined as positive SARS-CoV-2 by reverse transcription-polymerase chain reaction (RT-PCR). Before undergoing RT-PCR, questionnaires were used to obtain information on demographic characteristics, profession, contact with COVID-19 cases, personal protective equipment (PPE), health protocols adherence, exercise, and nutritional habits. RESULTS: A number of 57 (31%) participants were COVID-19 positive. Close contact with COVID-19 cases (adjusted RR 6.82, 95% CI: 1.97, 47.98, P = 0.044), being a resident doctor (adjusted RR 4.72, 95% CI: 1.11, 20.11, P = 0.036), improper mask-wearing (adjusted RR 2.36, 95% CI: 1.15, 4.85, P = 0.019), and lower frequency of eating fruit and vegetables (adjusted RR 2.73, 95% CI: 1.34, 5.57, P = 0.006) increased the risk of vaccine breakthrough. Compared to single surgical masks, KN95 and N95 significantly reduced the risk of COVID-19 (adjusted RR 0.27, 95% CI: 0.07, 0.97, P = 0.045 and adjusted RR 0.25, 95% CI: 0.07, 0.87, P = 0.029), respectively. CONCLUSION: As evidenced by the obtained results, being a resident doctor, close contact with confirmed COVID-19 cases, health protocol incompliance, as well as the lower frequency of fruit and vegetable consumption were associated with the risk of vaccine breakthrough among HCWs. Appropriate strategies are needed to prevent the risk of SARS-CoV-2 infection among HCWs.

[Hemophagocytic lymphohistiocytosis following mRNA-1273 COVID-19 vaccination]. A 34-year-old man with no medical history presented with fever 4 days after receiving the first dose of mRNA-1273 coronavirus disease 2019 (COVID-19) vaccine. He had no prior clinical evidence of severe acute respiratory syndrome coronavirus 2 infection and was negative for serial polymerase chain reaction testing. Ten days after vaccination, he was referred to our hospital because of no response to antibiotics and the emergence of neutropenia, thrombocytopenia, and liver dysfunction. Blood tests also showed elevated serum ferritin and plasma soluble interleukin-2 receptors. Serological and PCR testing excluded active infections of cytomegalovirus, Epstein-Barr virus, and hepatitis viruses. Blood culture yielded no growth. Computed tomography revealed mild hepatosplenomegaly and porta hepatis lymphadenopathy but no focus on infection. Bone marrow aspiration demonstrated hemophagocytosis but no infiltrating lymphoma cells. Immediately, 2-mg/kg intravenous methylprednisolone was commenced based on the presumptive diagnosis of hemophagocytic lymphohistiocytosis (HLH), leading to the rapid and durable improvement of his symptoms and

laboratory data. Later, without other causes triggering hemophagocytosis, and with the close link between vaccination and disease onset, the final diagnosis of vaccination-induced secondary HLH was made. HLH after COVID-19 vaccination, though extremely rare, can occur regardless of the vaccine type. Therefore, clinicians should recognize and deal with this occasionally fatal adverse event.
Second mRNA Vaccination of COVID-19 in a Patient Who Developed Pericarditis after the First Vaccination. The coronavirus infection 2019 (COVID-19) pandemic has led to the development of mRNA vaccines with proven efficacy. However, it remains unclear whether patients who developed pericarditis after the first COVID-19 mRNA would be fit to receive the second vaccination. Herein, we present the case of a 64-year-old man who visited our emergency department with substernal chest discomfort that began 4 days after his first mRNA COVID-19 vaccination. Acute pericarditis was diagnosed based on symptoms and ST-segment elevation on an electrocardiogram. Chest pain improved 2 days after treatment.Since there are no guidelines on whether to administer an additional vaccination to a patient who developed pericarditis after the initial vaccination, we considered whether or not to administer the additional vaccination. We informed the patient about the risks and benefits and decided to administer the second dose. He did not experience any major adverse reactions. The indications for the second vaccination need to be thoroughly considered.
Moderna, Pfizer-BioNTech, and Johnson & Johnson/Janssen Post-Covid Vaccine Hematological Adverse Events Including Cerebral Venous Sinus Thrombosis (CVST), Thrombotic Thrombocytopenia (VITT), Blood Clots, Increased Vaginal/Menstrual Bleeding and/or Miscarriage, Stillbirth Delivery, or Premature Birth. The Centers for Disease Control (CDC) indicated in 2021 that it would monitor for possible post-COVID-19 vaccination coagulopathy adverse events (AEs).
Influenza and COVID-19 Vaccine Concerns and Uptake Among Patients Cared for in a Safety-Net Health System. OBJECTIVES: To examine Influenza and COVID-19 vaccine concerns and uptake among adult patients in a Southern safety-net health system. METHODS: Trained research assistants conducted a structured telephone interview from April to October 2021. Of 118 participants, mean age was 57.7â€‰years, 63.6% were female, 55.1% were Black, 42.4% white, and 54.2% reported rural residence. RESULTS: Among participants, 44.9% had received the influenza vaccine during the 2020 to 2021 season, and 66.1% had received the COVID-19 vaccine. Participants who received the influenza vaccine were more likely to report getting a COVID-19 vaccine compared to those who reported not getting a flu vaccine (81.1% vs 53.8%, Pâ€‰=â€‰.002). Black adults were significantly less likely than white adults (29.2% vs 46.0%, Pâ€‰=â€‰.048) and bordering on significance, males less likely than females (27.9% vs 41.3%, Pâ€‰=â€‰.054) to have reported receiving both vaccines. Of note, 25.4% of participants did not get either vaccine. The most common reasons for not getting the influenza vaccine were not being concerned about getting the flu (13.8%) and belief the vaccine gave them the flu (12.3%). The primary reasons for not getting a COVID-19 vaccine were concern about vaccine safety (22.5%), concern about side effects (20.0%), and belief they were not going to get sick (20.0%). CONCLUSIONS: These findings could help direct regional vaccine messaging and clinical communication to improve vaccine uptake among underserved populations.
The role of miRNAs in viral myocarditis, and its possible implication in induction of mRNA-based COVID-19 vaccines-induced myocarditis. BACKGROUND: Several reports of unheeded complications secondary to the current mass international rollout of SARS-COV-2 vaccines, one of which is myocarditis occurring with the FDA fully approved vaccine, Pfizer, and others. MAIN BODY OF THE ABSTRACT: Certain miRNAs (non-coding RNA sequences) are involved in the pathogenesis in viral myocarditis, and those miRNAs are interestingly upregulated in severe COVID-19. We hypothesize that the use of mRNA-based vaccines may be triggering the release of host miRNAs or that trigger the occurrence of myocarditis. This is based on the finding of altered host miRNA expression promoting virus-induced myocarditis. SHORT CONCLUSION: In conclusion, miRNAs are likely implicated in

myocarditis associated with mRNA vaccines. Our hypothesis suggests the use of miRNA as a biomarker for the diagnosis of mRNA vaccine-induced myocarditis. Additionally, the interplay between viral miRNA and the host immune system could alter inflammatory profiles, hence suggesting the use of therapeutic inhibition to prevent such complications.

mRNA COVID-19 vaccines are well tolerated and myopericarditis is a rare adverse event following immunisation. mRNA vaccines are considered to be important tools for the management of the COVID-19 pandemic. Although mRNA COVID-19 vaccines are well tolerated in most recipients, post-marketing data have highlighted an association between myocarditis and mRNA vaccines. Post-vaccine myocarditis (PVM) is most commonly reported in male adolescents receiving the second dose of an mRNA vaccine. However, the incidence of PVM is low and the risk of myocarditis should be kept in perspective. Cases of PVM are mostly mild in severity, and may be managed using existing myocarditis guidelines. The pathology of PVM is under investigation, and current data suggest that cross reactivity or hypersensitivity reactions may be involved. Globally, mRNA vaccines are generally recommended for use in children/adolescents, and delaying the administration of the second dose may reduce the risk of PVM.

Association between menstrual cycle length and covid-19 vaccination: global, retrospective cohort study of prospectively collected data. OBJECTIVES: To identify whether covid-19 vaccines are associated with menstrual changes in order to address concerns about menstrual cycle disruptions after covid-19 vaccination. DESIGN: Global, retrospective cohort study of prospectively collected data. SETTING: International users of the menstrual cycle tracking application, Natural Cycles. PARTICIPANTS: 19 622 individuals aged 18-45 years with cycle lengths of 24-38 days and consecutive data for at least three cycles before and one cycle after covid (vaccinated group; n=14 936), and those with at least four consecutive cycles over a similar time period (unvaccinated group; n=4686). MAIN OUTCOME MEASURES: The mean change within individuals was assessed by vaccination group for cycle and menses length (mean of three cycles before vaccination to the cycles after first and second dose of vaccine and the subsequent cycle). Mixed effects models were used to estimate the adjusted difference in change in cycle and menses length between the vaccinated and unvaccinated. RESULTS: Most people (n=15 713; 80.08%) were younger than 35 years, from the UK (n=6222; 31.71%), US and Canada (28.59%), or Europe (33.55%). Two thirds (9929 (66.48%) of 14 936) of the vaccinated cohort received the Pfizer-BioNTech (BNT162b2) covid-19 vaccine, 17.46% (n=2608) received Moderna (mRNA-1273), 9.06% (n=1353) received Oxford-AstraZeneca (ChAdOx1 nCoV-19), and 1.89% (n=283) received Johnson & Johnson (Ad26.COV2.S). Individuals who were vaccinated had a less than one day adjusted increase in the length of their first and second vaccine cycles, compared with individuals who were not vaccinated (0.71 day increase (99.3% confidence interval 0.47 to 0.96) for first dose; 0.56 day increase (0.28 to 0.84) for second dose). The adjusted difference was larger in people who received two doses in a cycle (3.70 days increase (2.98 to 4.42)). One cycle after vaccination, cycle length was similar to before the vaccine in individuals who received one dose per cycle (0.02 day change (99.3% confidence interval -0.10 to 0.14), but not yet for individuals who received two doses per cycle (0.85 day change (99.3% confidence interval 0.24 to 1.46)) compared with unvaccinated individuals. Changes in cycle length did not differ by the vaccine's mechanism of action (mRNA, adenovirus vector, or inactivated virus). Menses length was unaffected by vaccination. CONCLUSIONS: Covid-19 vaccination is associated with a small and likely to be temporary change in menstrual cycle length but no change in menses length.

[Warm autoimmune hemolytic anemia and IgM-monoclonal gammopathy following BNT162b2 COVID-19 vaccine in a patient with splenic marginal zone lymphoma]. There is currently no evidence that a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine might be associated with the development of autoimmune hemolytic anemia or disease progression in

patients with mature B-cell neoplasm. Our patient was a 71-year-old man with indolent mature B-cell neoplasm who had been monitored for many years without treatment. After receiving the second dose of the BNT162b2 mRNA COVID-19 vaccine, he developed severe warm autoimmune hemolytic anemia. Although steroid therapy improved his anemia, he continued to develop IgM-monoclonal gammopathy, renal insufficiency, and splenomegaly. He was diagnosed with splenic marginal zone lymphoma after undergoing splenectomy. The splenectomy improved the patient's symptoms. We assessed his SARS-CoV-2 specific antibody response, but the patient's serologic response to the vaccine was impaired. In patients with mature B-cell neoplasm, a non-specific immune response after vaccination might be associated with paraneoplastic syndromes.

Safety, immunogenicity & effectiveness of the COVID-19 vaccine among healthcare workers in a tertiary care hospital. BACKGROUND & OBJECTIVES: The COVID-19 pandemic has caused significant global morbidity and mortality. As the vaccination was rolled out with prioritization on healthcare workers (HCWs), it was desirable to generate evidence on effectiveness of vaccine in prevailing real-life situation for policy planning. The objective of the study was to evaluate the safety, effectiveness and immunogenicity of COVID-19 vaccination among HCWs in a tertiary care hospital. METHODS: This prospective observational study was undertaken on the safety, immunogenicity and effectiveness of the ChAdOx1 nCoV- 19 coronavirus vaccine (Recombinant) during the national vaccine roll out in January-March 2021, in a tertiary care hospital, New Delhi, India. RESULTS: The vaccine was found to be safe, with local pain, fever and headache as the most common adverse events of milder nature which generally lasted for two days. The adverse events following vaccination were lower in the second dose as compared to the first dose. The vaccine was immunogenic, with seropositivity, which was 51 per cent before vaccination, increasing to 77 per cent after single dose and 98 per cent after two doses. Subgroup analysis indicated that those with the past history of COVID-19 attained seropositivity of 98 per cent even with single dose. The incidence of reverse transcription (RT)-PCR positive COVID-19 was significantly lower among vaccinated (11.7%) as compared to unvaccinated (22.2%). Seven cases of moderate COVID-19 needing hospitalization were seen in the unvaccinated and only one such in the vaccinated group. The difference was significant between the fully vaccinated (10.8%) and the partially vaccinated (12.7%). The hazard of COVID-19 infection was higher among male, age >50 yr and clinical role in the hospital. After adjustment for these factors, the hazard of COVID-19 infection among unvaccinated was 2.09 as compared to fully vaccinated. Vaccine effectiveness was 52.2 per cent in HCWs. INTERPRETATION & CONCLUSIONS: ChAdOx1 nCoV-19 coronavirus vaccine (Recombinant) was safe, immunogenic as well as showed effectiveness against the COVID-19 disease (CTRI/2021/01/030582).

A study on seroconversion following first & second doses of ChAdOx1 nCoV-19 vaccine in Central Kerala. BACKGROUND & OBJECTIVES: Vaccination against COVID-19 induces spike protein-binding IgG antibodies, a robust correlate of protection against COVID-19. This study was undertaken to assess the humoral response after completion of both the doses of ChAdOx1 nCoV vaccine in healthcare workers (HCWs) at a tertiary care health centre in India. METHODS: A cross-sectional COVID-19 vaccine-induced antibody study was conducted among HCWs. IgG antibodies against spike protein were measured at least 28 days after the first dose and the second dose of vaccination in both SARS CoV-2 naÃ¯ve and recovered HCWs. Mean and median antibody titre following each dose of vaccine and its association with age, gender, co-morbidities and factors such as exercise, stress and sleep deprivation were also explored. RESULTS: Among the 200 vaccine recipients, 91.5 per cent showed seroconversion after the first dose and 99.5 per cent after the second dose. The mean titre after the second dose was significantly higher when compared to the first dose (12.68Â±4.17 vs. 9.83Â±6.3, P=0.001). More than half (54%) had high antibody titre â‰¥12 S/Co (Signal/cut-off). Previous COVID-19 infection was the single most important factor influencing antibody production,

where the mean titre just after a single dose [mean-17.81Â±5.94, median-20.5 (interquartile range [IQR]-3.7)] surpassed the titre after the second dose in SARS CoV-2 naÃ¯ve individuals [mean-12.29Â±4.00, median-12.8 (IQR-3.7), P=0.001]. Furthermore, 28 per cent of vaccinees showed a reduction in titre after the second dose. The mean fall in titre was 2.25Â±1.40 and was more pronounced in males, the younger age group and those with previous COVID-19 infection. INTERPRETATION & CONCLUSIONS: ChAdOx1 nCov-19 vaccine after two doses elicited an excellent immune response. However, greater immunogenicity after the first dose was seen among those with previous COVID-19 infection, even surpassing the titre achieved by the second dose of vaccine in SARS CoV-2 naÃ¯ve recipients. A fall in antibody titre after the second dose is a matter of concern and requires further studies.

Inflammatory Sixth Nerve Palsy Post-COVID-19 Vaccination: Magnetic Resonance Imaging Findings. Sixth nerve palsy is the most common post-vaccination oculomotor palsy. It is generally transient with most patients making a complete recovery. We report the case of a 46-year-old healthy male patient who presented with a painless sixth nerve palsy after the second dose of the Pfizer BioNTech COVID-19 vaccine, which recovered over the course of the next month. We confirmed the lesion localisation by demonstrating enhancement of the root exit zone and the cisternal portion of the sixth nerve on sequential magnetic resonance imaging during the symptomatic period. Here, a temporal relationship between vaccine application and diplopia onset suggests an aetiologic relationship. Moreover, the lack of pre-existing medical conditions suggests a post-vaccination inflammatory process.

Immunogenicity and safety of SARS-CoV-2 vaccine with immunosuppressive agents. BACKGROUND: We conducted a prospective study of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) messenger RNA (mRNA) vaccination in children and adolescents who were taking immunosuppressive agents. METHODS: Two doses of SARS-CoV-2 mRNA vaccine were administered to patients taking immunosuppressive agents. Titers of SARS-CoV-2 spike protein receptor-binding domain antibodies were measured before and after vaccination. Vaccine failure was defined as a postvaccination antibody titer of <0.8â€‰U/mL. Seroconversion rates, factors associated with antibody titers after vaccination, clinical effectiveness against breakthrough infection, and adverse events were evaluated. RESULTS: A total of 42 patients (median age, 18.1â€‰years) were enrolled. Immunogenicity was measured in 34 patients. The median SARS-CoV-2 spike antibody titer was 329â€‰U/mL (interquartile range [IQR] 50-812â€‰U/mL). Seroconversion (â‰¥0.8â€‰U/mL) was achieved in 29 patients (85%), whereas vaccine failure was diagnosed in five (15%). All patients with vaccine failure were recipients of solid organ transplants (SOTs) and were taking two immunosuppressants. The median antibody titer in SOT recipients (57â€‰U/mL) was significantly lower than that in non-recipients (653â€‰U/mL, P =â€‰0.0002); that of patients taking two immunosuppressive agents (93â€‰U/mL) was lower than that of patients taking one (506â€‰U/mL, P =â€‰0.003). Breakthrough infection occurred in three patients (7%). Adverse events were non-specific, and no flares of primary disease or acute rejection in SOT recipients occurred. CONCLUSIONS: SARS-CoV-2 mRNA vaccine was immunogenic in children and adolescents taking immunosuppressive agents, although SOT recipients and patients taking two immunosuppressive agents tended to show lower postvaccination antibody titers.

An adolescent boy with takotsubo cardiomyopathy after COVID-19 vaccination.

Trigeminal neuropathy after tozinameran vaccination against COVID-19 in postmicrovascular decompression for trigeminal neuralgia: illustrative case. BACKGROUND: Vaccines against coronavirus disease 2019 have a high level of efficacy and safety across all populations. However, numerous case series have been published on neurological disorders, including Bell's palsy, Guillain-Barre syndrome, transverse myelitis, and multiple sclerosis. The authors presented a case of trigeminal neuropathy after coronavirus vaccination in a patient who had undergone microvascular

decompression (MVD) for trigeminal neuralgia (TN). OBSERVATIONS: A 77-year-old woman presented with acute trigeminal neuropathy after receiving a Pfizer-BioNtech vaccination (tozinameran) against severe acute respiratory syndrome coronavirus 2. The patient had undergone MVD for TN and the facial pain completely disappeared. One month later, she received the first injection of the tozinameran vaccine. Twelve hours after vaccination, she presented with numbness and pain induced by touching any place on the entire right face. No eruption was observed on her face. The serum herpes zoster virus antibodies were confirmed within the normal range. Magnetic resonance imaging revealed no abnormalities. The authors suspected a right trigeminal neuropathy after vaccination. Administration of carbamazepine and pregabalin improved TN but facial numbness persisted, especially in the mandibular division. LESSONS: The coronavirus is a possible etiology of secondary trigeminal neuropathy in the case of MVD for TN.
SARS-CoV-2 Infection and Vaccination Cutaneous Manifestations for the Inpatient Dermatologist. PURPOSE OF REVIEW: The overall purpose of this review was to characterize and summarize cutaneous eruptions associated with coronavirus disease 2019 (COVID-19) as well as COVID-19 vaccination. RECENT FINDINGS: Cutaneous eruptions associated with COVID-19 infection have a reported frequency of 1-20%. Increased COVID-19 disease severity has been associated with morbilliform exanthems, urticaria, retiform purpura, and livedo racemosa. Papulovesicular eruptions were associated with a milder COVID-19 disease course. A range of dermatoses have also been reported with COVID-19 vaccination but have rarely prevented subsequent vaccination. SUMMARY: Dermatologists should be aware of the associations between COVID-19 disease severity and cutaneous eruptions. Livedo racemosa and retiform purpura are particularly associated with increased disease severity and death. In the setting of COVID-19 vaccination, cutaneous eruptions can largely be managed symptomatically and very rarely do these reactions prevent subsequent vaccination.
The effect of job strain and worksite social support on reported adverse reactions of COVID-19 vaccine: A prospective study of employees in Japan. OBJECTIVES: This prospective study aimed to examine the association of psychosocial working conditions with adverse reactions after receiving COVID-19 vaccination in a sample of employees in Japan. METHODS: The data were retrieved from an online panel of full-time employees (E-COCO-J). The analysis included participants who were employed and were not vaccinated at baseline (June 2021) but received vaccination at a 4-month follow-up (October 2021). An 11-item scale measured the adverse reactions. Four types of psychosocial working conditions (i.e., job demands, job control, and supervisor and coworker support) were measured using the Brief Job Stress Questionnaire. Multiple linear regression analyses were conducted to examine the relationship between the psychosocial working conditions and adverse reactions of COVID-19 vaccines, adjusting for socioeconomic variables, chronic disease, the number of vaccination, type of vaccine, anxiety for adverse reactions, fear and worry about COVID-19, and psychological distress at baseline. RESULTS: Overall, 747 employees were included in the analysis. The average number of adverse reactions was 3.8 (standard deviationÂ =Â 2.2): Arm pain (81.1%), fatigues (64.1%), muscle pains (63.3%), and fever (37.5Â°C+) (53.5%) were reported more frequently. Coworker support score was significantly and negatively associated with the numbers of adverse reactions (standardized Î²Â =Â -0.100, PÂ =Â .023). Women, young age, second-time vaccination, Moderna, and high psychological distress were significantly associated with adverse reactions. CONCLUSIONS: Employees with low coworker support may be more likely to have adverse reactions after vaccinations. The findings of this study could support that increasing workplace support may reduce adverse reactions.
[Assessment of the pain induced by vaccination according to the injected arm (COVID-19 vaccination)]. Since its discovery, the concept of vaccination has continued to improve in order to

offer better efficacy and tolerance. Local or even diffuse reactions are often reported, but no study reports results on the injection side. We carried out a prospective observational study on the COVID-19 vaccination centers of the Landes regional hospital consortium (GHT) over three weeks. A questionnaire was given after the second injection, and assessed patientsâ€™ feelings about the first injection. During this period, 2797 patients received their second injection and 2487 responded to the questionnaire, of which 2301 are usable. 81% of vaccinations were performed on the weak arm and 19% on the dominant arm. Local pain/discomfort was reported by 47% of patients on both arms, occurring the same day as the vaccination took place for half of the patients and the next day for the other half, with an average intensity of 3.3. Extensive pain/discomfort was present in 19% of patients, regardless of which arm was injected. The choice of the injected arm does not seem to have influence on pain.

Editorial: Adverse Vaccine Reactions.

Unilateral Laterothoracic Exanthema (ULTE) as a Possible Adverse Effect of COVID-19 Vaccine.

COVID-19 Infection After Vaccination Among Healthcare Workers at a Tertiary Level Health Care Center in Northern India: A Cross-Sectional Study. BACKGROUND AND AIMS: COVID-19 vaccines are now accessible to all Indian citizens. Infection with COVID-19, on the other hand, continues to spread constantly. Our study aimed to determine the number of persons who had COVID-19 infections despite receiving the recommended number of doses of the COVID-19 vaccination at AIIMS Rishikesh, a tertiary care facility in Uttarakhand, India. METHODS: We analysed meticulously preserved data regarding COVID-19 vaccination, COVID-19 infection, clinical symptoms, and RT-PCR testing among all HCWs in our healthcare institution from 16 January 2021 to 30th June 2021. RESULTS: During this period, 5273 (90.3%) HCWs received two doses of the COVID-19 vaccine, while 566 (9.7%) received only one dose. 628 HCWs (10.8%) were BBV152 recipients and 5211 (89.2%) were AZD1222 (ChAdOx1-S) recipients. 423 HCWs (7.2%, confidence interval of 95% - 13.8, 22.0) reported COVID-19 infections. 274 (5.19% of total vaccinated HCWs) breakthrough infections and 149 non-breakthrough COVID-19 infections were reported in HCWs who had previously received a single dose of the COVID-19 vaccination. CONCLUSION: Viral infections, especially breakthrough infections, following adequate vaccination, are a cause for concern, but there is a lack of data on these infections in the actual world. Therefore, the primary focus of research should be on the emergence of illness in India following the completion of a full vaccine course.

Safety and effectiveness of COVID-19 SPUTNIK V vaccine in dialysis patients. INTRODUCTION: Given the vulnerability of chronic kidney disease individuals to SARS-CoV-2, nephrology societies have issued statements calling for prioritization of these patients for vaccination. It is not yet known whether COVID-19 vaccines grant the same high level of protection in patients with kidney disease compared to the non-dialysis population. The aims of this study were to evaluate the safety - measured by the adverse events potentially attributed to vaccines (ESAVI) - and the effectiveness - evaluated by the presence of antibodies - in dialysis patients immunized with the COVID-19 Sputnik V vaccine. METHODS: multicenter, observational and analytical study of a prospective cohort of hemodialysis patients from the Ciudad AutÃ³noma de Buenos Aires participating in an official vaccination program. Dialysis requiring individuals older than 18 years, who received both components of the COVID-19 vaccine were included. RESULTS: Data from 491 patients were included in the safety analysis. ESAVI with either the first or second component was detected in 186 (37.9%, 95% CI 33.6%-42.3%). Effectiveness analysis measuring antibodies levels against SARS-CoV-2 were performed in 102 patients; 98% presented these IgG antibodies at day 21 after the second component. In patients with COVID-19 prior to vaccination, antibodies at day 21 after the first component reached almost the highest levels compared to patients without previous COVID-19, but IgG rise among patients with previous COVID-19 was lower than in those without this previous

disease. CONCLUSION: The Sputnik V vaccine has been shown to be safe and effective in this patient's population.

Measles a Growing Global Threat as COVID-19 Disrupts Childhood Vaccinations.

Author response to comment on: Premenstrual and menstrual changes reported after COVID-19 vaccination: The EVA project.

Comment on: Premenstrual and menstrual changes reported after COVID-19 vaccination: The EVA project.

Seroprevalence of SARS-CoV-2 antibodies in vaccinated healthcare workers in Marrakech (Morocco). INTRODUCTION: The SARS-CoV-2 pandemic has had a considerable impact, causing millions of deaths worldwide, including many healthcare workers (HCWs). The pharmaceutical industry has been working diligently since the start of the pandemic to develop various vaccines to fight the spread of the virus and protect the population. OBJECTIVE: To study the seroprevalence of neutralizing anti-SARS-CoV-2 antibodies in vaccinated HCWs at the Mohamed VI University Hospital in Marrakech and to determine the parameters that can influence immune response. METHODS: A cross-sectional study of 138 HCWs was performed between October and December 2021 by measuring IgG antibodies directed against the spike antigen of SARS-CoV-2 using an Abbott Architect(Â®) SARS-CoV-2 IgG II assay. RESULTS: The mean age was 31.42 years, the sex ratio was 2.94 women to each man, and the overall prevalence was 97%. We found 39.5% of the participants had experienced COVID-19 infections pre-vaccination, which decreased to 26.8% after vaccination. Neutralizing antibody titers were dependent on the type of vaccine: they were higher with the Pfizer-BioNTech vaccine, the number of doses ($p < .001$), and post-vaccine COVID-19 form. The post-vaccine COVID-19 infection rates were lower with the Sinopharm vaccine. CONCLUSION: Heterologous vaccination with non-mRNA and mRNA vaccines and the consideration of post-vaccination COVID-19 infection as a booster could help optimize vaccine results while reducing potential side effects.

Acute-onset chronic inflammatory demyelinating polyneuropathy complicating SARS-CoV-2 infection and Ad26.COV2.S vaccination: report of two cases. BACKGROUND: The spectrum of reported neurological sequelae associated with SARS-CoV-2 is continuously expanding, immune mediated neuropathies like Guillain-Barre syndrome (GBS) and exacerbations of preexisting chronic inflammatory demyelinating polyneuropathy (CIDP) being among them. However, respective cases of acute onset CIDP (A-CIDP) are rare. CASE PRESENTATION: We hereby report two cases of A-CIDP after COVID-19 infection and Ad26.COV2.S vaccination that presented with flaccid paraparesis and acroparesthesias (Case presentation 1; female, 52) and facial diplegia accompanied by acroparesthesias (Case presentation 2; male, 62), respectively. In both instances clinical, neurophysiological and CSF findings were indicative of acute inflammatory demyelinating polyneuropathy, thus both patients were initially treated with intravenous immunoglobulins resulting in clinical improvement. Nevertheless, the first patient relapsed 5Â weeks after the initial episode, thus was diagnosed with GBS with treatment related fluctuations (GBS-TRF) and treated successfully with seven plasma exchange (PLEX) sessions. However, 11Â weeks from symptom onset she relapsed again. Taking into account that the second relapse occurred more than 8Â weeks after the first episode, the potential diagnosis of A-CIDP was reached and oral dexamethasone 40Â mg/d for 4 consecutive days every 4Â weeks was administered. With regards to the second patient, he relapsedâ€‰>â€‰8Â weeks after the initial episode, thus was also diagnosed with A-CIDP and treated with 7 PLEX sessions followed by similar to the aforementioned corticosteroid therapy. On 2Â month follow-up both patients exhibited remarkable clinical improvement. CONCLUSIONS: Close surveillance of patients presenting with immune neuropathies in the context of SARS-CoV-2 infection or immunization is crucial for timely implementation of appropriate treatment. Prompt A-CIDP distinction from GBS-TRF is of paramount importance as treatment approach and prognosis between

these two entities differ. SUPPLEMENTARY INFORMATION: The online version contains supplementary material available at 10.1186/s41983-022-00515-4.

Vaccine-induced immune thrombotic thrombocytopenia and patients with cancer. Vaccines to combat SARS-CoV-2 infection and the COVID-19 pandemic were quickly developed due to significant and combined efforts by the scientific community, government agencies, and private sector pharmaceutical and biotechnology companies. Following vaccine development, which took less than a year to accomplish, randomized placebo controlled clinical trials enrolled almost 100,000 people, demonstrating efficacy and no major safety signals. Vaccination programs were started, but shortly thereafter a small number of patients with a constellation of findings including thrombosis in unusual locations, thrombocytopenia, elevated D-dimer and often low fibrinogen led another intense and concentrated scientific effort to understand this syndrome. It was recognized that this occurred within a short time following administration of adenoviral vector SARS-CoV-2 vaccines. Critical to the rapid understanding of this syndrome was prompt communication among clinicians and scientists and exchange of knowledge. Now known as vaccine-induced immune thrombotic thrombocytopenia syndrome (VITT), progress has been made in understanding the pathophysiology of the syndrome, with the development of diagnostic criteria, and most importantly therapeutic strategies needed to effectively treat this rare complication of adenoviral vector vaccination. This review will focus on the current understanding of the pathophysiology of VITT, the findings that affected patients present with, and the rational for therapies, including for patients with cancer, as prompt recognition, diagnosis, and treatment of this syndrome has resulted in a dramatic decrease in associated mortality.

COVID-19 associated coagulopathy and thrombosis in cancer. Cancer patients are at risk for a more severe COVID-19 infection as well as an adverse outcome of such infection. This may be caused by the cancer itself (e.g haematological malignancies and lung cancer) or due to immune suppression caused by anti-cancer treatment. Severe COVID-19 infections are often complicated by a coagulopathy that clinically results in a high incidence of venous thromboembolic disease. Cancer itself is associated with a hypercoagulable state and a markedly increased incidence of thromboembolic complications, hence the combination of cancer and COVID-19 may amplify this risk. COVID-19 vaccination seems safe and effective in most cancer patients although adapted and bespoke vaccination schemes may increase the seroconversion rate and immune response in selected patients. Specific management strategies to improve outcomes of cancer patients in COVID-19 (e.g. higher intensity antithrombotic prophylaxis) are lacking and should be evaluated in clinical studies simultaneously focusing on efficacy and safety.

Immunogenicity and Safety of the SpikevaxÂ® (Moderna) mRNA SARS-CoV-2 Vaccine in Patients with Primary Humoral Immunodeficiency. INTRODUCTION: Reports on the immunogenicity and efficacy of the SpikevaxÂ® vaccine against SARS-CoV-2 in immunodeficient patients are still scarce. We aimed to evaluate the safety and immunogenicity of the vaccine in patients with primary humoral immunodeficiency. METHODS: We enrolled 46 patients, including 34 patients with common variable immunodeficiency (CVID), 10 patients with unclassified hypogammaglobulinemia (HypoIg), and 2 patients with X-linked agammaglobulinemia. We collected the blood samples before vaccination (D 0), and 10 days (D +38) and 90 days (D +118) after the second vaccination. Further, we quantified SARS-CoV-2-specific T-cell response (QuantiFERON ELISA test), serum anti-RBD IgG, and anti-RBD IgA-specific antibodies (enzyme immunoassay). RESULTS: We found that the vaccination elicited predominantly mild adverse events, comparable to healthy population. Vaccination response negatively correlated with a value of Immune Deficiency and Dysregulation Activity in all measured parameters. D +38, seroconversion for anti-RBD IgG and anti-RBD IgA was observed in 65% and 21% CVID patients, respectively. SARS-CoV-2-specific T-cell response was detected in less than 50% of

CVID patients. Meanwhile, HypoIg patients had 100%, 90%, and 60% positivity rates for anti-RBD IgG, anti-RBD IgA, and T-cell response, respectively. Three months after the second vaccination, 82% of the responders remained positive for anti-RBD IgG, but only less than 50% remained positive for T-cell activity in CVIDs. Low immunogenicity was observed in patients with lung involvement and/or rituximab treatment history. No SARS-CoV-2 infection was reported within 6 months after the second vaccination. CONCLUSION: SpikevaxÂ® seems to be safe with satisfactory immunogenicity in patients with primary humoral immunodeficiency.

Two Cases of Acute Myocarditis in Young Male Adults After mRNA Vaccines Against COVID-19: Similarities and Differences. BACKGROUND: The advent of the new coronavirus SARS-CoV-2 has created unprecedented situations, both in terms of health and socio-economic level, worldwide. The emergence of vaccines against this highly contagious virus has raised hopes for its effective inhibition. The efficacy of vaccines, in more than a year of their application in clinical practice, is indisputable, both in terms of reducing serious hospitalizations and deaths, especially in high-risk populations. As with any new medication, the quest and investigation for side effects are reasonable. Myocarditis is one of the extremely rare side effects reported in mRNA vaccines, especially in young males. CASE PRESENTATION: We present two cases of myocarditis that occurred in our hospital in a short time between them and compare them point by point to identify similarities and differences in order to draw conclusions about the severity of this side effect and its outcome. CONCLUSION: The benefits of vaccination against Covid-19 outweigh possible untoward effects and especially myocarditis. Health workers must close monitor the vaccinated patients for possible future cardiovascular complications.

Shoulder Injury Related to Vaccine Administration Following Misplaced SARS-CoV-2 Vaccination: A Case Report and Review of Literature. INTRODUCTION: To confront the SARS-CoV-2 pandemic, a large share of the population must be immunized. Intramuscular vaccination of the shoulder is the preferred technique as it is easily exposed and guarantees a good immune reaction. Local side effects, such as pain and swelling, are common after deltoid inoculation. They usually resolve within 3 days. Shoulder injury related to vaccine administration (SIRVA) should be considered if the symptoms persist. The aim of this presentation is to describe a typical case of SIRVA after SARS-CoV-2 vaccination and provide information to the general orthopedic surgeon to properly diagnose, report, and treat these cases. CASE REPORT: A 69-year-old female health-care professional without history of shoulder pain consulted the senior author for persistent severe left shoulder pain 3 months following the second dose of Sputnik V COVID-19 vaccination. She claimed an improper application technique that caused immediate pain and loss of active range of motion (ROM). She underwent medical treatment with several doctors during 3 months with poor results. A magnetic resonance imaging (MRI) of the left shoulder done 5 days after vaccination showed mild subacromial-subdeltoid bursitis. A follow-up MRI at 2 months after application revealed synovial hypertrophy and distention of the subacromial-subdeltoid bursa. We prescribed a dose of depot betamethasone and home-based program of gentle exercises. Although initial response was quick, the patient required shoulder arthroscopy the following months, due to persistence in pain and functional limitations. CONCLUSION: SIRVA cases may occur and should be suspected in all individuals without a history of shoulder symptoms or dysfunction who experience sudden pain and reduced ROM following deltoid muscle vaccination. Treatment must be initiated early with corticosteroids and rehabilitation. The low probability of this complication does not outweigh the advantages of vaccination.

[Heparin-induced thrombocytopenia and vaccine-induced immune thrombotic thrombocytopenia: novel insights on anti-platelet factor 4 antibodies]. The levels of anti-platelet factor 4 (PF4) antibodies, also known as anti-PF4 or heparin complex antibodies, are used to diagnose heparin-induced thrombocytopenia (HIT). In HIT, anti-PF4 antibodies induced by heparin exposure cause thrombocytopenia and thrombosis. However, anti-PF4 antibodies were recently reported to be

associated with the development of fatal vaccine-induced immune thrombotic thrombocytopenia (VITT) after adenoviral vector vaccination for coronavirus disease 2019. HIT and VITT are caused by anti-PF4 antibodies and have similar pathological conditions. However, the severity of these conditions differs and the detection sensitivity of their antibodies varies depending on the assays used. Herein, we review HIT and VITT associated with anti-PF4 antibodies.

[COVID-19 vaccination for allogeneic hematopoietic stem cell recipients]. The novel coronavirus disease 2019 (COVID-19) is caused by acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Hematopoietic stem cell transplant (HSCT) recipients are at increased risk of mortality and morbidity with COVID-19 due to severe immune dysfunction. Recombinant adenovirus vector-based vaccine, such as AstraZeneca ChAdOx1, and mRNA-based vaccines, such as Pfizer BNT162b2 and Moderna mRNA-1273 have been used in Japan. COVID-19 vaccine administration to HSCT recipients was reported to result in a 68-96.5% seroconversion for the spike protein. Factors associated with the absence of humoral responses were the time-interval from HSCT to vaccination, absolute lymphocyte count, systemic immunosuppressive treatments, graft versus host disease (GVHD), B-cell count, and hypogammaglobulinemia. New onset and exacerbation of chronic GVHD have been reported as an adverse events associated with vaccination. COVID-19 vaccination of HSCT recipients is relatively safe, and recipients should be vaccinated against COVID-19 6 months after transplantation. In the future, it is necessary to consider passive immunotherapy for HSCT patients who do not benefit from COVID1-19 vaccination.

Antineutrophil Cytoplasmic Antibody-associated Vasculitis after COVID-19 Vaccination with Pfizer-BioNTech. The extent of rare side effects of mRNA vaccines for coronavirus disease 2019 (COVID-19) remains unclear. Several cases of antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) following COVID-19 vaccination have been reported. We herein report a 72-year-old man who presented with a fever after receiving the second dose of the Pfizer-BioNTech COVID-19 vaccine. He was diagnosed with acute kidney injury due to myeloperoxidase-ANCA-associated vasculitis and was treated with intermittent hemodialysis, high-dose prednisolone, and intravenous rituximab. His general symptoms and renal impairment subsequently improved. When systemic symptoms are prolonged or renal abnormalities appear after COVID-19 vaccination, the possibility of AAV should be considered.

Reactogenicity of the BNT162b2 mRNA vaccine (Pfizer-BioNTech) against COVID-19 in workers of a tertiary hospital. OBJECTIVE: To analyze the local and systemic reactions that appearedÂ after the first and second dose of the BNT162b2 vaccine againstÂ COVIDâ€‘19 (Pfizer- BioNTech) in a sample of workers from a tertiary hospital,Â and to identify theÂ factors related to greater vaccine reactogenicity. METHOD: A self-administered questionnaire was used to interviewÂ 291 workersÂ from a tertiary hospital who received the BNT162b2 vaccineÂ against COVID-19Â between January and March 2021. The questionnaireÂ included questions aboutÂ the sociodemographic variables of the participants,Â previous COVID-19Â infection, and local and systemic reactions afterÂ the first and second dose ofÂ the vaccine. RESULTS: The most common adverse reaction was soreness at the injectionÂ site, which was reported more frequently after the first dose of theÂ Â vaccine. The systemic reactions evaluated were reported more frequentlyÂ after the second dose of the vaccine. Women, younger adults, andÂ subjectsÂ with a prior COVID-19 infection reported increased reactogenicity.Â Furthermore, high reactogenicity after the first dose was foundÂ to be relatedÂ to a higher number of adverse reactions after the second dose ofÂ theÂ vaccine. CONCLUSIONS: The distribution of reactogenicity in the present study isÂ consistent with the data reported in previous studies on the BNT162b2Â vaccine, especially in terms of its association with the participants'Â characteristics. These findings could facilitate the

identification of people at aÂ higher risk of developing high reactogenicity to the vaccine, thereby making itÂ possible to anticipate the appearance of adverse reactions and plan for theirÂ treatment.
Bilateral adrenal haemorrhage with renal infarction after ChAdOx1 nCoV-19 AstraZeneca vaccination. Vaccine-induced thrombotic thrombocytopaenia (VITT) is a rare syndrome associated with the ChAdOx1 nCoV-19 (AstraZeneca) vaccine. We detail a case of vaccine-induced thrombotic thrombocytopaenia in a 47-year-old female who was found to have bilateral adrenal haemorrhage, renal vein thrombosis, renal infarction and pulmonary embolism 13 days post-vaccination with ChAdOx1 nCoV-19.
[Cerebral venous thrombosis associated with COVID-19]. The literature reports that cerebral venous thrombosis (CVT) develops in 1-1.5% of patients with COVID-19. Recently, a new syndrome named vaccine-induced immune thrombotic thrombocytopenia (VITT) has been described. VITT is a rare side-effect of COVID-19 vaccination that also causes CVT. The article presents an overview of the above problem and a clinical case of a patient with CVT that developed within a month after the first component of the Sputnik V vaccination and COVID-19.
Presumed Autoimmune Optic Neuropathy After Pfizer-BioNTech (BNT162b2) COVID-19 Vaccine.
Bilateral Optic Neuropathy After First Dose of COVID-19 Vaccine.
A probable case of vaccine-induced immune thrombotic thrombocytopenia secondary to Pfizer Comirnaty COVID-19 vaccine. The accelerated development of various vaccines against COVID-19 was a global effort to curb the COVID-19 pandemic. As a result, several unique vaccine-related adverse events were observed. Vaccine-induced immune thrombotic thrombocytopenia (VITT) has been recognised as a clinically distinct entity with a predisposition for thrombosis at unusual sites with laboratory features of consumptive coagulopathy in addition to anti-PF4 assay seropositivity. The majority of cases reported were associated with adenoviral-based vectors such as ChAdOx1 nCoV-19 (Oxford-AstraZeneca) and Janssen Ad26.COV2.S (Johnson & Johnson). In our online search, we have not found any reports to date of VITT associated with Pfizer-BioNTech Comirnaty mRNA vaccine. We report a case of a previously healthy 76-year-old man who received his first-dose Pfizer Comirnaty vaccine on 11 October 2021 who developed left upper limb swelling on day 2 post-vaccination, which progressively worsened on day 4 post-vaccination. He was confirmed to have left axillary vein thrombosis on computer tomography arteriography/computed tomography venography of left upper limb on day 5 post-vaccination with new onset aphasia with unilateral limb weakness on day 8 post-vaccination. Magnetic resonance imaging/magnetic resonance angiography of the brain confirmed acute left middle cerebral artery thrombosis with infarction. Blood investigations showed thrombocytopenia, elevated D-dimer, hypofibrinogenemia in addition to his unusual sites of thrombosis involving both arterial and venous circulation. His IgG ELISA assay for anti-PF4 antibody was positive.
Guillain-Barre syndrome related to SARS-CoV-2 vaccinations.
Healthcare professionals & adverse events of ChAdOx1 nCoV-19 coronavirus vaccine.
Antibody profile in post-vaccinated & SARS-CoV-2 infected individuals. BACKGROUND & OBJECTIVES: During the COVID-19 pandemic it was important to assess the antibody profile in individuals vaccinated with Covaxin (BBV152) and Covishield (ChAdOx1 nCoV-19) with both 28 and 84 days gaps between two doses, those infected with SARS-CoV-2 and post-COVID-19-infected individuals vaccinated with only one dose of either of the vaccines. The present study was aimed to assess these objectives. METHODS: Fifty real time reverse transcription-polymerase chain reaction (qRT-PCR)-confirmed COVID-19-infected individuals, along with 90 COVID-19-naÃ¯ve (BBV152 and ChAdOx1 nCov-19)-vaccinated individuals, were included in the study. Individuals who received a single dose of either vaccine with a confirmed past diagnosis of SARS-CoV-2 infection (n=15) were also included. Blood samples were collected strictly between the 4(th) and 5(th) wk after

development of symptoms for SARS-CoV-2 infected individuals and after the first/second vaccination dose. Antibody profile assessment was done using whole-virus, spike-receptor binding domain (RBD) and nucleocapsid-specific ELISA kits along with neutralizing antibody kit. RESULTS: There was an overall 97.7 per cent seropositivity rate in vaccinated individuals, and a strong correlation (R(2)=0.8, P<0.001) between neutralizing and spike-RBD antibodies. Among individuals who received two standard doses of ChAdOx1 nCoV-19 vaccine, the spike antibody levels developed were of higher titre with a longer prime boost interval than in those with shorter intervals (P<0.01). Individuals vaccinated with two doses as well as only one dose post-SARS-CoV-2 infection had high neutralizing and spike-specific antibodies. INTERPRETATION & CONCLUSIONS: High neutralizing and spike-specific antibodies were developed in individuals vaccinated only with one dose of either vaccine post-SARS-CoV-2 infection. With the main priority being vaccinating majority of the population in our country, single-dose administration to such individuals would be a sensible way to make the most of the limited supplies. Furthermore, neutralizing antibody levels observed in COVID-19-naÃ¯ve vaccinees imply the need for booster vaccination.

Multiple sites of thrombosis without thrombocytopenia after a second dose of Pfizer-BioNTech COVID-19 vaccine. In the current international scientific panorama, rare cases of venous thrombotic complications following mRNA vaccine administration have been reported, consisting mainly of cerebral sinus thromboses and acute venous thromboembolism. The present paper describes the case of a 75-year-old woman in good health who developed cerebral venous thrombosis, deep venous thrombosis, and bilateral pulmonary emboli after receiving a second dose of Pfizer-BioNTech COVID-19 vaccine. A series of laboratory tests performed during hospitalization yielded interesting results, allowing us to exclude thrombophilic risk factors and to certify the absence of thrombocytopenia in the patient. Although COVID-19 vaccination is the most important tool in stopping the pandemic, pharmacovigilance is crucial for detecting potential multisystem thrombotic events, even for mRNA vaccines.

Neurological Complications of SARS-CoV-2 Infection and COVID-19 Vaccines: From Molecular Mechanisms to Clinical Manifestations. Coronavirus Disease 2019 (COVID-19) is an infectious disease, caused by the Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), that reached pandemic proportions in 2020. Despite the fact that it was initially characterized by pneumonia and acute respiratory distress syndrome, it is now clear that the nervous system is also compromised in one third of these patients. Indeed, a significant proportion of COVID-19 patients suffer nervous system damage via a plethora of mechanisms including hypoxia, coagulopathy, immune response to the virus, and the direct effect of SARS-CoV-2 on endothelial cells, neurons, astrocytes, pericytes and microglia. Additionally, a low number of previously healthy individuals develop a variety of neurological complications after receiving COVID-19 vaccines and a large proportion of COVID-19 survivors experience longlasting neuropsychiatric symptoms. In conclusion, COVID-19 is also a neurological disease, and the direct and indirect effects of the virus on the nervous system have a significant impact on the morbidity and mortality of these patients. Here we will use the concept of the neurovascular unit, assembled by endothelial cells, basement membrane, perivascular astrocytes, neurons and microglia, to review the effects of SARS-CoV-2 in the nervous system. We will then use this information to review data published to this date on the neurological manifestations of COVID-19, the post- COVID syndrome and COVID-19 vaccines.

Persisting, unilateral tinnitus 22 days after first dose of an mRNA-based SARS-CoV-2 vaccine. OBJECTIVES: Although vaccination with vector-based or mRNA-based SARS-CoV-2 vaccines is usually well tolerated, they are not free of side effects. Some of these side effects can be severe and concern the primary care physician, otorhinolaryngologist, and the neurologist. Persisting, unilateral tinnitus time-linked to the first dose and worsening after the second dose of an mRNA-based SARS-CoV-2

vaccine has not been reported. STUDY DESIGN: Case report. METHODS: Routine tests were applied to investigate the patient. RESULTS: A 35-year-old male experienced sudden onset of right-sided tinnitus, diffuse headache, and ear respectively facial pressure 22 days after the first dose of an mRNA-based SARS-CoV-2 vaccine. Since symptoms worsened after the second dose, 28 days later, the patient started a self-medication with non-steroidal anti-inflammatory drugs, without benefit. After an otolaryngologist suspected Meniere's disease, prednisone was given for 5 days with significant improvement. After discontinuation of steroids, however, previous symptoms recurred with similar intensity as before. Cetirizin and loratadin were started resulting in complete resolution of headache and pressures but persistence of tinnitus. After exclusion of various differentials, a causal relation between clinical presentation and vaccination was suspected. CONCLUSIONS: SARS-CoV-2 vaccination can be followed by unilateral persisting tinnitus, headache, and ear respectively facial pressure. Since steroids and anti-histamines had a beneficial effect, an immunological pathophysiology is quite likely.

Acceptance and adverse effects following COVID-19 vaccination among the health care workers at a health care centre in the most backward district of India. BACKGROUND: Coronavirus disease 2019 (COVID-19) was declared as a pandemic by the World Health Organization (WHO) on March 11, 2020. Researchers have evaluated many repurposed drugs for treating COVID-19 in terms of both efficacy and safety in the past several months. It has been seen that vaccination is an effective way to stop the pandemic from spreading further. Being frontline workers dealing with COVID-19 patients, the healthcare workers (HCWs) in public and private sectors were prioritized to get vaccinated first. Also, HCWs are a reliable source of information on vaccination to patients; therefore, their acceptance or otherwise of COVID-19 vaccines may influence the uptake of COVID-19 vaccine among the general population. METHODOLOGY: A cross-sectional study was conducted to assess the acceptance and adverse effects following the first dose of COVID-19 vaccine among HCWs of Shaheed Hasan Khan Mewati Government Medical College (SHKM GMC), a tertiary healthcare centre located in the district of Nuh Haryana. RESULT: In our study, more than half of the respondents (63.8%) experienced mild-moderate anxiety while the rest of the respondents experienced mild anxiety or moderately high levels of anxiety prior to the first dose, which is indicative of hesitancy towards the vaccine. Two-thirds of respondents in our study reported mild and common symptoms following vaccination while the remaining one-third did not report any symptom. More than half of the respondents (67.3%) claimed not taking the first dose even after two months after the initiation of vaccination drive at SHKM GMC, stating fear of some kind of reaction or side-effects, safety concerns regarding vaccine, reservations concerning the success of vaccination, and the efficiency of the vaccine. CONCLUSION: Our findings highlighted reasons for hesitancy among HCWs regarding COVID-19 vaccination along with the adverse effects encountered after the first dose. COVID-19 vaccine concerns among the HCW population should be addressed so that HCWs can be empowered to lead communication campaigns to improve COVID-19 vaccine uptake among the general population. Thus, it is important to hold such surveys.

SARS-CoV-2 neutralizing antibody response after three doses of mRNA1273 vaccine and COVID-19 in hemodialysis patients. BACKGROUND: In hemodialysis patients, a third vaccination is frequently administered to augment protection against coronavirus disease 2019 (COVID-19). However, the newly emerged B.1.1.159 (Omicron) variant may evade vaccinal protection more easily than previous strains. It is of clinical interest to better understand the neutralizing activity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants after booster vaccine or COVID-19 infection in these mostly immunocompromised patients. METHODS: Hemodialysis patients from four dialysis centers were recruited between June 2021 and February 2022. Each patient provided a median of six serum samples. SARS-CoV-2 neutralizing antibodies (nAbs) against wild type (WT) or

Omicron were measured using the GenScript SARS-CoV-2 Surrogate Virus Neutralization Test Kit. RESULTS: Forty-two patients had three doses of mRNA1273. Compared to levels prior to the third dose, nAb-WT increased 18-fold (peak at day 23) and nAb-Omicron increased 23-fold (peak at day 24) after the third dose. Peak nAb-WT exceeded peak nAb-Omicron 27-fold. Twenty-one patients had COVID-19 between December 24, 2021, and February 2, 2022. Following COVID-19, nAb-WT and nAb-Omicron increased 12- and 40-fold, respectively. While levels of vaccinal and post-COVID nAb-WT were comparable, post-COVID nAb-Omicron levels were 3.2 higher than the respective peak vaccinal nAb-Omicron. Four immunocompromised patients having reasons other than end-stage kidney disease have very low to no nAb after the third dose or COVID-19. CONCLUSIONS: Our results suggest that most hemodialysis patients have a strong humoral response to the third dose of vaccination and an even stronger post-COVID-19 humoral response. Nevertheless, nAb levels clearly decay over time. These findings may inform ongoing discussions regarding a fourth vaccination in hemodialysis patients.
Spectrum of Mucocutaneous Reactions to COVID-19 Vaccination: A Report from a Web-Based Study from India. BACKGROUND: With the COVID-19 vaccination taking stride all across the globe, there are multiple reports of vaccine-induced adverse reactions (cutaneous and systemic). OBJECTIVES: To study the frequency and characteristics of mucocutaneous reactions to COVID-19 vaccines. METHODS: An online questionnaire-based study was performed among the recipients of COVID-19 vaccines. RESULTS: Majority (73.6%) of the responders had received the Covishield vaccine (AstraZeneca-Oxford), while 26.4% had been vaccinated with Covaxin (Bharat Biotech-ICMR). One or more post-vaccination mucocutaneous effects were experienced in 87 (19.6%) participants. Vaccine-associated mucocutaneous changes were observed in 19.7% and 22.2% of individuals who received Covishield and Covaxin, respectively. Local injection site reaction was the predominant mucocutaneous finding, followed by urticarial rash, exacerbation of preexisting dermatoses, morbilliform rash, apthous ulcers, pityriasis rosea like eruption, telogen effluvium, herpes zoster, purpuric rash, erythema multiforme and others. Anaphylaxis was reported in three individuals. However, fatality was not reported in any of the vaccine recipients. Intergroup assessment of parameters with respect to type of vaccine was found to be insignificant. CONCLUSION: Majority reported mild and self-limiting reactions. This outcome should not discourage the common man in getting vaccinated.
A case of coronavirus disease 2019 vaccine-related myocarditis with late gadolinium enhancement on cardiac magnetic resonance imaging persisting over acute phase.
Pemphigus foliaceous after mRNA COVID-19 vaccine.
Disseminated herpes zoster following inactivated SARS-CoV-2 vaccine in a healthy old man.
Psoriatic arthritis flare-up after a second dose of BNT162b2 COVID-19 mRNA vaccine.
Myocarditis and myopericarditis cases following COVID-19 mRNA vaccines administered to 12-17-year olds in Victoria, Australia. IMPORTANCE: COVID-19 mRNA vaccine-associated myocarditis has previously been described; however specific features in the adolescent population are currently not well understood. OBJECTIVE: To describe myocarditis adverse events following immunisation reported following any COVID-19 mRNA vaccines in the adolescent population in Victoria, Australia. DESIGN: Statewide, population-based study. SETTING: Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) is the vaccine-safety service for Victoria, Australia. PARTICIPANTS: All SAEFVIC reports of myocarditis and myopericarditis in 12-17-year-old COVID-19 mRNA vaccinees submitted between 22 February 2021 and 22 February 2022, as well as accompanying diagnostic investigation results where available, were assessed using Brighton Collaboration criteria for diagnostic certainty. EXPOSURES: Any mRNA COVID-19 vaccine. MAIN OUTCOMES/MMEASURE: Confirmed myocarditis as per Brighton Collaboration criteria (levels 1-3).

RESULTS: Clinical review demonstrated definitive (Brighton level 1) or probable (level 2) diagnoses in 75 cases. Confirmed myocarditis reporting rates were 8.3 per 100â€‰000 doses in this age group. Cases were predominantly male (n=62, 82.7%) and post dose 2 (n=61, 81.3%). Rates peaked in the 16-17-year-old age group and were higher in males than females (17.7â€‰vs 3.9 per 100 000, p=<0.001).The most common presenting symptoms were chest pain, dyspnoea and palpitations. A large majority of cases who had a cardiac MRI had abnormalities (n=33, 91.7%). Females were more likely to have ongoing clinical symptoms at 1-month follow-up (p=0.02). CONCLUSION: Accurate evaluation and confirmation of episodes of COVID-19 mRNA vaccine-associated myocarditis enabled understanding of clinical phenotypes in the adolescent age group. Any potential vaccination and safety surveillance policies needs to consider age and gender differences.

Frequency and intensity of [(18)F]-PSMA-1007 uptake after COVID-19 vaccination in clinical PET. OBJECTIVES: To assess the frequency and intensity of [(18)F]-prostate-specific membrane antigen (PSMA)-1007 axillary uptake in lymph nodes ipsilateral to COVID-19 vaccination with BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna) in patients with prostate cancer referred for oncological [(18)F]-PSMA positron emission tomography (PET)/CT or PET/MR imaging. METHODS: 126 patients undergoing [(18)F]-PSMA PET/CT or PET/MR imaging were retrospectively included. [(18)F]-PSMA activity (maximum standardized uptake value) of ipsilateral axillary lymph nodes was measured and compared with the non-vaccinated contralateral side and with a non-vaccinated negative control group. [(18)F]-PSMA active lymph node metastases were measured to serve as quantitative reference. RESULTS: There was a significant difference in maximum standardized uptake value in ipsilateral and compared to contralateral axillary lymph nodes in the vaccination group ($n = 63$, $p < 0.001$) and no such difference in the non-vaccinated control group ($n = 63$, $p = 0.379$). Vaccinated patients showed mildly increased axillary lymph node [(18)F]-PSMA uptake as compared to non-vaccinated patients ($p = 0.03$). [(18)F]-PSMA activity of of lymph node metastases was significantly higher ($p < 0.001$) compared to axillary lymph nodes of vaccinated patients. CONCLUSION: Our data suggest mildly increased [(18)F]-PSMA uptake after COVID-19 vaccination in ipsilateral axillary lymph nodes. However, given the significantly higher [(18)F]-PSMA uptake of prostatic lymph node metastases compared to "reactive" nodes after COVID-19 vaccination, no therapeutic and diagnostic dilemma is to be expected. ADVANCES IN KNOWLEDGE: No specific preparations or precautions (e.g. adaption of vaccination scheduling) need to be undertaken in patients undergoing [(18)F]-PSMA PET imaging after COVID-19 vaccination.

Hesitation of the Tunisian population to COVID-19 vaccination, and its associated factors. BACKGROUND: Many people are reluctant to be vaccinated against COVID-19. AIM: To determine the intention to accept COVID19 vaccine and its associated factors among Tunisians. METHODS: We conducted a cross-sectional study among Tunisians from December 2020 to January 2021 using an online questionnaire. Factors associated with intention to accept coronavirus vaccine were analysed using multinomial logistic regression. RESULTS: In total, 169 Tunisians participated in our study. The majority were female (85.2%). The mean age was 48.3 Â± 11.8 years. Only 33.1% intended to accept to be vaccinated when COVID-19 vaccine will be available in Tunisia and 22.5% were still hesitant. In multinomial logistic regression, participants having high or very high perceived personal risk of COVID-19 infection (aOR: 3.257, 95% CI : 1.204 - 8.815) were more prone to hesitate to accept COVID-19 vaccine rather than those being willing to accept it. Respondents undergoing seasonal influenza vaccination (aOR: 0.091, 95% CI : 0.019 - 0.433) were less prone to refuse COVID-19 vaccine rather than those being willing to accept it. Young ones aged less than 40 years (aOR: 4.324, 95% CI: 1.180 - 15.843) were more prone to refuse COVID-19 vaccine rather than those being willing to accept it. CONCLUSION: The acceptance rate of coronavirus vaccination was moderate. Therefore, a good communication and health education at a community level are needed.

Understanding Questions and Concerns Regarding COVID-19 and the COVID-19 Vaccine Among Populations Presenting at a COVID-19 Vaccine Clinic Hub: A Qualitative Study. BACKGROUND: Skepticism among the public surrounding the COVID-19 vaccine is still prevalent despite vaccine-positive communication and many Americans having already received the vaccine. Side effects of the vaccine, as well as its expeditious research and development, are among the top concerns among those hesitant to receive the coronavirus vaccine. Moreover, there is additional concern regarding the association between comorbidities and severity of illness due to the coronavirus pandemic. OBJECTIVE: We aimed to describe the pandemic- and vaccine-related concerns of South Texas residents who attended the UT Health San Antonio School of Nursing's vaccine clinic with the goal of better understanding vaccine-related misconceptions and hesitancy for subsequent vaccination campaigns and boosters. METHODS: An electronic survey accessible via a QR code on printed flyers was distributed throughout the waiting areas and post-vaccine observation rooms within the COVID-19 vaccine clinic at UT Health San Antonio School of Nursing from April 5 to 16, 2021. The survey contained a primary open-ended question designed to obtain information on concerns of the clinic attendees regarding the COVID-19 pandemic and COVID-19 vaccine. A thematic analysis was performed on the qualitative data to identify major themes to better understand concerns of vaccine clinic visitors. RESULTS: During the 11-day period, 510 attendees received vaccinations through the vaccination clinic and completed the survey. Five areas of concern were identified by the 277 attendees: immunity, future vaccinations, vaccine symptoms and safety, protocol post-vaccination, and child vaccinations. Post-hoc sentiment analysis showed that responses were generally neutral or negative. CONCLUSION: This study provides a perspective regarding questions and concerns of South Texas residents regarding the COVID-19 pandemic, the vaccine, and their general health status within a vaccinated population. Vaccine recipients were found to still have questions even after receiving the vaccine, suggesting that eliminating uncertainty surrounding the COVID-19 vaccine is not necessary to motivate individuals to receive the vaccine. Instead, addressing concerns through public health messaging could be a useful strategy to address vaccine-related concerns and increase subsequent vaccine uptake in future vaccination campaigns and boosters.

Rhabdomyolysis after BNT162b2 mRNA Covid-19 vaccine in an adolescent male. Pfizer-BioNTech COVID-19 (BNT162b2) conferred a high level of protection against Covid-19 with a proven short-term safety profile. Although cases of vaccine-associated myopericarditis have been reported, the existence of rhabdomyolysis without myocarditis has not yet been published. A 16-year-old, healthy male patient, who did not use any herbal or illegal drugs before, was admitted with muscle pain that developed after the second dose of BNT162b2 vaccine. Cardiac examination and heart enzymes were normal and the patient had significantly higher creatinine kinase levels. The patient, whose enzymes returned to normal with only force hydration therapy, recovered without complications. Reporting the side effects of the vaccine, which has a short history of application to large populations, is of vital importance in the conduct of vaccine development studies and in identifying the risky group in terms of side effects.

Acquired hemophilia A after vaccination against SARS-CoV-2 with the mRNA-1273 (Moderna) vaccine. Acquired hemophilia A is a rare bleeding diathesis most typically seen in systemic rheumatic disease, solid and hematologic malignancies, and pregnancy. We present a case of this condition that occurred immediately after vaccination against SARS-CoV-2 with the mRNA-1273 (Moderna) vaccine.

A case of Guillain-Barre syndrome after the second dose of AstraZeneca COVID-19 vaccination. Coronavirus disease 2019 (COVID-19) is a novel virus that primarily involves the respiratory system. Due to the COVID-19 pandemic, an extensive vaccination program is underway worldwide. Herein, we present a 68-year-old woman with paresthesia of both hands associated with gait instability, which started three to four days after receiving the second dose of Oxford/AstraZeneca vaccine

against the COVID-19 infection. The acute inflammatory demyelinating polyradiculoneuropathy subtype of the Guillain-Barre syndrome, which is the most common subtype, was diagnosed. Regardless of the beneficial effects of the vaccines, this case report aimed to evaluate their severe complications, such as Guillain-Barre syndrome, to reduce their occurrence in the future.

COVID-19 vaccination and cardiac dysfunction. The coronavirus disease 2019 (COVID-19) mRNA vaccine against severe acute respiratory syndrome coronavirus 2 infections has reduced the number of symptomatic patients globally. A case series of vaccine-related myocarditis or pericarditis has been published with extensive vaccination, most notably in teenagers and young adults. Men seem to be impacted more often, and symptoms commonly occur within 1 wk after immunization. The clinical course is mild in the majority of cases. Based on the evidence, a clinical framework to guide physicians to examine, analyze, identify, and report suspected and confirmed cardiac dysfunction cases is needed. A standardized workup for every patient with strongly suspicious symptoms associated with the COVID-19 mRNA vaccine comprises serum cardiac troponin measurement and a 12-lead electrocardiogram (ECG). For patients with unexplained elevation of cardiac troponin and pathologic ECG, echocardiography is recommended. Consultation with a cardiovascular expert and hospitalization should be considered in this group of patients. Treatment is primarily symptomatic and supportive. Deferring a 2(nd) dose of the COVID-19 mRNA vaccination in individuals with suspected myocarditis or pericarditis after the 1(st) dose is suggested until further safety data become available.

Community voices around COVID-19 vaccine in Chennai, India: A qualitative exploration during early phase of vaccine rollout. BACKGROUND & OBJECTIVES: Globally, vaccination is considered as an important public health strategy to mitigate the impact of the COVID-19 pandemic. The purpose of the current study was to conduct an in-depth inquiry to explore perceptions of community members around COVID-19 vaccines in the southern city of Chennai, Tamil Nadu. This was conducted during the early phase of the vaccine rollout programme in India. METHODS: A qualitative investigation was conducted between January-February 2021 through in-depth interviews. Healthcare workers, religious leaders, community influencers, local administrators and representatives of marginalized communities were included. The key informant interview guides and probes explored five domains; (i) vaccine availability, (ii) trust in COVID-19 vaccines, (iii) vaccine-related concerns, (iv) health/risk balance and (v) vaccine prioritization. Transcripted interviews were coded using a thematic approach and analyzed manually as well as with the help of ATLAS.ti 9 software. RESULTS: Eagerness to receive COVID-19 vaccines amongst some of the respondents was linked with freedom from fear, possible restoration of normalcy, protection of family and ability to travel and work abroad. Concerns around threat of emergence of new variants, damage caused by such viral mutants and trust in policymakers were other facilitatory influencers for vaccine uptake. On the other hand, doubts surrounding safety and fear of side effects of COVID-19 vaccine were the feeders to vaccine hesitancy. Lack of accurate information, sensational media reports and rumours exacerbated this fear and provoked anxiety among people. Apprehensions around COVID-19 vaccine in the wake of its rapid development and approval for use and reluctance to take it during the declining phase of the epidemic were identified as other inhibitory factors. Participants underlined the importance of having responsive communication strategies in place focussing on vaccine safety. Making vaccines available to people free of cost and ensuring wider access were other programmatic suggestions. INTERPRETATION & CONCLUSIONS: In conclusion, our study findings suggest that it is essential to remain engaged with communities and execute evidence-based information dissemination strategy about the safety and efficacy of the vaccines. We identified that it is also imperative to sensitize and train media professionals on how to report side effects related to vaccines. Responsive communication strategies will thus have the potential to serve as a key public health approach pertaining to future pandemic

preparedness as well as to manage the demands of clinical and public health issues in an ongoing pandemic situation.

Chronic urticaria and COVID-19 vaccination: Qatar data (preliminary report of COVAC-CU-international). BACKGROUND: It is a well-known fact that patients with chronic urticaria (CU) are not at a higher risk for a serious allergic reaction such as anaphylaxis from medications. However, there is a fear and some misconceptions regarding allergic reactions to the COVID-19 vaccine among patients and physicians, which might result in resistance to vaccination. Data about the incidence and severity of COVID-19 vaccine reactions in the CU population are scarce. In this study, we aimed to evaluate the real-world (Qatar) experience of the effects of COVID-19 vaccination on patients with CU and analyze the rates of vaccine-associated reactions and risk factors associated. METHODS: This is a cross-sectional questionnaire-based study conducted as a part of COVAC-CU international under the GALEN UCARE program. Adult patients with CU who received one or more doses of COVID-19 vaccination were administered a questionnaire regarding their demographic characteristics and any potential unfavorable effect of the vaccination from the November 03 to December 31, 2021. RESULTS: These are preliminary results from an ongoing study. The data were collected from 91 patients with CU, of whom 79.12% had chronic spontaneous urticaria, 15.3% had chronic inducible urticaria, and the remaining had both. Of these patients, 74.7% were women. The average age of the patients was 39.3 (range 15-68) years. The majority (84.6%) of them received 2 vaccine doses, 13.1% received 3 doses, and the remaining received 1 dose. Most (70.3%) of these patients did not experience any worsening in CU after vaccination. A total of 62.6% patients reported some type of side effects to the vaccine (16.4% had CU exacerbation and 46.1% other types of reactions, such as fever and muscle pain). None of the patients reported anaphylaxis. Two patients reported improvement in their symptoms. CONCLUSION: Our local data suggest that patients with CU in Qatar can safely take the COVID-19 vaccine. Most patients with CU did not experience any worsening in symptoms, and there were no reports of a severe reaction (anaphylaxis). We recommend maximizing symptom control prior to vaccination to minimize the risk of worsening urticarial symptoms.

Long follow-up of symptomatic Multiple Myeloma patients after Covid-19 vaccination (BNT162b2): A single-institution retrospective experience. Myeloma patients are at an increased risk of severe forms of Covid-19. We examined response to mRNA vaccine between myeloma patients (n.127) and healthy volunteers (n.50). Anti-spike IgG antibody were detected in 76.9% of evaluable patients. 23.1% of MM patients failed to respond at two doses of COVID-19 mRNA vaccine. Univariate analyses identified three independent adverse predictive factors of absence of immunological response to COVID-19 vaccine: extreme plasmacytosis (pÂ <Â 0.001), B2M (p 0.006), and haemoglobin (p 0.008). Multivariate analysis confirmed the extreme plasmacytosis and haemoglobin value as statistically significant variables.

LEGAL AND SOCIAL CHALLENGES OF COVID-19 VACCINATION BEFORE AND AFTER THE 2022 RUSSIAN INVASION OF UKRAINE. OBJECTIVE: The study aims to develop ways of solving the social and legal problems of vaccination against COVID-19, showing them the example of Ukraine before and after the beginning of the active phase of Russian aggression. PATIENTS AND METHODS: The study is based on international documents and legal acts adopted to combat the COVID-19 epidemic, the survey results of 165 ordinary Ukrainians on vaccination, interviewing health care organizers; statistical information, and content analysis of the media on vaccination, as well as ways of avoiding it. Dialectical, analytical-synthetic, system-structural methods, as well as methods of content analysis, questionnaires, interviews, and included observation, were used. RESULTS: Legal restrictions on the realization of personsâ€™ rights who have not been vaccinated against COVID-19 are an acceptable remedy, as they aim to protect human rights to life and health. Restrictions on the realization of labor and other rights of unvaccinated persons introduced in Ukraine have caused the following related

social-legal problems: a) negative attitude of some persons to human rightsâ€™ restrictions due to mandatory vaccination for workers, related fears of the population; c) stratification of the population according to the availability of vaccine of a particular manufacturer; d) background phenomenon in the form of imitation of vaccination with subsequent forgery of certificates. These restrictions have been lifted during the martial law, and anti-epidemic measures are recommendatory. Despite the availability of vaccinations throughout the non-occupied territory, the pace of vaccination has been significantly reduced. CONCLUSION: Ways of overcoming the adverse socio-legal problems of vaccination and related background phenomena are to conduct quality information campaigns to inform the public about the benefits and safety of vaccination, counter misinformation, increase the availability of vaccines with a choice of vaccines from different manufacturers, and increase the effectiveness of criminal legal counteraction to forgery of documents confirming vaccination. After the imposition of martial law in Ukraine, there has been a change in the focus of public attention to solving vital problems, which, along with the transfer of anti-coronavirus restrictions to the status of recommendatory, creates danger of significant reduction in vaccination.

Safety and Tolerability of mRNA COVID-19 Vaccines in Kidney Transplant Recipients. BACKGROUND: COVID-19 mRNA vaccines have demonstrated excellent short-term safety in phase 3 trials. However, no kidney transplant recipients (KTR) were included. The aim of the study was to assess the safety and tolerability of COVID-19 mRNA vaccines in KTR. MATERIALS AND METHODS: A longitudinal controlled study was conducted in 300 KTR and 143 control patients (CRL) without chronic kidney disease who had received 2-dose vaccinations with the mRNA vaccine. Solicited local and systemic reactogenicity and unsolicited adverse events were assessed with a standardized questionnaire. The toxicity grading scales were derived from the FDA guidelines. RESULTS: KTR (62.7% men) with a median (interquartile range) age of 53 (41-63) and transplant vintage of 7.25 (3-13) years did not differ with respect to age and sex distribution from CRL. One hundred percent CRL and 83.3% KTR were vaccinated with BNT162b2 (BionTech/Pfizer); 16.7% KTR received mRNA-1273 (Moderna) vaccine. Any local reactions were present in 84.7% (first dose) and 65.3% (second dose) KTR vs 67.1% and 60.1% CRL within 7 days after the vaccination. Any systemic reactions were reported by 26.7% (first dose) and 20.9% (second dose) KTR vs 24.7 and 35.7% CRL. The most common systemic reactions in KTR were fatigue, headache and myalgia. No serious adverse events were observed. Many systemic reactions were observed less frequently in KTR than CRL. Younger KTR (<54 years) reported any local and any systemic reactions significantly more frequently than older patients. CONCLUSION: mRNA COVID-19 vaccines are safe and well-tolerated by KTR. The results may resolve patients' doubts and reduce their vaccine hesitancy.

Rapid Progression of Polypoidal Choroidal Vasculopathy following Third BNT162b2 mRNA Vaccination. The study aimed to describe a case of rapid progression of polypoidal choroidal vasculopathy (PCV) following the third administration of the Pfizer-BioNTech (BNT162b2) mRNA vaccine. A 79-year-old Japanese man visited our hospital with a 1-week history of blurred vision in the left eye 16 h following the administration of the third BNT162b2 mRNA vaccine. The clinical examinations and imaging tests revealed massive submacular hemorrhage (SMH) and excessive subretinal fluid (SRF), owing to PCV in the left eye. No ocular abnormality was observed in the right eye. His medical history included diabetes and ocular history included cataracts, nonproliferative diabetic retinopathy, glaucoma in both eyes, and irregular retinal pigment epithelium elevation in the left eye. Since he received a single intravitreal injection of aflibercept approximately 2 years ago for the treatment of diabetic macular edema in the left eye, the left eye was stable. We performed an intravitreal injection of bevacizumab and combined phacoemulsification with pars plana vitrectomy with gas, including subretinal injection of tissue plasminogen activator to displace the SMH. Thirteen

days after the surgery, the SMH and SRF decreased. Although rare, mRNA COVID-19 vaccine administrations could be associated with PCV deterioration.

Membranoproliferative Glomerulonephritis following the Oxford AstraZeneca COVID-19 Vaccine.

Adverse Events Following the First Dose of Immunization of COVID-19 Vaccine. BACKGROUND: The COVID-19 pandemic has challenged the entire globe and the need for a vaccine is supreme. Since many vaccines along with Covishield have been granted emergency use authorization, the evaluation and monitoring of safety are crucial. Covishield was rolled out in Nepal on January 27, 2021. So through this study, we aim to identify the prevalence of Adverse Events Following Immunization in general with the first dose of Covishield vaccine, compare Adverse Events Following Immunization in prior COVID-19 positive cases and Adverse Events Following Immunization in co-morbid individuals. METHODS: This was a descriptive cross-sectional study conducted in 440 sample from May 2021 till July 2021 in a provincial government hospital of western Nepal. Ethical approval was received from Ethical Review Board, Nepal Health Research Council (Registration no: 279/2021 P). Simple random sampling was used. Point estimate was done at 95% confidence interval and descriptive analysis was done to identify the prevalence of Adverse Events Following Immunization within one week after Covishield vaccination in the studied population. RESULTS: 79.77% of the study population complaint at least one or more Adverse Events Following Immunization. Fever, myalgia, headache, pain at the injection site, arthralgia, chills, and fever are the most common Adverse Events Following Immunization. 42.73% of the study population self-medicated to manage Adverse Events Following Immunization, 7.89% took leave from work while 0.28% needed medical attention. No major Adverse Events Following Immunization relevance with prior-COVID history or co-morbidity was seen. CONCLUSIONS: Majority of the vaccinated participants had minor adverse effects on the first-day post-vaccination while most of the Adverse Events Following Immunization subsided within seven days.

Myocarditis and pericarditis following mRNA vaccination in autoimmune inflammatory rheumatic disease patients: A single-center experience. INTRODUCTION: The mRNA vaccines Comirnaty (Pfizer/BioNTech) and Spikevax (Moderna) are considered safe and highly effective against SARS-COV2. However, they are also associated with a small increased risk of pericarditis and myocarditis. There is concern about an increased risk of these complications in patients with autoimmune inflammatory rheumatic diseases (AIRD). CASE REPORT: We describe three patients with pre-existing AIRD who developed myocarditis or pericarditis shortly after receiving their first dose of the Pfizer-BioNTech vaccine. The first case is a 31-year-old female with systemic lupus erythematosus (SLE) and anti-phospholipid syndrome (APLS) who presented 7 days after receiving the Pfizer-BioNTech vaccine and was diagnosed with myopericarditis following a positive troponin and abnormal transthoracic echocardiogram (TTE). The second case is a 29-year-old man with seronegative inflammatory arthritis and APLS who presented 7 days after receiving the first dose of the Pfizer-BioNTech vaccine. His troponin and TTE were unremarkable however his ECG showed widespread ST elevation. Lastly, the third case is a 34-year-old man with Behcet's disease with a history of recurrent pericarditis. He developed a recurrence of symptoms approximately 7 days after his Pfizer-BioNTech vaccine and self-commenced prednisolone at home. He had normal laboratory and radiological findings. All patients received prednisolone resulting in a quick recovery and resolution of symptoms. DISCUSSION: In this review we discuss the association between myocarditis, pericarditis and mRNA COVID-19 vaccines, those who are at greatest risk and current clinical considerations. We also discuss the possible increased risk in AIRD patients and the current research supporting this.

Ixekizumab successfully treated severe pityriasis rubra pilaris after COVID-19 vaccination. Pityriasis rubra pilaris is an inflammatory dermatologic disorder of unknown cause. We report a 67-year-old man with Pityriasis rubra pilaris might induced by COVID-19 vaccination. The patient

developed the lesions after the first dose of vaccine and significantly aggravated after the second dose. He had poor effect and liver function impairment developed after acitretin used, but achieved satisfactory efficacy after replacement to ixekizumab, an interleukin-17A inhibitor.

Acute myocarditis following coronavirus disease 2019 vaccination in a 14-year-old Japanese boy.

[Clinical study of awake prone positioning treatment in patients with common coronavirus disease 2019 caused by Omicron variant]. OBJECTIVE: To evaluate the clinical effect of awake prone positioning (APP) for common coronavirus disease 2019 (COVID-19) caused by Omicron variant. METHODS: Retrospectively analyze the clinical data of patients with COVID-19 caused by Omicron variant admitted by medical team of Tianjin Third Central Hospital during the period of supporting Tianjin COVID-19 designated hospital from January 8 to February 20, 2022. Patients who met the diagnostic criteria for common COVID-19 and had risk factors for developing severe disease or had pulse oxygen saturation (SpO(2)) â‰¤ 0.93 after exercise without supplementary oxygen were enrolled. Patients were divided into APP group and control group according to whether they completed the daily 12-hours APP in the first three days after enrollment. Demographic characteristics, clinical symptoms, COVID-19 vaccination status, laboratory examination, disease progression (progression to severe), time to nucleic acid negative conversion, length of hospital stay, and adverse reactions and tolerability [visual analog scale (VAS) score (the higher the score, the worse the tolerability] during APP were evaluated in two groups. Interleukin-6 (IL-6), C-reactive protein (CRP), SpO(2)/inhaled oxygen concentration (FiO(2)) ratio and ROX index (ROXI) were compared between two groups at enrollment, 3rd and 7th day after enrollment. RESULTS: There were no significant differences in demographic characteristics, clinical symptoms, vaccination rates of COVID-19 and laboratory tests between the two groups. There were no statistically significant differences in IL-6, CRP, SpO(2)/FiO(2) ratio and ROXI between two groups at the time of enrollment. Compared with the group at the time of enrollment, SpO(2)/FiO(2) ratio and ROXI in APP group increased significantly at the 3rd day after enrollment [SpO(2)/FiO(2) ratio: 461.90 (457.10, 466.70) vs. 446.67 (437.14, 457.10), ROXI: 25.40 (23.33, 25.93) vs. 22.57 (21.86, 24.40), all $P < 0.05$], and the levels of IL-6 and CRP in control group were significantly increased [IL-6 (ng/L): 18.30 (6.50, 37.75) vs. 7.40 (5.10, 11.15), CRP (mg/L): 11.46 (2.11, 17.96) vs. 4.11 (1.72, 9.05), all $P < 0.05$]. At the 3rd day of enrollment, the levels of IL-6 and CRP in APP group were significantly lower than those in control group [IL-6 (ng/L): 7.35 (4.35, 12.80) vs. 18.30 (6.50, 37.75), CRP (mg/L): 4.52 (1.98, 9.66) vs. 11.46 (2.11, 17.96), all $P < 0.05$], while SpO(2)/FiO(2) ratio and ROXI were significantly higher than those in control group [SpO(2)/FiO(2) ratio: 461.90 (457.10, 466.70) vs. 446.67 (441.90, 459.52), ROXI: 25.40 (23.33, 25.93) vs. 23.31 (22.10, 24.66), all $P < 0.05$]. At the 7th day of enrollment,there were no significant differences in IL-6, CRP, SpO(2)/FiO(2) ratio and ROXI between two groups. There were no severe cases in both groups. The time of nucleic acid negative conversion and length of hospital stay in APP group were significantly shorter than those in control group [10.0 (8.0, 12.0) days vs. 11.0 (9.0, 13.0) days, 12.0 (10.0, 14.0) days vs. 14.0 (12.0,16.0) days, respectively, all $P < 0.05$]. The main adverse reaction during APP was back pain, and the incidence in APP group was slightly lower than that in control group, but the difference was not statistically significant [17.9% (17/95) vs. 26.5% (27/102), $P = 0.149$]. VAS score in control group was significantly higher than that in APP group [score: 2.5 (2.0, 4.0) vs. 2.0 (1.0, 3.0), $P = 0.004$]. CONCLUSIONS: In common COVID-19 patients caused by Omicron variant with high risk factors for progression to severe disease or decreased oxygen reserve capacity, early APP can shorten the time of nucleic acid negative conversion and the length of hospital stay, but its effect on preventing disease progression cannot be determined.

Risk Factors Influencing Seroconversion after Inactive SARS-CoV-2 Vaccination in People Living with Obesity. INTRODUCTION: The aim of this study was to investigate the antibody titers against SARS-CoV-2 spike antigens and the risk factors affecting antibody levels in people living with obesity

(PwO) after inactive SARS-CoV-2 vaccine (CoronaVac) administration. METHODS: 169 consecutive patients with obesity who visited the Center for Obesity Management at Istanbul University-CerrahpaÅŸa, CerrahpaÅŸa Medical Faculty Hospitals, between May and August 2021, were invited to the study. The nonobese control group was recruited from 191 subjects who visited the CerrahpaÅŸa Hospitals Vaccination Unit. The study group and the nonobese control group have already received two doses of inactive SARS-CoV-2 vaccine. The SARS-CoV-2 IgG nucleocapsid antibody test was administered to patients and control subjects to discover those who had prior SARS-CoV-2 infection. Forty-one patients who had prior infection and received two doses of vaccine were also included in the study as a subgroup. Blood samples were taken on the 3rd to 4th week after the second vaccination. SARS-CoV-2 IgG antibody titers were determined by quantitative serological methods. RESULTS: Antibody titers against SARS-CoV-2 spike antigen of individuals with BMI â‰¥30.0 kg/m2 were significantly lower than those with BMI <30 kg/m2 (p = 0.001) in the study group. Moreover, the antibody titers in people with BMI â‰¥30.0 kg/m2 were significantly lower than in those having a BMI <30.0 kg/m2 in the subgroup (p = 0.03). Age (p = 0.03), BMI (p = 0.006), and hypertension (p = 0.03) were found to be independent risk factors for antibody response in PwO. Women with non-prior SARS-CoV-2 infection showed a significantly higher antibody response then men (p = 0.001). CONCLUSION: SARS-CoV-2-Immunoglobulin G antibody levels against inactive (CoronaVac) vaccine were found to be lower in PwO compared to nonobese individuals. Antibody titers may be measured, and booster doses should be delivered accordingly in PwO for optimal protection.

COVID-19 vaccination, do women suffer from more side effects than men? A retrospective cross-sectional study. The vaccine was the only way to fight against Coronavirus-19 (COVID-19) from its statement as a pandemic till day. COVID-19 vaccines were approved by the world health organization (WHO) in December 2020. Despite a large number of studies regarding the efficacy and safety of COVID-19 vaccines, to our knowledge, there were limited studies that outlined the gender disparity towards COVID-19 vaccine adverse effects. This study aims to outline the variety of side effects among men and women after getting COVID-19 vaccines (either single or two doses). It is a cross-sectional study accomplished electronically from September to November 2021. The participants involved were 843 Health Care Workers (HCWs) from different cities in Iraq. The majority of respondents were females (664). Around 65% of males experienced adverse effects compared to 77% of females. A high frequency of severe pain was reported among females. Regarding dermatological reactions like swelling, redness and skin rash were also higher reported among female subjects. In addition to that, higher frequencies of moderate and severe systemic adverse effects and mild to moderate nausea was also reported more frequently among females. In terms of cardiopulmonary adverse effects, all the reported adverse effects were found more frequently among females. In conclusion, COVID-19 vaccines produced limited adverse effects and the majority of them were reported among women. This may be associated with hormonal and psychological factors related to them.

Vaccine-induced immune thrombotic thrombocytopenia: current evidence, potential mechanisms, clinical implications, and future directions. Vaccine-induced immune thrombotic thrombocytopenia (VITT) (also termed thrombosis with thrombocytopenia syndrome or vaccine-induced thrombotic thrombocytopenia or vaccine-induced immune thrombocytopenia) is characterized by (i) venous or arterial thrombosis; (ii) mild-to-severe thrombocytopenia; (iii) positive antiplatelet factor 4 (PF4)-polyanion antibodies or anti-PF4-heparin antibodies detected by the HIT (heparin-induced thrombocytopenia) ELISA; (iv) occurring 5-30 days after ChAdOx1 nCoV-19 (AstraZeneca) or Ad26.COV2.S (Johnson & Johnson/Janssen) vaccination. VITT's incidence is 1 per 100 000 vaccinated people irrespective of age and up to 1 in 50 000 for people <50 years of age with the AstraZeneca COVID-19 vaccine. The exact mechanism by which adenovirus-vectored COVID-19

vaccines trigger this syndrome is still unclear, as for the increased risk for acute cerebral sinus venous thrombosis and splanchnic vein thrombosis as compared to other locations of venous thrombotic events. VITT is associated with the detection of anti-PF4 antibodies, unrelated to previous use of heparin therapy. PF4 antibodies are thought to activate platelets via the platelet FcÎ³RIIA receptors leading to further platelet activation that causes thrombosis and thrombocytopenia.

COVID-19 Vaccine-Induced Cerebral Sinus Thrombosis: Coincidence vs. Cause? Patients who were vaccinated against COVID-19 have experienced thrombosis-thrombocytopenia syndrome and cerebral venous sinus thrombosis (CVST). It is important to be aware of this potential side effect of the vaccine and to be able to recognize early clinical symptoms and signs of CVST. In this paper, we present two cases of COVID-19 vaccination-related CVST. The patients who suffered headaches and seizures were found to have CVST, which was treated with anticoagulation.

Subacute thyroiditis after the third dose of the COVID-19 mRNA vaccine. Case report. Subacute thyroiditis (SAT) is a thyroid inflammatory disease, whose pathogenesis is still unclear. We report a 52-year-old female with SAT after the third dose of COVID-19 mRNA vaccine BNT162b2 (Pfizer-BioNTech). This case was documented with laboratory tests and ultrasound examination. She needed therapy during the acute phase and subsequently thyroxine supplementation.

Vaccination against COVID-19 as prevention of occupational disease in University of Defence members in the Czech Republic - motivation for vaccination and reasons for hesitancy. OBJECTIVES: The aim of this cross-sectional study was to investigate the determinants of COVID-19 vaccine acceptance in University of Defence members. BACKGROUND: Vaccination is the most important method of prevention against COVID-19 and achieving sufficient vaccination rate is thus essential to maintain the military capability. METHODOLOGY: An online questionnaire was distributed electronically to 2,408 respondents in autumn 2021. The survey was designed to collect demographic predictors of vaccination, data on motivation and reasons for refusing vaccination. RESULTS: A total of 626 completed questionnaires were analyzed, of which 557 (89 %) were vaccinated and 69 (11 %) were unvaccinated respondents. The most significant predictors of vaccine acceptance were: concern about COVID-19 (OR 2.44, $p < 0.001$), history of COVID-19 (OR 0.39, $p = 0.001$). The most frequently cited motives for vaccination were health protection (74.7 %) and an easier social life (69.1 %), while concerns about vaccine safety and vaccine adverse effects (79.1 %) followed by lack of confidence in vaccine efficacy (68.7 %) were the main reasons for vaccine refusal. CONCLUSION: To increase the vaccination rate it is necessary to target the younger population and increase awareness of vaccine safety and efficacy. If these measures are not sufficient to encourage voluntary vaccine acceptance, consideration should be given to making vaccination mandatory for selected professional groups (Tab. 5, Fig. 1, Ref. 25).

Aspects of Humoral Immunity after Vaccination with Bnt162b2: A Small Study. Starting from December 2020, vaccination against COVID-19 became available in Romania. There are a lot of uncertainties regarding the kinetics of immunity and its persistance over time. This is a small prospective study developed between January-September 2021 in the Infectious Diseases Clinic from Craiova and comprising 61Â subjects immunised with BNT162b2 (Comirnaty). We have found that after two doses of vaccine there is a strong humoral response, but the immunity lowers six months later. Subjects with a diagnosis of COVID-19, previously or in between the two doses, have had the most significant immunological response, but, also, the sharpest decline in antibody titer. The immune response seems to be the same, regardless the gender of the subjects. There are a variety of responses at the individual level, but overall vaccine effectiveness is 96.72% two weeks following immunisation and 88.52% after six months; however for those who have been in contact with the virus, they all had an antibody titer well above the laboratory limit.

Acute Disseminated Encephalomyelitis (ADEM) After Consecutive Exposures to Mycoplasma and COVID Vaccine: A Case Report. Acute disseminated encephalomyelitis (ADEM) is an autoimmune demyelinating disease of the central nervous system, commonly triggered by viral infections or after immunization. ADEM occurrences in adults are rare.Â Full spectrum of complications is unknown for novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccines. A previously healthy 44-year-old female presented to the emergency room (ER) withÂ acute onset of tingling, numbness, and weakness of both lower extremities, urinary retention, blurred vision in right eye, and midline lower back pain. Physical examination revealed bilateral lower extremity weaknessÂ 1/5,Â absent deep tendon reflexes, and decreased sensation. She receivedÂ the first dose of SARS-CoV-2 vaccine six days prior to presentation to ER. Imaging of her lumbar spine and head were consistent with an active demyelinating plaque consistent with demyelinating disease either multiple sclerosis (MS) or ADEM. The patient was started on SoluMedrol 500 mg IV twice daily for five days.Â Serological workup and CSF analysis were nonsignificant except for Mycoplasma pneumonia IgM, elevated myelin basic protein, and positive IgG, IgA, and IgM. Patient gradually improved and was transferred to rehabilitation. Repeat MRI brain and spine showed improvement in previous lesions. However, she had worsening left eye symptoms that prompted her transfer to another facility for plasmapheresis. Plasma exchange was done for five treatments for ADEM. Patient started noticing improvement in vision and was discharged on steroid taper. WeÂ report a case of a possible association between ADEM and SARS-CoV-2 mRNA vaccine. It should be considered in the differential diagnosis in any case suggestive of acute demyelinationÂ after COVID-19 vaccination.

Dyshidrosiform Bullous Pemphigoid Triggered by COVID-19 Vaccination. Vaccination has made a substantial contribution to global health improvement throughout history. The coronavirus disease 2019 (COVID-19) vaccinations have provided us with a ray of hope for combatting the ongoing pandemic and saving lives. However, following COVID-19 vaccination, a wide spectrum of cutaneous adverse effects have been observed. We report a case of dyshidrosiform bullous pemphigoid, a rare clinical variant of bullous pemphigoid, following COVID-19 vaccination in an elderly female patient. The biopsy revealed subepidermal splitting with positive direct and indirect immunofluorescence studies.

Myocardial Infarction after ChAdOx1 nCoV-19 in a Young Male.

Hypopigmentation following intradermal allergy skin testing performed as part of mRNA COVID-19 vaccine allergy evaluation. BACKGROUND: Skin prick test (SPT) and intradermal test (IDT) are standard procedures in the allergy practice that are safe when performed. Individuals with a history of allergic reaction to the COVID-19 vaccine can undergo allergy skin testing for polyethylene glycol and polysorbate 80 to determine their eligibility for the same vaccine or a safe alternative. Hypopigmentation is an infrequent adverse effect of corticosteroids, including triamcinolone acetonide, following local and intralesional treatment. Exposure to high potency corticosteroids for a long duration and the intradermal injection route are risk factors for hypopigmentation. In this case report, we describe the development of hypopigmentation following triamcinolone ID testing. CASE REPORT: A 29-year-old lady with a history of immediate severe allergic reaction following the first dose of mRNA COVID-19 vaccine (Pfizer) underwent SPT and IDT for polysorbate 80 and polyethylene glycol. Triamcinolone acetonide and Prevnar 13 were used as an indicator of polysorbate 80. Following a negative SPT, IDT for triamcinolone acetonide was negative at 1:10 of 40 mg/mL and positive at 1:1 of 40 mg/mL. A few days later, she noticed hypopigmented lesions at the site of the intradermal skin test for both concentrations of triamcinolone. The lesions have increased in size since then (see image). The patient was diagnosed with steroid-induced hypopigmentation secondary to triamcinolone IDT injection. CONCLUSION: Skin hypopigmentation following intraarticular and intralesional triamcinolone injection has been reported previously. However, to the best of our

knowledge, this is the first reported case of steroid-induced hypopigmentation following intradermal skin testing. Furthermore, this report highlights that even a low dose of local triamcinolone can cause hypopigmentation. We believe that this case report regarding the rare adverse event will alert clinicians to the potential complication of corticosteroid IDT and help them counsel the patients and provide a thorough explanation before any procedure.

[Vaccination contre le SARS-CoV-2, le Graal ?]. ANTI-SARS-COV-2 VACCINATION, THE GRAIL? The Covid-19 pandemic, which caused an unprecedented health crisis, was partially controlled by the rapid development of effective vaccines against SARS-CoV-2. To date, 5 vaccines are approved in Europe, 10 are recognized by the World Health Organization and more than 150 vaccine candidates are in clinical development. This emerging pandemic disease context has shown the value of research and real-life data. The five vaccines used in France have been developed using different technologies with convincing Phase 3 results. Real-life data have provided additional information on the effectiveness and safety of these vaccines: they have shown the importance of a booster dose to protect against severe forms of delta and omicron variants; they have made it possible to characterize and measure the incidence of rare adverse events, such as myocardial toxicity in mRNA vaccines or the risk of thrombocytopenic thrombosis in vectorized vaccines. However, research must continue as many questions remain unanswered.

Pseudo-Pemphigoid Gestationis Eruption Following SARS-CoV-2 Vaccination with mRNA Vaccine. Auto-immune reactions, including auto-immune bullous disease, have been reported following SARS-CoV-2 virus vaccination. Few cases of bullous pemphigoid are described, but there has been no case of pemphigoid gestationis. We report the first case here.

Short-Term Side Effects and SARS-CoV-2 Infection after COVID-19 Pfizer-BioNTech Vaccine in Children Aged 5-11 Years: An Italian Real-World Study. Vaccination against COVID-19 is the most effective tool to protect both the individual and the community from this potentially life-threatening infectious disease. Data from phase-3 trials showed that two doses of the BNT162b2 vaccine were safe, immunogenic, and effective against COVID-19 in children aged 5-11 years. However, no surveys in real-life settings have been carried out in this age range. Here, we conducted a cross-sectional study to evaluate the short-term adverse reactions (ARs) and the rate of protection against infection of the BNT162b2 vaccine in children aged 5-11 years by the compilation of two surveillance questionnaires conceived using Google Forms. Five-hundred and ninety one children were included in the analysis. ARs were reported by 68.9% of the children, being mainly local. The incidence of systemic ARs, especially fever, was higher after the second dose. The incidence of infection after completing the immunization accounted for 13.6% of the children. COVID-19 symptoms reported were mild, with the exception of one case of pneumonia. Only 40% of infected participants needed to take medication to relieve symptoms, mostly paracetamol and NSAIDs, and none reported persistent symptoms. The Pfizer-BioNTech vaccine in children aged 5-11 years is safe and well tolerated. The mild clinical course of COVID-19 in immunized children confirmed the favorable risk-benefit ratio, encouraging parents to immunize their children.

SARS-CoV-2 Neutralizing Antibodies in Chile after a Vaccination Campaign with Five Different Schemes. Using levels of neutralizing antibodies (nAbs), we evaluate the successful Chilean SARS-CoV-2 vaccine campaign, which combines different vaccine technologies and heterologous boosters. From a population-based study performed in November 2021, we randomly selected 120 seropositive individuals, organized into six groups of positive samples (20 subjects each) according to natural infection history and the five most frequent vaccination schemes. We conclude that the booster dose, regardless of vaccine technology or natural infection, and mRNA vaccines significantly improve nAbs response.

A Comparative Analysis of a Self-Reported Adverse Events Analysis after Receiving One of the Available SARS-CoV-2 Vaccine Schemes in Ecuador. The COVID-19 pandemic has put a lot of pressure on health systems worldwide. Mass vaccination against SARS-CoV-2 has reduced morbidity and mortality worldwide. Despite their safety profiles, vaccines, as with any other medical product, can cause adverse events. Yet, in countries with poor epidemiological surveillance and monitoring systems, reporting vaccine-related adverse events is a challenge. The objective of this study was to describe self-reported vaccine adverse events after receiving one of the available COVID-19 vaccine schemes in Ecuador. A cross-sectional analysis based on an online, self-reported, 32-item questionnaire was conducted in Ecuador from 1 April to 15 July 2021. Participants were invited by social media, radio, and TV to voluntarily participate in our study. A total of 6654 participants were included in this study. Furthermore, 38.2% of the participants reported having at least one comorbidity. Patients received AstraZeneca, Pfizer, and Sinovac vaccines, and these were distributed 38.4%, 31.1%, and 30.5%, respectively. Overall, pain or swelling at the injection site 17.2% (n = 4500) and headache 13.3% (n = 3502) were the most reported adverse events. Women addressed events supposedly attributable to vaccination or immunization [ESAVIs] (66.7%), more often than men (33.2%). After receiving the first dose of any available COVID-19 vaccine, a total of 19,501 self-reported ESAVIs were informed (87.0% were mild, 11.5% moderate, and 1.5% severe). In terms of the vaccine type and brand, the most reactogenic vaccine was AstraZeneca with 57.8%, followed by Pfizer (24.9%) and Sinovac (17.3%). After the second dose, 6776 self-reported ESAVIs were reported (87.1% mild, 10.9% moderate, and 2.1% severe). AstraZeneca vaccine users reported a higher proportion of ESAVIs (72.2%) in comparison to Pfizer/BioNTech (15.9%) and Sinovac Vaccine (11.9%). Swelling at the injection site, headache, muscle pain, and fatigue were the most common ESAVIs for the first as well as second doses. In conclusion, most ESAVIs were mild. AstraZeneca users were more likely to report adverse events. Participants without a history of COVID-19 infection, as well as those who received the first dose, were more prone to report ESAVIs.

A Diagnostic Strategy for Gauging Individual Humoral Ex Vivo Immune Responsiveness Following COVID-19 Vaccination. Purpose: We describe a diagnostic procedure suitable for scheduling (re-)vaccination against severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) according to individual state of humoral immunization. Methods: To clarify the relation between quantitative antibody measurements and humoral ex vivo immune responsiveness, we monitored 124 individuals before, during and six months after vaccination with Spikevax (Moderna, Cambridge, MA, USA). Antibodies against SARS-CoV-2 spike (S1) protein receptor-binding domain (S1-AB) and against nucleocapsid antigens were measured by chemiluminescent immunoassay (Roche). Virus-neutralizing activities were determined by surrogate assays (NeutraLISA, Euroimmune; cPass, GenScript). Neutralization of SARS-CoV-2 in cell culture (full virus NT) served as an ex vivo correlate for humoral immune responsiveness. Results: Vaccination responses varied considerably. Six months after the second vaccination, participants still positive for the full virus NT were safely determined by S1-AB levels â‰¥1000 U/mL. The full virus NT-positive fraction of participants with S1-AB levels <1000 U/mL was identified by virus-neutralizing activities >70% as determined by surrogate assays (NeutraLISA or cPas). Participants that were full virus NT-negative and presumably insufficiently protected could thus be identified by a sensitivity of >83% and a specificity of >95%. Conclusion: The described diagnostic strategy possibly supports individualized (re-)vaccination schedules based on simple and rapid measurement of serum-based SARS-CoV-2 antibody levels. Our data apply only to WUHAN-type SARS-CoV-2 virus and the current version of the mRNA vaccine from Moderna (Cambridge, MA, USA). Adaptation to other vaccines and more recent SARS-CoV-2 strains will require modification of cut-offs and re-evaluation of sensitivity/specificity.

How Humoral Response and Side Effects Depend on the Type of Vaccine and Past SARS-CoV-2 Infection. Since the end of December 2020, it has been possible to vaccinate against COVID-19. Our aim was to evaluate and compare the effectiveness of the vaccines available at the time of the mass vaccination program in Poland and also to look into the most common adverse side effects. Patients' anti-SARS-CoV-2 antibodies levels were checked before vaccination and after the first and after the second/last dose by the anti-SARS-CoV-2 QuantiVac ELISA (IgG) (EUROIMMUN MedicinischeLabordiagnostica AG; Luebeck; Germany) test. Before each blood collection, all patients filled out a questionnaire regarding experienced side effects. We observed that 100% of patients responded to the vaccinations. After the first dose, convalescents had much higher levels of anti-SARS-CoV-2 antibodies than naive patients, although after the second dose, 61 out of 162 convalescents (37.7%) had lower results than before. The comparison of immunological responses in the convalescents group after the first dose and in the naive group after the second dose showed that convalescents had higher antibody titers, which may suggest the possibility of changing the vaccination schedule for convalescents. The highest antibody titers after both the first and second doses were observed after Moderna shots. Fever was identified as a significant factor regarding higher levels of antibodies after the first and second doses of the vaccine.

Variant Allele of ALDH2, rs671, Associates with Attenuated Post-Vaccination Response in Anti-SARS-CoV-2 Spike Protein IgG: A Prospective Study in the Japanese General Population. Uncovering the predictors of vaccine immunogenicity is essential for infection control. We have reported that the most prevalent polymorphism of the aldehyde dehydrogenase 2 gene (ALDH2), rs671, may be associated with an attenuated immune system. To test the inverse relationship between rs671 and antibody production after COVID-19 vaccination, the levels of anti-SARS-CoV-2 Spike protein S1 subunit (S1) IgG were repeatedly measured for four months before and after vaccination with BNT162b2 or mRNA-1273, in 88 Japanese workers and students (including 45 females, aged 21-56 years, with an rs671 variant allele frequency of 0.3). The mixed model including fixed effects of the vaccine type, weeks post vaccination (categorical variable), sex, age, height, smoking status, ethanol intake, exercise habit, perceived stress, steroid use, allergic diseases, and dyslipidemia, indicated an inverse association between log-transformed anti-S1 IgG levels and the number of rs671 variant alleles (partial regression coefficient = -0.15, $p = 0.002$). Our study indicated for the first time that the variant allele of ALDH2, rs671, is associated with the attenuated immunogenicity of COVID-19 mRNA vaccines. Our finding may provide a basis for personalized disease prevention based on a genetic polymorphism that is prevalent among East Asians.

A Case Presenting with Neuromyelitis Optica Spectrum Disorder and Infectious Polyradiculitis Following BNT162b2 Vaccination and COVID-19. A 37-year-old woman presented with paraparesis and paresthesia in both legs 19 and 3 days after BNT162b2 vaccination and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, respectively. Cerebrospinal fluid (CSF) analysis, nerve conduction study, electromyography, magnetic resonance imaging, and autoantibody tests were performed. Neurological examination showed hyperesthesia below the T7 level and markedly impaired bilateral leg weakness with absent deep tendon reflexes on the knees and ankles. CSF examination revealed polymorphonuclear dominant pleocytosis and elevated total protein levels. Enhancement of the pia mater in the lumbar spinal cord and positive sharp waves in the lumbar paraspinal muscles indicated infectious polyradiculitis. In contrast, a high signal intensity of intramedullary spinal cord on a T2-weighted image from C1 to conus medullaris and positive anti-aquaporin-4 antibody confirmed neuromyelitis optica spectrum disorder (NMOSD). The patient received intravenous methylprednisolone, antiviral agents, and antibiotics, followed by a tapering dose of oral prednisolone and azathioprine. Two months after treatment, she was ambulatory without assistance. The dual pathomechanism of NMOSD triggered by coronavirus disease 2019

(COVID-19) vaccination and polyradiculitis caused by SARS-CoV-2 infection may have caused atypical clinical findings in our patient. Therefore, physicians should remain alert and avoid overlooking the possibilities of diverse mechanisms associated with neurological manifestations after SARS-CoV-2 infection and COVID-19 vaccination.

Adult-Onset Still's Disease-like Syndrome following COVID-19 Vaccination: A Case Report and Review of the Literature. Adult-onset Still's disease (AOSD)-like syndrome has rarely been reported as a complication of COVID-19 vaccination. This study reports a 31-year-old female patient who presented with fever, myalgia, arthralgia, pleuropericarditis, leukocytosis, and transaminitis following ChAdOx1 vaccination, and met Yamaguchi's criteria. A PubMed literature search, performed up until March 2022, identified 10 such cases. A total of 11 cases, including the one in this report, developed AOSD-like syndrome after administration of the viral vector (ChAdOx1) vaccine (six patients) and mRNA vaccine (five patients: BNT162b2 in four and mRNA-1273 in one). There were four male and seven female patients, with their median (Q1, Q3) age and the onset of symptoms after vaccination being 36 years (29, 45) and 10 days (6, 13), respectively. Fever (100%), arthralgia/arthritis (90.9%), skin rashes (81.8%), and sore throat (81.8%) were the main clinical findings. Pericarditis (45.5%), myocarditis/cardiac dysfunction (36.4%), pleuritis (54.6%), and pulmonary infiltrations (36.4%) were also common. One patient developed macrophage activation syndrome. One patient responded well to non-steroidal anti-inflammatory drugs, and the other six showed a good response to high-dose corticosteroids alone. Of the remaining four patients, who showed partial responses to high dose corticosteroids, showed good responses to biological agents. AOSD-like syndrome following COVID-19 vaccination shared many similar clinical features and treatment outcomes to those of idiopathic AOSD (but with a higher prevalence of cardiopulmonary involvement in the former). Physicians should be aware of this extremely rare complication to achieve early diagnosis and provide proper management.

Fatal Outcome of COVID-19 Relapse in a Fully Vaccinated Patient with Non-Hodgkin Lymphoma Receiving Maintenance Therapy with the Anti-CD20 Monoclonal Antibody Obinutuzumab: A Case Report. Few data are available regarding the effectiveness of anti-SARS-CoV-2 vaccine in immunocompromised patients. Vaccination may have a suboptimal efficacy in this population, in particular if patients are exposed to anti-B-cell therapy. We report the virological and clinical characteristics of a patient with follicle center lymphoma under bimonthly maintenance therapy with obinutuzumab, an anti-CD20 monoclonal antibody. Despite three doses of BNT162b2 vaccine, the patient was infected by the SARS-CoV-2 Omicron variant. After an initial period of clinical and molecular remission due to early therapy with sotrovimab, the patient experienced a fatal relapse sustained by the same viral strain.

The Frequency and Patterns of Post-COVID-19 Vaccination Syndrome Reveal Initially Mild and Potentially Immunocytopenic Signs in Primarily Young Saudi Women. Vaccination is the most promising approach for ending or containing the SARS-CoV-2 pandemic. However, serious post-COVID-19 vaccine reactions, including immunocytopenia (ITP) syndrome, have been increasingly reported. Several factors cause increased risks including multiple doses, age-dependent heterogeneity in immune-responses, platelet cross-reactions with microbial components, and Long-COVID syndrome. Thus, in the absence of widely available specific therapeutics, vigilance is important while more studies are needed. Using a structured questionnaire sent to different regions in Saudi Arabia, we conducted a comprehensive investigation on the frequency, rates, disease patterns, and patient demographics of post-COVID-19 vaccine side effects on febrile patients after administration three major vaccines. Results indicated that the majority of respondents administered Pfizer BioNtech vaccine (81%, n = 809); followed by AstraZeneca (16%, n = 155); and Moderna (3%, n = 34). Overall 998 participants, 74% (n = 737) showed no serious symptoms; however, 26.2% (n = 261)

revealed typical syndromes. In a focused group of 722 participants, the following rates were identified: shortness of breath (20%), bruises or bleeding (18%), inattention (18%), GIT symptoms (17.6%), skin irritation (8.6%), and anosmia and ageusia (8%) were the most prominent among those who showed typical symptoms. The onset time was mostly between 1-3 days in 49% (n = 128), followed by 4-7 days in 21.8% (n = 57), 8-14 days in 16.5% (n = 43), and more than a month in 12.6% (n = 33). The onsets occurred mostly after the first, second, or both doses, 9%, 10%, and 7% of participants, respectively. The frequency of symptoms was significantly higher after Moderna(Â®) vaccine (p-value = 0.00006) and it was significantly lower in participants who received Pfizer (p-value = 0.00231). We did not find significant difference in symptoms related to differences in regions. Similarly, the region, age, sex, education, and nationality had no influence on the dose and onset timings. The findings of this study have significant clinical implications in disease management strategies, preventive measures, and vaccine development. Future vertical studies would reveal more insights into the mechanisms of post-COVID-19 vaccine syndrome.

Acquired Thrombotic Thrombocytopenic Purpura Following Inactivated COVID-19 Vaccines: Two Case Reports and a Short Literature Review. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) outbreak in December 2019, causing millions of deaths all over the world, and the lack of specific treatment for severe forms of coronavirus disease 2019 (COVID-19) have led to the development of vaccines in record time, increasing the risk of vaccine safety issues. Recently, several cases of thrombotic thrombocytopenic purpura (TTP) have been reported following COVID-19 vaccination. TTP is a rare disease characterized by thrombocytopenia, microangiopathic hemolytic anemia and ischemic end-organ lesions. It can be either congenital or acquired. Various events such as viral infections, medication, pregnancy, malignancies, and vaccinations may cause TTP. Here, we report two cases of acquired TTP following Sinopharm COVID-19 vaccine (BBIBP-CorV) and Sinovac COVID-19 vaccine (CoronaVac). Diagnosis was based on clinical presentation and confirmed with a severe reduction in the activity of von Willebrand factor-cleaving protease ADAMTS-13 and the presence of inhibitory autoantibodies. The two patients were successfully treated with corticosteroids, plasma exchange therapy and rituximab in the acute phase. In the literature, the reported cases of TTP induced by COVID-19 vaccination occurred after Adenoviral Vector DNA- and SARS-CoV-2 mRNA-Based COVID-19 vaccines. To the best of our knowledge, this is the first report of acquired TTP after inactivated virus COVID-19 vaccination.

Prevalence and Determinants of COVID-19 Vaccination Uptake Were Different between Chinese Diabetic Inpatients with and without Chronic Complications: A Cross-Sectional Survey. The health of people with chronic diabetes mellitus (DM) complications will worsen following coronavirus disease 2019 (COVID-19) infection. This cross-sectional study compared perceptions and factors related to COVID-19 vaccination uptake between subgroups of DM inpatients with and without chronic complications in China. A multivariate logistic regression model was used for data analysis. Of the 645 participants, those without any complications reported significantly higher uptake of at least one dose of COVID-19 vaccination (43.2% versus 11.2%, $p < 0.001$). For people with chronic DM complications, a perception of higher risk and severer consequences of COVID-19 infection, a belief that doctors would suggest they receive COVID-19 vaccination, and a belief that relativesâ€™ vaccination uptake would influence their own decision to receive a COVID-19 vaccination were all associated with higher COVID-19 vaccination uptake. For their counterparts without chronic complications, a perception of severer consequences of COVID-19 infection, a belief that receiving COVID-19 vaccination could reduce the risk of infection, and a belief that relativesâ€™ vaccination uptake would influence their own decision to receive a COVID-19 vaccination were all associated with higher COVID-19 vaccination uptake. Concerns about the safety and the side effects of vaccination were negatively associated with COVID-19 vaccination uptake in both groups of DM patients.

Different strategies might be applied to promote COVID-19 vaccination uptake in DM patients with and without chronic complications.
Increased EBV DNAemia after Anti-SARS-CoV-2 Vaccination in Solid Organ Transplants. The reactivation of latent viruses during SARS-CoV-2 infection is well recognized, and coinfection with Epsteinâ˜'Barr virus (EBV) has been associated with severe clinical cases of COVID-19 infection. In transplant patients, EBV infection presents a significant challenge. Assessing the potential impact of SARS-CoV-2 vaccinations on EBV infections in stable kidney and liver transplant recipients was the objective of our study. Ten solid-organ-transplant (SOT) patients (eight kidney and two liver) vaccinated with standard doses of mRNA COVID-19 vaccines were included. EBV DNA viral load measurements were conducted prior to the vaccination and during a follow-up period (at the first month and after six months) after the second vaccine dose. After the second dose, a significant increase in median viremia was observed ($p < 0.01$) in 9 patients, and in one patient, the reactivation of EBV infection was found. Six months later, the median viremia decreased significantly ($p < 0.05$). The EBV viral load should be closely monitored as it could lead to the earlier diagnosis and treatment of EBV-related complications. Despite experiencing a decrease in the viral load six months post-vaccination, some patients still had a viral load over the baseline, which increased the risk of potential complications.
COVID-19 Vaccination Might Induce Postural Orthostatic Tachycardia Syndrome: A Case Report. We report a case of new-onset postural orthostatic tachycardia syndrome in a healthy 46-year-old female after a single dose of the BNT162b2 (Pfizer-BioNTech) SARS-CoV-2 vaccine. There have been three prior reports of new-onset postural orthostatic tachycardia syndrome after COVID-19 vaccination. Predominant symptoms noted included fatigue, brain fog, headache, sinus tachycardia, and dizziness. Management includes noninvasive therapies, behavioral approaches, and pharmacologic regimens. Here, the patient presented with fatigue, palpitations, dizziness, and presyncope, with symptoms beginning 7 days after vaccination. Presenting vitals included temperature within normal limits, inappropriate tachycardia, up to 120 beats per minute, blood pressure of 128/87 mm of mercury, and 100% saturation in room air. Her management included lifestyle changes, dietary supplements, and ivabradine. Further studies are needed to evaluate prevalence, etiology, and optimal management.
Booster Vaccination Decreases 28-Day All-Cause Mortality of the Elderly Hospitalized Due to SARS-CoV-2 Delta Variant. (1) Background: SARS-CoV-2 infections are associated with an increased risk of hospital admissions especially in the elderly (age â‰¥ 65 years) and people with multiple comorbid conditions. (2) Methods: We investigated the effect of additional booster vaccinations following the primary vaccination series of mRNA, inactivated whole virus, or vector vaccines on infections with the SARS-CoV-2 delta variant in the total Hungarian elderly population. The infection, hospital admission, and 28-day all-cause mortality of elderly population was assessed. (3) Results: A total of 1,984,176 people fulfilled the criteria of elderly including 299,216 unvaccinated individuals, while 1,037,069 had completed primary vaccination and 587,150 had obtained an additional booster. The primary vaccination series reduced the risk of infection by 48.88%, the risk of hospital admission by 71.55%, and mortality by 79.87%. The booster vaccination had an additional benefit, as the risk of infection, hospital admission, and all-cause mortality were even lower (82.95%; 92.71%; and 94.24%, respectively). Vaccinated patients needing hospitalization suffered significantly more comorbid conditions, indicating a more vulnerable population. (4) Conclusions: Our data confirmed that the primary vaccination series and especially the booster vaccination significantly reduced the risk of the SARS-CoV-2 delta-variant-associated hospital admission and 28-day all-cause mortality in the elderly despite significantly more severe comorbid conditions.

Systematic Review on Pathophysiological Complications in Severe COVID-19 among the Non-Vaccinated and Vaccinated Population. COVID-19, caused by SARS-CoV-2, is one of the longest viral pandemics in the history of mankind, which have caused millions of deaths globally and induced severe deformities in the survivals. For instance, fibrosis and cavities in the infected lungs of COVID-19 are some of the complications observed in infected patients post COVID-19 recovery. These health abnormalities, including is multiple organ failure-the most striking pathological features of COVID-19-have been linked with diverse distribution of ACE2 receptor. Additionally, several health complications reports were reported after administration of COVID-19 vaccines in healthy individuals, but clinical or molecular pathways causing such complications are not yet studied in detail. Thus, the present systematic review established the comparison of health complication noted in vaccinated and non-vaccinated individuals (COVID-19 infected patients) to identify the association between vaccination and the multiorgan failure based on the data obtained from case studies, research articles, clinical trials/Cohort based studies and review articles published between 2020-2022. This review also includes the biological rationale behind the COVID-19 infection and its subsequent symptoms and effects including multiorgan failure. In addition, multisystem inflammatory syndrome (MIS) has been informed in individuals post vaccination that resulted in multiorgan failure but, no direct correlation of vaccination with MIS has been established. Similarly, hemophagocytic lymphohistiocytosis (HLH) also noted to cause multiorgan failure in some individuals following full vaccination. Furthermore, severe complications were recorded in elderly patients (+40 years of age), indicates that older age individuals are higher risk by COVID-19 and post vaccination, but available literature is not sufficient to comply with any conclusive statements on relationship between vaccination and multiorgan failure.

Hematologic Malignancies Diagnosed in the Context of the mRNA COVID-19 Vaccination Campaign: A Report of Two Cases. BACKGROUND: During the last two years, the COVID-19 pandemic led to millions of disease-related deaths worldwide. The efforts of the scientific community facing this global challenge resulted in outstanding achievements. Thus, within one year, new mRNA-based vaccines against SARS-CoV-2 viral infection were released, providing highly efficient protection and showing a very good safety profile in the general population. However, clinical data collection after vaccination is a continuous process for the long-term safety of any new medical product. The aim of our paper is to present two cases of hematological malignancies: diffuse large B-cell non-Hodgkin lymphoma and T/NK-cell lymphoma, diagnosed shortly after the administration of the mRNA COVID-19 vaccine. METHODS AND RESULTS: Case 1: A female patient was admitted with a suspicious cervical mass that emerged within one week after the administration of second dose of the BNT162b2 COVID-19 vaccine. Surgical removal followed by pathology assessment of the specimen confirmed the diagnosis of diffuse large B-cell non-Hodgkin lymphoma. Case 2: A male patient was admitted with multiple ulcerative oral lesions arising on the third day after the initial dose of the BNT162b2 COVID-19 vaccine. These lesions had a progressive character and during the following months were complicated with repetitive episodes of heavy oral bleeding, requiring blood transfusions. The incisional biopsy of the lesions and pathological assessment of the specimens confirmed the diagnosis of T/NK-cell lymphoma. CONCLUSIONS: The safety profile of the mRNA-based vaccines is an undeniable fact. In most cases, suspicions of potentially aggressive side effects were ruled out, proving to be transient post-vaccine reactions. Clinicians should remain alert to report any potentially aggressive manifestations emerging in the context of mRNA COVID-19 vaccination, such as these cases of hematological malignancies, in order to promote additional investigations on the particular mechanisms of action of COVID-19 vaccines and to provide the best medical care to the patients.

COVID-19-Related Mortality amongst Physicians in Italy: Trend Pre- and Post-SARS-CoV-2 Vaccination Campaign. Globally, there has been a high burden of COVID-19-related mortality amongst

physicians and other healthcare workers during the ongoing SARS-CoV-2 pandemic. Fortunately, anti-COVID-19 vaccination campaigns have helped to protect frontline workers and reduce COVID-19-related mortality amongst this occupational group. We analyzed COVID-19-related mortality data for doctors in Italy and compared the crude mortality rate between March-May 2020 (i.e., the beginning of the pandemic in Italy, with the highest rates of COVID-19-related deaths) and the same time period in March-May 2021 (high vaccination coverage amongst Italian physicians). The mortality rate was 12 times higher in March-May 2020 compared to the same time period after the start of the Italian vaccination campaign. Moreover, there was a strong inverse correlation between the number of deaths and the cumulative number of vaccine doses administered in the Italian population. Although non-pharmaceutical interventions, virus evolution and environmental factors probably had an effect, our analysis clearly supports the hypothesis that the vaccination campaign helped to protect Italian physicians and reduce COVID-19-related mortality. The latest available death trends from September to October 2021 for both physicians and the general population are also in favor of the need for the third vaccine dose, currently underway for the majority of the population at risk.

Current Evidence in SARS-CoV-2 mRNA Vaccines and Post-Vaccination Adverse Reports: Knowns and Unknowns. The novel mRNA vaccinations against COVID-19 are gaining worldwide attention for their potential efficacy, as well as for the diagnosis of some post-vaccination-reported adverse reactions. In this state-of-the-art review article, we present the current evidence regarding mainly the diagnosis of spontaneous allergic reactions, the skin occurrences, the vascular, blood, endocrine and heart events, the respiratory reports, the gastrointestinal, hepatic and kidney events, the reproductive and pregnancy issues and the muscle events, as well as the ear, eye, neurologic and psychiatric events following mRNA vaccination against COVID-19. We further present some evidence regarding the mRNA strategies, we provide important information for side effects associated with the spike protein based LNP-mRNA vaccine and its adjuvants, as well as evidence for all the possible dangerous roles of the spike protein, and we discuss our expert opinion on the knowns and the unknowns towards the topic.

Bilateral Cervical Lymphadenopathy after mRNA COVID-19 Vaccination on Oral Squamous Cell Carcinoma Patient: A Case Report. We report the case of a 59-year-old man with squamous cell carcinoma (SCC) of the right mandibular gingiva, who presented with bilateral cervical lymphadenopathy (CLA) after mRNA coronavirus disease 2019 (COVID-19) vaccination. The patient was diagnosed. Imaging studies performed prior to surgery revealed bilateral CLA and axillary lymphadenopathy (LA) ipsilateral to the vaccination site. Fine-needle aspiration (FNA) biopsy of the left CLA revealed reactive lymph nodes. The patient underwent surgical intervention for the malignant tumor, and the specimen was sent for histopathologic evaluation. The biopsy-proven cancer stage was pT3N0Mx. Positron emission tomography (PET-CT), performed six months after surgery, showed persistent bilateral CLA. However, FNA of the left axillary LA once again showed no evidence of metastasis or recurrence. Since the treatment plan may change based on the type of LA, it is important to figure out whether an mRNA vaccine has been administered to patients with head and neck cancer.

Vaccine mRNA Can Be Detected in Blood at 15 Days Post-Vaccination. COVID-19 mRNA vaccines effectively reduce incidence of severe disease, hospitalisation and death. The biodistribution and pharmacokinetics of the mRNA-containing lipid nanoparticles (LNPs) in these vaccines are unknown in humans. In this study, we used qPCR to track circulating mRNA in blood at different time-points after BNT162b2 vaccination in a small cohort of healthy individuals. We found that vaccine-associated synthetic mRNA persists in systemic circulation for at least 2 weeks. Furthermore, we used transmission electron microscopy (TEM) to investigate SARS-CoV-2 spike protein expression in human leukemic cells and in primary mononuclear blood cells treated in vitro with the BNT162b2 vaccine.

TEM revealed morphological changes suggestive of LNP uptake, but only a small fraction of K562 leukemic cells presented spike-like structures at the cell surface, suggesting reduced levels of expression for these specific phenotypes.

Assessment of the Humoral Immune Response Following COVID-19 Vaccination in Healthcare Workers: A One Year Longitudinal Study. The continuous variability of SARS-CoV-2 and the rapid waning of specific antibodies threatens the efficacy of COVID-19 vaccines. We aimed to evaluate antibody kinetics one year after SARS-CoV-2 vaccination with an mRNA vaccine in healthcare workers (HCW), with or without a booster. A marked decline in anti-Spike(S)/Receptor Binding Domain (RBD) antibody levels was registered during the first eight months post-vaccination, followed by a transitory increase after the booster. At three months post-booster an increased antibody level was maintained only in HCW vaccinated after a prior infection, who also developed a higher and long-lasting level of anti-S IgA antibodies. Still, IgG anti-nucleocapsid (NCP) fades five months post-SARS-CoV-2 infection. Despite the decline in antibodies one-year post-vaccination, 68.2% of HCW preserved the neutralization capacity against the ancestral variant, with a decrease of only 17.08% in the neutralizing capacity against the Omicron variant. Nevertheless, breakthrough infections were present in 6.65% of all participants, without any correlation with the previous level of anti-S/RBD IgG. Protection against the ancestral and Omicron variants is maintained at least three months after a booster in HCW, possibly reflecting a continuous antigenic stimulation in the professional setting.

Assessment and management of allergy history with a novel mRNA vaccine. CONTEXT: Tertiary care hospital provided onsite COVID-19 vaccine roll out as a work benefit for all care team members with medically supervised waiting period at the time of the distribution of the first round of the novel mRNA COVID-19 vaccines. Little was known about the immediate hypersensivity reactions or what might predispose to cross reactivity. OBJECTIVE: We developed a working protocol to continuously track the vaccines administered, the patient history of allergy and hypersensistivity, the reactions observed and the care plan developed (determination of allergy to mRNA vaccines or normal vaccine response). Continuous process improvement allowed us to change protocols as the CDC developed guidance. Every patient was observed for at least 15 minutes and every reaction was reviewed by a physician supervising the waiting area. We aimed to determine if there were predictors of adverse, immediate reaction to the vaccine and to assess prevalence of risk factors (history of allergy to polyethylene Glycol or polysorbate; allergy to other injectable medication or vaccines; hypersensitivity to multiple substances). STUDY DESIGN: Cohort study of all employees who received a first mRNA COVID-19 vaccine between December 16 and January 7th. Descriptive statistics were developed with demographic and medical history recorded, reactions noted and treatment given. SETTING OR DATASET: Tertiary care hospital in urban area. POPULATION STUDIED: Employees who received an mRNA COVID-19 vaccine. INTERVENTION/INSTRUMENT: Clinical records from employee vaccine clinic. OUTCOME MEASURES: Record of immediate response, determination of allergy. RESULTS: We served over 7000 individuals with approximately 10% having a history of anaphylactic reaction. We had fewer with history of anaphylaxis to medications or vaccines. We delivered these vaccines safely, and observed three cases of immediate anaphylaxis on first dose of mRNA and over 50 cases of immediate allergic hypersensitivity. We did not see any patterns that predicted these reactions (gender, age or medical history). EXPECTED OUTCOMES: We used this data to inform our employee health vaccination campaign and to inform the health system as strategies and safety protocols for vaccination of the population were developed.

Peripheral facial palsy following COVID-19 vaccination: a practical approach to use the clinical situation as a guide.

Declining neutralizing antibody levels after SARS-CoV-2 mRNA vaccination: observational data from community point-of-care testing service in Brno, Czechia. OBJECTIVES: Understanding immune

response is critical for control of COVID-19 pandemic. However, recent studies show that vaccine-induced humoral immunity may not be long-lasting and weaker in SARS-CoV-2 variants of concern. METHODS: In May 2021, 253 self-nominated persons were tested for antibodies against SARS-CoV-2 in 1 to 104 days (mean 41, median 28) after two doses of Moderna and Pfizer-BioNTech vaccines in the city of Brno, Czechia. Two point-of-care iCHROMAâ„¢ II immunofluorescence assays were used: COVID-19 Ab against mix of SARS-CoV-2 nucleocapsid and spike proteins (IgG Ab); and COVID-19 nAb against S1-RBD protein (nAb). Results were analysed in relation to gender, age, vaccine, and past COVID-19 disease. RESULTS: Antibodies nAb were detectable in 92.9% (95% CI: 89.7-96.0) of vaccinees. We observed statistically insignificant decrease of positive results from 93.9% (95% CI: 89.5-98.3) and 97.0% (95% CI: 92.8-100.0) in the first and second month after vaccination, respectively, to 91.7% (95% CI: 83.8-99.5) and 78.3% (95% CI: 61.4-95.1) in the third and fourth month, respectively. Quantitative results showed decreasing level of nAb in both genders, age groups and vaccines. Higher levels of nAb were found in younger age group and in COVID-19 convalescents. IgG Ab showed little dynamics in time. CONCLUSIONS: We found robust humoral response after vaccination with mRNA vaccines, however, decreasing nAb levels suggest that vaccine-induced humoral immunity is rapidly waning. This finding is relevant for adjustment of vaccination strategies with regard to inclusion of booster dose(s).

Association between Influenza vaccination and severity of lung involvement at CT images of the patients with COVID-19 infection: an Iranian retrospective case-control study. BACKGROUND: Frequent waves of corona virus disease (COVID-19) and lack of specific drugs against that, warrant studies to reduce the morbidity and mortality of this pandemic disease. In this study, we investigated the association between influenza vaccination and the severity and outcome of COVID-19 disease in Iranian patients living in the North. METHODS: This retrospective case-control study was performed on186 patients with COVID-19 infection between March and April, 2020. Patients with positive PCR were divided into two groups of case and control; Patients with moderate to severe and normal to mild lung involvement, respectively. The lung opacities in all of the 5 lobes were evaluated on chest CT images using a CT severity scoring system. The history of influenza vaccination during the fall of 2019-2020 was determined by a phone call. Statistical analysis was done using the chi-square test, student's t-test, and logistic regression. The significance level was $p<0.05$. RESULTS: The mean age of patients was 54.67Â±15.05years. Most patients had pulmonary manifestations including ground-glass opacity (57%), consolidation (80%) and pleural effusion (3.2%). Adjusting for age, gender, and history of underlying disease, vaccination is an effective factor in the severity of pulmonary involvement (AOR=0.39; 95%CI: (0.21, 0.73); P=0.003). Furthermore, the chance of ICU admission decreased via influenza vaccination (OR=0.21, P=0.001). CONCLUSION: The results showed that the severity of COVID-19 pulmonary involvement and outcome as ICU admission, and severe symptoms in patients with history of influenza vaccination were significantly lower than those without history of vaccination. This strategy can be used to prevent and reduce the complications of COVID-19.

Acquired thrombotic thrombocytopenic purpura after AstraZeneca vaccine: A case report. BACKGROUND: Rare cases of acquired thrombotic thrombocytopenic purpura (aTTP) have been reported since the administration of the COVID-19 vaccination. Based on our information, the present study provides the first case report of aTTP developed after the COVID-19 vaccination in Iran. CASE PRESENTATION: A 22-year-old Iranian woman presented with symptoms of ataxia, dysphasia, paresthesia, and acute numbness of her left upper limb four weeks after the AstraZeneca COVID-19 vaccination. Laboratory data suggested hemolytic anemia and thrombocytopenia. Also, schistocytes were noted on her peripheral blood smear. Acquired thrombotic thrombocytopenic purpura (aTTP) was diagnosed in accordance with clinical manifestations along with initial blood test results and was confirmed later through findings of ADAMTS-13 low level activity and the ADAMTS-13 positive

inhibitor. She underwent 22 sessions of plasma exchange, receiving corticosteroid and rituximab. Finally, the treatment was successful. CONCLUSION: Despite the presence of rare complications such as aTTP, vaccination is one of the best ways to prevent COVID-19 disease. The present case report describes the potential, but unproven, role of the AstraZeneca COVID-19 vaccine in aTTP pathogenesis. Vaccine-associated aTTP can be successfully treated with plasma exchange, corticosteroids, and rituximab.

A Case of Chronic Myelomonocytic Leukemia Unmasked After Receiving J&J COVID-19 Vaccine. Chronic myelomonocytic leukemia (CMML) is a clonal hematopoietic stem cell disease that comes under the overlap syndrome (myelodysplastic and myeloproliferative disorders). CMML is characterized by peripheral blood monocytosis and bone marrow dysplasia. The pathogenesis of CMML is poorly understood. Although cytogenetic and molecular abnormalities are common, they are not diagnostic. Herein, we present a rare case of CMML after receiving the J&J COVID-19 vaccineÂ with the rare association of limited scleroderma. Based on the Surveillance, Epidemiology, and End Result (SEER) cancer statistics review 2014-2018, the five-year age-adjusted incidence rate of CMML in both sexes is 0.5/100,000, with greater incidence in males (0.7/100,000) compared to females (0.3/100,000). We emphasize the fact that, based on the previous studies reported, the association of scleroderma with CMML is very rare. Our patient had concomitant CMML and scleroderma, which were unmasked after the patient received the COVID-19 vaccine. Our case suggests the possibility of developing CMML after receiving the J&J COVID vaccine. Immunization has always been a life-saving intervention in history. As the world is foreseeing getting the COVID-19 vaccine, it is essential to report all the possible adverse events for safety monitoring. Physicians should be aware of this unusual complication of the vaccine, and more cases are needed to confirm the association between them.

Post ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) (Covishield) Pulmonary Thromboembolism with Multiple Intracranial Ischemic Infarcts.

Reporting adverse events of ChAdOx1 nCoV-19 coronavirus vaccine (Recombinant) among the vaccinated healthcare professionals: A cross-sectional survey. BACKGROUND & OBJECTIVES: The safety of the ChAdOx1 nCoV-19 vaccine is a cause of concern for many who have been vaccinated. The people have multiple concerns and fear regarding the adverse events of the vaccine. Thus, this study was undertaken to establish the safety profile of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) among the healthcare professionals. METHODS: This was a descriptive cross-sectional survey. After taking clearance from the institutional ethics committee 1500 healthcare professionals, who had their vaccination in the past two weeks were selected. They were provided with an online survey proforma regarding adverse events following immunization (AEFIs) of COVID-19 vaccine developed using google forms with an informed consent form affixed to it. RESULTS: A total of 1036 individuals participated in the study. The mean and median (inter quartile range) age of the participants was 37.7 Â±11.25 and 35 (29-46) yr, respectively. Of these, 52.1 per cent were female, 29.3 per cent were doctors, 33.4 per cent were nurses and 9.5 per cent were paramedical staff. Forty six per cent participants experienced one or more minor AEFIs such as pain, tenderness, redness, etc. at the injection site. Fatigue (31.75%), generalized feeling of unwell (28.57%), muscle pain (23.16%) and fever (21.71%) were the most commonly reported systemic AEFIs followed by headache (20.07%), dizziness (10.03%) and joint pains (15.25%). Most of them experienced these AEFIs within 24 h of the first dose of administration. About 42 per cent of the participants took oral antipyretics/analgesics for managing the AEFIs. INTERPRETATION & CONCLUSIONS: ChAdOx1 nCoV-19 Corona Virus Vaccine was found to be associated with mild local and systemic AEFIs that were more common after the first dose as compared to the second dose. There adverse events could be dealt with oral over-the-counter medications, with no requirement of hospitalization.

Safety & effectiveness of COVID-19 vaccines: A narrative review. There are currently eight vaccines against SARS-CoV-2 that have received Emergency Use Authorization by the WHO that can offer some protection to the world's population during the COVID-19 pandemic. Though research is being published all over the world, public health officials, policymakers and governments are collecting evidence-based information to establish the public health policies. Unfortunately, continued international travel, violations of lockdowns and social distancing, the lack of mask use, the emergence of mutant strains of the virus and lower adherence by a sector of the global population that remains sceptical of the protection offered by vaccines, or about any risks associated with vaccines, hamper these efforts. Here we examine the literature on the efficacy, effectiveness and safety of COVID-19 vaccines, with an emphasis on select categories of individuals and against new SARS-CoV-2 strains. The literature shows that these eight vaccines are highly effective in protecting the population from severe disease and death, but there are some issues concerning safety and adverse effects. Further, booster shots and variant-specific vaccines would also be required.

[Guillain Barre syndrome associated with coronavac vaccine. Report of one case]. We report a 50-year-old woman with a history of celiac disease, who presented with lumbar pain and progressive flaccid tetraparesis 48 hours after the inoculation of the first dose of CoronaVac inactivated SARS-CoV-2 vaccine. CSF was normal and electrodiagnostic studies showed an axonal motor polyneuropathy. No other triggers were identified, and other etiologies were ruled out. The presentation was compatible with the AMAN (Acute Motor Axonal Neuropathy) subtype of GBS, and intravenous immunoglobulin halted the progression of symptoms. Intensive neurorehabilitation was performed. The patient was discharged five weeks after admission, walking with poles and climbing stairs with minimal assistance. To date no cases of inactivated SARSCoV-2 vaccine related GBS have been reported. Thus, description of its clinical presentation is relevant. We discuss the current evidence relating GBS with vaccines, highlighting that vaccine associated GBS is a controversial entity and causality must be interpreted cautiously given the actual COVID-19 pandemic context.

Myopericarditis in a Young Adult Secondary to COVID-19 Vaccination. We present the case of a healthy 29-year-old male with no significant medical history who presented with electrocardiogram findings consistent with pericarditis and elevated troponin levels, commonly seen in myocarditis, after receiving his second Pfizer-BioNTec vaccination for SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2). The patient had significant clinical improvement shortly after receiving aspirin and colchicine and was discharged home with these medications. His laboratory findings returned to baseline less than 2 weeks after his illness. While this case highlights the importance of diagnosis, intervention selection, and treatment of myopericarditis amid ongoing global vaccination campaigns, it should be emphasized that the benefits of vaccination considerably outweigh the risks.

Psoriasis Flares in Patients With COVID-19 Infection or Vaccination: A Case Series. Much of the literature involving COVID-19 and chronic inflammatory dermatological conditions have focused on the safety of immunomodulatory therapy in the setting of this highly infectious virus. While general mortality associated with the infection and vaccine has been studied in depth, the effects of the virus and vaccine on inflammatory skin disease states have not been. It is well known that psoriasis can be triggered by stress, infection, certain medications, and, although not as common, vaccinations.Â Further, existing literature has briefly commented on psoriasis flares after COVID vaccination, but these have not touched on flares among their patients' current therapy, nor flares after COVID infection. In this case report, we report five cases observed at our institution over the last year of either new-onset psoriasis or flares of previously well-controlled psoriasis shortly after infection with COVID-19 or COVID-19 vaccination, with no other identifiable triggers. These cases can serve to raise awareness of issues related to managing stubborn psoriatic flares and bringÂ to the forefront conversations that are likely to arise with our patients regarding the risks and benefits of

COVID vaccination and boosters. While the definitive etiology of the association between COVID and psoriasis remains unclear, it is important that the dermatologic community be aware when evaluating patients with new-onset or worsening psoriasis as we move forward in times of this COVID-19 era.

Acute acalculous cholecystitis following COVID-19 vaccination: a case report. Acute acalculous cholecystitis is an acute inflammation of the gallbladder in the absence of stones, usually occurring in elderly and critically ill patients with underlying conditions. A 29-year-old man presented to the hospital complaining of abdominal pain in the right hypochondrium with permanent fever three days after Janssen COVID-19 vaccine inoculation. Abdominal ultrasound revealed a thickened gallbladder wall without evidence of gallstone consistent of an acute acalculous cholecystitis. Blood analyses revealed thrombocytopenia, eosinophilia and liver dysfunction. The Polymerase Chain Reaction (PCR) COVID-19 test was negative. As treatment, the patient benefited of pain management, antibiotic and fluid. In the evolution, there was a regression of clinical signs with persistence of liver dysfunction. The patient was discharged ten days after hospitalization. The Janssen COVID-19 vaccine is likely to induce acute acalculous cholecystitis as adverse event following vaccination.

Successful Elimination of SARS-CoV-2 Following Vaccination with BNT162b2 after Prolonged Viral Infection in an Immunocompromised Lymphoma Patient. A 52-year-old man with mantle cell lymphoma treated with bendamustine and rituximab developed prolonged severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Despite elevated titers of anti-spike IgG antibody, protracted pancytopenia persisted for more than six months. Finally, the anti-SARS CoV-2 vaccine, BNT162b2, was administered, which improved his blood cell count and eliminated the virus. The increased anti-spike IgG titer and lymphocyte count after vaccination suggested that both humoral and cellular immunity acted in coordination to eliminate the virus.

Humoral Response and SARS-CoV-2 Infection Risk following the Third and Fourth Doses of the BNT162b2 Vaccine in Dialysis Patients. The optimal SARS-CoV-2 vaccination schedule in dialysis patients and the potential need for a fourth vaccine dose are debatable. We prospectively assessed the humoral responses to three and four doses of BNT162b2 among dialysis patients. The study included 106 dialysis patients; 60 (56.6%) and 46 (43.4%) received 3 and 4 vaccine doses, respectively. Anti-spike (anti-S) antibody titers significantly increased after the third vaccine dose, followed by a decline, yet still remained higher than all previous measurements. The fourth vaccine dose led to another profound rise in anti-S titers. The absolute increase following the fourth dose correlated with response to the third dose. Infection risk however was similar between patients vaccinated with three or four doses.

Clinical Characteristics of Omicron SARS-CoV-2 Variant Infection After Non-mRNA-Based Vaccination in China. INTRODUCTION: To date, little is known about the real-world protective role of Chinese inactivated and recombinant coronavirus disease 2019 (COVID-19) vaccines under the background of the long-term "Dynamic Zero COVID-19 Case" (i.e., no infection source) in China, especially when facing the widespread Omicron severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variant infection. METHODS: In this prospective, single-center cohort study, the clinical characteristics of post-vaccination Omicron SARS-CoV-2 variant infection were investigated in the initial largest outbreak of Omicron SARS-CoV-2 variant infection that occurred between the 8 January, 2022 and 29 January, 2022 in Anyang City, Henan Province, China. The primary endpoints were the rates of severe and critical diseases or death. The secondary endpoints were the SARS-CoV-2 shedding duration and length of hospitalization. RESULTS: A total of 380 post-vaccination patients infected with the Omicron SARS-CoV-2 variant were enrolled. The median age was 18 (interquartile range [IQR] 17-35) years, 219 (57.6%) cases were female, and 247 (65.0%) cases were students. Before confirmation of Omicron SARS-CoV-2 variant infection, patients had 3 (IQR 2-4) days of dry cough (40.3%), nasal congestion (26.3%), and sore throat (26.3%). On admission, 294 (77.4%) cases had normal chest

computerized tomography (CT) imaging. Additionally, only 5 (1.3%), 30 (7.9%), 4 (4/342, 1.2%), and 7 (7/379, 0.2%) patients had lymphocyte counts <800 per mm(3), C-reactive protein levels >10â€‰mg/L, lactate dehydrogenase levels â‰¥250â€‰U/L, and D-dimer levels â‰¥0.5â€‰mg/L on admission, respectively. During hospitalization, 308 (81.1%) and 72 (18.9%) were identified as mild and moderate cases, respectively, and no one progressed to severe and critical types, with a SARS-CoV-2 shedding period and length of hospital stay of 17 (IQR 12-22) and 19 (IQR 15-24) days, respectively. CONCLUSION: The current study found that approximately 80% of individuals infected with the Omicron SARS-CoV-2 variant were mild, approximately 20% of patients were moderate, and no severe, critical, or fatal cases were identified in a prospective cohort including 380 participants vaccinated with non-mRNA-based vaccines. DISCUSSION: This study supports the consideration of policy adjustments and changes to prevent and control the Omicron-predominant COVID-19 in China and other regions with high SARS-CoV-2 vaccination rates.

Seroconversion Rate After SARS-CoV-2 Infection and Two Doses of Either ChAdOx1-nCOV COVISHIELDâ„¢ or BBV-152 COVAXINâ„¢ Vaccination in Renal Allograft Recipients: An Experience of Two Public and Private Tertiary Care Center. INTRODUCTION: Vaccination is an effective strategy for preventing SARS-CoV-2 infection and associated mortality. Renal Transplant Recipients (RTRs) are vulnerable to acquiring infection and high mortality due to their immunocompromised state. Varying responses to the different vaccines, depending on types of vaccines and population, have been reported. Vaccines supply is also limited. The current study evaluated the seroconversion rate after SARS-CoV-2 infection and 2 doses of either COVAXINâ„¢ or COVISHIELDâ„¢ vaccination in RTR. METHODS: The serum anti-SARS-CoV-2 spike protein neutralizing antibody titer was measured in 370 RTRs who acquired SARS-CoV-2 infection (n=172), yet not vaccinated; and those vaccinated with COVAXINâ„¢ (n=78), and COVISHIELDâ„¢ (n=120) by chemiluminescence microparticle immunoassay methods from serum. RESULT: Overall, the seroconversion rate either after vaccination or infection was 85.13% (315/370). The vaccine-associated seroconversion was 80.30% (159/198). SARS-CoV-2 infection-associated seroconversion was 90.69% (156/172), COVISHIELDâ„¢ associated seroconversion was 79.2% (95/120), and COVAXINâ„¢ associated seroconversion was 82.05% (64/78). The median IgG titer in the SARS-CoV-2 infection group was 646.50 AU/ml (IQR: 232.52-1717.42), in the COVAXINâ„¢ group was 1449.75 AU/ml (IQR: 400.0-3068.55), and the COVISHIELDâ„¢ vaccination group was 1500.51 AU/ml (IQR: 379.47-4938.50). The seroconversion rate and antibody titers were similar irrespective of the place of sampling. Patient's age-associated seroconversion in <45 years was 88.01% (213/242), 45.1-60 years was 83.18% (94/113), and > 60 years was 58.3% (7/12). CONCLUSIONS: Both infection and vaccination induce robust antibody formation in RTRs. The seroconversion rate after SARS-CoV-2 infection was higher but with a lower antibody titer than vaccines. The vaccines, COVAXINâ„¢ and COVISHIELDâ„¢, induce more elevated antibody titers than natural infection. The seroconversion rate and antibody titer in Indian RTRs appears to be better than in the western population, irrespective of their vaccination status.

Serum Free Zinc Is Associated With Vaccination Response to SARS-CoV-2. BACKGROUND: Zinc (Zn) is an essential trace element with high relevance for the immune system, and its deficiency is associated with elevated infection risk and severe disease course. The association of Zn status with the immune response to SARS-CoV-2 vaccination is unknown. METHODS: A cohort of adult health care workers (n=126) received two doses of BNT162B2, and provided up to four serum samples over a time course of 6 months. Total SARS-CoV-2 IgG and neutralizing antibody potency was determined, along with total as well as free Zn concentrations. RESULTS: The SARS-CoV-2 antibodies showed the expected rise in response to vaccination, and decreased toward the last sampling point, with highest levels measured three weeks after the second dose. Total serum Zn concentrations were relatively stable over time, and showed no significant association with SARS-CoV-2 antibodies. Baseline total

serum Zn concentration and supplemental intake of Zn were both unrelated to the antibody response to SARS-CoV-2 vaccination. Time resolved analysis of free Zn indicated a similar dynamic as the humoral response. A positive correlation was observed between free Zn concentrations and both the induced antibodies and neutralizing antibody potency. CONCLUSION: While the biomarkers of Zn status and supplemental Zn intake appeared unrelated to the humoral immune response to SARS-CoV-2 vaccination, the observed correlation of free Zn to the induced antibodies indicates a diagnostic value of this novel biomarker for the immune system.
Characteristics and management of SARS-CoV-2 delta variant-induced COVID-19 infections from May to October 2021 in China: post-vaccination infection cases. SARS-CoV-2 variants have shown increased transmission capabilities and pandemic to an extent with severe presentation and mortality. The delta variant has been declared as an emerging variant of concern (VOC) by the World Health Organization (WHO) on May 10, 2021. This review summarizes the post-vaccination infection events related to SARS-CoV-2 delta variant outbreaks in many areas of China. The characteristics and measures of delta variant-induced COVID-19 infections from May 2021 to October 2021 were reported. We compared the delta variant with the omicron from the latest literature review.
Premenstrual and menstrual changes reported after COVID-19 vaccination: The EVA project. BACKGROUND: Menstrual disorders were not reported as a possible secondary effect in any of the clinical trials for the SARS-CoV-2 vaccines. AIM: To describe the prevalence of perceived premenstrual and menstrual changes after COVID-19 vaccine administration. DESIGN: Cross-sectional study. METHODS: A total of 14,153 women (mean age 31.5â€‰Â±â€‰9.3 years old) who had received the full course of vaccination at least three months earlier were included in this cross-sectional study. Data including the type of vaccine administered, perceived changes in the amount and duration of menstrual bleeding, presence of clots, cycle length, and premenstrual symptoms were collected through a retrospective online survey from June to September 2021. RESULTS: Of the women who participated in this study, 3136 reported no menstrual changes and 11,017 (78% of the study sample) reported experiencing menstrual cycle changes after vaccination. In summary, women who reported menstrual changes after vaccination were older (overall pâ€‰<â€‰0.001) and slightly more smokers (pâ€‰=â€‰0.05) than women who did not report any changes. The most prevalent changes in relation to premenstrual symptoms were increased fatigue (43%), abdominal bloating (37%), irritability (29%), sadness (28%), and headaches (28%). The most predominant menstrual changes were more menstrual bleeding (43%), more menstrual pain (41%), delayed menstruation (38%), fewer days of menstrual bleeding (34.5%), and shorter cycle length (32%). CONCLUSION: Women vaccinated against COVID-19 usually perceive mild menstrual and premenstrual changes. Future studies are warranted to clarify the physiological mechanisms behind these widely reported changes.
Myocarditis Following COVID-19 Vaccine Use: Can It Play a Role for Conditioning Immunization Schedules? Myocarditis (MYO) is a relatively uncommon inflammatory disease that involves the heart muscle. It can be a very severe disease as it can lead to the development of acute or chronic heart failure and, in a not marginal number of cases, to death. Most of the cases are diagnosed in healthy people younger than 30 years of age. Moreover, males are affected about twice as much as females. Viruses are among the most common causes of MYO, but how viral infection can lead to MYO development is not precisely defined. After COVID-19 pandemic declaration, incidence rate of MYO has significantly increased worldwide because of the SARS-CoV-2 infection. After the introduction of anti-COVID-19 vaccines, reports of post-immunization MYO have emerged, suggesting that a further cause of MYO together with the SARS-CoV-2 infection could increase the risk of heart damage during pandemic. Main aim of this study is to discuss present knowledge regarding etiopathogenesis and clinical findings of MYO associated with COVID-19 vaccine administration and whether the risk of this adverse events can modify the initially suggested recommendation for the

use of COVID-19 vaccines in pediatric age. Literature analysis showed that MYO is an adverse event that can follow the COVID-19 immunization with mRNA vaccines in few persons, particularly young adults, adolescents, and older children. It is generally a mild disease that should not modify the present recommendations for immunization with the authorized COVID-19 mRNA vaccines. Despite this, further studies are needed to evaluate presently undefined aspects of MYO development after COVID-19 vaccine administration and reduce the risk of development of this kind of vaccine complication. Together with a better definition of the true incidence of MYO and the exact role of the various factors in conditioning incidence variations, it is essential to establish long-term evolution of acute COVID-19 related MYO.

Central Retinal Vein Occlusion Following the First Dose of COVID Vaccine. The reports of vascular adverse events in the eye following COVID-19 vaccination are infrequent. We report the case of a healthy male who developed central retinal vein occlusion in his left eye three days following administration of the first dose of Covishield vaccine. As the underlying systemic and ocular risk factors were absent and laboratory investigations were normal, vein occlusion appeared to probably result from the vaccine. The patient developed retinal hemorrhages and non-perfusion ischemic areas all over the fundus. The macular edema was reduced with intravitreal triamcinolone acetonide, but the visual gain was not much, which appears to be due to the time lag in his initial presentation to the Ophthalmology Department. A close watch should be kept for ophthalmic adverse events to have an early intervention.

SARS-CoV-2 B.1.1.529 (Omicron) Variant Causes an Unprecedented Surge in Children Hospitalizations and Distinct Clinical Presentation Compared to the SARS-CoV-2 B.1.617.2 (Delta) Variant. BACKGROUND: In the midst of successive waves of SARS-CoV-2 variants, the B.1.1.529 (omicron) variant has recently caused a surge in pediatric infections and hospitalizations. This study aimed to describe and compare the symptoms, explorations, treatment and evolution of COVID-19 in hospitalized children during the successive B.1.617.2 (delta) and B.1.1.529 (omicron) waves. METHODS: This observational study was performed in the Pediatric Pulmonology Department of a University Hospital in Paris, France. All hospitalized children aged between 0 and 18 years who tested positive for SARS-CoV-2 using reverse transcription polymerase chain reaction (RT-PCR) in nasopharyngeal swabs from July 15th to December 15th 2021 (delta wave), and from December 15th 2021 to February 28th 2022 (omicron wave) were included. RESULTS: In total, 53 children were included, 14 (26.4%) during the delta wave and 39 (73.6%) during the omicron wave (almost three times as many hospitalizations in half the time during the latter wave). During the omicron wave, hospitalized patients were mostly aged < 5 years (90 vs. 71% of all the children during omicron and delta waves, respectively), and tended to have fewer underlying conditions (56 vs. 79% during omicron and delta waves, respectively, p = 0.20). The omicron variant was also responsible for a different clinical presentation when compared to the delta variant, with significantly higher and often poorly tolerated temperatures (p = 0.03) and increased digestive symptoms (p = 0.01). None of the three patients who were older than 12 years were fully vaccinated. CONCLUSION: The dramatic increase in the hospitalization of children with COVID-19 and the modification of the clinical presentation between the latest delta and omicron waves require pediatricians to remain vigilant. It should also encourage caregivers to ensure vaccination in children older than 5 years, for whom the BNT162b2 COVID-19 vaccine has been deemed safe, immunogenic, and effective.

Midface Infection after COVID-19 Vaccination in a Patient with Calcium Hydroxylapatite Dermal Filler: A Case Report and Literature Review. The emergence of vaccines for coronavirus disease 2019 (COVID-19) raises risk of possible adverse events from interaction between the vaccines and facial aesthetic care. A 47-year-old female with no medical comorbidities visited our emergency room due to midface painful swelling after 3â€‰hours following receiving the second dose of the messenger

RNA BNT162b2 COVID-19 vaccine. About 14 years ago, she underwent nonsurgical augmentation on the nasojugal groove with a calcium hydroxylapatite dermal filler. We performed incision and drainage under general anesthesia on the next day. During operation, yellowish pus-like materials bulged out. After an operation, we performed a combination therapy with antibiotics and methylprednisolone. Her symptoms improved day by day after surgery, and then a complete recovery was achieved at 3 weeks after the treatment. In conclusion, providers of aesthetic procedures are to be aware of the potential risks of such vaccines for patients who already had or seek to receive dermal filler injections.

COVID-19 in children: epidemic issues and candidate vaccines. A large-scale vaccination of coronavirus disease-19 (COVID-19) in adults has been conducted for nearly a year, and there is a growing recognition that immunization for children is also essential. It has been months since emergency use of pediatric COVID-19 vaccine was approved, we reviewed the prevalence and transmission of COVID-19 in children. The prevalence of COVID-19 in children is reduced due to vaccination even in a Delta prevalent period, so an increase in the vaccination rate is needed in children. Although the precise role of children in the transmission requires more research to uncover, they likely played a significant role, according to the available literature. We also described four candidate COVID-19 vaccines for children on their safety and immunogenicity and the impact of severe acute respiratory syndrome coronavirus 2 variants on childhood vaccination. Safety issues on pediatric vaccines post-approval, like adverse events following immunization and adverse events of special interest require studies on long-term and effective regulatory mechanisms.

A Transient Inflammatory Reaction with a B-Cell Lymphoid Infiltrate and Dysplastic Bone Marrow Changes Associated with the BNT162b2 COVID-19 Vaccine. COVID-19 vaccines were introduced soon after the COVID-19 pandemic emerged in 2020. Various side effects were reported worldwide, including several types of common systemic side effects such as fever and general fatigue. Reports of other rare manifestations also emerged. We report the case of an adult male with a rare systemic syndrome mimicking lymphoma after he had received the first dose of an mRNA-based COVID-19 vaccine. After nearly 6 months of investigation with suspicion for an infection or malignancy, all symptoms resolved, laboratory tests normalized, and imaging showed no sign of active disease. LEARNING POINTS: A lymphoma-like reaction is a possible side effect of COVID-19 vaccination.It is important to rule out other causes of systemic symptoms before diagnosing a reaction to a COVID-19 vaccine.A lymphoma-like reaction following administration of a COVID-19 vaccine has a good prognosis.

Low But Recoverable Markers of Humoral Immune Response to BNT162b2 in Elderly LTCF Residents Five to Seven Months After Two-Dose Vaccination. The immune response is known to wane after vaccination with BNT162b2, but the role of age, morbidity and body composition is not well understood. We conducted a cross-sectional study in long-term care facilities (LTCFs) for the elderly. All study participants had completed two-dose vaccination with BNT162b2 five to 7Â months before sample collection. In 298 residents (median age 86 years, range 75-101), anti-SARS-CoV-2 rector binding IgG antibody (anti-RBD-IgG) concentrations were low and inversely correlated with age (mean 51.60Â BAU/ml). We compared the results to Health Care Workers (HCW) aged 18-70Â years (n = 114, median age: 53 years), who had a higher mean anti-RBD-IgG concentration of 156.99 BAU/ml. Neutralization against the Delta variant was low in both groups (9.5% in LTCF residents and 31.6% in HCWs). The Charlson Comorbidity Index was inversely correlated with anti-RBD-IgG, but not the body mass index (BMI). A control group of 14 LTCF residents with known breakthrough infection had significant higher antibody concentrations (mean 3,199.65Â BAU/ml), and 85.7% had detectable neutralization against the Delta variant. Our results demonstrate low but recoverable markers of immunity in LTCF residents five to 7Â months after vaccination.

Second Wave of COVID-19 Pandemic in Argentinian Population: Vaccination Is Associated With a Decrease in Depressive Symptoms. BACKGROUND: Since the irruption of the coronavirus disease 2019 (COVID-19) the planet has submerged in a time of concern and uncertainty, with a direct impact on people's mental health. Moreover, the recurrent outbreaks that periodically harry different regions of the world constantly refocus people's concerns to the pandemic. Yet, each new wave heats the diverse countries in different situations, including the advances in their vaccination campaigns. In this research, we studied the levels of the general anxiety disorder (GAD) and depression in the Argentine population across the first and second waves of infections that occurred in our country. METHODS: We conducted an on-line survey, within each peak of the pandemic. People were asked to self-report GAD and depression symptoms using the GAD-7 and PHQ-9 questioners, inform their vaccination status, the frequency they performed physical activity as well as working condition and modality. Here, we identified the more vulnerable groups and evaluated factors that could mitigate the rise of these mental disorders, focusing on vaccination. RESULTS: Our data shows that reported GAD and depression levels were higher during the second wave than during the first one. More importantly, vaccinated people were less depressed than non-vaccinated people, while GAD levels remained equivalent in both groups. Other factors directly associated with lower GAD and depression levels were performing frequent physical activity and being employed, regardless of the employment modality. These observations were replicated in different age ranges and genders. CONCLUSION: This work evidences GAD and depression in different pandemic waves in Argentina, as well the factors that may contribute to reducing the magnitude of these disorders, including vaccination.

Humoral Response to mRNA-1273 SARS-CoV-2 Vaccine in Peritoneal Dialysis Patients: Is Boostering After Six Months Adequate? In dialysis patients the humoral response to anti-SARS-CoV-2 vaccines is attenuated and rapidly declines over time. However, data on the persistence of the immune response in peritoneal dialysis (PD) patients are scarce, particularly after a third (booster) dose with mRNA-1273 vaccine. In this prospective cohort study, we report anti-SARS-CoV-2 antibody levels in PD patients before and after the third dose of mRNA-1273 vaccine. Six months after the second dose, anti-SARS-CoV-2 antibodies were detected in all patients (n = 34). However, within this time period antibodies substantially declined in 31 of 34 patients (4.5-fold, median = 192 BAU/mL, p = 1.27 Ã— 10(-9)) and increased in three patients. In accordance with government regulations, a third dose of mRNA-1273 vaccine (50 Î¼g) was given to 27 PD patients 6 months after the second dose which induced a significant increase of anti-SARS-CoV-2 antibody titers (58.6-fold, median = 19405 BAU/mL, p = 1.24 Ã— 10(-29)). A mixed model analysis showed that a lower Davies Comorbidity Score and a higher GFR were associated with higher antibody titers (p = 0.03 and p = 0.02). The most common adverse events after the third dose were pain at the injection site (77.8%) and fatigue (51.9%). No hospitalizations were reported. In conclusion, 6 months after the second dose of mRNA-1273 vaccine, anti-SARS-CoV-2 antibodies substantially decreased in PD patients, whereas a well-tolerated third dose induced a robust humoral response. Our data suggest that the administration of a booster dose within a shorter interval than 6 months should be considered in PD patients in order to maintain high anti-SARS-CoV-2 antibody levels and assure protection from severe COVID-19 disease.

Profiling COVID-19 Vaccine Adverse Events by Statistical and Ontological Analysis of VAERS Case Reports. Since the beginning of the COVID-19 pandemic, vaccines have been developed to mitigate the spread of SARS-CoV-2, the virus that causes COVID-19. These vaccines have been effective in reducing the rate and severity of COVID-19 infection but also have been associated with various adverse events (AEs). In this study, data from the Vaccine Adverse Event Reporting System (VAERS) was queried and analyzed via the Cov19VaxKB vaccine safety statistical analysis tool to identify statistically significant (i.e., enriched) AEs for the three currently FDA-authorized or approved

COVID-19 vaccines. An ontology-based classification and literature review were conducted for these enriched AEs. Using VAERS data as of 31 December 2021, 96 AEs were found to be statistically significantly associated with the Pfizer-BioNTech, Moderna, and/or Janssen COVID-19 vaccines. The Janssen COVID-19 vaccine had a higher crude reporting rate of AEs compared to the Moderna and Pfizer COVID-19 vaccines. Females appeared to have a higher case report frequency for top adverse events compared to males. Using the Ontology of Adverse Event (OAE), these 96 adverse events were classified to different categories such as behavioral and neurological AEs, cardiovascular AEs, female reproductive system AEs, and immune system AEs. Further statistical comparison between different ages, doses, and sexes was also performed for three notable AEs: myocarditis, GBS, and thrombosis. The Pfizer vaccine was found to have a closer association with myocarditis than the other two COVID-19 vaccines in VAERS, while the Janssen vaccine was more likely to be associated with thrombosis and GBS AEs. To support standard AE representation and study, we have also modeled and classified the newly identified thrombosis with thrombocytopenia syndrome (TTS) AE and its subclasses in the OAE by incorporating the Brighton Collaboration definition. Notably, severe COVID-19 vaccine AEs (including myocarditis, GBS, and TTS) rarely occur in comparison to the large number of COVID-19 vaccinations administered in the United States, affirming the overall safety of these COVID-19 vaccines.

Branch retinal vein occlusion post severe acute respiratory syndrome coronavirus 2 vaccination. In this article, we report two patients who experienced the first onset of branch retinal vein occlusion (BRVO) 3 days after the administration of the BNT162b2 (Pfizer-BioNTech) severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. Case 1: A 50-year-old woman without any history of retinal disease developed vision loss in her right eye 3 days after receiving the first dose of the SARS-CoV-2 mRNA vaccine. Case 2: A 56-year-old woman without any history of retinal disease developed vision loss in her right eye 3 days after receiving the first dose of the SARS-CoV-2 mRNA vaccine. Case 1: Temporal superior BRVO and secondary macular edema (ME) were observed in the patient's right eye. Her best-corrected visual acuity (BCVA) was 20/25. Case 2: Temporal inferior BRVO and secondary ME were observed in the patient's right eye. Her BCVA was 13/20. Case 1: Three doses of intravitreal ranibizumab (IVR) were administered. Case 2: Three doses of IVR were administered. Case 1: ME resolved and BCVA improved to 20/20. Case 2: ME resolved and BCVA improved to 20/20. Both the cases showed a possible association between the SARS-CoV-2 vaccination and the first onset of BRVO.

Prevalence of COVID-19 Vaccine Side Effects among Early-Vaccinated Healthcare Workers in Eastern Ethiopia. BACKGROUND: The Ministry of Health of Ethiopia launched the COVID-19 vaccination campaign in March 2021, with frontline healthcare workers as first-round recipients and a goal of vaccinating 20% of the population by the end of 2021. The study aims to estimate the prevalence of COVID-19 vaccination side effects among early vaccinated healthcare workers in Adama hospital medical college. METHODS: A cross-sectional study was carried out between March and June 2021, following the vaccination of COVID-19 vaccine among healthcare workers in Adama hospital medical college. The study used a structured self-administered questionnaire and additional telephone surveys on items covering the participants' demographic data, local and systemic manifestations after vaccination. RESULTS: A total of 540 health care workers and supportive staff were enrolled in this study. The overall any-symptom report after the first dose of ChAdOx1 nCoV- 19 vaccine was 84.3%. The majority (39.6%) of participants had both systemic and local symptoms and 25.7% had only local and 18.9% had only systemic symptoms. Injection site pain was the most prevalent side effect symptom (64.1%), followed by fatigue (35.7%), headache (28.9%), joint pain (26.5%), and muscle pain (21.5%). CONCLUSION: Vaccine side effects were common and found to be well-tolerated among the recipients of the first dose of ChAdOx1 nCoV-19 at Adama hospital medical college healthcare

workers. The side effects were mainly mild to moderate. More side-effect profiles should be studied and disseminated to detect rare adverse reactions.

Thyroid Inconveniences With Vaccination Against SARS-CoV-2: The Size of the Matter. A Systematic Review. After the beginning of COVID-19 vaccination campaigns, several reports of thyroid disease possibly related to the COVID-19 vaccination progressively appeared in the literature, raising the question of whether the thyroid disorder might be a SARS-CoV-2 vaccine complication. The aim of this study was to analyze the data about COVID-19 vaccination and thyroid disease, evaluate the size and quality of related literature, assess the type of these events, and investigate their timing of onset with respect the vaccination. Pubmed/MEDLINE and Cochrane were systematically reviewed until February 2022 to retrieve the largest number of original papers, case reports, and case series articles reporting thyroid disease after SARS-CoV-2 vaccination. Forty-six articles were included with a total of 99 patients aged from 26 to 73 years were described, of whom 74.75% female. Regarding the vaccination received, 49.49% of patients received Comirnaty (Pfizer/BioNTech), 14.14% CoronaVac (Sinovac), 12.12% Vaxzevria (Oxford/Astrazeneca), 11.11% Spikevax (Moderna), 3.03% Ad26.COV2.S (Janssen, Johnson & Johnson), one patient Covaxin (Bharat Biotech) and one patient Convidecia (Cansino). In 7 cases the thyroid disorder developed after the third dose with a combination of different vaccines. Regarding the type of thyroid disorder, 59 were subacute thyroiditis (SAT), 29 Graves' disease (GD), 2 co-occurrence of SAT and GD, 6 painless thyroiditis (PT), and single cases of thyroid eye disease and hypothyroidism associated with mixedema. The timeline between vaccination and thyroid disorder ranged between 0.5 to 60 days, with an average of 10.96 days. Considering the limited follow-up time, a complete remission was reported in most of SAT and PT cases while a persistence was observed in GD. In conclusion, both size and quality of published data about thyroid inconveniences after COVID-19 vaccination are limited; thyroid disorders may occur within 2 months after COVID-19 vaccination; among all thyroid diseases after COVID-19 vaccination, GD and SAT seem to be more frequent.

Small Fiber Neuropathy Associated With the Moderna SARS-CoV-2 Vaccine. Efforts of controlling viral transmission began soon after the first cases of coronavirus disease 2019 (COVID-19) infections were identified. Initial efforts were related to contact precautions, hand hygiene, and mask-wearing; however, it was soon evident that a robust global immunization drive was the most effective way to curb disease transmission. In the United States, the first doses ofÂ COVID-19 vaccines were rolled out soon after the FDA granted emergency use authorization for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. What this also meant was that many of the routine phases that any new drug or vaccine goes through before being released publicly were bypassed. Over the past two years, various side effects and reactions have been seen after COVID-19 vaccine administration, the most common being local injection site events (e.g., pain, redness, swelling) and systemic effects (e.g., fatigue, headaches, myalgias). We report the case of a 64-year-old female who developed bilateral lower extremity numbness and tingling within weeks of receiving the third dose of Moderna SARS-CoV-2 vaccine. The patient underwent extensive testing to ascertain the diagnosis. She had negative autonomic testing and normal nerve conduction study/electromyography (EMG), which did not reveal large fiber neuropathy. Eventually, the patient underwent a skin biopsy, which revealed small fiber neuropathy. This case report highlights the importance of keeping a broad differential for rare side effects, such asÂ small fiber neuropathy, that are currently being seen and reported in the literature.

Acute Extensive Deep Vein Thrombosis After Heterogeneous Administration of Moderna mRNA Booster Vaccine: A Case Report. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) struck the world in 2019 and led to the development of the multisystem coronavirus disease-2019 (COVID-19) causing a worldwide pandemic. Vaccines with boosters were developed due to novel

mutations of SARS-CoV-2. Heterogeneous vaccination emerged with the perception that mixing vaccines can provide better protection. We presentÂ the case of a 68-year-old male patient who developed extensive acute deep vein thrombosis (DVT) of the left lower extremity, two weeks following the Moderna mRNA booster vaccine (mRNA-1273). His first two doses were AstraZeneca ChAdOx1-S [recombinant]. He was started on a heparin drip and prescribed rivaroxaban. We discuss the possible etiology of this DVT, the mechanism of action of the Moderna mRNA vaccine, the association of DVT with vaccine-induced inflammation, implications of heterogeneous vaccine combinations, and recommendations to advise people on possible thrombogenic adverse effects prior to mRNA vaccine administration.

Severe Ulcerative Colitis as a Complication of Mild COVID-19 Infection in a Vaccinated Patient. Prior studies have proposed a direct correlation between the severity of coronavirus disease 2019 (COVID-19) and the severity of ulcerative colitis (UC). This is explained by an autoimmune response from molecular mimicry or via angiotensin-converting enzyme 2 receptor. However, we present a novel case of an inverse correlation between asymptomatic COVID-19 causing severe UC. An 84-year-old male with prior infectious colitis and asymptomatic COVID-19 presented with septic shock secondary to presumed infectious colitis. Blood workup suggested inflammatory bowel disease, which was confirmed to be UC via flexible sigmoidoscopy and pathology. He was managed successfully with oral mesalamine and high-dose intravenous steroids, which were later transitioned to an oral taper. This case reflects that the intensity of the impact of COVID-19 on the gastrointestinal system can be as variable as the immune system reaction in an already labile environment such as in the elderly and malnourished patients. Therefore, in view of a lack of reports establishing a relationship between these two entities, we aim to report a case and propose an association between mild or asymptomatic COVID-19 and severe UC.

Graft-Versus-Host Disease in Allogeneic Hematopoietic Stem Cell Transplant: SARS-CoV-2 Vaccine as a Potential Trigger. Allogeneic hematopoietic stem cell transplant (AHSCT) recipients are at a risk of developing immune-mediated tissue damage from activation of the donor's immunocompetent T cells by the recipient's normally expressed antigens, a phenomenon called graft-versus-host disease (GVHD). With the emergence of the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), new vaccines have been developed to prevent morbidity and mortality, including the highly vulnerable hematologic malignancy patients after undergoing AHSCT. The early pathophysiologic events in GVHD include priming the donor T cells with molecules that are endogenous or pathogenic. In this case series, we present two cases of AHSCT recipients in which the SARS-CoV-2 vaccination series proceeded the development of GVHD manifesting with oral mucosal symptoms and derangement in the liver function tests. Our experience raises the question if any of the vaccine components serve as a molecular trigger for GVHD, making the current SARS-CoV-2 vaccines a risk factor for activating the immune system and developing GVHD.

Humoral and Cellular Immune Response After a 3-Dose Heterologous SARS-CoV-2 Vaccination Using the mRNA-BNT162b2 and Viral Vector Ad26COVS1 Vaccine in Hemodialysis Patients. BACKGROUND: Due to the waning humoral response after a two-dose SARS-CoV-2 mRNA vaccination, a third booster was recommended in hemodialyis patients. Data on aÂ heterologous mRNA-vector regimen, which might improve immunogenicity, are veryÂ limited. METHODS: In this observational study 36 chronic hemodialysis patients (mean (SD) age 66.9 (15.9) years, 33.3% females) were followed up for 13 months. All patients were vaccinated twice using the mRNA-BNT162b2 vaccine, followed by a 3(rd) dose of the vector vaccine Ad26COVS1 eight months later. We assessed the humoral response by quantifying the anti-SARS-CoV-2 spike IgG antibody and neutralizing antibody concentrations. The cellular immune response was evaluated via SARS-CoV-2 spike protein-specific interferon-Î³ release assay. RESULTS: The seroconversion rate was 47.2%, 100%, 69.4% and 100% one

month after the 1(st) dose, one and six months after the 2(nd) dose and four months after the heterologous 3(rd) dose. The median (Q1, Q3) anti-SARS-CoV-2 spike IgG concentrations at the same time were 28.7 (13.2, 69.4) BAU/ml, 1130.0 (594.5, 1735.0) BAU/ml, 89.7 (26.4, 203.8) BAU/ml, and 2080.0 (1062.5, 2080.0) BAU/ml. The percentage of patients with neutralizing antibodies was 58.3% after the 2(nd) dose and improved to 100% after the 3(rd) dose (P <0.001). A positive T-cell response was found in 50% of patients after the 3(rd) dose. CONCLUSIONS: A third heterologous booster dose helped to sustain humoral immunity in almost all hemodialysis patients and induced a significant T-cellular response in half of them. Stimulating the immune response against SARS-CoV-2 by two different vaccine platforms seems to be a promising approach.

Safety and Immunogenicity of an Inactivated COVID-19 Vaccine, WIBP-CorV, in Healthy Children: Interim Analysis of a Randomized, Double-Blind, Controlled, Phase 1/2 Trial. Safe and effective vaccines against SARS-CoV-2 for children are urgently needed. Here we aimed to assess the safety and immunogenicity of an inactivated COVID-19 vaccine candidate, WIBP-CorV, in participants aged 3-17 years. A randomized, double-blind, placebo-controlled, phase 1/2 clinical trial was conducted in Henan Province, China, in healthy children aged 3-17 years. 240 participants in phase 1 trial and 576 participants in phase 2 trial were randomly assigned to vaccine or control with an age de-escalation in three cohorts (3-5, 6-12 and 13-17 years) and dose-escalation in three groups (2.5, 5.0 and 10.0Î¼g/dose), and received 3 intramuscular injections at day 0, 28, and 56.Â WIBP-CorV showed a promising safety profile with approximately 17% adverse reactions within 30 days after injection and no grade 3 or worse adverse events. The most common adverse reaction was injection site pain, followed by fever, which were mild and self-limiting. The geometric mean titers of neutralizing antibody ranged from 102.2 to 1065.5 in vaccinated participants at 28 days after the third vaccination, and maintained at a range of 14.3 to 218.2 at day 180 after the third vaccination. WIBP-CorV elicited significantly higher titers of neutralizing antibody in the cohort aged 3-5 years than the other two cohorts. There were no detectable antibody responses in all alum-only groups. Taken together, our data demonstrate that WIBP-CorV is safe and well tolerated at all tested doses in participants aged 3-17 years, and elicited robust humoral responses against SARS-CoV-2 lasted for at least 6 months after the third vaccination. This study is ongoing and is registered with www.chictr.org.cn, ChiCTR2000031809.

Misdiagnosis of Reactive Lymphadenopathy Remotely After COVID-19 Vaccination: A Case Report and Literature Review.

Cutaneous Reactions to COVID-19 Vaccines in a Monocentric Study: A Case Series. After coronavirus disease 2019 (COVID-19) caused a global pandemic, vaccines were rapidly developed to control the spread of the virus. Although they were effective in most of the cases at protecting people from becoming seriously ill and being hospitalized, they showed side effects, too. Among other adverse vaccine reactions, cutaneous eruptions following SARS-CoV-2 have been described in the literature, but they are not well-characterized yet. We described the morphology and timing of the spectrum of cutaneous reactions following most of the COVID-19 vaccines available in Italy, which were observed in outpatients referred to our non-invasive diagnostic clinic. Most of these reactions appeared after the second or third COVID-19 vaccine dose (most of them after mRNA COVID-19 vaccines). Our data support that cutaneous reactions to COVID-19 vaccination are generally self-limited; in addition, history of allergic reaction to a specific food, medicine or vaccine should not discourage vaccination in the general population, although patients with immune dysregulation should be accurately selected and monitored. Further research is necessary to better assess the true prevalence and preventive measures of skin reactions to COVID-19 vaccination.

Collapsing Glomerulonephritis in a Kidney Transplant Recipient after mRNA SARS-CoV-2 Vaccination. With the vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), studies

are describing cases of glomerulonephritis arising after vaccination. We present the first case of a kidney transplant patient who, after mRNA vaccination against SARS-CoV-2, developed nephrotic proteinuria and renal dysfunction, with a biopsy diagnostic of collapsing glomerulonephritis. No other triggers for this glomerulonephritis were identified. Antibodies against the spike protein were negative, but the patient developed a specific T-cell response. The close time between vaccination and the proteinuria suggests a possible determinant role of vaccination. We should be aware of nephropathies appearing after COVID-19 vaccination in kidney transplant recipients also.

Intramyocardial Inflammation after COVID-19 Vaccination: An Endomyocardial Biopsy-Proven Case Series. Myocarditis in response to COVID-19 vaccination has been reported since early 2021. In particular, young male individuals have been identified to exhibit an increased risk of myocardial inflammation following the administration of mRNA-based vaccines. Even though the first epidemiological analyses and numerous case reports investigated potential relationships, endomyocardial biopsy (EMB)-proven cases are limited. Here, we present a comprehensive histopathological analysis of EMBs from 15 patients with reduced ejection fraction (LVEF = 30 (14-39)%) and the clinical suspicion of myocarditis following vaccination with Comirnaty(Â®) (Pfizer-BioNTech) (n = 11), Vaxzevria(Â®) (AstraZenica) (n = 2) and Janssen(Â®) (Johnson & Johnson) (n = 2). Immunohistochemical EMB analyses reveal myocardial inflammation in 14 of 15 patients, with the histopathological diagnosis of active myocarditis according the Dallas criteria (n = 2), severe giant cell myocarditis (n = 2) and inflammatory cardiomyopathy (n = 10). Importantly, infectious causes have been excluded in all patients. The SARS-CoV-2 spike protein has been detected sparsely on cardiomyocytes of nine patients, and differential analysis of inflammatory markers such as CD4(+) and CD8(+) T cells suggests that the inflammatory response triggered by the vaccine may be of autoimmunological origin. Although a definitive causal relationship between COVID-19 vaccination and the occurrence of myocardial inflammation cannot be demonstrated in this study, data suggest a temporal connection. The expression of SARS-CoV-2 spike protein within the heart and the dominance of CD4(+) lymphocytic infiltrates indicate an autoimmunological response to the vaccination.

Association between Social Integration, Social Exclusion, and Vaccination Behavior among Internal Migrants in China: A Cross-Sectional Study. Cross-sectional studies about the association between social integration, social exclusion, and vaccination behavior among internal migrants in China are lacking. In this study, we aimed to explore the association between the influenza vaccination behavior and social integration as well as social exclusion in China based on a cross-sectional study. We included 12,467 participants aged 15 years old or above from the 2017 Migrant Population Dynamic Monitoring Survey (MDMS). We used univariate analysis and logistic regression models to access the association between social integration, exclusion status, and influenza vaccination rates. Results suggested that the association between social integration and the vaccination rate was significantly positive. Moving between different districts impact on people's mental health and their health performance. Significant association between influenza vaccination behavior and education attainment, income status, health record, and awareness of basic public health services program was reported. Therefore, in order to reduce the incidence of influenza disease and increase the vaccination rate, policymakers and the public should promote social integration for internal migrants. Meanwhile, our finding also implies possible strategies to promote COVID-19 vaccination.

Functional Profiling of In Vitro Reactivated Memory B Cells Following Natural SARS-CoV-2 Infection and Gam-COVID-Vac Vaccination. Both SARS-CoV-2 infection and vaccination have previously been demonstrated to elicit robust, yet somewhat limited immunity against the evolving variants of SARS-CoV-2. Nevertheless, reports performing side-by-side comparison of immune responses

following infection vs. vaccination have been relatively scarce. The aim of this study was to compare B-cell response to adenovirus-vectored vaccination in SARS-CoV-2-naive individuals with that observed in the COVID-19 convalescent patients six months after the first encounter with the viral antigens. We set out to use a single analytical platform and performed comprehensive analysis of serum levels of receptor binding domain (RBD)-specific and virus-neutralizing antibodies, frequencies of RBD-binding circulating memory B cells (MBCs), MBC-derived antibody-secreting cells, as well as RBD-specific and virus-neutralizing activity of MBC-derived antibodies after Gam-COVID-Vac (Sputnik V) vaccination and/or natural SARS-CoV-2 infection. Overall, natural immunity was superior to Gam-COVID-Vac vaccination. The levels of neutralizing MBC-derived antibodies in the convalescent patients turned out to be significantly higher than those found following vaccination. Our results suggest that after six months, SARS-CoV-2-specific MBC immunity is more robust in COVID-19 convalescent patients than in Gam-COVID-Vac recipients. Collectively, our data unambiguously indicate that natural immunity outperforms Gam-COVID-Vac-induced immunity six months following recovery/vaccination, which should inform healthcare and vaccination decisions.

Acute Myocardial Infarction After COVID-19 Vaccination: A Case Report. Following the coronavirus disease 2019 (COVID-19) pandemic, nations all over the world started vaccination programs against the SARS-CoV2 virus. With the widespread administration of the vaccine across the globe, various cases were reported with thrombotic events after vaccination. Here, we are presenting a case of acute anterior wall myocardial infarction (AWMI) after ChAdOx1 nCoV- 19 corona virus (recombinant) vaccination. A 68-year-old male who was a known case of hypertension, non-smoker on antihypertensive took COVISHIELD vaccination and presented with acute anterior wall myocardial infarction within 12 hours and was taken up for primary angioplasty. On coronary angiography, mid-left anterior descending artery (LAD) was 99% stenosed. Following angiography percutaneous transluminal coronary angioplasty (PTCA), deployment of a drug eluting stent was done. Post-procedure time was uneventful. He was started on intravenous fluids and amiodarone infusion. The patient recovered and was discharged in stable condition. The leading approach to handling COVID-19 pandemic is mass vaccination. In this case, the MI after vaccination might be coincidental. We want to highlight this case as that the complication can occur during the mass vaccination programs and hence adequate precautionary measures like basic life support, EKG monitoring, andÂ emergency ambulance services should be present in all primary and community health centers (PHC and CHC). This will help in avoiding the COVID vaccination hesitancy among the general public.

Vaccine-induced thrombosis and thrombocytopenia (VITT); Exploring the unknown. Vaccination is supposed to be the most reliable means to end the COVID 19 pandemic, but recently there have been reports of thrombosis and thrombocytopenia in patients receiving the vaccine especially ChAdOx1 nCoV-19 (AstraZeneca University of Oxford and Serum Institute of India). This has been termed as vaccine-induced immune thrombotic thrombocytopenia (VITT), thrombosis with thrombocytopenia syndrome (TTS) and vaccine-induced prothrombotic immune thrombocytopenia (VIPIT). This is a challenging situation and patients are treated with Fondaparinaux and Rivaroxaban after thrombocytopenia is corrected. Herewith, we report a case of VITT who presented to our hospital and was successfully treated over a weeks' time.

Unilateral axillary lymph node fluorodeoxyglucose uptakes after coronavirus disease 2019 vaccination. Vaccination against coronavirus disease 2019 (COVID-19) started in early December 2020 worldwide, and healthcare workers in Japan were vaccinated in February 2021. We encountered three patients who underwent (18)F-fluorodeoxyglucose (FDG) positron emission tomography/computed tomography (PET/CT) for cancer screening at our institution, showing FDG uptakes in the axillary lymph nodes, which seemed to be reactive changes. Two of them were males in their 40s and one was a female in her 50s; all of them were healthcare workers. The medical

history revealed that they received the Pfizer-BioNTech COVID-19 vaccination twice at their left shoulders before the FDG PET/CT examination. The degree of FDG uptakes were maximum standardized uptake value (SUV(max))=3.2-9.9, SUV(max)=5.9-10.3, and SUV(max)=2.8-7.9, respectively. They were diagnosed with reactive lymph nodes because of vaccination owing to the absence of abnormal FDG PET/CT findings at other sites. As COVID-19 vaccination becomes more widespread in Japan, radiologists should be aware of these findings to avoid misdiagnosis of FDG uptakes in pathological lymph nodes and to prevent unnecessary additional examinations. Recently, similar FDG PET/CT findings have been reported after receiving the COVID-19 vaccination, and we will report it with a literature review.

Thalamic hemi-chorea: a rare complication after receiving the adenoviral vector-based COVID-19 vaccine: a case report. Lacunar strokes occur when a branch of a large cerebral artery is blocked. The thalamus is often affected, causing uncontrollable motions. A 72-year-old previously healthy man presented with involuntary motions in the right limbs, which were present at rest, and exacerbated during voluntary actions. He had received the first dose of the adenoviral vector-based coronavirus disease 2019 vaccine (ChAdOx1 nCoV-19) 9 days ago. Severe thrombocytopenia and elevated levels of lactate dehydrogenase, ferritin, C-reactive protein, and D-dimer were found, without any evidence of connective tissue disease. Electromyography demonstrated typical choreiform movements, and the brain magnetic resonance imaging indicated a small high signal lesion on the left side of the thalamus. Detection of the immunoglobulin G antibodies against platelet factor 4 in the blood, negative heparin-induced platelet activation (HIPA) test, and positive modified HIPA test confirmed the thalamic stroke due to the vaccine-induced prothrombotic immune thrombocytopenia (VIPIT). He was admitted to the intensive care unit and received nadroparin, sodium ozagrel, edaravone, methylprednisolone, and haloperidol. His hemi-chorea improved gradually over 2 weeks, and he was discharged after 21 days with rehabilitation advice. VIPIT due to the ChAdOx1 nCoV-19 is a novel immune-mediated response that needs clinicians' awareness and further investigations.

Subacute thyroiditis after receiving the vaccine for COVID-19: a case report and literature review. A 38-year-old female patient, with healthy history, was vaccinated with ChAdOx1 nCoV-19 (Astra Zeneca Cambridge, UK). Five days after the second injection, the patient presented headache, vertigo, then fatigue, nervousness, palpitations, shortness of breath, small amplitude tremors, and sweating episodes. Laboratory investigation revealed a suppressed thyroid-stimulating hormone (TSH), with elevated free thyroxine. However, the TSH receptor antibody and anti-thyroid peroxidase antibody were normal and thyroid-stimulating immunoglobulin negative. The patient was maintained on Metoprolol, and no specific treatment was added. After 3 months of following, the patient now feels comfortable. Our literature review found that 21 cases of subacute thyroiditis (SAT) following coronavirus disease 2019 (COVID-19) vaccines were reported. Most patients were young women who presented neck pain and systemic symptoms, with or without fever. These symptoms can appear as early (3 to 5 days), or later (1 month) after vaccination, regardless of vaccine type and mechanism of action. Laboratory tests showed decreased levels of TSH and elevated thyroid hormone. The mechanism of this event remains unknown. Further study is recommended to investigate the possible predisposing factors to developing SAT after receiving the COVID-19 vaccine.

Epstein-Barr virus reactivation after COVID-19 vaccination in a young immunocompetent man: a case report. We present the case of a 24-year-old Caucasian man, who developed a scaly erythematous skin rash after the second dose of coronavirus disease 2019 (COVID-19) vaccination with Comirnaty (BNT162b2, BioNTech/Pfizer; Pfizer, New York, NY, USA) and proved positive for Epstein-Barr virus (EBV) reactivation. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccines have been associated with an up-regulated T helper type 1-cell response, possibly favoring an immune system imbalance. Also, EBV reactivation has been postulated after

COVID-19 vaccination, but only in the immunosuppressed. Noteworthy we report the first case of EBV viral reactivation associated with cutaneous manifestations in an immunocompetent patient after the COVID-19 vaccine.

Comparison of IgA, IgG, and Neutralizing Antibody Responses Following Immunization With Moderna, BioNTech, AstraZeneca, Sputnik-V, Johnson and Johnson, and Sinopharm's COVID-19 Vaccines. In an ongoing multinational trial, we obtained blood samples from 365 volunteers vaccinated with mRNA vaccines (Moderna, BioNTech), viral DNA-vectored vaccines (AstraZeneca, Sputnik-V, and Johnson and Johnson), or the attenuated virus vaccine from Sinopharm. After collecting reactogenicity data, the expression of S-Protein binding IgG and IgA was analyzed using an automated sandwich ELISA system. Serum neutralizing potentials were then investigated using an ACE-2-RBD neutralizing assay. Moderna's vaccine induced the highest amounts of SARS-CoV-2 specific neutralizing antibodies compared to the other groups. In contrast, Sinopharm and Johnson and Johnson's vaccinees presented the lowest SARS-CoV-2-specific antibody titers. Interestingly, moderate to high negative correlations between age and virus-specific IgG expression were observed in the Johnson and Johnson (Ï• =-0.3936) and Sinopharm (Ï• =-0.6977) groups according to Spearman's rank correlation analysis. A negative correlation was seen between age and IgA expression in the Sputnik-V group (Ï• =-0.3917). The analysis of virus neutralization potentials in age categories demonstrated that no significant neutralization potential was observed in older vaccinees (61and 80 years old) in the Sputnik-V Johnson and Johnson and Sinopharm vaccinees' groups. In contrast, neutralization potentials in sera of Moderna, BioNTech, and AstraZeneca vaccinees were statistically comparable in all age categories. Furthermore, while the AstraZeneca vaccine alone induced moderate IgG and IgA expression, the combination with Moderna or BioNTech mRNA vaccines induced significantly higher antibody levels than a double dose of AstraZeneca and similar IgG expression and neutralization potential compared to Moderna or BioNTech vaccines used alone. These results suggest that mRNA vaccines are the most immunogenic after two doses. DNA vectored vaccines from AstraZeneca and Sputnik-V presented lower but significant antibody expression and virus neutralizing properties after two doses. The lowest antibody and neutralization potential were observed in the Sinopharm or Johnson and Johnson vaccinees. Especially elderly over 60 presented no significant increase in neutralizing antibodies after vaccination. The data also indicate that heterologous vaccination strategies combining the AstraZeneca DNA vectored vaccines and mRNA vaccines are more effective in the induction of neutralizing antibodies compared to their homologous counterparts.

Antibody Response Induced by Two Doses of ChAdOx1 nCoV-19, mRNA-1273, or BNT162b2 in Liver Transplant Recipients. Coronavirus disease 2019 (COVID-19) vaccination in immunocompromised, especially transplant recipients, may induce a weaker immune response. But there are limited data on the immune response after COVID-19 vaccination in liver transplant (LT) recipients, especially on the comparison of Ab responses after different vaccine platforms between mRNA and adenoviral vector vaccines. Thus, we conducted a prospective study on LT recipients who received two doses of the ChAdOx1 nCoV-19 (ChAdOx1), mRNA-1273, or BNT162b2 vaccines compared with healthy healthcare workers (HCWs). SARS-CoV-2 S1-specific IgG Ab titers were measured using ELISA. Overall, 89 LT recipients (ChAdOx1, n=16 [18%]) or mRNA vaccines (mRNA-1273 vaccine, n=23 [26%]; BNT162b2 vaccine, n=50 [56%]) received 3 different vaccines. Of them, 16 (18%) had a positive Ab response after one dose of COVID-19 vaccine and 62 (73%) after 2 doses. However, the median Ab titer after two doses of mRNA vaccines was significantly higher (44.6 IU/ml) than after two doses of ChAdOx1 (19.2 IU/ml, p=0.04). The longer time interval from transplantation was significantly associated with high Ab titers after two doses of vaccine (p=0.003). However, mycophenolic acid use was not associated with Ab titers (p=0.53). In conclusion, about 3-quarters of

LT recipients had a positive Ab response after 2 doses of vaccine, and the mRNA vaccines induced higher Ab responses than the ChAdOx1 vaccine.

Menstrual cycle disturbances after COVID-19 vaccination. INTRODUCTION: After COVID-19 vaccination, women of reproductive age reported changes in their menstrual cycle. MATERIALS AND METHODS: A retrospective study was carried out after a survey on social networks that included women aged 18-41 years with normal cycles according to International Federation of Gynecology and Obstetrics and who were vaccinated (complete schedule for two doses, except J&J/Janssen or incomplete with a single dose). Women with following conditions were excluded: pregnant or lactating women; history of diseases that cause menstrual irregularities or early menopause: anorexia, bulimia, polycystic ovary syndrome, hypothyroidism, obesity, or low weight; hysterectomized or oophorectomized patients; and high performance athletes. RESULTS: Overall, 950 women completed the survey between July and September 2021. In total, 408 women met the inclusion criteria, and 184 reported the following characteristics: frequency (normal 43.47%, infrequent 25%, and frequent 31.53%), regularity (regular 51.08%, irregular 42.93%, and absent/amenorrhea 5.97%), duration (normal 65.21%, prolonged 26.08%, absent/amenorrhea 8.69%), and volume (heavy 41.84%, light 20.65%, and absent/amenorrhea 6.52%). CONCLUSIONS: SARS-CoV-2 infection and COVID-19 vaccination can influence the menstrual cycle and cause alterations.

Immune Thrombocytopenia following COVID-19 Vaccine. Several vaccines have been developed and are being administered against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Common side effects include fever, chills, headache, myalgia, and soreness at the injection site. However, some rare adverse effects have also been reported. We present a case of induced thrombocytopenia presenting with petechiae and mucosal bleeding which developed as an adverse response after first-dose administration of the Moderna COVID-19 vaccine.

Milk of Cow and Goat, Immunized by Recombinant Protein Vaccine ZF-UZ-VAC2001(Zifivax), Contains Neutralizing Antibodies Against SARS-CoV-2 and Remains Active After Standard Milk Pasteurization. Here, we present the first experimental validation of the possibility for obtaining immune milk with neutralizing antibodies against SARS-CoV-2 from vaccinated cows and goat using approved recombinant protein human coronavirus vaccine, ZF-UZ-VAC2001, in the Republic of Uzbekistan. In the period of 2 weeks after first vaccination, we detected the neutralizing antibodies against coronavirus in the blood serum of vaccinated animals. The neutralizing activity, in its peak on the 21st day after receiving the third dose (77th day from first dose), was effective in neutralization test using a live SARS-CoV-2 in Vero E6 cells, even after 120-fold serum titration. In cows receiving three dose of human vaccine, the MAGLUMI(Â®) SARS-CoV-2 neutralizing antibody competitive chemiluminescence immunoassay revealed that colostrum of the first day after calving had a greater activity to neutralize the SARS-CoV-2 compared to colostrum of subsequent three days (4.080 Î¼g/ml vs 2.106, 1.960 and 1.126 Î¼g/ml). In comparison, the neutralizing activity for goat and cow milk was 1.486 Î¼g/ml and 0.222 Î¼g/ml, respectively. We observed a positive correlation of receptor-binding domain (RBD)-specific IgG antibodies between the serum of actively immunized cow and milk-feeding calf during the entire course of vaccination ($r = 0.95$, $p = 0.05$). We showed an optimal regime for immune milk pasteurization at 62.5Â°C for 30 min, which retained specific neutralizing activity to SARS-CoV-2, potentially useful for passive immunization against coronavirus infection threats as an additive approach to the vaccination. This strategy, as a supportive approach to the vaccination, could also be applicable for directly reducing the effect of COVID-19 infection in gastrointestinal tract, supporting mucosal immunity.

Adverse Reactions to Anti-Infective Vaccines: an Emerging Problem in the COVID-19 Era. PURPOSE OF REVIEW: Vaccines are an essential tool for preventing infectious diseases and reducing

associated morbidity and mortality. Vaccination has a significant impact at both individual and community levels, and COVID-19 vaccination programs are a new example of the great value of this public health strategy. However, adverse reactions, especially severe reactions such as anaphylaxis, prevent these programs from progressing properly, thus limiting vaccination uptake in the population. RECENT FINDINGS: The frequency of reactions and types of vaccine components, with special attention to COVID-19 vaccines studies, provides information on the magnitude and causes of adverse events. The understanding of mechanisms involved has made it possible to adequately guide diagnosis, especially to COVID-19 vaccine components, such as polyethylene glycol, trometamol, and polysorbate-80. SUMMARY: This review focuses on adverse reactions to vaccines, with emphasis on allergic reactions. A diagnostic pathway is suggested that, on the one hand, enables to take the necessary precautions in persons with a history of allergy to vaccine components or allergic reactions to vaccines and, on the other, supports administration of subsequent doses. The overall objective is to ensure that people with allergy can be vaccinated in the same way as the rest of the population, and that they are offered alternatives where necessary.

Effects of Obstructive Sleep Apnea on SARS-CoV-2 Antibody Response After Vaccination Against COVID-19 in Older Adults. INTRODUCTION: Previous studies have linked sleep disturbances (including sleep deprivation and obstructive sleep apnea) to an impairment in immune response after vaccination for several diseases, although it has not yet been tested for COVID-19. This study sought to evaluate the effects of obstructive sleep apnea on anti-SARS-CoV-2 IgG levels after vaccination against COVID-19 among older adults. METHODS: The study was based on a convenience sample of inpatients who underwent full night type-I polysomnography. Inclusion criteria included being â‰¥60 years with full COVID-19 vaccination schedule. Exclusion criteria included previous COVID-19 diagnosis (assessed via self-report), less than 15 days between last dose and IgG testing, self-report of continuous positive air pressure (CPAP) use in the last three months, having undergone CPAP or split-night polysomnography, or incomplete/invalid data. RESULTS: Out of 122 included patients (no/mild OSA: 35; moderate: 31; severe: 56), 9.8% were considered seronegative for the IgG anti-SARS-CoV-2 test (IgG count<50.0 AU/mL), and the median IgG levels for the whole sample was 273 AU/mL (IQR: 744), with no statistically significant differences among OSA severity groups. There was neither association between OSA severity and IgG serostatus nor correlation between IgG levels and apnea-hypopnea index. A linear regression model to predict IgG levels was built, produced an R(2) value of 0.066 and the only significant predictor was time from vaccination to testing; while OSA severity was considered non-significant. DISCUSSION: Our results demonstrate that the severity of OSA is not correlated with a decrease in anti-SARS-CoV-2 IgG levels among older adults, and that the efficiency of COVID-19 vaccinations are not reduced from mild to severe OSA.

Association of anti-SARS-COV-2 vaccine with increased incidence of myositis-related anti-RNA-synthetases auto-antibodies. INTRODUCTION: SARS-CoV-2 is a RNA virus that associates with heterogeneous clinical manifestations and complications. Auto-antibodies are identified in approximately 50% of hospitalized COVID-19 patients. OBJECTIVES: To determine the global incidence of myositis-related auto-antibodies (non Jo1-RNA synthetases: anti-PL7, anti-PL12, anti-EJ, anti-OJ and RNA-sensor: anti-MDA5) in our laboratory during COVID-19 pandemics, and to describe the clinical and laboratory features of these patients. STUDY DESIGN: A retrospective study was performed from 2015 to 2021 in a cohort of 444 patients with suspected inflammatory myopathy. The incidence of positive results for the MSA was expressed as absolute value per year for the reference population. Immunoblot analysis, indirect immunofluorescence and HLA typing of 36 patients with positivity for MSAs were collected and analyzed. RESULTS: We observed MSA positive in 28 patients in 2020 and 36 patients in 2021, representing a mean increase of 6-fold respect to previous years since 2015 (range, 0 to 19). In 2020, the most common antibody detected was anti-

MDA5 (68%). In contrast, in 2021 the most common antibodies were anti-PL7 and/or anti-PL12 (69%). All patients in 2021 with positive anti-synthetases were fully vaccinated, 4 had previous documented infection, with median time from vaccine to MSA positivity of 5 months. Eight out of 36 patients (22%) reported clinical onset after SARS-CoV-2 vaccination and 6 out of 36 (17%) presented clinical and/or radiological worsening after SARS-CoV-2 vaccination. All patients presented with a known human leukocyte antigen (HLA)-DRB1* allele associated with ASS. The most prevalent alleles identified were DRB1*03:01, DRB1*04, DRB1*11:01, corresponding to 70% (16/23) of our cohort. CONCLUSIONS: Our preliminary data show an increased incidence of anti-synthetase antibodies during COVID-19 pandemic and SARS-CoV-2 vaccination associated to HLA DRB1* risk allele. Differential profiles of MSA specificities were observed: mainly against RNA-sensors in 2020 and against RNA-synthetases in 2021. Further studies are needed to support the association between SARS-CoV-2 infection and/or vaccination and the occurrence of this autoimmune syndrome.

Neuralgic amyotrophy in COVID-19 infection and after vaccination.

Frequency of vaccine-associated syncope after COVID-19 vaccination in adolescents.

The Rise of mRNA COVID-19 Vaccine-Associated Myocarditis and Its Implications on the Future Use of This New Vaccine Platform. Vaccine-associated myocarditis is becoming increasingly documented as a complication of the messenger ribonucleic acid (mRNA) vaccination platform. This complication so far has been found to predominantly affect theÂ younger male population within seven days of receivingÂ the second dose of an mRNA vaccine. We present a case of a 45-year-old male found to have clinical, biochemical, and radiological evidence of myocarditis three days after receipt of the second dose of the Moderna COVID-19 vaccine. Troponin I and inflammatory marker trends, in addition to the use of cardiac MRI imaging, was important in making the diagnosis. Symptom resolution was achieved after two months of colchicine and anti-heart failure medications. We highlight the occurrence of this rare vaccine complication in an endeavor to stress the need for further research to better understand this condition so that better guidance can be provided to the medical community on how best to screen and manage it.

Specific Antibody and the T-Cell Response Elicited by BNT162b2 Boosting After Two ChAdOx1 nCoV-19 in Common Variable Immunodeficiency. Common variable immunodeficiency (CVID) patients have markedly decreased immune response to vaccinations. In this study we evaluated humoral and T cell-mediated responses against severe acute respiratory syndrome coronavirus-2 (SARS-Cov-2) with additional flow cytometric changes in CVID patients receiving booster vaccination with BNT162b2 after two ChAdOx1 nCoV-19. The BNT162b2 vaccine raised the anti-spike protein S immunoglobulin G over the cut-off value from 70% to 83% in CVID, anti-neutralizing antibody had been raised over a cut-off value from 70% to 80% but levels after boosting were significantly less in both tests than in healthy controls (*p=0.02; **p=0.009 respectively). Anti-SARS-CoV-2 immunoglobulin A became less positive in CVID after boosting, but the difference was not significant. The cumulative interferon-Î³ positive T cell response by ELISpot was over the cut-off value in 53% of the tested individuals and raised to 83% after boosting. This and flow cytometric control of cumulative CD4+ and CD8+ virus-specific T cell absolute counts in CVID were also statistically not different from healthy individuals after boosting. Additional flow cytometric measures for CD45+ lymphocytes, CD3+, and CD19+ cells have not shown significant differences from controls except for lower CD4+T cell counts at both time points (**p=0.003; **p=0.002), in parallel CD4+ virus-specific T-cell ratio was significantly lower in CVID patients at the first time point (*p: 0.03). After boosting, in more than 33% of both CVID patients and also in their healthy controls we detected a decrease in absolute CD45+, CD3+, CD3+CD4+, and CD3+CD8+, CD19+, and CD16+56+ cell counts. CD16+CD56+ cell counts were significantly lower compared to controls before and after boosting (*p=0.02, *p=0.02). CVID patients receiving immunosuppressive therapy throughout the previous year or

autologous stem cell transplantation two years before vaccination had worse responses in anti-spike, anti-neutralizing antibody, CD3+CD4+T, CD19+ B, and natural killer cell counts than the whole CVID group. Vaccinations had few side effects. Based on these data, CVID patients receiving booster vaccination with BNT162b2 after two ChadOx1 can effectively elevate the levels of protection against COVID-19 infection, but the duration of the immune response together with COVID-19 morbidity data needs further investigation among these patients.

COVID-19 Vaccine-Induced Parsonage-Turner Syndrome: A Case Report and Literature Review. All modern vaccines share the risk of neurological adverse effects. Only a few cases of Parsonage-Turner syndrome (PTS), an uncommon peripheral nerve condition associated with coronavirus disease 2019Â (COVID-19) immunization, have been reported to date. We describe a case of COVID-19 vaccine-induced PTS and provide a brief literature review. A 78-year-old male non-smoker with a medical history of coronary artery disease presented with non-exertional, constant chest pain for one hour and new onset of bilateral hand weakness for three days.Â He had no neurological disease or allergies and denied any recent trauma or infection. Three weeks before the onset of the symptoms, the patient received a second dose of the BNT162b2 COVID-19 vaccine, which was administered 21 days after the first dose. Physical examination was significant for weakness in right-hand grip and wrist flexion. There were no other motor deficits, upper motor neuron signs, bulbar weakness, or sensory deficits.Â Diagnostic workup for the underlying diabetes mellitus, infections, or other autoimmune diseases was negative. Imaging workup revealed no demyelination, fracture deformity, traumatic subluxation, or compressive myelopathy. Nerve conduction studies, including needle electromyography, showed decreased motor unit recruitment in the bilateral first dorsal interosseous and right deltoid, biceps, and triceps muscles confirming PTS. The patient was treated with 40 mg/day of oral prednisone and occupational therapy to maintain range of motion and activities of daily living.Â PTS is also known as neuralgic amyotrophy, brachial plexus neuritis, brachial plexopathy, and shoulder-girdle syndrome.Â It is characterized by asymmetrical, chronic, resistant upper extremity neuropathic pain and neurological defects such as paralysis and paresthesia. There are two different types of PTS: non-hereditary and inherited. The etiology and pathophysiology of PTS are not fully understood.Â Various aspects such as genetic, environmental, and immunological predisposition may play a role in developing the syndrome. Infections, vaccines, and injuries are typical causes of non-hereditary forms. After the COVID-19 epidemic and the commencement of a global immunization effort, similar instances happened. Presently there is no available test that unequivocally confirms or excludes PTS itself. Electrodiagnostic study and imaging modalities help to rule out other differential diagnoses.Â Also, there is no specific treatment available; however, it may resolve independently of treatment withÂ supportive care.

The Association Between Dissemination and Characteristics of Pro-/Anti-COVID-19 Vaccine Messages on Twitter: Application of the Elaboration Likelihood Model. BACKGROUND: Messages on one's stance toward vaccination on microblogging sites may affect the reader's decision on whether to receive a vaccine. Understanding the dissemination of provaccine and antivaccine messages relating to COVID-19 on social media is crucial; however, studies on this topic have remained limited. OBJECTIVE: This study applies the elaboration likelihood model (ELM) to explore the characteristics of vaccine stance messages that may appeal to Twitter users. First, we examined the associations between the characteristics of vaccine stance tweets and the likelihood and number of retweets. Second, we identified the relative importance of the central and peripheral routes in decision-making on sharing a message. METHODS: English-language tweets from the United States that contained provaccine and antivaccine hashtags (N=150,338) were analyzed between April 26 and August 26, 2021. Logistic and generalized negative binomial regressions were conducted to predict retweet outcomes. The content-related central-route predictors were measured using the numbers of

hashtags and mentions, emotional valence, emotional intensity, and concreteness. The content-unrelated peripheral-route predictors were measured using the numbers of likes and followers and whether the source was a verified user. RESULTS: Content-related characteristics played a prominent role in shaping decisions regarding whether to retweet antivaccine messages. Particularly, positive valence (incidence rate ratio [IRR]=1.32, P=.03) and concreteness (odds ratio [OR]=1.17, P=.01) were associated with higher numbers and likelihood of retweets of antivaccine messages, respectively; emotional intensity (subjectivity) was associated with fewer retweets of antivaccine messages (OR=0.78, P=.03; IRR=0.80, P=.04). However, these factors had either no or only small effects on the sharing of provaccine tweets. Retweets of provaccine messages were primarily determined by content-unrelated characteristics, such as the numbers of likes (OR=2.55, IRR=2.24, P<.001) and followers (OR=1.31, IRR=1.28, P<.001). CONCLUSIONS: The dissemination of antivaccine messages is associated with both content-related and content-unrelated characteristics. By contrast, the dissemination of provaccine messages is primarily driven by content-unrelated characteristics. These findings signify the importance of leveraging the peripheral route to promote the dissemination of provaccine messages. Because antivaccine tweets with positive emotions, objective content, and concrete words are more likely to be disseminated, policymakers should pay attention to antivaccine messages with such characteristics.

Shoulder Pain and Injury after COVID-19 Vaccination. Shoulder injury related to vaccine administration (SIRVA) is a term given to describe shoulder pain and dysfunction arising within 48 hours after vaccine administration and lasting for more than one week. While SIRVA is most commonly seen after influenza and tetanus vaccines, there have been a few recent case reports describing SIRVA-like symptoms after COVID-19 vaccine administration. Two patients presented to the shoulder surgeon's practice center with complaints of shoulder stiffness and pain following the COVID-19 vaccine. The first patient was a 33-year-old man; he presented within 2 days of onset of the pain and 14 days from the vaccine date. He had a complete restriction of shoulder motion (0Â° flexion, and no external or internal rotation) at presentation. This patient was treated with non-steroidal anti-inflammatory drugs (NSAID) and rested in a sling for a week. The second patient was a 53-year-old woman; she presented with a 6-week duration of mild restriction of active shoulder motion and shoulder pain. Her magnetic resonance imaging (MRI) revealed the presence of subacromial-subdeltoid bursitis. She was treated with subacromial steroid injection and range of motion shoulder exercises. Both patients recovered a near-normal range of motion recovery within a month, and their pain improved significantly. The main lessons from this case report were: (1) patients presenting with a recent increase in pain and acute loss of shoulder movements after vaccination may be managed conservatively with rest and NSAID medications and (2) in case of a subacromial-subdeltoid bursitis in the MRI, subacromial injection of steroid may provide good pain relief.

Myocarditis Following COVID-19 Vaccination: A Systematic Review of Case Reports. Introduction: COVID-19, the infectious disease caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), often presents with a spectrum of symptoms at varying levels of severity, ranging from asymptomatic patients to those with fatal complications, such as myocarditis. With increased availability of COVID-19 vaccines, the awareness of possible side effects has expanded as reports surface. This study reviewed cases of myocarditis following COVID-19 vaccination and with existing literature on COVID-19 infection-induced myocarditis to compare clinical courses and analyze possible mechanisms of action. Methods: A systematic review of literature was conducted to identify published case reports (as of February 3, 2022) pertaining to the development of myocarditis following COVID-19 vaccination with either Pfizer or Moderna for an in-depth analysis. Additional subgroup analyses were conducted based on age, past medical history, vaccine manufacturer, and

dose number. Results: There were 53 eligible case reports that were included in this study. Patients were mostly male with a median age of 24 years, and the most reported symptom upon presentation was chest pain. Seventy percent of the cases involved the Pfizer vaccine with a majority of myocarditis developing subsequent to second dose. Resolution of symptoms was achieved in all but one patient. Clinical severity, as measured primarily by left ventricular ejection fraction, appeared to be worse among adult patients than pediatric, as well as for patients with comorbidities. Conclusion: This study revealed an observable association between COVID-19 vaccines and myocarditis. However, the clinical course and prognosis seem favorable and less prevalent than those conferred from natural infection.

Polymyalgia rheumatica and polymyalgia-like syndromes as adverse events following COVID-19 vaccines: working notes from a narrative review of published literature. Since the 1990s, polymyalgia rheumatica (PMR) has been reported as a possible adverse event following immunization (AEFI). The aim of this narrative review is to provide an overview of PMR (and PMR-like syndromes) following the most common types of COVID-19 vaccines, namely mRNA (tozinameran and mRNA-1273) and adenovirus-vectored (ChAdOx1-S) vaccines. To date, published literature reports few cases of PMR as vaccine-linked AEFI. Yet Vigibase, the WHO pharmacovigilance database, reports a few hundred cases. Based on these data, we address the question whether PMR/PMR-like syndromes following COVID-19 vaccines can be a true adverse or a coincidental event, and discuss its possible pathogenetic mechanisms.

Analysis of Side Effects Following Vaccination Against COVID-19 Among Individuals With Multiple Sclerosis Treated With DMTs in Poland. BACKGROUND AND OBJECTIVES: Since vaccination against COVID-19 is available for over a year and the population of immunized individuals with autoimmune disorders is higher than several months before, an evaluation of safety and registered adverse events can be made. We conducted a large study of side effects following the COVID-19 vaccine among patients with multiple (MS) sclerosis treated with disease-modifying therapies (DMTs) and analyzed factors predisposing for particular adverse events. METHODS: We gathered data of individuals with MS treated with DMTs from 19 Polish MS Centers, who reported at least one adverse event following COVID-19 vaccination. The information was obtained by neurologists using a questionnaire. The same questionnaire was used at all MS Centers. To assess the relevance of reported adverse events, we used Fisher's exact test, t-test, and U-Menn-Whutney test. RESULTS: A total of 1,668 patients with MS and reports of adverse events after COVID-19 vaccination were finally included in the study. Besides one case marked as "red flag", all adverse events were classified as mild. Pain at the injection site was the most common adverse event, with a greater frequency after the first dose. Pain at the injection site was significantly more frequent after the first dose among individuals with a lower disability (EDSS â‰¤2). The reported adverse events following immunization did not differ over sex. According to age, pain at the injection site was more common among individuals between 30 and 40 years old, only after the first vaccination dose. None of the DMTs predisposed for particular side effects. CONCLUSIONS: According to our findings, vaccination against COVID-19 among patients with MS treated with DMTs is safe. Our study can contribute to reducing hesitancy toward vaccination among patients with MS.

Association Between Vaccination Coverage Disparity and the Dynamics of the COVID-19 Delta and Omicron Waves in the US. OBJECTIVE: The US recently suffered the fourth and most severe wave of the COVID-19 pandemic. This wave was driven by the SARS-CoV-2 Omicron, a highly transmissible variant that infected even vaccinated people. Vaccination coverage disparities have played an important role in shaping the epidemic dynamics. Analyzing the epidemiological impact of this uneven vaccination coverage is essential to understand local differences in the spread and outcomes of the Omicron wave. Therefore, the objective of this study was to quantify the impact of vaccination

coverage disparity in the US in the dynamics of the COVID-19 pandemic during the third and fourth waves of the pandemic driven by the Delta and Omicron variants. METHODS: This cross-sectional study used COVID-19 cases, deaths, and vaccination coverage from 2,417 counties. The main outcomes of the study were new COVID-19 cases (incidence rate per 100,000 people) and new COVID-19 related deaths (mortality rate per 100,000 people) at county level and the main exposure variable was COVID-19 vaccination rate at county level. Geospatial and data visualization analyses were used to estimate the association between vaccination rate and COVID-19 incidence and mortality rates for the Delta and Omicron waves. RESULTS: During the Omicron wave, areas with high vaccination rates (>60%) experienced 1.4 (95% confidence interval [CI] 1.3-1.7) times higher COVID-19 incidence rate compared to areas with low vaccination rates (<40%). However, mortality rate was 1.6 (95% CI 1.5-1.7) higher in these low-vaccinated areas compared to areas with vaccination rates higher than 60%. As a result, areas with low vaccination rate had a 2.2 (95% CI 2.1-2.2) times higher case-fatality ratio. Geospatial clustering analysis showed a more defined spatial structure during the Delta wave with clusters with low vaccination rates and high incidence and mortality located in southern states. CONCLUSIONS: Despite the emergence of new virus variants with differential transmission potential, the protective effect of vaccines keeps generating marked differences in the distribution of critical health outcomes, with low vaccinated areas having the largest COVID-19 related mortality during the Delta and Omicron waves in the US. Vulnerable communities residing in low vaccinated areas, which are mostly rural, are suffering the highest burden of the COVID-19 pandemic during the vaccination era.

A Case of Giant Cell Arteritis With a Normal Erythrocyte Sedimentation Rate (ESR) Post ChAdOx1 nCoV-19 Vaccination. Giant cell arteritis (GCA) has been reported post the coronavirus disease 2019 (COVID-19) vaccination, especially with the mRNA vaccine. A normal erythrocyte sedimentation rate (ESR) is seen in some GCA patients. This report describes a 68-year-old gentleman who presented with a right-sided temporal headache for three weeks, starting three to five days after his second dose of the ChAdOx1 nCoV-19 vaccine, a viral vector vaccine,Â which was given seven weeks post the first dose. On presentation, he developed blurred vision in the left eye, and it progressed to complete vision loss four days later. He also had episodes of blurred vision in the right eye. The blood test showed a mildly elevated C-reactive protein of 29 mg/L and a normal erythrocyte sedimentation rate (ESR) of 4 mm/hr. Optical coherence tomography showed anterior ischaemic optic neuropathy in the left eye and retinal ischemia in the right eye. Bilateral giant cell arteritis (GCA) was confirmed on temporal artery biopsy. He was treated with methylprednisolone pulse therapy followed by prednisolone. He re-presented with intermittent blurry vision in the right eye three months later. He was treated with methylprednisolone pulse therapy again, followed by prednisolone, aspirin, and tocilizumab. This case describes a patient who developed GCA post ChAdOx1 nCoV-19 vaccination with a normal ESR. Further studies are needed to investigate this relationship as causal or incidental and the likelihood of low-level inflammatory makers in such a situation.

Recurrence of Autoimmuneâ€¯Hepatitisâ€¯After COVID-19â€¯Vaccination. A 35-year-old Asian female with a pertinent past medical history of autoimmune hepatitis presented with an acute recurrence of autoimmune hepatitis two weeks after receiving the second dose of the Pfizer-BioNTech messenger RNA (mRNA) coronavirus disease 2019 (COVID-19) vaccine. Nine cases of autoimmune hepatitis after the administration of the COVID-19 vaccine have been reported, but this is the first documented case of a reactivation of autoimmune hepatitis in remission. As recommendations for COVID-19 vaccinations and booster shots continue to evolve, all adverse events should be reported to better educate and monitor patients.

Polymyalgia Rheumatica After ChAdOx1 nCov-19 Vaccine: A Case Report. Polymyalgia rheumatica (PMR) is an inflammatory rheumatic disease characterized by severe pain and morning stiffness,

mainly affecting the shoulder girdle. A 75-year-old woman, previously healthy, received the first dose of ChAdOx1 vaccine and two weeks later started with pain in the shoulder and pelvic girdles and knees of inflammatory characteristics, accompanied by morning stiffness (about one hour), anorexia, asthenia, and activities of daily living (ADL) dependence. She started analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) with no improvement. The symptoms aggravated three days after the second vaccine dose, and she was referred to our center. At observation, she presented shoulder, hip, and knee active range of motion limitation. Blood analysis revealed an Erythrocyte Sedimentation Rate (ESR) of 120mm/h (reference value < 20mm/h) and C-Reactive Protein (CRP) of 80mg/L (reference value < 5mg/L). Ultrasound showed effusion on both shoulders, hips, and knees. The paraneoplastic syndrome was ruled out. She started oral corticosteroids and a rehabilitation program, andÂ a month later, she presented controlled pain, normal analysis, and ADLÂ independence. This case shows symptomatic and analytic features of PRM after the first vaccine dose and aggravation soon after the second. As such, we consider establishing a potential relationship between the inoculation and the development of PRM. A few cases were published reporting a PRM-like syndrome following a COVID-19 vaccine;Â however, the underlying mechanism and prognosis are still unknown.

Reactivation of Herpes Simplex Keratitis on a Corneal Graft Following SARS-CoV-2 mRNA Vaccination. BACKGROUND: Ocular herpes simplex is usually caused by herpes simplex virus type 1 (HSV-1) and less commonly by the type 2 virus (HSV-2). Ocular manifestations of HSV include blepharitis, conjunctivitis, lacrimal system obstruction, corneal involvement, and uveitis. Corneal involvement is one of the causes of loss of vision and can be epithelial herpetic keratitis or stromal herpetic keratitis. OBJECTIVE: A significant population has a colonization of herpes viruses. Under certain circumstances, these viruses can reactivate with a significant ocular morbidity. Globally, COVID-19 vaccines are recommended; however, the vaccine safety data are limited. CASE REPORT: Herein, we reported a case of herpetic keratitis reactivation that occurred 2 days after receiving SARS-CoV-2 mRNA vaccine. The patient is a 50-year-old man who underwent penetrating keratoplasty (PKP) in 2020 for corneal opacity caused by a previous herpes simplex keratitis in 2013. Herpetic keratitis was treated successfully with topical antiviral acyclovir along with topical moxifloxacin and artificial tears. After treatment, prophylactic oral acyclovir was started. CONCLUSION: Both ophthalmologist and patients should be aware of this phenomenon. Long-term prophylactic antiviral treatment may be recommended for those patients.

Increased (18)F-FDG Uptake in the Axillary Lymph Nodes of the Vaccinated Side Associated with COVID-19 Vaccination. A 50-year-old female patient underwent ((18)fluorine-fluorodeoxyglucose ((18)F-FDG) positron emission tomography/computed tomography (PET/CT) following modified radical mastectomy for cancer of the left breast. Ten days before the PET/CT, the coronavirus disease-2019 (COVID-19) vaccine was injected intramuscularly into the right deltoid muscle. Increased ((18)F-FDG uptake of maximum standardized uptake value (11.0) was observed in the lymph nodes of the right axilla, which had not been observed in the previous PET/CT. The size of the oval-shaped lymph nodes was up to approximately 11Ã—9 mm; however, it was larger than that observed on the previous PET/CT. We contemplate that the increased ((18)F-FDG uptake was a reactive change in the lymph nodes associated with the COVID-19 vaccine.

Factors Associated With the Decay of Anti-SARS-CoV-2 S1 IgG Antibodies Among Recipients of an Adenoviral Vector-Based AZD1222 and a Whole-Virion Inactivated BBV152 Vaccine. BACKGROUND: The magnitude of protection conferred following recovery from COVID-19 or by vaccine administration, and the duration of protective immunity developed, remains ambiguous. METHODS: We investigated the factors associated with anti-SARS-CoV-2 S1 IgG decay in 519 individuals who recovered from COVID-19 illness or received COVID-19 vaccination with two commercial vaccines, viz., an adenoviral vector-based (AZD1222) and a whole-virion-based

inactivated (BBV152) vaccine in Chennai, India from March to December 2021. Blood samples collected during regular follow-up post-infection/-vaccination were examined for anti-SARS-CoV-2 S1 IgG by a commercial automated chemiluminescent immunoassay (CLIA). RESULTS: Age and underlying comorbidities were the two variables that were independently associated with the development of a breakthrough infection. Individuals who were >60 years of age with underlying comorbid conditions (viz., hypertension, diabetes mellitus and cardiovascular disease) had a ~15 times and ~10 times greater odds for developing a breakthrough infection and hospitalization, respectively. The time elapsed since the first booster dose was associated with attrition in anti-SARS-CoV-2 IgG, where each month passed was associated with an ebb in the anti-SARS-CoV-2 IgG antibody levels by a coefficient of -6 units. CONCLUSIONS: Our findings advocate that the elderly with underlying comorbidities be administered with appropriate number of booster doses with AZD1222 and BBV152 against COVID-19.

What the harm principle says about vaccination and healthcare rationing. Clinical ethicists hold near consensus on the view that healthcare should be provided regardless of patients' past behaviors. In classic cases, the consensus can be explained by two key rationales-a lack of acute scarcity and the intractability of the facts around those behaviors, which make discrimination on past behavior gratuitous and infeasible to do fairly. Healthcare providers have a duty to help those who can be helped. In contrast, the COVID-19 pandemic suggests the possible recurrence of a very different situation, where a foreseeable acute shortage of healthcare resources means that some cannot be helped. And that shortage is exacerbated by the discrete decision of some to decline a free, safe, and highly effective vaccine, where the facts are clear. In such a future case, if healthcare must be denied to some patients, rationers who ignore vaccination status will become complicit in externalizing the consequences of refusing vaccination onto those who did not refuse. I argue that giving the unvaccinated person healthcare resources that would have otherwise gone to other patients is to wrongfully set back the interests of, or harm, those patients. The article considers rejoinders around the voluntariness of the vaccination choice, which impinges both access and information, and how to scale this criterion proportionally with other rationing criteria that serve utility. Ultimately, the article speculates on why there will be some cognitive dissonance under this approach, while upholding a more general solidarity with and concern for all those seeking healthcare.

Acute T cell-mediated rejection after administration of the BNT162b2 mRNA COVID-19 vaccine in a kidney transplant recipient: a case report. The impact of the coronavirus disease 2019 (COVID-19) vaccination on humoral and cellular immunity in transplant recipients remains unknown. We report the case of a 78-year-old kidney transplant recipient who experienced acute T cell-mediated rejection after receiving the second dose of the BNT162b2 mRNA COVID-19 vaccine (Pfizer-BioNTech). She had no history of acute rejection throughout the 13 years after deceased donor kidney transplantation. Fifteen days after receiving the second dose of the BNT162b2 vaccine, the recipient visited our center with a mild headache and fever. Her serum creatinine level had increased from 0.61 to 4.95 mg/dL. Kidney allograft biopsy indicated acute T cell-mediated rejection (grade IB) with no pathologic evidence of antibody-mediated rejection. Anti-severe acute respiratory syndrome coronavirus 2 spike-immunoglobulin G and -immunoglobulin M measurements were weak positive and negative, respectively. Careful monitoring of kidney allograft function is vital for transplant recipients undergoing COVID-19 vaccination.

Comment on 'MOG antibody-associated encephalomyelitis mimicking bacterial meningomyelitis following ChAdOx1 nCoV-19 vaccination: a case report'.

Thrombotic thrombocytopenia After Sinopharm BBIBP-CorV COVID-19 vaccination. BACKGROUND: Severe side effects after vaccination with coronavirus disease 2019 (COVID-19) vaccines are rare but can be fatal. To date, vaccine-induced immune thrombotic thrombocytopenia

(VITT) cases have been reported after injection of mRNA and adenoviral vectors COVID-19 vaccines. Here, we report the second suspected case of VITT after vaccination with the Sinopharm vaccine, an inactive vaccine. KEY CLINICAL QUESTION: The Key Clinical Question was to determine whether inactivated COVID-19 vaccines could induce VITT and how to diagnose and treat such cases. CLINICAL APPROACH AND CONCLUSIONS: Our patient developed deteriorating symptoms the day after vaccination and was admitted to the emergency department on day 5 after vaccination. After performing laboratory analysis, thrombosis with thrombocytopenia was suggested, further confirmed by highly positive anti-heparin-platelet factor 4 antibodies assay and color Doppler ultrasonography. He was then treated with high-dose intravenous immunoglobulin, corticosteroid, and nonheparin anticoagulant.

Understanding the Trauma of Menstrual Irregularity After COVID Vaccination: A Bird's-Eye View of Female Immunology. The intricacies in various signaling routes involved in the menstrual cycle can be impacted by internal as well as external stimuli, and the role of stress, be it physical, psychological, or social, in disturbing the process could be debilitating for a woman. The global endeavor of vaccination rose to protect individuals from the severity of COVID-19, but a conjunction of a short-lived menace of menstrual disturbance in the female population came out as an unsettling side effect. An understanding of the immunological panorama in the female reproductive tract (FRT) becomes important to fathom this issue. The close-knit microenvironment in the FRT shows active microbiota in the lower FRT, but the latest findings are ascertaining the presence of low-biomass microbiota in the upper FRT as well. Concerted signaling, wherein inflammation becomes an underlying phenomenon, results when a stressor elicits molecules of the inflammatory cascade. Learning lessons from the gut microbiota, we need to address the exploration of how FRT microbiota would impose inflammation by manipulating the immune response to vaccines. Since there is a prominent sex bias in the immune response to infectious diseases in women and men, the role of sex hormones and cortisol becomes important. The treatment regimen may be considered differently in women who also consider their ovarian cycle phases. Women exert robust immune response to antigenic encounters via cell-mediated and humoral arms. The inclusion of women in vaccine trials has been marginalized over the years, which resulted in unwanted high dosage administration of vaccines in women.

Emergency room imaging findings in patients presenting after COVID-19 vaccination. OBJECTIVES: Data on potential side effects of COVID-19 vaccines remains limited. This study aims to evaluate the relationship between the clinical presentations and imaging findings of emergency room (ER) patients presenting with suspected side effects or complications of recent COVID-19 vaccination. MATERIALS AND METHODS: An Institutional Review Board-approved retrospective analysis of vaccinated patients who underwent imaging studies in the ER between December 2020 and August 2021 was conducted. Reports were analyzed for imaging modality, chief complaints, and imaging findings. RESULTS: A total of 173 studies on 161 patients were included: 73 X-rays, 57 computed tomographys, 12 magnetic resonance imagings, and 31 ultrasounds. Analysis of the 168 reports dictated in these 173 studies revealed chest pain (27%), shortness of breath (17%), headache (12.5%), fever (10%), and cough (11.9%) as the most common presenting signs/symptoms. About 57.7% of reports showed no post-vaccine complications. Of the 42.3% of reports with findings, lung opacities/consolidation (36.6%) and cervical and/or axillary adenopathy (35.2%) were most commonly seen; other major findings included saddle embolus (1.4%) and vertebral artery occlusion (1.4%). CONCLUSION: Chest pain, cough, shortness of breath, and headache were the most common presenting symptoms in the ER after COVID-19 vaccination, and chest X-ray and computed tomography chest angiography were the most commonly ordered studies to assess vaccine-related complications. Lung opacities/consolidations were the most common findings. Given that vascular

post-vaccine complications are considered the most dangerous and 2.8% of reports demonstrated positive vascular findings, concern for vascular complications should initiate appropriate imaging to ensure prompt diagnosis and management.

Comparability of clinical trials and spontaneous reporting data regarding COVID-19 vaccine safety. Severe adverse events (AEs) after COVID-19 vaccination are not well studied in randomized controlled trials (RCTs) due to rarity and short follow-up. To monitor the safety of COVID-19 vaccines ("Pfizer" vaccine dose 1 and 2, "Moderna" vaccine dose 1 and 2, and "Janssen" vaccine single dose) in the U.S., especially regarding severe AEs, we compare the relative rankings of these vaccines using both RCT and the Vaccine Adverse Event Reporting System (VAERS) data. The risks of local and systemic AEs were assessed from the three pivotal COVID-19 vaccine trials and also calculated in the VAERS cohort consisting of 559,717 reports between December 14, 2020 and September 17, 2021. AE rankings of the five vaccine groups calculated separately by RCT and VAERS were consistent, especially for systemic AEs. For severe AEs reported in VAERS, the reported risks of thrombosis and GBS after Janssen vaccine were highest. The reported risk of shingles after the first dose of Moderna vaccine was highest, followed by the second dose of the Moderna vaccine. The reported risk of myocarditis was higher after the second dose of Pfizer and Moderna vaccines. The reported risk of anaphylaxis was higher after the first dose of Pfizer vaccine. Limitations of this study are the inherent biases of the spontaneous reporting system data, and only including three pivotal RCTs and no comparison with other active vaccine safety surveillance systems.

Severe myopericarditis following the third dose of an mRNA COVID-19 vaccine: utility of a multimodal treatment approach. We report a rare case of severe myopericarditis in a healthy man in his 20s after the third dose of an mRNA COVID-19 vaccine. His symptoms and troponinemia resolved with a beta-blocker in addition to standard anti-inflammatory therapy, highlighting the utility of multimodal therapy.

Novel extreme regression-voting classifier to predict death risk in vaccinated people using VAERS data. COVID-19 vaccination raised serious concerns among the public and people are mind stuck by various rumors regarding the resulting illness, adverse reactions, and death. Such rumors are dangerous to the campaign against the COVID-19 and should be dealt with accordingly and timely. One prospective solution is to use machine learning-based models to predict the death risk for vaccinated people and clarify people's perceptions regarding death risk. This study focuses on the prediction of the death risks associated with vaccinated people followed by a second dose for two reasons; first to build consensus among people to get the vaccines; second, to reduce the fear regarding vaccines. Given that, this study utilizes the COVID-19 VAERS dataset that records adverse events after COVID-19 vaccination as 'recovered', 'not recovered', and 'survived'. To obtain better prediction results, a novel voting classifier extreme regression-voting classifier (ER-VC) is introduced. ER-VC ensembles extra tree classifier and logistic regression using soft voting criterion. To avoid model overfitting and get better results, two data balancing techniques synthetic minority oversampling (SMOTE) and adaptive synthetic sampling (ADASYN) have been applied. Moreover, three feature extraction techniques term frequency-inverse document frequency (TF-IDF), bag of words (BoW), and global vectors (GloVe) have been used for comparison. Both machine learning and deep learning models are deployed for experiments. Results obtained from extensive experiments reveal that the proposed model in combination with TF-TDF has shown robust results with a 0.85 accuracy when trained on the SMOTE-balanced dataset. In line with this, validation of the proposed voting classifier on binary classification shows state-of-the-art results with a 0.98 accuracy. Results show that machine learning models can predict the death risk with high accuracy and can assist the authors in taking timely measures.

Maternal immune response and placental antibody transfer after COVID-19 vaccination across trimester and platforms. The availability of three COVID-19 vaccines in the United States provides an unprecedented opportunity to examine how vaccine platforms and timing of vaccination in pregnancy impact maternal and neonatal immunity. Here, we characterize the antibody profile after Ad26.COV2.S, mRNA-1273 or BNT162b2 vaccination in 158 pregnant individuals and evaluate transplacental antibody transfer by profiling maternal and umbilical cord blood in 175 maternal-neonatal dyads. These analyses reveal lower vaccine-induced functions and FcÂ receptor-binding after Ad26.COV2.S compared to mRNA vaccination and subtle advantages in titer and function with mRNA-1273 versus BN162b2. mRNA vaccines have higher titers and functions against SARS-CoV-2 variants of concern. First and third trimester vaccination results in enhanced maternal antibody-dependent NK-cell activation, cellular and neutrophil phagocytosis, and complement depositionÂ relative to second trimester. Higher transplacental transfer ratios following first and second trimester vaccination may reflect placental compensation for waning maternal titers. These results provide novel insight into the impact of platform and trimester of vaccination on maternal humoral immune response and transplacental antibody transfer.

Immunogenicity and reactogenicity of SARS-CoV-2 vaccines BNT162b2 and CoronaVac in healthy adolescents. We present an interim analysis of a registered clinical study (NCT04800133) to establish immunobridging with various antibody and cellular immunity markers and to compare the immunogenicity and reactogenicity of 2-dose BNT162b2 and CoronaVac in healthy adolescents as primary objectives. One-dose BNT162b2, recommended in some localities for risk reduction of myocarditis, is also assessed. Antibodies and T cell immune responses are non-inferior or similar in adolescents receiving 2 doses of BNT162b2 (BB, Nâ€‰=â€‰116) and CoronaVac (CC, Nâ€‰=â€‰123) versus adults after 2 doses of the same vaccine (BB, Nâ€‰=â€‰147; CC, Nâ€‰=â€‰141) but not in adolescents after 1-dose BNT162b2 (B, Nâ€‰=â€‰116). CC induces SARS-CoV-2 N and N C-terminal domain seropositivity in a higher proportion of adolescents than adults. Adverse reactions are mostly mild for both vaccines and more frequent for BNT162b2. We find higher S, neutralising, avidity and Fc receptor-binding antibody responses in adolescents receiving BB than CC, and a similar induction of strong S-specific T cells by the 2 vaccines, in addition to N- and M-specific T cells induced by CoronaVac but not BNT162b2, possibly implying differential durability and cross-variant protection by BNT162b2 and CoronaVac, the 2 most used SARS-CoV-2 vaccines worldwide. Our results support the use of both vaccines in adolescents.

[COVID-19 vaccines primary features and research progress on possible trigger of liver injury post-vaccination]. The COVID-19 outbreak is a global pandemic that has had caused a profound impact on social stability, economic development and national security, and has further evolved into a major public health crisis. The rapid research and development and efficient deployment of vaccines is one of the effective means to prevent and control the epidemic. This article reviews the primary features of current COVID-19 vaccines, simultaneously focus the clinical features of liver injury post-vaccination and explore its possible pathogenesis.

Anti-SARS-CoV-2 IgG antibodies pre- and post-vaccination behavior in health workers from a Guatemalan cancer center. INTRODUCTION: The study of anti-SARS-CoV-2 IgG antibodies allows asymptomatic individuals with COVID-19 to be identified, and post-infection and post-vaccination immunity status to be evaluated. OBJECTIVE: To know the behavior of anti-SARS-CoV-2 IgG antibodies before and after vaccination in workers of a cancer center. METHODS: Prior to the application of the vaccine, the presence of anti-SARS-CoV-2 IgG antibodies (n = 171) was analyzed by evaluating anti-N IgG antibodies; post-vaccination, after receiving the second dose, anti-S IgG antibodies were evaluated (n = 60). RESULTS: Prior to vaccination, IgG antibodies were present in 18.71% of participants; they were detected in 65.22% of those with prior history of COVID-19 diagnosis and in

11.49% of those without it. The positions with the highest prevalence were nurses (28.26%), paramedics (27.59%) and administrative workers (27.78%), p < 0.01. Anosmia, ageusia and chest tightness were associated with the presence of IgG (p < 0.05). Post-vaccination, all participants developed IgG antibodies; people with a previous COVID-19 diagnosis had higher titers: 10,277 vs. 6,819 AU/mL, p < 0.001. CONCLUSIONS: The study of anti-SARS-CoV-2 IgG antibodies allowed asymptomatic health workers to be identified. A high percentage of participants with prior COVID-19 diagnosis had antibodies. All participants developed IgG antibodies after vaccination, with higher titers being identified in those with previous infection.

Immune Response after 2 Doses of BNT162b2 mRNA COVID-19 Vaccinations in Children and Adolescents with Cancer and Hematologic Diseases. BACKGROUND: The BNT162b2 mRNA COVID-19 vaccine has been administered to children and adolescents with cancer and hematologic diseases since they are at high risk of manifesting severe symptoms if they have COVID-19 infection but the adequate immune response after vaccination in these immunocompromised patients are questionable. OBJECTIVE: To evaluate the immune response of children and adolescents with cancer and hematologic diseases after receiving 2 doses of the BNT162b2 mRNA COVID-19 vaccine. METHODS: This is a prospective cohort study of patients with cancer and hematologic disease, who aged 12- 18 years old and received 2 doses the BNT162b2 vaccines at 4 weeks apart were enrolled. Immunogenicity was determined by measuring serum anti-SARS-CoV-2 immunoglobulin antibodies directed against the receptor binding domain (RBD) of S1 domain of the spike protein (Anti S-RBD), surrogated viral neutralization test (sVNT) of SARS-CoV-2 and Delta strain. Blood samples were collected and analyzed at 4 and 12 weeks after vaccination. The seroprotective rate was defined as sVNT â‰¥ 68%. RESULTS: From Oct 2021 to Jan 2022, 43 children were enrolled, 21 were on-therapy and 22 were off-therapy. 25 were hematologic malignancy, 15 solid tumor and 3 hematologic diseases with immunosuppressive drugs. The GMT (95%CI) of a anti S-RBD IgG level at 4 weeks after vaccination were 56.05 (13.2,238.2) and 3633 (2689,4908) BAU/mL in on-therapy and off-therapy group, respectively, p<0.001. The sVNT (95%CI) of delta strain were 26% (5.85-73.55%) and 97.05% (96.0-97.4%) as the seroprotective level which were 33.3% in on-therapy group and 100% in off-therapy group (p<0.001). 14 children in on-therapy group need an additional dose. CONCLUSION: After complete vaccination, the seroprotective rate and antibody level in pediatric and adolescent patients with cancer and hematologic disease who receive immunosuppressive agents are quite low, compared with patients who had complete treatment. Additional dose of primary series should be offered.

Bilateral Vocal Fold Paralysis After COVID-19 mRNA Vaccination: A Case Report. Since severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was noted to cause coronavirus disease 2019 (COVID-19) in 2019, there have been many trials to develop vaccines against the virus. Messenger ribonucleic acid (mRNA) vaccine as a type of the vaccine has been developed and commercialized rapidly, but there was not enough time to verify the long-term safety. An 82-year-old female patient was admitted to the emergency room with dyspnea accompanied by stridor three days after the 3rd COVID-19 mRNA vaccination (Comirnaty, Pfizer-BioNTech, USA). The patient was diagnosed with bilateral vocal fold paralysis (VFP) by laryngoscope. Respiratory distress was improved after the intubation and tracheostomy in sequence. The brain, chest, and neck imaging tests, serological tests, cardiological analysis, and immunological tests were performed to evaluate the cause of bilateral VFP. However, no definite cause was found except for the precedent vaccination. Because bilateral VFP can lead to a fatal condition, a quick evaluation is necessary in consideration of VFP when dyspnea with stridor occurs after vaccination.

Antibody-Positive Neuromyelitis Optica Spectrum Disorder After Second COVID-19 Vaccination: a Case Report. In the era of the COVID-19 pandemic declared in March 2020, widespread

vaccination protocols were initiated to mitigate the severity and spread of COVID-19. Although COVID-19 vaccines have been generally considered safe, adverse events post-vaccination have been reported, including the development of demyelinating disease. We report a rare case of de novo aquaporin-4-positive neuromyelitis optica spectrum disorder (NMOSD) in an 80-year-old man following BNT162b SARS-CoV-2 vaccination to raise the awareness of this possible severe adverse event in an older adult. An 80-year-old South Asian man presented 2Â days following his second dose of the Pfizer-BioNTech COVID-19 mRNA BNT162b2 vaccine with progressive left-sided leg weakness and numbness resulting in falls. MRI of the spine revealed a longitudinally extensive transverse myelitis from T3-T4 to T9-T10. Serum antibody testing revealed positive aquaporin-4 (AQP4) antibodies. He was diagnosed with AQP4-positive NMOSD and was treated with high-dose intravenous methylprednisolone and plasma exchange with some improvement. He was subsequently treated with mycophenolate mofetil and a slow steroid wean. This case report adds to the existing literature and suggests that COVID-19 vaccinations may trigger de novo NMOSD or NMOSD relapses in some individuals. Although rare, our patient presented with new-onset NMOSD in his 80Â s following COVID-19 vaccination. As such, it is relevant to consider AQP4 testing in those presenting with a post-vaccination myelitis, regardless of age. Ongoing vaccine surveillance and research are needed to understand the risk of NMOSD post-COVID-19 vaccinations further.

Safety and immunogenicity of a hybrid-type vaccine booster in BBIBP-CorV recipients in a randomized phase 2 trial. NVSI-06-08 is a potential broad-spectrum recombinant COVID-19 vaccine that integrates the antigens from multiple SARS-CoV-2 strains into a single immunogen. Here, we evaluate the safety and immunogenicity of NVSI-06-08 as a heterologous booster dose in BBIBP-CorV recipients in a randomized, double-blind, controlled, phase 2 trial conducted in the United Arab Emirates (NCT05069129). Three groups of healthy adults over 18 years of age (600 participants per group) who have administered two doses of BBIBP-CorV 4-6-month, 7-9-month and >9-month earlier, respectively, are randomized 1:1 to receive either a homologous booster of BBIBP-CorV or a heterologous booster of NVSI-06-08. The incidence of adverse reactions is low, and the overall safety profile is quite similar between two booster regimens. Both Neutralizing and IgG antibodies elicited by NVSI-06-08 booster are significantly higher than those by BBIBP-CorV booster against not only SARS-CoV-2 prototype strain but also multiple variants of concerns (VOCs). Especially, the neutralizing antibody GMT against Omicron variant induced by heterologous NVSI-06-08 booster reaches 367.67, which is substantially greater than that boosted by BBIBP-CorV (GMT: 45.03). In summary, NVSI-06-08 is safe and immunogenic as a booster dose following two doses of BBIBP-CorV, which is immunogenically superior to the homologous boost with another dose of BBIBP-CorV.

[Bell's Palsy Secondary to COVID-19 Vaccine Pfizer: Case report]. BACKGROUND: BNT162b2 (Pfizer-BioNTech) is a nucleosidemodified mRNA vaccine formulated with lipid nanoparticles for the prevention of COVID-19 disease caused by SARSCoV-2 infection. In early December 2020, BNT162b2 received an emergency use authorization, initial efficacy and safety data have been released, consumer / patient information sheets for vaccines distributed in North America do not warn of Bell's palsy as a possible adverse effect. We reported the case of a patient who developed Bell's palsy on the right side in less than 3 hours after the application of the first dose of the Pfizer-BioNTech COVID-19 vaccine. CLINICAL CASE: 32-year-old latina woman who developed right facial paralysis after receiving the first dose of the BNT162b2 mRNA vaccine on April 7, 2021; with right facial paresis, absence of forehead wrinkles, lip-buccal sulcus and nasolabial fold; spasms of the facial and periorbital muscles, laterocervical pain; possible etiologies were ruled out, prednisone, gabapentin and topiramate. CT without alterations, achieving gradual improvement; until full functional recovery after 15 days. With benign evolution, congruent with the natural history of the disease, classifying it as idiopathic Bell's palsy. CONCLUSIONS: Although a causal relationship cannot be established, the

time and mode of appearance of the paralysis suggested a relationship with the application of the BNT162b2 vaccine. Given the recommendation of the health authorities to monitor the cases of Bell's palsy, and the surveillance of events supposedly attributable to vaccination (ESAVI) and as it is the first case reported in the literature, in the mexican population, we believe that this case should be shared with the scientific community in a timely manner.

Immunogenicity, Effectiveness, and Safety of Inactivated Virus (CoronaVac) Vaccine in a Two-Dose Primary Protocol and BNT162b2 Heterologous Booster in Brazil (Immunita-001): A One Year Period Follow Up Phase 4 Study. BACKGROUND: Effective and safe vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are critical to controlling the COVID-19 pandemic and will remain the most important tool in limiting the spread of the virus long after the pandemic is over. METHODS: We bring pioneering contributions on the maintenance of the immune response over a year on a real-life basis study in 1,587 individuals (18-90 yrs, median 39 yrs; 1,208 female/379 male) who underwent vaccination with two doses of CoronaVac and BNT162b2 booster after 6-months of primary protocol. FINDINGS: Elevated levels of anti-spike IgG antibodies were detected after CoronaVac vaccination, which significantly decreased after 80 days and remained stable until the introduction of the booster dose. Heterologous booster restored antibody titers up to-1Â·7-fold, changing overall seropositivity to 96%. Titers of neutralising antibodies to the Omicron variant were lower in all timepoints than those against Delta variant. Individuals presenting neutralising antibodies against Omicron also presented the highest titers against Delta and anti-Spike IgG. Cellular immune response measurement pointed out a mixed immune profile with a robust release of chemokines, cytokines, and growth factors on the first month after CoronaVac vaccination followed by a gradual reduction over time and no increase after the booster dose. A stronger interaction between those mediators was noted over time. Prior exposure to the virus leaded to a more robust cellular immune response and a rise in antibody levels 60 days post CoronaVac than in individuals with no previous COVID-19. Both vaccines were safe and well tolerated among individuals. INTERPRETATION: Our data approach the effectiveness of CoronaVac association with BNT162b2 from the clinical and biological perspectives, aspects that have important implications for informing decisions about vaccine boosters. FUNDING: Fiocruz, Brazil.

"Marginal keratitis following COVID 19 vaccination". PURPOSE: To describe a novel case of marginal keratitis following COVID 19 vaccination. METHODS: Case report. RESULTS: A 68-year-old female received the Moderna COVID 19 vaccine. She then developed ocular irritation and peripheral corneal opacities that are characteristic of marginal keratitis. Her symptoms responded well to steroid and antibiotic ophthalmic medications. She received her second dose of the Moderna vaccine while still taking her eye drops and was then able to taper off her drops without a recurrence of symptoms. CONCLUSIONS: Marginal keratitis represents a localized type III hypersensitivity reaction of the cornea. The SARS-CoV-2 virus that causes COVID 19 gains entry into the cell via binding of the spike protein with the ACE2 receptor. It is this spike protein that is the target for mRNA COVID-19 vaccines, such as the Moderna vaccine, allowing spike protein antigen recognition by the human immune system. The cornea has been found to have significant levels of ACE2 receptors, potentially allowing for the cornea to become a site for the antigen-antibody complex deposition necessary for a type III hypersensitivity response. This reaction should be recognized so that treatment may be provided during the initial episode and the cornea may be monitored following subsequent vaccinations.

Cervical Transverse Myelitis Following COVID-19 Vaccination. Various COVID-19 vaccines are associated with numerous adverse side effects. Associations between vaccinations and neurological disorders, such as transverse myelitis, stroke, Bell's palsy, acute disseminated encephalomyelitis, and Guillain-BarrÃ© syndrome, have been reported. A 27-year-old Japanese woman presented with

paresthesia four days after receiving a second dose of the COVID-19 vaccine. One month after vaccination, she started to feel left lower limb weakness, and her symptoms almost improved after two steroid pulse therapies. Spinal cord tumor biopsy could potentially help make a definitive diagnosis in clinical situations. However, it is very important to review the patient's medical history, including vaccinations received, before performing a direct spinal cord biopsy, which is invasive and does not guarantee a definitive diagnosis.

Long-Term Humoral Response After a Second Dose of SARS-CoV-2 mRNA Vaccine in Japanese Kidney Transplant Recipients. BACKGROUND: The mortality rate due to COVID-19 in kidney transplant recipients (KTRs) is 16.8 to 32%. Vaccination against COVID-19 is expected to contribute to the prevention of infection, severe disease, and mortality; however, it has been reported that the humoral response to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine in KTRs is poor. Vaccination strategies against COVID-19 vary from country to country, and in Japan, the third dose is given 6â€‰months after the second dose. Few studies have evaluated long-term humoral responses after the second dose of SARS-CoV-2 mRNA vaccine. In addition, the superiority of BNT162b2 vaccine and mRNA-1,273 vaccine in KTRs regarding humoral response is controversial. METHODS: Ninety-four KTRs were administered a second dose of the BNT162b2 or mRNA-1,273 vaccines, and anti-spike (anti-S) and anti-nucleocapsid (anti-N) SARS-CoV-2 antibody levels were measured 5â€‰months (149.2â€‰Â±â€‰45.5â€‰days) later. The cutoff value of anti-S antibodies was defined â‰¥50â€‰AU/ml and 1.4 Index for anti-N antibodies. The primary outcome was the rate of seropositivity, and factors associated with an appropriate humoral response were assessed by univariate and multivariate analysis. RESULTS: Of 94 KTRs, only 45 (47.9%) patients were positive for anti-S antibodies. The median anti-S SARS-CoV-2 IgG antibody titers was 35.3 (Interquartile range 3.8 to 159.7). Anti-N SARS-CoV-2 IgG antibodies in all patients wereâ€‰<â€‰1.4 Index. Response to SARS-CoV-2 mRNA vaccines were 43.2 and 65% for BNT162b2 and mRNA-1,273, respectively (pâ€‰=â€‰0.152). In comparison with high-dose, low-dose of mycophenolic acid was a robust factor associated with an adequate humoral response. CONCLUSION: The long-term humoral response after a second dose of SARS-CoV-2 mRNA vaccine in Japanese KTRs was poor. In comparison with high-dose, low-dose mycophenolic acid was related to an appropriate humoral response. Five months is too long to wait for a 3rd dose after 2nd dose of SARS-CoV-2 vaccine in KTRs. In this cohort, there was no statistical difference in humoral response to the BNT162b2 and mRNA-1,273 vaccines. Additional large observational studies and meta-analyses are needed to clarify the factors related to an appropriate humoral immune response to COVID-19 vaccination.

COVID-19 Vaccine: A Possible Trigger for Pyoderma Gangrenosum. Pyoderma gangrenosum is an uncommon ulcerative auto-inflammatory dermatosis. Numerous studies suggest cutaneous side effects of the COVID-19 vaccine. Pyoderma gangrenosum has been reported as one of the rare side effects of the COVID-19 vaccine. In this report, a 36-year-old male was admitted to a hospital due to a progression of pyoderma gangrenosum on the lateral aspect of his upper arm which had developed eight months ago, following the first dose of Sinopharm BBIBP COVID-19 vaccine. The reported symptoms included headache, blurred vision, palpitation, fatigue on exertion, documented fever, chills and productive cough with yellow sputum, possibly due to the inflammatory effect of pyoderma gangrenosum. In the past, the patient's face had several abnormal skin lesions similar to the newly developed lesion. In addition, the newly developed lesion did not regress despite using medication. COVID-19 vaccinations could potentially trigger pyoderma gangrenosum, especially in patients with a past medical history of similar lesions in different body parts. Therefore, we recommend inquiring about the past medical history of pyoderma gangrenosum or abnormal skin lesions prior to vaccination.

Myopericarditis After mRNA COVID-19 Vaccine in a Patient With Recent History of COVID-19. Myopericarditis has been identified as a potential adverse event of several vaccines in the medical literature. Here we present a case of a 30-year-old male who had myopericarditis a week after receiving the second booster dose of the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine. The patient's clinical course was not severe and had a full recovery after a week of treatment.

Impact of BNT162b2 mRNA Vaccination on the Development of Short and Long-Term Vaccine-Related Adverse Events in Inflammatory Bowel Disease: A Multi-Center Prospective Study. INTRODUCTION: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination has been effective in protecting against severe COVID-19 infections and related mortality. It is recommended for all individuals including patients with inflammatory bowel disease (IBD). However, safety data are lacking in this group of patients. Therefore, we aim to evaluate the short- and long-term vaccine related adverse events (AEs) in patients with IBD. METHODS: This is a prospective, observational cohort study investigating short- and long-term AEs related to the BNT162b2 vaccine in patients with IBD (study group) after the first and second dose compared to healthy participants (control group). Patients were recruited at the time of attendance to the clinic or infusion rooms. Short term (<3 weeks) localized and systemic AEs were assessed via questionnaire. Follow-up phone-based survey was made to collect data on long term (up to 24 weeks) AEs. RESULTS: A total of 408 patients answered the questionnaires, 204 patients in each group, the study and control group. No serious adverse events were reported in either the study or the control group after the first or the second dose. Participants in the control group reported more frequent pain at the injection site than those in the study group after the first dose [58 (57%) vs. 38 (37%) respectively, P = 0.005]. After the second dose, tiredness was reported more frequently in the control group [49 (48%)] compared to the study group [25 (24%) (P < 0.001)]. At 20-24 weeks post vaccination, 386 out of 408 (94.6%) patients were willing to participate in the follow-up phone based questionnaire [196 (96.1%) in the study group vs. 190 (93.1%) in the control group]. In both groups, none of the patients reported local, systemic, or severe adverse events (0 out of 386) at week 20-24 post second dose. CONCLUSION: The BNT162b2 vaccine is safe in patients with IBD. No severe or long-term adverse events were reported in our study. The frequency of local and systemic adverse events after the second dose was generally higher among healthy participants compared to patients with IBD. Further studies including a larger cohort with a longer follow-up duration are needed to assess for possible rare adverse events.

Acute appendicitis following the COVID-19 vaccine. We report the case of a previously healthy 69-year-old female who developed appendicitis after receiving the third dose of the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) vaccine; no other triggers were identified. We speculate that an association exists which may be mediated by colonic lymphoid hyperplasia, a condition that might be indicative of an enhanced immunological mucosal response to antigenic stimulation. As widespread vaccination coverage continues, it is crucial to monitor and accurately report the adverse reactions that may otherwise remain unidentified in vaccination trials. Therefore, we suggest that adults experiencing spontaneous, severe abdominal pain following COVID-19 vaccination may benefit from seeking emergent medical care. Likewise, providers should have a low threshold to consider and evaluate patients for appendicitis. If a true causal link is identified, the risk must also be deliberated in context with the millions of patients who have been safely vaccinated and the known morbidity and mortality from COVID-19 infection.

COVID toes following vaccination. Cutaneous manifestations of COVID-19 infections include "COVID toes." These are pernio-like, pale purple, painful, ill-defined cyanotic lesions that have inflammatory infiltrates on histologic studies. COVID toes can also develop following COVID vaccination. COVID toes was reported by 29 individuals to the Vaccine Adverse Event Reporting

System maintained by the Centers for Disease Control and Prevention through May 25, 2021. The mean age of these individuals was 52â€‰Â±â€‰18 years; 23 (79%) were women. They had received both mRNA vaccines and the adenovirus vector-based vaccine. This discoloration developed 4.5â€‰Â±â€‰9.8 days following vaccination, usually after the first dose. Four individuals required hospitalization for systemic symptoms, and one died. This information indicates that some individuals develop important clinical syndromes following vaccination and suggests that some of the manifestations of COVID-19 infection represent immune responses and not necessarily active tissue infection.

Age and sex-specific risks of myocarditis and pericarditis following Covid-19 messenger RNA vaccines. Cases of myocarditis and pericarditis have been reported following the receipt of Covid-19 mRNA vaccines. As vaccination campaigns are still to be extended, we aimed to provide a comprehensive assessment of the association, by vaccine and across sex and age groups. Using nationwide hospital discharge and vaccine data, we analysed all 1612 cases of myocarditis and 1613 cases of pericarditis that occurred in France in the period from May 12, 2021 to October 31, 2021. We perform matched case-control studies and find increased risks of myocarditis and pericarditis during the first week following vaccination, and particularly after the second dose, with adjusted odds ratios of myocarditis of 8.1 (95% confidence interval [CI], 6.7 to 9.9) for the BNT162b2 and 30 (95% CI, 21 to 43) for the mRNA-1273 vaccine. The largest associations are observed for myocarditis following mRNA-1273 vaccination in persons aged 18 to 24 years. Estimates of excess cases attributable to vaccination also reveal a substantial burden of both myocarditis and pericarditis across other age groups and in both males and females.

SARS-CoV-2 vaccinations reduce the prevalence of post-COVID Guillain-Barre syndrome. Guillain-Barre Syndrome (GBS) has been repeatedly reported as a neurological complication of COVID-19 (post-COVID GBS [PCG]). Whether the introduction of SARS-CoV-2 vaccines reduced the prevalence of PCG is unknown. This narrative review aimed to compare the number of published PCG cases between the second halfÂ of 2020 (no vaccination available) with those of the first halfÂ of 2021 (vaccination available). A total ofÂ 124Â articles reportedÂ 300Â patients with PCG between January 2020 and June 2021. The ages ranged fromÂ 7Â toÂ 94y. There was male dominance. The latency between the onset of COVID-19 and the onset of PCG ranged fromÂ -10Â toÂ 90d Acute, inflammatory, demyelinating polyneuropathy was diagnosed inÂ 171Â patients, acute, motor axonal neuropathy inÂ 24, and acute, motor, and sensory axonal neuropathy inÂ 16Â patients. Regarding treatment, 241Â patients received immunoglobulins, 28Â patients' plasmaphereses, andÂ 7Â patients' steroids. Artificial ventilation was required inÂ 59Â patients. Full recovery was achieved inÂ 42Â cases, partial recovery inÂ 163Â cases, and 17Â patients died. The number of published PCG patients fell fromÂ 192Â in the second halfÂ of 2020Â toÂ 75Â patients in the first half ofÂ 2021. It is concluded that the prevalence of PCG has decreased since the introduction of SARS-CoV-2 vaccines. SARS-CoV-2 vaccinations have a positive effect on the prevalence of PCG.

Cutaneous leukocytoclastic vasculitis following COVID-19 vaccination with Ad26.COV2.S vaccine: a case report and literature review. Cutaneous vasculitis is a recognized and potentially serious adverse event of immunization with several vaccines, and COVID-19 vaccines are no exception. We present a case of cutaneous leukocytoclastic vasculitis occurring 17 days after inoculation with adenoviral vector vaccine (Ad26.COV2.S) in a previously healthy 30-year-old patient with no history of prior adverse events following vaccination. Transient laboratory abnormalities (mild proteinuria, cryoglobulinemia, and slightly diminished C3 complement level) were also noted, but they resolved with the resolution of skin changes after treatment with topical steroids. Although the frequency of cutaneous vasculitis after COVID-19 vaccines is extremely low, it presents an important challenge for the clinician when faced with an uncertain and delicate decision whether these patients can safely

receive booster doses of COVID-19 vaccine. Because vaccination certificates are necessary for day-to-day activities and have a limited validity date, this may be an uncomfortable issue.
Bilateral acute posterior multifocal placoid pigment epitheliopathy (APMPPE) following SARS-CoV-2 mRNA vaccine.
The prevalence of AstraZeneca COVID-19 vaccine side effects among Nigist Eleni Mohammed memorial comprehensive specialized hospital health workers. Cross sectional survey. INTRODUCTION: The best way to eradicate corona virus disease (COVID-19) viral infection is mass vaccination. Many studies demonstrate vaccination is associated with some local and systemic side effects. This study aimed to provide evidence on AstraZeneca COVID-19 vaccine side effects. METHODOLOGY: Institutional based cross-sectional survey was conducted among 254 health workers at Nigist Eleni Mohammed memorial comprehensive specialized hospital (from July 01/ 2021 to July 30/2021). Data were collected consecutively through self-administered online survey created on Google Forms of platform which had been randomly delivered via (Facebook or telegram pages). Demographic data of participants, side effect after first and second dose of vaccine were covered. RESULT: The prevalence of at least one side effect after first dose was 91.3% and after second dose was 67%. Injection site pain (63.8% vs. 50.4%), headache (48.8% vs. 33.5%), fever (38.8% vs. 20.9%), muscle pain (38.8% vs. 21.7%), fatigue (26% vs. 28.7%, tenderness at the site (27.6% vs. 21.7%), and joint pain (27.6% vs. 20.9%) were the most commonly reported side effects after first and second dose vaccine respectively. Most of participants reported that their symptoms emerged after 6hr of vaccination and only less than 5% of participant's symptoms lasted more than 72hr of post vaccination. The younger age (â‰¤29 year) were more susceptible to at least one side effect (Ï‡ 2 = 4.2; p = 0.04) after first dose. CONCLUSION: The prevalence of side effect after first and second dose vaccine was higher. Most of the symptoms were short lived and mild. This result might help to solve an emerging public health challenge (vaccine hesitancy) nurtured by misinformation related to vaccines safety.
Epidemiology of Myocarditis and Pericarditis Following mRNA Vaccination by Vaccine Product, Schedule, and Interdose Interval Among Adolescents and Adults in Ontario, Canada. IMPORTANCE: Increased rates of myocarditis or pericarditis following receipt of COVID-19 mRNA vaccines have been observed. However, few available data are associated with differences in rates of myocarditis or pericarditis specific to vaccine products, which may have important implications for vaccination programs. OBJECTIVE: To estimate rates of reported myocarditis or pericarditis following receipt of a COVID-19 mRNA vaccine by product, age, sex, dose number, and interdose interval. DESIGN, SETTING, AND PARTICIPANTS: This population-based cohort study was conducted in Ontario, Canada (population: 14.7 million) from December 2020 to September 2021 and used data from Ontario's COVID-19 vaccine registry and passive vaccine-safety surveillance system. All individuals in Ontario, Canada, who received at least 1 dose of COVID-19 mRNA vaccine between December 14, 2020, and September 4, 2021, and had a reported episode of myocarditis or pericarditis following receipt of the COVID-19 vaccine during this period were included. We obtained information on all vaccine doses administered in the province to calculate reported rates of myocarditis or pericarditis. EXPOSURES: Receipt of a COVID-19 mRNA vaccine (mRNA-1273 [Moderna Spikevax] or BNT162b2 [Pfizer-BioNTech Comirnaty]). MAIN OUTCOMES AND MEASURES: All reports of myocarditis or pericarditis meeting levels 1 to 3 of the Brighton Collaboration case definitions were included. Rates and 95% CIs of reported cases of myocarditis or pericarditis per 1â€¯000â€¯000 mRNA vaccine doses administered were calculated by age, sex, dose number, vaccine product, and interdose interval. RESULTS: Among 19â€¯740â€¯741 doses of mRNA vaccines administered, there were 297 reports of myocarditis or pericarditis meeting the inclusion criteria; 228 (76.8%) occurred in male individuals, and the median age of individuals with a reported event was 24 years (range, 12-81 years). Of the

reported cases, 207 (69.7%) occurred following the second dose of the COVID-19 mRNA vaccine. When restricted to individuals who received their second dose during the period of enhanced passive surveillance (on or after June 1, 2021), the highest rate of myocarditis or pericarditis was observed in male individuals aged 18 to 24 years following mRNA-1273 as the second dose (299.5 cases per 1â€¯000â€¯000 doses; 95% CI, 171.2-486.4 cases per 1â€¯000â€¯000 doses); the rate following BNT162b2 as the second dose was 59.2 cases per 1â€¯000â€¯000 doses (95% CI, 19.2-138.1 cases per 1â€¯000â€¯000 doses). Overall rates for both vaccine products were significantly higher when the interdose interval was 30 or fewer days (BNT162b2: 52.1 cases per 1â€¯000â€¯000 doses [95% CI, 31.8-80.5 cases per 1â€¯000â€¯000 doses]; mRNA-1273: 83.9 cases per 1â€¯000â€¯000 doses [95% CI, 47.0-138.4 cases per 1â€¯000â€¯000 doses]) compared with 56 or more days (BNT162b2: 9.6 cases per 1â€¯000â€¯000 doses [95% CI, 6.5-13.6 cases per 1â€¯000â€¯000 doses]; mRNA-1273: 16.2 cases per 1â€¯000â€¯000 doses [95% CI, 10.2-24.6 cases per 1â€¯000â€¯000 doses]). CONCLUSIONS AND RELEVANCE: The findings of this population-based cohort study of Ontario adolescents and adults with myocarditis or pericarditis following mRNA COVID-19 vaccination suggest that vaccine products and interdose intervals, in addition to age and sex, may be associated with the risk of myocarditis or pericarditis after receipt of these vaccines. Vaccination program strategies, such as age-based product considerations and longer interdose intervals, may reduce the risk of myocarditis or pericarditis following receipt of mRNA vaccines.

Multifocal lymphadenopathies with polyclonal reactions primed after EBV infection in a mRNA-1273 vaccine recipient. We report a case of recurrent tender, multifocal lymphadenopathies associated with B-symptoms, clinically mimicking lymphoma in a mRNA-1273 vaccine recipient after a recent Epstein-Barr virus (EBV) infection. In the lymph node biopsy, monocytoid B-cell hyperplasia, TH2 (GATA3+) predominance, and hyperplasia of interferon-gamma-producing plasmacytoid dendritic cells were observed along with sustained neutralising antibody production against SARS-CoV-2 wild-type and five variants. High titres of anti-S antibodies and neutralising antibodies were observed, excepted for variant B.1.529** (omicron) and B.1.351** (beta), due to several mutations in the spike protein, including the E484K mutation. We postulated that EBV acted as an immunological enhancer with the mRNA-1273 vaccine, inducing a sustained inflammatory response over several weeks. However, the polyclonal nature of the lymphadenopathy with polytypic plasmacytosis and pseudo-tumoural reaction cell hyperplasia were associated with failure to mount acute phase responses.

Correction Notice: Serologic Responses to COVID-19 Vaccines in Hematological Patients Are Predominantly Impaired in Lymphoid but not in Myeloid Malignancies. [This corrects the article DOI: 10.1097/HS9.0000000000000686.].

Severe Rhabdomyolysis Complicated With Acute Kidney Injury Required Renal Replacement Therapy After Pfizer COVID-19 Vaccine â€¯. The adverse effects of coronavirus disease 2019 (COVID-19) vaccines are somewhat common but rarely life-threatening. Diagnosing life-threatening vaccine-related adverse effects is heavily dependent on history taking and ruling out the other possible causes. Vaccine-related complications vary, so awareness of possible complications can lead to efficient management. We present the case of a 58-year-old woman with a history of schizophrenia who received the COVID-19 Pfizer vaccine and developed severe rhabdomyolysis. She required renal replacement therapy and fully recovered with possible transient autoimmune activity. This case highlights the importance of early awareness of adverse effects following vaccine administration and careful history taking and monitoring to avoid life-threatening conditions.

Reversible Autoimmune Cardiomyopathy Secondary to a Vaccine-Induced Multisystem Inflammatory Syndrome. The Dominican government started an early booster protocol, including a heterogeneous vaccination sequence needed based on availability.Â We report a case of a 25-year-old male who presented with jaundice, and vomiting for 6 days, associated with maculopapular rash

(Mucocutaneous features), elevated pro-B-type natriuretic peptide (pro-BNP), erythrocyte sedimentation rate (ESR), transaminitis (> 1000 U/L), thrombocytopenia, echocardiogram evidenced stigmata of heart failure after his third dose of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. He was started on steroids and immunoglobulin therapy for multisystemic organ failure syndrome. A significant improvement was noticed, then was discharge; in the post-discharge clinic, he was asymptomatic, inflammatory markers improved, and the echocardiogram showed a recovered ejection fraction. An accurate anamnesis, including a proper chronologic gathering of the events, is essential to recognize a vaccine-multisystem inflammatory syndrome; its prompt assessment and therapy would directly improve the outcome.

COVID-19 Vaccination Status Among Healthcare Workers and Its Effect on Disease Manifestations: A Study From Northeast India. Background and objective Since being declared a global pandemic, coronavirus disease 2019 (COVID-19) has led to millions of cases and deathsÂ worldwide. Although severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) continues to wreak havoc on individuals, healthcare systems, and economies, the intensive vaccination strategies adopted by several countries have significantly slowed the progress and the severity of the disease. In this study, we aimed toÂ determine the COVID-19 vaccination status among healthcare workers (HCWs)Â and examine the effects of vaccination on disease manifestations. Materials and methods This cross-sectional study was conducted at a teaching hospital in NortheastÂ India from April 2021 to September 2021, during the second phase of the COVID-19 pandemic. HCWs employed in the hospital who were laboratory-confirmed cases of COVID-19 based on semiquantitative real-time reverse transcriptase-polymerase chain reaction (RT-PCR) or cartridge-based nucleic acid amplification test (CBNAAT) on oropharyngeal samples were included in the study. Data analysis was performed using Microsoft Excel (Microsoft Office Professional Plus 2019, Microsoft Corp., Redmond, WA) Results A total of 178 HCWs reported positive for COVID-19 infection during the study period. Of these, 42 (23.59%) were males and 136 were females (76.40%).Â Among them, 86 (48.32%) HCWs were fully vaccinated, 58 (32.58%) were partially vaccinated, and 34 (19.10%) were not vaccinated.Â Most of the HCWs experienced mild disease (145, 81.46%), and only four (2.24%) reported moderate to severe disease. Compared with unvaccinated HCWs, individuals who have had either one or twoÂ doses of vaccines were less likely to have moderate to severe disease or seek treatment at the hospital. On symptoms analysis, shortness of breath was found to be more common in unvaccinated individuals than in vaccinated patients, and anosmia and loss of taste were more common in vaccinated than in unvaccinated individuals. No deaths were reported among the participants included in this study. Conclusions Following the first and second waves of the COVID-19 pandemic, a substantial proportion of HCWs were infected with SARS-CoV-2, likely as a result of the acquisition of the virus in the community during the early phase of local spread. Fully vaccinated individuals with COVID-19 were more likely to be completely asymptomatic or only mildly symptomatic compared to unvaccinated HCWs.

Reactivation of Herpes Zoster Virus After COVID-19 Vaccination: Is There Any Association? SARS-CoV-2 disease, COVID-19 infection, is a multi-system illness that has afflicted people all over the world. A number of vaccines have been produced to combat the current COVID-19 pandemic, and a variety of side effects have been recorded following the vaccination. However, there are limited data on the negative effects of immunological reactivation following vaccination. We report 10 incidences of herpes zoster reactivation within 7-21 days of getting the COVID-19 vaccination. Transient immunomodulation following vaccination, similar to that seen in COVID-19 illness, could be one explanation for this reactivation. These cases highlight the significance of continuing to examine vaccine safety during the COVID-19 pandemic's ongoing mass vaccination campaign. We also

underline the importance of peripheral health professionals in the management and reporting of any vaccination-associated adverse event.

High Incidence of SARS-CoV-2 Variant of Concern Breakthrough Infections Despite Residual Humoral and Cellular Immunity Induced by BNT162b2 Vaccination in Healthcare Workers: A Long-Term Follow-Up Study in Belgium. To mitigate the massive COVID-19 burden caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), several vaccination campaigns were initiated. We performed a single-center observational trial to monitor the mid- (3 months) and long-term (10 months) adaptive immune response and to document breakthrough infections (BTI) in healthcare workers (n = 84) upon BNT162b2 vaccination in a real-world setting. Firstly, serology was determined through immunoassays. Secondly, antibody functionality was analyzed via in vitro binding inhibition and pseudovirus neutralization and circulating receptor-binding domain (RBD)-specific B cells were assessed. Moreover, the induction of SARS-CoV-2-specific T cells was investigated by an interferon-Î³ release assay combined with flowcytometric profiling of activated CD4(+) and CD8(+) T cells. Within individuals that did not experience BTI (n = 62), vaccine-induced humoral and cellular immune responses were not correlated. Interestingly, waning over time was more pronounced within humoral compared to cellular immunity. In particular, 45 of these 62 subjects no longer displayed functional neutralization against the delta variant of concern (VoC) at long-term follow-up. Noteworthily, we reported a high incidence of symptomatic BTI cases (17.11%) caused by alpha and delta VoCs, although vaccine-induced immunity was only slightly reduced compared to subjects without BTI at mid-term follow-up.

Antibody Response Induced by BNT162b2 and mRNA-1273 Vaccines against the SARS-CoV-2 in a Cohort of Healthcare Workers. The aim of this study was to characterize the antibody response induced by SARS-CoV-2 mRNA vaccines in a cohort of healthcare workers. A total of 2247 serum samples were analyzed using the ElecsysÂ® Anti-SARS-CoV-2 S-test (Roche Diagnostics International Ltd., Rotkreuz, Switzerland). Sex, age, body mass index (BMI), arterial hypertension, smoking and time between infection and/or vaccination and serology were considered the confounding factors. Regarding the medians, subjects previously infected with SARS-CoV-2 who preserved their response to the nucleocapsid (N) protein showed higher humoral immunogenicity (BNT162b2: 6456.0 U/mL median; mRNA-1273: 2505.0 U/mL) compared with non-infected (BNT162b2: 867.0 U/mL; mRNA-1273: 2300.5 U/mL) and infected subjects with a lost response to N protein (BNT162b2: 2992.0 U/mL). After controlling for the confounders, a higher response was still observed for mRNA-1273 compared with BNT162b2 in uninfected individuals (FC = 2.35, $p < 0.0001$) but not in previously infected subjects (1.11 FC, $p = 0.1862$). The lowest levels of antibodies were detected in previously infected non-vaccinated individuals (39.4 U/mL). Clinical variables previously linked to poor prognoses regarding SARS-CoV-2 infection, such as age, BMI and arterial hypertension, were positively associated with increasing levels of anti-S protein antibody exclusively in infected subjects. The mRNA-1273 vaccine generated a higher antibody response to the S protein than BNT162b2 in non-infected subjects only.

Vaccination with BNT162b2 and ChAdOx1 nCoV-19 Induces Cross-Reactive Anti-RBD IgG against SARS-CoV-2 Variants including Omicron. SARS-CoV-2 variants of concern (VOCs) have caused a significant increase in infections worldwide. Despite high vaccination rates in industrialized countries, the fourth VOC, Omicron, has outpaced the Delta variant and is causing breakthrough infections in individuals with two booster vaccinations. While the magnitude of morbidity and lethality is lower in Omicron, the infection rate and global spread are rapid. Using a specific IgG multipanel-ELISA with the spike proteinâ€™s receptor-binding domain (RBD) from recombinant Alpha, Gamma, Delta, and Omicron variants, sera from health-care workers from the Medical University of Vienna were tested pre-pandemic and post-vaccination (BNT162b2; ChAdOx1 nCoV-19). The cohort was continuously

monitored by SARS-CoV-2 testing and commercial nucleocapsid IgG ELISA. RBD IgG ELISA showed significantly lower reactivity against the Omicron-RBD compared to the Alpha variant in all individuals ($p < 0.001$). IgG levels were independent of sex, but were significantly higher in BNT162b2 recipients <45 years of age for Alpha, Gamma, and Delta ($p < 0.001$; $p = 0.040$; $p = 0.004$, respectively). Pre-pandemic cross-reactive anti-Omicron IgG was detected in 31 individuals and was increased 8.78-fold after vaccination, regardless of vaccine type. The low anti-RBD Omicron IgG level could explain the breakthrough infections and their presence could also contribute to a milder COVID-19 course by cross-reactivity and broadening the adaptive immunity.

Detection of Platelet-Activating Antibodies Associated with Vaccine-Induced Thrombotic Thrombocytopenia by Flow Cytometry: An Italian Experience. Rare cases of thrombocytopenia and thrombosis after anti-COVID-19 adenovirus-associated mRNA vaccines (VITT) due to platelet-activating anti-platelet-factor 4 (PF4)/polyanion antibodies have been reported. VITT laboratory diagnosis, similarly to heparin-induced thrombocytopenia (HIT) diagnosis, requires immunoassays for anti-PF4/polyanion antibodies identification, such as ELISA assays and platelet-activating functional tests, such as heparin-induced platelet activation test (HIPA), to confirm their pathogenicity. We compared the flow cytometry (FC) measurement of platelet p-selectin exposure to the gold standard functional test HIPA for diagnosis confirmation in 13 patients with a clinical VITT syndrome (6M/7F; median age 56 (33-78)) who resulted positive to anti-PF4/polyanion antibodies ELISA assays (12/13). FC and HIPA similarly identified three different patterns: (1) a typical non-heparin-dependent VITT pattern (seven and six patients by FC and HIPA, respectively); (2) low/no platelet activation in patients under IvIg therapy (five out of five and two out of four patients by FC and HIPA, respectively); (3) a HIT pattern. Antibodies investigated by FC became negative after 7, 17, and 24 days of therapy in three patients. FC measurement of P-selectin exposure was as sensitive as HIPA but simpler to detect anti-PF4/polyanion antibodies in VITT patients. FC could reliably discriminate VITT from HIT, thus helping for the choice of the anticoagulant.

Broad Cross-Reactive IgA and IgG against Human Coronaviruses in Milk Induced by COVID-19 Vaccination and Infection. It is currently unclear if SARS-CoV-2 infection or mRNA vaccination can also induce IgG and IgA against common human coronaviruses (HCoVs) in lactating parents. Here we prospectively analyzed human milk (HM) and blood samples from lactating parents to measure the temporal patterns of anti-SARS-CoV-2 specific and anti-HCoV cross-reactive IgA and IgG responses. Two cohorts were analyzed: a vaccination cohort (n = 30) who received mRNA-based vaccines for COVID-19 (mRNA-1273 or BNT162b2), and an infection cohort (n = 45) with COVID-19 disease. Longitudinal HM and fingerstick blood samples were collected pre- and post-vaccination or, for infected subjects, at 5 time-points 14-28 days after confirmed diagnosis. The anti-spike(S) and anti-nucleocapsid(N) IgA and IgG antibody levels against SARS-CoV-2 and HCoVs were measured by multiplex immunoassay (mPlex-CoV). We found that vaccination significantly increased the anti-S IgA and IgG levels in HM. In contrast, while IgG levels increased after a second vaccine dose, blood and HM IgA started to decrease. Moreover, HM and blood anti-S IgG levels were significantly correlated, but anti-S IgA levels were not. SARS2 acute infection elicited anti-S IgG and IgA that showed much higher correlations between HM and blood compared to vaccination. Vaccination and infection were able to significantly increase the broadly cross-reactive IgG recognizing HCoVs in HM and blood than the IgA antibodies in HM and blood. In addition, the broader cross-reactivity of IgG in HM versus blood indicates that COVID-19 vaccination and infection might provide passive immunity through HM for the breastfed infants not only against SARS-CoV-2 but also against common cold coronaviruses.

Self-Reported COVID-19 Vaccines' Side Effects among Patients Treated with Biological Therapies in Saudi Arabia: A Multicenter Cross-Sectional Study. OBJECTIVE: The aim of this study was to explore the side effects of COVID-19 vaccines among a mixed gender sample of patients on

monoclonal antibody biologics (mAbs) in Saudi Arabia. METHODS: This was a prospective questionnaire-based cross-sectional study in which adult patients (â‰¥18 years) on mAbs who had received at least one dose of COVID-19 vaccine from three tertiary care centers in Saudi Arabia were included. Descriptive statistics and univariate logistic regressions were conducted to present the vaccine side effects and examine the association between the reported side effects and vaccine type. RESULTS: Four-hundred and seventeen patients, with a mean age of 39 years, consented to participate. Approximately 82% and 18% of the participants received Pfizer-BioNTech and Oxford-AstraZeneca vaccines, respectively, and nearly 71% received two doses of the vaccine. Diarrhea (9.59%), fever (51.32%), headache (32.13%), hypotension (13.67%), palpitation (9.11%), and temporary loss of smell (5.28%) were the most commonly reported side effects. CONCLUSION: COVID-19 vaccines are generally safe for patients treated with mAbs. Future studies should examine the rates of side effects across different COVID-19 vaccines among patients on mAbs using more robust study designs and representative samples.

Cellular and Humoral Immunity after the Third Vaccination against SARS-CoV-2 in Hematopoietic Stem-Cell Transplant Recipients. Protecting vulnerable groups from severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) infection is mandatory. Immune responses after a third vaccination against SARS-CoV-2 are insufficiently studied in patients after hematopoietic stem-cell transplantation (HSCT). We analyzed immune responses before and after a third vaccination in HSCT patients and healthy controls. Cellular immunity was assessed using interferon-gamma (IFN-Î³) and interleukin-2 (IL-2) ELISpots. Furthermore, this is the first report on neutralizing antibodies against 11 variants of SARS-CoV-2, analyzed by competitive fluorescence assay. Humoral immunity was also measured by neutralization tests assessing cytopathic effects and by ELISA. Neither HSCT patients nor healthy controls displayed significantly higher SARS-CoV-2-specific IFN-Î³ or IL-2 responses after the third vaccination. However, after the third vaccination, cellular responses were 2.6-fold higher for IFN-Î³ and 3.2-fold higher for IL-2 in healthy subjects compared with HSCT patients. After the third vaccination, neutralizing antibodies were significantly higher ($p < 0.01$) in healthy controls, but not in HSCT patients. Healthy controls vs. HSCT patients had 1.5-fold higher concentrations of neutralizing antibodies against variants and 1.2-fold higher antibody concentrations against wildtype. However, half of the HSCT patients exhibited neutralizing antibodies to variants of SARS-CoV-2, which increased only slightly after a third vaccination.

BNT162b2 Booster Vaccination Induced Immunity against SARS-CoV-2 Variants among Hemodialysis Patients. Background: The emergence of new SARS-CoV-2 variants, which evade immunity, has raised the urgent need for multiple vaccine booster doses for vulnerable populations. In this study, we aimed to estimate the BNT162b2 booster effectiveness against the spread of coronavirus variants in a hemodialysis population. Methods: We compared humoral and cell-mediated immunity in 100 dialysis patients and 66 age-matched volunteers, before and 2-3 weeks following the first booster vaccine dose. Participants were assessed for anti-spike (RBD) antibody titer, neutralizing antibodies against B.1.617.2 (Delta) and B.1.1.529 (Omicron) variants, spike-specific T-cell responses by FACS and infection outbreak after the first and second booster. Results: Anti-spike antibody titer was significantly increased following the booster, with reduced humoral and cellular response in the dialysis patients. Neutralizing antibody levels increased significantly after the booster dose, with an inferior effect (â‰¤2 fold) against Omicron compared with the Delta variant. Furthermore, CD4+ and CD8+ T-cell activation by Delta spike protein was preserved in 70% of PBMCs from the dialysis patients. A second booster dose tended to reduce breakthrough infections in the dialysis patients. Conclusions: Until the release of an updated vaccine, BNT162b2 booster doses will improve the humoral and cell-mediated immunity against variants. These findings support the importance of repetitive booster doses for hemodialysis patients.

Manifestation of Subclinical Extrapulmonary Tuberculosis after COVID-19 Vaccination as Supraclavicular Lymphadenopathy. Lymphadenopathy after coronavirus disease 2019 (COVID-19) vaccination is a common side effect that usually resolves within several days to weeks, and only observation is recommended. However, for prolonged lymphadenopathy, other possibilities, including malignancy or other lymphoproliferative diseases, may be considered. Herein, we report the case of a 66-year-old woman who experienced prolonged ipsilateral supraclavicular lymph node enlargement after the second dose of the ChAdOx1 (Oxford-AstraZeneca) COVID-19 vaccine, which was eventually diagnosed as extrapulmonary tuberculosis.

COVID-19 Vaccines and Autoimmune Hematologic Disorders. Worldwide vaccination against SARS-CoV-2 has allowed the detection of hematologic autoimmune complications. Adverse events (AEs) of this nature had been previously observed in association with other vaccines. The underlying mechanisms are not totally understood, although mimicry between viral and self-antigens plays a relevant role. It is important to remark that, although the incidence of these AEs is extremely low, their evolution may lead to life-threatening scenarios if treatment is not readily initiated. Hematologic autoimmune AEs have been associated with both mRNA and adenoviral vector-based SARS-CoV-2 vaccines. The main reported entities are secondary immune thrombocytopenia, immune thrombotic thrombocytopenic purpura, autoimmune hemolytic anemia, Evans syndrome, and a newly described disorder, so-called vaccine-induced immune thrombotic thrombocytopenia (VITT). The hallmark of VITT is the presence of anti-platelet factor 4 autoantibodies able to trigger platelet activation. Patients with VITT present with thrombocytopenia and may develop thrombosis in unusual locations such as cerebral beds. The management of hematologic autoimmune AEs does not differ significantly from that of these disorders in a non-vaccine context, thus addressing autoantibody production and bleeding/thromboembolic risk. This means that clinicians must be aware of their distinctive signs in order to diagnose them and initiate treatment as soon as possible.

Influenza Virus-like Particle-Based Hybrid Vaccine Containing RBD Induces Immunity against Influenza and SARS-CoV-2 Viruses. Several approaches have produced an effective vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Since millions of people are exposed to influenza virus and SARS-CoV-2, it is of great interest to develop a two-in-one vaccine that will be able to protect against infection of both viruses. We have developed a hybrid vaccine for SARS-CoV-2 and influenza viruses using influenza virus-like particles (VLP) incorporated by protein transfer with glycosylphosphatidylinositol (GPI)-anchored SARS-CoV-2 RBD fused to GM-CSF as an adjuvant. GPI-RBD-GM-CSF fusion protein was expressed in CHO-S cells, purified and incorporated onto influenza VLPs to develop the hybrid vaccine. Our results show that the hybrid vaccine induced a strong antibody response and protected mice from both influenza virus and mouse-adapted SARS-CoV-2 challenges, with vaccinated mice having significantly lower lung viral titers compared to naive mice. These results suggest that a hybrid vaccine strategy is a promising approach for developing multivalent vaccines to prevent influenza A and SARS-CoV-2 infections.

Ocular Complications after COVID-19 Vaccination, Vaccine Adverse Event Reporting System. In December 2020, the U.S. Food and Drug Administration licensed COVID-19 vaccines for emergency use authorization. We investigated the ocular adverse event reports in patients reported to the Vaccine Adverse Event Reporting System (VAERS) following vaccination against COVID-19. We searched the VAERS database for U.S. reports among persons who received COVID-19 vaccines between December 2020 and December 2021. Our goal was to analyze and quantify the ocular adverse events submitted to VAERS to provide clinicians and researchers with a broader view of these ocular side effects. During the analysis period, VAERS received 55,313 adverse event reports and, after data cleaning, 6688 reports met the inclusion criteria. Note that 2229 (33.33%) adverse events were classified as cases of eyelid swelling, ocular hyperemia and conjunctivitis, 1785 (26.69%) as

blurred vision and 1322 (19.77%) as visual impairment. Females accounted for 73.8% of adverse event reports and the age group between 40 and 59 years had the most frequent adverse events. A higher proportion of these adverse events reported to VAERS was linked with the Janssen and Moderna COVID-19 vaccines. At the time of vaccination, a high proportion of patients reported conditions like allergies, hypertension, diabetes, thyroid disease, vascular and other autoimmune diseases. A review of these data suggests a possible association between COVID-19 vaccines and ocular adverse events. Physicians are cautioned not only to be aware of this potential problem, but to check any underlying patient conditions, and to carefully document in VAERS within a few weeks of vaccination. Future COVID-19 vaccine safety studies in healthy subjects would help clarify the vaccine's safety profile.

Reduction of Precautionary Behaviour following Vaccination against COVID-19: A Test on a British Cohort. BACKGROUND: There is a risk that people vaccinated against COVID-19 will drop or reduce their precautionary behaviours (i.e., a phenomenon of risk homeostasis). Our aim is to assess the occurrence of this effect in a cohort of UK participants who were interviewed 141 days before and 161 days after the start of the vaccination programme. METHODS: Of the 765 people who could be followed up before and after the start of the programme and whose vaccination status was known, 178 had not received any injection and 583 were more or less advanced in the process (one vs. two doses since less vs. more than 14 days). The frequency of 14 precautionary behaviours was assessed at both times of measurement, as well as potential covariates (gender, age, comorbidities and history of COVID-19). RESULTS: Controlling for covariates, we didn't find more decrease in precautionary behaviours among vaccinated individuals, regardless of how far along they were in the process. CONCLUSION: The results observed in this sample show little risk for a massive change in behaviours among early vaccinated individuals. The pressure to adopt precautionary behaviours remains strong and probably prevents the emergence of a risk homeostasis effect.

Recurring Weakness in Rhabdomyolysis Following Pfizer-BioNTech Coronavirus Disease 2019 mRNA Vaccination. Rhabdomyolysis is a well-known clinical syndrome of muscle injury. Rhabdomyolysis following coronavirus disease 2019 (COVID-19) vaccination has recently been reported. The patients' weakness gradually subsided and did not recur. Rhabdomyolysis associated with COVID-19 vaccination has not been assessed by repeated magnetic resonance imaging (MRI) within a short time. We report a rare case of an older woman who developed recurring weakness with rhabdomyolysis after COVID-19 vaccination. A 76-year-old woman presented with myalgia 2 days after receiving a third dose of the COVID-19 vaccine. A physical examination showed weakness of the bilateral iliopsoas muscles. Her creatine kinase concentration was 9816 U/L. MRI showed hyperintensity of multiple limb muscles. She was treated with intravenous normal saline. Her symptoms disappeared within 3 days. However, MRI on day 4 of hospitalization showed exacerbation of the hyperintensity in the left upper limb muscles. On day 5 of hospitalization, weakness of the left supraspinatus and deltoid muscles appeared. MRI on day 8 of hospitalization showed attenuation of the hyperintensity in all muscles. Her weakness and elevated creatine kinase concentration disappeared by day 10. Repeated MRI over a short time may be useful to predict potential weakness and monitor the course of COVID-19 vaccine-induced rhabdomyolysis.

Anti-Vaccine Attitudes among Adults in the U.S. during the COVID-19 Pandemic after Vaccine Rollout. Even though vaccination is the most effective measure against COVID-19 infections, vaccine rollout efforts have been hampered by growing anti-vaccine attitudes. Based on current knowledge, we identified three domains (beliefs, discrimination, and news) as our correlates of primary interest to examine the association with anti-vaccine attitudes. This is one of the first studies to examine key correlates of anti-vaccine attitudes during the critical early stages of vaccine implementation in the United States. An online survey was administered in May 2021 to a non-representative, nationally

based sample of adults (N = 789). Using multivariable logistic regression analysis, we found that individuals who expressed worry about COVID-19 (OR = 0.34, 95% CI 0.21, 0.55) and had greater knowledge of COVID-19 (OR = 0.50, 95% CI 0.25, 0.99) were less likely to hold anti-vaccine attitudes. Conversely, individuals who held stigmatizing views of COVID-19 (OR = 2.47, 95% CI 1.53, 3.99), had experienced racial discrimination (OR = 2.14, 95% CI 1.25, 3.67) and discrimination related to COVID-19 (OR = 2.84, 95% CI 1.54, 5.24), and who had been watching Fox News (OR = 3.95, 95% CI 2.61, 5.97) were more likely to hold anti-vaccine attitudes. These findings suggest COVID-19 beliefs, experiences of discrimination, and news sources should be considered when designing targeted approaches to address the anti-vaccine movement.

Non-Arteritic Anterior Ischemic Optic Neuropathy Following COVID-19 Vaccination. People are advised to receive a vaccine booster as the Delta and Omicron variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerge, but various adverse ocular reactions after vaccination have been reported. NAION following COVID-19 vaccination appears extremely rarely. Here, we report a case of a 61-year-old female with sudden painless blurred vision developing NAION after receiving ChAdOx1 nCoV-19 (AstraZeneca) vaccination and provide an in-depth explanation of the possible mechanisms regarding the hypercoagulable state after vaccination. Our report adds to the literature on potential adverse ocular effects after COVID-19 vaccination, and we as ophthalmologists recommend that clinicians should increase awareness of this possible ocular complication when evaluating patients with sudden visual disturbance with a recent history of vaccination.

Sudden Onset of IgA Vasculitis Affecting Vital Organs in Adult Patients following SARS-CoV-2 Vaccines. IgA vasculitis is an immune complex-mediated small-vessel vasculitis that mainly occurs in children and is characterized by palpable purpura, arthralgia, abdominal pain, and glomerulonephritis. We report three cases of new-onset IgA vasculitis involving major organs in adult patients after they received either the ChAdOx1 viral vector (Oxford/AstraZeneca) vaccine or the messenger RNA-1273 (Moderna) vaccine. These cases suggest that COVID-19 vaccines have the potential to trigger IgA vasculitis and indicate that physicians need to monitor for this possible complication.

Ocular Adverse Events after Inactivated COVID-19 Vaccination. Purpose: To report the clinical characteristics of ocular adverse events that have occurred, in China, after vaccination with inactivated COVID-19 vaccines. Methods: A retrospective cross-sectional observational study was conducted of ocular disorders that occurred within 15 days from any dose of an inactivated COVID-19 vaccine. Information on gender, age, the interval between the vaccination and ocular symptoms, laterality, duration of the ocular symptoms, primary visual acuity, and clinical diagnosis were retrospectively collected. Results: Twenty-four patients were involved in the study, including 15 females and 9 males, with a mean age of 41 Â± 16 years (range of 8âˆ’71 years). The patients all denied a prior history of COVID-19 infection. Ocular adverse events occurred after the first dose of vaccine in 18 patients and, after the second or third doses, in six patients. The interval between vaccination with the inactivated COVID-19 vaccine and ocular symptoms was 6 Â± 5 days; six patients were bilaterally involved and 18 patients were unilaterally involved. Regarding the diagnosis, 10 patients were diagnosed with white dot syndrome (WDS), 9 patients were diagnosed with uveitis, and 5 patients were diagnosed with retinal vascular disorders. The ages of patients with WDS were younger than those with uveitis or retinal vascular disorders (32 Â± 10 vs. 48 Â± 18, $p < 0.05$). For patients diagnosed with WDS, the best-corrected visual acuity (BCVA) was 0.74 Â± 0.73 LogMAR. For patients diagnosed with retinal vascular disorders or uveitis, the BCVA was 1.44 Â± 1.26 LogMAR. There was no significant difference ($p > 0.05$). Conclusions: A relationship cannot be established between inactivated COVID-19 vaccines and ocular disorders; therefore, further investigation of the clinical spectrum of ocular adverse events after vaccination with an inactivated COVID-19 vaccine is necessary.

Parents' Intentions and Associated Factors to Vaccinating Their Children Aged 12-17 Years with COVID-19 Vaccines: A Cross Sectional Study. No available vaccine against COVID-19 had yet been proven for 12-17-year-olds in Egypt during the study period. This is the first study to assess Egyptian parents' intentions and associated factors in relation to vaccinating their children with COVID-19 vaccines. A cross-sectional study using a questionnaire was conducted between 17 October and 17 November 2021, via social media platforms. The target group was parents with children aged 12-17 years. Parents' intention to vaccinate their children and factors associated with vaccinating their children, reasons for not intending to vaccinate their children, and circumstances whereby the parents would change their mind were recorded. Among the 1458 parents recruited, 65.6% were planning to vaccinate their children. The main concerns were fear of the vaccine's side-effects (68.3%) and conspiracy theories (18%). The factors associated with parents' intention to vaccinate their children were mother's older age (40-49 years: aOR = 1.45, 95% CI = 1.05-1.99; â‰¥50 years: aOR = 2.09, 95% CI = 1.16-3.75), high family income (aOR = 1.99, 95% CI = 1.41-2.79), and children with a history of chronic conditions (aOR = 2.02, 95% CI = 1.25-3.25), while higher mother's education level was negatively associated (aOR = 0.41, 95% CI = 0.27, 0.64). A comprehensive health education program regarding vaccinating children with COVID-19 vaccines is highly recommended for parents, particularly for young and highly educated mothers, to enhance children vaccination rate when the vaccine becomes available.

Variation in the Humoral Immune Response Induced by the Administration of the BNT162b2 Pfizer/BioNTech Vaccine: A Systematic Review. The BNT162b2 Pfizer/BioNTech vaccine was the first emergency approved vaccine during the COVID-19 pandemic. The aim of this systematic review was to examine the variations in the humoral immune response induced by the administration of the BNT162b2 vaccine in patients with previous SARS-CoV-2 infection, the elderly, and those with comorbidities and immunosuppression states. Additionally, we analyzed the effect of generated neutralizing antibodies against the new variants of concern of SARS-CoV-2. Pubmed, Science Direct, Mendeley, and WorldWide Science were searched between 1 January 2020 and October 2021 using the keywords "BNT162b2", "serology", "comorbidity", "immunosuppression", and "variants of concern"dA total of 20 peer-reviewed publications were selected. The analysis showed that those individuals with previous infections have a considerably higher antibody response after the administration of BNT162b2 vaccine in contrast with seronegative individuals. With regard to variation in immune responses, elderly individuals, patients with cancer, or patients who had undergone a kidney transplant, dialysis, or who were pregnant had a lower antibody response in comparison to healthy individuals. Finally, antibodies developed against the S protein produced by the BNT162b2 vaccine, possessed lower neutralizing activity against the alpha, beta, gamma, and delta variants of SARS-CoV-2. In conclusion, patients with immunodeficiencies and comorbidities have a lesser antibody response, about which further studies need to be performed in order to analyze the effectiveness and duration of the humoral immunity associated with vaccination in these specific populations.

COVID-19 Impact on Australian Patients with Substance Use Disorders: Emergency Department Admissions in Western Sydney before Vaccine Roll Out. Background: In this study, we determined the impact of the COVID-19 pandemic on Western Sydney patients with substance use disorders (SUD) by comparing emergency department (ED) admission rates before and after the onset of the COVID-19 pandemic and before the rollout of COVID-19 vaccination. Methods: ED admission data for patients with SUD were retrieved from the local electronic medical record (eMR) on the hospital central database. ED data collected from 25 January to 25 July 2019 (before the COVID-19 pandemic) were compared with data from 25 January to 25 July 2020 (early pandemic). ED admission reasons were categorised based on the presenting complaints and ED diagnoses. Results: Despite an

overall reduction in ED admissions during the early pandemic, compared to the pre-pandemic period, admissions for patients with SUD increased significantly (1.7% to 3.4%, $p < 0.01$). ED admission rates related to infection (0.05% to 0.12%, $p < 0.01$), local infection (0.02% to 0.05%, $p < 0.01$), trauma (0.06% to 0.12%, $p < 0.01$), alcohol (0.01% to 0.03%, $p < 0.05$), and other issues (0.06% to 0.10%, $p < 0.05$) increased significantly among Indigenous patients with SUD. ED admission rates related to drugs (0.12% to 0.39%, $p < 0.01$), infection (0.21% to 0.34%, $p < 0.01$), local infection (0.07% to 0.18%, $p < 0.01$), gastrointestinal (0.15% to 0.23%, $p < 0.05$), trauma (0.14% to 0.25%, $p < 0.01$), alcohol (0.36% to 0.74%, $p < 0.01$), and â€˜otherâ€™ issues (0.47% to 0.91%, $p < 0.01$) increased significantly among non-Indigenous patients with SUD. Four cases of COVID-19 were reported among these patients. Conclusions: There was an increase in ED admissions for patients with SUD in the initial six months of the COVID-19 pandemic (before vaccine rollout), mainly for drugs, systemic infection, local infection, trauma, and alcohol-related reasons. Now that most people in New South Wales have been vaccinated against COVID-19, a further study is needed to quantify the effect of the pandemic on patients with SUD in the post-vaccine era.

Surveillance of Adverse Events Following Immunization (AEFI) after Third Dose Booster Vaccination with mRNA-Based Vaccine in Universitas Indonesia Hospital Health Personnel. Facing the rising cases of with higher fatalities COVID-19, some countries decided to give the third dose of vaccine as a booster. As of 9 January 2022, 90.31% of health workers in Indonesia have received the third dose vaccine. This study aims to provide an evaluation of adverse events following immunization (AEFI) in a single center in Indonesia to form a basis for ensuring safety for booster administration nationally. A retrospective, cross-sectional study was conducted using an online survey. Demographic data, AEFI complaints, and factors influencing AEFIs were evaluated. In this study, there were a total of 311 subjects were gathered. The most common AEFI symptoms found at onset <24 h to 28 days were pain at the injection site, fever, shoulder pain, and headache. Most of the AEFI severity of <24 h to 28 days post-vaccination was grade 1 (reduced or uninterrupted daily activities). There was a significant correlation between AEFI and several factors, such as the history of drug allergy, exercise after vaccination, age, BMI < 25, history of symptoms after the first and second vaccinations, and history of COVID-19. There was no anaphylactic reaction in this study. Several AEFI should be considered for the third dose of COVID-19 vaccine administration.

Factors Associated with Decisions of Arab Minority Parents in Israel to Vaccinate Their Children against COVID-19. The Arab ethnic community in Israel is characterized by low social economic status and is at risk due to the typically crowded households. Understanding parents' level of awareness is important to avoid new outbreaks. OBJECTIVES: This study seeks to identify predicting factors associated with perceived susceptibility to COVID-19, and barriers to COVID-19 vaccination. MATERIALS AND METHODS: A survey was conducted through social media, using snowball sampling via social networks. Additionally, t-tests, Chi-square tests, and Z tests were used to evaluate differences between independent proportions. Pearson correlations were calculated for the study variables. Multiple logistic regression examined the extent to which the background variables were related to the intention to vaccinate the child. RESULTS: A total of 2843 Arab parents participated in the study. Older parents, higher socioeconomic status, higher trust in the authorities, vaccinated parents, and low psychological and physical barriers were positively correlated with willingness to vaccinate children. Pandemic fatigue was associated with less positive attitudes and reduced perceived effectiveness toward vaccination. CONCLUSION: Addressing minorities' poor standards of living and physical and psychological barriers posed by the authorities to minorities' access to vaccination may increase compliance with COVID-19 vaccination and protect the health of the entire population.

Pulmonary Embolism after Moderna Vaccination in Kidney Transplant Patients: Two Case Reports and Literature Review. Currently, the coronavirus disease 2019 (COVID-19) pandemic is still an ongoing and constant medical issue, and with upcoming new variants, vaccinations and boosters remain important. The safety of vaccines in patients after kidney transplantation is an essential problem, with thrombosis being one of the severe side effects and vaccine-induced immune thrombotic thrombocytopenia (VITT) revealed as the most commonly reported syndrome for thromboembolic events following COVID-19 vaccination. Here, we present two cases of kidney transplantation developing pulmonary embolism post-Moderna vaccination within 30 days without thrombocytopenia. The first case was a 52-year-old man with history of type II diabetes, hypertension and hyperlipidemia who had had cadaveric kidney transplantation in September 2008, where right leg swelling with claudication occurred 23 days after the second Moderna vaccination. The second case was a 57-year-old man with history of type II diabetes and glaucoma who had had living-related kidney transplantation in April 2013 and then complained of exertional dyspnea 26 days after administration of the third Moderna vaccine. The advantages of vaccination even in immunocompromised patients far outweigh the disadvantages, although clinicians must understand the risks of deep-vein thrombosis or even pulmonary embolism for such patients, which might not occur after just the first vaccination.

What Should We Do after the COVID-19 Vaccination? Vaccine-Associated Diseases and Precautionary Measures against Adverse Reactions. COVID-19 vaccines have been used to counteract the global COVID-19 pandemic. While these are effective, adverse reactions have been reported, such as injection-site pain, muscle ache, fever, palpitation, and chest discomfort. The release of inflammatory cytokines, such as interleukin (IL)-6 and IL-1Î², is a potential mechanism for post-vaccine side-effects. Chest discomfort after the vaccination, including myocarditis and acute coronary syndrome, is a particularly serious adverse reaction. It is important to be familiar with the differential diagnoses of chest discomfort and organ-specific diseases associated with COVID-19 vaccines as the preparation for booster shots and vaccinations among children aged 5-11 years begins. High-intensity exercise, alcohol, tobacco smoking, and baths promote inflammatory cytokines, such as IL-6, which may exacerbate the adverse reactions after vaccination. Japanese data show that deaths during baths are the most common for several days after mRNA vaccination. Additionally, alcohol and tobacco smoking were identified as predictive factors of lower antibody titers after vaccination. In this review, we aimed to provide a few recommendations to prevent vaccine-associated disease.

Attitudes and Behavior toward COVID-19 Vaccination in Japanese University Students: A Cross-Sectional Study. BACKGROUND: It is said that safe and effective vaccination is an important tool to end the COVID-19 pandemic. However, recent studies have reported hesitation, especially in young adults. Promoting the vaccination of university students, who represent the young adults, will lead to infection prevention measures. The purpose of this study was to clarify to compare the vaccination rates, attitudes toward vaccines, and post-vaccination behavior of students and faculty members in order to understand the actual situation of young population. METHODS: We conducted large-scale vaccination of Hiroshima University from 21 June to 18 September 2021. This cross-sectional survey was conducted via e-mail from 27 September to 3 October 2021. RESULTS: The number of second inoculations was 10,833 /14,154 students (76.5%), and 2240/2583 staff members (86.7%). Regarding the impressions after vaccination, the most common answer was "I was able to prevent worsening of the disease even if I was infected". Many students answered that their range of activities had expanded after vaccination. However, many students (n = 1799, 87.8%) answered as having "no change after vaccination" regarding infection prevention. CONCLUSION: The high vaccination rate in this survey was thought to be due to the increased sense of security and confidence in the vaccine. The fact that young adults who perform a wide range of activities are

careful about infection prevention may be one of the factors that prevents the explosive spread of infection in Japan.

Vulnerability Predictors of Post-Vaccine SARS-CoV-2 Infection and Disease-Empirical Evidence from a Large Population-Based Italian Platform. We aimed to identify individual features associated with increased risk of post-vaccine SARS-CoV-2 infection and severe COVID-19 illness. We performed a nested case-control study based on 5,350,295 citizens from Lombardy, Italy, aged â‰¥ 12 years who received a complete anti-COVID-19 vaccination from 17 January 2021 to 31 July 2021, and followed from 14 days after vaccine completion to 11 November 2021. Overall, 17,996 infections and 3023 severe illness cases occurred. For each case, controls were 1:1 (infection cases) or 1:10 (severe illness cases) matched for municipality of residence and date of vaccination completion. The association between selected predictors (sex, age, previous occurrence of SARS-CoV-2 infection, type of vaccine received, number of previous contacts with the Regional Health Service (RHS), and the presence of 59 diseases) and outcomes was assessed by using multivariable conditional logistic regression models. Sex, age, previous SARS-CoV-2 infection, type of vaccine and number of contacts with the RHS were associated with the risk of infection and severe illness. Moreover, higher odds of infection and severe illness were significantly associated with 14 and 34 diseases, respectively, among those investigated. These results can be helpful to clinicians and policy makers for prioritizing interventions.

A Disproportionality Analysis for Association of Systemic Capillary Leak Syndrome with COVID-19 Vaccination Using the World Health Organization Pharmacovigilance Database. Systemic capillary leak syndrome (SCLS) is a rare and potentially life-threatening disorder characterized by reversible plasma extravasation and vascular collapse. This study aimed to investigate the association between different types of COVID-19 vaccine and SCLS in a real-world setting. We used individual case safety reports of SCLS after COVID-19 vaccination from the WHO pharmacovigilance database, VigiBase. A disproportionality analysis of ChAdOx1 nCoV-19 and mRNA-based vaccines was performed. The information component (IC) and reporting odds ratio (ROR) were calculated from the entire database and viral vaccines data subset. A positive 95% lower end of the IC (IC025) value (>0) using Bayesian neural network analysis and lower end of the ROR 95% confidence interval (ROR025) â‰¥1 were defined as the ADR signal detection threshold. A total of 101 (0.004%) events of SCLS were identified. A significant potential signal of disproportionality of SCLS was noted in ChAdOx1 nCoV-19 when applied as the denominator for entire database (IC025 = 0.24, ROR025 = 1.23) and all viral vaccines (IC025 = 0.41, ROR025 = 1.59). No significant potential signal was noted for two mRNA-based vaccines as denominators for the entire database (IC025 = âˆ’0.49, ROR025 = 0.71) and all viral vaccines (IC025 = âˆ’0.32, ROR025 = 0.77). Contrary to ChAdOx1 nCoV-1, no safety signal for developing SCLS was identified for mRNA-based vaccines.

Serological Response and Relationship with Gender-Sensitive Variables among Healthcare Workers after SARS-CoV-2 Vaccination. Vaccine-induced immunity is a key strategy in the long-term control of the COVID-19 pandemic. The aim of our study was to explore the relationship between mRNA vaccine-induced antibodies and gender-sensitive variables among healthcare workers. Two thousand-sixty-five volunteers who received the BNT162b2 vaccine were enrolled in the study and followed up. Demographic, clinical, and social variables (educational level, marital status, occupation, childcare) were evaluated through a self-administered questionnaire. Anti-Spike (S) IgG were measured at 1 month (T1) and at 5 months (T2) after the second vaccine dose. At T1, median anti-S IgG values were 693 [394âˆ’>800] AU/mL (1 AU = 2.6 BAU). Values > 800 AU/mL (2080 BAU/mL) were directly associated with a previous COVID-19 ($p < 0.001$) infection and inversely with age ($p < 0.001$), smoking habit ($p < 0.001$), and autoimmune diseases ($p < 0.001$). At T2, a significant decreasing in anti-S IgG values was observed (187 [81âˆ’262] AU/mL), with a median decrease of 72 [60âˆ’82]%. On multivariate data analysis, a reduction of more than 82% was directly associated with male sex ($p <$

0.021), age (p < 0.001), smoking (p = 0.038), hypertension (p = 0.042), and, inversely, with previous COVID-19 infection (p < 0.001) and being â€œcohabitingâ€• (p = 0.005). Our findings suggest that demographic, clinical, and social variables play a role in anti-S IgG values decreasing in long-term follow up and should be considered to find personalized vaccine schedules.

Emotional Reaction to the First Dose of COVID-19 Vaccine: Postvaccination Decline in Anxiety and Stress among Anxious Individuals and Increase among Individuals with Normal Prevaccination Anxiety Levels. Although vaccination has been adopted by the WHO to limit worldwide transmission of COVID-19, people's worries about COVID-19 vaccines may suppress their desire for vaccination despite vaccine availability. This study aimed to investigate anxiety and stress symptoms among 250 Jordanians (mean age = 43.18 Â± 6.34 years, 72% females) who received their first vaccine dose. The respondents completed the anxiety and stress subscales of the Depression Anxiety and Stress scale 21 (DASS-21) before and after vaccination. The respondents expressed more moderate-severe levels of stress before than after vaccination (20.8% and 13.2%, respectively). Meanwhile, 37.2% and 45.2% of the respondents expressed moderate-severe anxiety before and after vaccination, respectively. Wilcoxon signed-rank test revealed that the drop in the level of stress from before- (median (IQR) = 5 (1-8)) to after vaccination (median (IQR) = 3 (1-7)) was statistically significant (z = -3.81, p = 0.001, r = 0.17) while the increase in anxiety was not. Anxiety significantly dropped postvaccination among individuals experiencing mild to severe anxiety before vaccination. Similarly, stress and anxiety significantly increased among individuals expressing normal anxiety before vaccination (z = -3.57 and -8.24, p values = 0.001, r = 0.16 and 0.37, respectively). Age positively correlated with postvaccination anxiety among respondents with mild prevaccination anxiety, and it negatively correlated with the prevaccination level of stress in the normal-anxiety group. Gender, marital status, respondents' level of education, and history of COVID-19 infection had no significant correlation with anxiety or stress at either point of measurement. Overcoming their hesitancy to receive COVID-19 vaccines, individuals with normal levels of anxiety experienced a rise in their distress symptoms following immunization. On the contrary, vaccination seemed to desensitize anxious individuals. Policymakers need to formulate a population-specific plan to increase vaccine preparedness and promote psychological well-being over all during the pandemic.

Vision-Threatening Ocular Adverse Events after Vaccination against Coronavirus Disease 2019. A single-center retrospective observational case series was conducted. This case series enrolled patients who showed ophthalmic manifestations within one week after COVID-19 vaccination at Korea University Guro Hospital in Seoul, Korea, from May 2021 to January 2022. The medical records of patients who complained of ocular symptoms and showed ophthalmic adverse events within one week after COVID-19 vaccination were reviewed. Seventeen eyes from 16 patients with a mean age of 63.8 (range 33-83) years were included in the case series, and all symptoms developed within 1-7 days following inoculation. Retinal vein occlusion in nine eyes (52.9%), retinal artery occlusion in one eye (5.9%), newly developed anterior uveitis in one eye (5.9%), exacerbation of previously diagnosed panuveitis in two eyes (11.8%), and angle-closure attack with high intraocular pressure in four eyes (23.5%) were included. Twelve patients (75%) had been vaccinated with the AstraZeneca (AZD1222) and four (25%) with the Pfizer (BNT162b2) vaccines. Of these, 10 patients (62.5%) experienced ocular disease exacerbation after the first dose, 4 (25%) after the second dose, and 2 (12.5%) after the third dose (booster shot). Eleven patients (64.7%) underwent tests for hematological abnormalities, and three of them tested positive for anti-PF4 antibodies, but no abnormal findings were noted. A causal relationship between vaccination and the ocular manifestations could not be determined, which is a limitation of this study. However, clinicians should consider the effect of COVID-19 vaccination on ophthalmic disease. Further studies are required to elucidate the possible effects of COVID-19 vaccination on the eye.

Declining Course of Humoral Immune Response in Initially Responding Kidney Transplant Recipients after Repeated SARS-CoV-2 Vaccination. The immunogenicity of SARS-CoV-2 vaccines in kidney transplant recipients is limited, resulting in inadequately low serological response rates and low immunoglobulin (Ig) levels, correlating with reduced protection against death and hospitalization from COVID-19. We retrospectively examined the time course of anti-SARS-CoV-2 Ig antibody levels after up to five repeated vaccinations in 644 previously nonresponding kidney transplant recipients. Using anti SARS-CoV-2 IgG/IgA ELISA and the total Ig ECLIA assays, we compared antibody levels at 1 month with levels at 2 and 4 months, respectively. Additionally, we correlated the measurements of the used assays. Between 1 and 2 months, and between 1 and 4 months, mean anti-SARS-CoV-2 Ig levels in responders decreased by 14% and 25%, respectively, depending on the assay. Absolute Ig values and time course of antibody levels showed high interindividual variability. Ig levels decreased by at least 20% in 77 of 148 paired samples with loss of sufficient serological protection over time occurring in 18 out of 148 (12.2%). IgG ELISA and total Ig ECLIA assays showed a strong positive correlation (Kendall's tau = 0.78), yet the two assays determined divergent results in 99 of 751 (13.2%) measurements. IgG and IgA assays showed overall strong correlation but divergent results in 270 of 1.173 (23.0%) cases and only weak correlation of antibody levels in positive samples. Large interindividual variability and significant loss of serological response after 4 months supports repeated serological sampling and consideration of shorter vaccination intervals in kidney transplant recipients.

Comparison of Four Systems for SARS-CoV-2 Antibody at Three Time Points after SARS-CoV-2 Vaccination. BACKGROUND: Immunity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) wanes over time after vaccination. METHODS: We compared SARS-CoV-2 antibody levels in serial samples from 350 vaccinated individuals at 3 time points (3 weeks after the first or second dose and before the third dose) with 4 assays: GenScript cPASS SARS-CoV-2 neutralization antibody detection kits (cPASS), Siemens SARS-CoV-2 IgG (sCOVG), Abbott SARS-CoV-2 IgG II Quant (CoV-2 IgG II), and an Immuno-Onâ„¢ COVID-19 IgG test (Immuno-On IgG). Antibody levels by time, concordance between assays, and values from other tests corresponding to the percent inhibition results in cPASS were assessed. RESULTS: The median values at three time points were 49.31%, 90.87%, and 53.38% inhibition for cPASS, 5.39, 13.65, and 2.24 U/mL for sCOVG, 570.25, 1279.65, and 315.80 AU/mL for CoV-2 IgG II, and 223.22, 362.20, and 62.20 relative units (RU) for Immuno-On IgG. The concordance with cPASS at each time point ranged from 0.735 to 0.984, showing the highest concordance in the second sample and lowest concordance in the third in all comparative tests. The values corresponded to 30% inhibition, and the cutoffs of cPASS, were 2.02 U/mL, 258.6 AU/mL, and 74.2 RU for each test. Those for 50%, 70%, and 90% inhibition were 3.16, 5.66, and 8.26 U/mL for sCOVG, while they were 412.5, 596.9, and 1121.6 AU/mL for CoV-2 IgG II and 141.8, 248.92, and 327.14 RU for Immuno-On IgG. CONCLUSIONS: This study demonstrated the dynamic changes in antibody values at different time points using four test systems and is expected to provide useful baseline data for comparative studies and standardization efforts in the future.

T-Cell Defects Associated to Lack of Spike-Specific Antibodies after BNT162b2 Full Immunization Followed by a Booster Dose in Patients with Common Variable Immune Deficiencies. Following the third booster dose of the mRNA vaccine, Common Variable Immune Deficiencies (CVID) patients may not produce specific antibodies against the virus spike protein. The T-cell abnormalities associated with the absence of antibodies are still a matter of investigation. Spike-specific IgG and IgA, peripheral T cell subsets, CD40L and cytokine expression, and Spike-specific specific T-cells responses were evaluated in 47 CVID and 26 healthy donors after three doses of BNT162b2 vaccine. Testing was performed two weeks after the third vaccine dose. Thirty-six percent of the patients did not produce anti-SARS-CoV-2 IgG or IgA antibodies. Non responder patients had lower peripheral

blood lymphocyte counts, circulating naÃ¯ve and central memory T-cells, low CD40L expression on the CD4+CD45+RO+ and CD8+CD45+RO+ T-cells, high frequencies of TNFÎ± and IFNÎ³ expressing CD8+ T-cells, and defective release of IFNÎ³ and TNFÎ± following stimulation with Spike peptides. Non responders had a more complex disease phenotype, with higher frequencies of structural lung damage and autoimmunity, especially autoimmune cytopenia. Thirty-five percent of them developed a SARS-CoV-2 infection after immunization in comparison to twenty percent of CVID who responded to immunization with antibodies production. CVID-associated T cell abnormalities contributed to the absence of SARS-CoV-2 specific antibodies after full immunization.

Thrombotic Complications after COVID-19 Vaccination: Diagnosis and Treatment Options. Coronavirus disease 2019 (COVID-19) vaccines were developed a few months after the emergence of the pandemic. The first cases of vaccine-induced thrombotic complications after the use of adenoviral vector vaccines ChAdOx1 nCoV-19 by AstraZeneca, and Ad26.COV2.S by Johnson & Johnson/Janssen, were announced shortly after the initiation of a global vaccination program. In these cases, the occurrence of thrombotic events at unusual sites-predominantly located in the venous vascular system-in association with concomitant thrombocytopenia were observed. Since this new entity termed vaccine-induced thrombotic thrombocytopenia (VITT) shows similar pathophysiologic mechanisms as heparin-induced thrombocytopenia (HIT), including the presence of antibodies against heparin/platelet factor 4 (PF4), standard routine treatment for thrombotic events-arterial or venous-are not appropriate and may also cause severe harm in affected patients. Thrombotic complications were also rarely documented after vaccination with mRNA vaccines, but a typical VITT phenomenon has, to date, not been established for these vaccines. The aim of this review is to give a concise and feasible overview of diagnostic and therapeutic strategies in COVID-19 vaccine-induced thrombotic complications.

Hospitalization and Emergency Department Encounters for COVID-19 After Paxlovid Treatment - California, December 2021-May 2022. Nirmatrelvir/ritonavir (Paxlovid) is a combination protease inhibitor that blocks replication of SARS-CoV-2 (the virus that causes COVID-19) and has been shown to reduce the risk for hospitalization and death among patients with mild to moderate COVID-19 who are at risk for progression to severe disease* (1). In December 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for early treatment with Paxlovid among persons with mild to moderate cases of COVID-19 who are at high risk for progression to severe disease (2). FDA and a small number of published case reports have documented recurrence of COVID-19 symptoms or a positive viral test result (COVID-19 rebound) 2-8 days after recovery or a negative SARS-CoV-2 test result among patients treated with Paxlovid (3-7); however, large-scale studies investigating severe illness after Paxlovid treatment are limited. This study used electronic health record (EHR) data from a large integrated health care system in California (Kaiser Permanente Southern California [KPSC]) to describe hospital admissions and emergency department (ED) encounters related to SARS-CoV-2 infections during the 5-15 days after pharmacy dispensation of a 5-day treatment course of Paxlovid. Among 5,287 persons aged â‰¥12 years who received Paxlovid during December 31, 2021-May 26, 2022, 73% had received â‰¥3 doses of COVID-19 vaccine(â€), and 8% were unvaccinated. During the 5-15 days after Paxlovid treatment was dispensed, six hospitalizations and 39 ED encounters considered to be related to SARS-CoV-2 infection were identified, representing <1% of all patients to whom Paxlovid treatment was dispensed during the study period. Among these 45 persons, 21 (47%) were aged â‰¥65 years, and 35 (78%) had at least one underlying medical condition(Â§) (8). This study found that hospitalization or ED encounters for COVID-19 during the 5-15 days after Paxlovid treatment was dispensed for mild to moderate COVID-19 illness were rarely identified. When administered as an early-stage treatment, Paxlovid might

prevent COVID-19-related hospitalization among persons with mild to moderate cases of COVID-19 who are at risk for progression to severe disease.

Ophthalmic manifestation after SARS-CoV-2 vaccination: a case series. BACKGROUND: The aim of this report is to describe ocular side effects in patients who received one of the two COVID-19 vaccines - Astra Zeneca or Pfizer-Biontech and to contribute to the common understanding of the COVID-19 vaccination process. RESULTS: Three patients reactivated underlying herpetic disease and developed uveitis and keratitis. Two of them were vaccinated with Pfizer and one was with Astra Zeneca. Two patients were vaccinated with Pfizer-Biontech and had thrombosis on the 8th and 10th days following the day of vaccination. The man has diagnosed with nonarteritic anterior ischemic optic neuropathy and the woman had a subarachnoid haemorrhage, ptosis of upper eyelid and deviated eyeball. CONCLUSION: There is a causal relationship between vaccines and the underlying disease. For more details, further large studies are necessary.

Drug-induced vasculitis: Thiazide or the COVID-19 vaccine, which one is guilty? A case report and literature review. A middle-aged woman with a history of COVID-19 vaccine administration and valve replacement surgery was admitted with bilateral palpable purpuric lesions in the lower extremities and headache. Based on the initial diagnosis of vasculitis, corticosteroid therapy was initiated, which led to the resolution of skin lesions.

Severe Acute Respiratory Syndrome Coronavirus 2 Antibody Response After Heterologous Immunizations With ChAdOx1/BNT162b2 in End-Stage Renal Disease Patients on Hemodialysis. The Korean government decided to schedule heterologous vaccinations on dialysis patients for early achievement of immunization against Coronavirus disease 2019(COVID-19). However, the effects of heterologous immunizations in hemodialysis (HD) patients are unclear. One hundred (HD) patients from Gangdong Kyung Hee University Hospital and Kyung Hee Medical Center and 100 hospital workers from Gangdong Kyung Hee University Hospital were enrolled in this study. The HD patients received the mixing schedule of ChAdOx1/BNT162b2 vaccinations at 10-week intervals, while hospital workers received two doses of ChAdOx1 vaccines at 12-week intervals. Serum IgG to a receptor-binding domain (RBD) of the S1 subunit of the spike protein of SARS-CoV-2 was measured 1 month after the first dose, 2 months and 4 months after the second dose. The median [interquartile range] anti-RBD IgG was 82.1[34.5, 176.6] AU/ml in HD patients and 197.1[124.0, 346.0] AU/ml in hospital workers ($P < 0.001$) after the first dose. The percentage of positive responses (IgG > 50 AU/ml) was 65.0% and 96.0% among the both group, respectively ($P < 0.001$). The anti-RBD IgG levels increased significantly by 2528.8 [1327.6, 5795.1] AU/ml with a 100.0% positive response rate in HD patients 2 months after the second dose, which was higher than those in hospital workers 981.4[581.5, 1891.4] AU/ml ($P < 0.001$). Moreover, anti-RBD IgG remains constantly high, and positive response remains 100% in HD patients 4 months after the second dose. This study suggests that heterologous vaccinations with ChAdOx1/BNT162b2 can be an alternative solution on HD patients for early and strong induction of humoral response.

Who is pausing immunosuppressive medication for COVID-19 vaccination? Results of an exploratory observational trial. BACKGROUND: The influence of immunosuppressive therapy on immunogenicity after COVID-19 vaccination remains unclear. This study surveys patients who receive immunosuppressive therapy about whether or not they paused their immunosuppressive medication while receiving SARS-CoV-2 vaccination. METHODS: In this prospective observational study, immunosuppressed participants were asked by phone and email about their medication before and during vaccination and who-if anyone-advised them to pause their medication. In addition, a baseline paper-based questionnaire contributes general characteristics regarding age, gender, immunosuppressive medication(s) and the chronic disease(s) requiring immunosuppressive therapy. RESULTS: Of 207 surveyed participants, 59 persons (28.5%) paused their immunosuppressive

medication before/during vaccination. Persons with rheumatic conditions and women were significantly more likely to pause immunosuppressive therapy than others. Over half of those who paused their medication reported receiving a recommendation from their specialist and 22.0% (13 of 59) decided to pause medication themselves without consulting a physician in advance. CONCLUSIONS: Besides lack of evidence, many immunosuppressed individuals and their treating physicians choose to pause medication before COVID-19 vaccination and accepting the risk of worsening their underlying disease. TRIAL REGISTRATION: DRKS00023972, registered 12/30/2020.

Otolaryngology adverse events following COVID-19 vaccines. OBJECTIVE: Since the outbreak of COVID-19 pandemic, the international scientific community aimed at developing a vaccine to protect against the infection and prevent serious forms of the disease. To date, various adverse events of COVID-19 vaccines have been reported, mostly mild to moderate. MATERIALS AND METHODS: In this short communication, we reviewed available literature and described the most frequent otolaryngology adverse events reported after COVID-19 vaccination. RESULTS: The most frequent adverse events following COVID-19 vaccine described in the literature are represented by audiovestibular symptoms, such as tinnitus, sudden sensorineural hearing loss, vertigo, and dizziness. Other side effects include facial nerve palsy, epistaxis, and oral manifestations (lichen planus, bleeding, ulcers, and vesicles). CONCLUSIONS: COVID-19 vaccine is of utmost importance in limiting the spread of SARS-CoV-2. Otolaryngology-related side effects have been described, but none was severe or life threatening. The mechanisms underlying these effects are still mostly unknown.

Boosting corrects a memory B cell defect in SARS-CoV-2 mRNA-vaccinated patients with inflammatory bowel disease. Immunosuppressed patients with inflammatory bowel disease (IBD) generate lower amounts of SARS-CoV-2 spike antibodies after mRNA vaccination than healthy controls. We assessed SARS-CoV-2 spike S1 receptor binding domain-specific (S1-RBD-specific) B lymphocytes to identify the underlying cellular defects. Patients with IBD produced fewer anti-S1-RBD antibody-secreting B cells than controls after the first mRNA vaccination and lower amounts of total and neutralizing antibodies after the second. S1-RBD-specific memory B cells were generated to the same degree in IBD and control groups and were numerically stable for 5 months. However, the memory B cells in patients with IBD had a lower S1-RBD-binding capacity than those in controls, which is indicative of a defect in antibody affinity maturation. Administration of a third shot to patients with IBD elevated serum antibodies and generated memory B cells with a normal antigen-binding capacity. These results show that patients with IBD have defects in the formation of antibody-secreting B cells and affinity-matured memory B cells that are corrected by a third vaccination.

Sibling cases of gross hematuria and newly diagnosed IgA nephropathy following SARS-CoV-2 vaccination. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination has become a major part of the strategy to reduce Coronavirus disease 2019 (COVID-19) numbers worldwide. To date, vaccinations based on several mechanisms have been used clinically, although relapse of existent glomerulonephritis presenting as gross hematuria, and occurrence of de novo glomerulonephritis have been reported. CASE PRESENTATION: We report the first sibling cases newly diagnosed as immunoglobulin A (IgA) nephropathy after the second dose of SARS-CoV-2 vaccination. 15- and 18-year-old men presented with gross hematuria following the second dose of SARS-CoV-2 vaccine (Pfizer, BNT162b2) received on the same day. Pathological findings of each kidney biopsy specimen were consistent with IgA nephropathy. Gross hematuria in both cases spontaneously recovered within several days. CONCLUSIONS: These cases indicate that SARS-CoV-2 vaccination might trigger de novo IgA nephropathy or stimulate its relapse, and also highlight the necessity of understanding the immunological responses to the novel mRNA vaccines in patients with kidney diseases.

Does Maternal SARS-CoV-2 Infection or SARS-CoV-2 Vaccination Trigger an Inflammatory Response in the Fetus? A Prospective Cohort Study. OBJECTIVES: SARS-CoV-2 infection triggers a significant maternal inflammatory response. There is a dearth of information regarding whether maternal SARS-CoV-2 infection at admission for delivery or SARS-CoV-2 vaccination triggers an inflammatory response in the fetus. This study aims at evaluating fetal inflammatory response to maternal SARS-CoV-2 infection or SARS-CoV-2 vaccination compared to control group. Design, Participants, Setting, and Methods: A prospective cohort study was performed with a total of 61 pregnant women who presented for delivery at a single medical center (William Beaumont Hospital, Royal Oak, MI). All mothers were tested for SARS-CoV-2 infection using polymerase chain reaction (PCR) on admission to labor and delivery unit. Three groups were evaluated: 22 pregnant with a positive SARS-CoV-2 test (case group), 23 pregnant women with a negative SARS-CoV-2 test (control group), and 16 pregnant women who had recent SAR-CoV-2 vaccination and a negative SARS-CoV-2 test (vaccine group). At delivery, cord blood was collected to determine the levels of IL-6, C-reactive protein (CRP), and SARS-CoV-2 nucleocapsid IgG and IgM antibodies. In all cases, the newborn had a negative PCR test or showed no clinical findings consistent with SARS-CoV-2 infection. RESULTS: Mean (SD) IL-6 level was not significantly different for the three groups: case group 9.00 Â± 3.340 pg/mL, control group 5.19 Â± 0.759 pg/mL, and vaccine group 7.11 Â± 2.468 pg/mL (p value 0.855). Pairwise comparison also revealed no statistical difference for IL-6 concentrations with p values for case versus control, case versus vaccine, and control versus vaccine = 0.57, 0.91, and 0.74, respectively. Similarly, there was no statistically significant difference in the frequency of elevated IL-6 (>11 pg/mL) between groups (p value 0.89). CRP levels across the three groups were not statistically significant different (p value 0.634). Pairwise comparison of CRP levels among the different groups was also not statistically different. SARS-CoV-2 nucleocapsid IgG was positive in 12 out of 22 cord blood samples in the case group, 2 out of 23 of the control group (indicating old resolved maternal infection), and 0 out of 16 of the vaccine group. SARS-CoV-2 nucleocapsid IgM was negative in all cord blood samples of the case group, control group, and vaccine group. LIMITATIONS: A total number of 61 mothers enrolled in the study which represents a relatively small number of patients. Most patients with positive SARS-CoV-2 PCR were mainly asymptomatic. In addition, our vaccine group received the mRNA-based vaccines (mRNA1273 and BNT162b2). We did not study fetal response to other SARS-CoV-2 vaccines. CONCLUSION: In our prospective cohort, neither IL-6 nor CRP indicated increased inflammation in the cord blood of newborns of SARS-CoV-2-infected or vaccinated mothers.

Characterising the background incidence rates of adverse events of special interest for covid-19 vaccines in eight countries: multinational network cohort study. OBJECTIVE: To quantify the background incidence rates of 15 prespecified adverse events of special interest (AESIs) associated with covid-19 vaccines. DESIGN: Multinational network cohort study. SETTING: Electronic health records and health claims data from eight countries: Australia, France, Germany, Japan, the Netherlands, Spain, the United Kingdom, and the United States, mapped to a common data model. PARTICIPANTS: 126â€‰661â€‰070 people observed for at least 365 days before 1 January 2017, 2018, or 2019 from 13 databases. MAIN OUTCOME MEASURES: Events of interests were 15 prespecified AESIs (non-haemorrhagic and haemorrhagic stroke, acute myocardial infarction, deep vein thrombosis, pulmonary embolism, anaphylaxis, Bell's palsy, myocarditis or pericarditis, narcolepsy, appendicitis, immune thrombocytopenia, disseminated intravascular coagulation, encephalomyelitis (including acute disseminated encephalomyelitis), Guillain-BarrÃ© syndrome, and transverse myelitis). Incidence rates of AESIs were stratified by age, sex, and database. Rates were pooled across databases using random effects meta-analyses and classified according to the frequency categories of the Council for International Organizations of Medical Sciences. RESULTS: Background rates varied greatly between databases. Deep vein thrombosis ranged from 387 (95%

confidence interval 370 to 404) per 100â€‰000 person years in UK CPRD GOLD data to 1443 (1416 to 1470) per 100â€‰000 person years in US IBM MarketScan Multi-State Medicaid data among women aged 65 to 74 years. Some AESIs increased with age. For example, myocardial infarction rates in men increased from 28 (27 to 29) per 100â€‰000 person years among those aged 18-34 years to 1400 (1374 to 1427) per 100â€‰000 person years in those older than 85 years in US Optum electronic health record data. Other AESIs were more common in young people. For example, rates of anaphylaxis among boys and men were 78 (75 to 80) per 100â€‰000 person years in those aged 6-17 years and 8 (6 to 10) per 100â€‰000 person years in those older than 85 years in Optum electronic health record data. Meta-analytic estimates of AESI rates were classified according to age and sex. CONCLUSION: This study found large variations in the observed rates of AESIs by age group and sex, showing the need for stratification or standardisation before using background rates for safety surveillance. Considerable population level heterogeneity in AESI rates was found between databases.

Adverse events of special interest and mortality following vaccination with mRNA (BNT162b2) and inactivated (CoronaVac) SARS-CoV-2 vaccines in Hong Kong: A retrospective study.
BACKGROUND: Safety monitoring of coronavirus disease 2019 (COVID-19) vaccines is crucial during mass vaccination rollout to inform the choice of vaccines and reduce vaccine hesitancy. Considering the scant evidence directly comparing the safety profiles of mRNA and inactivated SARS-CoV-2 vaccines, this territory-wide cohort study aims to compare the incidence of various adverse events of special interest (AESIs) and all-cause mortality between CoronaVac (inactivated vaccine) and BNT162b2 (mRNA-based vaccine). Our results can help vaccine recipients make an informed choice.
METHODS AND FINDINGS: A retrospective, population-based cohort of individuals who had received at least 1 dose of BNT162b2 or CoronaVac from 23 February to 9 September 2021 in Hong Kong, and had data linkage to the electronic medical records of the Hong Kong Hospital Authority, were included. Those who had received mixed doses were excluded. Individuals were observed from the date of vaccination (first or second dose) until mortality, second dose vaccination (for first dose analysis), 21 days after vaccination, or 30 September 2021, whichever came first. Baseline characteristics of vaccinated individuals were balanced between groups using propensity score weighting. Outcome events were AESIs and all-cause mortality recorded during 21 days of post-vaccination follow-up after each dose, except anaphylaxis, for which the observation period was restricted to 2 days after each dose. Incidence rate ratios (IRRs) of AESIs and mortality comparing between CoronaVac and BNT162b2 recipients were estimated after each dose using Poisson regression models. Among 2,333,379 vaccinated individuals aged 18 years or above, the first dose analysis included 1,308,820 BNT162b2 and 955,859 CoronaVac recipients, while the second dose analysis included 1,116,677 and 821,560 individuals, respectively. The most frequently reported AESI among CoronaVac and BNT162b2 recipients was thromboembolism (first dose: 431 and 290 per 100,000 person-years; second dose: 385 and 266 per 100,000 person-years). After the first dose, incidence rates of overall AESIs (IRR = 0.98, 95% CI 0.89-1.08, p = 0.703) and mortality (IRR = 0.96, 95% CI 0.63-1.48, p = 0.868) associated with CoronaVac were generally comparable to those for BNT162b2, except for Bell palsy (IRR = 1.95, 95% CI 1.12-3.41, p = 0.018), anaphylaxis (IRR = 0.34, 95% CI 0.14-0.79, p = 0.012), and sleeping disturbance or disorder (IRR = 0.66, 95% CI 0.49-0.89, p = 0.006). After the second dose, incidence rates of overall AESIs (IRR = 0.97, 95% CI 0.87-1.08, p = 0.545) and mortality (IRR = 0.85, 95% CI 0.51-1.40, p = 0.516) were comparable between CoronaVac and BNT162b2 recipients, with no significant differences observed for specific AESIs. The main limitations of this study include residual confounding due to its observational nature, and the possibility of its being underpowered for some AESIs with very low observed incidences. CONCLUSIONS: In this study, we observed that the incidences of AESIs (cumulative incidence rate of 0.06%-0.09%) and mortality

following the first and second doses of CoronaVac and BNT162b2 vaccination were very low. The safety profiles of the vaccines were generally comparable, except for a significantly higher incidence rate of Bell palsy, but lower incidence rates of anaphylaxis and sleeping disturbance or disorder, following first dose CoronaVac versus BNT162b2 vaccination. Our results could help inform the choice of inactivated COVID-19 vaccines, mainly administered in low- and middle-income countries with large populations, in comparison to the safety of mRNA vaccines. Long-term surveillance on the safety profile of COVID-19 vaccines should continue.

Early Humoral Responses of Hemodialysis Patients After Inactivated SARS-CoV-2 Vaccination. PURPOSE: To detect antibody responses to inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine in patients undergoing hemodialysis and to investigate vaccine-related adverse events. PATIENTS AND METHODS: A total of 120 hemodialysis (HD) patients and 24 healthy controls (HCs) who had not been previously infected with SARS-CoV-2 and had received their first dose of the inactivated vaccine (CoronaVac; Sinovac Biotech Ltd) were recruited for this study. All participants were scheduled to receive a second dose of inactivated SARS-CoV-2 vaccine. Serum-specific immunoglobulin M (IgM) and immunoglobulin G (IgG) antibodies against the SARS-CoV-2 were detected at least 14 days after the second dose of vaccine using a commercial kit. Positive and negative results were defined as a sample/cutoff (S/CO) ratioâ‰¥1.00 and <1.00, respectively. Vaccination-related adverse events were assessed using a standardized questionnaire. RESULTS: There were no significant differences regarding the seroprevalences of IgG and IgM antibodies against SARS-CoV-2 and the self-reported vaccination-related adverse events between HD patients and HCs. The analysis results for HD patients suggest that 82 (68.3%) and 27 (22.5%) tested positive for IgG and IgM, respectively. The levels of IgG were higher than IgM levels ($P<0.0001$). In addition, the IgG-positive group had significantly higher serum albumin levels than the IgG-negative group ($P<0.05$). Only mild vaccine-related adverse events were observed in two patients (1.66%) and in one healthy individual (4.2%). CONCLUSION: The seroprevalences of IgG and IgM antibodies against SARS-CoV-2 and vaccination-related adverse effects are similar between HD and HCs. The inactivated SARS-CoV-2 vaccine is effective and safe in inducing near-term immunity in hemodialysis patients.

On the caveats of a multiplex test for SARS-CoV-2 to detect seroconversion after infection or vaccination. The Covid-19 pandemic, caused by SARS-CoV-2, has resulted in over 6 million reported deaths worldwide being one of the biggest challenges the world faces today. Here we present optimizations of all steps of an enzyme-linked immunosorbent assay (ELISA)-based test to detect IgG, IgA and IgM against the trimeric spike (S) protein, receptor binding domain (RBD), and N terminal domain of the nucleocapsid (N-NTD) protein of SARS-CoV-2. We discuss how to determine specific thresholds for antibody positivity and its limitations according to the antigen used. We applied the assay to a cohort of 126 individuals from Rio de Janeiro, Brazil, consisting of 23 PCR-positive individuals and 103 individuals without a confirmed diagnosis for SARS-CoV-2 infection. To illustrate the differences in serological responses to vaccinal immunization, we applied the test in 18 individuals from our cohort before and after receiving ChAdOx-1 nCoV-19 or CoronaVac vaccines. Taken together, our results show that the test can be customized at different stages depending on its application, enabling the user to analyze different cohorts, saving time, reagents, or samples. It is also a valuable tool for elucidating the immunological consequences of new viral strains and monitoring vaccination coverage and duration of response to different immunization regimens.

Multiple attacks of transient monocular visual loss in a previously healthy man: a possible complication after COVID-19 vaccination? BACKGROUND: The present case aims to describe a previously healthy man who presented multiple attacks of transient monocular visual loss after Pfizer-BioNTech COVID-19 vaccination and to discuss the possible mechanisms related to occurrence of this condition. CASE PRESENTATION: We report a case of multiple attacks of transient monocular

visual loss in a previously healthy middle-aged man two weeks after Pfizer-BioNTech COVID-19 vaccination. TVL attacks were described as sudden and painless complete visual loss, lasting about one minute, followed by a full recovery. He presented several non-simultaneous attacks in both eyes, 16 in the right eye, and 2 in the left eye on the same day, fifteen days after receiving the second dose of the Pfizer-BioNTech COVID-19 vaccine. The brain's magnetic resonance angiography, echocardiogram, and doppler ultrasound imaging of the carotid and vertebral arteries were non-revealing. The complete blood exam revealed a slightly elevated C-reactive protein test. We assessed fundus examination during the transient visual loss attack and revealed diffuse vascular narrowing for both arterial and venous branches, notably in the emergence of the optic disc in right eye. In addition, the circumpapillary optical coherence tomography angiography (OCTA) vessel density map was reduced. Oral verapamil hydrochloride 60Â mg twice daily was initiated, and the attacks of transient visual loss improved after two days. CONCLUSIONS: To date, and the best of our knowledge, this is the first case report of multiple transient monocular visual loss attacks due to retinal vasospasm in a previously healthy middle-aged man documented by fundus retinography and OCTA. We discuss in this article the possible association of retinal vasospasm and Pfizer-BioNTech COVID-19 vaccination, probably related to vaccine-induced inflammation.

Severe case of refractory immune thrombocytopenic purpura requiring splenectomy after the COVID-19 vaccine. Immune thrombocytopenic purpura (ITP) is an autoimmune disorder caused by autoantibodies against platelet antigens resulting in platelet destruction and inhibition of platelet production. Occasionally, an inciting event such as a virus or vaccination can precipitate ITP. Several cases of ITP have been reported after the BTN162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) SARS-CoV-2 (COVID-19) vaccines. All reported cases of post-vaccination ITP have resolved with medical therapy until this case.A man in his mid-20s developed bleeding from ITP 2 weeks after receiving the second dose of the Pfizer SARS-CoV-2 vaccine. All inpatient medical treatment attempts failed. On hospital day 40, a splenectomy was performed and he ultimately recovered and was discharged.Awareness of potential vaccination side effects is a fundamental element of refining and improving patient safety. This case illustrates that given the right circumstances, serious refractory ITP can develop in response to the second dose of the Pfizer SARS-CoV-2 vaccine.

A case of ChAdOx1 vaccine-induced thrombocytopenia and thrombosis syndrome leading to bilateral adrenal haemorrhage and adrenal insufficiency. SUMMARY: Vaccine-induced thrombosis and thrombocytopenia (VITT) after vaccination against SARS-CoV-2 with the adenoviral vector-based vaccines ChAdOx1 and Ad26.COV2.S has been associated with adrenal pathology, such as bilateral adrenal vein thrombosis, adrenal cortex haemorrhage and adrenal insufficiency in 6% of patients. We report the case of a 23-year-old woman who presented at 8 days after ChAdOx1 vaccination with a low platelet count of 43 Ã— 109/L, raised d dimers >100 000 ng/mL and multiple lobar and segmental pulmonary emboli. Anti-platelet factor 4 antibodies were detected confirming definite VITT in accordance with the UK diagneostic criteria. At 16 days post-vaccine, further imaging showed bilateral adrenal haemorrhage, non-occlusive splenic vein thrombosis and right ventricular thrombosis. Her cortisol level was <25 nmol/L. She was treated with anticoagulation, plasmapheresis, immunosuppression and steroid replacement. She had high anti-spike titre and positive anti-nucleocapsid titres for SARS-CoV-2. She developed seizures secondary to posterior reversible encephalopathy, requiring intensive care. After 4 weeks in hospital, she was discharged on warfarin, hydrocortisone and fludrocortisone replacement. Short synacthen tests 3 and 9 months later showed no recovery of adrenal function, although magnetic resonance imaging of the adrenal glands showed resolving adrenal haemorrhage. Adrenal insufficiency secondary to bilateral adrenal vein thrombosis and adrenal haemorrhage should be suspected in patients with VITT and treated promptly. Adrenal vein thrombosis can occur either as the initial presentation of VITT or days to weeks after the

development of thrombosis in other sites. Further studies are required to provide insight on adrenal function recovery after VITT. LEARNING POINTS: Adrenal insufficiency secondary to bilateral adrenal vein thrombosis and adrenal cortex haemorrhage should be suspected in patients with vaccine-induced thrombosis and thrombocytopenia (VITT) and treated promptly. Adrenal vein thrombosis can occur as the initial presentation of VITT or even days to weeks later after the development of thrombosis in other more classic sites (e.g. pulmonary or cerebral vasculature). Completion of vaccination schedule against SARS-CoV-2 post-VITT using an mRNA-based vaccine should be recommended to patients post-VITT as mRNA-based vaccines have not been associated with VITT but confer protection against SARS-CoV-2. There is paucity of data regarding the potential for recovery of adrenal function after bilateral adrenal haemorrhage in the context of VITT, and thus, more studies are needed to inform clinical practice. The need for disease registries for rare conditions, such as VITT, is crucial as direct cooperation and sharing of information by clinicians might enable quicker identification of disease patterns than would have been possible via established reporting tools of adverse events.

Adverse events of Oxford/AstraZeneca's COVID-19 vaccine among health care workers of Ayder Comprehensive Specialized Hospital, Tigray, Ethiopia. BACKGROUND: : The safety of COVID vaccines should be continuously followed. This study reports adverse events of the Oxford/AstraZeneca COVID-19 vaccine. METHODS: : A prospective single-cohort study design was conducted to assess adverse events following immunization and associated factors of the first dose of Oxford/AstraZeneca's COVID-19 vaccine in Ayder Comprehensive specialized hospital. A structured questionnaire was administered consecutively to 423 participants. Follow-up data were collected 72 hours after vaccination via phone. Bivariate and multivariate logistic regression models were used to find associations between adverse events and independent variables. Statistical significance was declared at P<0.05. RESULTS: : Out of 423 health care workers approached, 395 responded. At least one adverse event (95% CI: 63.58, 72.77) was reported by 270 participants. Local and systemic symptoms occurred in 46.8% (95% CI: 41.94, 51.79) and 58.48% (95% CI: 53.53, 63.26)], respectively. Muscle ache, fatigue, headache and fever were the most common local symptoms. No reports of hospitalization, disability or death. Age (adjusted odds ratio [AOR]=0.97, P=0.048), female sex (AOR=1.84, P=0.028), and comorbidity (AOR=2.28, P=0.040) were independent predictors of adverse events. CONCLUSION AND RECOMMENDATION: : Adverse events following immunization are commonly reported after the first dose of the Oxford/AstraZeneca COVID-19 vaccine; age, female sex and comorbidity are independent predictors.

Rates, types, and associated factors of acute adverse effects after the first dose of ChAdOx1 nCoV-19 vaccine administration in Thailand. OBJECTIVES: Effective vaccines are prioritized to curtail the transmission and burden of coronavirus disease 2019. Nevertheless, monitoring the safety of vaccines is crucial. As Thailand began the ChAdOx1 nCoV-19 vaccination, our study examined the acute adverse effects and associated factors after the first dose of vaccination. METHODS: A mobile self-report questionnaire was employed to assess the rates and types of different side-effects within 3 days of the first dose of ChAdOx1 nCoV-19 vaccine administration. The risk factors associated with these side-effects were analyzed. RESULTS: In total, 774 participants were included in the survey, with a mean (Â± standard deviation) age of 49.5 (Â± 17.2) years. The majority (57.8%) were females, and 59.1% were anxious before the vaccination. Side-effects after the vaccination were a common occurrence (65.2%), but most (42.6%) were mild. Side-effects were significantly associated (odds ratio [95% confidence interval]) with younger age (4.32 [2.26-8.23]; p < 0.001; age < 30 years vs â‰¥ 60 years), female sex (1.66 [1.19-2.30], pÂ =Â 0.003), anxiousness (2.10 [1.06-4.13]; pÂ =Â 0.033; moderate-severe anxiousness vs none), and allergic disease (2.60 [1.07-6.31]; pÂ =Â 0.035).

CONCLUSIONS: After the ChAdOx1 nCoV-19 vaccination, most acute adverse effects were mild and often noted among participants with younger age, female sex, anxiousness, and allergic disease.

Increased Seroprevalence and Improved Antibody Responses Following Third Primary SARS-CoV-2 Immunisation: An Update From the COV-AD Study. BACKGROUND: Patients with primary and secondary antibody deficiency are vulnerable to COVID-19 and demonstrate diminished responses following two-dose SARS-CoV-2 vaccine schedules. Third primary vaccinations have been deployed to enhance their humoral and cellular immunity. OBJECTIVES: To determine the immunogenicity of the third primary SARS-CoV-2 immunisation in a heterogeneous cohort of patients with antibody deficiency. METHODS: Participants enrolled in the COV-AD study were sampled before and after their third vaccine dose. Serological and cellular responses were determined using ELISA, live-virus neutralisation and ELISPOT assays. RESULTS: Following a two-dose schedule, 100% of healthy controls mounted a serological response to SARS-CoV-2 vaccination, however, 38.6% of individuals with antibody deficiency remained seronegative. A third primary SARS-CoV-2 vaccine significantly increased anti-spike glycoprotein antibody seroprevalence from 61.4% to 76.0%, the magnitude of the antibody response, its neutralising capacity and induced seroconversion in individuals who were seronegative after two vaccine doses. Vaccine-induced serological responses were broadly cross-reactive against the SARS-CoV-2 B.1.1.529 variant of concern, however, seroprevalence and antibody levels remained significantly lower than healthy controls. No differences in serological responses were observed between individuals who received AstraZeneca ChAdOx1 nCoV-19 and Pfizer BioNTech 162b2 during their initial two-dose vaccine schedule. SARS-CoV-2 infection-naive participants who had received a heterologous vaccine as a third dose were significantly more likely to have a detectable T cell response following their third vaccine dose (61.5% vs 11.1%). CONCLUSION: These data support the widespread use of third primary immunisations to enhance humoral immunity against SARS-CoV-2 in individuals with antibody deficiency.

Vaccination Against SARS-CoV-2 in Lung Transplant Recipients: Immunogenicity, Efficacy and Safety. Lung transplant (LuTx) recipients are considered to be at higher risk of developing serious illness from COVID-19. COVID-19 vaccines were shown in randomized clinical trials to substantially reduce the severity of COVID-19, however, patients receiving immunosuppressants were excluded from these trials. Observational studies report a proportion of solid organ transplant (SOT) recipients being able to mount sufficient titers of SARS-CoV-2 specific IgG antibodies, however, other studies demonstrate that more than 90% of the SOT recipients elicit neither humoral nor cellular immune response after vaccination. Currently, the third booster dose of the COVID-19 vaccines was shown to elicit strong immune responses and may, thus, represent a potent tool in the prevention of severe COVID-19 infection in SOT recipients, including patients after lung transplantation. To address the main challenges of SARS-CoV-2 vaccination in LuTx recipients in the era of COVID-19, we have closely collected all available data on the immunogenicity, efficacy and safety of COVID-19 vaccines in LuTx recipients.

Case Report: New-Onset Rheumatoid Arthritis Following COVID-19 Vaccination. Efficient protection against coronavirus disease 2019 (COVID-19) has been achieved by immunization with mRNA-based vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, efficient immune responses against this novel virus by vaccination are accompanied by a wide variety of side effects. Indeed, flares or new-onset of autoimmune disorders have been reported soon after the COVID-19 vaccination. Although pro-inflammatory cytokine responses play pathogenic roles in the development of autoimmunity, cytokines charactering COVID-19 vaccination-related autoimmune responses have been poorly understood. Given that mRNA derived from COVID-19 vaccine is a potent inducer for pro-inflammatory cytokine responses, these cytokines might mediate autoimmune responses after COVID-19 vaccination. Here we report a case with new-onset

rheumatoid arthritis (RA) following COVID-19 vaccination. Serum concentrations not only of arthrogenic cytokines, interleukin-6 (IL-6) and tumor necrosis factor-Î± (TNF-Î±), but also of type I interferon (IFN) were elevated at the active phase in this case. Induction of remission by methotrexate and tocilizumab was accompanied by a marked reduction in serum concentrations of type I IFN, IL-6, and TNF-Î±. These results suggest that production of type I IFN, IL-6, and TNF-Î± induced by COVID-19 vaccination might be involved in this case with new-onset RA.

Humoral and Cellular Responses to BNT162b2 as a Booster Following Two Doses of ChAdOx1 nCov-19 Determined Using Three SARS-CoV-2 Antibody Assays and an Interferon-Gamma Release Assay: A Prospective Longitudinal Study in Healthcare Workers. Data on humoral and cellular responses to BNT162b2 as a booster dose, following two doses of ChAdOx1 nCov-19 vaccine, have seldom been reported. The aim of this study was to assess the positivity rates of three representative antibody assays targeting total, IgG, and neutralizing antibodies, and an interferon-Î³ release assay (IGRA), and to determine the longitudinal changes in quantitative antibody titers after each vaccination. A total of 1027 samples were collected from healthcare workers. The number of participants after the booster dose was 153, and they all completed a questionnaire on adverse reactions. All antibody assays showed 100.0% positivity at 1 month after booster vaccination. The median antibody titers of the assays were significantly increased compared with those after the second dose (22.1-fold increase for Roche total antibody, 14.0-fold increase for Abbott IgG, and 1.1-fold increase (97.5% inhibition) for GenScript neutralizing antibody). Cellular responses determined using the IGRA were positive in 92.8% of the participants. Most participants (72.5%) reported mild adverse reactions. Correlations between the three antibody assays and IGRA were weak or negligible, indicating a difference between humoral and cellular responses. Overall, our study provides information about booster vaccine strategies and laboratory settings, which could subsequently contribute to the control of the spread of coronavirus disease 2019.

mRNA or ChAd0x1 COVID-19 Vaccination of Adolescents Induces Robust Antibody and Cellular Responses With Continued Recognition of Omicron Following mRNA-1273. Children and adolescents generally experience mild COVID-19. However, those with underlying physical health conditions are at a significantly increased risk of severe disease. Here, we present a comprehensive analysis of antibody and cellular responses in adolescents with severe neuro-disabilities who received COVID-19 vaccination with either ChAdOx1 (n=6) or an mRNA vaccine (mRNA-1273, n=8, BNT162b2, n=1). Strong immune responses were observed after vaccination and antibody levels and neutralisation titres were both higher after two doses. Both measures were also higher after mRNA vaccination and were further enhanced by prior natural infection where one vaccine dose was sufficient to generate peak antibody response. Robust T-cell responses were generated after dual vaccination and were also higher following mRNA vaccination. Early T-cells were characterised by a dominant effector-memory CD4+ T-cell population with a type-1 cytokine signature with additional production of IL-10. Antibody levels were well-maintained for at least 3 months after vaccination and 3 of 4 donors showed measurable neutralisation titres against the Omicron variant. T-cell responses also remained robust, with generation of a central/stem cell memory pool and showed strong reactivity against Omicron spike. These data demonstrate that COVID-19 vaccines display strong immunogenicity in adolescents and that dual vaccination, or single vaccination following prior infection, generate higher immune responses than seen after natural infection and develop activity against Omicron. Initial evidence suggests that mRNA vaccination elicits stronger immune responses than adenoviral delivery, although the latter is also higher than seen in adult populations. COVID-19 vaccines are therefore highly immunogenic in high-risk adolescents and dual vaccination might be able to provide relative protection against the Omicron variant that is currently globally dominant.

Multisystem Inflammatory Syndrome in Adult Following COVID-19 Vaccination (MIS-AV). The last 2 years have been dominated by coronavirus disease-2019 (COVID-19), its various presentations, complications, and their management. The first COVID-19 vaccine, produced by Pfizer-BioNTech, was granted regulatory approval on December 2, 2020, by the UK medicines regulator medicines and healthcare products regulatory agency (MHRA). It was evaluated for emergency use authorization (EUA) status by the US Food and Drug Administration (FDA) and in several other countries. Following millions of doses, during the early months of 2021, reports of side effects of the vaccines began to emerge. In this case report, we discuss the case of a 22-year-old female patient who presented with fever and confusion, with later progression to multiple organ failure, following administration of Pfizer-BioNTech vaccine. She was successfully treated with intravenous (IV) immunoglobulin (Ig) and high-dose IV corticosteroids. This case report is unique as lymph node biopsy was carried out-this showed marked suppurative inflammation with vasculitic changes, thus supporting the diagnosis. HOW TO CITE THIS ARTICLE: Ganapathiram RN, Hudson S. Multisystem Inflammatory Syndrome in Adult Following COVID-19 Vaccination (MIS-AV). Indian J Crit Care Med 2022;26(5):649-650.

Longitudinal Study of DNA Methylation and Epigenetic Clocks Prior to and Following Test-Confirmed COVID-19 and mRNA Vaccination. The host epigenetic landscape rapidly changes during SARS-CoV-2 infection, and evidence suggest that severe COVID-19 is associated with durable scars to the epigenome. Specifically, aberrant DNA methylation changes in immune cells and alterations to epigenetic clocks in blood relate to severe COVID-19. However, a longitudinal assessment of DNA methylation states and epigenetic clocks in blood from healthy individuals prior to and following test-confirmed non-hospitalized COVID-19 has not been performed. Moreover, the impact of mRNA COVID-19 vaccines upon the host epigenome remains understudied. Here, we first examined DNA methylation states in the blood of 21 participants prior to and following test-confirmed COVID-19 diagnosis at a median time frame of 8.35Â weeks; 756 CpGs were identified as differentially methylated following COVID-19 diagnosis in blood at an FDR adjusted p-value < 0.05. These CpGs were enriched in the gene body, and the northern and southern shelf regions of genes involved in metabolic pathways. Integrative analysis revealed overlap among genes identified in transcriptional SARS-CoV-2 infection datasets. Principal component-based epigenetic clock estimates of PhenoAge and GrimAge significantly increased in people over 50 following infection by an average of 2.1 and 0.84Â years. In contrast, PCPhenoAge significantly decreased in people fewer than 50 following infection by an average of 2.06Â years. This observed divergence in epigenetic clocks following COVID-19 was related to age and immune cell-type compositional changes in CD4(+) T cells, B cells, granulocytes, plasmablasts, exhausted T cells, and naÃ¯ve T cells. Complementary longitudinal epigenetic clock analyses of 36 participants prior to and following Pfizer and Moderna mRNA-based COVID-19 vaccination revealed that vaccination significantly reduced principal component-based Horvath epigenetic clock estimates in people over 50 by an average of 3.91Â years for those who received Moderna. This reduction in epigenetic clock estimates was significantly related to chronological age and immune cell-type compositional changes in B cells and plasmablasts pre- and post-vaccination. These findings suggest the potential utility of epigenetic clocks as a biomarker of COVID-19 vaccine responses. Future research will need to unravel the significance and durability of short-term changes in epigenetic age related to COVID-19 exposure and mRNA vaccination.

LGI-1 encephalopathy following ChAdOx1 nCov-19 vaccination. A 71-year-old male patient was diagnosed with LGI1 encephalopathy 4Â weeks following a first ChAdOx1 nCov-19 vaccination. Extensive work-up including analysis of CSF and PET examination did not reveal a tangible cause so that a vaccine-associated encephalopathy was considered as differential diagnosis. Under steroid treatment, the faciobrachial dystonic seizures subsided.

Acute Disseminated Encephalomyelitis After SARS-CoV-2 Vaccination. BACKGROUND Acute disseminated encephalomyelitis (ADEM) is a disorder of the central nervous system which has been associated with preceding infection as well as vaccinations. We present a case of a 61-year-old woman with ADEM after receiving her initial vaccination for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This case highlights management of this acute condition. CASE REPORT A 61-year-old woman with history of hypertension and anxiety presented with progressive generalized weakness and difficulty with communication which began a few weeks ago, shortly after receiving the Pfizer vaccine for the novel coronavirus (COVID-19). On arrival, she was found to be encephalopathic and tachypneic, ultimately requiring emergent intubation. During her hospital course, an MRI of her brain was obtained which showed nonspecific acute versus subacute leukoencephalopathy involving the brainstem and deep white matter. Her cerebrospinal fluid showed elevated protein but was otherwise unremarkable. Further testing to rule out tick-borne illnesses, viral etiology, and multiple sclerosis were negative. Electroencephalography showed nonspecific diffuse cerebral dysfunction but no seizures or epileptiform discharges. She was treated with 5 doses of methylprednisolone 1 g and intravenous immunoglobulin (IVIG) 2 g/kg over 5 days. She had marked improvement in her neurologic status after treatment. CONCLUSIONS In conclusion, ADEM should be acknowledged as a rare but potential complication related to COVID-19 vaccination. A proper history and physical exam in addition to a thorough work-up are necessary for prompt recognition of this condition. Initial treatment should consist of steroids followed by IVIG versus plasmapheresis for those not responsive to steroids.

Temporal changes in spike IgG levels after two doses of BNT162b2 vaccine in Japanese healthcare workers: Do spike IgG levels at 3 months predict levels 6 or 8 months after vaccination? BACKGROUND: Accurate timing of BNT162b2 boosters to prevent breakthrough infections of coronavirus disease 2019 (COVID-19) requires reliable estimates of immune status. We hypothesized that spike IgG levels at 3 months after two doses of the BNT162b2 vaccine might predict subsequent spike IgG levels. METHODS AND RESULTS: Spike IgG levels were tested at 3, 6, and 8 months after the second dose of the BNT162b2 vaccine in 251 Japanese health care workers (median age: 39 years, female: 187). The median level of spike IgG was 2,882 AU/mL at 3 months. This decreased to 875 AU/mL at 6 months and 579 AU/mL at 8 months. There were good correlations of log-transformed spike IgG levels between 3 and 6 months (r = 0.86) and between 3 and 8 months (r = 0.82). The correlation further improved after excluding three subjects who had possible COVID-19 infections (r = 0.91, r = 0.86). Log-transformed spike IgG levels at 6 or 8 months yields the following equation: log spike IgG at 6 (8) months = 0.92 (0.86) X log spike IgG at 3 months- 0.23 (0.18). Predicted spike IgG at 6 months of â‰¥ 300 or < 300 AU/mL had 98% sensitivity, 47% specificity, and 94% accuracy for discriminating subjects whose actual spike IgG titers at 6 months were above or below 300 AU/mL. Corresponding values of predicted spike IgG at 8 months were 97%, 70%, and 93%, respectively. CONCLUSIONS: We conclude that predictive formulae using spike IgG levels at 3 months after two-dose vaccination with BNT162b2 reliably estimate subsequent spike IgG levels up to 8 months and provide useful information in terms of vaccination booster timing.

Subacute Thyroiditis After Receiving Inactivated Virus Vaccine for COVID-19. The spread of SARS-COVID 19 infection has resulted in accelerated efforts at development and dissemination of vaccines throughout the globe. These vaccines have different mechanisms of actions and their efficacy and side effects are being monitored. There have been rare reports in literature of thyroid dysfunction after COVID-19 vaccine administration. Sub-acute thyroiditis is one such complication which can arise as a rare side-effect of vaccination. This has also been reported as a symptom of COVID-19 infection. Clinical features include fever, neck pain, palpitations and weight loss. We report sub-acute thyroiditis

in a 50-year-old male who presented with symptoms suggestive of thyroid abnormality one day after receiving the inactivated COVID-19 vaccine (CoronaVac Sinovac-Biotech Ltd).

Unilateral Erosive Arthritis Following Moderna COVID-19 Vaccination. A novel coronavirus was identified at the end of 2019, causing a pneumonia epidemic in China, which later rapidly spread to cause a global pandemic. However, most people who contracted the COVID-19 had mild to moderate symptoms. A fair percentage developed ARDS, Septic shock, and multi-organ failure. Given the necessity of immunization in combating this disease, COVID-19 vaccines were widely deployed, giving rise to multiple reported cases of post-vaccination autoimmune flareups and new onset of autoimmune phenomena. We present a case of an 81-year-old female who was diagnosed with erosive arthritis post COVID-19 vaccination.

The Effect of Age, Gender and Comorbidities Upon SARS-CoV-2 Spike Antibody Induction After Two Doses of Sinopharm Vaccine and the Effect of a Pfizer/BioNtech Booster Vaccine. Severe acute respiratory syndrome coronavirus (SARS-CoV)-2 emerged in China in 2019 and has since travelled the world infecting millions. SARS-CoV-2 causes Corona Virus Disease (COVID-19), that has to date taken over 4 million lives. The Kingdom of Bahrain's vaccine roll-out has consisted of Sinopharm's BBIBP-CorV (Sinopharm) and Pfizer/BioNtech's BNT162b2 (Pfizer/BioNtech). Testing for SARS-CoV-2 anti-Spike (S) antibodies is a useful technique in estimating an individual's immune protection against the infection. In this study we evaluated S antibody levels by electro-chemiluminescence immunoassay in 379 individuals double vaccinated with Sinopharm and 15 of whom were given a booster with the Pfizer/BioNtech vaccine. Among our double vaccinated cohort, we found a spectrum of S antibody levels. Indeed, we found that a significant proportion of individuals with low S antibody levels had clinical conditions, which were mainly immune-related disorders. Furthermore, a significant proportion of individuals with low S antibody levels were above 50 years of age. Finally, we observed a significant increase in S antibody levels after the Pfizer/BioNtech booster was administered. These findings reveal that while a large proportion of Sinopharm vaccinated individuals did not develop high levels of antibodies against the S protein, a booster dose of the Pfizer/BioNtech vaccine significantly enhances S antibody levels, revealing this "triple dose" vaccination strategy as a useful method of ensuring protective immunity against SARS-CoV-2.

Heterogeneous SARS-CoV-2-Neutralizing Activities After Infection and Vaccination.
BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants of concern (VOCs) with different resistance levels to existing immunity have recently emerged. Antibodies that recognize the SARS-CoV-2 spike (S) protein and exhibit neutralizing activities are considered the best correlate of protection and an understanding of humoral immunity is crucial for controlling the pandemic. We thus analyzed such antibodies in individuals recovered from infection in 2020 as well as vaccinees after two doses of an mRNA vaccine. METHODS: Neutralizing antibody responses against three SARS-CoV-2 variants (D614G, VOCs Beta and Delta) were determined in serum samples from 54 infected individuals (24 non-hospitalized, 30 hospitalized) and 34 vaccinees shortly after symptom onset or second vaccination, respectively, as well as six months later. In addition, the effect of the S sequence of the infecting strain on neutralization was studied. RESULTS: Non-hospitalized patients had the lowest neutralization titers against all variants, while those of hospitalized patients equaled or exceeded those of vaccinees. Neutralizing activity was lower against the two VOCs and declined significantly in all cohorts after six months. This decrease was more pronounced in hospitalized and vaccinated individuals than in non-hospitalized patients. Of note, the specific neutralizing activity (NT titer/ELISA value ratio) was higher in the infected cohorts than in vaccinees and did not differ between non-hospitalized and hospitalized patients. Patients infected with viral strains carrying mutations in the N-terminal domain of the spike protein were impaired in Beta VOC neutralization. CONCLUSIONS: Specific neutralizing activities were higher in infected than in vaccinated individuals,

and no difference in the quality of these antibodies was observed between hospitalized and non-hospitalized patients, despite significantly lower titers in the latter group. Additionally, antibody responses of infected individuals showed greater heterogeneity than those of vaccinees, which was associated with mutations in the spike protein of the infecting strain. Overall, our findings yielded novel insights into SARS-CoV-2-specific neutralizing antibodies, evolving differently after virus infection and COVID-19 vaccination, which is an important issue to consider in ongoing vaccine strategy improvements.

Multiple Autoimmune Syndromes Including Acute Disseminated Encephalomyelitis, Myasthenia Gravis, and Thyroiditis Following Messenger Ribonucleic Acid-Based COVID-19 Vaccination: A Case Report. The global pandemic has resulted from the emergence of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), causing coronavirus disease 2019 (COVID-19). To control the spread of the pandemic, SARS-CoV-2 vaccines have been developed. Messenger ribonucleic acid (mRNA)-based COVID-19 vaccines have been the most widely used. We present the case of a 65-year-old patient, who was diagnosed with acute disseminated encephalomyelitis, ocular myasthenia gravis, and autoimmune thyroiditis, following his third mRNA COVID-19 vaccination. On admission, the patient showed mild left-sided hemiparesis, contralateral dissociated sensory loss, dizziness, and right-sided deafness. Brain MRI revealed multiple acute inflammatory contrast-enhancing periventricular and brainstem lesions with involvement of vestibulo-cerebellar tract and cochlear nuclei. Despite steroid pulse and intravenous immunoglobulin therapy, clinical symptoms and MRI lesions worsened, and additional signs of ocular myasthenia gravis and elevated but asymptomatic thyroid antibodies developed. After repeated plasma exchange, all clinical symptoms resolved. This is, to the best of our knowledge, the first case report of multiple autoimmune syndromes triggered by COVID-19 vaccination. The rare occurrence of such treatable autoimmune complications should not question the importance of vaccination programs during the COVID-19 pandemic.

Evaluation of the safety and immunogenicity of different COVID-19 vaccine combinations in healthy individuals: study protocol for a randomized, subject-blinded, controlled phase 3 trial [PRIBIVAC]. BACKGROUND: Over 2021, COVID-19 vaccination programs worldwide focused on raising population immunity through the primary COVID-19 vaccine series. In Singapore, two mRNA vaccines (BNT162b2 and mRNA-1273) and the inactivated vaccine CoronaVac are currently authorized under the National Vaccination Programme for use as the primary vaccination series. More than 90% of the Singapore population has received at least one dose of a COVID-19 vaccine as of December 2021. With the demonstration that vaccine effectiveness wanes in the months after vaccination, and the emergence of Omicron which evades host immunity from prior infection and/or vaccination, attention in many countries has shifted to how best to maintain immunity through booster vaccinations. METHODS: The objectives of this phase 3, randomized, subject-blinded, controlled clinical trial are to assess the safety and immunogenicity of heterologous boost COVID-19 vaccine regimens (intervention groups 1-4) compared with a homologous boost regimen (control arm) in up to 600 adult volunteers. As non-mRNA vaccine candidates may enter the study at different time points depending on vaccine availability and local regulatory approval, participants will be randomized at equal probability to the available intervention arms at the time of randomization. Eligible participants will have received two doses of a homologous mRNA vaccine series with BNT162b2 or mRNA-1273 at least 6 months prior to enrolment. Participants will be excluded if they have a history of confirmed SARS or SARS-CoV-2 infection, are immunocompromised, or are pregnant. Participants will be monitored for adverse events and serious adverse events by physical examinations, laboratory tests and self-reporting. Blood samples will be collected at serial time points [pre-vaccination/screening (day - 14 to day 0), day 7, day 28, day 180, day 360 post-vaccination] for assessment of antibody and cellular immune parameters. Primary endpoint is the level of anti-SARS-CoV-2 spike immunoglobulins at day 28 post-

booster and will be measured against wildtype SARS-CoV-2 and variants of concern. Comprehensive immune profiling of the humoral and cellular immune response to vaccination will be performed. DISCUSSION: This study will provide necessary data to understand the quantity, quality, and persistence of the immune response to a homologous and heterologous third booster dose of COVID-19 vaccines. This is an important step in developing COVID-19 vaccination programs beyond the primary series. TRIAL REGISTRATION: ClinicalTrials.gov NCT05142319 . Registered on 2 Dec 2021.

Breakthrough Severe COVID-19 Infection After Triple Dose Pfizer Vaccination. The impact of COVID-19 was felt across the globe when it first emerged in December 2019. However, within a year, there was a new hope with the development and approval of mRNA vaccines. The Comirnaty and Pfizer-BioNTech BNT162b2 mRNA vaccine showed an efficacy of 95 percent in preventing COVID-19 disease. However, subsequent studies conducted on immunocompromised hosts showed the efficacy to be significantly lower than the initial reported 95 percent, making these patients prone to COVID-19 disease despite the initially recommended two doses. On Sept. 22, 2021, a third dose was approved for immunocompromised hosts. In this article, we report the case of a 67-year-old female with overlap connective tissue disease on mycophenolate mofetil who had a prolonged hospital course because of severe COVID-19 disease complicated by pulmonary embolism despite receiving three doses of the BNT162b2 mRNA vaccine.

How Vaccination Rumours Spread Online: Tracing the Dissemination of Information Regarding Adverse Events of COVID-19 Vaccines. Objectives: To trace the emergence and dissemination of the most prominent rumours about potential adverse effects of COVID-19 vaccines. Methods: We use a weekly Google Trends search to gather information about what alleged adverse events are being associated with COVID vaccines by the general population. We then use CrowdTangle and Factiva searches to examine how discussions about the five most prominent adverse events have spread through traditional media channels and Facebook. Results: Traditional mass media reporting remains crucial in both promoting and moderating discussions around alleged adverse events. While some cases illustrate that social media networks can synthesise and amplify rumours about adverse events, traditional media coverage remains crucial as a forum for exploring and debunking spurious claims. Conclusion: Traditional media stories still bear signficant responsibility as credibility markers for rumours about vaccine adverse events. Journalists should therefore be encouraged to be particularly earnest when reporting such stories, and the scientific community should aid journalists in this task by clearly responding to any rumours emerging online.

Posterior Reversible Encephalopathy Syndrome Onset Within 24 Hours Following Moderna mRNA Booster COVID-19 Vaccination: Vaccine Adverse Event Vs. Hypertension? We present a case of a female who presented with the acute onset of neurological changes within 24 hours of receiving her third, or booster, dose of the mRNA Moderna (Cambridge, Massachusetts) coronavirus disease 2019 (COVID-19) vaccination. Her clinicoradiological findings were most consistent with posterior reversible encephalopathy syndrome (PRES). Although PRES has been reported with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, this raised suspicion of a possible vaccine-induced PRES with her only confounder being hypertension managed with a beta-blocker. Extensive workup for other entities associated with PRES, including infection, autoimmune, paraneoplastic syndrome, and alcohol were unrevealing. Thus far, there have not been any reports of PRES post mRNA vaccination. We encourage providers to report similar cases with neurological manifestations post mRNA vaccination to the vaccine adverse event reporting system (VAERS). Timely diagnosis and treatment of PRES may help minimize any irreversible neurological sequelae.

Acute Onset of Remitting Seronegative Symmetrical Synovitis With Pitting Edema (RS3PE) Two Weeks After COVID-19 Vaccination With mRNA-1273 With Possible Activation of Parvovirus B19: A Case Report With Literature Review. Remitting seronegative symmetrical synovitis with pitting edema

(RS3PE) is a rare clinical entity characterized by "remitting," "seronegative," and "symmetrical" synovitis with pitting edema on the dorsum of the hands and feet. Although rheumatic or malignant diseases are diseases that are known to coexist with RS3PE, other factors such as medication, infection, and vaccination have been reported to be associated with RS3PE. Here, we present a case of RS3PE syndrome that satisfied all four diagnostic criteria of RS3PE (pitting edema in the limbs, acute onset, age â‰¥ 50 years, and/or rheumatoid factor negativity) after mRNA-1273 SARS-CoV-2 vaccination.
Post COVID-19 Large Atrial Thrombus Found Incidentally. BACKGROUND: Coronavirus disease 2019 (COVID-19) has become a leading cause of morbidity and mortality worldwide. One of the major complications of COVID-19 infection is the hypercoagulability state. Cardiac thrombi and venous thromboembolism (VTE) have been documented with severe COVID-19 infection. We present a case of large right atrial (RA) thrombus in transit incidentally diagnosed following a mild COVID-19 in a previously vaccinated patient. CASE SUMMARY: An 85-year-old male presented to the emergency department two weeks following resolution of a mild COVID-19 infection due to an incidentally discovered large RA thrombus. Computed tomography with angiography of the chest was positive for acute pulmonary thromboembolic disease with large clot burden and findings consistent with right heart strain. The patient remained hemodynamically stable and was successfully managed with anticoagulation. CONCLUSION: RA thrombi and VTE can occur in patients with mild COVID-19 infection and in the setting of full COVID-19 vaccination. Echocardiography is a useful imaging modality in this patient population.
Factors associated with vaccination against Covid-19 in pregnant and hospitalized postpartum women: A retrospective cohort study. OBJECTIVE: To analyze the characteristics associated with vaccination against Covid-19 in pregnant and postpartum women with Severe Acute Respiratory Syndrome in Brazil and to investigate a possible association between vaccination and the clinical course and outcome of the disease. METHODS: Retrospective cohort study of hospitalized pregnant and postpartum women diagnosed with Severe Acute Respiratory Syndrome (SARS) by SARS-CoV-2, presenting onset of signs and symptoms between May and October 2021. Secondary data were used, available in the Influenza Epidemiological Surveillance Information System (SIVEP-Gripe). Data were analyzed using the SPSS statistical program, medians were applied to present continuous variables and frequencies, and proportions were calculated for categorical variables, using logistic and multivariate regression analysis. RESULTS: The final study population included 3,585 pregnant and postpartum women, of whom 596 (16.6) were vaccinated: 443 (74.3%) received one dose and 153 (25.7%) received two doses. They were factors associated with non-vaccination against Covid-19 age â‰¤ 19 anos (OR: 2.57; IC95% 1.40;4.71), non-white women (OR: 1.34; IC95% 1.07;1.67) and those who required ventilatory support (OR: 1.51; IC95% 1.19;1.90) and invasive ventilation (OR: 2.05; IC95% 1.37;3.08). On the other hand, vaccination was associated with advanced maternal age (OR: 0.60; IC95% 0.48;0.76), presence of comorbidities (OR: 0.57; IC95% 0.45;0.72) and loss of taste (OR: 0.63; IC95% 0.48;0.82). CONCLUSIONS: Demographic, ethnic-racial and clinical characteristics were associated with the vaccination status of pregnant and postpartum women with SARS by SARS-CoV-2 in Brazil. Vaccination against Covid-19 in the obstetric population has already shown positive results in the evolution of severe cases, which reiterates its importance. It is essential that health services advance vaccination against Covid-19 in the obstetric population, especially adolescentes and non-white women.
Association between Covid-19 Vaccination and Influenza Vaccination Rates.
Psoriasiform Skin Eruptions Following COVID-19 Vaccination Unveiled Previously Undiagnosed post-COVID-19 Psoriatic Arthritis.
Case report: Pituitary apoplexy after COVID-19 vaccination.

Acute Transient Encephalopathy after Moderna COVID-19 Vaccine. Although mRNA vaccine responses following previous coronavirus disease 2019 (COVID-19) infection have not been assessed in trials, it has been shown that serological evidence of previous COVID-19 generates strong humoral and cellular responses to one dose of mRNA vaccine. We describe a patient with prior COVID-19 infection who developed acute transient encephalopathy with elevated inflammatory markers within 24 h of her first injection of Moderna COVID-19 vaccine. A 69-year-old cognitively normal woman presented with intermittent inattention, disorientation, left/right confusion, weakness, gait instability, and decreased speech. Head CT, brain MRI and MRA, complete blood count, liver enzymes, hepatitis B serology, ammonia, thyroid function, vitamin B12, and pulse oximetry were normal. Electroencephalography performed 48 h after symptom onset showed diffuse triphasic waves, diffuse theta and delta slowing, and no posterior dominant rhythm. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG was positive and inflammatory markers were elevated. On day 5 post-vaccine, she returned to her baseline, without neurological sequelae. The reported patient likely developed a transient inflammatory encephalopathy associated with an abnormal immunologic reaction to one dose of COVID-19 vaccine, in the setting of remote COVID-19 infection (1 year prior), SARS-CoV-2 IgG-positivity, and multiple comorbidities. Physicians should be alert to possible postvaccination reactogenicity in individuals with SARS-CoV-2 IgG-positivity, including risk of neuro-inflammation.

Accelerate the process of getting vaccinated: factors associated with consideration of and accessibility to COVID-19 vaccination in metropolises of China. BACKGROUND: Rapid mutation of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus is sweeping the world and delaying the full reopening of society. Acceleration of the vaccination process may be the key element in winning the race against this virus. We examine factors associated with personal considerations of and accessibility to the corona virus disease 2019 (COVID-19) vaccination in metropolises of China. METHODS: This multi-center, cross-sectional research was conducted using online questionnaires from April 1 to June 1, 2021, in community health service centers of Shanghai, Chengdu and Fuzhou. 9,047 vaccinated participants were included and data for 8,990 individuals were eligible for analysis. Chi-square test was conducted to find potential predictors, which were included in the logistic regressions. The odds ratios (ORs) and 95% confidence intervals (CIs) were calculated to assess the influence of region, socio-economic status (SES), and attitudes on vaccination process. RESULTS: In consideration phase, participants in Fuzhou (OR:2.26, 95%CI: 1.90 to 2.68) and Chengdu (OR: 2.48, 95%CI: 2.17 to 2.83) were more likely than those in Shanghai to consider longer than one month. These odds increased for participants with master or above degree (reference: illiteracy and primary school), higher monthly household income (reference:â€‰<â€‰Â¥5000), and greater vaccination hesitancy (reference: low hesitancy). Unemployed and household-based participants (OR: 3.37, 95%CI: 1.69 to 6.75, reference: farmer) and participants without brand preference (OR:1.13, 95%CI:1.02 to 1.26) may take longer time of consideration. In the accessibility phase, participants in Fuzhou (OR: 8.82, 95%CI: 7.28 to 10.68) and Chengdu (OR: 2.28, 95%CI: 1.98 to 2.63) were more likely to wait longer than one week. These odds decreased for participants with master or above degree (reference: illiteracy and primary school), monthly household income from Â¥5000 to Â¥10,000 (reference:â€‰<â€‰Â¥5000), and teacher or student (reference: farmer). Participants without brand preference (OR: 0.86, 95%CI: 0.77 to 0.95) were likely to wait shorter after appointment, while participants with higher risk awareness of domestic epidemic (medium, OR: 1.24, 95%CI: 1.12 to 1.37, reference: low) may wait longer. CONCLUSIONS: The influential factors changed over two phases of vaccination process. Regional disparity affected both consideration and accessibility phases. Expect that, SES, and hesitancy were major factors of the consideration phase, but had limited impact on accessibility phase.

Analysis of Thromboembolic and Thrombocytopenic Events After the AZD1222, BNT162b2, and MRNA-1273 COVID-19 Vaccines in 3 Nordic Countries. IMPORTANCE: Vaccinations are paramount to halt the COVID-19 pandemic, and safety data are essential to determine the risk-benefit ratio of each COVID-19 vaccine. OBJECTIVE: To evaluate the association between the AZD1222, BNT162b2, and mRNA-1273 vaccines and subsequent thromboembolic and thrombocytopenic events. DESIGN, SETTING, AND PARTICIPANTS: This self-controlled case series used individual-level data from national registries in Norway, Finland, and Denmark. Participants included individuals with hospital contacts because of coronary artery disease, coagulation disorders, or cerebrovascular disease between January 1, 2020, and May 16, 2021. EXPOSURES: AZD1222, BNT162b2, or mRNA-1273 vaccine. MAIN OUTCOMES AND MEASURE: Relative rate (RR) of hospital contacts for coronary artery disease, coagulation disorders, or cerebrovascular disease in a 28-day period following vaccination compared with the control period prior to vaccination. RESULTS: We found 265â€¯339 hospital contacts, of whom 112â€¯984 [43%] were for female patients, 246â€¯092 [93%] were for patients born in 1971 or earlier, 116â€¯931 [44%] were for coronary artery disease, 55â€¯445 [21%] were for coagulation disorders, and 92â€¯963 [35%] were for cerebrovascular disease. In the 28-day period following vaccination, there was an increased rate of coronary artery disease following mRNA-1273 vaccination (RR, 1.13 [95% CI, 1.02-1.25]), but not following AZD1222 vaccination (RR, 0.92 [95% CI, 0.82-1.03]) or BNT162b2 vaccination (RR, 0.96 [95% CI, 0.92-0.99]). There was an observed increased rate of coagulation disorders following all 3 vaccines (AZD1222: RR, 2.01 [95% CI, 1.75-2.31]; BNT162b2: RR, 1.12 [95% CI, 1.07-1.19]; and mRNA-1273: RR, 1.26 [95% CI, 1.07-1.47]). There was also an observed increased rate of cerebrovascular disease following all 3 vaccines (AZD1222: RR, 1.32 [95% CI, 1.16-1.52]; BNT162b2: RR, 1.09 [95% CI, 1.05-1.13]; and mRNA-1273: RR, 1.21 [95% CI, 1.09-1.35]). For individual diseases within the main outcomes, 2 notably high rates were observed: 12.04 (95% CI, 5.37-26.99) for cerebral venous thrombosis and 4.29 (95% CI, 2.96-6.20) for thrombocytopenia, corresponding to 1.6 (95% CI, 0.6-2.6) and 4.9 (95% CI, 2.9-6.9) excess events per 100â€¯000 doses, respectively, following AZD1222 vaccination. CONCLUSIONS AND RELEVANCE: In this self-controlled case series, there was an increased rate of hospital contacts because of coagulation disorders and cerebrovascular disease, especially for thrombocytopenia and cerebral venous thrombosis, following vaccination with AZD1222. Although increased rates of several thromboembolic and thrombocytopenic outcomes following BNT162b2 and mRNA-1273 vaccination were observed, these increases were less than the rates observed after AZD1222, and sensitivity analyses were not consistent. Confirmatory analysis on the 2 mRNA vaccines by other methods are warranted.

Elevated Histamine Etiology Model for Most Major Vaccine Associated Adverse Events including SARS-CoV-2 Spike Vaccines. Vaccinees experience no adverse events, mild adverse events, multiple adverse events, or serious adverse events post vaccination. Many of these vaccine adverse events occur with different vaccines with different occurrence frequencies. Many of these adverse events are generally considered as associated with immune responses to the active vaccine components (antigens) and/or to possibly one or more of the vaccine excipients. Most of these vaccine adverse events are self-limiting and resolve within days. Many of these adverse events symptoms overlap symptoms associated with elevated histamine levels. Based on these observations, the hypothesis that the majority of vaccine associated reactogenicity adverse events are caused by temporal histamine intolerance in vaccinees is proposed. This hypothesis is based on a model of innate immune responses releasing a surge of inflammatory molecules including histamine; this surge is hypothesized to exceed the normal histamine tolerance level for vaccinees with reactogenicity adverse events. Further, these symptoms resolve as histamine levels fall below the vaccinee's tolerance threshold. This model can be evaluated by the detection of elevated histamine levels in

vaccinees corresponding to timing of symptoms onset. If confirmed, a direct consequence of this model predicts that some antihistamine treatments, mast cell stabilizers, and possibly diamine oxidase enzyme may reduce the incidence or severity of adverse events experienced by vaccinees post vaccinations for most or all high reactogenicity vaccines including coronavirus disease 2019 (COVID-19) Spike vaccines.

Secondary Stabbing Headache Associated with COVID-19: a Case Report. Although COVID-19 is mainly an acute viral illness, persistent symptoms are common. However, headache is not a frequent sequela of this disease. Furthermore, stabbing/ice-pick cephalalgia has been reported inâ€‰<â€‰10% of cases of COVID-19, and recurrent forms occurring after vaccination against the disease have not been published yet. We present here an unusual short-lasting unilateral stabbing/ice-pick headache with recurrent periodicity over 10Â months, which may represent a sequela of COVID-19. The cephalalgia presented in a 55-year-old male with no significant medical problems approximately 4Â months after the acute onset of COVID-19, and recurred twice 12Â days after the second dose of COVID-19 vaccination with BNT162b2 (Pfizer). This report represents a contribution to the semiological pattern of COVID-19-related cephalea.

Outcome of SARS-CoV-2 associated Guillain-Barre syndrome depends on early treatment and vaccination.

Chilblain-like lesions onset during SARS-CoV-2 infection in a COVID-19-vaccinated adolescent: case report and review of literature. BACKGROUND: COVID toes or chilblain-like skin lesions have been widely reported during COVID-19 pandemic. Most cases were described in patients with negative microbiological tests for SARS-CoV-2, therefore the possible relationship with SARS-CoV-2 infection, as well as with the nowadays broadly available mRNA-based vaccination, has not been fully elucidated.Â CASE PRESENTATION: We here describe the case of a 14-year-old male who developed chilblain-like skin eruptions during SARS-CoV-2 infection despite two mRNA-based vaccineÂ doses and review the clinical and epidemiological characteristics of chilblain-like lesions as a cutaneous presentation of COVID-19 in children. CONCLUSIONS: Most children and adolescent with COVID toes have a mild or asymptomatic SARS-CoV-2 infection. Our report aims to highlight the possible onset of these skin lesions in vaccinated children, if infection has occurred, and the potential use of systemic corticosteroids as a first line treatment. Additional evidence is required to better understand SARS-CoV-2 infection and cutaneous manifestations in children and determine the relationship between chilblain-like lesions and COVID-19 vaccination.

Adverse cutaneous reactions after mRNA SARS-CoV-2 vaccination in 3 patients: a spectrum of severity.

Change in covid-19 risk over time following vaccination with CoronaVac: test negative case-control study. OBJECTIVE: To estimate the change in odds of covid-19 over time following primary series completion of the inactivated whole virus vaccine CoronaVac (Sinovac Biotech) in SÃ£o Paulo State, Brazil. DESIGN: Test negative case-control study. SETTING: Community testing for covid-19 in SÃ£o Paulo State, Brazil. PARTICIPANTS: Adults aged â‰¥18 years who were residents of SÃ£o Paulo state, had received two doses of CoronaVac, did not have a laboratory confirmed SARS-CoV-2 infection before vaccination, and underwent reverse transcription polymerase chain reaction (RT-PCR) testing for SARS-CoV-2 from 17 January to 14 December 2021. Cases were matched to test negative controls by age (in 5 year bands), municipality of residence, healthcare worker status, and epidemiological week of RT-PCR test. MAIN OUTCOME MEASURES: RT-PCR confirmed symptomatic covid-19 and associated hospital admissions and deaths. Conditional logistic regression was adjusted for sex, number of covid-19 associated comorbidities, race, and previous acute respiratory illness. RESULTS: From 202â€‰741 eligible people, 52â€‰170 cases with symptomatic covid-19 and 69â€‰115 test negative controls with covid-19 symptoms were formed into 43â€‰257 matched sets. Adjusted odds

ratios of symptomatic covid-19 increased with time since completion of the vaccination series. The increase in odds was greater in younger people and among healthcare workers, although sensitivity analyses suggested that this was in part due to bias. In addition, the adjusted odds ratios of covid-19 related hospital admission or death significantly increased with time compared with the odds 14-41 days after series completion: from 1.25 (95% confidence interval 1.04 to 1.51) at 70-97 days up to 1.94 (1.41 to 2.67) from 182 days onwards. CONCLUSIONS: Significant increases in the risk of moderate and severe covid-19 outcomes occurred three months after primary vaccination with CoronaVac among people aged 65 and older. These findings provide supportive evidence for the implementation of vaccine boosters in these populations who received this inactivated vaccine. Studies of waning should include analyses designed to uncover common biases.

Reported Side Effects of COVID-19 Vaccination among Adults in Saudi Arabia: A Cross-Sectional Study. BACKGROUND: The coronavirus disease 2019 (COVID-19) pandemic, caused by the severe acute respiratory syndrome coronavirus 2, is a major international crisis. Although vaccination is the only hope to end this pandemic, adverse effects attributable to vaccines are still being reported. Active surveillance is critical for generating near-real-time, high-quality evidence for potential safety hazards, allowing us to respond quickly to vaccination. PURPOSE: To investigate the prevalence of side effects following COVID-19 vaccination with Oxford-AstraZeneca among adults in northwestern Riyadh Province, Saudi Arabia. METHODS: This is a cross-sectional and community-based study performed among individuals who had received any type of COVID-19 vaccination. A convenience sampling method was used to collect data using an online survey. RESULTS: A total of 222 individuals responded to the survey, and the majority frequently reported both localized and systemic side effects after vaccination. The most reported side effects include pain at the site of injection, myalgia, headache, and fever. Some demographic factors were significantly associated with the reported post-vaccination side effects. CONCLUSION: The most prevalent side effects experienced by individuals after receiving the COVID-19 vaccine were determined in this study. Prior to the administration of a vaccination, counseling programs should be established to help people understand and deal with the possible side effects, with a special focus on demographic differences.

Safety and Efficacy of Combined Intramuscular/Intranasal RAZI-COV PARS Vaccine Candidate Against SARS-CoV-2: A Preclinical Study in Several Animal Models. Several vaccine candidates for COVID-19 have been developed, and few vaccines received emergency approval with an acceptable level of efficacy and safety. We herein report the development of the first recombinant protein-based vaccine in Iran based on the recombinant SARS-CoV-2 spike protein in its monomeric (encompassing amino acid 1-674 for S1 and 685-1211 for S2 subunits) and trimer form (S-Trimer) formulated in the oil-in-water adjuvant system RAS-01 (Razi Adjuvant System-01). The safety and immunity of the candidate vaccine, referred to as RAZI-COV PARS, were evaluated in Syrian hamster, BALB/c mice, Pirbright guinea pig, and New Zeeland white (NZW) rabbit. All vaccinated animals received two intramuscular (IM) and one intranasal (IN) candidate vaccine at 3-week intervals (days 0, 21, and 51). The challenge study was performed intranasally with 5Ã—10(6) pfu of SARS-CoV-2 35 days post-vaccination. None of the vaccinated mice, hamsters, guinea pigs, or rabbits showed any changes in general clinical observations; body weight and food intake, clinical indicators, hematology examination, blood chemistry, and pathological examination of vital organs. Safety of vaccine after the administration of single and repeated dose was also established. Three different doses of candidate vaccine stimulated remarkable titers of neutralizing antibodies, S1, Receptor-Binding Domain (RBD), and N-terminal domain (NTD) specific IgG antibodies as well as IgA antibodies compared to placebo and control groups ($P<0.01$). Middle and high doses of RAZI-COV PARS vaccine significantly induced a robust and quick immune response from the third-week post-immunization. Histopathological studies on vaccinated hamsters showed that the challenge with SARS-CoV-2 did not induce any modifications in

the lungs. The protection of the hamster was documented by the absence of lung pathology, the decreased virus load in the lung, rapid clearance of the virus from the lung, and strong humoral and cellular immune response. These findings confirm the immunogenicity and efficacy of the RAZI-COV PARS vaccine. Of the three tested vaccine regimens, the middle dose of the vaccine showed the best protective immune parameters. This vaccine with heterologous prime-boost vaccination method can be a good candidate to control the viral infection and its spread by stimulating central and mucosal immunity.
Autoimmune Skin Disease Exacerbations Following COVID-19 Vaccination. BACKGROUND: Vaccination against COVID-19 reduces the risk of severe COVID-19 disease and death. However, few studies have examined the safety of the COVID-19 vaccine in patients with autoimmune skin disease. OBJECTIVES: We sought to determine the incidence of disease exacerbation in this population following COVID-19 vaccination as well as the associated factors. METHODS: We performed a chart review of all patients seen in the autoimmune skin disease clinic of the principal investigator during the study period. All patients included for analysis were systematically and prospectively asked about COVID-19 vaccination status, manufacturers, vaccine dates, autoimmune symptoms after the vaccine, and timing of symptom onset using a standardized template as part of their visit. Demographics and autoimmune disease diagnosis were also collected. Analysis used Chi-square and Fisher's exact tests. RESULTS: 402 subjects were included for analysis. 85.6% of patients were fully vaccinated, with 12.9% unvaccinated and 1.5% partially vaccinated. 14.8% of fully vaccinated patients reported worsening autoimmune signs and symptoms after the vaccine. Fully vaccinated dermatomyositis patients were more likely to report worsening autoimmune signs and symptoms after the vaccine (22.7%) than fully vaccinated lupus erythematosus patients (8.6%) (p=0.009). Patients fully vaccinated with the Moderna vaccine trended towards an increased likelihood of reporting worsening autoimmune signs and symptoms after the vaccine (19.1%) than those with the Pfizer-BioNTech vaccine (12.0%) (p=0.076). Of the patients who had autoimmune symptoms after vaccination, 20% had symptoms after the 1st dose, 82% after the 2nd dose, and 4% after the 3rd dose with median onset (95% confidence interval) of 7 (2,14), 14 (14,21), and 18 (7,28) days later, respectively. CONCLUSIONS: More fully vaccinated dermatomyositis patients had exacerbation of autoimmune signs and symptoms after the vaccine than fully vaccinated lupus erythematosus patients. However, given the risks of COVID-19, clinicians should still promote vaccination in most patients with autoimmune skin disease.
Accelerated Hypertension and Intracerebral Haemorrhage Following First Dose of ChAdOx1-nCOV-19 Vaccination.
Post COVID-19 Vaccination GBS-Association or Causation?
An Unusual Case of Hemorrhagic Pleuropericarditis After COVID-19 Vaccination. As coronavirus disease 2019 (COVID-19) vaccines are being increasingly administered worldwide, subsequent side effects, such as myocarditis, pericarditis, and myopericarditis, are becoming increasingly more common. Our case describes a 64-year-old male who developed chest pain and shortness of breath one week after receiving the Moderna (Cambridge, Massachusetts) COVID-19 mRNA vaccine. He was found to have a large, left-sided pleural effusion and a small pericardial effusion. The patient underwent thoracentesis and video-assisted thoracoscopic procedure with chest tube placement, which drained bloody pleural and pericardial fluid. He was treated with a course of colchicine. Subsequent imaging revealed the resolution of pericardial and pleural effusions, along with the resolution of symptoms.
Cutaneous complications of COVID-19 vaccines.
Generalized Edema and Pseudothrombocytopenia After ChAdOx1 nCoV-19 COVID-19 Vaccination: A Case Report. Reports of side effects of vaccines against severe acute respiratory syndrome

coronavirus 2 (SARS-CoV-2) are increasing worldwide. Capillary leak syndrome and vaccine-induced immune thrombotic thrombocytopenia are very rare but life-threatening adverse events that should be identified early and treated. However, isolated thrombocytopenia can indicate pseudothrombocytopenia. In certain people, ethylenediaminetetraacetic acid (EDTA) induces an in vitro platelet aggregation, resulting in misleading underestimation of platelet counts. It is essential to recognize pseudothrombocytopenia to prevent diagnostic errors, overtreatment, anxiety, and unnecessary invasive procedures. We present a case who developed generalized edema and persistent pseudothrombocytopenia after the first dose of the ChAdOx1 nCoV-19 vaccine (AstraZeneca).

Safety and immunogenicity of the ChAdOx1 nCoV-19 (AZD1222) vaccine in children aged 6-17 years: a preliminary report of COV006, a phase 2 single-blind, randomised, controlled trial.
BACKGROUND: Vaccination of children and young people against SARS-CoV-2 is recommended in some countries. Scarce data have been published on immune responses induced by COVID-19 vaccines in people younger than 18 years compared with the same data that are available in adults. METHODS: COV006 is a phase 2, single-blind, randomised, controlled trial of ChAdOx1 nCoV-19 (AZD1222) in children and adolescents at four trial sites in the UK. Healthy participants aged 6-17 years, who did not have a history of chronic respiratory conditions, laboratory-confirmed COVID-19, or previously received capsular group B meningococcal vaccine (the control), were randomly assigned to four groups (4:1:4:1) to receive two intramuscular doses of 5â€ˆÃ—â€ˆ10(10) viral particles of ChAdOx1 nCoV-19 or control, 28 days or 84 days apart. Participants, clinical investigators, and the laboratory team were masked to treatment allocation. Study groups were stratified by age, and participants aged 12-17 years were enrolled before those aged 6-11 years. Due to the restrictions in the use of ChAdOx1 nCoV-19 in people younger than 30 years that were introduced during the study, only participants aged 12-17 years who were randomly assigned to the 28-day interval group had received their vaccinations at the intended interval (day 28). The remaining participants received their second dose at day 112. The primary outcome was assessment of safety and tolerability in the safety population, which included all participants who received at least one dose of the study drug. The secondary outcome was immunogenicity, which was assessed in participants who were seronegative to the nucleocapsid protein at baseline and received both prime and boost vaccine. This study is registered with ISRCTN (15638344). FINDINGS: Between Feb 15 and April 2, 2021, 262 participants (150 [57%] participants aged 12-17 years and 112 [43%] aged 6-11 years; due to the change in the UK vaccination policy, the study terminated recruitment of the younger age group before the planned number of participants had been enrolled) were randomly assigned to receive vaccination with two doses of either ChAdOx1 nCoV-19 (n=211 [n=105 at day 28 and n=106 at day 84]) or control (n=51 [n=26 at day 28 and n=25 at day 84]). One participant in the ChAdOx1 nCoV-19 day 28 group in the younger age bracket withdrew their consent before receiving a first dose. Of the participants who received ChAdOx1 nCoV-19, 169 (80%) of 210 participants reported at least one solicited local or systemic adverse event up to 7 days following the first dose, and 146 (76%) of 193 participants following the second dose. No serious adverse events related to ChAdOx1 nCoV-19 administration were recorded by the data cutoff date on Oct 28, 2021. Of the participants who received at least one dose of ChAdOx1 nCoV-19, there were 128 unsolicited adverse events up to 28 days after vaccination reported by 83 (40%) of 210 participants. One participant aged 6-11 years receiving ChAdOx1 nCoV-19 reported a grade 4 fever of 40Â·2Â°C on day 1 following first vaccination, which resolved within 24 h. Pain and tenderness were the most common local solicited adverse events for all the ChAdOx1 nCoV-19 and capsular group B meningococcal groups following both doses. Of the 242 participants with available serostatus data, 14 (6%) were seropositive at baseline. Serostatus data were not available for 20 (8%) of 262 participants. Among seronegative participants

who received ChAdOx1 nCoV-19, anti-SARS-CoV-2 IgG and pseudoneutralising antibody titres at day 28 after the second dose were higher in participants aged 12-17 years with a longer interval between doses (geometric means of 73â€ˆ371 arbitrary units [AU]/mL [95% CI 58â€ˆ685-91â€ˆ733] and 299 half-maximal inhibitory concentration [IC(50); 95% CI 230-390]) compared with those aged 12-17 years who received their vaccines 28 days apart (43â€ˆ280 AU/mL [95% CI 35â€ˆ852-52â€ˆ246] and 150 IC(50) [95% CI 116-194]). Humoral responses were higher in those aged 6-11 years than in those aged 12-17 years receiving their second dose at the same 112-day interval (geometric mean ratios 1Â·48 [95% CI 1Â·07-2Â·07] for anti-SARS-CoV-2 IgG and 2Â·96 [1Â·89-4Â·62] for pseudoneutralising antibody titres). Cellular responses peaked after a first dose of ChAdOx1 nCoV-19 across all age and interval groups and remained above baseline after a second vaccination. INTERPRETATION: ChAdOx1 nCoV-19 is well tolerated and immunogenic in children aged 6-17 years, inducing concentrations of antibody that are similar to those associated with high efficacy in phase 3 studies in adults. No safety concerns were raised in this trial. FUNDING: AstraZeneca and the UK Department of Health and Social Care through the UK National Institute for Health and Care Research.

Risk of myocarditis and pericarditis after the COVID-19 mRNA vaccination in the USA: a cohort study in claims databases. BACKGROUND: Several passive surveillance systems reported increased risks of myocarditis or pericarditis, or both, after COVID-19 mRNA vaccination, especially in young men. We used active surveillance from large health-care databases to quantify and enable the direct comparison of the risk of myocarditis or pericarditis, or both, after mRNA-1273 (Moderna) and BNT162b2 (Pfizer-BioNTech) vaccinations. METHODS: We conducted a retrospective cohort study, examining the primary outcome of myocarditis or pericarditis, or both, identified using the International Classification of Diseases diagnosis codes, occurring 1-7 days post-vaccination, evaluated in COVID-19 mRNA vaccinees aged 18-64 years using health plan claims databases in the USA. Observed (O) incidence rates were compared with expected (E) incidence rates estimated from historical cohorts by each database. We used multivariate Poisson regression to estimate the adjusted incidence rates, specific to each brand of vaccine, and incidence rate ratios (IRRs) comparing mRNA-1273 and BNT162b2. We used meta-analyses to pool the adjusted incidence rates and IRRs across databases. FINDINGS: A total of 411 myocarditis or pericarditis, or both, events were observed among 15â€ˆ148â€ˆ369 people aged 18-64 years who received 16â€ˆ912â€ˆ716 doses of BNT162b2 and 10â€ˆ631â€ˆ554 doses of mRNA-1273. Among men aged 18-25 years, the pooled incidence rate was highest after the second dose, at 1Â·71 (95% CI 1Â·31 to 2Â·23) per 100â€ˆ000 person-days for BNT162b2 and 2Â·17 (1Â·55 to 3Â·04) per 100â€ˆ000 person-days for mRNA-1273. The pooled IRR in the head-to-head comparison of the two mRNA vaccines was 1Â·43 (95% CI 0Â·88 to 2Â·34), with an excess risk of 27Â·80 per million doses (-21Â·88 to 77Â·48) in mRNA-1273 recipients compared with BNT162b2. INTERPRETATION: An increased risk of myocarditis or pericarditis was observed after COVID-19 mRNA vaccination and was highest in men aged 18-25 years after a second dose of the vaccine. However, the incidence was rare. These results do not indicate a statistically significant risk difference between mRNA-1273 and BNT162b2, but it should not be ruled out that a difference might exist. Our study results, along with the benefit-risk profile, continue to support vaccination using either of the two mRNA vaccines. FUNDING: US Food and Drug Administration.

Expansion of cytotoxic tissue-resident CD8(+) T cells and CCR6(+)CD161(+) CD4(+) T cells in the nasal mucosa following mRNA COVID-19 vaccination. Vaccines against SARS-CoV-2 have shown high efficacy in clinical trials, yet a full immunologic characterization of these vaccines, particularly within the human upper respiratory tract, is less well known. Here, we enumerate and phenotype T cells in nasal mucosa and blood using flow cytometry before and after vaccination with the Pfizer-BioNTech COVID-19 vaccine (nâ€‰=â€‰21). Tissue-resident memory (Trm) CD8(+) T cells expressing CD69(+)CD103(+) increase in number ~12 days following the first and second doses, by 0.31 and 0.43

log(10) cells per swab respectively (pâ€‰=â€‰0.058 and pâ€‰=â€‰0.009 in adjusted linear mixed models). CD69(+)CD103(+)CD8(+) T cells in the blood decrease post-vaccination. Similar increases in nasal CD8(+)CD69(+)CD103(-) T cells are observed, particularly following the second dose. CD4(+) cells co-expressing CCR6 and CD161 are also increased in abundance following both doses. Stimulation of nasal CD8(+) T cells with SARS-CoV-2 spike peptides elevates expression of CD107a at 2- and 6-months (pâ€‰=â€‰0.0096) post second vaccine dose, with a subset of donors also expressing increased cytokines. These data suggest that nasal T cells may be induced and contribute to the protective immunity afforded by this vaccine.

Relapse of cryoglobulinemic vasculitis with new-onset severe renal involvement in two patients following mRNA COVID-19 vaccination: A case report. RATIONALE: Since mass-scale severe acute respiratory syndrome coronavirus 2 vaccination, there have been case reports of several immune-mediated reactions, including new-onset and flares of glomerular disorders following immunization with mRNA coronavirus disease 2019 vaccines. Here, we report two cases, the first to our knowledge, of relapsing cryoglobulinemic vasculitis with new-onset severe renal involvement following mRNA coronavirus disease 2019 vaccination. PATIENT CONCERNS: The relapse of the cutaneous and the new onset of severe renal involvement of cryoglobulinemic vasculitis occurred three weeks after the second dose of the mRNA Moderna coronavirus disease 2019 vaccination and two days after the first dose of mRNA Pfizer coronavirus disease 2019 vaccination in the first and second patient, respectively. DIAGNOSIS: Kidney biopsies were performed. The first pacient's kidney biopsy showed a membranoproliferative pattern of glomerular injury with extensive mesangial and endocapillary hypercellularity, while severe endothelial swelling, loss of fenestrations and widening of subendothelial space were identified by electron-microscopy. The second patient's kidney biopsy was consistent with cryoglobulin associated membrano-proliferative pattern of glomerular injury. INTERVENTIONS: Our patients were managed with a combination of immunosuppressants consisting of corticosteroids, Cyclophosphamide and Rituximab with a favourable outcome at the end of the induction period. OUTCOMES: Clinical and immunological response was achieved in both patients after four months of follow-up. LESSONS: The temporal association of the relapse of the cryoglobulinemic vasculitis to mRNA coronavirus disease 2019 vaccination suggest that the vaccine might have been a trigger for the reactivation of the disease in our cases. This possible association should be acknowledged by physicians in order to provide optimal monitoring and treatment in case of reactivation of the disease post-immunization.

Reporting adverse events of COVID-19 vaccines: The case of Bulgaria. As a member state of the European Union, where vaccines against COVID-19 are available and affordable, Bulgaria reports the lowest immunization coverage and the most pronounced vaccine distrust. The present study aimed to assess the self-reported adverse reactions following COVID-19 vaccination as a possible tool to increase the trust in vaccines. A cross-sectional survey-based study, covering 761 vaccinated respondents, was conducted in Plovdiv (469 with an mRNA vaccine and 292 with an adenoviral vector vaccine). Descriptive statistics parametric and non-parametric methods were applied. Statistical significance was set at $p<0.05$. The median age of the respondents was 42 years, females (72.5%). At least one adverse reaction was reported in 89.9% of those immunized with mRNA vaccine and 93.8% in the adenoviral vector vaccine group ($p>0.05$). They were mild to moderate and resolved within several days. The levels of local reactions were comparable: 91.7% in those who received mRNA and 89.7% in those who received an adenoviral vector vaccine ($p = 0.366$). The most common types of systemic reactions were fatigue, headache, and muscle pains. An association was found between the systemic reactions and the type of vaccine administered: 59.7% in mRNA recipients and 89.4% in adenoviral vector vaccinees ($p<0.001$). None of the registered systemic reactions required medical attention. There were 3 reports of generalized urticaria after an mRNA and 2 after an adenoviral

vector vaccine. The reported reactions are relatively high but expected and no adverse events have been reported that are not listed in the official Summary of Product Characteristics.

Factors associated with anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein antibody titer and neutralizing activity among healthcare workers following vaccination with the BNT162b2 vaccine. The purpose of this study was to identify factors associated with the increase in the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike (S1) protein and neutralizing antibody titer following SARS-CoV-2 vaccination. This observational study was conducted among healthcare workers working for a private hospital group in Fukushima Prefecture, Japan. Two blood samples were obtained from each participant. The first sample was obtained before the first dose of BNT162b2 (Pfizer-BioNTech) vaccine, and a second sample was obtained approximately 6 weeks later. Immunoglobulin G (IgG) antibody against the SARS-CoV-2 spike (S1) protein, immunoglobulin M (IgM) antibody against SARS-CoV-2 N-protein, and neutralizing activity were measured using the chemiluminescent immunoassay with iFlash 3000. A total of 231 healthcare workers who agreed to participate, and were negative for anti-SARS-CoV-2 IgM antibodies at enrollment, were included in the analysis. All participants had elevated IgG antibodies and neutralizing activity above the cutoff values. A total of 174 (75.3%) and 208 (90.0%) participants experienced adverse reactions after the first and second vaccine doses, respectively. Younger age, female sex, not taking immunosuppressive or antipyretic analgesic medication regularly, a lack of local adverse reactions after the first dose, and the presence of adverse reactions (fever, muscle, and joint pain) after the second dose were associated with higher IgG antibody titers and neutralizing activity. Intake of analgesic antipyretic for adverse reactions to vaccines was not significantly associated with antibody and neutralizing activity titer production. Immune responses after vaccination may differ among individuals, and continued countermeasures to prevent SARS-CoV-2 infection are vital.

Proteomic and Metabolomic Signatures Associated With the Immune Response in Healthy Individuals Immunized With an Inactivated SARS-CoV-2 Vaccine. CoronaVac (Sinovac), an inactivated vaccine for SARS-CoV-2, has been widely used for immunization. However, analysis of the underlying molecular mechanisms driving CoronaVac-induced immunity is still limited. Here, we applied a systems biology approach to understand the mechanisms behind the adaptive immune response to CoronaVac in a cohort of 50 volunteers immunized with 2 doses of CoronaVac. Vaccination with CoronaVac led to an integrated immune response that included several effector arms of the adaptive immune system including specific IgM/IgG, humoral response and other immune response, as well as the innate immune system as shown by complement activation. Metabolites associated with immunity were also identified implicating the role of metabolites in the humoral response, complement activation and other immune response. Networks associated with the TCA cycle and amino acids metabolic pathways, such as phenylalanine metabolism, phenylalanine, tyrosine and tryptophan biosynthesis, and glycine, serine and threonine metabolism were tightly coupled with immunity. Critically, we constructed a multifactorial response network (MRN) to analyze the underlying interactions and compared the signatures affected by CoronaVac immunization and SARS-CoV-2 infection to further identify immune signatures and related metabolic pathways altered by CoronaVac immunization. These results help us to understand the host response to vaccination of CoronaVac and highlight the utility of a systems biology approach in defining molecular correlates of protection to vaccination.

Orbital inflammatory disease following mRNA SARS-CoV-2 vaccine. A 65-year-old woman reported orbital symptoms two days after her first dose and presented exacerbation of signs after the second dose of BNT162b2 mRNA vaccine. The temporal relationship between the COVID-19

vaccination and orbital symptoms suggests a probable link between SARS-CoV-2 mRNA vaccine and this orbital inflammatory disease.

Unraveling the Mystery of COVID-19 Postvaccination Myocarditis: A Systematic Review of Current Cases. From the early stages of the pandemic, the development and mass production of a safe and effective vaccine seemed like the greatest tool, to win the fight against the virus. In the present study, we comprehensively conducted a systematic review of all current cases worldwide to better understand whether there is a link between COVID-19 vaccination and one of the most devastating complications, cardiac Inflammation. Our search retrieved over 250 results, of which 130 met the inclusion criteria, and their respective data were extracted. The results suggest that postvaccination myocarditis and pericarditis are more likely to be seen in male, younger, and mRNA-vaccinated individuals. Most affected patients experienced symptoms following the second shot, and complaint of chest pain was the most prevalent presentation. Currently, no direct link can be drawn between the vaccines and the risk of cardiac inflammation.

Effect of Third and Fourth mRNA-Based Booster Vaccinations on SARS-CoV-2 Neutralizing Antibody Titer Formation, Risk Factors for Non-Response, and Outcome after SARS-CoV-2 Omicron Breakthrough Infections in Patients on Chronic Hemodialysis: A Prospective Multicenter Cohort Study. The aim of this study is to determine the effect of repeated vaccinations on neutralizing SARS-CoV-2 IgG antibody titers, evaluate risk factors for immunological non-response, and to report breakthrough infections in chronic hemodialysis patients. METHODS: A prospective, multi-center cohort study in 163 chronic hemodialysis patients was conducted. Antibody titers were measured three months after second, third, and fourth (10 pts) booster vaccinations. SARS-CoV-2 neutralizing antibody titers in BAU/mL and % inhibition were divided into three categories (<216, 216-433, >433 and <33, 33-66, and >66%). Somers's test, paired t-test, and univariable and multivariable logistic regression analysis were applied to evaluate differences in antibody levels and search for risk factors for vaccination failure defined as neutralizing titers <50% and/or need for repeated booster vaccinations. Furthermore, we report on a case series to describe characteristics of patients after four vaccinations (n = 10) and breakthrough infections (n = 20). RESULTS: Third dose boosters resulted in higher proportions of patients with neutralizing antibody levels >66% as compared to after the second dose (64.7% after second dose vs. 88.9% after third dose, p = 0.003), as well as in a respective increase in neutralizing titer levels in % from 68 Â± 33% to 89 Â± 24 (p <0.001). The proportion of patients with IgG-titers below 216 BAU/mL decreased from 38.6 to 10.5% (p â‰¤ 0.001). Age (p = 0.004, OR 1.066, 95% CI 1.020-1.114) and presence of immunosuppressive medications (p = 0.002, OR 8.267, 95% CI 2.206-30.975) were identified as major risk factors for vaccination failure. Repeated booster vaccinations â‰¥4 times were effective in 8 out of 10 former low-responders (80%) without any side effects or safety concerns. Breakthrough infections showed a clinically mild course but were associated with prolonged viral shedding on PCR-testing ranging 7-29 (mean 13) days. CONCLUSIONS: Third and fourth mRNA-based booster vaccinations resulted in higher and longer lasting SARS-CoV-2 antibody levels as compared to after two dosages. The presence of immunosuppressive medication and repeat vaccinations are major potentially modifiable measures to increase antibody levels in non- or low-responders. Breakthrough infections with SARS-CoV-2 Omicron were associated with prolonged viral shedding but clinically mild disease courses.

Estimated Oxygen Consumption with the Abbreviated Method and Its Association with Vaccination and PCR Tests for COVID-19 from Socio-Demographic, Anthropometric, Lifestyle, and Morbidity Outcomes in Chilean Adults. COVID-19 causes cardiovascular and lung problems that can be aggravated by confinement, but the practice of physical activity (PA) could lessen these effects. The objective of this study was to evaluate the association of maximum oxygen consumption (VË™O2max) with vaccination and PCR tests in apparently healthy Chilean adults. An observational

and cross-sectional study was performed, in which 557 people from south-central Chile participated, who answered an online questionnaire on the control of COVID-19, demographic data, lifestyles, and diagnosis of non-communicable diseases. VË™O2max was estimated with an abbreviated method. With respect to the unvaccinated, those who received the first (OR:0.52 [CI:0.29;0.95], p = 0.019) and second vaccine (OR:0.33 [CI:0.18;0.59], p = 0.0001) were less likely to have an increased VË™O2max. The first vaccine was inversely associated with VË™O2max (mL/kg/min) (Î²:âˆ’1.68 [CI:âˆ’3.06; âˆ’0.3], p = 0.017), adjusted for BMI (Î²:âˆ’1.37 [CI:âˆ’2.71; âˆ’0.03], p = 0.044) and by demographic variables (Î²:âˆ’1.82 [CI:âˆ’3.18; âˆ’0.46], p = 0.009); similarly occur for the second vaccine (Î²: between âˆ’2.54 and âˆ’3.44, p < 0.001) on models with and without adjustment. Having taken a PCR test was not significantly associated with VË™O2max (mL/kg/min). It is concluded that vaccination significantly decreased VË™O2max, although it did not indicate cause and effect. There is little evidence of this interaction, although the results suggest an association, since VË™ O2max could prevent and attenuate the contagion symptoms and effects.

Study protocol: cohort event monitoring for safety signal detection after vaccination with COVID-19 vaccines in Iran. BACKGROUND: New vaccines that are initially approved in clinical trials are not completely free of risks. Systematic vaccine safety surveillance is required for ensuring safety of vaccines. This study aimed to provide a protocol for safety monitoring of COVID-19 vaccines, including Sputnik V, Sinopharm (BBIBP-CorV), COVIran Barekat, and AZD1222. METHODS: This is a prospective cohort study in accordance with a template provided by the World Health Organization. The target population includes citizens of seven cities in Iran who have received one of the available COVID-19 vaccines according to the national instruction on vaccination. The participants are followed for three months after they receive the second dose of the vaccine. For each type of vaccine, 30,000 people will be enrolled in the study of whom the first 1,000 participants are in the reactogenicity subgroup. The reactogenicity outcomes will be followed seven days after vaccination. Any hospitalization, COVID-19 disease, or other minor outcomes will be investigated in weekly follow-ups. The data are gathered through self-reporting of participants in a mobile application or phone calls to them. The study outcomes may be investigated for the third and fourth doses of vaccines. Other long-term outcomes may also be investigated after the expansion of the follow-up period. We have planned to complete data collection for the current objectives by the end 2022. DISCUSSION: The results of this study will be published in different articles. A live dashboard is also available for managers and policymakers. All data will be available on reasonable requests from the corresponding author.The use of the good and comprehensive guidelines provided by WHO, along with the accurate implementation of the protocol and continuous monitoring of the staff performance are the main strengths of this study which may be very useful for policymaking about COVID-19 vaccination.

Accelerated national lot release on COVID-19 vaccines in Republic of Korea. Independent quality testing of samples from vaccine lots is part of quality assurance, especially to ensure the consistency of production lot by lot. Effective national lot release system that ensures the quality of each lot of vaccine before it is on the market is important because vaccines are intended to healthy people. In order to respond more quickly to public health crises such as the COVID-19 pandemic, the MFDS implements accelerated national lot release for rapid vaccination in Republic of Korea. For the accelerated system, improvement has been made in terms of timing of application for lot release and required documents. In addition, the processing period has been shortened and sampling method and test items have been streamlined. A thorough preparation for accelerated lot release has been developed by establishing test methods for a new platform in advance. As a result, a total of 43.88 million doses have been released within eight days on average. The accelerated lot release system has contributed significantly to rapid COVID-19 vaccination in Korea.

Subacute thyroiditis after COVID-19 vaccination.

The interaction between anti-PF4 antibodies and anticoagulants in vaccine-induced thrombotic thrombocytopenia. Life-threatening thrombotic events at unusual sites have been reported after vector-based vaccinations against severe acute respiratory syndrome coronavirus 2. This phenomenon isÂ now termed vaccine-induced immune thrombotic thrombocytopenia (VITT). The pathophysiology of VITT is similar to that of heparin-induced thrombocytopenia (HIT) and is associated with platelet-activating antibodies (Abs) against platelet factor 4 (PF4). Therefore, current guidelines suggest nonheparin anticoagulants to treat VITT patients. In this study, we investigated the interactions of heparin, danaparoid, fondaparinux, and argatroban with VITT-Ab/PF4 complexes using an ex vivo model for thrombus formation as well as inÂ vitro assays to analyze Ab binding and platelet activation. We found that immunoglobulin Gs (IgGs) from VITT patients induce increased adherent platelets/thrombus formation in comparison with IgGs from healthy controls. In this ex vivo flow-based model, the procoagulant activity of VITT IgGs was effectively inhibited with danaparoid and argatroban but also by heparin. Interestingly, heparin and danaparoid not only inhibited IgG binding to PF4 but were also able to effectively dissociate the preformed PF4/IgG complexes. Fondaparinux reduced the inÂ vitro generation of procoagulant platelets and thrombus formation; however, it did not affect platelet aggregation. In contrast, argatroban showed no effect on procoagulant platelets and aggregation but significantly inhibited VITT-mediated thrombus formation. Taken together, our data indicate that negatively charged anticoagulants can disrupt VITT-Ab/PF4 interactions, which might serve as an approach to reduce Ab-mediated complications in VITT. Our results should be confirmed, however, in a clinical setting before a recommendation regarding the selection of anticoagulants in VITT patients could be made.

Sarcoidosis presenting as bilateral optic neuritis after ChAdOx1 nCoV-19 vaccination. Sarcoidosis is an idiopathic granulomatous disease and can virtually affect any organ system. Multiple factors, including tubercular antigens organic and environmental exposures, have been implicated in its pathogenesis. In addition to drugs, sarcoid-like reactions have been reported following varicella and influenza vaccination. Few reports of erythema nodosum and Lofgren syndrome have been reported after the COVID19 vaccination, though no histologic diagnosis was pursued in these cases. We herein report a case of sarcoidosis presenting with bilateral acute onset vision loss with a temporal association with COVID19 vaccination (ChadOx-1 n-COV, COVISHIELDTM). Symptoms started within two weeks of receiving the vaccine. Alternate causes for optic neuritis were excluded. Transbronchial lung biopsy showed the presence of non-caseating epithelioid cell granulomas. The patient received high-dose corticosteroids immediately after diagnosis, albeit with incomplete clinical improvement in vision on a three-month follow-up. In conclusion, we report a novel case of sarcoidosis-related optic neuritis following COVID19 vaccination.

A Multicenter Cohort Study on the Adverse Effects Evaluation After Messenger RNA COVID-19 Vaccination Among Pregnant Healthcare Employees in Penang General Hospitals.
INTRODUCTION: The year 2020 saw the emergence of novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which became a great threat to public health worldwide. The exponential spread of the disease with millions of lives lost worldwide saw the emergence of an accelerated vaccine development with emergency approval from well-known regulatory bodies such as the US Food and Drug Administration, followed by widespread vaccine deployment despite a paucity in safety profile data. This issue becomes even more pronounced when it involves expectant mothers considering the possible undesirable effect toward the unborn child. METHOD: This was a retrospective cohort study which was conducted at six general hospitals in the state of Penang, Malaysia. All the pregnant employees who have consented to take the mRNA COVID-19 vaccine and participate in this study were monitored from the time of their first vaccination and up to 28 days after they delivered their babies. RESULTS: All the participants had adequate maximum vertical

pocket (MVP) and no obvious anomalies or detection of intrauterine growth restriction (IUGR) were detected during the second trimester. However, one subject was reported to have miscarried during the second trimester. The reported mean neonate birth weight was 3.0 kg with the mean Apgar score of 8.8 and 9.8 at 1 and 5 min, respectively. Approximately seven (5.8%) neonates were reported to be small for their gestational age. Another three (2.5%) neonates were reported to have anomalies. CONCLUSION: As a whole, the inference that can be made from this study is that mRNA COVID-19 vaccine appears to be safe in pregnant women regardless of the trimester as the findings did not show obvious safety warning signs.

Hypertensive Anaphylaxis After Moderna COVID-19 Vaccination: A Case Report. Hypotension after exposure to an allergen is a well-known indicator of an anaphylactic reaction. However, hypertensive anaphylaxis often goes unrecognized. Increased blood pressure can present as an anaphylactic reaction, which is called hypertensive anaphylaxis. A 48-year-old woman complained of a tickle sensation in the throat and dyspnea 30 minutes after being administered the first dose of the Moderna coronavirus disease 2019 (COVID-19) vaccine. The patient had no history of hypertension, anxiety, or panic disorder. Forty-five minutes after the vaccination, stridor was noted, and the patient developed severe hypertension with a blood pressure of 197/153 mmHg. The patient also had tachycardia, cervical angioedema, and nausea, which occurred in a short period of time, indicating type I hypersensitivity reaction, that is, an anaphylactic reaction. The patient was diagnosed with Brighton classification Level 1 anaphylaxis caused by COVID-19 vaccination. For managing the patient, two intramuscular adrenaline injections, famotidine, chlorpheniramine, metoclopramide, and methylprednisolone were administered via intravenous infusion. After the administration of medications, all symptoms resolved, and the blood pressure was reduced. Other differential diagnoses for increased blood pressure after vaccination were excluded; therefore, we concluded that this phenomenon of increased blood pressure was hypertensive anaphylaxis. Not only hypotension but also the acute onset of increased blood pressure after vaccination may occur as a premonitory symptom of anaphylaxis. In hypertensive anaphylaxis, both anaphylaxis and increased blood pressure can be treated with intramuscular adrenaline injection. Clinicians should be aware of the occurrence of hypertensive anaphylaxis.

Dementia in a patient with autoimmune disease and hypercoagulable state worsened by COVID-19 vaccination: A case report. BACKGROUND: Systemic autoimmune disorders are associated with an increased risk of hypercoagulability. The hypercoagulable state in people with systemic autoimmune disorders has lately gained attention. PRESENTATION OF CASE: We presented a 44-year-old male with a chief complaint of progressive difficulty concentrating, memory impairment, and weakness in all limbs. Seven months before admission to our Memory Clinic, the patient began to have infrequent short-term memory loss and sometimes got lost when he went for a drive. Three months later, he complained of feeling dizzy when in a crowd, being unable to watch television for a long time, and easily forgetting. Computed tomography (CT) scan showed brain infarction. After receiving the first dose of COVID-19 vaccine (Sinovac), the patient had difficulty communicating verbally and could only point at objects, as well as tetraparesis. These conditions severely intervened in his daily activities. The patient was then referred to an immunologist and diagnosed with autoimmune disease. In our Memory Clinic, his performances of attention, memory, language, visuospatial, and executive function were very poor. We diagnosed him with autoimmune dementia. The administration of methylprednisolone, mycophenolate mofetil, vitamin D3, donepezil, and memantine could improve his condition. DISCUSSION: Autoimmune disease can cause microvascular thrombosis and microembolism at the central nervous system level, which would cause vascular damage and cognitive impairment leading to brain infarction and dementia. CONCLUSION: There

seems to be a link between autoimmune disease, hypercoagulable state, and dementia, although the magnitude of this link and the underlying processes are not fully understood.

A Rare Case of Myocarditis After the First Dose of Moderna Vaccine in a Patient With Two Previous COVID-19 Infections. Myocarditis is the inflammation of the cardiac muscle caused by a variety of factors ranging from infections to autoimmune diseases. Most cases of vaccine-induced myocarditis occur after the second dose of vaccination; however, a few cases have been reported following the first dose of vaccination with or without previous coronavirus disease 2019 (COVID-19) infection. A case of myocarditisÂ occurring about three weeks after the first dose of the Moderna vaccine has been reported in a patient with one previous COVID-19 infection. However, there have not been any documented cases of myocarditis after the first dose of the Moderna vaccine in a patient with two prior COVID-19 infections. Our index patient had already experienced two COVID-19 infections in the past and was diagnosed with myocarditis eight hours after receiving the first dose of the Moderna vaccine. The susceptibility to developing this likely stems from the possibleÂ production of antibodies to the viral antigen from previous COVID-19 infections. Furthermore, the fact that our patient developed symptoms eight hours after receiving the vaccine suggests a possible additive effect of antibodies produced from the two previous COVID-19 infections. This case report suggests that individuals repeatedly infected with COVID-19 may be at increased risk of myocarditis following the administration of the Moderna vaccine.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody lateral flow assay for antibody prevalence studies following vaccination: a diagnostic accuracy study. Background: Lateral flow immunoassays (LFIAs) are able to achieve affordable, large scale antibody testing and provide rapid results without the support of central laboratories. As part of the development of the REACT programme extensive evaluation of LFIA performance was undertaken with individuals following natural infection. Here we assess the performance of the selected LFIA to detect antibody responses in individuals who have received at least one dose of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. Methods: This was a prospective diagnostic accuracy study. Sampling was carried out at renal outpatient clinic and healthcare worker testing sites at Imperial College London NHS Trust. Two cohorts of patients were recruited; the first was a cohort of 108 renal transplant patients attending clinic following two doses of SARS-CoV-2 vaccine, the second cohort comprised 40 healthcare workers attending for first SARS-CoV-2 vaccination and subsequent follow up. During the participants visit, finger-prick blood samples were analysed on LFIA device, while paired venous sampling was sent for serological assessment of antibodies to the spike protein (anti-S) antibodies. Anti-S IgG was detected using the Abbott Architect SARS-CoV-2 IgG Quant II CMIA. A total of 186 paired samples were collected. The accuracy of Fortress LFIA in detecting IgG antibodies to SARS-CoV-2 compared to anti-spike protein detection on Abbott Assay Results: The LFIA had an estimated sensitivity of 92.0% (114/124; 95% confidence interval [CI] 85.7% to 96.1%) and specificity of 93.6% (58/62; 95% CI 84.3% to 98.2%) using the Abbott assay as reference standard (using the threshold for positivity of 7.10 BAU/ml) Conclusions: Fortress LFIA performs well in the detection of antibody responses for intended purpose of population level surveillance but does not meet criteria for individual testing.

Evaluation of hematological parameters and thrombocytopenia following Pfizer-BioNTech (BNT162b2) SARS-CoV-2 vaccination. OBJECTIVES: To evaluate hematological parameters and thrombotic profiles of healthy individuals who received Pfizer-BioNTech (BNT162b2) vaccines in Saudi Arabia. METHODS: Hematological parameters and the incidence of anti-platelet factor-4 (anti/PF-4) antibodies were evaluated in 40 participants who were eligible for COVID-19 vaccination in Saudi Arabia (above 18 years old) at Jazan University Hospital. These parameters were assessed at 2 different timepoints; at day 0 (the day of receiving the first dose of Pfizer- BioNTech (BNT162b2) and

prior to vaccination) and 14-21 days after receiving the vaccine. RESULTS: Among the participants, 38 (80%) were men, while 12 (20%) were women, with a mean age of 27 years. A total of 15% of the participants reported previous infection with SARS-CoV-2 and 3 patients had a history of diabetes mellitus and hypertension. Hematological parameters results in those vaccines showed no significant changes between the 2 timepoints, such as, day 0 (just before receiving vaccination) and 14 to 21 days post vaccination. Further, anti/PF4 antibodies were negative for all participants following vaccination. CONCLUSION: Our data showed that the incidence of hematological abnormalities or induction of anti/PF4 antibodies following Pfizer-BioNTech (BNT162b2) vaccination is not common, which is consistent with several previous reports. However, larger studies with more participants evaluated at different timepoints following vaccination are warranted to exclude potential transient hematological abnormalities.
Frequency and Outcomes of Ipsilateral Axillary Lymphadenopathy After COVID-19 Vaccination. This case series reports on the frequency and outcomes of breast imagingâ€“identified ipsilateral axillary lymphadenopathy after recent COVID-19 vaccination among women.
Post Coronavirus Disease 2019 Vaccine-associated Acute Myeloradiculoneuropathy Responsive to Plasmapheresis.
Physicians' Perception About the Side Effects of COVID-19 Vaccine and Their Role in Vaccination Program. INTRODUCTION: The Coronavirus disease 2019 (COVID-19) caused many problems in the health sector. Effective and safe vaccines are the only tool to combat the COVID-19 disease. Researchers and regulatory agencies have made efforts to develop such vaccines and healthcare professionals were prioritized for the vaccination program as first-line care providers. Considering this prioritization, we aimed to assess the physicians' perceptions regarding the side effects of the COVID-19 vaccine. METHODS: An interview-based study was conducted from May 5 May to November 5, 2021 (6 months) in a teaching hospital in the capital city of Islamabad, Pakistan. RESULTS: Among the 200 physicians who agreed to participate in the interview, 74% were male. A total of 94% did not experience any side effects after receiving the COVID-19 vaccine, regardless of the type of vaccine; 6% experienced side effects. Furthermore, 90% of physicians were afraid of side effects due to the high number of vaccine doses. CONCLUSION: Conclusively, physicians had a positive perception regarding the COVID-19 vaccine. Healthcare authorities and related departments must take precautions to ensure the effective and safe COVID-19 vaccine to change the perceptions of physicians who had a negative perception. This will not only reduce the reluctance among physicians regarding administering COVID-19 vaccine, but will also boost and facilitate the vaccination program for the general public as well.
Multiple sclerosis in the era of COVID-19: disease course, DMTs and SARS-CoV2 vaccinations. PURPOSE OF REVIEW: As of January 21st 2022, over 340 million are confirmed cases of coronavirus disease 2019 (COVID-19), including nearly 5.6 million deaths. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is neurotropic and affects the neural parenchyma through direct viral invasion from the nasal mucosa and postinfectious cytokine storm. Further challenges of SARS-CoV-2 infection are nowadays linked to variants of concern. Multiple sclerosis is an inflammatory and progressive degenerative disorder of the central nervous system commonly affecting young adults and potentially generating irreversible disability. Since the beginning of the SARS-CoV-2 pandemic, people with multiple sclerosis (pwMS) have been considered 'extra' vulnerable because of the immune-mediated nature of the disease, the disability status, and the immunomodulatory therapies potentially increasing the risk for viral infection. Today multiple sclerosis neurologists are faced with several challenges in the management of pwMS to both prevent SARS-CoV-2 infection and protection from disease worsening. We aimed to highlight today's most relevant facts about the complex management of pwMS in the COVID-19 era. RECENT FINDINGS: The incidence of COVID-19 among

pwMS does not differ from the general population. The prognosis of COVID-19 among pwMS is driven by older age, male sex, nonambulatory status, comorbidity as in the general population, as well as by corticosteroid treatment and B-cell depleting agents which decrease seropositivity from SARS-CoV-2 infection and immune responses to SARS-CoV-2 vaccination. SUMMARY: Disease modifying treatments (DMTs) should be regularly continued in relation to SARS-CoV-2 vaccination, but an ad hoc timing is required with B-cell depleting agents. SARS-CoV-2 vaccination is recommended in pwMS with willingness improving through health education programs. Multiple sclerosis does not seem to worsen after SARS-Cov2 vaccination but COVID-19 may enhance disease activity.
[2022 Update on myocarditis and pericarditis following COVID-19 vaccination. Expert Opinion of the Italian Society of Cardiology]. Vaccine-associated myocarditis and pericarditis usually develop within 14 days of COVID-19 vaccination, are exceptionally rare, manifest with mild clinical pictures and are commonly characterized by a favorable evolution. Young men inoculated with two doses of an mRNA vaccine are the subgroup at higher risk. Recent epidemiological studies evaluated the incidence and risk of vaccine-associated myocarditis and pericarditis among men and women, in different ranges of age and specific types of vaccines. Long-term population analyses demonstrated that the cardiovascular risk conferred by COVID-19 extends beyond the acute phase, representing the rationale for implementing prevention strategies for SARS-CoV-2 infection, monitoring specific populations at higher risk and pursuing the completion of the vaccination campaign. This document provides an update on the most recent scientific evidence and critical interpretation of available data in constant evolution towards personalized strategies of immunization.
Misconceptions Related to COVID 19 Vaccines Among the Jordanian Population: Myth and Public Health. OBJECTIVE: This study assesses misconceptions about coronavirus disease 2019 (COVID-19) vaccine and the factors associated with misconception among Jordanians. METHODS: A cross-sectional online survey was conducted. The survey was formulated on Google Forms, and was hosted on an online platform. These questions were created based on extensive review of online information about the vaccines. Frequencies and percentages (%) were used for categorical variables, while means and standard deviations (SDs) were used for continuous variables. Stepwise binary logistic regression was conducted to evaluate variables associated with participant's misconception questions. RESULTS: Of 1195 survey respondents who participated in the study, 41.3% had received the COVID-19 vaccine. The mean misconception score was (60.0 Â± 19.1). The statement with the highest mean was "The vaccine hasn't been tested on enough people" (3.6 Â± 1.0). The statement with the lowest mean was "The COVID-19 vaccine includes a microchip to control us" (2.2 Â± 1.1) in the conspiracy theory portion. Females, 18- to 29-age group, higher educational level, living in a city, the participants who took lectures about the COVID-19 vaccine and vaccinated participants had higher odds of being in the low misconception level group. CONCLUSION: Targeted campaigns and vaccine safety information should be part of a broader health education campaign to alleviate vaccination safety concerns.
Acute Myocardial Infarction within 5 Days after COVID-19 Vaccination: Three Case Reports from a Regional Tertiary Center.
Acute ST-Segment Elevation Myocardial Infarction Happened Within 2 Hours after First Dose of COVID-19 Vaccine.
Vaccine Rollout and Shift in Public Sentiment: Twitter-Based Surveillance Study. This study aims to find out the variation of Twitter users' sentiment before and after the COVID-19 vaccine rollout. We analyzed all COVID-19 related tweets posted on Twitter within two timeframes: September 2020 (T1) and March 2021 (T2). A total of 3 million tweets from over 132 thousand users were analyzed. We then categorized the users into two groups whose overall sentiment shifted positively or negatively from T1 to T2. Our analysis showed that 27% of users' sentiment shifted from T1 to T2

positively and the users were more confident about vaccine safety and efficacy. Users reported positive sentiments about travelling and the easing of lockdown measures. Also, 20.4% of the users' sentiment shifted negatively from T1 to T2. This group of Twitter users were more concerned about the adverse side effects of the vaccine, the pace of vaccine development as well as the emerging novel coronavirus variants. Interestingly, over half of the users' overall sentiment remained the same in both periods of T1 and T2, indicating indifference about vaccine rollout. We believe that our analysis will support the exploration of public reaction to COVID-19 vaccine rollout and assess policy makers' decision to combat the pandemic.

Inactivated COVID-19 vaccine induced acute stroke-like focal neurologic symptoms: a case series. BACKGROUND: A subgroup of individuals experienced stroke-like symptoms after receiving an inactivated COVID-19 vaccine. We present clinical characteristics, neuroimaging, and outcome of these patients. METHODS: Medical personals who had neurological symptoms after receiving inactivated COVID-19 vaccine were enrolled. Clinical, laboratory investigation and neuroimaging were collected. Subjects were prospectively followed-up on clinical and neuroimaging to detect brain parenchymal or cerebrovascular abnormality. RESULTS: Nineteen out of 385 subjects (4.9%) developed neurological symptoms after vaccination. There was a female predominance (89.5%) with mean age of 34â€‰Â±â€‰7.5Â years. Majority of patients (52.6%) had symptoms within 60Â min after vaccination. The most common neurological symptoms were numbness (94.7%) followed by headache (52.6%) and weakness (47.4%). The most common neurological signs were sensory deficit (79%) followed by motor weakness (52.6%) and tongue deviation (26.3%). Recurrent headache was observed in most patients (89.5%) during followed up. Serial brain imaging was done in all patients with median follow-up interval of 18Â days. There was no evidence of acute brain infarction in any of the patients, 84.2% had no vascular abnormality, 15.8% had transient focal narrowing of cerebral vessels. Outcome was favorable, modified ranking scale 0-1 for all patients at 4Â weeks after vaccination. CONCLUSIONS: Transient focal neurological symptoms and deficits can be found after COVID-19 vaccination. However, benefit to stop COVID-19 pandemic by vaccination is outweighed by these seemingly reversible side effects. The pathophysiology underlined these phenomena should be further investigated.

Household and social characteristics associated with COVID-19 vaccine intent among Latino families in the San Francisco Bay Area. BACKGROUND: Latinos have had higher case counts, hospitalization rates and deaths during the COVID-19 pandemic nationally and in the state of California. Meanwhile, Latino vaccination rates remain lower than those of non-Hispanic Whites. COVID-19 vaccine nonintent, defined as intent to not vaccinate against COVID-19, among Latino individuals continues to be an issue in the state of California. METHODS: Families from three Latino longitudinal mother-child cohorts previously recruited in the San Francisco Bay Area were surveyed telephonically from February to June 2021 to assess attitudes towards vaccination against COVID-19 and prior vaccination, in general, for themselves and their children. Risk for vaccine nonintent was assessed using the Mann-Whitney rank sum non-parametric test for continuous predictors and chi-squared tests for categorical ones. RESULTS: Three hundred and nineteen families were surveyed from the Telomere at Birth (TAB), Hispanic Eating and Nutrition (HEN) and Latino Eating and Diabetes Cohort (LEAD). Approximately 36% from TAB and 28% from HEN/LEAD indicated COVID-19 vaccine nonintent for themselves and/or their children. Risk factors for vaccine nonintent included lower maternal age (pâ€‰=â€‰0.01), concern about vaccine side effects (pâ€‰<â€‰0.01) and prior history of a household members being infected with SARS-CoV-2 (pâ€‰<â€‰0.01)Â and indexes of household crowding including number of people sharing a bathroom (pâ€‰=â€‰0.048). Vaccine intent was also associated with receiving vaccine input from friends (pâ€‰=â€‰0.03), family (pâ€‰<â€‰0.01) and/or coworkers (pâ€‰=â€‰0.02) compared with those who were not planning

on getting vaccinated against COVID-19. CONCLUSIONS: Latino families living in crowded living situations who may not have received any COVID-19 advice fromÂ family, coworkers or friends are at particular risk for nonintent for vaccinatation against COVID-19. Community-based grassroots or promotor/a based interventions centered on trusted individuals with close community ties and counseling concerning vaccination against COVID-19 could help boost vaccination rates in this population group.
Vestibular neuronitis after COVID-19 vaccination. A woman in her 50s presented with acute vertigo and vomiting within 72 hours of receiving the Pfizer-BioNTech COVID-19 vaccine. The only neurological deficit was an impaired vestibulo-ocular reflex with horizontal nystagmus. The patient was subsequently diagnosed with vestibular neuronitis. She was managed symptomatically with prochlorperazine and betahistine, and underwent vestibular rehabilitation for 6 weeks. She made a full recovery and experienced no further symptoms. She received the second dose of the vaccine without complications.This case demonstrates a temporal association between COVID-19 vaccination and vestibular neuronitis. Neurological adverse events are rare but recognised side effects of COVID-19 vaccines and healthcare professionals should be aware of them. This ensures timely management of patients with such presentations. Treatment should be the same as for non-vaccine-associated vestibular neuronitis. The nature of the relationship between COVID-19 vaccination and vestibular neuronitis remains unclear and patients therefore require investigations to exclude other recognised causes of vestibular neuronitis.
Understanding factors associated with intent to receive the COVID-19 vaccine. INTRODUCTION: As of December 1, 2020, when the Advisory Committee on Immunization Practices published their COVID-19 vaccine distribution and prioritization recommendations, health care workers (HCWs) and the elderly were deemed to be at greatest risk of contracting the coronavirus. Limited extant research suggests that most HCWs are willing to receive the COVID-19 vaccine, and findings from studies examining vaccine uptake in non-HCW samples also have reported high vaccination willingness. The health belief model (HBM) and the theory of planned behavior (TPB) suggest that beliefs about severity and susceptibility of disease, perceived benefits of and obstacles to vaccination, and normative beliefs of others affect vaccine uptake. Further, perceptions of safety, side effects, and demographic factors can uniquely impact COVID-19 vaccine uptake. METHOD: Using a cross-sectional design, we recruited 526 participants via social media, through snowball emailing methods, and from university settings. RESULTS: The present findings demonstrate that 37% of participants intend to get the vaccine, and 35% reported that they might get the vaccine. No relationships among demographic factors, willingness to receive the vaccine, and level of intent were observed. However, those who reported that they would not receive the COVID-19 vaccine demonstrated fewer positive attitudes, less agreement, fewer normative views, and less anticipatory regret regarding the COVID-19 vaccine. Also, perceptions of susceptibility, severity, and barriers were associated with participants' willingness to get the COVID-19 vaccine. DISCUSSION: Our results suggest that factors related to the HBM and TPB might uniquely impact COVID-19 vaccine acceptability and could guide the crafting of interventions meant to encourage vaccine uptake. (PsycInfo Database Record (c) 2022 APA, all rights reserved).
Acute myopericarditis after administration of mRNA vaccines against the SARS-CoV-2 virus.
Symptomatic SARS-CoV-2 breakthrough with delta variant after 3rd mRNA vaccine shot (booster).
Antibody titers against SARS-CoV-2 spike protein 6 months after a third BNT162b2 vaccine in chronic hemodialysis patients.
Morbilliform Eruption After Administration of Second Dose of Oxford/AstraZeneca Vaccine. Morbilliform eruption typically implies a maculopapular rash of acute onset. Drugs are the predominant cause of this cutaneous reaction in adults, followed by infectious exanthems and some

rheumatological diseases. In this article, we report on the clinical and histopathological features of generalized pruritic morbilliform eruption in a 28-year-old female following her second dose of Oxford/AstraZeneca COVID-19 vaccine. The reaction started 12 hours after receiving the vaccine with no other identifiable cause. The patient had no improvement with IV antihistamine received in the emergency department. Afterward, she showed marked improvement after receiving a short course of oral corticosteroids along with topical corticosteroid and oral antihistamine. To the best of our knowledge, we hypothesize that the basic immunological mechanism is the cause behind COVID-19-vaccine-related morbilliform eruption. Therefore, physicians should be aware of the possible adverse reactions associated with COVID-19 vaccines, such as morbilliform eruptions and other cutaneous manifestations.

COVID-19 Vaccine Cardiac Complications: A Case Series on Implications of Marijuana in Adolescents With Myopericarditis. We report on two critically ill pediatric patients, aged 16Â and 18 years, presenting with acute myopericarditis at a tertiary-care center in New Jersey, United States. Both patients had their severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccinations, tested negative for SARS-CoV-2, and shared only significant history of asthma. Clinical presentations were similarÂ toÂ acute onset chest pain that worsened with deep inspiration. One patient reported a history of vaping and escalating marijuana use several hours preceding presentation. Both patients had elevated troponin on admission and had ST-segment elevation on electrocardiogram (EKG), thus prompting admission to the pediatric intensive care unit (PICU) for cardiac monitoring. Myopericarditis has multiple etiologies and is a newly described rare complication of the SARS-CoV-2 vaccine. It can also occur as a complication of vaping and frequent marijuana drug use. Our paper highlights the importance of a detailed social and drug history in adolescents presenting with chest pain. The clinical characterization is necessaryÂ to promote better case definitions and the design of targeted interventions for this vulnerable group.

COVID-19 mRNA Vaccine Induced Pericarditis With Large Pericardial Effusion Followed by New-Onset Arrhythmia. Several cases of myocarditis and pericarditis have been reported after mRNA COVID-19 vaccination. Interestingly, most cases were seen in male adolescents and young adults, commonly after 3-4 days of the second dose of mRNA vaccine. The vaccine contains the viral spike glycoprotein in the nucleoside-modified mRNA of the coronavirus that activates the proinflammatory cascades and immunological pathways, which can cause myocarditis and pericarditis. Here we report a case of a middle-aged Caucasian male who presented with progressive dyspnea, fever, and chills seven days after the second dose of the COVID-19 vaccine. He was found to have pericarditis with massive hemorrhagic pericardial effusion, large bilateral pleural effusions, circulatory shock, and cardiac arrhythmia. The patient required pericardiocentesis and thoracentesis and was discharged home on antiarrhythmic and anti-inflammatory therapy. Our case report describes a correlation between mRNA COVID-19 vaccine and pericarditis, suggesting the importance of pharmacovigilance and reporting of adverse outcomes and encourages a high index of clinical suspicion in physicians to facilitate early diagnosis and interventions.

Acceptance of COVID-19 vaccine and associated factors among pregnant women.

Bell's palsy as a possible complication of mRNA-1273 (Moderna) vaccine against COVID-19. INTRODUCTION: Vero Cell, AstraZeneca, Janssen, mRNA-1273 (Moderna), and Pfizer COVID-19 vaccines have been authorized for emergency use in Nepal. These vacines have been linked to some adverse effects, including fever, myalgia, and headache. Furthermore Bell's Palsy a rare adverse effect was also reported to be associated with the use of mRNA-1273 (Moderna) vaccine in some patients. CASE PRESENTATION: In this case report we present a 17-year-old female who acquired Bell's Palsy following the administration of mRNA-1273 (Moderna) COVID-19 vaccination. DISCUSSION: The possible etiology of BP that has been suggested is infection by reactivated viruses, such as the

varicella-zoster virus (VZV), herpes simplex virus type 1 (HSV-1), human herpesvirus 6, and the Usutu virus, [1] the most accepted hypothesis is the one with reactivation of latent Herpes Simplex Virus type 1 in the geniculate ganglia of the facial nerves, an autoimmune mechanism through the mimicry of host molecules by the antigens of the vaccines. CONCLUSION: Though the extent of association between the mRNA vaccination and the development of Bell's Palsy has yet to be confirmed, this example highlights the need to closely monitor side effects and repercussions after receiving a new vaccine.
Severe relapsed autoimmune hemolytic anemia after booster with mRNA-1273 COVID-19 vaccine.
Sputnik-V vaccine-induced panniculitis as a local reactions. Here, a case of Sputnik-V vaccine-induced panniculitis was reported. The patient developed erythema, induration, and local tenderness at the injection site after 13Â days of the injection. Ultra-sonography imaging showed inflammation in subcutaneous layers including fat tissue compatible with panniculitis. She received ibuprofen and warm compress, and all symptoms resolved.
Potent cross-reactive antibodies following Omicron breakthrough in vaccinees. Highly transmissible Omicron variants of SARS-CoV-2 currently dominate globally. Here, we compare neutralization of Omicron BA.1, BA.1.1, and BA.2. BA.2 RBD has slightly higher ACE2 affinity than BA.1 and slightly reduced neutralization by vaccine serum, possibly associated with its increased transmissibility. Neutralization differences between sub-lineages for mAbs (including therapeutics) mostly arise from variation in residues bordering the ACE2 binding site; however, more distant mutations S371F (BA.2) and R346K (BA.1.1) markedly reduce neutralization by therapeutic antibody Vir-S309. In-depth structure-and-function analyses of 27 potent RBD-binding mAbs isolated from vaccinated volunteers following breakthrough Omicron-BA.1 infection reveals that they are focused in two main clusters within the RBD, with potent right-shoulder antibodies showing increased prevalence. Selection and somatic maturation have optimized antibody potency in less-mutated epitopes and recovered potency in highly mutated epitopes. All 27 mAbs potently neutralize early pandemic strains, and many show broad reactivity with variants of concern.
The Possibility of Hypersensitivity Myocarditis following COVID-19 Vaccines: Implications for Contrast Echocardiography.
Global reports of myocarditis following COVID-19 vaccination: A systematic review and meta-analysis. BACKGROUND AND AIMS: Recent media reports of myocarditis after receiving COVID-19 vaccines, particularly the messenger RNA (mRNA) vaccines, are causing public concern. This review summarizes information from published case series and case reports, emphasizing patient and disease characteristics, investigation, and clinical outcomes, to provide a comprehensive picture of the condition. METHODS: A systematic literature search of PubMed and Google scholar was conducted from inception to April 27, 2022. Individuals who develop myocarditis after receiving the COVID-19 vaccine, regardless of the type of vaccine and dose, were included in the study. RESULTS: Sixty-two studies, including 218 cases, participated in the current systematic review. The median age was 29.2 years; 92.2% were male and 7.8% were female. 72.4% of patients received the Pfizer-BioNTech (BNT162b2) vaccine, 23.8% of patients received the Moderna COVID-19 Vaccine (mRNA-1273), and the rest of the 3.5% received other types of COVID-19 vaccine. Furthermore, most myocarditis cases (82.1%) occurred after the second vaccine dose, after a median time interval of 3.5 days. The most frequently reported symptoms were chest pain, myalgia/body aches and fever. Troponin levels were consistently elevated in 98.6% of patients. The admission ECG was abnormal in 88.5% of cases, and the left LVEF was lower than 50% in 21.5% of cases. Most patients (92.6%) resolved symptoms and recovered, and only three patients died. CONCLUSION: These findings may help public health policy to consider myocarditis in the context of the benefits of COVID-19 vaccination.

[Vaccination in Workplace and Compensation for Adverse Events]. Several types of SARS-Cov-2 vaccine have been quickly developed and officially approved for emergency use in accordance with the Pharmaceutical Act. Mass vaccination in workplaces in Japan was subsequently promoted, targeting health care workers and senior citizens. We overviewed the pathophysiology of COVID-19 and reviewed reports containing fatal outcomes, compensation programs, and remedial measures for health damage after vaccinations, in relation to their relevant legislations. The Immunization Act was amended prior to the mass vaccination to authorize the indemnity agreement between the government and pharmaceutical companies to compensate for losses based on health damages after vaccination. Pursuant to the Civil Code and the State Redress Act, employers reserve the right to obtain reimbursement when they are liable to pay compensation for damages inflicted on a third party. There are no provisions to exclude healthcare workers and occupational health staff who participated in practical procedures from lawsuits and liability. We propose legislative reformation and careful contracts with responsible organizations concerned with emergency vaccinations in order to confront forthcoming new or re-emerging infections beyond this pandemic.

Hypertension is associated with antibody response and breakthrough infection in health care workers following vaccination with inactivated SARS-CoV-2. Several types of vaccines have been developed to prevent the coronavirus disease 2019 (COVID-19). It is important to understand whether demographic and clinical variables affect the effectiveness of various types of vaccines. This study analysed the association between demographic/clinical factors, antibody response and vaccine effectiveness in healthcare workers vaccinated with inactivated virus. We enrolled 101 healthcare workers who received two doses of inactivated viral vaccine (CoronaVac). Blood samples were analysed at 1, 3, and 5Â months after the second dose of vaccination. Data regarding demographic characteristics, medical histories, and clinical parameters were collected by interview and medical examination. In a separate retrospective study, we analysed the incidence of vaccine breakthrough infection on 2714 healthcare workers who received two doses of inactivated viral vaccine. Medical histories and demographic data were collected using a structured self-reported questionnaire. We found that antibody titres markedly increased at 1Â month after vaccination but gradually decreased at 3-5Â months post-vaccination. We observed a significant association between age (â‰¥40Â years) and antibody level, whereas sex and body mass index (BMI) exhibited no effect on antibody titres. Amongst clinical variables analysed, high blood pressure and history of hypertension were significantly correlated with lower antibody titres. Consistently, we found a significant association in the retrospective study between hypertension and the incidence of breakthrough infection. In conclusion, our results showed that hypertension is associated with lower antibody titres and breakthrough infection following COVID-19 vaccination. Thus, blood pressure control might be important to improve the efficacy of inactivated virus vaccine.

Adverse effects of COVID-19 vaccines and measures to prevent them. Recently, The Lancet published a study on the effectiveness of COVID-19 vaccines and the waning of immunity with time. The study showed that immune function among vaccinated individuals 8Â months after the administration of two doses of COVID-19 vaccine was lower than that among the unvaccinated individuals. According to European Medicines Agency recommendations, frequent COVID-19 booster shots could adversely affect the immune response and may not be feasible. The decrease in immunity can be caused by several factors such as N1-methylpseudouridine, the spike protein, lipid nanoparticles, antibody-dependent enhancement, and the original antigenic stimulus. These clinical alterations may explain the association reported between COVID-19 vaccination and shingles. As a safety measure, further booster vaccinations should be discontinued. In addition, the date of vaccination should be recorded in the medical record of patients. Several practical measures to prevent a decrease in immunity have been reported. These include limiting the use of non-steroidal

anti-inflammatory drugs, including acetaminophen to maintain deep body temperature, appropriate use of antibiotics, smoking cessation, stress control, and limiting the use of lipid emulsions, including propofol, which may cause perioperative immunosuppression. In conclusion, COVID-19 vaccination is a major risk factor for infections in critically ill patients.

Reactivation of a BCG Vaccination Scar Following the First Dose of the Moderna COVID-19 Vaccine. The devastating effects of the COVID-19 pandemic have prompted rapid development and distribution of multiple vaccines. A 2-dose messenger RNA (mRNA) vaccine developed by Moderna (Moderna COVID-19 Vaccine) was approved in December 2020 for the prevention of COVID-19. We describe a case of BCG vaccination scar reactivation in a 48-year-old man after he received the first dose of the Moderna COVID-19 Vaccine.

[Research progress on physiological changes caused by wearing N95 mask in patients with chronic obstruction pulmonary disease]. N95 mask has been shown to reduce lower airway infections requiring hospitalization, mortality and exacerbation frequency in patients with chronic obstructive pulmonary disease(COPD), and therefore is recommended for all COPD patients by guidelines. However, the coverage of influenza vaccination in Chinese COPD patients is far from satisfactory. The large-scale COVID-19 vaccination may have a positive impact on the attitude towards influenza vaccines, and healthcare professionals should take active measures to improve the physical activation in patients with COPD.

Adamalysins in COVID-19 - Potential mechanisms behind exacerbating the disease. The coronavirus disease 2019 (COVID-19), caused by the SARS-CoV-2 virus, is a current pandemic that has resulted in nearly 250 million cases and over 5 million deaths. While vaccines have been developed to prevent infection, and most COVID-19 cases end up being fairly light, there are severe cases of COVID-19 that may end up in death, even with adequate healthcare treatment. New options to combat this disease's effects, therefore, could prove to be invaluable in saving lives. Adamalysins are proteins that have several roles in regulating different functions in the human body but are also known to have functions in inflammation. They are also known to have roles in several different diseases, including COVID-19, where ADAM17, in particular, is now well-known to have a prominent role, but also several diseases which include comorbidities that may worsen cases of COVID-19. Therefore, investigating the functions of adamalysins in disease may give us clues to the molecular workings of COVID-19 as well as potentially new therapeutic targets. Understanding these molecular mechanisms may also allow for an understanding of the mechanisms behind the rare severe side effects that occur in response to current COVID-19 vaccines, which may lead to better monitoring measures for people who may be more at risk of developing these side effects. This review investigates the known roles and functions of adamalysins in disease, including what is currently known of their involvement in COVID-19, and how these functions might be involved.

[Newly diagnosed melanoma diagnosed on the basis of cutaneous side effects from COVID-19 vaccine]. While the Danish Health Authority has withdrawn the vaxzevria vaccine from the Danish vaccination programme due to reports of rare cases of severe side effects, this case report presents a potential beneficial side effect of this vaccine. A patient presented, three days after her first jab, with localized itching and bleeding from a pigmented tumour on her lower leg, which was therefore excised, and, unexpectedly, diagnosed as a melanoma. We speculate if the vaccine-induced immune reaction resulted in increased immune activity within the tumour environment, and thus facilitated the early diagnosis of melanoma.

Rapidly Progressive Dementia with Asymmetric Rigidity Following ChAdOx1 nCoV-19 Vaccination.

A case of myocarditis after COVID-19 vaccination: incidental or consequential? Vaccination represents one of the fundamentals in the fight against SARS-CoV-2. Myocarditis has been reported as a rare but possible adverse consequence of different vaccines, and its clinical presentation can

range from mild symptoms to acute heart failure. We report a case of a 29-year-old man who presented with fever and retrosternal pain after receiving SARS-CoV-2 vaccine. Cardiac magnetic resonance imaging and laboratory data revealed typical findings of acute myocarditis.

Immune-Mediated Thrombotic Thrombocytopenic Purpura Following mRNA-Based COVID-19 Vaccine BNT162b2: Case Report and Mini-Review of the Literature. INTRODUCTION: An increasing number of case reports have associated vaccinations against coronavirus disease 2019 (COVID-19) with immune-mediated thrombotic thrombocytopenic purpura (iTTP), a very rare but potentially life-threatening thrombotic microangiopathy, which leads to ischemic organ dysfunction. Thrombus formation in iTTP is related to a severe deficiency of the specific von Willebrand-factor-cleaving protease ADAMTS13 due to ADAMTS13 autoantibodies. METHODS: We present a case of iTTP following exposure to the mRNA-based COVID-19 vaccine BNT162b2 (Comirnaty(Â®), Pfizer-BioNTech). In addition, we review previously reported cases in the literature and assess current evidence. RESULTS: Apart from our case, twenty cases of iTTP occurring after COVID-19 vaccination had been published until the end of November 2021. There were 11 male and 10 female cases; their median age at diagnosis was 50 years (range 14-84 years). Five patients (24%) had a preexisting history of iTTP. Recombinant adenoviral vector-based vaccines were involved in 19%, mRNA-based vaccines in 81%. The median onset of symptoms after vaccination was 12 days (range 5-37), with 20 cases presenting within 30 days. Treatment included therapeutic plasma exchange in all patients. Additional rituximab, caplacizumab, or both these treatments were given in 43% (9/21), 14% (3/21), and 24% (5/21) of cases, respectively. One patient died, despite a prolonged clinical course in one patient, all surviving patients were in clinical remission at the end of the observational period. CONCLUSION: Clinical features of iTTP following COVID-19 vaccination were in line with those of pre-pandemic iTTP. When timely initiated, an excellent response to standard treatment was seen in all cases. ADAMTS13 activity should be determined pre-vaccination in patients with a history of a previous iTTP episode. None of the reported cases met the WHO criteria for assessing an adverse event following immunization (AEFI) as a consistent causal association to immunization. Further surveillance of safety data and additional case-based assessment are needed.

Allergic Reactions After the Administration of COVID-19 Vaccines. BACKGROUND: Data on allergic reactions after the administration of coronavirus disease (COVID-19) vaccines are limited. Our aim is to analyze reports of allergic reactions after COVID-19 vaccine administration. METHODS: The Vaccine Adverse Event Reporting System database was searched for reported allergic reactions after the administration of any of the COVID-19 vaccines from December 2020 to June 2021. After data mapping, the demographic and clinical characteristics of the reported cases were analyzed. Potential factors associated with anaphylaxis were evaluated using multivariable logistic regression models. RESULTS: In total, 14,611 cases were reported. Most cases of allergic reactions comprised women (84.6%) and occurred after the first dose of the vaccine (63.6%). Patients who experienced anaphylaxis were younger (mean age 45.11 Â± 5.6 vs. 47.01 Â± 6.3 years, $P < 0.001$) and had a higher prevalence of a history of allergies, allergic rhinitis, asthma, and anaphylaxis than those who did not ($P < 0.05$). A history of allergies (odds ratio (OR) 1.632, 95% confidence interval (CI) 1.467-1.816, $P < 0.001$), asthma (OR 1.908, 95%CI 1.677-2.172, $P < 0.001$), and anaphylaxis (OR 7.164, 95%CI 3.504-14.646, $P < 0.001$) were potential risk factors for anaphylaxis. Among the 8,232 patients with reported outcomes, 16 died. CONCLUSIONS: Female predominance in allergic reaction cases after the receipt of COVID-19 vaccines was observed. Previous histories of allergies, asthma, or anaphylaxis were risk factors for anaphylaxis post-vaccination. People with these risk factors should be monitored more strictly after COVID-19 vaccination.

Acute cardiac side effects after COVID-19 mRNA vaccination: a case series. BACKGROUND: Vaccination against SARS-CoV-2 has been the main tool to contain the pandemic. The rush

development of the 3 vaccines and their expedited approval have led to inoculation of millions of patients around the world, leading to a containment of the disease. Despite continuous viral mutations and the identification of weaker variants, the severity of the infections has been mild, with many patients being either asymptomatic or recovering at home. Currently the focus has shifted from the host of organ damage related to the infection to potential side effects of the vaccine. Myocarditis has been reported as one of the potential side effects from the mRNA vaccine, affecting young healthy individuals. Up to September 30, 2021, 1.243 cases of myocarditis after vaccination with BNT162b2 ComirnatyÂ© were registered in young adults by the Paul-Ehrlich-Institute in Germany alone. The exact pathophysiology and the risk factors for myocarditis following vaccination remain unclear. We present a case series of eight patients with cardiac symptom shortly after SARS-CoV-2 mRNA vaccination (BNT162b6, Biontech, ComirnatyÂ© or mRNA-1237 Moderna, SpikevaxÂ©). PATIENTS AND METHODS: Eight patients between 13 and 56Â years of age, vaccinated with either BNT162b2 or mRNA-1273 mRNA vaccine between January and August 2021 developed cardiac side effects shortly after either their first or second dose of the vaccine. Clinical data were retrieved from the clinical information system and analyzed. To support diagnosis of myocarditis or pericarditis, cardiac magnetic resonance imaging (MRI) was performed shortly after the onset of symptoms, with further investigations in severe cases. Symptoms were defined as dyspnea, chest pain and cardiac arrhythmia as determined by electrocardiography. RESULTS: Eight patients (5 males and 3 females) developed cardiac symptoms compatible with myocarditis, according to the CDC criteria, shortly after SARS-CoV-2 mRNA vaccination. Three patients (2 males, 1 female) required hospitalization due to severe chest pain and elevated troponin levels. All patients recovered fully within 7Â days from the symptom onset. CONCLUSIONS: Our data suggest that cardiac adverse events such as myocarditis or pericarditis shortly after SARS-CoV-2 mRNA vaccination are rare but possible and occur particularly in male patients.

Post-vaccination outcomes in association with four COVID-19 vaccines in the Kingdom of Bahrain. With the emergence of new SARS-Cov2 variants, critical questions have arisen about: (1) the effectiveness of the available COVID-19 vaccines developed to protect against the original Wuhan (wild type) variant and (2) the magnitude and clinical consequences of post-vaccination infections in the context of the Delta variant of SARS-Cov2. While some "real world" experiences with various vaccines have been reported, to our knowledge, few have examined comparative outcomes of various vaccines in one country as new SARS-CoV-2 variants have emerged. Here we present an analysis of COVID-19 related outcomes from a national database in Bahrain, a country with a total population of 1.51 million, where four vaccines were deployed (total vaccinatedâ€‰=â€‰1,003,960 adults): AstraZeneca (AZ/Covishield), Pfizer/BioNtech, Sinopharm and Sputnik V. We compare the four vaccines, based on the following post-vaccination outcomes: SARS-CoV-2 infections, hospitalisations, ICU admissions and deaths, compared to unvaccinated individuals. We conclude that the four vaccines used in Bahrain were effective in significantly reducing all four COVID-19 related outcomes compared to unvaccinated individuals, prior to, and during the period when the Delta variant predominated in the country. However, compared to the three other vaccines, individuals vaccinated with Sinopharm vaccine had a higher risk of post-vaccination infections, hospitalisations and ICU admissions (e.g., 6.94%, 2.24%, 1.99% and 1.52% of COVID-19 cases of Sinopharm, Sputnik V, Pfizer and Covishield recipients, respectively, required hospitalisation versus 13.66% of COVID-19 cases among unvaccinated individuals); however, given the confounding factors, this needs to be confirmed by further studies. We find no evidence of biased selection for any vaccine, but note waning protection of the Pfizer/BioNtech vaccine during the January to June 2021 period in the ageâ€‰>â€‰60 y cohort; however, this cannot be distinguished from the overall fall in hospitalisations overall. Our findings support the value of vaccination in preventing COVID-19 related

outcomes, provide real world estimates on the outcomes and frequencies of post-vaccination infections for the four vaccines, which may inform vaccine selection in the context of the Delta variant across the globe.

Broad neutralization against SARS-CoV-2 variants induced by ancestral and B.1.351 AS03-Adjuvanted recombinant Plant-Derived Virus-Like particle vaccines. Since 2019, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection resulting in the coronavirus disease 2019 (COVID-19) has afflicted hundreds of millions of people in a worldwide pandemic. Several safe and effective COVID-19 vaccines are now available. However, the rapid emergence of variants and risk of viral escape from vaccine-induced immunity emphasize the need to develop broadly protective vaccines. A recombinant plant-derived virus-like particle vaccine for the ancestral COVID-19 (CoVLP) recently authorized by Canadian Health Authorities and a modified CoVLP.B1351 targeting the B.1.351 variant (both formulated with the adjuvant AS03) were assessed in homologous and heterologous prime-boost regimen in mice. Both strategies induced strong and broadly cross-reactive neutralizing antibody (NAb) responses against several Variants of Concern (VOCs), including B.1.351/Beta, B.1.1.7/Alpha, P.1/Gamma, B.1.617.2/Delta and B.1.1.529/Omicron strains. The neutralizing antibody (NAb) response was robust with both primary vaccination strategies and tended to be higher for almost all VOCs following the heterologous prime-boost regimen.

Phenotype Algorithms for the Identification and Characterization of Vaccine-Induced Thrombotic Thrombocytopenia in Real World Data: A Multinational Network Cohort Study. INTRODUCTION: Vaccine-induced thrombotic thrombocytopenia (VITT) has been identified as a rare but serious adverse event associated with coronavirus disease 2019 (COVID-19) vaccines. OBJECTIVES: In this study, we explored the pre-pandemic co-occurrence of thrombosis with thrombocytopenia (TWT) using 17 observational health data sources across the world. We applied multiple TWT definitions, estimated the background rate of TWT, characterized TWT patients, and explored the makeup of thrombosis types among TWT patients. METHODS: We conducted an international network retrospective cohort study using electronic health records and insurance claims data, estimating background rates of TWT amongst persons observed from 2017 to 2019. Following the principles of existing VITT clinical definitions, TWT was defined as patients with a diagnosis of embolic or thrombotic arterial or venous events and a diagnosis or measurement of thrombocytopenia within 7 days. Six TWT phenotypes were considered, which varied in the approach taken in defining thrombosis and thrombocytopenia in real world data. RESULTS: Overall TWT incidence rates ranged from 1.62 to 150.65 per 100,000 person-years. Substantial heterogeneity exists across data sources and by age, sex, and alternative TWT phenotypes. TWT patients were likely to be men of older age with various comorbidities. Among the thrombosis types, arterial thrombotic events were the most common. CONCLUSION: Our findings suggest that identifying VITT in observational data presents a substantial challenge, as implementing VITT case definitions based on the co-occurrence of TWT results in large and heterogeneous incidence rate and in a cohort of patints with baseline characteristics that are inconsistent with the VITT cases reported to date.

Side Effects of COVID-19 Inactivated Virus vs. Adenoviral Vector Vaccines: Experience of Algerian Healthcare Workers. Healthcare workers were prioritized in vaccination campaigns globally because they are exposed to the highest risk of contamination by SARS-CoV-2. This study evaluated the self-reported post-vaccination side effects of inactivated (BBIBP-CorV and CoronaVac) and adenoviral vector-based (AZD1222, Gam-COVID-Vac and Ad26.COV2.S) vaccines among Algerian healthcare workers using a validated questionnaire. The final analysis included 721 healthcare workers, with a predominance of females (59.1%) and younger individuals 20-30 years old (39.4%). Less than half (49.1%) of the respondents reported at least one local side effect, while 53.8% reported at least one systemic side effect. These side effects were more prevalent among viral vector

vaccinees than inactivated virus vaccinees. The most common local side effects were injection site pain (39%) and arm pain (25.4%), while fatigue (34.4%), fever (28.4%), headache (24.8%) and myalgia (22.7%) were the most prevalent systemic side effects. The side effects appeared earlier among inactivated virus vaccines recipients and generally lasted for 2 to 3 days for the two vaccinated groups. The risk factors associated with a higher prevalence of side effects included female gender, allergic individuals, individuals with regular medication, those who contracted the COVID-19 disease and those who received two doses for both inactivated and viral-based vaccines groups. Despite the higher prevalence of post-vaccination side effects among adenoviral vector vaccines recipients, both vaccines groups were equally effective in preventing symptomatic infections, and no life-threatening side effects were reported in either vaccine group.
COVID-19 Vaccination-Induced Cardiomyopathy Requiring Permanent Left Ventricular Assist Device. Myocarditis was identified as a rare but serious adverse event that can occur after mRNA-based coronavirus disease 2019 (COVID-19) vaccination, particularly in young males. During the COVID-19 pandemic, we report a case of a young obese male without multiple comorbiditiesÂ who presented with abdominal pain and was found to have severe myocarditis/cardiomyopathy, which was likely due to mRNA-based COVID-19 vaccination. The patient had left ventricular assist device (LVAD) implantation during hospitalization. Myocarditis/cardiomyopathy may be a rare complication of the mRNA-based COVID vaccine; however, one should maintain a high index of suspicion that these vaccines may cause irreversible cardiomyopathy if the patient had prior COVID-19 infection.
Chronic Inflammatory Demyelinating Polyneuropathy Post-mRNA-1273 Vaccination. Massive efforts are being made to develop coronavirus disease 2019 (COVID-19) vaccines at an unprecedented rate. The vaccinations' adverse impact profile, on the other hand, has not been well established. Neurological complications are increasingly reported as a result of these vaccines. One such complication identified is immune-mediated inflammatory polyneuropathy, which affects peripheral nerves and neurons. We report a case of chronic inflammatory demyelinating polyneuropathy (CIDP) post-mRNA-1273 (Moderna) COVID-19 vaccine. Recognizing this complication and distinguishing it from Guillain-BarrÃ© syndrome enables timely initiation of treatment. Additionally, our report highlights a possible link between vaccination and subsequent development of CIDP, but conclusive evidence of a causal relationship requires more extensive studies.
[Compliance with Vaccination against SARS-CoV-2; Information Transmission Based on Scientific Evidence and Its Difficulty]. The fight against coronavirus disease 2019 (COVID-19) in Japan began after January 2020. In order for the country to resume an active social life as a society, it is necessary to prevent an increase in the number of newly infected people with severe acute respiratory syndrome corona virus 2 (SARS-CoV-2), and to prevent aggravation and/or death after infection. Although several therapeutic agents have been developed to treat COVID-19 after infection, vaccination with SARS-CoV-2 is the most effective in controlling or even ending the COVID-19 pandemic in Japan. The Ministry of Health, Labour and Welfare has convened a council to publish the collected data on COVID-19 and to proceed with discussions for promoting safe and effective vaccination. However, no matter how we release to the public the scientific basis of our findings and proposed methods of prevention and treatment, there remain cases where false opinions have spread, and vaccinations are refused accordingly. This paper traces the course of the work of this council, and considers current challenges in communicating COVID-19 information to the public based on scientific evidence.
[Survey of side reactions of first dose COVID-19 vaccine at the nursing home].
COVID-19 Vaccination for Patients Undergoing Long-Term Hemodialysis.
Clinical Utility of COVID-19 Vaccination in Patients Undergoing Hemodialysis.

Severity of COVID-19 after Vaccination among Hemodialysis Patients: An Observational Cohort Study. BACKGROUND AND OBJECTIVES: Patients receiving hemodialysis are at high risk from coronavirus disease 2019 (COVID-19) and demonstrate impaired immune responses to vaccines. There have been several descriptions of their immunologic responses to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination, but few studies have described the clinical efficacy of vaccination in patients on hemodialysis. DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: In a multicenter observational study of the London hemodialysis population undergoing surveillance PCR testing during the period of vaccine rollout with BNT162b2 and AZD1222, all of those positive for SARS-CoV-2 were identified. Clinical outcomes were analyzed according to predictor variables, including vaccination status, using a mixed effects logistic regression model. Risk of infection was analyzed in a subgroup of the base population using a Cox proportional hazards model with vaccination status as a time-varying covariate. RESULTS: SARS-CoV-2 infection was identified in 1323 patients of different ethnicities (Asian/other, 30%; Black, 38%; and White, 32%), including 1047 (79%) unvaccinated, 86 (7%) after first-dose vaccination, and 190 (14%) after second-dose vaccination. The majority of patients had a mild course; however, 515 (39%) were hospitalized, and 172 (13%) died. Older age, diabetes, and immune suppression were associated with greater illness severity. In regression models adjusted for age, comorbidity, and time period, prior two-dose vaccination was associated with a 75% (95% confidence interval, 56 to 86) lower risk of admission and 88% (95% confidence interval, 70 to 95) fewer deaths compared with unvaccinated patients. No loss of protection was seen in patients over 65 years or with increasing time since vaccination, and no difference was seen between vaccine types. CONCLUSIONS: These data demonstrate a substantially lower risk of severe COVID-19 after vaccination in patients on dialysis who become infected with SARS-CoV-2.

Adverse events and overall health and well-being after COVID-19 vaccination: interim results from the VAC4COVID cohort safety study. OBJECTIVES: To describe the incidence of adverse events (AEs), reactogenicity symptoms, menstrual changes and overall self-rated improvement in health and well-being after COVID-19 vaccination. DESIGN: VAC4COVID is an ongoing prospective, active observational, post-authorisation cohort safety study (PASS) of UK-approved vaccines for COVID-19 disease. SETTING: The study is conducted through a secure website (www.vac4covid.com) by MEMO Research, University of Dundee, UK. PARTICIPANTS: 16â€‰265 adult (18 years or older) UK residents with a valid email address and internet access. INTERVENTIONS: Any UK-authorised COVID-19 vaccination. MAIN OUTCOME MEASURES: The outcomes reported in this interim analysis include AEs, reactogenicity-type AEs (headache, fatigue, muscle or joint pain, fever, nausea, dizziness or local vaccine reaction), menstrual changes and reported improvement in overall health and well-being. RESULTS: 11â€‰475 consented participants (mean age 54.8 years) provided follow-up data between 2 February and 5 October 2021 (mean follow-up duration 184 days), by which date 89.2% of participants had received two vaccine doses. 89.8% of 5222 participants who completed a follow-up questionnaire in the 7â€‰days after any COVID-19 vaccination reported no AEs. The risk of experiencing any event (not necessarily vaccine-related) requiring hospitalisation was less than 0.2%. 43.7% of post-vaccination follow-up records reported improvement in health and well-being. Reactogenicity-type reactions were more common in the week after the first dose of ChAdOx1 than BNT162b2 (7.8% vs 1.6%), but this relationship was reversed after the second dose (1.3% vs 3.1%). 0.3% of women reported menstrual symptoms after vaccination; no differences between vaccine type or dose order were detected. CONCLUSIONS: The study provides reassuring data on low rates of AEs after COVID-19 vaccination. Differences in reactogenicity-type AE profiles between ChAdOx1 and BNT162b2 and between first and second doses of these vaccines were observed. TRIAL REGISTRATION NUMBER: ISRCTN95881792; Pre-results.

Comparison of severe acute respiratory syndrome coronavirus 2 (COVID-19) vaccine side effects by age groups. OBJECTIVE: This online survey aims to compare the side effects that may occur after inactivated severe acute respiratory syndrome coronavirus 2 (COVID-19) vaccination by age groups. METHODS: A total of 411 participants aged 18-100 who received inactivated coronavirus disease 2019 vaccine were included in the study. RESULTS: Participants were divided into four groups according to their ages (i.e., 20-35, 36-50, 51-65, and over 65 years old). Vaccine-related side effects were primarily seen in the 20-35 age group and at least in the >65 age group ($p<0.001$). The most common side effects were pain, redness, swelling, and numbness at the injection site. Fatigue and headache were other common side effects. After vaccination, 3 (0.73%) participants had hypertension, and 1 (0.24%) had an asthma attack and was admitted to the hospital. No severe side effects were observed in any of the patients. The most critical factors determining the development of side effects were female gender and young age. CONCLUSION: According to the results of this study, different types and rates of side effects are seen in all age groups after the inactivated coronavirus disease 2019 vaccine. Since the 20-35 age group and female gender are at risk of side effects, it would be more appropriate to follow up the side effects after vaccination according to gender and age.

Side effects and antibody response of an inactive COVID-19 vaccine: correspondence.

Comment on: Stromal rejection in penetrating keratoplasty following COVID-19 vector vaccine (Covishield) - A case report and review of literature.

Retinal venous occlusion following COVID-19 vaccination: Report of a case after third dose and review of the literature. A 28-year-old, healthy male presented with blurring of vision in the right eye following third dose of the AstraZeneca/COVISHIELD vaccine. Further examination revealed ischemic central retinal vein occlusion, and subsequent laboratory investigations were inconclusive for his eye disease. He responded to pulse corticosteroid and tapering doses of oral corticosteroids without requiring any intra-vitreal injection. Twelve articles were identified with the help of a PubMed literature search, and a short review of these patients was performed. Retinal vein occlusion can occur because of inflammation-induced thrombosis after coronavirus disease 2019 vaccination and may respond to anti-inflammatory therapy.

Ischemic colitis after receiving the second dose of a COVID-19 inactivated vaccine: A case report. BACKGROUND: The outbreak of the coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 has been the most important clinical challenge worldwide since January 2020. COVID-19 inactivated vaccines play a crucial role in reducing the rates of morbidity and mortality. CASE SUMMARY: We presented a 48-year-old woman from Haidian District, Beijing, China who developed ischemic colitis after receiving the second dose of COVID-19 inactivated vaccine. Computed tomography of the abdomen showed edema and bowel wall thickening with hypodensity in the sigmoid colon and descending colon. Colonoscopy revealed hyperemia, edema and erosion of the mucosa with superficial ulceration and a yellow-white coating at the descending colon and sigmoid colon. The symptoms were relieved after 1 wk of receiving pinaverium bromide (50 mg, tid) and aspirin enteric-coated tablets (0.1 g, qd). CONCLUSION: The possible occurrence of ischemic colitis should be considered after administration of the COVID-19 inactivated vaccines.

Myopericarditis with hemorrhagic pericardial effusion following BNT162b2 mRNA COVID-19 vaccine. Since the onset of the COVID-19 pandemic, to date, around 385 million cases have been diagnosed worldwide leading to an estimated 5.7 million death toll. Mass vaccination campaigns have been conducted to control the spread of infection with the most commonly used vaccines being Pfizer-BioNTech and Moderna. However, the adverse effects of vaccination have not yet been fully investigated. Of concern are some serious cardiovascular events such as myocarditis, pericarditis, or perimyocarditis development post-vaccination. Hemorrhagic pericardial effusion has not been

reported. However, we report a case of myopericarditis with a hemorrhagic pericardial effusion that developed two weeks following BNT162b2 mRNA COVID-19 vaccination. We performed a complete workup identifying the underlying cause that did not yield any significant findings. Our patient was treated with colchicine and ibuprofen, and he made a full recovery. A follow-up cardiovascular magnetic resonance imaging (CMR) showed no signs of active inflammation.

Rupture of Vertebral Artery Dissecting Aneurysm after mRNA Anti-COVID-19 Vaccination: A Report of Two Cases. The coronavirus disease 2019 (COVID-19) pandemic continues to spread around the world, and widespread vaccination is considered the most effective way to end it. Although the efficacy of COVID-19 vaccines has been confirmed, their safety remains a concern. In this paper, we report two cases of ruptured vertebral artery dissecting aneurysm (VADA) immediately after messenger RNA (mRNA) anti-COVID-19 vaccination. In Case 1, a 60-year-old woman experienced sudden headache 3 weeks before her first dose of the Moderna mRNA-1273 COVID-19 vaccine. Magnetic resonance imaging showed dilatation of the right vertebral artery (VA) without intracranial hemorrhage. A day after the vaccination, she developed subarachnoid hemorrhage with pulmonary effusion due to a ruptured right VADA. She underwent endovascular internal trapping and parent artery occlusion under general anesthesia. In Case 2, a 72-year-old woman with a previous history of the left VA occlusion due to arterial dissection developed subarachnoid hemorrhage 7 days after the first dose of the Pfizer-BioNTech BNT162b2 COVID-19 mRNA vaccine due to a ruptured right VADA and underwent stent-assisted coil embolization under general anesthesia. The postoperative courses of these two cases were uneventful. The accumulation of more cases and further study are warranted to clarify the relationship between COVID-19 mRNA vaccination and ruptured intracranial dissecting aneurysms.

Clinical and Radiological Follow-Up of a Pfizer-BioNTech COVID-19 Vaccine-Induced Hemichorea-Hemiballismus; Insights Into Mechanisms of Basal Ganglia Dysfunction. Asymmetric chorea unrelated to structural lesions is typically due to systemic etiologies, such as metabolic, autoimmune, or other inflammatory disorders. This is an editorial commenting on a paper by Batot C, Chea M, Zeidan S, et al. Clinical and radiological follow up of Pfizer-BioNTech COVID-19 vaccine-induced hemichorea-hemiballismus. Tremor and Other Hyperkinetic Movements; 2022; 12(1). DOI: https://doi.org/10.5334/tohm.688. A 90-year-old patient is reported who developed hemichorea shortly after his second vaccination against COVID-19. Hypometabolism was noted in the contralateral striatum. This case provides potential insights and raises questions about mechanisms of immune-mediated hemichorea.

Clinical and Radiological Follow-Up of a Pfizer-BioNTech COVID-19 Vaccine-Induced Hemichorea-Hemiballismus. BACKGROUND: Hemichorea-hemiballismus is a rare hyperkinetic movement disorder. CASE REPORT: A 90-year-old male developed left hemichorea-hemiballismus after his second dose of the Pfizer-BioNTech COVID-19 vaccine. A wide range of investigations including magnetic resonance imaging did not reveal an alternative cause. [18F]-fluorodeoxyglucose-positron emission tomography (FDG-PET) showed increases in right putamen fixation compared to the left side. The patient showed significant improvement after five days of intravenous corticosteroids, with a normal FDG-PET. DISCUSSION: This hemichorea-hemiballismus case shows dynamic restoration of putamen metabolism mirroring clinical evolution after administration of corticosteroids, suggesting an autoimmune COVID-19 vaccine-induced reaction.

Guillain-BarrÃ© syndrome following coronavirus disease vaccine: First report from Nepal. ChAdOx1 nCoV-19 is an effective and well-tolerated coronavirus disease 2019 vaccine. However, rare cases of serious adverse events have been reported with it. We report a patient who did not have active or prior coronavirus disease 2019 infection, who developed Guillain-BarrÃ© syndrome 7â€‰days following the first dose of ChAdOx1 nCoV-19 vaccination. He was treated with intravenous

immunoglobulin, with stabilization of the disease. Proper monitoring and prompt reporting of such cases are required to ensure the safety of the vaccine.

Social anxiety disorder is Associated with Vaccination attitude, stress, and coping responses during COVID-19. BACKGROUND: Individuals with Social Anxiety Disorder (SAD) may be at a higher risk for negative outcomes during the COVID-19 pandemic due to isolation that is both characteristic of the disorder and also potentially exacerbated by quarantine and public health restrictions. Accordingly, we evaluated emotional and behavioral responses to stress during COVID-19 and attitudes towards COVID-19 vaccine adoption in socially anxious versus non-socially anxious adults. METHODS: Participants (Nâ€‰=â€‰84) were young adults between 18 and 24 years of age who completed a diagnostic interview and self-report measures assessing stress, anxiety and coping responses during COVID-19. Welch's t-tests assessed group differences on mental health outcomes between the SAD versus non-SAD group, and Pearson's Ï‡2 test evaluated COVID-19 vaccination status by group. Lastly, logistic regression examined whether SAD predicted positive COVID-19 vaccination attitude. RESULTS: Results indicated the SAD group demonstrated significantly elevated rates of anxiety and depression as compared to individuals without SAD and had significantly increased rates of engagement in safety behaviors as well as maladaptive coping mechanisms in response to COVID-19 stress. Individuals with SAD were significantly more likely to receive or plan to receive the COVID-19 vaccine. CONCLUSIONS: The current study provides evidence that social anxiety may be a significant factor associated with the impact of COVID-19 as well as attitudes with vaccine compliance. SUPPLEMENTARY INFORMATION: The online version contains supplementary material available at 10.1007/s10608-022-10310-3.

Heterologous COVID-19 Booster Vaccination in the Chronic Disorder of Consciousness: A Pilot Study. Significant anti-spike protein receptor-binding domain (S-RBD) antibody responses have been demonstrated in patients with chronic disorder of consciousness (DOC) completing a COVID-19 vaccine regime with BNT162b2 (Pfizer-BioNTech). We now provide further prospective data on the immunogenicity of these patients followed by heterologous booster injection with mRNA-1273 (Moderna). These patients were compared with two different demographically comparable healthcare workers (HCW) groups who underwent homologous booster injection with BNT162b2 vaccine or heterologous booster injection with mRNA-1273. Antibody responses were evaluated at 21 days after the administration of the booster dose of vaccination. Results: No severe adverse reactions were reported after each type of vaccination. Heterologous boosting with mRNA-1273 elicited a higher increase of S-RBD IgG levels than homologous boosting with BNT162b2 both in DOC patients and HCW who had previously received two doses of BNT162b2. No significant difference was detected between DOC and HCW patients who received heterologous boosting. Conclusions: Despite the small sample size, our preliminary results suggest that heterologous boosting with mRNA-1273, following initial vaccination with BNT162b2, is safe and tends to be more immunogenic than homologous boosting, either in fragile people or in healthy controls.

Arterial Thrombosis in an Unusual Site (Ulnar Artery) after COVID-19 Vaccination-A Case Report. Spontaneous events have been reported after COVID-19 vaccination. In this case, we report a thrombotic event in an unusual site (ulnar artery) after COVID-19 vaccination. The patient (69 year-old-male) had no changes after a laboratory investigation regarding thrombophilic pattern, but nevertheless had atherothrombotic predisposing conditions. Arterial thrombotic events have more frequently been reported after mRNA vaccines than after adenovirus vaccines. This is the first case reported of thrombosis of the ulnar artery occurring in the same side of the body where the vaccination took place. However, it must be noted that COVID-19 vaccines cumulatively offer a net positive effect, despite rare adverse effects.

Evaluation of Natural and Vaccine-Induced Anti-SARS-CoV-2 Immunity: A Comparative Study between Different Groups of Volunteers. (1) Background: The production of anti-SARS-CoV-2 antibodies should help minimize the severity of COVID-19 disease. Our focus was to investigate and compare different vaccination schedules, monitoring circulating S-RBD Ab (antibodies anti-Spike protein-Receptor Binding Domain) levels after administering two doses in naÃ¯ve patients. Likewise, vaccine-stimulated immunity in naÃ¯ve and previously infected patients was compared. (2) Methods: We included 392 patients. Sera were evaluated by Elecsys anti-SARS-CoV-2 S. Statistical analyses were conducted by MedCalc and JASP. (3) Results: In COVID-19 patients, the median value of Ab levels was 154 BAU/mL, stable up to 9 months after the infection. From the data observed in vaccinated patients, higher median values were recorded in COVID-19/Pfizer BioNTech (18913 BAU/mL) than in other groups (Pfizer BioNTech: 1841; ChadOx1 961; heterologous vaccination: 2687) BAU/mL. (4) Conclusions: In conclusion, a single booster dose given to previously infected patients raised an antibody response much higher than two doses given to naÃ¯ve individuals and heterologous vaccination generated a robust persistent antibody response at high levels, steady up to three months after administration.

Audiovestibular Disorders after COVID-19 Vaccine: Is There an Association? The SARS-CoV-2 vaccination campaign is probably one of the most historic public hygiene measures in modern medicine. The drama of the pandemic has forced the scientific community to accelerate the development and commercialization of vaccines, thereby enhancing the phases of active surveillance. Among the adverse events following immunization (AEFI) reported, those of an audiovestibular interest, such as sudden sensorineural hearing loss (SSNHL), tinnitus, dizziness, and vertigo, constitute a very small percentage. There are many plausible etiological hypotheses, and scientific research needs to pay more attention to the correct collection of data, which up until now have often been inadequate and fragmented, on which to base future studies. SSNHL, new onset tinnitus, vertigo, and dizziness require a prompt evaluation, while the proposed treatment is the same as it is for events unrelated to vaccination. These are uncommon adverse events, and the risk rates for these diseases have not increased in conjunction with the COVID-19 vaccinations, therefore there is no justification of any hesitation towards the vaccination campaign.

[Thrombosis with Thrombocytopenia Syndrome after ChAdOx1 nCoV-19 vaccination]. A 48-year-old Japanese man who had no previous medical history received his first dose of the ChAdOx1 nCoV-19 vaccine. Ten days after the vaccine administration, he developed a headache. Laboratory results indicated throm-bocytopenia and DIC. A head CT revealed microbleeding in the left parietal lobe. Contrast-enhanced CT showed thrombus in the left transverse sinus and left sigmoid sinus. A brain MRI demonstrated venous hemorrhagic infarction and subarachnoid hemorrhages in the left parietal lobe, and whole-body enhanced CT also revealed portal vein embolism and renal infarction. He was diagnosed with thrombosis with thrombocytopenia syndrome, and was treated according to the guideline. He has been recovering with the treatments. This is the first reported case of TTS associated with the ChAdOx1 nCoV-19 vaccine in Japan.

Safety of Pfizer-BioNTech vaccine in a cohort of healthcare providers: Differences between naÃ¯ve and previously infected by SARS-CoV-2. INTRODUCTION: The Spanish Society of Immunology recently warned that a history of past COVID-19 could result in a higher incidence of adverse events (AEs) related to vaccination. We set out to analyze whether there were any differences in AEs between healthcare workers vaccinated for COVID-19 (either after the first or second dose) who had had a prior diagnosis SARS-CoV-2 infection at any time compared to those who had not had COVID-19 before vaccination. METHODS: This was a retrospective cohort study in a population of healthcare workers. AEs related to the first and second doses of the Pfizer vaccine were recorded. We compared the incidence of AEs and compared individuals with 0-3 different AEs to those with 4 or more AEs.

The relative risks (RR) and their 95% confidence intervals were calculated. RESULTS: Past infection was associated with having more AEs after the first dose (pÂ <Â 0.001), but not the second one (pÂ =Â 0.476), as well as a higher incidence of AEs (pÂ <Â 0.001). Common AEs that were statistically associated with past COVID infection included arthralgia, asthenia, fever, chills, headache, and myalgia (pÂ â‰¤Â 0.001). The RR for having an increased absolute number of different AEs was 1.18 (95Â %CI [1.05, 1.33]) after the first dose and 1.05 (95Â %CI [0.96, 1.14]) after the second dose. The maximum number of days between past infection and vaccination was 306. CONCLUSIONS: Our results showed that the incidence of AEs was higher in individuals with a history of prior COVID-19 infection.

Reactogenicity after heterologous and homologous COVID-19 prime-boost vaccination regimens: descriptive interim results of a comparative observational cohort study. BACKGROUND: Due to safety signals after vaccination with COVID-19 vector vaccines, several states recommended to complete the primary immunization series in individuals having received one dose of ChAdOx1 (AstraZeneca) with an mRNA vaccine. However, data on safety and reactogenicity of this heterologous regimen are still scarce. The aim of this study was therefore to compare the reactogenicity and the frequency of medical consultations after boost vaccination in a heterologous regimen with ChAdOx1 and mRNA-vaccines (BNT162b2, BioNTech/Pfizer or mRNA-1273, Moderna) to homologous regimens with ChAdOx1 or mRNA-vaccines, respectively. METHODS: In an observational cohort study reactogenicity and safety were assessed 14-19Â days (short-term) and 40 to 56Â days (long-term) after the boost vaccination using web-based surveys. In the short-term survey solicited and unsolicited reactions were assessed, while the long-term survey focussed on health problems leading to medical consultation after the vaccination, including those that were not suspected to be vaccine-related. RESULTS: In total, 9146 participants completed at least one of the surveys (ChAdOx1/ChAdOx1: nâ€‰=â€‰552, ChAdOx1/mRNA: nâ€‰=â€‰2382, mRNA/mRNA: nâ€‰=â€‰6212). In the short-term survey, 86% with ChAdOx1/mRNA regimen reported at least one reaction, in the ChAdOx1/ChAdOx1 and mRNA/mRNA cohorts 58% and 76%, respectively (age and sex adjusted pâ€‰<â€‰0.0001). In the long-term survey, comparable proportions of individuals reported medical consultation (ChAdOx1/ChAdOx1 vs. ChAdOx1/mRNA vs. mRNA/mRNA: 15% vs. 18% vs. 16%, age and sex adjusted pâ€‰=â€‰0.398). Female gender was associated with a higher reactogenicity and more medical consultations. Younger age was associated with a higher reactogenicity, whereas elderly people reported more medical consultations. CONCLUSION: Although the short-term reactogenicity was higher with the heterologous regimen than with the homologous regimens, other factors such as higher efficacy and limited resources during the pandemic may prevail in recommending specific regimens.

Effectiveness, immunogenicity, and safety of COVID-19 vaccines for individuals with hematological malignancies: a systematic review. The efficacy of SARS-CoV-2 vaccination in patients with hematological malignancies (HM) appears limited due to disease and treatment-associated immune impairment. We conducted a systematic review of prospective studies published from 10/12/2021 onwards in medical databases to assess clinical efficacy parameters, humoral and cellular immunogenicity and adverse events (AE) following two doses of COVID-19 approved vaccines. In 57 eligible studies reporting 7393 patients, clinical outcomes were rarely reported and rates of SARS-CoV-2 infection (range 0-11.9%), symptomatic disease (0-2.7%), hospital admission (0-2.8%), or death (0-0.5%) were low. Seroconversion rates ranged from 38.1-99.1% across studies with the highest response rate in myeloproliferative diseases and the lowest in patients with chronic lymphocytic leukemia. Patients with B-cell depleting treatment had lower seroconversion rates as compared to other targeted treatments or chemotherapy. The vaccine-induced T-cell response was rarely and heterogeneously reported (26.5-85.9%). Similarly, AEs were rarely reported (0-50.9% â‰¥1 AE, 0-

7.5% â‰¥1 serious AE). In conclusion, HM patients present impaired humoral and cellular immune response to COVID-19 vaccination with disease and treatment specific response patterns. In light of the ongoing pandemic with the easing of mitigation strategies, new approaches to avert severe infection are urgently needed for this vulnerable patient population that responds poorly to current COVID-19 vaccine regimens.

Safety of COVID-19 Vaccine in Patients with Cancer in a High-Volume Comprehensive Cancer Center. BACKGROUND: Few data are available on the safety of COVID-19 vaccines in cancer patients undergoing active cancer-directed treatment. PATIENTS AND METHODS: This case series analyzes outcomes in terms of adverse events in 5297 patients undergoing anti-cancer treatment who were vaccinated with anti-SARS-CoV-2 Pfizer-BioNTech vaccine at a single cancer center from March 6, 2021 to May 9, 2021. Adverse events were retrieved from the national Italian pharmacovigilance platform (http://www.vigicovid.it). RESULTS: Of the 5297 patients treated for either solid tumors (87%) or onco-hematologic malignancies (13%) who were vaccinated, 8 adverse drug reactions (ADRs) were reported. One was a severe ADR and 7 were non-severe ADRs. Non-severe ADRs resolved within 48 hours. CONCLUSION: BNT162b2 Pfizer-BioNTech vaccine was safely administered in the largest cohort of cancer patients reported to date.

Kinetics of immune responses to SARS-CoV-2 proteins in individuals with varying severity of infection and following a single dose of the AZD1222. To characterize the IgG and IgA responses to different SARS-CoV-2 proteins, we investigated the antibody responses to SARS-CoV-2 following natural infection and following a single dose of AZD1222 (Covishield), in Sri Lankan individuals. The IgG and IgA responses were assessed to S1, S2, RBD, and N proteins in patients at 4 weeks and 12 weeks since the onset of illness or following vaccination. Antibodies to the receptor-binding domain of SARS-CoV-2 wild type (WT), Î±, Î², and Î» and ACE2 (Angiotensin Converting Enzyme 2) receptor blocking antibodies were also assessed in these cohorts. For those with mild illness and in vaccines, the IgG responses to S1, S2, RBD, and N protein increased from 4 weeks to 12 weeks, while it remained unchanged in those with moderate/severe illness. In the vaccines, IgG antibodies to the S2 subunit had the highest significant rise ($P < 0.0001$). Vaccines had several-fold lower IgA antibodies to all the SARS-CoV-2 proteins tested than those with natural infection. At 12 weeks, the haemagglutination test (HAT) titres were significantly lower to the Î± in vaccines and significantly lower in those with mild illness and in vaccines to Î² and for Î». No such difference was seen in those with moderate/severe illness. Vaccines had significantly less IgA to SARS-CoV-2, but comparable IgG responses those with natural infection. However, following a single dose vaccines had reduced antibody levels to the VOCs, which further declined with time, suggesting the need to reduce the gap between the two doses, in countries experiencing outbreaks due to VOCs.

Th1 Cytokines Signature in 2 Cases of IgA Nephropathy Flare after mRNA-Based SARS-CoV-2 Vaccine: Exploring the Pathophysiology. mRNA-based vaccines have dramatically shifted the course of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. IgA nephropathy (IgAN) flare is the most reported renal adverse effect after the administration of these vaccines. Unraveling the mechanistic pathways leading to these flares is necessary to confirm a causal association. Herein, we report 2 cases of IgAN flare after SARS-CoV-2 vaccination in patients previously diagnosed with IgAN. We describe and compare the clinical and analytical features of the disease at the time of the diagnostic with the post-vaccine flare. In addition, we obtained serum and urine of these patients at the moment of the flare and determined the levels of IL-2, TNF-Î±, and IFNÎ³ using a multiplex bead-based assay. As diseased controls, we included n = 13 patients diagnosed with IgAN who had available serum and urine samples at the moment of the diagnostic stored in our biobank. We also included 6 healthy controls. Compared to the first episode, postvaccination flares were more severe in terms of peak serum creatinine, albuminuria, and urinary erythrocyte count. The histological lesions found at

the biopsy performed during the post-vaccine flare were similar to those found at the diagnostic. One of the patients who suffered a post-vaccine flare showed increased serum IL-2 and TNFÎ± compared to the IgAN-diseased controls and the healthy controls. In conclusion, although several cases of post-vaccine IgAN flares have been reported, there are no mechanistic studies on the occurrence of these flares. We here suggest that hyperactivation of the Th1 pathway may be involved, but larger studies with more refined methods for numerical and functional Th1 lymphocytes evaluation are required.

Adverse effects following anti-COVID-19 vaccination with mRNA-based BNT162b2 are alleviated by altering the route of administration and correlate with baseline enrichment of T and NK cell genes. Ensuring high vaccination and even booster vaccination coverage is critical in preventing severe Coronavirus Disease 2019 (COVID-19). Among the various COVID-19 vaccines currently in use, the mRNA vaccines have shown remarkable effectiveness. However, systemic adverse events (AEs), such as postvaccination fatigue, are prevalent following mRNA vaccination, and the underpinnings of which are not understood. Herein, we found that higher baseline expression of genes related to T and NK cell exhaustion and suppression were positively correlated with the development of moderately severe fatigue after Pfizer-BioNTech BNT162b2 vaccination; increased expression of genes associated with T and NK cell exhaustion and suppression reacted to vaccination were associated with greater levels of innate immune activation at 1 day postvaccination. We further found, in a mouse model, that altering the route of vaccination from intramuscular (i.m.) to subcutaneous (s.c.) could lessen the pro-inflammatory response and correspondingly the extent of systemic AEs; the humoral immune response to BNT162b2 vaccination was not compromised. Instead, it is possible that the s.c. route could improve cytotoxic CD8 T-cell responses to BNT162b2 vaccination. Our findings thus provide a glimpse of the molecular basis of postvaccination fatigue from mRNA vaccination and suggest a readily translatable solution to minimize systemic AEs.

COVID-19 Vaccination Willingness and Associated Factors in Japanese Primary Care Patients: A Cross-Sectional Study. INTRODUCTION/OBJECTIVES: COVID-19 vaccination is important to stop the pandemic. It has been reported that willingness to be vaccinated is associated with system factors as well as individual attitudes and beliefs. Primary care patients include individuals at increased risk of poor outcomes after COVID-19 infection, such as elderly people and those with comorbidities. This study investigated attitudes in this population toward COVID-19 and COVID-19 vaccination, including willingness to be vaccinated and associated factors. This study was conducted in Japan, where the population has low vaccine confidence, during the initial phase of COVID-19 vaccination. METHODS: Patients from 1 primary care clinic in Kitaibaraki City, Ibaraki, Japan, participated in this study from March to April 2021. They were administered a self-reported questionnaire exploring factors such as willingness to undergo COVID-19 vaccination, perceived susceptibility, and perceived vaccine efficacy. Multivariable logistic regression analysis was conducted to identify factors associated with vaccination. RESULTS: Of the 717 patients (response rate, 88.3%), 512 (70.0%) reported they were willing to be vaccinated for COVID-19. Multivariate analysis revealed that vaccination willingness was associated with older age (odds ratio [OR] 1.03, 95% confidence interval [CI] 1.01-1.05), male gender (OR 1.95, 95% CI 1.15-3.30), influenza vaccination in in the 2020/2021 season (OR 2.54, 95% CI 1.49-4.32), recommendation from others (OR 3.11, 95% CI 1.58-6.18), high perceived susceptibility (OR 2.51, 95% CI 1.45-4.33), belief in vaccine efficacy (OR 3.83, 95% CI 1.54-9.56), high perceived susceptibility to vaccine-related adverse events (OR 0.37, 95% CI 0.22-0.64), and high espousal of social norms (OR 8.00, 95% CI 2.78-23.0). CONCLUSIONS: COVID-19 vaccination was widely acceptable to Japanese primary care patients. In addition to factors such as vaccine efficacy, and past influenza vaccination, social norms may be important in determining COVID-19 vaccination willingness.

Adverse events following BNT162b2 mRNA COVID-19 vaccination among healthcare workers: A single-centre experience in Malaysia. INTRODUCTION: The COVID-19 pandemic is a global health crisis that has resulted in a massive disease burden worldwide. Mass vaccination plays an important role in controlling the spread and severity of COVID-19 infections worldwide. MATERIALS AND METHODS: A cross-sectional study was conducted in Hospital Tuanku Ja'afar Seremban between 1 March 2021 and 4 May 2021 to describe the adverse events (AE) following BNT162b2 (Pfizer-BioNTech) vaccination. Healthcare personnel who received at least one dose of the vaccine were invited to complete an online questionnaire. RESULTS: Of 2282 analysed samples, AE were experienced in up to 64.5% (n=1472) of the study participants. Most AE were encountered after the second dose (56.5%, n=832). Pain at the injection site (41.5%, n=944), fever (35.1%, n=798) and lethargy (34.8%, n=792) were the most commonly reported AE. Severe AEFI were reported in a minority (2.9%, n=68). There were no documented anaphylaxis, vaccine-induced thrombosis, or myocarditis. The proportion of female recipients and recipients with a history of allergy were higher in the AE group compared to the non-AE group. CONCLUSION: Our study reinforces the safety of the BNT162b2 mRNA vaccine in the local population. The main adverse events were mild, although they occurred in most patients.

Letter to the Editor: Propacetamol-Induced Rhabdomyolysis or COVID-Vaccine-Related Inflammatory Myopathy?

Simultaneous Occurrence of Immune-Mediated Thrombocytopenia and Myocarditis After mRNA-1273 COVID-19 Vaccination: A Case Report. With the global spread of severe acute respiratory syndrome coronavirus 2, several vaccines were developed; messenger RNA (mRNA) vaccines have recently been widely used worldwide. However, the incidence of myocarditis following mRNA vaccination is increasing; although the cause of myocarditis has not yet been clearly identified, it is presumed to be caused by a problem in the innate immune system. Immune-mediated thrombocytopenia (ITP) after vaccination is rare but has been reported and is also assumed to occur by the same mechanism. We report the first case of simultaneous myocarditis and ITP after mRNA vaccination. A 38-year-old woman presented with chest pain, mild dyspnea, and sweating after vaccination with mRNA-1273 vaccine (Moderna) 4 days prior to admission. Upon admission to the emergency department, cardiac enzymes were elevated; blood test performed 5 months ago showed normal platelet count, but severe thrombocytopenia was observed upon admission. After administration of intravenous immunoglobulin, the platelet count improved; subsequently, myocarditis was observed on endomyocardial biopsy. Thus, myocarditis and ITP were judged to have occurred simultaneously due to the expression of the innate immune system markers after mRNA vaccination. The patient was discharged on day 6 of admission.

Combination of acute exacerbation of idiopathic nonspecific interstitial pneumonia and pulmonary embolism after booster anti-COVID-19 vaccination. Coronavirus disease-2019 (COVID-19) is a systemic disorder with the lung and the vasculature being the preferred targets. Patients with interstitial lung diseases represent a category at high risk of progression in the case of Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV)-2 infection, and as such deserve special attention. We first describe the combination of acute exacerbation and pulmonary embolism in an elderly ILD patient after booster anti-COVID-19 mRNA vaccination. Vaccines availability had significantly and safety impacted COVID-19 morbidity and mortality worldwide. Immunization against COVID-19 is indisputable but must not be separated from the awareness of potential adverse effects in fragile patients.

Perceptions and experiences of COVID-19 vaccines' side effects among healthcare workers at an Egyptian University Hospital: a cross-sectional study. BACKGROUND: A safe and effective vaccine is the ultimate key to mitigating the COVID-19 pandemic. Vaccine acceptance is influenced by various

factors, including perceptions about the vaccine's safety and side effects. The side effects vary depending on the type of the vaccine, but they are mainly mild, local, temporary, and self-limiting. METHODS: A cross-sectional study was carried out at Tanta University Hospitals, including 1246 healthcare workers who received either the first or the second dose of the COVID-19 vaccine, selected via a systematic random sampling technique using a self-administered structured validated questionnaire for data collection from November 2021 to January 2022. Qualitative data were presented as frequencies and percentages and analyzed using Chi-square and Fisher's exact tests. RESULTS: The prevalence of one or more side effects was 91.3%. Among participants, about two-thirds believed in vaccine safety and its necessity (65.4% and 63.6%, respectively). Significantly more participants (46.9%) were concerned about AstraZeneca thrombotic complications than other vaccine types. The top five side effects reported by participants were injection site pain (64.8%), sense of fatigue (57.1%), headache (49.9%), muscle pain (48.7%), and fever (46.5). Most of the side effects were significantly higher among participants vaccinated with AstraZeneca. Side effects impacted work capacity of 23.4%, which was significantly higher among participants who received AstraZeneca (33.6%). CONCLUSION: Participants had a good level of belief in vaccination safety and necessity. Healthcare workers who got the AstraZeneca vaccination reported more adverse effects than other vaccines. Injection site pain, fatigue, headache, muscle pains, and fever were the most frequently reported side effects. More research on vaccination safety is needed to understand the long-term adverse effects of vaccinations better, improve the public trust, and accelerate vaccine adoption.

Post-vaccination SARS-CoV-2 axillary adenopathy. Differences with axillary metastases from breast cancer. The differential diagnosis of the metastatic axillary lymphadenopathies of breast cancer with which they occur secondary to the Pfizer-BioNTech vaccine against COVID-19, is imperative. In a series of cases, we analyzed the characteristics of unilateral axillary lymphadenopathy in patients after Pfizer-BioNTech vaccination. Axillary lymphadenopathy were observed ipsilateral to the vaccination arm. The axillary ultrasound defined these as reactive and that they disappeared in 3 weeks. The pathological findings were benign. The anamnesis, the place and date of vaccination and the radiological findings, play an essential role to carry out a correct differential diagnosis and follow-up of these adenopathies.

COVID-19 Vaccines. This article is a narrative review of the rapidly moving coronavirus disease 2019 vaccine field with an emphasis on clinical efficacy established in both randomized trials and postmarketing surveillance of clinically available vaccines. We review the major clinical trials that supported authorization for general use of the Janssen (Ad.26.CoV2), Pfizer-BioNTech (BNT162b2), and Moderna (mRNA-1273) vaccines and the publicly available postmarketing information with the goal of providing a broad, clinically relevant comparison of efficacy and safety. This review is primarily focused on the US market.

COVID-19 and Pregnancy. Pregnancy seems to be a risk factor for severe disease with COVID-19. Although SARS-CoV-2 intrauterine transmission seems to be rare, most studies show COVID-19 during pregnancy increases the risk for pregnancy complications, with higher risk among those with severe disease compared with those mildly affected. Studies suggest that COVID-19 vaccination during pregnancy is safe and effective. Antibodies to SARS-CoV-2 have been found in umbilical cord blood and breast milk following maternal vaccination, which might provide protection to the infant. However, vaccination rates during pregnancy remain low. Studies are needed to understand ways to address SARS-CoV-2 vaccine hesitancy among pregnant persons.

Safety and Immunogenicity of Inactivated and Recombinant Protein SARS-CoV-2 Vaccines in Patients With Thyroid Cancer. BACKGROUND: This study aimed at assessing the safety and immunogenicity of SARS-CoV-2 vaccines in patients with thyroid cancer. METHODS: This observational study included thyroid cancer patients between April 1, 2021, and November 31, 2021,

in the Second Affiliated Hospital of Chongqing Medical University. All participants received at least one dose of the SARS-CoV-2 vaccine. SARS-CoV-2 IgG was tested, and the interval time between the last dose and humoral response test ranged from <1 to 8 months. The complications after SARS-CoV-2 vaccines were recorded. RESULTS: A total of 115 participants at least received one dose of SARS-CoV-2 vaccines with a 67.0% IgG-positive rate. Among them, 98 cases had completed vaccination, and the positivity of SARS-CoV-2 IgG antibodies was 96% (24/25) with three doses of ZF2001. SARS-CoV-2 IgG antibodies' positivity was 63.0% (46/73) of two doses of CoronaVac or BBIBP-CorV vaccine. Additionally, after 4 months of the last-dose vaccination, the IgG-positive rate (31.6%, 6/19) significantly decreased in thyroid cancer patients. The IgG-positive rate (81.0%, 64/79) was satisfactory within 3 months of the last-dose vaccination. Ten (10.2%) patients had side effects after SARS-CoV-2 vaccination. Among them, two (2.0%) patients had a fever, five (5.1%) patients had injection site pain, one (1.0%) patient felt dizzy, and one patient felt dizzy and had injection site pain at the same time. CONCLUSION: SARS-CoV-2 vaccines (CoronaVac, BBIBP-CorV, and ZF2001) are safe in thyroid cancer patients. The regression time of SARS-CoV-2 IgG is significantly shorter in thyroid cancer patients than in healthy adults. Therefore, a booster vaccination dose may be earlier than the systematic strategy for thyroid cancer patients.

Central Nervous System Demyelination Following COVID-19 mRNA-Based Vaccination: Two Case Reports and Literature Review. As the world embarks on mass vaccination against SARS-CoV2 to alleviate the spread of this highly contagious novel coronavirus, there are growing anecdotal reports on immune-related neurological complications following immunisation. Similarly, we encountered 2 cases of central nervous system demyelination at our centre with Comirnaty (BNT162b2), a mRNA-based COVID-19 vaccine. Our first patient had typical clinical-radiological manifestations of acute disseminated encephalomyelitis (ADEM) after his COVID-19 vaccination. This was the sixth reported case to date. Our second patient presented with an unusual complaint of trigeminal neuralgia, with an identifiable demyelinating lesion observed in the pons on neuroimaging. Both cases responded well to immunotherapy. However, larger prospective controlled studies and formal registries are much needed to ascertain a possible relationship between COVID-19 vaccines and acute central nervous system demyelination.

Progression from palindromic rheumatism to rheumatoid arthritis after COVID-19 vaccination. Infections including COVID-19 infection are associated with immune overactivation and hyperinflammation, and cases of incident inflammatory arthritis after COVID-19 and other respiratory viral infections have been reported. Theoretical concerns of autoimmunity due to molecular mimicry exist with vaccines including vaccines for COVID-19, and rare cases of flares of underlying chronic inflammatory disorders such as systemic lupus erythematosus have been reported after COVID-19 vaccination. Here we present the case of a patient with a 7-year history of well-controlled palindromic rheumatism who developed rheumatoid arthritis 2 weeks after vaccination for COVID-19. This is the first such case to our knowledge, and further studies can elaborate on the risk of autoimmunity due to COVID-19 vaccines if one exists. Given the overall safety and efficacy of COVID-19 vaccines, the proven benefits of vaccinating vulnerable patients with autoimmune disorders outweigh this potential theoretical risk of autoimmune disease flare, and vaccinations in this at-risk population shall be strongly encouraged.

Misuse of Antipyretic Amid Fear of COVID-19 Vaccine. The COVID-19 vaccination campaign is going on in Nepal through different phases of immunisation. It has been observed that people are misusing antipyretics and analgesics with the fear of adverse events following immunisation. The possibility of antipyretics and analgesics blunting the antibody response of the human body can be a potential cause for lower immune response and thus a reason for lower efficacy of the vaccine. Prophylactic use of over-the-counter analgesics and antipyretics is to be discouraged until the data

for or against its use is available. KEYWORDS: antipyretics; COVID-19 vaccine; drug misuse; vaccine immunogenicity.

Seroprevalence of SARS-CoV-2 IgG Antibodies and Factors Associated with SARS-CoV-2 IgG Neutralizing Activity among Primary Health Care Workers 6 Months after Vaccination Rollout in France. We aimed to investigate the immunoglobulin G response and neutralizing activity against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) among primary health care workers (PHCW) in France and assess the association between the neutralizing activity and several factors, including the coronavirus disease 2019 (COVID-19) vaccination scheme. A cross-sectional survey was conducted between 10 May 2021 and 31 August 2021. Participants underwent capillary blood sampling and completed a questionnaire. Sera were tested for the presence of antibodies against the nucleocapsid (N) protein and the S-1 portion of the spike (S) protein and neutralizing antibodies. In total, 1612 PHCW were included. The overall seroprevalences were: 23.6% (95% confidence interval (CI) 21.6-25.7%) for antibodies against the N protein, 94.7% (93.6-95.7%) for antibodies against the S protein, and 81.3% (79.4-83.2%) for neutralizing antibodies. Multivariate regression analyses showed that detection of neutralizing antibodies was significantly more likely in PHCW with previous SARS-CoV-2 infection than in those with no such history among the unvaccinated (odds ratio (OR) 16.57, 95% CI 5.96-59.36) and those vaccinated with one vaccine dose (OR 41.66, 95% CI 16.05-120.78). Among PHCW vaccinated with two vaccine doses, the detection of neutralizing antibodies was not significantly associated with previous SARS-CoV-2 infection (OR 1.31, 95% CI 0.86-2.07), but was more likely in those that received their second vaccine dose within the three months before study entry than in those vaccinated more than three months earlier (OR 5.28, 95% CI 3.51-8.23). This study highlights that previous SARS-CoV-2 infection and the time since vaccination should be considered when planning booster doses and the design of COVID-19 vaccine strategies.

COVID-19 Vaccination Might Induce Reversible Cerebral Vasoconstriction Syndrome Attacks: A Case Report. A 30-year-old male diagnosed three years previously with reversible cerebral vasoconstriction syndrome (RCVS) presented to the department of neurology with an accumulation of attacks mimicking previous RCVS attacks and fulfilling the diagnostic criteria for RCVS after receiving the first Pfizer COVID-19 vaccine. The neurologic exam, blood samples, electrocardiogram (ECG), and computer tomography of the head (CTC) were normal. The patient was treated with the angiotensin 2 receptor antagonist, losartan, with a good response and was discharged with a prescription for losartan lasting until three days after the second Pfizer COVID-19 vaccine. No further RCVS attacks were reported. These findings indicate that the COVID-19 vaccine might induce RCVS attacks in susceptible individuals, and targeting the angiotensin 2 receptor could be a preventive option.

Dose-Dependent Impairment of the Immune Response to the Moderna-1273 mRNA Vaccine by Mycophenolate Mofetil in Patients with Rheumatic and Autoimmune Liver Diseases. The purpose of this study was to evaluate the efficacy and safety of the Moderna-1273 mRNA vaccine for SARS-CoV-2 in patients with immune-mediated diseases under different treatments. Anti-trimeric spike protein antibodies were tested in 287 patients with rheumatic or autoimmune diseases (10% receiving mycophenolate mofetil, 15% low-dose glucocorticoids, 21% methotrexate, and 58% biologic/targeted synthetic drugs) at baseline and in 219 (76%) 4 weeks after the second Moderna-1273 mRNA vaccine dose. Family members or caretakers were enrolled as the controls. The neutralizing serum activity against SARS-CoV-2-G614, alpha, and beta variants in vitro and the cytotoxic T cell response to SARS-CoV-2 peptides were determined in a subgroup of patients and controls. Anti-SARS-CoV-2 antibody development, i.e., seroconversion, was observed in 69% of the mycophenolate-treated patients compared to 100% of both the patients taking other treatments and the controls ($p < 0.0001$). A dose-dependent impairment of the humoral response was observed in

the mycophenolate-treated patients. A daily dose of >1 g at vaccination was a significant risk factor for non-seroconversion (ROC AUC 0.89, 95% CI 0.80âˆ’98, p < 0.0001). Moreover, in the seroconverted patients, a daily dose of >1 g of mycophenolate was associated with significantly lower anti-SARS-CoV-2 antibody titers, showing slightly reduced neutralizing serum activity but a comparable cytotoxic response compared to other immunosuppressants. In non-seroconverted patients treated with mycophenolate at a daily dose of >1 g, the cytotoxic activity elicited by viral peptides was also impaired. Mycophenolate treatment affects the Moderna-1273 mRNA vaccine immunogenicity in a dose-dependent manner, independent of rheumatological disease.

Association of Cerebral Venous Thrombosis with mRNA COVID-19 Vaccines: A Disproportionality Analysis of the World Health Organization Pharmacovigilance Database. Cerebral venous thrombosis (CVT), a rare thrombotic event that can cause serious neurologic deficits, has been reported after some ChAdOx1 nCoV-19 vaccinations against coronavirus disease 2019 (COVID-19). However, there are few reports of associations between COVID-19 mRNA vaccination and CVT. We retrospectively analyzed CVT occurrence, time of onset after vaccination, outcomes (recovered/not recovered), and death after COVID-19 vaccination from adverse drug reactions (ADR) reports in VigiBase. A disproportionality analysis was performed regarding COVID-19 mRNA vaccines (BNT162b2 and mRNA-1273) and the ChAdOx1 nCoV-19 vaccine. We identified 756 (0.07%) CVT cases (620 (0.05%) after BNT162b2 and 136 (0.01%) after mRNA-1273) of 1,154,023 mRNA vaccine-related ADRs. Significant positive safety signals were noted for COVID-19 mRNA vaccines (95% lower end of information component = 1.56; reporting odds ratio with 95% confidence interval (CI) = 3.27). The median days to CVT onset differed significantly between the BNT162b2 and ChAdOx1 nCoV-19 vaccines (12 (interquartile range, 3âˆ’22) and 11 (interquartile range, 7âˆ’16), respectively; p = 0.02). Fewer CVT patients died after receiving mRNA vaccines than after receiving the ChAdOx1 nCoV-19 vaccine (odds ratio, 0.32; 95% CI, 0.22âˆ’0.45; p < 0.001). We noted a potential safety signal for CVT occurrence after COVID-19 mRNA vaccination. Therefore, awareness about the risk of CVT, even after COVID-19 mRNA vaccination, is necessary.

Increased Influenza Vaccination Coverage among Members of the Athens Medical Association Amidst COVID-19 Pandemic. Healthcare workers are at high risk of influenza virus infection as well as of transmitting the infection to vulnerable patients who may be at high risk of severe illness. The aim of this cross-sectional study was to investigate the prevalence and related factors of influenza vaccination coverage (2020-2021flu season), among members of the Athens Medical Association in Greece. This survey employed secondary analysis data from a questionnaire-based dataset on COVID-19 vaccination coverage and associated factors from surveyed doctors, registered within the largest medical association in Greece. All members were invited to participate in the anonymous online questionnaire-based survey over the period of 25 February to 13 March 2021. Finally, 1993 physicians (60% males; 40% females) participated in the study. Influenza vaccination coverage was estimated at 76%. Logistic regression analysis demonstrated that older age (OR = 1.02; 95% C.I. = 1.01-1.03), history of COVID-19 vaccination (OR = 2.71; 95% C.I. = 2.07-3.56) and perception that vaccines in general are safe (OR = 16.49; 95% C.I. = 4.51-60.25) were found to be independently associated factors with the likelihood of influenza vaccination coverage. Public health authorities should maximize efforts and undertake additional actions in order to increase the percentage of physicians/health care workers (HCWs) being immunized against influenza. The current COVID-19 pandemic offers an opportunity to focus on tailored initiatives and interventions aiming to improve the influenza vaccination coverage of HCWs in a spirit of synergy and cooperation.

The SARS-CoV-2 Variant Omicron Is Able to Escape Vaccine-Induced Humoral Immune Responses, but Is Counteracted by Booster Vaccination. The SARS-CoV-2 variant Omicron has spread world-wide and is responsible for rapid increases in infections, including in populations with high vaccination

rates. Here, we analysed in the sera of vaccinated individuals the antibody binding to the receptor-binding domain (RBD) of the spike protein and the neutralization of wild-type (WT), Delta (B.1.617.2), and Omicron (B.1.1.529; BA.1) pseudotyped vectors. Although sera from individuals immunized with vector vaccines (Vaxzevria; AZ and COVID-19 Janssen, Ad26.COV2.S; J&J) were able to bind and neutralize WT and Delta, they showed only background levels towards Omicron. In contrast, mRNA (Comirnaty; BNT) or heterologous (AZ/BNT) vaccines induced weak, but detectable responses against Omicron. While RBD-binding antibody levels decreased significantly six months after full vaccination, the SARS-CoV-2 RBD-directed avidity remained constant. However, this still coincided with a significant decrease in neutralization activity against all variants. A third booster vaccination with BNT significantly increased the humoral immune responses against all tested variants, including Omicron. In conclusion, only vaccination schedules that included at least one dose of mRNA vaccine and especially an mRNA booster vaccination induced sufficient antibody levels with neutralization capacity against multiple variants, including Omicron.

Factors Associated with COVID-19 Vaccine Acceptance in Morocco: Applying the Health Belief Model. To identify factors that influenced Moroccans' intention to get a COVID-19 vaccine, a cross-sectional survey among a Moroccan sample was conducted based on Health Belief Model constructs. Participants' sociodemographic characteristics, perceived susceptibility, perceived severity, perceived barriers, perceived benefits, self-efficacy, cues to action, and intention to receive vaccine data were collected and analyzed using a structural equation model (SEM). The survey was completed by 3800 individuals; 57.2% were men, 44.5% were aged 30 to 44, and 44.6% were married. After controlling for confounders, being a woman and having a chronic disease were associated with higher acceptance of the COVID-19 vaccine. The strongest predictor for the intention of receiving a vaccine was participants who were married. Most of the HBM constructs were shown to be significantly associated with vaccine acceptance. Susceptibility and Benefits were the strongest predictors of acceptance of the COVID-19 vaccine (standardized path coefficient, SPC = 0.23), followed by Severity (SPC = 0.22). Conversely, given the negative correlation between barriers and intention (SPC = -0.08), it is necessary to maintain a high level of transparency regarding the vaccines' safety. Our study provides guidance for an implementation of vaccination strategies, intending to bolster the overall COVID-19 immunization program.

Probable Vogt-Koyanagi-Harada Disease after COVID-19 Vaccination: Case Report and Literature Review. COVID-19 vaccination is considered the most effective and promising approach for the elimination of the SARS-CoV-2 pandemic globally. Although the vaccine has been proven to be safe, as evidenced by the promotion of mass vaccination, new side effects, including several ocular complications that were not described during the experimental stage, are now emerging. In the present study, we report a 33-year-old Chinese man who developed probable Vogt-Koyanagi-Harada (VKH) disease only one day after his first dose of an inactivated COVID-19 vaccine, without any systemic symptoms. His medical history was unremarkable, except for hypertension. Although successfully relieved by oral prednisone, the patient progressed to the chronic stage of VKH disease with ocular depigmentation 4 months after onset. By reviewing similar cases previously reported, we discuss and summarize the common characteristics of VKH disease associated with vaccines against SARS-CoV-2, as well as the possible mechanisms behind this phenomenon. Although the causality is unclear, ophthalmologists and generalists should be aware of this possible ocular adverse effect after COVID-19 vaccination.

Association of Impaired Fasting Glucose and Diabetes with SARS-CoV-2 Spike Antibody Titers after the BNT162b2 Vaccine among Health Care Workers in a Tertiary Hospital in Japan. Background: Hyperglycemia can alter the activation of innate and acquired immunity, but epidemiological evidence linking hyperglycemia to post-vaccination immunogenicity is limited. Objective: To examine

the association between SARS-CoV-2 spike antibody titers after the COVID-19 vaccine and impaired fasting glucose (IFG) and diabetes. Methods: Participants were 953 health care workers aged 21âˆ’75 years who were tested for SARS-CoV-2 spike IgG antibodies and underwent a health checkup two months after their second dose of the BNT162b2 vaccine. IFG was defined as a fasting plasma glucose (FPG) level of 100âˆ’125 mg/dL, and diabetes was defined as an FPG level â‰¥ 126 mg/dL or being under medical care for diabetes. Multivariable linear regression was used to calculate the ratio of the mean. Result: Spike IgG antibody titers were lower in the presence of hyperglycemia; the ratios of the means (95% CI) were 1.00, 0.79 (0.60âˆ’1.04), and 0.60 (0.42âˆ’0.87) for individuals with normoglycemia, IFG, and diabetes, respectively (p trend < 0.001). Restricted cubic spline regression analysis showed that IgG spike antibody titers decreased linearly with increasing concentrations of FPG. Conclusion: Diabetes and, to a lesser extent, IFG may be associated with poor humoral immune response after BNT162b2 vaccination.

Course of Fecal Calprotectin after mRNA SARS-CoV-2 Vaccination in Patients with Inflammatory Bowel Diseases. BACKGROUND: Two years into the pandemic, vaccination remains the most effective option to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Preliminary studies suggest vaccination efficacy in patients with inflammatory bowel diseases (IBD), but little is known about its impact on chronic intestinal inflammation. Here we assessed the mucosal inflammatory activity in patients with IBD before and after immunization with the mRNA-1273 (Moderna) vaccine by measurement of fecal calprotectin (fCP). METHODS: In 42 patients with IBD, the baseline fCP levels obtained prior to the first vaccine were compared with the highest levels measured during and after two doses of vaccination. Patients' sera were collected after the second dose to evaluate anti-SARS-CoV-2 antibodies' titers. RESULTS: We observed a significant fCP elevation in 31% of patients after any dose. Vedolizumab was identified as the only agent associated with an fCP increase (OR 12.4, 95% CI [1.6; 120.2], p = 0.0171). Gastrointestinal adverse events were reported in 9.5% of all subjects and in 75% of cases accompanied by an fCP increase. Anti-SARS-CoV-2 antibodies associated only weakly with the fCP increase after the first dose (p = 0.04). CONCLUSIONS: Our findings support possible collinearity in pathways of SARS-CoV-2 antigen expression and the pathogenesis of IBD.

Frequency and Nuisance Level of Adverse Events in Individuals Receiving Homologous and Heterologous COVID-19 Booster Vaccine. This study aimed to compare the occurrence and nuisance of adverse events following administration of each COVID-19 vaccine dose between two groups: individuals given three doses of mRNA vaccine (homologous group, 3 Ã— mRNA, n = 252) and those given two doses of adenoviral vector vaccine further boosted with mRNA vaccine (heterologous group, 2 Ã— AZ + 1 Ã— mRNA, n = 205). Although the studied groups differed significantly in the frequency and number of side effects after the first and second vaccine dose, no relevant differences were seen following the booster administration. Arm pain and fatigue were the most common effects, regardless of the vaccination group and vaccine dose. In the homologous group, female sex, lower BMI, and no history of regular influenza vaccination were associated with a higher frequency of side effects of a booster dose. In the heterologous group, the history of COVID-19 was associated with an increased number of side effects seen after a booster. In both groups, the number of side effects related to the first and second dose correlated with the number observed after administration of a booster dose. Individuals receiving a homologous booster reported a higher nuisance of side effects than the heterologous group. It was similar to the level reported after the second dose in both groups. The use of pharmaceuticals to counteract the side effects was more frequent after a first dose in the 2 Ã— AZ + 1 Ã— mRNA group, but higher after second dose in individuals receiving the 3 Ã— mRNA vaccination scheme. The frequency of pharmaceutical use after a booster dose was similar in both groups (approx. 60%). Paracetamol was most frequently chosen, regardless of the group and

vaccine dose. In addition, the vast majority of participants (93%) declared to accept future doses of the COVID-19 vaccine if their administration would be recommended. This study provides an overview of the response to homologous and heterologous mRNA vaccine booster dose that may be valuable in shaping accurate and honest communication with vaccinated individuals, especially in those regions which are yet to pursue booster strategies.

Significant Increase in Blood Pressure Following BNT162b2 mRNA COVID-19 Vaccination among Healthcare Workers: A Rare Event. This brief report examined the frequency and characteristics of a significant blood-pressure (BP) increase after Pfizer-BioNTech BNT162b2 vaccination among healthcare workers who were advised to measure their BP at home. A total of 797 participants (mean age 48.1 Â± 10.8 years, 63% women, 39% smokers) were included in the analysis. Seven participants reported an increase in their BP (three in the range of grade 2 and four in the range of grade 3 hypertension). Only one participant had a history of treated hypertension. The BP increase was observed at the end of the first week after the first dose, lasted for 3 to 4 days, and recurred promptly after the second dose. Only one case required hospitalization, mainly due to a history of cardiovascular disease (follow-up). Individuals experiencing a BP increase compared with those not reporting issues with their BP had a higher mean age and similar distribution of sex and non-smoking status. In conclusion, a significant BP increase after Pfizer-BioNTech vaccination seems to be rare and of a benign and transient nature. Monitoring the BP before and after vaccination might be advisable only for selected individuals with a high cardiovascular risk.

Anti-SARS-CoV-2S Antibody Levels in Healthcare Workers 10 Months after the Administration of Two BNT162b2 Vaccine Doses in View of Demographic Characteristic and Previous COVID-19 Infection. Antibody levels that confer full protection against SARS-CoV-2 infection after the administration of different vaccine brands as well as the factors influencing the humoral immune response have been analyzed extensively ever since the vaccination program was launched in late 2020. The aim of this study was to determine anti-SARS-CoV-2S antibody titers in 100 healthcare workers 10 months after the administration of two BNT162b2 vaccine doses, and to investigate the influence of demographic characteristics, the presence of comorbidities and history of COVID-19 infection. The results were compared with antibody levels that were determined eight months after the administration of two BNT162b2 vaccine doses in our previous study. Antibody levels in venous blood serum were measured by the ECLIA method with the use of the Roche Cobas e411 analyzer. In all tested subjects, antibody titers remained high 10 months after vaccination, particularly in recovered COVID-19 patients, and only a minor decrease was observed relative to the values noted two months earlier.

New-Onset Acute Kidney Disease Post COVID-19 Vaccination. The coronavirus disease 2019 (COVID-19) pandemic, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has caused an exceptional setback to the global economy and health. Vaccination is one of the most effective interventions to markedly decrease severe illness and death from COVID-19. In recent years, there have been increasingly more reports of new acute kidney injury (AKI) after COVID-19 vaccination. Podocyte injury, IgA nephropathy, vasculitis, tubulointerstitial injury, and thrombotic microangiopathy appear to be the main pathological phenotypes. Nonetheless, whether the link between the COVID-19 vaccine and acute kidney disease (AKD) is causal or coincidental remains to be verified. Here, we generalize some hypotheses for the emergence of AKD and its pathogenesis in response to certain COVID-19 vaccines. In fact, the enormous benefits of mass vaccination against COVID-19 in preventing COVID-19 morbidity and mortality cannot be denied. The purpose of this review is to assist in the clinical assessment and management of AKD following COVID-19 vaccination.

Adverse Mentions, Negative Sentiment, and Emotions in COVID-19 Vaccine Tweets and Their Association with Vaccination Uptake: Global Comparison of 192 Countries. Background: Many countries show low COVID-19 vaccination rates despite high levels of readiness and delivery of

vaccines. The public's misperceptions, hesitancy, and negative emotions toward vaccines are psychological factors discouraging vaccination. At the individual level, studies have revealed negative perceptual/behavioral outcomes of COVID-19 information exposure via social media where misinformation and vaccine fear flood. Objective: This study extends research context to the global level and investigates social media discourse on the COVID-19 vaccine and its association with vaccination rates of 192 countries in the world. Methods: COVID-19 vaccine tweets were compared by country in terms of (1) the number per million Twitter users, (2) mentions of adverse events-death, side-effects, blood clots, (3) negative sentiment (vs. positive), and (4) fear, sadness, or anger emotions (vs. joy). Artificial intelligence (AI) was adopted to classify sentiment and emotions. Such tweets and covariates (COVID-19 morbidity and mortality rates, GDP, population size and density, literacy rate, democracy index, institutional quality, human development index) were tested as predictors of vaccination rates in countries. Results: Over 21.3 million COVID-19 vaccine tweets posted between November 2020 and August 2021 worldwide were included in our analysis. The global average of COVID-19 vaccine tweets mentioning adverse events was 2% for 'death', 1.15% for 'side-effects', and 0.80% for 'blood clots'. Negative sentiment appeared 1.90 times more frequently than positive sentiment. Fear, anger, or sadness appeared 0.70 times less frequently than joy. The mention of 'side-effects' and fear/sadness/anger emotions appeared as significant predictors of vaccination rates, along with the human development index. Conclusions: Our findings indicate that global efforts to combat misinformation, address negative emotions, and promote positive languages surrounding COVID-19 vaccination on social media may help increase global vaccination uptakes.

New Onset of Eosinophilic Granulomatosis with Polyangiitis Following mRNA-Based COVID-19 Vaccine. Anti-SARS-CoV-2 vaccines are safe and effective, also in individuals with allergic and immune-mediated diseases (IMDs). There are reports suggesting that vaccines may be able to trigger de-novo or exacerbate pre-existing IMDs in predisposed individuals. Eosinophilic granulomatosis with polyangiitis (EGPA) is a small-vessel vasculitis characterized by asthma, eosinophilia, and eosinophil-rich granulomatous inflammation in various tissues. We describe the case of a 63-year-old man who experienced cardiac, pulmonary, and neurological involvement one day after the administration of the booster dose of anti-SARS-CoV-2 vaccine (mRNA-1273). A diagnosis of EGPA was made and the patient was treated with high-dose steroids and cyclophosphamide, with a good clinical response. Interestingly, our patient had experienced a significant worsening of his pre-existing asthma six months earlier, just after the first two vaccine shots with the ChAdOx1 anti-SARS-CoV-2 vaccine. It is impossible to know whether our patient would have had developed EGPA following natural SARS-CoV-2 infection or at some point in his life regardless of infectious stimuli. Nevertheless, our report may suggest that caution should be paid during the administration of additional vaccine doses in individuals who experienced an increase in IMD severity that persisted over time following previous vaccine shots.

Association of Current Active Illnesses and Severe Acute Kidney Injury after COVID-19 Vaccines: A Real-World Study. The administration of COVID-19 vaccines has become increasingly essential to curb the pandemic. However, adverse events of acute kidney injury (AKI) emerge rapidly as the COVID-19 vaccination promotes. To investigate the intervenable risk factors of AKI, we searched the Vaccine Adverse Event Reporting System database and recorded adverse effects after COVID-19 vaccines from Dec 2020 to Jun 2021. We included 1149 AKI cases, of which 627 (54.6%) cases were reported following the Pfizer-BNT COVID-19 vaccine, and 433 (37.7%) were reported after the Moderna vaccine. A univariate analysis revealed that coexisting active illnesses (infections, uncontrolled hypertension, heart failure, etc.) have an unfavorable prognosis, with an increased risk of death (OR 2.35, 95% CI 1.70â˜’3.25, $p < 0.001$). The other risk factors included older age and past disease histories. An adjusted regression analysis proved that coexisting active illnesses worsen AKI

prognosis after COVID-19 vaccination, with a higher mortality risk (OR 2.19, 95% CI 1.48âˆ’3.25, p < 0.001). In subgroup analysis, we stratified different variables, and none revealed a significant effect modification on the association between coexisting active illnesses and AKI-associated death after vaccination (p-interaction >0.05). We found that coexisting active illnesses could complicate AKI after vaccines, but the potential causal relationship needed further investigation.

Cardiac Adverse Events after Vaccination-A Systematic Review. The Vaccine Adverse Event Reporting System database has been used to report adverse events following several vaccines. We studied the patient population predisposed to such reactions and how these reactions differ with respect to the vaccine type. We searched the electronic databases PubMed, EMBASE, and Scopus up to 9 July 2021 for any study describing cardiac adverse events attributed to the vaccination. A total of 56 studies met the criteria comprising 340 patients. There were 20 studies describing cardiac adverse events following smallpox vaccination, 11 studies describing adverse events after influenza vaccination, and 18 studies describing adverse events after COVID-19 vaccination. There was a total of six studies describing cardiac adverse events after the pneumococcal vaccine, tetanus toxoid, cholera vaccine, and rabies vaccine. Adverse events following influenza vaccination occurred more commonly in older females within an average duration of four days from vaccination. Pericardial involvement was the most reported adverse event. Adverse events following COVID-19 vaccination happened at a mean age of 42.7 years, more commonly in males, and mostly after a second dose. Adverse events following smallpox vaccination occurred more commonly in younger males, with an average onset of symptoms from vaccination around 16.6 days. Adverse events were mostly myopericarditis; however, the acute coronary syndrome has been reported with some vaccines.

SARS-CoV-2 Antibody and T Cell Response after a Third Vaccine Dose in Hemodialysis Patients Compared with Healthy Controls. Hemodialysis (HD) patients have an increased risk of severe SARS-CoV-2 infection. In this study, we assess the impact of a third vaccine dose (3D) on antibody levels and T cell response in HD patients and a healthy control group in a prospective cohort study consisting of 60 HD patients and 65 healthy controls. Each participant received two doses of the BNT-162b2 mRNA vaccine and an mRNA vaccine 3D. The SARS-CoV-2 antibody response was measured 6 months after the second vaccine dose and 6 to 8 weeks after the 3D. We assessed INF-Î³ secretion 6-8 weeks post 3D in 24 healthy controls, 17 HD patients with a normal response, and 20 low responder HD patients. The groups were compared using univariate quantile regressions and multiple analyses. After the 3D, the SARS-CoV-2-specific antibody and INF-Î³ titers of most HD patients were comparable to those of healthy controls. A subgroup of HD patients who had shown a diminished antibody response after the first two vaccine doses developed a significantly lower antibody and INF-Î³ response compared to responder HD patients and controls even after the 3D. A new strategy is needed to protect low/non-responder HD patients from severe SARS-CoV-2 infection.

A Vaccine Construction against COVID-19-Associated Mucormycosis Contrived with Immunoinformatics-Based Scavenging of Potential Mucoralean Epitopes. Mucormycosis is a group of infections, caused by multiple fungal species, which affect many human organs and is lethal in immunocompromised patients. During the COVID-19 pandemic, the current wave of mucormycosis is a challenge to medical professionals as its effects are multiplied because of the severity of COVID-19 infection. The variant of concern, Omicron, has been linked to fatal mucormycosis infections in the US and Asia. Consequently, current postdiagnostic treatments of mucormycosis have been rendered unsatisfactory. In this hour of need, a preinfection cure is needed that may prevent lethal infections in immunocompromised individuals. This study proposes a potential vaccine construct targeting mucor and rhizopus species responsible for mucormycosis infections, providing immunoprotection to immunocompromised patients. The vaccine construct, with an antigenicity score of 0.75 covering, on average, 92-98% of the world population, was designed using an immunoinformatics approach.

Molecular interactions with major histocompatibility complex-1 (MHC-I), Toll-like receptors-2 (TLR2), and glucose-regulated protein 78 (GRP78), with scores of -896.0, -948.4, and -925.0, respectively, demonstrated its potential to bind with the human immune receptors. It elicited a strong predicted innate and adaptive immune response in the form of helper T (Th) cells, cytotoxic T (TC) cells, B cells, natural killer (NK) cells, and macrophages. The vaccine cloned in the pBR322 vector showed positive amplification, further solidifying its stability and potential. The proposed construct holds a promising approach as the first step towards an antimucormycosis vaccine and may contribute to minimizing postdiagnostic burdens and failures.

Dual-Positive MPO- and PR3-ANCA-Associated Vasculitis Following SARS-CoV-2 mRNA Booster Vaccination: A Case Report and Systematic Review. As the coronavirus disease 2019 (COVID-19) pandemic is ongoing, and new variants of severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) are emerging, vaccines are needed to protect individuals at high risk of complications and to potentially control disease outbreaks by herd immunity. After SARS-CoV-2 vaccination, antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) presenting with a pulmonary hemorrhage has been described. Previous studies suggested that monocytes upregulate major histocompatibility complex (MHC) II cell surface receptor human leukocyte antigen receptor (HLA-DR) molecules in granulomatosis with polyangiitis (GPA) patients with proteinase 3 (PR3)- and myeloperoxidase (MPO)-ANCA seropositivity. Here, we present a case of new-onset AAV after booster vaccination with the Pfizer-BioNTech SARS-CoV-2 mRNA vaccine. Moreover, we provide evidence that the majority of monocytes express HLA-DR in AAV after SARS-CoV-2 booster vaccination. It is possible that the enhanced immune response after booster vaccination and presence of HLA-DR(+) monocytes could be responsible for triggering the production of the observed MPO- and PR3-ANCA autoantibodies. Additionally, we conducted a systematic review of de novo AAV after SARS-CoV-2 vaccination describing their clinical manifestations in temporal association with SARS-CoV-2 vaccination, ANCA subtype, and treatment regimens. In light of a hundred million individuals being booster vaccinated for SARS-CoV-2 worldwide, a potential causal association with AAV may result in a considerable subset of cases with potential severe complications.

Blood Antibody Titers and Adverse Reactions after BNT162b2 mRNA Vaccination. This study aimed to measure, considering a prior history of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection (SCV-negative/positive), antibodies titer using Elecsys Anti-SARS-CoV-2 S immunoassay (Roche Diagnostics, Mannheim, Germany), in a serum of healthcare workers (HCW) who received two doses of BNT162b2 vaccines. The local and systemic adverse reactions occurrence was checked with a self-reported questionnaire. A total of 60 SCV-negative HCW showed lower antibody titers than those presented by SCV-positive subjects (n = 7). The highest antibody level was detected 8 days after the second dose of vaccine administration. At the same time, the titer was higher in the SCV2 -positive than the SCV2-negative group and comparable after the first dose in those who became infected to the level after the second dose of those who did not. The local and systemic effects in the SCV2-negative and SCV2-positive groups appeared independent of the vaccine dose. After the second dose, systemic reactions were reported more often than the local adverse effects. Whether no effect was observed or whether the response was local or systemic, the antibody level in a specific group remains constant. These results can be helpful in the improvement of vaccination programs, controlling the occurrence of adverse and long-term effects of the vaccination.

Clinical and Laboratory Features in the Israeli Population with COVID-19 Infection after Pfizer-BioNTech mRNA Booster Vaccination. Background: Immune protection following either vaccination or infection with SARS-CoV-2 decreases over time. Objective: We aim to describe clinical and sociodemographic characteristics associated with COVID-19 infection at least 14 days after booster vaccination in the Israeli population. Methods: We conducted a population-based study

among adult members of Leumit Health Services (LHS) in Israel. Nasopharyngeal swabs were examined for SARS-CoV-2 by real-time RT-PCR. The hematological and biochemical parameters in the peripheral blood before booster vaccination were evaluated. Results: Between 1 February 2021 and 30 November 2021, 136,683 individuals in LHS were vaccinated with a booster (third dose) of the BNT162b2 vaccine. Of these, 1171 (0.9%) were diagnosed with COVID-19 by testing positive for SARS-CoV-2 RT-PCR at least >14 days after the booster vaccination. The COVID-19-positive group was characterized by higher rates of chronic kidney disease than the matched COVID-19-negative group (43 (3.7%) vs. 3646 (2.7%); p = 0.039). Anemia, lower peripheral blood lymphocytes, monocytes, basophils, C3 Complement, cholesterol, and prothrombin time were also associated with COVID-19 after booster vaccination. Conclusion: People with chronic kidney disease and anemia should be included in possible future annual SARS-CoV-2 vaccination recommendations.

Persistence of Anti SARS-CoV-2 Antibodies in Breast Milk from Infected and Vaccinated Women after In Vitro-Simulated Gastrointestinal Digestion. Breastfeeding is key for infant development and growth. Breast milk contains different bioactive compounds including antibodies. Recent studies have demonstrated the presence of breast milk SARS-CoV-2 antibodies after maternal infection and vaccination. However, the potential impact on the infant has not been explored yet. As a first step, we aimed at assessing the potential persistence of SARS-CoV-2 IgA and IgG antibodies from infected and vaccinated women in the gastrointestinal tract of the infants by means of an in vitro-simulated gastrointestinal digestion approach. Breast milk samples from 10 lactating women receiving mRNA vaccination against SARS-CoV-2 (n = 5 with BNT162b2 mRNA and n = 5 with mRNA-1273) and also, COVID-19 infected (n = 5) were included. A control group with women with no exposure to the virus (n = 10 pre-pandemic) were also studied. The presence of IgA and IgG SARS-CoV-2 antibody levels was determined by ELISA after the gastric and intestinal stages. The impact of digested antibodies on infant gut microbiota was tested by simulating colonic fermentation with two different fecal inoculums: infants from vaccinated and non-vaccinated mothers. Specific gut microbial groups were tested by targeted qPCR. In vitro infant gastrointestinal digestion significantly decreased the levels of both anti-SARS-CoV-2 IgA and IgG. However, both remained resistant in all the study groups except in that evaluating breast milk samples from infected women, in which IgG was degraded below the cut-off values in the intestinal phase. No effect of the antibodies on microbiota were identified after digestion. In conclusion, antibody levels against SARS-CoV-2 are reduced after in vitro-simulated gastrointestinal tract but remain present, so a positive biological effect could be expected from this infant immunization pathway.

SARS-CoV-2 Vaccine Alpha and Delta Variant Breakthrough Infections Are Rare and Mild but Can Happen Relatively Early after Vaccination. (1) Background: Some COVID-19 vaccine recipients show breakthrough infection. It remains unknown, which factors contribute to risks and severe outcomes. Our aim was to identify risk factors for SCoV2 breakthrough infections in fully vaccinated individuals. (2) Methods: We conducted a retrospective case-control study from 28 December 2020 to 25 October 2021. Data of all patients with breakthrough infection was compared to data of all vaccine recipients in the Canton of Basel-City, Switzerland. Further, breakthrough infections by Alpha- and Delta-variants were compared. (3) Results: Only 0.39% (488/126,586) of all vaccine recipients suffered from a breakthrough infection during the observational period, whereof most cases were asymptomatic or mild (97.2%). Breakthrough infections after full vaccination occurred in the median after 78 days (IQR 47-123.5). Factors with lower odds for breakthrough infection were age (OR 0.987) and previous COVID-19 infection prior to vaccination (OR 0.296). Factors with higher odds for breakthrough infection included vaccination with Pfizer/BioNTech instead of Moderna (OR 1.459), chronic disease (OR 2.109), and healthcare workers (OR 1.404). (4) Conclusions: Breakthrough infections are rare and mild but can occur early after vaccination. This implies that booster

vaccination might be initiated earlier, especially for risk groups. Due to new variants emerging repeatedly, continuous monitoring of breakthrough infections is crucial.

Late Onset of ANCA Vasculitis as a Side Effect of Levamisole Treatment in Nephrotic Syndrome. Levamisole is effectively used in steroid-dependent nephrotic syndrome and the more frequent side effects reported are cytopenia and liver enzymes alterations. Several studies have demonstrated that this drug can induce high titers of circulating perinuclear antineutrophil cytoplasmic autoantibodies (ANCA) and vasculitis, most of them occurring in the case of prolonged use. A four-year-old boy that was affected with steroid-dependent nephrotic syndrome was treated with Levamisole as a steroid-sparing agent at a dose of 2 mg/kg/48 h. After initiation of the treatment, the number of relapses drastically decreased, enabling a significant reduction in the cumulative steroid dose. Levamisole was well tolerated, and was therefore administered for several years. At the age of 15, he was also diagnosed with celiac disease. After nine years of continuous Levamisole treatment, he presented with a high fever, hand and foot joint arthritis, and increased levels of total and direct bilirubin. Since the symptoms started two days after the injection of the second dose of the COVID-19 vaccine, it was initially concluded that these manifestations were rare vaccination side effects. Therefore, he did not receive any specific treatments, and Levamisole was continued at the same dose. After an initial improvement, two months later, the patient presented with the same symptoms. Suspecting Levamisole-induced vasculitis, an ANCA titer was measured and this returned positive. Clinical manifestations and double positivity for both myeloperoxidase (MPO) and anti-proteinase 3 (PR3) antibodies argued against the fact that that these findings were secondary to vaccination, cocaine abuse, or celiac disease. Assuming that we were facing a rare drug reaction, Levamisole was promptly interrupted. This resulted in a rapid remission of fever and arthritis improvement, and a decrease in ANCA titers. By reporting this case, we want to raise awareness among clinicians regarding a rare complication of treatment with Levamisole that is often misdiagnosed due to the fact that the current literature lacks univocal guidelines regarding the precise timing of ANCA titrations and the duration of the treatment.

Impaired Humoral Immunity with Concomitant Preserved T Cell Reactivity in IBD Patients on Treatment with Infliximab 6 Month after Vaccination with the SARS-CoV-2 mRNA Vaccine BNT162b2: A Pilot Study. Introduction: The Coronavirus Disease 2019 (COVID-19) pandemic has been caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). The most important approach to prevent severe disease progression and to contain the pandemic is the use of COVID-19 vaccines. The aim of this study was to investigate the humoral and cellular response in immunosuppressed patients with inflammatory bowel disease (IBD) on treatment with anti-TNF (infliximab, adalimumab) and anti-Î±4Ã Ÿ7-Integrin (vedolizumab) 6 months after mRNA vaccination against SARS-CoV-2 compared to healthy subjects. Methods: In this prospective study, 20 IBD patients and 9 healthy controls were included 6 months after the second BNT162b2 vaccination. In addition to quantitative determination of IgG antibody levels against the SARS-CoV-2 receptor-binding domain (RBD) of the spike protein subunit S1, a SARS-CoV-2 surrogate neutralization test (sVNT) was used to assess potential neutralization capacity. SARS-CoV-2-specific T-cell responses were measured using an interferon-Î³ (IFN-Î³) release assay (IGRA; Euroimmun Medical Laboratory Diagnostics, LÃ¼beck, Germany). Results: S-IgG could still be detected in the majority of IBD patients 6 months after second vaccination. Compared to healthy controls, IBD patients treated with anti-TNF agents showed both lower neutralizing activity in sVNT (percent inhibition of ACE2 receptor binding by RBD protein) and lower IgG-S (AU/mL) antibody levels (AB) (sVNT: 79% vs. 2%, $p < 0.001$; AB: 1018 AU/mL vs. 141 AU/mL, $p = 0.025$). In contrast, patients on therapy with vedolizumab showed no impairment in humoral immune response (sVNT, S-IgG) compared with healthy controls. Specific T-cellular reactivity was detected in 73% of IBD patients and in 67% of healthy controls independent of

immunosuppressive therapy (anti-TNF., vedolizumab) (p = 0.189). Conclusion: Six months after BNT162b2 vaccination, this study found significantly decreased antibody levels in patients under anti-TNF therapy. IBD patients under anti-TNF and vedolizumab therapy had no impairment of T-cellular reactivity compared to healthy controls at this time point. Further studies with larger collectives for confirmation should follow.

Early Cellular and Humoral Responses Developed in Oncohematological Patients after Vaccination with One Dose against COVID-19. Individuals with oncohematological diseases (OHD) may develop an impaired immune response against vaccines due to the characteristics of the disease or to its treatment. Humoral response against SARS-CoV-2 has been described to be suboptimal in these patients, but the quality and efficiency of the cellular immune response has not been yet completely characterized. In this study, we analyzed the early humoral and cellular immune responses in individuals with different OHD after receiving one dose of an authorized vaccine against SARS-CoV-2. Humoral response, determined by antibodies titers and neutralizing capacity, was overall impaired in individuals with OHD, except for the cohort of chronic myeloid leukemia (CML), which showed higher levels of specific IgGs than healthy donors. Conversely, the specific direct cytotoxic cellular immunity response (DCC) against SARS-CoV-2, appeared to be enhanced, especially in individuals with CML and chronic lymphocytic leukemia (CLL). This increased cellular immune response, developed earlier than in healthy donors, showed a modest cytotoxic activity that was compensated by significantly increased numbers, likely due to the disease or its treatment. The analysis of the immune response through subsequent vaccine doses will help establish the real efficacy of COVID-19 vaccines in individuals with OHD.

Does COVID-19 Vaccination Cause Storage Lower Urinary Tract Symptoms? We investigated the storage lower urinary tract symptoms (LUTS) before and after the first dose of coronavirus disease 2019 (COVID-19) vaccine and the association between pre-vaccinated overactive bladder (OAB) and the worsening of storage LUTS following COVID-19 vaccination. This cross-sectional study in a third-level hospital in Taiwan used the validated pre- and post-vaccinated Overactive Bladder Symptom Score (OABSS). Diagnosis of OAB was made using pre-vaccinated OABSS. The deterioration of storage LUTS was assessed as the increased score of OABSS following vaccination. Of 889 subjects, up to 13.4% experienced worsened storage LUTS after vaccination. OAB was significantly associated with an increased risk of worsening urinary urgency ($p = 0.030$), frequency ($p = 0.027$), and seeking medical assistance due to urinary adverse events ($p < 0.001$) after vaccination. The OAB group faced significantly greater changes in OABSS-urgency ($p = 0.003$), OABSS-frequency ($p = 0.025$), and total OABSS ($p = 0.014$) after vaccination compared to those observed in the non-OAB group. Multivariate regression revealed that pre-vaccinated OAB ($p = 0.003$) was a risk for the deterioration of storage LUTS. In conclusion, storage LUTS may deteriorate after vaccination. OAB was significantly associated with higher risk and greater changes in worsening storage LUTS. Storage LUTS should be closely monitored after COVID-19 vaccination, especially in those OAB patients.

COVID-19 Vaccine-A Potential Trigger for MOGAD Transverse Myelitis in a Teenager-A Case Report and a Review of the Literature. MOGAD-transverse myelitis is a rare disorder in children and adults, but with a higher incidence in pediatric patients. We report a case of MOGAD-transverse myelitis in a boy who was admitted to hospital with bilateral motor deficit of the lower limbs associated with the impossibility of defecating and urinating. The symptoms progressively developed with severe fatigue within the week prior to admission, with the impossibility to stand occurring 36 h before admission. The anamnesis found that he was vaccinated for COVID-19 approximately 6 weeks before admission to our clinic. The laboratory tests revealed a normal complete cellular blood count, without any signs of inflammation or infection, except for both cryoglobulins and IgG anti-MOG antibodies. MRI showed a T2 hypersignal on vertebral segments C2-C5, Th2-Th5 and Th7-Th11,

confirming the diagnosis of longitudinally extensive transverse myelitis. The patient received intravenous high-dose methylprednisolone (1 g) for 5 days, associated with prophylactic antibiotic treatment, subcutaneous low-molecular-weight heparin and other supportive treatment. The patient was discharged on the 12th day of admission, able to walk without support and with no bladder or bowel dysfunction. We can conclude that an early diagnosis was essential for improving the patient's long-term outcome.

Cerebral Venous Thrombosis after SARS-CoV-2 Infection and Pfizer-BioNTech Vaccination against COVID-19. In the last 3 years, COVID-19 pandemic has produced great impacts on global population in terms of health and social costs. Pneumonia represents only one of several pathologies associated to COVID-19 disease. Among these, the cerebral venous thrombosis (CVT), constitutes an important cause of stroke. Here, we report a case of CVT diagnosed approximately 2 weeks after first dose of Pfizer-BioNTech vaccination, in a patient affected by COVID-19 few months earlier. He presented with headache and severe asthenia. The laboratory tests put in evidence thrombocytopenia and D-dimer elevation. A brain magnetic resonance imaging (MRI) and a computed tomography (CT) demonstrated hemorrhagic and ischemic phenomena on the right ventral thalamic nuclei, left thalamus, hippocampal and parahippocampal regions and the splenium of the corpus callosum. The study revealed a poorly opacified vein of Galeno and straight sinus. Heparin administration improved his clinical status; platelets values also arose over time.

Post-RNA (mRNA) Vaccination Myocarditis: CMR Features. RNA (mRNA) vaccines used to prevent COVID-19 infection may cause myocarditis. We describe a case of acute myocarditis in a 27-year-old male after receiving the second dose of a Pfizer immunization. Three days after receiving the second dose of vaccine, he had acute chest pain. Electrocardiographic examination revealed non-specific ST-T changes in the inferior leads. Troponin levels in his laboratory tests were 733 ng/L. No abnormalities were detected on his echocardiography or coronary angiography. The basal inferoseptal segment was hypokinetic. The LV EF was 50%, whereas the RV EF was 46%. Epicardial and mesocardial LGE were shown in the left ventricle's basal and mid anterolateral, posterolateral, and inferoseptal segments. The native T1 was 1265 Â± 54 ms, and the native T2 was 57 Â± 10 ms. Myocardial strain indicated that the baseline values for LV GLS (-14.55), RV GLS (-15.8), and RVCS (-6.88) were considerably lower. The diagnosis of acute myocarditis was determined based on the clinical presentation and cardiac magnetic resonance (CMR) findings.

COVID-19 Vaccination in Patients with Cancer. Patients with cancer are concerned about the effects of the COVID-19 vaccination. We conducted an online survey on the COVID-19 vaccination status and side effects among patients with cancer in Japan between 8 and 14 August 2021. We included 1182 female patients with cancer aged 20-70 years and registered on an online patient website. Of the patients, 944 had breast cancer, 216 had gynecological cancer, 798 were undergoing drug/radiation therapy, and 370 were in follow-up. At the time of the survey, 885 patients had already received at least one dose. Of these, 580 had also received their second dose. The incidence rate of side effects was equivalent to previous reports. In patients with breast cancer, problems such as the onset or worsening of lymphedema or axillary lymphadenopathy metastasis requiring differential diagnosis were encountered following vaccination. A total of 768 patients were concerned about the vaccine at some point, and 726 consulted with their attending physicians about the timing or side effects of the vaccination. Of the 110 patients undergoing chemotherapy or radiation therapy, 75 adjusted the timing of the vaccination based on their therapy. The cross-analysis revealed that 81% of those who consulted their physician had received at least one dose of the COVID-19 vaccination compared with 65% of those who had not consulted their physician. Consulting with a physician about the COVID-19 vaccination was found to alleviate the concerns of patients with cancer and encourage them to get vaccinated.

Resilience of Spike-Specific Immunity Induced by COVID-19 Vaccines against SARS-CoV-2 Variants. The outbreak of SARS-CoV-2 leading to the declaration of the COVID-19 global pandemic has led to the urgent development and deployment of several COVID-19 vaccines. Many of these new vaccines, including those based on mRNA and adenoviruses, are aimed to generate neutralizing antibodies against the spike glycoprotein, which is known to bind to the receptor angiotensin converting enzyme 2 (ACE2) in host cells via the receptor-binding domain (RBD). Antibodies binding to this domain can block the interaction with the receptor and prevent viral entry into the cells. Additionally, these vaccines can also induce spike-specific T cells which could contribute to providing protection against the virus. However, the emergence of new SARS-CoV-2 variants can impair the immunity generated by COVID-19 vaccines if mutations occur in cognate epitopes, precluding immune recognition. Here, we evaluated the chance of five SARS-CoV-2 variants of concern (VOCs), Alpha, Beta, Gamma, Delta and Omicron, to escape spike-specific immunity induced by vaccines. To that end, we examined the impact of the SARS-CoV-2 variant mutations on residues located on experimentally verified spike-specific epitopes, deposited at the Immune Epitope Database, that are targeted by neutralizing antibodies or recognized by T cells. We found about 300 of such B cell epitopes, which were largely overlapping, and could be grouped into 54 B cell epitope clusters sharing â‰¥ 7 residues. Most of the B cell epitope clusters map in the RBD domain (39 out of 54) and 20%, 50%, 37%, 44% and 57% of the total are mutated in SARS-CoV-2 Alpha, Beta, Gamma, Delta and Omicron variants, respectively. We also found 234 experimentally verified CD8 and CD4 T cell epitopes that were distributed evenly throughout the spike protein. Interestingly, in each SARS-CoV-2 VOC, over 87% and 79% of CD8 and CD4 T cell epitopes, respectively, are not mutated. These observations suggest that SARS-CoV-2 VOCs-particularly the Omicron variant-may be prone to escape spike-specific antibody immunity, but not cellular immunity, elicited by COVID-19 vaccines.

Allergological study in patients vaccinated against COVID-19 with suspected allergic reactions. BACKGROUND: One of the main barriers to vaccination against SARS-CoV-2 is the fear of developing hypersensitivity reactions to any of its components. Although these reactions are very rare, it is necessary to establish an effective protocol to detect patients at risk of developing them. The aim of this study was to evaluate hypersensitivity reactions in vaccinated patients in order to allow or not to complete the vaccination protocol. METHODS: Descriptive and cross-sectional study in which patients with suspected hypersensitivity to SARS-CoV-2 vaccines were evaluated. All patients underwent skin prick test (SPT) and/or intradermal test (IDT) with the vaccines and their excipients. In patients with positive IDT with the vaccine, a histopathological and immunohistochemical study was performed by skin biopsy. A basophil activation test (BAT) and a lymphoblastic transformation test (LTT) were also performed. RESULTS: Sixteen patients with suspected hypersensitivity to SARS-CoV-2 vaccine (12 received Comirnaty(Â®), 3 received Vaxzevria(Â®), and 1 received Spikevax(Â®)) were evaluated. Half had immediate hypersensitivity reactions and half had delayed reactions. All SPTs to excipients and vaccines were negative. IDTs with all excipients were negative. IDTs with vaccines were positive in 11 patients and negative in 5. The histological and immunohistochemical study of the two selected patients with positive IDT with vaccine showed T-lymphocyte involvement. BAT and LTT were negative in both cases. The vaccination protocol could be completed in 7 of 16 patients (44%) studied. The remaining 9 patients did not receive the second dose: 5 because vaccination was not required and 4 because they refused to be vaccinated. CONCLUSIONS: Thanks to the allergological and immunohistochemical study, the vaccination protocol could be completed in about half of the patients who presented suspected hypersensitivity reactions to SARS-CoV-2 vaccines. IDTs with vaccines could be a valuable method for assessing the immunogenicity of the vaccines.

Safety of inactivated SARS-CoV-2 vaccines in patients with allergic diseases. BACKGROUND: Considering the considerable prevalence of allergic disease in the general population, an urgent need

exists for inactivated SARS-CoV-2 vaccines that can be safely administered to those subjects. METHODS: This retrospective cohort study including 1926 participants who received inactivated SARS-CoV-2 vaccines, compared their local and systemic reactions in 7Â days after each dose of inactivated SARS-CoV-2 vaccine, and anti-SARS-CoV-2 IgG after vaccination in all participants. RESULTS: Pain at the injection site within seven days after the first injection was the most commonly reported local reaction, occurring in 31.0% of the patients with allergic disease and 18.9% in the control group, respectively (Pâ€‰<â€‰0.001). After the first dose, systemic events were more frequently reported in patients with allergic disease than control group (30.2% vs. 22.9%, Pâ€‰<â€‰0.001). After the second dose, systemic events occurred less often, affecting 17.1% of the patients with allergic disease and 11.1% of the control group (Pâ€‰<â€‰0.002). The occurrence of fatigue, vertigo, diarrhea, skin rash, sore throat were the most frequent systemic reactions. Overall, a lower incidence of local and systemic reactive events was observed after the second dose than the first dose in patients with allergic disease and control group. Nearly all participants had positive IgG antibodies, and participants with allergic disease had higher frequencies compared with control group (100.0 vs.99.4%). CONCLUSIONS: Although local and systemic reactions were more frequently reported in patients with allergic disease than control group, administration of the inactivated SARS-CoV-2 vaccine was safe and well tolerated by all participants; no participants experienced a serious adverse event, and none were hospitalized. TRIAL REGISTRATION: Chinese Clinical Trial Registry, ChiCTR2100048549. Registered Jul 10, 2021.

Editorial: Time to explore the missing links: from activated platelets and platelet extracellular vesicles in SARS-CoV-2 infection, through heterogeneity in the host physiological, immuno-inflammatory and haemostatic responses to mRNA-based vaccine or infection induced polyclonal neutralizing antibodies and passive immunity.

Reply - Letter to the editor: "Micronutrient supplementation, COVID-19 vaccination and adverse effect".

COVID-19 breakthrough infections in rheumatic diseases patients after vaccination. BACKGROUND: Rheumatic diseases patients receiving Rituximab had severe COVID-19 disease. Although they had impaired humoral immune responses following COVID-19 vaccine, they had preserved cellular immune responses. Waning of COVID-19 antibody responses was observed within six months post vaccination among immunocompromised patients. Recent reports showed fatal outcome of breakthrough SARS-CoV-2 infections among vaccinated high-risk rheumatic diseases patients receiving Rituximab. SAR-CoV-2 serological tests were not performed. OBJECTIVE: Evaluation of COVID-19 vaccine humoral responses and breakthrough infections among low risk fully vaccinated rheumatic patients during the Delta Variant Era. METHODS: A case series of 19 fully vaccinated patients with rheumatic diseases were followed to determine post vaccine SARS-CoV-2 neutralizing antibody titers and to monitor the development of breakthrough infections up to eight months post vaccine at our tertiary care center in Jeddah, Saudi Arabia from 1st April until 30th November 2021. RESULTS: The mean age of patients was 49 years old. 10% of patients were receiving Rituximab. 73% of patients had positive SARS-CoV-2 serological testing post second vaccine. Two mild breakthrough COVID-19 infections were diagnosed six months post second dose of vaccine. Patients were less than 65 years, did not receive Rituximab, did not have interstitial lung diseases and had positive post vaccine serological testing. CONCLUSIONS: We demonstrated high SARS-CoV-2 neutralizing antibodies seroprevalence and self-limiting breakthrough infections in low risk rheumatic diseases patients during the Delta Era. Future studies are needed to study the outcome of rheumatic diseases patients in the Era of Omicron in view of viral immune escape responses.

Characteristics of COVID-19 Breakthrough Infections among Vaccinated Individuals and Associated Risk Factors: A Systematic Review. We sought to assess breakthrough SARS-CoV-2 infections in

vaccinated individuals by variant distribution and to identify the common risk associations. The PubMed, Web of Science, ProQuest, and Embase databases were searched from 2019 to 30 January 2022. The outcome of interest was breakthrough infections (BTIs) in individuals who had completed a primary COVID-19 vaccination series. Thirty-three papers were included in the review. BTIs were more common among variants of concern (VOC) of which Delta accounted for the largest number of BTIs (96%), followed by Alpha (0.94%). In addition, 90% of patients with BTIs recovered, 11.6% were hospitalized with mechanical ventilation, and 0.6% resulted in mortality. BTIs were more common in healthcare workers (HCWs) and immunodeficient individuals with a small percentage found in fully vaccinated healthy individuals. VOC mutations were the primary cause of BTIs. Continued mitigation approaches (e.g., wearing masks and social distancing) are warranted even in fully vaccinated individuals to prevent transmission. Further studies utilizing genomic surveillance and heterologous vaccine regimens to boost the immune response are needed to better understand and control BTIs.

Association of Zip Code Vaccination Rate With COVID-19 Mortality in Chicago, Illinois.
IMPORTANCE: There has been large geographic inequity in vaccination coverage across Chicago, Illinois, with higher vaccination rates in zip codes with residents who predominantly have high incomes and are White. OBJECTIVE: To determine the association between inequitable zip code-level vaccination coverage and COVID-19 mortality in Chicago. DESIGN, SETTING, AND PARTICIPANTS: This retrospective cohort study used Chicago Department of Public Health vaccination and mortality data and Cook County Medical Examiner mortality data from March 1, 2020, through November 6, 2021, to assess the association of COVID-19 mortality with zip code-level vaccination rates. Data were analyzed from June 1, 2021, to April 13, 2022. EXPOSURES: Zip code-level first-dose vaccination rates before the Alpha and Delta waves of COVID-19. MAIN OUTCOMES AND MEASURES: The primary outcome was deaths from COVID-19 during the Alpha and Delta waves. The association of a marginal increase in zip code-level vaccination rate with weekly mortality rates was estimated with a mixed-effects Poisson regression model, and the total number of preventable deaths in the least vaccinated quartile of zip codes was estimated with a linear difference-in-difference design. RESULTS: The study population was 2â€¯686â€¯355 Chicago residents in 52 zip codes (median [IQR] age 34 [32-38] years; 1â€¯378â€¯658 [51%] women; 773â€¯938 Hispanic residents [29%]; 783â€¯916 non-Hispanic Black residents [29%]; 894â€¯555 non-Hispanic White residents [33%]). Among residents in the least vaccinated quartile, 80% were non-Hispanic Black, compared with 8% of residents identifying as non-Hispanic Black in the most vaccinated quartile (Pâ€‰<â€‰.001). After controlling for age distribution and recovery from COVID-19, a 10-percentage point increase in zip code-level vaccination 6 weeks before the peak of the Alpha wave was associated with a 39% lower relative risk of death from COVID-19 (incidence rate ratio [IRR], 0.61 [95% CI, 0.52-0.72]). A 10-percentage point increase in zip code vaccination rate 6 weeks before the peak of the Delta wave was associated with a 24% lower relative risk of death (IRR, 0.76 [95% CI, 0.66-0.87]). The difference-in-difference estimate was that 119 Alpha wave deaths (72% [95% CI, 63%-81%]) and 108 Delta wave deaths (75% [95% CI, 66%-84%]) might have been prevented in the least vaccinated quartile of zip codes if it had had the vaccination coverage of the most vaccinated quartile. CONCLUSIONS AND RELEVANCE: These findings suggest that low zip code-level vaccination rates in Chicago were associated with more deaths during the Alpha and Delta waves of COVID-19 and that inequitable vaccination coverage exacerbated existing racial and ethnic disparities in COVID-19 deaths.

Blood Pressure Increase following COVID-19 Vaccination: A Systematic Overview and Meta-Analysis.
Coronavirus disease 2019 (COVID-19) vaccines proved a strong clinical efficacy against symptomatic or moderate/severe COVID-19 and are considered the most promising approach for curbing the pandemic. However, some questions regarding the safety of COVID-19 vaccines have been recently raised. Among adverse events to vaccines and despite a lack of signal during phase III clinical trials, an

increase in blood pressure (BP) after COVID-19 vaccination has been reported as a potential adverse reaction. We systematically analyze this topic and undertook a meta-analysis of available data to estimate the proportion of patients with abnormal BP or raise in BP after vaccination. Six studies entered the final analysis. Overall, studies accrued 357,387 subjects with 13,444 events of abnormal or increased BP. After exclusion of outlier studies, the pooled estimated proportion of abnormal/increased BP after vaccination was 3.20% (95% CI: 1.62-6.21). Proportions of cases of stage III hypertension or hypertensive urgencies and emergencies was 0.6% (95% CI: 0.1% to 5.1%). In conclusion, abnormal BP is not rare after COVID-19 vaccination, but the basic mechanisms of this phenomenon are still unclear and require further research.

Factors Associated With COVID-19 Vaccination Uptake Among Community-Dwelling Patients With Severe Mental Illness: A Cross-Sectional Study. Objective: Coronavirus disease 2019 (COVID-19) vaccination uptake among individuals with severe mental illness (SMI) is a public health challenge due to various individual level as well as systemic level barriers. The objective of this study was to explore COVID-19 vaccination status among community-dwelling patients with SMI and identify associated factors. Methods: A cross-sectional study was conducted among patients with SMI attending community psychiatry clinics in Northern Kerala from April 21, 2021, to August 3, 2021, using a structured questionnaire. Sociodemographic information and COVID-19-related information, including vaccination status and agreement with COVID-19 vaccination-related statements, were obtained. Results: Of the 62 respondents, only 27.9% received COVID-19 vaccination. Also, 59.7% of respondents received a recommendation for vaccination from their health care providers. The mean age of the vaccinated group was significantly higher than that of the unvaccinated group (Fâ€‰=â€‰1.33(59), Pâ€‰<â€‰.001). The rate of vaccination uptake among respondents who were contacted by their health care provider for COVID-19 vaccination was significantly higher (Pâ€‰=â€‰.001). Respondents in the vaccinated group perceived the vaccine to be more effective in preventing COVID-19 infection than those in the unvaccinated group (2.06 vs 2.64, Pâ€‰=â€‰.031). Also, vaccinated respondents were less in agreement regarding the statement about the risk of COVID-19 vaccine worsening mental illness (4.18 vs 3.67, Pâ€‰=â€‰.049). Age and recommendation for vaccination from health care providers were found to be significant predictors of COVID-19 vaccination uptake. Conclusions: On the basis of the study findings, it is recommended that tailored educational activities regarding the safety and efficacy of the COVID-19 vaccine along with recommendation by health care providers can significantly improve COVID-19 vaccination uptake among patients with SMI.

A Case Report of DVT following the Johnson and Johnson Vaccine against the Novel SARS-CoV-2. Deep vein thrombosis (DVT) is the formation of a blood clot typically in the deep veins of the extremities. The risk factors for venous thrombosis are primarily related to hypercoagulability, which can be genetic, acquired, or due to immobilization and venous stasis. The Johnson and Johnson (J&J) vaccine developed against the novel SARS-CoV-2 has been linked to more specific cases of thrombosis, associated with low platelet levels similar to that seen in heparin-induced thrombocytopenia. In this case report, we present a female who developed a DVT four days after receiving the J&J vaccine. We propose that the administration of this vaccine may further increase the risk of developing DVTs in patients with previous risk factors, and we hope to use this case to support screening all patients for previous risk factors for thrombosis before administration of the J&J vaccine.

Insights Into Immunothrombotic Mechanisms in Acute Stroke due to Vaccine-Induced Immune Thrombotic Thrombocytopenia. During the COVID-19 pandemic, vaccination is the most important countermeasure. Pharmacovigilance concerns however emerged with very rare, but potentially disastrous thrombotic complications following vaccination with ChAdOx1. Platelet factor-4

antibody mediated vaccine-induced immune thrombotic thrombocytopenia (VITT) was described as an underlying mechanism of these thrombotic events. Recent work moreover suggests that mechanisms of immunothrombosis including neutrophil extracellular trap (NET) formation might be critical for thrombogenesis during VITT. In this study, we investigated blood and thrombus specimens of a female patient who suffered severe stroke due to VITT after vaccination with ChAdOx1 in comparison to 13 control stroke patients with similar clinical characteristics. We analyzed cerebral thrombi using histological examination, staining of complement factors, NET-markers, DNase and LL-37. In blood samples at the hyper-acute phase of stroke and 7 days later, we determined cell-free DNA, myeloperoxidase-histone complexes, DNase activity, myeloperoxidase activity, LL-37 and inflammatory cytokines. NET markers were identified in thrombi of all patients. Interestingly, the thrombus of the VITT-patient exclusively revealed complement factors and high amounts of DNase and LL-37. High DNase activity was also measured in blood, implying a disturbed NET-regulation. Furthermore, serum of the VITT-patient inhibited reactive oxygen species-dependent NET-release by phorbol-myristate-acetate to a lesser degree compared to controls, indicating either less efficient NET-inhibition or enhanced NET-induction in the blood of the VITT-patient. Additionally, the changes in specific cytokines over time were emphasized in the VITT-patient as well. In conclusion, insufficient resolution of NETs, e.g. by endogenous DNases or protection of NETs against degradation by embedded factors like the antimicrobial peptide LL-37 might thus be an important factor in the pathology of VITT besides increased NET-formation. On the basis of these findings, we discuss the potential implications of the mechanisms of disturbed NETs-degradation for diagnostic and therapeutic approaches in VITT-related thrombogenesis, other auto-immune disorders and beyond.

The unintended consequences of COVID-19 vaccine policy: why mandates, passports and restrictions may cause more harm than good. Vaccination policies have shifted dramatically during COVID-19 with the rapid emergence of population-wide vaccine mandates, domestic vaccine passports and differential restrictions based on vaccination status. While these policies have prompted ethical, scientific, practical, legal and political debate, there has been limited evaluation of their potential unintended consequences. Here, we outline a comprehensive set of hypotheses for why these policies may ultimately be counterproductive and harmful. Our framework considers four domains: (1) behavioural psychology, (2) politics and law, (3) socioeconomics, and (4) the integrity of science and public health. While current vaccines appear to have had a significant impact on decreasing COVID-19-related morbidity and mortality burdens, we argue that current mandatory vaccine policies are scientifically questionable and are likely to cause more societal harm than good. Restricting people's access to work, education, public transport and social life based on COVID-19 vaccination status impinges on human rights, promotes stigma and social polarisation, and adversely affects health and well-being. Current policies may lead to a widening of health and economic inequalities, detrimental long-term impacts on trust in government and scientific institutions, and reduce the uptake of future public health measures, including COVID-19 vaccines as well as routine immunisations. Mandating vaccination is one of the most powerful interventions in public health and should be used sparingly and carefully to uphold ethical norms and trust in institutions. We argue that current COVID-19 vaccine policies should be re-evaluated in light of the negative consequences that we outline. Leveraging empowering strategies based on trust and public consultation, and improving healthcare services and infrastructure, represent a more sustainable approach to optimising COVID-19 vaccination programmes and, more broadly, the health and well-being of the public.

Heterologous ChAdOx1/BNT162b2 vaccination induces stronger immune response than homologous ChAdOx1 vaccination: The pragmatic, multi-center, three-arm, partially randomized HEVACC trial. BACKGROUND: Several COVID-19 vaccines have been approved. The mRNA vaccine from

Pfizer/BioNTech (Comirnaty, BNT162b2; BNT) and the vector vaccine from AstraZeneca (Vaxzevria, ChAdOx1; AZ) have been widely used. mRNA vaccines induce high antibody and T cell responses, also to SARS-CoV-2 variants, but are costlier and less stable than the slightly less effective vector vaccines. For vector vaccines, heterologous vaccination schedules have generally proven more effective than homologous schedules. METHODS: In the HEVACC three-arm, single-blinded, adaptive design study (ClinicalTrials.gov Identifier: NCT04907331), participants between 18 and 65 years with no prior history of SARS-CoV-2 infection and a first dose of AZ or BNT were included. The AZ/AZ and the AZ/BNT arms were randomized (in a 1:1 ratio stratified by sex and trial site) and single-blinded, the third arm (BNT/BNT) was observational. We compared the reactogenicity between the study arms and hypothesized that immunogenicity was higher for the heterologous AZ/BNT compared to the homologous AZ/AZ regimen using neutralizing antibody titers as primary endpoint. FINDINGS: This interim analysis was conducted after 234 participants had been randomized and 254 immunized (N=109 AZ/AZ, N=115 AZ/BNZ, N=30 BNT/BNT). Heterologous AZ/BNT vaccination was well tolerated without study-related severe adverse events. Neutralizing antibody titers on day 30 were statistically significant higher in the AZ/BNT and the BNT/BNT groups than in the AZ/AZ group, for B.1.617.2 (Delta) AZ/AZ median reciprocal titer 75.9 (99.9% CI 58.0 - 132.5), AZ/BNT 571.5 (99.9% CI 396.6 - 733.1), and BNT/BNT 404.5 (99.9% CI 68.3 - 1024). Similarly, the frequency and multifunctionality of spike-specific T cell responses was comparable between the AZ/BNT and the BNT/BNT groups, but lower in the AZ/AZ vaccinees. INTERPRETATION: This study clearly shows the immunogenicity and safety of heterologous AZ/BNT vaccination and encourages further studies on heterologous vaccination schedules. FUNDING: This work was supported by the Medical University of Innsbruck, and partially funded by NIAID contracts No. 75N9301900065, 75N93021C00016, and 75N93019C00051.

Risk factors associated with SARS-CoV-2 infection in a multiethnic cohort of United Kingdom healthcare workers (UK-REACH): A cross-sectional analysis. BACKGROUND: Healthcare workers (HCWs), particularly those from ethnic minority groups, have been shown to be at disproportionately higher risk of infection with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) compared to the general population. However, there is insufficient evidence on how demographic and occupational factors influence infection risk among ethnic minority HCWs. METHODS AND FINDINGS: We conducted a cross-sectional analysis using data from the baseline questionnaire of the United Kingdom Research study into Ethnicity and Coronavirus Disease 2019 (COVID-19) Outcomes in Healthcare workers (UK-REACH) cohort study, administered between December 2020 and March 2021. We used logistic regression to examine associations of demographic, household, and occupational risk factors with SARS-CoV-2 infection (defined by polymerase chain reaction (PCR), serology, or suspected COVID-19) in a diverse group of HCWs. The primary exposure of interest was self-reported ethnicity. Among 10,772 HCWs who worked during the first UK national lockdown in March 2020, the median age was 45 (interquartile range [IQR] 35 to 54), 75.1% were female and 29.6% were from ethnic minority groups. A total of 2,496 (23.2%) reported previous SARS-CoV-2 infection. The fully adjusted model contained the following dependent variables: demographic factors (age, sex, ethnicity, migration status, deprivation, religiosity), household factors (living with key workers, shared spaces in accommodation, number of people in household), health factors (presence/absence of diabetes or immunosuppression, smoking history, shielding status, SARS-CoV-2 vaccination status), the extent of social mixing outside of the household, and occupational factors (job role, the area in which a participant worked, use of public transport to work, exposure to confirmed suspected COVID-19 patients, personal protective equipment [PPE] access, aerosol generating procedure exposure, night shift pattern, and the UK region of workplace). After adjustment, demographic and household factors associated with increased odds of infection included

younger age, living with other key workers, and higher religiosity. Important occupational risk factors associated with increased odds of infection included attending to a higher number of COVID-19 positive patients (aOR 2.59, 95% CI 2.11 to 3.18 for â‰¥21 patients per week versus none), working in a nursing or midwifery role (1.30, 1.11 to 1.53, compared to doctors), reporting a lack of access to PPE (1.29, 1.17 to 1.43), and working in an ambulance (2.00, 1.56 to 2.58) or hospital inpatient setting (1.55, 1.38 to 1.75). Those who worked in intensive care units were less likely to have been infected (0.76, 0.64 to 0.92) than those who did not. Black HCWs were more likely to have been infected than their White colleagues, an effect which attenuated after adjustment for other known risk factors. This study is limited by self-selection bias and the cross sectional nature of the study means we cannot infer the direction of causality. CONCLUSIONS: We identified key sociodemographic and occupational risk factors associated with SARS-CoV-2 infection among UK HCWs, and have determined factors that might contribute to a disproportionate odds of infection in HCWs from Black ethnic groups. These findings demonstrate the importance of social and occupational factors in driving ethnic disparities in COVID-19 outcomes, and should inform policies, including targeted vaccination strategies and risk assessments aimed at protecting HCWs in future waves of the COVID-19 pandemic. TRIAL REGISTRATION: The study was prospectively registered at ISRCTN (reference number: ISRCTN11811602).

Safety and immunogenicity of heterologous boost immunization with an adenovirus type-5-vectored and protein-subunit-based COVID-19 vaccine (Convidecia/ZF2001): A randomized, observer-blinded, placebo-controlled trial. BACKGROUND: Heterologous boost vaccination has been proposed as an option to elicit stronger and broader, or longer-lasting immunity. We assessed the safety and immunogenicity of heterologous immunization with a recombinant adenovirus type-5-vectored Coronavirus Disease 2019 (COVID-19) vaccine (Convidecia, hereafter referred to as CV) and a protein-subunit-based COVID-19 vaccine (ZF2001, hereafter referred to as ZF). METHODS AND FINDINGS: We conducted a randomized, observer-blinded, placebo-controlled trial, in which healthy adults aged 18 years or older, who have received 1 dose of Convidecia, with no history of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection, were recruited in Jiangsu, China. Sixty participants were randomly assigned (2:1) to receive either 1 dose of ZF2001 or placebo control (trivalent inactivated influenza vaccine (TIV)) administered at 28 days after priming, and received the third injection with ZF2001 at 5 months, referred to as CV/ZF/ZF (D0-D28-M5) and CV/ZF (D0-M5) regimen, respectively. Sixty participants were randomly assigned (2:1) to receive either 1 dose of ZF2001 or TIV administered at 56 days after priming, and received the third injection with ZF2001 at 6 months, referred to as CV/ZF/ZF (D0-D56-M6) and CV/ZF (D0-M6) regimen, respectively. Participants and investigators were masked to the vaccine received but not to the boosting interval. Primary endpoints were the geometric mean titer (GMT) of neutralizing antibodies against wild-type SARS-CoV-2 and 7-day solicited adverse reactions. The primary analysis was done in the intention-to-treat population. Between April 7, 2021 and May 6, 2021, 120 eligible participants were randomly assigned to receive ZF2001/ZF2001 (n = 40) or TIV/ZF2001 (n = 20) 28 days and 5 months post priming, and receive ZF2001/ZF2001 (n = 40) or TIV/ZF2001 (n = 20) 56 days and 6 months post priming. Of them, 7 participants did not receive the third injection with ZF2001. A total of 26 participants (21.7%) reported solicited adverse reactions within 7 days post boost vaccinations, and all the reported adverse reactions were mild, with 13 (32.5%) in CV/ZF/ZF (D0-D28-M5) regimen, 7 (35.0%) in CV/ZF (D0- M5) regimen, 4 (10.0%) in CV/ZF/ZF (D0-D56-M6) regimen, and 2 (10.0%) in CV/ZF (D0-M6) regimen, respectively. At 14 days post first boost, GMTs of neutralizing antibodies in recipients receiving ZF2001 at 28 days and 56 days post priming were 18.7 (95% CI 13.7 to 25.5) and 25.9 (17.0 to 39.3), respectively, with geometric mean ratios of 2.0 (1.2 to 3.5) and 3.4 (1.8 to 6.4) compared to TIV. GMTs at 14 days after second boost of neutralizing antibodies increased to 107.2 (73.7 to 155.8)

in CV/ZF/ZF (D0-D28-M5) regimen and 141.2 (83.4 to 238.8) in CV/ZF/ZF (D0-D56-M6) regimen. Two-dose schedules of CV/ZF (D0-M5) and CV/ZF (D0-M6) induced antibody levels comparable with that elicited by 3-dose schedules, with GMTs of 90.5 (45.6, 179.8) and 94.1 (44.0, 200.9), respectively. Study limitations include the absence of vaccine effectiveness in a real-world setting and current lack of immune persistence data. CONCLUSIONS: Heterologous boosting with ZF2001 following primary vaccination with Convidecia is more immunogenic than a single dose of Convidecia and is not associated with safety concerns. These results support flexibility in cooperating viral vectored and recombinant protein vaccines. TRIAL REGISTRATION: Study on Heterologous Prime-boost of Recombinant COVID-19 Vaccine (Ad5 Vector) and RBD-based Protein Subunit Vaccine; ClinicalTrial.gov NCT04833101.

Multisystem Inflammatory Syndrome in an Adolescent Following SARS-CoV-2 Exposure Despite Three Doses of a COVID-19 Vaccine. The multisystem inflammatory syndrome in children (MIS-C) is a known complication of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in the pediatric population. Recent studies have demonstrated high efficacy of a two-dose vaccine series in preventing MIS-C among adolescents. To date, such studies have only included children exposed to SARS-CoV-2 prior to the emergence of the Omicron variant (B.1.1.529). We report a case of an adolescent who received three doses of a vaccine yet developed MIS-C following known exposure to SARS-CoV-2. Given the uncertainty in whether current vaccines offer as much protection against MIS-C due to the Omicron variant or any potential new variants as they have for older variants, pediatric providers should maintain a high index of suspicion for MIS-C regardless of vaccination status.

Post COVID-19 vaccine Guillain-BarrÃ© syndrome. Guillain-BarrÃ© syndrome is an acute generalized polyneuropathy which usually follows infection with a virus or bacteria, although rarely vaccination may be associated with it. We present a case of a 44-year-man who presented with progressive weakness of both lower limbs since 6?days, neurological examination findings were consistent with flaccid-type paraplegia and investigation findings including lumbar puncture and nerve conduction studies were consistent with the diagnosis of Guillain-BarrÃ© syndrome. He had received the Johnson and Johnson corona virus disease-19 vaccine intramuscularly 15 days before his presentation. Only potential triggering factor in this case was positive finding of Jansen Vaccine. Keywords: Guillain-BarrÃ© syndrome; immunoglobulin; jansen vaccine; polyneuropathy.

COVID-19-Related Perceived Threat Following a Second Dose Vaccination in Adults with Chronic Illness: A Mixed-Method Study. BACKGROUND: In patients with comorbidities such as chronic illness, the severity and mortality risk of the disease (COVID-19) are high. Even if they are fully vaccinated, they should follow all precautions for unvaccinated people because the vaccine may not provide them complete protection. As a result, understanding their response to a threat is essential because knowing their threat level can be a good predictor of behavioral changes and health-protective behaviors. METHODS: An institution-based cross-sectional mixed-method study design was used at the University of Gondar specialized hospital from May 1 to June 30, 2021. An interviewer-administered questionnaire was used for the quantitative, and tape recorders, field notes, and memos were properly taken during the in-depth interviews for the qualitative data. Multivariable logistic regression with consideration of adjusted odds ratio of 95% confidence interval and p-value of 0.05% was used for statistical significance. RESULTS: The study enrolled 239 people, with a 96% response rate, ranging from 24 to 67 years, with the majority (57.9%) male. Even after receiving the second dose of AstraZeneca, nearly half (46.5%) of participants with a chronic illness perceived a threat to COVID-19. The participant's age ranges from 24 to 34 years [3.24 (AOR= 3.24 (95% CI: 1.08, 9.68))], patients who are student [2.38 (AOR= 2.38 (95% CI: 1.12, 5.06))], participants applying the recommended behavioral response [2.36 (AOR=2.36 (95% CI: 1.16, 4.81))] and duration of illness ranged from four to six-year [3.17 (AOR=3.17 (95% CI (1.05, 9.58))] were statistically associated with

perceived threat. CONCLUSION: Most people with chronic illnesses do not see the disease as a threat. Particular emphasis should be placed on creating awareness programs and disseminating information through media on prevention, and ongoing health education is strongly advisable.

Increase of Macrolide-Resistance in Streptococcus pneumoniae Strains After the Introduction of the 13-Valent Pneumococcal Conjugate Vaccine in Lima, Peru. Streptococcus pneumoniae upper respiratory infections and pneumonia are often treated with macrolides, but recently macrolide resistance is becoming an increasingly important problem. The 13-valent pneumococcal conjugate vaccine (PCV13) was introduced in the National Immunization Program of Peru in 2015. This study aimed to evaluate the temporal evolution of macrolide resistance in S. pneumoniae isolates collected in five cross-sectional studies conducted before and after this vaccine introduction, from 2006 to 2019 in Lima, Peru. A total of 521 and 242 S. pneumoniae isolates recovered from nasopharyngeal swabs from healthy carrier children < 2 years old (2 carriage studies) and samples from normally sterile body areas from pediatric patients with invasive pneumococcal disease (IPD) (3 IPD studies), respectively, were included in this study. Phenotypic macrolide resistance was detected using the Kirby-Bauer method and/or MIC test. We found a significant increase in macrolide resistance over time, from 33.5% to 50.0% in carriage studies, and from 24.8% to 37.5% and 70.8% in IPD studies. Macrolide resistance genes [erm(B) and mef(A/E)] were screened using PCR. In carriage studies, we detected a significant decrease in the frequency of mef(A/E) genes among macrolide-resistant S. pneumoniae strains (from 66.7% to 50.0%) after introduction of PCV13. The most common mechanism of macrolide-resistant among IPD strains was the presence of erm(B) (96.0%, 95.2% and 85.1% in the 3 IPD studies respectively). Macrolide resistance was more common in serotype 19A strains (80% and 90% among carriage and IPD strains, respectively) vs. non-serotype 19A (35.5% and 34.4% among carriage and IPD strains, respectively). In conclusion, S. pneumoniae macrolide resistance rates are very high among Peruvian children. Future studies are needed in order to evaluate macrolide resistance trends among pneumococcal strains, especially now after the COVID-19 pandemic, since azithromycin was vastly used as empiric treatment of COVID-19 in Peru.

A Retrospective Global Assessment of Factors Associated With COVID-19 Policies and Health Outcomes. BACKGROUND: The 2019 Global Health Security (GHS) Index measured the capacities of countries to prepare for and respond to epidemics and pandemics. However, the COVID-19 pandemic revealed that GHS Index scores were poorly correlated with ability to respond to infectious disease threats. It is critical to understand how public health policies may reduce the negative impacts of pandemics. OBJECTIVE: To identify non-pharmaceutical interventions (NPIs) that can minimize morbidity and mortality during the COVID-19 and future pandemics, this study examined associations between country characteristics, NPI public health policies, and COVID-19 outcomes during the first year of the pandemic, prior to the introduction of the COVID-19 vaccine. This global analysis describes worldwide trends in policy implementation and generates a stronger understanding of how NPIs contributed to improved health outcomes. DESIGN: This cross-sectional, retrospective study relied on information drawn from publicly available datasets through December 31, 2020. PRIMARY AND SECONDARY OUTCOME MEASURES: We conducted multivariate regressions to examine associations between country characteristics and policies, and policies and health outcomes. RESULTS: Countries with higher health service coverage prior to the pandemic implemented more policies and types of policies. Countries with more bordering countries implemented more border control policies (0.78(**)), and countries with denser populations implemented more masking policies (0.24(*)). Across all countries, fewer COVID-19 cases and deaths per million were associated with masking (-496.10(*), -7.57), testing and tracing (-108.50(**), -2.47(**)), and restriction of movement (-102.30(*), -2.10(*)) policies, with stronger associations when these policies were mandatory rather than voluntary. CONCLUSIONS: Country characteristics,

including health service coverage, number of bordering countries, and population density, may predict the frequency and nature of public health interventions. Countries with higher health service coverage may have the infrastructure to react more efficiently to a pandemic, leading them to implement a greater number of policies. Mandatory masking, testing and tracing, and restriction of movement policies were associated with more favorable COVID-19 population health outcomes. While these results are consistent with existing COVID-19 mathematical models, policy effectiveness depends on how well they are implemented. Our results suggest that social distancing policies were less effective in reducing infectious disease risk, which may reflect difficulties with enforcement and monitoring.

Long COVID risk falls only slightly after vaccination, huge study shows.

Safety of COVID-19 vaccines in patients with non-communicable diseases: a protocol for systematic review and meta-analysis of randomised controlled trials. INTRODUCTION: The COVID-19 global pandemic has posed enormous threats to public health around the world. Vaccines are considered the best therapeutic strategy against the COVID-19 pandemic. However, the adverse reactions of vaccines significantly affect the rates of vaccination and may be more serious in patients with non-communicable diseases (NCDs). This protocol aims to conduct a systematic review and meta-analysis of randomised controlled trials (RCTs) which analysed the safety of vaccines in patients with NCDs. METHODS AND ANALYSIS: This study will be according to the guidelines of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols. A comprehensive search will be carried out to identify registered RCTs in PubMed, Embase, Web of Science, ClinicalTrials.gov and Cochrane Library between 1 January 2020 and 31 May 2022. Selection of trials, data extraction, risk of bias assessment and quality of evidence assessment will be done by two researchers, and disagreements will be resolved by the corresponding author. The primary outcomes are local and systemic adverse events of vaccines in patients with NCDs. Additional outcomes are related events caused by vaccine adverse events, including but not limited to cases of adverse events leading to discontinuation from a dose or withdrawal from participation in the trial. Heterogeneity will be assessed with I(2) statistics and data analysis will be conducted with RevMan V.5.4.1. ETHICS AND DISSEMINATION: This is a protocol and ethical approval is not necessary. The results of this protocol will be disseminated to peer-reviewed publications or conference presentations. PROSPERO REGISTRATION NUMBER: CRD42021254914.

Demographic and clinical characteristics associated with variations in antibody response to BNT162b2 COVID-19 vaccination among healthcare workers at an academic medical centre: a longitudinal cohort analysis. OBJECTIVES: We sought to understand the demographic and clinical factors associated with variations in longitudinal antibody response following completion of two-dose regiment of BNT162b2 vaccination. DESIGN: This study is a 10-month longitudinal cohort study of healthcare workers and serially measured anti-spike protein IgG (IgG-S) antibody levels using mixed linear models to examine their associations with participant characteristics. SETTING: A large, multisite academic medical centre in Southern California, USA. PARTICIPANTS: A total of 843 healthcare workers met inclusion criteria including completion of an initial two-dose course of BNT162b2 vaccination, complete clinical history and at least two blood samples for analysis. Patients had an average age of 45Â±13 years, were 70% female and 7% with prior SARS-CoV-2 infection. RESULTS: Vaccine-induced IgG-S levels remained in the positive range for 99.6% of individuals up to 10 months after initial two-dose vaccination. Prior SARS-CoV-2 infection was the primary correlate of sustained higher postvaccination IgG-S levels (partial R(2)=0.133), with a 1.74Â±0.11 SD higher IgG-S response (p<0.001). Female sex (beta 0.27Â±0.06, p<0.001), younger age (0.01Â±0.00, p<0.001) and absence of hypertension (0.17Â±0.08, p=0.003) were also associated with persistently higher IgG-S responses. Notably, prior SARS-CoV-2 infection augmented the associations of sex (-0.42 for male sex,

p=0.08) and modified the associations of hypertension (1.17, p=0.001), such that infection-naÃ¯ve individuals with hypertension had persistently lower IgG-S levels whereas prior infected individuals with hypertension exhibited higher IgG-S levels that remained augmented over time. CONCLUSIONS: While the IgG-S antibody response remains in the positive range for up to 10 months following initial mRNA vaccination in most adults, determinants of sustained higher antibody levels include prior SARS-CoV-2 infection, female sex, younger age and absence of hypertension. Certain determinants of the longitudinal antibody response appear significantly modified by prior infection status. These findings offer insights regarding factors that may influence the 'hybrid' immunity conferred by natural infection combined with vaccination.

Reports of myocarditis and pericarditis following mRNA COVID-19 vaccination: a systematic review of spontaneously reported data from the UK, Europe and the USA and of the scientific literature. OBJECTIVES: To combine spontaneously reported data from multiple countries to estimate reporting rate, and better understand risk factors for myocarditis and pericarditis following COVID-19 messenger RNA (mRNA) vaccines. DESIGN: Systematic review of spontaneously reported data from UK, USA and European Union/European Economic Area (EU/EEA) and of the scientific literature. DATA SOURCES: UK Yellow Card scheme, Vaccine Adverse Event Reporting System (VAERS), EudraVigilance were searched from date of vaccine launch to 14 March 2022-16 March 2022. PubMed/MEDLINE and Embase were searched to 15 March 2022. ELIGIBILITY CRITERIA: We included publicly available spontaneous reporting data for 'Myocarditis' and 'Pericarditis' from UK, USA and EU/EEA following COVID-19 mRNA vaccines. Pharmacoepidemiological observational studies investigating myocarditis/pericarditis following mRNA COVID-19 vaccines were included (no restrictions on language or date). Critical Appraisal Skills Programme tools assessed study quality. DATA EXTRACTION AND SYNTHESIS: Two researchers extracted data. Events of myocarditis and pericarditis were presented for each data source, stratified by vaccine, age, sex and dose (where available). Reporting rates were calculated for myocarditis and pericarditis for each population. For published pharmacoepidemiological studies, design, participant characteristics, and study results were tabulated. RESULTS: Overall, 18â€‰204 myocarditis and pericarditis events were submitted to the UK, USA and EU/EEA regulators during the study period. Males represented 62.24% (n=11â€‰331) of myocarditis and pericarditis reports. In the UK and USA, most reports concerned vaccinees aged <40 years (59.7% and 47.3% of reported events, respectively); trends in age were less clear for EU/EEA. Reports were more frequent following a second dose (47.1% of reports, where data available). Reporting rates were consistent between the data sources. Thirty-two pharmacoepidemiological studies were included; results were consistent with our spontaneous report analyses. CONCLUSIONS: Younger vaccinees more frequently report myocarditis and pericarditis following mRNA COVID-19 vaccines than older vaccinees. Results from published literature supported the results of our analyses.

Facial Angioedema after the first dose of Covishield (adenovirus-vectored severe acute respiratory syndrome coronavirus 2 vaccine): follow-up after the second and third booster doses. Mass vaccination campaigns are essential to control the ongoing novel severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) pandemic. The Covishield vaccine consists of the replication-deficient simian adenovirus vector ChAdOx1, which contains the full-length structural spike protein of SARS-CoV-2. Occasionally, it can lead to cutaneous reactions that contribute to fear of vaccination, hesitancy, and incomplete vaccination schedules. We report a case of facial angioedema following the first dose of Covishield in a 63-year-old woman with no previous history of allergies or hypersensitivity to drugs or vaccines. No rebound of angioedema was recorded after the second homologous and third heterologous doses.

Using FHIR to Support COVID-19 Vaccine Safety Electronic Case Reports in America. During the COVID-19 pandemic, the Pan American Health Organization (PAHO) promoted several activities to

strengthen the countries' emergency response. Vaccines represented a breakthrough in the pandemic evolution, even though they have not been equitably distributed. As most vaccines have received emergency authorizations for their timely delivery, vaccine safety surveillance has been highlighted for detecting early signals of potential adverse events following immunization (AEFI, also known as ESAVI). The objective of this article is to share the different steps, methodologies, and preliminary results of a regional policy to strengthen the ESAVI surveillance system in the Americas, including the adoption of HL7 FHIR for health information exchange between countries and PAHO.

Second-dose COVID-19 vaccines are well tolerated in patients with allergic reactions toÂ the first dose - a single center experience. COVID-19 vaccines contain additives such as Polyethylenglycol-2000 (PEG2000; mRNA vaccines) or Polysorbat 80 (vector vaccines), which have been described previously as culprits for anaphylactic events. This retrospective study included 46 individuals, who were referred to Comprehensive Allergy Center at the Department Dermatology and Venereology, Kepler University Hospital, Linz, Austria, with suspected allergic reactions to the first COVID-19 vaccine dose with either mRNA or vector-based vaccines. Patients underwent detailed anamnesis, clinical examination, and in most cases, skin prick testing using pure additive substances (PEG - different molecular weights, Polysorbate 80). Out of 46, 7 patients' reactions were classified as possibly anaphylactic and graded according to Ring & Messmer. Forty patients out of 46 were assessed with skin prick tests for potential allergens in COVID-19 vaccines. Only 1 patient showed an immediate positive prick test to PEG2000. Second-dose vaccination with mRNA or vector-based vaccines were tolerated well in all patients, including the individual with a positive skin prick test against PEG2000. The currently available COVID-19 vaccines have an overall low allergic potential and may be administered safely in patients with suspected allergic reactions to the first dose.

A Rare Case of COVID-19 Vaccine-Induced Thrombotic Thrombocytopenia in a Young Patient. The syndrome of pulmonary SARS-Cov-2 resulted in significant morbidity and mortality, with new variants spreading rapidly. Vaccines to prevent COVID-19Â have been developed to minimize the impact and severity; however, adverse effects of the vaccine have been documented in several studies. In our case, we report a case of a young female who presented to the emergency department with fever, dizziness, headache, vomiting, blurring of vision, numbness, and weakness of left upper and lower limbs. This weakness progressed rapidly to all limbs within two hours associated with altered behaviors and visual hallucinations. The family reported a history of the patient receiving her first dose of COVID-19 AstraZeneca vaccine 18 days before admission. Based on her clinical picture and investigation, she was diagnosed with vaccine-inducedÂ immuneÂ thrombotic thrombocytopenia (VITT). She was treated successfully with intravenous immunoglobulin (IVIG) and direct oral anticoagulant apixaban. In a time when there is a strategic goal to vaccinate the global population from COVID-19 to inhibit the spread of infection and reduce hospitalization, this particular clinical scenario emphasizes the need for all clinicians to remain vigilant for rare complications of the COVID-19 vaccination.

De novo Minimal Change Disease in an Adolescent after Pfizer-BioNTech COVID-19 Vaccination: A Case Report. This is the first report in an adolescent of minimal change disease (MCD) after the first injection of the BNT162b2 COVID-19 vaccine (Pfizer-BioNTech) with complete remission following steroid treatment. An 18-year-old white male with no prior medical history complained of gastrointestinal symptoms 11 days after his vaccination. Ascites and lower extremity edema were observed a few days later. He was admitted to a hospital as laboratory testing revealed proteinuria of 10.5 g/24 h, normal creatinine levels, and serum albumin of 1.8 g/dL, confirming the presence of nephrotic syndrome. Immunology and serology tests were unremarkable. A diagnostic kidney biopsy showed no significant glomerular or tubular abnormalities in light microscopy with negative immunofluorescence. Treatment with methylprednisolone 48 mg daily was initiated. A week after

discharge, proteinuria declined to 1.2 g/24 h, and edema had disappeared, and 6 weeks later, complete remission was evident. As COVID-19 vaccination has been associated with the development of de novo and relapsing MCD, and this case provides additional support for this possible correlation.
Orbital Cellulitis following COVID-19 Vaccination. A 72-year-old male patient was referred to our outpatient clinic with a painful left eye protrusion accompanied by marked conjunctival chemosis and external ophthalmoplegia being progressed despite topical and oral antibiotic therapy. He developed ocular symptoms 9 days after receiving his second SARS-CoV-2 vaccine (VeroCell). Of note, in previous history, 2 weeks after the first dose of the COVID-19 vaccine, he also developed a life-threatening laryngeal oedema treated at an emergency care unit. MRI of the orbit excluded pansinusitis as possible origin of the orbital cellulitis, and repeated COVID-19 antigen and antibody PCR tests were negative during his hospitalization. On the next day after his admittance, parenteral dexamethasone 250 mg/die treatment was commenced resulting in a quick and complete resolution of the symptoms. Due to the facts regarding this case, such as the temporal coincidence and the lack of respective comorbidity, there might be a causative relationship between the vaccination and the presented orbital cellulitis. To the best of our knowledge, this is the first report on orbital cellulitis as a possible ocular adverse event following COVID-19 vaccination.
Progressive Worsening of Neurological Manifestations in HIV-Associated Opportunistic Central Nervous System (CNS) Infection Patients After COVID-19 Vaccinations: A Possible Co-Incidence Causality. BACKGROUND The iceberg phenomenon (in which the most of a problem is invisible) of people living with HIV/AIDS, particularly those with unknown HIV status, has been epidemiologically challenging. Central nervous system (CNS) opportunistic infections in patients with HIV/AIDS are one of the leading causes of morbidity and mortality in people living with HIV/AIDS. There are currently limited data on the immunogenicity, safety, and efficacy of COVID-19 vaccines in people living with HIV/AIDS with its associated opportunistic CNS infections as well as those without antiretroviral treatment. CASE REPORT Two young men with previously unknown HIV status and its related opportunistic infections received their first doses of COVID-19 vaccine (Vero Cell), inactivated. Both patients had the risk factor of having sex with men (men who have sex with men). Fever and first neurological symptoms occurred within the first few days after vaccination. Both patients were hospitalized and were tested positive for HIV for the first time. Both were further diagnosed from brain imaging as having CNS opportunistic infections. A presumptive diagnosis of cerebral toxoplasmosis was established as the working diagnosis according to the laboratory and epidemiological factors. Despite the treatment, neurological and clinical deficits worsened and eventually led to death in both patients. CONCLUSIONS The causality analyses showed that both adverse events had a possible inconsistent causal relationship to COVID-19 vaccination. Our cases may reflect the need for further studies on the safety of COVID-19 vaccines in people with HIV/AIDS-associated CNS opportunistic infection as well as people with HIV/AIDS who never receive antiretroviral treatment (ART).
Parsonage-Turner Syndrome After COVID-19 Vaccination: A Case Report. CASE: One week after receiving a COVID-19 vaccine in his left deltoid, a 34-year-old man developed severe right periscapular pain that lasted 2 weeks and was followed by profound right shoulder girdle atrophy and weakness. Both the pain and motor deficits resolved over the subsequent 4 months. CONCLUSION: Parsonage-Turner syndrome (PTS) is an idiopathic brachial plexopathy that can develop in the setting of recent vaccination and lead to significant shoulder pain and weakness. Given the worldwide increase in newly vaccinated patients, orthopaedic surgeons should take detailed histories to identify potential triggers (recent vaccination or illness) that point toward PTS rather than musculoskeletal pathology.

Neutralizing antibody and T cell responses against SARS-CoV-2 variants of concern following ChAdOx-1 or BNT162b2 boosting in the elderly previously immunized with CoronaVac vaccine. BACKGROUND: The existence of SARS-CoV-2 variants of concern (VOCs) in association with evidence of breakthrough infections despite vaccination resulted in the need for vaccine boosting. In elderly individuals, information on the immunogenicity of booster vaccinations is limited. In countries where the CoronaVac inactivated vaccine is the primary vaccine, the appropriate boosting regimen is not clear. Immunologic studies of the effects of booster vaccination against VOCs, particularly Delta and Omicron, following CoronaVac in elderly individuals are helpful for policy makers. In this study, we determined the immune responses against VOCs following ChAdOx-1 or BNT162b2 boosting in elderly individuals previously immunized with CoronaVac. RESULTS: Before boosting, the median % inhibition of neutralizing antibodies (NAbs) against the wild-type (WT), Alpha, Beta, Delta and Omicron variants in the ChAdOx-1 and BNT162b2 groups was 52.8% vs. 53.4, 36.6% vs. 39.9, 5.2% vs. 13.7, 34.3% vs. 44.9, and 20.8% vs. 18.8%, respectively. After boosting with ChAdOx-1 or BNT162b2, the % inhibition of NAbs were increased to 97.3% vs. 97.4, 94.3% vs. 97.3%, 79.9 vs. 93.7, 95.5% vs. 97.5, and 26.9% vs. 31.9% for WT, Alpha, Beta, Delta and Omicron variants, respectively. Boosting with BNT162b2 induced significantly higher NAb levels than boosting with ChAdOx-1 against the Alpha, Beta and Delta variants but not the WT and Omicron variants. NAb levels against Omicron variant were not significantly different before and after boosting with ChAdOx-1 or BNT162b2. To evaluate T-cell responses, S peptides of the WT, Alpha, Beta and Delta variants were used to stimulate T cells. Upon stimulation, the expression of IL-17A in CD8 T cells was higher in the BNT162b2 group than in the ChAdOx-1 boosting group. However, IFN-Î³ production in CD4 and CD8 T cells did not significantly differ under all vaccination regimens. The expression of FasL in CD4 T cells, but not CD8 T cells, was higher in the BNT162b2-boosted group. CONCLUSION: Boosting with either ChAdOx-1 or BNT162b2 in CoronaVac-primed healthy elderly individuals induced high NAb production against all examined VOCs except Omicron. BNT162b2 stimulated higher NAb and some T-cell responses than ChAdOx-1. Vaccine boosting is, therefore, recommended for elderly individuals previously immunized with CoronaVac.

Antibody response and seroprevalence in healthcare workers after the BNT162b2 vaccination in a University Hospital at Tokyo. In 2020, we reported a low seroprevalence of N-specific antibodies in 4147 health care workers (HCWs) at a frontline hospital in Tokyo, Japan. In Japan, a vaccine campaign was launched in early 2021. We re-evaluated seroprevalences of N- and S-specific antibodies in 2202 HCWs who took two doses of the BNT162b2 vaccine. In 2021, N-specific seroprevalence remains as low as 1.59%. The seroprevalences were comparable among all HCWs regardless of exposure levels. Almost all of the HCWs elicited S-specific antibodies after vaccination. However, the HCWs who had COVID-19 elicited higher S-specific antibody titers than those who did not have COVID-19. In the HCWs without a history of COVID-19, 1.1% (23 out of 2185) were seropositive with N-specific antibodies, indicating the existence of asymptomatic infections. Also, S-specific antibody titers were higher in females and younger HCWs, and in those who had severe side effects. However, S-specific antibody titers were lower depending on the number of days after the second dose of vaccination specifically in elderly individuals. In conclusion, this study indicates N-specific seroprevalence remains low in HCWs at a frontline hospital in Tokyo. The mRNA vaccine elicited S-specific antibody in HCWs, however, the titers decreased as the days proceeded.

Effect of Immunosuppressive Diseases and Rituximab Infusions on Allowing COVID-19 Infection to Relapse. INTRODUCTION: Relapsing COVID-19 infections have been reported, but their etiology and severity are still unknown. In addition, there have been no cases in the literature that associate relapsing infection with immunosuppression, either from a disease course or medications. CASE PRESENTATION: This case series illustrates two patients who developed a relapsed infection, likely

from recent rituximab infusions. In addition, both cases depicted a severe form of infection than the initial one. Laboratory investigations revealed these patients were unable to produce COVID-19 antibodies, even though one of the patients received convalescent plasma. CONCLUSION: Clinicians should be aware of the possibility of relapsing COVID-19, especially in immunosuppressed patients. Because rituximab induces B-cell depletion, it can also decrease the effectiveness of the COVID-19 vaccine. Therefore, these patients should receive the vaccine before their scheduled rituximab infusion.

No evidence of fetal defects or anti-syncytin-1 antibody induction following COVID-19 mRNA vaccination. The impact of Coronavirus Disease 2019 (COVID-19) mRNA vaccination on pregnancy and fertility has become a major topic of public interest. We investigated 2 of the most widely propagated claims to determine (1) whether COVID-19 mRNA vaccination of mice during early pregnancy is associated with an increased incidence of birth defects or growth abnormalities; and (2) whether COVID-19 mRNA-vaccinated human volunteers exhibit elevated levels of antibodies to the human placental protein syncytin-1. Using a mouse model, we found that intramuscular COVID-19 mRNA vaccination during early pregnancy at gestational age E7.5 did not lead to differences in fetal size by crown-rump length or weight at term, nor did we observe any gross birth defects. In contrast, injection of the TLR3 agonist and double-stranded RNA mimic polyinosinic-polycytidylic acid, or poly(I:C), impacted growth in utero leading to reduced fetal size. No overt maternal illness following either vaccination or poly(I:C) exposure was observed. We also found that term fetuses from these murine pregnancies vaccinated prior to the formation of the definitive placenta exhibit high circulating levels of anti-spike and anti-receptor-binding domain (anti-RBD) antibodies to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) consistent with maternal antibody status, indicating transplacental transfer in the later stages of pregnancy after early immunization. Finally, we did not detect increased levels of circulating anti-syncytin-1 antibodies in a cohort of COVID-19 vaccinated adults compared to unvaccinated adults by ELISA. Our findings contradict popular claims associating COVID-19 mRNA vaccination with infertility and adverse neonatal outcomes.

Immunization with SARS-CoV-2 Nucleocapsid protein triggers a pulmonary immune response in rats. The SARS-CoV-2 pandemic have been affecting millions of people worldwide, since the beginning of 2020. COVID-19 can cause a wide range of clinical symptoms, which varies from asymptomatic presentation to severe respiratory insufficiency, exacerbation of immune response, disseminated microthrombosis and multiple organ failure, which may lead to dead. Due to the rapid spread of SARS-CoV-2, the development of vaccines to minimize COVID-19 severity in the world population is imperious. One of the employed techniques to produce vaccines against emerging viruses is the synthesis of recombinant proteins, which can be used as immunizing agents. Based on the exposed, the aim of the present study was to verify the systemic and immunological effects of IM administration of recombinant Nucleocapsid protein (NP), derived from SARS-CoV-2 and produced by this research group, in 2 different strains of rats (Rattus norvegicus); Wistar and Lewis. For this purpose, experimental animals received 4 injections of NP, once a week, and were submitted to biochemical and histological analysis. Our results showed that NP inoculations were safe for the animals, which presented no clinical symptoms of worrying side effects, nor laboratorial alterations in the main biochemical and histological parameters, suggesting the absence of toxicity induced by NP. Moreover, NP injections successfully triggered the production of specific anti-SARS-CoV-2 IgG antibodies by both Wistar and Lewis rats, showing the sensitization to have been well sufficient for the immunization of these strains of rats. Additionally, we observed the local lung activation of the Bronchus-Associated Lymphoid Tissue (BALT) of rats in the NP groups, suggesting that NP elicits specific lung immune response. Although pre-clinical and clinical studies are still required, our data support the recombinant NP produced by this research group as a potential immunizing agent for

massive vaccination, and may represent advantages upon other recombinant proteins, since it seems to induce specific pulmonary protection.
Pfizer mRNA COVID-19 Vaccination and Acute Inflammatory Demyelinating Polyneuropathy.
Parsonage Turner Syndrome Following Vaccination With mRNA-1273 SARS-CoV-2 Vaccine.
Myocarditis Cases After mRNA-Based COVID-19 Vaccination in the US.
Myocarditis Cases After mRNA-Based COVID-19 Vaccination in the US-Reply.
Cardiac Complications More Common After COVID-19 Than Vaccination.
Miller Fisher syndrome after COVID-19 vaccination: Case report and review of literature. RATIONALE: Miller Fisher syndrome (MFS) is a rare variant of Guillain-Barre syndrome, classically diagnosed based on the clinical triad of ataxia, areflexia, and ophthalmoplegia. MFS is usually preceded by viral infections and febrile illness; however, only a few cases have been reported after vaccinations. PATIENT CONCERNS: A 53-year-old hypertensive male presented with a 2-day history of progressive ascending paralysis of the lower limbs along with diplopia and ataxia, 8 days after the first dose of the Sinovac-Coronavac coronavirus disease 2019 (COVID-19) vaccination, with no prior history of any predisposing infections or triggers. DIAGNOSES: Physical examination showed moderate motor and sensory loss with areflexia in the lower limbs bilaterally. Routine blood investigations and radiological investigations were unremarkable. Cerebrospinal fluid analysis showed albuminocytologic dissociation and nerve conduction studies revealed prolonged latencies with reduced conduction velocities. The diagnosis of MFS was established based on the findings of physical examination, cerebrospinal fluid analysis, and nerve conduction studies. INTERVENTIONS: A management plan was devised based on intravenous immunoglobulins, pregabalin, and physiotherapy. However, due to certain socioeconomic factors, the patient was managed conservatively with regular physiotherapy sessions. OUTCOMES: Follow-up after 6 weeks showed remarkable improvement, with complete resolution of symptoms 10 weeks after the discharge. LESSONS: This case suggests that MFS is a rare adverse effect after COVID-19 vaccination and additional research is required to substantiate a temporal association. Further studies are needed to understand the pathophysiology behind such complications to enhance the safety of COVID-19 vaccinations in the future.
A Case Report of Herpes Zoster Ophthalmicus and Meningitis After COVID-19 Vaccination. There are several reports that herpes zoster characterized by reactivation of varicella zoster virus (VZV) following coronavirus disease 2019 (COVID-19) vaccines can occur. Herein, we report VZV meningitis, herpes zoster ophthalmicus (HZO), and late neurotrophic keratitis after receiving a second dose of messenger RNA (mRNA) COVID-19 vaccine. A 74-year-old man developed a vesicular skin rash on the forehead, scalp, nose, and left upper eyelid with a severe headache. Five days earlier, he received a second dose of the BNT162b2 mRNA vaccine on his left arm. Ocular examination revealed conjunctival hyperemia and pseudodendrite in the peripheral cornea. VZV was detected in the cerebrospinal fluid using polymerase chain reaction. The patient was diagnosed with HZO and meningitis. The patient was treated with intravenous acyclovir and topical acyclovir ointment and levofloxacin 1.5% eye drops. One month later, he developed a central epithelial defect with a rolled margin, typical of a neurotrophic ulcer. Treatment with a therapeutic contact lens and a combination of topical recombinant human epithelial growth factor and ofloxacin ointment was initiated. At six months after vaccination, the slit-lamp examination findings were stable with a mild corneal superficial stromal haze.
Immune-mediated adverse events post-COVID vaccination and types of vaccines: a systematic review and meta-analysis. BACKGROUND: In late 2019, Coronavirus disease 2019 has been declared as a global emergency by World Health Organization. Hopefully, recent reports of effective and safe vaccines were welcomed, and approved on emergency base. Millions of recipients had received one

of the approved COVID 19 vaccines, with lots of adverse events recorded global wide. OBJECTIVE: To assess post-COVID vaccination immune-mediated adverse events and evaluate its association to specific type of vaccine global wide. METHODS: Systematic literature review and meta-analysis of published reports (since December 2020 till December 2021) on immune-mediated adverse events post-COVID vaccination. RESULTS: We evaluated 34 published studies; 460 cases with various adverse events post-COVID vaccination. Studies in current literature are primarily retrospective case series, isolated case reports or narrative studies. Different COVID vaccines were involved. Results' data was subcategorized according to associated vaccine. Adverse effects of COVID-19 vaccinations included thrombotic, neurological, myocarditis, ocular, dermatological, renal, hematological events timely linked to inoculation. Each vaccine type was linked to adverse profile that differ from others. CONCLUSION: High suspicion of post-vaccination adverse events is mandatory to provoke earlier detection, better understanding, optimum prevention, and management. Specific vaccine/patient risk profile is needed to selectively categorize target population to reduce morbidity and mortality post-vaccination.

Longitudinal analysis of anti-SARS-CoV-2 S-RBD IgG antibodies before and after the third dose of the BNT162b2 vaccine. Immunosurveillance by evaluating anti-spike protein receptor-binding domain (S-RBD) antibodies represents a useful tool to estimate the long immunity against Severe Acute Respiratory Syndrome CoronaVirus 2 (SARS-CoV-2) infection. The aim of this study was to evaluate the kinetics of antibody response in vaccine recipients. We measured anti-S-RBD IgG levels by indirect chemiluminescence immunoassay on Maglumi 800 (SNIBE, California) in 1013 healthy individuals naÃ¯ve to SARS-CoV2 infection after two and three COVID-19 vaccine doses. We found that anti-S-RBD IgG levels are higher in females than males. Antibody levels gradually decrease to a steady state after four months since the peak, and the decay is independent of age, sex, vaccine doses, and baseline antibodies titer. The third dose induces a high anti-S-RBD IgG reactivity in individuals with previous high responses and triggers a moderate-high anti-S-RBD IgG reactivity. The assessment of anti-S-RBD IgG levels is essential for monitoring long-term antibody response. A third SARS-CoV-2 vaccine dose is associated with a significant immunological response. Thus, our results support the efficacy of the vaccine programs and the usefulness of the third dose.

Phase 1/2 clinical trial of COVID-19 vaccine in Japanese participants: A report of interim findings. We initiated a randomized, placebo-controlled, phase 1/2 trial to evaluate the safety and immunogenicity of the S-268019-b recombinant protein vaccine, scheduled as 2 intramuscular injections given 21Â days apart, in 60 randomized healthy Japanese adults. We evaluated 2 regimens of the S-910823 antigen (5Â Î¼g [nÂ =Â 24] and 10Â Î¼g [nÂ =Â 24]) with an oil-in-water emulsion formulation and compared against placebo (nÂ =Â 12). Reactogenicity was mild in most participants. No serious adverse events were noted. For both regimens, vaccination resulted in robust IgG and neutralizing antibody production at days 36 and 50 and predominant T-helper 1-mediated immune reaction, as evident through antigen-specific polyfunctional CD4+ T-cell responses with IFN-Î³, IL-2, and IL-4 production on spike protein peptides stimulation. Based on the interim analysis, the S-268019-b vaccine is safe, produces neutralizing antibodies titer comparable with that in convalescent serum from COVID-19-recovered patients. However, further evaluation of the vaccine in a large clinical trial is warranted.

High torque tenovirus (TTV) load before first vaccine dose is associated with poor serological response to COVID-19 vaccination in lung transplant recipients. BACKGROUND: Serological responses to COVID-19 vaccination are diminished in recipients of solid organ transplants, especially in lung transplant recipients (LTR), probably as result of immunosuppressive treatment. There is currently no marker of immunosuppression that can be used to predict the COVID-19 vaccination response. Here, we study whether torque tenovirus (TTV), a highly prevalent virus can be used as an

indicator of immunosuppression. METHODS: The humoral response to the mRNA 1273 vaccine was assessed in 103 LTR, who received a transplant between 4 and 237 months prior to vaccination, by measuring Spike (S)-specific IgG levels at baseline, 28 days after first, and 28 days after the second vaccination. TTV loads were determined by RT-PCR and Pearson's correlation coefficient was calculated to correlate serological responses to TTV load. RESULTS: Humoral responses to COVID-19 vaccination were observed in 41 of 103 (40%) LTR at 28 days after the second vaccination. Sixty-two of 103 (60%) were non-responders. Lower TTV loads at baseline (significantly) correlated with higher S-specific antibodies and a higher percentage of responders. Lower TTV loads also strongly correlated with longer time since transplantation, indicating that participants with lower TTV loads were longer after transplantation. CONCLUSIONS: This study shows a better humoral response to the SARS-CoV-2 vaccine in subjects with a lower TTV load pre-vaccination. In addition, TTV load correlates with the time after transplantation. Further studies on the use of TTV load in vaccination efficacy studies in immunocompromised cohorts should provide leads for the potential use of this marker for optimizing vaccination response.

Venous sinus thrombosis after the first dose of Pfizer BioNTech vaccine. mRNA vaccines including Pfizer BioNTech and Moderna have categorically been considered safe when it comes to preventing COVID-19. However, there is still a small associated risk of thromboembolic phenomenon including venous sinus thrombosis with it and our case report highlights one.We describe a patient who developed severe progressive headache, tinnitus and visual disturbance symptoms post-Pfizer-SARS-CoV-2 vaccination. His medical history included essential tremors, hypertension, type 2 diabetes mellitus, chronic kidney disease stage 3, anxiety, depression and long-term catheterisation. Systemic examination revealed hypotonia, generalised reduced power and central diplopia along with peripheral visual field defect in the left eye. He was extensively investigated, the COVID-19 PCR test was negative and all routine blood tests were in the normal range except a marginally raised D-dimer of 779â€‰ng/mL. CT head was unremarkable. He was also tested for myasthenia gravis; however, acetylcholine receptors antibodies were negative and nerve conduction studies were normal. Subsequent MRI of the brain with venography confirmed venous sinus thrombosis. A 24-hour Holter monitoring test did not reveal any cardiac rate or rhythm abnormality. He was treated with apixaban as per a neurologist's advice. His clinical condition started to improve and was later discharged from the hospital with an outpatient neurologist clinic follow-up.

Erythema multiforme in a young adult following COVID-19 infection and vaccination in Tanzania. We report the case of a young female adult in her early 20s, who had COVID-19 infection for 8 weeks and COVID-19 vaccination 4 weeks prior to presentation with an extensive rash associated with erythema multiforme, resembling varicella zoster on initial presentation. After initial acyclovir therapy with no improvement, systemic corticosteroid treatment dramatically resolved the patient's skin rash.

Seroprevalence of SARS-CoV-2 infection and associated factors among Bangladeshi slum and non-slum dwellers in pre-COVID-19 vaccination era: October 2020 to February 2021. BACKGROUND: Seroprevalence studies have been carried out in many developed and developing countries to evaluate ongoing and past infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Data on this infection in marginalized populations in urban slums are limited, which may offer crucial information to update prevention and mitigation policies and strategies. We aimed to determine the seroprevalence of SARS-CoV-2 infection and factors associated with seropositivity in slum and non-slum communities in two large cities in Bangladesh. METHODS: A cross-sectional study was carried out among the target population in Dhaka and Chattogram cities between October 2020 and February 2021. Questionnaire-based data, anthropometric and blood pressure measurements and blood were obtained. SARS-CoV-2 serology was assessed by Roche ElecsysÂ® Anti-SARS-CoV-2

immunoassay. RESULTS: Among the 3220 participants (2444 adults, â‰¥18 years; 776 children, 10-17 years), the overall weighted seroprevalence was 67.3% (95% confidence intervals (CI) = 65.2, 69.3) with 71.0% in slum (95% CI = 68.7, 72.2) and 62.2% in non-slum (95% CI = 58.5, 65.8). The weighted seroprevalence was 72.9% in Dhaka and 54.2% in Chattogram. Seroprevalence was positively associated with limited years of formal education (adjusted odds ratio [aOR] = 1.61; 95% CI = 1.43, 1.82), lower income (aOR = 1.23; 95% CI = 1.03, 1.46), overweight (aOR = 1.2835; 95% CI = 1.26, 1.97), diabetes (aOR = 1.67; 95% CI = 1.21, 2.32) and heart disease (aOR = 1.38; 95% CI = 1.03, 1.86). Contrarily, negative associations were found between seropositivity and regular wearing of masks and washing hands, and prior BCG vaccination. About 63% of the population had asymptomatic infection; only 33% slum and 49% non-slum population showed symptomatic infection. CONCLUSION: The estimated seroprevalence of SARS-CoV-2 was more prominent in impoverished informal settlements than in the adjacent middle-income non-slum areas. Additional factors associated with seropositivity included limited education, low income, overweight and pre-existing chronic conditions. Behavioral factors such as regular wearing of masks and washing hands were associated with lower probability of seropositivity.

Utilizing wearable sensors for continuous and highly-sensitive monitoring of reactions to the BNT162b2 mRNA COVID-19 vaccine. BACKGROUND: Clinical trial guidelines for assessing the safety of vaccines, are primarily based on self-reported questionnaires. Despite the tremendous technological advances in recent years, objective, continuous assessment of physiological measures post-vaccination is rarely performed. METHODS: We conducted a prospective observational study during the mass vaccination campaign in Israel. 160 participants >18 years who were not previously found to be COVID-19 positive and who received the BNT162b2 COVID-19 (Pfizer BioNTech) vaccine were equipped with an FDA-approved chest-patch sensor and a dedicated mobile application. The chest-patch sensor continuously monitored 13 different cardiovascular, and hemodynamic vitals: heart rate, blood oxygen saturation, respiratory rate, systolic and diastolic blood pressure, pulse pressure, mean arterial pressure, heart rate variability, stroke volume, cardiac output, cardiac index, systemic vascular resistance and skin temperature. The mobile application collected daily self-reported questionnaires on local and systemic reactions. RESULTS: We identify continuous and significant changes following vaccine administration in nearly all vitals. Markedly, these changes are observed even in presumably asymptomatic participants who did not report any local or systemic reaction. Changes in vitals are more apparent at night, in younger participants, and in participants following the second vaccine dose. CONCLUSION: the considerably higher sensitivity of wearable sensors can revolutionize clinical trials by enabling earlier identification of abnormal reactions with fewer subjects.

A Case of Membranous Nephropathy Hypothesized to be Associated With COVID-19 Vaccine. A 56-year-old male patient with a medical history of essential hypertension was referred to the emergency room after he was found to have a serum creatinine level of 13 mg/dL at his primary care physician's office. The patient reported that he had developed a coronavirus disease 2019 (COVID-19)-like infection six months prior that was not confirmed. Two months later, he started to notice dyspnea on exertion and bilateral lower limb swelling and was started on furosemide. He received the first dose of the Moderna COVID-19 vaccine a month before the presentation but did not receive the second dose. Subsequently, his lower limb swelling and exertional dyspnea started worsening. He denied any new medication, dysuria, oliguria, hematuria, fever, or any other symptoms. Initial evaluation was consistent with kidney failure. Hypocalcemia and hyperphosphatemia were noted, along with medical renal disease on renal ultrasound. Eosinophils and nephrotic-range proteinuria were found in the urine. His serum phospholipase A2 receptor (PLA2R) antibodies were positive. A renal biopsy showed membranous glomerulonephritis with moderate segmental sclerosis, as well as

tubulointerstitial fibrosis with neutrophils, consistent with acute interstitial nephritis. Positive staining for PLA2R in the glomerular deposits suggested primary membranous nephropathy (MN). He was treated with prednisone first, and when the kidney biopsy was conclusive for membranous glomerulopathy, he was started on rituximab. On admission, he received hemodialysis intermittently, but this was stopped a month after discharge as his renal function normalized. Recently, there have been numerous cases reported with new onset of glomerular disease after receiving the COVID-19 vaccine. Further studies of vaccinated patients are needed to determine whether the severe acute respiratory syndrome coronavirus 2 virus vaccination is associated with a higher risk of MN and to identify potential predisposing factors and mechanisms of kidney injury in patients in whom it occurs.

Neurologic Sequela of COVID-19: Guillain-BarrÃ© Syndrome Following Johnson & Johnson COVID-19 Vaccination. Guillain-BarrÃ© syndrome after Pfizer and Astra-Zeneca vaccinations against COVID-19 hasÂ been previously reported in the literature. The objective of this study was to report the first case of Guillain-BarrÃ© following the COVID-19 vaccination with the Johnson & Johnson COVID-19 vaccine. We report the case of a 53-year-old female who presented to the Emergency Department complaining of bilateral lower extremity weakness, paresthesias, and gait difficulties 14 days after having received the Johnson & Johnson COVID-19 vaccination. MRI of the lumbar spine with and without contrast revealed enhancement of the cauda equina nerve roots suggestive of acute inflammatory demyelinating polyradiculoneuropathy. Cerebrospinal fluid (CSF) analysis reported mildly elevated protein low white blood cells (WBCs). Ganglioside (GM1 and GQ1b) antibodies were reported as negative. After intravenous immunoglobulin (IVIg), the patient had significant improvement in her weakness and paresthesia and was discharged home. The case was reported to the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System. Guillain-BarrÃ© syndrome after COVID-19 immunization remains a rare complication. A clear mechanism of disease has not been clarified; however, it is believed that there could be some type of molecular mimicry between the spike glycoprotein produced with the help of the vaccines andÂ proteins in the myelin sheath.

A case of myopericarditis recurrence after third dose of BNT162b2 vaccine against SARS-CoV-2 in a young subject: link or causality? The rate of post-vaccine myocarditis is being studied from the beginning of the massive vaccination campaign against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Although a direct cause-effect relationship has been described, in most cases, the vaccine pathophysiological role is doubtful. Moreover, it is not quite as clear as having had a previous myocarditis could be a risk factor for a post-vaccine disease relapse. A 27-year-old man presented to the emergency department for palpitations and pericardial chest pain radiated to the upper left limb, on the 4th day after the third dose of BNT162b2 vaccine. He experienced a previous myocarditis 3â€‰years before, with full recovery and no other comorbidities. Electrocardiogram showed normal atrioventricular conduction, incomplete right bundle branch block, and diffuse ST-segment elevation. A cardiac echo showed lateral wall hypokinesis with preserved ejection fraction. Troponin-T was elevated (160â€‰ng/L), chest X-ray was normal, and the SARS-CoV-2 molecular buffer was negative. High-dose anti-inflammatory therapy with ibuprofen and colchicine was started; in the 3rd day high-sensitivity Troponin I reached a peak of 23000â€‰ng/L. No heart failure or arrhythmias were observed. A cardiac magnetic resonance was performed showing normal biventricular systolic function and abnormal tissue characterization suggestive for acute non-ischaemic myocardial injury (increased native T1 and T2 values, increased signal intensity at T2-weighted images and late gadolinium enhancement, all findings with matched subepicardial distribution) at the level of mid to apical septal, anterior, and anterolateral walls. A left ventricular electroanatomic voltage mapping was negative (both unipolar and bipolar), while the endomyocardial biopsy showed a picture consistent with active myocarditis. The patient was

discharged in good clinical condition, on bisoprolol 1.25â€‰mg, ramipril 2.5â€‰mg, ibuprofen 600â€‰mg three times a day, colchicine 0.5â€‰mg twice a day. We presented the case of a young man with history of previous myocarditis, admitted with a non-complicated acute myopericarditis relapse occurred 4â€‰days after SARS-CoV-2 vaccination (3rd dose). Despite the observed very low incidence of cardiac complications following BNT162b2 administration, and the lack of a clear proof of a direct cause-effect relationship, we think that in our patient this link can be more than likely. In the probable need for additional SARS-CoV-2 vaccine doses in the next future, studies addressing the risk-benefit balance of this subset of patient are warranted. We described a multidisciplinary management of a case of myocarditis recurrence after the third dose of SARS-CoV-2 BNT162b2 vaccine.

A case of restless legs syndrome after BNT162b2 mRNA COVID-19 vaccination. Restless legs syndrome (RLS) can be secondary to several disorders. We present an 87-year-old woman who developed RLS 2Â days after the first injection of BNT162b2 mRNA coronavirus disease 2019 vaccine. The symptoms of RLS tended to improve and eventually resolved with the administration of gabapentin.

Vaccine Side Effects Following COVID-19 Vaccination Among the Residents of the UAE-An Observational Study. COVID-19 vaccines have proven to be very safe in the clinical trials, however, there is less evidence comparing the safety of these vaccines in real-world settings. Therefore, we aim to investigate the nature and severity of the adverse effects reported and the differences based on the type of vaccine received. A survey was conducted among 1,878 adult (â‰¥18 years) COVID-19 vaccine recipients through online survey platforms and telephonic interviews during March to September 2021. The factors potentially associated with the reported side effects like age, gender, ethnicity, comorbidities, and previous COVID-19 infection were analyzed based on the type of vaccine received. Differences in adverse events and the severity were compared between inactivated and mRNA vaccine recipients. The major adverse effects reported by the COVID-19 vaccine recipients were pain at the site of injection, fatigue and drowsiness, and headache followed by joint/muscle pain. The adverse effects were more common among recipients of mRNA Pfizer-BioNTech vaccine than among recipients of inactive Sinopharm vaccine with the odds ratio of 1.39 (95% CI 1.14-1.68). The average number of adverse effects reported between individuals who had received Sinopharm and Pfizer-BioNTech vaccines was 1.61 Â± 2.08 and 2.20 Â± 2.58, respectively, and the difference was statistically significant (p <0.001). Severe adverse effects after COVID-19 vaccinations were rare and 95% of the adverse effects reported after either an inactivated or mRNA vaccine were mild requiring no or home-based treatment. The study found that individuals less than 55 years of age, female gender, with history of one or more comorbid conditions, who had received mRNA Pfizer- BioNTech vaccine, and with history of COVID-19 infections are at higher odds of developing an adverse effect post COVID-19 vaccination compared to the others.

Recurrence of Herpetic Keratitis after COVID-19 Vaccination: A Report of Two Cases. BACKGROUND: Recurrence of herpetic keratitis following vaccination has been documented following vaccination with the Zostavax, trivalent flu, hepatitis A, and rabies vaccines. The USFDA and WHO have acknowledged that the novel COVID-19 vaccines similarly have a risk of reactive immunologic-based inflammation, namely, myositis, pericarditis, and Guillain-BarrÃ© syndrome. Case Presentation. We present two patients with latent herpetic keratitis who experienced reactivation of keratitis within weeks of COVID-19 vaccination despite prolonged periods of prior latency. A 52-year-old healthy male with no herpes simplex virus (HSV) keratitis recurrences in two years developed visual decline and patchy stromal haze within 24-48 hours of receiving the second Pfizer-BioNTech (COVID-19 BNT162b2) vaccine. A 67-year-old female with chronic neurotrophic keratitis developed her most severe exacerbation of herpes zoster keratitis in over 10 years occurring 2-3 weeks after her

first Moderna (mRNA-1273) vaccine, which was later complicated by bacterial superinfection. CONCLUSIONS: The COVID-19 vaccines work by generating both adaptive humoral and cellular immune responses in humans, including elevation of anti-spike neutralizing antibody titers, antigen-specific CD4+ and CD8+ T-cell responses, and increased levels of proinflammatory cytokines such as interferon gamma (IFNÎ³). The general activation of the T-cell-mediated immune response and proinflammatory cytokines such as IFNÎ³ may underlie the role of the COVID vaccines in reactivation of herpetic stromal keratitis and the clinical findings in our reported cases.

A case of chronic inflammatory demyelinating polyneuropathy following COVID-19 vaccine. We report a 44-year-old woman who presented with bilateral weakness of the hands and distal paresthesia of the arms on the next day of the second COVID-19 vaccine, and gradually progressed ascending weakness of the arms and legs, and sensory ataxia beyond 2â€‰months. She was diagnosed as a chronic inflammatory demyelinating polyneuropathy (CIDP) following COVID-19 vaccine on the basis of clinical and electrophysiological findings. This is a first case diagnosed as a CIDP following COVID-19 vaccine alone.

Central Diabetes Insipidus Following Immunization With BNT162b2 mRNA COVID-19 Vaccine: A Case Report. INTRODUCTION: Cases of central diabetes insipidus (CDI) have been reported after COVID-19 infection, with hypophysitis being the most likely cause. COVID-19 vaccines potential adverse effects may mimetize some of these complications. CASE REPORT: Woman 37 years old, with rheumatoid arthritis under adalimumab (40 mg twice a month) since December 2018. She was in her usual state of health when she has received the second dose of BNT162b2 mRNA COVID-19 vaccine (June 2021). Seven days later, she started reporting intense thirst and polyuria and consulted her family physician. BLOOD ANALYSIS: creatinine 0.7 mg/dL, glucose 95mg/dL, Na+ 141mEq/L, K+ 3.9 mEq/L, TSH 3.8 mcUI/L (0.38-5.33), FT4 0.9 ng/dL (0.6-1.1), cortisol 215.4 nmol/L (185-624), ACTH 21.9 pg/mL (6- 48), FSH 4.76 UI/L, LH5.62 UI/L, estradiol 323 pmol/L, IGF1 74.8 ng/mL (88-209), PRL 24.7mcg/L (3.3-26.7) osmolality 298.2 mOs/Kg (250- 325); Urine analysis: volume 10200 mL/24h, osmolality 75 mOs/Kg (300-900), density 1.002. On water restriction test: 0' - Serum osmolality 308.8mOsm/Kg vs. urine osmolality 61.0 mOsm/Kg; 60' - urine osmolality 102 mOsm/Kg; urine osmolality 1 h after desmopressine was 511mOsm/kg. MRI revealed no abnormal signs consistent with hypophysitis except for the loss of the posterior pituitary bright spot on T1 weighted imaging. Diagnosis of CDI was assumed, and started therapy with desmopressine. A report of potential adverse effect was addressed to national health authorities. CONCLUSION: In hypophysitis MRI often shows loss of posterior pituitary bright spot on T1 weighted imaging, pituitary enlargement or stalk thickening but those findings were not present in this patient. To the best of our knowledge, CDI has never been reported following administration of a COVID-19 vaccine.

Response to "Nerve conduction studies support the classification of SARSCoV-2 associated Guillain-Barre subtypes".

Vaccine-induced prothrombotic immune thrombocytopenia without thrombosis may not require immune modulatory therapy: A case report. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare complication of the ChAdOx1 nCoV-19 and Ad26.COV2.S COVID-19 vaccines. It presents most commonly with severe thrombocytopenia and thrombotic complications with extremely high D-dimer levels 5-30Â days after vaccination. We report a patient who presented with mild thrombocytopenia and minimally elevated D-dimer levels without thrombosis, but who tested positive for antiplatelet factor 4 (PF4) platelet-activating antibodies on a PF4-enhanced serotonin-release assay. KEY CLINICAL QUESTION: Is immunomodulation necessary in patients who present without thrombosis? CLINICAL APPROACH AND CONCLUSIONS: Treatment with rivaroxaban alone was followed by platelet normalization despite persistence of anti-PF4 antibodies. This case provides support that vaccination for COVID-19 can induce a broad, heterogeneous

prothrombotic disorder characterized by anti-PF4 platelet-activating antibodies that shares features with classical heparin-induced thrombocytopenia (HIT) and autoimmune HIT syndromes and that immunomodulation may not be required in those without thrombosis.
Bilateral multifocal central serous retinopathy following mRNA COVID-19 vaccine. We present a case of acute bilateral multifocal CSCR in a young healthy Caucasian female occurring 3 days after receiving the first dose of the Pfizer-BioNTech BNT162b2 COVID-19 mRNA vaccine. The true incidence of this adverse reaction might be underreported in asymptomatic unilateral or paracentral cases. We believe that the post-COVID-19 vaccination occurrence of CSCR is not a sufficient reason to withhold the second dose of the vaccine. Further studies are required to ascertain the best way to prevent and manage this complication.
Waning of SARS-CoV-2 Vaccine-Induced Immune Response over 6 Months in Peritoneal Dialysis Patients and the Role of a Booster Dose in Maintaining Seropositivity. INTRODUCTION: Although lower than general population, newly developed SARS-CoV-2 vaccines generate immune responses in end-stage kidney disease patients. However, the persistence of immune responses in the long term is not known yet. This study aimed to evaluate humoral immune responses in peritoneal dialysis (PD) patients over 6 months and to analyze the effects of the booster dose. METHODS: Humoral immune responses of PD patients were measured after initial SARS-CoV-2 vaccinations and after 6 months following initial vaccinations. Immune responses were compared between patients who received and did not receive booster doses. PD patients were compared with 41 hemodialysis (HD) patients and 61 healthy controls. Humoral immune responses were measured by a commercial test that detects antibodies toward the receptor-binding domain of the spike protein of SARS-CoV-2. RESULTS: Twenty PD patients were evaluated over 6 months. The initial seropositivity rate was 90.9% with inactivated vaccine and 100% with mRNA vaccine. Seropositivity decreased to 44.4% after 6 months, and a booster dose helped in maintaining the 100% of seropositivity (p = 0.005). Magnitude of humoral response at the 6th month was also higher in patients who received the third dose (1,132.8 Â± 769.6 AU/mL vs. 400.0 Â± 294.6 AU/mL; p = 0.015). Among patients who did not receive the third dose, those who got mRNA vaccine could maintain higher seropositivity than others who got inactivated vaccine (75% vs. 40% for PD, 81.8% vs. 50% for HD). Seropositivity and antibody levels were similar for PD and HD patients after 6 months (p = 0.24 and 0.56) but lower than healthy controls (p = 0.0013). CONCLUSION: SARS-CoV-2 vaccine-induced antibody levels and seropositivity of PD patients significantly fall after 6 months. A booster dose after around 3 months following initial immunization might help in maintaining seropositivity.
New Onset of Inflammatory Arthritis Following Moderna COVID-19 Vaccination.
Critical Stepwise Decline of Antibodies against SARS-CoV-2 among Chronic Hemodialysis Patients 180 Days Post Comirnaty Vaccine. BACKGROUND: The reduced immune response of maintenance hemodialysis patients to coronavirus disease 2019 (COVID-19) vaccines is a major concern. OBJECTIVES: To analyze the late (6 months after full vaccination) antibody response and compare it to early post-vaccination titer. METHODS: We conducted a multicenter prospective study of 13 hemodialysis units in Israel. RESULTS: We demonstrated that the low titers observed among ESRD patients 2-3 months after vaccination with the Comirnaty vaccine (median 63.8 AU/ml) declined to critically lower values 6 months after full vaccination. (Medianti S antibodies, 31 AU/ml). Seropositivity significantly declined among hemodialysis patients from 89% to 74% (P < 0.0001), although it did not significantly change among controls. CONCLUSIONS: We recommend all patients on hemodialysis receive a booster COVID-19 vaccine 6 months after the second dose.
Hospitalised patients with breakthrough COVID-19 following vaccination during two distinct waves in Israel, January to August 2021: a multicentre comparative cohort study. BackgroundChanging patterns of vaccine breakthrough can clarify vaccine effectiveness.AimTo compare breakthrough

infections during a SARS-CoV-2 Delta wave vs unvaccinated inpatients, and an earlier Alpha wave.MethodsIn an observational multicentre cohort study in Israel, hospitalised COVID-19 patients were divided into three cohorts: breakthrough infections in Comirnaty-vaccinated patients (VD; Jun-Aug 2021) and unvaccinated cases during the Delta wave (ND) and breakthrough infections during an earlier Alpha wave (VA; Jan-Apr 2021). Primary outcome was death or ventilation.ResultsWe included 343 VD, 162 ND and 172 VA patients. VD were more likely older (OR: 1.06; 95% CI: 1.05-1.08), men (OR: 1.6; 95% CI: 1.0-2.5) and immunosuppressed (OR:â€‰2.5; 95% CI: 1.1-5.5) vs ND. Median time between second vaccine dose and admission was 179 days (IQR: 166-187) in VD vs 41 days (IQR: 28-57.5) in VA. VD patients were less likely to be men (OR: 0.6; 95% CI: 0.4-0.9), immunosuppressed (OR:â€‰0.3; 95% CI: 0.2-0.5) or have congestive heart failure (OR:â€‰0.6; 95% CI: 0.3-0.9) vs VA. The outcome was similar between all cohorts and affected by age and immunosuppression and not by vaccination, variant or time from vaccination.ConclusionsVaccination was protective during the Delta variant wave, as suggested by older age and greater immunosuppression in vaccinated breakthrough vs unvaccinated inpatients. Nevertheless, compared with an earlier post-vaccination period, breakthrough infections 6 months post-vaccination occurred in healthier patients. Thus, waning immunity increased vulnerability during the Delta wave, which suggests boosters as a countermeasure.

Serial Cardiovascular Magnetic Resonance Studies Prior to and After mRNA-Based COVID-19 Booster Vaccination to Assess Booster-Associated Cardiac Effects. BACKGROUND: mRNA-based COVID-19 vaccination is associated with rare but sometimes serious cases of acute peri-/myocarditis. It is still not well known whether a 3rd booster-vaccination is also associated with functional and/or structural changes regarding cardiac status. The aim of this study was to assess the possible occurrence of peri-/myocarditis in healthy volunteers and to analyze subclinical changes in functional and/or structural cardiac parameters following a mRNA-based booster-vaccination. METHODS AND RESULTS: Healthy volunteers aged 18-50 years (n = 41; m = 23, f = 18) were enrolled for a CMR-based serial screening before and after 3rd booster-vaccination at a single center in Germany. Each study visit comprised a multi-parametric CMR scan, blood analyses with cardiac markers, markers of inflammation and SARS-CoV-2-IgG antibody titers, resting ECGs and a questionnaire regarding clinical symptoms. CMR examinations were performed before (median 3 days) and after (median 6 days) 3rd booster-vaccination. There was no significant change in cardiac parameters, CRP or D-dimer after vaccination, but a significant rise in the SARS-CoV-2-IgG titer ($p < 0.001$), with a significantly higher increase in females compared to males ($p = 0.044$). No changes regarding CMR parameters including global native T1- and T2-mapping values of the myocardium were observed. A single case of a vaccination-associated mild pericardial inflammation was detected by T2-weighted CMR images. CONCLUSION: There were no functional or structural changes in the myocardium after booster-vaccination in our cohort of 41 healthy subjects. However, subclinical pericarditis was observed in one case and could only be depicted by multiparametric CMR.

HDAC Inhibition as Potential Therapeutic Strategy to Restore the Deregulated Immune Response in Severe COVID-19. The COVID-19 pandemic has had a devastating impact worldwide and has been a great challenge for the scientific community. Vaccines against SARS-CoV-2 are now efficiently lessening COVID-19 mortality, although finding a cure for this infection is still a priority. An unbalanced immune response and the uncontrolled release of proinflammatory cytokines are features of COVID-19 pathophysiology and contribute to disease progression and worsening. Histone deacetylases (HDACs) have gained interest in immunology, as they regulate the innate and adaptative immune response at different levels. Inhibitors of these enzymes have already proven therapeutic potential in cancer and are currently being investigated for the treatment of autoimmune diseases. We thus tested the effects of different HDAC inhibitors, with a focus on a selective HDAC6 inhibitor,

on immune and epithelial cells in in vitro models that mimic cells activation after viral infection. Our data indicate that HDAC inhibitors reduce cytokines release by airway epithelial cells, monocytes and macrophages. This anti-inflammatory effect occurs together with the reduction of monocytes activation and T cell exhaustion and with an increase of T cell differentiation towards a T central memory phenotype. Moreover, HDAC inhibitors hinder IFN-I expression and downstream effects in both airway epithelial cells and immune cells, thus potentially counteracting the negative effects promoted in critical COVID-19 patients by the late or persistent IFN-I pathway activation. All these data suggest that an epigenetic therapeutic approach based on HDAC inhibitors represents a promising pharmacological treatment for severe COVID-19 patients.

Kikuchi-Fujimoto's Disease or Histiocytic Necrotizing Lymphadenitis Following mRNA COVID-19 Vaccination: A Rare Case. Kikuchi-Fujimoto disease (KFD), also known as necrotizing histiocytic lymphadenopathy, is a rare and benign lymph node disorder that mainly occurs in young women. It is clinically characterized by fever with tender and painful cervical lymphadenopathy mostly; however, all areas of lymph nodes can be involved. This disorder is often mistaken for malignant lymphoma or infection. The precise pathophysiology of KFD remains unknown, but it is theorized that it may be post-viral or associated with an autoimmune disease. The diagnosis is based on the histological analysis of the excised involved lymph node.Â The treatment is mainly supportive with favorable outcomes within a few weeks or months. In this case, we present a 24-year-old woman without a past medical history, who consulted for painful bilateral cervical lymphadenopathy associated with fever that has been evolving for one month following the coronavirus disease 2019 (COVID-19) vaccination. The initial diagnostic workup was performed and the diagnosis of KFD was confirmed based on the histopathological findings of the excised lymphadenopathy. Therapeutic management was based on oral corticosteroid treatment with clinical and radiological improvement after a few days without recurrence during follow-up. This article aims to report a rare case of KFD in a patient after receiving the messenger ribonucleic acid (mRNA)-based COVID-19 vaccine. Therefore, this case highlights the possible association between COVID-19 vaccination and KFD and this should be considered in the differential diagnosis.

Safety of two-dose COVID-19 vaccination (BNT162b2 and CoronaVac) in adults with cancer: a territory-wide cohort study. BACKGROUND: The World Health Organization has defined a list of adverse events of special interest (AESI) for safety surveillance of vaccines. AESI have not been adequately assessed following COVID-19 vaccination in patients with cancer contributing to vaccine hesitancy in this population. We aimed to evaluate the association between BNT162b2 and CoronaVac vaccines and the risk of AESI in adults with active cancer or a history of cancer. PATIENTS AND METHODS: We conducted a territory-wide cohort study using electronic health records managed by the Hong Kong Hospital Authority and vaccination records provided by the Department of Health. Patients with a cancer diagnosis between January 1, 2018, and September 30, 2021, were included and stratified into two cohorts: active cancer and history of cancer. Within each cohort, patients who received two doses of BNT162b2 or CoronaVac were 1:1 matched to unvaccinated patients using the propensity score. Cox proportional hazards regression was used to estimate hazard ratios (HR) and 95% confidence intervals (CIs) for AESI 28 days after the second vaccine dose. RESULTS: A total of 74,878 patients with cancer were included (vaccinated: 25,789 [34%]; unvaccinated: 49,089 [66%]). Among patients with active cancer, the incidence of AESI was 0.31 and 1.02 per 10,000 person-days with BNT162b2 versus unvaccinated patients and 0.13 and 0.88 per 10,000 person-days with CoronaVac versus unvaccinated patients. Among patients with history of cancer, the incidence was 0.55 and 0.89 per 10,000 person-days with BNT162b2 versus unvaccinated patients and 0.42 and 0.93 per 10,000 person-days with CoronaVac versus unvaccinated patients. Neither vaccine was associated with a higher risk of AESI for patients with active cancer (BNT162b2: HR 0.30, 95% CI 0.08-1.09;

CoronaVac: 0.14, 95% CI 0.02-1.18) or patients with history of cancer (BNT162b2: 0.62, 95% CI 0.30-1.28; CoronaVac: 0.45, 95% CI 0.21-1.00). CONCLUSIONS: In this territory-wide cohort study of patients with cancer, the incidence of AESI following vaccination with two doses of either BNT162b2 or CoronaVac vaccines was low. The findings of this study can reassure clinicians and patients with cancer about the overall safety of BNT162b2 and CoronaVac in patients with cancer, which could increase the COVID-19 vaccination rate in this vulnerable group of patients.

Factors associated with anti-SARS-CoV-2 antibody titres 3 months post-vaccination with the second dose of BNT162b2 vaccine: a longitudinal observational cohort study in western Greece. OBJECTIVES: Vaccination against SARS-CoV-2 has been extensively deployed during COVID-19 pandemic. One efficient method to evaluate response to vaccination is the assessment of humoral immunity by measuring SARS-CoV-2 antibody titres. We investigated the association between anthropometric parameters (age, body mass index), smoking, diabetes, statin use, hypertension, levels of 25(OH)D and dehydroepiandrosterone sulfate (DHEAS), and SARS-CoV-2 antibody titres after vaccination. DESIGN: In this longitudinal observational cohort study, 712 subjects were tested for SARS-CoV-2 antibodies 3 months after the second dose of BNT162b2 vaccine. Multiple linear regression analysis was performed to identify which factors are associated with the antibody titres. SETTING: Healthcare units of western Greece (University Hospital of Patras and "St Andrews" State General Hospital of Patras). PARTICIPANTS: All adults receiving their second dose of BNT162b2 vaccine at the participating healthcare units were eligible to participate in the study. Exclusion criteria were SARS-CoV-2 infection or positive SARS-CoV-2 antibody titre at baseline. Patients who did not provide all necessary information were excluded from our analyses. RESULTS: We found age to be negatively associated with antibody titre (-0.005; 95% CI -0.009 to -0.001, p=0.0073), as was male gender (-0.11; 95% CI -0.1738 to -0.04617, p=0.0008). The interaction of age and gender was significant (-0.01090; 95% CI -0.01631 to -0.005490, p<0.0001), highlighting that the rate of decline in antibody titre with increasing age tends to be higher in men rather than in women. No linear trend was found between DHEAS levels and antibody titres when the lower quartile of DHEAS levels was used as reference. Tobacco use was associated with low antibody titre (-0.1097; 95% CI -0.174 to -0.046, p=0.0008) but overweight, obese or underweight subjects had similar antibody responses to normal-weight individuals. Although subjects with diabetes and hypertension had numerically lower antibody titres, this association was not statistically significant. Vitamin D levels showed no clear relationships with antibody titres. CONCLUSIONS: Age, male gender and tobacco use are negatively associated with antibody titres after COVID-19 vaccination, but our data showed no clear correlation with vitamin D levels. TRIAL REGISTRATION NUMBER: NCT04954651; Results.

Very low rate of humoral response after a third COVID-19 vaccine dose in patients with autoimmune diseases treated with rituximab and non-responders to two doses.

Vaccine-induced immune thrombocytopaenia and thrombosis (VITT) after COVID-19 vaccination. COVID-19 represents a global health emergency, causing significant morbidity and mortality. Multiple vaccines have been distributed worldwide to control the spread of this pandemic. Several reports of thrombosis and thrombocytopaenia have been described after vaccination. These have been termed vaccine-induced immune thrombocytopaenia and thrombosis (VITT). We report a fatal case of VITT after receiving the first dose of Ad26.COV2.S vaccine. A man in his 30s developed thrombocytopaenia, massive haemoperitoneum due to spleen rupture and extensive portal and femoral vein thrombosis. The patient rapidly developed multiple organ failure and died. We attributed this condition to the vaccine due to the temporal relationship, presence of thrombosis and thrombocytopaenia, high levels of platelet factor 4 antibodies and exclusion of other diagnoses. Healthcare providers should be aware of such rare but fatal complications of COVID-19 immunisation, as early diagnosis of VITT may improve prognosis by allowing timely appropriate treatment.

Acute interstitial nephritis after COVID-19 vaccination. A woman in her 70s presented to the hospital being generally unwell 8 days following the first dose of the AstraZeneca COVID-19 vaccination. She was in stage III acute kidney injury (AKI) with hyperkalaemia and metabolic acidosis. Urinalysis showed haematoproteinuria. Renal immunology screen was negative. She subsequently underwent two renal biopsies. The second biopsy showed features consistent with acute tubulointerstitial nephritis. She was commenced on oral steroids, which led to marked improvement of her renal function.There are reasons why AKI can occur post vaccination such as prerenal AKI from reduced oral intake postvaccination due to feeling unwell or developing vomiting or diarrhoea. Intravenous fluids were given to this patient but with no meaningful improvement in renal function. She developed a possible reaction to the AstraZeneca COVID-19 vaccine, which led to AKI as supported by the interstitial inflammation and presence of eosinophils on renal biopsy.

COVID-19 vaccine: A 2021 analysis of perceptions on vaccine safety and promise in a U.S. sample. BACKGROUND: Despite reliable evidence-based research supporting the COVID-19 vaccines, population-wide confidence and trust remain limited. We sought to expand prior knowledge about COVID-19 vaccine perceptions, while determining which population groups are at greatest risk for not getting a vaccine. METHODS: Study participants in the U.S. (79% female, median age group 46-60 years) were recruited through an online Qualtrics survey distributed as a Facebook advertisement from 3/19/21-4/30/21. We assumed that every participant is at risk of COVID-19 infection and should be able to get the vaccine with proper access. Bivariate and multivariable models were performed. Collinearity between variables was assessed. RESULTS: A total of 2,626 responses were generated and 2,259 were included in data analysis. According to our multivariate model analysis, vaccines were perceived as safe by those who had or planned to obtain full vaccination (adjusted odds ratio (aOR) (95% confidence interval) = 40.0 (19.0, 84.2); p< 0.0001) and those who indicated trust in science (aOR = 10.5 (5.1, 21.8); p< 0.0001); vaccines were perceived as not safe by those who self-identified as Republicans vs. self-identified Democrats (aOR = 0.2 (0.1, 0.5); p = 0.0020) and those with high school or lower education (aOR = 0.2 (0.1, 0.4); p = 0.0007). Similarly, according to our multivariate model analysis, the following groups were most likely to reject vaccination based on belief in vaccinations: those with lower income (aOR = 0.8 (0.6, 0.9); p = 0.0106), those who do not know anyone who had been vaccinated (aOR = 0.1 (0.1, 0.4); p< 0.0001), those who are unwilling to get vaccinated even if family and friends had done so (aOR = 0.1 (<0.1, 0.2); p< 0.0001), those who did not trust science (aOR < 0.1 (<0.1, 0.1); p< 0.0001), those who believe that vaccination was unnecessary if others had already been vaccinated (aOR = 2.8 (1.5, 5.1); p = 0.0007), and those who indicate refusal to vaccinate to help others (aOR = 0.1 (0.1, 0.2); p< 0.0001). An alpha of p<0.05 was used for all tests. CONCLUSION: Level of education and partisanship, but not race/ethnicity, were the most likely factors associated with vaccine hesitancy or likelihood to vaccinate. Also, low vaccination rates among underrepresented minorities may be due to distrust for healthcare industries. Population sub-groups less likely to be vaccinated and/or receptive to vaccines should be targeted for vaccine education and incentives.

Adverse reactions and attitudes toward vaccines among young populations one month after receiving a second dose of mRNA-1273 in Japan. To investigate adverse reactions and attitudes toward the vaccine during the first month after mRNA- 1273 vaccination in a larger sample including younger men and women in Japan, we distributed a 1-month post-vaccination questionnaire using a Google form to 8,566 people who received a second dose of mRNA-1273 at Okayama University. The response rate was about 40.2% (3,447 responses), the sex ratio was about the same, and 73.3 % (2,528 respondents) were students in their twenties or younger. Poisson regression with robust variance was performed to calculate the prevalence ratio of each symptom by different attributes. The most common adverse reactions after the second vaccine dose were local pain (80.4%), fever

(85.1%), malaise (82.0%), headache (64.0%), and chills (57.4%). Approximately 99% of respondents reported that their adverse reactions resolved within 1 week. Over 80% of respondents were satisfied with their vaccination (87.2%), expressed interest in receiving the third vaccination (83.3%), and would recommend vaccination to their loved ones (80.2%). However, among them, 22.0% (757 respondents) would recommend and 28.4% (980 respondents) also stated that they would consider the type of vaccine in these decisions.

Promotion of proper use of anti-SARS-CoV-2 drugs and SARS-CoV-2 vaccines by hospital pharmacists and establishment of an adverse drug reaction reporting system. Newly developed anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) drugs are being rapidly approved in countries worldwide. These new drugs are being approved after testing with a limited number of cases, and in real-world clinical practice, unknown and potentially serious adverse events that could not be detected in clinical trials may emerge. Accordingly, in the event of an adverse drug reaction for which a causal relationship with these new drugs cannot be ruled out, it is vital to promptly report the details of the case to the regulatory authorities. To date, through close cooperation between physicians and pharmacists, we have reported four cases of adverse drug reactions for which a causal relationship to anti-SARS-CoV-2 drugs cannot be ruled out. Herein, we introduce safety measures taken by pharmacists when using these new drugs in the hospital, and a system for reporting to the regulatory authorities when adverse events occur.

COVID-19 Vaccination in Patients With Malignancy; A Systematic Review and Meta-Analysis of the Efficacy and Safety. BACKGROUND: Data on the efficacy and safety of COVID-19 vaccines in patients with malignancy are immature. In this paper, we assessed the literature involving the use of COVID-19 vaccines in cancer patients and reported the seroconversion rates as the main outcome and severity of COVID-19 infection and side effects following COVID-19 vaccination as the secondary outcomes. METHODS: A systematic review with meta-analysis was performed. Searches were conducted in electronic websites, databases, and journals, including Scopus, PubMed, Embase, and Web of Science from January 01, 2019, to November 30, 2021. Studies reporting data on the safety and efficacy of COVID vaccine in cancer patients using any human samples were included. The risk of bias was assessed using the NEWCASTLE-OTTAWA scale in the included studies. RESULTS: A total of 724 articles were identified from databases, out of which 201 articles were duplicates and were discarded. Subsequently, 454 articles were excluded through initial screening of the titles and abstracts. Moreover, 41 studies did not report the precise seroconversion rate either based on the type of cancer or after injection of a second dose of COVID vaccine. Finally, 28 articles met all the inclusion criteria and were included in this systematic review. The overall seroconversion rates after receiving a second dose of COVID-19 vaccine, based on type of cancer were 88% (95% CI, 81%-92%) and 70% (95% CI, 60%-79%) in patients with solid tumors and hematologic malignancies, respectively. CONCLUSION: Overall, we conclude that vaccination against COVID-19 in patients with active malignancies using activated and inactivated vaccines is a safe and tolerable procedure that is also accompanied by a high efficacy.

A Case of Minimal Change Disease after SARS-CoV-2 Vaccination under the Age of 18. This is a care report of a 16-year-old-male who developed de novo minimal change disease following the second dose of the Pfizer vaccine. The patient developed sudden onset edema and 10â€‰kg weight gain. He had nephrotic range proteinuria with normal renal function. Kidney biopsy with adequate sample confirmed minimal change disease. The patient improved after 1 week of starting prednisone. This is the first case of minimal change disease after the Pfizer vaccine in the teenager population since expanding the age groups to allow younger subjects to receive the vaccine. Reporting cases at different age groups will help in trying to clarify whether the increasing reports of nephrotic syndrome following the vaccination are accidental or cause-effect relationship.

Severe disease exacerbation after mRNA COVID-19 vaccination unmasks suspected multiple sclerosis as neuromyelitis optica spectrum disorder: a case report. BACKGROUND: Since the beginning of the COVID-19 pandemic and development of new vaccines, the issue of post-vaccination exacerbation or manifestation of demyelinating central nervous system (CNS) disorders has gained increasing attention. CASE PRESENTATION: We present a case of a 68-year-old woman previously diagnosed with multiple sclerosis (MS) since the 1980s who suffered a rapidly progressive severe sensorimotor paraparesis with loss of bladder and bowel control due to an acute longitudinal extensive transverse myelitis (LETM) after immunization with the mRNA Pfizer-BioNTech COVID-19 vaccine. Detection of Aquaporin-4-antibodies (AQP4) in both serum and CSF led to diagnosis of AQP4-antibody positive neuromyelitis optica spectrum disorder (NMOSD). Treatment with intravenous corticosteroids and plasmapheresis led to a slight improvement of the patient's symptoms. CONCLUSIONS: Pathogenic mechanisms of post-vaccination occurrence of NMOSD are still unknown. However, cases like this should make aware of rare neurological disorders manifesting after vaccination and potentially contribute to improvement of management of vaccinating patients with inflammatory CNS disorders in the future. So far two cases of AQP4-antibody positive NMOSD have been reported in association with viral vector COVID-19 vaccines. To our knowledge, we report the first case of AQP4-antibody positive NMOSD after immunization with an mRNA COVID-19-vaccine.

Adverse effects following COVID-19 vaccination in Iran. BACKGROUND: Vaccination is a key intervention to prevent COVID-19. Many vaccines are administered globally, yet there is not much evidence regarding their safety and adverse effects. Iran also faces this challenge, especially as data regarding the Sputnik V vaccine is sparse. Therefore, the aim of this study is to determine the adverse effects of the most commonly used vaccines in Iran. METHODS: Using a retrospective cohort study design, 6600 subjects aged 18Â years or older who had received two doses of any of the three COVID-19 vaccines (Sinopharm, AstraZeneca, and Sputnik V) were selected using a random sampling method between March and August 2021. Subjects were asked about any adverse effects of the vaccines by trained interviewers via telephone interview. Vaccine-related adverse effects in individuals during the first 72Â h and subsequently following both doses of the vaccines were determined. The demographic variables, type of administered vaccine, adverse effects, and history of the previous infection with COVID-19 were collected. Descriptive statistics (mean, standard deviation) and analytical statistics (Chi-squared and Wilcoxon tests) were performed at a 95% significance level using STATA software version 15 (STATA Corp, College Station, TX, USA). RESULTS: From 6600 participants, 4775 responded (response rateâ€‰=â€‰72.3%). Of the participants, 1460 (30.6%) received the AstraZeneca vaccine, 1564 (32.8%) received the Sinopharm vaccine and 1751 (36.7%) received the Sputnik V vaccine. 2653 participants (55.56%) reported adverse effects after the first dose and 1704 (35.7%) after the second dose. Sputnik V caused the most adverse effects with 1449 (82.7%) vaccine recipients reporting symptoms after the first or second dose, compared with 1030 (70.5%) for AstraZeneca and only 585 (37.4%) for the Sinopharm vaccine. The most common adverse effects after the first dose were fatigue (28.37%), chill/fever (26.86%), and skeletal pain (22.38%). These three adverse effects were the same for the second dose, although their prevalence was lower. CONCLUSIONS: In this study, we demonstrate that the Sputnik V vaccine has the highest rate of adverse effects, followed by the AstraZeneca and Sinopharm vaccines. COVID-19 vaccines used in Iran are safe and there were no reports of serious adverse effects.

Trajectory of long covid symptoms after covid-19 vaccination: community based cohort study. OBJECTIVE: To estimate associations between covid-19 vaccination and long covid symptoms in adults with SARS-CoV-2 infection before vaccination. DESIGN: Observational cohort study. SETTING: Community dwelling population, UK. PARTICIPANTS: 28â€‰356 participants in the Office for National Statistics COVID-19 Infection Survey aged 18-69 years who received at least one dose of an

adenovirus vector or mRNA covid-19 vaccine after testing positive for SARS-CoV-2 infection. MAIN OUTCOME MEASURE: Presence of long covid symptoms at least 12 weeks after infection over the follow-up period 3 February to 5 September 2021. RESULTS: Mean age of participants was 46 years, 55.6% (n=15â€‰760) were women, and 88.7% (n=25â€‰141) were of white ethnicity. Median follow-up was 141 days from first vaccination (among all participants) and 67 days from second vaccination (83.8% of participants). 6729 participants (23.7%) reported long covid symptoms of any severity at least once during follow-up. A first vaccine dose was associated with an initial 12.8% decrease (95% confidence interval -18.6% to -6.6%, P<0.001) in the odds of long covid, with subsequent data compatible with both increases and decreases in the trajectory (0.3% per week, 95% confidence interval -0.6% to 1.2% per week, P=0.51). A second dose was associated with an initial 8.8% decrease (95% confidence interval -14.1% to -3.1%, P=0.003) in the odds of long covid, with a subsequent decrease by 0.8% per week (-1.2% to -0.4% per week, P<0.001). Heterogeneity was not found in associations between vaccination and long covid by sociodemographic characteristics, health status, hospital admission with acute covid-19, vaccine type (adenovirus vector or mRNA), or duration from SARS-CoV-2 infection to vaccination. CONCLUSIONS: The likelihood of long covid symptoms was observed to decrease after covid-19 vaccination and evidence suggested sustained improvement after a second dose, at least over the median follow-up of 67 days. Vaccination may contribute to a reduction in the population health burden of long covid, although longer follow-up is needed.

[Changes in the pattern of COVID-19 hospitalizations and deaths after substantial vaccination of the elderly in Manaus, Amazonas State, Brazil]. The impact of COVID-19 vaccination in the elderly has received relatively little attention, particularly in a scenario predominated by the gamma variant. The aim of this study was to assess vaccination coverage and its relationship to changes in the pattern of COVID-19 hospitalizations and deaths in the elderly in Manaus, Amazonas State, Brazil. This was an ecological study with Brazilian Ministry of Health data on hospitalizations and deaths, assessing vaccination coverage based on a two-dose regimen, in addition to two vaccination regimens associated with a significant protective effect, one partial (35 days or more after the first dose of the Oxford/AstraZeneca vaccine) and the other complete (14 days or more after the second dose of the Sinovac-CoronaVac vaccine). Based on the date of initial symptoms, patterns of COVID-19 hospitalizations and deaths were assessed comparatively in elderly 60-69 years and 70 years or more in two groups of Epidemiological Weeks (EW) in 2020 (unvaccinated) and 2021 (vaccinated). Hospitalization and death rates were estimated with Poisson regression. In the groups 60-69 and 70 years or more, vaccination coverage rates were 41.8% and 54.8%, as well as 53.5% and 90.1%, in the EW groups 18-20/2021 and 21-23/2021, respectively. Both EW groups in 2021 showed a substantial change in the patterns of COVID-19 hospitalizations and deaths, with an increase in the risk of hospitalization and death in unvaccinated younger individuals and an important reduction in vaccinated elderly, especially those 60-69 years of age, besides overall reductions of 62% (95%CI: 52-69) and 63% (95%CI: 43-75) in hospitalization and death rates, respectively. Our results emphasize the importance of mass vaccination, especially during an epidemic such as in Manaus, marked by high circulation of the gamma variant.

Concomitant myocarditis and painless thyroiditis after AstraZeneca coronavirus disease 2019 vaccination: a case report. BACKGROUND: Incidence of myocarditis following messenger RNA coronavirus disease 2019 vaccination has been widely described, but this clinical scenario after adenoviral vector coronavirus disease 2019 vaccination has only been rarely reported. In addition, a few case reports of thyroiditis after adenoviral vector coronavirus disease 2019 vaccination have been published. CASE PRESENTATION: A 55-year-old Thai woman presented with palpitation without neck pain 14 days after receiving AstraZeneca coronavirus disease 2019 vaccination. Electrocardiography revealed sinus tachycardia. Her blood tests showed elevation of cardiac troponin

and free triiodothyronine with suppressed serum thyroid stimulating hormone, reflecting a hyperthyroid status. Evidence of myocardial inflammation and necrosis from cardiac magnetic resonance imaging supported the diagnosis of recent myocarditis. Laboratory results and imaging findings were consistent with thyroiditis. After 3 weeks of symptomatic treatment, her symptom and blood tests had returned to normal. CONCLUSIONS: This case demonstrates that the adenoviral vector coronavirus disease 2019 vaccine could possibly cause myocarditis and painless thyroiditis. Clinicians should have a high index of suspicion and promptly evaluate these conditions, despite minimal symptoms.

Intranasal administration of a recombinant RBD vaccine induces long-term immunity against Omicron-included SARS-CoV-2 variants. The outbreak of coronavirus disease 2019 (COVID-19) has posed great threats to global health and economy. Several effective vaccines are available now, but additional booster immunization is required to retain or increase the immune responses owing to waning immunity and the emergency of new variant strains. The deficiency of intramuscularly delivered vaccines to induce mucosal immunity urged the development of mucosal vaccines. Here, we developed an adjuvanted intranasal RBD vaccine and monitored its long-term immunogenicity against both wild-type and mutant strains of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), including Omicron variants, in mice. Three-dose intranasal immunization with this vaccine induced and maintained high levels of neutralizing IgG antibodies in the sera for at least 1 year. Strong mucosal immunity was also provoked, including mucosal secretory IgA and lung-resident memory T cells (T(RM)). We also demonstrated that the long-term persistence of lung T(RM) cells is a consequence of local T-cell proliferation, rather than T-cell migration from lymph nodes. Our data suggested that the adjuvanted intranasal RBD vaccine is a promising vaccine candidate to establish robust, long-lasting, and broad protective immunity against SARS-CoV-2 both systemically and locally.

Adjuvant-free cellulose nanofiber vaccine induces permanent humoral immune response in mouse. Vaccines have become one of the most effective strategies to deal with various infectious diseases and chronic noninfectious diseases, such as SARS virus, Novel Coronavirus, cancer, etc. However, recent studies have found that the neutralizing antibody titers induced by vaccines would drop to half level or even lower after vaccination. In this study, we designed a novel small-sized positively charged nanofiber-1 (PEI-CNF-1) as a vaccine carrier, which can induce a high long-term humoral immune response by controlled release of antigen. Further studies showed that PEI-CNF-1 could significantly induce the release of immune response factor IL-1Î²and bone marrow-derived cell (BMDC) maturation. Moreover, compare to other cellulose nanofibers (CNFs), PEI-CNF-1 combined antigen (ovalbumin, OVA) induced and maintained the highest and longest antibody titers after vaccination. Interestingly, the antibody titers have no significant difference between at 21 and 90 d. Mechanically, we found that PEI-NCF-1 not only could control the slow-release of antigen, but also could be more easily swallowed by macrophages and metabolized by the bodies, thus presenting antigen more effectively. In conclusion, we believe that PEI-CNF-1 have a very high application prospect in inducing long-term humoral immune response, so as to achieve efficient prevention effect to epidemic viruses.

Vaccine-induced immune thrombotic thrombocytopenia after ChAdOx1 nCoV-19 vaccine in an older patient: Minireview and a case report. Rare cases of unusual thrombosis and thrombocytopenia after administration of the ChAdOx1 nCoV-19 vaccine (AstraZeneca) have been reported. The unusual symptoms are called vaccine-induced immune thrombotic thrombocytopenia (VITT). In the present study, a brief background about cases of unusual thrombosis and thrombocytopenia after administration of the ChAdOx1 nCoV-19 was provided. In addition, a description of a case of a 66-year-old woman who had received this vaccine and developed VITT was done. She presented to the hospital complaining of hematomas in the right upper limb 14 days after the ChAdOx1 nCoV-19 vaccine, without a history of trauma (Glasgow coma scale of 14) and thrombocytopenia even though

signs of thrombosis were absent. Cranium computed tomography scan indicated intraparenchymal hematoma and cerebral thrombosis, besides anastomotic LabbÃ©Â vein thrombosis. The woman received platelets transfusion, dexamethasone, and neuroprotection measures, but even so, on the twelfth postoperative day, she died of cerebral rebleeding. In conclusion, it is crucial to point out the immuno-hypersensitivity mechanisms associated with ChAdOx1 nCoV-19 vaccine reactions, helping to reduce their occurrences and reinforcing confidence in vaccine administration.

Antibody responses against SARS-CoV-2 variants induced by four different SARS-CoV-2 vaccines in health care workers in the Netherlands: A prospective cohort study. BACKGROUND: Emerging and future SARS-CoV-2 variants may jeopardize the effectiveness of vaccination campaigns. Therefore, it is important to know how the different vaccines perform against diverse SARS-CoV-2 variants. METHODS AND FINDINGS: In a prospective cohort of 165 SARS-CoV-2 naive health care workers in the Netherlands, vaccinated with either one of four vaccines (BNT162b2, mRNA-1273, AZD1222 or Ad26.COV2.S), we performed a head-to-head comparison of the ability of sera to recognize and neutralize SARS-CoV-2 variants of concern (VOCs; Alpha, Beta, Gamma, Delta and Omicron). Repeated serum sampling was performed 5 times during a year (from January 2021 till January 2022), including before and after booster vaccination with BNT162b2. Four weeks after completing the initial vaccination series, SARS-CoV-2 wild-type neutralizing antibody titers were highest in recipients of mRNA-1273, followed by recipients of BNT162b2 (geometric mean titers (GMT) of 358 [95% CI 231-556] and 214 [95% CI 153-299], respectively; $p<0.05$), and substantially lower in those vaccinated with the adenovirus vector-based vaccines AZD1222 and Ad26.COV2.S (GMT of 18 [95% CI 11-30] and 14 [95% CI 8-25] IU/ml, respectively; $p<0.001$). VOCs neutralization was reduced in all vaccine groups, with the greatest reduction in neutralization GMT observed against the Omicron variant (fold change 0.03 [95% CI 0.02-0.04], $p<0.001$). The booster BNT162b2 vaccination increased neutralizing antibody titers for all groups with substantial improvement against the VOCs including the Omicron variant. We used linear regression and linear mixed model analysis. All results were adjusted for possible confounding of age and sex. Study limitations include the lack of cellular immunity data. CONCLUSIONS: Overall, this study shows that the mRNA vaccines appear superior to adenovirus vector-based vaccines in inducing neutralizing antibodies against VOCs four weeks after initial vaccination and after booster vaccination, which implies the use of mRNA vaccines for both initial and booster vaccination.

Neutralizing antibody activity against SARS-CoV-2 variants in gestational age-matched mother-infant dyads after infection or vaccination. Pregnancy confers unique immune responses to infection and vaccination across gestation. To date, there are limited data comparing vaccine- and infection-induced neutralizing Abs (nAbs) against COVID-19 variants in mothers during pregnancy. We analyzed paired maternal and cord plasma samples from 60 pregnant individuals. Thirty women vaccinated with mRNA vaccines (from December 2020 through August 2021) were matched with 30 naturally infected women (from March 2020 through January 2021) by gestational age of exposure. Neutralization activity against the 5 SARS-CoV-2 spike sequences was measured by a SARS-CoV-2-pseudotyped spike virion assay. Effective nAbs against SARS-CoV-2 were present in maternal and cord plasma after both infection and vaccination. Compared with WT spike protein, these nAbs were less effective against the Delta and Mu spike variants. Vaccination during the third trimester induced higher cord-nAb levels at delivery than did infection during the third trimester. In contrast, vaccine-induced nAb levels were lower at the time of delivery compared with infection during the first trimester. The transfer ratio (cord nAb level divided by maternal nAb level) was greatest in mothers vaccinated in the second trimester. SARS-CoV-2 vaccination or infection in pregnancy elicits effective nAbs with differing neutralization kinetics that are influenced by gestational time of exposure.

Post COVID-19 Vaccination Acute Disseminated Encephalomyelitis: A Case Report. INTRODUCTION: A 67-year-old female with no significant past medical history presented to the critical care department with symptoms of encephalopathy. CASE PRESENTATION: The patient's Main Concerns and the Important Clinical Findings: The patient had a history of COVID -19 vaccination (recombinant ChAdOX1 nCoV-19) 14 days prior to the symptoms. She underwent an MRI of the brain and cervical spine and a lumbar puncture. The Primary Diagnoses, Interventions, and Outcomes: The patient was examined and sent for an MRI of the brain and cervical spine, followed by extensive blood and CSF investigations to rule out any infective, paraneoplastic, connective tissue disorder, or inflammatory disorder. The patient was given steroids, and a good response was reported. The primary diagnosis was made as vaccine-induced ADEM. CONCLUSION: The clinical exam, location, sparse contrast enhancement, and CSF findings were all consistent with an acute demyelinating event, and the history of vaccination, together with the clinical situation, was found to be favourable for the development of acute disseminated encephalomyelitis.

Subacute thyroiditis associated with thyrotoxic periodic paralysis after COVID-19 vaccination: a case report. SUMMARY: We report a 26-year-old Japanese man who visited our outpatient clinic presenting fever immediately after i.m. injection of the second dose of a coronavirus disease 2019 (COVID-19) vaccine (ModernaÂ®). At the first visit, the patient had a fever of 37.7Â°C and a swollen thyroid gland with mild tenderness. He was diagnosed with subacute thyroiditis (SAT) based on the presence of thyrotoxicosis (free tri-iodothyronine, 32.3 pg/mL; free thyroxine, >7.77 ng/dL; and thyroid-stimulating hormone (TSH) < 0.01 Î¼IU/mL), high C-reactive protein level (7.40 mg/dL), negative TSH receptor antibody, and characteristic ultrasound findings. His HLA types were A*02:01/24:02, B*15:11/35:01, Cw*03:03, DRB1*09:01/12:01, DQB1*03:03, and DPB1*05: 01/41:01. He was initially administered prednisolone 15 mg/day, following which the fever subsided. After 10 days, he developed limb weakness and could not walk. The serum potassium level decreased to 1.8 mEq/L, which confirmed the diagnosis of thyrotoxic periodic paralysis (TPP). Potassium supplementation was initiated. The muscle weakness gradually decreased. Prednisolone therapy was terminated 6 weeks after the first visit. His thyroid function returned to normal 5 months after the first visit, through a hypothyroid state. To our knowledge, this is the first reported case of TPP-associated SAT following COVID-19 vaccination. Persistent fever following vaccination should be suspected of SAT. Additionally, TPP may be associated with SAT in Asian male patients. LEARNING POINTS: Following coronavirus disease 2019 (COVID-19) vaccination, subacute thyroiditis may develop regardless of the vaccine type. If persistent fever, anterior neck pain, swelling and tenderness of thyroid gland, and symptoms of thyrotoxicosis are observed immediately after the COVID-19 vaccination, examination in consideration of the onset of subacute thyroiditis is recommended. HLA-B35 may be associated with the onset of subacute thyroiditis after the COVID-19 vaccination. Although rare, subacute thyroiditis can be associated with thyrotoxic periodic paralysis, especially in Asian men. Glucocorticoid therapy for subacute thyroiditis may induce thyrotoxic periodic paralysis through hypokalemia.

Small popliteal aneurysm thrombosis after SARS-CoV-2 vaccination.

Microscopic Polyangiitis Following mRNA COVID-19 Vaccination: A Case Report. Coronavirus disease 2019 (COVID-19) is one of the most widespread viral infections in human history. As a breakthrough against infection, vaccines have been developed to achieve herd immunity. Here, we report the first case of microscopic polyangiitis (MPA) following BNT162b2 vaccination in Korea. A 42-year-old man presented to the emergency room with general weakness, dyspnea, and edema after the second BNT162b2 vaccination. He had no medical history other than being treated for tuberculosis last year. Although his renal function was normal at last year, acute kidney injury was confirmed at the time of admission to the emergency room. His serum creatinine was 3.05 mg/dL.

Routine urinalysis revealed proteinuria (3+) and hematuria. When additional tests were performed for suspected glomerulonephritis, the elevation of myeloperoxidase (MPO) antibody (38.6 IU/mL) was confirmed. Renal biopsy confirmed pauci-immune anti-neutrophil cytoplasmic antibody (ANCA)-related glomerulonephritis and MPA was diagnosed finally. As an induction therapy, a combination of glucocorticoid and rituximab was administered, and plasmapheresis was performed twice. He was discharged after the induction therapy and admitted to the outpatient clinic 34 days after induction therapy. During outpatient examination, his renal function had improved with serum creatinine 1.51 mg/dL. We suggest that MPA needs to be considered if patients have acute kidney injury, proteinuria, and hematuria after vaccination.

Strong SARS-CoV-2 Antibody Response After Booster Dose of BNT162b2 mRNA Vaccines in Uninfected Healthcare Workers. Despite strict guidelines for coronavirus disease 2019 (COVID-19), South Korea is facing its fourth pandemic wave. In this study, by using an automated electrochemiluminescence immunoassay assay, we tracked anti-spike protein receptor-binding domain (anti-S-RBD) antibody titer from the second dose to 2 weeks after the booster dose vaccination. After the second dose, 234 participants had their anti-S-RBD antibody titers decrease over time. We also showed the booster dose (the third dose) increased antibody titer by average 14 (min-max, 2-255)-fold higher compared to the second dose among the 211-booster group participants, therefore, the booster dose could be recommended for low responders to the second dose. Our findings showed a distinct humoral response after booster doses of BNT162b2 mRNA vaccines and may provide further evidence of booster vaccination efficacy. These data will also be helpful in vaccination policy decisions that determine the need for the booster dose.

COVID-19 vaccines in patients with decompensated cirrhosis: a retrospective cohort on safety data and risk factors associated with unvaccinated status. BACKGROUND: Safety data reported from the large-scale clinical trials of the coronavirus disease 2019 (COVID-19) vaccine are extremely limited in patients with decompensated cirrhosis. The vaccination campaign in this specific population could be difficult due to uncertainty about the adverse events following vaccination. We aimed to assessed the COVID-19 vaccination rate, factors associated with unvaccinated status, and the adverse events following vaccination in patients with decompensated cirrhosis. METHODS: This is a retrospective study from Ruijin Hospial (Shanghai, China) on an ongoing prospective cohort designed for long-term survival analysis of decompensated cirrhotic patients who recovered from decompensating events or acute-on-chronic liver failure (ACLF) between 2016 and 2018. We assessed the COVID-19 vaccination rate, the number of doses, type of vaccine, safety data, patient-reported reasons for remaining unvaccinated, factors associated with unvaccinated status, and the adverse events of COVID-19 vaccine. Binary logistic regression was used for identifying factors associated with unvaccinated status. RESULTS: A total of 229 patients with decompensated cirrhosis without previous SARS-CoV-2 infection participated (mean age, 56â€‰Â±â€‰12.2Â years, 75% male, 65% viral-related cirrhosis). Mode of decompensation were grade IIâ€’III ascites (82.5%), gastroesophageal varices bleeding (7.9%), hepatic encephalopathy (7.9%). Eighty-five participants (37.1%) received at least one dose of vaccination (1 dose: nâ€‰=â€‰1, 2 doses: nâ€‰=â€‰65, 3 doses: nâ€‰=â€‰19) while 62.9% remained unvaccinated. Patient-reported reasons for remaining unvaccinated were mainly fear of adverse events (37.5%) and lack of positive advice from healthcare providers (52.1%). The experience of hepatic encephalopathy (ORâ€‰=â€‰5.61, 95% CI: 1.24-25.4) or ACLF (ORâ€‰=â€‰3.13, 95% CI: 1.12-8.69) and post-liver transplantation status (ORâ€‰=â€‰2.47, 95% CI: 1.06-5.76) were risk factors of remaining unvaccinated independent of residential areas. The safety analysis demonstrated that 75.3% had no adverse events, 23.6% had non-severe reactions (20% injection-site pain, 1.2% fatigue, 2.4% rash) and 1.2% had a severe event (development of acute decompensation requiring hospitalization). CONCLUSIONS: Patients with decompensated cirrhosisÂ in eastern China are largely

remained at unvaccinated status, particularly those with previous episodes ofÂ ACLF or hepatic encephalopathy and liver transplantation recipients. Vaccination against COVID-19 in this population is safe.
Management of BNT162b2 mRNA COVID-19 vaccine in children aged 5-11â€‰years with allergies, asthma, and immunodeficiency: consensus of the Italian Society of Pediatric Allergy and Immunology (SIAIP). BNT162b2 vaccine, developed by BioNTech and Pfizer ha recently approved for use in children aged 5 to 11â€‰years. Recent data show evidence of safety on the administration and serious adverse events have been rarely reported. However, allergic systemic reactions could occur. In some cases, a correct allergic evaluation allows identifying patients at risk of developing an anaphylactic reaction. Risk assessment of allergic reactions to COVID-19 vaccines is useful to limit contraindications to vaccination and help to safely vaccinate people supposed to be at risk of allergic reactions.
BNT162b2-induced memory T cells respond to the Omicron variant with preserved polyfunctionality. The Omicron variant (B.1.1.529) of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) extensively escapes neutralizing antibodies elicited by SARS-CoV-2 infection or vaccination. In the present study, we investigated whether BNT162b2 messenger RNA vaccine-induced memory T cells functionally respond to the Omicron spike protein. Experiments were performed using samples from healthcare workers who were immunized with two or three doses of the BNT162b2 mRNA vaccine and individuals with prior SARS-CoV-2 infection who were immunized with two doses of the BNT162b2 vaccine. Vaccine-induced memory T cells exhibited substantial responses to the Omicron spike protein, with no difference between healthcare workers with two versus three vaccine doses. In individuals with prior infection, two-dose vaccination robustly boosted memory T cells that responded to the Omicron spike protein and the SARS-CoV-2 wild-type (lineage B) spike protein. Importantly, polyfunctionality was preserved in vaccine-induced memory T cells responding to the Omicron spike protein. The present findings indicate that BNT162b2-induced memory T cells substantially respond to the Omicron variant with preserved polyfunctionality.
Central serous chorioretinopathy following the BNT162b2 mRNA vaccine. BACKGROUND AND PURPOSE: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has accelerated vaccine development. The BNT162b2 messenger RNA (mRNA) vaccine is being administered worldwide. The purpose of this case series is to report a possible association between the BNT162b2 mRNA vaccine and Central serous chorioretinopathy (CSC). Although rare, CSC has been reported following the administration of anthrax, influenza and smallpox vaccines. METHODS: Four individuals who developed CSC following the BNT162b2 mRNA vaccine were examined in our institution using multimodal imaging of the retina, and their demographic data were analyzed and compared to all the similar cases published to date. RESULTS: Four patients (3 males, 1 female) between the ages of 35 and 65 presented with acute CSC (n=3) and relapsed CSC (n=1) within the first week following the administration of the BNT162b2 mRNA vaccine. Three individuals demonstrated hyper-reflective foci in the outer segments of the retina. CONCLUSIONS: The timing of the BNT162b2 mRNA vaccine administration relative to the development of CSC suggests a possible causal relationship. Further research is necessary to explore this possible association.
Safety and immunogenicity of an egg-based inactivated Newcastle disease virus vaccine expressing SARS-CoV-2 spike: Interim results of a randomized, placebo-controlled, phase 1/2 trial in Vietnam. Production of affordable coronavirus disease 2019 (COVID-19) vaccines in low- and middle-income countries is needed. NDV-HXP-S is an inactivated egg-based Newcastle disease virus (NDV) vaccine expressing the spike protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Wuhan-Hu-1. The spike protein was stabilized and incorporated into NDV virions by removing the polybasic furin cleavage site, introducing the transmembrane domain and cytoplasmic tail of the

fusion protein of NDV, and introducing six prolines for stabilization in the prefusion state. Vaccine production and clinical development was initiated in Vietnam, Thailand, and Brazil. Here the interim results from the first stage of the randomized, dose-escalation, observer-blind, placebo-controlled, phase 1/2 trial conducted at the Hanoi Medical University (Vietnam) are presented. Healthy adults aged 18-59Â years, non-pregnant, and with self-reported negative history for SARS-CoV-2 infection were eligible. Participants were randomized to receive one of five treatments by intramuscular injection twice, 28Â days apart: 1Â Î¼g +/- CpG1018 (a toll-like receptor 9 agonist), 3Â Î¼g alone, 10Â Î¼g alone, or placebo. Participants and personnel assessing outcomes were masked to treatment. The primary outcomes were solicited adverse events (AEs) during 7Â days and subject-reported AEs during 28Â days after each vaccination. Investigators further reviewed subject-reported AEs. Secondary outcomes were immunogenicity measures (anti-spike immunoglobulin G [IgG] and pseudotyped virus neutralization). This interim analysis assessed safety 56Â days after first vaccination (day 57) in treatment-exposed individuals and immunogenicity through 14Â days after second vaccination (day 43) per protocol. Between March 15 and April 23, 2021, 224 individuals were screened and 120 were enrolled (25 per group for active vaccination and 20 for placebo). All subjects received two doses. The most common solicited AEs among those receiving active vaccine or placebo were all predominantly mild and included injection site pain or tenderness (<58%), fatigue or malaise (<22%), headache (<21%), and myalgia (<14%). No higher proportion of the solicited AEs were observed for any group of active vaccine. The proportion reporting vaccine-related AEs during the 28Â days after either vaccination ranged from 4% to 8% among vaccine groups and was 5% in controls. No vaccine-related serious adverse event occurred. The immune response in the 10Â Î¼g formulation group was highest, followed by 1Â Î¼gÂ +Â CpG1018, 3Â Î¼g, and 1Â Î¼g formulations. Fourteen days after the second vaccination, the geometric mean concentrations (GMC) of 50% neutralizing antibody against the homologous Wuhan-Hu-1 pseudovirus ranged from 56.07Â IU/mL (1Â Î¼g, 95% CI 37.01, 84.94) to 246.19Â IU/mL (10Â Î¼g, 95% CI 151.97, 398.82), with 84% to 96% of vaccine groups attaining aÂ â‰¥Â 4-fold increase over baseline. This was compared to a panel of human convalescent sera (NÂ =Â 29, 72.93 95% CI 33.00-161.14). Live virus neutralization to the B.1.617.2 (Delta) variant of concern was reduced but in line with observations for vaccines currently in use. Since the adjuvant has shown modest benefit, GMC ratio of 2.56 (95% CI, 1.4-4.6) for 1Â Î¼g +/- CpG1018, a decision was made not to continue studying it with this vaccine. NDV-HXP-S had an acceptable safety profile and potent immunogenicity. The 3Â Î¼g dose was advanced to phase 2 along with a 6Â Î¼g dose. The 10Â Î¼g dose was not selected for evaluation in phase 2 due to potential impact on manufacturing capacity. ClinicalTrials.gov NCT04830800.

Antibody response to the COVID-19 ChAdOx1nCov-19 and BNT162b vaccines after temporary suspension of DMARD therapy in immune-mediated inflammatory disease (RESCUE). OBJECTIVE: To assess the antibody response to disease-modifying antirheumatic drug (DMARD) therapy after the first and second dose of the ChAdOx1nCov-19 (AstraZeneca (AZ)) and BNT162b (Pfizer) vaccines in patients with immune-mediated inflammatory disease (IMID) compared with controls and if withholding therapy following the first vaccination dose has any effect on seroconversion and SARS-CoV-2 antibody (Ab) levels. METHODS: A multicentre three-arm randomised controlled trial compared the immunogenicity of the Pfizer and AZ vaccines in adult patients on conventional synthetic (csDMARD), biologic (bDMARD) or targeted synthetic (tsDMARD) therapy for IMID (n=181) with a control group (n=59). Patients were randomised to continue or withhold DMARD therapy for 1-2 weeks post first dose vaccination only. Serum SARS-CoV-2 IgG detection (IgG â‰¥1.0 U/mL) and titres against the S1/S2 proteins were measured at baseline, 3-4 weeks post first vaccination and 4 weeks post second vaccination. RESULTS: AZ vaccination was given to 47.5%, 41.5% and 52.5% in the continue, withhold and control groups, respectively while Pfizer vaccination was given to 52.5%,

58.5% and 47.5% among the continue, withhold and control groups, respectively. Seroconversion rates following the first dose in the AZ and Pfizer groups were only 27.3% vs 79.2% (p=0.000) and 64.58% vs 100% (p=0.000), respectively in the IMID groups who continued therapy compared with the AZ and Pfizer controls, respectively. Withholding DMARD therapy following the first vaccination dose resulted in higher seroconversion to 67.7% and 84.1% in the AZ and Pfizer groups, respectively. Following the second AZ and Pfizer vaccinations when all DMARDs were continued, despite a slightly lower seroconversion rate (83.7% vs 100%, p=0.000 and 95.9% vs 100%, p=0.413), respectively, the mean SARS-CoV2 IgG Ab titres were not significantly different in the csDMARD and bDMARD groups compared with the controls regardless of hold while it was significantly lower in patients taking tsDMARD (12.88 vs 79.49 U/mL, p=0.000). CONCLUSIONS: Following the first vaccination dose, antibody responses were lower in IMID on DMARD therapy, however the final responses were excellent regardless of hold with the exception of the tsDMARD group where withholding therapy is recommended. At least 2 vaccinations are therefore recommended preferably with an messenger RNA vaccine. TRIAL REGISTRATION NUMBER: ANZCTR: 12621000661875.

COVID-19 Vaccine-Related Hypersensitivity Reactions and Second-Dose Vaccine Administration: Correspondence.

Immunogenicity and safety of the CoronaVac vaccine in patients undergoing treatment for breast and lung cancer. OBJECTIVE: To compare seroconversion for SARS-CoV-2 receptor-binding domain (RBD) specific IgG positivity against two doses of the CoronaVac vaccine in breast and lung cancer patients receiving systemic therapy, to determine the factors affecting seropositivity, and to observe long-term results up to a secondary booster vaccine. RESULTS: The analysis included 201 cancer patients (99 breasts, 102 lungs; median age: 59 years (range: 28-92), 42.3 % men) and 97 controls (median age: 62 years (range: 24-87), 38.1 % men). The seropositivity rate for RBD IgG after 2 doses of vaccine in the cancer group was 81.6 % (n=164) and 93.8 % (n=91) in the control group (p=0.005). The median IgG titer of cancer patients was significantly lower than in the control group (338 (IQR, 95-933) AU/mL vs 676 (IQR, 389-1270) AU/mL; p<0.001). Multivariate analysis of all the patients determined that having cancer (OR: 0.303, 95%CI: 0.123-0.750, p=0.010) and being over 60 years of age (OR: 0.447, 95%CI: 0.218-0.917, p=0.028) was associated with a reduced vaccine response. A subgroup analysis of cancer patients revealed that seroconversion was lower in men than in women (75.3 % vs 86.2 %, p=0.049) and lower in â‰¥60 patients than in <60 patients (75.9 % vs 89.4 %, p=0.014). DISCUSSION AND CONCLUSION: Cancer patients receiving an active systemic therapy with two doses of the CoronaVac vaccine had a lower antibody response than the non-cancer population, and deaths due to COVID-19 may occur in these patients despite the vaccine. Therefore, extensive protective measures should be taken to protect against COVID-19 in cancer patients aged 60 years and older, who have received two doses of the CoronaVac vaccine (Tab. 4, Fig. 4, Ref. 27).

Association Between Menstrual Cycle Length and Coronavirus Disease 2019 (COVID-19) Vaccination: A U.S. Cohort.

Association between history of HBV vaccine response and anti-SARS-CoV-2 spike antibody response to the BioNTech/Pfizer's BNT162b2 mRNA SARS-CoV-2 vaccine among healthcare workers in Japan: A prospective observational study. INTRODUCTION: Inadequate vaccine response is a common concern among healthcare workers at the frontlines of the COVID-19 pandemic. We aimed to investigate if healthcare workers with history of weak immune response to HBV vaccination are more likely to have weak responses against the BioNTech/Pfizer's BNT162b2 mRNA SARS-CoV-2 vaccine. METHODS: We prospectively tested 954 healthcare workers for the Anti-SARS-CoV-2 spike (S) protein antibody titers prior to the first and second BNT162b2 vaccination doses and after four weeks after the second dose using Roche's ElecsysÂ® assay. We calculated the percentage of patients who seroconverted after the first and second doses. We estimated the relative risk of non-seroconversion

after the first BNT162b2 vaccine (defined as anti-SARS-CoV-2-S titer <15 U/mL) among HBV vaccine non-responders (HBs-Ab titer <10 mIU/mL) and weak responders (â‰¥10 and <100 mIU/mL) compared to normal responders (â‰¥100 mIU/mL). RESULTS: Among 954 healthcare workers recruited between March 9 and March 24, 2021 at Osaka Medical and Pharmaceutical University, weak and normal HBV vaccine responders had comparable S-protein titers after the first BNT162b2 dose (51.4 [95% confidence interval 25.2-137.0] versus 59.7 [29.8-138.0] U/mL, respectively). HBV vaccine non-responders were more likely than normal responders to not seroconvert after a single dose (age and sex-adjusted relative risk 1.85 95% confidence interval [1.10-3.13]) although nearly all participants seroconverted after the second dose. After limiting the analysis to 382 patients with baseline comorbidity data, the comorbidity-adjusted relative risk of non-seroconversion among HBV vaccine non-responders to normal responders was 1.32 (95% confidence interval [0.59-2.98]). DISCUSSION: Long term follow-up studies are needed to understand if protective immunity against SARS-CoV-2 wanes faster among those with history of HBV vaccine non-response and when booster doses are warranted for these healthcare workers.

Comparison of SARS-CoV-2 Antibody Response After 2-Dose mRNA-1273 vs BNT162b2 Vaccines in Incrementally Immunosuppressed Patients. This cohort study compares the antispike antibody titers of the mRNA-1273 and BNT162b2 vaccines for SARS-CoV-2 in incrementally immunosuppressed patients.

Acculturation, trust to health care system, and attitudes to COVID-19 vaccination: A comparative study between Polish immigrants in Norway, Polish in Poland, and Norwegians in Norway. Fast deployment of safe and efficient COVID-19 vaccines has changed the course of the pandemic in many countries reducing COVID-19 death rates and allowing countries to abandon strict measures such as social distancing and restrictions to public events. The vaccination strategy, however, is based on the expected high vaccination rate in the population. Several studies have indicated vaccination hesitancy to be higher in ethnic minority communities, which can lead to unnecessary suffering and loss of lives, worsening pre-existing health inequalities and marginalization of ethnic minority groups. The aim of the present study was to investigate the relationships between acculturation to Norwegian culture, trust in health authorities, and attitude to COVID-19 vaccine among Polish immigrants in Norway. An internet-based survey including questions about attitude to COVID-19 vaccination and trust in the health care system was filled by 150 Polish immigrants in Norway, 256 Polish living in Poland, and 264 Norwegians living in Norway. In addition, the Polish immigrants also answered questions about acculturation to Norway. The results showed that the Polish immigrants in Norway had less positive attitudes to COVID-19 vaccination than the Norwegians, while they did not differ from Polish living in Poland. The Polish immigrants also indicated lower trust in the Norwegian health care system than the Norwegians. In regression analysis, the trust in the values of the health care system was the most important predictor of COVID-19 vaccination attitudes in all three samples. A path model showed that trust in the values of the health care system mediated the effects of acculturation to Norway on COVID-19 vaccination attitudes among Polish immigrants. These results underline the importance of taking ethnic minorities and immigrants into account in the health care system to reduce COVID-19 vaccination hesitancy.

Facial and Abducens Nerve Palsies Following COVID-19 Vaccination: Report of Two Cases. A broad spectrum of neurological side effects has been reported after immunisation for COVID-19, including functional neurological disorders, cerebral vascular events, cerebral venous thrombosis, intracerebral haemorrhage, neuroleptic malignant syndrome, cranial nerve palsies, and otologic manifestations. Multiple cranial neuropathies have also been reported following vaccination in which involvement of VII nerve is the most prevalent, followed by the VI, III, and IV nerves. We describe two male patients, one with with facial nerve palsy and the other with abducens nerve palsy following

COVID-19 vaccination. The patient with facial nerve palsy received the AstraZeneca vaccine 2 days before the symptoms began. In contrast, the patient with the abducens palsy had received his first dose of the Sinopharm vaccine 7Â days previously. Both patients demonstrated a gradual recovery within the next 2Â months. Further studies are required to investigate the proper relationship between cranial nerve palsies and vaccinations.

Gastrointestinal Complications of COVID-19 Vaccines. Much of the control over the coronavirus disease 2019 (COVID-19) pandemic has been achieved by mass vaccination against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the etiologic agent that causes COVID-19. The COVID-19 mRNA (messenger RNA) vaccines are relatively newly approved and have been widely used in the US since they first became available. However, with passing time, data regarding adverse events associated with the mRNA vaccines have become clearer. Vaccines are safe in general, and the benefits outweigh the risks of adverse events. In this case report, we present the first documented case report of post-vaccination acute diverticulitis and colon micro-perforation following Moderna booster dose (Moderna Inc, Cambridge, USA) in a young adult.Â Vaccine recipients should be educated on vaccine-associated gastrointestinal (GI) adverse events in order to reduce morbidity and mortality. We also recommend that vaccine recipients with pre-existing GI disorders should be carefully monitored for the worsening of pre-existing conditions post-COVID-19 vaccination.

Symptomatic Myocarditis Post COVID-19 Vaccination. There are few major adverse events after the coronavirus disease 2019 (COVID-19) vaccination. However, increasing cases of myocarditis and pericarditis are being reported to the Vaccine Adverse Event Reporting System (VAERS) in young people, primarily after the second dose of messenger RNA (mRNA) COVID-19 vaccines. We present a case series of myopericarditis post mRNA (Moderna) and myocarditis post vector-based (Johnson & Johnson) COVID-19 vaccines. We intend to highlight the importance of early diagnosis and treatment of vaccine-related myocarditis to reduce mortality and morbidity.

Bullous Pemphigoid Following the Moderna mRNA-1273 Vaccine. As the onset of novel variants of the severe acute respiratory syndrome coronavirus 2 virus pushes policy-makers to push widespread vaccination efforts, it is likely that an increased number of severe cutaneous adverse reactions (SCARs) will present. Therefore, it is important to understand the presentation of possible SCARs. However, data are limited regarding which SCARs are most likely to be found following vaccination, and specific presentations in certain demographic groups, such as postmenopausal women, remain widely unknown. Here, we present the case of a 73-year-old female with no medical history or allergies presenting with a unique reaction of systemic bullous pemphigoid following the Moderna mRNA-1273 vaccine. To our knowledge at the time of this writing, based on a thorough review of the literature using PubMed, no such cases exist following the Moderna vaccine in the United States in elderly, postmenopausal women. We present a brief discussion on the presentation and management to hopefully alleviate future morbidity from similar reactions with increased distribution of the vaccine.

Case Report: Acute Necrotizing Encephalopathy Following COVID-19 Vaccine. OBJECTIVES: Acute necrotizing encephalopathy (ANE) is a rare neurological disorder arising from a para- or post-infectious "cytokine storm. "It has recently been reported in association with coronavirus disease 2019 (COVID-19) infection. METHODS: A 56-year-old male with a diagnosis of ANE 48 h following the first dose of ChAdOx1 nCoV-19 vaccination was investigated. Cytokine analyses on serum and cerebrospinal fluid (CSF) were performed. The patient was treated with high-dose corticosteroids and followed clinically and radiologically. RESULTS: Favorable clinical and radiological outcomes were noted. There was an upregulation in serum levels of CXCL5, CXCL1, Il-8, IL-15, CCL2, TGF-B, and EGF, and up-regulation in CSF levels of CXCL5, IL-2, IL-3, and IL-8. DISCUSSION: As COVID-19 infection has been previously reported as a possible rare cause of ANE, we speculate on an aberrant immune

response mechanism that was brought about by the vaccine. To increase our understanding of the pathogenesis of ANE in the context of COVID-19 vaccination and to better define its clinical features and outcomes, clinicians and scientists should continue reporting convincing cases of such entities.
Case Report: Exacerbation of Relapses Following mRNA COVID-19 Vaccination in Multiple Sclerosis: A Case Series. INTRODUCTION: mRNA coronavirus disease 2019 (COVID-19) vaccination has been widely used to arrest the spread of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. Rarely, autoimmune events such as relapses in patients with multiple sclerosis (MS) have been reported after vaccination. However, the possible effects of vaccination in a patient already experiencing the symptoms of a relapse represent an unusual scenario that has not been described. PATIENTS AND METHODS: This is a retrospective case series of four patients from three major tertiary referral centers that received mRNA COVID-19 vaccination after starting with symptoms of acute demyelination of the central nervous system due to non-recognized MS. A detailed description of each case, including MRI studies, serum light-neurofilament levels, and cerebrospinal fluid (CSF) cytokine profile, is provided. CASE DESCRIPTION: All patients presented exacerbation of ongoing symptoms after vaccination (range 14-112 days first dose). All patients presented MRI features suggestive of highly active MS and fulfilled McDonald 2017 criteria at the time of presentation. All patients presented high serum light-neurofilament levels and oligoclonal G bands restricted to the CSF. Higher levels of interleukin-6 in the CSF were present in the more severe cases. DISCUSSION: We describe exacerbation of relapses after mRNA COVID-19 vaccination. We hypothesize RNA sensors such as Toll-like receptor 7 may be activated and contribute to amplify the inflammatory response during a relapse. CONCLUSION: Patients should seek medical attention if experiencing acute neurological symptoms, especially before vaccination. Fast diagnostic procedures and prompt treatment should be performed in these patients. Pharmacovigilance and further study are warranted to confirm causality.
Arterial thrombosis following first-dose ChAdOx1 vaccination: a case series.
Toxic epidermal necrolysis-like linear IgA bullous dermatosis after third Moderna COVID-19 vaccine in the setting of oral terbinafine.
Reactive arthritis following COVID-19 vaccination with BNT162b2.
Case Report: Importance of MRI Examination in the Diagnosis and Evaluation of COVID-19 mRNA Vaccination Induced Myocarditis: Our Experience and Literature Review. Acute myocarditis is a rare but serious complication associated with mRNA-based coronavirus disease 2019 (COVID-19) vaccination. In this article, four COVID-19 mRNA vaccination induced myocarditis cases managed at our tertiary Medical Center have been discussed. Three patients had typical myocarditis. One patient suffered from atrioventricular block and heart failure, which required more intensive treatment, but eventually improved. Additionally, a review of cardiac magnetic resonance imaging (MRI) features related to the diagnosis of myocarditis showed that COVID-19 mRNA vaccine-associated myocarditis tend to have more late-gadolinium enhancement (LGE) accumulation in the inferior lateral wall direction. According to a report by the U.S. Centers for Disease Control and Prevention (CDC), the diagnosis of COVID-19 mRNA vaccine-associated myocarditis is based on clinical symptoms, altered myocardial enzymes, cardiac MRI finding, or histopathology. Cardiac MRI is relatively less invasive than myocardial biopsy and plays an important role in the diagnosis of myocarditis. This review may aid in the diagnosis of COVID-19 mRNA vaccine-associated myocarditis.
Case Report: Transient Increase of CMR T1 Mapping Indices in a Patient With COVID-19 mRNA Vaccine Induced Acute Myocarditis. BACKGROUND: Acute myocarditis is commonly associated with viral infections, including severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). Myocarditis following mRNA COVID-19 vaccination has also been reported, however this is rare and usually resolves within days or weeks. We present a case of acute myocarditis reported after

vaccination with mRNA-1273 COVID-19 vaccine (Moderna) diagnosed using cardiac magnetic resonance imaging (CMR). This report describes the utility of CMR in the diagnosis and follow-up of such patients using parameters which could suggest the clinical course of myocarditis. CASE SUMMARY: A 23-year-old male presented in the emergency department with complaints of chest pain radiating to the left arm following vaccination with the second dose of COVID-19 mRNA-1273 vaccine (Moderna). Patient's history revealed an incidence of myocarditis in the past. CMR showed a mid-range left ventricular ejection fraction (38%) and subepicardial late gadolinium enhancement (LGE) in the inferolateral and apical myocardial segments with diffuse elevation of native T1 mapping relaxation times in all myocardial segments. The patient was admitted briefly in the intensive care unit and after a favorable clinical course was discharged from the hospital in stable condition. A follow-up CMR after 3 months revealed normalization of LVEF (57%) and native T1- times in most segments. Scarred myocardium reflecting chronic myocarditis continued to show elevated T1 times. CONCLUSIONS: Our patient presenting with acute myocarditis after recent COVID-19 mRNA vaccination reported a favorable clinical course. CMR revealed increased T1 mapping relaxation times diffusely spread across the myocardium and an impairment of the left ventricular function (LVEF) during the acute phase. However, the LVEF as well as the T1 times normalized at follow-up in all segments except for myocardium affected by chronic myocarditis.

Reactogenicity to ChAdOx1 nCoV-19 vaccine in health care workers: A multicenter observational study in Sri Lanka. INTRODUCTION: The acceptability of a vaccine is an important factor during mass vaccination programs and this is largely dependent on the symptoms of local and systemic reactogenicity. There is paucity of data on the systemic and local reactions experienced by COVD-19 vaccine recipients in South Asia. OBJECTIVES: To identify the early local and systemic reactogenicity of ChAdOx1 nCoV-19 vaccine. METHOD: A multicenter observational study was performed to identify the reactogenicity to ChAdOx1 nCoV-19 vaccine in healthcare workers following the first dose. RESULTS: There were 4478 participants with a median age of 42 years (IQR 34-51) and 2863 (63.9%) were females. At least one symptom of reactogenicity was reported by 4151 (92.7%). Local reactions were reported by 2612 (58.3%). Systemic reactions were bodyache (3244,72.4%), fatigue (2379, 53.1%), headache (2277, 50.8%), fever (2290, 51.1%), feverishness (1912, 42.7%) and chills (2295, 51.3%). Lower age ($p<0.0001$) and female gender (p 0.002) were associated with a higher frequency of developing systemic reactions. There was no association between reactogenicity and comorbidities. There were 342 (7.6%) reports of palpitations and one case of ventricular bigeminy. There was one report of anaphylaxis and hospital admissions were reported by 24 (0.5%). One vaccine recipient was managed for possible aseptic meningitis. CONCLUSION: This study demonstrates that early systemic and local reactions are common. Systemic reactions were more frequent in females and in the younger population. Most symptoms were self- limiting and did not require medical attention or hospital admission. ChAdOx1 nCoV-19 vaccine appears safe in the studied population.

Graves' Disease after Administration of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine in a Type 1 Diabetes Patient. Although there is a great demand for increased coronavirus disease 2019 (COVID-19) vaccination worldwide, rare side effects of the vaccine in susceptible individuals are attracting attention. We recently treated a patient with type 1 diabetes who had HLA-A*240201/A*020101, B*5401/B*5601, DRB1*0405/DRB1*0405, DPB1*0501/DPB1*0501 and DQB1*0401/DQB1*040 and developed Graves' disease soon after the administration of a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. While causal relationships between vaccinations and adverse events are difficult to discern due to both confounding and masking factors, our findings suggest that attention to possible adjuvant-related endocrinological diseases in certain individuals receiving SARS-CoV-2 vaccines is appropriate.

Non-arteritic anterior ischaemic optic neuropathy (NA-AION) and COVID-19 vaccination. A woman in her 50s presented with diminution of vision in her left eye (OS) 4 days after COVISHIELD(TM) vaccination. She had been diagnosed with non-arteritic anterior ischaemic optic neuropathy (NA-AION) of right eye (OD) 8 months earlier. The present episode revealed a best-corrected visual acuity (BCVA) of 20/50 in OD and 20/20 in OS with grade 1 relative afferent pupillary defect. Fundus evaluation showed pale disc in OD and temporal disc oedema in OS. Humphrey's visual field analysis showed incomplete inferior altitudinal defect in OD and a centro-caecal scotoma in OS. Systemic investigations were normal. OS was diagnosed with NA-AION. She was started on oral aspirin 75 mg. At 1-month follow-up, disc oedema of OS had resolved with BCVA maintaining at 20/20. The patient was lost to follow-up later. The relationship between the vaccine and the ocular event is temporal with no causal association.

Case Series of Successful Intravenous Immunoglobulin (IVIG) Treatment in 4 Pregnant Patients with Severe COVID-19-Induced Hypoxia. BACKGROUND Despite unprecedented speed in the execution of the COVID-19 vaccine and therapeutic clinical trials, pregnant patients have been largely excluded from initial studies. In addition, pregnant patients who are unvaccinated against SARS-CoV-2 have greater morbidity risk with severe COVID-19 disease as compared to patients of similar age and comorbidity status. Intravenous immunoglobulin (IVIG) has been deemed safe in pregnancy in other diseases. Prior data demonstrate the possible benefit of utilizing IVIG for the treatment in hospitalized patients with severe respiratory symptoms associated with COVID-19 active infections when administered within 14 days of COVID symptom onset. CASE REPORT We administered IVIG (PrivigenÂ®, CSL Behring) 0.5 g/kg daily for 3 consecutive days to 4 pregnant patients (ages 24-34 years of age) who were hospitalized with moderate-to-severe COVID-19 and not vaccinated against SARS-CoV-2. All patients received concomitant glucocorticoid therapy. Gestational ages were 26, 17, 35, and 35 weeks. All patients were discharged home breathing room air after a mean hospital stay of 15 days. Two patients had uncomplicated cesarean section at 35 weeks during the hospitalization. The pre-term pregnancies at 17 and 26 weeks were intact at hospital discharge and resulted in normal vaginal deliveries at term. All 4 patients consented to participate in this case series report. CONCLUSIONS IVIG may be a safe treatment consideration in pregnant women with severe COVID-19 to avoid pregnancy complications. Its use warrants further study in pregnancy acute respiratory distress syndrome (ARDS) due to SARS-CoV-2, influenza, and other respiratory viruses to which pregnant patients are vulnerable.

Humoral and T-Cell Response before and after a Fourth BNT162b2 Vaccine Dose in Adults â‰¥60 Years. Both humoral and cellular anamnestic responses are significant for protective immunity against SARS-CoV-2. In the current study, the responses in elderly people before and after a fourth vaccine dose of BNT162b2 were compared to those of individuals immunized with three vaccine doses. Although a boost effect was observed, the high response following the third administration questions the necessity of an early fourth boost.

Obstetric and Neonatal Outcomes following COVID-19 Vaccination in Pregnancy. COVID-19 infection imposes a risk for pregnant individuals and may lead to adverse maternal and obstetric outcomes. This is a retrospective cohort study of all women giving birth between March and July 2021 at a single tertiary center. Obstetric and neonatal outcomes were compared between vaccinated and non-vaccinated pregnant women with singleton pregnancies. Women with prior COVID-19 infection, multiple gestations and stillbirth were excluded from the study. Of 4708 women who delivered during the study period, 3700 met the eligibility criteria, of whom 3240 were vaccinated during pregnancy. Compared with the non-vaccinated group, the vaccinated group was characterized by a lower rate of smoking (3.70% vs. 6.67%, p = 0.0028), whereasother maternal characteristics were not significantly different. Multivariable analysis demonstrated that COVID-19

mRNA vaccination was not significantly associated with increased risk of preterm birth as well as other adverse obstetric outcomes including hypertensive diseases of pregnancy, cesarean delivery and small for gestational age. However, a significantly lower risk for meconium-stained amniotic fluid was observed among the vaccinated group (adjusted odds ratio 0.63; 95% confidence interval, 0.46-0.86, p = 0.0039). Moreover, the vaccine was not significantly associated with increased risk of neonatal adverse outcomes including respiratory complications and NICU hospitalization. In conclusion, BNT162b2 messenger RNA vaccination during pregnancy was not associated with an increased rate of adverse obstetric and neonatal outcomes. Therefore, in view of its safety on one hand, and the risk associated with COVID-19 disease in pregnancy on the other hand, BNT 162b2 COVID-19 vaccine should be recommended for pregnant women.

Importance of Vaccination against SARS-CoV-2 in Patients with Interstitial Lung Disease Associated with Systemic Autoimmune Disease. Objectives: To describe the frequency of COVID-19 and the effect of vaccination in patients with interstitial lung disease and systemic autoimmune disease (ILD-SAD) and to identify factors associated with infection and severity of COVID-19. Methods: We performed a cross-sectional multicenter study of patients with ILD-SAD followed between June and October 2021. The main variable was COVID-19 infection confirmed by a positive polymerase chain reaction (PCR) result for SARS-CoV-2. The secondary variables included severity of COVID-19, if the patient had to be admitted to hospital or died of the disease, and vaccination status. Other variables included clinical and treatment characteristics, pulmonary function and high-resolution computed tomography. Two logistic regression was performed to explore factors associated with â€œCOVID-19â€• and â€œsevere COVID-19â€•. Results: We included 176 patients with ILD-SAD: 105 (59.7%) had rheumatoid arthritis, 49 (27.8%) systemic sclerosis, and 22 (12.54%) inflammatory myopathies. We recorded 22/179 (12.5%) SARS-CoV-2 infections, 7/22 (31.8%) of them were severe and 3/22 (13.22%) died. As to the vaccination, 163/176 (92.6%) patients received the complete doses. The factors associated with SARS-CoV-2 infection were FVC (OR (95% CI), 0.971 (0.946âˆ’0.989); p = 0.040), vaccination (OR (95% CI), 0.169 (0.030âˆ’0.570); p = 0.004), and rituximab (OR (95% CI), 3.490 (1.129âˆ’6.100); p = 0.029). The factors associated with severe COVID-19 were the protective effect of the vaccine (OR (95% CI), 0.024 (0.004âˆ’0.170); p < 0.001) and diabetes mellitus (OR (95% CI), 4.923 (1.508âˆ’19.097); p = 0.018). Conclusions: Around 13% of patients with ILD-SAD had SARS-CoV-2 infection, which was severe in approximately one-third. Most patients with severe infection were not fully vaccinated.

Common Variable Immunodeficiency Associated with a De Novo IKZF1 Variant and a Low Humoral Immune Response to the SARS-CoV-2 Vaccine. BACKGROUND AND AIMS: Common variable immunodeficiency (CVID) comprises a group of diseases with heterogeneous clinical and immunological manifestations. Several mutations have been identified in genes encoding proteins essential for immune function. Our aim was to phenotypically and genotypically characterize a patient diagnosed with CVID and study his response to the SARS-CoV-2 vaccine. METHODS: We performed a next-generation sequencing analysis, a CMIA, and an ELISA to analyze the humoral and cellular response to the SARS-CoV-2 vaccine, respectively. We also employed flow cytometry and immunoturbidimetry to assess the patient's global immune status. RESULTS: We found a low humoral but positive cellular response to the SARS-CoV-2 vaccine. NGS screening revealed a transition from guanine to adenine at position c.485 of the IKZF1 gene in heterozygosity, giving rise to the R162Q variant, which was not present in his parents. CONCLUSIONS: The R162Q variant of the IKZF1 gene has been associated with CVID type 13, but always with an autosomal dominant inheritance with high penetrance. Therefore, we present for the first time a case of CVID associated with a de novo heterozygous R162Q variant in the IKZF1 gene in a patient with a low humoral immune response to the complete COVID-19 vaccination program.

The COVID-19 Vaccination and Vaccine Inequity Worldwide: An Empirical Study Based on Global Data. Vaccination is critical for controlling the COVID-19 pandemic. However, the progress of COVID-19 vaccination varies from different countries, and global vaccine inequity has been a worldwide public health issue. This study collected data from the Our World in Data COVID-19 vaccination data set between 13 December 2020 and 1 January 2022. The measurement reflecting the pandemic situation included New cases, New deaths, Hospital patients, ICU patients, and the Reproduction rate. Indicators for measuring the vaccination coverage included Total vaccinations per hundred and People vaccinated per hundred. The Human Development Index (HDI) measured the country's development level. Findings indicated that countries with higher HDI have more adequate vaccine resources, and global vaccine inequity exists. The study also found that vaccination significantly mitigates the pandemic, and reaching 70% immunization coverage can further control the epidemic. In addition, the emergence of Omicron variants makes the COVID-19 epidemic situation even worse, suggesting the importance and necessity of addressing vaccine inequity. The globe will face a greater challenge in controlling the pandemic if lower-vaccinated countries do not increase their vaccination coverage. Addressing the issue of vaccine inequity needs the cooperation of HIC, LMIC, public health departments, and vaccine producers. Moreover, the media has to contribute to effective public health communication by raising public perceptions of the COVID-19 pandemic, vaccination, and vaccine inequity.

Immunogenicity and safety of heterologous versus homologous prime-boost schedules with an adenoviral vectored and mRNA COVID-19 vaccine: a systematic review. BACKGROUND: Heterologous prime-boost with ChAdOx1 nCoV-19 vector vaccine (ChAd) and a messenger RNA vaccine (BNT or mRNA-1273) has been widely facilitating mass coronavirus disease 2019 (COVID-19) immunisation. This review aimed to synthesize immunogenicity and reactogenicity of heterologous immunisations with ChAd and BNT (mRNA-1273) vaccine compared with homologous ChAd or BNT (mRNA-1273) immunisation. METHODS: PubMed, Web of Science, and Embase databases were searched from inception to March 7, 2022. Immunogenicity involving serum antibodies against different SAS-CoV-2 fragments, neutralizing antibody, or spike-specific T cells response were compared. Any, local and systemic reactions were pooled by meta-analysis for comparison. RESULTS: Of 14,571 records identified, 13 studies (3024 participants) were included for analysis. Compared with homologous BNT/BNT vaccination, heterologous ChAd/BNT schedule probably induced noninferior anti-spike protein while higher neutralizing antibody and better T cells response. Heterologous ChAd/BNT (mRNA-1273) immunisation induced superior anti-spike protein and higher neutralizing antibody and better T cells response compared with homologous ChAd/ChAd vaccination. Heterologous ChAd/BNT (mRNA-1273) had similar risk of any reaction (RRâ€‰=â€‰1.30, 95% CI: 0.86-1.96) while higher risk of local reactions (RRâ€‰=â€‰1.65, 95% CI: 1.27-2.15) and systemic reactions (RRâ€‰=â€‰1.49, 95% CI: 1.17-1.90) compared with homologous ChAd/ChAd vaccination. There was a higher risk of local reactions (RRâ€‰=â€‰1.16, 95% CI: 1.03-1.31) in heterologous ChAd/BNT (mRNA-1273) vaccination compare with homologous BNT/BNT but a similar risk of any reaction (RRâ€‰=â€‰1.03, 95% CI: 0.79-1.34) and systemic reactions (RRâ€‰=â€‰0.89, 95% CI: 0.60-1.30). CONCLUSIONS: Heterologous ChAd/BNT schedule induced at least comparable immunogenicity compared with homologous BNT/BNT and better immunogenicity compared with homologous ChAd/ChAd vaccination. The synthetical evidence supported the general application of heterologous prime-boost vaccination using ChAd and BNT COVID-19 vaccines.

MAIT cell compartment characteristics are associated with the immune response magnitude to the BNT162b2 mRNA anti-SARS-CoV-2 vaccine. Mucosa-associated invariant T (MAIT) cells are unconventional T cells with innate-like capacity to rapidly respond to microbial infection via MR1-restricted antigen recognition. Emerging evidence indicate that they can also act as rapid sensors of

viral infection via innate cytokine activation. However, their possible role in the immune response to mRNA vaccination is unknown. Here, we evaluated the involvement of MAIT cells in individuals vaccinated with the BNT162b2 mRNA SARS-CoV-2 vaccine. MAIT cell levels, phenotype and function in circulation were preserved and unperturbed through day 35 post-vaccination in healthy donor (HD) vaccinees, as well as people living with HIV (PLWH) or with primary immunodeficiency (PID). Unexpectedly, pre-vaccination and post-vaccination levels of MAIT cells correlated positively with the magnitude of the SARS-CoV-2 spike protein-specific CD4 T cell and antibody responses in the HD vaccinees. This pattern was largely preserved in the PID group, but less so in the PLWH group. Furthermore, in the HD vaccinees levels of MAIT cell activation and cytolytic potential correlated negatively to the adaptive antigen-specific immune responses. These findings indicate an unexpected association between MAIT cell compartment characteristics and the immune response magnitude to the BNT162b2 mRNA vaccine.

Vaccine-induced systemic and mucosal T cell immunity to SARS-CoV-2 viral variants. The first-generation COVID-19 vaccines have been effective in mitigating severe illness and hospitalization, but recurring waves of infections are associated with the emergence of SARS-CoV-2 variants that display progressive abilities to evade antibodies, leading to diminished vaccine effectiveness. The lack of clarity on the extent to which vaccine-elicited mucosal or systemic memory T cells protect against such antibody-evasive SARS-CoV-2 variants remains a critical knowledge gap in our quest for broadly protective vaccines. Using adjuvanted spike proteinâ€“based vaccines that elicit potent T cell responses, we assessed whether systemic or lung-resident CD4 and CD8 T cells protected against SARS-CoV-2 variants in the presence or absence of virus-neutralizing antibodies. We found that 1) mucosal or parenteral immunization led to effective viral control and protected against lung pathology with or without neutralizing antibodies, 2) protection afforded by mucosal memory CD8 T cells was largely redundant in the presence of antibodies that effectively neutralized the challenge virus, and 3) â€œunhelpedâ€• mucosal memory CD8 T cells provided no protection against the homologous SARS-CoV-2 without CD4 T cells and neutralizing antibodies. Significantly, however, in the absence of detectable virus-neutralizing antibodies, systemic or lung-resident memory CD4 and â€œhelpedâ€• CD8 T cells provided effective protection against the relatively antibody-resistant B1.351 (Î²) variant, without lung immunopathology. Thus, induction of systemic and mucosal memory T cells directed against conserved epitopes might be an effective strategy to protect against SARS-CoV-2 variants that evade neutralizing antibodies. Mechanistic insights from this work have significant implications in the development of T cellâ€“targeted immunomodulation or broadly protective SARS-CoV-2 vaccines.

Risk of Infection and Hospitalization Among Vaccinated and Unvaccinated Children and Adolescents in New York After the Emergence of the Omicron Variant. This database study examines vaccination for COVID-19 among children in New York after the emergence of the Omicron variant, including analysis of case rates and hospitalizations for COVID-19 disease.

Multi-site observational maternal and infant COVID-19 vaccine study (MOMI-vax): a study protocol. BACKGROUND: Pregnant women were excluded from investigational trials of COVID-19 vaccines. Limited data are available to inform pregnant and postpartum women on their decisions to receive a COVID-19 vaccine. METHODS: The goal of this observational, prospective cohort study is to evaluate the immunogenicity and safety of various Emergency Use Authorization (EUA) or licensed COVID-19 vaccines administered to pregnant or lactating women and describe the transplacental antibody transfer and kinetics of antibodies in mothers and infants. The study is adaptive, allowing additional groups to be added as new vaccines or vaccine regimens are authorized. Up to 20 clinical research institutions in the United States (U.S.) will be included. Approximately 200 pregnant women and 65 postpartum women will be enrolled per EUA or licensed COVID-19 vaccine formulation in the U.S.

This study will include pregnant and postpartum women of all ages with and without chronic medical conditions. Their infants will be enrolled and followed beginning at birth in the pregnant cohort and beginning at the earliest possible time point in the postpartum cohort. Blood samples will be collected for immunogenicity outcomes and pregnancy and birth outcomes assessed among women and infants. PrimaryÂ analyses will be descriptive and done by vaccine type and/or platform. DISCUSSION: Given the long-standing and legitimate challenges of enrolling pregnant individuals into clinical trials early in the vaccine development pipeline, this study protocol describes our current study and provides a template to inform the collection of data for pregnant individuals receiving COVID-19 or other vaccines. TRIAL REGISTRATION: NCT05031468 .

Acute Multiple Sclerosis Exacerbation After Vaccination With the Johnson & Johnson COVID-19 Vaccine: Novel Presentation and First Documented Case Report. Multiple sclerosis (MS) is a neurologic disease caused by a chronic autoimmune process resulting in the demyelination of axons within the central nervous system. MS occurs through combined genetic susceptibility and environmental triggers. MS relapses (MSR) are characterized by acute inflammatory reactions and symptoms. Here we present a novel case of MSR following the second dose of the Johnson & Johnson coronavirus disease 2019 (COVID-19) vaccine (Johnson & Johnson, New Brunswick, New Jersey, United States), presenting with paresthesias and left foot deficit. Additional research and studies are necessary to explore the relationship of COVID-19 vaccinations with MSR.

Impaired immune responses in blood cancers improved by third COVID-19 vaccine dose.

Seroconversion to mRNA SARS-CoV-2 vaccines in patients with autoimmune cytopenias and bone marrow failures. Data concerning the efficacy of SARS-CoV-2 vaccines in patients with non-oncological hematologic conditions are lacking. These include autoimmune cytopenias (autoimmune hemolytic anemia AIHA, immune thrombocytopenia ITP, and autoimmune neutropenia), and bone marrow failure syndromes (aplastic anemia, low risk myelodysplastic syndromes, and paroxysmal nocturnal hemoglobinuria). These conditions may relapse/reactivate after COVID-19 infection and vaccine. Moreover, they are mainly handled with immunosuppressive drugs that may hamper the response to vaccine. In this study, we prospectively evaluated the rate of seroconversion after mRNA SARS-CoV-2 vaccines in patients with autoimmune cytopenias or bone marrow failure syndrome after 2â€‰Â±â€‰1Â months from the last vaccine dose. Overall, 149 patients were tested and 135 (91%) seroconverted. The highest proportion of non-responders was observed in Evans syndrome (association of ITP and AIHA) and warm AIHA patients (pâ€‰=â€‰0.001), in those with lower levels of baseline serum IgG (pâ€‰=â€‰0.008), and in patients on active therapy with steroids (pâ€‰=â€‰0.03) who also had lower anti-Spike titers. The latter were inversely related with age, and a positively with lymphocyte counts. Additionally, patients who had received rituximab within 12Â months from vaccination showed higher rates of non-response (pâ€‰=â€‰0.03) as compared to those treated before. Contrarily, cyclosporine alone, complement inhibitors, and bone marrow stimulating agents had no detrimental effect on seroconversion. These data suggest maintaining high vigilance and adherence to preventive/protective measures in this population since a proportion of cases may not respond or exhibit low anti-Spike titers.

Management of a severe bilateral pulmonary embolism as a complication of VITT following vaccination with AstraZeneca COVID-19 vaccine. Since the start of vaccination against COVID-19 viral infection using adenovirus-based vector vaccine (eg, The Oxford-AstraZeneca vaccine, using the modified chimpanzee adenovirus ChAdOx1, and the Johnson & Johnson vaccine, using human adenovirus serotype 26), a rare, but potentially life-threatening complication called vaccine-induced thrombotic thrombocytopenia (VITT) was reported. As the number of cases increases every day, with the increase in the number of vaccinated people all over the world, this complication is a concern to the medical field. We report a case on the acute management of a patient who presented to us with

life-threatening bilateral pulmonary embolism as a complication of VITT after the first dose of vaccination with Oxford-AstraZeneca vaccine against COVID-19.
Distinct immune cell dynamics correlate with the immunogenicity and reactogenicity of SARS-CoV-2 mRNA vaccine. Two doses of Pfizer/BioNTech BNT162b2 mRNA vaccine elicit robust severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-neutralizing antibodies with frequent adverse events. Here, by applying a high-dimensional immune profiling on 92 vaccinees, we identify six vaccine-induced immune dynamics that correlate with the amounts of neutralizing antibodies, the severity of adverse events, or both. The early dynamics of natural killer (NK)/monocyte subsets (CD16(+) NK cells, CD56(high) NK cells, and non-classical monocytes), dendritic cell (DC) subsets (DC3s and CD11c(-) Axl(+) Siglec-6(+) [AS]-DCs), and NKT-like cells are revealed as the distinct cell correlates for neutralizing-antibody titers, severity of adverse events, and both, respectively. The cell correlates for neutralizing antibodies or adverse events are consistently associated with elevation of interferon gamma (IFN-Î³)-inducible chemokines, but the chemokine receptors CCR2 and CXCR3 are expressed in distinct manners between the two correlates: vaccine-induced expression on the neutralizing-antibody correlate and constitutive expression on the adverse-event correlate. The finding may guide vaccine strategies that balance immunogenicity and reactogenicity.
Evaluation of mRNA-1273 Covid-19 Vaccine in Children 6 to 11 Years of Age. BACKGROUND: Vaccination of children to prevent coronavirus disease 2019 (Covid-19) is an urgent public health need. The safety, immunogenicity, and efficacy of the mRNA-1273 vaccine in children 6 to 11 years of age are unknown. METHODS: Part 1 of this ongoing phase 2-3 trial was open label for dose selection; part 2 was an observer-blinded, placebo-controlled expansion evaluation of the selected dose. In part 2, we randomly assigned children (6 to 11 years of age) in a 3:1 ratio to receive two injections of mRNA-1273 (50 Î¼g each) or placebo, administered 28 days apart. The primary objectives were evaluation of the safety of the vaccine in children and the noninferiority of the immune response in these children to that in young adults (18 to 25 years of age) in a related phase 3 trial. Secondary objectives included determination of the incidences of confirmed Covid-19 and severe acute respiratory syndrome coronavirus 2 infection, regardless of symptoms. Interim analysis results are reported. RESULTS: In part 1 of the trial, 751 children received 50-Î¼g or 100-Î¼g injections of the mRNA-1273 vaccine, and on the basis of safety and immunogenicity results, the 50-Î¼g dose level was selected for part 2. In part 2 of the trial, 4016 children were randomly assigned to receive two injections of mRNA-1273 (50 Î¼g each) or placebo and were followed for a median of 82 days (interquartile range, 14 to 94) after the first injection. This dose level was associated with mainly low-grade, transient adverse events, most commonly injection-site pain, headache, and fatigue. No vaccine-related serious adverse events, multisystem inflammatory syndrome in children, myocarditis, or pericarditis were reported as of the data-cutoff date. One month after the second injection (day 57), the neutralizing antibody titer in children who received mRNA-1273 at a 50-Î¼g level was 1610 (95% confidence interval [CI], 1457 to 1780), as compared with 1300 (95% CI, 1171 to 1443) at the 100-Î¼g level in young adults, with serologic responses in at least 99.0% of the participants in both age groups, findings that met the prespecified noninferiority success criterion. Estimated vaccine efficacy was 88.0% (95% CI, 70.0 to 95.8) against Covid-19 occurring 14 days or more after the first injection, at a time when B.1.617.2 (delta) was the dominant circulating variant. CONCLUSIONS: Two 50-Î¼g doses of the mRNA-1273 vaccine were found to be safe and effective in inducing immune responses and preventing Covid-19 in children 6 to 11 years of age; these responses were noninferior to those in young adults. (Funded by the Biomedical Advanced Research and Development Authority and the National Institute of Allergy and Infectious Diseases; KidCOVE ClinicalTrials.gov number, NCT04796896.).

Factors Associated With Serological Response to SARS-CoV-2 Vaccination in Patients With Multiple Sclerosis Treated With Rituximab. IMPORTANCE: B-cell-depleting monoclonal antibodies are widely used for treatment of multiple sclerosis but are associated with an impaired response to vaccines. OBJECTIVE: To identify factors associated with a favorable vaccine response to tozinameran. DESIGN, SETTING, AND PARTICIPANTS: This prospective cohort study was conducted in a specialized multiple sclerosis clinic at a university hospital from January 21 to December 1, 2021. Of 75 patients evaluated for participation who received a diagnosis of multiple sclerosis with planned or ongoing treatment with rituximab, 69 were included in the study, and data from 67 were analyzed. EXPOSURES: Sex, age, number of previous rituximab infusions, accumulated dose of rituximab, previous COVID-19 infection, time since last rituximab treatment, CD19+ B-cell count before vaccination, CD4+ T-cell count, and CD8+ T-cell count were considered potential factors associated with the main outcome. MAIN OUTCOMES AND MEASURES: Serological vaccine responses were measured by quantitation of anti-spike immunoglobulin G (IgG) antibodies, anti-receptor-binding domain (RBD) IgG antibodies, and their neutralizing capacities. Cellular responses to spike protein-derived SARS-CoV-2 peptide pools were assessed by counting interferon gamma spot-forming units in a FluoroSpot assay. RESULTS: Among 60 patients with ongoing rituximab treatment (49 women [82%]; mean (SD) age, 43 [10] years), the median (range) disease duration was 9 (1-29) years, and the median (range) dose of rituximab was 2750 (500-10â€¯000) mg during a median (range) time of 2.8 (0.5-8.3) years. The median (range) follow-up from the first vaccination dose was 7.3 (4.3-10.0) months. Vaccine responses were determined before vaccination with tozinameran and 6 weeks after vaccination. By using established cutoff values for anti-spike IgG (264 binding antibody units/mL) and anti-RBD IgG (506 binding antibody units/mL), the proportion of patients with a positive response increased with the number of B cells, which was the only factor associated with these outcomes. A cutoff for the B-cell count of at least 40/Î¼L was associated with an optimal serological response. At this cutoff, 26 of 29 patients (90%) had positive test results for anti-spike IgG and 21 of 29 patients (72%) for anti-RBD IgG, and 27 of 29 patients (93%) developed antibodies with greater than 90% inhibition of angiotensin-converting enzyme 2. No factor associated with the cellular response was identified. Depending on the peptide pool, 21 of 25 patients (84%) to 22 of 25 patients (88%) developed a T-cell response with interferon gamma production at the B-cell count cutoff of at least 40/Î¼L. CONCLUSIONS AND RELEVANCE: This cohort study found that for an optimal vaccine response from tozinameran, rituximab-treated patients with multiple sclerosis may be vaccinated as soon as possible, with rituximab treatment delayed until B-cell counts have reached at least 40/Î¼L. An additional vaccination with tozinameran should be considered at that point.

[Vaccines against coronavirus disease 2019 (COVID-19) : Efficacy comparison, safety aspects, and current challenges]. Several RNA-, vector-, and protein-based coronavirus disease 2019 (COVID-19) vaccines are currently available in order to achieve high titers of neutralizing antibodies against the spike protein as well as strongly activated CD4+- and CD+ Tâ€‘cells. However, there are formulation-specific advantages and disadvantages with regard to physicochemical stability, spectrum of adverse effects, need for adjuvants or adaptability to potentially novel viral variants. Whereas children and pregnant women now have access to COVID-19 vaccines, it often remains difficult to achieve sufficient cellular and humoral immunity in heavily immunocompromised patients. As aÂ consequence, innovative vaccines need to be developed for these patients. Undoubtedly, reports addressing, e.g. vaccine-associated myocarditis or thrombotic thrombocytopenia have led to uncertainties; however, vaccination remains the most important cornerstone in containing the pandemic.

The first report of 2:1 atrioventricular block following COVID-19 vaccination. A 65-year-old man became ill a few days after being vaccinated against the COVID-19 by the Sinopharm vaccine.

Laboratory investigations, trans-thoracic echocardiography, and chest computed tomography scanning (CT-scan) retrieved normal results. The patient's electrocardiogram showed sinus rhythms with 2:1 AV-block and a narrow QRS complex. Coronary angiography showed mild coronary artery disease.

Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy. Safety and effectiveness of COVID-19 vaccines during pregnancy is a particular concern affecting vaccination uptake by this vulnerable group. Here we evaluated evidence from 23 studies including 117,552 COVID-19 vaccinated pregnant people, almost exclusively with mRNA vaccines. We show that the effectiveness of mRNA vaccination against RT-PCR confirmed SARS-CoV-2 infection 7 days after second dose was 89Â·5% (95% CI 69Â·0-96Â·4%, 18,828 vaccinated pregnant people, I(2)â€‰=â€‰73Â·9%). The risk of stillbirth was significantly lower in the vaccinated cohort by 15% (pooled OR 0Â·85; 95% CI 0Â·73-0Â·99, 66,067 vaccinated vs. 424,624 unvaccinated, I(2)â€‰=â€‰93Â·9%). There was no evidence of a higher risk of adverse outcomes including miscarriage, earlier gestation at birth, placental abruption, pulmonary embolism, postpartum haemorrhage, maternal death, intensive care unit admission, lower birthweight Z-score, or neonatal intensive care unit admission (pâ€‰>â€‰0.05 for all). COVID-19 mRNA vaccination in pregnancy appears to be safe and is associated with a reduction in stillbirth.

The effect of COVID-19 vaccine on ovarian reserve. OBJECTIVES: To Evaluate the effect of messenger ribonucleic acid (mRNA) vaccines developed for the coronavirus disease-19 (COVID-19) on ovarian reserve. METHODS: This prospective cross sectional study was carried out between June and September 2021, in the Gynecology Polyclinics of a tertiary hospital, Ankara, Turkey, with 60 patients. Patients between the ages of 25-30 years old, who applied to the gynecology outpatient clinic and who were considering mRNA vaccination against severe acute respiratory syndrome coronavirus 2 were included in the study group, and those who did not plan to be vaccinated were included in the control group. Anti-mÃ¼llerian hormone (AMH) was examined before vaccination (1-5 days before vaccination) and within 60-90 days after vaccination. In the unvaccinated group, AMH was examined once. RESULTS: The mean age of the study group was 27.30Â±1.66 and of the control group was 27.40Â±1.69 ($p<0.05$). Post-vaccine AMH values of the study and control groups were similar ($p>0.05$). There was no statistically significant difference between pre-vaccine and post-vaccine AMH values in the study group ($p>0.05$). CONCLUSION: It is of great value that people who are planning pregnancy and who have hesitation regarding the effect of vaccines on ovarian reserve should be carefully informed that vaccines, which are one of the most important means of fighting against COVID-19 infection, have no effect on AMH levels. Prospective larger studies with a longer follow-up period are needed to confirm our results.

Immune complex-mediated glomerulonephritis post COVID-19 vaccination in a patient with concomitant Brucellosis. COVID vaccinations have been an important step in controlling the COVID-19 pandemic. Despite the fact they were generally safe and effective, a few case reports of renal disorders have been published following COVID vaccines. We report a 29-year-old man with history of Chronic Kidney Disease who presented to our center with flank pain after receiving AstraZeneca COVID vaccine. He also had history of raw milk ingestion. His initial investigations showed high creatinine with high level of proteinuria. A renal biopsy was consistent with immune complex-mediated glomerulonephritis on top of renal fibrosis. His brucella serology also showed high titer. He was started on treatment for Brucellosis and planned for follow-up afterwards for further therapy. To the best of our knowledge, this is the first reported case of concomitant Brucellosis and post COVID vaccine glomerulonephritis.

Associations of vaccine status with characteristics and outcomes of hospitalized severe COVID-19 patients in the booster era. BACKGROUND: The resurgence of COVID-19 cases since June 2021,

referred to as the fourth COVID-19 wave, has led to the approval and administration of booster vaccines. Our study aims to identify any associations between vaccine status with the characteristics and outcomes of patients hospitalized with severe COVID-19 disease. METHODS: We retrospectively reviewed all COVID-19 patients admitted to a large tertiary center between July 25 and October 25, 2021 (fourth wave in Israel). Univariant and multivariant analyses of variables associated with vaccine status were performed. FINDINGS: Overall, 349 patients with severe or critical disease were included. Patients were either not vaccinated (58%), had the first two vaccine doses (35%) or had the booster vaccine (7%). Vaccinated patients were significantly older, male predominant, and with a higher number of comorbidities including diabetes, hyperlipidemia, ischemic heart disease, heart failure, immunodeficient state, kidney disease and cognitive decline. Time from the first symptom to hospital admission was longer among non-vaccinated patients (7.2 Â± 4.4 days, p = 0.002). Critical disease (p<0.05), admissions to the intensive care unit (p = 0.01) and advanced oxygen support (p = 0.004) were inversely proportional to the number of vaccines given, lowest among the booster vaccine group. Death (20%, p = 0.83) and hospital stay duration (8.05Â± 8.47, p = 0.19) were similar between the groups. CONCLUSION: Hospitalized vaccinated patients with severe COVID-19 had significantly higher rates of most known risk factors for COVID-19 adverse outcomes. Still, all disease outcomes were similar or better compared with the non-vaccinated patients.
Favorable vaccine-induced SARS-CoV-2-specific T cell response profile in patients undergoing immune-modifying therapies. BACKGROUNDPatients undergoing immune-modifying therapies demonstrate a reduced humoral response after COVID-19 vaccination, but we lack a proper evaluation of the effect of such therapies on vaccine-induced T cell responses.METHODSWe longitudinally characterized humoral and spike-specific T cell responses in patients with inflammatory bowel disease (IBD), who were on antimetabolite therapy (azathioprine or methotrexate), TNF inhibitors, and/or other biologic treatment (anti-integrin or anti-p40) for up to 6 months after completing 2-dose COVID-19 mRNA vaccination.RESULTSWe demonstrate that a spike-specific T cell response was not only induced in treated patients with IBD at levels similar to those of healthy individuals, but also sustained at higher magnitude for up to 6 months after vaccination, particularly in those treated with TNF inhibitor therapy. Furthermore, the spike-specific T cell response in these patients was mainly preserved against mutations present in SARS-CoV-2 B.1.1.529 (Omicron) and characterized by a Th1/IL-10 cytokine profile.CONCLUSIONDespite the humoral response defects, patients under immune-modifying therapies demonstrated a favorable profile of vaccine-induced T cell responses that might still provide a layer of COVID-19 protection.FUNDINGThis study was funded by the National Centre for Infectious Diseases (NCID) Catalyst Grant (FY2021ES) and the National Research Fund Competitive Research Programme (NRF-CRP25-2020-0003).
Mucocutaneous Adverse Reactions to COVID-19 Vaccines: Do Excipients Play a Role?
COVID-19 vaccine hesitancy after side effects to the first vaccine: what are our options?
Correspondence on COVID-19 Vaccination and Acquired Haemophila A.
Incidental findings on a Tc99m-SESTAMIBI parathyroid scan post COVID-19 vaccination. We present a case of abnormal findings on a Tc99m-Sestamibi parathyroid scan, post COVID-19 vaccination. The patient is a 48-year-old female presenting for evaluation of hyperparathyroidism who received the mRNA-1273 Moderna (ModernaTX, Inc.) vaccine seven days prior to the scan. The patient is right hand dominant and reported no traumatic events, inflammation, infection, or extraneous use of the left arm. The patient did report "soreness" of the extremity starting approximately 24 hours post injection which continued to the time of the study.
More Than Three-Fourths of AstraZeneca (ChAdox1 COV-19) COVID-19 Vaccinated Individuals Develop Post Immunization Adverse Event in Northwest Ethiopia. BACKGROUND: Ethiopia was using the ChAdOx1 COV-19 vaccine, and health professionals were targets of the first phase of the

vaccination strategy. Evidence on the adverse events following immunization (AEFI) was barely available. The study aimed to assess the magnitude and associated factors of adverse events following ChAdOx1 COV-19 immunization among health professionals of the University of Gondar Specialized and Comprehensive Hospital, 2021. METHODS: An institution-based cross-sectional study was conducted among health professionals of the University of Gondar Comprehensive and specialized referral hospital. All health professionals who took the ChAdOx1 COV-19 vaccine in the 1st phase were surveyed. A total of 314 health professionals who took the ChAdOx1 COV-19 vaccine were included. The EpiData version 4.6.0.0 and Stata 16 were used for data entry and analysis, respectively. A binary logistic regression was used to identify statistically significant factors associated with AEFI. Chi-square and multicollinearity assumptions were tested. A p-value <0.2 and 0.05 were used as cut-off values of significance in the bi- and multivariable logistic regression models, respectively. An adjusted odds ratio (AOR) with 95% CI was reported for statistically significant variables. RESULTS: Among 314 study participants, 263 of them had at least one mild to severe AEFI of ChAdOx1 COV-19 with a prevalence of AEFI of 83.76% (95% CI: 79.23, 87.46). The commonest AEFI observed were injection site tenderness (n=198/263), fatigue (114/263), headache (n=107/263), and muscle pain (n=85/263). Females (AOR=2.75, 95% CI: 1.15, 6.58), and participants who felt the vaccine was unsafe (AOR=2.84, 95% CI: 1.03, 7.85) were having nearly three times more odds of AEFI immunization as compared to males and those who felt the vaccine was safe, respectively. CONCLUSION: Adverse event following immunization has been a public health problem in Northwest Ethiopia. Being female and having a feeling that the vaccine is unsafe were statistically significantly associated with AEFI.

Achieving safe surgery after COVID-19 vaccination.

Increment of D-dimer Associated with Immune Thrombotic Thrombocytopenia in ChAdOx1 nCoV-19 Vaccinated Individuals. AIM OF THE STUDY: Development of thrombocytopenia and thrombosis after administration of the ChAdox1 nCoV-19 (AstraZeneca-Oxford) vaccine has recently been described. This new condition is called vaccine-induced immune thrombotic thrombocytopenia (VITT). Our objective was to summarize case reports on VITT with/without D-dimer increments in AstraZeneca-Oxford vaccinated individuals. DATA SOURCES: MEDLINE, PubMed, and Scopus databases were searched. STUDY SELECTION: Case series, case reports, letters to the editor; and abstracts of AstraZeneca-Oxford vaccinated patients with a clinical profile of thrombocytopenia (platelet count <150X10 3 /dL) and D-dimer determination, with or without thrombosis, and/or bleeding, and/or antibodies against platelet factor 4 (aPF4), were included. DATA EXTRACTION: Baseline risk factors, symptoms, physical signs; laboratory results, imaging findings, treatment; and outcome in patients with VITT reported in case series, were examined. DATA SYNTHESIS: Patients who developed VITT were more likely to be young women (ages 21 to 77) given the AstraZeneca-Oxford vaccine 5-14 days prior to presentation. Patients' signs, symptoms, and imaging findings were consistent with cerebral venous sinus thrombosis, or deep veins, lung, and other sites. Laboratory findings showed thrombocytopenia, low fibrinogen, and elevated D-dimer levels, while aPF4 was positive in most assays performed. Treatment was non-heparin anticoagulants, IV immunoglobulin, and steroids, as recommended by medical guidelines. CONCLUSIONS: Vaccine-induced immune thrombotic thrombocytopenia is a rare complication with high morbidity, related to administration of the AstraZeneca-Oxford vaccine. Clinicians should prepare for early identification of patients with suspicious symptoms, and prompt treatment initiated to avoid catastrophic events. D-dimer determination is useful for surveillance of cases with suspected VITT.

Rare occurrence of Guillain-BarrÃ© syndrome after Moderna vaccine. A Caucasian man in his 60s with a medical history significant for ruptured left middle cerebral artery aneurysm status post clipping 2005 with residual right eye blindness and right leg weakness with gait instability presented

with loss of balance, weakness of his legs and fatigue for 3â€‰days. No other antecedent event was identified other than receiving Moderna COVID-19 vaccine 4 weeks before the presentation and 3â€‰days before symptom onset. CT head and CT angiogram of the head and neck were performed and demonstrated no acute intracranial bleeding and no vascular abnormalities. With the findings of diffuse hyporeflexia and cerebrospinal fluid showing albumino-cytological dissociation, Guillain-BarrÃ© syndrome was high on the differentials. Electromyogram showed evidence of demyelination. He was treated with intravenous immune globulin (IVIG) and was discharged to rehab with complete symptom resolution.

Omicron variant infection and the associated immunological scenario. The million-dollar question that has been the talk of the day is how effective the COVID 19 vaccines are against the Omicron variant. Still, there is no clear-cut answer to this question but several studies have concluded that this Variant of Concern (VOC) successfully weakens the neutralizing capability of the antibodies acquired from the COVID 19 vaccines and prior infections, which indicates that Omicron can easily bypass an individual's humoral immune response. However, the most significant confusion revolves around cell-mediated immunity tackling the Omicron variant. This paper aims to provide a clear idea about the status of the body's immune surveillance concerning the infection caused by the Omicron variant by producing the effectivity of the humoral and cell-mediated immunity in handling the same. This work also provides complete detail of the various characteristics of the Omicron variant and how it may be a blessing in disguise. The effectiveness of the current vaccines, the transmissibility rate of the variant compared to the other variants, and the importance of administering a booster dose to prevent the spread of this variant are also discussed. Finally, this work aims to bridge the gap between the past and the current status of the Omicron infection and sheds light on the hypothetical idea that herd immunity developed from the SARS-COV2 infection may help tackle other dangerous variants.

Thrombotic thrombocytopenic purpura (TTP) after COVID-19 vaccination: A systematic review of reported cases. INTRODUCTION: With the advent of COVID-19 vaccines, hospitalization rates and progression to severe COVID-19 disease have reduced drastically. Most of the adverse events reported by the vaccine recipients were minor. However, autoimmune hematological complications such as vaccine-induced immune thrombotic thrombocytopenia (VITT), immune thrombocytopenic purpura (ITP) and TTP have also been reported post-COVID-19 vaccination. Given this, we sought to reflect on the existing cases of TTP, whether de novo or relapsing, reported after COVID-19 vaccination to further gain insight into any association, if present, and outcomes. METHODS: We searched PubMed, Embase, and Ebsco databases for published individual case reports on the occurrence or relapse of TTP after receiving any COVID-19 vaccine. A total of 23 articles (27 patients) were included in this qualitative analysis. RESULTS: The mean age for the patients who developed de novo TTP post-COVID-19 vaccination was 51.3Â years. TTP episodes were seen mostly after BNT162b2 vaccine, followed by mRNA-1273 vaccine. All patients with immune TTP except one received plasma exchange (PLEX) and steroids. One patient passed away after two days of hospitalization, likely due to a sudden cardiovascular event. CONCLUSION: Our review underscores the importance of in-depth anamnesis before vaccination and outlines characteristics of predisposed individuals. Evaluation of post-vaccine thrombocytopenia must include the possibility of TTP given the associated fatality with this condition.

Analysis of a SARS-CoV-2 convalescent cohort identified a common strategy for escape of vaccine-induced anti-RBD antibodies by Beta and Omicron variants. BACKGROUND: Evolutionary pressure has led to the emergence of SARS-CoV-2 variants, with the most recent Omicron variant containing an unparalleled 30 mutations in the spike protein. Many of these mutations are expected to increase immune evasion, thus making breakthrough cases and re-infection more common. METHODS: From June 2020 to December 2021 serial blood samples (initial post recovery, 6 months, 12 months) were

collected from a COVID-19 convalescent cohort in Boston, MA. Plasma was isolated for use in Mesoscale Discovery based antibody binding assays. Unvaccinated donors or those vaccinated prior to the primary blood draw were excluded from this analysis, as were those who did not have at least two blood draws. Wilcoxon signed rank tests were used to compare pre- and post-vaccination titers and antibody response against different variants, while McNemar tests were used to compare the proportions of achieving â‰¥ 4 fold increases against different variants. FINDINGS: Forty-eight COVID convalescent donors with post-infection vaccination (hybrid immunity) were studied to evaluate the levels of cross-reactive antibodies pre- and post- vaccination against various SARS-CoV-2 Spike and receptor binding domain (RBD) proteins. Vaccination with BNT162b2, mRNA-1273 or Ad26.COV2.S led to a 6Â·3 to 7Â·8 fold increase in anti-Spike antibody titers and a 7Â·0 to 7Â·4 fold increase in anti-WT, Alpha and Delta RBD antibody. However, a lower response was observed for Beta and Omicron RBDs with only 7/48 (15%) and 15/48 (31%) donors having a â‰¥4 fold increase in post-vaccination titers against Beta and Omicron RBDs. Structural analysis of the Beta and Omicron RBDs reveal a shared immune escape strategy involving residues K417-E484-N501 that is exploited by these variants of concern. INTERPRETATION: Through mutations of the K417-E484-N501 triad, SARS-CoV-2 has evolved to evade neutralization by the class I/II anti-RBD antibody fraction of hybrid immunity plasma as the polyclonal antibody response post-vaccination shows limitations in the ability to solve the structural requirements to bind the mutant RBDs. FUNDING: Massachusetts Consortium on Pathogen Readiness (280870.5116709.0016) and the National Institute of Allergy and Infectious Diseases (1R01AI161152-01A1).

Neuro-Ophthalmic Implications of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Related Infection and Vaccination. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic created a unique opportunity to study the effects of infection and vaccination on disease. The year 2020 was dominated by infection and its consequences. The year 2021 was dominated by vaccination and its consequences. It will still take several years for full maturation of databases required for robust epidemiological studies. Therefore, this review on the implications for neuro-ophthalmology draws on resources presently available including reported adverse reactions to vaccination. Illustrative clinical cases are presented.The spectrum of pathology following infection with SARS-CoV-2 falls into 4 main categories: autoimmune, vascular, sequelae of brain damage, and miscellaneous. This review is exhaustive, but the most common conditions discussed relate to headaches and associated symptoms; vertigo, diplopia, and nystagmus; vascular complications of the eye and brain; cranial nerve (mono-)neuropathies; photophobia, ocular discomfort, and optic neuritis. Of the 36 main adverse reactions reviewed, vaccine-induced immune thrombotic thrombocytopenia is a novel complication requiring specific hematological management. Updated diagnostic criteria are summarized. It is relevant to remember taking a medication history because of side effects and to recognize the relevance of comorbidities. The clinical assessment can frequently be performed virtually. Consensus recommendations on telemedicine and the virtual assessment are summarized in a practical and compressed format.The review concludes with an epidemiological tetralogy to interrogate, in future studies, associations with (1) SARS-CoV-2 pandemic infection, (2) SARS-CoV-2 worldwide vaccination, and (3) the possibility of a rebound effect of infections in the pandemic aftermath.

Aortic Mural Thrombosis Diagnosed After a Second Dose of mRNA-1273 SARS-CoV-2 Vaccine.

De novo altered mental state after SARS-CoV-2 vaccination requires extensive diagnostic work-up.

Septic and Crystal-Induced Arthritis (Pseudogout) Post-COVID-19 Vaccination. Severe acute respiratory syndrome coronavirus 2 infection has been a global public health crisis for the past two years. Vaccination has been a mainstay preventive approach among other strategies such as hand washing, social distancing, and wearing facemasks. Here, we present a case of concomitant calcium

pyrophosphate deposition disease flare and septic arthritis of the right knee following coronavirus disease 2019 (COVID-19) booster vaccination in a 69-year-old African American maleÂ who presented with a painful swollen right knee with associated fever, chills, and rigors three days post-vaccination. Right knee synovial fluid aspirate appeared turbid with elevated white cell count, positive for both intra and extracellular calcium pyrophosphate crystals, and positive for beta-hemolytic Streptococcus group C. The swollen joint improved with right knee arthroscopic irrigation and intravenous antibiotics on admission. The patient subsequently completed a total of six weeks of antibiotics with clinical improvement and normalization of inflammatory markers. No reported incidence of gout or pseudogout post-COVID-19 vaccination has been reported despite reported cases of gout flares with other vaccines. Improper aseptic vaccination technique has been implicated as a possible cause of septic arthritis post-vaccination. Healthcare providers must discuss such adverse events with their patients prior to vaccine administration.

Transient but recurrent complete heart block in a patient after COVID-19 vaccination - A case report. INTRODUCTION: Cardiovascular disorders have been extensively reported during COVID-19 illness, including arrhythmias such as atrioventricular conduction disturbances. To date, one case of transient heart block has been reported after COVID-19 vaccine. CASE PRESENTATION: A 73 years-old woman presented with shortness of breath and fatigue 2 weeks after receiving her second dose of BNT162b2 SARS-CoV-2 mRNA vaccine. ECG showed complete AV block with normal narrow QRS complexes. Chronic treatment with Bisoprolol for hypertension was stopped but complete AV block persisted 48 hours thereafter. Therefore, a permanent pacemaker was implanted. Three months later, pacemaker follow-up revealed no ventricular stimulation, suggesting complete recovery of AV conduction, even after resumption of bisoprolol. Five months after the second dose, she received a third dose of the same vaccine. Three weeks later, she once again complained of dyspnea on exertion. ECG showed sinus rhythm with permanent ventricular stimulation. After device inhibition, complete AV block was confirmed and, 2 weeks later, conduction was restored once more. CLINICAL DISCUSSION: It is known that vaccines can induce AV conduction disturbances, mostly reversible. The underlying mechanisms leading to high-degree AV block remain unclear and are probably multiple. Although being exceptional after COVID-19 vaccine, our case illustrates the fact that the latter can induce such a disturbance which may be transient and recurrent even in the absence of underlying conduction disorder. CONCLUSION: COVID-19 vaccination may transitorily interfere with cardiac conduction system even in subjects without known underlying heart disease.

Cutaneous vasculitis due to COVID-19 vaccination.

COVID-19 Vaccines in Inherited Retinal Degenerations (IRD), Fears, Ideas and Real Interactions. PURPOSE: In the COVID-19 pandemic era, vaccines are one of the most efficient weapons, as well established by WHO, that humans have, in all their variants (mRNA, AAV or others). Unfortunately, in western nations skepticism within different groups has been generated by the fast approval processes, driven by the urgent need to confront the rapid increase of hospitalized patients and number of deaths by regulation authorities as FDA and EMA. Moreover, several scientific and non-scientific perplexity, also amplified by the media, created hard no-vax strategies, that lead many patients to refuse vaccine administration. Also in this selected population higher rate of COVID-19 infections and severe diseases are registered and consequently there was an increase of death number. Furthermore, to avoid vaccine shots, people frequently ask exemption querying ophthalmological and systemic diseases, in this situation most patients affected with orphan ophthalmological conditions as inherited retinal degenerations have profound fears and doubt. The goal of our study was to ascertain if these fears are based on real facts and if there are interactions or severe visual impairment after each shot of vaccinations. METHODS: Five hundred randomically selected patients affected by IRD at each patient was asked anonymously, number of vaccine

administrations and eventually reported side effects. RESULTS: Of 500 selected patients 61 (12,2%) did not underwent to Covid-19 vaccination, reasons were various (fear, laziness, caregiver unavailability etc.). Remaining 439 patients (87,8%) had first shot of vaccine. Only 30% of patients complained side effects of vaccine, none of them was serious. CONCLUSION: The number of patients is wide enough to draw some considerations: In IRD vaccination is safe, in all doses ocular side effects were reported only in one third of subjects and this is not different from the percentage shown by normal people, COVID-19 effects may be more dangerous than vaccine.
A case of myopericarditis following administration of the Pfizer COVID-19 vaccine. Numerous vaccines have been developed to address the COVID-19 pandemic, the most frequently administered are the Moderna and Pfizer-BioNTech (Pfizer) mRNA COVID-19 vaccines. Of 177 million individuals that have full vaccination status, there have been 1,148 cases of myocarditis or pericarditis reported. At this time, the relationship between myopericarditis and the Pfizer mRNA COVID-19 vaccine has not been well established in current literature due to the novelty of the vaccine. We discuss a 16-year-old male who presented to the emergency department with chest pain 48 hours after receiving his second dose of the Pfizer COVID-19 vaccine. His laboratory and electrocardiogram findings were consistent with acute myopericarditis and work-up did not reveal an obvious etiology. After starting anti-inflammatory therapies, the patient's symptoms and laboratory markers improved and the patient was discharged from the hospital expected to make a full recovery. This case demonstrates the rapid recovery with no sequelae following this adverse effect, highlighting that the benefits of the COVID-19 vaccination most likely outweigh the risks.
A case of pityriasis rubra pilaris following AstraZeneca COVID-19 vaccine.
Messenger ribonucleic acid vaccine-associated immune thrombocytopenia: A rare complication of vaccine. Coronavirus disease-2019 continues to have a serious impact in countries with the effect of new variant viruses emerging with mutations. While the effectiveness and protection of the vaccine have been determined all over the world, some vaccine-related side effects can be detected in the form of cases. In our case, the patient was admitted to the emergency department of our hospital with complaints of weakness and progressive rash on his legs. Diffuse petechiae purpura on the legs of the patient was observed and complete blood count revealed thrombocytopenia. Peripheral blood smear supported the blood count test results with thrombocytopenia, secondary causes of thrombocytopenia were excluded, and the patient was diagnosed with vaccine-induced immune thrombocytopenia.
Acute Fulminant Myocarditis After ChAdOx1 nCoV-19 Vaccine: A Case Report and Literature Review. According to recent literatures, myocarditis is an uncommon side effect of mRNA vaccines against COVID-19. On the other hand, myocarditis after adenovirus based vaccine is rarely reported. Here we report a middle-aged healthy female who had acute fulminant perimyocarditis onset 2 days after the first dose of ChAdOx1 vaccine (AstraZeneca) without any other identified etiology. Detailed clinical presentation, serial ECGs, cardiac MRI, and laboratory data were included in the report. Possible mechanisms of acute myocarditis after adenoviral vaccine was reviewed and discussed. To our knowledge, a few cases of myocarditis after Ad26.COV2.S vaccine were reported, and this is the first case report after ChAdOx1 vaccine.
Assessment of Neonatal Cord Blood SARS-CoV-2 Antibodies after COVID-19 Vaccination in Pregnancy: A Prospective Cohort Study. Introduction Maternally derived antibodies are a key element of neonatal immunity. So far, limited data has shown transplacental transmission of antibodies after coronavirus disease 2019 (COVID-19) vaccination with BNT162b2 in the third trimester. Our aim was to detect vertically transferred immunity after COVID-19 vaccination with BNT162b2 (Comirnaty, BioNTech-Pfizer) or mRNA-1273 (Spikevax, Moderna) in the first, second or third trimester of pregnancy, and investigate the impact of maternal characteristics on umbilical cord antibody titre in

newborns after delivery. Study Design Women who gave birth in our department and were vaccinated against COVID-19 during pregnancy were enrolled in CRONOS Satellite, a subproject of the German COVID-19-Related Obstetric and Neonatal Outcome Study. The titre of immunoglobulin G (IgG) antibodies to the receptor-binding domain of the SARS-CoV-2 spike protein was quantified in umbilical cord blood using the SARS-CoV-2 IgGÂ II Quant immunoassay. Correlations between antibody titre and variables, including week of pregnancy when vaccinated, interval between vaccination and delivery, age and body mass index (BMI) were assessed with Spearman's rank correlation. A follow-up was conducted by phone interview 4â€Š-â€Š6 weeks after delivery. Results The study cohort consisted of 70 women and their 74Â newborns. Vaccine-generated antibodies were present in all samples, irrespective of the vaccination type or time of vaccination. None of the parameters of interest showed a meaningful correlation with cord blood antibody concentrations (rho values <â€‰0.5). No adverse outcomes (including foetal malformation) were reported, even after vaccination in the first trimester. Conclusions Transplacental passage of SARS-CoV-2 antibodies from mother to child was demonstrated in all cases in the present study. It can therefore be assumed that the newborns of mothers vaccinated at any time during pregnancy receive antibodies via the placenta which potentially provide them with protection against COVID-19. This is an additional argument when counselling pregnant women about vaccination in pregnancy.

[Case report of Guillain-BarrÃ© Syndrome after COVID BNT162b2 mRNA vaccine]. INTRODUCTION: Guillain-BarrÃ© syndrome (GBS) is a rare immune disorder that affects peripheral nerves and the cause is not known completely, but it is associated with infections by viruses or bacteria. CASE REPORT: We report the case of a 23-year-old male patient, a health student, who start 24 hours after received the second dose of COVID-19 vaccine, with proximal weakness of the right upper limb, later on the left side with descending and distal progression. DISCUSSION: GBS cases related to COVID-19 vaccines have been published, the most common being BNT162b2, which is mRNA, there are also cases published after the AZD1222 (ChAdOx1) vaccine, which is a non-replicating viral vector. The incidence of GBS is estimated at 0.43 per 100.00 doses applied, under registered national incidence of 1.1-1.8 per 100,000 persons per year. CONCLUSIONS: It is important to mention that although GBS can occur after vaccination against COVID-19, this incidence is much lower than which occurs in the community in Mexico associated with other diseases, considering more common the presence of cases related to infectious gastrointestinal diseases.

Knowledge and Attitude towards COVID-19 Vaccination and Associated Factors among College Students in Northwest Ethiopia,2021. BACKGROUND: It is imperative to ensure optimal vaccine uptake at the population level to combat the deadly COVID-19 pandemic disease. However, refusal of the COVID-19 vaccine, poor knowledge, and a negative attitude towards vaccination are the challenges of the world. College students are among the high-risk subgroups of the population to COVID-19 infection and the main source of information and trust in vaccines to the society. Also, their judgement on vaccine affect the public attitude towards vaccination. Therefore, this study aimed to assess knowledge and attitude towards COVID-19 vaccination and associated factors among college students in Gondar city, northwest Ethiopia. METHODS: An institution-based cross-sectional study was conducted among 626 study participants in Gondar city. A multistage sampling technique was used to recruit the study participants. A pretested self-administered questionnaire was used to collect the data. Bivariable and multivariable logistic regression analyses were performed to assess factors associated with knowledge and attitude towards COVID-19 vaccination. The level of significance was claimed based on a p-value < 0.05. RESULTS: In this study, 46.8% (95% CI: 43.3, 50.6) of study participants had good knowledge and 50% (95% CI: 45.9, 53.7) had a positive attitude towards COVID-19 vaccination. Having comorbidity disease and being male were significantly associated with good knowledge. In addition, being married, being a health science student, being

exposed to mass media, having a good knowledge of COVID-19 vaccination, and having paternal primary education were significantly associated with a positive attitude towards COVID-19 vaccination. CONCLUSION: In general, knowledge and attitude towards COVID-19 vaccination among college students are low. Comorbidity disease and sex were predictors of COVID-19 vaccination knowledge, whereas, marital status, category of college students, mass media, paternal education and knowledge about COVID-19 vaccination were predictors of COVID-19 vaccination attitude. Alleviating participants' concerns and improving their confidence through health education is crucial.

Safety of an inactivated COVID-19 vaccine in patients with - wheat-dependent exercise-induced anaphylaxis. BACKGROUND: Inactivated vaccines against coronavirus disease-2019 (COVID-19) offer an effective public health intervention to mitigate this devastating pandemic. However, little is known about their safety in patients with wheat-dependent exercise-induced anaphylaxis (WDEIA). METHODS: We recruited 72 WDEIA patients and 730 healthy matched controls who received an inactivated COVID-19 vaccine. Participants were monitored for 4 weeks after each immunization for adverse reactions and completed questionnaires regarding local and systemic reactions at 7 and 28 days after each vaccination. For those who had received the COVID-19 vaccine prior to enrollment, adverse event data were obtained retrospectively. RESULTS: Local and systemic adverse events occurred at similar rates in the WDEIA group and the control group. In both groups, injection-site pain and fatigue were the most common local and systemic reactions, respectively. Compared with healthy controls, more allergic events were reported in the WDEIA group (after dose 1, 0.5% vs. 4.2%, p=0.019; after dose 2, 0% vs. 1.4%, p=0.089). Allergic reactions mainly manifested as rash, urticaria, and edema, which were mild and controllable. No serious allergic events were reported. CONCLUSIONS: The adverse event profile of inactivated COVID-19 vaccine did not differ between WDEIA patients and healthy controls. The risk of allergic reactions in patients with WDEIA seems higher, but no anaphylaxis was reported, and the allergic reactions were controllable. Inactivated COVID-19 vaccines appear to be well-tolerated in WDEIA patients, but patients with potential allergy risks should be cautious.

Background incidence rates of adverse events of special interest related to COVID-19 vaccines in Ontario, Canada, 2015 to 2020, to inform COVID-19 vaccine safety surveillance. BACKGROUND: Background incidence rates are critical in pharmacovigilance to facilitate identification of vaccine safety signals. We estimated background incidence rates of 11 adverse events of special interest related to COVID-19 vaccines in Ontario, Canada. METHODS: We conducted a population-based retrospective observational study using linked health administrative databases for hospitalizations and emergency department visits among Ontario residents. We estimated incidence rates of Bell's palsy, idiopathic thrombocytopenia, febrile convulsions, acute disseminated encephalomyelitis, myocarditis, pericarditis, Kawasaki disease, Guillain-BarrÃ© syndrome, transverse myelitis, acute myocardial infarction, and anaphylaxis during five pre-pandemic years (2015-2019) and 2020. RESULTS: The average annual population was 14 million across all age groups with 51% female. The pre-pandemic mean annual rates per 100,000 population during 2015-2019 were 191 for acute myocardial infarction, 43.9 for idiopathic thrombocytopenia, 28.8 for anaphylaxis, 27.8 for Bell's palsy, 25.0 for febrile convulsions, 22.8 for acute disseminated encephalomyelitis, 11.3 for myocarditis/pericarditis, 8.7 for pericarditis, 2.9 for myocarditis, 2.0 for Kawasaki disease, 1.9 for Guillain-BarrÃ© syndrome, and 1.7 for transverse myelitis. Females had higher rates of acute disseminated encephalomyelitis, transverse myelitis and anaphylaxis while males had higher rates of myocarditis, pericarditis, and Guillain-BarrÃ© syndrome. Bell's palsy, acute disseminated encephalomyelitis, and Guillain-BarrÃ© syndrome increased with age. The mean rates of myocarditis and/or pericarditis increased with age up to 79Â years; males had higher rates than females: from 12 to 59Â years for myocarditis and â‰¥12Â years for pericarditis. Febrile convulsions and Kawasaki

disease were predominantly childhood diseases and generally decreased with age. CONCLUSIONS: Our estimated background rates will permit estimating numbers of expected events for these conditions and facilitate detection of potential safety signals following COVID-19 vaccination.
Breakthrough SARS-CoV-2 infections after COVID-19 mRNA vaccination in MS patients on disease modifying therapies during the Delta and the Omicron waves in Italy. BACKGROUND: In this study we aimed to monitor the risk of breakthrough SARS-CoV-2 infection in patients with MS (pwMS) under different DMTs and to identify correlates of reduced protection. METHODS: This is a prospective Italian multicenter cohort study, long-term clinical follow-up of the CovaXiMS (Covid-19 vaccine in Multiple Sclerosis) study. 1855 pwMS scheduled for SARS-CoV-2 mRNA vaccination were enrolled and followed up to a mean time of 10 months. The cumulative incidence of breakthrough Covid-19 cases in pwMS was calculated before and after December 2021, to separate the Delta from the Omicron waves and to account for the advent of the third vaccine dose. FINDINGS: 1705 pwMS received 2 m-RNA vaccine doses, 21/28 days apart. Of them, 1508 (88.5%) had blood assessment 4 weeks after the second vaccine dose and 1154/1266 (92%) received the third dose after a mean interval of 210 days (range 90-342 days) after the second dose. During follow-up, 131 breakthrough Covid-19 infections (33 during the Delta and 98 during the Omicron wave) were observed. The probability to be infected during the Delta wave was associated with SARS-CoV-2 antibody levels measured after 4 weeks from the second vaccine dose (HR=0.57, pÂ <Â 0.001); the protective role of antibodies was preserved over the whole follow up (HR=0.57, 95%CI=0.43-0.75, pÂ <Â 0.001), with a significant reduction (HR=1.40, 95%CI=1.01-1.94, p=0.04) for the Omicron cases. The third dose significantly reduced the risk of infection (HR=0.44, 95%CI=0.21-0.90,p=0.025) during the Omicron wave. INTERPRETATION: The risk of breakthrough SARS-CoV-2 infections is mainly associated with reduced levels of the virus-specific humoral immune response. FUNDING: Supported by FISM - Fondazione Italiana Sclerosi Multipla - cod. 2021/Special-Multi/001 and financed or co-financed with the '5 per mille' public funding.
SARS-CoV-2 vaccine response and rate of breakthrough infection in patients with hematological disorders. BACKGROUND: The clinical efficacy of SARS-CoV-2 vaccines according to antibody response in immunosuppressed patients such as hematological patients has not yet been established. PATIENTS AND METHODS: A prospective multicenter registry-based cohort study conducted from December 2020 to December 2021 by the Spanish transplant and cell therapy group was used to analyze the relationship of antibody response at 3-6Â weeks after full vaccination (2 doses) with breakthrough SARS-CoV-2 infection in 1394 patients with hematological disorders. RESULTS: At a median follow-up of 165Â days after complete immunization, 37 out of 1394 (2.6%) developed breakthrough SARS-CoV-2 infection at median of 77Â days (range 7-195) after full vaccination. The incidence rate was 6.39 per 100 persons-year. Most patients were asymptomatic (19/37, 51.4%), whereas only 19% developed pneumonia. The mortality rate was 8%. Lack of detectable antibodies at 3-6Â weeks after full vaccination was the only variable associated with breakthrough infection in multivariate logistic regression analysis (Odds Ratio 2.35, 95% confidence interval 1.2-4.6, pâ€‰=â€‰0.012). Median antibody titers were lower in cases than in non-cases [1.83 binding antibody units (BAU)/mL (range 0-4854.93) vs 730.81 BAU/mL (range 0-56,800), respectively (pâ€‰=â€‰0.007)]. We identified 250 BAU/mL as a cutoff above which incidence and severity of the infection were significantly lower. CONCLUSIONS: Our study highlights the benefit of developing an antibody response in these highly immunosuppressed patients. Level of antibody titers at 3 to 6Â weeks after 2-dose vaccination links with protection against both breakthrough infection and severe disease for non-Omicron SARS-CoV-2 variants.
Coronavirus disease 2019 vaccine and inÂ vitro fertilization outcomes: myths vs. facts.

Cardiovascular manifestations secondary to COVID-19: A narrative review. The coronavirus disease 2019 (COVID-19) pandemic has spread rapidly, becoming a major threat to global health. In addition to having required the adaptation of healthcare workers for almost 2 years, it has been much talked about, both in the media and among the scientific community. Beyond lung damage and respiratory symptoms, the involvement of the cardiovascular system largely explains COVID-19 morbimortality. In this review, we emphasize that cardiovascular involvement is common and is associated with a worse prognosis, and that earlier detection by physicians should lead to better management. First, direct cardiac involvement will be discussed, in the form of COVID-19 myocarditis, then secondary cardiac involvement, such as myocardial injury, myocardial infarction and arrhythmias, will be considered. Finally, worsening of previous cardiovascular disease as a result of COVID-19 will be examined, as well as long-term COVID-19 effects and cardiovascular complications of COVID-19 vaccines.

Icon arrays reduce concern over COVID-19 vaccine side effects: a randomized control study. On April 13, 2021, the CDC announced that the administration of Johnson and Johnson's COVID-19 vaccine would be paused due to a rare blood clotting side effect inâ€‰~â€‰0.0001% of people given the vaccine. Most people who are hesitant to get a COVID-19 vaccine list potential side effects as their main concern (PEW, 2021); thus, it is likely that this announcement increased vaccine hesitancy among the American public. Two days after the CDC's announcement, we administered a survey to a group of 2,046 Americans to assess their changes in attitudes toward COVID-19 vaccines. The aim of this study was to investigate whether viewing icon arrays of side effect risk would prevent increases in COVID-19 vaccine hesitancy due to the announcement. We found that using icon arrays to illustrate the small chance of experiencing the blood clotting side effect significantly prevented increases in aversion toward the Johnson and Johnson vaccine as well as all other COVID-19 vaccines.

Risk-benefit analysis of emergency vaccine use. Emergency vaccine use requires weighing a large number of uncertain risks and possible benefits. In the COVID-19 pandemic, decisions about what evidence is necessary to authorize emergency use have proven controversial, and vary between countries. We construct a simple mathematical model of the risks and benefits of emergency vaccination to an individual, and apply this to the hypothetical scenario of individual decision-making between emergency use of a COVID-19 vaccine without safety and efficacy data, versus waiting for efficacy and safety to be established. Even with conservative modelling assumptions and uncertainty distributions for vaccine efficacy (mean expectation = 17%) and serious adverse event risk (mean expectation = 0.3%), high risk individuals (e.g. those who are elderly and have a household contact with COVID-19) are better off using the 'emergency vaccine' rather than waiting for more information (absolute risk reduction for mortality up to 2%). Very early emergency authorization of vaccines despite very limited data may be the better public health strategy when confronted with a dangerous emerging infectious disease.

Unilateral parotitis following mRNA coronavirus disease 2019 vaccination.

An adaptive, asymptomatic SARS-CoV-2 workforce screening program providing real-time, actionable monitoring of the COVID-19 pandemic. COVID-19 remains a challenge worldwide, and testing of asymptomatic individuals remains critical to pandemic control measures. Starting March 2020, a total of 7497 hospital employees were tested at least weekly for SARS CoV-2; the cumulative incidence of asymptomatic infections was 5.64%. Consistently over a 14-month period half of COVID-19 infections (414 of 820, total) were detected through the asymptomatic screening program, a third of whom never developed any symptoms during follow-up. Prompt detection and isolation of these cases substantially reduced the risk of potential workplace and outside of workplace transmission. COVID-19 vaccinations of the workforce were initiated in December 2020. Twenty-one individuals tested positive after being fully vaccinated (3.9 per 1000 vaccinated). Most (61.9%) remained asymptomatic

and in majority (75%) the virus could not be sequenced due to low template RNA levels in swab samples. Further routine testing of vaccinated asymptomatic employees was stopped and will be redeployed if needed; routine testing for those not vaccinated continues. Asymptomatic SARS-CoV-2 testing, as a part of enhanced screening, monitors local dynamics of the COVID-19 pandemic and can provide valuable data to assess the ongoing impact of COVID-19 vaccination and SARS-CoV-2 variants, inform risk mitigation, and guide adaptive, operational planning including titration of screening strategies over time, based on infection risk modifiers such as vaccination.

A Case of Graves' Disease Following Vaccination with the Oxford-AstraZeneca SARS-CoV-2 Vaccine: Case Report and Review of the Literature. A 57-year-old man presented to the outpatient clinic with tremor, palpitations, weight loss and fatigue 1 week after receiving the first dose of the Oxford-AstraZeneca SARS-CoV-2 vaccine (ChAdOx1 nCoV-19). Laboratory studies showed a suppressed TSH with elevated total and free T4. Thyroid peroxidase and thyroglobulin antibodies were elevated but thyrotropin receptor autoantibodies were indeterminate. Thyroid scintigraphy with technetium Tc-99m pertechnetate revealed increased diffuse, symmetric uptake. The patient was treated with thiamazole 15 mg three times a day and propranolol with resolution of his symptoms and normalization of his thyroid function tests until discontinuation of the antithyroid drug 6 months after symptom onset. LEARNING POINTS: Thyroid autoimmunity triggered by SARS-CoV-2 vaccines is being increasingly recognized among patients with and without a history of autoimmune thyroid disease.Symptoms and signs of thyrotoxicosis, including fever and tachycardia, can be wrongly attributed to the systemic adverse events of these vaccines.Early recognition of this condition is mandatory to allow proper treatment with anti-thyroid medications and radioactive iodine when necessary.

Kounis syndrome following COVID-19 vaccination. Coronary stent thrombosis is a life-threatening condition induced by multiple factors, including allergic reactions. A 64-year-old man presented with stent thrombosis in the left anterior descending artery and multiple cardiorespiratory arrests immediately after the first dose of the BNT162b1 mRNA vaccine. He underwent emergent percutaneous coronary intervention. Anaphylaxis-induced stent thrombosis, or type III Kounis syndrome, is a highly possible diagnosis. Cardiogenic shock can hide the skin manifestations of anaphylaxis, making this syndrome challenging to diagnose. This clinical case underscores the importance of surveillance for at least 30Â minutes after vaccine administration, especially in patients at risk.

Anti-platelet factor 4 immunoglobulin G levels in vaccine-induced immune thrombocytopenia and thrombosis: Persistent positivity through 7 months. BACKGROUND: Anti-platelet factor 4 (PF4) antibodies that activate platelets via FcÎ³RIIA drive the pathophysiology of vaccine-induced immune thrombocytopenia and thrombosis (VITT). Evolution of these antibodies and their ability to activate platelets after initial treatment remains unknown. OBJECTIVES: To assess how clinical and platelet parameters, anti-PF4 antibody levels, and patient serum reactivity changes during follow-up after VITT presentation. METHODS: We describe cases of seven discharged VITT patients that were followed from diagnosis up to 280Â days (range 199-280) after vaccination. We measured anti-PF4 antibodies and PF4Â levels in patient serum during follow-up and tested the ability of patient serum to activate healthy donor platelets and patient platelets over time. RESULTS: Anti-PF4 immunoglobulin G antibody levels are very high at diagnosis (0.9-2.6 OD) and remain relatively high (>1.0 OD) in all patients, except one treated with rituximab, at 7 months post vaccination. All patients were on direct oral anticoagulants throughout follow-up and no patients had recurrent thrombosis. Patients' platelets during follow-up have normal FcÎ³RIIA levels and responsiveness to platelet agonists. Patient diagnostic serum strongly activated control platelets, either alone or with PF4. Most follow-up serum alone was weaker at stimulating donor and patient platelets. However, follow-up

serum beyond 150Â days still strongly activated platelets with PF4 addition in three patients. Patient serum PF4Â levels were lower than controls at diagnosis but returned within normal range by day 50. CONCLUSIONS: Explanations for reduced platelet activation during follow-up, despite similar total anti-PF4 antibody levels, remains unclear. Clinical implications of persistent anti-PF4 antibodies in VITT require further study.

Neuroleptic Malignant Syndrome with Adrenal Insufficiency After BNT162b2 COVID-19 Vaccination in a Man Taking Valproate: A Case Report. BACKGROUND Considering the ongoing coronavirus disease 2019 (COVID-19) pandemic, sufficient information about common and serious adverse events is needed to rapidly distribute COVID-19 vaccines worldwide. We report a case of neuroleptic malignant syndrome (NMS) with adrenal insufficiency after initial vaccination with Pfizer/BioNTech BNT162b2. CASE REPORT A 48-year-old man presented to the Emergency Department with fever and an altered mental status 7 days after receiving the first dose of the BNT162b2 COVID-19 vaccine. The patient had a history of end-stage renal disease and epilepsy treated with valproate. He was diagnosed with NMS based on the clinical findings of hyperthermia, muscular rigidity, and an elevated creatine kinase level. Additionally, a reduction in the response of cortisol to adrenocorticotropic hormone (ACTH) stimulation was observed in the rapid ACTH stimulation test. The patient was treated with dantrolene, bromocriptine, and hydrocortisone, and he responded well to treatment. Dantrolene and bromocriptine were tapered off over 4 weeks. Hydrocortisone was also tapered, and the patient was discharged on oral hydrocortisone (30 mg). CONCLUSIONS The present case suggests a possible link between the BNT162b2 COVID-19 vaccine and NMS with adrenal insufficiency based on the temporal relationship between vaccine administration and disease onset, although the patient was taking valproate, a potential cause of NMS. Having a high level of suspicion is important because the diagnosis of NMS with adrenal insufficiency is often challenging due to non-specific clinical manifestations. However, this case does not negate the utility of vaccination because these complications are extremely rare and can be treated with early diagnosis and proper management.

Comparative analysis of COVID-19 vaccine responses and third booster dose-induced neutralizing antibodies against Delta and Omicron variants. Two COVID-19 mRNA (of BNT162b2, mRNA-1273) and two adenovirus vector vaccines (ChAdOx1 and Janssen) are licensed in Europe, but optimization of regime and dosing is still ongoing. Here we show in health care workers (nâ€‰=â€‰328) that two doses of BNT162b2, mRNA-1273, or a combination of ChAdOx1 adenovirus vector and mRNA vaccines administrated with a long 12-week dose interval induce equally high levels of anti-SARS-CoV-2 spike antibodies and neutralizing antibodies against D614 and Delta variant. By contrast, two doses of BNT162b2 with a short 3-week interval induce 2-3-fold lower titers of neutralizing antibodies than those from the 12-week interval, yet a third BNT162b2 or mRNA-1273 booster dose increases the antibody levels 4-fold compared to the levels after the second dose, as well as induces neutralizing antibody against Omicron BA.1 variant. Our data thus indicates that a third COVID-19 mRNA vaccine may induce cross-protective neutralizing antibodies against multiple variants.

Pathogenesis of vaccine-induced immune thrombotic thrombocytopenia (VITT). Vaccine-induced immune thrombotic thrombocytopenia (VITT; synonym, thrombosis with thrombocytopenia syndrome, is associated with high-titer immunoglobulin G antibodies directed against platelet factor 4 (PF4). These antibodies activate platelets via platelet FcÎ³IIa receptors, with platelet activation greatly enhanced by PF4. Here we summarize the current concepts in the pathogenesis of VITT. We first address parallels between heparin-induced thrombocytopenia and VITT, and provide recent findings on binding of PF4 to adenovirus particles and non-assembled adenovirus proteins in the 2 adenovirus vector-based COVID-19 vaccines, ChAdOx1 nCoV-19 and Ad26.COV2.S. Further, we discuss the potential role of vaccine constituents such as glycosaminoglycans, EDTA, polysorbate 80, human cell-line proteins and nucleotides as potential binding partners of PF4. The immune response

towards PF4 in VITT is likely triggered by a proinflammatory milieu. Human cell-line proteins, non-assembled virus proteins, and potentially EDTA may contribute to the proinflammatory state. The transient nature of the immune response towards PF4 in VITT makes it likely that-as in heparin-induced thrombocytopenia -marginal zone B cells are key for antibody production. Once high-titer anti-PF4 antibodies have been formed 5 to 20 days after vaccination, they activate platelets and granulocytes. Activated granulocytes undergo NETosis and the released DNA also forms complexes with PF4, which fuels the Fcî³ receptor-dependent cell activation process, ultimately leading to massive thrombin generation. Finally, we summarize our initial observations indicating that VITT-like antibodies might also be present in rare patients with recurrent venous and arterial thrombotic complications, independent of vaccination.

Treatment of vaccine-induced immune thrombotic thrombocytopenia (VITT). Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a novel prothrombotic disorder characterized by thrombosis, thrombocytopenia, and disseminated intravascular coagulation identified in hundreds of recipients of ChAdOx1 nCoV-19 (Oxford/AstraZeneca), an adenovirus vector coronavirus disease 2019 (COVID-19) vaccine. VITT resembles heparin-induced thrombocytopenia (HIT) in that patients have platelet-activating anti-platelet factor 4 antibodies; however, whereas heparin typically enhances platelet activation by HIT antibodies, VITT antibody-induced platelet activation is often inhibited in vitro by pharmacological concentrations of heparin. Further, the thrombotic complications in VITT feature much higher frequencies of atypical thrombosis, most notably cerebral vein thrombosis and splanchnic vein thrombosis, compared with HIT. In this review, we outline the treatments that have been used to manage this novel condition since its recognition in March 2021, including anticoagulation, high-dose intravenous immune globulin, therapeutic plasma exchange, corticosteroids, rituximab, and eculizumab. We discuss the controversial issue of whether heparin, which often inhibits VITT antibody-induced platelet activation, is harmful in the treatment of VITT. We also describe a case of "long VITT," describing the treatment challenges resulting from platelet-activating anti-PF4 antibodies that persisted for more than 9 months.

Clinical picture of VITT. This chapter explores the clinical features of vaccine-induced immune thrombotic thrombocytopenia, also called vaccine-induced immune thrombocytopenia and thrombosis (VITT). Whilst the etiology is distinct from other causes of thrombotic thrombocytopenia syndrome (TTS), presentation may be similar and hence the need for strict diagnostic criteria to ensure accurate and prompt diagnosis and early treatment. Studies have identified prognostic markers of the disease, directing therapy and management pathways, and mortality and morbidity from this rare but life-threatening and potentially disabling consequence of the ChAdOx1 nCov-19 vaccine has declined.

Epidemiology of VITT. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a life-threatening syndrome of aggressive thrombosis, often profound thrombocytopenia, and frequently overt disseminated intravascular coagulation. It has been associated with 2 adenovirus vector COVID-19 vaccines: ChAdOx1 nCoV-19 (AstraZeneca) and Ad26.COV2.S (Janssen). Unlike the myriad of other conditions that cause thrombosis and thrombocytopenia, VITT has an important distinguishing feature: affected individuals have platelet activating anti-PF4 antibodies that appear in a predictable time frame following vaccination. The reported incidence of VITT differs between jurisdictions; it is dependent on accurate ascertainment of cases and accurate estimates of the size of the vaccinated population. The incidence ranges from 1 case per 26,500 to 127,3000 first doses of ChAdOx1 nCoV-19 administered. It is estimated at 1 case per 518,181 second doses of ChAdOx1 nCoV-19 administered, and 1 case per 263,000 Ad26.COV2.S doses administered. There are no clear risk factors for VITT, including sex, age, or comorbidities. VITT is a rare event, but its considerable morbidity and mortality merit ongoing pharmacovigilance, and accurate case ascertainment.

The psychiatric and psychological sequelae of vaccine-induced immune thrombotic thrombocytopenia (VITT). This review paper explores the potential psychiatric and psychological sequelae of vaccine-induced immune thrombotic thrombocytopenia, also called vaccine-induced immune thrombocytopenia, and thrombosis (VITT). In the absence of any literature to date we have extrapolated data from similar conditions, particularly data pertaining to the critical care population. We discuss both the direct and indirect effects of thrombosis, likely psychiatric and psychological challenges during recovery, and ethical issues around vaccination. We have also suggested a comprehensive guide to the psychiatric assessment and management of patients presenting with VITT with the aim of early identification of problems and maximizing rehabilitation potential and quality of life.

Longitudinal Aspects of VITT. In hundreds of patients worldwide, vaccination against COVID-19 with adenovirus vector vaccines (ChAdOx1 nCoV-19; Ad26.COV2.S) triggered platelet-activating anti-platelet factor 4 (PF4) antibodies inducing vaccine-induced immune thrombotic thrombocytopenia (VITT). In most VITT patients, platelet-activating anti-PF4-antibodies are transient and the disorder is discrete and non-recurring. However, in some patients platelet-activating antibodies persist, associated with recurrent thrombocytopenia and sometimes with relapse of thrombosis despite therapeutic-dose anticoagulation. Anti-PF4 IgG antibodies measured by enzyme-immunoassay (EIA) are usually detectable for longer than platelet-activating antibodies in functional assays, but duration of detectability is highly assay-dependent. As more than 1 vaccination dose against COVID-19 is required to achieve sufficient protection, at least 69 VITT patients have undergone subsequent vaccination with an mRNA vaccine, with no relevant subsequent increase in anti-PF4 antibody titers, thrombocytopenia, or thrombotic complications. Also, re-exposure to adenoviral vector-based vaccines in 5 VITT patients was not associated with adverse reactions. Although data are limited, vaccination against influenza also appears to be safe. SARS-CoV-2 infection reported in 1 patient with preceding VITT did not influence anti-PF4 antibody levels. We discuss how these temporal characteristics of VITT provide insights into pathogenesis.

Ischemic Stroke and Vaccine-Induced Immune Thrombotic Thrombocytopenia following COVID-19 Vaccine: A Case Report with Systematic Review of the Literature. INTRODUCTION: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a prothrombotic syndrome observed after adenoviral vector-based vaccines for severe acute respiratory syndrome coronavirus 2. It is characterized by thrombocytopenia, systemic activation of coagulation, extensive venous thrombosis, and anti-platelet factor 4 antibodies. Arterial thrombosis is less common and mainly affects the aorta, peripheral arteries, heart, and brain. Several cases of ischemic stroke have been reported in VITT, often associated with large vessel occlusion (LVO). Here, we describe a case of ischemic stroke with LVO after Ad26.COV2.S vaccine, then we systematically reviewed the published cases of ischemic stroke and VITT following COVID-19 vaccination. METHODS: We describe a 58-year-old woman who developed a thrombotic thrombocytopenia syndrome with extensive splanchnic vein thrombosis and ischemic stroke due to right middle cerebral artery (MCA) occlusion, 13 days after receiving Ad26.COV2.S vaccination. Then, we performed a systematic review of the literature until December 3, 2021 using PubMed and EMBASE databases. The following keywords were used: ("COVID-19 vaccine") AND ("stroke"), ("COVID-19 vaccine") AND ("thrombotic thrombocytopenia"). We have selected all cases of ischemic stroke in VITT. RESULTS: Our study included 24 patients. The majority of the patients were females (79.2%) and younger than 60 years of age (median age 45.5 years). Almost all patients (96%) received the first dose of an adenoviral vector-based vaccine. Ischemic stroke was the presenting symptom in 18 patients (75%). Splanchnic venous thrombosis was found in 10 patients, and cerebral venous thrombosis in 5 patients (21%). Most patients (87.5%) had an anterior circulation stroke, mainly involving MCA. Seventeen patients (71%) had an intracranial LVO. We found

a high prevalence of large intraluminal thrombi (7 patients) and free-floating thrombus (3 patients) in extracranial vessels, such as the carotid artery, in the absence of underlying atherosclerotic disease. Acute reperfusion therapy was performed in 7 of the 17 patients with LVO (41%). One patient with a normal platelet count underwent intravenous thrombolysis with alteplase, while 6 patients underwent mechanical thrombectomy. A malignant infarct occurred in 9 patients and decompressive hemicraniectomy was performed in 7 patients. Five patients died (21%). CONCLUSION: Our study points out that, in addition to cerebral venous thrombosis, adenoviral vector-based vaccines also appear to have a cerebral arterial thrombotic risk, and clinicians should be aware that ischemic stroke with LVO, although rare, could represent a clinical presentation of VITT.
Liver injury and cytopenia after BNT162b2 COVID-19 vaccination in an adolescent.
Vocal fold paralysis following first dose of Oxford-AstraZeneca coronavirus disease 2019 vaccine. BACKGROUND: In a bid to end the ongoing coronavirus disease 2019 pandemic, many countries, including the UK, have rolled out mass immunisation programmes. While considered generally safe and effective, vaccines against coronavirus disease 2019 have been reported to be associated with rare and potentially adverse reactions and side effects. CASE REPORT: This paper reports an unusual case of a patient who developed a unilateral vocal fold paralysis shortly after receiving the first dose of the Oxford-AstraZeneca ChAdOx1 nCov-19 vaccine. CONCLUSION: To our knowledge, this is the first reported case of vocal fold paralysis following administration of the Oxford-AstraZeneca vaccine. The authors support the position that currently approved coronavirus disease 2019 vaccines remain safe and effective; however, further surveillance and vigilance using real-world data are highly encouraged.
Total anti-SARS-CoV-2 antibodies measured 6 months after Pfizer-BioNTech COVID-19 vaccination in healthcare workers. BACKGROUND: This study aimed at monitoring the kinetics of serum total anti-SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) antibodies in a cohort of healthcare workers after voluntary vaccination with Pfizer-BioNTech coronavirus disease 2019 (COVID-19) mRNA-based vaccine. METHODS: The study population consisted of 787 healthcare workers (mean age 44Â±12 years; 66% females), who received two 30 mg doses of Pfizer-BioNTech COVID-19 vaccine, 3 weeks apart. Venous blood was drawn before the first vaccine dose, immediately before the second vaccine dose, and then at 1, 3 and 6 months after the second vaccine dose. Serological testing employed the total antiSARS-CoV-2 antibodies measurement with Roche Elecsys Anti-SARS-CoV-2 S chemiluminescent immunoassay. RESULTS: The median serum levels of total anti-SARS-CoV-2 antibodies reached the peak (1762 kU/L) 1 month after the second vaccine dose, but tended to progressively decline at the 3-month (1086 kU/L) and 6-month (802 kU/L) follow-up points. Overall, the values after 3and 6months were 37% and 57% lower than the corresponding concentrations measured at the peak. No healthcare worker had total anti-SARS-CoV-2 antibodies below the method-dependent cut-off after 6 months. The decline compared to the peak was more accentuated in baseline seropositive persons than in those who were baseline seronegative (74% vs. 52%) cohort. The 6-month post-vaccination anti-SARS-CoV-2 antibodies in subjects aged <65 years remained over 2-fold higher than in those aged â‰¥65 years (813 vs. 343 kU/L) and also remained consistently higher in women than in men. CONCLUSIONS: Gradual decline of total anti-SARS-CoV-2 antibodies occurred 6 months after Pfizer-BioNTech COVID-19 vaccination, though values remained higher than the method-dependent cut-off, with no case of sero-negativization.
Parsonage-Turner syndrome following COVID-19 vaccination and review of the literature. BACKGROUND: Parsonage-Turner syndrome (PTS) is a rare brachial plexopathy characterized by self-limiting shoulder girdle and upper arm pain followed by the upper extremity weakness and sensory changes. While the etiology is not well-understood, the most common cause of PTS is thought to be postviral. There are at least nine reports, to the best of our knowledge, of PTS associated with COVID-

19 infection and nine reports associated with COVID-19 vaccination. CASE DESCRIPTION: Here, we present a case of PTS after COVID-19 vaccination in a 64-year-old male and a review of the current literature. CONCLUSION: PTS can occur post-COVID-19 vaccination and should be on the differential diagnosis when patient continues to experience shoulder pain and develops weakness or sensory changes in the extremity.

Intracranial aneurysm rupture within three days after receiving mRNA anti-COVID-19 vaccination: Three case reports. BACKGROUND: Although neurological adverse events have been reported after receiving coronavirus disease 2019 (COVID-19) vaccines, associations between COVID-19 vaccination and aneurysmal subarachnoid hemorrhage (SAH) have rarely been discussed. We report here the incidence and details of three patients who presented with intracranial aneurysm rupture shortly after receiving messenger ribonucleic acid (mRNA) COVID-19 vaccines. CASE DESCRIPTION: We retrospectively reviewed the medical records of individuals who received a first and/ or second dose of mRNA COVID-19 vaccine between March 6, 2021, and June 14, 2021, in a rural district in Japan, and identified the occurrences of aneurysmal SAH within 3 days after mRNA vaccination. We assessed incidence rates (IRs) for aneurysmal SAH within 3 days after vaccination and spontaneous SAH for March 6-June 14, 2021, and for the March 6-June 14 intervals of a 5-year reference period of 2013-2017. We assessed the incidence rate ratio (IRR) of aneurysmal SAH within 3 days after vaccination and spontaneous SAH compared to the crude incidence in the reference period (2013-2017). Among 34,475 individuals vaccinated during the study period, three women presented with aneurysmal SAH (IR: 1058.7/100,000 person-years), compared with 83 SAHs during the reference period (IR: 20.7/100,000 persons-years). IRR was 0.026 (95% confidence interval [CI] 0.0087-0.12; $P < 0.001$). A total of 28 spontaneous SAHs were verified from the Iwate Stroke Registry database during the same period in 2021 (IR: 34.9/100,000 person-years), and comparison with the reference period showed an IRR of 0.78 (95%CI 0.53-1.18; $P = 0.204$). All three cases developed SAH within 3 days (range, 0-3 days) of the first or second dose of BNT162b2 mRNA COVID-19 vaccine by Pfizer/BioNTech. The median age at the time of SAH onset was 63.7 years (range, 44- 75 years). Observed locations of ruptured aneurysms in patients were the bifurcations of the middle cerebral artery, internal carotid-posterior communicating artery, and anterior communicating artery, respectively. Favorable outcomes (modified Rankin scale scores, 0-2) were obtained following microsurgical clipping or intra-aneurysm coiling. CONCLUSION: Although the advantages of COVID-19 vaccination appear to outweigh the risks, pharmacovigilance must be maintained to monitor potentially fatal adverse events and identify possible associations.

Broad humoral and cellular immunity elicited by one-dose mRNA vaccination 18 months after SARS-CoV-2 infection. BACKGROUND: Practical guidance is needed regarding the vaccination of coronavirus disease 2019 (COVID-19) convalescent individuals in resource-limited countries. It includes the number of vaccine doses that should be given to unvaccinated patients who experienced COVID-19 early in the pandemic. METHODS: We recruited COVID-19 convalescent individuals who received one or two doses of an mRNA vaccine within 6 or around 18 months after a diagnosis of severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) infection. Their samples were assessed for IgG-binding or neutralizing activity and cell-mediated immune responses against SARS-CoV-2 wild-type and variants of concern. RESULTS: A total of 43 COVID-19 convalescent individuals were analyzed in the present study. The results showed that humoral and cellular immune responses against SARS-CoV-2 wild-type and variants of concern, including the Omicron variant, were comparable among patients vaccinated within 6 versus around 18 months. A second dose of vaccine did not significantly increase immune responses. CONCLUSION: One dose of mRNA vaccine should be considered sufficient to elicit a broad immune response even around 18 months after a COVID-19 diagnosis.

In-vitro NET-osis induced by COVID-19 sera is associated to severe clinical course in not vaccinated patients and immune-dysregulation in breakthrough infection. Since neutrophil extracellular traps formation (NET-osis) can be assessed indirectly by treating healthy neutrophils with blood-derived fluids from patients and then measuring the NETs response, we designed a pilot study to convey high-dimensional cytometry of peripheral blood immune cells and cytokines, combined with clinical features, to understand if NET-osis assessment could be included in the immune risk profiling to early prediction of clinical patterns, disease severity, and viral clearance at 28Â days in COVID-19 patients. Immune cells composition of peripheral blood, cytokines concentration and in-vitro NETosis were detected in peripheral blood of 41 consecutive COVID-19 inpatients, including 21 mild breakthrough infections compared to 20 healthy donors, matched for sex and age. Major immune dysregulation in peripheral blood in not-vaccinated COVID-19 patients compared to healthy subjects included: a significant reduction of percentage of unswitched memory B-cells and transitional B-cells; loss of naÃ¯ve CD3(+)CD4(+)CD45RA(+) and CD3(+)CD8(+)CD45RA(+) cells, increase of IL-1Î², IL-17A and IFN-Î³. Myeloid compartment was affected as well, due to the increase of classical (CD14(++)CD16(-)) and intermediate (CD14(++)CD16(+)) monocytes, overexpressing the activation marker CD64, negatively associated to the absolute counts of CD8+â€‰CD45R0+â€‰cells, IFN-Î³ and IL-6, and expansion of monocytic-like myeloid derived suppressor cells. In not-vaccinated patients who achieved viral clearance by 28Â days we found at hospital admission lower absolute counts of effector cells, namely CD8(+)T cells, CD4(+) T-cells and CD4(+)CD45RO(+) T cells. Percentage of in-vitro NET-osis induced by patients' sera and NET-osis density were progressively higher in moderate and severe COVID-19 patients than in mild disease and controls. The percentage of in-vitro induced NET-osis was positively associated to circulating cytokines IL-1Î², IFN-Î³ and IL-6. In breakthrough COVID-19 infections, characterized by mild clinical course, we observed increased percentage of in-vitro NET-osis, higher CD4+â€‰CD45RO+â€‰and CD8+â€‰CD45RO+â€‰T cells healthy or mild-COVID-19 not-vaccinated patients, reduced by 24Â h of treatment with ACE inhibitor ramipril. Taken together our data highlight the role of NETs in orchestrating the complex immune response to SARS-COV-2, that should be considered in a multi-target approach for COVID-19 treatment.
Position Statement on Cardiovascular Safety of Vaccines Against COVID-19 - 2022.
Acute Myocarditis Following mRNA COVID-19 Vaccine.
Which vaccine attributes foster vaccine uptake? A cross-country conjoint experiment. Why do people prefer one particular COVID-19 vaccine over another? We conducted a pre-registered conjoint experiment (n = 5,432) in France, Germany, and Sweden in which respondents rated the favorability of and chose between pairs of hypothetical COVID-19 vaccines. Differences in effectiveness and the prevalence of side-effects had the largest effects on vaccine preferences. Factors with smaller effects include country of origin (respondents are less favorable to vaccines of Chinese and Russian origin), and vaccine technology (respondents exhibited a small preference for hypothetical mRNA vaccines). The general public also exhibits sensitivity to additional factors (e.g. how expensive the vaccines are). Our data show that vaccine attributes are more important for vaccine preferences among those with higher vaccine favorability and higher risk tolerance. In our conjoint design, vaccine attributes-including effectiveness and side-effect prevalence-appear to have more muted effects among the most vaccine hesitant respondents. The prevalence of side-effects, effectiveness, country of origin and vaccine technology (e.g., mRNA vaccines) determine vaccine acceptance, but they matter little among the vaccine hesitant. Vaccine hesitant people do not find a vaccine more attractive even if it has the most favorable attributes. While the communication of vaccine attributes is important, it is unlikely to convince those who are most vaccine hesitant to get vaccinated.
Efficacy and Safety of a Recombinant Plant-Based Adjuvanted Covid-19 Vaccine. BACKGROUND: Coronavirus-like particles (CoVLP) that are produced in plants and display the prefusion spike

glycoprotein of the original strain of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are combined with an adjuvant (Adjuvant System 03 [AS03]) to form the candidate vaccine. METHODS: In this phase 3, multinational, randomized, placebo-controlled trial conducted at 85 centers, we assigned adults (â‰¥18 years of age) in a 1:1 ratio to receive two intramuscular injections of the CoVLP+AS03 vaccine or placebo 21 days apart. The primary objective of the trial was to determine the efficacy of the CoVLP+AS03 vaccine in preventing symptomatic coronavirus disease 2019 (Covid-19) beginning at least 7 days after the second injection, with the analysis performed after the detection of at least 160 cases. RESULTS: A total of 24,141 volunteers participated in the trial; the median age of the participants was 29 years. Covid-19 was confirmed by polymerase-chain-reaction assay in 165 participants in the intention-to-treat population; all viral samples that could be sequenced contained variants of the original strain. Vaccine efficacy was 69.5% (95% confidence interval [CI], 56.7 to 78.8) against any symptomatic Covid-19 caused by five variants that were identified by sequencing. In a post hoc analysis, vaccine efficacy was 78.8% (95% CI, 55.8 to 90.8) against moderate-to-severe disease and 74.0% (95% CI, 62.1 to 82.5) among the participants who were seronegative at baseline. No severe cases of Covid-19 occurred in the vaccine group, in which the median viral load for breakthrough cases was lower than that in the placebo group by a factor of more than 100. Solicited adverse events were mostly mild or moderate and transient and were more frequent in the vaccine group than in the placebo group; local adverse events occurred in 92.3% and 45.5% of participants, respectively, and systemic adverse events in 87.3% and 65.0%. The incidence of unsolicited adverse events was similar in the two groups up to 21 days after each dose (22.7% and 20.4%) and from day 43 through day 201 (4.2% and 4.0%). CONCLUSIONS: The CoVLP+AS03 vaccine was effective in preventing Covid-19 caused by a spectrum of variants, with efficacy ranging from 69.5% against symptomatic infection to 78.8% against moderate-to-severe disease. (Funded by Medicago; ClinicalTrials.gov number, NCT04636697.).

Efficacy and Safety of the RBD-Dimer-Based Covid-19 Vaccine ZF2001 in Adults. BACKGROUND: The ZF2001 vaccine, which contains a dimeric form of the receptor-binding domain of severe acute respiratory syndrome coronavirus 2 and aluminum hydroxide as an adjuvant, was shown to be safe, with an acceptable side-effect profile, and immunogenic in adults in phase 1 and 2 clinical trials. METHODS: We conducted a randomized, double-blind, placebo-controlled, phase 3 trial to investigate the efficacy and confirm the safety of ZF2001. The trial was performed at 31 clinical centers across Uzbekistan, Indonesia, Pakistan, and Ecuador; an additional center in China was included in the safety analysis only. Adult participants (â‰¥18 years of age) were randomly assigned in a 1:1 ratio to receive a total of three 25-Î¼g doses (30 days apart) of ZF2001 or placebo. The primary end point was the occurrence of symptomatic coronavirus disease 2019 (Covid-19), as confirmed on polymerase-chain-reaction assay, at least 7 days after receipt of the third dose. A key secondary efficacy end point was the occurrence of severe-to-critical Covid-19 (including Covid-19-related death) at least 7 days after receipt of the third dose. RESULTS: Between December 12, 2020, and December 15, 2021, a total of 28,873 participants received at least one dose of ZF2001 or placebo and were included in the safety analysis; 25,193 participants who had completed the three-dose regimen, for whom there were approximately 6 months of follow-up data, were included in the updated primary efficacy analysis that was conducted at the second data cutoff date of December 15, 2021. In the updated analysis, primary end-point cases were reported in 158 of 12,625 participants in the ZF2001 group and in 580 of 12,568 participants in the placebo group, for a vaccine efficacy of 75.7% (95% confidence interval [CI], 71.0 to 79.8). Severe-to-critical Covid-19 occurred in 6 participants in the ZF2001 group and in 43 in the placebo group, for a vaccine efficacy of 87.6% (95% CI, 70.6 to 95.7); Covid-19-related death occurred in 2 and 12 participants, respectively, for a vaccine efficacy of 86.5% (95% CI, 38.9 to 98.5). The incidence of adverse events and serious adverse events was balanced in

the two groups, and there were no vaccine-related deaths. Most adverse reactions (98.5%) were of grade 1 or 2. CONCLUSIONS: In a large cohort of adults, the ZF2001 vaccine was shown to be safe and effective against symptomatic and severe-to-critical Covid-19 for at least 6 months after full vaccination. (Funded by the National Science and Technology Major Project and others; ClinicalTrials.gov number, NCT04646590.).
[Pericarditis after administration mRNA COVID-19 vaccine].
Injection site reactions after COVID-19 mRNA vaccination.
COVID-19 Vaccination Safety in Patients who have had SARS-CoV-2-induced Chilblains.
Herpes zoster seven days after SARS-CoV-2 vaccination in a patient with ankylosing spondylitis under adalimumab. Not available.
Erythema nodosum after COVID-19 vaccine. The current coronavirus disease 2019 (COVID-19) pandemic is a global challenge with strong medical and socioeconomic implications. Hopes have been placed in the development of various vaccines. As the vaccination campaign is in progress, adverse effects need to be monitored closely. Possible side effects range from minor events to more serious manifestations. In this article, we describe two cases of erythema nodosum (EN) after COVID-19 vaccination in two previously healthy female patients of 59 and 51 years, respectively. Most of the usual etiologies of EN were excluded by laboratory testing. EN was successfully treated with corticosteroids. Remarkably, in the first case, a relapse occurred 48 hours after the second dose of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. In this case series, we describe two unusual occurrences of EN after vaccination with an mRNA COVID-19 vaccine and a viral vector vaccine, respectively, and we discuss the available related literature.
Reply to: "Herpes zoster seven days after SARS-CoV-2 vaccination in a patient with ankylosing spondylitis under adalimumab" by Josef Finsterer. Not available.
Imaging of Myocarditis Following mRNA COVID-19 Booster Vaccination. Keywords: Echocardiography, MR-Functional Imaging, MRI, Cardiac Supplemental material is available for this article.
Humoral immunity against SARS-CoV-2 variants including omicron in solid organ transplant recipients after three doses of a COVID-19 mRNA vaccine. OBJECTIVES: Solid organ transplant recipients (SOTR) receiving post-transplant immunosuppression show increased COVID-19-related mortality. It is unclear whether an additional dose of COVID-19 vaccines can overcome the reduced immune responsiveness against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants. METHODS: We analysed humoral immune responses against SARS-CoV-2 and its variants in 53 SOTR receiving SARS-CoV-2 vaccination. RESULTS: Following the initial vaccination series, 60.3% of SOTR showed no measurable neutralisation and only 18.9% demonstrated neutralising activity of >â€‰90%. More intensive immunosuppression, antimetabolites in particular, negatively impacted antiviral immunity. While absolute IgG levels were lower in SOTR than controls, antibody titres against microbial recall antigens were higher. By contrast, SOTR showed reduced vaccine-induced IgG/IgA antibody titres against SARS-CoV-2 and its delta variants and fewer linear B-cell epitopes, indicating reduced B-cell diversity. Importantly, a third vaccine dose led to an increase in anti-SARS-CoV-2 antibody titres and neutralising activity across alpha, beta and delta variants and to the induction of anti-SARS-CoV-2 CD4(+) T cells in a subgroup of patients analysed. By contrast, we observed significantly lower antibody titres after the third dose with the omicron variant compared to the ancestral SARS-CoV-2 and the improvement in neutralising activity was much less pronounced than for all the other variants. CONCLUSION: Only a small subgroup of solid organ transplant recipients is able to generate functional antibodies after an initial vaccine series; however, an additional vaccine dose resulted in dramatically improved antibody responses against all SARS-CoV-2 variants except omicron where antibody responses and neutralising activity remained suboptimal.

Hyper inflammatory syndrome following COVID-19 mRNA vaccine in children: A national post-authorization pharmacovigilance study. BACKGROUND: Multisystem inflammatory syndrome in children (MIS-C) is the most severe clinical entity associated with pediatric SARS-CoV-2 infection with a putative role of the spike protein into the immune system activation. Whether COVID-19 mRNA vaccine can induce this complication in children is unknown. We aimed to assess the risk of hyper-inflammatory syndrome following COVID-19 mRNA vaccine in children. METHODS: We conducted a post-authorization national population-based surveillance using the French enhanced pharmacovigilance surveillance system for COVID-19 vaccines. All cases of suspected hyper-inflammatory syndrome following COVID-19 mRNA vaccine in 12-17-year-old children between June 15(th), 2021 and January 1(st), 2022, were reported. Cases were reviewed according to WHO criteria for MIS-C. The reporting rate of this syndrome was compared to the MIS-C rate per 1,000,000 12-17-year-old children infected by SARS-CoV-2. FINDINGS: Up to January 2022, 8,113,058 COVID-19 mRNA vaccine doses were administered to 4,079,234 12-17-year-old children. Among them, 12 presented a hyper-inflammatory syndrome with multisystemic involvement. Main clinical features included male predominance (10/12, 83%), cardiac involvement (10/12, 83%), digestive symptoms (10/12, 83%), coagulopathy (7/12, 58%), cytolytic hepatitis (6/12, 50%), and shock (5/12, 42%). 4/12 (33%) required intensive care unit transfer, and 3/12 (25%) hemodynamic support. All cases recovered. In eight cases, no evidence of previous SARS-CoV-2 infection was found. The reporting rate was 1.5 (95%CI [0.8; 2.6]) per 1,000,000 doses injected, i.e. 2.9 (95%CI [1.5; 5.1]) per 1,000,000 12-17-year-old vaccinated children. As a comparison, 113 MIS-C (95%CI [95; 135]) occurred per 1,000,000 12-17-year-old children infected by SARS-CoV-2. INTERPRETATION: Very few cases of hyper-inflammatory syndrome with multi-organ involvement occurred following COVID-19 mRNA vaccine in 12-17-year-old children. The low reporting rate of this syndrome, compared to the rate of post-SARS-CoV-2 MIS-C in the same age-group, largely supports the vaccination in a context of an important circulation of SARS-CoV-2. FUNDING: ESPID Fellowship Award; Grandir-Fonds de SolidaritÃ© Pour L'enfance.

Determinants of associated events following AZD1222 (Covishield) vaccination in a high-risk population in Nepal. BACKGROUND: Vaccination is the most effective method to prevent the spread of infectious diseases and helps reduce mortality rate and economic costs associated with the pandemic. Despite these advantages, misinformation on vaccine safety and efficacy can lead to increased hesitation towards vaccination. This study reports the incidence of adverse events following Covishield vaccination, their associated factors, medication used for their management, and attitudes about vaccine safety. METHODS: A cross-sectional study was conducted from the sample of Covishield-vaccinated individuals from a secondary hospital, two primary health centres, and 36 health posts in eastern Nepal. Individuals (nâ€‰=â€‰602) were randomly sampled from a population (nâ€‰=â€‰1013) who had received the first dose of Covishield, namely frontline workers and other high-risk populations. The second-round follow-up had 516 participants. Association of incidence and severity of post-vaccination events with socio-demographic variables, comorbidity status, and medication use were estimated. RESULTS: Among the 79.9% of participants who reported adverse events after receiving the first dose, two-thirds of complaints were mild (67.4%, 95% CI 63.2-71.6) with the most common complaint being pain at the injection site (86.5%). Paracetamol or its combination with NSAIDs were used in the majority of cases (95.2%). After the second dose, only 31.2% (95% CI 27.2-35.2) reported adverse events, the overwhelming majority of which were mild (95.7%) and required a lower frequency of medication (7.5% vs. 26.0%). Adverse event following immunization were significantly associated with being 18-30Â years old (Ï‡(2)â€‰=â€‰16.9, dfâ€‰=â€‰3, pâ€‰<â€‰0.001) and female gender (Ï‡(2)â€‰=â€‰5.2, dfâ€‰=â€‰1, pâ€‰<â€‰0.05). Prior to the first dose, 86.0% of participants (95% CI 83.3-88.8%) perceived the vaccine to be safe, and 96.0% recommended the vaccine post-vaccination, while 96.8%

were interested in receiving the second dose. AEFI severity was negatively associated with vaccine recommendation to the peers (odds-ratio 0.062, pâ€‰<â€‰0.05) following the first dose, whereas, the optimistic pre-vaccination perception was associated with positive vaccine recommendation post-vaccination (odds-ratio 28.658, pâ€‰<â€‰0.01). CONCLUSIONS: Overall, vaccination-associated events were mild and majority were managed with paracetamol or its combination. Effective counselling about adverse events before vaccination should be prioritized to reduce hesitation and fear.

COVID-19 vaccine development: milestones, lessons and prospects. With the constantly mutating of SARS-CoV-2 and the emergence of Variants of Concern (VOC), the implementation of vaccination is critically important. Existing SARS-CoV-2 vaccines mainly include inactivated, live attenuated, viral vector, protein subunit, RNA, DNA, and virus-like particle (VLP) vaccines. Viral vector vaccines, protein subunit vaccines, and mRNA vaccines may induce additional cellular or humoral immune regulations, including Th cell responses and germinal center responses, and form relevant memory cells, greatly improving their efficiency. However, some viral vector or mRNA vaccines may be associated with complications like thrombocytopenia and myocarditis, raising concerns about the safety of these COVID-19 vaccines. Here, we systemically assess the safety and efficacy of COVID-19 vaccines, including the possible complications and different effects on pregnant women, the elderly, people with immune diseases and acquired immunodeficiency syndrome (AIDS), transplant recipients, and cancer patients. Based on the current analysis, governments and relevant agencies are recommended to continue to advance the vaccine immunization process. Simultaneously, special attention should be paid to the health status of the vaccines, timely treatment of complications, vaccine development, and ensuring the lives and health of patients. In addition, available measures such as mix-and-match vaccination, developing new vaccines like nanoparticle vaccines, and optimizing immune adjuvant to improve vaccine safety and efficacy could be considered.

Effects of temporarily suspending low-dose methotrexate treatment for 2 weeks after SARS-CoV-2 vaccine booster on vaccine response in immunosuppressed adults with inflammatory conditions: protocol for a multicentre randomised controlled trial and nested mechanistic substudy (Vaccine Response On/Off Methotrexate (VROOM) study). INTRODUCTION: It is unknown if a temporary break in long-term immune-suppressive treatment after vaccination against COVID-19 improves vaccine response. The objective of this study was to evaluate if a 2-week interruption in low-dose weekly methotrexate treatment after SARS-CoV-2 vaccine boosters enhances the immune response compared with continuing treatment in adults with autoimmune inflammatory conditions. METHODS AND ANALYSIS: An open-label, pragmatic, prospective, parallel group, randomised controlled superiority trial with internal feasibility assessment and nested mechanistic substudy will be conducted in rheumatology and dermatology clinics in approximately 25 UK hospitals. The sample size is 560, randomised 1:1 to intervention and usual care arms. The main outcome measure is anti-spike receptor-binding domain (RBD) antibody level, collected at prebooster (baseline), 4 weeks (primary outcome) and 12 weeks (secondary outcome) post booster vaccination. Other secondary outcome measures are patient global assessments of disease activity, disease flares and their treatment, EuroQol 5- dimention 5-level (EQ-5D-5L), self-reported adherence with advice to interrupt or continue methotrexate, neutralising antibody titre against SARS-CoV-2 (mechanistic substudy) and oral methotrexate biochemical adherence (mechanistic substudy). Analysis of B-cell memory and T-cell responses at baseline and weeks 4 and 12 will be investigated subject to obtaining additional funding. The principal analysis will be performed on the groups as randomised (ie, intention to treat). The difference between the study arms in anti-spike RBD antibody level will be estimated using mixed effects model, allowing for repeated measures clustered within participants. The models will be adjusted for randomisation factors and prior SARS-CoV-2 infection status. ETHICS AND

DISSEMINATION: This study was approved by the Leeds West Research Ethics Committee and Health Research Authority (REC reference: 21/HRA/3483, IRAS 303827). Participants will be required to give written informed consent before taking part in the trial. Dissemination will be via peer review publications, newsletters and conferences. Results will be communicated to policymakers. TRIAL REGISTRATION NUMBER: ISRCTN11442263.

Longitudinal COVID-19-vaccination-induced antibody responses and Omicron neutralization in patients with lung cancer.

Studies Examine Risk of Hearing Loss After COVID-19 Vaccination.

Exploring COVID-19 Vaccine Side Effects: A Correlational Study Using Python. The COVID-19 pandemic had a great impact on the socio-economic stability of every country. To curb the effect and risk of transmission, governments implemented various measures including the mandatory vaccination of their citizens. However, despite these efforts, many people are still hesitant to take the vaccine because of various reasons and biases. This paper attempts to explore the perceptions of the people who have undergone vaccinations regarding the various side effects to provide inputs to vaccine manufacturers and assist people in making informed decisions in selecting the appropriate vaccine for them. The study further explored the correlation and association of age, weight category, diet category, blood type, and sleeping patterns with the severity of the selected vaccine side effects. The results revealed that vaccine side effects are associated with the vaccine type. Age, gender, weight category, diet category, blood type, and sleeping patterns have significant relationships to one or more side effects.

Early adverse events and immune response following COVID-19 booster vaccination in pregnancy.

Post-SARS-CoV-2 vaccination thrombosis is frequent and ubiquitous.

Comment on: Central retinal vein occlusion post-COVID-19 vaccination.

Comment on: Central retinal vein occlusion after mRNA SARS-CoV-2 vaccination.

Necrosis of uveal melanoma post-COVID-19 vaccination. A 49-year-old Indian male presented with rapidly progressive vision loss 1 day after receiving the second dose of BNT162b2 mRNA coronavirus disease 2019 (COVID-19) vaccine (Pfizer-BioNTech, NY, USA). The eye had secondary angle closure glaucoma, bullous retinal detachment, and massive intraocular hemorrhage. Ultrasound showed an ill-defined subretinal mass with moderate internal reflectivity. Magnetic resonance imaging (MRI) confirmed an enhancing heterogeneous subretinal mass. Histopathology showed a necrotic melanocytic lesion arising from the posterior edge of the ciliary body and choroid. Necrotic uveal melanoma was confirmed after expert histopathology opinion. Uveal melanomas can rarely present with tumor necrosis following mRNA COVID-19 vaccination.

Aquaporin-4 protein antibody-associated optic neuritis related to neuroendocrine tumor after receiving an inactive COVID-19 vaccine. Neuromyelitis optica (NMO), also known as Devic's disease, is a rare, autoimmune, and recurrent demyelinating disorder that primarily affects the spinal cord and optic nerve. We report a case with recurrent optic neuritis caused by the paraneoplastic NMO spectrum disorder in the setting of a gastric neuroendocrine tumor 2 weeks after receiving an inactive COVID-19 vaccine.

A case of acute endothelial corneal transplant rejection following immunization with ChAdOx1 nCoV-19 coronavirus vaccine. A 28-year-old female who underwent an uneventful femtosecond laser enabled keratoplasty (FLEK) in her left eye presented with pain, redness, and blurring of vision in the operated eye two weeks after getting immunized with COVID-19 vector vaccine (ChAdOx1 nCoV19 Vaccine Recombinant COVISHIELD, AstraZeneca). Slit-lamp examination showed donor stromal edema with Descemet's membrane folds and Khodadoust line (KP's on endothelium) with anterior chamber cells and flare. The patient was diagnosed with acute corneal graft rejection and advised

hourly topical steroids with cycloplegics and oral steroids. The patient responded to treatment and there was progressive reversal of graft rejection with the patient achieving best spectacle-corrected visual acuity (BSCVA) of 20/30 after five weeks of treatment. Our case highlights possible immune corneal graft rejection after COVID19 vaccination and the need to step up topical steroids before vaccination.

Safety and immunogenicity of NVX-CoV2373 (TAK-019) vaccine in healthy Japanese adults: Interim report of a phase I/II randomized controlled trial. BACKGROUND: We evaluated the safety and immunogenicity of NVX-CoV2373, a recombinant SARS-CoV-2 nanoparticle vaccine, in healthy Japanese participants. METHODS: This phase 1/2, randomized, observer-blind, placebo-controlled trial conducted in Japan (two sites), enrolled healthy Japanese adults agedÂ â‰¥Â 20Â years with no history/risk of SARS-CoV-2 infection and no prior exposure to other approved/investigational SARS-CoV-2 vaccines or treatments. Participants were stratified by age (< 65 orÂ â‰¥Â 65Â years) and randomized to receive two doses of either NVX-CoV2373 (5Â Î¼g SARS-CoV-2 rS; 50Â Î¼g Matrix-M1) or placebo, 21Â days apart. Primary outcomes were safety and immunogenicity assessed by serum IgG antibody levels against SARS-CoV-2 rS protein on day 36. Herein, we report the primary data analysis at 4Â weeks after the second dose, ahead of 12-month follow-up completion (data cut-off: 8 May 2021). RESULTS: Between 12 February 2021 and 17 March 2021, 326 subjects were screened, and 200 participants enrolled and randomized: NVX-CoV2373, nÂ =Â 150; placebo, nÂ =Â 50. Solicited adverse events (AEs) through 7Â days after each injection occurred in 121/150 (80.7%) and 11/50 (22.0%) participants in the NVX-CoV2373 and placebo arms, respectively. In the NVX-CoV2373 arm, tenderness and injection site pain were the most frequently reported solicited AEs after each vaccination, irrespective of age. Robust immune responses occurred with NVX-CoV2373 (nÂ =Â 150) by day 36: IgG geometric mean fold rise (95% confidence interval) 259 (219, 306); seroconversion rate 100% (97.6, 100). No such response occurred with placebo (nÂ =Â 49). CONCLUSION: Two doses of NVX-CoV2373 given with a 21-day interval demonstrated acceptable safety and induced robust anti-SARS-CoV-2 immune responses in healthy Japanese adults. FUNDING: Takeda Pharmaceutical Company Limited and Japan Agency for Medical Research and Development (AMED). CLINICALTRIALS: gov identifier: NCT04712110.

Immunogenicity and Safety of the COVID-19 Vaccines Compared With Control in Healthy Adults: A Qualitative and Systematic Review. OBJECTIVES: Emergence of severe acute respiratory syndrome coronavirus 2 infections and the resultant disease, COVID-19 led the world into 238 million cases and 4.8 million deaths over the first 22 months of the pandemic. While numerous vaccines have been developed to combat this pandemic, limited literature is available regarding the comparison of these vaccines. This study aims to systematically review and evaluate the immunogenicity and safety of COVID-19 vaccines compared with control arms in the healthy adult population. METHODS: A literature search was conducted in PubMed, MEDLINE, Embase, and Cochrane up to July 4, 2021. Randomized controlled trials assessing the immunogenicity of any dose of COVID-19 vaccine in adults by anti-severe acute respiratory syndrome coronavirus 2 immunoglobulin G antibodies geometric mean titers (GMTs) and neutralizing antibodies GMT response at 28 days postimmunization compared with the control groups in the healthy adults were considered for inclusion. Groups at day 28 with the highest GMT were further examined for their adverse events. RESULTS: Of the 341 citations retrieved, 19 were included. This covered a total of 16 vaccines involving 8342 subjects aged between 30.8 and 69.7 years, comprising 52.13% females. All studies reported GMT at or close to 28 days postvaccination compared with placebo and comparator, and 13 of 19 studies reported seroconversion rates. While 15 of 16 vaccines reported adverse events that ranged from mild to severe, 1 of 16 (AD26.COV2.S) noted 1 case of a vaccine-related serious adverse event-high fever 6 hours after vaccination. Local reactions (such as redness, pain, and swelling) and systematic reactions

(such as fatigue, fever, and headache) were commonly noted. Safety between vaccines was similar; however, higher rates of severe adverse events were noted in Ad5-vectored COVID-19, AD26.COV2.S, ChAdOx nCoV-19, and mRNA-1273. No all-cause mortality was documented in any vaccines. CONCLUSIONS: All 16 vaccines elicited an immune response substantially higher than the control groups while maintaining tolerable safety profiles.

Moderna COVID-19 vaccine was linked to myocarditis or myopericarditis at 28 d (4.2 events/100Â 000 persons). Husby A, Hansen JV, FosbÃ¸l E, et al. SARS-CoV-2 vaccination and myocarditis or myopericarditis: population based cohort study. BMJ. 2021;375:e068665. 34916207.

Neuromuscular complications after COVID-19 vaccination: a series of eight patients. BACKGROUND: Several neurologic complications have been reported in close temporal association with both severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection and following vaccination against SARS-CoV-2. Specifically, several cases of Guillain-BarrÃ© syndrome (GBS) have been reported in temporal relationship with COVID-19 vaccination, with two small case series describing a specific phenotype with bifacial weakness and paresthesia in the limbs. METHODS: We retrospectively collected patients who developed a new-onset neuromuscular disorder in the first 6Â weeks after receiving a COVID-19 vaccine (either first or second dose). The patients were collected from one tertiary care centre and one secondary careÂ centre from February to July 2021. RESULTS: We report eight patients who developed phenotypically diverse neuromuscular disorders in the weeks following COVID-19 vaccination, with a presumed immune-mediated etiology. In our case series, we report three patients with classical GBS, one patient with bifacial weakness with paresthesia variant of GBS, two patients with subacute-onset chronic inflammatory demyelinating polyneuropathy (CIDP), one patient with brachial plexopathy and one patient with subacute axonal sensorimotor polyneuropathy. CONCLUSIONS: New-onset neuromuscular disorders with onset in the weeks after COVID-19 vaccination can include diverse phenotypes. A causal relationship between these disorders and the vaccine cannot be proven at present, and further epidemiological studies are needed to further investigate this association.

[Serious shoulder injury after COVID-19 vaccination]. BACKGROUND: Since January 2021, over 24 million COVID-19 vaccines have been administered. Rarely vaccination in the deltoid muscle may lead to complications in the shoulder, called SIRVA (shoulder injury related to vaccine administration). General knowledge on SIRVA amongst doctors and other healthcare workers is lacking. However, due to the large amount of vaccinations which have been administered over the last year, SIRVA is seen more often. CASE REPORT: In this report, two cases of SIRVA due to septic arthritis and a shoulder abscess after administration of a COVID-19 vaccination, are described. CONCLUSION: SIRVA should be considered in case of shoulder complaints which persist longer than 48 hours after vaccination. Timely diagnosis and treatment by either the general practitioner or orthopaedic surgeon should be conducted to prevent long-term damage to the shoulder joint. Use of the correct vaccination technique is important to prevent the occurrence of SIRVA.

An acute, ulcerative, sarcoidal tattoo reaction following SARS-CoV-2 mRNA-1273 vaccination. Two weeks after her first dose of the SARS-CoV-2 mRNA-1273 (Moderna) vaccine, a 38-year-old woman developed acute-onset pain and ulceration within a tattoo on the distal left leg. Progressive ulceration was noted approximately one week following her second dose of the vaccine. A biopsy revealed sarcoidal granulomas and a dense neutrophilic infiltrate. Ultimately, the final diagnosis of what we have termed a "sarcoidal reaction with a Sweet-like phenomenon" was made; the patient experienced a reduction in pain and re-epithelialization of the ulcers with two weeks of the use of topical clobetasol 0.05% cream twice daily.

Clinical spectrum of gross haematuria following SARS-CoV-2 vaccination with mRNA vaccines. BACKGROUND: Novel messenger RNA (mRNA)-based vaccines play an important role in current

vaccination campaigns against SARS-CoV-2. They are highly efficacious and generally well tolerated. Vaccination in patients with immune-mediated kidney diseases is recommended. A number of cases with de novo or relapsing glomerulonephritis shortly after vaccine application have been reported, some of which presented with gross haematuria. METHODS: We collected 10 cases of macrohaematuria following mRNA-based severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination at our tertiary care institution and referring centres. Additionally, we pooled all 25 published cases from the literature with ours to analyse their clinical characteristics. RESULTS: Most macrohaematuria episodes (72.2%) began within 2 days after vaccination, the majority after the second dose. In some individuals, repeated episodes occurred after subsequent doses of the same vaccine. A total of 65.7% of patients never had macrohaematuria before. A total of 45.7% were known to suffer from immunoglobulin A nephropathy (IgAN); the rest had no prior renal diagnosis. IgAN was the most frequent new diagnosis, but anti-neutrophil cytoplasmic antibody-associated vasculitis and anti-glomerular basement membrane disease were also identified. Acute kidney injury (AKI) occurred in 28.6% of patients, with an increase in serum creatinine not meeting Kidney Disease: Improving Global Outcomes AKI criteria in 28.6%. Treatment ranged from conservative management, renin-angiotensin-aldosterone system inhibitors, steroids and cyclophosphamide to plasmapheresis. While renal outcomes were mainly favourable in isolated IgAN, they were poor in patients with additional or isolated small vessel vasculitis. CONCLUSION: Awareness of gross haematuria after SARS-CoV-2 vaccination is important. Close follow-up and additional work up, particularly in individuals without known underlying kidney disease or worsening renal function, is essential. For patients with vaccine-associated macrohaematuria, an alternative vaccine class might be considered for subsequent vaccinations.
COVID-19 vaccination precipitating de novo ANCA-associated vasculitis: clinical implications.
COVID-19 vaccination in anti-neutrophil cytoplasmic antibody-associated vasculitis: lessons from influenza vaccination?
Sustained humoral response 6 months after the anti-SARS-CoV-2 mRNA-BNT162b2 vaccine in haemodialysis patients: should booster vaccine doses be given to all patients at the same time?
SARS-CoV-2 antibody dynamics among kidney transplant recipients 3 months after BNT162b2 vaccination: a prospective cohort study. Data regarding immunogenicity of mRNA severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines among kidney transplant recipients in the months following vaccination are lacking. We aimed to investigate humoral immune response at 3-4 months post-vaccination among a cohort of kidney transplant recipients, compared with a control group of dialysis patients. Anti-spike antibodies were tested at 1 and 3-4 months after vaccination. Of 259 kidney transplant recipients tested at a median time of 110 days from second vaccine dose, 99 (38%) were seropositive, compared with 83% (101/122) of control patients. Younger age, better renal function and lower immunosuppression levels were associated with seropositivity. A total of 14% (13/94) of participants seropositive at 1 month became seronegative at follow-up and 11% (18/165) became seropositive. The latter were mainly individuals with higher antibody levels at 1 month. Antibody levels at 3-4 months were significantly reduced in both study groups, although the decline was more pronounced in the control group. Kidney transplant recipients present poor antibody response to mRNA SARS-CoV-2 vaccination, with only 38% seropositive at 3-4 months. Nevertheless, the decay in antibody response over time is modest, and some patients may present delayed response, reaching adequate antibody levels at 3-4 months. Low seropositivity rates in this group call for investigating other immunization strategies.
Acute hepatitis with autoimmune features after COVID-19 vaccine: coincidence or vaccine-induced phenomenon?

The Epidemiological, Clinical Features and Outcomes of Imported Chinese COVID-19 Patients Following Inactivated Vaccines Injection. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination had been demonstrated as an effective way to reduce the risk of coronavirus disease 2019 (COVID-19), and only a few vaccines suffered from SARS-CoV-2 infection. However, limited data concerning the clinical features of these vaccines infected with SARS-CoV-2 can be identified. METHODS: We retrospectively collected and analyzed epidemiological and clinical characteristics data of the imported COVID-19 cases who received Chinese inactivated vaccines abroad. Data were extracted from electronic medical records from a designated hospital in the Shaanxi Province of China between March 22 and May 17, 2021. RESULTS: Totally, 46 confirmed SARS-CoV-2 infection patients were enrolled. The mean age was 40.5 years (range 20-61), 41 (89.1%) are male. Eighteen (39.1%) patients were from Pakistan. Fourteen (30.4%) patients had at least one comorbidity. Forty (87.0%) and 6 cases were fully vaccinated and partly vaccinated. The time interval between vaccination and infection was 88 days (IQR, 33-123), 31 (67.4%) and 15 (32.6%) were asymptomatic and symptomatic cases, respectively. Fever (3/46, 6.5%) was the most common symptom; however, none had a body temperature higher than 38.0Â°C, and no severe case was observed. Notably, the rate of SARS-CoV-2 shedding discontinuation at 7 days after hospitalization in asymptomatic cases was higher than symptomatic one (93.5% vs 40%, $P < 0.0001$). CONCLUSION: Individuals who received Chinese inactivated vaccines abroad remain to have the probability of being infected with SARS-CoV-2, but all the vaccines infected with SARS-CoV-2 were asymptomatic or had mild symptoms with favorable clinical outcomes.

COVID-19 and COVID-19 vaccine-related dermatological reactions: An interesting case series with a narrative review of the potential critical and non-critical mucocutaneous adverse effects related to virus, therapy, and the vaccination. This narrative review article was conducted to lay out a summarized but exhaustive review of current literature over mucocutaneous manifestations in 4 dimensions of SARS-CoV-2 pandemic: virus itself, treatment-related, vaccine-induced, and alteration of chronic dermatologic diseases following infection. Virus and vaccine-related were mainly self-limited and non-severe. Treatment-related reactions could be life-threatening.

Graves' Disease Following COVID-19 Vaccination. Autoimmune endocrine diseases have been reported after influenza and the human papillomavirus vaccine, but there is limited data on autoimmune diseases after coronavirus disease 2019 (COVID-19) vaccination. Our report is about a 42-year-old Caucasian male and a 68-year-old Caucasian female who developed Graves' disease after receiving Moderna (Moderna, Inc., Cambridge, Massachusetts, United States) and Johnson & Johnson (Johnson & Johnson, New Brunswick, New Jersey, United States) vaccines, respectively. Both patients had no previous autoimmune thyroiditis and had normal thyroid function but developed hyperthyroidism characterized by suppressed thyroid-stimulating hormone (TSH), elevated free T4 level, and TSH receptor antibodies after vaccination. COVID-19 vaccines, either mRNA-based (Moderna) or non-mRNA-based (Johnson & Johnson), can cause Graves' disease. The clinical manifestations are similar to Graves' disease but without ocular manifestations.

Subacute thyroiditis after SARS-CoV-2 BNT162b2 vaccine in a multiple myeloma patient. Viral infections emerge in the pathogenesis of subacute thyroiditis. Aside from this, subacute thyroiditis following vaccines utilizing inactivated viruses has been shown on rare occasions. Due to the COVID-19 pandemic, several vaccines have been developed all over the world; mass and unprecedented vaccination has thus been initiated. However, it is known that cases such as subacute thyroiditis have been reported, albeit rarely, after administration of COVID-19 vaccines. In this case report, we present a 59-year-old patient with multiple myeloma developing subacute thyroiditis following BNT162b2 vaccine. Patient had swelling in the neck, and his symptoms were controlled with non-steroidal anti-inflammatory drugs. Subacute thyroiditis following administration of the COVID-19

vaccine is rare; however, it is likely an under-reported condition that is difficult to detect. Clinicians should stay informed and have increased awareness of post-COVID-19 vaccine subacute thyroiditis.

Association between coronavirus disease morbidity and mortality rates and BCG vaccination policies in OECD countries. Authors' reply. We appreciate the reviewer's comment to our article on the correlation between the national BCG vaccination policy and coronavirus disease 2019 among Organisation for Economic Co-operation and Development countries as of April 20, 2020. In this letter, we further updated the data up to November 1, 2020, and found that the updated results also arrive at the similar conclusion as the accepted article.

Vaccine-Induced Thrombotic Thrombocytopenia: A Case of Splanchnic Veins Thrombosis. Vaccines have been vital in preventing and curbing the spread of SARS-CoV-2 infection. Adenoviral vector-based vaccines, namely the ChAdOx1-S vaccine (AstraZeneca, Cambridge, UK) and Ad26.COV2.S (Janssen; Johnson & Johnson, New Brunswick, NJ, USA), have been associated with a possibly fatal adverse event known as vaccine-induced thrombotic thrombocytopenia (VITT), wherein thrombi form in unusual sites, mainly the cerebral and splanchnic veins. With the female gender predominantly affected, patients present with headache, abdominal pain, neurological symptoms and fever. It is hypothesized that certain components of the vaccine, including the adenovirus vector, may trigger the formation of antibodies against platelet factor 4 (PF4). The antigen-antibody complexes that form thereafter then activate a cascade of reactions eventually leading to the consumptive coagulopathy. This pathogenesis closely resembles a well-understood complication of heparin, known as heparin-induced thrombocytopenia. The lab results in VITT are reflective of its proposed pathophysiology: low platelets, low fibrinogen and high D-dimer, in addition to elevated anti-PF4 titers are classic findings. Treatment mainly includes non-heparin anticoagulants, intravenous immune globulin (IVIG) and plasma exchange. There is some role for surgical intervention, such as mechanical thrombectomy. Mortality due to VITT is usually caused by cerebral hemorrhage. We describe a case of a 36-year-old female who presented with epigastric pain two weeks after receiving her first dose of theÂ AstraZeneca vaccine, and upon workup, was subsequently found to have thrombosis of her right portal and right common iliac vein.

Post-vaccination Adverse Reactions After Receiving the Pfizer-BioNTech Coronavirus Disease 2019 Vaccines Among Healthcare Workers in Sapporo, Japan. Background/objective Although a third dose of the coronavirus disease 2019 vaccine was initiated, the reports of the post-vaccination adverse reactions after dose three from Japan were limited. We aimed to report on post-vaccination adverse reactions to the third dose of the vaccine among healthcare workers and compare the results with those after the first two doses of vaccine at a tertiary medical center in Japan. Materials and methods After each vaccine (Pfizer-BioNTech) administration, healthcare workers answered a Web-based questionnaire for two consecutive days regarding local and systemic adverse reactions and anaphylaxis reactions. Information about those who took antipyretics and analgesics was also collected. Data were collected using Microsoft Forms (Microsoft, Redmond, WA, USA), a web-based questionnaire software. We compared the proportions of post-vaccination adverse reactions among the three doses of vaccine using the chi-squared test. Results A total of 1,990 employees received the first dose in March 2021, 1,988 employees received the second dose in April 2021, and 1,748 employees received the third dose between December 2021 and January 2022. The median age was 32 years and 21% were men. Local and systemic adverse reactions were greater after dose three than those with the primary series, except for nausea and vomiting. Injected site pain, fatigue, and headache were the three most commonly reported adverse reactions throughout the three sessions. A total of four employees developed anaphylaxis reactions. Additionally, 944 and 1,016 employees reported taking antipyretics and analgesics after doses two and three. Conclusions The coronavirus

2019 booster vaccine was safe and well-tolerated. Clinicians should encourage the public to receive the coronavirus 2019 vaccine series.

The Side Effects of COVID-19 Vaccines and Its Association With ABO Blood Type Among the General Surgeons in Saudi Arabia. Introduction The benefits of vaccination outweigh its risks as it protects approximately two to three million individuals from infectious diseases annually. With the emergence of the coronavirus disease 2019 (COVID-19) pandemic, new vaccines have been developed. However, it is crucial to follow and recognize the side effects of COVID-19 vaccines. Previous studies have shown a relationship between ABO blood groups and coronavirus. Some vaccination side effects, such as muscle pain at the injection site and fatigue, may impair an individual's ability to perform tasks that require fine motor skills, such as those performed by a general surgeon. Therefore, this study aimed to identify the association between ABO blood groups and the side effects of COVID-19 vaccines among general surgeons in Saudi Arabia. Method A cross-sectional online survey-based study regarding the side effects following COVID-19 vaccination was conducted among Saudi and non-Saudi general surgeons working in public and private hospitals in Saudi Arabia who had received one or two doses of mRNA-based COVID-19 vaccines. Results A total of 612 surgeons responded. Approximately, 74.7% of the respondents reported side effects after receiving vaccines. Tiredness was the most commonly reported side effect of the vaccine, followed by severe local pain at the site of injection. Approximately, 16.2% of the participants started showing side effects 12 hours after receiving the vaccine. There was a significant relationship between the type of vaccine administered and the appearance of side effects ($p = 0.004$). The rate of appearance of side effects was higher in participants who received the Pfizer vaccine. However, there was no significant relationship between the appearance of side effects and age, gender, blood group, number of doses, and past history of COVID-19 infection ($p > 0.05$). Of the total participants, 256 (41.8%) stated that the side effects of the vaccine affected their work performance. Moreover, there was no significant difference in side effects, symptoms appearing after vaccination, the onset of symptoms, and duration of symptoms between the participants who received one dose and those who received two doses of the vaccine. In addition, there was no significant relationship between the severity of side effects and age, past history of COVID-19 infection, number of doses, and blood type ($p > 0.05$). However, there was a significant relationship between the severity of side effects and gender and type of vaccine ($p = 0.000$ and 0.004, respectively). A high percentage of females and those who received the AstraZeneca vaccine stated that their side effects affected their work performance. Conclusion Three-quarters of the participants reported side effects after the COVID-19 vaccination, which affected the work performance of 41% of participating general surgeons. There was no significant relationship between the appearance of symptoms and age, gender, blood group, number of doses, and past history of COVID-19 infection. However, there was a significant relationship between the severity of side effects and gender and type of vaccination. Future large-scale studies are recommended to further evaluate the implication of ABO blood type on COVID-19.

BNT162b2, mRNA-1273, and Sputnik V Vaccines Induce Comparable Immune Responses on a Par With Severe Course of COVID-19. Vaccines against the severe acute respiratory syndrome coronavirus 2, which have been in urgent need and development since the beginning of 2020, are aimed to induce a prominent immune system response capable of recognizing and fighting future infection. Here we analyzed the levels of IgG antibodies against the receptor-binding domain (RBD) of the viral spike protein after the administration of three types of popular vaccines, BNT162b2, mRNA-1273, or Sputnik V, using the same ELISA assay to compare their effects. An efficient immune response was observed in the majority of cases. The obtained ranges of signal values were wide, presumably reflecting specific features of the immune system of individuals. At the same time, these ranges were comparable among the three studied vaccines. The anti-RBD IgG levels after vaccination

were also similar to those in the patients with moderate/severe course of the COVID-19, and significantly higher than in the individuals with asymptomatic or light symptomatic courses of the disease. No significant correlation was observed between the levels of anti-RBD IgG and sex or age of the vaccinated individuals. The signals measured at different time points for several individuals after full Sputnik V vaccination did not have a significant tendency to lower within many weeks. The rate of neutralization of the interaction of the RBD with the ACE2 receptor after vaccination with Sputnik V was on average slightly higher than in patients with a moderate/severe course of COVID-19. The importance of the second dose administration of the two-dose Sputnik V vaccine was confirmed: while several individuals had not developed detectable levels of the anti-RBD IgG antibodies after the first dose of Sputnik V, after the second dose the antibody signal became positive for all tested individuals and raised on average 5.4 fold. Finally, we showed that people previously infected with SARS-CoV-2 developed high levels of antibodies, efficiently neutralizing interaction of RBD with ACE2 after the first dose of Sputnik V, with almost no change after the second dose.

Safety, Immunogenicity, and Efficacy of COVID-19 Vaccines in Adolescents, Children, and Infants: A Systematic Review and Meta-Analysis. BACKGROUND: As the epidemic progresses, universal vaccination against COVID-19 has been the trend, but there are still some doubts about the efficacy and safety of COVID-19 vaccines in adolescents, children, and even infants. PURPOSE: To evaluate the safety, immunogenicity, and efficacy of COVID-19 vaccines in the population aged 0-17 years. METHOD: A comprehensive search for relevant randomized controlled trials (RCTs) was conducted in PubMed, Embase, and the Cochrane Library from inception to November 9, 2021. All data were pooled by RevMan 5.3 statistical software, with risk ratio (RR) and its 95% confidence interval as the effect measure. This study protocol was registered on PROSPERO (CRD42021290205). RESULTS: There was a total of six randomized controlled trials included in this systematic review and meta-analysis, enrolling participants in the age range of 3-17 years, and containing three types of COVID-19 vaccines. Compared with mRNA vaccines and adenovirus vector vaccines, inactivated vaccines have a more satisfactory safety profile, both after initial (RR 1.40, 95% CI 1.04-1.90, P = 0.03) and booster (RR 1.84, 95% CI 1.20-2.81, P = 0.005) vaccination. The risk of adverse reactions was significantly increased after the first and second doses, but there was no significant difference between the first two doses (RR 1.00, 95%CI 0.99-1.02, P = 0.60). Nevertheless, the two-dose regimen is obviously superior to the single-dose schedule for immunogenicity and efficacy. After booster vaccination, both neutralizing antibodies (RR 144.80, 95%CI 44.97-466.24, P < 0.00001) and RBD-binding antibodies (RR 101.50, 95%CI 6.44-1,600.76, P = 0.001) reach optimal levels, but the cellular immune response seemed not to be further enhanced. In addition, compared with younger children, older children and adolescents were at significantly increased risk of adverse reactions after vaccination, with either mRNA or inactivated vaccines, accompanied by a stronger immune response. CONCLUSION: The available evidence suggests that the safety, immunogenicity and efficacy of COVID-19 vaccines are acceptable in people aged 3-17 years. However, there is an urgent need for additional multicenter, large-sample studies, especially in younger children under 3 years of age and even in infants, with long-term follow-up data. SYSTEMATIC REVIEW REGISTRATION: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021290205, identifier: CRD42021290205.

Acceptance of COVID-19 Vaccine and Its Associated Factors Among Ethiopian Population: A Systematic Review. INTRODUCTION: Coronavirus disease 2019 (COVID-19) is a global health threat. Millions of lives were lost to COVID-19 and it has caused a substantial economic crisis throughout the world. The development of coronavirus vaccines has pinned a new hope in combating the pandemic. The success of vaccination and development of herd immunity highly depend on the willingness to be vaccinated, not merely on the availability of a vaccine. This review aims to provide

comprehensive evidence on acceptance of COVID-19 vaccine and its associated factors in Ethiopia. METHODS: Literature searching was done using PubMed, Google scholar and Science direct databases. Studies conducted in Ethiopia, published in English language from inception until January 9, 2022 were included. Retrieved articles were screened based on titles, abstracts and full text reading to identify studies that met the inclusion criteria. About 21 eligible studies were included in this systematic review. The data were extracted using a data extraction checklist. RESULTS: A total of 2058 records were retrieved, of which 21 were eligible for this systematic review. All of the articles were cross-sectional studies published in 2021. In Ethiopia, the level of COVID-19 vaccine acceptance ranged from 31.4% to 92.33%. The vaccine acceptance level was significantly associated with age groups, sex, educational status, perceived susceptibility, perceived benefit, knowledge about COVID-19 vaccine, and other socio-demographic factors. CONCLUSION: A significant portion of the studies revealed vaccine acceptance level was low. Variation of vaccine acceptance was associated with socio-demographic factors (age, sex, educational status, etc.), information-related factors, and other health-related behaviors. Dissemination of clear and adequate information concerning the vaccine might be the required prior activity to increase acceptance of the vaccine. Hence, there should be a coordinated effort to halt the pandemic through increasing the acceptance of COVID-19 vaccine.

Down syndrome, cardiac defect, embolisation, and COVID-19 vaccination: correspondence.

[SARS-CoV2 anti-spike IgG response following COVID-19 mRNA vaccination (BNT162b2) in patients with hematological disorders]. This is a prospective study conducted to determine the level of anti-spike IgG to SARS-CoV-2 2-6 weeks following the BNT162b2 vaccination in 125 patients with hematological disorders. Compared with healthy controls, patients with malignant lymphoma had lower rates of seropositivity and lower levels of antibody titer. Furthermore, patients who received rituximab (R)-containing chemotherapy had lower antibody titers than those who were not treated with R or who had completed R-containing chemotherapy more than 9 months earlier. Despite having 71% IgG-seropositivity, patients with multiple myeloma had lower antibody titers than the control group. Furthermore, patients receiving daratumumab-containing chemotherapy had lower antibody titers than those not receiving treatment. Moreover, patients with acute myeloid leukemia or myelodysplastic syndrome had lower antibody titers than the control group. Overall, the number of peripheral blood lymphocytes was significantly correlated with IgG titers, with seropositive patients having more peripheral blood lymphocytes than seronegative patients. Patients with severe immunosuppression, such as those with hematological disorders, often have impaired seroconversion with COVID-19 vaccination that should be taken into consideration by clinicians.

Differences in Clinical Aspects Between Subacute Thyroiditis Associated with COVID-19 Vaccines and Classical Subacute Thyroiditis. Subacute thyroiditis (SAT) developed after SARS-CoV-2 vaccines has been less studied. We aimed to compare classical SAT and SAT developed after SARS-CoV-2 vaccines in the context of clinical aspects. Adults with SAT detected in 90 days of COVID-19 vaccination (CoronaVac or Pfizer/BioNTech) were grouped as Vac-SAT. Those with a history of SARS-CoV-2 or upper respiratory tract infection in 6 months before the vaccination, or vaccination with another antiviral vaccine after COVID-19 vaccination were excluded. Those with SAT detected before COVID-19 pandemic were grouped as Classical-SAT. Of total (n=85), female/male (54/31) ratio and age [43 (23-65)] were similar in Vac-SAT (n=23) and Classical-SAT (n=62). Duration between vaccine and SAT was 45 (7-90) days, and similar in CoronaVac-SAT (n=5) and BioNTech-SAT (n=18). SAT-duration was 28 (10-150) days, and higher in Vac-SAT than in Classical-SAT (p=0.023). SAT was developed after the 1st dose vaccine in minority in CoronaVac-SAT (n=2) and BioNTech-SAT (n=3) (p=0.263). Previous LT4 use, and TSH elevation after resolution were more frequent in Vac-SAT than in Classical-SAT (p=0.027 and p=0.041). We included a considerable number of patients with SAT occurred after COVID-19 vaccines. We cannot provide clear evidence regarding the association of

COVID-19 vaccines with SAT. SAT associated with CoronaVac or BioNTech seems unlikely to be occurred after the 1st dose, and to have a longer duration, more likely to be associated with previous LT4 use and lead TSH elevation after resolution than Classical-SAT. TSH should be followed-up after the resolution of SAT detected after COVID-19 vaccination.

Post-authorization surveillance of adverse events following COVID-19 vaccines in pregnant persons in the vaccine adverse event reporting system (VAERS), December 2020 - October 2021. BACKGROUND: Pregnant persons are at increased risk of severe illness from COVID-19 infection, including intensive care unit admission, mechanical ventilation, and death compared with non-pregnant persons of reproductive age. Limited data are available on the safety of COVID-19 vaccines administered during and around the time of pregnancy. OBJECTIVE: To evaluate and summarize reports to the Vaccine Adverse Event Reporting System (VAERS), a national spontaneous reporting system, in pregnant persons who received a COVID-19 vaccine to assess for potential vaccine safety problems. METHODS: We searched VAERS for US reports of adverse events (AEs) in pregnant persons who received a COVID-19 vaccine from 12/14/2020-10/31/2021. Clinicians reviewed reports and available medical records. Crude reporting rates for selected AEs were calculated, and disproportional reporting was assessed using data mining methods. RESULTS: VAERS received 3,462 reports of AEs in pregnant persons who received a COVID-19 vaccine; 1,831 (52.9%) after BNT162b2, 1,350 (38.9%) after mRNA-1273, and 275 (7.9%) after Ad26.COV2.S. Eight maternal deaths and 12 neonatal deaths were reported. Six-hundred twenty-one (17.9%) reports were serious. Pregnancy-specific outcomes included: 878 spontaneous abortions (<20â€¯weeks), 101 episodes of vaginal bleeding, 76 preterm deliveries (<37â€¯weeks), 62 stillbirths (â‰¥20â€¯weeks), and 33 outcomes with birth defects. Crude reporting rates for preterm deliveries and stillbirths, as well as maternal and neonatal mortality rates were below background rates from published sources. No disproportional reporting for any AE was observed. CONCLUSIONS: Review of reports to VAERS following COVID-19 vaccines in pregnant persons did not identify any concerning patterns of maternal or infant-fetal outcomes.

Predictors of hospitalisation and death due to SARS-CoV-2 infection in Finland: A population-based register study with implications to vaccinations. INTRODUCTION: The aim of this study was to investigate how age and underlying medical conditions affect the risk of severe outcomes following SARS-CoV-2 infection and how they should be weighed while prioritising vaccinations against COVID-19. METHODS: This population-based register study includes all SARS-CoV-2 PCR-test-positive cases until 24 Feb 2021, based on the Finnish National Infectious Diseases Register. The cases were linked to other registers to identify presence of predisposing factors and severe outcomes (hospitalisation, intensive care treatment, death). The odds of severe outcomes were compared in those with and without the pre-specified predisposing factors using logistic regression. Furthermore, population-based rates were compared between those with a given predisposing factor and those without any of the specified predisposing factors using negative binomial regression. RESULTS: Age and various comorbidities were found to be predictors of severe COVID-19. Compared to 60-69-year-olds, the odds ratio (OR) of death was 7.1 for 70-79-year-olds, 26.7 for 80-89-year-olds, and 55.8 forÂ â‰¥Â 90-year-olds. Among the 20-69-year-olds, chronic renal disease (OR 9.4), malignant neoplasms (5.8), hematologic malignancy (5.6), chronic pulmonary disease (5.4), and cerebral palsy or other paralytic syndromes (4.6) were strongly associated with COVID-19 mortality; severe disorders of the immune system (8.0), organ or stem cell transplant (7.2), chronic renal disease (6.7), and diseases of myoneural junction and muscle (5.5) were strongly associated with COVID-19 hospitalisation. Type 2 diabetes and asthma, two very common comorbidities, were associated with all three outcomes, with ORs from 2.1 to 4.3. The population-based rate of SARS-CoV-2 infection decreased with age. Taking the 60-69-year-olds as reference, the rate ratio was highest (3.0) for 20-29-year-olds andÂ <Â 1 for 70-79-year-olds and 80-89-year-olds. CONCLUSION: Comorbidities

predispose for severe COVID-19 among younger ages. In vaccine prioritisation both the risk of infection and the risk of severe outcomes, if infected, should be considered.

Immunogenicity and safety of a SARS-CoV-2 recombinant spike protein nanoparticle vaccine in people living with and without HIV-1 infection: a randomised, controlled, phase 2A/2B trial.
BACKGROUND: There is a paucity of data on COVID-19 vaccines in people living with HIV-1, who could be at increased risk of severe illness and death from COVID-19. We evaluated the safety and immunogenicity of a Matrix-M adjuvanted recombinant spike protein nanoparticle COVID-19 vaccine (NVX-CoV2373; Novavax) in HIV-negative people and people living with HIV-1. METHODS: In this randomised, observer-blinded, multicentre, placebo-controlled phase 2A/B trial in South Africa, participants aged 18-84 years, with and without underlying HIV-1, were enrolled from 16 sites and randomly assigned (1:1) to receive two intramuscular injections of NVX-CoV2373 or placebo, 21 days apart. People living with HIV-1 were on stable antiretroviral therapy and had an HIV-1 viral load of less than 1000 copies per mL. Vaccine dosage was 5 Î¼g SARS-CoV-2 recombinant spike protein with 50 Î¼g Matrix-M adjuvant, whereas 0Â·9% saline was used as placebo injection (volume 0Â·5 mL each). All study staff and participants remained masked to study group assignment. We previously reported an interim analysis on the efficacy and safety of the NVX-CoV2373 vaccine (coprimary endpoints). In this Article, we present an expanded safety analysis for the full cohort of participants and report on the secondary objective of vaccine immunogenicity in the full cohort of people living with HIV-1 and in HIV-negative individuals overall and stratified by baseline SARS-CoV-2 serostatus. This trial is registered with ClinicalTrials.gov, NCT04533399, and the Pan-African Clinical Trials Registry, PACTR202009726132275. FINDINGS: Participants were enrolled between Aug 17 and Nov 25, 2020. The safety analysis set included 4164 HIV-negative participants (2089 in the intervention group and 2075 in the placebo group) and 244 people living with HIV-1 (122 in the intervention group and 122 in the placebo group). 1422 (34Â·1%) of 4164 HIV-negative people and 83 (34Â·0%) of 244 people living with HIV-1 were categorised as baseline SARS-CoV-2-positive (ie, anti-spike IgG reactive at enrolment or had a reactive SARS-CoV-2 nucleic acid amplification test by 14 days after the second study vaccination). In the NVX-CoV2373 group, solicited local and systemic adverse events were more common in HIV-negative participants (427 [30Â·6%] local and 401 [28Â·7%] systemic) than in people living with HIV-1 (20 [25Â·3%] local and 20 [25Â·3%] systemic) among those who were baseline SARS-CoV-2-seronegative (naive). Of the serious adverse events that occurred among HIV-negative people (of whom, two [0Â·1%] were baseline SARS-CoV-2-negative and four [0Â·6%] were baseline SARS-CoV-2-positive) and people living with HIV-1 (for whom there were no serious adverse events) in the NVX-CoV2373 group, none were assessed as related to the vaccine. Among participants who were baseline SARS-CoV-2-negative in the NVX-CoV2373 group, the anti-spike IgG geometric mean titres (GMTs) and seroconversion rates (SCRs) were lower in people living with HIV-1 (n=62) than in HIV-negative people (n=1234) following the first vaccination (GMT: 508Â·6 vs 1195Â·3 ELISA units [EU]/mL; SCR: 51Â·6% vs 81Â·3%); and similarly so 14 days after the second vaccination for GMTs (14â€ˆ420Â·5 vs 31â€ˆ631Â·8 EU/mL), whereas the SCR was similar at this point (100Â·0% vs 99Â·3%). In the NVX-CoV2373 group, anti-spike IgG GMTs 14 days after the second vaccination were substantially higher in those who were baseline SARS-CoV-2-positive than in those who were baseline SARS-CoV-2-seronegative for HIV-negative participants (100â€ˆ666Â·1 vs 31â€ˆ631Â·8 EU/mL) and for people living with HIV-1 (98â€ˆ399Â·5 vs 14â€ˆ420Â·5 EU/mL). This was also the case for angiotensin-converting enzyme 2 receptor-binding antibody and neutralising antibody titres. INTERPRETATION: The safety of the NVX-CoV2373 vaccine in people living with HIV-1 was similar to that in HIV-negative participants. However, people living with HIV-1 not previously exposed to SARS-CoV-2 had attenuated humoral immune responses to NVX-CoV2373 compared with their HIV-negative vaccine counterparts, but not so if they were baseline SARS-CoV-2-positive. FUNDING:

Novavax and the Bill & Melinda Gates Foundation; investigational vaccine manufacturing support was provided by the Coalition for Epidemic Preparedness Innovations.

Pathological findings of clinically suspected myocarditis temporally associated with COVID-19 vaccination. Reports on the pathological findings of patients with myocarditis after coronavirus disease 2019 (COVID-19) vaccination are limited. We present a case series of four patients with clinically suspected myocarditis temporally associated with COVID-19 vaccination who underwent endomyocardial biopsy with no evidence of viral genomes in tissue specimens. Two patients had fulminant myocarditis with marked inflammatory cell infiltration comprised mostly of CD8+ T-cells and macrophages, and the other two had suspected myocarditis based on the biochemical evidence of myocardial injury and ST changes on an electrocardiogram. However, they did not meet the histological criteria of myocarditis. Immunosuppressive therapy effectively reduced myocardial damage, and all four patients had improved clinical courses. Temporal association does not prove causation, and it cannot be excluded that the two biopsy-proven cases reported are simply a random association of a naturally occurring virus-negative immune-mediated lymphocytic myocarditis occurring after vaccination.

Adverse Events Following COVID-19 Vaccination in Rivers State, Nigeria: A Cross-Sectional Study. CONTEXT: Coronavirus disease (COVID-19) has led to over 2,589,638 deaths globally as of March 2021 and speedy discovery of vaccines. Nigeria started the phase one COVID-19 vaccination in March 2021 using the Oxford AstraZeneca vaccine. Reports of severe adverse events with the Oxford AstraZeneca vaccine resulted in its suspension in some countries necessitating the need to determine its safety. AIMS: To assess the prevalence, types and severity of the adverse events following COVID-19 vaccination in Rivers State, Nigeria. SETTINGS AND DESIGN: A cross-sectional study design was adopted. SUBJECTS AND METHODS: Simple random sampling method was used to select a total of 428 adults from recipients of the first dose of COVID-19 vaccine within 28 days of vaccination. A questionnaire adapted from World Health Organisation was interviewer-administered through phone calls; responses were recorded on Kobo Toolbox. STATISTICAL ANALYSIS USED: Descriptive analysis of variables was done and the association between adverse events and age, allergy and medical history were determined. The level of statistical significance was predetermined at a $P < 0.05$. RESULTS: In this study, 50.5% of respondents reported post-vaccination adverse events out of which 10 (4.6%) were severe (30% of the severe cases were life-threatening, 60% were hospitalised and 10% were placed on bed rest). The most common side effects were fever (73.0%), pain at the injection site (41.2%), fatigue (33.3%), body ache (17.5%) and headache (13.8%). No significant association was observed between the incidence of severe adverse events and participants with allergies or medical history. CONCLUSIONS: The adverse events associated with the COVID-19 vaccine were largely mild and resolved within a few days. Further research is required to classify adverse events into categories.

De-escalation of asymptomatic testing and potential of future COVID-19 outbreaks in US nursing homes amidst rising community vaccination coverage: A modeling study. As of 2 September 2021, United States nursing homes have reported >675,000 COVID-19 cases and >134,000 deaths according to the Centers for Medicare & Medicaid Services (CMS). More than 205,000,000 persons in the United States had received at least one dose of a COVID-19 vaccine (62% of total population) as of 2 September 2021. We investigate the role of vaccination in controlling future COVID-19 outbreaks. We developed a stochastic, compartmental model of SARS-CoV-2 transmission in a 100-bed nursing home with a staff of 99 healthcare personnel (HCP) in a community of 20,000 people. We parameterized admission and discharge of residents in the model with CMS data, for a within-facility basic reproduction number (R(0)) of 3.5 and a community R(0) of 2.5. The model also included: importation of COVID-19 from the community, isolation of SARS-CoV-2 positive residents, facility-

wide adherence to personal protective equipment (PPE) use by HCP, and testing. We systematically varied coverage of mRNA vaccine among residents, HCP, and the community. Simulations were run for 6Â months after the second dose in the facility, with results summarized over 1,000 simulations. Expected resident cases decreased as community vaccination increased, with large reductions at high HCP coverage. The probability of a COVID-19 outbreak was lower as well: at HCP vaccination coverage of 60%, probability of an outbreak was below 20% for community coverage of 50% or above. At high coverage, stopping asymptomatic screening and facility-wide testing yielded similar results. Results suggest that high coverage among HCP and in the community can prevent infections in residents. When vaccination is high in nursing homes, but not in their surrounding communities, asymptomatic and facility-wide testing remains necessary to prevent the spread of COVID-19. High adherence to PPE may increase the likelihood of containing future COVID-19 outbreaks if they occur.

Recrudescence of severe polyneuropathy after receiving Pfizer-BioNTech COVID-19 vaccine in a patient with a history of eosinophilic granulomatosis with polyangiitis. A middle age man with a history of diabetes mellitus type 2, hypertension, migraine and eosinophilic granulomatosis with polyangiitis (EGPA) with polyneuropathy in remission presented with paresthesia and motor weakness soon after receiving the Pfizer-BioNTech COVID-19 messanger RNA (mRNA) vaccine. The patient had polyneuropathy 10 years ago secondary to EGPA, which had resolved. EGPA was diagnosed on the basis of typical symptoms and positive sural nerve biopsy. Five days after receiving the first dose of COVID-19 vaccine, he developed heaviness and reduced dexterity of both the upper extremities, which progressed to patchy and asymmetric motor weakness of all four extremities. Given the lack of clear alternative explanation after a thorough work up, recrudescence of underlying asymptomatic polyneuropathy due to a possible reaction to COVID-19 mRNA vaccine was considered although a temporal association with vaccine dose does not prove causality. He was treated with corticosteroids with slow improvement of his symptoms.

Letter reply "John Stuart Mill and COVID-19 vaccination".

Seroprevalence of SARS-CoV-2-specific antibodies and vaccination-related adverse events in systemic lupus erythematosus and rheumatoid arthritis. BACKGROUND: This study aimed to investigate the seroreactivity of Coronavirus disease 2019 (COVID-19) vaccination and its adverse events among systemic lupus erythematosus (SLE) patients, rheumatoid arthritis (RA) patients, and healthy controls (HCs). METHODS: A total of 60 SLE patients, 70 RA patients and 35 HCs, who received a complete inactivated COVID-19 vaccine (Vero cells) regimen, were recruited in the current study. Serum IgG and IgM antibodies against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) were determined by using chemiluminescent microparticle immunoassay (CMIA). RESULTS: There were no significant differences regarding the seroprevalences of IgG and IgM antibodies against SARS-CoV-2, and the self-reported vaccination-related adverse events among SLE patients, RA patients and HCs. The inactivated COVID-19 vaccines appeared to be well-tolerated and moderately immunogenic. In addition, case-only analysis indicated that in SLE patients, the disease manifestation of rash and anti-SSA autoantibody were associated with seroprevalence of IgG antibody against SARS-CoV-2, whereas the uses of ciclosporin and leflunomide had influence on the seroprevalence of IgM antibody against SARS-CoV-2. In RA patients, rheumatoid factor (RF) appeared to be associated with the seroprevalence of IgG antibody against SARS-CoV-2. CONCLUSION: Our study reveals that the seroprevalences of IgG and IgM antibodies against SARS-CoV-2 and vaccination-related adverse effects are similar among SLE, RA and HCs, suggesting that COVID-19 vaccine is safe and effective for SLE and RA patients to prevent from the pandemic of COVID-19.

Risk Factors Associated With SARS-CoV-2 Breakthrough Infections in Fully mRNA-Vaccinated Individuals: Retrospective Analysis. BACKGROUND: COVID-19 messenger RNA (mRNA) vaccines have demonstrated efficacy and effectiveness in preventing symptomatic COVID-19, while being

relatively safe in trial studies. However, vaccine breakthrough infections have been reported. OBJECTIVE: This study aims to identify risk factors associated with COVID-19 breakthrough infections among fully mRNA-vaccinated individuals. METHODS: We conducted a series of observational retrospective analyses using the electronic health records (EHRs) of the Columbia University Irving Medical Center/New York Presbyterian (CUIMC/NYP) up to September 21, 2021. New York City (NYC) adult residences with at least 1 polymerase chain reaction (PCR) record were included in this analysis. Poisson regression was performed to assess the association between the breakthrough infection rate in vaccinated individuals and multiple risk factors-including vaccine brand, demographics, and underlying conditions-while adjusting for calendar month, prior number of visits, and observational days in the EHR. RESULTS: The overall estimated breakthrough infection rate was 0.16 (95% CI 0.14-0.18). Individuals who were vaccinated with Pfizer/BNT162b2 (incidence rate ratio [IRR] against Moderna/mRNA-1273=1.66, 95% CI 1.17-2.35) were male (IRR against female=1.47, 95% CI 1.11-1.94) and had compromised immune systems (IRR=1.48, 95% CI 1.09-2.00) were at the highest risk for breakthrough infections. Among all underlying conditions, those with primary immunodeficiency, a history of organ transplant, an active tumor, use of immunosuppressant medications, or Alzheimer disease were at the highest risk. CONCLUSIONS: Although we found both mRNA vaccines were effective, Moderna/mRNA-1273 had a lower incidence rate of breakthrough infections. Immunocompromised and male individuals were among the highest risk groups experiencing breakthrough infections. Given the rapidly changing nature of the SARS-CoV-2 pandemic, continued monitoring and a generalizable analysis pipeline are warranted to inform quick updates on vaccine effectiveness in real time.

Age and sex associations of SARS-CoV-2 antibody responses post BNT162b2 vaccination in healthcare workers: A mixed effects model across two vaccination periods. This study aimed to examine the associations with epidemiological, behavioral and clinical parameters of IgG antibody responses against the spike protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) after immunization with two doses of the BNT162b2 vaccine in a cohort of healthcare workers (HCWs, n = 439) in Greece. We used a mixed effects model to investigate the potential associations of antibody levels one and three months after vaccination and examined by bootstrapping t-tests the putative effects of gender and age for each period. We also employed exact tests of independence in R Ã— C contingency tables to explore associations between behavioral and gender variables with vaccinations side effects. We found significant differences between males and females as well as between subjects in the youngest (21-30 years) and the older age groups in both study periods. We also detected a decrease in titers with age and time. Males had steeper elimination rates across the age span in both periods, in contrast to females who exhibited a softer elimination titer rate with age in the first period and almost constant titers in the second. Concerning side effects, we found a significant association between pain at the injection site and female sex. Hence, our real-world data analyses revealed potentially important clues into the associations of antibody responses to SARS-CoV-2 spike. We discuss the importance of these findings in view of current mass vaccination perspectives and provide useful clues for the design and optimal timing of booster doses for COVID-19.

Association of Influenza Vaccination With Cardiovascular Risk: A Meta-analysis. IMPORTANCE: Influenza infection is associated with increased cardiovascular hospitalization and mortality. Our prior systematic review and meta-analysis hypothesized that influenza vaccination was associated with a lower risk of cardiovascular events. OBJECTIVE: To evaluate, via an updated meta-analysis, if seasonal influenza vaccination is associated with a lower risk of fatal and nonfatal cardiovascular events and assess whether the newest cardiovascular outcome trial results are consistent with prior findings. DATA SOURCES: A previously published meta-analysis of randomized controlled trials (RCTs) and a

large 2021 cardiovascular outcome trial. STUDY SELECTION: Studies with RCTs published between 2000 and 2021 that randomized participants to either influenza vaccine or placebo/control. Eligible participants were inpatients and outpatients recruited for international multicenter RCTs and randomized to receive either influenza vaccine or placebo/control. DATA EXTRACTION AND SYNTHESIS: PRISMA guidelines were followed in the extraction of study details, and risk of bias was assessed using the Cochrane Collaboration tool. Trial quality was evaluated using Cochrane criteria. Data were analyzed January 2020 and December 2021. MAIN OUTCOMES AND MEASURES: Random-effects Mantel-Haenszel risk ratios (RRs) and 95% CIs were derived for a composite of major adverse cardiovascular events and cardiovascular mortality within 12 months of follow-up. Where available, analyses were stratified by patients with and without recent acute coronary syndrome (ACS) within 1 year of randomization. RESULTS: Six published RCTs comprising a total of 9001 patients were included (mean age, 65.5 years; 42.5% women; 52.3% with a cardiac history). Overall, influenza vaccine was associated with a lower risk of composite cardiovascular events (3.6% vs 5.4%; RR, 0.66; 95% CI, 0.53-0.83; Pâ€‰<â€‰.001). A treatment interaction was detected between patients with recent ACS (RR, 0.55; 95% CI, 0.41-0.75) and without recent ACS (RR, 1.00; 95% CI, 0.68-1.47) (P for interactionâ€‰=â€‰.02). For cardiovascular mortality, a treatment interaction was also detected between patients with recent ACS (RR, 0.44; 95% CI, 0.23-0.85) and without recent ACS (RR, 1.45; 95% CI, 0.84-2.50) (P for interactionâ€‰=â€‰.006), while 1.7% of vaccine recipients died of cardiovascular causes compared with 2.5% of placebo or control recipients (RR, 0.74; 95% CI, 0.42-1.30; Pâ€‰=â€‰.29). CONCLUSIONS AND RELEVANCE: In this study, receipt of influenza vaccination was associated with a 34% lower risk of major adverse cardiovascular events, and individuals with recent ACS had a 45% lower risk. Given influenza poses a threat to population health during the COVID-19 pandemic, it is integral to counsel high-risk patients on the cardiovascular benefits of influenza vaccination.

Evaluation of Safety and Side Effects COVID-19 Vaccine in Cancer Patients Being Treated. According to the instructions of Iran's National Corona Response Committee in the Iranian Ministry of Health and Medical Education, patients undergoing treatments for their cancer are prioritized in Covid-19 vaccination. The present study was therefore conducted to investigate the toxicity and acute side-effects of a Covid-19 vaccine in cancer patients presenting to Medical Oncology Clinic of Kermanshah University of Medical Science. After excluding the patients with active infection and the recently-infected ones with Covid-19, they underwent the vaccination. The patients with cell counts exceeding 3,000 received two doses of the vaccine with a 21-day interval and treatment of their underlying disease was postponed for 7 days. The side-effects were mild and tolerable and included fever (case 10), pain at the injection site (7), dizziness (7), body pain (6), abdominal pain (6), myalgia (6), headache (6), chills (3), shortness of breath (3), diarrhea (1), runny nose (1) and dryness of the throat (1). No significant toxicity was reported in the patients who were safely vaccinated under the supervision of the medical oncology clinic.

Increased emergency cardiovascular events among under-40 population in Israel during vaccine rollout and third COVID-19 wave. Cardiovascular adverse conditions are caused by coronavirus disease 2019 (COVID-19) infections and reported as side-effects of the COVID-19 vaccines. Enriching current vaccine safety surveillance systems with additional data sources may improve the understanding of COVID-19 vaccine safety. Using a unique dataset from Israel National Emergency Medical Services (EMS) from 2019 to 2021, the study aims to evaluate the association between the volume of cardiac arrest and acute coronary syndrome EMS calls in the 16-39-year-old population with potential factors including COVID-19 infection and vaccination rates. An increase of over 25% was detected in both call types during January-May 2021, compared with the years 2019-2020. Using Negative Binomial regression models, the weekly emergency call counts were significantly associated

with the rates of 1st and 2nd vaccine doses administered to this age group but were not with COVID-19 infection rates. While not establishing causal relationships, the findings raise concerns regarding vaccine-induced undetected severe cardiovascular side-effects and underscore the already established causal relationship between vaccines and myocarditis, a frequent cause of unexpected cardiac arrest in young individuals. Surveillance of potential vaccine side-effects and COVID-19 outcomes should incorporate EMS and other health data to identify public health trends (e.g., increased in EMS calls), and promptly investigate potential underlying causes.

Glycaemic control is associated with SARS-CoV-2 breakthrough infections in vaccinated patients with type 2 diabetes. Patients with type 2 diabetes (T2D) are characterized by blunted immune responses, which are affected by glycaemic control. Whether glycaemic control influences the response to COVID-19 vaccines and the incidence of SARS-CoV-2 breakthrough infections is unknown. Here we show that poor glycaemic control, assessed as mean HbA1c in the post-vaccination period, is associated with lower immune responses and an increased incidence of SARS-CoV-2 breakthrough infections in T2D patients vaccinated with mRNA-BNT162b2. We report data from a prospective observational study enroling healthcare and educator workers with T2D receiving the mRNA-BNT162b2 vaccine in Campania (Italy) and followed for one year (5 visits, follow-up 346â€‰Â±â€‰49 days) after one full vaccination cycle. Considering the 494 subjects completing the study, patients with good glycaemic control (HbA1c one-year mean < 7%) show a higher virus-neutralizing antibody capacity and a better CD4â€‰+â€‰T/cytokine response, compared with those with poor control (HbA1c one-year mean â‰¥ 7%). The one-year mean of HbA1c is linearly associated with the incidence of breakthrough infections (Betaâ€‰=â€‰0.068; 95% confidence interval [CI], 0.032-0.103; pâ€‰<â€‰0.001). The comparison of patients with poor and good glycaemic control through Cox regression also show an increased risk for patients with poor control (adjusted hazard ratio [HR], 0.261; 95% CI, 0.097-0.700; pâ€‰=â€‰0.008). Among other factors, only smoking (HRâ€‰=â€‰0.290, CI 0.146-0.576 for non-smokers; pâ€‰<â€‰0.001) and sex (HRâ€‰=â€‰0.105, CI 0.035-0.317 for females; pâ€‰<â€‰0.001) are significantly associated with the incidence of breakthrough infections.

Tachycardia as an undescribed adverse effect to the ComirnatyÂ© vaccine (BNT162b2 Pfizer-BioNTech Covid-19 vaccine): Description of 3 cases with a history of SARS-CoV-2 disease.

Case of Bilateral Optic Neuritis With Positive Myelin Oligodendrocyte Glycoprotein Antibody Testing Post-COVID-19 Vaccination.

Characterizing Anchoring Bias in Vaccine Comparator Selection Due to Health Care Utilization With COVID-19 and Influenza: Observational Cohort Study. BACKGROUND: Observational data enables large-scale vaccine safety surveillance but requires careful evaluation of the potential sources of bias. One potential source of bias is the index date selection procedure for the unvaccinated cohort or unvaccinated comparison time ("anchoring"). OBJECTIVE: Here, we evaluated the different index date selection procedures for 2 vaccinations: COVID-19 and influenza. METHODS: For each vaccine, we extracted patient baseline characteristics on the index date and up to 450 days prior and then compared them to the characteristics of the unvaccinated patients indexed on (1) an arbitrary date or (2) a date of a visit. Additionally, we compared vaccinated patients indexed on the date of vaccination and the same patients indexed on a prior date or visit. RESULTS: COVID-19 vaccination and influenza vaccination differ drastically from each other in terms of the populations vaccinated and their status on the day of vaccination. When compared to indexing on a visit in the unvaccinated population, influenza vaccination had markedly higher covariate proportions, and COVID-19 vaccination had lower proportions of most covariates on the index date. In contrast, COVID-19 vaccination had similar covariate proportions when compared to an arbitrary date. These effects attenuated, but were still present, with a longer lookback period. The effect of day 0 was present even when the patients

served as their own controls. CONCLUSIONS: Patient baseline characteristics are sensitive to the choice of the index date. In vaccine safety studies, unexposed index event should represent vaccination settings. Study designs previously used to assess influenza vaccination must be reassessed for COVID-19 to account for a potentially healthier population and lack of medical activity on the day of vaccination.

Adverse Reaction to COVID-19 mRNA Vaccination in a Patient With VEXAS Syndrome. VEXAS (vacuoles, E1 enzyme, X-linked, autoinflammatory, somatic) syndrome is a rare genetic disorder originating from a somatic mutation in the hematopoietic stem cells. This syndrome was first described in 2020 and carries many clinical features that other conditions cannot explain. Widespread autoinflammation is the primary process the disease presents, with high morbidity and mortality in those who show signs of bone marrow failure. Treatment is complex, and response to current therapies is poor. Long-term prognosis carries a mortality of 50%. In addition, the advancement of new-generation messenger ribonucleic acid (mRNA) vaccines raises concerns about their safety in this population since it could trigger a vaccine-related autoimmune response. This case describes the hospital course of a male in his 50s exhibiting an unexplained cutaneous reaction to an mRNA COVID-19 vaccine. He was later diagnosed with VEXAS syndrome based on symptoms presentation and diagnostic workup.

Impact of the first vaccine dose on COVID-19 and its complications in long-term care facilities and private residences for seniors in QuÃ©bec, Canada. BACKGROUND: Residents of long-term care facilities (LTCFs) and private residences for seniors (PRSs) were given priority for vaccination against coronavirus disease 2019 (COVID-19). Given the shortage of vaccine in the winter of 2021, the ComitÃ© sur l'immunisation du QuÃ©bec recommended postponing the administration of second doses to ensure more rapid and widespread administration of first doses. The objective of this study was to measure the impact of first-dose vaccination on 1) the incidence of cases and complications in LTCFs and PRSs and 2) the frequency of outbreaks in LTCFs. METHODS: In this ecological study, COVID-19 incidence and complications in residents of LTCFs and PRSs in QuÃ©bec were compared with the general (community) population at a point in time when there was still only limited eligibility for vaccination. RESULTS: After vaccination in LTCFs, the incidence rate of COVID-19 decreased by 92% compared with 49% in the community, and deaths decreased by 95%. By six weeks post-vaccination, almost no facility reported five or more cases per 100 beds per week. The incidence rate decreased by 91% in PRSs compared with 2% in the community. Hospitalizations and deaths in PRSs decreased by 94% and 90%, respectively. CONCLUSION: As a result of 1) vaccination of residents with one dose, 2) natural immunity already acquired in LTCFs and PRSs, 3) vaccination of healthcare workers and 4) other non-pharmaceutical prevention measures implemented, the circulation of the coronavirus in these settings was largely interrupted.

Myocarditis after BNT162b2 and mRNA-1273 COVID-19 vaccination: A report of 7 cases. BACKGROUND AND OBJECTIVES: According to some reports, there is a link between the development of myocarditis and the administration of messenger RNA (mRNA) vaccines against coronavirus disease (COVID-19). Here, we report seven cases that developed myocarditis after receiving a second dose of mRNA COVID-19 vaccine. METHODS: This is a multi-center case series study. In this study, we present 7 patients diagnosed with myocarditis following BNT162b2 and mRNA-1273 COVID-19 vaccinations on March 7, 2021, and March 3, 2022. RESULTS: All seven patients were males and hemodynamically stable. The median age was 24.5 years, ranging from 16 to 36 years old. All patients received the second dose of a messenger RNA (mRNA) vaccine between one and four days before being admitted to the hospital (5 received BNT162b2 [Pfizer-BioNTech] and 2 received mRNA-1273 [Moderna]). The electrocardiograms of all seven patients were abnormal, and their troponin levels were elevated. Moreover, all patients were treated with colchicine and NSAIDs. The average length of

stay in the hospital was 2.4 days, and all of the patients' symptoms had resolved by the time they were discharged. CONCLUSION: The results of the current study raise the possibility of an association between BNT162b2 [Pfizer-BioNTech] or mRNA-1273 [Moderna] COVID-19 vaccination and myocarditis.

Viral Load Among Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Persons Infected With the SARS-CoV-2 Delta Variant. We found no significant difference in cycle threshold values between vaccinated and unvaccinated persons infected with severe acute respiratory syndrome coronavirus 2 Delta, overall or stratified by symptoms. Given the substantial proportion of asymptomatic vaccine breakthrough cases with high viral levels, interventions, including masking and testing, should be considered in settings with elevated coronavirus disease 2019 transmission.

Case Report: Acquired Haemophilia A Following mRNA-1273 Booster Vaccination Against SARS-CoV-2 With Concurrent Diagnosis of Pleomorphic Dermal Sarcoma. While the global pandemic caused by severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) is still ongoing and new virus variants are emerging, there is a universal need for vaccines to protect individuals from severe complications and ideally control the pandemic by enabling herd immunity. Several vaccines against SARS-CoV-2 have been approved and are widely used to stem the recurring waves of coronavirus disease 2019 (COVID-19). Post-marketing surveillance is essential to record even rare safety issues related to these new vaccines. Among these issues, several autoimmune phenomena have been recorded in temporal association with and feasibly triggered by a vaccination. Acquired haemophilia A (AHA) is a rare condition characterized by new-onset haemorrhagic diathesis caused by an inhibitor of blood clotting factor VIII (FVIII), often in the elderly and most commonly associated with autoimmune or malignant disease. There have been a small number of AHA cases triggered by vaccinations, including those against SARS-CoV-2. We report the first case of AHA in temporal association with an mRNA-1273 booster vaccination. The diagnosis was made promptly, and the patient received appropriate care including immunosuppression using glucocorticoids, cyclophosphamide (CYC) and rituximab (RTX). The haemorrhage ceased after escalation of treatment, and the patient is recovering. Concurrent malignancy was initially ruled out using a wide scope of diagnostic tests, but pleomorphic dermal sarcoma (PDS) of the forehead occurred after initiation of specific AHA immunosuppressive treatment. Since large vaccination programs are ongoing worldwide and potential adverse events during post-marketing surveillance have been reported following vaccination against SARS-CoV-2, this case illustrates challenges in rare events occurring in association with SARS-CoV-2 vaccination and to proof a causal relationship. Therefore, there is an urgent need for reporting any events in association with SARS-CoV-2 vaccination, but also a crucial discussion about possible concurrent triggers and follow-up information about individual patients.

Broadly neutralizing antibodies against Omicron-included SARS-CoV-2 variants induced by vaccination. The SARS-CoV-2 Omicron variant shows substantial resistance to neutralization by infection- and vaccination-induced antibodies, highlighting the demands for research on the continuing discovery of broadly neutralizing antibodies (bnAbs). Here, we developed a panel of bnAbs against Omicron and other variants of concern (VOCs) elicited by vaccination of adenovirus-vectored COVID-19 vaccine (Ad5-nCoV). We also investigated the human longitudinal antibody responses following vaccination and demonstrated how the bnAbs evolved over time. A monoclonal antibody (mAb), named ZWD12, exhibited potent and broad neutralization against SARS-CoV-2 variants Alpha, Beta, Gamma, Kappa, Delta, and Omicron by blocking the spike protein binding to the angiotensin-converting enzyme 2 (ACE2) and provided complete protection in the challenged prophylactic and therapeutic K18-hACE2 transgenic mouse model. We defined the ZWD12 epitope by determining its structure in complex with the spike (S) protein via cryo-electron microscopy. This study affords the

potential to develop broadly therapeutic mAb drugs and suggests that the RBD epitope bound by ZWD12 is a rational target for the design of a broad spectrum of vaccines.

Timing and Duration of Axillary Lymph Node Swelling After COVID-19 Vaccination: Japanese Case Report and Literature Review. BACKGROUND/AIM: COVID-19 vaccination is now performed in most of the world to limit the spread of the disease. The first mRNA vaccine was approved in clinical settings and has specific side effects including axillary lymph node swelling, which can be misdiagnosed as breast cancer metastasis. The timing of axillary lymph node swelling and its duration are unclear. Here, we present a Japanese case and review of the existing literature. CASE REPORT: We report the case of a 67-year-old woman with breast calcification. She had regular follow ups in our hospital for this calcification and received ultrasonography of the breast and axilla at every visit. She visited 6 months before having her COVID-19 vaccination, and 7 days and 6 months after the first COVID-19 vaccination. She had a swollen axillary lymph node 7 days after the first vaccination, which although it was improved, remained for 6 months. CONCLUSION: Axillary lymph node swelling occurred 7 days after vaccination and remained up to 6 months after it.

[Skin manifestations of COVID-19 and after COVID-19 vaccination]. Coronavirus disease 2019 (COVID-19) is aÂ systemic disease induced by severe acute respiratory syndrome coronavirusÂ 2 (SARS-CoV-2) that frequently presents with skin manifestations. The five most common skin lesions are pseudo-chilblain and maculopapular, urticarial, vesicular, and livedo/necrotizing skin lesions. These skin lesions are of diagnostic and prognostic relevance. For example, in children, typical skin lesions may indicate aÂ life-threatening inflammatory syndrome, which rarely occurs after corona infection. Skin lesions have also been described after COVID-19 vaccination. These usually show an uncomplicated, self-limiting course and therefore do not represent aÂ contraindication for completing the vaccination status in the vast majority of cases.

Decreasing neutralization antibody levels following vaccination against SARS-CoV-2 in the elderly: an observational study in Southern Moravia, Czech Republic. INTRODUCTION: Understanding the immune response after SARS-CoV-2 vaccination is essential to control the COVID-19 pandemic. Recent studies indicate that vaccine-induced humoral immunity may not be long-lasting and is weaker in the elderly. METHODOLOGY AND SAMPLE: At the turn of June and July 2021, 653 seniors (426 women and 197 men with a mean age of 74 years) were tested once for antibodies against SARS-Cov-2 in the South Moravian Region between 9 and 161 days after the second dose of vaccine (558 Pfizer -BioNTech, 28 Moderna, 36 AstraZeneca, 1 Johnson & Johnson). Samples of the whole capillary blood were tested in two point-of-care iCHROMA II immunofluorescence assays: (1) COVID-19 Ab against mix of SARS-CoV-2 nucleocapsid and spike proteins (IgM Ab, IgG Ab) and (2) COVID-19 nAb against S1-RBD protein (nAb). Results were analysed in relation to gender, age, vaccine type, and past COVID-19 disease. RESULTS: Our results show high variability in the antibody response but indicate an overall relatively weak and decreasing antibody response in the first six months after vaccination. Only 58.4% (95% CI: 54.6-62.3) of subjects had virus neutralizing antibodies (nAb). The level of nAb decreased with time from vaccination - at post-vaccination months 4 and 5, nAb were only detected in 41.1% (95% CI: 30.9-51.3) and 15.4% (95% CI: 1.5-29.3) of subjects, respectively. Vaccinees in older age groups, those vaccinated with AstraZeneca, and naive individuals showed a lower antibody response. CONCLUSION: The antibody response to SARS-CoV-2 vaccine in the elderly was relatively weak and decreased in the first six months after vaccination. Although humoral immunity is complex and cellular immune memory is a key element of the humoral response after exposure to the wild virus, our results suggest that vaccine-induced humoral immunity may not be long-lasting. The oldest koncenage groups who have not acquired natural SARS-CoV-2 infection are particularly at risk. This finding is relevant for adjusting vaccination strategies in selected population

groups to include a booster dose. More research into the antibody response and the complex immune response after vaccination against SARS-CoV-2 over longer time is needed.

Reactivation of juvenile idiopathic arthritis associated uveitis with posterior segment manifestations following anti-SARS-CoV-2 vaccination. BACKGROUND/PURPOSE: Juvenile idiopathic arthritis (JIA) is the most common rheumatic disease in the pediatric population and anterior uveitis is its commonest extra-articular manifestation. Typically the uveitis presents as chronic anterior uveitis and there is limited literature of the posterior segment manifestations of the disease. Similar to other vaccines, anti-SARS-CoV-2 vaccination that began as an urgent measure to control the spread of the SARS-CoV-2 pandemic has not been without adverse events. We are reporting a 19-year-old Asian Indian female who was diagnosed and treated for JIA associated anterior uveitis that was unilateral and was under anti-inflammatory control but showed worsening of uveitis with posterior segment inflammation in both eyes following anti-SARS-CoV-2 vaccination. CASE REPORT: A 19-year-old Asian Indian female with a history of juvenile idiopathic arthritis on treatment with methotrexate, presented with right eye chronic anterior uveitis with peripheral subclinical retinal vasculitis and macular edema which was brought under control following administration of adalimumab. She was inflammation free for 6â€‰months until she received anti-SARS-CoV-2 vaccination and developed new onset floaters in both eyes that were initially noted after the first dose and increased after the second dose. Clinical examination revealed presence of keratic precipitates and grade 1+ anterior chamber inflammation along with vitiritis in both eyes. Fundus fluorescein angiography revealed angiographically active retinal vasculitis without the presence of macular edema in both eyes. This was managed with a short course of topical difluprednate and continuation of systemic immunosuppressive therapy with adalimumab and methotrexate. CONCLUSION: JIA associated uveitis results from an autoimmune process which can be controlled with timely immunosuppressive treatment. It is important to be aware of the potential risk of flare up of uveitis with posterior segment manifestations following anti- SARS-CoV-2 vaccination.

Association of COVID-19 Vaccination With Risk of COVID-19 Infection, Hospitalization, and Death in Heart Transplant Recipients. IMPORTANCE: Orthotopic heart transplant (OHT) recipients are at increased risk for morbidity and mortality after SARS-CoV-2 infection. Although antibody response to COVID-19 vaccination is lower in solid organ transplant recipients, there has been no study assessing the safety and effectiveness of COVID-19 vaccination in OHT recipients. OBJECTIVE: To assess the safety and effectiveness of COVID-19 vaccination and associations with SARS-CoV-2 infection and clinical outcomes in a large population of adult OHT recipients. DESIGN, SETTING, AND PARTICIPANTS: This case-control study examined data from a US heart transplant program at a single center for all adult recipients of OHT who were followed up from January 15, 2021, through January 31, 2022. MAIN OUTCOMES AND MEASURES: The primary outcome was number of SARS-CoV-2 infections and related hospitalizations, intensive care unit (ICU) admissions, and deaths between vaccinated vs unvaccinated adult recipients of OHT. RESULTS: A total of 436 patients who received OHT were included in the study, of which 106 patients were infected with COVID-19. The mean (SD) age was 54 (17) years; 303 (69.5%) were men and 133 (30.5%) were women. There were 366 patients in the vaccinated cohort with 72 COVID-19 infections (19.7%), 15 hospitalizations (4.1%), 4 ICU admissions (1.1%), and 3 deaths (0.8%). There were 70 patients in the unvaccinated cohort with 34 COVID-19 infections (48.6%), 10 hospitalizations (14.3%), 3 ICU admissions (4.3%), and 3 deaths (4.3%). COVID-19 vaccination was associated with a lower risk of COVID-19 infection (risk ratio [RR], 0.41; 95% CI, 0.30-0.56), hospitalization (RR, 0.29; 95% CI, 0.14-0.61), and death (RR, 0.19; 95% CI, 0.05-0.82). Among the 366 vaccinated OHT recipients, there was no echocardiographic evidence of graft dysfunction, clinically significant rejection, or allosensitization at 6 months after they received the COVID-19 vaccine. CONCLUSIONS AND RELEVANCE: Patients with OHT who are infected with SARS-

CoV-2 are at greater risk of severe infection and death compared with immunocompetent individuals. COVID-19 vaccination was associated with fewer COVID-19 infections, hospitalizations, and deaths, with no heart transplant-specific adverse events. COVID-19 vaccination for all OHT recipients is of paramount importance.

Association of Social Determinants of Health and Vaccinations With Child Mental Health During the COVID-19 Pandemic in the US. IMPORTANCE: The COVID-19 pandemic disproportionately affected mental health in socioeconomically disadvantaged children in the US. However, little is known about the relationship of preexisting and time-varying social determinants of health (SDoH) at individual and structural levels, vaccination eligibility/rates, and the racial and ethnic differences to trajectories of child mental health during the COVID-19 pandemic. OBJECTIVE: To estimate the association of trajectories of child mental health to multilevel SDoH and vaccination eligibility/rates. DESIGN, SETTING, AND PARTICIPANTS: This prospective longitudinal cohort study, conducted from May 16, 2020, to March 2, 2021, integrated structural-level, pandemic-related data with the Adolescent Brain Cognitive Development (ABCD) cohort data (release 4.0). The ABCD study recruited 11â€¯878 children (baseline) and conducted 6 COVID-19 rapid response surveys across 21 US sites (in 17 states) from May 16, 2020, to March 2, 2021. EXPOSURES: Preexisting individual (eg, household income) and structural (area deprivation) SDoH and time-varying individual (eg, food insecurity, unemployment) and structural (eg, social distancing, vaccination eligibility/rates) SDoH. MAIN OUTCOMES AND MEASURES: Perceived Stress Scale, the National Institutes of Health-Toolbox emotion measures, and COVID-19-related worry. RESULTS: The longitudinal sample included 8493 children (mean [SD] age, 9.93 [0.63] years; 5011 girls [47.89%]; 245 Asian [2.34%], 1213 Black [11.59%], 2029 Hispanic [19.39%], 5851 White [55.93%], and 1124 children of other/multiracial ethnicity [10.74%]). Trajectories of stress, sadness, and COVID-19-related worry decreased after adult vaccination rollout. Compared with younger children, boys, White children, or those living with married parents, those who reported greater perceived stress included older children aged 12 to 15 years (Î²â€‰=â€‰0.26; 95% CI, 0.12-0.41; Pâ€‰<â€‰.001); girls (Î²â€‰=â€‰0.75; 95% CI, 0.61-0.89; Pâ€‰<â€‰.001); Hispanic children (Î²â€‰=â€‰0.24; 95% CI, 0.01-0.47; Pâ€‰=â€‰.04); children living with separated parents (Î²â€‰=â€‰0.50; 95% CI, 0.03-0.96; Pâ€‰=â€‰.04); children experiencing disrupted medical health care access (Î²â€‰=â€‰0.19; 95% CI, 0.01-0.36; Pâ€‰=â€‰.04); children living in economically deprived neighborhoods (Î²â€‰=â€‰0.28; 95% CI, 0.05-0.51; Pâ€‰=â€‰.02); children living in areas with more full-time working-class adults who were unable to social distance (Î²â€‰=â€‰1.35; 95% CI, 0.13-2.67; Pâ€‰=â€‰.04); and children living in states with fewer fully vaccinated adults (Î²â€‰=â€‰0.59; 95% CI, 0.16-1.02; Pâ€‰=â€‰.007). COVID-19 pandemic-related worry was higher among Asian children (Î²â€‰=â€‰0.22; 95% CI, 0.08-0.37; Pâ€‰=â€‰.003), Black children (Î²â€‰=â€‰0.33; 95% CI, 0.22-0.43; Pâ€‰<â€‰.001), children of other/multiracial ethnicity (Î²â€‰=â€‰0.17; 95% CI, 0.09-0.25; Pâ€‰<â€‰.001), and children with disrupted medical health care (Î² = 0.15; 95% CI, 0.09-0.21) and disrupted mental health treatment (Î² = 0.11; 95% CI, 0.06-0.16). Inability to afford food was associated with increased sadness (Î²â€‰=â€‰1.50; 95% CI, 0.06-2.93; Pâ€‰=â€‰.04). States with later vaccination eligibility dates for all adults were associated with greater COVID-19-related worry (Î²â€‰=â€‰0.16; 95% CI, 0.01-0.31; Pâ€‰=â€‰.03) and decreased positive affect (Î²â€‰=â€‰-1.78; 95% CI, -3.39 to -0.18; Pâ€‰=â€‰.03) among children. CONCLUSIONS AND RELEVANCE: Results of this study suggest a disproportionately adverse association of the COVID-19 pandemic with child mental health among racial and ethnic minority groups, which may be improved by addressing modifiable individual (food insecurity, unemployment, health services, parental supervision) and structural (area deprivation, job protection, vaccination) SDoH.

Comparison of Multisystem Inflammatory Syndrome in Children-Related Myocarditis, Classic Viral Myocarditis, and COVID-19 Vaccine-Related Myocarditis in Children. Background Although rare, classic viral myocarditis in the pediatric population is a disease that carries significant morbidity and mortality. Since 2020, myocarditis has been a common component of multisystem inflammatory syndrome in children (MIS-C) following SARS-CoV-2 infection. In 2021, myocarditis related to mRNA COVID-19 vaccines was recognized as a rare adverse event. This study aims to compare classic, MIS-C, and COVID-19 vaccine-related myocarditis with regard to clinical presentation, course, and outcomes. Methods and Results In this retrospective cohort study, we compared patients aged <21Â years hospitalized at our institution with classic viral myocarditis from 2015 to 2019, MIS-C myocarditis from March 2020 to February 2021, and vaccine-related myocarditis from May 2021 to June 2021. Of 201 total participants, 43 patients had classic myocarditis, 149 had MIS-C myocarditis, and 9 had vaccine-related myocarditis. At presentation, ejection fraction was lowest for those with classic myocarditis, with ejection fraction <55% present in 58% of patients. Nearly all patients with MIS-C myocarditis (n=139, 93%) and all patients with vaccine-related myocarditis (n=9, 100%) had normal left ventricular ejection fraction at the time of discharge compared with 70% (n=30) of the classic myocarditis group (P<0.001). At 3 months after discharge, of the 21 children discharged with depressed ejection fraction, none of the 10 children with MIS-C myocarditis had residual dysfunction compared with 3 of the 11 (27%) patients in the classic myocarditis group. Conclusions Compared with classic myocarditis, those with MIS-C myocarditis had better clinical outcomes, including rapid recovery of cardiac function. Patients with vaccine-related myocarditis had prompt resolution of symptoms and improvement of cardiac function.

Risk of thrombosis with thrombocytopenia syndrome after COVID-19 vaccination prior to the recognition of vaccine-induced thrombocytopenia and thrombosis: A self-controlled case series study in England. BACKGROUND: Several studies have found increased risks of thrombosis with thrombocytopenia syndrome (TTS) following the ChAdOx1 vaccination. However, case ascertainment is often incomplete in large electronic health record (EHR)-based studies. OBJECTIVES: To assess for an association between clinically validated TTS and COVID-19 vaccination. METHODS: We used the self-controlled case series method to assess the risks of clinically validated acute TTS after a first COVID-19 vaccine dose (BNT162b2 or ChAdOx1) or severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Case ascertainment was performed uninformed of vaccination status via a retrospective clinical review of hospital EHR systems, including active ascertainment of thrombocytopenia. RESULTS: One hundred seventy individuals were admitted to the hospital for a TTS event at the study sites between January 1 and March 31, 2021. A significant increased risk (relative incidence [RI], 5.67; 95% confidence interval [CI], 1.02-31.38) of TTS 4 to 27Â days after ChAdOx1 was observed in the youngest age group (18- to 39-year-olds). No other period had a significant increase, although for ChAdOx1 for all ages combined the RI was >1 in the 4- to 27- and 28- to 41-day periods (RI, 1.52; 95% CI, 0.88-2.63; and (RI, 1.70; 95% CI, 0.73-3.8, respectively). There was no significant increased risk of TTS after BNT162b2 in any period. Increased risks of TTS following a positive SARS-CoV-2 test occurred across all age groups and exposure periods. CONCLUSIONS: We demonstrate an increased risk of TTS in the 4 to 27Â days following COVID-19 vaccination, particularly for ChAdOx1. These risks were lower than following SARS-CoV-2 infection. An alternative vaccine may be preferable in younger age groups in whom the risk of postvaccine TTS is greatest.

Inactivated COVID-19 vaccine triggering hemophagocytic lymphohistiocytosis in an immunocompetent adult - A case report. BACKGROUND AND AIM: Hemophagocytic lymphohistiocytosis (HLH) is a severe hyperinflammatory syndrome that is induced by hyper-activated macrophages, cytotoxic T cells, and reduced natural killer cell activity. A 46-year-old gentleman presented to us with complaints of intermittent fever for the past 2 weeks associated with

fatigue along with oral ulcers and skin rashes which resolved spontaneously. These symptoms started after he received the second dose of the BBIP-CorV COVID-19 vaccine. His complete blood picture showed pancytopenia. A detailed infectious disease workup was unrevealing; however, his bone marrow biopsy revealed increased histiocyte activity, with some showing hemophagocytosis and dysplasia. Immunohistochemistry profile demonstrated strong CD 68 positivity. Further investigations showed raised serum ferritin and fasting triglyceride levels. He was immediately started on dexamethasone acetate at a dose of 10 mg/m(2), after which his clinical symptoms, as well as his blood parameters, improved remarkably. This is the first documented case in Pakistan. CONCLUSION: The data from clinical trials support the general safety profile of inactivated COVID-19 vaccines. We endorse its mass implementation. However, we believe that robust data need to be generated to evidence any adverse events, especially those with serious outcomes. Physicians should be aware of inactivated COVID-19 vaccine as a possible trigger for HLH and start prompt treatment, resulting in favorable outcomes. RELEVANCE FOR PATIENTS: The presentation of HLH may vary and can present in an immunocompetent patient with no underlying risk factor. HLH should be kept in differentials when a patient presents with pancytopenia with a recent history of receiving COVID-19 vaccination. Steroids play a major role in the treatment of HLH, and definitive diagnosis and early treatment improve clinical outcomes.

Intermittent complete heart block with ventricular standstill after Pfizer COVID-19 booster vaccination: A case report. As the COVID-19 pandemic continues around the globe, vaccines are undoubtedly central to the fight to control the spread of the virus. However, as with any therapy, these vaccines are not without side effects. Documented cardiac complications of COVID-19 vaccination include myocarditis, pericarditis, and cardiac conduction abnormalities. Here, we report a novel case of intermittent complete heart block with ventricular standstill occurring within 24 hours of administration of a Pfizer-BioNTech COVID-19 booster vaccine. The patient presented to the emergency department (ED) via ambulance for evaluation of syncope. On arrival, the patient lost pulses as a result of intermittent complete heart block with ventricular standstill. He required cardiopulmonary resuscitation (CPR) with intubation, transcutaneous pacing, and subsequent transvenous pacing in the ED. After stabilization and extensive workup, the patient was diagnosed with lymphocytic myocarditis and complete heart block that is suspected to be secondary to COVID-19 booster vaccination. Ultimately, the patient's complete heart block resolved spontaneously, and he was discharged home with ambulatory rhythm monitoring.

Myocarditis Following the Second Dose of COVID-19 Vaccination in a Japanese Adolescent. As COVID-19 vaccines continue to be deployed worldwide, countries are now planning to vaccinate their pediatric populations as well. However, several vaccine-related adverse events, including myocarditis, have been reported. Although the incidence of myocarditis after BNT162b2 vaccination is low, it is higher, particularly after receiving the second dose, among young male recipients. A 13-year-old male adolescent presented with chest pain after the second dose of the BNT162b2 vaccination. Electrocardiography, echocardiography, cardiac magnetic resonance imaging, and blood examinations were consistent with myocarditis. He was treated conservatively because his symptoms were relatively mild. In Japan, it is expected that the chances of diagnosing vaccine-related myocarditis will increase as more children are getting vaccinated. Our case report raises concerns to physicians that the COVID-19 vaccination may cause rare cases of myocarditis, which must always be considered as a differential diagnosis.

Ad26.COV2.S breakthrough infections induce high titers of neutralizing antibodies against Omicron and other SARS-CoV-2 variants of concern. The Janssen (Johnson & Johnson) Ad26.COV2.S non-replicating viral vector vaccine has been widely deployed for COVID-19 vaccination programs in resource-limited settings. Here we confirm that neutralizing and binding antibody responses to

Ad26.COV2.S vaccination are stable for 6Â months post-vaccination, when tested against multiple SARS-CoV-2 variants. Secondly, using longitudinal samples from individuals who experienced clinically mild breakthrough infections 4 to 5Â months after vaccination, we show dramatically boosted binding antibodies, Fc effector function, and neutralization. These high titer responses are of similar magnitude to humoral immune responses measured in convalescent donors who had been hospitalized with severe illness, and are cross-reactive against diverse SARS-CoV-2 variants, including the neutralization-resistant Omicron (B.1.1.529) variant that currently dominates global infections, as well as SARS-CoV-1. These data have implications for population immunity in areas where the Ad26.COV2.S vaccine has been widely deployed, but where ongoing infections continue to occur at high levels.

Enhanced immunity after Ad26.COV2.S vaccine breakthrough infection. A study by Kitchin, Richardson etÂ al. finds that breakthrough infection with the SARS-CoV-2 Delta variant in Ad26.COV2.S-vaccinated individuals induces strong neutralizing antibody responses against multiple variants, including the Omicron variant.

A cross-sectional study of factors associated with COVID-19 testing among people who inject drugs: missed opportunities for reaching those most at risk. BACKGROUND: People who inject drugs (PWID) are vulnerable to SARS-CoV-2 infection. We examined correlates of COVID-19 testing among PWID in the U.S.-Mexico border region and described encounters with services representing potential opportunities (i.e., 'touchpoints') where COVID-19 testing could have been offered. METHODS: Between October, 2020 and September, 2021, participants aged â‰¥18â€‰years from San Diego, California, USA and Tijuana, Baja California, Mexico who injected drugs within the last month completed surveys and SARS-CoV-2, HIV, and HCV serologic testing. Logistic regression identified factors associated with COVID-19 testing including potential touchpoints, comorbidities and COVID-19 related misinformation and disinformation. RESULTS: Of 583 PWID, 30.5% previously had a COVID-19 test. Of 172 PWID who tested SARS-CoV-2 seropositive (30.1%), 50.3% encountered at least one touchpoint where COVID-19 testing could have been offered within the prior six months. Factors independently associated with at least two fold higher odds of COVID-19 testing were living in San Diego, recent incarceration, receiving substance use treatment, and experiencing â‰¥1 chronic health condition. Homelessness, having received â‰¥1 dose of COVID-19 vaccine, and having a HIV or HCV test since the COVID-19 epidemic began were also independently associated with having had a prior COVID-19 test. CONCLUSION: We identified several factors independently associated with COVID-19 testing and multiple touchpoints where COVID-19 testing could be scaled up for PWID, such as SUD treatment programs and syringe service programs. Integrated health services are needed to improve access to rapid, free COVID-19 testing in this vulnerable population.

Outcomes of single dose COVID-19 vaccines: Eight month follow-up of a large cohort in Saudi Arabia. BACKGROUND: Two vaccines for COVID-19 have been approved and administered in the Kingdom of Saudi Arabia (KSA); Pfizer-BioNtech BNT162b2 and AstraZeneca-Oxford AZD1222 vaccines. The purpose of this study was to describe the real-world data on the outcome of single dose of these COVID-19 vaccines in a large cohort in KSA and to analyse demographics and co-morbidities as risk factors for infection post one-dose vaccination. METHODS: In this prospective cohort study, a total of 18,543 subjects received one dose of either of the vaccines at a vaccination centre in KSA, and were followed up for three to eight months. Data were collected from three sources; clinical data from medical records, adverse events (AEs) from a self-reporting system, and COVID-19 infection data from the national databases. The study was conducted during the pandemic restrictions on travel, mobility, and social interactions. RESULTS: The median age of participants was 33 years with an average body mass index of 27.3. The majority were males (60.1%). Results showed that 92.17% of the subjects had no COVID-19 infection post-vaccination as infection post-vaccination was documented for 1452

(7.83%). Diabetes mellitus 03), organ transplantation (pÂ =Â 0.02), and obesity (pÂ <Â 0.01) were associated with infection post-vaccination. Unlike vaccine type, being Saudi, male, or obese was associated with the occurrence breakthrough infections more than other parameters. AEs included injection site pain, fatigue, fever, myalgia, headache and was reported by 5.8% of the subjects. CONCLUSION: Single dose COVID-19 vaccines showed a protection rate of 92.17% up to eight months follow-up in this cohort. This rate in AZD1222 was higher than what have been previously reported in effectiveness studies and clinical trials. Obese, male, and Saudi were at higher risk of contracting the infection post-vaccination, Saudi and male might have more social interaction with the public when mobility and social interactions were limited during the pandemic. Side effects and AEs were within what has been reported in clinical trials.

Accelerated waning of immunity to SARS-CoV-2 mRNA vaccines in patients with immune-mediated inflammatory diseases. BACKGROUNDLimited information is available on the impact of immunosuppressants on COVID-19 vaccination in patients with immune-mediated inflammatory diseases (IMID).METHODSThis observational cohort study examined the immunogenicity of SARS-CoV-2 mRNA vaccines in adult patients with inflammatory bowel disease, rheumatoid arthritis, ankylosing spondylitis, or psoriatic disease, with or without maintenance immunosuppressive therapies. Ab and T cell responses to SARS-CoV-2, including neutralization against SARS-CoV-2 variants, were determined before and after 1 and 2 vaccine doses.RESULTSWe prospectively followed 150 subjects, 26 healthy controls, 9 patients with IMID on no treatment, 44 on anti-TNF, 16 on anti-TNF with methotrexate/azathioprine (MTX/AZA), 10 on anti-IL-23, 28 on anti-IL-12/23, 9 on anti-IL-17, and 8 on MTX/AZA. Ab and T cell responses to SARS-CoV-2 were detected in all participants, increasing from dose 1 to dose 2 and declining 3 months later, with greater attrition in patients with IMID compared with healthy controls. Ab levels and neutralization efficacy against variants of concern were substantially lower in anti-TNF-treated patients than in healthy controls and were undetectable against Omicron by 3 months after dose 2.CONCLUSIONSOur findings support the need for a third dose of the mRNA vaccine and for continued monitoring of immunity in these patient groups.FUNDINGFunded by a donation from Juan and Stefania Speck and by Canadian Institutes of Health (CIHR)/COVID-Immunity Task Force (CITF) grants VR-1 172711 and VS1-175545 (to THW and ACG), CIHR FDN-143250 (to THW), GA2-177716 (to VC, ACG, and THW), and GA1-177703 (to ACG) and the CIHR rapid response network to SARS-CoV-2 variants, CoVaRR-Net (to ACG).

Incidence of Guillain-BarrÃ© Syndrome After COVID-19 Vaccination in the Vaccine Safety Datalink. IMPORTANCE: Postauthorization monitoring of vaccines in a large population may detect rare adverse events not identified in clinical trials such as Guillain-BarrÃ© syndrome (GBS), which has a background rate of 1 to 2 per 100â€¯000 person-years. OBJECTIVE: To describe cases and incidence of GBS following COVID-19 vaccination and assess the risk of GBS after vaccination for Ad.26.COV2.S (Janssen) and mRNA vaccines. DESIGN, SETTING, AND PARTICIPANTS: This cohort study used surveillance data from the Vaccine Safety Datalink at 8 participating integrated health care systems in the United States. There were 10â€¯158â€¯003 participants aged at least 12 years. Data analysis was performed from November 2021 to February 2022. EXPOSURES: Ad.26.COV2.S, BNT162b2 (Pfizer-BioNTech), or mRNA-1273 (Moderna) COVID-19 vaccine, including mRNA vaccine doses 1 and 2, December 13, 2020, to November 13, 2021. MAIN OUTCOMES AND MEASURES: GBS with symptom onset in the 1 to 84 days after vaccination, confirmed by medical record review and adjudication. Descriptive characteristics of confirmed cases, GBS incidence rates during postvaccination risk intervals after each type of vaccine compared with the background rate, rate ratios (RRs) comparing GBS incidence in the 1 to 21 vs 22 to 42 days postvaccination, and RRs directly comparing risk of GBS after Ad.26.COV2.S vs mRNA vaccination, using Poisson regression adjusted for age, sex, race and ethnicity, site, and calendar day. RESULTS: From December 13, 2020, through November 13, 2021,

15â€¯120â€¯073 doses of COVID-19 vaccines were administered to 7â€¯894â€¯989 individuals (mean [SE] age, 46.5 [0.02] years; 8â€¯138â€¯318 doses received [53.8%] by female individuals; 3â€¯671â€¯199 doses received [24.3%] by Hispanic or Latino individuals, 2â€¯215â€¯064 doses received [14.7%] by Asian individuals, 6â€¯266â€¯424 doses received [41.4%] by White individuals), including 483â€¯053 Ad.26.COV2.S doses, 8â€¯806â€¯595 BNT162b2 doses, and 5â€¯830â€¯425 mRNA-1273 doses. Eleven cases of GBS after Ad.26.COV2.S were confirmed. The unadjusted incidence rate of GBS per 100â€¯000 person-years in the 1 to 21 days after Ad.26.COV2.S was 32.4 (95% CI, 14.8-61.5), significantly higher than the background rate, and the adjusted RR in the 1 to 21 vs 22 to 42 days following Ad.26.COV2.S was 6.03 (95% CI, 0.79-147.79). Thirty-six cases of GBS after mRNA vaccines were confirmed. The unadjusted incidence rate per 100â€¯000 person-years in the 1 to 21 days after mRNA vaccines was 1.3 (95% CI, 0.7-2.4) and the adjusted RR in the 1 to 21 vs 22 to 42 days following mRNA vaccines was 0.56 (95% CI, 0.21-1.48). In a head-to-head comparison of Ad.26.COV2.S vs mRNA vaccines, the adjusted RR was 20.56 (95% CI, 6.94-64.66). CONCLUSIONS AND RELEVANCE: In this cohort study of COVID-19 vaccines, the incidence of GBS was elevated after receiving the Ad.26.COV2.S vaccine. Surveillance is ongoing.

Reactogenicity of COVID-19 vaccine in hemodialysis patients: a single-center retrospective study. Introduction: Some hemodialysis patients are reluctant to undergo COVID-19 vaccination for the fear of developing adverse events (AEs). The aim of this study was to verify the safety of the mRNA-1273 vaccine in hemodialysis patients. Methods: We conducted a retrospective analysis of in-center hemodialysis patients who underwent mRNA-1273 vaccine from March 1st to April 30th, 2021. All AEs occurring after the first and the second doses were collected and classified as local or systemic. Results: Overall, 126 patients on chronic maintenance dialysis without a prior COVID-19 diagnosis were vaccinated with two doses of mRNA-1273 vaccine. Mean age was 68 (IQR, 54,7-76) years and 53.6% of patients were aged â‰¥65 years. During the observational period of 68 (IQR, 66-70) days, AEs occurred in 57.9% and 61.9% of patients after the first dose and second dose, respectively. The most common AEs were: injection-site pain (61.9%), erythema (4.8%), itching (4.8%), swelling (16.7%), axillary swelling/tenderness (2.4%), fever (17.5%) headache (7.9%), fatigue (23.8%), myalgia (17.5%), arthralgia (12.7%), dyspnoea (2.4%), nausea/vomiting (7.1%), diarrhoea (5.6%), shivers (4%) and vertigo (1.6%). The rates of local AEs were similar after the first and second doses (P=0.8), whereas systemic AEs occurred more frequently after the second dose (P=0.001). Fever (P=0.03), fatigue (P=0.02) and nausea/vomiting (P=0.03) were significantly more frequent after the second dose of the vaccine. There were no age-related differences in the rate of AEs. Overall, vaccine-related AEs in hemodialysis patients seem to be lower than in the general population. Conclusion: The RNA-1273 vaccine was associated with the development of transient AEs after the first and second doses in patients on chronic maintenance hemodialysis. They were mostly local, whereas systemic AEs were more prevalent after the second dose. Overall, all AEs lasted for a few days, without any apparent sequelae.

[A possible relationship between anti-SARS-CoV-2 vaccination and glomerular diseases: food for thought for the nephrologist]. In order to fight the SARS-CoV-2 pandemic, mass-vaccination programs have been launched globally starting December 2020. The pace of COVID-19 vaccines development was impressive and although data from clinical trials and post-authorization studies showed acceptable safety profile, additional studies and long-term population-level surveillance are needed. A possible link between all type of vaccination and immunological diseases is perhaps one of the hottest topics in literature; correspondingly, there is growing concern over the small but growing number of case reports linking COVID-19 vaccines with the development of glomerular disease. Our group conducted a systematic review of such cases. Results showed that IgA nephropathy (IgAN) and Minimal Change Disease (MCD) are the most frequently associated glomerulopathies. Interestingly,

IgAN cases are mostly flares occurring few hours after the second dose of RNA vaccines and have a good clinical outcome, while both de novo and recurring MCD can occur up to 28 days after the first or second dose of vaccines. RNA vaccines are the most common vaccine type to be associated with glomerulopathy. Of course, this may simply reflect the more widespread use of these vaccines. However, compared to traditional vaccines, they do seem produce a higher antibody response and a stronger CD8+â€‰T- and CD4+â€‰T-cell response, including higher production of chemokines and cytokines.

A Case of Myocarditis Presenting With a Hyperechoic Nodule After the First Dose of COVID-19 mRNA Vaccine. Myocarditis and/or pericarditis have been reported as adverse events following coronavirus disease 2019 (COVID-19) messenger RNA vaccination, with most cases occurring within 1 week after the second dose. We report a rare case of myocarditis after the first dose of the BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine in a 17-year-old boy. Here, we describe the laboratory, electrocardiographic, and imaging findings of myocarditis.

Severe myocarditis after SARS-CoV-2 vaccination in a 49-year-old woman.

SARS-CoV2 wild type and mutant specific humoral and T cell immunity is superior after vaccination than after natural infection. OBJECTIVE: We investigated blood samples from fully SARS-CoV2-vaccinated subjects and from previously positive tested patients up to one year after infection with SARS-CoV2, and compared short- and long-term T cell and antibody responses, with a special focus on the recently emerged delta variant (B.1.617.2). METHODS AND RESULTS: In 23 vaccinated subjects, we documented high anti-SARS-CoV2 spike protein receptor binding domain (RBD) antibody titers. Average virus neutralization by antibodies, assessed as inhibition of ACE2 binding to RBD, was 2.2-fold reduced for delta mutant vs. wild type (wt) RBD. The mean specific antibody titers were lower one year after natural infection than after vaccination; ACE2 binding to delta mutant vs. wt RBD was 1.65-fold reduced. In an additional group, omicron RBD binding was reduced compared to delta. Specific CD4+ T cell responses were measured after stimulation with peptides pools from wt, alpha, beta, gamma, or delta variant SARS-CoV2 spike proteins by flow cytometric intracellular cytokine staining. There was no significant difference in cytokine production of IFN-Î³, TNF-Î±, or IL-2 between vaccinated subjects. T cell responses to wt or mutant SARS-CoV2 spike were significantly weaker after natural occurring infections compared to those in vaccinated individuals. CONCLUSION: Antibody neutralisation of the delta mutant was reduced compared to wt, as assessed in a novel inhibition assay with a finger prick blood drop. Strong CD4 T cell responses were present against wt and mutant SARS-CoV2 variants, including the delta (B.1.617.2) strain, in fully vaccinated individuals, whereas they were partly weaker 1 year after natural infection. Hence, immune responses after vaccination are stronger compared to those after naturally occurring infection, pointing out the need of the vaccine to overcome the pandemic.

Risk of Appendicitis After mRNA COVID-19 Vaccination in a Danish Population. This cohort study used data from Danish registers to assess whether recipients of mRNA COVID-19 vaccines had a higher risk of appendicitis after receiving the shot compared with individuals who did not receive the vaccine.

Structure of a Vaccine-Induced, Germline-Encoded Human Antibody Defines a Neutralizing Epitope on the SARS-CoV-2 Spike N-Terminal Domain. Structural characterization of infection- and vaccination-elicited antibodies in complex with antigen provides insight into the evolutionary arms race between the host and the pathogen and informs rational vaccine immunogen design. We isolated a germ line-encoded monoclonal antibody (mAb) from plasmablasts activated upon mRNA vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and determined its structure in complex with the spike glycoprotein by electron cryomicroscopy (cryo-EM). We show that the mAb engages a previously uncharacterized neutralizing epitope on the spike N-terminal

domain (NTD). The high-resolution structure reveals details of the intermolecular interactions and shows that the mAb inserts its heavy complementarity-determining region 3 (HCDR3) loop into a hydrophobic NTD cavity previously shown to bind a heme metabolite, biliverdin. We demonstrate direct competition with biliverdin and that, because of the conserved nature of the epitope, the mAb maintains binding to viral variants B.1.1.7 (alpha), B.1.351 (beta), B.1.617.2 (delta), and B.1.1.529 (omicron). Our study describes a novel conserved epitope on the NTD that is readily targeted by vaccine-induced antibody responses. IMPORTANCE We report the first structure of a vaccine-induced antibody to SARS-CoV-2 spike isolated from plasmablasts 7â€‰days after vaccination. The genetic sequence of the antibody PVI.V6-14 suggests that it is completely unmutated, meaning that this type of B cell did not undergo somatic hypermutation or affinity maturation; this cell was likely already present in the donor and was activated by the vaccine. This is, to our knowledge, also the first structure of an unmutated antibody in complex with its cognate antigen. PVI.V6-14 binds a novel, conserved epitope on the N-terminal domain (NTD) and neutralizes the original viral strain. PVI.V6-14 also binds the newly emerged variants B.1.1.7 (alpha), B.1.351 (beta), B.1.617.2 (delta), and B.1.1.529 (omicron). Given that this antibody was likely already present in the donor prior to vaccination, we believe that this antibody class could potentially "keep up" with the new variants, should they continue to emerge, by undergoing somatic hypermutation and affinity maturation.

Response to "An old entity, a new trigger: Post COVID-19 vaccine pityriasis rubra pilaris".

Acute Myocarditis Following Vaccination With the First Dose of the mRNA-1273 Vaccine. Viral infections are a common cause of acute myocarditis. However, vaccines including influenza and smallpox have also been rarely implicated. Recently, the coronavirus disease 2019 (COVID-19) vaccines have been associated with acute myocarditis. We describe a case of acute myocarditis in a 19-year-old male 2 days after the initial dose of the COVID-19 mRNA-1273 vaccine. He presented with chest pain radiating to his left arm and bilateral shoulders. COVID, influenza, coxsackie, respiratory syncytial virus polymerase chain reaction (PCR) tests were negative. Electrocardiogram revealed diffuse ST-segment elevation. Initial Troponin was 15.7 ng/mL. A coronary angiogram revealed patent coronary arteries and no wall motion abnormality. A transthoracic echocardiogram showed diffuse hypokinesis with an ejection fraction of 49%. Cardiac magnetic resonance scan was aborted after 2 attempts due to severe claustrophobia. His chest pain resolved following initiation of aspirin, tylenol, colchicine, lisinopril, and metoprolol.

Impact of COVID-19 vaccine-associated side effects on health care worker absenteeism and future booster vaccination. BACKGROUND: Short-term side effects related to mRNA vaccines against SARS-CoV-2 are frequent and bothersome, with the potential to disrupt work duties and impact future vaccine decision-making. OBJECTIVE: To identify factors more likely to lead to vaccine-associated work disruption, employee absenteeism, and future vaccine reluctance among healthcare workers (HCWs). HYPOTHESIS: Side effects related to COVID vaccination: 1- frequently disrupt HCW duties, 2- result in a significant proportion of HCW absenteeism, 3- contribute to uncertainty about future booster vaccination, 4- vary based on certain demographic, socioeconomic, occupational, and vaccine-related factors. METHODS: Using an anonymous, voluntary electronic survey, we obtained responses from a large, heterogeneous sample of COVID-19-vaccinated HCWs in two healthcare systems in Southern California. Descriptive statistics and regression models were utilized to evaluate the research questions. RESULTS: Among 2,103 vaccinated HCWs, 579 (27.5%) reported that vaccine-related symptoms disrupted their professional responsibilities, and 380 (18.1%) missed work as a result. Independent predictors for absenteeism included experiencing generalized and work-disruptive symptoms, and receiving the Moderna vaccine [ORÂ =Â 1.77 (95% CIÂ =Â 1.33 - 2.36), pÂ <Â 0.001]. Physicians were less likely to miss work due to side effects (6.7% vs 21.2% for all other HCWs, pÂ <Â 0.001). Independent predictors of reluctance toward future booster vaccination

included lower education level, younger age, having received the Moderna vaccine, and missing work due to vaccine-related symptoms. CONCLUSION: Symptoms related to mRNA vaccinations against SARS-CoV-2 may frequently disrupt work duties, lead to absenteeism, and impact future vaccine decision-making. This may be more common in Moderna recipients and less likely among physicians. Accordingly, health employers should schedule future booster vaccination cycles to minimize loss of work productivity.

Seroprevalence and Dynamics of anti-SARS-CoV-2 antibody among healthcare workers following ChAdOx1 nCoV-19 vaccination. Health care workers (HCWs) are in a higher risk of acquiring the disease owing to their regular contact with the patients. The aim of this study is to evaluate the seroprevalence among HCWs pre- and post-vaccination. The serological assessment of anti-SARS-CoV-2 antibody was conducted in pre- and post-vaccination of first or both doses of the ChAdOx1 nCoV-19 vaccine and followed up to 8 months for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and antibody titre. The neutralising antibody was positively correlated with IgG and total antibody. IgG was significantly decreased after 4â€“6 months post-infection. Almost all HCWs developed IgG after 2 doses of vaccine with comparable IgG to that of the infected HCWs. A follow-up of 6 to 8 months post vaccination showed a significant drop in antibody titre, while 56% of them didn't show a detectable level of IgG, suggesting the need for a booster dose. Around 21% of the vaccinated HCWs with significantly low antibody titre were infected with the SARS-CoV-2, but a majority of them showed mild symptoms and recovered in home isolation without any O(2) support. We noticed the effectiveness of the ChAdOx1 nCoV-19 vaccine as evident from the low rate of breakthrough infection with any severe symptoms.

COVID-19 mRNA Vaccine-Associated Myocarditis Presenting as STEMI in a 48-Year-Old Male. Myocarditis has been recognized as a rare complication of coronavirus disease 2019 (COVID-19) mRNA vaccinations. Young adult and adolescent males < 30 years of age are the most commonly affected group, with decreased incidence with older age. This is a case of a 48-year-old male who presented with chest pain and EKG findings of STEMI shortly after receiving the second dose of the Moderna COVID-19 mRNA vaccine. Emergent left heart catheterization revealed normal coronaries. Subsequently, the patient had rapid resolution of his symptoms and improvement in serum markers. The exact etiology factors to this new and rare phenomenon are yet to be fully understood. This patient did have a history of previous viral myocarditis 7 years ago; however, it remains unclear if this could be a predisposing factor to the development of mRNA vaccine-associated myocarditis.

Ischemic retinal events after COVID-19 vaccination. PURPOSE: We report 2 cases of ischemic retinal events occurring soon after administration of the Moderna and Johnson & Johnson/Janssen COVID-19 vaccines. To our knowledge, these are the first reports of isolated ischemic retinal events occurring after COVID-19 vaccination. OBSERVATIONS: A 57-year-old female had new onset floaters of the left eye within days of her second Moderna COVID-19 vaccination, which progressively worsened prompting her to present for evaluation. She was diagnosed with a branch retinal vein occlusion in the left eye. A 20-year-old female presented with persistent central scotomata in both eyes, which she first noticed two days after her Johnson & Johnson/Jannsen COVID-19 vaccination. She was diagnosed with acute macular neuroretinopathy of both eyes. CONCLUSIONS AND IMPORTANCE: The potential side effects of COVID-19 vaccines are still being established; however, there has been concern over pro-thrombotic events with these vaccines, with most concerns directed toward the Johnson & Johnson vaccine. We observed likely transient pro-thrombotic retinal milieu in patients who received these vaccines though it remains unclear whether there is a shared mechanism between systemic response to the COVID-19 spike protein and the highly pro-thrombotic state seen in COVID-19 infections. In the case of our patients, we postulate their immunologic responses to the vaccines - and possibly a resultant pro-thrombotic state - may have precipitated their ischemic retinal

events. We thus recommend that patients with ocular symptoms after COVID-19 vaccination undergo comprehensive ophthalmologic evaluation.

Comparing the human milk antibody response after vaccination with four COVID-19 vaccines: A prospective, longitudinal cohort study in the Netherlands. BACKGROUND: Vaccination of lactating women against COVID-19 may protect not only themselves but also their breastfed infant through human milk. Therefore, it is important to gain insight into the human milk antibody response after immunization with the various vaccines that are currently widely used. The aim of this study is to determine and compare the antibody response in human milk following vaccination with mRNA- and vector-based vaccines up to over two months post-vaccination. METHODS: This prospective cohort study was conducted in the Netherlands between January 06, 2021 and July 31, 2021. Participants were recruited through social media. Human milk samples were collected longitudinally during a period of 70 days from women receiving one of the four different severe acute respiratory coronavirus 2 (SARS-CoV-2) vaccines: Pfizer-BioNTech (BNT162b2), Moderna (mRNA-1273), Oxford/AstraZeneca (AZD1222) and Johnson&Johnson (Ad26.COV2.S). SARS-CoV-2-specific antibodies were measured using an enzyme-linked immunosorbent assay. The area under the curve (AUC) of the Immunoglobulins A (IgA) and G (IgG) antibody response was determined over 15 and 70 days following the first vaccination and compared between the different vaccines. FINDINGS: This study enrolled 134 vaccinated lactating women of whom 97 participated the entire study period. In total, 1887 human milk samples were provided. The human milk antibody response differed between SARS-CoV-2 vaccines over the study period. The mean AUC of SARS-CoV-2-specific IgA, but not IgG, in human milk over 15 days was higher after vaccination with an mRNA-based vaccine than a vector-based vaccine (AUC with respect to ground [AUCg] Â± the standard error of the mean [SEM] for IgA was 6Â·09 Â± 0Â·89 in the BNT162b2 group, 7Â·48 Â± 1Â·03 in the mRNA-1273 group, 4Â·17 Â± 0Â·73 in the AZD1222 group, and 5Â·71 Â± 0Â·70 in the Ad26.COV2.S group). Over a period of 70 days, the mean AUCg of both IgA and IgG was higher after vaccination with an mRNA-based vaccine than a vector-based vaccine (AUCg Â± SEM for IgA was 38Â·77 Â± 6Â·51 in the BNT162b2 group, 50Â·13 Â± 7Â·41 in the mRNA-1273 group, 24Â·12 Â± 5Â·47 in the AZD1222 group, and 28Â·15 Â± 6Â·69 in the Ad26.COV2.S group; AUCg Â± SEM for IgG was 40Â·43 Â± 2Â·67 in the BNT162b2 group, 37Â·01 Â± 2Â·38 in the mRNA-1273 group, 16Â·04 Â± 5Â·09 in the AZD1222 group, and 10Â·44 Â± 2Â·50 in the Ad26.COV2.S group). INTERPRETATION: Overall, maternal vaccination during lactation with an mRNA-based vaccine resulted in higher SARS-CoV-2 antibody responses in human milk compared to vector-based vaccines. Therefore, vaccination with mRNA-based vaccines, preferably with the mRNA-1273 vaccine, might not only provide better immunological protection for the mother but also for her breastfed infant. FUNDING: Stichting Steun Emma Kinderziekenhuis and the Amsterdam Infection and Immunity Institute (grant 24175).

Severe thrombocytopenia after Vaxzevria vaccination in a single patient: A case report. AstraZeneca vaccine became one of the four vaccines that encode different forms of the SARS-CoV-2 spike glycoprotein. We report the case of an 18-year-old medically free female with progressive bruising of the upper and lower extremities for 1â€‰week, beginning 3â€‰days after the first dose of AstraZeneca. Laboratory results showed severe thrombocytopenia of 4.3â€‰Ã—â€‰10(3)/ÂµL with a normal white blood cell count, renal profile, and hemolytic markers. She was treated conservatively with high-dose steroids and intravenous immunoglobulin, which resulted in a full recovery of her platelet count. In our case, the question was raised about the possibility of receiving a second dose of another vaccine product instead of not being vaccinated again, a subject for further research.

BNT162b2 COVID-19 Vaccine Induced Immune Thrombocytopenic Purpura. Immune thrombocytopenic purpura (ITP) has been reported following vaccinations such as MMR as well as

after viral infections such as hepatitis C and HIV. Few case reports have been reported of ITP after COVID-19 infections and COVID-19 vaccines. Herein, we present a patient who presented with severe ITP with a platelet count of 0 after receiving the second dose of the BNT162b2 mRNA COVID-19 vaccine (also known as the Pfizer BioNTech). She subsequently recovered with a prolonged treatment course.

Th2-Oriented Immune Serum After SARS-CoV-2 Vaccination Does Not Enhance Infection In Vitro. The relatively lower protection rate of the alum-adjuvanted inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines reminds us of the antibody-dependent enhancement (ADE) phenomenon observed in preclinical studies during the development of vaccines for Middle East respiratory syndrome coronavirus (MERS-CoV) and severe acute respiratory syndrome coronavirus 1 (SARS-CoV-1). In this study, using the S1 segment of the SARS-CoV-2 spike protein or inactivated whole SARS-CoV-2 virus as an antigen and aluminum as an adjuvant, the risk of ADE of infection with T helper 2 (Th2)-oriented immune serum from mice (N=6) and humans (N=5) was examined in immune cell lines, which show different expression patterns of Fc receptors. Neither the immune serum from alum-adjuvanted S1 subunit vaccines nor inactivated SARS-CoV-2 vaccination enhanced SARS-CoV-2 S pseudotyped virus infection in any of the tested cell lines in vitro. Because both of these Th2-oriented immune sera could block SARS-CoV-2 infection without ADE of infection, we speculate that the lower protection rate of the inactivated SARS-CoV-2 vaccine may be attributed to the lower neutralizing antibody titers induced or the pulmonary eosinophilic immunopathology accompanied by eosinophilic infiltration in the lungs upon virus exposure. Adjustment of the immunization schedule to elevate the neutralizing antibody levels and skew adjuvants toward Th1-oriented responses may be considered to increase the efficacies of both inactivated and spike protein-based subunit SARS-CoV-2 vaccines.

Case Report: Precision COVID-19 Immunization Strategy to Overcome Individual Fragility: A Case of Generalized Lipodystrophy Type 4. A 48-year-old patient affected with congenital generalized lipodystrophy type 4 failed to respond to two doses of the BNT162b2 vaccine, consisting of lipid nanoparticle encapsulated mRNA. As the disease is caused by biallelic variants of CAVIN1, a molecule indispensable for lipid endocytosis and regulation, we complemented the vaccination cycle with a single dose of the Ad26.COV2 vaccine. Adenovirus-based vaccine entry is mediated by the interaction with adenovirus receptors and transport occurs in clathrin-coated pits. Ten days after Ad26.COV2 administration, S- and RBD-specific antibodies and high-affinity memory B cells increased significantly to values close to those observed in Health Care Worker controls.

Decreased and Heterogeneous Neutralizing Antibody Responses Against RBD of SARS-CoV-2 Variants After mRNA Vaccination. The rapid spread of Severe Acute Respiratory SyndromeÂ Coronavirus 2 (SARS-CoV-2) emerging variants raises concerns about their capacity to evade immune protection provided by natural infection or vaccination. The receptor-binding domain (RBD) of the viral spike protein is the major target of neutralizing antibodies, and viral variants accumulate mutations in this region. In this study, we determined the antibody neutralization capacity against the RBD of SARS-CoV-2 variants Alpha (B.1.1.7), Gamma (P.1), Epsilon (B.1.427), Kappa (B.1.617.1), and Delta (B.1.617.2) in a cohort of healthcare workers naturally infected or receiving COVID-19 mRNA vaccines from Moderna or Pfizer-BioNTech. We show that the five RBD variants displayed an augmented binding to ACE2 compared to the original Wuhan strain. The most significant increase was observed in variants Epsilon and Delta, containing mutation L452R. Using a flow cytometry cell-based assay, we found that SARS-CoV-2-infected subjects presented low levels of RBD-specific neutralizing antibodies against all variants analyzed, except Alpha. However, the neutralizing activity incremented considerably after a subsequent mRNA-vaccine dose, to levels significantly higher than those in naÃ¯ve individuals receiving two vaccine doses. Importantly, we observed partially impaired

neutralizing responses against most variants in fully vaccinated individuals. Variants Gamma and Kappa encompassing RBD E484K/Q mutations presented the highest neutralizing resistance. Furthermore, a wide heterogeneity in the magnitude of RBD-specific neutralizing responses against all tested SARS-CoV-2 variants following both mRNA vaccines was detected. Altogether, our findings provide important knowledge regarding SARS-CoV-2 vaccine-induced immunity, and should be very useful to guide future vaccination regimens and personalized vaccine approaches.

The Effects of COVID-19 Vaccination on Lactating Women: A Systematic Review of the Literature. OBJECTIVES: The availability of new vaccines against COVID-19 urges for guidance about vaccination during lactation. We aimed to review the literature to get an insight into the effects of COVID-19 vaccination on lactating women. DESIGN: Systematic review. DATA SOURCES: We searched Ovid Embase Classic+Embase, PubMed and BioMed Central for articles published between December 1(st) 2020 and December 31(st) 2021. REVIEW METHODS: The search strategy contained terms and combinations related to COVID-19 vaccination during lactation, including the MeSH terms "COVID-19", "COVID-19 Vaccines", "SARS-CoV-2", "Lactation", "Breast Feeding", "Pregnancy" and "Postpartum period". The database search was completed with a manual search of the reference lists of included articles. Data concerning country, study period, number of participants, type of applied vaccine, time points of sampling and outcome measures were collected from the selected manuscripts. The data are summarized and synthesized in a descriptive way. RESULTS: 30 manuscripts were included in this review. Data on safety of COVID-19 vaccination during lactation indicate no severe vaccine-related local and systemic reactions, both after first and second dose, neither in the mother nor the nursing child. No significant amount of vaccine components seems to appear in breast milk. Milk supply data after vaccination are inconclusive as there are no quantitative data available. Some women however observe a temporary increase or reduction in milk supply, without long-term effects. All prospective cohort studies demonstrated the presence of SARS-CoV-2-specific antibodies in breast milk of nursing mothers vaccinated against SARS-CoV-2. Nearly all studies were conducted with mRNA vaccines. CONCLUSION: There is evidence that the administration of a COVID-19 vaccine is safe and poses no additional risk to the breastfeeding woman or the breastfed baby. After vaccination of the mother during the lactation period, antibodies appear in the milk, which could protect the infant against COVID-19. Professional associations and government health authorities should therefore recommend offering COVID-19 vaccines to breastfeeding women, as the potential benefits of maternal vaccination while breastfeeding outweigh the risks.

Coincidence of Sarcoidosis and a COVID-19 vaccine-associated hypermetabolic lymphadenopathy in a patient with a history of invasive breast cancer: A case report. INTRODUCTION AND IMPORTANCE: Vaccine-associated hypermetabolic lymphadenopathy (VAHL) after a COVID 19 vaccination is a common adverse event and also a diagnostic challenge especially in patients with a history of a malignancy. CASE PRESENTATIONS: A 47-year-old woman presented with enlarged lymph nodes in the right hilar, subcarinal, and right supraclavicular regions detected by computed tomography as a postoperative follow-up study of thyroid cancer. Fluorine-18 fluoro-2-deoxy-d-glucose positron emission tomography (FDG-PET) performed 3Â weeks later revealed an FDG uptake in those swollen lymph nodes and in the novel lymphadenopathy in the left axilla and left subclavicular regions. Both biopsy specimens from the right supraclavicular and hilar lymph nodes revealed only multiple small granulomas with multinucleated giant cells without malignancy, consistent with sarcoidosis. The left axilla and subclavicular lymphadenopathy detected by the FDG-PET subsequently spontaneously regressed. CLINICAL DISCUSSION: The coincidental occurrence of VAHL and lymphadenopathy in sarcoidosis patients could cause diagnostic confusion especially in those with breast cancer. CONCLUSION: Sufficient attention should be paid both to the injection site

and the time interval between the vaccination and imaging test in the era of nationwide mass vaccinations against COVID 19.

Case Series of Potential Cardiac Inflammation Associated With Various SARS-CoV-2 Vaccinations Assessed by Cardiac MRI. Serious adverse events associated with new vaccines targeting SARS-CoV-2 are of high interest to the public and to public health as a worldwide mass immunization campaign has been initiated to contain the ongoing COVID-19 pandemic. We describe a series of 4 individuals with signs of a myocarditis/pericarditis according to cardiac MRI results in temporal association with currently in the European Union authorized SARS-CoV-2 vaccines. We found mild abnormal MRI results independent of the type of SARS-CoV-2 vaccine. There is a need of continuing monitoring outcomes of myocarditis cases after COVID-19 vaccination as recently published cases suggest an uncomplicated short-term course whereas the long-term implications are not yet known but taking the available evidence into account the benefits of using COVID-19 vaccines still clearly outweigh the risks.

Development of Alveolar Hemorrhage After Pfizer-BioNTech COVID-19 mRNA Vaccination in a Patient With Renal-Limited Anti-neutrophil Cytoplasmic Antibody-Associated Vasculitis: A Case Report. Since the coronavirus disease 2019 (COVID-19) pandemic continues and a new variant of the virus has emerged, the COVID-19 vaccination campaign has progressed. Rare but severe adverse outcomes of COVID-19 vaccination such as anaphylaxis and myocarditis have begun to be noticed. Of note, several cases of new-onset antineutrophil cytoplasmic antibody-associated vasculitis (AAV) after COVID-19 mRNA vaccination have been reported. However, relapse of AAV in remission has not been recognized enough as an adverse outcome of COVID-19 vaccination. We report, to our knowledge, a first case of renal-limited AAV in remission using every 6-month rituximab administration that relapsed with pulmonary hemorrhage, but not glomerulonephritis, following the first dose of the Pfizer-BioNTech COVID-19 vaccine. The patient received the COVID-19 vaccine more than 6 months after the last dose of rituximab according to the recommendations. However, his CD19(+) B cell counts were found to be increased after admission, indicating that our case might have been prone to relapse after COVID-19 vaccination. Although our case cannot establish causality between AAV relapse and COVID-19 mRNA vaccination, a high level of clinical vigilance for relapse of AAV especially in patients undergoing rituximab maintenance therapy following COVID-19 vaccination should be maintained. Furthermore, elapsed time between rituximab administration and COVID-19 mRNA vaccination should be carefully adjusted based on AAV disease-activity.

CoronaVac/Sinovac COVID-19 Vaccine-Related Hypersensitivity Reactions and Second-Dose Vaccine Administration: Tertiary Allergy Center Experience. INTRODUCTION: The COVID-19 pandemic has caused a global health crisis. To prevent the disease, the Ministry of Health of Turkey gained approval for the CoronaVac COVID-19 vaccine for emergency use as the first-line. This study aimed to evaluate patients who developed hypersensitivity reactions (HRs) due to the CoronoVac vaccine and to share our experience of administering the second dose of vaccine to these patients. METHODS: The study group included the patients who presented to the Ege University Allergy and Immunology Division between January and May 2021. Demographic data, atopic status, allergic reactions to the first dose of the COVID-19 vaccine and the route of second-dose vaccine administrations were recorded. RESULTS: A total of 7 patients (four healthcare professionals), 6 (86%) of whom were women, with an average age of 53.4 years, were included in the study. The rate of allergic reactions among Ege University health workers was 0.036% (2/5,558). Six of our patients had a history of additional allergic diseases and comorbid diseases. None had any allergic reactions to previous vaccinations and latex allergy. Reactions developed commonly on the skin, as generalized urticaria/angioedema and pruritus. The severity of the reactions was evaluated as mild in 2, moderate in 3, and severe in 2 cases. The second-dose CoronaVac was safely administered by using a gradually increase dose in a

total of 6 patients. CONCLUSION: In patients with HRs due to Sinovac in the first dose, the second dose can be safely performed using a gradually increased dose.

Immunogenicity of the COVID-19 BNT162b2 vaccine in adolescents and young adults with cystic fibrosis. Data regarding immunogenicity of SARS-CoV-2 BNT162b2 vaccine in cystic fibrosis (CF) patients are limited. We prospectively measured total (TAbs-RBD; U/ml) and neutralizing (NAbs-RBD; %) antibodies of SARS-CoV-2 spike-receptor binding domain (RBD) protein in 33 CF patients and 66 healthy controls with median age (IQR): 19.6 (17.6-24.3) years and 31 (29-36) years, respectively and investigated possible associations with epidemiological and clinical parameters. Compared to healthy controls, CF patients had higher levels of TAbs-RBD and NAbs-RBD after both doses (P-valueÂ <Â 0.001). One month after the second dose, CF patients and controls had TAbs-RBD: median (IQR): 3396 (2443) and 1452 (1231) U/ml, respectively. Similarly, the NAbs-RBD (%) were: 97.30 (1.00) and 95.70 (3.71) %, respectively. CF patients also had fewer local and systemic adverse events (AEs) (P-valueÂ <Â 0.001). Among CF patients, no significant differences in immunogenicity were detected regarding the phenotype, genotype, medications, or severity of the disease. BNT162b2 vaccine was immunogenic with limited reactogenicity in CF patients regardless of the phenotype or severity of disease.

Persistent Spike-specific T cell immunity despite antibody reduction after 3 months from SARS-CoV-2 BNT162b2-mRNA vaccine. Vaccine is the main public health measure to reduce SARS-CoV-2 transmission and hospitalization, and a massive scientific effort worldwide resulted in the rapid development of effective vaccines. This work aimed to define the dynamics and persistence of humoral and cell-mediated immune response in Health Care Workers who received a two-dose BNT162b2-mRNA vaccination. Serological response was evaluated by quantifying anti-RBD and neutralizing antibodies while cell-mediated response was performed by a whole blood test quantifying Th1 cytokines (IFN-Î³, TNF-Î±, IL-2) produced in response to Spike peptides. BNT162b2-mRNA vaccine induced both humoral and cell-mediated immune response against Spike in all HCW early after the second dose. After 12Â weeks from vaccination, the titer of anti-RBD antibodies as well as their neutralization function decreased while the Spike-specific T-cells persisted at the same level as soon after vaccine boost. Of note, a correlation between cellular and humoral response persevered, suggesting the persistence of a coordinated immune response. The long lasting cell-mediated immune response after 3Â months from vaccination highlight its importance in the maintaining of specific immunity able to expand again to fight eventual new antigen encountering.

No increased incidence of venous thrombosis or pulmonary embolism after SARS-CoV-2 vaccination in Germany. OBJECTIVES: Vaccination is one of the most effective measures to combat the COVID-19 pandemic. The main reason for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination hesitancy is the potential side-effects. This study aimed to investigate the incidence of venous thrombosis and pulmonary embolism in patients who received SARS-CoV-2 vaccination. STUDY DESIGN: This was a retrospective cohort study. METHODS: Individuals aged â‰¥18 years who received an initial vaccination for COVID-19 in one of 1134 general practices in Germany between April and June 2021 were included in the study. Vaccinated patients were matched to unvaccinated individuals by age, sex, index month (April to June 2020 [unvaccinated cohort] or April to June 2021 [vaccinated cohort]) and diagnoses that may be associated with an increased incidence of thrombosis documented within 12 months before the index date. The incidences of thrombosis and non-fatal pulmonary embolism as a function of COVID-19 vaccination were analysed. RESULTS: The present study included 326,833 individuals who were vaccinated against COVID-19 and 326,833 matched unvaccinated individuals. During the follow-up period, 406 vaccinated patients and 342 individuals in the control group received a diagnosis of thrombosis or non-fatal pulmonary embolism. This resulted in an incidence rate of 11.9 vs 11.3 cases per 1000 patient-years for

vaccinated vs unvaccinated individuals, respectively, and a non-significant overall incidence rate ratio (IRR: 1.06; 95% confidence interval [CI]: 0.93-1.22). The highest IRR was observed in the 41-60 years age group (IRR: 1.30; 95% CI: 0.98-1.73), and the lowest IRR was seen in the 18-40 years age group (IRR: 0.6; 95% CI: 0.0-1.05); however, none of the individual age group incidence rates was significant. CONCLUSIONS: The results indicate that the occurrence of thrombosis or pulmonary embolism after COVID-19 vaccination is a coincidental finding rather than a consequence of vaccination.

Neuromyelitis optica complicating COVID vaccinations.

Autoimmune conditions following mRNA (BNT162b2) and inactivated (CoronaVac) COVID-19 vaccination: A descriptive cohort study among 1.1 million vaccinated people in Hong Kong. BACKGROUND: Concerns regarding the autoimmune safety of COVID-19 vaccines may negatively impact vaccine uptake. We aimed to describe the incidence of autoimmune conditions following BNT162b2 and CoronaVac vaccination and compare these with age-standardized incidence rates in non-vaccinated individuals. METHODS: This is a descriptive cohort study conducted in public healthcare service settings. Territory-wide longitudinal electronic medical records of Hong Kong Hospital Authority users (â‰¥16 years) were linked with COVID-19 vaccination records between February 23, 2021 and June 30, 2021. We classified participants into first/second dose BNT162b2 groups, first/second dose CoronaVac groups and non-vaccinated individuals for incidence comparison. The study outcomes include hospitalized autoimmune diseases (16 types of immune-mediated diseases across six body systems) within 28 days after first and second dose of vaccination. Age-standardized incidence rate ratios (IRRs) with exact 95% confidence intervals (CIs) were estimated using Poisson distribution. RESULTS: This study included around 3.9 million Hong Kong residents, of which 1,122,793 received at least one dose of vaccine (BNT162b2: 579,998; CoronaVac: 542,795), and 721,588 completed two doses (BNT162b2: 388,881; CoronaVac: 332,707). Within 28 days following vaccination, cumulative incidences for all autoimmune conditions were below 9 per 100,000 persons, for both vaccines and both doses. None of the age-standardized incidence rates were significantly higher than the non-vaccinated individuals, except for an observed increased incidence of hypersomnia following the first dose of BNT162b2 (standardized IRR: 1.47; 95% CI: 1.10-1.94). CONCLUSIONS: Autoimmune conditions requiring hospital care are rare following mRNA and inactivated COVID-19 vaccination with similar incidence to non-vaccinated individuals. The association between first dose BNT162b2 vaccination and immune-related sleeping disorders requires further research. Population-based robust safety surveillance is essential to detect rare and unexpected vaccine safety events.

Delirium after COVID-19 vaccination in nursing home residents: A case series.

Adverse events following third dose of mRNA COVID-19 vaccination among nursing home residents who received the primary series. BACKGROUND: We sought to compare rates of adverse events among nursing home residents who received an mRNA COVID-19 vaccine booster dose with those who had not yet received their booster. METHODS: We assessed a prospective cohort of 11,200 nursing home residents who received a primary COVID-19 mRNA vaccine series at least 6â€‰months prior to September 22, 2021 and received a third "booster dose" between September 22, 2021 and February 2, 2022. Residents lived in 239 nursing homes operated by Genesis HealthCare, spanning 21â€‰U.S. states. We screened electronic health records for 20 serious vaccine-related adverse events that are monitored following receipt of COVID-19 vaccination by the CDC's Vaccine Safety Datalink. We matched boosted and yet-to-be boosted residents during the same time period, comparing rates of events occurring 14â€‰days after booster administration with those occurring 14â€‰days prior to booster administration. To supplement previously reported background rates of adverse events, we report background rates of medical conditions among nursing home residents during 2020, before COVID-19 vaccines were administered in nursing homes. Events occurring in

2021-2022 were confirmed by physician chart review. We report unadjusted rates of adverse events and used a false discovery rate procedure to adjust for multiplicity of events tested. RESULTS: No adverse events were reported during the 14â€‰days post-booster. A few adverse events occurred prior to booster (ischemic stroke: 49.4 per 100,000 residents, 95% CI: 21.2, 115.7; venous thromboembolism: 9.9 per 100,000 residents, 95% CI: 1.7, 56.0), though differences in event rates pre- versus post-booster were not statistically significant (pâ€‰<â€‰0.05) after adjusting for multiple comparisons. No significant differences were detected between post-booster vaccination rates and prior year 14-day background rates of medical conditions. CONCLUSIONS: No safety signals were detected following a COVID-19 mRNA vaccine booster dose in this large multi-state sample of nursing home residents.
Baseline factors associated with self-reported disease flares following COVID-19 vaccination among adults with systemic rheumatic disease: results from the COVID-19 global rheumatology alliance vaccine survey. OBJECTIVE: To examine the frequency of, and risk factors for, disease flare following COVID-19 vaccination in patients with systemic rheumatic disease (SRD). METHODS: An international study was conducted from 2 April to 16 August 2021, using an online survey of 5619 adults with SRD for adverse events following COVID-19 vaccination, including flares of disease requiring a change in treatment. We examined risk factors identified a priori based on published associations with SRD activity and SARS-CoV-2 severity, including demographics, SRD type, comorbidities, vaccine type, cessation of immunosuppressive medications around vaccination and history of reactions to non-COVID-19 vaccines, using multivariable logistic regression. RESULTS: Flares requiring a change in treatment following COVID-19 vaccination were reported by 4.9% of patients. Compared with rheumatoid arthritis, certain SRD, including systemic lupus erythematosus (OR 1.51, 95% CI 1.03, 2.20), psoriatic arthritis (OR 1.95, 95% CI 1.20, 3.18) and polymyalgia rheumatica (OR 1.94, 95% CI 1.08, 2.48) were associated with higher odds of flare, while idiopathic inflammatory myopathies were associated with lower odds for flare (OR 0.54, 95% CI 0.31-0.96). The Oxford-AstraZeneca vaccine was associated with higher odds of flare relative to the Pfizer-BioNTech vaccine (OR 1.44, 95% CI 1.07, 1.95), as were a prior reaction to a non-COVID-19 vaccine (OR 2.50, 95% CI 1.76, 3.54) and female sex (OR 2.71, 95% CI 1.55, 4.72). CONCLUSION: SRD flares requiring changes in treatment following COVID-19 vaccination were uncommon in this large international study. Several potential risk factors, as well as differences by disease type, warrant further examination in prospective cohorts.
Acute herpes zoster radiculopathy mimicking cervical radiculopathy after ChAdOx1 nCoV-19/AZD1222 vaccination. This case report describes an 84-year-old man who presented with 3 weeks of gradually worsening right arm weakness associated with a painful vesicular rash across his arm. This occurred 3â€‰days after his first dose of the ChAdOx1 nCoV-19/AZD1222 (University of Oxford, AstraZeneca and the Serum Institute of India) vaccine. The diagnosis was complicated by the presence of right C5-C6 foraminal stenosis compressing on the C6 nerve root sheath on non-contrast MRI, leading to an initial diagnosis of cervical radiculopathy. However, a positive varicella zoster virus-PCR test and findings of abnormal contrast enhancement of his right C5-C7 nerve roots on gadolinium-enhanced MRI resulted in a revision of his diagnosis to zoster radiculopathy. He was subsequently commenced on oral valacilovir and made significant recovery. This report aims to highlight the diagnostic dilemma between cervical radiculopathy secondary to spondylosis and zoster radiculopathy and how an erroneous diagnosis could result in inappropriate, aggressive surgical intervention and delayed treatment with antiviral therapy.
Myelin oligodendrocyte glycoprotein associated disorder following SARS-CoV-2 vaccination.
Impaired humoral and T cell response to vaccination against SARS-CoV-2 in chronic myeloproliferative neoplasm patients treated with ruxolitinib.

Subacute Sclerosing Panencephalitis in Children: The Archetype of Non-Vaccination. Subacute sclerosing panencephalitis (SSPE) is a late complication of measles virus infection that occurs in previously healthy children. This disease has no specific cure and is associated with a high degree of disability and mortality. In recent years, there has been an increase in its incidence in relation to a reduction in vaccination adherence, accentuated by the COVID-19 pandemic. In this article, we take stock of the current evidence on SSPE and report our personal clinical experience. We emphasise that, to date, the only effective protection strategy against this disease is vaccination against the measles virus.

Epidemiology, Clinical Features, and Unusual Complications of Norovirus Infection in Taiwan: What We Know after Rotavirus Vaccines. Noroviruses (NoVs) are one of the emerging and rapidly spreading groups of pathogens threatening human health. A reduction in sporadic NoV infections was noted following the start of the COVID-19 pandemic, but the return of NoV gastroenteritis during the COVID-19 pandemic has been noted recently. Research in recent years has shown that different virus strains are associated with different clinical characteristics; moreover, there is a paucity of research into extraintestinal or unusual complications that may be associated with NoV. The genomic diversity of circulating NoVs is also complex and may vary significantly. Therefore, this short narrative review focuses on sharing the Taiwan experience of NoV infection including epidemiology, clinical features, and complications following suboptimal rotavirus immunization in Taiwan (after October 2006). We also highlight the unusual complications associated with NoV infections and the impacts of NoV infection during the COVID-19 pandemic in the literature for possible future research directions. To conclude, further research is needed to quantify the burden of NoV across the spectrum of disease severity in Taiwan. The evidence of the connection between NoV and the unusual complications is still lacking.

A Three-Case Series of Thrombotic Deaths in Patients over 50 with Comorbidities Temporally after modRNA COVID-19 Vaccination. Coronavirus disease 2019 (COVID-19) is the most dramatic pandemic of the new millennium; to counteract it, specific vaccines have been launched in record time under emergency use authorization or conditional marketing authorization by virtue of a favorable risk/benefit balance. Among the various technological platforms, there is that exploiting a nucleoside-modified messenger RNA (modRNA), such as Comirnaty(Â®), and that which is adenoviral vector-based. In the ongoing pharmacovigilance, the product information of the latter has been updated about the risk of thrombotic thrombocytopenia, venous thromboembolism without thrombocytopenia and immune thrombocytopenia without thrombosis. However, from an in-depth literature review, the same adverse events can rarely occur with modRNA vaccines too. In support of this, we here report a three-case series of thrombotic deaths in patients over 50 with comorbidities temporally after Comirnaty(Â®), investigated by means of post-mortem histopathology and immunohistochemistry. In two out of three cases, the cause of death is traced back to pulmonary microthromboses rich in activated platelets, quite similar morphologically to those described in patients who died from severe COVID-19. Even if remote in the face of millions of administered doses, clinicians should be aware of the possible thrombotic risk also after Comirnaty(Â®), in order to avoid a misdiagnosis with potentially lethal consequences. Since COVID-19 vaccines are inoculated in subjects to be protected, maximum attention must be paid to their safety, and prophylactic measures to increase it are always welcome. In light of the evidence, the product information of modRNA COVID-19 vaccines should be updated about the thrombotic risk, as happened for adenoviral vector-based vaccines.

Balancing Benefits and Harms of COVID-19 Vaccines: Lessons from the Ongoing Mass Vaccination Campaign in Lombardy, Italy. Background. Limited evidence exists on the balance between the benefits and harms of the COVID-19 vaccines. The aim of this study is to compare the benefits and

safety of mRNA-based (Pfizer-BioNTech and Moderna) and adenovirus-vectored (Oxford-AstraZeneca) vaccines in subpopulations defined by age and sex. Methods. All citizens who are newly vaccinated from 27 December 2020 to 3 May 2021 are matched to unvaccinated controls according to age, sex, and vaccination date. Study outcomes include the events that are expected to be avoided by vaccination (i.e., hospitalization and death from COVID-19) and those that might be increased after vaccine inoculation (i.e., venous thromboembolism). The incidence rate ratios (IRR) of vaccinated and unvaccinated citizens are separately estimated within strata of sex, age category and vaccine type. When suitable, number needed to treat (NNT) and number needed to harm (NNH) are calculated to evaluate the balance between the benefits and harm of vaccines within each sex and age category. Results. In total, 2,351,883 citizens are included because they received at least one dose of vaccine (755,557 Oxford-AstraZeneca and 1,596,326 Pfizer/Moderna). A reduced incidence of COVID-19-related outcomes is observed with a lowered incidence rate ranging from 55% to 89% and NNT values ranging from 296 to 3977. Evidence of an augmented incidence of harm-related outcomes is observed only for women aged <50 years within 28 days after Oxford-AstraZeneca (being the corresponding adjusted IRR of 2.4, 95% CI 1.1â^'5.6, and NNH value of 23,207, 95% CI 10,274â^'89,707). Conclusions. A favourable balance between benefits and harms is observed in the current study, even among younger women who received Oxford-AstraZeneca.

Assessment of Seroconversion after SARS-CoV-2 Vaccination in Patients with Lung Cancer. Background: SARS-CoV-2 mortality rates are significantly higher in patients with lung cancer compared with the general population. However, little is known on their immunization status after vaccination. Methods: To evaluate the humoral response (seroconversion) of patients with lung cancer following vaccination against SARS-COV-2 (Group A), we obtained antibodies against SARS-CoV-2 spike (S) protein both at baseline and at different time points after the first dose of SARS-CoV-2 vaccine (two to three weeks [T1], six weeks Â± one week [T2], 12 weeks Â± three weeks [T3], and 24 weeks Â± three weeks [T4]). Antibodies were also acquired from a control cohort of non-lung cancer patients (Group B) as well as a third cohort containing healthy controls (Group C) at all time points and at T4, respectively, to make comparisons with Group A. Analysis of antibody response at different time points, association with clinicopathologic parameters, and comparisons with control groups were performed. Results: A total of 125 patients with lung cancer were included in the analysis (96 males [74.3%], median age of 68 years [46â^'91]. All study participants received two vaccine doses (BNT162b2, mRNA-1273, AZD1222). Analysis of anti-SARS-CoV-2 S antibody titers showed minimal response at T1 (0.4 [0.4â^'48.6] IU/mL). Antibody response peaked at T2 (527.0 [0.4â^'2500] IU/mL) and declined over T3 (323.0 [0.4â^'2500] IU/mL) and T4 (141.0 [0.4â^'2500] IU/mL). Active smokers had lower antibody titers at T2 ($p = 0.04$), T3 ($p = 0.04$), and T4 ($p < 0.0001$) compared with former or never smokers. Peak antibody titers were not associated with any other clinicopathologic characteristic. No significant differences were observed compared with Group B. However, lung cancer patients exhibited significantly decreased antibody titers compared with Group C at T4 ($p < 0.0001$). Conclusions: Lung cancer patients demonstrate sufficient antibody response six weeks after the first dose of vaccine against SARS-CoV-2 when vaccinated with two-dose regimens. Rapidly declining antibody titers six weeks after the first dose underline the need for a third dose three months later, in patients with lung cancer, and especially active smokers.

Diminished Short- and Long-Term Antibody Response after SARS-CoV-2 Vaccination in Hemodialysis Patients. Short-term studies have shown an attenuated immune response in hemodialysis patients after COVID-19-vaccination. The present study examines how antibody response is maintained after vaccination against SARS-CoV-2 in a large population of hemodialysis patients from six outpatient dialysis centers. We retrospectively assessed serum antibody levels against SARS-CoV-2 spike protein and nucleocapsid protein (electrochemiluminescence immunoassays, Roche

Diagnostics) after COVID-19-vaccination in 298 hemodialysis and 103 non-dialysis patients (controls), comparing early and late antibody response. Compared to a non-dialysis cohort hemodialysis patients showed a favorable but profoundly lower early antibody response, which decreased substantially during follow-up measurement (median 6 months after vaccination). Significantly more hemodialysis patients had anti-SARS-CoV-2-S antibody titers below 100 U/mL ($p < 0.001$), which increased during follow-up from 23% to 45% but remained low in the control group (3% vs. 7%). In multivariate analysis, previous COVID-19 infections ($p < 0.001$) and female gender ($p < 0.05$) were significantly associated with higher early as well as late antibody vaccine response in hemodialysis patients, while there was a significant inverse correlation between patient age and systemic immunosuppression ($p < 0.001$). The early and late antibody responses were significantly higher in patients receiving vaccination after a SARS-CoV-2 infection compared to uninfected patients in both groups ($p < 0.05$). We also note that a higher titer after complete immunization positively affected late antibody response. The observation, that hemodialysis patients showed a significantly stronger decline of SARS-CoV-2 vaccination antibody titers within 6 months, compared to controls, supports the need for booster vaccinations to foster a stronger and more persistent antibody response.

Delayed Cutaneous Adverse Reaction of the AstraZeneca COVID-19 Vaccine in a Breastfed Female Infant: A Coincidence or a Rare Effect? The ChAdOx1 nCoV-19 vector vaccine (Vaxzevria, AstraZeneca, Cambridge, UK) was developed at Oxford University and is considered safe for the administration in lactating mothers. Nevertheless, as a novel vaccine, there are gaps in the knowledge regarding possible adverse events in breastfeeding infants of vaccinated mothers. This case report provides first-time data on a possible delayed, cutaneous, adverse reaction in a breastfed, 16-month-old female infant after the first administration of the AstraZeneca vaccine to her 33-year-old mother. Even though, no clinical adverse effects were observed in the mother, her daughter had a 2-day rash in the lower extremities and face. The infant's cutaneous rashes might be a coincidental event. However, all skin lesions were analogous to previous descriptions and photographs of dermatologic reactions, which resolved spontaneously with no medical intervention, in people who had been vaccinated with other COVID-19 vaccines. Our aim is that this short report contributes to the enhancement of parental awareness about the possibility of similar skin rashes in breastfed children when the mothers receive a vaccination and the importance of reporting those adverse reactions to the competent authorities.

SARS-CoV-2 Vaccine-Induced Immune Thrombotic Thrombocytopenia with Venous Thrombosis, Pulmonary Embolism, and Adrenal Haemorrhage: A Case Report with Literature Review. Vaccine-induced immune thrombotic thrombocytopenia (VITT) with venous thrombosis is a rare complication of SARS-CoV-2 vaccination with ChAdOx1 (AstraZeneca) and AD26.COV2.S (Johnson & Johnson, New Brunswick, NJ, USA) associated with high mortality. At present, there are no known differences in the pathophysiology or risk factors of VITT with the AstraZeneca vaccine (ChAdOx1) compared with the Johnson & Johnson vaccine (AD26.COV2.S). Herein, we present the case of a healthy 39-year-old patient with VITT after having received the vaccine Ad26.COV2.S. Ten days after vaccination, the patient developed a deep vein thrombosis and subsequent pulmonary embolism. A computed tomography scan of the abdomen showed adrenal gland bleeding and an adrenocorticotrophic hormone stimulation test diagnosed adrenal insufficiency. Therapy with intravenous immunoglobulin, argatroban and hydrocortisone was initiated immediately after diagnosis. The patient left the hospital 22 days after admission with the diagnosis of adrenal insufficiency but otherwise in good health. To the best of our knowledge, five cases of VITT and adrenal bleeding have been described to date in the literature but the presented case was the first to occur after immunisation with the vaccine of Johnson & Johnson. In summary, VITT-associated adrenal dysfunction is a very rare complication of vaccination with an adenoviral vector-based COVID-19 vaccine.

Impact of Moderna mRNA-1273 Booster Vaccine on Fully Vaccinated High-Risk Chronic Dialysis Patients after Loss of Humoral Response. The long-term effect of protection by two doses of SARS-CoV-2 vaccination in patients receiving chronic intermittent hemodialysis (CIHD) is an urging question. We investigated the humoral and cellular immune response of 42 CIHD patients who had received two doses of SARS-CoV-2 vaccine, and again after a booster vaccine with mRNA-1273 six months later. We measured antibody levels and SARS-CoV-2-specific surrogate neutralizing antibodies (SNA). Functional T cell immune response to vaccination was assessed by quantifying interferon-Î³ (IFN-Î³) and IL-2 secreting T cells specific for SARS-CoV-2 using an ELISpot assay. Our data reveal a moderate immune response after the second dose of vaccination, with significantly decreasing SARS-CoV-2-specific antibody levels and less than half of the study group showed neutralizing antibodies six months afterwards. Booster vaccines increased the humoral response dramatically and led to a response rate of 89.2% for antibody levels and a response rate of 94.6% for SNA. Measurement in a no response/low response (NR/LR) subgroup of our cohort, which differed from the whole group in age and rate of immunosuppressive drugs, indicated failure of a corresponding T cell response after the booster vaccine. We strongly argue in favor of a regular testing of surrogate neutralizing antibodies and consecutive booster vaccinations for CIHD patients to provide a stronger and persistent immunity.

Severe Acute Myocarditis after the Third (Booster) Dose of mRNA COVID-19 Vaccination. Vaccination with mRNA vaccines against coronavirus disease 2019 (COVID-19) has been associated with a risk of developing myocarditis and pericarditis, with an estimated standardized incidence ratio of myocarditis being 5.34 (95% CI, 4.48 to 6.40) as compared to the expected incidence based on historical data according to a large national study in Israel. Most cases of myocarditis in vaccine recipients occur in young males, particularly following the second dose, and the presentation is usually mild. Recently, the third (booster) dose has been shown to reduce confirmed infections and severe illness even against common variants of the virus. In Israel, over 4.4 million citizens (more than 45% of the population) have been vaccinated with the third dose of Pfizer-BioNTech vaccine BNT162b2. Herein, we report the first case of a histologically confirmed severe myocarditis following the third dose of BNT162b2 COVID-19 vaccine.

Hemophagocytic Lymphohistiocytosis Following BNT162b2 mRNA COVID-19 Vaccination. Although serious adverse events have remained uncommon, cases of myocarditis induced by messenger RNA (mRNA) COVID-19 vaccines have been reported. Here, we presented a rare but potentially fatal disorder, hemophagocytic lymphohistiocytosis, in a 14-year-old previously healthy adolescent after BNT162b2 mRNA vaccination. The initial evaluation showed splenomegaly, pancytopenia, hyperferritinemia, and hypofibrinogenemia. Further examination revealed positive blood EBV DNA, and other infectious pathogen surveys were all negative. Hemophagocytosis was observed in the bone marrow aspiration and biopsy. HLH was confirmed and intravenous immunoglobulin (IVIG) and methylprednisolone pulse therapy were given. Venoarterial extracorporeal membrane oxygenation (VA-ECMO) was set up for cardiopulmonary support for 3 days due to profound hypotension. The patient was kept on oral prednisolone treatment for 28 days with the following gradual tapering. The hemogram and inflammatory biomarkers gradually returned to normal, and the patient was discharged. The fulminant presentation of HLH in our case could be the net result of both acute immunostimulation after COVID-19 vaccination and EBV infection. Our case suggests that the immune activation after COVID-19 vaccination is likely to interfere with the adequate immune response to certain infectious pathogens, resulting in a hyperinflammatory syndrome.

Factors Associated with Non-Severe Adverse Reactions after Vaccination against SARS-CoV-2: A Cohort Study of 908,869 Outpatient Vaccinations in Germany. BACKGROUND: Vaccination

against SARS-CoV-2 significantly reduces the transmissibility of the virus and the likelihood of a severe course of COVID-19, and is thus a critical component in overcoming the current pandemic. The factors associated with adverse reactions after vaccination against SARS-CoV-2 have not yet been sufficiently evaluated. METHODS: We used the Disease Analyzer database (IQVIA) to identify 531,468 individuals who received a total of 908,869 SARS-CoV-2 vaccinations in 827 general practices in Germany between April and September 2021. Cox regression models were used to analyze the frequency of vaccination-related side effects reported within 14 days after SARS-CoV-2 vaccination, as well as subjects' demographic characteristics and comorbidities. RESULTS: The total number of side effects documented was 28,287 (3.1% of all vaccinations). Pain in the limb (24.3%), fatigue (21.0%), dizziness (17.9%), joint pain (15.7%), fever (9.5%), nausea (7.5%), and myalgia (6.4%) were the most common side effects documented among the 12,575 vaccinations with definite side effects. In the multivariate regression analysis, young age was associated with much higher odds of reported side effects (OR(18-30 years): 4.45, OR(31-40 years): 3.50, OR(41-50 years): 2.89). In addition, pre-existing comorbidities such as dementia (OR: 1.54), somatoform disorder (OR: 1.53), anxiety disorder (OR: 1.43), depression (OR: 1.37), chronic respiratory tract disease (OR: 1.27), hypertension (OR: 1.20), and obesity (1.14) significantly increased the odds of side effects. Finally, the male sex was associated with increased odds of reported side effects (OR: 1.17). CONCLUSION: Our study, based on a large outpatient database from Germany, identified young age, male sex, and pre-existing comorbidities such as dementia, somatoform disorders, anxiety disorders, and depression as factors associated with vaccine-related adverse events diagnosed in GP practices. These data could help to identify subgroups needing particular advice and care in the context of SARS-CoV-2 vaccinations.

An Association Study of HLA with the Kinetics of SARS-CoV-2 Spike Specific IgG Antibody Responses to BNT162b2 mRNA Vaccine. BNT162b2, an mRNA-based SARS-CoV-2 vaccine (Pfizer-BioNTech, New York, NY, USA), is one of the most effective COVID-19 vaccines and has been approved by more than 130 countries worldwide. However, several studies have reported that the COVID-19 vaccine shows high interpersonal variability in terms of humoral and cellular responses, such as those with respect to SARS-CoV-2 spike protein immunoglobulin (Ig)G, IgA, IgM, neutralizing antibodies, and CD4(+) and CD8(+) T cells. The objective of this study is to investigate the kinetic changes in anti-SARS-CoV-2 spike IgG (IgG-S) profiles and adverse reactions and their associations with HLA profiles (HLA-A, -C, -B, -DRB1, -DQA1, -DQB1, -DPA1 and -DPB1) among 100 hospital workers from the Center Hospital of the National Center for Global Health and Medicine (NCGM), Tokyo, Japan. DQA1*03:03:01 (p = 0.017; Odd ratio (OR) 2.80, 95%confidence interval (CI) 1.05-7.25) was significantly associated with higher IgG-S production after two doses of BNT162b2, while DQB1*06:01:01:01 (p = 0.028, OR 0.27, 95%CI 0.05-0.94) was significantly associated with IgG-S declines after two doses of BNT162b2. No HLA alleles were significantly associated with either local symptoms or fever. However, C*12:02:02 (p = 0.058; OR 0.42, 95%CI 0.15-1.16), B*52:01:01 (p = 0.031; OR 0.38, 95%CI 0.14-1.03), DQA1*03:02:01 (p = 0.028; OR 0.39, 95%CI 0.15-1.00) and DPB1*02:01:02 (p = 0.024; OR 0.45, 95%CI 0.21-0.97) appeared significantly associated with protection against systemic symptoms after two doses of BNT162b2 vaccination. Further studies with larger sample sizes are clearly warranted to determine HLA allele associations with the production and long-term sustainability of IgG-S after COVID-19 vaccination.

Public Health Surveillance for Adverse Events Following COVID-19 Vaccination in Africa. Local, national, and international health agencies have advocated multi-pronged public health strategies to limit infections and prevent deaths. The availability of safe and effective vaccines is critical in the control of a pandemic. Several adverse events have been reported globally following reception of different vaccines, with limited or no data from Africa. This cross-sectional epidemiological study investigated adverse events following COVID-19 vaccination in Africans from April-June, 2021 using a

structured online questionnaire. Out of 1200 participants recruited, a total of 80.8% (n = 969) respondents from 35 countries, including 22 African countries and 13 countries where Africans live in the diaspora, reported adverse events. Over half of the vaccinees were male (53.0%) and frontline healthcare workers (55.7%), respectively. A total of 15.6% (n = 151) reported previous exposure to SARS-CoV-2, while about one-fourth, 24.8% (n = 240), reported different underlying health conditions prior to vaccination. Fatal cases were 5.1% (n = 49), while other significant heterogenous events were reported in three categories: very common, common, and uncommon, with the latter including enlarged lymph nodes 2.4% (n = 23), menstrual disorder 0.5% (n = 5), and increased libido 0.2% (n = 2). The study provided useful data for concerned authorities and institutions to prepare plans that will address issues related to COVID-19 vaccines.

Neutralizing Antibodies Responses against SARS-CoV-2 in a Sardinian Cohort Group Up to 9 Months after BNT162b2 Vaccination. Severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2), the etiological agent of COVID-19, has caused over 460 million cases of infection and over 6 million deaths worldwide. The pandemic has called for science, technology, and innovation to provide solutions and, due to an incredible scientific and financial global effort, several prophylactic and therapeutic apparatuses such as monoclonal antibodies and vaccines were developed in less than one year to address this emergency. After SARS-CoV-2 infection, serum neutralizing antibodies are produced by B cells and studies on virus-neutralizing antibodies' kinetics are pivotal. The process of protective immunity and the duration of this kind of protection against COVID-19 remain to be clarified. We tested 136 sera from 3 groups of individuals, some of them providing multiple sequential sera (1-healthy, no previous CoV2-infected, vaccinated; 2-healthy, previous CoV2 infected, vaccinated; 3-healed, previous CoV2-infected, not vaccinated) to assess the kinetics of antibodies (Abs) neutralizing activity. We found that SARS-CoV-2 infection elicits moderate neutralizing antibody activity in most individuals; neither age nor gender appear to have any influence on Abs responses. The BNT162b2 vaccine, when administered in two doses, induces high antibodies titre endowed with potent neutralizing activity against bare SARS-CoV-2 in in vitro neutralizing assay. The residual neutralization capability and the kinetic of waning immunity were also evaluated over 9 months after the second dose in a reference group of subjects. Neutralization titre showed a decline in all subjects and the median level of S-protein IgG, over 270 days after the second vaccination dose, was below 10 AU/mL in 53% of serum tested.

Humoral Response after Three Doses of mRNA-1273 or BNT162b2 SARS-CoV-2 Vaccines in Hemodialysis Patients. The COVID-19 pandemic continues to be a worldwide health issue. Among hemodialysis (HD) patients, two-dose immunization schemes with mRNA vaccines have contributed to preventing severe COVID-19 cases; however, some have not produced a sufficient humoral response, and most have developed a rapid decline in antibody levels over the months following vaccination. This observational, prospective, multi-center study evaluated the humoral response in terms of presence and levels of IgG antibodies to the receptor-binding domain of the S1 spike antigen of SARS-CoV-2 (anti-S1-RBD IgG) to the third dose of SARS-CoV-2 mRNA vaccines, either the mRNA-1273 (Moderna) or BNT162b2 (Pfizer), in 153 patients from three dialysis units affiliated to Hospital ClÃ-nic of Barcelona (Spain). Most hemodialysis patients responded intensely to this third vaccine dose, achieving the seroconversion in three out of four non- or weak responders to two doses. Moreover, 96.1% maintained the upper limit or generated higher titers than after the second. BNT162b2 vaccine, active cancer, and immunosuppressive treatment were related to a worse humoral response. Every hemodialysis patient should be administered a third vaccine dose six months after receiving the second one. Despite the lack of data, immunosuppressed patients and those with active cancer may benefit from more frequent vaccine boosters.

The Willingness of Elderly Taiwanese Individuals to Accept COVID-19 Vaccines after the First Local Outbreak. Vaccination is the most effective intervention to prevent infection and subsequent complications from SARS-CoV-2. Because of their multiple comorbidities, the elderly population experienced the highest number of deaths from the COVID-19 pandemic. Although in most countries, older people have top priority for COVID-19 vaccines, their actual willingness and attitudes regarding vaccination are still unclear. Thus, we conducted a cross-sectional study to investigate their willingness, attitudes, awareness, and knowledge of COVID-19 through a web-based questionnaire after the first local outbreak of COVID-19 in Taiwan. A total of 957 questionnaires were completed, and 74.9% of elderly individuals were likely to receive COVID-19 vaccines. The results from a multiple logistic regression demonstrated that older people who need to visit the outpatient department and have a high level of concern about the safety of COVID-19 vaccines are prone to having a negative willingness to accept COVID-19 vaccines. The following items related to awareness of the COVID-19 pandemic were attributed to the acceptance of COVID-19 vaccines: "understanding the risk of being infected by SARS-CoV-2", "understanding the effectiveness of COVID-19 vaccines", "willingness to accept the COVID-19 vaccine for protecting others", and "safety of COVID-19 vaccines is a key factor for you to accept them". Furthermore, a positive association between COVID-19 vaccination and attitudes toward accepting booster doses of the COVID-19 vaccine was observed. Our results show that these factors could affect the willingness of older people to accept COVID-19 vaccines and that they are important for policymakers and medical staff to develop vaccination plans during the COVID-19 pandemic.

Side Effects of Mixing Vaccines against COVID-19 Infection among Saudi Population. BACKGROUND: Mixing two different vaccines has been utilized to minimize the impact of any supply chain interruptions and to combat the COVID-19 pandemic in Saudi Arabia. We conducted this study to evaluate the side effects, if any, associated with the mixed vaccination approach. METHODS: An online survey study was administered among COVID-19 vaccine recipients in Saudi Arabia. Symptoms post vaccination were assessed in 311 vaccinated participants with two matched doses of either Oxford-AstraZeneca or Pfizer-BioNTech vaccines, or two mixed doses, respectively. RESULTS: After the second dose, around 31% of the matched vaccine group reported no symptoms, while only 6% of the mixed vaccine group reported no symptoms. Most of the side effects after the second dose associated with matched vaccines were injection site pain (46%), while the mixed vaccines group reported significantly more symptoms compared with the matched vaccine group, which included fever (41%), fatigue (66%), muscle pain (44%), chills (17%) and injection site pain (60%). CONCLUSION: The data suggest the overall safety of the mixed vaccination protocol; however, it might be associated with side effects such as fever, fatigue, muscle pain, chills, and injection site pain. Further studies with a larger cohort size could shed more light on this aspect, which would be imperative for deciding to utilize a mixed vaccination approach.

Frequent Onsets of Cellulitis in Lower Limbs with Lymphedema Following COVID-19 mRNA Vaccination. Four patients with secondary lower limb lymphedema developed cellulitis at their lymphedema lesion following COVID-19 mRNA vaccinations. They did not develop adverse effects at their vaccination site. All the patients were Japanese females aged <60 years. Three patients developed cellulitis following the first vaccination. The date of onset of cellulitis following the first vaccination varied from 0 to 21 days. Two received BNT162b2 mRNA vaccines and the others received mRNA-1273 vaccines. All the patients were treated with oral antibiotics and recovered. Two patients had repeated cellulitis. The patients with the repeated development of cellulitis could not perform good skincare. One patient had joint contractures in their lower limbs and could not reach her lymphedema lesions, and the other patient could not master the skincare. According to previous studies, the development of cellulitis following vaccination was rare. In this study, four patients aged

<60 years developed cellulitis among the eight patients that regularly visited our hospital for rehabilitation for their lower limb lymphedema. In patients with lymphedema, prolonged inflammation may impair lymphatic functions and worsen edema. Therefore, at the time of vaccination, we should keep in mind the prevention and immediate management of cellulitis using intensive skincare and antibiotic treatment.

Validation of the GSP(Â®)/DELFIA(Â®) Anti-SARS-CoV-2 IgG Kit Using Dried Blood Samples for High-Throughput Serosurveillance and Standardized Quantitative Measurement of Anti-Spike S1 IgG Antibody Responses Post-Vaccination. Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) has caused a major global public health crisis. In response, researchers and pharmaceutical companies worked together for the rapid development of vaccines to reduce the morbidity and mortality associated with viral infection. Monitoring host immunity following virus infection and/or vaccination is essential to guide vaccination intervention policy. Humoral immune response to vaccination can be assessed with serologic testing, and indeed, many serological immunoassays are now in use. However, these many different assays make the standardization of test results difficult. Moreover, most published serological tests require venous blood sampling, which makes testing large numbers of people complex and costly. Here, we validate the GSP(Â®)/DELFIA(Â®) Anti-SARS-CoV-2 IgG kit using dried blood samples for high-throughput serosurveillance using standard quantitative measurements of anti-spike S1 IgG antibody concentrations. We then apply our validated assay to compare post-vaccination anti-SARS-CoV-2 S1 IgG levels from subjects who received a double dose of the AZD1222 vaccine with those vaccinated with a heterologous strategy, demonstrating how this assay is suitable for large-scale screening to achieve a clearer population immune picture.

Adverse Events Following BNT162b2 mRNA COVID-19 Vaccine Immunization among Healthcare Workers in a Tertiary Hospital in Johor, Malaysia. BACKGROUND: The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), or 2019 coronavirus disease (COVID-19), was declared as pandemic in early 2020. While several studies reported the short-term adverse events (AE) of the mRNA COVID-19 vaccines, medium-term AE have not been extensively evaluated. This study aimed to evaluate the 6-month side effect profiles of the BNT162b2 mRNA vaccine. METHODS: This was a descriptive cross-sectional study conducted in a tertiary hospital. Hospital workers who received two doses of the Cominarty (BNT162b2) mRNA vaccine, six months post-vaccination, were invited to participate in this study. All participants completed a self-reported survey assessing AEs occurrence and severity, duration of onset and recovery and if they previously reported these AEs. RESULTS: Of the 670 respondents who completed the survey, 229 (34.2%) experienced at least one AEs, with a total of 937 AEs reported during the 6-month period. After the first dose, the most common reported localized symptoms were pain (n = 106, 27.2%), swelling (n = 38, 9.8%) and erythematous (n = 12, 3.1%) at injection site. Systemic symptoms reported include fatigue (n = 72, 18.5%), fever (n = 55, 14.1%) and headache (n = 46, 11.8%). After the second dose, pain at site of injection (n = 112, 20.4%), swelling (n = 42, 7.7%) and erythematous (n = 14, 2.6%) were among the localized AE reported, while fever (n = 121, 22.1%), fatigue (n = 101, 18.4%) and headache (n = 61, 11.1%) were the most common systemic AE. The proportion of respondents who experienced moderate (first dose: 156 events; second dose: 272 events) and severe (1st dose: 21 events; 2nd dose: 30 events) AEs were higher after the second dose. Most AEs commonly resolved within 1-2 days, and none required hospitalization. No new onset of AE was observed 7 days post-vaccination. A total of 137 (59.8%) participants did not proceed to formal AE reporting. CONCLUSION: Most of the AEs reported were of mild to moderate intensity and short-term, consistent with those reported in previous studies. No medium-term finding was detected in the survey. AE reporting was not routinely performed, necessitating the attention of health authorities in order to enhance pharmacovigilance.

The Dynamics of Changes in the Concentration of IgG against the S1 Subunit in Polish Healthcare Workers in the Period from 1 to 12 Months after Injection, Including Four COVID-19 Vaccines. BACKGROUND: The presented research made it possible to obtain the characteristics of changes in anti-SARS-CoV-2 IgG within one year of vaccination in healthcare workers. MATERIALS AND METHODS: The research group consisted of 18,610 participants represented by medical and administration staff. IgG antibody concentrations were determined by ELISA. RESULTS: At 5-8 months after full vaccination, the levels of anti-SARS-CoV-2 IgG with equal vaccines were similar. The exception was JNJ-78436735, for which IgG levels were significantly lower. In the 9th month after vaccination, an increase in the anti-SARS-CoV-2 IgG level, suggesting asymptomatic infection, was observed in a large group of participants. Significantly higher levels of anti-SARS-CoV-2 IgG antibodies were observed after the booster dose compared to the second dose. The increase in antibodies was observed already around the 5th day after the injection of the booster dose, and was maximized at approximately the 14th day. CONCLUSION: The cut-off date for protection against the disease seems to be the period 8-9 months from the vaccination for mRNA vaccines and 5-6 months for vector vaccines. The introduction of a booster dose was the right decision, which could have a real impact on restricting the further transmission of the virus.

Humoral Response in Hemodialysis Patients Following COVID-19 Vaccination and Breakthrough Infections during Delta and Omicron Variant Predominance. BACKGROUND: The advancement of COVID-19 vaccination programs globally has been viewed as an integral strategy to reduce both the number of COVID-19 cases and consequential complications of COVID-19, particularly for high-risk patient groups. There are limited data on the antibody response and protection from disease infection and severity in patients requiring hemodialysis (HD) following COVID-19 vaccination during the Delta and Omicron variant predominance. We conducted a study aiming to evaluate humoral immunity derived from two different COVID-19 vaccines administered to our in-centre HD population and investigated the characteristics of breakthrough COVID-19 infections occurring post-vaccination within this population. METHODS: This is a prospective observational study including patients receiving HD at Salford Royal Hospital. The first and second doses of COVID-19 vaccinations (Pfizer BioNTech BNT162b2 or Oxford AstraZeneca ChAdOx1 nCoV-19) were administered to this patient cohort since January 2021. The incidence of any breakthrough COVID-19 infections occurring in double vaccinated patients between 1 April 2021 and 15 January 2022 was recorded. Patients were screened weekly with nasal and pharyngeal nasopharyngeal swabs for real-time Reverse Transcription Polymerase Chain Reaction (rRT-PCR) for COVID-19, whilst SARS-CoV-2 antibody testing was performed alongside monthly routine HD bloods. RESULTS: Four hundred eleven patients receiving HD were included in this study, of which 170 of 178 patients (95.5%) with available data on antibody status following two doses of the Pfizer BioNTech BNT162b2 vaccination had detectable antibody response, whilst this was the case for 97 of 101 patients (96.1%) who received two doses of the Oxford AstraZeneca ChAdOx1 nCoV-19 vaccine. For 12 seronegative patients who received a booster vaccine (third dose), nine seroconverted, while one remained negative and two were not tested. No statistically significant differences were observed with regards to antibody status between those receiving Pfizer BioNTech BNT162b2 and Oxford AstraZeneca ChAdOx1 nCoV-19 vaccines. Sixty-three of 353 patients with two doses of COVID-19 vaccination had breakthrough COVID-19 infection (40 during Delta and 23 during Omicron variant predominance). Of the 40 patients during the delta period, five were admitted into hospital and there were two reported deaths due to COVID-19-related illness. There were no COVID-19 associated hospitalizations or deaths during the Omicron variant predominance. CONCLUSIONS: The vast majority of HD patients who received two doses of the Pfizer BioNTech BNT162b2 or Oxford AstraZeneca ChAdOx1 nCoV-19 vaccinations developed detectable antibody responses. Our results support the value of booster vaccination with mRNA-

based COVID-19 vaccine in HD patients and highlight the need for ongoing surveillance programmes with rRT-PCR and antibody testing for timely detection of positive cases.

Evaluation of Two-Month Antibody Levels after Heterologous ChAdOx1-S/BNT162b2 Vaccination Compared to Homologous ChAdOx1-S or BNT162b2 Vaccination. We evaluated the post-vaccination humoral response of three real-world cohorts. Vaccinated subjects primed with ChAdOx1-S and boosted with BNT162b2 mRNA vaccine were compared to homologous dosing (BNT162b2/BNT162b2 and ChAdOx1-S/ChAdOx1-S). Serum samples were collected two months after vaccination from a total of 1248 subjects. The results showed that the heterologous vaccine schedule induced a significantly higher humoral response followed by homologous BNT162b2/BNT162b2 and ChAdOx1-S/ChAdOx1-S vaccines ($p < 0.0001$). Moreover, analyzing factors (i.e., vaccine schedule, sex, age, BMI, smoking, diabetes, cardiovascular diseases, respiratory tract diseases, COVID-19 diagnosis, vaccine side effects) influencing the IgG anti-S response, we found that only the type of vaccine affected the antibody titer ($p < 0.0001$). Only mild vaccine reactions resolved within few days (40% of subjects) and no severe side effects for either homologous groups or the heterologous group were reported. Our data support the use of heterologous vaccination as an effective and safe alternative to increase humoral immunity against COVID-19.

Comparison of CLEIA and ELISA for SARS-CoV-2 Virus Antibodies after First and Second Dose Vaccinations with the BNT162b2 mRNA Vaccine. The global severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has required rapid action to control its spread and vaccines are a fundamental solution to this pandemic. The development of rapid and reliable serological tests to monitor the antibody response to coronavirus disease vaccines is necessary for post-vaccination immune responses. Therefore, in this study, anti-SARS-CoV-2 antibody titers after the first and second doses were monitored using two different measurement systems, a highly sensitive analytical platform of chemiluminescent enzyme immunoassay (CLEIA) and an enzyme-linked immunosorbent assay (ELISA). Our study included 121 participants who received two doses of the BNT162b2 vaccine. Both methods show significant increase in anti-spike protein IgG antibody levels one week after the first vaccination, and then reached at a plateau at week five (week two after the second dose), with a 3.8 Ã— 103-fold rise in CLEIA and a 22-fold rise in ELISA. CLEIA and ELISA showed a good correlation in the high titer range, >10 binding antibody unit (BAU)/mL. Both methods detected higher IgG antibody levels in females compared with male participants after the second vaccination, while CLEIA exhibits the sex difference after the first dose. Thus, our study showed better performance of CLEIA over ELISA in sensitivity, especially in the low concentration range, however ELISA was also useful in the high titer range (>10 BAU/mL) corresponding to the level seen several weeks after the first vaccination.

Fresh Embryo Transfer Cycle Characteristics and Outcomes Following In Vitro Fertilization via Intracytoplasmic Sperm Injection Among Patients With and Without COVID-19 Vaccination. This cohort study examines the association of COVID-19 vaccination status and in vitro fertilization (IVF)-fresh embryo transfer cycle stimulation characteristics and outcomes.

Vaccine-induced and naturally-acquired protection against Omicron and Delta symptomatic infection and severe COVID-19 outcomes, France, December 2021 to January 2022. We assessed the protection conferred by naturally-acquired, vaccine-induced and hybrid immunity during the concomitant Omicron and Delta epidemic waves in France on symptomatic infection and severe COVID-19. The greatest levels of protection against both variants were provided by hybrid immunity. Protection against Omicron symptomatic infections was systematically lower and waned at higher speed than against Delta in those vaccinated. In contrast, there were little differences in variant-specific protection against severe inpatient outcomes in symptomatic individuals.

Vaccine-Inducted Thrombotic Thrombocytopenia and Covid-19 Vaccines: Case Series. Vaccine-induced thrombotic thrombocytopenia (VITT) is a condition similar to heparin-induced thrombocytopenia (HIT), but it is associated with prior administration of COVID-19 vaccines without prior exposure to heparin. The incidence of VITT is not certain, but it appears to be extremely rare. Reports of unusual and severe thrombotic events, including cerebral and splanchnic venous thrombosis and other autoimmune adverse reactions, such as immune thrombocytopenia or thrombotic microangiopathies in connection with some of the SARS-CoV-2 vaccines, have caused a great deal of concern within the population and the medical community. We would like to present 4 clinical cases of VITT, hospitalized and treated in intensive care unit (ICU) of University clinic of cardiology in Skopje.

[Measurement of Anti-SARS CoV-2 Antibodies following Vaccination: Valuable Monitoring or Irrelevant Tool?]. Vaccination against severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) provides effective protection against infection or severe coronavirus disease 2019 (COVID-19). Moreover, it is regarded as the single most important measure to end the pandemic. Individual vaccination effectiveness is often judged via measurement of anti-SARS-CoV-2 antibodies. However, considering the complexity of the humoral and cellular immune response the question arises whether the relation of anti-SARS-CoV-2 antibody titers and COVID-19 vaccine effectiveness is a myth or a fact? The current article aims to answer this question and provide a short review of the immunological mechanisms of SARS-CoV-2 vaccination. Recommendations for clinical practice are given based on the current evidence and known problems of anti-SARS-CoV-2 antibody measurements after vaccination.

Designing an evidence-based Bayesian network for estimating the risk versus benefits of AstraZeneca COVID-19 vaccine. Uncertainty surrounding the risk of developing and dying from Thrombosis and Thrombocytopenia Syndrome (TTS) associated with the AstraZeneca (AZ) COVID-19 vaccine may contribute to vaccine hesitancy. A model is urgently needed to combine and effectively communicate evidence on the risks versus benefits of the AZ vaccine. We developed a Bayesian network to consolidate evidence on risks and benefits of the AZ vaccine, and parameterised the model using data from a range of empirical studies, government reports, and expert advisory groups. Expert judgement was used to interpret the available evidence and determine the model structure, relevant variables, data for inclusion, and how these data were used to inform the model. The model can be used as a decision-support tool to generate scenarios based on age, sex, virus variant and community transmission rates, making it useful for individuals, clinicians, and researchers to assess the chances of different health outcomes. Model outputs include the risk of dying from TTS following the AZ COVID-19 vaccine, the risk of dying from COVID-19 or COVID-19-associated atypical severe blood clots under different scenarios. Although the model is focused on Australia, it can be adapted to international settings by re-parameterising it with local data. This paper provides detailed description of the model-building methodology, which can be used to expand the scope of the model to include other COVID-19 vaccines, booster doses, comorbidities and other health outcomes (e.g., long COVID) to ensure the model remains relevant in the face of constantly changing discussion on risks versus benefits of COVID-19 vaccination.

Characteristics and Comparison of Adverse Events of Coronavirus Disease 2019 Vaccines Reported to the United States Vaccine Adverse Event Reporting System Between 14 December 2020 and 8 October 2021. BACKGROUND: This study assessed and compared the frequency and type of adverse events (AEs) of the Pfizer-BioNTech, Moderna, and Janssen coronavirus disease 2019 (COVID-19) vaccines reported in the Vaccine Adverse Event Reporting System (VAERS). METHODS: A retrospective analysis examined VAERS reports between 14 December 2020 and 8 October 2021 and focused on AE reports related to COVID-19 vaccines and AE outcomes [e.g., emergency room (ER)

visits after being vaccinated, hospitalization, prolongation of existing hospitalization, life-threatening events, disability, birth defect, and death]. Reporting odds ratios (RORs) and Breslow-Day statistics were used to compare AE reporting between COVID-19 and non-COVID vaccines and between individual COVID-19 vaccines. RESULTS: A total of 604,157 AEs of COVID-19 vaccines were reported, including 43.51% for the Pfizer-BioNTech vaccine, 47.13% for the Moderna vaccine, and 9.12% for the Janssen COVID-19 vaccine. About 12.56% of patients visited ER after being vaccinated, 5.96% reported hospitalization, and 1.52% reported life-threatening events. Among the number of death cases (n = 7,674; mean age = 73), 2,025 patients (26.39%) had hypertension and 1,237 (16.12%) patients had cancer. RORs between COVID-19 vaccines and non-COVID vaccines identified increased ROR in ER visits, hospitalization, and life-threatening events. The results of the Breslow-Day statistics indicated heterogeneities between the disproportionality of reports across the four serious AE outcomes (i.e., ER visits, hospitalization, life-threatening events, and disability) between individual COVID-19 vaccines. CONCLUSION: Most current VAERS reports showed that the most commonly reported AEs of COVID-19 vaccines were mild. Cases with a mortality outcome tended to occur in older adults with underneath conditions. Close ongoing surveillance in the safety of COVID-19 vaccines is critical and will inform the use of individual COVID-19 vaccines. Given the known limitations associated with the passive spontaneous reporting system, such as VAERS, our findings need to be further assessed and verified through longitudinal, large healthcare data systems.

Vaccine-Induced Thrombotic Thrombocytopenia: A Case Report. While the number of people who have been vaccinated against coronavirus disease 2019 (COVID-19) in Portugal keeps rising, the risk of complications, although rare, keeps rising too. We report a case of vaccine-induced thrombotic thrombocytopenia (VITT) in a 30-year-old previously healthy male after vaccination with Ad26.COV2.S. The patient presented to the emergency department (ED) with abdominal pain and headache. Laboratory tests revealed thrombocytopenia, high D-dimer levels, and fibrinogen consumption. Thoracoabdominal CT scan showed a thrombus in the portal mesenteric venous axis. A positive PF4 heparin enzyme-linked immunosorbent assay confirmed the VITT diagnosis, and the patient was started on intravenous immunoglobulin. Both clinical complaints and laboratory findings resolved within six days, and he was discharged to follow-up. This case shows that general symptoms after vaccination should not be depreciated, highlights the importance of early diagnosis and treatment, and raises new questions about the follow-up and further study of these patients.

An Interesting Case of Fatal Myasthenic Crisis Probably Induced by the COVID-19 Vaccine.
AÂ myasthenic crisis is a severe, life-threatening exacerbation of myasthenia gravis that causes a rapid onset of muscle weakness and fatigue that may result in tetraparesis, dyspnea, respiratory insufficiency, aspiration, and death. Bulbar muscle functions are markedly affected resulting in depressed cough reflex, swallowing, and speech. Thus, mechanical ventilation, supportive feeding, and critical care are essential for the survival of patients in a myasthenic crisis. Numerous precipitating factors of this condition are well known and include infections, various medications, pregnancy, and childbirth. Patients with myasthenia gravis are at a considerably higher risk of developing a debilitating coronavirus disease 2019 (COVID-19) infection due to the associated immunosuppression resulting from long-term corticosteroid use, which makes vaccination of such individuals necessary. However, the relationship between an exacerbation of myasthenia gravis and the COVID-19 vaccination is currently unknown. In this paper, we report the case of a 55-year-old male patient who developed a myasthenic crisis after receiving the first dose of the ChAdOx1-S (recombinant) vaccineÂ (AstraZeneca batch number 210157; AstraZeneca plc, Cambridge, United Kingdom).Â Despite the administration of aggressive and intensive treatment over a period of 29-day hospitalization, the myasthenic crisis could not be reversed and the patient ultimately deteriorated and succumbed from multiple myocardial infarction events and organ failures. While it is still

uncommon, evidence associating the effects of the vaccine to the development of a crisis is mounting; therefore, it is crucial for clinicians to promptly identify clinical features that suggest an exacerbation of myasthenia gravis in order to intervene at the earliest possible stage for a more favorable outcome. The myasthenia gravis patient should be informed about the possible association between COVID-19 vaccination and the development of a myasthenic crisis.

PROmotion of COvid-19 VA(X)ccination in the Emergency Department-PROCOVAXED: study protocol for a cluster randomized controlled trial. BACKGROUND: We conducted in-depth interviews to characterize reasons for COVID-19 vaccine hesitancy in emergency department (ED) patients and developed messaging platforms that may address their concerns. In this trial, we seek to determine whether provision of these COVID-19 vaccine messaging platforms in EDs will be associated with greater COVID-19 vaccine acceptance and uptake in unvaccinated ED patients. METHODS: This is a cluster-randomized controlled trial (RCT) evaluating our COVID-19 vaccine messaging platforms in seven hospital EDs (mix of academic, community, and safety-net EDs) in four US cities. Within each study site, we randomized 30 1-week periods to the intervention and 30 1-week periods to the control. Adult patients who have not received a COVID-19 vaccine are eligible with these exclusions: (1) major trauma, intoxication, altered mental status, or critical illness; (2) incarceration; (3) psychiatric chief complaint; and (4) suspicion of acute COVID-19 illness. Participants receive an orally administered Intake survey. During intervention weeks, participants then receive three COVID-19 vaccine messaging platforms (4-min video, one-page informational flyer and a brief, scripted face-to-face message delivered by anÂ ED physician or nurse); patients enrolled during non-intervention weeks do not receive these platforms. Approximately, an hour after intake surveys, participants receive a Vaccine Acceptance survey during which the primary outcome of acceptance of the COVID-19 vaccine in the ED is ascertained. The other primary outcome of receipt of a COVID-19 vaccine within 32â€‰days is ascertained by electronic health record review and phone follow-up. To determine whether provision of vaccine messaging platforms is associated with a 7% increase in vaccine acceptance and uptake, we will need to enroll 1290 patients. DISCUSSION: Highlighting the difficulties of trial implementation during the COVID-19 pandemic in acute care settings, our novel trial will lay the groundwork for delivery of public health interventions to vulnerable populations whose only health care access occurs in EDs. CONCLUSIONS: Toward addressing vaccine hesitancy in vulnerable populations who seek care in EDs, our cluster-RCT will determine whether implementation of vaccine messaging platforms is associated with greater COVID-19 vaccine acceptance and uptake in unvaccinated ED patients. TRIAL STATUS: We began enrollment in December 2021 and expect to continue through 2022. TRIAL REGISTRATION: ClinicalTrials.gov NCT05142332 . Registered 02 December 2021.

Anti-SARS-CoV-2 IgA and IgG in human milk after vaccination is dependent on vaccine type and previous SARS-CoV-2 exposure: a longitudinal study. BACKGROUND: Breast milk is a vehicle to transfer protective antibodies from the lactating mother to the neonate. After SARS-CoV-2 infection, virus-specific IgA and IgG have been identified in breast milk, however, there are limited data on the impact of different COVID-19 vaccine types in lactating women. This study is aimed to evaluate the time course of induction of SARS-CoV-2-specific IgA and IgG in breast milk after vaccination. METHODS: In this prospective observational study in Spain, 86 lactating women from priority groups receiving the vaccination against SARS-CoV-2 were included. Breast milk samples were collected longitudinally at seven or eight-time points (depending on vaccine type). A group with confirmed SARS-CoV-2 infection (n=19) and a group of women from pre-pandemicÂ time (n=20) were included for comparison. RESULTS: Eighty-six vaccinated lactating women [mean age, 34.6 Â± 3.7 years] of whom 96% were Caucasian and 92% were healthcare workers. A total number of 582 milk samples were included, and vaccine distribution was BioNTech/Pfizer (BNT162b2, n=34), Moderna (mRNA-

1273, n=20), and AstraZeneca (ChAdOx1 nCoV-19, n=32). For each vaccine, 7 and 8 longitudinal time points were collected from baseline up to 30 days after the second dose for mRNA vaccines and adenovirus-vectored vaccines, respectively. A strong reactivity was observed for IgG and IgA after vaccination mainly after the 2(nd) dose. The presence and persistence of specific SARS-CoV-2 antibodies in breast milk were dependent on the vaccine type, with higher IgG and IgA levels in mRNA-based vaccines when compared to AstraZeneca, and on previous virus exposure. High intra- and inter-variability were observed, being relevant for IgA antibodies. In milk from vaccinated women, anti-SARS-CoV-2 IgG was significantly higher while IgA levels were lower than in milk from COVID-19-infected women. Women with previous COVID-19 increased their IgG antibodies levels after the first dose to a similar level observed in vaccinated women after the second dose. CONCLUSIONS: COVID-19 vaccination induced anti-SARS-CoV-2 IgA and IgG in breast milk with higher levels after the 2(nd) dose. Levels of anti-SARS-CoV-2 IgA and IgG are dependent on the vaccine type. Further studies are warranted to demonstrate the protective antibody effect against COVID-19 in infants from vaccinated and infected mothers. TRIAL REGISTRATION: NCT04751734 (date of registration is on February 12, 2021).

Case Report: Isolated, unilateral oculomotor palsy with anti-GQ1b antibody following COVID-19 vaccination. Neurological complications following vaccinations are extremely rare, but cannot be eliminated. Here, we report the first case of unilateral oculomotor nerve palsy (ONP) with anti-GQ1b antibody after receiving the Pfizer-BioNTech COVID-19 (BNT162b2) mRNA vaccine. A 65-year-old man developed diplopia and ptosis in the right eye 17 days after vaccination, without preceding infection. Neurological examination revealed mild blepharoptosis, limitation of adduction, and vertical gaze on the right side. Increased levels of anti-GQ1b ganglioside antibody in the serum and albuminocytologic dissociation in the cerebrospinal fluid were detected. Cranial magnetic resonance imaging showed swelling and enhancement of the right oculomotor nerve. The patient was diagnosed with right ONP accompanied with anti-GQ1b antibody, and intravenous immunoglobulin (IVIG) therapy for 5 days was administered. The limitation of adduction and vertical gaze improved, and ptosis markedly resolved after IVIG treatment. Given the temporal sequence of disease progression, laboratory findings, and a favorable response to IVIG, a causal relationship cannot be ruled out between the occurrence of ONP and COVID-19 immunization. Since immunomodulatory treatments significantly hasten the recovery and minimize the residual symptoms in anti-GQ1b antibody syndrome, clinicians should be aware of this clinical condition following COVID-19 vaccination.

Cubital Tunnel Syndrome Temporally after COVID-19 Vaccination. Coronavirus disease 2019 (COVID-19) is the most dramatic pandemic of the new millennium. To counter it, specific vaccines have been launched in record time under emergency use authorization or conditional marketing authorization and have been subjected to additional monitoring. The European Medicines Agency recommend reporting any suspected adverse reactions during this additional monitoring phase. For the first time in the available medical literature, we report a left cubital tunnel syndrome in a 28-year-old right-handed healthy male after seven days from the first dose of Spikevax(Â®) (formerly Moderna COVID-19 Vaccine). Histochemistry for Alcian Blue performed on the tissue harvested from the cubital site reveals myxoid degeneration of the small nerve collaterals, a clear sign of nerve injury. It still remains unclear why the syndrome occurs in a localized and not generalized form to all osteofibrous tunnels. Today, modified messenger ribonucleic acid vaccines as Spikevax(Â®) represent an avantgarde technological platform with a lot of potential, but one which needs careful monitoring in order to identify in advance those patients who may experience adverse events after their administration.

Psychiatric adverse reactions to COVID-19 vaccines: A rapid review of published case reports. We aimed to review the available reports of psychiatric adverse reactions to COVID vaccines. Electronic

databases such as PubMed and Google scholar were combed to identify relevant reports. We found a total of 11 reports describing 14 cases of psychiatric reactions; these were mostly altered mental states, psychosis, mania, depression, and functional neurological disorder. The index case was commonly a young or middle-aged adult. All reports pertained to the use of either mRNA or vector-based vaccines. Symptom onset was within 10 days of vaccination in all cases; as such, this seems to be a high-risk period warranting vigilance.
Guillain-BarrÃ© Syndrome Associated with COVID-19 Vaccination.
SARS-Cov-2 and Anti-COVID Vaccines Trigger Guillain-BarrÃ© Syndrome.
Monitoring User Opinions and Side Effects on COVID-19 Vaccines in the Twittersphere: Infodemiology Study of Tweets. BACKGROUND: In the current phase of the COVID-19 pandemic, we are witnessing the most massive vaccine rollout in human history. Like any other drug, vaccines may cause unexpected side effects, which need to be investigated in a timely manner to minimize harm in the population. If not properly dealt with, side effects may also impact public trust in the vaccination campaigns carried out by national governments. OBJECTIVE: Monitoring social media for the early identification of side effects, and understanding the public opinion on the vaccines are of paramount importance to ensure a successful and harmless rollout. The objective of this study was to create a web portal to monitor the opinion of social media users on COVID-19 vaccines, which can offer a tool for journalists, scientists, and users alike to visualize how the general public is reacting to the vaccination campaign. METHODS: We developed a tool to analyze the public opinion on COVID-19 vaccines from Twitter, exploiting, among other techniques, a state-of-the-art system for the identification of adverse drug events on social media; natural language processing models for sentiment analysis; statistical tools; and open-source databases to visualize the trending hashtags, news articles, and their factuality. All modules of the system are displayed through an open web portal. RESULTS: A set of 650,000 tweets was collected and analyzed in an ongoing process that was initiated in December 2020. The results of the analysis are made public on a web portal (updated daily), together with the processing tools and data. The data provide insights on public opinion about the vaccines and its change over time. For example, users show a high tendency to only share news from reliable sources when discussing COVID-19 vaccines (98% of the shared URLs). The general sentiment of Twitter users toward the vaccines is negative/neutral; however, the system is able to record fluctuations in the attitude toward specific vaccines in correspondence with specific events (eg, news about new outbreaks). The data also show how news coverage had a high impact on the set of discussed topics. To further investigate this point, we performed a more in-depth analysis of the data regarding the AstraZeneca vaccine. We observed how media coverage of blood clot-related side effects suddenly shifted the topic of public discussions regarding both the AstraZeneca and other vaccines. This became particularly evident when visualizing the most frequently discussed symptoms for the vaccines and comparing them month by month. CONCLUSIONS: We present a tool connected with a web portal to monitor and display some key aspects of the public's reaction to COVID-19 vaccines. The system also provides an overview of the opinions of the Twittersphere through graphic representations, offering a tool for the extraction of suspected adverse events from tweets with a deep learning model.
Understanding vaccine-induced thrombotic thrombocytopenia (VITT). Vaccine-induced thrombotic thrombocytopenia (VITT) is a rare, but serious, syndrome characterised by thrombocytopenia, thrombosis, a markedly raised D-dimer and the presence of anti-platelet factor-4 (PF4) antibodies following COVID-19 adenovirus vector vaccination. VITT occurs at a rate of approximately 2 per 100â€‰000 first-dose vaccinations and appears exceedingly rare following second doses. Our current understanding of VITT pathogenesis is based on the observations that patients with VITT have antibodies that bind to PF4 and have the ability to form immune complexes

that induce potent platelet activation. However, the precise mechanisms that lead to pathogenic VITT antibody development remain a source of active investigation. Thrombosis in VITT can manifest in any vascular bed and affect multiple sites simultaneously. While there is a predilection for splanchnic and cerebral venous sinus thrombosis, VITT also commonly presents with deep vein thrombosis and pulmonary embolism. Pillars of management include anticoagulation with a non-heparin anticoagulant, intravenous immunoglobulin and 'rescue' therapies, such as plasma exchange for severe cases. VITT can be associated with a high mortality rate and significant morbidity, but awareness and optimal therapy have significantly improved outcomes in Australia. A number of questions remain unanswered, including why VITT is so rare, reasons for the predilection for thrombosis in unusual sites, how long pathological antibodies persist, and the optimal duration of anticoagulation. This review will provide an overview of the presentation, diagnostic workup and management strategies for patients with VITT.

De novo and relapsed immune thrombocytopenia after COVID-19 vaccines: results of French safety monitoring.

Rapid resolution of severe pericardial effusion using anakinra in a patient with COVID-19 vaccine-related acute pericarditis relapse: a case report. BACKGROUND: Pericarditis, along with myocarditis, is being increasingly reported after the coronavirus disease 2019 (COVID-19) vaccine, but the best treatment strategy in this specific setting is still unclear. CASE SUMMARY: We report a case of acute pericarditis after the second dose of mRNA COVID-19 vaccine with recurrence of large pericardial effusion after a previous pericardiocentesis and anti-inflammatory drugs tapering. The patient was successfully treated with the recombinant interleukin-1 receptor antagonist anakinra, with full reabsorption of the pericardial effusion and an abrupt drop of the inflammatory markers within 72â€…h. The patient was discharged a few days later, with a further decrease of the inflammatory markers and no residual symptoms. DISCUSSION: Anakinra is being increasingly used in the treatment of recurrent pericarditis due to its capability to interrupt the autoinflammatory response leading to deleterious cytokine storms. On account of its high efficacy and rapid onset, it has been reported to rapidly reverse large inflammatory pericardial effusions. Pericarditis and myocarditis have been reported after the COVID-19 vaccine, but this is the first case of COVID-19 vaccine-related pericarditis and pericardial effusion successfully treated with anakinra, avoiding a second pericardiocentesis.

Myelin Oligodendrocyte Glycoprotein-Associated Disorders Post-ChAdOx1 Vaccination. ChAdOx1 nCoV-19 vaccine (AstraZeneca) has been associated with rare adverse events following vaccination such as thrombosis with thrombocytopenia syndrome, inflammatory myositis, and autoimmune encephalitis. Para-infectious or post-infectious myelin oligodendrocyte glycoprotein-associated disorders (MOGAD) have been reported in association with coronavirus disease. However, post-vaccine MOGAD (PV-MOGAD) has not yet been reported. Here, we report three cases of PV-MOGAD who presented with a prolonged severe headache after the ChAdOx1â€¯vaccination. Other features of MOGAD such as optic neuritis or tumefactive demyelination appeared much later. Aseptic meningitis can be a presenting feature of PV-MOGAD. When patients present with a severe headache after the ChAdOx1â€¯vaccination, PV-MOGAD should be considered along with thrombosis with thrombocytopenia syndrome.

A Case of Antineutrophil Cytoplasmic Antibodies (ANCA)-Associated Vasculitis Post COVID-19 Vaccination. In this report, we examine the case of a patient who developed antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis after receiving the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine. This is a case of a 62-year-old female who received the first dose of COVID-19 vaccine in July 2021 before presenting a few weeks later with migrating polyarthralgia and hemoptysis. Autoimmune workup was positive for ANCA against proteinase 3 (PR3).

Not All That Is Droopy Post Ad26.COV2.S (JNJ) Vaccine Is Bell's Palsy: A Rare Case of Isolated Dorsal Pontine Stroke Causing Ipsilateral Complete Hemi-Facial Palsy. The Ad26.COV2.S vaccine, developed by Janssen (Beerse, Belgium), the pharmaceutical wing of Johnson & Johnson (JNJ), is one of the three vaccines approved for use against coronavirus disease 2019 (COVID-19) infection in the United States. We present a case of a 66-year-old female who presented to the emergency department with a one-day history of nausea, vomiting, room-spinning vertigo, and complete right facial weakness immediately after getting vaccinated with Ad26.COV2.S. Initial workup focused on uncovering a possible association between the vaccine and Bell's palsy. However, her prior history of stroke, presence of predisposing risk factors, and additional symptoms of nausea, vomiting, and vertigo prompted further neurological testing, which revealed an isolated right pontine lacunar infarct involving the right facial colliculus, mimicking Bell's palsy. Isolated dorsal pontine lesion presenting as hemifacial palsy is very rare and can be easily missed by clinicians. Relevant history and thorough neurological examination can help guide appropriate diagnostic testing and prevent potential biases. It is crucial for clinicians to know the distinguishing features between true Bell's palsy and acute brainstem infarction masquerading as Bell's.

Impact of SARS-CoV-2 infection on vaccine-induced immune responses over time. OBJECTIVE: To determine the long-term impact of prior SARS-CoV-2 infection on immune responses after COVID-19 vaccination. METHODS: Using longitudinally collected blood samples from the COMMUNITY study, we determined binding (WHO BAU mL(-1)) and neutralising antibody titres against ten SARS-CoV-2 variants over 7â€‰months following BNT162b2 in SARS-CoV-2-recovered (nâ€‰=â€‰118) and SARS-CoV-2-naÃ¯ve (nâ€‰=â€‰289) healthcare workers with confirmed prior SARS-CoV-2 infection. A smaller group with (nâ€‰=â€‰47) and without (nâ€‰=â€‰60) confirmed prior SARS-CoV-2 infection receiving ChAdOx1 nCoV-19 was followed for 3â€‰months. SARS-CoV-2-specific memory T-cell responses were investigated in a subset of SARS-CoV-2-naÃ¯ve and SARS-CoV-2-recovered vaccinees. RESULTS: Vaccination with both vaccine platforms resulted in substantially enhanced T-cell responses, anti-spike IgG responses and neutralising antibodies effective against ten SARS-CoV-2 variants in SARS-CoV-2-recovered participants as compared to SARS-CoV-2-naÃ¯ve participants. The enhanced immune responses sustained over 7â€‰months following vaccination. CONCLUSION: These findings imply that prior SARS-CoV-2 infection should be taken into consideration when planning booster doses and design of current and future COVID-19 vaccine programmes.

Vaccine-Associated Enhanced Disease and Pathogenic Human Coronaviruses. Vaccine-associated enhanced disease (VAED) is a difficult phenomenon to define and can be confused with vaccine failure. Using studies on respiratory syncytial virus (RSV) vaccination and dengue virus infection, we highlight known and theoretical mechanisms of VAED, including antibody-dependent enhancement (ADE), antibody-enhanced disease (AED) and Th2-mediated pathology. We also critically review the literature surrounding this phenomenon in pathogenic human coronaviruses, including MERS-CoV, SARS-CoV-1 and SARS-CoV-2. Poor quality histopathological data and a lack of consistency in defining severe pathology and VAED in preclinical studies of MERS-CoV and SARS-CoV-1 vaccines in particular make it difficult to interrogate potential cases of VAED. Fortuitously, there have been only few reports of mild VAED in SARS-CoV-2 vaccination in preclinical models and no observations in their clinical use. We describe the problem areas and discuss methods to improve the characterisation of VAED in the future.

Acute Bilateral Descemet Membrane Endothelial Keratoplasty Graft Rejection After the BNT162b2 mRNA COVID-19 Vaccine. PURPOSE: We report a case of acute bilateral Descemet membrane endothelial keratoplasty (DMEK) rejection two weeks following BNT162b2 mRNA COVID-19 vaccine (Pfizer-BioNTech), reflecting on possible changes to the management of patients with DMEK scheduled for COVID-19 vaccination. PATIENTS AND METHODS: A 94-year-old woman with Fuchs'

endothelial dystrophy who underwent DMEK 24 months earlier (right eye) and 20 months earlier (left eye) demonstrated bilateral graft rejection two weeks after the first dose of COVID-19 vaccine. Standard treatment regimen was followed, and clinical status documented with slit-lamp examination and swept-source optical coherence tomography throughout. RESULTS: Preoperative best corrected visual acuity (BCVA) and corneal thickness (CT) were 0.3 and 679Âµm right eye and 0.2 and 668Âµm left eye. Postoperative BCVA and CT were 0.7 and 559Âµm right eye and 0.4 and 590Âµm left eye. Standard treatment regimen consisted of dexamethasone/tobramycin and ketorolac, four times daily. At one month, both preparations were discontinued, replaced by dexamethasone 0.1% four times daily. At three months, this was tapered to once daily. Post-rejection, BCVA and CT were 0.2 and 710Âµm right eye and 0.3 and 710Âµm left eye. Treatment was with dexamethasone/tobramycin six times daily. Poor response resulted in re-DMEK transplantation, starting in the left eye. At one-month follow-up, BCVA and CT were 0.5 and 538Âµm right eye and 0.63 and 504Âµm left eye. CONCLUSION: We report the first acute bilateral DMEK graft rejection after a single dose of COVID-19 vaccine. We recommend clinicians exercise vigilance and consider dexamethasone 0.1% during the vaccination period.

Cross-reactive antibodies elicited to conserved epitopes on SARS-CoV-2 spike protein after infection and vaccination. SARS-CoV-2 is a novel betacoronavirus that caused coronavirus disease 2019 and has resulted in millions of deaths worldwide. Novel coronavirus infections in humans have steadily become more common. Understanding antibody responses to SARS-CoV-2, and identifying conserved, cross-reactive epitopes among coronavirus strains could inform the design of vaccines and therapeutics with broad application. Here, we determined that individuals with previous SARS-CoV-2 infection or vaccinated with the Pfizer-BioNTech BNT162b2 vaccine produced antibody responses that cross-reacted with related betacoronaviruses. Moreover, we designed a peptide-conjugate vaccine with a conserved SARS-CoV-2 S2 spike epitope, immunized mice and determined cross-reactive antibody binding to SARS-CoV-2 and other related coronaviruses. This conserved spike epitope also shared sequence homology to proteins in commensal gut microbiota and could prime immune responses in humans. Thus, SARS-CoV-2 conserved epitopes elicit cross-reactive immune responses to both related coronaviruses and host bacteria that could serve as future targets for broad coronavirus therapeutics and vaccines.

Seroconversion panels demonstrate anti-SARS-CoV-2 antibody development after administration of the mRNA-1273 vaccine. Seroconversion panels are an important tool for investigating antibody responses in acute and chronic phases of disease and development of serological assays for viral diseases including COVID-19. Globally it is anticipated that vaccines against SARS-CoV-2 will facilitate control of the current pandemic. The two COVID-19 seroconversion panels analyzed in this study were obtained from healthcare workers with samples collected before vaccination with the mRNA-1273 vaccine (Moderna) and after the first and second doses of the vaccine. Panel samples were tested for antibodies to SARS-CoV-2 (IgG). Individual subjects with a positive response for anti-SARS-CoV2 IgG in their pre-vaccination samples showed a significantly enhanced response to the first vaccination. In older subjects, lower immunological responses to the first injection were observed, which were overcome by the second injection. All subjects in the study were positive for anti-SARS-CoV-2 IgG after the second dose of vaccine.

Breakthrough covid 19 infections after 2 doses of covid 19 vaccination and comparing severity between hospitalized and non hospitalized in tertiary care hospital. The COVID 19 infection is highly transmissible and spreading globally, including in populations with high vaccination rates. COVID-19 vaccination in India, was started in month of January 2021 with healthcare workers (HCWs) becoming the first to get vaccinated. However, there has been lot debate on the efficacy of the vaccine. This study highlights breakthrough COVID-19 infections among vaccinated HCWs comparing

clinical and lab parameter among hospitalized and non hospitalized. MATERIAL: This was a retrospective study conducted using questionnaire assessing COVID-19 like symptoms and confirmed COVID 19 infections among fully vaccinated HCWs (all faculty including nurses, wardboys, professors, post graduate students and interns) of the institute from a period of 4 months from March 2021 to June 2021. The number of infections was also matched with hospital records. OBSERVATION: Out of 36 HCWs, all had received both doses of covishield vaccine. Males were 18 and females were 18, mean age was found to ne 32.17. People with co-morbidities were 13.9% including diabetes and hypertension. Out 36 HCWs, 4 people required hospitalization ie 11%, all other cases had mild symptoms and none required oxygen support. There was no significant difference between hospitalized and non-hospitalized with regard to routine lab parameters, but there significant elevation of inflammatory marker -CRP being positive in 2 hospitalized cases, with p value being significant (p<0.001). CONCLUSION: This study identifies that breakthrough infections among vaccinated HCWs(health care workers) were common. Most breakthrough infections were mild or asymptomatic, although persistent symptoms did occur. The findings suggested that COVID-19 were more severe in hospitalized patients compared to non-hospitalized and even though infections did occur none resulted in any severe form or mortality, it also indicates that vaccination prevents from severe form of the disease. But, preventive measures should be continued even among vaccinated individuals.

Diabetes and Covid Associated Mucormucormycosis-A Cross Sectional Study in Kilpauk Medical College. To find the association between CAM and diabetes and correlate the severity of glycemic status,and clinical features and morbidity associated with them. MATERIAL: This descriptive study was conducted at a COVID Ward in govt kilpauk med college from Apr 10, 2021 to Aug 1 0, 2021. All laboratory confirmed COVID-19 cases by RTPCR (Real Time Reverse Transcription Polymerse Chain Reaction) nasopharyngeal & throat swab were admitted at this centre. Severe COVID-19 infection was defined bySp02<90%orRespiratory rate >30/min at admi during hospital stay. Post COVID 19 cases were defined who had either clinical recovery from respiratory symptoms or had passed 28 days since the onset of symptoms of COVID 19. Lymphocytopenia was defined by absolute lymphocyte count<1000/mm3.Data compiled in Ms-excel sheet and studied. OBSERVATION: In Patients with CAM30/32(93.8%) hadheadache,20/32(62.5%) had nasal symptoms in form of rhinorrhoea & nasal stuffiness and 19/32(59.4%) had eyes symptoms in form of red nessoreye pain. O n admission, 18/32 (56.2%) patients had history or presented with Severe COVID-19 pneumonia. At the time of diagnosis of CAM, 22/ 32 (68.8%) had hypoxemia and required supplemental oxygen. The mean duration from onset of COVID-19 to diagnosis of CAM was 17.28 (Â±11.76) days. In patients with CAM, none of them were fully vaccinated against COVID-19. Two patients had received a single dose of (Covishield) COVID-19 vaccine. Both the patients are still admitted at our centre and are on antifungal therapy. Among 822 hospitalized patients with COVID 19 infection, 36 patients had CAM with an incidence of 3.9%. In patients with CAM, 84.5% had Diabetes Mellitus as the most common co-morbidity. The majority of the patients had poor glycemic control with a mean HbA1c of 8.06%. Out of the total population, 88% had prior exposure to high dose corticosteroids.surgical debridement done for 65%of patients and others treated withantifungals. During the study period, 36% patients of CAM did not survive. CONCLUSION: Mucormycosis is a formidable angioinvasive opportunistic infection in an immunocompromised host. The spectrum of mucormycosis involves rhino-orbital-cerebral, pulmonary, disseminated, cutaneous, gastrointestinal and disseminated form of disease. The major risk factors for the disease are diabetes, neutropenia, iron overload, malignancy and organ transplant. Diabetes is the most common metabolic disorder and is an independent risk factor for Severe COVID-19 and Mucormycosis. In

patients with diabetes affected with COVID-19 superinfection with Mucormycosis will lead to adverse clinical outcome and prolonged hospital stay.

A rare case of grave's disease after SARS-CoV-2 vaccine: is it an adjuvant effect? The COVID-19 virus has been responsible for the development of several systemic diseases. Recently, the COVID-19 vaccine has also been incriminated in the development of autoimmune diseases. Currently, researchers have focused on the relationship between the COVID-19 vaccine and the activation of autoimmune phenomenon. We report a case of Graves' disease (GD) whose symptoms appeared 3 days after vaccination against COVID-19. A forty-three-year-old female, without pathological history, presented with diarrhea and palpitation. She received her first SARS-CoV-2 Vaccine dose (Pfizer-BioNTech), in August 2021. Three days after the vaccine, she felt palpitations, sleep disorders, muscle weakness, and heat intolerance. On examination, her pulse was 119 beats per minute, she weighed 63 kg, and she had lost 4 kg in only two months. GD was suspected. Thyroid hormone testing showed low thyroid-stimulating hormone, and an elevated serum free thyroxine hormone T4 level. Serology tests were positive for TSH receptor autoantibodies (TRAB). A GD induced by adjuvants of SARS-CoV-2 vaccine has been retained as a final diagnosis. Several autoimmune diseases have been attributed to adjuvant-induced autoimmune/inï¬,ammatory syndrome, including systemic sclerosis, systemic lupus erythematosus and rheumatoid arthritis, and recently few cases of GD have been explained by this phenomenon.

SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents. IMPORTANCE: Reports of myocarditis after SARS-CoV-2 messenger RNA (mRNA) vaccination have emerged. OBJECTIVE: To evaluate the risks of myocarditis and pericarditis following SARS-CoV-2 vaccination by vaccine product, vaccination dose number, sex, and age. DESIGN, SETTING, AND PARTICIPANTS: Four cohort studies were conducted according to a common protocol, and the results were combined using meta-analysis. Participants were 23â€¯122â€¯522 residents aged 12 years or older. They were followed up from December 27, 2020, until incident myocarditis or pericarditis, censoring, or study end (October 5, 2021). Data on SARS-CoV-2 vaccinations, hospital diagnoses of myocarditis or pericarditis, and covariates for the participants were obtained from linked nationwide health registers in Denmark, Finland, Norway, and Sweden. EXPOSURES: The 28-day risk periods after administration date of the first and second doses of a SARS-CoV-2 vaccine, including BNT162b2, mRNA-1273, and AZD1222 or combinations thereof. A homologous schedule was defined as receiving the same vaccine type for doses 1 and 2. MAIN OUTCOMES AND MEASURES: Incident outcome events were defined as the date of first inpatient hospital admission based on primary or secondary discharge diagnosis for myocarditis or pericarditis from December 27, 2020, onward. Secondary outcome was myocarditis or pericarditis combined from either inpatient or outpatient hospital care. Poisson regression yielded adjusted incidence rate ratios (IRRs) and excess rates with 95% CIs, comparing rates of myocarditis or pericarditis in the 28-day period following vaccination with rates among unvaccinated individuals. RESULTS: Among 23â€¯122â€¯522 Nordic residents (81% vaccinated by study end; 50.2% female), 1077 incident myocarditis events and 1149 incident pericarditis events were identified. Within the 28-day period, for males and females 12 years or older combined who received a homologous schedule, the second dose was associated with higher risk of myocarditis, with adjusted IRRs of 1.75 (95% CI, 1.43-2.14) for BNT162b2 and 6.57 (95% CI, 4.64-9.28) for mRNA-1273. Among males 16 to 24 years of age, adjusted IRRs were 5.31 (95% CI, 3.68-7.68) for a second dose of BNT162b2 and 13.83 (95% CI, 8.08-23.68) for a second dose of mRNA-1273, and numbers of excess events were 5.55 (95% CI, 3.70-7.39) events per 100â€¯000 vaccinees after the second dose of BNT162b2 and 18.39 (9.05-27.72) events per 100â€¯000 vaccinees after the second dose of mRNA-1273. Estimates for pericarditis were similar. CONCLUSIONS AND RELEVANCE: Results of this large cohort study indicated that both first and second doses of mRNA vaccines were associated with

increased risk of myocarditis and pericarditis. For individuals receiving 2 doses of the same vaccine, risk of myocarditis was highest among young males (aged 16-24 years) after the second dose. These findings are compatible with between 4 and 7 excess events in 28 days per 100â€¯000 vaccinees after BNT162b2, and between 9 and 28 excess events per 100â€¯000 vaccinees after mRNA-1273. This risk should be balanced against the benefits of protecting against severe COVID-19 disease.

Herpes zoster reactivation after COVID-19 vaccination - a retrospective case series of 22 patients.

COVID-19 Vaccination for Frail Older Adults in Singapore - Rapid Evidence Summary and Delphi Consensus Statements. OBJECTIVE: This study aimed to synthesize available evidence on the effectiveness and safety of COVID-19 vaccines for frail older adults through a rapid review, supplemented with geriatricians' consensus statements. METHODS: References were identified through MEDLINE and Web of Science on 1st February 2021 using relevant terms related to COVID-19, vaccine, and older adults. Searches were also conducted on reference lists of review articles and Google Scholar. The content was updated on 8th April via hand searching. We included studies on Phase III randomized controlled trials, and data from real world administration of vaccines. A two-round Delphi study was conducted with 15 geriatricians to elicit their thoughts and recommendations regarding COVID-19 vaccination for frail older adults. RESULTS: Five Phase III randomized controlled efficacy trials reported vaccine efficacy ranging from 66.7% to 95% among participants aged 16 to 95. The vaccine efficacy for participants aged 65 and above is 94.7% and 86.4% for Pfizer-BioNTech and Moderna respectively. Sputnik V reported a vaccine efficacy of 91.8% for participants 60 and above. Serious adverse events were reported by 0.27% to 1% of participants who received at least one dose of the four vaccines. For the Delphi study, 16 out of 24 statements achieved consensus. The Delphi panel opined that frail or very old adults, except those with limited life expectancy, should be vaccinated due to their vulnerability. They also agree that vaccination decisions should be made by patients when possible, with the involvement of next-of-kin should the frail older adult be unable to do so. Lastly, the panel thought that frail older adults should be included in future clinical trials. CONCLUSION: In early clinical trials, there is paucity of evidence on efficacy and safety of current COVID-19 vaccines among frail older adults. Geriatricians' consensus indicate that frail older adults should be vaccinated except where life expectancy is limited. Future trials assessing efficacy and safety should include frail older adults.

Omicron neutralizing antibody response following booster vaccination compared with breakthrough infection. The rapid spread of the vaccine-resistant Omicron variant of SARS-CoV-2 presents a renewed threat to both unvaccinated and fully vaccinated individuals, and accelerated booster vaccination campaigns are underway to mitigate the ongoing wave of Omicron cases. The degree of immunity provided by standard vaccine regimens, boosted regimens, and immune responses elicited by the combination of vaccination and natural infection remain incompletely understood. The relative magnitude, quality and durability of serological responses, and the likelihood of neutralizing protection against future SARS-CoV-2 variants following these modes of exposure are unknown but are critical to the future trajectory of the COVID-19 pandemic. In this study of 99 vaccinated adults, we find that compared with responses after two doses of an mRNA regimen, the immune responses three months after a third vaccine dose and one month after breakthrough infection due to prior variants show dramatic increases in magnitude, potency, and breadth, including increased antibody dependent cellular phagocytosis and robust neutralization of the recently circulating Omicron variant. These results suggest that as the number of Omicron cases rise and as global vaccination and booster campaigns continue, an increasing proportion of the worldÃ¢â‚¬â„¢s population will acquire potent immune responses that may be protective against future SARS-CoV-2 variants.

Guillain-BarrÃ© syndrome after mRNA-1273 (Moderna) COVID-19 vaccination: A case report. Guillain-Barre syndrome (GBS) is an acquired inflammatory polyradiculoneuropathy that often follows

infection with a virus or bacteria and in rare occasions, vaccination may precede GBS. We present a case of 80-year-old male patient who presented with chief complaints of progressive, ascending bilateral lower extremity paresthesia and weakness following first dose of Moderna vaccine. His symptoms got exacerbated after 2nd dose. Clinical examination and investigation findings including lumbar puncture, nerve conduction study, and electromyography were consistent with the diagnosis of GBS. The patient received treatment with intravenous immunoglobulin and there was significant improvement toward the end of 5th day. Though rare, this case report suggest that physician should remain vigilant for GBS following COVID-19 vaccination.

Myocarditis following AstraZeneca (an adenovirus vector vaccine) COVID-19 vaccination: A case report. Coronavirus disease-19 (COVID-19) vaccines are massively administered globally and some adverse events, such as myocarditis, are being reported. Most of the reported cases of post-vaccination myocarditis have occurred following mRNA vaccinations. However, there have also been recent reports of myocarditis following adenovirus vector vaccinations. We present a case of a 32-year-old female patient who developed myocarditis following the administration of the first dose of the AstraZeneca vaccine. The patient developed inappropriate exertional tachycardia and exertional dyspnea from Day 3 and was diagnosed with myocarditis by subsequent echocardiography about 3Â months later. We are unable to confirm a direct association between myocarditis and AstraZeneca vaccination. However, we would like to increase awareness regarding the possibility of developing myocarditis following AstraZeneca vaccination.

Inter-individual variation in objective measure of reactogenicity following COVID-19 vaccination via smartwatches and fitness bands. The ability to identify who does or does not experience the intended immune response following vaccination could be of great value in not only managing the global trajectory of COVID-19 but also helping guide future vaccine development. Vaccine reactogenicity can potentially lead to detectable physiologic changes, thus we postulated that we could detect an individual's initial physiologic response to a vaccine by tracking changes relative to their pre-vaccine baseline using consumer wearable devices. We explored this possibility using a smartphone app-based research platform that enabled volunteers (39,701 individuals) to share their smartwatch data, as well as self-report, when appropriate, any symptoms, COVID-19 test results, and vaccination information. Of 7728 individuals who reported at least one vaccination dose, 7298 received an mRNA vaccine, and 5674 provided adequate data from the peri-vaccine period for analysis. We found that in most individuals, resting heart rate (RHR) increased with respect to their individual baseline after vaccination, peaked on day 2, and returned to normal by day 6. This increase in RHR was greater than one standard deviation above individuals' normal daily pattern in 47% of participants after their second vaccine dose. Consistent with other reports of subjective reactogenicity following vaccination, we measured a significantly stronger effect after the second dose relative to the first, except those who previously tested positive to COVID-19, and a more pronounced increase for individuals who received the Moderna vaccine. Females, after the first dose only, and those aged <40 years, also experienced a greater objective response after adjusting for possible confounding factors. These early findings show that it is possible to detect subtle, but important changes from an individual's normal as objective evidence of reactogenicity, which, with further work, could prove useful as a surrogate for vaccine-induced immune response.

Seropositivity and neutralising antibodies at six months after BNT162b2 vaccination in patients with solid tumours. AIM: Patients with cancer are at an increased risk for severe coronavirus disease of 2019. We previously reported initial findings from a single centre prospective study evaluating antibody response after BNT162b2 vaccine, showing that adequate antibody response was achieved after two doses, but not after one, in patients with cancer vaccinated during anticancer therapy. Herein, we report a follow-up study, evaluating antibody response six months after the second

vaccine dose. METHODS: The study included patients with solid tumours undergoing anticancer treatment, and immunocompetent health-care workers serving as controls. Serum titres of the receptor-binding domain (RBD) IgG and neutralising antibodies (Nabs) were measured approximately six months after the second vaccine dose. Complete blood count values were collected and evaluated as predictors for antibody response. RESULTS: The analysis included 93 patients with cancer (66.7% metastatic). Six months after the second vaccine dose (mean 176Â Â±Â 20 days), seropositivity rate among patients and controls was 83.9% versus 96.3% (pÂ =Â 0.0001), respectively. Median RBD-IgG titre was lower among patients compared with controls (2.3 versus 3.2, pÂ =Â 0.0002). Among seropositive individuals, median Nabs titre was similar between patients with cancer and controls (pÂ =Â 0.566). Among patients with cancer, lymphocyte and neutrophil counts were not correlated with either RBD-IgG or Nabs titres. CONCLUSIONS: Seropositivity rates and RBD-IgG titre at six months after second BNT162b2 vaccine dose are lower among patients with cancer compared with healthy controls. However, Nabs titre is similar, suggesting a comparable protection among seropositive individuals. Lymphocyte count is not predictive of antibody response.

Biopsy-Proven Giant Cell Myocarditis Following the COVID-19 Vaccine.

Reactivation in major organ involvement following SARS-CoV-2 mRNA vaccination in BehÃ§et's syndrome patient receiving immunosuppressive therapy.

Autoimmune Hepatitis Following Vaccination for SARS-CoV-2 in Korea: Coincidence or Autoimmunity? Autoimmune hepatitis (AIH) is a chronic, autoimmune disease of the liver that occurs when the body's immune system attacks liver cells, causing the liver to be inflamed. AIH is one of the manifestations of a coronavirus disease 2019 (COVID-19), as well as an adverse event occurring after vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Few cases of AIH have been described after vaccination with two messenger RNA (mRNA)-based vaccines-BTN162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna)-against SARS-CoV-2. Herein, we report a case of AIH occurring after Pfizer-BioNTech COVID-19 vaccine. A 27-year-old female presented with jaundice and hepatomegaly, appearing 14 days after receiving the second dose of Pfizer-BioNTech vaccine. Her laboratory results showed abnormal liver function with high total immunoglobulin G level. She was diagnosed with AIH with histologic finding and successfully treated with oral prednisolone. We report an AIH case after COVID-19 vaccination in Korea.

Cerebral venous thrombosis after COVID-19 vaccines: Do we know the mechanism?

Risk Factors Associated With Hospitalization and Death in COVID-19 Breakthrough Infections. BACKGROUND: Characterizations of coronavirus disease 2019 (COVID-19) vaccine breakthrough infections are limited. We aim to characterize breakthrough infections and identify risk factors associated with outcomes. METHODS: This was a retrospective case series of consecutive fully vaccinated patients with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in a multicenter academic center in Southeast Michigan, between December 30, 2020, and September 15, 2021. RESULTS: A total of 982 patients were identified; the mean age was 57.9 years, 565 (59%) were female, 774 (79%) were White, and 255 (26%) were health care workers (HCWs). The median number of comorbidities was 2; 225 (23%) were immunocompromised. BNT162b2 was administered to 737 (75%) individuals. The mean time to SARS-CoV-2 detection was 135 days. The majority were asymptomatic or exhibited mild to moderate disease, 154 (16%) required hospitalization, 127 (13%) had severe-critical illness, and 19 (2%) died. Age (odds ratio [OR], 1.14; 95% CI, 1.04-1.07; Pâ€…<â€….001), cardiovascular disease (OR, 3.02; 95% CI, 1.55-5.89; Pâ€…=â€….001), and immunocompromised status (OR, 2.57; 95% CI, 1.70-3.90; Pâ€…<â€….001) were independent risk factors for hospitalization. Additionally, age (OR, 1.06; 95% CI, 1.02-1.11; Pâ€…=â€….006) was significantly associated with mortality. HCWs (OR, 0.15; 95% CI, 0.05-0.50; Pâ€…=â€….002) were less likely to be hospitalized, and prior receipt of BNT162b2 was associated with lower odds of

hospitalization (OR, 0.436; 95% CI, 0.303-0.626; Pâ€…<â€….001) and/or death (OR, 0.360; 95% CI, 0.145-0.898; Pâ€…=â€….029). CONCLUSIONS: COVID-19 vaccines remain effective at attenuating disease severity. However, patients with breakthrough infections necessitating hospitalization may benefit from early treatment modalities and COVID-19-mitigating strategies, especially in areas with substantial or high transmission rates.

COVID-19 Vaccines in Pancreatic Transplant Recipients: A Single-Center Observative Study. The SARS-CoV-2 pandemic was a real test of doctors' abilities to adapt and respond to patients' needs. The course of infection varied from influenza-like symptoms to severe infections with multi-organ failure and death. Therefore, the possibility of vaccination against the COVID-19 virus brought great hope. Since 2004, 240 pancreas and pancreas with kidney (simultaneous pancreas and kidney transplantation, pancreas after kidney, pancreas transplants alone) transplants were performed in our center. Currently, 130 transplant patients are under the care of the transplant clinic. All patients were informed about the possibility of vaccination against SARS-CoV-2 with the mRNA vaccine. The aim of the study was to evaluate the development of antibodies to SARS-CoV-2 in patients who had previously undergone transplantation. Fifty-three patients were vaccinated with the full double dose and 37 patients received an additional third dose. The level of antibodies in the IgM and IgG classes was assessed in patients' serum. The level of antibodies was assessed before administration of the vaccine and then after administration of the first and second doses. Most patients had no response to vaccination after 1 dose of the vaccine and 21 patients achieved therapeutic antibody levels after the full dose of vaccination. However, the highest titer of immunoglobulins was found in recipients who received the third dose. The use of vaccinations is safe and can protect the group of patients after pancreas transplantation from serious complications of SARS-CoV-2 infection despite the use of immunosuppressive drugs.

To Study Adverse Effect following Immunization (AEFI) and COVID-19 Infection amongst COVID-19 Vaccine Benefeciaries. COVID-19 vaccines have been rolled out recently in several parts of the world. Little is known about the post-vaccination experience outside of clinical trial conditions. The aim of this study was to investigate the adverse effects and infection rate of vaccinated people in a community scenario. It will help to educate the public, dispel misinformation and reduce vaccine hesitancy. AIM AND OBJECTIVES: Assessing total beneficiaries of COVID-19 vaccination and finding among them COVID-19 infection and AEFI after vaccination. SUBJECT AND METHODS: Cross sectional Study at COVID-19 Vaccination centre at DCH in Mumbai, since 1st February2021-31st July 2021, Data was collected by calling telephonically the registered beneficiaries in Vaccination Centre, data was collected and analysed in MS-excel sheet and SPSS using CHI-square test. RESULTS: 49.68% of the beneficiaries were from the age group of 45-60 years followed by >60 years age group (34.70%). 97.08% beneficiaries were from Mumbai. 3593(43.59%) had taken both the doses of COVID-19 vaccine while 4650(56.41%) had taken only first dose of COVID -19 vaccine. 36(0.44%) had contracted COVID-19 infection after vaccination. 88.71% had no AEFI after taking vaccine. 1.65% had mild AEFI 9.63% had moderate AEFI. CONCLUSION: Very few had contracted COVID-19 infection after vaccination. Out of all AEFI maximum were mild to moderate.

COVID-19 updates: Second booster vaccine dose for older and immunocompromised persons.

Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs. The mRNA SARS-CoV-2 vaccines were brought to market in response to the public health crises of Covid-19. The utilization of mRNA vaccines in the context of infectious disease has no precedent. The many alterations in the vaccine mRNA hide the mRNA from cellular defenses and promote a longer biological half-life and high production of spike protein. However, the immune response to the vaccine is very different from that to a SARS-CoV-2 infection. In this paper, we present evidence that vaccination induces a profound impairment in type I interferon signaling,

which has diverse adverse consequences to human health. Immune cells that have taken up the vaccine nanoparticles release into circulation large numbers of exosomes containing spike protein along with critical microRNAs that induce a signaling response in recipient cells at distant sites. We also identify potential profound disturbances in regulatory control of protein synthesis and cancer surveillance. These disturbances potentially have a causal link to neurodegenerative disease, myocarditis, immune thrombocytopenia, Bell's palsy, liver disease, impaired adaptive immunity, impaired DNA damage response and tumorigenesis. We show evidence from the VAERS database supporting our hypothesis. We believe a comprehensive risk/benefit assessment of the mRNA vaccines questions them as positive contributors to public health.

SARS-CoV-2 Omicron triggers cross-reactive neutralization and Fc effector functions in previously vaccinated, but not unvaccinated, individuals. The SARS-CoV-2 Omicron variant escapes neutralizing antibodies elicited by vaccines or infection. However, whether Omicron triggers cross-reactive humoral responses to other variants of concern (VOCs) remains unknown. We used plasma from 20 unvaccinated and 7 vaccinated individuals infected by Omicron BA.1 to test binding, Fc effector function, and neutralization against VOCs. In unvaccinated individuals, Fc effector function and binding antibodies targeted Omicron and other VOCs at comparable levels. However, Omicron BA.1-triggered neutralization was not extensively cross-reactive for VOCs (14- to 31-fold titer reduction), and we observed 4-fold decreased titers against Omicron BA.2. In contrast, vaccination followed by breakthrough Omicron infection associated with improved cross-neutralization of VOCs with titers exceeding 1:2,100. This has important implications for the vulnerability of unvaccinated Omicron-infected individuals to reinfection by circulating and emerging VOCs. Although Omicron-based immunogens might be adequate boosters, they are unlikely to be superior to existing vaccines for priming in SARS-CoV-2-naive individuals.

Short-term Adverse Events After the Third Dose of the BNT162b2 mRNA COVID-19 Vaccine in Adults 60 Years or Older. This survey study assesses the occurrence of short-term adverse events in adults 60 years or older who received a booster dose of the BNT162B2 mRNA vaccine.

Cardiovascular Events After COVID-19 Vaccination: A Comment.

Risk of strong antibody decline in dialysis and transplant patients after SARS-CoV-2mRNA vaccination: Six months data from the observational Dia-Vacc study. BACKGROUND: Vulnerable dialysis and kidney transplant patients show impaired seroconversion rates compared to medical personnel eight weeks after SARS-CoV-2mRNA vaccination. METHODS: We evaluated six months follow up data in our observational Dia-Vacc study exploring specific cellular (interferon-Î³ release assay) or/and humoral immune responses after 2x SARS-CoV-2mRNA vaccination in 1205 participants including medical personnel (125 MP), dialysis patients (970 DP) and kidney transplant recipients (110 KTR) with seroconversion (de novo IgA or IgG antibody positivity by ELISA) after eight weeks. FINDINGS: Six months after vaccination, seroconversion remained positive in 98% of MP, but 91%/87% of DP/KTR (pÂ =Â 0Â·005), respectively. Receptor binding domain-IgG (RBD-IgG) antibodies were positive in 98% of MP, but only 68%/57% of DP/KTR (pÂ <Â 0Â·001), respectively. Compared to MP, DP and KTR were at risk for a strong IgG or RBD-IgG decline (pÂ <Â 0Â·001). Within the DP but not KTR group male gender, peritoneal dialysis, short time on dialysis, BNT162b2mRNA vaccine, immunosuppressive drug use and diabetes mellitus were independent risk factors for a strong decline of IgG or RBD antibodies. The percentage of cellular immunity decline was similar in all groups. INTERPRETATION: Both vulnerable DP and KTR groups are at risk for a strong decline for IgG and RBD antibodies. In KTR, antibody titres peak at a markedly lower level and accelerated antibody decline is mixed with a delayed/increasing IgG, RBD-IgG, or cellular immune response in a 16% fraction of patients. In both populations, immune monitoring should be used for early timing of additional booster vaccinations.

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Multiple evanescent white dot syndrome following BNT162b2 mRNA COVID-19 vaccination. PURPOSE: To report a case with multiple evanescent white dot syndrome (MEWDS) following BNT162b2 mRNA COVID-19 vaccination. OBSERVATIONS: Case: A 67-year-old Japanese female presented with central visual field loss and photopsia in the right eye (OD) for 5 days. She was complaining blurred vision with bright spots in vision in OD, but denied any ocular symptoms in left eye (OS). She had received the second dose of BNT162b2 mRNA COVID-19 vaccine (Pfizer-BioNTech) one day before the onset of visual symptoms; flu-like symptoms such as mild fever and general fatigue also developed along with ocular symptoms such as decreased vision and hypersensitivity to light in OD following the second COVID-19 vaccine. The first dose of vaccine was administrated followed three weeks later by the second dose and was not associated with any ocular or systemic symptoms besides mild pain at the injection site. She had not been followed by any ophthalmologist before the initial visit. At the initial visit, best corrected visual acuity (BCVA) in decimal points was 0.2 in OD and 1.0 in OS. Ophthalmic examination showed multifocal white dots in the posterior retina with moderate vitritis (1+ haze and 2+ cells) in OD. Multimodal imaging in OD showed diffuse disruption of ellipsoid zone with variable punctate hyperreflective lesions at macula on optical coherence tomography, punctate hyperfluorescence in a wreath-like pattern and late staining on fluorescein angiography, and multiple hypofluorescent spots of various sizes in the late phases on indocyanine green angiography. Both multiple hypofluorescent spots and scattered hyperfluorescent spots corresponding to white dots in OD were also seen on fundus autofluorescence. Her laboratory and systemic evaluations were negative for syphilis, tuberculosis, or toxoplasma, and selected autoimmune diseases like sarcoidosis, Behcet's disease, rheumatoid arthritis, and systemic lupus erythematosus. No active intraocular inflammation or abnormality were seen in OS. One week later, the multifocal white dots disappeared in OD, and were almost invisible on fundus photography. At that time, multifocal electroretinogram showed decreased response with low amplitude density across the entire field in OD. The BCVA in OD spontaneously improved to 0.8 without any treatment. Collectively, these clinical course and findings were suggestive of a diagnosis of MEWDS after mRNA COVID-19 vaccination. CONCLUSIONS AND IMPORTANCE: In this present case, BNT162b2 mRNA COVID-19 vaccination might have been associated with MEWDS-like entity with vision loss. It is important for physicians to monitor the ocular status carefully in patients with visual disturbance after COVID-19 vaccination.

Cellular and Humoral Immune Responses and Breakthrough Infections After Two Doses of BNT162b Vaccine in Healthcare Workers (HW) 180 Days After the Second Vaccine Dose. BACKGROUND: Immunity and clinical protection induced by mRNA vaccines against SARS-CoV-2 have been shown to decline overtime. To gather information on the immunity profile deemed sufficient in protecting against hospitalization, we tested IgG levels, interferon-gamma (IFN-Î³) secretion, and neutralizing antibodies 180 days (d180) after the second shot of BNT162b vaccine, in HW. METHODS: A total of 392 subjects were enrolled. All received BioNTech/Pfizer from February 2020 to April 2021. The vaccine-specific humoral response was quantitatively determined by testing for IgG anti-S1 domain of SARS-CoV-spike protein. Live virus microneutralization (MN) was evaluated by an assay performing incubation of serial 2-fold dilution of human serum samples, starting from 1:10 to 1:5120, with an equal volume of Wuhan strain and Delta VOC viral solution and assessing the presence/absence of a cytopathic effect. SARS-CoV-2-spike protein-specific T-cell response was determined by a commercial IFN-Î³ release assay. RESULTS: In 352 individuals, at d180, IgG levels decreased substantially but no results below the assay's positivity threshold were observed. Overall, 22 naive (8.1%) had values above the highest threshold. Among COVID-naive, the impact of age, which was observed at earlier

stages, disappeared at d180, while it remained significant for 81 who had experienced a previous infection. Following the predictive model of protection by Khoury, we transformed the neutralizing titers in IU/ml and used a 54 IU/ml threshold to identify subjects with 50% protective immunity. Overall, live virus MN showed almost all subjects with previous exposure to SARS-CoV-2 neutralized the virus as compared to 33% of naive double-dosed subjects ($p < 0.0001$). All previously exposed subjects had strong IFN-Î³ secretion (>200 mIU/ml); among 271 naive, 7 (2.58%) and 17 (6.27%) subjects did not show borderline or strong secretion, respectively. CONCLUSIONS: In naive subjects, low IgG titers are relatively long-lasting. Only a third of naive subjects maintain neutralizing responses. After specific stimulation, a very limited number of naive were unable to produce IFN-Î³. The results attained in the small group of subjects with breakthrough infection suggest that simultaneous neutralizing antibody titers <20, binding antibody levels/ml <200, and IFN-Î³ <1,000 mIU/ml in subjects older than 58 may identify at-risk groups.
Torsades de pointes following vaccination for COVID-19.
Association of COVID-19 Vaccination and Clinical Severity of Patients Infected with Delta or Omicron Variants - China, May 21, 2021-February 28, 2022. WHAT IS ALREADY KNOWN ABOUT THIS TOPIC? Compared with the international mRNA and adenovirus-vectored coronavirus disease 2019 (COVID-19) vaccines, there is less real-world research data about breakthrough cases in people vaccinated with China-made COVID-19 vaccines. Analyses of clinical outcomes of breakthrough cases will be an important supplement to the clinical trial efficacy and observational effectiveness data of China-made COVID-19 vaccines. WHAT IS ADDED BY THIS REPORT? COVID-19 vaccine age-eligible individuals (â‰¥3 years old) who received full primary series and a booster dose of China-made COVID-19 vaccines had good protection from pneumonia caused by Delta variant infection. There was only one serious Delta case in children (unvaccinated), but among adults 18 years and older, there was good protection from serious illness with primary vaccination and booster vaccination. Among people â‰¥60 years, full vaccination and booster vaccination were associated with protection from pneumonia and risk of serious COVID-19 caused by Omicron variant infection. There were few serious Omicron cases. WHAT ARE THE IMPLICATIONS FOR PUBLIC HEALTH PRACTICE? Everyone 3 years and older without contraindications should be fully vaccinated against COVID-19; schedule-eligible adults should receive booster doses. The pace of booster dose administration, especially among the elderly, should be accelerated.
Two Case Reports of Subacute Thyroiditis after Receiving Vaccine for COVID-19. The ongoing COVID-19 pandemic, caused by a coronavirus named SARS-CoV-2, has struck the planet with great force. As of December 2019, the virus has made its devasting route across all continents . In January 2022, the World Health Organization (WHO) registered over 5.5 million COVID-19 related deaths. Most of these people had suffered from pneumonia and acute respiratory distress syndrome , and in some cases, extensive damage to all organ systems. To get hold of this pandemic, it was vital to find effective vaccines against it. The two vaccine candidates BNT162b2 (BioNTech/Pfizer) and ChAdOx1 (University of Oxford and AstraZeneca) offer a high level of protection against COVID-19 by providing immunity due to antibody production against the spike protein of SARS-CoV-2. In addition to general side effects, immunological side effects such as subacute thyroiditis can follow the vaccination. This transient inflammatory condition of the thyroid gland is characterized with hyperthyroxinemia, inflammation, pain, and tenderness in the thyroid region, as well as an elevation of serum thyroglobulin concentration. There are only a few reports on the occurrence of this disease after receiving a COVID-19 vaccine. We present two cases of subacute thyroiditis after vaccination with the vaccines BNT162b2 and ChAdOx1 and try to enlighten the problem of immunological phenomena after vaccination. It must be discussed whether cross-reactivity of the spike protein and tissue

proteins such as thyroid peroxidase (TPO), an "autoimmune/inflammatory syndrome by adjuvants" (ASIA), or the circulating spike protein itself after vaccination are responsible for the SAT.

Site Injection Reaction, Maculopapular Rash, and Rosacea Exacerbation after COVID-19 Vaccination. To date, the occurrence of adverse events following immunization after COVID-19 vaccine is rare, and their report is still very poor; however, causality assessment is conducted to identify the associated cause, if they occur. In this case report, we present a case of an association of three cutaneous manifestations (maculopapular exanthem with enanthem, site injection reaction, and rosacea exacerbation) occurring three days after taking the first dose of AstraZeneca AZD1222 vaccine.

A case of COVID-19 infection in a kidney transplant recipient after receiving the single dose of COVID-19 vaccination. INTRODUCTION AND IMPORTANCE: As immunocompromised individuals, kidney transplant recipients (KTR) were more prone to severe and prolonged COVID-19 infection. CASE PRESENTATION: A 52-year-old man with a history of two kidney transplants for polycystic kidney disease (PKD) was hospitalized due to COVID-19 illness after receiving the first dose of COVID-19 vaccination with Sputnik V. After being admitted to the hospital, the patient was given Remdesivir and oxygen therapy. CLINICAL DISCUSSION: We reported a COVID-19 infection after the first dose of Sputnik V vaccination in an immunocompromised patient who did not follow the protocols after vaccination. Regardless of vaccination, he had been infected, but the vaccination saved him from severe infection despite his comorbidity. CONCLUSION: To summarise, infection with COVID-19 should be considered after vaccinations, particularly the first dose, in immunocompromised patients such as KTR, and protocols for these patients should be strictly followed. It is worth mentioning that even a full dose of vaccination does not provide full protection from infection to anyone, including KTR.

Humoral and Cellular Immune Responses to SARS-CoV-2 mRNA Vaccination in Patients with Multiple Sclerosis: An Israeli Multi-Center Experience Following 3 Vaccine Doses. BACKGROUND: Immunomodulatory/immunosuppressive activity of multiple sclerosis (MS) disease modifying therapies (DMTs) might affect immune responses to SARS-CoV-2 exposure or vaccination in patients with MS (PwMS). We evaluated the effect of DMTs on humoral and cell-mediated immune responses to 2 and 3 vaccinations and the longevity of SARS-Cov-2 IgG levels in PwMS. METHODS: 522 PwMS and 68 healthy controls vaccinated with BNT162b2-Pfizer mRNA vaccine against SARS-CoV-2, or recovering from COVID-19, were recruited in a nation-wide multi-center study. Blood was collected at 3 time-points: 2-16 weeks and ~6 months post 2(nd) vaccination and 1-16 weeks following 3(rd) vaccination. Serological responses were measured by quantifying IgG levels against the spike-receptor-binding-domain of SARS-CoV-2, and cellular responses (in a subgroup analysis) by quantifying IFNÎ³ secretion in blood incubated with COVID-19 spike-antigen. RESULTS: 75% PwMS were seropositive post 2(nd) or 3(rd) vaccination. IgG levels decreased by 82% within 6 months from vaccination ($p<0.0001$), but were boosted 10.3 fold by the 3(rd) vaccination ($p<0.0001$), and 1.8 fold compared to â‰¤3m post 2(nd) vaccination ($p=0.025$). Patients treated with most DMTs were seropositive post 2(nd) and 3(rd) vaccinations, however only 38% and 44% of ocrelizumab-treated patients and 54% and 46% of fingolimod-treated patients, respectively, were seropositive. Similarly, in COVID-19-recovered patients only 54% of ocrelizumab-treated, 75% of fingolimod-treated and 67% of cladribine-treated patients were seropositive. A time interval of â‰¥5 months between ocrelizumab infusion and vaccination was associated with higher IgG levels ($p=0.039$ post-2(nd) vaccination; $p=0.036$ post-3(rd) vaccination), and with higher proportions of seropositive patients. Most fingolimod- and ocrelizumab-treated patients responded similarly to 2(nd) and 3(rd) vaccination. IFNÎ³-T-cell responses were detected in 89% and 63% of PwMS post 2(nd) and 3(rd) vaccination, however in only 25% and 0% of fingolimod-treated patients, while in 100% and 86% of ocrelizumab-treated patients, respectively. CONCLUSION: PwMS treated with most DMTs developed

humoral and T-cell responses following 2 and 3 mRNA SARS-CoV-2 vaccinations. Fingolimod- or ocrelizumab-treated patients had diminished humoral responses, and fingolimod compromised the cellular responses, with no improvement after a 3(rd) booster. Vaccination following >5 months since ocrelizumab infusion was associated with better sero-positivity. These findings may contribute to the development of treatment-stratified vaccination guidelines for PwMS.
Humoral and Cellular Immunogenicity and Safety of Five Different SARS-CoV-2 Vaccines in Patients With Autoimmune Rheumatic and Musculoskeletal Diseases in Remission or With Low Disease Activity and in Healthy Controls: A Single Center Study. BACKGROUND: Vaccine-induced immunity is essential for controlling the COVID-19 pandemic. Data on humoral and cellular immunogenicity and safety of different SARS-CoV-2 vaccines in patients with autoimmune rheumatic and musculoskeletal diseases (RMDs) are limited. METHODS: A single center observational study evaluated the immunogenicity and safety of the two-dose regimen of the BBIBP-CorV inactivated, Gam-COVID-Vac and AZD1222 adenovirus-based, and BNT162b2 and mRNA-1273 mRNA-based vaccines in patients with RMDs (n = 89) compared with healthy controls (n = 74). Neutralizing anti-RBD (receptor binding domain) specific antibodies and SARS-CoV-2 specific T-cell response were measured one and four months after the second vaccine dose in parallel with vaccination efficacy and safety. RESULTS: Disease-specific comparison showed that antibody response at four months was higher in spondylarthropathies compared to rheumatoid arthritis and autoimmune RMDs. Risk factors for reduced immunogenicity included longer disease duration, positive immunoserological profile and anti-CD20 therapy of patients. The rate of positive anti-RBD antibody response for healthy controls versus patients after 4 months post vaccination was 69% vs. 55% for the inactivated viral vaccine BBIBP-CorV, 97% vs. 53% for the pooled data of adenovirus vector-based vaccines Gam-COVID-Vac and AZD1222, or 100% vs. 81% for the pooled data of mRNA vaccines BNT162b2 and mRNA-1273, respectively. Patients who received the Gam-COVID-Vac or mRNA-1273 vaccines had a higher proportion of TNF-Î± producing CD4+ T-cells upon SARS-CoV-2 antigen stimulation compared to the inactivated viral vaccine. CONCLUSION: All five investigated vaccines were immunogenic in the majority of patients and healthy controls with variable antibody and T-cell response and an acceptable safety profile.
Uveitis after COVID-19 Vaccination. This report describes a case of acute uveitis following COVID-19 vaccination. A 21-year-old patient was referred to our department for decreased visual acuity and injection of the left eye. Two days prior, the patient received her second dose of the severe acute respiratory syndrome coronavirus 2 vaccine (BNT162b2, Pfizer-BioNTech). On ocular examination, her left eye's best-corrected visual acuity was 20/250, and its intraocular pressure was 16 mm Hg on a noncontact tonometer. Hypopyon, 4+ cells, and flares were observed in the anterior chamber. The patient was diagnosed with acute uveitis. She received topical dexamethasone (0.1%) hourly and systemic prednisone (50 mg/day). After 7 days, her inflammatory symptoms were mostly resolved. COVID-19 vaccination can cause acute anterior uveitis, which is responsive to steroids.
Erythema Multiforme after BNT162b2 Vaccination.
Prevalence and Safety of COVID-19 Vaccination in Community-Dwelling People with Dementia: Findings from a Tertiary Memory Clinic in Italy. This study aimed to explore the prevalence and safety of SARS-CoV-2 vaccination in individuals with dementia. Patients with mild cognitive impairment or dementia were recruited at a tertiary memory clinic, from March 15 to September 15, 2021. Information on COVID-19 vaccination and adverse events experienced after vaccine administration were collected from caregivers. Two-hundred-seventy subjects were finally recruited. Among them, 253 (93.7%) had received the vaccine and only 69 (27.3%) experienced adverse events. Cognitive and behavioral changes following immunization were only rarely reported. COVID-19

vaccination is safe and well-tolerated in patients with cognitive impairment who should be prioritized in the vaccination campaign.

Author Reply: Relapsed Disciform Stromal Herpetic Keratitis and mRNA COVID-19 Vaccination.

Relapsed Disciform Stromal Herpetic Keratitis and mRNA COVID-19 Vaccination.

Dynamic of anti-spike receptor binding domain (RBD) levels and short-term adverse events following a heterologous booster dose of BNT162b2 after two doses of CoronaVac in Thai health care workers. BACKGROUND: CoronaVac was administered as the primary COVID-19 vaccine for Thai health care workers (HCWs) in early 2021 in response to the epidemic of new variants. This study aimed to evaluate the dynamic of humoral immune response as well as the short-term side effects resulting from the booster dose of BNT162b2 following completion of a CoronaVac double-dose in Thai HCWs. METHODS: This study was conducted at a teaching hospital in Northern Thailand during August and September 2021. The participants were 50 HCWs who were vaccinated with 2 doses of CoronaVac and were scheduled to receive a booster dose of BNT162b2. Anti-SARS-CoV-2 IgG antibodies levels and short-term side effects were assessed. The anti-RBD level was determined using Architect SARS-CoV-2 IgG II Quant (Abbott). RESULT: Of the 50 participants, 37 were female. The median age was 33.0Â years old. The average time between the second CoronaVac shot and the BNT162b2 booster shot was 81.7Â days (SDÂ =Â 25.0). The median anti-SARS-CoV-2 IgG antibody level on booster vaccination date, as well as day 14, and day 28 after the booster were 335.5Â AU/ml, 31,613.5Â AU/ml, and 20,311.9Â AU/ml, respectively. Fourteen days after the booster, 94% of participants had anti-SARS-CoV-2 IgG antibody levels higher than 50.0Â AU/ml. Being female, higher log anti-SARS-CoV-2 IgG antibodies prior to booster vaccination, and longer interval between the second shot and the booster shot were found to be significantly associated with higher levels of anti-SARS-CoV-2 IgG antibodies at both day 14 and day 28 after the booster. There were no reports of serious adverse events. CONCLUSION: A booster dose of BNT162B2 promoted a high level of anti-SARS-CoV-2 IgG antibodies among HCWs who received 2 doses of CoronaVac. The time between the second CoronaVac shot and the booster shot should be at least three months. There were no severe adverse effects observed.

A case of myocarditis and isolated hypopotassemia after Biontech-Pfizer vaccine for Covid-19.

Vaccine-induced immune thrombocytopenia and thrombosis after mRNA-1273 booster vaccination.

The association of intensity and duration of non-pharmacological interventions and implementation of vaccination with COVID-19 infection, death, and excess mortality: Natural experiment in 22 European countries. BACKGROUND: Critical questions remain regarding the need for intensity to continue NPIs as the public was vaccinated. We evaluated the association of intensity and duration of non-pharmaceutical interventions (NPIs) and vaccines with COVID-19 infection, death, and excess mortality in Europe. METHODS: Data comes from Our Word in Data. We included 22 European countries from January 20, 2020, to May 30, 2021. The time-varying constrained distribution lag model was used in each country to estimate the impact of different intensities and duration of NPIs on COVID-19 control, considering vaccination coverage. Country-specific effects were pooled through meta-analysis. RESULTS: This study found that high-intensity and long-duration of NPIs showed a positive main effect on reducing infection in the absence of vaccines, especially in the intensity above the 80th percentile and lasted for 7 days (RRÂ =Â 0.93, 95% CI: 0.89-0.98). However, the adverse effect on excess mortality also increased with the duration and intensity. Specifically, it was associated with an increase of 44.16% (RRÂ =Â 1.44, 95% CI: 1.27-1.64) in the excess mortality under the strict intervention (the intensity above the 80th percentile and lasted for 21 days). As the vaccine rollouts, the inhibition of the strict intervention on cases growth rate was increased (RR dropped from 0.95 to 0.87). Simultaneously, vaccination also alleviated the negative impact of the strict intervention on excess mortality (RR decreased from 1.44 to 1.25). Besides, maintaining the strict

intervention appeared to more reduce the cases, as well as avoids more overall burden of death compared with weak intervention. CONCLUSIONS: Our study highlights the importance of continued high-intensity NPIs in low vaccine coverage. Lifting of NPIs in insufficient vaccination coverage may cause increased infections and death burden. Policymakers should coordinate the intensity and duration of NPIs and allocate medical resources reasonably with widespread vaccination.

Rheumatologists' knowledge and perception of COVID-19 and related vaccines: the vaXurvey2 online survey. The study aimed to explore the experience of coronavirus disease-2019 (COVID-19) infection and vaccine adverse events (AEs) among rheumatologists. A validated questionnaire was distributed as a Google form to rheumatologists across the country via social networking sites from late December 2021 till early January 2022. The questionnaire included questions regarding participants' socio-demographic details, COVID-19 infection and vaccination details with special emphasis on AEs. Out of 246 responses, 228 were valid. 200 (81.3%) responders had received the vaccine. The mean age of the 228 participants was 37.9 Â± 8.5 years, 196 were females and 32 males (F:M 6.1:1) from 18 governorates across the country. Comorbidities were present in 54 subjects (27%). There was a history of highly suspicious or confirmed COVID-19 infection in 66.7% that were all managed at home. The COVID-19 vaccine was received by 200 and a booster dose of 18.5%. Obesity and musculoskeletal involvement co-morbidities were present only in those with AEs (9.1% and 5.5% respectively). AEs were present in 82%; 66.7% had injection-site tenderness, 50% fatigue, 35.5% fever, 15% chills, 42.5% myalgia, 14.5% arthralgia, 8% low back pain, headache 31%, dizziness 10%, sleepliness 16% and 15% developed post-vaccine. There were no differences according to the geolocation regarding the occurrence of COVID-19 infection ($p = 0.19$) or AEs post-vaccine ($p = 0.58$). The adverse events were mostly mild to moderate and tolerable which makes this work in agreement with other studies that support the broad safety of the vaccine in favor of the global benefit from mass vaccination.

Dashboard development for near real-time visualization of COVID-19 vaccine safety surveillance data in the vaccine safety datalink. The Vaccine Safety Datalink (VSD) conducts active surveillance and vaccine safety research studies. Since the start of the U.S. COVID-19 vaccination program, the VSD has conducted near real-time safety surveillance of COVID-19 vaccines using Rapid Cycle Analysis. VSD investigators developed an internal dashboard to facilitate visualization and rapid reviews of large weekly automated vaccine safety surveillance data. Dashboard development and maintenance was informed by vaccine surveillance data users and vaccine safety partners. Key metrics include population demographics, vaccine uptake, pre-specified safety outcomes, sequential analyses results, and descriptive data on potential vaccine safety signals. Dashboard visualizations are used to provide situational awareness on dynamic vaccination coverage and the status of multiple safety analyses conducted among the VSD population. This report describes the development and implementation of the internal VSD COVID-19 Vaccine Dashboard, including metrics used to develop the dashboard, which may have application across various other public health settings.

High T-cell response rate after COVID-19 vaccination in belimumab and rituximab recipients. OBJECTIVE: To evaluate B-cell- and T-cell-mediated immune response to SARS-CoV-2 mRNA vaccination in patients with complex or rare systemic autoimmune diseases previously been treated with or under continuous treatment with B-cell-targeted therapies including rituximab (RTX) and belimumab (BEL). MATERIALS AND METHODS: Twenty-eight consecutive patients receiving RTX (nÂ =Â 11) or BEL (nÂ =Â 17) treatment and 13 age-/sex-matched controls (non-rheumatic healthcare personnel) were recruited. None of the patients had detectable anti-SARS-CoV-2 antibodies caused by prior exposure to the virus. All the patients and controls received mRNA vaccines and were tested three to four weeks after completion of vaccination. In all the RTX patients, vaccination was started within 5 months from the last infusion, and B-cell depletion was confirmed in all but one of them.

Total anti-SARS-CoV-2 RBD antibodies were analyzed using a diagnostic assay, while T-cell response was evaluated using the interferon-gamma release assay (IGRA). Further, SARS-CoV-2 pseudoviruses were employed to verify the strain-specific neutralizing capacity of the antibodies. RESULTS: Detectable anti-SARS-CoV-2 antibodies were documented in 1 out of the 11 RTX patients and 16 of the 17 BEL patients. The median concentration in the RTX and BEL patients was significantly lower than that in the controls (39.6 AU/ml vs. 1133 AU/ml, pÂ =Â 0.002). The result of IGRA was positive in 8 of the 11 (72.7%) RTX patients and 16 of the 17 (94.1%) BEL patients, and interferon release in both the RTX and BEL patients was comparable to that in the control participants. CONCLUSION: B-cell-targeted therapies do not preclude SARS-CoV-2 vaccination, since virus-specific cellular immunity can be induced even in the absence of circulating B cells. An important finding was that lupus patients treated with BEL developed immune responses to SARS-CoV-2; this indicates retention of the immunogenicity of the COVID-19 vaccine.

Immunogenicity and safety after the third dose of BNT162b2 anti-SARS-CoV-2 vaccine in patients with solid tumors on active treatment: a prospective cohort study. BACKGROUND: Although a full course of coronavirus disease 2019 (COVID-19) vaccine is effective in cancer patients, the duration of the protection and the efficacy of a booster dose against the new variants remain unknown. We prospectively evaluated the immunogenicity of the third dose of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) BNT162b2 messenger RNA vaccine in cancer patients undergoing active treatment. PATIENTS AND METHODS: Patients with solid cancer, vaccinated with a booster dose during active treatment, were enrolled in this study. Patients were classified into SARS-CoV-2 naÃ¯ve (without previous COVID-19 infection) and SARS-CoV-2 experienced (with previous COVID-19 infection). Neutralizing antibody (NT Ab) titer and total anti-Spike immunoglobulin G (IgG) concentration were quantified in serum. Heparinized whole blood samples were used for SARS-CoV-2 Interferon Gamma Release Assay (IGRA). The primary endpoint was to assess the increase of IgG antibody level between baseline and 3 weeks after the booster. RESULTS: One hundred and forty-two consecutive patients were recruited. In SARS-CoV-2-naÃ¯ve subjects, the median level of IgG was 157 BAU/ml [interquartile range (IQR) 62-423 BAU/ml] at T0 and reached a median of 2080 BAU/ml (IQRÂ 2080-2080 BAU/ml) at 3 weeks after booster administration (T1; $P < 0.0001$). A median 16-fold increase of SARS-CoV-2 NT Ab titer (IQR 4-32) was observed in naÃ¯ve subjects (from median 20, IQR 10-40, to median 640, IQR 160-640; $P < 0.0001$). Median interferon-Î³ level at T1 was significantly higher than that measured at T0 in SARS-CoV-2-naÃ¯ve subjects (PÂ = 0.0049) but not in SARS-CoV-2-experienced patients. The median level of SARS-CoV-2 NT Abs was 32-fold lower against Omicron compared to the wild-type strain (PÂ = 0.0004) and 12-fold lower compared to the Delta strain (PÂ = 0.0110). CONCLUSIONS: The third dose is able to trigger both the humoral and the cell-mediated immune response in cancer patients on active treatment. Our preliminary data about the neutralization of the SARS-CoV-2 vaccine against variants of concern seem to confirm the lower vaccine activity.

Neuro-Ophthalmological Complications of the COVID-19 Vaccines: A Systematic Review. BACKGROUND: A worldwide mass vaccination campaign against the coronavirus disease 2019 (COVID-19) pandemic is currently underway. Although the safety data of the clinical trials did not report specific concerns regarding neuro-ophthalmological adverse events, they involved a limited number of individuals and were conducted over a relatively short time. The aim of the current review is to summarize the available postmarketing data regarding the occurrence of neuro-ophthalmological and other ocular complications of the COVID-19 vaccines. EVIDENCE ACQUISITION: Electronic searches for published literature were conducted using Ovid MEDLINE, Embase, Web of Science, Google Scholar, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and ClinicalTrials.gov. The search strategy incorporated controlled vocabulary

and free-text synonyms for the concepts of COVID, vaccines, and visual and neuro-ophthalmologic diseases and symptoms. RESULTS: A total of 14 case reports and 2 case series have been selected for inclusion in the final report, reporting 76 cases of post-COVID-vaccination adverse events. The most common adverse event was optic neuritis (n = 61), followed by uveitis (n = 3), herpes zoster ophthalmicus (n = 2), acute macular neuroretinopathy (n = 2), optic disc edema as an atypical presentation of Guillain-BarrÃ© syndrome (n = 1), (arteritic anterior ischemic optic neuropathy; n = 1), abducens nerve palsy (n = 1), oculomotor nerve palsy (n = 1), Tolosa-Hunt syndrome (n = 1), central serous retinopathy (n = 1), acute zonal occult outer retinopathy (n = 1), and bilateral choroiditis (n = 1). Most cases were treated with high-dose steroids and had a favorable clinical outcome. CONCLUSION: Since the implementation of the COVID-19 vaccination campaign in the past year, several post-COVID-vaccination neuro-ophthalmological complications have been described. However, considering the number of individuals that have been exposed to the vaccines, the risk seems very low, and the clinical outcome in most cases is favorable. Therefore, on a population level, the benefits of the vaccines far outweigh the risk of neuro-ophthalmological complications.

Psychedelics and Mental Health: An Alternative Strategy to Treat Mental Impairments Triggered or Aggravated by COVID-19. Despite the discovery of vaccines for COVID-19, one of the best security measures to contain the spread of the virus is social distancing and isolation. However, isolation might trigger negative mental outcomes, such as onset of a depressive and anxious condition, increased consumption of alcohol and drugs, relapse to substances of abuse, and even induce post-traumatic stress disorder. Interestingly, recent research with psychedelics suggests that when these substances are used in combination with psychotherapy, they may reduce these mental impairments. Nevertheless, scientists are still working to elucidate the possible mechanisms behind these phenomena.

Guillain-BarrÃ© syndrome after BNT162b2 (Pfizer-BioNTec) vaccination.

Autoimmune Bullous Dermatosis Following COVID-19 Vaccination: A Series of Five Cases. Autoimmune bullous diseasesÂ (AIBDs) are a heterogeneous group of diseases characterized byÂ cutaneous and mucosal vesicles, blisters, and erosions. Several factors can trigger this disease, including vaccines; but this entity remains very rare. We hypothesized that vaccination against coronavirus disease 2019 (COVID-19) could triggerÂ an immunological response in genetically predisposed individuals. We report five cases of new-onset autoimmune bullous diseases triggered by the COVID-19 vaccine. Clinical and histopathological examinations confirmed the diagnosis of bullous pemphigoid (BP) in three patients andÂ pemphigus in the other two. According to the French method of imputability, the pharmacovigilance investigation showed an I5B4 causality assessment score for the vaccines, interpreted as highly probable, for all the patients. The diagnosis of vaccine-induced autoimmune bullous dermatosis was highly suspected. One patient's condition improved by dermocorticoids alone, while the other four required oral corticosteroid therapy at 0.5 mg/kg/day, which led to a favorable outcome.

Atypical Presentation of Erythema Nodosum Following Pfizer-BioNTech COVID-19 Vaccine. BACKGROUND: Erythema nodosum (EN) is a common form of panniculitis that could be triggered by numerous conditions including infectious and non-infectious conditions. So far, few cases of EN caused by COVID-19 vaccine had been reported. CASE REPORT: We report a case of atypical presentation of EN mimicking cellulitis in a patient who received the first dose of the Pfizer-BioNTech COVID-19 vaccine. A 38-year-old healthy woman who developed painful swelling on the left leg one week after receiving the first dose of Pfizer-BioNTech COVID-19 vaccine. Skin biopsy was revealed septal panniculitis. Due to the temporal association and the absence of other identifiable causes, Pfizer-BioNTech COVID-19 vaccine-related EN would be the most likely explanation. CONCLUSION: COVID-19 vaccines could be associated with rare side effects that should be reported for a better

understanding of related outcomes of COVID-19 vaccination. This case was reported to keep in mind that EN can have atypical presentation as a rare side effect of COVID-19 vaccines.
Study of immunogenicity, safety and efficacy of covishield vaccine among health care workers in a tertiary cardiac care centre. PURPOSE: The pandemic of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) might be curtailed by vaccination. We assessed the safety, and immunogenicity of Covishield vaccine among Health care workers (HCWs) in a tertiary cardiac care centre. METHODS: It's a prospective analytical study, conducted at Sri Jayadeva Institute of cardiovascular science and research centre, Mysore, between January 2021 to May 2021. Pre and Post vaccination SARS CoV2 IgG antibodies were assessed among 122 HCWs. Interval between two doses in this study were 4 and 6 weeks. Adverse events following immunisation b(AEFI) and efficacy were assessed and followed up for two month post vaccination. RESULTS: Post vaccination seropositivity was 69.67% in overall study participants. Seropositivity and P/N ratio median value in uninfected and infected group were 60.43% (nÂ â€‹=Â â€‹55),3.47 (IQR: 2.56-5.22) and 96.77% (nÂ â€‹=Â â€‹30),9.49 (IQR: 7.57-12.30) respectively (PÂ â€‹<Â â€‹0.001). Seropositivity and P/N ratio after 4 and 6 weeks were 48.3% (nÂ â€‹=Â â€‹60), 2.95 (IQR: 1.91-4.24), and 83.8% (nÂ â€‹=Â â€‹31), 4.88, (IQR: 3.39-6.43) respectively (PÂ â€‹<Â â€‹0.001). AEFI after first and second dose was 72.9% and 27.8% (pÂ â€‹<Â â€‹0.05) respectively. The most common symptoms after both doses of vaccination were local pain (73% & 88.2%), followed by fever (38.2% & 26.5%). The average duration of symptoms in both doses was 1.75 days. Of 122 participants only 10 (8.19%) had breakthrough infection after two doses of vaccination with mild severity. CONCLUSION: Covishield vaccine has showed seropositivity of 69.67%.It has acceptable level of safety profile. Seropositivity and P/N ratio has increased with increase in interval between two doses. Though it has not prevented breakthrough infection it has certainly reduced the severity of infection.
Predictors of impaired SARS-CoV-2 immunity in healthcare workers after vaccination with BNT162b2. Healthcare workers are at substantially increased risk for infection with SARS-CoV-2. Successful vaccination constitutes a crucial prerequisite to protect this group during the pandemic. Since post vaccination antibody monitoring is not standard of care in all healthcare institutions, data on risk factors of impaired vaccine induced immune response are urgently required. Moreover, there are no data on cellular immune responses in humoral low responders so far. Anti-SARS-CoV-2 spike IgG was assessed after vaccination with BNT162b2 in 1386 employees of three hospitals of a German healthcare provider. Concentrations were compared to those of 45 convalescent employees. Vaccine-induced cellular immunity was measured in employees with reduced humoral response by assessment of frequencies of SARS-CoV-2-reactive CD4(+) and CD8(+)Â T cell. Anti-SARS-CoV-2 spike IgG were detected in 99.9% of 1386 healthcare workers after completed vaccination. The median antibody concentration was significantly higher after vaccination than after infection with SARS-CoV-2 (pâ€‰=â€‰0.0001). 10 subjects (0.7%) generated an IgG concentrationâ€‰<â€‰100Â IU/ml, and only two persons (0.1%, solid organ recipients) did not produce detectable antibodies at all. T cell responses of those subjects with submaximal or lacking humoral response were comparable to employees with maximal antibody titers. 50% of those individuals with impaired or lacking humoral immune response were on immunosuppression. Vaccination to SARS-CoV-2 with BNT162b2 is very effective in healthcare workers yielding a seroconversion rate of 99.9%. Immunosuppression is the most important risk factor of an impaired immune response. There was no case of vaccination failure without immunosuppression. Thus, post vaccination antibody monitoring is highly recommendable in those employees with immunosuppression.
A Challenging Diagnosis: A Case of Multisystem Inflammatory Syndrome Following COVID-19 Vaccination.

Humoral response to SARS-CoV-2 infection and vaccines against COVID-19 in patients with neuromyelitis optica spectrum disorders: Impact of immunosuppressive treatment. The aim of this study was to evaluate the humoral response to the SARS-CoV-2 infection and vaccination in the NMOSD patients, treated with various immunosuppresants (ISs). Serum IgG against the complete sequence of the receptor binding domain of the spike protein was measured using ELISA SARS-CoV-2 IgG, INEP, Belgrade. Seroconversion occurred in 8/10 patients with COVID-19, and in 5/9 after vaccination. One out of four patients treated with inebilizumab seroconverted (after COVID-19); antibodies were not detected in any of the remaining 3 patients who were vaccinated. Antibodies developed after COVID-19 in 4/5 patients treated with azathioprine and all treated with mycophenolate-mofetil, and after vaccination, in 5/6 patients treated with these ISs. Post-vaccination humoral response was impaired in our NMOSD patients treated with B-cell depleting therapies; seroconversion occurred in almost all patients treated with conventional synthetic disease modifying ISs.
Humoral response after a fourth "booster" dose of a Coronavirus disease 2019 vaccine following a 3-dose regimen of mRNA-based vaccination in dialysis patients.
Dynamics of SARS-CoV-2 Antibody Response to CoronaVac followed by Booster Dose of BNT162b2 Vaccine. We evaluated the longitudinal dynamics of antibody response to the SARS-CoV-2 vaccine CoronaVac and the effect of a booster dose of BNT162b2 vaccine. We found a robust antibody response after the second dose of CoronaVac that wanes over time. The response was recovered by BNT162b2, which boosted anti-spike antibody titers.
Global project gears up to study vaccine safety. Pandemic propels international efforts to understand incidence of rare side effects.
Cerebrovascular Complications of COVID-19 and COVID-19 Vaccination. The risk of stroke and cerebrovascular disease complicating infection with SARS-CoV-2 has been extensively reported since the onset of the pandemic. The striking efforts of many scientists in cooperation with regulators and governments worldwide have rapidly brought the development of a large landscape of vaccines against SARS-CoV-2. The novel DNA and mRNA vaccines have offered great flexibility in terms of antigen production and led to an unprecedented rapidity in effective and safe vaccine production. However, as mass vaccination has progressed, rare but catastrophic cases of thrombosis have occurred in association with thrombocytopenia and antibodies against PF4 (platelet factor 4). This catastrophic syndrome has been named vaccine-induced immune thrombotic thrombocytopenia. Rarely, ischemic stroke can be the symptom onset of vaccine-induced immune thrombotic thrombocytopenia or can complicate the course of the disease. In this review, we provide an overview of stroke and cerebrovascular disease as a complication of the SARS-CoV-2 infection and outline the main clinical and radiological characteristics of cerebrovascular complications of vaccinations, with a focus on vaccine-induced immune thrombotic thrombocytopenia. Based on the available data from the literature and from our experience, we propose a therapeutic protocol to manage this challenging condition. Finally, we highlight the overlapping pathophysiologic mechanisms of SARS-CoV-2 infection and vaccination leading to thrombosis.
Surveillance of Safety of 3 Doses of COVID-19 mRNA Vaccination Using Electronic Health Records. IMPORTANCE: Recent reports on waning of COVID-19 vaccine-induced immunity have led to the approval and rollout of additional doses and booster vaccinations. Individuals at increased risk of SARS-CoV-2 infection are receiving additional vaccine doses in addition to the regimen that was tested in clinical trials. Risks and adverse event profiles associated with additional vaccine doses are currently not well understood. OBJECTIVE: To evaluate the safety of third-dose vaccination with US Food and Drug Administration (FDA)-approved COVID-19 mRNA vaccines. DESIGN, SETTING, AND PARTICIPANTS: This cohort study was conducted using electronic health record (EHR) data from

December 2020 to October 2021 from the multistate Mayo Clinic Enterprise. Participants included all 47â€¯999 individuals receiving 3-dose COVID-19 mRNA vaccines within the study setting who met study inclusion criteria. Participants were divided into 2 cohorts by vaccine brand administered and served as their own control groups, with no comparison made between cohorts. Data were analyzed from September through November 2021. EXPOSURES: Three doses of an FDA-authorized COVID-19 mRNA vaccine, BNT162b2 or mRNA-1273. MAIN OUTCOMES AND MEASURES: Vaccine-associated adverse events were assessed via EHR report. Adverse event risk was quantified using the percentage of study participants who reported the adverse event within 14 days after each vaccine dose and during a 14-day control period, immediately preceding the first vaccine dose. RESULTS: Among 47â€¯999 individuals who received 3-dose COVID-19 mRNA vaccines, 38â€¯094 individuals (21â€¯835 [57.3%] women; median [IQR] age, 67.4 [52.5-76.5] years) received BNT162b2 (79.4%) and 9905 individuals (5099 [51.5%] women; median [IQR] age, 67.7 [59.5-73.9] years) received mRNA-1273 (20.6%). Reporting of severe adverse events remained low after the third vaccine dose, with rates of pericarditis (0.01%; 95% CI, 0%-0.02%), anaphylaxis (0%; 95% CI, 0%-0.01%), myocarditis (0%; 95% CI, 0%-0.01%), and cerebral venous sinus thrombosis (no individuals) consistent with results from earlier studies. Significantly more individuals reported low-severity adverse events after the third dose compared with after the second dose, including fatigue (2360 individuals [4.92%] vs 1665 individuals [3.47%]; Pâ€‰<â€‰.001), lymphadenopathy (1387 individuals [2.89%] vs 995 individuals [2.07%]; Pâ€‰<â€‰.001), nausea (1259 individuals [2.62%] vs 979 individuals [2.04%]; Pâ€‰<â€‰.001), headache (1185 individuals [2.47%] vs 992 individuals [2.07%]; Pâ€‰<â€‰.001), arthralgia (1019 individuals [2.12%] vs 816 individuals [1.70%]; Pâ€‰<â€‰.001), myalgia (956 individuals [1.99%] vs 784 individuals [1.63%]; Pâ€‰<â€‰.001), diarrhea (817 individuals [1.70%] vs 595 individuals [1.24%]; Pâ€‰<â€‰.001), fever (533 individuals [1.11%] vs 391 individuals [0.81%]; Pâ€‰<â€‰.001), vomiting (528 individuals [1.10%] vs 385 individuals [0.80%]; Pâ€‰<â€‰.001), and chills (224 individuals [0.47%] vs 175 individuals [0.36%]; Pâ€‰=â€‰.01). CONCLUSIONS AND RELEVANCE: This study found that although third-dose vaccination against SARS-CoV-2 infection was associated with increased reporting of low-severity adverse events, risk of severe adverse events remained comparable with risk associated with the standard 2-dose regime. These findings suggest the safety of third vaccination doses in individuals who were eligible for booster vaccination at the time of this study.

Association of Psychiatric Disorders With Incidence of SARS-CoV-2 Breakthrough Infection Among Vaccinated Adults. IMPORTANCE: Psychiatric disorders may be associated with an increased risk for SARS-CoV-2 breakthrough infection after vaccination, but no studies have tested this hypothesis. OBJECTIVE: To evaluate whether past diagnoses of psychiatric disorders are associated with an increased incidence of SARS-CoV-2 breakthrough infection among fully vaccinated individuals. DESIGN, SETTING, AND PARTICIPANTS: This retrospective cohort study included data from the administrative and electronic health records of US Department of Veterans Affairs (VA) patients from February 20, 2020, to November 16, 2021. Participants included 263â€¯697 patients who accessed VA health care during the study period, had at least 1 SARS-CoV-2 test recorded in the electronic health record, had no record of SARS-CoV-2 infection prior to vaccination, and had completed a full SARS-CoV-2 vaccination regimen 14 days or more prior. EXPOSURES: Psychiatric disorder diagnoses in the past 5 years, including depressive, posttraumatic stress, anxiety, adjustment, alcohol use, substance use, bipolar, psychotic, attention-deficit/hyperactivity, dissociative, and eating disorders. MAIN OUTCOMES AND MEASURES: SARS-CoV-2 breakthrough infections, defined as positive SARS-CoV-2 tests, among fully vaccinated individuals. RESULTS: Of 263â€¯697 fully vaccinated VA patients (239â€¯539 men [90.8%]; mean [SD] age, 66.2 [13.8] years), 135â€¯481 (51.4%) had at least 1 psychiatric disorder diagnosis, and 39â€¯109 (14.8%) developed a breakthrough infection. A diagnosis

of any psychiatric disorder was associated with increased incidence of breakthrough infection, both in models adjusted for potential confounders (adjusted relative risk [aRR], 1.07; 95% CI, 1.05-1.09) and additionally adjusted for medical comorbidities and smoking (aRR, 1.03; 95% CI, 1.01-1.05). Most specific psychiatric disorder diagnoses were associated with an increased incidence of breakthrough infection, with the highest relative risk observed for adjustment disorder (aRR, 1.13; 95% CI, 1.10-1.16) and substance use disorders (aRR, 1.16; 95% CI, 1.12-1.21) in fully adjusted models. Stratifying the sample at 65 years of age revealed that associations between psychiatric diagnoses and incident breakthrough infection were present in both age groups but were stronger and robust to adjustment for medical comorbidities and smoking among older patients. CONCLUSIONS AND RELEVANCE: This cohort study suggests that psychiatric disorder diagnoses were associated with an increased incidence of SARS-CoV-2 breakthrough infection among VA patients, with the strongest associations observed for older individuals. Individuals with psychiatric disorders may be at heightened risk for contracting COVID-19 even after vaccination, suggesting the need for targeted prevention efforts.
Urticaria 12 Days After COVID-19 mRNA Booster Vaccination.
The Delta SARS-CoV-2 Variant of Concern Induces Distinct Pathogenic Patterns of Respiratory Disease in K18-hACE2 Transgenic Mice Compared to the Ancestral Strain from Wuhan. Compared to the original ancestral strain of SARS-CoV-2, the Delta variant of concern has shown increased transmissibility and resistance toward COVID-19 vaccines and therapies. However, the pathogenesis of the disease associated with Delta is still not clear. In this study, using K18-hACE2 transgenic mice, we assessed the pathogenicity of the Delta variant by characterizing the immune response following infection. We found that Delta induced the same clinical disease manifestations as the ancestral SARS-CoV-2, but with significant dissemination to multiple tissues, such as brain, intestine, and kidney. Histopathological analysis showed that tissue pathology and cell infiltration in the lungs of Delta-infected mice were the same as in mice infected with the ancestral SARS-CoV-2. Delta infection caused perivascular inflammation in the brain and intestinal wall thinning in K18-hACE2 transgenic mice. Increased cell infiltration in the kidney was observed in both ancestral strain- and Delta-infected mice, with no clear visible tissue damage identified in either group. Interestingly, compared with mice infected with the ancestral strain, the numbers of CD45(+) cells, T cells, B cells, inflammatory monocytes, and dendritic cells were all significantly lower in the lungs of the Delta-infected mice, although there was no significant difference in the levels of proinflammatory cytokines between the two groups. Our results showed distinct immune response patterns in the lungs of K18-hACE2 mice infected with either the ancestral SARS-CoV-2 or Delta variant of concern, which may help to guide therapeutic interventions for emerging SARS-CoV-2 variants. IMPORTANCE SARS-CoV-2 variants, with the threat of increased transmissibility, infectivity, and immune escape, continue to emerge as the COVID-19 pandemic progresses. Detailing the pathogenesis of disease caused by SARS-CoV-2 variants, such as Delta, is essential to better understand the clinical threat caused by emerging variants and associated disease. This study, using the K18-hACE2 mouse model of severe COVID-19, provides essential observation and analysis on the pathogenicity and immune response of Delta infection. These observations shed light on the changing disease profile associated with emerging SARS-CoV-2 variants and have potential to guide COVID-19 treatment strategies.
Adult-onset Still disease and adenovirus vector COVID-19 vaccination.
Comment on: mRNA SARS-CoV-2 vaccination in patients after allogeneic hematopoietic cell transplantation.
Cerebral Venous Sinus Thrombosis due to Thrombosis with Thrombocytopenia Syndrome Following Ad26.COV2.S: A First Real-World Case Report of a Male Subject. Thrombosis with Thrombocytopenia Syndrome (TTS) or Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT) had been reported in patients receiving the Ad26.COV2.S vaccination (Johnson & Johnson

[J&J]/Janssen) vaccine. They frequently presented with cerebral venous sinus thrombosis (CVST), but venous or arterial thrombosis at other locations can be present. The majority of those affected are younger adult females. Therefore, after a brief pause from April 13-23, 2021, the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) recommended caution in using this vaccine in females under 50Â years. Based on the reported 28 cases of TTS after this vaccination (data till April 21, 2021) by CDC, 22 were females (78%), and 6 were male. None of those males had CVST but had thrombosis at other locations. We report the first case of a young male with TTS and CVST following Ad26.COV2.S vaccine presented with severe headache and diagnosed with acute right transverse and sigmoid cerebral venous sinus thrombosis, multiple right-sided pulmonary emboli, and right hepatic vein thrombosis. He was treated with parenteral anticoagulation with argatroban and intravenous immune globulin with the improvement of his symptoms. A heparin-induced thrombocytopenia with thrombosis (HITT) like syndrome caused by the genesis of a platelet-activating autoantibody against platelet factor 4 (PF4) triggered by adenoviral vector-based COVID-19 vaccinations is understood to be the underlying pathophysiology. TTS with CVST should be considered when patients present with headaches, stroke-like neurological symptoms, thrombocytopenia, and symptom onset 6-15Â days after Ad26.COV2.S vaccination.

Sex, Age, and Ethnic Background Shape Adaptive Immune Responses Induced by the SARS-CoV-2 mRNA Vaccine. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine-induced adaptive responses have been well investigated. However, the effects of sex, age, and ethnic background on the immune responses elicited by the mRNA vaccine remain unclear. Here, we performed comprehensive analyses of adaptive immune responses elicited by the SARS-CoV-2 mRNA vaccine. Vaccine-induced antibody and T cell responses declined over time but persisted after 3 months, and switched memory B cells were even increased. Spike-specific CD4(+) T and CD8(+) T cell responses were decreased against the B.1.351 variant, but not against B.1.1.7. Interestingly, T cell reactivity against B.1.617.1 and B.1.617.2 variants was decreased in individuals carrying HLA-A24, suggesting adaptive immune responses against variants are influenced by different HLA haplotypes. T follicular helper cell responses declined with increasing age in both sexes, but age-related decreases in antibody levels were observed only in males, and this was associated with the decline of T peripheral helper cell responses. In contrast, vaccine-induced CD8(+) T cell responses were enhanced in older males. Taken together, these findings highlight that significant differences in the reactogenicity of the adaptive immune system elicited by mRNA vaccine were related to factors including sex, age, and ethnic background.

SEVERE LEUKOCYTOCLASTIC VASCULITIS AFTER COVID-19 VACCINATION - CAUSE OR COINCIDENCE? CASE REPORT AND LITERATURE REVIEW. Vaccination has been the most powerful tool to fight the COVID-19 pandemic while the specific treatment options in clinical practice have been under review for approval and authorization by regulatory bodies. After registration of different vaccines, it is important to ensure a post-marketing surveillance to identify potential risks not observed in controlled trials. Authors report on the case of an 80-year-old male patient who developed severe leukocytoclastic vasculitis of skin and oral mucous membrane after receiving the second dose of COVID-19 mRNA vaccine. He was treated successfully with prednisolone. We also provide a literature review on other reported cases of COVID-19 vaccine induced vasculitis. This type of an adverse reaction seems to be rare. Fortunately, most cases were temporary and well controlled by corticosteroids. The majority of vaccine-associated vasculitis cases have been observed in association with BONT162b2 mRNA vaccine although other vaccines also may cause the event. The knowledge of this possible adverse event is important for early diagnosis and intervention.

Relapse of Idiopathic Nephrotic Syndrome After SARS-CoV-2 Vaccination: Two Case Reports.

Immunogenicity and safety of COVID-19 vaccination in patients with primary SjÃ¶gren's syndrome. OBJECTIVES: To evaluate humoral and cellular immune responses and adverse events (AEs) after COVID-19 vaccination in patients with primary SjÃ¶gren's syndrome (pSS) compared to healthy controls (HC), and disease activity following vaccination in patients with pSS. METHODS: 67 patients with pSS and 33 HC (ratio 2:1) received COVID-19 vaccinations following the Dutch vaccination programme. Patients with pSS did not use immunomodulatory drugs, except hydroxychloroquine. Anti-spike 1 receptor binding domain IgG serum antibody levels were measured 28 days after complete vaccination. AEs were collected 7â€‰days after vaccination. In a subgroup, salivary anti-SARS-CoV-2 antibodies and T-cell response by interferon-Î³ enzyme-linked immune absorbent spot was measured. RESULTS: 47 patients with pSS (70%) and 14 HC (42%) received BNT162b2 (Pfizer-BioNtech), 13 (19%) and 5 (15%) received ChAdOx1 nCoV-19 (AstraZeneca), 6 (9%) and 8 (24%) received mRNA-1273 (Moderna), and 1 (1%) and 6 (18%) received Ad.26.COV2.S (Janssen). All participants had positive anti-SARS-CoV-2 antibody levels (>2500 AU/mL) postvaccination. No differences in anti-SARS-CoV-2 antibody levels were observed between patients with pSS and HC, for each vaccine type. Salivary anti-SARS-CoV-2 IgG antibodies also increased, and a T-cell response was observed in patients with pSS and HC. Frequencies of systemic AEs were comparable between patients with pSS and HC (first vaccination: 34/67 (51%) vs 16/33 (48%), p=0.83; second: 41/66 (62%) vs 14/25 (56%), p=0.59). No significant worsening was observed in patient-reported and systemic disease activity, including auto-antibodies. CONCLUSIONS: Patients with pSS had similar humoral and cellular immune responses as HC, suggesting COVID-19 vaccination is effective in patients with pSS. AEs were also comparable, and no increase in disease activity was seen in patients with pSS.

COVAX delivers its 1 billionth COVID-19 vaccine doseCOVID-19 pandemic triggers 25% increase in prevalence of anxiety and depression worldwide.

Side-effects of COVID-19 vaccines among the Saudi population: A cross-sectional study. OBJECTIVES: To measure and assess the side-effects of Pfizer/BioNTech and AstraZeneca vaccines on residents of Saudi Arabia, as well as provide a database that gives insight into the relative safety of these 2 COVID-19 vaccines. METHODS: A community-based cross-sectional study was conducted to determine the side-effects of the two COVID-19 vaccines. The study was initiated on the 5th of June 2021 at Hail University, Hail, Saudi Arabia. The information was collected through an online survey designed on Google forms. The questionnaire was pre-tested for validity, with all information carefully reviewed. RESULTS: The study included 2,530 participants from different regions of Saudi Arabia, with a mean age of 26.9 Â± 12.4 years old. The most common vaccine among the study group was Pfizer, which 73.8% of the population were provided; the remaining 26.2% received the AstraZeneca vaccine. Regarding the Pfizer vaccine, the common systemic side-effects followed the first dose, included headaches, followed by muscle pain, fever, and joint pain. Those who had the AstraZeneca vaccine reported a few more side-effects. For example, during the first dose fever was reported as the most common side-effect, followed by headache, muscle pain and fatigue. CONCLUSION: The present study confirmed that vaccine side-effects are more frequently reported by smokers and those who received the AstraZeneca vaccine. Further studies are needed to acquire a better understanding of the association between risk factors and the experiencing of post-vaccine side-effects.

Patients After Orthotopic Heart Transplantation With COVID-19: Are We Fast Enough With Vaccinations? BACKGROUND: Patients after orthotopic heart transplantation (HTx) are especially susceptible to infections owing to permanent need for immunosuppression. Vaccinations against COVID-19 have been available since January 2021 and are recommended in organ recipients. AIM: The aim of this study was to analyze COVID-19 susceptibility and mortality in HTx and number of patients with COVID-19 previously vaccinated against severe acute respiratory syndrome coronavirus

2 (SARS-CoV-2). PATIENTS AND METHODS: We analyzed a whole cohort of 552 patients after HTx who were SARS-CoV-2 positive and remained under surveillance of the transplantation center during March 2020 to September 2021. RESULTS: Among 552 patients after HTx, 10 were COVID-19 survivors prior to transplantation and 103 had SARS CoV-2 infection after transplantation. Mean age of patients with COVID-19 was 55.6 (Â±14) years, and mean time from transplantation to SARS-CoV-2 infection was 2856 (Â±2596) days (range, 16-9569 days; interquartile range, 397-4763 days). Among the patients who were COVID-19 positive, 15 were asymptomatic, 10 died, and 51 infections occurred in the era of vaccinations. In the group of patients who were positive for COVID-19 in 2021, 6 received only a single dose of the mRNA vaccine and 3 were vaccinated twice. Among the vaccinated patients with COVID-19, 2 died of severe COVID-19: 1 after a single dose and 1 after 2 standard doses of the vaccine. CONCLUSION: We observed high susceptibility to SARS-CoV-2 infection in the group of patients after HTx. The majority of patients infected in 2021 did not received the vaccine. Vaccination does not fully protect against severe COVID-19 in patients after HTx.

Serologic Status According Severe Acute Respiratory Syndrome Coronavirus 2 in Patients After Orthotopic Heart Transplantation. BACKGROUND: The SARS-CoV-2 pandemic is ongoing. In this context, patients after organ transplantation are especially endangered because of their increased susceptibility to infections. Real effectiveness of vaccinations against SARS-CoV-2 and exposition to the virus in populations after organ transplantation is still being assessed. METHODS: We investigated 371 adult patients (82.7% men, 17.3% women), aged 54 Â± 14 years, with a median time from transplantation of 1296 days (interquartile range, 473-400 days) after orthotopic heart transplantation consecutively admitted to the transplant center between February and September 2021. SARS-CoV-2 spike protein antibodies were assessed quantitatively by Elecsys Anti-SARS-CoV-2 S. Data according to past COVID-19 infection and vaccination were compared with the test results. Among the whole group, 59 patients were unvaccinated and had no past COVID-19 infection, 200 patients had a full course of vaccination (2 doses) with an mRNA vaccine, 1 patient had received a viral vector vaccine, 11 patients had had a single dose of an mRNA vaccine, and 99 patients had previously had a COVID-19 infection. Median time from vaccination to antibody assessment was 54 days (interquartile range, 30-76 days). AIM: The aim of this study was to determine exposure to the virus among patients after heart transplantation before vaccination and humoral response to the vaccination and assess the role of antispike antibodies in the prevention of infection. RESULTS: After vaccination, 22.3% had no antibodies (45 patients), 47.3% had titers between 0.8 U/mL [0.82 binding antibody units (BAU)/mL] and 250 U/mL (257.25 BAU/mL; 95 patients), and 30.2% had titers above 250 U/mL (257.25 BAU/mL; 61 patients). After a single dose of vaccine, 63% patients had no antibodies. In the group of unvaccinated patients, 3 patients had titers above 250 U/mL (257.25 BAU/mL; 5.1%) and 12 patients had titers up to 250 U/mL (257.25 BAU/mL; 20.3%). In patients after COVID-19 infection, only 2% did not show antispike antibodies, and in 61.4% the titers were above 250 U/mL (257.25 BAU/mL). In the group of patients infected after the full course of vaccination (4 patients after a single dose and 2 after 2 doses), none of the patients developed antibodies after vaccination. Up to the end of September 2021, none of the patients with antibodies against SARS-CoV-2 developed COVID-19. CONCLUSIONS: The presence of spike protein antibodies may be a relevant marker of effective vaccination. In patients after heart transplantation, exposure to SARS-CoV-2 is high.

Myocarditis following COVID-19 vaccination: incidence, mechanisms, and clinical considerations. INTRODUCTION: Vaccines have demonstrated protection against the morbidity and mortality of COVID-19, but concerns regarding the rare side effect of acute myocarditis have stymied immunization efforts. This review aims to describe the incidence and theorized mechanisms of COVID vaccine-associated myocarditis and review relevant principles for management of vaccine-associated

myocarditis. AREAS COVERED: Epidemiologic studies of myocarditis after COVID vaccination are reviewed, which show an incidence of approximately 20-30 per million patients. The vast majority of these cases are seen with mRNA vaccines especially in male patients under 30Â years of age. Mechanisms are largely theoretical, but molecular mimicry and dysregulated innate immune reactions have been proposed. While studies suggest that this subtype of myocarditis is mild and self-limited, long-term evidence is lacking. Principles of myocarditis treatment and surveillance are outlined as they apply to COVID vaccine-associated myocarditis. EXPERT OPINION: COVID vaccine-associated myocarditis is rare but well described in certain at-risk groups. Better understanding of its pathogenesis is key to mitigating this complication and advancing vaccination efforts. Risk-benefit analyses demonstrate that individual- and population-level benefits of vaccination exceed the risks of this rare and mild form of myocarditis.

Immunogenicity and safety of homologous and heterologous ChAdOx1-S and mRNA-1273 vaccinations in healthy adults in Taiwan. BACKGROUND: In Taiwan, the vaccination program started in March 2021, with ChAdOx1-S being the first available WHO-approved COVID-19 vaccine, followed by Moderna vaccine. This study aimed to investigate the immunogenicity and safety of homologous and heterologous prime-boost regimens with ChAdOx1-S and mRNA-1273. METHODS: From March to November 2021, homologous or heterologous regimens with ChAdOx1-S and mRNA-1273 vaccination (ChAdOx1-S/ChAdOx1-S, mRNA-1273/mRNA-1273, ChAdOx1-S/mRNA-1273) were given to 945 healthy participants. Serum samples were collected at designated time points. The anti-RBD/S1 antibody titers and neutralizing ability were measured by three different immunoassays: ElecsysÂ® Anti-SARS-CoV-2 S (Roche Diagnostics, Mannheim, Germany), AdviseDx SARS-CoV-2 IgG II (Abbott Diagnostics Division, Sligo, Ireland), and cPassâ„¢ SARS-CoV-2 Neutralization Antibody Detection Kit (GenScript, New Jersey, USA). RESULTS: We found that heterologous vaccination with ChAdOx1-S/mRNA-1273 had an acceptable safety profile and induced higher total anti-RBD/S1 antibody production (pÂ <Â 0.0001), yet lower anti-RBD/S1 IgG titer (pÂ <Â 0.0001) and neutralizing ability (pÂ =Â 0.0101) than mRNA-1273/mRNA-1273 group. Both regimens showed higher antibody titers and superior neutralizing abilities than ChAdOx1-S/ChAdOx1-S. An age-dependent antibody response to ChAdOx1-S/mRNA-1273 was shown after both the priming and the booster doses. Younger age was associated with higher antibody production and neutralizing ability. CONCLUSIONS: Heterologous ChAdOx1-S/mRNA-1273 vaccination regimen is generally safe and induces a robust humoral immune response that is non-inferior to that of mRNA-1273/mRNA-1273.

Immune responses following third COVID-19 vaccination are reduced in patients with hematological malignancies compared to patients with solid cancer.

Can B cell-deficient patients rely on COVID-19 vaccine-induced T-cell immunity? Anti-CD20 antibody treatments prevent humoral responses to vaccines against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccines, but the nature of T-cell responses in this setting is less well understood. Riise et al. assess vaccine-induced epitope-specific CD8 T cell responses in patients with lymphoma recently treated with rituximab and find a wide range of responses, with the most recently treated patients frequently failing to respond, while others exhibit responses stronger than healthy controls. They suggest these epitopes among others could be used in a T cell-targeted vaccine, and such strategies are indeed in clinical trials now. Commentary on: Riise J, et al. Rituximab-treated patients with lymphoma develop strong CD8 T-cell responses following COVID-19 vaccination. Br J Haematol. 2022;197:697-708.

Impact of COVID-19 and COVID-19 vaccination on high-risk patients with antiphospholipid syndrome: a nationwide survey. OBJECTIVES: Patients with APS and triple-positive for aPL are at high risk of recurrent events. As COVID-19 and COVID-19 vaccination may induce thrombotic complications, the objective of the study was to assess the course of COVID-19 and adverse events after vaccination in

these patients. METHODS: This is a nationwide multicentre survey conducted in nine APS referral centres by means of a questionnaire. Included patients are thrombotic APS with triple-positive aPL confirmed 12â€‰weeks apart. Reference specialist physicians used a four-graded scale of severity for COVID-19 [from 0 (asymptomatic) to 3 (hospitalization in intensive care unit)] and a six-graded scale for adverse reactions to vaccination [from 0 (transient local injection site sign/symptoms) to 5 (potentially life-threatening reactions)]. Outcomes were considered within a 30-day period. RESULTS: Out of 161 patients interviewed, 18 (11%) had COVID-19. All of them fully recovered without any progression to severe disease nor thromboembolic event. A total of 146 patients received the first (92%) and 129 (80%) the second dose of vaccine; side effects were minimal and, in most cases (83% after the first and 68% after the second vaccination) limited to a sore arm. Fifteen patients (9%) were unvaccinated. Most of them raised doubts on the need for vaccination, complained of poor safety and in general were reluctant about COVID-19 vaccination. CONCLUSION: Patients with triple-positive thrombotic APS did not suffer from severe COVID-19 outcomes. Importantly, COVID-19 vaccination was well tolerated. These data may reassure patients and physicians and contribute to reducing hesitancy in unvaccinated patients.

Large US Study Examines First 6 Months of COVID-19 Vaccine Safety Data.

Myocarditis Adverse Event Less Common After COVID-19 Vaccine Booster.

Case Report: Acute Posterior Multifocal Placoid Pigment Epitheliopathy after SARS-CoV-2 Vaccination. SIGNIFICANCE: Acute posterior multifocal placoid pigment epitheliopathy is an uncommon inflammatory chorioretinopathy that has been reported after vaccination. This is the first reported case, to our knowledge, after vaccination for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in a healthy adolescent boy. PURPOSE: This report aimed to inform the eye care community about a possible ocular sequela of SARS-CoV-2 vaccination. CASE REPORT: A 17-year-old boy presented to a clinic for a second opinion after sudden-onset blind spots in his right eye. His medical history was remarkable for receiving the first dose of the Pfizer-BioNTech SARS-CoV-2 vaccine 2 weeks before symptom onset. He had no history of ocular inflammation, autoimmune disease, or systemic infection. A diagnosis of unilateral acute posterior multifocal placoid pigment epitheliopathy was made based on the presence of typical fundus lesions and noninvasive imaging with fundus autofluorescence, retinal optical coherence tomography, and optical coherence tomography angiography. The diagnosis was further confirmed with fluorescein angiography. The patient developed an anterior vitritis in the right eye 42 days after initial symptom onset. His unilateral intraocular inflammation resolved after a 5-week course of prednisone. CONCLUSIONS: Acute posterior multifocal placoid pigment epitheliopathy is a self-limited inflammatory condition of the outer retina that usually affects young adults and often does not require treatment. It has been reported to occur after vaccination for influenza, polio, hepatitis B, meningococcus C, and varicella zoster virus. This is the first known case to occur after SARS-CoV-2 vaccination in a healthy adolescent boy.

[Cerebral venous sinus thrombosis : An overview of causes, diagnostics and treatment]. In some cases, cerebral venous sinus thrombosis shows aÂ fulminant progress but with an incidence of 1.32Â cases per 100,000 person-years it is relatively rare. Nevertheless, the disease is responsible for around 0.5-1% of all stroke cases. The neurological examination often reveals nonspecific findings but especially in younger patients with acute to subacute position-dependent headaches, this differential diagnosis should definitely be considered. This article presents the most common causes, including a digression on vaccine-induced immune thrombotic thrombocytopenia (VITT) as well as recommendations for clinical, laboratory testing and imaging diagnostics. In addition, relevant complications with particular reference to epileptic seizures within the framework of the disease entity and guideline-based acute treatment and secondary prophylaxis are presented.

Clinical Variables Correlate with Serum Neutralizing Antibody Titers after COVID-19 mRNA Vaccination in an Adult, US-based Population. BACKGROUND: We studied whether comorbid conditions impact strength and duration of immune responses after SARS-CoV-2 mRNA vaccination in a US-based, adult population. METHODS: Sera (pre-and-post-BNT162b2 vaccination) were tested serially up to 12 months after two doses of vaccine for SARS-CoV-2-anti-Spike neutralizing capacity by pseudotyping assay in 124 individuals; neutralizing titers were correlated to clinical variables with multivariate regression. Post-booster (third dose) effect was measured at 1 and 3 months in 72 and 88 subjects respectively. RESULTS: After completion of primary vaccine series, neutralizing antibody IC50 values were high at one month (14-fold increase from pre-vaccination), declined at six months (3.3-fold increase), and increased at one month post-booster (41.5-fold increase). Three months post-booster, IC50 decreased in COVID-naÃ¯ve individuals (18-fold increase) and increased in prior COVID-19+ individuals (132-fold increase). Age >65 years (Î²=-0.94, p=0.001) and malignancy (Î²=-0.88, p=0.002) reduced strength of response at 1 month. Both strength and durability of response at 6 months, respectively, were negatively impacted by end-stage renal disease [(Î²=-1.10, p=0.004); (Î²=-0.66, p=0.014)], diabetes mellitus [(Î²=-0.57, p=0.032); (Î²=-0.44, p=0.028)], and systemic steroid use [(Î²=-0.066, p=0.032); (Î²=-0.55, p=0.037)]. Post-booster IC50 was robust against WA-1 and B.1.617.2, but the immune response decreased with malignancy (Î² =-0.68, p=0.03) and increased with prior COVID-19 (p-value < 0.0001). CONCLUSION: Multiple clinical factors impact the strength and duration of neutralization response post-primary series vaccination, but not the post-booster dose strength. Prior COVID-19 infection enhances the booster-dose response except in individuals with malignancy, suggesting a need for clinically guiding vaccine dosing regimens. SUMMARY: Multiple clinical factors impact the strength and duration of neutralization response post-primary series vaccination. All subjects, irrespective of prior COVID infection, benefited from a third dose. Malignancy decreased response following third dose, suggesting the importance of clinically guided vaccine regimens.

Risk of adverse events after covid-19 in Danish children and adolescents and effectiveness of BNT162b2 in adolescents: cohort study. OBJECTIVES: To assess the risk of acute and post-acute adverse events after SARS-CoV-2 infection in children and adolescents in Denmark and to evaluate the real world effectiveness of the BNT162b2 mRNA vaccine (Pfizer-BioNTech) among adolescents. DESIGN: Cohort study. SETTING: Nationwide Danish healthcare registers. PARTICIPANTS: All Danish people younger than 18 years who were either tested for SARS-CoV-2 using reverse transcriptase polymerase chain reaction (RT-PCR) or vaccinated with BNT162b2 to 1 October 2021. MAIN OUTCOME MEASURES: Risk of hospital admissions (any hospital contact of â‰¥12 hours); intensive care unit (ICU) admissions; serious complications, including multisystem inflammatory syndrome in children (MIS-C), myocarditis, and neuroimmune disorders; and initiating drug treatment and health service use up to six months after being tested. Vaccine effectiveness in vaccine recipients compared with unvaccinated peers was evaluated as one minus the risk ratio at 20 days after the first dose and 60 days after the second dose. RESULTS: Of 991â€‰682 children and adolescents tested for SARS-CoV-2 using RT-PCR in Denmark, 74â€‰611 (7.5%) were positive. The risk of hospital admission with any variant for â‰¥12 hours was 0.49% (95% confidence interval 0.44% to 0.54%; 361/74â€‰350), and 0.01% (0.01% to 0.03%; 10/73â€‰187) of participants were admitted to an ICU within 30 days of testing positive. The risk of MIS-C within two months of SARS-CoV-2 infection was 0.05% (0.03% to 0.06%; 32/70â€‰666), whereas no participants had myocarditis outside of MIS-C or encephalitis and fewer than five had Guillain-BarrÃ© syndrome. In the post-acute phase (1-6 months after infection), participants who tested positive for SARS-CoV-2 showed a 1.08-fold (95% confidence interval 1.06-fold to 1.10-fold) increase in rate of contacts with general practitioners compared with a reference cohort sampled among all children tested for SARS-CoV-2 during the study period. Overall, 278â€‰649 adolescents received BNT162b2. Compared with unvaccinated adolescents, the

estimated vaccine effectiveness among 229â€‰799 adolescents vaccinated with one dose was 62% (95% confidence interval 59% to 65%) after 20 days, and among 175â€‰176 vaccinated with two doses was 93% (92% to 94%) after 60 days during a period when delta was the dominant variant. CONCLUSIONS: The absolute risks of adverse events after SARS-CoV-2 infection were generally low in Danish children and adolescents, although MIS-C occurred in 0.05% (32/70â€‰666) of participants with RT-PCR confirmed SARS-CoV-2 infection. In adjusted analyses, rates of general practitioner visits were slightly increased in SARS-CoV-2 positive children and adolescents, which could indicate persisting symptoms. BNT162b2 appeared to be effective in reducing the risk of SARS-CoV-2 infection with the delta variant in adolescents.

Clinical update on risks and efficacy of anti-SARS-CoV-2 vaccines in patients with autoimmune hepatitis and summary of reports on post-vaccination liver injury. Patients with liver diseases, especially those with cirrhosis, have an increased mortality risk when infected by SARS-CoV-2 and therefore anti-SARS-CoV-2 vaccine has been recommended by leading Scientific Associations for all patients with chronic liver diseases. However, previous reports have shown a reduced antibody response following the full course of vaccination in immunosuppressed patients, including liver transplant recipients and several rheumatic diseases. This document, drafted by an expert panel of hepatologists appointed by the Italian Association for the Study of the Liver (AISF), aims to present the updated scientific data on the safety and efficacy of anti-SARS-CoV-2 mRNA vaccines in patients with autoimmune hepatitis (AIH). Furthermore, given the recent reports of sporadic cases of AIH-like cases following anti-SARS-CoV-2 mRNA vaccines, we summarize available data. Finally, we provide experts recommendations based on the limited data available.

Erratum to 'COVID-19 vaccine-associated subclinical axillary lymphadenopathy on screening mammogram' [Academic Radiology Volume 29, Issue 4,Â April 2022, Pages 501-507].

Effects of Vaccination against COVID-19 in Chronic Spontaneous and Inducible Urticaria (CSU/CIU) Patients: A Monocentric Study. BACKGROUND: Patients affected by pre-existing chronic spontaneous/Inducible urticaria (CSU/CIU) still feel unsafe due to the potential risk of an Adverse Event Following Immunization (AEFI) and Cutaneous Adverse Reactions (CARs) of COVID-19 vaccines. The appropriate management in this field remains debated and evidence is still lacking. METHODS: We considered 160 CSU/CIU patients in Omalizumab/antihistamine therapy who received two doses of Comirnaty/Moderna mRNA vaccines; 20 of them also received a booster dose. Urticaria Activity Score-7 (UAS7) was used to assess the severity of the disease. Demographics, medical history, AEFI and CARs outcome after vaccination were collected by administering a web-based questionnaire completed by phone interview. RESULTS: In total, 147 patients did not show urticaria relapse (91.88%). Worsening cutaneous symptoms were experienced by 13 of our patients (8.12%). Exacerbation had a mean duration of 2 days and 11 h and mostly occurred after the first dose (69.23%). Systemic mild side effects were experienced by 9 patients (5.62%). No severe reactions were observed. CONCLUSIONS: Omalizumab can potentially prevent CARs and AEFI; however, major problems were registered during the 2-month stop period scheduled in the treatment. We suggest patients should not undergo vaccination during this period. CSU/CIU exacerbations appear to be transient and can be managed by antihistamines.

Plasma Metabolomic Alterations Induced by COVID-19 Vaccination Reveal Putative Biomarkers Reflecting the Immune Response. Vaccination is currently the most effective strategy for the mitigation of the COVID-19 pandemic. mRNA vaccines trigger the immune system to produce neutralizing antibodies (NAbs) against SARS-CoV-2 spike proteins. However, the underlying molecular processes affecting immune response after vaccination remain poorly understood, while there is significant heterogeneity in the immune response among individuals. Metabolomics have often been used to provide a deeper understanding of immune cell responses, but in the context of COVID-19

vaccination such data are scarce. Mass spectrometry (LC-MS) and nuclear magnetic resonance (NMR)-based metabolomics were used to provide insights based on the baseline metabolic profile and metabolic alterations induced after mRNA vaccination in paired blood plasma samples collected and analysed before the first and second vaccination and at 3 months post first dose. Based on the level of NAbs just before the second dose, two groups, "low" and "high" responders, were defined. Distinct plasma metabolic profiles were observed in relation to the level of immune response, highlighting the role of amino acid metabolism and the lipid profile as predictive markers of response to vaccination. Furthermore, levels of plasma ceramides along with certain amino acids could emerge as predictive biomarkers of response and severity of inflammation.

COVID-19 Pneumonia After SARS-CoV-2 Vaccination with CoronaVac: A Case Series from Turkey. Coronavirus disease 2019 is a novel viral infection that has caused a pandemic globally. Many kinds of vaccine development studies were conducted to prevent the spread and deaths. The CoronaVac is the most commonly used vaccine in Turkey. Phase 3 trials from various countries revealed that CoronaVac efficacy ranged from 50.7% to 91.25% but increased in moderate or severe cases to 100%. Additionally, it was remarkable owing to high seroconversion rates achieving up to 100%. After the vaccine campaign began in Turkey, critically ill patients continued to admit to our center's intensive care unit though they had been vaccinated with 2 doses of CoronaVac. The clinical course of these patients revealed that they are still at high risk of severe disease and death. Therefore, we aimed to share these patients' clinical characteristics and disease course, laboratory, and radiologic data.

Safety and immunogenicity of SARS-CoV-2 vaccines in Chinese patients with cirrhosis: a prospective multicenter study. BACKGROUND: Data on safety and immunogenicity of coronavirus disease 2019 (COVID-19) vaccination in patients with compensated (C-cirrhosis) and decompensated cirrhosis (D-cirrhosis) are limited. METHODS: In this prospective multicenter study, adult participants with C-cirrhosis and D-cirrhosis were enrolled and received two doses of inactivated whole-virion COVID-19 vaccines. Adverse events were recorded within 14Â days after any dose of vaccination, and serum samples of enrolled patients were collected and tested for SARS-CoV-2 neutralizing antibodies at least 14Â days after the second dose. Risk factors for negative neutralizing antibody were analyzed. RESULTS: In total, 553 patients were enrolled from 15 centers in China, including 388 and 165 patients with C-cirrhosis and D-cirrhosis. The vaccines were well tolerated, most adverse reactions were mild and transient, and injection site pain (23/388 [5.9%] vs 9/165 [5.5%]) and fatigue (5/388 [1.3%] vs 3/165 [1.8%]) were the most frequently local and systemic adverse events in both the C-cirrhosis and D-cirrhosis groups. Overall, 4.4% (16/363) and 0.3% (1/363) of patients were reported Grades 2 and 3 alanine aminotransferase (ALT) elevations (defined as ALTâ€‰>â€‰2 upper limit of normal [ULN] butâ€‰â‰¤â€‰5 ULN, and ALTâ€‰>â€‰5 ULN, respectively). The positive rates of COVID-19 neutralizing antibodies were 71.6% (278/388) and 66.1% (109/165) in C-cirrhosis and D-cirrhosis groups. Notably, Child-Pugh score of B and C levels was an independent risk factor of negative neutralizing antibody. CONCLUSIONS: Inactivated COVID-19 vaccinations are safe with acceptable immunogenicity in cirrhotic patients, and Child-Pugh score of B and C levels is associated with hyporesponsive to COVID-19 vaccination.

Impaired Antibody Response Following the Second Dose of the BNT162b2 Vaccine in Patients With Myeloproliferative Neoplasms Receiving Ruxolitinib. Data on the effect of ruxolitinib on antibody response to severe acute respiratory coronavirus 2 (SARS-CoV-2) vaccination in patients with myeloproliferative neoplasms (MPN) is lacking. We prospectively evaluated anti-spike-receptor binding domain antibody (anti-S Ab) levels after the second dose of the BNT162b2 (Pfizer-BioNTech) vaccine in MPN patients. A total of 74 patients with MPN and 81 healthy controls who were vaccinated were enrolled in the study. Of the MPN patients, 27% received ruxolitinib at the time of vaccination. Notably, MPN patients receiving ruxolitinib had a 30-fold lower median anti-S Ab level

than those not receiving ruxolitinib ($p < 0.001$). Further, the anti-S Ab levels in MPN patients not receiving ruxolitinib were significantly lower than those in healthy controls ($p < 0.001$). Regarding a clinical protective titre that has been shown to correlate with preventing symptomatic infection, only 10% of the MPN patients receiving ruxolitinib had the protective value. Univariate analysis revealed that ruxolitinib, myelofibrosis, and longer time from diagnosis to vaccination had a significantly negative impact on achieving the protective value ($p = 0.001$, 0.021, and 0.019, respectively). In subgroup analysis, lower numbers of CD3(+) and CD4(+) lymphocytes were significantly correlated with a lower probability of obtaining the protective value ($p = 0.011$ and 0.001, respectively). In conclusion, our results highlight ruxolitinib-induced impaired vaccine response and the necessity of booster immunisation in MPN patients. Moreover, T-cell mediated immunity may have an important role in the SARS-CoV-2 vaccine response in patients with MPN, though further studies are warranted.

Longevity of Humoral Response Six Months Following BNT162b2 Vaccine in Dialysis Patients. BACKGROUND: End-stage kidney disease substantially increases the risk of severe COVID-19. However, despite early robust immunogenicity of the mRNA-SARS-CoV-2 vaccination in patients with hemodialysis, the longevity of humoral response in this high-risk population is still unknown. METHODS: A prospective cohort study aimed to evaluate the longevity of serologic response in patients with hemodialysis, compared with a control group, 6 months following the second dose of the BNT162b2 vaccine. We assessed antibody response by quantitative measurement of IgG antibodies against the receptor-binding domain of the Spike protein (anti-S1-RBD IgG). Study outcomes were defined as a seropositivity rate and log-transformed anti-S1-RBD IgG levels at 6 months, and the change in antibody levels between 3 and 6 months. FINDINGS: The cohort included 104 patients with hemodialysis and 84 controls. At a median time of 184 days (IQR, 183-188) following the second dose of the vaccine, 83/104 (79.8%) patients with hemodialysis maintained seropositivity for the anti-S1-RBD IgG level compared to 83/84 (98.8%) in the control group ($p < 0.001$). The log-transformed antibody level was significantly lower in the hemodialysis group (2.23 Â± 0.39 log AU/ml vs. 2.69 Â± 0.65 log AU/ml, respectively, $p < 0.001$). Older age and hypoalbuminemia were the only variables that were found to be associated with reduced log-transformed antibody levels in univariate and multivariate analysis. There was no interaction between dialysis status and an antibody-level decline rate ($p = 0.972$). CONCLUSION: Among patients with hemodialysis, a seropositivity rate and anti-S1-RBD antibody titers were substantially reduced compared with a control group, at 6 months following the second dose of the BNT162b2 vaccine. These findings support the prioritization of patients with hemodialysis for a third "booster" dose.

Factors Associated With Psychological Outcomes Among Vaccinated and Unvaccinated Health Care Workers Against COVID-19 Infection in Bangladesh. BACKGROUND: Vaccination of healthcare workers (HCWs) is recommended during the COVID-19 pandemic to reduce the risk of infection for themselves and their patients, as well as to encourage their patients to get immunized. The present study aimed to investigate the psychological outcomes and associated factors among vaccinated and unvaccinated HCWs against COVID-19 infection in Bangladesh. METHODS: From March to August 2021, an online nationwide survey was conducted with a total of 2,038 Bangladeshi HCWs. The frequency of symptoms of general health problems, depression, anxiety, stress, post-traumatic stress disorder, insomnia, and loneliness was assessed using the Bangla versions of the GHQ-12, PHQ-2, GAD-2, PSS-4, PC-PTSD-5, ISI, and UCLA-LS scales, respectively. RESULTS: Compared with unvaccinated HCWs (n = 1,058), vaccinated HCWs (n = 980) had a statistically significant lower prevalence of general health problems (16.7 vs. 59.1%), depression (15.6 vs. 31.9%), post-traumatic stress disorder (22.3 vs. 30.8%), insomnia (23.8 vs. 64.9%), and loneliness symptoms (13.9 vs. 21.8%). Among vaccinated HCWs, females were significantly associated with a higher risk of symptoms of general health problems (AOR, 2.71; 95% CI, 0.97-7.60), anxiety (AOR, 2.17; 95% CI, 1.14-4.13), and

loneliness (AOR, 2.52; 95% CI, 1.11-5.73). Except for anxiety and post-traumatic stress disorder symptoms, participants living in urban areas had a significantly lower risk of all psychological outcomes (e.g., depression: AOR, 0.43; 95% CI, 0.27-0.67; stress: AOR, 0.64; 95% CI, 0.47-0.88). Respondents who were married were significantly less likely to experience symptoms of general health problems (AOR, 0.10; 95% CI, 0.02-0.39), depression (AOR, 0.31; 95% CI, 0.22-0.82), insomnia (AOR, 0.46; 95% CI, 0.20-1.03), and loneliness (AOR, 0.31; 95% CI, 0.10-0.92). Participants who worked as doctors were significantly less chance of experiencing symptoms of general health problems (AOR, 0.18; 95% CI, 0.08-0.37), depression (AOR, 0.51; 95% CI, 0.30-0.87), and anxiety (AOR, 0.54; 95% CI, 0.37-0.78). On the other hand, unvaccinated HCWs who were 18-29 years old and had <5 years of work experience were significantly associated with a higher risk of all psychological outcomes except anxiety and insomnia symptoms (e.g., depression among 18-29 years old: AOR, 1.83; 95% CI, 0.27-2.60; stress among those with <5 years of work experience: AOR, 2.37; 95% CI, 0.93-6.07). Participants who worked as nurses were significantly more likely to suffer from depression (AOR, 1.44; 95% CI, 0.84-2.46), anxiety (AOR, 1.42; 95% CI, 0.24-1.73), and stress (AOR, 1.55; 95% CI, 0.31-0.89) symptoms. Except for anxiety and stress symptoms, respondents who worked as frontline workers and provided direct care to infected patients were the significantly higher chance of experiencing all psychological outcomes (e.g., depression among who worked as frontline workers: AOR, 2.41; 95% CI, 0.23-3.73; insomnia among those who provide direct care to infected patients: AOR, 2.60; 95% CI, 0.34-3.06). Participants who were infected with COVID-19 had a significantly less chance of experiencing symptoms of general health problems (AOR, 0.89; 95% CI, 0.65-1.22), depression (AOR, 0.66; 95% CI, 0.48-0.92), and anxiety (AOR, 0.63; 95% CI, 0.46-0.87). CONCLUSIONS: To control the infection and improve psychological outcomes, this study suggests emphasizing the vaccinated to unvaccinated HCWs as soon as possible. They also required special attention, health-related education, and psychological support.

Superficial Thrombophlebitis of the Penis following AstraZeneca ChAdOx1-S Vaccination: A Rare Venous Thromboembolic Complication. Penile Mondor's disease is a rare condition characterised by superficial thrombophlebitis of the penis which is usually self-limiting. The cause is often unknown. The AstraZeneca ChAdOx1-S vaccine has been found to cause a hypercoagulable state, which is well documented. This case report describes a man who presented with Mondor's disease following ChAdOx1-S vaccination with no other risk factors. LEARNING POINTS: This is the first documented case of penile thrombophlebitis following ChAdOx1-S vaccination.We highlight a rare presentation of an uncommon condition.Clinicians should be aware of the clotting risks associated with ChAdOx1-S vaccination.

Comparison of antibody response following the second dose of SARS-CoV-2 mRNA vaccine in elderly patients with late-stage chronic kidney disease. BACKGROUND: Currently, it is unclear whether the progression of chronic kidney disease (CKD) could be an independent predictor of antibody response after administration of a COVID-19 vaccine. This study aimed to investigate the immune response to COVID-19 vaccination in patients with CKD stage G4 to G5 without renal replacement therapy and G5D using the recommended dose and schedule. METHODS: This retrospective single-center cohort study evaluated immunogenicity regarding antibody response after COVID-19 vaccination in our hospital for late-stage CKD patients agedâ€‰â‰¥â€‰60Â years. We evaluated antibody responses in 48 patients with CKD G4, 35 patients with CKD G5, and 70 patients undergoing hemodialysis (HD; CKD G5D). RESULTS: After the second vaccination, anti-SARS-CoV-2-S (Spike) IgG levels were found to be positive (>â€‰0.8 U/mL) in all CKD G4 and G5 patients (100%), and 69 of 70 HD patients (98.5%). The median (interquartile range [IQR] S-IgG level (Ab titers) was 358 [130.2-639.2], 218 [117-377], and 185.5 [95.1-323.5] U/mL in the CKD G4, G5, and HD groups, respectively. The median S-IgG levels were significantly lower in the HD group than in the CKD G4 group

(pâ€‰<â€‰0.01). However, there was no significant difference in the antibody titers between the CKD G4 and G5 groups. To further analyze the decline in S-IgG levels after 6Â months, we additionally assessed and compared antibody titers at 1Â month and 6Â months after the second vaccination in the HD group. Compared with the median S-IgG levels of 185.5 [95.1-323.5] U/mL 1Â month after the second dose, the median S-IgG level 6Â months thereafter was significantly decreased at 97.4 [62.5-205.5] U/mL (pâ€‰<â€‰0.05). CONCLUSIONS: We highlight two major factors of variability in the vaccine response. First, in elderly patients with late-stage CKD, antibody titers tended to be lower in the G5D group than in the G4 and G5 groups despite the shorter time since vaccination; therefore, CKD stage progression might cause a decline in antibody titers. Second, waning immune responses were observed 6Â months after second dose administration in HD patients advocating aÂ potential need for a third booster dose vaccine after 6Â months.

Guillain-BarrÃ© Syndrome with Rapid Onset and Autonomic Dysfunction Following First Dose of Pfizer-BioNTech COVID-19 Vaccine: A Case Report. Guillain-Barre syndrome (GBS) is an immune-mediated, often post-infectious illness manifesting as an acute, characteristically monophasic, polyradiculoneuropathy. We present a case of GBS with autonomic involvement following an mRNA-based vaccine against SARS-COV2 (Pfizer/BioNTech mRNA-BNT162b2). A 58-year-old woman presented with fatigue, distal extremity paresthesias, and severe back pain within 3Â days after receiving her first vaccine dose. She developed worsening back pain and paresthesias in distal extremities which prompted her initial presentation to the hospital. By the third week post-vaccine, she developed increasing gait unsteadiness, progression of paresthesias, and new autonomic symptoms including presyncopal episodes and constipation. Neurological exam showed bilateral distal predominant lower extremity weakness, decreased sensation in a length-dependent pattern, and areflexia. EMG/NCS showed a diffuse sensorimotor polyneuropathy with mixed demyelinating and axonal features consistent with GBS. She was treated with 2Â g/kg of IVIG over 3Â days and also received prednisone 60Â mg daily for 3Â days for severe back pain, with improvement of symptoms. This possible association with mRNA-based vaccination expands the potential triggers for an autoimmune-based attack on the peripheral nervous system.

A rare case of COVID-19 vaccine-induced myopericarditis in a young adult. Although extremely rare, the COVID-19 mRNA vaccine can induce myopericarditis without left ventricular dysfunction, and there have been rare reports of such incidents. However, these prior cases either did not have pericardial effusion without reduced left ventricular ejection fraction or had a more typical presentation of vaccine-induced myopericarditis such as shortness of breath or tactile temperature. We present a rare case of a 25-year-old man who developed myopericarditis following administration of the second dose of COVID-19 mRNA Vaccine. As vaccination plays a significant role in the fight against the COVID-19 pandemic, it is essential to highlight the physical manifestations of the vaccine's potential adverse effects and risk factors to increase the general population's awareness regarding the importance of emergent medical care.

Development of Potent Cellular and Humoral Immune Responses in Long-Term Hemodialysis Patients After 1273-mRNA SARS-CoV-2 Vaccination. Long-term hemodialysis (HD) patients are considered vulnerable and at high-risk of developing severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) infection due to their immunocompromised condition. Since COVID-19 associated mortality rates are higher in HD patients, vaccination is critical to protect them. The response towards vaccination against COVID-19 in HD patients is still uncertain and, in particular the cellular immune response is not fully understood. We monitored the humoral and cellular immune responses by analysis of the serological responses and Spike-specific cellular immunity in COVID-19-recovered and naÃ¯ve HD patients in a longitudinal study shortly after vaccination to determine the protective effects of 1273-mRNA vaccination against SARS-CoV-2 in these high-risk patients. In naÃ¯ve HD

patients, the cellular immune response measured by IL-2 and IFN-É£ secretion needed a second vaccine dose to significantly increase, with a similar pattern for the humoral response. In contrast, COVID-19 recovered HD patients developed a potent and rapid cellular and humoral immune response after the first vaccine dose. Interestingly, when comparing COVID-19 recovered healthy volunteers (HV), previously vaccinated with BNT162b2 vaccine to HD patients vaccinated with 1273-mRNA, these exhibited a more robust immune response that is maintained longitudinally. Our results indicate that HD patients develop strong cellular and humoral immune responses to 1273-mRNA vaccination and argue in favor of personalized immune monitoring studies in HD patients, especially if COVID-19 pre-exposed, to adapt COVID-19 vaccination protocols for this immunocompromised population.

Specific Anti-SARS-CoV-2 Humoral and Cellular Immune Responses After Booster Dose of BNT162b2 Pfizer-BioNTech mRNA-Based Vaccine: Integrated Study of Adaptive Immune System Components. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes coronavirus disease 2019 (COVID-19), is modifying human activity all over the world with significant health and economic burden. The advent of the SARS-CoV-2 pandemic prompted the scientific community to learn the virus dynamics concerning transmissibility, epidemiology, and usefulness of vaccines in fighting emerging health hazards. Pieces of evidence suggest that the first and second doses of mRNA vaccines induce a significant antibody response in vaccinated subjects or patients who recovered from SARS-CoV-2 infection, demonstrating the importance of the previously formed memory. The aim of this work has been to investigate the effects of BNT162b2 Pfizer-BioNTech mRNA-based vaccine booster dose in a cohort of 11 uninfected immunocompetent (ICs), evaluating the humoral and cellular responses, with more carefulness on memory B and T cells. Our findings underscore the potential benefit of the third dose of mRNA vaccine on the lifespan of memory B and T cells, suggesting that booster doses could increase protection against SARS-CoV-2 infection.

Case Report: Recanalization of Branch Retinal Artery Occlusion Due to Microthrombi Following the First Dose of SARS-CoV-2 mRNA Vaccination. Background: We report on a patient with a branch retinal artery occlusion (RAO) and its recanalization based on multimodal retinal and angiographic images after he was administered the first dose of the SARS-CoV-2 mRNA vaccine. Case summary: A 64-year-old man complained of a right, painless, inferior field defect 3Â days after the first dose of BNT162b2 vaccination. Fundus examination revealed decolorization of the right upper macula, including microthrombi in the superior proximal branch of the retinal artery. Optical coherence tomography angiography revealed upper macular hypoperfusion. Fluorescein angiography revealed prolonged arteriovenous transit to the macula. After paracentesis with antiplatelet medications, the artery was recanalized as the thrombi dissolved, and the right visual field was recovered. Re-occlusion did not occur during the 3Â months after the second mRNA vaccination. Conclusion: Non-embolic thrombotic RAO may develop shortly after the SARS-CoV-2 mRNA vaccine. Ophthalmologists should consider RAO as a possible post-vaccination adverse event. The temporal association between mRNA vaccination and RAO onset with evidence of microthrombi might provide additional clues to elucidate the unpredictive arterial thrombosis following SARS-CoV-2 mRNA vaccination.

Successful Treatment of Immune Thrombocytopenic Purpura with Intracranial Hemorrhaging and Duodenal Bleeding Following SARS-CoV-2 Vaccination. Several vaccines have been developed for coronavirus disease 2019 - caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) - in record time. A few cases of immune thrombocytopenic purpura (ITP) following SARS-CoV-2 vaccination have been reported. We herein report a 90-year-old man who received the Pfizer-BioNTech SARS-CoV-2 vaccine (BNT162b2) and developed severe thrombocytopenia with intracranial hemorrhaging and duodenal bleeding, consistent with vaccine-related ITP. He was successfully treated with intravenous immunoglobulin, prednisolone, and eltrombopag and discharged without

cytopenia. Vaccine-related ITP should be suspected in patients presenting with abnormal bleeding or purpura after vaccination.

A Meta-Analysis on the Safety and Immunogenicity of Covid-19 Vaccines. OBJECTIVE: The presented meta-analysis (MA) aims at identifying the vaccine safety and immunogenicity in published trials about SARS-CoV-2 vaccines. METHODS: All relevant publications were systematically searched and collected from different databases (Embase, Scopus, EBSCO, MEDLINE central/PubMed, Science Direct, Cochrane Central Register for Clinical Trials (CENTRAL), Clinical Trials.gov, WHO International Clinical Trials Registry Platform (ICTRP), COVID Trial, COVID Inato, Web of Science, ProQuest Thesis, ProQuest Coronavirus Database, SAGE Thesis, Google Scholar, Research Square, and Medxriv) up to January 10, 2021. The pooled vaccine safety and immunogenicity following vaccination in phase 1 and 2 vaccine clinical trials, as well as their 95% confidence intervals (CI), were estimated using the random-effects model. RESULTS: The predefined inclusion criteria were met in 22 out of 8592 articles. The proportion of anti-severe acute respiratory distress coronavirus 2 (SARS-CoV-2) antibody responses after 7â€‰days among 72 vaccinated persons included in 1 study was 81% (95% CI: 70-89), after 14â€‰days among 888 vaccinated persons included in 6 studies was 80% (95% CI: 58-92), after 28â€‰days among 1589 vaccinated persons included in 6 studies was 63% (95% CI: 59-67), after 42â€‰days among 478 vaccinated persons included in 5 studies was 93% (95% CI: 80-98), and after 56â€‰days among 432 vaccinated persons included in 2 studies was 93% (95% CI: 83-97). Meta regression explains more than 80% of this heterogeneity, where the main predictors were; the inactivated vaccine type (Î²â€‰=â€‰2.027, Pâ€‰=â€‰0.0007), measurement of antibodies at week 1 (Î²â€‰=â€‰-4.327, Pâ€‰<â€‰0.0001) and at week 3 of the first dose (Î²â€‰=â€‰-2.02, Pâ€‰=â€‰0.0025). Furthermore, the pooled proportion adverse effects 7â€‰days after vaccination was 0.01 (0.08-0.14) for fever, headache 0.23 (0.19-0.27), fatigue 0.10 (0.07-0.13), and 0.18 (0.14-0.23) for muscle pain. CONCLUSION: Immunogenicity following vaccination ranged from 63% to 93% depending on the time at which the antibody levels were measured.

The Effect of Reading Leaflets During the Observation Period After Vaccination on Knowledge of COVID-19 and Vaccines Among Chinese Small Town Residents: A Randomized Controlled Trial. BACKGROUND: Public health education is essential for epidemic prevention and control in the post-COVID-19 era. This randomized controlled trial (RCT) aims to evaluate the effect of reading leaflets during the observation period after vaccination on knowledge of COVID-19 disease and vaccines in Chinese small town residents and to provide suggestions for public health education. METHODS: Residents were recruited during the observation period after getting vaccinated against COVID-19 in Xidian and were randomly divided into an education group and a control group. The education group was asked to complete the questionnaire after reading a leaflet, whereas the control group directly completed the questionnaire. The questionnaire comprised two sections on COVID-19 knowledge and vaccine knowledge, and the scores were used to assess the resident's knowledge. RESULTS: A total of 142 participants in the education group and 154 participants in the control group were enrolled. The rates of correct knowledge in the education group and the control group were 90.7 and 83.1%, respectively. The scores of the two sections and the aggregate knowledge score of the education group were significantly higher than those of the control group ($P < 0.001$). The rates of correct responses to questions on clinical manifestations and transmission routes of COVID-19 and indications and contraindications of vaccines significantly increased after reading the leaflets ($P < 0.05$). Knowledge of different groups of genders, ages, marital statuses, education levels and occupations all improved ($P < 0.05$), and the 18-29-year-old and never-married group revealed a higher growth rate of correct responses. CONCLUSION: Chinese small town residents have a median level of knowledge regarding COVID-19 disease and vaccines. Reading leaflets during the observation

period after vaccination effectively improved their knowledge. This low-cost and efficient health education approach can be widely applied.

Thyroid eye disease reactivation associated with COVID-19 vaccination. To describe the presentation of both new-onset and reactivation of thyroid eye disease (TED) following COVID-19 vaccination. Single-institution retrospective case series of patients presenting with symptoms and signs of new or reactivated TED coinciding with recent COVID-19 vaccination. Data collected included patient age, gender, presenting symptoms, ocular history, clinical signs, and interval duration between vaccination and onset of ocular symptoms. Three female patients were identified. All patients were over 18 years of age (range 45-66 years). Patients received either the Moderna or Pfizer COVID-19 vaccine and presented with symptoms of TED within 24 h to 21 days of receiving their first or second dose. None of the patients had previous infections with severe acute respiratory syndrome coronavirus 2. Two patients had a history of inactive TED with stable thyroid function tests: One of these patients had stable disease for at least 15 years and the other had stable disease for 5 years. The third patient had no previous history of thyroid dysfunction or TED and presented with low levels of thyroid-stimulating hormone. All three cases presented with proptosis. In two of three cases, periorbital edema, eyelid retraction, and diplopia were present. None were current smokers. One had prior facial hyaluronic acid filler injections. Symptoms in all cases were improving at 4 to 8 months. While the possibility of unrelated TED flaring concurrently with COVID-19 vaccination exists, questions remain on the effects of the COVID-19 vaccine in patients with autoimmune ophthalmic diseases. Physicians should be aware of this potential association and counsel patients appropriately.

A Case of Recurrent Acute Anterior Uveitis After the Administration of COVID-19 Vaccine. We present a case of a 37-year-old healthy man who developed acute anterior uveitis after receiving the first and second doses of the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine. To the best of our knowledge, this is the first report of a recurring incidence of ocular side effects associated with COVID-19 immunization. Based on the timing of the start of symptoms with the first and second vaccinations, the absence of prior medical conditions, and unremarkable investigations, we believe that the patient's anterior uveitis may have been induced by the vaccine itself. This case suggests that vaccination could be a risk factor in uveitis development and recurrence following redosing. As a result, we recommend that ophthalmologists investigate the recent immunization status in each case of uveitis with a temporal association with COVID-19 vaccine administration and record these cases to improve the quality of data tracking of potential adverse responses to vaccines.

Eruptive Angiomatosis Triggered by COVID-19 Vaccination. Despite meeting strict standards of quality, safety, and effectiveness, rare systemic and cutaneous side effects of coronavirus disease 2019 (COVID-19) vaccinations continue to be reported throughout the world. We report a case of eruptive cherry angiomatosis in a female following her first dose of COVID-19 vaccination with subsequent crops appearing after the second dose. The biopsy revealed dilatedÂ capillaries within the superficial dermis consistent with the clinical diagnosis.

Rapid emergence of SARS-CoV-2 Omicron variant is associated with an infection advantage over Delta in vaccinated persons. BACKGROUND: The SARS-CoV-2 Omicron variant became a global concern due to its rapid spread and displacement of the dominant Delta variant. We hypothesized that part of Omicron's rapid rise was based on its increased ability to cause infections in persons that are vaccinated compared to Delta. METHODS: We analyzed nasal swab PCR tests for samples collected between December 12 and 16, 2021, in Connecticut when the proportion of Delta and Omicron variants was relatively equal. We used the spike gene target failure (SGTF) to classify probable Delta and Omicron infections. We fitted an exponential curve to the estimated infections to determine the doubling times for each variant. We compared the test positivity rates for each variant by vaccination status, number of doses, and vaccine manufacturer. Generalized linear models were used to assess

factors associated with odds of infection with each variant among persons testing positive for SARS-CoV-2. FINDINGS: For infections with high virus copies (CtÂ <Â 30) among vaccinated persons, we found higher odds that they were infected with Omicron compared to Delta, and that the odds increased with increased number of vaccine doses. Compared to unvaccinated persons, we found significant reduction in Delta positivity rates after two (43.4%-49.1%) and three vaccine doses (81.1%), while we only found a significant reduction in Omicron positivity rates after three doses (62.3%). CONCLUSION: The rapid rise in Omicron infections was likely driven by Omicron's escape from vaccine-induced immunity. FUNDING: This work was supported by the Centers for Disease Control and Prevention (CDC).

Acceptance of COVID-19 Vaccine and Associated Factors Among Pregnant Women in Saudi Arabia. BACKGROUND: Coronavirus disease 19 (COVID-19) vaccination has been established as preventing severe and mortal COVID-19. Vaccination is critical strategy in controlling the COVID-19 pandemic, to restrict infections and reduce disease severity. Vaccination coverage will be more extensive if we can better identify vaccination barriers in the population, especially among vulnerable groups, of which one is pregnant women. The aim of this study was to determine the level of acceptance of COVID-19 vaccination and detect the factors that influence vaccine acceptance among pregnant women in Saudi Arabia. METHODS: This was a cross-sectional, web-based study conducted in Western, Eastern, North, South, and Central Regions in Saudi Arabia between July and September 2021 among pregnant women, using multi-stage sampling. All pregnant women above 18 years were invited to participate in the study. Pregnant under 18 years of age and those with a contraindication to receiving COVID-19 vaccination were excluded. Binomial logistic regression (univariate and multivariate) was used to identify the influencing factors on vaccination acceptance. RESULTS: Among the 5307 pregnant women, the acceptance level of COVID-19 vaccine was 68%. In the multivariate regression model analysis, the most common predictors of acceptance were living in North Region (P = 0.001, OR = 1.9), living in South Region (P = 0.000, OR = 3.06), and living in Central Region (P = 0.035, OR = 1.42) in comparison to living in Western Region. Gestational week (P = 0.018, OR=0.98), income more than 8000 SR (P = 0.000, OR = 0.51), education level (primary, secondary, and university; P = 0.002, 0.008, and 0.010, respectively), having had gestational diabetes mellitus (P = 0.013, OR = 1.86), being vaccinated with influenza vaccine during present pregnancy (P = 0.000, OR = 4.55, OR = 1.81), being vaccinated with tetanus vaccine during present pregnancy (P = 0.039), and believing that the COVÄ°D-19 vaccine could harm their baby (P = 0.000, OR = 0.12). CONCLUSION: Our study reported high acceptance of COVID-19 vaccination. The major two reasons for refusal were concerns about a lack of data on COVID-19 vaccination safety and the possibility of harming the fetus. Continued public health efforts, such as educational television programs and awareness campaigns about the safety of the COVID-19 vaccine for pregnant women, are required to raise awareness. More studies of COVID-19 vaccine safety in pregnant women would assist in overcoming these obstacles and encourage pregnant women to be vaccinated.

COVID-19 vaccination-associated ipsilateral supraclavicular lymphadenopathy. Lymphadenopathy associated with COVID-19 vaccination can be a clinical conundrum for clinicians.

SARS-CoV-2 infections in mRNA vaccinated individuals are biased for viruses encoding spike E484K and associated with reduced infectious virus loads that correlate with respiratory antiviral IgG levels. INTRODUCTION: COVID-19 large scale immunization in the US has been associated with breakthrough positive molecular testing. In this study, we investigated whether a positive test is associated with a high anti-viral IgG, specific viral variant, recovery of infectious virus, or symptomatic infection during an early phase after vaccination rollout. METHODS: We identified 133 SARS-CoV-2 positive patients who had received two doses of either Pfizer-BioNTech (BNT162b2) or Moderna (mRNA-1273) vaccines, the 2nd of which was received between January and April of 2021. The positive samples

were collected between January and May of 2021. Samples were sequenced to characterize the whole genome and Spike protein changes and cycle thresholds that reflect viral loads were determined using a single molecular assay. Respiratory SARS-CoV-2 IgG antibodies were examined using ELISA and specimens were grown on cell culture to assess the recovery of infectious virus as compared to a control unvaccinated cohort. RESULTS: Of 133 specimens, 24 failed sequencing and yielded a negative or very low viral load on the repeat PCR. Of 109 specimens that were used for further genome analysis, 68 (62.4%) were from symptomatic infections, 11 (10.1%) were admitted for COVID-19, and 2 (1.8%) required ICU admission with no associated mortality. The predominant virus variant was the Alpha (B.1.1.7), however a significant association between lineage B.1.526 and amino acid change S: E484K with positives after vaccination was noted. A significant reduction of the recovery of infectious virus on cell culture was accompanied by an increase in localized IgG levels in respiratory samples of vaccinated individuals. CONCLUSIONS: Vaccination reduces the recovery of infectious virus in breakthrough infections caused primarily by the Alpha variant accompanied by an increase in upper respiratory tract IgG levels.

SARS-CoV2 antibody response after a third dose of heterologous ChAdOx1 nCoV-19 and Moderna vaccine in chronic dialysis patients.

Varicella-Zoster Virus (VZV) Meningitis in an Immunocompetent Adult after BNT162b2 mRNA COVID-19 Vaccination: A Case Report. We present, to our knowledge, the second case report of a 46-year old female who developed varicella-zoster virus (VZV) meningitis after BNT162b2 mRNA COVID-19 vaccination. The patient is immunocompetent and has no known predisposing risk factors for developing VZV meningitis. The patient received acyclovir therapy and subsequently had a complete recovery. We describe possible mechanisms of VZV meningitis after mRNA COVID-19 vaccination.

COV-BT Ire study: safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine in patients with brain tumors. BACKGROUND: The BNT162b2 vaccine conferred 95% protection against COVID-19 in people aged 16Â years or older. OBJECTIVE: The aim of this observational study was to evaluate safety and efficacy of vaccine in patients affected by primary brain tumor (PBT). METHODS: We proposed COVID-19 vaccine to all patients affected by PBT followed by Neuroncology Unit of National Cancer Institute Regina Elena. RESULTS: 102 patients received the first dose, 100 the second, and 73 patients received the booster dose. After first dose, we observed one patient with fever and severe fatigue, while after the second one, we recorded adverse events in ten patients. No correlation was observed between adverse events and comorbidities. CONCLUSIONS: The COVID-19 vaccine is safe and well tolerated in PBT patients.

Safety and immunogenicity of an inactivated virus particle vaccine for SARS-CoV-2, BIV1-CovIran: findings from double-blind, randomised, placebo-controlled, phase I and II clinical trials among healthy adults. OBJECTIVE: Assessing safety and immunogenicity of an inactivated whole virus particle vaccine. DESIGN: Single-centre, double-blind, randomised, placebo-controlled, phase I (stage I: 18-50, stage II: 51-75 years), phase II (18-75 years) clinical trials. SETTING: 29 December 2020 to 22 April 2021. PARTICIPANTS: Stage I-phase I: 56 participants; stage II-phase I: 32; phase II: 280. INTERVENTION: During stage I, participants randomly (3:3:1) received 3 Âµg, 5 Âµg vaccine or placebo in a 14-day interval. Participants in stage II received two shots of 5 Âµg vaccine or placebo (3:1). In phase II, participants received 5 Âµg vaccine or placebo (4:1) in a 28-day interval. PRIMARY AND SECONDARY OUTCOME MEASURES: Safety assessment and immunogenicity assessment via antibody response and conventional virus neutralisation test (cVNT). RESULTS: All adverse events (AEs) were mild or moderate and transient in both phase I and phase II, and no AEs of special interest were reported. The seroconversion-rate of neutralising, antireceptor binding-domain (RBD) and anti-spike-glycoprotein (anti-S) antibodies 14-days after second dose of 5 Âµg vaccine in stage I was 70.8% (95% CI 48.9% to 87.4%), 87.5% (95% CI 67.6% to 97.3%), 91.7% (95% CI 73.0% to 99.0%). The antibody

titres increased more among 5 Âµg than 3 Âµg. The corresponding rates for 3 Âµg vaccine were 45.8% (95% CI 25.6% to 67.2%), 54.2% (95% CI 32.8% to 74.5%) and 70.8% (95% CI 48.9% to 87.4%), respectively. In stage II, 100% (95% CI 84.6% to 100%), 86.4% (95% CI 65.1% to 97.1%) and 86.4% (95% CI 65.1% to 97.1%) of participants seroconverted for neutralising, anti-RBD and anti-S antibodies. In phase II, the seroconversion rate of neutralising-antibody was 82.8% (95% CI 77.0% to 87.6%), anti-RBD 77.0% (95% CI 70.7% to 82.6%) and anti-S 79.9% (95% CI 73.8% to 85.1%) on day 42. In the cVNT, the sera at 1/64 times dilution would neutralise SARS-CoV-2 among 91.7%, 77.3% and 82.5% of vaccinated participants in phase I-stage I, phase I-stage II and phase II clinical trials, respectively. CONCLUSIONS: These results support further evaluation of this inactivated whole virus particle vaccine. TRIAL REGISTRATION NUMBERS: IRCT20201202049567N1 and IRCT20201202049567N2 for phase I and IRCT20201202049567N3 for phase II.

Impact of immunotherapies on COVID-19 outcomes in multiple sclerosis patients. INTRODUCTION: SARS-CoV-2 pandemic has led the scientific community to maximize efforts to prevent infections and disease severity in patients with multiple sclerosis (pwMS). We analyze the impact of immunotherapies on COVID-19 outcomes in pwMS, providing our interpretation of data. AREAS COVERED: Infections, hospitalizations, intensive care unit admissions, and death rates in COVID-19 pwMS are comparable to the general population. Severity of disability, MS clinical phenotype, age, and comorbidities, along with the use of intravenous methylprednisolone and anti-CD20 treatments, are risk factors for COVID-19 severity. Disease-modifying treatments (DMTs) can be safely started and continued during the pandemic. Benefit-risk evaluation is mandatory when managing second-line therapies to balance risk of worse COVID-19 outcomes and MS reactivation. COVID-19 vaccination is safe in MS, and its efficacy could be reduced in fingolimod- and ocrelizumab-treated patients. EXPERT OPINION: The rate of (re)-infection and outcomes with SARS-CoV-2 variants in pwMS and antiviral properties of DMTs need to be further explored. Data on COVID-19 in pregnant MS women, children, and elderly pwMS are limited. Evidence on long-term effects of infection is needed. Impact of emerging DMTs on COVID-19 should be investigated. More data and longer follow-up are needed to characterize long-term efficacy and safety profile of vaccinations in pwMS.

Are SARS-CoV-2 Antibodies Detectable in Human Milk After Vaccination Against COVID-19? BACKGROUND: Human milk (HM) permits transfer of immunity against infections to infants via bioactive factors. The role of anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibodies in HM is poorly understood [1, 2]. This study evaluated SARS-CoV-2 antibodies in the HM of vaccinated healthcare workers (HCW). METHODS AND RESULTS: This prospective study of 122 HCWs was performed from February to April 2021 at the Hospital Universitario Nuestra SeÃ±ora de Candelaria. Immunoglobulin G (IgG) against nucleocapsid protein and IgG, immunoglobulin M (IgM), and immunoglobulin A (IgA) antibodies against spike 1 protein receptor-binding domain against SARS-CoV-2 (anti-SARS-CoV-2 RBD-S1) were analyzed. Unvaccinated breastfeeding mothers without COVID-19 were the control group.The 98 vaccinated participants underwent serum and HM evaluation 14 days after receiving 2 doses of either BNT162b2 mRNA (94%) or mRNA-1273 (6%) coronavirus disease 2019 (COVID-19) vaccines. The mean SARS-CoV-2 RBD-S1 IgG serum concentration was 3379.64 binding antibody units (BAUs)/mL with neutralizing antibody titers >560.9 BAUs/mL. Serum SARS-CoV-2 antibodies in the 24 unvaccinated participants were negative. The HM from vaccinated participants had anti-SARS-CoV-2 RBD-S1 IgG with a mean of 12.19 BAUs/mL compared to 0.02 BAUs/mL (P < .001) in HM from unvaccinated participants. Anti-SARS-CoV-2 S1 IgA was noted in 89% of HM from vaccinated women; no anti-SARS-CoV-2 S1 IgM was detected.A positive correlation was reported between anti-SARS-CoV-2 RBD-S1 IgG in serum and HM (r = 0.36; P < .001). This association was stronger if breastfeeding had been <24 months (r = 0.67; P < .001) vs â‰¥24 months (r = 0.32; P = 0.19). In subgroup analysis, breastfeeding for >24 months and high serum anti-SARS-CoV-2 RBD-S1

IgG levels predicted high HM IgG levels. This was an independent association in both linear and multiple regression models. Compared with breastfeeding <24 months, lactation >24 months was associated with increased HM anti-SARS-CoV-2 RBD-S1 levels. COMMENTS: This study in breastfeeding HCWs showed that the HM antibody levels were higher in women who had been breastfeeding for >24 months prior to receiving 2 doses of COVID-19 vaccine compared to participants who had been breastfeeding <24 months. Limitations include lack of in vitro plaque reduction neutralization tests which is the gold standard for evaluating SARS-CoV-2 antibody deactivation effectiveness. The study was conducted at a single site and did not assess infant serology or clinical outcome.According to the authors, breastfeeding by vaccinated women during a pandemic when young children are ineligible for vaccination may be encouraged. These results support findings from other studies of vaccines, such as influenza, in which the HM of vaccinated women may confer protection to their infants [3]. The benefits of maternal immunization, including the duration of protection afforded by HM from maternal recipients of mRNA COVID-19 vaccines, are research areas deserving of additional exploration. Additionally, further understanding of the association of the duration of receipt of HM from vaccinated women on infant immune responses would be beneficial in understanding the potential for passive protection through nutrition.

Applying lessons learned from nanomedicines to understand rare hypersensitivity reactions to mRNA-based SARS-CoV-2 vaccines. After over a billion of vaccinations with messenger RNA-lipid nanoparticle (mRNA-LNP) based SARS-CoV-2 vaccines, anaphylaxis and other manifestations of hypersensitivity can be considered as very rare adverse events. Although current recommendations include avoiding a second dose in those with first-dose anaphylaxis, the underlying mechanisms are unknown; therefore, the risk of a future reaction cannot be predicted. Given how important new mRNA constructs will be to address the emergence of new viral variants and viruses, there is an urgent need for clinical approaches that would allow a safe repeated immunization of high-risk individuals and for reliable predictive tools of adverse reactions to mRNA vaccines. In many aspects, anaphylaxis symptoms experienced by the affected vaccine recipients resemble those of infusion reactions to nanomedicines. Here we share lessons learned over a decade of nanomedicine research and discuss the current knowledge about several factors that individually or collectively contribute to infusion reactions to nanomedicines. We aim to use this knowledge to inform the SARS-CoV-2 lipid-nanoparticle-based mRNA vaccine field.

Seroprevalence of SARS-CoV-2 spike IgG antibodies after the second BNT162b2 mRNA vaccine in Japanese kidney transplant recipients. We aimed to evaluate the seroprevalence and investigated factors associated with seropositivity after the second SARS-CoV-2 mRNA vaccination in kidney transplant (KT) recipients. This retrospective study conducted between June and November 2021 included 106 KT recipients and 127 healthy controls who received the second dose of the BNT162b2 mRNA vaccine at least 7 days before the measurement of antibody titers. The antibody titer against the receptor-binding domain of SARS-CoV-2 spike (S) protein was determined. We compared seroprevalence rates (immunoglobulin G [IgG] level ofâ€‰â‰¥â€‰0.8 orâ€‰â‰¥â€‰15 U/mL) between the healthy controls and KT recipients and identified factors associated with impaired humoral response. The seroprevalence rate of the healthy controls and KT recipients was 98% and 22%, respectively. Univariate logistic regression analysis revealed that ageâ€‰>â€‰53Â years, rituximab use, mycophenolate mofetil use, and KT vintageâ€‰<â€‰7Â years were negatively associated with the rate of anti-SARS-CoV-2 S IgGâ€‰â‰¥â€‰15 U/mL in KT recipients. ABO blood type incompatible KT was not significantly associated with seroprevalence. Humoral response after the second BNT162b2 mRNA vaccine was greatly hindered by immunosuppression therapy in KT recipients. Older age, rituximab use, mycophenolate mofetil use, and KT vintage may play key roles in seroconversion.

Microvascular manifestations revealing vaccine-induced thrombotic thrombocytopenia after COVID-19 vaccination.
IgA nephropathy relapse following COVID-19 vaccination treated with corticosteroid therapy: case report. BACKGROUND: The flare of immune-mediated disease following coronavirus disease of 2019 (COVID-19) vaccination is a rare adverse event following immunization. De novo, as well as relapsing IgA nephropathy (IgAN) cases, have been reported following either mRNA-1273 (Moderna) or BNT162b2 (Pfizer-BioNTech) vaccination. To our knowledge, the majority of IgAN relapses did not result in severe acute kidney injury (AKI) and resolved spontaneously. CASE PRESENTATION: This is a case of a 54-year-old female with a previous diagnosis of IgAN who developed IgAN relapse following the second dose of Moderna vaccine. Gross hematuria developed 2Â days after vaccination, which was accompanied by significant AKI. Kidney biopsy showed mild tubular atrophy and IgA staining in mesangium without crescent formation. Significant improvement in serum creatinine (Cr) was observed on day 10 after initiating prednisone. Cr came back to normal within 3Â months after initiating corticosteroid. CONCLUSION: COVID-19 vaccination is associated with a flare of IgAN that may cause significant AKI. Steroid therapy is associated with recovery. IgAN flare after COVID-19 vaccination should be closely monitored to elucidate any adverse effect associated with the novel vaccine.
Vaccination Against SARS-CoV-2 Is Associated With a Lower Viral Load and Likelihood of Systemic Symptoms. BACKGROUND: Data conflict on whether vaccination decreases severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral load. The objective of this analysis was to compare baseline viral load and symptoms between vaccinated and unvaccinated adults enrolled in a randomized trial of outpatient coronavirus disease 2019 (COVID-19) treatment. METHODS: Baseline data from the first 433 sequential participants enrolling into the COVID-OUT trial were analyzed. Adults aged 30-85 with a body mass index (BMI)Â â‰¥25Â kg/m(2) were eligible within 3 days of a positive SARS-CoV-2 test and <7 days of symptoms. Log(10) polymerase chain reaction viral loads were normalized to human RNase P by vaccination status, by time from vaccination, and by symptoms. RESULTS: Two hundred seventy-four participants with known vaccination status contributed optional nasal swabs for viral load measurement: median age, 46 years; median (interquartile range) BMI 31.2 (27.4-36.4) kg/m(2). Overall, 159 (58%) were women, and 217 (80%) were White. The mean relative log(10) viral load for those vaccinated <6 months from the date of enrollment was 0.11 (95% CI, -0.48 to 0.71), which was significantly lower than the unvaccinated group (Pâ€…=â€….01). Those vaccinated â‰¥6 months before enrollment did not differ from the unvaccinated with respect to viral load (mean, 0.99; 95% CI, -0.41 to 2.40; Pâ€…=â€….85). The vaccinated group had fewer moderate/severe symptoms of subjective fever, chills, myalgias, nausea, and diarrhea (all Pâ€…<â€….05). CONCLUSIONS: These data suggest that vaccination within 6 months of infection is associated with a lower viral load, and vaccination was associated with a lower likelihood of having systemic symptoms.
Branch Retinal Artery Occlusions, Paracentral Acute Middle Maculopathy and Acute Macular Neuroretinopathy After COVID-19 Vaccinations. PURPOSE: Potential retinal adverse events after COVID-19 vaccinations reported previously include paracentral acute middle maculopathy (PAMM), acute macular neuroretinopathy (AMN), and central serous chorioretinopathy. We report four cases of branch retinal artery occlusion (BRAO), one case of PAMM, and one case of AMN that occurred after administration of the Pfizer-BioNTech COVID-19 vaccine. PATIENTS AND METHODS: We retrospectively reviewed the medical records of six patients who presented to Yame General Hospital or Oita University Hospital from July through October 2021. RESULTS: Four patients (2 males) presented with visual field defects associated with BRAO, one male patient with PAMM, and one female patient with AMN after receiving the Pfizer-BioNTech COVID-19 vaccine. The mean age was

59.3 years; the mean best-corrected visual acuity was 20/21. The mean time from the last vaccination to the onset of visual field defect was 22.8 days. Five patients had received two doses of the vaccine and one patient one dose. Patients' medical history included diabetes mellitus in case 2, hypertension in cases 2, 3 and 6, and Alport syndrome and end-stage renal disease in case 6 for which the patient was undergoing regular hemodialysis. CONCLUSION: Although rare, retinal adverse events may occur after COVID-19 vaccinations. Further studies with a larger sample size should determine whether these retinal abnormalities are causally associated with COVID-19 vaccinations or just coincidental. Potential risks of BRAO/PAMM/AMN after COVID-19 vaccinations must be carefully weighed against the substantial benefit of COVID-19 vaccinations.

Acute ischemic stroke after first dose of inactivated COVID-19 vaccine: A case report. The acute cerebral ischemia induced by the COVID-19 vaccine is one of the side effects. We report the first case of a patient who suffered from a neurological deficit mimicking a stroke after receiving his 1st dose of the inactivated COVID-19 vaccine BIBP (Sinopharm) and who mainly developed cerebral venous thrombosis. Our reported case is a 36-year-old man who was admitted to our intensive care unit 2 days after his first injection dose of the inactivated COVID-19 vaccine BIBP (Sinopharm). He presented a numbness in his left arm and legs with headaches 24 hours after the vaccine injection. In the second day, he had asymmetry of the face which was aggravated by the installation of disturbance of consciousness and a state of agitation. His vital signs were normal. A brain CT scan without injection was done showing a right deep parietal ischemic stroke. The treatment was initiated by aspirin. cerebral MRI showed a very extensive stroke ischemic in the superficial and deep right parietal territory with the onset of hemorrhagic rearrangement of the right basal ganglia, magnetic resonance imaging angiography of the supra-aortic trunks was normal. The patient gradually improved and was discharged after 15 days of his stay in the intensive care unit. The installation of ischemic stroke reported in our young patient after receiving his first dose of inactivated COVID-19 vaccine BIBP; could be a new immune response to the vaccine.

First report of post-transplant autoimmune hepatitis recurrence following SARS-CoV-2 mRNA vaccination. Whilst vaccination for the SARS-CoV-2 virus has been successful in reducing the severity and burden of the COVID-19 pandemic, there have been recent reports of mRNA vaccines triggering autoimmune hepatitis in the native liver. There have been no descriptions thus far of recurrent 'autoimmune hepatitis' after liver transplantation in the context of SARS-CoV-2 vaccination. We describe a patient transplanted for autoimmune hepatitis who was stable for many years until they had immune-mediated flares coinciding with Pfizer-BioNTech mRNA vaccination. Intravenous steroid treatment was required to suppress histologically evident interface hepatitis. We firmly believe that mRNA vaccination was responsible for this 'recurrence' and that clinicians should be vigilant for this reaction in patients transplanted for autoimmune hepatitis.

CHARM: COVID-19 Health Action Response for Marines-Association of antigen-specific interferon-gamma and IL2 responses with asymptomatic and symptomatic infections after a positive qPCR SARS-CoV-2 test. SARS-CoV-2 T cell responses are associated with COVID-19 recovery, and Class I- and Class II-restricted epitopes have been identified in the spike (S), nucleocapsid (N) and membrane (M) proteins and others. This prospective COVID-19 Health Action Response for Marines (CHARM) study enabled assessment of T cell responses against S, N and M proteins in symptomatic and asymptomatic SARS-CoV-2 infected participants. At enrollment all participants were negative by qPCR; follow-up occurred biweekly and bimonthly for the next 6 weeks. Study participants who tested positive by qPCR SARS-CoV-2 test were enrolled in an immune response sub-study. FluoroSpot interferon-gamma (IFN-Î³) and IL2 responses following qPCR-confirmed infection at enrollment (day 0), day 7 and 14 and more than 28 days later were measured using pools of 17mer peptides covering S, N, and M proteins, or CD4+CD8 peptide pools containing predicted epitopes from multiple SARS-

CoV-2 antigens. Among 124 asymptomatic and 105 symptomatic participants, SARS-CoV-2 infection generated IFN-Î³ responses to the S, N and M proteins that persisted longer in asymptomatic cases. IFN-Î³ responses were significantly (p = 0.001) more frequent to the N pool (51.4%) than the M pool (18.9%) among asymptomatic but not symptomatic subjects. Asymptomatic IFN-Î³ responders to the CD4+CD8 pool responded more frequently to the S pool (55.6%) and N pool (57.1%), than the M pool (7.1%), but not symptomatic participants. The frequencies of IFN-Î³ responses to the S and N+M pools peaked 7 days after the positive qPCR test among asymptomatic (S pool: 22.2%; N+M pool: 28.7%) and symptomatic (S pool: 15.3%; N+M pool 21.9%) participants and dropped by >28 days. Magnitudes of post-infection IFN-Î³ and IL2 responses to the N+M pool were significantly correlated with IFN-Î³ and IL2 responses to the N and M pools. These data further support the central role of Th1-biased cell mediated immunity IFN-Î³ and IL2 responses, particularly to the N protein, in controlling COVID-19 symptoms, and justify T cell-based COVID-19 vaccines that include the N and S proteins.

Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination - PCORnet, United States, January 2021-January 2022. Cardiac complications, particularly myocarditis and pericarditis, have been associated with SARS-CoV-2 (the virus that causes COVID-19) infection (1-3) and mRNA COVID-19 vaccination (2-5). Multisystem inflammatory syndrome (MIS) is a rare but serious complication of SARS-CoV-2 infection with frequent cardiac involvement (6). Using electronic health record (EHR) data from 40 U.S. health care systems during January 1, 2021-January 31, 2022, investigators calculated incidences of cardiac outcomes (myocarditis; myocarditis or pericarditis; and myocarditis, pericarditis, or MIS) among persons aged â‰¥5 years who had SARS-CoV-2 infection, stratified by sex (male or female) and age group (5-11, 12-17, 18-29, and â‰¥30 years). Incidences of myocarditis and myocarditis or pericarditis were calculated after first, second, unspecified, or any (first, second, or unspecified) dose of mRNA COVID-19 (BNT162b2 [Pfizer-BioNTech] or mRNA-1273 [Moderna]) vaccines, stratified by sex and age group. Risk ratios (RR) were calculated to compare risk for cardiac outcomes after SARS-CoV-2 infection to that after mRNA COVID-19 vaccination. The incidence of cardiac outcomes after mRNA COVID-19 vaccination was highest for males aged 12-17 years after the second vaccine dose; however, within this demographic group, the risk for cardiac outcomes was 1.8-5.6 times as high after SARS-CoV-2 infection than after the second vaccine dose. The risk for cardiac outcomes was likewise significantly higher after SARS-CoV-2 infection than after first, second, or unspecified dose of mRNA COVID-19 vaccination for all other groups by sex and age (RR 2.2-115.2). These findings support continued use of mRNA COVID-19 vaccines among all eligible persons aged â‰¥5 years.

Delayed-onset Anaphylaxis After mRNA-Based COVID-19 Vaccination in an Adolescent Male.

Disseminated and localised herpes zoster following Oxford-AstraZeneca COVID-19 vaccination.

Erythema multiforme after the third dose of mRNA-1273.

Reply to "New-onset bullous pemphigoid after inactivated Covid-19 vaccine: Synergistic effect of the Covid-19 vaccine and vildagliptin".

Vaccine-induced thrombosis and thrombocytopaenia with widespread abdominal venous thrombosis, venous ischaemia and bowel oedema. A 49-year-old woman presented with severe abdominal pain and per rectal bleed, 13 days after receiving the first dose of the AstraZeneca vaccine. Blood tests showed remarkably low platelet count, unmeasurable D-dimer levels and low fibrinogen levels, consistent with a diagnosis of vaccine-induced thrombotic thrombocytopaenia and disseminated intravascular coagulation. CT mesenteric angiogram revealed massive portosplenic mesenteric vein thrombosis. CT head also noted non-occlusive thrombosis at several sites. She was treated with intravenous immunoglobulins, plasma exchange, anticoagulants and transjugular intrahepatic portosystemic shunt procedure. Following a prolonged inpatient stay, she was discharged with

subsequent short bowel syndrome and long-term parenteral nutrition. This particular clinical scenario aims to highlight the importance for clinicians to remain vigilant for rare complications associated with the AstraZeneca vaccine and the subsequent management involved, at a time where it is vital to vaccinate globally in order to control the spread of the COVID-19 pandemic.

Association of Human Leukocyte Antigen Genotypes with Severe Acute Respiratory Syndrome Coronavirus 2 Vaccine-Induced Subacute Thyroiditis. Background: Despite mass vaccination, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine-induced subacute thyroiditis (SAT) is rarely seen as a complication. The reason why some individuals are susceptible to developing vaccine-induced SAT is not known. SAT develops in genetically predisposed individuals who carry specific human leukocyte antigen (HLA) haplotypes. It is unknown whether specific HLA alleles are associated with SARS-CoV-2 vaccine-induced SAT. Objective: This study compared the HLA profiles of patients with SARS-CoV-2 vaccine-induced SAT to controls, to assess whether there is an association between specific HLA genotypes and development of SAT. The relationship between HLA genotypes and the clinical course of SARS-CoV-2 vaccine-induced SAT was also evaluated. Methods: A case-control study was conducted in a Turkish tertiary care center. Fourteen patients with SARS-CoV-2 vaccine-induced SAT and 100 healthy controls were included. HLA-A, HLA-B, HLA-C, HLA-DQB1, and HLA-DRB1 frequencies were analyzed by next-generation sequencing. Results: The frequencies of HLA-B*35 and HLA-C*04 alleles were significantly higher in SARS-CoV-2 vaccine-induced SAT cohort when compared with controls (HLA-B*35: 13 [93%] vs. 40 [40%], pâ€‰<â€‰0.001; HLA-C*04: 13 [93%] vs. 43 [43%], pâ€‰<â€‰0.001, respectively). More severe thyrotoxicosis was seen in patients having HLA-B*35 and HLA-C*04 homozygous alleles (free thyroxine: 4.47â€‰ng/dL [3.77-5.18] vs. 1.41â€‰ng/dL [1.22-2.63], pâ€‰=â€‰0.048). Inflammation tended to be more severe in homozygous patients (C-reactive protein: 28.2â€‰mg/dL [13.6-42.9] vs. 4.8 [1.2-10.5], pâ€‰=â€‰0.07). Conclusions: The frequencies of HLA-B*35 and HLA-C*04 alleles were higher in SARS-CoV-2 vaccine-induced SAT compared with controls. Homozygosity for HLA-B*35 and HLA-C*04 was associated with thyrotoxicosis and a greater inflammatory reaction. Our findings should be confirmed in studies of other populations.

Description of Symptoms Caused by the Infection of the SARS-CoV-2 B.1.621 (Mu) Variant in Patients With Complete CoronaVac Vaccination Scheme: First Case Report From Santiago of Chile. Vaccine administration is one of the most efficient ways to control the current coronavirus disease 2019 (COVID-19) pandemic. However, the appearance of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants can avoid the immunity generated by vaccines. Thus, in patients with a complete vaccine schedule, the infection by SARS-CoV-2 may cause severe, mild, and asymptomatic manifestations of the disease. In this case report, we describe for the first time the clinical symptoms of four patients (three symptomatic; one asymptomatic) from Santiago of Chile, with a complete vaccination schedule with two doses of CoronaVac (Sinovac Life Science) infected with the variant of interest (VOI) B.1.621 (Mu). They were compared with four unvaccinated patients, who had a higher prevalence of symptoms after infection compared to vaccinated patients. In the CoronaVac-vaccinated group, an 80-year-old patient who registered various comorbidities required Invasive mechanical ventilation for 28 days with current home medical recovery discharge. By contrast, in the unvaccinated group, a 71-year-old presented more symptoms with more than 45 days of Invasive mechanical ventilation, which continues to date, presenting greater lung damage than the vaccinated hospitalized patient. This first report evidence differences in the clinical symptomatology of patients vaccinated and non-vaccinated infected with the VOI B.1.621 (Mu) and suggest the protective effects of CoronaVac against this variant.

A Case of Acute Pericarditis After COVID-19 Vaccination. A two-dose regimen of Pfizer-BioNTech COVID-19 vaccination confers 95% protection against COronaVIrus Disease 19 (COVID-19) and the

safety profile is adequate. To the submission date, there were no reports in literature of acute pericarditis after BNT162b2 vaccination. However, pericarditis has been reported as a rare event associated with COVID-19 infection, which could be due to the pro-inflammatory effects of the spike protein. Recent evidence of post-vaccine myocarditis has been published. Herein we describe the case of a middle-aged healthy women who developed symptoms and signs of acute pericarditis 7-10 days after the second dose of Pfizer-BioNTech COVID-19 vaccination. Although a direct effect cannot be stated, it is important to report a potential adverse vaccine reaction effect that could be associated with the expression of SARS-CoV-2 spike protein induced from the mRNA of the vaccine.

SARS-COV-2 Infection, Vaccination, and Immune-Mediated Diseases: Results of a Single-Center Retrospective Study. OBJECTIVES: The relationship between infections or vaccine antigens and exacerbations or new onset of immune-mediated diseases (IMDs) has long been known. In this observational study, conducted during the COVID-19 pandemic, we evaluated the onset of clinical and laboratory immune manifestations related to COVID-19 or SARS-CoV-2 vaccination. METHODS: Four groups of patients were evaluated: A) 584 COVID-19 inpatients hospitalized from March 2020 to June 2020 and from November 2020 to May 2021; B) 135 outpatients with previous SARS-CoV-2 infection, assessed within 6 months of recovery; C) outpatients with IMDs in remission and flared after SARS-COV-2 infection; D) outpatients with symptoms of probable immune-mediated origin after SARS-CoV-2 vaccination. RESULTS: In cohort A we observed n. 28 (4.8%) arthralgia/myalgia, n. 2 (0.3%) arthritis, n. 3 (0.5%) pericarditis, n. 1 (0.2%) myocarditis, n. 11 (1.9%) thrombocytopenia or pancytopenia, and in the follow up cohort B we identified 9 (6.7%) cases of newly diagnosed IMDs after the recovery from COVID-19. In all cases, serological alterations were not observed.In cohort C we observed n.5 flares of pre-existing IMD after SARS-COV2 infection, and in the cohort D n. 13 IMD temporally close with SARS-CoV-2 vaccination in 8 healthy subjects (with clinical classifiable IMD-like presentation) and in 5 patients affected by an anamnestic IMD. Also in these latter cases, except in 2 healthy subjects, there were not found serological alterations specific of a classifiable IMD. CONCLUSIONS: This study suggests that the interplay between SARS-CoV-2 and the host may induce complex immune-mediated reactions, probably induced by the anti-spike antibodies, in healthy people and IMD patients without specific serological autoimmunity. Moreover, our data suggest that the anti-SARS-CoV-2 antibodies generated by the vaccination may cause in healthy subjects' clinical manifestations similar to well-definite IMDs. These findings support theÂ hypothesis that SARS-Cov2 infection in COVID-19 induce an innate and adaptive immune response that may be both responsible of the symptoms correlated with the occurrence of the IMDs described in our study. And, in this context, the IMDs observed in healthy people in close temporal correlation with the vaccination suggest that the anti-Spike antibodies may play a key role in the induction of an abnormal and deregulated immune response.

COVID-19 vaccine-associated organizing pneumonia. We report the first case of organizing pneumonia (OP) associated with a new coronavirus disease (COVID-19) vaccination. A 78-year-old woman developed cough and dyspnoea 10â€‰days after receiving BNT162b2. Chest computed tomography (CT) revealed consolidation in the bilateral lower lobes of the lungs. Although antibiotic treatment did not improve her symptoms, she received a second vaccination as scheduled. She was referred to our hospital because of worsening dyspnoea on day 9 after the second vaccination, with reversed halo signs in the bilateral lower pulmonary lobes and new consolidation in the left lingual region on chest CT on day 15. She was diagnosed with OP based on bronchoalveolar lavage and transbronchial lung biopsy findings. Treatment with oral prednisolone 0.5Â mg/kg/day immediately improved the symptoms and chest imaging findings. In the absence of other triggering factors, we considered this case as being COVID-19 vaccine-associated following the first and second vaccinations.

Lichen Planus Eruption Following Oxford-AstraZeneca COVID-19 Vaccine Administration: A Case Report and Review of Literature. Lichen planus is an autoimmune inflammatory disease that can be associated with infections, drugs, and vaccines. Recently, it has been reported to occur following mRNA-based COVID-19 vaccines, particularly the Pfizer/BioNTech vaccine. We present the first reported case of lichen planus that developed after five days following the administration of the first dose of the Oxford-AstraZeneca vaccine in a 46-year-old healthy male. The skin eruption was purple, ill-defined, non-scaly, itchy, and distributed over his face, abdomen, back, and legs. The clinical appearance of the skin eruption and histopathology confirmed the diagnosis of lichen planus. The skin lesions were not responding well to topical steroid and oral antihistamine treatment. Thus, the patient was commenced on systemic hydroxychloroquine. The mechanism of lichen planus development following the administration of COVID-19 vaccines is unclear and needs more investigations and explanations. Healthcare providers should be aware of this possible adverse reaction following the administration of different severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines. The histopathological features of lichen planus in our case are different from those found in the lichenoid drug eruption. This finding indicates different pathophysiology that needs further investigation.
Small fiber neuropathy underlying dysautonomia in COVID-19 and in post-SARS-CoV-2 vaccination and long-COVID syndromes.
[Sudden hearing loss after COVID-19 vaccination].
[COVID-19 vaccine safety]. The development and production of safe and effective vaccines against coronavirus disease 2019 (COVID-19) provides hope for controlling the current pandemic. Adverse events following immunization are unwanted responses or unintended events that must be carefully monitored, as all vaccines, including those developed against SARS-CoV-2, are required to meet safety criteria for administration in humans. Information was collected from the PubMed/Medline database during the months of August 2020 to November 2021. Most adverse events reported in clinical trials were mild or moderate; however, thrombotic events associated with some viral vector-based vaccines against COVID-19 were identified in follow-up studies, although completion of the various ongoing studies and post-marketing surveillance is required to determine all potential adverse events, as well as those of special interest.
Diagnose Aseptic Meningitis Caused by SARS-CoV-2 Vaccination Only After Ruling Out All Possible Differentials.
Reply: Diagnose Aseptic Meningitis Caused by SARS-CoV-2 Vaccination Only After Ruling Out All Possible Differentials.
Anti-SARS-CoV-2 Neutralizing Antibody Responses after Two Doses of ChAdOx1 nCoV-19 vaccine (AZD1222) in Healthcare Workers. BACKGROUND: The kinetics of neutralizing antibodies against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) play an important role in evaluating vaccine efficacy and durability, herd immunity, additional vaccination, and prediction models of immune protection against coronavirus disease 2019. MATERIALS AND METHODS: Serum collection times were 4 and 8 weeks after 1st inoculation of AZD1222 (AstraZeneca, Cambridge, UK), and 2 and 16 weeks after 2nd inoculation with 12-week dosing intervals. Neutralizing antibody (Nab) titers were measured indirectly using commercially available R-FIND SARS-CoV-2 Neutralizing Antibody ELISA Kit (SG Medical Inc., Seoul, Korea). Possible influences of gender, age, and adverse events on neutralizing antibody titer were also investigated. RESULTS: Nab titers (median inhibition %) started to decrease shortly after reaching peaks. This decrease was more pronounced in the elderly group (â‰¥56 years) than in the young group (â‰¤39 years) at 8 weeks (49.5% vs. 55.4%, P = 0.021) and 16 weeks (40.6% vs. 53.9%, P = 0.006) after the 1st and 2nd inoculation. And Nab titers were inversely correlated with age in the 8-week (r = -0.2091, P = 0.0284) and the 28-week group (r = -0.2811, P = 0.0029).

Seropositive conversion of Nab reached 89.1% and 100% following 1st and 2nd inoculation. This 100% seropositivity was dropped sharply to 74.5% after 16 weeks. Compared to subjects without adverse events (51.8%), median inhibition was higher in subjects with one or more systemic adverse events (74.2%, P = 0.0203) or those with one or more local and systemic adverse events (77.1%, P = 0.0003). CONCLUSION: Nab induced by AZD1222 (AstraZeneca, UK) vaccination started to degrade shortly after the production period. Nab titers were lower in the elderly than in younger group during the degradation period. This seems to be because the degradation process of Nab is more pronounced in the elderly. This may explain why the frequency of breakthrough infections, disease severity, and mortality were higher in the elderly and may require revaccination to ensure robust immunity.
Hyaluronic acid delayed inflammatory reaction after third dose of SARS-CoV-2 vaccine. BACKGROUND: Treatments based on hyaluronic acid represent one of the most largely used practice of esthetic medicine. In the literature, it has already been described delayed reaction after vaccine like flu vaccine mediated by T-lymphocytes. AIM: We report three cases of dermal filler reactions following mRNA vaccination against SARS-CoV-2; all the patients had received the filler months or even years before the vaccine. PATIENTS: Patient one: A 60-year-old female patient that was treated one year ago in the lip developed swelling days after getting mRNA Pfizer Biotech vaccine. She received her booster of Pfizer vaccination one week before. Patient two: A 45-year-old female patient treated in the lip two years before developed angioedema days after getting her booster of Pfizer Biotech vaccine. In this case, it was necessary to prescribe cortisone per os. Patient three: A 40-year-old female patient treated for the nasolabial fold five months before developed erythema and edema after receiving the booster of Moderna Vaccine. RESULTS: As demonstrated in our three case reports, even the booster of vaccine can cause delayed inflammatory reactions in patients that have previously received fillers. CONCLUSION: Delayed inflammatory reactions in patients that have received filler in the past are uncommon and usually self-limited. Those are the first example reported in the literature of reaction after the booster dose without any previous symptoms.
COVID-19 vaccines and anaphylaxis-evaluation with skin prick testing, basophil activation test and Immunoglobulin E.
Ventricular tachycardia from myocarditis following COVID-19 vaccination: Correspondence.
Five Cases of Corneal Graft Rejection After Recent COVID-19 Vaccinations and a Review of the Literature. PURPOSE: The purpose of this study was to report 5 cases of acute corneal graft rejection after COVID-19 vaccination and perform a review of the literature. METHODS: This was a case series and review of literature dated on the October 10, 2021. RESULTS: We describe 5 cases-2 patients with Descemet stripping automated endothelial keratoplasty (for Fuchs endothelial dystrophy) who presented with acute corneal graft rejection after their first dose of mRNA (BNT162) vaccine. The other 3 patients who had penetrating keratoplasty performed more than 10 years ago for keratoconus presented with acute graft rejection-2 patients after their second dose of adenovirus vector (AZD1222) vaccine and 1 patient after first dose of mRNA (BNT162) vaccine. Three patients were not using any topical steroid treatment at the time of diagnosis of graft rejection. The mean duration between vaccination and onset of symptoms was 16.86 Â± 6.96 days for the mRNA vaccine and 17 Â± 11.89 days for the adenovirus vector vaccine. CONCLUSIONS: Corneal graft rejection has recently been reported after COVID-19 vaccination. Patients with keratoplasty need to be advised regarding the risk of corneal graft rejection and warning symptoms of rejection after COVID-19 vaccination. Seeking early referral to the emergency department and increasing topical steroids pre-COVID-19 and post-COVID-19 vaccination may reduce the risk of rejection.
Recurrence of Varicella-Zoster Virus Keratitis After SARS-CoV-2 Vaccination. PURPOSE: The purpose of this study was to report a case of acute exacerbation in varicella-zoster virus (VZV) keratitis after SARS-CoV-2 vaccination. METHODS: An 87-year-old man, with a history of herpes zoster

ophthalmicus 10 years ago, was referred for sudden visual impairment in his left eye that started 2 days after his second dose of SARS-CoV-2 mRNA vaccine BNT162b2. RESULTS: At presentation, his visual acuity was hand motion. Slitlamp examination revealed diffuse corneal stromal edema and nasal stromal infiltration. After treatment for 2 weeks with oral valacyclovir and topical corticosteroids, the problematic lesion was recovered and his visual acuity was restored to 20/30. CONCLUSIONS: We believe that this is the first report of possible association between recurrence of VZV keratitis and SARS-CoV-2 vaccination. We believe that T-cell activation by the host response after vaccination may affect the recurrence of VZV keratitis. Physicians should be aware of the potential of recurrence of VZV keratitis associated with the SARS-CoV-2 messenger RNA vaccine.

Safety of SARS-CoV-2 vaccination in patients with inflammatory bowel disease: A systematic review and meta-analysis. INTRODUCTION: Risk of adverse effects and flare of inflammatory bowel disease (IBD) are frequently cited reasons for COVID-19 vaccine hesitancy. METHODS: Electronic databases were searched to identify studies reporting the use of COVID-19 vaccine in IBD. We selected studies reporting the incidence of various adverse effects (local or systemic) and flares of IBD after COVID-19 vaccination. The pooled incidence rates for various adverse effects, stratified for the dose and the type of vaccine (adenoviral or mRNA) were estimated. RESULTS: Nine studies (16 vaccination cohorts) were included. The pooled incidence rate of overall adverse events was 0.55 (95%CI, 0.45-0.64, I(2)=Â 95%). The pooled incidence rate of local adverse events was 0.64 (0.47-0.78, I(2)=Â 100%). The pooled incidence rates of fatigue, headache, myalgia, fever and chills were 0.30 (0.21-0.40, I(2)=Â 99%), 0.23 (0.17-0.30, I(2)=Â 99%), 0.18 (0.13-0.24, I(2)=Â 99%), 0.10 (0.06-0.17, I(2)=Â 98%) and 0.15 (0.06-0.3, I(2)=Â 86%), respectively. The pooled incidence rates of severe adverse events, adverse events requiring hospitalization and flares of IBD following COVID-19 vaccination were 0.02 (0.00-0.12, I(2)=Â 97%), 0.00 (0.00-0.01, I(2)=Â 27%) and 0.01 (0.01-0.03, I(2)=Â 45%), respectively. CONCLUSION: COVID-19 vaccination in patients with IBD appears to be safe with only mild adverse events. Flares of IBD and severe adverse events requiring hospitalization were infrequent.

Factors associated with COVID-19 vaccine intent among Latino SNAP participants in Southern California. BACKGROUND: COVID-19 is significantly impacting the health and well-being of the country, particularly for ethnic minority populations and low-income groups. Our goal was to determine COVID-19 vaccination intent in a low-income, Latino population receiving aid from the Supplemental Nutrition Assistance Program (SNAP) in Southern California, and identify contributing factors and concerns. METHODS: A cross-sectional, mixed-methods survey was conducted among participants in the Southern California Nutrition Incentives Program (Â¡MÃ¡s Fresco! More Fresh). Only Latino respondents were included in this analysis. Primary outcome was vaccine intent trichotomized into: "definitely/likely yes", "not sure/don't know", and "definitely/likely not." RESULTS: The majority of participants (nâ€‰=â€‰486) were female (93%), Spanish speaking (74%), with a median age of 40â€‰years (IQRâ€‰=â€‰13). Approximately half (48%) reported they would get a COVID-19 vaccine, 39% were unsure, and 13% reported "definitely/likely not". In the multivariable multinomial logistic regression model, participants with a household member with a COVID-19 health risk factor were more likely to be unsure about getting the vaccine. Participants who were primarily English speaking, did not receive the influenza vaccine last season, and reported not reading or talking about COVID-19 were more likely to report not intending to receive the vaccine. Many respondents were concerned about "side effects and ingredients", and did not trust the vaccine development process, particularly with how fast it happened. CONCLUSION: Low-income Latinos in Southern California were generally hesitant to get a COVID-19 vaccine. Culturally sensitive vaccine promotion campaigns need to address the concerns of minority populations who experience increased morbidity and mortality from COVID-19.

Case Series of Three Neurological Side Effects in Younger-Aged Individuals After Pfizer's mRNA Vaccine. With the worldwide goal of ending the pandemic, mRNA vaccines have been introduced as a valuable tool to help achieve both herd immunity and protect the most vulnerable. Neurological side effects from such vaccines have been increasingly documented, but to date, they are still deemed rare with no caution advised per the Centers for Disease Control and Prevention (CDC). As more of the younger population (under 40) are getting vaccinated according to recent approval and CDC recommendations, the real-world safety reporting data on adverse events have yet had time to catch up. We present three distinct neurological events that occurred after the Pfizer mRNA vaccine (BioNTech,Â Mainz, Germany), without identifiable alternate etiologies, in patients with an average age of 36 years presenting to an urban Florida clinic, all within eight weeks of one another. The presented cases occurred within hours of the second dose and, in one case, after the third booster dose of the PfizerÂ mRNA vaccine. These cases illustrate rising concerns of risks in widely recognized very low-risk age categories. A clearly delineated risk-benefit strategy likely needs to be implemented.

Herpes zoster following vaccination with ChAdOx1 nCoV-19 Coronavirus vaccine (recombinant). Ever since the emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, science has unraveled much knowledge on SARS-CoV-2 which has led to extraordinary and unprecedented progress in developing COVID-19 vaccines. Several adverse cutaneous reactions, ranging from more common local injection site reaction, neutrophilic and pustular drug reactions to flare-up of preexisting dermatoses, have been reported with currently available vaccines. We report a case series of 7 patients who developed herpes zoster (HZ) following the first dose of ChAdOx1 nCoV-19 coronavirus vaccine (recombinant). HZ following vaccination is a rare entity. The occurrence of HZ in the patients presented in this series within the time window 1-21 days after vaccination defined for increased risk and postulated dysregulation of T-cell-mediated immunity, suggests that the ChAdOx1 nCoV-19 coronavirus vaccine (recombinant) could probably be a trigger for reactivation of varicella zoster virus to cause HZ in them.

Maternal COVID-19 Vaccine Safe for Infants.

Safety of an Inactivated SARS-CoV-2 Vaccine Among Healthcare Workers in Turkey: An Online Survey. BACKGROUND: As vaccination against coronavirus disase-19 (COVID-19) evolves, hesitancy has become a problematic issue that has gradually spread worldwide. The main reason for vaccine hesitancy is uncertainties about vaccine side effects. AIMS: To evaluate the safety of an inactivated COVID-19 vaccine, CoronaVac, and determine the risk factors of emergence of side effects. STUDY DESIGN: Cross-sectional study. METHODS: An online questionnaire was administered via the internet to healthcare workers who received one or two doses of CoronaVac. The online survey consisted of three sections detailing sociodemographic data, COVID-19 history, and post-vaccine side effects. Side effects that occurred in the period starting from immediately after the first vaccination to the end of the 14(th) day after the second vaccination were recorded. RESULTS: A total of 1628 healthcare workers responded to the online survey. Of these, 24.3% had a side effect either after the first or second dose of CoronaVac. Redness and/or pain at the inoculation site, headache, muscle and joint pains, palpitations, and dizziness were the most common side effects. Female sex, age <50 years, and thyroid disorder in the pre-vaccine period were found to be risk factors for the emergence of side effects. Blood pressure control could not be achieved in 2.2% of participants despite medication use, and permanent medication was needed in 2.5% of participants for blood pressure control. CONCLUSION: Almost a quarter of healthcare workers have at least one side effect after the first or second dose of CoronaVac. Female gender, age <50 years, and thyroid disorder appear to be risk factors for the occurrence of side effects.

A Case of Heart Transplantation for Fulminant Myocarditis After ChAdOx1 nCoV-19 Vaccination. Vaccines have become the mainstay of management against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection (coronavirus disease 2019; COVID-19) in the absence of effective antiviral therapy. Various adverse effects of COVID-19 vaccination have been reported, including cardiovascular complications such as myocarditis or pericarditis. Herein, we describe clinical records of a 63-year woman with fulminant myocarditis following ChAdOx1 nCoV-19 vaccination that was salvaged by heart transplantation. She complained chest pain, nausea, vomiting, and fever after the second vaccination. After the heart transplantation, the patient died due to necrotizing pneumonia on the 54th day of onset. Fulminant myocarditis is very rare after ChAdOx1 nCoV-19 vaccination but can be fatal.

Ipsilateral Lymphadenopathy After COVID-19 Vaccination in Patients With Newly Diagnosed Breast Cancer. This study aimed to evaluate the imaging and pathological findings in axillary lymph nodes in patients with breast cancer who received concurrent ipsilateral coronavirus disease 2019 (COVID-19) vaccination. Of the 19 women with breast cancer who received concurrent COVID-19 vaccination shot in the arm ipsilateral to breast cancer, axillary lymphadenopathy was observed in 84.2% (16 of 19) of patients on ultrasound (US) and 71.4% (10 of 14) of patients on magnetic resonance imaging (MRI), and 21.0% (4 of 19) of patients were diagnosed with metastasis. Abnormal US and MRI findings of cortical thickening, effacement of the fatty hilum, round shape, and asymmetry in the number or size relative to the contralateral side were noted in more than half of the non-metastatic and metastatic lymph nodes; however, statistical significance was not noted. Axillary lymphadenopathy is commonly observed in patients with breast cancer who receive concurrent ipsilateral COVID-19 vaccination without specific differential imaging features. Thus, understanding the limitations of axillary imaging and cautious interpretation is necessary to avoid overestimation or underestimation of the axillary disease burden.

Neutralizing activity of BBIBP-CorV vaccine-elicited sera against Beta, Delta and other SARS-CoV-2 variants of concern. The global pandemic of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has resulted in the generation of variants that may diminish host immune responses to vaccine formulations. Here we show a registered observational clinical trial (NCT04795414), we assess the safety and immunogenicity of the inactivated SARS-CoV-2 vaccine BBIBP-CorV in a cohort of 1006 vaccine recipients. No serious adverse events are observed during the term of the study. Detectable virus-specific antibody is measured and determined to be neutralizing in 698/760 (91.84%) vaccine recipients on day 28 post second vaccine dose and in 220/581 (37.87%) vaccine recipients on day 180 post second vaccine dose, whereas vaccine-elicited sera show varying degrees of reduction in neutralization against a range of key SARS-CoV-2 variants, including variant Alpha, Beta, Gamma, Iota, and Delta. Our work show diminished neutralization potency against multiple variants in vaccine-elicited sera, which indicates the potential need for additional boost vaccinations.

Haemostatic Disarray Following COVID-19 Vaccine - a Case of Acquired Haemophila A.

Menstrual Symptoms After COVID-19 Vaccine: A Cross-Sectional Investigation in the MENA Region. BACKGROUND: Since the emergence of COVID-19 vaccinations, many women around the world are reporting abnormalities in their menstrual periods post-vaccination. The aim of this study is to investigate the prevalence and impact of menstrual abnormalities after the COVID-19 vaccine among females residing within the Middle East and North Africa (MENA). METHODS: The study utilized a cross-sectional online self-administered survey from July 2021 to August 2021 targeting females living in the MENA region above the age of menarche who had received vaccine and were not pregnant or lactating, and do not have a history of primary ovarian insufficiency, hypothalamic menopause, or have undergone a hysterectomy. The survey was distributed regionally via social media. RESULTS: A total of 2269 females were included in our study, with a mean age of 34.3 Â± 8.5 years. About 66.3%

of participants reported menstrual symptoms post-vaccination, of which 46.7% experienced them after their first dose. However, in 93.6% of participants, the symptoms resolved within 2 months. Vaccine type did not significantly influence the incidence of abnormalities ($p > 0.05$). Participants who had confirmed previous COVID-19 infection had a very similar percentage of menstrual abnormalities compared to people who did not have COVID-19 infection or symptoms suspected of COVID-19 infection and did not test (67.5%, 66.8%, respectively); nevertheless, those who had experienced the COVID-19 vaccine general side effects had significantly more abnormalities ($p < 0.001$). Compared to their pandemic status, females reported significantly more abnormalities post-vaccination. CONCLUSION: The study showed a possible link between the COVID-19 vaccine and menstrual abnormalities that have impacted their quality of life.

Fulminant myocarditis in a patient with a lung adenocarcinoma after the third dose of modern COVID-19 vaccine. A case report and literature review. Introduction COVID-19 disease has caused a global health and economic crisis. The introduction of the different COVID-19 vaccines has resulted in a significant decrease in the morbidity and mortality associated with this disease. Adverse effects have been reported, including cardiological ones such as myocarditis or pericarditis after administration. Likewise, tyrosine kinase inhibitor drugs such as osimertinib used in lung cancer patients with epidermal growth factor receptor (EGFR) mutation are associated with heart failure or prolongation of the QT interval. Case report 62-year-old woman diagnosed in September 2019 of lung adenocarcinoma stage IV with bilateral lung and lymph node involvement, carrier of an EGFR mutation (Ex19Del) on treatment with osimertinib. She attended emergency department for fever and hypotension 24Â h after administration of the third dose of ModernaÂ® COVID-19 vaccine in the context of acute myocarditis with evidence of severe left ventricular (LV) dysfunction in cardiogenic shock. She required vasoactive support, non-invasive mechanical ventilation, corticotherapy, immunoglobulins and subsequent ventricular support with Impella, with improvement of the clinical picture after 3 days. Cardiac magnetic resonance imaging (MRI) showed evidence of global myocardial oedema compatible with acute myocarditis. Coronary CT showed a lesion in the anterior descending coronary artery requiring revascularization. A few days later, she presented febrile symptoms with isolation of Staphylococcus aureus in the central line catheter and antibiotherapy with cloxacillin was started, with subsequent resolution of the infectious symptoms. Conclusion This is an exceptional and controversial case of fulminant myocarditis probably related to the Modern COVID-19 vaccine in a patient diagnosed with metastatic lung adenocarcinoma on treatment with osimertinib. An increasing number of cases of myocarditis and pericarditis have been reported following vaccination with COVID-19 mRNA vaccines. In addition, retrospective data have shown an increased risk of QT prolongation and heart failure in patients treated with tyrosine kinase inhibitors. Hence, the need for close monitoring of cardiac function during treatment of these patients. Future studies will be necessary to evaluate unknown adverse reactions of these vaccines and their possible interaction with other antineoplastic drugs.

Autoimmune post-COVID vaccine syndromes: does the spectrum of autoimmune/inflammatory syndrome expand? To date, around 60% of the world population has been protected by vaccines against SARS-CoV-2, significantly reducing the devastating effect of the pandemic and restoring social economic activity through mass vaccination. Multiple studies have demonstrated the effectiveness and safety of vaccines against COVID-19 in healthy populations, in people with risk factors, in people with or without SARS-CoV-2 infection, and in immunocompromised people. According to the criteria for post-vaccine adverse events established by the World Health Organization, a minority of individuals may develop adverse events, including autoimmune syndromes. The exact mechanisms for the development of these autoimmune syndromes are under study, and to date, a cause-effect relationship has not been established. Many of these autoimmune syndromes meet sufficient criteria

for the diagnosis of Adjuvant-Induced Autoimmune Syndrome (ASIA syndrome). The descriptions of these autoimmune syndromes open new perspectives to the knowledge of the complex relationship between the host, its immune system, with the new vaccines and the development of new-onset autoimmune syndromes. Fortunately, most of these autoimmune syndromes are easily controlled with steroids and other immunomodulatory medications and are short-lived. Rheumatologists must be alert to the development of these autoimmune syndromes, and investigate the relationship between autoimmune/inflammatory symptoms and vaccination time, and assess their therapeutic response.

Impact of donor vaccination on recipient response to early SARS-CoV-2 mRNA vaccination after allogeneic HSCT.

Mechanistic Episodes on SARS-CoV-2-Mediated Neurological Manifestations and Their Possible Therapeutic Interventions. Recently, the emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been critically recognized and spread rapidly on this planet. Considerable recognition of SARS-CoV-2 has been known with a range of viruses that are more capable to cause diseases in avian and mammals including humans. The virus was found as a main culprit for major defects in respiratory system and thereby caused severe acute respiratory syndrome disease. This has led to depict the mortality in human population. Nevertheless, compromised reports on SARS-CoV-2 has also shown neurological complications in both central nervous system (CNS) and peripheral nervous system (PNS). This virus has notified with neurological defects as stroke, encephalopathy, cerebral edema, erythema, seizures, meningitis, ischemic, ageusia, loss of smell, myalgia and Guillain Barre Syndrome. In this review, we focused on COVID-19 mediated neurodegeneration and its mechanistic episodes on affected patients. We also discuss the possible available therapeutic interventions with clinically investigated drugs against COVID-19 mediated neurological impairment in patients and experimental in vitro and in vivo research models required for the development of drugs and/or vaccines against COVID-19 mediated neurological complications.

Safety of SARS-CoV-2 vaccination in patients with Behcet's syndrome and familial Mediterranean fever: a cross-sectional comparative study on the effects of M-RNA based and inactivated vaccine. Most of the published data relate to classical forms of rheumatic diseases (RD) and information on rare inflammatory disorders such as BehÃ§et's syndrome (BS) and familial Mediterranean fever (FMF) is limited. We studied the frequency of side effects and disease flares after COVID-19 vaccination with either Pfizer/BioNTech or Sinovac/CoronaVac in 256 patients with BS, 247 with FMF, and 601 with RD. Telephone interviews were conducted using a questionnaire survey in a cross-sectional design in patients with BS, FMF, and RD followed by a single university hospital. Study participants were vaccinated either with CoronaVac (BS:109, FMF: 90, and RD: 343,) or BioNTech (BS: 147, FMF: 157 and RD: 258). The majority have received double dose (BS: 94.9%, FMF 92.3% and RD: 86.2%). BioNTech ensured a significantly better efficacy than CoronaVac against COVID-19 in all patient groups (BS: 1.4% vs 10.1%; FMF: 3.2% vs 12.2%, RD:2.7% vs 6.4%). Those with at least one adverse event (AE) were significantly more frequent among those vaccinated with BioNTech than those with CoronaVac (BS: 86.4% vs 45%; FMF: 83.4% vs 53.3%; and RD: 83.3% vs 45.5%). The majority of AEs were mild to moderate and transient and this was true for either vaccine. There were also AEs that required medical attention in all study groups following CoronaVac (BS: 5.5%, FMF: 3.3%, and RD:2.9%) or BioNTech (BS: 5.4%, FMF: 1.9%, and RD: 4.7%). The main causes for medical assistance were disease flare and cardiovascular events. Patients with BS (16.0%) and FMF (17.4%) were found to flare significantly more frequently when compared to those with RD (6.0%) (pâ€‰<â€‰0.001). This was true for either vaccine. BS patients reported mainly skin-mucosa lesions; there were however, 11 (4.3%) who developed major organ attack such as uveitis, thrombosis or stroke. Flare in FMF patients were associated mainly with acute serositis with or without fever. Arthralgia/arthritis or

inflammatory back pain were observed mainly in the RD group. Our study demonstrates that BS and FMF patients vaccinated with either CoronaVac or BioNTech demonstrated similar AE profile and frequency compared to RD patients. AEs that required physician consultation or hospitalization occurred in all study groups after either CoronaVac or BioNTech. Increased frequency of flares in BS and FMF compared to that seen in RD might reflect defects in innate immunity and deserves further investigation. Caution should be required when monitoring these patients after vaccination.
COVID-19 vaccine (mRNA BNT162b2) and COVID-19 infection-induced thrombotic thrombocytopenic purpura in adolescents. The mRNA COVID-19 vaccine and COVID-19 infection caused by the SARS-CoV-2 virus may be immunologic triggers for the development of thrombotic thrombocytopenic purpura (TTP). There is not yet literature that discusses TTP induced by COVID-19 vaccination or infection in pediatric or adolescent patients. We describe three adolescents presenting with TTP (both de novo and relapsed disease) following administration of the Pfizer COVID-19 vaccine or after COVID-19 infection. Our observations demonstrate that the Pfizer-BioNTech mRNA vaccine and COVID-19 infection can act as triggers for the development/relapse of both congenital and acquired TTP.
Severe injection site reaction ensuing the first dose of mRNA COVID-19 vaccine.
Impaired Immune Response to SARS-CoV-2 Vaccination in Dialysis Patients and in Kidney Transplant Recipients. BACKGROUND: Patients with kidney failure on dialysis or after renal transplantation have a high risk for severe COVID-19 infection, and vaccination against SARS-CoV-2 is the only expedient prophylaxis. Generally, immune responses are attenuated in patients with kidney failure, however, systematic analyses of immune responses to SARS-CoV-2 vaccination in patients on dialysis and in kidney transplant recipients (KTRs) are still needed. METHODS: In this prospective, multicentric cohort study, antibody responses to COVID-19 mRNA vaccines (BNT162b2 [BioNTech/Pfizer] or mRNA-1273 [Moderna]) were measured in 32 patients on dialysis and in 28 KTRs. SARS-CoV-2-specific antibodies and neutralization capacity were evaluated and compared with controls (n=78) of a similar age range. RESULTS: After the first vaccination, SARS-CoV-2-specific antibodies were nearly undetectable in patients with kidney failure. After the second vaccination, 93% of the controls and 88% of patients on dialysis but only 37% of KTRs developed SARS-CoV-2-specific IgG above cutoff. Moreover, mean IgG levels were significantly lower in KTRs (54Â±93 BAU/ml) compared with patients on dialysis (503Â±481 BAU/ml; P<0.01). Both KTRs and patients on dialysis had significantly lower IgG levels compared with controls (1992Â±2485 BAU/ml; P<0.001 and P<0.01, respectively). Importantly, compared with controls, neutralizing antibody titers were significantly lower in KTRs and patients on dialysis. After the second vaccination, 76% of KTRs did not show any neutralization capacity against SARS-CoV-2, suggesting impaired seroprotection. CONCLUSIONS: Patients with kidney failure show a significantly weaker antibody response compared with controls. Most strikingly, only one out of four KTRs developed neutralizing antibodies against SARS-CoV-2 after two doses of vaccine. These data suggest that vaccination strategies need modification in KTRs and patients on dialysis.Clinical Trial registry name and registration number: Vaccination Against COVID-19 in Chronic Kidney Disease, NCT04743947.
Glomerular Disease in Temporal Association with SARS-CoV-2 Vaccination: A Series of 29 Cases. BACKGROUND: Immune responses to vaccination are a known trigger for a new onset of glomerular disease or disease flare in susceptible individuals. Mass immunization against SARS-CoV-2 in the COVID-19 pandemic provides a unique opportunity to study vaccination-associated autoimmune kidney diseases. In the recent literature, there are several patient reports demonstrating a temporal association of SARS-CoV-2 immunization and kidney diseases. METHODS: Here, we present a series of 29 cases of biopsy-proven glomerular disease in patients recently vaccinated against SARS-CoV-2 and identified patients who developed a new onset of IgA nephropathy, minimal change disease,

membranous nephropathy, ANCA-associated GN, collapsing glomerulopathy, or diffuse lupus nephritis diagnosed on kidney biopsies postimmunization, as well as recurrent ANCA-associated GN. This included 28 cases of de novo GN within native kidney biopsies and one disease flare in an allograft. RESULTS: The patients with collapsing glomerulopathy were of Black descent and had two APOL1 genomic risk alleles. A brief literature review of patient reports and small series is also provided to include all reported cases to date (n=52). The incidence of induction of glomerular disease in response to SARS-CoV-2 immunization is unknown; however, there was no overall increase in incidence of glomerular disease when compared with the 2 years prior to the COVID-19 pandemic diagnosed on kidney biopsies in our practice. CONCLUSIONS: Glomerular disease to vaccination is rare, although it should be monitored as a potential adverse event.

Patients With Suspected Severe Adverse Reactions to COVID-19 Vaccination Admitted to Intensive Care Unit: A Case Report. BACKGROUND: Several cases of adverse reactions following vaccination for coronavirus disease 2019 (COVID-19) with adenoviral vector vaccines or mRNA-based vaccines have been reported to date. The underlying syndrome has been named "vaccine-induced immune thrombotic thrombocytopenia" (VITT) or "thrombosis with thrombocytopenia syndrome (TTS)" with different clinical manifestations. METHODS: We report the clinical course of five patients who had severe adverse reactions to COVID-19 vaccines, either with VITT/TTS, abdominal or pulmonary thrombosis after adenoviral vaccines, or Stevens' Johnson syndrome because of mRNA vaccination, all of whom required admission to the intensive care unit (ICU). CONCLUSIONS: All patients with severe or life-threatening suspected reaction to different types of COVID-19 vaccination required ICU admission. A prompt evaluation of early symptoms and individualized clinical management is needed to improve outcomes.

[(18)F-Choline PET/MRI limphadenopathy related to SARS-CoV-2 vaccine].

Facial Diplegia Variant of Guillain-BarrÃ© Syndrome in Pregnancy Following COVID-19 Vaccination: A Case Report. Serious neurologic complications from coronavirus disease 2019 (COVID-19) vaccination are rare, and only a few cases of Guillain-BarrÃ© syndrome (GBS) have been reported after COVID-19 vaccination. We present the first reported case of the facial diplegia variant of GBS after recent COVID-19 vaccination in a pregnant woman. The 30-year-old patient was 27 weeks pregnant at the time she was diagnosed with the facial diplegia variant of GBS. Her symptoms began two weeks after she received the Ad26.COV2.S COVID-19 vaccine. A thorough evaluation for GBS was done, including a lumbar puncture that demonstrated elevated cerebrospinal fluid (CSF) protein and nerve conduction study (NCS) that found evidence of a diffuse sensorimotor demyelinating polyneuropathy. Nasal swab testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was negative on two occasions five days apart. All other diagnostic testing was unremarkable or nonexplanatory of the patient's clinical presentation. She was started on intravenous immunoglobulin (IVIG) and had significantly improved dysphasia, dysarthria, and facial strength. The patient recovered to baseline four weeks after presentation.

Recurrence of Pyoderma Gangrenosum Potentially Triggered by COVID-19 Vaccination. Pyoderma gangrenosum (PG) is a rare inflammatory skin disease of unknown origin. As with other vaccines, COVID-19 vaccines have been associated with many cutaneous reactions. Although COVID-19 vaccination is crucial, it is important for dermatologists and other physicians to be aware of the possible cutaneous reactions that can occur following COVID-19 vaccination. In this report, we describe a 73-year-old woman with a personal history of PG who experienced a recurrence after receiving her second dose of the tozinameran vaccine. Although extremely rare, flares of other inflammatory dermatoses, including lichen planus, have been reported following COVID-19 vaccination. Here we discuss theÂ overlap in pathogenesis of PG and COVID-19, proposing possible mechanisms behind this rare phenomenon.

Subacute Thyroiditis After Severe Acute Respiratory Syndrome Coronavirus 2 Vaxzevria Vaccination in a Patient With Thyroid Autoimmunity. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has been challenging the scientific community to promptly treat the patients and mitigate its spreading. The rapid development of vaccination against SARS-CoV-2 is being highly effective, but it is still lacking knowledge aboutÂ its side effects. Epidemiological studies point towardÂ virus infection as causative agents of subacute thyroiditis. More than 20 cases of thyroiditis after SARS-CoV-2 have also been described. Here,Â we aim to broad the spectrum of SARS-CoV-2 vaccination thyroid-associated disorders with the description of a new case of subacute thyroiditis associated with thyroid autoimmunity.Â The temporal association with the inoculation of the vaccine and the absence of other plausible etiological agents makes it highly possible that this thyroiditis was caused by Vaxzevria vaccine.Â It remains to be established whether the presence of thyroid autoimmunity can facilitate this condition, as this is one of the few described cases associated with autoimmunity.

Generalized Papulovesicular Eruption as a Side Effect of the Pfizer-BioNTech COVID-19 Vaccine. COVID-19Â is inflicted by SARS-CoV-2Â and resulted in a global health crisis that necessitated the urgency of vaccine development to prevent its spreading among the public. Pfizer-BioNTech COVID-19 is one of theÂ emergency use authorized (EUA) vaccines. This vaccine is efficacious against the SARS-CoV-2 virus; nonetheless, recipients have frequently reported side effects. Recipients of this vaccine experienced miscellaneous side effects like fatigue and headache. However, cutaneousÂ eruptions of varying degrees of severity and involvements have been manifesting post-vaccination. Dermatological eruptions following vaccination against COVID-19 disease are poorly recognized. Dermatological manifestations triggered post-vaccinationÂ differ in the clinical context and patient's demographic features. The only constant factor is various clinical and histopathological relations to establish the diagnosis of cutaneous eruption post-vaccination. Herein, we report a case of an 18-year-old male withÂ T-cell acute lymphocytic lymphoma (ALL) in remission since August 2018 and other comorbidities. After the administration of the first dose of the Pfizer-BioNTech COVID-19 vaccine, the patient developed pruritic eczematous eruption presenting as grouped erythematous-violaceous papulovesicular lesions with fine scales over his upper and lower extremities. These eruptions started two days after the administration of the vaccine. This eruption became generalized 21 days after receiving the second dose of the Pfizer-BioNTech COVID-19 vaccine. Clinical suspicion of the drug-induced vesicular eruption was suspected; thus, a biopsy was obtained and showed erosions and mixed inflammatory cell infiltrate. From a clinical and histopathological correlation, vesicular eruption following vaccination with Pfizer-BioNTech COVID-19 was confirmed. Nevertheless, other diagnoses cannot be ruled out, but from the clinical-histopathological association, the vaccine-inflicted eruption is the likely culprit. Reports are crucial to understanding the nature of such dermatological manifestation after emerging diseases and counteractions like vaccinations. The dermatological manifestations are vaguely recognized; thus, by reporting on the cases similar to the case in this report, more data will be available to understand the nature and underlying cause of such eruptions.

Psoriasis Flare-Up After COVAXIN BBV152 Whole Virion Inactivated Vaccine. Psoriasis is an inflammatory skin condition with a chronic relapsing course that can negatively impact a patient's quality of life. Various triggering factors can cause the flare-up of psoriasis, which also includeÂ vaccination. The most common vaccine associated with this is influenza. In this global pandemic of coronavirus disease 2019 (COVID-19), emergency authorization for mass vaccination has been adopted by many countries in the world.Â Psoriasis flare has been reported after the Pfizer COVID-19 vaccine andÂ CoronaVac vaccine. Currently, both the virus-causing disease and the vaccines are still being studied owing to their dynamicity. We report a case of a 21-year-old gentleman with

chronic plaque psoriasis of three years, who developed generalized pustular psoriasis eruption after administration of the first dose of COVAXIN. To the currently available literature, this was the first case of this complication associated with COVAXIN.

Antibody maintenance and breakthrough infections 6 months after complete COVID-19 vaccination with the mRNA-1273 and BNT162b2 vaccines in hemodialysis patients.

The COVID-19 Vaccines: A Description of Adverse Events of Reactions Reported in Kansas. INTRODUCTION: Coronavirus disease 2019 (COVID-19) is caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and has spread rapidly throughout the world since its discovery in 2019. Three vaccines (Pfizer-BioNTech, Moderna/NIAID/BARDA, and Johnson & Johnson's Janssen) have been developed for use in the U.S. to aid in the fight against this virus, but have been scrutinized intensely for their efficacy and safety. It is important to understand and interpret the adverse events or reactions (AERs) associated with these vaccines in an objective and analytical manner. The goal of this descriptive study was to provide a resource outlining AERs associated with the three available vaccines in Kansas. METHODS: Reports were obtained from the Vaccine Adverse Event Reporting System (VAERS), representing AERs observed in Kansas from December 11, 2020 to May 13, 2021. All data were screened and coded, and descriptive statistics were used to describe AERs based on vaccine manufacturer, patient age and biological sex, and reported deaths. RESULTS: Only 0.00068% of COVID-19 vaccine doses given in Kansas were associated with an AER (1,445/2,120,350). There were 4,297 individual AERs reported, and the most common were fatigue/tiredness (266; 6.2%), tingling/itching (251; 5.9%), fever (226; 5.3%), hives (223; 5.2%), and muscle/joint pain (209; 4.9%). Only 0.002% of COVID-19 vaccine doses in Kansas were associated with a death (38/2,120,350). The majority of VAERS reports were by females (1,139; 78.8%) and those aged 30 to 39 years (297; 20.6%). CONCLUSIONS: No reported AERs were unexpected compared to national data, and no VAERs report provided a causal relationship between vaccine administration and death. Vaccines are, and will continue to be, essential tools to fight COVID-19 in the quest to reach herd immunity. Providing a resource of potential AERs could aid in individual decisions to receive a vaccine and may help in the control of COVID-19. Future studies may include describing reported AERs for children under age 12 as the vaccines become available for those age groups, as well as reporting AERs for those who have received the vaccine after our study time period.

Case Report: Severe Rhabdomyolysis and Multiorgan Failure After ChAdOx1 nCoV-19 Vaccination. BACKGROUND: Severe skeletal muscle damage has been recently reported in patients with SARS-CoV-2 infection and as a rare vaccination complication. CASE SUMMARY: On Apr 28, 2021Â a 68-year-old man who was previously healthy presented with an extremely severe rhabdomyolysis that occurred nine days following the first dose of SARS-CoV-2 ChAdOx1 nCov-19 vaccination. He had no risk factors, and denied any further assumption of drugs except for fermented red rice, and berberine supplement. The clinical scenario was complicated by a multi organ failure involving bone marrow, liver, lung, and kidney. For the rapid increase of the inflammatory markers, a cytokine storm was suspected and multi-target biologic immunosuppressive therapy was started, consisting of steroids, anakinra, and eculizumab, which was initially successful resulting in close to normal values of creatine phosphokinase after 17 days of treatment. Unfortunately, 48 days after the vaccination an accelerated phase of deterioration, characterized by severe multi-lineage cytopenia, untreatable hypotensive shock, hypoglycemia, and dramatic increase of procalcitonin (PCT), led to patient death. CONCLUSION: Physicians should be aware that severe and fatal rhabdomyolysis may occur after SARS-CoV2 vaccine administration.

A Case Series of Ketoacidosis After Coronavirus Disease 2019 Vaccination in Patients With Type 1 Diabetes. INTRODUCTION: We report a case series of severe ketoacidosis after COVID-19 vaccination in a type 1 diabetes patients treated with insulin and an SGLT-2 inhibitor. CASE REPORT:

We present two cases of type 1 diabetes mellitus. One patient was treated with insulin therapy and an SGLT-2 inhibitor, and the other patient was treated with insulin therapy alone. Both patients became ill after coronavirus disease-2019 vaccination, making it difficult to continue their diet or insulin injections. On admission, they developed severe diabetic ketoacidosis. This is the first report of ketoacidosis after coronavirus disease-2019 vaccination. CONCLUSION: The vaccine should be carefully administered to type 1 diabetes patients receiving intensive insulin therapy and a sodium-glucose transporter due to the high risk ketoacidosis. It is important to instruct patients to drink sufficient fluids and to continue insulin injections when they become sick.

Miller Fisher Syndrome Following Vaccination against SARS-CoV-2. After BNT162b2 messenger ribonucleic acid (mRNA) coronavirus disease 2019 (COVID-19) vaccination, a 30-year-old man developed bilateral lateral gaze palsy, diplopia, absent tendon reflexes, and ataxic gait. Serum anti-GQ1b and anti-GT1a immunoglobulin G (IgG) antibodies were strongly positive. Based on those findings, he was diagnosed with Miller Fisher syndrome (MFS). Intravenous immunoglobulin therapy was administered, and his symptoms fully recovered within approximately 3 months. To the best of our knowledge, this is the first report to describe the development of MFS after COVID-19 mRNA vaccination.

Seroconversion after SARS-CoV-2 mRNA booster vaccine in cancer patients.

Cardiac Tamponade and COVID-19 Vaccination: Correspondence.

Vaccine-induced humoral response against SARS-CoV-2 dramatically declined but cellular immunity possibly remained at 6Â months post BNT162b2 vaccination. To evaluate vaccine-induced humoral and cell-mediated immunity at 6Â months after completion of two doses of BNT162b2 vaccination, immunoglobulin G against SARS-CoV-2 spike protein (SP IgG), 50% neutralizing antibody (NT(50)), and spot-forming cell (SFC) counts were evaluated by interferon-Î³ releasing ELISpot assay of 98 healthy subjects (median age, 43Â years). The geometric mean titers of SP IgG and NT(50) decreased from 95.2 (95% confidence interval (CI) 79.8-113.4) to 5.7 (95% CI 4.9-6.7) and from 680.4 (588.0-787.2) to 130.4 (95% CI 104.2-163.1), respectively, at 3Â weeks and 6Â months after the vaccination. SP IgG titer was negatively correlated with age and alcohol consumption. Spot-forming cell counts at 6Â months did not correlate with age, gender, and other parameters of the patients. SP IgG, NT(50,) and SFC titers were elevated in the breakthrough infected subjects. Although the levels of vaccine-induced antibodies dramatically declined at 6Â months after vaccination, a certain degree of cellular immunity was observed irrespective of the age.

Trends and disparities in the utilization of influenza vaccines among commercially insured US adults during the COVID-19 pandemic. OBJECTIVES: Little is known about how the coronavirus disease 2019 (COVID-19) pandemic affected influenza vaccine utilization and disparities. We sought to estimate changes in the likelihood of receiving an influenza vaccine across different demographic subgroups during the COVID-19 pandemic. METHODS: In this cohort study, we analyzed influenza vaccine uptake from 2019 to 2020 using Optum commercial insurance claims data. Eligible individuals were aged 18 or above in 2018 and continuously enrolled from 08/01/2018 through 12/31/2020. Multivariable logistic regressions were fitted for the individual-level influenza vaccine uptake. Adjusting for demographic factors and medical histories, we estimated probabilities of receiving influenza vaccines before and after the COVID-19 pandemic across demographic subgroups. RESULTS: From August to December 2019, unadjusted influenza vaccination rate was 42.3%, while in the same period of 2020, the vaccination rate increased to 45.9%. Females had a higher vaccination rate in 2019 (OR: 1.16, 95% CI 1.15-1.16), but the increase was larger for males. Blacks and Hispanics had lower vaccination rates relative to whites in both flu seasons. Hispanics showed a greater increase in vaccination rate, increasing by 7.8 percentage points (pÂ <Â .001) compared to 4.4 (pÂ <Â .001) for whites. The vaccination rate for Blacks increased by 5.2 percentage points (pÂ <Â .001). All income

groups experienced vaccination improvements, but poorer individuals had lower vaccination rates in both seasons. The most profound disparities occurred when educational cohort were considered. The vaccination rate increased among college-educated enrollees by 8.8 percentage points (pÂ <Â .001) during the pandemic compared to an increase of 2.8 percentage points (pÂ <Â .001) for enrollees with less than a 12th grade education. Past influenza infections or vaccination increased the likelihood of vaccination (pÂ <Â .001). CONCLUSIONS: The COVID-19 pandemic was associated with increased influenza vaccine utilization. Disparities persisted but narrowed with respect to gender and race but worsened with respect to income and educational attainment.

Benefit-risk assessment of COVID-19 vaccine, mRNA (Comirnaty) for age 16-29Â years. Since authorization of the Pfizer-BioNTech COVID-19 Vaccine, mRNA (Comirnaty), real-world evidence has indicated the vaccines are effective in preventing COVID-19 cases and related hospitalizations and deaths. However, increased cases of myocarditis/pericarditis have been reported in the United States associated with vaccination, particularly in adolescents and young adults. FDA conducted a benefit-risk assessment to determine whether the benefits of vaccination outweigh the risks among various age (16-17, 18-24, 25-29) and sex (M/F) subgroups being considered for approved use of the vaccine. We conducted a simulation study with sensitivity analysis of the benefits and risks of the vaccine across possible pandemic scenarios. The model results show benefits outweigh the risks for all scenarios including the high-risk subgroup, males 16-17Â years old. Our worst-case scenario used sex and age subgroup-specific incidences for COVID-19 cases (47-98 per million per day) and hospitalizations (1-4 per million per day) which are the US COVID-19 incidences as of July 10, 2021, vaccine efficacy of 70% against COVID-19 cases and 80% against hospitalization, and unlikely, pessimistic, non-zero vaccine-attributable myocarditis death rate. For males 16-17Â years old, the model predicts prevented COVID cases, hospitalizations, ICUs, and deaths of 13577, 127, 41, and 1, respectively; while the predicted ranges for excess myocarditis/pericarditis cases, hospitalizations, and deaths attributable to the vaccine are [98-196], [98-196], and 0, respectively, for the worst-case scenario. Considering the different clinical implications of hospitalization due to COVID-19 infection versus vaccine-attributable myocarditis/pericarditis cases, we determine the benefits still outweigh the risks even for this high-risk subgroup. Our results demonstrate that the benefits of the vaccine outweigh its risks for all age and sex subgroups we analyze in this study. Uncertainties exist in this assessment as both benefits and risks of vaccination may change with the continuing evolution of the pandemic.

Cardiovascular Complications of COVID-19 Vaccines. Coronavirus disease 2019 (COVID-19) has become a global public health catastrophe. Vaccination against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) is proven to be the most effective measure to suppress the pandemic. With the widespread application of the four vaccines, namely, ChAdOx1, Ad26.COV2.S, BNT162b2, and mRNA-1273.2, several adverse effects have been reported. The most serious type of complication is cardiovascularly related, including myocarditis, immune thrombocytopenia (ITP), cerebral sinus venous thrombosis, among others. All these adverse events undermine the health of the vaccinees and affect the administration of the vaccines. As the distribution of COVID-19 vaccines is surrounded by suspicion and rumors, it is essential to provide the public with accurate reports from trusted experts and journals. Monitoring the safety of COVID-19 vaccines is an important and ongoing process that is also urgent. Thus, we summarized the cardiovascular complications of the major types of COVID-19 vaccines, including mRNA vaccines, which are now generally considered to be innovative vaccines, and the future for vaccination against COVID-19, in addition to the underlying pathogenesis and potential therapeutics.

Case Report: Myocarditis Associated With COVID-19 mRNA Vaccination Following Myocarditis Associated With Campylobacter Jejuni. We herein present our experience with a case involving a

17-year-old Japanese boy suffering from acute myocarditis after his second coronavirus disease-2019 (COVID-19) messenger RNA (mRNA) vaccine shot. The patients had a history of myocarditis associated with Campylobacter jejuni 3 years prior. This has been the first-ever documented case of myocarditis associated with COVID-19 mRNA vaccination in a patient with a history of myocarditis. We present a series of images and blood biomarkers for different types of myocarditis that developed in this single patient.

Scope of SARS-CoV-2 variants, mutations, and vaccine technologies. BACKGROUND: The COVID-19 pandemic is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). SARS-CoV-2 is disseminated by respiratory aerosols. The virus uses the spike protein to target epithelial cells by binding to the ACE2 receptor on the host cells. As a result, effective vaccines must target the viral spike glycoprotein. However, the appearance of an Omicron variant with 32 mutations in its spike protein raises questions about the vaccine's efficacy. Vaccines are critical in boosting immunity, lowering COVID-19-related illnesses, reducing the infectious burden on the healthcare system, and reducing economic loss, according to current data. An efficient vaccination campaign is projected to increase innate and adaptive immune responses, offering better protection against SARS-CoV-2 variants. MAIN BODY: The presence of altered SARS-CoV-2 variants circulating around the world puts the effectiveness of vaccines already on the market at risk. The problem is made even worse by the Omicron variant, which has 32 mutations in its spike protein. Experts are currently examining the potential consequences of commercial vaccines on variants. However, there are worries about the vaccines' safety, the protection they provide, and whether future structural changes are required for these vaccines to be more effective. As a result of these concerns, new vaccines based on modern technology should be developed to guard against the growing SARS-CoV-2 variations. CONCLUSION: The choice of a particular vaccine is influenced by several factors including mode of action, storage conditions, group of the vaccinee, immune response mounted, cost, dosage protocol, age, and side effects. Currently, seven SARS-CoV-2 vaccine platforms have been developed. This comprises of inactivated viruses, messenger RNA (mRNA), DNA vaccines, protein subunits, nonreplicating and replicating vector viral-like particles (VLP), and live attenuated vaccines. This review focuses on the SARS-CoV-2 mutations, variants of concern (VOCs), and advances in vaccine technologies.

Antibody Response After a Second Dose of the BNT162b2 mRNA COVID-19 Vaccine in Liver Transplant Recipients.

Factors associated with poor antibody response to third-dose SARS-CoV-2 vaccination in patients with rheumatic and musculoskeletal diseases.

Varicella zoster meningitis following COVID-19 vaccination: a report of two cases. Most of the adverse effects reported in patients who have received COVID-19 vaccines have been mild. However, possible serious adverse effects are being monitored cautiously. There have also been a number of case reports of reactivation of varicella zoster infection within 28 days after immunization with mRNA COVID-19 vaccines. A few cases have also been reported after viral vector and inactivated COVID-19 vaccination. The incidence of meningitis following varicella zoster virus infection is rare. In the current study, we report two cases of male patients who received two different types of COVID-19 vaccine (inactivated and viral vector) and developed varicella zoster meningitis within 10 days after vaccination.

Efficacy, safety, and immunogenicity of the DNA SARS-CoV-2 vaccine (ZyCoV-D): the interim efficacy results of a phase 3, randomised, double-blind, placebo-controlled study in India. BACKGROUND: ZyCoV-D, a DNA-based vaccine, showed promising safety and immunogenicity in a phase 1/2 trial. We now report the interim efficacy results of phase 3 clinical trial with ZyCoV-D vaccine in India. METHODS: We conducted an interim analysis of a multicentre, double-blind, randomised, placebo-controlled phase 3 trial at 49 centres in India. Healthy participants aged at least 12 years were

enrolled and randomly assigned (1:1) to receive either ZyCov-D vaccine (Cadila Healthcare; 2 mg per dose) or placebo. An interactive web response system was used for randomisation (blocks of four) of participants as well as to enrol those aged 60 years and older with or without comorbid conditions, and those aged 12-17 years. It was also used to identify 600 participants for immunogenicity (blocks of six). Participants, investigators, and outcome assessors were masked to treatment assignment. Three doses of vaccine or placebo were administered intradermally via a needle-free injection system 28 days apart. The primary outcome was the number of participants with first occurrence of symptomatic RT-PCR-positive COVID-19 28 days after the third dose, until the targeted number of cases (interim analysis n=79, full analysis n=158) have been achieved. The analysis was done in the per-protocol population, which consisted of all participants with negative baseline SARS-CoV-2 status who received three doses of vaccine or placebo. Assessment of safety and tolerability was based on the safety population, which consisted of all enrolled participants who were known to have received at least one dose of study vaccine or placebo. This trial is registered with Clinical Trial Registry India, CTRI/2021/01/030416, and is ongoing. FINDINGS: Between Jan 16, and June 23, 2021 (data cutoff), 33â€ˆ194 individuals were screened, of whom 5241 did not meet screening criteria and 27â€ˆ703 were enrolled and randomly assigned to receive ZyCoV-D (n=13â€ˆ851) or placebo (n=13â€ˆ852). Per-protocol, 81 cases were eligible and included in efficacy analysis (20 of 12â€ˆ350 in the ZyCoV-D group and 61 of 12â€ˆ320 in placebo group). The ZyCoV-D vaccine efficacy was found to be 66Â·6% (95% CI 47Â·6-80Â·7). The occurrence of solicited adverse events was similar between the treatment groups (623 [4Â·49%] in the ZyCoV-D group vs 620 [4Â·47%] in the placebo group). There were two deaths (one in each group) reported at the data cutoff, neither of which was considered related to the study treatments. INTERPRETATION: In this interim analysis, ZyCoV-D vaccine was found to be efficacious, safe, and immunogenic in a phase 3 trial. FUNDING: National Biopharma Mission, Department of Biotechnology, Government of India and Cadila Healthcare, Ahmedabad, Gujarat India.

High failure rate of ChAdOx1-nCoV19 immunization against asymptomatic infection in healthcare workers during a Delta variant surge. Immunization is expected to confer protection against infection and severe disease for vaccines while reducing risks to unimmunized populations by inhibiting transmission. Here, based on serial serological studies of an observational cohort of healthcare workers, we show that during a Severe Acute Respiratory Syndrome -Coronavirus 2 Delta-variant outbreak in Delhi, 25.3% (95% Confidence Interval 16.9-35.2) of previously uninfected, ChAdOx1-nCoV19 double vaccinated, healthcare workers were infected within less than two months, based on serology. Induction of anti-spike response was similar between groups with breakthrough infection (541 U/ml, Inter Quartile Range 374) and without (342 U/ml, Inter Quartile Range 497), as was the induction of neutralization activity to wildtype. This was not vaccine failure since vaccine effectiveness estimate based on infection rates in an unvaccinated cohort were about 70% and most infections were asymptomatic. We find that while ChAdOx1-nCoV19 vaccination remains effective in preventing severe infections, it is unlikely to be completely able to block transmission and provide herd immunity.

Erythema nodosum triggered by BNT162b2 mRNA COVID-19 vaccine.

Predictors of poor seroconversion and adverse events to SARS-CoV-2 mRNA BNT162b2 vaccine in cancer patients on active treatment. Role of the Research Nurse. BACKGROUND: Vaccines have shown 95% protection from COVID-19 disease in healthy populations. Initial findings in cancer patients suggest a lower seroconversion and greater toxicity possibly related to myelo-immunosuppressive therapies. AIM: We conducted a prospective study to assess factors predicting poor seroconversion and adverse events following immunization (AEFI) to the BNT162b2 vaccine in cancer patients on active treatment. METHODS: Blood samples were collected by the research nurse

at first dose (visit 1), second dose (visit 2), after 42 days (visit 3) and after 6 months (visit 4). At visit 1, 3 and 4 participants received: Hospital Anxiety and Depression Scale (HADS) and Distress Thermometer. Patients who ended treatment >6 months on active surveillance served as controls. RESULTS: Between March and July 2021, 320 subjects were recruited and 291 were assessable. The lack of seroconversion at 21 days from the second dose was 1.6% (95% CI, 0.4-8.7) on active surveillance, 13.9% (8.2-21.6) on chemotherapy, 11.4% (5.1-21.3) on hormone therapy, 21.7% (7.5-43.7) on targeted therapy and 4.8% (0.12-23.8) on immunotherapy. Compared to controls, the risk of no IgG response was greater for chemotherapy (P=0.033), targeted therapy (0.005) and hormonotherapy (P=0.051). Lymphocyte count less than 1x109/L, older age and advanced stage also significantly predicted poor seroconversion. Overall, 43 patients (14.8%) complained of AEFI, mostly of mild grade. Risk of AEFI was greater in females (P=0.001) and younger patients (P=0.009). CONCLUSIONS: A third booster dose and long-term serological testing is required in subjects who have not responded to the vaccine. NURSING IMPLICATIONS: nurses must take responsibility for promoting and protecting the health of cancer patients.

Are COVID-19 mRNA vaccine side effects severe enough to cause missed work? Cross-sectional study of health care-associated workers. The Coronavirus Disease 2019 (COVID-19) pandemic, caused by the severe acute respiratory syndrome-coronavirus-2, has claimed 5,587,549 lives worldwide as of January 20, 2022. Fortunately, large-scale vaccination can mitigate the impact of COVID-19 by making the disease milder and less common. Although 75.2% of the United States population has received at least 1 dose of a COVID-19 vaccines thus far, concerns regarding vaccine side effects have contributed to vaccine hesitancy. Furthermore, nearly 50% of adults in the United States are concerned not only about side effects, but about their downstream impact, including missed work.The goal of this cross-sectional study was to investigate the effect of messenger RNA vaccine adverse effects on the propensity to miss work among employees associated with a single, large academic health center.Using Qualtrics, all employees, including faculty, staff, and trainees, of 5 large departments were surveyed to determine whether they received the COVID-19 vaccine and which type, and any symptoms they experienced after receipt of either vaccine dose. We hypothesized that vaccine recipients would be more likely to miss work or feel sick enough to miss work following the second dose.Thirty-seven percent of respondents experienced events severe enough that they needed to miss work from either of the doses, with the majority (27.8%) related to the second dose. These findings are consistent with and expand on the results from the phase 3 trials for Pfizer-BionTech and Moderna, which showed that vaccine side effects were more common after the second dose than after the first dose. Our statistically significant finding was more common among Asians, women, trainees/house staff, and nonphysician clinical employees.With an increasing number of individuals taking the vaccine, employers will need to account for the impact of adverse effects on their employees' ability to work. These findings will further help organizations better plan for staffing as vaccinations increase to mitigate the spread of COVID-19.

Immediate side effects of Comirnaty COVID-19 vaccine: A nationwide survey of vaccinated people in Israel, December 2020 to March 2021. BackgroundCOVID-19 vaccine safety is of major interest worldwide, since there is no prior experience with it. Israel was one of the first countries to widely use the Comirnaty vaccine.AimWe aimed to assess the vaccine's short-term side effects directly from a large population and to predict influencing factors for self-reporting side effects.MethodsIn a retrospective cohort study, we investigated self-reported systemic vaccine side-effects using electronic surveys sent to vaccinated individuals between 20 December 2020 and 11 March 2021, within 3 days following administration of the first and second dose. We determined predictors for reporting systemic side effects by logistic regression.ResultsA total of 1,213,693 patients received at least one vaccine dose and 301,537 (24.8%) answered at least one survey. Among them, 68,162

(30.4%) and 89,854 (59.9%) individuals filled the first and the second dose surveys, respectively, and reported one or more side effects. Most common side effects were fatigue, headache and myalgia. Several respondents reported facial paraesthesia after first and second dose, respectively (nâ€¯=â€¯1,675; 0.7% and nâ€¯=â€¯1,601; 1.1%). Individuals younger than 40 years and women reported side effects more frequently than others, but pregnant women reported less. Pregnancy was a weak predictor for reporting any side effect in general and in particular fatigue, myalgia, headache, chills and fever.ConclusionsWe found further support for minor short-term side effects, within 3 days of receiving the Comirnaty vaccine. These findings from vaccine recipients in general and pregnant women in particular can improve vaccine acceptance.

Correction: Clinical outcomes of breakthrough COVID-19 after booster vaccination in patients with systemic rheumatic diseases.

Factors associated with weight gain during the COVID-19 pandemic. BACKGROUND: To limit transmission of COVID-19, state governments issued shelter-in-place orders. These orders coincided with a decrease in daily step count and an increase in overeating. We evaluated factors associated with weight gain of â‰¥Â 15 pounds during the pandemic within an integrated health care system. METHODS: We included adults ages 18 and above with at least one weight measurement before the pandemic (March 19, 2019-March 19, 2020) and another measurement after COVID-19 vaccines became available, more than 9 months into the pandemic (December 14, 2020-December 14, 2021). Logistic regression was used to identify factors associated with weight gain of 15 pounds or more. RESULTS: Of 524,451 adults included in the study, median age was 61 years, 43.2% were men, 36.2% self identified as White, 8.6% Black, 35.7% Hispanic, and 16.2% Asian. During the pandemic, 38,213 (7.3%) adults gained â‰¥Â 15 pounds. A higher proportion of young adults gained weight (16.2% age 18-39, 7.6% age 40-64, 4.7% age 65-79%, and 3.1% age â‰¥Â 80). No significant difference was observed between men and women (7.2% men and 7.4% women). Weight gain was more prevalent among adults from low-income neighborhoods (8.9% low-income neighborhoods, 8.0% intermediate-income neighborhoods, and 6.5% high-income neighborhoods). Multivariable logistic regression demonstrated that compared to adults ages 65-79 years, young adults ages 18-39 years had the highest risk of gaining â‰¥Â 15 pounds (adjusted OR 5.19, 95% CI 5.01-5.38). Black race was associated with weight gain in an unadjusted analysis (OR 1.25, 95% CI 1.21-1.30). However, this association was significantly attenuated after adjusting for other risk factors including neighborhood income levels (adjusted OR 1.06, 95% CI 1.02-1.10). Having a diagnosis of depression pre-pandemic was also associated with weight gain during the pandemic (adjusted OR 1.54, 95% CI 1.50-1.58). CONCLUSION: In this racially and ethnically diverse population in southern California, significant weight gain of 15 pounds or more was observed in 7.3% of the adult population during the COVID-19 pandemic. Young adults, individuals who resided in low-income neighborhoods, and patients with depression were disproportionally affected.

COVID-19 vaccine and pregnancy: A safety weapon against pandemic. The ongoing COVID-19 pandemic is raising great concern all over the world. The recent introduction of vaccines has offered reason for optimism, however, new issues have arisen, such as vaccine reluctance. The safety of vaccines for pregnant women is one of the most serious of these concerns. The purpose of this review article is to provide updated international vaccine recommendations, results of ongoing studies and clinical trials, and the role of gynecologists in counseling the women to understand the risks versus benefits as well as form an informed decision towards vaccine acceptance for COVID-19. Although COVID-19 infection increases the risk of severe morbidity and mortality in pregnant women, pregnant women were not included in the initial vaccine trials. As a result, safety information is scarce. Nations have differing recommendations, though many have recently approved the COVID-19 immunization in pregnancy following a risk-benefit analysis. The Joint Committee on Vaccination and

Immunization (JCVI) of the United Kingdom recently approved an mRNA vaccination for pregnant women. Vaccination is recommended by the CDC, ACOG, ARFM, and WHO. India recently took a stand, with the ICMR and the Ministry of Health and Family Welfare recommending vaccination during pregnancy and lactation.

Patients With Myocarditis Associated With COVID-19 Vaccination.

Dermatomyositis post vaccine against SARS-COV2. BACKGROUND: Dermatomyositis belongs to an infrequent group of diseases predominantly found in patients older than 40Â years old and is characterized by dermal and muscular findings. This disease presents itself as proximal, ascending and symmetric weakness and typical dermatosis with findings such as elevated muscle enzymes, altered electromyography and typical changes in muscle biopsy; as of today, the etiology of the disease in unknown. The COVID-19 vaccine has been a fundamental tactic to achieve control of the coronavirus (SARS CoV2), and it's clear that the benefits of getting the vaccine overweight the risks that might come along with it. Although rare, all adverse effects should be reported, this could help us to understand the elusive pathophysiology of inflammatory idiopathic myopathy. CASE PRESENTATION: In this text we will describe the case of a patient with dermatomyositis who was vaccinated against SARS CoV2 with BNT162b2 mRNA (Pfizer-BioNTech), showing a temporal relation between the vaccination and the beginning of her symptoms. We realized all the diagnostic approach to the suspected disease including electromyography, muscle biopsy and laboratory findings, corroborating the diagnosis. The patient received standard treatment for this disease (steroid therapy) and have a classic slow improvement. CONCLUSIONS: Although itÂ´s not possible to confirm a direct correlation between the vaccine and the onset of the disease, we considered that there are enough data to suspect that this could be a trigger event and therefore should always be considered a possible cause for a case of inflammatory idiopathic myopathy.

Headache onset after vaccination against SARS-CoV-2: a systematic literature review and meta-analysis. BACKGROUND: Vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are used to reduce the risk of developing Coronavirus Disease 2019 (COVID-19). Despite the significant benefits in terms of reduced risk of hospitalization and death, different adverse events may present after vaccination: among them, headache is one of the most common, but nowadays there is no summary presentation of its incidence and no description of its main features. METHODS: We searched PubMed and EMBASE covering the period between January 1(st) 2020 and August 6(th), 2021, looking for record in English and with an abstract and using three main search terms (with specific variations): COVID-19/SARS-CoV-2; Vaccination; headache/adverse events. We selected manuscript including information on subjects developing headache after injection, and such information had to be derived from a structured form (i.e. no free reporting). Pooled estimates and 95% confidence intervals were calculated. Analyses were carried out by vaccine vs. placebo, by first vs. second dose, and by mRNA-based vs. "traditional" vaccines; finally, we addressed the impact of age and gender on post-vaccine headache onset. RESULTS: Out of 9338 records, 84 papers were included in the review, accounting for 1.57 million participants, 94% of whom received BNT162b2 or ChAdOx1. Headache was generally the third most common AE: it was detected in 22% (95% CI 18-27%) of subjects after the first dose of vaccine and in 29% (95% CI 23-35%) after the second, with an extreme heterogeneity. Those receiving placebo reported headache in 10-12% of cases. No differences were detected across different vaccines or by mRNA-based vs. "traditional" ones. None of the studies reported information on headache features. A lower prevalence of headache after the first injection of BNT162b2 among older participants was shown. CONCLUSIONS: Our results show that vaccines are associated to a two-fold risk of developing headache within 7Â days from injection, and the lack of difference between vaccine types enable to hypothesize that headache is secondary to systemic immunological reaction than to a vaccine-type specific reaction. Some descriptions report

onset within the first 24Â h and that in around one-third of the cases, headache has migraine-like features with pulsating quality, phono and photophobia; in 40-60% of the cases aggravation with activity is observed. The majority of patients used some medication to treat headache, the one perceived as the most effective being acetylsalicylic acid.

Mind the "Vaccine Fatigue". BACKGROUND: Omicron scares and speculations are gaining momentum. Amid the nonstop debates and discussions about COVID-19 vaccines, the "vaccine fatigue" phenomenon may become more prevalent. However, to date, no research has systematically examined factors that shape people's vaccine fatigue. To bridge the research gap, this study aims to investigate the antecedents that cause or catalyze people's vaccine fatigue. METHODS: A narrative literature review was conducted in PubMed, Scopus, and PsycINFO to identify factors that shape people's vaccine fatigue. The search was completed on December 6, 2021, with a focus on scholarly literature published in English. RESULTS: A total of 37 articles were reviewed and analyzed. Vaccine fatigue was most frequently discussed in the context of infectious diseases in general at the pre-vaccination stage. Vaccine fatigue has been identified in the general public, the parents, and the doctors. Overall, a wide range of antecedents to vaccine fatigue has been identified, ranging from the frequency of immunization demands, vaccine side effects, misconceptions about the severity of the diseases and the need for vaccination, to lack of trust in the government and the media. CONCLUSION: Vaccine fatigue is people's inertia or inaction towards vaccine information or instruction due to perceived burden and burnout. Our study found that while some contributors to vaccine fatigue are rooted in limitations of vaccine sciences and therefore can hardly be avoided, effective and empathetic vaccine communications hold great promise in eliminating preventable vaccine fatigue across sectors in society.

Extension and Severity of Self-Reported Side Effects of Seven COVID-19 Vaccines in Mexican Population. A few studies examined the comparative side effects of Coronavirus Disease-19 (COVID-19) vaccines. We compared the extension and severity of self-reported side effects of seven COVID-19 vaccines [BNT162b2 (Pfizer-BioNTech), ChAdOx1 (AstraZeneca), mRNA-1273 (Moderna), CoronaVac (Sinovac Life Sciences), Gam-COVID-Vac (Gamaleya's Sputnik V), Ad5-nCoV (CanSinoBIO), and Ad26.CoV2.S (Johnson & Johnson/Janssen)] in the Mexican population. We also evaluated the association of type of vaccine, sex, age, comorbidity, and history of allergies to the extent and severity of side effects. This was a cross-sectional study carried out online between August 12 and September 3, 2021 in Mexico. The first inclusion criterion was to receive a COVID-19 vaccine and the second, being at least 18 years old. The survey link was distributed via multiple social media platforms. We questioned about the type of vaccine and symptoms based on short-term side effects reported in the literature. Side effect extension was classified as local, systemic, or both. We asked about the need to take medicine, stop activities/miss work, or seek medical attention. Then, a severity index was constructed based on responses. Descriptive and stepwise multivariate logistic ordinal regression analyses were used to calculate odds ratio (OR) and 95% CI for each outcome adjusted by potential confounders. The mean age was 38.9 Â± 11.0 years (n = 4,024). Prevalence of at least one side effect varied between vaccines and by a number of doses. At dose 1, ChAdOx1 was the vaccine with the highest rate of at least one side effect (85%) followed by Gam-COVID-Vac (80%). Both were associated to greater extension (adjusted OR 2.53, 95% CI 2.16, 2.96 and adjusted OR 2.41, 95% CI 1.76, 3.29, respectively) and severity of side effects (adjusted OR 4.32, 95% CI 3.73, 5.00 and adjusted OR 3.00, 95% CI 2.28, 3.94, respectively). Young age (<50 years), female sex, comorbidity, and history of allergies were associated with greater extension and severity, independent of the type of vaccine and potential confounders. At dose 2, mRNA-1273 was the vaccine with the highest rate of side effects (88%) and the only vaccine associated to greater extension (adjusted OR 2.88, 95% CI

1.59, 5.21) and severity of symptoms (adjusted OR 3.14, 95% CI 1.82, 5.43). Continuous studies are necessary to acknowledge more post-vaccine symptoms in different populations.

Case Report: Anti-NF186+ CIDP After Receiving the Inactivated Vaccine for Coronavirus Disease (COVID-19). Corona Virus Disease 2019 (COVID-19), the novel coronavirus disease, is now a global pandemic. Vaccination can significantly reduce the mortality rate caused by the severe acute respiratory syndrome of coronavirus 2 (SARS-CoV-2). There are currently several effective vaccines that have been introduced. Inactivated COVID-19 vaccine is one of these options and is generally considered safe. Neurofascin (NF) plays an important role in keeping the functionality of the node of Ranvier. We report here a rare case of anti-NF186+ chronic inflammatory demyelinating polyneuropathy (CIDP) in a 23-year-old male patient who was vaccinated with inactivated COVID-19 vaccine prior to the onset. This report adds a new possible rare side effect of a COVID-19 vaccine and provides a case for the clinical effectiveness of rituximab (RTX) in patients with anti-NF186+ CIDP.

Thrombotic thrombocytopenic purpura and other immune-mediated blood disorders following vaccination against SARS-CoV-2.

COVID-19 and Vaccine-Induced Thrombosis. Coronavirus disease 2019 (COVID-19), a highly contagious infectious disease, has had a catastrophic effect on the world's demographics resulting in more than 2.9 million deaths worldwide till January 2021. It can lead to systemic multi-organ complications; in particular, venous and arterial thromboembolism risk is significantly increased. Venous thromboembolism (VTE) occurs in 22.7% of patients with COVID-19 in the ICU and 8% in non-ICU hospitalized patients. Studies evaluating thromboprophylaxis strategies in patients with COVID-19 are needed to improve the prevention of VTE. VTE is the most commonly reported thrombotic complication, with higher incidence rates among critically ill patients. Several vaccines have been licensed and are currently used to combat the COVID-19 pandemic. Also, several cases of vaccine-induced thrombosis have been reported. Vaccination remains the most critical measure to curb the COVID-19 pandemic. There is a broad consensus that the benefits of vaccination greatly outweigh the potential risks of rare vaccine side effects, such as vaccine-induced immune thrombotic thrombocytopenia (VITT). Therefore, the importance of vaccination should be emphasized. This statement aims to focus on VITT.

A novel flow cytometry procoagulant assay for diagnosis of vaccine-induced immune thrombotic thrombocytopenia. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a severe prothrombotic complication of adenoviral vaccines, including the ChAdOx1 nCoV-19 (Vaxzevria) vaccine. The putative mechanism involves formation of pathological anti-platelet factor 4 (PF4) antibodies that activate platelets via the low-affinity immunoglobulin G receptor FcÎ³RIIa to drive thrombosis and thrombocytopenia. Functional assays are important for VITT diagnosis, as not all detectable anti-PF4 antibodies are pathogenic, and immunoassays have varying sensitivity. Combination of ligand binding of G protein-coupled receptors (protease-activated receptor-1) and immunoreceptor tyrosine-based activation motif-linked receptors (FcÎ³RIIa) synergistically induce procoagulant platelet formation, which supports thrombin generation. Here, we describe a flow cytometry-based procoagulant platelet assay using cell death marker GSAO and P-selectin to diagnose VITT by exposing donor whole blood to patient plasma in the presence of a protease-activated receptor-1 agonist. Consecutive patients triaged for confirmatory functional VITT testing after screening using PF4/heparin ELISA were evaluated. In a development cohort of 47 patients with suspected VITT, plasma from ELISA-positive patients (n = 23), but not healthy donors (n = 32) or individuals exposed to the ChAdOx1 nCov-19 vaccine without VITT (n = 24), significantly increased the procoagulant platelet response. In a validation cohort of 99 VITT patients identified according to clinicopathologic adjudication, procoagulant flow cytometry identified 93% of VITT cases, including ELISA-negative and serotonin release assay-negative patients. The inÂ vitro effect of intravenous

immunoglobulin (IVIg) and fondaparinux trended with the clinical response seen in patients. Induction of FcÎ³RIIa-dependent procoagulant response by patient plasma, suppressible by heparin and IVIg, is highly indicative of VITT, resulting in a sensitive and specific assay that has been adopted as part of a national diagnostic algorithm to identify vaccinated patients with platelet-activating antibodies.
[Delayed local reaction with subcutaneous infiltration after vaccination with mRNA-1273-a previously undescribed reaction pattern of COVID arm]. The mRNA-1273 vaccine against SARS-CoVâ€‘2 was approved in Europe in early 2021. Meanwhile, there are aÂ number of case reports of delayed local reactions after vaccination ("COVID arm"). In these reports, superficial lymphocytic infiltrates were described, but no involvement of the deep dermis or subcutis. We report the case of aÂ healthy 32-year-old man with involvement of the deep dermis and subcutis after vaccination with mRNA-1273. This case is the first to show aÂ delayed Tâ€‘cell mediated reaction with aÂ deep pattern of reaction, with the dermal perivascular and periadnexal infiltrate extending from the papillary dermis into the deep reticular dermis and subcutis. The infiltrate was predominantly lymphocytic with an admixture of histiocytes and neutrophil granulocytes, scattered mast cells and sparse eosinophil granulocytes.
Rapid Quantitative Point-Of-Care Diagnostic Test for Post COVID-19 Vaccination Antibody Monitoring. Point-of-care (POC) quantification of antibody responses against SARS-CoV-2 spike protein can enable decentralized monitoring of immune responses after infection or vaccination. We evaluated a novel POC microfluidic cartridge-based device (ViroTrack Sero COVID-19 Total Ab) for quantitative detection of total antibodies against SARS-CoV-2 spike trimeric spike protein compared to standard laboratory chemiluminescence (CLIA)-based tests. Antibody responses of 101 individuals were measured on capillary blood, venous whole blood, plasma, and diluted plasma samples directly on the POC. Results were available within 7 min. As the reference, plasma samples were analyzed on DiaSorin LIAISON XL CLIA analyzer using LIAISON SARS-CoV-2 IgM, LIAISON SARS-CoV-2 S1/S2 IgG, and LIAISON SARS-CoV-2 TrimericS IgG assays. The Spearman rank's correlation coefficient between ViroTrack Sero COVID-19 Total Ab and LIAISON SARS-CoV-2 S1/S2 IgG and LIAISON SARS-CoV-2 TrimericS IgG assays was found to be 0.83 and 0.89, respectively. ViroTrack Sero COVID-19 Total Ab showed high correlation between the different matrixes. Agreement for determination of samples of >230 binding antibody units (BAU)/mL on POC and CLIA methods is estimated to be around 90%. ViroTrack Sero Covid Total Ab is a rapid and simple-to-use POC test with high sensitivity and correlation of numerical results expressed in BAU/mL compared to those of a commercial CLIA assay. IMPORTANCE Serological testing is an important diagnostic support tool in the fight against COVID-19. So far, serological testing has been performed on either lateral flow assays, which perform only qualitatively and can be difficult for the individual to read, or standard laboratory assays, which are time- and resource-consuming. The purpose of the study was to evaluate the performance of a new POC microfluidic cartridge-based device based on immunomagnetic agglutination assay that can provide an accurate numerical quantification of the total antibodies within only 7 min from a single drop of capillary blood. We demonstrated a high level of correlation between the POC and the two CLIA laboratory-based immunoassays from Diasorin, thus allowing a potentially wider use of quantitative serology tests in the COVID-19 pandemic.
Serum Neutralization of SARS-CoV-2 Omicron BA.1 and BA.2 after BNT162b2 Booster Vaccination. The SARS-CoV-2 Omicron variant BA.2 sublineage is rapidly replacing earlier Omicron lineages, suggesting BA.2 has increased vaccine evasion properties. We measured neutralization titers of authentic BA.1 and BA.2 isolates in serum samples from persons who received the BNT162b2 booster vaccine. All samples neutralized BA.1 and BA.2 at equal median values.
Severe Aplastic Anemia After Receiving SARS-CoV-2 Moderna mRNA Vaccination. A 60-year-old male patient presented to the emergency department with complaints of easy bruising and

worsening epistaxis after receiving severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Moderna mRNA vaccination. He had no personal or family history of hematological conditions. He had bruises in various stages involving the upper and lower extremities. Laboratory data revealed white blood cell count of 1.2 Ã—10(3)/mm(3), hemoglobin of 8.0 g/dL, platelet count of 1 Ã—10(3)/mm(3), immature platelet fraction of 0.7%, absolute neutrophil count of 0 Ã—10(3)/ÂµL, lymphocytes of 1.1 Ã—10(3)/ÂµL, neutrophils of 3% and lymphocytes of 93%. He had normal liver and renal function tests. Bone marrow biopsy confirmed very severe aplastic anemia with severely hypocellular bone marrow. His platelets continued to downtrend despite platelet transfusions and steroids. He was treated with immunosuppressive therapy with cyclosporine, anti-thymocyte globulin, eltrombopag and prednisone. The patient was discharged but was readmitted to the hospital secondary to recurrent neutropenic fever and pneumonia. He had high-grade vancomycin-resistant enterococcal infection and Clostridium difficile infection leading to septic shock and succumbing to cardiac arrest. This case demonstrates the possibility of very severe aplastic anemia following SARS-CoV-2 mRNA vaccination and clinicians need to be aware of this rare but serious side effect.

Intussusception in the setting of severe acute respiratory syndrome coronavirus 2 infection following rotavirus vaccination. Most cases of intussusception are thought to be idiopathic, related to viral infections, structural abnormalities, or certain vaccinations. In this report, we present the development of intussusception in a pediatric patient who was coronavirus 2019 (COVID-19) positive. Although the most common gastrointestinal symptoms of COVID-19 virus are diarrhea and vomiting, there recently have been rare case reports of intussusception in patients throughout the world who are severe acute respiratory syndrome coronavirus 2 positive. This case is only the second known report in the United States and the second case reported globally that required surgical intervention for definitive management.

Novel Synthetic Lipopeptides as Potential Mucosal Adjuvants Enhanced SARS-CoV-2 rRBD-Induced Immune Response. As TLR2 agonists, several lipopeptides had been proved to be candidate vaccine adjuvants. In our previous study, lipopeptides mimicking N-terminal structures of the bacterial lipoproteins were also able to promote antigen-specific immune response. However, the structure-activity relationship of lipopeptides as TLR2 agonists is still unclear. Here, 23 synthetic lipopeptides with the same lipid moiety but different peptide sequences were synthesized, and their TLR2 activities in vitro and mucosal adjuvant effects to OVA were evaluated. LP1-14, LP1-30, LP1-34 and LP2-2 exhibited significantly lower cytotoxicity and stronger TLR2 activity compared with Pam(2)CSK(4), the latter being one of the most potent TLR2 agonists. LP1-34 and LP2-2 assisted OVA to induce more profound specific IgG in sera or sIgA in BALF than Pam(2)CSK(4). Furthermore, the possibility of LP1-34, LP2-2 and Pam(2)CSK(4) as the mucosal adjuvant for the SARS-CoV-2 recombinant RBD (rRBD) was investigated. Intranasally immunized with rRBD plus either the novel lipopeptide or Pam(2)CSK(4) significantly increased the levels of specific serum and respiratory mucosal IgG and IgA, while rRBD alone failed to induce specific immune response due to its low immunogenicity. The novel lipopeptides, especially LP2-2, significantly increased levels of rRBD-induced SARS-CoV-2 neutralizing antibody in sera, BALF and nasal wash. Finally, Support vector machine (SVM) results suggested that charged residues in lipopeptides might be beneficial to the agonist activity, while lipophilic residues might adversely affect the agonistic activity. Figuring out the relationship between peptide sequence in the lipopeptide and its TLR2 activity may lay the foundation for the rational design of novel lipopeptide adjuvant for COVID-19 vaccine.

SARS-CoV-2 Humoral and Cellular Immune Responses of Patients With HIV After Vaccination With BNT162b2 mRNA COVID-19 Vaccine in the Tel-Aviv Medical Center. BACKGROUND: Little is known about vaccine efficacy and sustainability among people with HIV (PWH). We estimated

humoral and cellular immune responses postvaccination with BNT162b2 mRNA coronavirus disease 2019 (COVID-19) vaccine among PWH in Tel-Aviv Medical Center. METHODS: The vaccine humoral response was evaluated by measuring immunoglobulin G (IgG) titers of antispike receptor-binding domain antibodies (anti-RBD IgG). Cellular response was assessed by stimulating donor peripheral blood mononuclear cells with pooled complete S-peptide mix. RESULTS: One hundred thirty-six PWH who completed 2 doses of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine were tested for anti-RBD IgG and compared with 61 vaccinated health care workers (HCWs). The antibody titers were similar between the groups (median, 118 BAU/mL for PWH and 101.4 BAU/mL for HCWs; Pâ€…=â€….231), although the mean time from second vaccine was 4.5 months in PWH and 6.7 months in HCWs (Pâ€…<â€….0001). Longer time from second vaccine dose was associated with decreased antibody level, as were CD4 counts <300 cells/ÂµL compared with higher CD4 counts (25.1 BAU/mL vs 119.3 BAU/mL, respectively; Pâ€…=â€….047). There was no difference in cellular immune response between vaccinated PWH, convalescent unvaccinated PWH, and vaccinated HCWs. CONCLUSIONS: The humoral immune response of PWH was comparable to that of HCWs after BNT162b2 mRNA vaccination. Cellular immune response did not differ between vaccinated PWH, convalescent PWH, and vaccinated HCWs. PWH with CD4 counts <300 cells/ÂµL (nâ€…=â€…9) had lower antibody titers compared with patients with counts >300 cells/ÂµL (nâ€…=â€…127).

Humoral immune response in healthcare workers after two doses of a BNT162b2 mRNA vaccine in Yucatan, Mexico. The antibody response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as well as the host immune response after vaccination and viral infection have shown to be highly heterogeneous. This is a case series study analysing humoral immune response and vaccination side effects after two doses of a BNT162b2 mRNA among healthcare workers (HCWs) in Mexico. All participants were scheduled for their two doses of mRNA BNT162b2 vaccine and provided information through a questionnaire: demographic characteristics, antibody serum titres and vaccination-related side effects. Blood samples were obtained for serology testing after the first and second doses of vaccine. No serious adverse effects due to vaccination were reported; nonetheless, non-medical HCWs reported more side effects after the second dose. The previous infection with SARS-CoV-2 boosted immune response after receiving the first vaccination (roughly 30 times higher than those without previous infection); nonetheless, after the second dose, the immune response did not show a higher titre as might be expected.

COVID-19 association with purpura fulminans: report of a life threatening complication in a fully vaccinated patient. SARS-CoV-2 manifestations have been an ongoing evolving topic that has spread beyond its initial respiratory associations. Recently, there have been reports of COVID-19 infections found to be associated with vascular pathologies. Here, we describe a case of a fully vaccinated COVID-19 adult male with past medical history of purpura fulminans that presented with diffuse necrotic cutaneous tissue sequelae resulting in intensive care unit management and dry gangrene of upper extremity. On admission, it was found that the patient had decreased activity rather than quantity of coagulation pathway protein S. Early recognition and work up are essential in patients with known history of vascular disease and confirmed cases of SARS-CoV-2 positive polymerase chain reaction.

Acute disseminated encephalomyelitis (ADEM) after SARS- CoV-2 vaccination: A case report. Acute disseminated encephalomyelitis (ADEM) is an acute demyelinating disorder of the central nervous system that is ordinarily monophasic. ADEM can develop following infection or vaccination. Here, we present a 37 y/o male patient with progressive muscle weakness in all limbs along with dysphagia following COVID-19 vaccination. Brain magnetic resonance imaging (MRI) revealed typical imaging findings which presented as multifocal T2-FLAIR signal changes in the corticospinal tract, pons, and temporal lobe with diffusion restriction. Magnetic resonance spectroscopy (MRS) further

confirmed the diagnosis by the typical elevation of the Choline and Myoinositol peaks. Neurologic impairments have been reported as the potential side effects of COVID-19 vaccines. Appropriate imaging modalities together with a thorough clinical examination are essential for making a correct diagnosis.
Dermatomyositis following COVID-19 vaccination.
Effectiveness and safety of SARS-CoV-2 vaccine in Inflammatory Bowel Disease patients: a systematic review, meta-analysis and meta-regression. INTRODUCTION: There are concerns regarding the effectiveness and safety of SARS-CoV-2 vaccine in inflammatory Bowel Disease (IBD) patients. This systematic review and meta-analysis comprehensively summarises the available literature regarding the safety and effectiveness of SARS-CoV-2 vaccine in IBD. METHODS: Three independent reviewers performed a comprehensive review of all original articles describing the response of SARS-CoV-2 vaccines in patients with IBD. Primary outcomes were (1) pooled seroconversion rate SARS-CoV-2 vaccination in IBD patients (2) comparison of breakthrough COVID-19 infection rate SARS-CoV-2 vaccination in IBD patients with control cohort and (3) pooled adverse event rate of SARS-CoV-2 vaccine. All outcomes were evaluated for one and two doses of SARS-CoV-2 vaccine. Meta-regression was performed. Probability of publication bias was assessed using funnel plots and with Egger's test. RESULTS: Twenty-one studies yielded a pooled seroconversion rate of 73.7% and 96.8% in IBD patients after one and two doses of SARS-CoV-2 vaccine respectively. Sub-group analysis revealed non-statistically significant differences between different immunosuppressive regimens for seroconversion. Meta-regression revealed that the vaccine type and study location independently influenced seroconversion rates. There was no statistically significant difference in breakthrough infection in IBD patients as compared to control after vaccination. CONCLUSION: In summary, the systematic review and meta-analysis suggest that SARS-CoV-2 vaccine is safe and effective in IBD patients.
Acute Coronary Syndrome After Inactivated SARS-COV-2 Vaccine. CoronaVac is an inactivated coronavirus disease (COVID-19) vaccine that was granted an emergency authorization by the World Health Organization in June 2021. We present the two cases of patients presenting with chest pain, abnormal electrocardiography, and elevated troponin consistent with non-ST-elevation myocardial infarction within 24 hours after receiving the CoronaVac COVID-19 vaccine.
Serological Screening of Immunoglobulin G against SARS-CoV-2 Nucleocapsid and Spike Protein before and after Two Vaccine Doses among Healthcare Workers in Japan. This study sought to evaluate the effects of two vaccine doses and the extent of SARS-CoV-2 infection among healthcare workers. We measured immunoglobulin G antibody titers against SARS-CoV-2 nucleocapsid and spike protein among healthcare workers at Gunma University Hospital. In March 2021, prior to BNT-162b2 vaccination, two of 771 participants were seropositive for nucleocapsid and spike protein, whereas 768 were seronegative. The remaining one participant was seropositive for nucleocapsid protein but seronegative for spike protein. A total of 769 participants were seropositive for spike protein after two vaccination doses. The two seropositive participants prior to vaccination showed the highest antibody titers after the second vaccination. They were probably infected with SARS-CoV-2 without clinical symptoms before March 2021. Four weeks after the second vaccination, a younger age was associated with higher antibody titers against SARS-CoV-2 spike protein. Thirty-two weeks after the second vaccination, blood samples were collected from 342 of 769 participants. Antibody titers at 32 weeks after the second vaccination significantly decreased compared with those at 4 weeks after the second vaccination among all age groups. The rate of decrease in antibody titers between 4 and 32 weeks after the second vaccination was greater in the female participants. No sex differences were observed in the antibody titers within each age group. BNT-162b2 vaccination thus induced

seroconversion in an age-dependent manner. Serological screening could further establish the likelihood of subclinical SARS-CoV-2 infection.

Vaccination-associated immune thrombocytopenia possibly due to ChAdOx1 nCoV-19 (Covishield) coronavirus vaccine. Immune thrombocytopenia (ITP) is an acquired haemorrhagic diathesis of immune-mediated destruction, impaired production or increased splenic sequestration of platelets. It can be idiopathic (primary) or secondary (infections, medications, HIV infection, malignancies, connective tissue diseases or rarely secondary to vaccination). ITP postvaccination is termed vaccine-associated ITP (VITP) and is known to be caused by vaccines against various infectious agents such as measles-mumps-rubella, Haemophilus influenzae, pneumococcus, hepatitis B virus and human papilloma virus. Cases of VITP post SARS-CoV-2 vaccination have also been reported in the literature. Various hypotheses on the occurrence of the same are theorised, but no single theory has been proven to cause VITP conclusively. Management includes routine treatment of ITP with use of agents such as steroids, intravenous immunoglobulins, or on rare occasions a thrombopoietic agent or vinca alkaloids. We present a case of VITP possibly due to ChAdOx1 nCoV-19 (Covishield) vaccination in a middle-aged woman who responded to steroid therapy.

Multisystem inflammatory syndrome in children (MIS-C) possibly secondary to COVID-19 mRNA vaccination. Multisystem inflammatory syndrome in children (MIS-C) associated with COVID-19 is a postinfectious condition identified during the COVID-19 pandemic with specific Centers for Disease Control and Prevention and WHO criteria. Theoretical concerns have been raised whether MIS-C might also occur after COVID-19 vaccination, as the pathogenesis of MIS-C is not yet entirely understood. We present a woman in her late teens who developed MIS-C after having received two doses of Pfizer BioNTech COVID-19 vaccine 12 weeks prior, in the setting of documented anti-spike SARS-CoV-2 IgG positive, antinucleocapsid SARS-CoV-2 IgG negative, and multiple negative surveillance SARS-CoV-2 PCRs done in the 12-week period prior to development of MIS-C. While vaccination remains safe and critical in controlling the pandemic, it may be considered as a potential trigger for MIS-C in patients with no history of infection. Further surveillance is necessary to determine whether MIS-C will emerge as a confirmed adverse event after COVID-19 vaccination.

New Onset Biopsy-Proven Nephropathies after COVID Vaccination. INTRODUCTION: To date, almost 7 billion doses of the different types of vaccine against SARS-CoV-2 have been administered worldwide. Although the severity of new cases of SARS-CoV-2 has progressively decreased, and the pressure on national health systems has declined, the development of de novo glomerular injuries has been suggested. METHODS: This study aimed to examine the patients who were hospitalized in our Unit between April and November 2021 and underwent renal biopsy for new-onset urinary abnormalities (UA) and/or renal impairment within 3 months of SARS-CoV-2 vaccination. RESULTS: We identified 17 patients who developed UA and/or renal insufficiency within 3 months of vaccination. Minimal change disease was the most common disease in our cohort (5 patients, 29.4%) followed by acute tubulointerstitial nephritis (TIN; 3 patients, 17.6%), membranous nephropathy (3 patients, 17.6%), and rapidly progressive IgA nephropathy (2 patients, 11.8%). The other 4 patients had a diagnosis of membranoproliferative glomerulonephritis (1 patient), systemic lupus erythematosus (1 patient), ANCA-associated vasculitis (1 patient), and tip-variant focal segmental glomerulosclerosis (1 patient), respectively. Eight out of the 17 patients (47.1%) developed acute kidney injury. Two patients with acute TIN had to start hemodialysis that was discontinued after 1 and 2 months, respectively, due to the recovery of renal function. All patients underwent treatment with corticosteroids and/or immunosuppressants. DISCUSSION: Although it is not possible to conclusively determine whether there is a causal relationship between SARS-CoV-2 vaccination and new-onset nephropathies, based on the appearance of UA and/or renal insufficiency shortly after vaccination, we hypothesize that the immune response to the COVID-19 vaccine may be a trigger of

nephropathies. Therefore, our results highlight the need for pharmacovigilance. However, this report should not lead to vaccine hesitation during this pandemic as the benefits of vaccination strongly outweigh the potential risks.

Severe acute respiratory syndrome coronavirus-2 vaccine-induced B cells aspire to long-lived connections: Tracking B-cell memory over time. It is vitally important that we understand whether mRNA vaccines are capable of generating high-affinity, longlived immune memory cells to SARS-CoV-2. To this end, a recent study by Ellebedy, Kim and colleagues provide much-needed insight into the production and quality of humoral immune cells generated by the BNT162b2 vaccine.

Persistent Cardiac Magnetic Resonance Imaging Findings in a Cohort of Adolescents with Post-Coronavirus Disease 2019 mRNA Vaccine Myopericarditis. We describe the evolution of cardiacÂ magnetic resonance imaging findings in 16 patients, aged 12-17Â years, with myopericarditis after the second dose of the Pfizer mRNA coronavirus disease 2019 vaccine. Although all patients showed rapid clinical improvement, many had persistent cardiac magnetic resonance imaging findings at 3- to 8-month follow-up.

Factors Associated With Parental COVID-19 Vaccination Acceptance. As the coronavirus pandemic continues to impact families and children, understanding parental attitudes and likely acceptance of the COVID-19 vaccine is essential. We conducted a statewide survey with a representative sample of parents in Tennessee focused on COVID-19 and influenza vaccine acceptance and perspectives. Data from 1066 parents were analyzed using weighted survey methods to generalize results to the state of Tennessee. About 53% of parents reported a likelihood to vaccinate their children against COVID-19, and 45% were likely to vaccinate their child against COVID-19 and influenza. Female parents were less likely to vaccinate their children against COVID-19, but the strongest predictor of likely COVID-19 vaccine acceptance was influenza vaccine acceptance (adjusted odds ratio = 5.46; 95% confidence interval: 3.20-9.30). Parental acceptance of COVID-19 vaccines for children is closely tied to influenza vaccine acceptance. Public health approaches to maximize vaccine uptake could focus on children who have not been receiving influenza vaccines.

Evasion of vaccine-induced humoral immunity by emerging sub-variants of SARS-CoV-2. Background: Emergence of vaccine-escaping SARS-CoV-2 variants is a serious problem for global public health. The currently rampant Omicron has been shown to possess remarkable vaccine escape; however, the selection pressure exerted by vaccines might pave the way for other escape mutants in the near future. Materials & methods: For detection of neutralizing antibodies, the authors used the recently developed HiBiT-based virus-like particle neutralization test system. Sera after vaccination (two doses of Pfizer/BioNTech mRNA vaccine) were used to evaluate the neutralizing activity against various strains of SARS-CoV-2. Results: Beta+R346K, which was identified in the Philippines in August 2021, exhibited the highest vaccine resistance among the tested mutants. Surprisingly, Mu+K417N mutant exhibited almost no decrease in neutralization. Imdevimab retained efficacy against these strains. Conclusions: Mutations outside the receptor-binding domain contributed to vaccine escape. Both genomic surveillance and phenotypic analysis synergistically accelerate identifications of vaccine-escaping strains.

 Prior to the Omicron variant, the SARS-CoV-2 Beta sub-variant found in the Philippines in August 2021 exhibited remarkable vaccine-escaping capacity. Although Omicron is, at the time of writing, causing most of the infections globally, both genomic surveillance and phenotypic analysis should be reinforced to accelerate the identification of newly emerging vaccine-escaping SARS-CoV-2 variants.

Evaluation of menstrual irregularities after COVID-19 vaccination: Results of the MECOVAC survey. We investigated menstrual irregularities after the first and second doses of the COVID-19 vaccine. Women answered a customised online questionnaire (ClinicalTrial.gov ID: NCT05083065) aimed to assess the vaccine type, the phase of the menstrual cycle during which the vaccine was administered,

the occurrence of menstrual irregularities after the first and second doses, and how long this effect lasted. We excluded women with gynaecological and non-gynaecological diseases, undergoing hormonal and non-hormonal treatments, in perimenopause or menopause, as well as those who had irregular menstrual cycles in the last 12 months before vaccine administration. According to our data analysis, approximately 50-60% of reproductive-age women who received the first dose of the COVID-19 vaccine reported menstrual cycle irregularities, regardless of the type of administered vaccine. The occurrence of menstrual irregularities seems to be slightly higher (60-70%) after the second dose. Menstrual irregularities after both the first and second doses of the vaccine were found to self-resolve in approximately half the cases within two months. Based on these results, we suggest to consider these elements during the counselling of women who receive the COVID-19 vaccine, letting them know about the potential occurrence of temporary and self-limiting menstrual cycle irregularities in the subsequent month(s).

Parsonage-Turner Syndrome Following COVID-19 Vaccination: Clinical and Electromyographic Findings in 6 Patients. Parsonage-Turner syndrome (PTS) following COVID-19 infection or vaccination is rare. The pathophysiology may involve an immune-mediated inflammatory reaction against brachial plexus nerve fibers in a genetically predisposed individual. We describe the clinical and electromyographic features of 6 patients presenting with the clinical picture of PTS following COVID-19 vaccination. All patients were referred for electromyographic studies to evaluate the acute onset of pain in the shoulder girdle/upper limb accompanied by muscle weakness in the distribution of one or more branches of the brachial plexus. Each patient had received the COVID-19 vaccine within a few weeks prior to the onset of symptoms. Patients underwent detailed neurological examinations followed by nerve conduction and EMG studies. The patients developed symptoms after a mean duration of 17 days (5 days-8 weeks) after receiving the COVID-19 vaccine. The initial symptom was pain in the shoulder girdle/upper limb, followed within days by muscle weakness. Physical examinations and EMG studies showed upper trunk brachial plexopathy in 2 patients, lower trunk plexopathy in 1 patient, posterior cord brachial plexopathy in 1 patient, and anterior/posterior interosseous nerve involvement in 2 patients. All patients either improved or attained complete resolution of the arm pain at follow-up. Three (50%) patients did not have any improvement in the arm/hand weakness, while 3 (50%) patients had some recovery in strength. PTS may occur after the COVID-19 vaccine and should be suspected in patients with symptoms and signs suggestive of acute brachial plexopathy. Studies of a larger series may provide insight into predisposing factors.

People with HIV receiving suppressive antiretroviral therapy show typical antibody durability after dual COVID-19 vaccination, and strong third dose responses. BACKGROUND: Longer-term humoral responses to two-dose COVID-19 vaccines remain incompletely characterized in people living with HIV (PLWH), as do initial responses to a third dose. METHODS: We measured antibodies against the SARS-CoV-2 spike protein receptor-binding domain, ACE2 displacement and viral neutralization against wild-type and Omicron strains up to six months following two-dose vaccination, and one month following the third dose, in 99 PLWH receiving suppressive antiretroviral therapy, and 152 controls. RESULTS: Though humoral responses naturally decline following two-dose vaccination, we found no evidence of lower antibody concentrations nor faster rates of antibody decline in PLWH compared to controls after accounting for sociodemographic, health and vaccine-related factors. We also found no evidence of poorer viral neutralization in PLWH after two doses, nor evidence that a low nadir CD4+ T-cell count compromised responses. Post-third-dose humoral responses substantially exceeded post-second-dose levels, though anti-Omicron responses were consistently weaker than against wild-type.Nevertheless, post-third-dose responses in PLWH were comparable to or higher than controls. An mRNA-1273 third dose was the strongest consistent correlate of higher post-third-dose responses. CONCLUSION: PLWH receiving suppressive antiretroviral therapy mount strong

antibody responses after two- and three-dose COVID-19 vaccination. Results underscore the immune benefits of third doses in light of Omicron.
COVID-19 vaccine and autoimmune diabetes in adults: report of two cases.
Development of severe pemphigus vulgaris following ChAdOx1 nCoV-19 vaccination and review of literature. Vaccines are indeed a boon for tackling the present COVID-19 pandemic. In India, ChAdOx1 nCoV-19 (Covishield) is the most commonly used vaccine in the government vaccination program for adults more than 18Â years of age. It is a recombinant vaccine developed by Oxford-Astra Zeneca and manufactured in India by Serum Institute of India (SSI). Here, we report a case of severe pemphigus vulgaris following the second dose of ChAdOx1 nCoV-19 vaccination in an adult male. The patient developed septicemia during the course of hospital stay, and he was managed with systemic steroids, parenteral antibiotics, and intravenous immunoglobulins (IVIg) along with proper wound care. Patient started improving within 1Â month of therapy. This case is being reported in view of the rarity of pemphigus vulgaris following ChAdOx1 nCoV-19 vaccine.
Influence of the Coronavirus Disease 2019 Vaccine on Drug Therapy for Urological Cancer. BACKGROUND/AIM: We investigated whether coronavirus disease 2019 (COVID-19) vaccination and its adverse events would cause cancer treatment of patients with urological cancer to be postponed or changed. PATIENTS AND METHODS: We collected COVID-19 vaccination information including adverse events from the medical records of 214 patients with urological cancer receiving cancer drug therapy. RESULTS: The cancer types were renal cancer in 40 cases (18.7%), upper urinary tract cancer in 10 cases (4.7%), bladder cancer in 21 cases (9.8%), prostate cancer in 140 cases (65.4%), and others in 3 cases (1.4%). Of the 214 patients, 178 (83.2%) had received the second dose of the vaccine. Out of 180 vaccinated patients, some adverse events were observed in 69 (38.3%). Vaccination rates for males and females were 85.4% (169/198) and 68.8% (11/16), respectively, and were not significantly different (p=0.081). The incidence of adverse events was significantly higher in females [72.7% (8/11)] than in males [36.1% (61/169)]; p=0.015. Treatment was modified in 11 vaccinated patients; postponed or changed at the discretion of the attending physician in 8 cases, skipped at the discretion of the patient in 1 case, and postponed due to side effects of the immune checkpoint inhibitor in 1 case. Treatment for one patient with upper urinary tract cancer on pembrolizumab was postponed for three weeks due to adverse events of the vaccine. CONCLUSION: Only 0.6% of the adverse events of the vaccine required postponement of treatment, suggesting that vaccination is safe even during cancer drug therapy.
Rare Hypersensitivity Myocardial Reactions Following COVID-19 Vaccination: Hypersensitivity Myocardial Infarction (Kounis Syndrome) and Hypersensitivity Myocarditis.
Unwillingness or reluctance of Palestinians to get the COVID-19 vaccine: the reasons behind it and how to persuade them. OBJECTIVES: A brief discussion with policy leaders and citizens was conducted to understand the unwillingness of people to get the COVID-19 vaccine and their suggestions to increase the vaccination level. BACKGROUND: Despite the crucial benefits of the COVID-19 vaccine, people are unwilling to get vaccinated. Vaccine hesitancy is a significant problem globally. In Palestine, at the time of this study only about 30% of the population were vaccinated. METHODS: We used a descriptive qualitative design with semistructured interviews. DISCUSSION: The unwillingness of Palestinian people to get the COVID-19 vaccine was attributed to the spread of false rumours, misinformation, and conspiracy theories they received about the vaccine on the social media and mistrust towards vaccines the government purchased. There is a dire need to develop motivational strategies (i.e., incentives) and reconsider the media discourse and its unification to encourage people to get the vaccines. Social media and professionals should report the benefits/effectiveness of vaccination and avoid exaggerating its' side-effects.

IgG antibody production and persistence to 6Â months following SARS-CoV-2 vaccination: A Northern Ireland observational study. BACKGROUND: This study evaluates spike protein IgG antibody response following Oxford-AstraZeneca COVID-19 vaccination using the AbC-19â„¢ lateral flow device. METHODS: Plasma samples were collected from nÂ =Â 111 individuals from Northern Ireland. The majority were >50Â years old and/or clinically vulnerable. Samples were taken at five timepoints from pre-vaccination until 6-months post-first dose. RESULTS: 20.3% of participants had detectable IgG responses pre-vaccination, indicating prior COVID-19. Antibodies were detected in 86.9% of participants three weeks after the first vaccine dose, falling to 74.7% immediately prior to the second dose, and rising to 99% three weeks post-second vaccine. At 6-months post-first dose, this decreased to 90.5%. At all timepoints, previously infected participants had significantly higher antibody levels than those not previously infected. CONCLUSION: This study demonstrates that strong anti-spike protein antibody responses are evoked in almost all individuals that receive two doses of Oxford-AstraZeneca vaccine, and which largely persist beyond six months after first vaccination.

Effect of gender, age and vaccine on reactogenicity and incapacity to work after COVID-19 vaccination: a survey among health care workers. BACKGROUND: The aim of our study was to assess the impact the impact of gender and age on reactogenicity to three COVID-19 vaccine products: Biontech/Pfizer (BNT162b2), Moderna (mRNA-1273) and AstraZeneca (ChAdOx). Additional analyses focused on the reduction in working capacity after vaccination and the influence of the time of day when vaccines were administered. METHODS: We conducted a survey on COVID-19 vaccinations and eventual reactions among 73,000 employees of 89 hospitals of the Helios Group. On May 19th, 2021 all employees received an email, inviting all employees who received at least 1 dose of a COVID-19 to participate using an attached link. Additionally, the invitation was posted in the group's intranet page. Participation was voluntary and non-traceable. The survey was closed on June 21st, 2021. RESULTS: 8375 participants reported on 16,727 vaccinations. Reactogenicity was reported after 74.6% of COVID-19 vaccinations. After 23.0% vaccinations the capacity to work was affected. ChAdOx induced impairing reactogenicity mainly after the prime vaccination (70.5%), while mRNA-1273 led to more pronounced reactions after the second dose (71.6%). Heterologous prime-booster vaccinations with ChAdOx followed by either mRNA-1273 or BNT162b2 were associated with the highest risk for impairment (81.4%). Multivariable analyses identified the factors older age, male gender and vaccine BNT162b as independently associated with lower odds ratio for both, impairing reactogenicity and incapacity to work. In the comparison of vaccine schedules, the heterologous combination ChAdOxâ€‰+â€‰BNT162b or mRNA-1273 was associated with the highest and the homologue prime-booster vaccination with BNT162b with the lowest odds ratios. The time of vaccination had no significant influence. CONCLUSIONS: Around 75% of the COVID-19 vaccinations led to reactogenicity and nearly 25% of them led to one or more days of work loss. Major risk factors were female gender, younger age and the administration of a vaccine other than BNT162b2. When vaccinating a large part of a workforce against COVID-19, especially in professions with a higher proportion of young and women such as health care, employers and employees must be prepared for a noticeable amount of absenteeism. Assuming vaccine effectiveness to be equivalent across the vaccine combinations, to minimize reactogenicity, employees at risk should receive a homologous prime-booster immunisation with BNT162b2. TRIAL REGISTRATION: The study was approved by the Ethic Committee of the Aerztekammer Berlin on May 27th, 2021 (Eth-37/21) and registered in the German Clinical Trials Register (DRKS 00025745). The study was supported by the Helios research grant HCRI-ID 2021-0272.

Neutralization of SARS-CoV-2 Omicron after vaccination of patients with myelodysplastic syndromes or acute myeloid leukemia.

Outcomes After SARS-CoV-2 Vaccination Among Children With a History of Multisystem Inflammatory Syndrome. This case series evaluates the outcomes following COVID-19 vaccination in patients previously diagnosed with multisystem inflammatory syndrome in children at childrenâ€™s hospitals in Texas and Italy.
[A rare case of myocarditis and pulmonary embolism after BNT162b2 mRNA vaccine]. In the clinical research arsenal, the COVID-19 vaccines are the strongest weapons against the most important worldwide sanitary crisis of the last centuries. Even if vaccine adverse events have mild clinical relevance, several thromboembolic events occurring after adenoviral recombinant vaccine administration have been reported. Cases of myocarditis and pericarditis after administration of mRNA vaccines have also recently been described. We report the case of a patient who suffered from two rare adverse events after BNT162b2 mRNA vaccine administration (Pfizer-BioNTech): acute myocarditis and pulmonary embolism. Although the temporal consequentiality does not demonstrate a causal link, the strong analogies emerging in the latest clinical reports suggest a possible relation. Further studies are needed to understand the potential mechanisms of myocardial damage and atypical thrombosis. Despite the favorable and self-limiting clinical course of post-vaccinal myocarditis, in these cases a tight follow-up is advisable and vaccine adverse event reporting remains mandatory, especially if not described during pivotal clinical trials.
Comment on ""Multi inflammatory syndrome following first dose of m-RNA COVID-19 vaccination".
COVID-19 Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) and Cerebral Venous Sinus Thrombosis (CVST)- Lessons for India. The COVID-19 pandemic evolved rapidly, overwhelming health care systems around the world. The cost to life and socioeconomic burden prompted a search for new treatments and vaccines. Several collaborations developed and could deliver state-of-the-art vaccines with acceptable efficacy and safety in record time. Recently, vaccination with Oxford-AstraZeneca and Johnson and Johnson vaccines was halted due to the reported adverse effects of vaccine-induced immune thrombotic thrombocytopenia (VITT) and cerebral venous sinus thrombosis (CVST). Although a detailed risk-benefit analysis led to their reinstitution, physicians across the world are still trying to understand the pathophysiology and mechanisms of these neurological adverse effects in order to better identify, diagnose, and treat them. One of the mechanisms that have been implicated is related to the adenovirus-based vector of these vaccines. COVISHIELD, which is the most widely administered vaccine in India, also shares the same vector. As India enters the next phase of vaccine distribution for younger adults, there are chances that such adverse effects may emerge. In this review, we analyze the temporary suspension of the administration of the vaccines due to VITT/CVST, summarize the existing guidelines about diagnosis and treatment of these neurological disorders as well as the need for increasing pharmacovigilance and awareness among physicians. Screening for potential risk factors, avoiding aggravating factors like dehydration, and providing choices in vaccinating the high-risk populations could help in avoiding these rare but potentially fatal adverse outcome.
Sensory Ataxic Guillain-BarrÃ© Syndrome with Dysgeusia after mRNA COVID-19 Vaccination. Guillain-BarrÃ© syndrome (GBS) has occasionally occurred in people who have received coronavirus disease 2019 (COVID-19) vaccines. Dysgeusia is rare symptom of GBS. We herein report a rare case of sensory ataxic GBS with dysgeusia just after the second dose of the Pfizer-BioNTech COVID-19 vaccine. Although autoantibodies against glycolipids were not detected, immunotherapy with intravenous immunoglobulin and methylprednisolone pulse therapy effectively ameliorated the symptoms. Our report suggests that the COVID-19 vaccine may induce various clinical subtypes of GBS, including a rare variant with sensory ataxia and dysgeusia.
Polymyalgia Rheumatica Following COVID-19 Vaccination. We herein report a 71-year-old woman presented with a fever, arthralgia, general malaise and leg muscle stiffness following

administration of the COVID-19 mRNA vaccine (Comirnaty, Pfizer-BioNTech). Laboratory findings showed an elevated C-reactive protein level and erythrocyte sedimentation rate. In addition, Gallium-67 scintigraphy demonstrated an increased uptake in multiple joints. Typing of human leukocyte antigen (HLA) revealed the presence of the DRB1*0404/*0803 allele. These findings met the diagnostic criteria for polymyalgia rheumatica (PMR), and when we started steroid treatment, her symptoms improved rapidly. This patient developed PMR after receiving a COVID-19 mRNA vaccine (Comirnaty, Pfizer-BioNTech). This case is considered to be valuable, as the HLA-DRB1 allele was also confirmed.
A randomized clinical trial of a booster dose with low versus standard dose of AZD1222 in adult after 2 doses of inactivated vaccines. BACKGROUND: Immunogenicity of inactivated SARS-CoV-2 vaccine has waning antibody over time. With the emergence of the SARS-CoV-2 delta variant, which requires higher neutralizing antibody to prevent infection, a booster dose is needed. OBJECTIVE: To evaluate immunogenicity and reactogenicity of standard- versus low-dose ChAdOx1 nCoV-19 vaccine booster after CoronaVac in healthy adults. METHODS: A double-blinded, randomized, controlled trial of adult, aged 18-59Â years, with completion of 2-dose CoronaVac at 21-28Â days apart for more than 2Â months was conducted. Participants were randomized to receive AZD1222 (Oxford/AstraZeneca) intramuscularly; standard dose (SD, 5x10(10) viral particles) or low dose (LD, 2.5x10(10) viral particles). Surrogate virus neutralization test (sVNT) against wild type and delta variant, and anti-spike-receptor-binding-domain IgG (anti-S-RBD IgG) were compared as geometric mean ratio (GMR) at day 14 and 90 between LD and SD arms. RESULTS: From July-August 2021, 422 adults with median age of 44 (IQR 36-51) years were enrolled. The median interval from CoronaVac to AZD1222 booster was 77 (IQR 64-95) days. At baseline, geometric means (GMs) of sVNT against delta variant and anti-S-RBD IgG were 18.1%inhibition (95% CI 16.4-20.0) and 111.5 (105.1-118.3) BAU/ml. GMs of sVNT against delta variant and anti-S-RBD IgG in SD were 95.6%inhibition (95% CI 94.3-97.0) and 1975.1 (1841.7-2118.2) BAU/ml at day 14, and 89.4%inhibition (86.4-92.4) and 938.6 (859.9-1024.4) BAU/ml at day 90, respectively. GMRs of sVNT against delta variant and anti-S-RBD IgG in LD compared to SD were 1.00 (95% CI 0.98-1.02) and 0.84 (0.76-0.93) at day 14, and 0.98 (0.94-1.03) and 0.89 (0.79-1.00) at day 90, respectively. LD recipients had significantly lower rate of fever (6.8% vs 25.0%) and myalgia (51.9% vs 70.7%) compared to SD. CONCLUSION: Half-dose AZD1222 booster after 2-dose inactivated SARS-CoV-2 vaccination had non-inferior immunogenicity, yet lower systemic reactogenicity. Fractional low-dose AZD1222 booster should be considered especially in resource-constrained settings.
Polyradiculitis and encephalomyelitis in the same patient following a SARS-CoV-2 vaccination.
Systemic immune response development in Albino rats after retrograde instillation of COVID-19 vaccine to submandibular salivary gland: An experimental study. OBJECTIVE: This study aimed to investigate whether using the submandibular gland duct (SMD) as an alternative mucosal route for vaccine administration induced anti-COVID-19 specific immunity. MATERIAL AND METHODS: Forty rats were randomized equally into four groups; Group I: Rats did not receive any intervention. Group II: Rats were subjected to intramuscular (IM) injection of COVID-19 vaccine. Group III: Rats were subjected to ductal cannulation by retrograde instillation of sterile saline into right SMD. Group IV: Rats in this group who had 0.5Â ml of COVID-19 vaccine retrogradely injected into the right SMD. Subsequently, rats were examined for anti-COVID-19 specific antibodies (IgG). Also, light microscopic observation of glandular changes and immunohistochemical staining for CD20 was performed. RESULTS: The obtained results demonstrated a significant increase in anti-COVID-19 IgG levels in all rats vaccinated via intraductal immunization (group IV) compared to group II. Histologically, ectopic follicles were found within the glandular lobules of the inoculated submandibular gland (SMG) in group IV. In addition, the nearby lymph node in group IV demonstrated reactive follicle characteristics

in the form of activated secondary follicles with germinal centers (GCs). Immunohistochemically, CD20 was localized in group IV in GCs of the ectopic lymphoid tissue and the nearby lymph nodes while group I, group II, and III demonstrated negative immunoreactivity. CONCLUSION: The immune response demonstrated by intraductal SG immunization is generally more significant than that elicited by IM inoculation of the same vaccine.
Ischemic Optic Neuropathy After Administration of a SARS-CoV-2 Vaccine: A Report of 2 Cases. BACKGROUND Since the start of vaccination efforts against COVID-19, several presumed secondary ocular events have been described. We present 2 cases of non-arteritic anterior ischemic optic neuropathy (NA-AION) in patients whose symptoms appeared in the first 2 weeks after administration of the Pfizer-BioNTech COVID-19 mRNA BNT162b2/Cominarty vaccine. CASE REPORT The first patient was a 53-year-old man who presented visual field disturbance in the right eye 7 days after the first vaccine dose, and who consulted a physician 10 days after the second dose, when he experienced loss of vision in the left eye. After a full examination, bilateral anterior optic disc neuropathy was diagnosed. The second patient was a 65-year-old man who presented anterior optic disc neuropathy 12 days after his first vaccination. In both cases, arteritic origin was ruled out due to absence of systemic symptoms and because of normal levels of C-reactive protein and erythrocyte sedimentation rates. CONCLUSIONS Ischemic optic neuropathy is a rare adverse ocular secondary effect of COVID-19 vaccines. Further basic and clinical research is needed to elucidate the pathogenic mechanisms and better characterize the clinical picture of this entity.
Stroke Associated with COVID-19 Vaccines. OBJECTIVES: Development of safe and effective vaccines against coronavirus disease 2019 (COVID-19) remains the cornerstone of controlling this pandemic. However, there are increasing reports of various types of stroke including ischemic stroke, and hemorrhagic stroke, as well as cerebral venous sinus thrombosis (CVST) after COVID-19 vaccination. This paper aims to review reports of stroke associated with COVID-19 vaccines and provide a coherent clinical picture of this condition. MATERIALS AND METHODS: A literature review was performed with a focus on data from recent studies. RESULTS: Most of such patients are women under 60 years of age and who had received ChAdOx1 nCoV-19 vaccine. Most studies reported CVST with or without secondary ischemic or hemorrhagic stroke, and some with Vaccine-induced Thrombotic Thrombocytopenia (VITT). The most common clinical symptom of CVST seen after COVID-19 vaccination was headache. The clinical course of CVST after COVID-19 vaccination may be more severe than CVST not associated with COVID vaccination. Management of CVST following COVID-19 vaccination is challenging and may differ from the standard treatment of CVST. Low molecular weight heparin is commonly used in the treatment of CVST; however, it may worsen outcomes in CVST associated with VITT. Furthermore, administration of intravenous immunoglobulin and high-dose glucocorticoids have been recommended with various success rates. CONCLUSION: These contradictory observations are a source of confusion in clinical decision-making and warrant further study and development of clinical guidelines. Clinicians should be aware of clinical presentation, diagnosis, and management of stroke associated with COVID-19 vaccination.
Thrombosis patterns and clinical outcome of COVID-19 vaccine-induced immune thrombotic thrombocytopenia: A Systematic Review and Meta-Analysis. OBJECTIVES: To meta-analyse the clinical manifestations, diagnosis, treatment, and mortality of vaccine-induced immune thrombotic thrombocytopenia (VITT) after adenoviral vector vaccination. METHODS: Eighteen studies of VITT after ChAdOx1 nCoV-19 or Ad26.COV2.S vaccine administration were reviewed from PubMed, Scopus, Embase, and Web of Science. The meta-analysis estimated the summary effects and between-study heterogeneity regarding the incidence, manifestations, sites of thrombosis, diagnostic findings, and clinical outcomes. RESULTS: The incidence of total venous thrombosis after ChAdOx1 nCoV-19 vaccination was 28 (95% CI 12-52, I(2)=100%) per 100,000 doses administered. Of 664

patients included in the quantitative analysis (10 studies), the mean age of patients with VITT was 45.6 years (95% CI 43.8-47.4, I(2)=57%), with a female predominance (70%). Cerebral venous thrombosis (CVT), deep vein thrombosis (DVT)/pulmonary thromboembolism (PE), and splanchnic vein thrombosis occurred in 54%, 36%, and 19% of patients with VITT, respectively. The pooled incidence rate of CVT after ChAdOx1 nCoV-19 vaccination (23 per 100,000 person-years) was higher than that reported in the pre-pandemic general population (0.9 per 100,000 person-years). Intracranial haemorrhage and extracranial thrombosis accompanied 47% and 33% of all patients with CVT, respectively. The antiplatelet factor 4 antibody positivity rate was 91% (95% CI 88-94, I(2)=0%) and the overall mortality was 32% (95% CI 24-41, I(2)=69%), and no significant difference was observed between heparin- and non-heparin-based anticoagulation treatments (risk ratio 0.84, 95% CI 0.47-1.50, I(2)=0%). CONCLUSIONS: Patients with VITT after SARS-CoV-2 vaccination most frequently presented with CVT following DVT/PE and splanchnic vein thrombosis, and about one-third of patients had a fatal outcome. This meta-analysis should provide a better understanding of VITT and assist clinicians in identifying VITT early to improve outcomes and optimise management.

Severe immune thrombocytopenia following COVID-19 vaccination (Moderna) and immune checkpoint inhibitor. Safe and effective prophylactic vaccines are urgently needed to contain the coronavirus disease 2019 (COVID-19) pandemic. However, several vaccination-related adverse effects have been reported. Here, we report a rare case of severe immune thrombocytopenia occurring 3 days after receiving the mRNA-1273 (Moderna) COVID-19 vaccine in an Asian woman with a history of refractory lung adenocarcinoma treated with durvalumab, an immune checkpoint inhibitor. Treatment with platelet transfusion (12 units) and oral prednisolone (1 mg/kg per day) significantly improved her hemoptysis with thrombocytopenia. To the best of our knowledge, this is the first case of ITP following Moderna inoculation among Asians. This study highlights a potential adverse effect of mRNA-based COVID-19 vaccines in cancer patients receiving immune checkpoint inhibitors.

IgA nephropathy in a pediatric patient after receiving the first dose of Pfizer-BioNTech COVID-19 vaccine.

SIRVA (Shoulder Injury Related to Vaccine Administration) following mRNA COVID-19 Vaccination: Case discussion and literature review. Shoulder injury related to vaccine administration (SIRVA) is an increasingly recognised complication after vaccination and presents with significant shoulder pain and stiffness. SIRVA is thought to occur as a result of improper administration of vaccine into the subdeltoid bursa or shoulder joint. This results in an inflammatory cascade that damages the structures in the shoulder region. The incidence of SIRVA is relatively higher for influenza vaccination due its widespread administration. We present a reported case of SIRVA following a mRNA COVID-19 vaccination and review the current literature. As we embark on a worldwide scale of COVID-19 vaccination, it is of utmost important that we use proper vaccination techniques and screen patients at risk of SIRVA. This would improve the efficacy of the vaccine and improve the outcomes of the vaccination programme.

Incidence of Myocarditis after Messenger RNA Vaccine for COVID-19 in Young Male Recipients.

Safety and immunogenicity of CoronaVac in people living with HIV: a prospective cohort study. BACKGROUND: People living with HIV might have a poor or delayed response to vaccines, mainly when CD4 cell counts are low, and data concerning COVID-19 vaccines in this population are scarce. This prospective cohort study assessed the safety and immunogenicity of the inactivated SARS-CoV-2 vaccine CoronaVac in people with HIV compared with people with no known immunosuppression. METHODS: In this prospective cohort study, adults (aged â‰¥18 years) living with HIV who were regularly followed up at the University of Sao Paulo HIV/AIDS outpatient clinic in Sao Paulo, Brazil, were included in the study. Eligibility for people with HIV was independent of antiretroviral use, HIV viral load, or CD4 cell count. Adults with no known immunosuppression with CoronaVac vaccination

history were included as a control group. CoronaVac was given intramuscularly in a two-dose regimen, 28 days apart. Blood was collected before vaccine administration and 6 weeks after the second dose (day 69). Immunogenicity was assessed at baseline (day 0), before second vaccine (day 28), and 6 weeks after second vaccine dose (day 69) through SARS-CoV-2 IgG titre and seroconversion, neutralising antibody (NAb) positivity and percentage activity, and factor increase in IgG geometric mean titres (FI-GMT). We investigated whether HIV status and CD4 count (<500 or â‰¥500 cells per Î¼L) were associated with CoronaVac immunogenicity by use of multivariable models adjusted for age and sex. FINDINGS: Between Feb 9, 2021, and March 4, 2021, 776 participants were recruited. Of 511 participants included, 215 (42%) were people with HIV and 296 (58%) were people with no known immunosuppression. At 6 weeks after the second vaccine dose (day 69), 185 (91%) of 204 participants with HIV and 265 (97%) of 274 participants with no known immunosuppression had seroconversion (p=0Â·0055). 143 (71%) of 202 participants with HIV were NAb positive compared with 229 (84%) of 274 participants with no known immunosuppression (p=0Â·0008). Median IgG titres were 48Â·7 AU/mL (IQR 26Â·6-88Â·2) in people with HIV compared with 75Â·2 AU/mL (50Â·3-112Â·0) in people with no known immunosuppression (p<0Â·0001); and median NAb activity was 46Â·2% (26Â·9-69Â·7) compared with 60Â·8% (39Â·8-79Â·9; p<0Â·0001). In people with HIV who had CD4 counts less than 500 cells per Î¼L seroconversion rates, NAb positivity, and NAb activity were lower than in those with CD4 counts of at least 500 cells per Î¼L. In multivariable models for seroconversion, NAb positivity, IgG concentration, and NAb activity after a complete two-dose regimen, adjusted for age and sex, people with HIV who had CD4 counts of at least 500 cells per Î¼L and people with no known immunosuppression had higher immunogenicity than did people with HIV with CD4 counts less than 500 cells per Î¼L. No serious adverse reactions were reported during the study. INTERPRETATION: Immunogenicity following CoronaVac in people with HIV seems strong but reduced compared with people with no known immunosuppression. Our findings highlight the need for strategies to improve vaccine immunogenicity in people with HIV. FUNDING: FundaÃ§Ã£o de Amparo Ã Pesquisa do Estado de SÃ£o Paulo (FAPESP), Conselho Nacional de Desenvolvimento CientÃ-fico e TecnolÃ³gico (CNPq), and B3-Bolsa de Valores do Brasil.

Herpetic anterior uveitis following Pfizer-BioNTech coronavirus disease 2019 vaccine: two case reports. PURPOSE: To describe two cases of herpetic anterior uveitis after inoculation of the first dose of Pfizer-BioNTech coronavirus disease 2019 vaccine. METHODS: Case 1: a healthy 92-year-old Caucasian woman developed symptomatic unilateral anterior uveitis for 3 days after Pfizer-BioNTech coronavirus disease 2019 vaccination (Pfizer Inc.). The episode fully resolved with topical and oral antiviral treatment. Case 2: a previously healthy 85-year-old Caucasian woman with left hemicranial signs of herpes zoster infection, associated with herpetic keratouveitis for 3 days after Pfizer-BioNTech coronavirus disease 2019 vaccination. Treatment with topical antibiotics and both oral and topical antiherpetic medication was administered, and she recovered successfully in 5Â weeks. CONCLUSION: Clinicians should be aware of the possibility of eye inflammation in the form of herpetic reactivation after coronavirus disease 2019 vaccination.

Characterization of Serum and Mucosal SARS-CoV-2-Antibodies in HIV-1-Infected Subjects after BNT162b2 mRNA Vaccination or SARS-CoV-2 Infection. Only limited data are available regarding the immunogenicity of the BNT162b2 mRNA vaccine in HIV-1(+) patients. Therefore, we investigated the humoral immune response after BNT162b2-mRNA vaccination or SARS-CoV-2 infection in HIV-1(+) patients on antiretroviral therapy compared to HIV-1-uninfected subjects. Serum and saliva samples were analysed by SARS-CoV-2 spike-specific IgG and IgA ELISAs and a surrogate neutralization assay. While all subjects developed anti-spike IgG and IgA and neutralizing antibodies in serum after two doses of BNT162b2 mRNA vaccine, the HIV-1(+) subjects displayed significantly lower neutralizing capacity and anti-spike IgA in serum compared to HIV-1-uninfected subjects.

Serum levels of anti-spike IgG and neutralizing activity were significantly higher in vaccinees compared to SARS-CoV-2 convalescents irrespective of HIV-1 status. Among SARS-CoV-2 convalescents, there was no significant difference in spike-specific antibody response between HIV-1(+) and uninfected subjects. In saliva, anti-spike IgG and IgA antibodies were detected both in vaccinees and convalescents, albeit at lower frequencies compared to the serum and only rarely with detectable neutralizing activity. In summary, our study demonstrates that the BNT162b2 mRNA vaccine induces SARS-CoV-2-specific antibodies in HIV-1-infected patients on antiretroviral therapy, however, lower vaccine induced neutralization activity indicates a lower functionality of the humoral vaccine response in HIV-1(+) patients.
SARS-CoV-2 Vaccines during Pregnancy and Breastfeeding: A Systematic Review of Maternal and Neonatal Outcomes. (1) Objective: This systematic review summarizes current knowledges about maternal and neonatal outcomes following COVID-19 vaccination during pregnancy and breastfeeding. (2) Study design: PubMed, Cochrane Library, and the Education Resources Information Center (ERIC) were searched up to 27 October 2021. The primary outcome was to estimate how many pregnant and lactating women were reported to be vaccinated and had available maternal and neonatal outcomes. (3) Results: Forty-five studies sourcing data of 74,908 pregnant women and 5098 lactating women who received COVID-19 vaccination were considered as eligible. No major side-effects were reported, especially during the second and third trimester of pregnancy and during breastfeeding. Conversely, available studies revealed that infants received specific SARS-CoV-2 antibodies after maternal vaccination. (4) Conclusions: Vaccination against the SARS-CoV-2 virus should be recommended for pregnant women, after the pros and cons have been adequately explained. In particular, given the still limited evidence and considering that fever during the first months of gestation increases the possibility of congenital anomalies, they should be carefully counseled. The same considerations apply to breastfeeding women, also considering the immune responses that mRNA vaccines can generate in their human milk.
Stillbirth after COVID-19 in Unvaccinated Mothers Can Result from SARS-CoV-2 Placentitis, Placental Insufficiency, and Hypoxic Ischemic Fetal Demise, Not Direct Fetal Infection: Potential Role of Maternal Vaccination in Pregnancy. Stillbirth is a recently recognized complication of COVID-19 in pregnant women. Other congenitally transmitted infections from viruses, bacteria and parasites can cause stillbirth by infecting fetal organs following transplacental transmission of the agent from the maternal bloodstream. However, recent research on pregnant women with COVID-19 having stillbirths indicates that there is another mechanism of stillbirth that can occur in placentas infected with SARS-CoV-2. In these cases, viral infection of the placenta results in SARS-CoV-2 placentitis, a combination of concurrent destructive findings that include increased fibrin deposition which typically reaches the level of massive perivillous fibrin deposition, chronic histiocytic intervillositis and trophoblast necrosis. These three pathological lesions, in some cases together with placental hemorrhage, thrombohematomas and villitis, result in severe and diffuse placental parenchymal destruction. This pathology can involve greater than one-half of the placental volume, averaging 77% in the largest study of 68 cases, effectively rendering the placenta incapable of performing its function of oxygenating the fetus. This destructive placental process can lead to stillbirth and neonatal death via malperfusion and placental insufficiency which is independent of fetal infection. Fetal autopsies show no evidence that direct infection of fetal organs is contributory. Because all mothers examined have been unvaccinated, maternal vaccination may prevent viremia and consequent placental infection.
Cutaneous Complications of mRNA and AZD1222 COVID-19 Vaccines: A Worldwide Review. Because of the increasing emergence of cutaneous reactions from COVID-19 vaccines worldwide, we investigated the published reports of these complications. We searched the PubMed, Google Scholar,

and Scopus databases and the preprint server bioRxiv for articles on cutaneous complications linked to mRNA-1273 (Moderna), BNT162b2 (Pfizer-BioNTech), and AZD1222 (AstraZeneca-Oxford University) vaccines published until 30 September 2021. Eighty studies describing a total of 1415 reactions were included. Cutaneous reactions were more prevalent in females (81.6%). Delayed large local reactions were the most common complication (40.4%), followed by local injection site reactions (16.5%), zoster (9.5%), and urticarial eruptions (9.0%). Injection site and delayed large local reactions were predominantly caused by the mRNA-1273 vaccine (79.5% and 72.0%, respectively). BNT162b2 vaccination was more closely linked to distant reactions (50.1%) than mRNA-1273 (30.0%). Zoster was the most common distant reaction. Of reactions with adequate information for both vaccine doses, 58.3% occurred after the first dose only, 26.9% after the second dose only, and 14.8% after both doses. Overall, a large spectrum of cutaneous reaction patterns occurred following the COVID-19 vaccination. Most were mild and without long-term health implications. Therefore, the occurrence of such dermatologic complications does not contraindicate subsequent vaccination.

Ocular Adverse Events after Inactivated COVID-19 Vaccination in Xiamen. Aims: To report potential vaccine-induced ocular adverse events following inactivated COVID-19 vaccination (Sinopharm and Sinovac). Methods: This case series took place at a tertiary referral center in the southeast of China (Xiamen Eye Center in Fujian Province) from February 2021 to July 2021. Patients who received the first dose of inactivated COVID-19 vaccine and developed vaccine-related ocular adverse events within 10 days were included. The diagnosis of vaccine-related ocular adverse events was guided by the World Health Organization causality assessment and the Naranjo criteria. Results: Ten eyes of seven patients (two male individuals) presenting with ocular complaints following COVID-19 vaccine were included in the study. The mean (SD) age was 41.4 (9.3) years (range, 30-55 years). The mean time of ocular adverse event manifestations was 4.9 days (range, 1-10 days). Three patients were diagnosed with Vogt-Koyanagi-Harada (VKH)-like uveitis, one with multifocal choroiditis, one with episcleritis, one with iritis, and one with acute idiopathic maculopathy. Two patients received the second dose of vaccine. One patient had exacerbation of VKH, and one patient had no symptoms. An aqueous humor analysis in three patients revealed elevated proinflammatory cytokines and negative virus copy. All the patients had transient ocular disturbance and responded well to steroids. No recurrence was noted during 6 months of follow-up. Conclusions: Potential ocular adverse events should be reported to increase the awareness of the health community for timely detection and proper treatment.

Onset of Oral Lichenoid Lesions and Oral Lichen Planus Following COVID-19 Vaccination: A Retrospective Analysis of about 300,000 Vaccinated Patients. Introduction: Onset of oral lichenoid lesions (OLL) or oral lichen planus (OLP) can be rare adverse reactions to vaccines. Recently, the first solitary cases were reported after COVID-19 vaccination. The aim of the present study was to assess if an increased frequency of OLL/OLP can be found after COVID-19 vaccination within a large real-world cohort. It was assumed that the incidence of OLL/OLP was significantly higher in subjects who received COVID-19 vaccine (cohort I) compared to individuals who were not vaccinated (cohort II). Patients and Methods: Initial cohorts of 274,481 vaccinated and 9,429,892 not vaccinated patients were retrieved from the TriNetX database (TriNetX, Cambridge, Massachusetts, USA), and matched for age, gender and the frequency of use of non-steroidal anti-inflammatory drugs, beta blockers, and angiotensin-converting enzyme inhibitors. Results: After matching each cohort, we accounted for 217,863 patients. Among cohort I, 146 individuals had developed OLL/OLP within 6 days after COVID-19 vaccination (88 and 58 subjects had received mRNA- and adenovirus vector-based vaccines), whereas in cohort II, 59 patients were newly diagnosed with OLL/OLP within 6 days after having visited the clinic for any other reason. The risk of developing OLL/OLP was calculated as 0.067% vs. 0.027%, for cohorts I and II, whereby the risk difference was highly significant ($p < 0.001$; log-rank

test). RR and OR were 2.475 (95% CI = 1.829; 3.348) and 2.476 (95% CI = 1.830; 3.350), respectively. Discussion: The hypothesis was confirmed. Accordingly, the obtained results suggest that the onset of OLL/OLP is a rare adverse drug reaction to COVID-19 vaccines, especially to mRNA vaccines. Thus far, it remains unknown if specific components of the formulations cause a type IV hypersensitive reaction corresponding to OLL, or if the immune response post vaccination triggers a T cell-driven autoimmune reaction directed against the basal layer of keratinocytes of the oral mucosa in terms of OLP. Although OLL and OLP are both classified as premalignant lesions, spontaneous remission may be expected over time, at least in the case of OLL. Therefore, the presented findings should not place any limitation toward the use of COVID-19-vaccines in broad levels of the population.

Factors Influencing Level and Persistence of Anti SARS-CoV-2 IgG after BNT162b2 Vaccine: Evidence from a Large Cohort of Healthcare Workers. We aimed at evaluating quantitative IgG response to BNT162b2 COVID-19 vaccine among health care workers (HCW), and exploring the role of demographic, clinical, and occupational factors as predictors of IgG levels. On May 2021, among 6687 HCW at the largest tertiary care University-Hospital of Northwestern Italy, at a median of 15 weeks (Interquartile range-IQR 13.6â^'16.0) after second-dose, serological response was present in 99.8%. Seropositivity was >97% in all the subgroups, except those self-reporting immunodeficiency (94.9%). Overall, the median serological IgG value was 990 BAU/mL (IQR 551â^'1870), with most of subjects with previous SARS-CoV-2 infection or with shorter time lapse (2â^'8 weeks) between vaccination and serology with values in the highest quintile (>2080). At multivariable analysis, significant predictors of lower values were increasing age, male, current smoking, immunodeficiency, recent occupational contacts, and increasing time lapse from vaccination; conversely, previous infection and recent household contacts were significantly associated with higher IgG levels. Subjects with previous infection kept a very high level (around 2000 BAU/mL) up to 120 days. These results, besides supporting a high serological response up to 4â^'5 months, suggest predictive factors of faster decay of IgG levels that could be useful in tailoring vaccination strategies.

Immune Response to SARS-CoV-2 Vaccine and Following Breakthrough Omicron Infection in an Autoimmune Patient with Hashimoto's Thyroiditis, Pernicious Anemia, and Chronic Atrophic Autoimmune Gastritis: A Case Report. In healthy adults, hybrid immunity induced by prior SARS-CoV-2 infection followed by two doses of mRNA vaccination provide protection against symptomatic SARS-CoV-2 infection. However, the role of hybrid immunity in autoimmune patients against Omicron is not well documented. Here, we report a young autoimmune patient with prior infection and two doses of mRNA-1273 vaccination who was exposed to Omicron and developed a symptomatic disease. Prior to Omicron infection, the patient had strong neutralizing antibody titers against the vaccine strain, but no neutralization of Omicron. Post Omicron infection, high neutralizing titers against Omicron were observed. Furthermore, enhanced neutralizing antibody titers against other variants of concern-Alpha, Beta, Gamma, and Delta-were observed, suggesting an expansion of cross-reactive memory B-cell response by the SARS-CoV-2 Omicron infection. Autoimmune patients may require careful monitoring of immune function over time to optimize booster vaccine administration.

Fever after Vaccination against SARS-CoV-2 with mRNA-Based Vaccine Associated with Higher Antibody Levels during 6 Months Follow-Up. BACKGROUND: The effect of post-vaccination adverse events on immunogenicity is unknown. We aimed to explore relationship between post-vaccination adverse reactions and antibody levels during 6-month follow-up. METHODS: Blood was serially drawn from healthcare workers after the second dose of BNT162b2 mRNA vaccine (Day 12, 30, 60, 90, 120, 150, and 180) and anti-SARS-CoV-2 spike IgG (S-IgG) levels were measured. Following each vaccine dose, volunteers completed a questionnaire regarding adverse reactions (symptomatic vs. asymptomatic groups). RESULTS: A total of 395 subjects received the second dose of the vaccine. The main results were as follows: (i) fever after the 2nd dose was independently associated with the

median S-IgG level at all follow-up time points; (ii) significantly higher S-IgG levels were observed in the symptomatic group of patients without prior COVID-19 infection throughout the entire follow-up period; (iii) prior COVID-19 positivity resulted in higher S-IgG levels only in the asymptomatic group from Day 90 of the follow-up period; (iv) both prior COVID-19 disease with asymptomatic status and symptomatic status without prior COVID-19 infection resulted in similar S-IgG antibody levels; (v) significantly lower serum S-IgG levels were observed in smokers. CONCLUSION: Fever may play an important role in the post-vaccination immune response in the long term.

SARS-CoV-2 T-Cell Responses in Allogeneic Hematopoietic Stem Cell Recipients following Two Doses of BNT162b2 mRNA Vaccine. BACKGROUND: At variance to humoral responses, cellular immunity after anti-SARS-CoV-2 vaccines has been poorly explored in recipients of allogeneic hematopoietic stem-cell transplantation (Allo-HSCT), especially within the first post-transplant years where immunosuppression is more profound and harmful. METHODS: SARS-CoV-2 Spike protein-specific T-cell responses were explored after two doses of BNT162b2 mRNA vaccine in 45 Allo-HSCT recipients with a median time from transplant of less than 2 years by using INF-Î³ ELISPOT assay and flow-cytometry enumeration of CD4(+) and CD8(+) T lymphocytes with intracellular cytokine production of IFN-Î³ and TNF-Î±. RESULTS: A strong TNF-Î±(+) response from SARS-CoV-2-specific CD4(+) T-cells was detected in a majority of humoral responders (89%) as well as in a consistent population of non-humoral responders (40%). CONCLUSIONS: T-cells are likely to participate in protection against COVID-19 viral infection, even in the absence of detectable antibody response, especially in the first years post-transplant in Allo-HSCT recipients.

Durability of Humoral Responses after the Second Dose of mRNA BNT162b2 Vaccine in Residents of a Long Term Care Facility. Residents of long-term care facilities (LTCFs) have been dramatically hit by the COVID-19 pandemic on a global scale as older age and comorbidities pose an increased risk of severe disease and death. The aim of the study was to assess the quantity and durability of specific antibody responses to SARS-CoV-2 after the first cycle (two doses) of BNT162b2 vaccine. To achieve this, SARS-CoV-2 Spike-specific IgG (S-IgG) titers was evaluated in 432 residents of the largest Italian LTCF at months 2 and 6 after vaccination. By stratifying levels of humoral responses as high, medium, low and null, we did not find any difference when comparing the two time points; however, the median levels of antibodies halved overtime. As positive nucleocapsid serology was associated with a reduced risk of a suboptimal response at both time points, we conducted separate analyses accordingly. In subjects with positive serology, the median level of anti-S IgG slightly increased at the second time point, while a significant reduction was observed in patients without previous exposure to the virus. At month 6, diabetes alone was associated with an increased risk of impaired response. Our data provide additional insights into the longitudinal dynamics of the immune response to BNT162b2 vaccination in the elderly, highlighting the need for SARS-CoV-2 antibody monitoring following third-dose administration.

Investigation of a Cluster of Immunization Stress-Related Reactions after Coronavirus Disease 2019 (COVID-19) Vaccination, Thailand, 2021. On 28 April 2021, the investigation team of the Department of Disease Control, Ministry of Public Health, was notified of a cluster of people developing neurological symptoms following COVID-19 vaccination in a province in eastern Thailand. We conducted an investigation from 29 April to 20 May 2021 to confirm the outbreak, describe the epidemiological characteristics and identify possible risk factors. A matched case-control study was conducted. Matching factors were gender and vaccination site. A confirmed case was a person receiving COVID-19 vaccination in the province and developed at least one neurological symptom between 21 April and 20 May 2021. The rapid assessment of the vaccination cold chain system was carried out. We found a total of 36 cases out of 3920 vaccinees (attack rate = 0.92%), all cases were recovered and classified as an immunization stress-related reaction (ISRR) by the National AEFI Expert

Committee. An analytic study found that menstruation was significantly associated with ISRR (AOR = 6.84 [95%CI = 1.09-42.91]). The environmental survey suggested that the cold chain system was properly managed. Further studies on other precipitating causes of ISRR should be performed. In terms of recommendation, health providers should pay greater attention to women menstruating during and after COVID-19 immunization.

Short-Term Adverse Events and Antibody Response to the BNT162b2 SARS-CoV-2 Vaccine in 4156 Health Care Professionals. Short-term adverse events are common following the BNT162b2 vaccine for SARS-Cov-2 and have been possibly associated with IgG response. We aimed to determine the incidence of adverse reactions to the vaccine and the impact on IgG response. Our study included 4156 health-care professionals who received two doses of the BNT162b2 vaccine 21 days apart and obtained 6113 online questionnaires inquiring about adverse events. The serum response was tested in 2765 subjects 10 days after the second dose. Adverse events, most frequently a local reaction at the site of injection, were reported by 39% of subjects. Multivariate analysis showed that female sex (odds ratioâ€"ORâ€"1.95; 95% confidence intervalâ€"Clâ€"1.74âˆ'2.19; p < 0.001), younger age (OR 0.98 per year, p < 0.001), second dose of vaccine (OR 1.36, p < 0.001), and previous COVID-19 infection (OR 1.41, p < 0.001) were independently associated with adverse events. IgG response was significantly higher in subjects with adverse events (1110 AU/mLâ€"IQR 345-1630 vs. 386 AU/mL, IQR 261-1350, p < 0.0001), and the association was more pronounced in subjects experiencing myalgia, fever, and lymphadenopathy. We demonstrate that a more pronounced IgG response is associated with specific adverse events, and these are commonly reported by health care professionals after the BNT162b2 vaccine for SARS-Cov-2.

Waning Humoral Response after COVID-19 mRNA Vaccination in Maintenance Dialysis Patients and Recovery after a Complementary Third Dose. The aim of this study was to analyze the waning of anti-spike (S) antibodies after mRNA vaccination against COVID-19 in maintenance dialysis patients, and to assess the safety and effectiveness of the complementary third dose. This was a prospective, longitudinal study in which we analyzed the kinetics of antibodies up to six months after a two-dose vaccination (first protocol) in infection-naÃ¯ve dialysis patients (IN-Ds), previously infected dialysis patients (PI-Ds) and subjects without chronic kidney disease (the controls), as well as their humoral response to the third dose of the same mRNA vaccine (second protocol). The respective reduction in antibody titer after 3 and 6 months by 82.9% and 93.03% in IN-Ds (n = 109), 73.4% and 93.36% in PI-Ds (n = 32) and 75.5% and 88.8% in the controls (n = 20) was demonstrated. Consequently, a protective antibody titer above 141 BAU/mL was found in only 47.7% and 23.8% of IN-Ds after 3 and 6 months, respectively. After the third vaccine dose, a significant increase in antibody titer was observed in all groups, with increases by a factor of Ã—51.6 in IN-Ds, Ã—30.1 in the controls and Ã—8.4 in PI-Ds. The median antibody titer after the third dose differed significantly between groups, and was the highest in PI-Ds: PI-Ds, 9090 (3300âˆ'15,000) BAU/mL; the controls, 6945 (2130âˆ'11,800); IN-Ds, 3715 (1470âˆ'7325) (p < 0.001). In conclusion, we observed similar degrees of antibody waning in all patients. After 3 months, over half of the infection-naÃ¯ve dialysis patients had a very low antibody titer, and almost twenty percent of them had no antibodies at all. The humoral response to the third dose was very good, raising their titer of antibodies to a higher level than those in the general population who have received the primary two-dose scheme. The results support the administration of a complementary third dose of the mRNA vaccine for dialysis patients as soon as possible.

A Comparative Analysis of COVID-19 Vaccines Based on over 580,000 Cases from the Vaccination Adverse Event Reporting System. Background: The COVID-19 pandemic is being battled via the largest vaccination campaign in history, with more than eight billion doses administered thus far. Therefore, discussions about potentially adverse reactions, and broader safety concerns, are critical.

The U.S. Vaccination Adverse Event Reporting System (VAERS) has recorded vaccination side effects for over 30 years. About 580,000 events have been filed for COVID-19 thus far, primarily for the Johnson & Johnson (New Jersey, USA), Pfizer/BioNTech (Mainz, Germany), and Moderna (Cambridge, USA) vaccines. Methods: Using available databases, we evaluated these three vaccines in terms of the occurrence of four generally-noticed adverse reactionsâ€”namely, cerebral venous sinus thrombosis, Guillainâˆ’BarrÃ© syndrome (a severe paralytic neuropathy), myocarditis, and pericarditis. Our statistical analysis also included a calculation of odds ratios (ORs) based on total vaccination numbers, accounting for incidence rates in the general population. Results: ORs for a number of adverse events and patient groups were (largely) increased, most notably for the occurrence of cerebral venous sinus thrombosis after vaccination with the Johnson & Johnson vaccine. The overall population OR of 10 increases to 12.5 when limited to women, and further yet (to 14.4) among women below age 50 yrs. In addition, elevated risks were found (i) for Guillainâˆ’BarrÃ© syndrome (OR of 11.6) and (ii) for myocarditis/pericarditis (ORs of 5.3/4.1, respectively) among young men (<25 yrs) vaccinated with the Pfizer/BioNTech vaccine. Conclusions: Any conclusions from such a retrospective, real-world data analysis must be drawn cautiously, and should be confirmed by prospective double-blinded clinical trials. In addition, we emphasize that the adverse events reported here are not specific side effects of COVID vaccines, and the significant, well-established benefits of COVID-19 vaccination outweigh the potential complications surveyed here.

Gender and AB0 Blood Type Differences in a Unicentric Group of University Professors in Southern Italy Who Received the Vaxzevria COVID-19 Vaccine: A Cross-Sectional Survey of Vaccine Side Effects, Attitudes, and Hesitation. Vaccination has been a key protective behavior for COVID-19. This study investigated the clinical status of university professors administered the Vaxzevria COVID-19 vaccine, to monitor for any adverse reaction, and to understand attitude and hesitancy to vaccination. Data were collected through an online survey. The study received approval from the relevant ethics committee "Comitato Etico Campania Sud". Multivariate logistic regressions were used to calculate significant predictors of the outcomes of interest. A gender and AB0 blood type difference in adverse vaccine reactions was found. The multivariate logistic regression model showed that female gender, city residence, blood type A+ and B-, and chronic underlying medical conditions or comorbidities were more strongly implicated in the occurrence of adverse reactions, whereas blood type 0 Rh+ or blood type A Rh- were protective factors of adverse reactions to the Vaxzevria vaccine. Both genders did not show serious adverse reactions to the Vaxzevria vaccine. Based on our results, we are able to support the hypothesis that AB0 blood type and gender difference appear as predictors of Vaxzevria COVID-19 vaccine reactogenicity. Furthermore, in the study population, the degree of concern and hesitation to undergo vaccination was minimal.

Gam-COVID-Vac (Sputnik V) and Pfizer-BioNTech Vaccines Adverse Events following Immunization in Patients Affected by Parkinson's Disease and Multiple Sclerosis: A Longitudinal Study. The Republic of San Marino COVID-19 vaccination campaign used Gam-COVID-Vac and Pfizer-BioNTech vaccines. To assess adverse events following immunization (AEFIs), approximately 6000 vaccine recipients were monitored by the ROCCA study, including subgroups with Parkinson's Disease (PD) and Multiple Sclerosis (MS). The purpose of this study is to evaluate short-term AEFIs through a 1-month follow-up. We conducted a longitudinal study, using active surveillance to evaluate the safety profiles of COVID-19 vaccines in PD and MS patients. Participants were actively administered a standardized online questionnaire to collect information on AEFIs. Among all PD and MS assisted by the San Marino hospital, a total of 82 patients completed the questionnaires. One week after administration of the first dose, vaccine recipients reported AEFIs in 26% of cases in the PD group, 67% in the MS group, and 68% in the control group. Participants reported slightly higher rates of AEFIs after dose 2 compared with dose 1, being 29%, 75%, and 78% for PD, MS, control group,

respectively. Most of the reported symptoms were mild. Patients with PD and MS reported few AEFIs after administration of the COVID-19 vaccines. The frequency of AEFIs in the PD population was significantly lower than in the control group.

Intracranial Hemorrhage Due to Potential Rupture of an Arteriovenous Malformation after BNT162b2 COVID-19 mRNA Vaccination in a Young Korean Woman: Case Report. Inoculation with the Pfizer-BioNTech coronavirus infection-19 (COVID-19) vaccine (BNT162b2) has been approved in Korea. Although it is generally safe, several possible side effects have been reported. The present report describes a 28-year-old woman who developed an intracerebral hemorrhage in her right temporal lobe after the first dose of the Pfizer-BioNTech COVID-19 vaccine. The patient complained of a persistent headache for four days after the first dose, along with right third nerve palsy and drowsiness. Non-enhanced brain computed tomography confirmed a 5.0 Ã— 3.7 Ã— 5.0 cm(3)-sized intracranial hemorrhage in the right temporal lobe due to the rupture of an arteriovenous malformation (AVM). Transfemoral cerebral angiography revealed that blood was supplied to the AVM by the right middle cerebral artery branch and drained into the right transverse sinus. The patient underwent surgical treatment for AVM nidus removal with hematoma evacuation on the day of admission. Her condition stabilized 10 days postoperatively. These findings indicate that clinicians should be aware that cerebral hemorrhage caused by AVM rupture may be a side effect of inoculation with the BNT162b2 mRNA COVID-19 vaccine.

Susac Syndrome Following COVID-19 Vaccination: A Case Report. Due to the COVID-19 pandemic, numerous vaccines have been developed for the disease. However, with large-scale vaccination has come the gradual emergence of immunological phenomena caused by these new vaccines. Herein, we report a 48-year-old female with a sudden onset of inferior visual field defects in the left eye following her first dose of the ChAdOx1 vaccine. Dilated fundus examination combined with optical coherence tomography and fluorescein angiography confirmed the diagnosis of branch retinal artery occlusion. Within 4 weeks following vaccination, symptoms associated with hearing impairment developed, and magnetic resonance imaging revealed leptomeningeal enhancement. The diagnosis of Susac syndrome (SS) was confirmed. The development of SS may be caused by endotheliopathy resulting from the molecular mimicry of the ChAdOx1 vaccine. Clinicians should be aware of the symptoms of SS, which may develop after COVID-19 vaccination. Further experimental surveillance and case-control studies are required to confirm this relationship.

Duration of SARS-CoV-2 Immune Responses Up to Six Months Following Homologous or Heterologous Primary Immunization with ChAdOx1 nCoV-19 and BNT162b2 mRNA Vaccines. Heterologous primary immunization against SARS-CoV-2 is part of applied recommendations. However, little is known about duration of immune responses after heterologous vaccine regimens. To evaluate duration of immune responses after primary vaccination with homologous adeno-vectored ChAdOx1 nCoV-19 vaccine (ChAd) or heterologous ChAd/BNT162b2 mRNA vaccine (BNT), anti-spike-IgG and SARS-CoV-2 VOC-neutralizing antibody responses were measured in 354 healthcare workers (HCW) at 2 weeks, 3 months, 5 months and 6 months after the second vaccine dose. T-cell responses were investigated using a whole blood interferon gamma (IFN-Î³) release assay 2 weeks and 3 months post second vaccine dose. Two hundred and ten HCW immunized with homologous BNT were enrolled for comparison of antibody responses. In study participants naÃ¯ve to SARS-CoV-2 prior to vaccination, heterologous ChAd/BNT resulted in 6-fold higher peak anti-spike IgG antibody titers compared to homologous ChAd vaccination. The half-life of antibody titers was 3.1 months (95% CI 2.8-3.6) following homologous ChAd vaccination and 1.9 months (95% CI 1.7-2.1) after heterologous vaccination, reducing the GMT difference between the groups to 3-fold 6 months post vaccination. Peak T-cell responses were stronger in ChAd/BNT vaccinees, but no significant difference was observed 3 months post vaccination. SARS-CoV-2 infection prior to vaccination resulted in

substantially higher peak GMTs and IFN-Î³ levels and enhanced SARS-CoV-2 specific antibody and T cell responses over time. Heterologous primary SARS-CoV-2 immunization with ChAd and BNT elicits a stronger initial immune response compared to homologous vaccination with ChAd. However, although the differences in humoral responses remain over 6 months, the difference in SARS-CoV-2 specific T cell responses are no longer significant three months after vaccination.

Adverse Reactions to Anti-SARS-CoV-2 Vaccine: A Prospective Cohort Study Based on an Active Surveillance System. To date, Coronavirus disease (COVID-19) has caused high morbidity and mortality worldwide. To counteract the pandemic scenario, several vaccines against the etiological factor of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) were developed and tested. At the end of December 2020, BNT162b2 (Comirnaty, Pfizer-BioNTech) was the first and only authorized vaccine in Italy for selected categories, such as healthcare workers, fragile patients and people aged over 80 years old. To master our knowledge about BNT162b2 adverse reactions (ARs), an active surveillance system based on instant messaging was realized for voluntary participants who had been vaccinated at COVID-19 Vaccination Center of the Palermo University Hospital. Overall, 293 vaccinated persons were included in this study, which were more frequently healthcare workers (n = 207, 70.6% with a median age of 36 years, IQR = 29â^'55) followed by health professional students (n = 31, 10.6% with a median age of 27 years, IQR = 25â^'29), reporting 82.6% of at least one local or systemic AR. In details, the frequency of at least one local or systemic AR after the second dose of Comirnaty (n = 235, 80.2%) was statistically significant with higher value in comparison to the first one (n = 149, 50.9%; p < 0.001). However, local pain, swelling, joint pain and muscular pain after the second dose were the symptom causing a statistically significant working limitation. The youngest persons showed a higher risk to have either local or systemic ARs (aOR = 7.5, CI 95% = 2.9â^'18.9), while females had a higher risk of having systemic ARs (aOR = 1.8, CI 95% = 1.1â^'3.0). Despite the small sample examined, this active surveillance system by instant messaging seems to detect a higher ARs prevalence with respect to data obtained by the passive surveillance. Further studies could be required in order to optimize this clinical monitoring that could be considered an efficient and timely active surveillance.

Fulminant Giant Cell Myocarditis following Heterologous Vaccination of ChAdOx1 nCoV-19 and Pfizer-BioNTech COVID-19. A 48-year-old female patient underwent a heart transplantation for acute fulminant myocarditis, following heterologous vaccination with the ChAdOx1 nCoV-19 and Pfizer-BioNTech COVID-19. She had no history of severe acute respiratory syndrome coronavirus-2 infection. She did not exhibit clinical signs or have laboratory findings of concomitant infection before or after vaccination. Heart transplantation was performed because her heart failed to recover with venoarterial extracorporeal oxygenation support. Organ autopsy revealed giant cell myocarditis, possibly related to the vaccines. Clinicians may have to consider the possibility of the development of giant cell myocarditis, especially in patients with rapidly deteriorating cardiac function and myocarditis symptoms after COVID-19 vaccination.

Adverse Events and Immunogenicity of mRNA-Based COVID-19 Vaccine among Healthcare Workers: A Single-Centre Experience. Background and Objectives: The safety and effectiveness of vaccines are among the key priorities in COVID-19 pandemic management. Moreover, evidence-based data regarding vaccine safety and immunogenicity can play an important role in building the trust of the community regarding vaccination. The aim of this study was to investigate the safety and immunogenicity of Pfizer-BioNTech vaccine among healthcare workers in one hospital, 21 days after first dose. Materials and Methods: This study was conducted in the Hospital of the Lithuanian University of Health Sciences between February and March 2021. Hospital employees who arrived to receive the second dose of the Pfizer-BioNTech vaccine 21 days after the first one were invited to participate in the study: they were asked to complete an anonymous adverse events questionnaire

and were offered a SARS-CoV-2 IgG/IgM rapid test. The study was performed at a single point, 21 days after the first dose of the vaccine. Results: Data of 4181 vaccine recipients were analysed. The first vaccine dose was associated with a 53.6% incidence of adverse events, mainly local reactions. Adverse events occurred more frequently in younger participants and women. Moderate adverse events were experienced by 1.4% of the vaccine recipients; 6.2% were incapacitated. Of the 3439 participants who performed a rapid IgG test, 94.5% were positive for IgG antibodies after the first vaccine dose. Seroconversion rates were lower in participants older than 47 years. Conclusions: Despite 1.4% moderate adverse events, no safety concerns or anaphylaxis were identified. The Pfizer-BioNTech vaccine induced an immune response in the overwhelming majority of recipients after a single dose. Younger participants experienced adverse events and were positive for IgG antibodies more frequently than older counterparts. It is important to mention that this study specifically considered short-term safety and reactions following vaccination and that long-term adverse effects were not investigated in the study. Thus, future research into both long-term adverse reactions and immune system programming is essential.

COVID-19 vaccine associated axillary lymphadenopathy - A systematic review. INTRODUCTION: ; COVID-19 vaccines are commonly administered intramuscularly to the arm. Axillary lymphadenopathy has been reported as an adverse event after COVID-19 vaccination. In patients with breast cancers who received COVID-19 vaccination, presence of ipsilateral (or contralateral) lymphadenopathy poses diagnostic dilemma. This systematic review aims to evaluate the incidence and clinical characteristics of vaccine associated axillary lymphadenopathy. METHODS: ; The systematic review was conducted with accordance to the PRISMA statement. The search terms used were "Vaccine" OR "Vaccination" AND "Lymphadenopathy" OR "Lymph node" AND "Covid-19â€³. RESULTS: ; 31 studies or reports were identified using the predefined keywords from the systematic review protocol. After excluding irrelevant papers (such as guidelines, reviews, opinions and commentaries), 10 studies or reports were included in the review.Pooled incidence of clinically detectable lymphadenopathy after COVID-19 vaccination was 91/22,532 (0.4%). Mean size of the vaccine associated axillary lymphadenopathy was 18.2Â mm (Range 16 - 21Â mm). Mean duration from vaccination to occurrence of axillary lymphadenopathy was 6.9 days (Range 2 - 18 days). In a study on 119 patients, enlarged axillary lymphadenopathy resolves in 4 to 5 weeks. CONCLUSION: ; Vaccine associated axillary lymphadenopathy is not uncommon. Management of it is based on multidisciplinary decision with patient demographics, vaccination history and radiological finding being taken into account. Additional imaging and biopsy may lead to unnecessary healthcare burden. Proper arrangement of vaccination and imaging regarding timing and laterality should be advocated to avoid confusion and patient anxiety.

The Impact of Australian Childhood Vaccination Mandates on Immunization Specialists and Their Interactions With Families. BACKGROUND: Recent global outbreaks of vaccine-preventable diseases, both before and since the coronavirus disease 2019 pandemic, have led to the introduction or strengthening of vaccine mandate policies to target vaccine refusal. Globally, there is wide variation in how governments and jurisdictions implement and enforce mandatory vaccination as well as the financial and educational consequences to those who fail to comply. We explored the impact of mandate vaccination policies on Australian Immunization Specialists who work in Specialist Immunization Clinics (SIC) for approving vaccine exemptions outside of the mandated criteria. In particular, their interactions with patients and families. METHODS: A national, prospective, mixed methods, survey-based study conducted with members of the Australian Adverse Event Following Immunisation Clinical Assessment Network between February 2020 and June 2020. RESULTS: Sixteen Immunization physicians and nurse practitioner specialists working in a SIC completed the survey. All sixteen respondents had been requested by parents to provide a Medical Exemptions at least once.

88% of respondents felt pressure to provide an exemption that was not medically justified according to legislation. Seventy-five percent of SIC consultants felt that the "No Jab" policies created a moderate or extreme amount of stress to both themselves and parents. All respondents reported experiencing hostility from parents with three respondents having received threats of violence. CONCLUSIONS: Mandatory vaccination policies are associated with increased vaccination coverage but can result in widened financial and social inequity, and may harm families' relationships with health care providers. Countries considering the implementation of vaccination mandates should use the least restrictive health policies to ensure a balance between the public health and individual benefit whilst minimizing burdens on health care professionals, children and their parents.

Impaired Humoral and Cellular Responses to COVID-19 Vaccine in Heart and Lung Transplant Recipients.

Immune responses against SARS-CoV-2 variants after two and three doses of vaccine in B-cell malignancies: UK PROSECO study. Patients with hematological malignancies are at increased risk of severe COVID-19 outcomes due to compromised immune responses, but the insights of these studies have been compromised due to intrinsic limitations in study design. Here we present the PROSECO prospective observational study (NCT04858568) on 457 patients with lymphoma that received two or three COVID-19 vaccine doses. We show undetectable humoral responses following two vaccine doses in 52% of patients undergoing active anticancer treatment. Moreover, 60% of patients on anti-CD20 therapy had undetectable antibodies following full vaccination within 12 months of receiving their anticancer therapy. However, 70% of individuals with indolent B-cell lymphoma displayed improved antibody responses following booster vaccination. Notably, 63% of all patients displayed antigen-specific T-cell responses, which increased after a third dose irrespective of their cancer treatment status. Our results emphasize the urgency of careful monitoring of COVID-19-specific immune responses to guide vaccination schemes in these vulnerable populations.

IL-1 and IL-1ra are key regulators of the inflammatory response to RNA vaccines. The use of lipid-formulated RNA vaccines for cancer or COVID-19 is associated with dose-limiting systemic inflammatory responses in humans that were not predicted from preclinical studies. Here, we show that the 'interleukin 1 (IL-1)-interleukin 1 receptor antagonist (IL-1ra)' axis regulates vaccine-mediated systemic inflammation in a host-specific manner. In human immune cells, RNA vaccines induce production of IL-1 cytokines, predominantly IL-1Î², which is dependent on both the RNA and lipid formulation. IL-1 in turn triggers the induction of the broad spectrum of pro-inflammatory cytokines (including IL-6). Unlike humans, murine leukocytes respond to RNA vaccines by upregulating anti-inflammatory IL-1ra relative to IL-1 (predominantly IL-1Î±), protecting mice from cytokine-mediated toxicities at >1,000-fold higher vaccine doses. Thus, the IL-1 pathway plays a key role in triggering RNA vaccine-associated innate signaling, an effect that was unexpectedly amplified by certain lipids used in vaccine formulations incorporating N1-methyl-pseudouridine-modified RNA to reduce activation of Toll-like receptor signaling.

Thrombotic thrombocytopenic purpura following administration of the Moderna booster vaccine. Thrombotic thrombocytopenic purpura (TTP) is a type of thrombotic microangiopathy that is characterized by microangiopathic haemolytic anaemia, consumption thrombocytopenia and organ injury. It is caused by a severe deficiency of ADAMTS13, which can be either congenital or acquired. There is a plethora of things that can cause the acquired form, including medications and infections. Vaccines have also been shown to cause TTP. In the midst of the COVID-19 pandemic, with multiple new vaccines being developed and distributed to the masses, the medical community needs to be aware of adverse events associated with these new vaccines. We present a case of TTP following administration of the Moderna booster vaccine.

Micronutrient supplementation, COVID-19 vaccination and adverse effect: Correspondence.

Oral erythema multiforme after Pfizer-BioNTech COVID-19 vaccination: a report of four cases. BACKGROUND: The 2019 Coronavirus disease (Covid-19) has affected thousands of people worldwide. To date, vaccines appear to be the only method to prevent and reduce mortality. Four vaccinations have been outwardly approved by European Medicine Agency (EMA) in Europe: BNT162b2 (Comirnaty-BioNTech/Pfizer), mRNA-1273 (Spikevax-Moderna), ChAdOx1 (VaxzevriaAstrazeneca), and Ad26.COV2-S (Janssen-Johnson&Johnson). After vaccination, local and systemic adverse effects can occur. Cutaneous reactions like urticaria, local injection site pain, morbilliform rash have been documented after vaccination. CASES PRESENTATION: We report four cases of oral erythema multiforme flare arising after BNT162b2 vaccination administration. All the patients denied previous erythema-like and herpetic manifestations history. Two of the reported cases (number 1 and 2) presented with both oral and cutaneous lesions, while cases 3 and 4 showed only oral manifestations. Three of the cases presented the erythema after the first vaccination dosage administration, only one case reported lesions after the second vaccination dosage administration. All the cases were treated with prednisone via oral administration and topical 0.05% clobetasol ointment. CONCLUSIONS: The present reports represent some of the few cases of erythema multiforme occurring as a side effect of the BNT162b2 COVID-19 vaccination. The causal role of the vaccine for the erythema multiforme has not been proven yet; nevertheless, it is not uncommon for medications to trigger this disease. The vaccine could surface a silent herpes virus infection, which would induce the erythema multiforme instead.

The Risk of Spontaneous Abortion Does Not Increase Following First Trimester mRNA COVID-19 Vaccination. Clinical trials for COVID-19 vaccines initially excluded pregnant women due to safety concerns, and when the vaccines were authorized for emergency use, they were not recommended for this population. However, observational studies discovered that pregnant women infected with COVID-19 have higher risks of negative pregnancy and delivery outcomes compared to non-pregnant women, raising the question of the risks-benefits of administering COVID-19 vaccines to pregnant women. By mid-2021, there was general consensus on the relative safety of COVID-19 vaccination during pregnancy; therefore, it is critical to investigate the safety issues related to these vaccines, considering the increasing acceptance among pregnant women. To address these concerns, we developed a research project to study the short-term effects and outcomes of COVID-19 vaccination during the first trimester of pregnancy. Our research followed an observational retrospective design for 12 months from the beginning of the vaccination campaign, and included 124 cases of spontaneous abortions and 927 ongoing pregnancies. The odds of spontaneous abortion were non-significant for both versions of the mRNA vaccine (Pfizer BNT162b2 AOR = 1.04, CI = 0.91-1.12; Moderna mRNA-1273 AOR = 1.02, CI = 0.89-1.08). Overall, our data indicated that the risk of spontaneous abortion after mRNA COVID-19 immunization during the first trimester of pregnancy is commensurate with the predicted risk in non-vaccinated pregnant women. These findings contribute to the growing body of information regarding the safety of mRNA COVID-19 vaccination during pregnancy.

Hypersensitivity Myocarditis after COVID-19 mRNA Vaccination. BACKGROUND: Myocarditis, even in a severe and lethal form, may occur after COVID-19 mRNA (BNT162b2) vaccination. However, its pathway, morphomolecular characterization and treatment are still unknown. METHODS: Routine hematochemical screening, ECG, Holter monitoring, 2D echocardiogram cardiac magnetic resonance (CMR) and invasive cardiac studies (cardiac catheterization, selective coronary angiography, left ventriculography and left ventricular endomyocardial biopsy) are reported from three patients (39F-pt1, 78M-pt2, 52M-pt3) with severe compromise of conduction tissue (junctional rhythm and syncope, pt1) or cardiac function compromise (LVEF â‰¤ 35%, pt2 and pt3) after COVID-19 mRNA (BNT162b2). RESULTS: Hematochemical data and coronary angiography were normal in the patients

studied. Histology showed in all three patients extensive myocardial infiltration of degranulated eosinophils and elevation of serum cationic protein directly responsible for cardiomyocyte damage. These findings demonstrate myocarditis hypersensitivity to some component of the vaccine (spike protein?) acting as a hapten to some macromolecules of cardiomyocytes. Steroid administration (prednisone, 1 mg/kg die for 3 days, followed by 0.33 mg/kg for 4 weeks) was followed by complete recovery of cardiac contractility in pt2 and pt3. CONCLUSIONS: Eosinophilic myocarditis is a possible adverse reaction to the mRNA COVID-19 vaccine. Its pathway is mediated by release of cationic protein and responds to short courses of steroid administration.

Improving Risk Management by Learning from Adverse Events: Report on One Year of COVID-19 Vaccination Campaign in Verona (Northeastern Italy). BACKGROUND: The COVID-19 mass vaccination campaign posed new challenges not only from a healthcare perspective, but also in terms of distribution, logistics, and organization. Managing clinical risk in off-site vaccination centers during a pandemic provided a new opportunity for the training and acquisition of competencies through continuous learning from adverse events. The aim of this report, based on a review of activity, was to identify the most recurrent and high-risk failures of the vaccination process in a mass vaccination center. METHODS: Adverse events and near misses reported during the first 11 months of activity (February 2021-January 2022) in the mass vaccination center of Verona (Italy) were evaluated. RESULTS: From 15 February 2021 to 17 January 2022 the center administered about 460,000 doses to the population and nine adverse events and one near miss were reported. Most of the events were errors in vaccine administration, either in principle, dosage, or timing with respect to the indicated schedule. All events had minor outcomes. Communication errors, inadequate training, and general organizational issues were the most recurrent factors contributing to the events. CONCLUSIONS: Risk mitigation during mass vaccination in temporary sites is an essential element of a successful vaccination campaign. The reporting of adverse events should be encouraged in order to obtain as much information as possible for a continuous improvement of the activity.

COVID-19-Vaccination-Induced Myocarditis in Teenagers: Case Series with Further Follow-Up. Presently, the whole globe is struggling the tough challenge of the COVID-19 pandemic. Vaccination remains the most effective and safe COVID-19 weapon for adults and in the paediatric population. Aside from possible mild and moderate post-vaccination side effects, more severe side effects may occur. We retrospectively analysed a group of 5 teenagers aged from 15 to 17 years with obesity/overweight (BMI ranging from 24.8 to 30) who presented typical myocarditis symptoms following the first or second dose (3 and 2 patients, respectively) of the COVID-19 vaccine. In the whole study group, a significant increase in troponin serum concentration was observed (1674-37,279.6 ng/L) with a further quick reduction within 3-4 days. In all patients, ST segments elevation or depression with repolarisation time abnormalities in electrocardiography were noticed. Chest X-ray results were within normal limits. Echocardiography showed normal left ventricular diameter (47-56.2 mm) with ejection fraction between 61-72%. All patients were diagnosed with myocarditis based on cardiac magnetic resonance (CMR) imaging. During further hospitalisation, swift clinical improvement was notable. Follow-up in the whole study group was obtained after 106-134 days from initial CMR, revealing no myocarditis symptoms, proper troponin level, and no ECG or echocardiographic abnormalities. At the same time, persistent myocardium injury features were detected in the whole study group, including ongoing myocarditis. COVID-19-vaccine-induced myocarditis seems to be a mild disease with fast clinical recovery, but the complete resolution of the inflammatory process may last over 3 months. Further follow-up and investigation for assessing subsequent implications and long-term COVID-19-vaccine-induced myocarditis is required.

Coagulopathy and Fibrinolytic Pathophysiology in COVID-19 and SARS-CoV-2 Vaccination. Coronavirus Disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2

(SARS-CoV-2) and is frequently complicated by thrombosis. In some cases of severe COVID-19, fibrinolysis may be markedly enhanced within a few days, resulting in fatal bleeding. In the treatment of COVID-19, attention should be paid to both coagulation activation and fibrinolytic activation. Various thromboses are known to occur after vaccination with SARS-CoV-2 vaccines. Vaccine-induced immune thrombotic thrombocytopenia (VITT) can occur after adenovirus-vectored vaccination, and is characterized by the detection of anti-platelet factor 4 antibodies by enzyme-linked immunosorbent assay and thrombosis in unusual locations such as cerebral venous sinuses and visceral veins. Treatment comprises high-dose immunoglobulin, argatroban, and fondaparinux. Some VITT cases show marked decreases in fibrinogen and platelets and marked increases in D-dimer, suggesting the presence of enhanced-fibrinolytic-type disseminated intravascular coagulation with a high risk of bleeding. In the treatment of VITT, evaluation of both coagulation activation and fibrinolytic activation is important, adjusting treatments accordingly to improve outcomes.

SARS-CoV-2 mRNA Vaccine-Induced Cellular and Humoral Immunity in Hemodialysis Patients. BACKGROUND/AIMS: Chronic kidney disease CKD patients on intermittent hemodialysis IHD are exposed to SARS-CoV-2 infection and carry a risk of developing severe symptoms. The aim of this study was to evaluate the humoral and cellular immunity induced by two doses of mRNA vaccines, the Pfizer-BioNTech (Comirnaty) COVID-19 Vaccine and the Moderna (mRNA-1273) COVID-19 vaccine. PATIENTS AND METHODS: The study included 281 patients from five dialysis centers in northern Poland. Within 2 weeks prior to the first dose of the vaccine, a blood sample was collected for an evaluation of SARS-CoV-2 antibodies. Thirty to forty-five days after the second dose of the vaccine, a blood sample was taken to evaluate humoral and cellular response. RESULTS: Patients with stage 5 CKD on IHD were characterized by a considerable SARS-CoV-2 vaccine-induced seroconversion rate. The strongest factors influencing the antibodies AB level after vaccination were a pre-vaccination history of SARS-CoV-2 infection, age, the neutrophil-to-lymphocyte ratio NLR, neutrophil absolute count, and the hemoglobin level. Cellular immunity was higher in patients with a pre-vaccination history of SARS-CoV-2 infection. Cellular immunity depended on the albumin level. Positive cellular response to vaccination was a positive factor reducing all-cause mortality, except for COVID-19 mortality (no such deaths were reported during our follow-up). Cellular immunity and humoral immunity were positively mutually dependent. High levels of albumin and hemoglobin, low neutrophil count, and a reduced NLR, translated into better response to vaccination. CONCLUSIONS: Patients with stage 5 CKD on IHD were characterized by a considerable SARS-CoV-2 vaccine-induced seroconversion rate and a good rate of cellular immunity. The factors that change with exacerbating inflammation and malnutrition (albumin, hemoglobin, neutrophil count, the NLR) affected the efficacy of the vaccination.

Longitudinal Humoral and Cellular Immune Responses Following SARS-CoV-2 Vaccination in Patients with Myeloid and Lymphoid Neoplasms Compared to a Reference Cohort: Results of a Prospective Trial of the East German Study Group for Hematology and Oncology (OSHO). Purpose: To assess humoral responses longitudinally and cellular immunogenicity following SARS-CoV-2-vaccination in patients with hematologic and oncologic malignancies receiving checkpoint-inhibitors. Methods: This prospective multicenter trial of the East-German-Study-Group-for-Hematology-and-Oncology, enrolled 398 adults in a two (patients; n = 262) to one (controls; n = 136) ratio. Pre-vaccination, day 35 (d35), and day 120 (d120) blood samples were analyzed for anti-spike antibodies and d120 IL-2+IFNÎ³+TNFÎ±+-CD4+- and CD8+-cells. Laboratories were blinded for patients and controls. Results: Patients belonged to the myeloid (n = 131), lymphoid (n = 104), and checkpoint-inhibitor (n = 17) cohorts. While d35 seroconversion was higher in controls (98%) compared to patients (68%) ($p < 0.001$), d120 seroconversion improved across all patient cohorts [checkpoint-inhibitors (81% to 100%), myeloid (82% to 97%), lymphoid (48% to 66%)]. CD4+- and CovCD8+-cells in the lymphoid

(71%/31%) and control (74%/42%) cohorts were comparable but fewer in the myeloid cohort (53%, p = 0.003 /24%, p = 0.03). In patients with hematologic malignancies, no correlation between d120 humoral and cellular responses was found. A sizeable fraction of lymphoid patients demonstrated T-cell responses without detectable spike-specific-IgGs. Conclusions: Evidence of vaccine-elicited humoral and/or cellular immunogenicity in most patients is provided. Both humoral and cellular responses are crucial to determine which patients will generate/maintain immunity. The findings have implications on public health policy regarding recommendations for SARS-CoV-2 booster doses.

Vogt-Koyanagi-Harada Disease Exacerbation Associated with COVID-19 Vaccine. We describe a case of Vogt-Koyanagi-Harada (VKH) disease exacerbation after COVID-19 vaccination. A 46-year-old woman presented with a bilateral granulomatous uveitis 2 days after the first dose of COVID-19 mRNA vaccine (Comirnaty, Pfizer-BioNTech), and was diagnosed with a complete Vogt-Koyanagi-Harada (VKH) disease 4 days after receiving the second dose of the vaccine. Three weeks before the first dose, she had been consulted for blurred vision and mild headaches. The case resolved with high dose intravenous corticosteroids, followed by oral prednisone. The close temporal relationship between the COVID-19 vaccine doses and the worsening of VKH symptoms strongly suggests COVID-19 vaccination as the trigger of its exacerbation.

COVID-19 Vaccination and Neurological Manifestations: A Review of Case Reports and Case Series. BACKGROUND: With 10 vaccines approved by the WHO and nearly 48% of people fully vaccinated worldwide, we have observed several individual case studies of neurological manifestations post-COVID-19 vaccination. Through this systematic review, we aim to discern these CNS and PNS manifestations following the COVID-19 vaccine to help produce methods to mitigate them. METHODS: We conducted a thorough literature search of Google Scholar and PubMed from 1 December 2020 until 10 October 2021 and included all the case studies of COVID-19 vaccine-associated neurological side effects. The literature search and data analysis were performed by two independent reviewers according to prespecified inclusion and exclusion criteria using PRISMA. RESULTS: The most common CNS manifestation was CVST (14.47%), found in females (64%) younger than 50 years (71%) after the first AstraZeneca dose (93%). Others included CNS demyelinating disorders (TM, ADEM, MS, NMOSD) (9.30%), encephalopathy/encephalitis (3.10%), and others (4.13%). The most common PNS manifestation was GBS (14.67%) found in males (71%) older than 50 years (79%), followed by Bell's palsy (5.24%) and others (2.10%). Most occurred with the AstraZeneca (28.55%), Pfizer-BioNTech (9.18%), and Moderna (8.16%) vaccines. Nine (64%) out of the 14 patients with CVST died. However, most cases overall (42 out of 51) were non-fatal (82%). CONCLUSION: Several CNS and PNS adverse events have occurred post-COVID-19 vaccination, including CVST, GBS, and TM. High vigilance with early identification and treatment leads to better outcomes. Further studies with non-vaccinated controls might help in understanding the pathophysiologic mechanisms of these neurological manifestations following COVID-19 vaccination.

Epidemiology, clinical ramifications, and cellular pathogenesis of COVID-19 mRNA-vaccination-induced adverse cardiovascular outcomes: A state-of-the-heart review. The coronavirus disease 2019 (COVID-19) has overwhelming healthcare systems globally. To date, a myriad of therapeutic regimens has been employed in an attempt to curb the ramifications of a severe COVID-19 infection. Amidst the ongoing pandemic, the advent and efficacious uptake of COVID-19 vaccination has significantly reduced disease-related hospitalizations and mortality. Nevertheless, many side-effects are being reported after COVID-19 vaccinations and myocarditis is the most commonly reported sequelae post vaccination. Majority of these diseases are associated with COVID-19 mRNA vaccines. Various studies have established a temporal relationship between these complications, yet the causality and the underlying pathogenesis remain hypothetical. In this review, we aim to critically

appraise the available literature regarding the cardiovascular side effects of the various mRNA vaccines and the associated pathophysiology.

Antibodies Against SARS-CoV-2 in Human Breast Milk After Vaccination: A Systematic Review and Meta-Analysis. Background: CDC guidelines have recommended coronavirus disease-19 (COVID-19) vaccination for all people 5 years and older, including people who are breastfeeding. Breast milk has shown to be a valuable source of protection for immune-immature neonates. It has been shown that breast milk from mothers who have received vaccinations can transfer antibodies. Aim/Objective: This systematic review and meta-analysis investigate the presence of antibodies to SARS-CoV-2 in human breast milk after vaccination. Methods: Studies that evaluated immunoglobulins in breast milk of women receiving a SARS-CoV-2 vaccination were included. PubMed, Embase, Web of Science were searched for articles published between December 1, 2019 and September 30, 2021. Data from relevant articles were extracted manually or by WebPlotDigitizer version 4.1 to obtain the numeric values of antibody levels on peak days and the peak day then condensed into Excel. Additional raw data and information were supplied by corresponding authors. Results: One hundred ninety-two articles were obtained from the search. After excluding duplicates, screening titles and abstracts, 18 cohort studies were identified. For the rate of SARS-CoV-2 antibodies in breast milk after the first vaccine dose but before the second vaccine dose, we found 64% (95% CI 51-78%) were positive for IgA and 30% (95% CI 13.1-46%) were positive for IgG. For the rate for SARS-CoV-2 antibodies in breast milk after the second vaccine dose, we found 70% (95% CI 55-86%) were positive for IgA and 91% (95% CI 80-103%) were positive for IgG. Conclusions: Our analysis of the data published worldwide showed high rates of positivity for antibodies in breast milk following COVID-19 immunizations. Further research is necessary to find if the rate of positivity of IgA and IgG against SARS-CoV-2 in breast milk persists months after the full immunization, and their impact on the prevention of SARS-CoV-2 infection in infants.

COVID-19-Associated Hospitalizations Among Adults During SARS-CoV-2 Delta and Omicron Variant Predominance, by Race/Ethnicity and Vaccination Status - COVID-NET, 14 States, July 2021-January 2022. Beginning the week of December 19-25, 2021, the B.1.1.529 (Omicron) variant of SARS-CoV-2 (the virus that causes COVID-19) became the predominant circulating variant in the United States (i.e., accounted for >50% of sequenced isolates).* Information on the impact that booster or additional doses of COVID-19 vaccines have on preventing hospitalizations during Omicron predominance is limited. Data from the COVID-19-Associated Hospitalization Surveillance Network (COVID-NET)(â€) were analyzed to compare COVID-19-associated hospitalization rates among adults aged â‰¥18 years during B.1.617.2 (Delta; July 1-December 18, 2021) and Omicron (December 19, 2021-January 31, 2022) variant predominance, overall and by race/ethnicity and vaccination status. During the Omicron-predominant period, weekly COVID-19-associated hospitalization rates (hospitalizations per 100,000 adults) peaked at 38.4, compared with 15.5 during Delta predominance. Hospitalizations rates increased among all adults irrespective of vaccination status (unvaccinated, primary series only, or primary series plus a booster or additional dose). Hospitalization rates during peak Omicron circulation (January 2022) among unvaccinated adults remained 12 times the rates among vaccinated adults who received booster or additional doses and four times the rates among adults who received a primary series, but no booster or additional dose. The rate among adults who received a primary series, but no booster or additional dose, was three times the rate among adults who received a booster or additional dose. During the Omicron-predominant period, peak hospitalization rates among non-Hispanic Black (Black) adults were nearly four times the rate of non-Hispanic White (White) adults and was the highest rate observed among any racial and ethnic group during the pandemic. Compared with the Delta-predominant period, the proportion of unvaccinated hospitalized Black adults increased during the Omicron-predominant period. All adults should stay up

to date (1) with COVID-19 vaccination to reduce their risk for COVID-19-associated hospitalization. Implementing strategies that result in the equitable receipt of COVID-19 vaccinations, through building vaccine confidence, raising awareness of the benefits of vaccination, and removing barriers to vaccination access among persons with disproportionately higher hospitalizations rates from COVID-19, including Black adults, is an urgent public health priority.

Antibody response to mRNA SARS-CoV-2 vaccination in 182 patients after allogeneic hematopoietic cell transplantation. INTRODUCTION: Patients after allogeneic stem cell transplantation are at high risk for infection-related complications, and vaccination efficacy might be impaired depending on the immune reconstitution. In this study, we evaluate their response to mRNA vaccines against SARS-CoV-2. METHODS: During routine follow-up visits, patients were asked about their vaccination status and if they had a previous infection with SARS-CoV-2. In fully vaccinated patients, the antibody titer was measured using the Roche Elecsys Anti-SARS-CoV-2 S test. A titer of <1Â U/L was considered as negative, titers of â‰¥250Â U/ml as a high antibody titer, and a titer of 50-249Â U/ml as a low antibody titer. Patient characteristics were evaluated by chart review to identify risk factors for poor vaccination response. RESULTS: The majority of patients developed a high antibody titer (138 out 182 patients, 75.8%). Risk factors for a low antibody titer were immunosuppressive therapy, a lymphocyte count <0.9Â G/L, ongoing treatment for the underlying malignancy, and active graft-versus-host disease (GvHD). Donor type, underlying disease, a previous SARS-CoV-2 infection, and sex did not significantly influence the response to the vaccination. DISCUSSION: While patients undergoing allogeneic stem cell transplantation have been excluded from the initial registration trials, our real-world experience with a large patient cohort confirms the data of previous studies, showing that most patients do have a good response to mRNA vaccines against SARS-CoV-2. Nevertheless, a significant proportion of patients shows an inadequate vaccination, which can be improved after a third vaccination in most cases despite immunosuppressive therapy.

Natural Killer Cell-Mediated Antibody-Dependent Cellular Cytotoxicity Against SARS-CoV-2 After Natural Infection Is More Potent Than After Vaccination. We compared the ability of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike-specific antibodies to induce natural killer cell-mediated antibody-dependent cellular cytotoxicity (ADCC) in patients with natural infection and vaccinated persons. Analyzing plasma samples from 39 coronavirus disease 2019 (COVID-19) patients and 11 vaccinated individuals, significant induction of ADCC could be observed over a period of more than 3 months in both vaccinated and recovered individuals. Although plasma antibody concentrations were lower in recovered patients, we found antibodies elicited by natural infection induced a significantly stronger ADCC response compared to those induced by vaccination, which may affect protection conferred by vaccination.

Association of SARS-CoV-2 Vaccination During Pregnancy With Pregnancy Outcomes. IMPORTANCE: Data about the safety of vaccines against SARS-CoV-2 during pregnancy are limited. OBJECTIVE: To examine the risk of adverse pregnancy outcomes after vaccination against SARS-CoV-2 during pregnancy. DESIGN, SETTING, AND PARTICIPANTS: This registry-based retrospective cohort study included 157 521 singleton pregnancies ending after 22 gestational weeks from January 1, 2021, until January 12, 2022 (Sweden), or January 15, 2022 (Norway). The Pregnancy Register in Sweden and the Medical Birth Registry of Norway were linked to vaccination and other registries for identification of exposure and background characteristics. EXPOSURES: Data on mRNA vaccines-BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna)-and 1 viral vector vaccine-AZD1222 (AstraZeneca)-were collected from national vaccination registries. MAIN OUTCOMES AND MEASURES: The risk of preterm birth and stillbirth was evaluated using Cox regression models, with gestational day as the time metric and vaccination as a time-dependent exposure variable. The risk of small for gestational age, low Apgar score, and neonatal care admission was evaluated using logistic

regression. Random-effects meta-analysis was used to combine results between countries. RESULTS: Among the 157 521 singleton births included in the study (103 409 in Sweden and 54 112 in Norway), the mean maternal age at the time of delivery was 31 years, and 28 506 (18%) were vaccinated against SARS-CoV-2 (12.9% with BNT162b2, 4.8% with mRNA-1273, and 0.3% with AZD1222) while pregnant. A total of 0.7%, 8.3%, and 9.1% of individuals delivering were vaccinated during the first, second, and third trimester, respectively. Vaccination against SARS-CoV-2 was not significantly associated with increased risk of preterm birth (6.2 vs 4.9 per 10â€¯000 pregnancy days; adjusted hazard ratio [aHR], 0.98 [95% CI, 0.91 to 1.05]; I2â€‰=â€‰0%; P for heterogeneityâ€‰=â€‰.60), stillbirth (2.1 vs 2.4 per 100 000 pregnancy days; aHR, 0.86 [95% CI, 0.63 to 1.17]), small for gestational age (7.8% vs 8.5%; difference, -0.6% [95% CI, -1.3% to 0.2%]; adjusted OR [aOR], 0.97 [95% CI, 0.90 to 1.04]), low Apgar score (1.5% vs 1.6%; difference, -0.05% [95% CI, -0.3% to 0.1%]; aOR, 0.97 [95% CI, 0.87 to 1.08]), or neonatal care admission (8.5% vs 8.5%; difference, 0.003% [95% CI, -0.9% to 0.9%]; aOR, 0.97 [95% CI, 0.86 to 1.10]). CONCLUSIONS AND RELEVANCE: In this population-based study conducted in Sweden and Norway, vaccination against SARS-CoV-2 during pregnancy, compared with no SARS-CoV-2 vaccination during pregnancy, was not significantly associated with an increased risk of adverse pregnancy outcomes. The majority of the vaccinations were with mRNA vaccines during the second and third trimesters of pregnancy, which should be considered in interpreting the findings.

Association of COVID-19 Vaccination in Pregnancy With Adverse Peripartum Outcomes. IMPORTANCE: There is limited comparative epidemiological evidence on outcomes associated with COVID-19 vaccination during pregnancy; monitoring pregnancy outcomes in large populations is required. OBJECTIVE: To evaluate peripartum outcomes following COVID-19 vaccination during pregnancy. DESIGN, SETTING, AND PARTICIPANTS: Population-based retrospective cohort study in Ontario, Canada, using a birth registry linked with the provincial COVID-19 immunization database. All births between December 14, 2020, and September 30, 2021, were included. EXPOSURES: COVID-19 vaccination during pregnancy, COVID-19 vaccination after pregnancy, and no vaccination. MAIN OUTCOMES AND MEASURES: Postpartum hemorrhage, chorioamnionitis, cesarean delivery (overall and emergency cesarean delivery), admission to neonatal intensive care unit (NICU), and low newborn 5-minute Apgar score (<7). Linear and robust Poisson regression was used to generate adjusted risk differences (aRDs) and risk ratios (aRRs), respectively, comparing cumulative incidence of outcomes in those who received COVID-19 vaccination during pregnancy with those vaccinated after pregnancy and those with no record of COVID-19 vaccination at any point. Inverse probability of treatment weights were used to adjust for confounding. RESULTS: Among 97â€¯590 individuals (mean [SD] age, 31.9 [4.9] years), 22â€¯660 (23%) received at least 1 dose of COVID-19 vaccine during pregnancy (63.6% received dose 1 in the third trimester; 99.8% received an mRNA vaccine). Comparing those vaccinated during vs after pregnancy (nâ€‰=â€‰44â€¯815), there were no significantly increased risks of postpartum hemorrhage (incidence: 3.0% vs 3.0%; aRD, -0.28 per 100 individuals [95% CI, -0.59 to 0.03]; aRR, 0.91 [95% CI, 0.82-1.02]), chorioamnionitis (0.5% vs 0.5%; aRD, -0.04 per 100 individuals [95% CI, -0.17 to 0.09]; aRR, 0.92 [95% CI, 0.70-1.21]), cesarean delivery (30.8% vs 32.2%; aRD, -2.73 per 100 individuals [95% CI, -3.59 to -1.88]; aRR, 0.92 [95% CI, 0.89-0.95]), NICU admission (11.0% vs 13.3%; aRD, -1.89 per 100 newborns [95% CI, -2.49 to -1.30]; aRR, 0.85 [95% CI, 0.80-0.90]), or low Apgar score (1.8% vs 2.0%; aRD, -0.31 per 100 newborns [95% CI, -0.56 to -0.06]; aRR, 0.84 [95% CI, 0.73-0.97]). Findings were qualitatively similar when compared with individuals who did not receive COVID-19 vaccination at any point (nâ€‰=â€‰30â€¯115). CONCLUSIONS AND RELEVANCE: In this population-based cohort study in Ontario, Canada, COVID-19 vaccination during pregnancy, compared with vaccination after pregnancy and with no vaccination, was not significantly associated with increased risk of adverse peripartum outcomes. Study

interpretation should consider that the vaccinations received during pregnancy were primarily mRNA vaccines administered in the second and third trimester.
Orbital Inflammation Following COVID-19 Vaccination. Three patients presented with periorbital swelling, pain with extraocular movements, and binocular diplopia 1-4 days after receiving an mRNA Coronavirus Infectious Disease-19 (COVID-19) vaccine (BNT162b2, Pfizer/BioNTech; mRNA-1273, Moderna). All patients had a normal afferent function, unilateral limitation of extraocular motility, proptosis, and periorbital inflammation. Neuroimaging of the orbits with contrast revealed inflammation and enlargement of extraocular muscles in 2 cases and the lacrimal gland in 1 case. In all 3 cases, an extensive infectious and inflammatory laboratory work-up was unremarkable and signs and symptoms of orbital inflammation rapidly improved to complete resolution after treatment with high-dose oral prednisone. This is the first reported series of orbital inflammation occurring shortly after administration of the COVID-19 vaccine. Clinicians may consider an inflammatory postvaccine etiology as an alternative to presumed idiopathic diagnosis in such cases.
Comparative effectiveness and safety of homologous two-dose ChAdOx1 versus heterologous vaccination with ChAdOx1 and BNT162b2. Small trials have suggested that heterologous vaccination with first-dose ChAdOx1 and second-dose BNT162b2 may generate a better immune response than homologous vaccination with two doses of ChAdOx1. In this cohort analysis, we use linked data from Catalonia (Spain), where those aged <60 who received a first dose of ChAdOx1 could choose between ChAdOx1 and BNT162b2 for their second dose. Comparable cohorts were obtained after exact-matching 14,325/17,849 (80.3%) people receiving heterologous vaccination to 14,325/149,386 (9.6%) receiving homologous vaccination by age, sex, region, and date of second dose. Of these, 464 (3.2%) in the heterologous and 694 (4.8%) in the homologous groups developed COVID-19 between 1st June 2021 and 5th December 2021. The resulting hazard ratio (95% confidence interval) is 0.66 [0.59-0.74], favouring heterologous vaccination. The two groups had similar testing rates and safety outcomes. Sensitivity and negative control outcome analyses confirm these findings. In conclusion, we demonstrate that a heterologous vaccination schedule with ChAdOx1 followed by BNT162b2 was more efficacious than and similarly safe to homologous vaccination with two doses of ChAdOx1. Most of the infections in our study occurred when Delta was the predominant SARS-CoV-2 variant in Spain. These data agree with previous phase 2 randomised trials.
Case Report: Two Case Reports of Acute Myopericarditis After mRNA COVID-19 Vaccine. BACKGROUND: Cases of myocarditis and myopericarditis after mRNA COVID-19 vaccines have been reported, especially after the second dose and in young males. Their course is generally benign, with symptoms onset after 24-72 h from the dose. CASE SUMMARY: We report two cases of myopericarditis after the second dose of the mRNA-1273 COVID-19 vaccine in two young males. Both the patients were administered the mRNA-1273 COVID-19 vaccine from the same batch on the same day and experienced fever on the same day of the vaccine, and symptoms consisted of myopericarditis 3 days after the dose. DISCUSSION: Myopericarditis is usually considered an uncommon adverse reaction after various vaccinations, reported also after the mRNA COVID-19 vaccine. Several explanations have been proposed, including an abnormal activation of the immune system leading to a pro-inflammatory cascade responsible for myocarditis development. Both patients experienced the same temporal onset as well as the same symptoms, it is also useful to underscore that both vaccines belonged to the same batch of vaccines. However, despite these cases, vaccination against COVID-19 far outweighs the risk linked to COVID-19 infection and remains the best option to overcome this disease.
Severe Multisystem Inflammatory Symptoms in 2 Adults after Short Interval between COVID-19 and Subsequent Vaccination. We observed multisystem inflammatory syndrome in 2 older adults in

the United States who had received mRNA coronavirus disease vaccine soon after natural infection. We identified 5 similar cases from the Vaccine Adverse Events Reporting System. The timing of vaccination soon after natural infection might have an adverse effect on the occurrence of vaccine-related systemic inflammatory disorders.
Safety and Efficacy of a Third Dose of BNT162b2 Covid-19 Vaccine. BACKGROUND: Active immunization with the BNT162b2 vaccine (Pfizer-BioNTech) has been a critical mitigation tool against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection during the coronavirus disease 2019 (Covid-19) pandemic. In light of reports of waning protection occurring 6 months after the primary two-dose vaccine series, data are needed on the safety and efficacy of offering a third (booster) dose in persons 16 years of age or older. METHODS: In this ongoing, placebo-controlled, randomized, phase 3 trial, we assigned participants who had received two 30-Î¼g doses of the BNT162b2 vaccine at least 6 months earlier to be injected with a third dose of the BNT162b2 vaccine or with placebo. We assessed vaccine safety and efficacy against Covid-19 starting 7 days after the third dose. RESULTS: A total of 5081 participants received a third BNT162b2 dose and 5044 received placebo. The median interval between dose 2 and dose 3 was 10.8 months in the vaccine group and 10.7 months in the placebo group; the median follow-up was 2.5 months. Local and systemic reactogenicity events from the third dose were generally of low grade. No new safety signals were identified, and no cases of myocarditis or pericarditis were reported. Among the participants without evidence of previous SARS-CoV-2 infection who could be evaluated, Covid-19 with onset at least 7 days after dose 3 was observed in 6 participants in the vaccine group and in 123 participants in the placebo group, which corresponded to a relative vaccine efficacy of 95.3% (95% confidence interval, 89.5 to 98.3). CONCLUSIONS: A third dose of the BNT162b2 vaccine administered a median of 10.8 months after the second dose provided 95.3% efficacy against Covid-19 as compared with two doses of the BNT162b2 vaccine during a median follow-up of 2.5 months. (Funded by BioNTech and Pfizer; C4591031 ClinicalTrials.gov number, NCT04955626.).
Audio Interview: Covid-19: Why We Publish What We Do.
Presence and quantity of antibodies after vaccination Â«Gam-COVID-VacÂ». The determine is to study the presence and quantity of specific antibodies in individuals vaccinated against COVID-19. A study of 37 blood serums of healthy adults vaccinated against COVID-19 with the vaccine Â«Gam-COVID-VacÂ» (or Â«Sputnik VÂ», National Research Center of Epidemiology and Microbiology named after N.F. Gamalei) was conducted. Blood sampling was carried out 42 days after the introduction of the first component of the vaccine, and 3, 4, 5, 6 months after the end of the full course of vaccination. The presence and quantity of total IgM/IgG antibodies in the blood serum was determined by immunochemiluminescence analysis on an automatic immunochemical analyzer Â«Cobas e 411Â» (Â«Roche DiagnosticsÂ», Germany). The results were processed by modern statistical methods. 42 days after the introduction of the first component of the vaccine Â«Gam-COVID-VacÂ» AT was developed in all study participants, the values of their number were variable and ranged from 36,43 to 265,43 BAU/ ml. 3, 4, 5 and 6 months after the end of the full course of vaccination AT were detected in all study participants. 6 months after the end of the full course of vaccination the number antibodies decreased by 28,16%.
COVID-19 Vaccine-Induced Pro-thrombotic Immune Thrombocytopenia (VIPIT): State of the Art. In 2020, as the severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) pandemic spread rapidly throughout the world, scientists worked relentlessly to develop and test the safety and effectiveness of potential vaccines. Usually, the vaccine development process involves years of investigation and testing prior to gaining approval for use in practice. A pathogenic PF4-dependent syndrome, unrelated to the use of heparin therapy, may be manifested following the administration of viral vector vaccines. It leads to severe clot formation at unusual sites approximately in 1 out of

110.000 vaccinated persons. This side effect, although rare, represents a newly devastating clotting phenomenon manifested in otherwise healthy young adults, who are often female. An in-depth description of the specific biological mechanisms implicated in the syndrome is here summarized.

Post-pandemic COVID-19 estimated and forecasted hotspots in the Association of Southeast Asian Nations (ASEAN) countries in connection to vaccination rate. After a two-year pandemic, coronavirus disease 2019 (COVID-19) is still a serious public health problem and economic stability worldwide, particularly in the Association of Southeast Asian Nations (ASEAN) countries. The objective of this study was to identify the wave periods, provide an accurate space-time forecast of COVID-19 disease and its relationship to vaccination rates. We combined a hierarchical Bayesian pure spatiotemporal model and locally weighted scatterplot smoothing techniques to identify the wave periods and to provide weekly COVID-19 forecasts for the period 15 December 2021 to 5 January 2022 and to identify the relationship between the COVID-19 risk and the vaccination rate. We discovered that each ASIAN country had a unique COVID-19 time wave and duration. Additionally, we discovered that the number of COVID-19 cases was quite low and that no weekly hotspots were identified during the study period. The vaccination rate showed a nonlinear relationship with the COVID-19 risk, with a different temporal pattern for each ASEAN country. We reached the conclusion that vaccination, in comparison to other interventions, has a large influence over a longer time span.

Humoral response following SARS-CoV-2 vaccination: not all immunosuppressants are created equal.

Humoral responses after second and third SARS-CoV-2 vaccination in patients with immune-mediated inflammatory disorders on immunosuppressants: a cohort study. BACKGROUND: Disease-specific studies have reported impaired humoral responses after SARS-CoV-2 vaccination in patients with immune-mediated inflammatory disorders treated with specific immunosuppressants. Disease-overarching studies, and data on recall responses and third vaccinations are scarce. Our primary objective was to investigate the effects of immunosuppressive monotherapies on the humoral immune response after SARS-CoV-2 vaccination in patients with prevalent immune-mediated inflammatory disorders. METHODS: We did a cohort study in participants treated in outpatient clinics in seven university hospitals and one rheumatology treatment centre in the Netherlands as well as participants included in two national cohort studies on COVID-19-related disease severity. We included patients aged older than 18 years, diagnosed with any of the prespecified immune-mediated inflammatory disorders, who were able to understand and complete questionnaires in Dutch. Participants with immune-mediated inflammatory disorders who were not on systemic immunosuppressants and healthy participants were included as controls. Anti-receptor binding domain IgG responses and neutralisation capacity were monitored following standard vaccination regimens and a three-vaccination regimen in subgroups. Hybrid immune responses-ie, vaccination after previous SARS-CoV-2 infection-were studied as a proxy for recall responses. FINDINGS: Between Feb 2 and Aug 1, 2021, we included 3222 participants in our cohort. Sera from 2339 participants, 1869 without and 470 participants with previous SARS-CoV-2 infection were analysed (mean age 49Â·9 years [SD 13Â·7]; 1470 [62Â·8%] females and 869 [37Â·2%] males). Humoral responses did not differ between disorders. Anti-CD20 therapy, sphingosine 1-phosphate receptor (S1P) modulators, and mycophenolate mofetil combined with corticosteroids were associated with lower relative risks for reaching seroconversion following standard vaccination (0Â·32 [95% CI 0Â·19-0Â·49] for anti-CD20 therapy, 0Â·35 [0Â·21-0Â·55] for S1P modulators, and 0Â·61 [0Â·40-0Â·90] for mycophenolate mofetil combined with corticosteroids). A third vaccination increased seroconversion for mycophenolate mofetil combination treatments (from 52Â·6% after the second vaccination to 89Â·5% after the third) but not significantly for anti-CD20 therapies (from 36Â·8% to 45Â·6%) and S1P modulators (from 35Â·5% to 48Â·4%). Most other immunosuppressant groups showed moderately reduced antibody titres after standard vaccination that did not increase after a third vaccination, although

seroconversion rates and neutralisation capacity were unaffected. In participants with previous SARS-CoV-2 infection, SARS-CoV-2 antibodies were boosted after vaccination, regardless of immunosuppressive treatment. INTERPRETATION: Humoral responses following vaccination are impaired by specific immunosuppressants. After standard vaccination regimens, patients with immune-mediated inflammatory disorders taking most immunosuppressants show similar seroconversion to controls, although antibody titres might be moderately reduced. As neutralisation capacity and recall responses are also preserved in these patients, this is not likely to translate to loss of (short-term) protection. In patients on immunosuppressants showing poor humoral responses after standard vaccination regimens, a third vaccination resulted in additional seroconversion in patients taking mycophenolate mofetil combination treatments, whereas the effect of a third vaccination in patients on anti-CD20 therapy and S1P modulators was limited. FUNDING: ZonMw (The Netherlands Organization for Health Research and Development).
Transient Myopericarditis Following Vaccination for COVID-19. Clinical trials of the messenger ribonucleic acid (mRNA)-1273 vaccine developed by Moderna proved excellent safety and efficacy for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) prevention. However, the Centers for Disease Control and Prevention (CDC) has been investigating cases of myocarditis and pericarditis reported in the Vaccine Adverse Event Reporting System (VAERS) database. Currently, the CDC is reporting rates of 40.6 cases per million after second doses of mRNA vaccines administered to males 30 years or younger. Notably, the initial vaccine trials consisted of a limited number of adolescents and young adults; therefore, they were likely not powered to detect this rare potential side effect. We present a case of transient myopericarditis occurring in a young and healthy patient within 48 h of his second vaccination dose. Although a definitive causal relationship has yet to be determined, we came to this correlation because of the temporal association seen in our patient, secondary to the second dose of vaccination. Furthermore, we also suspect an autoimmune mechanism as the cause of cardiac injury, augmented by the increased vaccine reactogenicity seen in younger patients.
The Impact of COVID-19 and Vaccine on the Human Nervous System. The coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has precipitated a global health crisis of unprecedented proportions. Due to its severe impact, multiple COVID-19 vaccines are being developed, approved, and manufactured rapidly. However, some serious adverse events (AEs) were reported after the application of them, significantly increasing concerns about the safety and efficacy of the vaccines and doubts about the necessity of vaccination. Particularly, previous vaccination campaigns have shown us that partial vaccination can induce neurologic AEs. Herein, we discuss in depth the involvement of the nervous system during SARS-CoV-2 infection or after vaccination. On the one hand, COVID-19 could pose an enormous threat to human neurological health through direct infection and indirect neurotoxicity effects. On the other hand, our review indicated that only a few serious neurological AEs following vaccination occurred and among which headache was the most common. Moreover, some neurological AEs do not seem to be related to vaccination. Of course, the causal relationships between several vaccines and AEs are considered plausible, and it is not doubtful that these AEs should be taken seriously by clinicians in assessing the potential risks and benefits of vaccinations in special populations. Nevertheless, in the case of the rapid spread of COVID-19, the potential side effects of vaccination on the nervous system should be compared with adverse COVID-19 outcomes rather than being considered alone. Thus, it is obviously a wise option to be vaccinated instead of suffering from serious adverse symptoms of virus infection.
Hypersensitivity Myocarditis and the Pathogenetic Conundrum of COVID-19 Vaccine-Related Myocarditis.
Limited T cell response to SARS-CoV-2 mRNA vaccine among patients with cancer receiving different cancer treatments. INTRODUCTION: Patients with cancer (PC) are at high risk of acquiring COVID-

19 and can develop more serious complications. Deeper understanding of vaccines immunogenicity in this population is crucial for adequately planning vaccines programs. The ONCOVac study aimed to comprehensively assess the immunogenicity of mRNA-1273 vaccine in terms of humoral and cellular response. METHODS: We conducted a prospective, single-center study including patients with solid tumours treated with cyclin-dependent kinases 4 and 6 inhibitors (CDK4/6i), immunotherapy (IT) or chemotherapy (CT). Patients were enrolled previously to vaccination with mRNA-1273. We also involved health care workers (HCW) to serve as a control group. We took blood samples before first dose administration (BL), after first dose (1D), and after second dose (2D). The primary objective was to compare the rate and magnitude of T cell response after second dose whereas safety and humoral response were defined as secondary objectives. We also collected patient reported outcomes after both the first and second vaccine dose and a six-month follow-up period to diagnose incident COVID-19 cases was planned. RESULTS: The rate of specific anti-S serologic positivity (anti-S IgG cut-off point at 7,14 BAU/mL) was significantly higher in HCW compared to PC after 1D (100% versus 83.8%; pÂ =Â 0.04), but similar after 2D (100% versus 95.8%; pÂ =Â 0.5). This difference after 1D was driven by PC treated with CT (100% versus 64.5%; pÂ =Â 0.001). Cellular response after 2D was significantly lower in PC than in HCW for both CD4+ (91.7% versus 59.7%; pÂ =Â 0.001) and CD8+ (94.4% versus 55.6%; pÂ <Â 0.001) T cells. We found a difference on pre-existing CD4+ T cell response in HCW comparing to PC (36% and 17%, pÂ =Â 0.03); without difference in pre-existing CD8+ T cell response (31% and 23%, pÂ =Â 0.5). After excluding patients with pre-existing T cell response, PC achieved even lower CD4+ (50.9% versus 95.5%, pÂ <Â 0.001) and CD8+ (45.5% versus 95.5%, pÂ <Â 0.001) T cell response compared with HCW. Regarding safety, PC reported notably more adverse events than HCW (96.6% versus 69.2%, pÂ <Â 0.001). CONCLUSION: We demonstrated that PC showed a similar humoral response but a lower T cell response following two doses of mRNA-1273 vaccination. Further studies are needed to complement our results and determine the implication of low T cell response on clinical protection of PC against COVID-19.

A systematic review on mucocutaneous presentations after COVID-19 vaccination and expert recommendations about vaccination of important immune-mediated dermatologic disorders.
With dermatologic side effects being fairly prevalent following vaccination against COVID-19, and the multitude of studies aiming to report and analyze these adverse events, the need for an extensive investigation on previous studies seemed urgent, in order to provide a thorough body of information about these post-COVID-19 immunization mucocutaneous reactions. To achieve this goal, a comprehensive electronic search was performed through the international databases including Medline (PubMed), Scopus, Cochrane, Web of science, and Google scholar on July 12, 2021, and all articles regarding mucocutaneous manifestations and considerations after COVID-19 vaccine administration were retrieved using the following keywords: COVID-19 vaccine, dermatology considerations and mucocutaneous manifestations. A total of 917 records were retrieved and a final number of 180 articles were included in data extraction. Mild, moderate, severe and potentially life-threatening adverse events have been reported following immunization with COVID vaccines, through case reports, case series, observational studies, randomized clinical trials, and further recommendations and consensus position papers regarding vaccination. In this systematic review, we categorized these results in detail into five elaborate tables, making what we believe to be an extensively informative, unprecedented set of data on this topic. Based on our findings, in the viewpoint of the pros and cons of vaccination, mucocutaneous adverse events were mostly non-significant, self-limiting reactions, and for the more uncommon moderate to severe reactions, guidelines and consensus position papers could be of great importance to provide those at higher risks and those with specific worries of flare-ups or inefficient immunization, with sufficient

recommendations to safely schedule their vaccine doses, or avoid vaccination if they have the discussed contra-indications.

Pharmacological consideration of COVID-19 infection and vaccines in pregnancy. COVID-19 is a pandemic of the 21st century that recorded 234 809 103 confirmed cases and more than 4 800 375 deaths. Many studies report the effect of COVID-19 in the overall population; nevertheless, there is information scarceness related to pharmacological management and pregnancy and fetal outcomes during the epidemic. Pregnancy is a state of change in immune physiology and anatomy modulation in preference to immune suppression. Additionally, manifold interactions with the health care system during pregnancy increases the chance of infection, and managing, pregnant population poses a more significant challenge. This review will summarize the available data on pharmacological considerations and vaccines in pregnancy and their adverse effects on fetal outcomes. Several drug choices include but are not limited to antivirals and antimalarial and combinations, corticosteroids, nonsteroidal anti-inflammatory drugs, and antipyretics. Approved vaccines for pregnancy include Pfizer/BioNTech and mRNA-1273 Moderna/National Institutes of Health. COVID-19 treatment approaches vary across different countries; the WHO and the Centers for Disease Control and Prevention guidelines and country regulators advise managing adverse effects on pregnancy and fetal outcome. But the efficacy of these drugs is questionable. There is no adequate literature to demonstrate the safety of these drugs in pregnant and lactating women. Hence, well-conducted studies that assess the safety of anti-COVID-19 medications and vaccines in pregnancy and lactating women are needed.

Clinicopathological Characteristics of Inflammatory Myositis Induced by COVID-19 Vaccine (Pfizer-BioNTech BNT162b2): A Case Report. As more individuals were coronavirus disease 2019 (COVID-19) vaccinated, unexpected side effects appeared. Herein, we present the case of a 30-year-old man with myopathy in both extremities after the second dose of the Pfizer-BioNTech (BNT162b2) COVID-19 vaccine. Symptoms, swelling and pain, started from the proximal upper and lower extremities and extended to the distal parts. Although he underwent massive hydration, the muscle enzyme level continuously increased. He complained of dysphagia and dysarthria. Microscopically, muscle biopsy showed multifocal or scattered macrophage infiltration and degenerated myofibers. In contrast to general myopathy including inflammatory myositis and rhabdomyolysis, vaccine-induced inflammatory myositis shows a prolonged increase in muscle enzyme levels and multifocal macrophage infiltration with necrosis of the muscle fibers. Symptoms improved with glucocorticoid and immunosuppressive treatment. If vaccinated individuals experience severe and continuous muscle pain and swelling, clinicians should consider vaccine-induced inflammatory myositis, measure the muscle enzyme levels, and perform muscle biopsy for a definite diagnosis.

Bleeding risk of intramuscular injection of COVID-19 vaccines in adult patients with therapeutic anticoagulation.

Pustular rash triggered by Pfizer-BioNTech COVID-19 vaccination: A case report.

Description of Frequencies of Reported Adverse Events Following Immunization Among Four Different COVID-19 Vaccine Brands. INTRODUCTION: The rapid rollout of coronavirus disease 2019 (COVID-19) vaccines for a large proportion of the population necessitates a strong emphasis on safety. Complementary to the existing spontaneous reporting system, The Netherlands Pharmacovigilance Centre Lareb conducted patient-reported cohort event monitoring (CEM). OBJECTIVE: The primary aim was to investigate differences in the frequencies of any and commonly reported, 'well-known', systemic adverse events following immunization (AEFIs) with four COVID-19 vaccines (Pfizer's Comirnaty(Â®), Moderna's Spikevax(Â®), AstraZeneca's Vaxzevria(Â®) and the Janssen vaccine). As a secondary aim, we analyzed the frequencies of well-known systemic adverse events after the first and, if applicable, second COVID-19 vaccinations, taking into account age, sex

and prior COVID-19 infection. METHODS: Patient-reported outcomes (PROs) in the Netherlands starting in February 2021 were analyzed using a prospective cohort design. RESULTS: Data of 27,554 participants who received one vaccination and 20,682 participants who received complete immunization were analyzed. The percentage of patients reporting any AEFI was high and ranged from approximately 53% for the Pfizer vaccine to approximately 94% for the Moderna vaccine. The frequency of serious AEFIs was low, with the highest frequency found for the AstraZeneca vaccine (0.228%). AEFIs were most often experienced by participants receiving the first dose of the AstraZeneca and Janssen vaccines and the second dose of the Moderna vaccine; the Pfizer vaccine was associated with the lowest rate of AEFIs. Participants with a COVID-19 history before vaccination experienced commonly reported systemic AEFIs more frequently after the first vaccination than after the second vaccination. Women and young people experienced more AEFIs than men and older people, respectively. CONCLUSIONS: The analysis of a large cohort provides important information about the rates of AEFIs across age groups, among brands of vaccines and between those with and without prior COVID-19 infection. Participants reported a high number of AEFIs in general, but the frequency of serious AEFIs was low.

Pericarditis with Increased Vascular Permeability after COVID-19 Vaccination.

Severe Immune Thrombocytopenia after COVID-19 Vaccination: Two Case Reports and a Literature Review. We herein report two cases of coronavirus disease 2019 (COVID-19) vaccine-induced immune thrombocytopenia (ITP). A 69-year-old Japanese man developed severe thrombocytopenia after COVID-19 vaccination. He had oral bleeding and hemoptysis but no thrombotic symptoms. He improved rapidly with oral prednisolone therapy. A 34-year-old Japanese woman had generalized purpura after COVID-19 vaccination. Her platelet count improved rapidly after treatment with prednisolone and eltrombopag. The occurrence of two cases of ITP after COVID-19 vaccination at a single institution suggests that there could be more such undiagnosed cases, especially cases of mild secondary ITP.

A Case of Suspected COVID-19 Vaccine-related Thrombophlebitis.

Post-SARS-CoV-2-vaccine shoulder pain: Is it relevant to the vaccine injection? - Correspondence.

Oxidative stress and endogenous DNA damage in blood mononuclear cells may predict anti-SARS-CoV-2 antibody titers after vaccination in older adults. Immune senescence in the elderly has been associated with chronic oxidative stress and DNA damage accumulation. Herein we tested the hypothesis that increased endogenous DNA damage and oxidative stress in peripheral blood mononuclear cells of older adults associate with diminished humoral immune response to SARS-CoV-2 vaccination. Increased oxidative stress and DNA double-strand breaks (DSBs) were detected in 9 non-immunocompromised individuals aged 80-96Â years compared to 11 adults aged 27-44Â years, before, as well as on days 1 and 14 after the first dose, and on day 14 after the second dose of the BNT162B2-mRNA vaccine (all pÂ <Â 0.05). SARS-CoV-2 vaccination induced a resolvable increase in oxidative stress and DNA damage, but individual DSB-repair efficiency was unaffected by vaccination irrespective of age, confirming vaccination safety. Individual titers of anti-Spike-Receptor Binding Domain (S-RBD)-IgG antibodies, and the neutralizing capacity of circulating anti-SARS-CoV-2 antibodies, measured on day 14 after the second dose in all participants, correlated inversely with the corresponding pre-vaccination endogenous oxidative stress and DSB levels (all pÂ <Â 0.05). In particular, a strong inverse correlation of individual pre-vaccination DSB levels with both the respective anti-S-RBD-IgG antibodies titers (rÂ =Â -0.867) and neutralizing capacity of circulating anti-SARS-CoV-2 antibodies (rÂ =Â -0.983) among the 9 older adults was evident. These findings suggest that humoral responses to SARS-CoV-2 vaccination may be weaker when immune cells are under oxidative and/or genomic stress. Whether such measurements may serve as biomarkers of vaccine efficacy in older adults warrants further studies.

Current status of COVID-19 vaccination: safety and liability concern for children, pregnant and lactating women. INTRODUCTION: Since its inception, Coronavirus disease-19 (COVID-19), caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), has claimed a significant number of lives around the world. AREA COVERED: COVID-19 vaccine development involves several vaccine platforms, including traditional live-attenuated or killed viral particles, viral vectors or DNA, and mRNA-based vaccines. The efficacy and effectiveness (EV) of these vaccines must be assessed in order to determine the extent to which they can protect us against infection. Despite the fact that some affluent countries attempted to vaccinate the majority of their inhabitants, children and pregnant women were first excluded. EXPERT OPINION: While the severity of COVID-19 is less severe in children, the COVID-19-related complications are more severe.SARS-CoV-2 infection is also dangerous for pregnant women. The key to limiting disease spread is early discovery, isolation, and the development of safe and efficient vaccinations. As a result, the purpose of this study is to highlight the current development of various COVID-19 vaccine platforms for different groups of people at higher risk of COVID-19, with a special focus on children, pregnant and lactating women, as well as structural and pathogenicity elements of SARS CoV-2.

COVID-19 vaccination in cancer patients: a narrative review. Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has affected over 220 million individuals worldwide, and has been shown to cause increased disease severity and mortality in patients with active cancer versus healthy individuals. Vaccination is important in reducing COVID-19-associated morbidity and mortality. Thus, the aim of this article was to review the existing knowledge on effectiveness, immunogenicity and safety of COVID-19 vaccines in patients with cancer. Fifty-four articles were included following a search of PubMed and Google Scholar databases for studies published between January 2020 and September 2021 that investigated humoral and cell-mediated immune responses following COVID-19 vaccination in patients with cancer. Immunogenicity of vaccines was found to be lower in patients with cancer versus healthy individuals, and humoral immune responses were inferior in those with haematological versus solid cancers. Patient-, disease-, and treatment-related factors associated with poorer vaccine responses should be identified and corrected or mitigated when possible. Consideration should be given to offering patients with cancer second doses of COVID vaccine at shorter intervals than in healthy individuals. Patients with cancer warrant a third vaccine dose and must be prioritized in vaccination schedules. Vaccine adverse effect profiles are comparable between patients with cancer and healthy individuals.

COVID-19 mRNA Vaccine-Associated Uveitis Leading to Diagnosis of Sarcoidosis: Case Report and Review of Literature. A 34-year-old Japanese person with male gender identity who had been taking intramuscular injection of methyltestosterone depot for 11 years after bilateral mastectomy noticed blurred vision 5 days after the second vaccination for COVID-19 (Tozinameran; Pfizer-BioNTech) in the interval of 3 weeks following the first vaccination. The patient was diagnosed as granulomatous iritis with mutton-fat keratic precipitates and small iris nodules at the pupillary margin in the right eye and began to have 0.1% betamethasone eye drops with good response. The patient, however, continued to have fever and malaise and showed a high level of serum soluble interleukin-2 receptor (sIL-2R) even 4 weeks after the second vaccination. Computed tomographic scan disclosed mediastinal and bilateral hilar small lymphadenopathy together with limited granular lesion in the right lung. Gallium-67 scintigraphy demonstrated high uptake not only in mediastinal and hilar lymph nodes but also in bilateral parotid glands. Right parotid gland biopsy revealed noncaseating granulomas and proved pathological diagnosis of sarcoidosis. The systemic symptoms were relieved by oral prednisolone 20 mg daily. Even though the causal relationship remains undetermined, this case is unique at the point that vaccine-associated uveitis led to the detection of pulmonary lesions and lymphadenopathy, resulting in clinical and pathological diagnosis of sarcoidosis. In literature

review, 3 patients showed sarcoidosis-like diseases after COVID-19 vaccination: 2 patients were diagnosed clinically as Lofgren syndrome with acute onset of erythema nodosum and ankle swelling, with or without mediastinal and hilar lymphadenopathy, whereas 1 patient with mediastinal lymphadenopathy but no uveitis was diagnosed pathologically by biopsy as sarcoidosis.

Broad Cross-reactive IgA and IgG Against Human Coronaviruses in Milk Induced by COVID-19 Vaccination and Infection. It is currently unclear if SARS-CoV-2 infection or mRNA vaccination can also induce IgG and IgA against common human coronaviruses (HCoVs) in lactating parents. Here we prospectively analyzed human milk (HM) and blood samples from lactating parents to measure the temporal patterns of anti-SARS-CoV-2 specific and anti-HCoV cross-reactive IgA and IgG responses. Two cohorts were analyzed: a vaccination cohort (n=30) who received mRNA-based vaccines for COVID-19 (mRNA-1273 or BNT162b2), and an infection cohort (n=45) with COVID-19 disease. Longitudinal HM and fingerstick blood samples were collected pre- and post-vaccination or, for infected subjects, at 5 time-points 14 - 28 days after confirmed diagnosis. The anti-spike(S) and antinucleocapsid(N) IgA and IgG antibody levels against SARS-CoV-2 and HCoVs were measured by multiplex immunoassay (mPlex-CoV). We found that vaccination significantly increased the anti-S IgA and IgG levels in HM. In contrast, while IgG levels increased after a second vaccine dose, blood and HM IgA started to decrease. Moreover, HM and blood anti-S IgG levels were significantly correlated, but anti-S IgA levels were not. SARS2 acute infection elicited anti-S IgG and IgA that showed much higher correlations between HM and blood compared to vaccination. Vaccination and infection were able to significantly increase the broadly cross-reactive IgG recognizing HCoVs in HM and blood than the IgA antibodies in HM and blood. In addition, the broader cross-reactivity of IgG in HM versus blood indicates that COVID-19 vaccination and infection might provide passive immunity through HM for the breastfed infants not only against SARS-CoV-2 but also against common cold coronaviruses. IMPORTANCE: It is unknown if COVID-19 mRNA vaccination and infection in lactating mothers results in cross-reactive antibodies against other common human coronaviruses. Our study demonstrates that mRNA vaccination and COVID-19 infection increase anti-spike SARS-CoV-2 IgA and IgG in both blood and milk. IgA and IgG antibody concentrations in milk were more tightly correlated with concentrations in blood after infection compared to mRNA vaccination. Notably, both infection and vaccination resulted in increased IgG against common seasonal Î² -coronaviruses. This suggests that SARS-CoV-2 vaccination or infection in a lactating parent may result in passive immunity against SARS-CoV-2 and seasonal coronaviruses for the recipient infant.

Dynamic single-cell RNA sequencing reveals BCG vaccination curtails SARS-CoV-2 induced disease severity and lung inflammation. COVID-19 continues to exact a toll on human health despite the availability of several vaccines. Bacillus Calmette GuÃ©rin (BCG) has been shown to confer heterologous immune protection against viral infections including COVID-19 and has been proposed as vaccine against SARS-CoV-2 (SCV2). Here we tested intravenous BCG vaccination against COVID-19 using the golden Syrian hamster model together with immune profiling and single cell RNA sequencing (scRNAseq). We observed that BCG reduced both lung SCV2 viral load and bronchopneumonia. This was accompanied by an increase in lung alveolar macrophages, a reversal of SCV2-mediated T cell lymphopenia, and reduced lung granulocytes. Single cell transcriptome profiling showed that BCG uniquely recruits immunoglobulin-producing plasma cells to the lung suggesting accelerated antibody production. BCG vaccination also recruited elevated levels of Th1, Th17, Treg, CTLs, and Tmem cells, and differentially expressed gene (DEG) analysis showed a transcriptional shift away from exhaustion markers and towards antigen presentation and repair. Similarly, BCG enhanced lung recruitment of alveolar macrophages and reduced key interstitial macrophage subsets, with both cell-types also showing reduced IFN-associated gene expression. Our observations indicate that BCG vaccination protects against SCV2 immunopathology by promoting early lung immunoglobulin

production and immunotolerizing transcriptional patterns among key myeloid and lymphoid populations.

Breakthrough infections after COVID-19 vaccination: Insights, perspectives and challenges. Vaccination programs against SARS-CoV-2 constitute the mainstay of public health interventions against the global COVID-19 pandemic. Currently available vaccines have shown 90% or better rates of protection against severe disease and mortality. Barely a year after vaccines became available, the Omicron variant and its unprecedented speed of transmission has posed a new challenge. Overall, Omicron presents increased immune escape, transmissibility, and decreased pathogenicity. Vaccines do not offer a full protection against SARS-CoV-2 acquisition, since "breakthrough" infections may occur in fully vaccinated individuals, who may in turn spread the virus to others. Breakthrough infections may be causally related to the viral profile (viral variant and load, incubation period, transmissibility, pathogenicity, immune evasion), immunity characteristics (mucosal versus systemic immunity, duration of immunity, etc.), host determinants (age, comorbidities, immune status, immunosuppressive drugs) and vaccination properties (platform, antigen dose, dose number, dose interval, route of administration). Determining the rate of breakthrough infections may be challenging and necessitates the conduction of population-based studies regarding vaccine effectiveness as well as neutralizing antibody testing, a surrogate of immune protection. In this review, we analyze the causes of breakthrough infections, their clinical consequences (severity of infection and transmission), methods of determining their incidence as well as challenges and perspectives. Long COVID as well as multi-inflammatory syndrome in adolescents may be significantly reduced in breakthrough infections. The need for universal pancoranavirus vaccines that would aim at protecting against a plethora of SARS-CoV-2 variants as well as emerging variants is discussed. Finally, novel vaccine strategies, such as nasal vaccines, may confer robust mucosal and systemic protection, reducing efficiently transmission.

Real-world, single-center experience of SARS-CoV-2 vaccination in immune thrombocytopenia. BACKGROUND: Immune thrombocytopenic purpura (ITP) relapse following vaccination remains poorly reported in the adult population. OBJECTIVES: This report details real world data from the largest single-center cohort of ITP relapse following severe acute respiratory syndrome (SARS-CoV-2) vaccination. METHODS: The vaccination status of 294 patients under active follow-up was reviewed. A total of 17 patients were identified resulting in an incidence of ITP relapse following SARS-CoV-2 vaccination in this cohort of 6.6% and an incidence of newly diagnosed ITP following SARS-CoV-2 vaccination of 1.4%. RESULTS: Patients were noted to develop marked deviation of platelet count from baseline following vaccination (PÂ =<Â .0001). Fourteen patients had a prior diagnosis of ITP and median follow-up following diagnosis was 4Â years (range 0-45Â years). Days from vaccination to presentation ranged from 2-42 (median 14) and the follow-up period was 34Â weeks. Fifteen patients (88%) presented with symptoms and all 17 patients developed symptoms during the follow-up period. Nine patients (53%) received a second dose of vaccine during the follow-up period with seven patients (78%) requiring therapeutic support to facilitate second vaccination. Decision to treat patients was multi-factorial and aimed at decreasing bleeding symptoms and obtaining a platelet count >30Â Ã—Â 10(9) /L. Sixteen patients (94%) required therapeutic intervention and at the end of the follow-up period, four patients (24%) remained unresponsive to treatment with a platelet count <30Â Ã—Â 10(9) /L. CONCLUSION: Vaccination of ITP patients continues to have important clinical benefit; however, recommendations for patients who relapse remain lacking. This report outlines the real-world patient outcomes in the era of widespread SARS-CoV-2 vaccination.

A Review of Recent Studies on the Effects of SARS-CoV-2 Infection and SARS-CoV-2 Vaccines on Male Reproductive Health. According to world statistics, men are more susceptible to the coronavirus disease 2019 (COVID-19) than are women. Considering the interconnection between infections and

male infertility, investigation of the potential impact of COVID-19 on men's reproductive health is now a particularly relevant topic. Published data indicate decreased sperm quality and orchitis development in patients with COVID-19, including reduced sperm count, decreased sperm motility, and elevated DNA fragmentation index. Although mass vaccination against COVID-19 is currently being carried out worldwide using available authorized vaccines, the effect of these vaccines on men's reproductive health has not yet been investigated. There is currently no evidence that SARS-CoV-2 can be transmitted in semen, but available data suggest that it can infect spermatogonia, spermatids, Leydig cells, and Sertoli cells. Therefore, SARS-CoV-2 orchitis and reduced male fertility may be long-term complications of COVID-19, which requires further investigation. Currently, there is also no evidence that vaccines against SARS-CoV-2 have any pathological effects on spermatogenesis or male reproductive health. Thus, further studies are needed to determine the effects of COVID-19 and COVID-19 vaccines on men's reproductive health, which will help to optimize the management and rehabilitation of these patients. This review aims to discuss recent studies on the impact of the COVID-19 and COVID-19 vaccines on men's reproductive health. The article addresses various issues such as the effect of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) on testosterone biosynthesis, semen parameters, testicular tissue, and epididymis.

Inflammatory demyelinating polyneuropathy after the ChAdOx1 nCoV-19 vaccine may follow a chronic course. BACKGROUND: Rare autoimmune neurological events have been reported during the ongoing global drive for mass vaccination as a means of controlling the Covid-19 pandemic. Guillain-BarrÃ© syndrome, an acute inflammatory neuropathy well recognised as a rare complication of influenza vaccination, has been reported to follow administration of the ChAdOx1 nCoV-19 (AstraZeneca) vaccine. METHODS: We report four patients with inflammatory demyelinating polyneuropathy after vaccination in whom a relapsing or progressive course indicated the development of chronic inflammatory demyelinating polyneuropathy (CIDP). CONCLUSIONS: Awareness of this complication and distinction from Guillain-BarrÃ© syndrome enables the timely institution of maintenance immunomodulatory treatment. Our report also highlights the likely relationship between vaccination and the subsequent development of CIDP, but definitive demonstration of a causal link needs larger studies.

Post-vaccination SARS-cov-2 infection in nursing home residents, Bordeaux, France. OBJECTIVE: To describe COVID-19 breakthrough infections in two nursing homes (NHs) sites of active COVID-19 clusters despite optimal vaccination coverage. METHODS: A cross-sectional study was conducted in two NHs of south-western France, following the investigation of COVID-19 clusters (February-March 2021). SARS-CoV-2-confirmed infection was defined by positive RT-PCR. Antibodies neutralization capacities were tested in a subgroup of fully-vaccinated and seropositive-residents. RESULTS: Of the 152 residents, 66% were female with median age 87 years (IQR: 80.0-90.2). Overall, 132 (87%) residents received 2 doses of vaccine, 14 (9%) one dose and 6 (4%) were unvaccinated. Forty-seven (31%) residents had confirmed infection (45 (98%) with variant 20I/501Y.V1). All 6 non-vaccinated residents, 4 /14 who had one dose and 37/132 that had two doses, were infected. Of the 39 residents reporting symptoms, 12 and 3 presented severe and critical disease, respectively. One resident with a confirmed infection died. Infected-residents had a median anti-S IgG titre of 19 116.0 (IQR: 3 028.0-39 681.8 AU/mL), 19 times higher than that of non-infected vaccinated persons (1,207.0; IQR: 494.0-2,782.0). In the subgroup of 19 residents tested for neutralizing antibodies, the neutralizing titre (50%) was strongly positively correlated with the anti-S IgG titre (correlation coefficientÂ =Â 0.83), and 1.5 times higher for the infected than non-infected residents [5.9 (IQR: 5.3-6.9) vs. 3.6 (2.9-3.8)]. CONCLUSION: Institutionalized elderly persons who undergo breakthrough infection develop higher titres of anti-S IgGs, which are strongly correlated with the neutralizing capacity of the antibodies. These results advocate for additional vaccine doses in this population.

Acute Eosinophilic Pneumonia Following mRNA COVID-19 Vaccination: A Case Report.

Eosinophilic Pneumonia Associated to SARS-CoV-2 Vaccine.

COVID-19 mRNA-1273 vaccine induces production of vaccine-induced immune thrombotic thrombocytopenia antibodies. [Image: see text]

Neutralizing antibodies to SARS-CoV-2 Omicron variant after third mRNA vaccination in health care workers and elderly subjects. The emergence of SARS-CoV-2 Omicron variant (B.1.1.529) with major spike protein mutations has raised concern over potential neutralization escape and breakthrough infections among vaccinated and previously SARS-CoV-2-infected subjects. We measured cross-protective antibodies against variants in health care workers (HCW, n = 20) and nursing home residents (n = 9) from samples collected at 1-2 months, following the booster (3rd) dose. We also assessed the antibody responses in subjects infected before the Omicron era (n = 38) with subsequent administration of a single mRNA vaccine dose. Following booster vaccination, HCWs had high IgG antibody concentrations to the spike protein and neutralizing antibodies (NAb) were detectable against all variants. IgG concentrations among the elderly remained lower, and some lacked NAbs against the Beta and Omicron variants. NAb titers were significantly reduced against Delta, Beta, and Omicron compared to WT virus regardless of age. Vaccination induced high IgG concentrations and variable titers of cross-reactive NAbs in previously infected subjects, whereas NAb titers against Omicron were barely detectable 1 month postinfection. High IgG concentrations with cross-protective neutralizing activity were detected after three Coronavirus Disease 2019 (COVID-19) vaccine doses in HCWs. However, lower NAb titers seen in the frail elderly suggest inadequate protection against Omicron breakthrough infections, yet protection against severe COVID-19 is expected.

Strong Decay of SARS-CoV-2 Spike Antibodies after 2 BNT162b2 Vaccine Doses and High Antibody Response to a Third Dose in Nursing Home Residents. OBJECTIVES: To measure the antibody decay after 2 BNT162b2 doses and the antibody response after a third vaccine dose administered 6Â months after the second one in nursing home residents with and without prior COVID-19. DESIGN: Cohort study. SETTING AND PARTICIPANTS: Four hundred-eighteen residents from 18 nursing homes. METHODS: Blood receptor-binding domain (RBD)-IgG (IgG II Quant assay, Abbott Diagnostics; upper limit: 5680 BAU) and nucleocapsid-IgG (Abbott Alinity) were measured 21â€'28Â days after the second BNT162b2 dose, as well as 1â€'3Â days before and 21â€'28Â days after the third vaccine dose. RBD-IgG levels of â‰¥592 BAU/mL were considered as high antibody response. Residents with prior positive quantitative reverse transcription polymerase chain reaction on a nasopharyngeal swab or with N-IgG levels above 0.8 S/CO were considered as prior COVID-19 residents. RESULTS: In prior COVID-19 residents (nÂ = 122), RBD-IgG median levels decreased by 82% in 167Â days on average. In the same period, the number of residents with a high antibody response decreased from 88.5% to 54.9% (P < .0001) and increased to 97.5% after the third vaccine dose (PÂ = .02 vs the first measure). In residents without prior COVID-19 (nÂ = 296), RBD-IgG median levels decreased by 89% in 171Â days on average. The number of residents with a high antibody response decreased from 29.4% to 1.7% (P < .0001) and increased to 88.4% after the third vaccine dose (P < .0001 vs the first measure). CONCLUSIONS AND IMPLICATIONS: The strong and rapid decay of RBD-IgG levels after the second BNT162b2 dose in all residents and the high antibody response after the third dose validate the recommendation of a third vaccine dose in residents less than 6Â months after the second dose, prioritizing residents without prior COVID-19. The slope of RBD-IgG decay after the third BNT162b2 dose and the protection level against SARS-CoV-2 B.1.1.529 (omicron) and other variants of concern provided by the high post-boost vaccination RBD-IgG response require further investigation in residents.

A Case Series of Myocarditis Following Third (Booster) Dose of COVID-19 Vaccination: Magnetic Resonance Imaging Study. BACKGROUND: Myocarditis has been reported following the first two doses of Pfizer-BNT162b2 messenger RNA (mRNA) COVID-19 vaccination. Administration of a third dose (booster) of the vaccine was initiated recently in Israel. OBJECTIVE: The aim of this study was to describe the characteristics of patients referred for cardiac magnetic resonance (CMR) imaging with myocarditis following the booster. METHODS: Patients referred for CMR imaging with a clinical diagnosis of myocarditis within 21 days following the booster, between July 13 and November 11, 2021, were analyzed. RESULTS: Overall, 4 patients were included, 3/4 (75%) were men, and the mean age was 27 Â± 10 years. The time from booster administration to the onset of symptoms was 5.75 Â± 4.8 days (range 2-14). Obstructive coronary artery disease was excluded in 3 of the patients (75%). CMR was performed 34 Â± 15 days (range 8-47 days) following the 3rd vaccination. The mean left ventricular ejection fraction was 61 Â± 7% (range 53-71%), and regional wall motion abnormalities were present in one of the patients. Global T1 was increased in one of the patients, while focal T1 values were increased in 3 of the patients. Global T2 was increased in one of the patients, while focal T2 values were increased in all the patients. Global ECV was increased in 3 of the patients, while focal ECV was increased in all the patients. Median late gadolinium enhancement (LGE) was 4 Â± 3% (range 1-9%), with the inferolateral segment as the most common location (3 of the 4 patients). All the patients met the Updated Lake Louise Criteria. CONCLUSIONS: Patient characteristics and CMR imaging findings of myocarditis following the administration of the booster vaccine are relatively mild and consistent with those observed with the first two doses. Although larger-scale prospective studies are necessary, these initial findings are somewhat reassuring.

Decline of Humoral and Cellular Immune Responses Against SARS-CoV-2 6 Months After Full BNT162b2 Vaccination in Hospital Healthcare Workers. Clinical trials and real-world evidence on COVID-19 vaccines have shown their effectiveness against severe disease and death but the durability of protection remains unknown. We analysed the humoral and T-cell immune responses in 110 healthcare workers (HCWs) vaccinated according to the manufacturer's recommended schedule of dose 2 three weeks after dose 1 from a prospective on-going cohort in early 2021, 3 and 6 months after full vaccination with the BNT162b2 mRNA vaccine. Anti-RBD IgG titres were lower in HCWs over 60 years old 3 months after the second dose (p=0.03) and declined in all the subjects between 3 and 6 months with a median percentage change of -58.5%, irrespective of age and baseline comorbidities. Specific T-cell response measured by IGRA declined over time by at least 42% (median) in 91 HCWs and increased by 33% (median) in 17 others. Six HCWs had a negative T-cell response at 6 months. Ongoing follow-up should provide correlates of long-term protection according to the different immune response profiles observed. COVIDIM study was registered under the number NCT04896788 on clinicaltrials.gov.

Neutralizing Antibody Activity Against the B.1.617.2 (delta) Variant Before and After a Third BNT162b2 Vaccine Dose in Hemodialysis Patients. Hemodialysis patients are at high risk for severe COVID-19, and impaired seroconversion rates have been demonstrated after COVID-19 vaccination. Humoral immunity wanes over time and variants of concern with immune escape are posing an increasing threat. Little is known about protection against the B.1.617.2 (delta) variant of concern in hemodialysis patients before and after third vaccination. We determined anti-S1 IgG, surrogate neutralizing, and IgG antibodies against different SARS-CoV-2 epitopes in 84 hemodialysis patients directly before and three weeks after a third vaccine dose with BNT162b2. Third vaccination was performed after a median (IQR) of 119 (109-165) days after second vaccination. In addition, neutralizing activity against the B.1.617.2 (delta) variant was assessed in 31 seroconverted hemodialysis patients before and after third vaccination. Triple seropositivity for anti-S1 IgG, surrogate neutralizing, and anti-RBD antibodies increased from 31/84 (37%) dialysis patients after

second to 80/84 (95%) after third vaccination. Neutralizing activity against the B.1.617.2 (delta) variant was significantly higher after third vaccination with a median (IQR) ID(50) of 1:320 (1:160-1:1280) compared with 1:20 (0-1:40) before a third vaccine dose (P<0.001). The anti-S1 IgG index showed the strongest correlation with the ID(50) against the B.1.617.2 (delta) variant determined by live virus neutralization (r=0.91). We demonstrate low neutralizing activity against the B.1.617.2 (delta) variant in dialysis patients four months after standard two-dose vaccination but a substantial increase after a third vaccine dose. Booster vaccination(s) should be considered earlier than 6 months after the second vaccine dose in immunocompromised individuals.

Persistence of Immune Response in Health Care Workers After Two Doses BNT162b2 in a Longitudinal Observational Study. BACKGROUND: The mRNA-based vaccine BNT162b2 of BioNTech/Pfizer has shown high efficacy against SARS-CoV-2 infection and a severe course of the COVID-19 disease. However, little is known about the long-term durability of the induced immune response resulting from the vaccination. METHODS: In a longitudinal observational study in employees at a German hospital we compared the humoral and cellular immune response in 184 participants after two doses of the BioNTech/Pfizer vaccine (BNT162b2) with a mid-term follow-up after 9 months. Anti-SARS-CoV-2 binding antibodies were determined using both a quantitative and a semi-quantitative assay. For a qualitative assessment of the humoral immune response, we additionally measured neutralizing antibodies. Cellular immune response was evaluated by measuring Interferon-gamma release after stimulating blood-cells with SARS-CoV-2 specific peptides using a commercial assay. RESULTS: In the first analysis, a 100% humoral response rate was described after two doses of BNT162b2 vaccine with a mean antibody ratio of 8.01 Â± 1.00. 9 months after the second dose of BNT162b2, serological testing showed a significant decreased mean antibody ratio of 3.84 Â± 1.69 (p < 0.001). Neutralizing antibodies were still detectable in 96% of all participants, showing an average binding inhibition value of 68.20% Â± 18.87%. Older age (p < 0.001) and obesity (p = 0.01) had a negative effect on the antibody persistence. SARS-CoV-2 specific cellular immune response was proven in 75% of individuals (mean Interferon-gamma release: 579.68 mlU/ml Â± 705.56 mlU/ml). CONCLUSION: Our data shows a declining immune response 9 months after the second dose of BNT162b2, supporting the potentially beneficial effect of booster vaccinations, the negative effect of obesity and age stresses the need of booster doses especially in these groups.

Kinetics of the B- and T-Cell Immune Responses After 6 Months From SARS-CoV-2 mRNA Vaccination in Patients With Rheumatoid Arthritis. OBJECTIVE: To assess the kinetics of the humoral and cell-mediated responses after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination in rheumatoid arthritis (RA) patients treated with different immunosuppressive therapies. METHODS: Following vaccine completed schedule, health care workers (HCWs, n = 49) and RA patients (n = 35) were enrolled at 5 weeks (T1) and 6 months (T6) after the first dose of BNT162b2-mRNA vaccination. Serological response was assessed by quantifying anti-receptor-binding domain (RBD)-specific immunoglobulin G (IgG) and SARS-CoV-2 neutralizing antibodies, while cell-mediated response was assessed by a whole-blood test quantifying the interferon (IFN)-Î³ response to spike peptides. B-cell phenotype and IFN-Î³-specific T-cell responses were evaluated by flow cytometry. RESULTS: After 6 months, anti-RBD antibodies were still detectable in 91.4% of RA patients, although we observed a significant reduction of the titer in patients under Cytotoxic T-Lymphocyte Antigen 4 (CTLA-4)-Ig [median: 16.4 binding antibody units (BAU)/ml, interquartile range (IQR): 11.3-44.3, p < 0.0001] or tumor necrosis factor (TNF)-Î± inhibitors (median: 26.5 BAU/ml, IQR: 14.9-108.8, p = 0.0034) compared to controls (median: 152.7 BAU/ml, IQR: 89.3-260.3). All peripheral memory B-cell (MBC) subpopulations, in particular, the switched IgG(+) MBCs (CD19(+)CD27(+)IgD(-)IgM(-)IgG(+)), were significantly reduced in RA subjects under CTLA-4-Ig compared to those in HCWs (p = 0.0012). In RA patients, a significantly reduced anti-RBD IgG titer was observed at T6 vs. T1, mainly in those treated

with CTLA-4-Ig (p = 0.002), interleukin (IL)-6 inhibitors (p = 0.015), and disease-modifying antirheumatic drugs (DMARDs) Â± corticosteroids (CCSs) (p = 0.015). In contrast, a weak nonsignificant reduction of the T-cell response was reported at T6 vs. T1. T-cell response was found in 65.7% of the RA patients at T6, with lower significant magnitude in patients under CTLA-4-Ig compared to HCWs (p < 0.0001). The SARS-CoV-2 IFN-Î³-S-specific T-cell response was mainly detected in the CD4(+) T-cell compartment. CONCLUSIONS: In this study, in RA patients after 6 months from COVID-19 vaccination, we show the kinetics, waning, and impairment of the humoral and, to a less extent, of the T-cell response. Similarly, a reduction of the specific response was also observed in the controls. Therefore, based on these results, a booster dose of the vaccine is crucial to increase the specific immune response regardless of the immunosuppressive therapy.

Acute Myopericarditis After First Dose of mRNA-1273 SARS-CoV-2 Vaccine in a Young Adult. The coronavirus disease (COVID-19 or SARS-CoV-2) pandemic has brought the global community to a halt. A return to normalcy is dependent on effective reopening strategies that encourage herd immunity through the implementation of vaccines. Cardiopulmonary inflammation has been reported in SARS-CoV-2 infection, independent of the severity, mainly amongst the juvenile population. Cardiovascular involvement following SARS-CoV-2 infection is associated with higher mortality and morbidity. Cardiovascular complications following COVID-19 vaccination have been documented as less severe, with no link between cardiovascular injury and death. This case report describes the presentation of an otherwise healthy 18-year-old male who experienced retrosternal chest pain after receiving a first dose of the mRNA-1273 vaccine. The patient had a negative polymerase chain reaction (PCR) test for COVID-19 infection. An electrocardiogram revealed diffuse ST elevation and PR segment depression, with increased inflammatory markers consistent with pericarditis. Elevation of troponin (16 ng/mL), evidence of borderline reduced ejection fraction (50-55%), and global left ventricular hypokinesis were suggestive of myopericarditis. Infectious and autoimmune studies were negative. The patient was treated mainly with non-steroidal anti-inflammatory drugs and colchicine, which resulted in a significant improvement of clinical symptoms. As the administration of emergency COVID-19 vaccines continues worldwide, it is of paramount importance to be aware of possible adverse events, including those affecting the cardiovascular system.

Development of Venous Thromboembolism After COVID-19 mRNA-1273 Vaccine Inoculation. A 79-year-old man suddenly developed right lower extremity (RLE) pain and swelling a few days after receiving his 1st dose of the mRNA-1273 COVID-19 vaccine. Despite this, he proceeded to receive the 2nd dose of his mRNA-1273 COVID-19 vaccine. Investigations confirmed extensive acute deep venous thrombosis and a concurrent acute pulmonary embolism. Therapeutic anticoagulation was initiated and he was eventually discharged home on supplemental oxygen. The overall benefits of the vaccine in curbing severe disease overwhelmingly outweigh the handful of cases of reported adverse events. To our knowledge, this is one of the first few cases of provoked venous thrombosis after receiving the mRNA-1273 COVID-19 vaccine during the pharmacovigilance period.

Acute Pericarditis Post mRNA-1273 COVID Vaccine Booster. Cardiovascular complications such as arrhythmias, hypoxemic cardiomyopathy, pericarditis, myocardial infarction, heart failure, and myocarditis are rare but seen in COVID-19 patients. These cardiac injuries could be the result of direct SARS-CoV-2 effects. The most prominent mediator of this hypothesis is angiotensin-converting enzyme-2 (ACE2) receptors, which are highly expressed in heart and lung tissues. These ACE2 receptors are found to be the functional receptors for the Coronavirus. Another hypothesis for cardiac complications in COVID-19 patients is macrophage-induced inflammation. The SARS-CoV-2 infection leads to invasion of epithelial cells by binding with ACE-2 receptors, localized inflammation, endothelial and macrophage activation, tissue damage, and dysregulated cytokine release. Current data have shown that mRNA COVID-19 vaccines are efficacious and safe for indicated patients.

However, these vaccines can cause mild adverse reactions similar to those of traditional vaccines, and more severe side effects can also be seen infrequently. The exact pathogenesis of COVID-19 vaccine-induced pericarditis remains unknown, but there are several hypotheses regarding the pathophysiology of pericarditis after COVID-19 vaccine administrations. There has been speculation that mRNA vaccines can produce a large number of antibodies in a small subgroup of people, especially young individuals, and this elicits an inflammatory response similar to the multisystem inflammatory syndrome associated with SARS-CoV-2 infection. Another proposed mechanism is the cross-reaction between produced antibodies and the pericardium, leading to myocardial and pericardial inflammation induction. This report describes a 69-year-old female who presented with three days of chest pain that started one day after a booster shot of the Moderna COVID-19 vaccine. The patient was diagnosed with pericarditis, and she was effectively treated with colchicine and later steroids.
Clinico-Genomic Analysis Reiterates Mild Symptoms Post-vaccination Breakthrough: Should We Focus on Low-Frequency Mutations? Vaccine development against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been of primary importance to contain the ongoing global pandemic. However, studies have demonstrated that vaccine effectiveness is reduced and the immune response is evaded by variants of concern (VOCs), which include Alpha, Beta, Delta, and, the most recent, Omicron. Subsequently, several vaccine breakthrough (VBT) infections have been reported among healthcare workers (HCWs) due to their prolonged exposure to viruses at healthcare facilities. We conducted a clinico-genomic study of ChAdOx1 (Covishield) VBT cases in HCWs after complete vaccination. Based on the clinical data analysis, most of the cases were categorized as mild, with minimal healthcare support requirements. These patients were divided into two sub-phenotypes based on symptoms: mild and mild plus. Statistical analysis showed a significant correlation of specific clinical parameters with VBT sub-phenotypes. Viral genomic sequence analysis of VBT cases revealed a spectrum of high- and low-frequency mutations. More in-depth analysis revealed the presence of low-frequency mutations within the functionally important regions of SARS-CoV-2 genomes. Emphasizing the potential benefits of surveillance, low-frequency mutations, D144H in the N gene and D138Y in the S gene, were observed to potentially alter the protein secondary structure with possible influence on viral characteristics. Substantiated by the literature, our study highlights the importance of integrative analysis of pathogen genomic and clinical data to offer insights into low-frequency mutations that could be a modulator of VBT infections.
Upper Limb Ischemia Due to Arterial Thrombosis after COVID-19 Vaccination. This report describes a case of a 60-year-old male patient who received the first dose of the AstraZeneca vaccine and presented to the emergency department complaining of left hand pain and paresthesia. Investigations revealed upper limb ischemia; he was hospitalized for further management.
Erythema nodosum after COVID-19 vaccination in a pediatric patient.
A case report of anti-P200 pemphigoid following COVID-19 vaccination.
Hidradenitis suppurativa flares following COVID-19 vaccination: A case series.
A temporal association between COVID-19 vaccination and immune-mediated necrotizing myopathy.
Intranasal delivery of SARS-CoV-2 spike protein is sufficient to cause olfactory damage, inflammation and olfactory dysfunction in zebrafish. Anosmia, loss of smell, is a prevalent symptom of SARS-CoV-2 infection. Anosmia may be explained by several mechanisms driven by infection of non-neuronal cells and damage in the nasal epithelium rather than direct infection of olfactory sensory neurons (OSNs). Previously, we showed that viral proteins are sufficient to cause neuroimmune responses in the teleost olfactory organ (OO). We hypothesize that SARS-CoV-2 spike (S) protein is sufficient to cause olfactory damage and olfactory dysfunction. Using an adult zebrafish model, we report that intranasally delivered SARS-CoV-2 S RBD mostly binds to the non-sensory epithelium of

the olfactory organ and causes severe olfactory histopathology characterized by loss of cilia, hemorrhages and edema. Electrophysiological recordings reveal impaired olfactory function to both food and bile odorants in animals treated intranasally with SARS-CoV-2 S RBD. However, no loss of behavioral preference for food was detected in SARS-CoV-2 S RBD treated fish. Single cell RNA-Seq of the adult zebrafish olfactory organ indicated widespread loss of olfactory receptor expression and inflammatory responses in sustentacular, endothelial, and myeloid cell clusters along with reduced numbers of T(regs). Combined, our results demonstrate that intranasal SARS-CoV-2 S RBD is sufficient to cause structural and functional damage to the zebrafish olfactory system. These findings may have implications for intranasally delivered vaccines against SARS-CoV-2.

Diagnosing SARS-CoV-2 vaccination associated rhombencephalitis requires comprehensive work-up and exclusion of differentials. In this letter we raise several concerns regarding the interesting article by Walter and KrÃ¤mer about rhomb-encephalitis as a complication two months after the vaccination with an mRNA-based SARS-CoV_2 vaccine. The causal link between the vaccination and encephalitis remained unproven, a SARS-CoV-2 infection, Bickerstaff encephalitis were not excluded, the MRI rather suggests brainstem-encephlaitis than pure rhomb-encephalitis, and the cerebro-spinal fluid was not investigated for cytokines or glial markers. Neurologists are called to make all available effort to convincingly evaluate the etiology and the pathophysiological background of an undetermined condition.

Generalized erythrodermic psoriasis triggered by vaccination against severe acute respiratory syndrome Coronavirus 2. Generalized erythrodermic psoriasis (GEP) is a rare and potentially life-threatening variant of psoriasis. Possible triggers that have been identified to date include poorly controlled psoriasis, medications, abrupt discontinuation of anti-psoriatic treatment, and underlying systemic illnesses. However, vaccines have rarely been reported to exacerbate GEP. Herein, we report two unique cases with GEP exacerbated following a dose of the BNT162b2 mRNA vaccine for COVID-19 (as their second dose, the first being the mRNA-1273 vaccine). Based on our observations and a literature review, vaccination was considered the most likely trigger of GEP due to the close temporal relationship between the second vaccination and the onset of GEP.

SARS-CoV-2 vaccination-induced cutaneous vasculitis: Report of two new cases and literature review. Currently the most powerful tool in combating the COVID-19 pandemic is vaccination against SARS-CoV-2. A growing percentage of the world's population is being vaccinated. Various vaccines are worldwide on the market. Several adverse reactions have been reported as a part of post-marketing surveillance of COVID-19 vaccines. Among the possible adverse events, cutaneous vasculitis has occasionally been reported. We present a narrative review on cutaneous vasculitis related to COVID-19-vaccination to summarize clinical findings, histopathology, treatment and outcome. We searched for "COVID vaccine", "COVID vaccination" AND "cutaneous vasculitis" in PUBMED. Articles in English have been selected, from inception to December 2021, and analyzed for patient's characteristics, type of vaccine, time of appearance of cutaneous vasculitis and clinico-histopathologic type. Treatment and outcome have also been considered in this narrative review. Two new unpublished cases of ours were added. Cutaneous vasculitis is a rare adverse event to COVID-19 vaccination. It has been observed with mRNA and adenovirus-vector vaccines. IgA vasculitis, lymphocytic and ANCA-associated vasculitis, leukocytoclastic and urticarial vasculitis have been reported. This adverse event can occur after first or second shot. Most cases run a mild to moderate course. Cornerstone of medical treatment are systemic corticosteroids. Complete remission could be achieved in most patients. Vasculitis may not be considered as a contraindication of vaccination, being uncommonly reported and shows a favorable prognosis. The benefit of the vaccination remains high especially for immunocompromised patients. COVID-vaccine induced vasculitis is important in the differential diagnosis of purpuric and vasculitis disorders.

SARS-CoV-2 vaccine in patients with thymic epithelial tumours with and without active or pre-existing autoimmune disorders: Brief report of a TYME network safety analysis. BACKGROUND: International guidelines recommend severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine for patients with cancer. A substantial risk of developing vaccine-related autoimmune toxicities could be hypothesised for patients with thymic epithelial tumours (TETs) due to their high risk of autoimmune disorders (ADs). Moreover, a cross-reaction between SARS-CoV-2 spike protein antibodies and various tissue proteins has been shown, and antibodies against nucleoproteins showed overlaps in the autoimmune cross-reaction with antibodies to spike protein. Due to the rarity of TETs, no data addressing this hypothesis are available. METHODS: Patients with TETs who received SARS-CoV-2 vaccine, treated in 4 referral centres of the Italian Collaborative Group for ThYmic MalignanciEs (TYME) network between February 2021 and September 2021, were interviewed through a standardised 15-items questionnaire in order to describe the safety of SARS-CoV-2 vaccine in patients affected by TETs. RESULTS: Data from 245 doses of vaccine administered to 126 patients (41Â =Â thymic carcinoma, 85Â =Â thymoma; 38 with AD, of which 26 with active AD) were collected. Nine patients had a previous COVID-19-positive swab. No cases of AD reactivation or worsening of a pre-existing AD were seen in the study population. A new diagnosis of myasthenia gravis likely unrelated to the vaccine was made in two patients after the vaccination. Sixty-four patients (51%) experienced a total of 103 adverse events, all G1/G2, most commonly fatigue, new or worsening muscle pain and chills. None AE required patients' hospitalisation. CONCLUSIONS: SARS-CoV-2 mRNA vaccines appear to be safe in patients with TET, even in case of active or pre-existing AD.

COVID-19 vaccine associated demyelination & its association with MOG antibody. BACKGROUND: ChAdOx1-S (Covishieldâ„¢/Vaxzervria, AstraZeneca) and BBV152 (Covaxin) SARS-CoV-2 vaccines are proven to be safe and effective, but rare complications have been reported. OBJECTIVE: To describe reports of central nervous system (CNS) demyelination following ChAdOx1-S and BBV152 vaccinations. METHODS & RESULTS: We report 29 (17 female; mean 38 years) cases of CNS demyelination; twenty-seven occurred in temporal association with ChAdOx1-S vaccine; two in association with BBV152 vaccine. Eleven patients had presentation with myelitis, six patients developed optic neuritis, five had acute demyelinating encephalomyelitis, three presented with brainstem demyelination, and four had multiaxial involvement. Myelin oligodendrocyte glycoprotein (MOG) antibodies were positive in ten patients. One patient with ADEM and tumefactive demyelinating lesions died after a prolonged intensive care unit stay and superimposed infection. As compared to the control group (87); the postvaccinial cases were found to have a significantly higher mean age, presence of encephalopathy (p value:0.0007), CSF pleocytosis (p value: 0.0094) and raised CSF protein (p value: 0.0062). CONCLUSIONS: It is difficult to establish a causal relationship between vaccination and neurological adverse events such as demyelination. The temporal association with the vaccination and the presence of MOG antibodies raises the possibility of an immunogenic process triggered by the vaccine in susceptible individuals.

Antibody responses after two doses of SARS-CoV-2 mRNA-1273 vaccine in an individual with history of COVID-19 re-infection. We present a case of a 58-year-old Japanese man with a history of 2 previous COVID-19 infections, who received 2 doses of mRNA-1273 vaccine. We are not aware of any previous study regarding antibody tendency after 2 infections and 2 vaccinations. We evaluated his IgG titer of antispike protein and neutralizing activity from the first infection before and after 2 doses of vaccine. Both antispike IgG titer and neutralizing activity showed a tendency to decline almost 1 year after initial infection; they rapidly increased after the first vaccination, and they remained high after the second vaccination. Although this is a single case report, it seems to have generalizability because the findings are consistent with previous reports regarding single infections or 3 doses of vaccination. Our findings suggest that a single booster shot may provide sufficient protection and aid

the understanding of immunologic responses of vaccination in patients with COVID-19 with history of re-infection.
Immune response and safety of heterologous ChAdOx1-nCoV-19/mRNA-1273 vaccination compared with homologous ChAdOx1-nCoV-19 or homologous mRNA-1273 vaccination. BACKGROUND/PURPOSE: Efficacy and safety data of heterologous prime-boost vaccination against SARS-CoV-2 remains limited. METHODS: We recruited adult volunteers for homologous or heterologous prime-boost vaccinations with adenoviral (ChAdOx1, AstraZeneca) and/or mRNA (mRNA-1273, Moderna) vaccines. Four groups of prime-boost vaccination schedules were designed: Group 1, ChAdOx1/ChAdOx1 8 weeks apart; Group 2, ChAdOx1/mRNA-1273 8 weeks apart; Group 3, ChAdOx1/mRNA-1273 4 weeks apart; and Group 4, mRNA-1273/mRNA-1273 4 weeks apart. The primary outcome was serum anti-SARS-CoV-2 IgG titers and neutralizing antibody titers against B.1.1.7 (alpha) and B.1.617.2 (delta) variants on day 28 after the second dose. Adverse events were recorded up until 84 days after the second dose. RESULTS: We enrolled 399 participants with a median age of 41 years and 75% were female. On day 28 after the second dose, the anti-SARS-CoV-2 IgG titers of both heterologous vaccinations (Group 2 and Group 3) were significantly higher than that of homologous ChAdOx1 vaccination (Group 1), and comparable with homologous mRNA-1273 vaccination (Group 4). The heterologous vaccination group had better neutralizing antibody responses against the alpha and delta variant as compared to the homologous ChAdOx1 group. Most of the adverse events (AEs) were mild and transient. AEs were less frequent when heterologous boosting was done at 8 weeks rather than at 4 weeks. CONCLUSION: Heterologous ChAdOx1/mRNA-1273 vaccination provided higher immunogenicity than homologous ChAdOx1 vaccination and comparable immunogenicity with the homologous mRNA-1273 vaccination. Our results support the safety and efficacy of heterologous prime-boost vaccination using the ChAdOx1 and mRNA-1273 COVID-19 vaccines. (ClinicalTrials.gov number, NCT05074368).
SARS-CoV-2 triggered relapse of multiple sclerosis. OBJECTIVES: There are indications that SARS-CoV-2 can trigger new onset or relapses of neuro-immunological disease. We report a patient with relapsing remitting multiple sclerosis (RRMS) under disease-modifying therapy (DMT) who experienced a relapse of RRMS after mild COVID-19. CASE REPORT: The patient is a 27-year-old female with RRMS who developed a third exacerbation of RRMS under DMT two weeks after mild COVID-19. Compared to previous imaging findings, new studies revealed an increase in the lesion load and an enhancing lesion over two segments in the thoracic spine. The patient profited from steroids and replacement of her previous DMT. She tolerated the first SARS-CoV-2 vaccination without side effects 6 months after the SARS-CoV-2 infection. CONCLUSIONS: SARS-CoV-2 infections can be followed by exacerbation of MS and failure of DMT. More arguments in favour than against a causal relation can be raised. Neurologist should remain vigilant for new or relapsing neuro-immunological disease following SARS-CoV-2 infections.
A case of anti-MOG antibody-positive ADEM following COVID-19 mRNA vaccination.
Arterial and venous thrombotic stroke after ChAdOx1 nCoV-19 vaccine. Vaccine-induced thrombosis with thrombocytopenia (VITT) is a recently-described condition associated with arterial and venous thrombosis following vaccination with the ChAdOx1 nCoV-19 (AstraZeneca) vaccine. This report describes two cases of stroke caused by arterial and venous thromboses presenting within 28 days of receiving the AstraZeneca vaccine. The patients were otherwise young and healthy with minimal risk factors for thrombosis yet developed a rapid, ultimately fatal neurological deterioration.The patients were significantly thrombocytopenic with disproportionately raised D-dimers, both of which are widely reported in this condition. Both cases had measurable immunoglobulin G platelet factor-4 antibodies detected via enzyme-linked immunosorbent assay, similar to those described in heparin-induced thrombocytopenia.These cases illustrate that physicians

should be especially mindful of VITT in the context of evolving evidence on treatment and in view of the potentially rapid and catastrophic neurological deterioration, leading to fatality despite best supportive care.

Not only lymphadenopathy: case of chest lymphangitis assessed with MRI after COVID 19 vaccine. BACKGROUND: To date, no paper reports cases of lymphangitis after COVID 19 vaccination. We present a case of lymphangitis after vaccination from COVID 19, in a patient with colorectal liver metastases. METHODS: We described the case of a 56-year-old woman with history of a surgical resection of colorectal cancer and liver metastases, without any kind of drug therapy for about a month. In addition, a recent administration (2Â days ago) of Spikevax (mRNA-1273, Moderna vaccine), as a booster dose, on the right arm was reported. RESULTS: The magnetic resonance (MR) examination showed the effects of the previous surgical resection and five new hepatic metastases, located in the VIII, VI, V, IV and II hepatic segments. As an accessory finding the presence of lymphadenopathy in the axillary area and lymphangitis of the right breast and chest were identified. The computed tomography scan performed a week earlier, and re-evaluated in light of the MR data, did not identify the presence of lymphadenopathy in the axillary area and lymphangitis signs. CONCLUSIONS: Lymphangitis could occur after COVID 19 vaccine and it is important to know this data to avoid alarmism in patients and clinicians and economic waste linked to the execution of various radiological investigations for the search for a tumour that probably does not exist. TRIAL REGISTRATION: Not applicable.

Axillary lymphadenopathy in a high-risk breast screening patient following the COVID-19 vaccine: a diagnostic conundrum. A number of COVID-19 vaccines have been approved worldwide to help tackle the pandemic. As with many vaccines, this causes a reactive axillary lymphadenopathy which can mimic potentially metastatic disease in a breast screening patient. It is therefore important to be aware of this side-effect of the vaccination when evaluating the axilla in a breast screening patient. We present a case of biopsy-proven unilateral reactive axillary lymphadenopathy in a high risk BRCA carrier following administration of the Astra Zeneca vaccine.

A Cohort Study on the Immunogenicity and Safety of the Inactivated SARS-CoV-2 Vaccine (BBIBP-CorV) in Patients With Breast Cancer; Does Trastuzumab Interfere With the Outcome? AIM: To determine the efficacy and safety of inactivated SARS-CoV-2 vaccine (BBIBP-CorV) in patients with breast cancer. METHODS: In this multi- institutional cohort study, a total of 160 breast cancer patients (mean age of 50.01 Â± 11.5 years old) were assessed for the SARS-CoV-2 Anti-Spike IgG and SARS-CoV2 Anti RBD IgG by ELISA after two doses of 0.5 mL inactivated, COVID-19 vaccine (BBIBP-CorV). All patients were followed up for three months for clinical COVID-19 infection based on either PCR results or imaging findings. Common Terminology Criteria for Adverse Events were used to assess the side effects. RESULTS: The presence of SARS-CoV-2 anti-spike IgG, SARS-CoV2 anti-RBD IgG, or either of these antibodies was 85.7%, 87.4%, and 93.3%. The prevalence of COVID-19 infection after vaccination was 0.7%, 0% and 0% for the first, second and third months of the follow-up period. The most common local and systemic side-effects were injection site pain and fever which were presented in 22.3% and 24.3% of patients, respectively. DISCUSSION: The inactivated SARS-CoV-2 vaccine (BBIBP-CorV) is a tolerable and effective method to prevent COVID-19.

A severe case of Trichophyton rubrum-caused dermatomycosis exacerbated after COVID-19 vaccination that had to be differentiated from pustular psoriasis. We present a case of deep dermatomycosis caused by Trichophyton rubrum that developed after administration of SARS-CoV-2 BNT162b2 vaccination. A 75-year-old man was vaccinated with SARS-CoV-2 on day 0 and day 23. From day 25, pustules began to appear. A skin biopsy was performed. Tissue culture revealed the presence of Trichophyton rubrum. The patient was treated with topical luliconazole and 100 mg/day oral fosravuconazole for 84 days, after which the symptoms resolved.

MOG Antibody-Associated Disorders Following SARS-CoV-2 Vaccination: A Case Report and Literature Review. Myelin oligodendrocyte glycoprotein (MOG) antibody-associated disorder (MOGAD) is a newly identified autoimmune demyelinating disorder that is often associated with acute disseminated encephalomyelitis and usually occurs postinfection or postvaccination. Here we report a case of MOGAD after mRNA severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. A previously healthy 68-year-old woman presented to our department with gradually worsening numbness on the right side of her face, which began 14 days after her second dose of an mRNA-1273 vaccination. The patient's brain MRI revealed a right cerebellar peduncle lesion with gadolinium enhancement, a typical finding of MOGAD. A neurological examination revealed paresthesia on her right V2 and V3 areas. Other neurological examinations were unremarkable. Laboratory workups were positive for serum MOG-IgG as assessed by live cell-based assays and the presence of oligoclonal bands in the cerebrospinal fluid (CSF). The patient's serum test results for cytoplasmic-antineutrophil cytoplasmic antibodies, perinuclear-cytoplasmic-antineutrophil cytoplasmic antibodies, GQ1b-antibodies, and aquaporin-4 antibodies (AQP4-IgG) were all negative. Tests for soluble interleukin (IL)-2 receptors in the serum, IL-6 in the CSF and skin pricks, and angiotensin converting enzyme tests were all unremarkable. The patient was diagnosed with MOGAD after receiving an mRNA SARS-CoV-2 vaccination. After two courses of intravenous methylprednisolone treatment, the patient's symptoms improved and her cerebellar peduncle lesion shrunk slightly without gadolinium enhancement. To date, there have only been two cases of monophasic MOGAD following SARS-CoV-2 vaccination, including both the ChAdOx1 nCOV-19 and mRNA-1273 vaccines, and the prognosis is generally similar to other typical MOGAD cases. Although the appearance of MOG antibodies is relatively rare in post-COVID-19-vaccine demyelinating diseases, MOGAD should be considered in patients with central nervous system (CNS) demyelinating diseases after receiving a SARS-CoV-2 vaccine.

Diagnostic pitfalls after COVID-19 vaccination in melanoma and breast cancer patients: A case series. INTRODUCTION: During the current Coronavirus Disease 2019 (COVID-19) pandemic, significant COVID-19 disease-reducing developments have been made, culminating in the COVID-19 vaccines. However, COVID-19 vaccines may complicate oncological staging and follow-up oncological disease course since they may induce the enlargement of lymph nodes. Consequently, this uncertainty may lead to increased distress. PRESENTATION OF CASES: This case series describes seven patients diagnosed with melanoma or breast cancer in whom lymphadenopathy was observed on oncology imaging after COVID-19 vaccination. Four of these patients underwent additional diagnostic testing, all without malignant cells on pathological examination or suspected metastasis on imaging. The remaining patients were re-evaluated, and the lymphadenopathy was interpreted as an adverse outcome of the recent COVID-19 vaccination. In addition, four out of seven patients were vaccinated in the ipsilateral arm relative to the tumor. Abnormal lymph nodes could be observed up to sixty-nine days after COVID-19 vaccination. DISCUSSION AND CONCLUSION: These findings indicate that a COVID-19 vaccination may result in possible false-positive oncological imaging findings in melanoma and breast cancer patients. Moreover, it is advised to administer the vaccine in the contralateral arm of the primary tumor, suspected breast abnormalities, or after the oncologic imaging in melanoma and breast cancer patients.

Vascular retinal findings after COVID-19 vaccination in 11 cases: a coincidence or consequence? PURPOSE: The primary purpose of this study was to assess vascular retinal findings temporally related to COVID-19 vaccination. With greater information regarding all possible future adverse events, we hope to understand the real dimension and relevance of what was presented. METHODS: Eleven patients with visual complaints after COVID-19 vaccination were enrolled. Data on the following were included: age, sex, vaccine, time of symptom onset, systemic findings, medical history, best-corrected

visual acuity, and ocular findings by slit-lamp biomicroscopy as well as multimodal retinal imaging (color fundus, red-free photography, spectral-domain optical coherence tomography, optical coherence tomography angiography, and fluorescein-angiography). Inclusion criteria were the presence of ophthalmologic signs within 30 days after the first or second dose of any COVID-19 vaccine. RESULTS: Of 11 patients, five had arterial occlusion (45.4%), four had venous occlusion (36.4%), and two (18.2%) had nonspecific vascular alterations suggestive of retinal ischemia such as cotton-wool spots. The mean age was 57 (SD = 16; range: 27-84) years. The mean time of symptoms onset was 10 (SD = 5.4; range: 3-16) days. Nine patients were female (81.8%). Systemic risk factors were observed in 36.4% of patients. Two patients had both neurological and visual symptoms, with arterial occlusion. Overall, 36.4% patients had COVID-19 in the previous year. Seven patients (63.6%) received ChAdOx1 nCoV-19 (AZD1222) vaccine. CONCLUSIONS: Our data suggest that retinal events temporally related to COVID-19 vaccination are possible but are very rare. The relationship of these events with post-COVID-19 vaccination warrants further attention to derive a meaningful conclusion.

Multiple evanescent white dot syndrome (MEWDS) following inactivated COVID-19 vaccination (Sinovac-CoronaVac). A 38-year-old woman presented with photopsias and progressive but painless loss of vision in her right eye. Of note, she had received the first dose of inactivated COVID-19 vaccine (Sinovac/China National Pharmaceutical Group) 2 weeks prior to the onset of symptoms. Ophthalmic evaluation revealed a wreath-like foveal pattern and multiple gray-white dots throughout the posterior pole associated with discrete vitreous inflammatory reaction. Multimodal imaging analysis confirmed a diagnosis of multiple evanescent white dot syndrome. The patient underwent treatment with corticosteroids and, over the following weeks, her visual acuity improved to standard pattern.

Incidence of Cerebral Venous Thrombosis Following SARS-CoV-2 Infection vs mRNA SARS-CoV-2 Vaccination in Singapore. IMPORTANCE: Reports of cerebral venous thrombosis (CVT) after messenger RNA (mRNA)-based SARS-CoV-2 vaccination has caused safety concerns, but CVT is also known to occur after SARS-CoV-2 infection. Comparing the relative incidence of CVT after infection vs vaccination may provide a better perspective of this complication. OBJECTIVE: To compare the incidence rates and clinical characteristics of CVT following either SARS-CoV-2 infection or mRNA-based SARS-CoV-2 vaccines. DESIGN, SETTING, AND PARTICIPANTS: Between January 23, 2020, and August 3, 2021, this observational cohort study was conducted at all public acute hospitals in Singapore, where patients hospitalized with CVT within 6 weeks of SARS-CoV-2 infection or after mRNA-based SARS-CoV-2 vaccination (BNT162b2 [Pfizer-BioNTech] or mRNA-1273 [Moderna]) were identified. Diagnosis of SARS-CoV-2 infection was based on quantitative reverse transcription-polymerase chain reaction or positive serology. National SARS-CoV-2 infection data were obtained from the National Centre for Infectious Disease, Singapore, and vaccination data were obtained from the National Immunisation Registry, Singapore. EXPOSURES: SARS-CoV-2 infection or mRNA-based SARS-CoV-2 vaccines. MAIN OUTCOMES AND MEASURES: Clinical characteristics, crude incidence rate (IR), and incidence rate ratio (IRR) of CVT after SARS-CoV-2 infection and after mRNA SARS-CoV-2 vaccination. RESULTS: Among 62â€¯447 individuals diagnosed with SARS-CoV-2 infections included in this study, 58â€¯989 (94.5%) were male; the median (range) age was 34 (0-102) years; 6 CVT cases were identified (all were male; median [range] age was 33.5 [27-40] years). Among 3â€¯006â€¯662 individuals who received at least 1 dose of mRNA-based SARS-CoV-2 vaccine, 1â€¯626â€¯623 (54.1%) were male; the median (range) age was 50 (12-121) years; 9 CVT cases were identified (7 male individuals [77.8%]; median [range] age: 60 [46-76] years). The crude IR of CVT after SARS-CoV-2 infections was 83.3 per 100â€¯000 person-years (95% CI, 30.6-181.2 per 100â€¯000 person-years) and 2.59 per 100â€¯000 person-years (95% CI, 1.19-4.92 per 100â€¯000 person-years) after mRNA-based SARS-CoV-2 vaccination. Six (66.7%) received BNT162b2 (Pfizer-BioNTech) vaccine and 3

(33.3%) received mRNA-1273 (Moderna) vaccine. The crude IRR of CVT hospitalizations with SARS-CoV-2 infection compared with those who received mRNA SARS-CoV-2 vaccination was 32.1 (95% CI, 9.40-101; Pâ€‰<â€‰.001). CONCLUSIONS AND RELEVANCE: The incidence rate of CVT after SARS-CoV-2 infection was significantly higher compared with after mRNA-based SARS-CoV-2 vaccination. CVT remained rare after mRNA-based SARS-CoV-2 vaccines, reinforcing its safety.

Myocarditis Following a Third BNT162b2 Vaccination Dose in Military Recruits in Israel. This study assessed whether a third vaccine dose was associated with the risk of myocarditis among military personnel in Israel.

Broad Neutralization of SARS-CoV-2 Variants, Including Omicron, following Breakthrough Infection with Delta in COVID-19-Vaccinated Individuals. Numerous studies have shown that a prior SARS-CoV-2 infection can greatly enhance the antibody response to COVID-19 vaccination, with this so called "hybrid immunity" leading to greater neutralization breadth against SARS-CoV-2 variants of concern. However, little is known about how breakthrough infection (BTI) in COVID-19-vaccinated individuals will impact the magnitude and breadth of the neutralizing antibody response. Here, we compared neutralizing antibody responses between unvaccinated and COVID-19-double-vaccinated individuals (including both AZD1222 and BNT162b2 vaccinees) who have been infected with the Delta (B.1.617.2) variant. Rapid production of spike-reactive IgG was observed in the vaccinated group, providing evidence of effective vaccine priming. Overall, potent cross-neutralizing activity against current SARS-CoV-2 variants of concern was observed in the BTI group compared to the infection group, including neutralization of the Omicron (B.1.1.529) variant. This study provides important insights into population immunity where transmission levels remain high and in the context of new or emerging variants of concern. IMPORTANCE COVID-19 vaccines have been vital in controlling SARS-CoV-2 infections and reducing hospitalizations. However, breakthrough SARS-CoV-2 infections (BTI) occur in some vaccinated individuals. Here, we study how BTI impacts on the potency and the breadth of the neutralizing antibody response. We show that a Delta infection in COVID-19-vaccinated individuals provides potent neutralization against the current SARS-CoV-2 variants of concern, including the Omicron variant.

Pityriasis rubra pilaris in association with inactivated SARS-CoV-2 vaccine (CoronaVac).

Antibody decay, T cell immunity and breakthrough infections following two SARS-CoV-2 vaccine doses in inflammatory bowel disease patients treated with infliximab and vedolizumab. Anti tumour necrosis factor (anti-TNF)Â drugs increase the risk of serious respiratory infection and impair protective immunity following pneumococcal and influenza vaccination. Here we report SARS-CoV-2 vaccine-induced immune responses and breakthrough infections in patients with inflammatory bowel disease, who are treated either with the anti-TNF antibody, infliximab, or with vedolizumab targeting a gut-specific anti-integrin that does not impair systemic immunity. Geometric mean [SD] anti-S RBD antibody concentrations are lower and half-lives shorter in patients treated with infliximab than vedolizumab, following two doses of BNT162b2 (566.7â€‰U/mL [6.2] vs 4555.3â€‰U/mL [5.4], p <0.0001; 26.8 days [95% CI 26.2 - 27.5] vs 47.6 days [45.5 - 49.8], p <0.0001); similar results are also observed with ChAdOx1 nCoV-19 vaccination (184.7â€‰U/mL [5.0] vs 784.0â€‰U/mL [3.5], p <0.0001; 35.9 days [34.9 - 36.8] vs 58.0 days [55.0 - 61.3], p value < 0.0001). One fifth of patients fail to mount a T cell response in both treatment groups. Breakthrough SARS-CoV-2 infections are more frequent (5.8% (201/3441) vs 3.9% (66/1682), p = 0.0039) in patients treated with infliximab than vedolizumab, and the risk of breakthrough SARS-CoV-2 infection is predicted by peak anti-S RBD antibody concentration after two vaccine doses. Irrespective of the treatments, higher, more sustained antibody levels are observed in patients with a history of SARS-CoV-2 infection prior to vaccination. Our results thus suggest that adapted vaccination schedules may be required to induce immunity in at-risk, anti-TNF-treated patients.

Haemophagocytic lymphohistiocytosis following COVID-19 mRNA vaccination. The development of vaccinations has been instrumental in the ongoing effort to combat the COVID-19 pandemic. Although the benefits of vaccination are unquestionable, there have been reports of potentially rare life-threatening complications following vaccination including thrombocytopaenia, haemolytic anaemia, vasculitis and myocarditis. Haemophagocytic lymphohistiocytosis (HLH), a rare but life-threatening inflammatory condition, has also been described postadenoviral vector COVID-19 vaccination but it has never been reported post-messenger RNA (mRNA) COVID-19 vaccination. We report two cases of HLH admitted to our hospital after administration of COVID-19 mRNA vaccines. We also searched the vaccine adverse event reporting system and found 50 reports of suspected HLH following COVID-19 vaccination. Presently, we cannot define a causality between COVID-19 mRNA vaccination and HLH development. However, we hope the reporting of our two cases (and additional cases seen in the adverse event reporting database) will help us determine whether there is a potential relationship. Prompt recognition of this condition is of utmost importance to initiate life-saving therapy.

Association between covid-19 vaccination, SARS-CoV-2 infection, and risk of immune mediated neurological events: population based cohort and self-controlled case series analysis. OBJECTIVE: To study the association between covid-19 vaccines, SARS-CoV-2 infection, and risk of immune mediated neurological events. DESIGN: Population based historical rate comparison study and self-controlled case series analysis. SETTING: Primary care records from the United Kingdom, and primary care records from Spain linked to hospital data. PARTICIPANTS: 8â€‰330â€‰497 people who received at least one dose of covid-19 vaccines ChAdOx1 nCoV-19, BNT162b2, mRNA-1273, or Ad.26.COV2.S between the rollout of the vaccination campaigns and end of data availability (UK: 9 May 2021; Spain: 30 June 2021). The study sample also comprised a cohort of 735â€‰870 unvaccinated individuals with a first positive reverse transcription polymerase chain reaction test result for SARS-CoV-2 from 1 September 2020, and 14â€‰330â€‰080 participants from the general population. MAIN OUTCOME MEASURES: Outcomes were incidence of Bell's palsy, encephalomyelitis, Guillain-BarrÃ© syndrome, and transverse myelitis. Incidence rates were estimated in the 21 days after the first vaccine dose, 90 days after a positive test result for SARS-CoV-2, and between 2017 and 2019 for background rates in the general population cohort. Indirectly standardised incidence ratios were estimated. Adjusted incidence rate ratios were estimated from the self-controlled case series. RESULTS: The study included 4â€‰376â€‰535 people who received ChAdOx1 nCoV-19, 3â€‰588â€‰318 who received BNT162b2, 244â€‰913 who received mRNA-1273, and 120â€‰731 who received Ad26.CoV.2; 735â€‰870 people with SARS-CoV-2 infection; and 14â€‰330â€‰080 people from the general population. Overall, post-vaccine rates were consistent with expected (background) rates for Bell's palsy, encephalomyelitis, and Guillain-BarrÃ© syndrome. Self-controlled case series was conducted only for Bell's palsy, given limited statistical power, but with no safety signal seen for those vaccinated. Rates were, however, higher than expected after SARS-CoV-2 infection. For example, in the data from the UK, the standardised incidence ratio for Bell's palsy was 1.33 (1.02 to 1.74), for encephalomyelitis was 6.89 (3.82 to 12.44), and for Guillain-BarrÃ© syndrome was 3.53 (1.83 to 6.77). Transverse myelitis was rare (<5 events in all vaccinated cohorts) and could not be analysed. CONCLUSIONS: No safety signal was observed between covid-19 vaccines and the immune mediated neurological events of Bell's palsy, encephalomyelitis, Guillain-BarrÃ© syndrome, and transverse myelitis. An increased risk of Bell's palsy, encephalomyelitis, and Guillain-BarrÃ© syndrome was, however, observed for people with SARS-CoV-2 infection.

The neurological safety of covid-19 vaccines.

Impact of a delayed second dose of mRNA vaccine (BNT162b2) and inactivated SARS-CoV-2 vaccine (CoronaVac) on risks of all-cause mortality, emergency department visit, and unscheduled

hospitalization. BACKGROUND: Safety after the second dose of the SARS-CoV-2 vaccine remains to be elucidated, especially among individuals reporting adverse events after their first dose. This study aims to evaluate the impact of a delayed second dose on all-cause mortality and emergency services. METHODS: A territory-wide, retrospective cohort of people who had completed two doses of mRNA (BNT162b2) or inactivated SARS-CoV-2 (CoronaVac) vaccine between February 23 and July 3, 2021, in Hong Kong was analyzed, with linkage to electronic health records retrieved from the Hong Kong Hospital Authority. Vaccine recipients were classified as receiving a second dose within recommended intervals (21-28 days for BNT162b2; 14-28 days for CoronaVac) or delayed. Study outcomes were all-cause mortality, emergency department (ED) visits, and unscheduled hospitalizations within 28 days after the second dose of vaccination. RESULTS: Among 417,497 BNT162b2 and 354,283 CoronaVac second dose recipients, 3.8% and 28.5% received the second dose beyond the recommended intervals (mean 34.4 and 31.8 days), respectively. During the study period, there were < 5 daily new cases of COVID-19 infections in the community. Delaying the second dose was not associated with all-cause mortalityÂ (hazard ratio [HR] = 1.185, 95% CI 0.478-2.937, P = 0.714), risk of ED visit (HR = 0.966, 95% CI 0.926-1.008, P = 0.113), and risk of unscheduled hospitalizationÂ (HR = 0.956, 95% CI 0.878-1.040, P = 0.294) compared to that within the recommended interval for CoronaVac recipients. No statistically significant differences in all-cause mortalityÂ (HR = 4.438, 95% CI 0.951-20.701, P = 0.058), ED visit (HR = 1.037, 95% CI 0.951-1.130, P = 0.411), and unscheduled hospitalizationÂ (HR = 1.054, 95% CI 0.867-1.281, P = 0.597) were identified between people who received a second dose of BNT162b2 within and beyond the recommended intervals. CONCLUSIONS: No significant association between delayed second dose of BNT162b2 or CoronaVac and all-cause mortality, ED visit, and unscheduled hospitalization was observed in the present cohort. Regardless of the recommended or delayed schedule for SARS-CoV-2 vaccination, a second dose of both vaccines should be administered to obtain better protection against infection and serious disease. The second dose should be administered within the recommended interval following the manufacturer's product information, until further studies support the benefits of delaying vaccination outweighing the risks.

How (not) to mobilize health workers in the fight against vaccine hesitancy: Experimental evidence from Germany's AstraZeneca controversy. BACKGROUND: COVID-19 vaccine hesistancy is a serious policy issue in Germany as vaccinations have stagnated at low levels compared to most other European countries. In this context, we study whether and how health workers can be leveraged to promote the COVID-19 vaccination campaign. METHODS: We employed an information experiment with health workers in Germany to quantify how access to information related to (i) AstraZeneca's vaccine safety, (ii) misinformation, (iii) individual health risks, and (iv) public health risks can sway health workers' recommendations for any of the following vaccines: AstraZeneca, Johnson & Johnson, Moderna, Pfizer/BioNTech, Sinopharm, and Sputnik-V. The information experiment was conducted as a randomized controlled trial with four treatment arms and was embedded in an online survey. RESULTS: Health workers reduce their willingness to recommend four out of six vaccines once they learn about different statements of European and German health authorities with respect to the safety of the AstraZeneca vaccine. Consistent with the discussion on AstraZeneca's safety focusing on possible side effects among younger women, we find that especially female health workers become less likely to recommend the majority of COVID-19 vaccines. Lastly, we show that health workers vaccine recommendations are not affected by misinformation and appeals to individual or public health. CONCLUSION: In order to mobilize health workers in the fight against vaccine hesitancy, information campaigns need to be tailor-made for the target audience. In particular, health workers react to different types of information than the general public. As with the general public, we provide suggestive evidence that health workers require unambigious messages from drug authorities in

order to support vaccination efforts. We believe that a more coordinated and coherent approach of public authorities can reduce the amount of mixed signals that health workers receive and therefore contribute to health workers engagement in the outroll of mass COVID-19 vaccination campaigns. TRIAL REGISTRATION: The trial was registered retrospectively with the repository of the Open Science Framework (OSF) under the number osf.io/qa4n2 .

Shedding Light on SARS-CoV-2, COVID-19, COVID-19 Vaccination, and Auditory Symptoms: Causality or Spurious Conjunction? There are reports of associations between SARS-CoV2, COVID-19, COVID-19 vaccines, and auditory symptoms (hearing difficulty, tinnitus). However, most studies have relied on self-report and lack baseline and/or non-COVID control groups. This makes it problematic to differentiate if symptoms are associated with SARS-CoV2, COVID-19, the vaccine, psychosocial factors or recall bias. In this study, we differentiate these by comparing hearing and tinnitus survey data collected pre- and during the pandemic. The survey conducted during the pandemic asked about the onset and change in three types of symptom. Type One-known association (loss of smell, memory/concentration issues, persistent fatigue), Type Two-indeterminate association (auditory symptoms), and Type Three-no established association with COVID-19 (toothache). We hypothesized that if auditory symptoms are directly associated with COVID-19, their onset and change would be similar to Type One symptoms, but if indirectly associated (reflecting psychosocial factors and/or recall bias) would be more similar to Type Three symptoms. Of the 6,881 individuals who responded, 6% reported confirmed COVID-19 (positive test), 11% probably had COVID-19, and 83% reported no COVID-19. Those with confirmed or probable COVID-19 more commonly reported new and/or worsened auditory symptoms than those not reporting COVID-19. However, this does not imply causality because: (1) new auditory symptoms coincided with COVID-19 illness among just 1/3 of those with confirmed or probable COVID-19, and another 1/3 said their symptoms started before the pandemic-despite reporting no symptoms in the pre-pandemic survey. (2) >60% of individuals who had COVID-19 said it had affected their Type 3 symptoms, despite a lack of evidence linking the two. (3) Those with confirmed COVID-19 reported more Type 1 symptoms, but reporting of Type 2 and Type 3 symptoms did not differ between those with confirmed COVID-19 and those without COVID-19, while those who probably had COVID-19 most commonly reported these symptom types. Despite more reports of auditory symptoms in confirmed or probable COVID-19, there is inconsistent reporting, recall bias, and possible nocebo effects. Studies that include appropriate control groups and use audiometric measures in addition to self-report to investigate change in auditory symptoms relative to pre-COVID-19 are urgently needed.

Bullous Pemphigoid Associated With COVID-19 Vaccines: An Italian Multicentre Study. Bullous pemphigoid (BP) is an autoimmune bullous disease caused by circulating autoantibodies toward the hemidesmosomal antigens BP180 and BP230. Cases of BP have been described following vaccinations against tetanus, poliomyelitis, diphtheria, influenza, pneumococcus, meningococcus, hepatitis B and rabies. The putative mechanism by which COVID-19-vaccines may induce BP has not been clarified. An Italian multicentre study was conducted to collect clinical, histopathological and immunopathological data of patients with BP associated with COVID-19-vaccines. Twenty-one cases were collected, including 9 females and 12 males (M/F = 1.3) with a median age at diagnosis of 82 years. Seventeen patients received the COMIRNATY Pfizer-BioNTech vaccine, two the Moderna mRNA-1273 vaccine, one the ChAdOx1/nCoV-19-AstraZeneca/ Vaxzevria vaccine and one received the first dose with the ChAdOx1/nCoV-19-AstraZeneca/Vaxzevria vaccine and the second dose with the COMIRNATY Pfizer-BioNTech vaccine. Median latency time between the first dose of anti-SARS-CoV-2 vaccine and the onset of cutaneous manifestations was 27 days. Median BPDAI at onset was 42. Eleven out of seventeen patients (65%) had positive titres for anti-BP180 antibodies with a median value of 106.3 U/mL on ELISA; in contrast, only five out of seventeen (29%) were positive for

anti-BP230 antibodies, with a median of 35.3 U/mL. In conclusion, in terms of mean age, disease severity at diagnosis and clinical phenotype vaccine-associated BP patients seem to be similar to idiopathic BP with an overall benign course with appropriate treatment. On the other hand, the slight male predominance and the reduced humoral response to BP230 represent peculiar features of this subset of patients.

mRNA-encoded HIV-1 Env trimer ferritin nanoparticles induce monoclonal antibodies that neutralize heterologous HIV-1 isolates in mice. The success of nucleoside-modified mRNAs in lipid nanoparticles (mRNA-LNP) as COVID-19 vaccines heralded a new era of vaccine development. For HIV-1, multivalent envelope (Env) trimer protein nanoparticles are superior immunogens compared with trimers alone for priming of broadly neutralizing antibody (bnAb) B cell lineages. The successful expression of complex multivalent nanoparticle immunogens with mRNAs has not been demonstrated. Here, we show that mRNAs can encode antigenic Env trimers on ferritin nanoparticles that initiate bnAb precursor B cell expansion and induce serum autologous tier 2 neutralizing activity in bnAb precursor V(H)Â + V(L) knock-in mice. Next-generation sequencing demonstrates acquisition of critical mutations, and monoclonal antibodies that neutralize heterologous HIV-1 isolates are isolated. Thus, mRNA-LNP can encode complex immunogens and may be of use in design of germline-targeting and sequential boosting immunogens for HIV-1 vaccine development.

Audio Interview: Can We Make More Effective Covid-19 Vaccines?

Delayed inflammatory reaction to dermal fillers after COVID-19 vaccination: a case report.

Systemic lupus erythematous after Pfizer COVID-19 vaccine: a case report. The Pfizer-BioNTech COVID-19 vaccine has been authorized by the U.S. Food and Drug Administration as it demonstrated 95% effectiveness against the SARS-CoV-2 virus. Although the initial vaccine trials showed a favorable side effect profile, there have been concerns regarding activation of aberrant immune responses, triggering autoimmunity. This is a case report of a 68-year-old woman without history of autoimmune conditions, who presented to our emergency department 7Â days after receiving the Pfizer-BioNTech COVID-19 vaccine. Her initial symptoms were suggestive of polymyalgia rheumatica, and she had nearly complete response to steroids. Interestingly, she later met criteria for classified systemic lupus erythematous given the development of inflammatory arthritis, positive ANA, and positive dsDNA. The temporal relationship of her symptoms that started 2Â days after vaccine administration could suggest a possible association between the Pfizer-BioNTech COVID-19 and the development of systemic lupus erythematous.

Leukocytoclastic Vasculitic Rash Following Second Dose of Moderna COVID-19 Vaccine. The immunization against coronavirus disease (COVID-19) via vaccination serves as a significant milestone in the fight against the pandemic. Rapid introduction of various COVID-19 vaccines to stem the spread of virus has researchers scrambling to document the adverse effects left in its wake. Thus far, there have been singular examples of cutaneous vasculitis associated with COVID-19. A history of vasculitis leaves little error to miss its inclusion in diagnostic differentials. It also invokes the physiologic possibility that afflicted patients possess a more susceptible landscape for recurrence that was then triggered by the vaccine when compared with those who lack similar history. In our case report, we build on those findings with one of the first documented examples of vaccination-induced vasculitic rash in a previously asymptomatic patient.

Cutaneous adverse reactions to coronavirus vaccines: A Saudi nationwide study. The coronavirus vaccine was developed to help overcome the COVID-19 crisis. This study aimed to identify the cutaneous side effects secondary to Pfizer-BioNTech and Oxford-AstraZeneca COVID-19 vaccines in the general population of Saudi Arabia and to list the risk factors for the development of cutaneous side effects. This cross-sectional study was conducted in 2021, self-administered surveys were distributed electronically through social media, and telephonic interviews were conducted with a

sample size of 1000 participants. Data analysis was performed using Statistical Package for the Social Sciences. A total of 1021 patients (229 male and 722 female) aged 12Â years or older were included. While 833 participants were medically free, 188 had chronic illnesses. While 802 participants were not taking any medications, 219 were taking medications regularly. Oxford-Astra Zeneca and Pfizer BioNTech vaccines were administered to 319 and 702 participants, respectively. One-hundred and twenty-five participants previously had COVID-19 infection and 407 were exposed to a PCR positive case of COVID. Six hundred and fifty-nine patients (64.5%) reported experiencing injection site reactions: 606 (59.4%) had injection site pain, 168 (16.5%) had injection site swelling, and 107 (10.5%) had injection site redness. Only 51 patients (5%) experienced cutaneous side effects after injection. A significant association was found between chronic illnesses and cutaneous side effects post-vaccine (9% vs. 4.1%; p valueÂ =Â 0.005). Patients on medications showed a higher rate of symptoms (8.2% vs. 4.1%; p valueÂ =Â 0.005). Age, gender, vaccine types, and history of COVID-19 infection were not significantly associated with cutaneous side effects post-vaccine.

Russian COVID-19 vaccine in jeopardy after Ukraine invasion.

COVID-19-associated hospitalizations among children less than 12 years of age in the United States. OBJECTIVES: To describe the characteristics, healthcare resource use and costs associated with initial hospitalization and readmissions among pediatric patients with COVID-19 in the US. METHODS: Hospitalized pediatric patients, 0-11â€‰years of age, with a primary or secondary discharge diagnosis code for COVID-19 (ICD-10 code U07.1) were selected from 1 April 2020 to 30 September 2021 in the US Premier Healthcare Database Special Release (PHD SR). Patient characteristics, hospital length of stay (LOS), in-hospital mortality, hospital costs, hospital charges, and COVID-19-associated readmission outcomes were evaluated and stratified by age groups (0-4, 5-11), four COVID-19 disease progression states based on intensive care unit (ICU) and invasive mechanical ventilation (IMV) usage, and three sequential calendar periods. Sensitivity analyses were performed using the US HealthVerity claims database and restricting the analyses to the primary discharge code. RESULTS: Among 4,573 hospitalized pediatric patients aged 0-11â€‰years, 68.0% were 0-4â€‰years and 32.0% were 5-11â€‰years, with a mean (median) age of 3.2 (1) years; 56.0% were male, and 67.2% were covered by Medicaid. Among the overall study population, 25.7% had immunocompromised condition(s), 23.1% were admitted to the ICU and 7.3% received IMV. The mean (median) hospital LOS was 4.3 (2) days, hospital costs and charges were $14,760 ($6,164) and $58,418 ($21,622), respectively; in-hospital mortality was 0.5%. LOS, costs, charges, and in-hospital mortality increased with ICU admission and/or IMV usage. In total, 2.1% had a COVID-19-associated readmission. Study outcomes appeared relatively more frequent and/or higher among those 5-11 than those 0-4. Results using the HealthVerity data source were generally consistent with main analyses. LIMITATIONS: This retrospective administrative database analysis relied on coding accuracy and inpatient admissions with validated hospital costs. CONCLUSIONS: These findings underscore that children aged 0-11â€‰years can experience severe COVID-19 illness requiring hospitalization and substantial hospital resource use, further supporting recommendations for COVID-19 vaccination.

Systemic capillary leak syndrome (SCLS) after receiving BNT162b2 mRNA COVID-19 (Pfizer-BioNTech) vaccine. Systemic capillary leak syndrome (SCLS), also known as Clarkson's disease, is a rare disorder of unknown aetiology. Since SCLS was first described in 1960, fewer than 500 cases have been reported. SCLS is diagnosed by the classic triad of hypotension, haemoconcentration and hypoalbuminaemia resulting from fluid extravasation. Some reports show that SCLS may sometimes occur as a side effect of adenoviral vector COVID-19 vaccines, although there is only one report (two cases) of SCLS after receiving a messenger RNA vaccine. Survival rates for SCLS are very poor without treatment, so it is crucial for clinicians to recognise this disorder. A middle-aged woman who presented with generalised malaise and anasarca after receiving the BNT162b2 COVID-19 vaccine was

diagnosed with SCLS. Treatment with methylprednisolone and intravenous immunoglobulin was commenced and her symptoms resolved. We expect that this case report will add to the existing literature on this rare disorder and the side effects of vaccinations.

Aggregating human judgment probabilistic predictions of the safety, efficacy, and timing of a COVID-19 vaccine. Safe, efficacious vaccines were developed to reduce the transmission of SARS-CoV-2 during the COVID-19 pandemic. But in the middle of 2020, vaccine effectiveness, safety, and the timeline for when a vaccine would be approved and distributed to the public was uncertain. To support public health decision making, we solicited trained forecasters and experts in vaccinology and infectious disease to provide monthly probabilistic predictions from July to September of 2020 of the efficacy, safety, timing, and delivery of a COVID-19 vaccine. We found, that despite sparse historical data, a linear pool-a combination of human judgment probabilistic predictions-can quantify the uncertainty in clinical significance and timing of a potential vaccine. The linear pool underestimated how fast a therapy would show a survival benefit and the high efficacy of approved COVID-19 vaccines. However, the linear pool did make an accurate prediction for when a vaccine would be approved by the FDA. Compared to individual forecasters, the linear pool was consistently above the median of the most accurate forecasts. A linear pool is a fast and versatile method to build probabilistic predictions of a developing vaccine that is robust to poor individual predictions. Though experts and trained forecasters did underestimate the speed of development and the high efficacy of a SARS-CoV-2 vaccine, linear pool predictions can improve situational awareness for public health officials and for the public make clearer the risks, rewards, and timing of a vaccine.

Vesicular Rash Following Immunisation With BTN162b2 Messenger RNA (mRNA) COVID-19 Vaccine: Vaccine Related or Coincidence? The introduction of the COVID-19 vaccines has led to an immense sense of relief for the global population. However, since the introduction of these vaccines, there have been several reports related to the side effects. A young womanÂ presented to her primary care doctor with a vesicular rash three days after the BNT162b2 messenger RNA (mRNA) Pfizer-BioNTechÂ vaccine, which was preceded by a low-grade fever for one day. Our case report highlights the challenges in diagnosing a vesicular rash post the BNT162b2 mRNA vaccine. Identifying the cause of a vesicular rash following vaccinationÂ has remained a challenge among primary care practitioners.

Adverse Events Following COVID-19 Vaccination in Selected Apartments in Bangalore, India. Background Vaccination has provided a ray of hope in combating the coronavirus disease 2019 (COVID-19). Vaccines were rolled out as an emergency measure, with an expedited approval process. The available clinical trial data reveals the fact that vaccines mostly produce mild adverse events following immunization (AEFIs). Since the experiences are relatively new, it is important to monitor safety in a real-world setting. With this background, this survey was conducted. Methods This cross-sectional study was approved by the institutional ethics committee (IEC) of Vydehi Institute of Medical Sciences and Research Centre. This was conducted over a period of four months at select apartment complexes around Whitefield, Bangalore. The participants were invited to fill up data through online Google Forms (Google, Mountain View, CA, USA). They were requested to provide demographic details, information related to vaccination, and AEFIs. Eligibility to participate included recipients of vaccines who received Emergency Use Authorization (EUA) in India. Data were analyzed using SPSS version 20.00 (IBM Corporation,Â Armonk, NY, USA). Results The total number of participants in the study was 322. Out of this, 37.6% (121) were males and 62.4% (201) were females. The mean age of the participants was 34.9 Â± 12.4 (mean Â± standard deviation (SD)Â years. About 30% (96) of the study participants had comorbidities. Overall, 67.4% (217) of the participants suffered from AEFI. Of them, immediate reactions were reported by 18.3% (59) and 10.2% (32) of the participants after the first and second doses, respectively. A total of 0.9% (3) of the participants had

immediate allergic reactions. The most common local and systemic AEFIs were pain at the injection site and extreme tiredness. AEFIs were found to be mild and with a probable association with vaccination as per the WHO scale. The number of females experiencing AEFIs was found to be higher when compared with males for both local and systemic reactions. There was a statistically significant increase in the number of individuals experiencing general adverse effects following the first dose of Covishield(TM)Â (Serum Institute of India Private Limited, Pune, India) when compared with Covaxin(TM) (Â)(Bharat Biotech Limited, Hyderabad, India) (P < 0.05). Of the participants, 5.9% (19) were diagnosed with COVID-19 post-vaccination. Among them, 15.8% (3) required hospitalization, with 10.5% (2) of them requiring an oxygen bed. It was observed that 76.5% (166) of the participants did not report their reactions to concerned authorities. Conclusion Based on our sample, the study reflectsÂ that COVID-19 vaccination causes mild AEFI in most vaccine recipients. It also provides an insight that reporting of AEFI is very low. It is, therefore, important to take up more awareness campaigns about reporting of AEFIs through theÂ COVID Vaccine Intelligence NetworkÂ (CoWIN) portal.
Development of myocarditis and pericarditis after COVID-19 vaccination in adult population: A systematic review. OBJECTIVES: A clear temporal relationship between myocarditis and pericarditis after COVID-19 vaccination has led to the belief that the vaccine may act as a trigger for these cardiologic complications. The aim of this systematic review is to explore the incidence, clinical presentation, management, and association between them. METHODS: We conducted a systematic literature search on Cochrane, MEDLINE, and EMBASE as per guidelines of PRISMA (Preferred Reporting Items for Systematic Reviews). A total of 41 case reports and case series describing 97 patients, and 5 original articles describing 15,585,309 participants were selected as part of this review. RESULTS: Of the 97 reported cases describing vaccine-associated myocarditis/pericarditis, 67 (69%) patients received Pfizer-BioNTech and 25 (25.7%) received Moderna. The mean onset of symptoms after vaccine administration was 3.8Â Â±Â 4.5 days with three-quarters developing symptoms after the second dose. Chest pain (nÂ =Â 88, 90%) and fever (nÂ =Â 33, 34%) were the most common presenting complaints. Out of 97, 80 (82.5%) patients recovered while 4 (4.1%) patients expired. The pooled incidence of myocarditis and pericarditis extrapolated from original studies is 0.001% and 0.0004%, respectively. In the original studies, nearly all the cases of myocarditis and pericarditis were mild. Chest pain and fever were the most common presenting symptoms. CONCLUSION: Myocarditis and pericarditis after the COVID-19 vaccine have been reported more in young adult males and are most likely to occur after the second dose of mRNA vaccines. The presentation is mild and the majority of the patients recover either completely or partially.
Flare of myasthenia gravis induced by COVID-19 vaccines.
Isolated musculocutaneous involvement in neuralgic amyotrophy associated with SARS-CoV2 vaccination.
Acute Budd-Chiari syndrome with thrombotic thrombocytopenia after BNT162b2 mRNA vaccination.
Boosting of cross-reactive antibodies to endemic coronaviruses by SARS-CoV-2 infection but not vaccination with stabilized spike. Preexisting antibodies to endemic coronaviruses (CoV) that cross-react with SARS-CoV-2 have the potential to influence the antibody response to COVID-19 vaccination and infection for better or worse. In this observational study of mucosal and systemic humoral immunity in acutely infected, convalescent, and vaccinated subjects, we tested for cross-reactivity against endemic CoV spike (S) protein at subdomain resolution. Elevated responses, particularly to the Î²-CoV OC43, were observed in all natural infection cohorts tested and were correlated with the response to SARS-CoV-2. The kinetics of this response and isotypes involved suggest that infection boosts preexisting antibody lineages raised against prior endemic CoV exposure that cross-react. While further research is needed to discern whether this recalled response is

desirable or detrimental, the boosted antibodies principally targeted the better-conserved S2 subdomain of the viral spike and were not associated with neutralization activity. In contrast, vaccination with a stabilized spike mRNA vaccine did not robustly boost cross-reactive antibodies, suggesting differing antigenicity and immunogenicity. In sum, this study provides evidence that antibodies targeting endemic CoV are robustly boosted in response to SARS-CoV-2 infection but not to vaccination with stabilized S, and that depending on conformation or other factors, the S2 subdomain of the spike protein triggers a rapidly recalled, IgG-dominated response that lacks neutralization activity.

A Case Report of Thrombotic Thrombocytopenia After ChAdOx1 nCov-19 Vaccination and Heparin Use During Hemodialysis. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare but life-threatening complication. VITT strongly mimics heparin-induced thrombocytopenia (HIT) and shares clinical features. Heparin is commonly used to prevent coagulation during hemodialysis. Therefore, nephrologists might encounter patients needing dialysis with a history of heparin exposure who developed thrombotic thrombocytopenia after vaccination. A 70-year-old male presented with acute kidney injury and altered mental status due to lithium intoxication. He needed consecutive hemodialysis using heparin. Deep vein thrombosis of left lower extremity and accompanying severe thrombocytopenia of 15,000/ÂµL on 24 days after vaccination and at the same time, nine days after heparin use. Anti-platelet factor 4 antibody test was positive. Anticoagulation with apixaban and intravenous immunoglobulin (IVIG) infusion resolved swelling of his left calf and thrombocytopenia. There were no definitive diagnostic tools capable of differentiating between VITT and HIT in this patient. Although VITT and HIT share treatment with IVIG and non-heparin anticoagulation, distinguishing between VITT and HIT will make it possible to establish a follow-up vaccination plan in a person who has had a thrombocytopenic thrombotic event. Further research is needed to develop the tools to make a clear distinction between the clinical syndromes.

Early-Onset Myasthenia Gravis Following COVID-19 Vaccination. As coronavirus disease 2019 (COVID-19) has spread worldwide, the rate of COVID-19 vaccination uptake is encouraging. Neurological complications associated with COVID-19 vaccines such as stroke, Guillain-BarrÃ© syndrome, and Bell's palsy have been reported. Recently, late-onset myasthenia gravis (MG) following COVID-19 vaccination has been reported. To date, however, there has been no evidence of increased risk of early-onset MG following COVID-19. Here, we report a case of a patient with new-onset MG that arose after receiving a COVID-19 vaccine. A 33-year-old woman suddenly experienced generalized weakness and diplopia on the evening she had received the second dose of the Pfizer-BioNTech COVID-19 vaccine. The temporal relationship suggests that this new-onset MG is related to the vaccination. It also implies that COVID-19 vaccination could trigger early-onset MG symptoms in patients at risk of MG.

De novo severe pemphigus vulgaris following SARS-CoV-2 vaccination with BBIBP-CorV.

The Current Knowns and Unknowns of COVID-19 Vaccine-Induced Immunity in Patients With Inflammatory Bowel Disease.

Cutting Edge: Effect of Disease-Modifying Therapies on SARS-CoV-2 Vaccine-Induced Immune Responses in Multiple Sclerosis Patients. Multiple sclerosis (MS) is a demyelinating inflammatory disease of the CNS treated by diverse disease-modifying therapies that suppress the immune system. Severe acute respiratory syndrome coronavirus 2 mRNA vaccines have been very effective in immunocompetent individuals, but whether MS patients treated with modifying therapies are afforded the same protection is not known. This study determined that dimethyl fumarate caused a momentary reduction in anti-Spike (S)-specific Abs and CD8 T cell response. MS patients treated with B cell-depleting (anti-CD20) or sphingosine 1-phosphate receptor agonist (fingolimod) therapies lack significant S-specific Ab response. Whereas S-specific CD4 and CD8 T cell responses were largely

compromised by fingolimod treatment, T cell responses were robustly generated in anti-CD20-treated MS patients, but with a reduced proportion of CD4(+)CXCR5(+) circulating follicular Th cells. These data provide novel information regarding vaccine immune response in patients with autoimmunity useful to help improve vaccine effectiveness in these populations.

Myocarditis after RNA-based COVID-19 vaccines: Where do we stand?

Thrombotic events following Covid-19 vaccines compared to Influenza vaccines. IMPORTANCE: The actual risk of thrombotic events after Covid-19 vaccination is unknown. OBJECTIVE: To evaluate the risk of thrombotic events after Covid-19 vaccination. DESIGN: Retrospective cohort study which included consecutive adult patients vaccinated with the first dose of Covid-19 vaccine between January 1 and May 30, 2021, and a historic control group, defined as consecutive patients vaccinated with influenza vaccine between March 1 and July 30, 2019. SETTING: Hospital Italiano de Buenos Aires, a tertiary hospital in Argentina. PARTICIPANTS: Non-Hospitalized Adults vaccinated with the first dose of a Covid-19 vaccine. EXPOSURE: Vaccination with Covid-19 vaccines available during the study period: Gam-COVID-Vac (Sputnik), ChAdOx1 nCoV-19 (AstraZeneca/Oxford or Covishield), BBIBP-CorV (Beijing Institute of Biological Products) (Sinopharm). Active comparator group exposure was Influenza vaccine. MAIN OUTCOME: Primary endpoint was cumulative incidence of any symptomatic thrombotic event at 30 days, defined as the occurrence of at least one of the following: symptomatic acute deep venous thrombosis (DVT); symptomatic acute pulmonary embolism (PE); acute ischemic stroke (AIS); acute coronary syndrome (ACS) or arterial thrombosis. RESULTS: From a total of 29,985 adult patients who received at least a first dose of Covid-19 vaccine during study period and 24,777 who received Influenza vaccine in 2019, we excluded those who were vaccinated during hospitalization. We finally included 29,918 and 24,753 patients respectively. Median age was 73 years old (IQR 75-81) and 67% were females in both groups. Thirty six subjects in the Covid-19 vaccination group (36/29,918) and 15 patients in the Influenza vaccination group (15/24,753) presented at least one thrombotic event. The cumulative incidence of any thrombotic event at 30 days was 12 per 10,000 (95%CI 9-17) for Covid-19 group and 6 per 10,000 (95%CI 4-10) for Influenza group (p-value=0.022). CONCLUSIONS AND RELEVANCE: This study shows a significant increase in thrombotic events in subjects vaccinated with Covid-19 vaccines in comparison to a control group. The clinical implication of these findings should be interpreted with caution, in light of the high effectiveness of vaccination and the inherent risk of thrombosis from Covid-19 infection itself.

Dynamics of anti-Spike IgG antibody level after the second BNT162b2 COVID-19 vaccination in health care workers. INTRODUCTION: Many countries are administering a third dose of COVID-19 vaccines, but the evaluation of vaccine-induced immunity is insufficient. In addition, there are few reports of long-term observation of anti-spike IgG antibody titers after the vaccination in the Japanese population. This study aimed to evaluate anti-spike IgG levels in the Japanese health care workers six months after the BNT162b2 vaccination. METHODS: Dynamics of anti-spike IgG levels were assessed over a six-month period following the second vaccination in 49 participants (Analysis-1). A cross-sectional assessment of anti-spike IgG levels six months after the second vaccination was performed in 373 participants (Analysis-2). RESULTS: In Analysis-1, the geometric mean titer of anti-spike IgG was lower in the older age group and decreased consistently after the second vaccination regardless of age. In Analysis-2, the anti-spike IgG level was significantly negatively associated with age (rÂ =Â -0.35, pÂ <Â 0.01). This correlation remained statistically significant (rÂ =Â -0.28, pÂ <Â 0.01) after adjustment for sex, BMI, smoking habits, alcohol drinking habits, allergies, and fever or other adverse reactions at the time of vaccination. Additionally, participants who drank alcohol daily had significantly lower anti-spike IgG levels than participants who had never drunk alcohol. Sex, smoking habits, allergy, and fever and other side effects after vaccination did not show a significant association with anti-spike IgG levels. CONCLUSIONS: Six months post-vaccination, the anti-spike IgG

level was substantially lower in older persons and daily alcohol drinkers. This may be an indication for an additional vaccine dose for these at-risk categories.

Seropositivity to Nucleoprotein to detect mild and asymptomatic SARS-CoV-2 infections: A complementary tool to detect breakthrough infections after COVID-19 vaccination? BACKGROUND: With COVID-19 vaccine roll-out ongoing in many countries globally, monitoring of breakthrough infections is of great importance. Antibodies persist in the blood after a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Since COVID-19 vaccines induce immune response to the Spike protein of the virus, which is the main serosurveillance target to date, alternative targets should be explored to distinguish infection from vaccination. METHODS: Multiplex immunoassay data from 1,513 SARS-CoV-2 RT-qPCR-tested individuals (352 positive and 1,161 negative) without COVID-19 vaccination history were used to determine the accuracy of Nucleoprotein-specific immunoglobulin G (IgG) in detecting past SARS-CoV-2 infection. We also described Spike S1 and Nucleoprotein-specific IgG responses in 230 COVID-19 vaccinated individuals (Pfizer/BioNTech). RESULTS: The sensitivity of Nucleoprotein seropositivity was 85% (95% confidence interval: 80-90%) for mild COVID-19 in the first two months following symptom onset. Sensitivity was lower in asymptomatic individuals (67%, 50-81%). Participants who had experienced a SARS-CoV-2 infection up to 11Â months preceding vaccination, as assessed by Spike S1 seropositivity or RT-qPCR, produced 2.7-fold higher median levels of IgG to Spike S1Â â‰¥Â 14Â days after the first dose as compared to those unexposed to SARS-CoV-2 atÂ â‰¥Â 7Â days after the second dose (pÂ =Â 0.011). Nucleoprotein-specific IgG concentrations were not affected by vaccination in infection-naÃ¯ve participants. CONCLUSIONS: Serological responses to Nucleoprotein may prove helpful in identifying SARS-CoV-2 infections after vaccination. Furthermore, it can help interpret IgG to Spike S1 after COVID-19 vaccination as particularly high responses shortly after vaccination could be explained by prior exposure history.

Infection, cases due to SARS-CoV-2 in rural areas during early COVID-19 vaccination: findings from serosurvey study in a rural cohort of eastern India. COVID-19 serosurvey provides a better estimation of people who have developed antibody against the infection. But limited information on such serosurveys in rural areas poses many hurdles to understand the epidemiology of the virus and to implement proper control strategies. This study was carried out in the rural catchment area of Model Rural Health Research Unit in Odisha, India during March-April 2021, the initial phase of COVID vaccination. A total of 60 village clusters from four study blocks were identified using probability proportionate to size sampling. From each cluster, 60 households and one eligible participant from each household (60 per cluster) were selected for the collection of blood sample and socio-demographic data. The presence of SARS-CoV-2 antibody was tested using the Elecsys Anti-SARS-CoV-2 immunoassay. The overall seroprevalence after adjusting for test performance was 54.21% with an infection to case ratio of 96.89 along with 4.25% partial and 6.79% full immunisation coverage. Highest seroprevalence was observed in the age group of 19-44 years and females had both higher seroprevalence as well as vaccine coverage. People of other backward caste also had higher seropositivity than other caste categories. The study emphasises on continuing surveillance for COVID-19 cases and prioritizing COVID-19 vaccination for susceptible groups for better disease management.

Safety and immunogenicity of a synthetic multiantigen modified vaccinia virus Ankara-based COVID-19 vaccine (COH04S1): an open-label and randomised, phase 1 trial. BACKGROUND: COH04S1, a synthetic attenuated modified vaccinia virus Ankara vector co-expressing SARS-CoV-2 spike and nucleocapsid antigens, was tested for safety and immunogenicity in healthy adults. METHODS: This combined open-label and randomised, phase 1 trial was done at the City of Hope Comprehensive Cancer Center (Duarte, CA, USA). We included participants aged 18-54 years with a negative SARS-

CoV-2 antibody and PCR test, normal haematology and chemistry panels, a normal electrocardiogram and troponin concentration, negative pregnancy test if female, body-mass index of 30 kg/m(2) or less, and no modified vaccinia virus Ankara or poxvirus vaccine in the past 12 months. In the open-label cohort, 1Â·0â€‰Ã—â€‰10(7) plaque-forming units (PFU; low dose), 1Â·0â€‰Ã—â€‰10(8) PFU (medium dose), and 2Â·5â€‰Ã—â€‰10(8) PFU (high dose) of COH04S1 were administered by intramuscular injection on day 0 and 28 to sentinel participants using a queue-based statistical design to limit risk. In a randomised dose expansion cohort, additional participants were randomly assigned (3:3:1), using block size of seven, to receive two placebo vaccines (placebo group), one low-dose COH04S1 and one placebo vaccine (low-dose COH04S1 plus placebo group), or two low-dose COH04S1 vaccines (low-dose COH04S1 group). The primary outcome was safety and tolerability, with secondary objectives assessing vaccine-specific immunogenicity. The primary immunological outcome was a four times increase (seroconversion) from baseline in spike-specific or nucleocapsid-specific IgG titres within 28 days of the last injection, and seroconversion rates were compared with participants who received placebo using Fisher's exact test. Additional secondary outcomes included assessment of viral neutralisation and cellular responses. This trial is registered with ClinicalTrials.gov, NCT046339466. FINDINGS: Between Dec 13, 2020, and May 24, 2021, 56 participants initiated vaccination. On day 0 and 28, 17 participants received low-dose COH04S1, eight received medium-dose COH04S1, nine received high-dose COH04S1, five received placebo, 13 received low-dose COH04S1 followed by placebo, and four discontinued early. Grade 3 fever was observed in one participant who received low-dose COH04S1 and placebo, and grade 2 anxiety or fatigue was seen in one participant who received medium-dose COH04S1. No severe adverse events were reported. Seroconversion was observed in all 34 participants for spike protein and 32 (94%) for nucleocapsid protein (p<0Â·0001 vs placebo for each comparison). Four times or more increase in SARS-CoV-2 neutralising antibodies within 56 days was measured in nine of 17 participants in the low-dose COH04S1 group, all eight participants in the medium-dose COH04S1 group, and eight of nine participants in the high-dose COH04S1 group (p=0Â·0035 combined dose levels vs placebo). Post-prime and post-boost four times increase in spike-specific or nucleocapsid-specific T cells secreting interferon-Î³ was measured in 48 (98%; 95% CI 89-100) of 49 participants who received at least one dose of COH04S1 and provided a sample for immunological analysis. INTERPRETATION: COH04S1 was well tolerated and induced spike-specific and nucleocapsid-specific antibody and T-cell responses. Future evaluation of this COVID-19 vaccine candidate as a primary or boost vaccination is warranted. FUNDING: The Carol Moss Foundation and City of Hope Integrated Drug Development Venture programme.

Focal segmental glomerulosclerosis following the Pfizer-BioNTech COVID-19 vaccine.

Immune response and adverse events after vaccination against SARS-CoV-2 in adult patients with transfusion-dependent thalassaemia. Patients with transfusion-dependent thalassaemia (TDT) are considered an at increased-risk population for severe and/or morbid coronavirus disease 2019 (COVID-19) infection. Timely vaccination is the main preventive method for severe COVID-19. Different adverse events and reactions after vaccination have been reported, with severe ones being extremely rare. Patients with TDT may have altered immunity due to chronic transfusions, iron overload and chelation therapy, and splenic dysfunction. Here, we show that adult patients with TDT following vaccination with the novel messenger RNA vaccines have mild adverse events and can produce protective antibodies comparable to the healthy population.

Role of imaging in rare COVID-19 vaccine multiorgan complications. As of September 18th, 2021, global casualties due to COVID-19 infections approach 200 million, several COVID-19 vaccines have been authorized to prevent COVID-19 infection and help mitigate the spread of the virus. Despite the vast majority having safely received vaccination against SARS-COV-2, the rare complications following

COVID-19 vaccination have often been life-threatening or fatal. The mechanisms underlying (multi) organ complications are associated with COVID-19, either through direct viral damage or from host immune response (i.e., cytokine storm). The purpose of this manuscript is to review the role of imaging in identifying and elucidating multiorgan complications following SARS-COV-2 vaccination-making clear that, in any case, they represent a minute fraction of those in the general population who have been vaccinated. The authors are both staunch supporters of COVID-19 vaccination and vaccinated themselves as well.

Deficiency of SARS-CoV-2 T-cell responses after vaccination in long-term allo-HSCT survivors translates into abated humoral immunity. Recipients of allogeneic hematopoietic stem cell transplantation (allo-HSCT) for hematological diseases are at risk of severe disease and death from COVID-19. To determine the safety and immunogenicity of BNT162b2 and mRNA-1273 COVID-19 vaccines, samples from 50 infection-naive allo-HSCT recipients (median, 92 months from transplantation, range, 7-340 months) and 39 healthy controls were analyzed for serum immunoglobulin G (IgG) against the receptor binding domain (RBD) within spike 1 (S1) of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2; anti-RBD-S1 IgG) and for SARS-CoV-2-specific T-cell immunity, reflected by induction of T-cell-derived interferon-Î³ in whole blood stimulated ex vivo with 15-mer SI-spanning peptides with 11 amino acid overlapÂ S1-spanning peptides. The rate of seroconversion was not significantly lower in allo-transplanted patients than in controls with 24% (12/50) and 6% (3/50) of patients remaining seronegative after the first and second vaccination, respectively. However, 58% of transplanted patients lacked T-cell responses against S1 peptides after 1 vaccination compared with 19% of controls (odds ratio [OR] 0.17; P = .009, Fisher's exact test) with a similar trend after the second vaccination where 28% of patients were devoid of detectable specific T-cell immunity, compared with 6% of controls (OR 0.18; P = .02, Fisher's exact test). Importantly, lack of T-cell reactivity to S1 peptides after vaccination heralded substandard levels (<100 BAU/mL) of anti-RBD-S1 IgG 5 to 6 months after the second vaccine dose (OR 8.2; P = .007, Fisher's exact test). We conclude that although allo-HSCT recipients achieve serum anti-RBD-S1 IgG against SARS-CoV-2 after 2 vaccinations, a deficiency of SARS-CoV-2-specific T-cell immunity may subsequently translate into insufficient humoral responses.

Risk and Outcome of Breakthrough COVID-19 Infections in Vaccinated Patients With Cancer: Real-World Evidence From the National COVID Cohort Collaborative. PURPOSE: To provide real-world evidence on risks and outcomes of breakthrough COVID-19 infections in vaccinated patients with cancer using the largest national cohort of COVID-19 cases and controls. METHODS: We used the National COVID Cohort Collaborative (N3C) to identify breakthrough infections between December 1, 2020, and May 31, 2021. We included patients partially or fully vaccinated with mRNA COVID-19 vaccines with no prior SARS-CoV-2 infection record. Risks for breakthrough infection and severe outcomes were analyzed using logistic regression. RESULTS: A total of 6,860 breakthrough cases were identified within the N3C-vaccinated population, among whom 1,460 (21.3%) were patients with cancer. Solid tumors and hematologic malignancies had significantly higher risks for breakthrough infection (odds ratios [ORs] = 1.12, 95% CI, 1.01 to 1.23 and 4.64, 95% CI, 3.98 to 5.38) and severe outcomes (ORs = 1.33, 95% CI, 1.09 to 1.62 and 1.45, 95% CI, 1.08 to 1.95) compared with noncancer patients, adjusting for age, sex, race/ethnicity, smoking status, vaccine type, and vaccination date. Compared with solid tumors, hematologic malignancies were at increased risk for breakthrough infections (adjusted OR ranged from 2.07 for lymphoma to 7.25 for lymphoid leukemia). Breakthrough risk was reduced after the second vaccine dose for all cancers (OR = 0.04; 95% CI, 0.04 to 0.05), and for Moderna's mRNA-1273 compared with Pfizer's BNT162b2 vaccine (OR = 0.66; 95% CI, 0.62 to 0.70), particularly in patients with multiple myeloma (OR = 0.35; 95% CI, 0.15 to 0.72). Medications with major immunosuppressive effects and bone marrow transplantation were strongly

associated with breakthrough risk among the vaccinated population. CONCLUSION: Real-world evidence shows that patients with cancer, especially hematologic malignancies, are at higher risk for developing breakthrough infections and severe outcomes. Patients with vaccination were at markedly decreased risk for breakthrough infections. Further work is needed to assess boosters and new SARS-CoV-2 variants.

Correlation of Immunogenicity and Reactogenicity of BNT162b2 and CoronaVac SARS-CoV-2 Vaccines. COVID-19 infection is a global health issue, and vaccination is the main strategy to control this pandemic. In this study, 189 participants received BNT162b2 or CoronaVac vaccine, and 133 of them recorded adverse events (AEs) daily for 4â€‰weeks after vaccination. Their neutralizing antibody against SARS-CoV-2 was determined with live virus microneutralization (vMN) assay. The vMN geometric mean titer (GMT) on day 56 was 129.9 (95% confidence interval [CI],108.6 to 155.2) in the BNT162b2 group and 13.1 (95% CI, 11.2 to 15.3) in the CoronaVac group. Day 56 vMN GMT was 147.9 (95% CI, 118.9 to 184.1) in females and 129.9 (95% CI, 108.6 to 155.2) in males receiving BNT162b2, while it was 14.0 (95% CI, 11.6 to 17.0) in females and 11.4 (95% CI, 8.7 to 15.0) in males receiving CoronaVac. Injection site pain (88.8%) and redness (77.5%) were the most commonly BNT162b2-related AEs, and injection site pain (37.7%) and tiredness (26.4%) were more frequent in the CoronaVac group. Women showed a higher frequency of headache (45.7% versus 29.4%) and joint pain (26.1 versus 14.7%) than men in BTN162b2 group. Headache (26.5% versus 0%) and tiredness (38.2% versus 5.3%) were more common in women than in men vaccinated with CoronaVac. No correlation between any AE and antibody response was observed in BNT162b2 or CoronaVac platforms. After taking the gender factor into account, in the BNT162b2 group, a low correlation between day 21 vMN titer and redness (rhoâ€‰=â€‰0.34) or itching (rhoâ€‰=â€‰0.32) was presented in females, and a low correlation between day 56 vMN titer and fever (rhoâ€‰=â€‰0.35) was presented in males. Taken together, AEs could have a low correlation with BNT162b2 vaccine response. IMPORTANCE Effective vaccines against SARS-CoV-2 are vital tools for containing the COVID-19 pandemic by increasing population immunity. While currently available vaccines can elicit antibody response against SARS-CoV-2 with high efficacy, the associated side effects may cause vaccine hesitancy. Our work is important in that we have thoroughly analyzed the correlation between immunogenicity and reactogenicity of two COVID-19 vaccines (BNT162b2 and CoronaVac) in the study. Our results showed that women had higher levels of neutralizing antibodies than men after receiving BNT162b2 or CoronaVac. Furthermore, a low correlation was observed between day 21 vMN titer and local reactions (redness and itching) in females, as well as between day 56 vMN titer and fever in males receiving BNT162b2. Thus, common side effects are not always a negative impact of vaccination but may serve as an indicator of immunogenicity of vaccines. Our study may help in increasing the public's acceptance and confidence over COVID-19 vaccination and ultimately achieving the goal of containing COVID-19 pandemic.

A case of new-onset acute generalized pustular psoriasis following Pfizer-BioNTech COVID-19 vaccine.

COVID-19 Outcomes and Vaccination in People with Relapsing Multiple Sclerosis Treated with Ofatumumab. INTRODUCTION: The SARS-CoV-2 pandemic necessitated better understanding of the impact of disease-modifying therapies on COVID-19 outcomes and vaccination. We report characteristics of COVID-19 cases and vaccination status in ofatumumab-treated relapsing multiple sclerosis (RMS) patients. METHODS: COVID-19 data analyzed were from the ongoing, open-label, long-term extension phase 3b ALITHIOS study from December 2019 (pandemic start) and post-marketing cases from August 2020 (ofatumumab first approval) up to 25 September 2021. COVID-19 cases, severity, seriousness, outcomes, vaccination status, and breakthrough infection were evaluated. RESULTS: As of 25 September 2021, 245 of 1703 patients (14.4%) enrolled in ALITHIOS receiving ofatumumab (median exposure: 2.45Â years) reported COVID-19 (confirmed: 210;

suspected: 35). Most COVID-19 was of mild (44.1%) or moderate (46.5%) severity, but 9% had severe/life-threatening COVID-19. There were 24 serious cases (9.8%) with 23 patients hospitalized; 22 recovered and 2 died. At study cut-off, 241 patients (98.4%) had recovered or were recovering or had recovered with sequelae and 2 (0.8%) had not recovered. Ofatumumab was temporarily interrupted in 39 (15.9%) patients. Before COVID-19 onset, IgG levels were within the normal range in all COVID-19-affected patients, while IgM wasâ€‰<â€‰0.4Â g/l in 23 (9.4%) patients. No patient had a reinfection. Overall, 559 patients were vaccinated (full, 476; partial, 74; unspecified, 9). Breakthrough infection was reported in 1.5% (7/476) patients, and 11 reported COVID-19 after partial vaccination. As of 25 September 2021, the Novartis Safety Database (~â€‰4713 patient-treatment years) recorded 90 confirmed COVID-19 cases receiving ofatumumab. Most cases were non-serious (nâ€‰=â€‰80), and ten were serious (1 medically significant, 9 hospitalized, 0 deaths). Among 36 of 90 cases with outcomes reported, 30 recovered and 6 did not recover. CONCLUSION: COVID-19 in RMS patients on ofatumumab was primarily of mild/moderate severity and non-serious in these observational data. Most recovered from COVID-19 without treatment interruption. Two people died with COVID-19. Breakthrough COVID-19 despite being fully/partially vaccinated was uncommon.

COVID-19 vaccine acceptance and its associated factors in Ethiopia: A systematic review and meta-analysis. BACKGROUND: COVID-19 vaccination is considered as an effective intervention for controlling the burden of the pandemic. However, vaccine hesitation is increasing and hindering efforts targeting to reduce the burden of the COVID-19 disease. Hence, determining COVID-19 vaccine acceptance and identifying determinants that would hinder people to vaccinate against COVID-19 is crucial to effectively improve COVID-19 vaccine uptake. In Ethiopia, the pooled proportion of COVID-19 vaccine acceptance and its determinants is not well known. Thus, the aim of this study is to estimate the pooled proportion of COVID-19 vaccine acceptance and its determinants in Ethiopia. METHODS: A systematic search of articles was conducted from PubMed, Scopus, Web of Science, MEDLINE, CINAHL, Science Direct and Cochrane Library. Data were extracted using a data extraction tool which was adapted from the Joanna Briggs Institute. The quality of each included primary studies was evaluated using the Newcastle-Ottawa scale tool. Data analysis was performed using STATA 14. Heterogeneity in studies was assessed using Cochrane Q and I(2) test. Publication bias was assessed using visual inspection of funnel plots and Egger's test. A random effects model was applied to determine the pooled estimates if heterogeneity was exhibited; otherwise, a fixed-effects model was used. RESULTS: A total of 14 studies involving 6373 participants were included for the final analysis. The pooled proportion of COVID-19 vaccine acceptance in Ethiopia was 56.02% (95% CI: 47.84, 64.20). The likelihood of COVID-19 vaccine acceptance was higher among participants who had history of chronic disease (AORÂ =Â 1.33, 95% CI: 1.09, 2.97), good knowledge (AORÂ =Â 2.13, 95% CI: 1.59, 4.97), positive attitude (AORÂ =Â 2.23, 95% CI: 1.21, 4.66), good COVID-19 preventive practice (AORÂ =Â 1.97, 95% CI: 1.82, 2.12), and high perceived seriousness of COVID-19 (AORÂ =Â 3.21, 95% CI: 2.32, 5.98). CONCLUSION: More than half participants were willing to accept COVID-19 vaccine. Thus, awareness creation battles about the efficacy and safety of the COVID-19 vaccine should be provided to the community. Besides, policy-makers, health planners and other stakeholders should encourage COVID-19 vaccine uptake behaviors by providing trusted information.Systematic review and meta-analysis registration: PROSPERO CRD42021264708.

Fasciitis of the lower leg after COVID-19 vaccination. â€¢ The occurrence of fasciitis after COVID-19 vaccination is rare. â€¢ The BNT162b2 COVID-19 vaccine can cause fasciitis distant to the injection site. â€¢ The use of steroids is not essential for treatment of vaccine-associated fasciitis.

Drug-induced hepatitis after Sinopharm COVID-19 vaccination: A case study of a 62-year-old patient. INTRODUCTION: COVID-19 virus pandemic has begun since 2020 and became one of the most important causes of mortalities. Accordingly, vaccination has found a vital role in control of COVID-19

virus. Despite many advantages of vaccines in controlling the virus spread and reducing the mortal rate, these benefits came at the expense of side effects which have not been fully explored nor should be ignored. One of the most serious side effects of vaccination, which has been reported recently, is liver injury. CASE PRESENTATION: This study presents a case of hepatitis initiated by Sinopharm vaccine for COVID-19. A 62-year-old man presented with jaundice, weight loss and elevated liver enzymes three days after getting the second dose of COVID-19 vaccine. Microscopic sections showed hepatitis pattern of injury with both portal and lobular inflammation and marked eosinophils infiltration. DISCUSSION: Several cases of hepatitis have been reported after COVID-19 vaccines, but almost all of them were diagnosed as autoimmune hepatitis, triggered by COVID-19 mRNA or viral vector vaccines but the present case is one of the first reported cases of hepatitis after Sinopharm vaccine, an inactivated virus COVID-19 vaccine. Spontaneous decrease in liver enzyme levels, without corticosteroids therapy, is against to the diagnosis of autoimmune hepatitis in other reported cases. CONCLUSION: Considering the microscopic findings, along with the negative serologic studies for viral and autoimmune hepatitis, and by ruling out of other causes of hepatitis like COVID-19 or other viral infections, a probable relation between liver injury and Sinopharm vaccine may be interpreted.

Chronic spontaneous urticaria following ChAdOx1-S COVID-19 vaccination.

Kikuchi-Fujimoto disease following vaccination against COVID-19. The purpose of this study is to explore the clinicopathological features of Kikuchi-Fujimoto disease (KFD) following vaccination against coronavirus disease 2019 (COVID-19). One case of KFD following vaccination against COVID-19 was examined clinically, histologically, and immunohistochemically. The patient was a 36-year-old Chinese man who suffered from fever and cervical lymph node swelling following simultaneous administration of the COVID-19 vaccine. The patient was diagnosed with KFD based on the histopathological findings of a lymph node core needle biopsy, and his fever and swelling resolved 2 months later without therapy. Although the exact pathogenesis of the development of KFD following immunization remains unknown, this information should be added to the list of potential triggers or factors associated with the development of KFD.

SARS-CoV-2 infection after vaccination in Italian health care workers: a case report. Following the approval of COVID-19 vaccination program by EMA and national authorities, an immunization campaign started in Italy with BNT162b2mRNA vaccine, initially focused on healthcare workers. The active immunization was monitored by systemic antibody titration and continuous surveillance was guaranteed by antigenic/molecular tests on swabs. Cases of infection have been recently observed in vaccinated healthcare workers. Herein we describe an outbreak of infection occurring in five physicians out of 656 healthcare workers belonging to a private hospital, referring mild symptoms of COVID-19. Healthcare workers underwent complete vaccination and screening for antibody titration. Five out of 656 healthcare workers were tested positive for SARS-CoV-2 in nasopharyngeal swabs and referred mild COVID-19 symptoms. Molecular analyses were carried out to identify possible variants of Spike protein. Their genotyping performed on RNA extracts highlighted the presence of del69/70, N501Y, A570D, and 1841Aâ€‰>â€‰G (D614G) sequence variants, all indicative of VOC 202012/01-lineage B.1.1.7, suggesting a common source of infection. These cases might represent a serious emergency because outbreaks can compromise frail patients with important concomitant diseases.

Acute Meningoencephalitis after COVID-19 Vaccination in an Adult Patient with Rheumatoid Vasculitis. We herein report a 72-year-old woman with rheumatoid vasculitis who exhibited a depressed level of consciousness after receiving the first dose of the Pfizer-BioNTech mRNA BNT162b COVID-19 vaccine and was diagnosed with meningoencephalitis. Although there was no confirmatory examination, the diagnosis was based on magnetic resonance imaging (MRI) findings and etiological assessments, including microbiological and autoimmune investigations. Both intravenous steroid

pulse and gammaglobulin therapies alleviated the patient's symptoms, and the MRI findings improved. Although the efficacy of COVID-19 vaccination has been widely accepted, such neurologic complications might occur in patients with rheumatoid diseases or vasculitis syndromes.

Acute idiopathic maculopathy after COVID-19 vaccination. PURPOSE: We report a case of acute idiopathic maculopathy (AIM) that developed after COVID-19 vaccination. OBSERVATIONS: A 54-year-old woman complained of a sudden decrease of visual acuity in her right eye one day after receiving a second COVID-19 vaccination (Pfizer). Fundus photograph showed a circular yellow lesion at the fovea in right eye. Optical coherence tomography revealed the thickening of retinal pigment epithelium and the presence of subretinal fluid. Three months after the initial visit, the BCVA and the fundus images had favorable recovery in the right eye. CONCLUSIONS AND IMPORTANCE: We describe a case of AIM after receiving COVID-19 vaccination. These findings may be a helpful in understanding the pathogenesis of AIM.

TREATMENT OF MYASTHENIA GRAVIS PATIENTS WITH COVID-19: REVIEW OF THE LITERATURE. Coronavirus disease 2019 (COVID-19), caused by the late 2019 outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causes a respiratory disease which could put myasthenia gravis (MG) patients at a greater risk of developing severe disease course, since infections and some drugs are a well-recognized trigger of symptom exacerbation in MG patients. Out of ten most commonly used past and present drugs used in COVID-19 treatment, two (quinolone derivatives and azithromycin) are known to worsen MG symptoms, whereas another two (tocilizumab and eculizumab) might have positive effect on MG symptoms. Colchicine, remdesivir, lopinavir, ritonavir and favipiravir seem to be safe to use, while data are insufficient for bamlanivimab, although it is also probably safe to use. Considering MG treatment options in patients infected with SARS-CoV-2, acetylcholine esterase inhibitors are generally safe to use with some preliminary studies even demonstrating therapeutic properties in regard to COVID-19. Corticosteroids are in general safe to use, even recommended in specific circumstances, whereas other immunosuppressive medications (mycophenolate mofetil, azathioprine, cyclosporine, methotrexate) are probably safe to use. The only exception is rituximab since the resulting B cell depletion can lead to more severe COVID-19 disease. Concerning plasmapheresis and intravenous immunoglobulins, both can be used in COVID-19 while taking into consideration thromboembolic properties of the former and hemodynamic disturbances of the latter. As current data suggest, all known COVID-19 vaccines are safe to use in MG patients.

Cardiogenic shock temporally associated with COVID-19 vaccination after prior COVID-19 infection: A case report. The introduction of coronavirus 2019 (COVID-19) vaccination has been an integral force in stopping the spread of COVID-19 across the globe. While reported side effects of vaccination have predominantly been mild, in the last year reports have emerged of myocarditis following the BNT162b2 (Pfizer-BioNtech) and mRNA-1273 (Moderna) vaccinations. The adolescent and young adult population have been the population most reported, with over 1000 cases under review by the Centers for Disease Control (CDC) since April 2021. Here we report a case of a previously healthy 21-year-old male who developed Multisystem Inflammatory Syndrome in Adults (MIS-A) and following the second dose of the Pfizer-BioNtech vaccine. The young male initially presented with fever, leukocytosis with high neutrophil-lymphocyte ratio, severe cardiac illness, and positive COVID-19 nucleocapsid serology, consistent with MIS-A diagnosis. His case was complicated by cardiogenic shock, requiring brief venoarterial extracorporeal membrane oxygenation (VA-ECMO) support. While this report does not detract from the overwhelming benefit of vaccination from COVID-19, clinicians should be aware of this possible relationship in the future.

Case Report: Evolution of Humoral and Cellular Immunity in Two COVID-19 Breakthrough Infections After BNT162b2 Vaccine. BACKGROUND: SARS-CoV-2 breakthrough infections after complete vaccination are increasing whereas their determinants remain uncharacterized. METHODS: We

analyzed two cases of post-vaccination SARS-CoV-2 infections by Î± and Î² variants, respectively. For each participant both humoral (binding and neutralizing antibodies) and cellular (activation markers and cytokine expression) immune responses were characterized longitudinally. RESULTS: The first participant (P1) was infected by an Î± variant and displayed an extended and short period of viral excretion and symptom. Analysis of cellular and humoral response 72 h post-symptom onset revealed that P1 failed at developing neutralizing antibodies and a potent CD4 memory response (lack of SARS-CoV-2 specific CD4(+)IL-2(+) cells) and CD8 effector response (CD8(+)IFNÎ³(+) cells). The second participant (P2) developed post-vaccination SARS-CoV-2 infection by a Î² variant, associated with a short period of viral excretion and symptoms. Despite displaying initially high levels and polyfunctional T cell responses, P2 lacked initial Î²-directed neutralizing antibodies. Both participants developed and/or increased their neutralization activity and cellular responses against all variants, namely, Î² and Î´ variants that lasts up to 3 months after breakthrough infection. CONCLUSIONS: An analysis of cellular and humoral response suggests two possible mechanisms of breakthrough infection: a poor immune response to vaccine and viral evasion to neutralizing antibodies.

Decline in Antibody Concentration 6 Months After Two Doses of SARS-CoV-2 BNT162b2 Vaccine in Solid Organ Transplant Recipients and Healthy Controls. BACKGROUND: Previous studies have indicated inferior responses to severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccination in solid organ transplant (SOT) recipients. We examined the development of anti-receptor-binding domain (RBD) immunoglobulin G (IgG) after two doses of BNT162b2b in SOT recipients 6 months after vaccination and compared to that of immunocompetent controls. METHODS: We measured anti-RBD IgG after two doses of BNT162b2 in 200 SOT recipients and 200 matched healthy controls up to 6 months after first vaccination. Anti-RBD IgG concentration and neutralizing capacity of antibodies were measured at first and second doses of BNT162b2 and 2 and 6 months after the first dose. T-cell responses were measured 6 months after the first dose. RESULTS: In SOT recipients, geometric mean concentration (GMC) of anti-RBD IgG increased from first to second dose (1.14 AU/ml, 95% CI 1.08-1.24 to 11.97 AU/ml, 95% CI 7.73-18.77) and from second dose to 2 months (249.29 AU/ml, 95% CI 153.70-385.19). Six months after the first vaccine, anti-RBD IgG declined (55.85 AU/ml, 95% CI 36.95-83.33). At all time points, anti-RBD IgG was lower in SOT recipients than that in controls. Fewer SOT recipients than controls had a cellular response (13.1% vs. 59.4%, $p < 0.001$). Risk factors associated with humoral non-response included age [relative risk (RR) 1.23 per 10-year increase, 95% CI 1.11-1.35, $p < 0.001$], being within 1 year from transplantation (RR 1.55, 95% CI 1.30-1.85, $p < 0.001$), treatment with mycophenolate (RR 1.54, 95% CI 1.09-2.18, $p = 0.015$), treatment with corticosteroids (RR 1.45, 95% CI 1.10-1.90, $p = 0.009$), kidney transplantation (RR 1.70, 95% CI 1.25-2.30, $p = 0.001$), lung transplantation (RR 1.63, 95% CI 1.16-2.29, $p = 0.005$), and de novo non-skin cancer comorbidity (RR 1.52, 95% CI, 1.26-1.82, $p < 0.001$). CONCLUSION: Immune responses to BNT162b2 are inferior in SOT recipients compared to healthy controls, and studies aiming to determine the clinical impact of inferior vaccine responses are warranted.

Non-Invasive Monitoring for Rejection in Kidney Transplant Recipients After SARS-CoV-2 mRNA Vaccination. INTRODUCTION: Studies have shown reduced antiviral responses in kidney transplant recipients (KTRs) following SARS-CoV-2 mRNA vaccination, but data on post-vaccination alloimmune responses and antiviral responses against the Delta (B.1.617.2) variant are limited. MATERIALS AND METHODS: To address this issue, we conducted a prospective, multi-center study of 58 adult KTRs receiving mRNA-BNT162b2 or mRNA-1273 vaccines. We used multiple complementary non-invasive biomarkers for rejection monitoring including serum creatinine, proteinuria, donor-derived cell-free DNA, peripheral blood gene expression profile (PBGEP), urinary CXCL9 mRNA and de novo donor-specific antibodies (DSA). Secondary outcomes included development of anti-viral immune responses against the wild-type and Delta variant of SARS-CoV-2. RESULTS: At a median of 85

days, no KTRs developed de novo DSAs and only one patient developed acute rejection following recent conversion to belatacept, which was associated with increased creatinine and urinary CXCL9 levels. During follow-up, there were no significant changes in proteinuria, donor-derived cell-free DNA levels or PBGEP. 36% of KTRs in our cohort developed anti-wild-type spike antibodies, 75% and 55% of whom had neutralizing responses against wild-type and Delta variants respectively. A cellular response against wild-type S1, measured by interferon-Î³-ELISpot assay, developed in 38% of KTRs. Cellular responses did not differ in KTRs with or without antibody responses. CONCLUSIONS: SARS-CoV-2 mRNA vaccination in KTRs did not elicit a significant alloimmune response. About half of KTRs who develop anti-wild-type spike antibodies after two mRNA vaccine doses have neutralizing responses against the Delta variant. There was no association between anti-viral humoral and cellular responses.

Virus-related Knowledge in Covid-19 Times - Results from two Cross-sectional Studies in Austria and Implications for School. Viruses have become a prominent issue in public health, politics and economics due to the Covid-19 pandemic. Yet they have still met little attention in educational research, although misconceptions concerning viruses may contribute to antibiotics misuse, disbelief in existence of viruses and distrust in vaccination. We investigated knowledge and attitudes in Austria concerning Covid-19, viruses in general and vaccination. We conducted two cross-sectional online surveys. Study A was performed Austrian-wide (N = 1027), study B specifically targeted Austrian students from middle and high schools (N = 1728). Several participants did not believe in the existence of SARS-CoV-2. General vaccination damage was highly overrated. Many defined viruses as unicellular organisms or bacteria, and 6-10 % believed that they can be killed by antibiotics. Very many participants were unable to identify, whether a specific disease was caused by a virus or another pathogen. Knowledge was significantly correlated with level of education/grade and interest in virology. Additionally, willingness to become vaccinated was significantly correlated with knowledge. Many participants felt insufficiently informed about viruses at school. We strongly recommend that virus-related school education must highly improve to enable the population to correctly assess health-related information, counter fake news and come to scientifically informed decisions.

A Single-Health System Case Series of New-Onset CNS Inflammatory Disorders Temporally Associated With mRNA-Based SARS-CoV-2 Vaccines. BACKGROUND: Since 2020, over 250 million doses of mRNA-based SARS-CoV-2 vaccines have been administered in the United States and hundreds of millions worldwide between the Pfizer-BioNTech and Moderna SARS-CoV-2 vaccines. To date, there have been rare reports associating mRNA-based SARS-CoV-2 vaccines with episodes of inflammatory and autoimmune CNS disorders. We report a case series of five patients with new-onset neurological disorders of inflammatory or immunological origin temporally associated with these vaccines. METHODS: A case-series of five patients within a single 23-hospital health system who developed new-onset CNS inflammatory disease within 2 weeks of receiving a dose of an mRNA-based SARS-CoV-2 vaccine. RESULTS: Five cases of post-vaccination CNS disorders of immune origin (fatal ADEM; n = 1, new-onset NMOSD; n = 2, new-clinical onset MS-like syndrome but with preexisting clinically silent mild demyelination; n = 1, meningoencephalitis; n = 1) observed within 2 weeks of inoculation with either the first or second dose of mRNA-based SARS-CoV-2 vaccines (Moderna = 3, Pfizer = 2). DISCUSSION: To our knowledge, these are among the emerging cases of CNS adverse events of immunological or inflammatory origin. These findings should be interpreted with great caution as they neither prove a mechanistic link nor imply a potential long-term increased risk in post-vaccination CNS autoimmunity. Larger prospective studies assessing the potential association between mRNA-based vaccination and the development of neurological adverse events of suspected immune origin, particularly among those with underlying CNS or systemic autoimmune disorders, are

needed. The use of mRNA-based SARS-CoV-2 vaccines should continue to be strongly encouraged given their high efficacy in overcoming this pandemic.

Extrafollicular proliferation of B-blasts: Morphologic correlate to Spikevax-induced lymphadenopathy. A 30-year-old male developed a PET-positive left-sided cervical lymphadenopathy that was suspected representing metastasis of a known right-sided papillary thyroid cancer. First-dose-application of Spikevax three weeks ago was neither reflected, nor reported to the pathologists. Diagnostic lymphadenectomy was performed showing extrafollicular proliferation of B-blasts, likely attributable to the vaccine application.

The BNT162b2 mRNA Covid-19 vaccine does not impair sperm parameters. RESEARCH QUESTION: Does the BNT162b2 COVID-19 vaccine affect sperm parameters of patients with a normal or an abnormal semen analysis? DESIGN: Data were collected from male patients undergoing IVF treatment after completing vaccination between February 2021 and June 2021 (post-vaccine). For comparison, records of the same patients were reviewed before the vaccination (pre-vaccine) back to January 2017. Patients with azoospermia were excluded. Sperm parameters were compared between pre- and post-vaccine groups. Each patient served as self-control. RESULTS: Seventy-two patients were included in the study (median interquartile range [IQR] age 35.7 [33.0-43.0] years), of whom 57 had a normal semen analysis. The time between the first vaccine and the post-vaccine sperm analysis was 71.0 (40.5-104.8) days. The sperm parameters before and after the vaccination were as follows: sperm volume before 3.0 (2.0-4.0) and after 3.0 (1.6-3.9) ml, Pâ€¯=â€¯0.02; sperm concentration before 26.5 (14.0-64.7) and after 31.0 (14.2-80.0) 10(6)/ml, Pâ€¯=â€¯0.35; and total motile sperm count before 33.7 (9.0-66.0) and after 29 (6.0-97.5)10(6), Pâ€¯=â€¯0.96. Sub-group analyses were conducted for patients with male infertility and patients with a normal semen analysis. Neither of the sub-groups showed significant changes after vaccination. CONCLUSION: Sperm parameters showed no significant changes after vaccination among men with a normal and abnormal semen analysis. Therefore, the BNT162b2 vaccine does not seem to affect sperm parameters. The preliminary results are reassuring for the entire global population, currently undergoing intense vaccination campaigns against COVID-19.

Autoimmune mucocutaneous blistering diseases after SARS-Cov-2 vaccination: A Case report of Pemphigus Vulgaris and a literature review. BACKGROUND: Cases of severe autoimmune blistering diseases (AIBDs) have recently been reported in association with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. AIMS: To describe a report of oropharyngeal Pemphigus Vulgaris (OPV) triggered by the mRNABNT162b2 vaccine (ComirnatyÂ®/ Pfizer/ BioNTech) and to analyze the clinical and immunological characteristics of the AIBDs cases reported following the SARS-CoV-2 vaccination. METHODS: The clinical and immunological features of our case of OPV were documented. A review of the literature was conducted and only cases of AIBDs arising after the SARS-CoV-2 vaccination were included. CASE REPORT: A 60-year old female patients developed oropharyngeal and nasal bullous lesions seven days after the administration of a second dose of the mRNABNT162b2 vaccine (ComirnatyÂ®/ Pfizer/BioNtech). According to the histology and direct immunofluorescence findings showing the presence of supra-basal blister and intercellular staining of IgG antibodies and the presence of a high level of anti-Dsg-3 antibodies (80Â U/ml; normal < 7Â U/ml) in the serum of the patients, a diagnosis of oropharyngeal Pemphigus Vulgaris was made. REVIEW: A total of 35 AIBDs cases triggered by the SARS-CoV-2 vaccination were found (including our report). 26 (74.3%) were diagnosed as Bullous Pemphigoid, 2 (5.7%) as Linear IgA Bullous Dermatosis, 6 (17.1%) as Pemphigus Vulgaris and 1Â (2.9%) as Pemphigus Foliaceus. The mean age of the sample was 72.8 years and there was a predominance of males over females (F:M=1:1.7). In 22 (62.9%) cases, the disease developed after Pfizer vaccine administration, 6 (17.1%) after Moderna, 3 (8.6%) after AstraZeneca, 3 (8.6%) after CoronaVac (one was not specified). All patients were treated with topical

and/or systemic corticosteroids, with or without the addition of immunosuppressive drugs, with a good clinical response in every case. CONCLUSION: Clinicians should be aware of the potential, though rare, occurrence of AIBDs as a possible adverse event after the SARS-CoV-2 vaccination. However, notwithstanding, they should encourage their patients to obtain the vaccination in order to assist the public health systems to overcome the COVID-19 pandemic.

Ischemic stroke shortly after vaccination against SARS-CoV-2: A case-control study. BACKGROUND AND PURPOSE: Vaccination against SARS-CoV-2 has been associated with rare occurrences of severe venous thromboses. Very little data exist about arterial ischemic strokes. We have assessed the features of ischemic strokes occurring shortly after vaccination against SARS-CoV-2 in the Cremona area, Italy. METHODS: From February 1, to July 31, 2021, all patients with ischemic stroke within four weeks of vaccination against COVID-19 admitted to our stroke unit were consecutively collected, and their main features were compared with those of all other patients with ischemic strokes admitted during the same period. RESULTS: Sixteen strokes after vaccination were collected. They represented 10.5% of all ischemic strokes. Median interval from vaccination was 12Â days (range 1-24). Fifteen (93.8%) had received the BNT162b2 (Pfizer-BioNTech) vaccine and 1 (6.2%) the ChAdOx1 nCoV-19 (AstraZeneca). Two patients (12.5%) had a mild thrombocytopenia on admission (128,000 and 142,000/ml), without any evidence of bleeding or venous thrombosis. Thrombolysis and/or thrombectomy were carried out in 4 cases (25.0%). When compared with 137 strokes without recent vaccination, none of the demographic, clinical, and laboratory features of post-vaccination strokes were significantly different. CONCLUSIONS: Ischemic strokes occurring shortly after COVID-19 vaccination at our center were similar to those of non-vaccinated patients. Therefore, the relatively high percentage of such patients probably relates to the very high fraction of elderly people vaccinated against SARS-CoV-2 in the Cremona area, rather than to a consequence of vaccination.

COVID-19 vaccine coverage and factors associated with vaccine uptake among 23â€‰247 adults with a recent history of homelessness in Ontario, Canada: a population-based cohort study. BACKGROUND: People experiencing homelessness face a high risk of SARS-CoV-2 infection and transmission, as well as health complications and death due to COVID-19. Despite being prioritised for receiving the COVID-19 vaccine in many regions, little data are available on vaccine uptake in this vulnerable population. Using population-based health-care administrative data from Ontario, Canada-a region with a universal, publicly funded health system-we aimed to describe COVID-19 vaccine coverage (ie, the estimated percentage of people who have received a vaccine) and determinants of vaccine receipt among individuals with a recent history of homelessness. METHODS: We conducted a retrospective, population-based cohort study of adults (aged â‰¥18 years) with a recent experience of homelessness, inadequate housing, or shelter use as recorded in routinely collected health-care databases between June 14, 2020, and June 14, 2021 (a period within 6 months of Dec 14, 2020, when COVID-19 vaccine administration was initiated in Ontario). Participants were followed up from Dec 14, 2020, to Sept 30, 2021, for the receipt of one or two doses of a COVID-19 vaccine using the province's real-time centralised vaccine information system. We described COVID-19 vaccine coverage overall and within predefined subgroups. Using modified Poisson regression, we further identified sociodemographic factors, health-care usage, and clinical factors associated with receipt of at least one dose of a COVID-19 vaccine. FINDINGS: 23â€‰247 individuals with a recent history of homelessness were included in this study. Participants were predominantly male (14â€‰752 [63Â·5%] of 23â€‰247); nearly half were younger than 40 years (11â€‰521 [49Â·6%]) and lived in large metropolitan regions (12â€‰123 [52Â·2%]); and the majority (18â€‰226 [78Â·4%]) visited a general practitioner for an in-person consultation during the observation period. By Sept 30, 2021, 14â€‰271 (61Â·4%; 95% CI 60Â·8-62Â·0) individuals with a recent history of homelessness had

received at least one dose of a COVID-19 vaccine and 11â€‰082 (47Â·7%; 47Â·0-48Â·3) had received two doses; in comparison, over the same period, 86Â·6% of adults in the total Ontario population had received a first dose and 81Â·6% had received a second dose. In multivariable analysis, factors positively associated with COVID-19 uptake were one or more outpatient visits to a general practitioner (adjusted risk ratio [aRR] 1Â·37 [95% CI 1Â·31-1Â·42]), older age (50-59 years vs 18-29 years: 1Â·18 [1Â·14-1Â·22], â‰¥60 years vs 18-29 years: 1Â·27 [1Â·22-1Â·31]), receipt of an influenza vaccine in either of the two previous influenza seasons (1Â·25 [1Â·23-1Â·28]), being identified as homeless via a visit to a community health centre versus exclusively a hospital-based encounter (1Â·13 [1Â·10-1Â·15]), receipt of one or more SARS-CoV-2 tests between March 1, 2020, and Sept 30, 2021 (1Â·23 [1Â·20-1Â·26]), and the presence of chronic health conditions (one condition: 1Â·05 [1Â·03-1Â·08]; two or more conditions: 1Â·11 [1Â·08-1Â·14]). By contrast, living in a smaller metropolitan region (aRR 0Â·92 [95% CI 0Â·90-0Â·94]) or rural location (0Â·93 [0Â·90-0Â·97]) versus large metropolitan regions were associated with lower uptake. INTERPRETATION: In Ontario, COVID-19 vaccine coverage among adults with a recent history of homelessness has lagged and, as of Sept 30, 2021, was 25 percentage points lower than that of the general adult population in Ontario for a first dose and 34 percentage points lower for a second dose. With high usage of outpatient health services among individuals with a recent history of homelessness, better utilisation of outpatient primary care structures might offer an opportunity to increase vaccine coverage in this population. Our findings underscore the importance of leveraging existing health and service organisations that are accessed and trusted by people who experience homelessness for targeted vaccine delivery. FUNDING: The Public Health Agency of Canada. TRANSLATION: For the French translation of the abstract see Supplementary Materials section.

Thrombosis with thrombocytopenia after the second ChAdOx1 nCoV-19 vaccination: A possible immunological mechanism independent of anti-platelet factor 4 antibody. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a distinctive syndrome characterized by unusual site thrombosis accompanied by thrombocytopenia following adenoviral vector vaccines against severe acute respiratory syndrome coronavirus 2. Platelet-activating anti-platelet factor 4-dependent antibodies (anti-PF4 Abs) have been identified as pathogenic antibodies in almost all patients. OBJECTIVE: We proposed an immunological mechanism of VITT independent of anti-PF4 Abs. METHODS: Case report. RESULTS: A 68-year-old Thai woman developed pulmonary embolism and deep vein thrombosis with thrombocytopenia one week after the second ChAdOx1 nCoV-19 vaccination with undetectable anti-PF4 Abs. The platelet count responded rapidly to intravenous immunoglobulin and steroids. Therefore, the high clinical suspicion is essential for early recognition and prompt management irrespective of anti-PF4 Ab results. CONCLUSIONS: We hypothesize that platelet and endothelial activation following ChAdOx1 nCoV-19 vaccination may lead to generation of pathogenic antibodies which account for VITT independent of anti-PF4 Abs.

Life-threatening autoimmune hemolytic anemia following mRNA COVID-19 vaccination: don't be too prudent with the red gold.

Acute Calcium Pyrophosphate Crystal Arthritis of the Wrist Elicited by Anti-COVID-19 Vaccination After Carpal Tunnel Release. BACKGROUND Calcium pyrophosphate dihydrate deposition disease includes a variety of clinical syndromes, including acute calcium pyrophosphate (CPP) crystal arthritis. Most patients with CPP crystal arthritis have a primary/idiopathic form presenting with severe pain, swelling, and stiffness. COVID-19 infection, which originated in China in December 2019, required extraordinary efforts to develop and test new vaccines to halt the pandemic. The Vaxzervria vaccine has shown excellent safety and efficacy in phase 3 trials with a mechanism based on the expression of the SARS-CoV-2 spike protein gene coding for the S-antigen, which stimulates the immune response. CASE REPORT We describe an acute event of crystal arthritis after a carpal tunnel syndrome release

followed by administration of the second dose of anti-COVID-19 Vaccine Oxford-AstraZeneca (ChAdOx1 nCoV-19). Medical treatment resulted in full resolution of the symptoms in 2 weeks. CONCLUSIONS Although most episodes of acute arthritis happen spontaneously, certain factors may trigger the acute CPP crystal arthritis such as intercurrent illnesses or surgeries. Although the association between carpal tunnel syndrome and CPP arthritis has been known for over 40 years, surgical release of the carpal ligament has always been associated with full resolution of symptoms. This is the first case report describing an exacerbation after carpal canal release, concomitant with the administration of the vaccine. According to our opinion, the vaccination associated with a prior surgery in the same anatomical site could have synergically triggered the arthritis flare-up, in a predisposed patient, with a mechanism still unknown.

Stroke Among SARS-CoV-2 Vaccine Recipients in Mexico: A Nationwide Descriptive Study. BACKGROUND AND OBJECTIVES: Information on stroke among severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines remains scarce. We report stroke incidence as an adverse event following immunization (AEFI) among recipients of 79,399,446 doses of 6 different SARS-CoV-2 vaccines (BNT162b2, ChAdOx1 nCov-19, Gam-COVID-Vac, CoronaVac, Ad5-nCoV, and Ad26.COV2-S) between December 24, 2020, and August 31, 2021, in Mexico. METHODS: This retrospective descriptive study analyzed stroke incidence per million doses among hospitalized adult patients (â‰¥18 years) during an 8-month interval. According to the World Health Organization, AEFIs were defined as clinical events occurring within 30 days after immunization and categorized as either nonserious or serious, depending on severity, treatment, and hospital admission requirements. Acute ischemic stroke (AIS), intracerebral hemorrhage (ICH), subarachnoid hemorrhage (SAH), and cerebral venous thrombosis (CVT) cases were collected through a passive epidemiologic surveillance system in which local health providers report potential AEFI to the Mexican General Board of Epidemiology. Data were captured with standardized case report formats by an ad hoc committee appointed by the Mexican Ministry of Health to evaluate potential neurologic AEFI against SARS-COV-2. RESULTS: We included 56 patients (31 female patients [55.5%]) for an overall incidence of 0.71 cases per 1,000,000 administered doses (95% CI 0.54-0.92). Median age was 65 years (interquartile range [IQR] 55-76 years); median time from vaccination to stroke (of any subtype) was 2 days (IQR 1-5 days). In 27 (48.2%) patients, the event was diagnosed within the first 24 hours after immunization. The most frequent subtype was AIS in 43 patients (75%; 0.54 per 1,000,000 doses, 95% CI 0.40-0.73), followed by ICH in 9 (16.1%; 0.11 per 1,000,000 doses, 95% CI 0.06-0.22) and SAH and CVT, each with 2 cases (3.6%; 0.03 per 1,000,000 doses, 95% CI 0.01-0.09). Overall, the most common risk factors were hypertension in 33 (58.9%) patients and diabetes in 22 (39.3%). Median hospital length of stay was 6 days (IQR 4-13 days). At discharge, functional outcome was good (modified Rankin Scale score 0-2) in 41.1% of patients; in-hospital mortality rate was 21.4%. DISCUSSION: Stroke is an exceedingly rare AEFI against SARS-CoV-2. Preexisting stroke risk factors were identified in most patients. Further research is needed to evaluate causal associations between SARS-COV-2 vaccines and stroke.

Controversies around the statistical presentation of data on mRNA-COVID 19 vaccine safety in pregnant women. The work entitled "Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons" published on April 21, 2021, in The New England Journal of Medicine, presented data collected from American surveillance systems and registries. However, problems with an unanimous interpretation of those results appeared in the public debate and citing articles. Some stated that the risk of miscarriage in vaccinated women was similar to historical values reported before the vaccines' approval. The others stated that risk was highly above-normative in women vaccinated during the first and second trimesters. We found several problems with the statistical treatment/interpretation of the originally presented values: a substantial percentage (up to 95.6%) of missing data, an incorrect denominator used for risk estimation, and too short follow-up that disabled

the evaluation of the study's endpoint in numerous participants. Eventually, the Authors published a corrigendum on September 8, 2021, and pointed to updated data. Herein, we explain the statistical controversies raised by the original presentation and stress that analyzing the trade-off between knowledge and confusion brought by the release of incomplete results of such a high social interest, should aid in solving the dilemma of whether to publish preliminary data or none.
Is pulmonary embolism occurring after SARS COV-2 vaccination provoked or unprovoked?
Adverse events following COVID-19 vaccination in South Korea between February 28 and August 21, 2021: A nationwide observational study. OBJECTIVES: To investigate the clinical characteristics of adverse events (AEs) after COVID-19 vaccination in patients in South Korea. DESIGN: Data from the Korean Disease Control and Prevention Agency on AEs from 4 COVID-19 vaccines, including AZD1222, BNT162b2, JNJ-78436735, and mRNA-1273, from February 26, 2021, to August 21, 2021, were assessed. The epidemiological characteristics, clinical symptoms, severity, complications, and mortality were descriptively analyzed. RESULTS: Overall, 36.3 million individuals who completed the COVID-19 vaccination doses during the study period were included, and 153,183 AEs were reported. Most AEs occurred after the first dose (80.6%) and within a day (63.2%) after vaccination. Of the AEs, 95.5% were nonsevere cases; however, 4.5% were severe. Most mild AEs showed a similar frequency across all age groups, but major severe AEs and mortality events increased with age. CONCLUSIONS: Although there were differences in the frequency of occurrence, various adverse reactions were confirmed in using all 4 COVID-19 vaccines, even with the BNT162b2 (Pfizer-BioNTech) vaccine. Caution is needed, and further research should be continuously conducted.
Aducanumab and adenoviral COVID-19 vaccines: increased cerebral hemorrhage risk?
Persistence of Platelets Activation Prior to Second Doses of Covid-19 Vaccine After Vaccine-Induced Immune Thrombotic Thrombocytopenia.
Central nervous system adverse events after ChAdOx1 vaccination. INTRODUCTION: Post-ChAdOx1 vaccine (AZD1222) adverse events following immunization (AEFI) are uncommon. Recently described neurological events include thrombocytopenia with thrombosis syndrome (TTS) with cerebral venous thrombosis and Guillain-BarrÃ© syndrome. There are very few AEFI reports following COVID vaccination from India, because of underreporting or other factors. A few cases of acute transverse myelitis (ATM) and post-vaccinal encephalitis have also been reported. MATERIALS AND METHODS: Over 11Â months, in 2 districts of Kerala, India, 8.19 million people were vaccinated with the ChAdOx1 vaccine. RESULTS: During this period, we encountered five cases of autoimmune central nervous system (CNS) AEFI following ChAdOX1 (Oxford/AstraZeneca, Covishieldâ„¢) vaccination. These included three cases of acute disseminated encephalomyelitis (ADEM), one case of opsoclonus myoclonus ataxia syndrome (OMAS), and one case of limbic encephalitis. The calculated crude incidence of post-ChAdOX1 autoimmune CNS AEFI was approximately 0.24 cases per million for encephalitis and 0.36 per million for ADEM. This was compared to the crude annual incidence of community-acquired ADEM worldwide (3.2-4 per million) and the crude annual incidence of community-acquired encephalitis in India (8.35-10 per million). CONCLUSION: There was no increase in the incidence of post-vaccination CNS AEFI (ADEM or encephalitis) as compared to the community incidence of ADEM or encephalitis. While this emphasizes the safety of ChAdOX1 nCoV-19 vaccination for COVID-19, it is important to recognize these post-vaccination autoimmune syndromes early to initiate immunosuppressive therapy.
Multisystem Inflammatory Syndrome in Children after SARS-CoV-2 Vaccination. Multisystem inflammatory syndrome in children (MIS-C) is a hyperinflammatory state that occurs after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. We present 2 cases of MIS-C after SARS-CoV-2 vaccination; 1 patient had evidence of recent SARS-CoV-2 infection. Our findings suggest that vaccination modulates the pathogenesis of MIS-C.

Arterial Embolic Infarction After COVID-19 Vaccination Associated With Antiplatelet Factor 4 Antibody.

Impact of Therapy in Patients with Hematologic Malignancies on Seroconversion Rates After SARS-CoV-2 Vaccination. INTRODUCTION: The leading professional organizations in the field of hematology have recommended severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) vaccination for all patients with hematologic malignancies notwithstanding efficacy concerns. Here we report a systematic literature review regarding the antibody response to SARS-CoV-2 vaccination in patients with hematologic malignancies and its key determinants. METHODS: We conducted a systematic search of original articles evaluating the seroconversion rates with SARS-CoV-2 vaccines in hematological malignancies from the PubMed database published between April 1, 2021 and December 4, 2021. Calculated risk differences (RD) and 95% confidence intervals (CI) to compare seroconversion rates between patients with hematologic malignancies versus healthy control subjects used the Review Manager software, version 5.3. RESULTS: In our meta-analysis, we included 26 studies with control arms. After the first dose of vaccination, patients with hematologic malignancies had significantly lower seroconversion rates than controls (33.3% vs 74.9%; RD: -0.48%, 95% CI: -0.60%, -0.36%, P < .001). The seroconversion rates increased after the second dose, although a significant difference remained between these 2 groups (65.3% vs 97.8%; RD: -0.35%, 95% CI: -0.42%, -0.28%, P < .001). This difference in seroconversion rates was particularly pronounced for Chronic Lymphocytic Leukemia (CLL) patients (RD: -0.46%, 95% CI: -0.56, -0.37, P < .001), and for patients with B-lineage leukemia/lymphoma treated with anti-CD20 antibodies (RD: -0.70%, 95% CI: -0.88%, -0.51%, P < .001) or Bruton Tyrosine Kinase Inhibitors (BTKi; RD: -0.63%, 95% CI: -0.85%, -0.41%, P < .001). The RD was lower for patients under remission (RD: -0.10%, 95% CI: -0.18%, -0.02%, P = .01). CONCLUSION: The seroconversion rates following SARS-CoV-2 vaccination in patients with hematologic malignancies, especially in CLL patients and patients treated with anti-CD20 antibodies or BTKi, were significantly lower than the seroconversion rates in healthy control subjects. Effective strategies capable of improving vaccine efficacy in these vulnerable patient populations are urgently needed.

COVID-19 Vaccination as a Potential Trigger for New-Onset Systemic Lupus Erythematosus. Immune hyperactivation has been linked to various vaccines. We presentÂ a potential association of new-onset systemic lupus erythematosus (SLE) post-COVID-19 immunization. The patient is a 54-year-old male admitted for evaluation of flu-like symptoms two weeks after receiving the second dose of the COVID-19 vaccine. Physical examination revealed high-grade fever, diffuse bilateral non-tender cervical lymphadenopathy, and erythematous maculopapular palpable purpuric lesions on bilateral feet. Laboratory evaluation showed a significant hypocomplementemia (C3 < 11 mg/dL, C4 < 3 mg/dL, and CH50 < 10 U/mL), high titer antinuclear antibody, anti-dsDNA antibodies, anti-Sjogren's syndrome-related antigen A antibodies, anti-Sjogren's syndrome-related antigen B antibodies, anti-Smith antibodies, anti-ribonucleoprotein antibodies, anti-histone antibodies with a negative malignancy, and infection workup. The patient was treated with a high dose of steroids with a positive response. This case highlights the possibility of SLE, a rare adverse event following COVID-19 vaccination.

Interstitial Lung Disease and Transverse Myelitis: A Possible Complication of COVID-19 Vaccine. The clinical impact of the severe acute respiratory syndrome 2 (SARS-CoV-2) pandemic is growing, and vaccine-associated complications are becoming more evident. Although global vaccination against coronavirus disease 19 (COVID-19) is an outstanding accomplishment, safety concerns and adverse outcomes are also emerging that need to be addressed promptly. The most reported side effects of the COVID-19 vaccine include fever, myalgia, headache, and injection site reactions. Acute transverse myelitis (ATM) and interstitial lung disease (ILD) following the CoronaVac vaccine are

rarely reported. We report a case of ILD followed by acute myelopathy in a female who presentedÂ with dyspnea, cough, and fever after the second dose of the COVID-19 vaccine. On the third day of admission, she developed paresthesia and bilateral upper andÂ lower limb weakness. She was diagnosed with ILD and ATM due to the COVID-19 vaccine based on imaging and detailed investigations after ruling out all possible causes. Her neurological and respiratory manifestations improved gradually after starting intravenous methylprednisolone.

Incidence, Pattern and Severity of Adverse Events Following Immunization (AEFIs) Associated With Chadox1 nCOV-19 Corona Virus Vaccine (Recombinant) Among the Healthcare Workers of a Tertiary Care Institute of Eastern Uttar Pradesh, India. Background In January 2020, the Government of India based on the recommendation of the Drugs Controller General ofÂ IndiaÂ (DCGI) and National Technical Advisory Group on Immunization (NTAGI) started the rollout of the COVID-19 vaccine in the country. Two vaccines, ChAdOx1 nCoV-19 coronavirus vaccine (recombinant), i.e., COVISHIELD produced by Serum Institute of India and COVAXIN developed indigenously by Bharat Biotech, were given emergency use authorisation (EUA) by the DCGI. Methods In this cohort study, we assessed the incidence, pattern and severity of adverse events following immunization (AEFI) observed among the healthcare workers of a large tertiary care institute in eastern U.P., India vaccinated with ChAdOx1 nCoV-19 Coronavirus vaccine (recombinant) within 30 minutes of vaccination by direct observation. Results Out of the total 836 healthcare workers who were vaccinated with the first dose of the vaccine, around 10% experienced any AEFI within the directly observed period. The most common AEFI was pain/tenderness at the injection site experienced by 59.3% of those who experienced any AEFI followed by headache/dizziness (35.3%), itching/rashes at the injection site (8.1%), nausea/vomiting (5.8%) and fever/chills (4.7%). The majority (95.3%) of the AEFIs observed were of minor severity with no serious AEFIs observed as per the WHO severity classification. Conclusion ChAdOx1 nCoV-19 Coronavirus vaccine (recombinant) is proven to be safe based on our findings as the majority of AEFIs observed were of minor grade only. However, the vaccine beneficiaries should be strictly observed for a minimum of 30 minutes at the vaccination site to look for any serious AEFI with arrangements to manage the same.

Perspectives and experiences with COVID-19 vaccines in people with MS. BACKGROUND: People with MS may have unique perspectives on COVID-19 vaccines due to their condition and/or medications. OBJECTIVE: Assess perspectives and experiences with COVID-19 vaccination, and quantify variables impacting COVID-19 vaccine willingness in people with MS. METHODS: A survey captured demographics, MS characteristics, and COVID-19 infection and exposures data; opinions on COVID-19 vaccine safety, side effects, and efficacy; and experiences following vaccination. Chi-square tests and a logistic regression model were used to denote between-group differences and variables predicting vaccine willingness, respectively. RESULTS: Most (87.8%) of the 237 participants were willing to receive the vaccine. Fifteen percent held or delayed a DMT dose for vaccination. MS symptoms worsened in a minority (7.6% first/only dose; 14.7% second dose), and most side effects were mild (80.0%; 55.3%). Those not planning to receive the vaccine were primarily concerned with long-term safety (70.4%). Medical comorbidities (adjusted odds ratio [aOR]=5.222; p=0.04) and following infection prevention precautions (aOR=6.330; p=0.008) were associated with vaccine willingness. CONCLUSION: Most individuals with MS surveyed plan to receive the COVID-19 vaccine. People with MS experience similar side effects to the general population, and few experience transient MS symptom worsening. These results can inform conversations on vaccination between providers and people with MS.

Immune-Mediated Platelet Activation in COVID-19 and Vaccine-Induced Immune Thrombotic Thrombocytopenia. Both qualitative and quantitative platelet abnormalities are common in patients with coronavirus disease 2019 (COVID-19) and they correlate with clinical severity and

mortality. Activated platelets contribute to the prothrombotic state in COVID-19 patients. Several groups have shown immune-mediated activation of platelets in critically ill COVID-19 patients. Vaccine-induced immune thrombotic thrombocytopenia is an autoimmune condition characterized by thrombocytopenia and life-threatening thrombotic events in the arterial and venous circulation. Although the initial trigger has yet to be determined, activation of platelets by immune complexes through Fc gamma RIIA results in platelet consumption and thrombosis. A better understanding of platelet activation in COVID-19 as well as in vaccine-induced thrombotic complications will have therapeutic implications. In this review, we focused on the role of immune-mediated platelet activation in thrombotic complications during COVID-19 infection and vaccine-induced immune thrombotic thrombocytopenia.

Severe acute interstitial lung disease after BNT162b2 mRNA COVID-19 vaccination in a patient post HLA-haploidentical hematopoietic stem cell transplantation.

The aetiopathogenesis of vaccine-induced immune thrombotic thrombocytopenia. In the new science emanating from the COVID-19 pandemic, effective vaccine development has made a huge difference and saved countless lives. Vaccine roll-out led to the identification of rare cases of severe thrombotic and thrombocytopenic problems in some recipients. This apparent coupling of thrombosis with haemorrhagic potentiation might seem baffling but the ensuing clinical investigation rapidly shed important light on its molecular mechanism. This review outlines the current understanding on the role of adenovirus-based platforms, the immunogenic triggers and the immunothrombotic response underlying vaccine-induced immune thrombotic thrombocytopenia.

Frequency of Ipsilateral Axillary Lymphadenopathy After the Inactivated COVID-19 Vaccine. OBJECTIVE: During COVID-19 vaccine development studies, vaccines' efficacy and safety profiles should be carefully investigated. Only a few studies have shown that the COVID-19 vaccine can cause axillary lymphadenopathy on the injection arm. This study aimed to investigate the incidence of axillary lymphadenopathy and imaging findings using B-mode and Doppler ultrasonography (US) examinations in volunteers who had recently been vaccinated against COVID-19. METHODS: The ipsilateral and contralateral axillae of 101 volunteers who received the COVID-19 vaccine were evaluated using B-mode and Doppler US examinations. The volunteers were asked when and to which arm the vaccine had been applied, and the type and dose of the vaccine were recorded. It was also questioned whether the individual experienced any side effects after vaccination, such as pain, tenderness, fever, and redness at the injection site. In addition, the demographic data of the participants, such as age and gender, were recorded. RESULTS: The B-mode US examinations revealed that the long- and short-axis diameters, size, cortical thickness, and asymmetric cortical thickening of the left axillary lymph nodes were significantly higher compared to the right side in individuals having received the CoronaVac vaccine ($p<0.05$). When the individuals were evaluated separately according to gender, the frequency of cortical thickness and asymmetric cortical thickening in the left axillary lymph nodes was higher than on the right side in both males and females ($p=0.011$). CONCLUSION: It should be kept in mind that ipsilateral reactive lymphadenopathy may develop after the COVID-19 vaccine. This knowledge can prevent unnecessary axillary lymph node biopsies.

Comparison of antibody responses after the 1st and 2nd doses of COVID-19 vaccine with those of patients with mild or severe COVID-19. BACKGROUND/AIMS: Data comparing the antibody responses of different coronavirus disease 2019 (COVID-19) vaccine platforms according to dose with natural severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection-induced antibody responses are limited. METHODS: Blood samples from adult patients with mild and severe COVID-19 and healthcare workers who received ChAdOx1 nCoV-19 vaccine (2nd dose at 12-week intervals) and BNT162b2 vaccine (2nd dose at 3-week intervals) were collected and compared by immunoglobulin G immune responses to SARS-CoV-2 specific spike protein using an in-house-developed enzyme-linked

immunosorbent assay. RESULTS: A total of 53 patients, including 12 and 41 with mild and severe COVID-19, respectively, were analyzed. In addition, a total of 73 healthcare workers, including 37 who received ChAdOx1 nCoV-19 and 36 who received BNT162b2, were enrolled. Antibody responses after the first and second doses of the ChAdOx1 nCoV-19 vaccine or the first dose of the BNT162b2 vaccine were similar to those in convalescent patients with mild COVID-19, but lower than those in convalescent patients with severe COVID-19, respectively. However, after the second dose of the BNT162b2 vaccine, the antibody response was comparable to that in convalescent patients with severe COVID-19. CONCLUSION: Our data suggest that the second dose of mRNA vaccination may be more beneficial in terms of long-term immunity and prevention of SARS-CoV-2 variant infection than a single dose of COVID-19 vaccination or homologous second challenge ChAdOx1 nCoV-19.

COVID-19 mRNA vaccine safety during the first 6 months of roll-out in the USA.

Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to the Vaccine Adverse Event Reporting System and v-safe. BACKGROUND: In December, 2020, two mRNA-based COVID-19 vaccines were authorised for use in the USA. We aimed to describe US surveillance data collected through the Vaccine Adverse Event Reporting System (VAERS), a passive system, and v-safe, a new active system, during the first 6 months of the US COVID-19 vaccination programme. METHODS: In this observational study, we analysed data reported to VAERS and v-safe during Dec 14, 2020, to June 14, 2021. VAERS reports were categorised as non-serious, serious, or death. Reporting rates were calculated using numbers of COVID-19 doses administered as the denominator. We analysed v-safe survey reports from days 0-7 after vaccination for reactogenicity, severity (mild, moderate, or severe), and health impacts (ie, unable to perform normal daily activities, unable to work, or received care from a medical professional). FINDINGS: During the study period, 298â€‰792â€‰852 doses of mRNA vaccines were administered in the USA. VAERS processed 340â€‰522 reports: 313â€‰499 (92Â·1%) were non-serious, 22â€‰527 (6Â·6%) were serious (non-death), and 4496 (1Â·3%) were deaths. Over half of 7â€‰914â€‰583 v-safe participants self-reported local and systemic reactogenicity, more frequently after dose two (4â€‰068â€‰447 [71Â·7%] of 5â€‰674â€‰420 participants for local reactogenicity and 4â€‰018â€‰920 [70Â·8%] for systemic) than after dose one (4â€‰644â€‰989 [68Â·6%] of 6â€‰775â€‰515 participants for local reactogenicity and 3â€‰573â€‰429 [52Â·7%] for systemic). Injection-site pain (4â€‰488â€‰402 [66Â·2%] of 6â€‰775â€‰515 participants after dose one and 3â€‰890â€‰848 [68Â·6%] of 5â€‰674â€‰420 participants after dose two), fatigue (2â€‰295â€‰205 [33Â·9%] participants after dose one and 3â€‰158â€‰299 participants [55Â·7%] after dose two), and headache (1â€‰831â€‰471 [27Â·0%] participants after dose one and 2â€‰623â€‰721 [46Â·2%] participants after dose two) were commonly reported during days 0-7 following vaccination. Reactogenicity was reported most frequently the day after vaccination; most reactions were mild. More reports of being unable to work, do normal activities, or of seeking medical care occurred after dose two (1â€‰821â€‰421 [32Â·1%]) than after dose one (808â€‰963 [11Â·9%]); less than 1% of participants reported seeking medical care after vaccination (56â€‰647 [0Â·8%] after dose one and 53â€‰077 [0Â·9%] after dose two). INTERPRETATION: Safety data from more than 298 million doses of mRNA COVID-19 vaccine administered in the first 6 months of the US vaccination programme show that most reported adverse events were mild and short in duration. FUNDING: US Centers for Disease Control and Prevention.

Immune-mediated thrombotic thrombocytopenic purpura following COVID-19 vaccination.

Seroprevalence of COVID-19 infection among vaccine naÃ¯ve population after the second surge (June 2020) in a rural district of South India: A community-based cross-sectional study. OBJECTIVE: To determine the seroprevalence of the SARS Cov 2 infection among vaccine naive population in a rural district of South India post-second surge. METHODOLOGY: We conducted a cross-sectional study in

the five villages of a randomly chosen sub-district in the Bangalore rural district. We did house to house surveys and recruited 831 vaccine naive adults in July 2021. We tested samples for the presence of antibodies (including IgG & IgM) to SARS CoV-2 using the Roche Elecsys SARS-CoV-2 -S assay that quantifies antibodies against the receptor-binding domain (RBD) of the spike (S) protein. RESULTS: We estimated an overall prevalence of 62.7% (95% CI: 59.3-66.0) and an age-and gender-adjusted seroprevalence of 44.9% (95% CI: 42.5-47.4). When adjusted for test performance, the seroprevalence was 74.64% (95% CI: 70.66-78.47). The case-to-undetected-infected ratio (CIR) was 1: 8.65 (95% CI 1:8.1-1:9.1), and the Infection Fatality Rate (IFR) was 16.27 per 100,00 infections as of 13 July 2021. A history of at least one symptom suggestive of COVID-19 or a positive COVID-19 test of self or a family member in the past were significantly associated with seropositivity. CONCLUSION: We report a high seroprevalence of COVID-19 infection despite the advantages of low population density and well-ventilated landscapes in rural areas. CIR and IFR were higher than the previous serosurvey conducted in the same population during the first surge. The thought of achieving herd immunity comes with relief. However, it's vital to put efforts into building population health and rural health infrastructure to avert future health catastrophes.

COVID-19 vaccination: The road ahead. A diverse array of successful, first-generation SARS-CoV-2 vaccines have played a huge role in efforts to bring the COVID-19 pandemic under control, even though inequitable distribution still leaves many vulnerable. Additional challenges loom for the next phase. These include optimizing the immunological rationale for boosting-how often and with what- and the best approaches for building a future-proofed, durable immune repertoire to protect against oncoming viral variants, including in children. The landscape of vaccine producers and technologies is likely to become even more heterogeneous. There is a need now for appraisal of future approaches: While some favor frequent boosting with the first-generation, ancestral spike vaccines, others propose frequent readjustment using current variant sequences, polyvalent vaccines, or pan-coronavirus strategies.

COVID-19 Vaccination within the Context of Reactogenicity and Immunogenicity of ChAdOx1 Vaccine Administered to Teachers in Poland. In February 2021, Polish teachers were offered the ChAdOx1-S vaccine as a priority group. However, there have been concerns among educators regarding the efficacy of this vaccine, as compared to the other types of vaccines (e.g., mRNA). The objective of this study was to investigate the reactogenicity and the immunogenicity of this vaccine. Participants, specifically teachers, were invited for serological testing â‰¥ 4 weeks post-vaccination. Antibodies against the receptor-binding domain (RBD) were measured. Of the 192 participants, the mean age was 50.5 Â± 8.3 years and the mean (range) dosing interval was 69.6 Â± (25â^'111) days. Adverse reactions included feeling feverish (44.8%), headache (41.7%), malaise/chills (38.0%), and injection-site tenderness (37.5%); these were reported more frequently after the first dose (84.9%). Fewer males than females (54.8% vs. 80.1%) and fewer older participants (65.7% vs. 90.4%) reported side effects ($p < 0.002$; $p < 0.0001$, respectively). All participants presented detectable anti-RBD IgG; the median (range) reading was 525.0 BAU/mL (20.6â^'5680.0); 1008.02 BAU/mL (115.3â^'5680.0) in those with prior SARS-CoV-2 infection; and 381.42 BAU/mL (20.6â^'3108.8) in those without ($p = 0.001$). In 27.6%, the anti-RBD IgG level was >500 BAU/mL. A multivariate logistic regression revealed that previous infection and longer dose intervals were predictors of higher immunologic responses ($p < 0.0001$; $p = 0.01$, respectively). The results demonstrated good tolerability and immunogenicity of the ChAdOx1-S vaccine. Our study justified the longer dose interval to enhance a higher antibody response. Our findings may also support the prioritization of uninfected individuals in regions where COVID-19 vaccine-sparing strategies are required.

Adverse Events Associated with BNT162b2 and AZD1222 Vaccines in the Real World: Surveillance Report in a Single Italian Vaccine Center. AIM: Despite huge efforts in developing specific drugs,

vaccination represents the only effective strategy against COVID-19. Efficacy and safety of the COVID-19 vaccines were established during clinical trials. Nonetheless, it is very important to perform continuous surveillance. This observational study aimed to report potential Adverse Events Following Immunization (AEFI) following the first dose of two different COVID-19 vaccines, BNT162b2 and AZD1222. METHODS AND RESULTS: Subjects who underwent vaccination at the vaccine center of the University Hospital of Salerno, Italy, were interviewed using an ad hoc questionnaire. AZD-vac group (n = 175) who received AZD1222 had a higher number of AEFI than the BNT-vac group (n = 1613) who received BNT162b2 (83% vs. 42%). The most frequent AEFI associated with AZD1222 and BNT162b2 were fever and pain at the injection site, respectively. The AZD-vac group used drugs to contrast AEFI more frequently than the BNT-vac group. In the BNT-vac group, there was a higher incidence of AEFI in women than in men (26.2% vs. 15.8%, p = 0.01), while no gender-related difference was observed in the AZD-vac group. CONCLUSIONS: AZD1222 and BNT162b2 vaccines show a good safety profile. Based on our results and literature data, there are no reasons to justify the reluctance that persists towards immunization.

Consensus on COVID-19 Vaccination in Pediatric Oncohematological Patients, on Behalf of Infectious Working Group of Italian Association of Pediatric Hematology Oncology. Vaccines represent the best tool to prevent the severity course and fatal consequences of the pandemic by the new Coronavirus 2019 infection (SARS-CoV-2). Considering the limited data on vaccination of pediatric oncohematological patients, we developed a Consensus document to support the Italian pediatric hematological oncological (AIEOP) centers in a scientifically correct communication with families and patients and to promote vaccination. The topics of the Consensus were: SARS-CoV-2 infection and disease (COVID-19) in the pediatric subjects; COVID-19 vaccines (type, schedule); who and when to vaccinate; contraindications and risk of serious adverse events; rare adverse events; third dose and vaccination after COVID-19; and other general prevention measures. Using the Delphi methodology for Consensus, 21 statements and their corresponding rationale were elaborated and discussed with the representatives of 31 centers, followed by voting. A high grade of Consensus was obtained on topics such as the potential risk of severe COVID-19 outcome in pediatric oncohematological patients, the need for vaccination as a preventative measure, the type, schedule and booster dose of vaccine, the eligibility of the patients for vaccination, and the timing, definition, and management of contraindications and serious adverse events, and other general prevention measures. All 21 of the statements were approved. This consensus document highlights that children and adolescents affected by hematological and oncological diseases are a fragile category. Vaccination plays an important role to prevent COVID-19, to permit the regular administration of chemotherapy or other treatments, to perform control visits and hospital admissions, and to prevent treatment delays.

Danger ahead: COVID-19 infections after vaccination.

Myocarditis following rAd26 and rAd5 vector-based COVID-19 vaccine: correspondence.

Vitiligo worsened following the second dose of mRNA SARS-CoV-2 vaccine.

Association of Vaccination with the Persistence of Post-COVID Symptoms. BACKGROUND: Patients who have had COVID-19 often report persistent symptoms after resolution of their acute illness. Recent reports suggest that vaccination may be associated with improvement in post-acute symptoms. We used data from a prospective cohort to assess differences in post-acute sequelae of COVID (PASC) among vaccinated vs. unvaccinated patients. METHODS: We used data from a cohort of COVID-19 patients enrolled into a prospective registry established at a tertiary care health system in New York City. Participants underwent a baseline evaluation before COVID-19 vaccines were available and were followed 6 months later. We compared unadjusted and propensity score-adjusted baseline to 6-month change for several PASC-related symptoms and measures: anosmia, respiratory (cough, dyspnea, phlegm, wheezing), depression, anxiety, post-traumatic stress disorder (PTSD; COVID-19-

related and other trauma), and quality-of-life domains among participants who received vs. those who did not receive COVID-19 vaccination. RESULTS: The study included 453 COVID-19 patients with PASC, of which 324 (72%) were vaccinated between the baseline and 6-month visit. Unadjusted analyses did not show significant differences in the baseline to 6-month change in anosmia, respiratory symptoms, depression, anxiety, PTSD, or quality of life ($p > 0.05$ for all comparisons) among vaccinated vs. unvaccinated patients. Similar results were found in propensity-adjusted comparisons and in secondary analyses based on the number of vaccine doses received. CONCLUSIONS: Our findings suggest that COVID vaccination is not associated with improvement in PASC. Additional studies are needed to better understand the mechanisms underlying PASC and to develop effective treatments.

Acquired Hemophilia A Post-COVID-19 Vaccination: A Case Report and Review. Acquired hemophilia A (AHA) is an inhibitory coagulopathy that represents a rare variant of hemorrhagic syndromes.Â We present a case of idiopathic AHA in a 75-year-old male patient with a cutaneous hematoma that could be attributed to a recent COVID-19 vaccination.Â The aim of this report is to raise awareness of a possible association between AHA and COVID-19 vaccination and to review similar reported cases and management plans to prevent the development of possible morbidity and debilitating complications. This case illustrates an exceptionally rare side effect of the COVID-19 vaccination. The advantages of obtaining the COVID-19 vaccine outweigh the risks.

Acute myocarditis caused by COVID-19 disease and following COVID-19 vaccination. Myocarditis and pericarditis are inflammatory conditions of the heart that present a range of symptoms, often including chest pain, fatigue, breathlessness and palpitations that may be irregular due to cardiac rhythm disturbances. Myocarditis has been proposed to account for a fraction of cardiac injury among patients infected with SARS-CoV-2 and associated systemic inflammation; and it might be one of the reasons for the high mortality seen in COVID-19 patients. Furthermore, following vaccination with mRNA COVID-19 vaccines (ie, Comirnaty and Spikevax), myocarditis and pericarditis can develop within a few days of vaccination, particularly following the second dose. Based on recent reviewed data, the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have determined that the risk for both of these conditions is overall 'very rare' (~1 in 10â€‰000 vaccinated people may be clinically affected), with the highest risk among younger males. Both EMA and FDA agree that the benefits of all authorised COVID-19 vaccines continue to outweigh their risks, given the threat of serious COVID-19 illness and related complications. Since myocarditis has a very wide clinical spectrum, ranging from mild to fulminant life-threatening disease, we present in this review a sum of the latest findings and considerations for the proper diagnosis and management of affected patients.

Case of acquired haemophilia a in Southeast Asia following COVID-19 vaccine. Acquired haemophilia A (AHA) is a rare bleeding disorder with high morbidity and mortality, but it is eminently treatable if diagnosis and treatment are prompt. We report a case of AHA in Southeast Asia following the administration of the Pfizer-BioNTech COVID-19 vaccine. A man in his 80s developed multiple bruises 2â€‰weeks after his first dose of the COVID-19 vaccine. Diagnosis was delayed due to his cognitive impairment and low clinical suspicion. This led to a representation with worsening ecchymosis, a left thigh haematoma and symptomatic anaemia. Laboratory testing was notable for an isolated prolongation of the activated partial thromboplastin time, which remained uncorrected in the mixing test. Further testing confirmed the presence of factor VIII (FVIII) inhibitors and low FVIII titres of 6.7%. He responded to treatment with intravenous methylprednisolone and recombinant activated FVII. Screening for autoimmune diseases and malignancies was negative.

Tumefactive Demyelinating Brain Lesion Developing after Administration of Adenovector-Based COVID-19 Vaccine: A Case Report. BACKGROUND: Postmarketing surveillance of COVID-19

vaccination reveals that the COVID-19 vaccine administration is associated with several rare but serious neurological complications. CASE REPORT: We report a case of new-onset tumefactive demyelinating brain lesion that developed after administration of an adenovector-based COVID-19 vaccine. A middle-aged female presented with recent right hemiparesis, which was noticed 2 days after she received the first dose of the vaccine. Magnetic resonance imaging (MRI) revealed a large subcortical T2/FLAIR hyperintensities involving corpus callosum as well. The patient responded to oral methylprednisolone. At 4 weeks, a follow-up MRI revealed a reduction in size of the lesion. CONCLUSION: To conclude, adenovector-based COVID-19 vaccination may be associated with a tumefactive demyelinating lesion.

Development of factor IX inhibitor in an adult with severe haemophilia B following COVID-19 vaccination: A case report.

Attitudes towards COVID-19 vaccination: A comparison between persons with different chronicity of pre-pandemic depressive, anxiety or obsessive-compulsive disorders.

Cerebral venous thrombosis due to vaccine-induced immune thrombotic thrombocytopenia after a second ChAdOx1 nCoV-19 dose.

Natural history of PF4 antibodies in vaccine-induced immune thrombocytopenia and thrombosis. The COVID-19 pandemic has resulted in the rapid development of a range of vaccines against SARS-CoV-2. Vaccine-induced immune thrombocytopenia and thrombosis (VITT) is a rare but life-threatening complication of primarily adenoviral-based vaccines associated with the presence of antibodies to a PF4/polyanion neoepitope and measured by using enzyme-linked immunosorbent assays. Presented are serial anti-PF4/polyanion antibody, platelet, and D-dimer measurements in a large cohort of patients and their relation to relapse. Overall, 51% of patients using the Stago assay had persistently positive anti-PF4/polyanion levels 100 days' postdiagnosis, whereas 94% of patients monitored by using the Immucor assay remain positive. The median duration of positivity of the PF4 assay is 87 days, with 72% of patients remaining positive after a median follow-up of 105 days. The use of plasma exchange seemed to reduce anti-PF4/polyanion levels and increase platelet counts in the acute setting more rapidly than other therapies. The rate of relapse in this study was 12.6%, with all relapsed cases exhibiting persistently positive PF4 antibodies and falling platelet counts. Only one patient had extension of their thrombosis. Overall, despite the persistence of PF4 antibodies in 72% of patients, the rate of relapse was low and did not seem to result in recrudescence of the aggressive clinical picture seen at index presentation. Monitoring of these patients in the UK cohort is ongoing and will aid in definition of the natural history of this novel condition.

Evaluation of Adverse Effects in Nursing Mothers and Their Infants After COVID-19 mRNA Vaccination. Background and Objectives: Breastfeeding women are generally excluded from clinical trials with new vaccines. The objective of the study was to explore whether the BNT162b2 mRNA and mRNA-1273 COVID-19 vaccines are safe for breastfeeding mothers and their breastfed infants. Methods: A convenience sample prospective cohort single institution study was performed on breastfeeding health care professionals, who were exposed to second dose of SARS-CoV2 vaccine at the beginning of the study period. They and their breastfed children's symptoms were followed up through online questionnaires for 14 days. Results: Of the 95 finally included participants, only 1 was lost to follow-up on day 7. Mean age of the mothers was 35.9â€‰Â±â€‰3.9 years and that of their infants was 14.6â€‰Â±â€‰12.1 months. At least one adverse event was reported by 85% (95% confidence interval [CI]: 76-91.5%) of the mothers. The most frequent was injection site pain in 81% of cases. Moreover, 31% (95% CI: 22-41%) observed some event in their breastfed children. Most frequently, 19% (95% CI: 13-30%) of the children were irritable. During the 14 days of follow-up, 36% of the children (95% CI: 27-46%) were diagnosed with respiratory infection. Conclusions: Most mothers' reactions were mild and transitory, generally limited to the first 3 days after vaccination.

Many children's events were associated with concomitant infectious processes and we did not detect a notable peak on any particular day of follow-up. Neither mothers nor their infants developed serious adverse events nor were they diagnosed with COVID-19 within the study period.

A Recombinant Subunit Vaccine Induces a Potent, Broadly Neutralizing, and Durable Antibody Response in Macaques against the SARS-CoV-2 P.1 (Gamma) Variant. FDA-approved and emergency use-authorized vaccines using new mRNA and viral-vector technology are highly effective in preventing moderate to severe disease; however, information on their long-term efficacy and protective breadth against severe acute respiratory syndrome coronavirus 2 variants of concern (VOCs) is currently scarce. Here, we describe the durability and broad-spectrum VOC immunity of a prefusion-stabilized spike (S) protein adjuvanted with liquid or lyophilized CoVaccine HT in cynomolgus macaques. This recombinant subunit vaccine is highly immunogenic and induces robust spike-specific and broadly neutralizing antibody responses effective against circulating VOCs (B.1.351 [Beta], P.1 [Gamma], and B.1.617 [Delta]) for at least three months after the final boost. Protective efficacy and postexposure immunity were evaluated using a heterologous P.1 challenge nearly three months after the last immunization. Our results indicate that while immunization with both high and low S doses shorten and reduce viral loads in the upper and lower respiratory tract, a higher antigen dose is required to provide durable protection against disease as vaccine immunity wanes. Histologically, P.1 infection causes similar COVID-19-like lung pathology as seen with early pandemic isolates. Postchallenge IgG concentrations were restored to peak immunity levels, and vaccine-matched and cross-variant neutralizing antibodies were significantly elevated in immunized macaques indicating an efficient anamnestic response. Only low levels of P.1-specific neutralizing antibodies with limited breadth were observed in control (nonvaccinated but challenged) macaques, suggesting that natural infection may not prevent reinfection by other VOCs. Overall, these results demonstrate that a properly dosed and adjuvanted recombinant subunit vaccine can provide protective immunity against circulating VOCs for at least three months.

Humoral response and safety of the BNT162b2 and mRNA-1273 COVID-19 vaccines in patients with haematological diseases treated with anti-CD20 antibodies: An observational study.

Vaccine-Induced Antibody Responses against SARS-CoV-2 Variants-Of-Concern Six Months after the BNT162b2 COVID-19 mRNA Vaccination. The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants has raised concern about increased transmissibility, infectivity, and immune evasion from a vaccine and infection-induced immune responses. Although COVID-19 mRNA vaccines have proven to be highly effective against severe COVID-19 disease, the decrease in vaccine efficacy against emerged Beta and Delta variants emphasizes the need for constant monitoring of new virus lineages and studies on the persistence of vaccine-induced neutralizing antibodies. To analyze the dynamics of COVID-19 mRNA vaccine-induced antibody responses, we followed 52 health care workers in Finland for 6 months after receiving two doses of BNT162b2 vaccine with a 3-week interval. We demonstrate that, although anti-S1 antibody levels decrease 2.3-fold compared to peak antibody levels, anti-SARS-CoV-2 antibodies persist for months after BNT162b2 vaccination. Variants D614G, Alpha, and Eta are neutralized by sera of 100% of vaccinees, whereas neutralization of Delta is 3.8-fold reduced and neutralization of Beta is 5.8-fold reduced compared to D614G. Despite this reduction, 85% of sera collected 6 months postvaccination neutralizes Delta variant. IMPORTANCE A decrease in vaccine efficacy against emerging SARS-CoV-2 variants has increased the importance of assessing the persistence of SARS-CoV-2 spike protein-specific antibodies and neutralizing antibodies. Our data show that after 6 months post two doses of BNT162b2 vaccine, antibody levels decrease yet remain detectable and capable of neutralizing emerging variants. By monitoring the vaccine-induced antibody responses, vaccination strategies and administration of booster doses can be optimized.

Two Cousins with Acute Hemichorea after BBIBP-CorV (Sinopharm) COVID-19 Vaccine.

Vaccination-infection interval determines cross-neutralization potency to SARS-CoV-2 Omicron after breakthrough infection by other variants. BACKGROUND: The immune profile against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has dramatically diversified due to a complex combination of exposure to vaccines and infection by various lineages/variants, likely generating a heterogeneity in protective immunity in a given population. To further complicate this, the Omicron variant, with numerous spike mutations, has emerged. These circumstances have created the need to assess the potential of immune evasion by Omicron in individuals with various immune histories. METHODS: The neutralization susceptibility of the variants, including Omicron and their ancestors, was comparably assessed using a panel of plasma/serum derived from individuals with divergent immune histories. Blood samples were collected from either mRNA vaccinees or from those who suffered from breakthrough infections of Alpha/Delta with multiple time intervals following vaccination. FINDINGS: Omicron was highly resistant to neutralization in fully vaccinated individuals without a history of breakthrough infections. In contrast, robust cross-neutralization against Omicron was induced in vaccinees that experienced breakthrough infections. The time interval between vaccination and infection, rather than the variant types of infection, was significantly correlated with the magnitude and potency of Omicron-neutralizing antibodies. CONCLUSIONS: Immune histories with breakthrough infections can overcome the resistance to infection by Omicron, with the vaccination-infection interval being the key determinant of the magnitude and breadth of neutralization. The diverse exposure history in each individual warrants a tailored and cautious approach to understanding population immunity against Omicron and future variants. FUNDING: This study was supported by grants from the Japan Agency for Medical Research and Development (AMED).

Factors associated with intention to receive COVID-19 vaccine among HIV positive patients attending ART clinic.

SARS-CoV-2 vaccination and practical points in psoriasis patients: A narrative review. SARS-CoV2 vaccines were approved without long-term monitoring due to emergent situations. This has raised some issues about timing and protocol of receiving vaccines in specific situations including patients with chronic inflammatory disorders such as psoriasis. Here, we present different aspects of SARS-CoV-2 infection and vaccination in psoriasis patients and aim to provide solutions to overcome the potential challenges. In brief, the benefits of vaccination outweigh the potential risk; vaccine-triggered de novo or flares of psoriasis is uncommon. As such, all psoriasis patients, especially those receiving systemic treatments including anti tumor necrosis factor agents, are strongly recommended to get SARS-CoV-2 vaccines. It is recommended that new immunosuppressive/immunomodulatory therapies be initiated at least 1Â week after the second SARS-CoV-2 vaccine dose, if possible. In addition, in severe and active forms of psoriasis, it is better to delay vaccination until stabilization of the disease.

Various painful oral adverse reactions following COVID-19 vaccination: a case series. BACKGROUND: Adverse events are increasingly being reported with the growing COVID-19 vaccination rate. However, the current literature on orofacial adverse effects following COVID-19 vaccination are severely limited. With the continuation of the global vaccination campaign the incidence of oral adverse effects will inevitably increase. CASE PRESENTATION: Clinical characteristics and treatment results of nine patients who complained of pain and discomfort of the oral cavity following SARS-CoV-2 vaccination were analyzed. Swelling and pain of the posterior palatal area, pain on palatal area of the central incisor, pain on the mucosa of the lip and lower gingiva, right preauricular region and right posterior lower gingiva, the buccal mucosa, tongue, and the right lower second molar area were the reported symptoms. Ulceration and swelling of the oral mucosa were

found in certain cases. The symptoms were generally mild and responded well to medication within a relatively short period of time. CONCLUSION: Oral adverse reactions following COVID-19 vaccination were manageable with treatment. Clinicians should understand the true nature of orofacial adverse reactions following COVID-19 vaccines and guide patients in decision-making.

Anti-SARS-CoV-2 antibody response after 2 and 3 doses of BNT162b2 mRNA vaccine in patients with lymphoid malignancies. OBJECTIVES: COVID-19 patients affected by haematological malignancies have a more severe course of the disease and higher mortality, prompting for effective prophylaxis. The present study aims to evaluate the humoral response after mRNA vaccination as well as the impact of a third vaccine dose in patients with lymphoid malignancies. METHODS: We conducted a single-centre study, evaluating the serological responses of mRNA vaccination amongst a cohort of 200 patients affected by lymphoid malignancies after two or three doses using an industrial SARS-CoV-2 serology assay for anti-receptor binding domain (RBD) Spike IgG detection and quantification. RESULTS: Among patients with plasma cell disorders, 59 of 96 (61%) had seroconversion (anti-RBD >50 AU/mL), and recent anti-CD38 therapies were associated with lower serological anti-RBD IgG concentrations (median IgG concentration 137 (IQR 0-512) AU/mL vs. 543 (IQR 35-3496) AU/mL; pÂ <Â 0.001). Patients with B-cell malignancies had a lower seroconversion rate (20/84, 24%) mainly due to the broad usage of anti-CD20 monoclonal antibodies; only 2 of 53 (4%) patients treated by anti-CD20 antibodies during the last 12Â months experienced a seroconversion. A total of 78 patients (44 with plasma cell disorders, 27 with B-cell malignancies, and 7 with other lymphomas) received a third dose of vaccine. The seroconversion rate and antibody concentrations increased significantly, especially in patients with plasma cell disorders, where an increment of anti-RBD IgG concentrations was observed in 31 of 44 (70%) patients, with an anti-RBD concentration median-fold increase of 10.6 (IQR 2.4-25.5). Its benefit in B-cell malignancies is uncertain, with only 2 of 25 (8%) patients having seroconverted after the vaccine booster, without increased median antibody concentration. DISCUSSION: A third mRNA vaccine dose significantly improved humoral responses among patients with plasma cell disorders, whereas the effect was limited among patients with B-cell malignancies.

SARS-CoV-2 vaccination and immune thrombotic thrombocytopenic purpura.

COVID-19 Vaccination in Hemodialysis Patients Correspondence.

Cardiac Complications Associated with COVID-19, MIS-C, and mRNA COVID-19 Vaccination. The COVID-19 vaccine is now approved for individuals greater than 5Â years of age, but vaccination rates remain lower than expected in the pediatric age group. Misinformation and widespread reporting of vaccine-related myocarditis are contributing to vaccine hesitancy. When compared to severe cardiac complications that are associated with COVID-19, vaccine-related myocarditis has a milder presentation, is easily treated, and has a good prognosis. Acute COVID-19 has been associated with higher rates of myocarditis and myocardial injury. Multisystem inflammatory syndrome in children occurs weeks after initial infection with SARS-CoV-2 and can be associated with severe cardiovascular complications and death. Cardiac complications associated with acute COVID-19 and MIS-C are more severe and occur more frequently than myocarditis after mRNA COVID-19 vaccination. Furthermore, some of the academic and social disruptions caused by the pandemic expect to be eased by widespread vaccination. For all these reasons, COVID-19 vaccination is strongly recommended for all eligible age groups.

Characterization of immune responses in fully vaccinated individuals after breakthrough infection with the SARS-CoV-2 delta variant. Breakthrough infections with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants have been reported frequently in vaccinated individuals with waning immunity. In particular, a cluster of over 1000 infections with the SARS-CoV-2 delta variant was identified in a predominantly fully vaccinated population in Provincetown, Massachusetts in July 2021. In this study, vaccinated individuals who tested positive for SARS-CoV-2

(n = 16) demonstrated substantially higher serum antibody responses than vaccinated individuals who tested negative for SARS-CoV-2 (n = 23), including 32-fold higher binding antibody titers and 31-fold higher neutralizing antibody titers against the SARS-CoV-2 delta variant. Vaccinated individuals who tested positive also showed higher mucosal antibody responses in nasal secretions and higher spike protein-specific CD8(+) T cell responses in peripheral blood than did vaccinated individuals who tested negative. These data demonstrate that fully vaccinated individuals developed robust anamnestic antibody and T cell responses after infection with the SARS-CoV-2 delta variant. Moreover, these findings suggest that population immunity will likely increase over time by a combination of widespread vaccination and breakthrough infections.
Vocal cord dysfunction/inducible laryngeal obstruction(s) mimicking anaphylaxis during SARS-CoV-2 (COVID-19) vaccination.
Graded coronavirus disease 2019 vaccine administration: A safe alternative to vaccine avoidance.
Clinical Features of Patients Presenting to the Emergency Department With Cardiovascular Adverse Reactions After COVID-19 mRNA Vaccination. BACKGROUND: Since the implementation of the nationwide coronavirus disease 2019 (COVID-19) vaccination campaign, emergency departments (EDs) have had an increasing number of patients reporting postvaccination cardiovascular adverse effects. We investigated the clinical features of patients who visited the ED for cardiovascular adverse reactions after COVID-19 mRNA vaccination. METHODS: We conducted a retrospective observational study in two EDs. Patients with cardiovascular adverse reactions after COVID-19 mRNA vaccination who visited EDs between June 1, 2021, and October 15, 2021, were selected. The clinical data of these patients were collected by reviewing medical records. RESULTS: Among 683 patients, 426 (62.4%) were female. The number of patients in their 20s was the highest (38.9% of males, 28.2% of females) ($P < 0.001$). More patients visited the ED for adverse reactions following the first vaccine dose than following the second dose (67.6% vs. 32.2%). Chief complaints were chest pain/discomfort (74.4%), dyspnea (14.3%) and palpitation (11.3%). The final diagnosis was a nonspecific cause (63.1%), and 663 (97.1%) patients were discharged from the ED. The admission rate was higher in males than in females (3.9% vs. 1.9%). Myocarditis was diagnosed in four males, who showed mild clinical progression and were discharged within 5 hospital days. CONCLUSION: Most patients who visited the ED with cardiovascular adverse reactions were discharged from the ED, but some were admitted for other medical diseases as well as adverse vaccine reactions. Therefore, further surveillance and a differential diagnosis of cardiovascular adverse events after COVID-19 mRNA vaccination should be considered by emergency physicians.
Correspondence on "Diabetic ketoacidosis shortly after COVID-19 vaccination in a non-small-cell lung cancer patient".
Stroke after COVID-19 vaccination.
Myocarditis following COVID-19 mRNA vaccination. Messenger RNA vaccines are the main COVID-19 vaccines authorized for use in the United States. Side effects are typically minor and transient. We report a case series of four subjects with an acute myocarditis-like illness following mRNA COVID-19 vaccination who were hospitalized at our hospital in Lubbock, Texas. Three patients were young men who presented with acute chest pain after the second dose of the mRNA-1273 vaccine. Another patient was a 53-year-old white woman who presented with acute left arm pain 3 days after the first dose of the mRNA-1273 vaccine. She was later found to have acute decompensated heart failure, and endomyocardial biopsy revealed eosinophilic injury-mediated myocarditis.
Acute exacerbation of psoriasis after COVID-19 Pfizer vaccination. The novel coronavirus (COVID-19) pandemic has caused many deaths worldwide. Managing and diagnosing dermatological conditions has become difficult during this era, especially with the widespread administration of

vaccines. We report a 58-year-old man with a history of psoriasis and multiple comorbidities who presented with a worsening pruritic rash 1 week after receiving the COVID-19 Pfizer vaccine. He was treated with triamcinolone-based wet wraps, triamcinolone ointment, and hydroxyzine, which improved his rash significantly after 6 days of hospitalization.
Acute-onset dacryoadenitis following immunisation with mRNA COVID-19 vaccine. A 14-year-old boy was referred to the ophthalmology department with a 4-day history of rapid-onset right upper lid pain, swelling and erythema starting 9â€‰hours after his first dose of COVID-19 mRNA vaccination (BNT162b2/Comirnaty, Pfizer-BioNTech). On examination, he had significant right upper lid ptosis, oedema and erythema, with associated limitation of right eye abduction and elevation. He was found to have acute dacryoadenitis with orbital inflammatory disease on clinical and laboratory investigations. He was given tapering oral prednisone and had full resolution of symptoms within 2â€‰weeks. This is the first known case of orbital inflammation after COVID-19 mRNA vaccination. Given the temporal association between the patient's vaccination and symptom onset, we believe it is likely that immunisation prompted the onset of disease.
Systemic capillary leak syndrome after SARS-CoV-2 infection and after COVID-19 vaccination: A scoping review in relation to a clinical case.
Safety of mRNA-based vaccines against SARS-CoV-2 in people with cystic fibrosis aged 12 years and over.
Reassuring transfer outcomes after COVID-19 vaccination.
Lichen planus and vitiligo occurring after ChAdOx1 nCoV-19 vaccination against SARS-CoV-2.
Rituximab-treated patients with lymphoma develop strong CD8 T-cell responses following COVID-19 vaccination. B-cell depletion induced by anti-cluster of differentiation 20 (CD20) monoclonal antibody (mAb) therapy of patients with lymphoma is expected to impair humoral responses to severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccination, but effects on CD8 T-cell responses are unknown. Here, we investigated humoral and CD8 T-cell responses following two vaccinations in patients with lymphoma undergoing anti-CD20-mAb therapy as single agent or in combination with chemotherapy or other anti-neoplastic agents during the last 9Â months prior to inclusion, and in healthy age-matched blood donors. Antibody measurements showed that seven of 110 patients had antibodies to the receptor-binding domain of the SARS-CoV-2 Spike protein 3-6Â weeks after the second dose of vaccination. Peripheral blood CD8 T-cell responses against prevalent human leucocyte antigen (HLA) class I SARS-CoV-2 epitopes were determined by peptide-HLA multimer analysis. Strong CD8 T-cell responses were observed in samples from 20/29 patients (69%) and 12/16 (75%) controls, with similar median response magnitudes in the groups and some of the strongest responses observed in patients. We conclude that despite the absence of humoral immune responses in fully SARS-CoV-2-vaccinated, anti-CD20-treated patients with lymphoma, their CD8 T-cell responses reach similar frequencies and magnitudes as for controls. Patients with lymphoma on B-cell depleting therapies are thus likely to benefit from current coronavirus disease 2019 (COVID-19) vaccines, and development of vaccines aimed at eliciting T-cell responses to non-Spike epitopes might provide improved protection.
Acute interstitial nephritis after vaccination with BNT162b2.
Hypersensitivity Reactions to COVID-19 Vaccines-Identify High-risk Children and Vaccinate the Rest.
Coronavirus disease 2019 and vaccination in patients with Shwachman-Diamond syndrome. Because they can experience neutropenia due to bone marrow failure, patients with Shwachman-Diamond syndrome (SDS) carry increased risk for serious infections compared with the general population; however, there has been a paucity of data on the incidence and severity of coronavirus disease 2019 (COVID-19) in patients with SDS. We compiled results from a survey distributed to participants in the SDS Registry in May-June 2021. In this report, we describe the characteristics and

outcomes of patients with SDS who had COVID-19. Patients reported a short clinical course without significant complications or cytopenias. Additionally, COVID-19 vaccines were well tolerated with minor side effects.
Acute disseminated encephalomyelitis following vaccination against SARS-CoV-2: A case report. Acute disseminated encephalomyelitis (ADEM) is an inflammatory emyelinating disease of the central nervous system that is usually considered a monophasic disease Post-vaccination ADEM has been associated with several vaccines, however, there is scarce information related to SARS-CoV-2 vaccines. We present the case of a 26- year-old female who suffered from ADEM four weeks after Gam-COVID-Vac administration.
COVID-19 vaccine-associated dermatomyositis.
Presumed oculomotor nerve palsy following COVID-19 vaccination. We herein report the case of an 84-year-old female who presented to the outpatient clinic one day following her first dose of the Pfizer-BioNTech COVID-19 vaccine with mydriasis, ptosis, and a "down and out" gaze. She was subsequently diagnosed with oculomotor nerve palsy, and treated with corticosteroids and valacyclovir for a total of 7 days, with no clear improvement. On subsequent visits, ophthalmic examination improved steadily and showed complete resolution after 8 weeks. This article aims to report this unusual incidence that occurred following vaccination with the Pfizer-BioNTech COVID-19 vaccine. It is important for physicians to identify and report abnormal occurrences which may potentially be related to the COVID-19 vaccines, in order to reach a complete understanding of their possible side effects.
Bullous pemphigoid after second dose of mRNA- (Pfizer-BioNTech) Covid-19 vaccine: A case report. INTRODUCTION AND IMPORTANCE: Messenger RNA vaccines, commonly known as mRNA vaccines, are the first COVID-19 vaccines that have been authorized and licensed in the United States. Two mRNA vaccines, BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) are available. Mass vaccination remains the most critical way to halt the spread of the COVID pandemic. The most common adverse effects of the COVID vaccines are headache, muscular soreness, weariness, redness, swelling, and tenderness at the injection site. The dermatological adverse effects of mRNA vaccines, on the other hand, are little understood. We present a case of bullous fixed medication eruption following delivery of the second dose of Pfizer's Covid-19 vaccination. CASE PRESENTATION: We discuss the case of a 78-year-old man who went to the Emergency Department at King Fahad Medical City in Riyadh, Saudi Arabia, with numerous bullae throughout his extremities one day after receiving the second dosage of Pfizer Covid-19 vaccine. The bullae began three days before his presentation, and they were preceded by intense pruritus and urticated plaques. A skin biopsy was performed which revealed IgG (+1), IgM (+1), and C3 (+1) staining of the basement membrane. Another punch skin biopsy taken from an intact bulla was suboptimal compressing of dermal tissue only, revealing modest perivascular lymphocytic infiltrative and scattered eosinophils. This pathological picture with superficial perivascular inflammatory dermatitis, and the presence of eosinophils suggests drug-induced bullous pemphigoid. The patient was treated with topical and systemic corticosteroids, fusidic acid cream, and emollients after a confirmed diagnosis of bullous pemphigoid was obtained. He was hospitalized for 3 weeks as a case of severe sepsis due to a skin infection, and he was started initially on empiric antibiotics with piperacillin-tazobactam plus vancomycin that was later upgraded to meropenem and vancomycin based on the results of the blood and wound cultures. The patient suffered a pulmonary embolism on the second day of hospitalization and was placed on a heparin infusion that could potentially contribute to his death one month after discharge from our hospital. CLINICAL DISCUSSION: Bullous pemphigoid is the most frequent autoimmune bullous disease. It occurs in the elderly. The cause of this disease is unknown, although it sometimes can be triggered by taking certain medications. Two case reports have also revealed bullous pemphigoid eruption

following immunization. One case report reported a 78-year-old lady with diabetes and Alzheimer's disease who developed tense bullae on her face and torso after getting the second dosage of the Pfizer-BioNTech COVID-19 Vaccine. Another case study described a 77-year-old male patient who developed generalized pruritis and bullae on erythematous bases one day after receiving the AstraZeneca COVID-19 vaccination. This new-onset bullous pemphigoid phenomenon has also been observed with other vaccinations such as rabies and swine flu. CONCLUSION: Although uncommon, several dermatological side reactions like bullous eruptions have been reported following the mRNA Pfizer Covid-19 vaccination. According to this case report, Bullous pemphigoid might be caused by the mRNA- (Pfizer) Covid-19 Vaccine.

Increased Interleukin 18-Dependent Immune Responses Are Associated With Myopericarditis After COVID-19 mRNA Vaccination. Myocarditis and myopericarditis may occur after COVID-19 vaccination with an incidence of two to twenty cases per 100,000 individuals, but underlying mechanisms related to disease onset and progression remain unclear. Here, we report a case of myopericarditis following the first dose of the mRNA-1273 COVID-19 vaccine in a young man who had a history of mild COVID-19 three months before vaccination. The patient presented with chest pain, elevated troponin I level, and electrocardiogram abnormality. His endomyocardial biopsy revealed diffuse CD68(+) cell infiltration. We characterized the immune profile of the patient using multiplex cytokine assay and flow cytometry analysis. Sex-matched vaccinated individuals and healthy individuals were used as controls. IL-18 and IL-27, Th1-type cytokines, were highly increased in the patient with COVID-19 vaccine-related myopericarditis compared with vaccinated controls who experienced no cardiac complications. In the patient, circulating NK cells and T cells showed an activated phenotype and mRNA profile, and monocytes expressed increased levels of IL-18 and its upstream NLRP3 inflammasome. We found that recombinant IL-18 administration into mice caused mild cardiac dysfunction and activation of NK cells and T cells in the hearts, similar to the findings in the patient with myopericarditis after COVID-19 mRNA vaccination. Collectively, myopericarditis following COVID-19 mRNA vaccination may be associated with increased IL-18-mediated immune responses and cardiotoxicity.

Absolving COVID-19 Vaccination of Autoimmune Bullous Disease Onset.

High-dose Mycophenolate Use at Vaccination Is Independently Associated With Breakthrough COVID-19 Among Lung Transplant Patients.

Acute Myocarditis in a Patient Following mRNA-1273 SARS-CoV-2 Vaccination. We herein report a case of acute myocarditis possibly related to the second dose of an mRNA-coronavirus disease 2019 vaccine in a 45-year-old woman with no remarkable medical history. She had a fever for one week following the second dose of the mRNA-1273 severe acute respiratory syndrome coronavirus 2 vaccine. One week later, she presented with chest pain and electrocardiogram changes. Her serum troponin levels were elevated upon admission. Echocardiography showed segmental wall motion abnormalities of the apex, apical portion of the anterior and inferior walls. The findings of cardiac magnetic resonance imaging were consistent with acute myocarditis.

An idiotypic network dysregulation could be related to the pathogenesis of vaccine-induced immune thrombotic thrombocytopenia (VITT) following vaccination with vaccines expressing Spike protein of SARS CoV2.

Two flares of Still's disease after two doses of the ChAdOx1 vaccine. We report the case of an 18-year-old male with Still's disease for the last 3Â years, in remission, who developed two flares of his disease after receiving two doses of the ChAdOX1 nCoV-19 vaccine. While the first flare was mild requiring steroid initiation and resolved rapidly, the second flare after the second dose was much severe, requiring pulse steroid and tocilizumab. We also review three reported cases of flares of Still's disease after COVID-19 vaccination. The temporal association of the flares with both vaccine doses

strengthens the association between the vaccine administration and the flare. The proposed mechanism may be due to activation of the innate immune system by the vaccine adjuvants. This review serves to inform the medical community regarding a possible role of the vaccine in producing a systemic inflammatory response. Early detection and treatment can help reduce morbidity in these cases.

Third dose of SARS-CoV-2 vaccination in hemato-oncological patients and health care workers: immune responses and adverse events - a retrospective cohort study. BACKGROUND: Due to potentially immune-escaping virus variants and waning immunity, a third SARS-CoV-2 vaccination dose is increasingly recommended. However, data in patients with cancer are limited. PATIENTS AND METHODS: We measured anti-SARS-CoV-2 spike protein antibody levels after the third vaccination dose in 439 patients with cancer and 41 health care workers (HCW) at an academic centre in Austria and a rural community hospital in Italy. Adverse events were retrieved from questionnaires. RESULTS: Overall, 439 patients and 41 HCW were included. SARS-CoV-2 infections were observed in 62/439 (14.1%) patients before vaccination and in 5/439 (1.1%) patients after â‰¥1 dose. Longitudinal analysis revealed a decrease of antibody levels between 3 and 6 months after second vaccination in patients with solid tumours (pÂ <Â 0.001) and haematological malignancies without anti-B cell therapies (pÂ <Â 0.001). After the third dose, anti-S levels increased compared to the first/second dose. Patients receiving B cell-targeted agents had lower antibody levels than patients with haematological malignancies undergoing other treatments (pÂ <Â 0.001) or patients with solid tumours (pÂ <Â 0.001). Moreover, anti-S levels correlated with CD19+ (B cell) and CD56+ (NK cell) counts in peripheral blood. The most frequent adverse events after the third dose were local pain (75/160, 46.9%), fatigue (25/160, 15.6%)Â and fever/chills (16/160, 10.0%). Patients with cancer had lower anti-S levels than HCW (pÂ =Â 0.015). CONCLUSIONS: This study in patients with cancer shows improved antibody levels after the third vaccination dose at an acceptable side-effect profile. Lower antibody levels than in controls underline the need for further follow-up studies and dedicated trials.

Adverse effect investigation using application software after vaccination against SARS-CoV-2 for healthcare workers. INTRODUCTION: The usefulness of smartphone-based application software as a way to manage adverse events (AEs) after vaccination is well known. The purpose of this study is to clarify the usefulness and precautions of employing a smartphone application for collecting AEs after the administration of ComirnatyÂ®ï¸•. METHODS: Healthcare workers (HCWs) who were vaccinated with ComirnatyÂ®ï¸• were asked to register for the application software and to report AEs for 14 days after vaccination. AEs were self-reported according to severity. The software was set to output an alert in case of fever. RESULTS: The number of HCWs who received the first dose was 2,551, and 2,406 (94.3%) reported their vaccinations. 2,547 received the second dose, and 2,347 (92.1%) reported their vaccinations. With the first dose, the reporting rate stayed above 83.3% until the final day. On the other hand, that of the second dose decreased rapidly after 6 days. The most frequent symptom was "pain at injection site" (more than 70%). Severe AEs were 6.6% after the second dose, with 0.6% visiting a clinic. Many AEs peaked on the day after administration and disappeared within 1 week. There were few reports of fever. CONCLUSION: Smartphone applications can be used to collect information on AEs after vaccination. Application settings and dissemination are necessary to maintain the reporting rate of HCWs.

A one year follow of patients with multiple sclerosis during COVID-19 pandemic: A cross-sectional study in Qom province, Iran. BACKGROUND: In the current COVID-19 pandemic, Multiple Sclerosis (MS) patients represent a population of particular interest as they might be at higher risk of COVID-19 infection and it's complications. The present study aimed to investigate a one year follow up of patients with MS during the COVID-19 pandemic, in Qom province, Iran. METHODS: This study was performed at the MS Clinic of Beheshti Hospital from June 1, 2020 to November 1, 2021. 202

patients with a diagnosis of MS and negative self-reported history of COVID-19 at the beginning of the pandemic, were enrolled. First, the demographic characteristics of patients were collected. Second, the patients underwent serological testing for anti-SARS-CoV-2 IgG antibodies. Then, a year later, they were revalauted and asked about the occurrence of clinical relapse leading to hospitalization, disease progression, DMT profile, COVID-19 vaccination, and history of COVID-19 infection. We considered six weeks after COVID-19 regarding relapse occurrence. Eventually, statistical analysis was carried out by using SPSS 26.0 RESULTS: Of 202 patients, 26 patients (12.87%) had initially a positive index antibody result. During the follow-up periods, 25 patients (12.37%) were infected with COVID-19 which was mainly mild (74.8%), and significantly lower than general population. 118 patients (58.41%) were vaccinated for COVID-19 which reduced the risk of COVID-19 development (P<001). Except a case of myelitis associated with vaccination, no serious adverse event was reported. Additionally, only one patient developed MS relapse following COVID-19 infection. Except clinical relapse (PÂ =Â 0.001), other demographic and MS characteristics, and DMT type were not associated with COVID-19. In terms of MS course, 12 patients (5.94%) discontinued their DMTs regardless of the DMT adverse events or treatment failure. 41 patients (20.3%) experienced a clinical relapse, of whom 12 were escalated to a second line DMT. Further, 27 patients (13.4%) noted a history of worsening disability which mainly occurred after COIVD-19 infection. CONCLUSION: The present study showed a significant lower incidence of COVID-19 infection in MS patients. Except for clinical relapse, other demographic and MS characteristics, and DMT type were not associated with COVID-19 infection. In addition, COVID-19 vaccination reduced the risk of COVID-19 development, and the prognosis was favorable in the majority of MS patients.

Diffuse cutaneous systemic sclerosis following SARS-Co V-2 vaccination. The largest world-wide vaccination rollout ever is currently underway to tackle the covid-19 pandemic. We report a case of diffuse cutaneous systemic sclerosis (SSc) in a 70-year-old male with rapidly progressive skin thickening which developed two weeks after receiving the first dose of the ChAdOx1 nCOV-19 vaccine. As the onset of SSc skin was in close temporal proximity to the administration of the first dose vaccine with no other triggers, we suspected a possible adverse reaction to the ChAdOx1 nCOV-19 vaccine. We hypothesise that the recombinant adenoviral vector encoding the spike protein antigen of SARS-CoV-2 triggered an unexpected immune activation resulting in an atypical presentation of late-onset SSc, within the well-recognised ANA positive, ENA negative subgroup of patients.We review the possible mechanisms underlying autoimmunity when provoked by vaccination and other published rheumatological phenomenon occurring shortly after COVID vaccination.

Neutralizing antibody responses 300 days after SARS-CoV-2 infection and induction of high antibody titers after vaccination. Neutralizing antibodies against SARS-CoV-2 are important to protect against infection and/or disease. Using an assay to detect antibodies directed against the receptor binding domain (RBD) of SARS-CoV-2 Spike, we identified individuals with SARS-CoV-2 infection after an outbreak at a local health institution. All but one COVID-19 patient developed detectable anti-RBD antibodies and 77% had virus neutralizing antibody titers of >1:25. Antibody levels declined slightly over time. However, we still detected virus neutralizing antibody titers in 64% of the COVID-19 patients at >300 days after infection, demonstrating durability of neutralizing antibody levels after infection. Importantly, full COVID-19 vaccination of these individuals resulted in higher antibody titers compared to fully vaccinated individuals in the absence of prior infection. These data demonstrate long-lived antibody-mediated immunity after SARS-CoV-2 infection, and a clear benefit of two vaccine doses for recovered individuals.

Clinical outcomes of breakthrough COVID-19 after booster vaccination in patients with systemic rheumatic diseases.

Nephrotic syndrome with minimal change disease after the Pfizer-BioNTech COVID-19 vaccine: two cases. We present two cases of nephrotic syndrome with minimal change disease after the Pfizer-BioNTech COVID-19 vaccine. We discuss the initial presentation, investigation and management of these patients along with a discussion around the current evidence base for vaccine-induced nephrotic syndrome.

Mild disease course of SARS-CoV-2 infections and mild side effects of vaccination in Pompe disease: a cohort description. INTRODUCTION: Patients with Glycogen Storage Disease type II (GSDII), an inheritable metabolic myopathy also known as Pompe disease, are considered to be at risk for severe COVID-19 due to a reduced respiratory function and a tendency to be overweight. However, so far little is known about the course of SARS-CoV-2 infection and side effects of COVID-19 vaccinations in patients with GSDII. METHODS: 169 Dutch Pompe patients are followed at the Erasmus MC Rotterdam. During the COVID-19 pandemic patients were requested to directly inform their physicians about SARS-CoV-2 infection. Infected patients were interviewed regularly by telephone until their symptoms subsided. Furthermore, all patients eligible for vaccination on 16-7-2021 (â‰¥â€‰17Â years, nâ€‰=â€‰122) were asked to complete a questionnaire. RESULTS: To date, fifteen patients (8.9% of our cohort) reported a SARS-CoV-2 infection (classic infantile Pompe disease nâ€‰=â€‰5, late onset nâ€‰=â€‰10). No patients were admitted to hospital or needed intensivation of ventilatory support. All patients made a recovery within 19Â days. 41.8% of patients filled in our questionnaire regarding vaccination, of whom 98% were vaccinated. Besides one case of perimyocarditis, only mild side effects were reported. CONCLUSION: Overall, patients with Pompe disease showed mild symptoms from infection with SARS-CoV-2. All patients made a full recovery. Side effects after vaccination were mostly mild.

Vaccine-induced thrombotic thrombocytopenia (VITT): first report from India. BACKGROUND: Vaccine-induced thrombotic thrombocytopenia (VITT) is a rare but devastating adverse event following adenoviral vector-based vaccinations for COVID-19, resulting in thrombosis, especially of the cerebral and splanchnic vasculature. Despite the progress in laboratory techniques for early diagnosis, VITT remains a clinical diagnosis supplemented by coagulation studies. We report on VITT for the first time from India. CASE: We describe cortical venous sinus thrombosis and intracerebral bleed associated with severe thrombocytopenia in two young men who had no other contributory cause besides a recent ChAdOx1 nCoV-19 vaccination. The diagnosis was supported with PF-4 antibodies in one patient. The second patient's test could not be processed to technical limitations. Both patients were treated with IVIG at 1â€‰g/kg for 2 days and anticoagulation (Apixaban). One patient fully recovered with no residual deficits, and the other is under treatment and recovering. CONCLUSION: VITT can cause devastating fatality and morbidity in otherwise healthy patients via potential immune-mediated effects. Clinicians should have a high suspicion index and treat VITT in the appropriate setting even if the PF-4 antibody testing by ELISA is unavailable or delayed. Though counterintuitive, clinicians must not delay the administration of non-heparin anticoagulation, IVIG and restrict platelet transfusion even in the presence of intracerebral haemorrhage.

The Immediate Effect of COVID-19 Vaccination on Anticoagulation Control in Patients Using Vitamin K Antagonists. BACKGROUND: â€ƒIn January 2021, the Dutch vaccination program against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was started. Clinical studies have shown that systemic reactions occur in up to 50% of vaccine recipients. Therefore, COVID-19 vaccination could affect anticoagulation control, potentially leading to an increased risk of thrombotic events and bleeding complications. AIMS: â€ƒThis article investigates whether the BNT162b2 vaccine affects anticoagulation control in outpatients using vitamin K antagonists (VKAs). METHODS: â€ƒA case-crossover study was performed in a cohort of outpatient VKA users from four Dutch anticoagulation clinics who received a BNT162b2 vaccine. International normalized ratio (INR) results and VKA

dosages before the first vaccination, the reference period, were compared with those after the first and second vaccination. RESULTS: â€ƒA total of 3,148 outpatient VKA users were included, with a mean age (standard deviation) of 86.7 (8.7) years, of whom 43.8% were male, 67.0% used acenocoumarol, and 33.0% phenprocoumon. We observed a decrease of 8.9% of INRs within range in the standard intensity group (target INR 2.0-3.0). There was both an increased risk of supratherapeutic (odds ratio [OR]â€‰=â€‰1.34 [95% confidence interval [CI] 1.08-1.67]) and subtherapeutic levels (ORâ€‰=â€‰1.40 [95% CI 1.08-1.83]) after first vaccination. In the high-intensity group (target INR 2.5-3.5), the risk of a supratherapeutic INR was 2.3 times higher after first vaccination (ORâ€‰=â€‰2.29 [95% CI 1.22-4.28]) and 3.3 times higher after second vaccination (ORâ€‰=â€‰3.25 [95% CI 1.06-9.97]). CONCLUSION: â€ƒBNT162b2 was associated with an immediate negative effect on anticoagulation control in patients treated with VKAs, so it is advisable to monitor the INR shortly after vaccination, even in stable patients.

Survival and risk of COVID-19 after SARS-COV-2 vaccination in a series of 2391 cancer patients. BACKGROUND: Patients with cancer are at high risk of severe or lethal COVID-19. The impact of SARS-COV-2 vaccination on the risk of developing COVID-19 was investigated in an exhaustive series of patients from a comprehensive cancer center. METHODS: This is a study of the exhaustive population of 2391 cancer patients who were prescribed SARS-COV-2 vaccination until 09/21. Patient characteristics, documented SARS-COV-2 infection with RT-PCR, and survival were collected. The primary endpoint was the rate of COVID-19 after vaccination. Secondary endpoints included risk factors to develop COVID-19 after vaccination, with a comparison with the cohort of vaccinated health care workers (HCW), and risk factors for death. RESULTS: From January to September 2021, among 2391 patients with cancer under active treatment in whom a SARS-COV-2 vaccine was prescribed, 659 (28%), 1498 (63%) and 139 (6%) received 1, 2, and 3 doses, respectively. Ninety five patients received a single dose of vaccine after a previous COVID-19. Two thousand two hundred eighty five health care workers (HCW) received one (NÂ =Â 17, 0.7%), 2-3 (NÂ =Â 2026, 88.7%) vaccine doses and one dose after COVID-19 (NÂ =Â 242, 10.6%). With a median follow-up of 142 and 199 days for patients and HCW, respectively. Thirty nine (1.6%) patients and 35 (1.5%) HCW developed COVID-19 after vaccination. Six of 39 cancer patients and no HCW died because ofCOVID-19 within 50 days after diagnosis. Independent risk factors for COVID-19 in vaccinated patients were age, single dose of vaccine without previous COVID-19 and anti-CD20 treatment in the last three months. Independent risk factors for death included metastatic disease, gender, cancer type, but also documented COVID-19 before vaccination. CONCLUSIONS: Patients receiving two or more doses of COVID-19 vaccine have reduced risk of COVID-19. The risk of death of vaccinated cancer patients presenting COVID-19 remains high. COVID-19 before vaccination is associated with an increased overall risk of death.

Rapid decline of humoral response to two doses of BNT162b2 vaccine in patients with solid cancer after six months: The urgent need of the additional dose! INTRODUCTION: We previously reported on the immunogenicity and safety of BNT162b2 in a large cohort of patients with cancer after the first and second doses (Di Noia etÂ al., 2021) [1]. Herein, we present result after six months of follow-up. METHODS: This prospective study included patients affected by solid tumors and afferent to our institution who received two doses of BNT162b2 vaccine. A cohort of vaccinated healthcare workers (HCW) was used as control-group. Both cohorts were evaluated for the titer of anti-Spike (S) IgG at prefixed time-points (TPs). Time-point 4 was scheduled at 24-26 weeks after the second dose. RESULTS: In the current analysis, 400 patients and 232 healthcare workers were evaluated. Responders (IgG > 15 AU/mL) in patients group were 86.5% compared with 94.4% among healthcare workers. Also the IgG titer at TP4 was significantly inferior in patients than in healthcare workers (70.81 vs 134.64 AU/ml, pÂ <Â 0.001). There was a more rapid decline of the antibody level

from TP3 to TP4 in patients than in healthcare workers (1.78 vs 1.3 fold). The estimated IgG half-life was significantly shorter for patients (73 days) than in healthcare workers (118 days) as well as the time to reach negative serological status (340 vs 532 days). CONCLUSION: The decline of humoral response to the vaccine observed in patients with solid cancer after six months from the first dose support the urgent need of an early additional dose.

Shoulder Injury Related to Vaccine Administration and a Growing Challenge: A Focused Review. Shoulder injury related to vaccine administration (SIRVA), an entity that causes acute shoulder pain and may limit range of motion (ROM) after vaccination, is a condition where a small but significant percentage of patients are experiencing in light of the current push for mass immunizations against SARS-CoV-2 worldwide. A search of literature related to SIRVA was performed across multiple electronic databases. Women, patients reporting vaccine injection location to be too high, and patients without prior history of shoulder pain were the most common historical factors in those experiencing SIRVA. Tenderness to palpation and limited shoulder ROM were the most associated physical examination findings. When using magnetic resonance imaging, tendinopathy, subacromial-subdeltoid bursitis, and rotator cuff tears (partial or complete) were the most common findings. Radiographic imaging rarely aided the diagnosis. SIRVA is an entity that health care providers should be aware of to improve the care of patients that may experience these symptoms after vaccine administration.

Three cases of drug-induced hypersensitivity syndrome associated with mRNA-based coronavirus disease 2019 vaccines. Drug-induced hypersensitivity syndrome (DiHS) is a severe drug eruption that can induce reactivation of herpesviruses such as human herpesvirus 6, resulting in symptom flare-up and organ damage. DiHS is known as drug reaction with eosinophilia and systemic symptoms (DRESS) in Europe. We report three cases of DiHS that could have been triggered by mRNA-based coronavirus disease 2019 (COVID-19) vaccines. In these three patients, symptoms of DiHS developed 2-6Â days after the first dose of an mRNA-based COVID-19 vaccine. Although there have been no reports of DiHS/DRESS induced by mRNA-based COVID-19 vaccines in domestic and international journals despite the progress in vaccination worldwide, we speculate that mRNA-based COVID-19 vaccines might have triggered the development of DiHS/DRESS in our patients. In the current coronavirus epidemic, it might be important to assess mRNA-based COVID-19 vaccination status and date of vaccination when evaluating a patient with DiHS/DRESS.

Immune response to SARS-CoV-2 after a booster of mRNA-1273: an open-label phase 2 trial. Rising breakthrough infections of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in previously immunized individuals have raised concerns for the need for a booster vaccine dose to combat waning antibody levels and new variants. Here we report the results of the open-label, non-randomized part B of a phase 2 trial in which we evaluated the safety and immunogenicity of a booster injection of 50â€‰Âµg of the coronavirus disease 2019 (COVID-19) vaccine mRNA-1273 in 344 adult participants immunized 6-8 months earlier with a primary series of two doses of 50â€‰Âµg or 100â€‰Âµg of mRNA-1273 (NCT04405076). Neutralizing antibody (nAb) titers against wild-type SARS-CoV-2 at 1 month after the booster were 1.7-fold (95% confidence interval (CI): 1.5, 1.9) higher than those at 28 days after the second injection of the primary series, which met the pre-specified non-inferiority criterion (primary immunogenicity objective) and might indicate a memory B cell response. The nAb titers against the Delta variant (B.1.617.2) (exploratory objective) at 1 month after the booster were 2.1-fold (95% CI: 1.8, 2.4) higher than those at 28 days after the second injection of the primary series. The seroresponse rate (95% CI (four-fold rise from baseline)) was 100% (98.7, 100.0) at 28 days after the booster compared to 98.3% (96.0, 99.4) after the primary series. The higher antibody titers at 28 days after the booster dose compared to 28 days after the second dose in the phase 3 COVE study were also observed in two assays for anti-spike IgG antibody

measured by ELISA and by Meso Scale Discovery (MSD) Multiplex. The frequency of solicited local and systemic adverse reactions after the booster dose was similar to that after the second dose in the primary two-dose series of mRNA-1273 (50â€‰Âµg or 100â€‰Âµg); no new signals were observed in the unsolicited adverse events; and no serious adverse events were reported in the 1-month follow-up period. These results show that a booster injection of mRNA-1273 more than 6 months after completing the primary two-dose series is safe and elicited nAb titers that were statistically significantly higher than the peak titers detected after the primary vaccination series, suggesting that a booster dose of mRNA-1273 might result in increased vaccine effectiveness against infection and disease caused by SARS-CoV-2.

Axillary Lymph Node Swelling Mimicking Breast Cancer Metastasis After COVID-19 Vaccination: A Japanese Case Report and Literature Review. BACKGROUND/AIM: COVID-19 started to spread as a pandemic in December 2019 and COVID-19 vaccination has been initiated worldwide. The efficacy of vaccination has been scientifically proven, but it might cause axillary lymph node swelling. To diagnose patients with axillary lymph node swelling caused by COVID-19 vaccination, we herein reviewed existing literature on this symptom. CASE REPORT: We report the case of a 70-year-old woman with a breast tumour. She had undergone cecum cancer surgery and regular computed tomography (CT). During breast tumour follow-up, she received scheduled CT that indicated severe axillary lymph node swelling mimicking breast cancer metastasis. We performed aspiration biopsy cytology of that lymph node, and determined this was not cancer metastasis but an effect of the COVID-19 vaccine. We confirmed this diagnosis at one month after computed tomography showed that the lymph node swelling had improved. CONCLUSION: Axillary lymph node swelling can occur after COVID-19 vaccination. Therefore, it is important to consider the effect of the COVID-19 vaccination on axillary lymph node swelling when diagnosing breast tumours.

Spontaneous tumor regression following COVID-19 vaccination. Vaccination against COVID-19 is critical for immuno-compromised individuals, including patients with cancer. Systemic reactogenicity, a manifestation of the innate immune response to vaccines, occurs in up to 69% of patients following vaccination with RNA-based COVID-19 vaccines. Tumor regression can occur following an intense immune-inflammatory response and novel strategies to treat cancer rely on manipulating the host immune system. Here, we report spontaneous regression of metastatic salivary gland myoepithelial carcinoma in a patient who experienced grade 3 systemic reactogenicity, following vaccination with the mRNA-1273 COVID-19 vaccine. Histological and immunophenotypic inspection of the postvaccination lung biopsy specimens showed a massive inflammatory infiltrate with scant embedded tumor clusters (<5%). Highly multiplexed imaging mass cytometry showed that the postvaccination lung metastasis samples had remarkable immune cell infiltration, including CD4+ T cells, CD8+ T cells, natural killer cells, B cells, and dendritic cells, which contrasted with very low levels of these cells in the prevaccination primary tumor and lung metastasis samples. CT scans obtained 3, 6, and 9â€‰months after the second vaccine dose demonstrated persistent tumor shrinkage (50%, 67%, and 73% reduction, respectively), suggesting that vaccination stimulated anticancer immunity. Insight: This case suggests that the mRNA-1273 COVID-19 vaccine stimulated anticancer immunity and tumor regression.

Alterations in the oral microbiome of individuals with a healthy oral environment following COVID-19 vaccination. BACKGROUND: Several reports suggest that the microbiome of the digestive system affects vaccine efficacy and that the severity of coronavirus disease (COVID-19) is associated with decreased diversity of the oral and/or intestinal microbiome. The present study examined the effects of a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine on the oral microbiome. METHODS: Forty healthy Japanese oral healthcare personnel were recruited, and unstimulated saliva was collected before vaccination, after the 1st vaccination, and after the 2nd

vaccination. Genomic DNA was extracted from saliva samples, and PCR amplicons of the 16S rRNA gene were analyzed using next-generation sequencing. Microbial diversity and composition were analyzed using Quantitative Insights into Microbial Ecology 2. In addition, alterations in microbial function were assessed using PICRUSt2. RESULTS: SARS-CoV-2 mRNA vaccination significantly increased oral bacterial diversity and significantly decreased the proportion of the genus Bacteroides. CONCLUSIONS: The SARS-CoV-2 mRNA vaccine alters the oral microbiome; accordingly, vaccination might have beneficial effects on oral health.

Herpes simplex encephalitis following ChAdOx1 nCoV-19 vaccination: a case report and review of the literature. BACKGROUND: Ever since the administration of early doses of COVID-19 vaccines, instances of adverse effects have been reported. Viral infections, specifically herpes simplex reinfection and coinfections, have been reported following administration of different types of vaccines. To our knowledge, there have not been any reports of herpes simplex encephalitis following administration of any type of COVID-19 vaccine to date. CASE PRESENTATION: In this article intends to report a case of herpes simplex encephalitis in a 27-year-old male patient who was vaccinated with the ChAdOx1 nCoV-19 vaccine. CONCLUSIONS: Our study suggests a possible but very rare side effect of ChAdOx1 nCoV-19 vaccine, which requires immediate medical attention and can lead to devastating consequences if left undiagnosed and untreated.

The Conundrum on Covid Vaccination.

Cerebral Venous Thrombosis in Patients With Heparin-Induced Thrombocytopenia a Systematic Review. BACKGROUND: Cerebral venous thrombosis (CVT) has recently been reported as a common thrombotic manifestation in association with vaccine-induced thrombotic thrombocytopenia, a syndrome that mimics heparin-induced thrombocytopenia (HIT) and occurs after vaccination with adenovirus-based SARS-CoV-2 vaccines. We aimed to systematically review the incidence, clinical features, and prognosis of CVT occurring in patients with HIT. METHODS: The study protocol was registered with PROSPERO (CRD42021249652). MEDLINE, EMBASE and Cochrane CENTRAL were searched up to June 1, 2021 for HIT case series including >20 patients, or any report of HIT-related CVT. Demographic, neuroradiological, clinical, and mortality data were retrieved. Meta-analysis of proportions with random-effect modeling was used to derive rate of CVT in HIT and in-hospital mortality. Pooled estimates were compared with those for CVT without HIT and HIT without CVT, to determine differences in mortality. RESULTS: From 19073 results, we selected 23 case series of HIT (n=1220) and 27 cases of HIT-related CVT (n=27, 71% female). CVT developed in 1.6% of 1220 patients with HIT (95% CI,1.0%-2.5%, I(2)=0%). Hemorrhagic brain lesions occurred in 81.8% of cases of HIT-related CVT and other concomitant thrombosis affecting other vascular territory was reported in 47.8% of cases. In-hospital mortality was 33.3%. HIT-related CVT carried a 29% absolute increase in mortality rate compared with historical CVT controls (33.3% versus 4.3%, P<0.001) and a 17.4% excess mortality compared with HIT without CVT (33.3% versus 15.9%, P=0.046). CONCLUSIONS: CVT is a rare thrombotic manifestation in patients with HIT. HIT-related CVT has higher rates of intracerebral hemorrhage and a higher mortality risk, when compared with CVT in historical controls. The recently reported high frequency of CVT in patients with vaccine-induced thrombotic thrombocytopenia was not observed in HIT, suggesting that additional pathophysiological mechanisms besides anti-platelet factor-4 antibodies might be involved in vaccine-induced thrombotic thrombocytopenia-related CVT.

Safety Monitoring of COVID-19 Vaccine Booster Doses Among Persons Aged 12-17 Years - United States, December 9, 2021-February 20, 2022. As of February 20, 2022, only BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine has been authorized for use in persons aged 12-17 years in the United States (1). The Food and Drug Administration (FDA) amended the Emergency Use Authorization (EUA) for Pfizer-BioNTech vaccine on December 9, 2021, to authorize a homologous* booster dose for

persons aged 16-17 years â‰¥6 months after receipt of dose 2 (1). On January 3, 2022, authorization was expanded to include persons aged 12-15 years, and for all persons aged â‰¥12 years, the interval between dose 2 and booster dose was shortened to â‰¥5 months (1). To characterize the safety of Pfizer-BioNTech booster doses among persons aged 12-17 years (adolescents), CDC reviewed adverse events and health impact assessments during the week after receipt of a homologous Pfizer-BioNTech booster dose reported to v-safe, a voluntary smartphone-based safety surveillance system for adverse events after COVID-19 vaccination, and adverse events reported to the Vaccine Adverse Event Reporting System (VAERS), a passive vaccine safety surveillance system managed by CDC and FDA. During December 9, 2021-February 20, 2022, approximately 2.8 million U.S. adolescents received a Pfizer-BioNTech booster dose.(â€) During this period, receipt of 3,418 Pfizer-BioNTech booster doses were reported to v-safe for adolescents. Reactions were reported to v-safe with equal or slightly higher frequency after receipt of a booster dose than after dose 2, were primarily mild to moderate in severity, and were most frequently reported the day after vaccination. VAERS received 914 reports of adverse events after Pfizer-BioNTech booster dose vaccination of adolescents; 837 (91.6%) were nonserious and 77 (8.4%) were serious. Health care providers, parents, and adolescents should be advised that local and systemic reactions are expected among adolescents after homologous Pfizer-BioNTech booster vaccination, and that serious adverse events are rare.

Effect of disease-modifying treatments on antibody-mediated response to anti-COVID19 vaccination in people with multiple sclerosis. BACKGROUND: Few data are available so far on the antibody-mediated immune response to anti-SARS-Cov2 vaccination in people with multiple sclerosis (pwMS) treated with disease-modifying treatments (DMTs), therefore this issue was explored in a real-life cohort of pwMS. MATERIALS AND METHODS: Retrospective monocentric study on anti-spike protein antibody response in pwMS who had received vaccination for Sars-Cov2. Adverse events following vaccination were also recorded. RESULTS: One hundred and twenty pwMS were included: 83 females (69%); median age at vaccination 42Â years (range 21-73); 112/120 patients (93%) were receiving DMTs at vaccination. Anti-spike protein IgG antibodies were detectable in 102/120 (85%) cases overall, being the proportion lower in pwMS receiving anti-CD20 antibodies (14/31, 45%) compared to non-depletive treatments (77/78, 99%), pâ€‰<â€‰0.0001. Median anti-spike titre was lower in anti-CD20 antibodies and fingolimod-treated pwMS compared to those receiving other DMTs, and it correlated with anti-CD20 treatment duration (Râ€‰-â€‰0.93, pâ€‰<â€‰0.0001) and with age at vaccination in pwMS not receiving depletive treatments (Râ€‰-â€‰0.25, pâ€‰=â€‰0.028). Baseline CD19+â€‰cell count (where available) was higher in the responder group than in non-responders, pâ€‰<â€‰0.0001. Two symptomatic COVID-19 infections were diagnosed over a median follow-up of 5Â months (range 2-7); adverse events were aligned with the published literature. CONCLUSION: Antibody response to anti-COVID-19 vaccines was detected in most of the pwMS analysed, but frequency of responders was reduced in those receiving CD20 depleting therapies compared to other DMTs-treated pwMS. Investigations on cell-mediated immune response are needed to assess whether a protective immune response is elicited also in non-antibody responders.

Safety of the BNT162b2 mRNA COVID-19 vaccine in patients with familial Mediterranean fever. OBJECTIVES: Evidence suggests a possible association between the COVID-19 vaccine and autoimmune disease flares or new onset of various autoinflammatory manifestations, such as pericarditis and myocarditis. The objective of this study was to assess the safety of an mRNA-based BNT162b2 anti-COVID-19 vaccine in individuals with FMF, a prototypic autoinflammatory disease. METHODS: Patients participating in this study fulfilled the criteria for diagnosis of FMF, were older than 18â€‰years and received at least one dose of the vaccine. Data on baseline characteristics, features of FMF, post-vaccination side effects, and disease flares were acquired using electronic

medical files and telephone interviews. RESULTS: A total of 273 FMF patients were recruited for the study. >95% were vaccinated with two doses of the vaccine. The rates of local reactions following the first and second vaccine doses were 65.5% and 60%, respectively, and 26% and 50.4%, respectively, for systemic adverse events. These rates are lower than those reported for the general population from real-world and clinical trial settings. Postvaccination FMF activity remained stable in most patients. None of the patients reported an attack of pericarditis or myocarditis, considered the most serious vaccine-associated adverse events. Patients with a more active FMF disease and patients harboring the M694V mutation had a significantly higher rate of post-vaccination systemic side effects and attacks. CONCLUSION: The BNT162b2 mRNA COVID-19 vaccine is safe in patients with FMF. Our results support the administration of this vaccine to FMF patients according to guidelines applicable to the general population.

An extremely rare mucocutaneous adverse reaction following COVID-19 vaccination: Toxic epidermal necrolysis. Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN), is a type of delayed hypersensitivity reaction that requires urgent medical intervention. In the COVID-19 era, COVID-19 vaccines are currently being widely administered and mucocutaneous adverse reactions following vaccination have been reported; however, severe cutaneous adverse reactions associated with COVID-19 vaccines including SJS/TEN, are extremely rare. Herein, we describe a case of COVID-19 vaccination induced TEN which developed 1Â day after receiving the first dose of Sinopharm COVID-19 vaccine with favorable clinical outcome.

Case Report: Myocarditis After COVID-19 Vaccination - Case Series and Literature Review. BACKGROUND: The ongoing COVID-19 pandemic demands a series of measures and, above all, the vaccination of a substantial proportion of the population. Acute myocarditis is a rare complication of the widely used mRNA-based vaccines. CASE PRESENTATION: We present a case series of four patients (three men and one woman, 16 to 47 years old) with acute pericarditis/myocarditis 3 to 17 days after mRNA vaccination. They presented with chest pain, fever, and flu-like symptoms. Diagnosis was made based on the synopsis of clinical presentation, elevated levels of troponin T and NT-proBNP, impaired systolic function on echocardiography, and findings in non-invasive tissue characterization by cardiovascular magnetic resonance imaging. Two patients also underwent endomyocardial biopsies. As none of the patients showed signs of cardiogenic shock, they were discharged from ward care only a few days after their initial presentations. CONCLUSIONS: Our data are consistent with other case reports of myocarditis early after mRNA vaccination and demonstrate the need for multimodal diagnostics. In view of its rarity and mild course, the risk-benefit ratio of vaccination remains positive compared to potential SARS-CoV-2 infection.

Reactivation of varicella-zoster virus following mRNA COVID-19 vaccination in a patient with moderately differentiated adenocarcinoma of rectum: A case report. Herpes zoster which is the reactivation of varicella-zoster virus, a pathogenic human alpha-herpes virus, following primary infection or chicken pox, is known to occur especially in advanced age and in the immunocompromised among other predisposing factors. COVID-19 vaccination-induced immunomodulation is a novel scenario, hypothesized to be a result of shifting of T-lymphocyte population towards vaccine-induced naÃ¯ve CD8+ subset, offsetting the balance of varicella-zoster virus responsive T-helper cells, thereby defecting the cell-mediated immunity which suppresses the latent varicella-zoster virus. The exact mechanism, however, is still elusive. Herein, we discuss a case of reactivation of varicella-zoster virus following BNT162b2 mRNA COVID-19 vaccine in an elderly female on oral medication for long-term diabetes and hypertension with good control who has undergone local radiotherapy for an underlying adenocarcinoma of rectum awaiting surgical resection, highlighting the key features of pathogenesis of the disease in relation to COVID-19 vaccination with a pertinent survey of the literature. This case report highlights the importance of

differentiating vaccine-related cutaneous reactions with clinically more significant adverse events, early specific therapy thus preventing poorer acute and chronic outcomes.

Antigen-Specific CD4(+) T-Cell Activation in Primary Antibody Deficiency After BNT162b2 mRNA COVID-19 Vaccination. Previous studies on immune responses following COVID-19 vaccination in patients with common variable immunodeficiency (CVID) were inconclusive with respect to the ability of the patients to produce vaccine-specific IgG antibodies, while patients with milder forms of primary antibody deficiency such as immunoglobulin isotype deficiency or selective antibody deficiency have not been studied at all. In this study we examined antigen-specific activation of CXCR5-positive and CXCR5-negative CD4(+) memory cells and also isotype-specific and functional antibody responses in patients with CVID as compared to other milder forms of primary antibody deficiency and healthy controls six weeks after the second dose of BNT162b2 vaccine against SARS-CoV-2. Expression of the activation markers CD25 and CD134 was examined by multi-color flow cytometry on CD4(+) T cell subsets stimulated with SARS-CoV-2 spike peptides, while in parallel IgG and IgA antibodies and surrogate virus neutralization antibodies against SARS-CoV-2 spike protein were measured by ELISA. The results show that in CVID and patients with other milder forms of antibody deficiency normal IgG responses (titers of spike protein-specific IgG three times the detection limit or more) were associated with intact vaccine-specific activation of CXCR5-negative CD4(+) memory T cells, despite defective activation of circulating T follicular helper cells. In contrast, CVID IgG nonresponders showed defective vaccine-specific and superantigen-induced activation of both CD4(+)T cell subsets. In conclusion, impaired TCR-mediated activation of CXCR5-negative CD4(+) memory T cells following stimulation with vaccine antigen or superantigen identifies patients with primary antibody deficiency and impaired IgG responses after BNT162b2 vaccination.

Acute kidney rejection after anti-SARS-CoV-2 virus-vectored vaccine-case report. COVID-19 infection remains a threat to the health systems of many countries. Potential success in the fight against the COVID-19 pandemic is the vaccination of high-risk groups, including patients with end-stage kidney disease (ESKD) and after solid organ transplantation (SOT). Immunosuppression in kidney transplant recipients can also reduce the immunogenicity of SARS-CoV-2 vaccines (varied by vaccine platform), available data suggest that they are efficacious in approximately 50-70%, compared to non-transplant situations. In this paper, we present a newly developed acute humoral and cellular rejection with acute allograft failure and need of hemodialysis 14 days after administration of the adenovirus vectored SARS-CoV-2 vaccine (AstraZeneca; CHADOx1, AZD1222). This occurred in a patient who previously had an asymptomatic COVID-19 infection. Case reports of acute allograft rejection after vaccination against SARS-CoV-2 can help stratify risk groups of patients who develop hyperimmune reactions. However, it is also possible that those with a previous mild primary COVID-19 infection may also develop acute allograft rejections upon COVID-19 re-infection.

Use of analgesics/antipyretics in the management of symptoms associated with COVID-19 vaccination. COVID-19 vaccines are effective and important to control the ongoing pandemic, but vaccine reactogenicity may contribute to poor uptake. Analgesics or antipyretic medications are often used to alleviate vaccine side effects, but their effect on immunogenicity remains uncertain. Few studies have assessed the effect of analgesics/antipyretics on vaccine immunogenicity and reactogenicity. Some studies revealed changes in certain immune response parameters post-vaccination when analgesics/antipyretics were used either prophylactically or therapeutically. Still, there is no evidence that these changes impact vaccine efficacy. Specific data on the impact of analgesic/antipyretic medications on immunogenicity of COVID-19 vaccines are limited. However, available data from clinical trials of licensed vaccines, along with recommendations from public health bodies around the world, should provide reassurance to both healthcare professionals and

vaccine recipients that short-term use of analgesics/antipyretics at non-prescription doses is unlikely to affect vaccine-induced immunity.

Marked increase of interferon-Î² after BNT162b2 mRNA vaccination: a case of polyarthritis with pleurisy. Exacerbation of rheumatic disease after vaccination against SARS-CoV-2 is being reported. However, there are only a few cases of new-onset rheumatic diseases. We present two cases of new-onset persistent polyarthritis that developed in patients after receiving the mRNA vaccine against SARS-CoV-2. One patient had bilateral pleural effusions with markedly elevated serum interferon (IFN)-Î², while the other had no effusion, with serum IFN-Î² comparable with that in healthy subjects. Other cytokines were unaltered in association with effusion. Both patients responded well to treatment with 20â€‰mg prednisolone. Although more investigations are needed, the marked increase in serum IFN-Î² levels observed in the case with pleural effusion may reflect an excessive response from the innate immune system to mRNA vaccines.

Risk factors associated with short-term adverse events after SARS-CoV-2 vaccination in patients with immune-mediated inflammatory diseases. BACKGROUND: Studies have suggested incremental short-term adverse events (AE) after repeated vaccination. In this report, we assessed occurrence and risk factors for short-term AEs following repeated SARS-CoV-2 vaccination in patients with various immune-mediated inflammatory diseases (IMIDs). METHODS: Self-reported daily questionnaires on AEs during the first 7 days after vaccination were obtained of 2259 individuals (2081 patients and 178 controls) participating in an ongoing prospective multicenter cohort study on SARS-CoV-2 vaccination in patients with various IMIDs in the Netherlands (T2B-COVID). Relative risks were calculated for potential risk factors associated with clinically relevant AE (rAE), defined as AE lasting longer than 2 days or impacting daily life. RESULTS: In total, 5454 vaccinations were recorded (1737 first, 1992 second and 1478 third vaccinations). Multiple sclerosis, Crohn's disease and rheumatoid arthritis were the largest disease groups. rAEs were reported by 57.3% (95% CI 54.8-59.8) of patients after the first vaccination, 61.5% (95% CI 59.2-63.7) after the second vaccination and 58% (95% CI 55.3-60.6) after the third vaccination. At day 7 after the first, second and third vaccination, respectively, 7.6% (95% CI 6.3-9.1), 7.4% (95% CI 6.2-8.7) and 6.8% (95% CI 5.4-8.3) of patients still reported AEs impacting daily life. Hospital admissions and allergic reactions were uncommon (<0.7%). Female sex (aRR 1.43, 95% CI 1.32-1.56), age below 50 (aRR 1.14, 95% CI 1.06-1.23), a preceding SARS-CoV-2 infection (aRR 1.14, 95% CI 1.01-1.29) and having an IMID (aRR 1.16, 95% CI 1.01-1.34) were associated with increased risk of rAEs following a vaccination. Compared to the second vaccination, the first vaccination was associated with a lower risk of rAEs (aRR 0.92, 95% CI 0.84-0.99) while a third vaccination was not associated with increased risk on rAEs (aRR 0.93, 95% CI 0.84-1.02). BNT162b2 vaccines were associated with lower risk on rAEs compared to CX-024414 (aRR 0.86, 95% CI 0.80-0.93). CONCLUSIONS: A third SARS-CoV-2 vaccination was not associated with increased risk of rAEs in IMID patients compared to the second vaccination. Patients with an IMID have a modestly increased risk of rAEs after vaccination when compared to controls. Most AEs are resolved within 7 days; hospital admissions and allergic reactions were uncommon. TRIAL REGISTRATION: NL74974.018.20 , Trial ID: NL8900. Registered on 9 September 2020.

SARS-CoV-2 mRNA Vaccination and Graves' Disease: A Report of 12 Cases and Review of the Literature. CONTEXT AND OBJECTIVE: Thyroid autoimmunity has been reported to be associated with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the SARS-CoV-2 vaccination recently. We report a series of patients who presented with new onset or relapse of Graves' disease-related hyperthyroidism shortly after receiving the SARS-CoV-2 messenger RNA (mRNA) vaccine at a single tertiary institution in Singapore. METHODS AND RESULTS: We describe 12 patients who developed hyperthyroidism within a relatively short interval (median onset, 17 [range, 5-63] days) after receiving the SARS-CoV-2 mRNA vaccine. The majority were females (11/12) with median age of

35.5 (range, 22-74) years. Six patients had new-onset hyperthyroidism, whereas the other 6 had relapse of previously well-controlled Graves' disease. TSH receptor antibody concentrations ranged from 2.4 to 32 IU/L. The majority of the patients were able to go for the second dose of the vaccine without any further exacerbations. Literature review revealed 21 other similar cases reported from across the world. CONCLUSION: Our case series provides insight into the characteristics of individuals in whom Graves' disease was triggered by the SARS-CoV-2 vaccination. Clinicians need to be vigilant of precipitation or exacerbation of autoimmune thyroid disorders in predisposed individuals after exposure to the SARS-CoV-2 vaccination. Further epidemiological and mechanistic studies are required to elucidate the possible associations between the SARS-CoV-2 vaccines and the development of thyroid autoimmunity.

COVID-19 vaccine-related functional neurological disorders in theÂ emergency department.

FDG PET/MRI of Acute Myocarditis After mRNA COVID-19 Vaccination. A 22-year-old man visited the emergency department with chest pain. He had received a second dose of the coronavirus disease 2019 (COVID-19) mRNA (Moderna) vaccine 5 days prior. 18F-FDG PET/MR revealed a focal FDG uptake and late gadolinium enhancement on the basal posterolateral wall of the left ventricle. Myocarditis after a COVID-19 vaccination has been reported predominantly after the second dose of mRNA vaccines in young men. This was a case of acute focal myocarditis after a COVID-19 mRNA vaccination, which was well-visualized by FDG PET/MRI.

Neurological Events Reported after COVID-19 Vaccines: An Analysis of VAERS. OBJECTIVE: To identify the rates of neurological events following administration of mRNA (Pfizer, Moderna) or adenovirus vector (Janssen) vaccines in the U.S.. METHODS: We utilized publicly available data from the U.S. Vaccine Adverse Event Reporting System (VAERS) collected between January 1, 2021-June 14, 2021. All free text symptoms that were reported within 42â€‰days of vaccine administration were manually reviewed and grouped into 36 individual neurological diagnostic categories. Post-vaccination neurological event rates were compared between vaccine types and to age-matched baseline incidence rates in the U.S. and rates of neurological events following COVID. RESULTS: Of 306,907,697 COVID vaccine doses administered during the study timeframe, 314,610 (0.1%) people reported any adverse event and 105,214 (0.03%) reported neurological adverse events in a median of 1 day (IQR0-3) from inoculation. Guillain-Barre Syndrome (GBS), and cerebral venous thrombosis (CVT) occurred in fewer than 1 per 1,000,000 doses. Significantly more neurological adverse events were reported following Janssen (Ad26.COV2.S) vaccination compared to either Pfizer-BioNtech (BNT162b2) or Moderna (mRNA-1273; 0.15% versus 0.03% versus 0.03% of doses, respectively,P<0.0001). The observed-to-expected ratios for GBS, CVT and seizure following Janssen vaccination were â‰¥1.5-fold higher than background rates. However, the rate of neurological events after acute SARS-CoV-2 infection was up to 617-fold higher than after COVID vaccination. INTERPRETATION: Reports of serious neurological events following COVID vaccination are rare. GBS, CVT and seizure may occur at higher than background rates following Janssen vaccination. Despite this, rates of neurological complications following acute SARS-CoV-2 infection are up to 617-fold higher than after COVID vaccination. This article is protected by copyright. All rights reserved.

Successful surgical-multimodal treatment for vaccine-induced complete splanchnic vein thrombosis after ChAdOx1 nCoV-19 vaccination.

Efficient recall of Omicron-reactive B cell memory after a third dose of SARS-CoV-2 mRNA vaccine. Despite a clear role in protective immunity, the durability and quality of antibody and memory B cell responses induced by mRNA vaccination, particularly by a 3 (rd) dose of vaccine, remains unclear. Here, we examined antibody and memory B cell responses in a cohort of individuals sampled longitudinally for â^¼9-10 months after the primary 2-dose mRNA vaccine series, as well as for â^¼3 months after a 3 (rd) mRNA vaccine dose. Notably, antibody decay slowed significantly between 6-

and 9-months post-primary vaccination, essentially stabilizing at the time of the 3 (rd) dose. Antibody quality also continued to improve for at least 9 months after primary 2-dose vaccination. Spike- and RBD-specific memory B cells were stable through 9 months post-vaccination with no evidence of decline over time, and âˆ¼40-50% of RBD-specific memory B cells were capable of simultaneously recognizing the Alpha, Beta, Delta, and Omicron variants. Omicron-binding memory B cells induced by the first 2 doses of mRNA vaccine were boosted significantly by a 3rd dose and the magnitude of this boosting was similar to memory B cells specific for other variants. Pre-3 (rd) dose memory B cell frequencies correlated with the increase in neutralizing antibody titers after the 3 (rd) dose. In contrast, pre-3 (rd) dose antibody titers inversely correlated with the fold-change of antibody boosting, suggesting that high levels of circulating antibodies may limit reactivation of immunological memory and constrain further antibody boosting by mRNA vaccines. These data provide a deeper understanding of how the quantity and quality of antibody and memory B cell responses change over time and number of antigen exposures. These data also provide insight into potential immune dynamics following recall responses to additional vaccine doses or post-vaccination infections.

Clinical course impacts early kinetics,magnitude, and amplitude of SARS-CoV-2 neutralizing antibodies beyond 1 year after infection. To understand the determinants of long-term immune responses to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the concurrent impact of vaccination and emerging variants, we follow a prospective cohort of 332 patients with coronavirus disease 2019 (COVID-19) over more than a year after symptom onset. We evaluate plasma-neutralizing activity using HIV-based pseudoviruses expressing the spike of different SARS-CoV-2 variants and analyze them longitudinally using mixed-effects models. Long-term neutralizing activity is stable beyond 1 year after infection in mild/asymptomatic and hospitalized participants. However, longitudinal models suggest that hospitalized individuals generate both short- and long-lived memory B cells, while the responses of non-hospitalized individuals are dominated by long-lived B cells. In both groups, vaccination boosts responses to natural infection. Long-term (>300Â days from infection) responses in unvaccinated participants show a reduced efficacy against beta, but not alpha nor delta, variants. Multivariate analysis identifies the severity of primary infection as an independent determinant of higher magnitude and lower relative cross-neutralization activity of long-term neutralizing responses.

Neutralizing-antibody-independent SARS-CoV-2 control correlated with intranasal-vaccine-induced CD8(+) TÂ cell responses. Effective vaccines are essential for the control of the coronavirus disease 2019 (COVID-19) pandemic. Currently developed vaccines inducing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike (S)-antigen-specific neutralizing antibodies (NAbs) are effective, but the appearance of NAb-resistant S variant viruses is of great concern. A vaccine inducing S-independent or NAb-independent SARS-CoV-2 control may contribute to containment of these variants. Here, we investigate the efficacy of an intranasal vaccine expressing viral non-S antigens against intranasal SARS-CoV-2 challenge in cynomolgus macaques. Seven vaccinated macaques exhibit significantly reduced viral load in nasopharyngeal swabs on day 2 post-challenge compared with nine unvaccinated controls. The viral control in the absence of SARS-CoV-2-specific NAbs is significantly correlated with vaccine-induced, viral-antigen-specific CD8(+) TÂ cell responses. Our results indicate that CD8(+) TÂ cell induction by intranasal vaccination can result in NAb-independent control of SARS-CoV-2 infection, highlighting a potential of vaccine-induced CD8(+) TÂ cell responses to contribute to COVID-19 containment.

SARS-CoV-2 Beta and Delta variants trigger Fc effector function with increased cross-reactivity. Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) variants of concern (VOCs) exhibit escape from neutralizing antibodies, causing concern about vaccine effectiveness. However, while non-neutralizing cytotoxic functions of antibodies are associated with improved disease outcome and

vaccine protection, Fc effector function escape from VOCs is poorly defined. Furthermore, whether VOCs trigger Fc functions with altered specificity, as has been reported for neutralization, is unknown. Here, we demonstrate that the Beta VOC partially evades Fc effector activity in individuals infected with the original (D614G) variant. However, not all functions are equivalently affected, suggesting differential targeting by antibodies mediating distinct Fc functions. Furthermore, Beta and Delta infection trigger responses with significantly improved Fc cross-reactivity against global VOCs compared with D614G-infected or Ad26.COV2.S-vaccinated individuals. This suggests that, as for neutralization, the infecting spike sequence affects Fc effector function. These data have important implications for vaccine strategies that incorporate VOCs, suggesting these may induce broader Fc effector responses.

Effusive-constrictive pericarditis after the second dose of BNT162b2 vaccine (Comirnaty): a case report. BACKGROUND: Whereas effusive-constrictive pericarditis (ECP) can rarely occur in coronavirus disease 2019 (COVID-19), to date no cases of ECP related to severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) vaccine have been documented. CASE SUMMARY: A 59-year-old Caucasian man presented to our emergency department with ECP. Symptoms occurred shortly after the second dose of BNT162b2 (Comirnaty) vaccine. No other aetiological causes were identified. Guidelines-directed therapy for acute pericarditis was implemented, with clinical benefit. DISCUSSION: Systemic inflammatory response to COVID-19 can rarely trigger pericarditis. In our case, a strong temporal relationship between the second dose of BNT162b2 vaccine and symptoms occurrence was documented, indicating a possible rare adverse reaction to the vaccine, similarly to natural infection. Further research is needed to confirm a causal relationship.

[Peripheral facial palsy following COVID-19 vaccination: a case report]. We conducted a clinical study of a patient with no particular medical history and without a personal or family history presenting with right facial asymmetry occurred two days after COVID-19 vaccination (recombinant vaccine). Full clinical examination, laboratory assessments and magnetic resonance imaging (MRI) were normal, suggesting the diagnosis of post-vaccine peripheral facial palsy (COVID-19). The diagnosis of peripheral facial palsy following COVID-19 vaccination with complete recovery was retained.

COVID-19 Update for the GRAPPA 2021 Annual Meeting: Focus on COVID-19 Vaccination. The efficacy and safety of coronavirus disease 2019 (COVID-19) vaccination in patients with autoimmune inflammatory diseases (AIRDs) who are treated with immunomodulatory therapies was the focus of a symposium at the 2021 virtual annual meeting of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA). The keynote address was delivered by Dr. Jeffrey Curtis, chair of the American College of Rheumatology COVID-19 Vaccine Clinical Guidance task force, detailing what we do and do not know about vaccine efficacy and safety in patients with AIRDs and providing guidance about the need for modification of dosing in some immunomodulatory medications for optimal vaccine response. A consensus of the task force was that all patients with AIRDs should be vaccinated as soon as it is allowed in their respective locations, since the benefits of increased protection against COVID-19 infection outweigh the potential for vaccination reactions, including flares of underlying disease, or for reduced efficacy of vaccination because of disease state or medications. Key issues among patient research partners with psoriatic disease expressed in the premeeting survey and panel discussion/question-and-answer period included: vaccine efficacy and safety, the need to continue safe social habits and masking, how to assess efficacy of vaccination, how to deal with vaccine hesitancy among social contacts, medication management relative to vaccination, and concerns about the adequacy of ongoing telehealth visits vs the convenience of that technology.

Autoimmune hepatitis or drug-induced autoimmune hepatitis following Covid-19 vaccination?

Morphea and COVID-19 mRNA vaccine.

Immunoglobulin A vasculitis post-severe acute respiratory syndrome coronavirus 2 vaccination and review of reported cases. Immunoglobulin (Ig)A vasculitis/nephropathy is a systemic immune complex-mediated vasculitis. Although severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination is widely recommended in individuals without specific allergy to the vaccine components, it is arguable whether vaccination is advisable for patients with IgA vasculitis or for predisposed individuals. We and others have presented cases of IgA vasculitis occurring after SARS-CoV-2 vaccination. In total, these 19 cases, including ours, involved predominantly female patients, and half of them were suffering from de novo vasculitis onset. The most frequent manifestation was gross hematuria (89.5%) while skin lesions were relatively infrequent, occurring in only five cases (26.3%), of which three (15.8%) were confirmed to be IgA vasculitis. Taken together, these cases suggest that SARS-CoV-2 vaccination might be a trigger for development/deterioration of IgA vasculitis/nephropathy.

Chilblain-like Lesions after COVID-19 Vaccination: A Case Series.

A Case of Giant Cell Arteritis Presenting After COVID-19 Vaccination: Is It Just a Coincidence? Giant cell arteritis (GCA) is a large vessel vasculitis with variable presentations, including fevers, myalgias, headache, and jaw claudication. A particularly concerning symptom is transient vision loss, which may become irreversible without prompt recognition and treatment. The pathogenesis of GCA is incompletely understood, but it seems that the innate and adaptive immune systems play a key role in vessel inflammation, remodeling, and occlusion. We present a case of a 79-year-old male who developed GCA two days after he received his second dose of a COVID-19 mRNA vaccine. He presented with headaches, fever, and myalgias. Lab workup revealed elevated inflammatory markers, with C-reactive protein (CRP) 272 mg/L (<8.1 mg/L) and erythrocyte sedimentation rate (ESR) 97 mm/hr (0-20mm/hr). Imaging of the head, with CT and MRI, was unremarkable. His headache persisted despite supportive treatment, and he developed new, transient blurred vision, which increased suspicion for GCA. He underwent bilateral temporal artery biopsies, which were consistent with GCA. His symptoms resolved quickly with oral prednisone 60mg daily, and his inflammatory markers returned to normal within a month. A review of the literature revealed several case reports of giant cell arteritis following influenza vaccination. However, no large-scale studies have demonstrated a causal relationship between GCA and immunization. Our case demonstrates the first instance of GCA following a COVID-19 mRNA vaccine. We propose that the upregulated immune response to the vaccine acted as a trigger for GCA in this patient with predisposing factors. While causation cannot be determined based on one case alone, our case demonstrates an opportunity for further research into the relationship between vasculitis and immunizations. Despite this isolated case, the proven benefits of COVID-19 mRNA vaccines significantly outweigh any theoretical risk of immune dysregulation following administration.

Early Flare-Ups of Myasthenia Gravis After Thoracoscopic Thymectomy in a Patient Recently Receiving BNT162b2 mRNA COVID-19 Vaccination. Myasthenia gravis (MG) is an autoimmune disorder characterized by abnormal neuromuscular transmission. The thymus is believed to play a key role in the pathogenesis of MG, and thymectomy has been an optional treatment for the disease. Relapse of MG after thymectomy has been reported. Exacerbations and new onset of MG following COVID-19 vaccination have also been documented. This report presents a case of a stable MG patient with recent COVID-19 vaccination experiencing flare-ups of symptoms shortly after video-assisted thoracoscopic (VATS) thymectomy. A 31-year-old female received the second dose of the BNT162b2 mRNA COVID-19 vaccine eight days before thymectomy and developed flare-ups of symptoms four days after the surgery. Although the substantial link between MG exacerbations post-thymectomy and pre-thymectomy COVID-19 vaccination cannot be concluded, this observation warrants further research.

COVID-19 vaccine-induced Radiation Recall Dermatitis: Report of a case. Radiation Recall Dermatitis (RRD) is an inflammatory process in the site of irradiation, induced by physical and medical agents. Few cases of RRD in the skin and lung have been reported after COVID-19 vaccination. Here, we report radiation recall dermatitis after both doses of inactivated SARS-CoV-2 vaccine (Sinopharm, China).
Bell's palsy after Sputnik V COVID-19 (Gam-COVID-Vac) vaccination. A possible association between Bell's palsy and COVID-19 vaccination has been suggested previously. Here, we report two cases of facial nerve hemiparalysis following the Sputnik V COVID-19 vaccination in a 27-year-old female patient and a 58-year-old male patient who were both clinically diagnosed with Bell's palsy.
Post-COVID-19 vaccine medium-vessel vasculitis and acute anterior uveitis, causation vs temporal relation; case report and literature review. INTRODUCTION: and importance: Multiple immunologic phenomena were reported following the administration of COVID-19 vaccines. However, the important point is that their possible association with medium-vessel vasculitis involving the celiac trunk and its branches with acute anterior uveitis in the same patient has not been reported before. CASE PRESENTATION: In this manuscript, we are reporting a case of a middle-aged gentleman who developed vasculitis involving the celiac trunk and its branches, and acute anterior uveitis one week and three weeks after the second dose of Pfizer BioNTech COVID-19 vaccine, respectively. The patient showed significant clinical and radiographic improvement after receiving corticosteroids and azathioprine. CLINICAL DISCUSSION: Previously reported cases of vasculitis following COVID-19 vaccines included both renal-limited and more generalized vasculitis with some being positive and others negative for ANCA (anti-neutrophil cytoplasmic antibodies). Nevertheless, it is worth mentioning that most cases responded to immunosuppressive treatment. Post-COVID-19 vaccine uveitis was reported in patients with different age spans including both anterior and posterior uveitis, with remission being achieved after the use of corticosteroids. CONCLUSIONS: Multiple cases of vasculitis and acute anterior uveitis were reported following COVID-19 vaccines; however, it is important to mention that more research is needed to establish an association between the COVID-19 vaccine and both vasculitis and acute anterior uveitis. In our opinion, the benefits of the COIVID-19 vaccine largely outweigh the expected risks.
Is COVID-19 vaccination beneficial or harmful to endothelial cells?
[A case of cerebral venous sinus thrombosis following the vaccination with Tozinameran]. A 31-year-old man visited our hospital due to experiencing severe headaches, vomiting, and hypesthesia in the left side of his body. He had no past illnesses and had had no severe headaches before. The symptoms started the day after receiving the coronavirus disease 2019 (COVID-19) vaccination with Tozinameran. An MRI revealed cerebral venous sinus thrombosis and high intensity (DWI & FLAIR) of the right thalamus. Anticoagulant therapy was initiated, and his symptoms improved gradually. The follow-up MRI showed recanalization in a large part of the occluded venous sinuses. Most of the coagulation tests were normal, except for slightly high value of D-dimer, and the polymerase chain reaction (PCR) test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was negative. Further cases are needed to judge if there is some sort of relationship between the vaccination and the cerebral venous sinus thrombosis.
Peak IgG antibody titers against SARS-CoV-2 spike protein following immunization with the Pfizer/BioNTech BNT162b2 vaccine. This study investigated the immune response and outcome of BNT162b2 vaccination among 12 staff at a hospital in Fukushima, Japan. Blood samples were collected from participants before their first vaccination, with subsequent sampling performed during the participants' work days for six weeks thereafter. Antibody titers peaked 6-13 days after the second vaccination (days 27-34 after the first), followed by a steady decrease. Six males had significantly lower peak antibody titers than six females ($p = 0.016$ with t-test); the older six (median

age 53 years) had lower antibody titers than the younger six (median age 35 years) but without statistical significance (p value=0.24 with t-test).

Myocarditis Following COVID-19 Vaccination: A Systematic Review (October 2020-October 2021). INTRODUCTION: Reports of SARS-CoV-2 coronavirus (COVID-19) vaccine-related myocarditis, particularly after mRNA vaccines, have raised concerns amongst the general public. This review examined the literature regarding myocarditis post COVID-19 vaccination, drawing from vaccine safety surveillance databases and case reports. METHODS: Combinations of search terms were used in PubMed and COVID-19-specific repositories - LitCovid and the Cochrane COVID-19 Study Register - between 1 October 2020 and 31 October 2021. Manual searches of GoogleScholar and screening of article bibliographies were also performed. RESULTS: Information was obtained from five vaccine safety surveillance databases. Fifty-two (52) case reports totalling 200 cases of possible COVID-19 vaccine-related myocarditis were summarised. Vaccine surveillance databases differed in reporting formats and vaccination rates; however, gross estimates suggested low overall incidence rates of 2-5 per million mRNA vaccines. The incidence appeared to be higher in younger male populations, with onset of symptoms within a few days, usually after the second dose. Some with prior COVID-19 infections had onset after the first dose. Cases with prior unrelated myocarditis were also noted. Almost all presented with chest pain (98.0%). Troponin elevation was universally described and cardiac magnetic resonance imaging was commonly reported based on the updated Lake Louise criteria. Clinical course was mild in the majority, with response to anti-inflammatory treatment. CONCLUSION: COVID-19 vaccine-related myocarditis is an important but rare adverse event. More research is needed into its pathogenesis and reasons for its predominance in young males, while gaps in data exist in those aged <16 years, as well as those with prior COVID-19 infections and prior myocarditis.

Early safety and tolerability profile of the BNT162b2 COVID-19 vaccine in myasthenia gravis. Although the COVID-19 vaccines are currently recommended for people with myasthenia gravis (MG), there is no data regarding the safety of the vaccines in this population. In order to investigate the real-life safety data of the BNT162b2 COVID-19 vaccine in people with MG, an anonymous survey was distributed to 142 MG patients. Fifty-six MG patients completed the questionnaire. The median age was 53 years (range 23-83 years); 35 (62.5%) were males, and 25 (44.6%) had associated comorbidities. Thirty-seven participants (66.1%) were treated with immunotherapies. Fifty-five participants (98.2% of the responders) received the BNT162b2 COVID-19 vaccine. Of these, 32 (58.2%) were < 55 years old, and 23 (41.8%) were > 55 years old. Adverse events were more common in patients younger than 55 years old (46.9% Vs. 17.4%; pâ€¯=â€¯0.0428). Eight participants (14.5%) reported worsening neurological symptoms following the vaccination. Three of those who reported worsening of neurological symptoms (37.5%) required additional treatment. Most events occurred within the first few days after vaccination and resolved within a few weeks. This survey indicates an overall favorable safety and tolerability profile of the BNT162b2 vaccine in people with MG. Additional prospective, large-scale studies are warranted to confirm these findings.

Implications of COVID-19 Vaccination on Hospital Encounters and Outcomes. Adverse events, including cardiac involvement, after vaccination for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been reported. We sought to evaluate trends of hospital encounters for vaccine recipients before and after vaccination. We analyzed patients who received the coronavirus disease 2019 (COVID-19) vaccine in the MedStar Health system (11 hospitals in Washington, District of Columbia and Maryland) from December 2020 through August 2021. We then compared hospital encounters (emergency department visits) of patients 60 days before a vaccine dose and 30 days after a vaccine dose, along with encounters related to the SARS-CoV-2 infection itself. The cohort included 5,217 patients who were vaccinated against COVID-19. Our analysis revealed a total of 6,751

emergency department visits, and we divided this total into 3 cohorts: fully vaccinated (nÂ =Â 1,779), in vaccination window (nÂ =Â 1,420), and before vaccination (nÂ =Â 3,552). We found no significant association between vaccination and rate of presentation for acute coronary syndrome, pericarditis, myocarditis, heart failure, conduction abnormality, or noncardiac conditions. Further, encounters for complications related to SARS-CoV-2 infection decreased significantly from those before vaccination (5.4%) to those in vaccination window (4.2%) to those who were fully vaccinated (1.6%). These findings were consistent when all vaccinated encounters were combined into 1 cohort (fully vaccinatedÂ +Â in vaccination window). In conclusion, our analysis suggests that there is no significant association of COVID-19 vaccination with the rate of hospital encounters for cardiac disease, including acute coronary syndrome, pericarditis, myocarditis, congestive heart failure, and conduction abnormality. Further, administration of the vaccine resulted in a significant decrease in hospital encounters for SARS-CoV-2 infections and associated complications.

A Case Report of Prolonged Anaphylaxis after COVID-19 Vaccine. INTRODUCTION: As the medical community and world have combatted the coronavirus disease 2019 (COVID-19) pandemic, a significant advance was the development of a vaccine against the virus that has already claimed over 4.5 million lives worldwide. Vaccines manufactured by Pfizer-BioNTech and Moderna were the first two COVID-19 vaccines given emergency use authorization by the United States Food and Drug Administration. Preliminary data demonstrated not only the vaccines' efficacy rates of greater than 95% after a second dose, but also marked safety. Initial data showed only 21 cases of anaphylaxis of greater than 1.8 million doses administered. The majority of those patients had a history of anaphylaxis and presented within the first 15 minutes after administration of the vaccine. CASE REPORT: We describe a patient who had an anaphylactic reaction to her second dose of the Pfizer BioNTech severe acute respiratory syndrome coronavirus 2 (SARS CoV-2) vaccine with no prior history of allergic reactions or anaphylaxis. This reaction required multiple doses of epinephrine and a four-day hospitalization. We review both the available reports of anaphylaxis to the SAR CoV-2 vaccine and information on other prolonged cases of anaphylaxis. CONCLUSION: Our case report is unique in that the patient, despite no prior history of anaphylaxis, had a prolonged course requiring a four-day hospitalization. To our knowledge this is one of the first case reports of prolonged anaphylaxis after the second dose of Pfizer BioNTech COVID-19 vaccine in a patient with no history of prior anaphylaxis.

Acute cerebellitis requiring posterior fossa decompression after COVID-19 vaccination in an ocrelizumab-treated patient with multiple sclerosis.

Non-clinical immunogenicity, biodistribution and toxicology evaluation of a chimpanzee adenovirus-based COVID-19 vaccine in rat and rhesus macaque. Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged in 2019 has rapidly expanded into a serious global pandemic. Due to the high morbidity and mortality of COVID-19, there is an urgent need to develop safe and effective vaccines. AdC68-19S is an investigational chimpanzee adenovirus serotype 68 (AdC68) vector-based vaccine which encodes the full-length spike protein of SARS-CoV-2. Here, we evaluated the immunogenicity, biodistribution and safety profiles of the candidate vaccine AdC68-19S in Sprague Dawley (SD) rat and rhesus macaque under GLP conditions. To characterize the biodistribution profile of AdC68-19S, SD rats were given a single intramuscular injection of AdC68-19S 2â€‰Ã—â€‰10(11) VP/dose. Designated organs were collected on day 1, day 2, day 4, day 8 and day 15. Genomic DNA was extracted from all samples and was further quantified by real-time quantitative polymerase chain reaction (qPCR). To characterize the toxicology and immunogenicity profiles of AdC68-19S, the rats and rhesus macaques were injected intramuscularly with AdC68-19S up to 2â€‰Ã—â€‰10(11)vp/dose or 4â€‰Ã—â€‰10(11)vp/dose (2 and fourfold the proposed clinical dose of 1â€‰Ã—â€‰10(11)vp/dose) on

two or three occasions with a 14-day interval period, respectively. In addition to the conventional toxicological evaluation indexes, the antigen-specific cellular and humoral responses were evaluated. We proved that multiple intramuscular injections could elicit effective and long-lasting neutralizing antibody responses and Th1 T cell responses. AdC68-19S was mainly distributed in injection sites and no AdC68-19S related toxicological reaction was observed. In conclusion, these results have shown that AdC68-19S could induce an effective immune response with a good safety profile, and is a promising candidate vaccine against COVID-19.

Acute Demyelinating Encephalomyelitis Post-COVID-19 Vaccination: A Case Report and Literature Review. New advancements in the medical community have rapidly occurred with the development of medical information across the globe during the COVID-19 pandemic. Several vaccine manufacturers were able to obtain clearance to administer vaccines in selected age groups and for those at high risk for COVID-19 complications. As vaccines became more readily available, there was a significant effort supported by scientific information to get people vaccinated to boost herd immunity. Acute demyelinating encephalomyelitis (ADEM) is a rare autoimmune disease, causing demyelination in the brain and spinal cord, presenting as monophasic, acute-onset, and rapidly progressive multifocal neurological deficits. A wide variety of precipitating factors can trigger ADEM, and it has long been known to be a rare adverse event following some types of vaccinations including rabies, diphtheria-tetanus-polio, smallpox, measles, mumps, rubella, pertussis, influenza, and hepatitis B vaccines. Recently, ADEM has also been associated with COVID-19 infection and (very rarely) with COVID-19 vaccination. We have a 56-year-old female who was not known to have any medical issues. She voluntarily received her first COVID-19 vaccination (AstraZeneca) ten days after immunization; she developed weakness of the lower limbs and slurred speech. She tested negative for COVID-19, and a brain MRI showed T2-weighted white-matter hyperintense lesions suggesting acute demyelinating encephalomyelitis. She was managed with pulse-dose steroids, which resulted in a marked improvement in her symptoms, and discharged in a stable condition. Physicians should be aware of this neurological disorder and the management options for better patient care and outcomes.

Successful mRNA SARS-Cov-2 vaccine rechallenge after a first episode of immune thrombocytopenic purpura. In 2021, the world experienced the most extensive vaccination campaign to defeat COVID-19. Many cases of idiopathic thrombocytopenia have been reported following injections of SARS-Cov-2 mRNA vaccine. We present the case of a 73-year-old woman with de novo ITP after a first injection of SARS-Cov-2 mRNA vaccine (Moderna vaccine) who experienced a successful rechallenge of SARS-Cov-2 mRNA vaccine (Pfizer vaccine) a few months later.

Are COVID-19 vaccines safe for people with epilepsy? A cross-sectional study. BACKGROUND: COVID-19 disease was first seen in December 2019 and was declared a pandemic soon after. To fight the pandemic, there is an immense need for effective vaccines. The purposes of our study were to investigate the effect of coronavirus vaccines on seizures in people with epilepsy (PWE) and assess the adverse events of COVID-19 vaccine in PWE. METHODS: This was a cross-sectional study. We included epilepsy patients who got vaccinated with two or three doses at least 1Â month earlier. We gathered the data using a standardized form. The form contained questions about patients' demographic features, clinical features, and information about the vaccination and its adverse events. The questionnaire included questions about epilepsy-related adverse events. RESULTS: We included 178 people with epilepsy in our study. The frequency of adverse events was lower than clinical studies of the vaccines. The mean number of seizures in the month before the vaccination was 1.62, between the doses was 1.61, and after vaccination was 1.64. There was no significant difference in the number of monthly seizures before the vaccination, the month between the doses, or the month after the vaccination (pâ€‰=â€‰0.46). CONCLUSIONS: The vaccines under consideration in

our study were tolerated well by the epilepsy patients. The vaccines did not affect the monthly number of seizures of the PWE. A small number of patients had more seizures than normal after vaccination. We think that benefits of the vaccines outweigh the slightly increased possibility of having a seizure after vaccination.
Graves' disease after COVID-19 vaccination.
Pericarditis and myocarditis after COVID-19 mRNA vaccination in a nationwide setting. INTRODUCTION: Despite reports suggesting an association between COVID-19 mRNA vaccination and pericarditis and myocarditis, detailed nationwide population-based data are sparsely available. We describe the incidence of pericarditis and myocarditis by age categories and sex after COVID-19 mRNA vaccination from a nationwide mass vaccination programme in Singapore. METHODS: The incidence of adjudicated cases of pericarditis and myocarditis following COVID-19 mRNA vaccination that were reported to the vaccine safety committee between January to July 2021 was compared with the background incidence of myocarditis in Singapore. RESULTS: As of end July 2021, a total of 34 cases were reported (9 pericarditis only, 14 myocarditis only, and 11 concomitant pericarditis and myocarditis) with 7,183,889 doses of COVID-19 mRNA vaccine administered. Of the 9 cases of pericarditis only, all were male except one. The highest incidence of pericarditis was in males aged 12-19 years with an incidence of 1.11 cases per 100,000 doses. Of the 25 cases of myocarditis, 80% (20 cases) were male and the median age was 23 years (range 12-55 years) with 16 cases after the second dose. A higher-than-expected number of cases were seen in males aged 12-19 and 20-29 years, with incidence rates of 3.72 and 0.98 case per 100,000 doses, respectively. CONCLUSION: Data from the national registry in Singapore indicate an increased incidence of pericarditis and myocarditis in younger men after COVID-19 mRNA vaccination.
Sclerotic skin disease development following COVID-19 vaccination.
Case Report: Hypergranular Platelets in Vaccine-Induced Thrombotic Thrombocytopenia After ChAdOx1 nCov-19 Vaccination. BACKGROUND: Vaccine-induced thrombotic thrombocytopenia (VITT) post SARS-CoV-2 vaccination is characterized by thrombocytopenia and severe thrombosis. Platelet function during patient recovery in the medium-/long-term has not been investigated fully. Here, we undertook a 3-month study, assessing the recovery of a VITT patient and assessing platelet morphology, granule content and dense-granule release at two distinct time points during recovery. CASE PRESENTATION: A 61 year-old female was admitted to hospital 15 days post ChAdOx1 nCov-19 vaccination. Hematological parameters and peripheral blood smears were monitored over 3 months. Platelet morphology and granule populations were assessed using transmission electron microscopy (TEM) at two distinct time points during recovery, as was agonist-induced platelet dense-granule release. Upon admission, the patient had reduced platelet counts, increased D-dimer and high anti-PF4 antibodies with multiple sites of cerebral venous sinus thrombosis (CVST). Peripheral blood smears revealed the presence of large, hypergranular platelets. Following treatment, hematological parameters returned to normal ranges over the study period. Anti-PF4 antibodies remained persistently high up to 90 days post-admission. Two days after admission, VITT platelets contained more granules per-platelet when compared to day 72 and healthy platelets. Additionally, maximal ATP release (marker of dense-granule release) was increased on day 2 compared to day 72 and healthy control platelets. CONCLUSION: This study highlights a previously unreported observation of platelet hypergranularity in VITT which may contribute to the thrombotic risk associated with VITT. Optimal approaches to monitoring recovery from VITT over time remains to be determined but our findings may help inform therapeutic decisions relating to anticoagulation treatment in this novel pathology.
Alopecia areata after COVID-19 vaccination. The coronavirus disease 2019 (COVID-19) vaccines are authorized for use in numerous countries worldwide. Several cutaneous findings are reported

after severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) vaccination. Here, we report the case of a patient with a rapid onset of alopecia areata immediately after receiving the second dose of the COVID-19 vaccine. Alopecia areata is a common autoimmune disease leading to non-scarring hair loss. Among the many cutaneous adverse effects reported after the anti-SARS-COV2 vaccination, no episodes of alopecia areata have been described to date. In this paper, we report the first case of alopecia areata after COVID-19 vaccination described in the literature with a revision of cases of alopecia areata reported after other types of vaccination. Although the significance of these skin reactions is not yet known, further studies will certainly clarify whether the development of alopecia areata or other forms of immune-mediated reactions could represent a positive prognostic factor regarding immune protection from SARS-CoV-2.

The risk of confusion between AstraZeneka COVID-19 vaccine side effects and signs of COVID-19 infection: a case report. Post-vaccination side effects of AstraZeneca (AZ) coronavirus disease 2019 (COVID-19) vaccine are common. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) infection immediately after the first dose of AZ COVID-19 vaccine has not been reported. In this case, a 30-year-old female without a past medical history of SARS-CoV2 infection presented to an outpatient clinic with lightheadedness and weakness 2 hours after getting the first dose of the AZ COVID-19 vaccine. Blood pressure (BP) was 80/60 mm Hg, and oxygen saturation (SpO(2)) was 98%. After administering normal saline intravenous fluid, the BP was 110/80 mm Hg. On the first day, fever (oral temperature of 39â„ƒ), sweating, dry cough, sore throat, and injection-site pain were presented. On the second day, diarrhea, productive cough, and hypotension occurred in addition to fever (oral temperature of 39.9â„ƒ). The fever did not stop and productive cough, change in smell, and fatigue were reported. SpO(2) was 96%. On the third day, no abnormality of the spiral lung computed tomography and the positive reverse transcriptase-polymerase chain reaction (RT-PCR) test were reported. Simultaneously, two out of three members of the family became symptomatic on the second day and their RT-PCR tests were positive. Dexamethasone ampule, Cefixime tablet, Acetaminophen tablet, and Diphenhydramine syrup were prescribed. After a week, fever subsided and SpO(2) was 98%. After 3 weeks of self-quarantine at home, her general condition improved. Despite the similarity between SARS-CoV2 infection signs and symptoms and AZ COVID-19 vaccine side effects, none of the approved vaccines contain the live virus that causes disease. Therefore, any unusual post-vaccination signs and symptoms should not be attributed to the vaccine itself and need to be considered for further evaluations and early actions in order to prevent the spread of the disease in society.

Severity of adverse reactions is associated with T-cell response in mRNA-1273 vaccinated health care workers. Knowledge about mRNA-1273 elicited T-cell response is limited. We investigated adverse reactions and interferon gamma release by specific T-cells among mRNA-1273 vaccinated health care workers. Seven to 13 weeks after complete vaccination low levels of specific T-cells were detected not correlating with antibody response. Severity of symptoms after first and number of symptoms after second immunization were associated with T-cell response. Assessment of T-cell response in addition to antibody response is crucial because even few specific T-cells could add to protection against infection. Investigation of mRNA-1273 induced inflammatory processes might help improve reactogenicity and immunogenicity.

Factors associated with side effects of COVID-19 vaccine in Indonesia. PURPOSE: As coronavirus disease 2019 (COVID-19) continues to spread rapidly causing approximately 186 million confirmed cases around the world, the urgency to reach herd immunity through vaccination is increasing. However, vaccine safety is a top priority to limit the occurrence of adverse events. Henceforth, this study aims to recognize and perceive COVID-19 vaccine safety in Indonesia during the pandemic. MATERIALS AND METHODS: This is a cross-sectional study and was conducted in Indonesia during the

COVID-19 pandemic using an online survey of demographic information and a qualitative questionnaire. Responses were recorded and the association between demographic characteristics from survey questions was tested using chi-square with a risk estimate and 95% confidence interval. RESULTS: A total of 311 participants from 33 out of 34 provinces in Indonesia participated in this study. Recorded responses showed multiple side effects of the COVID-19 vaccine both short- and long-term experienced by the participants. Significant associations were found between demographic factors and COVID-19 vaccine side effects such as female gender with short-term puncture site (odds ratio [OR], 0.463; 95% confidence interval [CI], 0.263-0.816) and short-term other reactions (OR, 0.463; 95% CI, 0.263-0.816), domicile outside Java island with long-term puncture site (OR, 4.219; 95% CI, 1.401-12.701) and immune reactions (OR, 3.375; 95% CI, 1.356-8.398), also between married marital status and long-term vagal reaction (OR, 4.655; 95% CI, 1.321-16.409). CONCLUSION: Gender, domicile and marital status factors were associated with COVID-19 vaccine side effects in Indonesian people.
Post-COVID-19 vaccination shoulder abscess and pleuroparenchymal pulmonary lesion due to Burkholderia pseudomallei.
Clinical recrudescence of chronic untreated P. malariae infection after BNT162b2 CoVID-19 vaccine. We described a case of clinical reactivation of chronic P. malariae infection following CoVID-19 vaccination with BNT162b2 (Pifzer-Biontech CoVID-19 vaccine) in a 48-year old Italian man.The patient came to our attention for fever of unknown origin show a quartan pattern (every third day) associated to splenomegaly, the onset of the fever occurred one month after CoVID-19 vaccination with BNT162b2. P. malariae was diagnosed using Carestartâ„¢ malaria rapid test and Polymerase-Chain Reaction. Post-vaccine transient reduction of immune reactivity is described in literature, although the mechanism is unknown.
Interstitial lung disease after receiving the mRNA-based COVID-19 vaccine tozinameran. Tozinameran, a messenger ribonucleic acid (mRNA)-based coronavirus disease 19 (COVID-19) vaccine, has a favorable safety profile and is highly efficacious in preventing COVID-19. Adverse reactions such as pain at the vaccination site, fever, malaise, headache, rash, and anaphylaxis have been commonly reported for mRNA-based COVID-19 vaccines. We report a case involving a 71-year-old Japanese woman who developed interstitial lung disease (ILD) after receiving an mRNA-based COVID-19 vaccine. We also review case reports of COVID-19 mRNA vaccine-associated ILD. Dyspnea or hypoxia that develops within 1-3 days after COVID-19 mRNA vaccination should be differentiated from ILD. Further studies to elucidate mechanisms and risk factors of rare adverse reactions such as ILD are warranted.
Acute Myocardial Infarction After Coronavirus Vaccine: A Rare Adverse Effect. A 61-year-old male presented to the emergency department with left arm and jaw pain for three hours which started 90 minutes after receiving the first dose of Moderna vaccine for coronavirus disease 2019 (COVID-19). He had a prior history of ischemic heart disease. Initial investigations confirmed the diagnosis of acute coronary syndrome. The patient was managed for non-ST-elevation myocardial infarction and percutaneous coronary intervention to the right posterior descending artery was done, and he was discharged after two days of hospital stay. As the patient was doing well for many years and was compliant with medications, this event was likely triggered by the coronavirus vaccine. Healthcare providers should be aware of the side effects of the vaccine and further investigations should be carried out in high-risk patients before vaccination. However, worldwide coronavirus vaccination programs play a significant role to halt this pandemic and these rare adverse side effects of the vaccine should never discourage people from the vaccination but monitoring of evolving data by the concerned authorities is very important so that these events can be prevented in future.

Widespread Arterial Thrombosis after ChAdOx1 nCov-19 Vaccination. Vaccine-induced thrombotic thrombocytopenia is an uncommon complication of COVID-19 vaccines using adenovirus mRNA carriers and has been associated with thrombosis of the cerebral venous sinuses and portal system. We report a case of a 69-year-old woman admitted to the intensive care unit due to stroke caused by thrombosis of the right carotid artery 9 days after receiving the ChAdOx1 nCov-19 vaccine. Further investigations demonstrated multiple thrombi in the arterial tree in the absence of any venous involvement. The clinical course and the treatment are described and discussed.

Retinal hemorrhage of late post-COVID-19 and post-vaccine-related pathogenic mechanisms: A new challenge for ophthalmologist in COVID era. COVID-19 infection results in extensive organ dysfunction. Thrombotic problems linked to COVID-19 disease are common and can affect the retina. We will report a case of retina hemorrhage with possibility of linkage between COVID-19 infection and immunization to determine whether these abnormalities are causal or coincidental.

Impact on HIV-1 RNA Levels and Antibody Responses Following SARS-CoV-2 Vaccination in HIV-Infected Individuals. This study aims to assess the immunological response and impact on virological control of the mRNA vaccines for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) among people living with HIV (PLWH). In this single-center observational study, all PLWH were offered vaccination with mRNA1273 or BNT162b2. Both anti-N and anti-S1-receptor binding domain (RBD) antibodies were measured together with HIV-1 RNA levels after the first dose (M0) and then at 1 (M1), 2 (M2) and 6 (M6) months later. A total of 131 individuals (median age: 54 years [IQR: 47.0-60.5]; male: 70.2%; median baseline CD4 T-cell: 602/Âµl [IQR 445.0-825.5]; median nadir CD4 T-cells 223/Âµl [IQR 111.0-330.0]) were included. All participants were positive for anti-RBD antibodies at 30 days, 60 days and 6 months after the first dose, with no statistical difference between those with HIV-1 RNA below or >20 copies/ml. HIV-1 RNA data were collected for 128 patients at baseline and 30 days after the first dose; for 124 individuals, 30 days after the second dose; and for 83 patients, 6 months after the first dose. Nineteen (14.8%) of 128 had detectable HIV-1 RNA (>20 copies/ml) at M0, 13/128 (10.2%) at M1 (among which 5 were newly detectable), 15/124 (12.1%) at M2 (among which 5 were newly detectable), and 8/83 (9.6%) at M6. No serious adverse effects were reported. All participants elicited antibodies after two doses of mRNA vaccines, with only a minor impact on HIV-1 RNA levels over a 6-month period.

Influence of Aerosol Delivered BCG Vaccination on Immunological and Disease Parameters Following SARS-CoV-2 Challenge in Rhesus Macaques. The tuberculosis vaccine, Bacille Calmette-Guerin (BCG), also affords protection against non-tuberculous diseases attributable to heterologous immune mechanisms such as trained innate immunity, activation of non-conventional T-cells, and cross-reactive adaptive immunity. Aerosol vaccine delivery can target immune responses toward the primary site of infection for a respiratory pathogen. Therefore, we hypothesised that aerosol delivery of BCG would enhance cross-protective action against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection and be a deployable intervention against coronavirus disease 2019 (COVID-19). Immune parameters were monitored in vaccinated and unvaccinated rhesus macaques for 28 days following aerosol BCG vaccination. High-dose SARS-CoV-2 challenge was applied by intranasal and intrabronchial instillation and animals culled 6-8 days later for assessment of viral, disease, and immunological parameters. Mycobacteria-specific cell-mediated immune responses were detected following aerosol BCG vaccination, but SARS-CoV-2-specific cellular- and antibody-mediated immunity was only measured following challenge. Early secretion of cytokine and chemokine markers associated with the innate cellular and adaptive antiviral immune response was detected following SARS-CoV-2 challenge in vaccinated animals, at concentrations that exceeded titres measured in unvaccinated macaques. Classical CD14+ monocytes and VÎ´2 Î³Î´ T-cells quantified by whole-blood immunophenotyping increased rapidly in vaccinated animals following SARS-CoV-2

challenge, indicating a priming of innate immune cells and non-conventional T-cell populations. However, viral RNA quantified in nasal and pharyngeal swabs, bronchoalveolar lavage (BAL), and tissue samples collected at necropsy was equivalent in vaccinated and unvaccinated animals, and in-life CT imaging and histopathology scoring applied to pulmonary tissue sections indicated that the disease induced by SARS-CoV-2 challenge was comparable between vaccinated and unvaccinated groups. Hence, aerosol BCG vaccination did not induce, or enhance the induction of, SARS-CoV-2 cross-reactive adaptive cellular or humoral immunity, although an influence of BCG vaccination on the subsequent immune response to SARS-CoV-2 challenge was apparent in immune signatures indicative of trained innate immune mechanisms and primed unconventional T-cell populations. Nevertheless, aerosol BCG vaccination did not enhance the initial clearance of virus, nor reduce the occurrence of early disease pathology after high dose SARS-CoV-2 challenge. However, the heterologous immune mechanisms primed by BCG vaccination could contribute to the moderation of COVID-19 disease severity in more susceptible species following natural infection.

Branch Retinal Vein Occlusion after Messenger RNA-Based COVID-19 Vaccine. Two days after the second dose of the messenger RNA-based COVID-19 vaccine (BNT162b2), a healthy 38-year-old man developed branch retinal vein occlusion (BRVO) in his left eye (OS). His previous medical history was unremarkable and he was a nonsmoker. His blood pressure was 117/78 mm Hg. Blood examination did not suggest thrombophilia. His best-corrected visual acuity (BCVA) was 0.9 OS with myopic correction. A fundus examination showed a retinal hemorrhage and cotton wool spots in the superotemporal region of the posterior pole OS. Optical coherence tomography macular scans showed subfoveal fluid accumulation and retinal thickening in the superior macular region OS. Two intravitreal injections of aflibercept were administered 2 months apart. By 7 months after the initial visit, the BCVA was 1.2 OS and the retinal hemorrhage and macular edema have resolved. BRVO can be seen after BNT162b2 vaccinations. Because the third doses of the vaccine are beginning to be administered more widely, ocular complications including RVO can develop and require attention.

Predictive Model for Adverse Events and Immune Response Based on the Production of Antibodies After the Second-Dose of the BNT162b2 mRNA Vaccine. BACKGROUND: The BNT162b mRNA vaccine for coronavirus disease 2019, which is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), mimics the immune response to natural infection. Few studies have predicted the adverse effects (AEs) after the second-dose vaccination. We present a predictive model for AEs and immune response after the second-dose of the BNT162b mRNA vaccine. METHODS: To predict AEs, 282 healthcare workers (HCWs) were enrolled in this prospective observational study. The classification and regression tree (CART) model was established, and its predictive efficacy was assessed. To predict immune response, 282 HCWs were included in the analysis. Moreover, the factors affected by anti-SARS-CoV-2 spike protein RBD antibody (s-IgG) were evaluated using serum samples collected 2 months after the second-dose vaccination. The s-IgG level was assessed using Lumipulse G1200. Multiple regression analyses were conducted to evaluate variables associated with anti-s-IgG titer levels. RESULTS: The most common AEs after the second-dose vaccination were pain (87.6%), redness (17.0%) at the injection site, fatigue (68.8%), headache (53.5%), and fever (37.5%). Based on the CART model, headache after the first-dose vaccination and age < 30 years were identified as the first and second discriminators for predicting the headache after the second-dose vaccination, respectively. In the multiple linear regression model, anti-s-IgG titer levels were associated with age, female sex, and AEs including headache and induration at the injection site after the second-dose vaccination. CONCLUSION: Headache after the first-dose vaccination can be a predictor of headache after the second-dose vaccination, and AEs are indicators of immune response.

Acquired thrombotic thrombocytopenic purpura: A rare disease associated with BNT162b2 vaccine: Reply to comment from Doyle et al.

Acquired thrombotic thrombocytopenic purpura: A rare disease associated with BNT162b2 vaccine: Comment from Doyle et al.
A case of herpes zoster ophthalmicus after third dose of Comirnaty (BNT162b2 mRNA) vaccine.
"Large-vessel vasculitis following the Pfizer-BioNTech COVID-19 vaccine": comment.
Acute Vulvar Aphthous Ulceration After COVID-19 Vaccination: 3 Cases. OBJECTIVE: We present a case series of acute vulvar aphthosis immediately following COVID-19 vaccination. MATERIALS AND METHODS: We describe 3 cases of acute vulvar aphthosis following Pfizer Comirnaty BNT162b2 mRNA and AstraZeneca (Vaxzevria) ChAdOx1 nCoV-19 COVID-19 vaccination in adolescent girls. RESULTS: All patients developed vulvar aphthosis within a few days after receiving COVID-19 vaccination. The onset of vulvar aphthosis was observed to correlate with the dosing schedule known to produce the highest likelihood of adverse effects, first dose in AstraZeneca (Vaxzevria) ChAdOx1 nCoV-19 and second dose in Pfizer Comirnaty BNT162b2 mRNA COVID-19 vaccine. Two patients required oral prednisolone and hospital admission for indwelling urinary catheterization due to urinary retention. Full disease resolution with no sequalae was achieved in all three patients. CONCLUSIONS: Clinicians should be aware of the possible risk of vulvar aphthosis after COVID-19 vaccine administration. Nevertheless, its occurrence should not prevent affected patients from receiving future doses of COVID-19 vaccines, as the mortality and morbidity of COVID-19 infection significantly outweigh the risk of vulvar aphthosis recurrence.
Relapsed and newly diagnosed Graves' disease due to immunization against COVID-19: A case series and review of the literature. In addition to genetic factors, environmental factors such as viruses are thought to be triggers in the development of autoimmune thyroid diseases (AITD) such as Graves' disease (GD). In this context, AITD cases that may be associated with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection or immunization have begun to be reported in increasing numbers. Although it is not clear by which pathogenetic mechanisms immunization against coronavirus disease 2019 (COVID-19) triggers the development of AITD, both the potential effect of the adjuvants in the vaccines and the cross-reactivity that can be generated by the molecular similarity of viral particles with mammalian proteins seem to be possible mechanisms. In this article, 7 GD patients consisting of relapsed and newly diagnosed cases following the COVID-19 vaccination were presented. Of these 7 cases, 5 (71.4%) were female, and the median age of the patients was 47 years (range, 31-53). One of the patients was associated with the inactivated COVID-19 vaccine, while the others were associated with the mRNA COVID-19 vaccine. The median post-vaccination symptom onset was 7 days (range, 4-30). Three of the patients had a history of GD and one had a history of Hashimoto's thyroiditis. Rapidly developing Graves' ophthalmopathy was detected in one patient. These cases are cautionary that GD and its extrathyroidal manifestations may develop in a short period after COVID-19 vaccination. When considered together with the literature review, the history of AITD in approximately half of the patients suggests that more attention should be paid to these patients in the post-vaccination period. Nevertheless, multicenter, prospective studies are needed to better understand this possible causal relationship.
Trajectory of SARS-CoV-2 anti-S IgG levels following transfusion and a third dose of BNT162b2 vaccine in a patient with massive postoperative bleeding: A case report. OBJECTIVE: Vaccination against SARS-CoV-2 has been shown to be effective in preventing infection and severe disease. Massive bleeding and transfusion after vaccination can lead to a decrease in the antibody level. The effect of an additional dose of vaccine after blood transfusion has not been described previously. In this case report, we report the SARS-CoV-2 anti-S IgG trajectory in a male patient who received a third dose of vaccine after a massive postoperative bleed and blood and plasma transfusion. CASE PRESENTATION: A 57-year-old male physician had a SARS-CoV-2 anti-S IgG level of 44 AU/mL, measured using the Lumipulse Presto chemiluminescence assay 3 months after receiving 2 doses of the BNT162b2

vaccine. The patient underwent a hemicolectomy for colon cancer, experienced massive postoperative bleeding, and required a transfusion. The patient's SARS-CoV-2 anti-S IgG level dropped to 9.2 AU/mL. A third dose of BNT162b2 vaccination was administered to reduce the risk of breakthrough infection. Fifteen days after receiving the third vaccine dose, the patient's SARS-CoV-2 anti-S IgG level increased to 421 AU/mL, likely to reflect protection. CONCLUSION: This report suggests that administering an extra dose of vaccine is useful for restoring protective antibody levels in vaccinated patients who experience massive postoperative bleeding.

Previous SARS-CoV-2 Infection, Age, and Frailty Are Associated With 6-Month Vaccine-Induced Anti-Spike Antibody Titer in Nursing Home Residents. OBJECTIVES: Older nursing home residents make up the population at greatest risk of morbidity and mortality from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. No studies have examined the determinants of long-term antibody responses post vaccination in this group. DESIGN: Longitudinal cohort study. SETTING AND PARTICIPANTS: Residents from 5 nursing homes assessed before vaccination, and 5Â weeks and 6Â months post vaccination, with the BNT162b2 messenger RNA SARS-CoV-2 vaccine. METHODS: Comprehensive clinical assessment was performed, including assessment for comorbidity, frailty, and SARS-CoV-2 infection history. Serum nucleocapsid and anti-spike receptor binding domain (RBD) antibodies were analyzed at all timepoints. An inÂ vitro angiotensin-converting enzyme (ACE2) receptor-spike RBD neutralization assay assessed serum neutralization capacity. RESULTS: Of 86 participants (81.1 Â± 10.8Â years; 65% female), just under half (45.4%; 39 of 86) had evidence of previous SARS-CoV-2 infection. All participants demonstrated a significant antibody response to vaccination at 5Â weeks and a significant decline in this response by 6Â months. SARS-CoV-2 infection history was the strongest predictor of antibody titer (log-transformed) at both 5Â weeks [Î²: 3.00; 95% confidence interval (CI): 2.32-3.70; P < .001] and 6Â months (Î²: 3.59; 95% CI: 2.89-4.28; P < .001). Independent of SARS-CoV-2 infection history, both age in years (Î²:Â -0.05; 95% CI:Â -0.08 toÂ -0.02; P < .001) and frailty (Î²:Â -0.22; 95% CI:Â -0.33 toÂ -0.11; P < .001) were associated with a significantly lower antibody titer at 6Â months. Anti-spike antibody titers at both 5Â weeks and 6Â months significantly correlated with inÂ vitro neutralization capacity. CONCLUSIONS AND IMPLICATIONS: In older nursing home residents, SARS-CoV-2 infection history was the strongest predictor of anti-spike antibody titers at 6Â months, whereas age and frailty were independently associated with lower titers at 6Â months. Antibody titers significantly correlated with inÂ vitro neutralization capacity. Although older SARS-CoV-2 naÃ¯ve nursing home residents may be particularly vulnerable to breakthrough SARS-CoV-2 infection, the relationship between antibody titers, SARS-CoV-2 infection, and clinical outcomes remains to be fully elucidated in this vulnerable population.

Real-world data about the side effects of SARS-CoV-2 vaccinations can be obtained only from representative samples undergoing comprehensive investigations.

Assessing humoral immune response after two doses of an inactivated SARS-CoV-2 vaccine (CoronaVac) in healthcare workers. OBJECTIVES: During COVID-19 pandemic, the absence of immunity in the population left them susceptible to infection with SARS-CoV-2; healthcare workers (HCWs) being in the highest risk group. This study intends to assess and follow up the humoral immunity in HCWs vaccinated with an inactive virus vaccine (CoronaVac). STUDY DESIGN: This is a prospective observational study. METHODS: A total of 1072 HCWs were investigated for the presence of immunoglobulin G antibodies to the receptor-binding domain of the S1 subunit of the spike protein of SARS-CoV-2 after vaccination. Blood samples were obtained after 28 days of the first dose, 21 days of the second dose, and 3 months after the second dose. Detection of antispike antibodies was performed by the chemiluminescent microparticle immunoassay method (SARS-CoV-2 IgG II Quant, Abbott, Ireland). The results greater than or equal to the cutoff value of 50.0 AU/mL were reported as positive. RESULTS: Four weeks after the first dose of vaccine, antispike antibodies were detected in

834/1072 (77.8%) of HCWs. Seropositivity was higher among females (84.6%) than males (70.6% pÂ <Â 0.001) and was found to be highest in both women and men between the ages of 18-34 years. Antispike antibodies were detected in 1008 of 1012 (99.6%) after 21 days of the second dose and in 803 of 836 (96.1%) after 3 months of the second dose. CONCLUSIONS: CoronaVac was found to be highly immunogenic after two consecutive doses performed 28 days apart to HCWs; however, the immunogenicity declined significantly (pÂ <Â 0.001) after 3 months following the second dose of vaccine.

B Cell Aplasia Is the Most Powerful Predictive Marker for Poor Humoral Response after BNT162b2 mRNA SARS-CoV-2 Vaccination in Recipients of Allogeneic Hematopoietic Stem Cell Transplantation. Little is known about the immune response to SARS-CoV-2 vaccination in recipients of allogeneic hematopoietic stem cell transplantation (allo-HSCT). However, several studies have reported that adequate protection could be provided to this population. The purpose of this study was to evaluate which factors can predict the efficacy of SARS-CoV-2 vaccination in these specifically immunosuppressed patients. Specific anti-Spike (S) antibody responses were assessed in a cohort of 117 allo-HSCT recipients after 2 injections of BNT162b2 mRNA SARS-CoV-2 vaccine (V1 and V2). Factors considered liable to influence the antibody response and analyzed in this series were the interval between allo-HSCT and V1, donor source, recipient and donor age, current immunosuppressive/chemotherapy (I/C) treatment, and levels of CD4(+)and CD8(+) T cells, B cells, and natural killer cells at the time of V1. Overall, the S-antibody response rate, evaluated at a median of 35 days after V2, was 82.9% for the entire cohort, with 71 patients (61%) reaching the highest titer. In univariate analysis, a lower pre-V1 median total lymphocyte count, lower CD4(+) T cell and B cell counts, ongoing I/C treatment, and a haploidentical donor were characteristic of nonhumoral responders. However, multiparameter analysis showed that B cell aplasia was the sole factor predicting the absence of a specific immune response (odds ratio, 0.01; 95% confidence interval, 0.00 to 0.10; P < 10(-3)). Indeed, the rate of humoral response was 9.1% in patients with B cell aplasia versus 95.9% in patients with a B cell count >0 (P < 10(-9)). These results advocate for the administration of anti-SARS-CoV-2 vaccination in allo-HSCT recipients as early as peripheral B cell levels can be detected, and also suggest the need for close monitoring of B-cell reconstitution after Allo-HSCT.

Diagnostic performance of two serological assays for the detection of SARS-CoV-2 specific antibodies: surveillance after vaccination. Massive vaccination programs are being carried out to limit the SARS-CoV-2 pandemic that started in December 2019. Serological tests are of major importance as an indicator of circulation of the virus and to assess how vaccine-induced immunity progresses. An Enzyme-Linked Immunosorbent Assay (ELISA) and a Lateral Flow Assay (LFA) have been developed based on the SARS-CoV-2 recombinant Receptor Binding Domain (RBD) and the combination of Spike and Nucleoprotein, respectively. The validation with 1272 serum samples by comparison with INgezim COVID 19 DR showed good diagnostic performance (sensitivity: 93.2%-97.2%; specificity: 98.3%-99.3%) for detection of previous contact with SARS-CoV-2. Moreover, according to our results, these assays can help in the serosurveillance during and after vaccination, by detecting the humoral immune response as soon as 15 days postvaccination and identifying low-respondents. Hence, these tests could play a key role in the progression to a COVID-19 free world, helping to adjust future vaccination protocols.

A global survey in the developmental landscape of possible vaccination strategies for COVID-19. The development of COVID-19 vaccines was promptly regulated to ensure the best possible approach. By January 2022, 75 candidates reached preclinical evaluation in various animal models, 114 vaccines were in clinical trials on humans, and 48 were in the final testing stages. Vaccine platforms range from whole virus vaccines to nucleic acid vaccines, which are the most promising in

prompt availability and safety. The USA and Europe have approved vaccines developed by Pfizer-BioNTech (BNT162b2) and Moderna (mRNa1273). So far, Pfizer-BioNTech, Moderna, Johnson & Johnson, AstraZeneca-University of Oxford, Sinopharm, Sinovac Biotech Gamaleya, Bharat Biotech, and Novavax have documented effective vaccines. Even with technological advances and a fast-paced development approach, many limitations and problems need to be overcome before a large-scale production of new vaccines can start. The Key is to ensure equal and fair distribution globally through regulatory measures. Recent studies link Bacillus Calmette-GuÃ©rin (BCG) vaccination programs and lower disease severity.

Seroconversion after anti-SARS-CoV-2 mRNA vaccinations among moderate-to-severe psoriatic patients receiving systemic biologicals-Prospective observational cohort study. It is unclear whether biological antipsoriatic therapies affect seroconversion after messenger ribonucleic acid (mRNA)-based antisevere acute respiratory syndrome coronavirus 2 (anti-SARS-CoV-2) vaccinations. To assess antibody formation and the incidence of side effects after anti-SARS-CoV-2 mRNA vaccinations in psoriatic patients receiving different biologicals compared to healthy controls. 102 moderate-to-severe psoriatic patients (56.2 [Â±13.5] years) and 55 age-matched healthy (56.4â€‰Â±â€‰13.6â€‰years) volunteers were included in our study. Ten to 21â€‰days after the administration of the second dosage of BNT162b2 or mRNA-1273 vaccine, antibody levels specific to the SARS-CoV-2 spike (S) protein receptor binding domain were monitored. The incidence of postvaccination side effects was recorded and compared to real-life data in the literature. Of the 102 patients, 57 (55.88%) received tumor necrosis factor (TNF), 28 (27.45%) received interleukin (IL)-12/23, 16 (15.68%) received IL-17, and 1 (0.99%) received IL-23 inhibitors. No significant differences in the median serum level of anti-SARS-CoV-2S antibody were observed between the study population and the control group (median IQR range: 1681.0Â U/mL (600.0-4844.0) versus 1984.0â€‰U/mL (1000.0-3136.0; pÂ =Â 0.82). The most frequent side effects of the mRNA vaccines within 7â€‰days after the administration of both dosages were arm pain on the side of injection (23.53% and 23.53%), fatigue (9.80% and 13.72%), headache (4.9% and 5.88%), and chills or shivering (4.9% and 8.82%). Detectable antibodies against SARS-CoV-2S protein appear 10-21â€‰days after the administration of the second dosage of BNT162b2 or mRNA-1273 vaccines in moderate-to-severe psoriatic patients receiving biologicals, similar to those of healthy controls.

Covid-19 vaccine associated erythema nodosum: Factors to consider.

Cutaneous reactions after coronavirus disease 2019 vaccination: Summary of 20 Japanese cases.

Cerebral venous thrombosis without thrombocytopenia after a single dose of COVID-19 (Ad26.COV2.S) vaccine injection: a case report. BACKGROUND: The coronavirus pandemic became the hard challenge for the modern global health system. To date, vaccination is the best strategy against Sars-Cov-2-related illness. About 3 billions of people received at least one of the approved vaccines. The related adverse events were reported during the various experimental phases, but newer and less common side effects are emerging post-marketing. Vaccine-induced thrombocytopenia with thrombosis (VITT) is one of these insidious adverse reactions and it is considered responsible of venous thrombosis, in both the splanchnic and the cerebral circulation. Although its mechanism has been presumably established, resembling that observed in heparin-induced thrombocytopenia, some venous thromboses seem not to recognize this etiology and their pathogenesis remains unknown. Here we described a case of cerebral venous thrombosis after administration of the Ad26.COV2.S, presenting without thrombocytopenia, paving the way for possible novel causes of this vaccine-induced pathological condition. CASE PRESENTATION: A 45-year-old woman came to our observation for bilateral periorbital headache associated with retro-orbital pain started 8Â days after administration of COVID vaccine Jannsen. Ophthalmologic exam showing a bilateral papilledema raised the suspicion of intracranial hypertension. Cerebral magnetic resonance

imaging revealed signal alteration with T1-positive contrast enhancement in the right temporal and insular lobes suggestive of cerebral venous thrombosis. The absence of thrombocytopenia and platelet factor 4 (PF-4) antibodies led the clinicians to rule out VITT. The patient was treated successfully with warfarin. CONCLUSION: Venous thrombosis occurring after COVID-19 vaccination represents an adverse event of special interest. Patients with thrombosis and thrombocytopenia appear to be affected by a general thrombophilic state, sustained by an autoimmune mechanism, and show a higher mortality. Thrombosis without thrombocytopenia's pathogenesis has not yet been clarified, but laboratory data and good response to vitamin K antagonists help clinicians in the differential diagnosis with VITT. Future research will allow us to discover other possible mechanisms and maybe identify a subgroup of patients with a higher risk of developing this medical complication.

Risk of disease relapse following COVID-19 vaccination in patients with AQP4-IgG-positive NMOSD and MOGAD. Post-vaccination disease relapses have been reported in patients with MOGAD and AQP4-IgG+NMOSD. In this retrospective multicenter Italian study we assessed the frequency of relapses after SARS-CoV-2 vaccination. We included 56 cases: MOGAD, 30; AQP4-IgG+NMOSD, 26. Vaccines received were BNT162b2-Pfizer-BioNTech in 42 patients and mRNA-1273-Moderna in 14 patients. Six patients had a history of SARS-CoV-2 infection; two of them experienced a post-infection disease relapse (MOGAD). The frequency of relapses within one month of SARS-CoV-2 vaccination was 4% (1/26) in the AQP4-IgG+NMOSD group and 0% in the MOGAD group. In these patients the potential benefits of vaccination overcome the risk of relapses.

Anti-Spike IgG in multiple sclerosis patients after BNT162b2 vaccine: An exploratory case-control study in Italy. BACKGROUND: Patients with neuroimmunological conditions such as multiple sclerosis (MS) often receive disease-modifying therapies (DMTs) or immunosuppressants which may reduce the response to vaccines. BNT162b2 (Pfizer-BioNTech) is the first COVID-19 vaccine authorized in Italy. Its clinical efficacy and serological response were not evaluated in MS patients receiving DMTs or immunosuppressants. This early multicenter study evaluated serological response to BNT162b2 and safety in these patients. METHODS: From February 2021 we enrolled consecutive MS patients, treated with at least one DMT and all healthcare workers (HCWs), having received or being scheduled to receive the first dose of BNT162b2. Blood samples were collected after the second vaccine dose and analyzed to quantitatively detect the presence of anti-Spike antibodies. Serological response was compared to the one from a control population of HCWs, with neither neuroimmunological conditions nor receiving immunosuppressants. Patients receiving treatments associated with a possible reduced response (Under-scrutiny treatment group) were also compared to those undergoing other treatments. Anti-Spike levels were described as median and interquartile range (IQR). Comparisons were performed with Wilcoxon-Mann-Whitney test. Solicited and unsolicited adverse events (AEs) were collected. RESULTS: 39 MS patients and a control population of 273 HCWs were included. One patient, under treatment with ocrelizumab, did not respond to BNT162b2, while all the remaining patients and all controls developed a serological response to the vaccine. Median anti-Spike levels were similar between patients (1471.0 BAU/ml; IQR 779.7 to 2357.0) and controls (1479.0 BAU/ml; IQR 813.1 to 2528.0) (pÂ =Â 0.53). Patients included in the Under-scrutiny treatments group showed reduced anti-Spike levels (156.4 BAU/ml; IQR 33.4 to 559.1) compared to those receiving other treatments (1582.4 BAU/ml; IQR 1296.5 to 2219.0) (pÂ =Â 0.001). Solicited AEs were all mild to moderate in severity, generally reported in the first days after vaccination, and resolved in the following days. Two MS patients reported a clinical relapse after the second vaccine dose. CONCLUSION: BNT162b2 induced a serological response in MS patients treated with DMTs similar to controls not receiving DMTs or immunosuppressants. Some treatments were associated with reduced levels of anti-Spike antibodies in patients. These observations have relevant implications for treated patients receiving BNT162b2 and the community.

Newly diagnosed neuromyelitis optica spectrum disorders following vaccination: Case report and systematic review. INTRODUCTION: The pathogenesis of neuromyelitis optica spectrum disorder (NMOSD) has been vigorously illustrated, but triggers of the disease remain unclear. Viral infection and vaccination have been observed to precede certain cases of NMOSD. Amidst the Coronavirus disease 2019 (COVID-19) pandemic, mass vaccination takes place across the globe. We report two cases of newly diagnosed NMOSD following COVID-19 vaccination and systematically review previous reports. METHOD: Searching of Ovid MEDLINE and EMBASE databases was done using predefined search terms related to NMOSD and vaccination. Duplicates were removed. Newly diagnosed NMOSD cases fulfilling the 2015 International Panel for NMO Diagnosis criteria with symptoms presenting between 2-30 days after vaccination were included. Data on age, sex, comorbidity, vaccine name, type, and dose number, duration from vaccination to symptom onset, clinical phenotype(s), MRI findings, CSF profiles, severity of attack, initial and maintenance treatment, number of relapses after vaccination, and clinical outcomes were extracted using a standardized table and compared. RESULT: Ten cases of postvaccination NMOSD were identified. Patients aged between 15-46 years old. Nine patients (90%) presented with transverse myelitis and 3 (30%) with optic neuritis. The mean duration from vaccination to clinical onset was 8.2 days (median 9 days). Five patients (50%) tested positive for aquaporin 4 (AQP4) antibody. One patient had a family history of NMOSD. Three-fourths of AQP4-IgG seropositive patients with myelopathy had short transverse myelitis. The reported vaccines included CoronaVac, ChAdOx1 nCoV-19, yellow fever, quadrivalent influenza, H1N1 influenza, quadrivalent human papillomavirus, Japanese encephalitis, rabies, and recombinant hepatitis B virus together with tetanus-diphtheria-pertussis vaccines. All patients received high-dose steroids for initial treatment and 2 received additional therapeutic plasma exchange. Maintenance therapy was given in 4 patients. Five patients (50%) experienced no subsequent relapses within the follow-up period ranging between 3-34 months. Almost all patients returned to baseline functional status. DISCUSSION: The temporal relationship between vaccination and onset of symptoms suggests that vaccine might be a trigger of NMOSD. Genetic predisposition could be a risk factor for postvaccination NMOSD as there are evidences of family history and presence of an associated HLA allele. The prevalence of short-segment transverse myelitis seems to be higher than in typical cases of NMOSD, but the natural history is otherwise similar. All patients received acute treatment with high-dose corticosteroids, most with excellent response. Long-term immunomodulation therapy should be initiated for relapse prevention. Limitations of this study are lack of some relevant data, precision of temporal relationship, and the small number of reports. CONCLUSION: Postvaccination NMOSD is a rare condition that can occur with various types of vaccines. The short temporal relationship between vaccination and onset of NMOSD and the history of NMOSD in one patient's sibling indicate that vaccine might be a trigger for genetically predisposed individuals.

Vaccination in neuromyelitis optica spectrum disorders: Friend or enemy? Neuromyelitis optica spectrum disorders (NMOSDs) are uncommon antibody-mediated autoimmune diseases of the central nervous system (CNS), mainly occurring in optic nerves and spinal cord, which can cause visual impairment, paralysis, and occasionally bulbar dysfunction. Such neurological deficits can adversely affect pulmonary functions and increase complicated infection risk. Besides, most NMOSD patients undergo immunosuppressive therapy. All these factors make NMOSD patients the potential high-risk group under the current pandemic of coronavirus disease 2019 (COVID-19). Meanwhile, COVID-19 infection has already been demonstrated as a risk factor for NMOSD relapses. This review discusses the basic immunology of vaccination and common problems, including immunogenicity, safety, and efficacy of vaccination on NMOSD patients. Additionally, we offered vaccination recommendations, health care and treatment advice for NMOSD patients under the background of COVID-19.

Coronavirus disease 2019 messenger RNA vaccine skin tests and serum histamine levels in allergic reactions.
Immune parameters during anaphylaxis to messenger RNA coronavirus disease 2019 vaccines: Not the usual suspects?
Antibody responses following third mRNA COVID-19 vaccination in patients with cancer and potential timing of a fourth vaccination.
Reported cases of multisystem inflammatory syndrome in children aged 12-20 years in the USA who received a COVID-19 vaccine, December, 2020, through August, 2021: a surveillance investigation. BACKGROUND: Multisystem inflammatory syndrome in children (MIS-C) is a hyperinflammatory condition associated with antecedent SARS-CoV-2 infection. In the USA, reporting of MIS-C after vaccination is required under COVID-19 vaccine emergency use authorisations. We aimed to investigate reports of individuals aged 12-20 years with MIS-C after COVID-19 vaccination reported to passive surveillance systems or through clinician outreach to the US Centers for Disease Control and Prevention (CDC). METHODS: In this surveillance activity, we investigated potential cases of MIS-C after COVID-19 vaccination reported to CDC's MIS-C national surveillance system, the Vaccine Adverse Event Reporting System (co-administered by CDC and the US Food and Drug Administration), and CDC's Clinical Immunization Safety Assessment Project. A multidisciplinary team adjudicated cases by use of the CDC MIS-C definition. Any positive SARS-CoV-2 serology test satisfied case criteria; although anti-nucleocapsid antibodies indicate previous SARS-CoV-2 infection, anti-spike protein antibodies indicate either past or recent infection or COVID-19 vaccination. We describe the demographic and clinical features of cases, stratified by laboratory evidence of SARS-CoV-2 infection. To calculate the reporting rate of MIS-C, we divided the count of all individuals meeting the MIS-C case definition, and of those without evidence of SARS-CoV-2 infection, by the number of individuals aged 12-20 years in the USA who received one or more COVID-19 vaccine doses up to Aug 31, 2021, obtained from CDC national vaccine surveillance data. FINDINGS: Using surveillance results from Dec 14, 2020, to Aug 31, 2021, we identified 21 individuals with MIS-C after COVID-19 vaccination. Of these 21 individuals, median age was 16 years (range 12-20); 13 (62%) were male and eight (38%) were female. All 21 were hospitalised: 12 (57%) were admitted to an intensive care unit and all were discharged home. 15 (71%) of 21 individuals had laboratory evidence of past or recent SARS-CoV-2 infection, and six (29%) did not. As of Aug 31, 2021, 21â€‰335â€‰331 individuals aged 12-20 years had received one or more doses of a COVID-19 vaccine, making the overall reporting rate for MIS-C after vaccination 1Â·0 case per million individuals receiving one or more doses in this age group. The reporting rate in only those without evidence of SARS-CoV-2 infection was 0Â·3 cases per million vaccinated individuals. INTERPRETATION: Here, we describe a small number of individuals with MIS-C who had received one or more doses of a COVID-19 vaccine before illness onset; the contribution of vaccination to these illnesses is unknown. Our findings suggest that MIS-C after COVID-19 vaccination is rare. Continued reporting of potential cases and surveillance for MIS-C illnesses after COVID-19 vaccination is warranted. FUNDING: US Centers for Disease Control and Prevention.
Safety of Inactivated and mRNA COVID-19 Vaccination Among Patients Treated for Hypothyroidism: A Population-Based Cohort Study. Background: Thyroiditis and Graves' disease have been reported after coronavirus disease 2019 (COVID-19) vaccination. We evaluated the risks of adverse events after COVID-19 vaccination among patients treated for hypothyroidism. Methods: In this retrospective population-based cohort study of Hong Kong Hospital Authority electronic health records with the Department of Health vaccination records linkage, levothyroxine (LT4) users were categorized into unvaccinated, vaccinated with BNT162b2 (mRNA vaccine), or CoronaVac (inactivated vaccine) between February 23, 2021, and September 9, 2021. Study outcomes were dosage reduction or escalation in LT4, emergency department (ED) visit, unscheduled hospitalization, adverse events of

special interest (AESI) according to the World Health Organization's Global Advisory Committee on Vaccine Safety, and all-cause mortality. Inverse probability of treatment weighting for propensity score was applied to balance baseline patient characteristics among the three groups. Hazard ratios (HR) were estimated using Cox regression models. Patients were observed from the index date until the occurrence of study outcome, death, or censored on September 30, 2021, whichever came first. Results: In total, 47,086 LT4 users were identified (BNT162b2: nâ€‰=â€‰12,310; CoronaVac: nâ€‰=â€‰11,353; and unvaccinated: nâ€‰=â€‰23,423). COVID-19 vaccination was not associated with increased risks of LT4 dosage reduction (BNT162b2: HRâ€‰=â€‰0.971 [confidence interval; CI 0.892-1.058]; CoronaVac: HRâ€‰=â€‰0.968 [CI 0.904-1.037]) or escalation (BNT162b2: HRâ€‰=â€‰0.779 [CI 0.519-1.169]; CoronaVac: HRâ€‰=â€‰0.715 [CI 0.481-1.062]). Besides, COVID-19 vaccination was not associated with a higher risk of ED visits (BNT162b2: HRâ€‰=â€‰0.944 [CI 0.700-1.273]; CoronaVac: HRâ€‰=â€‰0.851 [CI 0.647-1.120]) or unscheduled hospitalization (BNT162b2: HRâ€‰=â€‰0.905 [CI 0.539-1.520]; CoronaVac: HRâ€‰=â€‰0.735 [CI 0.448-1.207]). There were two (0.016%) deaths and six (0.062%) AESI recorded for BNT162b2 recipients, and one (0.009%) and three (0.035%) for CoronaVac recipients, respectively. Conclusions: BNT162b2 or CoronaVac vaccination is not associated with unstable thyroid status or an increased risk of adverse outcomes among patients treated for hypothyroidism in general. These reassuring data should encourage them to get vaccinated against COVID-19 for protection from potentially worse COVID-19-related outcomes.

T Cell Response following Anti-COVID-19 BNT162b2 Vaccination Is Maintained against the SARS-CoV-2 Omicron B.1.1.529 Variant of Concern. The progression of the COVID-19 pandemic has led to the emergence of variants of concern (VOC), which may compromise the efficacy of the currently administered vaccines. Antigenic drift can potentially bring about reduced protective T cell immunity and, consequently, more severe disease manifestations. To assess this possibility, the T cell responses to the wild-type Wuhan-1 SARS-CoV-2 ancestral spike protein and the Omicron B.1.1.529 spike protein were compared. Accordingly, peripheral blood mononuclear cells (PBMC) were collected from eight healthy volunteers 4-5 months following a third vaccination with BNT162b2, and stimulated with overlapping peptide libraries representing the spike of either the ancestral or the Omicron SARS-CoV-2 virus variants. Quantification of the specific T cells was carried out by a fluorescent ELISPOT assay, monitoring cells secreting interferon-gamma (IFNg), interleukin-10 (IL-10) and interleukin-4 (IL-4). For all the examined individuals, comparable levels of reactivity to both forms of spike protein were determined. In addition, a dominant Th1 response was observed, manifested mainly by IFNg-secreting cells and only limited numbers of IL-10- and IL-4-secreting cells. The data demonstrate stable T cell activity in response to the emerging Omicron variant in the tested individuals; therefore, the protective immunity to the variant following BNT162b2 vaccination is not significantly affected.

Risk of Vaccine Breakthrough SARS-CoV-2 Infection and Associated Factors in Healthcare Workers of Trieste Teaching Hospitals (North-Eastern Italy). Background: Healthcare workers (HCWs) are particularly exposed to biological risk, including SARS-CoV-2 infection. In order to contrast the current pandemic and alleviate the burden of the disease on the healthcare system, a mass vaccination campaign against COVID-19 has been launched worldwide. Aim To evaluate the impact of COVID-19 vaccination in HCWs exposed to SARS-CoV-2, to describe the clinical presentation of COVID-19 in infected HCWs, and to investigate clinical and occupational risk factors for breakthrough infection. Design: Retrospective cohort study. Methods: The cohort of HCWs of Trieste Hospitals were followed up from 1 March 2020, to 30 November 2021 (21 months). All HCWs were periodically screened for SARS-CoV-2 infection by real-time PCR (RT-PCR) analysis. Clinical data were obtained through routine medical surveillance records. Risk factors for SARS-CoV-2 infection were investigated by univariable as well as multivariable logistic regression analysis. Results: Among 4394 HCWs routinely screened for

SARS-CoV-2 by PCR on nasopharyngeal swab, a total of 800 incident cases were identified during the entire study period (1 March 2020 to 30 November 2021). Five hundred and sixty-four cases occurred before, and 236 after the start of the vaccination campaign against COVID-19, of whom 155 received a complete vaccination scheme before SARS-CoV-2 infection. Breakthrough infection was featured by mild or no symptoms and was significantly associated with the male sex, BMI > 25, and diabetes mellitus. Some categories of HCWs (physicians and nurse aids/auxiliary personnel) were at a higher risk of breakthrough infection. Conclusions: Fully vaccinated HCWs were less likely to acquire symptomatic as well as asymptomatic SARS-CoV-2 infection. Risk factors for SARS-CoV-2 infection after a full COVID-19 vaccination scheme included the male gender, diabetes mellitus, and overweight. HCWs with higher exposure to COVID-19 patients were at higher risk of breakthrough infection.

Antibody Responses after SARS-CoV-2 Vaccination in Patients with Liver Diseases. The novel mRNA-based vaccines against SARS-CoV-2 display encouraging safety and efficacy profiles. However, there is a paucity of data regarding their immunogenicity and safety in patients with liver diseases (PWLD), especially in those with cirrhosis. We prospectively assessed anti-SARS-CoV-2 S-spike IgG antibodies and neutralizing activity in fully vaccinated PWLD (n = 87) and controls (n = 40). Seroconversion rates were 97.4% (37/38) in cirrhotic PWLD, 87.8% (43/49) in non-cirrhotic PWLD and 100% (40/40) in controls. Adequate neutralizing activity was detected in 92.1% (35/38), 87.8% (43/49) and 100% (40/40) of cirrhotics, non-cirrhotics and controls, respectively. On multivariable analysis, immunosuppressive treatment was negatively correlated with anti-SARS-CoV-2 antibody titers (coefficient (SE): -2.716 (0.634), $p < 0.001$) and neutralizing activity (coefficient (SE): -24.379 (4.582), $p < 0.001$), while age was negatively correlated only with neutralizing activity (coefficient (SE): -0.31(0.14), $p = 0.028$). A total of 52 responder PWLD were reassessed approximately 3 months post-vaccination and no differences were detected in humoral responses between cirrhotic and non-cirrhotic PWLD. No significant side effects were noted post vaccination, while no symptomatic breakthrough infections were reported during a 6-month follow up. Overall, our study shows that m-RNA-based SARS-CoV-2 vaccines are safe and efficacious in PWLD. However, PWLD under immunosuppressive treatment and those of advanced age should probably be more closely monitored after vaccination.

Venous Thrombosis within 30 Days after Vaccination against SARS-CoV-2 in a Multinational Venous Thromboembolism Registry. BACKGROUND: Venous thromboembolism (VTE)-including deep vein thrombosis, pulmonary embolism, and cerebral venous sinus thrombosis (CVST)-may occur early after vaccination against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). We sought to describe the site, clinical characteristics, and outcomes of VTE after vaccination against SARS-CoV-2. METHODS: In a prospective study using the Registro Informatizado de Enfermedad TromboEmbÃ³lica (RIETE) platform, patients with VTE 4-30 days after vaccination against SARS-CoV-2 (1 February 2021 through 30 April 2021) were included. VTE patients recruited from the same centers into RIETE in the same months in 2018-2019 were selected as the reference group. All-cause mortality and major bleeding were the main study outcomes. RESULTS: As of 30 April 2020, 102 patients with post-vaccination VTEs had been identified (28 after adenovirus-based vaccination [ChAdOx1 nCov-19; AstraZeneca] and 74 after mRNA-based vaccination [mRNA-1273; Moderna, and BNT162b2; Pfizer]). Compared with 911 historical controls, patients with VTE after adenovirus-based vaccination more frequently had CVST (10.7% vs. 0.4%, $p < 0.001$) or thrombosis at multiple sites (17.9% vs. 1.3%, $p < 0.001$), more frequently had thrombocytopenia (40.7% vs. 14.7%, $p < 0.001$), and had higher 14-day mortality (14.3% vs. 0.7%; odds ratio [OR]: 25.1; 95% confidence interval [CI]: 6.7-94.9) and major bleeding rates (10.3% vs. 1.0%, OR: 12.03, 95% CI: 3.07-47.13). The site of thrombosis, accompanying thrombocytopenia, and 14-day mortality rates were not significantly different for patients with VTE

after mRNA-based vaccination, compared with historical controls. CONCLUSIONS: Compared with historical controls, VTE after adenovirus-based vaccination against SARS-CoV-2 is accompanied by thrombocytopenia, occurs in unusual sites, and is associated with worse clinical outcomes.

Ocular Complications Following Vaccination for COVID-19: A One-Year Retrospective. Vaccination efforts as a mitigation strategy in the corona virus disease 2019 (COVID-19) pandemic are fully underway. A vital component of understanding the optimal clinical use of these vaccines is a thorough investigation of adverse events following vaccination. To date, some limited reports and reviews have discussed ocular adverse events following COVID-19 vaccination, but a systematic review detailing these reports with manifestations and clinical courses as well as proposed mechanisms has yet to be published. This comprehensive review one-year into vaccination efforts against COVID-19 is meant to furnish sound understanding for ophthalmologists and primary care physicians based on the existing body of clinical data. We discuss manifestations categorized into one of the following: eyelid, orbit, uveitis, retina, vascular, neuro-ophthalmology, ocular motility disorders, and other.

Association of SARS-CoV-2 Vaccinations with SARS-CoV-2 Infections, ICU Admissions and Deaths in Greece. The available coronavirus disease 2019 (COVID-19) vaccines have shown their effectiveness in clinical trials. We aimed to assess the real-world effects of SARS-CoV-2 vaccinations in Greece. We combined national data on vaccinations, SARS-CoV-2 cases, COVID-19-related ICU admissions and COVID-19-related deaths. We observed 3,367,673 vaccinations (30.68% of the Greek population), 278,821 SARS-CoV-2 infections and 7401 COVID-19-related deaths. The vaccination rate significantly increased from week 2 to week 6 by 85.70%, and from week 7 to 25 by 15.65%. The weekly mean of SARS-CoV-2 cases, COVID-19 ICU patients and COVID-19 deaths markedly declined as vaccination coverage accumulated. The rate of SARS-CoV-2 cases increased significantly from week 2 to week 13 by 16.15%, while from weeks 14-25 the rate decreased significantly by 13.50%. The rate of COVID-19-related ICU admissions decreased significantly by 7.41% from week 2 to week 4, increased significantly by 17.22% from weeks 5-11, then decreased significantly from weeks 17-20, by 11.99%, and from weeks 21-25, by 16.77%. The rate of COVID-19-related deaths increased significantly from week 2 to week 15 by 12.08% and decreased significantly by 16.58% from weeks 16-25. The data from this nationwide observational study underline the beneficial impact of the national vaccination campaign in Greece, which may offer control of the SARS-CoV-2 pandemic.

Homologous and Heterologous Anti-COVID-19 Vaccination Does Not Induce New-Onset Formation of Autoantibodies Typically Accompanying Lupus Erythematodes, Rheumatoid Arthritis, Celiac Disease and Antiphospholipid Syndrome. The COVID-19 pandemics has caused the death of almost six million people worldwide. In order to establish collective immunity, the first vaccines that were approved in Germany were the vector virus-based vaccine Vaxzevria and the mRNA vaccines Comirnaty and Spikevax, respectively. As it was reported that SARS-CoV-2 can trigger autoimmunity, it is of significant interest to investigate whether COVID-19 vaccines evoke the formation of autoantibodies and subsequent autoimmunity. Here, we analyzed immune responses after different vaccination regimens (mRNA/mRNA, Vector/Vector or Vector/mRNA) with respect to anti-SARS-CoV-2-specific immunity and the development of autoantibodies well known for their appearance in distinct autoimmune diseases. We found that anti-SARS-CoV-2 antibody levels were 90% lower after Vector/Vector vaccination compared to the other vaccinations and that Vector/mRNA vaccination was more effective than mRNA/mRNA vaccination in terms of IgM and IgA responses. However, until 4 months after booster vaccination we only detected increases in autoantibodies in participants with already pre-existing autoantibodies whereas vaccinees showing no autoantibody formation before vaccination did not respond with sustained autoantibody production. Taken together, our study suggests that all used COVID-19 vaccines do not significantly foster the appearance of autoantibodies

commonly associated with lupus erythematodes, rheumatoid arthritis, Celiac disease and antiphospholipid-syndrome but provide immunity to SARS-CoV-2.

Humoral Responses and Chronic GVHD Exacerbation after COVID-19 Vaccination Post Allogeneic Stem Cell Transplantation. The COVID-19 pandemic threatens patients with a compromised immune and endothelial system, including patients who underwent allogeneic stem cell transplantation (alloSCT). Thus, there is an unmet need for optimizing vaccination management in this high-risk cohort. Here, we monitored antibodies against SARS-CoV-2 spike protein (anti-S1) in 167 vaccinated alloSCT patients. Humoral immune responses were detectable in 81% of patients after two vaccinations with either mRNA-, vector-based, or heterologous regimens. Age, B-cell counts, time interval from vaccination, and the type of vaccine determined antibody titres in patients without systemic immunosuppression (sIS). Similar to a healthy control cohort, mRNA vaccine-based regimens induced higher titres than vector-based vaccines. Patients on two or more immunosuppressants rarely developed immunity. In contrast, 62% and 45% of patients without or on only one immunosuppressant, respectively, showed a strong humoral vaccination response (titre > 100). Exacerbation of cGVHD upon vaccination was observed in 6% of all patients and in 22% of patients receiving immunosuppression for cGVHD. cGVHD exacerbation and low antibody titres were both associated with higher angiopoietin-2 (ANG2) serum levels. In conclusion, mRNA-based vaccines elicit strong humoral responses in alloSCT patients in the absence of double sIS. Biomarkers such as ANG2 might help with weighing cGVHD risk versus beneficial responses.

Decline of Humoral Responses 6 Months after Vaccination with BNT162b2 (Pfizer-BioNTech) in Patients on Hemodialysis. This study analyzed binding and neutralizing antibody titers up to 6 months after standard vaccination with BNT162b2 (two doses of 30 Âµg each) in SARS-CoV-2 naÃ¯ve patients (n = 59) on hemodialysis. Humoral vaccine responses were measured before and 6, 12, and 24 weeks after the first vaccination. A chemiluminescent immunoassay (CLIA) was used to quantify SARS-CoV-2 IgG against the spike glycoprotein. SARS-CoV-2 neutralizing activity was tested against the wild-type virus. A multivariable binary regression model was used to identify risk factors for the absence of humoral immune responses at 6 months. At week 6, vaccine-specific seroconversion was detected in 96.6% of all patients with median anti-SARS-CoV-2 IgGs of 918 BAU/mL. At weeks 12 and 24, seroconversion rates decreased to 91.5% and 79.7%, and corresponding median binding antibody titers declined to 298 BAU/mL and 89 BAU/mL, respectively. Neutralizing antibodies showed a decay from 79.6% at week 6 to 32.8% at week 24. The risk factor with the strongest association for vanishing immune responses was low serum albumin (p = 0.018). Regarding vaccine-specific humoral responses 6 months after the standard BNT162b2 vaccination schedule, SARS-CoV-2 naÃ¯ve patients receiving hemodialysis must be considered at risk of becoming infected with SARS-CoV-2 and being infectious.

Aseptic Meningitis, Mucocutaneous Lesions and Arthritis after COVID-19 Vaccination in a 15-Year-Old Boy. We report a 15-year-old boy who developed aseptic meningitis 10 days after administration of the second dose of the COVID-19 vaccine BNT162b2. Although accompanying aphthous mouth ulcers resembling herpetic stomatitis initially led us to suspect an underlying viral infection, broad virological and microbiological screening did not identify any causative pathogen. Gonarthritis and skin lesions, which both developed within three days after admission, extended the clinical presentation eventually resembling an acute BehÃ§et's disease episode. This is the first description of a juvenile patient with aseptic and pathogen-negative meningitis occurring in close temporal association with vaccination against COVID-19, along with a few previously reported adult patients with isolated meningitis and a further case with meningitis and an accompanying BehÃ§et's disease-like multisystem inflammation episode as seen in our patient. With billions of individuals being vaccinated worldwide so far and only a few cases of aseptic pathogen-negative meningitis reported in

close temporal relation, causality is unclear. However, aseptic meningitis should be kept in mind in the differential diagnosis of patients with persistent or delayed onset of headache and fever following COVID-19 vaccination.

Demographic Characteristics and Status of Vaccinated Individuals with a History of COVID-19 Infection Pre- or Post-Vaccination: A Descriptive Study of a Nationally Representative Sample in Saudi Arabia. BACKGROUND: Saudi Arabia expedited the approval of some COVID-19 vaccines and launched mass vaccination campaigns. The aim of this study was to describe the demographics of vaccinated COVID-19 cases and compare the mortality rates of COVID-19 cases who were infected post-vaccination in Saudi Arabia. METHODS: This was a retrospective cohort study. We retrieved data for COVID-19 cases who were infected pre- or post-vaccination and had received at least one injection of the Oxford-AstraZeneca or Pfizer-BioNTech vaccine from 4 December 2020 to 15 October 2021. RESULTS: The number of patients who were infected and had received at least one dose of a COVID-19 vaccine was 281,744. Approximately 45% of subjects were infected post-vaccination, and 75% of subjects had received the Pfizer-BioNTech vaccine. Only 0.342% of the patients who were infected post-vaccination died, and 447 patients were admitted to ICUs. Most of the patients who were infected with COVID-19 post-vaccination and were admitted to ICUs (69.84%) had received only one dose of the vaccine ($p < 0.0001$). The mean time to infection for patients who had received one and two doses of the Oxford-AstraZeneca vaccine were 27 and 8 days longer than their counterparts who had received one and two doses of Pfizer-BioNTech vaccine, respectively. No difference in the odds of mortality between the Pfizer-BioNTech and Oxford-AstraZeneca vaccines was found (OR = 1.121, 95% CI = [0.907-1.386], p-value = 0.291). Patients who had received two doses of the vaccine had significantly lower odds of mortality compared to those who had received one dose ($p < 0.0001$). CONCLUSIONS: Vaccines are vital in combating the COVID-19 pandemic. The results of this study show no difference between the Pfizer-BioNTech and Oxford-AstraZeneca vaccines in the rate of mortality. However, the number of vaccine doses was significantly associated with a lower risk of mortality. Future studies should examine the effectiveness of different COVID-19 vaccines using real-world data and more robust designs.

Higher SARS-CoV-2 Spike Binding Antibody Levels and Neutralization Capacity 6 Months after Heterologous Vaccination with AZD1222 and BNT162b2. Within a year after the emergence of SARS-CoV-2, several vaccines had been developed, clinically evaluated, proven to be efficacious in preventing symptomatic disease, and licensed for global use. The remaining questions about the vaccines concern the duration of protection offered by vaccination and its efficacy against variants of concern. Therefore, we set out to analyze the humoral and cellular immune responses 6 months into homologous and heterologous prime-boost vaccinations. We recruited 190 health care workers and measured their anti-spike IgG levels, their neutralizing capacities against the Wuhan-Hu-1 strain and the Delta variant using a surrogate viral neutralization test, and their IFNÎ³-responses towards SARS-CoV-2-derived spike peptides. We here show that IFNÎ³ secretion in response to peptide stimulation was significantly enhanced in all three vaccination groups and comparable in magnitude. In contrast, the heterologous prime-boost regimen using AZD1222 and BNT162b2 yielded the highest anti-spike IgG levels, which were 3-4.5 times more than the levels resulting from homologous AZD1222 and BNT162b2 vaccination, respectively. Likewise, the neutralizing capacity against both the wild type as well as the Delta receptor binding domains was significantly higher following the heterologous prime-boost regimen. In conclusion, our results suggest that mixing different SARS-CoV-2 vaccines might lead to more efficacious and longer-lasting humoral protection against breakthrough infections.

Intensity and Dynamics of Anti-SARS-CoV-2 Immune Responses after BNT162b2 mRNA Vaccination: Implications for Public Health Vaccination Strategies. The aim of our study was to investigate the immunogenicity of the BNT162b2 vaccination according to the age and medical status of vaccinated

individuals. A total of 511 individuals were enrolled (median age: 54.0 years, range: 19-105); 509 of these individuals (99.6%) received two doses of BNT162b2 at an interval of 21 days. IgG and IgA responses were evaluated on days 21, 42, 90, and 180 after the first dose with chemiluminescent microparticle and ELISA assays. The cell-mediated immune responses were assessed by an automated interferon-gamma release assay. We demonstrated positive antibody responses after vaccination for the majority of enrolled participants, although waning of IgG and IgA titers was also observed over time. We further observed that the intensity of humoral responses was positively correlated with increased age and prior COVID-19 infection (either before or after the first vaccination). Moreover, we found that only a medical history of autoimmune disease could affect the intensity of IgA and IgG responses (3 weeks after the primary and secondary immunization, respectively), while development of systemic adverse reactions after the second vaccination dose was significantly associated with the height of IgG responses. Finally, we identified a clear correlation between humoral and cellular responses, suggesting that the study of cellular responses is not required as a routine laboratory test after vaccination. Our results provide useful information about the immunogenicity of COVID-19 vaccination with significant implications for public health vaccination strategies.
Adverse Events Reporting Quality of Randomized Controlled Trials of COVID-19 Vaccine Using the CONSORT Criteria for Reporting Harms: A Systematic Review. BACKGROUND: Assessing the quality of evidence from vaccine clinical trials is essential to ensure the safety and efficacy of the vaccine and further enhance public acceptance. This study aims to summarize and critically evaluate the quality of harm reporting on randomized controlled trials for the COVID-19 vaccine and determine the factors associated with reporting quality. METHODS: We systematically searched the literature using PRISMA guidelines for randomized controlled trials (RCT) on COVID-19 Vaccine until 30 December 2021. Published articles were searched from electronic databases such as PubMed, Science Direct, Google Scholar, and Bibliovid. Bias analysis was performed using RoB-2 tools. The quality of reporting was assessed by the Consolidated Standards of Reporting Trials (CONSORT) harm extension modified into 21 items. RESULTS: A total of 61 RCT studies (402,014 patients) were analyzed. Over half the studies demonstrated adequate reporting (59.02%), and 21 studies (34.4%) reported a low risk of bias. All studies reported death and serious adverse events (AEs), but only six studies mentioned how to handle the recurrent AEs. Reporting of AEs in subgroup analysis was also poor (25%). CONCLUSION: The RCTs on the COVID-19 vaccine were less biased with good quality on reporting harm based on the modified CONSORT harm extension. However, study quality must be considered, especially for a balance of information between effectivity and safety.
Death after the Administration of COVID-19 Vaccines Approved by EMA: Has a Causal Relationship Been Demonstrated? More than eight billion doses of COVID-19 vaccines have been administered globally so far and 44.29% of people are fully vaccinated. Pre-authorization clinical trials were carried out and the safety of vaccines is still continuously monitored through post-commercialization surveillance. However, some people are afraid of vaccine side effects, claiming they could lead to death, and hesitate to get vaccinated. Herein, a literature review of COVID-19-vaccine-related deaths has been carried out according to the PRISMA standards to understand if there is a causal relationship between vaccination and death and to highlight the real extent of such events. There have been 55 cases of death after COVID-19 vaccination reported and a causal relationship has been excluded in 17 cases. In the remaining cases, the causal link between the vaccine and the death was not specified (8) or considered possible (15), probable (1), or very probable/demonstrated (14). The causes of deaths among these cases were: vaccine-induced immune thrombotic thrombocytopenia (VITT) (32), myocarditis (3), ADEM (1), myocardial infarction (1), and rhabdomyolysis (1). In such cases, the demonstration of a causal relationship is not obvious, and more studies, especially with post-mortem investigations, are needed to deepen understanding

of the possible pathophysiological mechanisms of fatal vaccine side effects. In any event, given the scarcity of fatal cases, the benefits of vaccination outweigh the risks and the scientific community needs to be cohesive in asserting that vaccination is fundamental to containing the spread of SARS-CoV-2.

New-Onset Kidney Diseases after COVID-19 Vaccination: A Case Series. Various vaccines against COVID-19 have been developed and proven to be effective, but their side effects, especially on kidney function, are not yet known in detail. In this study, we report the clinical courses and histopathologic findings of new-onset kidney diseases after COVID-19 vaccination as confirmed via kidney biopsy. Five patients aged 42 to 77 years were included in this study, and baseline kidney function was normal in all patients. The biopsy-proven diagnosis indicated newly developed kidney diseases: (1) IgA nephropathy presenting with painless gross hematuria, (2) minimal change disease presenting with nephrotic syndrome, (3) thrombotic microangiopathy, and (4) two cases of acute tubulointerstitial nephritis presenting with acute kidney injury. Individualized treatment was applied as per disease severity and underlying pathology, and the treatment outcomes of all patients were improved. Since this is not a controlled study, the specific pathophysiologic link and causality between the incidence of kidney diseases and COVID-19 vaccination are difficult to confirm. However, clinicians need to consider the possibility that kidney diseases may be provoked by vaccines in patients who have renal symptoms.

Modelling SARS-CoV-2 Binding Antibody Waning 8 Months after BNT162b2 Vaccination. Several lines of evidence suggest that binding SARS-CoV-2 antibodies such as anti-SARS-CoV-2 RBD IgG (anti-RBD) and neutralising antibodies (NA) are correlates of protection against SARS-CoV-2, and the correlation of anti-RBD and NA is very high. The effectiveness (VE) of BNT162b2 in preventing SARS-CoV-2 infection wanes over time, and this reduction is mainly associated with waning immunity, suggesting that the kinetics of antibodies reduction might be of interest to predict VE. In a study of 97 health care workers (HCWs) vaccinated with the BNT162b2 vaccine, we assessed the kinetics of anti-RBD 30-250 days after vaccination using 388 individually matched plasma samples. Anti-RBD levels declined by 85%, 92%, and 95% at the 4th, 6th, and 8th month from the peak, respectively. The kinetics were estimated using the trajectories of anti-RBD by various models. The restricted cubic splines model had a better fit to the observed data. The trajectories of anti-RBD declines were statistically significantly lower for risk factors of severe COVID-19 and the absence of vaccination side effects. Moreover, previous SARS-CoV-2 infection was associated with divergent trajectories consistent with a slower anti-RBD decline over time. These results suggest that anti-RBD may serve as a harbinger for vaccine effectiveness (VE), and it should be explored as a predictor of breakthrough infections and VE.

Propensity-Score-Matched Evaluation of Adverse Events Affecting Recovery after COVID-19 Vaccination: On Adenovirus and mRNA Vaccines. This study aimed to observe adverse events following immunisation (AEFIs) that affected recovery within two weeks after COVID-19 vaccination and investigate their risks in propensity-score-matched populations. Data were collected from 447,346 reports from the VAERS between 1 January 2021 and 31 July 2021. Propensity-score-matched populations were constructed by adjusting for demographic characteristics and 11 underlying diseases in eligible subjects who received 1 of 3 COVID-19 vaccines: 19,462 Ad26.COV2.S, 120,580 mRNA-1273, and 100,752 BNT162b2. We observed that 88 suspected AEFIs (22 in Ad26.COV2.S, 62 in mRNA-1273, and 54 in BNT162b2) were associated with an increased risk of delayed recovery within 2 weeks after COVID-19 vaccinations. Nervous system, musculoskeletal and connective tissue, gastrointestinal, skin, and subcutaneous tissue disorders were the most common AEFIs after COVID-19 vaccination. Interestingly, four local and systemic reactions affected recovery in different vaccine recipients during our study period: asthenic conditions and febrile disorders in

Ad26.COV2.S and mRNA-1273; general signs and symptoms in mRNA-1273 and BNT162b2; injection site reactions in Ad26.COV2.S and BNT162b2. Although it is necessary to confirm a causal relationship with COVID-19 vaccinations, some symptoms, including paralysis, allergic disorders, breathing abnormalities, and visual impairment, may hinder the recovery of these recipients.

Significance of HLA Haplotypes in Two Patients with Subacute Thyroiditis Triggered by mRNA-Based COVID-19 Vaccine. Subacute thyroiditis (SAT) can be triggered by several viral factors in genetically predisposed individuals. In the case of COVID-19, SAT can be induced by SARS-CoV-2 infection as well as COVID-19 vaccination. The aim of this study was to present two cases of SAT triggered by mRNA-based COVID-19 vaccines, with special attention paid to the possible significance of HLA-related SAT susceptibility. In our patients, a strong similarity of HLA profiles with regard not only to SAT high-risk alleles but also to other SAT-unrelated ones was observed. The rare phenomenon of SAT occurrence after COVID-19 vaccination can be HLA-dependent and related to a co-presence of HLA-B*35:03 and -C*04:01. Taking into account the similarity of HLA profiles in both our patients, the co-presence of other alleles, such as HLA-A*03:01, -DQA1:01, DQB1*05:01 as well as some of HLA-DRB1, can also play a role. This hypothesis is strongly consistent with autoimmune/inflammatory syndrome induced by adjuvants (ASIA) being the postulated mechanism of this post-vaccine reaction, as ASIA-related immune reactions are directly associated with HLA-based genetic susceptibility. Further research is necessary to confirm these findings.

Post-Vaccination SARS-CoV-2 Infections among Health Workers at the University Hospital of Verona, Italy: A Retrospective Cohort Survey. BACKGROUND: The SARS-CoV-2 vaccination campaign began on 27 December 2020 in Europe, primarily involving health workers. This study aimed to assess the SARS-CoV-2 vaccination effectiveness, as assessed by reductions in incidence, symptom severity, and further infection spreading. METHODS: A retrospective cohort study was conducted on 9811 health workers operating at the Verona University Hospital, Italy, from 27 December 2020 to 3 May 2021. All health workers were offered vaccination with Comirnaty (BNT162b2, BioNTech/Pfizer, Mainz, Germany/New York, United States), and a health surveillance program was implemented with periodical swab testing. Vaccination status and clinical data were collected using an ad hoc semi-structured questionnaire and health surveillance charts. RESULTS: As of 3rd of May, 82.5% of health workers had been vaccinated against SAR-CoV-2, and 177 (1.8%) had tested positive for SARS-CoV-2. Vaccination more than halved the cumulative incidence of SARS-CoV-2 infection and reduced by two-thirds the cumulative incidence of symptomatic subjects. In detail, most unvaccinated HWs were symptomatic; 50% reported fever, 45% reported ageusia/anosmia, and nearly 20% reported dyspnea. These percentages were much lower in HWs who had been vaccinated for at least 14 days (18% for fever and anosmia, 6% for dyspnea and ageusia). Moreover, cases of vaccine breakthrough were sixfold less likely to further spread the infection than unvaccinated HWs. CONCLUSIONS: SARS-CoV-2 vaccination reduced the infection frequency among HWs, further spreading of the infection, and the presence, severity, and duration of COVID-19-related symptoms.

Metrics from Wearable Devices as Candidate Predictors of Antibody Response Following Vaccination against COVID-19: Data from the Second TemPredict Study. There is significant variability in neutralizing antibody responses (which correlate with immune protection) after COVID-19 vaccination, but only limited information is available about predictors of these responses. We investigated whether device-generated summaries of physiological metrics collected by a wearable device correlated with post-vaccination levels of antibodies to the SARS-CoV-2 receptor-binding domain (RBD), the target of neutralizing antibodies generated by existing COVID-19 vaccines. One thousand, one hundred and seventy-nine participants wore an off-the-shelf wearable device (Oura Ring), reported dates of COVID-19 vaccinations, and completed testing for antibodies to the SARS-CoV-2 RBD during the U.S. COVID-19 vaccination rollout. We found that on the night immediately

following the second mRNA injection (Moderna-NIAID and Pfizer-BioNTech) increases in dermal temperature deviation and resting heart rate, and decreases in heart rate variability (a measure of sympathetic nervous system activation) and deep sleep were each statistically significantly correlated with greater RBD antibody responses. These associations were stronger in models using metrics adjusted for the pre-vaccination baseline period. Greater temperature deviation emerged as the strongest independent predictor of greater RBD antibody responses in multivariable models. In contrast to data on certain other vaccines, we did not find clear associations between increased sleep surrounding vaccination and antibody responses.

Gender Differences in Adverse Events Following the Pfizer-BioNTech COVID-19 Vaccine. Background: The adverse events reported from the COVID-19 mRNA vaccines have varied from very mild, such as pain near the vaccination site, to more severe, with occasional anaphylaxis. Details of age-specific gender differences for the adverse effects are not well documented. Methods: Age and gender disaggregated data on reports of adverse events following two or three doses of the Pfizer-BioNTech COVID-19 vaccine were obtained from four cross-sectional studies. The first was from reports submitted to the Israel Ministry of Health national adverse events database (for ages 16 and above). The second was from a national cross-sectional survey based on an internet panel (for ages 30 and above), and the third and fourth were from cross-sectional surveys among employees of a large company (for ages 20-65) using links to a self-completed questionnaire. Results: In all studies, the risks of adverse events were higher following the second dose and consistently higher in females at all ages. The increased risk among females at all ages included local events such as pain at the injection site, systemic events such as fever, and sensory events such as paresthesia in the hands and face. For the combined adverse reactions, for the panel survey the female-to-male risk ratios (RRs) were 1.89 for the first vaccine dose and 1.82 for the second dose. In the cross-sectional workplace studies, the female-to-male RRs for the first, second and third doses exceeded 3.0 for adverse events, such as shivering, muscle pain, fatigue and headaches. Conclusions: The consistent excess in adverse events among females for the mRNA COVID-19 vaccine indicates the need to assess and report vaccine adverse events by gender. Gender differences in adverse events should be taken into account when determining dosing schedules.

Cerebral Venous Sinus Thrombosis following COVID-19 Vaccination: Analysis of 552 Worldwide Cases. To date, billions of vaccine doses have been administered to restrain the current COVID-19 pandemic worldwide. Rare side effects, including intravascular blood clots, were reported in the general population after vaccination. Among these, cerebral venous sinus thrombosis (CVST) has been considered the most serious one. To shed further light on such an event, we conducted a literature search for case descriptions of CVST in vaccinated people. Findings were analyzed with emphasis on demographic characteristics, type of vaccine, site of thrombosis, clinical and histopathological findings. From 258 potential articles published till September 2021, 41 studies were retrieved for a total of 552 patients. Of these, 492 patients (89.1%) had received AZD1222/Vaxzevria, 45 (8.2%) BNT162b2/CX-024414 Spikevax, 15 (2.7%) JNJ-78436735, and 2 (0.3%) Covishield vaccine. CVST occurred in 382 women and 170 men (mean aged 44 years), and the median timing from the shot was 9 days (range 2-45). Thrombi were predominantly seen in transverse (84%), sigmoid (66%), and/or superior sagittal (56%) sinuses. Brain injury (chiefly intracranial bleeding) occurred in 32% of cases. Of 426 patients with detailed clinical course, 63% were discharged in good clinical conditions, at times with variable neurological sequelae, whereas 37% deceased, largely due to brain injury. This narrative review confirmed CVST as a rare event after (adenoviral vector) COVID-19 vaccination, with a women/men rate ratio of 2.25. Though the pathogenesis of thrombosis is still under discussion, currently available histopathological findings likely indicate an underlying immune vasculitis.

Human Milk Antibodies after BNT162b2 Vaccination Exhibit Reduced Binding against SARS-CoV-2 Variants of Concern. SARS-CoV-2-specific antibody responses are engendered in human milk after BNT162b2 vaccination. However, the emergence of variants of concern (VOCs) raises concerns about the specificity of and potential cross-protection mediated by milk antibody responses, which are crucial for passive immunity transferred from breastfeeding mothers to their infants. In this study, we collected milk samples at three different time points pre- and post-vaccination, and measured milk IgA antibody binding to the receptor binding domain (RBD) of the original Wuhan-Hu-1 strain, and the four VOCs, namely Alpha, Beta, Gamma and Delta. We report a significant level of anti-RBD IgA in milk collected at 4-6 weeks after the second dose of vaccination compared to pre-vaccination. We observed around a 30% reduction in binding to most VOCs, including the major circulating Delta variant, compared to the original Wuhan-Hu-1 strain. As COVID-19 vaccines may take some time to be approved for infants, these individuals remain at risk for severe disease and rely mainly on transferred passive immunity. Our findings support the current recommendations for vaccinating lactating women with the aim of transferring mucosal immunity to breastfeeding infants.

Comparing SARS-CoV-2 Antibody Responses after Various COVID-19 Vaccinations in Healthcare Workers. Coronavirus disease 2019 (COVID-19) vaccination began for healthcare workers in South Korea at the end of February 2021. This study investigated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody responses after various COVID-19 vaccinations in healthcare workers. Blood specimens of 497 vaccinated healthcare workers were collected. Inoculated vaccines were ChAdOx1 (AstraZeneca/Oxford), BNT162b2 (Pfizer/BioNTech), JNJ-78436735 (Janssen), and mRNA-1273 (Moderna). Each specimen was tested for antibodies against SARS-CoV-2 using Elecsys Anti-SARS-CoV-2 S assay (Roche Diagnostics), SARS-CoV-2 IgG II Quant assay (Abbott), and R-FIND SARS-CoV-2 Neutralizing Antibody kit (SG medical Inc.). A questionnaire was used to investigate adverse events related to vaccination. We found that 99.5% of the subjects showed a 96-100% positive rate in all three antibody assays, regardless of the vaccine type. The antibody-positive rate of completed vaccination groups reached 96-100%, and antibody quantities significantly increased 2 weeks after vaccination. The antibody values measured approximately 3 months after BNT162b2 inoculation significantly correlated with adverse events.

Which Type of the Promising COVID-19 Vaccines Produces Minimal Adverse Effects? A Retrospective Cross-Sectional Study. Since the declaration of Coronavirus-2019 (COVID-19) as a pandemic by the World Health Organization (WHO), it was clear that vaccination is the best way to overcome it. Sinopharm, AstraZeneca and Pfizer were the first vaccines introduced to defeat it. To recognize the short-term adverse effects among Iraqi health care workers (HCWs) after vaccination, the three COVID-19 vaccines that are currently available in Iraq were compared. An online survey was distributed to Iraqi HCWs who had received at least one of the COVID-19 vaccines as part of a retrospective cross-sectional study. Data were statistically analyzed using SPSS. The total number of participants was 843. The majority of the participants (85.9%) were under 39 years old, with 78.8% of them being females. Around 60% of individuals had received the Pfizer vaccine. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) had infected 46.7% of the total participants. A total of 628 out of 843 participants experienced adverse effects after receiving the vaccine, accounting for 74.49% of the overall respondents. After receiving the COVID-19 vaccine, the vast majority of respondents who received the three vaccines experienced pain at the injection site (n = 800), while other side effects like headache, myalgia, tiredness and fever mainly appeared with Pfizer and AstraZeneca vaccines. Most of the reported adverse effects were tolerable and self-limited and they were linked to the AstraZeneca and Pfizer vaccines.

Cellular Immune Response after Vaccination in Patients with Cancer-Review on Past and Present Experiences. Patients with cancer are at particular risk for infection but also have diminished

vaccine responses, usually quantified by the level of specific antibodies. Nonetheless, vaccines are specifically recommended in this vulnerable patient group. Here, we discuss the cellular part of the vaccine response in patients with cancer. We summarize the experience with vaccines prior to and during the SARS-CoV-2 pandemic in different subgroups, and we discuss why, especially in patients with cancer, T cells may be the more reliable correlate of protection. Finally, we provide a brief outlook on options to improve the cellular response to vaccines.

Clinical Profiles and CMR Findings of Young Adults and Pediatrics with Acute Myocarditis Following mRNA COVID-19 Vaccination: A Case Series. Messenger RNA (mRNA) coronavirus disease of 2019 (COVID-19) vaccines have been recently associated with acute myocarditis, predominantly in healthy young males. Out of 231,989 vaccines administrated in our region (Marche, Italy), we report a case series of six healthy patients (four males and two females, 16.5 years old (Q1, Q3: 15, 18)) that experienced mRNA-COVID-19-vaccines side effects. All patients were hospitalized due to fever and troponins elevation following the second dose of an mRNA-based COVID-19 vaccine. Cardiovascular magnetic resonance (CMR) was performed 72-96 h after vaccination. All patients were treated with colchicine and ibuprofen. Myocarditis was prevalent in males. It was characterized by myocardial edema and late gadolinium enhancement (LGE) in the lateral wall of the left ventricle (LV). One patient showed sole right ventricular involvement, while the females presented with myopericarditis (myocarditis + pericardial effusion). All patients in our series had preserved LV ejection fraction and remained clinically stable during a relatively short inpatient hospital stay. One case presented with atrial tachycardia. At the follow-up, no significant CMR findings were documented after a three-month medical treatment. According to other recently published case series, our report suggests a possible association between acute myocarditis and myopericarditis with mRNA COVID-19 vaccination in healthy young adults and pediatric patients. Not only males are involved, while some arrhythmic manifestations are possible, such as atrial tachycardia. Conversely, we here highlight the benign nature of such complications and the absence of CMR findings after a three-month medical treatment with colchicine and ibuprofen.

Monitoring of SARS-CoV-2 Specific Antibodies after Vaccination. Vaccination is considered the most important measure to control the COVID-19 pandemic. Extensive follow-up studies with distinct vaccines and populations are able to promote robust and reliable data to better understand the effectiveness of this pharmacologic strategy. In this sense, we present data regarding binding and neutralizing (achieved by surrogate ELISA assay) antibodies throughout time, from vaccinated and previously infected (PI) health care workers (HCW) in Portugal. We analyzed serum samples of 132 HCW, who were vaccinated and with previous SARS-CoV-2 infection. Samples were collected before vaccination (baseline, M1), at second dose vaccine uptake (M2), and 25-70 days (M3) and 150-210 days (M4) after the second dose for vaccinated individuals. The IgG (anti-RBD/S) antibody geometric mean titers found on vaccinated HCW at M2 (GM = 116.1 BAU/mL; CI: 92.3-146.1) were significantly higher than those found on PI HCW at recruitment (M1) (GM = 35.9 BAU/mL; CI:15.4-83.4), and the neutralizing antibodies (nAb) were similar between these groups, of 93.2 UI/mL (95% CI 73.2-118.5) vs. 84.1 UI/mL (95% CI 40.4-155.9), respectively. We detected around 10-fold higher IgG (anti-RBD/S) antibodies titers in M3 when compared with M2, with a slight but significant decrease in titers from 36 days after the second dose vaccine uptake. The increase of nAb titers was correlated with IgG (anti-RBD/S) antibodies titers; however, in contrast to IgG (anti-RBD/S) antibodies titers, we did not detect a decrease in the nAb titer 36 days after a second vaccine dose uptake. At M4, a decrease of 8-fold in binding IgG (anti-RBD/S) and nAb was observed. No significant differences in antibody titers were observed by sex, age or chronic diseases. Our results suggest that IgG (anti-RBD/S) antibodies titers and nAb titers could be correlated, but an ongoing follow up of the cohort is required to better understand this correlation, and the duration of the immune response.

Reduced Titers of Circulating Anti-SARS-CoV-2 Antibodies and Risk of COVID-19 Infection in Healthcare Workers during the Nine Months after Immunization with the BNT162b2 mRNA Vaccine. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has had a tremendous impact on health services; hundreds of thousands of healthcare workers (HCWs) have died from coronavirus disease 2019 (COVID-19). The introduction of the BNT162b2 mRNA vaccine in Italy provided recipients with significant protection against COVID-19 within one to two weeks after the administration of the second of the two recommended doses. While the vaccine induces a robust T cell response, the protective role of factors and pathways other than those related to memory B cell responses to specific SARS-CoV-2 antigens remains unclear. This retrospective study aimed to evaluate the determinants of serological protection in a group of vaccinated HCWs (n = 793) by evaluating circulating levels of antiviral spike receptor-binding domain (S-RBD) antibodies during the nine-month period following vaccination. We found that 99.5% of the HCWs who received the two doses of the BNT162b2 vaccine developed protective antibodies that were maintained at detectable levels for as long as 250 days after the second dose of the vaccine. Multivariate analysis was performed on anti-S-RBD titers in a subgroup of participants (n = 173) that were evaluated twice during this period. The results of this analysis reveal that the antibody titer observed at the second time point was significantly related to the magnitude of the primary response, the time that had elapsed between the first and the second evaluation, and a previous history of SARS-CoV-2 infection. Of importance is the finding that despite waning antibody titers following vaccination, none of the study participants contracted severe COVID-19 during the observational period.

Visceral disseminated varicella zoster virus infection following COVID-19 vaccination in an allogeneic stem cell transplant recipient.

Omicron-Specific Cytotoxic T-Cell Responses After a Third Dose of mRNA COVID-19 Vaccine Among Patients With Multiple Sclerosis Treated With Ocrelizumab. IMPORTANCE: The SARS-CoV-2 variant B.1.1.529 (Omicron) escapes neutralizing antibodies elicited after COVID-19 vaccination, while T-cell responses might be better conserved. It is crucial to assess how a third vaccination modifies these responses, particularly for immunocompromised patients with readily impaired antibody responses. OBJECTIVE: To determine T-cell responses to the Omicron spike protein in anti-CD20-treated patients with multiple sclerosis (MS) before and after a third messenger RNA COVID-19 vaccination. DESIGN, SETTING, AND PARTICIPANTS: In this prospective cohort study conducted from March 2021 to November 2021 at the University Hospital Geneva, adults with MS receiving anti-CD20 treatment (ocrelizumab) were identified by their treating neurologists and enrolled in the study. A total of 20 patients received their third dose of messenger RNA COVID-19 vaccine and were included in this analysis. INTERVENTIONS: Blood sampling before and 1 month after the third vaccine dose. MAIN OUTCOMES AND MEASURES: Quantification of CD4 and CD8 (cytotoxic) T cells specific for the SARS-CoV-2 spike proteins of the vaccine strain as well as the Delta and Omicron variants, comparing frequencies before and after the third vaccine dose. RESULTS: Of 20 included patients, 11 (55%) were male, and the median (IQR) age was 45.8 (37.8-53.3) years. Spike-specific CD4 and CD8 T-cell memory against all variants were maintained in 9 to 12 patients 6 months after their second vaccination, albeit at lower median frequencies against the Delta and Omicron variants compared with the vaccine strain (CD8 T cells: Delta, 83.0%; 95% CI, 73.6-114.5; Omicron, 78.9%; 95% CI, 59.4-100.0; CD4 T cells: Delta, 72.2%; 95% CI, 67.4-90.5; Omicron, 62.5%; 95% CI, 51.0-89.0). A third dose enhanced the number of responders to all variants (11 to 15 patients) and significantly increased CD8 T-cell responses, but the frequencies of Omicron-specific CD8 T cells remained 71.1% (95% CI, 41.6-96.2) of the responses specific to the vaccine strain. CONCLUSIONS AND RELEVANCE: In this cohort study of patients with MS treated with ocrelizumab, there were robust T-cell responses recognizing spike proteins from the Delta and Omicron variants, suggesting that COVID-19 vaccination in patients

taking B-cell-depleting drugs may protect them against serious complications from COVID-19 infection. T-cell response rates increased after the third dose, demonstrating the importance of a booster dose for this population.

Rapid colloidal gold immunochromatographic assay for the detection of SARS-CoV-2 total antibodies after vaccination. An epidemic caused by the severe acute respiratory syndrome coronavirus (SARS-CoV-2) spread globally in just a few months. To prevent the further spread of the virus, millions of people around the world have been vaccinated for COVID-19. Although the plaque reduction neutralization test (PRNT) has become the gold standard method for determining neutralizing antibodies, this method has many limitations; therefore, there remains an urgent need for a quick and accurate technique to evaluate the immune efficacy of COVID-19 vaccines. Here, after the recombinant expression of the SARS-CoV-2 spike protein receptor binding domain (S-RBD), we established a colloidal gold immunochromatographic assay (GICA) based on the principle of a double antigen sandwich for the detection of total antibodies in sera. Under the developed conditions, the GICA was capable of the rapid detection of SARS-CoV-2 total antibodies within 15 min. In addition, the anti-S-RBD antibodies measured by the GICA had a good correlation with the results measured by ELISA, indicating that the GICA may be used as a rapid tool for the detection of neutralizing antibodies derived from SARS-CoV-2 infection. Clinical detection was performed using serum samples obtained from 40 subjects who had received their two doses of the COVID-19 vaccine and 20 unvaccinated serum samples. We found that our method had high sensitivity and specificity; therefore, our convenient and rapid GICA method could preliminarily evaluate the protection rate and effectiveness of vaccines by monitoring total antibody levels.

Identification of intrinsically disorder regions in non-structural proteins of SARS-CoV-2: New insights into drug and vaccine resistance. The outbreak of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) emerged in December 2019 and caused coronavirus disease 2019 (COVID-19), which causes pneumonia and severe acute respiratory distress syndrome. It is a highly infectious pathogen that promptly spread. Like other beta coronaviruses, SARS-CoV-2 encodes some non-structural proteins (NSPs), playing crucial roles in viral transcription and replication. NSPs likely have essential roles in viral pathogenesis by manipulating many cellular processes. We performed a sequence-based analysis of NSPs to get insights into their intrinsic disorders, and their functions in viral replication were annotated and discussed in detail. Here, we provide newer insights into the structurally disordered regions of SARS-CoV-2 NSPs. Our analysis reveals that the SARS-CoV-2 proteome has a chunk of the disordered region that might be responsible for increasing its virulence. In addition, mutations in these regions are presumably responsible for drug and vaccine resistance. These findings suggested that the structurally disordered regions of SARS-CoV-2 NSPs might be invulnerable in COVID-19.

Branch retinal vein occlusion in a healthy young man following mRNA COVID-19 vaccination. PURPOSE: To report a case of a branch retinal vein occlusion (BRVO) following mRNA COVID-19 vaccination. OBSERVATIONS: A 34-year-old healthy male presented with blurriness in the inferior visual field, intermittent photopsia, multiple retinal hemorrhages, dilated and tortuous retinal vessels, and cotton wools spots in the right eye. The clinical examination and ancillary tests confirmed the diagnosis of a right eye BRVO. The visual symptoms started 2 days following first dose COVID-19 vaccination with the BNT162b2 (Pfizer-BioNTech) mRNA vaccine. CONCLUSIONS AND IMPORTANCE: This is a rare case of BRVO in an otherwise healthy young man, presenting after vaccination for COVID-19 in the absence of other coagulable risk factors. As the literature on venous thrombosis after COVID-19 vaccinations remains sparse, it is critical to raise awareness that BRVO could be a vaccine-related thrombotic adverse event. We highlight that as more of the population is vaccinated, an increased incidence of BRVO may confirm the link to COVID-19 vaccination.

Glomerular endothelial injury following vaccination for SARS-CoV-2.
De novo IgA vasculitis following adenovirus-based SARS-CoV-2 vaccination.
Acute interstitial nephritis following SARS-CoV-2 vaccination.
Two cases of glomerular involvement after vaccination against COVID-19: epiphenomenon or causality?
De novo and relapsing necrotizing vasculitis after COVID-19 vaccination. We describe five cases of severe necrotizing vasculitis following the RNA-based vaccine for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), including four relapsing anti neutrophil cytoplasmic antibodies (ANCA) vasculitis, 27 days (1-60) after vaccination and one patient with quiescent chronic hepatitis B and de novo polyarteritis nodosa (PAN) 21 days after vaccination. Ten other cases were reported to the French national pharmacovigilance database: six patients with ANCA-associated vasculitis and four patients with PAN (first symptoms 19 days on average after vaccination). Five of these 10 patients developed kidney dysfunction. In conclusion, coronavirus disease 2019 (COVID-19) vaccines can be associated with de novo or recurrent ANCA vasculitis or PAN. Attention should be paid to patients with known ANCA vasculitis or patients with a history of hepatitis B infection.
Acquired Hemophilia A Developed Post COVID-19 Vaccine: An Extremely Rare Complication. Acquired hemophilia A (AHA) is a rare autoimmune bleeding disorder caused by circulating autoantibodies (inhibitor) directed against coagulation factor VIII (FVIII). We report a 39-year-old single female who presented to emergency department with sudden onset gross hematuria 10 days following her first dose of Pfizer-BioNTech severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA (coronavirus disease 2019 (COVID-19)) vaccine. Coagulation profile revealed isolated prolongation of the activated partial thromboplastin time due to FVIII deficiency with normal von Willebrand factor and activity. Mixing study revealed time-dependent inhibitor pattern that was successively identified as directed against FVIII using the Nijmegen-modified Bethesda assay. FVIII inhibitor in a titer of 17.2 Bethesda Units/mL was detected. While thrombosis is a frequent complication of severe COVID-19 infection, on the other hand, bleeding is rare in the setting of COVID-19 infection/vaccination with no anticoagulants. Till date, a couple of cases of acquired hemophilia developed after receiving mRNA derived COVID-19 vaccines (Pfizer-BioNTech SARS-CoV-2 mRNA vaccine and Moderna mRNA vaccines) had been reported. It is important to raise the awareness about this rare side effect that might be directly induced by the mRNA COVID-19 vaccine or that the vaccine could have triggered it in a genetically predisposed individual. We recommend considering screening for an inhibitor (by mixing study) in cases with otherwise unexplained onset hemorrhagic disorder and/or isolated activated partial thromboplastin time prolongation.
Are There Hidden Genes in DNA/RNA Vaccines? Due to the fast global spreading of the Severe Acute Respiratory Syndrome Coronavirus - 2 (SARS-CoV-2), prevention and treatment options are direly needed in order to control infection-related morbidity, mortality, and economic losses. Although drug and inactivated and attenuated virus vaccine development can require significant amounts of time and resources, DNA and RNA vaccines offer a quick, simple, and cheap treatment alternative, even when produced on a large scale. The spike protein, which has been shown as the most antigenic SARS-CoV-2 protein, has been widely selected as the target of choice for DNA/RNA vaccines. Vaccination campaigns have reported high vaccination rates and protection, but numerous unintended effects, ranging from muscle pain to death, have led to concerns about the safety of RNA/DNA vaccines. In parallel to these studies, several open reading frames (ORFs) have been found to be overlapping SARS-CoV-2 accessory genes, two of which, ORF2b and ORF-Sh, overlap the spike protein sequence. Thus, the presence of these, and potentially other ORFs on SARS-CoV-2 DNA/RNA vaccines, could lead to the translation of undesired proteins during vaccination. Herein, we discuss the translation of overlapping genes in connection with DNA/RNA vaccines. Two mRNA vaccine spike

protein sequences, which have been made publicly-available, were compared to the wild-type sequence in order to uncover possible differences in putative overlapping ORFs. Notably, the Moderna mRNA-1273 vaccine sequence is predicted to contain no frameshifted ORFs on the positive sense strand, which highlights the utility of codon optimization in DNA/RNA vaccine design to remove undesired overlapping ORFs. Since little information is available on ORF2b or ORF-Sh, we use structural bioinformatics techniques to investigate the structure-function relationship of these proteins. The presence of putative ORFs on DNA/RNA vaccine candidates implies that overlapping genes may contribute to the translation of smaller peptides, potentially leading to unintended clinical outcomes, and that the protein-coding potential of DNA/RNA vaccines should be rigorously examined prior to administration.

Side effects of COVID-19 vaccines: a systematic review and meta-analysis protocol of randomised trials. INTRODUCTION: SARS-CoV-2 is responsible for a large number of global COVID-19 cases. Strategies such as social isolation, personal hygiene and frequent hand washing have been implemented; however, a protective vaccine is required to achieve sufficient herd immunity to SARS-CoV-2 infection to ultimately control the COVID-19 pandemic. To meet the urgent need for a vaccine, a reduction in the development schedule has been proposed from 10-15 years to 1-2 years. For this reason, this systematic review and meta-analysis protocol aims to compare the side effects, safety and toxicity of COVID-19 vaccines available globally, including their combinations. METHODS AND ANALYSIS: We will select randomised controlled trial-type studies that evaluate the side effects of the COVID-19 vaccine. PubMed, Web of Science, Embase, CINAHL, PsycINFO, LILACS, SCOPUS, ClinicalTrials.gov, International Clinical Trials Registry Platform (ICTRP), medRxiv.org, biorxiv.org, preprints.org and the Cochrane Library will be searched for eligible studies until December 2021. Three reviewers will independently screen and select studies, assess methodological quality and extract data. A meta-analysis will be performed, if possible, and the Grading of Recommendations, Assessment, Development and Evaluations summary of findings will be presented. ETHICS AND DISSEMINATION: This study will review published data, and thus it is unnecessary to obtain ethical approval. The findings of this systematic review will be published in a peer-reviewed journal. PROSPERO REGISTRATION NUMBER: CRD42021231101.

Ofeleein i mi Vlaptin-Volume II: Immunity Following Infection or mRNA Vaccination, Drug Therapies and Non-Pharmacological Management at Post-Two Years SARS-CoV-2 Pandemic. The persistence of the coronavirus disease 2019 (COVID-19) pandemic has triggered research into limiting transmission, morbidity and mortality, thus warranting a comprehensive approach to guide balanced healthcare policies with respect to people's physical and mental health. The mainstay priority during COVID-19 is to achieve widespread immunity, which could be established through natural contact or vaccination. Deep knowledge of the immune response combined with recent specific data indicates the potential inferiority of induced immunity against infection. Moreover, the prevention of transmission has been founded on general non-pharmacological measures of protection, albeit debate exists considering their efficacy and, among other issues, their socio-psychological burden. The second line of defense is engaged after infection and is supported by a plethora of studied agents, such as antibiotics, steroids and non-steroid anti-inflammatory drugs, antiviral medications and other biological agents that have been proposed, though variability in terms of benefits and adverse events has not allowed distinct solutions, albeit certain treatments might have a role in prevention and/or treatment of the disease. This narrative review summarizes the existing literature on the advantages and weaknesses of current COVID-19 management measures, thus underlining the necessity of acting based on the classical principle of "ofeleein i mi vlaptin", that is, to help or not to harm.

Atypical Sites of Lymphadenopathy after Anti-COVID-19 Vaccine: Ultrasound Features. Background and Objectives: Several authors have reported cervical and axillary lymphadenopathies as known side effects following anti-COVID-19 vaccine administration. Few data are available about atypical locations of post-anti-COVID-19 vaccine lymphadenopathy. In this investigation, we evaluated the incidence and prevalence of postvaccine lymphadenopathy ultrasound (US) features in atypical sites. Materials and Methods: In this retrospective study, we retrospectively selected 64 patients on whom US was performed between January and October 2021 due to COVID-19 vaccine-related lymphadenopathy. We investigated lymph node anatomical sites, presence, number, size, shape, cortical profile, hilum outline, superb microvascular imaging (SMI), and elastosonography. Results: A total of 170 nodes were assessed. Atypical location was demonstrated in 5/64 patients (7.8%). In all these cases, atypical nodal involvement was associated with lymphadenopathy in a typical site (axillary, supraclavicular) ipsilateral to the vaccine injection site. Two patients presented lymphadenopathy in the infraclavicular station (3.1%), one in the pectoralis major muscle (1.6%), one in the left arm (1.6%), and one in the nuchal site (1.6%). All lymphadenopathies were oval-shaped, with a median size of 0.9 Â± 0.2 cm. US features included a symmetric cortex with hilum evidence (4/6, 60%), vascular signal at SMI in both the hilar region and periphery of lymph node (5/6, 83.3%), and a US elastography pattern resembling that of adjacent tissues (5/6, 83.3%). The median age of patients with lymphadenopathies in an atypical location was 23 years. The main type of vaccine associated with lymph node appearance in atypical sites was Moderna's mRNA-1273 (60% of patients, 4/6 lymph nodes accounting for 66.7% among atypical locations). Conclusion: Post-COVID-19 vaccine administration lymphadenopathies in an atypical location represent an intense immune response to antigenic stimuli and they may show alarming US traits superimposed on malignant pathologies, which may complicate the patient's clinical and diagnostic pathway. Despite no distinctive US features between reactive post-COVID-19 vaccination and malignant lymph nodes being available, careful examination of atypical lymph node locations associated with accurate knowledge of patients' clinical background and delay of US exam to four to six weeks after vaccine injection should be considered.

Case Report of Cerebral Sinus Thrombosis Related to Immune Thrombotic Thrombocytopenia Following Administration of ChAdOx1 nCoV-19 for Vaccination against COVID-19. Vaccine-induced immune thrombotic thrombocytopenia (VITT) with cerebral venous sinus thrombosis (CVST) has been recently reported after vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). We present a case of a patient with fulminant CVST and thrombocytopenia after receiving the ChAdOx1 nCoV-19 vaccine. Although the patient received immediate anticoagulant and intravenous immune globulin treatment, he died within 24 h after hospital admission. VITT and CVST are rare conditions; however, the course may be fatal. Therefore, clinicians should be familiarized with the clinical and laboratory features of VITT.

Immune Response of Adult Sickle Cell Disease Patients after COVID-19 Vaccination: The Experience of a Greek Center. Vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are essential weapons to control the spread of the coronavirus disease-19 (COVID-19) pandemic and protect immunocompromised patients. With a greater susceptibility to infection, sickle cell disease (SCD) patients are considered as "high risk" patients during the current COVID-19 pandemic. In our study, we try to determine the immune response of adult SCD patients monitored at our center after the first and second dose of the qualified mRNA vaccines available and correlate them to several disease-specific markers, as well as complement activation. The results demonstrate that the levels of neutralizing antibodies (nAbs) against SARS-CoV-2 were adequate for most patients studied after the second dose and there seemed to be a certain association with complement activation. Further

studies are critical to determine the durability of this immune response and the potential benefit of a third dose.
Comparison of Neutralizing Antibody Responses at 6 Months Post Vaccination with BNT162b2 and AZD1222. Along with their level of protection against COVID-19, SARS-CoV-2-specific antibodies decline over time following vaccination with BNT162b2. However, relevant data on AZD1222 are scarce. In this context, the aim of this study was to compare SARS-CoV-2 neutralizing antibody (NAb) levels at one, three and six months after second vaccination with the BNT162b2 mRNA vaccine and the ChAdOx1 (AZD1222) viral vector vaccine (NCT04743388). The measurements were performed with the GenScript's cPassTM SARS-CoV-2 NAbs Detection Kit (GenScript, Inc.; Piscataway, NJ, USA). Overall, data from 282 individuals were included (BNT162b2 n = 83, AZD1222 n = 199). Both vaccines induced strong NAbs responses at 1 month following vaccination. Interestingly, NAb activity seemed superior with BNT162b2 compared with AZD1222. A gradual decline in NAbs titers was evident at 3 and 6 months post vaccination with both vaccines. However, the superiority of NAb response with BNT162b2 over AZD1222 remained consistent at all time points examined. Furthermore, the elimination rate of the NAb titer was higher throughout during the study period for those vaccinated with AZD1222 compared with BNT162b2. Age, gender, body mass index or comorbidities did not have a significant impact on NAbs levels over time. Our results may inform public health policies regarding the timing of booster COVID-19 vaccine shots.
Predictive Factors for Neutralizing Antibody Levels Nine Months after Full Vaccination with BNT162b2: Results of a Machine Learning Analysis. Vaccination against SARS-CoV-2 with BNT162b2 mRNA vaccine plays a critical role in COVID-19 prevention. Although BNT162b2 is highly effective against COVID-19, a time-dependent decrease in neutralizing antibodies (NAbs) is observed. The aim of this study was to identify the individual features that may predict NAbs levels after vaccination. Machine learning techniques were applied to data from 302 subjects. Principal component analysis (PCA), factor analysis of mixed data (FAMD), k-means clustering, and random forest were used. PCA and FAMD showed that younger subjects had higher levels of neutralizing antibodies than older subjects. The effect of age is strongest near the vaccination date and appears to decrease with time. Obesity was associated with lower antibody response. Gender had no effect on NAbs at nine months, but there was a modest association at earlier time points. Participants with autoimmune disease had lower inhibitory levels than participants without autoimmune disease. K-Means clustering showed the natural grouping of subjects into five categories in which the characteristics of some individuals predominated. Random forest allowed the characteristics to be ordered by importance. Older age, higher body mass index, and the presence of autoimmune diseases had negative effects on the development of NAbs against SARS-CoV-2, nine months after full vaccination.
Diminishing Immune Responses against Variants of Concern in Dialysis Patients 4 Months after SARS-CoV-2 mRNA Vaccination. Patients undergoing chronic hemodialysis were among the first to receive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccinations because of their increased risk for severe coronavirus disease and high case-fatality rates. By using a previously reported cohort from Germany of at-risk hemodialysis patients and healthy donors, where antibody responses were examined 3 weeks after the second vaccination, we assessed systemic cellular and humoral immune responses in serum and saliva 4 months after vaccination with the Pfizer-BioNTech BNT162b2 vaccine using an interferon-Î³ release assay and multiplex-based IgG measurements. We further compared neutralization capacity of vaccination-induced IgG against 4 SARS-CoV-2 variants of concern (Alpha, Beta, Gamma, and Delta) by angiotensin-converting enzyme 2 receptor-binding domain competition assay. Sixteen weeks after second vaccination, compared with 3 weeks after,

cellular and humoral responses against the original SARS-CoV-2 isolate and variants of concern were substantially reduced. Some dialysis patients even had no detectable B- or T-cell responses.
Durability of Antibody Response and Frequency of SARS-CoV-2 Infection 6 Months after COVID-19 Vaccination in Healthcare Workers. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibodies decay but persist 6 months postvaccination; lower levels of neutralizing titers persist against Delta than wild-type virus. Of 227 vaccinated healthcare workers tested, only 2 experienced outpatient symptomatic breakthrough infections, despite 59/227 exhibiting serologic evidence of SARS-CoV-2 infection, defined as presence of nucleocapsid protein antibodies.
Potentiation of humoral response to the BNT162b2 vaccine after the third dose in patients with solid cancer.
SARS-CoV-2 Breakthrough Infections after introduction of 4 COVID-19 Vaccines, South Korea, 2021. We conducted a nationwide retrospective cohort study to estimate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) breakthrough infection among recipients of 4 different vaccines in South Korea. Age-adjusted breakthrough infection rate per month was highest for Janssen (42.6/100,000 population), followed by AstraZeneca (21.7/100,000 population), Pfizer-BioNTech (8.5/100,000 population), and Moderna (1.8/100,000 population).
COVID-19 vaccine in patients with dermal hyaluronic acid fillers in the tear trough: A retrospective study.
Clinical care pathway for the evaluation of patients with suspected VITTÂ after ChAdOx1 nCoV-19 vaccination. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare complication after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) adenoviral vector vaccination. In British Columbia (BC), Canada, a provincial clinical care pathway was developed to guide clinicians in evaluating for VITT among patients who present with thrombocytopenia or thrombosis symptoms within 4 to 28 days after adenoviral vector vaccine exposure. All patients had enzyme-linked immunosorbent assay (ELISA) testing for platelet factor 4 (PF4) antibodies, and all cases with positive PF4-ELISA or d-dimer levels â‰¥2.0 mg/L fibrinogen equivalent units (FEU) had further testing for platelet-activating PF4 antibodies using a modified serotonin release assay (SRA). Between 1 May and 30 June 2021, 37% of 68 patients investigated for VITT had thrombosis, but only 3 had VITT confirmed by PF4-ELISA and SRA. Platelet counts, d-dimer levels, and ELISA optical density values were significantly different between those with and without VITT. Three patients had thrombocytopenia and thrombosis with d-dimer levels >4.0 mg/L FEU but had negative PF4-ELISA and SRA results. Patients with VITT were treated successfully with IV immunoglobulin, nonheparin anticoagulants, and corticosteroids. Our pathway demonstrated that thrombosis is common among patients investigated for VITT and that PF4-ELISA testing is necessary to confirm VITT in those presenting with thrombosis and thrombocytopenia.
Rare Sudden Sensorineural Hearing Loss Potentially Associated With COVID-19 Vaccination Does Not Outweigh the Benefit of COVID-19 Vaccines.
Association Between the BNT162b2 Messenger RNA COVID-19 Vaccine and the Risk of Sudden Sensorineural Hearing Loss. IMPORTANCE: Identification of adverse events after vaccination increases awareness of vaccine-associated complications, leading to early diagnosis and treatment. Evidence remains scarce on the association between the BNT162b2 messenger RNA (mRNA) COVID-19 vaccine (Pfizer-BioNTech) and sudden sensorineural hearing loss (SSNHL). OBJECTIVE: To assess the association between the BNT162b2 mRNA COVID-19 vaccine and SSNHL. DESIGN, SETTING, AND PARTICIPANTS: This retrospective, population-based cohort study was performed from December 20, 2020, to May 31, 2021, using data from the largest health care organization in Israel. Patients 16 years or older who received the first vaccine dose between December 20, 2020, and April 30, 2021, and the second vaccine dose between January 10, 2021, and April 30, 2021, were included.

EXPOSURES: Receipt of first and second BNT162b2 mRNA COVID-19 vaccine doses. MAIN OUTCOMES AND MEASURES: The main outcome was SSNHL based on International Classification of Diseases, Ninth Revision (ICD-9) codes in conjunction with concurrent prednisone dispensing. Observed cases of SSNHL, occurring within 21 days after each of the first and second vaccine doses, were compared with the expected cases based on the experience of the population in 2018 and 2019. Standardized incidence ratios (SIRs) and attributable risks were computed. RESULTS: Overall, 2â€¯602â€¯557 patients (mean [SD] age, 46.8 [19.6] years; 51.5% female) received the first dose of BNT162b2 mRNA COVID-19 vaccine, with 91 cases of SSNHL reported. Of these patients, 2â€¯441â€¯719 (93.8%) received the second vaccine dose, with 79 cases of SSNHL reported. The age- and sex-weighted SIRs were 1.35 (95% CI, 1.09-1.65) after the first vaccine dose and 1.23 (95% CI, 0.98-1.53) after the second vaccine dose. After the first vaccine dose, the estimated SIRs were more pronounced in female patients aged 16 to 44 years (SIR, 1.92; 95% CI, 0.98-3.43) and female patients 65 years or older (SIR, 1.68; 95% CI, 1.15-2.37). After the second vaccine dose, the highest estimated SIR was observed in male patients 16 to 44 years (SIR, 2.45; 95% CI, 1.36-4.07). The attributable risks were generally small, and the results were similar when 2019 was used as a reference to estimate the expected number of SSNHL cases. CONCLUSIONS AND RELEVANCE: This study suggests that the BNT162b2 mRNA COVID-19 vaccine might be associated with increased risk of SSNHL; however, the effect size is very small. Further studies are warranted to establish this possible association.

Assessment of Sudden Sensorineural Hearing Loss After COVID-19 Vaccination. IMPORTANCE: Emerging reports of sudden sensorineural hearing loss (SSNHL) after COVID-19 vaccination within the otolaryngological community and the public have raised concern about a possible association between COVID-19 vaccination and the development of SSNHL. OBJECTIVE: To examine the potential association between COVID-19 vaccination and SSNHL. DESIGN, SETTING, AND PARTICIPANTS: This cross-sectional study and case series involved an up-to-date population-based analysis of 555 incident reports of probable SSNHL in the Centers for Disease Control and Prevention Vaccine Adverse Events Reporting System (VAERS) over the first 7 months of the US vaccination campaign (December 14, 2020, through July 16, 2021). In addition, data from a multi-institutional retrospective case series of 21 patients who developed SSNHL after COVID-19 vaccination were analyzed. The study included all adults experiencing SSNHL within 3 weeks of COVID-19 vaccination who submitted reports to VAERS and consecutive adult patients presenting to 2 tertiary care centers and 1 community practice in the US who were diagnosed with SSNHL within 3 weeks of COVID-19 vaccination. EXPOSURES: Receipt of a COVID-19 vaccine produced by any of the 3 vaccine manufacturers (Pfizer-BioNTech, Moderna, or Janssen/Johnson & Johnson) used in the US. MAIN OUTCOMES AND MEASURES: Incidence of reports of SSNHL after COVID-19 vaccination recorded in VAERS and clinical characteristics of adult patients presenting with SSNHL after COVID-19 vaccination. RESULTS: A total of 555 incident reports in VAERS (mean patient age, 54 years [range, 15-93 years]; 305 women [55.0%]; data on race and ethnicity not available in VAERS) met the definition of probable SSNHL (mean time to onset, 6 days [range, 0-21 days]) over the period investigated, representing an annualized incidence estimate of 0.6 to 28.0 cases of SSNHL per 100â€¯000 people per year. The rate of incident reports of SSNHL was similar across all 3 vaccine manufacturers (0.16 cases per 100â€¯000 doses for both Pfizer-BioNTech and Moderna vaccines, and 0.22 cases per 100 000 doses for Janssen/Johnson & Johnson vaccine). The case series included 21 patients (mean age, 61 years [range, 23-92 years]; 13 women [61.9%]) with SSNHL, with a mean time to onset of 6 days (range, 0-15 days). Patients were heterogeneous with respect to clinical and demographic characteristics. Preexisting autoimmune disease was present in 6 patients (28.6%). Of the 14 patients with posttreatment audiometric data, 8 (57.1%) experienced improvement after receiving treatment. One patient experienced SSNHL 14 days after receiving each dose of the Pfizer-BioNTech vaccine. CONCLUSIONS AND RELEVANCE: In this cross-sectional study,

findings from an updated analysis of VAERS data and a case series of patients who experienced SSNHL after COVID-19 vaccination did not suggest an association between COVID-19 vaccination and an increased incidence of hearing loss compared with the expected incidence in the general population.

Metabolic Activity Assessment by 18F-Fluorodeoxyglucose Positron Emission Tomography in Patients after COVID-19 Vaccination. In the following report, we describe 11 patients with various diagnoses and different treatment statuses (newly diagnosed, receiving treatment, or follow-up) of oncological diseases (breast, lymphoma, melanoma, and head and neck cancers). The patients underwent PET-CT for disease staging or follow-up and it was noted that all patients had areas of hypermetabolic uptake in the axillary lymph-nodes of the ipsilateral upper extremity where the Pfizer-BioNTech coronavirus (COVID-19) vaccine was administered. Following further investigations, including an ultrasound (US), biopsies and an examination of medical records, it was concluded that these findings were the result of the vaccination and not a progression of pre-existing disease.

Vaccine-Induced Subacute Thyroiditis (De Quervain's) after mRNA Vaccine against SARS-CoV-2: A Case Report and Systematic Review. De Quervain's thyroiditis, sometimes referred to as subacute thyroiditis (SAT), is the most common granulomatous disease of the thyroid, typically found after a viral infection in middle-aged women. The mRNA encoding for the angiotensin-converting enzyme-2 (ACE-2) receptor is expressed in follicular thyroid cells, making them a potential target for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Besides infection, SARS-CoV-2 vaccines have also been implicated in SAT pathogenesis. We present a case of a woman developing SAT following vaccination with Comirnaty by Pfizer Inc. (New-York, USA). We performed a systematic review of similar cases available in the literature to provide a better understanding of the topic. We searched the databases PubMed and Embase and followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. Patient records were then sorted according to the type of administered vaccine and a statistical analysis of the extracted data was performed. No statistically significant difference between mRNA vaccines and other vaccines in inducing SAT was found, nor was any found in terms of patient demographics, symptoms at presentation, initial, or follow-up blood tests. In our case report, we described the possible association between SARS-CoV-2 mRNA-based vaccine Comirnaty and SAT.

Central retinal artery occlusion following COVID-19 vaccine administration. INTRODUCTION: Increased risk of thromboembolic events has been associated with SARS-CoV-2 infections and more recently, with COVID-19 vaccination. To date, however, there are no reports of an association between the COVID-19 vaccination and retinal artery occlusions. We report a case of a patient who developed central retinal artery occlusion (CRAO) 2 days following the administration of the AstraZeneca COVID-19 vaccine. CASE DESCRIPTION: A 76-year-old woman presented to our Department of Ophthalmology complaining of painless vision loss in her left eye 48 hours after she had received her first dose of the AstraZeneca COVID-19 vaccine. Her best-corrected visual acuity was only hand movement in the left eye. Left eye ophthalmologic examination showed the presence of arterial narrowing and a cherry red spot. Optical coherence tomography showed severe macular swelling of the inner retinal layers in the left eye Fluorescein angiography performed the following day confirmed the diagnosis. The cardiovascular examination including Holter ECG was unremarkable. Complete blood count was within normal limits, without thrombocytopenia. A subsequent cerebral CT and CT-angiography scans did not show any other acute vascular event. Doppler angiography of the carotid artery was performed and showed normal flow without clinically significant plaques, stenoses, occlusions or dissections. CONCLUSIONS: To our knowledge, this is the first case of an isolated CRAO following the administration of the AstraZeneca COVID-19 vaccine. Further studies are needed to evaluate this potential association and identify pathophysiologic relationships between COVID-19 vaccinations and CRAO.

Severe panuveitis with iridis rubeosis activation and cystoid macular edema after BioNTech-Pfizer COVID-19 vaccination in a 17-year-old. We report a case of severe uveitis flare-up with iridis rubeosis recurrence and cystoid macular edema early after the first BioNTech-Pfizer COVID-19 vaccination in a 17-year-old boy. We also performed a systematic literature review on ocular inflammation after COVID-19 vaccinations.
Analysis of Neurological Adverse Events Reported in VigiBase From COVID-19 Vaccines. BACKGROUND: Fifteen COVID-19 vaccines have been granted emergency approval before the completion of conventional phases of clinical trials. The present study aimed to analyze the neurological adverse events (AEs) post-COVID-19 vaccination and focuses on determining the association of AEs with the vaccine. METHODOLOGY: The neurological AEs reported for COVID-19 vaccines in the WHO pharmacovigilance database (VigiBase) were extracted from the System Organ Classes - neurological disorders and investigations. Descriptive statistics are reported as percentage and frequency and the disproportionality analysis was also conducted. RESULTS: Â For the neurological system, 19,529 AEs were reported. Of these, 15,638 events were reported from BNT162b2 vaccine, 2,751 from AZD1222 vaccine, 1,075 from mRNA-1273 vaccine, eight from Vero vaccine, two from Covaxin, and for 55 AEs, vaccine name was not mentioned. The reason for more AEs reported with BNT162b2 can be maximum vaccination with BNT162b2 vaccine in the study period. According to the disproportionality analysis based on IC(025) value, ageusia, anosmia, burning sensation, dizziness, facial paralysis, headache, hypoaesthesia, lethargy, migraine, neuralgia, paresis, parosmia, poor sleep quality, seizure, transient ischemic attack, and tremor are some of the AEs that can be associated with the administration of the vaccine. CONCLUSION: The vaccines should be monitored for these AEs till the causality of these AEs with COVID-19 vaccines is established through further long-term follow-up studies. These neurological AEs reported in VigiBase should not be taken as conclusive and mass vaccination should be carried out to control the pandemic until a definite link of these adverse effects is established.
Multiple Sclerosis Relapse Following COVID-19 Vaccination: A Case Report and Literature Review. Mass vaccination against coronavirus disease 19 (COVID-19) has effectively controlled the pandemic and has been remarkably effective and safe. Reports of a few adverse events have been reported after post-marketing surveillance. We present a rare case of multiple sclerosis (MS) relapse in a female who presented with fatigue, involuntary eye movements, and numbness; autoimmunity following the COVID-19 vaccine has also been described. She was diagnosed with MS six years back and was in remission. She received her COVID-19 vaccine 18 days ago. Her clinical and radiological features confirmed the MS relapse. Her serology for COVID-19 immunoglobulin G (IgG) and IgM was positive, and she was managed with intravenous methylprednisolone and symptomatic management. Our case provides a possible association of vaccine-associated MS relapse; however, more evidence is warranted from future studies.
Cardiac Adverse Reactions With COVID-19 Vaccinations. The coronavirus disease 2019 (COVID-19) pandemic has resulted in millions of deaths worldwide. The emergency use authorization for both the Pfizer-BioNTech and Moderna mRNA COVID-19 vaccinations was a major turning point in the battle against COVID-19. These vaccines have been well-tolerated; however, there have been reported cases of myocarditis and pericarditis after receiving the second dose of the vaccine. We present two cases of myocarditis and pericarditis that occurred after receiving the COVID-19 vaccination. Although there are other potential etiologies that could explain myocarditis and pericarditis in these cases, it is important to consider the COVID-19 vaccine as a plausible cause. More research is required to investigate the potential adverse effects of the available COVID-19 vaccines.
Reactivation of minimal change disease and IgA nephropathy after COVID-19 vaccination.

Minimal change disease with thrombotic microangiopathy following the Pfizer-BioNTech COVID-19 vaccine.

Comparison of antibody response to SARS-CoV-2 after two doses of inactivated virus and BNT162b2 mRNA vaccines in kidney transplant. BACKGROUND: Antibody response against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) after mRNA or adenoviral vector-based vaccines is weak in kidney transplant (KT) patients. However, few studies have focused on humoral response after inactivated virus-based vaccines in KT. Here, we compare antibody response following vaccination with inactivated virus (CoronaVacÂ®) and BNT162b2 mRNA. METHODS: A national multicentre cross-sectional study was conducted. The study group was composed of patients from all KT centres in Uruguay, vaccinated between 1 and 31 May 2021 (CoronaVacÂ®, n = 245 and BNT162b2, n = 39). The control group was constituted of 82 healthy individuals. Participants had no prior confirmed coronavirus disease 2019 (COVID-19) test. Blood samples were collected between 30 and 40 days after the second dose. Serum-specific immunoglobulin G (IgG) antibodies against the receptor-binding domain (RBD) of SARS-CoV-2 Spike protein were determined using the COVID-19 IgG QUANT ELISA Kit. RESULTS: Only 29% of KT recipients showed seroconversion (36.5% BNT162b2, 27.8% inactivated virus, P = 0.248) in comparison with 100% in healthy control with either vaccine. Antibody levels against RBD were higher with BNT162b mRNA than with inactivated virus [median (interquartile range) 173 (73-554) and 29 (11-70) binding antibody units (BAU)/mL, P < 0.034] in KT and 10 times lower than healthy control [inactivated virus: 308 (209-335) and BNT162b2: 2638 (2608-3808) BAU/mL, P < 0.034]. In multivariate analysis, variables associated with negative humoral response were age, triple immunosuppression, estimated glomerular filtration rate and time post-KT. CONCLUSION: Seroconversion was low in KT patients after vaccination with both platforms. Antibody levels against SARS-CoV-2 were lower with inactivated virus than BNT162b mRNA. These findings support the need for strategies to improve immunogenicity in KT recipients after two doses of either vaccine.

COVID-19 vaccine-induced immune thrombotic thrombocytopenia: A review. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a highly transmissible and pathogenic coronavirus responsible for the pandemic coronavirus disease 19 (COVID-19). It has significant impact on human health and public safety along with negative social and economic consequences. Vaccination against SARS-CoV-2 is likely the most effective approach to sustainably control the global COVID-19 pandemic. Vaccination is highly effective in reducing the risk of severe COVID-19 disease. Mass-scale vaccination will help us in attaining herd immunity and will lessen the negative impact of the disease on public health, social and economic conditions. The present pandemic stimulated the development of several effective vaccines based on different platforms. Although the vaccine is safe and efficacious, rare cases of thrombosis and thrombocytopenia following the use of vaccination with the ChAdOx1 CoV-19 vaccine (AstraZeneca, University of Oxford, and Serum Institute of India) or the Ad26.COV2.S vaccine (Janssen/Johnson & Johnson) have been reported globally. This review focussed on the definition, epidemiology, pathogenesis, clinical features, diagnosis, and management of vaccine associated thrombosis.

The impact of glucose tolerance state on seropositivity rate after hepatitis B vaccination. Immunization is recommended for people with diabetes mellitus (DM), but little information is available on their seropositivity rates. To determine the impact of glucose tolerance state on seropositivity rate after hepatitis B vaccination, we included 7645 adult participants from the National Health and Nutrition Examination Survey 2005-2016 who reported three doses of hepatitis B vaccine and were seropositive for anti-hepatitis B surface antibody (â‰¥â€‰12.0 mIU/mL), after exclusion of those positive for anti-hepatitis B core antibody and/or hepatitis B surface antigen. We classified the states of glucose tolerance as normal glucose tolerance (NGT, 61.68%), abnormal

glucose tolerance (AGT, 26.02%), or DM (13.30%). We observed a stepwise decline in hepatitis B seropositivity rate from NGT (53.64%) to AGT (45.52%) to DM (28.84%) (Pâ€‰<â€‰0.0001). We confirmed these results after standardization for age and BMI (Pâ€‰<â€‰0.0001 for all subgroup analyses) and in subgroup analyses by gender and racial/ethnic group. Dysregulated glucose metabolism is associated with a decreased seropositivity rate after hepatitis B vaccination. Our observations suggest that regular follow-up screening for anti-hepatitis B surface antibody, with additional booster vaccination as necessary, is especially important in patients with DM. Whether a similar phenomenon exits for other vaccines, especially COVID-19, remains to be investigated.

Durability and expansion of neutralizing antibody breadth following Ad26.COV2.S vaccination of mice. Emerging SARS-CoV-2 variants with the potential to escape binding and neutralizing antibody responses pose a threat to vaccine efficacy. We recently reported expansion of broadly neutralizing activity of vaccine-elicited antibodies in humans 8 months following a single immunization with Ad26.COV2.S. Here, we assessed the 15-month durability of antibody responses and their neutralizing capacity to B.1.617.2 (delta) and B.1.351 (beta) variants following a single immunization of Ad26.COV2.S in mice. We report the persistence of binding and neutralizing antibody titers following immunization with a concomitant increase in neutralizing antibody breadth to delta and beta variants over time. Evaluation of bone marrow and spleen at 15 months postimmunization revealed that Ad26.COV2.S-immunized mice tissues contained spike-specific antibody-secreting cells. We conclude that immunization with Ad26.COV2.S elicits a robust immune response against SARS-CoV-2 spike, which expands over time to neutralize delta and beta variants more robustly, and seeds bone marrow and spleen with long-lived spike-specific antibody-secreting cells. These data extend previous findings in humans and support the use of a mouse model as a potential tool to further explore the dynamics of the humoral immune response following vaccination with Ad26.COV2.S.

Impact of age, sex and medical history on adverse reactions to the first and second dose of BNT162b2 mRNA COVID-19 vaccine in Japan: a cross-sectional study. BACKGROUND: Vaccines for coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are being promoted worldwide. In this study, we analyzed the relationship between adverse reactions and the profile of vaccinated recipients. METHODS: Vaccinated subjects who received two doses of BNT162b2 between May 17 and June 11, 2021, at Osaka University Dental Hospital were included in this study. Adverse reactions and profiles were collected by questionnaires, and the relationship between the presence of adverse reactions and the profiles of the vaccinated persons was analyzed by logistic regression analysis. The correlation between the severity of adverse reactions and age was analyzed by Spearman's rank correlation. RESULTS: Logistic regression analysis showed that, for many kinds of adverse reactions, the incidence was significantly higher in females than in males and in younger than in older people. There was a very weak but significant negative correlation between age and the severity of many kinds of adverse reactions. The relationship between sex and the incidence of each adverse reaction was significant for injection site reactionsÂ andÂ fatigue in the first vaccination, whereas significant relationships were found for fatigue, chills,Â fever, arthralgia,Â myalgia and headache in the second vaccination, all of which were clearly more likely to occurÂ in females. CONCLUSION: Adverse reactions to BNT162b2 were found to be more frequent and more intense in females and younger people in Japan, especially after the second vaccination.

New presentations and exacerbations of immune thrombocytopenia after coronavirus disease 2019 vaccinations: the Taiwan experience. Immune thrombocytopenia (ITP) is a condition that is distinct from thrombosis with thrombocytopenia syndrome (TTS) that may also occur after coronavirus disease 2019 (COVID-19) vaccinations. Previous reports revealed an increased ITP incidence after ChAdOx1, a vaccine for COVID-19. Our study aimed to highlight the key features of ITP

after COVID-19 vaccination. From April to October 2021, we collected data on 23 patients, including nine men and 14 women, with ITP from five hospitals across Taiwan who received either the ChAdOx1 or mRNA-1273 vaccine before development or exacerbation of ITP. Our findings revealed that both ChAdOx1 and mRNA-1273 vaccines were associated with ITP. Many patients responded well to steroids and immune suppressants, which may also suggest that the nature of thrombocytopenia is more like ITP rather than TTS. Lack of thrombosis, low D-dimer level, and negative anti-PF4 result could help to exclude TTS, which is also a rare but a far more lethal condition.

[BREAST CANCER COMPLICATIONS DURING THE COVID-19 PANDEMIC - LESSONS LEARNT]. In their article published in this issue of Harefuah, Greenhouse et al. describe a complicated case of a woman with delayed diagnosis of breast cancer, presenting with spinal cord compression due to spin metastases and a locally advanced breast lesion. The patient had concurrent symptomatic infection with COVID-19, and was successfully diagnosed and treated, resulting in neurologic recovery. This case raises several issues, relevant to the care of patients with breast cancer. Late diagnosis of breast cancer is not uncommon, but little is known regarding the reasons why some women forego breast cancer screening or delay diagnosis of symptomatic breast lesions. Available information points at fear of breast cancer and fear of surgery as common causes, and it seems that interventions aimed to increase screening rates should take these findings into account. The patient described by Greenhouse et al. complained of back ache and was treated by telemedicine for a month preceding hospitalization, during the initial stages of the COVID-19 outbreak. As the implementation of telemedicine increases, organizations should issue guidelines for its use. It seems prudent to avoid using telemedicine in patients with new symptoms or recurring symptoms without a definite diagnosis. There is currently sufficient data showing that breast cancer patients are not at higher risk for COVID-19 complications compared with the general population, even while treated for their cancer. Serologic studies performed in Israel following COVID-19 vaccination found that 85-90% of patients with solid tumors have positive serologic tests after the 2nd dose of the vaccine. Studies have estimated that delaying breast cancer screening during the pandemic would result in increased breast cancer mortality. Thus, efforts should be made to continue breast cancer screening, diagnostic workup of suspicious findings and treatment of confirmed breast cancer in the event of additional outbreaks of COVID-19.

Antibody response after two doses of the SARS-CoV-2 Comirnaty vaccine in a Covid-19 positive and Covid-19 negative Italian healthcare workers cohort. BACKGROUND: Extensive vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is now universally regarded as one of the most effective strategies for counteracting the current pandemic. The durability of the immune response of available vaccines is not known, therefore the quantitative dynamics of serum anti-S antibodies after Comirnaty vaccine in health care workers (HCW) of Desio Hospital was conducted. METHODS: 51 previously infected and 198 not infected HCW, from Desio, Italy were enrolled in the study. Comirnaty double dose schedule was completed by each subject. Specific anti-S antibodies against the SARS-CoV-2â€‰S protein were measured by ECLIA in sequential blood samples. RESULTS: A significant difference was observed beginning at pre priming dose (T0) of the anti-S antibodies between the two subgroups which persisted throughout the study (4â€‰months). A significant reduction occurred after 4â€‰months post-priming dose (T3). Finally, a subgroup of low and late responders with an increasing trend was found. CONCLUSIONS: Specific anti-S antibodies are significantly decreased 4â€‰months post priming dose of Comirnaty vaccine although prior COVID-19 infection seems to escalate humoral response. Further evaluation concerning antibody persistence beyond this point, and the proportion of neutralizing antibodies with higher affinity towards SARS-CoV-2 is needed, especially in naÑ—ve and immunosuppressed subjects.

Myocarditis following mRNA COVID-19 vaccination: call for endomyocardial biopsy. Acute myocarditis following mRNA COVID-19 vaccination was reported by the European Medicine Agency safety committee as a rare adverse event. We present a case series of three young male patients with suspected acute myocarditis following BNT162b2 mRNA COVID-19 vaccination including results of endomyocardial biopsies (EMB). Additionally, we analysed EMB of another 21 patients with clinically suspected acute myocarditis following vaccination to determine the pathohistological pattern. Overall, EMB revealed acute lymphocytic myocarditis in 5 (20.8%), chronic lymphocytic myocarditis in 6 (25%), cardiac sarcoidosis in 1 (4.2%), healed myocarditis in 6 (25%), and other diagnoses with cardiac damage of unclear aetiology in 6 (25%) cases. Our findings support the necessity of EMB in patients with suspected acute myocarditis following mRNA COVID-19 vaccination presenting with reduced EF to establish a correct and definite diagnosis. Concerns of these rare severe adverse events after COVID-19 immunization should not undermine its value for the global community.
Cutaneous adverse reactions of COVID-19 vaccines: A systematic review. Numerous vaccines are under clinical development and implementation for the prevention of severe course and lethal outcomes of coronavirus disease 2019 (COVID-19). This systematic review aims to summarize and integrated the findings of studies regarding cutaneous side effects of COVID-19 vaccines. This systematic review conducted by searching the scientific databases of PubMed, Scopus, Science direct, and Web of knowledge from the beginning of the COVID-19 to May 10, 2021. Articles were reviewed and analyzed based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist. Seventeen studies on cutaneous side effects of COVID-19 vaccines were included after the screening of search results based on to the eligibility criteria. The results showed that the most common injection site reactions and delayed large local reactions, arising from all vaccine types, were redness/erythema (39%), followed by: itchiness (28%), urticarial rash (17%) on the neck, upper limbs, and trunk, morbilliform eruptions (6.5%), Pityriasis rosea (3%), swelling, and burning, and so forth. Most cutaneous reactions occurred in women (84%), and middle-aged people, after the first dose of vaccine, with the onset ranged from 1 to 21â€‰days after vaccination. In addition, cutaneous reactions were generally self-limiting, and needed little or no therapeutic intervention, that were not regarded as a barrier to injecting a second dose. In conclusion, severe cutaneous side effects are very rare and approved vaccines have satisfactory safety profiles. Therefore, mild or moderate cutaneous reactions should not discourage people from vaccination. In certain groups such as patients with allergies and a history of local injection reactions, pre-vaccination counseling and assurance, also use of appropriate medications may be helpful. However, more studies are needed to investigate the side effect profile of all COVID-19 vaccines.
Unusual contact dermatitis after SARS-CoV-2 vaccinations.
Symptoms After COVID-19 Vaccination in Patients with Post-Acute Sequelae of SARS-CoV-2.
Increased Potency and Breadth of SARS-CoV-2 Neutralizing Antibodies After a Third mRNA Vaccine Dose. The omicron variant of SARS-CoV-2 infected very large numbers of SARS-CoV-2 vaccinated and convalescent individuals (1-3) . The penetrance of this variant in the antigen experienced human population can be explained in part by the relatively low levels of plasma neutralizing activity against Omicron in people who were infected or vaccinated with the original Wuhan-Hu-1 strain (4-7) . The 3 (rd) mRNA vaccine dose produces an initial increase in circulating anti-Omicron neutralizing antibodies, but titers remain 10-20-fold lower than against Wuhan-Hu-1 and are, in many cases, insufficient to prevent infection (7) . Despite the reduced protection from infection, individuals that received 3 doses of an mRNA vaccine were highly protected from the more serious consequences of infection (8) . Here we examine the memory B cell repertoire in a longitudinal cohort of individuals receiving 3 mRNA vaccine doses (9,10) . We find that the 3 (rd) dose is accompanied by an increase in, and evolution of, anti-receptor binding domain specific memory B cells. The increase is due to

expansion of memory B cell clones that were present after the 2 (nd) vaccine dose as well as the emergence of new clones. The antibodies encoded by these cells showed significantly increased potency and breadth when compared to antibodies obtained after the 2 (nd) vaccine dose. Notably, the increase in potency was especially evident among newly developing clones of memory cells that differed from the persisting clones in targeting more conserved regions of the RBD. Overall, more than 50% of the analyzed neutralizing antibodies in the memory compartment obtained from individuals receiving a 3 (rd) mRNA vaccine dose neutralized Omicron. Thus, individuals receiving 3 doses of an mRNA vaccine encoding Wuhan-Hu-1, have a diverse memory B cell repertoire that can respond rapidly and produce antibodies capable of clearing even diversified variants such as Omicron. These data help explain why a 3 (rd) dose of an mRNA vaccine that was not specifically designed to protect against variants is effective against variant-induced serious disease.
Cutaneous reactions to COVID-19 vaccines: A review. BACKGROUND: The increasing number of reports on cutaneous reactions following COVID-19 vaccination has led to growing concerns among certain groups. OBJECTIVE: We reviewed the published reports of cutaneous lesions after COVID-19 vaccination. METHODS: We conducted a literature search for original and review articles published between January 1, 2020, and September 27, 2021. RESULTS: Eleven cutaneous reactions associated with COVID-19 vaccines were determined; the most prevalent reactions were local injection site reactions, delayed local reactions, urticaria, angioedema, and morbilliform eruptions. There were more reports on skin reactions following the administration of messenger RNA-based vaccines than on those following the administration of adenoviral vector or inactivated whole-virus vaccines, in part, due to their higher administration rate.Â Most reported skin reactions occurred after the first vaccine dose. LIMITATIONS: A reporting bias could not be excluded, and skin biopsy results were not available for most included individuals. Moreover, given that the included trials focused on vaccine efficacy, there was a lack of details concerning cutaneous reactions and participant information. CONCLUSION: Not all cutaneous reactions observed after COVID-19 vaccination are hypersensitivity reactions. Different cutaneous reactions may reflect underlying immune responses to the vaccines. A large majority of COVID-19 vaccination reactions were mild and self-limiting, and people should be encouraged to complete their vaccination regimen.
How Losing Sleep Following Vaccination May Weaken the Response to SARS-CoV Vaccines. With the emergence of new SARS-CoV-2 variants, a close analysis of factors that affect the efficacy of the vaccine in different groups is a must. It is important to elucidate the role of clinical, behavioral and host factors on modulation of immunogenicity of the SARS-CoV-2 vaccine. Data from other vaccines have shown that duration and efficiency of sleep affect the immunogenicity of the vaccine. There is a need for identification of circadian influence and sleep on SARS-CoV-2 vaccine using validated immune correlates of protection. We propose that sleep acts as a natural adjuvant by promoting the immunological synapse formation between the antigen presenting cells and CD4(+) T cells thereby leading to activation of cellular and humoral immunity in SARS-CoV-2 infection. Thus, apart from the titer of neutralizing antibodies, the cellular immunity including CD4(+) T cells and memory T cells must be assessed to clearly demarcate the long-term effect of sleep duration and efficiency on vaccine immunogenicity.
Possible association between rhabdomyolysis and mRNA SARS-CoV-2 vaccination in a patient with RYR1 gene mutation.
Adverse reactions and production of neutralizing anti-SARS-CoV-2 antibodies after ChAdOx1 COVID-19 vaccination: A cross-sectional study in a single center. Adverse events following vaccination with the ChAdOx1 COVID-19 vaccine may be associated with the titer of neutralizing antibodies (NAbs) against SARS-CoV-2. In this cross-sectional study, a total of 82 HCWs who received the ChAdOx1 COVID-19 vaccine and did not have previous COVID-19 history were enrolled during March

2021. Blood samples were collected from HCWs 3 weeks after the first and second doses of vaccine, and NAbs were estimated using two types of commercially available kits, the cPassâ„¢ SARS-CoV-2 NAbs Kit (Genscript Biotech, Piscataway, NJ, USA) and R-FIND SARS-CoV-2 NAbs ELISA (SG Medical, Seoul, Korea). Median percent signal inhibition of NAbs was significantly higher after the second than after the first dose of vaccine, as determined using both the Genscript (median 43.1[IQR 71.2] vs. 93.6[83.1], pÂ =Â 0.004) and R-FIND (53.2[82.6] vs. 76.8 [90.6], pÂ =Â 0.03) kits. The percent signal inhibition of NAbs after the second dose of vaccine was higher in HCWs with than without systemic adverse events after the second dose, as determined using both the Genscript (pÂ =Â 0.03) and R-FIND (pÂ =Â 0.07) kits. The two doses of the ChAdOx1 vaccine induced high value of NAbs 3 weeks after vaccination. Immune responses were stronger in HCWs with than without adverse reactions after the second dose of ChAdOx1 vaccine.

Vocal Fold Paralysis Following COVID-19 Vaccination: Query of VAERS Database. OBJECTIVE: Vocal fold paresis or paralysis (VFP) may severely affect quality of life due to dysphonia and respiratory distress. As an increasing percentage of the United States population receives the COVID-19 vaccination, the objective of this study is to determine the correlation of COVID-19 postvaccination recurrent laryngeal neuropathy and resulting VFP. METHODS: The Vaccine Adverse Event Reporting System database was queried for patients exhibiting symptoms of VFP following COVID-19 vaccination. Patient demographics and clinical information including presenting symptoms, time of symptom onset, time of diagnosis and laterality. RESULTS: Twenty patients were found to have laryngoscopy confirmed VFP following COVID-19 vaccination. Vaccinations for Pfizer-BioNTech, Moderna, and Janssen were reported. Of those reported, 13 patients were female (65.0%) and seven were male (35.0%), with a mean age of 61.8â€‰years. The most common presenting symptom was a hoarse voice (30.0%). A majority of these cases were unilateral in nature (64.0%). Mean time from vaccination to symptom onset was 12.1 days and mean time from vaccination to diagnosis was 37.6 days. CONCLUSION: For patients presenting with voice or swallowing complaints after receiving the COVID-19 vaccine, prompt evaluation by an otolaryngologist should occur. However, the potential VFP side effect of vaccination is very rarely cited in the literature and largely outweighed by the benefits of vaccination. Further research is needed to delineate the exact pathophysiology of this complication and determine whether a causal relationship exists.

Antibody response after a third dose mRNA-1273 vaccine among vaccinated healthcare workers with two doses of inactivated SARS-CoV-2 vaccine. BACKGROUND: Health care workers (HCWs), a high-risk group for contracting COVID-19 disease, are being prioritized to receive COVID-19 vaccination. A third dose messenger RNA (mRNA) vaccine, mRNA-1273 (Moderna), after 2 doses of inactivated vaccine (CoronaVac), has been used to increase the level of protection against SARS-CoV-2 among Indonesian HCWs. However, data regarding antibody response after mRNA-1273 booster dose are limited. OBJECTIVE: To evaluate the receptor-binding domain (RBD) of the SARS-CoV-2 spike (S) protein (anti-S) titers induced by the third mRNA-1273 vaccine among fully vaccinated HCWs with CoronaVac. RESULTS: A total of 90 HCWs with no history of SARS-CoV-2 infection and who had received the third dose of vaccination were included in this study. The mRNA-1273 vaccine booster was administered 6 months after completing primary vaccination with CoronaVac. After the third dose, the anti-S antibodies level significantly increased, from a median of 41.7 U/mL (interquartile range [IQR], 22.4-92.5) to 28 394 U/mL (IQR, 20 837-41 646) (pÂ <0.0001). After the third dose, seropositivity with the anti-S antibodies level >210 U/mL was observed in all HCWs. Age was negatively associated with the anti-S antibodies level after the mRNA-1273 booster. CONCLUSION: The heterologous prime booster with CoronaVac and mRNA-1273 vaccine booster elicit a pronounced antibody response against SARS-CoV-2 infection.

SARS-CoV-2 reinfection after previous infection and vaccine breakthrough infection through the second wave of pandemic in India: An observational study. BACKGROUND: There are sparse longitudinal data on SARS-CoV-2 infection after previous infection and after partial or full vaccination. METHODS: This study of a cohort of healthcare workers used Kaplan-Meier analysis with appropriate definition of events and censoring and used Cox models to assess outcomes, with data cut-off on June 18, 2021. RESULTS: A total of 1806 individuals with median age of 32 (18-64) years, 1483 (82.1%) with at least one vaccine dose, 1085 (60.1%) with 2 vaccine doses, 408 (22.6%) with at least one episode of SARS-CoV-2 infection, and 6 (1.47%) with 2 episodes of infection were included in the analysis. At median follow-up of 38.4 weeks after first SARS-CoV-2 infection (n=408), the 52-week probability of reinfection was 2.2% (95% CI, 1.0-4.91%); and at median follow-up of 13.3 weeks after second dose, the 16-week probability of breakthrough infection was 5.6% (95% CI, 4.33-7.23%), which was significantly higher among those without previous SARS-CoV-2 infection versus with previous infection (6.4% vs 1.8%, p=0.016, adjusted Cox HR=3.49, 95% CI, 1.09-11.20, p=0.036) and females versus males (7.9% vs 3.8%, p=0.007, adjusted Cox HR=2.06, 95% CI 1.19-3.56, p=0.01). CONCLUSIONS: There was low probability of reinfection after previous SARS-CoV-2 infection and higher vaccine breakthrough infections among females and those without previous infection.

COVID-19 vaccination experience among United States dental professionals and students: Safety, confidence, concerns, and side effects. OBJECTIVES: The purpose of this study was to evaluate the COVID-19 vaccination experience among United States-based dental professionals and students: to understand their beliefs, concerns, safety and confidence levels, and side effects experienced after vaccination; striving to boost vaccination acceptability to curtail the pandemic. METHODS: An observational survey study approved by The University of Texas Health San Antonio Institutional Review Board was distributed to members of the School of Dentistry community using Qualtrics XM software. The survey was completed anonymously. Data were analyzed using R statistical computing software, Ï‡2 test and Fisher's Exact test. RESULTS: Over 80% of all participants felt moderately to very safe working after the COVID-19 vaccine was made available, and more than 75% were moderately to very confident that the vaccine can protect them during the pandemic. At least 35% were moderately to very concerned about immediate and long-term side effects of the vaccine; despite the concerns, 94% received the vaccine. Side effects were more common after the second dose of the vaccine. Most common side effects were injection site pain, and general side effects of fatigue/tiredness, headache, muscle/body ache, and chills/fever. 74% reported no effect of the vaccine on daily activities, and the severity of side effects no worse than mild (about 60%). CONCLUSIONS: Majority of the participants felt safe and confident that the vaccine would protect them against COVID-19 infection. Sharing these findings and reliable information that the vaccine is safe and effective is paramount to fostering the vaccine uptake and curtailing the pandemic. PRACTICAL IMPLICATIONS: Findings of this study demonstrated the confidence of the UT Health San Antonio, School of Dentistry community that the benefits of the vaccines greatly outweigh the risks; boosting the vaccination acceptance while creating a COVID-19 free environment both for the academic dental setting and the community it serves.

First dose ChAdOx1 and BNT162b2 COVID-19 vaccinations and cerebral venous sinus thrombosis: A pooled self-controlled case series study of 11.6 million individuals in England, Scotland, and Wales. BACKGROUND: Several countries restricted the administration of ChAdOx1 to older age groups in 2021 over safety concerns following case reports and observed versus expected analyses suggesting a possible association with cerebral venous sinus thrombosis (CVST). Large datasets are required to precisely estimate the association between Coronavirus Disease 2019 (COVID-19) vaccination and CVST due to the extreme rarity of this event. We aimed to accomplish this by combining national data from England, Scotland, and Wales. METHODS AND FINDINGS: We created data platforms consisting

of linked primary care, secondary care, mortality, and virological testing data in each of England, Scotland, and Wales, with a combined cohort of 11,637,157 people and 6,808,293 person years of follow-up. The cohort start date was December 8, 2020, and the end date was June 30, 2021. The outcome measure we examined was incident CVST events recorded in either primary or secondary care records. We carried out a self-controlled case series (SCCS) analysis of this outcome following first dose vaccination with ChAdOx1 and BNT162b2. The observation period consisted of an initial 90-day reference period, followed by a 2-week prerisk period directly prior to vaccination, and a 4-week risk period following vaccination. Counts of CVST cases from each country were tallied, then expanded into a full dataset with 1 row for each individual and observation time period. There was a combined total of 201 incident CVST events in the cohorts (29.5 per million person years). There were 81 CVST events in the observation period among those who a received first dose of ChAdOx1 (approximately 16.34 per million doses) and 40 for those who received a first dose of BNT162b2 (approximately 12.60 per million doses). We fitted conditional Poisson models to estimate incidence rate ratios (IRRs). Vaccination with ChAdOx1 was associated with an elevated risk of incident CVST events in the 28 days following vaccination, IRR = 1.93 (95% confidence interval (CI) 1.20 to 3.11). We did not find an association between BNT162b2 and CVST in the 28 days following vaccination, IRR = 0.78 (95% CI 0.34 to 1.77). Our study had some limitations. The SCCS study design implicitly controls for variables that are constant over the observation period, but also assumes that outcome events are independent of exposure. This assumption may not be satisfied in the case of CVST, firstly because it is a serious adverse event, and secondly because the vaccination programme in the United Kingdom prioritised the clinically extremely vulnerable and those with underlying health conditions, which may have caused a selection effect for individuals more prone to CVST. Although we pooled data from several large datasets, there was still a low number of events, which may have caused imprecision in our estimates. CONCLUSIONS: In this study, we observed a small elevated risk of CVST events following vaccination with ChAdOx1, but not BNT162b2. Our analysis pooled information from large datasets from England, Scotland, and Wales. This evidence may be useful in risk-benefit analyses of vaccine policies and in providing quantification of risks associated with vaccination to the general public.

Association of COVID-19 vaccines ChAdOx1 and BNT162b2 with major venous, arterial, or thrombocytopenic events: A population-based cohort study of 46 million adults in England. BACKGROUND: Thromboses in unusual locations after the Coronavirus Disease 2019 (COVID-19) vaccine ChAdOx1-S have been reported, although their frequency with vaccines of different types is uncertain at a population level. The aim of this study was to estimate the population-level risks of hospitalised thrombocytopenia and major arterial and venous thromboses after COVID-19 vaccination. METHODS AND FINDINGS: In this whole-population cohort study, we analysed linked electronic health records from adults living in England, from 8 December 2020 to 18 March 2021. We estimated incidence rates and hazard ratios (HRs) for major arterial, venous, and thrombocytopenic outcomes 1 to 28 and >28 days after first vaccination dose for ChAdOx1-S and BNT162b2 vaccines. Analyses were performed separately for ages <70 and â‰¥70 years and adjusted for age, age2, sex, ethnicity, and deprivation. We also prespecified adjustment for anticoagulant medication, combined oral contraceptive medication, hormone replacement therapy medication, history of pulmonary embolism or deep vein thrombosis, and history of coronavirus infection in analyses of venous thrombosis; and diabetes, hypertension, smoking, antiplatelet medication, blood pressure lowering medication, lipid lowering medication, anticoagulant medication, history of stroke, and history of myocardial infarction in analyses of arterial thromboses. We selected further covariates with backward selection. Of 46 million adults, 23 million (51%) were women; 39 million (84%) were <70; and 3.7 million (8.1%) Asian or Asian British, 1.6 million (3.5%) Black or Black British, 36 million (79%)

White, 0.7 million (1.5%) mixed ethnicity, and 1.5 million (3.2%) were of another ethnicity. Approximately 21 million (46%) adults had their first vaccination between 8 December 2020 and 18 March 2021. The crude incidence rates (per 100,000 person-years) of all venous events were as follows: prevaccination, 140 [95% confidence interval (CI): 138 to 142]; â‰¤28 days post-ChAdOx1-S, 294 (281 to 307); >28 days post-ChAdOx1-S, 359 (338 to 382), â‰¤28 days post-BNT162b2-S, 241 (229 to 253); >28 days post-BNT162b2-S 277 (263 to 291). The crude incidence rates (per 100,000 person-years) of all arterial events were as follows: prevaccination, 546 (95% CI: 541 to 555); â‰¤28 days post-ChAdOx1-S, 1,211 (1,185 to 1,237); >28 days post-ChAdOx1-S, 1678 (1,630 to 1,726), â‰¤28 days post-BNT162b2-S, 1,242 (1,214 to 1,269); >28 days post-BNT162b2-S, 1,539 (1,507 to 1,572). Adjusted HRs (aHRs) 1 to 28 days after ChAdOx1-S, compared with unvaccinated rates, at ages <70 and â‰¥70 years, respectively, were 0.97 (95% CI: 0.90 to 1.05) and 0.58 (0.53 to 0.63) for venous thromboses, and 0.90 (0.86 to 0.95) and 0.76 (0.73 to 0.79) for arterial thromboses. Corresponding aHRs for BNT162b2 were 0.81 (0.74 to 0.88) and 0.57 (0.53 to 0.62) for venous thromboses, and 0.94 (0.90 to 0.99) and 0.72 (0.70 to 0.75) for arterial thromboses. aHRs for thrombotic events were higher at younger ages for venous thromboses after ChAdOx1-S, and for arterial thromboses after both vaccines. Rates of intracranial venous thrombosis (ICVT) and of thrombocytopenia in adults aged <70 years were higher 1 to 28 days after ChAdOx1-S (aHRs 2.27, 95% CI: 1.33 to 3.88 and 1.71, 1.35 to 2.16, respectively), but not after BNT162b2 (0.59, 0.24 to 1.45 and 1.00, 0.75 to 1.34) compared with unvaccinated. The corresponding absolute excess risks of ICVT 1 to 28 days after ChAdOx1-S were 0.9 to 3 per million, varying by age and sex. The main limitations of the study are as follows: (i) it relies on the accuracy of coded healthcare data to identify exposures, covariates, and outcomes; (ii) the use of primary reason for hospital admission to measure outcome, which improves the positive predictive value but may lead to an underestimation of incidence; and (iii) potential unmeasured confounding. CONCLUSIONS: In this study, we observed increases in rates of ICVT and thrombocytopenia after ChAdOx1-S vaccination in adults aged <70 years that were small compared with its effect in reducing COVID-19 morbidity and mortality, although more precise estimates for adults aged <40 years are needed. For people aged â‰¥70 years, rates of arterial or venous thrombotic events were generally lower after either vaccine compared with unvaccinated, suggesting that either vaccine is suitable in this age group.

Waning but persistent humoral response 6Â months after the third dose of the mRNA BNT162b2 vaccine in hemodialysis and peritoneal dialysis patients.

A homologous or variant booster vaccine after Ad26.COV2.S immunization enhances SARS-CoV-2-specific immune responses in rhesus macaques. Ad26.COV2.S has demonstrated durability and clinical efficacy against symptomatic COVID-19 in humans. In this study, we report the correlates of durability of humoral and cellular immune responses in 20 rhesus macaques immunized with single-shot Ad26.COV2.S and the immunogenicity of a booster shot at 8 to 10 months after the initial immunization. Ad26.COV2.S elicited durable binding and neutralizing antibodies as well as memory B cells and long-lived bone marrow plasma cells. Innate immune responses and bone marrow plasma cell responses correlated with durable antibody responses. After Ad26.COV2.S boost immunization, binding and neutralizing antibody responses against multiple SARS-CoV-2 variants increased 31- to 69-fold and 23- to 43-fold, respectively, compared with preboost concentrations. Antigen-specific B cell and T cell responses also increased substantially after the boost immunization. Boosting with a modified Ad26.COV2.S.351 vaccine expressing the SARS-CoV-2 spike protein from the beta variant led to largely comparable responses with slightly higher beta- and omicron-specific humoral immune responses. These data demonstrate that a late boost with Ad26.COV2.S or Ad26.COV2.S.351 resulted in a marked increase in humoral and cellular immune responses that were highly cross-reactive across multiple SARS-CoV-2 variants in rhesus macaques.

Exacerbation of systemic lupus erythematosus after receiving mRNA-1273-based coronavirus disease 2019 vaccine.
Kounis syndrome associated with BNT162b2 mRNA COVID-19 vaccine presenting as ST-elevation acute myocardial infarction.
Herpes zoster and simplex reactivation following COVID-19 vaccination: new insights from a vaccine adverse event reporting system (VAERS) database analysis. BACKGROUND: A few cases of Herpes Zoster and Simplex reactivation following COVID-19 immunization have been recently described, but the real extent of this suspected adverse event has not been elucidated yet. METHODS: We performed a nested case/control study by using the U.S. Vaccine Adverse Event Reporting System database. We carried out a case-level clinical review of all Herpes reactivation cases following the administration of COVID-19 vaccines. For cases and controls, significance was set at P =Â 0.05, differential risk of reporting was assessed for each vaccine as reporting odds ratio and incidence was estimated based on the total number of vaccine doses administered. RESULTS: Of 6,195 cases included in the analysis (5,934 and 273 reporting Herpes Zoster and Herpes Simplex, respectively) over 90% were non-serious. We found a slightly higher risk of reporting both for Zoster (RORÂ =Â 1.49) and Simplex (RORÂ =Â 1.51) infections following the Pfizer-BioNTech vaccine. The estimated incidence was approximately 0.7/100,000 and 0.03/100,000 for Zoster and Simplex, respectively. CONCLUSIONS: The paucity of cases (almost all of non-serious nature) makes the potential occurrence of this adverse effect negligible from clinical standpoints, thus supporting the good safety profile of the COVID-19 vaccination, which remains strongly recommended.
Guillain-Barre Syndrome After Two COVID-19 Vaccinations: Two Case Reports With Follow-up Electrodiagnostic Study. Guillain-Barre syndrome (GBS) is an immune-mediated acute polyradiculoneuropathy and commonly occurs after a preceding infection or immunization sequalae. Following the severe acute respiratory syndrome-coronavirus-2 virus pandemic with co-introduction of massive vaccinations, several GBS cases associated with coronavirus disease 2019 (COVID-19) infection per se or after vaccination for COVID-19 were reported internationally. Herein, we report two cases of Korean GBS presenting with tetraplegia after two different COVID-19 vaccinations (42-year old man by AstraZeneca and 48-year woman by Pfizer vaccines) within four weeks after vaccination. The patients were diagnosed with clinical examination, serial electromyography, and compatible laboratory results and improved after comprehensive rehabilitative treatment and intravenous immunoglobulin therapy. Furthermore, we performed an electrodiagnostic follow-up study of each case to examine their unique characteristics.
Case Reports of Acute Transverse Myelitis Associated With mRNA Vaccine for COVID-19. Acute transverse myelitis (ATM) has been reported as rare complication of vaccination. Herein, we report 2 cases of ATM after the administration of an mRNA vaccine for coronavirus disease 2019 (COVID-19). The first one is an 81-year-old man who received the BNT162b2 vaccine. He presented with bilateral hand weakness. Spine magnetic resonance imaging (MRI) showed high signal intensity from the C1 to C3 vertebrae. The second is a 23-year-old woman who received the BNT162b2 vaccine and experienced tingling in her legs. Spine MRI showed a high signal intensity lesion at the conus medullaris. These patients were treated with intravenous methylprednisolone and their symptoms improved slightly. Careful follow-up is needed to identify adverse events after the administration of mRNA vaccines for COVID-19.
Background rates of five thrombosis with thrombocytopenia syndromes of special interest for COVID-19 vaccine safety surveillance: Incidence between 2017 and 2019 and patient profiles from 38.6 million people in six European countries.
Investigation of the incidence of immunisation stress-related response following COVID-19 vaccination in healthcare workers. INTRODUCTION: Safe vaccination worldwide is critical to end

the coronavirus disease 2019 (COVID-19) pandemic. We aimed to evaluate adverse reactions to vaccination using a web-based questionnaire and examine the risk factors for the occurrence of immunisation stress-related response (ISRR). METHODS: We conducted a questionnaire survey using Google FormÂ® among the employees of St. Marianna University Hospital who had received the COVID-19 vaccine between April 2021 and May 2021, 1 week after the first and second vaccinations. We developed and used a questionnaire to identify individuals with ISRR according to the World Health Organization diagnostic criteria. A generalised linear mixed model was constructed with ISRR onset as the dependent variable, subjects as the random factor, and each parameter as a fixed factor. A multivariate model was constructed using the forced imputation method with factors that were significant in the univariate analysis. RESULTS: We enrolled 2,073 and 1,856 respondents in the first and second questionnaire surveys, respectively. Fifty-five and 33 ISRR cases were identified in the first and second vaccinations, respectively. In the univariate analysis, strong pre-vaccination anxiety (odds ratio [OR], 2.3; 95% confidence interval [CI], 1.30-4.12, pÂ =Â 0Â·004) and history of allergy (OR, 1.6; 95% CI, 1.14-2.24, pÂ =Â 0Â·007) were significant risk factors. Multivariate analysis also showed that strong pre-vaccination anxiety (OR, 2.1; 95% CI, 1.15-3.80, pÂ =Â 0.016) and history of allergy (OR, 1.5; 95% CI, 1.09-2.15, pÂ =Â 0.014) were significant risk factors. CONCLUSIONS: Confirmation of allergy prior to vaccination and subsequent action are essential for addressing ISRR.

Immune response to one dose of BNT162b2 mRNA Covid-19 vaccine followed by SARS-CoV-2 infection: An Italian prospective observational study. INTRODUCTION: A mass vaccination campaign against SARS-CoV-2 was initiated in European countries on December 27, 2020. This study compared the antibody response in a sample of healthcare workers (HCWs) who, after the first dose of the BNT162b2 mRNA vaccine, were infected with SARS-CoV-2 (infection group) with the response in a control group of HCWs immunized with two doses (vaccine group). METHODS: This two-arm observational cohort study was carried out using routine health surveillance data obtained from HCWs at Bari Policlinico General Hospital (Italy). The antibody response was determined infection group and vaccine group. RESULTS: Among the 100 HCWs, 25 (25.0%) were in the infection group and 75 (75.0%) in the full-vaccine group. At the serological evaluation, all of the HCWs tested positive, with a geometric mean titer (GMT) of 7106.8 (95Â %CIÂ =Â 5628.5-8973.4) and a statistically significant difference (pÂ <Â 0.0001) between the infection group (GMTÂ =Â 2139.7; 95Â %CIÂ =Â 1310.4-3493.6) and the vaccine group (GMTÂ =Â 10603.6; 95Â %CIÂ =Â 8698.0-12926.8). DISCUSSION: Our results shed light on the vaccine response of individuals in different risk categories. It also emphasizes the need for the continued use by HCWs of PPE and good practices during the window between the first and second anti-SARS-CoV-2 vaccinations.

Fatal thrombotic microangiopathy with rhabdomyolysis as an initial symptom after the first dose of mRNA-1273 vaccine: A case report. We report a case of a Japanese man with severe rhabdomyolysis and multiple thrombosis of arterioles after the first dose of mRNA-1273 vaccine. He developed rapidly progressive rhabdomyolysis and infarctions of multiple organs. Antiplatelet factor 4 antibody test was negative. Despite the intensive supportive care, including aggressive fluid administration, hemodialysis, administration of anticoagulants, high-dose steroid, and eculizumab, the patient ultimately died of multiple organ failure. Autopsy revealed multiple thrombosis in the arterioles and organ necrosis. Low serum complements and C3 deposition in the renal glomeruli detected by immunofluorescence suggested a possible immune-mediated mechanism. To our knowledge, this is the first case report of rhabdomyolysis and multiple thrombosis of the arterioles as an adverse event following COVID-19 vaccination.

The vaccinia-based Sementis Copenhagen Vector coronavirus disease 2019 vaccine induces broad and durable cellular and humoral immune responses. The ongoing coronavirus disease 2019 (COVID-19) pandemic perpetuated by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants

has highlighted the continued need for broadly protective vaccines that elicit robust and durable protection. Here, the vaccinia virus-based, replication-defective Sementis Copenhagen Vector (SCV) was used to develop a first-generation COVID-19 vaccine encoding the spike glycoprotein (SCV-S). Vaccination of mice rapidly induced polyfunctional CD8 T cells with cytotoxic activity and robust type 1 T helper-biased, spike-specific antibodies, which are significantly increased following a second vaccination, and contained neutralizing activity against the alpha and beta variants of concern. Longitudinal studies indicated that neutralizing antibody activity was maintained up to 9â€‰months after vaccination in both young and middle-aged mice, with durable immune memory evident even in the presence of pre-existing vector immunity. Therefore, SCV-S vaccination has a positive immunogenicity profile, with potential to expand protection generated by current vaccines in a heterologous boost format and presents a solid basis for second-generation SCV-based COVID-19 vaccine candidates incorporating additional SARS-CoV-2 immunogens.

Comparison of Symptoms and Antibody Response Following Administration of Moderna or Pfizer SARS-CoV-2 Vaccines. CONTEXT.â€”: Moderna (mRNA-1272) and Pfizer (BNT162b2) SARS-CoV-2 vaccines demonstrate favorable safety and efficacy profiles, but direct comparison data are lacking. OBJECTIVE.â€”: To determine the vaccines' side effect profiles and expected antibody responses. These data may help personalize vaccine selection and identify individuals with a suboptimal vaccine response. DESIGN.â€”: One hundred forty-nine healthy, largely seronegative adults were assigned Moderna (n = 79) or Pfizer (n = 70). Following the second dose, participants completed a survey documenting their side effects. Serum was collected 0 to 4 days prior to dose 2, and 14 Â± 4 days, 30 Â± 4 days, 90 Â± 10 days, and 180 Â± 20 days after dose 2. Convalescent serum specimens were collected 32 to 54 days from donors after a polymerase chain reaction-confirmed SARS-CoV-2 infection (n = 20). Anti-spike antibodies were measured using the Roche Diagnostics Elecys Anti-SARS-CoV-2 S assay on a Roche cobas e801 instrument. RESULTS.â€”: Participants receiving the Moderna vaccine experienced side effects with greater frequency and severity. Both vaccines elicited a robust antibody response, but median signal was higher in Moderna recipients. Symptom severity decreased with age. Antibody response in Pfizer recipients negatively correlated with age. Antibody response decreased after 6 months (84% reduction in Moderna, 79% Pfizer), but values remained greater than for convalescent donors. Antibody response did not correlate with gender or symptom severity. CONCLUSIONS.â€”: Moderna may be preferred in individuals in need of greater immune stimulation (eg, older individuals), whereas Pfizer may be preferred in those concerned about vaccine reactions. Anti-spike antibody signal varies by vaccine, so specific reference intervals will be needed to identify individuals with a suboptimal response.

Risk of Second Allergic Reaction to SARS-CoV-2 Vaccines: A Systematic Review and Meta-analysis. IMPORTANCE: Vaccination against SARS-CoV-2 is a highly effective strategy to prevent infection and severe COVID-19 outcomes. The best strategy for a second dose of vaccine among persons who had an immediate allergic reaction to their first SARS CoV-2 vaccination is unclear. OBJECTIVE: To assess the risk of severe immediate allergic reactions (eg, anaphylaxis) to a second dose of SARS-CoV-2 mRNA vaccine among persons with immediate allergic reactions to their first vaccine dose. DATA SOURCES: MEDLINE, Embase, Web of Science, and the World Health Organization Global Coronavirus database were searched from inception through October 4, 2021. STUDY SELECTION: Included studies addressed immediate allergic reactions of any severity to a second SARS-CoV-2 vaccine dose in persons with a known or suspected immediate allergic reaction (<4 hours after vaccination) after their first SARS-CoV-2 vaccine dose. Studies describing a second vaccine dose among persons reporting delayed reactions (>4 hours after vaccination) were excluded. DATA EXTRACTION AND SYNTHESIS: Paired reviewers independently selected studies, extracted data, and assessed risk of bias. Random-effects models were used for meta-analysis. The GRADE (Grading of Recommendation,

Assessment, Development, and Evaluation) approach evaluated certainty of the evidence. MAIN OUTCOMES AND MEASURES: Risk of severe immediate allergic reaction and repeated severe immediate allergic reactions with a second vaccine dose. Reaction severity was defined by the reporting investigator, using Brighton Collaboration Criteria, Ring and Messmer criteria, World Allergy Organization criteria, or National Institute of Allergy and Infectious Diseases criteria. RESULTS: Among 22 studies of SARS-CoV-2 mRNA vaccines, 1366 individuals (87.8% women; mean age, 46.1 years) had immediate allergic reactions to their first vaccination. Analysis using the pooled random-effects model found that 6 patients developed severe immediate allergic reactions after their second vaccination (absolute risk, 0.16% [95% CI, 0.01%-2.94%]), 232 developed mild symptoms (13.65% [95% CI, 7.76%-22.9%]), and, conversely, 1360 tolerated the dose (99.84% [95% CI, 97.09%-99.99%]). Among 78 persons with severe immediate allergic reactions to their first SARS-CoV-2 mRNA vaccination, 4 people (4.94% [95% CI, 0.93%-22.28%]) had a second severe immediate reaction, and 15 had nonsevere symptoms (9.54% [95% CI, 2.18%-33.34%]). There were no deaths. Graded vaccine dosing, skin testing, and premedication as risk-stratification strategies did not alter the findings. Certainty of evidence was moderate for those with any allergic reaction to the first dose and low for those with severe allergic reactions to the first dose. CONCLUSIONS AND RELEVANCE: In this systematic review and meta-analysis of case studies and case reports, the risk of immediate allergic reactions and severe immediate reactions or anaphylaxis associated with a second dose of an SARS-CoV-2 mRNA vaccine was low among persons who experienced an immediate allergic reaction to their first dose. These findings suggest that revaccination of individuals with an immediate allergic reaction to a first SARS-CoV-2 mRNA vaccine dose in a supervised setting equipped to manage severe allergic reactions can be safe.

Pemphigus vulgaris after SARS-CoV-2 vaccination: A case with new-onset and two cases with severe aggravation. Pemphigus may be induced or aggravated by certain drugs and vaccines. People worldwide are currently vaccinated with several SARS-CoV-2 vaccines which may be associated with increased number of aggravated or triggered autoimmune bullous diseases in subjects with an underlying genetic predisposition. Herein, a case of new-onset pemphigus vulgaris (PV) and two cases with aggravation of PV after vaccinations for SARS-CoV-2 are reported.

Multi inflammatory syndrome in a 16-year-old male following first dose of m-RNA COVID-19 vaccination. Multisystem Inflammatory Syndrome (MIS) is an uncommon systemic illness that occurs 4-6Â weeks after primary infection with SARS-CoV-2. There are emerging reports of MIS arising following vaccination against SARS-CoV-2. We report a 16-year-old male with a multi system inflammatory condition meeting the case definition for MIS following BTN162b2 mRNA SARS-CoV-2 (Pfizer BioNTech) vaccine with no other identifiable precipitant or evidence of primary infection with SARS-Cov-2.

Biopsy-Proven Fulminant Myocarditis Requiring Mechanical Circulatory Support Following COVID-19 mRNA Vaccination. A 48-year-old woman suffered from cardiogenic shock with fulminant myocarditis following the second dose of COVID-19 vaccine (mRNA-1273). Venoarterial extracorporeal membrane oxygenation and Impella support were essential in achieving hemodynamic stability. Endomyocardial biopsy revealed lymphocytic infiltration with predominant immunostaining for CD8- and CD68-positive cells. The left ventricular ejection fraction improved significantly after treatment with mechanical circulatory support. Myocarditis following COVID-19 mRNA vaccination may also occur in middle-aged women; it may be fulminant and require mechanical circulatory support. Although our results suggest the involvement of cytotoxic T lymphocytes and macrophages, further investigation is needed before these can be established as pathogenetic mechanisms.

Seroconversion Rates After the Second COVID-19 Vaccination in Patients With Systemic Light Chain (AL) amyloidosis.

Serologic Responses to COVID-19 Vaccines in Hematological Patients Are Predominantly Impaired in Lymphoid but not in Myeloid Malignancies.

Reply to "Widespread Cutaneous Reaction to the Johnson & Johnson Ad26.Cov2.S Vaccine".

B Cell Composition Is Altered After Kidney Transplantation and Transitional B Cells Correlate With SARS-CoV-2 Vaccination Response. BACKGROUND: The COVID-19 pandemic has major implications on kidney transplant recipients (KTRs) since they show increased mortality due to impaired immune responses to SARS-CoV-2 infection and a reduced efficacy of SARS-CoV-2 vaccination. Surprisingly, dialysis patients have shown superior seroconversion rates after vaccination compared to KTRs. Therefore, we investigated peripheral blood B cell (BC) composition before and after kidney transplantation (KT) and aimed to screen the BC compartment to explain impaired antibody generation. METHODS: A total of 105 patients were recruited, and multicolor flow cytometric phenotyping of peripheral venous blood BC subpopulations was performed before and 1 year after KT. Complete follow-up was available for 71 individuals. Anti-SARS-CoV-2 antibodies were collected retrospectively and were available for 40 subjects, who had received two doses of an mRNA-based vaccine (BNT162b2 or mRNA-1273). RESULTS: Overall, relative BC frequencies within lymphocytes decreased, and their absolute counts trended in the same direction 1 year after KT as compared to CKD G5 patients. Frequencies and absolute numbers of naÃ¯ve BCs remained stable. Frequencies of double negative BCs, a heterogeneous subpopulation of antigen experienced BCs lacking CD27 expression, were increased after KT, yet their absolute counts were similar at both time points. Transitional BCs (TrBCs) and plasmablasts were significantly reduced after KT in absolute and relative terms. Memory BCs were affected differently since class-switched and IgM-only subsets decreased after KT, but unswitched and IgD-only memory BCs remained unchanged. CD86(+) and CD5(+) expression on BCs was downregulated after KT. Correlational analysis revealed that TrBCs were the only subset to correlate with titer levels after SARS-CoV-2 vaccination. Responders showed higher TrBCs, both absolute and relative, than non-responders. CONCLUSION: Together, after 1 year, KTRs showed persistent and profound compositional changes within the BC compartment. Low TrBCs, 1 year after KT, may account for the low serological response to SARS-CoV-2 vaccination in KTRs compared to dialysis patients. Our findings need confirmation in further studies as they may guide vaccination strategies.

Prevalence of Antibodies to SARS-CoV-2 Following Natural Infection and Vaccination in Irish Hospital Healthcare Workers: Changing Epidemiology as the Pandemic Progresses. BACKGROUND: In October 2020 SARS-CoV-2 seroprevalence among hospital healthcare workers (HCW) of two Irish hospitals was 15 and 4. 1%, respectively. We compare seroprevalence in the same HCW population 6 months later, assess changes in risk factors for seropositivity with progression of the pandemic and serological response to vaccination. METHODS: All staff of both hospitals (N = 9,038) were invited to participate in an online questionnaire and SARS-CoV-2 antibody testing in April 2021. We measured anti-nucleocapsid and anti-spike antibodies. Frequencies and percentages for positive SARS-CoV-2 antibodies were calculated and adjusted relative risks for participant characteristics were calculated using multivariable regression analysis. RESULTS: Five thousand and eighty-five HCW participated. Seroprevalence increased to 21 and 13%, respectively; 26% of infections were previously undiagnosed. Black ethnicity (aRR 1.7, 95% CI 1.3-2.2, $p < 0.001$), lower level of education (aRR 1.4 for secondary level education, 95% CI 1.1-1.8, $p = 0.002$), living with other HCW (aRR 1.2, 95% CI 1.0-1.4, $p = 0.007$) were significantly associated with seropositivity. Having direct patient contact also carried a significant risk being a healthcare assistant (aRR 1.8, 95% CI 1.3-2.3, $p < 0.001$), being a nurse (aRR 1.4, 95% CI 1.0-1.8, $p = 0.022$), daily contact with COVID-19 patients (aRR 1.4, 95% CI 1.1-1.7, p =

0.002), daily contact with patients without suspected or confirmed COVID-19 (aRR 1.3, 95% CI 1.1-1.5, p = 0.013). Breakthrough infection occurred in 23/4,111(0.6%) of fully vaccinated participants; all had anti-S antibodies. CONCLUSION: The increase in seroprevalence reflects the magnitude of the third wave of the pandemic in Ireland. Genomic sequencing is needed to apportion risk to the workplace vs. the household/community. Concerted efforts are needed to mitigate risk factors due to ethnicity and lower level of education, even at this stage of the pandemic. The undiagnosed and breakthrough infections call for ongoing infection prevention and control measures and testing of HCW in the setting of close contact. Vaccinated HCW with confirmed infection should be actively assessed, including SARS-CoV-2 whole genome sequencing (WGS), serology testing and assessment of host determinants, to advance understanding of the reasons for breakthrough infection.

Frequency and Associations of Adverse Reactions of COVID-19 Vaccines Reported to Pharmacovigilance Systems in the European Union and the United States. INTRODUCTION: This study aims to provide a risk assessment of the adverse reactions related to the COVID-19 vaccines manufactured by AstraZeneca, Janssen, Moderna, and Pfizer-BioNTech which have been in use in the European Union and the United States between December 2020 and October 2021. METHODS: Data from the European Database of Suspected Adverse Drug Reaction (EudraVigilance) and the Vaccine Adverse Events Reporting System (VAERS) from 2020 to October 2021 are analysed. More than 7.8 million adverse reactions of about 1.6 million persons are included. The adverse reactions are classified with the Common Toxicity Criteria (CTC) categories. COVID-19 vaccine exposures and adverse reactions reported between December 2020 and October 2021 are compared to influenza vaccine exposures and adverse reactions reported between 2020 and 2021. The population-level vaccine exposures to COVID-19 and influenza vaccines comprised about 451 million and 437 million exposures, respectively. Absolute and relative risk estimates are calculated by CTC categories and COVID-19 vaccines for the EU and US populations aged 18 years and older. RESULTS: A higher risk of reporting serious adverse reactions was observed for the COVID-19 vaccines in comparison to the influenza vaccines. Individuals age 65 and older were associated with a higher frequency of death, hospitalisations, and life-threatening reactions than younger individuals (relative risk estimates between 1.49 99% CI [1.44-1.55] and 8.61 99% CI [8.02-9.23]). Outcome onset of serious adverse reactions occurred within the first 7 days after vaccination in about 77.6-89.1% of cases. The largest absolute risks were observed for allergic, constitutional reactions, dermatological, gastrointestinal, neurological reactions, and localised and non-localised pain. The largest relative risks between COVID-19 vs. influenza vaccines were observed for allergic reactions, arrhythmia, general cardiovascular events, coagulation, haemorrhages, gastrointestinal, ocular, sexual organs reactions, and thrombosis. CONCLUSION: The present study provides an overview of adverse reactions frequently reported to the pharmacovigilance systems following COVID-19 vaccination in the EU and US populations. Despite the limitations of passive reporting systems, these results may inform further clinical research investigating in more detail the pathophysiological mechanisms potentially associated with the COVID-19 vaccines.

COVID-19 Vaccination Does Not Affect Reproductive Health Parameters in Men. With the implementation of COVID-19 vaccine up-take, doubts regarding the impact of immunization on future fertility have begun to emerge. We have examined vaccine safety on male reproductive health. We set up a multicentre (three infertility centers), retrospective study in order to assess semen parameters and fertilization rate of one hundred-six men in a pairwise comparison between the first and second assisted reproduction technology (ART) attempt, performed respectively before and after COVID-19 vaccination. Median time (range) between the first vaccine dose and the second ART cycle was 75 days (39-112). Semen parameters did not change before and after the exposure. Fertilization rate was also similar before and after vaccination. Twenty-five patients (24%) were oligozoospermic

before the vaccination while 26 (25%) after the exposure (P = 0.87). Severe asthenozoospermia were present in 11 patients before as well as after the exposure. No difference was observed even after considering different types of vaccines (mRNA or viral vector). COVID-19 vaccination did not affect sperm quality and fertilization capacity of men undergoing ART treatments and should be considered safe for men's reproductive health.
Zoster meningitis in an immunocompetent young patient post first dose of BNT162b2 mRNA COVID-19 vaccine, a case report. Recently published observational data suggests an increased risk of herpes zoster infection post-vaccination with the BNT162b2 mRNA vaccine. We describe the case of VZV meningitis post BNT162b2 mRNA vaccination in a young immunocompetent patient. A 39-year-old patient with no medical history presented with a vesicular rash, headache, nausea and fever, days after receiving BNT162b2 mRNA vaccination. CSF analysis revealed a pleocytosis, and VZV DNA was confirmed by PCR testing. The patient received intravenous aciclovir with resolution of symptoms within 48Â h. He was discharged after 14 days of treatment. Case reports of herpes zoster reactivation post vaccination and details of subsequent successful vaccination course completion have allowed us to recommend the patient receive his second dose of the BNT162b2 mRNA vaccine. At the time of writing, however, the patient has declined to receive further vaccination due to fears of an adverse event. To the best of our knowledge, this is the first reported case in a young patient of herpes zoster meningitis following COVID-19 mRNA vaccination. The sharing of clinical experiences and reporting of suspected side effects, particularly for vaccines that employ novel technology, increases knowledge of the safety profile of these vaccines and allows clinicians to better aid patients make informed decisions with regard to commencing and completing vaccination.
Adult-Onset Still's Disease After the ChAdOx1 nCoV-19 Vaccine. Adult-onset Still's disease (AOSD) is a rare autoimmune disorder without clear etiology. It is known that genetic and infectious causes trigger diseases. AOSD cases have been reported afterÂ coronavirus disease 2019 (COVID-19)Â infection and post influenza vaccine. Here, we report this challenging case of adult-onset Still's disease in a patient who recently received the ChAdOx1 nCoV-19Â vaccine (Oxford-AstraZeneca).
A Rare Case of Brachial Plexus Neuropraxia After COVID-19 Vaccination. The brachial plexus injury is a rare complication after vaccination like that of the Influenza virus. Though a well-known and reported complication, there is still a dearth of literature mentioning its pathophysiology, the trend of involvement, symptoms, and treatment. This has also been reported after the coronavirus disease 2019 (COVID-19) vaccination. To the best of our knowledge, to date, only four cases have been reported so far. Every case needs to be reported to better understand the complication and formulate a line of management for better outcomes. We report a case of brachial plexus involvement after Covishield vaccination with complete recovery after treatment.
Organizing Pneumonia Following Recombinant Zoster Vaccination: A Rare Adverse Reaction. We describe a case of a severe but rare adverse reaction to recombinant varicella-zoster virus (VZV) vaccination: a 67-year-old female admitted with gradual onset of shortness of breath, hypoxia, and fever following VZV vaccination. The clinical picture and radiologic presentation mimicked COVID-19 pneumonia. However, repeated testing for COVID-19 by PCR was negative. A diagnosis of organizing pneumonia was made on transbronchial biopsies. The patient responded well to steroids and improved both clinically and radiographically. This case illustrates not only a rare and unreported complication from vaccination but also raises the awareness during the COVID-19 pandemic that other etiologies can mimic COVID-19 pneumonia. Physicians should be aware of other diagnoses that can mimic COVID-19 infection.
New-Onset Systemic Lupus Erythematosus after mRNA SARS-CoV-2 Vaccination. Systemic lupus erythematosus (SLE) is a multisystem autoimmune disease resulting from the interaction of genetic and environmental factors. In addition, some antiviral vaccines have been associated with the onset

of SLE. Few cases of SLE occurring after SARS-CoV-2 mRNA have been reported. Herein, we report the case of a 27-year-old woman with type I diabetes mellitus and family history of SLE who presented with symmetric inflammatory polyarthritis of the proximal interphalangeal joints, metacarpophalangeal joints, wrists, knees, and ankles two weeks after receiving the second dose of the SARS-CoV-2 mRNA-1273 vaccine. Laboratory results revealed positive antinuclear, anti-dsDNA, anti-Ro, and anti-La/SSB antibodies and low C4 levels. She was initially treated with low-dose prednisone and hydroxychloroquine. Hydroxychloroquine was discontinued after she developed an urticarial rash. Subsequently, mycophenolate mofetil was added after she developed proteinuria. This case highlights the importance of considering the diagnosis of SLE in patients who present with inflammatory polyarthritis after COVID-19 vaccination.

Population-Based Incidence of Guillain-BarrÃ© Syndrome During Mass Immunization With Viral Vaccines: A Pooled Analysis. Misunderstanding temporal coincidence of adverse events during mass vaccination and invalid assessment of possible safety concerns have negative effects on immunization programs, leading to low immunization coverage. We conducted this systematic review and meta-analysis to identify the incidence rates of GBS that are temporally associated with viral vaccine administration but might not be attributable to the vaccines. By literature search in Embase and PubMed, we included 48 publications and 2,110,441,600 participants. The pooled incidence rate of GBS was 3.09 per million persons (95% confidence interval [CI]: 2.67 to 3.51) within six weeks of vaccination, equally 2.47 per 100,000 person-year (95%CI: 2.14 to 2.81). Subgroup analyses illustrated that the pooled rates were 2.77 per million persons (95%CI: 2.47 to 3.07) for individuals who received the influenza vaccine and 2.44 per million persons (95%CI: 0.97 to 3.91) for human papillomavirus (HPV) vaccines, respectively. Our findings evidence the GBS-associated safety of virus vaccines. We present a reference for the evaluation of post-vaccination GBS rates in mass immunization campaigns, including the SARS-CoV-2 vaccine.

Case Series: Acute Hemorrhagic Encephalomyelitis After SARS-CoV-2 Vaccination. We present three cases fulfilling diagnostic criteria of hemorrhagic variants of acute disseminated encephalomyelitis (acute hemorrhagic encephalomyelitis, AHEM) occurring within 9 days after the first shot of ChAdOx1 nCoV-19. AHEM was diagnosed using magnetic resonance imaging, cerebrospinal fluid analysis and brain biopsy in one case. The close temporal association with the vaccination, the immune-related nature of the disease as well as the lack of other canonical precipitating factors suggested that AHEM was a vaccine-related adverse effect. We believe that AHEM might reflect a novel COVID-19 vaccine-related adverse event for which physicians should be vigilant and sensitized.

[Assessment of the humoral immunity induced by Sputnik V COVID-19 vaccine (Gam-COVID-Vac) in healthcare workers]. BACKGROUND: Vaccination for COVID-19 in healthcare workers (HCW) is essential to protect one of the populations most exposed to this disease. However, data on the humoral response rate to the vaccine and the factors associated with it in this population are limited. Therefore, we aimed to evaluate the antibody response against SARS-CoV-2 in HCWs with complete Sputnik V vaccine scheme and factors associated with an increased antibody response. MATERIAL AND METHODS: Prospective study to evaluate the anti-SARS-CoV-2 humoral response in HCWs vaccinated with two doses of the Sputnik V vaccine (April-July 2021). The assessment of anti-Spike IgG antibodies in plasma was performed using the COVIDAR IgG enzyme-linked immunosorbent assay. A logistic regression was performed to identify independent factors associated with a positive IgG serology test and an elevated antibody response. RESULTS: A total of 630 HCWs were enrolled. Median age (IQR): 47 years (35-56). Female sex: 462 (73.33%). Previous COVID-19: 158 (25%). The median interval time between vaccine doses was 3 (3-4) weeks. Positive serology was observed in 607 (96.35%) HCWs. In the multivariate analysis, a history of systemic reactogenicity was identified as

an independent variable associated with a positive serology; and history of systemic reactogenicity, COVID-19, interval between doses â‰¥Â 4 weeks and time to serology <Â 14 weeks were associated with an elevated antibody response. CONCLUSIONS: This study provides data on the humoral response to the Sputnik V vaccine in a real-life setting. These initial data can contribute to the development of future immunization strategies in HCWs.
Post-adenoviral-based vaccines Guillain-Barre Syndrome: A proposed mechanism. Despite great public health advances achieved by COVID-19 vaccines, rare side effects may impact the public acceptance. Guillain-Barre Syndrome has increasingly been reported with adenoviral-based vaccines. This perspective proposes a possible mechanism underlying this rare but clinically significant side effect thereby providing insights for improving our current vaccines against COVID-19.
Factors Associated with Change in SARS-CoV-2 Antibody Titers from Three to Six Months after the Administration of the BNT162b2 mRNA COVID-19 Vaccine among Healthcare Workers in Japan: A Prospective Study. Objective We evaluated the change in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody titers from three to six months after the administration of the BNT162b2 vaccine among healthcare workers. Methods A total of 337 healthcare workers who received 2 doses of the BNT162b2 vaccine were included in this study. Factors associated with SARS-CoV-2 antibody titers at three and six months and the change in SARS-CoV-2 antibody titers between three and six months after vaccine administration were analyzed using a logistic regression analysis. Results The SARS-CoV-2 antibody titer at 3 months was 4,812.1Â±3,762.9 AU/mL in all subjects and was lower in older workers than in younger ones. The SARS-CoV-2 antibody titer at 6 months was 1,368.9Â±1,412.3 AU/mL in all subjects. The SARS-CoV-2 antibody titers that were found to be high at three months were also high at six months. The change in SARS-CoV-2 antibody titers from 3 to 6 months was -68.9%Â±16.1%. The higher SARS-CoV-2 antibody titers at three months showed a more marked decrease from three to six months than lower titers. Conclusion This study demonstrates that SARS-CoV-2 antibody titers at three months decreased with age and were associated with the antibody titers at six months and the change in titer from three to six months. Older individuals in particular need to be aware of the declining SARS-CoV-2 antibody titers at six months after the BNT162b2 vaccine. The results of this study may provide insight into COVID-19 vaccine booster strategies.
Clinical, histopathological, and dermatoscopic characterization of eruptive pseudoangioma developing after COVID-19 vaccination-A case-series.
Potential risk factors for Varicella-zoster virus reactivation after COVID-19 vaccination.
Cerebral venous sinus thrombosis after adenovirus-vectored COVID-19 vaccination: review of the neurological-neuroradiological procedure. Cerebral venous and sinus thrombosis (CVST) after adenovirus-vectored COVID-19 ChAdOx1 nCov-19 (Oxford-AstraZeneca) and Ad26.COV2.S (Janssen/Johnson & Johnson) is a rare complication, occurring mainly in individuals under 60 years of age and more frequently in women. It manifests 4-24 days after vaccination. In most cases, antibodies against platelet factor-4/polyanion complexes play a pathogenic role, leading to thrombosis with thrombocytopenia syndrome (TTS) and sometimes a severe clinical or even fatal course. The leading symptom is headache, which usually increases in intensity over a few days. Seizures, visual disturbances, focal neurological symptoms, and signs of increased intracranial pressure are also possible. These symptoms may be combined with clinical signs of disseminated intravascular coagulation such as petechiae or gastrointestinal bleeding. If TTS-CVST is suspected, checking D-dimers, platelet count, and screening for heparin-induced thrombocytopenia (HIT-2) are diagnostically and therapeutically guiding. The imaging method of choice for diagnosis or exclusion of CVST is magnetic resonance imaging (MRI) combined with contrast-enhanced venous MR angiography (MRA). On T2*-weighted or susceptibility weighted MR sequences, the thrombus causes

susceptibility artefacts (blooming), that allow for the detection even of isolated cortical vein thromboses. The diagnosis of TTS-CVST can usually be made reliably in synopsis with the clinical and laboratory findings. A close collaboration between neurologists and neuroradiologists is mandatory. TTS-CVST requires specific regimens of anticoagulation and immunomodulation therapy if thrombocytopenia and/or pathogenic antibodies to PF4/polyanion complexes are present. In this review article, the diagnostic and therapeutic steps in cases of suspected TTS associated CSVT are presented.

A Case With New-Onset Neuromyelitis Optica Spectrum Disorder Following COVID-19 mRNA BNT162b2 Vaccination. INTRODUCTION: In the midst of the coronavirus disease of 2019 pandemic, active immunization by effective vaccination gained utmost importance in terms of global health. The messenger RNA (mRNA) vaccines are novel strategies requiring clinical surveillance for adverse events. CASE REPORT: We report a 43-year-old previously healthy female with an optic neuritis attack 24 hours following immunization with the second dose of coronavirus disease of 2019 mRNA BNT162b2 vaccine. A second transverse myelitis attack together with an elevated anti-AQP-4 antibody titer confirmed the diagnosis of neuromyelitis optica spectrum disorder. CONCLUSION: Our case identifies the BNT162b2 vaccine as a possible trigger for neuromyelitis optica spectrum disorder. This rare and potentially coincidental event has no implications for vaccine administration practices. However, further research is needed to elucidate the effects of mRNA vaccines on humoral and cell-mediated immunity.

Covid-19 vaccination, fear and anxiety: Evidence from Google search trends. Covid-19 vaccination was associated with a general feeling of hesitancy, and its arrival increased fear and economic anxiety. This paper investigates the impacts of Covid-19 vaccination on fear and economic anxiety using a worldwide sample of 194 countries observed from December 1st, 2020 to March 4th, 2021. The difference-in-differences investigation approach shows that with the vaccine's arrival, the Google search trends measuring fear and anxiety are increasing. The arrival of the vaccine has created a general feeling of fear, and people have a lack of confidence in the vaccine's efficiency to overcome the Covid-19 crisis. Specifically, anxiety increased when the delta variant was discovered in India. Governments' interventions must ensure that the Covid-19 vaccine does not have adverse side effects that can harm public health. We suggested that policy makers should focus on increasing the number of older adults willing to receive the vaccine. It can be effective in explaining the benefits of the vaccine, and denying false information about the vaccine and its serious side effects.

The effect of ChAdOx1 nCov-19 vaccine on arterial thrombosis development and platelet aggregation in female rats. ChAdOx1 nCoV-19 adenoviral vector vaccine (ChAd) against coronavirus disease 2019 has been associated with vaccine-induced thrombosis and thrombocytopenia (VITT), especially in young women who have presented with unusual localized thrombosis after receiving the vaccine. The pathogenesis of VITT remains incompletely understood. We tried to provide new insights into mechanisms underlying this phenomenon in the model of arterial thrombosis electrically induced in the carotid artery of female rats. At 28Â days post-vaccination, ChAd induced SARS-CoV-2-specific neutralizing antibody responses in all animals. The analysis of the blood vessel/thrombus area showed slight luminal narrowing of the carotid artery with extravasation of blood in vaccinated rats. These small changes were not accompanied by differences in thrombus weight and composition. The vaccinated animals presented a slight increase (by around 14-24%) in platelet aggregation. ChAd did not significantly affect blood coagulation, platelet counts, and their activation markers. Unaffected thrombus formation, the lack of thrombocytopenia and all the measured blood and hemostasis parameters that predominantly stayed unchanged, indicate that the ChAd does not increase the risk of arterial thrombosis development in female rats.

Association between reactogenicity and SARS-CoV-2 antibodies after the second dose of the BNT162b2 COVID-19 vaccine. High vaccine reactogenicities may reflect stronger immune responses, but the epidemiological evidence for coronavirus disease 2019 (COVID-19) vaccines is sparse and inconsistent. We observed that a fever ofÂ â‰¥38â„ƒ after two doses of the BNT162b2 vaccine was associated with higher severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike IgG titers.

Safety and humoral response rate of inactivated and mRNA vaccines against SARS-CoV-2 in patients with Multiple Sclerosis. BACKGROUND: Safety and effectiveness outcomes in Multiple Sclerosis (MS) patients receiving different disease-modifying therapies (DMT) and different types of vaccines against SARS-CoV-2 are limited. Growing evidence coming mainly from Israel, Europe and North America using mRNA and adenoviral vector vaccines has been published. OBJECTIVES: To assess the safety and humoral response of inactivated virus and mRNA vaccines against SARS-CoV-2 in patients with MS. METHODS: Ongoing, multicentric, prospective, observational study performed between February and September 2021. Humoral response (antibodies against spike-1 protein) was determined at least 4 weeks after the complete schedule of anti-SARS-CoV-2 vaccines. Categorical outcome (positive/negative) and total antibody titres were recorded. Adverse events supposedly attributable to vaccination (AESAV) were collected. RESULTS: 178 patients, 68% women, mean age 39.7Â Â±Â 11.2 years, 123 received inactivated (Coronavac-Sinovac), 51 mRNA (Pfizer-BioNtech), and 4 adenoviral vector vaccines (CanSino nÂ =Â 2, Jonhson&Johnson-Jannsen nÂ =Â 1, Oxford-AstraZeneca nÂ =Â 1). Six patients had a history of COVID-19 before vaccination. Overall humoral response was observed in 66.9% (62.6% inactivated vs. 78.4% mRNA, pÂ =Â 0.04). Positive anti-S1-antibodies were observed in 100% of patients with no DMT (nÂ =Â 3), 100% with interferon/glatiramer-acetate (nÂ =Â 11), 100% with teriflunomide/dimethyl-fumarate (nÂ =Â 16), 100% with natalizumab (nÂ =Â 10), 100% with alemtuzumab (nÂ =Â 8), 90% with cladribine (nÂ =Â 10), and 88% with fingolimod (nÂ =Â 17), while 43% of patients receiving antiCD20 (nÂ =Â 99) were positive (38% inactivated vaccine vs. 59% mRNA vaccine, pÂ =Â 0.05). In the multivariate analysis including antiCD20 patients, the predictors for a positive humoral response were receiving the mRNA vaccine (OR 8.11 (1.79-36.8), pÂ =Â 0.007) and a lower number of total infusions (OR 0.44 (0.27-0.74) pÂ =Â 0.002. The most frequent AESAV was local pain (14%), with 4 (2.2%) patients experiencing mild-moderate relapses within 8 weeks of first vaccination compared to 11 relapses (6.2%) within the 8 weeks before vaccination (Chi-squared 3.41, pÂ =Â 0.06). DISCUSSION: A higher humoral response rate was observed using the mRNA compared to the inactivated vaccine, while patients using antiCD20 had a significantly lower response rate, and patients using antiCD20 and fingolimod had lower antibody titres. In this MS patient cohort, inactivated and mRNA vaccines against SARS-CoV-2 appear to be safe, with no increase in relapse rate. This information may help guidelines including booster shots and types of vaccines in selected populations.

Reactogenicity among health care workers following a BNT162b2 or mRNA-1273Â second dose after priming with a ChAdOx1 nCOV-19 vaccine. OBJECTIVES: In March 2021, French authorities recommended a heterologous second dose of the mRNA vaccine for persons aged <55Â years, with administration 9 to 12Â weeks after the first dose of ChAdOx1 nCoV-19. This recommendation was despite a lack of data on the reactogenicity and safety of the regimen. Since then, several studies have shown an acceptable short-term safety profile of ChAdOx1 nCoV-19 and BNT162b2 heterologous vaccination, although some transient increased reactogenicity has been described. METHODS: We performed a single-centre prospective observational cohort study among health care workers (HCWs) at a tertiary care hospital to assess the reactogenicity of the BNT162b2 and mRNA-1273 vaccines administered as a second dose in participants primed with ChAdOx1 nCoV-19. RESULTS: Among 1184 HCWs, 356 (30%) agreed to participate. Of the participants, 32.3% were male,

and the mean age was 35Â years (standard deviation: 10.1Â years). Of the participants, 229 received BNT162b2 and 127 received mRNA-1273. A systemic reaction was observed in 130 of 229 (56.8%) and 100 of 127 (78.7%) HCWs, respectively. Injection site reactions were generally limited (grade 1 or 2 in 163 of 229 (97.6%) and 90 of 127 (85.7 %) HCWs, respectively). After adjustment for age, sex, and HCW role, receiving the mRNA-1273 vaccine was associated with higher reactogenicity with more grade 3 side effects (adjusted OR (aOR): 3.34; 95% CI, 1.91-5.85), more systemic symptoms (aOR: 2.82; 95% CI, 1.69-4.7), and not being able to work (aOR: 8.35; 95% CI, 3.78-18.44) compared with receiving the BNT162b2 vaccine. DISCUSSION: Among patients receiving the mRNA1273 vaccine as a second dose, our study confirms good tolerance of the heterologous schedule with a higher risk of short-term side effects in comparison with patients receiving the BNT162b2 vaccine.

Hypersensitivity Cross-Reactivity for Ultrasound-Enhancing Agents and COVID-19 Vaccines.

MOG antibody-associated disease after vaccination with ChAdOx1 nCoV-19.

Linking COVID-19 vaccine and male infertility - not on fertile ground.

COVID-19-booster vaccine-induced encephalitis.

Flare of adult-onset Still's disease following mRNA COVID-19 vaccination: a case report and review of literature. The upheaval caused by the coronavirus disease 2019 (COVID-19) pandemic has allowed to large population to use new vaccines urgently. Although vaccine development programs and available epidemiological data reassure us, there are concerns about specific risks associated with vaccinations in patients with autoimmune-autoinflammatory diseases. These patients have the potential to decrease humoral and cellular immune responses caused by biologic agents and develop an acute flare of underlying disease following vaccination. We herein present a rare case of a 49-year-old female with a flare of adult-onset Still's disease (AOSD) after the first dose of BNT162b2 mRNA COVID-19 vaccination. She had been diagnosed with AOSD 7Â years earlier and had achieved remission with tocilizumab. This patient came to the emergency room with fever and nausea that occurred 4Â days after the first vaccination. Based on laboratory results and clinical manifestations, we suspected AOSD flare and was treated with steroid pulse therapy. In this report, we also discuss possible mechanisms linking vaccination with a flare of AOSD. Considering the close time relationship between COVID-19 vaccinations and a flare of AOSD, physicians should be aware of adverse events from this new vaccination and evaluate the benefits and risks of vaccination for each patient. KEY POINTS: â€¢Â COVID-19 vaccination may cause an AOSD flare in patients who are in remission with tocilizumab.

Evaluation of antibody response after two doses of the Sinovac vaccine and the potential need for booster doses in cancer patients. Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) is more severe in some specific patient groups, such as cancer patients with a mortality rate of 26.5%. The main way of protection is vaccination. In this study, we aimed to evaluate the antibody responses of our cancer patients who received two doses of the inactivated COVID-19 vaccine manufactured by Sinovac Life Sciences. Patients over the age of 18, who had not been suspected or polymerase chain reaction-confirmed COVID-19 positive, who received two doses of the vaccine, and at least 28 days passed after the second dose, and who received at least one dose of cancer treatment before the vaccination-were included in the study. Immunoglobulin class GÂ antibodies against the receptor binding region (S-RBD) of the spike protein S1 subunit of SARS-CoV-2 were studied. A total of 200 patients with a diagnosis of cancer were included in the study. The median time between the second dose of the Sinovac vaccine and the time of blood collection was 3.44 (3.20-3.84) months. SARS-CoV-2 antibody positivity was detected in 110 (55%) patients. The two subgroups with the highest antibody levels were gynecological cancers and breast cancers, with median 158.5â€‰AU/mlÂ (38.4-764.5) and 106.3â€‰AU/mlÂ (61.9-162.9) levels, respectively. Antibody positivity rate was 46.8% in patients who received chemotherapy at any time between the first dose of the vaccine and the date

of blood collection; and it was 73.8% in the group that did not receive chemotherapy (pâ€‰<â€‰0.001). As a result, the expected antibody response was not obtained with two doses of the Sinovac vaccine. Therefore, if the Sinovac vaccine is to be preferred for these patients, the appropriate booster time for the third dose should be determined or other vaccines, such as messenger RNA vaccines, with reported higher antibody responses should be considered.
A Rare Case of Coronavirus Disease 2019 Vaccine-Associated Cerebral Venous Sinus Thrombosis Treated with Mechanical Thrombectomy. BACKGROUND Vaccine-related thrombosis and thrombocytopenia syndrome (TTS) is a rare life-threatening syndrome reported after vaccination against COVID-19. CASE REPORT We describe a case of 56-year-old postmenopausal, obese woman with hypothyroidism and hyperlipidemia, who presented to the Emergency Department (ED) with fluctuating mental status and left-side weakness for 5 days. She received her first and second dose of mRNA-1273 vaccine (Moderna) at 12 and 8 weeks, respectively, prior to presentation. She was found to have multiple hemorrhages and infarcts on a computed tomography (CT) scan of the head. She was intubated in the ED for airway protection and mechanically ventilated. Magnetic resonance angiogram and venogram showed multiple infarcts in right frontal, parietal, and left parietal lobes, along with occlusion of left-side transverse sinus, sagittal sinuses, and left internal jugular vein, suggesting cerebral venous sinus thrombosis (CVST). Despite anticoagulation, her clinical condition continued to worsen, and she was referred for emergent endovascular thrombectomy. Her clinical condition improved after thrombectomy, and she was discharged on warfarin. At 4-month follow-up, she was able to walk with an assistive device and able to carry out activities of daily living with assistance. She is planned for further work-up for hypercoagulable state at follow-up. CONCLUSIONS This case highlights the occurrence of vaccine-related thrombosis 3 months after vaccine administration. Only 2 cases of TTS have been reported so far after mRNA-1273 vaccination (Moderna). To the best of our knowledge, this is the first reported case of CVST presenting 3 months after the first dose of COVID-19 mRNA-1273 vaccine (Moderna).
Herpes Zoster Following a Nucleoside-Modified Messenger RNA COVID-19 Vaccine. Herpes zoster (HZ) was suspected as a predictive cutaneous manifestation of COVID-19, with a debated prognostic significance. We report a series of 5 cases of HZ occurring after vaccination with a nucleoside-modified messenger RNA (mRNA) COVID-19 vaccine (Comirnaty, Pfizer-BioNTech). These new cases do not prove causality between COVID-19 vaccination and HZ. The pathophysiologic mechanism remains elusive, but local vaccine-induced immunomodulation may be involved. The occurrence of HZ does not justify avoiding the second injection of vaccine due to the benefit of vaccination.
Myocarditis and pericarditis following mRNA COVID-19 vaccination in younger patients: is there a shared thread? Rare cases of myocarditis and pericarditis after COVID-19 mRNA vaccination have been recently reported in male adolescents and young adults. Acute myocarditis and pericarditis following COVID-19 mRNA vaccination in male adolescents and young adults may be connected with age-related lower levels of T-bet and PD-1 in predisposed individulas with T-bet polymorphisms by the release od autoreactive CD8+CTL. Upregulatiomn of T-Bet and PD-1 by estrogen might explai the higher incidence of men developing myocarditis or pericarditis in comparison to women.
Evaluating the safety and efficacy of COVID-19 vaccination in patients with hidradenitis suppurativa.
First Identified Case of Fatal Fulminant Eosinophilic Myocarditis Following the Initial Dose of the Pfizer-BioNTech mRNA COVID-19 Vaccine (BNT162b2, Comirnaty): an Extremely Rare Idiosyncratic Necrotizing Hypersensitivity Reaction Different to Hypersensitivity or Drug-Induced Myocarditis.
Serial histopathologic assessment of fulminant myocarditis after the first mRNA COVID-19 vaccine dose.
A phase 1/2 randomised placebo-controlled study of the COVID-19 vaccine mRNA-1273 in healthy Japanese adults: An interim report. INTRODUCTION: The mRNA vaccine, mRNA-1273/TAK-919,

encodes the prefusion-stabilised spike protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). We report interim results of the first study evaluating safety and immunogenicity of mRNA-1273 in healthy Japanese participants. METHODS: This phase 1/2, randomised, observer-blind, placebo-controlled trial, conducted in Japan (two sites), enrolled healthy adults aged≥ 20 years with no prior exposure to investigational coronavirus vaccines/treatments, and no known history/risk of SARS-CoV-2 infection. Participants were stratified by age (< 65/≥ 65 years) and randomised to receive two doses of 100 µg mRNA-1273 or placebo administered as intramuscular injections 28 days apart. Primary outcomes were safety and immunogenicity assessed by anti-SARS-CoV-2-spike protein-binding antibody level (bAb). A secondary outcome was SARS-CoV-2 neutralising antibody (nAb) response. RESULTS: Participants were enrolled between 21 January and 3 February 2021, and 200 were randomised: mRNA-1273, n = 150 (< 65 years, n = 100; ≥ 65 years, n = 50); placebo, n = 50 (< 65 years, n = 40; ≥ 65 years, n = 10). Solicited adverse events (AEs) through 7 days after each vaccination occurred in 144/150 (96%) and 19/50 (38%) participants in the mRNA-1273 and placebo arms, respectively. In the mRNA-1273 arm, injection-site pain, myalgia and fatigue were the most frequently reported solicited AEs after each vaccination, irrespective of age. Robust immune responses occurred with mRNA-1273 (n = 147) with a bAb geometric mean fold rise (95% confidence interval [CI]) from baseline of 1009 (865, 1177) and a nAb of 21.7 (19.8, 23.8) at day 57. Seroconversion rates (95% CI) for bAb and nAb were both 100% (97.5, 100) at day 57. No such response occurred with placebo (n = 49). CONCLUSION: Two doses of 100 µg mRNA-1273 given 28 days apart demonstrated an acceptable safety profile and induced significant anti-SARS-CoV-2 immune responses in a Japanese population aged≥ 20 years. FUNDING: Takeda Pharmaceutical Company Limited and Japan Agency for Medical Research and Development (AMED). CLINICALTRIALS: gov: NCT04677660.

How frequent are acute reactions to COVID-19 vaccination and who is at risk? INTRODUCTION: Our objective was to describe and compare self-reported side effects ofCOVID-19 vaccinesin theUSA. METHODS: Aweb-basedregistry enrolled volunteers who received a COVID-19 vaccine between March 19-July 15, 2021. We collected self-reported short-term side effects, medical consultation, hospitalization, and quality of life impact following completed vaccination regimens (Pfizer, Moderna, J&J). RESULTS: We recruited 6,966 volunteers who completed their full course of vaccination (median age 48 years, IQR 35.0-62.0; 83.6% female): Pfizer 3,486; Moderna 2,857; J&J 623. Few (3.1%) sought medical care for post-vaccination side effects. Hospitalization (n = 17; 0.3%) and severe allergic reactions (n = 39; 0.6%) also were rare. Those with autoimmune disease or lung disease were approximately twice as likely to seek medical care (adjusted odds ratio (aOR) 2.01, 95% CI:1.39; 2.92 and aOR 1.70, 95% CI: 1.12; .58 respectively). 92.4% of participantsreported≥ 1side effect (median 3), with injection site reactions (78.9%), fatigue (70.3%), headache (49.0%) reported most frequently. More side effects were reported after the second dose of two-dose vaccines (medians: 1 vs. 2 for Pfizer and 1 vs. 3 for Moderna for first and second doses respectively) versus 3 for J&J's single-dose vaccine. For the employed, the median number of workdays missed was one. Diabetics and those vaccinated against influenza were substantially less likely to report 3 or more symptoms (aOR 0.68, 95% CI: 0.56;0.82] and aOR 0.82, 95% CI: 0.73;0.93, respectively). DISCUSSION: The total side effect burden was, not unexpectedly, greater with two-dose regimens but all three vaccines appear relatively safe. Very few subjects reported side effects serious enough to warrant medical care or reported post-vaccination hospitalization. While these findings do not address possible long-term effects, they do inform on their short-term safety and tolerability and will hopefully provide some reassurance and positively inform the benefit-risk and pharmacoeconomic assessment for all three vaccines. See Clinicaltrials.gov NCT04368065.

Relation of fever intensity and antipyretic use with specific antibody response after two doses of the BNT162b2 mRNA vaccine. BACKGROUND: The reactogenicity of BNT162b2 COVID-19 vaccine has been commonly reported and antipyretic medications are often used for mitigating adverse reactions. Possible associations between the reactogenicity events and specific antibody responses have not been fully investigated, nor has the influence of using antipyretics. METHODS: Serum samples were collected from hospital healthcare workers with no COVID-19 history and the SARS-CoV-2 spike-specific IgG titer after two doses was measured. Degree of solicited adverse reactions in a day, including the highest body temperature, were reported using a self-reporting diary for five days after each dose. The highest body temperature during the five days was divided into three grades (<37.0Â Â°C, 37.0-37.9Â Â°C, orÂ â‰¥Â 38.0Â Â°C). Self-medicated antipyretics were reported using a questionnaire. RESULTS: The data of 335 participants were available for analysis. Multivariate analysis extracted the fever grade after the second dose (standardized coefficient betaÂ =Â 0.301, pÂ <Â 0.0001), female sex (betaÂ =Â 0.196, pÂ =Â 0.0014), and age (betaÂ =Â -0.119, pÂ =Â 0.0495) as being significantly correlated with the IgG titers. The positive correlation of the fever grade after the second dose with the IgG titers was also observed when analyzed by sex and age. The use of antipyretics did not interfere with the IgG titers irrespective of the fever grade. CONCLUSIONS: The fever intensity after the second dose was associated with the IgG titer and antipyretic medications may be beneficial to mitigate the suffering from adverse reactions, without interfering with the acquisition of sufficient antibody responses.

Unilateral linear purpuric rash heralding SARS-CoV-2 vaccine-induced immune thrombotic thrombocytopenia.

A case of psoriatic spondyloarthritis exacerbation triggered by COVID-19 messenger RNA vaccine.

Safety Monitoring of COVID-19 Vaccine Booster Doses Among Adults - United States, September 22, 2021-February 6, 2022. During September 22, 2021-February 6, 2022, approximately 82.6 million U.S. residents aged â‰¥18 years received a COVID-19 vaccine booster dose.* The Food and Drug Administration (FDA) has authorized a booster dose of either the same product administered for the primary series (homologous) or a booster dose that differs from the product administered for the primary series (heterologous). These booster authorizations apply to all three COVID-19 vaccines used in the United States (1-3).(â€) The Advisory Committee on Immunization Practices (ACIP) recommended preferential use of an mRNA COVID-19 vaccine (mRNA-1273 [Moderna] or BNT162b2 [Pfizer-BioNTech]) for a booster, even for persons who received the Ad26.COV2.S (Janssen [Johnson & Johnson]) COVID-19 vaccine for their single-dose primary series.(Â§) To characterize the safety of COVID-19 vaccine boosters among persons aged â‰¥18 years during September 22, 2021-February 6, 2022, CDC reviewed adverse events and health impact assessments following receipt of a booster that were reported to v-safe, a voluntary smartphone-based safety surveillance system for adverse events after COVID-19 vaccination, and adverse events reported to the Vaccine Adverse Event Reporting System (VAERS), a passive vaccine safety surveillance system managed by CDC and FDA. Among 721,562 v-safe registrants aged â‰¥18 years who reported receiving a booster, 88.8% received homologous COVID-19 mRNA vaccination. Among registrants who reported a homologous COVID-19 mRNA booster dose, systemic reactions were less frequent following the booster (58.4% [Pfizer-BioNTech] and 64.4% [Moderna], respectively) than were those following dose 2 (66.7% and 78.4%, respectively). The adjusted odds of reporting a systemic reaction were higher following a Moderna COVID-19 vaccine booster, irrespective of the vaccine received for the primary series. VAERS has received 39,286 reports of adverse events after a COVID-19 mRNA booster vaccination for adults aged â‰¥18 years, including 36,282 (92.4%) nonserious and 3,004 (7.6%) serious events. Vaccination providers should educate patients that local and systemic reactions are expected following a homologous COVID-19 mRNA vaccine booster; however, these reactions appear less

common than those following dose 2 of an mRNA-based vaccine. CDC and FDA will continue to monitor vaccine safety and provide data to guide vaccine recommendations and protect public health.
COVID-19 Vaccine-Induced Multisystem Inflammatory Syndrome With Polyserositis Detected by FDG PET/CT. Of the various adverse reactions to COVID-19 vaccines, fever is a common systemic symptom that often resolves spontaneously without treatment. However, rare vaccine-induced conditions that present with fever and systemic inflammation have been reported. In this case, a 65-year-old man with BNT162b2 mRNA COVID-19 vaccination underwent 18F-FDG PET/CT to evaluate prolonged fever and elevated serum C-reactive protein. PET/CT showed hypermetabolic infiltration in the pericardium and peritoneum suggesting immune-mediated pericarditis and peritonitis. After administration of high-dose corticosteroids, the patient's symptom resolved. This case suggests that multisystem inflammatory syndrome and polyserositis can be induced by the COVID-19 vaccine.
Systemic Vasculitis Following SARS-CoV-2 mRNA Vaccination Demonstrated on FDG PET/CT. Causality regarding adverse events following SARS-CoV-2 mRNA vaccine is undetermined for vasculitis. Herein, we report the case of an 80-year-old man who presented with a persistent high fever of 7 days' duration that began shortly after receiving a COVID-19 vaccination. There was also a complaint of persistent lower limb pain and walking difficulty on emergency transportation. FDG PET/CT demonstrated extensive linear hypermetabolic foci along the vessels of both legs, including the hips, and the arms, supraclavicular area, chest wall, and temporal regions, suggesting systemic vasculitis. Subsequent temporal artery biopsy revealed arteritis, which is not typical of giant cell arteritis.
Bacillus Calmette-GuÃ©rin Scar erythema in a 14-year-old girl post-BNT162b2 vaccination.
Antibody titers after SARS-CoV-2 mRNA vaccination in patients with aplastic anemia-A single-center study.
Letter to the editor: Liver transplantation following severe acute respiratory syndrome-coronavirus-2 vaccination-induced liver failure.
Study of the epidemiology of COVID-19 in Ontario elementary and secondary school education workers: an interim analysis following the first school year. OBJECTIVE: To estimate the incidence of SARS-CoV-2 in education workers and the factors associated with infection between March 2020 and July 2021. METHODS: A prospective cohort study of education workers working â‰¥8 h per week in Ontario, Canada. Participants self-reported results of tests for SARS-CoV-2 and completed online surveys about demographic information, exposures, and vaccinations against SARS-CoV-2. Participants submitted self-collected dried blood spots. Antibodies to SARS-CoV-2 spike, the receptor binding domain of spike, and nucleocapsid were assessed. Multivariable regression was used to assess risk factors for infection. RESULTS: Of 2834 participants, 85% were female, 81% were teaching staff, and 86% had received at least one dose of SARS-CoV-2 vaccine. Of the 1983 who had been tested via a respiratory specimen, 4.9% reported a positive test. Five additional participants had serologic testing suggestive of a previous infection (3.6% overall incidence). In multivariable regression analysis, risk factors for infection included exposure to a SARS-CoV-2 infected adult (adjusted incidence rate ratio (aIRR) 13.6; 95% confidence interval 8.6, 21.3) or child (aIRR 2.3; 1.3, 4.2) in the household, or school student (aIRR 1.9; 1.2, 3.2), or travel outside the province within 14 days of testing (aIRR 6.0; 1.5, 23.6). CONCLUSION: In the first 18 months of the pandemic, education workers had a similar risk of infection with SARS-CoV-2 as other Ontario residents. Practicing protective measures whenever any household member has been exposed to a possible case and at all times when exposed to anyone from outside the home would help reduce the risk of infection.
Systemic lupus erythematosus with acute pancreatitis and vasculitic rash following COVID-19 vaccine: a case report and literature review. Coronavirus disease-19 (COVID-19) is a global pandemic that

is caused by COVID-19 virus, which was initially identified in December 2019 in Wuhan, China. Vaccination is one of the most effective public health interventions, and soon after the Pfizer/BioNTech (BNT162b2) vaccine became available late in 2020, it began to be actively used to fight against COVID-19. Since then, cases of vaccine-associated immune-mediated diseases (IMDs) have been reported. There have been few cases of IMD flare-ups or onset after COVID-19 vaccine administration, and emerging IMDs may be identified over next few years after high use of this vaccine. To this day, few cases of newly diagnosed systemic lupus erythematosus (SLE) following COVID-19 vaccine exposure were reported. Herein, we present the case of a patient diagnosed with SLE, acute pancreatitis, and vasculitic skin rash on the extremities 1Â week after the first dose of the Pfizer-BioNTech COVID-19 vaccine. Key Point â€¢ COVID-19 Vaccine induced Systemic Lupus Erythematosus.
Lichen Ruber Planus occurring after SARS-CoV-2 vaccination.
Comparative assessment of allergic reactions to COVID-19 vaccines in Europe and the United States.
Healthcare Workers in South Korea Maintain a SARS-CoV-2 Antibody Response Six Months After Receiving a Second Dose of the BNT162b2 mRNA Vaccine. BACKGROUND: Effective vaccines against coronavirus disease 2019 (COVID-19) are available worldwide; however, the longevity of vaccine effectiveness is not known. OBJECTIVE: We performed a prospective observational study to assess the antibody response of healthcare workers against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) after BNT162b2 mRNA COVID-19 vaccination. METHODS: SARS-CoV-2 neutralizing antibody (nAb) and spike (S) protein-IgG (S-IgG) antibody titers were examined in participants who received two doses of the BNT162b2 mRNA COVID-19 vaccine in a single center between March 1, 2021, and October 11, 2021. Antibody levels were analyzed at four times: before vaccination (visit 1), 4 weeks after the first vaccination (visit 2), 3 months after the second vaccination (visit 3), and 6 months after the second vaccination (visit 4). RESULTS: A total of 249 healthcare workers at Jeju National University Hospital were enrolled in this study, and 982 blood samples were analyzed. The mean age was 38.1 Â± 9.5 years, and 145 (58.2%) participants were females. Positive nAbs (inhibition rates â‰¥ 20%) were measured in 166/249 (66.7%) subjects at visit 2, 237/243 (97.5%) subjects at visit 3, and 150/237 (63.3%) subjects at visit 4. A S-IgG (â‰¥50 AU/mL) positivity was detected in 246/249 (98.8%) subjects at visit 1, and all participants had positive S-IgG antibody levels at visits 3 and 4 after being fully vaccinated. Further analysis of S-IgG levels revealed a median quantitative antibody level of 1275.1 AU/mL (interquartile range [IQR] 755.5-2119.0) at visit 2, 2765.9 AU/mL (IQR 1809.8-4138.4) at visit 3, and 970.1 AU/mL (IQR 606.0-1495.9) at visit 4. Patient characteristics, such as age, body mass index, and comorbidity, had no relationship with nAb or S-IgG levels at any of the visits. Considering the change in antibody levels over time, both nAb and S-IgG levels at visit 4 decreased compared with the corresponding levels at visit 3. No evidence of SARS-CoV-2 infection was found among any of the participants throughout the study. CONCLUSIONS: The BNT162b2 mRNA vaccine was effective in protecting healthcare personnel working in COVID-19-related departments. While the level of S-IgG antibodies was maintained for 6 months after the second vaccination, nAb levels waned over this 6-month period, indicating the need for a booster vaccination in some healthcare workers 6 months after full vaccination. Herein, we suggest that further studies are needed to evaluate the need for an interval of booster vaccination after full vaccination.
mRNA vaccine-induced antibodies more effective than natural immunity in neutralizing SARS-CoV-2 and its high affinity variants. Several variants of SARS-CoV-2 have emerged. Those with mutations in the angiotensin-converting enzyme (ACE2) receptor binding domain (RBD) are associated with increased transmission and severity. In this study, we developed both antibody quantification and functional neutralization assays. Analyses of both COVID-19 convalescent and diagnostic cohorts

strongly support the use of RBD antibody levels as an excellent surrogate to biochemical neutralization activities. Data further revealed that the samples from mRNA vaccinated individuals had a median of 17 times higher RBD antibody levels and a similar degree of increased neutralization activities against RBD-ACE2 binding than those from natural infections. Our data showed that N501Y RBD had fivefold higher ACE2 binding than the original variant. While some antisera from naturally infected subjects had substantially reduced neutralization ability against N501Y RBD, all blood samples from vaccinated individuals were highly effective in neutralizing it. Thus, our data indicates that mRNA vaccination may generate more neutralizing RBD antibodies than natural immunity. It further suggests a potential need to maintain high RBD antibody levels to control the more infectious SARS-CoV-2 variants.

Population antibody responses following COVID-19 vaccination in 212,102 individuals. Population antibody surveillance helps track immune responses to COVID-19 vaccinations at scale, and identify host factors that may affect antibody production. We analyse data from 212,102 vaccinated individuals within the REACT-2 programme in England, which uses self-administered lateral flow antibody tests in sequential cross-sectional community samples; 71,923 (33.9%) received at least one dose of BNT162b2 vaccine and 139,067 (65.6%) received ChAdOx1. For both vaccines, antibody positivity peaks 4-5 weeks after first dose and then declines. At least 21 days after second dose of BNT162b2, close to 100% of respondents test positive, while for ChAdOx1, this is significantly reduced, particularly in the oldest age groups (72.7% [70.9-74.4] at ages 75 years and above). For both vaccines, antibody positivity decreases with age, and is higher in females and those with previous infection. Antibody positivity is lower in transplant recipients, obese individuals, smokers and those with specific comorbidities. These groups will benefit from additional vaccine doses.

Myocarditis, Pulmonary Hemorrhage, and Extensive Myositis with Rhabdomyolysis 12 Days After First Dose of Pfizer-BioNTech BNT162b2 mRNA COVID-19 Vaccine: A Case Report. BACKGROUND The COVID-19 pandemic is a current global crisis, and there are hundreds of millions of individuals being vaccinated worldwide. At present, there have been few reports of COVID-19 vaccine-induced autoimmune processes manifested as myositis, thrombocytopenia, and myocarditis. CASE REPORT A 37-year-old man presented to the Emergency Department (ED) with a 3-day history of back pain and a 1-day history of left upper limb swelling with paresthesia and shortness of breath, 12-days after receiving the first dose of Pfizer/BioNTech BNT162b2 mRNA COVID-19 vaccine. He was diagnosed with severe myositis complicated with rhabdomyolysis and non-oliguric acute kidney injury, thrombocytopenia, myocarditis with pulmonary edema, and pulmonary hemorrhage. Screens for potential toxic, infectious, paraneoplastic, and autoimmune disorders were unremarkable. The patient was treated with a 5-day course of intravenous methylprednisolone and intravenous immunoglobulin, with a good response. He was hospitalized for 16 days and discharged home on a tapering dose of oral prednisolone for 6 weeks. CONCLUSIONS The case describes a possible link between Pfizer/BioNTech BNT162b2 mRNA COVID-19 vaccine and immune-mediated myocarditis, pulmonary vasculitis, myositis, and thrombocytopenia. However, further data are required to confirm such an association.

Depletion of CD38-positive regulatory T cells by anti-CD38 monoclonal antibodies induces a durable response to SARS-CoV-2 vaccination in patients with plasma cell dyscrasia. This study reports the relationship between CD38(+) regulatory T cells (Tregs) and messenger RNA coronavirus disease 2019 (mRNA-COVID-19) vaccination in 60 patients with plasma cell dyscrasia. Patients treated with anti-CD38 monoclonal antibodies (mAbs) had significantly lower CD38(+) Tregs than those not treated (0.9 vs. 13.2/Î¼l). Late-responders, whose antibody titres increased from weeks 4-12 after the second vaccination, had significantly lower CD38(+) Treg counts than non-late-responders (2.5 vs. 10.3/Î¼l). Antibody titres in patients with lower CD38(+) Treg levels were maintained from weeks 4-12 but

decreased in those with higher CD38(+) Treg levels. Therefore, depletion of CD38(+) Tregs by anti-CD38 mAbs may induce a durable response to mRNA-COVID-19 vaccination.
Humoral Response to Pfizer BNT162b2 Vaccine Booster in Maintenance Hemodialysis Patients. INTRODUCTION: Coronavirus disease is associated with increased morbidity and mortality in maintenance hemodialysis (MHD) patients. Recent breakthrough infection in vaccinated people has led some authorities to recommend a booster dose for patients fully vaccinated 5-8 months ago. We aimed to assess the humoral response of MHD patients following a booster dose with the BNT162b2 vaccine. METHODS: The study included 102 MHD patients vaccinated with 2 doses of the BNT162b2 (Pfizer-BioNTech) vaccine. A third dose (booster) was recommended to all MHD patients in our center and was given to those who opted to receive it, resulting in a booster group and a control group that did not receive the booster. Previous exposure was excluded by testing for the presence of the anti-nucleocapsid antibody (SARS-CoV-2) or positive PCR. We assessed the humoral response before and after the booster dose. RESULTS: Of 66 patients in the booster group, 65 patients (98.5%) developed a positive antibody response, from 472.7 Â± 749.5 to 16,336.8 Â± 15,397.3, as compared to a sustained decrease in the control group (695.7 Â± 642.7 to 383.6 Â± 298.6), $p < 0.0001$. No significant adverse effects were reported. Prior antibody titers were positively correlated to IgG levels following the booster dose. There was a significant association between malnutrition-inflammation markers and the humoral response. CONCLUSIONS: Almost all MHD patients developed a substantial humoral response following the booster dose, which was significantly higher than levels reported for MHD patients following administration of 2 doses alone. Further studies and observations are needed to determine the exact timing and dosing schedule.
Patient with agammaglobulinemia produces anti-SARS-CoV-2 reactive T-cells after CoronaVac vaccine.
Acantholytic Dyskeratosis Post-COVID Vaccination. Acantholytic dyskeratosis mimicking Grover disease as a cutaneous manifestation of a side effect to the Moderna (mRNA-1273) COVID vaccine is rare with only one documented case in the literature to date. Herein, we present a case of an eruptive, erythematous, vesiculopapular rash developing in a patient after the Moderna vaccine. Histopathology of a representative biopsy [x2, done 8 weeks apart] of the rash revealed similar histopathologic findings of patchy suprabasal acantholysis with dyskeratotic keratinocytes and an underlying inflammatory infiltrate of lymphocytes and neutrophils. Direct immunofluorescence was negative. In contrast to the only case previously reported in the literature, a confounding feature in our case, was that patient had a medical history significant for Grover disease, which had been successfully treated with complete resolution and seemed to be in remission. Given the temporal relationship of the onset of the rash to vaccine administration, the changes were likely vaccine-related with the caveat that, in light of the medical history, the differential diagnosis includes reactivation of Grover disease by the vaccine as a trigger factor.
COVID-19 vaccination including 198 patients with history of severe anaphylactic reaction - own observations. INTRODUCTION: The SARS-CoV-2 pandemic has taken a heavy toll of 4 million deaths. We were all looking forward to the authorisation of safe vaccines. Soon after vaccination programmes started, the reports about anaphylaxis began to emerge. Growing anxiety has urged regulatory agencies and academic societies to issue adequate recommendations regarding patient eligibility to vaccination. AIM OF THE STUDY: Observation of patients who had a history of a severe anaphylactic reaction and/or anaphylactic shock and were vaccinated against COVID-19. MATERIAL AND METHODS: A single-centre, prospective, observational study was conducted at the Department of Infectious Diseases and Paediatrics at Stefan Å»eromski Specialist Hospital in Krakow, Poland. Adult patients with a history of a severe anaphylactic reaction and/or anaphylactic shock and patients without it were administered the Comirnaty vaccine by Pfizer-BioNTech or the ChAdOx1-S vaccine by

AstraZeneca in a two-dose schedule at the department. The patients were then observed at the department for 60 minutes. A week after each vaccination dose, the patients were contacted by telephone in order to collect data about a late allergic reaction. RESULTS: In total, 403 patients were enrolled. For the Pfizer BioNTech Comirnaty vaccine, the study group (i.e. patients with a history of severe anaphylactic reactions to various substances, other than those present in the vaccine) included 151 patients, and there were 161 controls. For the AstraZeneca ChAdOx1-S vaccine, the study group included 47 patients, and 44 patients formed the control group. Nine cases of severe anaphylactic reactions were reported: 3 in the study groups (1.5%) and 6 in the control groups (3%). Anaphylactic shock after vaccine administration occurred in one patient from the control group. CONCLUSIONS: COVID-19 vaccination with using Pfizer-BioNTech Comirnaty and AstraZeneca ChAdOx1-S is safe also for patients with a history of a severe anaphylactic reaction and/or anaphylactic shock. Severe anaphylactic reactions and anaphylactic shock, although rare, may also develop in patients without a prior history of allergic conditions. The Personnel od vaccination centres should be therefore trained to provide medical help. Incorrect patient exclusions delay the attainment of the goal determined for the vaccination programme.
New onset of pemphigus foliaceus following BNT162b2 vaccine.
Erythrodermic psoriasis eruption associated with SARS-CoV-2 vaccination.
Post-SARS-CoV-2 Vaccine Monitoring of Disease Flares in Autoinflammatory Diseases.
Livedo reticularis on bilateral knees after the third dose of messenger RNA-1273 SARS-CoV-2 vaccine.
Herpes zoster following COVID-19 vaccination in an immunocompetent and vaccinated for herpes zoster adult: A two-vaccine related event? Reactivation of varicella-zoster virus (VZV) has been reported after the administration of different vaccine platforms against SARS-CoV-2, also among individuals without known immunosuppressive states. Herein, we describe for the first time a case of herpes zoster after mRNA vaccination against SARS-CoV-2 in a 53-year-old immunocompetent adult without any known comorbidities, who was previously vaccinated with a live attenuated zoster vaccine. The fact that the patient had no history of varicella and had been tested seronegative for VZV prior to immunization with the live attenuated zoster vaccine further contribute to the challenge of this unusual case. This advocates for a high level of vigilance on the part of clinicians regarding this rare complication among receivers of COVID-19 vaccines.
A report of two cases of myocarditis following mRNA coronavirus disease 2019 vaccination. BACKGROUND: Vaccination is the most important measure to control the coronavirus disease 2019 (COVID-19) pandemic. Myocarditis has been reported as a rare adverse reaction to COVID-19 vaccines. The clinical presentation of myocarditis in such cases can range from mild general symptoms to acute heart failure. CASE SUMMARY: We report the cases of two young men who presented with chest pain and dyspnoea following the administration of the mRNA COVID-19 vaccine. Cardiac investigations revealed findings typical of acute myocarditis. DISCUSSION: Myocarditis is a rare complication following mRNA COVID-19 vaccination. In this case series, the temporal proximity of the development of acute myocarditis and the administration of the mRNA COVID-19 vaccine was acknowledged. In the absence of other causative factors, myocarditis in these patients potentially occurred due to an adverse reaction to the mRNA COVID-19 vaccine. However, a causal relationship remains speculative. Clinical suspicion of myocarditis should be high if patients present with chest pain or dyspnoea after receiving COVID-19 vaccination.
Severe flare of pemphigus vulgaris after first dose of COVID-19 vaccine.
Performance evaluation of an automatic chemiluminescence immune platform for SARS-CoV-2 neutralizing antibody after vaccination in real world. OBJECTIVE: Reliable high-throughput serological assays for SARS-CoV-2 antibodies present an important role in the strength and duration of immunity after vaccination. The study investigated the analytical and clinical performances of

neutralizing antibodies (NTAb) assay by chemiluminescent (CLIA), and SARS-CoV-2 neutralizing antibody after vaccination in real world. METHODS: The analytical performances of CLIA for SARS-CoV-2 NTAb were evaluated, followed by the sensitivity and specificity identified with a PRNT test from 50 volunteers. Then, a cohort of vaccine recipients (nâ€‰=â€‰37) were tracked with SARS-CoV-2 NTAb assay at prior to vaccination, one, three and six months post two doses. In real world, a total of 737 cases were recruited from physical examination center in Shenzhen Luohu People's Hospital (from Jun to August 2021) to analyze vaccination status. RESULTS: Serological assays on the CLIA were found with excellent characteristics including imprecision, repeatability and linearity. Besides, it was robust to icterus, lipemia and hemolysis. The good sensitivity and specificity were obtained at 98% and 100%, respectively. NTAb results showed a high correlation with PRNT(50) titers (r 0.61). Until July 2021, the BBIBP-CorV (76.3%) and Sinovac CoronaVac (20.5%) were the predominant vaccines injection in Shenzhen, China. Adolescent less than 18Â years was the main unvaccinated group (52.1%). The seropositive rate of inactive SRAR-CoV-2 vaccines exceeded 97% after inoculation. The NTAb generated by Sinovac CoronaVac with the schedule of 0-56Â days was found significantly lower than that by BBIBP-CorV (Pâ€‰<â€‰0.001). The follow-up of NTAb changes in a cohort and the dynamic variation of NTAb in real world disclosed steep downward by almost three times for NTAb level occurred at three months post twice vaccinations. The seropositive ratio was at least 50% over 6 months. CONCLUSIONS: SARS-CoV-2 neutralizing antibodies assay show excellent analytical and clinical performances, and a high correlation with neutralizing activity. Anti-epidemic measures and the urgent trial of SARS-CoV-2 vaccine was calling for adolescents.

COVID vaccine's hot problems: erratic serious blood clotting, ill-defined prion-like reactogenicity of the spike, unclear roles of other factors.

Immune response to vaccination in adults with mental disorders: A systematic review. BACKGROUND: Mental disorders are associated with immune dysregulation as measured by serum levels of biological markers of immunity. Adults with mental disorders have also been reported to have attenuated post vaccine immune response. The COVID-19 pandemic has invited the need to determine whether individuals with mental disorders exhibit differential immune response following the administration of vaccines for other infections. METHODS: A systematic search of MEDLINE, Embase, Cochrane, and PsycInfo was conducted from inception to May 2021 investigating vaccine response in persons with mental disorders, as measured by biological markers of immunity (i.e., antibodies, cytokines). RESULTS: Thirteen articles were identified which evaluated vaccine efficacy in persons with mental disorders. Individuals with major depressive disorder (MDD) or schizophrenia revealed attenuated immune response to vaccination, or no statistical difference compared to control subjects. Individuals with anorexia nervosa or post-traumatic stress disorder (PTSD) displayed no attenuated post-vaccination antibody level. Individuals with insomnia displayed lower levels of antibodies after vaccination, whereas individuals with obstructive sleep apnea (OSA) displayed no difference in vaccine response compared to control subjects. LIMITATIONS: The limitations of this review include the relatively few articles included (nÂ =Â 13) and small sample sizes (less than thirty subjects) in the majority of articles. CONCLUSION: Vaccine response in adults with a mental disorder remains inconclusive. Notwithstanding the heterogeneity and relatively small number of studies, available evidence does suggest attenuated immune response across disparate vaccinations. Future research is required to confirm vaccine efficacy in persons with mental disorders, especially regarding immune responses to COVID-19 vaccination.

A coronavirus disease 2019-vaccinated patient with phosphoinositide 3-kinase disease with mild illness after severe acute respiratory syndrome coronavirus 2 infection.

A fourth SARS-CoV-2 mRNA vaccine in strictly seronegative kidney transplant recipients.

The role of anti-platelet factor 4 antibodies and platelet activation tests in patients with vaccine-induced immune thrombotic thrombocytopenia: Brief report on a comparison of the laboratory diagnosis and literature review. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a novel human pathogen causing coronavirus disease 2019 (COVID-19). Rare cases of COVID-19 vaccine-induced immune thrombotic thrombocytopenia (VITT) after the ChAdOx1 nCoV-19 (AstraZeneca) vaccination have been reported. We performed a test for anti-heparin/ platelet factor 4 (PF4) antibodies and functional assay using flow cytometry. METHOD: A healthy woman presented to the emergency department with chest pain, headache, and abdominal pain after the first vaccination with AstraZeneca. Polymerase chain reaction (PCR) test for SARS-CoV-2 was negative. Chest computed tomography (CT) showed pulmonary artery embolism and brain magnetic resonance imaging (MRI) revealed cerebral sinus-venous thrombosis. Abdominal CT demonstrated the thrombosis with occlusion in her right hepatic vein. Laboratory studies revealed decreased platelet counts, and high D-dimer level. Finally, laboratory results indicated high PF4 antibodies level high and a positive platelet activation test, confirming the diagnosis of VITT. RESULTS: Treatments including intravenous immunoglobulin, methylprednisolone and direct oral anticoagulant were administered. The results of a follow-up platelet count and D-dimer were normal. In addition, the titer of PF4 antibodies (optical density: 0.425; normalÂ â‰¤Â 0.4, enzyme-linked immunosorbent assay) fell. After a 3-month follow-up, her general condition improved gradually. CONCLUSIONS: The use of COVID-19 vaccines to prevent SARS-CoV-2 infections and complications is considered the most practicable policy for controlling the COVID-19 pandemic and is being forcefully pursued in the global area. Appropriate laboratory diagnosis facilitates the accurate and rapid diagnosis. Early recognizing and appropriate strategies for VITT are required and can provide these patients with more favorable patient outcomes. This report also elected to make comparisons of clinical manifestation, laboratory diagnosis, and management in patients with VITT.

Pityriasis Rosea Associated With COVID-19 Vaccination: A Common Rash Following Administration of a Novel Vaccine. Pityriasis rosea is a common, self-limited, papulosquamous eruption, classically presenting along the Langer lines of the skin. We report a clinically typical case of pityriasis rosea that developed following COVID-19 vaccination. As the novel COVID-19 vaccine becomes more widely available during the ongoing COVID-19 pandemic, it is imperative for both patients and clinicians to be aware of its association with the onset of this benign cutaneous eruption.

An Update on the Status of Vaccine Development for SARS-CoV-2 Including Variants. Practical Considerations for COVID-19 Special Populations. The progress in the development of various vaccine platforms against SARS-CoV-2 have been rather remarkable owing to advancement in molecular and biologic sciences. Most of the current vaccines and those in development focus on targeting the viral spike proteins by generating antibodies of varying spectrum. These vaccines represent a variety of platforms including whole virus vaccines, viral vector vaccines, nucleic acid vaccines representing RNA, DNA, and their hybrid forms.The therapeutic efficacy of these vaccines varies owing to their pharmacodynamic individualities. COVID-19 variants are capable of inducing different pathologic responses and some of which may be resistant to antibodies generated by current vaccines. The current clinical use of these vaccines has been through emergency use authorization until recently. Moreover, the efficacy and safety of these vaccines have been tested in substantial numbers of individuals but studies in special populations that better reflect the global population are pending results. These specialized populations include young children, immunocompromised patients, pregnant individuals, and other specialized groups. Combination approaches, molecularly modified vaccination approaches, and vaccines conferring longer periods of immunity are being currently being investigated, as well as pharmacovigilance studies.The continual transformation of SARS-CoV-2 and its variants are of concern along with the breakthrough infections.

These considerations pose new challenges for the development of vaccination platforms. For this purpose, booster doses, combination vaccine approaches, and other modalities are being discussed. This review provides an updated account of currently available vaccines and those in advanced development with reference to their composition and mechanisms of action.A discussion on the use of vaccines in special populations including immunocompromised patients, pregnant women and other specialized populations are also included.

Eosinophilic pneumonia and COVID-19 vaccination.

A case report: Clozapine-induced leukopenia and neutropenia after mRNA COVID-19 vaccination. Clozapine is an atypical antipsychotic used for treatment-resistant schizophrenia and is known to cause serious side effects, such as leukopenia and neutropenia. We encountered the case of a 44-year-old female patient with a good response to clozapine, who experienced inflammatory reaction and cytopenia after coronavirus disease 2019 (COVID-19) vaccination. Soon after clozapine discontinuation, the inflammatory reaction resolved, and cell counts recovered. There are only a few reports on the interaction between clozapine and COVID-19 vaccine. Our findings suggest that caution is required when a patient who is receiving clozapine scheduled for COVID-19 vaccination, owing to the possibility of cytopenia. Moreover, blood tests and the measurement of clozapine concentration should be performed before and after the inoculation to ensure patient safety.

Factors Associated With Willingness to Receive a COVID-19 Vaccine Among 23,819 Adults Aged 50 Years or Older: An Analysis of the Canadian Longitudinal Study on Aging. Identifying persons who are least willing to receive a coronavirus disease 2019 (COVID-19) vaccine is critical for increasing uptake via targeted outreach. We conducted a survey of 23,819 Canadian Longitudinal Study on Aging participants from September 29 to December 29, 2020, to assess factors associated with COVID-19 vaccination willingness and reasons for willingness or lack thereof. Among adults aged 50-96 years, 84.1% (95% confidence interval (CI): 83.7, 84.6) were very or somewhat willing to receive a COVID-19 vaccine; 15.9% (95% CI: 15.4, 16.3) were uncertain or very or somewhat unwilling. Based on logistic regression, those who were younger, female, had lower education and income, were non-White, and lived in a rural area were less willing to receive a COVID-19 vaccine. After controlling for these factors, recent receipt of influenza vaccine (adjusted odds ratioÂ =Â 14.3, 95% CI: 12.5, 16.2) or planning to receive influenza vaccine (adjusted odds ratioÂ =Â 10.5, 95% CI: 9.5, 11.6), as compared with no receipt or planning, was most strongly associated with COVID-19 vaccination willingness. Willingness was also associated with believing one had never been infected with severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) and experiencing negative pandemic consequences. Safety concerns were most common among those unwilling. Our comprehensive assessment of COVID-19 vaccination willingness among older adults in Canada, a prioritized group for vaccination due to their risk of severe COVID-19 outcomes, provides a road map for conducting outreach to increase uptake, which is urgently needed.

Subacute Thyroiditis After Receiving the mRNA COVID-19 Vaccine (Moderna): The First Case Report and Literature Review in Korea. Subacute thyroiditis (SAT) is a painful thyroiditis that often requires steroid therapy. Here, we report the first case of severe SAT in a patient who received the first dose of mRNA coronavirus disease 2019 (COVID-19) vaccination. A 34-year-old man without a viral prodrome felt a lump when swallowing 5 days after his first dose of mRNA-1273 (Moderna) vaccination. Ten days after vaccination, the patient visited the hospital and was advised to rest and take nonsteroidal anti-inflammatory drugs. He revisited the hospital 10 days later as symptoms aggravated with anterior neck pain, headache, fatigue, muscle weakness, and weight loss. Thyroid hormone levels and inflammatory markers were consistent with thyrotoxicosis. A thyroid ultrasound scan revealed typical SAT findings. His symptoms rapidly improved after receiving prednisone. A week later, the patient successfully completed his second dose of the vaccine. The thyroid function test

results were nearly normal 1 month after the completion of the vaccination. We report this case to raise awareness of the occurrence of SAT after COVID-19 vaccination. As the risk of COVID-19 outweighs the minor risks of the vaccine, managing the side effects of the first vaccine dose is crucial to complete COVID-19 vaccination.

Diabetic ketoacidosis shortly after COVID-19 vaccination in a non-small-cell lung cancer patient receiving combination of PD-1 and CTLA-4 inhibitors: A case report. We describe a case of diabetic ketoacidosis (DKA) shortly after the SARS-CoV-2 (COVID-19) vaccination in a 65-year-old woman with non-small-cell lung cancer under a combination treatment of programmed cell death protein 1 (PD-1) and cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) inhibitors. She had no history of diabetic mellitus. A few days after the second shot of COVID-19 vaccination, she developed DKA. We speculate that the immune-related adverse event and immunogenicity of vaccination synergistically induced DKA.

Performance comparison of a flow cytometry immunoassay for intracellular cytokine staining and the QuantiFERONÂ® SARS-CoV-2 test for detection and quantification of SARS-CoV-2-Spike-reactive-IFN-Î³-producing T cells after COVID-19 vaccination. PURPOSE: We compared the performance of an in-house-developed flow cytometry assay for intracellular cytokine staining (FC-ICS) and a commercially-available cytokine release assay (the QuantiFERONÂ® SARS-CoV-2 Test [QF]) for detection and quantification of SARS-CoV-2-Spike (S)-reactive-IFN-Î³-producing T cells after COVID-19 vaccination. PATIENTS AND METHODS: The sample included 141 individuals (all male; median age, 42 years; 20-72) who had been fully vaccinated with the ComirnatyÂ® COVID-19 vaccine (at a median of 114 days; 34-145). Prior to vaccination, 91 were categorized as being SARS-CoV-2-naÃ¯ve and 50 as SARS-CoV-2-experienced. A whole blood-based FC-ICS using 15-mer overlapping peptides encompassing the entire SARS-CoV-2 S protein was used for enumeration of virus-specific IFN-Î³-producing CD4(+) and CD8(+) T cells. The QF test (Ag1 for CD4(+) T cells and Ag2 for CD4(+) and CD8(+) T cells in combination) was carried out following the manufacturer's instructions. RESULTS: The FC-ICS and the QF assays returned significantly discordant qualitative results in both the entire cohort (P<0.001 with QF Ag1 and QF Ag2) and in SARS-CoV-2-naÃ¯ve participants alone (P=0.005 and P=0.01, respectively). Discrepant results mostly involved FC-ICS positive/QF negative specimens. Overall, no correlation was found either between SARS-CoV-2 IFN-Î³- CD4(+) T-cell frequencies and IFN-Î³ levels measured in the QF Ag1 tube (P=0.78) or between the sum of SARS-CoV-2 IFN-Î³ CD4(+) and CD8(+) T-cell frequencies and IFN-Î³ levels quantified in the QF Ag2 tube. CONCLUSION: The data suggest a greater sensitivity for the FC-ICS assay than the QF test, and urge caution when comparing SARS-CoV-2 T-cell immune responses assessed using different analytical platforms.

Comparison of SARS-CoV-2 anti-spike receptor binding domain IgG antibody responses after CoronaVac, BNT162b2, ChAdOx1 COVID-19 vaccines, and a single booster dose: a prospective, longitudinal population-based study. BACKGROUND: Vaccination is an efficient strategy to control the COVID-19 pandemic. In north Cyprus, vaccine distribution started with CoronaVac followed by BNT162b2, and ChAdOx1 vaccines. An option to obtain a third booster dose with BNT162b2 or CoronaVac was later offered to people fully inoculated with CoronaVac. There are few simultaneous and comparative real-world antibody data for these three vaccines as well as boosters after CoronaVac vaccination. Our study was aimed at evaluating antibody responses after these vaccination schemes. METHODS: We did a prospective, longitudinal population-based study to measure SARS-CoV-2 anti-spike receptor binding domain (RBD) IgG concentrations, assessed by assaying blood samples collected, in participants in north Cyprus who had received the BNT162b2, ChAdOx1, or CoronaVac vaccine at 1 month and 3 months after the second dose. Participants were recruited when they voluntarily came to the laboratory for testing after vaccination, solicited from health-care access points, or from the general population. We also evaluated antibody responses 1

month after a booster dose of BNT162b2 or CoronaVac after primary CoronaVac regimen. Demographics, baseline characteristics, vaccination reactions, and percentage of antibody responders were collected by phone interviews or directly from the laboratory summarised by vaccine and age group. Antibody levels were compared between groups over time by parametric and non-parametric methods. FINDINGS: Recruitment, follow-up, and data collection was done between March 1 and Sept 30, 2021. BNT162b2 induced the highest seropositivity and anti-spike RBD IgG antibody titres, followed by ChAdOx1, and then by CoronaVac. In addition, the rate of decline of antibodies was fastest with CoronaVac, followed by ChAdOx1, and then by BNT162b2. For the older age group, the rate of seropositivity at 3 months after the second dose was 100% for BNT162b2, 90% for ChAdOx1, and 60% for CoronaVac. In the multivariate repeated measures model, lower antibody titres were also significantly associated with male sex, older age, and time since vaccination. Boosting a two-dose CoronaVac regimen at 6 months with a single BNT162b2 dose led to significantly increased titres of IgG compared with boosting with CoronaVac; for the 60 years and older age group, the geometric mean fold rise in antibody titre after the booster relative to 1 month post-baseline was 7Â·9 (95% CI 5Â·8-10Â·8) in the BNT162b2 boost group versus 2Â·8 (1Â·6-5Â·0) in the CoronaVac group. INTERPRETATION: These longitudinal data can help shape vaccination strategies. Given the low antibody titres and fast decline in the CoronaVac group in individuals 60 years or older, more potent vaccine options could be considered as the primary vaccination or booster dose in these high-risk populations to sustain antibody responses for longer. FUNDING: Crowdfunded in north Cyprus.

Acute-onset Vogt-Koyanagi-Harada like uveitis following Covid-19 inactivated virus vaccination. PURPOSE: We report a case of a 19-year-old male who presented with bilateral Vogt-Koyanagi-Harada (VKH)-like panuveitis following an injection of an inactivated Covid-19 vaccine. OBSERVATIONS: A 19-year-old male was referred to our clinic with a 2-week history of blurred vision on both eyes and headaches, 12 hours following the administration of the first dose of an inactivated Covid-19 virus vaccine (Sinovac). He denied any past ocular or medical history. Clinical examination and multimodal imaging tests identified serous retinal detachment and choroidal thickening posteriorly and deep yellow foci in the far peripheral retina. Aqueous humor analysis ruled out viral and bacterial infection including Covid-19, but demonstrated an elevated interleukin-6 level. A workup ruled out systemic infection or autoimmune disease. Although the patient received a single positive T-SPOT result, no other clinical evidence supported active tuberculosis infection. Non-infectious panuveitis was diagnosed and treated with periocular steroids that quickly resolved the serous retinal detachment. CONCLUSIONS AND IMPORTANCE: This is the first report of VKH-like uveitis following an inactivated Covid-19 vaccine, with aqueous humor analysis ruling out viral or bacterial infection and demonstrating an elevated interleukin-6 level. Though rare, VKH-like uveitis may be associated with administration of an inactivated Covid-19 vaccine.

A Case of Acute Viral Pericarditis Complicated With Pericardial Effusion Induced by Third Dose of COVID Vaccination. COVID-19 vaccines were safe and efficacious in clinical trials. A two-dose regimen of the Pfizer-BioNTech COVID-19 vaccine confers no less than 95% protection against COVID-19 with an adequate safety profile. To date, no reports have been made in the literature regarding the onset of acute viral pericarditis after vaccination with the Pfizer BNT162b2 vaccine. But on the other hand, pericarditis is reported to occur in rare instances of COVID-19 infection, and this may be attributed to the pro-inflammatory effects of the spike protein. In this article, we describe the case of an elderly male patient with a known case of hypothyroidism who presented to our emergency department with fever, chills, and dry cough for ten days after the third dose of the Pfizer-BioNTech COVID-19 vaccine. Although we cannot mention a direct effect, it is essential to note a potential adverse reaction to vaccine administration following the expression of SARS-CoV-2 spike protein-induced from the vaccine's mRNA.

Eosinophilic Granulomatosis With Polyangiitis Diagnosed in an Elderly Female After the Second Dose of mRNA Vaccine Against COVID-19. Eosinophilic granulomatosis with polyangiitis is a type of medium and small-vessel vasculitis that is characterized by asthma, polyneuropathy, peripheral eosinophilia, rhinosinusitis, and other organÂ involvement, such as the lung and skin. Here, we present an interesting case of eosinophilic granulomatosis with polyangiitis after the mRNA-1273 (Moderna) vaccine against coronavirus disease 2019 (COVID-19). The patient presented with progressive weakness and paresthesia in the upper and lower extremities. She was found to have peripheral eosinophilia and elevated anti-myeloperoxidase antibodies. Nerve and muscle biopsies showed focal vasculitis with infiltration by eosinophils. The patient was started on steroids and a steroid-sparing agent shortly after that and had marked improvement of her symptoms.

Humoral and cellular responses after a third dose of SARS-CoV-2 BNT162b2 vaccine in patients with lymphoid malignancies. Patients with hematological malignancies have impaired immune response after two doses of BNT162b2 (Pfizer/BioNTech) vaccine against SARS-CoV-2. Here, in this observational study (registration number HDH F20210324145532), we measure SARS-CoV-2 anti-Spike antibodies, neutralizing antibodies and T-cell responses after immune stimulation with a third dose (D3) of the same vaccine in patients with chronic lymphocytic leukemia (nâ€‰=â€‰13), B cell non-Hodgkin lymphoma (nâ€‰=â€‰14), and multiple myeloma (nâ€‰=â€‰16)). No unexpected novel side effects are reported. Among 25 patients with positive anti-S titers before D3, 23 (92%) patients increase their anti-S and neutralizing antibody titer after D3. All 18 (42%) initially seronegative patients remain negative. D3 increases the median IFN-Î³ secretion in the whole cohort and induces IFN-Î³ secretion in a fraction of seronegative patients. Our data thus support the use of a third vaccine dose amongst patients with lymphoid malignancies, even though some of them will still have vaccine failure.

A randomized, double-blind phase I clinical trial of two recombinant dimeric RBD COVID-19 vaccine candidates: Safety, reactogenicity and immunogenicity. BACKGROUND: The Receptor Binding Domain (RBD) of the SARS-CoV-2 spike protein is the target for many COVID-19 vaccines. Here we report results for phase I clinical trial of two COVID-19 vaccine candidates based on recombinant dimeric RBD (d-RBD). METHODS: We performed a randomized, double-blind, phase I clinical trial in the National Centre of Toxicology in Havana. Sixty Cuban volunteers aged 19-59Â years were randomized into three groups (20 subjects each): 1) FINLAY-FR-1 (50Â Âµg d-RBD plus outer membrane vesicles from N. meningitidis); 2) FINLAY-FR-1A-50 (50Â Âµg d-RBD, three doses); 3) FINLAY-FR-1A-25 (25Â Âµg d-RDB, three doses). The FINLAY-FR-1 group was randomly divided to receive a third dose of the same vaccine candidate (homologous schedule) or FINLAY-FR-1A-50 (heterologous schedule). The primary outcomes were safety and reactogenicity. The secondary outcome was vaccine immunogenicity. Humoral response at baseline and following each vaccination was evaluated using live-virus neutralization test, anti-RBD IgG ELISA and in-vitro neutralization test of RBD:hACE2 interaction. RESULTS: Most adverse events were of mild intensity (63.5%), solicited (58.8%), and local (61.8%); 69.4% with causal association with vaccination. Serious adverse events were not found. The FINLAY-FR-1 group reported more subjects with adverse events than the other two groups. After the third dose, anti-RBD seroconversion was 100%, 94.4% and 90% for the FINLAY-FR-1, FINLAY-FR-1A-50 and FINLAY-FR-1A-25 respectively. The in-vitro inhibition of RBD:hACE2 interaction increased after the second dose in all formulations. The geometric mean neutralizing titres after the third dose rose significantly in the group vaccinated with FINLAY-FR-1 with respect to the other formulations and the COVID-19 Convalescent Serum Panel. No differences were found between FINLAY-FR-1 homologous or heterologous schedules. CONCLUSIONS: Vaccine candidates were safe and immunogenic, and induced live-virus neutralizing antibodies against SARS-CoV-2. The

highest values were obtained when outer membrane vesicles were used as adjuvant. TRIAL REGISTRY: https://rpcec.sld.cu/en/trials/RPCEC00000338-En.

Risk-Perception Change Associated with COVID-19 Vaccine's Side Effects: The Role of Individual Differences. The COVID-19 vaccine appears to be a crucial requirement to fight the pandemic. However, a part of the population possesses negative attitudes towards the vaccine. The spread of conspiracy theories and contradictory information about the pandemic have altered the population's perception of risk. The risk-perception of the vaccine's side effects may be affected by individual differences. The complex relationship between risk-perception and individual differences is relevant when people have to make decisions based on ambiguous and constantly changing information, as in the early phases of the Italian vaccination campaign. The present study aimed at measuring the effect of individual differences in risk-perception associated with the COVID-19 vaccine's side effects in a context characterized by information ambiguity. An online survey was conducted to classify a sample of Italian pro-vaccine people into cognitive/behavioral style groups. Furthermore, changes in vaccine risk-perception after inconsistent communications regarding the vaccine's side effects were compared between groups. The results showed that "analytical" individuals did not change their perception regarding the probability of vaccine side effects but changed their perception regarding the severity of side effects; "open" and "polarized" individuals neither changed their perception regarding the probability nor of the severity of side effects, showing a different kind of information processing, which could interfere with an informed decision-making process.

The Effects of Non-Pharmaceutical Interventions on COVID-19 Epidemic Growth Rate during Pre- and Post-Vaccination Period in Asian Countries. There is little knowledge about how the influence of non-pharmaceutical interventions (NPIs) reduces the COVID-19 infection rate during the period of vaccine rollout. This study aimed to examine the effectiveness of NPIs on decreasing the epidemic growth of COVID-19 between before and after the vaccine rollout period among Asian countries. Our ecological study included observations from 30 Asian countries over the 20 weeks of the pre- and post-vaccination period. Data were extracted from the Oxford COVID-19 Government Response Tracker and other open databases. Longitudinal analysis was utilized to evaluate the impacts of public health responses and vaccines. The facial covering policy was the most effective intervention in the pre-vaccination period, followed by border control and testing policies. In the post-vaccination period, restrictions on gatherings and public transport closure both play a key role in reducing the epidemic growth rate. Vaccine coverage of 1-5%, 5-10%, 10-30%, and over 30% of the population was linked with an average reduction of 0.12%, 0.32%, 0.31%, and 0.59%, respectively. Our findings support the evidence that besides the vaccine increasingly contributing to pandemic control, the implementation of NPIs also plays a key role.

Anti-HBs titers are not decreased after treatment with oral Cladribine in patients with Multiple Sclerosis vaccinated against Hepatitis B virus. BACKGROUND: Oral cladribine is a novel treatment for Multiple Sclerosis (MS). It is a purine nucleoside antimetabolite analogue that is incorporated into the DNA, resulting in single-strand breaks in DNA and apoptosis of replicating lymphocytes. Specifically, Cladribine induces limited depletion of CD4 and CD8 T cell subsets and more marked depletion of memory B cell subsets. Therefore, natural and acquired humoral responses against pathogens may be potentially reduced. The aim of this study was to assess longitudinal variation of antiHBs titers in patients with MS treated with Cladribine. METHODS: Patients with MS treated with 1 cycle of Cladribine (3,5Â mg/kg) and previously vaccinated against Hepatitis B virus (HBV) were enrolled. Anti-HBs titers were compared before and after 12 months from Cladribine treatment. Total lymphocyte count was also analysed. RESULTS: Among the 13 RMS patients (10 F, 3Â M, mean age 33,8, SD 5,9) enrolled, all had anti-HBs titers >10Â mg/dl at baseline. Anti-HBs titer dropped below the reference value at 12 months after Cladribine only in 1 case. Pre-post Cladribine mean anti-HBs

values were not significantly different considering the whole cohort (Wilcoxon-Mann-Whitney Test pÂ =Â 0,762). Four patients had grade 1 and 1 patient grade 2 lymphocytopenia at 12 months. CONCLUSIONS: Cladribine does not seem to reduce humoral immune responses in subjects previously vaccinated against HBV, even in case of lymphocytopenia. These results, if confirmed in larger populations, appear reassuring also for other vaccinations (i.e. COVID19). The low impact of Cladribine on plasma cells may explain such findings.

New relapse of multiple sclerosis and neuromyelitis optica as a potential adverse event of AstraZeneca AZD1222 vaccination for COVID-19. We report on nine patients (eight cases of MS and one case of NMOSD) who presented a disease relapse in close temporal association with their first AZD1222 vaccination dose against COVID-19. These patients had been stable for a median period of six years, with no evidence of disease activity and no change in their medication. After a median of 13 days (7 to 25 days) from vaccination, they developed a new relapse with increased disability and new lesions on magnetic resonance imaging. Although this association may be rare, it might be an adverse event of AZD1222.

The study of COVID-19 infection following vaccination in patients with multiple sclerosis. BACKGROUND: At this time vaccination against SARS-CoV2 is a global priority. Cases with multiple sclerosis (MS) were among the first vaccinated populations in Iran. We evaluated the change in the frequency of COVID-19 after vaccination and the associated factors with severe COVID-19 infection before and after full vaccination. METHODS: A questionnaire was validated to investigate the basic characteristics (age, gender, education, body mass index, smoking status, and comorbidities), MS disease and treatment status (MS type, MS duration, The Expanded Disability Status Scale (EDSS), disease modifying treatments) and the information about COVID-19 infection and severity. RESULTS: 692 (91.9%) of participants have received both doses of vaccines, of which Sinopharm appeared to be the most common type. Significant difference of COVID-19 infection prevalence was seen before vaccination and after full vaccination (difference: 0.16, 95% CI: 0.12-0.20) (p valueÂ <Â 0.001). The difference was not significant for severe cases (those who were admitted in the ward or ICU) relative to the COVID-19 cases or the whole participants. Of all the basic and disease factors, only EDSS showed a significant association with severe COVID-19 before vaccination. Severe COVID-19 in fully vaccinated cases did not show any significant relation to any of basic or disease characteristics except with prior history of severe allergic reactions (OR: 17.1, p value: 0.001). DISCUSSION: The decreased frequency of infection with SARS-CoV2 was predictable but the insignificant difference in cases with the severe forms of the disease raise concern. The only significant predictor was found to be severe allergic reactions. As there are debates on antiCD20Â s association with severe COVID-19 and vaccine efficacy, we could not find such significant relation. The other noticeable point about the found relation of EDSS and critical COVID-19 before vaccination is the absence of such relation after full vaccination.

COVID-19 and vaccination against SARS-CoV-2 in patients with neuromyelitis optica spectrum disorders. BACKGROUND: Reports on outcomes of COVID-19 in patients with neuromyelitis optica spectrum disorder (NMOSD) are scarce, as well as those related to the safety profile of the vaccines in this population. The aim of this survey is to present demographic and clinical characteristics of patients with NMOSD who developed COVID-19 and safety data of the COVID-19 vaccines in these persons. METHODS: This study comprise all patients from the Hospital registry of NMOSD, of the Clinic of Neurology in Belgrade, who fulfilled the 2015 NMOSD diagnostic criteria, and who after invitation by phone call, from April 10 to May 10, 2021, accepted to participate and provide information regarding COVID-19 and vaccination against Sars-CoV-2 (nÂ =Â 53). RESULTS: Sixteen out of 53 enrolled NMOSD patients were diagnosed with COVID-19. In three cases (18.8%), severity of COVID-19 clinical manifestations warranted hospitalization, and one of these patients, died due to

COVID-19 (case fatality ratioÂ =Â 6.25%), after invasive mechanical ventilation. The remaining two patients had grade II COVID -19 severity and were hospitalized because of pneumonia, not requiring supplemental oxygen. Median EDSS in patients requiring hospitalization was 4.5, and in the non-hospitalized group, it was 3.0. Nine out of 53 patients received two doses of vaccine against Sars-Cov-2 (8 Sinopharm and one Pfizer). Pain at the site of application was the only vaccine-related adverse effect. CONCLUSIONS: Our survey indicates overall favourable COVID-19 outcome and encouraging safety profile of the vaccines in persons with NMOSD, in our cohort. Prospective studies are warranted to confirm these data.

Breakthrough omicron COVID-19 infections in patients receiving the REGEN-Cov antibody combination.

Guillain-BarrÃ© Syndrome After Ad26.COV2.S Vaccination. BACKGROUND Since December 2020, multiple vaccines have mobilized mass immunization campaigns capable of mitigating the current SARS-COV-2 pandemic. Ad26.COV2.S (Johnson & Johnson/Janssen) is a recombinant, replication-incompetent vector vaccine encoding the SARS-CoV-2 spike (s) protein and is especially protective against severe-critical disease. It is a single-dose injection; adverse effects after vaccine administration are usually mild and self-limited, including pain at the injection site, headache, fatigue, muscle aches, and nausea. Severe adverse events involving hospitalization and death after Ad26.COV2.S rarely occur. However, not unlike previous viral vector vaccines, ongoing clinical trials may unveil rare complications of Ad26.COV2.S. Guillain-Barre Syndrome (GBS) is an autoimmune demyelinating polyneuropathy that can potentially manifest severe neurological symptoms after vaccination. CASE REPORT This report describes a case of classic GBS features that manifested 14 days after a single Ad26.COV2.S vaccine injection. The patient developed flaccid paralysis with treatment-related fluctuations. Our findings warrant further investigation into the potential relationship between SARS-CoV-2 vaccinations and the development of GBS. CONCLUSIONS A temporal association between the Ad26.COV2.S (Johnson & Johnson/Janssen) vaccine and the onset of GBS was demonstrated in this case report. A feasible underlying pathogenic mechanism involves the cross-reactivity of antibodies stimulated by adenovirus vaccine components and peripheral nerve glycoproteins. However, there is currently insufficient evidence to support a causal relationship between Ad26.COV2.S and the development of GBS. Further evidence gathered from clinician surveillance and clinical trials are needed to draw these conclusions.

A systematic review of vaccine-induced thrombotic thrombocytopenia in individuals who received COVID-19 adenoviral-vector-based vaccines. Reports of thrombotic response after receiving COVID-19 Adenoviral-Vector Based Vaccines raise concerns about vaccine-induced thrombotic thrombocytopenia (VITT); therefore, we conduct this systematic review to report susceptible demographics outcomes, commonalities, and prognosis of reporting cases. We identified published articles by searching PubMed, SCOPUS, and Web of Science from December 2020 till May 2021, with an updated search in September 2021. All case reports and case series reporting thrombotic response after receiving COVID-19 Adenoviral-Vector Based Vaccines were eligible for including. In addition, two authors independently extracted data and assessed the quality of the included studies. A total of 157 patients with thrombotic events after the ChAdOx1 nCoV-19 vaccine and 16 patients with thrombotic events after Ad26.COV2. S vaccine was included in our study. 72% of the ChAdOx1 nCoV-19 cases were females, while in Ad26.COV2.S subgroup, all reported patients were females. The commonest presentations were deep vein thrombosis 20 (12.7%) and cerebral venous sinus thrombosis 18 (11.5%) in the ChAdOx1 nCoV-19 subgroup while cerebral venous sinus thrombosis 14 (87.5%) and pulmonary embolism 2 (12.5%) in the Ad26.COV2. S subgroup. In this study, we described the certain demographics associated with VITT and the clinical presentations of those cases in the ChAdOx1 nCoV-19 and Ad26.COV2. S vaccines. Young individuals, particularly females, may be

more susceptible to VITT, and future studies should seek to confirm this association. In addition, the clinical presentation of VITT commonly includes cerebral thrombi, pulmonary embolism, and deep venous thrombosis, but other presentations are also possible, highlighting the importance of clinical vigilance in recent vaccine recipients.

Model-Estimated Association Between Simulated US Elementary School-Related SARS-CoV-2 Transmission, Mitigation Interventions, and Vaccine Coverage Across Local Incidence Levels. IMPORTANCE: With recent surges in COVID-19 incidence and vaccine authorization for children aged 5 to 11 years, elementary schools face decisions about requirements for masking and other mitigation measures. These decisions require explicit determination of community objectives (eg, acceptable risk level for in-school SARS-CoV-2 transmission) and quantitative estimates of the consequences of changing mitigation measures. OBJECTIVE: To estimate the association between adding or removing in-school mitigation measures (eg, masks) and COVID-19 outcomes within an elementary school community at varying student vaccination and local incidence rates. DESIGN, SETTING, AND PARTICIPANTS: This decision analytic model used an agent-based model to simulate SARS-CoV-2 transmission within a school community, with a simulated population of students, teachers and staff, and their household members (ie, immediate school community). Transmission was evaluated for a range of observed local COVID-19 incidence (0-50 cases per 100â€¯000 residents per day, assuming 33% of all infections detected). The population used in the model reflected the mean size of a US elementary school, including 638 students and 60 educators and staff members in 6 grades with 5 classes per grade. EXPOSURES: Variant infectiousness (representing wild-type virus, Alpha variant, and Delta variant), mitigation effectiveness (0%-100% reduction in the in-school secondary attack rate, representing increasingly intensive combinations of mitigations including masking and ventilation), and student vaccination levels were varied. MAIN OUTCOMES AND MEASURES: The main outcomes were (1) probability of at least 1 in-school transmission per month and (2) mean increase in total infections per month among the immediate school community associated with a reduction in mitigation; multiple decision thresholds were estimated for objectives associated with each outcome. Sensitivity analyses on adult vaccination uptake, vaccination effectiveness, and testing approaches (for selected scenarios) were conducted. RESULTS: With student vaccination coverage of 70% or less and moderate assumptions about mitigation effectiveness (eg, masking), mitigation could only be reduced when local case incidence was 14 or fewer cases per 100â€¯000 residents per day to keep the mean additional cases associated with reducing mitigation to 5 or fewer cases per month. To keep the probability of any in-school transmission to less than 50% per month, the local case incidence would have to be 4 or fewer cases per 100â€¯000 residents per day. CONCLUSIONS AND RELEVANCE: In this study, in-school mitigation measures (eg, masks) and student vaccinations were associated with substantial reductions in transmissions and infections, but the level of reduction varied across local incidence. These findings underscore the potential role for responsive plans that deploy mitigation strategies based on local COVID-19 incidence, vaccine uptake, and explicit consideration of community objectives.

BNT162b2 Vaccine-Associated Myo/Pericarditis in Adolescents: A Stratified Risk-Benefit Analysis. BACKGROUND: Male patients ages 12-17Â years have an elevated risk of mRNA vaccination-associated myo/pericarditis. A risk-benefit analysis of first and second doses of mRNA vaccination in adolescent boys by health status and history of SARS-CoV-2 infection has not been performed. METHODS: Using the Vaccine Adverse Event Reporting System (VAERS), we identified BNT162b2 [Pfizer-BioNTech] myo/pericarditis occurrence according to CDC criteria. Main outcomes were as follows: 1) post-vaccination myo/pericarditis crude incidence in adolescents aged 12-15 and 16-17; and 2) two risk-benefit analyses by age, sex, comorbidity, variant and history of infection. RESULTS: Cases of myo/pericarditis (nÂ =Â 253) included 129 after dose 1 and 124 after dose 2; 86.9% were

hospitalized. Incidence per million after dose two in male patients aged 12-15 and 16-17 was 162.2 and 93.0, respectively. Weighing post-vaccination myo/pericarditis against COVID-19Â hospitalization during delta, our risk-benefit analysis suggests that among 12-17-year-olds, two-dose vaccination was uniformly favourable only in nonimmune girls with a comorbidity. In boys with prior infection and no comorbidities, even one dose carried more risk than benefit according to international estimates. In the setting of omicron, one dose may be protective in nonimmune children, but dose two does not appear to confer additional benefit at a population level. CONCLUSIONS: Our findings strongly support individualized paediatric COVID-19 vaccination strategies which weigh protection against severe disease vs. risks of vaccine-associated myo/pericarditis. Research is needed into the nature and implications of this adverse effect as well as immunization strategies which reduce harms in this overall low-risk cohort.

Platelet size as a mirror for the immune response after SARS-CoV-2 vaccination.

Safety and immunogenicity of two recombinant DNA COVID-19 vaccines containing the coding regions of the spike or spike and nucleocapsid proteins: an interim analysis of two open-label, non-randomised, phase 1 trials in healthy adults. BACKGROUND: We assessed the safety and immunogenicity of two recombinant DNA vaccines for COVID-19: GX-19 containing plasmid DNA encoding the SARS-CoV-2 spike protein, and GX-19N containing plasmid DNA encoding the SARS-CoV-2 receptor-binding domain (RBD) foldon, nucleocapsid protein, and plasmid DNA encoding the spike protein. METHODS: Two open-label non-randomised phase 1 trials, one of GX-19 and the other of GX-19N were done at two hospitals in South Korea. We enrolled healthy adults aged 19-49 years for the GX-19 trial and healthy adults aged 19-54 years for the GX-19N trial. Participants who tested positive by serological testing for SARS-CoV-2 were excluded. At 4-week intervals, the GX-19 trial participants received two vaccine doses (either 1Â·5 mg or 3Â·0 mg), and the GX-19N trial participants received two 3Â·0 mg doses. The vaccines were delivered intramuscularly using an electroporator. The participants were followed up for 52 weeks after first vaccination. Data collected up to day 57 after first vaccination were analysed in this interim analysis. The primary outcome was safety within 28 days after each vaccination measured in the intention-to-treat population. The secondary outcome was vaccine immunogenicity using blood samples collected on day 43 or 57 after first vaccination measured in the intention-to-treat population. The GX-19 (NCT044445389) and GX-19N (NCT04715997) trials are registered with ClinicalTrials.gov. FINDINGS: Between June 17 and July 30, 2020, we screened 97 individuals, of whom 40 (41%) participants were enrolled in the GX-19 trial (20 [50%] in the 1Â·5 mg group and 20 [50%] in the 3Â·0 mg group). Between Dec 28 and 31, 2020, we screened 23 participants, of whom 21 (91%) participants were enrolled on the GX-19N trial. 32 (52%) of 61 participants reported 80 treatment-emergent adverse events after vaccination. All solicited adverse events were mild except one (2%) case of moderate fatigue in the 1Â·5 mg GX-19 group; no serious vaccine-related adverse events were detected. Binding antibody responses increased after second dose of vaccination in all groups (p=0Â·0002 in the 1Â·5 mg GX-19 group; p<0Â·0001 in the 3Â·0 mg GX-19; and p=0Â·0004 for the spike protein and p=0Â·0001 for the RBD in the 3Â·0 mg GX-19N group). INTERPRETATION: GX-19 and GX-19N are safe and well tolerated. GX-19N induces humoral and broad SARS-CoV-2-specific T-cell responses. GX-19N shows lower neutralising antibody responses and needs improvement to enhance immunogenicity. FUNDING: The Korea Drug Development Fund, funded by the Ministry of Science and ICT, Ministry of Trade, Industry, and Energy, and Ministry of Health and Welfare.

Pityriasis rosea-like rash after messenger RNA COVID-19 vaccination: A case report and review of the literature. A spectrum of cutaneous reactions to SARs-CoV-2 (COVID-19) vaccines have been reported in the literature. We present a case of a pityriasis rosea-like rash occurring after Pfizer COVID-19 vaccination and review cases of pityriasis rosea (PR)/PR-like eruption (PR-LE) after mRNA

COVID-19 vaccine published in the medical literature. Of the 30 cases found, none experienced severe adverse effects and the rash resolved in an average of 5.6 weeks. It is important for physicians to be aware of this self-limited reaction so they can reassure and appropriately counsel patients that it is safe to receive subsequent vaccine doses despite the cutaneous eruption. Additionally, differences in incidence of this reaction after Pfizer and Moderna vaccination may suggest a differing host immune response incited by these vaccines which warrants further investigation.

Clinical relapse of immune-mediated thrombotic thrombocytopenic purpura following COVID-19 vaccination. De novo and relapsed immune-mediated thrombotic thrombocytopenic purpura (iTTP) have been documented to have occurred following severe acute respiratory syndrome coronavirus 2 (COVID-19) vaccination. Here, we present a case of a 28-year-old woman who received the tozinameran (BNT162b2, Pfizer-BioNtech) vaccine for COVID-19 and experienced an iTTP relapse during longitudinal follow-up. She received the vaccine 30Â months after her initial diagnosis, while she was in clinical remission. She was not in complete ADAMTS-13Â remission, as she had undetectable ADAMTS-13 activity during follow-up except for one isolated measurement of 48%. Shortly after vaccination, she developed complaints of bruising, petechiae, ataxia, and an episode of slurred speech. Laboratory testing demonstrated thrombocytopenia, schistocytes, and eventually undetectable ADAMTS-13 activity. She was successfully treated with caplacizumab, rituximab, and corticosteroids without plasma exchange. She achieved complete clinical and ADAMTS-13Â remission after treatment. We recommend caution in the administration of COVID-19 vaccines for survivors of iTTP in remission with severely deficient ADAMTS-13 activity.

COVID-19 vaccine acceptance and associated factors among women attending antenatal and postnatal cares in Central Gondar Zone public hospitals, Northwest Ethiopia. INTRODUCTION: The Coronavirus disease 2019 pandemic is a public health problem, which caused a major impact on morbidity and mortality around the world. Even though an effective vaccine is the most awaited resolution for the pandemic, little is known about COVID-19 vaccine acceptance in Ethiopia. This study aimed to assess vaccine acceptance and its associated factors among pregnant and postnatal mothers. METHOD: Institution-based cross-sectional study was conducted on 527 pregnant and postnatal mothers from August 15 to September 15, 2021. Data were collected using an interviewer-administered structured questionnaire. A systematic random sampling technique was used to select the study participants. Epi-Data version 4.6 and Stata 16 software were used for data entry and analysis respectively. Participant characteristics and rate of vaccine acceptance were presented using descriptive statistics. Multi-variable logistic regression was performed to identify statistically significant variables. Adjusted odds ratio with 95% confidence interval was used to declare statistical significance based on pÂ <Â 0.05 in the multivariable logistic regression model. RESULT: The overall prevalence of intent to accept COVID-19 vaccine was 62.04% (95% CI: 57.65, 66.25). Of those 40.08% were pregnant mothers and 21.97% of them were postpartum mothers. Urban residence (AORÂ =Â 2.03, 95% CI: 1.09-3.77), respondents who were worry about COVID-19 disease (AORÂ =Â 3.46, 95% CI: 2.16-5.52), and participants who had favorable attitude towards vaccine (AORÂ =Â 8.54, 95% CI: 5.18-14.08) were significantly associated with COVID-19 vaccine acceptance. CONCLUSION: Our findings showed that the willingness to accept COVID-19 vaccination was low. Residence, worry about COVID-19 disease, and attitudes towards vaccine were factors significantly associated with COVID-19 vaccine acceptance. Evidence-based and clear information on COVID-19 vaccines should be provided to pregnant and postnatal mothers for both rural and urban residences to improve attitude towards the COVID-19 vaccine and increase vaccination rates.

Incidence and severity of SARS-CoV-2 virus post COVID-19 vaccination: A cross-sectional study in India. INTRODUCTION: Several sociodemographic variables, including ethnic inequality, have been identified as potentially influencing the uptake of COVID-19 vaccinations. To develop herd

immunity against COVID-19, at least 70-85% of the population must be vaccinated. As the situation with COVID-19 changes, the public's perception keeps fluctuating. We designed a survey to determine the prevalence of vaccinated individuals and the rate of infectivity post-vaccination. We also aimed to study the clinical manifestations and infectivity of the SARS-CoV-2 virus post-vaccination. MATERIALS AND METHODS: A cross-sectional study was conducted from May 10, 2021 to July 10, 2021 across India through a pre-tested validated semi-structured self-administered electronic questionnaire, to the study subjects with objectives explained and the confidentiality of the data and results had been assured. The questionnaires were prepared using Google forms and the link was sent across social media platforms such as WhatsApp, Facebook, and various social platforms where people are actively engaged following the restrictions and protocols of social distancing. General demographic data, followed by their lifestyle and comorbid conditions, and data on their vaccination, infectivity, and side effects were collected. RESULTS: We included 2334 participants in the study, of which the majority of the study participants were in the age group of 25-34 years (38.6%). 1729 were vaccinated individuals of which 80.7% had received Covishield and 17.8% had received Covaxin. Around 61.1% have received both doses among 1729 vaccinated individuals and 38.9% had received only one dose of vaccine. The majority of the fully vaccinated individuals had a gap of 4-5 weeks for the second dose (37.1%) followed by 5-6 weeks (11.2%). Post-vaccination 50.8% had experienced muscle pain, 46% had experienced fatigue, 36.5% weakness, and 12.3% back pain. Among vaccinated 26% turned out to be COVID-19 positive and 44.5% non-vaccinated got infected. The odds of infection among non -vaccinated individuals was 2.27 times higher than vaccinated individuals. Individuals who encountered the viral antigen for the second time experienced either through vaccination or infection demonstrated exaggerated inflammatory response which is explained by the antibody-dependent enhancement phenomenon without life-threatening complications. CONCLUSION: Although more than 50% of the vaccinated individuals experienced some form of musculoskeletal side effects, we noted a high acceptance rate (74%) of vaccination among the participants. The vaccinated individuals were two times safer from infection compared to the non-vaccinated individuals.

Neurological Conditions Following COVID-19 Vaccinations: Chance or Association? Coronavirus disease 2019 (COVID-19) has been labeled a global pandemic with the first reported case of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) occurring in Wuhan, China in December 2019. To combat the alarming, increasing rate of those affected by the virus, vaccine development ensued. As mass vaccination initiatives against COVID-19 ensued, adverse reactions began emerging. This non-consecutive, population-based case series focuses on four vaccine-associated neurological adverse events across the central and peripheral nervous system detailing the diagnosis, treatment and subsequent follow-up management. These four patients presented to public and private hospitals in Trinidad and Tobago with new-onset neurological diseases soon after their first doses of a COVID-19 vaccine: two after the Pfizer-BioNTech vaccine (one case of new-onset seizures and one case of longitudinally extensive transverse myelitis) and two after the ChAdOx1 nCoV-19 vaccine (one case of Guillain-Barre syndrome and one case of meningitis-retention syndrome). The background incidence rates of neurological conditions in the population and the large numbers of persons being vaccinated means that some of these conditions will appear in the post-vaccination window by chance. Hence, establishing causal links is difficult. The close temporal relationship between vaccination and the presenting symptoms, the biological plausibility, and the extensive diagnostic workup to exclude other causes fulfill criteria provided by the World Health Organization for causality assessment of an adverse event following immunization on an individual level. On this basis, it was determined that these adverse events were likely due to the vaccines. However, establishing causal links on a population level requires large epidemiological studies and cannot be done on individual case reports alone. While physicians should be cognizant of even these

rare adverse events of vaccines, it should be reiterated that the overall safety profile of vaccines is well established.
COVID-19 mRNA Vaccine-Associated Myocarditis. Coronavirus disease 2019 (COVID-19) has been reported to cause cardiovascular complications including myocarditis, pericardial effusion, pericarditis, and arrhythmias. With the introduction of the vaccine, there have been reports of myocarditis possibly associated with the mRNA COVID-19 vaccine. We report a case of cardiac involvement following the second dose of Pfizer-BioNTech COVID-19 vaccine in a young male. A healthy 24-year-old male presented to the emergency department with complaints of non-radiating mid-sternal chest pain and pressure.Â He noticed his symptoms started six hours after he received the second dose of Pfizer COVID vaccine.Â Laboratory tests revealed elevated cardiac troponin I-CtNI levels. Computed tomography angiography of the chest did not show evidence of pulmonary embolism.Â Given his presentation of acute chest pain associated with elevated troponin levels, a coronary angiogram was performed which revealed normal coronary arteries. He was subsequently treated for acute peri-myocarditis with colchicine, non-steroidal anti-inflammatory drugs (NSAIDs), and beta-blockers for tachycardia and the prevention of arrhythmia. Although rare, clinicians should be aware of the risk for myocarditis and pericarditis, which should be considered in individuals presenting with chest pain within a week after vaccination, especially in the younger population. Although the long-term risk in these patients is uncertain, early diagnosis and treatment are key to minimizing complications.
Herpetic Keratitis and Corneal Endothelitis Following COVID-19 Vaccination: A Case Series. Herpetic corneal disease is the most common infectious cause of corneal blindness in developed countries. The majority of the infections areÂ caused by the reactivation of the latent virus in the trigeminal ganglion. Environmental factors and physical stress are thought to contribute to viral reactivation. The pathognomonic lesion of the herpes simplex virus (HSV) is dendritic keratitis, which is visible on slit-lamp examination after fluorescein dye staining. A potential association between HSV reactivation and coronavirus disease 2019 (COVID-19) vaccines has been reported. In this case series, we present four cases of HSV reactivation in patients who received COVID-19 vaccination in Saudi Arabia from different medical centers. This report emphasizes the necessity of evaluating HSV reactivation as a potential side effect of COVID-19 vaccination. This is important because early diagnosis and timely management of herpetic lesions can potentially reduce the severity of infection.
First Presentation of Systemic Lupus Erythematosus in a 24-Year-Old Male following mRNA COVID-19 Vaccine. The SARS-CoV-2 viral pandemic has had an immeasurable global impact, resulting in over 5 million deaths worldwide. Numerous vaccines were developed in an attempt to quell viral dissemination and reduce symptom severity among those infected. Systemic lupus erythematosus (SLE) is an autoimmune disease characterized by the production of antinuclear autoantibodies (ANAs) with heterogenic clinical manifestations, secondary to immune complex deposition in a multitude of organ systems. There are scarcely reported cases of SLE development following COVID-19 mRNA vaccination. We present a case of a 24-year-old male without preexisting conditions or family history of autoimmune disorders, presenting with SLE following the first dose of the SARS-CoV-2 Pfizer-BioNTech mRNA vaccine.
Fulminant myocarditis after the second dose of COVID-19 mRNA vaccination. Myocarditis is an adverse event associated with coronavirus disease 2019 (COVID-19) mRNA vaccination. A 50-year-old man presented with dyspnea and resting chest pain after receiving the second dose of the COVID-19Â mRNA vaccine and developed cardiogenic shock. Fulminant myocarditis was diagnosed by endomyocardial biopsy and treated with intravenous corticosteroids.
Recurrent Kounis syndrome - a life-threatening event after COVID-19 vaccine administration. Kounis syndrome is an acute coronary syndrome occurring in the setting of a hypersensitivity

reaction. It occurs as a consequence of mast-cell activation and degranulation causing coronary artery spasm, atherosclerotic plaque erosion, or stent thrombosis. We report the case of a man who presented to the emergency department with typical angina that started 20 minutes after coronavirus disease 2019 (COVID-19) vaccine administration. Electrocardiogram showed inferior ST-elevation myocardial infarction, and coronary angiography confirmed right coronary artery stent thrombosis. Five months before, he had an acute coronary syndrome after influenza vaccine administration. Both vaccines share a common excipient, polysorbate 80. Considering the reproducibility of the reaction and the temporal association between vaccine administration and coronary events, a hypersensitivity reaction to polysorbate 80 was admitted and the patient was instructed to further avoid drugs containing it. To our knowledge, this constitutes the first reported case of type 3 Kounis syndrome after COVID-19 vaccine administration. Kounis syndrome is an uncommon disease, often undiagnosed. Its recognition and proper management are crucial to prevent future events. <Learning objective: Kounis syndrome is an acute coronary syndrome occurring in the setting of a hypersensitivity reaction and is a potential life-threatening adverse effect of multiple drugs, including vaccines. It is an uncommon disease often undiagnosed. A correct diagnosis and prompt referring for drug hypersensitivity investigation are essential to prevent future events.>.

Antigen Specific Humoral and Cellular Immunity Following SARS-CoV-2 Vaccination in ANCA-Associated Vasculitis Patients Receiving B-Cell Depleting Therapy. Humoral vaccine responses are known to be suboptimal in patients receiving B-cell targeted therapy, and little is known about vaccine induced T-cell immunity in these patients. In this study, we characterized humoral and cellular antigen-specific anti-SARS-CoV2 responses following COVID-19 vaccination in patients with ANCA-associated vasculitis (AAV) receiving anti-CD20 therapy, who were either B-cell depleted, or B-cell recovered at the time of vaccination and in normal control subjects. SARS-CoV-2 anti-spike (S) and anti-nucleocapsid (NC) antibodies were measured using electrochemiluminescence immunoassays, while SARS-CoV-2 specific T-cell responses to S glycoprotein subunits 1 (S1) and 2 (S2) and receptor binding domain peptide pools were measured using interferon-gamma enzyme-linked immunosorbent spot (ELISPOT) assays. In total, 26 recently vaccinated subjects were studied. Despite the lack of a measurable humoral immune response, B-cell depleted patients mounted a similar vaccine induced antigen-specific T-cell response compared to B-cell recovered patients and normal controls. Our data indicate that to assure a humoral response in patients receiving anti-CD20 therapy, SARS-CoV-2 vaccination should ideally be delayed until B-cell recovery (CD-20 positive B-cells > 10/Î¼l). Nevertheless, SARS-CoV-2 vaccination elicits robust, potentially protective cellular immune responses in these subjects. Further research to characterize the durability and protective effect of vaccine-induced anti-SARS-CoV-2 specific T-cell immunity are needed.

Guillain-BarrÃ© Syndrome and Variants Following COVID-19 Vaccination: Report of 13 Cases. BACKGROUND: Amidst growing concern about an increased risk of Guillain-BarrÃ© syndrome (GBS) following COVID-19 vaccination, clinical and electrodiagnostic features have not been fully characterized. METHODS: We retrospectively reviewed medical records of the patients diagnosed with GBS and its variants following COVID-19 vaccination at four referral hospitals during the period of the mass vaccination program in South Korea (February to October 2021). RESULTS: We identified 13 patients with GBS and variants post COVID-19 vaccination: AstraZeneca vaccine (Vaxzevria) in 8, and Pfizer-BioNTech vaccine (Comirnaty) in 5. The mean time interval from vaccination to symptom onset was 15.6 days (range 4-30 days). Electrodiagnostic classification was demyelinating in 7, axonal in 4 and normal in 2 cases. Clinical manifestations were diverse with varying severity: classical GBS in 8 cases, paraparetic variant in 3, Miller-Fisher syndrome in 1 and acute cervicobrachial weakness in 1. Four patients developed respiratory failure, and 2 of them showed treatment-related fluctuations.

CONCLUSION: Our observations suggest that COVID-19 vaccines may be associated with GBS of distinctive clinical features characterized by severe quadriplegia, disproportionately frequent bilateral facial palsy or atypical incomplete variants. Continuous surveillance and further studies using robust study designs are warranted to fully assess the significance of the association.

Myocarditis following mRNA Covid-19 vaccination: A pooled analysis. BACKGROUND: Post-marketing surveillance studies have raised concerns of increased myocarditis rates following coronavirus disease-19 (Covid-19) mRNA vaccines. The present study aims to accumulate the published mRNA Covid-19 vaccine-associated myocarditis cases, describe their clinical characteristics and determine the factors predisposing to critical illness. METHODS: Medline, Scopus, Web of Science, CENTRAL and Google Scholar were systematically searched from inception. Studies reporting adult myocarditis cases following BNT162b2 or mRNA-1273 vaccination were included. Individual participant data coming from case reports/series were pooled. Proportional random-effects meta-analysis was conducted by combining the pooled cohort and observational studies with aggregated data. RESULTS: Overall, 39 studies were included with a total of 129 patients. Most cases occurred in young males after the second vaccine dose. Myocarditis after the first dose was significantly associated with prior Covid-19 (p-value: 0.025). The most common electrocardiographic finding was ST-segment elevation, while late gadolinium enhancement was invariably observed in cardiac magnetic reasoning. Logistic regression analysis demonstrated that signs of heart failure were predictive of subsequent critical illness (Odds ratio: 19.22, 95% confidence intervals-CI: 5.57-275.84). Proportion meta-analysis indicated that complete resolution of symptoms is achieved in 80.5% of patients (95% CI: 59.3-92.1), while the proportion of participants necessitating intensive care unit admission is 7.0% (95% CI: 3.8-12.9). CONCLUSIONS: Myocarditis following mRNA Covid-19 vaccination is typically mild, following an uncomplicated clinical course with rapid improvement of symptoms. Future research is needed to define its exact incidence, clarify its pathophysiology and determine the optimal management plan depending on its severity. Protocol registration: dx.https://doi.org/10.17504/protocols.io.bxwtppen.

MOG antibody-associated longitudinal extensive myelitis after Oxford-Astra Zeneca's COVID-19 vaccination.

Newly-developed vitiligo following COVID-19 mRNA vaccine.

Prominent J Waves and Ventricular Fibrillation Caused by Myocarditis and Pericarditis After BNT162b2 mRNA COVID-19 Vaccination.

Acute disseminated encephalomyelitis with bilateral optic neuritis following ChAdOx1 COVID-19 vaccination. BACKGROUND: Acute disseminated encephalomyelitis (ADEM) is a rare immune-mediated inflammatory demyelinating disease of the central nervous system. We report a case of ADEM presenting with bilateral optic neuritis temporally associated with the ChAdOx1 vaccine against SARS-COVID19 virus. CASE PRESENTATION: A 36-year-old female presented with bilateral optic neuritis following her first dose of the ChAdOx1 vaccine. Initial MRI Brain showed evidence of demyelination within the subcortical white matter, with no radiological involvement of the optic nerves. Visual evoked potentials were consistent with bilateral optic neuritis which was confirmed radiologically on follow up MRI. She was treated with intravenous steroids with improvement both in symptoms and radiological appearance. A pseudo-relapse occurred which was treated with a further course of intravenous steroids followed by an oral taper. The clinical, radiological and serological results were most consistent with diagnosis of ADEM. CONCLUSIONS: ADEM is an exceedingly rare complication of ChAdOx1 vaccine despite millions of doses. While it is imperative clinicians remain aware of neurological complications of vaccines, the importance of vaccination to control a pandemic should not be undermined.

Humoral antibody kinetics with ChAdOx1-nCOV (Covishieldâ„¢) and BBV-152 (Covaxinâ„¢) vaccine among Indian Healthcare workers: A 6-month longitudinal cross-sectional Coronavirus Vaccine-induced antibody titre (COVAT) study. BACKGROUND AND AIMS: There is limited data available on longitudinal humoral antibody dynamics following two doses of ChAdOx1-nCOV (Covishieldâ„¢) and BBV-152 (Covaxinâ„¢) vaccine against SARS-CoV-2 among Indians. METHODS: We conducted a 6-month longitudinal study in vaccinated healthcare workers by serially measuring quantitative anti-spike antibody at 3-weeks, 3-months and 6-months after the completion of second dose. Geometric mean titer (GMT) and linear mixed models were used to assess the dynamics of antibody levels at 6 months. RESULTS: Of the 481 participants, GMT of anti-spike antibody decreased by 56% at 6-months regardless of age, gender, blood group, body-mass index and comorbidities in 360 SARS-CoV-2 naive individuals but significantly more in hypertensives. Participants with past infection had significantly higher GMT at all time points compared to the naive individuals. Among SARS-CoV-2 naive cohorts, a significantly higher GMT was noted amongst the Covishield recipients at all time points, but there was a 44% decline in GMT at 6-month compared to the peak titer period. Decline in GMT was insignificant (8%) in Covaxin recipients at 6-month despite a lower GMT at all time points vs. Covishield. There was 5.6-fold decrease in seropositivity rate at 6-month with both vaccines. Participants with type 2 diabetes mellitus have a lower seropositivity rate at all the time points. Seropositivity rate was significantly higher with Covishield vs. Covaxin at all time points except at 6-month where Covaxin recipients had a higher seropositivity rate but no difference noted in propensity-matched analysis. CONCLUSIONS: There is waning humoral antibody response following two doses of either vaccine at six months. Covishield recipients had a higher anti-spike antibody GMT compared with Covaxin at all-time points, however a significant decline in antibody titers was seen with Covishield but not with Covaxin at 6-months.

COVID-19 vaccination in adolescents and young adults with type 1 diabetes: Glycemic control and side effects. BACKGROUND: Two vaccines against SARS-CoV-2 are approved by the World Health Organization (WHO) for minors aged 12â€‰years and over. Currently, people with both type 1 diabetes (T1D) and type 2 diabetes (T2D) are prioritized for vaccination. OBJECTIVE: To evaluate possible glycemic control modification, insulin dose adjustment and adverse effects after COVID-19 vaccination in young T1D individuals, users of different technology levels. METHODS: Thirty-nine T1D individuals, who received a whole vaccination cycle of either Moderna or Pfizer- BioNTech vaccines, were enrolled, 24 of whom using advanced hybrid closed loop systems (AHCLs) and 15 using intermittently scanned continuous glucose monitoring (isCGM). Symptoms after each dose and the following variables were considered: time in range 70-180â€‰mg/dl (TIR), time in different glucose ranges, mean glucose levels, coefficient of variation (CV), total daily dose (TDD) and bolus proportion RESULTS: No significant differences in TIR, time in different glucose ranges, mean glucose levels, TDD, bolus proportion, were observed before and after any dose nor before and after the whole vaccination cycle. CV was significantly lower after the whole vaccination cycle (CV pre-vaccination 35.1â€‰Â±â€‰6.9% vs. CV post-vaccination 33.5â€‰Â±â€‰6.3%; p 0.031) in subjects treated by AHCLs. Side effects after the vaccination were mild and more frequent after the second dose. No severe adverse reactions were reported. CONCLUSIONS: COVID-19 vaccination was safe and not associated with significant perturbation of glycemic control in adolescents and young adults with T1D. This information could be of clinical use when counseling families about SARS-CoV-2 vaccination in young people with T1D.

Late inflammatory reactions in patients with soft tissue fillers after SARS-CoV-2 infection and vaccination: A systematic review of the literature. INTRODUCTION: Soft tissue fillers are used for cosmetic and reconstructive purposes, and soft tissue filler procedures are among the most common nonsurgical procedures in the USA. Although soft tissue filler procedures are relatively quick and safe,

adverse events such as late inflammatory reactions have been reported with every filler product. Infections and vaccinations have been proposed as potential triggers for late inflammatory reactions (LIRs), and it is therefore not surprising that these adverse events have been reported after SARS-CoV-2 infection and vaccination. Therefore, this review aims to give a detailed overview of these cases. MATERIALS AND METHODS: A literature search was undertaken on LIRs in patients with a history of soft tissue filler use after SARS-CoV-2 infection or vaccination. This systematic review was reported according to the PRISMA guidelines. We searched the electronic database PubMed from January 2020 to August 2021. Data on patient characteristics, filler characteristics, clinical findings, and treatment options were included. RESULTS: This review included 7 articles with a total of 19 patients with LIRs after SARS-CoV-2 infection or vaccination. Three patients with postinfection LIRs and 16 patients with postvaccination LIRs were reported. These LIRS mainly occurred in females who had HA injections for cosmetic purposes. Three patients with postinfection LIRs had symptoms of facial swelling and/or lip angioedema in a matter of weeks. Sixteen patients reported reactions after SARS-CoV-2 vaccination (13 following Moderna vaccination and 3 after Pfizer vaccination, after both the first and second doses) from 13Â hours up to three weeks. These patients presented with similar clinical symptoms as patients with postinfection LIRs. All patients were treated in a conservative manner. DISCUSSION: This review shows a relationship between LIRs and SARS-CoV-2 infection andÂ vaccination. In the case of vaccination, these adverse events have been reported only after Moderna and Pfizer vaccinations. The reported adverse events are generally minor and self-limiting, and we encourage patients with soft tissue fillers to participate in vaccination programs.

Adverse events following immunization of COVID-19 (Covaxin) vaccine at a tertiary care center of India. The study aimed to assess the adverse events following COVID-19 vaccine (Covaxin) immunization at a tertiary care institution and also assess the predictors of the adverse events following immunization (AEFI). The prospective observational study was conducted in a tertiary care institute among the Covaxin beneficiaries between June 28 and September 6, 2021. A total of 1826 participants were assessed for any local or systemic adverse events after seven days of vaccination. A telephonic interview was conducted, and the beneficiaries were assessed according to the adverse event grading. A total of 1826 participants were assessed for AEFI, and 544 (29.8%) reported at least one of the AEFI. No severe adverse events were reported, and about 1.6% had moderate AEFI. Pain at the injection site (14.6%), fever (9.7%), and myalgia (5.9%) were the common adverse events reported by the participants. AEFI incidence was higher in the first dose (38.1%) when compared to the second dose (26.4%), and this finding was significant with a pâ€‰<â€‰0.001. The major factors associated with AEFI were female sex, history of an allergic reaction, presence of comorbidities, acute infection in the past 3 months, and intake of chronic medications. Precaution needs to be taken while vaccinating individuals having allergies, comorbidities, acute infection in the last 3 months, and individuals on chronic medication.

Multisystem Inflammatory Syndrome in Adult after First Dose of mRNA Vaccine. A 32-year-old man in Japan experienced respiratory failure after receiving the first dose of coronavirus disease (COVID-19) vaccine. He was treated with noninvasive ventilation and corticosteroids. Serologic test results suggested previous COVID-19; therefore, he received a diagnosis of multisystem inflammatory syndrome. COVID-19 vaccination could be a trigger for this condition.

Reply to "COVID vaccine-induced lichen planus on areas previously affected by vitiligo".

Analysis of COVID-19 Risk Following a Ring Vaccination Intervention to Address SARS-CoV-2 Alpha Variant Transmission in Montreal, Canada. IMPORTANCE: Given limited COVID-19 vaccine availability early in the pandemic, optimizing immunization strategies was of paramount importance. Ring vaccination has been used successfully to control transmission of other airborne respiratory viruses. OBJECTIVE: To assess the association of a ring vaccination intervention on COVID-19 spread in

the initial epicenter of SARS-CoV-2 Alpha variant transmission in Montreal, Canada. DESIGN, SETTING, AND PARTICIPANTS: This cohort study compared COVID-19 daily disease risk in 3 population-based groups of neighborhoods in Montreal, Canada, defined by their intervention-specific vaccine coverage at the neighborhood level: the primary intervention group (500 or more vaccinated persons per 10â€¯000 persons), secondary intervention group (95 to 499), and control group (0 to 50). The groups were compared within each of 3 time periods: before intervention (December 1, 2020, to March 16, 2021), during and immediately after intervention (March 17 to April 17, 2021), and 3 weeks after the intervention midpoint (April 18 to July 18, 2021). Data were analyzed between June 2021 and November 2021. EXPOSURES: Vaccination targeted parents and teachers of children attending the 32 schools and 48 childcare centers in 2 adjacent neighborhoods with highest local transmission (case counts) of Alpha variant shortly after its introduction. Participants were invited to receive 1 dose of mRNA vaccine between March 22 and April 9, 2021 (before vaccine was available to these age groups). MAIN OUTCOMES AND MEASURES: COVID-19 risk in 3 groups of neighborhoods based on intervention-specific vaccine coverage. RESULTS: A total of 11â€¯794 residents were immunized, with a mean (SD) age of 43 (8) years (range, 16-93 years); 5766 participants (48.9%) lived in a targeted neighborhood, and 9784 (83.0%) were parents. COVID-19 risk in the primary intervention group was significantly higher than in the control group before (unadjusted risk ratio [RR], 1.58; 95% CI 1.52-1.65) and during (RR, 1.63; 95% CI, 1.52-1.76) intervention, and reached a level similar to the other groups in the weeks following the intervention (RR, 1.03; 95% CI, 0.94-1.12). A similar trend was observed when restricting to SARS-CoV-2 variants and persons aged 30 to 59 years (before: RR, 1.72; 95% CI, 1.63-1.83 vs after: RR, 1.01; 95% CI, 0.88-1.17). CONCLUSIONS AND RELEVANCE: Our findings show that ring vaccination was associated with a reduction in COVID-19 risk in areas with high local transmission of Alpha variant shortly after its introduction. Ring vaccination may be considered as an adjunct to mass immunization to control transmission in specific areas, based on local epidemiology.

Association of Homologous and Heterologous Vaccine Boosters With COVID-19 Incidence and Severity in Singapore. This study estimates SARS-CoV-2 infections and disease severity with the receipt of a booster and by type of booster.

New-onset lichen planus arising after COVID-19 vaccination.

The effects of intravascular photobiomodulation on sleep disturbance caused by Guillain-BarrÃ© syndrome after Astrazeneca vaccine inoculation: Case report and literature review. RATIONALE: Sleep disturbance is commonly noted after Guillain-BarrÃ© syndrome (GBS) and is often caused by persistent discomfort after disease survival. Intravascular laser irradiation of blood (ILIB) has been shown to be effective in pain modulation owing to the influence of nociceptive signals in the peripheral nervous system. We investigated the application of ILIB on post-Oxford -AstraZeneca vaccination GBS and evaluated its effect on sleep quality. PATIENT CONCERNS: A 48-year-old woman was subsequently diagnosed with GBS after Oxford-AstraZeneca vaccination. The patient was discharged after a 5-day course of intravenous immunoglobulin administration. However, 1 week after discharge, the previously relieved symptoms flared with accompanying sleep disturbance. DIAGNOSIS AND INTERVENTIONS: The patient was diagnosed with post-vaccination GBS, and persistent pain and sleep disturbances persisted after disease survival. ILIB was performed. OUTCOMES: We used the Pittsburgh Sleep Quality Index before and after intravascular laser irradiation. There was a marked improvement in the sleep duration, efficiency, and overall sleep quality. The initial score was 12 out of 21 and the final score was 7 out of 21. LESSONS: We found that ILIB was effective in pain modulation in post-vaccination GBS and significantly improved sleep quality.

Moyamoya disease with Sjogren disease and autoimmune thyroiditis presenting with left intracranial hemorrhage after messenger RNA-1273 vaccination: A case report. RATIONALE: The new

vaccines are emergently authorized and currently approved for use to protect against the coronavirus disease 2019 (COVID-19) pandemic and serious adverse events are uncommon. Moyamoya disease (MMD) with autoimmune disease is a rare entity and usually presents with intracranial hemorrhage in adults. PATIENT CONCERNS: We reported a 40-year-old female patient with Sjogren disease and autoimmune thyroiditis, who had received the second dose of Moderna (mRNA-1273) vaccination. Three days later, she presented with left intraventricular and intracerebral hemorrhage as a complication. DIAGNOSIS: After a series of diagnostic workups, left intracranial hemorrhage was associated with MMD. INTERVENTIONS: Emergent external ventricular drainage and subsequent stereotactic evacuation of hematoma with insertion of intracranial pressure monitoring were performed. OUTCOMES: Under the care of the neurocritical care team, her physical condition improved gradually. The neurological sequelae was noted by defects of cognitive function, apraxia, agnosia, and impaired executive function. She was discharged after eight weeks with a follow-up in the vascular neurology clinic planning for performing revascularization. LESSONS: To the best of our knowledge, no similar case has been reported before, and this is the first case of MMD complicated with intracerebral and intraventricular hemorrhage after mRNA-1273 vaccination. It is noticeable to assess the vaccine safety surveillance and raise the alertness about moyamoya in patients with autoimmune diseases during the COVID-19 pandemic. Further studies for risk evaluation of COVID-19 vaccines in patients with autoimmune diseases might be required in the future.

A naturally hypersensitive porcine model may help understand the mechanism of COVID-19 mRNAÂ vaccine-inducedÂ rare (pseudo) allergic reactions: complement activation as a possible contributing factor. A tiny fraction of people immunized with lipid nanoparticle (LNP)-enclosed mRNA (LNP-mRNA) vaccines develop allergic symptoms following their first or subsequent vaccinations, including anaphylaxis. These reactions resemble complement (C) activation-related pseudoallergy (CARPA) to i.v. administered liposomes, for which pigs provide a naturally oversensitive model. Using this model, we injectedÂ i.v. the human vaccination dose (HVD)Â of BNT162b2 (Comirnaty, CMT) orÂ its 2-fold (2x)Â or 5-fold (5x)Â amountsÂ andÂ measured the hemodynamic changes and other parameters of CARPA. We observed in 6 of 14 pigs transient pulmonary hypertension along with thromboxane A2 release into the blood and other hemodynamic and blood cell changes, including hypertension, granulocytosis, lymphopenia, and thrombocytopenia. One pig injected with 5xÂ CMT developed an anaphylactic shock requiring resuscitation, while a repeat dose failed to induce the reaction, implying tachyphylaxis. These typical CARPA symptoms could not be linked to animal age, sex, prior immune stimulation with zymosan, immunization of animals with Comirnaty i.v., or i.m. 2Â weeks before the vaccine challenge, and anti-PEG IgM levels in Comirnaty-immunized pigs. Nevertheless, IgM binding to the whole vaccine, used as antigen in an ELISA, was significantly higher in reactive animals compared to non-reactive ones. Incubation of Comirnaty with pig serum in vitro showed significant elevations of C3a anaphylatoxin and sC5b-9, the C-terminal complex. These data raise the possibility that C activation plays a causal or contributing role in the rare HSRs to Comirnaty and other vaccines with similar side effects. Further studies are needed to uncover the factors controlling these vaccine reactions in pigs and to understand their translational value to humans.

Longitudinal waning of mRNA vaccine-induced neutralizing antibodies against SARS-CoV-2 detected by an LFIA rapid test. Although mRNA vaccines against SARS-CoV-2 were highly efficacious against severe illness and hospitalization, they seem to be less effective in preventing infection months after vaccination, especially with the Delta variant. Breakthrough infections might be due to higher infectivity of the variants, relaxed protective measures by the general public in "COVID-19 fatigue", and/or waning immunity post-vaccination. Determining the neutralizing antibody levels in a longitudinal manner may address this issue, but technical complexity of classic assays precludes easy

detection and quick answers. We developed a lateral flow immunoassay NeutraXpressâ„¢ (commercial name of the test kit by Antagen Diagnostics, Inc.) and tested fingertip blood samples of subjects receiving either Moderna or Pfizer vaccines at various time points. With this device, we confirmed the reported clinical findings that mRNA vaccine-induced neutralizing antibodies quickly wane after 3-6Â months. Thus, using rapid tests to monitor neutralizing antibody status could help identify individuals at risk, prevent breakthrough infections, and guide social behavior to curtail the spread of COVID-19.

Comparative Analysis of Mortality From Coronavirus Disease 2019 Across the European Union Countries and the Effects of Vaccine Coverage. BACKGROUND: Mortality is a critical measure of disease impact. The European Union (EU) countries share the same regulatory framework but different implementation policies. METHODS: We extracted cumulative COVID-19 mortality data across the EU countries. We evaluated the 27 member states using the location quotient (LQ) to adjust for the expected mortality in the whole EU region, where an LQ <1 signifies a more and an LQ >1 a less favorable outcome. We categorized EU members into 3 distinct profiles based on their LQ estimates: favorable profile, LQ â‰¤0.9; unfavorable profile, LQâ€…>1.10; and average profile, LQ between 0.9 and 1.10. We compared LQ estimates and profiles with the prevaccination era that ended in December 2020 with the COVID-19 vaccine rollout. RESULTS: Twelve member states had a favorable profile, 4 had an average profile, and 11 had an unfavorable profile. In quantitative analysis, an improvement (negative LQ difference) was noted across countries with higher vaccination coverage (median, 71% fully vaccinated vs 57% for countries with positive LQ differences). There was a significant negative association between the share of fully vaccinated and LQ changes (Ï•â€…=â€…-0.62, Pâ€…<â€….001) and a significant 4-month lag effect. After COVID-19 vaccines became available, 4 countries improved their profile and 5 moved to a worse profile. CONCLUSIONS: There is significant variability in mortality and impact of COVID-19 between countries, even if they share the same regulatory framework. Extending immunization coverage may lead the transition to a more favorable profile, and alter the trajectory of COVID-19 mortality.

Tinnitus, Sudden Sensorineural Hearing Loss, and Vestibular Neuritis As Complications of the Astra Zeneca COVID-19 Vaccine. BACKGROUND: Sudden sensorineural hearing loss is most commonly defined as a sensorineural hearing loss of 30dB or greater over at least three contiguous audiometric frequencies occurring within a 72-hr period. The Astra Zeneca COVID-19 vaccine is suspicious of causing thrombotic complications following its administration, and could theoretically induce hearing loss by damaging the hearing organs through this mechanism, as well as vestibular damage through similar mechanisms. MATERIAL AND METHODS: We reviewed the files of patients with otological symptoms after exposure to the Astra Zeneca COVID-19 vaccine during the year 2021. CASE SERIES: We studied a total of six cases with otologic symptoms temporally related to the Astra Zeneca COVID-19 vaccine. We report four cases of patients presenting with hearing loss and tinnitus a few days after the second dose of the Astra Zeneca vaccine, and one case with the same symptoms after the first dose. Four cases were successfully treated with steroids; however, one case presented to the office two months after the onset of symptoms and did not improve with treatment. We also report the first case of vestibular neuritis temporally related to the administration of the first dose of the vaccine, which also had a good outcome after medical treatment. CONCLUSIONS: Prompt treatment in the present cases was a factor associated with a good prognosis.

Vitiligo Possibly Triggered by COVID-19 Vaccination. Several cutaneous manifestations following COVID-19 vaccination have been cited in the literature since the beginning of the pandemic. Two case reports regarding the development of vitiligo after receiving the COVID-19 vaccine. Herein, we present a case report of a patient who developed new-onset vitiligo two weeks after receiving her COVID-19 vaccine. Although the pathogenesis is unclear, it may be related to the inflammatory cells

involved in both the pathogenesis of vitiligo and the mechanism by which the COVID-19 vaccine stimulates the immune system.Â This case report highlights the need for further investigation into the link between COVID-19 and the development of vitiligo.
Serious events following COVID-19 vaccination with ChAdOx1 nCoV-19 vaccine (Vaxzevria): A short case series from Iran. In 2020, the SARS-COV-2 diseaseÂ (COVID-19) imposed huge challenges on the health, economic, and political systems, and by the end of the year, hope had been born with the release of COVID-19 vaccines aimed at bringing the pandemic to an end. However, the COVID-19 vaccination programs have sparked several concerns and ongoing debates over safety issues. Here, we presented three cases of patients with serious adverse events, encephalopathy, vaccine-induced thrombotic thrombocytopenia, and leukocytoclastic vasculitis, after receiving the ChAdOx1 nCoV-19 vaccine. Therefore, it is critical to investigate and report the occurrence of adverse reactions following vaccination, particularly serious ones, as it contributes to the growing body of research and assists clinicians in better diagnosing and managing them.
First reported case of delayed-type hypersensitivity reaction to non-hyaluronic acid Polycaprolactone dermal filler following COVID-19 vaccination: A case report and a review of the literature. Cases of filler reactions after COVID-19 vaccination have been reported. Here, we present the first case of delayed-type reaction (DTR) to non-hyaluronic acid Polycaprolactone dermal filler after the second dose of Sinopharm COVID-19 vaccine which was improved with administration of topical and intralesional steroids.
Immune Response in Moderate to Critical Breakthrough COVID-19 Infection After mRNA Vaccination. SARS-CoV-2 variants of concern (VOCs) can trigger severe endemic waves and vaccine breakthrough infections (VBI). We analyzed the cellular and humoral immune response in 8 patients infected with the alpha variant, resulting in moderate to fatal COVID-19 disease manifestation, after double mRNA-based anti-SARS-CoV-2 vaccination. In contrast to the uninfected vaccinated control cohort, the diseased individuals had no detectable high-avidity spike (S)-reactive CD4+ and CD8+ T cells against the alpha variant and wild type (WT) at disease onset, whereas a robust CD4+ T-cell response against the N- and M-proteins was generated. Furthermore, a delayed alpha S-reactive high-avidity CD4+ T-cell response was mounted during disease progression. Compared to the vaccinated control donors, these patients also had lower neutralizing antibody titers against the alpha variant at disease onset. The delayed development of alpha S-specific cellular and humoral immunity upon VBI indicates reduced immunogenicity against the S-protein of the alpha VOC, while there was a higher and earlier N- and M-reactive T-cell response. Our findings do not undermine the current vaccination strategies but underline a potential need for the inclusion of VBI patients in alternative vaccination strategies and additional antigenic targets in next-generation SARS-CoV-2 vaccines.
Innate Immune Responses of Vaccinees Determine Early Neutralizing Antibody Production After ChAdOx1nCoV-19 Vaccination. BACKGROUND: Innate immunity, armed with pattern recognition receptors including Toll-like receptors (TLR), is critical for immune cell activation and the connection to anti-microbial adaptive immunity. However, information regarding the impact of age on the innate immunity in response to SARS-CoV2 adenovirus vector vaccines and its association with specific immune responses remains scarce. METHODS: Fifteen subjects between 25-35 years (the young group) and five subjects between 60-70 years (the older adult group) were enrolled before ChAdOx1 nCoV-19 (AZD1222) vaccination. We determined activation markers and cytokine production of monocyte, natural killer (NK) cells and B cells ex vivo stimulated with TLR agonist (poly (I:C) for TLR3; LPS for TLR4; imiquimod for TLR7; CpG for TLR9) before vaccination and 3-5 days after each jab with flow cytometry. Anti-SARS-CoV2 neutralization antibody titers (surrogate virus neutralization tests, sVNTs) were measured using serum collected 2 months after the first jab and one month after full vaccination. RESULTS: The older adult vaccinees had weaker vaccine-induced sVNTs than young

vaccinees after 1(st) jab (47.2Â±19.3% vs. 21.2Â±22.2%, p value<0.05), but this difference became insignificant after the 2(nd) jab. Imiquimod, LPS and CpG strongly induced CD86 expression in IgD(+)CD27(-) naÃ¯ve and IgD(-)CD27(+) memory B cells in the young group. In contrast, only the IgD(+) CD27(-) naÃ¯ve B cells responded to these TLR agonists in the older adult group. Imiquimode strongly induced the CD86 expression in CD14(+) monocytes in the young group but not in the older adult group. After vaccination, the young group had significantly higher IFN-Î³ expression in CD3(-) CD56(dim) NK cells after the 1(st) jab, whilst the older adult group had significantly higher IFN-Î³ and granzyme B expression in CD56(bright) NK cells after the 2(nd) jab (all p value <0.05). The IFN-Î³ expression in CD56(dim) and CD56(bright) NK cells after the first vaccination and CD86 expression in CD14(+) monocyte and IgD(-)CD27(-)double-negative B cells after LPS and imiquimod stimulation correlated with vaccine-induced antibody responses. CONCLUSIONS: The innate immune responses after the first vaccination correlated with the neutralizing antibody production. Older people may have defective innate immune responses by TLR stimulation and weak or delayed innate immune activation profile after vaccination compared with young people.

Acute exacerbation of idiopathic pulmonary fibrosis after SARS-CoV-2 vaccination. Although the association between acute exacerbation of interstitial lung disease and vaccination is not yet clarified, this is the first case report describing the possibility that SARS-CoV-2 vaccination may trigger acute exacerbation https://bit.ly/3tpu6Cz

 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection has spread worldwide and coronavirus disease 2019 remains a major health concern. Several SARS-CoV-2 vaccines have been produced and are playing important roles in the prevention of infection and worsening to a severe state, and in improving mortality [1]. However, some concerns about adverse effects related to SARS-CoV-2 vaccination have been raised. Recently, various adverse effects have been reported, but there is little data on adverse effects on the lungs [2].

Reply: Takotsubo Cardiomyopathy After Receiving mRNA COVID-19 Vaccination is Very Rare.

Artificial Intelligence-Enabled Social Media Analysis for Pharmacovigilance of COVID-19 Vaccinations in the United Kingdom: Observational Study. BACKGROUND: The rollout of vaccines for COVID-19 in the United Kingdom started in December 2020. Uptake has been high, and there has been a subsequent reduction in infections, hospitalizations, and deaths among vaccinated individuals. However, vaccine hesitancy remains a concern, in particular relating to adverse effects following immunization (AEFIs). Social media analysis has the potential to inform policy makers about AEFIs being discussed by the public as well as public attitudes toward the national immunization campaign. OBJECTIVE: We sought to assess the frequency and nature of AEFI-related mentions on social media in the United Kingdom and to provide insights on public sentiments toward COVID-19 vaccines. METHODS: We extracted and analyzed over 121,406 relevant Twitter and Facebook posts, from December 8, 2020, to April 30, 2021. These were thematically filtered using a 2-step approach, initially using COVID-19-related keywords and then using vaccine- and manufacturer-related keywords. We identified AEFI-related keywords and modeled their word frequency to monitor their trends over 2-week periods. We also adapted and utilized our recently developed hybrid ensemble model, which combines state-of-the-art lexicon rule-based and deep learning-based approaches, to analyze sentiment trends relating to the main vaccines available in the United Kingdom. RESULTS: Our COVID-19 AEFI search strategy identified 46,762 unique Facebook posts by 14,346 users and 74,644 tweets (excluding retweets) by 36,446 users over the 4-month period. We identified an increasing trend in the number of mentions for each AEFI on social media over the study period. The most frequent AEFI mentions were found to be symptoms related to appetite (n=79,132, 14%), allergy (n=53,924, 9%), injection site (n=56,152, 10%), and clots (n=43,907, 8%). We also found some rarely reported AEFIs such as Bell palsy (n=11,909, 2%) and Guillain-Barre syndrome (n=9576, 2%) being discussed as frequently as more well-known side effects like headache (n=10,641, 2%), fever

(n=12,707, 2%), and diarrhea (n=16,559, 3%). Overall, we found public sentiment toward vaccines and their manufacturers to be largely positive (58%), with a near equal split between negative (22%) and neutral (19%) sentiments. The sentiment trend was relatively steady over time and had minor variations, likely based on political and regulatory announcements and debates. CONCLUSIONS: The most frequently discussed COVID-19 AEFIs on social media were found to be broadly consistent with those reported in the literature and by government pharmacovigilance. We also detected potential safety signals from our analysis that have been detected elsewhere and are currently being investigated. As such, we believe our findings support the use of social media analysis to provide a complementary data source to conventional knowledge sources being used for pharmacovigilance purposes.

Histological and immunohistochemical findings in a fatal case of thrombotic thrombocytopenia after ChAdOx1 nCov-19 vaccination. This case report describes a fatal case of a young woman with superior sagittal, transverse and sigmoid sinus thrombosis after administration of the ChAdOx1 nCov-19 vaccination. Eleven days post-vaccination she was found unconscious and transferred to the Emergency Department. Blood parameters showed low platelets, and a CT scan showed an extensive left intracranial hemorrhage and the presence of an occlusive thrombus of the superior sagittal sinus. She under-went a craniectomy, but after the intervention, she remained in a comatose state. After a few days, her clinical conditions worsened, and she died. A complete autopsy was performed which showed a thrombosis of the cerebral venous district, of the upper and lower limbs. A blood sample was also performed to carry out a gene study about the predisposition to thrombosis. The organ samples were studied through light microscope both in hematoxylin-eosin and immunohistochemical examination, and showed a strong inflammatory response in all samples and at the site of thrombosis. Our study aims to provide a proper autopsy technique to study the entire cerebral venous system through a multidisciplinary approach (anatomical dissection and neurosurgery) in post-vaccine venous thrombosis.

B cell receptor repertoire kinetics after SARS-CoV-2 infection and vaccination. B cells are important in immunity to both severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection and vaccination, but B cell receptor (BCR) repertoire development in these contexts has not been compared. We analyze serial samples from 171 SARS-CoV-2-infected individuals and 63 vaccine recipients and find the global BCR repertoire differs between them. Following infection, immunoglobulin (Ig)G1/3 and IgA1 BCRs increase, somatic hypermutation (SHM) decreases, and, in severe disease, IgM and IgA clones are expanded. In contrast, after vaccination, the proportion of IgD/M BCRs increase, SHM is unchanged, and expansion of IgG clones is prominent. VH1-24, which targets the N-terminal domain (NTD) and contributes to neutralization, is expanded post infection except in the most severe disease. Infection generates a broad distribution of SARS-CoV-2-specific clones predicted to target the spike protein, while a more focused response after vaccination mainly targets the spike's receptor-binding domain. Thus, the nature of SARS-CoV-2 exposure differentially affects BCR repertoire development, potentially informing vaccine strategies.

Broad anti-SARS-CoV-2 antibody immunity induced by heterologous ChAdOx1/mRNA-1273 vaccination. Heterologous prime-boost immunization strategies have the potential to augment COVID-19 vaccine efficacy. We longitudinally profiled severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike (S)-specific serological and memory B cell (MBC) responses in individuals who received either homologous (ChAdOx1:ChAdOx1) or heterologous (ChAdOx1:mRNA-1273) prime-boost vaccination. Heterologous messenger RNA (mRNA) booster immunization induced higher serum neutralizing antibody and MBC responses against SARS-CoV-2 variants of concern (VOCs) compared with that of homologous ChAdOx1 boosting. Specificity mapping of circulating B cells revealed that mRNA-1273 boost immunofocused ChAdOx1-primed responses onto epitopes

expressed on prefusion-stabilized S. Monoclonal antibodies isolated from mRNA-1273-boosted participants displayed overall higher binding affinities and increased breadth of reactivity against VOCs relative to those isolated from ChAdOx1-boosted individuals. Overall, the results provide molecular insight into the enhanced quality of the B cell response induced after heterologous mRNA booster vaccination.

Association of BNT162b2 COVID-19 Vaccination During Pregnancy With Neonatal and Early Infant Outcomes. IMPORTANCE: Pregnant women were excluded from the BNT162b2 messenger RNA (mRNA) COVID-19 vaccine (Pfizer-BioNTech) preauthorization trial. Therefore, observational data on vaccine safety for prenatally exposed newborns are critical to inform recommendations on maternal immunization. OBJECTIVE: To examine whether BNT162b2 mRNA vaccination during pregnancy is associated with adverse neonatal and early infant outcomes among the newborns. DESIGN, SETTING, AND PARTICIPANTS: Population-based cohort study comprising all singleton live births in March through September 2021, within a large state-mandated health care organization in Israel, followed up until October 31, 2021. EXPOSURE: Maternal BNT162b2 mRNA vaccination during pregnancy. MAIN OUTCOMES AND MEASURES: Risk ratios (RR) of preterm birth, small birth weight for gestational age (SGA), congenital malformations, all-cause hospitalizations, and infant death. Stabilized inverse probability weighting was used to adjust for maternal age, timing of conception, parity, socioeconomic status, population subgroup, and maternal influenza immunization status. RESULTS: The cohort included 24â€¯288 eligible newborns (49% female, 96% born at â‰¥37 weeks' gestation), of whom 16â€¯697 were exposed (nâ€‰=â€‰2134 and nâ€‰=â€‰9364 in the first and second trimesters, respectively) to maternal vaccination in utero. Median (IQR) follow-up after birth was 126 days (76-179) among exposed and 152 days (88-209) among unexposed newborns. No substantial differences were observed in preterm birth rates between exposed and unexposed newborns (RRâ€‰=â€‰0.95; 95% CI, 0.83-1.10) or SGA (RRâ€‰=â€‰0.97; 95% CI, 0.87-1.08). No significant differences were observed in the incidence of all-cause neonatal hospitalizations (RRâ€‰=â€‰0.99; 95% CI, 0.88-1.12), postneonatal hospitalizations after birth (RRâ€‰=â€‰0.95; 95% CI, 0.84-1.07), congenital anomalies (RRâ€‰=â€‰0.69; 95% CI, 0.44-1.04), or infant mortality over the study period (RRâ€‰=â€‰0.84; 95% CI, 0.43-1.72). CONCLUSIONS AND RELEVANCE: This large population-based study found no evident differences between newborns of women who received BNT162b2 mRNA vaccination during pregnancy, vs those of women who were not vaccinated, and contributes to current evidence in establishing the safety of prenatal vaccine exposure to the newborns. Interpretation of study findings is limited by the observational design.

De novo or recurrent glomerulonephritis and acute tubulointerstitial nephritis after COVID-19 vaccination: A report of six cases from a single center. Billions of COVID-19 vaccine doses have been administered to combat the ongoing global pandemic caused by severe acute respiratory syndrome coronavirus-2. While these vaccines are considered safe, with most adverse events being mild to moderate and transient, uncommon systemic side effects of the vaccines, including de novo or re-activation of various glomerular diseases have recently been observed. We report 6 patients who developed glomerular or acute tubulointerstitial disease shortly after receiving COVID-19 vaccinations. Five of these patients received mRNA vaccines (3 Moderna, 2 Pfizer-BioNTech) and 1 received adenovirus-26 vector vaccine (Johnson and Johnson/Janssen). Four of our patients developed de novo glomerulonephritis or acute tubulointerstitial nephritis (ATIN), while the other 2 had re-activation of prior glomerulonephritis. Two patients presented with acute kidney injury (AKI) characterized by severe ATIN. While both of them also had evidence of immune complex glomerular disease, ATIN was the dominant feature on the biopsies. Two other patients presented with high-grade proteinuria and AKI. Like the aforementioned patients, these patients had evidence of immune complex glomerular disease, but acute onset nephrotic syndrome was the leading clinical feature.

Another patient presented with de novo myeloperoxidase-anti-neutrophil-cytoplasmic-antibody-associated pauci-immune crescentic glomerulonephritis. Yet another patient had re-activation of immunoglobulin-A glomerulonephritis that had been quiescent for several years prior to the vaccination. It is difficult to ascertain any causal relationship between COVID-19 vaccination and onset/recurrence of kidney diseases. However, vigilance about occurrence of such complications is imperative. Importantly, all our cases responded well to the immunosuppressive treatment.
Cerebral Venous Sinus Thrombosis Following COVID-19 Vaccination: A Systematic Review. INTRODUCTION: COVID-19 vaccines became available after being carefully monitored in clinical trials with safety and efficacy on the human body. However, a few recipients developed unusual side effects, including cerebral venous sinus thrombosis (CVST). We aim to systematically review the baseline features, clinical characteristics, treatment, and outcomes in patients developing CVST post-COVID-19 vaccination. METHODS: This study was conducted according to the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) 2020 guideline. Investigators independently searched PubMed, Embase, and Google Scholar for English language articles published from inception up until September 10, 2021, reporting the incidence of CVST post-COVID-19 vaccines. We analyzed CVST patients' baseline data, type of vaccines, clinical findings, treatment, and outcomes. Our systematic review process yielded patient-level data. RESULT: The final analysis included 25 studies that identified 80 patients who developed CVST after the COVID-19 vaccination. Of the 80 CVST cases, 31 (39.24%) patients died. There was no significant relationship between mortality and age (Pâ€‰=â€‰.733), sex (Pâ€‰=â€‰.095), vaccine type (Pâ€‰=â€‰.798), platelet count (Pâ€‰=â€‰.93), and comorbidities such as hypertension (Pâ€‰=â€‰.734) and diabetes mellitus (Pâ€‰=â€‰.758). However, mortality was associated with the duration of onset of CVST symptoms after vaccination (Pâ€‰=â€‰.022). Patients with CVST post-COVID-19 vaccination were more likely to survive if treated with an anticoagulant (Pâ€‰=â€‰.039). Patients who developed intracranial hemorrhage (Pâ€‰=â€‰.012) or thrombosis in the cortical vein (Pâ€‰=â€‰.021) were more likely to die. CONCLUSION: COVID-19 vaccine-associated CVST is associated with high mortality rate. Timely diagnosis and management can be lifesaving for patients.
Psoriasis exacerbation after COVID-19 vaccination in high-risk group: How to manage it?
Vasculitis in the setting of COVID-19: From the disease to the vaccine. Report of a case of cutaneous vasculitis after immunization.
Reproducible leukocytoclastic vasculitis following severe acute respiratory syndrome coronavirus 2 vaccination.
A Small but Significantly Greater Incidence of Inflammatory Heart Disease Identified After Vaccination for Severe Acute Respiratory Syndrome Coronavirus 2. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines are being administered on an unprecedented scale. Assessing the risks of side effects is needed to aid clinicians in early detection and treatment. This study examined the risk of inflammatory heart disease, including pericarditis and myocarditis, after SARS-CoV-2 vaccination. METHODS: Intermountain Healthcare patients with inflammatory heart disease from December 15, 2020 to June 15, 2021, and with or without preceding SARS-CoV-2 vaccinations, were studied. Relative rates of inflammatory heart disease were examined for vaccinated patients compared to unvaccinated patients. RESULTS: Of 67 patients identified with inflammatory heart disease, 21 (31.3%) had a SARS-Cov-2 vaccination within the previous 60 days. Overall, 914 611 Intermountain Healthcare patients received a SARS-CoV-2 vaccine, resulting in an inflammatory heart disease rate of 2.30 per 100 000 vaccinated patients. The relative risk of inflammatory heart disease for the vaccinated patients compared to the unvaccinated patients was 2.05 times higher rate within the 30-day window (Pâ€…=â€….01) and had a trend toward increase in the 60-day window (relative rate = 1.63; PÂ =Â .07). All vaccinated patients with inflammatory heart

disease were treated successfully with 1 death related to a pre-existing condition. CONCLUSIONS: Although rare, the rate of inflammatory heart disease was greater in a SARS-CoV-2-vaccinated population than the unvaccinated population. This risk is eclipsed by the risk of contracting coronavirus disease 2019 and its associated, commonly severe outcomes. Nevertheless, clinicians and patients should be informed of this risk to facilitate earlier recognition and treatment.
Case Report: COVID-19 Vaccination Associated Fulminant Myocarditis. Herein, we describe a novel finding of fulminant myocarditis (FM) in two subjects the day after administration of the first dose of the currently available inactivated SARS-CoV-2 vaccine (Vero cell). Cardiac magnetic resonance imaging revealed extensive myocardial edema and necrosis. A pathologic evaluation of the endocardial biopsy tissues revealed inflammatory cell (lymphocytes) infiltration and interstitial edema, myocyte necrosis, and focal areas of fibrosis. A life-support-based comprehensive treatment regimen comprising mechanical circulatory support using intra-aortic balloon pulsation and immunomodulatory therapy-glucocorticoids and intravenous immunoglobulin-was used to treat the patients with FM; eventually, the patients recovered and were discharged. To our knowledge, these are the first two reported cases of FM, with no other identified cause or associated illness, after receiving the inactivated SARS-CoV-2 vaccine (Vero cell). These findings suggest a novel pathogenesis of myocarditis which mentions to pay more attention to this rare, but lethal complication of COVID-19 vaccination.
COVID-19 vaccine-related new-onset lichen planus. Coronavirus disease 2019 (COVID-19) vaccines significantly impacted world health and well-being. However, various adverse events have been observed following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. Cutaneous reactions have been prevalent following many vaccines, including COVID-19 vaccines. Here, we present a case of new-onset lichen planus in a patient who received the COVID-19 vaccine at the same time as being infected with SARS-CoV-2. A 52-year-old woman presented to the clinic with extensive pruritic skin lesions. The eruptions had appeared a week after her second dose of the Sinopharm COVID-19 vaccine. She mentioned a history of SARS-CoV-2 infection approximately 10Â days following the first dose of her vaccine, causing a 1-month delay in getting the second dose. Her past medical history was not significant. On examination, erythematous and squamous papules were demonstrated predominantly on the extremities, including inguinal and axillary folds. Moreover, desquamation of the lips was visible, and buccal lesions were also found. After consultation with a dermatologist, a skin biopsy was indicated for the patient, but she refused to undergo the procedure. Therefore, considering the typical appearance of the eruptions, lichen planus was suspected, for which she was treated with oral antihistamines and topical corticosteroids.
Humoral responses to BNT162b2 SARS-CoV-2 and hepatitis B vaccines are associated in patients on maintenance hemodialysis: a single-centre experience in Belgium.
MPO-ANCA-associated vasculitis after the Pfizer/BioNTech SARS-CoV-2 vaccination. Vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has demonstrated high efficacy at preventing coronavirus disease 2019 (COVID-19) and a favorable safety profile, however it has also been reported that COVID-19 vaccines may put increase of immune-mediated disease. We herein report a case of MPO-anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis following the mRNA vaccine BNT162b2 (Pfizer/BioNTech) for COVID-19. Although the causal relationship between vaccine and ANCA-associated vasculitis is uncertain, environmental and genetic factors may have set the stage for the development of vasculitis, and the vaccine may have triggered a domino effect.
Post COVID-19 Vaccination-Associated Neurological Complications. PURPOSE: Neurological sequelae after COVID-19 vaccination are rare. We investigated the possible pathogenesis behind the development of neurological complications within a short period after Saudi residents received a

COVID-19 vaccine. PATIENTS AND METHODS: We evaluated 18 patients who recently received a COVID-19 vaccine (Comirnaty and Vaxzevria vaccines) and presented with neurological complications to the Saudi German Hospitals in Jeddah, Saudi Arabia. Neurologists assessed the patients' clinical presentation, radiological investigations, and laboratory findings. RESULTS: Three patients who received the first dose of the Vaxzevria vaccine experienced severe cerebral venous thrombosis, two of them were complicated by intracranial hemorrhage. Their laboratory investigations showed very high d-dimers and severe thrombocytopenia, which have been linked to higher mortality and poor outcome. Ischemic stroke occurred in eight cases (44.4%) with a predominance in older male patients. Three patients presented with seizures, two had optic neuritis. Guillain-BarrÃ© syndrome (GBS) and Miller Fisher syndrome (MFS) occurred in two male patients following vaccination with Comirnaty. CONCLUSION: Neurological complications after COVID-19 vaccinations are very rare, and only a few cases have been reported worldwide. The shared pathophysiological basis between COVID-19 viral infection and COVID-19 vaccines stands behind the very rare neurological complications resulting from the hypercoagulable state triggered by the general inflammatory condition. We suspect some differences in the pathogenesis of ischemic stroke caused by COVID-19 infection and COVID-19 vaccines, which render COVID-19 vaccine-associated ischemic stroke more responsive to treatment. To date, no definitive association between the vaccine and GBS has been proven by any strong evidence, but it has recently been added as a very rare side effect of the Janssen COVID-19 vaccine. No possible links of Miller Fisher syndrome to COVID-19 vaccines have been reported before the one reported in this study.

A challenging case of heparin-induced skin necrosis without thrombocytopenia. Heparin-induced skin necrosis (HISN) is a rare complication of heparin anticoagulation. The condition occurs in various situations, including in heparin-naive and exposed individuals, in areas local or distant from the heparin injection site, and with or without frank thrombocytopenia. We present a case in which a patient treated for a pulmonary embolism with therapeutic unfractionated heparin (UFH) develops this adverse event. Symptoms were reversed with cessation of UFH and transition to bivalirudin without surgical debridement. The patient initially had anti-PF4 antibodies present but subsequent testing showed borderline antibodies and a negative serotonin release assay. After starting bivalirudin, the patient was later switched to fondaparinux without further consequences. This case illustrates the pathogenesis of HISN and provides an example of inconsistently abnormal laboratory values. Additionally, it provides two novel exposures the mRNA-1273 vaccine and the immune checkpoint inhibitor pembrolizumab that, to our knowledge, have not been previously reported.

Gut microbiota composition is associated with SARS-CoV-2 vaccine immunogenicity and adverse events. OBJECTIVE: The gut microbiota plays a key role in modulating host immune response. We conducted a prospective, observational study to examine gut microbiota composition in association with immune responses and adverse events in adults who have received the inactivated vaccine (CoronaVac; Sinovac) or the mRNA vaccine (BNT162b2; BioNTech; Comirnaty). DESIGN: We performed shotgun metagenomic sequencing in stool samples of 138 COVID-19 vaccinees (37 CoronaVac and 101 BNT162b2 vaccinees) collected at baseline and 1 month after second dose of vaccination. Immune markers were measured by SARS-CoV-2 surrogate virus neutralisation test and spike receptor-binding domain IgG ELISA. RESULTS: We found a significantly lower immune response in recipients of CoronaVac than BNT162b2 vaccines ($p<0.05$). Bifidobacterium adolescentis was persistently higher in subjects with high neutralising antibodies to CoronaVac vaccine ($p=0.023$) and their baseline gut microbiome was enriched in pathways related to carbohydrate metabolism (linear discriminant analysis (LDA) scores >2 and $p<0.05$). Neutralising antibodies in BNT162b2 vaccinees showed a positive correlation with the total abundance of bacteria with flagella and fimbriae including Roseburia faecis ($p=0.028$). The abundance of Prevotella copri and two Megamonas species

were enriched in individuals with fewer adverse events following either of the vaccines indicating that these bacteria may play an anti-inflammatory role in host immune response (LDA scores>3 and p<0.05). CONCLUSION: Our study has identified specific gut microbiota markers in association with improved immune response and reduced adverse events following COVID-19 vaccines. Microbiota-targeted interventions have the potential to complement effectiveness of COVID-19 vaccines.

Inflammatory laboratory findings associated with severe illness among hospitalized individuals with COVID-19 in Medan, Indonesia: a cross-sectional study. Background: Coronavirus disease (COVID-19) remains a global health problem. COVID-19 patients with severe pneumonia have a higher risk for critical illness, mostly complicated by acute respiratory distress syndrome. The inflammatory response is critical, and the cytokine storm increases the severity of COVID-19. Many factors could be associated with a cytokine storm but they are incompletely understood. This study presents characteristics of COVID-19 patients and explore the clinical and inflammatory parameters of severe and critically ill COVID-19 patients in the intensive care unit (ICU). Method: This cross-sectional study was conducted in all severe COVID-19 patients admitted to the ICU. Peripheral blood was taken for laboratory examination within 24 hours of admission. Haematologic parameters, serum electrolyte, renal function, liver function, pancreas enzyme, D-dimer, inflammatory cytokines interferon (IFN)-gamma, tumour necrosis factor (TNF)-alpha, interleukin (IL)-6, IL-10, monocyte chemoattractant protein-1 (MCP-1), and C-reactive protein (CRP) were assessed in this study. Comparative analyses were done between sex, existing comorbidities, body mass index (BMI), and COVID-19 vaccination status. Results: A total of 80 subjects were included in the study. The most frequent comorbidities found among the subjects were obesity (36.35%) and diabetes (22.5%). Only 13.75% of subjects were vaccinated. Laboratory results indicated leucocytosis and neutrophilia, with a neutrophil-lymphocyte-ratio (NLR) of 7. The mean inflammatory findings (IL-6, IL-10, TNF-alpha, IFN-gamma, MCP-1), D-dimer, CRP, and lipase increased. Lipase levels were higher in men (p = 0.003) and in comorbidity groups. No significant differences were found among different BMI groups. Lipase, IL-6, and MCP-1 levels were significantly higher (p=0.019, <0.0001, and 0.03, respectively) in the non-vaccinated group. Conclusions: Most patients with severe COVID-19 have comorbidities and increased inflammatory markers.

Final Analysis of Efficacy and Safety of Single-Dose Ad26.COV2.S. BACKGROUND: The Ad26.COV2.S vaccine was highly effective against severe-critical coronavirus disease 2019 (Covid-19), hospitalization, and death in the primary phase 3 efficacy analysis. METHODS: We conducted the final analysis in the double-blind phase of our multinational, randomized, placebo-controlled trial, in which adults were assigned in a 1:1 ratio to receive single-dose Ad26.COV2.S (5Ã—10(10) viral particles) or placebo. The primary end points were vaccine efficacy against moderate to severe-critical Covid-19 with onset at least 14 days after administration and at least 28 days after administration in the per-protocol population. Safety and key secondary and exploratory end points were also assessed. RESULTS: Median follow-up in this analysis was 4 months; 8940 participants had at least 6 months of follow-up. In the per-protocol population (39,185 participants), vaccine efficacy against moderate to severe-critical Covid-19 at least 14 days after administration was 56.3% (95% confidence interval [CI], 51.3 to 60.8; 484 cases in the vaccine group vs. 1067 in the placebo group); at least 28 days after administration, vaccine efficacy was 52.9% (95% CI, 47.1 to 58.1; 433 cases in the vaccine group vs. 883 in the placebo group). Efficacy in the United States, primarily against the reference strain (B.1.D614G) and the B.1.1.7 (alpha) variant, was 69.7% (95% CI, 60.7 to 76.9); efficacy was reduced elsewhere against the P.1 (gamma), C.37 (lambda), and B.1.621 (mu) variants. Efficacy was 74.6% (95% CI, 64.7 to 82.1) against severe-critical Covid-19 (with only 4 severe-critical cases caused by the B.1.617.2 [delta] variant), 75.6% (95% CI, 54.3 to 88.0) against Covid-19 leading to medical intervention (including hospitalization), and 82.8% (95% CI, 40.5 to 96.8) against Covid-19-related

death, with protection lasting 6 months or longer. Efficacy against any severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection was 41.7% (95% CI, 36.3 to 46.7). Ad26.COV2.S was associated with mainly mild-to-moderate adverse events, and no new safety concerns were identified. CONCLUSIONS: A single dose of Ad26.COV2.S provided 52.9% protection against moderate to severe-critical Covid-19. Protection varied according to variant; higher protection was observed against severe Covid-19, medical intervention, and death than against other end points and lasted for 6 months or longer. (Funded by Janssen Research and Development and others; ENSEMBLE ClinicalTrials.gov number, NCT04505722.).

SARS-CoV-2 infection and vaccination trigger long-lived B and CD4+ T lymphocytes with implications for booster strategies. BACKGROUNDImmunization against SARS-CoV-2, the causative agent of COVID-19, occurs via natural infection or vaccination. However, it is currently unknown how long infection- or vaccination-induced immunological memory will last.METHODSWe performed a longitudinal evaluation of immunological memory to SARS-CoV-2 up to 1 year after infection and following mRNA vaccination in naive individuals and individuals recovered from COVID-19 infection.RESULTSWe found that memory cells are still detectable 8 months after vaccination, while antibody levels decline significantly, especially in naive individuals. We also found that a booster injection is efficacious in reactivating immunological memory to spike protein in naive individuals, whereas it was ineffective in previously SARS-CoV-2-infected individuals. Finally, we observed a similar kinetics of decay of humoral and cellular immunity to SARS-CoV-2 up to 1 year following natural infection in a cohort of unvaccinated individuals.CONCLUSIONShort-term persistence of humoral immunity, together with the reduced neutralization capacity versus the currently prevailing SARS-CoV-2 variants, may account for reinfections and breakthrough infections. Long-lived memory B and CD4+ T cells may protect from severe disease development. In naive individuals, a booster dose restored optimal anti-spike immunity, whereas the needs for vaccinated individuals who have recovered from COVID-19 have yet to be defined.FUNDINGThis study was supported by funds to the Department of Experimental and Clinical Medicine, University of Florence (Project Excellence Departments 2018-2022), the University of Florence (project RICTD2122), the Italian Ministry of Health (COVID-2020-12371849), and the region of Tuscany (TagSARS CoV 2).

Acceptance of SARS-CoV-2 vaccination and the associated factors among dental health care professionals: A cross-sectional survey. BACKGROUND: One of the greatest inventions of the 21st century is the development of vaccines against the life-threatening pandemic of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Whenever a new medication or treatment modality is introduced globally, it is accompanied by anxiety in the general public and among health care professionals. OBJECTIVES: The aim of the study was to explore factors that may influence the acceptance of COVID-19 vaccination among dental health care professionals, as they are the first subgroup in the population to receive the vaccine. MATERIAL AND METHODS: A survey-based cross-sectional study was conducted on 164 health care professionals (general dentists, dental specialists with 2 years of experience after graduation and dental assistants). Data was collected by sending a URL link to the hardand soft-copy questionnaire on Google Forms through all social media platforms. The questionnaire had 2 sections - the 1st part concerned the demographic details and the 2nd part was designed to assess the acceptance of SARS-CoV-2 vaccination among dental health care professionals and the related factors. The normality of the data was assessed with the Shapiro-Wilk test. The Cox regression algorithm was applied to evaluate the factors associated with the acceptance of SARS-CoV-2 vaccination. RESULTS: Out of 164 participants, 85.37% showed a positive attitude toward vaccination and only 7.32% of dental health care professionals were not willing to get vaccinated; out of them, 5 were males and 7 were females. Those who refused to get vaccinated included 3.6% of general dentists, 21.1% of dental specialists

and 11.7% of dental assistants. The complications of major concern were fever, myalgia and the lethargic condition immediately after vaccination. CONCLUSIONS: A small percentage of health care professionals declined to get vaccinated against COVID-19 and the main reason was uncertainty about the associated side effects. The respondents were mostly concerned about such side effects as fever, myalgia and the lethargic condition immediately after vaccination.
Figurate purpuric eruption post-COVID-19 vaccination.
COVID-19 and the peripheral nervous system. A 2-year review from the pandemic to the vaccine era. Increasing literature has linked COVID-19 to peripheral nervous system (PNS) diseases. In addition, as we move from the pandemic to the vaccination era, literature interest is shifting towards the potential association between COVID-19 vaccines and PNS manifestations. We reviewed published literature on COVID-19, COVID-19 vaccines and PNS manifestations between 1 January 2020 and 1 December 2021. For Guillain-BarrÃ© syndrome (GBS), isolated cranial neuropathy (ICN) and myositis associated with COVID-19, the demographic, clinical, laboratory, electrophysiological and imaging features were included in a narrative synthesis. We identified 169 studies on COVID-19-associated complications, including 63 papers (92 patients) on GBS, 29 papers (37 patients) on ICN and 11 papers (18 patients) on myositis. Additional clinical phenotypes included chronic inflammatory demyelinating polyneuropathy, vasculitic neuropathies, neuralgic amyotrophy, critical care-related complications, and myasthenia gravis. PNS complications secondary to COVID-19 vaccines have been reported during randomized clinical trials, in real-world case reports, and during large-scale surveillance programs. These mainly include cases of GBS, Bell's palsy, and cases of neuralgic amyotrophy. Based on our extensive review of the literature, any conclusion about a pathophysiological correlation between COVID-19 and PNS disorders remains premature, and solely supported by their temporal association, while epidemiological and pathological data are insufficient. The occurrence of PNS complications after COVID-19 vaccines seems limited to a possible higher risk of facial nerve palsy and GBS, to a degree that widespread access to the ongoing vaccination campaign should not be discouraged, while awaiting for more definitive data from large-scale surveillance studies.
Subungual hematomas after mRNA Covid-19 vaccine administration. Large bilateral subungual haemorrhages and hematomas were observed in an adult woman after receiving the second dose of a mRNA COVID-19 vaccine. Improvement was achieved after a course of prednisone. Unusual, rare cutaneous adverse effects are likely to be increasingly noticed as the accelerated massive worldwide COVID-19 vaccination campaign intensifies.
COVID-19 vaccine-induced T-cell responses in patients with rheumatoid arthritis: preferential induction by ChAdOx1.
Imaging findings in a patient with suspected vaccine induced immune thrombotic thrombocytopenia. Covid-19 vaccine was developed in response to the SARS Cov2 pandemic. Despite the effectiveness of the vaccine, various complications have been reported after vaccination. We present the case of a 55-year-old patient with post-vaccination complication. The patient was vaccinated with ChAdOx1 nCov-19 Vaccine and 2 weeks later presented with headache, confusion and abdominal pain for 1 week duration. Clinical examination demonstrated reduced Glasgow Coma Scale (GCS), reduced muscle power bilaterally and dysphasia. Blood test showed thrombocytopenia, high titres of D-Dimer and mildly raised INR. The CT scan of the head showed a fairly large left temporoparietal intracranial hemorrhage with midline shift and subsequent CT venogram demonstratedthrombosis of the left transverse and sigmoid dural venous sinuses. CT scan of the abdomen and pelvis showed thrombosis of the portal and hepatic veins and multiple infarcts of the liver, left kidney and lingular segment of the partially imaged lungs (Figure 2). Patient tested positive for antibodies directed against platelet factor-4 and was treated for vaccine induced thrombotic thrombocytopenia. Treatment included Intravenous immunoglobulin, Fresh Frozen Plasma, non-heparin based anticoagulant and required

care in tertiary center. Incidence of vaccine-induced immune thrombotic thrombocytopenia is unknown and strongly mimics autoimmune heparin-induced thrombocytopenia with typical clinical features of thrombocytopenia and thrombosis. Of the reported cases, the common imaging finding is thrombosis in various sites such as cerebral venous thrombosis, portal vein thrombosis, pulmonary embolism and ischemic stroke.
Paroxysmal supra-ventricular ventricular tachycardia after AstraZeneca COVID-19 vaccine injection.
Blood donor eligibility after COVID-19 vaccination: the current state of recommendations. The medical screening practices for blood donor eligibility after vaccination against several conventional infectious agents are well known to blood transfusion centres worldwide. Classically, blood donations are contraindicated for four weeks after vaccination with a live attenuated virus vaccine. For other types of vaccines, no postponement is necessary as there is no proven infectious risk. But for the COVID-19 vaccine, besides the classic platforms for the vaccine, two new types of vaccine platforms have been developed and based on viral vectors vaccines and vaccines from viral genetic material. Thus, blood establishments could be worried that these COVID-19 vaccine production platforms can pose any particular safety concerns for recipients of blood or blood products from vaccinated subjects. Our work aims to provide professionals in blood transfusion centres with all the available information to clarify any confusion relating to the need or not to defer donors who have received a COVID-19 vaccination. So in this paper, we provide an international review of the data available to date about the recommendations of international scientific societies about blood donation after COVID-19 vaccination, all types of COVID-19 vaccines included. We also present some experiences of blood transfusion establishments worldwide concerning this topic and among them our institution, the Moroccan National Centre for Blood Transfusion and Haematology.
Circulating extracellular vesicle microRNAs associated with adverse reactions, proinflammatory cytokine, and antibody production after COVID-19 vaccination. mRNA-based vaccines have been used globally to eradicate the coronavirus-disease 2019 (COVID-19) pandemic. Vaccine efficacy and adverse reactions depend on immune responses, such as proinflammatory cytokine production and lymphocyte activation. We conducted a prospective cohort study to investigate relationships among specific antibody titers, adverse reactions, proinflammatory cytokine production, and immune-regulatory microRNA (miRNA) levels in serum extracellular vesicles (EVs) after COVID-19 vaccination (BNT162b2). Local adverse reactions after the second dose, such as local pain and swelling, were less correlated with those of systemic symptoms, such as fever and muscle pain, whereas serum TNF-Î± levels were associated with systemic adverse reactions and with specific antibody titers. Interestingly, EV miR-92a-2-5p levels in sera were negatively correlated with degrees of adverse reactions, and EV miR-148a levels were associated with specific antibody titers. Our data suggest a potential of circulating EV miRNAs as biomarkers for vaccine efficacy and adverse reactions.
Extensive Cerebral Venous Sinus Thrombosis (CVST) After the First Dose of Pfizer-BioNTech BNT162b2 mRNA COVID-19 Vaccine without Thrombotic Thrombocytopenia Syndrome (TTS) in a Healthy Woman. BACKGROUND COVID-19 is an acute respiratory disease caused by the SARS-CoV-2 virus, which was discovered in 2019. The high transmission and seriousness of COVID-19 necessitated the development of an effective vaccine to control spread of the disease. Multiple vaccines have been granted emergency use authorization (EUA) by the U.S. Food and Drug Administration, namely, the Pfizer-BioNTech, Moderna (mRNA), and the Johnson & Johnson/Janssen (vector) vaccines. As these novel vaccines have been used, adverse effects have been reported, ranging from mild myalgia to severe anaphylaxis and thrombotic events. Thrombotic consequences raised suspicion for the development of cerebral venous sinus thrombosis (CVST), which is a severe condition associated with occlusion of venous sinuses and disruption of the venous system flow. CASE REPORT A 28-year-old healthy woman presented with a 2-week history of persistent and progressive headache 4 days after

receiving an mRNA COVID-19 vaccine (Pfizer-BioNTech). Cerebral computed tomography (CT) and CT venography confirmed the presence of extensive thrombus involving the left transverse and sigmoid sinus as well as the internal jugular vein. Furthermore, other than recent the COVID-19 vaccination, there were no precipitant risk factors in her clinical history or in the detailed laboratory work-up. CONCLUSIONS Headache associated with red flags following administration of any COVID-19 vaccine should prompt urgent neuroimaging to rule out secondary causes and determine the appropriate management. Our patient lacked the typical profile of CVST commonly seen following administration of the Oxford-Astrazeneca vaccine. The findings of low platelet count may indicate the peculiar pathophysiology of a thrombotic event associated with with the Pfizer vaccine.

New-onset Type 1 Diabetes after COVID-19 mRNA Vaccination. During the ongoing coronavirus disease 2019 (COVID-19) pandemic, it is critical to ensure the safety of COVID-19 vaccines. We herein report a 51-year-old Japanese woman who developed acute-onset type 1 diabetes with diabetic ketoacidosis six weeks after receiving the first dose of a COVID-19 messenger ribonucleic acid (mRNA) vaccine. Laboratory tests indicated exhaustion of endogenous insulin secretion, a positive result for insulin autoantibody, and latent thyroid autoimmunity. Human leukocyte antigen typing was homozygous for DRB1*09:01-DQB1*03:03 haplotypes. This case suggests that COVID-19 vaccination can induce type 1 diabetes in some individuals with a genetic predisposition.

Third cranial nerve palsy in an 88-year-old man after SARS-CoV-2 mRNA vaccination: change of injection site and type of vaccine resulted in an uneventful second dose with humoral immune response. Vaccines for SARS-CoV-2 currently authorised by the European Medicine Agency are effective, safe and well tolerated in practice. Awareness of rare potential vaccine-related adverse effects (AEs) is important to improve their recognition, management and reporting. An 88-year-old man attended the emergency department with incomplete palsy of the right third cranial nerve 3â€‰days after the first administration of Moderna mRNA-1273 SARS-CoV-2 vaccine. Imaging ruled out a vascular accident and a vaccine AE was hypothesised. Two weeks of oral steroids led to the patient's recovery, but without evidence of humoral immune response to vaccine. Thus, full immunisation with a dose of Pfizer mRNA-BNT162b2 SARS-CoV-2 vaccine in a different site was attempted. This was uneventful and followed by a robust antibody response. Empirical change of site and vaccine brand may represent a tailored option to obtain full immune protection in selected patients, after vaccine AEs.

Active Symptom-Based Surveillance of Adverse Events Following Immunization Among Individuals Vaccinated with ChAdOx1 nCoV-19 Coronavirus Vaccine in a Tertiary Hospital of Kerala. BACKGROUND: The reports on adverse experiences following vaccination are scanty from India. It is important to know the real-world post-vaccination experience outside of clinical trial conditions. OBJECTIVES: The study aims to estimate the incidence of adverse events following immunization with the ChAdOx1 nCoV-19 coronavirus vaccine and to identify the predictors for the development of vaccine adverse events. METHODS: A prospective observational study was conducted among health care workers who received the ChAdOx1 nCoV-19 coronavirus vaccine. Study participants were monitored at the site for 30 min following vaccination and were followed up for 7 days after receiving the second dose, with a purpose-specific designed online surveillance form to enquire about any adverse events following vaccination. We used the Chi-squared test for categorical variables and multivariate regression analysis to identify predictors for the development of vaccine adverse effects. RESULTS: Of 411 participants, the mean age was 30.77 Â± 12.5 years and 76.2% were females. Overall, 207 (50.4%) respondents reported at least one post-vaccination symptom receiving either dose of coronavirus vaccination. Fever (34.8%), local pain at the injection site (28.0%), tiredness (25.5%), chills (20%), myalgia (18.7%), headache (17.8%), injection site stiffness (5.4%), joint pain (4.6%) and nausea-vomiting (3.8%) were the most prevalent symptoms following the first dose.

Adverse reactions reported after the second dose were milder and less frequent. Postvaccination symptoms were more likely in the younger age group, those with comorbidity particularly, bronchial asthma , and a history of allergy to food/drugs. CONCLUSION: All the adverse reactions were of a minor type and non-serious. Side effects were less common in older adults (>60 years). Reactions to the second dose were lesser in intensity and frequency. Younger age, history of allergy, and comorbidities, particularly asthma, were found to be major predictors for the development of adverse events and require more watchful vaccine administration.
COVID-19 in Patients with Hematologic Malignancies: Outcomes and Options for Treatments. Patients with hematologic malignancies are particularly vulnerable to infections due to underlying humoral and cellular immune dysfunction, cytotoxic chemotherapy regimens, advanced age, and the presence of comorbid conditions. Infection from severe acute respiratory syndrome coronavirus 2, the causative agent of the COVID-19 pandemic, has become a leading cause of death globally and has disproportionally affected this high-risk population. Here, we review the cumulative evidence demonstrating worse outcomes for patients with hematologic malignancies when compared to patients with solid tumors and the general population. We examine risk factors shared with the general population (age, sex, comorbid conditions, and race) and those that are cancer-specific (cytotoxic chemotherapy, progressive disease, and cancer type), all of which confer an increased risk of severe COVID-19. Despite the historical exclusion of cancer patients from COVID-19 therapy trials, we review the emerging evidence that patients with hematologic malignancies benefit from specific treatments such as convalescent plasma. Although COVID-19 vaccines are significantly less effective in this patient population, encouraging results are observed in a subset of these patients after receiving a booster dose.
Persistent B cell memory after SARS-CoV-2 vaccination is functional during breakthrough infections. Breakthrough SARS-CoV-2 infections in fully vaccinated individuals are considered a consequence of waning immunity. Serum antibodies represent the most measurable outcome of vaccine-induced B cell memory. When antibodies decline, memory B cells are expected to persist and perform their function, preventing clinical disease. We investigated whether BNT162b2 mRNA vaccine induces durable and functional BÂ cell memory inÂ vivo against SARS-CoV-2 3, 6, and 9Â months after the second dose in a cohort of health care workers (HCWs). While we observed physiological decline of SARS-CoV-2-specific antibodies, memory BÂ cells persist and increase until 9Â months after immunization. HCWs with breakthrough infections had no signs of waning immunity. In 3-4Â days, memory B cells responded to SARS-CoV-2 infection by producing high levels of specific antibodies in the serum and anti-Spike IgA in the saliva. Antibodies to the viral nucleoprotein were produced with the slow kinetics typical of the response to a novel antigen.
Development of Acute Seroma Around Breast Implants Following Administration of COVID-19 Vaccination.
COVID-19 Updates: Pfizer-BioNTech COVID-19 vaccine.
Erythroderma related with the first dose of Pfizer-BioNTech BNT16B2b2 COVID-19 mRNA vaccine in a patient with psoriasis.
Stevens-Johnson syndrome induced by Vaxvetria (AZD1222) COVID-19 vaccine.
Development of eruptive pseudoangiomatosis following immunization with COVISHIELD vaccine in an adult.
COVID-19 and vaccination induced changes in hospital activity in Malta, Q1 2020 to Q1 2021: a population-based study. BACKGROUND: COVID-19 has severely impacted global healthcare services. Malta has only one acute state hospital, Mater Dei Hospital (MDH), and at the time of writingÂ is the most vaccinated country in Europe. Malta thus provides an ideal setting to assess the impact of COVID-19 on healthcare services at population level, including the impact of vaccination on

hospital admissions. METHODS: Hospital data was obtained as anonymised totals from MDH's Clinical Performance Unit and the European Centre for Disease Prevention and Control. COVID-19-related data was obtained from the Ministry of Health dashboard. Comparative assessments were performed to explore associations between the COVID-19 situation, vaccination, and hospital activity. Poisson regression was used to model the counts of monthly accident and emergency (A&E), outpatient clinics attendances and hospital admissions. RESULTS: A&E, hospital admissions, and outpatient clinics attendances declined (31.88%; 23.89%; 29.57%; $p < 0.01$ respectively) with onset of COVID-19 till April 2021 when compared to pre-COVID years (2017-2019). Admissions due to COVID-19 initially increased in parallel to the population's COVID positivity. Vaccination rollout led to a decline in COVID-19 admissions. CONCLUSIONS: The drastic drop in admissions and outpatient attendees was expected but not for A&E attendees as acutely ill patients should still have attended. This is of public health concern since delayed or deferred medical management increases population morbidity, mortality and increases the eventual burden on the healthcare system. Mass vaccination saw the return to normality with an increase in A&E burden.

Factors associated with SARS-CoV-2 antibody titers and prognosis of breakthrough infection in hemodialysis patients. BACKGROUND: The mortality rate of Coronavirus disease 2019 (COVID-19) is extremely high in hemodialysis patients (HDP). These patients also develop lower antibody titers after vaccination. Therefore, factors associated with antibody titers and vaccine efficacy in HDP with breakthrough infection need to be investigated. METHODS: We measured anti-S1 antibody titers in HDP (nâ€‰=â€‰104) and controls (nâ€‰=â€‰35), evaluating the influence of background on HDP by multivariable regression analysis. We classified 26 HDP patients admitted with COVID-19 into the unvaccinated (nâ€‰=â€‰15) and breakthrough infection group (nâ€‰=â€‰11), performing between-group comparisons of laboratory findings and prognosis. Vaccinated COVID-19 patients were classified into HDP and non-HDP controls, and compared the relationship between antibody titer and severity, and the prognosis of breakthrough infection. RESULTS: The antibody titer was significantly lower in the HDP group than in the control group. Among HDP, age and smoking history were significantly independent factors associated with antibody titer. The breakthrough infection group had significantly better laboratory findings (KL-6 and LDH), severity, and hospitalization period than the unvaccinated group even if antibody titers were lower than the known threshold for neutralization (pâ€‰<â€‰0.05). There was no significant difference in prognosis between the HDP and non-HDP with breakthrough infection. Severity of COVID-19 tended to be higher with lower antibody titer in non-HDP, but not in HDP. CONCLUSION: Vaccines improved the severity of COVID-19 and hospitalization period of breakthrough infection in HDP, although HDP, especially in elderly smokers had lower antibody titers than control. There was no significant association between antibody titer and severity in HDP.

Axillary Adenopathy after COVID-19 Vaccine: No Reason to Delay Screening Mammogram. Online supplemental material is available for this article.

Dermatomyositis Following BNT162b2 mRNA COVID-19 Vaccination. Dermatomyositis (DM) is one of the uncommon multi-organ idiopathic inflammatory myopathies that has been reported following the hepatitis B, Influenza, tetanus toxoid, H1N1, and BCG vaccines. However, an association with the coronavirus disease 2019 (COVID-19) vaccine is yet to be reported. In this case, we present the case of a 43-year-old Asian Indian female who was diagnosed with DM 10 days after receiving the second dosage of BNT162b2 mRNA COVID-19 vaccination, in the absence of any additional triggering factors. The diagnosis was established based on physical examination, serological antibodies, magnetic resonance imaging of the muscles, skin biopsy, and electromyography. She received standard treatment for DM, including oral high doses of prednisolone, hydroxychloroquine, mycophenolate, and physiotherapy. The treatment successfully reversed skin changes and muscle

weakness. This is the first reported case of classic DM complicated by interstitial lung disease following COVID-19 vaccination. More clinical and functional studies are needed to elucidate this association. Clinicians should be aware of this unexpected adverse event following COVID-19 vaccination and arrange for appropriate management.
Aseptic Meningitis Following Second Dose of an mRNA Coronavirus Disease 2019 Vaccine in a Healthy Male: Case Report and Literature Review. Vaccines are one of the most important strategies against pandemics or epidemics involving infectious diseases. With the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), there have been global efforts for rapid development of coronavirus disease 2019 (COVID-19) vaccine and vaccination is being performed globally on a massive scale. With rapid increase in vaccination, rare adverse events have been reported. Well-known neurological adverse events associated with COVID-19 vaccination include Guillain-BarrÃ© syndrome, myelitis, and encephalitis. However, COVID-19 vaccine-related aseptic meningitis has rarely been reported. A 32-year-old healthy man visited our hospital with a complaint of headache for 1 week. He had received the second dose of the BNT162b2 mRNA COVID-19 vaccine 2 weeks before the onset of headache. Since the initial cerebrospinal fluid (CSF) profile suggested viral meningitis, we started treatment with an antiviral agent. However, the symptoms and follow-up CSF profile on day 7 of hospitalization showed no improvement and SARS-CoV-2 IgG antibodies were detected in the CSF. We suspected aseptic meningitis associated with the vaccination and intravenous methylprednisolone (500 mg/day) was administered for 3 days. The symptoms improved and the patient was discharged on day 12 of hospitalization.
Persistence of Ad26.COV2.S-associated vaccine-induced immune thrombotic thrombocytopenia (VITT) and specific detection of VITT antibodies. Rare cases of COVID-19 vaccinated individuals develop anti-platelet factor 4 (PF4) antibodies that cause thrombocytopenia and thrombotic complications, a syndrome referred to as vaccine-induced immune thrombotic thrombocytopenia (VITT). Currently, information on the characteristics and persistence of anti-PF4 antibodies that cause VITT after Ad26.COV2.S vaccination is limited, and available diagnostic assays fail to differentiate Ad26.COV2.S and ChAdOx1 nCoV-19-associated VITT from similar clinical disorders, namely heparin-induced thrombocytopenia (HIT) and spontaneous HIT. Here we demonstrate that while Ad26.COV2.S-associated VITT patients are uniformly strongly positive in PF4-polyanion enzyme-linked immunosorbent assays (ELISAs); they are frequently negative in the serotonin release assay (SRA). The PF4-dependent p-selectin expression assay (PEA) that uses platelets treated with PF4 rather than heparin consistently diagnosed Ad26.COV2.S-associated VITT. Most Ad26.COV2.S-associated VITT antibodies persisted for >5â€‰months in PF4-polyanion ELISAs, while the PEA became negative earlier. Two patients had otherwise unexplained mild persistent thrombocytopenia (140-150 x 10(3) /ÂµL) 6â€‰months after acute presentation. From an epidemiological perspective, differentiating VITT from spontaneous HIT, another entity that develops in the absence of proximate heparin exposure, and HIT is important, but currently available PF4-polyanion ELISAs and functional assay are non-specific and detect all three conditions. Here, we report that a novel un-complexed PF4 ELISA specifically differentiates VITT, secondary to both Ad26.COV2.S and ChAdOx1 nCoV-19, from both spontaneous HIT, HIT and commonly-encountered HIT-suspected patients who are PF4/polyanion ELISA-positive but negative in functional assays. In summary, Ad26.COV2.S-associated VITT antibodies are persistent, and the un-complexed PF4 ELISA appears to be both sensitive and specific for VITT diagnosis.
Minimal change disease and acute interstitial nephritis following SARS-CoV-2 BNT162b2 vaccination.
Early immune responses have long-term associations with clinical, virologic, and immunologic outcomes in patients with COVID-19. The great majority of SARS-CoV-2 infections are mild and uncomplicated, but some individuals with initially mild COVID-19 progressively develop more severe

symptoms. Furthermore, there is substantial heterogeneity in SARS-CoV-2-specific memory immune responses following infection. There remains a critical need to identify host immune biomarkers predictive of clinical and immunologic outcomes in SARS-CoV-2-infected patients. Leveraging longitudinal samples and data from a clinical trial in SARS-CoV-2 infected outpatients, we used host proteomics and transcriptomics to characterize the trajectory of the immune response in COVID-19 patients within the first 2 weeks of symptom onset. We identify early immune signatures, including plasma RIG-I levels, early interferon signaling, and related cytokines (CXCL10, MCP1, MCP-2 and MCP-3) associated with subsequent disease progression, control of viral shedding, and the SARS-CoV-2 specific T cell and antibody response measured up to 7 months after enrollment. We found that several biomarkers for immunological outcomes are shared between individuals receiving BNT162b2 (Pfizer-BioNTech) vaccine and COVID-19 patients. Finally, we demonstrate that machine learning models using 7-10 plasma protein markers measured early within the course of infection are able to accurately predict disease progression, T cell memory, and the antibody response post-infection in a second, independent dataset.

Exercise after influenza or COVID-19 vaccination increases serum antibody without an increase in side effects. Vaccination is an effective public health measure, yet vaccine efficacy varies across different populations. Adjuvants improve vaccine efficacy but often increase reactogenicity. An unconventional behavioral "adjuvant" is physical exercise at the time of vaccination. Here, in separate experiments, we examined the effect of 90-minute light- to moderate-intensity cycle ergometer or outdoor walk/jog aerobic exercise performed once after immunization on serum antibody response to three different vaccines (2009 pandemic influenza H1N1, seasonal influenza, and COVID-19). Exercise took place after influenza vaccination or after the first dose of Pfizer-BioNTech COVID-19 vaccine. A mouse model of influenza A immunization was used to examine the effect of exercise on antibody response and the role of IFNÎ± as a potential mechanism by treating mice with anti-IFNÎ± antibody. The results show that 90Â min of exercise consistently increased serum antibody to each vaccine four weeks post-immunization, and IFNÎ± may partially contribute to the exercise-related benefit. Exercise did not increase side effects after the COVID-19 vaccination. These findings suggest that adults who exercise regularly may increase antibody response to influenza or COVID-19 vaccine by performing a single session of light- to moderate-intensity exercise post-immunization.

A prospective study of the impact of glycaemic status on clinical outcomes and anti-SARS-CoV-2 antibody responses among patients with predominantly non-severe COVID-19. AIMS: We carried out this prospective study of predominantly non-severe COVID-19 patients, to evaluate the influence of glycaemic status on clinical outcomes and neutralising antibody (Nab) responses, potentially relevant to the COVID-19 vaccination programme. METHODS: We included consecutive adults admitted to Queen Mary Hospital for COVID-19 from July 2020-May 2021. Glycaemic status was defined by admission HbA1c. Clinical deterioration was defined by radiological progression/new oxygen requirement/intensive care requirement/death. COVID-19 survivors had Nab measurements at 1-month, 2-month, 3-month and 6-month post-discharge. RESULTS: Among 605 patients (96.9% non-severe COVID-19; 325 normoglycaemia, 185 prediabetes, 95 diabetes), 74 (12.2%) had clinical deterioration, more likely with worse glycaemic status and higher HbA1c (pÂ <Â 0.001). Older age (pÂ <Â 0.001), higher viral loads (pÂ <Â 0.001), higher C-reactive protein (CRP) (pÂ <Â 0.001) and symptomatic presentation (pÂ =Â 0.008), but not glycaemic status/HbA1c, independently predicted clinical deterioration. Older age (pÂ =Â 0.001), higher CRP (pÂ =Â 0.038), elevated lactate dehydrogenase (pÂ =Â 0.046) and interferon treatment (pÂ =Â 0.001), but not glycaemic status/HbA1c, independently predicted Nab titres. Rate of Nab titre decline was comparable across glycaemic status. CONCLUSIONS: COVID-19 patients with worse glycaemic status were more likely to deteriorate clinically, mediated through the association of worse glycaemic status with older age,

more severe inflammation and higher viral loads. Importantly, Nab responses did not differ across glycaemic status.

Real-world data on immune responses following heterologous prime-boost COVID-19 vaccination schedule with Pfizer and AstraZeneca vaccines in England. BACKGROUND: There are limited data on immune responses to heterologous COVID-19 immunisation schedules, especially following an extended â‰¥12-week interval between doses. METHODS: SARS-CoV-2 infection-naÃ¯ve and previously-infected adults receiving ChAd-BNT (ChAdOx1 nCoV-19, AstraZeneca followed by BNT162b2, Pfizer-BioNTech) or BNT-ChAd as part of the UK national immunisation programme provided blood samples at 30 days and 12 weeks after their second dose. Geometric mean concentrations (GMC) of anti-SARS-CoV-2 spike (S-antibody) and nucleoprotein (N-antibody) IgG antibodies and geometric mean ratios (GMR) were compared with a contemporaneous cohort receiving homologous ChAd-ChAd or BNT-BNT. RESULTS: During March-October 2021, 75,827 individuals were identified as having received heterologous vaccination, 9,489 invited to participate, 1,836 responded (19.3%) and 656 were eligible. In previously-uninfected adults, S-antibody GMC at 30 days post-second dose were lowest for ChAd-ChAd (862 [95% CI, 694 - 1069]) and significantly higher for ChAd-BNT (6233 [5522-7035]; GMR 6.29; [5.04-7.85]; p<0.001), BNT-ChAd (4776 [4066-5610]; GMR 4.55 [3.56-5.81]; p<0.001) and BNT-BNT (5377 [4596-6289]; GMR 5.66 [4.49-7.15]; p<0.001). By 12 weeks after dose two, S-antibody GMC had declined in all groups and remained significantly lower for ChAd-ChAd compared to ChAd-BNT (GMR 5.12 [3.79-6.92]; p<0.001), BNT-ChAd (GMR 4.1 [2.96-5.69]; p<0.001) and BNT-BNT (GMR 6.06 [4.32-8.50]; p<0.001). Previously infected adults had higher S-antibody GMC compared to infection-naÃ¯ve adults at all time-points and with all vaccine schedules. CONCLUSIONS: These real-world findings demonstrate heterologous schedules with adenoviral-vector and mRNA vaccines are highly immunogenic and may be recommended after a serious adverse reaction to one vaccine product, or to increase programmatic flexibility where vaccine supplies are constrained.

Intensity of hypermetabolic axillary lymph nodes in oncologic patients in relation to timeline following COVID-19 vaccination. PURPOSE: First discovered in Wuhan, China in December 2019, severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) is a highly contagious and deadly novel virus that quickly wreaked havoc throughout the world. As mass vaccination are now underway worldwide, clinicians have started to encounter a new clinical entity, COVID-19 vaccine-associated axillary lymphadenopathy. This presents a unique challenge to medical imagers, particularly in oncologic patients. METHODS: In this retrospective study, we assessed metabolic activity, size, and timeline of COVID-19 vaccine-associated axillary hypermetabolic lymph nodes in 202 oncologic patients post vaccination with 18-fluorodeoxyglucose positron emission tomography (18-FDG PET). RESULTS: When present, COVID-19 vaccine-associated hypermetabolic lymph nodes demonstrate a mean maximum standard uptake value (SUV(max)) of 2.5 Â± 0.3, and more common in younger patients. The metabolic activity is the most intense in the first two weeks post vaccination and diminishes over time. By approximately 5-6 weeks, only about half of the patients demonstrated appreciable, low grade uptake compared to background. CONCLUSION: Based on our preliminary results, we would recommend correlation with a history and time of vaccination and routine use of a pre-study patient questionnaire to guide interpretation to prevent over-diagnosis of axillary nodal metastases and/or unnecessary work-up in oncologic patients.

An Acute Exacerbation of Idiopathic Pulmonary Fibrosis After BNT162b2 mRNA COVID-19 Vaccination: A Case Report. Idiopathic pulmonary fibrosis (IPF) is a fatal interstitial lung disease characterized by progressive scar tissue formation. An acute exacerbation of IPF (AE-IPF) is a clinically significant respiratory decompensation that accounts for a significant proportion of IPF-related morbidity and mortality. AE-IPF can be idiopathic or associated with pulmonary embolism, infection,

aspiration, surgery, and drug toxicity. In this novel case report, we describe a potential association between AE-IPF and BNT162b2 mRNA COVID-19 vaccination that was successfully treated with a short course of glucocorticoids. While our aim is to raise awareness for this yet-to-be-described adverse event, immunization against vaccine-preventable disease remains widely recommended in vulnerable patients with chronic lung disease such as IPF.

Risk of infection, hospitalisation, and death up to 9 months after a second dose of COVID-19 vaccine: a retrospective, total population cohort study in Sweden. BACKGROUND: Vaccine effectiveness against COVID-19 beyond 6 months remains incompletely understood. We aimed to investigate the effectiveness of COVID-19 vaccination against the risk of infection, hospitalisation, and death during the first 9 months after vaccination for the total population of Sweden. METHODS: This retrospective, total population cohort study was done using data from Swedish nationwide registers. The cohort comprised all individuals vaccinated with two doses of ChAdOx1 nCoV-19, mRNA-1273, or BNT162b2, and matched unvaccinated individuals, with data on vaccinations and infections updated until Oct 4, 2021. Two outcomes were evaluated. The first was SARS-CoV-2 infection of any severity from Jan 12 to Oct 4, 2021. The second was severe COVID-19, defined as hospitalisation for COVID-19 or all-cause 30-day mortality after confirmed infection, from March 15 to Sept 28, 2021. FINDINGS: Between Dec 28, 2020, and Oct 4, 2021, 842â€‰974 individuals were fully vaccinated (two doses), and were matched (1:1) to an equal number of unvaccinated individuals (total study cohort n=1â€‰685â€‰948). For the outcome SARS-CoV-2 infection of any severity, the vaccine effectiveness of BNT162b2 waned progressively over time, from 92% (95% CI 92 to 93; p<0Â·001) at 15-30 days, to 47% (39 to 55; p<0Â·001) at 121-180 days, and to 23% (-2 to 41; p=0Â·07) from day 211 onwards. Waning was slightly slower for mRNA-1273, with a vaccine effectiveness of 96% (94 to 97; p<0Â·001) at 15-30 days and 59% (18 to 79; p=0Â·012) from day 181 onwards. Waning was also slightly slower for heterologous ChAdOx1 nCoV-19 plus an mRNA vaccine, for which vaccine effectiveness was 89% (79 to 94; p<0Â·001) at 15-30 days and 66% (41 to 80; p<0Â·001) from day 121 onwards. By contrast, vaccine effectiveness for homologous ChAdOx1 nCoV-19 vaccine was 68% (52 to 79; p<0Â·001) at 15-30 days, with no detectable effectiveness from day 121 onwards (-19% [-98 to 28]; p=0Â·49). For the outcome of severe COVID-19, vaccine effectiveness waned from 89% (82 to 93; p<0Â·001) at 15-30 days to 64% (44 to 77; p<0Â·001) from day 121 onwards. Overall, there was some evidence for lower vaccine effectiveness in men than in women and in older individuals than in younger individuals. INTERPRETATION: We found progressively waning vaccine effectiveness against SARS-CoV-2 infection of any severity across all subgroups, but the rate of waning differed according to vaccine type. With respect to severe COVID-19, vaccine effectiveness seemed to be better maintained, although some waning became evident after 4 months. The results strengthen the evidence-based rationale for administration of a third vaccine dose as a booster. FUNDING: None.

Guillain-BarrÃ© syndrome and fulminant encephalomyelitis following Ad26.COV2.S vaccination: double jeopardy. This correspondence comments on a published article presenting a case of rhombencephalitis following SARS-CoV-2-vaccination with the mRNA vaccine BNT162b2 (Pfizer/BioNTech). We also present the case of a 47-year-old man who developed Guillain-BarrÃ©-syndrome and a fulminant encephalomyelitis 28Â days after immunization with Ad26.COV2.S (Janssen/Johnson & Johnson). Based on the presented cases, we underscore the importance of clinical awareness for early recognition of overlapping neuroimmunological syndromes following vaccination against SARS-CoV-2. Additionally, we propose that that role of autoantibodies against angiotensin-converting enzyme 2 (ACE2) and the cell-surface receptor neuropilin-1, which mediate neurological manifestations of SARS-CoV-2, merit further investigation in patients presenting with neurological disorders following vaccination against SARS-CoV-2.

SARS-CoV-2 Variants Associated with Vaccine Breakthrough in the Delaware Valley through Summer 2021. The severe acute respiratory coronavirus-2 (SARS-CoV-2) is the cause of the global outbreak of COVID-19. Evidence suggests that the virus is evolving to allow efficient spread through the human population, including vaccinated individuals. Here, we report a study of viral variants from surveillance of the Delaware Valley, including the city of Philadelphia, and variants infecting vaccinated subjects. We sequenced and analyzed complete viral genomes from 2621 surveillance samples from March 2020 to September 2021 and compared them to genome sequences from 159 vaccine breakthroughs. In the early spring of 2020, all detected variants were of the B.1 and closely related lineages. A mixture of lineages followed, notably including B.1.243 followed by B.1.1.7 (alpha), with other lineages present at lower levels. Later isolations were dominated by B.1.617.2 (delta) and other delta lineages; delta was the exclusive variant present by the last time sampled. To investigate whether any variants appeared preferentially in vaccine breakthroughs, we devised a model based on Bayesian autoregressive moving average logistic multinomial regression to allow rigorous comparison. This revealed that B.1.617.2 (delta) showed 3-fold enrichment in vaccine breakthrough cases (odds ratio of 3; 95% credible interval 0.89-11). Viral point substitutions could also be associated with vaccine breakthroughs, notably the N501Y substitution found in the alpha, beta and gamma variants (odds ratio 2.04; 95% credible interval of1.25-3.18). This study thus overviews viral evolution and vaccine breakthroughs in the Delaware Valley and introduces a rigorous statistical approach to interrogating enrichment of breakthrough variants against a changing background. IMPORTANCE SARS-CoV-2 vaccination is highly effective at reducing viral infection, hospitalization and death. However, vaccine breakthrough infections have been widely observed, raising the question of whether particular viral variants or viral mutations are associated with breakthrough. Here, we report analysis of 2621 surveillance isolates from people diagnosed with COVID-19 in the Delaware Valley in southeastern Pennsylvania, allowing rigorous comparison to 159 vaccine breakthrough case specimens. Our best estimate is a 3-fold enrichment for some lineages of delta among breakthroughs, and enrichment of a notable spike substitution, N501Y. We introduce statistical methods that should be widely useful for evaluating vaccine breakthroughs and other viral phenotypes.

Adverse Events Reported by Patients With Cancer After Administration of a 2-Dose mRNA COVID-19 Vaccine. BACKGROUND: Most safety and efficacy trials of the SARS-CoV-2 vaccines excluded patients with cancer, yet these patients are more likely than healthy individuals to contract SARS-CoV-2 and more likely to become seriously ill after infection. Our objective was to record short-term adverse reactions to the COVID-19 vaccine in patients with cancer, to compare the magnitude and duration of these reactions with those of patients without cancer, and to determine whether adverse reactions are related to active cancer therapy. PATIENTS AND METHODS: A prospective, single-institution observational study was performed at an NCI-designated Comprehensive Cancer Center. All study participants received 2 doses of the Pfizer BNT162b2 vaccine separated by approximately 3 weeks. A report of adverse reactions to dose 1 of the vaccine was completed upon return to the clinic for dose 2. Participants completed an identical survey either online or by telephone 2 weeks after the second vaccine dose. RESULTS: The cohort of 1,753 patients included 67.5% who had a history of cancer and 12.0% who were receiving active cancer treatment. Local pain at the injection site was the most frequently reported symptom for all respondents and did not distinguish patients with cancer from those without cancer after either dose 1 (39.3% vs 43.9%; P=.07) or dose 2 (42.5% vs 40.3%; P=.45). Among patients with cancer, those receiving active treatment were less likely to report pain at the injection site after dose 1 compared with those not receiving active treatment (30.0% vs 41.4%; P=.002). The onset and duration of adverse events was otherwise unrelated to active cancer treatment. CONCLUSIONS: When patients with cancer were compared with those without cancer,

few differences in reported adverse events were noted. Active cancer treatment had little impact on adverse event profiles.
New-onset cutaneous lupus erythematosus after the COVID-19 vaccine. Vaccine development for COVID-19 has progressed expeditiously. To date, the Food and Drug Administration (FDA) has authorized the Moderna/mRNA-1273, Pfizer-BioNTech (BNT162b2), and Johnson & Johnson's Janssen (JNJ-78436735) vaccines for use in the United States. Immediate side effects have included myalgia fatigue, chills, fever, and headache. We report an elderly patient with a history of lung cancer and no prior history of autoimmune disease who developed cutaneous lupus erythematosus two Â½ months after the second dose of the Pfizer-BioNTech COVID-19 vaccine.
Reply to "Caution Regarding Conclusions about COVID-19 Vaccine and Encephalitis".
Transient Lymphocytic Colitis After SARS-CoV2 mRNA Vaccine. This is the first scientific report describing lymphocytic colitis after administration of the Pfizer severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) messenger RNA (mRNA) vaccine. The patient developed liquid stools, abdominal pain, and nausea within 24 hours of receiving the second dose. Symptoms were persistent for 3 months but improved 113 days after onset. Laboratory profiles and gastrointestinal polymerase chain reaction were normal. Esophagogastroduodenoscopy and colonoscopy performed 98 days after onset revealed patchy erythema in the descending colon and rectosigmoid. Mucosal evaluation revealed lymphocytic colitis. Review of the Vaccine Adverse Event Reporting System revealed 5 cases of microscopic colitis after the second mRNA dose. This report and Vaccine Adverse Event Reporting System cases suggest providers should consider microscopic colitis in the differential diagnosis of patients with severe, persistent diarrhea after the SARS-CoV2 mRNA vaccine.
Cutaneous Small-vessel Vasculitis after ChAdOx1 COVID-19 Vaccination: A Report of Five Cases. Amidst the Coronavirus Disease 2019 (COVID-19) pandemic, vaccination against severe acute respiratory syndrome 2 (SARS-CoV-2) is recommended for everyone over 18 years in South Korea, with the exception of pregnant women. Unexpected adverse cutaneous reactions after the COVID-19 vaccination have been recently reported. Cutaneous small-vessel vasculitis (CSVV) predominantly affects small blood vessels, defined as small intraparenchymal arteries, arterioles, capillaries, and venules, without any detectable involvement of non-cutaneous organs. We report five cases of CSVV after the ChAdOx1 COVID-19 vaccination in 44- to 68-year-old women. The symptoms commonly appeared within 2 days after vaccination. The lesion was localized to the lower limbs in four patients and spread to the upper limbs in one patient. All patients demonstrated a favorable response to oral methylprednisolone, antihistamines, and topical steroids. Considering the importance of the COVID-19 vaccination, clinicians should be aware of CSVV as a potential adverse event. Further studies are required to elucidate the causative link and pathogenesis.
Severe COVID pneumonia and undetectable B cells after vaccination in patients previously treated with rituximab: a case series. INTRODUCTION: The risk of developing severe COVID-19 illness despite completing vaccination for patients who have previously received immunosuppressive therapy is unclear. CASE PRESENTATION: We present three patients who received rituximab for treatment of autoimmune disorders who subsequently developed severe COVID-19 pneumonia post-vaccination requiring intensive care unit admission and found to have undetectable B cells. DISCUSSION: While there have been concerns about the effectiveness of COVID-19 vaccines in this patient cohort, this is the first case series to report development of severe COVID-19 illness after completing vaccination in those who previously received rituximab. Guidelines for the optimal timing of COVID-19 vaccination in relation to immunosuppressive therapy have been recently published, albeit after many patients in this subpopulation have already been vaccinated. CONCLUSION: This case series brings attention to the limited humoral response to vaccines in patients treated with

rituximab, highlights existing guidelines and their limitations, and raises future considerations about the potential benefits to testing vaccine responsiveness.

Herpes zoster related hospitalization after inactivated (CoronaVac) and mRNA (BNT162b2) SARS-CoV-2 vaccination: A self-controlled case series and nested case-control study. BACKGROUND: Stimulation of immunity by vaccination may elicit adverse events. There is currently inconclusive evidence on the relationship between herpes zoster related hospitalization and COVID-19 vaccination. This study aimed to evaluate the effect of inactivated virus (CoronaVac, Sinovac) and mRNA (BNT162b2, BioNTech/Fosun Pharma) COVID-19 vaccine on the risk of herpes zoster related hospitalization. METHODS: Self-controlled case series (SCCS) analysis was conducted using the data from the electronic health records in Hospital Authority and COVID-19 vaccination records in the Department of Health in Hong Kong. We conducted the SCCS analysis including patients with a first primary diagnosis of herpes zoster in the hospital inpatient setting between February 23 and July 31, 2021. A confirmatory analysis by nested case-control method was also conducted. Each herpes zoster case was randomly matched with ten controls according to sex, age, Charlson comorbidity index, and date of hospital admission. Conditional Poisson regression and logistic regression models were used to assess the potential excess rates of herpes zoster after vaccination. FINDINGS: From February 23 to July 31, 2021, a total of 16 and 27 patients were identified with a first primary hospital diagnosis of herpes zoster within 28 days after CoronaVac and BNT162b2 vaccinations. The incidence of herpes zoster was 7.9 (95% Confidence interval [CI]: 5.2-11.5) for CoronaVac and 7.1 (95% CI: 4.1-11.5) for BNT162b2 per 1,000,000 doses administered. In SCCS analysis, CoronaVac vaccination was associated with significantly higher risk of herpes zoster within 14 days after first dose (adjusted incidence rate ratio [aIRR]=2.67, 95% CI: 1.08-6.59) but not in other periods afterwards compared to the baseline period. Regarding BNT162b2 vaccination, a significantly increased risk of herpes zoster was observed after first dose up to 14 days after second dose (0-13 days after first dose: aIRR=5.23, 95% CI: 1.61-17.03; 14-27 days after first dose: aIRR=5.82, 95% CI: 1.62-20.91; 0-13 days after second dose: aIRR=5.14, 95% CI: 1.29-20.47). Using these relative rates, we estimated that there has been an excess of approximately 5 and 7 cases of hospitalization as a result of herpes zoster after every 1,000,000 doses of CoronaVac and BNT162b2 vaccination, respectively. The findings in the nested case control analysis showed similar results. INTERPRETATION: We identified an increased risk of herpes zoster related hospitalization after CoronaVac and BNT162b2 vaccinations. However, the absolute risks of such adverse event after CoronaVac and BNT162b2 vaccinations were very low. In locations where COVID-19 is prevalent, the protective effects on COVID-19 from vaccinations will greatly outweigh the potential side effects of vaccination. FUNDING: The project was funded by Research Grant from the Food and Health Bureau, The Government of the Hong Kong Special Administrative Region (Ref. No.COVID19F01). FTTL (Francisco Tsz Tsun Lai) and ICKW (Ian Chi Kei Wong)'s posts were partly funded by D(2)4H; hence this work was partly supported by AIR@InnoHK administered by Innovation and Technology Commission.

COVID-19 Vaccination-Induced Myopericarditis: An Imager's Perspective. COVID-19 vaccine-induced myocarditis is a rare adverse event in the current pandemic. The following is a case series of 10 individuals with COVID-19 vaccine-related myocarditis confirmed by cardiac magnetic resonance imaging. In this cohort of predominantly male patients, with a mean age of 23 years, chest discomfort and positive cardiac biomarkers occurred at a median of 3 days after the second COVID-19 vaccine dose. Although systolic function was relatively preserved on noninvasive cardiac imaging, evidence was seen of delayed enhancement on cardiac magnetic resonance imaging, confirming myocarditis. As COVID-19 vaccine-induced myocarditis has a relatively benign clinical course, the benefits of vaccination still, by far, outweigh this small risk.

Response to Vaccination Against SARS-CoV-2 in Patients With Antineutrophil Cytoplasmic Antibody-Associated Vasculitis With Renal Involvement. BACKGROUND: Patients with anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitides (AAV) present with multisystem disease including renal impairment. The treatment for AAV involves a high burden of immunosuppression. Patients with renal involvement are treated especially intensively. As a result, we identified these patients as being potentially at high risk of failure to seroconvert to COVID-19 vaccination. METHODS: We collected data on seroconversion response rates to COVID-19 vaccination in a multi-ethnic cohort of patients with AAV and renal involvement treated at a busy tertiary nephrology centre as part of a retrospective review of patient notes. Blood samples were taken following vaccination with either Pfizer or Astra-Zeneca COVID-19 vaccines and median fluorescence intensity was measured using the validated MULTICOV-Ab Magnetic Luminex(â“‡) Assay. We also evaluated whether seroconversion was affected by immunosuppression regimen. RESULTS: 81 patients were included. The mean age was 62, and there were 49 (60%) females. 55 patients had a blood test after the first dose; 46 after the second dose. Patients were in remission with a median BVAS of 0 (IQR 2). Seroconversion after the first dose with either vaccine was 35/55 (63.6%). After the second it was 38/46 (82.6%). Subgroup analyses revealed a trend to impaired seroconversion in non-white versus white patients (77.8 vs. 81.7% ($p = 0.69$) after the first dose of vaccine and in those treated with Rituximab in the last 12 months (73.3 vs. 87.1%, $p = 0.41$). CONCLUSIONS: These data offer real-world evidence of lower seroconversion in response to vaccination with one dose in patients with AAV and renal involvement than the general UK population. After two doses, seroconversion is in line with national data. These data provide a rationale for hospital-led identification of patients most at risk of COVID-19 and underscore the importance of local connexions between hospitals and their communities. These data provide further support for targeting booster vaccination programmes to vulnerable patient cohorts. They add to the growing evidence of reduced seroconversion in response to vaccination in patients with renal disease of any cause.

Virological and Serological Characterisation of SARS-CoV-2 Infections Diagnosed After mRNA BNT162b2 Vaccination Between December 2020 and March 2021. BACKGROUND: Vaccines for coronavirus disease 2019 (COVID-19) are proving to be very effective in preventing severe illness; however, although rare, post-vaccine infections have been reported. The present study focuses on virological and serological features of 94 infections that occurred in Lazio Region (Central Italy) between 27 December 2020, and 30 March 2021, after one or two doses of mRNA BNT162b2 vaccine. METHODS: We evaluated clinical features, virological (viral load; viral infectiousness; genomic characterisation), and serological (anti-nucleoprotein Ig; anti-Spike RBD IgG; neutralising antibodies, nAb) characteristics of 94 post-vaccine infections at the time of diagnosis. Nasopharyngeal swabs (NPSs) and serum samples were collected in the framework of the surveillance activities on SARS-CoV-2 variants established in Lazio Region (Central Italy) and analysed at the National Institute for Infectious Diseases "L. Spallanzani" in Rome. RESULTS: The majority (92.6%) of the post-vaccine infections showed pauci/asymptomatic or mild clinical course, with symptoms and hospitalisation rate significantly less frequent in patients infected after full vaccination course as compared to patients who received a single dose vaccine. Although differences were not statistically significant, viral loads and isolation rates were lower in NPSs from patients infected after receiving two vaccine doses as compared to patients with one dose. Most cases (84%) had nAb in serum at the time of infection diagnosis, which is a sub-group of vaccinees, were found similarly able to neutralise Alpha and Gamma variants. Asymptomatic individuals showed higher nAb titres as compared to symptomatic cases (median titre: 1:120 vs. 1:40, respectively). Finally, the proportion of post-vaccine infections attributed either to Alpha and Gamma variants was similar to the proportion observed in the contemporary unvaccinated population in the Lazio region, and mutational analysis did not reveal

enrichment of a defined set of Spike protein substitutions depending on the vaccination status. CONCLUSION: Our study conducted using real-life data, emphasised the importance of monitoring vaccine breakthrough infections, through the characterisation of virological, immunological, and clinical features associated with these events, in order to tune prevention measures in the next phase of the COVID-19 pandemic.

Covid-19 vaccine acceptance and associated factors among pregnant women in Pennsylvania 2020. Data on factors associated with vaccine acceptance among pregnant women are critical to the rapid scale up of interventions to improve vaccine uptake. When COVID-19 vaccines were still in the testing phases of research, we surveyed pregnant women accessing prenatal care at an academic medical institution in Central Pennsylvania, United States to examine factors associated with vaccine acceptance. Willingness to receive a COVID-19 vaccine once a vaccine became available was asked as part of an ongoing study on the COVID-19 pandemic and pregnancy (nÂ =Â 196). Overall, 65% of women reported they would be willing or somewhat willing to receive the COVID-19 vaccine. Women who had received an influenza vaccine within the past year were more likely to be willing to receive the COVID-19 vaccine than women who had never received an influenza vaccine or those who received it over one year ago (aOR 4.82; 95% CI 2.17, 10.72). Similarly, women who were employed full-time were more willing to receive the COVID-19 vaccine than women who were not employed full time (aOR 2.22; 95% CI 1.02, 4.81), and women who reported feeling overloaded were more willing to receive the COVID-19 vaccine than women who did not feel overloaded (aOR 2.18; 95% CI 1.02, 4.68). Our findings support the need to increase vaccination education among pregnant women before vaccines are rolled out, especially those who have not received an influenza vaccine within the past year. Improved understanding of willingness to vaccinate among pregnant women will improve future pandemic responses and current vaccination efforts.

Cytologic and histologic features of COVID-19 post-vaccination lymphadenopathy. In this study, we present six cases of axillary or supraclavicular lymphadenopathies in the days following to the Pfizer-BioNTech vaccine's first dose and its study for fine-needle aspiration cytology (two patients), biopsy with a gross needle (two patients), and the evolution of two other patients. Cytological smears and histological sections reveal reactive nodes, predominantly T, CD8, and the presence of atypia with striking mitosis. Differential diagnosis with viral lymphadenopathies and lymphoma is important, so the clinical correlation, in a vaccination context, sudden appearance, and progressive decrease in days of the adenopathy, is essential. In this article, we have studied the cytohistological manifestations of post-Pfizer-BioNTech vaccination lymphadenopathy and discussed its differential diagnosis.

A decade of data: Adolescent vaccination in the vaccine safety datalink, 2007 through 2016. BACKGROUND: Between May 2005 and March 2007, three vaccines were recommended by the Advisory Committee on Immunization Practices for routine use in adolescents in the United States: quadrivalent meningococcal conjugate vaccine (MenACWY), tetanus, diphtheria and acellular pertussis vaccine (Tdap), and human papillomavirus vaccine (HPV). Understanding historical adolescent vaccination patterns may inform future vaccination coverage efforts for these and emerging adolescent vaccines, including COVID-19 vaccines. METHODS: This was a descriptive, retrospective cohort study. All vaccines administered to adolescents aged 11 through 18Â years in the Vaccine Safety Datalink population between January 1, 2007 and December 31, 2016 were examined. Vaccination coverage was assessed by study year for â‰¥1 dose Tdap or Td, â‰¥1 dose Tdap, â‰¥1 dose MenACWY, â‰¥1 dose HPV, and â‰¥3 dose HPV. The proportion of vaccine visits with concurrent vaccination (â‰¥2 vaccines administered at the same visit) was calculated by sex and study year. The most common vaccine combinations administered in the study population were described by sex for two time periods: 2007-2010 and 2011-2016. RESULTS: The number of 11-18-

year-olds in the study population averaged 522,565 males and 503,112 females per study year. Between January 2007 and December 2016 there were 4,884,553 vaccine visits in this population (45% among males). The overall proportion of concurrent vaccine visits among males was 43% (33-61% by study year). Among females, 39% of all vaccine visits included concurrent vaccination (32-48% by study year). Vaccine coverage for Tdap, MenACWY, and 1- and 3-dose HPV increased across the study period. A wide variety of vaccine combinations were administered among both sexes and in both time periods. CONCLUSIONS: The high vaccine uptake and multitude of vaccine combinations administered concurrently in the adolescent population of the Vaccine Safety Datalink provide historical patterns with which to compare future adolescent vaccination campaigns.

Laboratory testing for platelet factor 4 antibodies: differential utility for diagnosis/exclusion of heparin induced thrombocytopenia versus suspected vaccine induced thrombotic thrombocytopenia. Platelet factor 4 (PF4), a protein stored in the alpha-granules of platelets and released upon activation, forms cationic tetramers that bind with various polymeric anions, including heparin. Some individuals develop antibodies against PF4 in complex with heparin (PF4/H), which potentially lead to the onset of heparin induced thrombocytopenia (HIT). In some patients, this may cause activation and aggregation of platelets, promoting pathological thrombosis, in a process called heparin induced thrombocytopenia with thrombosis ('HITT'). Laboratories can assess for the presence of these antibodies using many PF4 antibody tests, including by enzyme linked immunosorbent assay (ELISA), latex immunoassay (LIA), chemiluminescence immunoassay (CLIA) and even rapid nanoparticle based lateral flow immunoassays. All these assays can identify such antibodies with high sensitivity, but methods may have variable specificity. For example, several studies have shown CLIA assays to have higher specificity to HITT than ELISA assays. Very recently, a new 'HITT-like' syndrome has been described in some individuals receiving adenovirus based COVID-19 (coronavirus disease 2019) vaccines. This condition has been given several names, including vaccine induced thrombotic thrombocytopenia (VITT) and thrombosis with thrombocytopenia syndrome (TTS), and also involves a mechanism mediated by antibodies formed against PF4. These antibodies can also be detected by PF4 antibody tests, but detection sensitivity appears to favour ELISA assays, with most other tests (including CLIA and LIA) not generally capable of detecting such antibodies. Additional functional assays assessing for PF4 mediated platelet activation may also be performed. The current review is focussed on laboratory testing for PF4 antibodies, in particular to distinguishing patterns in HITT versus VITT.

ANCA-associated vasculitis following ChAdOx1 nCoV19 vaccination: case-based review. For the foreseeable future, vaccines are the cornerstone in the global campaign against the Coronavirus Disease-19 (COVID-19) pandemic. As the number and fatalities due to COVID-19 decline and the lockdown anywise rescinded, we recognize an increase in the incidence of autoimmune disease post-COVID-19 vaccination. However, the causality of the most vaccine-induced side effects is debatable and, at best, limited to a temporal correlation. We herein report a case of a 51-year-old gentleman who developed Anti-Neutrophil Cytoplasmic Antibody (ANCA)-associated vasculitis (AAV) 2 week post-COVID-19 vaccination. The patient responded favorably to oral steroids and rituximab. Additionally, we conducted a case-based review of vaccine-associated AAV describing their clinical manifestations and treatment response of this emerging entity.

Signals of Significantly Increased Vaccine Breakthrough, Decreased Hospitalization Rates, and Less Severe Disease in Patients with Coronavirus Disease 2019 Caused by the Omicron Variant of Severe Acute Respiratory Syndrome Coronavirus 2 in Houston,Â Texas. Genetic variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) continue to dramatically alter the landscape of the coronavirus disease 2019 (COVID-19) pandemic. The recently described variant of concern designated Omicron (B.1.1.529) has rapidly spread worldwide and is now responsible for the majority of COVID-

19 cases in many countries. Because Omicron was recognized recently, many knowledge gaps exist about its epidemiology, clinical severity, and disease course. A genome sequencing study of SARS-CoV-2 in the Houston Methodist health care system identified 4468 symptomatic patients with infections caused by Omicron from late November 2021 through January 5, 2022. Omicron rapidly increased in only 3 weeks to cause 90% of all new COVID-19 cases, and at the end of the study period caused 98% of new cases. Compared with patients infected with either Alpha or Delta variants in our health care system, Omicron patients were significantly younger, had significantly increased vaccine breakthrough rates, and were significantly less likely to be hospitalized. Omicron patients required less intense respiratory support and had a shorter length of hospital stay, consistent with on average decreased disease severity. Two patients with Omicron stealth sublineage BA.2 also were identified. The data document the unusually rapid spread and increased occurrence of COVID-19 caused by the Omicron variant in metropolitan Houston, Texas, and address the lack of information about disease character among US patients.

COVID-19 vaccine-induced antibody responses in immunosuppressed patients with inflammatory bowel disease (VIP): a multicentre, prospective, case-control study. BACKGROUND: The effects that therapies for inflammatory bowel disease (IBD) have on immune responses to SARS-CoV-2 vaccination are not yet fully known. Therefore, we sought to determine whether COVID-19 vaccine-induced antibody responses were altered in patients with IBD on commonly used immunosuppressive drugs. METHODS: In this multicentre, prospective, case-control study (VIP), we recruited adults with IBD treated with one of six different immunosuppressive treatment regimens (thiopurines, infliximab, a thiopurine plus infliximab, ustekinumab, vedolizumab, or tofacitinib) and healthy control participants from nine centres in the UK. Eligible participants were aged 18 years or older and had received two doses of COVID-19 vaccines (either ChAdOx1 nCoV-19 [Oxford-AstraZeneca], BNT162b2 [Pfizer-BioNTech], or mRNA1273 [Moderna]) 6-12 weeks apart (according to scheduling adopted in the UK). We measured antibody responses 53-92 days after a second vaccine dose using the Roche Elecsys Anti-SARS-CoV-2 spike electrochemiluminescence immunoassay. The primary outcome was anti-SARS-CoV-2 spike protein antibody concentrations in participants without previous SARS-CoV-2 infection, adjusted by age and vaccine type, and was analysed by use of multivariable linear regression models. This study is registered in the ISRCTN Registry, ISRCTN13495664, and is ongoing. FINDINGS: Between May 31 and Nov 24, 2021, we recruited 483 participants, including patients with IBD being treated with thiopurines (n=78), infliximab (n=63), a thiopurine plus infliximab (n=72), ustekinumab (n=57), vedolizumab (n=62), or tofacitinib (n=30), and 121 healthy controls. We included 370 participants without evidence of previous infection in our primary analysis. Geometric mean anti-SARS-CoV-2 spike protein antibody concentrations were significantly lower in patients treated with infliximab (156Â·8 U/mL [geometric SD 5Â·7]; p<0Â·0001), infliximab plus thiopurine (111Â·1 U/mL [5Â·7]; p<0Â·0001), or tofacitinib (429Â·5 U/mL [3Â·1]; p=0Â·0012) compared with controls (1578Â·3 U/mL [3Â·7]). There were no significant differences in antibody concentrations between patients treated with thiopurine monotherapy (1019Â·8 U/mL [4Â·3]; p=0Â·74), ustekinumab (582Â·4 U/mL [4Â·6]; p=0Â·11), or vedolizumab (954Â·0 U/mL [4Â·1]; p=0Â·50) and healthy controls. In multivariable modelling, lower anti-SARS-CoV-2 spike protein antibody concentrations were independently associated with infliximab (geometric mean ratio 0Â·12, 95% CI 0Â·08-0Â·17; p<0Â·0001) and tofacitinib (0Â·43, 0Â·23-0Â·81; p=0Â·0095), but not with ustekinumab (0Â·69, 0Â·41-1Â·19; p=0Â·18), thiopurines (0Â·89, 0Â·64-1Â·24; p=0Â·50), or vedolizumab (1Â·16, 0Â·74-1Â·83; p=0Â·51). mRNA vaccines (3Â·68, 2Â·80-4Â·84; p<0Â·0001; vs adenovirus vector vaccines) were independently associated with higher antibody concentrations and older age per decade (0Â·79, 0Â·72-0Â·87; p<0Â·0001) with lower antibody concentrations. INTERPRETATION: For patients with IBD, the immunogenicity of COVID-19 vaccines varies according to immunosuppressive drug

exposure, and is attenuated in recipients of infliximab, infliximab plus thiopurines, and tofacitinib. Scheduling of third primary, or booster, doses could be personalised on the basis of an individual's treatment, and patients taking anti-tumour necrosis factor and tofacitinib should be prioritised. FUNDING: Pfizer.

Prolonged SARS-CoV-2 infection following rituximab treatment: clinical course and response to therapeutic interventions correlated with quantitative viral cultures and cycle threshold values. BACKGROUND: Detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA is completed through reverse transcriptase-PCR (RT-PCR) from either oropharyngeal or nasopharyngeal swabs, critically important for diagnostics but also from an infection control lens. Recent studies have suggested that COVID-19 patients can demonstrate prolonged viral shedding with immunosuppression as a key risk factor. CASE PRESENTATION: We present a case of an immunocompromised patient with SARS-CoV-2 infection demonstrating prolonged infectious viral shedding for 189Â days with virus cultivability and clinical relapse with an identical strain based on whole genome sequencing, requiring a multi-modal therapeutic approach. We correlated clinical parameters, PCR cycle thresholds and viral culture until eventual resolution. CONCLUSIONS: We successfully demonstrate resolution of viral shedding, administration of COVID-19 vaccination and maintenance of viral clearance. This case highlights implications in the immunosuppressed patient towards infection prevention and control that should consider those with prolonged viral shedding and may require ancillary testing to fully elucidate viral activity. Furthermore, this case raises several stimulating questions around complex COVID-19 patients around the role of steroids, effect of antiviral therapies in absence of B-cells, role for vaccination and the requirement of a multi-modal approach to eventually have successful clearance of the virus.

Serologic response following SARS-COV2 vaccination in patients with cancer: a systematic review and meta-analysis. PURPOSE: Patients with cancer have an increased risk of coronavirus disease 2019 (COVID-19) and an attenuated responses to various vaccines. This meta-analysis aims to assess the serologic response to COVID-19 vaccination in patients with cancer. METHODS: Electronic databases were systematically searched on August 1, 2021 for studies that reported the serologic response to COVID-19 vaccine in cancer patients. Random effects models were used to achieve pooled serologic response rates and odds ratios (ORs). RESULTS: We analyzed 16 observational studies with a total of 1453 patients with cancer. A majority of studies used mRNA vaccines (BNT162b2 or mRNA-1273). The proportion of patients achieving a serologic response after a single and two doses of COVID-19 vaccine were 54.2% (95% confidence interval [CI] 41.0-66.9) and 87.7% (95% CI 82.5-91.5), respectively. Patients with hematologic cancers had a lower response rate after the second dose of vaccine compared to those with solid organ cancers (63.7% vs. 94.9%), which was attributable to the low response rates associated with certain conditions (chronic lymphocytic leukemia, lymphoma) and therapies (anti-CD20, kinase inhibitors). A lower proportion of patients with cancer achieved a serologic response compared to control patients after one and two doses of vaccine (OR0.073 [95% CI 0.026-0.20] and 0.10 [95% CI 0.039-0.26], respectively). CONCLUSIONS: Patients with cancer, especially those with hematologic B-cell malignancies, have a lower serologic response to COVID-19 vaccines. The results suggest that cancer patients should continue to follow safety measures including mask-wearing after vaccination and suggest the need for additional strategies for prophylaxis.

COVID-19 vaccination in the setting of mastocytosis-Pfizer-BioNTech mRNA vaccine is safe and well tolerated.

Coronary thrombo-embolic events after Covid-19 vaccination- a single centre study. Thrombo-embolic complications after Corona virus disease-19 (COVID-19) vaccination have been previously reported. We aimed to study the coronary thrombo-embolic complications (CTE) after COVID-19 vaccination in a single centre during the initial 3 months of vaccination drive in India. All patients

admitted to our hospital between 1st March 2021 and 31st May 2021 with Acute coronary syndrome (ACS) were included. Of the 89 patients [Age 55 (47-64)y, 13f] with ACS and angiographic evidence of coronary thrombus, 37 (42%) had prior vaccination history. The timing from last vaccination dose to index event was <1, 1-2, 2-4 and >4 weeks in 9(24%), 4(11%), 15(41%) and 9 (24%) respectively. ChAdOx1 nCoV-19/AZD1222 (Covishield) was the most used vaccine- 28 (76%), while 9 (24%) had BBV152 (Covaxin). Baseline characteristics were similar in both vaccinated (VG) and non-vaccinated group (NVG), except for symptom to door time [8.5 (5.75-14) vs 14.5 (7.25-24) hrs, pÂ =Â 0.003]. Thrombocytopenia was not noted in any of the VG patients, while 2 (3.8%) of NVG patient had thrombocytopenia (pÂ =Â 0.51). The pre- Percutaneous Coronary Intervention (PCI) Thrombolysis in Myocardial Infarction (TIMI) flow was significantly lower [1 (0-3) vs2 (1-3), pÂ =Â 0.03) and thrombus grade were significantly higher [4 (2.5-5) vs 2 (1-3), pÂ =Â 0.0005] in VG. The in-hospital (2.7% vs 1.9%, pÂ =Â 1.0) and 30-day mortality were also similar (5.4% vs 5.8%, pÂ =Â 1.0). This is the first report of CTE after COVID-19 vaccination during the first 3 months of vaccination drive in India. We need further reports to identify the incidence of this rare but serious adverse events following COVID-19 vaccination.

Early assessment of the safety and immunogenicity of a third dose (booster) of COVID-19 immunization in Chinese adults. Inducing durable and effective immunity against severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) via vaccination is essential to combat the current pandemic of coronavirus disease 2019 (COVID-19). It has been noticed that the strength of anti-COVID-19 vaccination-induced immunity fades over time, which calls for an additional vaccination regime, as known as booster immunization, to restore immunity among previously vaccinated populations. Here we report a pilot open-label trial of a third dose of BBIBP-CorV, an inactivated SARS-CoV-2 vaccine (Vero cell), on 136 participants aged between 18 to 63 years. Safety and immunogenicity in terms of neutralizing antibody titers and cytokine/chemokine responses were analyzed as the main endpoint until day 28. While systemic reactogenicity was either absent or mild, SARS-CoV-2-specific neutralizing antibody titers rapidly arose in all participants within 4 weeks, surpassing the peak antibody titers elicited by the initial two-dose immunization regime. Broad increases of cellular immunity-associated cytokines and chemokines were also detected in the majority of participants after the third vaccination. Furthermore, in an exploratory study, a newly developed recombinant protein vaccine, NVSI-06-08 (CHO Cells), was found to be safe and even more effective than BBIBP-CorV in eliciting humoral immune responses in BBIBP-CorV-primed individuals. Together, these results indicate that a third immunization schedule with either homologous or heterologous vaccine showed favorable safety profiles and restored potent SARS-CoV-2-specific immunity, providing support for further trials of booster vaccination in larger populations.

A review of the safety and efficacy of current COVID-19 vaccines. Vaccination is the most effective and feasible way to contain the Coronavirus disease 2019 (COVID-19) pandemic. The rapid development of effective COVID-19 vaccines is an extraordinary achievement. This study reviewed the efficacy/effectiveness, immunogenicity, and safety profile of the 12 most progressed COVID-19 vaccines and discussed the challenges and prospects of the vaccine-based approaches in a global crisis. Overall, most of the current vaccines have shown safety and efficacy/effectiveness during actual clinical trials or in the real-world studies, indicating a development of pandemic control. However, many challenges are faced by pandemic control in terms of maximizing the effect of vaccines, such as rapid vaccine coverage, strategies to address variants with immune escape capability, and surveillance of vaccine safety in the medium- and long-terms.

Adaptive immunity and neutralizing antibodies against SARS-CoV-2 variants of concern following vaccination in patients with cancer: the CAPTURE study. Coronavirus disease 2019 (COVID-19) antiviral response in a pan-tumor immune monitoring (CAPTURE) (NCT03226886) is a prospective

cohort study of COVID-19 immunity in patients with cancer. Here we evaluated 585 patients following administration of two doses of BNT162b2 or AZD1222 vaccines, administered 12 weeks apart. Seroconversion rates after two doses were 85% and 59% in patients with solid and hematological malignancies, respectively. A lower proportion of patients had detectable titers of neutralizing antibodies (NAbT) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants of concern (VOC) versus wild-type (WT) SARS-CoV-2. Patients with hematological malignancies were more likely to have undetectable NAbT and had lower median NAbT than those with solid cancers against both SARS-CoV-2 WT and VOC. By comparison with individuals without cancer, patients with hematological, but not solid, malignancies had reduced neutralizing antibody (NAb) responses. Seroconversion showed poor concordance with NAbT against VOC. Previous SARS-CoV-2 infection boosted the NAb response including against VOC, and anti-CD20 treatment was associated with undetectable NAbT. Vaccine-induced T cell responses were detected in 80% of patients and were comparable between vaccines or cancer types. Our results have implications for the management of patients with cancer during the ongoing COVID-19 pandemic.

Safety of COVID-19 vaccination in patients with clonal mast cell disorders.

Pandemic preparedness and COVID-19: an exploratory analysis of infection and fatality rates, and contextual factors associated with preparedness in 177 countries, from Jan 1, 2020, to Sept 30, 2021. BACKGROUND: National rates of COVID-19 infection and fatality have varied dramatically since the onset of the pandemic. Understanding the conditions associated with this cross-country variation is essential to guiding investment in more effective preparedness and response for future pandemics. METHODS: Daily SARS-CoV-2 infections and COVID-19 deaths for 177 countries and territories and 181 subnational locations were extracted from the Institute for Health Metrics and Evaluation's modelling database. Cumulative infection rate and infection-fatality ratio (IFR) were estimated and standardised for environmental, demographic, biological, and economic factors. For infections, we included factors associated with environmental seasonality (measured as the relative risk of pneumonia), population density, gross domestic product (GDP) per capita, proportion of the population living below 100 m, and a proxy for previous exposure to other betacoronaviruses. For IFR, factors were age distribution of the population, mean body-mass index (BMI), exposure to air pollution, smoking rates, the proxy for previous exposure to other betacoronaviruses, population density, age-standardised prevalence of chronic obstructive pulmonary disease and cancer, and GDP per capita. These were standardised using indirect age standardisation and multivariate linear models. Standardised national cumulative infection rates and IFRs were tested for associations with 12 pandemic preparedness indices, seven health-care capacity indicators, and ten other demographic, social, and political conditions using linear regression. To investigate pathways by which important factors might affect infections with SARS-CoV-2, we also assessed the relationship between interpersonal and governmental trust and corruption and changes in mobility patterns and COVID-19 vaccination rates. FINDINGS: The factors that explained the most variation in cumulative rates of SARS-CoV-2 infection between Jan 1, 2020, and Sept 30, 2021, included the proportion of the population living below 100 m (5Â·4% [4Â·0-7Â·9] of variation), GDP per capita (4Â·2% [1Â·8-6Â·6] of variation), and the proportion of infections attributable to seasonality (2Â·1% [95% uncertainty interval 1Â·7-2Â·7] of variation). Most cross-country variation in cumulative infection rates could not be explained. The factors that explained the most variation in COVID-19 IFR over the same period were the age profile of the country (46Â·7% [18Â·4-67Â·6] of variation), GDP per capita (3Â·1% [0Â·3-8Â·6] of variation), and national mean BMI (1Â·1% [0Â·2-2Â·6] of variation). 44Â·4% (29Â·2-61Â·7) of cross-national variation in IFR could not be explained. Pandemic-preparedness indices, which aim to measure health security capacity, were not meaningfully associated with standardised infection rates or IFRs. Measures of trust in the government and interpersonal trust, as well as less government

corruption, had larger, statistically significant associations with lower standardised infection rates. High levels of government and interpersonal trust, as well as less government corruption, were also associated with higher COVID-19 vaccine coverage among middle-income and high-income countries where vaccine availability was more widespread, and lower corruption was associated with greater reductions in mobility. If these modelled associations were to be causal, an increase in trust of governments such that all countries had societies that attained at least the amount of trust in government or interpersonal trust measured in Denmark, which is in the 75th percentile across these spectrums, might have reduced global infections by 12Â·9% (5Â·7-17Â·8) for government trust and 40Â·3% (24Â·3-51Â·4) for interpersonal trust. Similarly, if all countries had a national BMI equal to or less than that of the 25th percentile, our analysis suggests global standardised IFR would be reduced by 11Â·1%. INTERPRETATION: Efforts to improve pandemic preparedness and response for the next pandemic might benefit from greater investment in risk communication and community engagement strategies to boost the confidence that individuals have in public health guidance. Our results suggest that increasing health promotion for key modifiable risks is associated with a reduction of fatalities in such a scenario. FUNDING: Bill & Melinda Gates Foundation, J Stanton, T Gillespie, J and E Nordstrom, and Bloomberg Philanthropies.

Experience of danaparoid to treat vaccine-induced immune thrombocytopenia and thrombosis, VITT. BACKGROUND: Vaccine-induced immune thrombocytopenia and thrombosis (VITT) is triggered by nCOV-19 adenovirus-vectored vaccines against SARS-CoV2. Pathogenesis has been mainly related to platelet activation via PF4-reactive antibodies that activate platelets and may cross-react with heparin. Data concerning optimal anticoagulation are anecdotal, and so far, there are scattered reports of danaparoid use in VITT management. Danaparoid has good efficacy and safety in treatment of heparin-induced thrombocytopenia. We report here our experience of the administration and monitoring danaparoid in VITT. METHODS: We diagnosed a series of six hospitalized cases of VITT, based on the international diagnostic guidance. All VITT-related data were from the local electronic medical and laboratory record system and were analyzed with IBM SPSS Statistics. RESULTS: Predominately women in their late 40's developed VITT on average 24â€‰days (range 9-59) after the first ChAdOx1 dose. Clinical presentation included single or multiple venous and/or arterial thrombosis, moderate thrombocytopenia and high D-dimer levels. After detecting PF4 antibodies subcutaneous danaparoid was our first-line antithrombotic treatment with an average duration of three weeks. The median plasma anti-FXa activity was in the lower part of the therapeutic range and during the first week of danaparoid administration clinical symptoms, platelet counts, and fibrin turnover resolved or significantly improved. The average duration of hospital admission was 10â€‰days [2-18]. One patient died but the other five patients recovered completely. CONCLUSIONS: The clinical outcomes of our small cohort align with the earlier published reports, and support danaparoid as a rational option for the initial anticoagulation of VITT patients.

No aggravation of congenital thrombotic thrombocytopenic purpura by mRNA-based vaccines against COVID-19: a Japanese registry survey.

Cognizance, adverse effects and motivation regarding COVID-19 vaccination amongst health care professionals: A cross-sectional study. BACKGROUND: Coronavirus disease 2019 (COVID-19) vaccines are currently at the forefront of India's fight against the pandemic. They have been shown to prevent the disease or reduce its severity, following 2 doses given at an interval of 6-8 weeks. OBJECTIVES: The present cross-sectional survey was carried out on 1,145 health care practitioners in order to recognize and evaluate the adverse effects of vaccination as well as knowledge, motivation and attitudes with regard to vaccines amongst the respondents after the 1st dose of vaccination. MATERIAL AND METHODS: An anonymous survey was carried out among different age and gender groups in the medical colleges situated in the state of Maharashtra, India. The participants' responses

were collected with the use of the Google Forms platform through sending a URL link to the questionnaire. The validity of the questionnaire was pilot-tested and the obtained Cronbach's alpha value was 0.80. Amongst the 1,145 participants, 92.2% of the respondents received COVISHIELDâ„¢ and 7.8% received COVAXINÂ®. The subjects were further scrutinized in 4 different age groups:18-27 years (73.0%); 28-37 years (14.8%); 38-47 years (9.6%); and above 47 years (2.5%). RESULTS: Adverse effects were common in the age group of 18-27 years and were observed significantly more frequently in females than males. A very common symptom was pain at the site of injection with an occurrence of 85.2%. Fever was present in 62.6% of the respondents, with 39.1% having low-grade fever and very few having high-grade fever. CONCLUSIONS: Knowledge about adverse effects and what to expect after vaccination would help to educate people, dispel misinformation and reduce vaccination hesitancy. It can also help to promote awareness about the incidence of adverse effects and the safety of COVID-19 vaccines.

Possible mechanisms of neuropathies associated with the COVID-19 vaccines.

Thromboembolic events following mRNA vaccines for COVID 19: a case series.

Common Variable Immunodeficiency Disorders as a Model for Assessing COVID-19 Vaccine Responses in Immunocompromised Patients.

Case Report: Cytomegalovirus Reactivation and Pericarditis Following ChAdOx1 nCoV-19 Vaccination Against SARS-CoV-2. As the coronavirus disease 2019 (COVID-19) pandemic is ongoing and new variants of severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) are emerging, there is an urgent need for vaccines to protect individuals at high risk for complications and to potentially control disease outbreaks by herd immunity. Surveillance of rare safety issues related to these vaccines is progressing, since more granular data emerge about adverse events of SARS-CoV-2 vaccines during post-marketing surveillance. Varicella zoster virus (VZV), Epstein-Barr virus (EBV) and cytomegalovirus (CMV) reactivation has already been reported in COVID-19 patients. In addition, adverse events after SARS-CoV-2 mRNA vaccination have also been in the context of varicella zoster virus (VZV) reactivation and directly associated with the mRNA vaccine. We present the first case of CMV reactivation and pericarditis in temporal association with SARS-CoV-2 vaccination, particularly adenovirus-based DNA vector vaccine ChAdOx1 nCoV-19 against SARS-CoV-2. After initiation of antiviral therapy with oral valganciclovir, CMV viremia disappeared and clinical symptoms rapidly improved. Since huge vaccination programs are ongoing worldwide, post-marketing surveillance systems must be in place to assess vaccine safety that is important for the detection of any events. In the context of the hundreds of millions of individuals to be vaccinated against SARS-CoV-2, a potential causal association with CMV reactivation may result in a considerable number of cases with potentially severe complications.

Two Patients with Schizophrenia Treated with Clozapine Developed Neutropenia After Receiving a COVID-19 Vaccine. BACKGROUND: We observed two cases of patients with schizophrenia who were treated with clozapine (250mg/day and 275mg/day, respectively) and showed neutropenia after receiving a COVID-19 vaccine (BNT162b2). CASE PRESENTATION: Case 1 is a twenty-two year old woman with a diagnosis of schizophrenia. She enrolled in Clozaril(Â®) Patient Monitoring Service in 2017 and had been taking clozapine for 4 years. She received two doses of a COVID-19 vaccine and developed neutropenia (1850/mm(3) (37.9% of white blood cell 4880/mm(3))) 6 days after the second vaccination, but her neutropenia self-resolved naturally. Case 2 is a twenty year old woman with a diagnosis of schizophrenia. She enrolled in Clozaril(Â®) Patient Monitoring Service in 2020 and had been taking clozapine for 10 months. She received two doses of a COVID-19 vaccine and white blood cell and neutrocyte counts were below (3730/mm(3) and 1440/mm(3) (38.6%), respectively) the lower limits 3 days after the second vaccination. She had to discontinue clozapine according to the withdrawal definition (her neutrocyte count was <1500/mm(3)), and her neutropenia self-

resolved naturally. CONCLUSION: Physicians need to have a strict follow-up protocol in place for patients after vaccination for COVID-19.

Simple, sensitive, specific self-sampling assay secures SARS-CoV-2 antibody signals in sero-prevalence and post-vaccine studies. At-home sampling is key to large scale seroprevalence studies. Dried blood spot (DBS) self-sampling removes the need for medical personnel for specimen collection but facilitates specimen referral to an appropriately accredited laboratory for accurate sample analysis. To establish a highly sensitive and specific antibody assay that would facilitate self-sampling for prevalence and vaccine-response studies. Paired sera and DBS eluates collected from 439 sero-positive, 382 sero-negative individuals and DBS from 34 vaccine recipients were assayed by capture ELISAs for IgG and IgM antibody to SARS-CoV-2. IgG and IgM combined on DBS eluates achieved a diagnostic sensitivity of 97.9% (95%CI 96.6 to 99.3) and a specificity of 99.2% (95% CI 98.4 to 100) compared to serum, displaying limits of detection equivalent to 23 and 10 WHO IU/ml, respectively. A strong correlation (râ€‰=â€‰0.81) was observed between serum and DBS reactivities. Reactivity remained stable with samples deliberately rendered inadequate, (pâ€‰=â€‰0.234) and when samples were accidentally damaged or 'invalid'. All vaccine recipients were sero-positive. This assay provides a secure method for self-sampling by DBS with a sensitivity comparable to serum. The feasibility of DBS testing in sero-prevalence studies and in monitoring post-vaccine responses was confirmed, offering a robust and reliable tool for serological monitoring at a population level.

Phase I interim results of a phase I/II study of the IgG-Fc fusion COVID-19 subunit vaccine, AKS-452. To address the coronavirus disease 2019 (COVID-19) pandemic caused by infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a recombinant subunit vaccine, AKS-452, is being developed comprising an Fc fusion protein of the SARS-CoV-2 viral spike protein receptor binding domain (SP/RBD) antigen and human IgG1 Fc emulsified in the water-in-oil adjuvant, Montanideâ„¢ ISA 720. A single-center, open-label, phase I dose-finding and safety study was conducted with 60 healthy adults (18-65Â years) receiving one or two doses 28Â days apart of 22.5Â Âµg, 45Â Âµg, or 90Â Âµg of AKS-452 (i.e., six cohorts, NÂ =Â 10 subjects per cohort). Primary endpoints were safety and reactogenicity and secondary endpoints were immunogenicity assessments. No AEsÂ â‰¥Â 3, no SAEs attributable to AKS-452, and no SARS-CoV-2 viral infections occurred during the study. Seroconversion rates of anti-SARS-CoV-2 SP/RBD IgG titers in the 22.5, 45, and 90Â Âµg cohorts at day 28 were 70%, 90%, and 100%, respectively, which all increased to 100% at day 56 (except 89% for the single-dose 22.5Â Âµg cohort). All IgG titers were Th1-isotype skewed and efficiently bound mutant SP/RBD from several SARS-CoV-2 variants with strong neutralization potencies of live virus infection of cells (including alpha and delta variants). The favorable safety and immunogenicity profiles of this phase I study (ClinicalTrials.gov: NCT04681092) support phase II initiation of this room-temperature stable vaccine that can be rapidly and inexpensively manufactured to serve vaccination at a global scale without the need of a complex distribution or cold chain.

COVID-19 vaccine acceptance among patients with glomerulonephritis.

Evaluation of the Autoimmunity and Preexisting Risky Conditions for Hypersensitivity Reactions to COVID-19 Vaccines. INTRODUCTION: The role of autoimmunity and other preexisting risky conditions in hypersensitivity reactions (HSRs) to COVID-19 vaccines seems unclear. The aim of the study was to investigate the autoimmunity and preexisting risky conditions in HSRs to COVID-19 vaccines. METHODS: The patients aged â‰¥18 years with a history of HSR to CoronaVac or Pfizer-BioNTech COVID-19 vaccines within 24 h in 2 tertiary centers were assessed. The patients were divided according to the type of vaccine which they showed immediate-type (<4 h) HSR to (group A1 for CoronaVac and group B1 for Pfizer-BioNTech). Equal number of subjects who did not show HSR to two doses of either CoronaVac or Pfizer-BioNTech was recruited into the study as control groups (group A2 for CoronaVac and group B2 for Pfizer-BioNTech). The autologous serum skin test (ASST)

was performed on patient and control groups. Later, the demographic, clinical, and laboratory features were compared between groups. RESULTS: A total number of 27 patients were included in the study. Subjects with chronic spontaneous urticaria (CSU) were more frequent in group B1 than in group B2 (p:0.041). In addition to CSU, the presence of HSRs to drugs was higher in group A1 than in A2 (both p:0.007). The presence of autoimmunity and autoimmune diseases, positivity of antithyroid peroxidase antibody, and ASST were less in group A2 than in A1 (p:0.015, p:0.048, p:0.048, and p:0.037). Additionally, COVID-19 infection history was less in group A2 than in A1 (p:0.037). DISCUSSION/CONCLUSION: Type IIb autoimmunity seems to play a role in immediate type HSRs to the CoronaVac vaccine as previously shown in autoimmune CSU and multidrug hypersensitivity.

Ulcers on the bilateral palate mucosa following mRNA-based vaccination for coronavirus disease 2019 (COVID-19): A case report. Severe acute respiratory syndrome coronavirus 2 has spread globally. Vaccination for coronavirus disease 2019 (COVID-19) is anticipated to reduce morbidity and mortality. However, the safety of vaccines against COVID-19 is a cause for concern and uncertainty, which leads to vaccine hesitancy. There have been some self-reported questionnaire studies regarding adverse effects after COVID-19 vaccination; however, adverse effects on the oral region are rare. In this report, we present one case of ulcers arising on the bilateral palate mucosa following COVID-19 vaccination, which was suspected to be an adverse effect of vaccination.

Safety and immunogenicity of a high-dose quadrivalent influenza vaccine administered concomitantly with a third dose of the mRNA-1273 SARS-CoV-2 vaccine in adults aged â‰¥65 years: a phase 2, randomised, open-label study. BACKGROUND: Concomitant seasonal influenza vaccination with a COVID-19 vaccine booster could help to minimise potential disruption to the seasonal influenza vaccination campaign and maximise protection against both diseases among individuals at risk of severe disease and hospitalisation. This study aimed to assess the safety and immunogenicity of concomitant administration of high-dose quadrivalent influenza vaccine (QIV-HD) and a mRNA-1273 vaccine booster dose in older adults. METHODS: This study is an ongoing, phase 2, multicentre, open-label, descriptive trial at six clinical research sites in the USA. We describe the interim results up to 21 days after vaccination (July-August, 2021). Community-dwelling adults aged 65 years and older, who were previously vaccinated with a two-dose primary schedule of the mRNA-1273 SARS-CoV-2 vaccine, were eligible for inclusion. The second dose of the primary mRNA-1273 vaccination series was required to have been received at least 5 months before enrolment in the study. Participants were randomly assigned (1:1:1) using a permuted block method stratified by site and by age group (<75 years vs â‰¥75 years), to receive concomitant administration of QIV-HD and mRNA-1273 vaccine, QIV-HD alone, or mRNA-1273 vaccine alone. Randomisation lists, generated by Sanofi Pasteur biostatistics platform, were provided to study investigators for study group allocation. Unsolicited adverse events occurring immediately, solicited local and systemic reactions up to day 8, and unsolicited adverse events, serious adverse events, adverse events of special interest, and medically attended adverse events up to day 22 were reported. Haemagglutination inhibition antibody responses to influenza A/H1N1, A/H3N2, B/Yamagata, and B/Victoria strains and SARS CoV-2 binding antibody responses (SARS-CoV-2 pre-spike IgG ELISA) were assessed at day 1 and day 22. All analyses were descriptive. The study is registered with ClinicalTrials.gov, NCT04969276. FINDINGS: Between July 16 and Aug 31, 2021, 306 participants were enrolled and randomly assigned, of whom 296 received at least one vaccine dose (100 in the coadministration group, 92 in the QIV-HD, and 104 in the mRNA-1273 group). Reactogenicity profiles were similar between the coadministration and mRNA-1273 groups, with lower reactogenicity rates in the QIV-HD group (frequency of solicited injection site reactions 86Â·0% [95% CI 77Â·6-92Â·1], 91Â·3% [84Â·2-96Â·0], and 61Â·8% [50Â·9-71Â·9]; frequency of solicited systemic reactions 80Â·0%, [70Â·8-87Â·3], 83Â·7% [75Â·1-90Â·2], and 49Â·4% [38Â·7-60Â·2], respectively). Up to day 22, unsolicited adverse events were reported for

17Â·0% (95% CI 10Â·2-25Â·8) of participants in the coadministration group and 14Â·4% (8Â·3-22Â·7) of participants in the mRNA-1273 group, and tended to be reported at a slightly lower rate (10Â·9% [5Â·3-19Â·1]) in participants in the QIV-HD group. Seven participants each reported one medically attended adverse event (three in the coadministration group, one in the QIV-HD group, and three in the mRNA-1273 group). There were no serious adverse events, adverse events of special interest, or deaths. Haemagglutination inhibition antibody geometric mean titres increased from day 1 to day 22 to similar levels in the coadministration and QIV-HD groups, for each influenza strain (A/H1N1: 363 [95% CI 276-476] vs 366 [272-491]; A/H3N2: 286 [233-352] vs 315 [257-386]; B/Yamagata: 429 [350-525] vs 471 [378-588]; B/Victoria: 377 [325-438] vs 390 [327-465] for the coadministration and QIV-HD groups, respectively). SARS-CoV-2 binding antibody geometric mean concentrations also increased to similar levels in the coadministration and mRNA-1273 groups at day 22 (7634 [95% CI 6445-9042] and 7904 [6883-9077], respectively). INTERPRETATION: No safety concerns or immune interference were observed for concomitant administration of QIV-HD with mRNA-1273 booster in adults aged 65 years and older, supporting co-administration recommendations. FUNDING: Sanofi Pasteur.

Predictive factors of a viral neutralizing humoral response after a third dose of COVID-19 mRNA vaccine. Kidney transplant recipients (KTRs) have reduced ability to mount adequate antibody response after two doses of the COVID-19Â mRNA vaccine. French health authorities have allowed a third booster dose (D3) for KTRs, but their response is heterogeneous and tools able to discriminate the responders are lacking. Anti-RBD IgG titers (chemiluminescence immunoassay), spike-specific cellular responses (IFN-Î³-releasing assay, IGRA), and in vitro serum neutralization of the virus (the best available correlate of protection), were evaluated 7-14Â days after the second dose (D2) of BNT162b2 vaccine in 93Â KTRs. Among the 73Â KTRs, whose serum did not neutralize SARS-CoV-2 in vitro after D2, 14 (19%) acquired this capacity after D3, and were considered as "responders." Exploratory univariate analysis identified short time from transplantation and high maintenance immunosuppression as detrimental factors for the response to D3. In addition, any of the presence of anti-RBD IgGs and/or positive IGRA after D2 was predictive of response to D3. By contrast, none of the KTRs with both a negative serology and IGRA responded to D3. In summary, routinely available bioassays performed after D2 allow identifying KTRs that will respond to a booster D3. These results pave the way for the personalization of vaccination strategy in KTRs.

Most anti-PF4 antibodies in vaccine-induced immune thrombotic thrombocytopenia are transient. Vaccine-induced thrombotic thrombocytopenia (VITT) is triggered by vaccination against COVID-19 with adenovirus vector vaccines (ChAdOx1 nCoV-19; Ad26.COV2-S). In this observational study, we followed VITT patients for changes in their reactivity of platelet-activating antiplatelet factor 4 (PF4) immunoglobulin G (IgG) antibodies by an anti-PF4/heparin IgG enzyme immunoassay (EIA) and a functional test for PF4-dependent, platelet-activating antibodies, and new thrombotic complications. Sixty-five VITT patients (41 females; median, 51 years; range, 18-80 years) were followed for a median of 25 weeks (range, 3-36 weeks). In 48/65 patients (73.8%; CI, 62.0% to 83.0%) the functional assay became negative. The median time to negative functional test result was 15.5 weeks (range, 5-28 weeks). In parallel, EIA optical density (OD) values decreased from median 3.12 to 1.52 ($P < .0001$), but seroreversion to a negative result was seen in only 14 (21.5%) patients. Five (7.5%) patients showed persistent platelet-activating antibodies and high EIA ODs for >11 weeks. None of the 29 VITT patients who received a second vaccination dose with an mRNA COVID-19 vaccine developed new thromboses or relevant increase in anti-PF4/heparin IgG EIA OD, regardless of whether PF4-dependent platelet-activating antibodies were still present. PF4-dependent platelet-activating antibodies are transient in most patients with VITT. VITT patients can safely receive a second COVID-19 mRNA-vaccine shot.

Retinal vein occlusion following COVID-19 vaccination.
ACE inhibitors-An effective treatment for hyaluronic acid soft tissue filler delayed inflammatory reaction following COVID-19 vaccination.
HIV and SARS-CoV-2 Co-infection: Epidemiological, Clinical Features, and Future Implications for Clinical Care and Public Health for People Living with HIV (PLWH) and HIV Most-at-Risk Groups. PURPOSE OF REVIEW: The purpose of this review is to use the currently available clinical and epidemiological data, to identify key aspects to improve both the clinical management and public health response to SARS-CoV-2/HIV co-infection among HIV vulnerable populations and people living with HIV (PLWH). RECENT FINDINGS: While at the beginning of the COVID-19 pandemic, the lack of robust information on SARS-CoV-2/HIV co-infection, prevented a clear picture of the synergies between them, currently available data strongly support the importance of common structural factors on both the acquisition and clinical impact of these infections and the relevance of age, comorbidities, and detectable HIV viral load as associated worse prognostic factors among PLWH. Although more information is needed to better understand the biological, clinical, and epidemiological relationship between both infections, a syndemic approach to prevent SARS-CoV-2 among HIV high-risk groups and PLWH, targeting these populations for SARS-CoV-2 vaccines and protocolizing early identification of PLWH with worse COVID-19 prognosis factors, is crucial strategies to decrease the overall impact of SARS-CoV-2 /HIV co-infection.
Acute interstitial nephritis following SARS-CoV-2 virus vaccination. A number of reports have described new onset or relapse of existing glomerular disease after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. More and more of these cases continue to emerge, and the European Medicines Agency (EMA) has recently launched an in-depth investigation to ascertain the true frequency of such renal side effects. In comparison, acute interstitial nephritis after SARS-CoV-2 vaccination has only been described in 1 solitary case. Here, we describe a case of acute kidney injury due to biopsy-proven acute interstitial nephritis soon after SARS-CoV-2 vaccination with the Astra-Zeneca vaccine. The patient responded well to steroids, although he required temporary renal replacement therapy. A thorough medical history failed to elucidate any plausible explanation or trigger other than the preceding vaccination. We acknowledge the possibility that other factors could have triggered acute interstitial nephritis in the case described here. Similar uncertainty exists regarding glomerular disease reported in conjunction with SARS-CoV-2 vaccination. However, we note that acute interstitial nephritis associated with vaccination has been described before the pandemic, and we therefore feel that a link is possible. We suggest that nephrologists should be vigilant when they see cases of unexplained acute interstitial nephritis. A history of preceding SARS-CoV-2 vaccination should be explored, and cases should be reported within national systems of pharmacovigilance.
Association of COVID-19 vaccination with herpes zoster: a systematic review and meta-analysis. BACKGROUND: Following COVID-19 vaccination, several herpes zoster cases have been reported, making it critical to explore the association between herpes zoster and COVID-19 vaccination. This is especially true in the context of increasing the number of participants enrolled to receive COVID-19 vaccination. RESEARCH DESIGN AND METHODS: Three databases, including the Cochrane Library, PubMed, and EMBASE, were searched for relevant studies before 25 December 2021 according to preliminarily determined inclusion and exclusion criteria without any language limitations. Four cohort studies were included in this systematic review and meta-analysis. RESULTS: Compared with the placebo group, there was no evidence that the COVID-19 vaccination group was associated with increased incidence of herpes zoster (Risk ratio [RR]: 1.06; 95% confidence interval [CI]: 0.91 to 1.24). There is no evidence that the COVID-19 vaccination from Moderna is associated with the incidence of

herpes zoster compared with vaccination from Pfizer (RR: 0.20; 95% CI: 0.01 to 2.99). CONCLUSIONS: To date, there is no evidence of an association between covid-19 vaccination and herpes zoster.

Comparison of immune responses induced by two or three doses of an alum-adjuvanted inactivated SARS-CoV-2 vaccine in mice. Waning antibodies and rapidly emerging variants are challenges for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine development. Adjusting existing immunization schedules and further boosting strategies are under consideration. Here, the immune responses induced by an alum-adjuvanted inactivated SARS-CoV-2 vaccine in mice were compared among immunization schedules with two or three doses. For the two-dose schedule, a 0-28-day schedule induced 5-fold stronger spike-specific IgG responses than a 0-14-day schedule, with only a slight elevation of spike-specific cellular immunity 14 days after the last immunization. A third homologous boost 2 or 5 months after the second dose for the 0-28-day schedule slightly strengthened humoral responses (1.3-fold for the 0-1-3-month schedule, and 1.8-fold for the 0-1-6-month schedule) 14 days after the last immunization. Additionally, a third homologous boost (especially with the 0-1-3-month schedule) induced significantly stronger cell-mediated immunity than both two-dose immunization schedules for all indexes tested, with a response similar to that induced by a one-dose heterologous boost with BNT162b2 in clinical trials, according to cellular immunity analysis (1.5-fold). These T cell responses were Th2 oriented, with good CD4+ and CD8+ memory. These results may offer clues for applying a homologous boosting strategy for alum-adjuvanted inactivated SARS-CoV-2 vaccines.

New-onset giant cell arteritis following COVID-19 mRNA (BioNTech/Pfizer) vaccine: a double-edged sword?

Case Report: Associated Ocular Adverse Reactions With Inactivated COVID-19 Vaccine in China. The vaccine is still the best clinical measure for effective prevention and control of coronavirus disease 2019 (COVID-19). The vaccine-associated ocular adverse reactions should be noted in detail among the medical community. We reported twelve eyes of 9 patients presented at the Department of Ophthalmology, Qilu Hospital of Shandong University from March to August 2021 with ocular complaints following COVID-19 vaccination. The main inclusion criterion was the development of ocular symptoms within 14 days after receiving a dose of an inactivated COVID-19 vaccine. The mean (SD) age was 44.7 Â± 16.5 years (range, 19-78 years), among which seven (77.8%) cases were women. The mean time of ocular adverse events was 7.1 days (range, 1-14 days) after receiving the inactivated COVID-19 vaccine. One patient was diagnosed with choroiditis, 1 with uveitis, 4 with keratitis, 1 with scleritis, 1 with acute retinal necrosis, and 1 with iridocyclitis. Although the causal relationship between vaccines and ocular adverse events cannot be established from this case series report, physicians should pay attention to the ocular adverse reactions following the COVID-19 vaccine administration.

Challenges in Establishing Vaccine Induced Herd Immunity through Age Specific Community Vaccinations. Presently, the second wave of COVID-19 pandemic is driving the world towards a devastating total failure of the healthcare system. The purpose of the review is to search for the studies reporting on the implication of herd immunity into a naÃ¯ve population through age specific mass vaccination. This review is based on selected publications on the effect herd immunity to COVID 19 in communities. We searched published scientific articles, review articles, reports, published in 2020 as well as read some basic, cult publications related to establishment of indirect immunity to a population. We have focused on use of application of vaccine induced herd immunity into community to confer indirect immunity against COVID-19 and searched on electronic databases, including PubMed (http://www.pubmed.com), Scopus (http://www.scopus.com), Google Scholar (http://www.scholar.google.com), Web of Science (www.webofscience.com) and Science Direct by using key words such as Herd immunity, indirect or passive immunization, Coronavirus disease 2019

(COVID-19), severe acute respiratory syndrome, coronavirus 2 (SARS-CoV-2), and immune-technique. This review proposes the implication of mass vaccination-induced herd immunity in a population to curb the infection, and to every individual in a given population irrespective of their age.
B- and T-Cell Responses After SARS-CoV-2 Vaccination in Patients With Multiple Sclerosis Receiving Disease Modifying Therapies: Immunological Patterns and Clinical Implications. BACKGROUND: Vaccination campaign to contrast the spread of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) has raised the issue of vaccine immunogenicity in special populations such as people with multiple sclerosis (PwMS) on highly effective disease modifying treatments (DMTs). While humoral responses to SARS-CoV-2 mRNA vaccines have been well characterized in the general population and in PwMS, very little is known about cell-mediated responses in conferring protection from SARS-CoV-2 infection and severe coronavirus disease-2019 (COVID-19). METHODS: PwMS on ocrelizumab, fingolimod or natalizumab, vaccinated with two doses of mRNABNT162b2 (Comirnaty(Â®)) vaccine were enrolled. Anti-Spike (S) and anti-Nucleoprotein (N) antibody titers, IFN-gamma production upon S and N peptide libraries stimulation, peripheral blood lymphocyte absolute counts were assessed after at least 1 month and within 4 months from vaccine second dose administration. A group of age and sex matched healthy donors (HD) were included as reference group. Statistical analysis was performed using GraphPad Prism 8.2.1. RESULTS: Thirty PwMS and 9 HDs were enrolled. All the patients were negative for anti-N antibody detection, nor reported previous symptoms of COVID-19. Peripheral blood lymphocyte counts were assessed in PwMS showing: (i) reduction of circulating B-lymphocytes in PwMS on ocrelizumab; (ii) reduction of peripheral blood B- and T-lymphocyte absolute counts in PwMS on fingolimod and (iii) normal B- and T-lymphocyte absolute counts with an increase in circulating CD16+CD56+ NK-cells in PwMS on natalizumab. Three patterns of immunological responses were identified in PwMS. In patients on ocrelizumab, anti-S antibody were lacking or reduced, while T-cell responses were normal. In patients on fingolimod both anti-S titers and T-cell mediated responses were impaired. In patients on natalizumab both anti-S titers and T-cell responses were present and comparable to those observed in HD. CONCLUSIONS: The evaluation of T-cell responses, anti-S titers and peripheral blood lymphocyte absolute count in PwMS on DMTs can help to better characterize the immunological response after SARS-CoV-2 vaccination. The evaluation of T-cell responses in longitudinal cohorts of PwMS will help to clarify their protective role in preventing SARS-CoV-2 infection and severe COVID-19. The correlation between DMT treatment and immunological responses to SARS-CoV-2 vaccines could help to better evaluate vaccination strategies in PwMS.
IgA Nephropathy with Gross Hematuria Following COVID-19 mRNA Vaccination. A 28-year-old woman experienced gross hematuria after the administration of the second dose of an messenger ribonucleic acid (mRNA) vaccine (BNT162b2). She was diagnosed with Immunogloblin A nephropathy (IgAN) by a renal biopsy two weeks after vaccination, which revealed a mild increase in mesangial cells and a matrix with co-depositions of galactose-deficient IgA1 and C3 in the mesangial region. The gross hematuria and proteinuria gradually improved without any medication, suggesting that immune activation by the mRNA vaccine may not elicit continuous disease progression of IgAN. Thus, further studies investigating the relationship between mRNA vaccines against COVID-19 and the progression of IgAN should be conducted.
Breakthrough infection after three doses of COVID-19 mRNA vaccine in systemic autoimmune rheumatic diseases: two cases in patients on TNF inhibitor monotherapy.
The Impact of Vaccination on Incidence and Outcomes of SARS-CoV-2 Infection in Patients with Kidney Failure in Scotland. BACKGROUND: Patients with kidney failure requiring KRT are at high risk of complications and death following SARS-CoV-2 infection, with variable antibody responses to vaccination reported. We investigated the effects of COVID-19 vaccination on the incidence of

infection, hospitalization, and death from COVID-19 infection. METHODS: The study design was an observational data linkage cohort study. Multiple health care datasets were linked to ascertain all SARS-CoV-2 testing, vaccination, hospitalization, and mortality data for all patients treated with KRT in Scotland from the start of the pandemic over a period of 20 months. Descriptive statistics, survival analyses, and vaccine effectiveness were calculated. RESULTS: As of September 19, 2021, 93% (n=5281) of the established KRT population in Scotland had received two doses of an approved SARS-CoV-2 vaccine. Over the study period, there were 814 cases of SARS-CoV-2 infection (15.1% of the KRT population). Vaccine effectiveness rates against infection and hospitalization were 33% (95% CI, 0 to 52) and 38% (95% CI, 0 to 57), respectively. Within 28 days of a SARS-CoV-2-positive PCR test, 9.2% of fully vaccinated individuals died (7% patients on dialysis and 10% kidney transplant recipients). This compares to <0.1% of the vaccinated general Scottish population admitted to the hospital or dying due to COVID-19 during that period. CONCLUSIONS: These data demonstrate that a primary vaccine course of two doses has limited effect on COVID-19 infection and its complications in patients with KRT. Adjunctive strategies to reduce risk of both COVID-19 infection and its complications in this population are urgently required.
Reversible radiculomyelitis after ChAdOx1 nCoV-19 vaccination. Adverse events occurring after SARS-CoV-2 vaccination have been reported and are the subject of ongoing research. We present the case of a young woman with fully reversible radiculomyelitis, which happened after the first dose of the ChAdOx1 nCOVID-19 vaccine. A previously healthy woman in her 20s presented with a subacute onset of legs' weakness and sensory disturbances, urinary dysfunction and cramping pain after receiving the first dose of the ChAdOx1 nCoV-19 vaccine. A diagnostic workup led to the diagnosis of inflammatory radiculomyelitis. Her clinical status improved, with complete recovery after a few months. The case described a reversible radiculomyelitis associated with the ChAdOx1 nCOVID-19 vaccine. The clinical picture and evolution supported the diagnosis. No other identifiable causes of myelopathy were found. Our patient showed clinically moderate symptoms and signs, showing good recovery. The post-vaccine inflammatory radiculomyelitis is a rare side effect of the anti-COVID-19 vaccination, and it should not discourage the SARS-CoV-2 vaccination programme.
Renal side effects of COVID-19 vaccines in patients with immunoglobulin A nephropathy.
Safety and efficacy of the COVID-19 vaccine in children and/or adolescents:A meta-analysis.
New-onset class III lupus nephritis with multi-organ involvement after COVID-19 vaccination.
Investigating potential mechanisms underlying FVIII inhibition in acquired hemophilia A associated with mRNA COVID-19 vaccines.
Pemphigus vulgaris relapse during the coronavirus disease pandemic. Pemphigus vulgaris (PV) is the most common type of pemphigus group of autoimmune skin diseases. The treatment of PV relapse is challenging especially during the coronavirus disease (COVID-19) pandemic. In this prospective study, we aimed to evaluate the treatment of patients with relapsing PV during the pandemic. Twelve patients with PV who experienced relapse from March 2020 to January 2022 were included. The patients were asked whether they experienced COVID-19 symptoms and the pemphigus disease area index (PDAI) was measured. PCR for COVID-19, chest computed tomography, routine investigations, and electrocardiography were performed for the admitted patients. The mean PDAI of the patients during relapse was 23.6Â Â±â€‰14.8 (range 5-60). Seven patients received azathioprine; one patient received mycophenolate mofetil; and six patients received 1000â€‰mg of rituximab (RTX) twice at an interval of 14â€‰days. None of the 12 patients had COVID-19-suggestive symptoms. Only 1 patient relapsed after receiving the COVID-19 vaccine. The six admitted patients who received RTX were negative for COVID-19 based on the PCR testing results. Out of the 12 patients, eight achieved complete remission, while four achieved partial remission. No major adverse effects were observed. In conclusion, the treatments with systemic steroids, immunosuppressive

drugs, and rituximab were well tolerated by the patients with relapsing PV, provided that there was no contact with individuals with COVID-19. These treatments can then be provided to patients with PV during the pandemic with careful follow-up.

mRNA Covid-19 vaccines in pregnancy: A systematic review. OBJECTIVE: Pregnancy is a known risk factor for severe Coronavirus disease 2019. It is important to develop safe vaccines that elicit strong maternal and fetal antibody responses. METHODS: Registries (ClinicalTrials.gov, the WHO Clinical Trial Registry, and the European Union Clinical Trial Registry) and databases (MEDLINE, ScienceDirect, Cochrane Library, Proquest, Springer, medRxiv, and bioRxiv) were systematically searched in June 20-22, 2021, for research articles pertaining to Covid-19 and pregnancy. Manual searches of bioRxiv and medRxiv were also conducted. Inclusion criteria were studies that focused on Covid-19 vaccination among pregnant women, while review articles and non-human studies were excluded. Infection rate, maternal antibody response, transplacental antibody transfer, and adverse events were described. RESULTS: There were 13 observational studies with a total of 48,039 pregnant women who received mRNA vaccines. Of those, three studies investigated infection rate, six studies investigated maternal antibody response, seven studies investigated antibody transfer, three studies reported local adverse events, and five studies reported systemic adverse events. The available data suggested that the mRNA-based vaccines (Pfizer-BioNTech and Moderna) can prevent future SARS-CoV-2 infection. These vaccines did not show clear harm in pregnancy. The most commonly encountered adverse reactions were pain at the injection site, fatigue, and headache, but these were transient. Antibody responses were rapid after the first vaccine dose. After the booster, antibody responses were stronger and associated with better transplacental antibody transfer. Longer intervals between first vaccination dose and delivery were also associated with higher antibody fetal IgG and a better antibody transfer ratio. CONCLUSIONS: The SARS-CoV-2 mRNA vaccines are encouraged for pregnancy. These vaccines can be a safe option for pregnant women and their fetuses. Two vaccine doses are recommended for more robust maternal and fetal antibody responses. Longer latency is associated with higher fetal antibody responses. Further research about its long-term effect on pregnancy is needed. SYSTEMATIC REVIEW REGISTRATION: PROSPERO (CRD42021261684).

Immune Thrombocytopenia (ITP): Relapse Versus de novo After COVID-19 Vaccination.

Safety and antibody response to inactivated COVID-19 vaccine in patients with chronic hepatitis B virus infection. BACKGROUND AND AIMS: The safety and antibody responses of coronavirus disease 2019 (COVID-19) vaccination in patients with chronic hepatitis B (CHB) virus infection is still unclear, and exploration in safety and antibody responses of COVID-19 vaccination in CHB patients is significant in clinical practice. METHODS: 362 adult CHB patients and 87 healthy controls at an interval of at least 21 days after a full-course vaccination (21-105Â days) were enrolled. Adverse events (AEs) were collected by questionnaire. The antibody profiles at 1, 2 and 3Â months were elucidated by determination of anti-spike IgG, anti-receptor-binding domain (RBD) IgG, and RBD-angiotensin-converting enzyme 2 blocking antibody. SARS-CoV-2 specific B cells were also analysed. RESULTS: All AEs were mild and self-limiting, and the incidence was similar between CHB patients and controls. Seropositivity rates of three antibodies were similar between CHB patients and healthy controls at 1, 2 and 3Â months, but CHB patients had lower titers of three antibodies at 1Â month. Compared to healthy controls, HBeAg-positive CHB patients had higher titers of three antibodies at 3Â months (all PÂ <Â .05) and a slower decline in antibody titers. Frequency of RBD-specific B cells was positively correlated with titers of anti-RBD IgG (ORÂ =Â 1.067, PÂ =Â .004), while liver cirrhosis, antiviral treatment, levels of HBV DNA, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) and total bilirubin (TB) were not correlated with titers of anti-RBD IgG. CONCLUSIONS: Inactivated COVID-19 vaccines were well tolerated, and induced effective antibody response against SARS-CoV-2 in CHB patients.

Alopecia areata following COVID-19 vaccination: vaccine-induced autoimmunity?
Myocarditis following rAd26 and rAd5 vector-based COVID-19 vaccine: case report. SARS-CoV-2 vaccines provide a safe solution with a major impact on reducing the spread of the virus and mild side effects. Research has shown rare cases of myocarditis after mRNA vaccines. This study presents a 29-year-old male with chest pain after 48Â h of receiving rAd26 and rAd5 vector-based COVID-19 vaccine (Sputnik V vaccine). The electrocardiogram revealed ST-segment elevation. Also, the laboratory screening was remarkable for elevated cardiac Troponin-I level, and leukocytosis; and echocardiography depicted severe left ventricular systolic dysfunction. Overall, endomyocardial biopsy proved lymphocytic myocarditis such that the patient was successfully treated with immunosuppressive and guideline-directed medical treatment.
SARS-CoV-2 breakthrough infection and viral load among healthcare workers after COVID-19 vaccines.
Immunogenicity and safety of the BNT162b2 COVID-19 mRNA vaccine in PLWH: A monocentric study in Bari, Italy. In March, people living with HIV infection (PLWH) were included in the risk category of fragile people for severe COVID-19 receiving priority access to vaccination with BNT162b2 vaccine. The aim of the study was to evaluate the immunogenicity and safety of the two doses regimen. The antibodies titer for severe acute respiratory syndrome-related coronavirus-2 (SARS-CoV-2) was evaluated after 21 days since the first administration (Time 1),Â 1 (Time 2),Â and 3 (Time 3) months post-vaccination. Information regarding virological and immunological conditions at baseline, previous SARS-CoV-2 state of infection, other immunodeficiencies, current antiretroviral therapy (ART), comorbidities, and severe adverse events (SAE) to vaccination was collected. Six hundred and ninety-sevenÂ patients were tested for quantitative anti-spike antibodies at Time 1, 577 patients had a second detection at Time 2,Â and 491 patients had the third detection. Baseline characteristics of the study population are reported in Table 1. At the time of vaccine administration, all patients were on ART (except one long-term nonprogressor); 632 (90.7%) patients had undetectable HIV-RNA; 12 (1.7%) patients were immunosuppressed due to chemotherapy or other immunosuppressive drugs; 345 (49.5%) patients had at least one COVID-19 related comorbidity and 155 (22.2%) had two or more comorbidities. No SAEs were reported. Final serological results are available for 694 patients after the first dose, 577 and 491 after the second and third ones, respectively; positive titer (valuesâ€‰â‰¥â€‰50â€‰AU/ml) was demonstrated in 653 (94.1%), 576 (99.8%), 484 (98.6%) patients, respectively. Only one patient was a nonresponder after completing vaccination, who was a newly diagnosed one for HIV infection. All vaccinations were well tolerated, with no SAEs. BNT162b2 mRNA vaccine was immunogenic and safe in PLWH.
Cutaneous polyarteritis nodosa following ChAdOx1 nCoV-19 vaccination.
B-cell cytopenia and time to last B-cell-depleting therapy predict response to SARS-COV-2 vaccines in patients with lymphoproliferative disorders. Patients with B-non-Hodgkin lymphoma (NHL) are at increased risk of morbidity and mortality from SARS-CoV-2. We investigated the relationship between B cell cytopenia and the SARS-CoV-2 vaccine response in B-NHL patients. We measured anti-RBD antibodies and the lymphocyte immunophenotype in 19 controls, 22 lymphoma patients on observation (cohort 1) and 55 lymphoma patients receiving their vaccines post B-cell depleting therapy (cohort 2). Half of the lymphoma patients in both cohorts achieved seropositivity compared to 100% of controls. In cohort 2, only 5% achieved an antibody response in the first year post B-cell depleting treatment, vs 88% treated >2Â years prior. Also, 28% of patients with <50 B cells/Âµl achieved a serologic response vs 86% of patients with B-cell >50 B cells/Âµl. B-cell cytopenia is profound within the first year of exposure to B-cell depleting treatment, therefore an additional dose of vaccine within that timeframe is unlikely to raise antibody levels.

Incidence, Clinical Presentation, and Management of Myocarditis following mRNA-Based Covid-19 Vaccines: A Brief Report. BACKGROUND: Recent surveillance studies following nationwide mass vaccination are investigating rare complications such as myocarditis, pericarditis, and thromboembolic events related to mRNA-based Covid-19 vaccines. SUMMARY: In the current report, we present an overview of the incidence, clinical presentation and management of post-mRNA vaccine myocarditis, and pericarditis in view of the currently available data. Our main focus is directed toward myocarditis. KEY MESSAGES: Myocarditis following mRNA-based Covid-19 vaccines is rare, more frequently affects younger men <30 years and is usually of mild severity with spontaneous recovery. The overall benefit of mRNA vaccines in terms of protecting from severe Covid-19 infection and associated cardiovascular complications outweighs the risk of postvaccination myocarditis. Currently, there are no dedicated guidelines for patients with postvaccination myocarditis or pericarditis in terms of the frequency of follow-up including clinical assessment, repeated echocardiography, and cardiac resonance imaging. However, follow-up studies in terms of long-term consequences are underway.

Antibody response following SARS-CoV-2 vaccination among patients with type 2 diabetes mellitus: A systematic review. BACKGROUND AND AIM: DM patients' antibody response after the COVID-19 vaccine is still unknown amid the COVID-19 vaccination rollout. This study aimed to explore the SARS-CoV-2 antibody response or seropositivity among DM patients following the COVID-19 vaccine administration. METHODS: We performed a systematic review of the literature consisting of observational or cross-sectional studies, which reported the antibody serology or seropositivity among DM patients by following the PRISMA 2020 guidelines. RESULTS: Eight studies with a total of 64468 patients were identified, and 5156 (7.9%) of them had diabetes. Most studies showed that antibody response and seropositivity in DM patients were lower than healthy population after one until four weeks following full COVID-19 vaccination dose. CONCLUSION: The antibody response and seropositivity after the COVID-19 vaccine in DM patients were lower than in healthy subjects. Therefore, DM patients are expected to receive vaccines according to the dose and schedule appropriately and might be prioritized to receive vaccine boosters.

Preparation for COVID-19 vaccines rollout: Interventions to increase trust, acceptability, and uptake in West African countries. INTRODUCTION: The approval of COVID-19 vaccines for use has come as a relief to West Africa and world. However, concerns raised about the vaccines in America and Europe have created anxiety among some citizens in Africa. These concerns are likely to affect the acceptance, and uptake of the COVID-19 vaccines in West Africa. METHODS: Guided by the principles of effective community engagement, this research reviewed typical case studies of past vaccination exercises to document concerns, challenges and lessons learnt. These were then used to propose pre-immunisation interventions in West Africa to increase the COVID-19 vaccines acceptance and uptake. RESULTS: Concerns about safety can undermine the rollout of the COVID-19 vaccines. These concerns can be addressed through effective community engagement. Community leaderships could be engaged through courtesy calls, workshops and durbars to sensitise them on immunisation. Engaging the scientific community can help build trust and reduce concerns about vaccine safety. In vaccines rollout, managing misinformation is important and the media can play a critical role in addressing these in their reportage. In addition, social media is an effective monitoring tool for vaccine-related misinformation. CONCLUSION: The analysis underscores the need for more community engagement before the importation and deployment of COVID-19 vaccines in West Africa. Experiences from community responses to previous vaccination exercises for emerging and remerging infectious diseases should inform the current efforts and enhance the process to achieve high uptake and reduce vaccine hesitancy.

COVID-19 vaccine, myocardial infarction and Kounis syndrome.

Neutralizing Antibodies and Cytokines in Breast Milk After Coronavirus Disease 2019 (COVID-19) mRNA Vaccination. OBJECTIVE: To evaluate immune responses to coronavirus disease 2019 (COVID-19) mRNA-based vaccines present in breast milk and transfer of the immune responses to breastfeeding infants. METHODS: We enrolled 30 lactating women who received mRNA-based COVID-19 vaccines from January through April 2021 in this cohort study. Women provided serial milk samples, including milk expressed before vaccination, across 2-3 weeks after the first dose, and across 3 weeks after the second dose. Women provided their blood, spotted on cards (dried blood spots), 19 days after the first dose and 21 days after the second dose. Stool samples from the breastfed infants were collected 21 days after mothers' second vaccination. Prepandemic samples of milk, dried blood spots, and infant stool were used as controls. Milk, dried blood spots, and infant stool were tested by enzyme-linked immunosorbent assay for receptor-binding domain (RBD)-specific immunoglobulin (Ig)A and IgG. Milk samples were tested for the presence of neutralizing antibodies against the spike and four variants of concern: D614G, Alpha (B.1.1.7), Beta (B.1.351), and Gamma (P.1). Levels of 10 cytokines were measured in milk samples. RESULTS: Milk from COVID-19-immunized women neutralized the spike and four variants of concern, primarily driven by anti-RBD IgG. The immune response in milk also included significant elevation of interferon-Î³. The immune response to maternal vaccination was reflected in breastfed infants: anti-RBD IgG and anti-RBD IgA were detected in 33% and 30% of infant stool samples, respectively. Levels of anti-RBD antibodies in infant stool correlated with maternal vaccine side effects. Median antibody levels against RBD were below the positive cutoffs in prepandemic milk and infant stool samples. CONCLUSION: Humoral and cellular immune responses to mRNA-based COVID-19 vaccination are present in most women's breast milk. The milk anti-RBD antibodies can neutralize severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike and variants of concern. Anti-RBD antibodies are transferred to breastfed infants, with the potential to confer passive immunity against SARS-CoV-2.

Prevalence of Common Infectious Diseases After COVID-19 Vaccination and Easing of Pandemic Restrictions in Israel. IMPORTANCE: Social restrictions intended to limit the transmission of SARS-CoV-2 may have also been associated with decreased rates of other communicable diseases. Evidence suggests that infection incidence rates (IRs) are rebounding after easing of social restrictions (eg, mask mandates). The reemergence of infectious disease complicates efforts to manage the ongoing COVID-19 pandemic. OBJECTIVE: To examine IRs of frequently occurring infectious diseases after a successful SARS-CoV-2 vaccination campaign in Israel and cessation of social restrictions. DESIGN, SETTING, AND PARTICIPANTS: This cross-sectional study was conducted using records for respiratory and gastrointestinal infectious diseases at 209 community clinics in southern Israel from 2017 to 2021. Included patients attended community clinics from January 1, 2017, to June 30, 2021. EXPOSURES: Incidence of infectious diseases was estimated in the first 3 months after the easing of social restrictions (ie, April-June 2021) across age groups. MAIN OUTCOMES AND MEASURES: Age-specific and disease-specific weekly IRs per 100â€¯000 population for April to June were compared between 2017 and 2021 and expected current IR was estimated using segmented linear regression. Growth rates of respiratory infections across years and weekly diagnoses detected by real-time polymerase chain reaction testing were also compared. RESULTS: Among 386â€¯711 patients with a total of 1â€¯221â€¯568 visits to community clinics, the mean (SD) age was 27.29 (23.93) years, and there were 202â€¯494 (52.3%) male patients and 184â€¯217 (47.7%) female patients. Children aged 0 to 3 years had significantly increased rates of respiratory and gastrointestinal infection diagnoses (IR ratio, 2.64; 95% CI, 2:30-2.91; Pâ€‰<â€‰.001). In addition, incidence of non-SARS-CoV-2 respiratory infections were significantly increased across age groups (IR ratio, 1.74; 95% CI, 1.56-1.94; Pâ€‰<â€‰.001). CONCLUSIONS AND RELEVANCE: These morbidity trends observed in Israel suggest

that similar trends could occur in coming months in other countries after easing of COVID-19-related restrictions, particularly with the ongoing challenges of SARS-CoV-2 variants.

Association of AZD1222 and BNT162b2 COVID-19 Vaccination With Thromboembolic and Thrombocytopenic Events in Frontline Personnel : A Retrospective Cohort Study. BACKGROUND: In March 2021, several European countries suspended the use of the AZD1222 (Oxford-AstraZeneca) COVID-19 vaccine because of thromboembolic safety concerns. Reports from Norway and Germany subsequently described patients with venous thrombosis and thrombocytopenia within 5 to 16 days of vaccination. OBJECTIVE: To evaluate the risk for outcomes related to thrombosis and thrombocytopenia after AZD1222 or BNT162b2 (Pfizer-BioNTech) COVID-19 vaccination. DESIGN: Nationwide exploratory retrospective cohort study. SETTING: Danish linkable registers on vaccinations, hospitalizations, occupation, and other covariates. PARTICIPANTS: 355Â 209 Danish frontline personnel designated for priority COVID-19 vaccination followed from 27 December 2020 (the day of the first COVID-19 vaccination in Denmark) to 13 April 2021. MEASUREMENTS: Study outcomes were cerebral venous sinus thrombosis, splanchnic vein thrombosis, pulmonary embolism, deep venous thrombosis, arterial thrombosis, thrombocytopenia, and death. Cumulative incidences of study outcomes within 28 days of vaccination and unvaccinated risk time were compared using adjusted survival curves resulting in risk differences (RDs) at day 28 after vaccination. Adjustment for birth cohort, sex, calendar period, occupation, comorbid conditions, and prescription drug use was included. RESULTS: Vaccination with AZD1222 versus no vaccination was associated with a significant RD at day 28 for deep venous thrombosis (RD, 8.35 [95% CI, 0.21 to 16.49] per 100Â 000 vaccinations). The RDs for cerebral venous sinus thrombosis (RD, 1.68 [CI, -0.64 to 4.00] per 100Â 000 vaccinations) and thrombocytopenia (RD, 2.39 [CI, -1.09 to 5.87] per 100Â 000 vaccinations) were not significant. No adverse associations were seen for BNT162b2 vaccination. LIMITATION: No medical record review; surveillance bias. CONCLUSION: In this exploratory retrospective cohort study among frontline personnel in Denmark, receipt of the AZD1222 vaccine was associated with a small excess risk for deep venous thrombosis. Although the corresponding risks for the more rare and severe thrombotic outcomes (such as cerebral venous sinus thrombosis) were not statistically significantly increased, statistical precision was low, and clinically relevant risks could not be excluded with certainty. There was no statistically significant association of BNT162b2 vaccination with thrombotic or thrombocytopenic events. PRIMARY FUNDING SOURCE: Lundbeck Foundation.

Breast Radiation Recall Phenomenon After Astra-Zeneca COVID-19 Vaccine: A Case Series. We report three cases of AstraZeneca vaccine (AZV)-induced radiation recall phenomenon (RRP) in three women who had previously undergone radiotherapy for breast cancer. RRP is a rare complication of vaccination that can mimic the more common pathology of breast cellulitis. Emergency physicians, primary care specialists, and surgeons should be aware of RRP when treating patients in the current coronavirus disease 2019 (COVID-19) climate.

A Case of Autoimmune Hemolytic Anemia after the First Dose of COVID-19 mRNA-1273 Vaccine with Undetected Pernicious Anemia. By this time, multiple vaccines have been approved to limit the spread of SARS-CoV-2 worldwide. These include new-generation vaccines that contain mRNA of the target organism. Some common side effects were identified and reported during phase 3 clinical trials of vaccination, but more rare adverse events were reported in the literature. One such concern is autoimmune conditions that SARS-CoV-2 viral antigens could have possibly incited. We are presenting here a case of a young female with no known autoimmune diseases, diagnosed with autoimmune hemolytic anemia about a week after receiving her first dose of the COVID-19 mRNA vaccine. We discuss the possible culprit for precipitation of autoimmune hemolytic anemia after the SARS-CoV-2 mRNA vaccine, which encodes virus spike protein. This case highlights the importance of being vigilant for identifying rare adverse events that could appear during mass vaccination.

Antibody Response 3 Months After 2-Dose SARS-CoV-2 mRNA Vaccination in Patients With Inflammatory Bowel Disease. INTRODUCTION: The response to SARS-CoV-2 vaccination of patients with inflammatory bowel disease (IBD) on immune-modifying therapies requires further investigation because previous studies indicate that patients on immune therapy might have decreased antibody concentrations. METHODS: We present the antireceptor binding domain antibody response over a period of 3 months in 217 patients with IBD who completed standard 2-dose SARS-CoV-2 mRNA vaccine series. RESULTS: Almost all (98.6%) IBD vaccine recipients had a positive antireceptor binding domain antibody response at least 3 months after vaccination. Decreased antibody titers at 3 months were seen in a subset of patients on antitumor necrosis factor-alpha. Approximately 10% of the participants with high-titer antibodies at 1 month had a decrease to low-positive titers at 3 months, which was mostly observed in those on combination therapy and antitumor necrosis factor-alpha monotherapy. DISCUSSION: Larger longitudinal studies are required to define the response in IBD population and its clinical impact.

Hematuria after COVID-19 vaccination: A case report.

Boosting of the SARS-CoV-2-Specific Immune Response after Vaccination with Single-Dose Sputnik Light Vaccine. Despite measures taken world-wide, the coronavirus disease 2019 (COVID-19) pandemic continues. Because efficient antiviral drugs are not yet widely available, vaccination is the best option to control the infection rate. Although this option is obvious in the case of COVID-19-naive individuals, it is still unclear when individuals who have recovered from a previous SARS-CoV-2 infection should be vaccinated and whether the vaccination raises immune responses against the coronavirus and its novel variants. In this study, we collected peripheral blood from 84 healthy human donors of different COVID-19 status who were vaccinated with the Sputnik Light vaccine and measured the dynamics of the Ab and T cell responses, as well as the virus-neutralizing activity (VNA) in serum, against two SARS-CoV-2 variants, B.1.1.1 and B.1.617.2. We showed that vaccination of individuals previously exposed to the virus considerably boosts the existing immune response. In these individuals, receptor-binding domain (RBD)-specific IgG titers and VNA in serum were already elevated on the 7th day after vaccination, whereas COVID-19-naive individuals developed the Ab response and VNA mainly 21 d postvaccination. Additionally, we found a strong correlation between RBD-specific IgG titers and VNA in serum, and according to these data vaccination may be recommended when the RBD-specific IgG titers drop to 142.7 binding Ab units/ml or below. In summary, the results of the study demonstrate that vaccination is beneficial for both COVID-19-naive and recovered individuals, especially since it raises serum VNA against the B.1.617.2 variant, one of the five SARS-CoV-2 variants of concern.

Myocarditis Associated With COVID-19 Booster Vaccination.

SARS-CoV-2 Vaccine-induced Thyroiditis: Safety of Revaccinations and Clinical Follow-up. CONTEXT: The number of reported cases with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccine-induced subacute thyroiditis (SAT) and Graves' disease (GD) is growing. However, active debate continues about managing such side effects and the safety of repeat or booster doses of the vaccines in such cases. OBJECTIVES: This study aims to present long-term clinical follow-up of SARS-CoV-2 vaccine-induced SAT or GD cases and provide data regarding the safety of revaccinations. METHODS: Patients diagnosed with SARS-CoV-2 vaccine-induced SAT or GD were included. Data regarding the long-term clinical follow-up of SARS-CoV-2 vaccine-induced SAT and GD cases and outcomes of repeat or booster SARS-CoV-2 vaccinations were documented. The literature, including cases of SARS-CoV-2 vaccine-induced SAT or GD, was reviewed. RESULTS: Fifteen patients with SARS-CoV-2 vaccine-induced SAT and 4 with GD were included. Pfizer/BioNTech COVID-19 vaccine (BNT162b2) was associated with symptoms in a majority of cases with SAT and all with GD. Median time from vaccination to symptom onset was 7 and 11.5 days, respectively, while 7 and 2

patients required medical treatment in SAT and GD groups, respectively. Remission was documented in 10 SAT patients, with a median time to remission of 11.5 weeks. No exacerbation/recurrence of SAT occurred in 7 of 9 patients who received a repeat vaccination dose, while symptoms of SAT worsened following the second vaccination in 2 cases. None of the patients experienced severe side effects that could be associated with revaccinations. CONCLUSIONS: Revaccinations appear to be safe in patients with SARS-CoV-2 vaccine-induced SAT cases, while more evidence is needed regarding SARS-CoV-2 vaccine-induced GD.

Lower probability and shorter duration of infections after COVID-19 vaccine correlate with anti-SARS-CoV-2 circulating IgGs. The correlation between immune responses and protection from SARS-CoV-2 infections and its duration remains unclear. We performed a sanitary surveillance at the European Institute of Oncology (IEO) in Milan over a 17 months period. Pre-vaccination, in 1,493 participants, we scored 266 infections (17.8%) and 8 possible reinfections (3%). Post-vaccination, we identified 30 infections in 2,029 vaccinated individuals (1.5%). We report that the probability of infection post-vaccination is i) significantly lower compared to natural infection, ii) associated with a significantly shorter median duration of infection than that of first infection and reinfection, iii) anticorrelated with circulating antibody levels.

COVID-19 vaccination in patients with rheumatic diseases: Vaccination rates, patient perspectives, and side effects. INTRODUCTION: To investigate the vaccination rate, reported side effects, and patient concerns for COVID-19 vaccination in patients with rheumatic diseases. METHODS: A multicentre cross-sectional study from rheumatology clinics in two major hospitals in Hong Kong was conducted between June 3, 2021 and October 8, 2021. Patient interviews for demographics, clinical characteristics, vaccination status, reported side effects, and factors influencing decisions about vaccination were supplemented with structured questionnaires. RESULTS: Out of 1367 patients, 413 (30.2%) had received COVID-19 vaccination. Side effects were reported in 335 (81.1%) of patients, of which the most common were injection site pain or swelling (66.3%), fatigue (57.1%), fever (19.9%), and headache (19.6%). Multivariate logistic regression models showed that males (odds ratio [OR]â€‰=â€‰1.80; pâ€‰<â€‰.001), higher education level (ORâ€‰=â€‰1.64; pâ€‰<â€‰.001) and healthcare professionals (ORâ€‰=â€‰4.5; pâ€‰<â€‰.001) were significantly more likely to have received the vaccine. In contrast, patients with hypertension (ORâ€‰=â€‰0.73; pâ€‰=â€‰.04), systemic lupus erythematous (ORâ€‰=â€‰0.53; pâ€‰<â€‰.001), stroke (ORâ€‰=â€‰0.29; pâ€‰=â€‰.01), steroid therapy (ORâ€‰=â€‰0.59; pâ€‰=â€‰.01), and leflunomide therapy (ORâ€‰=â€‰0.45; pâ€‰=â€‰.05) were significantly less likely to be vaccinated. Younger age (age, ORâ€‰=â€‰0.96; pâ€‰=â€‰.003) and messenger RNA (mRNA) vaccines (ORâ€‰=â€‰4.79; pâ€‰<â€‰.001) were associated with more side effects. There was no difference in risk of side effects between specific rheumatic diseases or drug therapies. CONCLUSION: COVID-19 vaccination is associated with no increased risk of side effects in any particular disease or drug therapy, therefore vaccination should be encouraged in patients with rheumatic disease. In addition, younger age is associated minimally, while mRNA vaccine is associated with increased side effects.

Leukocytoclastic vasculitis in possible relation to the BNT162b2 mRNA COVID-19 vaccine.

Heterologous immunization with BNT162b2 followed by mRNA-1273 in dialysis patients: seroconversion and presence of neutralizing antibodies. INTRODUCTION: The vital renal replacement therapy makes it impossible for dialysis patients to distance themselves socially. This results in a high risk of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and developing coronavuris disease 2019, with excess mortality due to disease burden and immunosuppression. We determined the efficacy of a 100-Âµg booster of mRNA-1273 (Moderna, Cambridge, MA, USA) 6Â months after two doses of BNT162b2 (BioNTech/Pfizer, Mainz,

Germany/New York, USA) in 194 SARS-CoV-2-naÃ¨ve dialysis patients. METHODS: Anti-SARS-CoV-2 spike antibodies were measured with the Elecsys Anti-SARS-CoV-2 S assay (Roche Diagnostics, Mannheim, Germany) 4 and 10-12 weeks after two doses of BNT162b2 as well as 4 weeks after the mRNA-1273 booster. The presence of neutralizing antibodies was measured by the SARS-CoV-2 Surrogate Virus Neutralization Test (GenScript Biotech, Piscataway, NJ, USA). Two different cut-offs for positivity were used, one according to the manufacturer's specifications and one correlating with positivity in a plaque reduction neutralization test (PRNT). Receiver operating characteristics analyses were performed to match the anti-SARS-CoV-2 spike antibody cut-offs with the cut-offs in the surrogate neutralization assay accordingly. RESULTS: Any level of immunoreactivity determined by the anti-SARS-CoV-2 spike antibody assay was found in 87.3% (nÂ =Â 144/165) and 90.6% (nÂ =Â 164/181) of patients 4 and 10-12 weeks, respectively, after two doses of BNT162b2. This was reduced to 68.5% or 60.6% 4 weeks and 51.7% or 35.4% 10-12 weeks, respectively, when using the ROC cut-offs for neutralizing antibodies in the surrogate neutralization test (manufacturer's cut-offÂ â‰¥103Â U/mL and cut-off correlating with PRNTÂ â‰¥196Â U/mL). Four weeks after the mRNA-1273 booster, the concentration of anti-SARS-CoV-2 spike antibodies increased to 23Â 119.9Â U/mL and to 97.3% for both cut-offs of neutralizing antibodies. CONCLUSION: Two doses of BNT162b2 followed by one dose of mRNA-1273 within 6 months in patients receiving maintenance dialysis resulted in significant titres of SARS-CoV-2 spike antibodies. While two doses of mRNA vaccine achieved adequate humoral immunity in a minority, the third vaccination boosts the development of virus-neutralizing quantities of SARS-CoV-2 spike antibodies (against wild-type SARS-CoV-2) in almost all patients.

[(18)F]FDG uptake in axillary lymph nodes and deltoid muscle after COVID-19 mRNA vaccination: a cohort study to determine incidence and contributing factors using a multivariate analysis. PURPOSE: Reactive FDG uptake in the axillary lymph nodes (ALN) and deltoid muscle (DM) after COVID-19 mRNA vaccination has been recognized, although the actual situation in the Japanese population remains unknown. To determine the incidence of reactive FDG uptake and its contributing factors, we retrospectively studied a cohort of subjects who were vaccinated at our hospital. METHODS: Whole-body FDG-PET/CT examinations performed in 237 subjects out of 240 subjects with a definite history of COVID-19 vaccination (BNT162b2; BioNTech-Pfizer) were analyzed. Positivity and SUVmax of FDG uptake in the ALN and DM ipsilateral to vaccination, various subject characteristics, and the grade of the pathological FDG-PET/CT findings were evaluated using a multivariate analysis. RESULTS: FDG uptake in the ALN and DM ipsilateral to vaccination was seen in about 60% of the subjects even soon (0-4Â days) after the first vaccination, with percentages reaching 87.5% and 75.0%, respectively, after the second vaccination. DM uptake had almost disappeared at around 2 weeks, while ALN uptake persisted for 3Â weeks or longer. A multivariate analysis showed that a short duration since vaccination, a younger age, a female sex, and a low FDG-PET/CT grade (minimal pathological FDG uptake) contributed significantly to positive ALN uptake, while a short duration since vaccination and a female sex were the only significant contributors to positive DM uptake. This study is the first to identify factors contributing to positive FDG uptake in ALN and DM after COVID-19 vaccination. CONCLUSION: A high incidence of FDG uptake in ALN and DM was observed after vaccination. ALN uptake seemed to be associated with a younger age, a female sex, and minimal pathological FDG uptake. After vaccination, an acute inflammatory reaction in DM followed by immune reaction in ALN linked to humoral immunity may be speculated.

Bilateral optic neuritis after COVID vaccination.

Safety and immunogenicity of the SARS-CoV-2 ARCoV mRNA vaccine in Chinese adults: a randomised, double-blind, placebo-controlled, phase 1 trial. BACKGROUND: Safe and effective vaccines are urgently needed to end the COVID-19 pandemic caused by SARS-CoV-2 infection. We aimed to assess

the preliminary safety, tolerability, and immunogenicity of an mRNA vaccine ARCoV, which encodes the SARS-CoV-2 spike protein receptor-binding domain (RBD). METHODS: This single centre, double-blind, randomised, placebo-controlled, dose-escalation, phase 1 trial of ARCoV was conducted at Shulan (Hangzhou) hospital in Hangzhou, Zhejiang province, China. Healthy adults aged 18-59 years negative for SARS-CoV-2 infection were enrolled and randomly assigned using block randomisation to receive an intramuscular injection of vaccine or placebo. Vaccine doses were 5 Î¼g, 10 Î¼g, 15 Î¼g, 20 Î¼g, and 25 Î¼g. The first six participants in each block were sentinels and along with the remaining 18 participants, were randomly assigned to groups (5:1). In block 1 sentinels were given the lowest vaccine dose and after a 4-day observation with confirmed safety analyses, the remaining 18 participants in the same dose group proceeded and sentinels in block 2 were given their first administration on a two-dose schedule, 28 days apart. All participants, investigators, and staff doing laboratory analyses were masked to treatment allocation. Humoral responses were assessed by measuring anti-SARS-CoV-2 RBD IgG using a standardised ELISA and neutralising antibodies using pseudovirus-based and live SARS-CoV-2 neutralisation assays. SARS-CoV-2 RBD-specific T-cell responses, including IFN-Î³ and IL-2 production, were assessed using an enzyme-linked immunospot (ELISpot) assay. The primary outcome for safety was incidence of adverse events or adverse reactions within 60 min, and at days 7, 14, and 28 after each vaccine dose. The secondary safety outcome was abnormal changes detected by laboratory tests at days 1, 4, 7, and 28 after each vaccine dose. For immunogenicity, the secondary outcome was humoral immune responses: titres of neutralising antibodies to live SARS-CoV-2, neutralising antibodies to pseudovirus, and RBD-specific IgG at baseline and 28 days after first vaccination and at days 7, 15, and 28 after second vaccination. The exploratory outcome was SARS-CoV-2-specific T-cell responses at 7 days after the first vaccination and at days 7 and 15 after the second vaccination. This trial is registered with www.chictr.org.cn (ChiCTR2000039212). FINDINGS: Between Oct 30 and Dec 2, 2020, 230 individuals were screened and 120 eligible participants were randomly assigned to receive five-dose levels of ARCoV or a placebo (20 per group). All participants received the first vaccination and 118 received the second dose. No serious adverse events were reported within 56 days after vaccination and the majority of adverse events were mild or moderate. Fever was the most common systemic adverse reaction (one [5%] of 20 in the 5 Î¼g group, 13 [65%] of 20 in the 10 Î¼g group, 17 [85%] of 20 in the 15 Î¼g group, 19 [95%] of 20 in the 20 Î¼g group, 16 [100%] of 16 in the 25 Î¼g group; p<0Â·0001). The incidence of grade 3 systemic adverse events were none (0%) of 20 in the 5 Î¼g group, three (15%) of 20 in the 10 Î¼g group, six (30%) of 20 in the 15 Î¼g group, seven (35%) of 20 in the 20 Î¼g group, five (31%) of 16 in the 25 Î¼g group, and none (0%) of 20 in the placebo group (p=0Â·0013). As expected, the majority of fever resolved in the first 2 days after vaccination for all groups. The incidence of solicited systemic adverse events was similar after administration of ARCoV as a first or second vaccination. Humoral immune responses including anti-RBD IgG and neutralising antibodies increased significantly 7 days after the second dose and peaked between 14 and 28 days thereafter. Specific T-cell response peaked between 7 and 14 days after full vaccination. 15 Î¼g induced the highest titre of neutralising antibodies, which was about twofold more than the antibody titre of convalescent patients with COVID-19. INTERPRETATION: ARCoV was safe and well tolerated at all five doses. The acceptable safety profile, together with the induction of strong humoral and cellular immune responses, support further clinical testing of ARCoV at a large scale. FUNDING: National Key Research and Development Project of China, Academy of Medical Sciences China, National Natural Science Foundation China, and Chinese Academy of Medical Sciences.

Palmoplantar lichenoid drug eruption following the administration of Pfizer-BioNTech COVID-19 vaccine.

A Pediatric Case of Sensory Predominant Guillain-BarrÃ© Syndrome Following COVID-19 Vaccination. Over six billion doses of Coronavirus Disease 2019 (COVID-19) vaccines have been administered worldwide. Amidst the global COVID-19 vaccination campaign, vaccine-related side effects are of ongoing concern and investigation. According to the Centers for Disease Control and Prevention (CDC) and the United States Department of Health and Human Services, three main conditions in adults have surfaced in association with receiving the COVID-19 vaccines. These include thrombosis with thrombocytopenia syndrome (TTS), a rare syndrome involving venous or arterial thrombosis and thrombocytopenia, Guillain-Barre syndrome (GBS), and myocarditis. While a number of GBS cases in adults have been published, to our knowledge, only one pediatric case of COVID-19 vaccine-related GBS has been reported. Herein we describe a case of sensory predominant GBS following the Pfizer-BioNTech COVID-19 vaccine in a 16-year-old female presenting with bilaterally ascending upper and lower extremity numbness and paresthesia.

Multisystem Inflammatory Syndrome after Ad26.COV2.S vaccination. BACKGROUND: The multisystem inflammatory syndrome (MIS) is a rare and sometime life-threatening post-infectious complication of coronavirus disease 2019 (Covid-19) in children and adults. To date, only a very few reports have associated such systemic reaction with SARS-CoV-2 vaccination. CASE REPORT: we describe a case that resembled MIS, in a 46-year-old White man, 12 days after vaccination with Ad26. COV2. S vaccine (Johnson &Johnson/Janssen), a recombinant adenovirus serotype 26 vector encoding the SARS-CoV-2 spike glycoprotein. The patient experienced high grade fever, cutaneous rash, severe weakness, pericardial effusion and raised inflammatory markers, which met the criteria for definition of MIS. The symptoms improved with steroidal therapy. CONCLUSIONS: Our case suggests that MIS could occur after SARS-CoV-2 vaccination.

SARS-CoV-2 vaccine-associated-tinnitus: A review. The global vaccination drive against severe acute respiratory syndrome coronavirus-2 is being pursued at a historic pace. Unexpected adverse effects have been reported following vaccination, including thrombotic thrombocytopenia, myocarditis, amongst others. More recently, some cases of tinnitus are reported post-vaccination. According to the Vaccine Adverse Events Reporting System (VAERS), 12,247 cases of coronavirus post-vaccination tinnitus have been reported till September 14, 2021. To the best of our knowledge, this is the first review evaluating any otologic manifestation following vaccine administration and aims to evaluate the potential pathophysiology, clinical approach, and treatment. Although the incidence is infrequent, there is a need to understand the precise mechanisms and treatment for vaccine-associated-tinnitus.

Potential Anionic Substances Binding to Platelet Factor 4 in Vaccine-Induced Thrombotic Thrombocytopenia of ChAdOx1-S Vaccine for SARS-CoV-2. Recent reports of rare ChAdOx1-S vaccine-related venous thrombosis led to the suspension of its usage in several countries. Vaccine-induced thrombotic thrombocytopenia (VITT) is characterized by thrombocytopenia and thrombosis in association with anti-platelet factor 4 (PF4) antibodies. Herein, we propose five potential anionic substances of the ChAdOx1-S vaccine that can combine with PF4 and trigger VITT, including (1) the proteins on the surface of adenovirus, e.g., negative charged glycoprotein, (2) the adjuvant components of the vaccine, e.g., Tween 80, (3) the DNA of adenovirus, (4) the S protein antigen expressed by the vaccine, and (5) the negatively charged impurity proteins expressed by the vaccine, e.g., adenovirus skeleton proteins. After analysis of each case, we consider the most possible trigger to be the negatively charged impurity proteins expressed by the vaccine. Then, we display the possible extravascular route and intravascular route of the formation of PF4 autoantibodies triggered by the negatively charged impurity proteins, which is accordant with the clinical situation. Accordingly, the susceptible individuals of VITT after ChAdOx1-S vaccination may be people who express negatively charged impurity proteins and reach a certain high titer.

Adenoviral vector-based COVID-19 vaccines-associated cerebral venous sinus thromboses: Are those adverse events related to the formation of neutrophil extracellular traps? In March and April 2021 several countries temporarily suspended vaccinations with adenoviral vector-based COVID-19 vaccines. Concerns of national regulators particularly regarded very rare cases of cerebral venous sinus thrombosis after immunization with this type of vaccine. Until now, these adverse events were interpreted as standard hypercoagulable events, but their clinical characteristics suggest that they may actually represent unique thrombotic disorders referred to as immunothrombosis. In this paper it is speculated that it is possible that immunothrombosis after this type of vaccine results from formation of neutrophil extracellular traps (NETs) in veins affected by stagnant blood flow. Such a stasis occurs in individuals with anatomical variants of cerebral venous outflow, which may explain why these events are primarily seen in the cerebral veins. It has already been found that SARS-CoV-2 spike protein can evoke release of NETs. There is also a question if thrombotic events after adenoviral vector-based COVID-19 vaccines could be avoided. These vaccines will still be needed to curb COVID-19 worldwide, since they do not require transportation and storage at very low temperatures. Perhaps, vaccinations with these vaccines should be performed in combination with prophylactic administration of dipyridamole, which is an inexpensive pharmaceutical agent reducing the release of NETs.

Adverse drug reactions from two COVID-19 vaccines reported in Saudi Arabia. BACKGROUND: Several reports have been published about the impact of coronavirus disease 2019 (COVID-19) vaccines on human health, and each vaccine has a different safety and efficacy profile. The aim of this study was to reveal the nature and classification of reported adverse drug reactions (ADRs) of the two COVID-19 vaccines (tozinameran and ChAdOx1) among citizens and residents living in Saudi Arabia, and show possible differences between the two vaccines and the differences between each batch on the health of populations. METHODS: A cross-sectional study was conducted in Saudi Arabia between December 2020 and March 2021. Saudi citizens and residents aged â‰¥Â 16 years who had at least one dose of any batch of either of the two approved COVID-19 vaccines (tozinameran and ChAdOx1) and who reported at least one ADR from the vaccines were included. The study excluded people who reported ADRs after receiving tozinameran or ChAdOx1 vaccines but no information was provided about the vaccine's batch number. RESULTS: During the study period, 12,868 vaccinated people, including a high-risk group (i.e., those with chronic illness or pregnant women), reported COVID-19 vaccine ADRs that had been documented in the General Directorate of Medical Consultations, Saudi Ministry of Health. The study reported several ADRs associated with COVID-19 vaccines, with the most common (>Â 25%) being fever/chills, general pain/weakness, headache, and injection site reactions. Among healthy and high-risk people, the median onset of all reported ADRs for tozinameran and ChAdOx1 vaccine batches were 1.96 and 1.64 days, respectively (pÂ <Â 0.01). Furthermore, significant differences ($p < 0.05$) were recorded between the two studied vaccines in regard to fever/chills, gastrointestinal symptoms, headache, general pain/weakness, and neurological symptoms, with higher incidence rates of these ADRs observed with the ChAdOx1 vaccine than the tozinameran vaccine. However, the tozinameran vaccine was found to cause significantly (pÂ <Â 0.05) more palpitation, blood pressure variations, upper respiratory tract symptoms, lymph node swelling, and other unspecified ADRs than the ChAdOx1 vaccine. Among patients vaccinated with seven different batches of the tozinameran vaccine, people vaccinated with the T4 and T5 batches reported the most ADRs. CONCLUSION: There were significant differences regarding most of the reported ADRs and their onset among tozinameran and ChAdOx1 vaccines on both healthy people and high-risk individuals living in Saudi Arabia. Moreover, the study found that the frequencies of most listed ADRs were statistically different when seven batches of tozinameran vaccine were compared.

Isolated Renal Arteritis With Infarction Identified After SARS-CoV-2 Vaccine.

An AAV vaccine targeting the RBD of the SARS-CoV-2 S protein induces effective neutralizing antibody titers in mice and canines. The coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) has resulted in catastrophic damage worldwide. Accordingly, the development of powerful, safe, easily accessible vaccines with long-term effectiveness is understood as an urgently needed countermeasure against this ongoing pandemic. Guided by this strong promise of using AAVs, we here designed, optimized, and developed an AAV-based vaccines (including AAV-RBD(max), AAV-RBD(wt), AAV-2xRBD, and AAV-3xRBD) that elicit strong immune responses against the RBD domain of the SARS-CoV-2 S protein. These immunogenic responses have proven long-lived, with near peak levels for at least six months in mice. Notably, the sera immunized with AAV-3xRBD vaccine contains powerful neutralizing antibodies against the SARS-CoV-2 pseudovirus. Further evidence proven that potent specific antibodies could also be elicited in canines after vaccination with AAV-3xRBD vaccine.

Inflammatory myopathy occurring shortly after severe acute respiratory syndrome coronavirus 2 vaccination: two case reports. BACKGROUND: Vaccination remains the cornerstone approach to exiting the current global coronavirus disease 2019 pandemic caused by severe acute respiratory syndrome coronavirus 2. The novel messenger ribonucleic acid vaccines offer a high level of protection and are widely used throughout the world. With more people receiving the vaccines, better understanding of their relative safety can be reached. In this report, we describe two patients who developed inflammatory myopathy within 48Â hours of receiving the Pfizer BNT162b2 vaccine. CASE PRESENTATION: Patient A, a 55-year-old South East Asian woman, presented with a 6-week history of pruritic facial and torso rash and a 1-week history of worsening proximal myopathy. Her rash first developed 2Â days after receiving the first dose of BNT162b2 vaccine. Patient B, a 72-year-old Caucasian woman, presented with a 2-week history of proximal myopathy a day after receiving the second dose of BNT162b2 vaccine. Both patients had elevated creatine kinase on admission. Patient A tested positive for anti-Mi-2a antibody and anti-Ro-52 antibody, while Patient B was positive for anti-fibrillarin antibody. Magnetic resonance imaging subsequently confirmed generalized acute muscle inflammation and subcutaneous inflammation consistent with inflammatory myositis. Both patients did not have a previous history or family history of autoimmune disease. Patients A and B were diagnosed with dermatomyositis and inflammatory myositis, respectively. They were initially treated with pulsed intravenous methylprednisolone followed by oral prednisolone. However, as their conditions were resistant to corticosteroids, both eventually received and responded well to intravenous immunoglobulin therapy. CONCLUSION: There are previously reported cases of severe acute respiratory syndrome coronavirus 2-induced and other vaccine-related inflammatory myopathies. However, the precise mechanisms are not elucidated. Without more evidence and convincing pathophysiology, it is not possible to conclude that our patients developed inflammatory myopathy because of the vaccine. However, the timing of the disease onset and the lack of previous history raise an important question of this novel messenger ribonucleic acid therapy.

Investigating vaccine-induced immunity and its effect in mitigating SARS-CoV-2 epidemics in China. BACKGROUND: To allow a return to a pre-COVID-19 lifestyle, virtually every country has initiated a vaccination program to mitigate severe disease burden and control transmission. However, it remains to be seen whether herd immunity will be within reach of these programs. METHODS: We developed a compartmental model of SARS-CoV-2 transmission for China, a population with low prior immunity from natural infection. Two vaccination programs were tested and model-based estimates of the immunity level in the population were provided. RESULTS: We found that it is unlikely to reach herd immunity for the Delta variant given the relatively low efficacy of the vaccines used in China throughout 2021 and the lack of prior natural immunity. We estimated that, assuming a vaccine efficacy of 90% against the infection, vaccine-induced herd immunity would require a coverage of

93% or higher of the Chinese population. However, even when vaccine-induced herd immunity is not reached, we estimated that vaccination programs can reduce SARS-CoV-2 infections by 50-62% in case of an all-or-nothing vaccine model and an epidemic starts to unfold on December 1, 2021. CONCLUSIONS: Efforts should be taken to increase population's confidence and willingness to be vaccinated and to develop highly efficacious vaccines for a wide age range.

Uncommon causes of acute appendicitis: foreign bodies in the cecal appendix. A 50-year-old woman with a history of hysterectomy for endometrial cancer in 2015 visited because of abdominal pain for 1 week and fever simultaneous with her third dose of the COVID-19 vaccine. Physical examination revealed a mobile mass in the right iliac fossa, and laboratory testing showed C-reactive protein at 3 mg/dL, with no further changes. Ultrasound results were consistent with an appendiceal inflammatory mass, and a CT scan revealed an appendicolith as likely cause. The patient was subjected to laparoscopy, which found inside the mass a metallic piece (dental prosthesis) that perforated the appendiceal lumen at the mid portion of the appendix. Appendectomy was completed and the patient was discharged on the third day post-procedure.

Shared and Data-Driven Decision-Making with Transplant Recipients About COVID-19 Vaccination Is Crucial.

RNA-based COVID-19 vaccine is not a contraindication to phototherapy: Real-life data on minimal erythema dose changes.

SARS-CoV-2 vaccine-associated subacute thyroiditis: insights from a systematic review. PURPOSE: To perform a systematic review on published cases of subacute thyroiditis (SAT) secondary to SARS-CoV-2 vaccination, to highlight main features and increase the awareness of this condition. METHODS: Original reports of SAT developed after SARS-CoV-2 vaccination (mRNA, viral vector, or inactivated virus vaccines) were retrieved from a search of electronic databases. Individual patient data on demographics, medical history, type of vaccine, workup and therapies were collected. Wilcoxon rank-sum, Kruskal-Wallis and chi-squared tests were employed for comparisons. RESULTS: 30 articles including 48 reports were retrieved, 3 additional cases evaluated by the Authors were described and included for analysis. Of the 51 patients, 38 (74.5%) were women, median age was 39.5Â years (IQR 34-47). Patients developed SAT after a median of 10Â days (IQR 4-14) after the vaccine shot. Baseline thyroid exams revealed thyrotoxicosis in 88.2% of patients, decreasing at 31.6% at follow-up. Corticosteroids were used in 56.4% of treated patients. Patients undergoing non-mRNA vaccines were most frequently Asian (pâ€‰=â€‰0.019) and reported more frequently weight loss (pâ€‰=â€‰0.021). All patients with a previous diagnosis of thyroid disease belonged to the mRNA vaccine group. CONCLUSION: SARS-CoV-2 vaccine-associated SAT is a novel entity that should be acknowledged by physicians. Previous history of thyroid disease may predispose to develop SAT after mRNA vaccines, but further studies and larger cohorts are needed to verify this suggestion. SARS-CoV-2 vaccine-associated SAT is usually of mild/moderate severity and could be easily treated in most cases, thus it should not raise any concern regarding the need to be vaccinated.

Optimization of FDG PET study after mRNA COVID-19 vaccination to reduce the interference of vaccine-associated hypermetabolic lymphadenopathy.

Late-Onset Vaccine-Induced Immune Thombotic Thrombocytopenia (VITT) with Cerebral Venous Sinus Thrombosis. OBJECTIVES: Vaccine-induced thrombotic thrombocytopenia (VITT) is a rare complication after adenoviral vector vaccination against COVID-19 reported up to 24 days after ChAdOx1 nCOV-19 (AZD1222) vaccination. This report describes a case with a significantly later onset of VITT with cerebral venous sinus thrombosis. CASE DESCRIPTION: We report a 42-year-old woman presenting to the emergency department 53 days after AZD1222 vaccination with sudden onset sensory aphasia and an 18-day history of headache. Cranial computed tomography (CT) showed acute intracranial hemorrhage and CT venogram demonstrated thrombosis of the left vein of LabbÃ© and

transverse and sigmoid sinus. D-dimers were elevated and despite a normal platelet count, platelet-activating anti-PF4 antibody testing was positive, confirming the diagnosis of VITT. The patient was treated with intravenous immunoglobulins and argatroban, and was discharged without any neurological deficit on day 12. CONCLUSION: Our report of VITT with symptom onset on day 35 and diagnosis of cerebral sinuous thrombosis on day 53 after AZD1222 vaccination significantly enhances the time window during which VITT may occur.

Comparative analyses of IgG/IgA neutralizing effects induced by three COVID-19 vaccines against variants of concern. BACKGROUND: Few studies have directly compared virus-specific antibodies and their neutralizing capacity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) wild type (WT) and circulating variants of concern despite the reported high efficacy of messenger RNA (mRNA)- and vector-based vaccines. OBJECTIVE: We assessed SARS-CoV-2 spike protein region 1 (S1)-specific antibodies of BNT162b2, mRNA-1273, and ChAdOx1 vaccinated as well as convalescent coronavirus disease 2019 (COVID-19) patients. We also determined the neutralization ability against SARS-CoV-2 WT and B.1.1.7 (Alpha), B1.1.7 E484K (Alpha-E484K), B.1.351 (Beta), and B.1.617.2 (Delta) variants. METHODS: Serum samples of 107 fully vaccinated or convalescent individuals were analyzed for anti-SARS-CoV-2-S1 IgG and IgA as well as for total anti-SARS-CoV-2 receptor binding domain Ig. Furthermore, neutralization capacity as 50% and 90% neutralization titer values against SARS-CoV-2 WT virus and circulating variants were determined. RESULTS: We observed a robust IgG response in all participants; however, the highest titers were detected in mRNA-based vaccine recipients. In case of serum IgA responses, the difference between mRNA- and vector-based vaccines or convalescent patients was even more pronounced. Interestingly, all 3 vaccines could neutralize all tested variants of concern in addition to WT virus, but in some individuals, only low or no neutralization, especially against Alpha-E484K and the Delta variant, was detected. CONCLUSION: Our study of the efficacy of various COVID-19 vaccines found that mRNA-1273 had the highest neutralization abilities compared to BNT162b2 and ChAdOx1. COVID-19 convalescent patients demonstrated the most heterogeneous range of antibody titers and neutralization abilities, making it hard to assess protection. Furthermore, a significant positive relation between antibodies and the 50% neutralization titer values for immunized and convalescent individuals was determined.

Antibody Response to SARS-CoV-2 Vaccination in Patients following Allogeneic Hematopoietic Cell Transplantation. Vaccines against SARS-CoV-2 have been rapidly approved. Although pivotal studies were conducted in healthy volunteers, little information is available on the safety and efficacy of mRNA vaccines in immunocompromised patients, including recipients of allogeneic hematopoietic cell transplantation (allo-HCT). Here we used a novel assay to analyze patient- and transplantation-related factors and their influence on immune responses to SARS-CoV-2 vaccination over an extended period (up to 6 months) in a large and homogenous group of allo-HCT recipients at a single center in Switzerland. We examined longitudinal antibody responses to SARS-CoV-2 vaccination with BNT162b2 (BioNTech/Pfizer) and mRNA-1273 (Moderna) in 110 allo-HCT recipients and 86 healthy controls. Seroprofiling recording IgG, IgA, and IgM reactivity against SARS-CoV-2 antigens (receptor-binding domain, spike glycoprotein subunits S1 and S2, and nucleocapsid protein) was performed before vaccination, before the second dose, and at 1, 3, and 6 months after the second dose. Patients were stratified to 3 groups: 3 to 6 months post-allo-HCT, 6 to 12 months post-allo-HCT, and >12 months post-allo-HCT. Patients in the 3 to 6 months and 6 to 12 months post-allo-HCT groups developed significantly lower antibody titers after vaccination compared with patients in the >12 months post-allo-HCT group and healthy controls ($P < .001$). Within the cohort of allo-HCT recipients, patients age >65 years (PÂ =Â .030), those receiving immunosuppression for prevention or treatment of graft-versus-host disease (GVHD) (PÂ =Â .033), and patients with relapsed disease (PÂ =Â .014) displayed low humoral immune responses to the vaccine. In contrast, the intensity of the

conditioning regimen, underlying disease (myeloid/lymphoid/other), and presence of chronic GVHD had no impact on antibody levels. Antibody titers achieved the highest levels at 1 month after the second dose of the vaccine but waned substantially in all transplantation groups and healthy controls over time. This analysis of long-term vaccine antibody response is of critical importance to allo-HCT recipients and transplant physicians to guide treatment decisions regarding revaccination and social behavior during the SARS-CoV-2 pandemic.
Bullous neutrophilic dermatosis with severe acral oedema post-COVID-19 mRNA vaccination.
A modified self-controlled case series method for event-dependent exposures and high event-related mortality, with application to COVID-19 vaccine safety. We propose a modified self-controlled case series (SCCS) method to handle both event-dependent exposures and high event-related mortality. This development is motivated by an epidemiological study undertaken in France to quantify potential risks of cardiovascular events associated with COVID-19 vaccines. Event-dependence of vaccinations, and high event-related mortality, are likely to arise in other SCCS studies of COVID-19 vaccine safety. Using this case study and simulations to broaden its scope, we explore these features and the biases they may generate, implement the modified SCCS model, illustrate some of the properties of this model, and develop a new test for presence of a dose effect. The model we propose has wider application, notably when the event of interest is death.
Elevated Clozapine Blood Concentrations After Second COVID-19 Vaccination With Spikevax (COVID-19 Vaccine Moderna).
First episode psychosis following receipt of first dose of COVID-19 vaccine: A case report.
COVID-19 vaccination in patients with multiple sclerosis: Safety and humoral efficacy of the third booster dose. BACKGROUND: As immunity against SARS-COV-2 wanes following first and second doses of vaccination, a third dose is administered in several countries around the world. Similarly to the first doses, risks related to vaccination and humoral immune response in patients with multiple sclerosis (MS) need to be assessed. OBJECTIVE: Characterize safety and humoral immune response following the third dose of COVID-19 vaccination in a large cohort of MS patients. METHODS: We assessed the safety of the third dose of the BNT162b2-COVID-19 mRNA vaccination in adult MS patients and evaluated SARS-CoV-2 IgG response. RESULTS: Two hundred and eleven adult MS patients received a third dose of BNT162b2 COVID-19 vaccination. Median follow up time was 66Â days from vaccine administration (IQR 54-84). The frequency of any adverse event was 54.5%, with the most common reported adverse events being fatigue, local pain at the injection site, fever and muscle or joint pain. Transient increase in MS symptoms was reported in 3.8% of patients, none of them requiring treatment. The rate of acute relapses treated with IV steroids was 3.3%. In a sub-group of 55 patients, 20 untreated and 35 treated with vaccination-safe disease-modifying treatments, SARS-CoV-2 IgG levels increased 21-fold (medianÂ Â±Â SD 21.6Â Â±Â 53.05). CONCLUSIONS: The third dose of COVID-19-BNT162b2 vaccine proved safe for MS patients, with no increased risk of relapse activity. Untreated patients and patients treated with vaccination-safe disease-modifying treatments show significant increase in SARS-CoV-2 IgG levels following the third dose of vaccination.
Fulminant type 1 diabetes after COVID-19 vaccination.
Safety and immunogenicity of the COVID-19 vaccine BNT162b2 in patients undergoing chemotherapy for solid cancer. BACKGROUND: Although COVID-19 severity in cancer patients is high, the safety and immunogenicity of the BNT162b2 mRNA COVID-19 vaccine in patients undergoing chemotherapy for solid cancers in Japan have not been reported. METHODS: We investigated the safety and immunogenicity of BNT162b2 in 41 patients undergoing chemotherapy for solid cancers and in healthy volunteers who received 2 doses of BNT162b2. We evaluated serum IgG antibody titers for S1 protein by ELISA at pre-vaccination, prior to the second dose and 14 days after the second vaccination

in 24 cancer patients undergoing cytotoxic chemotherapy (CC group), 17 cancer patients undergoing immune checkpoint inhibitor therapy (ICI group) and 12 age-matched healthy volunteers (HV group). Additionally, inflammatory cytokine levels were compared between the HV and ICI groups at pre and the next day of each vaccination. RESULTS: Anti-S1 antibody levels were significantly lower in the ICI and CC groups than in the HV group after the second dose (median optimal density: 0.241 [0.063-1.205] and 0.161 [0.07-0.857] vs 0.644 [0.259-1.498], pÂ =Â 0.0024 and pÂ <Â 0.0001, respectively). Adverse effect profile did not differ among the three groups, and no serious adverse event occurred. There were no differences in vaccine-induced inflammatory cytokines between the HV and ICI groups. CONCLUSION: Although there were no significant differences in adverse events in three groups, antibody titers were significantly lower in the ICI and CC groups than in the HV group. Further protection strategies should be considered in cancer patients undergoing CC or ICI.

Safety and immunogenicity of an AS03-adjuvanted SARS-CoV-2 recombinant protein vaccine (CoV2 preS dTM) in healthy adults: interim findings from a phase 2, randomised, dose-finding, multicentre study. BACKGROUND: We evaluated our SARS-CoV-2 prefusion spike recombinant protein vaccine (CoV2 preS dTM) with different adjuvants, unadjuvanted, and in a one-injection and two-injection dosing schedule in a previous phase 1-2 study. Based on interim results from that study, we selected a two-injection schedule and the AS03 adjuvant for further clinical development. However, lower than expected antibody responses, particularly in older adults, and higher than expected reactogenicity after the second vaccination were observed. In the current study, we evaluated the safety and immunogenicity of an optimised formulation of CoV2 preS dTM adjuvanted with AS03 to inform progression to phase 3 clinical trial. METHODS: This phase 2, randomised, parallel-group, dose-ranging study was done in adults (â‰¥18 years old), including those with pre-existing medical conditions, those who were immunocompromised (except those with recent organ transplant or chemotherapy) and those with a potentially increased risk for severe COVID-19, at 20 clinical research centres in the USA and Honduras. Women who were pregnant or lactating or, for those of childbearing potential, not using an effective method of contraception or abstinence, and those who had received a COVID-19 vaccine, were excluded. Participants were randomly assigned (1:1:1) using an interactive response technology system, with stratification by age (18-59 years and â‰¥60 years), rapid serodiagnostic test result (positive or negative), and high-risk medical conditions (yes or no), to receive two injections (day 1 and day 22) of 5 7mu;g (low dose), 10 7mu;g (medium dose), or 15 7mu;g (high dose) CoV2 preS dTM antigen with fixed AS03 content. All participants and outcome assessors were masked to group assignment; unmasked study staff involved in vaccine preparation were not involved in safety outcome assessments. All laboratory staff performing the assays were masked to treatment. The primary safety objective was to describe the safety profile in all participants, for each candidate vaccine formulation. Safety endpoints were evaluated for all randomised participants who received at least one dose of the study vaccine (safety analysis set), and are presented here for the interim study period (up to day 43). The primary immunogenicity objective was to describe the neutralising antibody titres to the D614G variant 14 days after the second vaccination (day 36) in participants who were SARS-CoV-2 naive who received both injections, provided samples at day 1 and day 36, did not have protocol deviations, and did not receive an authorised COVID-19 vaccine before day 36. Neutralising antibodies were measured using a pseudovirus neutralisation assay and are presented here up to 14 days after the second dose. As a secondary immunogenicity objective, we assessed neutralising antibodies in non-naive participants. This trial is registered with ClinicalTrials.gov (NCT04762680) and is closed to new participants for the cohort reported here. FINDINGS: Of 722 participants enrolled and randomly assigned between Feb 24, 2021, and March 8, 2021, 721 received at least one injection (low dose=240, medium dose=239, and high dose=242). The proportion of participants reporting at least one solicited adverse reaction

(injection site or systemic) in the first 7 days after any vaccination was similar between treatment groups (217 [91%] of 238 in the low-dose group, 213 [90%] of 237 in the medium-dose group, and 218 [91%] of 239 in the high-dose group); these adverse reactions were transient, were mostly mild to moderate in intensity, and occurred at a higher frequency and intensity after the second vaccination. Four participants reported immediate unsolicited adverse events; two (one each in the low-dose group and medium-dose group) were considered by the investigators to be vaccine related and two (one each in the low-dose and high-dose groups) were considered unrelated. Five participants reported seven vaccine-related medically attended adverse events (two in the low-dose group, one in the medium-dose group, and four in the high-dose group). No vaccine-related serious adverse events and no adverse events of special interest were reported. Among participants naive to SARS-CoV-2 at day 36, 158 (98%) of 162 in the low-dose group, 166 (99%) of 168 in the medium-dose group, and 163 (98%) of 166 in the high-dose group had at least a two-fold increase in neutralising antibody titres to the D614G variant from baseline. Neutralising antibody geometric mean titres (GMTs) at day 36 for participants who were naive were 2189 (95% CI 1744-2746) for the low-dose group, 2269 (1792-2873) for the medium-dose group, and 2895 (2294-3654) for the high-dose group. GMT ratios (day 36: day 1) were 107 (95% CI 85-135) in the low-dose group, 110 (87-140) in the medium-dose group, and 141 (111-179) in the high-dose group. Neutralising antibody titres in non-naive adults 21 days after one injection tended to be higher than titres after two injections in adults who were naive, with GMTs 21 days after one injection for participants who were non-naive being 3143 (95% CI 836-11â€ˆ815) in the low-dose group, 2338 (593-9226) in the medium-dose group, and 7069 (1361-36â€ˆ725) in the high-dose group. INTERPRETATION: Two injections of CoV2 preS dTM-AS03 showed acceptable safety and reactogenicity, and robust immunogenicity in adults who were SARS-CoV-2 naive and non-naive. These results supported progression to phase 3 evaluation of the 10 7mu;g antigen dose for primary vaccination and a 5 7mu;g antigen dose for booster vaccination. FUNDING: Sanofi Pasteur and Biomedical Advanced Research and Development Authority.

Omicron neutralising antibodies after third COVID-19 vaccine dose in patients with cancer.

mRNA-1273 vaccine-induced antibodies maintain Fc effector functions across SARS-CoV-2 variants of concern. SARS-CoV-2 mRNA vaccines confer robust protection against COVID-19, but the emergence of variants has generated concerns regarding the protective efficacy of the currently approved vaccines, which lose neutralizing potency against some variants. Emerging data suggest that antibody functions beyond neutralization may contribute to protection from the disease, but little is known about SARS-CoV-2 antibody effector functions. Here, we profiled the binding and functional capacity of convalescent antibodies and Moderna mRNA-1273 COVID-19 vaccine-induced antibodies across SARS-CoV-2 variants of concern (VOCs). Although the neutralizing responses to VOCs decreased in both groups, the Fc-mediated responses were distinct. In convalescent individuals, although antibodies exhibited robust binding to VOCs, they showed compromised interactions with Fc-receptors. Conversely, vaccine-induced antibodies also bound robustly to VOCs but continued to interact with Fc-receptors and mediate antibody effector functions. These data point to a resilience in the mRNA-vaccine-induced humoral immune response that may continue to offer protection from SARS-CoV-2 VOCs independent of neutralization.

Clinical characteristics of healthcare workers with SARS-CoV-2 infection after vaccination with BNT162b2 vaccine. BACKGROUND: The pandemic of coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), had a significant impact worldwide. Vaccines against COVID-19 appear as a tool able to curb out mortality and reduce the circulation of the virus. Little is known so far about the clinical characteristics of individuals who developed SARS-CoV-2 infection after having received the vaccination, as well as the temporal relationship between vaccine administration and symptoms onset. METHODS: Retrospective cohort

study among the 3219 healthcare workers (HCWs) of the Fondazione IRCCS Ospedale Maggiore Policlinico of Milano who received a full immunization with the BNT162b2 vaccine andÂ who developed SARS-CoV-2 infection (documented through positive RT-PCR on nasopharyngeal swab) in March-April 2021. RESULTS: Overall, we have identified 15 HCWs with SARS-CoV-2 infection after vaccination, 7 (46.7%) of them were male and the mean age was 38.4Â years (SD 14). In 4 of them, the presence of SARS-CoV-2 anti-nucleocapsid (anti-N) antibodies was assessed before vaccination and resulted positive in 1 case. In all HCWs the presence of SARS-CoV-2 anti-spike (anti-S1) antibodies was assessed, on average 42.2Â days after the completion of vaccination, with a mean value of 2055 U/mL (SD 1927.3). SARS-CoV-2 infection was ascertained on average 56.2Â days after vaccination. The mean cycle threshold (Ct) of SARS-CoV-2 PCR was 26.4, the lineage was characterized in 9 HCWs. None of the HCWs reported a primary or secondary immunodeficiency. Regarding symptoms, they were reported only by 7 (46.7%) HCWs and appeared on average 55Â days after the second dose of vaccination. Of those who reported symptoms, one (14.3%) had fever, 7 (100%) rhinitis/conjunctivitis, 4 (57.1%) taste and smell alterations, none had respiratory symptoms, 4 headache/arthralgia (57.1%) and 1 gastrointestinal symptom (14.3%). All symptoms disappeared in a few days and no other unclassified symptoms were reported. CONCLUSIONS: Infections occurring after vaccination with the BNT162b2 vaccine are mostly asymptomatic and are not associated with the serum titre of anti-S1 antibodies. We did not find a predominance of specific viral variants, with several lineages represented.

Vaccination associated with gross domestic product and fewer deaths in countries and regions: A verification study. BACKGROUND: Vaccination can have a substantial impact on mitigating COVID-19 outbreaks. However, the vaccine rollout rates associated with the gross domestic product (GDP) and few deaths are required for verification. Three hypotheses were made: 1. the inflection point (IP) days on the cumulative number of confirmed cases (CNCCs) in 2021 are improved (i.e., shorter than 2021); 2. the vaccinations are associated with national GDP and fewer deaths; and 3. the association is weak between vaccinations and CNCC IP based on the argument that vaccinations are limited to protection against milder infection. METHODS: The corresponding CNCCs and deaths were downloaded from the GitHub website. Four variables, including IP days on CNCCs and deaths, GDP per capita, and vaccine doses administered per 100 people (VD100) in countries/regions, were collected. Correlation coefficients (CCs) between variables were computed to verify the association with vaccination rates. Four tasks were achieved: 1. determining IP days for each country/region; 2. drawing forest plots to identify the improvement in 2021; 3. using a pyramid plot to identify the improvement in US states; and 4. applying the Kano diagram to verify the three hypotheses mentioned above. RESULTS: We observed that: 1. the IP days on CNCCs in 2021 were shorter than those in 2021 among continents and US states; 2. the CCs were 0.66 (tâ€Š=â€Š12.21, Pâ€Š<â€Š.01) and âˆ’0.15 (tâ€Š=â€Š2.11, Pâ€Š<â€Š.01) using the paired variables of [VD100, GDP] and [VD100, deaths IP], respectively; and 3. the CC between CNCC IP and deaths IP was 0.73 (tâ€Š=â€Š14.84, Pâ€Š<â€Š.01), but a weak association with CCâ€Š=â€Šâˆ’0.01 existed between CNCC IP and VD100. CONCLUSION: Our results indicate that vaccination has a significant effect on mitigating COVID-19 outbreaks, even with limited protection against infection. Continued compliance with nonpharmaceutical interventions is essential to the fight against COVID-19 in the future.

[Antibody Response After Two Doses of Inactivated SARS-CoV-2 Vaccine in Healthcare Workers with and without Previous COVID-19 Infection: A Prospective Observational Study]. In this study, we aimed to investigate the anti-S1 IgG response that occurs after inactivated severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccine and the factors affecting this response in healthcare workers (HCWs) who are in the risk group for coronavirus disease 2019 (COVID-19). A total of 276 HCWs, of whom 82 previously exposed to COVID-19 infection and 194 naive who are working in

Kafkas University Faculty of Medicine, Health Research and Application Center were included in this study. Anti-SARS-CoV-2 QuantiVac ELISA IgG (Euroimmun, Lubeck, Germany) kit, coated with recombinant S1 antigen including the receptor binding domain of the SARS-CoV-2 S protein was used for quantitative determination of the humoral immune response in serum samples 28 days after the first and second dose of vaccination. The antibody responses and the mean antibody levels of 194 naive HCWs 28 days after the first and second doses of vaccine were determined to be 27.2%, 98.5% and 19.72 Â± 38.73 BAU, 222.09 Â± 119.18 binding antibody unit (BAU), respectively. The mean antibody levels of 82 HCWs previously exposed to COVID-19 infection 28 days after the first and second doses of vaccine were 268.27 Â± 112.91 BAU and 309.45 Â± 112.75 BAU, respectively. The antibody response reached 100% after the first dose of vaccination. A statistically significant difference was observed between the antibody levels after the first and second doses of vaccine in both groups (p<0.001). It was determined that the mean antibody level formed after the first dose of vaccine administration of HCWs who had COVID-19 infection was statistically higher than the mean antibody level formed after the second dose of vaccine in naive individuals (p= 0.003). There was no significant difference in mean antibody levels after the first (269.10 Â± 117.24 BAU and 266.59 Â± 105.65 BAU, respectively) and second doses (309.98 Â± 113.17 and 308.36 Â± 114.04 BAU, respectively) between individuals previously exposed to COVID-19 infection in the last three months and more than three months (p= 0.925 and p= 0.951, respectively). The highest antibody levels were detected in the 19-30 age group (251.50 Â± 119.81 BAU), women (249.03 Â± 118.57 BAU), body mass index (BMI)<20 kg/m2 group (267.08 Â± 137.51) and non-smokers (237.85 Â± 124.83 BAU) in naive HCWs after the second dose of vaccination. A statistically significant difference was found between age, gender, BMI, smoking and vaccine response (p= 0.003, p= 0.005, p= 0.008 and p= 0.036, respectively). The post-vaccination adverse effects after the first and second doses of vaccination were not observed in 76.1% and 73.9% of HCWs, respectively. There was no increase in the frequency of post-vaccination adverse events after the first and second doses in individuals previously exposed to COVID-19 infection and naive persons (p= 0.46 and p= 0.43, respectively). It was determined that the mean antibody level after the first dose of vaccination in HCWs previously exposed to COVID-19 infection was higher than naive individuals after the second dose vaccination. Prospective clinical studies on antibody levels and their duration of protection are needed for the prevention of COVID-19 infection.

Newly developedâ€‰type 1 diabetes after coronavirus disease 2019 vaccination: A case report.
The vaccine for the coronavirus disease 2019 (COVID-19) has been reported to potentially cause or worsen diabetes. A 73-year-old Japanese woman received two doses of Moderna COVID-19 vaccine. Four weeks after the second vaccination, her glycemic control began to deteriorate, and 8â€‰weeks after the second vaccination, the patient was diagnosed with new-onset typeâ€‰1 diabetes that was strongly positive for autoantibodies and showed a disease-susceptible human leukocyte antigen haplotype, DRB1*04:05:01-DQB1*04:01:01. The glucagon stimulation test suggested an insulin-dependent state, and induction of intensive insulin therapy brought about fair glycemic control. The time period from the COVID-19 vaccination to the development of typeâ€‰1 diabetes was relatively longer than to the onset or exacerbation of typeâ€‰2 diabetes, as previously reported, suggesting the complicated immunological mechanisms for the destruction of Î²-cells associated with the vaccination. In recipients with the disease-susceptible haplotypes, one should be cautious about autoimmune responses for several months after the vaccination.

Interstitial glucose monitoring, type 1 diabetes and COVID-19 vaccine: the patient-reported outcomes and vaccine-associated changes in glucose and side effects (PRO-VACS).

Fulminant myocarditis following coronavirus disease 2019 vaccination: a case report.
BACKGROUND: The BNT162b2 vaccine received emergency use authorization from the U.S. Food and

Drug Administration for the prevention of severe coronavirus disease 2019 (COVID-19) infection. We report a case of biopsy and magnetic resonance imaging (MRI)-proven severe myocarditis that developed in a previously healthy individual within days of receiving the first dose of the BNT162b2 COVID-19 vaccine. CASE SUMMARY: An 80-year-old female with no significant cardiac history presented with cardiogenic shock and biopsy-proven fulminant myocarditis within 12 days of receiving the BNT162b2 COVID-19 vaccine. She required temporary mechanical circulatory support, inotropic agents, and high-dose steroids for stabilization and management. Ultimately, her cardiac function recovered, and she was discharged in stable condition after 2 weeks of hospitalization. A repeat cardiac MRI 3 months after her initial presentation demonstrated stable biventricular function and continued improvement in myocardial inflammation. DISCUSSION: Fulminant myocarditis is a rare complication of vaccination. Clinicians should stay vigilant to recognize this rare, but potentially deadly complication. Due to the high morbidity and mortality associated with COVID-19 infection, the clinical benefits of the BNT162b2 vaccine greatly outweighs the risks of complications.
Heterologous AD5-nCOV plus CoronaVac versus homologous CoronaVac vaccination: a randomized phase 4 trial. The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants and the waning of vaccine-elicited neutralizing antibodies suggests that additional coronavirus disease 2019 (COVID-19) vaccine doses may be needed for individuals who initially received CoronaVac. We evaluated the safety and immunogenicity of the recombinant adenovirus type 5 (AD5)-vectored COVID-19 vaccine Convidecia as a heterologous booster versus those of CoronaVac as homologous booster in adults previously vaccinated with CoronaVac in an ongoing, randomized, observer-blinded, parallel-controlled phase 4 trial (NCT04892459). Adults who had received two doses of CoronaVac in the past 3-6 months were vaccinated with Convidecia (nâ€‰=â€‰96) or CoronaVac (nâ€‰=â€‰102). Adults who had received one dose of CoronaVac in the past 1-3 months were also vaccinated with Convidecia (nâ€‰=â€‰51) or CoronaVac (nâ€‰=â€‰50). The co-primary endpoints were the occurrence of adverse reactions within 28â€‰d after vaccination and geometric mean titers (GMTs) of neutralizing antibodies against live wild-type SARS-CoV-2 virus at 14â€‰d after booster vaccination. Adverse reactions after vaccination were significantly more frequent in Convidecia recipients but were generally mild to moderate in all treatment groups. Heterologous boosting with Convidecia elicited significantly increased GMTs of neutralizing antibody against SARS-CoV-2 than homologous boosting with CoronaVac in participants who had previously received one or two doses of CoronaVac. These data suggest that heterologous boosting with Convidecia following initial vaccination with CoronaVac is safe and more immunogenic than homologous boosting.
Resistant breast abscess due to covid-19 vaccination.
Optic neuritis following COVID-19 vaccination: Coincidence or side-effect? - A case series. The whole world waiting for the elimination of COVID-19. This is a short series of three cases that presented with optic neuritis. On further inquiry, all had received the Covishield vaccine within 5-12 days just before the presentation, with no history of COVID-19 positive RT-PCR. The range of age was 27-48 years. All patients improved after pulse steroid therapy and are still under follow-up. After being plagued by COVID-19 for nearly 2 years, the whole world wishes for little more than complete eradication of the disease. Our country commenced the much-awaited vaccination drive from Jan 2021. Ophthalmic manifestations have appeared in many forms post-COVID-19, among which neuro-ophthalmic manifestations are infrequent. To the best of our knowledge, this is the first report of a short case series from our country presenting with optic neuritis after COVID-19 vaccination, without any sign of active infection.
In brief: Pfizer/BioNTech COVID-19 vaccine authorized for children 5-11 years old.

Higher Proinflammatory Cytokines Are Associated With Increased Antibody Titer After a Third Dose of SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients. BACKGROUND: Solid organ transplant recipients (SOTRs) are at increased risk for severe COVID-19 and exhibit lower antibody responses to SARS-CoV-2 vaccines. This study aimed to determine if prevaccination cytokine levels are associated with antibody response to SARS-CoV-2 vaccination. METHODS: A cross-sectional study was performed among 58 SOTRs before and after two-dose mRNA vaccine series, 35 additional SOTRs before and after a third vaccine dose, and comparison to 16 healthy controls (HCs). Antispike antibody was assessed using the IgG Euroimmun ELISA. Electrochemiluminescence detection-based multiplexed sandwich immunoassays (Meso Scale Diagnostics) were used to quantify plasma cytokine and chemokine concentrations (n = 20 analytes) and compare concentrations between SOTRs and HCs, stratified by ultimate antibody response to the vaccine using Wilcoxon-rank-sum test with false discovery rates computed to correct for multiple comparisons. RESULTS: In the study population, 100% of HCs, 59% of SOTRs after 2 doses and 63% of SOTRs after 3 doses had a detectable antibody response. Multiple baseline cytokines were elevated in SOTRs versus HCs. There was no significant difference in baseline cytokine levels between SOTRs with high versus low-titer antibodies after 2 doses of vaccine. However, as compared with poor antibody responders, SOTRs who went on to develop a high-titer antibody response to a third dose of vaccine had significantly higher prethird dose levels of several innate immune cytokines including IL-17, IL-2Ra, IL-6, IP-10, MIP-1Î±, and TNF-Î± (false discovery rates < 0.05). CONCLUSIONS: A specific inflammatory profile may be associated with developing higher antibodies in response to a third dose of SARS-CoV-2 vaccine in SOTRs.

Vaccines may cause rare, Long Covid-like symptoms. [Figure: see text].

Humoral immunogenicity and tolerability of heterologous ChAd/BNT compared with homologous BNT/BNT and ChAd/ChAd SARS-CoV-2 vaccination in hemodialysis patients : A multicenter prospective observational study. BACKGROUND: After the reports ofÂ severe adverse reactions to the AstraZeneca ChAdOx1-S-nCoV-19 vaccine, patients who had received one dose of ChAdOx1-S-nCoV-19 vaccine were recommended a second dose of Pfizer's BNT162b2 vaccine. In hemodialysis patients, we compared the humoral immunogenicity and tolerability of homologous vaccination with ChAdOx1-nCoV-19/ChAdOx1-nCoV-19 (ChAd/ChAd) and BNT162b2/BNT162b2 (BNT/BNT) with heterologous vaccination of first dose of ChAdOx1-nCoV-19 and a second dose with BNT162b2 (ChAd/BNT). METHODS: In a multicenter prospective observational study, SARS-CoV-2 spike-IgG antibody levels, Nucleocapsid-protein-IgG-antibodies, and vaccine tolerability were assessed 6 weeks after second SARS-CoV-2 vaccination in 137 hemodialysis patients and 24 immunocompetent medical personnel. RESULTS: In COVID-19-naÃ¯ve hemodialysis patients, significantly higher median SARS-CoV-2-spike IgG levels were found after ChAd/BNT (Nâ€‰=â€‰16) compared to BNT/BNT (Nâ€‰=â€‰100) or ChAd/ChAd (Nâ€‰=â€‰10) (1744 [25th-75th percentile 276-2840] BAU/mL versus 361 [25th-75th percentile 120-936] BAU/mL; pâ€‰=â€‰0.009; 1744 [25th-75th percentile 276-2840] BAU/mL versus 100 [25th-75th percentile 41-346] BAU/mL; pâ€‰=â€‰0.017, respectively). Vaccinated, COVID-19-naÃ¯ve medical personnel had median SARS-CoV-2 spike-IgG levels of 650 (25th-75th percentile 217-1402) BAU/mL and vaccinated hemodialysis patients with prior COVID-19 7047 (25th-75th percentile 685-10,794) BAU/mL (Nâ€‰=â€‰11). In multivariable regression analysis, heterologous vaccination (ChAd/BNT) of COVID-19-naÃ¯ve hemodialysis patients was independently associated with SARS-CoV-2 spike-IgG levels. The first dose of ChAd and the second dose of BNT after the first vaccination with ChAd (heterologous vaccination, ChAd/BNT) were associated with more frequent but manageable side effects compared with homologous BNT. CONCLUSIONS: Within the limitations of this study, heterologous vaccination with ChAd/BNT appears to induce stronger humoral immunity and more frequent but manageable side effects than

homologous vaccination with BNT/BNT or with ChAd/ChAd in COVID-19-naÃ¯ve hemodialysis patients.
COVID-19 mRNA vaccine safety, immunogenicity, and effectiveness in a hospital setting: confronting the challenge.
High seroconversion rate after vaccination with mRNA BNT162b2 vaccine against SARS-CoV-2 among people with HIV - but HIV viremia matters? Our clinical trial of SARS-COV-2 mRNA vaccine in 90 HIV-infected persons on antiviral treatment demonstrated high seroconversion rate and high levels of spike IgG antibodies after two doses of vaccine. The vaccine was well tolerated and not associated with HIV RNA blips. However, the levels of spike IgG antibodies were lower in HIV patients than in healthy controls, especially among those with HIV RNA more than 50â€Šcopies/ml at baseline.
Vaccine-induced COVID-19 mimicry syndrome. To fight the COVID-19 pandemic caused by the RNA virus SARS-CoV-2, a global vaccination campaign is in progress to achieve the immunization of billions of people mainly with adenoviral vector- or mRNA-based vaccines, all of which encode the SARS-CoV-2 Spike protein. In some rare cases, cerebral venous sinus thromboses (CVST) have been reported as a severe side effect occurring 4-14 days after the first vaccination and were often accompanied by thrombocytopenia. Besides CVST, splanchnic vein thromboses (SVT) and other thromboembolic events have been observed. These events only occurred following vaccination with adenoviral vector-based vaccines but not following vaccination with mRNA-based vaccines. Meanwhile, scientists have proposed an immune-based pathomechanism and the condition has been coined vaccine-induced immune thrombotic thrombocytopenia (VITT). Here, we describe an unexpected mechanism that could explain thromboembolic events occurring with DNA-based but not with RNA-based vaccines. We show that DNA-encoded mRNA coding for Spike protein can be spliced in a way that the transmembrane anchor of Spike is lost, so that nearly full-length Spike is secreted from cells. Secreted Spike variants could potentially initiate severe side effects when binding to cells via the ACE2 receptor. Avoiding such splicing events should become part of a rational vaccine design to increase safety of prospective vaccines.
Macrophage activation syndrome after BNT162b2 mRNA vaccination successfully treated with corticosteroids.
Differing kinetics of anti-spike protein IgGs and neutralizing antibodies against SARS-CoV-2 after Comirnaty (BNT162b2) immunization. AIMS: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection has had a serious worldwide impact on human health. On December 2020, an immunization campaign with a COVID-19 mRNA vaccine (Comirnaty-BNT162b2 Pfizer-BioNTech) was started in Italy, first targeting healthcare workers (HCWs). This study aims to investigate the antibodies that are response against SARS-CoV-2 vaccine. METHODS AND RESULTS: The kinetics and the persistence of both anti-S1/S2 IgGs and neutralizing antibodies (Nt-Abs) were investigated in 76 HCWs through a 4-month follow-up with multiple testing points starting at the first dose. Temporal analysis of SARS-CoV-2 Abs titre kinetics showed three different stages, with an initial slow growth in the anti-S1/S2 IgGs and Nt-Abs titres, corresponding to the first 4Â weeks after the first dose of vaccine, followed by a second stage with peaks in titres, around 35Â days after the first dose, and by a third stage (38 to 90-120Â days after the first dose) showing a steady decrease in anti-S1/S2 IgGs while Nt-Abs are maintained at stable levels. Moreover, the levels of specific Nt-Abs to SARS-CoV-2 Spike protein are correlated to the anti-S1/S2 IgG titre (R-squaredÂ =Â 0.47; pÂ <Â 0.001). CONCLUSIONS: The levels of specific Nt-Abs to SARS-CoV-2 Spike protein are correlated to the anti-S1/S2 IgG titre, although Nt-Abs could maintain a more stable titre over the time despite declining IgG Abs titre. SIGNIFICANCE AND IMPACT: This study highlights the kinetics and the persistence of Nt-Abs in HCWs vaccinated with Comirnaty (BNT162b2) Pfizer-BioNTech, and compared the Nt-Abs levels

with anti-SARS-CoV-2 S1/S2 IgGs titres during a 4-month follow-up starting at the first dose of vaccine.
Rare cerebral vein thrombosis and COVID-19 vaccine: the role of orbit ultrasound.
Deep venous thrombosis and pulmonary embolism after COVID-19 mRNA vaccination.
Relief After COVID-19 Vaccination: A Doubtful or Evident Outcome? Background: Since development of the first COVID-19 vaccine, the landscape of public confidence in these vaccines is uncertain. Building confidence is crucial for better preparedness of future pandemics. Following the mandatory COVID-19 vaccination policy in the country, the aim of this study was to examine whether the Saudi public feels relieved post-vaccination and to identify the factors predicting such relief. Methods: An online cross-sectional survey was conducted in July 2021 among COVID-19 vaccine recipients in Saudi Arabia. A multivariable logistic regression analysis was employed to examine and identify the variables associated with feeling relieved post-vaccination. Results: Most of the respondents (66%) stated feeling more relieved post-vaccination. Male gender [adjusted odds ratio (AOR): 1.380; 95% confidence interval (CI): 0.981-1.943], being a student (AOR: 3.902; 95% CI: 1.674-9.096), and received two doses of the vaccine (AOR: 2.278; 95% CI: 1.630-3.182) were associated with feeling more relieved after getting vaccinated. Respondents who were anxious about the vaccine before receiving it (AOR: 0.220; 95% CI: 0.160-0.302), and experienced a severe reaction after vaccination (AOR: 0.288; 95% CI: 0.165-0.504) had lower odds of feeling relieved post-vaccination. Respondents who relied on social media as the main source of vaccine-related information and those having no information about the vaccine were also less likely to feel relieved post-vaccination. Conclusions: Individuals' attitudes toward COVID-19 vaccines may not necessarily alter post-vaccination. Although mandatory vaccination policies can significantly contribute to achieving herd immunity, public confidence toward vaccines might be eroded, which could in turn impose significant challenges in future pandemics efforts.
Menstruation and covid-19 vaccination.
Acute Pancreatitis in an Adolescent Following COVID Vaccination.
Efficacy and safety profile of COVID-19 vaccine in cancer patients: a prospective, multicenter cohort study. Aim: To compare the seropositivity rate of cancer patients with noncancer controls after inactive SARS-CoV-2 vaccination and evaluate the factors affecting seropositivity. Method: Spike IgG antibodies against SARS-CoV-2 were measured in blood samples of 776 cancer patients and 715 noncancer volunteers. An IgG level â‰¥50Â AU/ml is accepted as seropositive. Results: The seropositivity rate was 85.2% in the patient group and 97.5% in the control group. The seropositivity rate and antibody levels were significantly lower in the patient group (pÂ <Â 0.001). Age and chemotherapy were associated with lower seropositivity in cancer patients (pÂ <Â 0.001). Conclusion: This study highlighted the efficacy and safety of the inactivated vaccine in cancer patients. ClinicalÂ Trials Registration: NCT04771559Â (ClinicalTrials.gov).   Cancer patients are at high risk for infection with SARS-CoV-2 and of developing the associated disease, COVID-19, which therefore puts them in the priority group for vaccination. This study evaluated the efficacy and safety of inactive SARSCoV-2 vaccination, an inactivated virus vaccine, in cancer patients. The immune response rate, defined as seropositivity, was 85.2% in the cancer patient group and 97.5% in the control group. The levels of antibodies, which are blood markers of immune response to the vaccine, were also significantly lower in the patient group, especially in those older than 60Â years and receiving chemotherapy. These results highlight the importance of determining the effective vaccine type and dose in cancer patients to protect them from COVID-19 without disrupting their cancer treatment.
Rural prioritization may increase the impact of COVID-19 vaccines in a representative COVAX AMC country setting due to ongoing internal migration: A modeling study. How COVID-19 vaccine is

distributed within low- and middle-income countries has received little attention outside of equity or logistical concerns but may ultimately affect campaign impact in terms of infections, severe cases, or deaths averted. In this study we examined whether subnational (urban-rural) prioritization may affect the cumulative two-year impact on disease transmission and burden of a vaccination campaign using an agent-based model of COVID-19 in a representative COVID-19 Vaccines Global Access (COVAX) Advanced Market Commitment (AMC) setting. We simulated a range of vaccination strategies that differed by urban-rural prioritization, age group prioritization, timing of introduction, and final coverage level. Urban prioritization averted more infections in only a narrow set of scenarios, when internal migration rates were low and vaccination was started by day 30 of an outbreak. Rural prioritization was the optimal strategy for all other scenarios, e.g., with higher internal migration rates or later start dates, due to the presence of a large immunological naive rural population. Among other factors, timing of the vaccination campaign was important to determining maximum impact, and delays as short as 30 days prevented larger campaigns from having the same impact as smaller campaigns that began earlier. The optimal age group for prioritization depended on choice of metric, as prioritizing older adults consistently averted more deaths across all of the scenarios. While guidelines exist for these latter factors, urban-rural allocation is an orthogonal factor that we predict to affect impact and warrants consideration as countries plan the scale-up of their vaccination campaigns.

Four cases of acquired hemophilia A following immunization with mRNA BNT162b2 SARS-CoV-2 vaccine. Acquired hemophilia A (AHA) is a rare autoimmune disease caused by neutralizing autoantibodies against coagulation Factor VIII. Immunomodulatory effects of SARS-CoV-2 vaccination are still poorly understood, with reports of immune-mediated conditions developing after immunization. In the province of Reggio Emilia, Northern Italy, we observed four cases of AHA following SARS-CoV-2 immunization with mRNA BNT162b2 vaccine (produced by Pfizer-BioNTech) during the first eight months from the beginning of SARS-CoV-2 vaccination campaign. During this time frame, 235,597 people received at least one dose of BNT162b2 vaccine. The total population of Reggio Emilia province is 526,349. The unusual observation of four cases of AHA in our province could be of interest and could sensitize healthcare personnel toward a possible complication of SARS-Cov-2 immunization. Nonetheless, vaccination benefits exceed potential side effects and play a central role in individual and public health to effectively protect people from COVID-19 and to stop the pandemic.

Homologous and Heterologous Covid-19 Booster Vaccinations. BACKGROUND: Although the three vaccines against coronavirus disease 2019 (Covid-19) that have received emergency use authorization in the United States are highly effective, breakthrough infections are occurring. Data are needed on the serial use of homologous boosters (same as the primary vaccine) and heterologous boosters (different from the primary vaccine) in fully vaccinated recipients. METHODS: In this phase 1-2, open-label clinical trial conducted at 10 sites in the United States, adults who had completed a Covid-19 vaccine regimen at least 12 weeks earlier and had no reported history of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection received a booster injection with one of three vaccines: mRNA-1273 (Moderna) at a dose of 100 Î¼g, Ad26.COV2.S (Johnson & Johnson-Janssen) at a dose of 5Ã—10(10) virus particles, or BNT162b2 (Pfizer-BioNTech) at a dose of 30 Î¼g. The primary end points were safety, reactogenicity, and humoral immunogenicity on trial days 15 and 29. RESULTS: Of the 458 participants who were enrolled in the trial, 154 received mRNA-1273, 150 received Ad26.COV2.S, and 153 received BNT162b2 as booster vaccines; 1 participant did not receive the assigned vaccine. Reactogenicity was similar to that reported for the primary series. More than half the recipients reported having injection-site pain, malaise, headache, or myalgia. For all combinations, antibody neutralizing titers against a SARS-CoV-2 D614G pseudovirus increased by a factor of 4 to 73, and binding titers increased by a factor of 5 to 55. Homologous boosters increased

neutralizing antibody titers by a factor of 4 to 20, whereas heterologous boosters increased titers by a factor of 6 to 73. Spike-specific T-cell responses increased in all but the homologous Ad26.COV2.S-boosted subgroup. CD8+ T-cell levels were more durable in the Ad26.COV2.S-primed recipients, and heterologous boosting with the Ad26.COV2.S vaccine substantially increased spike-specific CD8+ T cells in the mRNA vaccine recipients. CONCLUSIONS: Homologous and heterologous booster vaccines had an acceptable safety profile and were immunogenic in adults who had completed a primary Covid-19 vaccine regimen at least 12 weeks earlier. (Funded by the National Institute of Allergy and Infectious Diseases; DMID 21-0012 ClinicalTrials.gov number, NCT04889209.).

Hypersensitivity reactions to vaccines in children: from measles to SARS-CoV-2. Allergic individuals at risk for hypersensitivity reactions to measles vaccine marketed for a long time are well established. On the other hand, risk factors for hypersensitivity reactions to the new mRNA COVID-19 vaccines currently include a history of allergy, allergy to excipient of the vaccine, or hypersensitivity reactions to the first dose of COVID-19 vaccine. In the last two cases, the recipient should be assessed by an allergist before vaccination to share a decision on the choice of vaccination. Studies on skin testing accuracy and desensitization protocols to the COVID-19 vaccines and the efficacy of potential alternatives in patients with confirmed hypersensitivity reactions to the first COVID-19 vaccine are necessary to improve the safety of COVID-19 vaccines.

Can Covid-19 vaccines cause or exacerbate bullous pemphigoid? A report of seven cases from one center.

COVID-19 vaccines and risks of hematological abnormalities: Nested case-control and self-controlled case series study. Several studies reported hematological abnormalities after vaccination against the coronavirus disease 2019 (COVID-19). We evaluated the association between COVID-19 vaccines (CoronaVac and BNT162b2) and hematological abnormalities. We conducted nested case-control and self-controlled case series analyses using the data from the Hong Kong Hospital Authority and the Department of Health, HKSAR. Outcomes of interest were thrombocytopenia, leukopenia, and neutropenia. Adjusted odds ratios (aORs), incidence rate ratios (IRRs), and 95% confidence intervals (CIs) were estimated using conditional logistic regression. In total, 1Â 643â€‰419 people received COVID-19 vaccination (738â€‰609 CoronaVac; 904â€‰810 BNT162b2). We identified 457 and 422 cases after CoronaVac and BNT162b2 vaccination, respectively. For CoronaVac, the incidence of thrombocytopenia, leukopenia, and neutropenia was 2.51, 1.08, and 0.15 per 10Â 000 doses. For BNT162b2, the corresponding incidence was 1.39, 1.17, and 0.26 per 10Â 000 doses. The incidence per 10Â 000 COVID-19 cases were 1254, 2341, and 884, respectively. We only observed an increased risk of leukopenia following the second dose of BNT162b2 (aOR 1.58, 95% CI 1.24-2.02; day 0-14, IRR 2.21; 95% CI 1.59-3.08). There was no increased risk of any hematological abnormalities after CoronaVac vaccination. We observed an increased risk of leukopenia shortly after the second dose of BNT162b2. However, the incidence was much lower than the incidence following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections. There was no association between CoronaVac and hematological abnormalities. The benefits of vaccination against COVID-19 still outweigh the risk of hematological abnormalities.

In Vitro Fertilization and Early Pregnancy Outcomes After Coronavirus Disease 2019 (COVID-19) Vaccination. OBJECTIVE: To assess whether coronavirus disease 2019 (COVID-19) mRNA vaccination is associated with controlled ovarian hyperstimulation or early pregnancy outcomes. METHODS: This retrospective cohort study included patients who underwent controlled ovarian hyperstimulation or single euploid frozen-thawed embryo transfer at a single academic center. Patients fully vaccinated with a COVID-19 mRNA vaccine were compared with unvaccinated patients who cycled during the same time period. The primary outcome was the fertilization rate for controlled ovarian hyperstimulation and the clinical pregnancy rate for frozen-thawed embryo

transfer. Secondary outcomes for controlled ovarian hyperstimulation included eggs retrieved, mature oocytes retrieved, mature oocytes ratio, blastulation rate, and euploid rate. Secondary outcomes for frozen-thawed embryo transfer included pregnancy rate, ongoing pregnancy rate, biochemical pregnancy loss rate, and clinical pregnancy loss rate. RESULTS: Among 222 vaccinated patients and 983 unvaccinated patients who underwent controlled ovarian hyperstimulation cycles between February and September 2021, there was no association on adjusted analysis between COVID-19 vaccination and fertilization rate (Î²=0.02Â±0.02, P=.20) or any of the secondary outcomes assessed: eggs retrieved (Î²=0.01Â±0.57, P=.99), mature oocytes retrieved (Î²=0.26Â±0.47, P=.58), mature oocytes ratio (Î²=0.02Â±0.01, P=.12), blastulation rate (Î²=0.02Â±0.02, P=.27), or euploid rate (Î²=0.05Â±0.03, P=.08). Among 214 vaccinated patients and 733 unvaccinated patients undergoing single euploid frozen-thawed embryo transfer, adjusted analysis demonstrated no significant association between vaccination and clinical pregnancy (adjusted odds ratio [aOR] 0.79, 95% CI 0.54-1.16) or any of the secondary outcomes: pregnancy (aOR 0.88, 95% CI 0.58-1.33), ongoing pregnancy (aOR 0.90, 95% CI 0.61-1.31), biochemical pregnancy loss (aOR 1.21, 95% CI 0.69-2.14), or clinical pregnancy loss (aOR 1.02, 95% CI 0.51-2.06). CONCLUSION: Administration of COVID-19 mRNA vaccines was not associated with an adverse effect on stimulation or early pregnancy outcomes after IVF. Our findings contribute to the growing body of evidence regarding the safety of COVID-19 vaccination in women who are trying to conceive.

Comments on "Patients' findings afterÂ COVID-19 infection andÂ vaccinations: what toÂ expect fromÂ [(18)F]FDG PET/CT".

SARS-CoV-2 DNA Vaccine INO-4800 Induces Durable Immune Responses Capable of Being Boosted in a Phase 1 Open-Label Trial. BACKGROUND: Additional severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines that are safe and effective as primary vaccines and boosters remain urgently needed to combat the coronavirus disease 2019 (COVID-19) pandemic. We describe safety and durability of immune responses following 2 primary doses and a homologous booster dose of an investigational DNA vaccine (INO-4800) targeting full-length spike antigen. METHODS: Three dosage strengths of INO-4800 (0.5Â mg, 1.0Â mg, and 2.0Â mg) were evaluated in 120 age-stratified healthy adults. Intradermal injection of INO-4800 followed by electroporation at 0 and 4 weeks preceded an optional booster 6-10.5 months after the second dose. RESULTS: INO-4800 appeared well tolerated with no treatment-related serious adverse events. Most adverse events were mild and did not increase in frequency with age and subsequent dosing. A durable antibody response was observed 6 months following the second dose; a homologous booster dose significantly increased immune responses. Cytokine-producing T cells and activated CD8+ T cells with lytic potential were significantly increased in the 2.0-mg dose group. CONCLUSIONS: INO-4800 was well tolerated in a 2-dose primary series and homologous booster in all adults, including elderly participants. These results support further development of INO-4800 for use as primary vaccine and booster. CLINICAL TRIALS REGISTRATION: NCT04336410.

Herpes zoster dermatitis in a COVID-19 vaccinated healthy man after 1 dose of varicella vaccine.

Psoriatic flare following Oxford-AstraZeneca ChAdOx1 COVID-19 and influenza vaccines.

Unmasked type 1 Brugada ECG pattern without a fever after a COVID-19 vaccination.

Could Guillain-BarrÃ© syndrome be triggered by COVID-19 vaccination? Due to SARS-COV-2 (COVID-19) pandemic and its catastrophic impact on society, the FDA granted emergency use authorization for some vaccines. Possible rare side effects could not have been observed in this relatively short period. We are reporting an elderly lady with multiple comorbidities who presented with progressive lower limb weakness that started seven days after receiving the first dose of the COVID-19 vaccine. The electrodiagnostic study showed demyelinating polyneuropathy with secondary axonal degeneration consistent with Guillain-BarrÃ© syndrome. We ruled out other

possible causes for GBS, suggesting a postvaccine nature for her presentation. The patient received intravenous immunoglobulin (IVIG) for five days and gradually improved, which supports our initial diagnosis.

Combined Central Retinal Artery and Vein Occlusion with Ischemic Optic Neuropathy After COVID-19 Vaccination. PURPOSE: To report a case of combined central retinal vein and artery occlusion that evolved into ischemic optic neuropathy following the Pfizer COVID-19 vaccination. METHODS: Patient was followed with optical coherence tomography (OCT), fluorescein angiography, and Humphrey visual field. RESULTS: Patient was able to recover vision from count fingers to 20/30 on a combination of aflibercept, steroidal and non-steroidal anti-inflammatories, a diuretic (acetazolamide), antiplatelet agents (aspirin and pentoxifylline), and an anticoagulant (apixaban). CONCLUSION: COVID-19 vaccination may be associated with a myriad of sight-threatening ocular thrombotic conditions, which may respond to a combination of anti-inflammatory and anticoagulant therapies.

COVID-19 vaccination-associated anti-Jo-1 syndrome. Post-vaccination inflammatory myositis is a rare but known entity in the literature. We encountered a 46-year-old female patient, who presented with complains of fever, arthralgia, and weakness 1 week after taking the second dose of COVID-19 (Oxford-AstraZeneca) vaccine. On workup the patient had raised inflammatory markers, evidence of myositis on magnetic resonance imaging of thighs, and evidence of interstitial lung disease on high-resolution computed tomography of the chest. The patient was further found to be positive for anti-Jo-1 antibody. The initial treatment was glucocorticosteroids and methotrexate initially. The patient briefly developed pneumocystis pneumonia and recovered. The treatment was switched to mycophenolate mofetil with good response. We presented the first case of anti-Jo-1 syndrome reported following COVID-19 vaccination in the literature. Our aim is to sensitise the clinicians to such rare but occasionally life-threatening complications that may arise in the post-vaccination period.

Impact of prior SARS-CoV-2 infection on incidence of hospitalization and adverse events following mRNA SARS-CoV-2 vaccination: A nationwide, retrospective cohort study. BACKGROUND: Previous studies evaluated the SARS-CoV-2 vaccine safety or compared adverse events following vaccination to those from infection. Limited data about the impact of prior infection on post-vaccine adverse events are available. The objective of this study was to evaluate the impact of prior SARS-CoV-2 infection on outcomes shortly after vaccination using a longitudinal design. METHODS: Nationwide, multicenter, retrospective cohort study of hospitalization, death, and pre-specified adverse event rates among Veterans who received mRNA vaccines within the Veterans Health Administration between 12/11/2020 and 8/31/2021. Daily incidence rates were compared before and after vaccine doses, stratified by history of microbiologically-confirmed SARS-CoV-2. RESULTS: 3,118,802 patients received a first dose and 2,979,326 a second, including 102,829 with a history of SARS-CoV-2 infection. Daily incident hospitalization rates were unchanged before and after the second dose among patients without previous infection (28.8/100,000 post-dose versus 28.6/100,000 pre-dose, pÂ =Â 0.92). In previously-infected patients, the hospitalization rate increased above baseline one day following vaccination (158.2/100,000 after dose 2 versus 57.3/100,000 pre-dose, pÂ <Â 0.001), then returned to baseline. Chart review indicated vaccine side effects, such as fever, constitutional symptoms, weakness, or falls, as the definite (39%) or possible (18%) cause of hospitalization. Affected patients had mean age 75, and 90% had at least one serious comorbidity. Hospitalizations were brief (median 2Â days), with rapid return to baseline health. Worse baseline health among previously-infected patients prevented conclusions about mortality risk. CONCLUSIONS: Two-dose mRNA vaccine regimens are safe in a population with many comorbidities. Transient increased risks of hospitalization were identified among patients with prior SARS-CoV-2,

absolute risk âˆ¼1:1000. Findings support additional study regarding the optimal dosing schedule in this population. FUNDING: None.
A recombinant SARS-CoV-2 receptor-binding domain expressed in an engineered fungal strain of Thermothelomyces heterothallica induces a functional immune response in mice. Since the beginning of the COVID-19 pandemic, the development of effective vaccines against this pathogen has been a priority for the scientific community. Several strategies have been developed including vaccines based on recombinant viral protein fragments. The receptor-binding domain (RBD) in the S1 subunit of S protein has been considered one of the main targets of neutralizing antibodies. In this study we assess the potential of a vaccine formulation based on the recombinant RBD domain of SARS-CoV-2 expressed in the thermophilic filamentous fungal strain Thermothelomyces heterothallica and the hepatitis B virus (HBV) core protein. Functional humoral and cellular immune responses were detected in mice. To our knowledge, this is the first report on the immune evaluation of a biomedical product obtained in the fungal strain T. heterothallica. These results together with the intrinsic advantages of this expression platform support its use for the development of biotechnology products for medical purpose.
Post COVID-19 vaccine deaths - Singapore's early experience. Singapore has been using mRNA vaccines developed by Pfizer-BioNTech and Moderna as part of the nation's COVID vaccination program since 30 December 2020. From 1 February 2021-30Â June 2021, a total of 34 deaths that occurred within 72Â h of the deceased receiving their COVID-19 vaccination were referred to the Forensic Medicine Division of the Health Sciences Authority of Singapore. Autopsies, histological sampling and ancillary investigations consisting of total tryptase level, Immunoglobulin E (IgE), and C-reactive Protein (CRP), were performed on 29 of these cases. Our study has shown no definite causative relationship between the mRNA vaccination and deaths of individuals who died within 72Â h after receiving the vaccination, in particular with regards to anaphylactic reactions, myocarditis and pericarditis, and thrombotic complications. Further studies may consider increasing the incident time frame from 72Â h to seven days post-vaccination or longer to include any potential delayed presentation of adverse effects.
Antibody titres before and after a third dose of the SARS-CoV-2 BNT162b2 vaccine in patients with cancer.
Coincidental Onset of Ocular Myasthenia Gravis Following ChAdOx1 n-CoV-19 Vaccine against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). The Oxford-AstraZeneca vaccine ChAdOx1 (AZD1222, Vaxzevria) is playing a crucial role in counteracting the coronavirus disease-2019 (COVID-19) pandemic [1]. Since March 2021, reports of unexpected thrombotic events associated with thrombocytopenia and vaccination have been published [2]. To the best of our knowledge there is only one report about vaccination-associated myasthenia gravis (MG) occurring after a second dose of BNT162b2 (Pfizer-BioNTech).
Association of Ad26.COV2.S COVID-19 Vaccine With Presumptive Guillain-BarrÃ© Syndrome.
Presumptive Guillain-BarrÃ© Syndrome Associated With Receipt of the Ad26.COV2.2.S COVID-19 Vaccine-Reply.
Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021. IMPORTANCE: Vaccination against COVID-19 provides clear public health benefits, but vaccination also carries potential risks. The risks and outcomes of myocarditis after COVID-19 vaccination are unclear. OBJECTIVE: To describe reports of myocarditis and the reporting rates after mRNA-based COVID-19 vaccination in the US. DESIGN, SETTING, AND PARTICIPANTS: Descriptive study of reports of myocarditis to the Vaccine Adverse Event Reporting System (VAERS) that occurred after mRNA-based COVID-19 vaccine administration between December 2020 and August 2021 in 192â€¯405â€¯448 individuals older than 12 years of age in the US; data were

processed by VAERS as of September 30, 2021. EXPOSURES: Vaccination with BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna). MAIN OUTCOMES AND MEASURES: Reports of myocarditis to VAERS were adjudicated and summarized for all age groups. Crude reporting rates were calculated across age and sex strata. Expected rates of myocarditis by age and sex were calculated using 2017-2019 claims data. For persons younger than 30 years of age, medical record reviews and clinician interviews were conducted to describe clinical presentation, diagnostic test results, treatment, and early outcomes. RESULTS: Among 192â€¯405â€¯448 persons receiving a total of 354â€¯100â€¯845 mRNA-based COVID-19 vaccines during the study period, there were 1991 reports of myocarditis to VAERS and 1626 of these reports met the case definition of myocarditis. Of those with myocarditis, the median age was 21 years (IQR, 16-31 years) and the median time to symptom onset was 2 days (IQR, 1-3 days). Males comprised 82% of the myocarditis cases for whom sex was reported. The crude reporting rates for cases of myocarditis within 7 days after COVID-19 vaccination exceeded the expected rates of myocarditis across multiple age and sex strata. The rates of myocarditis were highest after the second vaccination dose in adolescent males aged 12 to 15 years (70.7 per million doses of the BNT162b2 vaccine), in adolescent males aged 16 to 17 years (105.9 per million doses of the BNT162b2 vaccine), and in young men aged 18 to 24 years (52.4 and 56.3 per million doses of the BNT162b2 vaccine and the mRNA-1273 vaccine, respectively). There were 826 cases of myocarditis among those younger than 30 years of age who had detailed clinical information available; of these cases, 792 of 809 (98%) had elevated troponin levels, 569 of 794 (72%) had abnormal electrocardiogram results, and 223 of 312 (72%) had abnormal cardiac magnetic resonance imaging results. Approximately 96% of persons (784/813) were hospitalized and 87% (577/661) of these had resolution of presenting symptoms by hospital discharge. The most common treatment was nonsteroidal anti-inflammatory drugs (589/676; 87%). CONCLUSIONS AND RELEVANCE: Based on passive surveillance reporting in the US, the risk of myocarditis after receiving mRNA-based COVID-19 vaccines was increased across multiple age and sex strata and was highest after the second vaccination dose in adolescent males and young men. This risk should be considered in the context of the benefits of COVID-19 vaccination.

Psoriasis flare-up after AZD1222 and BNT162b2 COVID-19 mRNA vaccines: report of twelve cases from a single centre.

An analysis of antibody response following the second dose of CoronaVac and humoral response after booster dose with BNT162b2 or CoronaVac among healthcare workers in Turkey. Limited data are available on the short- to midterm levels of antibodies to the CoronaVac vaccine and quantitative change in humoral response after homologous or heterologous booster doses. In this prospective cohort study, we evaluated the anti-receptor-binding domain (RBD) immunoglobulin G (IgG) levels after two doses of CoronaVac and heterologous/homologous booster administration among healthcare workers in a university hospital in Turkey. Quantitative anti-RBD IgG antibody levels were measured at first and fourth months in 560 healthcare workers who had completed two doses of CoronaVac vaccine, and within 2 months after the third dose of CoronaVac or BNT162b2. Participants were asked to complete a questionnaire during the first blood draw. The seropositivity rate was 98.9% and 89.1%, and the median antibody level was 469.2â€‰AU/ml and 166.5â€‰AU/ml at first and fourth month, respectively. In theÂ fourthÂ month, a mean reduction of 61.4%â€‰Â±â€‰20% in antibody levels was observed in 79.8% of the participants. The presence of chronic disease (odds ratio [OR]: 1.76, 95% confidence interval [CI]: 1.15-2.69) and being in the 36-50 age group (OR: 2.11, 95% CI: 1.39-3.19) were identified as independent predictors for low antibody response. The antibody level increased 104.8-fold (median: 17â€‰609.4 vs. 168â€‰AU/ml) and 8.7-fold (median: 1237.9 vs. 141.4â€‰AU/ml) in the participants who received BNT162b2 and CoronaVac, respectively. During the follow-up, 25 healthcare workers (4.5%) were infected with severe acute respiratory syndrome

coronavirus 2. Considering the waning immunity and circulating variants, a single booster dose of messenger RNA vaccine seems reasonable after the inactivated vaccine especially in risk groups.

COVID-19 mRNA vaccine (Comirnaty)-induced myocarditis.

BNT162b2 mRNA COVID-19 vaccine booster induces seroconversion in patients with B-cell non-Hodgkin lymphoma who failed to respond to two prior vaccine doses. This prospective study evaluated seroconversion rates in response to BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine booster in 44 B-cell non-Hodgkin lymphoma (B-NHL) patients who failed to respond to two prior doses [42 previously exposed to anti-CD20Â monoclonal antibodies (moAbs) including 13 under maintenance treatment]. Seroconversion was obtained in 29.5% of the patients. Longer time from last anti-CD20Â moAb (>6Â months) and diagnosis of aggressive lymphoma compared to other, incurable B-NHLs were associated with increased seroconversion rates (47.8% vs.10.5%, pÂ =Â 0.019 and 50% vs. 17.9%, pÂ =Â 0.025 respectively). Thus, seronegative patients with B-NHL that completed anti-CD20 therapy more than 6Â months prior to the booster have greater chances to achieve seroconversion.

Limited Cross-Variant Immunity after Infection with the SARS-CoV-2 Omicron Variant Without Vaccination. SARS-CoV-2 Delta and Omicron strains are the most globally relevant variants of concern (VOCs). While individuals infected with Delta are at risk to develop severe lung disease (1) , Omicron infection causes less severe disease, mostly upper respiratory symptoms (2,3) . The question arises whether rampant spread of Omicron could lead to mass immunization, accelerating the end of the pandemic. Here we show that infection with Delta, but not Omicron, induces broad immunity in mice. While sera from Omicron-infected mice only neutralize Omicron, sera from Delta-infected mice are broadly effective against Delta and other VOCs, including Omicron. This is not observed with the WA1 ancestral strain, although both WA1 and Delta elicited a highly pro-inflammatory cytokine response and replicated to similar titers in the respiratory tracts and lungs of infected mice as well as in human airway organoids. Pulmonary viral replication, pro-inflammatory cytokine expression, and overall disease progression are markedly reduced with Omicron infection. Analysis of human sera from Omicron and Delta breakthrough cases reveals effective cross-variant neutralization induced by both viruses in vaccinated individuals. Together, our results indicate that Omicron infection enhances preexisting immunity elicited by vaccines, but on its own may not induce broad, cross-neutralizing humoral immunity in unvaccinated individuals.

Case report of acute myocarditis after administration of coronavirus disease 2019 vaccine in Japan. BACKGROUND: The worldwide spread of coronavirus disease 2019 (COVID-19) is still not under control and vaccination in Japan started in February 2021, albeit later than in Europe and the USA. The COVID-19 vaccination frequently leads to minor adverse reactions, which may be more intense after the second dose. The number of case reports of myocarditis following COVID-19 vaccination have been recently increased. CASE SUMMARY: We report a case of a 26-year-old healthy man who presented to our hospital with chest pain on 24 May 2021, 4â€‰days after his second COVID-19 vaccination. The electrocardiogram showed ST elevation with upward concavity in I, II, aVL, aVF, V4 to V6, and small Q wave in II, III, aVF. Laboratory studies revealed elevation of troponin I, creatine kinase, C-reactive protein, and negative viral serologies. Acute aortic dissection and pulmonary thromboembolism were ruled out by contrast-enhanced thoracoabdominal computed tomography. An urgent coronary angiogram was performed because an acute coronary syndrome was suspected, but no significant stenosis was found. Cardiac magnetic resonance imaging demonstrated oedema and late gadolinium enhancement of the left ventricle in a mid-myocardial and epicardial distribution. DISCUSSION: Although the temporal association does not prove causation, the very short span between the second vaccination and the onset of myocarditis suggests that this acute myocarditis seemed to be an adverse reaction to COVID-19 vaccine. To the best of our knowledge, this is the first published case of acute myocarditis following COVID-19 vaccine in Asia.

Bilateral acute macular neuroretinopathy in a young woman after the first dose of Oxford-AstraZeneca COVID-19 vaccine. PURPOSE: To report a case of bilateral acute macular neuroretinopathy following the first dose of Oxford-AstraZeneca COVID-19 (coronavirus disease 2019) vaccine in a young, Caucasian, and healthy woman. OBSERVATIONS: A 25-year-old Caucasian female patient presented to the ophthalmology department of Dijon University Hospital with a 3-week history of black spots and paracentral scotoma in both eyes. She had no past medical history and was using the combined estrogen-progestin oral contraceptive (COC). These symptoms occurred 24 h after receiving the first Oxford-AstraZeneca COVID-19 vaccination dose. The ophthalmologic signs were preceded a few hours earlier by fever and flu-like symptoms. Ophthalmologic examination revealed a preserved visual acuity with a quiet anterior segment and normal fundus in both eyes. Findings on multimodal retinal imaging, particularly near-infrared reflectance (NIR) and optical coherence tomography (OCT) imaging, were classical of an acute macular neuroretinopathy in both eyes. CONCLUSIONS AND IMPORTANCE: COVID-19 vaccination is justified as an essential public health measure. Acute macular neuroretinopathy may occur in patient receiving a COVID-19 vaccination dose. Further reports are needed to confirm this association. Physicians should be aware of this complication and request an eye examination with at least OCT or NIR imaging in the case of any visual symptoms after vaccination, notably in young women using COC.

Bell's palsy following COVID-19 vaccine administration in HIV+ patient. PURPOSE: COVID-19 immunizations are novel and there is widespread public concern for the lack of data on their potential adverse effects. Cases of Bell's palsy following COVID-19 vaccination were reported disproportionately in the vaccine group during phase 3 clinical trials and have now been reported multiple times post-licensure. The U.S. Food and Drug Administration has stated the frequency of Bell's palsy in the vaccine group is consistent with the expected background rate of Bell's palsy in the population but recommends "surveillance for cases of Bell's palsy with deployment of the vaccine into larger populations."(1) Here we present a case of Bell's palsy following Pfizer/BioNTech BNT162b2 COVID-19 vaccine administration in an HIV(+)Â patient as a potential adverse event following immunization. OBSERVATIONS: A 60-year-old male with HIV presented to the emergency department for evaluation of left facial droop. He had received the first dose of Pfizer/BioNTech BNT162b2 vaccination approximately 42 hours prior to symptom onset. Physical examination in the ED revealed left-sided facial weakness with involvement of the forehead, inability to raise left eyebrow, and inability to close left eye with sensation and strength intact in bilateral upper and lower extremities. Physical examination in our outpatient ophthalmology clinic on day 2 following symptom onset was revealing for mild exposure keratopathy, 5 mm lagophthalmos and very poor Bell's reflex in the left eye with otherwise normal exam findings. These findings were judged to be consistent with uncomplicated Bell's palsy. He was provided ophthalmic lubricating ointment to use hourly, artificial tears as needed, moisture goggles and suggested to tape eyelids nightly in addition to standard systemic glucocorticoid and antiviral therapy. The patient's facial weakness and exposure keratopathy were completely resolved at approximately 90 days following symptom onset. CONCLUSIONS: Though there is insufficient evidence at this time to support any causal association between COVID-19 vaccines and Bell's palsy, the temporal relationship between vaccination and classic clinical features of Bell's palsy in our patient certainly raises suspicion for association with Pfizer/BioNTech BNT162b2 COVID-19 vaccination. It will be important to monitor for cases of Bell's palsy following COVID-19 immunization as an increasing percentage of the global population receives vaccination.

COVID-19 vaccine trials must include helminth-infected cohorts.

COVID-19 vaccine distrust in Colombian university students: Frequency and associated variables. BACKGROUND AND AIM OF THE WORK: The frequency of distrust towards the COVID-19 vaccine varies widely depending on the context, way of measurement, and pandemic stage. However, little

information is available about Colombian populations. The study aimed to know the frequency and variables associated with COVID-19 vaccine distrust in students of a Colombian university. METHODS: A cross-sectional study was carried out which participated emerging adult students of a Colombian university. RESULTS: A total of 1,136 students between 18 and 29 years (M= 22.0, SD = 3.0); most of participants were female (66.0%), non-health students (82.8%), low-income (79.0%), and residents of urban areas (84.9%). It was frequent low institutional trust (74.8%), low cognitive, social capital (27.9%), low fear of COVID-19 (49.5%), low perceived stress related to COVID-19 (83.5%), and high COVID-19 vaccine distrust (78.9%). Non-health carrier (Adjusted OR = 3.63, 95%CI 2.58-5.10), rural residence (AOR = 1.85, 95%CI 1.13-3.04), low income (AOR = 1.84, 95%CI 1.31-2.57), and perceived stress related to COVID-19 (AOR = 1.74, 95%CI 1.20-2.54) were related to high COVID-19 vaccine distrust. CONCLUSIONS: COVID-19 vaccine distrust is high among emerging adult Colombian university students. The COVID-19 vaccine distrust is related to non-health science carriers, rural residents, low-income, and low-perceived stress related to COVID-19. The COVID-19 related health literacy should be improved in students of this university considering socio-cultural background.

Myocarditis after RNA-based vaccines for coronavirus. BACKGROUND: The incidence of myocarditis after RNA-based vaccines for coronavirus has gained social and medical interest. METHODS: We performed an intention-to-treat meta-analysis, following the PRISMA statement. After a systematic search, without language restriction, 9 publications were selected. Two were excluded (one was only in subjects with age 12-17 and other might had included subjects from a larger publication). We followed the PRISMA guidelines for abstracting data and assessing data quality and validity. Data was verified by 2 investigators. RESULTS: We analyzed 17,704,413 subjects, from 7 studies, that included 627 cases of confirmed myocarditis). The incidence of myocarditis was 0.0035% (95% CI 0.0034-0.0035). Mean incidence rate was 10.69 per 100.000 persons-year. Cases reported from Israel represented 45.14% from total (283 out of the 627). Only 1 case of fatal myocarditis or death was reported. There was significant heterogeneity between results. The meta-regression analysis excluded mean age, region, number of cases or number of people included as sources of heterogeneity. No small-study effect was observed (pÂ =Â 0.19). CONCLUSIONS AND RELEVANCE: Myocarditis incidence after RNA vaccines is very rare (0.0035%) and has a very favorable clinical course.

RBD-specific antibody responses after two doses of BBIBP-CorV (Sinopharm, Beijing CNBG) vaccine. BACKGROUND: Limited information is available on the effectiveness of the BBIBP-CorV (Sinopharm, Beijing CNBG) vaccine, especially in the elderly, despite the fact that it is approved in more than 50 countries. METHODS: RBD-specific antibody titres, as a rapidly available and highly predictive surrogate marker, were measured after two doses of the BBIBP-CorV vaccine in 450 subjects. Results were analyzed in a multivariable model accounting for age, sex and time since the administration of the second dose of the vaccine. RESULTS: Sex and time since the second dose had little association with the antibody titres. Age, however, was highly relevant: measurable antibody levels were present in about 90% of individuals below the age of 50, but antibody production after BBIBP-CorV vaccination was strongly reduced with increasing age. A large number of elderly subjects, reaching 25% at 60Â years, and up to 50% at ages over 80, were found not to produce any protective antibody. CONCLUSIONS: RBD-specific antibody titre, as a correlate of protection for COVID-19 disease susceptibility, should help to evaluate the effectiveness of the BBIBP-CorV vaccine. Results suggest that proper measures should be undertaken to prevent a potential outbreak of COVID-19 in BBIBP-CorV vaccinated but eventually unprotected elderly individuals.

Longitudinal Study after Sputnik V Vaccination Shows Durable SARS-CoV-2 Neutralizing Antibodies and Reduced Viral Variant Escape to Neutralization over Time. Recent studies have shown a temporal increase in the neutralizing antibody potency and breadth to SARS-CoV-2 variants in

coronavirus disease 2019 (COVID-19) convalescent individuals. Here, we examined longitudinal antibody responses and viral neutralizing capacity to the B.1 lineage virus (Wuhan related), to variants of concern (VOC; Alpha, Beta, Gamma, and Delta), and to a local variant of interest (VOI; Lambda) in volunteers receiving the Sputnik V vaccine in Argentina. Longitudinal serum samples (Nâ€‰=â€‰536) collected from 118 volunteers obtained between January and October 2021 were used. The analysis indicates that while anti-spike IgG levels significantly wane over time, the neutralizing capacity for the Wuhan-related lineages of SARS-CoV-2 and VOC is maintained within 6 months of vaccination. In addition, an improved antibody cross-neutralizing ability for circulating variants of concern (Beta and Gamma) was observed over time postvaccination. The viral variants that displayed higher escape to neutralizing antibodies with respect to the original virus (Beta and Gamma variants) were the ones showing the largest increase in susceptibility to neutralization over time after vaccination. Our observations indicate that serum neutralizing antibodies are maintained for at least 6 months and show a reduction of VOC escape to neutralizing antibodies over time after vaccination. IMPORTANCE Vaccines have been produced in record time for SARS-CoV-2, offering the possibility of halting the global pandemic. However, inequalities in vaccine accessibility in different regions of the world create a need to increase international cooperation. Sputnik V is a recombinant adenovirus-based vaccine that has been widely used in Argentina and other developing countries, but limited information is available about its elicited immune responses. Here, we examined longitudinal antibody levels and viral neutralizing capacity elicited by Sputnik V vaccination. Using a cohort of 118 volunteers, we found that while anti-spike antibodies wane over time, the neutralizing capacity to viral variants of concern and local variants of interest is maintained within 4 months of vaccination. In addition, we observed an increased cross-neutralization activity over time for the Beta and Gamma variants. This study provides valuable information about the immune response generated by a vaccine platform used in many parts of the world.

Incident bullous pemphigoid in a psoriatic patient following mRNA-1273 SARS-CoV-2 vaccination.

A case of morphea following the COVID-19 mRNA vaccine: on the basis of viral spike proteins.

Official Websites Providing Information on COVID-19 Vaccination: Readability and Content Analysis. BACKGROUND: Online information on COVID-19 vaccination may influence people's perception and willingness to be vaccinated. Official websites of vaccination programs have not been systematically assessed before. OBJECTIVE: This study aims to assess and compare the readability and content quality of web-based information on COVID-19 vaccination posted on official/governmental websites. Furthermore, the relationship between evaluated website parameters and country vaccination rates were calculated. METHODS: By referring to an open data set hosted at Our World in Data, the 58 countries/regions with the highest total vaccination count as of July 8, 2021, were identified. Together with the websites from the World Health Organization and European Union, a total of 60 vaccination campaign websites were targeted. The "frequently asked questions" or "questions and answers" section of the websites were evaluated in terms of readability (Flesch Reading Ease score and Flesch-Kincaid Grade Level), quality (Health On the Net Foundation code [HONcode] certification and Quality Evaluation Scoring Tool), and content stating vaccination duration of protection and potential side effects. RESULTS: In terms of readability, the Flesch Reading Ease score of the vaccination frequently asked questions websites ranged between 11.2 and 69.5, with a mean of 40.9 (SD 13.2). Meanwhile, the Flesch-Kincaid Grade Level ranged between 6.5 and 17.6, with a mean of 12.1 (SD 2.8). In terms of quality, only 2 websites were HONcode certified, and the Quality Evaluation Scoring Tool score of the websites ranged between 7 and 20, with a mean of 15.3 (SD 3.1). Half of the websites (25/50) did not present a publication date or date of the last update. Regarding the duration of protection offered by the vaccines, 46% (23/50) of the websites stated that they do not know, and another 40% (20/50) did not address it. Five side effects of the vaccinations were most frequently

mentioned, namely, fever/chill (41/50, 82%), various injection site discomfort events (eg, swelling, redness, or pain; 39/50, 78%), headache (36/50, 72%), fatigue (33/50, 66%), and muscle/joint pain (31/50, 62%). CONCLUSIONS: In general, the content quality of most of the evaluated websites was good, but HONcode certification should be considered, content should be written in a more readable manner, and a publication date or date of the last update should be presented.

Carditis After COVID-19 Vaccination With a Messenger RNA Vaccine and an Inactivated Virus Vaccine : A Case-Control Study. BACKGROUND: Case reports of carditis after BNT162b2 vaccination are accruing worldwide. OBJECTIVE: To examine the association of BNT162b2 and CoronaVac (Sinovac) vaccination with carditis. DESIGN: Case-control study with hospital control participants. SETTING: Territory-wide, public health care database with linkage to population-based vaccination records in Hong Kong. PATIENTS: Inpatients aged 12 years or older first diagnosed with carditis were selected as case patients. All other hospitalized patients without carditis were treated as control participants. Ten control participants were randomly matched with each case patient by age, sex, and admission date. INTERVENTION: Vaccination with BNT162b2 or CoronaVac. MEASUREMENTS: Incident diagnosis of carditis based on the International Classification of Diseases, Ninth Revision, and elevated troponin levels. RESULTS: A total of 160 case patients and 1533 control participants were included. Incidence of carditis per 100Â 000 doses of CoronaVac and BNT162b2 administered was estimated to be 0.31 (95% CI, 0.13 to 0.66) and 0.57 (CI, 0.36 to 0.90), respectively. Multivariable analyses showed that recipients of the BNT162b2 vaccine had higher odds of carditis (adjusted odds ratio [OR], 3.57 [CI, 1.93 to 6.60]) than unvaccinated persons. Stratified by sex, the OR was 4.68 (CI, 2.25 to 9.71) for males and 2.22 (CI, 0.57 to 8.69) for females receiving the BNT162b2 vaccine. The ORs for adults and adolescents receiving the BNT162b2 vaccine were 2.41 (CI, 1.18 to 4.90) and 13.79 (CI, 2.86 to 110.38), respectively. Subanalysis showed an OR of 9.29 (CI, 3.94 to 21.91) for myocarditis and 1.06 (CI, 0.35 to 3.22) for pericarditis associated with BNT162b2. The risk was mainly seen after the second dose of BNT162b2 rather than the first. No association between CoronaVac and carditis with a magnitude similar to that for BNT162b2 was seen. LIMITATION: Limited sample size, absence of electrocardiography and other clinical investigative data, and unrecorded overseas vaccination exposure. CONCLUSION: Despite a low absolute risk, there is an increased risk for carditis associated with BNT162b2 vaccination. This elevated risk should be weighed against the benefits of vaccination. PRIMARY FUNDING SOURCE: Health and Medical Research Fund.

Self-Adjuvanting Lipoprotein Conjugate Î±GalCer-RBD Induces Potent Immunity against SARS-CoV-2 and its Variants of Concern. Safe and effective vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and its variants are the best approach to successfully combat the COVID-19 pandemic. The receptor-binding domain (RBD) of the viral spike protein is a major target to develop candidate vaccines. Î±-Galactosylceramide (Î±GalCer), a potent invariant natural killer T cell (iNKT) agonist, was site-specifically conjugated to the N-terminus of the RBD to form an adjuvant-protein conjugate, which was anchored on the liposome surface. This is the first time that an iNKT cell agonist was conjugated to the protein antigen. Compared to the unconjugated RBD/Î±GalCer mixture, the Î±GalCer-RBD conjugate induced significantly stronger humoral and cellular responses. The conjugate vaccine also showed effective cross-neutralization to all variants of concern (B.1.1.7/alpha, B.1.351/beta, P.1/gamma, B.1.617.2/delta, and B.1.1.529/omicron). These results suggest that the self-adjuvanting Î±GalCer-RBD has great potential to be an effective COVID-19 vaccine candidate, and this strategy might be useful for designing various subunit vaccines.

Immunogenicity and Safety of a Third SARS-CoV-2 Vaccine Dose in Patients With Multiple Sclerosis and Weak Immune Response After COVID-19 Vaccination. This cohort study investigates the immunogenicity and safety of a third SARS-CoV-2 vaccine dose in patients with multiple sclerosis who had a weak immune response to COVID-19 vaccination.

Comprehensive characterization of the antibody responses to SARS-CoV-2 Spike protein finds additional vaccine-induced epitopes beyond those for mild infection. BACKGROUND: Control of the COVID-19 pandemic will rely on SARS-CoV-2 vaccine-elicited antibodies to protect against emerging and future variants; an understanding of the unique features of the humoral responses to infection and vaccination, including different vaccine platforms, is needed to achieve this goal. METHODS: The epitopes and pathways of escape for Spike-specific antibodies in individuals with diverse infection and vaccination history were profiled using Phage-DMS. Principal component analysis was performed to identify regions of antibody binding along the Spike protein that differentiate the samples from one another. Within these epitope regions, we determined potential sites of escape by comparing antibody binding of peptides containing wild-type residues versus peptides containing a mutant residue. RESULTS: Individuals with mild infection had antibodies that bound to epitopes in the S2 subunit within the fusion peptide and heptad-repeat regions, whereas vaccinated individuals had antibodies that additionally bound to epitopes in the N- and C-terminal domains of the S1 subunit, a pattern that was also observed in individuals with severe disease due to infection. Epitope binding appeared to change over time after vaccination, but other covariates such as mRNA vaccine dose, mRNA vaccine type, and age did not affect antibody binding to these epitopes. Vaccination induced a relatively uniform escape profile across individuals for some epitopes, whereas there was much more variation in escape pathways in mildly infected individuals. In the case of antibodies targeting the fusion peptide region, which was a common response to both infection and vaccination, the escape profile after infection was not altered by subsequent vaccination. CONCLUSIONS: The finding that SARS-CoV-2 mRNA vaccination resulted in binding to additional epitopes beyond what was seen after infection suggests that protection could vary depending on the route of exposure to Spike antigen. The relatively conserved escape pathways to vaccine-induced antibodies relative to infection-induced antibodies suggests that if escape variants emerge they may be readily selected for across vaccinated individuals. Given that the majority of people will be first exposed to Spike via vaccination and not infection, this work has implications for predicting the selection of immune escape variants at a population level. FUNDING: This work was supported by NIH grants AI138709 (PI JMO) and AI146028 (PI FAM). JMO received support as the Endowed Chair for Graduate Education (FHCRC). The research of FAM was supported in part by a Faculty Scholar grant from the Howard Hughes Medical Institute and the Simons Foundation. Scientific Computing Infrastructure at Fred Hutch was funded by ORIP grant S10OD028685.

 When SARS-CoV-2 â€“ the virus that causes COVID-19 â€“ infects our bodies, our immune system reacts by producing small molecules called antibodies that stick to a part of the virus called the spike protein. Vaccines are thought to work by triggering the production of similar antibodies without causing disease. Some of the most effective antibodies against SARS-CoV-2 bind a specific area of the spike protein called the â€˜receptor binding domainâ€™ or RBD. When SARS-CoV-2 evolves it creates a challenge for our immune system: mutations, which are changes in the virusâ€™s genetic code, can alter the shape of its spike protein, meaning that existing antibodies may no longer bind to it as effectively. This lowers the protection offered by past infection or vaccination, which makes it harder to tackle the pandemic. As it stands, it is not clear which mutations to the virusâ€™s genetic code can affect antibody binding, especially to portions outside the RBD. To complicate things further, the antibodies people produce in response to mild infection, severe infection, and vaccination, while somewhat overlapping, exhibit some differences. Studying these differences could help minimize emergence of mutations that allow the virus to â€˜escapeâ€™ the antibody response. A phage display library is a laboratory technique in which phages (viruses that infect bacteria) are used as a â€˜repositoryâ€™ for DNA fragments that code for a specific protein. The phages can then produce the protein (or fragments of it), and if the protein fragments bind to a target, it can be easily detected. Garrett, Galloway et al. exploited this technique to study how different portions of the

SARS-CoV-2 spike protein were bound by antibodies. They made a phage library in which each phage encoded a portion of the spike protein with different mutations, and then exposed the different versions of the protein to antibodies from people who had experienced prior infection, vaccination, or both. The experiment showed that antibodies produced during severe infection or after vaccination bound to similar parts of the spike protein, while antibodies from people who had experienced mild infection targeted fewer areas. Garrett, Galloway et al. also found that mutations that affected the binding of antibodies produced after vaccination were more consistent than mutations that interfered with antibodies produced during infection. While these results show which mutations are most likely to help the virus escape existing antibodies, this does not mean that the virus will necessarily evolve in that direction. Indeed, some of the mutations may be impossible for the virus to acquire because they interfere with the virusâ€™s ability to spread. Further studies could focus on revealing which of the mutations detected by Garrett, Galloway et al. are most likely to occur, to guide vaccine development in that direction. To help with this, Garrett, Galloway et al. have made the data accessible to other scientists and the public using a web tool.

Safety and efficiency of COVID-19 vaccination during pregnancy and breastfeeding. Despite the development of effective and safe vaccines, the contributions of pregnant women in clinical trials of vaccines have been excluded. Similarly, vaccine trials did not include breastfeeding women. This article is an overview of studies on immunization during pregnancy and breast-feeding. The manuscript is intended to collect the current data on the effectiveness and safety of COVID-19 vaccines in order to facilitate medical decision.

Antibody durability 6 months after two doses of SARS-CoV-2 mRNA vaccines in patients with rheumatic and musculoskeletal disease.

Sub-acute Onset of Guillain-BarrÃ© Syndrome Post-mRNA-1273 Vaccination: a Case Report. Ever since the start of the pandemic, SARS-CoV-2 has taken the lives of millions of people around the globe. Several COVID-19 vaccines have been developed with rapidity to prevent acquiring COVID-19 infection, hospitalizations, and deaths. The routine side effects of these vaccines are commonly known and non-severe. Few serious side effects such as thrombosis with thrombocytopenia syndrome (TTS) and Guillain-BarrÃ© syndrome (GBS) are increasingly reported particularly after inoculation with ChAdOx1 nCoV-19 (Oxford/AstraZeneca) and Ad26.COV 2.S (Johnson & Johnson's Janssen). Rare cases of GBS after BNT162b2 (Pfizer-BioNTech), an mRNA vaccine, are also reported. However, the true association of these cases to COVID-19 continues to be unclear and the safety of these vaccines continues to be great in preventing deaths from COVID-19 infection. We report a case of middle-aged female who had a gradual onset of lower extremity weakness with a nadir of symptoms reached 10 and 12 weeks after the onset. This protracted course (sub-acute) is atypical for a "classical" GBS. The presence of an antecedent event, autonomic symptoms such as hypotension, and the need for ventilator support favored the diagnosis of GBS than chronic inflammatory demyelinating polyneuropathy (CIDP). This is the first known case to be reported of sub-acute onset of Guillain-BarrÃ© syndrome after receiving the mRNA-1273 vaccine. SUPPLEMENTARY INFORMATION: The online version contains supplementary material available at 10.1007/s42399-022-01124-1.

Vaccine-induced immune thrombotic thrombocytopenia with ChAdOx1 nCoV-19 is rare in Asia. BACKGROUND: Vaccination with ChAdOx1 n-CoV-19 is associated with a rare syndrome called vaccine-induced immune thrombotic thrombocytopenia (VITT). VITT has been reported mainly in Western countries, whereas the report of VITT in Asians is sparse. OBJECTIVES: To report a case series of VITT following ChAdOx1 n-CoV-19 in Thailand and to estimate the incidence of VITT among Asian countries. METHODS: We retrieved the number of VITT patients and the total inoculation doses from the database of the Thai Ministry of Public Health. We performed a literature search including

published articles and gray literature to estimate the incidence of VITT. The incidences of VITT by countries and respective confidence intervals were calculated. RESULTS: By the end of August 2021, five VITT cases occurred after 15Â million doses of ChAdOx1 n-CoV-19 in Thailand. The median age was 31Â years, and 60% were women. The incidence of VITT is estimated at 1 in 3Â million. In other Asian countries, only a few cases of VITT have been reported. The incidence of VITT is much lower than in those of Western countries, which is estimated at 1 in 100,Â 000. The fatality rate was 44% in this study. CONCLUSIONS: Although the incidence of VITT in Asians is low, the mortality rate is substantially higher. We urge that public awareness of this syndrome be raised, as early recognition and appropriate treatment of this syndrome following ChAdOx1 n-CoV-19 are crucial to improve the outcome.

Acute Vertigo After COVID-19 Vaccination: Case Series and Literature Review. Objective: The aim of this study was to present some cases of acute vertigo potentially related to the coronavirus disease 2019 (COVID-19) vaccine and review the available literature about cochleovestibular dysfunction after the COVID-19 vaccination. Methods: In the period from May to July 2021, we evaluated 33 patients (mean age 54.3 Â± 14.1) with "acute vertigo" post COVID-19 vaccination. A detailed medical history was taken on comorbidities, types of vaccines received, and symptoms associated. All patients underwent otoneurological evaluation, such as head impulse test, nystagmus evaluation, test of skew (HINTS) examination. Head shaking test-induced nystagmus, hyperventilation-induced nystagmus, and parossistic positional nystagmus were studied to search for vestibular impairment. Results: Symptoms included 16 patients (48.5%) with objective vertigo, 14 patients (42.4%) with subjective vertigo, and 3 patients (9.1%) with dizziness. Of the associated ear, nose, and throat (ENT) symptoms, the most expressed was tinnitus (18.2%). Bedside examination showed absent nystagmus in 7 patients (21.2%), 9 patients (27.3%) had horizontal or rotatory nystagmus, 17 patients (51.5%) had a vertical or oblique nystagmus, negative HST, or "central HINTS." Discussion and Conclusions: The 9 patients had an evoked nystagmus pathognomonic for benign paroxysmal positional vertigo; in the remaining 17 cases, peripheral vestibular dysfunction could be excluded and central disorder may be suggested. Due to the prevalence of nystagmus of non-peripheral origin, a central nervous system involvement could not be excluded. However, due to the small sample size, a definite cause-effect relationship between vaccination and vertigo cannot be inferred. In light of expected third dose, large-scale and well-designed studies are needed to better define possible adverse reactions of the COVID-19 vaccine.

Incomplete Subacute Transverse Myelitis Following Vaccination With Pfizer-BioNTech COVID-19 mRNA Vaccine: A Case Report. In response to the coronavirus disease 2019 (COVID-19) pandemic, rapid development, clinical testing, and regulatory approval of vaccines occurred. The tozinameran COVID-19 vaccine is the first mRNA vaccine approved for use in humans. Transverse myelitis is a rare inflammatory disorder of the spinal cord that is associated with traditional vaccinations. There are rare case reports describing an association between mRNA vaccines and transverse myelitis. Herein, we describe a case of transverse myelitis following mRNA vaccination. A healthy 26-year-old woman developed saddle anesthesia, numbness, and allodynia in the S1-S4 distribution within three days of receiving the first dose of tozinameran COVID-19 vaccine. She had decreased sensation to pinprick, temperature, and light touch in S1-S4 distribution and a positive Rhomberg test. An MRI brain and spine demonstrated a short segment T2 hyperintense and diffusely enhancing lesion at T5. Cerebrospinal fluid studies demonstrated pleocytosis and elevated IgG index. A five-day course of IV methylprednisolone resulted in minimal improvements in her symptoms. Stage III clinical trials may be underpowered to detect more rare adverse effects such as transverse myelitis. Therefore, it is imperative to have ongoing surveillance and reporting of adverse events associated with COVID-19 vaccines to ensure transparency with regard to potential risks to patients

obtaining the vaccine and algorithms in place for detection and urgent treatment if required. Nonetheless, the safety and efficacy of vaccination against COVID-19 are well established and greatly outweigh any potential risks associated with the vaccine. Given the individual, societal, and global health benefits of vaccination we strongly advocate for ongoing vaccinations against COVID-19.

A Case of Hepatotoxicity After Receiving a COVID-19 Vaccine. The coronavirus disease 2019 (COVID-19) has led to a global health crisis. Its clinical manifestations are well-documented, and severe complications among patients who survived the infection are being continuously reported. Several vaccines with well-established efficacies and excellent safety profiles have also been approved. To date, few side effects of vaccines have been reported. Drug-induced hepatotoxicity is an extremely rare side effect of these vaccines, with few reported instances. In this case report, we describe a patient who experienced hepatotoxicity after receiving the COVID-19 vaccine from Pfizer BioNTech.

Severe Immune Thrombocytopenia (ITP) Following SARS-CoV-2 mRNA Vaccine in a Girl on Immunosuppressive Treatment and in Prolonged Stable Phase of ITP.

Gastrointestinal and hepatic side effects of potential treatment for COVID-19 and vaccination in patients with chronic liver diseases. The outbreak of coronavirus disease 2019 (COVID-19) is a global pandemic. Many clinical trials have been performed to investigate potential treatments or vaccines for this disease to reduce the high morbidity and mortality. The drugs of higher interest include umifenovir, bromhexine, remdesivir, lopinavir/ritonavir, steroid, tocilizumab, interferon alpha or beta, ribavirin, fivapiravir, nitazoxanide, ivermectin, molnupiravir, hydroxychloroquine/chloroquine alone or in combination with azithromycin, and baricitinib. Gastrointestinal (GI) symptoms and liver dysfunction are frequently seen in patients with COVID-19, which can make it difficult to differentiate disease manifestations from treatment adverse effects. GI symptoms of COVID-19 include anorexia, dyspepsia, nausea, vomiting, diarrhea and abdominal pain. Liver injury can be a result of systemic inflammation or cytokine storm, or due to the adverse drug effects in patients who have been receiving different treatments. Regular monitoring of liver function should be performed. COVID-19 vaccines have been rapidly developed with different technologies including mRNA, viral vectors, inactivated viruses, recombinant DNA, protein subunits and live attenuated viruses. Patients with chronic liver disease or inflammatory bowel disease and liver transplant recipients are encouraged to receive vaccination as the benefits outweigh the risks. Vaccination against COVID-19 is also recommended to family members and healthcare professionals caring for these patients to reduce exposure to the severe acute respiratory syndrome coronavirus 2 virus.

MOG antibody-associated encephalomyelitis mimicking bacterial meningomyelitis following ChAdOx1 nCoV-19 vaccination: a case report. We report a case of anti-myelin oligodendrocyte glycoprotein (MOG) antibody-associated encephalomyelitis following vector-based vaccination against SARS-CoV-2 that mimicked bacterial meningomyelitis upon initial presentation. A 43-year-old woman who had received a first dose of ChAdOx1 nCoV-19 (Vaxzevria; Astra Zeneca, UK Limited) 9 days earlier presented with subacute sensorimotor paraparesis, urinary retention, headache, meningism, and fever. Clinical findings and cerebrospinal fluid (CSF) features were highly suggestive of bacterial infection; however, despite receiving broad anti-infective treatment alongside with high-dose glucocorticoids, symptoms deteriorated. Imaging findings and the detection of immunoglobulin G against MOG substantiated diagnosis of an anti-MOG associated disorder. Treatment with high-dose intravenous (IV) methylprednisolone and plasma exchange resulted in substantial clinical improvement, which sustained under monthly regimen of IV Tocilizumab at 3-month follow-up. Awareness of this post-vaccinal presentation of a rare autoimmune disorder is important to not miss potential treatment options.

Case Report: Anti-LGI1 Encephalitis Following COVID-19 Vaccination. Anti-leucine rich glioma inactivated 1 (LGI1) autoimmune encephalitis (AE) is characterized by cognitive impairment or rapid progressive dementia, psychiatric disorders, faciobrachial dystonic seizures (FBDS) and refractory hyponatremia. Since December 2020, millions of people worldwide have been vaccinated against COVID-19. Several soft neurological symptoms like pain, headache, dizziness, or muscle spasms are common and self-limited adverse effects after receiving the COVID-19 vaccine. However, several major neurological complications, despite the unproven causality, have been reported since the introduction of the COVID-19 vaccine. Herein, we describe a 48 years old man presenting with rapidly progressive cognitive decline and hyponatremia diagnosed with anti LGI1 AE, occurring shortly after the second dose of mRNA COVID -19 vaccine and possibly representing a severe adverse event related to the vaccination. Response to high dose steroid therapy was favorable. As millions of people worldwide are currently receiving COVID-19 vaccinations, this case should serve to increase the awareness for possible rare autoimmune reactions following this novel vaccination in general, and particularly of anti-LGI1 AE.

Association of Bacillus Calmette Guerin Vaccine Strains with COVID-19 Morbidity and Mortality - Evaluation of Global Data. BACKGROUND: Literature suggests that the presence of the current Bacillus Calmette Guerin (BCG) policy appears to mitigate COVID-19 disease burden but no information exists on the nature of the BCG strain and disease burden. OBJECTIVES: To study the association between type of BCG strain, BCG coverage (%), and COVID-19 disease burden. METHODOLOGY: An audit of global data on strains and disease burden was done. Country-specific data for COVID-19 cases and deaths, BCG-related data, and income level were obtained from the online databases, and the association was analyzed using linear regression. RESULTS: Data of 139 countries were studied and 117 (84%) had a current BCG policy. Data on BCG strains were available for 51 countries and 18/51 (35%) used the Danish strain. While the choice of strain did not impact COVID-19-related disease burden, the presence of a current BCG policy was significantly associated with lower COVID-19 mortality. CONCLUSION: The presence of current BCG policy is associated with decreased COVID-19-related disease burden, but the type of strain used by a country in its vaccination program does not impact disease burden.

Vaccine-induced immune thrombotic thrombocytopenia with atypical vein thrombosis: Implications for clinical practice. OBJECTIVES: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a new and rare syndrome resulting from the largest vaccination campaign against SARS-CoV-2 in the history of mankind. The aim of this review is to clarify underlying mechanisms, pathology, diagnosis, and therapy, with the related clinical implications. METHODS: We performed a comprehensive literature review in order to collect the clinical and treatment data about patients suffering from VITT. PubMed, Ovid Medline, Ovid EMBASE, Scopus, and Web of Science were screened regarding patients who developed VITT. Last search was launched on June 30(th) 2021. RESULTS: Abdominal and/or neurological symptoms develop between 5 and 20Â days after vaccine administration and do not involve the lower extremities. VITT is suspected if the platelet count is lower than 100.000/mm(3) and D-dimer is higher than the age-adjusted range. Medical treatment is mainly based on intravenous immunoglobulins, corticosteroids, and anticoagulant drugs with a short plasma half-life, but the complete avoidance of low molecular weight heparin is recommended. Endovascular treatment and/or decompressive craniectomy might be an option in a minority of cases. CONCLUSION: Due to widespread vaccination concerns, the vascular specialist and phlebologist are increasingly consulted to prevent or diagnose VITT. The latter has peculiar and completely different localizations, symptoms, and treatment compared to the common pictures of venous thrombosis.

Hyperinflammation after anti-SARS-CoV-2 mRNA/DNA vaccines successfully treated with anakinra: Case series and literature review. The current SARS-CoV-2 pandemic diffused worldwide has

encouraged the rapid development of vaccines to counter the spread of the virus. At present in Italy, 75.01% of the population completed the vaccination course (AIFA.gov.it) and very few adverse events have been recorded by now. Side-effects related to a theoretical over-reaction of the immune system in response to vaccines administration have been described, and the possibility that an autoimmune or a hyperinflammatory condition may occur was recently observed. Herein, we report four cases of hyperinflammatory syndrome with features indicative of Adult-onset Still's disease (AOSD) and macrophage activation syndrome (MAS), occurred after anti-SARS-CoV-2 vaccine injection and seen at our Unit between March and May 2021. Since interleukin (IL)-1 is one of the pivotal cytokines involved in AOSD pathogenesis, the inhibition of IL-1 is crucial in ameliorating the clinical symptoms of those patients. Moreover, it has been highlighted the central role of IL-1 as a hallmark of the hyperinflammatory status elicited by SARS-CoV-2 infection. In this case series, we successfully employed the IL-1 receptor antagonist anakinra to curb the cytokine release likely unleashed by the vaccine stimulation in potentially predisposed subjects. We also made a literature search to detect other patients with hyperinflammation temporally related to vaccines injection who benefited from IL-1 inhibition, while other AOSD/MAS-like described syndromes improved with other immunomodulatory strategies.
Atopic dermatitis exacerbation after Covid-19 vaccination in Dupilumab-treated patients.
Reply to 'The first dose of COVID-19 vaccine may trigger pemphigus and bullous pemphigoid flares: is the second dose therefore contraindicated?' by Damiani G etÂ al.
A study of COVID-19 vaccine (Covishield) induced dermatological adverse effects from India.
A first case of 'Covid toes' from a viral vector-based COVID-19 vaccine.
Large-vessel vasculitis following the Pfizer-BioNTech COVID-19 vaccine.
Investigation of anxiety sensitivity levels of cancer patients in terms of COVID-19 vaccine: a cross-sectional study. INTRODUCTION: Our study's purpose was to investigate the viewpoints of cancer patients who had not yet been vaccinated. Cancer patients usually cannot get every vaccine because their immunity is low. For this reason, we aimed to detect their anxiety and curiosity for new vaccines for a new disease. METHODS: The goal of this descriptive cross-sectional study was to investigate cancer patients' perceptions of COVID vaccination. Over 18Â years of age who have not yet been vaccinated for COVID-19 and who agreed to participate were included in the study. We applied three questionnaires between May and June 2021, one of them was prepared by us; the other two questionnaires were The State-Trait Anxiety Inventory (STAI) form and Anxiety Sensitivity index to a total of 497 participants. Chi-square, Spearmen correlation test, and multivariable multinomial logistic regression tests were used when comparing. RESULTS: Our participants' ages were between 21 and 88, with a mean age of 61.38 (SDâ€‰=â€‰11.68), 48.6% (nâ€‰=â€‰251) of the participants were female. We discovered that 79.1% (nâ€‰=â€‰408) of respondents were not afraid of getting the COVID-19 vaccine. 27.7% (nâ€‰=â€‰143) of these patients were concerned about the COVID-19 vaccine's adverse effects, and 24.2% (nâ€‰=â€‰125) were afraid of its side effects with their treatments. 91.1% (nâ€‰=â€‰470) of the patients did not know which vaccine they would have and the type of the vaccine. Since the anxiety level is generally higher in women, anxiety scores were also higher in cancers seen in women, such as breast and ovarian cancer. Of course, in parallel with this, anxiety scores were lower in prostate cancers. Special patient groups should not be neglected during this vaccine season, and their concerns should be addressed. When a new vaccine is found, it can have long-term effects, which should not be ignored.
Immune Response Induced by SARS-CoV-2 Vaccines in Patients With Inflammatory Bowel Disease Under Biologic Therapy.
Response to "Bilateral Retinal Detachments in a Healthy 22-Year-Old Woman After Moderna SARS-CoV-2 Vaccination"R.

Concomitant pulmonary and neurological embolisation in a Down patient after SARS-CoV-2 vaccine: what is missing? A 40-year-old Down patient without previous cardiological history was admitted to our institution for dyspnoea after COVID-19 vaccine. CT scan revealed a pulmonary thromboembolism. One week later, he developed neurological impairment and CT scan evidenced a left parietal ischaemic lesion. Concomitantly, he underwent echocardiography showing an atrioventricular septal defect typically associated to Down syndrome and never diagnosed earlier. The diagnosis of paradoxical embolisation was then supposed. Echocardiography also revealed a severe right heart section dilatation, with bidirectional shunt on the septal defects and systemic right heart pressure. Down patients affected by CHD are more prone to develop pulmonary vasculopathy than non-syndromic patients. In this case, the pulmonary vasculopathy was further exacerbated by the pulmonary embolism and by the late diagnosis of CHD. Finally, an appropriate timely diagnosis of atrioventricular septal defect could potentially avoid the neurological complication in this patient.
Nonarteritic Anterior Ischemic Optic Neuropathy Following COVID-19 Vaccination: A Case Report.
Exacerbations of generalized pustular psoriasis, palmoplantar psoriasis, and psoriasis vulgaris after mRNA COVID-19 vaccine: A report of three cases.
Cutaneous arteritis following mRNA-1273 Moderna COVID-19 vaccination.
Guillain-Barre Syndrome, Facial Diplegia, and Pfizer COVID-19 Vaccine.
A Woman with Painful Neck after COVID-19 Vaccination.
Acute ST-Segment Elevation Myocardial Infarction After ChAdOx1 nCoV-19 Vaccination in a 33-Year-Old Man.
Papilledema due to Vaccine-Induced Thrombocytopenia.
Omicron neutralising antibodies after COVID-19 vaccination in haemodialysis patients.
Response to Letter to the Editor on the article "Acute disseminated encephalomyelitis after SARS-CoV-2 vaccination".
Association between COVID-19 morbidity, mortality, and gross domestic product, overweight/ obesity, non-communicable diseases, vaccination rate: A cross-sectional study. BACKGROUND: The spread of COVID-19 depends on a lot of social and economic factors. THE AIM: to study the influence of country's gross domestic product, population prevalence of overweight/ obesity, NCD mortality, and vaccination on COVID-19 morbidity and mortality rates. METHODS: A cross-sectional study with two phases: correlation-regression interrelations in 1) all world countries; 2) all world non-island countries. The study includes the following data from 218 world countries: COVID-19 morbidity/mortality rates, GDP per capita, the prevalence of overweight/ obesity, NCD mortality among adults (both sexes), people fully vaccinated against COVID-19. RESULTS: An average percentage of the prevalence of overweight among adults in world countries by 2019 was 47.31Â Â±Â 15.99%, obesity 18.34Â Â±Â 9.64%, while the prevalence by 2016 were 39% and 13%, respectively. Overweight and obesity among adults during three years grew by 21.2% and 40.8%, respectively. Data from the world countries provide significant correlations (pÂ <Â 0.0001) between COVID-19 morbidity, and: GDP (rÂ =Â 0.517), overweight (rÂ =Â 0.54), obesity (rÂ =Â 0.528), NCD mortality (rÂ =Â 0.537); COVID-19 mortality, and: GDP (rÂ =Â 0.344), overweight (rÂ =Â 0.514), obesity (rÂ =Â 0.489), NCD mortality (rÂ =Â 0.611); GDP, and: overweight (rÂ =Â 0.507), obesity (rÂ =Â 0.523), NCD mortality (rÂ =Â 0.35), fully vaccinated people (rÂ =Â 0.754). An increase in fully vaccinated people, from 3% to 30% of world population, decreases new confirmed COVID-19 cases, although the dependence was not significant (pÂ =Â 0.07). Data from non-island world countries provides more highly significant correlations (pÂ <Â 0.0001) between COVID-19 morbidity, and: GDP (rÂ =Â 0.616), overweight (rÂ =Â 0.581), obesity (rÂ =Â 0.583); COVID-19 mortality, and: GDP (rÂ =Â 0.43), overweight (rÂ =Â 0.556), obesity (rÂ =Â 0.539); GDP, and: overweight (rÂ =Â 0.601),

obesity (rÂ =Â 0.633). The differences of correlation coefficients between data of 176 world countries and data of 143 world non-island countries were not significant (Z-scores<1.29; pÂ >Â 0.05). CONCLUSION: The study provides evidence of a significant impact of overweight/obesity prevalence on the increase in COVID-19 morbidity/mortality. Countries with higher GDP have a high overweight/obesity prevalence and possibility to get vaccinated.

Case report: Acute exacerbation of interstitial pneumonia related to messenger RNA COVID-19 vaccination. Messenger RNA (mRNA) vaccines that protect against COVID-19 are widely used in many countries owing to their high efficacy and safety profiles. Recently, few severe adverse events, such as anaphylaxis and myocarditis, were reported in healthy individuals. The safety of mRNA COVID-19 vaccines has not been adequately studied in patients with interstitial lung disease. We report 2 cases of acute exacerbation of preexisting interstitial pneumonia associated with mRNA COVID-19 vaccination. In both cases, lung disease was stable before the vaccination. Initial responses to steroid therapy were unfavorable, and intravenous cyclophosphamide was administered in both cases. Both patients were diagnosed with vaccine-related exacerbation of interstitial pneumonia based on laboratory results, radiologic features, and the observed clinical course, which lacked other causative events. We suggest that clinicians should note the possibility of acute exacerbation of pneumonia after mRNA COVID-19 vaccination and carefully monitor patients with interstitial lung disease.

Spontaneous Reporting to Regulatory Authorities of Suspected Adverse Drug Reactions to COVID-19 Vaccines Over Time: The Effect of Publicity. INTRODUCTION: The UK Medicines and Healthcare products Regulatory Agency (MHRA) has published frequent summaries of spontaneous reports of suspected adverse drug reactions (ADRs) (Yellow Cards) to vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The EudraVigilance database has provided similar data for the European Economic Area. OBJECTIVE: Our objective was to characterize the evolution over time of spontaneous reports of suspected ADRs to coronavirus disease 2019 (COVID-19) vaccines and to observe the effect of a publicized reaction (cerebral venous and sinus thrombosis [CVST]) on reporting rates. METHODS: We used publicly available data on reports of suspected ADRs and doses of vaccine administered, published by the MHRA, EudraVigilance, and the European Centre for Disease Prevention and Control to calculate reporting rates. RESULTS: Approximately 4814 Yellow Card reports (23 fatal) per million doses of ChAdOx1 nCoV-19 (AstraZeneca) and 2890 (13 fatal) per million doses of tozinameran (Pfizer/BioNTech) have been lodged. Between 15 March and 31 October 2021, cumulative European reports of CVST rose from 0 to 443 (183 with thrombocytopenia, 72 fatal) with ChAdOx1 nCoV-19 and from 2 to 315 (9 with thrombocytopenia, 28 fatal) with tozinameran. European cases of retinal vein occlusion and thrombosis rose from 0 to 168 with ChAdOx1 nCoV-19 and from 1 to 220 with tozinameran; four of the ChAdOx1 nCoV-19 cases were associated with thrombocytopenia. CONCLUSION: Reports of fatal adverse reactions to coronavirus vaccines are very rare. Reports of CVST have been made in relation to both vaccines. Most were submitted after the reaction had been publicized. Thrombocytopenia occurred in a minority of cases. Reports linked both vaccines to cases of retinal vein thrombosis, just fourÂ cases with thrombocytopenia. This suggests two different mechanisms of thrombosis associated with the vaccines.

Myocarditis and pericarditis after COVID-19 messenger RNA vaccines. QUESTION: With the approval of coronavirus disease 2019 (COVID-19) vaccine for children 5 to 11 years of age and concerns among parents in the past year following reported cases of myocarditis and pericarditis in adolescents, should my office continue to encourage all children and young adults to receive the COVID-19 messenger RNA vaccine? ANSWER: Since April 2021 reports have documented cases of myocarditis and pericarditis in adolescents and young adults after messenger RNA COVID-19 vaccination, and several hundred such reports were documented in Canada. Clinical presentations

were mostly mild, with rare instances of admission to the hospital, and were typically among male adolescents 16 years of age and older within several days after the second dose of the vaccine. After vaccination, children and adolescents with symptoms of chest pain, shortness of breath, or palpitations should be evaluated with a physical examination, an electrocardiogram, and measurement of cardiac troponin levels. If results are abnormal, an echocardiogram or cardiac magnetic resonance imaging should be considered. Myocarditis and pericarditis after vaccination are much less common, and much milder, than cardiac complications of COVID-19 infection, and vaccines should continue to be recommended to all those eligible.

Constrictive pericarditis after SARS-CoV-2 vaccination: A case report. Coronavirus disease 2019 (COVID-19) and vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are associated with cardiovascular complications. Here, we report a case of right-sided heart failure caused by constrictive pericarditis that developed after the administration of messenger ribonucleic acid (mRNA) vaccine against SARS-CoV-2. A 70-year-old woman presented with body weight gain, peripheral edema, and dyspnea on effort, which developed over a period of 1 week after the second dose of vaccine. The jugular venous pressure was high with a prominent y descent (Friedreich's sign) and paradoxical increase on inspiration (Kussmaul's sign). The results of IgM and IgG testing specific to SARS-CoV-2 spike and nucleocapsid proteins indicated the presence of mRNA vaccine-induced antibody and were not suggestive of COVID-19 infection. Echocardiography showed pericardial thickening and septal bounce of the interventricular septum. Computed tomography (CT) also showed pericardial thickening compared with the results of the previous CT scan performed 4 months earlier. A diagnosis of right-sided heart failure due to constrictive pericarditis was confirmed on the basis of pressure analysis during cardiac catheterization.

Hypersensitivity reaction to hyaluronic acid dermal filler after COVID-19 vaccination: A series of cases in SÃ£o Paulo, Brazil. Brazil ranked second in the world for the number of aesthetic procedures carried out in 2019. Five case reports of delayed hypersensitivity reaction to hyaluronic acid dermal filler after COVID-19 vaccination are presented in this paper. Additional vaccination for new variants, including omicron, will be necessary; therefore, aesthetic professionals should be aware of this possibility and advise patients accordingly.

Letter to the Editor Regarding: What Triggers Takotsubo After a SARS-CoV-2 Vaccination? Heart Lung Circ. 2021;30(12):e119-20.

Meta-Analysis of Risk of Myocarditis After Messenger RNA COVID-19 Vaccine.

Prolonged migraine aura resembling ischemic stroke following CoronaVac vaccination: an extended case series. BACKGROUND: After the initiation of the COVID-19 vaccination program in Thailand, thousands of patients have experienced unusual focal neurological symptoms. We report 8 patients with focal neurological symptoms after receiving inactivated virus vaccine, CoronaVac. CASE SERIES: Patients were aged 24-48â€‰years and 75% were female. Acute onset of focal neurological symptoms occurred within the first 24â€‰h after vaccination in 75% and between 1-7d in 25%. All presented with lateralized sensory deficits, motor deficits, or both, of 2-14â€‰day duration. Migraine headache occurred in half of the patients. Magnetic resonance imaging of the brain during and after the attacks did not demonstrate any abnormalities suggesting ischemic stroke. All patients showed moderately large regions of hypoperfusion and concurrent smaller regions of hyperperfusion on SPECT imaging while symptomatic. None developed permanent deficits or structural brain injury. DISCUSSIONS: Here, we present a case series of transient focal neurological syndrome following Coronavac vaccination. The characteristic sensory symptoms, history of migraine, female predominant, and abnormal functional brain imaging without structural changes suggest migraine aura as pathophysiology. We propose that pain related to vaccine injection, component of vaccine,

such as aluminum, or inflammation related to vaccination might trigger migraine aura in susceptible patients.

Autoimmune Haemolytic Anaemia following ChAd Ox 1 nCoV-19 in Haemodialysis. Autoimmune haemolytic anaemia (AIHA) is caused by autoantibodies that react with self-red blood cells (RBCs) and cause them to be destroyed with or without complement mediated mechanism. Its clinical presentation is heterogeneous, ranging from asymptomatic to severe forms with fatal outcomes, also it can be either idiopathic or secondary to a coexisting disorder. We report an elderly gentleman on haemodialysis, who presented with severe haemolytic anaemia after one month of first dose of ChAd Ox 1 nCoV-19 vaccine (viral vector vaccine) for SARS- CoV - 2, who also had asymptomatic COVID 19 infection around 6 months prior to vaccination. This is the first reported case of AIHA following COVISHIELD vaccine and till now there are no other reported cases from India.

Polyneuritis Cranialis Associated with BNT162b2 mRNA COVID-19 Vaccine in a Healthy Adolescent. A 16-year-old Thai girl developed right facial palsy, a lower motor neuron lesion, and numbness 3 h after receiving the first dose of the BNT162b2 mRNA vaccine. Neurological examination showed the involvement of the right cranial nerves (CN) V, VII, IX, and X. Electrophysiological tests revealed the absence of an F wave response, suggesting a proximal demyelinating process. Magnetic resonance imaging of the brain demonstrated abnormal enhancement of the right CN VII. The cerebrospinal fluid profile on day 7 after the onset of symptoms was normal. The patient was diagnosed with polyneuritis cranialis, a rare variant of Guillain-Barre syndrome. She was successfully treated with intravenous immunoglobulin therapy.

Atypical Kawasaki Disease after COVID-19 Vaccination: A New Form of Adverse Event Following Immunization. Kawasaki disease (KD) is a medium-vessel vasculitis that is typically presented during childhood; fewer than 100 cases of KD have been reported worldwide in adult patients who met the criteria according to the American College of Rheumatology. This study presents the case of an 18-year-old patient with no previous history of any disease, who presented atypical KD with liver and kidney dysfunction, with a good response to intravenous immunoglobulin therapy. The symptoms began 22 days after the application of the COVID-19 vaccine (nonreplicating viral vector Vaxzevria), and other conditions were ruled out. The term Adverse Events Following Immunization (AEFI)encompasses all the reactions that follow the application of any vaccine with no necessary causal relationship and can be due to the vaccine product, quality of the vaccine, immunization errors, or anxiety or just happen to be coincident events. These reactions should be reported so that clinicians can identify compatible cases and consider that the presentation of this disease, despite being atypical, can be manifested in adult patients. Likewise, case reports are an important basis for the pharmacovigilance of vaccines.

IgG and IgA Antibodies Post SARS-CoV-2 Vaccine in the Breast Milk and Sera of Breastfeeding Women. The COVID-19 pandemic has carried massive global health and economic burden that is currently counteracted by a challenging anti-COVID-19 vaccination campaign. Indeed, mass vaccination against COVID-19 is expected to be the most efficacious intervention to mitigate the pandemic successfully. The primary objective of the present study is to test the presence of neutralizing anti-SARS-CoV-2 antibodies (IgA and IgG) in the breast milk and sera samples from vaccinated women at least 20 days after the complete vaccine cycle. A secondary aim is to compare the IgG antibodies level in maternal serum and breast milk. The third target is to evaluate the presence of the IgG antibodies in breast milk after several weeks from the vaccination. Finally, we collected information on the health status of infants in the days following maternal vaccination. Forty-two mothers were enrolled in the study. Thirty-six received the Pfizer/BioNTech vaccine, four the Astra Zeneca vaccine, one the Moderna vaccine and another woman Astra Zeneca in the first dose and Pfizer/BioNTech in the second dose. All 42 milk samples confirmed the presence of anti-SARS-CoV-2 IgG, and none showed IgA presence.

Regarding the matched 42 sera samples, 41 samples detected IgG presence, with one sample testing negative and only one positive for seric IgA. None of the 42 infants had fever or changes in sleep or appetite in the seven days following the maternal vaccination. The level of IgG antibodies in milk was, on average, lower than that in maternal serum. According to our analysis, the absence of IgA could suggest a rapid decrease after vaccination even if frequent breastfeeding could favour its persistence. IgG were present in breast milk even 4 months after the second vaccine dose. Information on the immunological characteristics of breast milk could change mothers' choices regarding breastfeeding.

Benign Fasciculation Syndrome and Migraine Aura without Headache: Possible Rare Side Effects of the BNT162b2 mRNA Vaccine? A Case Report and a Potential Hypothesis. The BNT162b2 (Pfizer BioNTech) mRNA vaccine is an effective vaccine against COVID-19 infection. Here, we report an adverse event following immunization (AEFI) in a 48-year-old female patient who presented with fasciculations, migraine auras without headaches and in an increased discomfort of previously present palpitations, as well as excitation and insomnia. Her fasciculations were intermittently present until the time this paper was written, starting from the 6th day post-vaccination; they changed localization and frequency, but most commonly they were generalized, affecting almost all muscle groups. The patient also suffered from two incidents of migraine auras with visual kaleidoscope-like phenomena without headaches a few months after the vaccination. These symptoms were considered to be AEFI and no causal relation with the vaccine could be proven.

Comparison of Dental Anxiety While Visiting Dental Clinics before and after Getting Vaccinated in Midst of COVID-19 Pandemic. Vaccination is critical to control the rate of coronavirus transmission and infectivity. Dental practices are a high-risk area for contracting coronavirus; this fact generates psychological disturbances amongst patients. In this study, we aimed to assess the levels of anxiety of patients while visiting dental practices before and after getting vaccinated. This cross-sectional study was carried out between March and December 2021. An electronic survey was distributed among the vaccinated individuals who visited dental clinics before and after getting vaccinated. The survey consisted of the following four parts: demographic characteristics, questions related to coronavirus, and anxiety scores before and after getting vaccinated. SPSS-25 was used to perform the statistical analysis, where paired t-test was used to compare the anxiety scores, and Mann-Whitney U test to assess the association of gender with anxiety scores. A p-value of â‰¤0.05 was considered to be statistically significant. A total of 400 vaccinated individuals participated in this study, with a response rate of 88.23%. The majority of the respondents (71.0%) did not test positive for coronavirus. More than half of the participants (54.0%) reported to not be suffering from any coronavirus-related symptoms. About 100 (25.0%) of the individuals stated that dental clinics are an environment in which there is a high risk of contracting coronavirus. In regards to the comparison of the mean MDAS scores of the participants before and after getting vaccinated, a significant difference ($p = 0.001$) was found. Vaccination has been recommended for all eligible individuals to control the transmission and infectivity of coronavirus. Vaccinations have decreased the dental anxiety of patients while visiting dental clinics. However, the protective measures are still valid and should be followed, regardless of the vaccination status.

Using a Machine Learning Approach to Monitor COVID-19 Vaccine Adverse Events (VAE) from Twitter Data. Social media can be used to monitor the adverse effects of vaccines. The goal of this project is to develop a machine learning and natural language processing approach to identify COVID-19 vaccine adverse events (VAE) from Twitter data. Based on COVID-19 vaccine-related tweets (1 December 2020-1 August 2021), we built a machine learning-based pipeline to identify tweets containing personal experiences with COVID-19 vaccinations and to extract and normalize VAE-related entities, including dose(s); vaccine types (Pfizer, Moderna, and Johnson & Johnson); and symptom(s) from tweets. We further analyzed the extracted VAE data based on the location, time,

and frequency. We found that the four most populous states (California, Texas, Florida, and New York) in the US witnessed the most VAE discussions on Twitter. The frequency of Twitter discussions of VAE coincided with the progress of the COVID-19 vaccinations. Sore to touch, fatigue, and headache are the three most common adverse effects of all three COVID-19 vaccines in the US. Our findings demonstrate the feasibility of using social media data to monitor VAEs. To the best of our knowledge, this is the first study to identify COVID-19 vaccine adverse event signals from social media. It can be an excellent supplement to the existing vaccine pharmacovigilance systems.

Initial Mix-and-Match COVID-19 Vaccination Perceptions, Concerns, and Side Effects across Canadians. Research indicates that mixing the first two doses of COVID-19 vaccine types (i.e., adenoviral vector and mRNA) produces potent immune responses against the coronavirus, but it is unclear how individuals may perceive these benefits, or whether there are different concerns compared to individuals who received two doses of the same vaccine. This research examines the demographic characteristics, psychological perceptions, and vaccination-related opinions and experiences of a large Canadian sample (N = 1002) who had received two initial doses of any COVID-19 vaccine combination. Participants included 791 (78.9%) who received two doses of the exact same brand and type of vaccine, 164 (16.4%) who received two doses of the same type of vaccine (i.e., either mRNA or adenoviral vector) but from different brands (e.g., Pfizer-BioNTech + Moderna), and 47 (4.7%) who received two doses from different types and brands of vaccine (e.g., Oxford-AstraZeneca + Pfizer-BioNTech). Results showed that, after the first vaccine dose, participants who received an adenoviral vector vaccine (e.g., Oxford-AstraZeneca) experienced the highest number of common side effects, and more severe levels of each side effect compared to those who received an mRNA vaccine (e.g., Pfizer-BioNTech or Moderna). After the second dose, participants who received Moderna as their second vaccine experienced the highest number of and most severe side effects, regardless of whether they received Moderna, Pfizer-BioNTech, or Oxford-AstraZeneca as their first dose. Real-world implications of these findings are discussed.

Acceptance of a Third Dose of COVID-19 Vaccine and Associated Factors in China Based on Health Belief Model: A National Cross-Sectional Study. COVID-19 infections are returning to many countries because of the emergence of variants or declining antibody levels provided by vaccines. An additional dose of vaccination is recommended to be a considerable supplementary intervention. We aim to explore public acceptance of the third dose of the COVID-19 vaccine and related influencing factors in China. This nationwide cross-sectional study was conducted in the general population among 31 provinces in November, 2021. We collected information on basic characteristics, vaccination knowledge and attitudes, and vaccine-related health beliefs of the participants. Univariable and multivariable logistic regression models were used to assess factors associated with the acceptance of a third COVID-19 vaccine. A total of 93.7% (95% CI: 92.9-94.6%) of 3119 Chinese residents were willing to receive a third dose of the COVID-19 vaccine. Individuals with low level of perceived susceptibility, perceived benefit, cues to action cues, and high level of perceived barriers, old age, low educational level, low monthly household income, and low knowledge score on COVID-19 were less likely to have the acceptance of a third dose of COVID-19 (all $p < 0.05$). In the multivariable logistic regression model, acceptance of the third dose of COVID-19 vaccine was mainly related to previous vaccination history [Sinopharm BBIP (aOR = 6.55, 95% CI 3.30-12.98), Sinovac (aOR = 5.22, 95% CI:2.72-10.02), Convidecia (aOR = 5.80, 95% CI: 2.04-16.48)], high level of perceived susceptibility (aOR = 2.48, 95% CI: 1.48-4.31) and high level of action cues (aOR = 23.66, 95% CI: 9.97-56.23). Overall, residents in China showed a high willingness to accept the third dose of COVID-19 vaccines, which can help vaccine manufacturers in China to manage the vaccine production and distribution for the huge domestic and international vaccine demand. Relevant institutions could increase people's willingness to booster shots by increasing initial COVID-19 vaccination rates,

public's perception of COVID-19 susceptibility and cues to action through various strategies and channels. Meanwhile, it also has certain reference significance for other countries to formulate vaccine promotion strategies.

Pyoderma Gangrenosum Induced by BNT162b2 COVID-19 Vaccine in a Healthy Adult. (1) Background: Pyoderma gangrenosum (PG) is a rare neutrophilic dermatosis of unknown etiology. Coronavirus disease 2019 (COVID-19) vaccines can cause a variety of adverse cutaneous manifestations. PG associated with mRNA vaccines has not previously been described. This case study reports on the first patient to develop PG after receiving BNT162b2. (2) Case Presentation: An otherwise-healthy 27-year-old man developed multiple skin lesions 24 h after receiving the first dose of the messenger RNA-based Pfizer/BioNTech BNT162b2 COVID-19 vaccine. When in hospital, he developed a new painful ulcerative lesion on his right hand. Skin ulcer edge biopsy showed severe epidermal neutrophilic infiltrate with epidermal and dermal edema, underlying superficial dermal necrosis, and characteristic undermining with extensive mixed inflammatory infiltration of the dermis and abscess formation consistent with an ulcer with mixed dermal inflammation compatible with pyoderma gangrenosum. The lesion showed rapid improvement after the initiation of immunosuppressive therapy. (3) Conclusions: PG may be a rare adverse event related to the BNT162b2 vaccine, which could be more frequently encountered with the wide-scale use of mRNA vaccines. The continuous monitoring and surveillance of skin manifestations post-vaccination is essential.

Rapid Weight Loss, Central Obesity Improvement and Blood Glucose Reduction Are Associated with a Stronger Adaptive Immune Response Following COVID-19 mRNA Vaccine. Obesity is associated with a poor COVID-19 prognosis, and it seems associated with reduced humoral response to vaccination. Public health campaigns have advocated for weight loss in subjects with obesity, hoping to eliminate this risk. However, no evidence proves that weight loss leads to a better prognosis or a stronger immune response to vaccination. We aimed to investigate the impact of rapid weight loss on the adaptive immune response in subjects with morbid obesity. Twenty-one patients followed a hypocaloric, very-low-carbohydrate diet one week before to one week after the two mRNA vaccine doses. The diet's safety and efficacy were assessed, and the adaptive humoral (anti-SARS CoV-2 S antibodies, Abs) and cell-mediated responses (IFNÎ³ secretion on stimulation with two different SARS CoV-2 peptide mixes, IFNÎ³-1 and IFNÎ³-2) were evaluated. The patients lost ~10% of their body weight with metabolic improvement. A high baseline BMI correlated with a poor immune response (R -0.558, p = 0.013 for IFNÎ³-1; R -0.581, p = 0.009 for IFNÎ³-2; R -0.512, p = 0.018 for Abs). Furthermore, there was a correlation between weight loss and higher IFNÎ³-2 (R 0.471, p = 0.042), and between blood glucose reduction and higher IFNÎ³-1 (R 0.534, p = 0.019), maintained after weight loss and waist circumference reduction adjustment. Urate reduction correlated with higher Abs (R 0.552, p = 0.033). In conclusion, obesity is associated with a reduced adaptive response to a COVID-19 mRNA vaccine, and weight loss and metabolic improvement may reverse the effect.

The Association of Previous Vaccination with Live-Attenuated Varicella Zoster Vaccine and COVID-19 Positivity: An Israeli Population-Based Study. The Bacillus Calmette-GuÃ©rin (BCG) vaccine affords indirect protection against COVID-19, which is presumably due to priming of the innate immune system. It was hypothesized that the live attenuated Varicella Zoster (LAVZ) vaccine, recommended for the elderly population, would also protect against COVID-19 infection. A retrospective population-based cross-sectional study was conducted using the Leumit Health Services (LHS) database. LAVZ-vaccinated patients were matched with controls based on a propensity score model using 1:9 nearest-neighbor matching. Matching was based on age, gender, and the presence of some chronic disorders, which were selected according to their association with COVID-19 infection. Multivariate logistic regression analyses, adjusted for sex, age, smoking status, comorbidities, and

chronic medications associated with COVID-19 risk, were used to estimate the association between LAVZ vaccination and COVID-19 RT-PCR results. Subjects (625) vaccinated with LAVZ and RT-PCR-tested for COVID-19 were identified. After 1:9 matching of subjects who received the LAVZ vaccine, 6250 subjects were included in the study. Multivariate logistic regression analysis demonstrated a significant and independent negative association between having received the LAVZ vaccine and the likelihood of COVID-19 infection (adjusted OR = 0.47 (95% CI 0.33-0.69, p < 0.001)). This association was further strengthened after separate analysis based on the time of LAVZ vaccination before COVID-19 RT-PCR testing. Individuals aged â‰¥50 years vaccinated with LAVZ had a decreased likelihood of being tested positive for COVID-19.

After 100 Years of BCG Immunization against Tuberculosis, What Is New and Still Outstanding for This Vaccine? In 2021, most of the world was reasonably still concerned about the COVID-19 pandemic, how cases were up and down in different countries, how the vaccination campaigns were ongoing, and most people were familiar with the speed with which vaccines against SARS-Co-V2 were developed, analyzed, and started to be applied in an attempt to curb the pandemic. Because of this, it may have somehow passed relatively inadvertently for people outside of the field that the vaccine used to control tuberculosis (TB), Mycobacterium bovis Bacille Calmette-GuÃ©rin (BCG), was first applied to humans a century ago. Over these years, BCG has been the vaccine applied to most human beings in the world, despite its known lack of efficacy to fully prevent respiratory TB. Several strategies have been employed in the last 20 years to produce a novel vaccine that would replace, or boost, immunity and protection elicited by BCG. In this work, to avoid potential redundancies with recently published reviews, I only aim to present my current thoughts about some of the latest findings and outstanding questions that I consider worth investigating to help develop a replacement or modified BCG in order to successfully fight TB, based on BCG itself.

Vaccine Breakthrough Infections by SARS-CoV-2 Variants after ChAdOx1 nCoV-19 Vaccination in Healthcare Workers. This study elucidated the clinical, humoral immune response and genomic analysis of vaccine breakthrough (VBT) infections after ChAdOx1 nCoV-19/Covishield vaccine in healthcare workers (HCWs). Amongst 1858 HCWs, 1639 had received either two doses (1346) or a single dose (293) of ChAdOx1 nCoV-19 vaccine. SARS-CoV-2 IgG antibodies and neutralizing antibodies were measured in the vaccinated group and the development of SARS-CoV-2 infection was monitored.Forty-six RT-PCR positive samples from the 203 positive samples were subjected to whole genome sequencing (WGS). Of the 203 (10.92%) infected HCWs, 21.46% (47/219) were non-vaccinated, which was significantly more than 9.52% (156/1639) who were vaccinated and infection was higher in doctors and nurses. Unvaccinated HCWs had 1.57 times higher risk compared to partially vaccinated HCWs and 2.49 times higher risk than those who were fully vaccinated.The partially vaccinated were at higher risk than the fully vaccinated (RR 1.58). Antibody non-response was seen in 3.44% (4/116), low antibody levels in 15.51% (18/116) and medium levels were found in 81.03% (94/116). Fully vaccinated HCWs had a higher antibody response at day 42 than those who were partially vaccinated (8.96 + 4.00 vs. 7.17 + 3.82). Whole genome sequencing of 46 samples revealed that the Delta variant (B.1.617.2) was predominant (69.5%). HCWs who had received two doses of vaccine showed better protection from mild, moderate, or severe infection, with a higher humoral immune response than those who had received a single dose. The genomic analysis revealed the predominance of the Delta variant (B.1.617.2) in the VBT infections.

Effect of SARS-CoV-2 Vaccination on Symptoms from Post-Acute Sequelae of COVID-19: Results from the Nationwide VAXILONG Study. INTRODUCTION: Few data are available concerning the effect of SARS-CoV-2 vaccination on the persistent symptoms associated with COVID-19, also called long-COVID or post-acute sequelae of COVID-19 (PASC). PATIENTS AND METHODS: We conducted a nationwide online study among adult patients with PASC as defined by symptoms persisting over 4

weeks following a confirmed or probable COVID-19, without any identified alternative diagnosis. Information concerning PASC symptoms, vaccine type and scheme and its effect on PASC symptoms were studied. RESULTS: 620 questionnaires were completed and 567 satisfied the inclusion criteria and were analyzed. The respondents' median age was 44 (IQR 25-75: 37-50) and 83.4% were women. The initial infection was proven in 365 patients (64%) and 5.1% had been hospitalized to receive oxygen. A total of 396 patients had received at least one injection of SARS-CoV-2 vaccine at the time of the survey, after a median of 357 (198-431) days following the initially-reported SARS-CoV-2 infection. Among the 380 patients who reported persistent symptoms at the time of SARS-CoV-2 vaccination, 201 (52.8%) reported a global effect on symptoms following the injection, corresponding to an improvement in 21.8% and a worsening in 31%. There were no differences based on the type of vaccine used. After a complete vaccination scheme, 93.3% (28/30) of initially seronegative patients reported a positive anti-SARS-CoV-2 IgG. A total of 170 PASC patients had not been vaccinated. The most common reasons for postponing the SARS-CoV-2 vaccine were fear of worsening PASC symptoms (55.9%) and the belief that vaccination was contraindicated because of PASC (15.6%). CONCLUSION: Our study suggests that SARS-CoV-2 vaccination is well tolerated in the majority of PASC patients and has good immunogenicity. Disseminating these reassuring data might prove crucial to increasing vaccine coverage in patients with PASC.
Multisystem Inflammatory-like Syndrome in a Child Following COVID-19 mRNA Vaccination. A 12-year-old male was presented to the hospital with acute encephalopathy, headache, vomiting, diarrhea, and elevated troponin after recent COVID-19 vaccination. Two days prior to admission and before symptom onset, he received the second dose of the Pfizer-BioNTech COVID-19 vaccine. Symptoms developed within 24 h with worsening neurologic symptoms, necessitating admission to the pediatric intensive care unit. Brain magnetic resonance imaging within 16 h of admission revealed a cytotoxic splenial lesion of the corpus callosum (CLOCC). Nineteen days prior to admission, he developed erythema migrans, and completed an amoxicillin treatment course for clinical Lyme disease. However, Lyme antibody titers were negative on admission and nine days later, making active Lyme disease an unlikely explanation for his presentation to hospital. An extensive workup for other etiologies on cerebrospinal fluid and blood samples was negative, including infectious and autoimmune causes and known immune deficiencies. Three weeks after hospital discharge, all of his symptoms had dissipated, and he had a normal neurologic exam. Our report highlights a potential role of mRNA vaccine-induced immunity leading to MIS-C-like symptoms with cardiac involvement and a CLOCC in a recently vaccinated child and the complexity of establishing a causal association with vaccination. The child recovered without receipt of immune modulatory treatment.
Reduced Humoral Response of SARS-CoV-2 Antibodies following Vaccination in Patients with Inflammatory Rheumatic Diseases-An Interim Report from a Danish Prospective Cohort Study. Background/Purpose: In light of the current COVID-19 pandemic, whether patients with rheumatic musculoskeletal disease (RMD) treated with conventional (cs) or biologic (b) disease-modifying drugs (DMARDs) exhibit an adequate immune response to the currently available SARS-CoV-2 vaccinations remains a major concern. There is an urgent need for more SARS-CoV-2 vaccine efficacy data to inform healthcare providers on the potential need for a booster vaccine. We established the 'Detection of SARS-CoV-2 antibodies in Danish Inflammatory Rheumatic Outpatients' study (DECODIR) in March 2021 in order to assess and compare the immunoglobulin G (IgG response) of the SARS-CoV-2 BNT162b2 vaccine (Pfizer, Groton, CT, USA/BioNTech, Mainz, Germany) and mRNA-1273 vaccine (Moderna, Cambridge, MA, USA) administered as part of the national vaccine roll out in patients with RMDs, irrespective of treatment. Patients' SARS-CoV-2 IgG level was used as proxy to determine vaccination response. Methods: The study is a longitudinal prospective cohort study in which the SARS-CoV-2 antibody response was measured and compared at baseline and at six weeks following

vaccination. The study population consisted of patients with rheumatoid arthritis (RA), spondyloarthropathies (SpA), or psoriatic arthritis (PsA) receiving their outpatient treatment at the Danish Hospital for Rheumatic Diseases, Sonderborg. Bloods, patient reported outcome measurements (PROMS), clinical data, and treatment information (cs/bDMARD) were collected at baseline/6 weeks and documented in the Danish DANBIO registry. Commercially available antibody tests (ThermoFisher, Waltham, MA, USA) were used, and SARS-CoV-2 IgG levels were reported in EliA U/mL. Sufficient IgG response was defined as â‰¥10 EliA U/mL (manufacturers cut-off). Associations between antibody response, age, gender, disease (RA/PsA/SpA), no treatment or cs/bDMARD treatment, and disease activity were tested using proportional odds regression and bootstrapped tests of medians. Results were reported using mean, median (IqR), and bootstrapped 95% confidence interval (CI) of the median. Results: A total of 243 patients were included. We observed a significant increase in IgG levels (median of <0.7 EliA U/mL at baseline versus 34.5 EliA U/mL at 6 weeks). Seventy-two patients (32%) had an insufficient IgG response. The median IgG level in patients treated with cs/bDMARD combination therapy was significantly lower compared to patients without any DMARD treatment (12 EliA U/mL vs. 92 EilA U/mL ($p < 0.01$)). Conclusion: Patients treated with a combination of cs/bDMARD are at significantly higher risk of an inadequate response to SARS-CoV-2 vaccines as measured by IgG level compared to patients without DMARD treatment. IgG SARS-CoV-2 are only part of the immune response, and further data are urgently needed. At present, our results may inform healthcare providers and policy makers on the decision for the need of a booster vaccine in this particular patient group.

Factors Associated with Adverse Reactions to BNT162b2 COVID-19 Vaccine in a Cohort of 3969 Hospital Workers. Factors associated with adverse reactions to BNT162b2 COVID-19 vaccine reported by hospital workers are unclear. Our aim was to collect all reported adverse events in a cohort of hospital workers and to analyze the factors associated with their presence. We conducted an observational longitudinal study on all hospital workers of our center who received COVID-19 vaccination from 27 December 2020 to 1 September 2021. Information on adverse events was reported telephonically and confirmed through clinical records. Chi-square and t tests as well as multivariate logistic regression models were used. Cluster analysis was designed to explore associations between reactions. A total of 3969 hospital workers were included in the sample. Of the total sample, 182 workers (4.6%) reported adverse events. The most frequent symptoms were general malaise (n = 95), fever (n = 92), arthromyalgia (n = 80), and headache (n = 47). The factors associated with adverse events in adjusted analyses were an antecedent of COVID-19 infection (OR = 2.09, 95% CI: 1.47-2.98), female sex (OR = 1.51, 95% CI: 1.03-2.20), and professional category (OR for physicians = 0.41, 95% CI: 0.21-0.80). We report a low frequency of adverse events in hospital workers after COVID-19 vaccination and no severe reaction. Men and physicians underreported their symptoms. These data should guide future strategies for recording adverse events and future research on COVID-19 vaccination safety.

Eosinophilic Granulomatosis with Polyangiitis Relapse after COVID-19 Vaccination: A Case Report. BACKGROUND: We here describe the case of a 71-year-old Caucasian woman previously diagnosed with Eosinophilic Granulomatosis with Polyangiitis (EGPA) that had been treated with Mepolizumab, an anti-IL5 monoclonal antibody, since 2019 with a good clinical response. METHODS: She had a mild COVID-19 in December 2020 and she tested negative for SARS-CoV-2 infection in only late January 2021. In April 2021 she received the first dose of mRNA BNT162b2 vaccine. Ten days later she developed myalgia, dyspnea and numbness of the limbs due to a relapse of EGPA that occurred during Mepolizumab treatment.

Vaccines to prevent COVID-19: A living systematic review with Trial Sequential Analysis and network meta-analysis of randomized clinical trials. BACKGROUND: COVID-19 is rapidly spreading causing

extensive burdens across the world. Effective vaccines to prevent COVID-19 are urgently needed. METHODS AND FINDINGS: Our objective was to assess the effectiveness and safety of COVID-19 vaccines through analyses of all currently available randomized clinical trials. We searched the databases CENTRAL, MEDLINE, Embase, and other sources from inception to June 17, 2021 for randomized clinical trials assessing vaccines for COVID-19. At least two independent reviewers screened studies, extracted data, and assessed risks of bias. We conducted meta-analyses, network meta-analyses, and Trial Sequential Analyses (TSA). Our primary outcomes included all-cause mortality, vaccine efficacy, and serious adverse events. We assessed the certainty of evidence with GRADE. We identified 46 trials; 35 trials randomizing 219 864 participants could be included in our analyses. Our meta-analyses showed that mRNA vaccines (efficacy, 95% [95% confidence interval (CI), 92% to 97%]; 71 514 participants; 3 trials; moderate certainty); inactivated vaccines (efficacy, 61% [95% CI, 52% to 68%]; 48 029 participants; 3 trials; moderate certainty); protein subunit vaccines (efficacy, 77% [95% CI, -5% to 95%]; 17 737 participants; 2 trials; low certainty); and viral vector vaccines (efficacy 68% [95% CI, 61% to 74%]; 71 401 participants; 5 trials; low certainty) prevented COVID-19. Viral vector vaccines decreased mortality (risk ratio, 0.25 [95% CI 0.09 to 0.67]; 67 563 participants; 3 trials, low certainty), but comparable data on inactivated, mRNA, and protein subunit vaccines were imprecise. None of the vaccines showed evidence of a difference on serious adverse events, but observational evidence suggested rare serious adverse events. All the vaccines increased the risk of non-serious adverse events. CONCLUSIONS: The evidence suggests that all the included vaccines are effective in preventing COVID-19. The mRNA vaccines seem most effective in preventing COVID-19, but viral vector vaccines seem most effective in reducing mortality. Further trials and longer follow-up are necessary to provide better insight into the safety profile of these vaccines.

Chronic Lymphocytic Leukemia in the SARS-CoV-2 Pandemic. PURPOSE OF REVIEW: Chronic lymphocytic leukemia (CLL) is the most frequent lymphoproliferative disease in the elderly of the western world. Immune defective responses and treatment can worsen the immune system's competence of CLL patients. Consequently, they may present a higher incidence of recurrent severe infections, second malignancies, and reduced efficacy of vaccines. The outbreak of COVID-19 is an ongoing pandemic, and patients with comorbidities experience more severe forms of the disease. Hematological malignancies are associated with higher case fatality rates (CFRs) than other cancers. Knowledge about COVID-19 incidence, clinical course, and immune response to the infection and vaccination in CLL may contribute to design strategies that improve the outcomes of patients in the future. RECENT FINDINGS: The prevalence of SARS-CoV-2 positivity in CLL is not significantly higher than seen in the general population. CFRs for CLL patients are 16.5-fold more elevated than the median reported worldwide and even higher in older patients, those who require hospitalization have significant comorbidities or need oxygen therapy. CLL status decreases the anti-SARS-CoV-2 positivity after infection or vaccination by around 40%, and the spike-specific antibody titers are 74-fold lower than healthy age-matched controls. The response rate to COVID-19 vaccines is even worse in patients with active CLL-directed therapies like BTKi, BCL-2 antagonists, or anti-CD20 monoclonal antibodies. CLL patients are at a greater risk of death from COVID-19. Inherent immunosuppression of CLL and immune deficiencies caused by treatment significantly decrease the ability to produce natural or vaccine-induced anti-SARS-CoV-2 immune responses.

Pfizer/BioNtech BNT162b2: adverse events and insights from an Australian mass vaccination clinic for COVID-19. The Pfizer/BioNtech BNT162b2 is a major vaccine used in the Australian COVID-19 immunisation programme. We report on BNT162b2 safety in the observation period in a dedicated vaccination clinic linked to a quaternary teaching hospital. We performed a retrospective review of medical records for 57â€‰842 vaccinations, and describe the model of care and adverse event rate at the clinic during its firstâ€‰2 months of operation. A total of 243 adverse events following

immunisation (0.42% of total vaccine doses) were recorded in the immediate observation period post-vaccination, which were predominantly immunisation stress-related responses. Of the 110 patients who experienced an adverse event with their first dose of the vaccine, 90% returned for their second dose of the vaccine, with 87% not reporting any further adverse reaction with the subsequent dose. Nineteen (0.03% of total doses) people were reviewed for an allergic reaction, of which 10 (53%) reported a history of prior allergies. A female predominance was present in both total adverse reactions (70%) and allergic vaccine reactions (79%). Only two patients experienced anaphylaxis (0.003% of total doses), in keeping with low rates of adverse reactions to the BNT162b2 vaccine in the current literature. Overall, the present study reinforces the safety of BNT162b2 in the Australian population, describes vaccination completion rates after adverse events and identifies predisposing factors for rare allergic reactions to the vaccine.

Lymphadenopathy post-COVID-19 vaccination with increased FDG uptake may be falsely attributed to oncological disorders: A systematic review. Coronavirus disease 2019 (COVID-19) has caused a global pandemic that continues to cause numerous deaths to date. Four vaccines have been approved by the Food and Drug Administration as of July 2021 to prevent the transmission of COVID-19: Pfizer, Moderna, AstraZeneca, and Janssen. These vaccines have shown great efficacy and safety profile. One side effect that has been widely reported is post-COVID-19 vaccination lymphadenopathy. Due to the mimicry of the lymphadenopathy for metastases in some oncologic patients, there have been reports of patients who underwent biopsies that showed pathologic confirmation of benign reactive lymphadenopathy secondary to the COVID-19 vaccine. Therefore, understanding the incidence of lymphadenopathy post-COVID-19 vaccinations will help guide radiologists and oncologists in their management of patients, both present oncologic patients, and patients with concerns over their newly presenting lymphadenopathy. A systematic literature search was performed using several databases to identify relevant studies that reported lymphadenopathy post-COVID-19 vaccination. Our results revealed that several cases have been detected in patients undergoing follow-up fluorodeoxyglucose (FDG)-positron emission tomography-computerized tomography scans where lymph nodes ipsilateral to the vaccine injection site show increased uptake of FDG. Thus, knowledge of the incidence of lymphadenopathy may help avoid unnecessary biopsies, interventions, and changes in management for patients, especially oncologic patients who are at risk for malignancies.

Interferon-gamma release assays outcomes in healthy subjects following BNT162b2 mRNA COVID-19 vaccination. The pathogenesis of COVID-19 involves both humoral and cellular immunological responses, with cell-mediated immunity being discussed as the primary and most effective immune response to viral infection. It is supposed that COVID-19 vaccines also elicited effective cell immune response, and specifically IFNÎ³ secreted by SARS-CoV-2-specific T-helper 1 and Tcytotoxic cells. Using an interferon-gamma release assay (IGRA) test, we aimed to monitor cellular post-vaccination immunity in healthy subjects vaccinated with BNT162b2 mRNA COVID-19 vaccine (Comirnaty). We tested 37 healthcare workers (mean age 54.3Â years, range 28-72, 22 females, 15 males) following COVID-19 mRNA COVID-19 vaccine and 15 healthy unvaccinated native persons as control subjects using QuantiFERON SARS-CoV-2 RUO test, performed approximately 1Â month after vaccination. We also measured virus-neutralizing antibodies. Thirty-one out of 37 tested subjects had significantly raised levels of SARS-CoV-2 specific IFNÎ³ against SARS-CoV-2 Ag1 and Ag2 1Â month following COVID-19 vaccination. In addition, we found a significant difference between the IFNÎ³ levels in fully vaccinated subjects and the control group (pâ€‰<â€‰0.01).We also found a substantial correlation (râ€‰=â€‰0.9; pâ€‰<â€‰0.01) between virus-neutralizing antibodies titers and IFNÎ³ concentrations released by T cells. We believe that IGRA tests are an excellent tool to assess the development of a post-vaccination immune response when immunized against SARS-CoV-2. However,

IGRA-based tests should be performed within a few weeks following vaccination. Therefore, we can speculate that the application of these tests to assess long-term immune response is debatable.

Thrombocytopenia in COVIDâ€‘19 and vaccineâ€‘induced thrombotic thrombocytopenia. The highly heterogeneous symptomatology and unpredictable progress of COVIDâ€‘19 triggered unprecedented intensive biomedical research and a number of clinical research projects. Although the pathophysiology of the disease is being progressively clarified, its complexity remains vast. Moreover, some extremely infrequent cases of thrombotic thrombocytopenia following vaccination against SARSâ€‘CoVâ€‘2 infection have been observed. The present study aimed to map the signaling pathways of thrombocytopenia implicated in COVIDâ€‘19, as well as in vaccineâ€‘induced thrombotic thrombocytopenia (VITT). The biomedical literature database, MEDLINE/PubMed, was thoroughly searched using artificial intelligence techniques for the semantic relations among the topÂ 50 similar words (>0.9) implicated in COVIDâ€‘19â€‘mediated human infection or VITT. Additionally, STRING, a database of primary and predicted associations among genes and proteins (collected from diverse resources, such as documented pathway knowledge, highâ€‘throughput experimental studies, crossâ€‘species extrapolated information, automated text mining results, computationally predicted interactions, etc.), was employed, with the confidence threshold set atÂ 0.7. In addition, two interactomes were constructed: i)Â AÂ network including 119Â andÂ 56Â nodes relevant to COVIDâ€‘19 and thrombocytopenia, respectively; and ii)Â a second network containing 60Â nodes relevant to VITT. Although thrombocytopenia is a dominant morbidity in both entities, three nodes were observed that corresponded to genes (AURKA, CD46 and CD19) expressed only in VITT, whilst ADAM10, CDC20, SHC1 and STXBP2 are silenced in VITT, but are commonly expressed in both COVIDâ€‘19 and thrombocytopenia. The calculated average node degree was immense (11.9Â in COVIDâ€‘19 and 6.43Â in VITT), illustrating the complexity of COVIDâ€‘19 and VITT pathologies and confirming the importance of cytokines, as well as of pathways activated following hypoxic events. In addition, PYCARD, NLP3 and P2RX7 are key potential therapeutic targets for all three morbid entities, meriting further research. This interactome was based on wildâ€‘type genes, revealing the predisposition of the body to hypoxiaâ€‘induced thrombosis, leading to the acute COVIDâ€‘19 phenotype, the 'longâ€‘COVID syndrome', and/or VITT. Thus, common nodes appear to be key players in illness prevention, progression and treatment.

Case Report: A Case of COVID Vaccine-Induced Thrombotic Thrombocytopenia Manifested as Pulmonary Embolism and Hemorrhagia. A First Reported Case From Slovakia. COVID-19 vaccine-induced thrombotic thrombocytopenia (VITT) is a rare complication of adenoviral vector (ChAdOx1 nCoV-19) vaccine administration. It is presented as thrombocytopenia and thrombotic manifestations in various sites, especially in cerebral veins. Pulmonary emboli have been reported rarely. We present a case of a young male patient who developed severe thrombocytopenia and pulmonary embolism 12 days after the first dose of the vaccine. Severe thrombocytopenia, skin hematomas, and segmental pulmonary emboli were detected. Anti-platelet factor 4 (aPF-4) antibody was highly positive supporting the diagnosis of VITT. Prompt treatment with fondaparinux, intravenous immunoglobulin, and prednisone led to a marked improvement of clinical condition and thrombocytes count. We report the first known case of VITT in Slovakia.

Multimorbidity and adverse events of special interest associated with Covid-19 vaccines in Hong Kong. Prior research using electronic health records for Covid-19 vaccine safety monitoring typically focuses on specific disease groups and excludes individuals with multimorbidity, defined as â‰¥2 chronic conditions. We examine the potential additional risk of adverse events 28 days after the first dose of CoronaVac or Comirnaty imposed by multimorbidity. Using a territory-wide public healthcare database with population-based vaccination records in Hong Kong, we analyze a retrospective cohort of patients with chronic conditions. Thirty adverse events of special interest

according to the World Health Organization are examined. In total, 883,416 patients are included and 2,807 (0.3%) develop adverse events. Results suggest vaccinated patients have lower risks of adverse events than unvaccinated individuals, multimorbidity is associated with increased risks regardless of vaccination, and the association of vaccination with adverse events is not modified by multimorbidity. To conclude, we find no evidence that multimorbidity imposes extra risks of adverse events following Covid-19 vaccination.

COVID-19 Vaccination and Subclinical Axillary Lymphadenopathy on Mammogram: Correspondence.

Adverse reactions to the BNT162b2 and mRNA-1273 mRNA COVID-19 vaccines in Japan. INTRODUCTION: The BNT162b2 and mRNA-1273 COVID-19 vaccines are the main vaccines that have been used for mass vaccination in Japan. Information on adverse reactions to COVID-19 vaccines in the Japanese population is limited. METHODS: We conducted an online survey on self-reported adverse reactions in individuals who had received two doses of the BNT162b2 or mRNA-1273 vaccine. The incidence of adverse events after each dose of vaccine was investigated. Propensity score matching was used to compare the incidence of adverse reactions after the second dose of the BNT162b2 and mRNA-1273 vaccines. RESULTS: After the first and second doses of the BNT162b2 vaccine, and the first and second doses of the mRNA-1273 vaccine, 890, 853, 6401, and 3965 individuals, respectively, provided complete responses. Systemic reactions, including fever, fatigue, headache, muscle/joint pain, and nausea were significantly more common in females, individuals aged <50 years, and after the second dose. The incidence of injection site pain did not differ significantly according to the dose. The incidence of delayed injection site reactions after the first dose of mRNA-1273 vaccine was 3.9% and 0.8% among females and males, respectively, and 10.6% among females aged 40-69 years. Local and systemic reactions after the second dose, including fever, fatigue, headache, muscle/joint pain, nausea, and skin rash were more common in individuals who had received the mRNA-1273 vaccine. CONCLUSIONS: Adverse reactions were more frequently reported in females, younger individuals, and after the mRNA-1273 vaccine.

Takotsubo Rather Than Kounis Syndrome Complicating SARS-CoV-2 Vaccination.

Humoral immune response after different SARS-CoV-2 vaccination regimens. BACKGROUND: The humoral immune response after primary immunisation with a SARS-CoV-2 vector vaccine (AstraZeneca AZD1222, ChAdOx1 nCoV-19, Vaxzevria) followed by an mRNA vaccine boost (Pfizer/BioNTech, BNT162b2; Moderna, m-1273) was examined and compared with the antibody response after homologous vaccination schemes (AZD1222/AZD1222 or BNT162b2/BNT162b2). METHODS: Sera from 59 vaccinees were tested for anti-SARS-CoV-2 immunoglobulin G (IgG) and virus-neutralising antibodies (VNA) with three IgG assays based on (parts of) the SARS-CoV-2 spike (S)-protein as antigen, an IgG immunoblot (additionally contains the SARS-CoV-2 nucleoprotein (NP) as an antigen), a surrogate neutralisation test (sVNT), and a Vero-cell-based virus-neutralisation test (cVNT) with the B.1.1.7 variant of concern (VOC; alpha) as antigen. Investigation was done before and after heterologous (n = 30 and 42) or homologous booster vaccination (AZD1222/AZD1222, n = 8/9; BNT162b2/BNT162b2, n = 8/8). After the second immunisation, a subgroup of 26 age- and gender-matched sera (AZD1222/mRNA, n = 9; AZD1222/AZD1222, n = 9; BNT162b2/BNT162b2, n = 8) was also tested for VNA against VOC B.1.617.2 (delta) in the cVNT. The strength of IgG binding to separate SARS-CoV-2 antigens was measured by avidity. RESULTS: After the first vaccination, the prevalence of IgG directed against the (trimeric) SARS-CoV-2 S-protein and its receptor binding domain (RBD) varied from 55-95% (AZD1222) to 100% (BNT162b2), depending on the vaccine regimen and the SARS-CoV-2 antigen used. The booster vaccination resulted in 100% seroconversion and the occurrence of highly avid IgG, which is directed against the S-protein subunit 1 and the RBD, as well as VNA against VOC B.1.1.7, while anti-NP IgGs were not detected. The results of the three anti-SARS-CoV-2 IgG tests showed an excellent correlation to the VNA titres against this VOC. The agreement of cVNT and sVNT

results was good. However, the sVNT seems to overestimate non- and weak B.1.1.7-neutralising titres. The anti-SARS-CoV-2 IgG concentrations and the B.1.1.7-neutralising titres were significantly higher after heterologous vaccination compared to the homologous AZD1222 scheme. If VOC B.1.617.2 was used as antigen, significantly lower VNA titres were measured in the cVNT, and three (33.3%) vector vaccine recipients had a VNA titre <â€‰1:10. CONCLUSIONS: Heterologous SARS-CoV-2 vaccination leads to a strong antibody response with anti-SARS-CoV-2 IgG concentrations and VNA titres at a level comparable to that of a homologous BNT162b2 vaccination scheme. Irrespective of the chosen immunisation regime, highly avid IgG antibodies can be detected just 2 weeks after the second vaccine dose indicating the development of a robust humoral immunity. The reduction in the VNA titre against VOC B.1.617.2 observed in the subgroup of 26 individuals is remarkable and confirms the immuneÂ escape of the delta variant.

De Novo Minimal Change Disease following Vaccination with the Pfizer/BioNTech SARS-CoV-2 Vaccine in a Living Kidney Donor. Coronavirus disease 2019 has developed as a pandemic. Immunization with the introduction of vaccines against COVID-19 seems be the only way to end this pandemic. We report on a case of a kidney donor, who developed minimal change disease (MCD) within 4 days post-vaccination with the SARS-CoV-2 BNT162b2 mRNA vaccine (Pfizer/BioNTech). She donated her kidney to her husband 4 years ago. After receiving the 1st vaccine dose, she presented with nephrotic syndrome, with complete remission 5 days later. She proceeded with the second dose of the BNT162b2 vaccine at the appointed time. Two days later, she presented with a relapse of full-blown nephrotic syndrome with preserved renal function. We performed an ultrasound-guided percutaneous kidney biopsy and the final diagnosis was consistent with minimal change disease. Oral prednisolone was promptly initiated at a dosage of 1 mg/kg daily and complete remission was achieved 10 days later. More data about this rare appearance of de novo glomerular diseases after SARS-CoV-2 vaccination are emerging and should be interpreted rigorously.

Six-Month Follow-Up after Vaccination with BNT162b2: SARS-CoV-2 Antigen-Specific Cellular and Humoral Immune Responses in Hemodialysis Patients and Kidney Transplant Recipients. Hemodialysis patients (HDP) and kidney transplant recipients (KTR) have a high risk of infection with SARS-CoV-2 with poor clinical outcomes. Because of this, vaccination of these groups of patients against SARS-CoV-2 is particularly important. However, immune responses may be impaired in immunosuppressed and chronically ill patients. Here, our aim was to compare the efficacy of an mRNA-based vaccine in HDP, KTR, and healthy subjects. DESIGN: In this prospective observational cohort study, the humoral and cellular response of prevalent 192 HDP, 50 KTR, and 28 healthy controls (HC) was assessed 1, 2, and 6 months after the first immunization with the BNT162b2 mRNA vaccine. RESULTS: After 6 months, 97.5% of HDP, 37.9% of KTR, and 100% of HC had an antibody response. Median antibody levels were 1539.7 (Â±3355.8), 178.5 (Â±369.5), and 2657.8 (Â±2965.8) AU/mL in HDP, KTR, and HC, respectively (p â‰¤ 0.05). A SARS-CoV-2 antigen-specific cell response to vaccination was found in 68.8% of HDP, 64.5% of KTR, and 90% of HC. CONCLUSION: The humoral response rates to mRNA-based vaccination of HDPs are comparable to HCs, but antibody titers are lower. Furthermore, HDPs have weaker T-cell response to vaccination than HCs. KTRs have very low humoral and antigen-specific cellular response rates and antibody titers, which requires other vaccination strategies in addition to booster vaccination.

Symptomatic SARS-CoV-2 Infection with Ageusia after Two mRNA Vaccine Doses. To raise awareness about preventive measures in COVID-19 pandemic, even though fully vaccinated. Although recent trials showed high efficacy of vaccines in preventing symptomatic infections, there are some individuals experiencing symptomatic SARS-CoV-2 infection. In this case report, a fully vaccinated young dental practitioner experienced symptomatic SARS-CoV-2 infection 55 days postvaccination with BNT162b2 Pfizer vaccine with evident ageusia. Diagnostic swabs were performed and used for

viral genome sequencing. The patient fully recovered 15 days after diagnosis. Loss of smell and taste, together with nasal congestion were the main reported symptoms. The use of personal protective equipment prevented spread of infection in patients and co-workers. With the increase of people being fully vaccinated, it is still necessary to follow infection preventive protocols by correctly applying personal protective equipment. Although high efficacy has been proved, some individuals may still be vulnerable to symptomatic infection and new guidelines and markers should be adopted and investigated to find out patients for whom vaccination may not determine full immunization.

Seven-Month Analysis of Five SARS-CoV-2 Antibody Assay Results after ChAdOx1 nCoV-19 Vaccination: Significant Decrease in SARS-CoV-2 Antibody Titer. We investigated the longevity rates of antibodies to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) after a complete ChAdOx1 nCoV-19 vaccination, which are rare and important to estimate their efficacy and establish a vaccination strategy. We assessed the positivity rates and changes of titers before (T0) and at one month (T1), four months (T2), and seven months (T3) after a ChAdOx1 nCoV-19 vaccination using five SARS-CoV-2 antibody assays. A total of 874 serum samples were obtained from 228 (T0 and T1), 218 (T2), and 200 (T3) healthcare workers. The positive rates for all five assays were 0.0-0.9% at T0, 66.2-92.5% at T1, 98.2-100.0% at T2, and 66.0-100.0% at T3. The positive rates at T3 were decreased compared to those at T2. The median antibody titers of all the assays at T3 were significantly decreased compared to those at T2 (860.5 to 232.0 U/mL for Roche total, 1041.5 to 325.5 AU/mL for Abbott IgG, 10.9 to 2.3 index for Siemens IgG, 99.5% to 94.7% for SD Biosensor V1, and 88.5% to 38.2% for GenScript). A third-dose scheme can be considered based on our data generated from five representative assays. Our findings contribute insights into SARS-CoV-2 antibody assays and appropriate vaccination strategies.

Acute Mild Pancreatitis Following COVID-19 mRNA Vaccine in an Adolescent. A 17-year-old male was referred to the emergency room with sharp abdominal pain, pallor, sweating, and vomiting 12 h after the administration of his first Pfizer-BioNTech vaccine for coronavirus disease 2019 (COVID-19). He had abdominal pain, an increase in serum lipase value of > 3 times the upper limits of normal, and magnetic resonance imaging (MRI) findings consistent with acute mild pancreatitis (AP). He was started on treatment with fluid therapy and non-steroidal anti-inflammatory drugs for pain management, after which he recovered rapidly and was discharged on the fourth day after hospitalization. The available data are difficult to interpret as AP is a relatively frequent disease, but its occurrence after vaccination seems extremely rare. Although it is a rare event, AP should be considered after COVID-19 vaccination, especially in those exhibiting abdominal tenderness and vomiting, which should be promptly treated and adequately investigated.

Two Doses of BNT162b2 mRNA Vaccine in Patients after Hematopoietic Stem Cell Transplantation: Humoral Response and Serological Conversion Predictors. Vaccination against SARS-CoV-2 is currently the best tool in the fight against the COVID-19 pandemic. However, there are limited data on its efficacy and safety after hematopoietic stem cell transplantation (HCT). We present the results of a prospective analysis of the humoral response to two doses of BNT162b2 mRNA vaccine in 93 adult patients, including 29 after autologous HCT (autoHCT) and 64 after allogeneic HCT (alloHCT). Positive anti-SARS-CoV-2 antibodies were detected before vaccination in 25% of patients despite a negative medical history of COVID-19. Seroconversion after vaccination was achieved in 89% of patients after alloHCT and in 96% after autoHCT, without grade 3/4 adverse events. Post-vaccination anti-SARS-CoV-2 antibody level correlated with the time from transplant and absolute B-cell count at the vaccination. In univariate analysis restricted to the alloHCT group, short time since transplantation, low B-cell count, low intensity conditioning, GvHD, and immunosuppressive treatment at the vaccination were associated with lack of seroconversion. In the multivariate model, the only negative predictor of seroconversion remained treatment with calcineurin inhibitor (CNI). In

conclusion, the BNT162b2 mRNA vaccine is highly immunogenic in patients after HCT, but treatment with CNI at the time of vaccination has a strong negative impact on the humoral response.

Humoral Immune Response in IBD Patients Three and Six Months after Vaccination with the SARS-CoV-2 mRNA Vaccines mRNA-1273 and BNT162b2. Severe acute respiratory syndrome coronovirus-2 (SARS-CoV-2) is the cause of the coronavirus disease 2019 (COVID-19) pandemic. Vaccination is considered the core approach to containing the pandemic. There is currently insufficient evidence on the efficacy of these vaccines in immunosuppressed inflammatory bowel disease (IBD) patients. The aim of this study was to investigate the humoral response in immunosuppressed IBD patients after COVID-19 mRNA vaccination. In this prospective study, IgG antibody levels (AB) against the SARS-CoV-2 receptor-binding domain (spike-protein) were quantitatively determined. For assessing the potential neutralizing capacity, a SARS-CoV-2 surrogate neutralization test (sVNT) was employed in IBD patients (n = 95) and healthy controls (n = 38). Sera were examined prior to the first/second vaccination and 3/6 months after second vaccination. Patients showed lower sVNT (%) and IgG-S (AU/mL) AB both before the second vaccination (sVNT $p < 0.001$; AB $p < 0.001$) and 3 (sVNT $p = 0.002$; AB $p = 0.001$) and 6 months (sVNT $p = 0.062$; AB $p = 0.061$) after the second vaccination. Although seroconversion rates (sVNT, IgG-S) did not differ between the two groups 3 months after second vaccination, a significant difference was seen 6 months after second vaccination (sVNT $p = 0.045$). Before and three months after the second vaccination, patients treated with anti-tumor necrosis factor (TNF) agents showed significantly lower AB than healthy subjects. In conclusion, an early booster shot vaccination should be discussed for IBD patients on anti-TNF therapy.

Anti-COVID-19 vaccines and rare cases of cerebral venous sinus thrombosis with thrombocytopenia: what about the pragmatic benefit/risk evaluation for still unvaccinated young women.

Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices - United States, December 2021. On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the adenovirus-vectored COVID-19 vaccine (Janssen Biotech, Inc., a Janssen Pharmaceutical company, Johnson & Johnson), and on February 28, 2021, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for its use as a single-dose primary vaccination in persons aged â‰¥18 years (1,2). On April 13, 2021, CDC and FDA recommended a pause in the use of Janssen COVID-19 vaccine after reports of thrombosis with thrombocytopenia syndrome (TTS), a rare condition characterized by low platelets and thrombosis, including at unusual sites such as the cerebral venous sinus (cerebral venous sinus thrombosis [CVST]), after receipt of the vaccine.* ACIP rapidly convened two emergency meetings to review reported cases of TTS, and 10 days after the pause commenced, ACIP reaffirmed its interim recommendation for use of the Janssen COVID-19 vaccine in persons aged â‰¥18 years, but included a warning regarding rare clotting events after vaccination, primarily among women aged 18-49 years (3). In July, after review of an updated benefit-risk assessment accounting for risks of Guillain-BarrÃ© syndrome (GBS) and TTS, ACIP concluded that benefits of vaccination with Janssen COVID-19 vaccine outweighed risks. Through ongoing safety surveillance and review of reports from the Vaccine Adverse Event Reporting System (VAERS), additional cases of TTS after receipt of Janssen COVID-19 vaccine, including deaths, were identified. On December 16, 2021, ACIP held an emergency meeting to review updated data on TTS and an updated benefit-risk assessment. At that meeting, ACIP made a recommendation for preferential use of mRNA COVID-19 vaccines over the Janssen COVID-19 vaccine, including both primary and booster doses administered to prevent COVID-19, for all persons aged â‰¥18 years. The Janssen COVID-19 vaccine may be considered in some situations, including for persons with a contraindication to receipt of mRNA COVID-19 vaccines.

SARS-CoV-2 vaccine-related neurological complications. OBJECTIVE: To describe three cases with neurological symptoms after SARS-CoV-2 vaccination. METHODS: A case series followed by a review of the literature, describing hypotheses on how neurological symptoms might develop after vaccination. RESULTS: The different temporal relationship between the onset or worsening of different neurological symptoms suggests different pathophysiological mechanisms. Progression of post-infectious myoclonus, caused by a previous SARS-CoV-2-infection, shortly after vaccination suggests a renewed auto-immune mediated crossreaction of antibodies to both viral epitopes and central nervous system components. Thunderclap headache after vaccination suggests a similar pathophysiological mechanism to the headache and other flu-like symptoms described after vaccination against other viruses. This might be ascribed to the activation of immunoinflammatory mediators or accompanying fever. Although headache accompanied by encephalopathy and focal neurological deficit might occur as part of a cytokine release syndrome, this is clinically less likely. CONCLUSIONS: A variety of symptoms, including thunderclap headache, focal deficits and movement disorders, can occur after SARS-CoV-2 vaccination, and an activation or reactivation of the immune system is suggested as most likely cause. However, one should be careful about claiming a direct correlation. It remains important to exclude other causes, such as structural lesions, infections or subarachnoid hemorrhage, and future research is required to understand possible pathophysiological mechanisms and associations with the SARS-CoV-2 vaccine.
mRNA-based SARS-CoV-2 vaccination is associated with reduced ICU admission rate and disease severity in critically ill COVID-19 patients treated in Switzerland.
Booster dose of the Pfizer/BioNTech COVID-19 vaccine (Comirnaty).
Transient lower extremity lymphedema following COVID-19 vaccination: A case report. RATIONALE: Complications from COVID-19 vaccines have yet to be sufficiently analyzed because they are rapidly approved without long-term data. In particular, there are no case reports of lymphedema in a healthy patient following vaccination. Herein, we report a patient who underwent transient lymphedema after vaccination with BNT16b2. PATIENT CONCERNS: A 79-year-old woman with pitting edema in both lower legs after administration of a second dose of Pfizer vaccine was referred to our clinic. In the absence of clinical evidence of swelling during the laboratory evaluation, we suspected deep vein thrombosis. However, ultrasonographic findings revealed no evidence of venous thrombosis or varicose veins. DIAGNOSIS: On the basis of lymphoscintigraphy, the patient was diagnosed with transient lymphedema with decreased lymphatic transport in both lower extremities. INTERVENTION: The patient received intensive physiotherapy, including complex decongestive physiotherapy and pneumatic pump compression, to improve the lymphatic circulation. Furthermore, the patient was trained to apply a multilayer compressive bandage to the lower extremities. OUTCOMES: At 2 months follow-up after rehabilitative treatment, the patient's symptoms improved without recurring lymphedema. LESSONS: In the absence of clinical evidence of swelling during laboratory evaluation or ultrasonographic investigations suggesting deep vein thrombosis, we should consider the possibility of lymphatic disorders.
Massive bullous local reaction following administration of Ad26.COV2.S COVID-19 vaccine.
Acute embolisms in multiple arterial districts following Ad26.COV2-S vaccine. A case of multiple arterial thrombosis/embolisms in a 74-year-old Caucasian man with no other cardiovascular risk factors who received Ad26.COV2-S vaccine 16 days before is reported. The unusual presentation required a longer diagnostic workup. The clinical manifestations and the therapy-specific response suggest an unusual presentation of Vaccine-induced immune thrombotic thrombocytopenia (VITT).
Ultrastructural findings of lung injury due to Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT) following COVID-19 vaccination: a scanning electron microscopic study. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare new syndrome occurring after the

ChAdOx1 nCoV-19 vaccine immunization. Patients with VITT are characterized by a variable clinical presentation, likewise also the outcome of these patients is very variable. Here we report the lung ultrastructural findings in the course of VITT of a 58-year-old male patient. Alveoli were mainly dilated, irregular in shape, and occupied by a reticular network of fibrin, while interalveolar septa appeared thickened. The proliferation of small capillaries gave rise to plexiform structures and pulmonary capillary hemangiomatosis-like features. Near the alveoli occupied by a dense fibrin network, the medium-sized arteries showed a modified wall and an intraluminal thrombus. This scenario looks quite similar to that found during COVID-19, where the lungs suffer from the attack of the antigen-antibodies complexes and the virus respectively. In both diseases, the final outcome is a severe inflammation, activation of the haemostatic system and fibrinolysis.
COVID-19 Vaccination and Mental Health Distress.
Non-infectious endocarditis and myocarditis after COVID-19 mRNA vaccination.
Adverse Effects and Antibody Titers in Response to the BNT162b2 mRNA COVID-19 Vaccine in a Prospective Study of Healthcare Workers. BACKGROUND: The relationship between postvaccination symptoms and strength of antibody responses is unclear. The goal of this study was to determine whether adverse effects caused by vaccination with the Pfizer/BioNTech BNT162b2 vaccine are associated with the magnitude of vaccine-induced antibody levels. METHODS: We conducted a single-center, observational cohort study consisting of generally healthy adult participants that were not severely immunocompromised, had no history of coronavirus disease 2019, and were seronegative for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein before vaccination. Severity of vaccine-associated symptoms was obtained through participant-completed questionnaires. Testing for immunoglobulin G antibodies against SARS-CoV-2 spike protein and receptor-binding domain was conducted using microsphere-based multiplex immunoassays performed on serum samples collected at monthly visits. Neutralizing antibody titers were determined by microneutralization assays. RESULTS: Two hundred six participants were evaluated (69.4% female, median age 41.5 years old). We found no correlation between vaccine-associated symptom severity scores and vaccine-induced antibody titers 1 month after vaccination. We also observed that (1) postvaccination symptoms were inversely correlated with age and weight and more common in women, (2) systemic symptoms were more frequent after the second vaccination, (3) high symptom scores after first vaccination were predictive of high symptom scores after second vaccination, and (4) older age was associated with lower titers. CONCLUSIONS: Lack of postvaccination symptoms after receipt of the BNT162b2 vaccine does not equate to lack of vaccine-induced antibodies 1 month after vaccination.
Autoimmune Hemolytic Anemia After mRNA COVID Vaccine. Discussion of the hematologic complications of vaccination for severe acute respiratory syndrome coronavirus-2 (COVID-19) has primarily focused on the development of vaccine-associated immune thrombosis with thrombocytopenia (VITT). Other hematologic complications are uncommon. We report the case of a patient who developed immunoglobulin G (IgG)-mediated autoimmune hemolytic anemia (AIHA) after the Moderna COVID-19 messenger ribonucleic acid (mRNA) vaccine.
Serological response following anti-SARS-CoV-2 vaccination in hematopoietic stem cell transplantation patients depends upon time from transplant, type of transplant and "booster" dose.
T-cell immune responses following vaccination with mRNA BNT162b2 against SARS-CoV-2 in patients with chronic lymphocytic leukemia: results from a prospective open-label clinical trial.
Comparative analysis of ChAdOx1 nCoV-19 and Ad26.COV2.S SARS-CoV-2 vector vaccines. Vector-based SARS-CoV-2 vaccines have been associated with vaccine- induced thrombosis with thrombocytopenia syndrome (VITT/TTS), but the causative factors are still unresolved. We comprehensively analyzed the ChAdOx1 nCoV-19 (AstraZeneca) and Ad26.COV2.S (Johnson and

Johnson) vaccines. ChAdOx1 nCoV-19 contains significant amounts of host cell protein impurities, including functionally active proteasomes, and adenoviral proteins. A much smaller amount of impurities was found in Ad26.COV2.S. Platelet factor 4 formed complexes with ChAdOx1 nCoV-19 constituents, but not with purified virions from ChAdOx1 nCoV-19 or with Ad26.COV2.S. Vascular hyperpermeability was induced by ChAdOx nCoV-19 but not by Ad26.COV2.S. These differences in impurities together with EDTAinduced capillary leakage might contribute to the higher incidence rate of VITT associated with ChAdOx1 nCoV-19 compared to Ad26.COV2.S.

Preclinical evaluation of a SARS-CoV-2 mRNA vaccine PTX-COVID19-B. Safe and effective vaccines are needed to end the COVID-19 pandemic. Here, we report the preclinical development of a lipid nanoparticleâ€“formulated SARS-CoV-2 mRNA vaccine, PTX-COVID19-B. PTX-COVID19-B was chosen among three candidates after the initial mouse vaccination results showed that it elicited the strongest neutralizing antibody response against SARS-CoV-2. Further tests in mice and hamsters indicated that PTX-COVID19-B induced robust humoral and cellular immune responses and completely protected the vaccinated animals from SARS-CoV-2 infection in the lung. Studies in hamsters also showed that PTX-COVID19-B protected the upper respiratory tract from SARS-CoV-2 infection. Mouse immune sera elicited by PTX-COVID19-B vaccination were able to neutralize SARS-CoV-2 variants of concern, including the Alpha, Beta, Gamma, and Delta lineages. No adverse effects were induced by PTX-COVID19-B in either mice or hamsters. Based on these results, PTX-COVID19-B was authorized by Health Canada to enter clinical trials in December 2020 with a phase 2 clinical trial ongoing.

Post-Covid-19-vaccination adverse events and healthcare utilization among individuals with or without previous SARS-CoV-2 infection. BACKGROUND: Post-marketing pharmacovigilance data are scant on the safety of Covid-19 vaccines among people with previous SARS-CoV-2 infection compared with ordinary vaccine recipients. We compared the post-vaccination adverse events of special interests (AESI), accident and emergency room (A&E) visit, and hospitalization between these two groups. METHODS: We conducted a retrospective cohort study using a territory-wide public healthcare database with population-based vaccination records in Hong Kong. RESULTS: In total, 3922 vaccine recipients with previous SARS-CoV-2 infection and 1,137,583 vaccine recipients without previous SARS-CoV-2 infection were included. No significant association was observed between previous SARS-CoV-2 infection and AESI or hospitalization. Previous SARS-CoV-2 infection was significantly associated with a lower risk of A&E visit (CoronaVac: hazard ratios [HR] = 0.56, 95% confidence intervals [CI]: 0.32-0.99; Comirnaty: HR = 0.62, 95% CI: 0.47-0.82). CONCLUSION: No safety signal of Covid-19 vaccination was detected from the comparison between vaccine recipients with previous SARS-CoV-2 infection and those without infection.

Acute Arterial Occlusion Following ChAdOx1 nCov-19 (Oxford-AstraZeneca) Vaccination.

High Rate of Asymptomatic Carriage Associated with Variant Strain Omicron. The early widespread dissemination of Omicron indicates the urgent need to better understand the transmission dynamics of this variant, including asymptomatic spread among immunocompetent and immunosuppressed populations. In early December 2021, the Ubuntu clinical trial, designed to evaluate efficacy of the mRNA-1273 vaccine (Moderna) among persons living with HIV (PLWH), began enrolling participants. Nasal swabs are routinely obtained at the initial vaccination visit, which requires participants to be clinically well to receive their initial jab. Of the initial 230 participants enrolled between December 2 and December 17, 2021, 71 (31%) were PCR positive for SARS-CoV-2: all of whom were subsequently confirmed by S gene dropout to be Omicron; 48% of the tested samples had cycle threshold (CT) values <25 and 18% less than 20, indicative of high titers of asymptomatic shedding. Asymptomatic carriage rates were similar in SARS-CoV-2 seropositive and seronegative persons (27% respectively). These data are in stark contrast to COVID-19 vaccine studies

conducted pre-Omicron, where the SARS-CoV-2 PCR positivity rate at the first vaccination visit ranged from <1%-2.4%, including a cohort of over 1,200 PLWH largely enrolled in South Africa during the Beta outbreak. We also evaluated asymptomatic carriage in a sub study of the Sisonke vaccine trial conducted in South African health care workers, which indicated 2.6% asymptomatic carriage during the Beta and Delta outbreaks and subsequently rose to 16% in both PLWH and PHLWH during the Omicron period.

Novel case of takotsubo cardiomyopathy following COVID-19 vaccination. We present an unusual case of takotsubo cardiomyopathy (TTC) following administration of the second dose of the DNA ChadOX1 nCOV-19 (AZD122) vaccination. This woman in her early 50s presented to the emergency department 8 days following her vaccine with central chest pain. Initial investigations revealed a raised troponin and evolving T wave inversion on ECG. Acute coronary syndrome management was commenced. Further investigations revealed non-obstructive coronary arteries on coronary angiography and imaging revealed hypokinesia of the anterior and anterior-septal walls in the apex and midcavity level, myocardial oedema and no infarction, all in keeping with TTC. Given the large-scale roll out of vaccinations during the COVID-19 pandemic better understanding of potential adverse events is essential. This is the first case report of TTC following a second dose of the DNA ChadOX1 nCOV-19 (AZD122) vaccination.

Cerebral arterial and venous thrombosis due to COVID-19 vaccine-induced immune thrombotic thrombocytopenia. Vaccine-induced immune thrombotic thrombocytopenia (VITT) rarely develops after many COVID-19 vaccines. A 51-year-old woman re-presented to hospital with a 4â€‰day history of headache, vomiting, diarrhoea and left calf pain, 11 days after her first dose of ChAdOx1nCoV-19 (AstraZenica) vaccine. Her neurological examination was normal. Blood tests demonstrated a low platelet count, raised D-dimer and CRP, and a positive heparin/anti-PF4 antibody assay. CT venogram demonstrated widespread cerebral venous sinus thrombosis. She was commenced on fondaparinux and intravenous immunoglobulins. The following day she developed an asymmetric quadriplegia and aphasia. CT angiogram demonstrated new bilateral cervical internal carotid artery (ICA) thrombi. She underwent stent-retriever mechanical thrombectomy of bilateral ICA and cerebral venous sinuses. Next day she had right hemiparesis and expressive dysphasia, which are improving. Thromboses due to VITT can progress rapidly to involve cerebral arteries and venous sinuses, and may warrant urgent arterial and venous thrombectomy to reduce morbidity and mortality.

Single-dose SARS-CoV-2 vaccinations with either BNT162b2 or AZD1222 induce disparate Th1 responses and IgA production. BACKGROUND: While vaccination programs against the severe acute respiratory syndrome virus 2 (SARS-CoV-2) are globally ongoing, disparate strategies for the deployment of spike antigen show varying effectiveness. METHODS: In order to explore this phenomenon, we sought to compare the early immune responses against AZD1222 and BNT162b2. SARS-CoV-2 seronegative participants received a single dose of either vaccine and were analyzed for immune cell, effector T cell, and antibody dynamics. RESULTS: AZD1222 induced transient leukopenia and major changes among innate and adaptive subpopulations. Both vaccines induced spike protein-specific effector T cells which were dominated by type 1 helper T cell responses following AZD1222 vaccination. A significant reduction of anti-inflammatory T cells upon re-stimulation was also restricted to AZD1222 vaccinees. While IgM and IgG were the dominant isotypes elicited by AZD1222, BNT162b2 led to a significant production of IgG and IgA. CONCLUSIONS: Our results suggest that the strategy for spike protein delivery impacts on how and to what extent immune priming against the main SARS-CoV-2 antigen proceeds.

SARS-CoV-2 vaccination does not induce relapses of patients with inflammatory bowel disease. BACKGROUND: Vaccination against SARS-CoV-2 is a promising strategy to protect

immunocompromised IBD patients from a severe course of COVID-19. As these patients were excluded from initial clinical vaccination trials, patients frequently express concerns regarding the safety of these vaccines, especially whether vaccination might trigger IBD flares ("hit-and-run-hypothesis"). METHODS: In order to assess the risk of an IBD flare after vaccination against SARS-CoV-2, an anonymous survey was performed at five German IBD centers and one patient organization (Deutsche Morbus Crohn/Colitis ulcerosa Vereinigung (DCCV) e.V.) in August and October 2021. RESULTS: The questionnaire was answered by 914 patients, 781 of whom reported a previous vaccination against SARS-CoV-2 (85.4%). Vaccination against SARS-CoV-2 was not associated with an increased risk of IBD flares (p=0.319) or unscheduled visits to the IBD physician (p=0.848). Furthermore, typical symptoms of an IBD flare including abdominal pain, increases in stool frequency, or rectal bleeding were not influenced by the vaccination. CONCLUSION: Vaccination against SARS-CoV-2 is safe in IBD patients. These results may help to reduce fears regarding the vaccination in IBD patients. Our results can help to reduce fears in IBD patients regarding the SARS-CoV-2 vaccine. A close communication between patients and physicians before and after the vaccination may be beneficial.

New-onset Adult-onset Still's disease-like syndrome after ChAdOx1 nCoV-19 vaccination-a case series with review of literature. We report a series of 3 Adult-onset Still's disease (AOSD)-like presentations in previously healthy females following vaccination with the ChAdOx1 nCoV-19 vaccine, and also compare them with similar cases reported in literature through a PubMed database search. Our first patient had a high spiking bi-quotidian type of fever with myalgia, sore throat, and arthritis with onset 10-day post-vaccination, with laboratory features of hyper inflammation responding to only naproxen. She was off treatment after 2Â months. The second patient, with onset 3-week post-vaccination, had a more severe illness, requiring high dose immunosuppression. In our third case, the onset of illness was slightly delayed i.e., 3-month post-vaccination, but she had the most severe disease with macrophage activation syndrome at presentation requiring immunosuppression and biologicals. The underlying mechanism may be linked to the activation of Toll-like receptors (TLR)-TLR-7 and TLR-9-leading to a robust immune response. These 3 cases highlight the immunogenicity of COVID-19 vaccines, with the possibility of occurrence of new-onset systemic hyper-inflammation illness which can happen a few days following the vaccination, sometimes even delayed to months, and can range in severity from mild to even life-threatening. More cases need to be studied to understand the profile and prognosis of these syndromes in the long run.

Frequency of Adverse Events in the Placebo Arms of COVID-19 Vaccine Trials: A Systematic Review and Meta-analysis. IMPORTANCE: Adverse events (AEs) after placebo treatment are common in randomized clinical drug trials. Systematic evidence regarding these nocebo responses in vaccine trials is important for COVID-19 vaccination worldwide especially because concern about AEs is reported to be a reason for vaccination hesitancy. OBJECTIVE: To compare the frequencies of AEs reported in the placebo groups of COVID-19 vaccine trials with those reported in the vaccine groups. DATA SOURCES: For this systematic review and meta-analysis, the Medline (PubMed) and Cochrane Central Register of Controlled Trials (CENTRAL) databases were searched systematically using medical subheading terms and free-text keywords for trials of COVID-19 vaccines published up to July 14, 2021. STUDY SELECTION: Randomized clinical trials of COVID-19 vaccines that investigated adults aged 16 years or older were selected if they assessed solicited AEs within 7 days of injection, included an inert placebo arm, and provided AE reports for both the vaccine and placebo groups separately. Full texts were reviewed for eligibility by 2 independent reviewers. DATA EXTRACTION AND SYNTHESIS: Data extraction and quality assessment were performed independently by 2 reviewers, adhering to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guideline and using the Cochrane risk-of-bias tool. Meta-analyses were based on random-effects

models. MAIN OUTCOMES AND MEASURES: The primary outcomes were the proportions of placebo recipients reporting overall, systemic, and local (injection-site) AEs as well as logarithmic odds ratios (ORs) to evaluate group differences. Outcomes were tested for significance using z tests with 95% CIs. RESULTS: Twelve articles with AE reports for 45â€¯380 participants (22â€¯578 placebo recipients and 22â€¯802 vaccine recipients) were analyzed. After the first dose, 35.2% (95% CI, 26.7%-43.7%) of placebo recipients experienced systemic AEs, with headache (19.3%; 95% CI, 13.6%-25.1%) and fatigue (16.7%; 95% CI, 9.8%-23.6%) being most common. After the second dose, 31.8% (95% CI, 28.7%-35.0%) of placebo recipients reported systemic AEs. The ratio between placebo and vaccine arms showed that nocebo responses accounted for 76.0% of systemic AEs after the first COVID-19 vaccine dose and for 51.8% after the second dose. Significantly more vaccine recipients reported AEs, but the group difference for systemic AEs was small after the first dose (OR, -0.47; 95% CI, -0.54 to -0.40; Pâ€‰<â€‰.001; standardized mean difference, -0.26; 95% CI, -0.30 to -0.22) and large after the second dose (OR, -1.36; 95% CI, -1.86 to -0.86; Pâ€‰<â€‰.001; standardized mean difference, -0.75; 95% CI, -1.03 to -0.47). CONCLUSIONS AND RELEVANCE: In this systematic review and meta-analysis, significantly more AEs were reported in vaccine groups compared with placebo groups, but the rates of reported AEs in the placebo arms were still substantial. Public vaccination programs should consider these high rates of AEs in placebo arms.

Early non-neutralizing, afucosylated antibody responses are associated with COVID-19 severity. A damaging inflammatory response is implicated in the pathogenesis of severe coronavirus disease 2019 (COVID-19), but mechanisms contributing to this response are unclear. In two prospective cohorts, early non-neutralizing, afucosylated immunoglobulin G (IgG) antibodies specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) were associated with progression from mild to more severe COVID-19. To study the biology of afucosylated IgG immune complexes, we developed an in vivo model that revealed that human IgG-Fc-gamma receptor (FcÎ³R) interactions could regulate inflammation in the lung. Afucosylated IgG immune complexes isolated from patients with COVID-19 induced inflammatory cytokine production and robust infiltration of the lung by immune cells. In contrast to the antibody structures that were associated with disease progression, antibodies that were elicited by messenger RNA SARS-CoV-2 vaccines were highly fucosylated and enriched in sialylation, both modifications that reduce the inflammatory potential of IgG. Vaccine-elicited IgG did not promote an inflammatory lung response. These results show that human IgG-FcÎ³R interactions regulate inflammation in the lung and define distinct lung activities mediated by the IgG that are associated with protection against, or progression to, severe COVID-19.

AMA-positive hepatitis induced by the SARS-CoV-2 vaccine. We present the case of a 56-year-old female admitted to our centre for hepatitis. She had recieved the first dose of the BNT162b2 vaccine against SARS-CoV-2 10 days before the admission. Etiologic study was negative. The patient was diagnosed with vaccine-induced hepatitis.

Analyses of Confirmed COVID-19 Cases Among Korean Military Personnel After Mass Vaccination. BACKGROUND: The military was one of the first groups in Korea to complete mass vaccination against the coronavirus disease 2019 (COVID-19) due to their high vulnerability to COVID-19. To confirm the effect of mass vaccination, this study analyzed the patterns of confirmed cases within Korean military units. METHODS: From August 1 to September 15, 2021, all epidemiological data regarding confirmed COVID-19 cases in military units were reviewed. The number of confirmed cases in the units that were believed to have achieved herd immunity (i.e., â‰¥ 70% vaccination) was compared with the number of cases in the units that were not believed to have reached herd immunity (< 70% vaccination). Additionally, trends in the incidence rates of COVID-19 in the military and the entire Korean population were compared. RESULTS: By August 2021, 85.60% of military personnel were fully vaccinated. During the study period, a total of 174 COVID-19 cases were confirmed in the 39 units.

More local transmission (herd immunity group vs. non-herd immunity group [%], 1 [0.91] vs. 39 [60.94]) and hospitalizations (12 [11.01] vs. 13 [27.08]) occurred in the units that were not believed to have achieved herd immunity. The percentage of fully vaccinated individuals among the confirmed COVID-19 cases increased over time, possibly due to the prevalence of the delta variant. Nevertheless, the incidence rate remained lower in military units than in the general Korean population. CONCLUSION: After completing mass vaccination, the incidence rates of COVID-19 infection in the military were lower than those in the national population. New cluster infections did not occur in vaccinated units, thereby suggesting that herd immunity has been achieved in these military units. Further research is needed to determine the extent to which levels of non-pharmacological intervention can be reduced in the future.

Attenuated response to fourth dose SARS-CoV-2 vaccination in patients with autoimmune disease: a case series.

Investigating the association between COVID-19 vaccination and care home outbreak frequency and duration. OBJECTIVES: At the end of 2020, many countries commenced a vaccination programme against SARS-CoV-2. Public health authorities aim to prevent and interrupt outbreaks of infectious disease in social care settings. We aimed to investigate the association between the introduction of the vaccination programme and the frequency and duration of COVID-19 outbreaks in Northern Ireland (NI). STUDY DESIGN: We undertook an ecological study using routinely available national data. METHODS: We used Poisson regression to measure the relationship between the number of RT-PCR confirmed COVID-19 outbreaks in care homes, and as a measure of community COVID-19 prevalence, the Office for National Statistics COVID-19 Infection Survey estimated the number of people testing positive for COVID-19 in NI. We estimated the change in this relationship and estimated the expected number of care home outbreaks in the absence of the vaccination programme. A Cox proportional hazards model estimated the hazard ratio of a confirmed COVID-19 care home outbreak closure. RESULTS: Care home outbreaks reduced by two-thirds compared to expected following the introduction of the vaccination programme, from a projected 1625 COVID-19 outbreaks (95% prediction interval 1553-1694) between 7 December 2020 and 28 October 2021 to an observed 501. We estimated an adjusted hazard ratio of 2.53 of the outbreak closure assuming a 21-day lag for immunity. CONCLUSIONS: These findings describe the association of the vaccination with a reduction in outbreak frequency and duration across NI care homes. This indicates probable reduced harm and disruption from COVID-19 in social care settings following vaccination. Future research using individual level data from care home residents will be needed to investigate the effectiveness of the vaccines and the duration of their effects.

Case Series of Thrombosis With Thrombocytopenia Syndrome After COVID-19 Vaccination-United States, December 2020 to August 2021. BACKGROUND: Thrombosis with thrombocytopenia syndrome (TTS) is a potentially life-threatening condition associated with adenoviral-vectored COVID-19 vaccination. It presents similarly to spontaneous heparin-induced thrombocytopenia. Twelve cases of cerebral venous sinus thrombosis after vaccination with the Ad26.COV2.S COVID-19 vaccine (Janssen/Johnson & Johnson) have previously been described. OBJECTIVE: To describe surveillance data and reporting rates of all reported TTS cases after COVID-19 vaccination in the United States. DESIGN: Case series. SETTING: United States. PATIENTS: Case patients receiving a COVID-19 vaccine from 14 December 2020 through 31 August 2021 with thrombocytopenia and thrombosis (excluding isolated ischemic stroke or myocardial infarction) reported to the Vaccine Adverse Event Reporting System. If thrombosis was only in an extremity vein or pulmonary embolism, a positive enzyme-linked immunosorbent assay for antiplatelet factor 4 antibodies or functional heparin-induced thrombocytopenia platelet test result was required. MEASUREMENTS: Reporting rates (cases per million vaccine doses) and descriptive epidemiology. RESULTS: A total of 57 TTS cases were confirmed

after vaccination with Ad26.COV2.S (nÂ = 54) or a messenger RNA (mRNA)-based COVID-19 vaccine (nÂ = 3). Reporting rates for TTS were 3.83 per million vaccine doses (Ad26.COV2.S) and 0.00855 per million vaccine doses (mRNA-based COVID-19 vaccines). The median age of patients with TTS after Ad26.COV2.S vaccination was 44.5 years (range, 18 to 70 years), and 69% of patients were women. Of the TTS cases after mRNA-based COVID-19 vaccination, 2 occurred in men older than 50 years and 1 in a woman aged 50 to 59 years. All cases after Ad26.COV2.S vaccination involved hospitalization, including 36 (67%) with intensive care unit admission. Outcomes of hospitalizations after Ad26.COV2.S vaccination included death (15%), discharge to postacute care (17%), and discharge home (68%). LIMITATIONS: Underreporting and incomplete case follow-up. CONCLUSION: Thrombosis with thrombocytopenia syndrome is a rare but serious adverse event associated with Ad26.COV2.S vaccination. The different demographic characteristics of the 3 cases reported after mRNA-based COVID-19 vaccines and the much lower reporting rate suggest that these cases represent a background rate. PRIMARY FUNDING SOURCE: Centers for Disease Control and Prevention.
The Epidemiology of Thrombosis With Thrombocytopenia Syndrome: Analogies With Heparin-Induced Thrombocytopenia. In their article, See and colleagues reported a study of thrombosis with thrombocytopenia syndrome (TTS), also known as vaccine-induced immune thrombotic thrombocytopenia (VITT), a rare complication associated with receipt of the adenoviral-vectored COVID-19 vaccines ChAdOx1 nCoV-19 (Oxford/AstraZeneca) and Ad26.COV2.S (Janssen/Johnson & Johnson). The editorialists discuss the similarities of TTS with spontaneous heparin-induced thrombocytopenia.
Atrial fibrillation as a precursor of mRNA-1273 SARS-CoV-2 vaccine-induced pericarditis.
Skin adverse reactions to Sars-CoV-2 vaccination: a relevant responsibility issue for dermatologists.
Sweet syndrome after severe acute respiratory syndrome coronavirus 2 mRNA vaccine: A case report and literature review.
Radiation recall phenomenon after administration of the mRNA-1273 SARS-CoV-2 vaccine. Several types of SARS-CoV-2 vaccine have been developed. However, the relationship between SARS-CoV-2 vaccine and radiation therapy (RT) is unclear. Recently, there have been some reports of radiation recall phenomenon (RRP) caused by a SARS-CoV-2 vaccine. We report a case of RRP after administration of the mRNA-1273 SARS-CoV-2 vaccine. A 51-year-old female was diagnosed with breast cancer (cT4N1M0, cStage IIIB) and underwent breast total mastectomy with axillary lymph node dissection after neoadjuvant chemotherapy. After mastectomy, the patient received RT with 50Â Gy in 25 fractions. An acute side effect of grade 2 dermatitis according to the National Cancer Institute Common Terminology Criteria for Adverse Events version 4.0. occurred after RT. The patient had not started any new systemic medication after RT; however, the patient received the mRNA-1273 SARS-CoV-2 vaccine (Moderna) 1Â month after the end of the initial RT. Seven days after vaccination, the patient had a skin reaction with burning sensation and redness. This skin reaction was induced in an area corresponding to the irradiation field of the chest wall. There was no skin reaction in areas other than that described. The reaction was cured within 1Â week with topical hydrocortisone. This report is an interesting case report with a RPP after administration of the mRNA-1273 SARS-CoV-2 vaccine.
Chronic Spontaneous Urticaria Triggered by the AstraZeneca/Oxford COVID-19 Vaccine with Achieved Remission: A Case Report. New adverse reactions to the COVID-19 vaccines are being identified as vaccination rates increase worldwide. Recently, there have been two reports of Moderna (mRNA-1273) vaccine induced relapse of chronic spontaneous urticaria (CSU) that was previously well controlled. Herein, we report a case of AstraZeneca/Oxford (ChAdOx1) vaccine triggered CSU in a patient with no history of CSU with achieved remission.

Whole-blood cytokine secretion assay as a high-throughput alternative for assessing the cell-mediated immunity profile after two doses of an adjuvanted SARS-CoV-2 recombinant protein vaccine candidate. OBJECTIVES: We previously described the Phase I-II evaluation of SARS-CoV-2 recombinant protein candidate vaccine, CoV2-PreS-dTM, with AF03- or AS03-adjuvant systems (ClinicalTrials.gov, NCT04537208). Here, we further characterise the cellular immunogenicity profile of this vaccine candidate using a whole-blood secretion assay in parallel to intracellular cytokine staining (ICS) of cryopreserved peripheral blood mononuclear cells (PBMCs). METHODS: A randomly allocated subset of 90 healthy, SARS-CoV-2-seronegative adults aged â‰¥ 18â€‰years who had received (random allocation) one or two separate injections (on study day [D]1 and D22) of saline placebo or CoV2-PreS-dTM formulated with AS03 or AF03 were included. Cytokine secretion was assessed using a TruCulture(Â®) whole-blood stimulation system in combination with multiplex bead array, and intracellular cytokine profiles were evaluated on thawed PBMCs following exâ€‰vivo stimulation with recombinant S protein at pre-vaccination (D1), post-dose 1 (D22) and post-dose 2 (D36). RESULTS: Both methods detected similar vaccine-induced responses after the first and second doses. We observed a Th1 bias (Th1/Th2 ratioâ€‰>â€‰1.0) for most treatment groups when analysed in whole blood, mainly characterised by increased IFN-Î³, IL-2 and TNF-Î± secretion. Among participants agedâ€‰â‰¥â€‰50â€‰years, the Th1/Th2 ratio was higher for those who received vaccine candidate with AS03 versus AF03 adjuvant. ICS revealed that this higher Th1/Th2 ratio resulted from higher levels of IFN-Î³ expression and that the vaccine induced polyfunctional CD4(+) T cells. CONCLUSIONS: The whole-blood cytokine secretion assay is a high-throughput alternative for assessing the quantity and character of vaccine-induced cellular responses.

Adult-onset nephrotic syndrome following coronavirus disease vaccination. A 22-year-old healthy man was admitted for oedema 15 days after the first injection of the COVISHIELD coronavirus disease 2019 (COVID-19) vaccine (Oxford AstraZeneca) vaccine. Nephrotic syndrome was diagnosed and a kidney biopsy showed minimal change disease. Oral prednisolone was started at 1 mg/kg/day resulting in complete remission within 1 week.

Acute axillary lymphadenopathy detected shortly after COVID-19 vaccination found to be due to newly diagnosed metastatic melanoma. As the administration of COVID-19 vaccines continues to increase, so too does awareness of the associated ipsilateral axillary lymphadenopathy. This has created a diagnostic challenge in the field of radiology, in particular among patients with cancer, as post-vaccination reactive adenopathy has been reported to be mistakenly interpreted as malignancy. As radiology departments improve their protocols for obtaining vaccine-related patient history, and radiologists become acclimated to attributing axillary lymphadenopathy to recent COVID-19 vaccination, there is a risk of the pendulum swinging too far and under-diagnosing true oncologic disease. This report describes an otherwise healthy 53-year-old man who presented with discomfort due to ipsilateral axillary lymphadenopathy shortly after receiving a COVID-19 vaccine. Fine needle aspiration performed within 2 months of receiving the vaccine revealed metastatic melanoma and subsequent (18)F-FDG PET/CT demonstrated intensely avid axillary and supraclavicular adenopathy without visualization of a primary lesion. This case serves as a cautionary report to remind clinicians to remain suspicious of possible underlying malignancy with the presence of axillary adenopathy, despite a history of recent COVID-19 vaccination.

Silent thyroiditis following vaccination against COVID-19: report of two cases. PURPOSE: It is well established that thyroiditis and other thyroid disorders can be induced by COVID-19 infection, but there is limited information about the autoimmune/inflammatory syndrome induced by adjuvants (ASIA) after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. We report two cases of thyrotoxicosis following SARS-CoV-2 vaccine. METHODS AND RESULTS: Two young health care peoples (wife and husband) received a first dose of SARS-CoV-2 vaccine, and few weeks

later developed clinical manifestations of thyroid hyperactivity, with increased thyroid hormone levels on thyroid function tests, suppressed thyroid-stimulating hormone and negative antithyroid antibodies, despite being healthy before vaccination. They were diagnosed at the 4th week after first dose of SARS-Cov-2 vaccine as silent thyroiditis and followed without treatment, since their symptoms were not severe. At the 6th week, the patients became wholly asymptomatic and their thyroid function returned to normal. CONCLUSIONS: Thyrotoxicosis can occur after SARS-CoV-2 vaccination probably related to silent thyroiditis.

Safety Profile and Low Risk of Disease Relapse After BNT162b2 mRNA SARS-CoV-2 Vaccination in Patients With Rare Rheumatic Diseases.

First Report of Cerebral Venous Thrombosis Following Inactivated-Virus Covid Vaccination (Sinopharm and Sinovac). Cerebral venous thrombosis (CVT) is an uncommon cerebrovascular disease, which has been reported with covid infection as well as covid vaccines, particularly AstraZeneca and Janssen vaccines. We present four consecutive cases of CVT after receiving either Sinopharm or Sinovac vaccine, both of which are composed of an inactivated-virus. All the patients recovered well with anticoagulation and discharged with a good functional outcome. This is the first case series reporting CVT following the administration of these vaccines.

Immune Thrombotic Thrombocytopenic Purpura following Pfizer-BioNTech anti-COVID-19 vaccination in a patient healed from lymphoma after allogeneic hematopoietic stem cell transplantation.

Fingolimod impairs inactivated vaccine (CoronaVac)-induced antibody response to SARS-CoV-2 spike protein in persons with multiple sclerosis. BACKGROUND: The impact of disease-modifying treatments on humoral response induced by inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines is understudied. METHODS: We recruited 34 persons with multiple sclerosis (MS) under fingolimod treatment and 25 healthy individuals. Anti-SARS-CoV-2 spike IgG indices were measured by ELISA in sera of participants after CoronaVac vaccinations. RESULTS: Persons with MS displayed significantly lower antibody levels and seropositivity prevalence. Persons with MS with longer fingolimod treatment durations displayed lower anti-SARS-CoV-2 indices. CONCLUSION: Our results support previous findings regarding humoral response impairing effect of fingolimod after vaccinations. Patients under fingolimod treatment may require closer monitoring for COVID-19.

Young age, female sex, and presence of systemic adverse reactions are associated with high post-vaccination antibody titer after two doses of BNT162b2 mRNA SARS-CoV-2 vaccination: An observational study of 646 Japanese healthcare workers and university staff. BACKGROUND: SARS-CoV-2 vaccination has started worldwide, including Japan. Although high rates of vaccine response and adverse reactions of BNT162b2 vaccine have been reported, knowledge about the relationship between sex differences and antibody response is limited. Furthermore, it is uncertain whether adverse reactions are associated with the vaccine response. METHODS: This prospective observational study included 673 Japanese participants working in a medical school and its affiliated hospital in Tokyo, Japan (UMIN000043340). Serum samples were collected before the first dose and three weeks after the second dose of BNT162b2 vaccine, and antibody titers against the receptor-binding domain of the spike protein of SARS-CoV-2 were measured. Answers to questionnaires about background characteristics and adverse reactions were obtained at the time of sample collection, and the relationship between antibody titers was analyzed. RESULTS: After excluding participants who did not complete receiving two doses of vaccination or two series of serum sample collection, 646 participants were analyzed. Although all participants became sero-positive after vaccination, antibody titers were highly variable among individuals (260.9-57,399.7A U/mL), with a median titer of 13478.0AU/mL. Mean titer was higher in females than in males and higher in young (â‰¤45â€¯years old) participants than in aged (>45â€¯years old) participants. Participants who experienced adverse

reactions demonstrated a higher antibody titer after vaccination than those without adverse reactions. Multivariable analysis demonstrated that young age, female sex, and adverse reactions after the second dose were independently related to higher antibody titers after the second dose. DISCUSSION: A favorable antibody response was observed after two doses of BNT162b2 vaccination among mostly healthy Japanese participants, especially among female and young participants. Although further investigation is essential, our results imply that the systemic adverse reactions (i.e., fever and general fatigue) are associated with a higher antibody response that indicates the acquisition of humoral immunity.

Sinopharm COVID-19 vaccine-induced Stevens-Johnson syndrome.

Determinants of early antibody responses to COVID-19 mRNA vaccines in a cohort of exposed and naÃ¯ve healthcare workers. BACKGROUND: Two doses of mRNA vaccination have shown >94% efficacy at preventing COVID-19 mostly in naÃ¯ve adults, but it is not clear if the second dose is needed to maximize effectiveness in those previously exposed to SARS-CoV-2 and what other factors affect responsiveness. METHODS: We measured IgA, IgG and IgM levels against SARS-CoV-2 spike (S) and nucleocapsid (N) antigens from the wild-type and S from the Alpha, Beta and Gamma variants of concern, after BNT162b2 (Pfizer/BioNTech) or mRNA-1273 (Moderna) vaccination in a cohort of health care workers (N=578). Neutralizing capacity and antibody avidity were evaluated. Data were analyzed in relation to COVID-19 history, comorbidities, vaccine doses, brand and adverse events. FINDINGS: Vaccination induced robust IgA and IgG levels against all S antigens. Neutralization capacity and S IgA and IgG levels were higher in mRNA-1273 vaccinees, previously SARS-CoV-2 exposed, particularly if symptomatic, and in those experiencing systemic adverse effects (p<0Â·05). A second dose in pre-exposed did not increase antibody levels. Smoking and comorbidities were associated with 43% (95% CI, 19-59) and 45% (95% CI, 63-18) lower neutralization, respectively, and 35% (95% CI, 3-57%) and 55% (95% CI, 33-70%) lower antibody levels, respectively. Among fully vaccinated, 6Â·3% breakthroughs were detected up to 189 days post-vaccination. Among pre-exposed non-vaccinated, 90% were IgG seropositive more than 300 days post-infection. INTERPRETATION: Our data support administering a single-dose in pre-exposed healthy individuals as primary vaccination. However, heterogeneity of responses suggests that personalized recommendations may be necessary depending on COVID-19 history and life-style. Higher mRNA-1273 immunogenicity would be beneficial for those expected to respond worse to vaccination and in face of variants that escape immunity such as Omicron. Persistence of antibody levels in pre-exposed unvaccinated indicates maintenance of immunity up to one year. FUNDING: This work was supported by Institut de Salut Global de Barcelona (ISGlobal) internal funds, in-kind contributions from Hospital ClÃ-nic de Barcelona, the FundaciÃ³ Privada Daniel Bravo Andreu, and European Institute of Innovation and Technology (EIT) Health (grant number 20877), supported by the European Institute of Innovation and Technology, a body of the European Union receiving support from the H2020 Research and Innovation Programme. We acknowledge support from the Spanish Ministry of Science and Innovation and State Research Agency through the "Centro de Excelencia Severo Ochoa 2019-2023" Program (CEX2018-000806-S), and support from the Generalitat de Catalunya through the CERCA Program. L. I. work was supported by PID2019-110810RB-I00 grant from the Spanish Ministry of Science & Innovation. Development of SARS-CoV-2 reagents was partially supported by the National Institute of Allergy and Infectious Diseases Centers of Excellence for Influenza Research and Surveillance (contract number HHSN272201400008C). The funders had no role in study design, data collection and analysis, the decision to publish, or the preparation of the manuscript.

Comparison of SARS-CoV-2 antibody response after two doses of mRNA and inactivated vaccines in multiple sclerosis patients treated with disease-modifying therapies. BACKGROUND: Disease-modifying therapy could weaken the immune system and decrease the immune response to vaccines.

It is essential to know which vaccine is more protective against SARS-CoV-2 in the multiple sclerosis population. OBJECTIVE: To assess immune response after messenger RNA BNT162b2 (Pfizer/BioNTech) and inactivated Sinovac vaccines in people with multiple sclerosis (pwMS) treated with a disease-modifying therapy (DMT) compared to healthy controls. METHODS: This single-center cross-sectional study included 526 MS patients treated with DMT, 44 healthy controls, and 21 untreated patients with MS between May 2021 and September 2021. Serum samples were collected at least two weeks after the second dose of the vaccine. RESULTS: Participants vaccinated with BNT162b2 had a higher antibody titer than the Sinovac group (95%CI=1.023 - 1.473; p< .001). No significant difference between antibody titer of pwMS without treatment and HC was found [95%CI= -0.882; - 0.935 p > .99]. In 65 adults without DMT use (HC+pwMSwithout treatment), no seronegative cases were observed in any vaccine group. In patients treated with DMT, BNT162b2 was associated with a 16.3% greater absolute risk of seropositivity than Sinovac. CONCLUSION: The mRNA vaccine could be a preferred choice of protection against SARS-CoV-2 in pMS treated with DMT.

Impaired seroconversion after SARS-CoV-2 mRNA vaccines in patients with solid tumours receiving anticancer treatment. BACKGROUND: Patients with solid tumours have high COVID-19 mortality. Limited and heterogeneous data are available regarding the immunogenicity of SARS-CoV-2 mRNA vaccines in this population. METHODS AND FINDINGS: This is a prospective, single-centreÂ cohort study aiming at evaluating seroconversion in terms of anti-spike antibodies in a population of patients with solid tumours undergoing cancer therapy within 2 months before the second vaccine dose, as compared with a cohort of controls. Subjects who were not SARS-CoV-2 naÃ¯ve were excluded, and 171 patients were included in the final study population (150 vaccinated with BNT162b2, 87.7%; 21 with mRNA-1273, 12.3%) and compared with 2406 controls. The median follow-up time from the second dose of vaccination was 30 days (12-42; IQR: 26-34). Most patients had metastatic disease (138, 80.7%). Seroconversion rate was significantly lower in cancer patients than in controls (94.2% versus 99.8%, pÂ <Â 0.001). At univariate logistic regression analysis, Odds ratio (OR) for seroconversion was also reduced in older individuals (>70 years). A multivariate logistic model confirmed cancer as the only significant variable in impairing seroconversion (OR 0.03, pÂ <Â 0.001). In the cancer population, a multivariate analysis among clinical variables, including the type of cancer treatment, showed ECOG PSÂ >Â 2 as the only one of impact (OR 0.07, pÂ =Â 0.012). CONCLUSIONS: There is a fraction of 6% of patients with solid tumours undergoing cancer treatment, mainly with poorer performance status, who fail to obtain seroconversion after SARS-CoV-2 mRNA vaccines. These patients should be considered for enhanced vaccination strategies and carefully monitored for SARS-CoV-2 infection during cancer treatment.

Painless thyroiditis following mRNA vaccination for COVID-19.

Preliminary nonclinical safety and immunogenicity of an rVSV-Î”G-SARS-CoV-2-S vaccine in mice, hamsters, rabbits and pigs. rVSV-Î”G-SARS-CoV-2-S is a clinical stage (Phase 2) replication competent recombinant vaccine against SARS-CoV-2. To evaluate the safety profile of the vaccine, a series of non-clinical safety, immunogenicity and efficacy studies were conducted in four animal species, using multiple doses (up to 10(8) Plaque Forming Units/animal) and dosing regimens. There were no treatment-related mortalities or any noticeable clinical signs in any of the studies. Compared to unvaccinated controls, hematology and biochemistry parameters were unremarkable and no adverse histopathological findings. There was no detectable viral shedding in urine, nor viral RNA detected in whole blood or serum samples seven days post vaccination. The rVSV-Î”G-SARS-CoV-2-S vaccination gave rise to neutralizing antibodies, cellular immune responses, and increased lymphocytic cellularity in the spleen germinal centers and regional lymph nodes. No evidence for neurovirulence was found in C57BL/6 immune competent mice or in highly sensitive type I interferon knock-out mice. Vaccine virus replication and distribution in K18-human Angiotensin-converting

enzyme 2-transgenic mice showed a gradual clearance from the vaccination site with no vaccine virus recovered from the lungs. The nonclinical data suggest that the rVSV-Î”G-SARS-CoV-2-S vaccine is safe and immunogenic. These results supported the initiation of clinical trials, currently in Phase 2.
Morbilliform rashes as an unusual manifestation of vaccine-induced immune thrombotic thrombocytopenia.
Seroconversions After Withdrawal From Mycophenolate Mofetil in Solid Organ Transplant Recipients Without a Third Dose of BNT162b2 mRNA Coronavirus Disease 2019 Vaccine: A Case Series.
Multiple sclerosis therapies differentially affect SARS-CoV-2 vaccine-induced antibody and T cell immunity and function. BACKGROUNDVaccine-elicited adaptive immunity is a prerequisite for control of SARS-CoV-2 infection. Multiple sclerosis (MS) disease-modifying therapies (DMTs) differentially target humoral and cellular immunity. A comprehensive comparison of the effects of MS DMTs on SARS-CoV-2 vaccine-specific immunity is needed, including quantitative and functional B and T cell responses.METHODSSpike-specific Ab and T cell responses were measured before and following SARS-CoV-2 vaccination in a cohort of 80 study participants, including healthy controls and patients with MS in 6 DMT groups: untreated and treated with glatiramer acetate (GA), dimethyl fumarate (DMF), natalizumab (NTZ), sphingosine-1-phosphate (S1P) receptor modulators, and anti-CD20 mAbs. Anti-spike-Ab responses were assessed by Luminex assay, VirScan, and pseudovirus neutralization. Spike-specific CD4+ and CD8+ T cell responses were characterized by activation-induced marker and cytokine expression and tetramer.RESULTSAnti-spike IgG levels were similar between healthy control participants and patients with untreated MS and those receiving GA, DMF, or NTZ but were reduced in anti-CD20 mAb- and S1P-treated patients. Anti-spike seropositivity in anti-CD20 mAb-treated patients was correlated with CD19+ B cell levels and inversely correlated with cumulative treatment duration. Spike epitope reactivity and pseudovirus neutralization were reduced in anti-CD20 mAb- and S1P-treated patients. Spike-specific CD4+ and CD8+ T cell reactivity remained robust across all groups, except in S1P-treated patients, in whom postvaccine CD4+ T cell responses were attenuated.CONCLUSIONThese findings from a large cohort of patients with MS exposed to a wide spectrum of MS immunotherapies have important implications for treatment-specific COVID-19 clinical guidelines.FUNDINGNIH grants 1K08NS107619, K08NS096117, R01AI159260, R01NS092835, R01AI131624, and R21NS108159; NMSS grants TA-1903-33713 and RG1701-26628; Westridge Foundation; Chan Zuckerberg Biohub; Maisin Foundation.
Two cases of subacute thyroiditis after different types of SARS-CoV-2 vaccination. Although the development of subacute thyroiditis (SAT) following viral infections is well-documented, the actual mechanism has not been clearly elucidated. The occurrence of SAT after vaccination has been reported in several case series and possible mechanisms such as molecular mimicry due to the exposure to viral proteins and/or abnormal reactogenicity by adjuvants have been implicated. We describe two cases who developed SAT three days after the messenger RNA vaccine against COVID-19 (Pfizer-BioNTechÂ®) and six days after the inactivated COVID-19 vaccine (CoronaVacÂ®). SAT diagnosis of these patients was delayed for more than two weeks. When the current cases were evaluated together with 1 Pfizer-BioNTechÂ® and 3 CoronaVacÂ® related cases reported previously, the patients were female aged between 30-42, except for the male patient we presented, and the complaints of the patients initiated within the first 2-7 days. While two Pfizer-BioNTechÂ® vaccine-related cases were severely symptomatic and thyrotoxic at presentation, there were cases with mild to moderate clinical manifestations in CoronaVacÂ® vaccine-related group. Physicians should be aware of SAT that may occur within a few days following the COVID-19 vaccination.
[Multisegmental herpes zoster in aÂ healthy 20-year-old man after COVID-19 vaccination].
The impact of COVID-19 vaccination on patients with a history of heparin-induced thrombocytopenia.

Multiple evanescent white dot syndrome following vaccination for COVID-19: A case report. RATIONALE: Multiple evanescent white dot syndrome (MEWDS) is an acute, usually unilateral, retinal disorder of unknown etiology that predominantly occurs in healthy young women. We report a case of bilateral asymmetric MEWDS that developed following the first vaccination for coronavirus-19 and worsened after a second vaccination. PATIENT CONCERNS: A 30-year-old Japanese woman was examined in an eye clinic for blurred vision in her left eye for 1 week duration. Thirteen days before her examination, she had received her first BNT162b2 mRNA SARS-CoV-2 vaccination. Her best-corrected visual acuity was 20/20 in both eyes. Fundus examination revealed multiple yellowish-white spots in the perifoveal area of both eyes. Visibility of the spots gradually decreased during the following week. She was then vaccinated with a second dose, and 3 days later, her vision worsened in her left eye. She was then referred to our hospital because of worsened vision and the appearance of white spots on other parts of the retina. Ophthalmological examination revealed a best-corrected visual acuity of 30/20 both eyes. DIAGNOSIS: The flare value in the anterior chamber was elevated in both the eyes. Fundus examination showed multiple white spots in the perifoveal area of both eyes, but they were more prominent in the left eye. Fundus fluorescein angiography revealed early hyperfluorescent spots located circumferentially around the fovea in both eyes. We concluded that the patient had MEWDS, which was most likely due to mRNA COVID-19 immunization. INTERVENTIONS: The patient was treated with topical betamethasone sodium phosphate/fradiomycin sulfate 0.1% thrice daily for 2 months. OUTCOMES: Two months after treatment, her blurry vision resolved with the disappearance of the fundus lesions. LESSON: Clinicians should be aware of potential adverse ocular events following similar vaccinations.

Safety of the BNT162b2 mRNA COVID-19 vaccine in oncologic patients undergoing numerous cancer treatment options: A retrospective single-center study. The COVID-19 pandemic, caused by the SARS-CoV2 virus, has infected millions worldwide with cancer patients demonstrating a higher prevalence for severe disease and poorer outcomes. Recently, the BNT162b2 mRNA COVID-19 vaccine was released as the primary means to combat COVID-19. The currently reported incidence of local and systemic side effects was 27% in the general public. The safety of the BNT162b2 mRNA COVID-19 vaccine has not been studied in patients with an active cancer diagnosis who are either ongoing or plan to undergo oncologic therapy.This single center study reviewed the charts of 210 patients with active cancer diagnoses that received both doses of the BNT162b2 mRNA COVID-19 vaccine. The development of side effects from the vaccine, hospitalizations or exacerbations from various oncologic treatment were documented. Type of oncologic treatment (immunotherapy, chemotherapy, hormonal, biologic, radiation or mixed) was documented to identify if side effects were related to treatment type. The time at which the vaccine was administered in relation to treatment onset (on long term therapy, within 1 month of therapy or prior to therapy) was also documented to identify any relationships.Sixty five (31%) participants experienced side effects from the BNT162b2 mRNA COVID-19 vaccine, however most were mild to moderate. Treatment protocol was not linked to the development of vaccine related side effects (Pâ€Š=â€Š.202), nor was immunotherapy (Pâ€Š=â€Š.942). The timing of vaccine administered in relation to treatment onset was also not related to vaccine related side effects (Pâ€Š=â€Š.653). Six (2.9%) participants were hospitalized and 4 (2%) died.The incidence of side effects in cancer patients is similar to what has been reported for the general public (31% vs 27%). Therefore, we believe that the BNT162b2 mRNA COVID-19 vaccine is safe in oncologic patients undergoing numerous cancer treatments.

Acute pancreatitis soon after COVID-19 vaccination: A case report. RATIONALE: In response to the global coronavirus infectious disease 2019 (COVID-19) pandemic, several vaccines against severe acute respiratory syndrome coronavirus 2 have been developed. Although many infrequent side effects of COVID-19 mRNA vaccine have been reported, only a few cases of pancreatitis have been

reported. PATIENT CONCERNS: A 71-year-old woman was presented to the hospital with upper abdominal pain and vomiting. She had no history of alcohol consumption, pancreatitis, or allergic reactions to vaccines. She had received the first dose of the Pfizer/BioNTech COVID-19 mRNA vaccine 2 days prior to her current presentation. Laboratory tests revealed elevated serum pancreatic enzymes. An abdominal computed tomography scan showed diffuse enlargement of the pancreas with fat stranding extending to below the kidneys bilaterally. DIAGNOSIS: The patient was diagnosed with acute pancreatitis. INTERVENTIONS: The patient was treated with the administration of intravenous antimicrobials, proteolytic enzyme inhibitors, and proton pump inhibitors. OUTCOMES: The patient had an uneventful recovery with no complications. LESSONS: Acute pancreatitis can develop shortly after COVID-19 mRNA vaccination. Therefore, of great importance to differentiate acute pancreatitis when abdominal pain occurs after COVID-19 mRNA vaccination.
Cutaneous reactions due to Pfizer's BNT162b2 mRNA and Moderna's mRNA-1273 vaccines.
Allergists Can Safely Evaluate and Revaccinate Individuals With Immediate Allergic Reactions to mRNA COVID-19 Vaccines.
First Report of Acute Myocarditis Post-Pfizer-BioNTech COVID-19 Vaccination in the Kingdom of Bahrain. We present a case of a 24-year-old male patient who presented to our institution five days after receiving his first dose of Pfizer-BioNTech vaccine to rule out acute coronary syndrome due to chest pain along with troponin increase and ECG changes. Acute coronavirus disease 2019 (COVID-19) infection was excluded based on a negative real-time reverse transcription-polymerase chain reaction (RT-PCR) test of specimens acquired using nasopharyngeal swabs for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and all other viral serologies were found to be negative. Coronary angiogram showed normal coronaries, and the presence of late gadolinium enhancement, which is indicative of myocarditis, was identified using cardiac magnetic resonance imaging (MRI). Our case report raises concern that the COVID-19 vaccine may cause myocarditis as a rare side effect.
Post-COVID-19 Vaccine Parosmia: A Case Report. We present the case of a healthy 38-year-old male who developed parosmia following a second dose of AstraZeneca with a negative nasal swab of coronavirus disease 2019 (COVID-19) infection. The patient noted parosmia that started suddenly after one week of receiving the second dose of AstraZeneca with no association with other symptoms. The patient has still not recovered from hisÂ parosmia until the publication of this article. The olfactory disorder was confirmed using a validated questionnaire for parosmia assessment and examination by rhinoscopy. Parosmia is a rare side effect of COVID-19, and its pathophysiological mechanism is still unknown. More research in the future is needed to know the association of parosmia with COVID-19 vaccine.
Additional heterologous versus homologous booster vaccination in immunosuppressed patients without SARS-CoV-2 antibody seroconversion after primary mRNA vaccination: a randomised controlled trial. OBJECTIVES: SARS-CoV-2-induced COVID-19 has led to exponentially rising mortality, particularly in immunosuppressed patients, who inadequately respond to conventional COVID-19 vaccination. METHODS: In this blinded randomised clinical trial, we compare the efficacy and safety of an additional booster vaccination with a vector versus mRNA vaccine in non-seroconverted patients. We assigned 60 patients under rituximab treatment, who did not seroconvert after their primary mRNA vaccination with either BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna), to receive a third dose, either using the same mRNA or the vector vaccine ChAdOx1 nCoV-19 (Oxford-AstraZeneca). Patients were stratified according to the presence of peripheral B cells. The primary efficacy endpoint was the difference in the SARS-CoV-2 antibody seroconversion rate between vector (heterologous) and mRNA (homologous) vaccinated patients by week 4. Key secondary endpoints included the overall seroconversion and cellular immune response; safety was

assessed at week 1 and week 4. RESULTS: Seroconversion rates at week 4 were comparable between vector (6/27 patients, 22%) and mRNA (9/28, 32%) vaccines (p=0.6). Overall, 27% of patients seroconverted; specific T cell responses were observed in 20/20 (100%) vector versus 13/16 (81%) mRNA vaccinated patients. Newly induced humoral and/or cellular responses occurred in 9/11 (82%) patients. 3/37 (8%) of patients without and 12/18 (67%) of the patients with detectable peripheral B cells seroconverted. No serious adverse events, related to immunisation, were observed. CONCLUSIONS: This enhanced humoral and/or cellular immune response supports an additional booster vaccination in non-seroconverted patients irrespective of a heterologous or homologous vaccination regimen.

Waning antibody levels after COVID-19 vaccination with mRNA Comirnaty and inactivated CoronaVac vaccines in blood donors, Hong Kong, April 2020 to October 2021. The mRNA vaccine Comirnaty and the inactivated vaccine CoronaVac are both available in Hong Kong's COVID-19 vaccination programme. We observed waning antibody levels in 850 fully vaccinated (at least 14 days passed after second dose) blood donors using ELISA and surrogate virus neutralisation test. The Comirnaty-vaccinated group's (nâ€¯=â€¯593) antibody levels remained over the ELISA and sVNT positive cut-offs within the first 6 months. The CoronaVac-vaccinated group's (nâ€¯=â€¯257) median antibody levels began to fall below the cut-offs 4 months after vaccination.

Vaccine Liability in the Light of Covid-19: A Defence of Risk-Benefit. Vaccines have played an essential role in advancing medical treatment in the twentieth and twenty-first centuries. However, no medical intervention is risk free, and vaccines are no exception to that rule. This article considers how lawyers have confronted or eschewed risk-benefit in the context of determining defectiveness in vaccine liability, with emphasis on the UK, European Union, and US experiences. It explores the potential role that risk-benefit may play in assessing liability for vaccines against the COVID-19 pandemic. It argues that a holistic, flexible approach to determining defectiveness embracing risk-benefit allows consideration of the overwhelming public interest derived from the continued availability and supply of vaccines, as well as immunity conferring benefits on both the individual and the community. If cases do emerge concerning the liability of a COVID-19 vaccine, immunity conferring benefits on both the individual and the community of the COVID-19 vaccines should be relevant in any determination of defectiveness. Such a holistic, flexible approach to defectiveness embracing risk-benefit can be used effectively to determine the entitled safety of a vaccine and may help to mitigate against the dangers of weakening confidence in the public's vaccine uptake.

Advances and gaps in SARS-CoV-2 infection models. The global response to Coronavirus Disease 2019 (COVID-19) is now facing new challenges such as vaccine inequity and the emergence of SARS-CoV-2 variants of concern (VOCs). Preclinical models of disease, in particular animal models, are essential to investigate VOC pathogenesis, vaccine correlates of protection and postexposure therapies. Here, we provide an update from the World Health Organization (WHO) COVID-19 modeling expert group (WHO-COM) assembled by WHO, regarding advances in preclinical models. In particular, we discuss how animal model research is playing a key role to evaluate VOC virulence, transmission and immune escape, and how animal models are being refined to recapitulate COVID-19 demographic variables such as comorbidities and age.

Systemic Immune Response Syndrome After COVID-19 Immunization-Initial and Follow-up 18F-FDG PET/CT Imaging Appearances. A 46-year-old woman with previous history of breast cancer had follow-up 18F-FDG PET/CT 5 days after COVID-19 vaccination. In addition to avid axillary nodes, a well-documented feature, the scan demonstrated diffuse splenic and marrow uptake. Clinical history, laboratory, and scan findings were in keeping with SIRS (systemic inflammatory response). The patient recovered with supportive management. On follow-up, 18F-FDG PET/CT imaging 3 months later features had resolved. SIRS after vaccination may be observed on 18F-FDG PET/CT.

Alterations in 18F-FDG PET/MRI and 15O-Water PET Brain Findings in Patients With Neurological Symptoms After COVID-19 Vaccination: A Pilot Study. PURPOSE: This study aimed to investigate functional abnormalities in the brain of patients with neurological adverse effects following COVID-19 (coronavirus disease 2019) vaccination using 18F-FDG PET/MRI and 15O-water PET. METHODS: Eight patients (1 man and 7 women, aged 26-47 years [median age, 36.5 years]) who experienced neurological symptoms after the first COVID-19 vaccination underwent CT, MRI, 18F-FDG PET/MRI, and 15O-water PET of the brain. After 7 days, each patient underwent a follow-up 18F-FDG PET/MRI and 15O-water PET of the brain. Imaging data were analyzed using visual and semiquantitative analyses, which included a cluster subtraction workflow (P = 0.05). RESULTS: There was no evidence of vascular abnormalities, acute infarction, or hemorrhage on the CT or MRI scans. On the 15O-water PET images, 1 patient had mildly significant decreases in perfusion in the bilateral thalamus and bilateral cerebellum, and another patient showed a diffuse increase in perfusion in the cerebral white matter. The visual and semiquantitative analyses showed hypometabolism in the bilateral parietal lobes in all 8 patients on both the first and follow-up 18F-FDG PET/MRI scans. Metabolic changes in the bilateral cuneus were also observed during the first visit; all patients exhibited neurological symptoms. Moreover, 6 patients showed hypometabolism, and 2 patients showed hypermetabolism. CONCLUSION: All regions of metabolic abnormality were part of the fear network model that has been implicated in anxiety. Our study findings support the concepts of and provide evidence for the immunization stress-related response and the biopsychosocial model.

The Evaluation of Oxidative Stress in the Young Adults with COVID-19 mRNA Vaccines Induced Acute Pericarditis- Myopericarditis. BACKGROUND: During COVID-19 pandemic, several vaccines have been developed such as mRNA vaccines. However, acute pericarditis and myocarditis/myopericarditis cases have been described after mRNA vaccination. The mechanism for the development of cardiac involvement is unknown. Potential mechanism for oxidative stress associated with vaccine-induced heart involvement is unidentified. This study aimed to examine the role of oxidative stress and the heart involvement in young adults vaccinated with COVID-19 mRNA vaccines. METHODS: In this cross-sectional study, a total of 23 participants were included and 10 of these participants were asymptomatic patients (control group). Comparison of the cardiac involvement and control group was made by using troponin I, C-reactive protein (hsCRP), D-dimer levels, and oxidative stress tests including nitric oxide, and imaging techniques (ECG, echocardiography, cardiovascular magnetic resonance). RESULTS: The median age of acute pericarditis group (10 patients) was 22 years (Q1-Q3: 18.5-31), and the mean age was 24.4Â±7.5 years. The median age of myopericarditis group (3 patients) was 22 years (Q1-Q3 18.0-25.0), and the mean age was 21.6 Â±3.5 years. All the myopericarditis cases were male. The patients with myopericarditis had higher troponin I level, hsCRP, and D-dimer levels (troponin I level; 1600.00 ng/mL; D-dimer; 1.20 Î¼g/mL, hsCRP; 3.0 mg/L, respectively; $p < 0.05$). Serum nitric oxide levels and OSI (total oxidant status, H(2)O(2)/total antioxidant status) were lower in myopericarditis group than the control and acute pericarditis group ($p < 0.05$). This shows inflammatory and procoagulant state. CONCLUSION: Vaccine-induced myopericarditis cases are associated with oxidative stress test abnormality (abnormal NO, OSI levels). However, there is no relationship between NO levels and other oxidative stress tests difference in vaccine-induced acute pericarditis. It is thought that vaccine-induced pericarditis and myopericarditis could have different pathogenesis. This could make it necessary to reassess the second dose of vaccination for vaccine-induced cardiac involvement cases.

Subacute thyroiditis during the COVID-19 pandemic: a prospective study. PURPOSE: Subacute thyroiditis(SAT) is a destructive thyroiditis associated with viral infections. Several SAT cases associated with SARS-CoV-2 infection/vaccination were recently reported. We aimed to evaluate prospectively all cases applied to our tertiary center and their relationship with SARS-CoV-2 during

16Â months of the pandemic. Cases during similar pre-pandemic period were recorded for numeric comparison. METHODS: Prospective study took place between March 2020 and July 2021. SAT was diagnosed by classical criteria. Swabs for SARS-CoV-2 and a wide respiratory viral panel (RV-PCR) were taken. Previous COVID-19 was assessed by SARS-CoV-2 IgM&IgG levels. Study group was divided into three as: CoV-SAT, patients who had or still have COVID-19, Vac-SAT, patients diagnosed within three months after SARS-CoV-2 vaccination and NonCoV-SAT, those not associated with COVID-19 or vaccination. RESULTS: Out of 64 patients, 18.8% (nâ€‰=â€‰12) was classified as CoV-SAT, 9.3% (nâ€‰=â€‰6) as Vac-SAT and 71.9% as (nâ€‰=â€‰46) NonCoV-SAT. SARS-CoV-2 RT-PCR tests on the diagnosis of SAT were negative in all, but two patients tested positive five days later, in second testing, performed upon clinical necessity. CoV-SAT and NonCoV-SAT groups were similar in terms of clinical, laboratory, and treatment characteristics. However, symptoms were milder and treatment was easier in Vac-SAT group (pâ€‰=â€‰0.006). CONCLUSIONS: Total number of SAT cases during the pandemic period was comparable to pre-pandemic period. However, a considerable rate of SARS-CoV-2 exposure in SAT patients was established. COVID-19 presented with SAT, as the first manifestation in three cases. Vaccine-related cases developed in a shorter time period, clinical presentation was milder, and only a few required corticosteroids.

Arterial intracranial thrombosis as the first manifestation of vaccine-induced immune thrombotic thrombocytopenia (VITT): a case report. OBJECTIVE: We describe a severe case of vaccine-induced immune thrombotic thrombocytopenia (VITT) after the first dose of the ChAdOx1 nCoV-19 vaccine leading to massive ischemic stroke. METHODS: A 42-year-old woman developed acute left hemiparesis (NIHSS 12) 9Â days after the first vaccine dose. RESULTS: The blood tests revealed low platelets (70 10(3)/Î¼L) and severe increment of D-dimer (70,745Â ng/mL FEU). Brain non-contrast computed tomography and multiphasic CT angiography demonstrated a right middle cerebral artery occlusion. The patient was treated with primary thrombectomy, steroids, immunoglobulin, and fondaparinux. Despite the treatment, the neurological status deteriorated and underwent decompressive hemicraniectomy. She was transferred to the rehab's unit 52Â days after the onset. DISCUSSION: Healthcare providers should be aware of the possibility of ischemic stroke as a manifestation of VITT. Awareness on this very rare and possibly fatal complication should be reinforced on both the vaccine recipients and general practitioners.

[Immune thrombocytopenia after BNT162b2 mRNA COVID-19 vaccination]. A 95-year-old male developed general subcutaneous petechiae, tongue hematoma, and melena two days after receiving the second BNT162b2 mRNA COVID-19 vaccine. Two days later, his platelet count decreased to below 1,000/Âμl. Laboratory testing was positive for a slight increase in D-dimer, Helicobacter pylori (H. pylori) immunoglobulin G (IgG) antibody, lupus anticoagulant, and anticardiolipin IgG antibody levels. There were no severe infections or symptomatic thrombosis. Platelet transfusions were transiently effective. He was diagnosed with newly developed immune thrombocytopenia (ITP). We administered prednisolone (PSL) at 0.5 mg/kg/day and intravenous immunoglobulin (IVIG) at 0.4 g/kg/day. From the following day, his platelet count rapidly increased, with an improvement in bleeding tendency. H. pylori was eradicated after platelet count recovery. Thrombocytopenia did not relapse although PSL was tapered three months later. Causes of thrombocytopenia after SARS-CoV-2 vaccination include ITP, vaccine-induced immune thrombotic thrombocytopenia, and thrombotic thrombocytopenic purpura. Differential diagnosis is important to determine the proper therapy. Case reports of newly diagnosed ITP after SARS-CoV-2 vaccination have been increasing recently. In these cases, including ours, the responses to steroids and IVIG were good. Further follow-up studies are needed to manage thrombocytopenia following SARS-CoV-2 vaccination.

[Severe thrombocytopenia after COVID-19 mRNA vaccination]. The Japanese Society of Hematology recently published on acute exacerbation of immune-mediated thrombocytopenia (ITP)

after mRNA-based severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. In addition, there is a growing concern for the development of the newly diagnosed ITP after SARS-CoV-2 vaccination. Herein, we report two cases of severe thrombocytopenia associated with bleeding tendencies at 4 and 14 days after BNT162b2 mRNA vaccination. Platelet counts returned to normal following platelet transfusion or treatment with intravenous immunoglobulin and dexamethasone. To our knowledge at the time of the draft of this manuscript, nine cases of SARS-CoV-2 vaccine-induced ITP have been reported. Although most patients showed favorable clinical courses similar to that of our cases, critical thrombocytopenia can lead to unfavorable outcomes. A national survey may be required to examine the causal relationship between SARS-CoV-2 vaccination and the emergence of the newly diagnosed ITP and clinical outcomes of vaccine-induced thrombocytopenia.
Autoimmune Encephalitis as an Adverse Event of COVID-19 Vaccination.
SARS-CoV-2 vaccine responses following CD20-depletion treatment in patients with haematological and rheumatological disease: a West Midlands Research Consortium study. B-cell-depleting agents are among the most commonly used drugs to treat haemato-oncological and autoimmune diseases. They rapidly induce a state of peripheral B-cell aplasia with the potential to interfere with nascent vaccine responses, particularly to novel antigens. We have examined the relationship between B-cell reconstitution and SARS-CoV-2 vaccine responses in two cohorts of patients previously exposed to B-cell-depleting agents: a cohort of patients treated for haematological B-cell malignancy and another treated for rheumatological disease. B-cell depletion severely impairs vaccine responsiveness in the first 6 months after administration: SARS-CoV-2 antibody seroprevalence was 42.2% and 33.3% in the haemato-oncological patients and rheumatology patients, respectively and 22.7% in patients vaccinated while actively receiving anti-lymphoma chemotherapy. After the first 6 months, vaccine responsiveness significantly improved during early B-cell reconstitution; however, the kinetics of reconstitution was significantly faster in haemato-oncology patients. The AstraZeneca ChAdOx1 nCoV-19 vaccine and the Pfizer BioNTech 162b vaccine induced equivalent vaccine responses; however, shorter intervals between vaccine doses (<1 m) improved the magnitude of the antibody response in haeamto-oncology patients. In a subgroup of haemato-oncology patients, with historic exposure to B-cell-depleting agents (>36 m previously), vaccine non-responsiveness was independent of peripheral B-cell reconstitution. The findings have important implications for primary vaccination and booster vaccination strategies in individuals clinically vulnerable to SARS-CoV-2.
Can SARS-CoV-2 vaccinations induce auto-inflammatory diseases?
Epigastric Pain After COVID-19 Vaccination.
COVID-19: Testing Landscape Post-Infection, -Vaccination, and Future Perspectives. On March 11, 2020, the World Health Organization declared the coronavirus disease 2019 (COVID-19) outbreak a global pandemic. Although molecular testing remains the gold standard for COVID-19 diagnosis, serological testing enables the evaluation of the immune response to severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) infection and vaccination, and can be used to assess community viral spread. This review summarizes and analyzes the current landscape of SARS-CoV-2 testing in the United States and includes guidance on both when and why it is important to use direct pathogen detection and/or serological testing. The usefulness of monitoring humoral and cellular immune responses in infected and vaccinated patients is also addressed. Finally, this review considers current challenges, future perspectives for SARS-CoV-2 testing, and how diagnostics are being adapted as the virus evolves.
A Pilot Study for the Evaluation of an Interferon Gamma Release Assay (IGRA) To Measure T-Cell Immune Responses after SARS-CoV-2 Infection or Vaccination in a Unique Cloistered Cohort. Assessment of T-cell responses to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

antigens may be of value to determine long-lasting protection to breakthrough infections or reinfections. Interferon gamma release assay is a validated method to test cellular immunity in mycobacterial infections and has been proposed for patients with SARS-CoV-2 infection or vaccination. Quantitative IgG to spike and qualitative IgG to nucleocapsid antigens were determined by chemiluminescence microparticle immunoassay using the Architect platform (Abbott), and interferon gamma release assays against two Qiagen proprietary mixes of SARS-CoV-2 spike protein (antigen 1 and antigen 2) were performed for a selected group of subjects. A total of 121 subjects in a cloistered institution after a COVID-19 outbreak was studied. IgG spike levels and interferon gamma concentrations were highest among subjects after two doses of vaccine, followed by patients with a longer history of past COVID-19 and no vaccination. The best cutoff for the interferon gamma assay was 25 IU/L for all subgroups of individuals and the two sets of SARS-CoV-2 antigens studied. Testing T-cell response may be of clinical utility to determine immunity after exposure to SARS-CoV-2 antigens, with the interferon gamma concentration of 25 IU/L as the best cutoff either after infection or vaccination.

A case of Steven-Johnson syndrome after COVID-19 vaccination.

Eosinophilic panniculitis: a new side effect of Sinopharm COVID-19 vaccine.

SARS-CoV-2 BNT162b2 vaccine-induced humoral response and reactogenicity in individuals with prior COVID-19 disease. BACKGROUNDMost individuals with prior COVID-19 disease manifest long-term protective immune responses against reinfection. Accordingly, we tested the hypothesis that humoral immune and reactogenicity responses to a SARS-CoV-2 mRNA vaccine differ in individuals with and without prior COVID-19 disease.METHODSHealth care workers (n = 61) with (n = 30) and without (n = 31) prior COVID-19 disease received two 30 Î¼g doses of Pfizer BNT162b2 vaccine 3 weeks apart. Serum IgG antibody against the spike receptor-binding domain; serum neutralizing activity; and vaccine reactogenicity were assessed longitudinally every 2 weeks for 56 days after the first injection.RESULTSThe COVID-19 group manifested more rapid increases in spike IgG antibody and serum neutralizing activity after the first vaccine dose but showed little or no increase after the second dose compared with the infection-naive group. In fact, spike IgG was at its maximum level after the first dose in 36% of the COVID-19 group versus 0% of the infection-naive group. Peak IgG antibody levels were lower but appeared to fall more slowly in the COVID-19 group versus the infection-naive group. Finally, adverse systemic reactions, e.g., fever, headache, and malaise, were more frequent and lasted longer after both the first and second injection in the COVID-19 group than in the infection-naive group.CONCLUSIONIndividuals with prior COVID-19 disease demonstrate a robust, accelerated humoral immune response to the first dose but an attenuated response to the second dose of BNT162b2 vaccine compared with controls. The COVID-19 group also experienced greater reactogenicity. Humoral responses and reactogenicity to BNT162b2 differ qualitatively and quantitatively in individuals with prior COVID-19 disease compared with infection-naive individuals.FUNDINGThis work was supported by Temple University institutional funds.

Acute myocarditis after receiving first dose of BNT162b2 mRNA vaccine. A 40-year-old man with history of prior coronavirus disease 2019 (COVID-19) infection developed pleuritic chest pain 3 days after receiving the first dose of the BNT162b2 mRNA vaccine. Echocardiography results were significant for mild dysfunction and left ventricular hypertrophy. Cardiac magnetic resonance imaging showed myocardial edema as well as delayed enhancement in the inferior wall of the basal left ventricular myocardium, suggestive of acute myocarditis. This case describes the work-up, diagnosis, risk-stratification, and management of acute myocarditis post BNT162b2 mRNA vaccine. <Learning objective:1.To suspect acute myocardial inflammation in patients who present with chest symptoms after receiving the BNT162b2 COVID-19 vaccine.2.To review the clinical presentation and laboratory,

electrocardiographic, and imaging parameters for diagnosing acute myocarditis.3.To review the indications for endomyocardial biopsy in patients presenting with possible myocarditis.>.
COVID-19 messenger ribonucleic acid vaccination and abnormal radiopharmaceutical uptake in the axilla visualized on (68)Ga-DOTATATE positron-emission tomography/computed tomography. As COVID-19 vaccination rates continue to rise, it is becoming increasingly important to understand diagnostic imaging associations' resultant from the vaccines. Here, we report a case of a 59-year-old female who was in remission for gastrointestinal neuroendocrine carcinoma and presented for standard follow-up imaging evaluation. Positron-emission tomography (PET) images from a (68)Ga-DOTATATE PET (NETSPOT) demonstrated moderate focal radiotracer uptake in the right axilla. Interestingly, this uptake localized to several normal-sized lymph nodes on the corresponding computed tomography (CT). A medical history revealed the patient received both doses of an ipsilateral COVID-19 messenger ribonucleic acid vaccine injection at 17 and 38 days before the PET/CT study. Subsequent scans 2 months later revealed no radiotracer uptake.
COVID-19 outbreak in a long-term care facility in Kelowna, British Columbia after rollout of COVID-19 vaccine in March 2021. BACKGROUND: In March 2021, a coronavirus disease 2019 (COVID-19) outbreak was declared at a large long-term care and short stay facility in British Columbia, Canada-well after introduction of the vaccination program in long-term care facilities that resulted in a dramatic decline in the number of outbreaks in this type of setting. The objective of this study is to provide the descriptive epidemiology of this outbreak, in the context of partial immunization of both residents and staff at the facility. METHODS: The cases' information was extracted from a provincial information system (Panorama). Descriptive analysis was performed using Microsoft Excel and SAS. Outbreak management controls included, but were not limited to, asymptomatic testing and efforts to increase vaccination. RESULTS: Twenty-six cases among the 241 resident and three cases among the 418 staff (corresponding to attack rates of 10% and less than 1%, respectively) were identified. The attack rate in residents was considerably lower than the average attack rate for COVID-19 outbreaks in long-term care facilities before the vaccine rollout. Seventeen resident cases were either partially or fully immunized. Four of the eight hospitalized cases and two of the three deceased cases were partially immunized. Seventeen cases were temporary stay residents. The three staff cases were not vaccinated. Ten cases were identified as part of asymptomatic testing. CONCLUSION: Introduction of vaccination at facilities contributed to lower attack rates and higher numbers of asymptomatic cases in this outbreak. Screening asymptomatic individuals identified additional cases among vaccinated residents. Findings underscore the importance of achieving high vaccine coverage, including among temporary stay residents, to prevent virus introduction and subsequent unrecognized transmission opportunities.
[Pleuropericardial effusion and systemic inflammatory syndrome secondary to the administration of the mRNA-1273 vaccine for SARS-CoV-2].
Chronic graft-versus-host disease exacerbation after SARS-CoV-2 vaccination.
The incidence of COVID-19 infection following emergency use authorization of BBIBP-CORV inactivated vaccine in frontline workers in the United Arab Emirates. Based on the findings from the Phase III clinical trials of inactivated SARS COV-2 Vaccine, (BBIBP-CORV) emergency use authorization (EUA) was granted for the vaccine to frontline workers in the UAE. A prospective cohort study was conducted among frontline workers to estimate the incidence rate and risk of symptomatic COVID-19 infection 14Â days after the second dose of inoculation with BBIBP-CORV inactivated vaccine. Those who received two doses of the BBIBP-CORV vaccine in the period from 14th of September 2020 (first dose) to 21st of December 2020 (second dose) were followed up for COVID-19 infections.Â 11,322 individuals who received the two-dose BBIBP-CORV vaccine were included and were followed up post the second dose plus fourteen days. The incidence rate of symptomatic

infection was 0.08 per 1000-person days (95% CI 0.07, 0.10). The estimated absolute risk of developing symptomatic infection was 0.97% (95% CI 0.77%, 1.17%). The confirmed seroconversion rate was 92.8%. There were no serious adverse events reported and no individuals suffered from severe disease.Â Our findings show that vaccinated individuals are likely to remain protected against symptomatic infection or becoming PCR positive for SARS COV 2 following the second dose of the vaccination.

Impaired SARS-CoV-2 mRNA Vaccine Antibody Response in Chronic Medical Conditions: A Real-World Analysis.

Cross reactivity of spike glycoprotein induced antibody against Delta and Omicron variants before and after third SARS-CoV-2 vaccine dose in healthy and immunocompromised individuals.

Antibody responses induced by the BNT162b2 mRNA COVID-19 vaccine in healthcare workers in a single community hospital in Japan. INTRODUCTION: The effectiveness of several vaccines against coronavirus disease (COVID-19) has been reported in the real-world setting. However, it is still unknown how long antibodies persist following vaccination and whether or not the persistence of antibodies has a protective effect against COVID-19. METHODS: Healthcare workers who had received two doses of the BNT162b2 mRNA COVID-19 vaccine were enrolled, and a single-center study was conducted at the National Hospital Organization Hakodate National Hospital. Serum samples from all participants were collected 13-21 weeks (median: 20 weeks) after the second dose of vaccination. The antibody titers were measured using an electrochemiluminescence immunoassay (ElecsysÂ® Anti-SARS-CoV-2 S). Data on characteristics of the participants were gathered from patient records and interview sheets. RESULTS: A total of 401 participants, among whom 70.1% were women and the median age was 42 years, were evaluated in this study. None of the participants had a definite COVID-19 history, and all participants who received complete vaccination showed positive antibody titers. The antibody titer was observed to be higher in participants with younger age (pÂ <Â 0.001) and those who were females (pÂ =Â 0.028). Despite the higher risk of infection than that of the general public, no vaccinated staff developed breakthrough infections. CONCLUSIONS: This study demonstrates the significant contribution of the BNT162b2 vaccine in the acquisition of anti-SARS-CoV-2S antibodies; therefore, the general population should benefit from these two vaccine doses, which are expected to be protective for at least five months.

Low frequency of disease flare in patients with rheumatic musculoskeletal diseases who received SARS-CoV-2 mRNA vaccine. BACKGROUND: Little is known about the safety of SARS-CoV-2 vaccination in patients with rheumatic musculoskeletal disease (RMD). We evaluated the occurrence of adverse events following immunization (AEFI) in RMD patients and heathy subjects who received anti-SARS-CoV-2 mRNA vaccine. METHODS: We performed a telephone interview collecting any adverse event (AE) following immunization (AEFI) that occurred in RMD patients and healthy controls after the two doses of mRNA vaccine including common local reactogenicity and systemic events (for example, fever, fatigue/malaise, joint and muscle pain). We also investigated the onset of new signs or symptoms of the RMD after the vaccination. RESULTS: We evaluated 126 patients with RMDs [105 females and 19 males, median age 51(IQR 17)] and 85 controls [62 females and 23 males, (median age 49 (20)]. Seventy patients (55.6%) were taking immunosuppressants, conventional synthetic (n=31, 43.3%) and/or biological [TNF inhibitors (n=49, 68.6%)], and 30 (23.8%) were taking hydroxychloroquine; treatment remained unchanged in 77% of patients. Eleven out of 126 patients and none of the 85 controls previouslyÂ contracted COVID-19. The median follow-up from the completion of vaccination was 15 (3) weeks both in patients and controls. We reviewed 5 suspected cases confirming mild articular flares in 3 women (2.8) with inflammatory arthritis (2 psoriatic arthritis and 1 rheumatoid arthritis) while no disease reactivation was recorded in patients with connective tissue diseases; the incidence rate of RMD reactivation was 0.007 person/month. Multivariable

logistic regression analysis showed similar frequencies of local and systemic AEFI in patients and controls with no effect of therapies or previous COVID-19. Local reaction-pain in the injection site-was the most frequently reported AEFI both in RMD and controls (71% and 75% of all the AEFI, respectively) after the first dose. Overall, up to 66% of patients experienced at least one AEFI at the second dose and up to 62% in the control group. Most of AEFI occurred within 2 days of vaccine administration. Two RMD patients developed pauci-symptomatic COVID-19 after the first dose of vaccine. CONCLUSION: The low incidence rate of disease reactivation and the similar AEFI occurrence compared to controls should reassure on mRNA vaccine safety in RMD patients.
Wells' syndrome following Oxford-AstraZeneca COVID-19 vaccination.
COVID vaccine-induced pustular psoriasis in patients with previous plaque type psoriasis.
Trigger of Type 2 Lepra reaction with acute foot drop following Covid-19 vaccination.
BNT162b2 mRNA SARS-CoV-2 vaccination does not cause upregulation of endothelial activation markers or hypercoagulability: A prospective, single-arm, longitudinal study.
Thyrotoxicosis following SARS-COV-2 vaccination: a case series and discussion. AIM: To describe a case series of thyrotoxicosis likely triggered by SARS-CoV-2 vaccination and to warn physicians about this potential correlation. To report clinical, laboratory and imaging findings and provide further information that goes in line with the underlying mechanisms. METHODS: Single-center case series based on all the information collected in the hospital medical records, as well as the temporal sequence between the onset of symptoms and COVID-19 vaccination. RESULTS: We report 8 cases with thyrotoxicosis after SARS-CoV-2 vaccination. 4 cases of Graves' disease (GD), 2 cases of subacute painful thyroiditis (SAT), 1 case of concurrent GD and SAT and 1 case of atypical subacute thyroiditis. Five patients received BNT162b2 mRNA vaccine, 3 patients 1273 mRNA vaccine. TheÂ onset of symptoms following vaccination ranged from 10 to 14Â days in six of eight patients and from 7 to 8Â weeks in two patients. CONCLUSIONS: Several hypotheses have been proposed to explain the potential correlation between SARS-CoV-2 vaccination and thyrotoxicosis, including immune system hyper-stimulation, molecular mimicry and Autoimmune/Autoinflammatory Syndrome Induced by Adjuvants (ASIA). We should pay greater attention to thyroid disorders in patients receiving vaccine against SARS-CoV-2.
Estimating COVID-19 Infections, Hospitalizations, and Deaths Following the US Vaccination Campaigns During the Pandemic. This decision analytic modeling study uses a simulation model to evaluate the association of US COVID-19 vaccination campaigns with infections, hospitalizations, and deaths.
COVID-19 Vaccines Have Been Available in the US for More Than a Year-What's Been Learned and What's Next?
Lymphatic osteopathic manipulative treatment reduces duration of deltoid soreness after Pfizer/BioNTech COVID-19 vaccine. Pfizer-BioNTech BNT162b2 is one of the three U.S. Food and Drug Administration (FDA)-approved vaccines for the prevention of COVID-19. Its most common sideÂ effect, injection site pain, occurs because of locally recruited inflammatory mediators and is mitigated by the lymphatic system. Side effects may discourage individuals from receiving vaccines; therefore, reducing the duration of injection site pain can promote vaccination compliance. Osteopathic manipulative treatments (OMT) can directly affect the physiology underlying muscle soreness; however, there is currently no literature that supports the use of OMT in this scenario. In this case report, an otherwise healthy male presented with acute left deltoid soreness after receiving the Pfizer COVID-19 vaccine. The pain began 5Â h prior to the visit. Three hours after being treated with lymphatic OMT, the severity of the pain was significantly reduced and was alleviated 8h after onset in comparison to the median duration of 24-48Â h. He received his second dose 3Â weeks later. This case report can provide future studies with the groundwork for further investigating the role of

OMT in treating postvaccination muscle soreness, which can improve patient satisfaction and potentially promote vaccination compliance.
Fulminant type 1 diabetes mellitus triggered by coronavirus disease 2019 vaccination in an advanced melanoma patient given adjuvant nivolumab therapy.
The surprising course of multiple sclerosis relapse in a patient after SARS-CoV-2 vaccination.
Anti-SARS-CoV-2 antibody levels and kinetics of vaccine response: potential role for unresolved inflammation following recovery from SARS-CoV-2 infection. The immune response after SARS-CoV-2 vaccine administration appears to be characterized by high inter-individual variation, even in SARS-CoV-2 positive subjects, who could have experienced different post-infection, unresolved conditions. We monitored anti-SARS-CoV-2 IgG levels and kinetics along with circulating biomarkers in a cohort of 175 healthcare workers during early immunization with COVID-19 mRNA-LNP BNT162b2 vaccine, to identify the associated factors. Subjects with a previous SARS-CoV-2 infection were characterized by higher BMI and CRP levels and lower neutrophil count with respect to naÃ¯ve subjects. Baseline IgG levels resulted associated with CRP independently on BMI and inflammatory diseases. Among 137 subjects undergoing vaccination and monitored after the first and the second dose, three kinetic patterns were identified. The pattern showing a rapid growth was characterized by higher IgG levels at baseline and higher CRP and MCHC levels than negative subjects. Subjects previously exposed to SARS-CoV-2 showed higher levels of CRP, suggesting persistence of unresolved inflammation. These levels are the main determinant of IgG levels at baseline and characterized subjects belonging to the best performing, post-vaccine antibody kinetic pattern.
Population homogeneity for the antibody response to COVID-19 BNT162b2/Comirnaty vaccine is only reached after the second dose across all adult age ranges. While mRNA vaccines are administrated worldwide in an effort to contain the COVID-19 pandemic, the heterogeneity of the humoral immune response they induce at the population scale remains unclear. Here, in a prospective, longitudinal, cohort-study, including 1245 hospital care workers and 146 nursing home residents scheduled for BNT162b2 vaccination, together covering adult ages from 19 to 99 years, we analyse seroconversion to SARS-CoV-2 spike protein and amount of spike-specific IgG, IgM and IgA before vaccination, and 3-5 weeks after each dose. We show that immunogenicity after a single vaccine dose is biased to IgG, heterogeneous and reduced with increasing age. The second vaccine dose normalizes IgG seroconversion in all age strata. These findings indicate two dose mRNA vaccines is required to reach population scale humoral immunity. The results advocate for the interval between the two doses not to be extended, and for serological monitoring of elderly and immunosuppressed vaccinees.
Impaired antibody response to COVID-19 vaccination in advanced HIV infection. OBJECTIVES: Coronavirus disease 2019 (COVID-19) vaccination is reportedly efficient in people with HIV (PWH) but vaccine trials included participants with normal CD4+ T-cell counts. We analyzed seroconversion rates and antibody titers following two-dose vaccination in PWH with impaired CD4+ T-cell counts. METHODS: We collected retrospective postvaccination SARS-COV-2 serology results available in a university hospital for PWH vaccinated between March and September, 2021 who were tested for antispike antibodies from 8 to 150 days following dose 2. Antibody titers were compared in PWH with CD4+ T-cell count less than 200 cells/Î¼l, 200â€Š<â€ŠCD4+ T-cell countsâ€Š<â€Š500 cells/Î¼l and CD4+ T-cell count greater than 500 cells/Î¼l at vaccination. RESULTS: One hundred and five PWH were included: nâ€Š=â€Š54 in the CD4+ T-cell count less than 500 cells/Î¼l group (nâ€Š=â€Š18 with CD4+ <200 cells/Î¼l, nâ€Š=â€Š36 with 200â€Š<â€ŠCD4+â€Š<â€Š500 cells/Î¼l) and 51 in the CD4+ T-cell count greater than 500 cells/Î¼l group. They received two doses of BNT162b2 (75%), mRNA-1273 (8.5%), or ChAdOx1 nCoV-19 (16.5%). The median time from vaccine dose 2 to serology was consistent across all groups (73â€Šdays, interquartile range [29-97], Pâ€Š=â€Š0.14). Seroconversion

rates were 100% in the CD4+ T-cell count greater than 500 cells/Î¼l group but 89% in participants with CD4+ T-cell counts less than 500 cells/Î¼l (22 and 5.5% seronegative in the CD4+ T-cell counts <200 cells/Î¼l and 200â€Š<â€ŠCD4+â€Š<â€Š500 cells/Î¼l groups, respectively). Median antibody titers were 623.8â€ŠBAU/ml [262.2-2288] in the CD4+ greater than 500 cells/Î¼l group versus 334.3â€ŠBAU/ml [69.9-933.9] in the CD4+ less than 500 cells/Î¼l group (Pâ€Š=â€Š0.003). They were lowest in the CD4+ less than 200 cells/Î¼l group: 247.9â€ŠBAU/ml [5.88-434.9] (Pâ€Š=â€Š0.0017) with only 44% achieving antibody titers above the putative protection threshold of 260â€ŠBAU/ml. CONCLUSION: PWH with CD4+ T-cell counts less than 500 cells/Î¼l and notably less than 200 cells/Î¼l had significantly lower seroconversion rates and antispike antibody titers compared with PWH with CD4+ T-cell counts greater than 500 cells/Î¼l, warranting the consideration of targeted vaccine strategies in this fragile population.

Third COVID-19 vaccine dose with BNT162b2 in patients with ANCA-associated vasculitis.

Pityriasis Rosea-like eruptions following COVID-19 mRNA-1273 vaccination: A case report and literature review. Pityriasis rosea (PR) is a self-limited disease with exanthematous papulosquamous rashes mostly associated with reactivation of human herpesvirus (HHV)-6 or HHV-7. PR-like eruptions, which occur along with peripheral eosinophilia, interface dermatitis, and eosinophils on histopathology, may result from medications or vaccinations. Previously, PR-like eruptions had been noted following vaccination for influenza or other vaccines. During this pandemic, acute COVID-19 infection has been related to PR or PR-like eruptions in several cases. Various COVID-19 vaccines associated with PR-like eruptions were rarely reported. Herein, we report a case of cutaneous PR-like eruptions following COVID-19 mRNA-1273 vaccination.

Axillary Lymphadenopathy on Ultrasound after COVID-19 Vaccination and Its Influencing Factors: A Single-Center Study. PURPOSE: This study aimed to assess the incidence of axillary lymphadenopathy on ultrasound after COVID-19 vaccination and to investigate the factors affecting lymphadenopathy. METHODS: We evaluated patients who had received a COVID-19 vaccination within 12 weeks before an ultrasound examination between August and October 2021. The incidence of vaccine-related ipsilateral axillary lymphadenopathy was evaluated using ultrasound. Age, sex, presence of axillary symptoms, injection site, vaccine type, interval from vaccination, and dose were compared between the groups with and without axillary lymphadenopathy. RESULTS: We included 413 patients, 202 (49%) of whom showed axillary lymphadenopathy on ultrasound after COVID-19 vaccination. Age, interval from vaccine, vaccine brand, vaccine type, dose, and symptom were significantly different between the lymphadenopathy and non-lymphadenopathy groups ($p < 0.001$), while the injection site and sex were not. Receiving an mRNA vaccine was the most important factor for axillary lymphadenopathy ($p < 0.001$), followed by intervals of 1-14 ($p < 0.001$) and 15-28 days ($p < 0.001$), younger age ($p = 0.006$), and first dose ($p = 0.045$). CONCLUSION: COVID-19 vaccine-related axillary lymphadenopathy on ultrasound is common. mRNA type, an interval of 4 weeks, younger age, and first dose were the important factors. Breast clinicians should be well aware of these side effects when performing imaging examinations and provide accurate information to patients.

Antibody Response to mRNA Vaccines against SARS-CoV-2 with Chronic Kidney Disease, Hemodialysis, and after Kidney Transplantation. Most trials on mRNA vaccines against SARS-CoV-2 did not include patients with chronic kidney disease (CKD), hemodialysis (HD) patients, or kidney transplant recipients (KTR). However, those patients have a higher risk for a severe course of COVID-19 disease and mortality. Available literature has demonstrated a reduced efficacy of mRNA vaccines in HD patients and KTR, while data on CKD patients is scarce. Additionally, factors associated with non-response are poorly understood and not well characterized. We assessed antibody (AB) response (n = 582, 160 CKD patients, 206 patients on HD, 216 KTR) after the administration of two doses of a mRNA-vaccine with either BNT162b2 or mRNA-1273. AB measurements were carried out after a

median of 91 days after first vaccinations, demonstrating non-response in 12.5% of CKD patients, 12.1% of HD patients, and 50% of KTR. AB titers were significantly higher in CKD patients than in HD patients or KTR. Factors associated with non-response were treated with rituximab in CKD patients, the use of calcineurin inhibitors in HD patients and older age, and the use of BNT162b2, mycophenolic acid, or glucocorticoids and lower hemoglobin levels in KTR. This study contributes to the understanding of the extent and conditions that predispose for non-response in patients with impaired kidney function.

Waning Humoral Response 3 to 6 Months after Vaccination with the SARS-COV-2 BNT162b2 mRNA Vaccine in Dialysis Patients. BACKGROUND AND OBJECTIVES: The short-term reported antibody response to SARS-COV-2 vaccination in dialysis patients is high, with a seroconversion response rate up to 97%. Data on the long-term durability of this response are scarce. Our objective was to characterize the long-term anti-spike antibody level in dialysis patients. DESIGN, SETTING, PARTICIPANTS, AND MEASUREMENTS: In an observational study, we measured SARS-COV-2 anti-spike antibody levels in dialysis patients who completed 2 doses of the BNT162b2 mRNA SAR S-COV-2 vaccine at 1, 3 and 6 months after the second vaccine dose. We compared the response to dialysis patients who were infected with COVD-19 and to a control group of healthcare-employees. RESULTS: One hundred and forty-two dialysis patients who had been vaccinated (ages 64 Â± 11.9 years, 61% male), 33 dialysis patients who had COVID-19 infection (ages 54 Â± 14.3 years, 55% male) and 104 individuals in the control group (ages 50 Â± 12.2 years, 44% male) were included. The response rate in the vaccinated dialysis patients was 94%, 78% and 73% at 1, 3 and 6 months after the second vaccine dose. In the COVID-19 infected dialysis group and in the control group, the response rate remained at 100% over 6 months. The percentage of change in antibody levels between one and 6 months was -66% in the vaccinated dialysis group, -28% in the control group ($p < 0.001$) and +48% in dialysis patients who had been infected with COVID-19 ($p < 0.001$). A non-responder status at 6 months was associated with a lower albumin level. No serious adverse events following vaccination were reported. In conclusion: the initially high response rate to the BNT162b2 vaccine in dialysis patients decreases rapidly. Our results indicate that an early booster (3rd) dose, at three months after the second dose, may be advised for this population to preserve the humoral immunity.

Systematic review of risk of SARS-CoV-2 infection and severity of COVID-19 with therapies approved to treat multiple sclerosis. There is growing concern that multiple sclerosis (MS) patients on certain therapies may be at higher risk for severe coronavirus disease 2019 (COVID-19). We conducted a systematic literature review to examine the available data on U.S. therapies approved to treat MS and the risk of SARS-CoV-2 infection or severe COVID-19 outcomes. We conducted searches in PubMed, Embase, and the WHO COVID-19 database through May 2, 2021, and retrieved articles describing clinical data on therapies approved to treat MS and the risk of infection with SARS-CoV-2 or the effects of such therapies on clinical outcomes of COVID-19. The literature search identified a total of 411 articles: 97 in PubMed, 227 in Embase, and 87 in the WHO database. After excluding duplicates and screening, we identified 15 articles of interest. We identified an additional article through a broader secondary weekly search in PubMed. Thus, ultimately, we reviewed 16 observational studies. Available data, which suggest that MS patients treated with anti-CD20 monoclonal antibodies may be at increased risk for severe COVID-19, are subject to relevant limitations. Generally, studies did not identify increased risk for COVID-19 worsening with other therapies approved to treat MS. Based on observational data, biological plausibility, novelty of the drug-event association, and public health implications in a subpopulation with potential impaired response to the COVID-19 vaccines, this safety signal merits further monitoring.

Association of a Third Dose of BNT162b2 Vaccine With Incidence of SARS-CoV-2 Infection Among Health Care Workers in Israel. IMPORTANCE: Administration of a BNT162b2 booster dose (Pfizer-

BioNTech) to fully vaccinated individuals aged 60 years and older was significantly associated with lower risk of SARS-CoV-2 infection and severe illness. Data are lacking on the effectiveness of booster doses for younger individuals and health care workers. OBJECTIVE: To estimate the association of a BNT162b2 booster dose with SARS-CoV-2 infections among health care workers who were previously vaccinated with a 2-dose series of BNT162b2. DESIGN, SETTING, AND PARTICIPANTS: This was a prospective cohort study conducted at a tertiary medical center in Tel Aviv, Israel. The study cohort included 1928 immunocompetent health care workers who were previously vaccinated with a 2-dose series of BNT162b2, and had enrolled between August 8 and 19, 2021, with final follow-up reported through September 20, 2021. Screening for SARS-CoV-2 infection was performed every 14 days. Anti-spike protein receptor binding domain IgG titers were determined at baseline and 1 month after enrollment. Cox regression with time-dependent analysis was used to estimate hazard ratios of SARS-CoV-2 infection between booster-immunized status and 2-dose vaccinated (booster-nonimmunized) status. EXPOSURES: Vaccination with a booster dose of BNT162b2 vaccine. MAIN OUTCOMES AND MEASURES: The primary outcome was SARS-CoV-2 infection, as confirmed by reverse transcriptase-polymerase chain reaction. RESULTS: Among 1928 participants, the median age was 44 years (IQR, 36-52 years) and 1381 were women (71.6%). Participants completed the 2-dose vaccination series a median of 210 days (IQR, 205-213 days) before study enrollment. A total of 1650 participants (85.6%) received the booster dose. During a median follow-up of 39 days (IQR, 35-41 days), SARS-CoV-2 infection occurred in 44 participants (incidence rate, 60.2 per 100â€¯000 person-days); 31 (70.5%) were symptomatic. Five SARS-CoV-2 infections occurred in booster-immunized participants and 39 in booster-nonimmunized participants (incidence rate, 12.8 vs 116 per 100â€¯000 person-days, respectively). In a time-dependent Cox regression analysis, the adjusted hazard ratio of SARS-CoV-2 infection for booster-immunized vs booster-nonimmunized participants was 0.07 (95% CI, 0.02-0.20). CONCLUSIONS AND RELEVANCE: Among health care workers at a single center in Israel who were previously vaccinated with a 2-dose series of BNT162b2, administration of a booster dose compared with not receiving one was associated with a significantly lower rate of SARS-CoV-2 infection over a median of 39 days of follow-up. Ongoing surveillance is required to assess durability of the findings.

HLA-Aâˆ—03:01 is associated with increased risk of fever, chills, and stronger side effects from Pfizer-BioNTech COVID-19 vaccination. COVID-19 vaccines are safe and highly effective, but some individuals experience unpleasant reactions to vaccination. As the majority of adults in the United States have received a COVID-19 vaccine this year, there is an unprecedented opportunity to study the genetics of reactions to vaccination via surveys of individuals who are already part of genetic research studies. Here, we have queried 17,440 participants in the Helix DNA Discovery Project and Healthy Nevada Project about their reactions to COVID-19 vaccination. Our genome-wide association study identifies an association between severe difficulties with daily routine after vaccination and HLA-Aâˆ—03:01. This association was statistically significant only for those who received the Pfizer-BioNTech vaccine (BNT162b2; n = 3,694; p = 4.70E-11; OR = 2.07 [95% CI 1.67-2.56]), and showed a smaller effect size in those who received the Moderna vaccine (mRNA-1273; n = 3,610; p = 0.005; OR = 1.32 [95% CI 1.09-1.59]). In Pfizer-BioNTech recipients, HLA-Aâˆ—03:01 was associated with a 2-fold increase in risk of self-reported severe difficulties with daily routine following vaccination. The effect was consistent across ages, sexes, and whether the person had previously had a COVID-19 infection. The reactions experienced by HLA-Aâˆ—03:01 carriers were driven by associations with chills, fever, fatigue, and generally feeling unwell.

Lower Severe Acute Respiratory Syndrome Coronavirus 2 Viral Shedding Following Coronavirus Disease 2019 Vaccination Among Healthcare Workers in Los Angeles, California. Among 880 healthcare workers with a positive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) test, 264 (30.0%) infections were identified following receipt of at least 1 vaccine dose. Median SARS-

CoV-2 cycle threshold values were highest among individuals receiving 2 vaccine doses, corresponding to lower viral shedding. Vaccination might lead to lower transmissibility of SARS-CoV-2.

Exacerbation of Psoriasis Following COVID-19 Vaccination: Report From a Single Center. The temporal association had been reported between vaccination and exacerbation of psoriasis, and episodes of psoriasis flare-up have recently been attributed to COVID-19 vaccines. We recruited 32 unimmunized controls and 51 vaccinated psoriasis patients, 49 of whom were under biological therapy, with regular clinic visits receiving a total of 63 shots of vaccines, including 30 doses of Moderna mRNA-1273 and 33 doses of AstraZeneca-Oxford AZD1222. Fifteen episodes of exacerbation attacked within 9.3 Â± 4.3 days, which is higher than two episodes in the control group ($p = 0.047$). The mean post-vaccination severity of the worsening episodes increased from PASI 3.1 to 8.0 ($p < 0.001$). Three patients showed morphologic change from chronic plaque-type to guttate psoriasis. Deterioration of psoriasis following COVID-19 vaccination was not associated with age, sex, disease duration, psoriatic arthritis, family history of psoriasis, history of erythroderma, current biologics use, comorbidities, vaccine types, human leukocyte antigen (HLA)-C genotypes, baseline PASI nor pre-vaccination PASI. For those who received two doses of vaccination, all but one patient aggravated after the first shot but not the second. The mechanism of psoriasis exacerbation in immunized individuals is unclear, but Th17 cells induced by COVID-19 vaccines may play a role. In the pandemic era, psoriasis patients and physicians should acknowledge the possibility of fluctuation of disease activity when vaccinated against COVID-19. Nevertheless, compared to a treatable dermatologic disease with rapid resolution of exacerbation, psoriasis patients who do not have contraindications to vaccination should benefit from COVID-19 vaccines in the prevention of severe COVID-19 infection and fatality.

Persistence of Antibodies Against Spike Glycoprotein of SARS-CoV-2 in Healthcare Workers Post Double Dose of BBV-152 and AZD1222 Vaccines. Purpose: We investigated the persistence of the vaccine-induced immunoglobulin G (IgG) antibodies against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) among healthcare workers (HCWs) in Odisha who received a complete dose of either Covaxin or Covishield vaccine. Methods: This 24-week longitudinal cohort study was conducted from January to July 2021 with participants from 6 healthcare and research facilities of Odisha to understand the dynamicity of the vaccine-induced IgG antibodies against SARS-CoV-2 after the complete dose of vaccines. Results: Serum samples were collected from 614 participants during each follow-up and were tested in two chemiluminescent microparticle immunoassay (CLIA)-based platforms to detect SARS-CoV-2 antibodies both qualitatively and quantitatively. Among these participants, 308 (50.2%) participants were Covishield recipients and the rest 306 (49.8%) participants took Covaxin. A total of 81 breakthrough cases were recorded and the rest 533 HCWs without any history of postvaccination infection showed significant antibody waning either from T3 (Covaxin recipient) or T4 (Covishield recipient). The production of vaccine-induced IgG antibodies is significantly higher ($p < 0.001$) in Covishield compared with Covaxin. Covishield recipients produced higher median anti-S IgG titer than Covaxin. No statistically significant differences in antibody titers were observed based on age, gender, comorbidities, and blood groups. Conclusion: This 6-month follow-up study documents a 2-fold and 4-fold decrease in spike antibody titer among Covishield and Covaxin recipients, respectively. The clinical implications of antibody waning after vaccination are not well understood. It also highlights the need for further data to understand the long-term persistence of vaccine-induced antibody and threshold antibody titer required for protection against reinfection.

COVID-19 Vaccine-Induced Pneumonitis, Myositis and Myopericarditis. A 63-year-old male, with no significant past history and not on any regular medications previously, had mild respiratory symptoms post the first dose of the AstraZeneca (Cambridge, England) coronavirus disease 2019

(COVID-19) vaccine, which were self-limiting. Following the second dose of the vaccine, he arrived at the emergency department (ED) with worsening shortness of breath. During this admission, he was assumed to have interstitial lung diseaseÂ due to a possible past history of occupational exposure. He responded to a short-term course of corticosteroids and antibiotics and was discharged home. However, he reported again to the emergency department three weeks later, with persistentÂ dyspnoea along with myalgia. His blood tests and imaging from scans suggested myositis, pneumonitis, and myopericarditis. Since he recently had the COVID-19 AstraZeneca vaccine, it was postulated as the most likely cause of the symptoms. He was managed with intravenous (IV) corticosteroids followed by oral corticosteroids with symptom resolution.

Post COVID-19 Vaccine Related Cerebral Venous Sinus Thrombosis and Thrombocytopenia. During the height of the COVID-19 pandemic, there was great relief with the global mass rollout of the Covid-19 vaccination programs. While they have proven to be safe and effective, the gradual emergence of side effects to the vaccines has undermined public trust in the vaccination program and, whilst rare, can lead to significant morbidity and mortality. The most serious was the emergence of vaccine-induced immune thrombocytopenia and thrombosis (VITT), also known as thrombosis with thrombocytopenia syndrome (TTS) or vaccine-induced prothrombotic immune thrombocytopenia (VIPIT). VITT is a serious and often fatal complication of some COVID vaccines that seem more prevalent in younger people and women. We present a case of a 48-year-old woman who presented with VITT following COVID vaccination.

Varicella-Zoster Virus Reactivation in AIDS Patient After Pfizer-BioNTech COVID-19 Vaccine. Since early 2020, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has affected millions of individuals and changed the face of medicine. As the fight against COVID continues, there is still unclear long term effects; although as time passes, more and more is being updated, in regards to the risks of exposure, length of recovery, outcomes of those infected, effectiveness of vaccines, and both expected and unique side effects of both the virus and vaccines, all in an array of individuals.Â This paper will review a unique topic of the SARS-CoV-2Â virus and the abnormal immune response in a young patient. This case is unique due to the fact that there have been an abundance of side effects reported that are associated with the virus that affects every organ system, yet very few have affected the neurological and integumentary (skin) system. This case emphasizes the reactivation of a Herpes/Varicella-Zoster virus (VZV) in a young male shortly after he received the Pfizer-BioNTech COVID-19 vaccine. The other interesting aspect about this case is the patient's immunocompromised state, as he was diagnosed with HIV several years before this viral reactivation occurred. The interesting aspect about this was trying to understand whether the VZV was truly reactivated because of an overly stressful immune reaction in response to the Pfizer-BioNTech COVID-19 vaccine or was it mainly due to the patient's already weak immune system, or even a combination of both?Â The in-depth review will evaluate whether there should be more done in regards to bringing more awareness about potential side effects and preparing for a VZV reactivation and/or other dermatological complications after being vaccinated. This presentation could also simply be a very unique, isolated case, and that each individual should have no hesitations regarding the Pfizer-BioNTech COVID-19 vaccine.

Global Perspectives on Immunization Against SARS-CoV-2 During Pregnancy and Priorities for Future Research: An International Consensus Paper From the World Association of Infectious Diseases and Immunological Disorders. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in pregnancy is associated with a higher risk for severe morbidity and mortality when compared with infection in non-pregnant women of childbearing age. An increasing number of countries recommend immunization against SARS-CoV-2 in pregnant women. Recent studies provide preliminary and supportive evidence on safety, immunogenicity and effectiveness of coronavirus

disease 2019 (COVID-19) vaccines in pregnant women; however, important knowledge gaps remain which warrant further studies. This collaborative consensus paper provides a review of the current literature on COVID-19 vaccines in pregnant women, identifies knowledge gaps and outlines priorities for future research to optimize protection against SARS-CoV-2 in the pregnant women and their infants.

Characterization of SARS-CoV-2-Specific Humoral and Cellular Immune Responses Induced by Inactivated COVID-19 Vaccines in a Real-World Setting. While the immunogenicity of inactivated vaccines against coronavirus disease 2019 (COVID-19) has been characterized in several well-conducted clinical trials, real-world evidence concerning immune responses against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) raised by such vaccines is currently missing. Here, we comprehensively characterized various parameters of SARS-CoV-2-specific cellular and humoral immune responses induced by inactivated COVID-19 vaccines in 126 individuals under real-world conditions. After two doses of vaccination, S-receptor binding domain IgG (S-RBD IgG) and neutralizing antibody (NAb) were detected in 87.06% (74/85) and 78.82% (67/85) of individuals, respectively. Female participants developed higher concentrations of S-RBD IgG and NAb compared to male vaccinees. Interestingly, a longer dosing interval between the first and second vaccination resulted in a better long-term SARS-CoV-2 S-RBD IgG response. The frequencies of CD4+ T cells that produce effector cytokines (IFN-Î³, IL-2, and TNF-Î±) in response to stimulation with peptide pools corresponding to the SARS-CoV-2 spike (S), nucleocapsid (N) or membrane (M) protein were significantly higher in individuals received two doses of vaccine than those received one dose of vaccine and unvaccinated individuals. S, N, or M-specific CD4+ and CD8+ T cell responses were detectable in 95.83% (69/72) and 54.16% (39/72) of double-vaccinated individuals, respectively. The longitudinal analysis demonstrated that CD4+ T cell responses recognizing S, N, and M waned quickly after a single vaccine dose, but were boosted and became more sustained following a second dose. Overall, we provide a comprehensive characterization of immune responses induced by inactivated COVID-19 vaccines in real-world settings, suggesting that both humoral and cellular SARS-CoV-2-specific immunity are elicited in the majority of individuals after two doses of inactivated COVID-19 vaccines.

Response and Duration of Serum Anti-SARS-CoV-2 Antibodies After Inactivated Vaccination Within 160 Days. BACKGROUND: A vaccine against coronavirus disease 2019 (COVID-19) with highly effective protection is urgently needed. The anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody response and duration after vaccination are crucial predictive indicators. OBJECTIVES: To evaluate the response and duration for 5 subsets of anti-SARS-CoV-2 antibodies after vaccination and their predictive value for protection. METHODS: We determined the response and duration for 5 subsets of anti-SARS-CoV-2 antibodies (neutralizing antibody, anti-RBD total antibody, anti-Spike IgG, anti-Spike IgM, and anti-Spike IgA) in 61 volunteers within 160 days after the CoronaVac vaccine. A logistic regression model was used to determine the predictors of the persistence of neutralizing antibody persistence. RESULTS: The seropositivity rates of neutralizing antibody, anti-RBD total antibody, anti-Spike IgG, anti-Spike IgM, and anti-Spike IgA were only 4.92%, 27.87%, 21.31%, 3.28% and 0.00%, respectively, at the end of the first dose (28 days). After the second dose, the seropositivity rates reached peaks of 95.08%, 100.00%, 100.00%, 59.02% and 31.15% in two weeks (42 days). Their decay was obvious and the seropositivity rate remained at 19.67%, 54.10%, 50.82%, 3.28% and 0.00% on day 160, respectively. The level of neutralizing antibody reached a peak of 149.40 (101.00-244.60) IU/mL two weeks after the second dose (42 days) and dropped to 14.23 (7.62-30.73) IU/mL at 160 days, with a half-life of 35.61(95% CI, 32.68 to 39.12) days. Younger participants (â‰¤31 years) had 6.179 times more persistent neutralizing antibodies than older participants (>31 years) (P<0.05). Participants with anti-Spike IgA seropositivity had 4.314

times greater persistence of neutralizing antibodies than participants without anti-Spike IgA seroconversion (P<0.05). CONCLUSIONS: Antibody response for the CoronaVac vaccine was intense and comprehensive with 95.08% neutralizing seropositivity rate, while decay was also obvious after 160 days. Therefore, booster doses should be considered in the vaccineÂ strategies.

On the association between COVID-19 vaccination levels and incidence and lethality rates at a regional scale in Spain. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes the coronavirus disease 2019 (COVID-19), has led to the deepest global health and economic crisis of the current century. This dramatic situation has forced the public health authorities and pharmaceutical companies to develop anti-COVID-19 vaccines in record time. Currently, almost 80% of the population are vaccinated with the required number of doses in Spain. Thus, in this paper, COVID-19 incidence and lethality rates are analyzed through a segmented spatio-temporal regression model that allows studying if there is an association between a certain vaccination level and a change (in mean) in either the incidence or the lethality rates. Spatial dependency is included by considering the Besag-York-MolliÃ© model, whereas natural cubic splines are used for capturing the temporal structure of the data. Lagged effects between the exposure and the outcome are also taken into account. The results suggest that COVID-19 vaccination has not allowed yet (as of September 2021) to observe a consistent reduction in incidence levels at a regional scale in Spain. In contrast, the lethality rates have displayed a declining tendency which has associated with vaccination levels above 50%.

COVID-19 Vaccine Could Trigger the Relapse of Secondary Hypersomnia. The coronavirus disease (COVID-19) has brought significant social and economic disruptions and devastating impacts on public health, and vaccines are being developed to combat the disease. Timely vaccination may prevent complications and morbidity but may also potentially result in unforeseen outcomes in some special clinical populations. We report on a case of hypersomnia relapse after the COVID-19 vaccination, with the aim of informing the development of the guideline on vaccination in specific groups. A 19-year old female presented with persistent daytime sleepiness after receiving the COVID-19 vaccine. She had a known history of hypersomnia secondary to infectious mononucleosis but has fully recovered for 8 months. A series of examinations were performed on this patient. Neurologic and psychiatric examinations were unremarkable. Despite normal nocturnal subjective sleep quality (Pittsburgh Sleep Quality Index score = 5, Insomnia Severity Index score = 7), her Epworth sleepiness scale score (15) suggested an abnormal level of subjective sleepiness. Consistent with the subjective report, the objective assessment by Multiple Sleep Latency Test found mean sleep latency was 1.3 min with no sleep onset rapid-eye-movement (REM) period. We speculate that COVID-19 vaccine may potentially trigger the relapse of hypersomnia. The immune memory could be an explanation for the increased response to vaccine in patients with secondary hypersomnia. Caution should be warranted when administering COVID-19 vaccine in patients with hypersomnia secondary to infections.

Proposed mechanism for rare thrombotic events after use of some Covid-19 vaccines. Administration of AstraZeneca/Oxford and Johnson & Johnson/Janssen Covid-19 vaccines which use an adenovirus vector for DNA delivery has been associated with very rare thromboembolic complications coupled with an immune response to platelet factor 4 protein. The cause of this has not yet been identified. It is known that binding of coagulation factor proteins to the surface of some adenoviruses can protect their function. Here I propose that the thromboembolic events are caused by impairment of coagulation factor X binding to the virus capsid. The unprotected capsid then stimulates an immune response leading to platelet activation, increased thrombogenicity and formation of an antibody complex with platelet factor 4. Impaired binding of factor X may be due to an undiagnosed mutation in affected individuals. Options to test this mechanism experimentally and potential remedial actions to resolve the hazard are described. This mechanism offers a remedial

route to address concerns about the safety of these vaccines, which are otherwise well-positioned to deliver global Covid-19 immunity across diverse healthcare economies.

Massive cerebral venous sinus thrombosis in vaccine-induced immune thrombotic thrombocytopenia after ChAdOx1 nCoV-19 serum: case report of a successful multidisciplinary approach. We report a case of massive cerebral venous sinus thrombosis in the contest of vaccine-induced immune thrombotic thrombocytopenia that required the rapid coordination of many specialists from different departments, notably emergency, neurology, neuroradiology, hematology, and neurosurgery. The patient was rapidly treated with steroids, immunoglobulin, and fondaparinux. She underwent within 6Â h after hospital admission a mechanical thrombectomy in order to allow flow restoration in cerebral venous systems. Neuroendovascular treatment in cerebral venous thrombosis related to VITT has never been described before. It can represent a complementary tool along with the other therapies and a multidisciplinary approach.

Impaired neutralisation of SARS-CoV-2 delta variant in vaccinated patients with B cell chronic lymphocytic leukaemia. BACKGROUND: Immune suppression is a clinical feature of chronic lymphocytic leukaemia (CLL), and patients show increased vulnerability to SARS-CoV-2 infection and suboptimal antibody responses. METHOD: We studied antibody responses in 500 patients following dual COVID-19 vaccination to assess the magnitude, correlates of response, stability and functional activity of the spike-specific antibody response with two different vaccine platforms. RESULTS: Spike-specific seroconversion post-vaccine was seen in 67% of patients compared to 100% of age-matched controls. Amongst responders, titres were 3.7 times lower than the control group. Antibody responses showed a 33% fall over the next 4Â months. The use of an mRNA (nâ€‰=â€‰204) or adenovirus-based (nâ€‰=â€‰296) vaccine platform did not impact on antibody response. Male gender, BTKi therapy, prophylactic antibiotics use and low serum IgA/IgM were predictive of failure to respond. Antibody responses after CD20-targeted immunotherapy recovered 12Â months post treatment. Post-vaccine sera from CLL patients with Spike-specific antibody response showed markedly reduced neutralisation of the SARS-CoV-2 delta variant compared to healthy controls. Patients with previous natural SARS-CoV-2 infection showed equivalent antibody levels and function as healthy donors after vaccination. CONCLUSIONS: These findings demonstrate impaired antibody responses following dual COVID-19 vaccination in patients with CLL and further define patient risk groups. Furthermore, humoural protection against the globally dominant delta variant is markedly impaired in CLL patients and indicates the need for further optimisation of immune protection in this patient cohort.

Should steroids be used for anaphylaxis after the COVID-19 vaccine?

Anti-SARS-CoV-2 spike protein and neutralizing antibodies at 1 and 3 months after three doses of SARS-CoV-2 vaccine in a large cohort of solid organ transplant patients. The immunogenicity of the severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) vaccine was improved by the administration of a third dose. The aim of our retrospective study was to assess the evolution of binding and neutralizing antibody concentration until 3Â months after the third dose in a large cohort of solid organ transplant (SOT) patients (nÂ =Â 872). At 1Â month after the third dose, anti-SARS-CoV-2 antibodies were detected by means of enzyme-linked immunosorbent assay tests in 578 patients (66.3%). In a subgroup of patients, 70% (180 out of 257) had anti-SARS-CoV-2 antibody concentrations ranging from 1.2 to 18Â 411 binding antibody units (BAU)/ml and 48.5% (115 out of 239) had a neutralizing antibodies titer that can confer clinical protection against SARS-CoV-2. Three-hundred ninety-three patients out of the 416 (94.5%) who were seropositive at month 1 and were tested at 3Â months after vaccination remained seropositive. Between months 1 and 3 after vaccination, binding and neutralizing antibodies concentrations decreased significantly. The proportion of protected patients against the SARS-CoV-2 also slightly decreased. In conclusion, this

study shows that although two-third of SOT develop anti-SARS-CoV-2 antibodies after three doses, one-third of them remain weak or non-protected. It is important to measure anti-SARS-CoV-2 antibodies to define the strategy that can optimize SOT protection against SARS-CoV-2.
Seasonal Betacoronavirus Antibodies' Expansion Post-BNT161b2 Vaccination Associates with Reduced SARS-CoV-2 VoC Neutralization. SARS-CoV-2 vaccination is known to induce antibodies that recognize also variants of concerns (VoCs) of the virus. However, epidemiological and laboratory evidences indicate that these antibodies have a reduced neutralization ability against VoCs. We studied binding and neutralizing antibodies against the Spike protein domains and subunits of the Wuhan-Hu-1 virus and its alpha, beta, delta VoCs and of seasonal betacoronaviruses (HKU1 and OC43) in a cohort of 31 health care workers prospectively followed post-vaccinationÂ with BNT162b2-Comirnaty. The study of sequential samples collected up to 64Â days post-vaccination showed that serological assays measuring IgG against Wuhan-Hu-1 antigens were a poor proxy for VoC neutralization. In addition, in subjects who had asymptomatic or mild COVID-19 prior to vaccination, the loss of nAbs following disease could be rapid and accompanied by post-vaccination antibody levels similar to those of naÃ¯ve vaccinees. Interestingly, in health care workers naÃ¯ve for SARS-CoV-2 infection, vaccination induced a rapid and transient reactivation of pre-existing seasonal coronaviruses IgG responses that was associated with a subsequent reduced ability to neutralize alpha and beta VoCs.
A comparative safety study of reported neurological adverse events with three COVID-19 vaccines.
Tracking Side Effects of the COVID-19 Vaccine in Mymensingh District of Bangladesh. The Coronavirus disease 2019 (COVID-19) has turned into a worldwide human tragedy and economic devastation. There had an intensive search for an effective drug against the coronavirus but not led to any breakthrough agents. Only one choice was left namely an effective and safe vaccine. Many people are ambivalent regarding corona vaccines because they also fear possible side effects from vaccination. This study was designed to track the side effects after first and second dose of the Oxford-AstraZeneca vaccines used in Mymensingh district of Bangladesh. This cross-sectional descriptive type of observational study was conducted in Mymensingh Medical College, Mymensingh, Bangladesh during the period of five months from 1 February, 2021 to 30 June, 2021 among 293 purposively selected vaccine recipients who received two doses of the Oxford-AstraZeneca vaccines. Data were collected by face to face interview of the selected vaccine recipients using a semi-structured questionnaire. Data were inputted into SPSS version 26.0. Qualitative data were summarized by percentage and quantitative data were summarized by mean and standard deviation. Necessary bivariate and multivariate analysis was done. Mean age of the respondents was 40.3 years with a standard deviation of Â±8.7 years. Among the vaccine recipients female were 159(54.3%) and male were 134(45.7%). The most of the vaccine recipients were graduate and master 256(87.3%) and more than half of the vaccine recipients (156, 53.2%) were government service holder. The most of the vaccine recipients (242, 86.0%) were from urban area and 263(89.8%) vaccine recipients were non-smoker. Sixty eight (23.2%) of the vaccine recipients had different types of co-morbidities. It was found that 217(74.1%) vaccine recipients had side effects after first dose while 162(55.3%) had side effects after second dose. The difference in occurrence of side effects of first and second dose was statistically highly significant ($p<0.001$). Pain on the injection site was present in 172(58.7%) vaccine recipients after first dose and in 142 (48.5%) after second dose. Fever was prevalent in 98 (33.4%) after first dose and in 61 (20.8) after second dose. Headache was in 61(20.8%) and in 22(7.5%) after first and second dose respectively. Thirty one (10.6%) vaccine recipients had loose motion after first dose and 26(8.9%) had this after second dose. First dose of vaccination caused nausea in 28(9.6%) and second dose caused it in 16(5.5%) vaccine recipients. Joint pain was prevalent in 24(8.2%) after first dose and in 15(5.1%) after second dose. Rash was present in 9(3.1%) and in 3(1.0%) after first

and second dose respectively. Cough was present in 5(1.7%) after first dose and in 2(0.7%) after second dose. Each 2(0.7%) had history of fainting and bodyache and 1(0.3%) reported intense weakness after first dose only. Side effects of first dose of AstraZeneca vaccine were more prevalent in female (124, 78.0%) than male (93, 69.4%). The side effects of second dose of AstraZeneca vaccine were also more prevalent in female (103, 64.8%) than male (59, 44.0%). The study results revealed that 217(74.1%) vaccine recipients had side effects after first dose while 162(55.3%) had side effects on second dose of the Oxford-AstraZeneca vaccine. Commonly experienced side effects were pain in the injection site, fever, headache, diarrhoea and joint pain. Most of the people tolerated these side effects and did not use any medicine.
Acute Kidney Injury With Endothelial Injury and Podocytopathy Following COVID-19 Vaccination.
Safety and Immunogenicity of SARS-CoV-2 vaccines in people with HIV. OBJECTIVE: To evaluate the safety and the serological response after two doses of mRNA-based SARS-CoV-2 vaccination in people with HIV (PWH). METHODS: Participants were evaluated 4 weeks after the second dose of mRNA-1273 or BNT162b2 vaccine. Tolerability was evaluated with a specific adverse event questionnaire. Patient's sera were analysed using LIAISON SARS-CoV-2 TrimericS IgG (DiaSorin). RESULTS: One-hundred PWH were included, 75% of them men, with a mean age of 44â€Â±â€11â€Šyears old, all receiving antiretroviral treatment and mostly with controlled viral loads (98% with HIV RNA <50â€Šcopies/ml) and 96% had >200â€ŠCD4+/Î¼l. All patients seroconverted after vaccination (antibody concentration â‰¥33.8â€Šbinding antibody units [BAU]/ml). Only 3% of the patients had a low antibody concentration (<520â€ŠBAU/ml), whereas 67% of them had concentrations above the assay's detection range (>2080â€ŠBAU/ml). Fifty-six patients had local or systemic symptoms, with mild arthromyalgia being the most common systemic symptom. No severe adverse events were reported. CONCLUSIONS: Vaccination with two doses of mRNA-1273 or BNT162b2 is well tolerated in PWH under effective antiretroviral treatment and it leads to a successful antibody response.
Rapid evaluation of the safety of COVID-19 vaccines: how well have we done?
Diagnosing SARS-CoV-2 vaccination associated aseptic meningitis is intricate.
[Anaphylaxis caused by vaccines]. Even though the SARS-CoV-2 pandemic represents a historical challenge, science has had an exponential development, and the current vaccination campaigns are proof of this. Unfortunately, along came misinformation and myths regarding their production and their adverse effects. For this reason, we have considered of utter importance to review anaphylaxis, one of the most feared vaccine adverse events.Anaphylaxis can be defined as a life-threatening acute and systemic allergic reaction, with a wide clinical spectrum, which can be explained by many immunological mechanisms, and whose diagnostic complexity demands the fulfillment of strict criteria. Though infrequent, any vaccine has the potential to trigger anaphylaxis. In the United States, for the new SARS-CoV-2 vaccines, rates from 1:200 000 (Pfizer-BioNTech) to 1:360 000 doses (Moderna) have been estimated. Vaccine adverse events can be mediated by hypersensitivity reactions, either allergic or not. Unlike a typical drug allergy, rarely is the active ingredient responsible for the reaction. Therefore, excipients must be considered during the approach to this problem. Vaccine associated anaphylaxis has to be referred to an allergist so as to guarantee the maximum benefit for the patient and improve the vaccines' security profile.
Lack of evidence of significant homology of SARS-CoV-2 spike sequences to myocarditis-associated antigens. BACKGROUND: COVID-19 mRNA vaccines have proven to be highly safe and effective. Myocarditis is an adverse event associated with mRNA vaccination, especially in young male subjects. These events are rare and, in the majority of cases, resolve quickly. As myocarditis can be driven by autoimmune responses, we wanted to determine if the SARS-CoV-2 spike protein antigen encoded in the mRNA COVID vaccines had potential cross-reactivity with auto-antigens previously associated

with myocarditis. METHODS: We performed a sequence identity comparison between SARS-CoV-2 spike protein-derived peptides and myocarditis-associated antigens. We also performed a structural analysis of these antigens and the SARS-CoV-2 spike protein to identify potential discontinuous 3-D epitope similarities. FINDINGS: We found no significant enrichment in the frequency of spike-derived peptides similar to myocarditis-associated antigens as compared to several controls. INTERPRETATION: Our results do not support the notion that increased occurrence of myocarditis after SARS-CoV-2-spike vaccination is mediated by a cross-reactive adaptive immune response.

Inverse lichen planus post Oxford-AstraZeneca COVID-19 vaccine.

Cardiac Tamponade After COVID-19 Vaccination. BACKGROUND: Acute pericarditis is a diffuse inflammation of the pericardial sac with many well-defined etiologies. Acute pericarditis as a vaccine-related adverse event is a rare entity, and the association between pericarditis and the immunogenic response to Coronavirus disease 2019 (COVID-19) vaccines is still being fully characterized. CASE REPORT: A previously healthy 18-year-old man presented with fever, pleuritic chest pain, and shortness of breath 3 weeks after receiving the first dose of a COVID-19 mRNA-based vaccine. The patient was found to have a large pericardial effusion with early tamponade physiology requiring pericardiocentesis. WHY SHOULD AN EMERGENCY PHYSICIAN BE AWARE OF THIS?: As COVID-19 vaccination becomes more prevalent globally, physicians should be aware of pericarditis as a rare but potentially serious adverse reaction. Although a direct causal link cannot be demonstrated, we present this case to increase awareness among emergency physicians of pericarditis as a rare, but potentially serious adverse event associated with COVID-19 vaccination.

Dentist-administered vaccines: An American Dental Association Clinical Evaluators Panel survey. BACKGROUND: With many states in the United States permitting dentists to administer the COVID-19 vaccine, there is much discussion about their scope of practice in relation to delivering other vaccines. METHODS: Survey questions were developed to assess dentists' awareness about their vaccine administration scope of practice and attitudes and barriers if choosing to incorporate vaccine delivery into their practice scope. The survey was deployed electronically to members of the American Dental Association Clinical Evaluators (ACE) Panel (NÂ = 989) on September 2, 2021, and remained open for 2 weeks. Data were summarized descriptively in Qualtrics and SAS Version 9.4. RESULTS: Of the 330 ACE Panel members who responded to the survey, 42% were not aware of which vaccines their state permits them to deliver. More than one-half (55%) would be willing to administer influenza or COVID-19 vaccines in their practice setting, but at present only 2% of respondents administer vaccines. To overcome vaccine administration barriers, the top 3 resources respondents want access to are the following: training or education, financial support, and access to protocols. Of all the respondents, 91% indicated the dental hygienist should be involved in certain capacities. CONCLUSIONS: Few dentists are administering vaccines, possibly owing to a number of challenges. Dental hygienists may play an integral role in the administration of vaccines in the dental clinic, but few dentists are educating their patients about vaccines. PRACTICAL IMPLICATIONS: Although dentists wishing to administer vaccines in their practice may encounter barriers, support at the state, federal, and organizational levels could help them overcome these challenges.

The myth of vaccination and autism spectrum. BACKGROUND: Among all of the studied potential causes of autism, vaccines have received some of the most scrutiny and have been the topic of many evidence-based studies. These efforts have led the great majority of scientists, physicians, and public health researchers to refute causation between vaccines and autism. RATIONALE: This presumed association and concern has been a major contributor to parents' refusal to immunize their children and has become a major threat to public health in secluded populations over the last two decades, even prior to the COVID-19 pandemic. With the emergence of COVID-19 immunizations, sentiments towards this topic were addressed as a public health concern that may influence the ability to

overcome the Corona virus worldwide. SCIENTIFIC REVIEW OF DATA: Despite the overwhelming data demonstrating that there is no link between vaccines and autism, many parents are hesitant to immunize their children because of the alleged association. Other contributing factors to the myths and conspiracy theories surrounding the association between vaccines and autism include the fact that the diagnosis of autism is typically made after the age of receiving the main childhood immunizations, as well as the occasional occurrence of regression after the age of first year vaccinations. In spite of vast evidence that the main contribution to the increase in incidence is from improvement of the diagnostic process, this rapid and publicized rise in autism diagnoses feeds parental concerns regarding any medical intervention that may be associated with the health of their children. RECOMMENDATIONS: It is plausible that with more evidence-based studies linking autism to specific etiologies the myth will diminish and disappear eventually. In an era where conspiracy theories are prevalent on social media, it is critical that evidence-based studies relating autism to specific etiologies be made public, and that information concerning autism diagnosis and causes be made more readily available through social media and parental organizations.

Collapsing glomerulopathy following SARS-CoV-2 adenovirus-vector-based vaccine: report of 2 cases.

SARS-CoV-2 vaccination-associated collapsing glomerulopathy in a kidney transplant recipient.

Nitric oxide-mediated cutaneous microvascular function is not altered in young adults following mild-to-moderate SARS CoV-2 infection. Vascular dysfunction has been reported in adults who have recovered from COVID-19. To date, no studies have investigated the underlying mechanisms of persistent COVID-19-associated vascular dysfunction. Our purpose was to quantify nitric oxide (NO)-mediated vasodilation in healthy adults who have recovered from SARS-CoV-2 infection. We hypothesized that COVID-19-recovered adults would have impaired NO-mediated vasodilation compared with adults who have not had COVID-19. In methods, we performed a cross-sectional study including 10 (5 men/5 women, 24â€‰Â±â€‰4 yr) healthy control (HC) adults who were unvaccinated for COVID-19, 11 (4 men/7 women, 25â€‰Â±â€‰6 yr) healthy vaccinated (HV) adults, and 12 (5 men/7 women, 22â€‰Â±â€‰3 yr) post-COVID-19 (PC, 19â€‰Â±â€‰14 wk) adults. COVID-19 symptoms severity (survey) was assessed. A standardized 39Â°C local heating protocol was used to assess NO-dependent vasodilation via perfusion (intradermal microdialysis) of 15 mM N(G)-nitro-l-arginine methyl ester during the plateau of the heating response. Red blood cell flux was measured (laser-Doppler flowmetry) and cutaneous vascular conductance (CVC = flux/mmHg) was expressed as a percentage of maximum (28 mM sodium nitroprusside + 43Â°C). In results, the local heating plateau (HC: 61â€‰Â±â€‰20%, HV: 60â€‰Â±â€‰19%, PC: 67â€‰Â±â€‰19%, P = 0.80) and NO-dependent vasodilation (HC: 77â€‰Â±â€‰9%, HV: 71â€‰Â±â€‰7%, PC: 70â€‰Â±â€‰10%, P = 0.36) were not different among groups. Neither symptom severity (25â€‰Â±â€‰12 AU) nor time since diagnosis correlated with the NO-dependent vasodilation (r = 0.46, P = 0.13; r = 0.41, P = 0.19, respectively). In conclusion, healthy adults who have had mild-to-moderate COVID-19 do not have altered NO-mediated cutaneous microvascular function.NEW & NOTEWORTHY Healthy young adults who have had mild-to-moderate COVID-19 do not display alterations in nitric oxide-mediated cutaneous microvascular function. In addition, healthy young adults who have COVID-19 antibodies from the COVID-19 vaccinations do not display alterations in nitric oxide-mediated cutaneous microvascular function.

A lethal mouse model for evaluating vaccine-associated enhanced respiratory disease during SARS-CoV-2 infection. One safety concern during severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine development has been the vaccine-associated enhanced disease, which is characterized by eosinophilic immunopathology and T helper cell type 2 (T(H)2)â€“biased immune responses with insufficient neutralizing antibodies. In this study, we established a lethal animal model using BALB/c mice and a mouse-passaged isolate (QHmusX) from a European lineage of SARS-CoV-2.

The QHmusX strain induced acute respiratory illness, associated with diffuse alveolar damage and pulmonary edema, in T(H)2-prone adult BALB/c mice, but not in young mice or T(H)1-prone C57BL/6 mice. We also showed that immunization of adult BALB/c mice with recombinant spike protein without appropriate adjuvant caused eosinophilic immunopathology with T(H)2-shifted immune response and insufficient neutralizing antibodies after QHmusX infection. This lethal mouse model is useful for evaluating vaccine-associated enhanced respiratory disease during SARS-CoV-2 infection and may provide new insights into the disease pathogenesis of SARS-CoV-2.

Isolated thrombosis after COVID-19 vaccination: case series. BACKGROUND: Data regarding thrombosis after COVID-19 vaccination are scarce. METHODS: Clinical and laboratory data were collected from all patients who developed thrombosis within 4Â weeks of receiving the Pfizer or Oxford/AstraZeneca vaccine. None had a COVID-19-positive swab. RESULTS: Seventeen patients were included, with average age of 48.8Â years and equal proportion of females to males. Our data suggest that thrombosis occurred in 1 in 163,000 of all individuals who had received any dose of any type of COVID-19 vaccine: six (1 in 123,000) patients after the first dose of Oxford/AstraZeneca, none after the second dose of Oxford/AstraZeneca, four (1 in 257,000) patients after the first dose of the Pfizer vaccine, and seven (1 in 102,000) patients after the second dose of Pfizer vaccine. Three of 17 patients with thrombosis (17.6%) died. CONCLUSIONS: We believe this report to be one of the earliest in the literature to address the question of whether isolated thrombosis is a possible complication of COVID-19 vaccination.

Minority Healthcare Workers' Perception of Safety and COVID-19 Vaccination Uptake.

Cerebral Venous Sinus Thrombosis With Severe Thrombocytopenia: A Fatal Adverse Event After Johnson & Johnson COVID-19 Vaccination.

A Single Dose SARS-CoV-2 Replicon RNA Vaccine Induces Cellular and Humoral Immune Responses in Simian Immunodeficiency Virus Infected and Uninfected Pigtail Macaques. The ongoing COVID-19 vaccine rollout is critical for reducing SARS-CoV-2 infections, hospitalizations, and deaths worldwide. Unfortunately, massive disparities exist in getting vaccines to vulnerable populations, including people living with HIV. Preliminary studies indicate that COVID-19 mRNA vaccines are safe and immunogenic in people living with HIV that are virally suppressed with potent antiretroviral therapy but may be less efficacious in immunocompromised individuals. This raises the concern that COVID-19 vaccines may be less effective in resource poor settings with limited access to antiretroviral therapy. Here, we evaluated the immunogenicity of a single dose COVID-19 replicon RNA vaccine expressing Spike protein (A.1) from SARS-CoV-2 (repRNA-CoV2S) in immunocompromised, SIV infected and immune competent, naÃ¯ve pigtail macaques. Moderate vaccine-specific cellular Th1 T-cell responses and binding and neutralizing antibodies were induced by repRNA-CoV2S in SIV infected animals and naÃ¯ve animals. Furthermore, vaccine immunogenicity was elicited even among the animals with the highest SIV viral burden or lowest peripheral CD4 counts prior to immunization. This study provides evidence that a SARS-CoV-2 repRNA vaccine could be employed to induce strong immunity against COVID-19 in HIV infected and other immunocompromised individuals.

Factors associated with COVID-19 vaccine receipt at two integrated healthcare systems in New York City: a cross-sectional study of healthcare workers. OBJECTIVES: To examine the factors associated with COVID-19 vaccine receipt among healthcare workers and the role of vaccine confidence in decisions to vaccinate, and to better understand concerns related to COVID-19 vaccination. DESIGN: Cross-sectional anonymous survey among front-line, support service and administrative healthcare workers. SETTING: Two large integrated healthcare systems (one private and one public) in New York City during the initial roll-out of the COVID-19 vaccine. PARTICIPANTS: 1933 healthcare workers, including nurses, physicians, allied health professionals, environmental services staff, researchers and administrative staff. PRIMARY OUTCOME MEASURES: The primary

outcome was COVID-19 vaccine receipt during the initial roll-out of the vaccine among healthcare workers. RESULTS: Among 1933 healthcare workers who had been offered the vaccine, 81% had received the vaccine at the time of the survey. Receipt was lower among black (58%; OR: 0.14, 95%â€‰CI 0.1 to 0.2) compared with white (91%) healthcare workers, and higher among non-Hispanic (84%) compared with Hispanic (69%; OR: 2.37, 95%â€‰CI 1.8 to 3.1) healthcare workers. Among healthcare workers with concerns about COVID-19 vaccine safety, 65% received the vaccine. Among healthcare workers who agreed with the statement that the vaccine is important to protect family members, 86% were vaccinated. Of those who disagreed, 25% received the vaccine ($p<0.001$). In a multivariable analysis, concern about being experimented on (OR: 0.44, 95%â€‰CI 0.31 to 0.6), concern about COVID-19 vaccine safety (OR: 0.39, 95%â€‰CI 0.28 to 0.55), lack of influenza vaccine receipt (OR: 0.28, 95%â€‰CI 0.18 to 0.44), disagreeing that COVID-19 vaccination is important to protect others (OR: 0.37, 95%â€‰CI 0.27 to 0.52) and black race (OR: 0.38, 95%â€‰CI 0.24 to 0.59) were independently associated with COVID-19 vaccine non-receipt. Over 70% of all healthcare workers responded that they had been approached for vaccine advice multiple times by family, community members and patients. CONCLUSIONS: Our data demonstrated high overall receipt among healthcare workers. Even among healthcare workers with concerns about COVID-19 vaccine safety, side effects or being experimented on, over 50% received the vaccine. Attitudes around the importance of COVID-19 vaccination to protect others played a large role in healthcare workers' decisions to vaccinate. We observed striking inequities in COVID-19 vaccine receipt, particularly affecting black and Hispanic workers. Further research is urgently needed to address issues related to vaccine equity and uptake in the context of systemic racism and barriers to care. This is particularly important given the influence healthcare workers have in vaccine decision-making conversations in their communities.

Association Between Menstrual Cycle Length and Coronavirus Disease 2019 (COVID-19) Vaccination: A U.S. Cohort. OBJECTIVE: To assess whether coronavirus disease 2019 (COVID-19) vaccination is associated with changes in cycle or menses length in those receiving vaccination as compared with an unvaccinated cohort. METHODS: We analyzed prospectively tracked menstrual cycle data using the application "Natural Cycles." We included U.S. residents aged 18-45 years with normal cycle lengths (24-38 days) for three consecutive cycles before the first vaccine dose followed by vaccine-dose cycles (cycles 4-6) or, if unvaccinated, six cycles over a similar time period. We calculated the mean within-individual change in cycle and menses length (three prevaccine cycles vs first- and second-dose cycles in the vaccinated cohort, and the first three cycles vs cycles four and five in the unvaccinated cohort). We used mixed-effects models to estimate the adjusted difference in change in cycle and menses length between the vaccinated and unvaccinated cohorts. RESULTS: We included 3,959 individuals (vaccinated 2,403; unvaccinated 1,556). Most of the vaccinated cohort received the Pfizer-BioNTech vaccine (55%) (Moderna 35%, Johnson & Johnson/Janssen 7%). Overall, COVID-19 vaccine was associated with a less than 1-day change in cycle length for both vaccine-dose cycles compared with prevaccine cycles (first dose 0.71 day-increase, 98.75% CI 0.47-0.94; second dose 0.91, 98.75% CI 0.63-1.19); unvaccinated individuals saw no significant change compared with three baseline cycles (cycle four 0.07, 98.75% CI -0.22 to 0.35; cycle five 0.12, 98.75% CI -0.15 to 0.39). In adjusted models, the difference in change in cycle length between the vaccinated and unvaccinated cohorts was less than 1 day for both doses (difference in change: first dose 0.64 days, 98.75% CI 0.27-1.01; second dose 0.79 days, 98.75% CI 0.40-1.18). Change in menses length was not associated with vaccination. CONCLUSION: Coronavirus disease 2019 (COVID-19) vaccination is associated with a small change in cycle length but not menses length.

Call for Papers on potential toxic effects of COVID-19 vaccines.

Neutralization breadth of SARS-CoV-2 viral variants following primary series and booster SARS-CoV-2 vaccines in patients with cancer. Patients with cancer are more likely to have impaired immune responses to SARS-CoV-2 vaccines. We study the breadth of responses against SARS-CoV-2 variants after primary vaccination in 178 patients with a variety of tumor types and after booster doses in a subset. Neutralization of alpha, beta, gamma, and delta SARS-CoV-2 variants is impaired relative to wildtype, regardless of vaccine type. Regardless of viral variant, mRNA1273 is the most immunogenic, followed by BNT162b2, and then Ad26.COV2.S. Neutralization of more variants (breadth) is associated with a greater magnitude of wildtype neutralization, and increases with time since vaccination; advancing age associates with a lower breadth. The concentrations of anti-spike protein antibody are a good surrogate for breadth (positive predictive value ofÂ =90% at >1,000Â U/mL). Booster SARS-CoV-2 vaccines confer enhanced breadth. These data suggest that achieving a high antibody titer is desirable to achieve broad neutralization; a single booster dose with the current vaccines increases the breadth of responses against variants.

Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans. BackgroundAdenovirus-vectored (Ad-vectored) vaccines are typically administered via i.m. injection to humans and are incapable of inducing respiratory mucosal immunity. However, aerosol delivery of Ad-vectored vaccines remains poorly characterized, and its ability to induce mucosal immunity in humans is unknown. This phase Ib trial evaluated the safety and immunogenicity of human serotype-5 Ad-vectored tuberculosis (TB) vaccine (AdHu5Ag85A) delivered to humans via inhaled aerosol or i.m. injection.MethodsThirty-one healthy, previously BCG-vaccinated adults were enrolled. AdHu5Ag85A was administered by single-dose aerosol using Aeroneb Solo Nebulizer or by i.m. injection. The study consisted of the low-dose (LD) aerosol, high-dose (HD) aerosol, and i.m. groups. The adverse events were assessed at various times after vaccination. Immunogenicity data were collected from the peripheral blood and bronchoalveolar lavage samples at baseline, as well as at select time points after vaccination.ResultsThe nebulized aerosol droplets were < 5.39 Î¼m in size. Both LD and HD of AdHu5Ag85A administered by aerosol inhalation and i.m. injection were safe and well tolerated. Both aerosol doses, particularly LD, but not i.m., vaccination markedly induced airway tissue-resident memory CD4+ and CD8+ T cells of polyfunctionality. While as expected, i.m. vaccination induced Ag85A-specific T cell responses in the blood, the LD aerosol vaccination also elicited such T cells in the blood. Furthermore, the LD aerosol vaccination induced persisting transcriptional changes in alveolar macrophages.ConclusionInhaled aerosol delivery of Ad-vectored vaccine is a safe and superior way to elicit respiratory mucosal immunity. This study warrants further development of aerosol vaccine strategies against respiratory pathogens, including TB and COVID-19.Trial registrationClinicalTrial.gov, NCT02337270.FundingThe Canadian Institutes for Health Research (CIHR) and the Natural Sciences and Engineering Research Council of Canada funded this work.

Response to and outcomes of the Pfizer BNT162B2 vaccine in hemodialysis patients-A prospective observational study. INTRODUCTION: COVID-19 infection is associated with high mortality among hemodialysis patients. Standard vaccine response is generally lower among these patients. The adequate antibody titer response and the outcome of COVID-19 vaccine responders versus non-responders are unknown. METHODS: Hemodialysis patients on maintenance hemodialysis who have received two doses of Pfizer BNT162B2 vaccine were studied. Antibody response was tested after 14â€‰days of the second dose. LIAISON SARS-CoV2 S1/S2 IgG test by DiaSorin (Italy) was used to assess antibody response. Patients were followed between 3 and 7Â months after vaccination for COVID-19 infection, hospitalization and death related to COVID-19. FINDINGS: A total of 138 patients received two doses of Pfizer BNT162B2 vaccine. One hundred and twenty-seven patients had adequate response to the vaccine with IgG levelâ€‰â‰¥â€‰15â€‰AU/ml versus 11 patients had

poor response with IgG levelâ€‰â‰¤â€‰15â€‰AU/ml. The response was 92% (127/138). Patient with history of prior COVID-19 infection had higher antibody titer mean of 339â€‰Â±â€‰113 versus 157â€‰Â±â€‰140 for patient with no prior history of COVID-19. Seven patients in both groups had COVID-19 infection post vaccine. Among the responders, five patients had COIVD-19 infection and two were hospitalized. These two patients had lower antibody titer of 23.9 and 75.2â€‰AU/ml. In comparison, three patients who were not hospitalized had higher antibody titer 96.3, 118, and 319â€‰AU/ml, respectively. In the non-responders one patient was hospitalized and one death occurred with rate of infection of 18%. DISCUSSION: Seropositive patients with low antibody titer might be associated with worse outcome among responders. The ideal antibody titer level among dialysis patient is not known. Also, prior COVID-19 infection is associated with higher response to vaccine with higher antibody titer. All non-responders did not have prior COVID-19 infection. More research is required to further evaluated protective antibody titer.

The First Guillain-Barr? Syndrome After SARS-CoV-2 Vaccination in Taiwan. PURPOSE: Guillain-Barre syndrome (GBS) is an immune-mediated disease of the peripheral nerves and could be fatal and has severe neurologic complications. This study herein reports the clinical course of the first patient of GBS after SARS-CoV-2 Oxford/AstraZeneca vaccination in Taiwan. CASE REPORT: A 38-year-old woman who presented with progressive numbness and weakness of both upper and lower limbs over 1 week. Ascending patterns was noted, and bilateral leg were more severe with diffused absence of deep tendon reflex. Clinical examination and investigation findings confirmed with the diagnosis of GBS. Deterioration of muscle power and respiratory failure had developed during the hospitalization. She had no common GBS predisposing history, but she had received her first SARS-CoV-2 Oxford/AstraZeneca vaccination intramuscularly 10 days prior to her symptoms. Clinical symptoms had much improved after double filtration plasmapheresis. CONCLUSION: Our case is the first case of GBS developed after AstraZeneca vaccine injection in Taiwan, presenting with atypical manifestation of early facial and bulbar involvement. The vaccination associated GBS should be closely monitored as other safety profile, since it may result in respiratory failure and severe neurologic complications. Keyword: Guillain-Barre Syndrome, SARS-CoV-2 Vaccination.

Change in COVID-19 risk over time following vaccination with CoronaVac: A testnegative case-control study. OBJECTIVE: To estimate the change in odds of covid-19 over time following primary series completion of the inactivated whole virus vaccine, CoronaVac (Sinovac Biotech) in SÃ£o Paulo state, Brazil. DESIGN: Test negative case-control study. SETTING: Community testing for covid-19 in SÃ£o Paulo state, Brazil. PARTICIPANTS: Adults aged 18-120 years who were residents of SÃ£o Paulo state, without a previous laboratory-confirmed covid-19 infection, who received only two doses of CoronaVac, and underwent reverse transcription polymerase chain reaction (RT-PCR) testing for SARS-CoV-2 from 17 January to 30 September 2021. MAIN OUTCOME MEASURES: RT-PCR-confirmed symptomatic covid-19 and associated hospital admissions and deaths. Cases were pair-matched to test-negative controls by age (in 5-year bands), municipality of residence, healthcare worker (HCW) status, and date of RT-PCR test (Â±3 days). Conditional logistic regression was adjusted for sex, number of covid-19-associated comorbidities, race, and previous acute respiratory infection. RESULTS: From 137,820 eligible individuals, 37,929 cases with symptomatic covid-19 and 25,756 test-negative controls with covid-19 symptoms were formed into 37,929 matched pairs. Adjusted odds ratios of symptomatic covid-19 increased with time since series completion, and this increase was greater in younger individuals, and among HCWs compared to non-HCWs. Adjusted odds ratios of covid-19 hospitalisation or death were significantly increased from 98 days since series completion, compared to individuals vaccinated 14-41 days previously: 1.40 (95% confidence interval 1.09 to 1.79) from 98-125 days, 1.55 (1.16 to 2.07) from 126-153 days, 1.56 (1.12 to 2.18) from 154-181 days, and 2.12 (1.39-3.22) from 182 days. CONCLUSIONS: In the general population of SÃ£o Paulo state, Brazil,

an increase in odds of moderate and severe covid-19 outcomes was observed over time following primary series completion with CoronaVac.
A Call for Caution in the Immunocompromised: Coronavirus Disease 2019 Associated With Mortality in a Vaccinated Lung Transplant Recipient. We describe a vaccinated lung transplant recipient who experienced a fatal outcome associated with coronavirus disease 2019 (COVID-19). Tocilizumab was administered. The patient exhibited clinical and radiographic evidence of colitis during the course of multiple secondary infections. This report emphasizes the need for more conservative precautions to prevent COVID-19 infection in transplant recipients.
First Reported Case of Reversible Cerebral Vasoconstriction Syndrome After a SARS-CoV-2 Vaccine. This is the first report of reversible cerebral vasoconstriction syndrome (RCVS) as a complication of a SARS-CoV-2 vaccination. A 38-year-old female developed visual impairment due to scotomas and thunderclap headache 18 days after the second shot of the Moderna SARS-CoV-2 vaccine. Multimodal cerebral MRI revealed anÂ acute cortical ischemic lesion in the territory of the right posterior cerebral artery (PCA) on T2-weighted images, diffusion-weighted imaging (DWI), apparent diffusion coefficient (ADC) maps and absence of the PCAÂ on magnetic resonance angiography (MRA). RCVS was diagnosed as the cause of the ischemic lesion. RCVS partially resolved upon nimodipine and anti-seizure drugs within nine days. In conclusion, this case shows that a SARS-CoV-2 vaccination can be followed by RCVS, manifesting as headache, stroke, and epileptiform discharges, and responding favorably to nimodipine.
Case Report: Clinical Management of a Patient With Metastatic Non-Small Cell Lung Cancer Newly Receiving Immune Checkpoint Inhibition During Symptomatic COVID-19. Effects of initiation of programmed-death-protein 1 (PD1) blockade during active SARS-CoV-2 infection on antiviral immunity, COVID-19 course, and underlying malignancy are unclear. We report on the management of a male in his early 40s presenting with highly symptomatic metastatic lung cancer and active COVID-19 pneumonia. After treatment initiation with pembrolizumab, carboplatin, and pemetrexed, the respiratory situation initially worsened and high-dose corticosteroids were initiated due to suspected pneumonitis. After improvement and SARS-CoV-2 clearance, anti-cancer treatment was resumed without pembrolizumab. Immunological analyses with comparison to otherwise healthy SARS-CoV-2-infected ambulatory patients revealed a strong humoral immune response with higher levels of SARS-CoV-2-reactive IgG and neutralizing serum activity. Additionally, sustained increase of Tfh as well as activated CD4(+) and CD8(+) T cells was observed. Sequential CT scans showed regression of tumor lesions and marked improvement of the pulmonary situation, with no signs of pneumonitis after pembrolizumab re-challenge as maintenance. At the latest follow-up, the patient is ambulatory and in ongoing partial remission on pembrolizumab. In conclusion, anti-PD1 initiation during active COVID-19 pneumonia was feasible and cellular and humoral immune responses to SARS-CoV-2 appeared enhanced in our hospitalized patient. However, distinguishing COVID-19-associated changes from anti-PD1-associated immune-related pneumonitis posed a considerable clinical, radiographic, and immunologic challenge.
Blood pressure measurements after mRNA-SARS-CoV-2 tozinameran vaccination: a retrospective analysis in a university hospital in France.
The Chance of COVID-19 Infection after Vaccination. The outbreak of COVID-19 that was first reported in Wuhan, China, has constituted a new emerging epidemic that has spread around the world. There are some reports illustrating the patients getting re-infected after recovering from COVID-19. Here, we provide an overview of the biphasic cycle of COVID-19, genetic diversity, immune response, and a chance of reinfection after recovering from COVID-19. The new generation of COVID-19 is a highly contagious and pathogenic infection that can lead to acute respiratory distress syndrome. Whilst most patients suffer from a mild form of the disease, there is a rising concern that

patients who recover from COVID-19 may be at risk of reinfection. The proportion of the infected population is increasing worldwide; meanwhile, the rate and concern of reinfection by the recovered population are still high. Moreover, there is little evidence on the chance of COVID-19 infection even after vaccination, which is around one percent or less. Although the hypothesis of zero reinfections after vaccination has not been clinically proven, further studies should be performed on the recovered class in clusters to study the progression of the exposure with the re-exposed subpopulations to estimate the possibilities of reinfection and, thereby, advocate the use of these antibodies for vaccine creation.

Vaccine-induced massive pulmonary embolism and thrombocytopenia following a single dose of Janssen Ad26.COV2.S vaccination. Vaccine-induced immune thrombotic thrombocytopenia (VITT) has emerged as a rare side effect of adenoviral vector-based vaccines against coronavirus disease 2019 (COVID-19), and is most frequently reported after use of the Vaxzevria (AstraZeneca) vaccine. This report describes a case of severe thrombocytopenia associated with massive pulmonary embolism and portal vein thrombosis occurring 13 days after the administration of the single-dose adenoviral vector-based vaccine Ad26.COV2.S (Janssen Vaccines). Based on early clinical suspicion, the patient quickly received treatment with corticosteroids and intravenous immunoglobulin, followed by a rapid increase in platelet count that allowed timely administration of full-dose anticoagulation. Treatment with intravenous immunoglobulin, however, could mask the ability of anti-platelet factor 4-heparin antibodies to bind and activate platelets in the presence of heparin, leading to false-negative results on the immunoassay functional test. Therefore, if VITT is suspected, blood samples for diagnostic confirmation should be collected prior to any treatment to improve diagnostic performance.

Cellular and humoral functional responses after BNT162b2 mRNA vaccination differ longitudinally between naive and subjects recovered from COVID-19. We have analyzed BNT162b2 vaccine-induced immune responses in naive subjects and individuals recovered from coronavirus disease 2019 (COVID-19), both soon after (14Â days) and later after (almost 8Â months) vaccination. Plasma spike (S)-specific immunoglobulins peak after one vaccine shot in individuals recovered from COVID-19, while a second dose is needed in naive subjects, although the latter group shows reduced levels all along the analyzed period. Despite how the neutralization capacity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mirrors this behavior early after vaccination, both groups show comparable neutralizing antibodies and S-specific B cell levels late post-vaccination. When studying cellular responses, naive individuals exhibit higher SARS-CoV-2-specific cytokine production, CD4(+) TÂ cell activation, and proliferation than do individuals recovered from COVID-19, with patent inverse correlations between humoral and cellular variables early post-vaccination. However, almost 8Â months post-vaccination, SARS-CoV-2-specific responses are comparable between both groups. Our data indicate that a previous history of COVID-19 differentially determines the functional T and B cell-mediated responses to BNT162b2 vaccination over time.

Adverse events reported after administration of BNT162b2 and mRNA-1273 COVID-19 vaccines among hospital workers: a cross-sectional survey-based study in a Spanish hospital. BACKGROUND: The World Health Organization declared COVID-19 a pandemic in March 2020. The first vaccine became available in December, with practically no post-marketing data. METHODS: An analytical cross-sectional survey-based study was conducted in a third-level hospital in Spain between March and April 2021 to describe the difference in adverse events with the BNT162b2 and mRNA-1273 COVID-19 vaccines. The participants were hospital workers who completed a survey voluntarily at least 14Â days after the last vaccine. The STROBE checklist was followed. RESULTS: One thousand two hundred and forty-nine respondents completed the survey; 48% (599) received mRNA-1273 and 52% (650) BNT162b2. Fourteen thousand four hundred and two adverse reactions were recorded,

6896 local (3939 with mRNA-1273 and 2957 with BNT162b2 (6.6 vs 4.4 reactions per patient)) and 7506 systemic (4460 with mRNA-1273 and 3046 with BNT162b2 (7.4 vs 4.7 per patient)). Local reactions were more frequent after the first dose, while systemic reactions were higher after the second, for both vaccines and in a higher percentage with mRNA-1273 compared to BNT162b2 (p-value<0.05). CONCLUSIONS: Licensed mRNA vaccines were highly safe when administered under post-marketing conditions among working-age adults. The main adverse events were mild, although they occurred in most patients, especially after the mRNA-1273 vaccine.

[Hypertension after COVID-19 vaccination]. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) rapidly spread across the world, killing more than 4 million individuals globally, with 240 million individuals being confirmed by laboratory tests. Among different therapeutic strategies to prevent SARS-CoV-2 infection, vaccines are the most promising approach for curbing the pandemic. They elicit an immune neutralizing response and thus offer protection against coronavirus disease 2019 (COVID-19). However, some questions regarding the safety of COVID-19 vaccines have been raised and based on sparse reports of severe systemic reactions after vaccination. Among these, evidences on the potential effect of vaccination on the acute rise in blood pressure have been recently accrued. Approved vaccines in Europe increase the endogenous synthesis of SARS-CoV-2 Spike proteins from a variety of cells. Once synthetized in the cells reached by the vaccine, the Spike proteins first assemble in the cytoplasm and then migrate to the cell surface to protrude with a native-like conformation. Spike proteins are recognized by the immune system which rapidly develops an immune response. Furthermore, the Spike proteins assembled in the cells which are eventually destroyed by the immune response circulate in the blood as free-floating forms. Free-floating Spike proteins may interact with angiotensin-converting enzyme 2 (ACE2) receptors leading to internalization, degradation, and dysregulation of the catalytic activities of these receptors. The consequent loss of ACE2 receptor activity leads to a rapid drop in the generation of angiotensin1,7 resulting from inactivation of angiotensin II. The imbalance between angiotensin II (overactivity) and of angiotensin1,7 (deficiency) might play a role in the genesis of acute elevation in blood pressure.

Erythema nodosum after Moderna mRNA-1273 COVID-19 vaccine.

De Novo Immunoglobulin A Vasculitis Following Exposure to SARS-CoV-2 Immunization. Background: Immunizations have been previously described as potential triggering events for the development of certain glomerular diseases. However, glomerular disease occurrences are being reported after exposure to a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. Case Report: A 50-year-old male presented to a nephrology clinic for evaluation of persistent proteinuria. Six weeks prior to evaluation, the patient had reported developing a rash 2 weeks after receiving the first dose of a SARS-CoV-2 vaccine (BNT162b2 mRNA, Pfizer, Inc). His primary care provider treated the rash with corticosteroids, leading to partial improvement of the skin lesions. Three weeks after the first vaccine injection, the patient received his scheduled second vaccine injection. Within 2 days, the rash reappeared. This time, the lesions were more severe in nature. Skin biopsy revealed immunoglobulin A (IgA)-dominant leukocytoclastic vasculitis. After the patient completed 2 weeks of oral corticosteroids, urinalysis revealed proteinuria, and consultation with nephrology was requested. On examination, healing papules were noted on his legs. Serum creatinine 2 weeks after the second dose of vaccine was 0.9 mg/dL. Microscopic examination of the urinary sediment revealed acanthocytes. Urine protein to creatinine ratio 3 weeks after the second dose of vaccine was 1.1 g/day. Serum complements were normal, and all pertinent serology was negative. Kidney biopsy findings were consistent with IgA nephropathy. Conclusion: The clinical presentation and pathologic findings in this case strongly suggest that the Pfizer SARS-CoV-2 vaccine can trigger a clinical syndrome compatible with Henoch-SchÃ¶nlein purpura. The recurrence of the rash following the second dose argues for a definite causal association by the Naranjo criteria.

COVID-19 Vaccine Uptake and Associated Factors Among Health Professionals in Ethiopia. BACKGROUND: Ethiopia has received 2.2 million doses of COVID-19 vaccine from the COVID-19 Vaccines Global Access (COVAX) facility and planned to vaccinate 20% of its population by the end of 2021. However, evidence on the current uptake of the vaccine in our country is scanty. Therefore, this study aimed to assess COVID-19 vaccine uptake and associated factors among health professionals in Ethiopia. METHODS: A national online cross-sectional E-survey was conducted on COVID-19 vaccine Uptake and associated factors among health professionals in Ethiopia from June 1 to 30, 2021. A semi-structured questionnaire was created on Google forms and disseminated online. The snowball sampling technique through the authors' network with Ethiopian residents on the popular social media like Facebook, telegram, and email was used. Descriptive statistics were performed. Multivariable logistic regression analysis was performed using Statistical Package for Social Sciences version 25, and all variables with P-value <0.05 and adjusted odds ratio at 95% CI were used to declare the predictors of the outcome variable. RESULTS: A total of 522 health professionals participated in the survey, of which about 324 (62.1%) of them were vaccinated with any of the COVID-19 vaccines at least once. The study indicated that COVID-19 vaccine uptake was associated with age range from 35 to 44 years [AOR = 12.97, 95% CI: 2.36-71.21], age beyond 45 years [AOR = 18.95, 95% CI = 2.04-36.29], being male [AOR = 2.91, 95% CI = 1.05,8.09], being only an academician [AOR = 0.23, 95% CI: 0.10-0.49], academicians working in University hospitals [AOR = 0.19, 95% CI: 0.05-0.83], perceiving their family as healthy [AOR = 4.40, 95% CI: 2.21-8.75], no history of receiving other vaccine before as an adult [AOR = 4.07, 95% CI: 2.07-8.01] and no history of contact with confirmed COVID-19 patients or clients [AOR = 0.42, 95% CI: 0.20-0.86]. CONCLUSION: The study found that COVID-19 vaccine uptake among health professionals was low. This was not sufficient to achieve herd immunity as at least nine out of ten health professionals are required for herd immunity. Ages, sex, place of work, perceived family health status, previous experience of receiving a vaccine as an adult and history of contact with COVID-19 clients or patients were the factors that influence the vaccine uptake among health professionals in Ethiopia. Hence, decision makers and health managers should consider instituting mandatory vaccination for health professionals and design strategies for the provision of the vaccine.

Safety, immunogenicity, and protection provided by unadjuvanted and adjuvanted formulations of a recombinant plant-derived virus-like particle vaccine candidate for COVID-19 in nonhuman primates. Although antivirals are important tools to control severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, effective vaccines are essential to control the current coronavirus disease 2019 (COVID-19) pandemic. Plant-derived virus-like particle (VLP) vaccine candidates have previously demonstrated immunogenicity and efficacy against influenza. Here, we report the immunogenicity and protection induced in rhesus macaques by intramuscular injections of a VLP bearing a SARS-CoV-2 spike protein (CoVLP) vaccine candidate formulated with or without Adjuvant System 03 (AS03) or cytidine-phospho-guanosine (CpG) 1018. Although a single dose of the unadjuvanted CoVLP vaccine candidate stimulated humoral and cell-mediated immune responses, booster immunization (at 28 days after priming) and adjuvant administration significantly improved both responses, with higher immunogenicity and protection provided by the AS03-adjuvanted CoVLP. Fifteen micrograms of CoVLP adjuvanted with AS03 induced a polyfunctional interleukin-2 (IL-2)-driven response and IL-4 expression in CD4 T cells. Animals were challenged by multiple routes (i.e., intratracheal, intranasal, and ocular) with a total viral dose of 10(6) plaque-forming units of SARS-CoV-2. Lower viral replication in nasal swabs and bronchoalveolar lavage fluid (BALF) as well as fewer SARS-CoV-2-infected cells and immune cell infiltrates in the lungs concomitant with reduced levels of proinflammatory cytokines and chemotactic factors in the BALF were observed in animals immunized with the CoVLP adjuvanted with AS03. No clinical, pathologic, or virologic evidence of vaccine-associated enhanced disease was

observed in vaccinated animals. The CoVLP adjuvanted with AS03 was therefore selected for vaccine development and clinical trials.

Delayed systemic urticarial reactions following mRNA COVID-19 vaccination. Background: As the vaccination campaign in response to the coronavirus disease 2019 (COVID-19) pandemic continues, concerns with regard to adverse reactions to the vaccine remain. Although immediate hypersensitivity reactions have received much attention, delayed systemic urticarial reactions after vaccination can occur. Objective: To describe the clinical presentation, vaccine excipient skin testing results, and outcomes of subsequent COVID-19 vaccination in patients who experienced delayed systemic urticarial reactions after messenger RNA (mRNA) COVID-19 vaccination. Methods: This was a retrospective case series of 12 patients referred to the Mayo Clinics in Rochester, Minnesota, and Jacksonville, Florida, between January 19, 2021, and April 30, 2021, for evaluation of delayed systemic urticarial reactions after mRNA COVID-19 vaccination. Demographics, medical and allergic history, reaction details, vaccine excipient skin testing results (when performed), and the outcome after subsequent vaccination were collected for each patient. Results: The mean age of the patients was 52 years, all were white, and 9 (75%) were women. Half of the patients had a history of drug allergy, and one had a history of chronic spontaneous urticaria. Seven patients reacted to the Pfizer-BioNTech vaccine and five reacted to the Moderna vaccine. Seven patients developed symptoms between 8 and 24 hours after vaccination. Nine patients required antihistamines for treatment. The median time to symptom resolution was 4 days. Nine patients underwent allergist-directed COVID-19 vaccine excipient skin testing, all of which were negative. Ten patients chose to receive their next mRNA COVID-19 vaccine dose, and four patients experienced recurrent delayed urticaria. Conclusion: Delayed systemic urticarial reactions after mRNA COVID-19 vaccination were not life-threatening, could be treated with antihistamines, and were not predicted with vaccine excipient skin testing. They were not a contraindication to subsequent vaccination, although patients should be counseled with regard to the possibility of recurrence.

Monitored COVID-19 mRNA vaccine second doses for people with adverse reactions after the first dose. Background: After Emergency Use Authorization of the coronavirus disease 2019 (COVID-19) vaccines, guidance was provided by the Centers for Disease Control and Prevention that persons with an immediate allergic reaction to a messenger RNA (mRNA) COVID-19 vaccine should be evaluated by an allergist/immunologist before receipt of the second dose. Methods: In vaccinating health-care personnel, we referred those with significant reactions to allergy/immunology specialists so that they could safely receive the second dose. Results: We found that many reactions after the first dose were nonallergic but could be debilitating and a barrier to the second dose. We created a protocol of premedications to allow health-care personnel to safely receive their second mRNA COVID-19 vaccine dose. Conclusion: This protocol is adaptable and can be used in settings where allergy/immunology referral is not immediately available.

Chronic spontaneous urticaria after BNT162b2 mRNA (Pfizer-BioNTech) vaccination against SARS-CoV-2. Background: The factors that trigger and exacerbate chronic spontaneous urticaria (CSU) are well known, but it is not unclear whether messenger RNA (mRNA) vaccination against severe acute respiratory syndrome coronavirus 2 can trigger new cases of CSU or a relapse of CSU after long-term remission. Objective: To study the clinical cases of patients with new-onset CSU and CSU in remission who relapsed within 3 months after BNT162b2 mRNA vaccination. Methods: All patients with a CSU diagnosis within 12 weeks of BNT162b2 mRNA vaccination were retrospectively identified and included in the new-onset CSU and the relapsed CSU groups. The first control group (CSU control group) retrospectively consisted of patients diagnosed with CSU in complete clinical remission for â‰¥ 6 months, with no CSU relapse after vaccination. The second control group (healthy control group) consisted of subjects who were fully vaccinated and without CSU, matched 1:2 for age and sex

with patients with CSU. Results: Twenty-seven patients were included in the relapsed CSU group, 32 patients in the new-onset CSU group, 179 patients in the CSU control group, and 476 subjects in the healthy control group. The relapsed CSU and new-onset CSU groups had more allergic comorbidities overall (19 [70.4%] and 13 [40.6%], respectively) than the CSU control group and the healthy control group (50 [27.9%] and 110 [23.1%], respectively; $p < 0.001$). Multiple logistic regression analysis showed that a positive autologous serum skin test result, overall allergic comorbidities, and basopenia were positively associated with the probability of CSU relapse within 3 months after BNT162b2 mRNA vaccination (odds ratio [OR] 5.54 [95% confidence interval {CI}, 2.36-13.02], $p < 0.001$); OR 6.13 [95% CI, 2.52-14.89], $p = 0.001$; and OR 2.81 [95% CI, 1.17-6.72, $p = 0.020$, respectively). Conclusion: It is possible that BNT162b2 mRNA vaccination serves as a provoking and/or relapsing factor of CSU in individuals with allergic diseases and/or predisposed autoimmunity.

Delayed allergic skin reactions to vaccines. Background: Recent advances in vaccination against the severe acute respiratory syndrome coronavirus 2 pandemic have brought allergists and dermatologists to the forefront because both immediate and delayed hypersensitivity reactions have been reported. Objective: This literature review focused on delayed reactions to vaccines, including possible causative agents and practical information on how to diagnose, evaluate with patch testing, and manage subsequent dose administration. Methods: Currently published reviews and case reports in PubMed, along with data on vaccines from the Centers for Disease Control and Prevention web site. Relevant case reports and reviews that focused on delayed reactions to vaccines were selected. Results: Most delayed hypersensitivity reactions to vaccines include cutaneous manifestations, which vary from local persistent pruritic nodules to systemic rashes. The onset is usually within a few days but can be delayed by weeks. Multiple excipients have been identified that have been implicated in delayed vaccine reactions, including thimerosal, formaldehyde, aluminum, antibiotics, and gelatin. Treatment with antihistamines, topical corticosteroids, or systemic corticosteroids alleviates symptoms in most patients. Such reactions are generally not contraindications to future vaccination. However, for more-severe reactions, patch testing for causative agents can be used to aid in diagnosis and approach further vaccination. Conclusion: Delayed-type hypersensitivity reactions to vaccines are not uncommon. If needed, patch testing can be used to confirm agents, including antibiotics, formaldehyde, thimerosal, and aluminum. In most cases, delayed cutaneous reactions are not contraindications to further vaccine administration.

Evaluation and management of adverse reactions to the COVID-2019 vaccines.

Real-world Effectiveness of the Pfizer-BioNTech BNT162b2 and Oxford-AstraZeneca ChAdOx1-S Vaccines Against SARS-CoV-2 in Solid Organ and Islet Transplant Recipients. BACKGROUND: The clinical effectiveness of vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in immunosuppressed solid organ and islet transplant (SOT) recipients is unclear. METHODS: We linked 4 national registries to retrospectively identify laboratory-confirmed SARS-CoV-2 infections and deaths within 28 d in England between September 1, 2020, and August 31, 2021, comparing unvaccinated adult SOT recipients and those who had received 2 doses of ChAdOx1-S or BNT162b2 vaccine. Infection incidence rate ratios were adjusted for recipient demographics and calendar month using a negative binomial regression model, with 95% confidence intervals. Case fatality rate ratios were adjusted using a Cox proportional hazards model to generate hazard ratio (95% confidence interval). RESULTS: On August 31, 2021, it was found that 3080 (7.1%) were unvaccinated, 1141 (2.6%) had 1 vaccine dose, and 39 260 (90.3%) had 2 vaccine doses. There were 4147 SARS-CoV-2 infections and 407 deaths (unadjusted case fatality rate 9.8%). The risk-adjusted infection incidence rate ratio was 1.29 (1.03-1.61), implying that vaccination was not associated with reduction in risk of testing positive for SARS-CoV-2 RNA. Overall, the hazard ratio for death within 28 d of SARS-CoV-2 infection was 0.80 (0.63-1.00), a 20% reduction in risk of death in vaccinated patients ($P = 0.05$). Two

doses of ChAdOx1-S were associated with a significantly reduced risk of death (hazard ratio, 0.69; 0.52-0.92), whereas vaccination with BNT162b2 was not (0.97; 0.71-1.31). CONCLUSIONS: Vaccination of SOT recipients confers some protection against SARS-CoV-2-related mortality, but this protection is inferior to that achieved in the general population. SOT recipients require additional protective measures, including further vaccine doses, antiviral drugs, and nonpharmaceutical interventions.

Host factors and history of SARS-CoV-2 infection impact the reactogenicity of BNT162b2 mRNA vaccine: results from a cross-sectional survey on 7,014 workers in healthcare. OBJECTIVE: This study aimed to improve the post-marketing surveillance on mRNA anti-SARS-CoV-2 vaccines, characterizing the adverse events (AEs) after the first dose of mRNA BNT162b vaccine. The associations between the AEs and individuals' characteristics were explored. PATIENTS AND METHODS: All adult healthcare workers at Niguarda Hospital (Milan, Italy) who were referred for the first dose of vaccine were offered to participate in a cross-sectional survey during the second-dose administration, between 18 January and 7 February 2021. All participants completed a questionnaire about age, gender, weight, height, medical history, concurrent therapies, employment status, previous diagnosis/testing for SARS-CoV-2 infection, and a list of 24 AEs (solicited AEs). The development of at least one solicited AEs was the main outcome. AEs were stratified by the presence of injection-site symptoms, systemic symptoms or both, and the differences between strata were assessed as a secondary outcome. Biometric data and reports of a previous diagnosis of SARS-CoV-2 infection were also explored, as predictors of the main outcome. RESULTS: 7,014 healthcare workers were included. An incidence of 3 per 10.000 persons for serious AEs following the first administration of the mRNA BNT162b vaccine was found. An association between the development of non-serious AEs with young age, female gender, low body mass index, and previous history of SARS-CoV-2 was described. CONCLUSIONS: This real-life study supported data on the safety profile of the BNT162b2 mRNA vaccine. Our findings on the associations between the development of non-serious AEs with some individual characteristics may help physicians and patients make educated and informed medical decisions towards anti-COVID-19 vaccination.

Ocular inflammatory events following COVID-19 vaccination: a multinational case series. BACKGROUND: Inflammatory adverse events following COVID-19 vaccination are being reported amidst the growing concerns regarding vaccine's immunogenicity and safety, especially in patients with pre-existing inflammatory conditions. METHODS: Multinational case series of patients diagnosed with an ocular inflammatory event within 14â€‰days following COVID-19 vaccination collected from 40 centres over a 3â€‰month period in 2021. RESULTS: Seventy patients presented with ocular inflammatory events within 14â€‰days following COVID-19 vaccination. The mean age was 51â€‰years (range, 19-84â€‰years). The most common events were anterior uveitis (nâ€‰=â€‰41, 58.6%), followed by posterior uveitis (nâ€‰=â€‰9, 12.9%) and scleritis (nâ€‰=â€‰7, 10.0%). The mean time to event was 5â€‰days and 6â€‰days (range, 1-14â€‰days) after the first and second dose of vaccine, respectively. Among all patients, 36 (54.1%) had a previous history of ocular inflammatory event. Most patients (nâ€‰=â€‰48, 68.6%) were managed with topical corticosteroids. Final vision was not affected in 65 (92.9%), whereas 2 (2.9%) and 3 (4.3%) had reduction in visual acuity reduced by â‰¤3 lines andâ€‰>â€‰3 lines, respectively. Reported complications included nummular corneal lesions (nâ€‰=â€‰1, 1.4%), cystoid macular oedema (nâ€‰=â€‰2, 2.9%) and macular scarring (nâ€‰=â€‰2, 2.9%). CONCLUSION: Ocular inflammatory events may occur after COVID-19 vaccination. The findings are based on a temporal association that does not prove causality. Even in the possibility of a causal association, most of the events were mild and had a good visual outcome.

Work Absence Following COVID-19 Vaccination in a Cohort of Healthcare Personnel. OBJECTIVE: To identify rates of work absence following receipt of COVID-19 vaccine in a cohort of healthcare personnel (HCP). METHODS: Short-term disability (STD) usage by HCP attributed to side effects of the COVID-19 vaccine was calculated for each vaccine manufacturer, job category, age group, and work region. Analysis was performed for the cohort of HCP during the initial vaccination campaign. RESULTS: 4.1% of COVID-19 vaccinations generated a STD claim for lost work due to side effects, with increased STD rates after dose 2 than dose 1 (7.4% and 0.9%, respectively). Rates were higher for younger HCP and allied health staff. CONCLUSIONS: While side effects from mRNA vaccine dose 2 resulted in more work absence, statistically significant geographic differences in STD suggest cultural and staffing factors may impact HCP to utilize STD following vaccination.
Angioedema Following COVID-19 Vaccination.
Re: "Transient Eyelid Edema Following COVID-19 Vaccination".
Reply re: "Thyroid Eye Disease Following COVID-19 Vaccine in a Patient With a History Graves' Disease: A Case Report".
Re: "Thyroid Eye Disease Following COVID-19 Vaccine in a Patient With a History Graves' Disease: A Case Report".
Guillain-BarrÃ© syndrome associated with BNT162b2 COVID vaccination: a first case report from South Korea.
Human Milk SARS-CoV-2 Antibodies up to 6 Months After Vaccination. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-specific antibodies have been detected in human milk up to 6 weeks post-coronavirus disease 2019 (COVID-19) vaccination. We evaluated SARS-CoV-2-specific antibodies, neutralization activity, effect of pasteurization, and persistence through 6 months after vaccination. METHODS: This prospective longitudinal study enrolled 30 pregnant or lactating women. SARS-CoV-2 antibodies and neutralization capacity were analyzed using an enzyme-linked immunosorbent assay compared at prevaccination and 1, 3, and 6 months postvaccination, and through Holder pasteurization. RESULTS: Human milk SARS-CoV-2-specific IgG levels peaked at 1 month postvaccination and persisted above prevaccination levels for at least 6 months (P = .005). SARS-CoV-2-specific IgA was detected at 1 and 3 months (both P < .001) but waned by 6 months compared with baseline (P = .07). Milk SARS-CoV-2-specific IgG and IgA correlated with serum IgG at the same time point (R2 = 0.37, P < .001 and R2 = 0.19, P < .001). Neutralization activity was seen in 83.3%, 70.4%, and 25.0% of milk samples at 1, 3, and 6 months postvaccination. Neutralization most strongly correlated with SARS-CoV-2-specific IgG (R2 = 0.57, P < .001). Pre- and postpasteurization samples showed similar IgG (0.84 vs 1.07, P = .36) and neutralizing activity (57.7% vs 58.7% inhibition, P = .27), but lower IgM and IgA levels postpasteurization (0.09 vs 0.06, P = .004 and 0.21 vs 0.18, P = .043). CONCLUSIONS: The data suggest that human milk SARS-CoV-2-specific antibodies may be available to milk-fed infants for up to 6 months. In addition, donor milk from vaccinated mothers retain IgG and neutralizing activity.
Cardiogenic shock revealing myocarditis after mRNA vaccination against covid-19: Case report and brief review for the first case in Morocco. INTRODUCTION: and importance: After its unexpected effectiveness in the clinical trials, the anti-COVID-19 vaccine type mRNA was launched on December 11, 2020, but a few months later, several reports of post-mRNA vaccination myocarditis were published, but without any proven causal link. CASE PRESENTATION: We report the case of a 14-year-old teenager admitted to the emergency department for a cardiogenic shock, the patient mentioned that he had an anti-COVID 19 vaccination 10 days before his admission. First, the vasoactive drugs had stabilized the patient; the troponins came back highly favorable but later confirmed myocarditis by magnetic resonance imaging. In this sense an etiological analysis was made and it came back without any particularities, leaving us relating the myocarditis to the vaccination. CLINICAL

DISCUSSION: Post-vaccination myocarditis is a rare event, with very few reports in the literature. After the introduction of COVID vaccination, several reports were published, mostly after the mRNA vaccine. Until now, no causal link has been proven, so we need to have more reports in this sense to have a better knowledge of this phenomenon. CONCLUSION: Until we obtain a more precise explanation of the mechanism of myocarditis after vaccination with the anti-COVID-19 vaccine, all symptoms suggesting myocarditis should be systematically monitored during the first 7 days after vaccination.
Outcomes of patients with thromboembolic events following coronavirus disease 2019 AstraZeneca vaccination: a systematic review and meta-analysis. AstraZeneca coronavirus disease 2019 (COVID-19) vaccinations have recently been implicated in thromboembolism formations. Our aim was to investigate the outcomes of patients with thromboembolic events following the AstraZeneca vaccine (ChAdOx1 nCoV-19, AZD1222). A literature search was performed from December 2019 to September 2021. Eligible studies must report participants older than 18â€Šyears vaccinated with AstraZeneca and outcomes of thromboembolic events. Pooled mean or proportion were analyzed using a random-effects model. A total of 45 unique studies (number of patientsâ€Š=â€Š144, 64.6% women, mean age 21-68â€Šyears) were included. The most common presenting adverse events were headache (12.1%), intracerebral hemorrhage (7.5%), and hemiparesis (7%). The most common thromboembolic adverse events were cerebral venous sinus thrombosis (38.5%) and deep vein thrombosis/pulmonary embolism (21.1%). The most common radiologic finding were intracerebral hemorrhage and cerebral venous thrombosis. Laboratory findings included thrombocytopenia (75%) and hypofibrinogenemia (41%). On admission, 64 patients tested positive for PF4-Heparin ELISA assay (80%). Seventy-four patients were hospitalized with 22 being admitted to the ICU. A total of 78 patients recovered while 39 patients died. This meta-analysis presents evidence to suggest vaccine-induced immune thrombotic thrombocytopenia (VITT) following AstraZeneca vaccine. Clinical practice must, therefore, account for the possibility of VITT and subsequent embolic events in certain individuals' postvaccination with adenovirus-based COVID-19 vaccines. Serum anti-PF4 suggests diagnostic value for VITT and could subsequently inform treatment choices in such instances.
Self-limited Polymyalgia Rheumatica-like Syndrome Following mRNA-1273 SARS-CoV-2 Vaccination. Polymyalgia rheumatica (PMR) is an inflammatory rheumatic disease characterized by stiffness and aching mainly in the shoulders, neck and hip girdles. The underlying pathogenesis of PMR involves myeloid lineage activation with a high expression of pattern recognition receptors. In addition, vaccination against severe acute respiratory syndrome coronavirus 2 with mRNA-1273 functions as both an immunogen and intrinsic adjuvant. It leads to the activation of innate immunity, resulting in antibody production. We herein report the first case of PMR-like syndrome seven days after mRNA-1273 vaccination. Reassuringly, the symptoms, such as pain of the neck, shoulder girdle and pelvic girdle, as well as elevated inflammatory markers were resolved within a month without glucocorticoid or immunosuppressant administration.
Manifestation of paroxysmal nocturnal hemoglobinuria after COVID-19 mRNA vaccination.
Janssen COVID-19 vaccine tolerated in 10 patients with confirmed polyethylene glycol allergy.
A Case of Multisystem Inflammatory Syndrome in a 12-Year-old Male After COVID-19 mRNA Vaccine. The pathophysiology of multisystem inflammatory syndrome (MIS) in children (MIS-C) is unknown. It occurs several weeks after COVID-19 infection or exposure; however, MIS is rarely reported after COVID-19 vaccination, and cases are mostly in adults. Herein, we present a 12-year-old male who had no prior COVID-19 infection or exposure and developed MIS-C after his first dose of COVID-19 mRNA vaccine.
Humoral Immune Response to COVID-19 Vaccination in Hemodialysis Patients: A Retrospective, Observational Case-Control Pilot Study. INTRODUCTION: Coronavirus 2 disease is associated with

increased mortality and morbidity in chronic hemodialysis patients METHODS: A retrospective, observational case-control pilot study was conducted on consecutive hemodialysis outpatients (cases) and control group of individuals with preserved renal function. Complete SARS-CoV-2 vaccination with BNT162b2 mRNA vaccine, followed by determination of serum antibodies after the second dose, were required from participants in both groups. Previous COVID-19 was an exclusion criterium. RESULTS: 21 hemodialysis patients (M:Fâ€‰=â€‰13:8, mean age 67.5â€‰Â±â€‰13.4) and 16 controls without chronic kidney disease (M:Fâ€‰=â€‰4:12, mean age 46.8â€‰Â±â€‰12.7) were included. Hemodialysis patients had lower mean titers of serum antibodies to the SARS-CoV-2 spike antigen compared with controls (492.39 vs 1901.20 IU/mL, respectively; pâ€‰<â€‰0.001), a finding that was confirmed in the age-matched analysis on 18 participants (580.8 vs 1836.4 IU/mL, pâ€‰=â€‰0.006). CONCLUSIONS: This study supports the finding of hyporesponsiveness to mRNA vaccination among hemodialysis patients.
COVID-19 vaccine-induced encephalitis and status epilepticus.
Early experience of COVID-19 vaccine-related adverse events among adolescents and young adults with rheumatic diseases: A single-center study. OBJECTIVE: Considering the concerns regarding the coronavirus disease-2019 (COVID-19) vaccine safety among pediatric patients with inflammatory rheumatic diseases (IRD) due to a lack of data, an urgent need for studies evaluating safety profiles of vaccines emerged. METHODS: Among participants vaccinated by CoronaVac inactive SARS-CoV-2 or BNT162b2 messenger RNA (mRNA) COVID-19 (Pfizer-BioNTech) vaccine, healthy children under 18 and patients under 21 with an at least 1-year follow-up period in our department for a childhood-onset rheumatic disease were included into this cross-sectional study. RESULTS: Overall, 246 subjects (141 [57.3%] females) (biologic group: 43, non-biologic group: 180, healthy control group: 23) were eligible for the study. The median age was 15.34 (12.02-20.92) years. The most common adverse events were fatigue (nÂ =Â 68, 27.6%), headache (nÂ =Â 44, 17.9%), myalgia (nÂ =Â 38, 15.4%), arthralgia (nÂ =Â 38, 15.4%), and fever (nÂ =Â 35, 14.2%). Only 3 subjects (2 patients with familial Mediterranean fever, and one healthy child) were considered to experienced serious adverse events, since they required hospitalization. Local reactions were seen in 20 (8.13%), and 27 patients (12.1%) had disease flares within 1 month after the vaccines. Although it was significantly higher in those who received the BNT162b2 mRNA vaccine (PÂ <Â .001), there was no significant relationship between adverse event frequency and age, gender, the existing diseases, ongoing treatment regimens and pre-vaccination COVID-19 histories. CONCLUSION: Although immunogenicity studies for efficacy of the vaccines and long-term follow-up studies for adverse events monitoring are required, our study indicates an acceptable safety profile of COVID-19 vaccines and encourages children with IRD to be vaccinated.
Sarcoidal immune reaction following SARS-CoV-2 vaccination. Vaccination against the SARS-CoV-2 virus is a milestone in combating the current pandemic. Nevertheless, there is increasing evidence that COVID-19 vaccination also may trigger immune- or autoimmune-mediated skin diseases. We here report the association of COVID-19 vaccination with sarcoidal immune reaction.
COVID-19 vaccination can occasionally trigger autoimmune phenomena, probably via inducing age-associated B cells.
First Identified Case of Fatal Fulminant Necrotizing Eosinophilic Myocarditis Following the Initial Dose of the Pfizer-BioNTech mRNA COVID-19 Vaccine (BNT162b2, Comirnaty): an Extremely Rare Idiosyncratic Hypersensitivity Reaction. RATIONALE: Transient myopericarditis has been recognised as an uncommon and usually mild adverse event predominantly linked to mRNA-based COVID-19 vaccines. These have mostly occurred in young males after the second dose of mRNA COVID-19 vaccines. OBJECTIVES: Fulminant necrotising eosinophilic myocarditis triggered by a variety of drugs or vaccines is an extremely rare hypersensitivity reaction carrying a substantial mortality risk.

Early recognition of this medical emergency may facilitate urgent hospital admission for investigation and treatment. Timely intervention can lead to complete cardiac recovery, but the non-specific clinical features and rarity make early diagnosis challenging. FINDINGS: The clinical and pathological observations from a case of fatal fulminant necrotising myocarditis in a 57-year-old woman, following the first dose of the Pfizer-BioNTech vaccine, are described. Other causes have been discounted with reasonable certainty. CONCLUSION: These extremely rare vaccine-related adverse events are much less common than the risk of myocarditis and other lethal complications from COVID-19 infection. The benefits of vaccination far exceed the risks of COVID-19 infection.

COVID-19 hospitalizations and deaths averted under an accelerated vaccination program in northeastern and southern regions of the USA. BACKGROUND: The fourth wave of COVID-19 pandemic peaked in the US at 160,000 daily cases, concentrated primarily in southern states. As the Delta variant has continued to spread, we evaluated the impact of accelerated vaccination on reducing hospitalization and deaths across northeastern and southern regions of the US census divisions. METHODS: We used an age-stratified agent-based model of COVID-19 to simulate outbreaks in all states within two U.S. regions. The model was calibrated using reported incidence in each state from October 1, 2020 to August 31, 2021, and parameterized with characteristics of the circulating SARS-CoV-2 variants and state-specific daily vaccination rate. We then projected the number of infections, hospitalizations, and deaths that would be averted between September 2021 and the end of March 2022 if the states increased their daily vaccination rate by 20 or 50% compared to maintaining the status quo pace observed during August 2021. FINDINGS: A 50% increase in daily vaccine doses administered to previously unvaccinated individuals is projected to prevent a total of 30,727 hospitalizations and 11,937 deaths in the two regions between September 2021 and the end of March 2022. Southern states were projected to have a higher weighted average number of hospitalizations averted (18.8) and lives saved (8.3) per 100,000 population, compared to the weighted average of hospitalizations (12.4) and deaths (2.7) averted in northeastern states. On a per capita basis, a 50% increase in daily vaccinations is expected to avert the most hospitalizations in Kentucky (56.7 hospitalizations per 100,000 averted with 95% CrI: 45.56 - 69.9) and prevent the most deaths in Mississippi, (22.1 deaths per 100,000 population prevented with 95% CrI: 18.0 - 26.9). INTERPRETATION: Accelerating progress to population-level immunity by raising the daily pace of vaccination would prevent substantial hospitalizations and deaths in the US, even in those states that have passed a Delta-driven peak in infections. FUNDING: This study was supported by The Commonwealth Fund. SMM acknowledges the support from the Canadian Institutes of Health Research [OV4 - 170643, COVID-19 Rapid Research] and the Natural Sciences and Engineering Research Council of Canada, Emerging Infectious Disease Modelling, MfPH grant. MCF acknowledges support from the National Institutes of Health (5 K01 AI141576).

Recurrent erythema nodosum after the second dose of the Pfizer-BioNTech BNT162b2 COVID-19 messenger RNA vaccine.

Primary Podocytopathies After COVID-19 Vaccination.

Early solicited adverse events following the BNT162b2 mRNA vaccination, a population survey from Saudi Arabia. Post rollout safety for the coronavirus disease vaccines is crucial and recommended. To explore the early solicited adverse events (AE) following BNT162b2 mRNA vaccination in Saudi Arabia, we distributed an online survey to adults vaccinated with BNT162b2 over the first week of June 2021, to collect data on first (V1), second doses (V2), symptoms, severity, and outcome after an informed consent was obtained. We recruited 3639 BNT162b2 vaccinated individuals, of which one-third had received two doses, 63.3% were female, 77% were healthy, and 89% had 18-55Â years of age, while only 9.8% had a history of allergy. Overall, 50.3% had any AEs after any dose, especially those younger than 55Â years of age, female, history of comorbidity, and

when adjusted for age and gender, lung or cardiovascular diseases. Overall, the most common AE were pain at the injection site (44%), tiredness (39%), or body ache (31%). Compared to V1, a higher rate of post-V2 systemic AE (36% vs. 51%). Most AEs started very early (within 3Â days), and rarely delayed in recovery (>2 weeks). Anti-pyretic was the most commonly used (51.7%), a third of which was unnecessary. Only 1.7% required hospital admission. By multivariate analysis, predictors for admission were the presence of lung or immunocompromising diseases. In conclusion, common AEs after BNT162b2 in the real world were generally mild, self-limiting, higher after the second dose, and largely mimicking that reported in clinical trials. The causality of these AE and the persistence of post-vaccination symptoms needs to be investigated further.

Post coronavirus disease-2019 vaccination Guillain-BarrÃ© syndrome. Guillain-BarrÃ© syndrome (GBS) is an acute inflammatory demyelinating disorder of the peripheral nerve. Different variants of GBS can produce a wide array of symptoms among which motor weakness, areflexia without bladder-bowel involvement are commonly encountered. ChAdOx1 nCoV-19 is a recombinant Corona Virus Vaccine and it is incorporated into India's coronavirus disease-2019 (COVID-19) vaccination program. Few rare instances of serious neurological complications have been reported following COVID-19 vaccination. Our case received 2 dose of COVID-19 vaccine. After receiving 1(st) dose he had rapid onset of ascending paralysis without any sensory and bladder bowel involvement. He received Intra Venous Immuno Globulin and Injection prednisolone for 5 days. Following that his lower limb weakness resolved rapidly but there was no improvement in upper limb weakness. Nerve conduction study showed demyelinating etiology and along with clinical features, it was appeared to be a case of GBS. However, more evidence is needed before establishing the causal relationship between COVID-19 vaccines and GBS.

From COVID-19 Vaccination Intention to Actual Vaccine Uptake: A Longitudinal Study Among Chinese Adults After Six Months of a National Vaccination Campaign. BACKGROUND: Mass COVID-19 vaccination campaigns have been launched globally, but the translation from vaccination intention to actual vaccine uptake by the public remains unknown, hindering the evaluation of present promotion strategies. METHODS: Six months after the national vaccination campaign in China, a longitudinal study was conducted among the Chinese adult population, whose vaccination intention has been previously surveyed, to examine the vaccine uptake, the relationship between intention and actual vaccination, and factors associated with actual vaccination behaviors with multiplelogistic models. RESULTS: Among the total 1047 participants, 81.8% (834/936) of those who had a prior COVID-19 vaccination intention before the campaign actually received the vaccine, while 61.3% (68/111) of those without a prior intention got vaccinated. Having a prior vaccination intention, believing in vaccine safety and receiving frequent recommendations from community sources were significant predictors of vaccine uptake, while the shortage of vaccine supply would reduce the likelihood of getting vaccinated. CONCLUSIONS: Promotion interventions for vaccination intentions need to be launched well before the availability of the vaccine. Sustaining vaccination attitudes and intentions, reducing barriers (e.g. vaccine safety concerns, accessibility, affordability) and shaping vaccination behavior would be effective in closing the intention-action gap and motivating vaccine uptake.

SARS-CoV-2 vaccination in patients with inflammatory bowel disease: A systemic review and meta-analysis. BACKGROUND: In the coronavirus disease 2019 (COVID-19) pandemic, severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccination has been effective in preventing COVID-19 infections and related mortality. The SARS-CoV-2 vaccination was also recommended by the international society for patients with inflammatory bowel disease (IBD). However, IBD patients were not recruited in prospective randomized clinical vaccine studies. To evaluate the efficacy and safety of SARS-CoV-2 vaccination in IBD patients, we conducted this systemic review and meta-analysis. METHODS: We systematically searched PubMed, Medline, and the Cochrane Library for

studies published between January 1, 2019, and September 9, 2021. Studies written in English reported the efficacy, seroconversion (anti-SARS-CoV-2 anti-spike (S) antibody titer beyond the threshold) rate, and adverse events after the SARS-CoV-2 vaccination in IBD patients. We extracted the author, date, study design, country, types of SARS-CoV-2 vaccination, number of IBD patients receiving SARS-CoV-2 vaccinations, and study outcomes. Published data from the enrolled studies were pooled to determine effect estimates. The study protocol was registered in PROSPERO (CRD42021264993). RESULTS: We analyzed findings from 27â€‰454 IBD patients who received SARS-CoV-2 vaccinations in 11 studies that met the inclusion criteria. The post-SARS-CoV-2 vaccination COVID-19 infection rate was comparable between the IBD patients and non-IBD patients (odds ratio [OR], 1.28 [95% CI, 0.96-1.71]) and higher in nonvaccinated IBD patients compared with vaccinated IBD patients (OR, 8.63 [95% CI, 5.44-13.37]). The adverse event rate, severe adverse events, and mortality after the SARS-CoV-2 vaccination were 69%, 3%, and 0%, respectively. CONCLUSION: The SARS-CoV-2 vaccine is effective and tolerated in preventing COVID-19 infections in IBD patients. Over 98% of patients had seroconversion after receiving all doses of the SARS-CoV-2 vaccination, and the influence of biologics on vaccination was limited. The SARS-CoV-2 vaccination is recommended for IBD patients.
Multisystem Inflammatory Syndrome in Children After Breakthrough Infection in a COVID-19-vaccinated Child.
Organ Donation From a Brain Dead Donor With Vaccine-induced Immune Thrombotic Thrombocytopenia After Ad26.COV2.S: The Risk of Organ Microthrombi.
SARS-CoV-2 vaccination triggered Guillain-Barre syndrome.
Leukocytoclastic vasculitis (cutaneous small-vessel vasculitis) after COVID-19 vaccination. Vaccinations may induce cutaneous adverse events, due to nonspecific inflammation or immuno-mediated reactions. Several types of vasculitis have been observed. We report on a 71-year-old woman who developed cutaneous small-vessel vasculitis after the second dose of Vaxzevria COVID-19 vaccination, showing leukocytoclastic vasculitis on histopathological examination of a skin biopsy. Cutaneous small-vessel vasculitis is a rare condition which can be idiopathic or secondary to underlying infections, connective tissue disorders, malignancy, and medications. The pathogenesis involves immune complex deposition in small blood vessels, leading to activation of the complement system and recruitment of leukocytes. Exacerbation of small-vessel vasculitis has been reported following the administration of various vaccines, particularly influenza vaccine. It is expected that SARS-CoV-2 vaccine results in the activation of B- and T-cells and antibody formation. We hypothesize that leukocytoclastic vasculitis caused by immune complex deposition within cutaneous small vessels could be a rare side effect of Vaxzevria COVID-19 vaccination.
Analysis of the humoral and cellular immune response after a full course of BNT162b2 anti-SARS-CoV-2 vaccine in cancer patients treated with PD-1/PD-L1 inhibitors with or without chemotherapy: an update after 6 months of follow-up. BACKGROUND: The durability of immunogenicity of SARS-CoV-2 vaccination in cancer patients remains to be elucidated. We prospectively evaluated the immunogenicity of the vaccine in triggering both the humoral and the cell-mediated immune response in cancer patients treated with anti-programmed cell death protein 1/programmed death-ligand 1 with or without chemotherapy 6 months after BNT162b2 vaccine. PATIENTS AND METHODS: In the previous study, 88 patients were enrolled, whereas the analyses below refer to the 60 patients still on immunotherapy at the time of the follow-up. According to previous SARS-CoV-2 exposure, patients were classified as SARS-CoV-2-naive (without previous SARS-CoV-2 exposure) and SARS-CoV-2-experienced (with previous SARS-CoV-2 infection). Neutralizing antibody (NT Ab) titer against the B.1.1 strain and total anti-spike immunoglobulin G concentration were quantified in serum samples. The enzyme-linked immunosorbent spot assay was used for quantification of anti-spike interferon-Î³

(IFN-Î³)-producing cells/10(6) peripheral blood mononuclear cells. Fifty patients (83.0%) were on immunotherapy alone, whereas 10 patients (7%) were on chemo-immunotherapy. We analyzed separately patients on immunotherapy and patients on chemo-immunotherapy. RESULTS: The median T-cell response at 6 months was significantly lower than that measured at 3 weeks after vaccination [50 interquartile range (IQR) 20-118.8 versus 175 IQR 67.5-371.3 IFN-Î³-producing cells/10(6) peripheral blood mononuclear cells; P < 0.0001]. The median reduction of immunoglobulin G concentration was 88% in SARS-CoV-2-naive subjects and 2.1% in SARS-CoV-2-experienced subjects. SARS-CoV-2 NT Ab titer was maintained in SARS-CoV-2-experienced subjects, whereas a significant decrease was observed in SARS-CoV-2-naive subjects (from median 1 : 160, IQR 1 : 40-1 : 640 to median 1 : 20, IQR 1 : 10-1 : 40; P < 0.0001). A weak correlation was observed between SARS-CoV-2 NT Ab titer and spike-specific IFN-Î³-producing cells at both 6 months and 3 weeks after vaccination (rÂ = 0.467; PÂ = 0.0002 and rÂ = 0.428; PÂ = 0.0006, respectively). CONCLUSIONS: Our work highlights a reduction in the immune response in cancer patients, particularly in SARS-CoV-2-naive subjects. Our data support administering a third dose of COVID-19 vaccine to cancer patients treated with programmed cell death protein 1/programmed death-ligand 1 inhibitors.

A Year of Pandemic-Comparison of Depression Among Neurosurgeons After the Advent of the COVID-19 Vaccine. OBJECTIVE: To determine factors associated with anxiety and depression among neurosurgeons after vaccination during the coronavirus disease 2019 (COVID-19) pandemic. METHODS: An online survey was completed by neurosurgeons worldwide over 4 weeks. Depression in neurosurgeons was assessed by the 20-item self-reporting questionnaire. RESULTS: A total of 534 responses were received and analyzed. Almost half of the respondents were from Asia (50.9%), followed by Europe (38.8%). The majority of the respondents were <40 years old (88%), and almost two thirds were trainees (62.2%). Half of the respondents worked in departments with <40 beds (50.7%), and the majority were practicing in the private sector (72.5%). Most of the respondents (85.8%) had COVID-19-positive colleagues in their department, and 64% had exposure to a COVID-19-positive colleague, family member, and/or patient. More than half of the respondents were exposed to infected patients and/or colleagues, and almost half (43.1%) underwent COVID-19 testing when exposed. Nearly half of the respondents underwent COVID-19 testing more than twice (52.4%). Of respondents, 83% had received at least the first dose of the vaccine. The odds of depression among vaccinated respondents were found to be significantly less than among unvaccinated respondents in the univariable model. CONCLUSIONS: Among health care workers, neurosurgeons are one of the groups indirectly affected by the pandemic. Adaptation to the new normal and advent of vaccines is speculated to control psychological distress among all groups of health care workers, including neurosurgeons. We found that odds of depression among vaccinated people were lower than among people who were not vaccinated.

Safety of vaccination against SARS-CoV-2 in people with rheumatic and musculoskeletal diseases: results from the EULAR Coronavirus Vaccine (COVAX) physician-reported registry. OBJECTIVES: To describe the safety of vaccines against SARS-CoV-2 in people with inflammatory/autoimmune rheumatic and musculoskeletal disease (I-RMD). METHODS: Physician-reported registry of I-RMD and non-inflammatory RMD (NI-RMDs) patients vaccinated against SARS-CoV-2. From 5 February 2021 to 27 July 2021, we collected data on demographics, vaccination, RMD diagnosis, disease activity, immunomodulatory/immunosuppressive treatments, flares, adverse events (AEs) and SARS-CoV-2 breakthrough infections. Data were analysed descriptively. RESULTS: The study included 5121 participants from 30 countries, 90% with I-RMDs (n=4604, 68% female, mean age 60.5 years) and 10% with NI-RMDs (n=517, 77% female, mean age 71.4). Inflammatory joint diseases (58%), connective tissue diseases (18%) and vasculitis (12%) were the most frequent diagnostic groups; 54% received conventional synthetic disease-modifying antirheumatic drugs (DMARDs), 42% biological DMARDs

and 35% immunosuppressants. Most patients received the Pfizer/BioNTech vaccine (70%), 17% AstraZeneca/Oxford and 8% Moderna. In fully vaccinated cases, breakthrough infections were reported in 0.7% of I-RMD patients and 1.1% of NI-RMD patients. I-RMD flares were reported in 4.4% of cases (0.6% severe), 1.5% resulting in medication changes. AEs were reported in 37% of cases (37% I-RMD, 40% NI-RMD), serious AEs in 0.5% (0.4% I-RMD, 1.9% NI-RMD). CONCLUSION: The safety profiles of SARS-CoV-2 vaccines in patients with I-RMD was reassuring and comparable with patients with NI-RMDs. The majority of patients tolerated their vaccination well with rare reports of I-RMD flare and very rare reports of serious AEs. These findings should provide reassurance to rheumatologists and vaccine recipients and promote confidence in SARS-CoV-2 vaccine safety in I-RMD patients.

Attitudes toward COVID-19 Pandemic among Fully Vaccinated Individuals: Evidence from Greece Two Years after the Pandemic. BACKGROUND: Considering the major effects of COVID-19 pandemic on health, social, economic, and political dimensions of all countries, positive attitudes toward COVID-19 pandemic are essential to control the pandemic. In our study, we investigated attitudes toward COVID-19 pandemic among fully COVID-19 vaccinated individuals two years after the pandemic and we identified predictors of attitudes. MATERIALS AND METHODS: We conducted an on-line cross-sectional study with 815 fully COVID-19 vaccinated individuals in Greece during May 2022. A self-administered and valid questionnaire was disseminated through social media platforms. We measured socio-demographic variables and COVID-19-related variables as potential predictors of attitudes toward COVID-19 pandemic. The outcome variable was attitudes toward COVID-19 pandemic (compliance with hygiene measures, trust in COVID-19 vaccination, fear of COVID-19, and information regarding the COVID-19 pandemic and vaccination). RESULTS: We found a very high level of compliance with hygiene measures, a high level of trust and information about the COVID-19 pandemic and vaccination, and a moderate level of fear of COVID-19. Also, we identified that females, participants with a higher educational level, those with a chronic disease, those with a better self-perceived physical health, and those without a previous COVID-19 diagnosis adhered more in hygiene measures. Trust in COVID-19 vaccination was higher among females, older participants, those with a higher educational level, those with a better self-perceived physical health, and those without a previous COVID-19 diagnosis. Moreover, females, older participants, those with a higher educational level, those with a chronic disease, those with a better self-perceived physical health, those that received a flu vaccine in previous season, and those without a previous COVID-19 diagnosis experienced more fear of COVID-19. Finally, level of information regarding COVID-19 pandemic and vaccination was higher for participants with a higher educational level, those without a chronic disease, those with a better self-perceived physical health, and those that received a flu vaccine in previous season. CONCLUSIONS: Understanding predictors of attitudes toward COVID-19 pandemic among fully vaccinated individuals is crucial for developing appropriate public health campaigns in the future. Vaccination should be accompanied by positive attitudes in order to decrease the frequency of negative outcomes of COVID-19, such as hospitalization, complications and mortality.

[Chu DK, Abrams EM, Golden DBK, Blumenthal KG, Wolfson AR, Stone CA Jr, et al. Risk of second allergic reaction to SARS-CoV-2 vaccines: a systematic review and meta-analysis. JAMA Intern Med 2022; 182: 376 (Meta-Analyse oder systematische Ãœbersicht)].

Population-Based Incidence, Severity, and Risk Factors Associated with Treated Acute-Onset COVID-19 mRNA Vaccination-Associated Hypersensitivity Reactions. BACKGROUND: COVID-19 mRNA vaccination-associated acute-onset hypersensitivity reactions have caused anxiety and may be contributing to vaccine hesitancy. OBJECTIVE: To determine the incidence, severity, and risk factors for treated acute-onset COVID-19 mRNA vaccination-associated hypersensitivity reactions in a well-characterized population. METHODS: All Kaiser Permanente Southern California (KPSC) members who

received COVID-19 mRNA vaccinations between December 15, 2020, and March 11, 2021, at a KPSC facility were identified and characterized, along with all treated acute-onset vaccination-associated hypersensitivity events. RESULTS: We identified 391,123 unique vaccine recipients (59.18% female, age 64.19 Â± 17.86 years); 215,156 received 2 doses (53.54% Moderna), 157,615 only a first dose (50.13% Moderna) (1961 [1.46%] >2 weeks late getting a second dose), and 18,352 (74.43% Moderna) only a second dose. Only 104 (0.028%) (85.58% female, age 53.18 Â± 15.96 years) had treated first dose events, 68 (0.030%) Moderna. Only 32 (0.014%) (93.75% female, age 57.28 Â± 17.09 years) had treated second dose events, 21 (0.016%) Moderna. Only 2 (0.00033%) vaccinations resulted in anaphylaxis. Only 27 (20.77%) of those with treated first dose reactions failed to get a second dose. Only 6 of 77 (7.8%) with first dose reactions also had second dose reactions. Individuals with treated events were more likely to be female (P < .0001), younger (P < .0001), and had more pre-existing drug "allergies" (2.11 Â± 2.12 vs 1.02 Â± 1.41 [P < .0001] for average recipients). CONCLUSIONS: Treated acute-onset hypersensitivity events were mostly benign, more common with first COVID-19 mRNA vaccine doses, more likely to occur in younger females with typical risk factors associated with multiple drug intolerance syndrome, and very unlikely to be primarily immunologically mediated.
Using Twitter for the identification of COVID-19 vaccine-associated haematological adverse events.
Fear about adverse effect on fertility is a major cause of COVID-19 vaccine hesitancy in the United States. Although COVID-19 vaccine access has increased nationwide, vaccination rates have been slow-moving, with many studies showing significant vaccine hesitancy in the U.S. We conducted an online survey using Amazon Mechanical Turk (MTurk) to identify reasons for vaccine hesitancy among unvaccinated adults between June 30 and July 1, 2021. We found that 58% of unvaccinated respondents were worried about unknown long-term adverse effects. Of these, 41% believed that the COVID-19 vaccines can negatively impact reproductive health and or fertility, and 38% were unsure of the effects on fertility. Our study demonstrates that fear regarding COVID-19 vaccine adverse effects and belief that they can negatively impact fertility is a major cause of vaccine hesitancy in the United States. We identified that urban residents, married individuals, those born outside the U.S., those with health insurance, and people with higher education and income greater than $100,000 felt that the vaccine would affect fertility more than their counterparts did. Finally, we found that 48% of unvaccinated respondents cited 'more information and research conducted on the COVID-19 vaccines' as the action that would most encourage vaccine uptake.
Immune-mediated necrotizing myopathy after BNT162b2 vaccination in a patient with antibodies against receptor-binding domain of SARS-CoV-2 and signal recognition particle.
Molecular Evolution of Severe Acute Respiratory Syndrome Coronavirus 2: Hazardous and More Hazardous Strains Behind the Coronavirus Disease 2019 Pandemic and Their Targeting by Drugs and Vaccines. Within almost the last 2 years, the world has been shaken by the coronavirus disease 2019 (COVID-19) pandemic, which has affected the lives of all people. With nearly 4.92 million deaths by October 19, 2021, and serious health damages in millions of people, COVID-19 has been the most serious global challenge after the Second World War. Besides lost lives and long-term health problems, devastating impact on economics, education, and culture will probably leave a lasting impression on the future. Therefore, the actual extent of losses will become obvious only after years. Moreover, despite the availability of different vaccines and vaccination programs, it is still impossible to forecast what the next steps of the virus are or how near we are to the end of the pandemic. In this article, the route of molecular evolution of the coronavirus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is thoroughly compiled, highlighting the changes that the virus has undergone during the last 2 years and discussing the approaches that the medical community has undertaken in the fight against virus-induced damages.

Axillary adenopathy after COVID-19 vaccine in patients undergoing breast ultrasound. After COVID-19 vaccination, a spectrum of axillary lymphadenopathy were observed in patients undergoing routine breast ultrasound. Malignancy remains the most serious differential in cases of unilateral axillary adenopathy. Knowledge of axillary ultrasound findings after COVID-19 vaccination is essential to prevent unnecessary biopsy or change in therapy in oncological patients. From March to May 2021, 10 female patients underwent breast ultrasound in our Department for the evaluation of axillary lumps. All the patients received their first or second dose of COVID-19 vaccine 20-30 days before the exam in the same extremity of the ultrasound evaluation where lymphadenopathy was found. Five patients had a personal history of previous breast cancer, and the radiologist decided to perform a core biopsy (the histology was negative for malignancy). The other five patients with no personal history of cancer underwent ultrasound and returned after a short-term follow-up. Regression of the enlarged lymph nodes was found.

Graves' disease following administration of second dose of SARS-CoV-2 vaccine. The SARS-CoV-2 vaccines have had an overwhelming success in curbing the COVID-19 global pandemic, accounting for countless lives saved. Adverse reactions are inevitable, given the vast scale of vaccination required to mitigate future surges of COVID-19. Hyperthyroid disorders have been reported as potential adverse reactions to SARS-CoV-2 vaccines in two patients with Graves' disease and a group of adults with subacute thyroiditis occurring in young women healthcare workers. We report a case of clinical Graves' disease in a woman with a previously stable multinodular goitre that occurred 14 days following her second dose of Pfizer-BioNTech SARS-CoV-2 vaccine.

Bipolar Mania Following ChAdOx1-S/nCoV-19 Vaccination.

COVID-19 Vaccine Safety in Children Aged 5-11 Years - United States, November 3-December 19, 2021. On October 29, 2021, the Food and Drug Administration (FDA) amended the Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 (BNT162b2) mRNA vaccine to expand its use to children aged 5-11 years, administered as 2 doses (10 Î¼g, 0.2mL each) 3 weeks apart (1). As of December 19, 2021, only the Pfizer-BioNTech COVID-19 vaccine is authorized for administration to children aged 5-17 years (2,3). In preauthorization clinical trials, Pfizer-BioNTech COVID-19 vaccine was administered to 3,109 children aged 5-11 years; most adverse events were mild to moderate, and no serious adverse events related to vaccination were reported (4). To further characterize safety of the vaccine in children aged 5-11 years, CDC reviewed adverse events after receipt of Pfizer-BioNTech COVID-19 vaccine reported to the Vaccine Adverse Event Reporting System (VAERS), a passive vaccine safety surveillance system co-managed by CDC and FDA, and adverse events and health impact assessments reported to v-safe, a voluntary smartphone-based safety surveillance system for adverse events after COVID-19 vaccination,* during November 3-December 19, 2021. Approximately 8.7 million doses of Pfizer-BioNTech COVID-19 vaccine were administered to children aged 5-11 years(â€) during this period; VAERS received 4,249 reports of adverse events after vaccination with Pfizer-BioNTech COVID-19 vaccine in this age group, 4,149 (97.6%) of which were not serious. Approximately 42,504 children aged 5-11 years were enrolled in v-safe after vaccination with Pfizer-BioNTech COVID-19 vaccine; after dose 2, a total of 17,180 (57.5%) local and 12,223 systemic (40.9%) reactions (including injection-site pain, fatigue, or headache) were reported. The preliminary safety findings are similar to those from preauthorization clinical trials (4,5). The Advisory Committee on Immunization Practices (ACIP) recommends the Pfizer-BioNTech COVID-19 vaccine for children aged 5-11 years for the prevention of COVID-19 (6). Parents and guardians of children aged 5-11 years vaccinated with Pfizer-BioNTech COVID-19 vaccine should be advised that local and systemic reactions are expected after vaccination. Vaccination is the most effective way to prevent COVID-19. CDC and FDA will continue to monitor vaccine safety and will provide updates as needed to guide COVID-19 vaccination recommendations.

Plasma exchange as an effective salvage therapy in AZD1222 vaccine-induced thrombotic thrombocytopenia: a case report.

Cardiovascular and haematological events post COVID-19 vaccination: A systematic review. Since COVID-19 took a strong hold around the globe causing considerable morbidity and mortality, a lot of effort was dedicated to manufacturing effective vaccines against SARS-CoV-2. Many questions have since been raised surrounding the safety of the vaccines, and a lot of media attention to certain side effects. This caused a state of vaccine hesitancy that may prove problematic in the global effort to control the virus. This review was undertaken with the aim of putting together all the reported cardiovascular and haematological events post COVID-19 vaccination in published literature and to suggest possible mechanisms to explain these rare phenomena.

Guillain-Barre syndrome following COVID-19 vaccines: A scoping review. Guillain-Barre syndromeÂ following COVID-19 vaccines (GBSfCV19v) is a reported adverse effect that remains unclear. We present a structured review based on two case reports of GBSfCV19v, a systematic review, and Vaccine Adverse Event Reporting System (VAERS) analysis to estimate the risk and describe the clinical characteristics (CC) of these events. We've searched on MEDLINE and Embase, from the inception to May 20, 2021, using the keywords: "Guillain barre syndrome" and cross-referenced with "covid-19 vaccines." We estimated the risk of GBSfCV19v, comparing it with the risk of GBS following the influenza vaccine (GBSfIv), considering the VAERS sensitivity. The clinical characteristics included: age, sex, comorbidities, type of vaccine, administered dose, clinical onset, deaths, cerebrospinal fluid (CSF), and electromyography (EMG) pattern. We found 43 cases, considering the risk of GBSfCV19v lower than GBSfIv (160-320 cases). The patients had a mean age of 54Â years and 23 (56%) were male. The types of vaccines used: Pfizer (22), Moderna (9), AstraZeneca (3), Janssen (3), and Johnson & Johnson (1). 24 cases of GBS occurred after the first dose, with clinical onset of 7Â days. CSF albuminocytological dissociation was reported in 7 patients, and EMG revealed a predominant demyelinating pattern. GBSfCV19v risk appears to be lower than what was expected from other respiratory virus vaccines. Most cases of GBS were middle-aged males within a week following the first dose of the COVID-19 vaccine, showing a typical demyelinating neuropathy with albuminocytological dissociation.

Predictive Factors for Humoral Response After 2-dose SARS-CoV-2 Vaccine in Solid Organ Transplant Patients. BACKGROUND: A weak immunogenicity has been reported in solid organ transplant (SOT) recipients after 2 doses of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. The aim of this retrospective study was to identify the predictive factors for humoral response in SOT patients. METHODS: Three hundred and ninety-three SOT patients from our center with at least 4 wk of follow-up after 2 doses of mRNA-based vaccine were included in this study. Anti-SARS-Cov-2 spike protein antibodies were assessed before and after vaccination. RESULTS: Anti-SARS-CoV-2 antibodies were detected in 34% of the patients: 33.7% of kidney transplant patients, 47.7% of liver transplant patients, and 14.3% of thoracic transplant patients (P = 0.005). Independent predictive factors for humoral response after vaccination were male gender, a longer period between transplantation and vaccination, liver transplant recipients, a higher lymphocyte count at baseline, a higher estimated glomerular filtration rate and receiving the tacrolimus + everolimus Â± steroids combination. Conversely, the nondevelopment of anti-SARS-CoV-2 antibodies after vaccination was associated with younger patients, thoracic organ recipients, induction therapy recipients, and tacrolimus + mycophenolic acid Â± steroids recipients. CONCLUSIONS: The immunosuppressive regimen is a modifiable predictive factor for humoral response to SARS-CoV-2 vaccine.

The adverse impact of COVID-19 on men's health. PURPOSE OF REVIEW: The COVID-19 pandemic has led to devastating health outcomes across the world. Initially thought to primarily affect the respiratory system, there is now clear and abundant evidence that COVID-19 can impact upon the

male genitourinary system and overall men's health. In this review article, we explore the potential mechanisms by which COVID-19 specifically affects men and we review the literature examining the adverse effects of the disease on men's health. RECENT FINDINGS: Studies suggest that men are at higher risk for severe COVID-19 infection and death. COVID-19 infection has a negative impact on men's health including worsening semen parameters, potentially lower testosterone levels, and an increased risk of erectile dysfunction. SUMMARY: COVID-19 is a highly pathogenic virus that exerts adverse effects upon the male genitourinary system in myriad ways. The COVID-19 infection can impact serum testosterone, fertility, sexual function, and mental health. Fortunately, the COVID-19 vaccine is safe and effective in preventing COVID-19 infection and many of these sequelae.

Safety of SARS-CoV-2 vaccines in patients with chronic myeloid leukemia: a multicenter survey in China.

Kikuchi-Fujimoto disease associated with hemophagocytic lymphohistiocytosis following the BNT162b2 mRNA COVID-19 vaccination.

Comparing self-reported reactogenicity between adolescents and adults following the use of BNT162b2 (Pfizer-BioNTech) messenger RNA COVID-19 vaccine: a prospective cohort study. OBJECTIVES: Although clinical data have shown that the BNT162b2 vaccine, which is widely used in many countries, is safe and effective as a protection against the SARS-CoV-2 infection, extant research in adverse reactions using real-world data of various sociodemographic characteristics is scant. METHODS: We conducted a prospective cohort study to compare age differences in self-reported reactogenicity of BNT162b2 in Hong Kong. A total of 1,516 participants were intensively followed up for two weeks following both doses of BNT162b2 vaccination, during which their basic demographic, health conditions, and medication information were collected. RESULTS: Results from the generalized mixed model showed that compared with adults aged 18 to 59 years, older adults aged 60 years or above had a lower risk of adverse reactions and adolescents aged 12 to 17 years had a moderately higher risk. CONCLUSIONS: Results of this study should be informative to parents considering BNT162b2 vaccination for their children in that moderately increased reactogenicity compared with adults is anticipated.

Kinetics and persistence of anti-SARS-CoV-2 neutralisation and antibodies after BNT162b2 vaccination in a Swiss cohort. INTRODUCTION: Since the emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), substantial effort has been made to gain knowledge about the immunity elicited by infection or vaccination. METHODS: We studied the kinetics of antibodies and virus neutralisation induced by vaccination with BNT162b2 in a Swiss cohort of SARS-CoV-2 naÃ¯ve (nâ€‰=â€‰40) and convalescent (nâ€‰=â€‰9) persons. Blood sera were analysed in a live virus neutralisation assay and specific IgG and IgA levels were measured by enzyme-linked immunoassay and analysed by descriptive statistics. RESULTS: Virus neutralisation was detected in all individuals 2-4 weeks after the second vaccine. Both neutralisation and antibodies remained positive for >4 months. Neutralisation and antibodies showed positive correlation, but immunoglobulin G (IgG) and immunoglobulin A (IgA) seroconversion took place 2-4 weeks faster than neutralisation. Spike-protein specific IgG levels rose significantly faster and were more stable over time than virus neutralisation titres or IgA responses. For naÃ¯ve but not convalescent persons, a clear boosting effect was observed. Convalescent individuals showed faster, more robust and longer-lasting immune responses after vaccination compared to noninfected persons. No threshold could be determined for spike protein-specific IgG or IgA that would confer protection in the neutralisation assay, implicating the need for a better correlate of protection then antibody titres alone. CONCLUSIONS: This study clearly shows the complex translation of antibody data and virus neutralisation, while supporting the evidence of a single dose being sufficient for effective antibody response in convalescent individuals.

Management Strategies for Patients Presenting With Symptomatic Lymphadenopathy and Breast Edema After Recent COVID-19 Vaccination. Ipsilateral axillary lymphadenopathy is a well-documented finding associated with COVID-19 vaccination. Varying guidelines have been published for the management of asymptomatic patients who have a history of recent vaccination and present with incidental lymphadenopathy at screening mammography. Some experts recommend follow-up imaging, and others suggest that clinical management, rather than repeat imaging or biopsy, is appropriate. Symptomatic patients with lymphadenopathy and/or additional abnormal imaging findings should be treated differently depending on risk factors and clinical scenarios. Although ipsilateral lymphadenopathy is well documented, ipsilateral breast edema after COVID-19 vaccination has been rarely reported. The combination of ipsilateral lymphadenopathy and diffuse breast edema after COVID-19 vaccination presents a clinical management challenge because edema can obscure underlying abnormalities at imaging. For symptomatic patients with lymphadenopathy and associated breast parenchymal abnormality, prompt action is appropriate, including diagnostic evaluation and consideration of tissue sampling. This approach may prevent delays in diagnosis and treatment of patients with malignancy masked by symptoms from the vaccination.

Association between perceived organizational support and COVID-19 vaccination intention: A cross-sectional study. OBJECTIVES: We examined the association between perceived organizational support (POS) and COVID-19 vaccination intention as well as the influence of the implementation of workplace infection prevention measures. METHODS: We analyzed data from an Internet survey of workers aged 20-65Â years conducted in December 2020, during a period of widespread COVID-19 infection in Japan. RESULTS: Of the 23Â 846 participants in this survey, 1958 (8%) reported very high POS. In the group with very high POS, 836 (43%) workers wanted the COVID-19 vaccination; in contrast 1382 (36%) workers in the group with very low POS wanted the vaccination. POS was associated with COVID-19 vaccination intention (odds ratio [OR]Â =Â 1.11). The OR decreased after additional adjustment for the number of workplace infection control measures (ORÂ =Â 1.06). In the analysis with POS as a categorical variable, very high POS was associated with COVID-19 vaccination intention (reference: very low POS) (ORÂ =Â 1.34). The OR decreased after additional adjustment for the number of workplace infection control measures (ORÂ =Â 1.17). High POS was associated with COVID-19 vaccination intention (ORÂ =Â 1.17) but not with vaccination intention after additional adjustment for the number of workplace infection control measures (ORÂ =Â 1.05). CONCLUSIONS: High POS during the COVID-19 pandemic increased employees' vaccination intention. The relationship between POS and vaccination intention was strongly influenced by implementation of workplace infection prevention measures. Implementing appropriate workplace infection prevention measures in the event of an emerging infectious disease outbreak may influence the vaccination behavior of employees, which may contribute to the acquisition of herd immunity in the community.

Severe Acute Respiratory Syndrome Coronavirus 2 Antibodies Among Healthcare Workers After Vaccine Administration in an Intensive Care Unit. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and coronavirus disease 2019 (COVID-19) emerged in China in December 2019. Healthcare workers (HCWs) are one of the high-risk groups of infection and knowledge of the seroprevalence of SARS-CoV-2 antibodies among this class is very important, not onlyÂ to understand the spread of COVID-19 among health institutions but also to assess the success of public health interventions. The objective of this prospective study was to determine the seroprevalence of COVID-19 immunoglobulin G (IgG) antibodies after vaccine administration and assess the symptomatology associated with the number of IgG antibodies. A total of 75 HCWs from an intensive care unit were studied three and six months after the second administration of the COVID-19 vaccine. They were divided into three groups: IgG antibodies between 4,160 and 6,350 (group one), greater than 6,350 (group two), and less than 4,160 (group three). After the first administration of the vaccine, 80% had

symptoms in both groups one and two, whereas only 13.8% had symptoms in group three. After the second dose of the vaccine, all elements of group one and 80% of group two developed symptoms, but only 40% of group three manifested symptoms. With the exception of one, all professionals showed a decrease in the number of IgG antibodies from three to six months. Our findings show that professionals with a higher number of IgG antibodies had more symptoms and that these rapidly declined over the three-to-six-month period.

Association of Gestational Age at Coronavirus Disease 2019 (COVID-19) Vaccination, History of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection, and a Vaccine Booster Dose With Maternal and Umbilical Cord Antibody Levels at Delivery. OBJECTIVE: To describe maternal and umbilical cord blood anti-spike immunoglobulin (Ig)G levels at delivery with coronavirus disease 2019 (COVID-19) vaccination before and during pregnancy and to assess the association of prior severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and a vaccine booster dose with anti-spike maternal and umbilical cord IgG levels. METHODS: We conducted a retrospective cohort study of women with self-reported COVID-19 vaccination (Pfizer-BioNTech, Moderna, or Johnson & Johnson/Janssen), including a booster dose, during or before pregnancy, who delivered at 34 weeks of gestation or more. Maternal and umbilical cord blood samples at delivery were analyzed for semi-quantitative anti-spike IgG. We examined the association between timing of maternal vaccination and maternal and umbilical cord anti-spike levels using a rank sum test. The relationships between a prior history of SARS-CoV-2 infection and maternal and umbilical cord anti-spike IgG levels, and between a booster dose and maternal and umbilical cord anti-spike levels, were also evaluated using a rank sum test. RESULTS: We included data from 1,359 vaccinated pregnant women, including 20 women who received a booster dose, and 1,362 umbilical cord samples. Maternal anti-spike IgG levels were detectable at delivery regardless of timing of vaccination throughout pregnancy among fully vaccinated women; however, early third-trimester vaccination was associated with the highest anti-spike IgG levels in maternal and umbilical cord blood. Among women with a history of SARS-CoV-2 infection, maternal and cord blood antibody response achieved with vaccination in early pregnancy was comparable with third-trimester vaccination in pregnant women without a history of SARS-CoV-2 infection. A booster dose in the third trimester was associated with maternal anti-spike IgG levels greater than third-trimester vaccination in women with or without a history of SARS-CoV-2 infection. DISCUSSION: Vaccination against COVID-19 before and throughout pregnancy was associated with detectable maternal anti-spike IgG levels at delivery. A complete vaccination course, prior history of SARS-CoV-2 infection, and a third-trimester booster dose were associated with the highest maternal and umbilical cord antibody levels.

Neutralizing Response Against SARS-CoV-2 Variants 8 Months After BNT162b2 Vaccination in Naive and COVID-19-Convalescent Individuals. We have investigated the evolution of the neutralizing response against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants at 8 months after Pfizer-BNT162b2 vaccination in coronavirus disease 2019 (COVID-19)-naive (nÂ =Â 21) and COVID-19-convalescent (nÂ =Â 21) individuals. Neutralizing levels declined for all variants (range 2- to 3.7-fold). Eight months after vaccination, a significant proportion (4/21) of naive individuals lacked detectable neutralizing activity against the highly transmissible SARS-CoV-2 delta variant. In the convalescent group, the impressive high initial humoral response resulted in detectable neutralizing antibody levels against all variants throughout this period.

Longitudinal dynamics of SARS-CoV-2-specific cellular and humoral immunity after natural infection or BNT162b2 vaccination. The timing of the development of specific adaptive immunity after natural SARS-CoV-2 infection, and its relevance in clinical outcome, has not been characterized in depth. Description of the long-term maintenance of both cellular and humoral responses elicited by real-world anti-SARS-CoV-2 vaccination is still scarce. Here we aimed to understand the development

of optimal protective responses after SARS-CoV-2 infection and vaccination. We performed an early, longitudinal study of S1-, M- and N-specific IFN-Î³ and IL-2 T cell immunity and anti-S total and neutralizing antibodies in 88 mild, moderate or severe acute COVID-19 patients. Moreover, SARS-CoV-2-specific adaptive immunity was also analysed in 234 COVID-19 recovered subjects, 28 uninfected BNT162b2-vaccinees and 30 uninfected healthy controls. Upon natural infection, cellular and humoral responses were early and coordinated in mild patients, while weak and inconsistent in severe patients. The S1-specific cellular response measured at hospital arrival was an independent predictive factor against severity. In COVID-19 recovered patients, four to seven months post-infection, cellular immunity was maintained but antibodies and neutralization capacity declined. Finally, a robust Th1-driven immune response was developed in uninfected BNT162b2-vaccinees. Three months post-vaccination, the cellular response was comparable, while the humoral response was consistently stronger, to that measured in COVID-19 recovered patients. Thus, measurement of both humoral and cellular responses provides information on prognosis and protection from infection, which may add value for individual and public health recommendations.

COVID-19 vaccine failure in chronic lymphocytic leukaemia and monoclonal B-lymphocytosis; humoural and cellular immunity. Chronic lymphocytic leukaemia (CLL) is associated with immunocompromise and high risk of severe COVID-19 disease and mortality. Monoclonal B-cell lymphocytosis (MBL) patients also have immune impairment. We evaluated humoural and cellular immune responses in 181 patients with CLL (160) and MBL (21) to correlate failed seroconversion [<50Â AU/ml SARS-CoV-2 II IgG assay, antibody to spike protein; Abbott Diagnostics)] following each of two vaccine doses with clinical and laboratory parameters. Following first and second doses, 79.2% then 45% of CLL, and 50% then 9.5% of MBL patients respectively remained seronegative. There was significant association between post dose two antibody level with pre-vaccination reduced IgM (pÂ <Â 0.0001), IgG2 (pÂ <Â 0.035), and IgG3 (pÂ <Â 0.046), and CLL therapy within 12Â months (pÂ <Â 0.001) in univariate analysis. By multivariate analysis, reduced IgM (pÂ <Â 0.0002) and active therapy (pÂ <Â 0.0002) retained significance. Anti-spike protein levels varied widely and were lower in CLL than MBL patients, and both lower than in normal donors. Neutralisation activity showed anti-spike levels <1000Â AU/ml were usually negative for both an early viral clade and the contemporary Delta variant and 72.9% of CLL and 53.3% of MBL failed to reach levels â‰¥1000Â AU/ml. In a representative sample, ~80% had normal T-cell responses. Failed seroconversion occurred in 36.6% of treatment-naÃ¯ve patients, in 78.1% on therapy, and in 85.7% on ibrutinib.

Association Between Immune Dysfunction and COVID-19 Breakthrough Infection After SARS-CoV-2 Vaccination in the US. IMPORTANCE: Persons with immune dysfunction have a higher risk for severe COVID-19 outcomes. However, these patients were largely excluded from SARS-CoV-2 vaccine clinical trials, creating a large evidence gap. OBJECTIVE: To identify the incidence rate and incidence rate ratio (IRR) for COVID-19 breakthrough infection after SARS-CoV-2 vaccination among persons with or without immune dysfunction. DESIGN, SETTING, AND PARTICIPANTS: This retrospective cohort study analyzed data from the National COVID Cohort Collaborative (N3C), a partnership that developed a secure, centralized electronic medical record-based repository of COVID-19 clinical data from academic medical centers across the US. Persons who received at least 1 dose of a SARS-CoV-2 vaccine between December 10, 2020, and September 16, 2021, were included in the sample. MAIN OUTCOMES AND MEASURES: Vaccination, COVID-19 diagnosis, immune dysfunction diagnoses (ie, HIV infection, multiple sclerosis, rheumatoid arthritis, solid organ transplant, and bone marrow transplantation), other comorbid conditions, and demographic data were accessed through the N3C Data Enclave. Breakthrough infection was defined as a COVID-19 infection that was contracted on or after the 14th day of vaccination, and the risk after full or partial vaccination was assessed for patients with or without immune dysfunction using Poisson regression with robust SEs. Poisson

regression models were controlled for a study period (before or after [pre- or post-Delta variant] June 20, 2021), full vaccination status, COVID-19 infection before vaccination, demographic characteristics, geographic location, and comorbidity burden. RESULTS: A total of 664â€¯722 patients in the N3C sample were included. These patients had a median (IQR) age of 51 (34-66) years and were predominantly women (nâ€‰=â€‰378â€¯307 [56.9%]). Overall, the incidence rate for COVID-19 breakthrough infection was 5.0 per 1000 person-months among fully vaccinated persons but was higher after the Delta variant became the dominant SARS-CoV-2 strain (incidence rate before vs after June 20, 2021, 2.2 [95% CI, 2.2-2.2] vs 7.3 [95% CI, 7.3-7.4] per 1000 person-months). Compared with partial vaccination, full vaccination was associated with a 28% reduced risk for breakthrough infection (adjusted IRR [AIRR], 0.72; 95% CI, 0.68-0.76). People with a breakthrough infection after full vaccination were more likely to be older and women. People with HIV infection (AIRR, 1.33; 95% CI, 1.18-1.49), rheumatoid arthritis (AIRR, 1.20; 95% CI, 1.09-1.32), and solid organ transplant (AIRR, 2.16; 95% CI, 1.96-2.38) had a higher rate of breakthrough infection. CONCLUSIONS AND RELEVANCE: This cohort study found that full vaccination was associated with reduced risk of COVID-19 breakthrough infection, regardless of the immune status of patients. Despite full vaccination, persons with immune dysfunction had substantially higher risk for COVID-19 breakthrough infection than those without such a condition. For persons with immune dysfunction, continued use of nonpharmaceutical interventions (eg, mask wearing) and alternative vaccine strategies (eg, additional doses or immunogenicity testing) are recommended even after full vaccination.

Rituximab Impairs B Cell Response But Not T Cell Response to COVID-19 Vaccine in Autoimmune Diseases. OBJECTIVE: Antibody response to the messenger RNA (mRNA) COVID-19 vaccine has been shown to be diminished in rituximab (RTX)-treated patients. We undertook this study to compare humoral and T cell responses between healthy controls, patients with autoimmune diseases treated with RTX, and those treated with other immunosuppressants, all of whom had been vaccinated with 2 doses of the mRNA COVID-19 vaccine. METHODS: We performed anti-spike IgG and neutralization assays just before and 28â€‰days after the second BNT162b2 (Pfizer-BioNTech) vaccine dose. The specific T cell response was assessed in activated CD4 and CD8 T cells using intracellular flow cytometry staining of cytokines (interferon-Î³, tumor necrosis factor, and interleukin-2) after stimulation with SARS-CoV-2 spike peptide pools. RESULTS: A lower proportion of responders with neutralizing antibodies to the vaccine was observed in the RTX group (29%; nâ€‰=â€‰24) compared to the other immunosuppressants group (80%; nâ€‰=â€‰35) (Pâ€‰=â€‰0.0001) and the healthy control group (92%; nâ€‰=â€‰26) (Pâ€‰<â€‰0.0001). No patients treated with RTX in the last 6 months showed a response. Time since last infusion was the main factor influencing humoral response in RTX-treated patients. The functional CD4 and CD8 cellular responses to SARS-CoV-2 peptides for each single cytokine or polyfunctionality were not different in the RTX group compared to the other immunosuppressants group or the control group. In RTX-treated patients, the T cell response was not different between patients with and those without a humoral response. CONCLUSION: RTX induced a diminished antibody response to the mRNA COVID-19 vaccine, but the functional T cell response was not altered compared to healthy controls and autoimmune disease patients treated with other immunosuppressants. Further work is needed to assess the clinical protection granted by a functionally active T cell response in the absence of an anti-spike antibody response.

Adult-onset Still's Disease after BNT162b2 mRNA COVID-19 Vaccine. The coronavirus disease 2019 (COVID-19) pandemic is being overcome by widespread inoculation with various COVID-19 vaccines, but concerns about the safety of the vaccines are a major hurdle to widespread vaccination. We report the first case of adult-onset Still's disease (AOSD) developing in a 36-year-old, previously healthy woman after the first dose of BNT162b2 mRNA COVID-19 vaccine (Pfizer). She visited our

hospital due to high spiking fever and sore throat that developed 10 days after vaccination. Based on thorough investigations and changes in symptoms and signs after admission, she was diagnosed with AOSD and treated with high dose steroids and tocilizumab. This report suggests the possibility that AOSD could be triggered by COVID-19 vaccines through activation of the innate immune system.

L-lysine in herpesvirus reactivation after ChAdOx1 nCoV-19 vaccine (AZD1222): Minor literature review and case report.

Erythema multiforme after Covishield/ChAdOx1 vaccination.

Lichenoid drug eruption after coronavirus disease 2019 vaccination.

Reduced COVID-19 hospitalizations among New York City residents following age-based SARS-CoV-2 vaccine eligibility: Evidence from a regression discontinuity design. BACKGROUND: In clinical trials, several SARS-CoV-2 vaccines were shown to reduce risk of severe COVID-19 illness. Local, population-level, real-world evidence of vaccine effectiveness is accumulating. We assessed vaccine effectiveness for community-dwelling New York City (NYC) residents using a quasi-experimental, regression discontinuity design, leveraging a period (January 12-March 9, 2021) whenÂ â‰¥Â 65-year-olds were vaccine-eligible but younger persons, excluding essential workers, were not. METHODS: We constructed segmented, negative binomial regression models of age-specific COVID-19 hospitalization rates among 45-84-year-old NYC residents during a post-vaccination program implementation period (February 21-April 17, 2021), with a discontinuity at age 65Â years. The relationship between age and hospitalization rates in an unvaccinated population was incorporated using a pre-implementation period (December 20, 2020-February 13, 2021). We calculated the rate ratio (RR) and 95% confidence interval (CI) for the interaction between implementation period (pre or post) and age-based eligibility (45-64 or 65-84Â years). Analyses were stratified by race/ethnicity and borough of residence. Similar analyses were conducted for COVID-19 deaths. RESULTS: Hospitalization rates among 65-84-year-olds decreased from pre- to post-implementation periods (RR 0.85, 95% CI: 0.74-0.97), controlling for trends among 45-64-year-olds. Accordingly, an estimated 721 (95% CI: 126-1,241) hospitalizations were averted. Residents just above the eligibility threshold (65-66-year-olds) had lower hospitalization rates than those below (63-64-year-olds). Racial/ethnic groups and boroughs with higher vaccine coverage generally experienced greater reductions in RR point estimates. Uncertainty was greater for the decrease in COVID-19 death rates (RR 0.85, 95% CI: 0.66-1.10). CONCLUSION: The vaccination program in NYC reduced COVID-19 hospitalizations among the initially age-eligibleÂ â‰¥Â 65-year-old population by approximately 15% in the first eight weeks. The real-world evidence of vaccine effectiveness makes it more imperative to improve vaccine access and uptake to reduce inequities in COVID-19 outcomes.

Macrophage activation syndrome in a patient with adult-onset Still's disease following first COVID-19 vaccination with BNT162b2. BACKGROUND: Adult-onset Still's disease (AOSD) is an autoinflammatory multi-systemic syndrome. Macrophage activation syndrome (MAS) is a potentially life-threatening complication of AOSD with a mortality rate of 10-20%. Especially viral infection is thought to be a common trigger for development of MAS. On the other hand, the occurrence of MAS following vaccinations is extremely rare and has been described in a few cases after measles or influenza vaccinations and more recently after ChAdOx1 nCoV-19 (COVID-19 viral vector vaccine, Oxford-AZ). CASE PRESENTATION: We report the case of a twenty-year-old female with adult-onset Still's disease (AOSD), who developed a MAS six days after receiving her first COVID-19 vaccine dose of BNT162b2 (mRNA vaccine, BioNTech/Pfizer) with ferritin levels of 136,680Â Âµg/l (ref.: 13-150Â Âµg/l). CONCLUSIONS: To the best of our knowledge, this is the first case report of development of MAS in a patient with preexisting AOSD after vaccination in general, and SARS-CoV-2 vaccination in particular. The new mRNA vaccines have generally shown a reassuring safety profile, but it has been shown that nucleic acids in general, including mRNA can act as pathogen-associated molecular

patterns that activate toll-like receptors with extensive production of pro-inflammatory cytokines and further activation of immune cells. Proving an interferon 1 response in our patient directly after vaccination, we think that in this particular case the vaccination might have acted as trigger for the development of MAS. Even if it remains difficult to establish causality in the case of rare adverse events, especially in patients with autoimmune or autoinflammatory conditions, these complications are important to monitor and register, but do not at all diminish the overwhelming positive benefit-risk ratio of licensed COVID-19 vaccines.

Safety and antibody response to two-dose SARS-CoV-2 messenger RNA vaccination in patients with multiple myeloma. BACKGROUND: Patients with multiple myeloma (MM) were excluded from the original SARS-CoV-2 mRNA vaccine trials, which may influence vaccine hesitancy in this population. We prospectively characterized the safety and immunogenicity of two-dose SARS-CoV-2 mRNA vaccination in 44 patients with MM, who underwent vaccination from 12/17/2020 to 3/18/2021. RESULTS: Rates adverse reactions were low and consistent with those documented in vaccine trials. Among those on MM therapy, 93% developed detectable anti-receptor binding domain (RBD) antibodies after dose 2, while 94% of patients not on MM therapy seroconverted. CONCLUSIONS: Two-dose SARS-CoV-2 mRNA vaccination is mildly reactogenic and leads to high rates of seroconversion in patients with MM. These findings can provide reassurance to MM patients who are hesitant to receive SARS-CoV-2 mRNA vaccines.

Reverse Takotsubo Cardiomyopathy as a Cause of Acute Chest Pain in a Young Woman Following COVID-19 Vaccination. Supplemental Digital Content is available in the text.

Cardiomyopathy Associated with Anti-SARS-CoV-2 Vaccination: What Do We Know? The SARS-CoV-2 pandemic has mobilized many efforts worldwide to curb its impact on morbidity and mortality. Vaccination of the general population has resulted in the administration of more than 6,700,000,000 doses by the end of October 2021, which is the most effective method to prevent hospitalization and death. Among the adverse effects described, myocarditis and pericarditis are low-frequency events (less than 10 per 100,000 people), mainly observed with messenger RNA vaccines. The mechanisms responsible for these effects have not been specified, considering an exacerbated and uncontrolled immune response and an autoimmune response against specific cardiomyocyte proteins. This greater immunogenicity and reactogenicity is clinically manifested in a differential manner in pediatric patients, adults, and the elderly, determining specific characteristics of its presentation for each age group. It generally develops as a condition of mild to moderate severity, whose symptoms and imaging findings are self-limited, resolving favorably in days to weeks and, exceptionally, reporting deaths associated with this complication. The short- and medium-term prognosis is favorable, highlighting the lack of data on long-term evolution, which should be determined in longer follow-ups.

Assessment of Post-Vaccination Antibody Response Eight Months after the Administration of BNT1622b2 Vaccine to Healthcare Workers with Particular Emphasis on the Impact of Previous COVID-19 Infection. At the end of 2020, COVID-19 vaccination programs were initiated in many countries, including Poland. The first vaccine approved in Poland was the BNT162b2 mRNA preparation (Pfizer/BioNTech), and the first vaccinated group were healthcare workers. The aim of the present study was to evaluate post-vaccine antibody titers 8 months after the second vaccine dose had been administered to a group of employees of the Hospital of the Ministry of the Interior and Administration in Olsztyn (Poland). The employees were divided into two groups: persons who had COVID-19 in the fourth quarter of 2020 and were vaccinated in January-February 2021, and persons without a history of COVID-19 who were vaccinated during the same period. The analyzed material was venous blood serum collected from 100 hospital employees on 23-28 September 2021. The level of anti-SARS-CoV-2 S antibodies was measured with a Roche Cobas e411 analyzer using the

electrochemiluminescence (ECLIA) method. The study demonstrated that persons with a history of SARS-CoV-2 infection had significantly higher antibody levels (taking into account gender, age, type of work performed, and severity of post-vaccination symptoms) than employees without a history of COVID-19. The study also revealed that the type of work, age, gender, and the course of SARS-CoV-2 infection can influence the humoral immune response. The presented results may prove helpful in the context of administering additional vaccine doses.

Chronic Inflammatory Demyelinating Polyneuropathy after ChAdOx1 nCoV-19 Vaccination. Recently several patients, who developed Guillain-BarrÃ© syndrome characterized by prominent bifacial weakness after ChAdOx1 nCoV-19 vaccination, were described from different centers. We recently observed a patient who developed a similar syndrome, later in the follow up he showed worsening of the neuropathy two months after the initial presentation. Repeat EMG showed reduced nerve sensory and motor conduction velocities of both upper and lower limbs, and a diagnosis of chronic inflammatory demyelinating polyneuropathy (typical CIDP) was made according to established criteria. Our report expands on the possible outcomes in patients who develop Guillain-BarrÃ¨ syndrome after COVID-19 vaccinations and suggest that close monitoring after the acute phase is needed in these patients to exclude a chronic evolution of the disease, which has important implications for long-term treatment.

Attenuation of Antibody Titers from 3 to 6 Months after the Second Dose of the BNT162b2 Vaccine Depends on Sex, with Age and Smoking Risk Factors for Lower Antibody Titers at 6 Months. OBJECTIVE: We aimed to determine antibody titers at six months and their percentage change from three to six months after the second dose of the BNT162b2 coronavirus disease 2019 (COVID-19) mRNA vaccine (Pfizer/BioNTech) and to explore clinical variables associated with titers in Japan. METHODS: We enrolled 365 healthcare workers (250 women, 115 men) whose three-month antibody titers were analyzed in our previous study and whose blood samples were collected 183 Â± 15 days after the second dose. Participant characteristics, collected previously, were used. The relationships of these factors with antibody titers at six months and percentage changes in antibody titers from three to six months were analyzed. RESULTS: Median age was 44 years. Median antibody titer at six months was 539 U/mL. Older participants had significantly lower antibody titers (20s, 752 U/mL; 60s-70s, 365 U/mL). In age-adjusted analysis, smoking was the only factor associated with lower antibody titers. Median percentage change in antibody titers from three to six months was -29.4%. The only factor significantly associated with the percentage change in Ab titers was not age or smoking, but sex (women, -31.6%; men, -25.1%). CONCLUSION: The most important factors associated with lower antibody titers at six months were age and smoking, as at three months, probably reflecting their effect on peak antibody titers. However, the only factor significantly associated with the attenuation in Ab titers from three to six months was sex, which reduced the sex difference seen during the first three months. Antibody titers may be affected by different factors at different time points.

Immune Thrombocytopenia Induced by the Chimpanzee Adenovirus-Vectored Vaccine against SARS-CoV-2 Infection. We present a case of immune thrombocytopenia (ITP) induced by the chimpanzee adenovirus-vectored vaccine, without evidence of thrombosis, eight days after vaccine administration. The thrombocytopenia condition improved after administering steroid treatment. This adenovirus vaccine had been reported to induce rare side effects, such as immune thrombotic thrombocytopenia. This case report showed that it could also induce immune thrombocytopenia without the presence of thrombosis. Therefore, we should be cautious of this rare side effect as global vaccine administrations against coronavirus disease increase.

Comparison of SARS-CoV-2-Specific Antibodies in Human Milk after mRNA-Based COVID-19 Vaccination and Infection. SARS-CoV-2-specific antibodies are secreted into human milk of infected or vaccinated lactating women and might provide protection to the breastfed infant against

COVID-19. Differences in antibody response after these types of exposure are unknown. In this longitudinal cohort study, we compared the antibody response in human milk following SARS-CoV-2 vaccination or infection. We analyzed 448 human milk samples of 28 lactating women vaccinated with the SARS-CoV-2 vaccine BNT162b2 as well as 82 human milk samples of 18 lactating women with a prior SARS-CoV-2 infection. The levels of SARS-CoV-2-specific IgA in human milk were determined over a period of 70 days both after vaccination and infection. The amount of SARS-CoV-2-specific IgA in human milk was similar after SARS-CoV-2 vaccination and infection. After infection, the variability in IgA levels was higher than after vaccination. Two participants with detectable IgA prior to vaccination were analyzed separately and showed higher IgA levels following vaccination compared to both groups. In conclusion, breastfed infants of mothers who have been vaccinated with the BNT162b2 vaccine receive human milk with similar amounts of SARS-CoV-2-specific antibodies compared to infants of previously infected mothers.

Humoral Immune Response after the Third SARS-CoV-2 mRNA Vaccination in CD20 Depleted People with Multiple Sclerosis. CD20 depletion is a risk factor for unfavorable outcomes of COVID-19 in people with MS (pwMS). Evidence suggests that protective IgG response to mRNA-based vaccines in B cell-depleted individuals is limited. We studied the seroconversion after the third mRNA SARS-CoV-2 vaccine in B cell-depleted pwMS with limited or no IgG response after the standard immunization. Sixteen pwMS treated with ocrelizumab or rituximab received a third homologous SARS-CoV-2 mRNA vaccine, either the Moderna mRNA-1273 or Pfizer-BioNTech's BNT162b2 vaccine. We quantified the response of IgG antibodies against the spike receptor-binding domain of SARS-CoV-2 four weeks later. An antibody titer of 100 AU/mL or more was considered clinically relevant. The median time between the last infusion of the anti-CD20 treatment and the third vaccination was 22.9 weeks (range 15.1-31.3). After the third vaccination, one out of 16 patients showed an IgG titer deemed clinically relevant. Only the seroconverted patient had measurable B-cell counts at the time of the third vaccination. The development of a humoral immune response remains rare in pwMS on anti-CD20 therapy, even after third dose of the homologous SARS-CoV-2 mRNA vaccine. It remains to be determined whether T-cell responses can compensate for the lack of seroconversion and provide sufficient protection against CoV-2 infections.

Local and Systemic Adverse Reactions to mRNA COVID-19 Vaccines Comparing Two Vaccine Types and Occurrence of Previous COVID-19 Infection. The aim of this study was to assess adverse reactions to COVID-19 vaccines, comparing the BNT162b2 or the mRNA-1273 COVID-19 vaccines and the presence and seriousness of a previous COVID-19 infection. We conducted a cross-sectional online survey of vaccinated healthcare workers at a tertiary hospital in Barcelona (Spain). Thirty-eight percent of vaccine recipients responded to the questionnaire. We compared the prevalence of adverse reactions by vaccine type and history of COVID-19 infections. A total of 2373 respondents had received the BNT162b2 vaccine, and 506 the mRNA-1273 vaccine. The prevalence of at least one adverse reaction with doses 1 and 2 was 41% and 70%, respectively, in the BNT162b2 group, and 60% and 92% in the mRNA-1273 group ($p < 0.001$). The BNT162b2 group reported less prevalence of all adverse reactions. Need for medical leave was significantly more frequent among the mRNA-1273 group (12% versus 4.6% $p < 0.001$). Interestingly, respondents with a history of allergies or chronic illnesses did not report more adverse reactions. The frequency of adverse reactions with dose 2 was 96% (95% CI 88-100%) for those with a history of COVID-19 related hospitalization, and 86% (95% CI 83-89%) for those with mild or moderate symptomatic COVID-19, significantly higher than for participants with no history of COVID-19 infections (67%, 95% CI 65-69%). Our results could help inform vaccine recipients of the probability of their having adverse reactions to COVID-19 vaccines.

Comparison of the Development of SARS-Coronavirus-2-Specific Cellular Immunity, and Central Memory CD4+ T-Cell Responses Following Infection versus Vaccination. Memory T-cell responses

following infection with coronaviruses are reportedly long-lived and provide long-term protection against severe disease. Whether vaccination induces similar long-lived responses is not yet clear since, to date, there are limited data comparing memory CD4+ T-cell responses induced after SARS-CoV-2 infection versus following vaccination with BioNTech/Pfizer BNT162b2. We compared T-cell immune responses over time after infection or vaccination using ELISpot, and memory CD4+ T-cell responses three months after infection/vaccination using activation-induced marker flow cytometric assays. Levels of cytokine-producing T-cells were remarkably stable between three and twelve months after infection, and were comparable to IFNÎ³+ and IFNÎ³+IL-2+ T-cell responses but lower than IL-2+ T-cell responses at three months after vaccination. Consistent with this finding, vaccination and infection elicited comparable levels of SARS-CoV-2 specific CD4+ T-cells after three months in addition to comparable proportions of specific central memory CD4+ T-cells. By contrast, the proportions of specific effector memory CD4+ T-cells were significantly lower, whereas specific effector CD4+ T-cells were higher after infection than after vaccination. Our results suggest that T-cell responses-as measured by cytokine expression-and the frequencies of SARS-CoV-2-specific central memory CD4+T-cells-indicative of the formation of the long-lived memory T-cell compartment-are comparably induced after infection and vaccination.

Humoral Immune Response following SARS-CoV-2 Vaccination in Liver Transplant Recipients. As COVID-19 remains an issue in transplantation medicine, a successful vaccination can prevent infections and life-threatening courses. The probability of poor immune response in liver transplant recipients gained attention and insecurity among those patients, leading us to investigate the humoral immune response alongside the influence of underlying diseases and immunosuppressive regimen on seroconversion rates. We included 118 patients undergoing anti-spike-protein-IgG testing at least 21 days after completed SARS-CoV-2 vaccination. Ninety-seven patients also underwent anti-spike-protein-IgA testing. The influence of baseline demographics, immunosuppressive regimen and underlying disease on seroconversion was analyzed, and 92 of 118 patients (78.0%) developed anti-spike-protein-IgG antibodies. Patients with a history of alcoholic liver disease before transplantation showed significantly lower seroconversion rates ($p = 0.006$). Immunosuppression also significantly influenced antibody development ($p < 0.001$). Patients run on a mycophenolate mofetil (MMF)-based regimen were more likely not to develop antibodies compared to patients run on a non-MMF regimen ($p < 0.001$). All patients weaned off immunosuppression were seropositive. The seroconversion rate of 78.0% in our cohort of liver transplant recipients is promising. The identification of alcohol-induced cirrhosis as underlying disease and MMF for immunosuppression as risk factors for seronegativity may serve to identify vaccination non-responder after liver transplantation.

Questionnaire Survey of Possible Association of Allergic Diseases with Adverse Reactions to SARS-CoV-2 Vaccination. To protect against COVID-19, SARS-CoV-2 vaccines have been widely used. Besides anaphylaxis, some less severe adverse effects may occur at higher frequencies. It remains unclear whether present or past histories of allergic diseases exert effects on local and systemic reactions. We conducted a questionnaire survey among workers in our hospital. We analyzed the adverse effects occurring after the first and second doses of the Pfizer-BioNTech vaccine in 955 subjects. The presence or absence of local injection reactions and systemic reactions (headache, fatigability, fever, muscle pain, and joint pain) was questioned. The intensities of these reactions were graded on a scale of 0-4 (except fever) or 0-2 (fever). The allergic diseases that we focused on were bronchial asthma, atopic dermatitis, food allergy, pollinosis, and hand eczema. For the systemic reactions, fatigability after the first dose tended to be more severe in the bronchial asthma than in the non-allergic group. Headache, joint pain, and fever tended to be more severe in the food allergy than in the non-allergic group after the second dose. For the local skin reactions, atopic dermatitis

subjects tended to show rather less severe local skin reactions after the second dose. The results contribute to the guidelines for the care of individuals with different allergy histories, so that they may safely receive their vaccine.

Humoral Immune Response to SARS-CoV-2 Vaccination after a Booster Vaccine Dose in Two Kidney Transplant Recipients with Fabry Disease and Variable Secondary Immunosuppressive Regimens. The urgent need to fight the COVID-19 pandemic has accelerated the development of vaccines against SARS-CoV-2 and approval processes. Initial analysis of two-dose regimens with mRNA vaccines reported up to 95% efficacy against the original strain of the SARS-CoV-2 virus. Challenges arose with the appearance of new strains of the virus, and reports that solid organ transplant recipients may have reduced vaccination success rates after a two-dose mRNA vaccination regimen encouraged health authorities to recommend a booster in immunocompromised patients. Fabry disease is an X-linked inherited lysosomal disorder, which may lead to chronic end-stage renal disease. We report on two patients with advanced Fabry disease, renal graft and adjunctive immunosuppressive therapies who exhibited variable humoral vaccination-related immune responses against SARS-CoV-2 after three vaccine doses. The first patient developed mild COVID-19 infection, while the second patient did not seroconvert after three shots of an mRNA vaccine. Both cases emphasize that patients with Fabry disease and renal graft are susceptible to develop a weak response to COVID-19 vaccination and highlight the importance of maintaining barrier protection measures. Vaccination of family members should be encouraged to lower the risk of viral transmission to immunocompromised, transplanted patients, including vaccinated ones.

Ocular Manifestations after Receiving COVID-19 Vaccine: A Systematic Review. The coronavirus disease 2019 (COVID-19) pandemic has had profound and lasting consequences since 2019. Although vaccines against COVID-19 have been developed and approved under emergency use authorization, various adverse events have also been reported after COVID-19 vaccination. This review was undertaken to help clinicians recognize the possible manifestations and systemic pathogenesis, especially those related to the eye, after receiving COVID-19 vaccination. A systemic search was performed on 22 August 2021 through Embase, Medline, and Cochrane Library for publications on ocular manifestations after COVID-19 vaccination. Two case-control studies/retrospective cohort studies, one cross-sectional study, three case series, sixteen case reports, two images, and seven letters were included. Ocular manifestations after receiving COVID-19 vaccines may appear on the eyelid, cornea and ocular surface, retina, uvea, nerve, and vessel. The ocular manifestations occurred up to forty-two days after vaccination, and vaccine-induced immunologic responses may be responsible. Although the incidence rate of ocular symptoms is considerably lower in the vaccinated subjects than in COVID-19 patients, physicians should be aware of the possible associations between COVID-19 vaccines and ocular symptoms for the early diagnosis and treatment of vision problems or life-threatening complications.

The Differences in the Level of Anti-SARS-CoV-2 Antibodies after mRNA Vaccine between Convalescent and Non-Previously Infected People Disappear after the Second Dose-Study in Healthcare Workers Group in Poland. (1) Background: In many infections, antibodies play a crucial role in controlling infection. In COVID-19, the dynamics of the immune system response to SARS-CoV-2 is not fully understood. (2) Methods: The study was conducted on 120 healthcare workers from Dr. Antoni Jurasz University Hospital No. 1 in Bydgoszcz, between June and December 2020. In all participants, IgA and IgG antibody serum concentrations were measured using the semi-quantitative Anti-SARS-CoV-2 ELISA test (Euroimmun). After vaccination, in January and February 2021, antibody levels were examined using the quantitative IgG Anti-SARS-CoV-2 Quantivac ELISA test (Euroimmun). (3) Results: During the whole study period, the SARS-CoV-2 infection was confirmed in 29 (24.2%) participants. In all infected participants, IgA and IgG antibodies were detectable after

infection by semi-quantitative serological tests. Levels of antibodies were higher one month after the first dose in the convalescents than in the non-previously infected participants. In this second group, the level of antibodies increased significantly after the second dose of vaccines compared to the first dose. (4) Conclusions: The level of antibodies after the first dose of vaccine in the convalescents' group is higher than in the SARS-CoV-2 non-infected group, but the differences disappear after the second vaccination.

COVID-19 Vaccination Acceptance in China after It Becomes Available: A Cross-Sectional Study. The outbreak of coronavirus disease 2019 (COVID-19) has led to numerous tragic deaths all over the world. Great efforts have been made by worldwide nations for COVID-19 targeted vaccine development since the disease outbreak. In January 2021, the Chinese government started to provide free vaccination among nationwide communities, which was optional for citizens. As no evidence has been provided so far regarding COVID-19 vaccination acceptance since the initiation of nationwide vaccination, this study aims to investigate COVID-19 vaccination acceptance among Chinese citizens as well as its associated factors as an attempt to bridge such gap embedded in the current literature. An anonymous cross-sectional study was conducted online in March and April 2021 among adults, with the survey questionnaire designed based on the framework of the health belief model (HBM). Information on socio-demographics, risk perception, past pandemic-related experience, awareness of vaccination as well as acceptance of COVID-19 vaccination were collected. Chi-squared test and multi-level regression were performed to distinguish the acceptance between different groups as well as to identify the significant predictors. A total of 3940 participants completed the survey, with 90.6% of the participants reporting strong willingness to get vaccinated. A list of factors were found to be significantly associated with individuals' acceptance of vaccination, including the region of residence, ethnicity, annual income, whether or not they had experienced a major pandemic event in the past, risk perception of the COVID-19 as well as the awareness of receiving vaccination. Safety concerns about the vaccine (27.7%), concerns about receiving vaccination immediately after newly developed vaccines were released into the market (22.4%) as well as concerns about the potential side effects induced by vaccination (22.1%) were identified as the primary reasons of residents' resistance against vaccination. Overall, residents demonstrated strong willingness to receive vaccination against COVID-19 in China. However, the improvement of vaccination-related knowledge among Chinese residents should be highlighted as a critical strategy to facilitate the penetration of nationwide vaccination in order to ultimately achieve the establishment of herd immunity in China.

Serum Antibody Response Comparison and Adverse Reaction Analysis in Healthcare Workers Vaccinated with the BNT162b2 or ChAdOx1 COVID-19 Vaccine. The COVID-19 pandemic is changing rapidly and requires different strategies to maintain immunization. In Korea, different COVID-19 vaccines are recommended and available for various populations, including healthcare workers (HCWs) at high risk of SARS-CoV-2 infection. We plan to evaluate the adverse events (AEs) and immunogenicity of the BNT162b2 and ChAdOx1 vaccines in HCWs at a single center. This cohort study included HCWs fully vaccinated with either BNT162b2 or ChAdOx1. Blood samples were taken eight weeks after the second vaccination with both COVID-19 vaccines and six months after the second vaccination from participants with the BNT162b2 vaccine. The primary endpoint for immunogenicity was the serum neutralizing antibody responses eight weeks after vaccination. The secondary endpoint was the incidence of various AEs within 28 days of each vaccination. Between 16 March and 23 June 2021, 115 participants were enrolled (65 in the ChAdOx1 group and 50 in the BNT162b2 group). Significantly higher surrogate virus neutralization test (sVNT) inhibition was observed in participants vaccinated with two doses of BNT162b2 (mean (SD) 91.4 (9.68)%) than in those vaccinated with ChAdOx1 (mean (SD) 73.3 (22.57)%). The effectiveness of the BNT162b2 vaccine was maintained across all age and gender categories. At six months after the second dose,

serum antibody levels declined significantly in the BNT162b2 group. The main adverse events, including fever, myalgia, fatigue, and headache, were significantly higher in the ChAdOx1 group after the first dose, whereas, after the second dose, those AEs were significantly higher in the BNT162b2 group ($p < 0.05$). Two doses of either the ChAdOx1 or the BNT162b2 COVID-19 vaccine resulted in very high seropositivity among the HCWs at our center. The quality of the antibody response, measured by sVNT inhibition, was significantly better with the BNT162b2 vaccine than with the ChAdOx1 vaccine. There was no significant association between neutralizing antibody response and AE after each vaccination in our cohort.

Clinical Phenotype and Contagiousness of Early Breakthrough SARS-CoV-2 Infections after BNT162b2 COVID-19 mRNA Vaccine: A Parallel Cohort Study in Healthcare Workers. We evaluated the clinical protection of BNT162b2 mRNA vaccine in healthcare workers (HCWs) and how COVID-19 manifestations and contagiousness change as the time since first dose increases. A matched (1:2 ratio) parallel cohort study was performed. During the first three months of vaccination campaign, HCWs of the entire health district ASL CittÃ di Torino (Turin, Italy) were classified according to SARS-CoV-2-positivity in respect of the vaccination schedule: post-first-dose (fHCWs, <12 days), partially (PHCWs, â‰¥12 from first dose to â‰¤7 days after the second), and totally vaccinated (THCWs, â‰¥8 days after the second dose). Age-/sex-matched unvaccinated controls were randomly selected from all the SARS-CoV-2-positivity detected in the same district and period. Previous infections were excluded. Clinical and virologic data (ORF1ab gene cycle threshold values, Ct) were recorded. In total, 6800 HCWs received at least one dose, and 55 tested positive subsequently: 20 fHCWs, 25 PHCWs, 10 THCWs. Furthermore, 21.8% of breakthrough infections were in male, with a median age of 49 years (32-56), and 51.4% occurred while SARS-CoV-2 B.1.1.7 variant was predominant. The incident relative risk was 0.13 (0.12-0.15) for PHCWs and 0.06 (0.05-0.07) for THCWs. Compared to controls (n = 110), no difference was observed in fHCWs, while PHCWs and THCWs showed higher prevalence of asymptomatic infections, fewer signs/symptoms with a milder systemic involvement, and significantly higher Ct values (PHCWs 30.3 (24.1-35.5) vs. 22.3 (19.6-30.6), p = 0.023; THCWs 35.0 (31.3-35.9) vs. 22.5 (18.2-30.6), p = 0.024). Duration of symptoms was also shorter in THCWs (5 days (3-6) vs. 9 (7-14), p = 0.028). A linear increase of 3.81 points in Ct values was observed across the groups by vaccination status (p = 0.001) after adjusting for age, sex, comorbidities, and time between COVID-19 onset and swab collection. BNT162b2 decreased the risk of PCR-confirmed infections and severe disease, and was associated with a virologic picture of lesser epidemiologic concern as soon as 12 days after the first vaccine dose.

Clinical significance of hepatosplenic thrombosis in vaccine-induced immune thrombotic thrombocytopenia after ChAdOx1 nCoV-19 vaccination. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare, serious complication after adenoviral COVID-19 vaccine administration that can involve various organ systems. We aimed to investigate the clinical significance of hepatosplenic thrombosis in patients with VITT. METHODS: We searched PubMed ePubs, Scopus, Embase, and Web of Science databases for studies published until April 28, 2021, involving patients with VITT after ChAdOx1 nCoV-19 vaccination. Demographic and clinical characteristics, including laboratory measurements, were collected and compared. RESULTS: Four case series and three case reports involving 48 cases of VITT were included. Hepatosplenic thrombosis was present in 8 cases (17%). Patients with hepatosplenic thrombosis had lower platelet counts (13,000 vs. 29,500/Î¼L, p=0.016) and higher D-dimer levels (140.0 vs. 57.3 times upper limit of normal range, p=0.028). Multiple-site thrombosis was also associated with hepatosplenic thrombosis (88% vs. 15%, p<0.001). CONCLUSIONS: This is the first study comparing clinical profiles of patients with VITT according to the presence of hepatosplenic thrombosis. Patients with hepatosplenic thrombosis had more severe presentations with lower platelet counts, higher D-dimer levels, and a

higher rate of multiple-site thrombosis. Further studies with larger sample sizes are required to establish definitive evidence regarding the significance of hepatosplenic thrombosis in VITT.
Outbreak of SARS-CoV-2 B.1.617.2 (delta) variant in a nursing home 28 weeks after two doses of mRNA anti-COVID-19 vaccines: evidence of a waning immunity. OBJECTIVES: To describe a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) B.1.617.2 (Delta) variant outbreak among residents (nÂ =Â 69) and health workers (nÂ =Â 69) of a small nursing home in northeastern Italy, with full vaccination coverage of 91% and 82%, respectively. Evaluation of the anti-Spike IgG titres 28Â weeks after the mRNA vaccine booster dose against SARS-CoV-2 infection and severe coronavirus disease 2019 (COVID-19). MATERIALS AND METHODS: Sera were collected within 48Â hours from the index case; anti-Spike IgG was determined (expressed as WHO binding antibody units (BAU)/mL) through a commercial quantitative assay; SARS-CoV-2 was diagnosed using RT-PCR, and full-genome sequencing was performed for lineage characterization. Residents were grouped according to anti-Spike IgG titres (â‰¤50, 51-1000 andÂ >Â 1000 BAU/mL) and the resulting protection against infection and severe disease was measured. RESULTS: None of the health workers and 14 of the 59 (24%) residents fully vaccinated and without a previous SARS-CoV-2 infection showed anti-Spike IgG â‰¤50 BAU/mL (one-sided Fisher exact test, p 0.011). Among these residents, a level of anti-Spike IgG â‰¤50 BAU/mL resulted in a higher risk of SARS-CoV-2 infection (relative risk 1.55, 95% CI 1.17-2.05) and severe COVID-19 (relative risk 5.33, 95% CI 1.83-15.57). CONCLUSION: Low levels of SARS-CoV-2 neutralizing anti-Spike IgG in serum 28Â weeks after the administration of the second dose parallel the waning of vaccine protection.
Low Immunoglobulin G Antibody Levels Against Severe Acute Respiratory Disease Coronavirus 2 After 2-Dose Vaccination Among Liver Transplantation Recipients.
Immunogenicity and Safety of a 3-Dose Regimen of a SARS-CoV-2 Inactivated Vaccine in Adults: A Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial. BACKGROUND: Control of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic needs effective vaccines. METHODS: In a phase 2 randomized, double-blind, placebo-controlled trial, 500 adults aged 18-59 years or â‰¥60 years were randomized in 2:2:1 ratio to receive 3 doses of 5 Î¼g or 10 Î¼g of a SARS-CoV-2 inactivated vaccine, or placebo separated by 28 days. Adverse events (AEs) were recorded through day 28 after each dosing. Live virus or pseudovirus neutralizing antibodies, and receptor binding domain immunoglobulin G (RBD-IgG) antibody were tested after the second and third doses. RESULTS: Two doses of the vaccine elicited geometric mean titers (GMTs) of 102-119, 170-176, and 1449-1617 for the 3 antibodies in younger adults. Pseudovirus neutralizing and RBD-IgG GMTs were similar between older and younger adults. The third dose slightly (<1.5 fold) increased GMTs. Seroconversion percentages were 94% or more after 2 doses, which were generally similar after 3 doses. The predominant AEs were injection-site pain. All the AEs were grade 1 or 2 in intensity. No serious AE was deemed related to study vaccination. CONCLUSIONS: Two doses of this vaccine induced robust immune response and had good safety profile. A third dose given 28 days after the second dose elicited limited boosting antibody response.
Need for symptom monitoring in IgA nephropathy patients post COVID-19 vaccination.
Expected Rates of Select Adverse Events After Immunization for Coronavirus Disease 2019 Vaccine Safety Monitoring. Using meta-analytic methods, we calculated expected rates of 20 potential adverse events of special interest (AESI) that would occur after coronavirus disease 2019 (COVID-19) vaccination within 1-, 7-, and 42-day intervals without causal associations. Based on these expected rates, if 10Â 000Â 000 persons are vaccinated, (1) 0.5, 3.7, and 22.5 Guillain-Barre syndrome cases, (2) 0.3, 2.4, and 14.3 myopericarditis cases, (3) and 236.5, 1655.5, and 9932.8 all-cause deaths would occur coincidentally within 1, 7, and 42 days postvaccination, respectively. Expected rates of potential AESI can contextualize events associated temporally with immunization, aid in safety signal detection,

guide COVID-19 vaccine health communications, and inform COVID-19 vaccine benefit-risk assessments.
Successes of the CDC monitoring systems in evaluating post-authorization safety of COVID-19 vaccines.
New-onset autoimmune phenomena post-COVID-19 vaccination. Coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has led to an unprecedented setback for global economy and health. Vaccination is one of the most effective interventions to substantially reduce severe disease and death due to SARS-CoV-2 infection. Vaccination programmes are being rolled out globally, but most of these vaccines have been approved without extensive studies on their side-effects and efficacy. Recently, new-onset autoimmune phenomena after COVID-19 vaccination have been reported increasingly (e.g. immune thrombotic thrombocytopenia, autoimmune liver diseases, Guillain-BarrÃ© syndrome, IgA nephropathy, rheumatoid arthritis and systemic lupus erythematosus). Molecular mimicry, the production of particular autoantibodies and the role of certain vaccine adjuvants seem to be substantial contributors to autoimmune phenomena. However, whether the association between COVID-19 vaccine and autoimmune manifestations is coincidental or causal remains to be elucidated. Here, we summarize the emerging evidence about autoimmune manifestations occurring in response to certain COVID-19 vaccines. Although information pertaining to the risk of autoimmune disease as a consequence of vaccination is controversial, we merely propose our current understanding of autoimmune manifestations associated with COVID-19 vaccine. In fact, we do not aim to disavow the overwhelming benefits of mass COVID-19 vaccination in preventing COVID-19Â morbidity and mortality. These reports could help guide clinical assessment and management of autoimmune manifestations after COVID-19 vaccination.
Temporary exacerbation of pre-existing psoriasis and eczema in the context of COVID-19 messenger RNA booster vaccination: A case report and review of the literature.
Reply to the letter "Venous sinus thrombosis after the second dose of SARS-CoV-2 vaccine administration" by Mungmunpuntipantip and Wiwanitkit.
Sudden sensorineural hearing loss after covid-19 vaccine; A possible adverse reaction? BACKGROUND: Sudden Sensorineural Hearing Loss (SSNHL) is a relatively rare symptom after immunisation from commonly used vaccines such as rabies, hepatitis B, measles and H1N1 and it could be an occasional symptom of COVID-19, even in mild manifestations of the disease. CASE REPORT: We describe the case of a 57-year-old patient that reported SSNHL and tinnitus in his right ear 2 days after the inoculation of the Oxford-AstraZeneca (VAXZEVRIA) Covid-19 vaccine. The patient almost fully recovered after therapy and was referred to a long term follow-up program. CONCLUSION: The current report underlines the importance to consider SSNHL as a possible rare adverse effect of the Covid-19 vaccine and take in account this possibility to promptly proceed with diagnosis and treatment of suspect cases.
Inactivated COVID-19 Vaccine Induces a Low Humoral Immune Response in a Subset of Dermatological Patients Receiving Immunosuppressants. Inactivated Sinovac-CoronaVac vaccine (Sinovac Life Sciences, Beijing) for coronavirus disease 2019 (COVID-19) has been used in many countries. However, its immunogenicity profile in immunosuppressed dermatological patients is lacking. This prospective observational case-control study compared the humoral immune response between adult dermatological patients receiving systemic immunosuppressive therapies (n = 14) and those who did not (n = 18); excluding patients with HIV infection, cancer, non-dermatological autoimmune conditions, previous COVID-19 infection, and positive anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG prior to vaccination. The subjects were advised to withhold methotrexate for 1 week after each vaccine dose while continuing other therapies unadjusted. Anti-

SARS-CoV-2 IgG antibody, surrogate neutralizing antibody (sNAb), and seroconversion rates (calculated from the percentages of participants in the group with positive sNAb) were used to assess immunogenicity. We found that participants using azathioprine, cyclosporin, mycophenolate mofetil, or prednisolone â‰¥ 10 mg/day had a lower level of serum anti-SARS-CoV-2 IgG antibody and sNAb than those received methotrexate â‰¤ 10 mg/week, prednisolone < 10 mg/day, or biologics (i.e., secukinumab, ixekizumab, omalizumab). Patients who received methotrexate â‰¤ 10 mg/week, prednisolone < 10 mg/day or the biologics had a similar immunogenicity profile to those without immunosuppressive therapies. Despite the lack of statistical significance, a reduction of humoral immune response was observed among the study participants who used â‰¥2 immunosuppressants or pemphigus patients. Our findings suggest that a subset of patients with immune-mediated skin conditions respond poorly to the vaccine despite having low-level immunosuppression. These patients could benefit from vaccines that trigger a greater level of immunogenicity or booster doses.

Myocarditis Post Moderna Vaccination: Review of Criteria for Diagnosis. Case reports of myocarditis post-coronavirus disease 2019 (COVID-19) mRNA vaccination have not uniformly reported long-term follow-up beyond 90 days. We present a 23-year-old male who is typical of a patient presenting with myocarditis post-COVID-19 mRNA-1273 Moderna vaccination (young males, onset several days after second dose of the mRNA vaccine, and excellent short term complete recovery). Follow-up at 128 days revealed no residual sequelae in our patient. Although a definitive diagnosis of myocarditis requires an endomyocardial biopsy (EMB), diagnosis is usually made clinically and with imaging in most clinical settings unless part of an approved research protocol or if indicated clinically. We recommend active surveillance and reporting for myocarditis post mRNA vaccination and even consider reporting those with symptom onset beyond 90 days.

De-novo Antineutrophil Cytoplasmic Antibody-Associated Vasculitis Following the mRNA-1273 (Moderna) Vaccine for COVID-19. Antineutrophil cytoplasmic antibody (ANCA) is a systemic autoimmune disorder characterized by antibodies directed against small- and moderate-sized vessels. While there are few reported cases of autoimmune illnesses associated with influenza vaccination, two cases of de-novo anti-proteinase (PR3) ANCA-associated pauci immune glomerulonephritis are reported after the mRNA-1273 coronavirus disease 2019 (COVID-19) vaccine. Here, we report the third case of ANCA-associated glomerulonephritis after the mRNA-1273 COVID-19 vaccine. Our patient presented with acute kidney injury and sub-nephrotic proteinuria four days after receiving the second dose of the COVID vaccine. He was found to have elevated c-ANCA and anti-PR3 antibodies. Renal biopsy confirmed focal necrotizing and diffuse crescentic glomerulonephritis. He was diagnosed with pauci immune glomerulonephritis. The patient achieved remission 10 weeks after the diagnosis with successful treatment.

Post-SARS-CoV-2 vaccination venous sinus thrombosis: a literature review of 308 cases. There is accumulating evidence that SARS-CoV-2 vaccinations can be complicated by venous sinus thrombosis (VST). This review aimed at summarising and discussing previous and recent advances regarding the diagnosis, pathogenesis, treatment, and outcome of post-SARS-CoV-2 vaccination VST. At least 308 patients with post-SARS-CoV-2 vaccination VST have been reported as per the end of July 2021. Ages among these 308 patients ranged between 22 and 81Â years, 69 were male and 197 were female. Post-SARS-CoV-2 vaccination VST most commonly occurred with the ChAdOx1-S vaccine followed by the BNT126b2 vaccine. In the vast majority of cases, VST occurred after the first dose. Only in six patients did VST occur after the second dose. Latency between vaccination and onset of VST ranged between 0 and 24Â days. Regarding treatment, most patients received heparin followed by oral anticoagulants. Seven patients received IVIGs and six patients received steroids because of concomitant vaccine-induced immune thrombotic thrombocytopenia. Complete recovery was reported in 5 patients. Partial recovery was reported in 9 patients. Eight patients were alive or

discharged. Sixty-two patients died. The outcome was not specified in the remainder. In conclusion, SARS-CoV-2 vaccinations can be complicated by VST. There is female preponderance and the outcome is frequently poor.
Multisystem Inflammatory Syndrome in a Previously Vaccinated Adolescent Female With Sickle Cell Disease. Multisystem inflammatory syndrome in children (MIS-C) is a serious complication that is observed most commonly in pediatric patients following severe acute respiratory syndrome coronavirus 2 infections. However, the mechanism and predictors of disease are poorly understood. There are no prior reports of MIS-C among patients who have been fully vaccinated, and only a single case of MIS in an adult patient who had received his second shot just 4 days prior to symptom onset. Here, we present an adolescent with sickle cell disease who was fully vaccinated against severe acute respiratory syndrome coronavirus 2 and had no prior history of known or suspected infection, who presented in shock and was ultimately diagnosed with MIS-C. This case highlights the importance of clinical suspicion for MIS-C even when patients are fully vaccinated.
Multisystem Inflammatory Syndrome in a 12-Year-old Boy After mRNA-SARS-CoV-2 Vaccination. Multisystem inflammatory syndrome in children (MIS-C) following SARS-CoV-2 infection is well known. We describe a 12-year-old child developing MIS-C after receiving 2 doses of mRNA COVID-19 vaccines without clinical evidence of COVID-19 infection. A possible association between the SARS-CoV-2 vaccine and MIS-C cannot be excluded.
Eosinophilic Myocarditis Following Coronavirus Disease 2019 (COVID-19) Vaccination.
Aseptic meningitis following AZD1222 COVID-19 vaccination. The AZD1222 is one of the vaccines used against coronavirus disease 2019 (COVID-19), which is currently being used in many countries worldwide. Some important neurological side effects have been reported in association with this vaccine, but aseptic meningitis has not yet been reported. Herein, we report a case of aseptic meningitis in a 26-year-old health care worker, following the first dose of the AZD1222 vaccine.
Diabetic ketoacidosis (DKA) in type 1 diabetes mellitus (T1DM) temporally related to COVID-19 vaccination. SARS-CoV-2 pandemic has claimed millions of lives since its first identification in December 2019. Patients with diabetes are at a high risk of adverse outcomes after COVID-19 infection, whereas infection itself can be associated with severe hyperglycemia, including hyperglycemic emergencies. While the accelerated vaccine development and rollout have considerably decreased morbidity and mortality with reasonable safety, there are emerging reports of worsening of hyperglycemia in response to vaccination, with possible shared pathophysiology with COVID-19 infection-related hyperglycemia. We hereby report two young patients with type 1 diabetes (T1DM) who presented with severe diabetic ketoacidosis (DKA) after receiving second doses of COVISHIELD (ChAdOx1 nCoV-19) and COVAXIN (BBV152- inactivated whole virion) vaccines. Though a causal link cannot be established, post-vaccination immune response can potentially explain this transient worsening of hyperglycemia and hyperglycemic emergencies. We, hence report diabetic ketoacidosis (DKA) following COVID-19 vaccination in T1DM. We suggest that people with diabetes, particularly patients with T1DM with inadequate glycemic control should ideally be closely monitored for hyperglycemia and ketonemia for at least 2 weeks after receiving vaccination for COVID 19.
COVID-19 Vaccine Is Effective in Inflammatory Bowel Disease Patients and Is Not Associated With Disease Exacerbation. BACKGROUND & AIMS: Studies have shown decreased response to coronavirus disease 2019 (COVID-19) vaccinations in some populations. In addition, it is possible that vaccine-triggered immune activation could trigger immune dysregulation and thus exacerbate inflammatory bowel diseases (IBD). In this population-based study we used the epi-Israeli IBD Research Nucleus validated cohort to explore the effectiveness of COVID-19 vaccination in IBD and to assess its effect on disease outcomes. METHODS: We included all IBD patients insured in 2 of the 4

Israeli health maintenance organizations, covering 35% of the population. Patients receiving 2 Pfizer-BioNTech BNT162b2 vaccine doses between December 2020 and June 2021 were individually matched to non-IBD controls. To assess IBD outcomes, we matched vaccinated to unvaccinated IBD patients, and response was analyzed per medical treatment. RESULTS: In total, 12,109 IBD patients received 2 vaccine doses, of whom 4946 were matched to non-IBD controls (mean age, 51 Â± 16 years; median follow-up, 22 weeks; interquartile range, 4-24). Fifteen patients in each group (0.3%) developed COVID-19 after vaccination (odds ratio, 1; 95% confidence interval, 0.49-2.05; PÂ = 1.0). Patients on tumor necrosis factor (TNF) inhibitors and/or corticosteroids did not have a higher incidence of infection. To explore IBD outcomes, 707 vaccinated IBD patients were compared with unvaccinated IBD patients by stringent matching (median follow-up, 14 weeks; interquartile range, 2.3-20.4). The risk of exacerbation was 29% in the vaccinated patients compared with 26% in unvaccinated patients (PÂ = .3). CONCLUSIONS: COVID-19 vaccine effectiveness in IBD patients is comparable with that in non-IBD controls and is not influenced by treatment with TNF inhibitors or corticosteroids. The IBD exacerbation rate did not differ between vaccinated and unvaccinated patients.
A case of multisystem inflammatory syndrome in adults following natural infection and subsequent immunization. Multisystem inflammatory syndrome in adults is a rare and life-threatening complication that follows natural COVID-19 infection and primarily affects young unvaccinated adults. This complication is seldom described following vaccination, which would have important implications for the vaccination timing and platform in this population. COVID-19 vaccines are extremely effective; however, the risk of rare adverse events needs to be balanced with the vaccination benefits.
Response to "Facial nerve palsy following the administration of COVID-19 mRNA vaccines: analysis of a self-reporting database" by Sato etÂ al.
Polymyalgia rheumatica following COVID-19 vaccination: A case-series of ten patients.
Evaluation of the Gam-COVID-Vac and vaccine-induced neutralizing response against SARS-CoV-2 lineage P.1 variant in an Argentinean cohort. We evaluated humoral immune-response elicited by Sputnik-V by measuring anti-Spike (S) IgG antibodies (Abs) and neutralizing antibodies (NAb) prior to, 14 and 42Â days after-vaccination. The safety and disease rates among vaccinated individuals were also evaluated. Since SARS-CoV-2 lineage P.1 is rapidly spreading in Argentina, virus-neutralizing activity of Sputnik-V-elicited and infection-elicited NAb faced to P.1 were also assessed. A total of 285 participants were recruited; all reported good tolerance, without any severe adverse event. Nine COVID-19 cases were confirmed in fully vaccinated individuals and viable P.1 variant was successfully isolated from one of them. At day 42, 99.65% of the individuals had anti-S IgG; however, 23.15% had not detectable NAbs. Significantly higher neutralization potency against WT compared to P.1 (pÂ <Â 0Â·001) was observed. Some samples failed to neutralize P.1, mainly among vaccinated-naÑ—ve subjects; however, no significant differences were observed among previously infected-vaccinated individuals. Our results corroborated that Sputnik-V is safe and induces an efficient humoral immune response, although not all immunized subjects develop Nabs. Herein, we show for the first time, evidence of infectious SARS-CoV-2 shedding from Sputnik-V fully vaccinated individuals, by the isolation of viable virus from the nasopharyngeal swab of one participant of our study, 139Â days after receiving the second dose. Thereby, we provide evidence indicating that the vaccine might avoid severe forms of COVID-19 but does not prevent infection nor prevents transmission from a fully vaccinated individual.
Final efficacy analysis, interim safety analysis, and immunogenicity of a single dose of recombinant novel coronavirus vaccine (adenovirus type 5 vector) in adults 18 years and older: an international, multicentre, randomised, double-blinded, placebo-controlled phase 3 trial. BACKGROUND: The

Ad5-nCoV vaccine is a single-dose adenovirus type 5 (Ad5) vectored vaccine expressing the SARS-CoV-2 spike protein that was well-tolerated and immunogenic in phase 1 and 2 studies. In this study, we report results on the final efficacy and interim safety analyses of the phase 3 trial. METHODS: This double-blind, randomised, international, placebo-controlled, endpoint-case driven, phase 3, clinical trial enrolled adults aged 18 years older at study centres in Argentina, Chile, Mexico, Pakistan, and Russia. Participants were eligible for the study if they had no unstable or severe underlying medical or psychiatric conditions; had no history of a laboratory-confirmed SARS-CoV-2 infection; were not pregnant or breastfeeding; and had no previous receipt of an adenovirus-vectored, coronavirus, or SARS-CoV-2 vaccine. After informed consent was obtained, 25 mL of whole blood was withdrawn from all eligible participants who were randomised in a 1:1 ratio to receive a single intramuscular dose of 0Â·5 mL placebo or a 0Â·5 mL dose of 5â€‰Ã—â€‰10(10) viral particle (vp)/mL Ad5-nCoV vaccine; study staff and participants were blinded to treatment allocation. All participants were contacted weekly by email, telephone, or text message to self-report any symptoms of COVID-19 illness, and laboratory testing for SARS-CoV-2 was done for all participants with any symptoms. The primary efficacy objective evaluated Ad5-nCoV in preventing symptomatic, PCR-confirmed COVID-19 infection occurring at least 28 days after vaccination in all participants who were at least 28 days postvaccination on Jan 15, 2021. The primary safety objective evaluated the incidence of any serious adverse events or medically attended adverse events postvaccination in all participants who received a study injection. This trial is closed for enrolment and is registered with ClinicalTrials.gov (NCT04526990). FINDINGS: Study enrolment began on Sept 22, 2020, in Pakistan, Nov 6, 2020, in Mexico, Dec 2, 2020, in Russia and Chile, and Dec 17, 2020, in Argentina; 150 endpoint cases were reached on Jan 15, 2021, triggering the final primary efficacy analysis. One dose of Ad5-nCoV showed a 57Â·5% (95% CI 39Â·7-70Â·0, p=0Â·0026) efficacy against symptomatic, PCR-confirmed, COVID-19 infection at 28 days or more postvaccination (21â€‰250 participants; 45 days median duration of follow-up [IQR 36-58]). In the primary safety analysis undertaken at the time of the efficacy analysis (36â€‰717 participants), there was no significant difference in the incidence of serious adverse events (14 [0Â·1%] of 18â€‰363 Ad5-nCoV recipients and 10 [0Â·1%] of 18â€‰354 placebo recipients, p=0Â·54) or medically attended adverse events (442 [2Â·4%] of 18â€‰363 Ad5-nCoV recipients and 411 [2Â·2%] of 18â€‰354 placebo recipients, p=0Â·30) between the Ad5-nCoV or placebo groups, or any serious adverse events considered related to the study product (none in both Ad5-nCoV and placebo recipients). In the extended safety cohort, 1004 (63Â·5%) of 1582 of Ad5-nCoV recipients and 729 (46Â·4%) of 1572 placebo recipients reported a solicited systemic adverse event (p<0Â·0001), of which headache was the most common (699 [44%] of Ad5-nCoV recipients and 481 [30Â·6%] of placebo recipients; p<0Â·0001). 971 (61Â·3%) of 1584 Ad5-nCoV recipients and 314 (20Â·0%) of 1573 placebo recipients reported an injection-site adverse event (p<0Â·0001), of which pain at the injection site was the most frequent; reported by 939 (59%) Ad5-nCoV recipients and 303 (19%) placebo recipients. INTERPRETATION: One dose of Ad5-nCoV is efficacious and safe in healthy adults aged 18 years and older. FUNDING: CanSino Biologics and the Beijing Institute of Biotechnology.
Immunogenicity and safety of BNT162b2 mRNA vaccine booster in actively treated patients with cancer.
Acute transverse myelitis after BNT162b2 vaccination against COVID-19: Report of a fatal case and review of the literature.
Clinical Images: Severe proteinase 3 antineutrophil cytoplasmic antibody glomerulonephritis temporally associated with Sinovac Biotech's inactivated SARS-CoV-2 vaccine.
Lichen planus and lichen planopilaris flare after COVID-19 vaccination. We report two cases of lichen planus following COVID-19 vaccination in two middle-aged women, where the first patient

presented with lichenplanopilaris (LPP) relapse and development of lichen planus 14â€‰days after the second dose of AstraZeneca vaccine, and the other patient who had a previous scattered lesion of LP which extended and increased in severity after the first and second dose of Sinopharm. The suggested cause could be due to immune dysregulation and up regulation of T cell lymphocytes which was triggered after COVID-19 vaccination. What supports our hypothesis that LP had occurred due to COVID-19 vaccination, is that one of the patients responded successfully to Metronidazole. This means that the infection process after vaccination could be the cause in aggravating LP. To add, one of the suggested mechanisms for the appearance of LP or reactivation of a dormant LPP can be cytotoxic CD8 T-lymphocytes which increase the secretion of IFN-Î³ and IL-5 cytokines and may also result in basal keratinocytes' apoptosis leading to cutaneous manifestations. This was supported by the efficacy of Tofacitinib that was used in the other patient who presented with reactivation of LPP in addition to LP. Tofacitinib decrease the number of T cell infiltration and adjust IFN expression.
Anti-CD20 monoclonal antibodies inhibit seropositive response to Covid-19 vaccination in non-Hodgkin lymphoma patients within 6 months after treatment. The Covid-19 pandemic has caused millions of deaths worldwide. Although vaccines have been developed, patients on immunosuppressive therapy are less likely to respond. This study was aimed at investigating the efficacy of a Covid-19 vaccine (Pfizer-BioNTech) in patients with non-Hodgkin lymphoma treated with anti-CD20 monoclonal antibodies. Only 1 of 28 lymphoma patients (3.6%) developed a seropositive response, compared with 100% (28/28) of the healthy volunteers. The low levels of CD19(+) lymphocytes among the lymphoma patients suggest that anti-CD20 treatment prevents the seropositive response to the vaccine. An additional vaccination might be indicated in these patients once B cells are repopulated.
Immunogenicity and tolerability of COVID-19 messenger RNA vaccines in primary immunodeficiency patients with functional B-cell defects. BACKGROUND: Data on the safety and efficacy of coronavirus disease 2019 (COVID-19) vaccination in people with a range of primary immunodeficiencies (PIDs) are lacking because these patients were excluded from COVID-19 vaccine trials. This information may help in clinical management of this vulnerable patient group. OBJECTIVE: We assessed humoral and T-cell immune responses after 2 doses of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) messenger RNA (mRNA) vaccines in patients with PID and functional B-cell defects. METHODS: A double-center retrospective review was performed of patients with PID who completed COVID-19 mRNA vaccination and who had humoral responses assessed through SARS-CoV-2 spike protein receptor binding domain (RBD) IgG antibody levels with reflex assessment of the antibody to block RBD binding to angiotensin-converting enzyme 2 (ACE2; hereafter referred to as ACE2 receptor blocking activity, as a surrogate test for neutralization) and T-cell response evaluated by an IFN-Î³ release assay. Immunization reactogenicity was also reviewed. RESULTS: A total of 33 patients with humoral defect were evaluated; 69.6% received BNT162b2 vaccine (Pfizer-BioNTech) and 30.3% received mRNA-1273 (Moderna). The mRNA vaccines were generally well tolerated without severe reactions. The IFN-Î³ release assay result was positive in 24 (77.4%) of 31 patients. Sixteen of 33 subjects had detectable RBD-specific IgG responses, but only 2 of these 16 subjects had an ACE2 receptor blocking activity level of â‰¥50%. CONCLUSION: Vaccination of this cohort of patients with PID with COVID-19 mRNA vaccines was safe, and cellular immunity was stimulated in most subjects. However, antibody responses to the spike protein RBD were less consistent, and, when detected, were not effective at ACE2 blocking.
mRNA Coronavirus Disease 2019 Vaccine-Associated MyopericarditisÂ inÂ Adolescents: A Survey Study. In this survey study of institutions across the US, marked variability in evaluation, treatment, and follow-up of adolescents 12 through 18Â years of age with mRNA coronavirus disease

2019 (COVID-19) vaccine-associated myopericarditis was noted. Only one adolescent with life-threatening complications was reported, with no deaths at any of the participating institutions.
Multiform Erythema After COVID-19 mRNA Vaccination.
Caution Regarding Conclusions about COVID-19 Vaccine and Encephalitis.
Adaptive immunity and neutralizing antibodies against SARS-CoV-2 variants of concern following vaccination in patients with cancer: The CAPTURE study. CAPTURE (NCT03226886) is a prospective cohort study of COVID-19 immunity in patients with cancer. Here we evaluated 585 patients following administration of two doses of BNT162b2 or AZD1222 vaccines, administered 12 weeks apart. Seroconversion rates after two doses were 85% and 59% in patients with solid and hematological malignancies, respectively. A lower proportion of patients had detectable neutralizing antibody titers (NAbT) against SARS-CoV-2 variants of concern (VOCs) vs wildtype (WT). Patients with hematological malignancies were more likely to have undetectable NAbT and had lower median NAbT vs solid cancers against both WT and VOCs. In comparison with individuals without cancer, patients with haematological, but not solid, malignancies had reduced NAb responses. Seroconversion showed poor concordance with NAbT against VOCs. Prior SARS-CoV-2 infection boosted NAb response including against VOCs, and anti-CD20 treatment was associated with undetectable NAbT. Vaccine-induced T-cell responses were detected in 80% of patients, and were comparable between vaccines or cancer types. Our results have implications for the management of cancer patients during the ongoing COVID-19 pandemic.
Heterogeneous neutralizing antibodies production after SARS-CoV-2 vaccination in haemodialysis patients.
Identifying asymptomatic cases during the mass COVID-19 vaccination campaign: insights and implications for policy makers.
Mechanical Thrombectomy for Treatment of Cerebral Venous Sinus Thrombosis in Vaccine-Induced Immune Thrombotic Thrombocytopenia. Reports of a rare form of cerebral venous sinus thrombosis with profound thrombocytopenia have emerged following introduction of the adenovirus-vectored coronavirus disease 2019 (COVID-19) vaccines. Between March and June 2021, seven cases of refractory vaccine-induced immune thrombotic thrombocytopenia were referred to our institution for mechanical thrombectomy. The condition of 1 patient deteriorated during interhospital transfer, and the remaining 6 underwent successful recanalization. No procedure-related adverse events were reported. At the time of this writing, 3 patients have been discharged with a good functional outcome (mRS 0-1), one required rehabilitation for mild dysarthria and vocal cord palsy (mRS 3), and 2 have died due to severe mass effect. Our anecdotal experience suggests that endovascular therapy may be safe and effective in reducing thrombus burden in selected cases of postvaccination cerebral venous sinus thrombosis.
Central serous chorioretinopathy following Pfizer-BioNTech COVID-19 vaccine: A case report.
Heparin-induced thrombocytopenia: An update for the COVID-19 era. The increased use of heparin during the current COVID-19 pandemic has highlighted the risk of a rare but potentially serious complicationÂ of heparin therapy, viz. heparin-induced thrombocytopenia (HIT). This is a short review on the pharmacology of heparin and itsÂ derivatives, and the pathophysiology of HIT. Guidance on laboratory testing for and clinical management of HIT is presented in accordanceÂ with international guidelines. There are important similarities and differences between HIT and the new entity of vaccine-induced immune thrombotic thrombocytopenia, also known as thrombosis with thrombocytopenia syndrome, which clinicians need to be aware of.
Immune Response after SARS-CoV-2 Vaccination in Kidney Transplant Patients. Background and Objectives: The prospective study was conducted to evaluate humoral and cellular immune responses after two doses of BNT162b2 (Pfizer-BioNTech) vaccine and possible relation with other factors

(medication, etc.) in kidney transplant patients. Materials and Methods: Out of 167 vaccinated patients, 136 agreed to a follow-up visit three to six weeks after vaccination. Results: Only 39 patients (29%) developed antibody response against SARS-CoV-2 (â‰¥35.2 binding antibody units (BAU)/mL) after full vaccination. Multivariate binary logistic regression analysis showed that predictive factors for good antibody response to the COVID-19 vaccine were better kidney function, higher hemoglobin level, and no use of mycophenolate mofetil for immunosuppression. For seropositive kidney transplant patients there was a significant negative correlation between anti-SARS-CoV-2 antibody titer and CD4/CD8 ratio (Spearman's correlation coefficient -0.4, p = 0.02), percentage of CD19+ cells (r = -0.37, p = 0.02), and a positive correlation with percentage of CD8+ cells (r = 0.4, p = 0.01). There was an increase of total leucocyte count after vaccination in the total studied population, and in the group of responders. Conclusions: Only one third of kidney transplant patients develop sufficient antibody responses after full COVID-19 vaccination with Pfizer-BioNTech. Better kidney function, higher hemoglobin level, and no use of mycophenolate mofetil for immunosuppression increases the adequacy of response. The antibody titers correlated positively with relative number of CD8+ cells and negatively with CD4/CD8 ratio in responders.

Uveitis and Other Ocular Complications Following COVID-19 Vaccination. Coronavirus disease 2019 (COVID-19) vaccines can cause transient local and systemic post-vaccination reactions. The aim of this study was to report uveitis and other ocular complications following COVID-19 vaccination. The study included 42 eyes of 34 patients (20 females, 14 males), with a mean age of 49.8 years (range 18-83 years). The cases reported were three herpetic keratitis, two anterior scleritis, five anterior uveitis (AU), three toxoplasma retinochoroiditis, two Vogt-Koyanagi-Harada (VKH) disease reactivations, two pars planitis, two retinal vasculitis, one bilateral panuveitis in new-onset BehÃ§et's disease, three multiple evanescent white dot syndromes (MEWDS), one acute macular neuroretinopathy (AMN), five retinal vein occlusions (RVO), one non-arteritic ischemic optic neuropathy (NAION), three activations of quiescent choroidal neovascularization (CNV) secondary to myopia or uveitis, and one central serous chorioretinopathy (CSCR). Mean time between vaccination and ocular complication onset was 9.4 days (range 1-30 days). Twenty-three cases occurred after Pfizer-BioNTech vaccination (BNT162b2 mRNA), 7 after Oxford-AstraZeneca vaccine (ChAdOx1 nCoV-19), 3 after ModernaTX vaccination (mRNA-1273), and 1 after Janssen Johnson & Johnson vaccine (Ad26.COV2). Uveitis and other ocular complications may develop after the administration of COVID-19 vaccine.

Headache Worsening after COVID-19 Vaccination: An Online Questionnaire-Based Study on 841 Patients with Migraine. Vaccines have represented the breakthrough in the fight against COVID-19. Based on reported headache attacks after vaccination in randomized controlled trials, we focused on the effects of COVID-19 vaccine administration on the migraine population, using an online questionnaire published on Italian Facebook groups oriented to headache patients. We collected data about the demographics and clinical parameters of migraine severity, COVID-19 infection, vaccination, and characteristics of headaches following vaccination. Out of 841 migraine patients filling in the questionnaire, 66.47% and 60.15% patients experienced a headache attack (from 1 hour to 7 days) after the first and the second vaccine dose, respectively. The main finding concerns headaches perceived by 57.60% of patients: attacks following vaccination were referred to as more severe (50.62% of patients), long-lasting (52.80% of patients) and hardwearing (49.69% of patients) compared to the usually experienced migraine attacks. This could be related to the production of inflammatory mediators such as type Iβ² interferon. Considering the high prevalence of migraine in the general population, awareness of the possibility of headaches worsening following COVID-19 vaccination in these patients may allow both patients and clinicians to face this clinical entity with conscious serenity, and to reduce the waste of resources towards inappropriate health-care.

Anti-SARS-CoV-2 S-RBD IgG Antibody Responses after COVID-19 mRNA Vaccine in the Chronic Disorder of Consciousness: A Pilot Study. OBJECTIVE: In the last year, a large amount of research has investigated the anti-spike protein receptor-binding domain (S-RBD) antibody responses in patients at high risk of developing severe acute respiratory syndrome because of COVID-19 infection. However, no data are available on the chronic disorder of consciousness (DOC). METHODS: Here, we evaluated anti-S-RBD IgG levels after vaccination in chronic DOC patients compared with demographically matched healthy controls (HC) by indirect chemiluminescence immunoassay. All individuals completed a two-dose-cycle vaccination with Pfizer mRNA vaccine (BNT162b2), and antibody responses were evaluated at 30 and 180 days after the administration of the second dose of vaccination. RESULTS: We compared 32 DOC patients with 34 demographically matched healthy controls. Both DOC and HC groups showed a similar antibody response at 30 days, whereas at follow-up (180 days) DOC patients were characterized by lower S-RBD IgG levels with respect to controls. Additional multiple regression analyses including demographical and clinical comorbidities as predictors revealed that age was the only factor associated with the decrease in S-RBD IgG levels at follow-up (180 days). Elderly individuals of both groups were characterized by a reduction in the antibody responses with respect to younger individuals. CONCLUSIONS: Our results show an efficacy seroconversion in DOC patients in the first period after vaccination, which significantly declines over time with respect to healthy controls.

Pediatric Atypical Hemolytic Uremic Syndrome Advances. Atypical hemolytic uremic syndrome (aHUS) is a rare disorder characterized by dysregulation of the alternate pathway. The diagnosis of aHUS is one of exclusion, which complicates its early detection and corresponding intervention to mitigate its high rate of mortality and associated morbidity. Heterozygous mutations in complement regulatory proteins linked to aHUS are not always phenotypically active, and may require a particular trigger for the disease to manifest. This list of triggers continues to expand as more data is aggregated, particularly centered around COVID-19 and pediatric vaccinations. Novel genetic mutations continue to be identified though advancements in technology as well as greater access to cohorts of interest, as in diacylglycerol kinase epsilon (DGKE). DGKE mutations associated with aHUS are the first non-complement regulatory proteins associated with the disease, drastically changing the established framework. Additional markers that are less understood, but continue to be acknowledged, include the unique autoantibodies to complement factor H and complement factor I which are pathogenic drivers in aHUS. Interventional therapeutics have undergone the most advancements, as pharmacokinetic and pharmacodynamic properties are modified as needed in addition to their as biosimilar counterparts. As data continues to be gathered in this field, future advancements will optimally decrease the mortality and morbidity of this disease in children.

COVID-19 vaccination in patients with immune thrombocytopenia. Immune thrombocytopenia (ITP) is an acquired autoimmune disorder that is characterized by low platelet count and increased bleeding risk. COVID-19 vaccination has been described as a risk factor for de novo ITP, but the effects of COVID-19 vaccination in patients with ITP are unknown. We aimed to investigate the effects of COVID-19 vaccination in patients with ITP on platelet count, bleeding complications, and ITP exacerbation (â‰¥50% decline in platelet count, or nadir platelet count < 30 Ã— 109/L with a >20% decrease from baseline, or use of rescue therapy). Platelet counts in patients with ITP and healthy controls were collected immediately before and 1 and 4 weeks after the first and second vaccinations. Linear mixed-effects modeling was applied to analyze platelet counts over time. We included 218 patients with ITP (50.9% female; mean age, 55 years; and median platelet count, 106 Ã— 109/L) and 200 healthy controls (60.0% female; mean age, 58 years; median platelet count, 256 Ã— 109/L). Platelet counts decreased by 6.3% after vaccination. We did not observe any difference in decrease between the groups. Thirty patients with ITP (13.8%; 95% confidence interval [CI], 9.5-19.1)

had an exacerbation and 5 (2.2%; 95% CI, 0.7-5.3) suffered from a bleeding event. Risk factors for ITP exacerbation were platelet count < 50 Ã— 109/L (odds ratio [OR], 5.3; 95% CI, 2.1-13.7), ITP treatment at time of vaccination (OR, 3.4; 95% CI, 1.5-8.0), and age (OR, 0.96 per year; 95% CI, 0.94-0.99). Our study highlights the safety of COVID-19 vaccination in patients with ITP and the importance of the close monitoring of platelet counts in a subgroup of patients with ITP. Patients with ITP with exacerbation responded well on therapy.

Acute autoimmune transverse myelitis following COVID-19 vaccination: A case report. RATIONALE: Transverse myelitis is an infectious or noninfectious inflammatory spinal cord syndrome. We report a rare case of transverse myelitis following vaccination against COVID-19. PATIENT CONCERNS: A 70-year-old male presented with progressive sensorimotor dysfunction of the bilateral lower limbs 7â€Šdays after receiving the mRNA-1273 vaccine against COVID-19. Spinal magnetic resonance imaging revealed intramedullary lesions with gadolinium enhancement on the Th1/2 and Th5/6 vertebral levels. Cerebrospinal fluid (CSF) testing showed a mildly increased level of total protein and positive oligoclonal bands (OCB). DIAGNOSIS: The patient was diagnosed with acute transverse myelitis. INTERVENTION: The patient received 5â€Šdays of intravenous methylprednisolone pulse (1000â€Šmg/day) followed by oral prednisolone (30â€Šmg/day with gradual tapering). OUTCOMES: The patient fully recovered from muscle weakness of the lower limbs. He was discharged from our hospital and able to independently walk without unsteadiness. LESSON: This is a rare case of transverse myelitis following COVID-19 vaccination. Positive OCB in CSF in the present case highlights the possibility of autoimmune processes, including polyclonal activation of B lymphocytes, following vaccination.

Intravenous immunoglobulin as an important adjunct in the prevention and therapy of coronavirus 2019 disease. The coronavirus disease-19 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) challenged globally with its morbidity and mortality. A small percentage of affected patients (20%) progress into the second stage of the disease clinically presenting with severe or fatal involvement of lung, heart and vascular system, all contributing to multiple-organ failure. The so-called 'cytokines storm' is considered the pathogenic basis of severe disease and it is a target for treatment with corticosteroids, immunotherapies and intravenous immunoglobulin (IVIg). We provide an overview of the role of IVIg in the therapy of adult patients with COVID-19 disease. After discussing the possible underlying mechanisms of IVIg immunomodulation in COVID-19 disease, we review the studies in which IVIg was employed. Considering the latest evidence that show a link between new coronavirus and autoimmunity, we also discuss the use of IVIg in COVID-19 and anti-SARS-CoV-2 vaccination related autoimmune diseases and the post-COVID-19 syndrome. The benefit of high-dose IVIg is evident in almost all studies with a rapid response, a reduction in mortality and improved pulmonary function in critically ill COVID-19 patients. It seems that an early administration of IVIg is crucial for a successful outcome. Studies' limitations are represented by the small number of patients, the lack of control groups in some and the heterogeneity of included patients. IVIg treatment can reduce the stay in ICU and the demand for mechanical ventilation, thus contributing to attenuate the burden of the disease.

Axillary Lymphadenopathy After COVID-19 Vaccination in a Woman With Breast Cancer.

Graves Disease Following the SARS-CoV-2 Vaccine: Case Series. Widespread vaccination is a principal strategy to mitigate the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and lessen the global burden of coronavirus disease 2019 (COVID-19). Information is rapidly evolving about the impact of SARS-CoV-2 vaccines on the immune and endocrine systems. This case series heightens clinical awareness of possible thyroid effects and conveys knowledge of what to monitor, which are fundamental components of public health and pharmacovigilance. We present a case series of Graves disease following mRNA SARS-CoV-2 vaccination, with symptoms and altered

thyroid function tests developing within 7 days of the first dose in 2 women aged 38 and 63 years, and 28 days after the second dose in a 30-year-old man. New-onset Graves disease occurred following administration of mRNA vaccines against SARS-CoV-2. Based on the timing of signs and symptoms relative to administration of the vaccine and the absence of other probable causes, we consider the vaccine as a potential contributor to the diagnosis. The viral spike protein, delivered indirectly through an encoded mRNA vaccine, may be capable of triggering an inflammatory cascade and immune response triggering thyroid dysfunction.

One year of SARS-CoV-2 pandemic: comparison of infection between health care workers and general population before and after vaccination. BACKGROUND: The Covid-19 pandemic in Italy has been characterized by three waves of infection during 2020. Vaccination of healthcare workers started in January 2021, earlier than that of other population groups. The main aim of this study is to compare the spread of the pandemic between HCW and the general population focusing on potential effects of the vaccination. METHODS: The study consisted of a retrospective analysis of results of RT-PCR tests performed between 6 March 2020 and 4 April 2021 among HCWs from Bologna, Italy, and those of the general population of Emilia Romagna region. We calculated the crude proportion of positive RT-PCR tests over total tests and the crude prevalence of positive test in population; then, we conducted joinpoint analyses using the Joinpoint Regression Program of the National Cancer Institute. RESULTS: The results of the joinpoint analysis show that both Ï† and Ïˆ ratio indicators have a similar pattern, with a sharp increase during the early phase of the pandemic, and a strong decrease at the end of the first wave around week 15. In both indicators there are no significant changes in the trend after week 25. Pandemic spread among HCWs appeared earlier than in the general population, but it otherwise appeared to have comparable features. A decline in infection was apparent among HCWs after vaccination. CONCLUSIONS: Surveillance of HCWs would inform on the epidemic in the general population. The apparent effectiveness of the anti-SarsCoV2 vaccine will likely occur in the general population.

Side effects among healthcare workers from a large Milan university hospital after second dose of BNT162b2 mRNA COVID-19 vaccine. BACKGROUND: In Italy, healthcare workers (HCWs) were among the first to receive COVID-19 vaccination. Aim of the present study is to evaluate frequency and severity of adverse events (AEs) following the second dose of BNT162b2 vaccine among HCWs of a large university hospital in Milan, Italy. METHODS: One month after having received the second dose of vaccine, HCWs filled-in a form about type, severity, and duration of post-vaccination local and systemic symptoms. We calculated the overall frequency of AEs and used multivariable Poisson regression models (adjusted for sex, age, BMI, smoking, allergy history, previous SARS-CoV-2 infection, anti-hypertensive therapy, and occupation) to calculate risk ratios (RR) and 95% confidence intervals (CI) of AEs according to selected variables. RESULTS: We included 3659 HCWs. Overall, 2801 (76.6%) experienced at least one local event, with pain at injection site being the most frequent (2788, 76.2%). Systemic events were reported by 2080 (56.8%) HCWs, with fatigue (52.3%), muscle pain (42.2%), headache (37.7%), joint pain (31.9%), and fever (26.2%) being the most frequent. Risks of systemic events were associated with female gender (RR=1.14, CI: 1.06-1.23), age (strong decrease with increasing age, p-trend<0.001), allergy history (RR=1.13, CI: 1.05-1.20), and current smoking (RR=0.90, CI: 0.84-0.97). HCWs with previous SARS-CoV-2 infection (even if symptomatic) were not at increased risk. CONCLUSIONS: Both local and systemic acute effects after second dose of BNT162b2 vaccine were frequently reported. However, symptoms were mostly light/mild and of short duration. Thus, our findings support the safety of COVID-19 vaccination in adults in relatively good health.

Adult-onset Still disease post-adenovirus vector COVID-19 vaccine.

Potential implications of lipid nanoparticles in the pathogenesis of myocarditis associated with the use of mRNA vaccines against SARS-CoV-2. Although mRNA-based vaccines BNT162b2 and

mRNA-1273 exhibit a remarkable efficacy and effectiveness in preventing particularly severe Covid-19 with an overall favorable adverse event profile, their use has been associated with rare cases of acute myocarditis. These occur most commonly after the second dose, with the highest incidence among young male recipients. This complication has not been frequently observed among adenoviral vector vaccine receivers, and its clinical, laboratory and imaging features resemble those of other common causes of acute myocarditis. The pathogenesis of mRNA-vaccine associated myocarditis has not yet been elucidated, although a number of mechanisms have been proposed, typically implicating the administered S-protein mRNA and likely mediated through an autoimmune mechanism. Nonetheless, other mechanisms may be implicated given the fact that myocarditis cases are very rarely observed among recipients of non mRNA vaccines. The recent observation of a similar adverse event in a recipient of the non-mRNA, peptide-based NVX-CoV2373 in the frame of a phase III clinical trial with 7020 participants in the active treatment arm raises the question whether the lipid nanoparticle sheath, which is a common structural component of these platforms could be implicated in the pathogenesis of vaccine-induced myocarditis.

Acute thyroid swelling with severe hypothyroid myxoedema after COVID-19 vaccination. The SARS-CoV-2 virus can trigger thyroid dysfunction. Thyroid dysfunctions after COVID-19 vaccination have been rarely reported. We report the case of overt hypothyroidism in a 61-year-old woman seen after BNT162b2-mRNA vaccination. This case underlines the fact that thyroid function should also be monitored after COVID-19 vaccination, especially in at-risk subjects.

Nephrotic syndrome and acute kidney injury following CoronaVac anti-SARS-CoV-2 vaccine. A 67-year-old female with Type 2 diabetes mellitus developed nephrotic syndrome within 1 week of receiving the first dose of severe acute respiratory syndrome coronavirus 2 CoronaVac vaccine. A kidney biopsy was consistent with minimal change nephrotic syndrome and treatment was symptomatic with antiproteinuric therapy and improvement in proteinuria. Oedema returned within 1 week of the second dose of CoronaVac. On this occasion, acute kidney injury and massive proteinuria were noted. In kidney biopsy, glomeruli were normal, but tubulointerstitial inflammation consistent with acute tubulointerstitial nephritis was noted. Pulse followed by oral steroids was followed by recovery of kidney function. Proteinuria decreased after initiation of cyclosporine A.

Minimal change disease soon after Pfizer-BioNTech COVID-19 vaccination. We report on the onset of minimal change disease (MCD) presenting with anasarca after a second dose of the messenger RNA (mRNA)-based Pfizer-BioNTech vaccine against coronavirus disease 2019 (COVID-19). A 75-year-old previously healthy male was admitted with rapidly progressive anasarca and proteinuria of 7.7 g/day following the second dose. A kidney biopsy revealed MCD with nephrotic syndrome. He was treated with intravenous methylprednisolone followed by prednisolone, leading to complete remission after 35 days in the hospital. Since definite causality between the vaccine and MCD remains unclear, awareness of this potential adverse effect of mRNA vaccines is important to determine its true incidence and frequency.

Preclinical Immune Response and Safety Evaluation of the Protein Subunit Vaccine Nanocovax for COVID-19. The coronavirus disease 2019 (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has become a global health concern. The development of vaccines with high immunogenicity and safety is crucial for controlling the global COVID-19 pandemic and preventing further illness and fatalities. Here, we report the development of a SARS-CoV-2 vaccine candidate, Nanocovax, based on recombinant protein production of the extracellular (soluble) portion of the spike (S) protein of SARS-CoV-2. The results showed that Nanocovax induced high levels of S protein-specific IgG and neutralizing antibodies in three animal models: BALB/c mouse, Syrian hamster, and a non-human primate (Macaca leonina). In addition, a viral challenge study using the hamster model showed that Nanocovax protected the upper

respiratory tract from SARS-CoV-2 infection. Nanocovax did not induce any adverse effects in mice (Mus musculus var. albino) and rats (Rattus norvegicus). These preclinical results indicate that Nanocovax is safe and effective.

The Impact of Age Difference on the Efficacy and Safety of COVID-19 Vaccines: A Systematic Review and Meta-Analysis. OBJECTIVE: This meta-analysis compared the efficacy and safety of five kinds of COVID-19 vaccines in different age groups (young adults and older adults), aiming to analyze the difference of adverse events (AEs) rate and virus geometric mean titer (GMT) values between young and older people, in order to find a specific trend, and explore the causes of this trend through meta-analysis. METHOD: Meta-analysis was used to analyze the five eligible articles. The modified Jadad scoring scale was used to evaluate the quality of eligible literature with a scoring system of 1 to 7. The primary endpoint of the effectiveness index was GMT. The primary endpoints of the safety index were the incidence of local AEs and systemic AEs. Stata 12.0 software was used for meta-analysis. Revman 5.0 software was used to map the risk of publication bias, and Egger's test was used to analyze publication bias. RESULTS: The GMT values of young adults were higher than older adults (SMD = 1.40, 95% CI (0.79, 2.02), P<0.01). There was a higher incidence of local and systemic AEs in young people than in the elderly (OR = 1.10, 95% CI (1.08, 1.12), P<0.01; OR = 1.18, 95% CI (1.14, 1.22), P<0.01). CONCLUSION: The immune effect of young people after being vaccinated with COVID-19 vaccines was better than that of the elderly, but the safety was worse than that of old people, the most common AEs were fever, rash, and local muscle pain, which were tolerable for young people. As the AEs of the elderly were lower, they can also be vaccinated safely; the reason for the low level of GMT in the elderly was related to Immunosenescence. The vaccine tolerance of people of different ages needs to be studied continuously.

Perceptions and Experiences of COVID-19 Vaccine Side-Effects Among Healthcare Workers in Southern Ethiopia: A Cross-Sectional Study. BACKGROUND: We examined the perceptions of healthcare workers about the side-effects of COVID-19 vaccine and the types of side-effects they experienced in the post-vaccination period. METHODS: An institutional-based cross-sectional survey research design was used in which a semi-structured questionnaire was distributed to collect quantitative data from healthcare workers in Southern Ethiopia that were selected on the basis of a multi-stage cluster sampling technique. After inserting the completed cases into SPSS software, descriptive statistical techniques, such as frequencies, percentages, charts and inferential statistical tool, particularly binary logistic regression analysis, were used to analyze and present the data. RESULTS: Majority (43.6%) of respondents perceive that COVID-19 vaccine will have muscle pain around the injection site, followed by fever (39.9%), problems of blood clots (37.8%), headache (35.6%), fatigue (33.5%), and aching limbs (16%). And 63.6%) of them reported that they have experienced muscle pain around the injection site after receiving the COVID-19 vaccine, followed by fatigue (42%), headache (37.2%), fever (34.2%), redness around the injection site (21.6%), and swelling around the injection site (17.8%). Moreover, 25% reported that the fear of potential side-effects of COVID-19 vaccine inhibited them from taking the vaccine. Above all, it is found that respondents' expectation of COVID-19 vaccine to have such serious side-effects is significantly associated to their educational status (OR = 0.229; P < 0.01; 95%C.I.: 0.080-0.651). CONCLUSION: While the expectations of most of the healthcare workers regarding the side-effects of the vaccine are parallel to the normal reactions of the vaccine, a significant proportion of the study participants have reported that they perceive COVID-19 vaccine will have life-threatening side-effects. Such fears have also played a role in affecting vaccine uptake. Therefore, the Ministry of Health, and other concerned government bodies should create further awareness on COVID-19 vaccine and related safety issues.

Parents' Willingness to Vaccinate Their Children Against Seasonal Influenza After the COVID-19 Pandemic in Saudi Arabia: A Retrospective Cross-Sectional Survey. PURPOSE: To explore the impact of the novel coronavirus (COVID-19) pandemic on caregivers' willingness to vaccinate their children against influenza in 2021 in Saudi Arabia and the factors influencing this decision. PATIENTS AND METHODS: An online survey of 2501 caregivers in Saudi Arabia with children aged 6 months-18 years was conducted between July 15, 2021, and August 2, 2021. A convenience sample of participants that met the inclusion criteria was used as the study sample. Social Science Package Statistical (SPSS) was used for the statistical analysis. Categorical variables were reported as frequencies and percentages. The Chi-square test was used for categorical variables to assess the difference between the variables and the parents' willingness to vaccinate their children against seasonal influenza after the COVID-19 pandemic. RESULTS: Of the 2501 respondents to the survey, 1185 (47.3%) parents plan to give their children the influenza vaccine next year, which is an increase from 745 (29.8%) in the previous year. The following were the main reasons for not giving children the vaccine: children were less likely to get seasonal flu (617, 24.7%), fear of side effects (491, 19.6%), and fear of needles and syringes (484, 19.4%). Among the parents, 1222 (48.9%) were more likely to receive the seasonal flu vaccine themselves the following year, and 1361 (54.4%), which is more than half, were concerned about their children contracting seasonal influenza. CONCLUSION: Parents' decision-making to vaccinate their children against seasonal influenza has been influenced by the COVID-19 pandemic. Numerous factors including a caregiver who had received the seasonal influenza vaccine themselves, who had vaccinated or planned to vaccinate their children during the previous or current seasonal influenza season, and/or who had a higher education level were associated with increased willingness to receive the flu vaccine.

SARS-CoV-2 specific cellular response following COVID-19 vaccination in patients with chronic lymphocytic leukemia.

Neutralization of SARS-CoV-2 Variants of Concern in Kidney Transplant Recipients after Standard COVID-19 Vaccination. BACKGROUND AND OBJECTIVES: Antibody response after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination is impaired in kidney transplant recipients. Emerging variants, such as B.1.617.2 (Î´), are of particular concern because of their higher transmissibility and partial immune escape. Little is known about protection against these variants in immunocompromised patients. DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: In this prospective two-center study, antispike 1 IgG and surrogate neutralizing antibodies were measured in 173 kidney transplant recipients and 166 healthy controls with different vaccination schedules. In addition, different SARS-CoV-2 epitope antibodies from 135 vaccinated kidney transplant recipients were compared with antibodies in 25 matched healthy controls after second vaccination. In 36 kidney transplant recipients with seroconversion, neutralization against B.1.1.7 (Î±), B.1.351 (Î²), and B.1.617.2 (Î´) was determined on VeroE6 cells and compared with neutralization in 25 healthy controls. RESULTS: Kidney transplant recipients had significantly lower seroconversion rates compared with healthy controls. After the second vaccination, antispike 1, antireceptor-binding domain, and surrogate neutralizing antibodies were detectable in 30%, 27%, and 24% of kidney transplant recipients, respectively. This compares with 100%, 96%, and 100% in healthy controls, respectively (P<0.001). Neutralization against B.1.1.7 was detectable in all kidney transplant recipients with seroconversion, with a median serum dilution that reduces infection of cells by 50% of 80 (interquartile range, 80-320). In contrast, only 23 of 36 (64%) and 24 of 36 (67%) kidney transplant recipients showed neutralization against B.1.351 and B.1.617.2, respectively, with median serum dilutions that reduce infection of cells by 50% of 20 (interquartile range, 0-40) and 20 (interquartile range, 0-40), respectively. Neutralization against different variants was significantly higher in healthy controls (P<0.001), with all patients showing neutralization against all tested variants. CONCLUSIONS:

Seroconverted kidney transplant recipients show impaired neutralization against emerging variants of concern after standard two-dose vaccination. CLINICAL TRIAL REGISTRY NAME AND REGISTRATION NUMBER: Observational study to assess the SARS-CoV-2 specific immune response in kidney transplant recipients (COVID-19 related immune response), DRKS00024668.
The road to achieving herd immunity: factors associated with Singapore residents' uptake and hesitancy of the COVID-19 vaccination. OBJECTIVE: Achieving high vaccination rates is key to containing the coronavirus disease 2019 (COVID-19). This study evaluated the factors associated with uptake of the COVID-19 vaccine. METHODS: Six hundred and seventy-six respondents were surveyed online between May and June 2021. Data on demographics, perception of the COVID-19 pandemic, and vaccine willingness and hesitancy factors were collected. RESULTS: Approximately 54.6% of the respondents had received the COVID-19 vaccination. Age (pÂ =Â 0.001), males (OR 1.7, 95% CI 1.1-2.6, p =Â 0.026), ethnicity (pÂ =Â 0.004), occupation (pÂ =Â 0.003)), working in healthcare (OR 6.1, 95% CI 2.8-13.2, p <Â 0.001), smoking (OR 3.3, 95% CI 1.3-8.8, p =Â 0.014), seeing vaccination as a social responsibility (OR 3.8, 95% CI 1.2-12.0, p =Â 0.022) and believing the vaccine is important to end the COVID-19 pandemic (OR 2.7, 95% CI 1.1-6.1, p =Â 0.020) were associated with greater vaccination uptake. CONCLUSION: Social responsibility and well-being of collective society are important values associated with vaccine uptake in an Asian society. Understanding factors behind vaccine uptake can help advise public health measures and strategies to achieve high levels of vaccination.
Vascular Disease Patient Information Page: Vascular considerations with COVID-19 vaccines.
Response to comment on: Facial nerve palsy after COVID-19 vaccination - A rare association or coincidence.
Comment on: Facial nerve palsy after COVID-19 vaccination - A rare association or coincidence.
Isolated peripheral facial nerve palsy post COVID-19 vaccination with complete clinical recovery.
Post-SARS-CoV-2 vaccination facial palsy requires extensive work-up and appropriate treatment.
Harada-like syndrome post-Covishield vaccination: A rare adverse effect. Covishield is in wide use in India with about 80% efficacy. Serious side effects are still under study. A 30-year-old female presented to us 7 days post-vaccination with a 5-day history of sudden diminution of vision in both eyes. The clinical findings were suggestive of the Vogt-Koyanagi-Harada (VKH) syndrome. She was treated with high-dose oral steroids. At this juncture, the association was unclear. However, it was justified by an acute flare-up of uveitis on day 2 post the second dose of vaccination despite ongoing steroids. A direct correlation of Harada-like syndrome with the Covishield vaccine is observed here.
Stromal rejection in penetrating keratoplasty following COVID-19 vector vaccine (Covishield) - A case report and review of literature. Endothelial rejection has been described following both m-RNA and vector-based vaccines for COVID-19. There is one case report of a stromal rejection described following influenza vaccination. We report a case of stromal rejection following vector-based COVID-19 vaccination, which might be the first case reported so far.
Central retinal vein occlusion post-COVID-19 vaccination. Coronavirus disease 2019 (COVID-19) is known to cause thromboembolic episodes apart from acute respiratory distress syndrome (ARDS). With large vaccine drives all across the world, there are a few case reports on post-vaccine thrombotic events seen with the AZD1222, ChAdO Ã— 1 vaccine. Here, we present two cases of central retinal vein occlusion presenting immediately after receiving the second dose of the Covishield vaccine. Although the causal relationship cannot be drawn, the ophthalmologist should be aware of this adverse reaction.
VITT and Second Doses of Covid-19 Vaccine.
Extensive cutaneous lichen planus triggered by viral vector COVID-19 vaccination (ChAdOx1 nCoV-19).

The change in glycaemic control immediately after COVID-19 vaccination in people with type 1 diabetes. AIMS: Evidence suggests that some people with type 1 diabetes mellitus (T1DM) experience temporary instability of blood glucose (BG) levels after COVID-19 vaccination. We aimed to assess this objectively. METHODS: We examined the interstitial glucose profile of 97 consecutive adults (ageÂ â‰¥Â 18Â years) with T1DM using the FreeStyle Libre(Â®) flash glucose monitor in the periods immediately before and after their first COVID-19 vaccination. The primary outcome measure was percentage (%) interstitial glucose readings within the target range 3.9-10Â mmol/L for 7Â days prior to the vaccination and the 7Â days after the vaccination. Data are meanÂ Â±Â standard error. RESULTS: There was a significant decrease in the % interstitial glucose on target (3.9-10.0) for the 7Â days following vaccination (mean 52.2%Â Â±Â 2.0%) versus pre-COVID-19 vaccination (mean 55.0%Â Â±Â 2.0%) (pÂ =Â 0.030). 58% of individuals with T1DM showed a reduction in the 'time in target range' in the week after vaccination. 30% showed a decrease of time within the target range of over 10%, and 10% showed a decrease in time within target range of over 20%. The change in interstitial glucose proportion on target in the week following vaccination was most pronounced for people taking metformin/dapagliflozinÂ +Â basal bolus insulin (change -7.6%) and for people with HbA(1c) below the median (change -5.7%). CONCLUSION: In T1DM, we have shown that initial COVID-19 vaccination can cause temporary perturbation of interstitial glucose, with this effect more pronounced in people talking oral hypoglycaemic medication plus insulin, and when HbA(1c) is lower.

Analysis of COVID-19 Vaccine Type and Adverse Effects Following Vaccination. IMPORTANCE: Little is known about the factors associated with COVID-19 vaccine adverse effects in a real-world population. OBJECTIVE: To evaluate factors potentially associated with participant-reported adverse effects after COVID-19 vaccination. DESIGN, SETTING, AND PARTICIPANTS: The COVID-19 Citizen Science Study, an online cohort study, includes adults aged 18 years and older with a smartphone or internet access. Participants complete daily, weekly, and monthly surveys on health and COVID-19-related events. This analysis includes participants who provided consent between March 26, 2020, and May 19, 2021, and received at least 1 COVID-19 vaccine dose. EXPOSURES: Participant-reported COVID-19 vaccination. MAIN OUTCOMES AND MEASURES: Participant-reported adverse effects and adverse effect severity. Candidate factors in multivariable logistic regression models included age, sex, race, ethnicity, subjective social status, prior COVID-19 infection, medical conditions, substance use, vaccine dose, and vaccine brand. RESULTS: The 19â€¯586 participants had a median (IQR) age of 54 (38-66) years, and 13â€¯420 (68.8%) were women. Allergic reaction or anaphylaxis was reported in 26 of 8680 participants (0.3%) after 1 dose of the BNT162b2 (Pfizer/BioNTech) or mRNA-1273 (Moderna) vaccine, 27 of 11â€¯141 (0.2%) after 2 doses of the BNT162b2 or mRNA-1273 vaccine or 1 dose of the JNJ-78436735 (Johnson & Johnson) vaccine. The strongest factors associated with adverse effects were vaccine dose (2 doses of BNT162b2 or mRNA-1273 or 1 dose of JNJ-78436735 vs 1 dose of BNT162b2 or mRNA-1273; odds ratio [OR], 3.10; 95% CI, 2.89-3.34; Pâ€‰<â€‰.001), vaccine brand (mRNA-1273 vs BNT162b2, OR, 2.00; 95% CI, 1.86-2.15; Pâ€‰<â€‰.001; JNJ-78436735 vs BNT162b2: OR, 0.64; 95% CI, 0.52-0.79; Pâ€‰<â€‰.001), age (per 10 years: OR, 0.74; 95% CI, 0.72-0.76; Pâ€‰<â€‰.001), female sex (OR, 1.65; 95% CI, 1.53-1.78; Pâ€‰<â€‰.001), and having had COVID-19 before vaccination (OR, 2.17; 95% CI, 1.77-2.66; Pâ€‰<â€‰.001). CONCLUSIONS AND RELEVANCE: In this real-world cohort, serious COVID-19 vaccine adverse effects were rare and comparisons across brands could be made, revealing that full vaccination dose, vaccine brand, younger age, female sex, and having had COVID-19 before vaccination were associated with greater odds of adverse effects. Large digital cohort studies may provide a mechanism for independent postmarket surveillance of drugs and devices.

The effect of Covid-19 mRNA vaccine on serum anti-MÃ¼llerian hormone levels. STUDY QUESTION: Does the administration of the severe acute respiratory syndrome coronavirus 2 (SARS-

CoV-2) mRNA vaccine have an association with ovarian reserve as expressed by circulating anti-MÃ¼llerian hormone (AMH) levels? SUMMARY ANSWER: Ovarian reserve as assessed by serum AMH levels is not altered at 3 months following mRNA SARS-CoV-2 vaccination. WHAT IS KNOWN ALREADY: A possible impact of SARS-CoV-2 infection or vaccination through an interaction between the oocyte and the somatic cells could not be ruled out, however, data are limited. STUDY DESIGN, SIZE, DURATION: This is a prospective study conducted at a university affiliated tertiary medical center between February and March 2021. PARTICIPANTS/MATERIALS, SETTING, METHODS: Study population included reproductive aged women (18-42â€‰years) that were vaccinated by two Pfizer-BioNTech Covid-19 vaccines (21â€‰days apart). Women with ovarian failure, under fertility treatments, during pregnancy, previous Covid-19 infection or vaccinated were excluded from the study. Blood samples were collected for AMH levels before the first mRNA vaccine administration. Additional blood samples after 3 months were collected for AMH and anti-Covid-19 antibody levels. Primary outcome was defined as the absolute and percentage change in AMH levels. MAIN RESULTS AND THE ROLE OF CHANCE: The study group consisted of 129 women who received two mRNA vaccinations. Mean AMH levels were 5.3 (Â±SD 4.29) Âµg/l and 5.3 (Â±SD 4.50) Âµg/l at baseline and after 3 months, respectively (Pâ€‰=â€‰0.11). To account for possible age-specific changes of AMH, sub-analyses were performed for three age groups: <30, 30-35 and >35â€‰years. AMH levels were significantly lower for women older than 35â€‰years at all times (Pâ€‰=â€‰0.001 for pre and post vaccination AMH levels versus younger women). However, no significant differences for the changes in AMH levels before and after vaccinations (Delta AMH) were observed for the three age groups (Pâ€‰=â€‰0.46). Additionally, after controlling for age, no association was found between the degree of immunity response and AMH levels. LIMITATIONS, REASONS FOR CAUTION: Although it was prospectively designed, for ethical reasons we could not assign a priori a randomized unvaccinated control group. This study examined plasma AMH levels at 3 months after the first vaccination. It could be argued that possible deleterious ovarian and AMH changes caused by the SARS-CoV-2 mRNA vaccinations might take effect only at a later time. Only longer-term studies will be able to examine this issue. WIDER IMPLICATIONS OF THE FINDINGS: The results of the study provide reassurance for women hesitant to complete vaccination against Covid 19 due to concerns regarding its effect on future fertility. This information could be of significant value to physicians and patients alike. STUDY FUNDING/COMPETING INTEREST(S): The study was supported by Sheba Medical Center institutional sources. All authors have nothing to disclose. TRIAL REGISTRATION NUMBER: The study protocol was approved by the 'Sheba Medical Center' Ethical Committee Review Board (ID 8121-21-SMC) on 8 February 2021 and was registered at the National Institutes of Health (NCT04748172).

Single-cell profiling of T and B cell repertoires following SARS-CoV-2 mRNA vaccine. mRNA vaccines for SARS-CoV-2 have shown exceptional clinical efficacy, providing robust protection against severe disease. However, our understanding of transcriptional and repertoire changes following full vaccination remains incomplete. We used scRNA-Seq and functional assays to compare humoral and cellular responses to 2 doses of mRNA vaccine with responses observed in convalescent individuals with asymptomatic disease. Our analyses revealed enrichment of spike-specific B cells, activated CD4+ T cells, and robust antigen-specific polyfunctional CD4+ T cell responses following vaccination. On the other hand, although clonally expanded CD8+ T cells were observed following both vaccination and natural infection, CD8+ T cell responses were relatively weak and variable. In addition, TCR gene usage was variable, reflecting the diversity of repertoires and MHC polymorphism in the human population. Natural infection induced expansion of CD8+ T cell clones that occupy distinct clusters compared to those induced by vaccination and likely recognize a broader set of viral antigens of viral epitopes presented by the virus not seen in the mRNA vaccine. Our study highlights a coordinated adaptive immune response in which early CD4+ T cell responses facilitate the

development of the B cell response and substantial expansion of effector CD8+ T cells, together capable of contributing to future recall responses.
Allergic Reactions After Administration of Pfizer-BioNTech COVID-19 Vaccine to Health Care Workers at a Tertiary Hospital.
COVID-19 Vaccine-Related Axillary Adenopathy on Breast Imaging: Follow-Up Recommendations and Histopathologic Findings. This study describes 94 patients who presented with suspected COVID-19 vaccine-related axillary adenopathy on breast imaging. All biopsies recommended within 12 weeks of the second vaccine dose were benign. Among women not recommended for biopsy, the median interval between the second vaccine dose and ultrasound follow-up was 15.9 weeks. Three biopsies yielding malignant diagnoses were recommended 12.0-13.1 weeks after the second vaccine dose. Lengthening imaging follow-up to 12-16 weeks after the second dose may reduce unnecessary biopsy recommendations.
Cardiac MRI Assessment of Nonischemic Myocardial Inflammation: State of the Art Review and Update on Myocarditis Associated with COVID-19 Vaccination. Myocarditis is a nonischemic inflammatory disease of the myocardium that can be triggered by a multitude of events, including viral infection and toxins. Recently, there has been heightened interest in myocarditis given its association with COVID-19 vaccination. Timely identification of myocarditis can affect patient management and prognosis. Therefore, it is crucial for radiologists and cardiac imagers to understand the role of cardiac imaging to establish a diagnosis and inform treatment decisions. Cardiac MRI is the most important noninvasive imaging modality for evaluation of myocarditis, with typical findings of focal or diffuse myocardial edema and myocardial damage, including presence of late gadolinium enhancement. There are currently limited data available to indicate that the pattern of myocardial injury following COVID-19 vaccination is similar to other causes of myocarditis, although the severity of disease may be relatively mild. A description of the role of imaging and typical imaging features will be reviewed here, with a focus on emerging data in the setting of myocarditis after COVID-19 vaccination. Keywords: MRI, Heart, Inflammation Â©â€‰RSNA, 2021.
Thyroiditis After COVID-19 mRNA Vaccine: A Case Series. BACKGROUND: Although SARS-CoV-2 virus infection has been reported to cause subacute thyroiditis, the mRNA vaccine for SARS-CoV-2 is suspected to induce thyroiditis with thyrotoxicosis. CASE REPORT: : We describe 3 patients with no history of thyroid disease who presented with symptomatic, biochemical, and radiological evidence of thyroiditis with thyrotoxicosis, 10 to 20 days after receiving either Pfizer Bio-NTech or Moderna COVID-19 mRNA vaccines. All patients presented with thyrotoxicosis but with negative thyroid-stimulating immunoglobulins for Graves disease and no autonomous nodules. Two patients underwent thyroid uptake scans that confirmed thyroiditis. One patient had significantly increased erythrocyte sedimentation rate and interleukin-6. All patients showed improvement in symptoms with nonsteroidal anti-inflammatory drugs, and 1 patient eventually required steroids for symptom control. DISCUSSION: The mRNA vaccine for SARS-CoV-2 was associated with thyroiditis and led to thyrotoxicosis. Elevated proinflammatory markers and cytokines after vaccines may play a major role. CONCLUSION: Our case series report highlights a possible relationship between the COVID-19 mRNA vaccine and thyroiditis with thyrotoxicosis, which has not been recognized by health providers.
Delayed-type hypersensitivity skin reaction to Covid-19 vaccine. Delayed-Type Hypersensitivity Skin Reaction following the Moderna mRNA COVID-19 Vaccine. This case is an unusually prolonged presentation of skin rash following vaccination for the novel COVID-19 virus. This case is clinically significant as it highlights an uncommon but not contraindicated potential side effect and details appropriate medical management. This case highlights that while potentially distressing patients who experience this side effect should be offered reassurance and conservative treatment.

A case report of new onset graves' disease induced by SARS-CoV-2 infection or vaccine? The virus responsible for the COVID-19 pandemic continues to pose unmatched challenges in the world. It can cause systemic inflammation, which can lead to multiorgan involvement and subsequent damage. The relationship that possibly exists between the COVID-19 infection, the newly developed vaccines, and thyroid disease are still under extensive investigation. We are reporting the first case of new-onset graves' disease in a young, healthy man after COVID-19 infection and receiving a COVID-19 vaccine dose.

First Case of Erythema Nodosum Associated With Pfizer Vaccine. Vaccine-related erythema nodosum is uncommon, especially after the coronavirus disease 2019 (COVID-19) vaccine. This study presents the first case of the Pfizer vaccine associated with erythema nodosum. A 22-year-old healthy woman presented with a five-dayÂ history of several red painful areas with swelling in the lower extremities that started one day after receiving the first dose of Pfizer vaccine. Past medical history, laboratory investigation, and chest radiographÂ revealed normal results. Erythema nodosum is an immune reaction that manifests as multiple, painful nodules commonly seen on the shin that resolved spontaneously two to eight weeks after the onset. In the absence of laboratory and chest radiograph abnormalities and shortly after receiving the Pfizer vaccine, vaccine-related erythema nodosum is the only possible explanation.

Reactivation of herpes zoster after vaccination with an inactivated vaccine: A case report from Nepal. COVID-19Â has been linked to a number of cutaneous symptoms in COVID-19 patients. Although herpes zoster (HZ) was the first sign of COVID-19 infection in several patients, cases of HZ after COVID-19 vaccination are rare. Here, we report a case of 51-year-old male patient with herpes zoster after Sinopharm (Vero cell) vaccination.

Lichen planus flare following COVID-19 vaccination: A case report. We report the third case of cutaneous lichen planus (LP) following COVID-19 BNT162b2 vaccination in a 59-year-old woman with previous LP. The reactivation of LP in patients with dormant LP suggests a possible vaccine-induced immune dysregulation. We suggest that the already described vaccine-induced upregulation of Th1 response may play a relevant role in LP reactivation, through an increase in inflammatory cytokines involved in the pathogenesis of LP. Interestingly, LP has already been associated with vaccinations and viral infections including COVID-19 disease. However, the exact mechanism underlying LP (re)activation after Pfizer-BiotNtech COVID-19 vaccination is still widely unknown and needs to be further investigated.

From Epidemic to Pandemic: Comparing Hospital Staff Emotional Experience Between MERS and COVID-19. Objective: Both Middle East Respiratory Syndrome (MERS) and Coronavirus Disease 2019 (COVID-19) have an emotional toll on healthcare workers (HCWs), but the difference of the impact between the two diseases remains unknown.Design: A cross sectional descriptive survey.Setting: A tertiary care hospital.Participants: 125 HCWs who worked during the 2014 MERS as well as the 2020 COVID-19 outbreaks in high-risk areas of the hospital including critical care, emergency room and COVID-19 clinics.Methods: The comprehensive survey comprised 5 sections and 68 questions and was administered to HCWs before availability of the COVID-19 vaccine. The survey evaluated hospital staff emotions, perceived stressors, external factors that reduced stress, personal coping strategies, and motivators for future outbreaks. The participants rated each question for MERS and COVID-19 simultaneously on a scale from 0-3. The responses were reported as mean and standard deviation, while Wilcoxon signed-rank test was used to calculate the difference in responses.Results: There were 102 (82%) participants who returned the questionnaire. The ritual of obsessive hand washing, emotional and physical fatigue, ongoing changes in infection control guidelines, fear of community transmission, and limitations on socialization and travel were the major stressors that were significantly worse during COVID-19 compared to MERS ($P<0.05$) and led to HCWs

adoption of additional 'personal' coping strategies during COVID-19. There was no difference between COVID-19 and MERS, however, among preferences for 'external' factors made available to HCWs that could reduce stress or in their preferences for motivators to work in future outbreaks (P>.05).Conclusion: Both the MERS and COVID-19 outbreaks were emotionally draining for HCWs. However, COVID-19 was a relatively more stressful experience than MERS for HCWs and led to greater personal, behavioral, and protective adaptations by the hospital staff.

De novo and relapsing glomerulonephritis after COVID-19 vaccination: how much do we know?

Breakthrough COVID-19 after SARS-CoV-2 vaccination in solid organ transplant recipients: An analysis of symptomatic cases and monoclonal antibody therapy. BACKGROUND: Solid organ transplant (SOT) recipients are at increased risk for complications from SARS-CoV-2 infection. Little is known regarding clinical course and outcomes of breakthrough COVID-19 in the fully vaccinated SOT population. We sought to describe our cohort of SOT recipients who developed symptomatic breakthrough COVID-19 after full vaccination. METHODS: We conducted a retrospective review of SOT recipients diagnosed with COVID-19 at least 14 days after completing SARS-CoV-2 vaccination. Patients were analyzed according to those presenting with mild-to-moderate and severe COVID-19, respectively. We described presenting characteristics, COVID-19 therapy, and analyzed outcomes including emergency department (ED) visits, hospitalization, and intensive care unit (ICU) admission. RESULTS: Thirty-five patients met inclusion criteria. These had a mean age of 60.8 years and kidney transplant was the most common SOT type. Five patients presented with severe COVID-19 at diagnosis, all requiring hospitalization without ICU admission. From the 30 patients who presented with mild-to-moderate infection, 28 received casirivimab-imdevimab. Four of these 28 (14.3%) had an ED visit, with one requiring hospital admission (3.4%). No patients required ICU admission. CONCLUSION: Breakthrough COVID-19 may occur in SOT recipients after full vaccination, though they appear to have acceptable outcomes. Anti-spike monoclonal antibody therapy for eligible SOT patients may have mitigated clinical progression and improved the outcomes. Further study with large cohorts is warranted.

Infectious disease scenarios in a post-vaccine view of COVID-19 and future pandemics.

Adverse events following the first dose of Covishield (ChAdOx1 nCoV-19) vaccination among health workers in selected districts of central and western Nepal: A cross-sectional study. INTRODUCTION: The study aimed at exploring the adverse events following immunization (AEFI) and their incidences among health workers in three different districts of central and western Nepal following the first dose of Covishield vaccine,. It also aimed at studying the association of AEFI with demographic and clinical characteristics of vaccinees, pre-vaccination anxiety level and prior history of COVID-19 infection (RT- PCR confirmed) status. MATERIALS AND METHODS: This was a cross-sectional study carried out via face-to-face or telephonic interview among 1006 health workers one week after receiving their first dose of the Covishield vaccine. Incidence of adverse events was calculated in percentage while Chi-square Test was used to check the association of AEFI with independent variables. Logistic regression was used to find out the adjusted odd's ratio at 95% CI. RESULTS: Incidence of AEFI was 79.8% with local and systemic AEFI being 68.0% and 59.7% respectively. Injection site tenderness was the commonest manifestation. Local and systemic symptoms resolved in less than one week among 96.8% and 98.7% vaccinees respectively. Females were more likely to develop AEFI than males (AOR = 1.7, 95% CI = 1.2-2.4). Vaccinees aged 45-59 years were 50% less likely to develop AEFI as compared to those aged less than 30 years (AOR 0.5, 95% CI = 0.3-0.8). Most of the vaccinees had not undergone RT-PCR testing for COVID-19 (59.8%). Those who were not tested for COVID-19 prior were 1.5 odds more likely to develop AEFI compared to those who were negative (AOR = 1.5, 95% CI = 1.1-2.1). CONCLUSION: More than two-third of the

vaccinees developed one or more forms of adverse events, but most events were self-limiting. Females and young adults were more prone to develop AEFI.

Maternal and Neonatal SARS-CoV-2 Immunoglobulin G Antibody Levels at Delivery After Receipt of the BNT162b2 Messenger RNA COVID-19 Vaccine During the Second Trimester of Pregnancy. IMPORTANCE: BNT162b2 messenger RNA (mRNA) COVID-19 vaccination in the third trimester was found to be associated with a strong maternal humoral IgG response that crossed the placenta and approached maternal titers in the newborn. OBJECTIVE: To evaluate maternal and neonatal SARS-CoV-2 immunoglobulin G (IgG) antibody levels at birth after mRNA COVID-19 vaccination during the second trimester of pregnancy. DESIGN, SETTING, AND PARTICIPANTS: This prospective cohort study, conducted at a single medical center in Haifa, Israel, from May to July 2021, included women with a singleton pregnancy over 24 weeks of gestation at least 7 days after receipt of their second COVID-19 vaccine dose who were not known to be previously infected with COVID-19. EXPOSURES: BNT162b2 (Pfizer/BioNTech) vaccination. MAIN OUTCOMES AND MEASURES: The primary outcomes were SARS-CoV-2 IgG antibody titers measured in the parturient at admission and in the umbilical cord blood within 30 minutes after delivery. Secondary outcomes were the correlation between antibody titers, feto-maternal characteristics, maternal adverse effects after vaccination, and time interval from vaccination to delivery. RESULTS: Antibody levels were measured for 129 women (mean [SD] age, 31.9 [4.9] years) and 114 neonates, with 100% of the tests having positive results. The mean (SD) gestational age at administration of the second vaccine dose was 24.9 (3.3) weeks. Neonatal IgG titers were 2.6 times higher than maternal titers (median [range], 3315.7 [350.1-17â€¯643.5] AU/mL vs 1185.2 [146.6-32â€¯415.1] AU/mL). A positive correlation was demonstrated between maternal and neonatal antibodies (râ€‰=â€‰0.92; 95% CI, 0.89-0.94). Multivariable analysis revealed that for each week that passed since receipt of the second vaccine dose, maternal and neonatal antibody levels changed by -10.9% (95% CI, -17.2% to -4.2%; Pâ€‰=â€‰.002) and -11.7% (95% CI, -19.0 to -3.8%; Pâ€‰=â€‰.005), respectively. For each 1-year increase in the mother's age, maternal and neonatal antibody levels changed by -3.1% (95% CI, -5.3% to -0.9%; Pâ€‰=â€‰.007) and -2.7% (95% CI, -5.2% to -0.1%; Pâ€‰=â€‰.04), respectively. CONCLUSIONS AND RELEVANCE: In this cohort study, receipt of the BNT162b2 mRNA COVID-19 vaccine during the second trimester of pregnancy was associated with maternal and neonatal humoral responses, as reflected in maternal and neonatal SARS-CoV-2 IgG antibody levels measured after delivery. These findings support COVID-19 vaccination of pregnant individuals during the second trimester to achieve maternal protection and newborn safety during the pandemic.

COVID-19 Vaccination in Children: An Open Question. BACKGROUND: A safe and effective vaccine represents the best way to control the COVID-19 pandemic, which has caused more than 4 million deaths to date. Several vaccines have now been approved worldwide, depending on the country. Being administered to healthy people, anti-SARS-CoV-2 vaccines must meet high safety standards, and this is even more important among the pediatric population in which the risk of developing severe disease is significantly lower than adults. However, vaccination of the pediatric population could help in reducing viral spread in the whole population. OBJECTIVE: Our narrative review analyzes and discusses the currently available literature on the advantages and disadvantages of COVID-19 vaccination in the pediatric population. METHODS: A bibliographic research was conducted through Pubmed, Read, and Scopus using COVID-19, SARS-CoV-2, immunization, antibody, COVID-19 vaccine efficacy, COVID-19 vaccine safety, children, adolescents, MIS-C, adverse effects as keywords. RESULTS: Although children are less susceptible to COVID-19 infection, they can develop serious consequences, including multi-inflammatory syndrome. However, any vaccine-related side effects should be evaluated before administering vaccination to children while ensuring complete safety. To date, adverse effects are reported in adolescents and young adults following vaccination;

however, these are mostly isolated reports. CONCLUSION: Further investigation is needed to establish whether there is indeed a cause-and-effect relationship in the development of vaccine-related adverse effects. However, to date, COVID-19 vaccination is recommended for children and adolescents older than 12 years of age. However, this question is still under debate and involves ethical, political, and social issues.

MOG-antibody-associated longitudinal extensive myelitis after ChAdOx1 nCoV-19 vaccination. This case report describes a 59-year-old man with myelin oligodendrocyte glycoprotein (MOG)-positive longitudinal extensive transverse myelitis (LETM) after being vaccinated with the COVID-19 vaccine ChAdOx1 nCoV-19. He presented with urinary retention, gait disturbance, hypoesthesia and brisk reflexes in his lower extremities without paresis. Due to the ineffectiveness of high-dose intravenous methylprednisolone, therapeutic plasma exchange was performed, gradually improving the patient's condition. Vaccination as a trigger for an excessive immunological response seems plausible, though unspecific for the ChAdOx1 nCoV-19 vaccine.

Post-vaccine COVID-19 in patients with multiple sclerosis or neuromyelitis optica. INTRODUCTION: Recent studies suggested that anti-CD20 and fingolimod may be associated with lower anti-spike protein-based immunoglobulin-G response following COVID-19 vaccination. We evaluated if COVID-19 occurred despite vaccination among patients with multiple sclerosis (MS) and neuromyelitis optica (NMO), using the COVISEP registry. CASE SERIES: We report 18 cases of COVID-19 after two doses of BNT162b2-vaccination, 13 of which treated with anti-CD20 and four with fingolimod. COVID-19 severity was mild. DISCUSSION: These results reinforce the recommendation for a third COVID-19 vaccine dose among anti-CD20 treated patients and stress the need for a prospective clinical and biological study on COVID-19 vaccine efficacy among MS and NMO patients.

Leukocytoclastic vasculitis after COVID-19 vaccination. Leukocytoclastic vasculitis (LCV) is the vasculitis of small vessels. In this report, we describe a 38-year-old male patient who presented to our outpatient clinic with a 1-week history of rash on his lower extremities that had started 4â€‰days after receiving the Pfizer-BioNTech SARS-CoV-2 vaccine. A diagnosis of LCV was made based on clinical and histopathological findings. The patient was treated with antihistamines and prednisolone, after which improvement was observed in the lesions. With this paper, we aim to raise awareness concerning the possibility of LCV development after COVID-19 vaccination.

Worsening of the vitiligo following the second dose of the BNT162B2 mRNA COVID-19 vaccine.

Urticarial vasculitis following mRNA anti-COVID-19 vaccine.

How compassionate use enabled Israel to deliver the Pfizer-BioNTech COVID-19 vaccination to vulnerable children aged 12-15Â years before regulatory approval. AIM: This paper describes the emergency, compassionate use of the COVID-19 vaccination for high-risk adolescents aged 12-15Â years prior to approval by the American Food and Drugs Administration in May 2021. The target audience had underlying health conditions associated with severe disease and multisystem inflammatory syndrome in children (MIS-C) or severely immunosuppressed household members. METHODS: An orderly approval system was established in Israel for adolescents aged 12-15Â years, based on a professional position paper and compassionate treatment regulations. From 12 February 2021, eligible adolescents were referred to the Israeli Ministry of Health for permission to vaccinate, via four health maintenance organisations. Data were collected about adverse events after vaccinations and the incidence of any cases of COVID-19. RESULTS: By 15 March 2021, the vaccine had been approved for 607 adolescents: 333 had received one dose, and 92 had received two doses. The median age was 14.6Â years, and the major indication was obesity. Only one child tested positive for the virus, 4Â days after vaccination, and no adverse effects were recorded. CONCLUSION: The emergency use of COVID-19 vaccination for 333 adolescents aged 12-15, 92 of them with 2 doses, based on a position paper and compassionate treatment regulations, did not result in any adverse

effects. Since 27 July 2021, the same process was further applied in Israel among younger children, aged 5-11, preceding formal release of the clinical trial.

mRNA-based COVID-19 vaccine boosters induce neutralizing immunity against SARS-CoV-2 Omicron variant. Recent surveillance has revealed the emergence of the SARS-CoV-2 Omicron variant (BA.1/B.1.1.529) harboring up to 36 mutations in spike protein, the target of vaccine-induced neutralizing antibodies. Given its potential to escape vaccine-induced humoral immunity, we measured neutralization potency of sera from 88 mRNA-1273, 111 BNT162b, and 40 Ad26.COV2.S vaccine recipients against wild type, Delta, and Omicron SARS-CoV-2 pseudoviruses. We included individuals that were vaccinated recently (<3 months), distantly (6-12 months), or recently boosted, and accounted for prior SARS-CoV-2 infection. Remarkably, neutralization of Omicron was undetectable in most vaccinated individuals. However, individuals boosted with mRNA vaccines exhibited potent neutralization of Omicron only 4-6-fold lower than wild type, suggesting that boosters enhance the cross-reactivity of neutralizing antibody responses. In addition, we find Omicron pseudovirus is more infectious than any other variant tested. Overall, this study highlights the importance of boosters to broaden neutralizing antibody responses against highly divergent SARS-CoV-2 variants.

Drug reaction with eosinophilia and systemic symptoms syndrome following vaccination with the AstraZeneca COVID-19 vaccine.

Alopecia areata after SARS-CoV-2 vaccination.

Association of cerebral venous thrombosis with recent COVID-19 vaccination: case-crossover study using ascertainment through neuroimaging in Scotland. BACKGROUND: To investigate the association of primary acute cerebral venous thrombosis (CVT) with COVID-19 vaccination through complete ascertainment of all diagnosed CVT in the population of Scotland. METHODS: Case-crossover study comparing cases of CVT recently exposed to vaccination (1-14 days after vaccination) with cases less recently exposed. Cases in Scotland from 1 December 2020 were ascertained through neuroimaging studies up to 17 May 2021 and diagnostic coding of hospital discharges up to 28 April 2021, linked to national vaccination records. The main outcome measure was primary acute CVT. RESULTS: Of 50 primary acute CVT cases, 29 were ascertained only from neuroimaging studies, 2 were ascertained only from hospital discharges, and 19 were ascertained from both sources. Of these 50 cases, 14 had received the Astra-Zeneca ChAdOx1 vaccine and 3 the Pfizer BNT162b2 vaccine. The incidence of CVT per million doses in the first 14 days after vaccination was 2.2 (95% credible interval 0.9 to 4.1) for ChAdOx1 and 1 (95% credible interval 0.1 to 2.9) for BNT162b2. The rate ratio for CVT associated with exposure to ChAdOx1 in the first 14 days compared with exposure 15-84 days after vaccination was 3.2 (95% credible interval 1.1 to 9.5). CONCLUSIONS: These findings support a causal association between CVT and the AstraZeneca vaccine. The absolute risk of post-vaccination CVT in this population-wide study in Scotland was lower than has been reported for populations in Scandinavia and Germany; the explanation for this is not clear.

Reactivation of BCG vaccination scars after vaccination with mRNA-Covid-vaccines: two case reports. BACKGROUND: From May 2020 to January 2021, we enrolled 1233 health care workers (HCW) from Danish Hospitals in a randomized trial evaluating whether Bacille Calmette-GuÃ©rin (BCG) provides protection against COVID-19. Participants were randomized 1:1 to BCG vs saline and followed for 6Â months. From December 2020, Covid-19 vaccines were offered to the HCW. In most cases, BCG vaccination results in a characteristic scar. Reactivation of the BCG scar has been described in children during viral infections and following influenza vaccination, but is mostly associated to Kawasaki's disease, a disease entity with pathogenesis likely similar to the child Covid-19 complication MIS-C: Multi-System Inflammatory Syndrome. Reactivation of scars after neonatal BCG vaccination has recently been described in four women after Covid-19 mRNA vaccination. Two of our trial participants

experienced reactivation of their novel BCG scars after receiving mRNA Covid-19 vaccination 6 to 8Â months post-BCG. CASE PRESENTATIONS: Two female HCW participants that had been randomly allocated to BCG in the BCG-DENMARK-COVID trial, spontaneously reported itching and secretion at the BCG scar site after having received mRNA Covid-19 vaccination (Moderna and Pfizer-BioNTech) 6 to 8Â months following inclusion and BCG vaccination. One participant, who had a larger BCG skin reaction, noticed re-appearing symptoms after both the first and the second COVID-vaccine dose, while the other participant only noted symptoms after the second dose. Both had been BCG vaccinated during childhood, and no reactivation was noted in the older scars. No treatment was needed or provided. CONCLUSIONS: The reactivation of the BCG scar after receiving mRNA vaccine might have been caused by cross-reactivity between BCG and SARS-CoV-2. In both cases, the symptoms were bothersome, but self-limiting and left no sequelae. The risk of reactivation at the scar site is thus not a reason to avoid vaccination with either vaccine.
Guillain-BarrÃ© syndrome after vaccination against COVID-19.
Correction: Antibody Responses After SARS-CoV-2 mRNA Vaccination in Adults With Inflammatory Bowel Disease.
SCLE manifestation after mRNA COVID-19 vaccination.
Bullous pemphigoid in a young male after COVID-19 mRNA vaccine: a report and brief literature review.
Patients' findings after COVID-19 infection and vaccinations: what to expect from [18F]FDG PET/CT.
Comparison of SARS-CoV-2 Antibody Response 4 Weeks After Homologous vs Heterologous Third Vaccine Dose in Kidney Transplant Recipients: A Randomized Clinical Trial. IMPORTANCE: Fewer than 50% of kidney transplant recipients (KTRs) develop antibodies against the SARS-CoV-2 spike protein after 2 doses of an mRNA vaccine. Preliminary data suggest that a heterologous vaccination, combining mRNA and viral vector vaccines, may increase immunogenicity. OBJECTIVE: To assess the effectiveness of a third dose of an mRNA vs a vector vaccine in KTRs who did not have antibodies against the SARS-CoV-2 spike protein after 2 doses of an mRNA vaccine. DESIGN, SETTING, AND PARTICIPANTS: This was a single center, single-blinded, 1:1 randomized clinical trial of a third dose of vaccine against SARS-CoV-2, conducted from June 15 to August 16, 2021, in 201 KTRs who had not developed SARS-CoV-2 spike protein antibodies after 2 doses of an mRNA vaccine. Data analyses were performed from August 17 to August 31, 2021. INTERVENTIONS: mRNA (BNT162b2 or mRNA-1273) or vector (Ad26COVS1) as a third dose of a SARS-CoV-2 vaccine. MAIN OUTCOMES AND MEASURES: The primary study end point was seroconversion after 4 weeks (29-42 days) following the third vaccine dose. Secondary end points included neutralizing antibodies and T-cell response assessed by interferon-Î³ release assays (IGRA). In addition, the association of patient characteristics and vaccine response was assessed using logistic regression, and the reactogenicity of the vaccines was compared. RESULTS: Among the study population of 197 kidney transplant recipients (mean [SD] age, 61.2 [12.4] years; 82 [42%] women), 39% developed SARS-CoV-2 antibodies after the third vaccine. There was no statistically significant difference between groups, with an antibody response rate of 35% and 42% for the mRNA and vector vaccines, respectively. Only 22% of seroconverted patients had neutralizing antibodies. Similarly, T-cell response assessed by IGRA was low with only 17 patients showing a positive response after the third vaccination. Receiving nontriple immunosuppression (odds ratio [OR], 3.59; 95% CI, 1.33-10.75), longer time after kidney transplant (OR, 1.44; 95% CI, 1.15-1.83, per doubling of years), and torque teno virus plasma levels (OR, 0.92; 95% CI, 0.88-0.96, per doubling of levels) were associated with vaccine response. The third dose of an mRNA vaccine was associated with a higher frequency of local pain at the injection site compared with the vector vaccine, while systemic symptoms were comparable between groups. CONCLUSIONS AND RELEVANCE: This randomized clinical trial found that 39% of KTRs without an immune response

against SARS-CoV-2 after 2 doses of an mRNA vaccine developed antibodies against the SARS-CoV-2 spike protein 4 weeks after a third dose of an mRNA or a vector vaccine. The heterologous vaccination strategy with a vector-based vaccine was well tolerated and safe but not significantly better than the homologous mRNA-based strategy. TRIAL REGISTRATION: EudraCT Identifier: 2021-002927-39.
Cutaneous manifestations following COVID-19 vaccination: a multicentric descriptive cohort.
Varicella zoster virus reactivation after coronavirus disease 2019 vaccination in Japanese patients: A series of 14 cases.
Risk of venous thrombotic events and thrombocytopenia in sequential time periods after ChAdOx1 and BNT162b2 COVID-19 vaccines: A national cohort study in England. BACKGROUND: Thrombosis with thrombocytopenia, or thrombocytopenia on its own, have been reported after Covid-19 vaccines. We assessed the risk after ChAdOx1 adenovirus-vector and BNT162b2 mRNA vaccines in a national cohort study in England. METHODS: Hospital admissions for a cerebral venous thrombosis (CVT), other venous thrombosis or thrombocytopenia between 30(th) November 2020 and 18(th) April 2021 were linked to the national Covid-19 immunisation register. The incidence of events by dose in pre-defined post-vaccination risk periods relative to the unvaccinated cohort was estimated after adjustment for age, gender, co-morbidities, care home residency and health/social care worker status. Elevated relative incidence (RI) estimates with p<0.001 were considered strong evidence of an association. FINDINGS: The RI for CVT after a first ChAdOx1 dose in 15-39 and 40-64 year olds was 8.7 (95% confidence interval 5.8-13.0) and 2.2 (1.4-3.2) respectively, p<0.001. The elevated risk period in 15-39 year olds was highest 4-13 days post-vaccination (16.3, 9.9-27.0). The attributable risk (AR) was 16.1 per million doses for 15-39 and 3.2 per million for 40-64 year olds. RIs for other thrombosis admissions were elevated in these age groups with ARs of 36.3 and 16.4 per million respectively as were RIs for thrombocytopenia, with ARs of 11.3 and 10.1 per million respectively. No elevated RIs were found for 65+ year olds or after a second ChAdOx1 dose, nor for BNT162b2 vaccine recipients of any age. INTERPRETATION: This epidemiological study shows an increased risk of thrombotic episodes and thrombocytopenia in adults under 65 years of age within a month of a first dose of ChAdOx1 vaccine but not after the BNT162b2 vaccine. FUNDING: EM receives support from the National Institute for Health Research (NIHR) Health Protection Research Unit in Immunisation at the London School of Hygiene and Tropical Medicine in partnership with Public Health England (Grant Reference NIHR200929).
Aseptic meningitis after BNT-162b2 COVID-19 vaccination. The COVID-19 pandemic has had an unprecedented impact on healthcare systems globally, giving rise to significant morbidity and mortality. Vaccination has been widely regarded as the most important strategy to contain the pandemic. Whilst local side-effects of the BNT-162b2 (Pfizer-BioNTech) vaccine are well known, concern has emerged due to sporadic reports of immune-mediated adverse effects (Cines and Bussel, 2021; Rela etÂ al., 2021). As of August 19, 2021, 4.54 million individuals had received COVID-19 vaccines in Singapore (Oxford Martin School UoO, 2021). We report a case series of two patients who developed aseptic meningitis after vaccination.
Humoral Responses After SARS-CoV-2 mRNA Vaccination and Breakthrough Infection in Cancer Patients. OBJECTIVE: To evaluate the magnitude of humoral response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) messenger RNA (mRNA) vaccines in patients with cancer receiving active therapies. PATIENTS AND METHODS: Patients 18 years or older in whom SARS-CoV-2 spike antibody (anti-S Ab) levels were measured after 2 doses of SARS-CoV-2 mRNA vaccines were included. Patients with prior coronavirus disease 2019 (COVID-19) infection or receiving other immunosuppressive therapy were excluded. RESULTS: Among 201 patients who met the criteria, 61 were immunocompetent, 91 had a hematologic malignancy, and 49 had a solid malignancy while

receiving treatments associated with cytopenia, including chemotherapy or cyclin-dependent kinase 4 and 6 inhibitors. A significantly greater proportion of immunocompetent patients (96.7% [59 of 61]) had anti-S Ab titers of 500 U/mL or greater compared to patients with hematologic (7.7% [7 of 91) and solid (55.1% [27 of 49]) malignancy (P<.001). Despite 2 doses of SARS-CoV-2 mRNA vaccines, 52.7% of patients with hematologic malignancy (48 of 91) and 8.2% of those with solid malignancy (4 of 49) receiving cytopenic therapy had no seroconversion (spike antibody titers <0.8 U/mL). Two patients subsequently had development of breakthrough COVID-19 infection after full vaccination. CONCLUSION: A substantial proportion of patients with hematologic and solid malignancies receiving chemotherapies and CDK4/6i had poor humoral responses after SARS-CoV-2 mRNA vaccination. Our study adds to a growing body of literature suggesting that immunosuppressed patients have a suboptimal humoral response to COVID-19 vaccination. Our study also underscores the importance of assessing antibody response after COVID-19 vaccines in these vulnerable patients.

Rare lymphomatoid reactions following SARS-CoV-2 vaccination.

Previous COVID-19 Infection and Antibody Levels After Vaccination. Background: The emergence of new COVID-19 variants of concern coupled with a global inequity in vaccine access and distribution has prompted many public health authorities to circumvent the vaccine shortages by altering vaccination protocols and prioritizing persons at high risk. Individuals with previous COVID-19 infection may not have been prioritized due to existing humoral immunity. Objective: We aimed to study the association between previous COVID-19 infection and antibody levels after COVID-19 vaccination. Methods: A serological analysis to measure SARS-CoV-2 immunoglobulin (Ig)G, IgA, and neutralizing antibodies was performed on individuals who received one or two doses of either BNT162b2 or ChAdOx1 vaccines in Kuwait. A Student t-test was performed and followed by generalized linear regression models adjusted for individual characteristics and comorbidities were fitted to compare the average levels of IgG and neutralizing antibodies between vaccinated individuals with and without previous COVID-19 infection. Results: A total of 1,025 individuals were recruited. The mean levels of IgG, IgA, and neutralizing antibodies were higher in vaccinated subjects with previous COVID-19 infections than in those without previous infection. Regression analysis showed a steeper slope of decline for IgG and neutralizing antibodies in vaccinated individuals without previous COVID-19 infection compared to those with previous COVID-19 infection. Conclusion: Previous COVID-19 infection appeared to elicit robust and sustained levels of SARS-CoV-2 antibodies in vaccinated individuals. Given the inconsistent supply of COVID-19 vaccines in many countries due to inequities in global distribution, our results suggest that even greater efforts should be made to vaccinate more people, especially individuals without previous COVID-19 infection.

Acute liver failure after vaccination against of COVID-19; a case report and review literature. BACKGROUND: Vaccination against COVID-19 remains as a main root of COVID-19 prevention. Few vaccines have been launched for this purpose recently with different side effects. Thrombotic events have been reported as a rare side effect after ChAdox1nCOV-19 vaccination that may cause death of recipient. CASE PRESENTATION: We report a case of hepatic artery occlusion after the first dose vaccination by ChAdOx1nCov-19. The patient was a health care worker, aged 34-year old. Past medical history was unremarkable and had not used heparin. Over the next couple of days after the vaccination, he reported headache, nausea, and dizziness as well as abdominal pain. His general status and the laboratories studies deteriorate quickly by increasing liver enzymes and severe coagulopathy. Clinically he had presented acute hepatic failure. He had been received blood products, prednisolone pulse along with broad antibiotics without benefit. He died on the sixth day. CONCLUSIONS: Thrombotic events after vaccination is very rare but can develop in main arteries with lethal outcome. This event may mimic autoimmune thrombosis clinically.

Complex Regional Pain Syndrome Post COVID-19 Vaccine Shot: An Autobiographical Case Report. Complex regional pain syndrome (CRPS) is a pathological exaggeration caused by trauma from injections and vaccine administration characterized by severe pain (often burning), hyperesthesia, allodynia, edema, vasomotor changes, decreased range of motion, hyperhidrosis, and trophic changes. It occurs at all ages with female predominance, and the incidence increases until late middle age. Hand and foot involvement is well recognized, and this may spread proximally. Treatment usually requires a multimodal approach, including medications and physical and cognitive therapy. Reports of CRPS after vaccination are rare. The incidence of CRPS post coronavirus disease 2019 (COVID-19)Â vaccination is not yet reported. This case report describes my experience with deltoid hematoma, tennis elbow, and living with CRPS post COVID-19 vaccine shot, including the psychosocial adaptations I made in my day-to-day life.

Antibody Response and Safety After mRNA-1273 SARS-CoV-2 Vaccination in Peritoneal Dialysis Patients - the Vienna Cohort. BACKGROUND: Dialysis patients are at high risk for a severe clinical course after infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Safety and early immune responses after mRNA-based vaccination have been reported mostly in patients on hemodialysis (HD), whereas reports of peritoneal dialysis (PD) patients remain rare. METHODS: In this retrospective observational study, 39 PD patients had received two doses of the mRNA-1273 Moderna(Â®) vaccine. We analyzed SARS-CoV-2 Spike (S) antibody titers 4 weeks after each dose of mRNA-1273 and report local and systemic side effects in PD patients that occurred within one week after each mRNA-1273 dose. Using a quantile regression model we examined factors that might influence SARS-CoV-2 S antibody levels in PD patients. RESULTS: Four weeks after the first dose of mRNA-1273 vaccine 33 of 39 (84.6%) PD patients seroconverted and presented with 6.62 U/mL (median; IQR 1.57-22.5) anti-SARS-CoV-2 S antibody titers. After the second dose, 38 of 39 (97.4%) PD patients developed anti-SARS-CoV-2 S antibodies and titers increased significantly (median 968 U/mL; IQR 422.5-2500). Pain at the injection site was the most common local adverse event (AE) (71%). Systemic AEs occurring after the first dose were mostly fatigue (33%) and headache (20%). No severe systemic AEs were reported after the first injection. After the second dose the incidence and the severity of the systemic AEs increased. The most common systemic AEs were: fatigue (40.5%), headache (22.5%), joint pain (20%), myalgia (17.5%) and fever (13%). Lower Davies Comorbidity Score (p=0.04) and shorter dialysis vintage (p=0.017) were associated with higher antibody titers after the first dose. Patients with higher antibody titers after the first dose tended to have higher antibody titers after the second dose (p=1.53x10(-05)). CONCLUSIONS: Peritoneal dialysis patients in this cohort had a high seroconversion rate of 97.4%, showed high antibody titers after full vaccination and tolerated the anti-SARS-CoV-2 mRNA-1273 vaccine well without serious adverse events.

The Humoral Immune Response to BNT162b2 Vaccine Is Associated With Circulating CD19+ B Lymphocytes and the NaÃ¯ve CD45RA to Memory CD45RO CD4+ T Helper Cells Ratio in Hemodialysis Patients and Kidney Transplant Recipients. BACKGROUND: The humoral and cellular immune responses to SARS-COV-2 vaccination remain to be elucidated in hemodialysis (HD) patients and kidney transplant recipients (KTRs), considering their baseline immunosuppressed status. The aim of our study was to assess the associations of vaccine-induced antibody responses with circulating lymphocytes sub-populations and their respective patterns of alterations in maintenance HD patients and KTRs. MATERIALS AND METHODS: We included 34 HD patients and 54 KTRs who received two doses of the mRNA-vaccine BNT162b2. Lymphocyte subpopulations were analyzed by flow cytometry before vaccination (T0), before the second vaccine dose (T1) and 2 weeks after the second dose (T2). The anti-SARS-CoV2 antibody response was assessed at T1 and at T2. RESULTS: 31 HD patients (91.8%) and 16 KTRs (29.6%) became seropositive at T2. HD patients who became seropositive following the first dose displayed higher CD19+ B lymphocytes compared to their seronegative HD

counterparts. A positive correlation was established between CD19+ B cells counts and antibody titers at all time-points in both groups ($p < 0.001$). KTRs showed higher naÃ¯ve CD4+CD45RA+ T helper cells compared to HD patients at baseline and T2 whereas HD patients displayed higher memory CD45RO+ T cells compared to KTRs at T2. The naÃ¯ve CD4+CD45RA to memory CD4+CD45RO+ T helper cells fraction was negatively associated with antibody production in both groups. CONCLUSIONS: Our study provides a potential conceptual framework for monitoring vaccination efficacy in HD patients and KTRs considering the correlation established between CD19+ B cells, generation of memory CD4+ T helper cells and anti SARS-CoV2 antibody response to vaccination.

Durable humoral responses after the second anti-SARS-CoV-2 vaccine dose in chronic myeloid leukaemia patients on tyrosine kinase inhibitors.

Evaluation of neutralizing antibodies after vaccine BNT162b2: Preliminary data. It is well-known that the Coronavirus Disease 2019, which is caused by the beta-coronavirus severe acute respiratory syndrome (SARS-CoV-2), emerged in December 2019 followed by an outbreak first reported in Wuhan, China. Thus far, vaccination appears to be the only way to bring the pandemic to an end. In the present study, immunogenicity data was evaluated using LIAISONÂ® SARS-CoV-2 TrimericS IgG assay (DiaSorin S.p.A) among a sample of 52 vaccinated healthcare workers, five of whom were previously infected with SARS-CoV-2 and 47 who were seronegative, over a time span of â‰¤90 days following the second dose of the BNT162b2 mRNA vaccine. The test detects antibodies against the Trimeric complex (S1, S2 and receptor binding domain). The overall mean value of the serum levels of IgG antibodies to SARS-CoV-2 30 days following the second dose of the vaccine was 1,901.8 binding arbitrary unit (BAU)/ml, after 60 days the mean value declined to 1,244.9 BAU/ml. The antibody levels then reached a plateau, as confirmed by the antibody test carried out 90 days following the second dose, which revealed a mean value of 1,032.4 BAU/ml ($P<0.0001$). A higher level was observed at all three times in male subjects compared with female subjects, and in younger male participants compared with female participants, although these differences did not reach a statistically significant level. Similarly, no significant difference was found in antibody values at different times according to age. After the second dose of the vaccine, two subjects were infected with SARS-CoV-2, and an increase in antibody values in the third assay was observed in both individuals.

Re: Real-world safety data for the Pfizer BNT162b2 SARS-CoV-2 vaccine, historical cohort study: authors' response.

Inflammatory Bowel Disease Triggered by BNT162b2 mRNA Vaccination for SARS-CoV-2.

New insights into Covid-19 disease. Apo-A1 antibodies are generated after mRNA Covid-19 vaccination and after Covid-19 infection.

Neurological Immune-Related Adverse Events After COVID-19 Vaccination: A Systematic Review. The coronavirus disease 2019 (COVID-19) pandemic has affected millions of individuals worldwide. The global scientific effort to design an effective vaccine against this virus has led to the development of several vaccine candidates. The expedited rollout of these vaccines has created some public distrust regarding the safety of these new vaccines. This review compiles clinical data from reports of diagnosed immune-related neurological events that have occurred after COVID-19 vaccine administration with the exception of those secondary to hematological abnormalities. A systematic literature search was performed, using several databases, to identify reports of postvaccination adverse neurological events. The search resulted in 18 studies that met our criteria. These studies included 61 patients who had received COVID-19 vaccines and experienced at least 1 neurological adverse effect. The most common neurological event was facial nerve palsy (50% of all events). Other less frequently reported events included the reactivation of herpes zoster, Guillain-Barre syndrome,

other demyelinating diseases, and neuropathy. The underlying mechanism was hypothesized to be related to vaccine-induced type 1 interferon production leading to decreased tolerance of the myelin sheath antigens. Other hypotheses include vaccine-induced transient lymphopenia and immune dysregulation. Most of the reported events were time limited and resolved spontaneously. Given the rarity of reported neurological events compared to the total number of vaccines administered, and the similarity in the incidence of events between COVID-19 vaccines and other more common vaccines, there is little evidence to support a causal relationship between COVID-19 vaccines and adverse neurological events.

Age-Stratified Risk of Cerebral Venous Sinus Thrombosis After SARS-CoV-2 Vaccination. BACKGROUND AND OBJECTIVES: Cerebral venous sinus thrombosis (CVST) as a part of the thrombosis and thrombocytopenia syndrome is a rare adverse drug reaction of severe acute respiratory syndrome coronavirus disease 2 (SARS-CoV-2) vaccination. Estimated background rate of CVST with thrombocytopenia is 0.1 per million per month. We assessed the age-stratified risk of CVST with and without thrombocytopenia after SARS-CoV-2 vaccination. METHODS: We estimated the absolute risk of CVST with and without thrombocytopenia within 28 days of a first dose of 4 SARS-CoV-2 vaccinations using data from the European Medicines Agency's EudraVigilance database (until June 13, 2021). As a denominator, we used data on vaccine delivery from 31 European countries. For 22.8 million adults from 25 countries, we estimated the absolute risk of CVST after the first dose of ChAdOx1 nCov-19 per age category. RESULTS: The absolute risk of CVST within 28 days of first-dose vaccination was 7.5 (95% confidence interval [CI] 6.9-8.3), 0.7 (95% CI 0.2-2.4), 0.6 (95% CI 0.5-0.7), and 0.6 (95% CI 0.3-1.1) per million of first doses of ChAdOx1 nCov-19, Ad26.COV2.S, BNT162b2, and mRNA-1273, respectively. The absolute risk of CVST with thrombocytopenia within 28 days of first dose vaccination was 4.4 (95% CI 3.9-4.9), 0.7 (95% CI 0.2-2.4), 0.0 (95% CI 0.0-0.1), and 0.0 (95% CI 0.0-0.2) per million of first doses of ChAdOx1 nCov-19, Ad26.COV2.S, BNT162b2, and mRNA-1273, respectively. In recipients of ChAdOx1 nCov-19, the absolute risk of CVST, both with and without thrombocytopenia, was the highest in the 18- to 24-year-old group (7.3 per million, 95% CI 2.8-18.8 and 3.7 per million, 95% CI 1.0-13.3, respectively). The risk of CVST with thrombocytopenia in ChAdOx1 nCov-19 recipients was the lowest in the age group â‰¥70 years (0.2, 95% CI 0.0-1.3). Age <60 years compared to â‰¥60 years was a predictor for CVST with thrombocytopenia (incidence rate ratio 5.79, 95% CI 2.98-11.24, $p < 0.001$). DISCUSSION: The risk of CVST with thrombocytopenia within 28 days of first-dose vaccination with ChAdOx1 nCov-19 was higher in younger age groups. The risk of CVST with thrombocytopenia was slightly increased in patients receiving Ad26.COV2.S compared with the estimated background risk. The risk of CVST with thrombocytopenia was not increased in recipients of SARS-CoV-2 mRNA vaccines.

Adverse reactions to BNT162b2 mRNA COVID-19 vaccine in medical staff with a history of allergy. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, COVID-19) vaccination is progressing globally. Several adverse reactions have been reported with vaccination against COVID-19. It is unknown whether adverse reactions to COVID-19 vaccination are severe in individuals with allergies. METHODS: We administered the COVID-19 vaccine to the medical staff at Yamagata University Hospital from March to August 2021. Subsequently, we conducted an online questionnaire-based survey to investigate the presence of allergy and adverse reactions after vaccination and examine the association between allergy and adverse reactions after immunization. RESULTS: Responses were collected from 1586 to 1306 participants after the first and second administration of the BNT162b2 mRNA COVID-19 vaccine, respectively. Adverse reactions included injection site pain, injection site swelling, fever, fatigue or malaise, headache, chills, nausea, muscle pain outside the injection site, and arthralgia. The frequency of some adverse reactions and their severity were higher, and the duration of symptoms was longer in participants with allergies than in

those without allergies. Although several participants visited the emergency room for treatment after the first and second vaccinations, no participant was diagnosed with anaphylaxis. CONCLUSIONS: This study suggests that the frequency and severity of adverse reactions after injection of BNT162b2 mRNA COVID-19 vaccine were higher in individuals with allergy; however, no severe adverse reactions such as anaphylaxis or death were observed. These results indicate that individuals with allergic histories may tolerate the BNT162b2 mRNA COVID-19 vaccine.
Acute venous thromboembolism after COVID-19 vaccination.
The histologic and molecular correlates of COVID-19 vaccine-induced changes in the skin. A total of 22 patients who had developed an adverse cutaneous reaction to the Moderna or Pfizer vaccine underwent biopsies. Each patient was assessed light microscopically, and, in select biopsies, spike glycoprotein and cytokine assessment were also conducted. The patients developed self-limited cutaneous reactions often described clinically as urticarial or eczematous within 1 day to 4 weeks after receiving the first or second dose of the Pfizer or Moderna vaccine. Classic clinical and morphologic depictions of type IV cutaneous hypersensitivity with features of eczematous dermatitis, interface dermatitis, granulomatous inflammation, and/or lymphocytic vasculitic component were observed. Clinical and/or histologic features of perniosis, pityriasis rosea, pityriasis rubra pilaris, and guttate psoriasis were seen in select cases. In 2 cases the dominant picture was urticarial vasculitis, possibly reflective of an Arthus type III immune complex action. The biopsy specimens of normal skin post vaccine and of skin affected by the post-vaccine eruption showed rare deep microvessels positive for spike glycoprotein with no complement deposition contrasting with greater vascular deposition of spike protein and complement in skin biopsies from patients experiencing severe coronavirus disease 2019 (COVID-19). It is concluded that self-limited hypersensitivity reactions to the vaccine occur possibly owing to a substance found in the vaccine vehicle (eg, polyethylene glycol). An immune response that is directed against human-manufactured spike has to be considered because some of the reactions clinically and or histologically closely resemble mild COVID-19. Finally, vaccine-associated immune enhancement largely attributable to the adjuvant properties of the vaccine may unmask certain inflammatory milieus operational in psoriasis, atopic dermatitis, and subclinical hypersensitivity.
Hypermetabolic abdominal and cervical lymph nodes mimicking Hodgkin lymphoma relapse on FDG PET/CT after adenovirus-vectored COVID-19 vaccine. Vaccine-associated hypermetabolic lymphadenopathy (VAHL) has been reported as a common post-vaccination side effect, especially with mRNA-based COVID-19 vaccines. Most VAHL cases present normal or enlarged regional lymph nodes close to the injection site, usually with mild-moderate FDG (18Â F-Fluorodeoxyglucose) uptake on FDG positron emission tomography (PET)/CT. Here, we describe the case of a 33-year-old woman with past history of Classic Hodgkin Lymphoma (CHL) who underwent follow-up FDG PET/CT 3 days (d) after the first dose of the adenovirus-vectored Oxford-AstraZeneca COVID-19 vaccine. FDG PET/CT showed unexpected small hypermetabolic cervical and abdominal lymph nodes in the same location as at the onset of the disease, suggesting radiological relapse. Considering temporal relationship and other cases of VAHL, a new image was performed 2Â months later, which revealed decreased lymph nodes and normalization of FDG uptake. This case illustrates that the possibility of a false-positive should always be considered by physicians in this new context, even when hypermetabolic lymph nodes appear far from the vaccination site.
Severe aplastic anemia after COVID-19 mRNA vaccination: Causality or coincidence? The development of various autoimmune diseases has been reported after COVID-19 infections or vaccinations. However, no method for assessing the relationships between vaccines and the development of autoimmune diseases has been established. Aplastic anemia (AA) is an immune-mediated bone marrow failure syndrome. We report a case of severe AA that arose after the

administration of a COVID-19 vaccine (the Pfizer-BioNTech mRNA vaccine), which was treated with allogeneic hematopoietic stem cell transplantation (HSCT). In this patient, antibodies against the SARS-CoV-2 spike protein were detected both before and after the HSCT. After the patient's hematopoietic stem cells were replaced through HSCT, his AA improved despite the presence of anti-SARS-CoV-2 antibodies. In this case, antibodies derived from the COVID-19 vaccine may not have been directly involved in the development of AA. This case suggests that the measurement of vaccine antibody titers before and after allogeneic HSCT may provide clues to the pathogenesis of vaccine-related autoimmune diseases. Although causality was not proven in this case, further evaluations are warranted to assess the associations between vaccines and AA.
Novel nanostructure-coupled biosensor platform for one-step high-throughput quantification of serum neutralizing antibody after COVID-19 vaccination. COVID-19 vaccination efficacy depends on serum levels of the neutralizing antibodies (NAs) specific to the receptor-binding domain of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein. Therefore, a high-throughput rapid assay capable of measuring the total SARS-CoV-2 NA level is urgently needed for COVID-19 serodiagnosis, convalescent plasma therapy, vaccine development, and assessment. Here, we developed a novel nanoplasmonic immunosorbent assay (NanoPISA) platform for one-step rapid quantification of SARS-CoV-2 NAs in clinical serum samples for high-throughput evaluation of COVID-19 vaccine effectiveness. The NanoPISA platform enhanced by the use of nanoporous hollow gold nanoparticle coupling was able to detect SARS-CoV-2 NAs with a limit of detection of 0.2 pM within 15Â min without washing steps. The one-step NanoPISA for SARS-CoV-2 NA detection in clinical specimens yielded good results, comparable with those obtained in the gold-standard seroneutralization test and the surrogate virus-neutralizing enzyme-linked immunosorbent assay. Collectively, the one-step NanoPISA might be a rapid and high-throughput NA-quantification platform for evaluating the effectiveness of COVID-19 vaccines.
Autoimmune hepatitis developing after COVID 19 vaccine: Presumed guilty?
Geographical distribution of TTS cases following AZD1222 (ChAdOx1 nCoV-19) vaccination.
Immunosuppressive therapy reduction and early post-infection graft function in kidney transplant recipients with COVID-19. Background: Kidney transplant (KT) recipients with COVID-19 are at high risk of poor outcomes due to the high burden of comorbidities and immunosuppression. The effects of immunosuppressive therapy (IST) reduction are unclear in patients with COVID-19. Methods: A retrospective study on 45 KT recipients followed at the University Hospital of Modena (Italy) who tested positive for COVID-19 by RT-PCR analysis. Results: The median age was 56.1 years (interquartile range,[IQR] 47.3-61.1), with a predominance of males (64.4%). Kidney transplantation vintage was 10.1 (2.7-16) years, and 55.6 % of patients were on triple IST before COVID-19. Early immunosuppression minimization occurred in 27 (60%) patients (reduced-dose IST group) and included antimetabolite (88.8%) and calcineurin inhibitor withdrawal (22.2%). After SARS-CoV-2 infection, 88.9% of patients became symptomatic and 42.2% required hospitalization. One patient experienced irreversible graft failure. There were no differences in serum creatinine level and proteinuria in non-hospitalized patients before and post-COVID-19, whereas hospitalized patients experienced better kidney function after hospital discharge (P=0.019). Overall mortality was 17.8%. without differences between full- and reduced-dose IST. Risk factors for death were age (odds ratio [OR]: 1.19; 95%CI: 1.01-1.39), and duration of kidney transplant (OR: 1.17; 95%CI: 1.01-1.35). One KT recipient developed IgA glomerulonephritis and two ones experienced symptomatic COVID-19 after primary infection and SARS-CoV-2 mRNA vaccine, respectively. Conclusions: Despite the reduction of immunosuppression, COVID-19 affected the survival of KT recipients. Age of patients and time elapsed from kidney transplantation were independent predictors of death . Early kidney function was favorable in most survivors after COVID-19.

Decreased Long-Term Severe Acute Respiratory Syndrome Coronavirus 2-Specific Humoral Immunity in Liver Transplantation Recipients 12 Months After Coronavirus Disease 2019. Long-term humoral immunity and its protective role in liver transplantation (LT) patients have not been elucidated. We performed a prospective multicenter study to assess the persistence of immunoglobulin G (IgG) antibodies in LT recipients 12Â months after coronavirus disease 2019 (COVID-19). A total of 65 LT recipients were matched with 65 nontransplanted patients by a propensity score including variables with recognized impact on COVID-19. LT recipients showed a lower prevalence of anti-nucleocapsid (27.7% versus 49.2%; PÂ =Â 0.02) and anti-spike IgG antibodies (88.2% versus 100.0%; PÂ =Â 0.02) at 12Â months. Lower index values of anti-nucleocapsid IgG antibodies were also observed in transplantation patients 1 year after COVID-19 (median, 0.49 [interquartile range, 0.15-1.40] versus 1.36 [interquartile range, 0.53-2.91]; PÂ <Â 0.001). Vaccinated LT recipients showed higher antibody levels compared with unvaccinated patients (PÂ <Â 0.001); antibody levels reached after vaccination were comparable to those observed in nontransplanted individuals (PÂ =Â 0.70). In LT patients, a longer interval since transplantation (odds ratio, 1.10; 95% confidence interval, 1.01-1.20) was independently associated with persistence of anti-nucleocapsid IgG antibodies 1 year after infection. In conclusion, compared with nontransplanted patients, LT recipients show a lower long-term persistence of anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibodies. However, SARS-CoV-2 vaccination after COVID-19 in LT patients achieves a significant increase in antibody levels, comparable to that of nontransplanted patients.

Factors associated with vaccine intention in adults living in England who either did not want or had not yet decided to be vaccinated against COVID-19. Early studies showed that 28-36% of UK adults were unsure or unwilling to be vaccinated against COVID-19. We wanted to identify which socio-demographic, socio-economic, personal health and psychological factors were associated with COVID-19 vaccine intentions (CVI) in adults living in England who did not want, yet to consider, or not sure whether to vaccinate. In October/November 2020, prior to vaccine availability, we surveyed adults stratified by gender, region, and deprivation, with additional purposive sampling of those aged 50 and over and those from an ethnic minority. Two hundred and ten did not want; 407 had yet to consider; and 1,043 were not sure whether to be vaccinated. Factors positively associated with CVI were: favorable vaccine views, trust in institutions associated with vaccine approval, vaccine subjective norms, anticipated regret of not having a vaccine, perceived vaccine benefits, perceived safety knowledge sufficiency, and a history of having an influenza vaccine. Factors negatively associated were: anti-lockdown views, and being a health or social care worker. Whilst showing significant relationships with CVI when analyzed in isolation, neighborhood deprivation and ethnicity did show an independent relationship to intention when all study measures were controlled for. Our findings suggest vaccine promotion focusing on the anticipated regret of not having a vaccine, the benefits of a mass COVID-19 immunization program, and the safety of a vaccine whilst ensuring or engendering trust in those bodies that brand a campaign may be most supportive of COVID-19 vaccine uptake.

Sick leave request following anti-COVID-19 vaccine administration is low among healthcare workers: results from a retrospective cross-sectional monocentric study. OBJECTIVE: Anti-COVID-19 vaccines were mainly associated with non-serious adverse events (AEs), whose prevalence was reported to be up to 70% in healthcare workers (HCWs). This may lead to sick leave requests, but this impact has never been quantified. This study aimed to investigate the absence from work among HCWs following anti-COVID-19 vaccination. Its association with age and previous COVID-19 infection was also assessed. PATIENTS AND METHODS: This is a retrospective observational cross-sectional study on administrative data about sick leave requests after anti-COVID-19 vaccination. All the HCWs employed at the Niguarda Hospital (Milan, Italy) who received the vaccine from December 27, 2020

to February 28, 2021 were included. RESULTS: In total, 4,088 HCWs received the first dose of the vaccine and 4,043 completed the vaccination cycle. After the first injection, 1.6% of HCWs requested sick leave, while after the second injection, the number of requests significantly increased (+6.1%, p<0.001). A significant increase in sick leave was detected for those who have had SARS-CoV-2 infection after the first injection (+2.3%, p<0.001). After the second dose, a significant increase in sick leave was observed in the 20-30-year-old group compared to >30 years (+3.6%, p=0.017), if HCWs without a history of SARS-CoV-2 infection were considered. CONCLUSIONS: The requests for sick leave among HCWs following the anti-COVID-19 vaccine were limited and higher after the second injection. This may help the management of the human resources when the large-scale administration of the anti-COVID-19 vaccines will involve other categories of workers.

Neuroleptic malignant syndrome associated with COVID-19 vaccination.

Nephrotic Syndrome After Vaccination Against COVID-19: Three New Cases From Germany.

Exacerbation of branch retinal vein occlusion post SARS-CoV2 vaccination: Case reports. RATIONALE: In this paper, we report on 2 patients who developed branch retinal vein occlusion (BRVO) exacerbation 1 day after administration of the BNT162b2 (Pfizer-BioNTech) SARS-CoV-2 vaccine. PATIENT CONCERNS: Case 1: A 71 year-old female developed vision loss in her left eye 1 day after receiving a second dose of the SARS-CoV-2 mRNA vaccine. This patient was diagnosed with temporal inferior BRVO and secondary macular edema (ME) in her left eye. ME resolved after 3 doses of intravitreal aflibercept (IVA). After treatment, no recurrence of ME was observed.Case 2: A 72 year-old man developed vision loss in his right eye 1 day after receiving the first dose of the SARS-CoV-2 mRNA vaccine. This patient was diagnosed with temporal superior BRVO in the right eye without ME. The patient was followed up and did not undergo any additional treatment. DIAGNOSES: Case1: Temporal superior BRVO and secondary ME were observed in the left eye. Her best-corrected visual acuity (BCVA) was 20/30.Case2: Temporal superior BRVO recurrence and secondary ME were observed in the right eye. BCVA was 20/25. INTERVENTIONS: Case1: Additional dose of IVA was administered. Case2: Two times of Intravitreal ranibizumab was administered twice. OUTCOMES: Case1: Subsequently, ME resolved BCVA was 20/20. Case2: Subsequently, ME resolved BCVA was 20/25. LESSONS: Both cases showed a possible association between SARS-CoV-2 vaccination and the exacerbation of BRVO.

Comparison of Covid-19 antibody status after vaccination between residents in long-term geriatric care and residents assisted-living facilities. OBJECTIVE: To compare 2 CoV-SARS-2 ('anti-s') antibody levels after vaccination between residents in long-term geriatric care (LTGC) and residents in assisted-living facilities who had received two doses of the BNT162b2 vaccine. SARS-CoV-2 serology was tested with Quant II IgG CoV-SARS-2. Blood samples were collected 3-4â€‰months after administration of the second vaccine dose. RESULTS: Anti-sâ€‰â‰¥â€‰50â€‰AU/ml was found in 85.4% of 90 residents in LTGC (median 498â€‰AU/ml) and 94.9% of 214 residents in assisted living (median 728â€‰AU/ml). p = .006. Factors associated with anti-sâ€‰<â€‰300â€‰AU/ml were multi-morbidity, diabetes mellitus and cancer.

Relationship between COVID-19 and movement disorders: A narrative review. BACKGROUND AND PURPOSE: The scientific literature on COVID-19 is increasingly growing. METHODS: In this paper, we review the literature on movement disorders in the context of the COVID-19 pandemic. RESULTS: First, there are a variety of transient movement disorders that may manifest in the acute phase of COVID-19, most often myoclonus, with more than 50 patients described in the literature. New onset parkinsonism, chorea, and tic-like behaviours have also been reported. Movement disorders as a side effect after COVID-19 vaccination are rare, occurring with a frequency of 0.00002-0.0002 depending on the product used, mostly manifesting with tremor. Current evidence for potential long-term manifestations, for example, long COVID parkinsonism, is separately discussed. Second, the pandemic

has also had an impact on patients with pre-existing movement disorder syndromes, with negative effects on clinical status and overall well-being, and reduced access to medication and health care. In many parts, the pandemic has led to reorganization of the medical system, including the development of new digital solutions. The movement disorder-related evidence for this is reviewed and discussed. CONCLUSIONS: The pandemic and the associated preventive measures have had a negative impact on the clinical status, access to health care, and overall well-being of patients with pre-existing movement disorders.
Cell fusion as a link between the SARS-CoV-2 spike protein, COVID-19 complications, and vaccine side effects. A distinctive feature of the SARS-CoV-2 spike protein is its ability to efficiently fuse cells, thus producing syncytia found in COVID-19 patients. This commentary proposes how this ability enables spike to cause COVID-19 complications as well as side effects of COVID-19 vaccines, and suggests how these effects can be prevented.
Factors Associated with Intention to Receive COVID-19 Vaccine Among HIV Positive Patients Attending ART Clinic in Southwest Ethiopia. INTRODUCTION: By the end of 2021, Ethiopia plans to vaccinate 20% of the population. The prioritized group includes people older than 65 years, health care workers, teachers, soldiers, and people living with comorbid diseases, including HIV/AIDS. However, due to a lack of intention and other reasons, only less than one percent of the population has taken COVID-19 vaccine. Therefore, this study aimed to assess the determinant factors of intention to receive the COVID-19 vaccine among HIV-positive patients attending ART clinics in southern Ethiopia. METHODS: A facility-based cross-sectional study was conducted among 398 HIV-positive patients from March 1 to April 28, 2021. Data were collected using a structured questionnaire by three midwives. We entered the data into Epi InfoTM 3.5.1. Binary logistic regression was used to identify independently associated variables in bivariate and multivariate analyses using SPSS version 20. RESULTS: Currently, the intention to take COVID-19 vaccine among HIV-positive patients was 33.7%. The probability of PLWHA to take COVID-19 vaccine was two (AOR = 2 (1.08-3.44)) times higher among those who have been diagnosed with chronic diseases (exclude HIV) with those with not been diagnosed. PLWHA who were male in sex were five (AOR = 5 (2.96-8.68)) times more likely to take COVID-19 vaccine than female. The study also indicated that the odds of intention to take the COVID-19 vaccine were 4.1 times (AOR = 4.1 (2.33-7.31)) times higher among those participants who had good knowledge of COVID-19 practice compared with those who had poor knowledge. CONCLUSION: The overall intention to receive the COVID-19 vaccine among PLWHA is low. Therefore, there is a need to improve the intention to receive the COVID-19 vaccine among HIV-positive patients to achieve the 2021 goal of Ethiopia for 20% of the population vaccination. Patients with chronic illness, knowledge of the COVID-19 vaccine, and sex were factors associated with the intention to receive COVID-19 vaccine.
COVID-19 vaccination in cancer patients: Is it the time or should we wait?
COVID-19 vaccination in a cancerous patient: A comment.
Myocarditis after vaccination against covid-19.
SARS-CoV-2 vaccination and myocarditis or myopericarditis: population based cohort study. OBJECTIVE: To investigate the association between SARS-CoV-2 vaccination and myocarditis or myopericarditis. DESIGN: Population based cohort study. SETTING: Denmark. PARTICIPANTS: 4â€‰931â€‰775 individuals aged 12 years or older, followed from 1 October 2020 to 5 October 2021. MAIN OUTCOME MEASURES: The primary outcome, myocarditis or myopericarditis, was defined as a combination of a hospital diagnosis of myocarditis or pericarditis, increased troponin levels, and a hospital stay lasting more than 24 hours. Follow-up time before vaccination was compared with follow-up time 0-28 days from the day of vaccination for both first and second doses, using Cox proportional hazards regression with age as an underlying timescale to estimate hazard

ratios adjusted for sex, comorbidities, and other potential confounders. RESULTS: During follow-up, 269 participants developed myocarditis or myopericarditis, of whom 108 (40%) were 12-39 years old and 196 (73%) were male. Of 3â€‰482â€‰295 individuals vaccinated with BNT162b2 (Pfizer-BioNTech), 48 developed myocarditis or myopericarditis within 28 days from the vaccination date compared with unvaccinated individuals (adjusted hazard ratio 1.34 (95% confidence interval 0.90 to 2.00); absolute rate 1.4 per 100â€‰000 vaccinated individuals within 28 days of vaccination (95% confidence interval 1.0 to 1.8)). Adjusted hazard ratios among female participants only and male participants only were 3.73 (1.82 to 7.65) and 0.82 (0.50 to 1.34), respectively, with corresponding absolute rates of 1.3 (0.8 to 1.9) and 1.5 (1.0 to 2.2) per 100â€‰000 vaccinated individuals within 28 days of vaccination, respectively. The adjusted hazard ratio among 12-39 year olds was 1.48 (0.74 to 2.98) and the absolute rate was 1.6 (1.0 to 2.6) per 100â€‰000 vaccinated individuals within 28 days of vaccination. Among 498â€‰814 individuals vaccinated with mRNA-1273 (Moderna), 21 developed myocarditis or myopericarditis within 28 days from vaccination date (adjusted hazard ratio 3.92 (2.30 to 6.68); absolute rate 4.2 per 100â€‰000 vaccinated individuals within 28 days of vaccination (2.6 to 6.4)). Adjusted hazard ratios among women only and men only were 6.33 (2.11 to 18.96) and 3.22 (1.75 to 5.93), respectively, with corresponding absolute rates of 2.0 (0.7 to 4.8) and 6.3 (3.6 to 10.2) per 100â€‰000 vaccinated individuals within 28 days of vaccination, respectively. The adjusted hazard ratio among 12-39 year olds was 5.24 (2.47 to 11.12) and the absolute rate was 5.7 (3.3 to 9.3) per 100â€‰000 vaccinated individuals within 28 days of vaccination. CONCLUSIONS: Vaccination with mRNA-1273 was associated with a significantly increased risk of myocarditis or myopericarditis in the Danish population, primarily driven by an increased risk among individuals aged 12-39 years, while BNT162b2 vaccination was only associated with a significantly increased risk among women. However, the absolute rate of myocarditis or myopericarditis after SARS-CoV-2 mRNA vaccination was low, even in younger age groups. The benefits of SARS-CoV-2 mRNA vaccination should be taken into account when interpreting these findings. Larger multinational studies are needed to further investigate the risks of myocarditis or myopericarditis after vaccination within smaller subgroups.

Acute unsolicited adverse events following BNT162b2 vaccine in Saudi Arabia, a real-world data. BACKGROUND: Acute adverse events and anaphylaxis were reported after the administration of coronavirus disease (COVID-19) mRNA vaccines. We aim to explore the nature and outcome of adverse events following BNT162B2 vaccine in a community vaccination center, Riyadh, Saudi Arabia. METHOD: Within 30Â min post vaccination, all acute adverse events (AAEs) that occurred before March 31st, 2021, and in people older than 16Â years were reviewed (AAE group). We used the case definition of Brighton collaboration on vaccine safety to define anaphylaxis. Patients' demographics, comorbidities, allergy history, and outcome at disposition were collected. Observation duration after vaccination was short (<15Â min) or extended (<3Â h). Statistical analysis was performed to study AAEs association with the study variables and outcomes. RESULTS: Out of 71,221 vaccine recipients, 144 (0.002%) had developed 345 AAEs, at a rate of 48.4 events per 10,000 dose administered. The majority of cases in AAE group were first dose recipients (93.8%) and previously healthy (59%), while the minority had a previous history of allergy (6.3%) or a laboratory-confirmed COVID-19 (4.2%). We found a significant association between female gender and the occurrence of any AAE (p-valueÂ =Â 0.002). Per every 10,000 doses administered, non-anaphylactic AAEs were dizziness (17.8), headache (9.7), nausea (7.1), or syncope (3.2). Only one in every ten AAEs was considered serious and resulted in an extended observation (4.8 per 10,000 doses), but only 1/144 required hospitalization for non-anaphylaxis reasons (0.1 per 10,000 doses). According to the Brighton collaboration definition of anaphylaxis, no single case of high certainty anaphylaxis was recorded. No death was documented in this cohort. CONCLUSION: Acute adverse events due toBNT162b2 vaccinewere rare andmostlynon-

seriouswith a tendency to occur more in women. Further prospectivestudieson largervaccine recipientsto evaluatethe incidenceof anaphylaxis in the Saudi population are warranted.

New mimic of relapse or regional lymph node metastasis in a cancer survivor: a case of mRNA COVID-19 vaccine-induced lymphadenitis with high FDG uptake. Western countries that were first to administer the COVID-19 vaccination report cases of vaccine-induced axillary lymphadenitis with high FDG uptake. However, no such findings have been reported from any Asian countries. We report here a confusing case of a 31-year-old female cancer survivor with high FDG uptake in her axillary lymph nodes, suggesting recurrence, following mRNA COVID-19 vaccination. Although the value of SUV(max) was elevated (12.7), additional imaging revealed that her lymphatic lesions were benign, and they resolved spontaneously. This case of a strong immune reaction to COVID-19 vaccination in regional lymph nodes is the first reported in a Japanese patient. We should be aware of this new mimic and optimize diagnostic imaging methods accordingly in the era of COVID-19.

Fulminant Reversible Cerebral Vasoconstriction Syndrome in Breakthrough COVID 19 Infection. COVID 19 infection continues to afflict people worldwide. Neurological complications of COVID infection are common. We report a case of fulminant reversible cerebrovascular constriction syndrome (RCVS) in a patient with breakthrough COVID 19 infection who was fully vaccinated. A 64 year old lady, fully vaccinated 2 months back, presented with headache, drowsiness, partial seizures, visual impairment and quadriplegia. Her nasopharyngeal swab was tested positive for SARS COV2 on real time PCR assay. MRI brain FLAIR images showed multifocal hyperintensities with MR angiogram showing arterial vasoconstriction suggestive of RCVS. Despite initiation of nimodipine, patient's symptoms worsened and she succumbed to sepsis. RCVS following COVID infection has been reported to have a benign outcome. However, despite vaccination, fulminant RCVS following a breakthrough COVID infection was observed in our patient.

Postvaccination infections among staff of a tertiary care hospital after vaccination with severe acute respiratory syndrome coronavirus 2 vector and mRNA-based vaccines. OBJECTIVES: The identification of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen or RNA in respiratory specimens â‰¥14Â days after administration of all recommended doses of authorized coronavirus disease 2019 (COVID-19) vaccines is defined as breakthrough infection. In the present investigation, mRNA and vector-based SARS-CoV-2 vaccines were analysed with respect to postvaccination infections in vaccinated hospital employees. METHODS: A total of 8553 staff members were vaccinated with BNT162b2 (47%) or ChAdOx1-S (53%) between January and May 2021. In a retrospective observational cohort study, incidence of SARS-CoV-2 postvaccination infections was analysed in relation to demographic data, viral load, virus variants, vaccine brand and vaccination status at time of positive PCR test (fully vaccinated: â‰¥14Â days since second dose; partially vaccinated: >21Â days since first, but <14Â days after second dose; insufficiently vaccinated: <22Â days since first dose). RESULTS: Within the follow-up period, ending on 31 July 2021, person-time at risk-adjusted monthly rates for SARS-CoV-2 postvaccination infections were 0.18% (BNT162b2) and 0.57% (ChAdOx1-S) for insufficiently vaccinated, 0.34% (BNT162b2) and 0.32% (ChAdOx1-S) for partially vaccinated and 0.06% (BNT162b2) and 0.04% (ChAdOx1-S) for fully vaccinated participants. The two vaccine types did not differ with respect to hazard ratios for any of the respective postvaccination infection types. No cases of COVID-19-related hospitalizations or deaths were reported. Genotyping of positive PCR specimens revealed 42 variants of concern: B.1.1.7 (Alpha variant; nÂ =Â 34); B.1.351 (Beta variant; nÂ =Â 2), B.1.617.2 (Delta variant; nÂ =Â 6). CONCLUSIONS: BNT162b2 and ChAdOx1-S are both effective in preventing breakthrough infections; however, it seems important, that all recommended vaccine doses are administered.

Critical review of nucleic acid nanotechnology to identify gaps and inform a strategy for accelerated clinical translation. With numerous recent advances, the field of therapeutic nucleic acid

nanotechnology is now poised for clinical translation supported by several examples of FDA-approved nucleic acid nanoformulations including two recent mRNA-based COVID-19 vaccines. Within this rapidly growing field, a new subclass of nucleic acid therapeutics called nucleic acid nanoparticles (NANPs) has emerged in recent years, which offers several unique properties distinguishing it from traditional therapeutic nucleic acids. Key unique aspects of NANPs include their well-defined 3D structure, their tunable multivalent architectures, and their ability to incorporate conditional activations of therapeutic targeting and release functions that enable diagnosis and therapy of cancer, regulation of blood coagulation disorders, as well as the development of novel vaccines, immunotherapies, and gene therapies. However, non-consolidated research developments of this highly interdisciplinary field create crucial barriers that must be overcome in order to impact a broader range of clinical indications. Forming a consortium framework for nucleic acid nanotechnology would prioritize and consolidate translational efforts, offer several unifying solutions to expedite their transition from bench-to-bedside, and potentially decrease the socio-economic burden on patients for a range of conditions. Herein, we review the unique properties of NANPs in the context of therapeutic applications and discuss their associated translational challenges.

Antibody Response and Variant Cross-Neutralization After SARS-CoV-2 Breakthrough Infection. This study of fully vaccinated health care workers examines antibody levels and variant cross-neutralization after COVID-19 breakthrough infection.

Prior COVID-19 Infection, Mental Health, Food and Financial Insecurity, and Association With COVID-19 Vaccination Coverage and Intent Among College-Aged Young Adults, US, 2021. INTRODUCTION: More than 700,000 COVID-19 cases have been linked to American colleges and universities since the beginning of the pandemic. However, studies are limited on the effects of the pandemic on college-aged young adults and its association with their COVID-19 vaccination status and intent. METHODS: Using the Census Bureau's Household Pulse Survey (HPS), a large, nationally representative survey fielded from April 14 through May 24, 2021, we assessed the effects of the pandemic (COVID-19 infection, mental health, food and financial security) on COVID-19 vaccination coverage (â‰¥1 dose) and intentions toward vaccination among college-aged young adults in the United States (N = 6,758). We examined factors associated with vaccination coverage and intent, and reasons for not getting vaccinated. RESULTS: Approximately one-fifth (19.6%) of college-aged young adults had a previous diagnosis of COVID-19, 43.5% and 39.1% reported having anxiety or depression, respectively, 10.9% reported that they sometimes or often did not have enough food to eat, and 22.6% and 12.3% found it somewhat or very difficult, respectively, to pay for household expenses. Of college-aged young adults, 63.1% had received at least 1 dose of the COVID-19 vaccine, 15.4% probably would be vaccinated or were unsure about getting the vaccine, and 14.0% probably will not or definitely will not get vaccinated. Adults who were non-Hispanic Black (vs non-Hispanic White) or had food or financial insecurities (vs did not) were less likely to be vaccinated or intend to be vaccinated. Among adults who probably will not or definitely will not be vaccinated, more than one-third said that they did not believe a vaccine was needed. CONCLUSION: Ensuring high and equitable vaccination coverage among college-aged young adults is critical for safely reopening in-person learning and resuming prepandemic activities.

Missed shots.

Techniques for Developing and Assessing Immune Responses Induced by Synthetic DNA Vaccines for Emerging Infectious Diseases. Vaccines are one of mankind's greatest medical advances, and their use has drastically reduced and in some cases eliminated (e.g., smallpox) disease and death caused by infectious agents. Traditional vaccine modalities including live-attenuated pathogen vaccines, wholly inactivated pathogen vaccines, and protein-based pathogen subunit vaccines have successfully been used to create efficacious vaccines against measles, mumps, rubella, polio, and

yellow fever. These traditional vaccine modalities, however, take many months to years to develop and have thus proven less effective for use in creating vaccines to emerging or reemerging infectious diseases (EIDs) including influenza, Human immunodeficiency virus (HIV), dengue virus (DENV), chikungunya virus (CHIKV), West Nile virus (WNV), Middle East respiratory syndrome (MERS), and the severe acute respiratory syndrome coronaviruses 1 and 2 (SARS-CoV and SARS-CoV-2). As factors such as climate change and increased globalization continue to increase the pace of EID development, newer vaccine modalities are required to develop vaccines that can prevent or attenuate EID outbreaks throughout the world. One such modality, DNA vaccines, has been studied for over 30Â years and has numerous qualities that make them ideal for meeting the challenge of EIDs including; (1) DNA vaccine candidates can be designed within hours of publishing of a pathogens genetic sequence; (2) they can be manufactured cheaply and rapidly in large quantities; (3) they are thermostable and have reduced requirement for a cold-chain during distribution, and (4) they have a remarkable safety record in the clinic. Optimizations made in plasmid design as well as in DNA vaccine delivery have greatly improved the immunogenicity of these vaccines. Here we describe the process of making a DNA vaccine to an EID pathogen and describe methods used for assessing the immunogenicity and protective efficacy of DNA vaccines in small animal models.

Waves and variants of SARS-CoV-2: understanding the causes and effect of the COVID-19 catastrophe. The coronavirus disease-19 has left a permanent mark on the history of the human race. Severe acute respiratory syndrome coronavirus-2 is a positive-sense single-stranded RNA virus, first reported in Wuhan, China, in December 2019 and from there took over the world. Being highly susceptible to mutations, the virus's numerous variants started to appear, and some were more lethal and infectious than the parent. The effectiveness of the vaccine is also affected severely against the new variant. In this study, the infectious mechanism of the coronavirus is explained with a focus on different variants and their respective mutations, which play a critical role in the increased transmissibility, infectivity, and immune escape of the virus. As India has already faced the second wave of the pandemic, the future outlook on the likeliness of a third wave with respect to the Indian variants such as kappa, delta, and Delta Plus is also discussed. This review article aims to reflect the catastrophe of the variants of SARS-CoV-2 and the possibility of developing even more severe variants in the near future.

Supraclavicular lymphadenopathy after COVID-19 vaccination.

Exuberant lichenoid eruption after Oxford-AstraZeneca COVID-19 vaccine: a singular case.

Risk Factors Associated With an Impaired Antibody Response in Kidney Transplant Recipients Following 2 Doses of the SARS-CoV-2 mRNA Vaccine. BACKGROUND: Data about vaccine efficacy in solid organ transplant patients are limited. We previously reported our initial observation of a 6.2% immunogenicity rate in kidney transplant recipients (KTRs) after administration of 1 dose of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccine. We sought to report our observations of anti-SARS-CoV-2 antibody in KTRs after 2 doses of the SARS-CoV-2 mRNA vaccine. METHODS: We identified 105 KTRs who received 2 doses of the Pfizer-BioNTech or Moderna mRNA-1273 vaccine per availability and had anti-SARS-CoV-2 labs obtained at least 2 wk following administration of the second dose. Antibody testing was performed using 3 clinically validated qualitative and semiquantitative assays. RESULTS: KTRs had a 36.2% antibody response rate, whereas an age â‰¥68 years and a longer time from transplant were factors associated with antibody response. CONCLUSIONS: The low antibody response in KTRs may be associated with the immunosuppressive state. More data are needed to evaluate if KTRs may require higher vaccine doses or an additional booster dose to increase their ability to mount an immune response to the SARS-CoV-2 vaccine.

Evaluation of adverse effects with COVID-19 vaccination in Pakistan. OBJECTIVES: Vaccinations work with different mechanisms to offer protection against disease; however, process of immunity building can cause symptoms. Therefore, this study aimed to determine the immediate side effects of COVID-19 vaccination in the Pakistani Population. METHODS: This cross-sectional analytical study was conducted at Foundation University College of Dentistry, Islamabad from February to April 2021. 0.5 mL per dose of the Covid-19 vaccine was administered to the candidates. These 205 candidates receiving vaccination were then interviewed investigating the adverse effects of the vaccine. Post-vaccination side effects were compared among categorical groups using the Chi-Square test, whereas post-vaccination side effects were compared with age using independent samples T-test. A p-value of â‰¤0.05 was statistically significant. RESULTS: Among post-vaccination side effects, fever was reported by 69 participants, while 56 of 205 reported soreness, redness, and swelling at the injection site. It was reported by 42/205 participants to have felt chills and rigor, whereas gastrointestinal disturbance and flu-like symptoms were reported in 55/205 and 28/205 participants, respectively. Younger participants were more likely to develop gastrointestinal disturbance and flu-like symptoms following vaccination as compared to older participants. CONCLUSION: Malaise, headache, and fever were observed to be the most common side effects of the vaccine, moreover there was a linear relationship between manifestations of adverse effects and history of comorbidities.

COVID-19 Vaccine-Related Thrombosis: A Systematic Review and Exploratory Analysis. INTRODUCTION: The World Health Organization declared the coronavirus disease 2019 (COVID-19) pandemic on March 11, 2020. Two vaccine types were developed using two different technologies: viral vectors and mRNA. Thrombosis is one of the most severe and atypical adverse effects of vaccines. This study aimed to analyze published cases of thrombosis after COVID-19 vaccinations to identify patients' features, potential pathophysiological mechanisms, timing of appearance of the adverse events, and other critical issues. MATERIALS AND METHODS: We performed a systematic electronic search of scientific articles regarding COVID-19 vaccine-related thrombosis and its complications on the PubMed (MEDLINE) database and through manual searches. We selected 10 out of 50 articles from February 1 to May 5, 2021 and performed a descriptive analysis of the adverse events caused by the mRNA-based Pfizer and Moderna vaccines and the adenovirus-based AstraZeneca vaccine. RESULTS: In the articles on the Pfizer and Moderna vaccines, the sample consisted of three male patients with age heterogeneity. The time from vaccination to admission was â‰¤3 days in all cases; all patients presented signs of petechiae/purpura at admission, with a low platelet count. In the studies on the AstraZeneca vaccine, the sample consisted of 58 individuals with a high age heterogeneity and a high female prevalence. Symptoms appeared around the ninth day, and headache was the most common symptom. The platelet count was below the lower limit of the normal range. All patients except one were positive for PF4 antibodies. The cerebral venous sinus was the most affected site. Death was the most prevalent outcome in all studies, except for one study in which most of the patients remained alive. DISCUSSION: Vaccine-induced thrombotic thrombocytopenia (VITT) is an unknown nosological phenomenon secondary to inoculation with the COVID-19 vaccine. Several hypotheses have been formulated regarding its physiopathological mechanism. Recent studies have assumed a mechanism that is assimilable to heparin-induced thrombocytopenia, with protagonist antibodies against the PF4-polyanion complex. Viral DNA has a negative charge and can bind to PF4, causing VITT. New experimental studies have assumed that thrombosis is related to a soluble adenoviral protein spike variant, originating from splicing events, which cause important endothelial inflammatory events, and binding to endothelial cells expressing ACE2. CONCLUSION: Further studies are needed to better identify VITT's pathophysiological mechanisms and genetic, demographic, or clinical predisposition of high-risk patients, to investigate the correlation of VITT with the different vaccine types, and to test the significance of the findings.

Vasculitis as Temporally Associated With COVID-19 Infection or Vaccination: A Single-center Experience.

SARS-CoV-2 anti-spike antibodies after vaccination in pediatric heart transplantation: A first report. BACKGROUND: BACKGROUND: There is a paucity of data regarding the antibody response to SARS-CoV-2 vaccination in children after solid organ transplant. METHODS: We retrospectively reviewed the SARS-CoV-2 Anti-Spike IgG antibodies measured following SARS-CoV-2 vaccination at our pediatric heart transplant (HTx) center. RESULTS: Among patients (median age 17.1 years) in whom antibody testing was performed (median 118 days post-vaccine completion), a SARS-CoV-2 Anti-Spike IgG antibody was detected in 28 of 40 (70%) post-HTx recipients (median antibody level 10.9 AU/ml). Neutropenia, diabetes mellitus, and previous use of rituximab were associated with absence of a detectable antibody. All 7 post-HTx patients with a known pre-vaccination SARS-CoV-2 viral infection had a detectable SARS-CoV-2 Anti-Spike IgG. All 12 vaccinated pre-HTx patients had a detectable antibody (median antibody level 11.6 AU/ml) including 5 patients that maintained detectable antibodies post-HTx. There were no cases of myocarditis among the total of 17 pre-HTx and 81 post-HTx patients that underwent SARS-CoV-2 vaccination. CONCLUSION: Our data suggest that a significant proportion of pediatric HTx recipients have no detectable antibody response after SARS-CoV-2 vaccination and support the recommendation to complete the vaccination series prior to HTx in those pediatric patients waiting for HTx.

The COVID-19 vaccination experience in Bangladesh: Findings from a cross-sectional study. OBJECTIVES: Vaccination rollout against COVID-19 has started in developed countries in early December 2020. Mass immunization for poor or low-income countries is quite challenging before 2023. Being a lower-middle-income country, Bangladesh has begun a nationwide COVID-19 vaccination drive in early February 2021. Here, we aimed to assess the opinions, experiences, and adverse events of the COVID-19 vaccination in Bangladesh. METHODS: We conducted this online cross-sectional study from 10 February 2021, to 10 March 2021, in Bangladesh. A self-reported semi-structured survey questionnaire was used using Google forms. We recorded demographics, disease history, medication records, opinions and experiences of vaccination, and associated adverse events symptoms. RESULTS: We observed leading comorbid diseases were hypertension (25.9%), diabetes (21.1%), heart diseases (9.3%), and asthma (8.7%). The most frequently reported adverse events were injection site pain (34.3%), fever (32.6%), headache (20.2%), fatigue (16.6%), and cold feeling (15.4%). The chances of having adverse events were significantly higher in males than females ($p = 0.039$). However, 36.4% of respondents reported no adverse events. Adverse events usually appeared after 12Â h and went way within 48Â h of vaccination. Besides, 85.5% were happy with the overall vaccination management, while 88.0% of the respondents recommended the COVID-19 vaccine for others for early immunization. CONCLUSION: According to the present findings, reported adverse events after the doses of Covishield in Bangladesh were non-serious and temporary. In Bangladesh, the early vaccination against COVID-19 was possible due to its prudent vaccine deal, previous mass vaccination experience, and vaccine diplomacy.

Neutralizing antibody titers six months after Comirnaty vaccination: kinetics and comparison with SARS-CoV-2 immunoassays. OBJECTIVES: mRNA vaccines, including Comirnaty (BNT162b2 mRNA, BioNTech-Pfizer), elicit high IgG and neutralizing antibody (NAb) responses after the second dose, but theÂ progressive decrease in serum antibodies against SARS-CoV-2 following vaccination have raised questions concerning long-term immunity, decreased antibody levels being associated with breakthrough infections after vaccination, prompting the consideration of booster doses. METHODS: A total number of 189 Padua University-Hospital healthcare workers (HCW) who had received a second vaccine dose were asked to collect serum samples for determining Ab at 12 (t(12)) and 28 (t(28)) days, and 6Â months (t(6m)) after their first Comirnaty/BNT162b2 inoculation. Ab titers were

measured with plaque reduction neutralization test (PRNT), and three chemiluminescent immunoassays, targeting the receptor binding domain (RBD), the trimeric Spike protein (trimeric-S), and surrogate viral neutralization tests (sVNT). RESULTS: The median percentages (interquartile range) for decrease in antibodies values 6Â months after the first dose were 86.8% (67.1-92.8%) for S-RBD IgG, 82% (58.6-89.3%) for trimeric-S, 70.4% (34.5-86.4%) for VNT-Nab, 75% (50-87.5%) for PRNT(50) and 75% (50-93.7%) for PRNT(90). At 6Â months, neither PRNT titers nor VNT-Nab and S-RBD IgG bAb levels correlated with age (p=0.078) or gender (p=0.938), while they were correlated with previous infection (p<0.001). CONCLUSIONS: After 6Â months, a method-independent reduction of around 90% in anti-SARS-CoV-2 antibodies was detected, while no significant differences were found between values of males and females aged between 24 and 65 years without compromised health status. Further efforts to improve analytical harmonization and standardization are needed.

Efficacy and Safety of NVX-CoV2373 in Adults in the United States and Mexico. BACKGROUND: NVX-CoV2373 is an adjuvanted, recombinant spike protein nanoparticle vaccine that was shown to have clinical efficacy for the prevention of coronavirus disease 2019 (Covid-19) in phase 2b-3 trials in the United Kingdom and South Africa, but its efficacy had not yet been tested in North America. METHODS: We conducted a phase 3, randomized, observer-blinded, placebo-controlled trial in the United States and Mexico during the first half of 2021 to evaluate the efficacy and safety of NVX-CoV2373 in adults (â‰¥18 years of age) who had not had severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Participants were randomly assigned in a 2:1 ratio to receive two doses of NVX-CoV2373 or placebo 21 days apart. The primary objective was to determine vaccine efficacy against reverse-transcriptase-polymerase-chain-reaction-confirmed Covid-19 occurring at least 7 days after the second dose. Vaccine efficacy against moderate-to-severe disease and against different variants was also assessed. RESULTS: Of the 29,949 participants who underwent randomization between December 27, 2020, and February 18, 2021, a total of 29,582 (median age, 47 years; 12.6% â‰¥65 years of age) received at least one dose: 19,714 received vaccine and 9868 placebo. Over a period of 3 months, 77 cases of Covid-19 were noted - 14 among vaccine recipients and 63 among placebo recipients (vaccine efficacy, 90.4%; 95% confidence interval [CI], 82.9 to 94.6; P<0.001). Ten moderate and 4 severe cases occurred, all in placebo recipients, yielding vaccine efficacy against moderate-to-severe disease of 100% (95% CI, 87.0 to 100). Most sequenced viral genomes (48 of 61, 79%) were variants of concern or interest - largely B.1.1.7 (alpha) (31 of the 35 genomes for variants of concern, 89%). Vaccine efficacy against any variant of concern or interest was 92.6% (95% CI, 83.6 to 96.7). Reactogenicity was mostly mild to moderate and transient but was more frequent among NVX-CoV2373 recipients than among placebo recipients and was more frequent after the second dose than after the first dose. CONCLUSIONS: NVX-CoV2373 was safe and effective for the prevention of Covid-19. Most breakthrough cases were caused by contemporary variant strains. (Funded by Novavax and others; PREVENT-19 ClinicalTrials.gov number, NCT04611802.).

A new-onset vitiligo following the inactivated COVID-19 vaccine.

Why Parents Still Hesitate to Vaccinate Their Children Against COVID-19.

Side effects and antibody response of an inactive severe acute respiratory syndrome coronavirus 2 vaccine among health care workers. OBJECTIVE: This study aims to investigate the antibody response and the side effects of the two-dose inactive SARS-CoV-2 vaccine (CoronaVac, Sinovac, China) among a health care worker population in Turkey. METHODS: This study was a prospective, cross-sectional, single-center study conducted between December 16, 2020, and March 15, 2021. We evaluated the side effects from a questionnaire, and anti-spike immunoglobulin G response to the vaccine (0- and 28-day schedule) using an enzyme-linked immunosorbent assay. RESULTS: A total of 94 of 184 health care workers completed this study. The percentages of participants who were seronegative at baseline and achieved to the seropositivity were 21.3 and 97.9%, respectively, on day

21 after vaccinations. The seropositivity was predominantly detected in 31-45 years of the age group (55.4%, p=0.636), normal body mass index (47.8%, p=0.999), nonsmokers (64.1%, p=0.999), those without any comorbidities (73.9%, p=0.463), and those without any side effects (70.2%, p=0.256). The frequencies of overall side effects within seven days after the first and second doses of CoronaVac were 37.2 and 28.7%, respectively. The most common side effects was localized pain at the injection site (15.7 and 11.6%, respectively). CONCLUSIONS: We found that vaccination by two-dose CoronaVac could elicit a specific humoral response, and it was well tolerated in health care workers. The high seropositivity developed after the second dose attracted attention. Our study will be useful in terms of showing short-term immunity and side effects.

Review of the current literature regarding cardiac adverse events following COVID-19 vaccination.

Post-Vaccination Symptoms after A Third Dose of mRNA SARS-CoV-2 Vaccination in Patients with Inflammatory Bowel Disease. Symptoms after SARS-CoV-2 primary vaccination among patients with inflammatory bowel disease (IBD) are generally of similar frequency, severity, and duration to those reported in the general population. The symptom profile after a 3 (rd) mRNA vaccine dose in the predominantly immune-compromised IBD population is unknown. We aimed to assess symptomology after a 3 (rd) or booster dose of mRNA vaccination in adults with IBD. We surveyed participants of the Coronavirus Risk Associations and Longitudinal Evaluation in IBD (CORALE-IBD) post-vaccination registry for symptom frequency and severity after a 3 (rd) mRNA vaccine dose in an observational cohort study. In total, 524 participants (70% female, mean age 45 years) reported a third dose of mRNA vaccination through October 11, 2021. Overall, 41% reported symptoms after a third dose, with symptoms generally more frequent and more severe among participants younger than 55 years. The most frequent postvaccination symptoms were injection site pain (39%), fatigue or malaise (34%), and headache (23%). These symptoms were all less frequently reported after dose 3 than after dose 2. Gastrointestinal symptoms were reported by 8.8%, which was slightly more frequent than after dose 2 (7.8%). Those with severe symptoms after dose 2 were more likely to have severe symptoms after dose 3. These findings can reassure the IBD patient and provider communities that the likelihood and distribution of symptoms after a third mRNA vaccine dose are generally similar to those after a second dose, and that the frequency of postvaccination symptoms after dose 3 are generally lower than after dose 2.

COVID-19 infections post-vaccination by HIV status in the United States. IMPORTANCE: Recommendations for additional doses of COVID vaccine are restricted to people with HIV who have advanced disease or unsuppressed HIV viral load. Understanding SARS-CoV-2 infection risk post-vaccination among PWH is essential for informing vaccination guidelines. OBJECTIVE: Estimate the risk of breakthrough infections among fully vaccinated people with (PWH) and without (PWoH) HIV in the US. DESIGN SETTING AND PARTICIPANTS: The Corona-Infectious-Virus Epidemiology Team (CIVET)-II cohort collaboration consists of 4 longitudinal cohorts from integrated health systems and academic health centers. Each cohort identified individuals Ã¢â€°Â¥18 years old, in-care, and fully vaccinated for COVID-19 through 30 June 2021. PWH were matched to PWoH on date fully vaccinated, age group, race/ethnicity, and sex at birth. Incidence rates per 1,000 person-years and cumulative incidence of breakthrough infections with 95% confidence intervals ([,]) were estimated by HIV status. Cox proportional hazards models estimated adjusted hazard ratios (aHR) of breakthrough infections by HIV status adjusting for demographic factors, prior COVID-19 illness, vaccine type (BNT162b2, [Pfizer], mRNA-1273 [Moderna], Jansen Ad26.COV2.S [J&J]), calendar time, and cohort. Risk factors for breakthroughs among PWH, were also investigated. EXPOSURE: HIV infection. OUTCOME: COVID-19 breakthrough infections, defined as laboratory evidence of SARS-CoV-2 infection or COVID-19 diagnosis after an individual was fully vaccinated. RESULTS: Among 109,599 individuals (31,840 PWH and 77,759 PWoH), the rate of breakthrough infections was higher

in PWH versus PWoH: 44 [41, 48] vs. 31 [29, 33] per 1,000 person-years. Cumulative incidence at 210 days after date fully vaccinated was low, albeit higher in PWH versus PWoH overall (2.8% versus 2.1%, log-rank p<0.001, risk difference=0.7% [0.4%, 1.0%]) and within each vaccine type. Breakthrough infection risk was 41% higher in PWH versus PWoH (aHR=1.41 [1.28, 1.56]). Among PWH, younger age (18-24 versus 45-54), history of COVID-19 prior to fully vaccinated date, and J&J vaccination (versus Pfizer) were associated with increased risk of breakthroughs. There was no association of breakthrough with HIV viral load suppression or CD4 count among PWH. CONCLUSIONS AND RELEVANCE: COVID-19 vaccination is effective against infection with SARS-CoV-2 strains circulating through 30 Sept 2021. PWH have an increased risk of breakthrough infections compared to PWoH. Recommendations for additional vaccine doses should be expanded to all PWH.
Acquired thrombotic thrombocytopenic purpura following Pfizer COVID-19 vaccination. Acquired thrombotic thrombocytopenic purpura (aTTP) is a rare disease and has occasionally been described after vaccination, especially against viral agents. We present a case of a patient who presents with the classic pentad of TTP a few days after receiving the first dose of the mRNA Pfizer COVID-19 vaccine. To our knowledge, this is the second report of a de novo TTP following mRNA Pfizer COVID-19 vaccination.
Corrigendum to: A Case Report of Capsular Contracture Immediately Following COVID-19 Vaccination. [This corrects the article DOI: 10.1093/asjof/ojab021.].
Severe breakthrough COVID-19 with a heavily mutated variant in a multiple myeloma patient 10 weeks after vaccination. BACKGROUND: Patients with multiple myeloma have unpredictable responses to vaccination for COVID-19. Anti-spike antibody levels can determine which patients develop antibodies at levels similar to healthy controls, and are a known correlate of protection. CASE REPORT: A multiple myeloma patient developed protective anti-spike antibodies after vaccination (608Â IU/mL), but nonetheless developed severe breakthrough COVID-19 just 10Â weeks following his second vaccination with mRNA-1273. RESULTS: Sequencing of the viral isolate revealed an extensively mutated variant with 10 spike protein mutations, including E484Q and N440K. Serology testing showed a dramatic decline in anti-spike antibodies immediately prior to virus exposure. CONCLUSIONS: Multiple myeloma patients who do develop detectable antibody responses to vaccination may be at increased risk for breakthrough infections due to rapid decline in antibody levels. Viral variants with immune escape mutations such as N440K, also seen independently in the SARS-CoV-2 Omicron variant (B.1.1.529) and in viral passaging experiments, likely require a higher level of anti-spike antibodies to prevent severe COVID-19.
Catastrophic antiphospholipid syndrome complicated with essential thrombocythaemia after COVID-19 vaccination: in search of the underlying mechanism.
Oral Herpes Zoster Infection Following COVID-19 Vaccination: A Report of Five Cases. Recently, two cases of oral herpes zoster (HZ) following COVID-19 vaccines were reported. It was suggested that COVID-19 vaccine-related oral HZ cases might be missed or misdiagnosed as stomatitis or isolated oral herpes. In this report, five cases of oral HZ following COVID-19 vaccinations are presented. Four cases were observed on the hard palate (V2), and one case was found on the mandible (V3). Four patients did not receive any treatment for their oral HZ, but one patient also had skin reactions on her right orbit and ear and was thus treated with an antiviral drug. As these cases were seen during such a short period of time and in one practice, the relationship with the COVID-19 vaccination appears to be related.
B Cell Reconstitution Is Strongly Associated With COVID-19 Vaccine Responsiveness in Rheumatic Disease Patients Who Received Treatment With Rituximab. OBJECTIVE: To assess the association of a detectable antibody response to COVID-19 vaccination with factors including B cell depletion in patients who received treatment with rituximab (RTX). METHODS: We conducted a retrospective

review of the charts of adult patients who received treatment with RTX and completed messenger RNA vaccination for SARS-CoV-2. The primary outcome measure was the presence or absence and strength of the serologic antibody response to vaccination. Comparisons between those with and those without a detectable serologic response were calculated using t-tests, Fisher's exact test, and Wilcoxon's rank sum test. The relationship between the serologic response to COVID-19 vaccination and B cell reconstitution status was assessed using negative predictive values and positive predictive values with data reported as percentages with 95% confidence intervals (95% CIs). RESULTS: In 56 patients being treated with RTX, a significant difference in terms of the level of B cell reconstitution was observed in those with a positive serologic response compared to those with a negative serologic response to vaccination (proportion of B cells reconstituted among total lymphocytes, median 2% [interquartile range (IQR) 0.13-10%] versus median 0% [IQR 0-0%]; Pâ€‰<â€‰0.001).There was also a significant difference in the time since the last RTX infusion between patients with a positive serologic response compared to those with a negative serologic response to vaccination (median time since last infusion 594â€‰days [IQR 262-1,163] versus median 138â€‰days [IQR 68-197]; Pâ€‰<â€‰0.001). There was no serologic response to COVID-19 vaccination after the last exposure to RTX in 13% of patients (3 of 24) at >12 months after last exposure, 55% of patients (6 of 11) at 6-12 months after last exposure, and 86% of patients (18 of 21) at <6 months after last exposure. CONCLUSION: B cell reconstitution and a longer time since a patient's last exposure to RTX are associated with a positive serologic response to the COVID-19 vaccine. Strategies for maximizing vaccine responsiveness in patients who receive treatment with RTX should incorporate assessment of B cell reconstitution.

Corneal Graft Rejection After Inactivated SARS-CoV-2 Vaccine: Case Report. PURPOSE: Our aim was to report the case of endothelial corneal allograft rejection after inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine with an atypical presentation. METHODS: This was a case report. RESULTS: A 63-year-old woman with previous penetrating keratoplasty and laser in situ keratomileusis presented with clinical signs of endothelial corneal graft rejection 24 hours after CoronaVac (SinoVac Biotech, Beijing/China) vaccine. Slitlamp examination showed corneal edema and interface fluid accumulation. It was partially resolved after treatment with topical corticosteroids and polydimethylsiloxane. CONCLUSIONS: Corneal allograft rejection was already reported after another SARS-CoV-2 vaccine. This is the first report in the literature describing a possible association with inactivated SARS-CoV-2 vaccine and corneal allograft rejection, especially with laser in situ keratomileusis interface fluid accumulation presentation. Ophthalmologists should be aware of this potential complication.

Subacute thyroiditis post-Pfizer-BioNTech mRNA vaccination for COVID-19. SUMMARY: There is emerging evidence of an association between COVID-19 vaccination and subacute thyroiditis. We present the case of a 42-year-old female healthcare worker who was diagnosed with subacute thyroiditis 4 days after receiving her second dose of Pfizer-BioNTech vaccine. Her clinical course followed the classical pattern for thyroiditis with spontaneous return to euthyroidism at 6 months post-presentation. The autoimmune/inflammatory syndrome induced by adjuvants has been implicated as a cause of autoimmune conditions post-vaccination and is a potential mechanism for subacute thyroiditis in our case. LEARNING POINTS: Subacute thyroiditis should be considered in all patients who receive any kind of vaccine for COVID-19 and subsequently develop symptoms or signs of hyperthyroidism or neck pain. Subacute thyroiditis is a self-limiting condition, and recognising it is important as no specific thyroid treatment (antithyroid drugs or thyroid hormone replacement) is necessary for most patients. The autoimmune/inflammatory syndrome induced by adjuvants may be an under-recognised cause of endocrinopathies and should particularly be considered post-vaccination.

Thrombosis with Thrombocytopenia Syndrome After Administration of AZD1222 or Ad26.COV2.S Vaccine for COVID-19: A Systematic Review. BACKGROUND: Cases of thrombosis with thrombocytopenia syndrome (TTS) have been reported following vaccination with AZD1222 or Ad26.COV2.S. This review aimed to explore the pathophysiology, epidemiology, diagnosis, management, and prognosis of TTS. METHODS: A systematic review was conducted to identify evidence on TTS till 4(th) September 2021. Case reports and series reporting patient-level data were included. Descriptive statistics were reported and compared across patients with different sexes, age groups, vaccines, types of thrombosis, and outcomes. FINDINGS: Sixty-two studies reporting 160 cases were included from 16 countries. Patients were predominantly females with a median age of 42.50 (22) years. AZD1222 was administered to 140 patients (87Â·5%). TTS onset occurred in a median of 9 (4) days after vaccination. Venous thrombosis was most common (61.0%). Most patients developed cerebral venous sinus thrombosis (CVST; 66.3%). CVST was significantly more common in female vs male patients (pâ€‰=â€‰0Â·001) and in patients aged <45 years vs â‰¥45 years (pâ€‰=â€‰0Â·004). The mortality rate was 36.2%, and patients with suspected TTS, venous thrombosis, CVST, pulmonary embolism, or intraneural complications, patients not managed with non-heparin anticoagulants or IVIG, patients receiving platelet transfusions, and patients requiring intensive care unit admission, mechanical ventilation, or inpatient neurosurgery were more likely to expire than recover. INTERPRETATION: These findings help to understand the pathophysiology of TTS while also recommending diagnostic and management approaches to improve prognosis in patients. FUNDING: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection. Although myocarditis and pericarditis were not observed as adverse events in coronavirus disease 2019 (COVID-19) vaccine trials, there have been numerous reports of suspected cases following vaccination in the general population. We undertook a self-controlled case series study of people aged 16 or older vaccinated for COVID-19 in England between 1 December 2020 and 24 August 2021 to investigate hospital admission or death from myocarditis, pericarditis and cardiac arrhythmias in the 1-28â€‰days following adenovirus (ChAdOx1, nâ€‰=â€‰20,615,911) or messenger RNA-based (BNT162b2, nâ€‰=â€‰16,993,389; mRNA-1273, nâ€‰=â€‰1,006,191) vaccines or a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) positive test (nâ€‰=â€‰3,028,867). We found increased risks of myocarditis associated with the first dose of ChAdOx1 and BNT162b2 vaccines and the first and second doses of the mRNA-1273 vaccine over the 1-28 days postvaccination period, and after a SARS-CoV-2 positive test. We estimated an extra two (95% confidence interval (CI) 0, 3), one (95% CI 0, 2) and six (95% CI 2, 8) myocarditis events per 1â€‰million people vaccinated with ChAdOx1, BNT162b2 and mRNA-1273, respectively, in the 28â€‰days following a first dose and an extra ten (95% CI 7, 11) myocarditis events per 1â€‰million vaccinated in the 28â€‰days after a second dose of mRNA-1273. This compares with an extra 40 (95% CI 38, 41) myocarditis events per 1â€‰million patients in the 28â€‰days following a SARS-CoV-2 positive test. We also observed increased risks of pericarditis and cardiac arrhythmias following a positive SARS-CoV-2 test. Similar associations were not observed with any of the COVID-19 vaccines, apart from an increased risk of arrhythmia following a second dose of mRNA-1273. Subgroup analyses by age showed the increased risk of myocarditis associated with the two mRNA vaccines was present only in those younger than 40.

COVID-19 timeline of events.

Eight unanswered questions about the COVID-19 pandemic.

Can families believe the accuracy of websites' information regarding COVID-19 vaccines' side effects?

COVID-19 Vaccine-Associated Subclinical Axillary Lymphadenopathy on Screening Mammogram. BACKGROUND: Women who received a COVID-19 vaccination may display subclinical unilateral axillary lymphadenopathy on screening mammography, which can appear suspicious for malignancy, leading to additional diagnostic evaluation. PURPOSE: To evaluate the prevalence of subclinical unilateral axillary lymphadenopathy (sLAD) on screening mammogram in women who received either the first or second dose of the Pfizer-BioNTech (Pfizer) or Moderna COVID-19 vaccines compared to women who have not. MATERIALS AND METHODS: In this IRB-approved, HIPAA complaint study from 12/14/2020 to 4/14/2021, 1027 patients presented for screening mammography and met study inclusion criteria. Patients with history of baseline lymphadenopathy or prior cancer diagnosis were excluded. RESULTS: Of the 1027 women, 43 were recalled for unilateral sLAD. 34 women received a COVID-19 vaccination ipsilateral to the sLAD (Pfizer n=19, 44.2%; Moderna n=15, 34.9%), 9 did not (20.9%). Incidence of unilateral axillary sLAD was significantly higher (p-value<0.01) in those who received a COVID-19 vaccination within approximately 7 weeks preceding screening mammogram. 13.2% of patients who received the Pfizer vaccine and 9.5% of patients who received the Moderna vaccine developed sLAD. Moderna's vaccine elicited a more robust reaction in the elderly (Moderna 63.7 years vs. Pfizer 59.7 years). For both vaccines, sLAD resolved on average 46.5 days after the last COVID-19 vaccine (p=0.44). CONCLUSION: Women who have received either mRNA COVID-19 vaccines may benefit from scheduling their screening mammogram before vaccination or consider delaying screening mammography 8 weeks. While Pfizer may have an overall more robust immune response, Moderna may elicit a stronger immune response in elderly women. SUMMARY: Women who received a COVID-19 vaccination before screening mammography were significantly more likely to present with subclinical axillary lymphadenopathy than women who did not receive the vaccine. KEY RESULTS: 13.2% of women who received a Pfizer-BioNTech vaccine exhibited subclinical axillary lymphadenopathy compared to 9.5% of those who received the Moderna vaccine. Only 1.2 % of those who did not receive a vaccine presented with subclinical unilateral axillary lymphadenopathy. The average time of resolution of the lymphadenopathy on diagnostic mammogram was 46.5 days overall, with Pfizer-BioNTech taking 50.7 days and Moderna 41.5 days.

Caution in Using the Activated Partial Thromboplastin Time to Monitor Argatroban in COVID-19 and Vaccine-Induced Immune Thrombocytopenia and Thrombosis (VITT). INTRODUCTION: Argatroban is licensed for patients with heparin-induced thrombocytopenia and is conventionally monitored by activated partial thromboplastin time (APTT) ratio. The target range is 1.5 to 3.0 times the patients' baseline APTT and not exceeding 100 s, however this baseline is not always known. APTT is known to plateau at higher levels of argatroban, and is influenced by coagulopathies, lupus anticoagulant and raised FVIII levels. It has been used as a treatment for COVID-19 and Vaccine-induced Immune Thrombocytopenia and Thrombosis (VITT). Some recent publications have favored the use of anti-IIa methods to determine the plasma drug concentration of argatroban. METHODS: Plasma of 60 samples from 3 COVID-19 patients and 54 samples from 5 VITT patients were tested by APTT ratio and anti-IIa method (dilute thrombin time dTT). Actin FS APTT ratios were derived from the baseline APTT of the patient and the mean normal APTT. RESULTS: Mean APTT ratio derived from baseline was 1.71 (COVID-19), 1.33 (VITT) compared to APTT ratio by mean normal 1.65 (COVID-19), 1.48 (VITT). dTT mean concentration was 0.64â€…Âµg/ml (COVID-19) 0.53â€…Âµg/ml (VITT) with poor correlations to COVID-19 baseline APTT ratio r(2)â€‰=â€‰0.1526 p <0.0001, mean normal r(2)â€‰=â€‰0.2188 pâ€‰<â€‰0.0001; VITT baseline APTT ratio r(2)â€‰=â€‰0.04 pâ€‰<â€‰0.001, VITT mean normal r(2)â€‰=â€‰0.0064 pâ€‰<â€‰0.001. CONCLUSIONS: We believe that dTT is a superior method to monitor the concentration of argatroban, we have demonstrated significant differences between APTT ratios and dTT levels, which could have clinical impact. This is especially so in COVID-19 and VITT.

Booster effect after SARS-CoV-2 vaccination in immunocompromised hematology patients with prior COVID-19.
Clinical characteristics of COVID-19 in solid organ transplant recipients following COVID-19 vaccination: A multicenter case series. BACKGROUND: Solid organ transplant recipients (SOTR) have diminished humoral immune responses to COVID-19 vaccination and higher rates of COVID-19 vaccine breakthrough infection than the general population. Little is known about COVID-19 disease severity in SOTR with COVID-19 vaccine breakthrough infections. METHODS: Between 4/7/21 and 6/21/21, we requested case reports via the Emerging Infections Network (EIN) listserv of SARS-CoV-2 infection following COVID-19 vaccination in SOTR. Online data collection included patient demographics, dates of COVID-19 vaccine administration, and clinical data related to COVID-19. We performed a descriptive analysis of patient factors and evaluated variables contributing to critical disease or need for hospitalization. RESULTS: Sixty-six cases of SARS-CoV-2 infection after vaccination in SOTR were collected. COVID-19 occurred after the second vaccine dose in 52 (78.8%) cases, of which 43 (82.7%) occurredÂ â‰¥14 days post-vaccination. There were six deaths, three occurring in fully vaccinated individuals (7.0%, nÂ =Â 3/43). There was no difference in the percentage of patients who recovered from COVID-19 (70.7%Â vs. 72.2%, pÂ =Â .90) among fully and partially vaccinated individuals. We did not identify any differences in hospitalization (60.5%Â vs. 55.6%, pÂ =Â .72) or critical disease (20.9%Â vs. 33.3%, pÂ =Â .30) among those who were fully versus partially vaccinated. CONCLUSIONS: SOTR vaccinated against COVID-19 can still develop severe, and even critical, COVID-19 disease. Two doses of mRNA COVID-19 vaccine may be insufficient to protect against severe disease and mortality in SOTR. Future studies to define correlates of protection in SOTR are needed.
Systemic inflammatory reactions after COVID-19 vaccinations: Consider the diagnosis of ASIA.
Letter to the editor: Autoimmune hepatitis after COVID-19 vaccination: Need for population-based epidemiological study.
Axillary lymph nodes on PET in Hodgkin lymphoma after COVID-19 vaccination.
Recurrence of Myopericarditis Following mRNA COVID-19 Vaccination in a Male Adolescent. COVID-19 is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The disease has spread worldwide, resulting in health and economic crises. Vaccination against SARS-CoV-2 infection is considered a valid prevention measure to control this pandemic. There have been reports of cases of myopericarditis following mRNA COVID-19 vaccination. We present a case of a 20-year-old man with recurrent myopericarditis following an initial episode of influenza virus-induced myopericarditis and after a second dose of the mRNA-1273 Moderna COVID-19 vaccine. Careful attention should be paid to patients with a history of myocarditis following COVID-19 vaccination.
"Guillain-BarrÃ© Syndrome After COVID-19 Vaccination in an Adolescent" [Pediatric Neurology, Volume 126, January 2022, Pages 9-10].
Correlation of Anti-SARS-CoV-2 S1-specificIgG antibody levels and adverse events following vaccination with BNT162b2 mRNA COVID-19 vaccine in healthcare workers. Currently approved anti-COVID-19 vaccines have been found to be safe and effective and almost 60% of Israeli residents are already vaccinated with BNT162b2 vaccine. This observational study was designed to evaluate the adverse events of vaccine reported by 61 healthcare workers at least 7Â days after the 2nd vaccination, and to investigate the correlation of adverse events and anti-SARS-CoV-2 IgG antibody levels. The median participant's age was 51.25Â years, 16 men and 45 women; 77% (44% of male and 84.5% of female participants) reported adverse events. Injection site pain, fatigue and fever were the most common symptoms, and significantly higher antibody levels (average 19,387 AU/mL) were found in participants who had fever compared to those who did not experience fever (average antibody levels of 9,977 AU/mL, pÂ <Â 0.001). This finding corresponds to previous observations of higher anti-SARS-CoV-2 IgG antibody levels in COVID-19 patients presented with fever.

Parsonage-Turner syndrome following coronavirus disease 2019 immunization with ChAdOx1-S vaccine:Â a case report and review of theÂ literature. BACKGROUND: Parsonage-Turner syndrome is an acute peripheral neuropathy that affects the upper brachial plexus region. Previously published reports demonstrate that the condition can be triggered by surgery, infection, autoimmune diseases, strenuous exercise, trauma, radiation, and vaccination. Parsonage-Turner syndrome has already been reported in three other patients who were vaccinated against coronavirus disease 2019. CASE PRESENTATION: We report the case of a 51-year-old Caucasian man without comorbidities who received the first dose of the ChAdOx1-S recombinant vaccine (Vaxzevria, AstraZeneca, Oxford, UK) against coronavirus disease 2019 and was diagnosed with Parsonage-Turner syndrome. A few days after getting vaccinated, the patient reported a progressive increase in pain in the region of vaccine administration. One month later, the shoulder pain was followed by symptoms of hypoesthesia and muscle weakness on abduction and elevation of the left upper limb. Neurological examination revealed an atrophy of the proximal muscles of the left upper limb, accompanied by paresis of the left deltoid, biceps brachii, triceps brachii, and infraspinatus muscles. Electroneuromyography carried out 3Â months after the onset of symptoms showed signs consistent with brachial plexus neuritis. The adverse reaction has been properly reported to the Italian Pharmacovigilance System (Italian Medicines Agency-Agenzia Italiana del Farmaco. CONCLUSION: The increased awareness of such association is essential for early identification and diagnosis and, thus, better clinical outcomes.

A case report of ChAdOx1 nCoV-19 vaccine-associated encephalitis. BACKGROUND: Vaccination against COVID-19 continues apace, but side-effects, both common and severe, continue to be reported. We report here the first published case of COVID-19 vaccine-related encephalitis. CASE PRESENTATION: A young woman presented with acute neuropsychiatric symptoms following recent ChAdOx1 nCoV-19 vaccination. Extensive investigation did not identify alternative causes. CONCLUSIONS: This difficult case is here described, including presentation, investigation, and management. Further study on neuropsychiatric side-effects of COVID-19 vaccination, including investigation as to whether there may be a causal link, is required.

Antibody affinity maturation and cross-variant activity following SARS-CoV-2 mRNA vaccination: Impact of prior exposure and sex. BACKGROUND: Limited knowledge exists regarding antibody affinity maturation following mRNA vaccination in naÃ¯ve vs. COVID-19 recovered individuals and potential sex differences. METHODS: We elucidated post-vaccination antibody profiles of 69 naÃ¯ve and 17 COVID-19 convalescent adults using pseudovirus neutralization assay (PsVNA) covering SARS-CoV-2 WA-1, variants of concern (VOCs) and variants of interest (VOIs). Surface Plasmon Resonance (SPR) was used to measure antibody affinity against prefusion spike and receptor binding domain (RBD) and RBD mutants. FINDINGS: Higher neutralizing antibodies were observed in convalescent vs. naÃ¯ve adults against, WA-1, VOCs, and VOIs. Antibody binding to RBD and RBD mutants showed lower binding of post-vaccination sera from naÃ¯ve compared with convalescent individuals. Moreover, we observed early antibody affinity maturation in convalescent individuals after one vaccine dose and higher antibody affinity after two doses compared with the naÃ¯ve group. Among the naÃ¯ve participants, antibody affinity against the SARS-CoV-2 prefusion spike was significantly higher for males than females even though there were no difference in neutralization titers between sexes. INTERPRETATION: This study demonstrates the impact of prior infection on vaccine-induced antibody affinity maturation and difference in antibody affinity between males and females. Further studies are needed to determine whether antibody affinity may contribute to correlates of protection against SARS-CoV-2 and its variants. FUNDING: The antibody characterization work described in this manuscript was supported by FDA's Medical Countermeasures Initiative (MCMi) grant #OCET 2021-1565 to S.K and intramural FDA-CBER COVID-19 supplemental funds. The SPARTA program was supported by the National Institute of Allergy and Infectious Diseases (NIAID), U.S. National Institutes

of Health (NIH), Department of Health and Human Services contract 75N93019C00052, and the University of Georgia (US) grant UGA-001. T.M.R is also supported by the Georgia Research Alliance (US) grant GRA-001. The CTRU was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR002378.

CD19 B cell repopulation after ocrelizumab, alemtuzumab and cladribine: Implications for SARS-CoV-2 vaccinations in multiple sclerosis. BACKGROUND: Ocrelizumab maintains B-cell depletion via six-monthly dosing. Whilst this controls relapsing multiple sclerosis, it also inhibits seroconversion following SARS-CoV-2 vaccination unlike that seen following alemtuzumab and cladribine treatment. Emerging reports suggest that 1-3% B-cell repopulation facilitates seroconversion after CD20-depletion. OBJECTIVE: To determine the frequency of B-cell repopulation levels during and after ocrelizumab treatment. METHODS: Relapse data, lymphocyte and CD19 B-cell numbers were obtained following requests to clinical trial data-repositories. Information was extracted from the phase II ocrelizumab extension (NCT00676715) trial and the phase III cladribine tablet (NCT00213135) and alemtuzumab (NCT00530348/NCT00548405) trials obtained clinical trial data requests RESULTS: Only 3-5% of people with MS exhibit 1% B-cells at 6 months after the last infusion following 3-4 cycles of ocrelizumab, compared to 50-55% at 9 months, and 85-90% at 12 months. During this time relapses occurred at consistent disease-breakthrough rates compared to people during standard therapy. In contrast most people (90-100%) exhibited more than 1% B-cells during treatment with either cladribine or alemtuzumab. CONCLUSIONS: Most people demonstrate B cell repletion within 3 months of the last treatment of alemtuzumab and cladribine. However, few people repopulate peripheral B-cells with standard ocrelizumab dosing. Controlled studies are warranted to examine a view that delaying the dosing interval by 3-6 months may allow more people to potentially seroconvert after vaccination.

Dynamic of humoral response to SARS-CoV-2 anti-Nucleocapsid and Spike proteins after CoronaVac vaccination. This study aimed to calculate the seroconversion rate and IgG antibody dynamic range of the CoronaVac vaccine in healthcare workers (HCWs) after immunization. Serum samples from 133 HCWs from Southern Brazil were collected 1 day before (Day 0) and +10, +20, +40,Â +Â 60, +110 days after administering the vaccine's first dose. Immunoglobulin G (IgG) was quantified using immunoassays for anti-N-protein (nucleocapsid) antibodies (Abbott, Sligo, Ireland) and for anti-S1 (spike) protein antibodies (Euroimmun, LÃ¼beck, Germany). Seroconversion by day 40 occurred in 129 (97%) HCWs for the S1 protein, and in 69 (51.87%) HCWs for the N protein. An absence of IgG antibodies (by both methodologies), occurred in 2 (1.5%) HCWs undergoing semiannual rituximab administration, and also in another 2 (1.5%) HCWs with no apparent reason. This study showed that CoronaVac has a high seroconversion rate when evaluated in an HCW population.

Clinical Cardiovascular Adverse Events Reported Post-COVID-19 Vaccination: Are They a Real Risk? Given the urgent need to control the spread of the novel COVID-19 virus, 13 vaccines have been approved for emergency use before completing all 3 phases of the clinical trials. Thereby a careful monitor of the adverse effects postvaccination is essential. We searched through PubMed and other reporting systems like VAERS for the reported cardiovascular adverse events post-COVID-19 vaccination. Through our review, we determined that the incidence of all the reported cardiovascular events is very rare. Additionally, the vaccine was initially given to the elderly and high-risk populations in which cardiovascular events such as myocardial infarction and arrhythmias are already more prevalent, while other cardiovascular events such as myocarditis or vaccine-induced thrombotic thrombocytopenia were more common in younger populations. Moreover, a direct causal relationship, if any, between vaccination and adverse events is yet to be fully elucidated. Thus, at this time point, the benefits of vaccination far outweigh the risk.

Reply to 'New-onset cutaneous lichen planus triggered by COVID-19 vaccination' by Merhy et al.

Most cases of Thrombosis and Thrombocytopenia Syndrome (TTS) post ChAdOx-1 nCov-19 are Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT).

Laboratory confirmed vaccine-induced immune thrombotic thrombocytopenia: Retrospective analysis of reported cases after vaccination with ChAdOx-1 nCoV-19 in Germany. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a severe adverse event of SARS-CoV-2 vaccination. We describe the characteristics of patients reported in Germany based on the Brighton Collaboration (BC) case definition criteria for Thrombosis and Thrombocytopenia Syndrome (TTS) and focus on patients with complete anti-platelet factor 4 (PF4)-antibody laboratory work up. METHODS: The adverse drug reaction database of the Paul-Ehrlich Institute was queried for TTS cases following ChAdOx1 nCoV-19 vaccination from February 1, until May 21, 2021. Cases with reports from the Greifswald laboratory were analysed in detail. FINDINGS: PF4 antibody tests were available for 69 suspected TTS cases reported to the Paul-Ehrlich Institute, of whom 52 patients fulfilled the BC case definition; 37 (71%) women, 15 (29%) men, median age 46Â·0 years (interquartile range 31Â·0-60Â·3 years). Cerebral venous sinus thrombosis was confirmed in 37 (71%), (additional) multiple thromboses in 19 (37%) patients. Twelve patients died. Non-survivors showed lower platelet counts compared to survivors (median nadir 15,000/ÂµL vs 49,000/ÂµL; p<0Â·0001). Combined anti-PF4/heparin IgG ELISA and PF4-dependent platelet activation testing yielded sensitivity of 96% (95% confidence interval 87-100%) and specificity of 77% (50-93%) for TTS. Four patients with thrombocytopenia but without thrombosis presented with severe headache or cerebral bleeding, explaining the lower specificity. INTERPRETATION: VITT has high mortality and can present with isolated thrombocytopenia, severe headache, and bleeding. Demonstration of platelet activating anti-PF4 IgG has high sensitivity for TTS and captures a wider spectrum of clinically relevant VITT than the current BC case definition. FUNDING: Deutsche Forschungsgemeinschaft: 374031971-TRR240; Domagk-Programm UniversitÃ¤tsmedizin Greifswald.

Venous sinus thrombosis after the second jab of an mRNA-based SARS-CoV-2 vaccine. OBJECTIVES: Venous sinus thrombosis (VST) after vaccination with the mRNA-based vaccine produced by Pfizer is comparatively rare and usually occurs after the first dose. VST after the second dose has been reported in only few patients. CASE REPORT: The patient is a 33yo male who experienced an episode of sudden onset focal, stabbing headache in the left temporal region for about 4Â h. Three days later a similar episode occurred accompanied by a focal seizure. Twenty days before he had received the second dose of the Pfizer vaccine. Clinical exam was normal but MRI of the brain revealed a VST of the left transverse and sigmoid sinuses. Anticoagulation with low molecular weight heparin followed by dabigatran resulted in complete recovery. CONCLUSIONS: This case shows that also the second dose of the Pfizer vaccine can be followed by a VST. Currently, there are more arguments in favour of a causal relation between the vaccination and the VST than against it.

Data Mining on COVID-19 Vaccines: Side Effects. COVID-19 is a pandemic disease affecting billions of people worldwide. Taking vaccines is a most effective approach to gain fully control. Thanks to the coordinated efforts from all over the world, several brands of vaccines targeting COVID-19 have passed through clinical trials and been brought to the public. Growing numbers of people are taking vaccines and share their feedback on social media, mostly on Twitter. In this study, we used Twitter data to analyze the side effects on each individual and quantify these side effects in a brand-wise and country-wise manner. Based on Twitter data, we found that the United States has the largest number of people getting vaccinated, Pfizer is the most widely used vaccine brand around the world and the most frequent side effect is cold. From our analysis, the side effects of vaccines are under controllable and are acceptable, and everyone can join the vaccinated camping without hesitation.

Rapid Progression of Angioimmunoblastic T Cell Lymphoma Following BNT162b2 mRNA Vaccine Booster Shot: A Case Report. Since nucleoside-modified mRNA vaccines strongly activate T follicular helper cells, it is important to explore the possible impact of approved SARS-CoV-2 mRNA vaccines on neoplasms affecting this cell type. Herein, we report and discuss unexpected rapid progression of lymphomatous lesions after administration of a BNT162b2 mRNA vaccine booster in a man recently diagnosed with AITL.

Immune thrombocytopenia purpura flare post COVID-19 vaccine. INTRODUCTION AND IMPORTANCE: Coronavirus disease 2019 (COVID-19) is a recently discovered disease that has yet to be thoroughly described. It is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a novel virus that can be transmitted easily from human to human, mainly by the respiratory route. The disease often presents with non-specific symptoms such as fever, headache, and fatigue, accompanied by respiratory symptoms (e.g., cough and dyspnea) and other systemic involvement. Currently, vaccination is the primary strategy to prevent transmission and reduce disease severity. However, vaccines have side effects, and the consequences of vaccination in different diseases are not well established. Moreover, the impact of SARS-CoV-2 vaccination during pregnancy is another not well-known area. CASE PRESENTATION: We present a young lady known to have ITP, which was controlled for years, presented with relapse after taking the SARS-CoV-2 vaccine during pregnancy. CLINICAL DISCUSSION: The patient had a relapse of ITP after the introduction of the first dose of the COVID-19 vaccine, which worsened further after the second dose. This suggests that patients with ITP who develop flare post-SARS-CoV-2 vaccine should have their second dose delayed, particularly if pregnant. CONCLUSION: To avoid further deterioration in platelet count, and avoid confusion due to the presence of different causes of thrombocytopenia and avoid complications related to thrombocytopenia during pregnancy which can affect the mode of delivery. THE CASE IS REPORTED IN LINE WITH THE SCARE 2020 CRITERIA: Agha RA, Franchi T, Sohrabi C, Mathew G, for the SCARE Group. The SCARE 2020 Guideline: Updating Consensus Surgical CAse REport (SCARE) Guidelines, International Journal of Surgery 2020; 84:226-230.

Guillain-BarrÃ© syndrome after coronavirus disease 2019 vaccine: A temporal association. BACKGROUND: Guillain-BarrÃ© syndrome (GBS) is an acute monophasic immune-mediated polyradiculoneuropathy, preceded by gastrointestinal or respiratory infections in up to two-thirds of patients. On rare occasions, people develop GBS after vaccination, but no causal association has been proven. In the current coronavirus disease 2019 (COVID-19) pandemic, some cases have been reported associating COVID-19 vaccine with GBS. CASE PRESENTATION: We report a case of a 62-year-old woman with GBS after the first dose of the Oxford/AstraZeneca vaccine against SARS-CoV-2. The symptoms started 3Â weeks after the vaccine, and were characterized by ascending and progressive paresthesia in the upper and lower limbs, followed by loss of strength of the upper limbs and dysphagia for solids. The hypothesis of GBS was confirmed by clinical presentation compatible with albuminocytologic dissociation in cerebrospinal fluid and based on the Brighton criteria levelÂ 2. The treatment was a 5-day course of intravenous immunoglobulin with an improvement of symptoms. CONCLUSIONS: In the absence of other causes, the diagnosis of GBS was made, with evidence of a clear temporal association with COVID-19 vaccine. However, a cautious position is important when assigning a particular side-effect directly to a vaccine. It is important to emphasize that it is a temporal association only and the benefits of COVID-19 vaccination continue to outweigh the possible consequences.

Anti-SARS-CoV-2 Spike Protein RBD Antibody Levels After Receiving a Second Dose of ChAdOx1 nCov-19 (AZD1222) Vaccine in Healthcare Workers: Lack of Association With Age, Sex, Obesity, and Adverse Reactions. Response to vaccines generally varies according to individual factors of the vaccinated subjects such as demographics and immune status. While there are various reports of factors

associated with immunogenicity of mRNA COVID-19 vaccines, little is known about those of adenovirus vector vaccines. We conducted a prospective observational study to assess the relationships of antibody level with age, sex, body mass index (BMI), and adverse reactions (ARs) to an adenovirus vector vaccine, ChAdOx1 nCoV-19. Healthcare workers who planned to receive both the first and second injections of the ChAdOx1 nCoV-19 vaccine at Hanyang University Hospital, Seoul, Korea, were enrolled in the study. Seven days after each injection, participants were asked to complete an online adverse reaction survey. In addition, anti-SARS-CoV-2 spike (S) protein receptor binding domain (RBD) antibody concentration was measured 4 weeks after the second injection. All participants (n = 447, 100%) showed serologic positivity (â‰¥ 0.8 U/mL) 4 weeks after the second injection of ChAdOx1 nCoV-19 vaccine. Furthermore, the anti-SARS-CoV-2 S protein RBD concentration was similar among groups when stratified by age, sex, BMI, or presence and severity of AR; multivariable linear regression found no associations between antibody response to the ChAdOx1 nCoV-19 vaccine and age, BMI, sex, and vaccine-induced ARs. In conclusion, age, sex, obesity, and ARs were not associated with antibody responses after two doses of ChAdOx1 nCoV-19 vaccination.

A National Representative, Cross-Sectional Study by the Hellenic Academy of NeuroImmunology (HEL.A.NI.) on COVID-19 and Multiple Sclerosis: Overall Impact and Willingness Toward Vaccination. Background: In the context of the coronavirus disease 2019 (COVID-19) pandemic, the constant needs of people with multiple sclerosis (PwMS) and their caregivers were urgently highlighted. Aim: The present study aims to capture the effects of the COVID-19 pandemic in several aspects of the quality of life of PwMS, in perception and behavior to COVID-19 and multiple sclerosis (MS), as well as concerning healthcare, working conditions, and the willingness toward COVID-19 vaccination. Methods: This study is an initiative of the Hellenic Academy of Neuroimmunology (HEL.A.NI.) and it has been included in the MS Data Alliance (MSDA) Catalog, which can be accessed after creating an account on https://msda.emif-catalogue.eu/login. Two online questionnaires were administered: (i) impact of the COVID-19 pandemic on the quality of life, behavior, and healthcare of PwMS (Questionnaire A) and (ii) vaccination against COVID-19 (Questionnaire B). People with MS were invited to participate by the Hellenic Federation of Persons with Multiple Sclerosis (HFoPwMS). Results: Three-hundred-ninety PwMS responded to Questionnaire A, whereas 176 PwMS provided answers for Questionnaire B. Older age, longer disease duration, and higher MS-related disability were associated with the increased perceived sensitivity toward severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, as well as the increased perceived severity of COVID-19 upon potential infection. A significant proportion of PwMS experienced restricted access to MS-related health professionals, disease-modifying therapy (DMT) prescription, and/or to MS-related laboratory examination due to the pandemic. Subgroups of PwMS reported exacerbated symptoms (i.e., chronic MS-related symptoms, fatigue and/or worsening of pre-existing fatigue, and sexual dysfunction and or/worsening of pre-existing sexual dysfunction). Overall, the majority of the participants reported either a strong willingness to get vaccinated against COVID-19 or a likeliness to undergo vaccination. Being aware of the HEL.A.NI. recommendations regarding COVID-19 vaccination for PwMS were reported to increase the willingness of the participants to receive the vaccine. Conclusions: Our results highlight the necessity of scientific and patient organizations in taking joint action to increase awareness on health-related issues during the pandemic and to provide accurate and up-to-date guidance for PwMS. Online information and communications technology (ICT) tools for polling public belief and behavior may prove valuable as means of retaining active routes of communication between stakeholders.

Vestibular neuritis after COVID-19 vaccination. Coronavirus disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 and presents with pneumonia as the most frequent and serious manifestation. COVID-19 vaccination is an important and urgent interest globally due to

COVID-19's rapid spread and high rates of mortality and morbidity. Vestibular neuritis (VN) is an acute vestibular syndrome that causes acute and spontaneous vertigo due to unilateral vestibular deafferentiation, leading to nausea or vomiting and unsteadiness that can last from days to weeks. Reactivation of latent type 1 herpes simplex virus, autoimmune disorders, and microvascular ischemia are hypothesized to be etiologies. Herein, the case of a 54-year-old man who developed VN within three days after COVID-19 vaccination is presented. There have been no reports of VN after vaccination for COVID-19 or other viral diseases. Although the association between VN and COVID-19 vaccination remains unclear, clinicians should be aware that VN may occur as an adverse event of COVID-19 vaccination.
Heterologous prime-boost vaccination against COVID-19: is it safe and reliable? Throughout the globe, many nations are struggling to cope with the consecutive waves of the COVID-19. Several vaccines have been employed to overcome this ongoing pandemic and are available as single and double-dose inoculations; however, homologous vaccine efficacy is being reconsidered due to the rapidly emerging SARS-CoV-2 variants. Many studies have been conducted on the heterologous prime-boost vaccine regimens and have shown good efficacy results against COVID-19. This article aims to highlight the safety and reliability of heterologous prime-boost vaccination against COVID-19. We have also made some recommendations towards using these combinations of vaccines for the global mitigation of the subsequent waves of COVID-19.
Emergence of BehÃ§et's disease post-SARS-CoV2-vaccination: two clinical cases in Japan.
Koebner phenomenon with lichen planus in an area of previous vitiligo after COVID-19 vaccination and the creation of a locus minoris resistentiae.
Immunogenicity and safety of anti-SARS-CoV-2 BNT162b2 vaccine in psoriasis patients treated with biologic drugs.
Heart inflammation risk after COVID-19 vaccine.
Association of COVID-19 mortality with COVID-19 vaccination rates in Rhineland-Palatinate (Germany) from calendar week 1 to 20 in the year 2021: a registry-based analysis. Vaccination is among the measures implemented by authorities to control the spread of the COVID-19 pandemic. However, real-world evidence of population-level effects of vaccination campaigns against COVID-19 are required to confirm that positive results from clinical trials translate into positive public health outcomes. Since the age group 80â€‰+â€‰years is most at risk for severe COVID-19 disease progression, this group was prioritized during vaccine rollout in Germany. Based on comprehensive vaccination data from the German federal state of Rhineland-Palatinate for calendar week 1-20 in the year 2021, we calculated sex- and age-specific vaccination coverage. Furthermore, we calculated the proportion of weekly COVID-19 fatalities and reported SARS-CoV-2 infections formed by each age group. Vaccination coverage in the age group 80â€‰+â€‰years increased to a level of 80% (men) and 75% (women). Increasing vaccination coverage coincided with a reduction in the age group's proportion of COVID-19 fatalities. In multivariable logistic regression, vaccination coverage was associated both with a reduction in an age-group's proportion of COVID-19 fatalities [odds ratio (OR) per 5 percentage pointsâ€‰=â€‰0.89, 95% confidence interval (CI)â€‰=â€‰0.82-0.96, pâ€‰=â€‰0.0013] and of reported SARS-CoV-2 infections (OR per 5 percentage pointsâ€‰=â€‰0.82, 95% CI 0.76-0.88, pâ€‰<â€‰0.0001). The results are consistent with a protective effect afforded by the vaccination campaign against severe COVID-19 disease in the oldest age group.
Refractory Longitudinally Extensive Transverse Myelitis after Severe Acute Respiratory Syndrome Coronavirus 2 Vaccination in a Japanese Man. Vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been developed and administered worldwide. There have been reports of neurological adverse events following immunization (AEFIs). We herein report a case

of refractory longitudinally extensive transverse myelitis in a 75-year-old Japanese man following the first dose of the BNT162b2 vaccine. The patient developed total sensory loss below the umbilicus and complete paralysis in both legs. Although he was treated with steroid therapy and plasma exchange, his recovery was limited, and severe sequelae remained. Further studies, including large epidemiological studies, are required to understand the association between SARS-CoV-2 vaccines and neurological AEFI.
New-onset Polymyalgia Rheumatica Following the Administration of the Pfizer-BioNTech COVID-19 Vaccine. We herein report the case of an 80-year-old Japanese woman who presented to our hospital with bilateral pain in the shoulders and hips lasting for a month since 2 days after the second dose of the BNT162b2 COVID-19 vaccine. Her physical findings, laboratory data, and ultrasonographic findings of bilateral biceps tenosynovitis and lateral subacromial bursitis were consistent with a diagnosis of polymyalgia rheumatica (PMR). She was successfully treated with oral prednisolone 15 mg/day. Although a causal relationship could not be definitively confirmed, PMR should be considered as a differential diagnosis in cases of persistent myalgia after administration of the BNT162b2 vaccine.
Impaired hearing following SARS-CoV-2 vaccinations.
SARS-CoV-2 antibody and T cell responses one year after COVID-19 and the booster effect of vaccination: A prospective cohort study. OBJECTIVES: First, to describe SARS-CoV-2 T cell and antibody responses in a prospective cohort of healthcare workers that suffered from mild to moderate COVID-19 approximately one year ago. Second, to assess COVID-19 vaccine-induced immune responses in these prior-infected individuals. METHODS: SARS-CoV-2-specific T cell and anti-SARS-CoV-2-Spike-RBD immunoglobulin G (IgG) responses in blood were determined before COVID-19 vaccination with mRNA-1273, BNT162b2, Ad26.CoV2-S or ChAdOx1-S, two weeks after first vaccination, and after second vaccination. RESULTS: 55 prior SARS-CoV-2 infected and seroconverted individuals were included. S1-specific T cell responses and anti-RBD IgG were detectable one year post SARS-CoV-2 infection: 24 spot-forming cells per 10(6) peripheral blood mononuclear cells (SFCs/10(6) PBMCs) after S1 stimulation and anti-RBD IgG concentration of 74 (IQR 36-158)Â IU/mL. Responses after the first and second vaccination were comparable with S1-specfic T cell responses of 198 (IQR 137-359) and 180 (IQR 103-347) SFCs/10(6) PBMCs, and IgG concentrations of 6792 (IQR 3386-15,180) and 6326 (IQR 2336-13,440)Â IU/mL, respectively. These responses retained up to four months after vaccination. CONCLUSIONS: Both T cell and IgG responses against SARS-CoV-2 persist for up to one year after COVID-19. A second COVID-19 vaccination in prior-infected individuals did not further increase immune responses in comparison to one vaccination.
SARS-CoV-2-antibody response in health care workers after vaccination or natural infection in a longitudinal observational study. BACKGROUND: Following a year of development, several vaccines have been approved to contain the global COVID-19 pandemic. Real world comparative data on immune response following vaccination or natural infection are rare. METHODS: We conducted a longitudinal observational study in employees at a secondary care hospital affected by the COVID-19 pandemic. Comparisons were made about the presence of anti-SARS-CoV-2 immunglobulin G (IgG) antibody ratio after natural infection, or vaccination with one or two doses of BioNTech/Pfizer (BNT162b2), or one dose of AstraZenca (Vaxzevria) vaccine. RESULTS: We found a 100% humoral response rate in participants after 2 doses of BNT162b2 vaccine. The antibody ratio in participants with one dose BNT162b2 and Vaxzevria did not differ significantly to those with previous PCR-confirmed infection, whereas this was significantly lower in comparison to two doses of BioNTech/Pfizer. We could not identify a correlation with previous comorbidities, obesity or age within this study. Smoking showed a negative effect on the antibody response (pÂ =Â 0.006) CONCLUSION: Our data provide an overview about humoral immune response after natural SARS-

CoV-2 infection or following vaccination, and supports the usage of booster vaccinations, especially in patients after a natural SARS-CoV-2 infection.

Adverse event of Sinovac Coronavirus vaccine: Deafness. COVID-19 has spread worldwide and is one of the most threatening infectious diseases in the world. Vaccination is known as an effective method to protect susceptible populations against such diseases. The Coronavirus vaccine developed by Sinovac has been shown to have a high protective effect, but it also has potential adverse events. For example, our department saw two patients with reported cases of deafness that occurred after inoculation with the Sinovac Coronavirus vaccine. While deafness is only a rare adverse event from the Coronavirus vaccine, whether other vaccination centers, hospitals, and centers for disease control (CDCs) have encountered similar cases still needs to be investigated, reported, and analyzed.

First diagnosis of thrombotic thrombocytopenic purpura after SARS-CoV-2 vaccine - case report. BACKGROUND: We report a case of a 25-year-old male patient, who developed acquired thrombotic thrombocytopenic purpura (aTTP) after receiving a first dose of mRNA-based SARS-CoV-2 vaccine Spikevax (mRNA-1273, Moderna Biotech, USA). While this is the first case in literature describing a case of aTTP after receiving the Spikevax vaccine, there are two other cases after mRNA-based Covid-19 vaccine and two after adenoviral SARS-CoV-2 vaccine. CASE PRESENTATION: The patient presented with persisting malaise, fever, headache, word-finding difficulties, nausea, vomiting, petechial bleeding, and hematuria 13â€‰days after receiving a first dose of vaccination. Laboratory testing showed low platelet count, Coombs-negative hemolytic anemia, and mild acute kidney injury. We excluded vaccine induced immune thrombotic thrombocytopenia (VITT) as another important differential diagnosis and the final diagnosis was established after ADAMTS-13 (A Disintegrin And Metalloproteinase with a ThromboSpondin type 1 motif, member 13) activity was found to be <â€‰1% (reference rangeâ€‰>â€‰40%) and ADAMTS-13 antibodies being 72.2â€‰IU/L (reference rangeâ€‰<â€‰12â€‰IU/L). We initiated empiric therapy of plasmapheresis and corticosteroids on admission and started caplacizumab the day after. The patient's thrombocyte count normalized 3â€‰days after admission, hemolysis and acute kidney injury resolved after 2â€‰weeks. The patient received 2 doses of rituximab (1â€‰g each) after the diagnosis of immune TTP was established. One month after the initial presentation, the patient is in good overall condition, but still receives daily caplacizumab due to ADAMTS-13 activity of <â€‰1%. CONCLUSIONS: Low platelet count after vaccination against SARS-CoV-2 has gained attraction after vaccine-induced immune thrombotic thrombocytopenia (VITT) has been described as a rare but severe complication of adenoviral-based vaccines. Thrombotic thrombocytopenic purpura (TTP) is an important differential diagnosis, but there are only few reports of TTP following SARS-CoV-2 vaccination. Despite pathophysiological and clinical differences of both entities, diagnostic uncertainty can result in the acute setting, since they share main symptoms such as headache and neurological alterations in addition to thrombocytopenia. In difference to other cases reported, this patient developed first symptoms of TTP as early as 4 days after vaccination, which suggests that vaccination merely acted as trigger for occult TTP, instead of truly inducing an autoimmunological process.

Detection of anti-GPIbÎ± autoantibodies in a case of immune thrombocytopenia following COVID-19 vaccination.

SARS-CoV-2 vaccine-induced immune thrombotic thrombocytopenia. SARS-CoV-2 vaccines have been carefully developed and significantly alleviate the global pandemic. However, a rare but severe complication after vaccination of adenoviral vector vaccines has attracted worldwide attention. It is characterized by thrombosis at unusual sites (often cerebral or abdominal), thrombocytopenia, and the presence of antibodies against platelet factor 4 (PF4), termed vaccine-induced immune thrombotic thrombocytopenia (VITT). Its pathogenesis is similar to that of heparin-induced

thrombocytopenia (HIT). VITT progresses rapidly and has a high mortality rate. Clinicians and the public should raise their vigilance to this disease so that accurate and timely treatment is provided.

The race to make vaccines for a dangerous respiratory virus.

Humoral anti-SARS-CoV-2 immune response after two doses of Comirnaty vaccine in nursing home residents by previous infection status. BACKGROUND: Coronavirus disease 2019 (COVID-19) is associated with increased morbidity and mortality in older adults. Although the advent of the first vaccines has significantly reduced these rates, data on older adults in clinical trials are scarce. OBJECTIVES: We quantified and compared the humoral response in individuals with vs. without pre-existing seropositivity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), in a cohort of 69 patients living in a nursing home and who had received the recommended two doses of the Comirnaty (Pfizer-BioNTechÂ®) vaccine. RESULTS: All 69 patients (100%) tested positive for antibodies against SARS-CoV-2 at 2Â months post-vaccination. Residents with a pre-vaccination infection had significantly higher titers of anti-spike 1 IgG than those with no prior infection (median [interquartile range]: 55,726 [14463-78852] vs. 1314 [272-1249] arbitrary units, respectively; pÂ <Â 0.001). The same result was observed for neutralizing antibodies titers (704 [320-1280] vs. 47 [20-40] respectively; pÂ <Â 0.001). Between the pre-vaccination and post-vaccination periods, for IgG and neutralizing antibodies, we observed a 49 and 8-fold increase respectively. In comparison to the wild-type Receptor Binding Domain (RBD), the binding capacity of these vaccine sera was significantly decreased on the B.1.351 and P.1 variants RBD but not decreased with respect to the B.1.1.7 RBD. Although all nursing home residents developed a humoral response following Comirnaty vaccine, its intensity appeared to depend on the pre-vaccination serological status. CONCLUSION: Our results raise the question of how many doses of vaccine should be administered in older and how long the protection will be effective.

Subacute thyroiditis after SARS-CoV-2 vaccination: report of two clinical cases.

COVID-19 mRNA vaccine may trigger subacute thyroiditis. Subacute thyroiditis is the most common cause of painful thyroiditis, which usually occurs after an acute viral upper respiratory tract infection. Rare cases of subacute thyroiditis have been reported after administration of viral vaccines. Here, we report four cases of subacute thyroiditis after administration of the COVID-19 mRNA vaccine (Pfizer/BioNTechÂ®). We describe the clinical, laboratory and imaging features of five cases of subacute thyroiditis after COVID-19 mRNA vaccine (Pfizer/BioNTechÂ®). COVID-19 mRNA vaccine (Pfizer/BioNTechÂ®)-associated subacute thyroiditis may present with clinical findings typical of classic subacute thyroiditis such as fever, neck pain, weakness, and tremor within a few days following vaccination. Subacute thyroiditis may be focal or may progress with diffuse bilateral involvement. Depending on the extent of subacute thyroiditis involvement, significant increases in acute-phase reactants can be observed. COVID-19 mRNA vaccine (Pfizer/BioNTechÂ®) associated subacute thyroiditis responds quite well to non-steroidal anti-inflammatory therapy. Clinicians should be aware of the risk of developing subacute thyroiditis after vaccination.

Immunogenicity and safety of a third dose of CoronaVac, and immune persistence of a two-dose schedule, in healthy adults: interim results from two single-centre, double-blind, randomised, placebo-controlled phase 2 clinical trials. BACKGROUND: Large-scale vaccination against COVID-19 is being implemented in many countries with CoronaVac, an inactivated vaccine. We aimed to assess the immune persistence of a two-dose schedule of CoronaVac, and the immunogenicity and safety of a third dose of CoronaVac, in healthy adults aged 18 years and older. METHODS: In the first of two single-centre, double-blind, randomised, placebo-controlled phase 2 clinical trials, adults aged 18-59 years in Jiangsu, China, were initially allocated (1:1) into two vaccination schedule cohorts: a day 0 and day 14 vaccination cohort (cohort 1) and a day 0 and day 28 vaccination cohort (cohort 2); each cohort was randomly assigned (2:2:1) to either a 3 Î¼g dose or 6 Î¼g dose of CoronaVac or a

placebo group. Following a protocol amendment on Dec 25, 2020, half of the participants in each cohort were allocated to receive an additional dose 28 days (window period 30 days) after the second dose, and the other half were allocated to receive a third dose 6 months (window period 60 days) after the second dose. In the other phase 2 trial, in Hebei, China, participants aged 60 years and older were assigned sequentially to receive three injections of either 1Â·5 Î¼g, 3 Î¼g, or 6 Î¼g of vaccine or placebo, administered 28 days apart for the first two doses and 6 months (window period 90 days) apart for doses two and three. The main outcomes of the study were geometric mean titres (GMTs), geometric mean increases (GMIs), and seropositivity of neutralising antibody to SARS-CoV-2 (virus strain SARS-CoV-2/human/CHN/CN1/2020, GenBank accession number MT407649.1), as analysed in the per-protocol population (all participants who completed their assigned third dose). Our reporting is focused on the 3 Î¼g groups, since 3 Î¼g is the licensed formulation. The trials are registered with ClinicalTrials.gov, NCT04352608 and NCT04383574. FINDINGS: 540 (90%) of 600 participants aged 18-59 years were eligible to receive a third dose, of whom 269 (50%) received the primary third dose 2 months after the second dose (cohorts 1a-14d-2m and 2a-28d-2m) and 271 (50%) received a booster dose 8 months after the second dose (cohorts 1b-14d-8m and 2b-28d-8m). In the 3 Î¼g group, neutralising antibody titres induced by the first two doses declined after 6 months to near or below the seropositive cutoff (GMT of 8) for cohort 1b-14d-8m (n=53; GMT 3Â·9 [95% CI 3Â·1-5Â·0]) and for cohort 2b-28d-8m (n=49; 6Â·8 [5Â·2-8Â·8]). When a booster dose was given 8 months after a second dose, GMTs assessed 14 days later increased to 137Â·9 (95% CI 99Â·9-190Â·4) for cohort 1b-14d-8m and 143Â·1 (110Â·8-184Â·7) 28 days later for cohort 2b-28d-8m. GMTs moderately increased following a primary third dose, from 21Â·8 (95% CI 17Â·3-27Â·6) on day 28 after the second dose to 45Â·8 (35Â·7-58Â·9) on day 28 after the third dose in cohort 1a-14d-2m (n=54), and from 38Â·1 (28Â·4-51Â·1) to 49Â·7 (39Â·9-61Â·9) in cohort 2a-28d-2m (n=53). GMTs had decayed to near the positive threshold by 6 months after the third dose: GMT 9Â·2 (95% CI 7Â·1-12Â·0) in cohort 1a-14d-2m and 10Â·0 (7Â·3-13Â·7) in cohort 2a-28d-2m. Similarly, in adults aged 60 years and older who received booster doses (303 [87%] of 350 participants were eligible to receive a third dose), neutralising antibody titres had declined to near or below the seropositive threshold by 6 months after the primary two-dose series. A third dose given 8 months after the second dose significantly increased neutralising antibody concentrations: GMTs increased from 42Â·9 (95% CI 31Â·0-59Â·4) on day 28 after the second dose to 158Â·5 (96Â·6-259Â·2) on day 28 following the third dose (n=29). All adverse reactions reported within 28 days after a third dose were of grade 1 or 2 severity in all vaccination cohorts. There were three serious adverse events (2%) reported by the 150 participants in cohort 1a-14d-2m, four (3%) by 150 participants from cohort 1b-14d-8m, one (1%) by 150 participants in each of cohorts 2a-28d-2m and 2b-28d-8m, and 24 (7%) by 349 participants from cohort 3-28d-8m. INTERPRETATION: A third dose of CoronaVac in adults administered 8 months after a second dose effectively recalled specific immune responses to SARS-CoV-2, which had declined substantially 6 months after two doses of CoronaVac, resulting in a remarkable increase in the concentration of antibodies and indicating that a two-dose schedule generates good immune memory, and a primary third dose given 2 months after the second dose induced slightly higher antibody titres than the primary two doses. FUNDING: National Key Research and Development Program, Beijing Science and Technology Program, and Key Program of the National Natural Science Foundation of China. TRANSLATION: For the Mandarin translation of the abstract see Supplementary Materials section.

Uptake and adverse reactions of COVID-19 vaccination among people living with HIV in China: a case-control study. OBJECTIVES: The coronavirus disease-2019 (COVID-19) pandemic continues to ravage the world. People living with HIV (PLHIV) are one of the most vulnerable groups. This study aims to identify the factors associated with the uptake and adverse reactions of COVID-19

vaccination. METHODS: We recruited PLHIV in China by convenience sampling between 7 and 23 February 2021. Participants were asked to complete an online questionnaire. Chi-squared test and multivariable logistic regression were used to assess factors associated with vaccine uptake. RESULTS: A total of 527 vaccinated and 1091 unvaccinated PLHIV were recruited. Individuals who had a higher education, engaged in occupations with a higher risk of COVID-19 infection, received influenza or pneumonia vaccine in the past 3Â years (5.40, 3.36-8.77), believed in the effectiveness of vaccines (3.01, 2.20-4.12), and received media information regarding COVID-19 vaccine (2.23, 1.61-3.11), were more likely to be vaccinated. Concerning about adverse reactions (0.31, 0.22-0.44), negative impact on the progression of HIV/AIDS (0.36, 0.26-0.50) or antiretroviral therapy (ART) (0.61, 0.44-0.85), disclosure of HIV infection status (0.69, 0.49-0.96), comorbidities (0.33, 0.22-0.47), being unmarried (0.43, 0.28-0.66) and older age were negatively associated with vaccination. Of the 527 vaccinated PLHIV, 155 (29.4%) PLHIV reported adverse reactions, with pain at the injection site being the most common (18.2%). CONCLUSIONS: PLHIV, who are concerned about adverse reactions, negative impact on ART outcome and disclosure of HIV infection status, were less likely to adopt COVID-19 vaccination. To increase vaccination coverage among PLHIV, health-care professionals should emphasize the benefits and necessity of vaccination and provide consultancy regarding adverse reactions.

HIV and SARS-CoV-2 Co-infection: Epidemiological, Clinical Features, and Future Implications for Clinical Care and Public Health for People Living with HIV (PLWH) and HIV Most-at-Risk Groups. PURPOSE OF REVIEW: The purpose of this review is using the currently available clinical and epidemiological data, to identify key aspects to improve both the clinical management and public health response with regard SARS-CoV-2/HIV co-infection among HIV vulnerable populations and people living with HIV (PLWH). RECENT FINDINGS: While at the beginning of the COVID-19 pandemic, the lack of robust information on SARS-CoV-2/HIV coinfection prevented to have a clear picture of the synergies between them, currently available data strongly supports the importance of common structural factors on both the acquisition and clinical impact of these infections and the relevance of age, co-morbidities, and HIV viral load as associated worse prognosis factors among PLWH. Although more information is needed to better understand the biological, clinical, and epidemiological relationship between both infections, in the meanwhile, syndemic approaches to prevent SARS-CoV-2 among HIV higher risk groups and PLWH, targeting these population for SARS-CoV-2 vaccines and protocolizing early identification of HIVâ€‰+â€‰patients with worse COVID-19 prognosis factors, are crucial strategies to decrease the overall impact of SARS-CoV-2 /HIV coinfection.

Population-based Incidence of Myopericarditis After COVID-19 Vaccination in Danish Adolescents. In this prospective nationwide multicenter study from Denmark, myopericarditis after Pfizer-BioNTech mRNA COVID-19 vaccination was identified in 13 males and 2 females between May 15 and September 15, 2021, among 133,477 vaccinated males and 127,857 vaccinated females 12-17 years of age, equaling 97 males and 16 females per million. In conclusion, the incidence of myopericarditis after COVID-19 vaccination among males appears higher than reports from the United States.

Infectious complications and vaccines. Infections are a major cause of morbidity and can result in mortality in long-term survivors after allogeneic hematopoietic cell transplantation. Chronic graft-versus-host disease and delayed immune reconstitution are recognized risk factors. Different strategies must be utilized depending on the individual patient's situation but include prolonged antimicrobial prophylaxis and vaccination. Some important infections due to pathogens preventable by vaccination are pneumococci, influenza, varicella-zoster virus, and SARS-CoV-2. Despite the fact that such recommendations have been in place for decades, implementation of these recommendations has been reported to be poor.

How to recognize and manage COVID-19-associated coagulopathy. COVID-19 is frequently associated with abnormalities on coagulation testing and a coagulopathy driven by inflammation, intravascular coagulation activation, and microvascular thrombosis. Elevated D-dimer is the most common finding and is a predictor of adverse outcomes including thrombosis, critical illness, and death. Although COVID-19-associated coagulopathy has some similarities to disseminated intravascular coagulation, the platelet count is usually preserved, coagulation times are usually normal or minimally prolonged, and thrombosis is more common than bleeding, at least in noncritically ill patients. Bleeding is uncommon but may be a significant problem in critically ill patients, including those who may develop a consumptive coagulopathy with frank disseminated intravascular coagulation and those on extracorporeal membrane oxygenation. Blood product support to correct coagulopathy is reserved for bleeding patients or those requiring invasive procedures. Current recommendations suggest that all hospitalized patients should receive at least a prophylactic dose of anticoagulation. Results from a multiplatform randomized clinical trial suggest that therapeutically dosed anticoagulation may improve outcomes, including the need for organ support and mortality in moderately ill patients but not in those requiring critical care. The results of ongoing trials evaluating the impact of different antithrombotic strategies (therapeutic agents and intensity) on COVID-19 outcomes are eagerly awaited and are expected to have important implications for patient management. We also discuss COVID-19 vaccine-associated cytopenias and bleeding as well as vaccine-induced thrombotic thrombocytopenia, in which thrombosis is associated with thrombocytopenia, elevated D-dimer, and, frequently, hypofibrinogenemia.

COVID-19 and thrombosis: searching for evidence. Early in the pandemic, COVID-19-related increases in rates of venous and arterial thromboembolism were seen. Many observational studies suggested a benefit of prophylactic anticoagulation for hospitalized patients using various dosing strategies. Randomized trials were initiated to compare the efficacy of these different options in acutely ill and critically ill inpatients as the concept of immune-mediated inflammatory microthrombosis emerged. We present a case-based review of how we approach thromboembolic prophylaxis in COVID-19 and briefly discuss the epidemiology, the pathophysiology, and the rare occurrence of vaccine-induced thrombotic thrombocytopenia.

Clots in unusual places: lots of stress, limited data, critical decisions. Although much less common than deep vein thrombosis of the lower extremities or lungs, clots in unusual locations, including the splanchnic, cerebral, retinal, upper-extremity, and renal locations, present with significant morbidity and mortality. In the last 2 decades, treatment of clots in these unusual locations is primarily managed medically, with interventional and surgical approaches reserved for more severe or refractory cases. The hematologist is well positioned to provide consultation to organ-specific specialties (ie, neurosurgery, hepatology, ophthalmology), especially because acquired and congenital hypercoagulability plays a major role, and anticoagulation is often the primary treatment. Historically, treatment has been based on expert opinion, but systematic reviews and meta-analyses have recently been published. Various societies have produced guidelines for the treatment of clots in unusual locations; however, randomized clinical trial data remain scarce. In the last few years, increasing data have emerged concerning the efficacy of the direct oral anticoagulants in treating clots in unusual locations. Cases have recently been described highlighting atypical thrombosis associated with COVID-19 infection as well as with the ChAdOx1 nCoV-19 (AstraZeneca) vaccine and Johnson and Johnson's Janssen Ad26.COV2.S vaccine. This article reviews clots in unusual locations with an emphasis on the splanchnic (mesenteric, portal, splenic, hepatic) and cerebral circulation. Through a case-based approach, key questions are posed, and data are presented to help guide diagnosis and treatment.

Sub-acute hypersensitive reaction to botulinum toxin type A following Covid-19 vaccination: Case report and literature review. RATIONALE: Botulinum toxin type A (BTA) is one of the most widely used injectable agents in cosmetic surgery. Corona virus disease 2019 (Covid-19) infection and vaccination, which can induce specific and nonspecific activation of the immune system, has been reported to induce delayed inflammatory reactions to previously injected hyaluronic acid fillers. However, there are no reports about the interaction between BTA and Covid-19. We aimed to report 2 sub-acute cases of allergic reactions to BTA in facial cosmesis following the Covid-19 vaccination. PATIENT CONCERN: A 35-year-old and a 34-year-old female who has several previous BTA injections without any adverse effects experienced facial swelling, flu-like symptoms after BTA treatment following the Covid-19 vaccination. DIAGNOSE: According to the typical clinical manifestation, a hypersensitive reaction to BTA was considered. INTERVENTION: Corticosteroids and antihistamine were administered empirically. OUTCOMES: The flu-like symptoms recovered over the next day, but the facial swelling gradually faded within 1 to 2 weeks. LESSONS: A literature review was also conducted to summarize the hypersensitive actions to cosmesis related to Covid-19. We recommend BTA injection be administered at least 2 to 3â€Šmonths after Covid-19 vaccination.

Vulvar aphthous ulcer after COVID-19 vaccination. Vulvar aphthous ulcer, also known as acute genital ulceration or Lipschutz ulcers, is an uncommon, non-sexually acquired condition characterized by sudden onset ulcerations of the vulva in young girls and women. It is thought to represent an immunologic reaction to an infection or other source of inflammation and is commonly preceded by prodromal symptoms including fever, chills, fatigue, and malaise. During the COVID-19 pandemic, vulvar aphthous ulcer associated with COVID-19 infection has been reported. Here, we report a case of vulvar aphthous ulcer in response to COVID-19 vaccination.

Comment on "A case of acute necrotising pancreatitis following the second dose of Pfizer-BioNTech COVID-19 mRNA vaccine".

Development of Graves' Disease After SARS-CoV-2 mRNA Vaccination: A Case Report and Literature Review. Background: Mounting evidence has revealed the interrelationship between thyroid and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to explain the thyroid dysfunction and autoimmune thyroid disorders observed after coronavirus disease 2019 (COVID-19). There are limited reports of thyroid dysfunction after SARS-CoV-2 vaccination. Methods: We report a case of a 40-year-old Chinese woman who developed Graves' disease after BNT162b2 mRNA vaccine. A search of PubMed and Embase databases from 1 September 2019 to 31 August 2021 was performed using the following keywords: "COVID," "vaccine," "thyroid," "thyroiditis," and "Graves." Results: A 40-year-old Chinese woman who had 8-year history of hypothyroidism requiring thyroxine replacement. Her anti-thyroid peroxidase and anti-thyroglobulin antibodies were negative at diagnosis. She received her first and second doses of BNT162b2 mRNA vaccine on 6 April and 1 May 2021, respectively. She developed thyrotoxicosis and was diagnosed to have Graves' disease 5 weeks after the second dose of vaccine, with positive thyroid stimulating immunoglobulin level, diffuse goiter with hypervascularity on thyroid ultrasonography and diffusely increased thyroid uptake on technetium thyroid scan. Both anti-thyroid peroxidase and anti-thyroglobulin antibodies became positive. She was treated with carbimazole. Literature search revealed four cases of Graves' disease after SARS-CoV-2 vaccination, all after mRNA vaccines; and nine cases of subacute thyroiditis, after different types of SARS-CoV-2 vaccines. Conclusion: Our case represents the fifth in the literature of Graves' disease after SARS-CoV-2 vaccination, with an unusual presentation on a longstanding history of hypothyroidism. Clinicians should remain vigilant about potential thyroid dysfunction after SARS-CoV-2 vaccination in the current pandemic.

Inflammation and Platelet Activation After COVID-19 Vaccines - Possible Mechanisms Behind Vaccine-Induced Immune Thrombocytopenia and Thrombosis. Introduction of vaccines against COVID-19

has provided the most promising chance to control the world-wide COVID-19 pandemic. However, the adenovirus-vector based Oxford/AstraZeneca [ChAdOx1] (AZ) and Johnson & Johnson [Ad26.CoV2.S] COVID-19 vaccines have been linked with serious thromboembolic events combined with thrombocytopenia, denominated Vaccine-induced Immune Thrombocytopenia and Thrombosis (VITT). The pathogenesis of COVID-19 VITT remain incompletely understood; especially the initial events that trigger platelet activation, platelet factor (PF)4 release, complex formation and PF4 antibody production are puzzling. This is a prospective study investigating the impact of different COVID-19 vaccines on inflammation (CRP, TNF-Î±, IL-1Î², IL-6, IL-8, IL-10), vascular endothelial activation (syndecan-1, thrombomodulin, E-selectin, ICAM-1, ICAM-3, VCAM-1), platelet activation (P-selectin, TGF-Î², sCD40L) and aggregation (Multiplate(Â®) impedance aggregometry), whole blood coagulation (ROTEM(Â®)), thrombin generation and PF4 antibodies to reveal potential differences between AZ and mRNA vaccines in individuals without VITT. The study included 80 (55 AZ and 55 mRNA) vaccinated individuals and 55 non-vaccinated age- and gender matched healthy controls. The main findings where that both vaccines enhanced inflammation and platelet activation, though AZ vaccination induced a more pronounced increase in several inflammatory and platelet activation markers compared to mRNA vaccination and that post-vaccination thrombin generation was higher following AZ vaccination compared to mRNA vaccination. No difference in neither the PF4 antibody level nor the proportion of individuals with positive PF4 antibodies were observed between the vaccine groups. This is the first study to report enhanced inflammation, platelet activation and thrombin generation following AZ vaccination compared to mRNA vaccination in a head-to-head comparison. We speculate that specific components of the AZ adenovirus vector may serve as initial trigger(s) of (hyper)inflammation, platelet activation and thrombin generation, potentially lowering the threshold for a cascade of events that both trigger complications related to excessive inflammation, platelet and coagulation activation as observed in epidemiological studies and promote development of VITT when combined with high-titer functionally active PF4 antibodies.

A Case of Acute Interstitial Nephritis After Two Doses of the BNT162b2 SARS-CoV-2 Vaccine.
BACKGROUND: The development of vaccines to prevent COVID-19 breakouts came with highly positive results but some unexpected side effects. Rare side effects have been seen with the BNT162b2 SARS-CoV 2 vaccine. CASE PRESENTATION: We present the case of a 45-year-old female patient who developed an acute kidney injury needing urgent hemodialysis one week after the second administration of the BNT162b2 SARS-CoV 2 vaccine. She developed a macular rash on her lower limbs and palms as well. A kidney biopsy was performed 10 days after vaccine inoculation, diagnosing acute interstitial nephritis and acute tubular necrosis with cellular casts. The patient was treated with three corticosteroid pulses followed by daily prednisolone. We witnessed clinical improvement 4 days after the initial corticosteroid treatment with progressive recovery of kidney function and hemodialysis withdrawal. After 2 weeks, the patient had recovered her kidney function. Immunophenotyping was performed, diagnosing a hypersensitivity to the vaccine and the polyethylene glycol excipient. CONCLUSION: Patients may develop acute reactions to vaccines. In this case, symptoms seem to correlate significantly with its inoculation and, although this case had a favourable outcome, these side effects must be made aware for clinicians and patients.

Myocarditis after COVID-19 mRNA vaccination: clinical observations and potential mechanisms.
The risk of acute myocarditis associated with COVID-19 mRNA vaccination has garnered intense (social) media attention. However, myocarditis after COVID-19 mRNA vaccination is rare and usually resolves within days or weeks. Moreover, the risks of hospitalization and death associated with COVID-19 are greater than the risk associated with COVID-19 vaccination. Therefore, COVID-19 vaccination should be recommended in adolescents and adults.

Immune-Mediated Thrombotic Thrombocytopenic Purpura after BNT162b2 Vaccine.

Passive Immunity to SARS-CoV-2 at Birth Induced by Vaccination in the First Trimester of Pregnancy. As is well known, the COVID-19 infection is affecting the whole world, causing a serious health, social and economic crisis. The viral infection can cause a mild or severe illness, depending on how effectively the virus is countered by the immune system. In this context, the position of pregnant women remains rather unknown. The case described here reports the immune response in a woman in good health and in her newborn son, having undergone complete vaccination during the first trimester of her pregnancy. We performed a serological assay, measuring IgG antibodies to SARS-CoV-2, by a fully automated solid phase DELFIA (time-resolved fluorescence) immunoassay in a few drops of blood, collected by a finger-prick and spotted on filter paper. The dried blood spot (DBS) sample we used is the same type of sample routinely used in a newborn screening program test. Such a simple and minimally invasive approach allowed us to monitor both the mother and the newborn soon after birth for their anti-SARS-CoV-2 IgG levels. The serological test on the DBS carried out on both mother and newborn revealed the presence of anti-SARS-CoV-2 IgG antibodies up to 7 months after vaccination in the mother, and already at 48 h of life in the newborn.

Unveiling Associations of COVID-19 Vaccine Acceptance, Hesitancy, and Resistance: A Cross-Sectional Community-Based Adult Survey. COVID-19 vaccines are essential to limit and eliminate the infectious disease. This research aims to identify strong vaccination resistance profiles and/or hesitation considering health, psychosocial, and COVID-related variables. A cross-sectional online survey (N = 300) was conducted in the context of strict COVID-related gathering and mobility restrictions (January-March 2021). Data collected were vaccine acceptance, hesitancy and resistance rates, general psychosocial status, and preventive practices and beliefs regarding COVID-19 and its vaccination, among other factors. Logistic regression was applied to a real-world data set and a significant model (Ï‡(2) (7, N = 278) = 124.548, $p < 0.001$) explaining 51.3% (R(2) Nagelkerke) of attitudes towards vaccination was obtained, including the following predictors for acceptance: to have greater confidence in the COVID vaccine security (OR = 0.599) and effectiveness (OR = 0.683), older age (OR = 0.952), to be a healthcare professional (OR = 0.363), to have vulnerable individuals in charge (OR = 0.330), and sustain the belief that the vaccine will end the pandemic situation (OR = 0.346) or not being sure but give some credence to that belief (OR = 0.414). Findings could help understand the rate and determinants of COVID-19 vaccine resistance/hesitancy among a Spanish population sample and facilitate multifaceted interventions to enhance vaccine acceptance.

Retinal Hemorrhage after SARS-CoV-2 Vaccination. To report retinal vein occlusion (RVO) and age-related macular degeneration (AMD)-related submacular hemorrhage developing after administration of SARS-CoV-2 vaccines, a single-center, retrospective observational case series was conducted. Clinical data including fundus photographs and optical coherence tomography (OCT) scans were reviewed. Twenty-three eyes of 21 patients were included with the median age at symptom presentation being 77 years (range: 51-85 years). Twelve eyes (52.2%) had submacular hemorrhage and 11 (47.8%) had RVO. Twelve patients (60.9%) had been vaccinated with the Pfizer vaccine (BNT162b2) and 8 with the AstraZeneca (ChAdOx1) vaccine. Sixteen patients (76.2%) experienced ocular disease exacerbation after the first vaccination and 4 (19.0%) after the second vaccination. The median visual acuity (logarithm of the minimal angle of resolution; logMAR) before symptom development was 0.76 (interquartile range: 0.27-1.23); the median logMAR at symptom presentation was 1.40 (interquartile range 0.52-1.70). The median time between vaccination and symptom exacerbation was 2.0 days (interquartile range: 1.0-3.0 days). Five patients (23.8%) underwent tests for hematological abnormalities, including the presence of anti-PF4 antibodies; all were negative. Further studies with larger patient group for evaluation of effect of SARS-CoV-2 vaccination on retinal hemorrhage are necessary.

Lymphocytopenia and Anti-CD38 Directed Treatment Impact the Serological SARS-CoV-2 Response after Prime Boost Vaccination in Patients with Multiple Myeloma. Even though several SARS-CoV-2 vaccines have shown high effectiveness in the prevention of COVID-19 in healthy subjects, vaccination response in patients with plasma-cell-related disorders (PCD) remains widely unknown. Here, we report on an analysis describing the serological response after prime-boost SARS-CoV-2 vaccination in PCD patients, as compared to a healthy control group, and on possible influencing factors of serological responses. Blood samples were analyzed for the presence of quantitative anti-SARS-CoV-2 spike RBD Ig. A total of 82 patients were included; 67 received mRNA-, eight vector-based and four heterologous vaccinations. SARS-CoV-2 antibody titers (SP-AbT) were assessed in a mean of 23 days (SD Â± 11 days) after the first and in a mean 21 days (SD Â± 9) after prime-boost vaccination. A positive SP-AbT was detected in 31.9% of PCD patients after the first vaccination, and in 88.9% (44/49) after prime-boost vaccination, which was significantly less likely than that in the control group (100%, 78/78) ($p = 0.008$). Furthermore, we have been able to validate our previously suggested threshold of 30 CD19+ B lymphocytes/ÂµL as being predictive for SP-AbT development. Despite anti-CD38 directed therapy, quadruplet treatment, higher age and missing deep remission, which correlated negatively with SP-AbT appearance, SP-AbT formation is possible in a majority of myeloma patients after prime-boost vaccination.

Repeated Cardioembolic Stroke after COVID-19 mRNA Vaccination: A Case Report. OBJECTIVE: There have been no reports suggesting a relationship between the COVID-19 mRNA vaccines that encodes the spike glycoprotein of SARS-CoV-2 and cerebrovascular disease. A case of repeated cardioembolic stroke after vaccination with the BNT162b2 (Pfizer) COVID-19 mRNA vaccine is presented. METHODS: Imaging and laboratory findings, treatment decisions, and the outcome of this case are presented. RESULTS: An 83-year-old Japanese woman developed right hemiplegia and motor aphasia three days after receiving her first dose of the BNT162b2 (Pfizer) COVID-19 mRNA vaccine. She had been taking rivaroxaban for persistent atrial fibrillation for 10 years, but had no symptomatic ischemic strokes. On magnetic resonance imaging (MRI) the left middle cerebral artery (MCA) was occluded. Intravenous recombinant tissue-plasminogen activator (rt-PA) therapy and mechanical thrombectomy were performed, and she recovered almost fully. However, three days after the second dose, she developed left hemiplegia and left hemispatial neglect. MRI showed occlusion of the right MCA. Only mechanical thrombectomy was performed again, but it could not be resumed due to the hard thrombus. DISCUSSION: In this case, it is difficult to exclude a causal relationship between the COVID-19 mRNA vaccine and ischemic stroke. This association needs to be carefully monitored.

Immunogenicity, safety, and reactogenicity of heterologous COVID-19 primary vaccination incorporating mRNA, viral-vector, and protein-adjuvant vaccines in the UK (Com-COV2): a single-blind, randomised, phase 2, non-inferiority trial. BACKGROUND: Given the importance of flexible use of different COVID-19 vaccines within the same schedule to facilitate rapid deployment, we studied mixed priming schedules incorporating an adenoviral-vectored vaccine (ChAdOx1 nCoV-19 [ChAd], AstraZeneca), two mRNA vaccines (BNT162b2 [BNT], Pfizer-BioNTech, and mRNA-1273 [m1273], Moderna) and a nanoparticle vaccine containing SARS-CoV-2 spike glycoprotein and Matrix-M adjuvant (NVX-CoV2373 [NVX], Novavax). METHODS: Com-COV2 is a single-blind, randomised, non-inferiority trial in which adults aged 50 years and older, previously immunised with a single dose of ChAd or BNT in the community, were randomly assigned (in random blocks of three and six) within these cohorts in a 1:1:1 ratio to receive a second dose intramuscularly (8-12 weeks after the first dose) with the homologous vaccine, m1273, or NVX. The primary endpoint was the geometric mean ratio (GMR) of serum SARS-CoV-2 anti-spike IgG concentrations measured by ELISA in heterologous versus homologous schedules at 28 days after the second dose, with a non-inferiority criterion of the

GMR above 0Â·63 for the one-sided 98Â·75% CI. The primary analysis was on the per-protocol population, who were seronegative at baseline. Safety analyses were done for all participants who received a dose of study vaccine. The trial is registered with ISRCTN, number 27841311. FINDINGS: Between April 19 and May 14, 2021, 1072 participants were enrolled at a median of 9Â·4 weeks after receipt of a single dose of ChAd (n=540, 47% female) or BNT (n=532, 40% female). In ChAd-primed participants, geometric mean concentration (GMC) 28 days after a boost of SARS-CoV-2 anti-spike IgG in recipients of ChAd/m1273 (20â€‰114 ELISA laboratory units [ELU]/mL [95% CI 18â€‰160 to 22â€‰279]) and ChAd/NVX (5597 ELU/mL [4756 to 6586]) was non-inferior to that of ChAd/ChAd recipients (1971 ELU/mL [1718 to 2262]) with a GMR of 10Â·2 (one-sided 98Â·75% CI 8Â·4 to âˆž) for ChAd/m1273 and 2Â·8 (2Â·2 to âˆž) for ChAd/NVX, compared with ChAd/ChAd. In BNT-primed participants, non-inferiority was shown for BNT/m1273 (GMC 22â€‰978 ELU/mL [95% CI 20â€‰597 to 25â€‰636]) but not for BNT/NVX (8874 ELU/mL [7391 to 10â€‰654]), compared with BNT/BNT (16â€‰929 ELU/mL [15â€‰025 to 19â€‰075]) with a GMR of 1Â·3 (one-sided 98Â·75% CI 1Â·1 to âˆž) for BNT/m1273 and 0Â·5 (0Â·4 to âˆž) for BNT/NVX, compared with BNT/BNT; however, NVX still induced an 18-fold rise in GMC 28 days after vaccination. There were 15 serious adverse events, none considered related to immunisation. INTERPRETATION: Heterologous second dosing with m1273, but not NVX, increased transient systemic reactogenicity compared with homologous schedules. Multiple vaccines are appropriate to complete primary immunisation following priming with BNT or ChAd, facilitating rapid vaccine deployment globally and supporting recognition of such schedules for vaccine certification. FUNDING: UK Vaccine Task Force, Coalition for Epidemic Preparedness Innovations (CEPI), and National Institute for Health Research. NVX vaccine was supplied for use in the trial by Novavax.

Age-related mortality in 61,993 confirmed COVID-19 cases over three epidemic waves in Aragon, Spain. Implications for vaccination programmes. BACKGROUND: Risk for severe COVID-19 increases with age. Different vaccination strategies are currently being considered, including those aimed at slowing down transmission and those aimed at providing direct protection to those most at risk. METHODS: The objectives of the current study were i) to assess age-related incidence and survival between PCR-diagnosed COVID-19 cases (n = 61,993) in the Autonomous Community of Aragon from March to November 2020, and ii) to characterize age differences regarding the course of the disease in hospitalized patients in a tertiary university hospital. RESULTS: We found a similar incidence of COVID-19 in individuals between 10 and 79 years. Incidence increased in those over 80 years possibly because of the elevated transmission within the nursing homes. We observed a profound disparity among age groups; case fatality rates (CFRs) were near 0 in cases younger than 39 years throughout different waves. In contrast, there was an age-dependent and progressive increase in the CFRs, especially during the first pandemic wave. SARS-CoV-2 infection caused a more severe and rapid progression in older patients. The elderly required faster hospitalization, presented more serious symptoms on admission, and had a worse clinical course. Hospitalized older individuals, even without comorbidities, had an increased mortality risk directly associated with their age. Lastly, the existence of comorbidities dramatically increased the CFRs in the elderly, especially in males. CONCLUSION: The elevated incidence of COVID-19 and the vulnerability of the elderly call for their prioritization in vaccination and targeted prevention measures specifically focused on this aged population.

Inactivated Whole-virus Vaccine Triggers Low Response Against SARS-CoV-2 Infection Among Renal Transplant Patients: Prospective Phase 4 Study Results. BACKGROUND: Anti-severe acute respiratory syndrome coronavirus 2 mRNA vaccines elicit lower humoral responses in solid-organ transplant recipients. This is the first prospective trial investigating the effect of an inactivated whole-virion vaccine in kidney transplant recipients. METHODS: Prospective, single-center, phase 4,

interventional study. Kidney transplant recipients aged 30-69 y with >30 d of transplantation received two 3 Âµg intramuscular doses of CoronaVac 28 d apart and are being followed for 6 mo. Primary outcomes: (1) reactogenicity after first dose; (2) antibody responses 28 d after each dose; and (3) incidence/severity of confirmed coronavirus disease 2019 (COVID-19) and 28-d lethality rate. For this analysis, clinical effectiveness was assessed for 3 mo, starting 15 d after the second dose, and compared with 3-mo period before vaccination. RESULTS: Of the 3371 individuals who received the first dose, 99% completed vaccination schedule. Mild/local adverse reactions were reported by 33% of the patients. In the immunogenicity cohort (n = 942), the proportion of patients with IgG antibodies to severe acute respiratory syndrome coronavirus 2 increased from 15.2% after first dose to 43% after second dose. Increase in antibody values after second dose was associated with higher proportion of patients with detected neutralizing antibodies. A significant reduction in the incidence of COVID-19 was observed (6.4% versus 4.2%; P < 0.0001), although the 28-d lethality rate remained unchanged (25% versus 22%; P = 0.534). In 45 patients from the immunogenicity cohort who developed COVID-19, all the 6 deaths occurred among those without antibody response (n = 22; 49%). CONCLUSIONS: CoronaVac vaccine was associated with low reactogenicity, low immunogenicity but reduced incidence of COVID-19 among kidney transplant recipients. The lack of reduction in lethality rates is perhaps associated with the low percentage of patients developing humoral response after the second dose.

Pityriasis rosea like eruption: A dermatological manifestation of Coronavac-COVID-19 vaccine.

Drug-induced lichenoid exanthema by a vaccine against COVID-19 (Vaxzevria). A 66-year-old white female presented with a generalized, erythematous, and itchy eruption for 3 days after. She reported having fever on the first day of eruption, complaints of asthenia, and anorexia with no other systemic symptoms. She received her first dose of Vaxzevria (AstraZeneca, Cambridge, UK) against COVID-19 three weeks prior. The eruption started on the right arm at the vaccine injection site and then spread progressively throughout the entire body. We noticed multiform erythema- like patches with three or four concentric circles with different shades of redness. Anatomopathological analysis indicated a lichenoid histological pattern compatible with adverse event of vaccine. Degressive general corticotherapy was prescribed with an improvement of the symptomatology and complete healing in ten days. Physicians should be aware if this rare adverse event. Drug-induced lichenoid exanthema is considered a non-severe reaction and does not contraindicate the readministration of essential drugs. In this case, the patient refused the second injection of Vaxzevria.

Humoral immune response and lymphocyte levels after complete vaccination against COVID-19 in a cohort of multiple sclerosis patients treated with cladribine tablets. BACKGROUND: Patients with multiple sclerosis (MS) receiving immunomodulatory drugs were excluded from clinical trials on COVID-19 vaccines. Therefore, data regarding the efficacy of COVID-19 vaccines to induce humoral immunity in MS patients treated with B- and T-cell depleting agents is urgently warranted. Cladribine tablets are a high-efficacy disease-modifying treatment that exerts its therapeutic effect via sustained but transient lymphocyte depletion. AIM: We report humoral responses in a German cohort of MS patients treated with cladribine tablets. METHODS: This retrospective analysis included patients â‰¥18Â years who were treated with cladribine tablets for relapsing MS in the first or second year and were fully vaccinated against COVID-19. Two weeks after the second vaccination at the earliest, blood samples were obtained for the assessment of anti-SARS-CoV-2 IgG antibodies, lymphocyte counts, B-cells, CD4(+) T-cells, and CD8(+) T-cells. Anti-SARS-CoV-2 IgG antibodies were quantified with the LIAISON(Â®) SARS-CoV-2 TrimericS IgG assay. Positivity was defined at a cutoff value of 33.8 BAU/mL. RESULTS: In total, 38 patients (73.7% female, aged 23-66Â years) were included in the analysis. Ten patients (26.3%) were treatment-naÃ¯ve before initiating treatment with cladribine tablets. Most patients (84.2%) received mRNA vaccines. The time between the last dose of cladribine

tablets and vaccination ranged between 2 and 96Â weeks. Six patients (15.8%) were vaccinated within 4Â weeks of their last cladribine dose. All patients achieved positive anti-SARS-CoV-2 IgG antibody levels. Humoral immune response was independent of age, time of vaccination in relation to the last cladribine dose, lymphocyte counts as well as B- and T-cell counts. CONCLUSIONS: Treatment with cladribine tablets did not impair humoral response to COVID-19 vaccination. Time since last cladribine dose, age, prior therapy, lymphocyte count as well as B- and T-cell counts had no effect on seropositivity of anti-SARS-CoV-2 IgG antibodies.

Allergic reactions to the Ad26.COV2.S vaccine in South Africa. BACKGROUND: The Janssen-Ad26.COV2.S vaccine is authorized for use in several countries, with more than 30 million doses administered. Mild and severe allergic adverse events following immunization (AEFI) have been reported. OBJECTIVE: We sought to detail allergic reactions reported during the Sisonke phase 3B study in South Africa. METHODS: A single dose of the Ad26.COV2.S vaccine was administered to 4,77,234 South African health care workers between February 17 and May 17, 2021. Monitoring of adverse events used a combination of passive reporting and active case finding. Telephonic contact was attempted for all adverse events reported as "allergy." Anaphylaxis adjudication was performed using the Brighton Collaboration and National Institute of Allergy and Infectious Disease case definitions. RESULTS: Only 251 (0.052%) patients reported any allergic-type reaction (<1 in 2000), with 4 cases of adjudicated anaphylaxis (Brighton Collaboration level 1, nÂ = 3) (prevalence of 8.4 per million doses). All anaphylaxis cases had a previous history of drug or vaccine-associated anaphylaxis. Cutaneous allergic reactions were the commonest nonanaphylatic reactions and included self-limiting, transient/localized rashes requiring no health care contact (nÂ = 92) or isolated urticaria and/or angioedema (nÂ = 70; median onset, 48 [interquartile range, 11.5-120] hours postvaccination) that necessitated health care contact (81%), antihistamine (63%), and/or systemic/topical corticosteroid (16%). All immediate (including adjudicated anaphylaxis) and most delayed AEFI (65 of 69) cases resolved completely. CONCLUSIONS: Allergic AEFI are rare following a single dose of Ad26.COV, with complete resolution in all cases of anaphylaxis. Although rare, isolated, delayed-onset urticaria and/or angioedema was the commonest allergic AEFI requiring treatment, with nearly half occurring in participants without known atopic disease.

BNT162b2 Vaccine Booster and Mortality Due to Covid-19. BACKGROUND: The emergence of the B.1.617.2 (delta) variant of severe acute respiratory syndrome coronavirus 2 and the reduced effectiveness over time of the BNT162b2 vaccine (Pfizer-BioNTech) led to a resurgence of coronavirus disease 2019 (Covid-19) cases in populations that had been vaccinated early. On July 30, 2021, the Israeli Ministry of Health approved the use of a third dose of BNT162b2 (booster) to cope with this resurgence. Evidence regarding the effectiveness of the booster in lowering mortality due to Covid-19 is still needed. METHODS: We obtained data for all members of Clalit Health Services who were 50 years of age or older at the start of the study and had received two doses of BNT162b2 at least 5 months earlier. The mortality due to Covid-19 among participants who received the booster during the study period (booster group) was compared with that among participants who did not receive the booster (nonbooster group). A Cox proportional-hazards regression model with time-dependent covariates was used to estimate the association of booster status with death due to Covid-19, with adjustment for sociodemographic factors and coexisting conditions. RESULTS: A total of 843,208 participants met the eligibility criteria, of whom 758,118 (90%) received the booster during the 54-day study period. Death due to Covid-19 occurred in 65 participants in the booster group (0.16 per 100,000 persons per day) and in 137 participants in the nonbooster group (2.98 per 100,000 persons per day). The adjusted hazard ratio for death due to Covid-19 in the booster group, as compared with the nonbooster group, was 0.10 (95% confidence interval, 0.07 to 0.14; P<0.001). CONCLUSIONS:

Participants who received a booster at least 5 months after a second dose of BNT162b2 had 90% lower mortality due to Covid-19 than participants who did not receive a booster.
Comment on: Risk of giant cell arteritis and polymyalgia rheumatica following COVID-19 vaccination: a global pharmacovigilance study.
Papular acrodermatitis of childhood-like eruption triggered by SARS-CoV-2 vaccination: Report of two cases.
Clinical Presentation and Outcomes of Myocarditis Post mRNA Vaccination: A Meta-Analysis and Systematic Review. BACKGROUND: Myocarditis is being increasingly reported as a potential complication of both Pfizer-BioNTech and Moderna vaccines for COVID-19. One thousand five hundred and twenty-two cases were reported as of September 02, 2021, as per CDC's (CentersÂ for Disease Control) vaccine adverse event reporting system. Most of the published data is available in the form of case reports and series. There is a need to compile the demographic data, clinical features, and outcomes in these patients.Â Methods: A systematic search was conducted in PubMed, Embase, Web of science, and google scholar for published literature between January 01, 2020, and July 17, 2021. Individual data of 69 patients were pooled from 25 qualifying case reports and case series. RESULTS: The median age of onset was 21 years. 92.7% of the patients were male. 76.8% of patients received the Pfizer-BioNTech vaccine, and 23.2% received the Moderna vaccine. 88.5% developed symptoms after the second dose. Patients were admitted to the hospital a median of three days post-vaccination. All the patients had chest pain and elevated troponin. The myocarditis was confirmed on cardiac MRI in 87% of the patients. Most of the patients had late gadolinium enhancement on MRI. The median length of stay was four days. All the reported patients recovered and were discharged. CONCLUSION: Post-mRNA vaccination myocarditis is seen predominantly in young males within a few days after their second dose of vaccination. The pathophysiology of myocarditis is not well known. The prognosis is good as all the reported patients recovered. The presence of late gadolinium enhancement on cardiac MRI indicated myocardial necrosis/fibrosis and further studies are needed to establish the long-term prognosis of the condition.
Acute myocarditis associated with COVID-19 vaccination: A case report. Recently, new vaccine platforms-including mRNA vaccines for coronavirus disease 2019 (COVID-19) have been given emergency use authorization in Japan. Here, we present a rare case of myocarditis following a COVID-19 vaccine. In this case, myocarditis was confirmed by cardiac magnetic resonance imaging, endomyocardial biopsy, and troponin levels. The degree of myocardial inflammation in the endomyocardial biopsy samples was mild and the patient's clinical course was not severe. Although the pathology of myocarditis in this case was mild, further investigation would be needed. <Learning objective: Vaccination for coronavirus disease 2019 is advancing worldwide, but post-vaccination myocarditis is getting attention as a rare side effect. Although the myocarditis in this case was mild, the pathogenesis of the disease is unclear and needs to be thoroughly investigated in the vaccination.>.
SARS-CoV-2 breakthrough infections in vaccinated individuals: measurement, causes and impact. Breakthrough infections with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in fully vaccinated individuals are receiving intense scrutiny because of their importance in determining how long restrictions to control virus transmission will need to remain in place in highly vaccinated populations as well as in determining the need for additional vaccine doses or changes to the vaccine formulations and/or dosing intervals. Measurement of breakthrough infections is challenging outside of randomized, placebo-controlled, double-blind field trials. However, laboratory and observational studies are necessary to understand the impact of waning immunity, viral variants and other determinants of changing vaccine effectiveness against various levels of coronavirus disease 2019 (COVID-19) severity. Here, we describe the approaches being used to measure vaccine effectiveness

and provide a synthesis of the burgeoning literature on the determinants of vaccine effectiveness and breakthrough rates. We argue that, rather than trying to tease apart the contributions of factors such as age, viral variants and time since vaccination, the rates of breakthrough infection are best seen as a consequence of the level of immunity at any moment in an individual, the variant to which that individual is exposed and the severity of disease being considered. We also address key open questions concerning the transition to endemicity, the potential need for altered vaccine formulations to track viral variants, the need to identify immune correlates of protection, and the public health challenges of using various tools to counter breakthrough infections, including boosters in an era of global vaccine shortages.
Risk and prognosis of SARS-CoV-2 infection and vaccination against SARS-CoV-2 in rheumatic and musculoskeletal diseases: a systematic literature review to inform EULAR recommendations. OBJECTIVES: Perform a systematic literature review (SLR) on risk and prognosis of SARS-CoV-2 infection and vaccination against SARS-CoV-2 in patients with rheumatic and musculoskeletal diseases (RMDs). METHODS: Literature was searched up to 31 May 2021, including (randomised) controlled trials and observational studies with patients with RMD. Pending quality assessment, data extraction was performed and risk of bias (RoB) was assessed. Quality assessment required provision of (1) an appropriate COVID-19 case definition, and (2a) a base incidence (for incidence data) or (2b) a comparator, >10 cases with the outcome and risk estimates minimally adjusted for age, sex and comorbidities (for risk factor data). RESULTS: Of 5165 records, 208 were included, of which 90 passed quality assessment and data were extracted for incidence (n=42), risk factor (n=42) or vaccination (n=14). Most studies had unclear/high RoB. Generally, patients with RMDs do not face more risk of contracting SARS-CoV-2 (n=26 studies) or worse prognosis of COVID-19 (n=14) than individuals without RMDs. No consistent differences in risk of developing (severe) COVID-19 were found between different RMDs (n=19). Disease activity is associated with worse COVID-19 prognosis (n=2), possibly explaining the increased risk seen for glucocorticoid use (n=13). Rituximab is associated with worse COVID-19 prognosis (n=7) and possibly Janus kinase inhibitors (n=3). Vaccination is generally immunogenic, though antibody responses are lower than in controls. Vaccine immunogenicity is negatively associated with older age, rituximab and mycophenolate. CONCLUSION: This SLR informed the July 2021 update of the European Alliance of Associations for Rheumatology recommendations for the management of RMDs in the context of SARS-CoV-2.
Herpes zoster reactivation after mRNA-1273 vaccination in patients with rheumatic diseases.
Post-COVID-19 vaccination occurrence of splenic infarction due to arterial thrombosis. We present the case of an 82-year-old woman admitted to a regional emergency general surgery centre with severe left upper quadrant abdominal pain and tenderness within 21 days of receiving the first dose of the ChAdOx1 nCov-19 vaccine (Vaxzevria, AstraZeneca). Following further investigation through CT imaging, a thrombus was discovered in the patient's splenic artery resulting in a large splenic infarct. Splenic infarcts are rare and it is important to note the association between time of administration of the first dose of vaccine and the occurrence of thromboembolic complications in the noted absence of other risk factors for this condition. We hypothesise a link between Vaxzevria vaccine injection and a rare form of thromboembolic complication: thrombosis of the splenic artery.
SARS-CoV-2 serology among people with multiple sclerosis on disease-modifying therapies after BBIBP-CorV (Sinopharm) inactivated virus vaccination: Same story, different vaccine. BACKGROUND: Various studies indicated blunted humoral responses to COVID-19 mRNA and viral vector vaccines among people with multiple sclerosis (pwMS) on sphingosine 1-phosphate receptor (S1PR) modulators and anti-CD20 therapies (aCD20); however, limited evidence was found regarding SARS-CoV-2 serology after inactivated virus vaccination. OBJECTIVE: To provide evidence regarding humoral response to COVID-19 inactivated virus vaccination among pwMS on disease-modifying

therapies (DMTs). METHODS: A cohort study was carried out in Isfahan, Iran, enrolling DMT-exposed pwMS and unexposed (UX) healthy participants. Post-vaccination anti-SARS-CoV-2 Spike IgG serology testing was carried out among the participants and compared between participants based on their DMT exposure, using proper statistical tests. A multivariable logistic regression model was used to control for confounding. Association between the second vaccine dose-to-phlebotomy (vac2phleb) and the humoral response was investigated in each DMT-exposed cohort, using linear regression. Among the aCD20 cohort, the association of the last aCD20 infusion-to-first vaccine dose period with serostatus was investigated using an unpaired t-test. RESULTS: After enrolling 358 participants (144 pwMS and 214 healthy), blunted humoral responses were only observed in fingolimod (Log(10) mean diff. [SE]: 0.72 [0.18], PÂ =Â 0.001) and aCD20 (Log(10) mean diff. [SE]: 0.75 [0.15], P < 0.001) cohorts compared to the UX cohort. Multivariable analysis confirmed the results. The study did not achieve enough statistical power to detect a significant association between the vac2phleb period and humoral responses. The last aCD20 infusion to first vaccination dose period was longer in the seroconverted pwMS on aCD20 (mean diff. [SE]: 8.43 weeks [2.57], PÂ =Â 0.005). CONCLUSION: The results of this study mirrored the results of previous studies among mRNA- or viral vector-vaccinated pwMS on DMTs. Therefore, it can be concluded that mode of action contributes less than timing, to the efficiency of vaccination strategies among pwMS on DMTs - especially the ones on S1PR modulators and aCD20. Meanwhile, the mentioned pwMS should be advised to receive early boosters and remain vigilant until further data becomes available and more efficient vaccination strategies are crafted.

Corrigendum to: Myopericarditis following SARS-CoV-2 mRNA vaccine: the role of cardiac biomarkers and multimodality imaging.

Comment on: Risk of giant cell arteritis and polymyalgia rheumatica following COVID-19 vaccination: a global pharmacovigilance study: reply.

Catastrophic antiphospholipid syndrome triggered by mRNA COVID-19 vaccine.

Reinfection with new variants of SARS-CoV-2 after natural infection: a prospective observational cohort in 13 care homes in England. BACKGROUND: Understanding the duration of protection and risk of reinfection after natural infection is crucial to planning COVID-19 vaccination for at-risk groups, including care home residents, particularly with the emergence of more transmissible variants. We report on the duration, neutralising activity, and protection against the alpha variant of previous SARS-CoV-2 infection in care home residents and staff infected more than 6 months previously. METHODS: We did this prospective observational cohort surveillance in 13 care homes in Greater London, England. All staff and residents were included. Staff and residents had regular nose and throat screening for SARS-CoV-2 by RT-PCR according to national guidelines, with ad hoc testing of symptomatic individuals. From January, 2021, antigen lateral flow devices were also used, but positive tests still required RT-PCR confirmation. Staff members took the swab samples for themselves and the residents. The primary outcome was SARS-CoV-2 RT-PCR positive primary infection or reinfection in previously infected individuals, as determined by previous serological testing and screening or diagnostic RT-PCR results. Poisson regression and Cox proportional hazards models were used to estimate protective effectiveness of previous exposure. SARS-CoV-2 spike, nucleoprotein, and neutralising antibodies were assessed at multiple timepoints as part of the longitudinal follow-up. FINDINGS: Between April 10 and Aug 3, 2020, we recruited and tested 1625 individuals (933 staff and 692 residents). 248 participants were lost to follow-up (123 staff and 125 residents) and 1377 participants were included in the follow-up period to Jan 31, 2021 (810 staff and 567 residents). There were 23 reinfections (ten confirmed, eight probable, five possible) in 656 previously infected individuals (366 staff and 290 residents), compared with 165 primary infections in 721 susceptible individuals (444 staff and 277 residents). Those with confirmed reinfections had no or

low neutralising antibody concentration before reinfection, with boosting of titres after reinfection. Kinetics of binding and neutralising antibodies were similar in older residents and younger staff. INTERPRETATION: SARS-CoV-2 reinfections were rare in older residents and younger staff. Protection from SARS-CoV-2 was sustained for longer than 9 months, including against the alpha variant. Reinfection was associated with no or low neutralising antibody before reinfection, but significant boosting occurred on reinfection. FUNDING: Public Health England.

Disentangling post-vaccination symptoms from early COVID-19. BACKGROUND: Identifying and testing individuals likely to have SARS-CoV-2 is critical for infection control, including post-vaccination. Vaccination is a major public health strategy to reduce SARS-CoV-2 infection globally. Some individuals experience systemic symptoms post-vaccination, which overlap with COVID-19 symptoms. This study compared early post-vaccination symptoms in individuals who subsequently tested positive or negative for SARS-CoV-2, using data from the COVID Symptom Study (CSS) app. METHODS: We conducted a prospective observational study in 1,072,313 UK CSS participants who were asymptomatic when vaccinated with Pfizer-BioNTech mRNA vaccine (BNT162b2) or Oxford-AstraZeneca adenovirus-vectored vaccine (ChAdOx1 nCoV-19) between 8 December 2020 and 17 May 2021, who subsequently reported symptoms within seven days (N=362,770) (other than local symptoms at injection site) and were tested for SARS-CoV-2 (N=14,842), aiming to differentiate vaccination side-effects per se from superimposed SARS-CoV-2 infection. The post-vaccination symptoms and SARS-CoV-2 test results were contemporaneously logged by participants. Demographic and clinical information (including comorbidities) were recorded. Symptom profiles in individuals testing positive were compared with a 1:1 matched population testing negative, including using machine learning and multiple models considering UK testing criteria. FINDINGS: Differentiating post-vaccination side-effects alone from early COVID-19 was challenging, with a sensitivity in identification of individuals testing positive of 0.6 at best. Most of these individuals did not have fever, persistent cough, or anosmia/dysosmia, requisite symptoms for accessing UK testing; and many only had systemic symptoms commonly seen post-vaccination in individuals negative for SARS-CoV-2 (headache, myalgia, and fatigue). INTERPRETATION: Post-vaccination symptoms per se cannot be differentiated from COVID-19 with clinical robustness, either using symptom profiles or machine-derived models. Individuals presenting with systemic symptoms post-vaccination should be tested for SARS-CoV-2 or quarantining, to prevent community spread. FUNDING: UK Government Department of Health and Social Care,Â WellcomeÂ Trust, UK Engineering and Physical Sciences Research Council, UK National Institute for Health Research, UK Medical Research Council and British Heart Foundation, Chronic Disease Research Foundation, ZoeÂ Limited.

A Survey on the Side Effects of Pfizer/BioNTech COVID-19 Vaccine Among Vaccinated Adults in Saudi Arabia. BACKGROUND: Pfizer-BioNTech vaccine was the first of all coronavirus disease (COVID) vaccines to be used in Saudi Arabia. There have been over 17 million doses already administered to the general public in order to successfully reach herd immunity. OBJECTIVE: The study aimed to explore the side effects of the Pfizer-BioNTech vaccine. MATERIALS AND METHODS: This is a cross-sectional study comprising a sample of 386 participating adults of different age groups and genders. A validated modified questionnaire was distributed as a Google form to residents of the kingdom via social networking sites from February to March 2021. The questionnaire included questions regarding participants' socio-demographic details, vaccination details, and symptom analyses items. RESULTS: The most common to least reported symptoms were local pain (79.3%), fatigue (42%), muscle pain (39.1%), local swelling (27.7%), joint pain (23.1%), headache (21.8%), fever (21.0%), chills (15.5%), local redness (14.8%), nausea (7.3%), with no reports of anaphylaxis, facial paralysis or syncope. There were more side effects after the second dose than the first ($p<0.001$). Significant predictors of a higher number of side effects after both doses of the vaccine were the female gender (($p<0.001$)) and

the presence of allergies (p=0.044). CONCLUSION: Pfizer/BioNTech vaccination was quite safe with no reported anaphylaxis or serious events. The most common reported side effects were local pain and fatigue. Symptoms began within 24 hours and were mild to moderate in nature with a regressive course, especially after analgesics. More side effects were experienced after the second dose than the first. The significant predictors of side effects were the female gender and a history of allergies.

Metabolic disorders, COVID-19 and vaccine-breakthrough infections. Obesity and impaired metabolic health are important risk factors for severe COVID-19. Novel data indicate that these risk factors might also promote vaccine-breakthrough SARS-CoV-2 infections in fully vaccinated people. Here, these relationships are discussed and post-acute sequelae of COVID-19 that are related to obesity and impaired metabolic health are addressed.

 Novel data reveal a causal role for increased BMI in the development of severe COVID-19 (ref.). Solid scientific evidence indicates that there is a linearly increased risk of hospital admission or death due to COVID-19 at a BMI >23â€‰kg/m(2), particularly in younger people. Novel data indicate not only that hyperglycaemia and insulin resistance might drive immunosenescence, but also that hyperinsulinaemia might promote increased risk of SARS-CoV-2 infection and complicated COVID-19 (ref.). Studies indicate that obesity and impaired metabolic health might increase the risk of vaccine-breakthrough SARS-CoV-2 infections(â€“).

(18)F-Fluciclovine-Avid Axillary Lymph Nodes After COVID-19 Vaccination on PET/CT for Suspected Recurrence of Prostate Cancer. Abnormally increased (18)F-FDG avidity of axillary lymph nodes has become a frequent diagnostic dilemma on PET/CT in the current climate of global vaccinations directed against severe acute respiratory syndrome coronavirus 2. This avidity is due to the inflammatory response evoked by vaccines and the nonspecific nature of (18)F-FDG uptake, which is increased in both malignant and inflammatory processes. Similarly, (18)F-fluciclovine, an amino acid analog indicated for the assessment of biochemical recurrence of prostate cancer, may also demonstrate nonspecific inflammatory uptake. We report a case of (18)F-fluciclovine PET/CT obtained for concern about prostate cancer. In this case, isolated avid lymph nodes were seen in the left axilla. A screening questionnaire revealed that the patient had recently received the second dose of the Pfizer-BioNTech coronavirus disease 2019 vaccine in his left shoulder, and hence, the uptake was determined to be reactive.

COVID-19 Vaccine Responses in Patients With Plasma Cell Dyscrasias After Complete Vaccination. INTRODUCTION: Due to functional hypogammaglobulinemia, patients with multiple myeloma are at increased risk for infection and generally have poorer responses to vaccines. In this study, we examined antibody responses after complete COVID-19 vaccination in patients with plasma cell dyscrasias, most of whom were receiving treatment. PATIENTS AND METHODS: Real world study of consecutive patients with multiple myeloma and other plasma cell dyscrasias (PCD) were evaluated after complete vaccination with either the 2-shot mRNA vaccines from BioNTech and Moderna or the 1-shot adenoviral vector vaccine from Johnson & Johnson (J&J). Patients received vaccines 1-4 months before antibody testing without controlling for the type of vaccine or the timing of drug therapy. Patients with a clinical history or antibody evidence of prior infection were excluded. Antinucleocapsid and quantitative anti-spike antibody levels were measured with the Roche Elecys assay. RESULTS: Ninety-five percent of patients had detectable antibody responses. Multivariate analysis showed that higher age, ongoing anti-CD38 monoclonal antibody therapy and the J&J vaccine negatively affected quantitative response. A small number of ineffectively vaccinated patients receiving IVIG subsequently had detectable nucleocapsid and spike antibodies confirming the presence of the latter in currently administered IVIG. CONCLUSIONS: Nearly all PCD had detectable anti-spike antibodies after vaccination but age, anti-CD38 monoclonal antibody therapy, and the single-shot J&J vaccine negatively affected responses. In patients who received the J&J vaccine,

second doses or heterologous mRNA vaccines should be tested. Quantitative antibody testing might make future management more rational, particularly in patients with poor responses.

A case of sensory ataxic Guillain-BarrÃ© syndrome with immunoglobulin G anti-GM1 antibodies following the first dose of mRNA COVID-19 vaccine BNT162b2 (Pfizer).

COVID-19 vaccine-related presumed allergic reactions and second dose administration by using a two-step graded protocol. Background: Acute allergic reactions to messenger RNA (mRNA) vaccines are rare but may limit public health immunization efforts. Objectives: To characterize suspected allergic reactions to the first dose of coronavirus disease 2019 (COVID-19) mRNA vaccine and to assess the safety and utility of a two-step graded-dose protocol for the second dose of the Pfizer-BioNTech vaccine in patients with a history of low suspicion of anaphylaxis to their first dose. Methods: This was a retrospective evaluation of referrals to the allergy and immunology clinic for a presumed allergic reaction to the first dose of the COVID-19 mRNA vaccine (Pfizer-BioNTech or Moderna) between December 17, 2020, and February 28, 2021. Recommendations for the second dose and outcomes were evaluated by trained board-certified allergists. Results: Seventy-seven patients presented with a Pfizer-BioNTech reaction (56 [72.7%]) or with a Moderna reaction (21 [27.3%]). Most patients (69.7%) had symptom onset within 4 hours. Most commonly reported symptoms were cutaneous (51.9%), cardiovascular (48.1%), and respiratory (33.8%) symptoms. Recommendations included to proceed with the single dose (70.1%), two-step graded dose (19.5%), or deferral (10.4%). Twelve of 15 patients completed the second dose with a graded-dose protocol. Of these patients, five reported at least one or more similar symptoms as experienced with their first dose. Conclusion: Of the patients with presumed allergic reactions to their first dose of COVID-19 mRNA vaccine, most were able to safely receive the second dose. For those with a low suspicion of anaphylaxis, the two-step graded protocol with the Pfizer-BioNTech vaccine was well tolerated. A graded-dose protocol could be an effective strategy for second-dose vaccination in those who may otherwise defer the second dose.

A case of trigeminal neuralgia developing after a COVID-19 vaccination. In this case, we report a patient who developed acute trigeminal neuritis after using a Pfizer-BioNtech vaccination against SARS-CoV-2. The patient was completely recovered with steroid treatment.

Seasonal influenza vaccination coverage and its association with COVID-19 in Saudi Arabia. Coronavirus Disease 2019 (COVID-19) pandemic is still on-going worldwide. The available information regarding the seasonal influenza vaccine (SIV) coverage during the COVID-19 pandemic and its impact on SARS-CoV-2 spread are limited. Moreover, it is argued that SIV may or may not lessen the COVID-19 severity. No previous studies have been revealed SIV coverage among COVID-19 patients and its association with COVID-19 spread and severity, especially in Saudi Arabia. Hence, this study aimed to estimate the influenza vaccine uptake in confirmed COVID-19 patients and investigate its impact on COVID-19 spread and severity. Accordingly, 1734 COVID-19 confirmed patients were included from three government hospitals in Saudi Arabia (SA). The data were collected electronically through a newly formed, self-administrated questionnaire. Among those patients, 335 were covered with SIV (19.31%), and the coverage rate of females and males was 23.4% and 15.8%, respectively. Severe COVID-19 cases were less in vaccinated patients than in non-vaccinated (2.69% vs. 3.5%, respectively). Additionally, the results showed a significant decrease in getting infected by SARS-CoV-2 after receiving SIV (PÂ =Â 0.022). Even with the tremendous efforts to promote SIV uptake among the general population and high-risk groups, the SIV coverage in SA is not optimal yet. Nevertheless, there is a significant decrease in the probability of getting infected with SARS-CoV-2 after receiving SIV. Such findings with the continuous progression of the COVID-19 pandemic call for a novel approach regarding vaccination policies to increase SIV and COVID-19 vaccine uptake.

New onset and exacerbation of psoriasis after COVID-19 vaccination.

Beware of the ambiguous enemy of multisystem inflammatory syndrome in adult (MIS-A) following Covid-19 infection or vaccination. Multisystem Inflammatory Syndrome is a rare and novel clinical presentation described during the evolving COVID-19 pandemic. The condition is usually presenting as a sepsis-like syndrome leading to secondary multi-organ dysfunction post-COVID-19 infection. Although the syndrome has been mainly described in children, rare adults' form has been similarly described. We are describing a 37-year-old female patient presented with fever and neck pain after 1Â month of a mild SARS-CoV-2 infection course and 10Â days post her second COVID-19 vaccine. Examination demonstrated fever, hypotension, and hypoxemia, in addition to multiple tender cervical lymph nodes. Initial laboratory workup showed evidence of significant inflammation with raised markers, including C-reactive protein, ferritin, and interleukin-6. Extensive evaluation to rule out active infection was done, and all return negative, including repeat SARS-CoV-2 test. Furthermore, cardiac evaluation showed moderately reduced systolic ventricular function. Despite all negative test and supportive measures, the patient continued to deteriorate requiring critical care admission for ionotropic support, non-invasive ventilation in addition to presumptive broad-spectrum antimicrobial management. There was no significant improvement with supportive care until the presentation of multisystem involvement on in the context of a recent history of COVID 19 and negative infective screen was raised. The diagnosis of multisystem inflammatory syndrome-adult form (MIS-A) was embraced, and the patient was commenced on methylprednisolone leading to a dramatic resolution of symptoms both clinically and biochemically with stabilization of vital functions allowing for safe outcomes.

Change of blood viscosity after COVID-19 vaccination: estimation for persons with underlying metabolic syndrome. The COVID-19 vaccine is a new vaccine aiming at control of COVID-19 pandemic. This new vaccine is useful for pandemic management, however, an important consideration is on its safety. Thrombosis is a problem might occur after COVID-19 vaccination and the increased blood viscosity is a pathomechanism. Here, the authors estimate on blood viscosity change after COVID-19 vaccination for vaccine recipient with underlying metabolic syndrome. Based on mathematical modelling and simulating technique, the authors estimate the change of blood viscosity after COVID-19 vaccination for persons with underlying metabolic syndrome. According to the estimation, blood viscosity in a healthy person is estimated 2.7 times higher than the normal value while blood viscosity in person with the underlying metabolic syndrome is estimated 2.99 times higher than the normal value. Based on this preliminary report, a more increased blood viscosity level is detected in vaccine recipients with the underlying metabolic syndrome. Monitoring of the blood viscosity problem among a vaccine recipient who has metabolic syndrome is recommended.

MODERNA mRNA-1273 vaccine-associated myopericarditis in a patient with a subclinical autoimmune predisposition. We present a rare case of myopericarditis developing one day after the injection of the second dose of the MODERNA mRNA-1273 vaccine (Cambridge, MA, USA). The patient complained of typical positional chest pain with initial laboratory results significant for elevated troponin, erythrocyte sedimentation rate, and C-reactive protein. Autoimmune predisposition was suggested by elevated anti-nuclear antibodies and anti-SjÃ¶gren's-syndrome-related antigen A autoantibodies titers. Subsequent cardiac magnetic resonance imaging (cMRI) revealed mild global hypokinesis with an ejection fraction of 48%, diffuse pericardial hyperenhancement suggestive of acute pericarditis, and T2-weighted short tau inversion recovery apical septal hyperenhancement suggestive of myocardial edema. Based on clinical, laboratory, and cMRI findings, a diagnosis of acute myopericarditis was made and the patient was treated with colchicine and ibuprofen with prompt resolution of symptoms. Vaccine-associated myopericarditis is rare, however, there have been reports of myocarditis developing after smallpox vaccination. The American College of Rheumatology has expressed concern about flaring or development of autoimmune inflammatory rheumatic disease

(AIIRD) after COVID vaccination. Further studies are required to quantify AIIRD flaring/development including myopericarditis after mRNA-1273 vaccination. <Learning objective: With the recent reports of myocarditis developing after COVID vaccination, our case report highlights the need for further studies to investigate a possible link between the mRNA-1273 vaccine and autoimmune inflammatory rheumatic disease development including myopericarditis. In addition to clinical findings and laboratory workup, our case also assesses the clinical utility of cardiac magnetic resonance imaging for the diagnosis of myopericarditis.>.

Impaired Functional T-Cell Response to SARS-CoV-2 After Two Doses of BNT162b2 mRNA Vaccine in Older People. Long-term care facility (LTCF) older residents display physiological alterations of cellular and humoral immunity that affect vaccine responses. Preliminary reports suggested a low early postvaccination antibody response against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The aim of this study was to focus on the specific T-cell response. We quantified S1-specific IgG, neutralizing antibody titers, total specific IFNÎ³-secreting T cells by ELISpot, and functionality of CD4(+)- and CD8(+)-specific T cells by flow cytometry, after two doses of the BNT162b2 vaccine in younger and older people, with and without previous COVID-19 infection (hereafter referred to as COVID-19-recovered and COVID-19-naive subjects, respectively). Frailty, nutritional, and immunosenescence parameters were collected at baseline in COVID-19-naive older people. We analyzed the immune response in 129 young adults (median age 44.0Â years) and 105 older residents living in a LCTF (median age 86.5Â years), 3Â months after the first injection. Humoral and cellular memory responses were dramatically impaired in the COVID-19-naive older (nÂ =Â 54) compared with the COVID-19-naive younger adults (nÂ =Â 121). Notably, older participants' neutralizing antibodies were 10 times lower than the younger's antibody titers (pÂ <Â 0.0001) and LCTF residents also had an impaired functional T-cell response: the frequencies of IFNÎ³(+) and IFNÎ³(+)IL-2(+)TNFÎ±(+) cells among specific CD4(+) T cells, and the frequency of specific CD8(+) T cells were lower in COVID-19-naive older participants than in COVID-19-naive young adults (pÂ <Â 0.0001 and pÂ =Â 0.0018, respectively). However, COVID-19-recovered older participants (nÂ =Â 51) had greater antibody and T-cell responses, including IFNÎ³(+) and IFNÎ³(+)IL-2(+)TNFÎ±(+)-specific CD4(+) T cells (pÂ <Â 0.0001), as well as TNFÎ±(+)-specific CD8(+) T cells (pÂ <Â 0.001), than COVID-19-naive older adults. We also observed that "inflammageing" and particularly high plasma levels of TNFÎ± was associated to poor antibody response in the older participants. In conclusion, our results show that the COVID-19-naive older people had low counts and impaired specific CD4(+) and CD8(+) T cells, in addition to impaired antibody response, and that specific studies are warranted to assess the efficiency of SARS-CoV-2 mRNA-based vaccines, as in other immunocompromised subjects. Our study also shows that, despite their physiological alterations of immunity, vaccination is highly efficient in boosting the prior natural memory response in COVID-19-recovered older people.

Pre-Existing Cross-Reactive Antibody Responses Do Not Significantly Impact Inactivated COVID-19 Vaccine-Induced Neutralization. Recent exposure to seasonal coronaviruses (sCoVs) may stimulate cross-reactive antibody responses against severe acute respiratory syndrome CoV 2 (SARS-CoV-2). However, previous studies have produced divergent results regarding protective or damaging immunity induced by prior sCoV exposure. It remains unknown whether pre-existing humoral immunity plays a role in vaccine-induced neutralization and antibody responses. In this study, we collected 36 paired sera samples from 36 healthy volunteers before and after immunization with inactivated whole-virion SARS-CoV-2 vaccines for COVID-19, and analyzed the distribution and intensity of pre-existing antibody responses at the epitope level pre-vaccination as well as the relationship between pre-existing sCoV immunity and vaccine-induced neutralization. We observed large amounts of pre-existing cross-reactive antibodies in the conserved regions among sCoVs, especially the S2 subunit. Excep t for a few peptides, the IgG and IgM fluorescence intensities against

S, M and N peptides did not differ significantly between pre-vaccination and post-vaccination sera of vaccinees who developed a neutralization inhibition rate (%inhibition) <40 and %inhibition â‰¥40 after two doses of the COVID-19 vaccine. Participants with strong and weak pre-existing cross-reactive antibodies (strong pre-CRA; weak pre-CRA) had similar %inhibition pre-vaccination (10.9% Â± 2.9% vs. 12.0% Â± 2.2%, P=0.990) and post-vaccination (43.8% Â± 25.1% vs. 44.6% Â± 21.5%, P=0.997). Overall, the strong pre-CRA group did not show a significantly greater increase in antibody responses to the S protein linear peptides post-vaccination compared with the weak pre-CRA group. Therefore, we found no evidence for a significant impact of pre-existing antibody responses on inactivated vaccine-induced neutralization and antibody responses. Our research provides an important basis for inactivated SARS-CoV-2 vaccine use in the context of high sCoV seroprevalence.

Potential Association Between Dietary Fibre and Humoral Response to the Seasonal Influenza Vaccine. Influenza vaccination is an effective public health measure to reduce the risk of influenza illness, particularly when the vaccine is well matched to circulating strains. Notwithstanding, the efficacy of influenza vaccination varies greatly among vaccinees due to largely unknown immunological determinants, thereby dampening population-wide protection. Here, we report that dietary fibre may play a significant role in humoral vaccine responses. We found dietary fibre intake and the abundance of fibre-fermenting intestinal bacteria to be positively correlated with humoral influenza vaccine-specific immune responses in human vaccinees, albeit without reaching statistical significance. Importantly, this correlation was largely driven by first-time vaccinees; prior influenza vaccination negatively correlated with vaccine immunogenicity. In support of these observations, dietary fibre consumption significantly enhanced humoral influenza vaccine responses in mice, where the effect was mechanistically linked to short-chain fatty acids, the bacterial fermentation product of dietary fibre. Overall, these findings may bear significant importance for emerging infectious agents, such as COVID-19, and associated de novo vaccinations.

Perimyocarditis Following COVID-19 Vaccination. A 39-year-old male was admitted in the emergency room with chest pain. He had been given the second dose of Pfizer-BioNTech COVID-19 vaccine 3 days before. The patient denied taking any other medication beyond the usual. He didn't feel sick in the previous days/weeks. Laboratory studies revealed elevated serum levels of troponin and C-reactive protein. An autoantibody screen and a serologic panel to detect common viruses were negative. A cardiac MRI showed myocardial edema/inflammation and confirmed the diagnosis of perimyocarditis which was considered to be a consequence of COVID-19 vaccination. Physicians should be aware of the possibility of cardiovascular complications after COVID-19 vaccination.

A Web-Based Survey on Factors for Unvaccination and Adverse Reactions of SARS-CoV-2 Vaccines in Chinese Patients with Psoriasis. PURPOSE: Vaccination is one of the most important strategy to prevent infections and control epidemics, but it also raises concerns about safety in patients receiving treatments. This study aimed to investigate the rate and factors for unvaccination, as well as adverse reactions and deterioration of disease after SARS-CoV-2 vaccination in psoriatic patients. METHODS: A web-based questionnaire survey on SARS-CoV-2 vaccination, adverse reactions, and self-reported change of disease condition after vaccination in patients with psoriasis was conducted. Demographic, clinical, and psychological data were collected. Multivariable logistic regression was used in the estimation of associations. RESULTS: A total of 788 psoriatic patients were investigated, and 68.9% reported SARS-CoV-2 vaccination. Younger age, use of interleukin-17 inhibitors, and symptoms of anxiety were associated with unvaccination. The incidence of overall adverse reactions after vaccination was 30.8%, and no severe adverse reaction was reported. The most common local and systemic adverse reactions were pain at the injection site and fatigue, respectively. Most patients reported no change in psoriasis after vaccination, while 16.6% and 4.4% reported slight and significant deteriorations of the disease, respectively. Nonadherence to treatment, symptoms of

anxiety and depression, and perceived stress were associated with self-reported deterioration of psoriasis after vaccination. CONCLUSION: While a favorable safety profile of SARS-CoV-2 vaccines is observed, receiving biologic treatment is factor for unvaccination in patients with psoriasis. Deterioration of psoriasis reported by a small proportion of patients is partially attributable to mental and behavioral factors.
Definite Acute Myocarditis After Coronavirus Disease 2019 mRNA Vaccination.
[Immune thrombocytopenia after BNT162b2 mRNA COVID-19 vaccination]. Coronavirus disease 2019 (COVID-19) has emerged as a global pandemic until today, but treatment options remain limited. COVID-19 vaccination is expected to decrease the number of patients with COVID-19 worldwide. In Japan, two types of mRNA COVID-19 vaccine, BNT162b2 (Pfizer/BioNTech) and mRNA-1273 (Moderna), have been approved and administered. However, their side effects remain poorly elucidated. This paper presents two cases of immune thrombocytopenia (ITP) after BNT162b2 mRNA COVID-19 vaccination. Whether or not ITP is triggered by the vaccination or not is difficult to identify. Further investigation with a large number of cases is warranted to clarify the side effects of BNT162b2 mRNA COVID-19 vaccination.
Clinically Suspected Myocarditis Temporally Related to COVID-19 Vaccination in Adolescents and Young Adults: Suspected Myocarditis After COVID-19 Vaccination. BACKGROUND: Understanding the clinical course and short-term outcomes of suspected myocarditis after the coronavirus disease 2019 (COVID-19) vaccination has important public health implications in the decision to vaccinate youth. METHODS: We retrospectively collected data on patients <21 years old presenting before July 4, 2021, with suspected myocarditis within 30 days of COVID-19 vaccination. Lake Louise criteria were used for cardiac MRI findings. Myocarditis cases were classified as confirmed or probable on the basis of the Centers for Disease Control and Prevention definitions. RESULTS: We report on 139 adolescents and young adults with 140 episodes of suspected myocarditis (49 confirmed, 91 probable) at 26 centers. Most patients were male (n=126, 90.6%) and White (n=92, 66.2%); 29 (20.9%) were Hispanic; and the median age was 15.8 years (range, 12.1-20.3; interquartile range [IQR], 14.5-17.0). Suspected myocarditis occurred in 136 patients (97.8%) after the mRNA vaccine, with 131 (94.2%) after the Pfizer-BioNTech vaccine; 128 (91.4%) occurred after the second dose. Symptoms started at a median of 2 days (range, 0-22; IQR, 1-3) after vaccination. The most common symptom was chest pain (99.3%). Patients were treated with nonsteroidal anti-inflammatory drugs (81.3%), intravenous immunoglobulin (21.6%), glucocorticoids (21.6%), colchicine (7.9%), or no anti-inflammatory therapies (8.6%). Twenty-six patients (18.7%) were in the intensive care unit, 2 were treated with inotropic/vasoactive support, and none required extracorporeal membrane oxygenation or died. Median hospital stay was 2 days (range, 0-10; IQR, 2-3). All patients had elevated troponin I (n=111, 8.12 ng/mL; IQR, 3.50-15.90) or T (n=28, 0.61 ng/mL; IQR, 0.25-1.30); 69.8% had abnormal ECGs and arrhythmias (7 with nonsustained ventricular tachycardia); and 18.7% had left ventricular ejection fraction <55% on echocardiogram. Of 97 patients who underwent cardiac MRI at a median 5 days (range, 0-88; IQR, 3-17) from symptom onset, 75 (77.3%) had abnormal findings: 74 (76.3%) had late gadolinium enhancement, 54 (55.7%) had myocardial edema, and 49 (50.5%) met Lake Louise criteria. Among 26 patients with left ventricular ejection fraction <55% on echocardiogram, all with follow-up had normalized function (n=25). CONCLUSIONS: Most cases of suspected COVID-19 vaccine myocarditis occurring in persons <21 years have a mild clinical course with rapid resolution of symptoms. Abnormal findings on cardiac MRI were frequent. Future studies should evaluate risk factors, mechanisms, and long-term outcomes.
Newly diagnosed IgA nephropathy with gross haematuria following COVID-19 vaccination.
Erythema multiforme after SARS-CoV-2 messenger RNA vaccination.

Anaphylaxis rates associated with COVID-19 vaccines are comparable to those of other vaccines. We retrieved data on 8940 anaphylaxis cases post-COVID-19 vaccination from the US Vaccine Adverse Event Reporting System and the European EudraVigilance from week 52/2020 through week 31/2021 and compared them with those of other vaccines. Overall, 837,830,000 COVID-19 vaccine doses were delivered in the US and Europe during the study period, for which the vaccine name was known. The mean anaphylaxis rate was estimated at 10.67 cases per 10(6) doses of COVID-19 vaccines (range: 7.99-19.39 cases per 10(6) doses depending on the vaccine). COVID-19 vaccines ranked fifth in reported anaphylaxis rates, behind rabies, tick-borne encephalitis, measles-mumps-rubella-varicella, and human papillomavirus vaccines (70.77, 20, 19.8, and 13.65 cases per 10(6) vaccine doses, respectively). COVID-19 vaccines are within the range of anaphylaxis rates reported across several common vaccines in these two passive reporting systems. These data should be communicated to reassure the general population about the safety profile of COVID-19 vaccines.

Trends in COVID-19 vaccination intent and factors associated with deliberation and reluctance among adult homeless shelter residents and staff, 1 November 2020 to 28 February 2021 - King County, Washington. INTRODUCTION: Little is known about COVID-19 vaccination intent among people experiencing homelessness. This study assesses surveyed COVID-19 vaccination intent among adult homeless shelter residents and staff and identifies factors associated with vaccine deliberation (responded "undecided") and reluctance (responded "no"), including time trends. METHODS: From 11/1/2020-2/28/21, we conducted repeated cross-sectional surveys at nine shelters in King County, WA as part of ongoing community-based SARS-CoV-2 surveillance. We used a multinomial model to identify characteristics associated with vaccine deliberation and reluctance. RESULTS: A total of 969 unique staff (nÂ =Â 297) and residents (nÂ =Â 672) participated and provided 3966 survey responses. Among residents, 53.7% (nÂ =Â 361) were vaccine accepting, 28.1% reluctant, 17.6% deliberative, and 0.6% already vaccinated, whereas among staff 56.2% were vaccine accepting, 14.1% were reluctant, 16.5% were deliberative, and 13.1% already vaccinated at their last survey. We observed higher odds of vaccine deliberation or reluctance among Black/African American individuals, those who did not receive a seasonal influenza vaccine, and those with lower educational attainment. There was no significant trend towards vaccine acceptance. CONCLUSIONS: Strong disparities in vaccine intent based on race, education, and prior vaccine history were observed. Increased vaccine intent over the study period was not detected. An intersectional, person-centered approach to addressing health inequities by public health authorities planning vaccination campaigns in shelters is recommended. Clinical Trial Registry Number: NCT04141917.

mRNA COVID-19 Vaccine-Related Anaphylactoid Reaction and Coronary Thrombosis.

Flare-up of generalized pustular psoriasis combined with systemic capillary leak syndrome after coronavirus disease 2019 mRNA vaccination. Generalized pustular psoriasis (GPP) is characterized by acute flare-ups induced by various factors, but few reports have described GPP onset or flare-up induced by vaccination. To our knowledge, only three such cases following coronavirus disease 2019 (COVID-19) vaccination have been reported. We herein report a case of GPP flare-up after COVID-19 mRNA vaccination. A 65-year-old man with GPP controlled by infliximab presented with widespread pustular erythema, fever, and malaise following his second COVID-19 mRNA vaccination. A skin eruption was apparent at the injection site. He also exhibited systemic capillary leak syndrome (SCLS), which responded rapidly to secukinumab and systemic corticosteroids. Two biopsies, one of which was of the injection site, revealed not only findings typical of GPP, but also a dermal mixed-cell infiltration with eosinophils, and microthrombi in the small dermal vessels. The latter findings have been observed in cutaneous lesions induced by both COVID-19 infection and vaccination. This is the first case of a GPP flare-up accompanied by SCLS induced by a

COVID-19 mRNA vaccine. Also, this is the first flare-up induced by the second vaccine dose, and the first such report including detailed histological data, including for the injection site.
Letter to the editor: Exacerbation of autoimmune hepatitis after COVID-19 vaccination.
Clinical characteristics and prognostic factors of myocarditis associated with the mRNA COVID-19 vaccine. To analyze the clinical presentation and outcomes of myocarditis after administration of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) messenger RNA (mRNA) vaccine. Nine case series and 15 case reports (74 patients) of myocarditis after administration of the BNT162b2 or mRNA-1273 vaccine were reviewed from PubMed, Scopus, Embase, and Web of Science. We analyzed clinical manifestations, diagnostic findings, and outcomes. In addition, we performed a pooled analysis and investigated risk factors leading to admission to the intensive care unit and recovery with conservative care. Most patients were male (94.6%), and the median age (range) was 17.6 (14-70) years. Patients who received the BNT162b2 (nâ€‰=â€‰58, 78.4%) vaccine presented fewer systemic symptoms and left ventricular dysfunction than mRNA-1273 recipients. Although patients under 20 years experienced more fever and myalgia, they had better ejection fraction and less prominent myocardial inflammation in magnetic resonance imaging than older patients. The clinical course of all patients was favorable without mortality, and one-third of patients resolved with conservative care alone. Risk factor analyses revealed that patients with gastrointestinal symptoms required intensive care (odds ratio: 20.3, 95% confidence interval 1.90-217, pâ€‰=â€‰0.013). The risk of fatality in myocarditis subjected to mRNA vaccination seems to be low. However,Â patients with gastrointestinal symptoms received more intensive care, and a significant proportion of patients recovered with conservative management.
Lessons of the month 3: Haemophagocytic lymphohistiocytosis following COVID-19 vaccination (ChAdOx1 nCoV-19). A 36-year-old woman presented to hospital 9 days after receiving her first dose of the ChAdOx1 nCoV-19 vaccine with fever, myalgia and a sore throat. She was previously fit and well with no prior vaccine reactions.There was no clinical response to initial treatment with intravenous (IV) antibiotics. Microbiology tests including for COVID-19 were negative. At day 5, she developed pleuritic pain and a pericardial rub. Echocardiography and subsequent cardiac magnetic resonance imaging showed evidence of constrictive pericarditis. Computed tomography revealed gross hepatomegaly and moderate splenomegaly. Blood tests showed raised inflammatory markers, deranged clotting, low platelets and a marked hyperferritinaemia.A presumptive diagnosis of a multi-system inflammatory disorder secondary to recent COVID-19 vaccination was made and high-dose IV methylprednisolone initiated. Following a high 'H score' of 70%-80% a diagnosis of secondary haemophagocytic lymphohistiocytosis (HLH) was made. She was treated with IV immunoglobulin with subsequent clinical response.HLH is a rare syndrome of acute and rapidly progressive systemic inflammation characterised by cytopenias, excessive cytokine production and hyperferritinaemia. The adult form has multiple triggers, including recent vaccination. This case prompts awareness among clinicians of HLH as a rare complication of COVID-19 vaccination but should not discourage individuals from vaccination.
Safety and efficacy of the mRNA BNT162b2 vaccine against SARS-CoV-2 in five groups of immunocompromised patients and healthy controls in a prospective open-label clinical trial. BACKGROUND: Patients with immunocompromised disorders have mainly been excluded from clinical trials of vaccination against COVID-19. Thus, the aim of this prospective clinical trial was to investigate safety and efficacy of BNT162b2 mRNA vaccination in five selected groups of immunocompromised patients and healthy controls. METHODS: 539 study subjects (449 patients and 90 controls) were included. The patients had either primary (n=90), or secondary immunodeficiency disorders due to human immunodeficiency virus infection (n=90), allogeneic hematopoietic stem cell transplantation/CAR T cell therapy (n=90), solid organ transplantation (SOT) (n=89), or chronic

lymphocytic leukemia (CLL) (n=90). The primary endpoint was seroconversion rate two weeks after the second dose. The secondary endpoints were safety and documented SARS-CoV-2 infection. FINDINGS: Adverse events were generally mild, but one case of fatal suspected unexpected serious adverse reaction occurred. 72.2% of the immunocompromised patients seroconverted compared to 100% of the controls (p=0.004). Lowest seroconversion rates were found in the SOT (43.4%) and CLL (63.3%) patient groups with observed negative impact of treatment with mycophenolate mofetil and ibrutinib, respectively. INTERPRETATION: The results showed that the mRNA BNT162b2 vaccine was safe in immunocompromised patients. Rate of seroconversion was substantially lower than in healthy controls, with a wide range of rates and antibody titres among predefined patient groups and subgroups. This clinical trial highlights the need for additional vaccine doses in certain immunocompromised patient groups to improve immunity. FUNDING: Knut and Alice Wallenberg Foundation, the Swedish Research Council, Nordstjernan AB, Region Stockholm, Karolinska Institutet, and organizations for PID/CLL-patients in Sweden.

Features of Inflammatory Heart Reactions Following mRNA COVID-19 Vaccination at a Global Level. Myocarditis and pericarditis may constitute adverse reactions of mRNA coronavirus disease 2019 (COVID-19) vaccines. This study aimed to document these reactions and to assess the association with patient sex and age. This is as an observational retrospective study using a case-non-case design (also called disproportionality study) on inflammatory heart reactions reported with mRNA COVID-19 vaccines within the World Health Organization (WHO) global safety database (VigiBase), up to June 30, 2021. Results are expressed using reporting odds ratios (RORs) and their 95% confidence interval (95% CI). Of 716,576 reports related to mRNA COVID-19 vaccines, 2,277 were cases of inflammatory heart reactions, including 1241 (55%) myocarditis and 851 (37%) pericarditis. The main age group was 18-29Â years (704, 31%), and mostly male patients (1,555, 68%). Pericarditis onset was delayed compared with myocarditis with a median time to onset of 8 (3-21) vs. 3 (2-6) days, respectively (PÂ =Â 0.001). Regarding myocarditis, an important disproportionate reporting was observed in adolescents (ROR, 22.3, 95% CI 19.2-25.9) and in 18-29Â years old (ROR, 6.6, 95% CI 5.9-7.5) compared with older patients, as well as in male patients (ROR, 9.4, 95% CI 8.3-10.6). Reporting rate of myocarditis was increased in young adults and adolescents. Inflammatory heart reactions may rarely occur shortly following mRNA COVID-19 vaccination. Although an important disproportionate reporting of myocarditis was observed among adolescents and young adults, particularly in male patients, reporting rates support a very rare risk, that does not seem to compromise the largely positive benefit-risk balance of these vaccines. Furthermore, this study confirmed the value of disproportionality analyses for estimation of relative risks among subgroups of patients.

Immunogenicity and safety of mRNA COVID-19 vaccines in people with multiple sclerosis treated with different disease-modifying therapies. The potential impact of disease-modifying therapies (DMTs) for multiple sclerosis (MS) on COVID-19 vaccination is poorly understood. According to recent observations, the humoral immune response could be impaired in patients treated with ocrelizumab or fingolimod. Our study evaluated the immunogenicity and safety of mRNA COVID-19 vaccines in a convenience sample of 140 MS patients treated with different DMTs, undergoing vaccination between April and June 2021. Humoral immune response was tested 1Â month after the second dose, using a chemiluminescent microparticle immunoassay to detect IgG against SARS-CoV-2 nucleoprotein. We explored the potential correlation between the IgG titer and DMTs. All patients in treatment with first-line DMTs, natalizumab, cladribine, and alemtuzumab, developed a measurable humoral response. In patients treated with ocrelizumab and fingolimod, the IgG level was significantly lower, but only some patients (22.2% for fingolimod and 66% for ocrelizumab) failed to develop a measurable humoral response. In the ocrelizumab group, the IgG level was positively correlated with the time from last infusion. No SARS-CoV-2 infections were reported after vaccination. The most

reported side effects were pain at the injection site (57.1%) and fatigue (37.9%). No patient experienced severe side effects requiring hospitalization. Our study confirms that COVID-19 vaccination is safe and well-tolerated in MS patients and should be recommended to all patients regardless of their current DMTs. Since fingolimod and ocrelizumab could reduce the humoral immune response, in patients treated with these drugs, detecting SARS-CoV-2 antibodies could be helpful to monitor the immune response after vaccination.

Case Report: Anti-neutrophil Cytoplasmic Antibody-Associated Vasculitis With Acute Renal Failure and Pulmonary Hemorrhage May Occur After COVID-19 Vaccination. The rare and severe adverse effects associated with coronavirus disease of 2019 (COVID-19) vaccination have been under-appreciated, resulting in many instances of inappropriate management. We describe the case of an elderly woman who developed anti-neutrophil cytoplasmic antibody-associated vasculitis with pulmonary renal syndrome approximately 3 weeks after the first dose of COVID-19 mRNA vaccination (Moderna). Her nasopharyngeal polymerase chain reaction test for the COVID-19 RNA virus was negative. Gross hematuria, heavy proteinuria, acute renal failure (serum creatinine up to 6.5 mg/dL), and hemoptysis coupled with a marked increase in serum anti-myeloperoxidase-O antibody were observed. Renal biopsy showed severe vasculitis with pauci-immune crescent glomerulonephritis. The pulmonary hemorrhage was resolved and renal function improved following combined plasma exchange and the administration of systemic steroids and anti-CD20 therapy. The early examination of urinalysis and renal function may be crucial for identifying glomerulonephritis and acute renal failure in susceptible patients after COVID-19 vaccination.

Intranasal Delivery of MVA Vector Vaccine Induces Effective Pulmonary Immunity Against SARS-CoV-2 in Rodents. Antigen-specific tissue-resident memory T cells (Trms) and neutralizing IgA antibodies provide the most effective protection of the lungs from viral infections. To induce those essential components of lung immunity against SARS-CoV-2, we tested various immunization protocols involving intranasal delivery of a novel Modified Vaccinia virus Ankara (MVA)-SARS-2-spike vaccine candidate. We show that a single intranasal MVA-SARS-CoV-2-S application in mice strongly induced pulmonary spike-specific CD8(+) T cells, albeit restricted production of neutralizing antibodies. In prime-boost protocols, intranasal booster vaccine delivery proved to be crucial for a massive expansion of systemic and lung tissue-resident spike-specific CD8(+) T cells and the development of Th1 - but not Th2 - CD4(+) T cells. Likewise, very high titers of IgG and IgA anti-spike antibodies were present in serum and broncho-alveolar lavages that possessed high virus neutralization capacities to all current SARS-CoV-2 variants of concern. Importantly, the MVA-SARS-2-spike vaccine applied in intramuscular priming and intranasal boosting treatment regimen completely protected hamsters from developing SARS-CoV-2 lung infection and pathology. Together, these results identify intramuscular priming followed by respiratory tract boosting with MVA-SARS-2-S as a promising approach for the induction of local, respiratory as well as systemic immune responses suited to protect from SARS-CoV-2 infections.

Recognition of Variants of Concern by Antibodies and T Cells Induced by a SARS-CoV-2 Inactivated Vaccine. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the virus responsible of the current pandemic ongoing all around the world. Since its discovery in 2019, several circulating variants have emerged and some of them are associated with increased infections and death rate. Despite the genetic differences among these variants, vaccines approved for human use have shown a good immunogenic and protective response against them. In Chile, over 70% of the vaccinated population is immunized with CoronaVac, an inactivated SARS-CoV-2 vaccine. The immune response elicited by this vaccine has been described against the first SARS-CoV-2 strain isolated from Wuhan, China and the D614G strain (lineage B). To date, four SARS-CoV-2 variants of concern described have circulated worldwide. Here, we describe the neutralizing capacities of antibodies

secreted by volunteers in the Chilean population immunized with CoronaVac against variants of concern Alpha (B.1.1.7), Beta (B.1.351) Gamma (P.1) and Delta (B.617.2). METHODS: Volunteers enrolled in a phase 3 clinical trial were vaccinated with two doses of CoronaVac in 0-14 or 0-28 immunization schedules. Sera samples were used to evaluate the capacity of antibodies induced by the vaccine to block the binding between Receptor Binding Domain (RBD) from variants of concern and the human ACE2 receptor by an in-house ELISA. Further, conventional microneutralization assays were used to test neutralization of SARS-CoV-2 infection. Moreover, interferon-Î³-secreting T cells against Spike from variants of concern were evaluated in PBMCs from vaccinated subjects using ELISPOT. RESULTS: CoronaVac promotes the secretion of antibodies able to block the RBD of all the SARS-CoV-2 variants studied. Seropositivity rates of neutralizing antibodies in the population evaluated were over 97% for the lineage B strain, over 80% for Alpha and Gamma variants, over 75% for Delta variant and over 60% for the Beta variant. Geometric means titers of blocking antibodies were reduced when tested against SARS-CoV-2 variants as compared to ancestral strain. We also observed that antibodies from vaccinated subjects were able to neutralize the infection of variants D614G, Alpha, Gamma and Delta in a conventional microneutralization assay. Importantly, after SARS-CoV-2 infection, we observed that the blocking capacity of antibodies from vaccinated volunteers increased up to ten times for all the variants tested. We compared the number of interferon-Î³-secreting T cells specific for SARS-CoV-2 Spike WT and variants of concern from vaccinated subjects and we did not detect significant differences. CONCLUSION: Immunization with CoronaVac in either immunization schedule promotes the secretion of antibodies able to block SARS-CoV-2 variants of concern and partially neutralizes SARS-CoV-2 infection. In addition, it stimulates cellular responses against all variants of concern.
COVID-19 vaccine-induced cellulitis and myositis.
Antibody titers against the Alpha, Beta, Gamma, and Delta variants of SARS-CoV-2 induced by BNT162b2 vaccination measured using automated chemiluminescent enzyme immunoassay. BACKGROUND: Levels of 50% neutralizing titer (NT50) reflect the a vaccine-induced humoral immunity after the vaccination against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). Measurements of NT50 are difficult to implement in large quantities. A high-throughput laboratory test is expected for determining the level of herd immunity against SARS-CoV-2. METHODS: We analyzed samples from 168 Japanese healthcare workers who had completed two doses of the BNT162b2 vaccine. We analyzed immunoglobulin G (IgG) index values against spike protein (SP) using automated chemiluminescent enzyme immunoassay system AIA-CL and analyzed the background factors affecting antibody titer. SP IgG index was compared with 50% neutralization titers. RESULTS: The median SP IgG index values of the subjects (mean ageÂ =Â 43 years; 75% female) were 0.1, 1.35, 60.80, and 97.35 before and at 2, 4, and 6 weeks after the first dose, respectively. At 4 and 6 weeks after the first dose, SP IgG titers were found to have positive correlation with NT50 titer (rÂ =Â 0.7535 in 4 weeks; rÂ =Â 0.4376 in 6 weeks). Proportions of the SP IgG index values against the Alpha, Beta, Gamma, and Delta variants compared with the original strain were 2.029, 0.544, 1.017, and 0.6096 respectively. Older age was associated with lower SP IgG titer index 6 weeks after the first dose. CONCLUSIONS: SP IgG index values were rised at 3 weeks after two doses of BNT162b2 vaccination and have positive correlation with NT50. SP IgG index values were lower in the older individuals and against Beta and Delta strain.
A retrospective analysis of social media posts pertaining to COVID-19 vaccination side effects. OBJECTIVES: With an uprising influence of social media platforms like Twitter and Instagram a multitude of worldwide accessible information is available. Since the beginning of COVID-19 pandemic the exchange of medical information about several topics related to this infectious disease and its vaccination has increased rapidly. The purpose of this investigation was to assess the content

associated with COVID-19 vaccination and its side effects and evaluate its educational quality. METHODS: We conducted this retrospective study to investigate 600 Twitter and Instagram posts by #covidvaccinesideeffects due to number of 'likes', comments, type of post, language, its purpose and source. In addition, posts were evaluated due to educational quality by three examiners of different educational levels. RESULTS: The majority of posts showed 0 to 50 "likes" and 0 to 5 comments in English language. A comparison between Twitter and Instagram by the influence of application showed significant differences in number of posts and "likes" or comments (pÂ <Â 0.05). The major post type were texts for Twitter (251; 83.7%) and videos for Instagram (104; 34.7%). While a majority of posts by #covidvaccinesideeffects report about the occurrence of side effects, the majority of them were mild and general COVID-19 vaccination feedback during the first 4Â months was positive. But, only 3 to 7% were rated by "excellent" educational and validatable content. Interrater reliability between all three examiners presented a high concordance with 89% (pÂ =Â 0.001). CONCLUSIONS: This study presents an analysis of quantity and quality of social media content according to COVID-19 vaccinations and its side effects. It supports the deduction that most of the content on Twitter and Instagram is shared by patients and unclear sources and thus is limited informative. Nevertheless, influence of social media on medical information especially during COVID-19 pandemic is increasing and practitioners have to face its effect on their patients.

Immunogenicity and safety of SARS-CoV-2 vaccines in clinical trials. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections were first detected in Wuhan, China in December 2019 and resulted in a worldwide pandemic in 2020. SARS-CoV-2 infections totalled more than 180 million with 3.9 million deaths as of June 24, 2021. Tremendous research efforts have resulted in the development of at least 64 vaccine candidates that have reached Phase I to III clinical trials within 14 months. The primary efficacy endpoint for a random placebo-controlled clinical trial of a COVID-19 vaccine to be approved by US FDA should confer at least 50% protection against COVID-19. Three COVID-19 vaccines (BNT162b2, mRNA-1273 and Sputnik V) in clinical Phase III trials have now achieved >90% efficacy in preventing COVID-19. Since SARS-CoV-2 is highly contagious, vaccines are expected to achieve at least 80% herd immunity in the world's population to effectively prevent SARS-CoV-2 infections. An overview of safety, immunogenicity and efficacy of the current frontrunner vaccines are reviewed.

Post-vaccination SARS-CoV-2 infection among healthcare workers in tertiary care hospitals in Saudi Arabia: A case series. Healthcare workers have been categorized among the priority groups for COVID-19 vaccination. However, post-vaccination infections have been identified. This study was conducted to investigate SARS-CoV-2 infection among healthcare workers (HCWs) who received the COVID-19 vaccine. A case series in a multicenter healthcare system in Saudi Arabia was created from HCWs who had (PCR-RT) confirmed SARS-CoV-2 infection after at least one dose of Pfizer-BioNTech vaccination. A total of 20 healthcare workers (HCWs) have been included. The majority (70.0%) were males and the average age was 39.4 Â± 10.1 years. They included physicians (55.0%), nurses (25.0%) and other HCWs (20.0%). Eighteen (90%) HCWs had infection after the first dose; 47.1% within the first week, 41.2% within the second week, and 11.8% within the third week. Only two HCWs (10.0%) had infection one week after the second dose. The majority (63.2%) had mild (52.6%) or moderate (10.3%) disease with no severe disease or hospitalization. The majority of post-vaccination COVID-19 infections among HCWs occurred before the full protection of the vaccine is gained. Suspicion of COVID-19 infection should be considered even with a history of COVID-19 vaccination. Recently vaccinated HCWs should be advised to fully comply with all recommended precautions to prevent COVID-19 transmission.

First and fatal case of autoimmune acquired factor XIII/13 deficiency after COVID-19/SARS-CoV-2 vaccination.

Reduced neutralisation of the Delta (B.1.617.2) SARS-CoV-2 variant of concern following vaccination. Vaccines are proving to be highly effective in controlling hospitalisation and deaths associated with SARS-CoV-2 infection but the emergence of viral variants with novel antigenic profiles threatens to diminish their efficacy. Assessment of the ability of sera from vaccine recipients to neutralise SARS-CoV-2 variants will inform the success of strategies for minimising COVID19 cases and the design of effective antigenic formulations. Here, we examine the sensitivity of variants of concern (VOCs) representative of the B.1.617.1 and B.1.617.2 (first associated with infections in India) and B.1.351 (first associated with infection in South Africa) lineages of SARS-CoV-2 to neutralisation by sera from individuals vaccinated with the BNT162b2 (Pfizer/BioNTech) and ChAdOx1 (Oxford/AstraZeneca) vaccines. Across all vaccinated individuals, the spike glycoproteins from B.1.617.1 and B.1.617.2 conferred reductions in neutralisation of 4.31 and 5.11-fold respectively. The reduction seen with the B.1.617.2 lineage approached that conferred by the glycoprotein from B.1.351 (South African) variant (6.29-fold reduction) that is known to be associated with reduced vaccine efficacy. Neutralising antibody titres elicited by vaccination with two doses of BNT162b2 were significantly higher than those elicited by vaccination with two doses of ChAdOx1. Fold decreases in the magnitude of neutralisation titre following two doses of BNT162b2, conferred reductions in titre of 7.77, 11.30 and 9.56-fold respectively to B.1.617.1, B.1.617.2 and B.1.351 pseudoviruses, the reduction in neutralisation of the delta variant B.1.617.2 surpassing that of B.1.351. Fold changes in those vaccinated with two doses of ChAdOx1 were 0.69, 4.01 and 1.48 respectively. The accumulation of mutations in these VOCs, and others, demonstrate the quantifiable risk of antigenic drift and subsequent reduction in vaccine efficacy. Accordingly, booster vaccines based on updated variants are likely to be required over time to prevent productive infection. This study also suggests that two dose regimes of vaccine are required for maximal BNT162b2 and ChAdOx1-induced immunity.

Prior SARS-CoV-2 infection increases reactogenicity after SARS-COV-2 mRNA vaccine and could delay the administration of the vaccine based on timing of infection.

Association of COVID-19 Vaccination With SARS-CoV-2 Infection in Patients With Cancer: A US Nationwide Veterans Affairs Study. IMPORTANCE: Patients with cancer are at increased risk for severe COVID-19, but it is unknown whether SARS-CoV-2 vaccination is effective for them. OBJECTIVE: To determine the association between SARS-CoV-2 vaccination and SARS-CoV-2 infections among a population of Veterans Affairs (VA) patients with cancer. DESIGN, SETTING, AND PARTICIPANTS: Retrospective, multicenter, nationwide cohort study of SARS-CoV-2 vaccination and infection among patients in the VA health care system from December 15, 2020, to May 4, 2021. All adults with solid tumors or hematologic cancer who received systemic cancer-directed therapy from August 15, 2010, to May 4, 2021, and were alive and without a documented SARS-CoV-2 positive result as of December 15, 2020, were eligible for inclusion. Each day between December 15, 2020, and May 4, 2021, newly vaccinated patients were matched 1:1 with unvaccinated or not yet vaccinated controls based on age, race and ethnicity, VA facility, rurality of home address, cancer type, and treatment type/timing. EXPOSURES: Receipt of a SARS-CoV-2 vaccine. MAIN OUTCOMES AND MEASURES: The primary outcome was documented SARS-CoV-2 infection. A proxy for vaccine effectiveness was defined as 1 minus the risk ratio of SARS-CoV-2 infection for vaccinated individuals compared with unvaccinated controls. RESULTS: A total of 184â€¯485 patients met eligibility criteria, and 113â€¯796 were vaccinated. Of these, 29â€¯152 vaccinated patients (median [IQR] age, 74.1 [70.2-79.3] years; 95% were men; 71% were non-Hispanic White individuals) were matched 1:1 to unvaccinated or not yet vaccinated controls. As of a median 47 days of follow-up, 436 SARS-CoV-2 infections were detected in the matched cohort (161 infections in vaccinated patients vs 275 in unvaccinated patients). There were 17 COVID-19-related deaths in the vaccinated group vs 27 COVID-19-related deaths in the unvaccinated group. Overall vaccine effectiveness in the matched cohort was 58% (95% CI, 39% to

72%) starting 14 days after the second dose. Patients who received chemotherapy within 3 months prior to the first vaccination dose were estimated to have a vaccine effectiveness of 57% (95% CI, -23% to 90%) starting 14 days after the second dose vs 76% (95% CI, 50% to 91%) for those receiving endocrine therapy and 85% (95% CI, 29% to 100%) for those who had not received systemic therapy for at least 6 months prior. CONCLUSIONS AND RELEVANCE: In this cohort study, COVID-19 vaccination was associated with lower SARS-CoV-2 infection rates in patients with cancer. Some immunosuppressed subgroups may remain at early risk for COVID-19 despite vaccination, and consideration should be given to additional risk reduction strategies, such as serologic testing for vaccine response and a third vaccine dose to optimize outcomes.

[A red and swollen arm after vaccination for covid-19]. In this case report, we present a 41-year old male with a red rash on his arm 7 days post vaccination with the mRNA Moderna vaccine. While the patient received antibiotics for the suspicion of a cellulitis, this was actually a delayed type 4 local allergic reaction to the vaccine or a so called 'Covid arm'. This reaction occurs frequently, is usually self-limiting and a conservative treatment is recommended. Conflict of interest and financial support: none declared.

Potential therapeutic application of mesenchymal stem cells in COVID-19 complications. Mesenchymal stem cells (MSCs) have remarkable immunomodulatory properties, low immunogenicity, and paracrine properties as well as the ability to differentiate into multiple cell lines. These properties make them potential candidates for clinical applications in the treatment of neurodegenerative, cardiovascular, and lung diseases, which may be occupational diseases. Preclinical studies using experimental animal models have demonstrated regenerative properties of MSCs in diseases such as silicosis and occupational asthma. Currently, treatment of the novel disease COVID-19 could be enhanced by using MSC therapies. This disease affects many professional groups with great intensity and its consequences might be considered as an occupational disease. It is a significant public health problem and a therapeutic challenge. Despite the development of vaccines against COVID-19, there is growing concern about the emergence of new mutations of the SARS-CoV-2 virus in addition to the known alpha, beta, gamma, and delta variants. There is still no effective COVID-19 treatment and the existing ones only play a supporting role. MSCs offer treatment possibilities as an alternative or complementary therapy. The clinical trials to date using MSCs in patients with COVID-19 give hope for the safe and effective use of this stem cell population. Med Pr. 2021;72(6):693-700.

Patients presenting high fever with lymphadenopathy after COVID-19 vaccination were diagnosed with hemophagocytic lymphohistiocytosis. BACKGROUND: The coronavirus disease 2019 (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is still continuing worldwide. Currently, two mRNA-based vaccines and two DNA vaccines using an adenovirus vector are representative vaccines. Since the SARS-CoV-2 vaccines began to be administered, a significant decrease in new infections and COVID-19-associated death has been reported. However, various adverse events from mild symptoms to death have also been described after vaccination. CASE DESCRIPTION: Patients with high fever and lymphadenopathy who are diagnosed with hemophagocytic lymphohistiocytosis (HLH) after COVID-19 vaccination are very rare, and there is no standard management guideline for these patients thus far. Herein, we described two cases of HLH after the administration of an mRNA-based vaccine and adenovirus vector vaccine. DISCUSSION: HLH is a life-threatening hyperinflammatory syndrome that occurs due to persistent stimulation of lymphocytes and histiocytes in various underlying conditions at all ages. Although the exact mechanisms and risk factors of COVID-19 vaccination-related HLH are still unknown, vigorous immune stimulation may trigger a huge cytokine storm, rarely resulting in HLH. It is important to note that early suspicion by clinicians can lower the mortality rate.

New-onset bullous pemphigoid after inactivated Covid-19 vaccine: Synergistic effect of the Covid-19 vaccine and vildagliptin.

Specialist allergy advice allows vaccination in patients with reactions to COVID-19 vaccines.

Immunogenicity and tolerability of COVID-19 vaccination in peritoneal dialysis patients-A prospective observational cohort study. BACKGROUND: In peritoneal dialysis (PD) patients, information on the immunogenicity and tolerability of SARS-CoV-2 vaccination is still scarce. We compared the immunogenicity and tolerability of SARS-CoV-2 vaccination of PD patients with that of medical personnel. METHODS: In a prospective observational cohort study, PD patients and immunocompetent medical personnel were evaluated for SARS-CoV-2 spike-IgG- and Nucleocapsid-IgG-antibody-levels before, 2Â weeks after the first, and 6Â weeks after the second SARS-CoV-2 vaccination and vaccine tolerability after the first and second vaccination. RESULTS: In COVID-19-naÃ¯ve PD patients (Nâ€‰=â€‰19), lower SARS-CoV-2-spike-IgG-levels were found compared with COVID-19-naÃ¯ve medical personnel (Nâ€‰=â€‰24) 6Â weeks after second vaccination (median 1438â€‰AU/ml [25th-75th percentile 775-5261] versus 4577 [1529-9871]; pâ€‰=â€‰0.045). This finding resulted in a lower rate of strong vaccine response (spike-IgGâ€‰â‰¥â€‰1000â€‰AU/ml) of COVID-19-naÃ¯ve PD patients compared with medical personnel (58% versus 92%; pâ€‰=â€‰0.013), but not for seroconversion rate (spike-IgGâ€‰â‰¥â€‰50â€‰AU/ml: 100% vs. 100%; pâ€‰>â€‰0.99). After first vaccination, COVID-naÃ¯ve PD patients presented with significantly fewer side effects than medical personnel (number of any side effect: 1 [1-2] vs. 4 [1-7]; pâ€‰=â€‰0.015). A similar pattern with slightly decreased frequencies of side effects was observed for tolerability of second SARS-CoV-2 vaccination in PD patients and medical personnel (number of any side effects: 1 [1-1] vs. 2 [1-5]; pâ€‰=â€‰0.006). CONCLUSIONS: SARS-CoV-2 vaccination in COVID-19-naÃ¯ve PD patients appeared to induce a very high rate of seroconversion but a substantially lower rate of patients with a strong response compared with medical personnel. Vaccination appeared to be safe in the PD patients studied.

Leukocytoclastic vasculitis after the third dose of CoronaVac vaccination.

Cutaneous Leukocytoclastic Vasculitis Induction Following ChAdOx1 nCoV-19 Vaccine. The coronavirus disease 2019 (COVID-19)Â pandemic is an unprecedented event, and in order to control its spread and minimize its damages, all efforts are immediately mobilized. Mass vaccinationÂ is considered a promisingÂ solution to combat this universal issue. However, given the urgent need for vaccine production, some of the side effects may not have been presented during trials and will only appear during the mass vaccination. Limited vasculitis cases have been reported so far following vaccination against COVID-19. We present a case of cutaneous leukocytoclastic vasculitis (LCV) induced following the first dose of the ChAdOx1 nCoV-19 vaccine in an otherwise healthy individual.

A message of the majority with scientific evidence encourages young people to show their prosocial nature in COVID-19 vaccination. The most promising way to prevent the explosive spread of COVID-19 infection is to achieve herd immunity through vaccination. It is therefore important to motivate those who are less willing to be vaccinated. To address this issue, we conducted an online survey ofÂ 6232 Japanese people to investigate age- and gender-dependent differences in attitudes towards COVID-19 vaccination and the underlying psychological processes. We asked participants to read one of nine different messages about COVID-19 vaccination and rate their willingness to be vaccinated. We also collected their 17 social personality trait scores and demographic information. We found that males 10-20Â years old were least willing to be vaccinated. We also found that prosocial traits are the driving force for young people, but the motivation in older people also depends on risk aversion and self-interest. Furthermore, an analysis of 9 different messages demonstrated that for young people (particularly males), the message emphasizing the majority's intention to vaccinate and scientific evidence for the safety of the vaccination had the strongest

positive effect on the willingness to be vaccinated, suggesting that the "majorityâ€‰+â€‰scientific evidence" message nudges young people to show their prosocial nature in action.

Post-vaccination survey for monitoring the side effects associated with COVID-19 vaccines among healthcare professionals of Jazan province, Saudi Arabia. OBJECTIVES: To identify the self-reported vaccine-related side effects among healthcare professionals (HCPs) in the Jazan province, Saudi Arabia, and determine the associated socio-demographic factors. With the recent second and third waves of coronavirus disease -19 (COVID-19) infections worldwide, the race is not only to encourage but also to achieve mass vaccination. METHODS: A total of 397 HCPs from across Jazan province participated in an anonymous online cross-sectional survey conducted for a period of 45 days (March 30, 2021 to May 13, 2021) in Jazan province, Saudi Arabia. Data was collected using a validated 22-items self-report survey. RESULTS: For both COVID-19 vaccines, majority of reports were related to flu-like symptoms including fever, chills, headache, fatigue, tiredness, and myalgia. Statistically significant associations were observed between the severity of side effects and gender (Ï‡(2)=73.32; p<0.001), type of vaccine (Ï‡(2)=112.08; p<0.001), and presence of known allergies (Ï‡(2)=99.69; p<0.001). Female HCPs were more likely to report any side effects compared with male HCPs (adjusted odds ratio [AOR]: 3.72; p<0.001). Furthermore, HCPs with known allergies were more likely to report any side effects than their counterparts with unknown allergies (AOR: 16.29; p<0.001). CONCLUSION: The findings of the present study would help in designing educational programs aimed at combating the misconstrued fear of vaccination and highlighting the urgent need of getting vaccinated. This study also helps in the identification of factors affecting the presence and severity of side effects.

Incidence of Myopericarditis and Myocardial Injury in Coronavirus Disease 2019 Vaccinated Subjects. Several recent publications have described myopericarditis cases after the coronavirus disease 2019 (COVID-19) vaccination. However, it is uncertain if these cases occurred secondary to the vaccination or more common etiologies of myopericarditis. To help determine whether a correlation exists between COVID-19 vaccination and myopericarditis, the present study compared the gender-specific cumulative incidence of myopericarditis and myocardial injury in a cohort of COVID-19 vaccinated patients at a tertiary care center in 2021 with the cumulative incidence of these conditions in the same subjects exactly 2 years earlier. We found that the age-adjusted incidence rate of myopericarditis in men was higher in the vaccinated than the control population, rate ratio 9.7 (pÂ =Â 0.04). However, the age-adjusted incidence rate of myopericarditis in women was no different between the vaccinated and control populations, rate ratio 1.28 (pÂ =Â 0.71). We further found that the rate of myocardial injury was higher in both men and women in 2021 than in 2019 both before and after vaccination, suggesting that some of the apparent increase in the diagnosis of myopericarditis after vaccination may be attributable to factors unrelated to the COVID-19 vaccinations. In conclusion, our study reaffirms the apparent increase in the diagnosis of myopericarditis after COVID-19 vaccination in men but not in women, although this finding may be confounded by increased rates of myocardial injury in 2021. The benefits of COVID-19 vaccination to individual and public health clearly outweigh the small potential increased risk of myopericarditis after vaccination.

Immunogenicity of COVID-19 vaccines in patients with hematologic malignancies: a systematic review and meta-analysis. The objectives of this study were to assess the immunogenicity and safety of COVID-19 vaccines in patients with hematologic malignancies. A systematic review and meta-analysis of clinical studies of immune responses to COVID-19 vaccination stratified by underlying malignancy and published from January 1, 2021, to August 31, 2021, was conducted using MEDLINE, EMBASE, and Cochrane CENTRAL. Primary outcome was the rate of seropositivity after 2 doses of COVID-19 vaccine with rates of seropositivity after 1Â dose, rates of positive neutralizing antibodies, cellular

responses, and adverse events asÂ secondary outcomes. Rates were pooled from single-arm studies while rates of seropositivity were compared against the rate in healthy controls for comparator studies using a random effects model and expressed as a pooled odds ratios with 95% confidence intervals. Forty-four studies (16 mixed group, 28 disease specific) with 7064 patients were included in the analysis (2331 after first dose, 4733 after second dose). Overall seropositivity rates were 62% to 66% after 2 doses of COVID-19 vaccine and 37% to 51% after 1 dose. The lowest seropositivity rate was 51% in patients with chronic lymphocytic leukemia and was highest in patients with acute leukemia (93%). After 2 doses, neutralizing antibody response rates were 57% to 60%, and cellular response rates were 40% to 75%. Active treatment, ongoing or recent treatment with targeted and CD-20 monoclonal antibody therapies within 12 months were associated with poor immune responses to COVID-19 vaccine. New approaches to prevention are urgently required to reduce COVID-19 infection morbidity and mortality in high-risk patient groups that respond poorly to COVID-19 vaccination.

Factors associated with early receipt of COVID-19 vaccination and adherence to second dose in the Veterans Affairs healthcare system. BACKGROUND: We aimed to determine factors independently associated with early COVID-19 vaccination and adherence to two-dose regimens. METHODS: Among persons receiving care in the Veterans Affairs (VA) healthcare system (n = 5,766,638), we identified those who received at least one dose of COVID-19 vaccination through the VA, during the first ~3months following emergency use authorization, from December 11, 2020 to March 9, 2021 (n = 1,569,099, or 27.2%, including 880,200 (56.1%) Moderna, 676,279 (43.1%) Pfizer-BioNTech and 12,620 (0.8%) Janssen vaccines). RESULTS: Follow-up for receipt of vaccination began on December 11, 2020. After adjustment for baseline characteristics ascertained as of December 11, 2020, factors significantly associated with vaccination included older age, higher comorbidity burden, higher body mass index category, Black (vs. White) race (adjusted hazard ratio [AHR] 1.19, 95% CI 1.19-1.20), Hispanic (vs. non-Hispanic) ethnicity (AHR 1.12, 95% CI 1.11-1.13), urban (vs. rural) residence (AHR 1.31, 95% CI 1.31-1.31), and geographical region, while AI/AN race (vs. White), was associated with lower vaccination rate (AHR 0.85, 95% CI 0.84-0.87). Among persons who received both doses of Moderna or Pfizer-BioNTech vaccines, 95.3% received the second dose within Â±4 days of the recommended date. Among persons who received the first vaccine dose, only 3.2% did not receive the second dose within 42 days for Pfizer versus 4.0% for Moderna (p<0.001). Factors independently associated with higher likelihood of missing the second dose included younger age (10.83% in 18-50 yo vs. 2.72% in 70-75 yo), AI/AN race, female sex, rural location, geographical region and prior positive test for SARS-CoV-2. CONCLUSIONS: We identified sociodemographic and clinical factors that may be used to target vaccination efforts and to further improve adherence to second vaccine dosing.

Acute Abducens Nerve Palsy Following the Second Dose of the AstraZeneca COVID-19 Vaccine. The authors report the case of an otherwise healthy 65-year-old man who presented with an acute right abducens nerve palsy 3 days after receiving the second dose of the AstraZeneca coronavirus disease 2019 (COVID-19) vaccine. Abducens nerve palsies typically results from microvascular disease or compressive tumors, although they are known to arise following routine vaccinations. Given the lack of preexisting risk factors, normal computed tomography scan results, and the timing of the symptoms, the abducens nerve palsy was believed to be related to the vaccination. This report highlights the potential neurologic adverse effects associated with COVID-19 vaccines. [J Pediatr Ophthalmol Strabismus. 2021;58(6):e49-e50.].

Age-Dependent Reduction in Neutralization against Alpha and Beta Variants of BNT162b2 SARS-CoV-2 Vaccine-Induced Immunity. Vaccines against severe acute respiratory syndrome coronavirus-2 have been introduced. To investigate the relationship between vaccine-induced humoral immunity

and patient age, we measured antibody levels and neutralization in vaccinated sera. Sera from 13 to 17â€‰days after the second dose of the BNT162b2 vaccine were collected from health care workers at the University of Toyama (nâ€‰=â€‰740). Antibody levels were measured by the anti-receptor binding domain antibody test (anti-RBD test), and neutralization against wild-type (WT), Î±- and Î²-variant pseudotyped viruses were assayed using a high-throughput chemiluminescent reduction neutralizing test (htCRNT; positivity cutoff, 50% neutralization at serum dilution 1:100). Basic clinical characteristics were obtained from questionnaires. Antibodies were confirmed in all participants in both the anti-RBD test (median, 2,112 U/ml; interquartile range [IQR], 1,275 to 3,390 U/ml) and the htCRNT against WT (median % inhibition, >99.9; IQR, >99.9 to >99.9). For randomly selected sera (nâ€‰=â€‰61), 100.0% had positive htCRNT values against the Î±- and Î²-derived variants. Among those who answered the questionnaire (nâ€‰=â€‰237), the values of the anti-RBD test were negatively correlated with age in females ($P < 0.01$). An age-dependent decline in neutralization was observed against the variants but not against the wild-type virus (wild type, Pâ€‰=â€‰0.09; Î±, $P < 0.01$; Î², $P < 0.01$). The neutralizing activity induced by BNT162b2 was obtained not only against the wild-type virus, but also against the variants; however, there was an age-dependent decrease in the latter. Age-related heterogeneity of vaccine-acquired immunity is a concern in preventive strategies in the era dominated by variants. IMPORTANCE Since mRNA vaccines utilize wild-type SARS-CoV-2 spike protein as an antigen, there are potential concerns about acquiring immunity to variants of this virus. The neutralizing activity in BNT162b2-vaccinated individuals was higher against the wild-type virus than against its variants; this effect was more apparent in older age groups. This finding suggests that one of the weaknesses of the mRNA vaccine is the high risk of variant infection in the elderly population. Because the elderly are at a higher risk of SARS-CoV-2 infection, the age-dependent decline of neutralization against viral variants should be considered while planning vaccination programs that include boosters.

Myocarditis associated with COVIDâ€‘19 vaccination in three male teenagers.

Low clinical utility of testing for anti-platelet factor 4 in asymptomatic individuals after ChAdOx1 nCoV-19 vaccine. INTRODUCTION: The development of anti-platelet factor 4 (PF4) antibodies is linked to a rare thrombotic complication described now as vaccine-induced immune thrombotic thrombocytopenia (VITT). This clinical syndrome with thrombosis and thrombocytopenia was reported after exposure to the Oxford-AstraZeneca COVID-19 vaccine, ChAdOx1 nCoV-19 vaccine (AZD1222), and Ad26.COV2.S vaccine (Janssen/Johnson & Johnson). In the absence of the clinical features, the incidence of positive anti-PF4 antibodies in asymptomatic individuals post-vaccination is unclear. METHODS: The aim of this study was to evaluate the development of anti-PF4 antibodies in asymptomatic individuals 14-21Â days after receiving the first dose of ChAdOx1 nCoV-19 vaccine (AZD1222) and BNT162b2 vaccine. Prospectively, we collected serum from individuals before and after ChAdOx1 nCoV-19 vaccine and BNT162b2 vaccine and measured anti-PF4 antibodies using the Asserachrom HPIA IgG ELISA (Stago, Asnieres, France). RESULTS: We detected positive anti-PF4 antibodies in 5 of 94 asymptomatic individuals post-vaccine with a rate of 5.3% with low titers (OD 0.3-0.7). Four of 5 individuals who tested positive after the vaccine had also positive anti-PF4 antibodies before the vaccine, which indicates that a majority of the positive results are due to preexisting anti-PF4 antibodies. We did not find a relation between the development of anti-PF4 antibodies and the immune response to the vaccine, status of prior COVID-19 infection, and baseline characteristics of participants. None of the participants developed thrombosis nor thrombocytopenia. CONCLUSION: Our results provide new evidence to guide the diagnostic algorithm of suspected cases of VITT. In the absence of thrombosis and thrombocytopenia, there is a low utility of testing for anti-PF4 antibodies.

Early Immunogenicity and Safety of the Third Dose of BNT162b2 Messenger RNA Coronavirus Disease 2019 Vaccine Among Adults Older Than 60 Years: Real-World Experience. BACKGROUND: Despite high vaccine coverage, an increase in breakthrough coronavirus disease 2019 (COVID-19) infections, prompted administration of a third BNT162b2 dose to people aged >60 years in Israel since July 2021. Here, we report real-world immunogenicity following third dose. METHODS: Overall, 208 healthcare workers aged >60 years were included. Paired pre- and post-second and/or third dose immunoglobulin G (IgG) and neutralizing antibody titers were compared. A subpopulation of low responders to the second dose was also tested for T-cell activation. For 25 paired serum samples, we tested neutralization of wild-type vs neutralization of Delta and Lambda variants, pre- and post-third dose. Active surveillance of vaccine adverse events was conducted through surveys. RESULTS: A pronounced immune response was observed following the third dose, including a 33-fold and 51-fold increase in IgG and neutralizing antibody, respectively. The neutralizing antibody levels post-third dose were 9.34 times higher than post-second dose (geometric mean titer, 2598 [95% confidence interval {CI}, 2085-3237] vs 207 [95% CI, 126-339]). Nine previously low responders had a significant antibody increase post-third dose, and 7 of 9 showed increase in T-cell activation. Additionally, sera obtained post-third dose highly and comparably neutralized the wild-type and Delta and Lambda variants. Of 1056 responders to the adverse-event survey, none had serious events. CONCLUSIONS: We demonstrate a rapid and broad immune response to the third BNT162b2 dose in individuals >60 years of age.

Immune Responses to the ChAdOx1 nCoV-19 and BNT162b2 Vaccines and to Natural Coronavirus Disease 2019 Infections Over a 3-Month Period. BACKGROUND: There are limited data directly comparing immune responses to vaccines and to natural infections with coronavirus disease 2019 (COVID-19). This study assessed the immunogenicity of the BNT162b2 and ChAdOx1 nCoV-19 vaccines over a 3-month period and compared the immune responses with those to natural infections. METHOD: We enrolled healthcare workers who received BNT162b2 or ChAdOx1 nCoV-19 vaccines and patients with confirmed COVID-19 and then measured S1 immunoglobulin (Ig) G and neutralizing antibodies and T-cell responses. RESULTS: A total of 121 vaccinees and 26 patients with confirmed COVID-19 were analyzed. After the second dose, the BNT162b2 vaccine yielded S1 IgG antibody responses similar to those achieved with natural infections (mean IgG titer [standard deviation], 2241 [899] vs 2601 [5039]; Pâ€…=â€….68) but significantly stronger than responses to the ChAdOx1 vaccine (174 [96]; Pâ€…<â€….001). The neutralizing antibody titer generated by BNT162b2 was 6-fold higher than that generated by ChAdOx1 but lower than that by natural infection. T-cell responses persisted for 3 months with BNT162b2 and natural infection but decreased with ChAdOx1. CONCLUSIONS: Antibody responses after the second dose of BNT162b2 are higher than after the second dose of ChAdOx1 and like those occurring after natural infection. T-cell responses are maintained longer in BNT162b2 vaccinees than in ChAdOx1 vaccinees.

Myocarditis and pericarditis in adolescents after first and second doses of mRNA COVID-19 vaccines. AIMS: While some concerns about vaccination-related pericarditis and/or myocarditis have been raised, no published data are available on pericarditis and/or myocarditis with mRNA COVID-19 vaccines in the age group of adolescents, particularly 12-15 years. The objective of this study was to determine whether the risk of reporting pericarditis and/or myocarditis with mRNA COVID-19 vaccines varied according to dose of vaccination, age, sex, and type of pericarditis and/or myocarditis in adolescents between 12 and 17 years. METHODS AND RESULTS: We performed an observational study reviewing all reports of adolescents vaccinated with mRNA COVID-19 vaccines and recorded in VigiBaseÂ®, the World Health Organization global database of individual case safety reports. We included all reports registered between 1 January 2021 and 14 September 2021. Reporting odds ratios (RORs) with their 95% confidence interval (CI) were calculated to estimate the risk of reporting

pericarditis and/or myocarditis. Among 4942 reports with mRNA COVID-19 vaccines in adolescents, we identified 242 pericarditis and/or myocarditis. Compared with the first dose of mRNA COVID-19 vaccines, the second dose was associated with an increased risk of reporting pericarditis and/or myocarditis (ROR 4.95; 95% CI 3.14, 7.89). The risk of reporting pericarditis and/or myocarditis was 10 times higher in boys than in girls and no difference between the two types of vaccines could be demonstrated. CONCLUSION: This investigation including only adolescent data suggests for the first time that the second dose of mRNA COVID-19 vaccines increases the risk of reporting myocarditis/pericarditis compared with the first dose particularly in boys without significant difference between tozinameran and elasomeran.

Corrigendum to: Intravenous Injection of Coronavirus Disease 2019 (COVID-19) mRNA Vaccine Can Induce Acute Myopericarditis in Mouse Model.

Severe nonanaphylactic allergic reaction to the Pfizer-BioNTech COVID-19 vaccine.

Cervical longitudinally extensive myelitis after vaccination with inactivated virus-based COVID-19 vaccine. Myelitis, including longitudinally extensive transverse myelitis (LTEM), is reported in more than forty patients after coronavirus disease 2019 (COVID-19). Among COVID-19 vaccines, only Oxford-AstraZeneca COVID-19 vaccine (AZD1222) has been associated with few cases of myelitis (1 LTEM). We report the first case of myelitis/LTEM after BBIBP-CorV/Sinopharm vaccine, interestingly presented as a hemicord syndrome. A 71-year-old male presented with left-side diplegia, right-side hemihyposthesis with facial sparing and impaired position sensation in left foot after vaccination with BBIBP-CorV. MRI revealed a longitudinal signal in left cervical hemicord. This is the first reported myelitis and LTEM with COVID-19 vaccines other than AZD1222.

[De novo IgA nephropathy in a kidney transplant recipient after SARS-CoV-2 vaccination].

BNT162b2 vaccine induces divergent B cell responses to SARS-CoV-2 S1 and S2. The first ever US Food and Drug Administration-approved messenger RNA vaccines are highly protective against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)(1-3). However, the contribution of each dose to the generation of antibodies against SARS-CoV-2 spike (S) protein and the degree of protection against novel variants warrant further study. Here, we investigated the B cell response to the BNT162b2 vaccine by integrating B cell repertoire analysis with single-cell transcriptomics pre- and post-vaccination. The first vaccine dose elicits a recall response of IgA(+) plasmablasts targeting the S subunit S2. Three weeks after the first dose, we observed an influx of minimally mutated IgG(+) memory B cells that targeted the receptor binding domain on the S subunit S1 and likely developed from the naive B cell pool. This response was strongly boosted by the second dose and delivers potently neutralizing antibodies against SARS-CoV-2 and several of its variants.

Reactivation of IgA vasculitis following COVID-19 vaccination. A 23-year-old man presented to the acute assessment unit with acute-onset haematuria within 24 hours of receiving his second dose of the Pfizer-BioNTech COVID-19 vaccine. He had been diagnosed with IgA vasculitis 8 months previously. IgA vasculitis is an autoimmune condition characterised by palpable purpura affecting the lower limbs, abdominal pain, arthralgia and renal disease. He was diagnosed with an acute exacerbation of IgA vasculitis and was discharged with oral prednisolone. Reactivation or first presentation of IgA vasculitis is a rare but increasingly recognised complication of COVID-19 vaccination. This is an important new differential in the assessment of patients with haematuria following COVID-19 vaccination.

Miller-Fisher Syndrome and Guillain-Barre Syndrome overlap syndrome in a patient post Oxford-AstraZeneca SARS-CoV-2 vaccination. We describe a patient who developed bilateral oculomotor nerve palsy, ataxia, facial diplegia and lower limb weakness 2â€‰weeks post-Oxford-AstraZeneca SARS-CoV2 vaccination, consistent with Miller-Fisher syndrome (MFS) and Guillain-Barre syndrome (GBS) overlap syndrome. Although some features of the patient's presentation were typical of

recently reported cases of a rare GBS variant post-Oxford-AstraZeneca vaccination, including severe facial weakness and a lack of respiratory involvement, to our knowledge this is the first reported case of MFS associated with SARS-CoV2 vaccination. While postvaccination GBS remains rare, it appears to have a favourable prognosis, and recognising this entity is therefore important for patient counselling and monitoring for potential complications.
Multimodality imaging and histopathology in a young man presenting with fulminant lymphocytic myocarditis and cardiogenic shock after mRNA-1273 vaccination. A 38-year-old man presented with several days of chest pain and shortness of breath 8 days after receiving the first dose of an mRNA-1273 vaccine. The patient was found to have new left ventricular ejection fraction of 10% in the setting of hypotension and cardiogenic shock requiring mechanical support with an axial flow catheter pump. The presentation was concerning for acute fulminant myocarditis secondary to an inflammatory response from the recent mRNA-1273 vaccine. The patient was treated with pulse dose steroids for 3 days, ultimately leading to haemodynamic recovery and removal of mechanical circulatory support. Endomyocardial biopsy was performed and showed focal lymphocytic interstitial infiltrate with myocyte damage consistent with lymphocytic myocarditis. The patient had improvement of cardiac function which was seen on serial imaging.
European Pediatric Societies Call for an Implementation of Regular Vaccination Programs to Contrast the Immunity Debt Associated to Coronavirus Disease-2019 Pandemic in Children.
Association of clinical and epidemiological characteristics with COVID-19 BNT162b2 mRNA vaccine short-term adverse reactions in healthcare workers. INTRODUCTION: The aim of the study was to investigate the prevalence and severity of adverse reactions (ARs) after immunization of healthcare workers (HCWs) with BNT162b2 vaccine and to associate them with clinical and epidemiological characteristics. METHODS: A form containing demographic and clinical data as well as ARs after both doses of the vaccine was completed, and statistical association analysis was performed. RESULTS: A total of 502 HCWs (females 78.3%) with mean age (Â±SD) 48.17Â years (Â±12.97) participated. After the first dose, 404 (80.5%) HCWs reported at least one local AR (LAR) and 366 (72.9%) after the second dose (p-value=0.004). After the first dose, 121 (24.1%) HCWs reported at least one systemic AR (SAR) and 275 (54.8%) after the second dose (p-value<0.0001).In the logistic regression analysis, there was no association of gender or medical history of underlying disease with LARs. There was a negative association of age with the cumulative score (CS) of LARs (OR: 0.82, 95% CI: 0.69-0.96) after the first dose. Females had a positive association with CS of SARs following both doses (OR, 95% CI: 2.57, 1.39-4.73 and 2.71, 1.76-4.19, respectively). Age was negatively associated with CS of SARs (OR: 0.66, 95% CI: 0.57-0.76) after the second dose. Severe ARs included Bell's palsy (1) and tinnitus with temporary hearing loss (1). CONCLUSION: The administration of the BNT162b2 vaccine in our HCWs cohort had a good safety profile with the most common ARs being self-limited. An increasing rate of SARs following the second vaccine dose was noticed. Rare but severe possible ARs should be further investigated.
Fatal exacerbation of ChadOx1-nCoV-19-induced thrombotic thrombocytopenia syndrome after initial successful therapy with intravenous immunoglobulins - a rational for monitoring immunoglobulin G levels.
COVID-19 Vaccination in Kidney Transplant Recipients: An Ounce Pre-Transplant is Worth a Pound Post-Transplant.
Longitudinal humoral response after SARS-CoV-2 vaccination in ocrelizumab treated MS patients: To wait and repopulate? OBJECTIVE: The objective of this study was to measure humoral responses after SARS-CoV-2 vaccination in MS patients treated with ocrelizumab (OCR) compared to MS patients without disease modifying therapies (DMTs) in relation to timing of vaccination and B-cell count. METHODS: OCR treated patients were divided into an early and a late group (cut-off time 12

weeks between infusion and first vaccination). Patients were vaccinated with mRNA-1273 (Moderna). B-cells were measured at baseline (time of first vaccination) and SARS-CoV-2 antibodies were measured at baseline, day 28, 42, 52 and 70. RESULTS: 87 patients were included (62 OCR patients, 29 patients without DMTs). At day 70, seroconversion occurred in 39.3% of OCR patients compared to 100% of MS patients without DMTs. In OCR patients, seroconversion varied between 26% (early group) to 50% (late group) and between 27% (low B-cells) to 56% (at least 1 detectable B-cell/ÂµL). CONCLUSIONS: Low B-cell counts prior to vaccination and shorter time between OCR infusion and vaccination may negatively influence humoral response but does not preclude seroconversion. We advise OCR treated patients to get their first vaccination as soon as possible. In case of an additional booster vaccination, timing of vaccination based on B-cell count and time after last infusion may be considered.
Autoimmune encephalitis following ChAdOx1-S SARS-CoV-2 vaccination.
COVID-19 vaccinations: The unknowns, challenges, and hopes. The entire world has been suffering from the coronavirus disease 2019 (COVID-19) pandemic since March 11, 2020. More than a year later, the COVID-19 vaccination brought hope to control this viral pandemic. Here, we review the unknowns of the COVID-19 vaccination, such as its longevity, asymptomatic spread, long-term side effects, and its efficacy on immunocompromised patients. In addition, we discuss challenges associated with the COVID-19 vaccination, such as the global access and distribution of vaccine doses, adherence to hygiene guidelines after vaccination, the emergence of novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants, and vaccine resistance. Despite all these challenges and the fact that the end of the COVID-19 pandemic is still unclear, vaccines have brought great hope for the world, with several reports indicating a significant decline in the risk of COVID19-related infection and hospitalizations.
Multiple cranial nerve palsies and COVID-19 vaccination.
Cardiovascular Complications of SARS-CoV-2 Vaccines: An Overview. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the cause of the deadly disease known as coronavirus disease 2019 (COVID-19) that has reached pandemic proportions. Currently, there is no definitive treatment for COVID-19, although many vaccines have been developed. The World Health Organization has approved the safety and efficacy of the AstraZeneca/Oxford, Johnson and Johnson/Janssen (JnJ), Moderna, Pfizer/BioNTech, Sinopharm, and Sinovac vaccines so far. The approved formulations of AstraZeneca, JnJ, and Gam-COVID-vac (Sputnik V) contain DNA delivered within non-replicating recombinant adenovirus vector-based systems, while the Pfizer and Moderna vaccines utilize mRNA technology and lipid nanoparticle delivery systems. All of these vaccines encode production of the SARS-CoV-2 spike (S) protein, ultimately triggering immunity in the human body. COVID-19 causes several cardiovascular complications, such as arrhythmias, myocarditis, pericarditis, and venous thromboembolism. SARS-CoV-2 vaccines have been associated with rare, but sometimes fatal, cardiovascular side effects, which are the topics of this review. SARS-CoV-2 vaccines in general may cause thromboembolic events, such as cerebral vein thrombosis, and mRNA-based vaccines in particular may cause myocarditis/pericarditis, with the latter more likely to occur in younger adults after the second vaccination dose. Nevertheless, the advantages of these vaccines for ending the pandemic and/or decreasing the mortality rate outweigh any risk for the rare cardiovascular complications.
Undetectable SARS-CoV-2 active adaptive immunity-post-vaccination or post-COVID-19 severe disease-after immunosuppressants use. Since the beginning of COVID-19 vaccination in New Jersey in December 2020, we have observed multiple cases of undetectable adaptive immunity, post-vaccination or post-COVID-19 infection, in patients using immunosuppressants. Here, we present three cases of patients using immunosuppressants: mycophenolate and tacrolimus for renal

transplant; ocrelizumab for multiple sclerosis and rituximab for peripheral ulcerative keratitis. All three patients were admitted for acute respiratory distress syndrome (ARDS) from COVID-19 pneumonia; two patients reported having received full COVID-19 vaccination prior to admission and one unvaccinated patient required readmission. Our findings showed that these patients tested negative for SARS-CoV-2 IgM spike and CoV-2 IgG nucleocapsid antibodies. All three patients were treated with standard-of-care remdesivir, dexamethasone and convalescent plasma; two recovered successfully and one patient died from respiratory failure secondary to worsening ARDS from COVID-19 pneumonia. We highlight the challenges of treating immunosuppressed patients with COVID-19 pneumonia, in an era where dissemination of such information is paramount to helping doctors standardise and improve the quality of care for these patients.

Vaccinal antibodies: Fc antibody engineering to improve the antiviral antibody response and induce vaccine-like effects. The coronavirus disease 2019 (COVID-19) pandemic highlights the urgent clinical need for efficient virus therapies and vaccines. Although the functional importance of antibodies is indisputable in viral infections, there are still significant unmet needs that require vast improvements in antibody-based therapeutics. The IgG Fc domain can be engineered to produce antibodies with tailored and potent responses that will meet these clinical demands. Engaging Fc receptors (FcRs) to perform effector functions as cytotoxicity, phagocytosis, complement activation, intracellular neutralization and controlling antibody persistence. Furthermore, it produces vaccine-like effects by activating signals to stimulate T-cell responses, have proven to be required for protection, as neutralization alone does not off the full protection capacity of antibodies. This review highlights antiviral Fc functions and FcRs' contributions in linking innate and adaptive immunity against viral threats. Moreover, it provides the latest Fc engineering strategies to improve the safety and efficacy of human antiviral antibodies and vaccines.

Differences in the case fatality risks associated with SARS-CoV-2 Delta and non-Delta variants in relation to vaccine coverage: An early ecological study in the United Kingdom. The circulation of SARS-CoV-2 Delta (i.e., B.1.617.2) variants challenges the pandemic control. Our analysis showed that in the United Kingdom (UK), the reported case fatality ratio (CFR) decreased from May to July 2021 for non-Delta variant, whereas the decreasing trends of the CFR of Delta variant appeared weak and insignificant. The association between vaccine coverage and CFR might be stratified by different circulating variants. Due to the limitation of ecological study design, the interpretation of our results should be treated with caution.

A case of unusual mild clinical presentation of COVID-19 vaccine-induced immune thrombotic thrombocytopenia with splanchnic vein thrombosis.

Correction to: Gross hematuria after SARS-CoV-2 vaccination: questionnaire survey in Japan.

Spectrum of Neuroimaging Findings in Post-COVID-19 Vaccination: A Case Series and Review of Literature. Background and Purpose: The novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first detected in Wuhan, China in December 2019. Symptoms range from mild flu-like symptoms to more severe presentations, including pneumonia, acute respiratory distress syndrome (ARDS), and even death. In response to the COVID-19 pandemic, the Emergency Use Authorization (EUA) approved the use of several vaccines. Because vaccines have been fast-tracked for emergency use, the short and long-term safety profile has been an area of concern. The aim of this paper is to extensively review published literature regarding post-COVID-19 vaccination neurological complications and characterize neuroimaging findings from three case presentations for early diagnosis and treatment. Methods: The analysis includes data from PubMed and Google Scholar. Articles included were retrieved from database inception beginning December 2020 with no language restrictions. Terms used include "SARS-CoV-2", "post Covid vaccination", "neurological complications", "Guillain-barre Syndrome", "Transverse-myelitis", "Cerebral Venous Sinus

thrombosis", and "Cerebral hemorrhage". Results: The literature review yielded several neurological complications post vaccination, including cerebral sinus venous thrombosis, transverse myelitis, Guillain-BarrÃ© Syndrome and optic neuritis, to name a few. Patient case presentation findings were consistent with documented results in published literature. Conclusions: We present a case series with a thorough literature review documenting adverse neurological affects following COVID-19 vaccination. Our case presentations and literature review highlight the importance of neuroimaging when diagnosing post-COVID-19 vaccination adverse effects. MRI imaging study is an important tool to be considered in patients presenting with post-COVID-19 vaccination-related unexplained neurological symptoms for accurate diagnosis.

Anti-SARS-CoV-2 mRNA vaccines as inducers of humoral response against apolipoprotein A-1? BACKGROUND: COVID-19 and some anti-SARS-CoV-2 vaccines trigger a humoral autoimmune response against a broad range of endogenous components, which may affect recipients' prognosis in predisposed individuals. Autoantibodies directed against apolipoprotein A-1 (AAA1 IgG) the major protein fraction of High Density Lipoprotein have been shown to be raised in COVID-19 and in rheumatoid arthritis (RA) patients and other populations where they have been associated with poorer outcomes. We wanted to assess the impact of anti-SARS-CoV-2 mRNA-based vaccination on AAA1 autoimmune biomarkers in RA patients. METHODS: 20 healthy controls and 77 RA mRNA-based vaccinated patients were collected at baseline, 3 weeks after the first vaccination, 2 and 8 weeks after the second vaccination. AAA1 and SARS-CoV-2 serologies were measured by immunoassays. Systemic and local symptoms occurring during the vaccination protocol were recorded. RESULTS: mRNA-based vaccination induced a significant increase in median AAA1 IgG levels in both healthy controls and RA patients overtime. However, in both populations, these medians trend did not translate into significant increase in AAA1 IgG seropositivity rates despite evolving from 5 to 10% in healthy controls, and from 9 to 12.9% in RA patients. No associations were retrieved between AAA1 IgG and symptoms of any kind during the vaccination protocol. CONCLUSIONS: mRNA-based vaccination seems to induce a light AAA1 IgG response in immunocompetent individuals within 2 months after the last injection. Although we did not observe any warning signs, the formal demonstration of the harmlessness of such biological warrants further studies.

Hybrid immunity versus vaccine-induced immunity against SARS-CoV-2 in patients with autoimmune rheumatic diseases.

An 88-year-old woman with acute disseminated encephalomyelitis following messenger ribonucleic acid-based COVID-19 vaccination. A global pandemic has resulted from the emergence of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (COVID-19). To control the spread of SARS-CoV-2 infection, several SARS-CoV-2 vaccines have been developed and administered in a wide range of age groups. Messenger ribonucleic acid (mRNA)-based COVID-19 vaccines are the most widely used. We present the case of an 88-year-old woman who was diagnosed with acute disseminated encephalomyelitis (ADEM) following her second mRNA COVID-19 vaccination. She was admitted to hospital with disturbed consciousness (Glasgow Coma Scale E1V1M4) and gaze-evoked nystagmus. Brain magnetic resonance imaging revealed bilateral presence of middle cerebellar peduncle sign. Following steroid pulse therapy, clinical symptoms improved. The occurrence of ADEM following COVID-19 vaccination does not question the importance of vaccination programs during the COVID-19 pandemic. COVID-19 vaccines have been administered to individuals of a wide range of ages, from children to older adults. Thus, ADEM could occur following COVID-19 vaccination at any age, although ADEM is rare in older adults.

Widespread cutaneous reaction to the Johnson & Johnson Ad26.COV2.S vaccine.

Physical Characteristics of Injection Site Pain After COVID-19 mRNA BNT162b2 Vaccination. BACKGROUND: BNT162b2, an mRNA COVID-19 vaccine, was launched in many countries as an

intramuscular vaccination for COVID-19 infection. Few studies have assessed the physical indications of pain at the immunization site. This study aimed to characterize pain at the injection site and investigate morphological attributes using ultrasound. METHODS: Forty-three of 211 healthcare workers who received a second dose of BNT162b2 between February 2021 and March 2021 were enrolled in the study. The mean age of the subjects was 40 years. We evaluated patients' pain at the injection site using the Numerical Rating Pain Scale (NRPS). We also assessed the thickness of the deltoid muscle fascia at the injection site by ultrasound. Bayesian robust correlation was employed to explore the relationship between the pain intensity scores and ultrasound measurements. RESULTS: All eligible subjects complained of pain at the injection site. A median pain onset of 8 hours post-vaccination and a median peak intensity score of 4 were reported. Onset of relief occurred after 2 days. Ultrasound images demonstrated a 2.5-fold increase in fascia thickness at the injection site without intramuscular echogenicity change in all subjects. A correlation was established between the NRPS score and the non-injection-to-injection-side ratio of fascia thickness at the injection site (rho = 0.66). CONCLUSION: A sore arm was the most prevalent side effect of BNT162b2 vaccination and could be attributed to temporal fasciitis.
Myocarditis Following a COVID-19 Messenger RNA Vaccination: A Japanese Case Series. COVID-19 vaccine-related myocarditis has been reported worldwide. We herein report two Japanese cases with suspected vaccine-related myocarditis. A 27-year-old man was admitted with chest pain 4 days after the second vaccination. An electrocardiogram (ECG) did not reveal any significant abnormalities. The second patient, a 37-year-old man, was admitted with chest pain 9 days after the first vaccination. His ECG exhibited ST-elevation in multiple leads. In both cases, cardiac magnetic resonance imaging findings were consistent with myocarditis. They recovered with symptomatic relief within a few days. These cases suggest that the benefit of COVID-19 vaccination exceeds the risk of vaccine-related myocarditis.
Unusual Site of Deep Vein Thrombosis After mRNA Coronavirus Disease-2019 (COVID-19) Vaccination.
Genital necrosis with cutaneous thrombosis after COVID-19 mRNA vaccination.
COVID-19: Update on Its Ocular Involvements, and Complications From Its Treatments and Vaccinations. The coronavirus disease 2019 (COVID-19) came under the attention of the international medical community when China first notified the World Health Organization of a pneumonia outbreak of then-unknown etiology in Wuhan in December 2019. Since then, COVID-19 caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has appalled the world by spreading at a pandemic speed. Although ophthalmologists do not directly engage in the clinical care of COVID-19 patients, the ophthalmology community has become aware of the close ties between its practice and the pandemic. Not only are ophthalmologists at heightened risk of SARS-CoV-2 exposure due to their physical proximity with patients in routine ophthalmic examinations, but SARS-CoV-2 possesses ocular tropism resulting in ocular complications beyond the respiratory tract after viral exposure. Furthermore, patients could potentially suffer from adverse ocular effects in the therapeutic process. This review summarized the latest literature to cover the ophthalmic manifestations, effects of treatments, and vaccinations on the eye to aid the frontline clinicians in providing effective ophthalmic care to COVID-19 patients as the pandemic continues to evolve.
Coronavirus disease 2019 and cardiovascular diseases: collateral damage? PURPOSE OF REVIEW: Cardiovascular involvement in coronavirus disease 2019 (COVID-19) is relatively common and portends an increased risk of morbidity and mortality. Manifestations of myocardial injury may exhibit significant overlap and result in diagnostic uncertainty. This review will summarize recent literature around cardiovascular complications of COVID-19. RECENT FINDINGS: Venous thromboembolism, atrial fibrillation, and type II myocardial infarction are observed commonly in COVID-19, while severe acute respiratory syndrome coronavirus 2 viral myocarditis remains quite

rare. Although infrequent, COVID-19 vaccination has been associated with myocarditis and pericarditis in young individuals. SUMMARY: Various forms of COVID-19-related myocardial injury have been associated with increased utilization of mechanical ventilation, hemodynamic deterioration, and mortality. Manifestations of myocardial injury in COVID-19 are varied, but share common drivers of illness including sequelae of sepsis, immune-mediated factors, and a prothrombotic state. Understanding the forms of myocardial injury in COVID-19 may aid in rapid diagnosis and treatment.

Epilepsy and the risk of severe coronavirus disease 2019 outcomes: A systematic review, meta-analysis, and meta-regression. BACKGROUND: Patients with epilepsy experience seizures, which have been reported to increase and worsen during the coronavirus disease (COVID-19) pandemic. However, the association between epilepsy and COVID-19 outcomes remains unclear. The aim of this study was to analyze whether patients with epilepsy have an increased risk of having poor COVID-19 outcomes. METHODS: We comprehensively evaluated potential articles extracted from the medRxiv, Europe PMC, and PubMed databases until June 30, 2021, using selected keywords. All published studies on epilepsy and COVID-19 were selected. We used the Review Manager 5.4 and Comprehensive Meta-Analysis 3 software for statistical analysis. RESULTS: Thirteen studies with 67,131 patients with COVID-19 were included in the analysis. Evaluation of the collated data revealed an association between epilepsy and increased severity of COVID-19 (OR, 1.69; 95%CI: 1.11-2.59; pâ€¯=â€¯0.010; I(2)â€¯=â€¯29%; random-effect modeling) and mortality from COVID-19 (OR, 1.71; 95%CI: 1.14-2.56; pâ€¯=â€¯0.010; I(2)â€¯=â€¯53%; random-effect modeling). The results also showed that the association between epilepsy and increased risk of developing severe COVID-19 is influenced by sex and neurodegenerative disease. CONCLUSIONS: The findings of this study suggest that patients with epilepsy are at risk of having poor COVID-19 outcomes. Patients with epilepsy need special attention and should be prioritized for administration of the COVID-19 vaccine. Registration details: PROSPERO (CRD42021264979).

A systematic review of cases of CNS demyelination following COVID-19 vaccination. BACKGROUND: Since the emergency use approval of different types of COVID-19 vaccines, several safety concerns have been raised regarding its early and delayed impact on the nervous system. OBJECTIVE: This study aims to systematically review the reported cases of CNS demyelination in association with COVID-19 vaccination, which has not been performed, to our knowledge. METHODS: A systematic review was performed by screening published articles and preprints of cases of CNS demyelination in association with COVID-19 vaccines in PubMed, SCOPUS, EMBASE, Google Scholar, Ovid and medRxiv databases, until September 30, 2021. This study followed PRISMA guidelines. Descriptive findings of reported cases were reviewed and stratified by demographic and clinical findings, diagnostic work-up, management, and overall outcome. RESULTS: A total of 32 cases were identified, with female predominance (68.8%) and median age of 44Â years. Eleven cases were reported after Pfizer vaccine, 8 following AstraZeneca vaccine, 6 following Moderna, 5 following Sinovac/ Sinopharm vaccines, and one following each of Sputnik and Johnson&Johnson vaccines. The majority of cases (71.8%) occurred after the first dose of the vaccine, with neurological symptoms manifesting after a median of 9Â days. The most common reported presentations were transverse myelitis (12/32) and MS-like pictures (first diagnosis or a relapse) in another 12/32 cases, followed by ADEM- like (5/32), and NMOSD- like (3/32) presentations. History of a previous immune-mediated disease was reported in 17/32 (53.1%) cases. The mRNA-based vaccines resulted in the greatest number of demyelinating syndromes (17/32), followed by viral vector vaccines (10/32), and inactivated vaccines (5/32). Most MS-like episodes (9/12) were triggered by mRNA-based vaccines, while TM occurred following both viral vector and mRNA-based vaccines. Management included high dose methylprednisolone, PLEX, IVIg, or a combination of those, with a favorable outcome in the

majority of case; marked/complete improvement (25/32) or stabilized/ partial recovery in the remaining cases. CONCLUSION: This systematic review identified few cases of CNS demyelination following all types of approved COVID-19 vaccines so far. Clinical presentation was heterogenous, mainly following the first dose, however, half of the reported cases had a history of immune-mediated disease. Favorable outcome was observed in most cases. We suggest long-term post-marketing surveillance for these cases, to assess for causality, and ensure the safety of COVID-19 vaccines.
Real-world safety data for the Pfizer BNT162b2 SARS-CoV-2 vaccine, historical cohort study' by Shasha et al.
Lack of effects on female fertility or pre- and postnatal development of offspring in rats after exposure to AS03-adjuvanted recombinant plant-derived virus-like particle vaccine candidate for COVID-19. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection resulting in the coronavirus disease 2019 (COVID-19) has afflicted tens of millions of people in a worldwide pandemic. A recently developed recombinant Plant-Derived Virus-Like Particle Vaccine candidate for COVID-19 (CoVLP) formulated with AS03 has been shown to be well-tolerated and highly immunogenic in healthy adults. Since the target population for the vaccine includes women of childbearing potential, the objective of the study was to evaluate any untoward prenatal and postnatal effects of AS03-adjuvanted CoVLP administered intramuscularly to Sprague-Dawley female rats before cohabitation for mating (22 and 8 days prior) and during gestation (Gestation Days [GD] 6 and 19). The embryo-fetal development (EFD) cohort was subjected to cesarean on GD 21 and the pre/post-natal (PPN) cohort was allowed to naturally deliver. Effects of AS03-adjuvanted CoVLP was evaluated on pregnant rats, embryo-fetal development (EFD), during parturition, lactation and the development of the F1 offspring up to weaning Vaccination with AS03-adjuvanted CoVLP induced an antibody response in F0 females and anti-SARS-CoV-2 spike-specific maternal antibodies were detected in the offspring at the end of the gestation and lactation periods. Overall, there was no evidence of untoward effects of AS03-adjuvanted CoVLP on the fertility or reproductive performance of the vaccinated F0 females. There was no evidence of untoward effects on embryo-fetal development (including teratogenicity), or early (pre-weaning) development of the F1 offspring. These results support the acceptable safety profile of the AS03-adjuvanted CoVLP vaccine for administration to women of childbearing potential.
Auricular acupressure for adverse events following immunization related to COVID-19 vaccine injection: study protocol for a multicenter, three-arm, blinded randomized controlled trial. BACKGROUND: Some pain, fatigue, and gastrointestinal adverse events were observed in potential association with injection of COVID-19 vaccines, while there was no preventive intervention for it. We aim to investigate the efficacy of auricular acupressure (AA) therapy in preventing and relieving AEFI after injection of COVID-19 vaccine. METHODS: The study design is a randomized, multicentre, three-arm controlled, single-blind trial. Participants meeting the inclusion criteria will be advertised and enrolled and assigned in the medical institutions randomly for post-injection observation. No less than 360 participants will be randomized into one of three groups: auricular acupressure group, sham auricular acupressure group, and wait-list group. Interventions will be performed immediately and will happen 4 to 5 times per day for 5â€‰days. The primary clinical outcomes will be quality and quantity evaluation among participants who reported any AEFI and who reported local pain at injection site. Secondary outcomes will concern headache, muscle and (or) joint pain, fatigue, nausea, vomiting, diarrhoea, and other potential events. All the outcomes will be assessed at baseline and 1, 3, 5, 7, and 14â€‰days after the injection. Both intention-to-treat and per-protocol analyses will be performed, with significance level determined as 5%. DISCUSSION: Results of this trial will help to clarify the value of auricular acupressure therapy in preventing and relieving overall and certain

adverse events following immunization after injection of COVID-19 vaccine. TRIAL REGISTRATION: China Clinical Trial Registry (ChiCTR) (ChiCTR2100043210). Registered on 8 February, 2021.

COVID-19 Vaccination Acceptance and Its Associated Factors among Cancer Patients in Tunisia. BACKGROUND: Vaccination is the most effective way to fight the COVID-19 pandemic and to protect people who have a higher risk of developing severe illness and death from COVID-19 such as cancer patients. We aimed in this study to determine the acceptance rate of COVID-19 vaccination of the Salah Azaiez Institute (SAI) of cancer of Tunisia patients and to identify its associated factors. METHODS: It was a cross sectional study about patients admitted to the SAI for treatment during the month of February 2021. Univariate and multivariate analyses were performed to identify factors associated with the COVID-19 vaccine acceptance among Tunisian cancer patients. RESULTS: A total of 200 patients were included in this study with a mean age of 54.4Â±12.7 years and a gender ratio of 0.5. Only 35.0% of surveyed patients reported their acceptance to receive the COVID-19 vaccine. Multivariate analysis showed that believing in COVID-19 vaccine safety and efficacy (OR=3.1 [1.3-7.4]), enrollment in the COVID-19 vaccine platform (OR=8.3 [1.8-38.1]) and the willingness to receive influenza vaccine (OR=3.9 [1.6-9.3]) were independently associated with the COVID-19 vaccine acceptance among SAI cancer patients. CONCLUSIONS: The COVID-19 vaccine acceptance rate found in this study was low. Communication strategies of the vaccination campaigns should provide clear, simple and detailed messages about the efficacy and the benefits of the COVID-19 vaccines. More engagement of health authorities to promote COVID-19 vaccination is necessary.

Cutaneous reactions to COVID-19 vaccine at the dermatology primary care. INTRODUCTION: Coronavirus disease 2019 (COVID-19) vaccines can cause adverse reactions, mainly from vaccine-induced immune responses. Some of these may also involve the skin and worry unaware patients. A better understanding of such adverse reactions may reduce concerns and help promote the vaccination of large population groups. METHODS: All the reports of patients admitted to our Dermatology Primary Care, from March 2021 to June 2021, were retrospectively examined to collect descriptive data on skin reactions arising after COVID-19 vaccination. RESULTS: Out of 200 vaccinated patients admitted to the Dermatology Primary Care, 21 (10.5%) referred cutaneous reactions with onset after vaccination. Only one patient required hospitalization for generalized bullous erythema multiforme, which occurred 48â€‰h after the second vaccine dose. The other patients' cutaneous reactions to vaccination were of mild/moderate degree. Three patients presented exacerbation of their cutaneous diseases. CONCLUSIONS: Cutaneous reactions observed in our sample were mostly mild or moderate. Awareness must be raised to recognize and treat eventual severe reactions. Future studies are needed to assess the incidence of cutaneous reactions following COVID-19 vaccination.

Spectrum of short-term inflammatory musculoskeletal manifestations after COVID-19 vaccine administration: a report of 66 cases.

Post-vaccination (COVID-19) impacts in healthcare personnel. The COVID-19 pandemic has brought attention back to its spread in medical staff. A survey-based study was conducted to combine general information related to COVID-19 exposures, acceptances, vaccines received, and side effects. The majority (62.3%) of healthcare professionals had acquired COVID-19 infection from hospital environment (51.5%) mainly who treated (64%) COVID-19 patients. 54% healthcare respondents expressed 'high acceptance' towards COVID-19 vaccines. 88% received COVID-19 vaccination. The majority of healthcare personnel received SinoPharm (65%). 82.3% did not acquire COVID-19 post-vaccination. 38% mild side effects were observed from vaccination. Following were the general side-effects: myalgia (18.2%), the feeling of sickness (16%), fever (15.6%), dizziness (7.8%), joint pain (7.4%), chills (4.8%), and flu (4.8%). Following were the common neurological side-effects reported: headache (18.2%), fatigue (16.5%), muscle pain (16%), numbness/tingling (3%), and migraine (2.6%). Nausea and diarrhoea were reported in only 3.5% of respondents. Bad taste was reported in only 3%

of respondents. The 1.7% reported rash and itching. The majority of the healthcare professionals did not report significant side effects related to neurological, gastroenterological, skin and oral categories. To assess the vaccines' potential for substantial and long-term or chronic effects, more study with a larger sample size and a longer follow-up time is required.

Mutations of SARS-CoV-2 spike protein: Implications on immune evasion and vaccine-induced immunity. Responsible for more than 4.9 million deaths so far, COVID-19, caused by SARS-CoV-2, is instigating devastating effects on the global health care system whose impacts could be longer for the years to come. Acquiring a comprehensive knowledge of host-virus interaction is critical for designing effective vaccines and/or drugs. Understanding the evolution of the virus and the impact of genetic variability on host immune evasion and vaccine efficacy is helpful to design novel strategies to minimize the effects of the emerging variants of concern (VOC). Most vaccines under development and/or in current use target the spike protein owning to its unique function of host receptor binding, relatively conserved nature, potent immunogenicity in inducing neutralizing antibodies, and being a good target of T cell responses. However, emerging SARS-CoV-2 strains are exhibiting variability on the spike protein which could affect the efficacy of vaccines and antibody-based therapies in addition to enhancing viral immune evasion mechanisms. Currently, the degree to which mutations on the spike protein affect immunity and vaccination, and the ability of the current vaccines to confer protection against the emerging variants attracts much attention. This review discusses the implications of SARS-CoV-2 spike protein mutations on immune evasion and vaccine-induced immunity and forward directions which could contribute to future studies focusing on designing effective vaccines and/or immunotherapies to consider viral evolution. Combining vaccines derived from different regions of the spike protein that boost both the humoral and cellular wings of adaptive immunity could be the best options to cope with the emerging VOC.

Parent intentions to vaccinate children with autism spectrum disorder against COVID-19. PURPOSE: The purpose of this study was to investigate associations between parent vaccine confidence and intention to have their child with autism vaccinated against COVID-19. DESIGN AND METHODS: A cross-sectional, web-based survey was conducted from May to July 2021 with parents of children with autism spectrum disorder (NÂ =Â 322) who were members of an integrated healthcare system in Southern California. RESULTS: Approximately 35% of parents intended to vaccinate their child against COVID-19. In adjusted models, positive vaccine beliefs-but not belief in vaccine harm, healthcare provider trust, or parent vaccination status-were associated with intention to vaccinate. CONCLUSIONS: Though parents usually trust recommendations from pediatric healthcare providers to make decisions about their child's health, these findings suggest that relying on trusted relationships alone may not be sufficient when discussing COVID-19 vaccines and that additional education to bolster vaccine confidence may be needed. PRACTICE IMPLICATIONS: Pediatric healthcare providers should reinforce the benefits of vaccines for parents who are undecided about COVID-19 vaccines for their children and provide education and evidence-based recommendations to parents who hold erroneous vaccine beliefs about risks, benefits, and current evidence, especially those related to autism.

COVID-19 vaccine-related axillary lymphadenopathy in breast cancer patients: Case series with a review of literature. PURPOSE: Lymphadenopathy (LAP) after COVID-19 vaccination in patients with a diagnosis of cancer has been challenging. We analyzed imaging and clinical features from early cases of axillary LAP in six COVID-19 vaccine recipients with a history of breast cancer. METHOD: Among the patients with a history of breast cancer and recent COVID-19 vaccine administration, six patients who showed isolated axillary LAP were gathered. Radiologic features were reviewed from breast ultrasound, chest computed tomography, and breast magnetic resonance imaging. Clinical and pathological information were obtained for analysis. RESULTS: The interval between ultrasound

detection of LAP and last COVID-19 vaccine administration ranged from 14 to 28 days (mean 21.67 days). Round shape of the lymph node and irregular cortex were noted in 2 and 0 cases, respectively. Mean maximum cortical thickness, length to width ratio and interval aggravation in maximum cortical thickening were 4.2 mm, 1.34, and 2.81-fold with cut-off value of 3 mm, 1.5, 2.0-fold, respectively. CONCLUSION: We observed axillary LAP ipsilateral to a recent vaccine administration persisting longer than what the Centers for Disease Control and Prevention announced. In our patients, COVID-19 vaccine-related LAP tended to show increased cortical thickness without cortical irregularity. Oncologist as well as radiologist should be familiar with the fact that COVID-19 vaccines, regardless of vaccine type or dosage, can frequently cause ipsilateral axillary LAP, showing some suspicious features more often than others, and can persist longer than anticipated so that both over- and underdiagnosis can be avoided. We report our observations in six patients and provide an exhaustive review of the published literature.

A meta-analysis of influenza vaccination following correspondence: Considerations for COVID-19. BACKGROUND: High vaccination rates are needed to protect against influenza and to end the COVID-19 pandemic. Health authorities need to know if supplementing mass communications with direct correspondence to the community would increase uptake. OBJECTIVES: The primary objective is to determine if sending a single written message directly to individuals increases influenza vaccine uptake, and a secondary objective is to identify any identified content shown to increase influenza vaccine uptake. METHODS: MEDLINE, Embase, Cochrane CENTRAL, PsycINFO, and PubMed were searched for RCTs testing a single correspondence for members of the community in OECD countries to obtain influenza vaccination. A meta-analysis with inverse-variance, random-effects modelling was used to estimate a mean, weighted risk ratio effect size measure of vaccine uptake. Studies were quality assessed and analysis was undertaken to account for potential publication bias. RESULTS: Twenty-eight randomized controlled trials were included, covering 45 interventions. Of the 45 interventions, 37 (82.2%) report an increase in influenza vaccination rates. A formal meta-analysis shows that sending a single written message increased influenza vaccine uptake by 16%, relative to the no contact comparator group (RRÂ =Â 1.16, 95% CI [1.13-1.20], ZÂ =Â 9.25, pÂ <Â .001). Analysis shows that the intervention is effective across correspondence type, age group, time, and location, and after allowing for risk of publication bias. LIMITATIONS: The generalizability of results across the OECD may be questioned. CONCLUSIONS AND IMPLICATIONS: The implication for public health authorities organizing vaccination programs for influenza, and arguably also for COVID-19, is that sending written vaccination correspondence to members of the community is likely to increase uptake. This study is pre-registered on osf.io; details can be found at https://osf.io/98mr7.

Unfolding the Mild to Moderate Short-Term Side Effects of Four COVID-19 Vaccines Used in Bahrain: A Cross-Sectional Study. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) created a global pandemic (COVID-19) that has resulted in massive health and economic losses. The current unavailability of treatments leaves vaccination as the only way to control this disease. There are four vaccines (Sinopharm, Pfizer-BioNTech, Sputnik, and AstraZeneca) available in Bahrain. This project aimed to study the most common side effects resulting from the first and second doses of these four vaccines. Data were collected through an online questionnaire answered by 311 individuals who received both doses of one of these four vaccines. The results of this study revealed that regardless of the vaccine identity, participants experienced more side effects from the second dose. Among the different side effects, pain at the site of injection was primarily observed after the first dose of the Pfizer vaccine (43%), which was followed by the AstraZeneca vaccine (31%). Moreover, fever was observed in participants after the first dose of the Sputnik vaccine (37%), while headache was mainly observed after the first dose of the Pfizer vaccine (32%). It is important to note that fatigue was observed after the first dose of all four vaccines but was reported by the highest proportion of

respondents in the Pfizer group (28%). Interestingly, there are some side effects, such as pain at the site of injection, that are correlated with fever (r = 0.909). Similarly, headache is correlated with fever (r = 0.801) and pain at the site of injection (r = 0.868). Overall, it was observed that recipients of the Sinopharm vaccine reported the mildest side effects among all four vaccines. The crucial finding of this study is that the first and second dosage post-vaccination side effects were modest and predictable with no occurrences of hospitalization; this information can assist in lessening vaccine apprehension.

Antibody Titer Kinetics and SARS-CoV-2 Infections Six Months after Administration with the BNT162b2 Vaccine. BACKGROUND: Studies reporting the long-term humoral response after receiving the BNT162b2 COVID-19 vaccine are important to drive future vaccination strategies. Yet, available literature is scarce. Covidiagnostix is a multicenter study designed to assess the antibody response in >1000 healthcare professionals (HCPs) who received the BNT162b2 vaccine. METHODS: Serum was tested at time-0 (T(0)), before the first dose, T(1), T(2,) and T(3), respectively, 21, 42, and 180 days after T(0). Antibodies against the SARS-CoV-2 nucleocapsid-protein were measured to assess SARS-CoV-2 infections, whereas antibodies against the receptor-binding domain of the spike protein were measured to assess the vaccine response. Neutralization activity against the D614G, B.1.1.7, and B.1.351 variants were also analyzed. RESULTS: Six months post-vaccination HCPs showed an antibody titer decrease of approximately 70%, yet, the titer was still one order of magnitude higher than that of seropositive individuals before vaccination. We identified 12 post-vaccination infected HCPs. None showed severe symptoms. Interestingly, most of them showed titers at T(2) above the neutralization thresholds obtained from the neutralization activity experiments. CONCLUSION: Vaccination induces a humoral response which is well detectable even six months post-vaccination. Vaccination prevents severe COVID-19 cases, yet post-vaccination infection is possible even in the presence of a high anti-S serum antibody titer.

Retinal Vascular Events after mRNA and Adenoviral-Vectored COVID-19 Vaccines-A Case Series. BACKGROUND: To describe cases of retinal vascular events shortly after administration of mRNA or adenoviral-vectored COVID-19 vaccines. DESIGN: Retrospective, multicenter case series. METHODS: Six cases of retinal vascular events shortly after receiving COVID-19 vaccines. RESULTS: A 38-year-old, otherwise healthy male patient presented with branch retinal arterial occlusion four days after receiving his second dose of SARS-CoV-2 vaccination with Comirnaty(Â®) (BioNTech(Â®), Mainz, Germany; Pfizer(Â®), New York City, NY, USA). An 81-year-old female patient developed visual symptoms twelve days after the second dose of SARS-CoV-2 vaccination with Comirnaty(Â®) and was diagnosed with a combined arterial and venous occlusion in her right eye. A 40-year-old male patient noticed blurry vision five days after his first dose of SARS-CoV-2 vaccination with Comirnaty(Â®) and was diagnosed with venous stasis retinopathy in his left eye. A 67-year-old male was diagnosed with non-arteritic anterior ischemic optic neuropathy in his right eye four days after receiving the first dose of Vaxzevria(Â®) (AstraZeneca(Â®), Cambridge, UK). A 32-year-old man presented with a sudden onset of a scotoma two days after receiving the second dose of SARS-CoV-2 vaccination with Spikevax(Â®) (Moderna, Cambridge, UK) and was diagnosed with a circumscribed nerve fiber infarction. A 21-year-old female patient developed an acute bilateral acute macular neuroretinopathy three days after receiving the first dose of SARS-CoV2-vaccine Vaxzevria(Â®) (AstraZeneca(Â®), Cambridge, UK). CONCLUSION: This case series describes six cases of retinal vascular events shortly after receiving mRNA or adenoviral-vectored COVID-19 vaccines. The short time span between received vaccination and occurrence of the observed retinal vascular events raises the question of a direct correlation. Our case series adds to further reports of possible side effects with potential serious post-immunization complications of COVID-19 vaccinations.

Complicated Long Term Vaccine Induced Thrombotic Immune Thrombocytopenia-A Case Report. BACKGROUND AND OBJECTIVES: Vaccine induced thrombotic thrombocytopenia (VITT) may occur after COVID-19 vaccination with recombinant adenoviral vector-based vaccines. VITT can present as cerebral sinus and venous thrombosis (CSVT), often complicated by intracranial hemorrhage. Today it is unclear, how long symptomatic VITT can persist. Here, we report the complicated long-term course of a VITT patient with extremely high titers of pathogenic anti-platelet factor 4 (PF4)-IgG antibodies. METHODS: Clinical and laboratory findings are presented, including the course of platelet counts, D-Dimer levels, clinical presentation, imaging, SARS-CoV-2-serological and immunological, platelet activating anti-PF4-IgG, as well as autopsy findings. RESULTS: The patient presented with extended superior sagittal sinus thrombosis with accompanying bifrontal intracerebral hemorrhage. Repeated treatment with intravenous immune globuline (IVIG) resolved recurrent episodes of thrombocytopenia. Moreover, the patient's serum remained strongly positive for platelet-activating anti-PF4-IgG over three months. After a period of clinical stabilization, the patient suffered a recurrent and fatal intracranial hemorrhage. CONCLUSIONS: Complicated VITT with extremely high anti-PF4-IgG titers over three months can induce recurrent thrombocytopenia despite treatment with IVIG and anticoagulation. Plasma exchange, immunoadsorption, and /or immunosuppressive treatment may be considered in complicated VITT to reduce extraordinarily high levels of anti-PF4-IgG. Long-term therapy in such cases must take the individual bleeding risk and CSVT risk into account.

Effect of COVID-19 on Anti-S Antibody Response in Healthcare Workers Six Months Post-Vaccination. The current study aimed to determine to what extent prior COVID-19 infection affects the response of specific antibodies following vaccination. The study involved 173 healthcare professionals who completed the two-dose vaccination course with BNT162b2, including 40 who previously experienced clinical COVID-19. The levels of anti-SARS-CoV-2 S1S2 IgG (anti-S) and, in some cases, anti-SARS-CoV-S-RBD IgG (anti-S-RBD) were determined six months after complete vaccination. A level exceeding the cut-off values for both anti-S and anti-S-RBD was observed in 100% of subjects, but after setting the analysis to 5- and 10-fold cut-off levels, the percentage of subjects meeting this criterion was significantly higher for anti-S-RBD. The 100-fold cut-off level was achieved by only 21% and 16% for anti-S and anti-S-RBD, respectively. Anti-S and anti-S-RBD levels above ten times the positive cut-off were respectively observed in 91% and 100% individuals with a history of COVID-19, while among those without COVID-19, these values were 64% and 90%, respectively. Significantly higher incidence of values above 10 and 100 times the cut-off became apparent among people with a history of COVID-19. In conclusion, vaccination against COVID-19 following infection with the disease provides higher levels of specific antibodies 6 months after vaccination than those of individuals without a history of the disease, which supports the use of a booster dose, particularly for those who have not experienced SARS-CoV-2 infection.

Thrombotic Adverse Events Reported for Moderna, Pfizer and Oxford-AstraZeneca COVID-19 Vaccines: Comparison of Occurrence and Clinical Outcomes in the EudraVigilance Database. Vaccination against COVID-19 is the cornerstone of controlling and mitigating the ongoing pandemic. Thrombotic adverse events linked to Moderna, Pfizer and the Oxford-AstraZeneca vaccine have been documented and described as extremely rare. While the Oxford-AstraZeneca vaccine has received much of the attention, the other vaccines should not go unchallenged. This study aimed to determine the frequency of reported thrombotic adverse events and clinical outcomes for these three COVID-19 vaccines, namely, Moderna, Pfizer and Oxford-AstraZeneca. A retrospective descriptive analysis was conducted of spontaneous reports for Moderna, Pfizer and Oxford-AstraZeneca COVID-19 vaccines submitted to the EudraVigilance database in the period from 17 February to 14 June 2021. There were 729,496 adverse events for the three vaccines, of which 3420 were thrombotic, mainly Oxford-

AstraZeneca (n = 1988; 58.1%) followed by Pfizer (n = 1096; 32.0%) and Moderna (n = 336; 9.8%). As serious adverse events, there were 705 reports of pulmonary embolism for the three vaccines, of which 130 reports (18.4%) were for Moderna, 226 reports (32.1%) for Pfizer and 349 (49.5%) for Oxford-AstraZeneca vaccines. The occurrence of pulmonary embolism is significantly associated with a fatal outcome (p â‰¤ 0.001). Sixty-three fatalities were recorded (n = 63/3420; 1.8%), of which Moderna (n = 6), Pfizer (n = 25) and Oxford-AstraZeneca (n = 32).

Association between COVID-19 Vaccine Side Effects and Body Mass Index in Spain. COVID-19 vaccines have shown high efficacy, with most side effects being mild-moderate and more frequently reported by females and people at younger ages. Since no studies have assessed the impact that weight status could have on the reported adverse reactions, we aim to study the association between weight status and reported side effects. We included data on 2136 adults from an online survey conducted from 6 May to 9 June 2021. The questionnaire was filled in by participants over Google forms. Generalized Linear Mixed Models were used. A higher risk of presenting fever â‰¥38Â°, vomiting, diarrhea and chills was found in those with a non-overweight status compared to those overweight after adjusting for age, sex, education, medication to prevent/relieve post-vaccination effects and vaccine administered. When adjusting, most of the significant effects, in the association between side effects of the COVID-19 vaccine and weight status, did not remain significant. In conclusion, a non-overweight status was associated with a higher risk of presenting fever â‰¥38Â°, vomiting, diarrhea and chills compared to those overweight. Nevertheless, most of the reported side effects to COVID-19 vaccine were not associated with a higher risk of presenting more adverse effects, and individual differences were determined by sex and age.

Optimizing a Protocol to Assess Immune Responses after SARS-CoV-2 Vaccination in Kidney-Transplanted Patients: In Vivo DTH Cutaneous Test as the Initial Screening Method. Previously, the delayed-type hypersensitivity (DTH) cutaneous test with the spike protein of SARS-CoV-2 has been shown to be a simple in vivo method to measure T-cell functionality after natural infection and in vaccinated individuals. METHODS: Twenty-five kidney-transplanted recipients were immunized with two doses of the mRNA-based Pfizer-BioNTech COVID19 vaccine three weeks apart. Cell-immune response (CIR) was evaluated ten weeks later using an in vivo DTH skin test and in vitro with an interferon gamma release assay (IGRA). Humoral Immune Response (HIR) was determined by the measurement of specific IgG anti-S1 SARS-CoV-2. RESULTS: Ten weeks after the second dose of the vaccine, 23 out of 25 transplanted patients had a positive DTH skin test, while in vitro CIR was considered positive in 20 patients. Unspecific stimulation was positive in all 25 patients, showing no T-cell defect. Seven out of twenty-five patients had a negative specific anti-spike IgG. CIR was positive in all immune-competent control patients. CONCLUSIONS: DTH is a useful, simple, and cheaper tool that can be used to assess cellular immune response, with an excellent correlation with the in vitro CIR. CIR assessment after vaccination in these immunocompromised patients is an excellent complement to HIR-based methods. This skin test could be used if classical in vitro methods cannot be applied.

First Report of Two Cases of LÃ¶fgren's Syndrome after SARS-CoV-2 Vaccination-Coincidence or Causality? Sarcoidosis can present as an acute form or take a chronic course. One of the acute presentations is LÃ¶fgren's syndrome (LS), consisting of the symptom triad of bilateral hilar lymphadenopathy, erythema nodosum, and ankle periarthritis. In addition, there are occasional reports of sarcoid-like reactions following drug exposures. Nevertheless, reports of sarcoidosis or LS after vaccination have not been published. Here, we report two cases of de novo LS in a temporal association with different vaccines against the new coronavirus SARS-CoV-2. One patient developed the first symptoms three days after the second vaccination (first vaccination ChadOx-1, Astra Zeneca; second vaccination CX-024414, Moderna); in the second patient, symptoms started 28 days after the

first vaccination (ChadOx-1, Astra Zeneca). Both patients eventually required treatment with glucocorticoids. Both patients achieved clinical improvement with treatment. In conclusion, we report the first two cases of LS shortly after SARS-CoV-2 vaccination.

Thrombotic Events after COVID-19 Vaccination in the Over-50s: Results from a Population-Based Study in Italy. Several European countries suspended or changed recommendations for the use of Vaxzevria (AstraZeneca) for suspected adverse effects due to atypical blood-clotting. This research aims to identify a reference point towards the number of thrombotic events expected in the Italian population over 50 years of age who received Vaxzevria from 22 January to 12 April 2021. The venous thromboembolism (VT) and immune thrombocytopenia (ITP) event rates were estimated from a population-based cohort. The overall VT rate was 1.15 (95% CI 0.93-1.42) per 1000 person-years, and the ITP rate was 2.7 (95% CI 0.7-11) per 100,000 person-years. These figures translate into 83 and two expected events of VT and ITP, respectively, in the 15 days following the first administration of Vaxzevria. The number of thrombotic events reported from the Italian Medicines Agency does not appear to have increased beyond that expected in individuals over 50 years of age.

Prevalence and Factors Associated with Parents' Non-Intention to Vaccinate Their Children and Adolescents against COVID-19 in Latin America and the Caribbean. We aimed to estimate the prevalence and factors associated with parents' non-intention to vaccinate their children and adolescents against COVID-19 in Latin America and the Caribbean (LAC). We performed a secondary analysis using a database generated by the University of Maryland and Facebook (Facebook, Inc., Menlo Park, CA, USA). We included adult (18 and over) Facebook users residing in LAC who responded to the survey between 20 May 2021 and 14 July 2021. We included sociodemographic characteristics, comorbidities, mental health, economic and food insecurity, compliance with mitigation strategies against COVID-19, and practices related to vaccination against this disease. We estimated the crude (cPR) and adjusted (aPR) prevalence ratios with their respective 95%CI. We analyzed a sample of 227,740 adults from 20 LAC countries. The prevalence of parents' non-intention to vaccinate their children and adolescents against COVID-19 was 7.8% (n = 15,196). An age above 35 years old, educational level above college, compliance with physical distancing, use of masks, having economic insecurity, having had COVID-19, anxiety symptoms, depressive symptoms, having a chronic condition or two or more comorbidities, and being vaccinated were associated with a lower prevalence of non-intention to vaccinate children and adolescents against COVID-19. Living in a town, a village, or a rural area was associated with a higher prevalence of non-intention to vaccinate children and adolescents against COVID-19. Approximately nine out of ten parents in LAC intended to vaccinate their children and adolescents against COVID-19. Our results allow for understanding parents' intentions to vaccinate children and adolescents and help promote and develop education strategies for national vaccination plans against COVID-19.

Side Effects of COVID-19 Pfizer-BioNTech mRNA Vaccine in Children Aged 12-18 Years in Saudi Arabia. Background: Massive vaccination campaigns have been undertaken globally to combat the spread of the Coronavirus Disease 2019 (COVID-19). While most COVID-19 vaccines have shown excellent efficacy and safety profiles in clinical studies, real-world monitoring of vaccine safety is still important. In this study, we aimed to investigate the early side effects of Pfizer-BioNTech (BNT162b2) mRNA vaccine in children between 12-18 years old in Saudi Arabia. Method: To investigate the side effects in children in this age range following the administration of either one or two doses of Pfizer-BioNTech (BNT162b2) mRNA vaccine, we conducted a retrospective, cross-sectional study using a self-administered online survey. General and demographic data were collected, and vaccine-associated side effects following vaccination were evaluated. Results: The study recruited a total of 965 eligible participants. Overall, 571 (60%) of the study participants reported at least one side effect following Pfizer-BioNTech (BNT162b2) mRNA vaccination. The most frequently reported side effects

were pain or redness at the site of injection (90%), fatigue (67%), fever (59%), headache (55%), nausea or vomiting (21%), and chest pain and shortness of breath (20%). Joint or bone pain were reported less frequently among our participants (2%). Our data showed that more female participants reported side effects compared to male participants, with 52% and 48%, respectively. Side effects were more common after the second dose compared to the first dose in our study cohort. Conclusions: While 60% of the children (12-18 years old) who received Pfizer-BioNTech (BNT162b2) mRNA vaccine reported side effects, our data showed that these side effects were not different from those that were reported in the clinical trials which lasted only for a few days. Side effects were more common after the second dose. Larger epidemiological and molecular studies are needed to evaluate the safety and the effectiveness of COVID-19 vaccine in protection of children against SARS-CoV-2 reinfections.

Dual Corneal-Graft Rejection after mRNA Vaccine (BNT162b2) for COVID-19 during the First Six Months of Follow-Up: Case Report, State of the Art and Ethical Concerns. Present mass vaccination against Coronavirus Disease-19 (COVID-19) is the most widely used health policy and the most promising approach to curb the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic globally. However, new side effects are emerging from the mass vaccination not described during the experimental stages. In the present study, we discuss a case of acute corneal graft rejection, which has occurred 25 years after transplantation and 13 days after the administration of the BNT162b2 vaccine (Comirnaty, BioNTech/Pfizer), which was followed-up for a period of six months. In this period, the corneal inflammation appeared twice but was successfully managed with topical therapy and supplementation of Vitamin D. A risk of corneal graft rejection must be included in the list of potential vaccine complications, in order to inform the transplanted patient to undergo a preliminary and a follow-up ocular examination, and eventually to include corneal graft in the list of contraindications to vaccination.

New-Onset and Relapsed Kidney Histopathology Following COVID-19 Vaccination: A Systematic Review. INTRODUCTION: The introduction of COVID-19 vaccination programs has become an integral part of the major strategy to reduce COVID-19 numbers worldwide. New-onset and relapsed kidney histopathology have been reported following COVID-19 vaccination, sparking debate on whether there are causal associations. How these vaccines achieve an immune response to COVID-19 and the mechanism that this triggers kidney pathology remains unestablished. We describe the results of a systematic review for new-onset and relapsed kidney histopathology following COVID-19 vaccination. METHODS: A systematic literature search of published data up until 31 August 2021 was completed through the Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) guideline. Research articles reporting new onset or relapsed kidney histopathology in adult patients (>18 years) following COVID-19 vaccination were included for qualitative review. Only full-text articles published in the English language were selected for review. RESULTS: Forty-eight cases from thirty-six articles were included in the qualitative synthesis of this systematic review. Minimal change disease (19 cases) was the most frequent pathology observed, followed by IgA nephropathy (14 cases) and vasculitis (10 cases). Other cases include relapse of membranous nephropathy, acute rejection of kidney transplant, relapse of IgG4 nephritis, new-onset renal thrombotic microangiopathy, and scleroderma renal crisis following COVID-19 vaccination. There was no mortality reported in any of the included cases. Patients in all but one case largely recovered and did not require long-term renal replacement therapy. CONCLUSION: This systematic review provides insight into the relationship between various kidney pathologies that may have followed COVID-19 vaccination. Despite these reported cases, the protective benefits offered by COVID-19 vaccination far outweigh its risks. It would be recommended to consider early biopsy to identify histopathology

amongst patients presenting with symptoms relating to new-onset kidney disease following vaccination and to monitor symptoms for those with potential relapsed disease.

Kikuchi-Fujimoto Disease Post COVID-19 Vaccination: Case Report and Review of Literature. With the rapid development of various coronavirus disease 2019 (COVID-19) vaccines in a bid to counter and contain the COVID-19 pandemic, unusual and uncommon side effects of COVID-19 vaccination have been increasingly reported in the literature. Ipsilateral lymphadenopathy is a fairly common side effect of vaccination of any kind, with its etiology most commonly related to reactive lymphadenopathy. However, Kikuchi-Fujimoto Disease (KFD) or necrotizing histiocytic lymphadenitis is rarely observed post-vaccination, with only one other case of KFD post COVID-19 vaccination reported to date. We report two more cases of KFD post COVID-19 vaccination in the Asian population, highlighting the clinical course and salient clinical, radiological and histologic findings. In addition, we provide a literature review of the existing cases of lymphadenopathy post COVID-19 vaccination with cytologic and/or histologic correlation.

Pfizer-BioNTech and Sinopharm: A Comparative Study on Post-Vaccination Antibody Titers. COVID-19 (coronavirus disease 2019) vaccines induce immunity through different mechanisms. The aim of this study is to compare the titers of specific antibodies in subjects vaccinated with either the Pfizer-BioNTech COVID-19 vaccine or the Sinopharm vaccine. This prospective observational cohort included Jordanian adults vaccinated with two doses, 21 days apart, of either of the two aforementioned vaccines. Titers were collected 6 weeks after the administration of the second dose. Overall, 288 participants were included, of which 141 were administered the Pfizer-BioNTech vaccine, while 147 were administered the Sinopharm vaccine. Remarkably, 140 (99.3%) of the Pfizer-BioNTech vaccine recipients had positive IgG titers, while 126 (85.7%) of Sinopharm recipients had positive IgG ($p < 0.001$). The mean titer for IgG among Pfizer-BioNTech recipients was 515.5 Â± 1143.5 BAU/mL, compared to 170.0 Â± 230.0 BAU/mL among Sinopharm subjects ($p < 0.001$). Multivariable regression analysis showed that the Pfizer-BioNTech vaccine positively correlated with positive IgG titers (OR: 25.25; 95% CI: 3.25-196.15; $p = 0.002$), compared with a negative effect of cardiovascular diseases (OR: 0.33; 95% CI: 0.11-0.99; $p = 0.48$) on IgG titers. In conclusion, fully vaccinated recipients of the Pfizer-BioNTech vaccine had superior quantitative efficiency compared to Sinopharm recipients. A booster dose is supported for Sinopharm recipients, or those with chronic immunosuppressive diseases.

Severe but Self-Limiting Polyarthralgia with Functional Impairment Following ChAdOx1 nCov-19 Vaccination in an Elderly Recipient. A 79-year-old female patient with no pre-existing rheumatological conditions presented with severe functional impairment secondary to polyarthralgia, most likely an adverse reaction following her first dose of Oxford/AstraZeneca ChAdOx1 nCov-19 vaccination against SARS-CoV-2, the causative agent of Coronavirus Disease 2019 (COVID-19). The presentation mimicked clinical features of polymyalgia rheumatica and was distinctive in its pattern and delayed onset. Its severity in an elderly patient was significant against trial findings of decreasing reactogenicity of ChAdOx1 nCov-19 vaccine with increasing age, and traumatic to the patient. Acute phase reactants were elevated, consistent with recent similar reports among mostly elderly, female patients. New onset rheumatological conditions and flares of pre-existing, well-controlled conditions had been well established in COVID-19 and, to a lesser extent, post-vaccination. Viral arthralgias as a distinct clinical entity in COVID-19 is only beginning to be recognized. It could be that this case report represents a similar entity which occurs following vaccination against SARS-CoV-2. Despite this, the benefits of vaccination continue to outweigh such risks, although this case report is important for providing understanding of clinical progression when such reactions occur, aiding in patient discussions and clinical decisions to weigh up further investigations or empirical treatment against reassurance and close monitoring.

Sweet Syndrome Following SARS-CoV2 Vaccination. Vaccines are today considered one of the most effective means against the Sars-CoV-2 pandemic. The BNT162b2 vaccine by Pfizer/BioNTech has been massively administered throughout the globe; since its approval, a wide spectrum of cutaneous reactions has been reported. Here we report the case of a 52-year-old Caucasian male who presented with an acute febrile eruption that arose 72 h after the first dose of the BNT162b2 vaccine. The clinicopathological findings were consistent with Sweet's syndrome. The short latency time suggested a possible role of the vaccine in triggering Sweet's syndrome in this case.

Dynamics of Neutralizing Antibody Responses Following Natural SARS-CoV-2 Infection and Correlation with Commercial Serologic Tests. A Reappraisal and Indirect Comparison with Vaccinated Subjects. Neutralising antibodies (NAbs) represent the real source of protection against SARS-CoV-2 infections by preventing the virus from entering target cells. The gold standard in the detection of these antibodies is the plaque reduction neutralization test (PRNT). As these experiments must be done in a very secure environment, other techniques based on pseudoviruses: pseudovirus neutralization test (pVNT) or surrogate virus neutralization test (sVNT) have been developed. Binding assays, on the other hand, measure total antibodies or IgG, IgM, and IgA directed against one epitope of the SARS-CoV-2, independently of their neutralizing capacity. The aim of this study is to compare the performance of six commercial binding assays to the pVNT and sVNT. In this study, we used blood samples from a cohort of 62 RT-PCR confirmed COVID-19 patients. Based on the results of the neutralizing assays, adapted cut-offs for the binding assays were calculated. The use of these adapted cut-offs does not permit to improve the accuracy of the serological assays and we did not find an adapted cut-off able to improve the capacity of these tests to detect NAbs. For a part of the population, a longitudinal follow-up with at least two samples for the same patient was performed. From day 14 to day 291, more than 75% of the samples were positive for NAbs (n = 87/110, 79.1%). Interestingly, 6 months post symptoms onset, the majority of the samples (N = 44/52, 84.6%) were still positive for NAbs. This is in sharp contrast with the results we obtained 6 months post-vaccination in our cohort of healthcare workers who have received the two-dose regimens of BNT162b2. In this cohort of vaccinated subjects, 43% (n = 25/58) of the participants no longer exhibit NAbs activity 180 days after the administration of the first dose of BNT162b2.

Persistence of Neutralizing Antibodies to SARS-CoV-2 in First Wave Infected Individuals at Ten Months Post-Infection: The UnIRSA Cohort Study. Longitudinal mapping of antibody-based SARS-CoV-2 immunity is critical for public health control of the pandemic and vaccine development. We performed a longitudinal analysis of the antibody-based immune response in a cohort of 100 COVID-19 individuals who were infected during the first wave of infection in northern Italy. The SARS-CoV-2 humoral response was tested using the COVID-SeroIndex, Kantaro Quantitative SARS-CoV-2 IgG Antibody RUO Kit (R&D Systems, Bio-Techne, Minneapolis, USA) and pseudotype-based neutralizing antibody assay. Using sequential serum samples collected from 100 COVID-19 recovered individuals from northern Italy-mostly with mild disease-at 2 and 10 months after their first positive PCR test, we show that 93% of them seroconverted at 2 months, with a geometric mean (GeoMean) half-maximal neutralization titer (NT50) of 387.9. Among the 35 unvaccinated subjects retested at 10 months, 7 resulted seronegative, with an 80% drop in seropositivity, while 28 showed decreased anti-receptor binding domain (RBD) and anti-spike (S) IgG titers, with a GeoMean NT50 neutralization titer dropping to 163.5. As an NT50 > 100 is known to confer protection from SARS-CoV-2 re-infection, our data show that the neutralizing activity elicited by the natural infection has lasted for at least 10 months in a large fraction of subjects.

Impairment of CD4+ T and Memory B Cell Responses but Normal Memory CD8+T-Cell Activation on Crohn's Disease after COVID-19 Vaccination: A Twin Case. Vaccines to prevent the impact of SARS-CoV-2 are now available, including for patients with autoimmune diseases. However, there is no

information about how inflammatory bowel disease (IBD) treatment could impact the cellular and humoral immune responses. This study evaluated SARS-CoV-2-specific humoral and cellular responses after vaccination with a two-dose schedule in a Crohn's disease patient treated with Infliximab (10 mg/kg); we included comparisons with a monozygotic twin. The results showed that the Crohn's disease's twin (twin 2) had no antibody detection and reduced activation of CD4+ T cell responses, unlike the twin without the autoimmune disease (twin 1). Twin 2 developed antigen-specific central memory CD8+ T-cells and IFNÎ³ production after the second dose of COVID-19 vaccination, similar to twin 1. These findings elucidated the role of T-cell immunity after COVID-19 immunization on IBD patients despite the lack of antibody production. Finally, our observation supports the consensus recommendation for IBD patients to receive COVID-19 vaccines.

Clusters of SARS-CoV-2 Lineage B.1.1.7 Infection after Vaccination with Adenovirus-Vectored and Inactivated Vaccines. A SARS-CoV-2 B.1.1.7 variant of concern (VOC) has been associated with increased transmissibility, hospitalization, and mortality. This study aimed to explore the factors associated with B.1.1.7 VOC infection in the context of vaccination. On March 2021, we detected SARS-CoV-2 RNA in nasopharyngeal samples from 14 of 22 individuals vaccinated with a single-dose of ChAdOx1 (outbreak A, n = 26), and 22 of 42 of individuals with two doses of the CoronaVac vaccine (outbreak B, n = 52) for breakthrough infection rates for ChAdOx1 of 63.6% and 52.4% for CoronaVac. The outbreaks were caused by two independent clusters of the B.1.1.7 VOC. The serum of PCR-positive symptomatic SARS-CoV-2-infected individuals had ~1.8-3.4-fold more neutralizing capacity against B.1.1.7 compared to the serum of asymptomatic individuals. These data based on exploratory analysis suggest that the B.1.1.7 variant can infect individuals partially immunized with a single dose of an adenovirus-vectored vaccine or fully immunized with two doses of an inactivated vaccine, although the vaccines were able to reduce the risk of severe disease and death caused by this VOC, even in the elderly.

Myocarditis and Pericarditis following COVID-19 Vaccination: Inequalities in Age and Vaccine Types. An increasing number of myocarditis/pericarditis incidences has been reported after coronavirus disease-19 (COVID-19) vaccination in adolescents and young adults. This study was designed to investigate the incidence rate of-and risk for-myocarditis and pericarditis following COVID-19 vaccination in the United States according to age and vaccine type. This study used the Vaccine Adverse Events Reporting System (VAERS) from 11 December 2020 to 13 August 2021. A population-based data mining approach was performed based on the reporting odds ratio (ROR). Adverse events of myocarditis and pericarditis following COVID-19 vaccination were rare, with an incidence rate of 5.98 (95% CI = 5.73-6.24) cases per million doses administered. The incidence rate was higher in adolescents and after the administration of the second dose of messenger RNA (mRNA) vaccines. Overall, two mRNA vaccines were significantly associated with increased risks for myocarditis/pericarditis (mRNA-1273 (Moderna): ROR = 2.91, 95% CI = 2.21-3.83; BNT162b2 (Pfizer-BioNTech): ROR = 5.37, 95% CI = 4.10-7.04) compared to all other vaccines from VAERS. The viral vector vaccine of Ad26.COV2.S (Janssen) was not associated with signals of myocarditis/pericarditis (ROR = 1.39; 95% CI = 0.99-1.97). This study found increased risks for myocarditis/pericarditis following mRNA COVID-19 vaccines. For patients at high risk for myocarditis/pericarditis or with myocardial injuries, the viral vector vaccine may be an alternative for consideration.

Vaccinated Patients Admitted in ICU with Severe Pneumonia Due to SARS-CoV-2: A Multicenter Pilot Study. Background: The aim of this study was to analyze the percentage of patients admitted to the ICU having received the vaccine against COVID-19, to describe the clinical profile of vaccinated patients admitted to the ICU, and to assess the humoral immune response to vaccination. Methods: In this multicenter prospective descriptive cohort study, consecutive critically ill patients with confirmed SARS-CoV-2 pneumonia who received at least one dose of the SARS-CoV-2 vaccine were

included. The time of study was from 1 July to 10 August of 2021. Results: Of the 94 consecutive patients from seven Andalusian ICUs admitted during the time of study, 50 (53.2%) received at least one dose of anti SARS-CoV-2 vaccine. No patient was admitted having previously had SARS-CoV-2 infection. The B.1.617.2 (Delta) variant was the most frequently identified, in 80.76% of cases. Patients with a complete vaccination with non-optimal antibody levels were immunocompromised. Fifteen patients were admitted to the ICU with Acute Respiratory Distress Syndrome (ARDS) without having completed their vaccination; the clinical profile was younger and with less comorbidities compared to patients with full vaccination. There were no differences in severity of ARDS. Conclusions: Most of the patients who were admitted to the ICU having received a dose of the vaccine were not optimally vaccinated; fully vaccinated patients who did not obtain optimal serum antibody levels were patients considered immunocompromised.

Vaccine-Associated Thrombocytopenia and Thrombosis: Venous Endotheliopathy Leading to Venous Combined Micro-Macrothrombosis. Serious vaccine-associated side effects are very rare. Major complications of vaccines are thrombocytopenia and thrombosis in which pathogenetic mechanism is consistent with endotheliopathy characterized by "attenuated" sepsis-like syndrome, leading to the activation of inflammatory and microthrombotic pathway. In the COVID-19 pandemic, acute respiratory distress syndrome caused by microthrombosis has been the major clinical phenotype from the viral sepsis in association with endotheliopathy-associated vascular microthrombotic disease (EA-VMTD), sometimes presenting with thrombotic thrombocytopenic purpura (TTP)-like syndrome. Often, venous thromboembolism has coexisted due to additional vascular injury. In contrast, clinical phenotypes of vaccine complication have included "silent" immune thrombocytopenic purpura (ITP-like syndrome), multiorgan inflammatory syndrome, and deep venous thrombosis (DVT), cerebral venous sinus thrombosis (CVST) in particular. These findings are consistent with venous (v) EA-VMTD. In vEA-VMTD promoted by activated complement system following vaccination, "consumptive" thrombocytopenia develops as ITP-like syndrome due to activated unusually large von Willebrand factor (ULVWF) path of hemostasis via microthrombogenesis. Thus, the pathologic phenotype of ITP-like syndrome is venous microthrombosis. Myocarditis/pericarditis and other rare cases of inflammatory organ syndrome are promoted by inflammatory cytokines released from activated inflammatory pathway, leading to various organ endotheliitis. Vaccine-associated CVST is a form of venous combined "micro-macrothrombosis" composed of binary components of "microthrombi strings" from vEA-VMTD and "fibrin meshes" from vaccine-unrelated incidental vascular injury perhaps such as unreported head trauma. This mechanism is identified based on "two-path unifying theory" of in vivo hemostasis. Venous combined micro-macrothrombosis due to vaccine is much more serious thrombosis than isolated distal DVT made of macrothrombus. This paradigm changing novel concept of combined micro-macrothrombosis implies the need of combined therapy of a complement inhibitor and anticoagulant for CVST and other complex forms of DVT.

What Happens to the Immune System after Vaccination or Recovery from COVID-19? Due to its leading role in fighting infections, the human immune system has been the focus of many studies in the context of Coronavirus disease 2019 (COVID-19). In a worldwide effort, the scientific community has transitioned from reporting about the effects of the novel coronavirus on the human body in the early days of the pandemic to exploring the body's many immunopathological and immunoprotecting properties that have improved disease treatment and enabled the development of vaccines. The aim of this review is to explain what happens to the immune system after recovery from COVID-19 and/or vaccination against SARS-CoV-2, the virus that causes the disease. We detail the way in which the immune system responds to a SARS-CoV-2 infection, including innate and adaptive measures. Then, we describe the role of vaccination, the main types of COVID-19 vaccines and how they protect us. Further, we explain the reason why immunity after COVID-19 infection plus a vaccination appears to

induce a stronger response compared with virus exposure alone. Additionally, this review reports some correlates of protection from SARS-CoV-2 infection. In conclusion, we reinforce that vaccination is safe and important in achieving herd immunity.

Use of Quantitative Dried Blood Spots to Evaluate the Post-Vaccination Level of Neutralizing Antibodies against SARS-CoV-2. To combat the COVID-19 pandemic, vaccines against SARS-CoV-2 are now given to protect populations worldwide. The level of neutralizing antibodies following the vaccination will evolve with time and vary between individuals. Immunoassays quantifying immunoglobulins against the viral spike (S) protein in serum/plasma have been developed, but the need for venous blood samples could limit the frequency and scale of control in populations. The use of a quantitative dried blood spot (DBS) that can be self-collected would simplify this monitoring. The objective of this study was to determine whether a quantitative DBS device (Capitainer qDBS 10 ÂµL) could be used in combination with an Elecsys anti-SARS-CoV-2 S immunoassay from Roche to follow the development and persistence of anti-S antibodies. This objective was carried out through two clinical studies. The first study investigated 14 volunteers who received two doses of the Comirnaty (Pfizer) vaccine. The levels of anti-S antibodies and the progression over time post-vaccination were studied for three months. The level of produced antibodies varied between subjects, but a similar trend was observed. The anti-S antibodies were highly stimulated by the second dose (Ã—100) and peaked two weeks later. The antibody levels subsequently decreased and three months later were down to 65%. DBS proved to be sufficiently sensitive for use in evaluating the immune status against SARS-CoV-2 over a prolonged time. The second cohort was composed of 200 random patients from a clinical chemistry department in Stockholm. In this cohort, we had no information on previous COVID-19 infections or vaccination. Nevertheless, 87% of the subjects had anti-S immunoglobulins over 0.8 U/mL, and the bias between plasma and DBS proved to be variable, as was also seen in the first vaccination study.

B Cell Response Induced by SARS-CoV-2 Infection Is Boosted by the BNT162b2 Vaccine in Primary Antibody Deficiencies. BACKGROUND: Patients with primary antibody deficiencies are at risk in the current COVID-19 pandemic due to their impaired response to infection and vaccination. Specifically, patients with common variable immunodeficiency (CVID) generated poor spike-specific antibody and T cell responses after immunization. METHODS: Thirty-four CVID convalescent patients after SARS-CoV-2 infection, 38 CVID patients immunized with two doses of the BNT162b2 vaccine, and 20 SARS-CoV-2 CVID convalescents later and immunized with BNT162b2 were analyzed for the anti-spike IgG production and the generation of spike-specific memory B cells and T cells. RESULTS: Spike-specific IgG was induced more frequently after infection than after vaccination (82% vs. 34%). The antibody response was boosted in convalescents by vaccination. Although immunized patients generated atypical memory B cells possibly by extra-follicular or incomplete germinal center reactions, convalescents responded to infection by generating spike-specific memory B cells that were improved by the subsequent immunization. Poor spike-specific T cell responses were measured independently from the immunological challenge. CONCLUSIONS: SARS-CoV-2 infection primed a more efficient classical memory B cell response, whereas the BNT162b2 vaccine induced non-canonical B cell responses in CVID. Natural infection responses were boosted by subsequent immunization, suggesting the possibility to further stimulate the immune response by additional vaccine doses in CVID.

Cutaneous Adverse Reactions Associated with SARS-CoV-2 Vaccines. Many patients are receiving SARS-CoV-2 vaccinations, which have been associated with a variety of adverse effects. Cutaneous adverse reactions to SARS-CoV-2 vaccinations have been progressively reported, but they have not been reviewed according to their morphological clinical patterns. The objective of this review was to summarize the existing data concerning the cutaneous adverse reactions following SARS-CoV-2

vaccines and group them according to common morphological and pathogenetic patterns. We reviewed the English language literature up to 15 August 2021, using predefined keywords to identify the relevant studies evaluating cutaneous adverse reactions associated with SARS-CoV-2 vaccines. We search for recurrent morphological patterns sharing clinical signs and symptoms and physio-pathological mechanisms. Timing to onset following the first or booster dose of the vaccine, predisposing conditions, therapeutic management, and outcome were also collected. Among the dermatological manifestations associated with SARS-CoV-2 vaccinations, we distinguished: (1) new onset reactions and (2) flares of preexisting dermatoses. The most common were injection site reactions, affecting 30-70% and generally mild or moderate. Small case series or single case reports included filler reactions, exanthemas, vascular lesions, urticaria, eczematous dermatitis, autoimmune bullous reactions, and severe cutaneous adverse reactions. In addition, the exacerbation of chronic immuno-mediated dermatoses (mainly psoriasis and atopic dermatitis) and reactivations of herpes infection were reported. The cutaneous reactions were generally mild, self-limiting, and resembled common cutaneous drug eruptions and/or COVID-19 skin manifestations.

Self-Reported Adverse Events of COVID-19 Vaccines in Polish Healthcare Workers and Medical Students. Cross-Sectional Study and Pooled Analysis of CoVaST Project Results in Central Europe. BACKGROUND: Optimization of COVID-19 vaccination rate among healthcare personnel is of utmost priority to secure provision of uninterrupted care and to protect the most vulnerable patients. This study, as part of the global CoVaST project, aimed to assess the occurrence of short-term adverse events (SRAEs) of two most administered COVID-19 vaccines, mRNA-based (Pfizer-BioNTech and Moderna) and viral vector-based (AstraZeneca) in healthcare sector workers (HWs). METHODS: A cross-sectional survey-based study was carried out for the first time among 317 Polish healthcare sector personnel and medical students using a validated and pre-tested questionnaire. The online questionnaire included 25 pre-tested, validated questions concerning demographic data, medical parameters, COVID-19-related anamneses, and local or systemic reactions (reactogenicity) associated with COVID-19 vaccination. Descriptive statistics, inferential tests and binary logistic regression were performed. RESULTS: Out of the 247 participating HWs, 79.8% were females, and 77.5% received mRNA-based vaccines, while 24.5% received a viral vector-based vaccine. Cumulatively, 78.9% and 60.7% of the participants reported at least one local and one systemic SRAE respectively, following their COVID-19 first or second dose of vaccine. A wide array of SRAEs was observed, while pain at injection site (76.9%) was the most common local SRAE, and fatigue (46.2%), headache (37.7%), muscle pain (31.6%) were the most common systemic SRAEs. The vast proportion of local (35.2%) and systemic (44.8%) SRAEs subsided up to 1 day after inoculation with both types of vaccines. The mRNA-based vaccine versions seem to cause higher prevalence of local SRAEs, mainly pain within injection site (81.3% vs. 71.7%; $p = 0.435$), while the viral vector-based vaccine was linked with increased incidents of mild systemic side effects (76.7% vs. 55.3%; $p = 0.004$) after both doses. Pooled analysis revealed uniform results while comparing the prevalence of SRAEs in HWs as recipients in four central European countries (OR = 2.38; 95% CI = 2.03-2.79). CONCLUSIONS: The study confirmed the safety of commonly administered vaccines against COVID-19, which were associated with mild, self-resolving adverse events. No major vaccine-related incidents were reported which would affect every day functioning, significantly. The younger age group (below 29 y.o.) were associated with an increased risk of adverse events generally. The results enhanced current data regarding COVID-19 vaccination active surveillance in selected occupational groups.

A Rapid and Simple Multiparameter Assay to Quantify Spike-Specific CD4 and CD8 T Cells after SARS-CoV-2 Vaccination: A Preliminary Report. mRNA and Adenovirus vaccines for COVID-19 are used to induce humoral and cell-mediated immunity, with the aim to generate both SARS-CoV-2 B and T memory cells. In present study, we described a simple assay to detect and quantify Spike-specific

CD4(+) and CD8(+) T cell responses induced by vaccination in healthy donors and in subjects with B cell compart impairment, in which antibody response is absent due to primary immunodeficiencies or CD20 depleting therapy. We detect and quantified memory T cell immune responses against SARS-CoV-2 evocated by vaccination in both groups, irrespective to the humoral response. Furthermore, we identified TNF-Î± as the main cytokine produced by T memory cells, after antigen-specific stimulation in vitro, that could be considered, other than IFN-Î³, an additional biomarker of induction of T memory cells upon vaccination. Further studies on the vaccine-induced T cell responses could be crucial, not only in healthy people but also in immunocompromised subjects, where antigen specific T cells responses play a protective role against SARS-CoV-2.

Acute abducens nerve palsy after COVID-19 vaccination in a young adult. We present the case of a 23-year-old young man with left-eye abducens nerve palsy following the COVID-19 vaccination. Given the temporal relationship between vaccination and the onset of symptoms, the lack of systemic history, and unremarkable magnetic resonance imaging, the patient's abducens nerve palsy was related to his vaccination. The ophthalmologist should be aware of this neurotropic sequela of COVID-19 vaccination in young adults.

Acute graft rejection in a high-risk corneal transplant following COVID-19 vaccination: A case report. As COVID-19 vaccination is being undertaken all over the world, its side effects are materializing slowly. One such emerging side effect is acute graft rejection in corneal transplant (CT) cases post COVID-19 vaccination. We report a case of left eye (LE) repeat penetrating keratoplasty presenting with diminished vision in LE within 2 days of COVID-19 vaccination (ChAdOx1 nCoV-19 Corona Virus Vaccine Recombinant, COVISHIELDâ„¢). The patient was diagnosed with acute graft rejection post vaccination and was treated with topical and systemic immunosuppression therapy with successful outcome in terms improvement of visual acuity and corneal graft clarity. Timely presentation, diagnosis, and management may help to survive acute rejection episodes post vaccination.

After the Storm: Ophthalmic Manifestations of COVID-19 Vaccines. Several COVID-19 vaccines have been developed and approved for use around the world from December 2020, to combat the pandemic caused by the novel SARS-CoV-2 virus. Several ophthalmic manifestations of the COVID-19 vaccines have been reported by ophthalmologists. This review was undertaken to recognize, encourage active reporting and determine the pathogenesis and time of appearance for better awareness and understanding of the ophthalmic manifestations of COVID-19 vaccines. A literature search was performed for publications on the ophthalmic manifestations of COVID-19 vaccines between January 1, 2021 and November 7, 2021. 23 case reports, 17 letters to editors, 3 ophthalmic images, 4 brief communications, 4 retrospective cohort studies and 2 case control studies were included. Posterior segment, including the uvea, choroid and retinal vasculature, was most commonly affected and the reported clinical features developed at a median of four days from the time of vaccination. The possible mechanisms include molecular mimicry of the vaccine components with host ocular tissues, antigen-specific cell and antibody-mediated hypersensitivity reactions to viral antigens and adjuvants present in the vaccines. The causal relationship of the ocular signs and symptoms and COVID-19 vaccines has not been established and requires long-term and large multicentre data. Most of the reported manifestations are mild, transient and adequately treated when diagnosed and managed early. The benefits of COVID-19 vaccination outweighs the reported rare adverse events and should not be a deterrent to vaccination.

Acute corneal graft rejection after anti-severe acute respiratory syndrome-coronavirus-2 vaccination: A report of four cases. PURPOSE: This study intends to add to previous reports on acute corneal graft rejection following anti-severe acute respiratory syndrome-coronavirus-2 vaccination, providing data to corroborate a possible causative relationship between anti-COVID-19 immunization and corneal graft rejection, regardless of vaccine or graft type. METHODS AND RESULTS: This report

describes 4 cases of acute-onset rejection as early as 5 days following the first dose of anti-severe acute respiratory syndrome-coronavirus-2 vaccine types not yet referred for corneal allograft. Patients were individually given the Moderna messenger RNA-1273 COVID-19 vaccine (2 patients) and the AstraZeneca COVID-19 vaccine, Vaxzevria, AZD1222 (2 patients). CONCLUSIONS: Even though a direct causative effect is hard to prove, temporal proximity between anti-severe acute respiratory syndrome-coronavirus-2 vaccines of different types and consecutive reports of corneal graft rejection indicates the need for further investigation. Consistent advice must be given to corneal transplant patients regarding such risk.
Higher frequency of comorbidities in fully vaccinated patients admitted to the ICU due to severe COVID-19: a prospective, multicentre, observational study. Severe COVID-19 disease requiring ICU admission is possible in the fully vaccinated population, especially in those with immunocompromised status and other comorbidities. Interventions to improve vaccine response might be necessary in this population. https://bit.ly/3Fw6vCP   The coronavirus disease 2019 (COVID-19) vaccination campaign in Spain began on 27 December 2020 [1]. To date, more than 36 million people have been fully vaccinated, with most of the population, namely 25.3 million people (69.1%), receiving BNT 162b2 (Pfizer/BioNTech) [1]. With respect to other vaccines and figures, 4.8 million (13.2%) people have received AZD1222 (Oxford/AstraZeneca); 4.5 million (12.3%) mRNA-1273 (Moderna); and 2.0 million (5.4%) JNJ-78436735 (Janssen) [1].
Safety and disease flare of autoimmune inflammatory rheumatic diseases: a large real-world survey on inactivated COVID-19 vaccines.
SARS-COV-2 Vaccines: What Indicators are Associated with the Worldwide Distribution of the First Doses. The present study aimed to identify the factors associated with the distribution of the first doses of the COVID-19 vaccine. In this study, we used 9 variables: human development index (HDI), gross domestic product (GDP per capita), Gini index, population density, extreme poverty, life expectancy, COVID cases, COVID deaths, and reproduction rate. The time period was until February 1, 2021. The variable of interest was the sum of the days after the vaccine arrived in the countries. Pearson's correlation coefficients were calculated, and t-test was performed between the groups that received and did not receive the immunizer, and finally, a stepwise linear regression model was used. 58 (30.4%) of the 191 countries received the SARS-CoV-2 vaccine. The countries that received the most doses were the United States, China, the United Kingdom, and Israel. Vaccine access in days showed a positive Pearson correlation HDI, GDP, life expectancy, COVID-19 cases, deaths, and reproduction rate. Human development level, COVID-19 deaths, GDP per capita, and population density are able to explain almost 50% of the speed of access to immunizers. Countries with higher HDI and per capita income obtained priority access.
Relapsed Disciform Stromal Herpetic Keratitis Following mRNA COVID-19 Vaccination: A Case Report.
Distinct glomerular disease association after vaccination with BNT162b2 and mRNA-1273: a VigiBase analysis.
Post-SARS-CoV-2 vaccination acute hemolysis in an older man: don't forget to look at the blood smear.
Case of atypical erythema multiforme following coronavirus disease 2019 vaccination.
A case of erythroderma with elevated serum immunoglobulin E and thymus and activation-regulated chemokine levels following coronavirus disease 2019 vaccination.
Cutaneous adverse events related to COVID-19 vaccines: A cross-sectional questionnaire-based study of 867 patients. Considering the emergency approval of the Food and Drug Administration for widespread use of coronavirus disease 2019 (COVID-19) vaccines, evaluating potential vaccine-related adverse effects is critical as it will allow physicians to diagnose and manage these complications properly. In this descriptive cross-sectional questionnaire-based study, we evaluated

the possible side effects of the COVID-19 vaccine from June 1, 2021 to June 21, 2021. The Iranian population is generally vaccinated with AstraZeneca, Sputnik V, Sinopharm, and Bharat vaccines. The continuous and categorical variables were described and data analyzed by the SPSS software version 25. Cutaneous reactions occurred in 30% of individuals vaccinated against COVID-19. The most common cutaneous complications were focal injection site reaction, exanthematous rash, and urticaria. There were infrequent cutaneous adverse events that included vesicular eruption, pernio-like lesions, angioedema, erythema multiforme-like eruption, and zoster. Acquainting physicians with COVID-19 vaccine-related cutaneous complications will assist them in detection and management. In addition, introducing these complications to individuals might improve acceptance of vaccine-related adverse effects in the general population.

A Case of Idiopathic Thrombocytopenic Purpura After Booster Dose of BNT162b2 (Pfizer-Biontech) COVID-19 Vaccine. Vaccination is now considered the best measure in minimizing the morbidity and mortality from the Covid-19Â pandemic. Almost all the vaccines are considered safe except for minor and occasional side effects. SomeÂ of the commonly reported complications from the COVID-19 vaccines are vaccine-inducedÂ thromboticÂ thrombocytopeniaÂ (VITT)/thrombosis with thrombocytopenia syndrome/vaccine-induced pro-thrombotic immune thrombocytopeniaÂ syndrome. In this case report,Â weÂ present a case of a 75-year-old female who had an uncomplicated first and second vaccine doseÂ butÂ developedÂ VITT after the booster dose of the vaccine. The patient was treated with dexamethasone and platelet transfusions.Â SoÂ farÂ no such cases have been reported after the third (booster) dose of the Pfizer-Biontech vaccine. With this case report, we present the case of the patient and discuss the literature related to vaccine-induced thrombocytopenia.

Bilateral Thalamic Stroke: A Case of COVID-19 Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) or a Coincidence Due to Underlying Risk Factors? Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare but potentially life-threatening side effect that has only been observed in adenovirus-based vaccines for coronavirus disease 2019 (COVID-19). VITT is an immune-mediated condition that generally presents within five to 10 days post-vaccination with thrombosis, thrombocytopenia, and coagulation abnormalities. A diagnosis of VITT is made clinically and through laboratory testing. Although VITT is an important differential to consider, it is believed that more emphasis should be placed on vaccination due to the safety and efficacy in overcoming COVID-19.

Correlates of neutralizing/SARS-CoV-2-S1-binding antibody response with adverse effects and immune kinetics in BNT162b2-vaccinated individuals. While mRNA vaccines against SARS-CoV-2 are exceedingly effective in preventing symptomatic infection, their immune response features remain to be clarified. In the present prospective study, 225 healthy individuals in Japan, who received two BNT162b2 doses, were enrolled. Correlates of BNT162b2-elicited SARS-CoV-2-neutralizing activity (50% neutralization titer: NT(50); assessed using infectious virions) with various determinants were examined and the potency of sera against variants of concerns was determined. Significant rise in NT(50)s was seen in sera on day 28 post-1st dose. A moderate inverse correlation was seen between NT(50)s and ages, but no correlation seen between NT(50)s and adverse effects. NT(50)s and SARS-CoV-2-S1-binding-IgG levels on day 28 post-1st dose and pain scores following the 2nd dose were greater in women than in men. The average half-life of NT(50)s wasâ€‰~â€‰68Â days, and 23.6% (49 out of 208 individuals) failed to show detectableÂ neutralizing activity on day 150. While sera from elite-responders (NT(50)sâ€‰>â€‰1,500: the top 4% among the participants) potently to moderately blocked all variants of concerns examined, some sera with low NT(50)s failed to block the B.1.351-beta strain.

Since BNT162b2-elicited immunity against SARS-CoV-2 is short, an additional vaccine or other protective measures are needed.
Flares of mixed cryoglobulinaemia vasculitis after vaccination against SARS-CoV-2.
Antibody response after 2 and 3 doses of SARS-CoV-2 mRNA vaccine in allogeneic hematopoietic cell transplant recipients.
Enterovirus D68-Associated Acute Respiratory Illness â"€ New Vaccine Surveillance Network, United States, July-November 2018-2020. Enterovirus D68 (EV-D68) is associated with a broad spectrum of illnesses, including mild to severe acute respiratory illness (ARI) and acute flaccid myelitis (AFM). Enteroviruses, including EV-D68, are typically detected in the United States during late summer through fall, with year-to-year fluctuations. Before 2014, EV-D68 was infrequently reported to CDC (1). However, numbers of EV-D68 detection have increased in recent years, with a biennial pattern observed during 2014-2018 in the United States, after the expansion of surveillance and wider availability of molecular testing. In 2014, a national outbreak of EV-D68 was detected (2). EV-D68 was also reported in 2016 via local (3) and passive national (4) surveillance. EV-D68 detections were limited in 2017, but substantial circulation was observed in 2018 (5). To assess recent levels of circulation, EV-D68 detections in respiratory specimens collected from patients aged <18 years* with ARI evaluated in emergency departments (EDs) or admitted to one of seven U.S. medical centers(â€) within the New Vaccine Surveillance Network (NVSN) were summarized. This report provides a provisional description of EV-D68 detections during July-November in 2018, 2019 and 2020, and describes the demographic and clinical characteristics of these patients. In 2018, a total of 382 EV-D68 detections in respiratory specimens obtained from patients aged <18 years with ARI were reported by NVSN; the number decreased to six detections in 2019 and 30 in 2020. Among patients aged <18 years with EV-D68 in 2020, 22 (73%) were non-Hispanic Black (Black) persons. EV-D68 detections in 2020 were lower than anticipated based on the biennial circulation pattern observed since 2014. The circulation of EV-D68 in 2020 might have been limited by widespread COVID-19 mitigation measures; how these changes in behavior might influence the timing and levels of circulation in future years is unknown. Ongoing monitoring of EV-D68 detections is warranted for preparedness for EV-D68-associated ARI and AFM.
COVID-19-Associated Deaths After SARS-CoV-2 Infection During Pregnancy - Mississippi, March 1, 2020-October 6, 2021. Pregnant and recently pregnant women are at increased risk for severe illness and death from COVID-19 compared with women who are not pregnant or were not recently pregnant (1,2). CDC recommends COVID-19 vaccination for women who are pregnant, recently pregnant, trying to become pregnant, or might become pregnant in the future.*(,)(â€) This report describes 15 COVID-19-associated deaths after infection with SARS-CoV-2 (the virus that causes COVID-19) during pregnancy in Mississippi during March 1, 2020-October 6, 2021.
Influenza vaccine update, 2021-22. Give the vaccine by the end of October. The CDC states that COVID-19 vaccines can be co-administered with influenza vaccines, but reactogenicity is possible.
Bullous Sweet syndrome following SARS-CoV-2 Oxford AstraZeneca vaccine.
Proposed Pathogenesis, Characteristics, and Management of COVID-19 mRNA Vaccine-Related Myopericarditis. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the novel coronavirus causing coronavirus disease 2019 (COVID-19), has affected human lives across the globe. On 11 December 2020, the US FDA granted an emergency use authorization for the first COVID-19 vaccine, and vaccines are now widely available. Undoubtedly, the emergence of these vaccines has led to substantial relief, helping alleviate the fear and anxiety around the COVID-19 illness for both the general public and clinicians. However, recent cases of vaccine complications, including myopericarditis, have been reported after administration of COVID-19 vaccines. This article discusses the cases, possible pathogenesis of myopericarditis, and treatment of the condition. Most cases were

mild and should not yet change vaccine policies, although prospective studies are needed to better assess the risk-benefit ratios in different groups.
Miller Fisher syndrome following Pfizer COVID-19 vaccine. INTRODUCTION: Miller Fisher syndrome (MFS) is a rare variant of Guillain-Barre syndrome characterized by ataxia, areflexia, and ophthalmoplegia. We present a case of MFS following Pfizer COVID-19 vaccine. CASE PRESENTATION: A previously healthy 24-year-old female presented with binocular horizontal diplopia 18 days after receiving the first dose of Pfizer COVID-19 vaccine (ComirnatyÂ®). Anti-ganglioside testing revealed positive anti-GQ1b antibodies. Intravenous immunoglobulins were administered, in a dose of 2 g per kg of body weight over 5 days. On a follow-up exam 3 weeks after the treatment, clinical improvement was noted with normal bulbomotor examination. CONCLUSION: Patients with acute ophthalmoplegia occurring after COVID-19 vaccination should be screened for the presence of anti-GQ1b antibody. If the antibody is present, intravenous immunoglobulin should be administered as it may hasten clinical improvement.
Morally Injurious Experiences and Emotions of Health Care Professionals During the COVID-19 Pandemic Before Vaccine Availability. IMPORTANCE: Moral injury in health care professionals (HPs) has worsened over the course of the COVID-19 pandemic. The trauma and burnout associated with moral injury has profound implications for the mental health of HPs. OBJECTIVE: To explore the potential factors associated with moral injury for HPs who were involved in patient care during the COVID-19 pandemic in 2020, prior to the availability of vaccines. DESIGN, SETTING, AND PARTICIPANTS: In this qualitative study, HPs were actively recruited to participate in a survey via snowball sampling via email and social media in 2 phases of 5 weeks each: April 24 to May 30, 2020 (phase 1), and October 24 to November 30, 2020 (phase 2). Overall, 1831 respondents answered demographic questions and assessments for moral injury, intrinsic religiosity, and burnout. Of those, 1344 responded to the open-ended questions. Responses to open-ended questions were coded iteratively and thematically analyzed within the framework of moral injury. EXPOSURES: Working in a patient care setting during the COVID-19 pandemic prior to the availability of vaccines. MAIN OUTCOMES AND MEASURES: Inductive thematic analysis of open-response survey answers identified dominant emotions and common stressors associated with moral injury. RESULTS: There were 335 individuals (109 [32.6%] aged 35-44 years; 288 [86.0%] women; 294 [87.8%] White) in phase 1 and 1009 individuals (384 [38.1%] aged 35-44 years; 913 [90.5%] women; 945 [93.7%] White) in phase 2. In phase 1, the respondents were predominantly nurses (100 [29.9%]), physicians (78 [23.3%]), advanced practice practitioners (APPs) (70 [20.9%]), and chaplains (55 [16.4%]). In phase 2, the respondents were predominantly nurses (589 [58.4%]), physicians (114 [11.3%]), and APPs (104 [10.3%]). HPs faced numerous stressors, such as fear of contagion, stigmatization, short-staffing, and inadequate personal protective equipment. The emotions experienced were (1) fear in phase 1, then fatigue in phase 2; (2) isolation and alienation; and (3) betrayal. CONCLUSIONS AND RELEVANCE: These findings suggest that HPs experienced moral injury during the COVID-19 pandemic. Moral injury was not only experienced after a single moral dilemma but also from working in morally injurious environments. These experiences can serve as potential starting points for organizations to engender and enhance organizational and individual recovery, team building, and trust. System-level solutions that address shortages in staffing and personal protective equipment are needed to promote HP well-being.
Sudden Sensorineural Hearing Loss and COVID-19 Vaccination.
Sudden Sensorineural Hearing Loss and COVID-19 Vaccination-Reply.
Evaluation of Humoral Immune Response after SARS-CoV-2 Vaccination Using Two Binding Antibody Assays and a Neutralizing Antibody Assay. Multiple vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been developed and administered to mitigate the

coronavirus disease 2019 (COVID-19) pandemic. We assessed the humoral response of BNT162b2 and ChAdOx1 nCoV-19 using Siemens SARS-CoV-2 IgG (sCOVG; cutoffâ€‰of â‰¥1.0 U/ml), Abbott SARS-CoV-2 IgG II Quant (CoV-2 IgG II; cutoffâ€‰of â‰¥50.0â€‰AU/ml), and GenScript cPASS SARS-CoV-2 neutralization antibody detection kits (cPASS; cutoffâ€‰of â‰¥30% inhibition). We collected 710 serum samples (174 samples after BNT162b2 and 536 samples after ChAdOx1 nCoV-19). Venous blood was obtained 3 weeks after first and second vaccinations. In both vaccines, sCOVG, CoV-2 IgG II, and cPASS showed a high seropositive rate (>95.7%) except for cPASS after the first vaccination with ChAdOx1 nCoV-19 (68.8%). Using sCOVG and CoV-2 IgG II, the ratios of antibody value (second/first) increased 10.6- and 11.4-fold in BNT162b2 (first 14.1, second 134.8 U/ml; first 1,416.2, second 14,326.4â€‰AU/ml) and 2.3- and 2.0-fold in ChAdOx1 nCoV-19 (first 4.0, second 9.1 U/ml; first 431.0, second 9,744.0â€‰AU/ml). cPASS-positive results indicated a very high concordance rate with sCOVG and CoV-2 IgG II (>98%), whereas cPASS-negative results showed a relatively low concordance rate (range of 22.2% to 66.7%). To predict cPASS positivity, we suggested additional cutoffs for sCOVG and CoV-2 IgG II at 2.42 U/ml and 284â€‰AU/ml, respectively. In conclusion, BNT162b2 and ChAdOx1 nCoV-19 evoked robust humoral responses. sCOVG and CoV-2 IgG II showed a very strong correlation with cPASS. sCOVG and CoV-2 IgG II may predict the presence of neutralizing antibodies against SARS-CoV-2. IMPORTANCE The Siemens severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG (sCOVG; Siemens Healthcare Diagnostics Inc., NY, USA) and Abbott SARS-CoV-2 IgG II Quant (CoV-2 IgG II; Abbott Laboratories, Sligo, Ireland), which are automated, quantitative SARS-CoV-2-binding antibody assays, have been recently launched. This study aimed to evaluate the humoral immune response of BNT162b2 and ChAdOx1 nCoV-19 vaccines using sCOVG and CoV-2 IgG II and compare the quantitative values with the results of the GenScript surrogate virus neutralization test (cPASS; GenScript, USA Inc., NJ, USA). Our findings demonstrated that both BNT162b2 and ChAdOx1 nCoV-19 elicited a robust humoral response after the first vaccination and further increased after the second vaccination. sCOVG and CoV-2 IgG II showed a strong correlation, and the concordance rates among sCOVG, CoV-2 IgG II, and cPASS were very high in the cPASS-positive results. The additional cutoff sCOVG and CoV-2 IgG II could predict the results of cPASS.

Thrombosis and thrombocytopenia after HPV vaccination. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia (VITT) has so far only been reported after adenovirus vector severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines. OBJECTIVE: We report findings in a 25-year-old woman who presented with thrombocytopenia, venous thrombosis, elevated D-dimer levels, and high levels of platelet-activating antibodies to platelet factor 4-polyanion complexes 10Â days after Gardasil 9 vaccination for human papillomavirus (HPV). The patient exhibited clinical and laboratory features in line with the recently defined VITT syndrome, described after adenoviral vector vaccination to prevent coronavirus disease 2019. CONCLUSION: We report a case of VITT following HPV vaccination. This should raise awareness of the possibility of VITT also occurring after other vaccines, not exclusively adenoviral vector-based SARS-CoV-2 vaccines.

An unusual presentation of pemphigus foliaceus following COVID-19 vaccination.

Leg paralysis after AstraZeneca COVID-19 vaccination diagnosed as neuralgic amyotrophy of the lumbosacral plexus: a case report. The ongoing global administration of vaccines for coronavirus disease 2019 (COVID-19) means that increasing numbers of patients are likely to present with post-vaccination complications. We describe the first reported case of neuralgic amyotrophy (NA) involving the lumbosacral plexus occurring after AstraZeneca COVID-19 vaccination. The patient presented with acute-onset leg paralysis following administration of the vaccine. Based on the clinical, electrodiagnostic, and radiologic findings, the patient was diagnosed with post-vaccination NA. We speculate that the COVID-19 vaccine elicited an immune-mediated inflammatory response to the injected antigen due to inflammatory immunity in a patient with predisposed susceptibility to NA.

Adverse Events with the Pfizer-BioNTech COVID-19 Vaccine among Korean Healthcare Workers. The Pfizer-BioNTech COVID-19 vaccine has shown excellent clinical effectiveness; however, adverse events of the vaccine remain a concern in Korea. We surveyed adverse events in 2498 healthcare workers vaccinated with the Pfizer-BioNTech COVID-19 vaccine at a university hospital. The survey was conducted using a diary card for 7 days following each injection. The questionnaire response rate was 75.1% (1876/2498) for the first dose and 73.8% (1840/2493) for the second dose. Among local reactions, pain was the most commonly reported (84.9% after the first dose and 90.4% after the second dose). After the second dose, two people visited the emergency room due to severe local pain, but no hospitalization or skin necrosis occurred. Among systemic reactions, fatigue was most frequently reported (52.8% after the first dose and 77.0% after the second dose), followed by myalgia (49.0% and 76.1%), headache (28.7% and 59.2%), chills (16.7% and 54.0%), and arthralgia (11.4% and 39.2%). One or more critical adverse events occurred in 0.2% and 0.7% of the vaccinees. Except for urticaria, more adverse events were reported after the second dose than after the first dose. In the future, adverse events should be investigated in older adults, and a future study with a longer observation period should be conducted.

IgA nephropathy following SARS-CoV-2 vaccination in a renal transplant recipient with a history of aristolochic acid nephropathy.

The form of PEG matters: PEG conjugated with lipids and not PEG alone could be the specific form involved in allergic reactions to COVID-19 vaccines.

Stevens-Johnson Syndrome due to COVID-19 vaccination. As public COVID-19 vaccination programs are being implemented, it is possible that more rare and serious adverse effects such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrosis (TEN) may occur.

A guide on how to work in vaccine science.

Does mRNA SARS-CoV-2 vaccine detrimentally affect male fertility, as reflected by semen analysis? RESEARCH QUESTION: Does Pfizer's coronavirus disease 2019 (COVID-19) vaccination detrimentally affect semen analysis parameters? DESIGN: A prospective cohort study was conducted at a single large tertiary centre in Israel between February and March of 2021. Semen samples from 75 fertile men were analysed 1-2 months following their second dose of Pfizer's COVID-19 vaccine. The semen parameters were compared with the World Health Organization (WHO) reference ranges. The primary outcome was the percentage of abnormal semen parameters in those who were vaccinated, i.e. the rates of oligozoospermia, reduced percentage of motile spermatozoa and abnormal sperm morphology. RESULTS: The interval from the time of the second vaccination to the date of participation was on average 37 days, with most subjects describing either mild or no side effects after the first or second dose. The mean sperm concentration was 63.2Â Â±Â 33.6Â â€¯Ã— â€¯Â 10(6)/ml, with only a single participant (1.3%) with a sperm count of 12.5Â â€¯Ã— â€¯Â 10(6)/ml, considered by the WHO to be oligozoospermic. The mean sperm motility percentage was 64.5Â Â±Â 16.7%, with only a single man (1.3%) displaying reduced motility. No notable morphological abnormalities were observed. This constituted a lower percentage of abnormal semen parameters compared with the 5% rates reported in fertile men by the WHO. CONCLUSIONS: The semen parameters following COVID-19 vaccination were predominantly within the normal reference ranges as set by the WHO and do not reflect any causative detrimental effect from COVID-19 vaccination. The results strengthen the notion that the Pfizer's severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine is safe and should be recommended to men wishing to conceive.

Herpes zoster infection following mRNA COVID-19 vaccine in a patient with ankylosing spondylitis. Since the severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2) pandemic outbreak, vaccines gained a growing role. Possible vaccine-related side effects range from minor local events to more prominent systemic manifestations up to anaphylactic reactions. A heterogeneous spectrum of

cutaneous reactions has been reported, ranging from local injection site reactions to urticarial and morbilliform eruptions, pernio/chilblains and zoster flares. Here, we describe a case of varicella zoster virus reactivation following mRNA coronavirus 2019 vaccine and discuss the available literature upon the topic published so far.

A COVID-19 peptide vaccine for the induction of SARS-CoV-2 T cell immunity. T cell immunity is central for the control of viral infections. CoVac-1 is a peptide-based vaccine candidate, composed of SARS-CoV-2 T cell epitopes derived from various viral proteins(1,2), combined with the Toll-like receptor 1/2 agonist XS15 emulsified in Montanide ISA51 VG, aiming to induce profound SARS-CoV-2 T cell immunity to combat COVID-19. Here we conducted a phase I open-label trial, recruiting 36 participants aged 18-80Â years, who received a single subcutaneous CoVac-1 vaccination. The primary end point was safety analysed until dayÂ 56. Immunogenicity in terms of CoVac-1-induced T cell response was analysed as the main secondary end point until dayÂ 28 and in the follow-up until monthÂ 3. No serious adverse events and no gradeÂ 4Â adverse events were observed. Expected local granuloma formation was observed in all study participants, whereas systemic reactogenicity was absent or mild. SARS-CoV-2-specific T cell responses targeting multiple vaccine peptides were induced in all study participants, mediated by multifunctional T helper 1 CD4(+) and CD8(+) T cells. CoVac-1-induced IFNÎ³ T cell responses persisted in the follow-up analyses and surpassed those detected after SARS-CoV-2 infection as well as after vaccination with approved vaccines. Furthermore, vaccine-induced T cell responses were unaffected by current SARS-CoV-2 variants of concern. Together, CoVac-1 showed a favourable safety profile and induced broad, potent and variant of concern-independent T cell responses, supporting the presently ongoing evaluation in a phase II trial for patients with B cellÂ orÂ antibody deficiency.

Delayed hypersensitivity to the Comirnaty coronavirus disease 2019 vaccine presenting with pneumonitis and rash.

Trends in ambulatory cardiology consultations for suspected myocarditis after COVID-19 vaccination.

Comment on "Caution against injudicious vaccine allergy skin test and adverse reactions after intradermal COVID-19 vaccine testing".

New Onset of Smell and Taste Loss Are Common Findings Also in Patients With Symptomatic COVID-19 After Complete Vaccination. The aim of this study is to investigate the clinical profile of patients who developed coronavirus disease 2019 (COVID-19) after full vaccination. Demographic, epidemiological and clinical data were collected through medical records and online patient-reported outcome questionnaire from patients who developed symptomatic SARS-CoV-2 infection, confirmed by nasopharyngeal swab, at least 2â€‰weeks after completion of vaccination. A total of 153 subjects were included. The most frequent symptoms were: asthenia (82.4%), chemosensory dysfunction (63.4%), headache (59.5%), runny nose (58.2%), muscle pain (54.9%), loss of appetite (54.3%), and nasal obstruction (51.6%). Particularly, 62.3% and 53.6% of subjects reported olfactory and gustatory dysfunction, respectively. Symptom severity was mild or moderate in almost all cases. Chemosensory dysfunctions have been observed to be a frequent symptom even in subjects who contracted the infection after full vaccination. For this reason, the sudden loss of smell and taste could continue to represent a useful and specific diagnostic marker to raise the suspicion of COVID-19 even in vaccinated subjects. In the future, it will be necessary to establish what the recovery rate is in these patients. LEVEL OF EVIDENCE: 4 Laryngoscope, 132:419-421, 2022.

Reduced antibody activity against SARS-CoV-2 B.1.617.2 delta virus in serum of mRNA-vaccinated individuals receiving tumor necrosis factor-Î± inhibitors. BACKGROUND: Although vaccines effectively prevent coronavirus disease 2019 (COVID-19) in healthy individuals, they appear to be less immunogenic in individuals with chronic inflammatory disease (CID) or receiving chronic immunosuppression therapy. METHODS: Here we assessed a cohort of 77 individuals with CID treated

as monotherapy with chronic immunosuppressive drugs for antibody responses in serum against historical and variant severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viruses after immunization with the BNT162b2 mRNA vaccine. FINDINGS: Longitudinal analysis showed the greatest reductions in neutralizing antibodies and Fc effector function capacity in individuals treated with tumor necrosis factor alpha (TNF-Î±) inhibitors (TNFi), and this pattern appeared to be worse against the B.1.617.2 delta virus. Within 5Â months of vaccination, serum neutralizing titers of all TNFi-treated individuals tested fell below the presumed threshold correlate for antibody-mediated protection. However, TNFi-treated individuals receiving a third mRNA vaccine dose boosted their serum neutralizing antibody titers by more than 16-fold. CONCLUSIONS: Vaccine boosting or administration of long-acting prophylaxis (e.g., monoclonal antibodies) will likely be required to prevent SARS-CoV-2 infection in this susceptible population. FUNDING: This study was supported by grants and contracts from theÂ NIH (R01 AI157155, R01AI151178, and HHSN75N93019C00074; NIAID Centers of Excellence for Influenza Research and Response (CEIRR) contracts HHSN272201400008C and 75N93021C00014; and Collaborative Influenza Vaccine Innovation Centers [CIVIC] contract 75N93019C00051).

Acute Eosinophilic Pneumonia Associated With the Anti-COVID-19 Vaccine AZD1222. SARS-CoV-2 is an emerging virus causing the contemporary global pandemic. No cure has yet been discovered. Therefore, vaccination remains the only hope. We report the case of a 66-year-old male patient with a history of allergies. Five hours after his vaccination with the anti-COVID-19 vaccine AZD1222 (ChAdOx1 nCoV-19, AstraZeneca), he developed acute respiratory distress. The biological assessment showed hyperleukocytosis, 20% of which are eosinophils. Diagnosis of severe postvaccination acute eosinophilic pneumonia was retained given the history of allergy, lack of improvement on antibiotics, elimination of all other probable causes of eosinophilia, and improvement on corticosteroids. Such reactions of eosinophilic pneumonia have only been described twice: once following vaccination with the influenza vaccine (Vaxigrip*) and the other after vaccination with the 23-valent pneumococcal polysaccharide vaccine (Pneumovax 23*). Hypereosinophilia must be taken into consideration, feared, and prevented. Although rare and severe, post-COVID-19 vaccination acute eosinophilic pneumonia remains well manageable with corticosteroids with a good outcome. Therefore, in some poorly monitored patients with allergy or asthma,Â the use of another less allergenic vaccine could be considered to avoid such reactions.

Cross-reactive antibodies after SARS-CoV-2 infection and vaccination. Current SARS-CoV-2 vaccines are losing efficacy against emerging variants and may not protect against future novel coronavirus outbreaks, emphasizing the need for more broadly protective vaccines. To inform the development of a pan-coronavirus vaccine, we investigated the presence and specificity of cross-reactive antibodies against the spike (S) proteins of human coronaviruses (hCoV) after SARS-CoV-2 infection and vaccination. We found an 11- to 123-fold increase in antibodies binding to SARS-CoV and MERS-CoV as well as a 2- to 4-fold difference in antibodies binding to seasonal hCoVs in COVID-19 convalescent sera compared to pre-pandemic healthy donors, with the S2 subdomain of the S protein being the main target for cross-reactivity. In addition, we detected cross-reactive antibodies to all hCoV S proteins after SARS-CoV-2 vaccination in macaques and humans, with higher responses for hCoV more closely related to SARS-CoV-2. These findings support the feasibility of and provide guidance for development of a pan-coronavirus vaccine.

Safety Monitoring after the BNT162b2 COVID-19 Vaccine among Adults Aged 75 Years or Older. BACKGROUND: Older adults are given high priority for coronavirus disease 2019 (COVID-19) vaccination; however, little is known about the safety of vaccines. This study was conducted to examine the safety of the COVID-19 vaccine for people who were â‰¥ 75 years of age, specifically those who first took two doses of the vaccine at the COVID-19 central vaccination center in South

Korea. METHODS: Safety monitoring after the BNT162b2 vaccine was conducted in three ways for older adults who received the first dose of the vaccine at our center between April 5 and April 23, 2021. For immediate adverse reactions, every person who was vaccinated was observed for 15-30 minutes after injection at the center. For active surveillance, a telephone interview was conducted for stratified randomly sampled people after 7 days of each vaccination to enquire regarding types of adverse reactions they experienced, and its severity and duration. For passive surveillance, reported adverse event data were collected from the COVID-19 vaccine adverse event following immunization (AEFI) surveillance system-run by the Korea Disease Control and Prevention Agency (KDCA). The data were then reviewed. RESULTS: In total, 2,123 older adults received at least one vaccine dose during the study period. The frequency of acute adverse reactions that developed during the observed 15-30 minutes after injection was 8.5 cases per 1,000 doses. None of the reactions was assessed as acute allergic reactions to the vaccine and no cases required special treatment or drug administration. Overall, 638 people were followed up at least once by telephone interview 7 days post vaccination. The overall response rate was 82.3%. The rates of local reactions were 50.3% after the first dose and 45.2% after the second dose, and the rates of systemic reactions were 15.2% and 26.0%, respectively. During the study period, 23 medically attended adverse events (5.4 cases per 1,000 administered doses) were reported to the KDCA AEFI surveillance system. The most common symptoms of medically attended cases were nonspecific general weakness (26%) and dizziness (26%), followed by muscle pain (22%), headache (13%), fever (13%), and skin rash or urticaria (13%). Among them, there were five serious adverse events reported, which required hospitalization, including one death. However, most of them were not related to the vaccines. CONCLUSION: BNT162b2 vaccination was tolerable among adults who were â‰¥ 75 years of age.

Multisystem Inflammatory Syndrome in an Adult after COVID-19 Vaccination: a Case Report and Literature Review. As the number of people vaccinated increases, people who complain of adverse reactions continue to occur. We experienced a case characterized by low blood pressure, persistent fever, edema due to increased systemic vascular permeability, and systemic inflammation confirmed by image and laboratory examinations after ChAdOx1 coronavirus disease 2019 (COVID-19) vaccination. The diagnostic criteria for multisystem inflammatory syndrome (MIS) in adults are known as fever of 3 days or more in adults, 2 or more mucocutaneous/gastrointestinal/neurologic symptoms, elevation of inflammatory markers, and clinical/imaging diagnosis of heart failure. A 67-year-old man who was medicated for hypertension and diabetes was admitted complaining of fever, maculopapular rash, diarrhea, headache, chills, and dizziness 6 days after the first vaccination of ChAdOx1 nCoV-19 in Korea. The COVID-19 test was negative but with low blood pressure, leukocytosis, skin rash, pulmonary edema, and increased inflammation markers. His lab findings and clinical course were consistent with those of MIS after COVID-19 vaccination. He was medicated with methylprednisolone 1 mg/kg and diuretics and recovered rapidly. He was discharged after 2 weeks and confirmed cure at outpatient clinic. We report an MIS case after COVID-19 vaccination in Korea.

A case of hemichorea following administration of the Pfizer-BioNTech COVID-19 vaccine.

Guillain-BarrÃ© syndrome after SARS-CoV-2 vaccination in a patient with previous vaccine-associated Guillain-BarrÃ© syndrome.

Acute worsening of clinical presentation in CRPS after SARS-CoV-2 (COVID-19) vaccination: a case series. We present the acute worsening of clinical presentation inÂ complex regional pain syndrome (CRPS), following mRNA-based COVID-19Â vaccination. We report the case series of three patients diagnosed with CRPS type I who presented with acute worsening of symptoms after mRNA-based COVID-19 vaccination and their medical management. The acute clinical worsening after mRNA-based COVID-19 vaccination was transient and effectively managed with adjustment of individualized therapy in all three patients. The mortality and morbidity of COVID-19 infection are

serious, and vaccination is recommended in the general population, including patients with a diagnosis of CRPS. However, clinicians should be aware of the possibility that there may be a clinical worsening CRPS after mRNA-based COVID-19 vaccination.   This case series presents the worsening of symptoms in complex regional pain syndrome (CRPS), following mRNA-based COVID-19Â vaccination. We report on three patients diagnosed with CRPS who presented with worsening of symptoms after mRNA-based COVID-19 vaccination and their medical management. The worsening of symptoms was temporary and managed with adjustment of individualized therapy in all three patients. The dangers of COVID-19 infection are serious, and vaccination is highly recommended in the general population, including patients with a diagnosis of CRPS. However, healthcare providers should be aware of the possibility of clinical worsening of CRPS after mRNA-based COVID-19 vaccination.
Clinical Variant of Guillain-Barre Syndrome With Prominent Facial Diplegia After AstraZeneca Coronavirus Disease 2019 Vaccine.
Miller Fisher Syndrome Presenting After a Second Dose of Pfizer-BioNTech Vaccination in a Patient With Resolved COVID-19: A Case Report.
Radiation recall reactions: An oncologic enigma. Radiation recall reactions (RRR) are uncommon but are a well-known phenomenon to oncologists. Tissue damage in a prior irradiation portal is 'recalled' after the administration of a drug, historically cytotoxics, or more recently, targeted or immunotherapeutic agents. Even COVID-19 vaccines are a reported cause. RRR are enigmatic in that their cause is unknown, but they generally have the histopathological and clinical features of acute or chronic inflammation. They can occur in a variety of tissues, the commonest being skin, which accounts for two-thirds of reported cases. They are generally relatively mild and self-limiting once the trigger drug is stopped, although severe cases with tissue necrosis have occurred. Rechallenge with drug does not necessarily cause reactivation of the reaction. Symptomatic treatment with steroids and antihistamines are usually effective, but their impact on the clinical course is unclear. Various hypotheses have been proposed as to the mechanism of RRR; a non-immune fixed drug reaction-like condition, dysregulated release of reactive oxygen species, abnormalities of tissue vasculature and impaired DNA repair. All could lead to a characteristic inflammatory microenvironment, resulting in dysfunction of tissue stem cells, keratinocyte necrosis and dermal abnormalities. Alternatively or in addition, low levels of inflammatory tissue cytokines induced by previous irradiation might be further upregulated by drug exposure. Most information in this review refers to data derived from cutaneous RRR, since they are the most common form reported.
Neutralization of SARS-CoV-2 Variants in Transplant Recipients After Two and Three Doses of mRNA-1273 Vaccine : Secondary Analysis of a Randomized Trial. BACKGROUND: COVID-19 is more severe in transplant recipients. Variants of concern have supplanted wild-type virus. In transplant recipients, data are limited on 2-dose or 3-dose vaccine immunogenicity against variant viruses. OBJECTIVE: To assess neutralizing antibody responses against SARS-CoV-2 variants in transplant recipients after 2 and 3 vaccine doses. DESIGN: Secondary analysis of a randomized, double-blind, controlled trial of a third dose of mRNA-1273 vaccine versus placebo. (ClinicalTrials.gov: NCT04885907). SETTING: Single-center transplant program. PATIENTS: Organ transplant recipients. INTERVENTION: Third dose of mRNA-1273 vaccine versus placebo. MEASUREMENTS: Sera were analyzed for neutralization against wild-type virus and the Alpha, Beta, and Delta variants using a surrogate virus neutralization assay and a spike-pseudotyped lentivirus assay. RESULTS: A total of 117 transplant recipients were analyzed (60 in the mRNA-1273 group and 57 in the placebo group). Sera were obtained before and 4 to 6 weeks after the third dose. After 2 doses, the proportion of patients with positive neutralization for all 3 variants was small compared with wild-type virus. After the third dose of mRNA-1273 vaccine, the proportion with a positive neutralization response versus placebo

was improved for all 3 variants as measured by both assays. Based on the pseudovirus neutralization assay against the Delta variant, 33 of 60 (55%) patients were positive in the mRNA-1273 group versus 10 of 57 (18%) in the placebo group (difference, 37 [95% CI, 19 to 53] percentage points). The differences were 36 (CI, 17 to 51) percentage points for the Alpha variant and 31 (CI, 15 to 46) percentage points for the Beta variant. In the mRNA-1273 group, lower neutralization values were observed for variants compared with wild-type virus, especially the Beta variant. LIMITATIONS: There is no clear correlate of protection for neutralizing antibody. This was a secondary analysis. CONCLUSION: In organ transplant recipients, a third dose of mRNA vaccine increases neutralizing antibody response against SARS-CoV-2 variants compared with placebo. PRIMARY FUNDING SOURCE: Ajmera Transplant Centre.

Subacute cutaneous lupus erythematosus induction after SARS-CoV-2 vaccine in a patient with primary biliary cholangitis.

Status migrainosus: a potential adverse reaction to Comirnaty (BNT162b2, BioNtech/Pfizer) COVID-19 vaccine-a case report. BACKGROUND: Coronavirus disease-19 (COVID-19) due to acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection is the largest emergency that humanity had to be dealing with in the last century. During the last months, different types of vaccines have been designed to contain the ongoing SARS-CoV-2 pandemic, with successful results in many countries. Comirnaty (Pfizer/BioNtech) COVID-19 vaccine is a lipid nanoparticle-formulated, nucleoside mRNA vaccine encoding the prefusion spike glycoprotein of SARS-CoV-2. Although vaccines have an undeniable efficacy, they can also present several neurological side effects, including headache. According to ICHD-3 Classification, status migrainosus (SMg) is described as a debilitating migraine attack lasting for more than 72 h. Symptoms of SMg can be very severe, preventing the normal daily activities of the individual. CASE PRESENTATION: In the present report, we describe a case of SMg that lasted 11 days, time correlated with the second dose of COVID-19 vaccine (Pfizer/Comirnaty) in a 37-year-old woman with a history of migraine without aura. CONCLUSIONS: In patients with a history of migraine, COVID-19 vaccination could lead to a worsening of headache and, in rare cases, to the development of a SMg. This may be related to the inflammatory response that occurs after vaccination.

Myocardial Infarction, Stroke, and Pulmonary Embolism After BNT162b2 mRNA COVID-19 Vaccine in People Aged 75 Years or Older. This population-based study evaluates the short-term risk of severe cardiovascular events among French residents aged 75 years or older after receipt of the BNT162b2 mRNA COVID-19 vaccination.

Impact of Distinct Therapies on Antibody Response to SARS-CoV-2 Vaccine in Systemic Lupus Erythematosus. OBJECTIVE: To date, the only study that has assessed the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 mRNA) vaccine in systemic lupus erythematosus (SLE) observed a moderate response, but the sample size precluded an accurate analysis of the effect of individual drugs. Therefore, we evaluated the immunogenicity of an inactivated SARS-CoV-2 vaccine (Sinovac-CoronaVac) and the influence of different medications in SLE. Safety was also assessed. METHODS: We conducted a prospective controlled study of 232 SARS-CoV-2-naive SLE patients and 58 SARS-CoV-2-naive controls who were vaccinated with 2 doses of Sinovac-CoronaVac with a 28-day interval (day 0/day 28 [D0/D28]). Immunogenicity analysis at D0/D28 and D69 included anti-SARS-CoV-2 S1/S2 IgG seroconversion (SC) and neutralizing antibodies (NAb) positivity. The influence of individual drugs on immune response and safety was assessed. RESULTS: Patients and controls were well balanced for age (Pâ€‰=â€‰0.771). At D69, SLE patients showed a moderate SC (70.2% versus 98.1%; Pâ€‰<â€‰0.001) and moderate frequency of NAb positivity (61.5% versus 84.6%; Pâ€‰=â€‰0.002), although both frequencies were lower than in controls. Factors associated with lower SC in univariate analysis at D69 were prednisone use (odds ratio [OR] 0.215 [95%

confidence interval (95% CI) 0.108-0.427], Pâ€‰<â€‰0.001) and mycophenolate mofetil (MMF) use (OR 0.201 [95% CI 0.107-0.378], Pâ€‰<â€‰0.001), whereas hydroxychloroquine (HCQ) use led to a 2.5 increase in SC (Pâ€‰=â€‰0.011). SLE patients who were receiving HCQ monotherapy had similar SC to controls at D69 (100% versus 98.1%; Pâ€‰=â€‰1.000). In multivariate analysis, prednisone and MMF use were independently associated with lower SC (Pâ€‰<â€‰0.001) and NAb positivity (Pâ€‰<â€‰0.001). Safety analysis revealed no moderate/severe adverse events. CONCLUSION: Sinovac-CoronaVac has a moderate immunogenicity in SARS-CoV-2-naive SLE patients with an excellent safety profile. We further demonstrate that HCQ may improve SC, whereas prednisone and MMF had a major deleterious effect in vaccine response, reinforcing the need to investigate the role of temporary MMF withdrawal or a vaccine-booster dose (ClinicalTrials.gov identifier: NCT04754698).

COVID-19 vaccine take-up rate and safety in adults with epilepsy: Data from a multicenter study in China. OBJECTIVE: This study was undertaken to investigate the COVID-19 vaccine uptake rate and possible postvaccination effects in adults with epilepsy. METHODS: We invited adults with epilepsy attending three centers in China from July 24 to August 31, 2021 to participate in this study. We also asked age- and sex-matched controls among people attending for other chronic neuropsychiatric conditions and healthy controls accompanying people with illness attending the hospitals to participate. We excluded people who, under the national guidelines, had evident contradictions to vaccination. Participants were interviewed face-to-face using questionnaires. Vaccine uptake and postvaccine adverse events among the people with epilepsy were compared with those with neuropsychiatric conditions and controls. We also compared the willingness and reasons for hesitancy among unvaccinated participants. RESULTS: We enrolled 981 people, of whom 491Â had epilepsy, 217Â had other neuropsychiatric conditions, and 273 were controls. Forty-two percent of those with epilepsy had had the first dose of a vaccine, compared with 93% of controls and 84% of the people with neuropsychiatric conditions (pÂ <Â .0001). The majority (93.8%) of those immunized had inactivated vaccines. Among the unvaccinated people with epilepsy, 59.6% were willing to have the vaccine. Their main reasons for hesitation were potential adverse effects (53.3%) and concerns about losing seizure control (47.0%). The incidence of adverse events in the epilepsy group was similar to controls. Nineteen people with epilepsy reported an increase in seizure frequency. No episode of status epilepticus or prolonged seizures was reported. Two controls had their first-ever seizure, which was unlikely related to the vaccine. SIGNIFICANCE: The vaccine uptake rate in people with epilepsy was lower than in their same-age controls. The postvaccination effect was no higher than in controls. We found no evidence suggesting worsening seizures after vaccination. Measurement and education focused on increasing the vaccination rate in epilepsy are warranted.

SARS CoV-2 Delta variant exhibits enhanced infectivity and a minor decrease in neutralization sensitivity to convalescent or post-vaccination sera. Since their identification, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Kappa and Delta have rapidly spread to become globally dominant. However, their infectivity and sensitivity to administered vaccines have not been documented. We monitored the neutralization potential of convalescent or BNT162b2 post-vaccination sera against Kappa and Delta SARS-CoV-2 pseudoviruses. We show that both variants were successfully neutralized by convalescent and post-vaccination sera, exhibiting a mild decrease in their neutralization sensitivity. Of the two variants, Delta presented enhanced infectivity levels compared with Kappa or wild-type SARS-CoV-2. Nevertheless, both variants were not as infectious or resistant to post-vaccination sera as the Beta variant of concern. Interestingly, the Delta plus variant (AY.1/B.1.617.2.1) exhibited high resistance to post-vaccination sera, similar to that of the Beta SARS-CoV-2. However, its infectivity levels were close to those of wild-type SARS-CoV-2. These results account for the worldwide prevalence of Delta variant of concern and confirm the efficacy of the BNT162b2 vaccine against circulating other Delta variants.

Myocarditis and pericarditis in association with COVID-19 mRNA-vaccination: cases from a regional pharmacovigilance centre. In this article we summarize suspected adverse events following immunization (AEFI) of pericarditis, myocarditis and perimyocarditis that were reported by our regional pharmacovigilance centre after COVID-19 mRNA-vaccination and discuss their association with these vaccines. Seventeen cases were reported between March and July 2021. Of these, nine had perimyocarditis, five myocarditis and three pericarditis. Twelve patients were male (71%). The median age was 38 years (range 17-88). The most commonly observed presenting symptom was acute chest pain (65%). While 47% of the patients were previously healthy, 53% had at least one pre-existing comorbidity, with hypertension being the most prevalent (24%). The European Society of Cardiology diagnostic criteria for the reported AEFIs were fulfilled in twelve cases (71%). The AEFIs occurred after the first vaccine dose in six cases (35%), after the second vaccine dose in ten cases (59%) and after both doses in one case (6%). The median latency of all AEFIs taken together was 14 days (range 1-28) after the first vaccination and 3 days (range 1-17) after the second one. All patients except one were hospitalized (94%) with a median length of stay of 7.5 days (range 3-13). The majority of patients (nÂ =Â 11, 65%) did not experience any complications, and 13 (77%) of the patients had recovered or were recovering at the time of discharge. In 16 of the 17 cases (94%), the association between the AEFI and mRNA-vaccination was considered possible by the pharmacovigilance centre.

Immune thrombocytopenia relapse post covid-19 vaccine in young male patient. Immune thrombocytopenic purpura (ITP) is a blood disorder in which antibodies coating platelets cause platelets destruction in the spleen with resultant low platelets count and an increased tendency for bleeding. Coronavirus disease 2019 (COVID-19) is an illness caused by SARS-COV2; it was first identified in December/2019; though it mainly affects the respiratory system, multisystemic complications are identified. Several ITP cases post mRNA SARS-CoV-2 vaccines were reported, and different pathophysiology theories about the underlying pathophysiology were discussed, but only a few ITP relapse cases have been reported so far. We present a 28-year-old Asian male, a known patient of ITP and in partial remission for eighteen months, who presented to the emergency department with ITP relapse (platelets count of 1Â Ã—Â 10^3 /ÂµL), four days after receiving the second dose of Pfizer SARS-CoV-2 vaccine, which required treatment with intravenous immunoglobulins and dexamethasone. We further discuss the preferred approach in ITP patients who are willing to receive the COVID-19 vaccine.

Acute Myocarditis Following the Administration of the Second BNT162b2 COVID-19 Vaccine Dose. COVID-19 disease hasÂ infected millions of people worldwide during the pandemic; hence, the need for an effective and safe vaccine was urgently required. A two-dose of the BNT162b2 mRNA COVID-19 vaccine was reported to have 95% efficacy in preventing COVID-19. The short-term safety profile recorded mild to moderate pain at the injection site, fatigue, and headache. The critical adverse effects were low and similar in the placebo group. However, we report the case of an 18-year-old male who developed acute central crushing chest pain four days following administration of the second dose of the BNT162b2 COVID-19 vaccine. After extensive cardiac workup, including coronary arteries diagnostic angiography, myocarditisÂ was suspectedÂ and confirmed by a cardiac MRI. Fortunately, the patient's clinical conditionÂ gradually improved in the form of clinical symptoms and laboratory findings. He was discharged after one week of stay in hospital with regular follow-up in the cardiac clinic.

Minimal Change Disease After First Dose of Pfizer-BioNTech COVID-19 Vaccine: A Case Report and Review of Minimal Change Disease Related to COVID-19 Vaccine. RATIONALE: While severe complications are generally uncommon with novel coronavirus disease 2019 (COVID-19) vaccine, there has been a steady increase in the number of patients presenting with nephrotic syndrome and

acute kidney injury after the administration of COVID-19 vaccine. Physicians should be made aware of minimal change disease as a potential complication associated with COVID-19 vaccine. PRESENTING CONCERNS: A 60-year-old male without significant past medical history presented with new onset of nephrotic syndrome approximately 10 days after his first dose of Pfizer-BioNTech COVID-19 vaccine. Laboratory findings showed hypoalbuminemia (20 g/L), elevated urine albumin/creatinine ratio (668 mg/mmol), and elevated creatinine of 116 Âµmol/L from a baseline of 79 Âµmol/L. DIAGNOSIS: A diagnostic kidney biopsy was performed 6 weeks after the onset of the edema and approximately 8 weeks after his first dose of Pfizer-BioNTech COVID-19 vaccine. The kidney biopsy findings were consistent with minimal change disease with focal acute tubular injury. INTERVENTIONS: The patient was treated conservatively with ramipril 10 mg and furosemide 80 mg daily 5 weeks after the onset of swelling. Prednisone 1 mg/kg was initiated immediately when the kidney biopsy result became available (approximately 6 weeks after the onset of edema). OUTCOMES: The patient remitted with rapid weight loss starting 2 weeks post prednisone initiation. NOVEL FINDINGS: De novo minimal change disease with acute tubular injury is a kidney manifestation following the administration of Pfizer-BioNTech COVID-19 vaccine. Minimal change disease is potentially a rare complication of Pfizer-BioNTech COVID-19 vaccine.
Minimal change disease following vaccination with CoronaVac.
Isolated pulmonary embolism following COVID vaccination: 2 case reports and a review of post-acute pulmonary embolism complications and follow-up. Acute pulmonary embolism (PE) is a frequent cause of hypoxemic respiratory failure and presentation to the emergency department. The incidence is on the increase since the COVID-19 outbreak. While COVID infection represents a prothrombotic state, the introduction of COVID vaccines to a lesser extent increased the risk of unprovoked venous thrombus formation and risk of pulmonary embolism. PE is mostly associated with deep vein thrombosis (DVT) and only a few cases of isolated or De novo PE exist in literature. We report two cases of isolated PE associated with COVID-19 vaccinations. We aimed to highlight the need to suspect isolated PE in patients presenting with hypoxemic respiratory failure days to several weeks following COVID-19 vaccination and emphasize the importance of post-discharge follow-up for evaluating chronic thromboembolic pulmonary hypertension (CTEPH).
A Case of COVID-19 Vaccine-Induced Thrombotic Thrombocytopenia. SARS-CoV-2, which originated in China in late 2019, has spread rapidly resulting in a global pandemic. Multiple vaccines have been developed to help prevent COVID-19 infection. Similar to other vaccines, common side effects including fever, fatigue, myalgias have occurred; however, episodes of more serious side effects have been noted. One such potentially serious sequalae is vaccine-induced thrombocytopenia (VITT), an autoimmune-mediated phenomenon hypothesized to occur due to molecular mimicry and the production of platelet PF4 antibodies, ultimately leading to thrombocytopenia and easy bruising. In this report, we present the case of a 34-year-old, otherwise, healthy female who presented with easy bruising and thrombocytopenia following completion of the two-dose Moderna COVID-19 vaccine, suspicious for a diagnosis of VITT. The patient was managed conservatively with steroids. Steroids and intravenous immune globulin therapy have been reported in the literature. This report highlights that VITT should be considered in the differential diagnosis for patient presenting with increased bruising in the setting of recent COVID-19 vaccine administration, and furthermore highlights the diagnostic workup and management options for such patients.
A rare presentation of undiagnosed multiple sclerosis after the COVID-19 vaccine. Multiple sclerosis (MS) is an auto-immune mediated neurological disorder that affects the central nervous system and leads to myelin sheath destruction. The pathogenesis of MS involves T helper cells causing inflammation and eventual death of the oligodendrocytes. Etiologies for the development of MS include a combination of genetic, environmental, and immune factors. Vaccines have been

proposed to increase the immune response and have reportedly activated some autoimmune disorders. Although certain vaccines such as hepatitis B have been associated with MS, studies have refuted these cases. We present a rare case of a 32-year-old patient who presented with symptoms and suggestive of MS a few days after receiving the COVID vaccine. Laboratory and imaging findings confirmed the diagnosis of MS, and she was started on steroids and discharged in a stable condition a few days after.

Long QT interval and syncope after a single dose of COVID-19 vaccination: a case report. Adverse consequences of the coronavirus disease 2019 (COVID-19) vaccination which have been reported in scientific papers are varied. One possible but rare consequence is myocarditis, which may have a diversity of clinical manifestations. We report a case of a 70-year-old man who presented to the hospital for some syncope, 3 days after his first COVID-19 AstraZeneca Vaccination. Initial electrocardiogram (ECG) showed a long QT interval (QTc = 600 milliseconds). Laboratory tests revealed elevated troponin and lack of evidence of viral infection. Further investigations revealed the vaccine-induced myocarditis and arrhythmias linked to it. Within one week of magnesium treatment, the QT interval was completely corrected, and the patient discharged with no typical syncope attacks. This case like the previous reported one confirms that myocarditis is a complication of COVID-19 vaccine, but implies its clinical manifestations may be varied and even may happen after the single dose of vaccination.

Serious adverse events following immunization after ChAdOx1 nCov-19 vaccination in India: a single center experience.

COVID-19 mRNA Vaccination in Lactation: Assessment of Adverse Events and Vaccine Related Antibodies in Mother-Infant Dyads. BACKGROUND: Data regarding symptoms in the lactating mother-infant dyad and their immune response to COVID-19 mRNA vaccination during lactation are needed to inform vaccination guidelines. METHODS: From a prospective cohort of 50 lactating individuals who received mRNA-based vaccines for COVID-19 (mRNA-1273 and BNT162b2), blood and milk samples were collected prior to first vaccination dose, immediately prior to 2nd dose, and 4-10 weeks after 2nd dose. Symptoms in mother and infant were assessed by detailed questionnaires. Anti-SARS-CoV-2 antibody levels in blood and milk were measured by Pylon 3D automated immunoassay and ELISA. In addition, vaccine-related PEGylated proteins in milk were measured by ELISA. Blood samples were collected from a subset of infants whose mothers received the vaccine during lactation (4-15 weeks after mothers' 2nd dose). RESULTS: No severe maternal or infant adverse events were reported in this cohort. Two mothers and two infants were diagnosed with COVID-19 during the study period before achieving full immune response. PEGylated proteins were not found at significant levels in milk after vaccination. After vaccination, levels of anti-SARS-CoV-2 IgG and IgM significantly increased in maternal plasma and there was significant transfer of anti-SARS-CoV-2-Receptor Binding Domain (anti-RBD) IgA and IgG antibodies to milk. Milk IgA levels after the 2nd dose were negatively associated with infant age. Anti-SARS-CoV-2 IgG antibodies were not detected in the plasma of infants whose mothers were vaccinated during lactation. CONCLUSIONS: COVID-19 mRNA vaccines generate robust immune responses in plasma and milk of lactating individuals without severe adverse events reported.

COVID-19 in B Cell-Depleted Patients After Rituximab: A Diagnostic and Therapeutic Challenge. B cell-targeting strategies such as rituximab are widely used in B cell hematologic malignancies, rheumatologic and musculoskeletal diseases and a variety of autoimmune disorders. The purpose of this paper is to illustrate how exposure to anti-CD20 treatment profoundly affects B cell functions involved in anti-SARS-CoV-2 immunity and significantly impacts on the clinical and serological course of SARS-CoV-2 infection, long term immunity and vaccine responses. The data presented here suggest that the effects of B cell-depleting agents on adaptive immunity should be taken into account for the

proper selection and interpretation of SARS-CoV-2 diagnostics and to guide appropriate therapeutic approaches and protective measures. Combination therapeutic strategies including immunotherapy in association with prolonged antiviral treatment may play a decisive role in the setting of B cell immune deficiencies.

Acute Psychosis Due to Anti-N-Methyl D-Aspartate Receptor Encephalitis Following COVID-19 Vaccination: A Case Report. Anti-N-methyl D-aspartate (NMDA) receptor (anti-NMDAR) encephalitis has been reported after SARS-CoV-2 infection, but not after SARS-CoV-2 vaccination. We report the first known case of anti-NMDAR encephalitis after SARS-CoV-2 immunization in a young female presenting with acute psychosis, highlighting a rare potential immunological complication of vaccination against SARS-CoV-2 that is currently being distributed worldwide. The patient presented initially with anxiety and hypochondriacal delusions which progressed to psychosis and catatonia but returned to baseline with aggressive immunomodulatory therapy consisting of intravenous immunoglobulin, high-dose glucocorticoids, and rituximab. This study highlights that the workup of acute psychosis should include establishing a history of recent vaccination followed by a thorough neurological assessment, including for anti-NMDAR antibodies in blood and cerebrospinal fluid.

CoronaVac (Sinovac) COVID-19 vaccine-induced molecular changes in healthy human serum by infrared spectroscopy coupled with chemometrics. From the beginning of the COVID-19 coronavirus pandemic in December of 2019, the disease has infected millions of people worldwide and caused hundreds of thousands of deaths. Since then, several vaccines have been developed. One of those vaccines is inactivated CoronaVac-Sinovac COVID-19 vaccine. In this proof of concept study, we first aimed to determine CoronaVac-induced biomolecular changes in healthy human serum using infrared spectroscopy. Our second aim was to see whether the vaccinated group can be separated or not from the non-vaccinated group by applying chemometricÂ techniques to spectral data. The results revealed that the vaccine administration induced significant changes in some functional groups belonging to lipids, proteins and nucleic acids. In addition, the non-vaccinated and vaccinated groups were successfully separated from each other by principal component analysis (PCA) and linear discriminant analysis (LDA). This proof-of-concept study will encourage future studies on CoronaVac as well as other vaccines and will lead to make a comparison between different vaccines to establish a better understanding of the vaccination outcomes on serum biomolecules.

Acquired Thrombotic Thrombocytopenic Purpura Following BNT162b2 mRNA Coronavirus Disease Vaccination in a Japanese Patient. A 57-year-old man without underlying diseases presented with fatigue, loss of appetite, and jaundice 1 week after receiving the first dose of the BNT162b2 mRNA coronavirus disease 2019 (COVID-19) vaccine and showed hemolytic anemia with fragmented erythrocytes and severe thrombocytopenia 2 weeks after receiving the vaccine. An a disintegrin-like and metalloproteinase with thrombospondin type 1 motifs 13 (ADAMTS13) activity level of <10% and ADAMTS13 inhibitor positivity confirmed the diagnosis of acquired thrombotic thrombocytopenic purpura (TTP). Combination therapy with plasma exchange, corticosteroid, and rituximab improved the clinical outcome. We herein report the first Japanese case of TTP possibly associated with vaccination. Physicians should be alert for this rare but life-threatening hematological complication following COVID-19 vaccination.

Thrombotic events and COVID-19 vaccines. COVID-19 vaccines are considered promising agents in the control of the pandemic. Although their safety was assessed in randomised clinical trials, severe adverse events (AEs) have been reported after large-scale administration. This study aims to evaluate thromboembolic AEs reported after vaccination in a real-world context and how they led to the interruption of vaccination campaigns. We also review the benefits and risks of the vaccines approved in the European Union and provide recommendations. A review of the literature was performed using Medline/PubMed electronic database as well as institutional and pharmacovigilance

official reports. Our findings show that vaccine-induced prothrombotic immune thrombocytopenia has been suggested as a very rare AE associated with viral vector vaccines. Unusual thrombotic events combined with moderate-to-severe thrombocytopenia were reported mainly in women under 60 years of age. As safety signals emerged, Vaxzevria and JanssenÂ´s COVID-19 vaccine campaigns have been paused while investigations proceed. On the other hand, the number of deep vein thrombosis and pulmonary embolism reports have not increased. Post-marketing surveillance indicated that mRNA vaccines are safe and should continue to be used. The thrombotic events report rate is not increased in people over 60 years. As they are at greater risk for COVID-19 complications and death, no vaccine restrictions are recommended in this group. Risk factors for vaccine-induced prothrombotic immune thrombocytopenia should be established so that evidence-based decisions can be made. Systematic monitoring of COVID-19 vaccine safety is essential to ensure that the benefits of vaccination outweigh the risks.
COVID-19 vaccine-induced thrombosis.
Impaired neutralizing antibody response to COVID-19 mRNA vaccines in cancer patients. There is currently a critical need to determine the efficacy of SARS-CoV-2 vaccination for immunocompromised patients. In this study, we determined the neutralizing antibody response in 160 cancer patients diagnosed with chronic lymphocytic leukemia (CLL), lung cancer, breast cancer, and various non-Hodgkin's lymphomas (NHL), after they received two doses of mRNA vaccines. Serum from 46 mRNA vaccinated health care workers (HCWs) served as healthy controls. We discovered that (1) cancer patients exhibited reduced neutralizing antibody titer (NT(50)) compared to HCWs; (2) CLL and NHL patients exhibited the lowest NT(50) levels, with 50-60% of them below the detection limit; (3) mean NT(50) levels in patients with CLL and NHL was ~2.6 fold lower than those with solid tumors; and (4) cancer patients who received anti-B cell therapy exhibited significantly reduced NT(50) levels. Our results demonstrate an urgent need for novel immunization strategies for cancer patients against SARS-CoV-2, particularly those with hematological cancers and those on anti-B cell therapies.
Mechanisms of COVID-19-induced kidney injury and current pharmacotherapies. The COVID-19 pandemic created a worldwide debilitating health crisis with the entire humanity suffering from the deleterious effects associated with the high infectivity and mortality rates. While significant evidence is currently available online and targets various aspects of the disease, both inflammatory and noninflammatory kidney manifestations secondary to COVID-19 infection are still largely underrepresented. In this review, we summarized current knowledge about COVID-19-related kidney manifestations, their pathologic mechanisms as well as various pharmacotherapies used to treat patients with COVID-19. We also shed light on the effect of these medications on kidney functions that can further enhance renal damage secondary to the illness.
Response to McMahon etÂ al's "Cutaneous reactions reported after Moderna and Pfizer COVID-19 vaccination: A registry-based study of four hundred fourteen cases".
Prevalence of COVID-19 vaccines (Sputnik V, AZD-1222, and Covaxin) side effects among healthcare workers in Birjand city, Iran. BACKGROUND: The prevalence of vaccine side effects plays an important role in public perception about vaccination programs. This study was designed to investigate the side effects of the first dose of COVID-19 vaccine; Sputnik-V, AZD-1222, and Covaxin. METHODS: A study was performed to evaluate the side effects of these vaccine among 503 health care workers in Birjand (Iran). Our study used the questionnaire consisted of 4 main categories including demographic data, previous COVID-19 infection, vaccine information, and local and systemic side effects of vaccines. RESULTS: 81.9%, 88.8%, and 92.9% of people who have been vaccinated with Sputnik-V, AZD1222, and Covaxin vaccines, respectively, have reported at least one side effect. The prevalence of systemic side effects in AZD-1222 vaccine was higher than Sputnik V and Covaxin vaccines. Injection site pain (62.1%), fatigue (43.9%), muscle pain (42.5%), and fever

(40.6%) were the most common side effects in all three vaccines. Side effect frequency was higher in the female group (90.6%) than the male group (79.5%). The prevalence of side effects with Sputnik V and Covaxin vaccines was reduced in the elderly. Moreover, the prevalence of side effects was higher in the case of convalescent patients (92.4 %) than in the group with no history of infection. The prevalence of side effects was higher in person with a BMI above 25 in the AZD-1222 and Covaxin vaccines. CONCLUSIONS: The most common side effects of the Sputnik-V, AZD-1222, and Covaxin vaccine among Birjand (Iran) healthcare workers were injection site pain, muscle pain, fatigue, fever, and headache. Age and gender were the most important variables in the prevalence of vaccine side effects.
Skin reactions to COVID-19 vaccines: An American Academy of Dermatology/International League of Dermatological Societies registry update on reaction location and COVID vaccine type.
COVID-19 vaccination and cancer immunotherapy: should they stick together? The combination of COVID-19 vaccination with immunotherapy by checkpoint inhibitors in cancer patients could intensify immunological stimulation with potential reciprocal benefits. Here, we examine more closely the possible adverse events that can arise in each treatment modality. Our conclusion is that caution should be exercised when combining both treatments.
Perceptions and barriers to the annual influenza vaccine compared with the coronavirus disease 2019 vaccine in an urban underserved population. BACKGROUND: For a vaccine to be successful, communities must perceive it as important, safe, effective, and necessary. However, there are many barriers and hesitancies to vaccination. Underserved patient populations may face additional challenges related to access and cost. Because community pharmacists improve vaccine access and increase vaccination rates, it is beneficial for pharmacists to understand perceptions and barriers to vaccinations in their community to increase vaccine confidence. OBJECTIVES: This study aims to assess and compare barriers and perceptions of the annual influenza to the coronavirus disease 2019 (COVID-19) vaccine for underserved patients of a charitable pharmacy. METHODS: Patients who qualified to receive medications from an outpatient charitable pharmacy took an electronic survey when receiving medications. The survey incorporated questions developed by the World Health Organization's Strategic Advisory Group of Experts on Vaccine Hesitancy on a 5-point Likert scale. Questions about the influenza and COVID-19 vaccines mirrored one another. Demographic data such as age, race, sex, and education level were also collected. RESULTS: Of the 189 patients surveyed at the charitable pharmacy, 71.7% were 55 years old and older and 58.9% were female. Of note, 78% and 77% of participants agreed or strongly agreed that the influenza and COVID-19 vaccines, respectively, were important for the health of others in their community. Adverse effects and the cost of the COVID-19 vaccine were noted to be statistically significantly more of a concern with the COVID-19 vaccine than that of the influenza vaccine ($P < 0.001$). CONCLUSION: Ensuring equitable vaccine access, promoting the COVID-19 vaccine as free, and eliciting and addressing individual persons' concerns related to vaccine safety and adverse effects are all important ways pharmacists and other health care providers and community stakeholders can help promote vaccine confidence within the populations they serve.
The pathogenesis of potential myocarditis induced by COVID-19 vaccine.
Steroid-responsive aseptic meningitis after BNT162b2 SARS-CoV-2 vaccine.
Evaluation of COVID-19 vaccine response in patients with cancer: An interim analysis. BACKGROUND: Efficacy and safety data of COVID-19 vaccines among cancer populations have been limited; however, preliminary data from recent studies have emerged regarding their immunogenicity and safety in this population. In this review, we examined current peer-reviewed publications containing serological and safety data afterÂ COVID-19 vaccination of patients with cancer. METHODS: This analysis examined 21 studies with a total of 5012 patients with cancer, of which 2676

(53%) had haematological malignancies, 2309 (46%) had solid cancersÂ and 739 were healthy controls. Serological responses by anti-SARS-CoV-2 spike protein S1/S2 immunoglobulin G antibody levels and post-vaccination patient questionnaires regarding vaccine-related side-effects after the first and second dose were collected and analysed. RESULTS: In general, a single dose of the COVID-19 vaccine yields weaker and heterogeneous serological responses in both patients with haematological and solid malignancies. On receiving a second dose, serological response rates indicate a substantial increase in seropositivity to the SARS-CoV-2 spike protein in all cancer cohorts, but antibody titres remain reduced in comparison with healthy controls. Furthermore, seroconversion in patients with haematological malignancies was significantly lower than that in patients with solid tumours. COVID-19 vaccines are safe and well-tolerated in patients with cancer based on current data of local and systemic effects. CONCLUSION: Together, these data support the prioritisation of patients with cancer to receive their first and second doses to minimise the risk of COVID-19 infection and severe complications in this vulnerable population. Additional prophylactic measures must be considered for high-risk patients where current vaccination programs may not mount sufficient protection against SARS-CoV-2 infection.

Utility and futility of skin testing to address concerns surrounding messenger RNA coronavirus disease 2019 vaccine reactions. BACKGROUND: The mechanism of coronavirus disease 2019 (COVID-19) vaccine hypersensitivity reactions is unknown. COVID-19 vaccine excipient skin testing has been used in evaluation of these reactions, but its utility in predicting subsequent COVID-19 vaccine tolerance is also unknown. OBJECTIVE: To evaluate the utility of COVID-19 vaccine and vaccine excipient skin testing in both patients with an allergic reaction to their first messenger RNA COVID-19 vaccine dose and patients with a history of polyethylene glycol allergy who have not yet received a COVID-19 vaccine dose. METHODS: In this multicenter, retrospective review, COVID-19 vaccine and vaccine excipient skin testing was performed in patients referred to 1 of 3 large tertiary academic institutions. Patient medical records were reviewed after skin testing to determine subsequent COVID-19 vaccine tolerance. RESULTS: A total of 129 patients underwent skin testing, in whom 12 patients (9.3%) had positive results. There were 101 patients who received a COVID-19 vaccine after the skin testing, which was tolerated in 90 patients (89.1%) with no allergic symptoms, including 5 of 6 patients with positive skin testing results who received a COVID-19 vaccine after the skin testing. The remaining 11 patients experienced minor allergic symptoms after COVID-19 vaccination, none of whom required treatment beyond antihistamines. CONCLUSION: The low positivity rate of COVID-19 vaccine excipient skin testing and high rate of subsequent COVID-19 vaccine tolerance suggest a low utility of this method in evaluation of COVID-19 vaccine hypersensitivity reactions. Focus should shift to the use of existing vaccine allergy practice parameters, with consideration of graded dosing when necessary. On the basis of these results, strict avoidance of subsequent COVID-19 vaccination should be discouraged.

Letter to the editor: "Autoimmune hepatitis after COVID-19 vaccination".

Influenza vaccination coverage among emergency department personnel is associated with perception of vaccination and side effects, vaccination availability on site and the COVID-19 pandemic. INTRODUCTION: Influenza is a major concern in hospitals, including the emergency department (ED), mainly because of a high risk for ED personnel to acquire and transmit the disease. Although influenza vaccination is recommended for health care workers, vaccination coverage is low. METHODS: This survey was conducted in the 2016/2017 and 2020/2021 influenza seasons. Questionnaires were sent to ED personnel in 12 hospitals in Bavaria, South-Eastern Germany. The response rates were 62% and 38% in 2016/2017 and 2020/2021, respectively. Data were compared between the two seasons as well as between vaccinated and not vaccinated respondents in 2020/2021. RESULTS: Significantly more ED personnel reported having been vaccinated in the

2020/2021 season. Factors associated with vaccination coverage (or the intention to get vaccinated) were profession (physician / medical student), having been vaccinated at least twice, the availability of an influenza vaccination on site (in the ED) as well as the COVID-19 pandemic. Additionally, significant differences in the assessment and evaluation of influenza, its vaccination side effects and ethical aspects were found between vaccinated and not vaccinated ED personnel in 2020/2021. Unvaccinated respondents estimated higher frequencies of almost all potential vaccination side effects, were less likely to accept lay-offs if employees would not come to work during an influenza pandemic and more likely to agree that work attendance should be an employeeÂ´s decision. Vaccinated participants instead, rather agreed that vaccination should be mandatory and were less likely to consider job changes in case of a mandatory vaccination policy. CONCLUSION: The COVID-19 pandemic might have contributed to a higher influenza vaccination rate among ED workers. Vaccination on site and interventions targeting the perception of influenza vaccination and its side effects may be most promising to increase the vaccination coverage among ED personnel.

Eltrombopag for refractory vaccine-induced immune thrombotic thrombocytopenia. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a life-threatening complication described after administration of recombinant adenoviral vector encoding the spike protein antigen of Severe Acute Respiratory Syndrome CoronaVirus-2. The syndrome is characterized by platelet consumption and thrombosis. High levels of antibodies to platelet factor 4 (PF4)-polyanion complexes were identified in many patients with VITT by enzyme-linked immunosorbent assay (ELISA). A 64-year-old woman presented with thrombocytopenia, right renal vein thrombosis with renal infarction, right intra-right atrium and intra-right ventricle thrombosis and pulmonary embolism after ChAdOx1-S vaccine administration. ELISA for antibodies to PF4-polyanion complexes tested positive, while functional tests were not. Thrombocytopenia was refractory to intravenous immunoglobulins and corticosteroids. Eltrombopag was introduced and platelet gradually rose to normal values. VITT is a novel complication yet to be understood. The clinical case we reported highlights the difficulties in the management of this disorder and discloses Â a new potential therapy in refractory conditions.

A flare of Still's disease following COVID-19 vaccination in a 34-year-old patient. Vaccination is a cornerstone for reducing the risk of COVID-19 infection during a pandemic. Although the currently used COVID-19 vaccine is considered safe, some concerns persist regarding the likelihood of flares of rheumatic diseases. Still's disease is a rare auto-inflammatory disorder of unknown etiology, and the data on the flare of Still's disease following COVID-19 vaccination are limited. Therefore, we hereby present the case of a 34-year-old female patient with Still's disease who experienced a flare after a ChAdOx1 nCoV-19 vaccination. The patient visited the emergency department complaining of fever, arthralgia, myalgia, pleuritic chest pain and macular salmon-pink rash on her back for the past 2Â days. She had maintained low Still's disease activity with etanercept and low-dose glucocorticoid for 14Â years. She received the ChAdOx1 nCoV-19 vaccine 7Â days before the flare. Laboratory investigations revealed leucocytosis and elevated serum levels of erythrocyte sedimentation rate, C-reactive protein, and ferritin. Computed tomography showed no specific findings. She received methylprednisolone pulse therapy, etanercept, and methotrexate for treating the Still's disease flare. However, her symptoms were not fully controlled, and she developed pericarditis, pleuritis, fever and macular rashes expanding to her extremities. After excluding infectious conditions by blood culture and pleural fluid analysis, we administered tocilizumab with methotrexate and prednisolone. Her symptoms and laboratory findings improved significantly, and she was discharged without symptoms 7Â days later. Although rare, this case of a patient with Still's disease undergoing a flare following vaccination suggests that close observation of disease activity is warranted following COVID-19 vaccination.

COVID-19 vaccines mix-and-match: The concept, the efficacy and the doubts. The search for developing effective vaccines against SARS-CoV-2 began with the start of the COVID-19 pandemic, and the first vaccine dose was administered in December 2020. Today, full vaccination of most of the world's population is considered the most important means to overcome the COVID-19 pandemic. Vaccination has been associated with various struggles. Some adverse reactions have resulted in the discontinuation of the specific vaccines use in some countries. Countries in poor regions have faced difficulties supplying enough vaccine doses, and the emergence of new variants of concern has resulted in reduced effectiveness of available vaccines against COVID-19. The mix-and-match strategy, using heterologous vaccines in the first and second doses, might successfully solve the mentioned struggles. Moreover, this strategy has been associated with higher cellular and humoral immune responses without significantly increasing the adverse reactions. Hence, this strategy can help improve the vaccines' effectiveness, and act as a solution for vaccine shortage in poor regions.

Guillain-BarrÃ© syndrome following the first dose of Pfizer-BioNTech COVID-19 vaccine: case report and review of reported cases. BACKGROUND: Since the SARS-CoV-2 pandemic has started in December 2019, millions of people have been infected all over the world. Vaccination is the most efficient tool to end this pandemic, but vaccine surveillance is necessary to identify side effects. Some studies have shown that neurological complications after COVID-19 vaccination are rare and dominated by demyelinating disease. CASE PRESENTATION: We present a case of a 67-year-old man who presented 7 days following his first dose of Pfizer-BioNTech COVID-19 vaccine a rapidly progressive ascending muscle weakness. The diagnosis of Guillain-BarrÃ© syndrome (GBS) was confirmed according to the clinical features, the albumino-cytological dissociation in the cerebrospinal fluid, and the electroneuromyography findings. The workup for all known infections associated with immune-mediated GBS was negative. The patient received treatment with intravenous immunoglobulin. Neurological examination 1 month after discharge showed full recovery and he regained his baseline functional status. CONCLUSIONS: As far as we know, this is the first reported case in Tunisia. Although extremely rare, neurologists should remain vigilant for acute inflammatory demyelinating polyradiculoneuropathy after COVID-19 vaccination.

Local and Systemic Reaction after Receiving Coronavirus Disease Vaccines among Healthcare Workers in Sapporo, Japan.

From Muscles to Wires: Report of Two Cases and Literature Review on COVID-19 Vaccination and Cardiac Conduction Disturbance. Since the end of 2020, several vaccines have become available as part of the global efforts to contain the adverse health outcomes of the coronavirus disease 2019 (COVID-19) pandemic. Although research has confirmed their safety on large scales, several post-marketing reports have revealed some rare cardiovascular side effects. Towards the end of the first half of 2021, multiple reports indicate possible links between COVID-19 vaccines (both mRNA-based vaccine and vector-based vaccines) and myopericarditis. Nevertheless, cardiac conduction disease in this context has only rarely been reported. In this report, we present two cases of probable vaccination-induced cardiac conduction disturbances along with a thorough literature review. In addition, we discuss probable pathophysiological mechanisms and insights into the suggested areas for future research. To our knowledge, these are the first published cases to result in permanent pacemaker implantation.

Cerebral Venous Sinus Thrombosis After BNT162b2 mRNA COVID-19 Vaccination. W present a rare case of cerebral venous sinus thrombosis after the BNT162b2 mRNA COVID-19 vaccine. A 61-year-old Japanese man developed a headache 10 days after the first dose of the vaccine. Magnetic resonance venography and contrast-enhanced brain MRI showed thrombosis in the superior sagittal sinus and the right transverse sinus. Anticoagulation with intravenous unfractionated heparin followed by oral warfarin was started. His headache improved, and brain MRI on day 22 showed

resolution of thrombus. He was maintained on anticoagulation with warfarin and discharged without any neurological sequelae. This case is presented in the context of the relevant literature.

Myopericarditis with Significant Left Ventricular Dysfunction Following COVID-19 Vaccination: A Case Report. BACKGROUND Since Emergency Use Authorization of COVID-19 vaccines in December 2020, more is becoming known about their adverse effects. Growing numbers of myopericarditis cases after COVID-19 vaccination are being reported, mostly in younger adults. While most of these patients have recovered rapidly and without complications, it is still unclear whether patients who are older and have greater cardiac dysfunction secondary to myopericarditis will also experience the same recovery. CASE REPORT We report the case of a middle-aged man with myopericarditis and significant left ventricular dysfunction after the second dose of the Pfizer/BioNTech BNT162b2 COVID-19 vaccine. He presented several days after vaccination, and with non-steroidal anti-inflammatory treatment, he quickly recovered ventricular function, and symptoms resolved within 1 week after vaccination. CONCLUSIONS Vaccines are a key tool in combating the COVID-19 pandemic, yet many people are hesitant to seek vaccination, perhaps for fear of adverse events. Our report of a middle-aged patient with significant left ventricular dysfunction, who still experienced rapid recovery, should reassure the public about the safety of vaccines. Such rare adverse effects should not deter people from receiving COVID-19 vaccination.

Immunogenicity and risk of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection after Coronavirus Disease 2019 (COVID-19) vaccination in patients with cancer: a systematic review and meta-analysis. BACKGROUND: Patients with cancer are considered a priority group for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccination given their high risk of contracting severe Coronavirus Disease 2019 (COVID-19). However, limited data existÂ regarding the efficacy of immunisation in this population. In this study, we assess the immunologic response after COVID-19 vaccination of cancer versus non-cancer population. METHODS: PubMed, Cochrane Central Register of Controlled Trials (CENTRAL),Â and Web of Science databases were searched from 01st MarchÂ 2020Â through 12th August 12Â 2021. Primary end-points were anti-SARS-CoV-2 spike protein (S) immunoglobulin G (IgG) seroconversion rates, T-cell response, and documented SARS-CoV-2 infection after COVID-19 immunisation. Data were extracted following the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA)Â guidelines. Overall effects were pooled using random-effects models. RESULTS: This systematic review and meta-analysis included 35 original studies. Overall, 51% (95% confidence interval [CI], 41-62) and 73% (95% CI, 64-81) ofÂ patients with cancer developed anti-S IgG above the threshold level after partial and complete immunisation, respectively. Patients with haematologic malignancies had a significantly lower seroconversion rate than those with solid tumours after complete immunisation (65% vs 94%; PÂ <Â 0.0001). Compared with non-cancer controls, oncological patients were less likely to attain seroconversion after incomplete (risk ratio [RR] 0.45 [95% CI 0.35-0.58]) and complete (RR 0.69 [95% CI 0.56-0.84]) COVID-19 immunisation schemes. Patients with cancer had a higher likelihood of having a documented SARS-CoV-2 infection after partial (RR 3.21; 95% CI 0.35-29.04) and complete (RR 2.04; 95% CI 0.38-11.10) immunisation. CONCLUSIONS: Patients with cancer have an impaired immune response to COVID-19 vaccination compared with controls. Strategies that endorse the completion of vaccination schemes are warranted. Future studies should aim to evaluate different approaches that enhance oncological patients' immune response.

Heterogeneity of Vaccine-Induced Immune Thrombotic Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination and Safety of Second Vaccination with BNT162b2.

Mask use among health care workers and feelings of safety at work pre- and post- COVID-19 vaccine. BACKGROUND: Correct mask use can prevent the spread of COVID-19 and hospitals require correct mask use. Despite this, there is variation in mask use among health care workers (HCW). Incorrect

mask use may lead to increased infections and decreased feelings of safety. The purpose of this study was to determine variation in mask use among HCW as well as feelings of safety from exposure to COVID-19 when around colleagues before and after COVID-19 vaccine roll out. METHODS: This study used direct observation to assess mask use in patient-facing areas before and after COVID-19 vaccine. A staff survey was used to assess feelings of safety. RESULTS: Over 1,600 mask observations showed increased compliance from 94.6% to 97.5% (PÂ =Â .001). Three hundred survey responses showed significantly increased feelings of safety (P < .001) after vaccine roll out, and 203 free-text responses with respondant reasoning were categorized into 6 themes. DISCUSSION: Understanding mask use behaviors and safety attitudes of HCW can help improve policies, workplace culture, and reduce HCW to HCW infections. CONCLUSIONS: Correct mask use was a highly adopted habit in patient-facing areas. The COVID-19 vaccine led to significantly increased feelings of safety among HCW, though the diverging narratives seen in the survey may be helpful to consider when crafting safety interventions.

Multistate Outbreak of SARS-CoV-2 Infections, Including Vaccine Breakthrough Infections, Associated with Large Public Gatherings, United States. During July 2021, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) B.1.617.2 variant infections, including vaccine breakthrough infections, occurred after large public gatherings in Provincetown, Massachusetts, USA, prompting a multistate investigation. Public health departments identified primary and secondary cases by using coronavirus disease surveillance data, case investigations, and contact tracing. A primary case was defined as SARS-CoV-2 detected <14 days after travel to or residence in Provincetown during July 3-17. A secondary case was defined as SARS-CoV-2 detected <14 days after close contact with a person who had a primary case but without travel to or residence in Provincetown during July 3-August 10. We identified 1,098 primary cases and 30 secondary cases associated with 26 primary cases among fully and non-fully vaccinated persons. Large gatherings can have widespread effects on SARS-CoV-2 transmission, and fully vaccinated persons should take precautions, such as masking, to prevent SARS-CoV-2 transmission, particularly during substantial or high transmission.

COVID-19 vaccines for children. Earlier this month, the US Centers for Disease Control and Prevention (CDC) recommended Pfizer's COVID-19 messenger RNA (mRNA) vaccine for children between 5 and 11 years of age-that's 28 million children. Yet surveys show that 42 to 66% of parents of these children are reluctant or opposed to seeking this protection. Without vaccination, it is likely that almost everyone-including young children-will be infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) at some point in their lives. So, the question for parents and caregivers is: Which is worse, vaccination or natural infection?

[BIOLOGICAL TREATMENT OF PSORIASIS IN TIME OF NEW CORONAVIRUS INFECTION COVID-19]. Currently, the ongoing pandemic of the novel coronavirus infection is still a major public health problem worldwide. The questions of immunosuppressive therapy of patients with psoriasis and psoriatic arthritis, the possibility of vaccination against the background of the use of genetically engineered drugs remain open. The article is of an overview nature and includes up-to-date information on the feasibility and safety of the use of genetically engineered biological drugs in patients with psoriasis in a pandemic (COVID-19). According to the international recommendations of the National Psoriasis Foundation COVID-19 Task Force expert group, treatment of psoriasis and/or PsA does not significantly alter the risk of SARS-CoV-2 infection and does not lead to worse prognosis of COVID-19. Therefore, patients not infected with SARS-CoV-2 should continue biological or other systemic therapy for psoriasis and/or PsA. According to a registry from 25 countries, hospitalization with SARS-CoV-2 infection was more common in patients receiving nonbiological systemic therapy than in patients receiving BAs. Thus, genetically engineered biological drugs do not appear to cause an increased risk of coronavirus infection and do not determine a more severe course. With regard to vaccination of patients with psoriasis, many issues require further study. According to international

agreements, vaccination is not contraindicated in patients with psoriatic disease. However, there is still insufficient data on how the treatment of psoriatic disease affects vaccination. Avoiding COVID-19 or reducing the severity of infection following SARS-CoV-2 vaccination is thought to far outweigh any risk directly related to vaccination complications.
Thyroid as a target of adjuvant autoimmunity/inflammatory syndrome due to mRNA-based SARS-CoV2 vaccination: from Graves' disease to silent thyroiditis. BACKGROUND: As COVID-19 became a pandemic, the urgent need to find an effective treatment vaccine has been a major objective. Vaccines contain adjuvants which are not exempt from adverse effects and can trigger the autoimmune/inflammatory syndrome induced by adjuvants (ASIA). There is very little information about autoimmune endocrine disease and the ASIA after the use of mRNA-based SARS-CoV2 vaccination. CASE SERIES: We report three cases and also review the literature showing that the thyroid gland can be involved in the ASIA induced by the mRNA-based SARS-CoV2 vaccination. We present the first case to date of silent thyroiditis described in the context of SARS-CoV2 vaccination with Pfizer/BioNTech. Also, we discuss the first subacute thyroiditis in the context of SARS-CoV2 vaccination with the Moderna's vaccine. Finally, we provide another case to be added to existing evidence on Graves' disease occurring post-vaccination with the Pfizer/BioNTech vaccine. DISCUSSION: Adjuvants play an important role in vaccines. Their ability to increase the immunogenicity of the active ingredient is necessary to achieve the desired immune response. Both the Moderna and the Pfizer/BioNTech vaccines use mRNA coding for the SARS-CoV2 S protein enhanced by adjuvants. In addition, the cross-reactivity between SARS-CoV2 and thyroid antigens has been reported. This would explain, at least, some of the autoimmune/inflammatory reactions produced during and after SARS-CoV2 infection and vaccination. CONCLUSION: The autoimmune/inflammatory syndrome induced by adjuvants involving the thyroid could be an adverse effect of SARS-CoV2 vaccination and could be underdiagnosed.
Letter of Reply to "Response to: COVID-19 Vaccination Willingness and Hesitancy in Patients With Inflammatory Bowel Diseases: Analysis of Determinants in a National Survey of the Italian IBD Patients' Association".
Radiation recall pneumonitis after COVID-19 vaccination.
Pigmented purpuric dermatosis after BNT162B2 mRNA COVID-19 vaccine administration.
Cutaneous and Allergic reactions due to COVID-19 vaccinations: A review. INTRODUCTION: The pandemic caused by the novel coronavirus disease 2019 (COVID-19) has had an unprecedented impact on the overall health and the global economy. Vaccination is currently the most dependable strategy to end the pandemic, despite the slower-than-hoped-for rollout, particularly for low-to-middle-income countries, and the uncertain duration of protection afforded by vaccination. The spike protein of the virus (immunodominant antigen of the virus) is the main target of the approved and candidate SARS-CoV-2 vaccines. This protein binds to the ACE2 receptor of the host cell, initiating the entry of the virus into the cell and the chain of subsequent events ending to Acute Respiratory Distress Syndrome. The safety profile of these vaccines needs is closely assessed. METHODS: This comprehensive review includes searching the PubMed, EMBASE, and Web of Science databases using the keywords "coronavirus", "COVID-19", "vaccine", "cutaneous reactions", "allergic reactions", and "SARS-CoV-2". Manual searching of reference lists of included articles augmented the research. The research was updated in June 2021. RESULTS: In this narrative review, we tried to investigate and discuss the cutaneous and allergic reactions related to SARS-CoV-2 vaccines currently available in the literature. As a result, although COVID-19 vaccines can be reported to develop allergic and anaphylactic reactions, especially after m-RNA vaccines, they remain at a low rate, and it is observed that these reactions may develop more frequently, especially in patients with previous allergies and mast cell disorders. Fortunately, these reactions are generally transient, benign, self-limited.

CONCLUSION: Although there is still no definitive evidence, as dermatologists, we must be aware of the possibility of cutaneous reactions, newly diagnosed dermatoses, or exacerbation of existing dermatoses that may develop after the COVID-19 vaccinations.
Motor and non-motor symptom improvement after mRNA-1273 vaccine in a Parkinson's disease patient.
Combined central retinal artery and vein occlusion shortly after mRNA-SARS-CoV-2 vaccination.
Equivalent humoral and cellular immune response but different side effect rates following SARS-CoV-2 vaccination in peritoneal and haemodialysis patients using messenger RNA vaccines.
VT storm in long QT resulting from COVID-19 vaccine allergy treated with epinephrine.
An unusual presentation of acute deep vein thrombosis after the Moderna COVID-19 vaccine-a case report. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has caused a worldwide pandemic of the multisystem disease coronavirus disease-2019 (COVID-19). Since the development of COVID-19 vaccines, there has been extensive monitoring for potential serious side effects. We report an unusual presentation of acute deep vein thrombosis (DVT) in the right upper extremity of a 27-year-old Caucasian female, 3 days after receipt of her second dose of the Moderna COVID-19 vaccine. Her relevant thrombophilia workup was negative on initial presentation. She was treated with rivaroxaban for 3 months and her symptoms of right upper extremity swelling, and pain improved. Considering our case did not have any evidence of thrombocytopenia, we discuss the possible pathophysiology of acute DVT following Moderna COVID-19 vaccine in contrast to adenoviral vector COVID-19 vaccines (ChAdOx1 nCoV-19 and Ad26.COV2.S), including mRNA COVID-19 vaccine binding to pattern recognition receptors (PRR) in the endosomes and cytosol leading to a pro inflammatory cascade and coagulopathy. We highlight the importance of initial workup for acute DVT post COVID-19 vaccination, that should include complete blood count (CBC) with platelet count, international normalized ratio (INR), prothrombin time (PTT), D-dimer levels, fibrinogen levels, platelet factor 4 (PF4)/heparin enzyme-linked immunosorbent assays (ELISA) followed by a confirmatory PF4 platelet activation assay such as serotonin release assay, P-selectin expression assay, or heparin induced platelet aggregation (HIPA) assay, and imaging for thrombosis.
Case Report: Vaccine-Induced Immune Thrombotic Thrombocytopenia in a Pancreatic Cancer Patient After Vaccination With Messenger RNA-1273. Vaccination plays an important role during the COVID-19 pandemic. Vaccine-induced thrombotic thrombocytopenia (VITT) is a major adverse effect that could be lethal. For cancer patients, cancer-related thromboembolism is another lethal complication. When cancer patients receive their COVID-19 vaccines, the following thromboembolic events will be more complicated. We presented a case recently diagnosed with pancreatic cancer, who had received the mRNA-1273 (Moderna) vaccination 12 days prior. Ischemic stroke and VITT were also diagnosed. We aggressively treated the patient with steroids, immunoglobulin, and plasma exchange. The titer of anti-platelet factor four and d-dimer level decreased, but the patient ultimately died. The complicated condition of VITT superimposed cancer-related thromboembolism was considered. To our knowledge, only one case of mRNA-1273 related VITT was reported, and this case study was the first to report a cancer patient who was diagnosed with VITT after mRNA-1273 vaccination. Therefore, when the need for vaccination among cancer patients increased under the current COVID-19 pandemic, the possible risk of VITT for cancer patients should be carefully managed. Further studies of the risk evaluation of the COVID-19 vaccine in cancer patients might be required in the future.
Antibody Response to an mRNA SARS-CoV-2 Vaccine Following Initial Vaccination With Ad.26.COV2.S in Solid Organ Transplant Recipients: A Case Series.
Miller Fisher syndrome following BNT162b2 mRNA coronavirus 2019 vaccination. BACKGROUND: The coronavirus disease 2019 (COVID-19) pandemic, caused by severe acute respiratory syndrome

coronavirus 2 (SARS-CoV-2), began in late 2019. One of the vaccines approved against COVID-19 is the BNT162b2 mRNA COVID-19 vaccine (Pfizer/BioNTech). CASE PRESENTATION: We present the case of a 71-year-old man with no history of the SARS-CoV-2 infection or any recent viral or bacterial illnesses who presented with bilateral oculomotor palsy and limb ataxia after BNT162b2 mRNA COVID-19 vaccination. The diagnosis of Miller Fisher syndrome (MFS) was established based on physical examination, brain magnetic resonance imaging (MRI), cerebrospinal fluid analysis (CSF), and positron emission tomography (PET). There was no evidence of other predisposing infectious or autoimmune factors, and the period from COVID-19 vaccination to the appearance of neurological symptoms was similar to that of other vaccines and preceding events, such as infection. CONCLUSION: Guillain-BarrÃ© syndrome (GBS) and its variants after COVID-19 vaccination are extremely rare. Note that more research is needed to establish an association between MFS and COVID-19 vaccines. In our opinion, the benefits of COVID-19 vaccination largely outweigh its risks.

Cerebral venous sinus thrombosis (CVST) associated with SARS-CoV-2 vaccines: clues for an immunopathogenesis common to CVST observed in COVID-19. Severe acute respiratory syndrome coronavirus type 2 has been responsible for an unprecedented pandemic, and nowadays, several vaccines proved to be effective and safe, representing the only available strategy to stop the pandemic. While millions of people have safely received vaccine, rare and unusual thrombotic events have been reported and are undergoing investigations to elucidate their nature. Understanding initial trigger, underlying pathophysiology and the reasons for specific site localization of thrombotic events are a matter of debate.We here propose that rare cases of cerebral venous sinus thrombosis, a clinical event that may rapidly evolve to brain death, reported after COVID-19 vaccine, might be consequent to an immune response resulting in inflamed/damaged endothelium, an event similar to that described for cases of cerebral venous sinus thrombosis reported during COVID-19 and not necessarily related to anti-Platelets Factor 4 antibodies, as recently described. Remarkably, in the two patients presenting at our hospital with cerebral venous sinus thrombosis and evolved to brain death, proper tissue perfusion and function maintenance allowed organ donation despite extensive thrombosis in the organ donors, with favorable outcome at 6 months.Increased vigilance, close multidisciplinary collaboration, and further prospective research will help to better elucidate a very rare and still not fully understood pathophysiological event associated with vaccines for severe acute respiratory syndrome coronavirus 2.

Cardiac magnetic resonance characteristics of acute myocarditis occurring after mRNA-based COVID-19 vaccines immunization.

Vertical transmission of maternal COVID-19 antibodies after CoronaVac vaccine: A case report.
The use of coronavirus disease 2019 RNA vaccines in pregnant women led to reports on the first cases of newborns with antibodies to sudden acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a phenomenon that was unknown when using immunizations with inactivated viruses. Thus, this study aimed to report a case of passive anti-SARS-CoV-2 immunity in a newborn through immunoprophylaxis of a pregnant woman who received the CoronaVacÂ® vaccine in the third trimester of pregnancy. Twenty-four hours after delivery, samples were collected from the newborn and screened by enzyme immunoassays, which revealed antibodies to SARS-CoV-2.

COVID 19 vaccine in patients of hypercoagulable disorders: a clinical perspective. COVID 19 is an infectious disease caused by severe acute respiratory syndrome corona virus 2. Thromboembolism has been a characteristic manifestation in most of the severely ill COVID-19 patients. Thromboembolism in COVID 19 infection is attributed to injury to the vascular endothelial cell, hypercoagulability and blood stasis. The hypercoagulable state of blood and thrombophilic diseases leads to hypercoagulability. COVID 19 infected patients with pre-existing hypercoagulable disorders have higher risk of developing thrombosis and thromboembolism and such thrombotic episodes may

prove to be severely morbid in these patients. As immune-prophylaxis COVID 19 vaccines are being administered to the public. The known side effects of the COVID 19 vaccine are mild to moderate and include fever, chills, nausea, vomiting, headache, fatigue, myalgia, malaise, pain and swelling at injection site and diarrhea. Thrombosis with thrombocytopenia has been noted as a rare side effect of COVID 19 vaccine. Such side effect of COVID 19 vaccine in patients of hypercoagulable disorder may prove to be fatal. The health care workers should be cautious and judicious in managing such patients. A detailed lab profile for coagulable state of blood should be carried out in all patients COVID 19 infected patients with pre-existing hypercoagulability diseases. The patients should also be health educated regarding side effects of vaccine especially with those indicating thrombosis and they should be warranted to receive immediate medical care in case of any side effects or complications. Paucity of literature gave us an impetus to review management profile in patients of hypercoagulable disorders.

Bullous pemphigoid triggered by COVID-19 vaccine: Rapid resolution with corticosteroid therapy.

Acute-onset polyradiculoneuropathy after SARS-CoV2 vaccine in the West and North Midlands, United Kingdom. INTRODUCTION/AIMS: We aimed to determine whether specific severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) vaccines may be associated with acute-onset polyradiculoneuropathy and if they may result in particular clinical presentations. METHODS: We retrospectively reviewed records of all persons presenting with acute-onset polyradiculoneuropathy from January 1, 2021, to June 30, 2021, admitted to two Neuroscience centers, of the West and North Midlands, United Kingdom. We compared subjects with previous SARS-CoV2 vaccine exposure with a local cohort of persons with acute-onset polyradiculoneuropathy admitted between 2005 and 2019 and compared admission numbers for the studied time frame with that of the previous 3 years. RESULTS: Of 24 persons with acute-onset polyradiculoneuropathy, 16 (66.7%) presented within 4â€‰ weeks after first SARS-CoV2 vaccine. Fourteen had received the AstraZeneca vaccine and one each, the Pfizer and Moderna vaccines. The final diagnosis was Guillain-BarrÃ© syndrome (GBS) in 12 and acute-onset chronic inflammatory demyelinating polyneuropathy in 4. Among AstraZeneca vaccine recipients, facial weakness in nine persons (64.3%), bulbar weakness in seven (50%), and the bifacial weakness and distal paresthesias GBS variant in three (21.4%), were more common than in historical controls (PÂ =â€‰.01; PÂ =â€‰.004, and PÂ =â€‰.002, respectively). A 2.6-fold (95% confidence interval: 1.98-3.51) increase in admissions for acute-onset polyradiculoneuropathy was noted during the studied time frame, compared to the same period in the previous 3 years. DISCUSSION: Despite a low risk, smaller than that of SARS-CoV2 infection and its complications, exposure to the first dose of AstraZeneca SARS-CoV2 vaccine may be a risk factor for acute-onset polyradiculoneuropathy, characterized by more common cranial nerve involvement.

IgA nephropathy presenting as rapidly progressive glomerulonephritis following first dose of COVID-19 vaccine.

Utility of skin testing in assessment of post-AZD1222 vaccine (AstraZeneca) allergic reactions: case series in Vietnam.

Vaccination against COVID-19 and society's return to normality in England: a modelling study of impacts of different types of naturally acquired and vaccine-induced immunity. OBJECTIVES: To project impacts of mass vaccination against COVID-19, and investigate possible impacts of different types of naturally acquired and vaccine-induced immunity on future dynamics of SARS-CoV-2 transmission from 2021 to 2024 in England. DESIGN: Deterministic, compartmental, discrete-time Susceptible-Exposed-Infectious-Recovered (SEIR) modelling. PARTICIPANTS: Population in England. INTERVENTIONS: Mass vaccination programmes. OUTCOME MEASURES: Daily and cumulative number of deaths from COVID-19. RESULTS: If vaccine efficacy remains high (85%), the vaccine-induced sterilising immunity lasts â‰¥182 days, and the reinfectivity is greatly reduced (by

â‰¥60%), annual mass vaccination programmes can prevent further COVID-19 outbreaks in England. Under optimistic scenarios, with annual revaccination programmes, the cumulative number of COVID-19 deaths is estimated to be from 130â€‰000 to 150â€‰000 by the end of 2024. However, the total number of COVID-19 deaths may be up to 431â€‰000 by the end of 2024, under scenarios with compromised vaccine efficacy (62.5%), short duration of natural and vaccine immunity (365/182 days) and small reduction in reinfectivity (30%). Under the assumed scenarios, more frequent revaccinations are associated with smaller total numbers and lower peaks of daily deaths from COVID-19. CONCLUSIONS: Under optimistic scenarios, mass immunisation using efficacious vaccines may enable society safely to return to normality. However, under plausible scenarios with low vaccine efficacy and short durability of immunity, COVID-19 could continue to cause recurrent waves of severe morbidity and mortality despite frequent vaccinations. It is crucial to monitor the vaccination effects in the real world, and to better understand characteristics of naturally acquired and vaccine-induced immunity against SARS-CoV-2.
Absent antibody production following COVID19 vaccination with mRNA in patients under immunosuppressive treatments. Patients undergoing immunosuppressive treatments have a higher need for protection against coronavirus disease (COVID19) that follows infection with the SARS-CoV-2 virus but their ability to respond sufficiently to COVID vaccines is uncertain. We retrospectively evaluated SARS-CoV-2 spike subunit 1 (S1)-specific antibody levels after two mRNA doses in 242 patients with underlying chronic inflammatory, hematooncological or metabolic diseases and in solid organ transplant recipients. S1-specific antibodies were measured 30Â days after the second dose. In 15.9% of these patients, no S1-specific antibodies were detectable. Non-responsiveness was linked to administration of B-cell depleting therapies as well as to ongoing therapies that block lymphocyte trafficking (Fingolimod) or inhibit T cell proliferation (Tacrolimus). Thus, it is important to inform immunosuppressed patients about the risk of vaccine non-responsiveness and the necessity to maintain non-pharmaceutical protection measures. In these risk patients antibody testing and cellular analysis are helpful to estimate the benefit/responsiveness to further booster vaccinations.
Correspondence on "Acute corneal endothelial graft rejection following COVID-19 vaccination".
Cerebral venous sinus thrombosis after mRNA-based COVID-19 vaccination.
Intracerebral hemorrhage due to vasculitis following COVID-19 vaccination: a case report. Several vaccines have been approved worldwide for the prevention of morbidity and mortality against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, the development of these vaccines has raised concerns regarding their adverse effects. Herein, we report the first case of intracerebral hemorrhage (ICH) due to vasculitis after the first dose of mRNA vaccine (BNT162b2, Pfizer/BioN-Tech). Although this case cannot demonstrate a direct relationship between COVID-19 vaccination and vasculitis, the clinical and histological features of this patient are highly consistent with the adverse effects of COVID-19 vaccine.
Disc edema in one eye and central serous chorioretinopathy in the other eye shortly after AstraZeneca COVID-19 vaccination.
A case of severe aplastic anaemia after SARS-CoV-2 vaccination.
Before attributing encephalomyelitis to SARS-CoV-2 vaccinations thoroughly exclude differentials.
Safety and immunogenicity of inactivated COVID-19 vaccine in health care workers. Effective vaccines are essential for controlling the coronavirus disease 2019 (COVID-19) pandemic. CoronaVac, which is an inactivated virus vaccine, was the first imported COVID-19 vaccine in Thailand. To investigate the safety and immunogenicity of CoronaVac within the Thai population, we conducted a prospective cohort study among health care workers aged 18-59 years, who received a 2-dose regimen of CoronaVac 21 days apart between March and April 2021 at the hospital in Samut Sakhon,

Thailand. We recruited 185 participants with a mean age of 32 years. Total antibodies against receptor-binding domain (RBD) and immunoglobulin G (IgG) against nucleocapsid (N) protein of SARS-CoV-2 were tested. Total antibodies against RBD were negative before immunization. One volunteer was positive for N, although negative for the RBD antibodies. The seroconversion rate of total antibodies against RBD after the first CoronaVac dose was 67% with a Geometric mean concentration (GMC) of 1.98 U/ml. Following CoronaVac dose 2, the seroconversion rate increased to 100% with a GMC of 92.9 U/ml. The seroconversion rates of IgG against N protein were 1% after dose 1 and 62.8% after dose 2. The overall incidence of adverse reactions was 59.5%. Injection-site pain was the most common local adverse event (52.4%), while myalgia was the most common systemic adverse event (31.9%). No serious adverse events were observed. A 0-21 days, 2-dose CoronaVac regimen appears safe, inducing a satisfactory response compared with convalescent serum obtained 4-6 weeks postnatural infection. Antibody responses after 2-dose CoronaVac were comparable to the convalescent plasma but waned rapidly after 3 months. Therefore, we recommend 2-dose CoronaVac administration with possible booster doses.

New-onset pediatric nephrotic syndrome following Pfizer-BioNTech SARS-CoV-2 vaccination: a case report and literature review. Various new vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been rapidly developed. The new onset and recurrence of nephrotic syndrome triggered by some vaccines have been documented and several adult cases of minimal change nephrotic syndrome newly developing after SARS-CoV-2 vaccination have been reported. However, no reports of pediatric cases have been published. Indications for SARS-CoV-2 vaccines have been expanded to those as young as 12Â years old and vaccination of children has just started in Japan. We encountered a 15-year-old boy without underlying disease who newly developed nephrotic syndrome after SARS-CoV-2 vaccination with BNT162b2 (Pfizer-BioNTech). He developed eyelid edema 4Â days after vaccination and peripheral edema of the lower extremities a further 4Â days later. Twenty-one days after vaccination, 60Â mg of oral daily prednisolone was started. He achieved complete remission in 12Â days without complications such as hypertension or acute kidney injury. We clinicians should be aware of the possibility of nephrotic syndrome developing after SARS-CoV-2 vaccination, not only in adults, but also in children.

Side effects and flares risk after SARS-CoV-2 vaccination in patients with systemic lupus erythematosus. The objective of this study is to identify post SARS-CoV-2 vaccine BNT162b2 (BioNTech & Pfizer) side effects in patients with systemic lupus erythematosus (SLE) at the Cayetano Heredia Hospital, Lima, Peru. A descriptive observational study was designed in patients with SLE at the Immuno-Rheumatology Department of the Cayetano Heredia Hospital, Lima, Peru, immunized with the BNT162b2 vaccine from May 21 to June 30, 2021. Of the total number of patients seen in the service, 100 received the vaccine's 1st dose, and 90 patients received the 2nd dose; 90% and 92.2% presented symptoms within 10Â days after immunization (1st and 2nd doses, respectively), being pain at the inoculation site the most frequent (87%); most of the symptoms presented were of mild intensity. There were 27 episodes of post-immunization flare, 9% and 20% after the 1st and 2nd doses, respectively; the predominant type of flare was articular (85.1%), followed by dermal (18.5%). It was found that a history of renal involvement was associated with the risk of developing flare RR 0.38 (0.15-0.91) and the use of hydroxychloroquine and azathioprine prior to immunization 0.20 (0.06-0.63) and 7.96 (2.70-23.43) respectively. In 100 SLE patients immunized with BNT162b2 vaccine against SARS-CoV-2, 27% of SLE reactivation episodes occurred, two patients were hospitalized for flare severity, and none died. Key Points â€¢ Up to 92.2% presented some type of symptom after vaccination, being mostly local and of mild intensity. â€¢ Of the population studied, there were 27 episodes of post-vaccination flare, most of which were mild. â€¢ In the studied population, taking

hydroxychloroquine and having a history of renal disease were associated with a lower risk of presenting post-vaccination flare.
Safety and immunogenicity of a SARS-CoV-2 inactivated vaccine in patients with chronic hepatitis B virus infection.
COVID-19 Update: Saskatchewan intensive care crisis, new vaccine safety data, and pushback on health worker mandates.
Suppression of the hypothalamic-pituitary-thyroid axis is associated with the severity of prognosis in hospitalized patients with COVID-19. BACKGROUND: The outbreak of severe acute respiratory syndrome novel coronavirus 2 (SARS-CoV-2) has spread rapidly worldwide. SARS-CoV-2 has been found to cause multiple organ damage; however, little attention has been paid to the damage to the endocrine system caused by this virus, and the subsequent impact on prognosis. This may be the first research on the hypothalamic-pituitary-thyroid (HPT) axis and prognosis in coronavirus disease 2019 (COVID-19). METHODS: In this retrospective observational study, 235 patients were admitted to the hospital with laboratory-confirmed SARS-CoV-2 infection from 22 January to 17 March 2020. Clinical characteristics, laboratory findings, and treatments were obtained from electronic medical records with standard data collection forms and compared among patients with different thyroid function status. RESULTS: Among 235 patients, 17 (7.23%) had subclinical hypothyroidism, 11 (4.68%) severe non-thyroidal illness syndrome (NTIS), and 23 (9.79%) mild to moderate NTIS. Composite endpoint events of each group, including mortality, admission to the ICU, and using IMV were observed. Compared with normal thyroid function, the hazard ratios (HRs) of composite endpoint events for mild to moderate NTIS, severe NTIS, subclinical hypothyroidism were 27.3 (95% confidence interval [CI] 7.07-105.7), 23.1 (95% CI 5.75-92.8), and 4.04 (95% CI 0.69-23.8) respectively. The multivariate-adjusted HRs for acute cardiac injury among patients with NTF, subclinical hypothyroidism, severe NTIS, and mild to moderate NTIS were 1.00, 1.68 (95% CI 0.56-5.05), 4.68 (95% CI 1.76-12.4), and 2.63 (95% CI 1.09-6.36) respectively. CONCLUSIONS: Our study shows that the suppression of the HPT axis could be a common complication in COVID-19 patients and an indicator of the severity of prognosis. Among the three different types of thyroid dysfunction with COVID-19, mild to moderate NTIS and severe NTIS have a higher risk of severe outcomes compared with subclinical hypothyroidism.
Evaluation of Allergic Reactions following COVID - 19 Vaccination in Patients with Documented Allergies. BACKGROUND AND RATIONALE: The government guidance regarding COVID-19 vaccination lists food allergy, drug allergy and history of anaphylaxis as contraindications for receiving vaccination. This study was planned to evaluate such patients listed in the database of an allergy center and who took any COVID-19 vaccine. METHODS: Data on n=255 patients was mined. Inclusions were those over 18 years, any allergic diathesis and receipt of at least one dose of any COVID-19 vaccine. Age, gender, nature of allergy and type of COVID vaccine taken along with outcome of interest [occurrence or otherwise of all allergic reaction post vaccination] was collated. RESULTS: Data of 227 patients were finally analysed. Eighty one took the first dose and 33 took both doses. None with food and/or drug allergy and/or a history of anaphylaxis developed any adverse event (AE) post vaccination. Three AEs were seen in those with other allergic diathesis. Two AEs [One to COVAXINâ„¢ and one to COVISHIELDâ„¢] were only generalized itching that were self-limiting. A female patient had itching with palmar erythema [post COVISHIELDâ„¢] which subsided after a week's treatment with an antihistamine. She had a history of allergy to radiocontrast media containing polyethylene glycol/PEG] indicating possible allergy to polysorbate 80 [PEG related compound contained in COVISHIELDâ„¢]. CONCLUSION: No patient fitting contraindications for COVID-19 vaccination laid down by the Indian government developed any allergic reaction post vaccination. The guidelines for vaccination may be revisited to make them more inclusive with appropriate training of the vaccination centre staff.

Addressing Risk of Allergy following COVID-19 Vaccination in India - Reassure, Rethink and Revise.
Case study of thrombosis and thrombocytopenia syndrome following administration of the AstraZeneca COVID-19 vaccine. Cerebral venous sinus thrombosis is a complication of the ChAdOx1 nCoV-19 vaccine that should elicit a high index of suspicion when patients present with persistent headache post vaccination.
Autoimmune hepatitis after SARS-CoV-2 vaccine: New-onset or flare-up? Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection has been reported to trigger several autoimmune diseases. There are also recent reports of autoimmune diseases that develop after SARS-CoV-2 vaccines. Autoimmune hepatitis is a polygenic multifactorial disease, which is diagnosed using a scoring system. A 61-year-old woman presented with malaise, fatigue, loss of appetite, nausea and yellow eyes. She had a Pfizer/BioNTech BNT162b2 mRNA vaccine a month ago. Her physical examination revealed jaundice all over the body, especially in the sclera. The laboratory tests showed elevated liver enzymes and bilirubin levels. Antinuclear antibody and anti-smooth muscle antibody were positive and immunoglobulin G was markedly elevated. The liver biopsy revealed histopathological findings consistent with autoimmune hepatitis (AIH). The patient was diagnosed with AIH and initiated on steroid therapy. She rapidly responded to steroid therapy. A few cases of AIH have been reported after the COVID-19 vaccine so far. Although the exact cause of autoimmune reactions is unknown, an abnormal immune response and bystander activation induced by molecular mimicry is considered a potential mechanism, especially in susceptible individuals. As intensive vaccination against SARS-CoV-2 continues, we would like to emphasize that clinicians should be cautious and consider AIH in patients presenting with similar signs and symptoms.
Pancreas allograft rejection occurring after ChAdOx1 nCoV-19 vaccine.
Guillan-BarrÃ© Syndrome after First Vaccination Dose against COVID-19: Case Report. A number of neurological complications have been reported after the administration of flu vaccine, including Guillain-BarrÃ© syndrome (GBS), especially after vaccination against swine flu. Only facial nerve neuropathy has thus far been reported after vaccination against COVID-19. More recently, there was a case of an elderly woman with GBS. In our report, we describe a case of a 42-year-old, previously almost healthy male who developed sensory symptoms 14 days after the first dose of Pfizer vaccine. One week later, the patient developed right facial nerve palsy and lower limb weakness and was no longer able to walk. Albuminocytological dissociation was detected in the cerebrospinal fluid, and there were inflammatory radicular changes in MRI scans of the lumbosacral spine. EMG indicated significant demyelinating polyradiculoneuritis and no antibodies against gangliosides were demonstrated. A 5-day course of immunoglobulins at a dose of 2 g/kg lead to a significant improvement and the patient was soon able to walk. In conclusion, we report a case of Guillan-BarrÃ© syndrome after COVID-19 vaccine in a young patient with a rapid diagnosis and prompt administration of immunoglobulins.
Report of two cases of minimal change disease following vaccination for COVID -19.
Post-COVID-19 vaccination IgA vasculitis in an adult. Leukocytoclastic vasculitis has been reported in the setting of COVID-19 infection and post-COVID-19 vaccination. We report a case of IgA vasculitis (IgAV) post-COVID-19 vaccination, with immunoglobulin A (IgA)Â immuneÂ deposits in the skin and renal involvement. SARS-CoV spike protein immunohistochemical staining was negative. IgAV with skin and renal involvement is a potential reaction to COVID-19 vaccination.
Kinetics of anti-SARS-CoV-2 neutralizing antibodies development after BNT162b2 vaccination in patients with amyloidosis and the impact of therapy.
Immunity after COVID-19 vaccinations in immunocompromised patients with psoriasis.
Predictors of Humoral Response to SARS-CoV-2 Vaccination after Hematopoietic Cell Transplantation and CAR T-cell Therapy. Cellular therapies including allogeneic hematopoietic cell transplant

(allo-HCT) and autologous hematopoietic cell transplant (auto-HCT) and chimeric antigen receptor (CAR) T-cell therapy render patients severely immunocompromised for extended periods after therapy, and data on responses to COVID-19 vaccines are limited. We analyzed anti-SARS-CoV-2 spike IgG Ab (spike Ab) titers and neutralizing Ab among 217 recipients of cellular treatments (allo-HCT, n = 149; auto-HCT, n = 61; CAR T-cell therapy, n = 7). At 3 months after vaccination, 188 patients (87%) had positive spike Ab levels and 139 (77%) had positive neutralization activity compared with 100% for both in 54 concurrent healthy controls. Time from cellular therapy to vaccination and immune recovery post-cellular therapy were associated with response. Vaccination against COVID-19 is an important component of post-cellular therapy care, and predictors of quantitative and qualitative response are critical in informing clinical decisions about optimal timing of vaccines and the requirement for booster doses. SIGNIFICANCE: Identifying predictors of response to vaccination against SARS-CoV-2 in patients following cellular therapy is critical to managing this highly vulnerable patient population. To date, this is the most comprehensive study evaluating quantitative and qualitative responses to vaccination, providing parameters most predictive of response and potentially informing booster vaccination strategies.See related article by Chung et al., p. 568. This article is highlighted in the In This Issue feature, p. 549.

Late Gadolinium Enhancement after COVID-19 Vaccination.

Case Report: Acute Fulminant Myocarditis and Cardiogenic Shock After Messenger RNA Coronavirus Disease 2019 Vaccination Requiring Extracorporeal Cardiopulmonary Resuscitation. Recently, myocarditis following messenger RNA (mRNA) coronavirus disease 2019 (COVID-19) vaccination has become an important social issue worldwide. According to the reports so far, myocarditis related to mRNA COVID-19 vaccination is rare and usually associated with a benign clinical course without intensive care or any sequelae of fulminant myocarditis. Here, we report a case of acute fulminant myocarditis and cardiogenic shock after the mRNA COVID-19 vaccination, requiring extracorporeal cardiopulmonary resuscitation. Clinicians should keep in mind the possibility of progression to fulminant myocarditis in patients who presented with suggestive symptoms or signs of myocarditis after the COVID-19 vaccination.

A Case Report of Subacute Thyroiditis following mRNA COVID-19 Vaccine. BACKGROUND: Subacute thyroiditis has been reported after administration of influenza vaccine. We describe a case of a patient who developed subacute thyroiditis after administration of. Moderna mRNA COVID-19 vaccine. Case Presentation. A 42-year-old female, with a past medical history of stage IIIB pT3N1aM0 right adenocarcinoma of colon status, after right hemicolectomy on 01/2020, followed by adjuvant chemotherapy, paroxysmal supraventricular tachycardia, iron deficiency anemia, chemotherapy-induced neuropathy, and lumbar radiculopathy, presented to our clinic with anterior neck pain that started 6â€‰days after the second dose of Moderna mRNA COVID-19 vaccine. She was diagnosed with subacute thyroiditis and treated conservatively with pain medications. CONCLUSION: Subacute thyroiditis could represent one of the side effects of Moderna mRNA COVID-19 vaccine. Further reports are lacking.

Aseptic meningoencephalitis after COVID-19 vaccination: A case report. INTRODUCTION: Several types of vaccine have been shown to significantly reduce the risk of severe coronavirus disease 2019 (COVID-19). This study aims to report the first case of meningoencephalitis after receiving the second dose of Pfizer COVID-19 vaccine. CASE REPORT: A 62-year-old lady presented with headache, fever and rigor for 4 days. She had acute confessional state and inability to talk. She was conscious, disoriented, not obeying commands. Acyclovir vial IV 750 mg three times a day for 14 days were prescribed. She responded very well. DISCUSSION: Concern has been raised about the safety of vaccinations. The most common side effects of COVID-19 vaccinations are local responses at the injection site, followed by non-specific systemic symptoms such as headache, tiredness, myalgia, and

fever. These may appear shortly after immunization and disappear in a short period of time. CONCLUSION: Although extremely rare, aseptic meningoencephalitis could occur after COVID-19 vaccination. The patient could be managed conservatively with a good clinical outcome.

New Portal Vein Thrombosis in Cirrhosis - is the Thrombophilia Exacerbated due to Vaccine or COVID-19?

[Subjective well-being and ability to work after SARS-CoV-2 immunization with the vector vaccine ChAdOx1-S (AstraZeneca COVID-19 vaccine)]. BACKGROUND: The SARS coronavirusÂ 19 vaccine ChAdOx1â€'S (Vaxzevria, AstraZeneca) has been licensed since January 2021 by the Paul Ehrlich Institute for Germany. In several campaigns, healthcare workers and medical students were offered this vaccine on aÂ voluntary basis. AIM: The primary endpoint of the study was to assess the rate and duration of the incapacity to work as aÂ result of initial immunization with ChAdOx1â€'S. Secondary endpoints were type and severity of adverse events and self-perceived tolerability. MATERIAL AND METHODS: Anonymized online questionnaire to be completed once by all vaccinated individuals after receiving the first dose of ChAdOx1â€'S. The severity of side effects was queried using an ordinal numerical rating scale with values ranging from 0 toÂ 10. Other key data points were age, sex, and occupational group. Ability to work in the days following the injection was also assessed by self-reporting. RESULTS: Data from 1988 respondents were analyzed. The mean age was 37.13 years (standard deviation 13.7 years). Of the respondents 69.8% were female, 48.1% belonged to therapeutic and technical professions with patient contact, 38% were students, 10.6% were nursing personnel and 4% were physicians. Only 14.4% of respondents reported having tolerated the vaccination without side effects. The most common side effect was fatigue, followed by pain at the injection site. This was followed in descending frequency by headache, aching limbs, and chills. After vaccination 18% of respondents felt able to return to work immediately, 51% of all respondents had to report themselves unfit for work for at least 1 day after vaccination. Side effects were more prevalent in male and younger respondents. CONCLUSION: Vaccination with ChAdOx1â€'S frequently resulted in side effects. These resulted in 37% of respondents reporting sick. Nevertheless, 89.6% of all respondents would choose coronavirus vaccination with ChAdOx1â€'S again.

Post-COMIRNATY(Â®) Non-episodic Angioedema with Eosinophilia: An Elderly Case.

Effect of gentle exercises on injection site reaction after Covid-19 vaccination. A case report. INTRODUCTION: A series of atypical acute respiratory diseases were caused in Wuhan, China, in December 2019 by a novel coronavirus (COVID-19). Over six million confirmed COVID-19 cases had been reported worldwide, and total deaths in the USA from March 1 to May 30, 2020, were approximately 7,81,000. Worldwide, scientists are developing many potential COVID-19 vaccines. Few of the companies got success in the development of a vaccine for COVID-19, but most of the recipients reported injection site reactions like pain, redness, or erythema after vaccination. The present study aimed to evaluate the effect of gentle upper limb exercises to reduce injection site reactions, and here we present a case with post vaccination site reaction that reported pre-assessment score 7 for visual analog scale for pain and score 2 for redness and erythema with Investigator-reported and rated injection site reactions. Then he performed gentle upper limb exercises after 8 and 24 hours of vaccination. RESULT: The study reported a beneficial effect of these exercises to reduce pain and redness or erythema after Covid-19 vaccination. DISCUSSION: The potential benefit of gentle exercises may be due to their blood flow boost-up and anti-inflammatory effects. However, high-quality controlled trials are warranted further to evaluate the potential benefit of upper limb gentle exercises for the reduction of injection site reactions after the Covid-19 vaccination injection. CONCLUSION: The clinical experience with the subect shows that gentle exercises for upper limb may reduce the inection site reaction after COVID-19 vaccination.

Effectiveness and safety of SARS-CoV-2 vaccine in real-world studies: a systematic review and meta-analysis. BACKGROUND: To date, coronavirus disease 2019 (COVID-19) becomes increasingly fierce due to the emergence of variants. Rapid herd immunity through vaccination is needed to block the mutation and prevent the emergence of variants that can completely escape the immune surveillance. We aimed to systematically evaluate the effectiveness and safety of COVID-19 vaccines in the real world and to establish a reliable evidence-based basis for the actual protective effect of the COVID-19 vaccines, especially in the ensuing waves of infections dominated by variants. METHODS: We searched PubMed, Embase and Web of Science from inception to July 22, 2021. Observational studies that examined the effectiveness and safety of SARS-CoV-2 vaccines among people vaccinated were included. Random-effects or fixed-effects models were used to estimate the pooled vaccine effectiveness (VE) and incidence rate of adverse events after vaccination, and their 95% confidence intervals (CI). RESULTS: A total of 58 studies (32 studies for vaccine effectiveness and 26 studies for vaccine safety) were included. A single dose of vaccines was 41% (95% CI: 28-54%) effective at preventing SARS-CoV-2 infections, 52% (31-73%) for symptomatic COVID-19, 66% (50-81%) for hospitalization, 45% (42-49%) for Intensive Care Unit (ICU) admissions, and 53% (15-91%) for COVID-19-related death; and two doses were 85% (81-89%) effective at preventing SARS-CoV-2 infections, 97% (97-98%) for symptomatic COVID-19, 93% (89-96%) for hospitalization, 96% (93-98%) for ICU admissions, and 95% (92-98%) effective for COVID-19-related death, respectively. The pooled VE was 85% (80-91%) for the prevention of Alpha variant of SARS-CoV-2 infections, 75% (71-79%) for the Beta variant, 54% (35-74%) for the Gamma variant, and 74% (62-85%) for the Delta variant. The overall pooled incidence rate was 1.5% (1.4-1.6%) for adverse events, 0.4 (0.2-0.5) per 10 000 for severe adverse events, and 0.1 (0.1-0.2) per 10 000 for death after vaccination. CONCLUSIONS: SARS-CoV-2 vaccines have reassuring safety and could effectively reduce the death, severe cases, symptomatic cases, and infections resulting from SARS-CoV-2 across the world. In the context of global pandemic and the continuous emergence of SARS-CoV-2 variants, accelerating vaccination and improving vaccination coverage is still the most important and urgent matter, and it is also the final means to end the pandemic.

Booster or additional vaccination doses in patients vaccinated against COVID-19. Several health organizations, mainly in Western countries, have recently authorized the use of a booster dose of the COVID-19 vaccine for patients previously vaccinated with mRNA vaccines, with criteria that do not always coincide. The COVID Scientific Committee of the Illustrious College of Physicians of Madrid (ICOMEM) has received and asked several questions about this situation, to which the group has tried to give answers, after deliberation and consensus. The efficacy of the vaccines administered so far is beyond doubt and they have managed to reduce, fundamentally, the severe forms of the disease. The duration of this protection is not well known, is different in different individuals and for different variants of the virus and is not easily predictable with laboratory tests. Data on the real impact of a supplementary or "booster" dose in the scientific literature are scarce for the moment and its application in large populations such as those in the state of Israel may be associated with a decrease in the risk of new and severe episodes in the short observation period available. We also lack sufficient data on the safety and potential adverse effects of these supplementary doses and we do not know the ideal time to administer them in different situations. In this state of affairs, it seems prudent to administer supplemental doses to those exposed to a higher risk, such as immunocompromised individuals and the elderly. On the other hand, we consider that this is not the time to accelerate, on the spur of the moment, a massive administration of a third dose to other population groups that are less exposed and at lower risk, without waiting for adequate scientific information, which will undoubtedly arrive gradually. We do not believe that this position is

incompatible with the practical and ethical warnings made by the World Health Organization in this respect.

Mental health outcomes after SARS-CoV-2 vaccination in the United States: A national cross-sectional study. BACKGROUND: Worsening of anxiety and depressive symptoms have been widely described during the COVID-19 pandemic. It can be hypothesized that vaccination could link to reduced symptoms of anxiety and/or depression. However, to date, no study has assessed this. This study aims to examine anxiety and depressive symptoms after vaccination in US adults, meanwhile test sociodemographic disparities in these outcomes. METHODS: Data from the January 6-June 7 2021, cross-sectional Household Pulse Survey were analyzed. Using survey-weighted logistic regression, we assessed the relationships between SARS-CoV-2 vaccination and anxiety and/or depressive symptoms, both on overall and sociodemographic subgroups. We controlled for a variety of potential socioeconomic and demographic confounding factors. RESULTS: Of the 453,167 participants studied, 52.2% of the participants had received the COVID-19 vaccine, and 26.5% and 20.3% of the participants reported anxiety and depression, respectively. Compared to those not vaccinated, the vaccinated participants had a 13% lower odds of anxiety (adjusted odds ratio [AOR]Â =Â 0.85, 95%CI 0.83-0.90) and 17% lower odds of depression (AORÂ =Â 0.83, 95%CI 0.79-0.85). Disparities on the above associations were identified in age, marital status, education level, ethnic/race, and income level, but not on gender. LIMITATIONS: The causal inference was not able to be investigated due to the cross-sectional study design. CONCLUSION: Being vaccinated for SARS-CoV-2 was associated with lower odds of anxiety and/or depressive symptoms. While those more middle-aged or more affluent, were more likely to show these negative associations, the contrary was observed in ethnic minorities and those with lower educational attainment. More strategic and demography-sensitive public health communications could perhaps temper these issues.

Vaccine-induced immune thrombotic thrombocytopenia. In response to the COVID-19 pandemic, vaccines for SARS-CoV-2 were developed, tested, and introduced at a remarkable speed. Although the vaccine introduction had a major impact on the evolution of COVID-19, some potential rare side-effects of the vaccines were observed. Within a short period, three scientific groups from Norway, Germany, and the UK reported cerebral venous sinus thrombosis with thrombocytopenia and anti-platelet factor 4 (anti-PF4) antibodies in individuals following AstraZeneca-Oxford vaccination and named this new syndrome vaccine-induced immune thrombotic thrombocytopenia (VITT). This syndrome was subsequently reported in individuals who received Johnson & Johnson vaccination. In this Viewpoint, we discuss the epidemiology, pathophysiology, and optimal diagnostic and therapeutic management of VITT. Presentation of an individual with possible VITT should raise prompt testing for anti-PF4 antibodies and initiation of treatment targeting autoimmune processes with intravenous immunoglobulin and prothrombotic processes with non-heparin anticoagulation.

Safety and preliminary efficacy of the Gam-COVID-Vac vaccine and outcomes of SARS-CoV-2 infection in Russian patients with genitourinary malignancies. BACKGROUND: To our knowledge, there is no clinical data pertaining to COVID-19 outcomes and safety of COVID-19 vaccination in Russian patients with genitourinary (GU) malignancies. Aim of our analysis was to describe the characteristics of the COVID-19 infection course as well as preliminary safety and efficacy of Gam-COVID-Vac vaccine in patients with active GU malignancies. METHODS: Patients were retrospectively identified at nine cancer centers in different regions. Patients were included if COVID-19 was diagnosed by a polymerase chain reaction. Data from additional patients with GU cancers who had no positive SARS-CoV-2 RT-PCR test before vaccination and who received two doses of Gam-COVID-Vac (Sputnik V) between 11 February and 31 August 2021 were collected for safety assessment. Anonymized data were collected through an online registry covering demographics, treatments, and outcomes. RESULTS: The Gam-COVID-Vac vaccine was well tolerated; no grade 3-5 toxicities were reported in

112 vaccinated metastatic GU cancer patients. The most common grade 1 adverse events (81%) were injection site reactions (76%), flu-like illness (68%), and asthenia (49%). Five patients experienced grade 2 chills (4.5%) and 3 patients had grade 2 fever (2.7%). With median follow-up of 6.2Â months, two COVID-19 cases were confirmed by RT-PCR test in the vaccine group (of 112 participants; 1.8%). Eighty-eight patients with COVID-19 disease were included in the analysis. The average age as of the study enrollment was 66 (range 39-81) and the majority of patients were male with renal cell carcinoma (RCC). Thirty-six patients (41%) had evidence of metastatic disease, of these 22 patients were receiving systemic therapy. More than half of patients required hospitalization. Fifty-four patients (61%) experienced complications. Sixteen patients who developed COVID-19 pneumonia required mechanical ventilator support. Sixteen patients (18%) died in a median of 23.5Â days after the date of COVID-19 diagnosis was established. The 3-month survival rate was 82%. Clinical and/or radiographic progression of cancer during COVID-19 infection or the subsequent 3Â months was observed in 10 patients (11.4%). CONCLUSION: Patients with GU malignancies are at increased risk of mortality from COVID-19 infection when compared to the general population. Vaccination could be safe in GU cancer patients. TRIAL REGISTRATION: retrospectively registered.

Utilization of health care services before and after media attention about fatal side effects of the AstraZeneca vaccine: a nation-wide register-based event study. BACKGROUND: Survey studies have found that vaccinated persons tend to report more side effects after being given information about side effects rather than benefits. However, the impact of high media attention about vaccine-related side effects on the utilization of health care is unknown. We aimed to assess whether utilization of health care services for newly vaccinated health care workers changed after media attention about fatal side effects of the AstraZeneca vaccine on March 11th, 2021, and whether changes differed by age, sex, or occupation. METHODS: We utilized individual-level data on health care use, vaccination, employment, and demographics available in the Norwegian emergency preparedness register Beredt C19. In all 99,899 health care workers in Norway who were vaccinated with AstraZeneca between February 11th and March 11th, we used an event-study design with a matched comparison group to compare the change in primary and inpatient specialist care use from 14â€‰days before to 14â€‰days after the information shock on March 11th, 2021. RESULTS: Primary health care use increased with 8.2 daily consultations per 1000 health care workers (95% CI 7.51 to 8.89) the week following March 11th for those vaccinated with AstraZeneca (nâ€‰=â€‰99,899), compared with no increase for the unvaccinated comparison group (nâ€‰=â€‰186,885). Utilization of inpatient care also increased with 0.8 daily hospitalizations per 1000 health care workers (95% CI 0.37 to 1.23) in week two after March 11th. The sharpest increase in daily primary health care use in the first week after March 11th was found for women aged 18-44 (10.6 consultations per 1000, 95% CI 9.52 to 11.68) and for cleaners working in the health care sector (9.8 consultations per 1000, 95% CI 3.41 to 16.19). CONCLUSIONS: Health care use was higher after the media reports of a few cases of fatal or severe side effects of the AstraZeneca vaccine. Our results suggest that the reports did not only lead vaccinated individuals to contact primary health care more, but also that physicians referred and treated more cases to specialist care after the new information.

Bullous pemphigoid after SARS-CoV-2 vaccination: spike-protein-directed immunofluorescence confocal microscopy and T-cell-receptor studies.

Gross hematuria after SARS-CoV-2 vaccination: questionnaire survey in Japan. BACKGROUND: Recent clinical reports indicate a correlation between gross hematuria after the coronavirus 2019 (COVID-19) vaccination in patients with glomerulonephritis, especially immunoglobulin A nephropathy (IgAN). Furthermore, healthcare workers in Japan were initially vaccinated with an mRNA vaccine from February 17, 2021, and some of them experienced gross hematuria after receiving the vaccination. METHODS: We conducted a web-based survey of the councilor members of

the Japanese Society of Nephrology (581 members, 382 facilities) to elucidate the relationship between gross hematuria and COVID-19 vaccination. RESULTS: In the first survey, 27 cases (female: 22, 81.5%) of gross hematuria were reported after receiving a COVID-19 vaccination. Of them, 19 (70.4%) patients were already diagnosed with IgAN at the occurrence of gross hematuria. Proteinuria appeared in eight of the 14 (57.1%) cases with no proteinuria before vaccination and hematuria in five of the seven (71.4%) cases with no hematuria before vaccination. The second survey revealed that a renal biopsy was performed after vaccination in four cases, all of whom were diagnosed with IgAN. Only one case showed a slightly increased serum creatinine level, and no patients progressed to severe renal dysfunction. CONCLUSION: This study clarified the clinical features of gross hematuria after a COVID-19 vaccination. Because there was no obvious progression to severe renal dysfunction, safety of the COVID-19 vaccination is warranted at least in the protocol of inoculation twice.
Acceptance of COVID-19 Vaccination and Its Associated Factors Among Cancer Patients Attending the Oncology Clinic of University Clinical Hospital Mostar, Bosnia and Herzegovina: A Cross-Sectional Study. BACKGROUND The pandemic of Coronavirus infectious disease 2019 (COVID-19) poses a major public health challenge, and an effective vaccine is the potential mechanism to resolve this specific situation. The present study aimed to evaluate acceptance of COVID-19 vaccination among patients attending the Oncology Clinic of University Clinical Hospital Mostar. MATERIAL AND METHODS This cross-sectional observational study enrolled 364 patients with cancer from the Oncology Clinic of University Clinical Hospital Mostar during February 2021. Data were collected using a questionnaire that captured general information about the participants and their attitudes toward COVID-19 vaccination. RESULTS Of the participants, 41.8% answered "Yes" when asked if they would take the vaccine once it becomes available, 37.6% answered "Not sure", and 20.6% answered "No". For patients in favor of vaccination, the main reasons reported were fear of getting sick (77.6%), the desire to contribute to herd immunity (57.8%), and trusting the recommendations of health professionals (57.2%). The main reasons for the patients' vaccination -refusal/indecision were doubts about the results from clinical trials of COVID-19 vaccines (49.1%), concerns about adverse effects (24.5%), and confusion about the various vaccine options (19.8%). The majority of participants (82.4%) stated that recommendation by their oncologist could influence their decision about vaccination. Of the participants who indicated unwillingness (refusal or indecision) to be vaccinated against COVID-19, 65.3% stated that recommendation by their oncologist could influence their decision about vaccination. CONCLUSIONS The findings from the present study showed most patients had refused or were indecisive regarding immunization with COVID-19 vaccine. Increasing physician awareness of this situation may result in higher rates of vaccination.
Immediate reactions after mRNA SARS-CoV-2 vaccination.
Interstitial pneumonitis after COVID-19 vaccination: A report of three cases.
An Insight into the Role of Postmortem Immunohistochemistry in the Comprehension of the Inflammatory Pathophysiology of COVID-19 Disease and Vaccine-Related Thrombotic Adverse Events: A Narrative Review. On 11 March 2020, the World Health Organization (WHO) declared a pandemic due to the spread of COVID-19 from Wuhan, China, causing high mortality rates all over the world. The related disease, which mainly affects the lungs, is responsible for the onset of Diffuse Alveolar Damage (DAD) and a hypercoagulability state, frequently leading to Severe Acute Respiratory Syndrome (SARS) and multiorgan failure, particularly in old and severe-critically ill patients. In order to find effective therapeutic strategies, many efforts have been made aiming to shed light on the pathophysiology of COVID-19 disease. Moreover, following the late advent of vaccination campaigns, the need for the comprehension of the pathophysiology of the fatal, although rare, thrombotic adverse events has become mandatory as well. The achievement of such purposes needs a multidisciplinary approach, depending on a correct interpretation of clinical, biochemical,

biomolecular, and forensic findings. In this scenario, autopsies have helped in defining, on both gross and histologic examinations, the main changes to which the affected organs undergo and the role in assessing whether a patient is dead "from" or "with" COVID-19, not to mention whether the existence of a causal link exists between vaccination and thrombotic adverse events. In the present work, we explored the role of postmortem immunohistochemistry, and the increasingly used ancillary technique, in helping to understand the mechanism underlying the pathophysiology of both COVID-19 disease and COVID-19 vaccine-related adverse and rare effects.

Belatacept Use after Kidney Transplantation and Its Effects on Risk of Infection and COVID-19 Vaccine Response. Belatacept is a common immunosuppressive therapy used after kidney transplantation (KT) to avoid calcineurin-inhibitor (CNI) use and its related toxicities. It is unclear whether its use exposes KT recipients (KTx) to a greater risk of infection or a poorer response to vaccines. Areas covered: We reviewed PubMed and the Cochrane database. We then summarized the mechanisms and impacts of belatacept use on the risk of infection, particularly opportunistic, in two settings, i.e., de novo KTx and conversion from CNIs. We also focused on COVID-19 infection risk and response to SARS-CoV-2 vaccination in patients whose maintenance immunosuppression relies on belatacept. Expert opinion: When belatacept is used de novo, or after drug conversion the safety profile regarding the risk of infection remains good. However, there is an increased risk of opportunistic infections, mainly CMV disease and Pneumocystis pneumonia, particularly in those with a low eGFR, in older people, in those receiving steroid-based therapy, or those that have an early conversion from CNI to belatacept (i.e., <six months post-transplantation). Thus, we recommend, if possible, delaying conversion from CNI to belatacept until at least six months post-transplantation. Optimal timing seems to be eight months post-transplantation. In addition, KTx receiving belatacept respond poorly to SARS-CoV-2 vaccination.

Evolution of SARS-CoV-2-Neutralizing Antibodies after Two Standard Dose Vaccinations, Risk Factors for Non-Response and Effect of a Third Dose Booster Vaccination in Non-Responders on Hemodialysis: A Prospective Multi-Centre Cohort Study. The aim of this investigation was to determine the effect of SARS-Cov-2 vaccination in hemodialysis patients, search for risk factors for non- or low-response, and to measure the effect of a third booster vaccination in non- or low-responders. Methods SARS-CoV-2 IgG antibodies and the virus-neutralizing capacity were measured 4-5 weeks after a full standard vaccination in 95 chronic hemodialysis patients and 60 controls. IgG titers > 30 AU/mL served to classify participants as responders. Multivariable binary logistic regression analysis was used to search for risk factors of reduced vaccination success. Patients with vaccination failure were offered a third booster dosage. Results 82.1% of the patient cohort as compared to 98.3% of the healthy control group were able to mount SARS-CoV-2 titers above 30 AU/mL after two standard vaccine doses. Mean IgG antibody titers were lower in hemodialysis patients than controls (78 Â± 35 vs. 90 Â± 20 AU/mL, p = 0.002). Multivariable binary logistic regression analysis showed age and immunosuppressive medication as major risk factors for vaccination failure with a decreased probability of successful vaccination of -6.1% (95% CI -1.2 to -10.9) per increase in age of one year and -87.4% (95% CI -98.0 to -21.5) in patients on immunosuppressive therapy (crude odds ratio for vaccination failure for immunosuppressive therapy 6.4). Ten out of 17 patients with non-response to vaccination were offered a third dose. Booster vaccination after the second dose induced an increase in effective antibody titers of >30 AU/mL in seven out of ten patients 4-5 weeks later (70%). Conclusion Standard SARS-CoV-2 vaccination schemes are highly effective in mounting protective neutralizing IgG antibodies in chronic hemodialysis patients. Nevertheless, response to vaccination is diminished as compared to a healthy control group. Major risk factors for vaccination failure are older age and immunosuppressive therapy. In non- or low-responders to standard vaccination a third booster vaccination was able to

induce effective antibody titers in about 70% of patients, indicating that a third booster vaccination might be preferable to decreasing immunosuppressive therapy.

COVID-19 adenovirus vaccine triggers antibodies against PF4 complexes to activate complement and platelets. BACKGROUND: Vaccine-induced thrombotic thrombocytopenia (VITT) is a rare coagulation disorder reported after administration of COVID-19 adenovirus-vectored vaccines. VITT is mediated by anti-platelet factor 4 (PF4) antibodies activating platelets through the FcÎ³-receptor II (FcÎ³RII), and it is associated with strong fibrin turnover. The complement system is involved in several other immunothrombotic entities, but its impact on VITT is not established. OBJECTIVE: To assess antibodies in interaction with the activation of platelets and complement triggered by VITT. METHODS: Antibodies against adenovirus type 2 hexon protein, ChAdOx1 adenoviral vector-specific IgG and PF4 were analyzed by enzyme immunoassays from VITT patients (nÂ =Â 5). The EDTA plasma samples of the patients and controls were used to measure both terminal complement complexes (TCC) by ELISA and aggregation of healthy donor platelets. We studied the effects of human immunoglobulin (IVIG) and glycoprotein IIb/IIIa inhibitor (GPIIb/IIIa) on spontaneous and collagen-induced platelet aggregation supplemented with VITT plasma. RESULTS: None of the patients had experienced a COVID-19 infection. Antibody analyses confirmed the immunogenicity of the adenovirus-vectored ChAdOx1 vaccine. Moreover, VITT plasma had anti-PF4 antibodies and elevated TCC levels as a sign of complement activation. In isolated healthy donor platelets, VITT patient plasma caused marked, spontaneous aggregation of platelets, which was abolished by eptifibatide and high-dose therapeutic IVIG. CONCLUSIONS: Our findings suggest that VITT is triggered by antibodies against adenovirus vector and PF4-polyanion complexes which strongly co-activate complement and platelets. The spontaneous platelet aggregation was suppressed by IVIG or eptifibatide, indicating that besides FcÎ³RII, also GPIIb/IIIa receptor exerts platelet procoagulant role in VITT.

mRNA-1273 COVID-19 vaccination in patients receiving chemotherapy, immunotherapy, or chemoimmunotherapy for solid tumours: a prospective, multicentre, non-inferiority trial. BACKGROUND: Patients with cancer have an increased risk of complications from SARS-CoV-2 infection. Vaccination to prevent COVID-19 is recommended, but data on the immunogenicity and safety of COVID-19 vaccines for patients with solid tumours receiving systemic cancer treatment are scarce. Therefore, we aimed to assess the impact of immunotherapy, chemotherapy, and chemoimmunotherapy on the immunogenicity and safety of the mRNA-1273 (Moderna Biotech, Madrid, Spain) COVID-19 vaccine as part of the Vaccination Against COVID in Cancer (VOICE) trial. METHODS: This prospective, multicentre, non-inferiority trial was done across three centres in the Netherlands. Individuals aged 18 years or older with a life expectancy of more than 12 months were enrolled into four cohorts: individuals without cancer (cohort A [control cohort]), and patients with solid tumours, regardless of stage and histology, treated with immunotherapy (cohort B), chemotherapy (cohort C), or chemoimmunotherapy (cohort D). Participants received two mRNA-1273 vaccinations of 100 Î¼g in 0Â·5 mL intramuscularly, 28 days apart. The primary endpoint, analysed per protocol (excluding patients with a positive baseline sample [>10 binding antibody units (BAU)/mL], indicating previous SARS-CoV-2 infection), was defined as the SARS-CoV-2 spike S1-specific IgG serum antibody response (ie, SARS-CoV-2-binding antibody concentration of >10 BAU/mL) 28 days after the second vaccination. For the primary endpoint analysis, a non-inferiority design with a margin of 10% was used. We also assessed adverse events in all patients who received at least one vaccination, and recorded solicited adverse events in participants who received at least one vaccination but excluding those who already had seroconversion (>10 BAU/mL) at baseline. This study is ongoing and is registered with ClinicalTrials.gov, NCT04715438. FINDINGS: Between Feb 17 and March 12, 2021, 791 participants were enrolled and followed up for a median of 122 days (IQR 118 to 128). A SARS-CoV-2-binding antibody response was found in 240 (100%; 95% CI 98 to 100) of 240 evaluable participants in

cohort A, 130 (99%; 96 to >99) of 131 evaluable patients in cohort B, 223 (97%; 94 to 99) of 229 evaluable patients in cohort C, and 143 (100%; 97 to 100) of 143 evaluable patients in cohort D. The SARS-CoV-2-binding antibody response in each patient cohort was non-inferior compared with cohort A. No new safety signals were observed. Grade 3 or worse serious adverse events occurred in no participants in cohort A, three (2%) of 137 patients in cohort B, six (2%) of 244 patients in cohort C, and one (1%) of 163 patients in cohort D, with four events (two of fever, and one each of diarrhoea and febrile neutropenia) potentially related to the vaccination. There were no vaccine-related deaths. INTERPRETATION: Most patients with cancer develop, while receiving chemotherapy, immunotherapy, or both for a solid tumour, an adequate antibody response to vaccination with the mRNA-1273 COVID-19 vaccine. The vaccine is also safe in these patients. The minority of patients with an inadequate response after two vaccinations might benefit from a third vaccination. FUNDING: ZonMw, The Netherlands Organisation for Health Research and Development.
The Use of COVID-19 Vaccines in Patients with SLE. PURPOSE OF REVIEW: Three COVID-19 vaccines obtained emergency authorization from the Food and Drug Administration (FDA) and are widely used in the USA. Unfortunately, there is a paucity of evidence on the safety and efficacy of these vaccines in patients with autoimmune inflammatory rheumatic diseases (AIIRD), as these patients were excluded from all phases of vaccine development. Here we reviewed current data on COVID-19 vaccination in patients with AIIRD, with emphasis on systemic lupus erythematosus (SLE), and provided a comprehensive update on the benefits and risks of vaccination. RECENT FINDINGS: Patients with SLE have worse immune responses following SARS-CoV-2 vaccination than healthy controls. The efficacy of the COVID-19 vaccines seems to be further reduced by immunosuppressive medications, such as glucocorticoids (GC), methotrexate (MTX), mycophenolate/mycophenolic acid (MMF), and rituximab (RTX). However, these data do not substantiate that AIIRD patients are at greater risk of disease flares or have a higher incidence of side effects following vaccination. There is no significant safety concern for the use of COVID-19 vaccines in patients with AIIRD. The benefits of vaccination far outweigh the risks in patients with AIIRD, including SLE. More data are needed to determine the necessity of a booster vaccine dose and appropriate adjustment of immunosuppressants around the administration of vaccine.
Gross haematuria after mRNA COVID-19 vaccination in two patients with histological and clinical diagnosis of IgA nephropathy.
Multisystem Inflammation and Organ Dysfunction After BNT162b2 Messenger RNA Coronavirus Disease 2019 Vaccination. The U.S. Food and Drug Administration has to date granted approval or emergency use authorization to three vaccines against severe acute respiratory syndrome coronavirus 2 and coronavirus disease 2019. In clinical trials and real-use observational studies, the Pfizer-BioNTech BNT162b2 messenger RNA coronavirus disease 2019 vaccine, as well as the Moderna mRNA-1273 messenger RNA coronavirus disease 2019 vaccine, have demonstrated high efficacy and few adverse events. CASE SUMMARY: A 20-year-old male college student in good health developed tinnitus and hematuria shortly after vaccination and progressed swiftly to a syndrome of: systemic inflammation; acute kidney injury requiring hemodialysis; acute, bilateral, complete sensorineural hearing loss; radiographic evidence of acute multifocal ischemic strokes; pericardial effusion complicated by tamponade physiology requiring pericardial evacuation; pleural effusions requiring evacuation; and systemic capillary leak. An extensive clinical and research investigation, including cytokine analysis, whole blood cytometry by time of flight, and whole exome sequencing, did not reveal a definitive explanatory mechanism. CONCLUSION: While the overall safety profile of the BNT162b2 coronavirus disease 2019 vaccine remains excellent for the general population, rare serious events have been reported. In this report, we describe a case of multisystem inflammation

and organ dysfunction of unknown mechanism beginning shortly after administration of the first dose of BNT162b2 coronavirus disease 2019 vaccine in a previously healthy recipient.

Rapid response to mycophenolate mofetil in combination with romiplostim in a case of severe refractory immune thrombocytopenia post COVID-19 vaccination. Vaccine mediated immune mediated thrombocytopenia (ITP) is exceedingly rare. We present a case of a young female who developed severe refractory ITP with multiple bleeding sites post second dose of COVID-19 vaccination. She was treated with a combination of romiplostim and mycophenolate mofetil that resulted in rapid platelet count recovery.

Minimal change disease following the Moderna COVID-19 vaccine: first case report. BACKGROUND: There have been cases of minimal change disease (MCD) reported following previous vaccines. During the COVID-19 era, only 3 cases of new-onset MCD and a case of MCD relapse were reported following the Pfizer-BioNTech COVID-19 vaccine. We herein report the first case of MCD after receiving the Moderna COVID-19 vaccine. CASE PRESENTATION: A 43-year-old man presented to hospital 3â€‰weeks after receiving the first dose of the Moderna vaccine, with both bilateral lower extremities and scrotal edema. He initially developed a sudden-onset bilateral lower extremities swelling on day 7 post-vaccine. He, then, developed dyspnea and scrotal swelling over a time span of 2 weeks. On physical examination, his blood pressure was 150/92â€‰mmHg. There was a decreased air entry at lung bases, bilateral lower extremities and scrotal edema. Labs revealed hypoalbuminemia, hyperlipidemia and 15â€‰g of proteinuria. His immunologic and serologic work up was negative. Renal biopsy showed concomitant MCD and IgA nephropathy. Patient was treated with oral steroids and had a good response; his edema resolved, serum albumin improved, and proteinuria decreased to 1â€‰g within 2â€‰weeks of treatment. CONCLUSIONS: To the best of our knowledge, MCD has not been previously reported after receiving the Moderna COVID-19 vaccine. It remains unclear whether the COVID-19 mRNA vaccines are associated with the development of MCD, or it coincided with the mass vaccination. Further studies are needed to determine the incidence of MCD post COVID-19 vaccines and the underlying pathophysiology of glomerular injury post vaccination.

Left Bell's palsy following the first dose of mRNA-1273 SARS-CoV-2 vaccine: A case report. Even though no definitive link has been established, Bell's palsy has been described as a potential side effect of SARS-CoV-2 mRNA vaccines in a few reports, and the US Food and Drug Administration has recommended strict surveillance of its occurrence in the vaccinated general population. We present the case of a previously healthy 35-year-old female patient who developed Bell's palsy 12Â h after receiving the first dose of the mRNA-1273 vaccine. Her general practitioner performed the diagnosis, and corticosteroid treatment was initiated, with slow symptoms improvement. The neurologist's evaluation and a contrast-enhanced brain Magnetic Resonance Imaging revealed a subtle enhancement of the left facial nerve, confirming the diagnosis of Bell's palsy.

Safety and cross-variant immunogenicity of a three-dose COVID-19 mRNA vaccine regimen in kidney transplant recipients. BACKGROUND: The immunogenicity of a two-dose mRNA COVID-19 vaccine regimen is low in kidney transplant (KT) recipients. Here, we provide a thorough assessment of the immunogenicity of a three-dose COVID-19 vaccine regimen in this population. METHODS: We performed a prospective longitudinal study in sixty-one KT recipients given three doses of the BNT162b2 COVID-19 vaccine. We performed semi-structured pharmacovigilance interviews and monitored donor-specific antibodies and kidney function. We compared levels of anti-spike IgG, pseudo-neutralization activity against vaccine homologous and heterologous variants, frequency of spike-specific interferon (IFN)-Î³-secreting cells, and antigen-induced cytokine production 28 days after the second and third doses. FINDINGS: Reactions to vaccine were mild. One patient developed donor-specific anti-HLA antibodies after the second dose which could be explained by non-adherence

to immunosuppressive therapy. Spike-specific IgG seroconversion raised from 44Â·3% (n=27) after the second dose to 62Â·3% (n=38) after the third dose (p<0Â·05). The mean level of spike-specific IgG increased from 1620 (SD, 3460) to 8772 (SD, 16733) AU/ml (p<0Â·0001). Serum neutralizing activity increased after the third dose for all variants of concern tested including the Delta variant (p<0Â·0001). The frequency of spike-specific IFN-Î³-secreting cells increased from 19Â·9 (SD, 56Â·0) to 64Â·0 (SD, 76Â·8) cells/million PBMCs after the third dose (p<0Â·0001). A significant increase in IFN-Î³ responses was also observed in patients who remained seronegative after three doses (p<0Â·0001). INTERPRETATION: A third dose of the BNT162b2 vaccine increases both cross-variant neutralizing antibody and cellular responses in KT recipients with an acceptable tolerability profile. FUNDING: Nice University Hospital, University Cote d'Azur.

Adult-onset Still's disease following mRNA COVID-19 vaccination.

The association of maternal SARS-CoV-2 vaccination-to-delivery interval and the levels of maternal and cord blood antibodies. OBJECTIVE: To evaluate the correlation of maternal and cord blood levels of SARS-CoV-2 antibodies in pregnant women immunized against COVID-19. METHODS: A prospective cohort study was performed of pregnant women who delivered at a single university affiliated tertiary medical center. Women who received the COVID-19 vaccine (BNT162b2 PfizerÂ©) were approached. The correlation between levels of maternal sera and umbilical cord SARS-CoV-2 specific IgG was assessed. RESULTS: Overall, 58 women were included; of them, 19 had received a single dose and 39 received two doses of the COVID-19 vaccine. Positive levels of umbilical cord IgG were found in 13/19 (68.4%) and 38/39 (97.4%) women after the administration of a single dose and two doses of the vaccine, respectively. The levels of SARS-CoV-2 IgG antibodies in the maternal sera of vaccinated women were positively correlated to their respective concentrations in cord blood sera (Ï•Â =Â 0.857; R(2) linearÂ =Â 0.719; PÂ <Â 0.001). Thirteen days after vaccination, the ratio of maternal-to-umbilical cord anti Spike IgG antibodies was approximately 1, indicating relatively similar levels in maternal and cord sera. CONCLUSION: After the SARS-CoV-2 vaccine, levels of maternal and cord blood antibodies were positively correlated, especially when tested after 13Â days following administration of the first dose of the vaccine.

Benign cutaneous reactions post-COVID-19 vaccination: A case series of 16 patients from a tertiary care center in India.

Linear IgA bullous dermatosis following Oxford AstraZeneca COVID-19 vaccine. A case of linear IgA bullous dermatosis developing 3 days after the second dose of Oxford AstraZeneca COVID-19 vaccine in an adult patient, suggesting a possible causal association. It is worth keeping in mind that COVID-19 vaccination could induce immune-mediated bullous disease in susceptible people.

Nicolau Syndrome After Glatiramer Acetate Injection in Close Proximity to Administration of SARS-CoV-2 mRNA Vaccine.

Longitudinal SARS-CoV-2 mRNA Vaccine-Induced Humoral Immune Responses in Patients with Cancer. Longitudinal studies of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine-induced immune responses in patients with cancer are needed to optimize clinical care. In a prospective cohort study of 366 (291 vaccinated) patients, we measured antibody levels [anti-spike (IgG-(S-RBD) and anti-nucleocapsid immunoglobulin] at three time points. Antibody level trajectories and frequency of breakthrough infections were evaluated by tumor type and timing of treatment relative to vaccination. IgG-(S-RBD) at peak response (median = 42 days after dose 2) was higher (P = 0.002) and remained higher after 4 to 6 months (P = 0.003) in patients receiving mRNA-1273 compared with BNT162b2. Patients with solid tumors attained higher peak levels (P = 0.001) and sustained levels after 4 to 6 months (P < 0.001) compared with those with hematologic malignancies. B-cell targeted treatment reduced peak (P = 0.001) and sustained antibody responses (P = 0.003). Solid tumor patients receiving immune checkpoint inhibitors before vaccination had lower sustained

antibody levels than those who received treatment after vaccination (P = 0.043). Two (0.69%) vaccinated and one (1.9%) unvaccinated patient had severe COVID-19 illness during follow-up. Our study shows variation in sustained antibody responses across cancer populations receiving various therapeutic modalities, with important implications for vaccine booster timing and patient selection. SIGNIFICANCE: Long-term studies of immunogenicity of SARS-CoV-2 vaccines in patients with cancer are needed to inform evidence-based guidelines for booster vaccinations and to tailor sequence and timing of vaccinations to elicit improved humoral responses.

Antibody Response 3 Months after 2 Doses of BNT162b2 mRNA COVID-19 Vaccine in Residents of Long-Term Care Facilities. BACKGROUND: Older adults living in long-term care facilities (LTCFs) are at increased risk for severe outcomes from COVID-19 and were identified as a priority group in COVID-19 vaccination strategies. Emerging evidence suggests vaccine effectiveness in LTCF populations, but data about median and long-term durability of immune response after vaccination are still limited. OBJECTIVES: In this study, we assessed the humoral response to BNT162b2 mRNA COVID-19 vaccine 3 months after the second dose, in a cohort of 495 residents aged â‰¥65 years from 11 LTCF in Granada, Spain. METHOD: Between April 19 and April 30, 2021, we measured anti-SARS-CoV-2 Spike IgG to evaluate the humoral vaccination response. Antibody titers were reported in binding antibody units (BAU/mL). Bivariate and multivariate logistic regression models were performed to investigate the impact of age, sex, underlying health conditions, and prior COVID-19 infection on the antibody levels. RESULTS: Over 96% of the participants developed an adequate humoral response. We detected higher antibody titers in previously infected individuals, compared with those previously uninfected (B: 1,150.059 BAU/mL, $p < 0.001$). Moreover, we found a significant inverse association between age and antibody levels (B: -7.943 BAU/mL, $p < 0.05$). This negative age-dependent response was more noticeable among residents over 85 years old. In contrast, baseline health conditions and cognitive status were not associated with different antibody levels. CONCLUSIONS: These findings support monitoring COVID-19 vaccination response trend in older adults, in order to optimize future disease prevention and control strategies in this vulnerable population.

Coronavirus Disease 2019 Vaccination Is Associated With Reduced Severe Acute Respiratory Syndrome Coronavirus 2 Infection and Death in Liver Transplant Recipients.

Audio Interview: Covid-19 in Brazil and New Evidence for Vaccinating Younger Children.

BCG vaccination induces enhanced frequencies of memory T cells and altered plasma levels of common Î³c cytokines in elderly individuals. BCG vaccination is known to induce innate immune memory, which confers protection against heterologous infections. However, the effect of BCG vaccination on the conventional adaptive immune cells subsets is not well characterized. We investigated the impact of BCG vaccination on the frequencies of T cell subsets and common gamma c (Î³c) cytokines in a group of healthy elderly individuals (age 60-80 years) at one month post vaccination as part of our clinical study to examine the effect of BCG on COVID-19. Our results demonstrate that BCG vaccination induced enhanced frequencies of central ($p<0.0001$) and effector memory ($p<0.0001$) CD4+ T cells and diminished frequencies of naÃ¯ve ($p<0.0001$), transitional memory ($p<0.0001$), stem cell memory ($p = 0.0001$) CD4+ T cells and regulatory T cells. In addition, BCG vaccination induced enhanced frequencies of central ($p = 0.0008$), effector ($p<0.0001$) and terminal effector memory ($p<0.0001$) CD8+ T cells and diminished frequencies of naÃ¯ve ($p<0.0001$), transitional memory ($p<0.0001$) and stem cell memory ($p = 0.0034$) CD8+T cells. BCG vaccination also induced enhanced plasma levels of IL-7 ($p<0.0001$) and IL-15 ($p = 0.0020$) but diminished levels of IL-2 ($p = 0.0033$) and IL-21 ($p = 0.0020$). Thus, BCG vaccination was associated with enhanced memory T cell subsets as well as memory enhancing Î³c cytokines in elderly individuals, suggesting its ability to induce non-specific adaptive immune responses.

Plantar herpes zoster following heterologous recombinant adenovirus-based COVID-19 vaccine.

A prospective multicenter study assessing humoral immunogenicity and safety of the mRNA SARS-CoV-2 vaccines in Greek patients with systemic autoimmune and autoinflammatory rheumatic diseases. OBJECTIVES: To investigate humoral responses and safety of mRNA SARS-CoV-2 vaccines in systemic autoimmune and autoinflammatory rheumatic disease (SAARD) patients subjected or not to treatment modifications during vaccination. METHODS: A nationwide, multicenter study, including 605 SAARD patients and 116 controls, prospectively evaluated serum anti-SARS-CoV-2 S1-protein IgG antibody titers, side-effects, and disease activity, one month after complete vaccination, in terms of distinct treatment modification strategies (none, partial and extended modifications). Independent risk factors associated with hampered humoral responses were identified by data-driven multivariable logistic regression analysis. RESULTS: Patients with extended treatment modifications responded to vaccines similarly to controls as well as SAARD patients without immunosuppressive therapy (97.56% vs 100%, p = 0.2468 and 97.56% vs 97.46%, pÂ >Â 0.9999, respectively). In contrast, patients with partial or without therapeutic modifications responded in 87.50% and 84.50%, respectively. Furthermore, SAARD patients with extended treatment modifications developed higher anti-SARS-CoV-2 antibody levels compared to those without or with partial modifications (median:7.90 vs 7.06 vs 7.1, pÂ =Â 0.0003 and pÂ =Â 0.0195, respectively). Mycophenolate mofetil (MMF), rituximab (RTX) and methotrexate (MTX) negatively affected anti-SARS-CoV-2 humoral responses. In 10.5% of vaccinated patients, mild clinical deterioration was noted; however, no differences in the incidence of deterioration were observed among the distinct treatment modification SAARD subgroups. Side-effects were generally comparable between SAARD patients and controls. CONCLUSIONS: In SAARD patients, mRNA SARS-CoV-2 vaccines are effective and safe, both in terms of side-effects and disease flares. Treatment with MMF, RTX and/or MTX compromises anti-SARS-CoV-2 antibody responses, which are restored upon extended treatment modifications without affecting disease activity.

Post-acute COVID-19 syndrome after reinfection and vaccine breakthrough by the SARS-CoV-2 Gamma variant in Brazil. We describe a case of prolonged COVID-19 caused by the SARS-CoV-2 Gamma variant in a fully vaccinated healthcare worker, 387 days after an infection caused by lineage B.1.1.33. Infections were confirmed by whole-genome sequencing and corroborated by the detection of neutralizing antibodies in convalescent serum samples. Considering the permanent exposure of this healthcare worker to SARS-CoV-2, the waning immunity after the first infection, the low efficacy of the inactivated vaccine at preventing COVID-19, the immune escape of the Gamma variant (VOC), and the burden of post-COVID syndrome, this individual would have benefited from an additional dose of a heterologous vaccine.

Probable autoimmune hepatitis reactivated after COVID-19 vaccination.

Immune thrombocytopenia following immunisation with Vaxzevria ChadOx1-S (AstraZeneca) vaccine, Victoria, Australia. Emerging evidence suggest a possible association between immune thrombocytopenia (ITP) and some formulations of COVID-19 vaccine. We conducted a retrospective case series of ITP following vaccination with Vaxzevria ChadOx1-S (AstraZeneca) and mRNA Comirnaty BNT162b2 COVID-19 (Pfizer-BioNTech) vaccines and compare the incidence to expected background rates for Victoria during the first six months of the Australian COVID-19 vaccination roll-out in 2021. Cases were identified by reports to the Victorian state vaccine safety service, SAEFVIC, of individuals aged 18Â years or older presenting with thrombocytopenia following COVID-19 vaccination without evidence of thrombosis. Twenty-one confirmed or probable cases of ITP were identified following receipt of AstraZeneca (nÂ =Â 17) or Pfizer-BioNTech (nÂ =Â 4) vaccines. This translates to an observed incidence of 8 per million doses for AstraZeneca vaccine, twice the expected background rate of 4.1 per million. The observed rate for Pfizer-BioNTech was consistent with the expected

background rate. The median time to onset for the cases post AstraZeneca vaccination was 10Â days (range 1-78) and median platelet nadir 5Â Ã—Â 10(9)/L (range 0-67Â Ã—Â 10(9)/L). Hospital presentations or admissions for management of symptoms such as bleeding occurred in 18 (86%) of the cases. The majority of cases (nÂ =Â 11) required intervention with at least 2 therapy modalities. In conclusion, we observed a substantially higher than expected rate of ITP following AstraZeneca vaccination. ITP is the second haematological adverse event, distinct from that of thrombosis with thrombocytopenia syndrome (TTS), observed following AstraZeneca vaccination.

STEMI Mimic: Focal Myocarditis in an Adolescent Patient After mRNA COVID-19 Vaccine. BACKGROUND: In May 2021, the U.S. Food and Drug Administration expanded the Emergency Use Authorization for the Pfizer-BioNTech mRNA Coronavirus disease 2019 (COVID-19) Vaccine (BNT162b2) to include adolescents 12-15 years of age. As vaccine administration continues to increase, potential adverse outcomes, to include myocarditis, are being reported to the Vaccine Adverse Event Reporting System. CASE REPORT: This case report describes a 17-year-old male patient who developed focal myocarditis mimicking an ST-segment elevation myocardial infarction (STEMI) 3 days after administration of an mRNA COVID-19 vaccine. Why Should an Emergency Physician Be Aware of This? Myocarditis is a rare complication in adolescents receiving mRNA COVID-19 vaccines. Focal myocarditis may demonstrate localizing electrocardiographic changes consistent with a STEMI. Overall, complications of the mRNA COVID-19 vaccines are extremely rare. The vaccine continues to be recommended by public health experts, as the benefits of vaccinations greatly outweigh the rare side effects.

Monitoring the safety of COVID-19 vaccines in pregnancy in the US. Pregnant persons are at increased risk of severe illness from COVID-19. The first COVID-19 vaccines in the U.S. were authorized for emergency use in December 2020 and pregnant persons were eligible and could get vaccinated despite scarce safety data in this population. To monitor the safety of COVID-19 vaccination during pregnancy, four surveillance systems are used by the Centers for Disease Control and Prevention (CDC). The Vaccine Adverse Event Reporting System is a national, passive system that captures reports of potential adverse events. V-safe is a novel, active system that uses text messaging and web-based surveys to provide health check-ins after vaccination; and enrolls eligible v-safe participants in the v-safe pregnancy registry. The Vaccine Safety Datalink is a collaboration between the CDC and nine integrated health care organizations which performs near-real time surveillance and traditional epidemiologic studies on pregnant vaccine recipients. The CDC is committed to timely and comprehensive monitoring of COVID-19 vaccine safety in pregnancy.

Differences in IgG Antibody Responses following BNT162b2 and mRNA-1273 SARS-CoV-2 Vaccines. Studies examining antibody responses by vaccine brand are lacking and may be informative for optimizing vaccine selection, dosage, and regimens. The purpose of this study is to assess IgG antibody responses following immunization with BNT162b2 (30â€‰Î¼g mRNA) and mRNA-1273 (100â€‰Î¼g mRNA) vaccines. A cohort of clinicians at a nonprofit organization is being assessed clinically and serologically following immunization with BNT162b2 or mRNA-1273. IgG responses were measured at the Remington Laboratory by an IgG assay against the SARS-CoV-2 spike protein-receptor binding domain. Mixed-effect linear (MEL) regression modeling was used to examine whether the SARS-CoV-2 IgG level differed by vaccine brand, dosage, or number of days since vaccination. Among 532 SARS-CoV-2 seronegative participants, 530 (99.6%) seroconverted with either vaccine. After adjustments for age and gender, MEL regression modeling revealed that the average IgG antibody level increased after the second dose compared to the first dose (Pâ€‰<â€‰0.001). Overall, titers peaked at week 6 for both vaccines. Titers were significantly higher for the mRNA-1273 vaccine on days 14 to 20 (Pâ€‰<â€‰0.05), 42 to 48 (Pâ€‰<â€‰0.01), 70 to 76 (Pâ€‰<â€‰0.05), and 77 to 83 (Pâ€‰<â€‰0.05) and higher for the BNT162b2 vaccine on days 28 to 34

(Pâ€‰<â€‰0.001). In two participants taking immunosuppressive drugs, the SARS-CoV-2 IgG antibody response remained negative. mRNA-1273 elicited higher IgG antibody responses than BNT162b2, possibly due to the higher S-protein delivery. Prospective clinical and serological follow-up of defined cohorts such as this may prove useful in determining antibody protection and whether differences in antibody kinetics between the vaccines have manufacturing relevance and clinical significance. IMPORTANCE SARS-CoV-2 vaccines using the mRNA platform have become one of the most powerful tools to overcome the COVID-19 pandemic. mRNA vaccines enable human cells to produce and present the virus spike protein to their immune system, leading to protection from severe illness. Two mRNA vaccines have been widely implemented, mRNA-1273 (Moderna) and BNT162b2 (Pfizer/BioNTech). We found that, following the second dose, spike protein antibodies were higher with mRNA-1273 than with BNT162b2. This is biologically plausible, since mRNA-1273 delivers a larger amount of mRNA (100â€‰Î¼g mRNA) than BNT162b2 (30â€‰Î¼g mRNA), which is translated into spike protein. This difference may need to be urgently translated into changes in the manufacturing process and dose regimens of these vaccines.

[mRNA Covid vaccines: What do we know eight months after deployment]. This paper summarizes the main knowledge on mRNA vaccines in September 2021. The only contraindication for a 1st dose of vaccine is an allergy to one of the components of the vaccine, but a specialized consultation is possible for an eventual split vaccination under medical supervision. Serious side effects are rare and consist mainly of myocarditis, shingles and appendicitis, but the risk/benefit ratio is always favorable for vaccination. Efficacy against severe COVID-19 is > 90 % after 6 months, and this against all variants. It is recommended to vaccinate pregnant women. A 3rd dose is not recommended at this time, except for immunosuppressed individuals without detectable antibodies after 2 doses. Vaccine mixing is possible, including with a viral vector vaccine.

IgG antibodies against SARS-CoV-2 decay but persist 4Â months after vaccination in a cohort of healthcare workers. BACKGROUND AND AIMS: Monitoring the immune response against SARS-CoV-2 is pivotal in the evaluation of long-term vaccine efficacy. Immunoglobulin G (IgG) antibodies represent an advisable tool to reach this goal, especially for the still poorly defined antibody trend induced by the new class of mRNA vaccines against SARS-CoV-2. MATERIALS AND METHODS: Anti-Spike RBD IgG antibodies were monitored in a cohort of healthcare workers at CRO Aviano, National Cancer Institute, through MAGLUMIÂ® chemiluminescence assay, at 1 and 4Â months after full-schedule of BNT162b2 or mRNA-1273 vaccination. RESULTS: At 1Â month after vaccination, 99.9% of 767 healthcare workers showed a reactive antibody response, which was inversely correlated with age, and positively associated with a previous history of COVID-19, and mRNA-1273 vaccination. Serological response was maintained in 99.6% of the 516 subjects monitored also at follow-up. An antibody decay from 559.8 AU/mL (IQR 359.7-845.7) to 92.7 AU/mL (IQR 65.1-148.6; pÂ <Â 0.001) was observed, independently from age and sex. CONCLUSION: Our data supported the ability of SARS-CoV-2 mRNA vaccines to induce at least a 4Â months-lasting IgG response, even outside the rules of clinical trials. The antibody decay observed at follow-up suggested to deepen the immune response characterization to identify subjects with low anti-SARS-CoV-2 immunity possibly requiring a vaccination boost.

Thrombosis After Adenovirus-Vectored COVID-19 Vaccination: A Concern on Underlying Illness.

Editorial Comment: Cardiac MRI as a Fundamental Tool in the Evaluation of Suspected Myocarditis After COVID-19 mRNA Vaccination in Young Patients.

Relapsed ANCA associated vasculitis following Oxford AstraZeneca ChAdOx1-S COVID-19 vaccination: A case series of two patients.

Severe immune thrombocytopenic purpura after SARS-CoV-2 vaccine. Immune thrombocytopenic purpura (ITP) is a rare hematologic condition through to affect 3.3 in 100,000

adults per year in the United States. Many cases of immune thrombocytopenia are diagnosed incidentally with laboratory tests that reveal low platelet count, without a clear cause. However, when platelet counts are very low, patients may show signs of bleeding. Here we present the case of a 24-year-old female with mucocutaneous bleeding ten days after receiving her first dose of SARS-CoV-2 vaccine, who was subsequently found to have severe thrombocytopenia. Extensive work up for new thrombocytopenia was unremarkable suggesting a diagnosis of ITP, potentially secondary to vaccination. Empiric treatment with glucocorticoids was initiated without response prompting the use of intravenous immunoglobulin G. The patient was discharged on hospital day five with a platelet count over 20,000 platelets per microliter. In summary, ITP is a potential sequela of the SARS-CoV-2 vaccine, and otherwise healthy young individuals may be at risk for hematologic side effects.

The RECOVAC Immune-response Study: The Immunogenicity, Tolerability, and Safety of COVID-19 Vaccination in Patients With Chronic Kidney Disease, on Dialysis, or Living With a Kidney Transplant. BACKGROUND: In kidney patients COVID-19 is associated with severely increased morbidity and mortality. A comprehensive comparison of the immunogenicity, tolerability, and safety of COVID-19 vaccination in different cohorts of kidney patients and a control cohort is lacking. METHODS: This investigator driven, prospective, controlled multicenter study included 162 participants with chronic kidney disease (CKD) stages G4/5 (eGFR < 30â€‰mL/min/1.73m2), 159 participants on dialysis, 288 kidney transplant recipients, and 191 controls. Participants received 2 doses of the mRNA-1273 COVID-19 vaccine (Moderna). The primary endpoint was seroconversion. RESULTS: Transplant recipients had a significantly lower seroconversion rate when compared with controls (56.9% versus 100%, Pâ€‰<â€‰0.001), with especially mycophenolic acid, but also, higher age, lower lymphocyte concentration, lower eGFR, and shorter time after transplantation being associated with nonresponder state. Transplant recipients also showed significantly lower titers of neutralizing antibodies and T-cell responses when compared with controls. Although a high seroconversion rate was observed for participants with CKD G4/5 (100%) and on dialysis (99.4%), mean antibody concentrations in the CKD G4/5 cohort and dialysis cohort were lower than in controls (2405 [interquartile interval 1287-4524] and 1650 [698-3024] versus 3186 [1896-4911] BAU/mL, Pâ€‰=â€‰0.06 and Pâ€‰<â€‰0.001, respectively). Dialysis patients and especially kidney transplant recipients experienced less systemic vaccination related adverse events. No specific safety issues were noted. CONCLUSIONS: The immune response following vaccination in patients with CKD G4/5 and on dialysis is almost comparable to controls. In contrast, kidney transplant recipients have a poor response. In this latter, patient group development of alternative vaccination strategies are warranted.

COVID-19 Vaccination Reactogenicity in Persons With Multiple Sclerosis. BACKGROUND AND OBJECTIVES: There are limited data on severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine reactogenicity in persons with multiple sclerosis (PwMS) and how reactogenicity is affected by disease-modifying therapies (DMTs). The objective of this retrospective cross-sectional study was to generate real-world multiple sclerosis-specific vaccine safety information, particularly in the context of specific DMTs, and provide information to mitigate specific concerns in vaccine hesitant PwMS. METHODS: Between 3/2021 and 6/2021, participants in iConquerMS, an online people-powered research network, reported SARS-CoV-2 vaccines, experiences of local (itch, pain, redness, swelling, or warmth at injection site) and systemic (fever, chills, fatigue, headache, joint pain, malaise, muscle ache, nausea, allergic, and other) reactions within 24 hours (none, mild, moderate, and severe), DMT use, and other attributes. Multivariable models characterized associations between clinical factors and reactogenicity. RESULTS: In 719 PwMS, 64% reported experiencing a reaction after their first vaccination shot, and 17% reported a severe reaction. The most common reactions were pain at injection site (54%), fatigue (34%), headache (28%), and malaise (21%). Younger age, being

female, prior SARS-CoV-2 infection, and receiving the ChAdOx1 nCoV-19 (Oxford-AstraZeneca) vs BNT162b2 (Pfizer-BioNTech) vaccine were associated with experiencing a reaction after the first vaccine dose. Similar relationships were observed for a severe reaction, including higher odds of reactions among PwMS with more physical impairment and lower odds of reactions for PwMS on an alpha4-integrin blocker or sphingosine-1-phosphate receptor modulator. In 442 PwMS who received their second vaccination shot, 74% reported experiencing a reaction, whereas 22% reported a severe reaction. Reaction profiles after the second shot were similar to those reported after the first shot. Younger PwMS and those who received the mRNA-1273 (Moderna) vs BNT162b2 vaccine reported higher reactogenicity after the second shot, whereas those on a sphingosine-1-phosphate receptor modulator or fumarate were significantly less likely to report a reaction. DISCUSSION: SARS-CoV-2 vaccine reactogenicity profiles and the associated factors in this convenience sample of PwMS appear similar to those reported in the general population. PwMS on specific DMTs were less likely to report vaccine reactions. Overall, the short-term vaccine reactions experienced in the study population were mostly self-limiting, including pain at the injection site, fatigue, headache, and fever.
COVID-19 vaccine-associated subacute thyroiditis: an unusual suspect for de Quervain's thyroiditis. Subacute thyroiditis following vaccination is an uncommon presentation of thyrotoxicosis. As the world undertakes its largest immunisation campaign to date in an attempt to protect the population from COVID-19 infections, an increasing number of rare post vaccine side effects are being observed. We report a case of a middle-aged woman who presented with painful thyroid swelling following the second dose of the COVID-19 mRNA vaccine BNT162b2 (Pfizer-BioNTech) with clinical, biochemical and imaging features consistent with destructive thyrotoxicosis. Symptomatic management only was required for the self-limiting episode. Thyroiditis typically has a mild and self-limiting course and thus this observation should not deter people from vaccination, as COVID-19 infection has a far greater morbidity and mortality risk than thyroiditis.
Similar humoral immune responses in peritoneal dialysis and haemodialysis patients after two doses of the SARS-CoV-2 vaccine BNT162b2.
Eosinophilic dermatosis after AstraZeneca COVID-19 vaccination.
Response to Letter to the Editor From Raven: Three Cases of Subacute Thyroiditis Following SARS-CoV-2 Vaccine.
Letter to the Editor From Raven et al: "Three Cases of Subacute Thyroiditis Following SARS-CoV-2 Vaccine".
Lymphomatoid drug reaction developed after BNT162b2 (Comirnaty) COVID-19 vaccine manifesting as pityriasis lichenoides et varioliformis acuta-like eruption.
A case of toxic epidermal necrolysis after ChAdOx1 nCov-19 (AZD1222) vaccination.
mRNA Vaccines Induce Rapid Antibody Responses in Mice. mRNA vaccines can be developed and produced quickly, making them attractive for immediate outbreak responses. Furthermore, clinical trials have demonstrated rapid protection following mRNA vaccination. We sought to investigate how quickly mRNA vaccines elicit antibody responses compared to other vaccine modalities. We first examined immune kinetics of mRNA and DNA vaccines expressing SARS-CoV-2 spike in mice. We observed rapid induction of antigen-specific binding and neutralizing antibodies by day 5 following mRNA, but not DNA, immunization. The mRNA vaccine also induced increased levels of IL-5, IL-6 and MCP-1. We then evaluated immune kinetics of an HIV-1 mRNA vaccine in comparison to DNA, protein, and rhesus adenovirus 52 (RhAd52) vaccines with the same HIV-1 envelope antigen in mice. Induction of envelope-specific antibodies was observed by day 5 following mRNA vaccination, whereas antibodies were detected by day 7-14 following DNA, protein, and RhAd52 vaccination. Eliciting rapid humoral immunity may be an advantageous property of mRNA vaccines for controlling infectious disease outbreaks. IMPORTANCE: mRNA vaccines can be developed and produced in

record time. Here we demonstrate induction of rapid antibody responses by mRNA vaccines encoding two different viral antigens by day 5 following immunization in mice. The rapid immune kinetics of mRNA vaccines can be an advantageous property that makes them well suited for rapid control of infectious disease outbreaks.

Association between vaccination with the BNT162b2 mRNA COVID-19 vaccine and Bell's palsy: a population-based study. BACKGROUND: An excess risk of Bell's palsy has been suggested after mRNA vaccines. We examined the association between the BNT162b2 mRNA COVID-19 vaccine and Bell's palsy. METHODS: Using the database of the largest healthcare provider in Israel, we retrieved data from different periods in 2018-2021. Observed cases of Bell's palsy occurring within 21-days after the first vaccine dose and within 30-days after the second vaccine dose were compared to the expected cases, based on the experience of the population in 2019. Standardized incidence ratios (SIRs) and attributable risks (ARs) were computed. FINDINGS: Overall, 132 cases of Bell's palsy were reported in 2,594,990 vaccinees with the first dose, and 152 cases in 2,434,674 vaccinees after the second dose. The age and sex weighted SIRs were 1.36(95% CI, 1.14-1.61) and 1.16(0.99-1.36) after the first and second vaccine dose, respectively. SIRs tended to be higher in older age groups after the first and second vaccine doses. The estimates were more pronounced in older females after the first vaccine dose; SIR=1.71(1.10-2.54) at age 45-64, and 2.51(1.65-3.68) at age â‰¥65 years. The highest AR was 4.46 per 100,000 vaccinees detected in females aged â‰¥65 years. In patients with previous history of Bell's palsy, only 4 cases of Bell's palsy were reported in 7,567 vaccinees and 10 cases in 7,045 vaccinees after the first and the second dose, respectively. The age and sex weighted SIRs were 1.15(0.36-2.76) and 2.15(1.09-3.83) after the first and second vaccine dose, respectively. INTERPRETATION: This study suggests that the BNT162b2 mRNA COVID-19 vaccine might be associated with increased risk of Bell's palsy. The small estimated attributable risks suggest that the impact on public health is relatively minor. The benefits of vaccinations explicitly outweigh the possible link to Bell's palsy that has high recovery rate if timely treated with corticosteroids. FUNDING: No external funding was available for this study.

[Association between influenza vaccination and mortality due to COVID-19]. BACKGROUND: It has recently been suggested that influenza vaccination may be a factor associated with decreased COVID-19 mortality. METHODS: An age-matched case-control study based on hospital cases. We included subjects aged 18 years and older with a diagnosis of moderate to severe COVID-19. Infection was corroborated by RT-PCR test for SARS-COV-2. Deceased subjects were considered cases, controls were patients discharged due to improvement of acute symptoms. We used bivariate analysis to determine factors associated with death from COVID-19, and calculated odds ratios and 95% confidence intervals. RESULTS: A total of 560 patients were included in the study, 214 (38.2%) were considered cases and 346 (61.7%) controls. A significant difference was observed with the presence of type 2 diabetes mellitus [54% vs. 39.3% between cases and controls, respectively (p=.04)] and having received influenza vaccination (p= .02). Type 2 diabetes mellitus was associated with higher COVID-19 mortality [OR 1.8 (95% CI 1.2-2.5) p=.01], whereas having been immunised against influenza in 2019 was associated with lower mortality in this group of patients [OR .6 (95% CI .4-.9) p=.02]. CONCLUSIONS: Influenza vaccination in the previous year appears to be associated with lower mortality from COVID-19; whereas type 2 diabetes mellitus is confirmed as a condition associated with higher mortality.

A Case Report of Immune Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination. Immune thrombocytopenia (ITP) is an autoimmune condition characterized by platelet destruction through antibody-mediated mechanism. ITP is one of the manifestations of a coronavirus disease, as well as an adverse event occurring after vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Several cases of ITP have been described after vaccination with two mRNA-based

vaccines-BTN162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna)-against SARS-CoV-2. Herein, we report a case of ITP occurring after vaccination with ChAdOx1 adenovirus vector nCoV-19 (AstraZeneca) vaccine in Korea. A 66-year-old woman presented with multiple ecchymoses on both upper and lower extremities and gingival bleeding, appearing 3 days after receiving the first dose of ChAdOx1 nCoV-19. Her laboratory results showed isolated severe thrombocytopenia without evidence of combined coagulopathy. She was diagnosed with ITP and successfully treated with high-dose dexamethasone and intravenous immunoglobulin. Clinical suspicion to identify vaccine-related ITP is important to promptly initiate appropriate treatment.

"Covid arm": Abnormal side effect after Moderna COVID-19 vaccine.

Neurological side effects of SARS-CoV-2 vaccinations. SARS-CoV-2 and adverse reactions to SARS-CoV-2 vaccinations show a tropism for neuronal structures and tissues. This narrative review was conducted to collect and discuss published data about neurological side effects of SARS-CoV-2 vaccines in order to discover type, frequency, treatment, and outcome of these side effects. The most frequent neurological side effects of SARS-CoV-2 vaccines are headache, Guillain-Barre syndrome (GBS), venous sinus thrombosis (VST), and transverse myelitis. Other neurological side effects occur in a much lower frequency. Neurological side effects occur with any of the approved vaccines but VST particularly occurs after vaccination with vector-based vaccines. Treatment of these side effects is not at variance from similar conditions due to other causes. The worst outcome of these side effects is associated with VST, why it should not be missed and treated appropriately in due time. In conclusion, safety concerns against SARS-CoV-2 vaccines are backed by an increasing number of studies reporting neurological side effects. The most frequent of them are headache, GBS, VST, and transverse myelitis. Healthcare professionals, particularly neurologists involved in the management of patients having undergone SARS-CoV-2 vaccinations, should be aware of these side effects and should stay vigilant to recognize them early and treat them adequately.

How protein-based COVID vaccines could change the pandemic.

SARS-CoV-2 mRNA vaccine BNT162b2 triggers a consistent cross-variant humoral and cellular response. As the SARS-CoV-2 pandemic continues to rage worldwide, the emergence of numerous variants of concern (VOC) represents a challenge for the vaccinal protective efficacy and the reliability of commercially available high-throughput immunoassays. Our study demonstrates the administration of two doses of the BNT162b2 vaccine that elicited a robust SARS-CoV-2-specific immune response which was assessed up to 3 months after full vaccination in a cohort of 37 health care workers (HCWs). SARS-CoV-2-specific antibody response, evaluated by four commercially available chemiluminescence immunoassays (CLIA), was qualitatively consistent with the results provided by the gold-standard in vitro neutralization assay (NTA). However, we could not observe a correlation between the quantity of the antibody detected by CLIA assays and their neutralizing activity tested by NTA. Almost all subjects developed a SARS-CoV-2-specific T-cell response. Moreover, vaccinated HCWs developed a similar protective neutralizing antibodies response against the EU (B.1), Alpha (B.1.1.7), Gamma (P.1), and Eta (B.1.525) SARS-CoV-2 variants, while Beta (B.1.351) and Delta (B.1.617.2) strains displayed a consistent partial immune evasion. These results underline the importance of a solid vaccine-elicited immune response and a robust antibody titre. We believe that these relevant results should be taken into consideration in the definition of future vaccinal strategies.

Acute pericarditis and cardiac tamponade after Covid-19 vaccination.

INACTIVATED COVID-19 VACCINE CAN INDUCE REACTIVE POLYARTHRITIS IN OLDER PATIENTS: REPORT OF TWO CASES. Reactive arthritis is an acute, sterile, non-suppurative and inflammatory arthropathy that usually follows infection process. Gastrointestinal, genitourinary and respiratory tract infections generally provoke reactive arthritis. Also, reactive arthritis can be seen after

vaccination. Reactive arthritis cases have been reportedÂ after tetanus, combined diphteria-poliomyelitis-tetanus toxoid, hepatitis B or influenza vaccination. Although reactive arthritis is more common in youngs, healthcare workers should be aware of the development of post inactivated COVID-19 vaccine reactive arthritis in older patients. We present two cases with ReA induced by inactivated coronavirus 2019 (COVID-19) vaccination (CoronaVac, Sinovac). Both patients in our study were over 70 years old and presented with polyarthritis that developed after vaccination. Rheumatoid factor and anti-nucleer antibody were negative and patients responded well to short-term steroid therapy, arthritis were not resistant.

Phenotypic spectrum of serious cutaneous-only adverse event following immunization with COVID-19 vaccines: a multicentre case series and literature review.

The mRNA COVID-19 vaccine in patients with cancer receiving checkpointÂ inhibitorÂ therapy: what we know and what we don't.

(68)Ga-DOTATOC digital-PET imaging of inflammatory cell infiltrates in myocarditis following COVID-19 vaccination.

Lymphadenopathy after the third Covid-19 vaccine. Axillary lymphadenopathy ipsilateral to the vaccination site has been clinically and radiologically reported after administration of COVID-19 vaccines. This can be an important diagnostic dilemma, particularly in cancer patients who are being staged or re-staged, as this benign entity may mimic metastasis, cause unnecessary biopsies and changes in therapy. Here we present a breast cancer patient and a patient with squamous cell carcinoma of the head and neck, who had already received the first two doses of mRNA type COVID-19 vaccines before, now presenting with new hypermetabolic reactive lymphadenopathy on FDG PET/CT after the third booster dose.

The Pfizer-BNT162b2 mRNA-based vaccine against SARS-CoV-2 may be responsible for awakening the latency of herpes varicella-zoster virus. BACKGROUND: To prevent the invasion and transmission of SARS-CoV-2, mRNA-based vaccines, non-replicating viral vector vaccines, and inactivated vaccines have been developed. The European Medicines Agency (EMA) authorized the use of the anti-SARS-CoV-2 vaccine in January 2021, the date on which the vaccination program began in Spain and across Europe. The aim of this study is to monitor the safety of anti-SARS-CoV-2 vaccines and report any cases of undesirable effects that have occurred, that are not included in the health profile of mRNA-based vaccines for commercialisation in humans. Furthermore, a brief review is given of the mechanism of action of the anti-SARS-CoV-2 vaccine on the host's immune system in triggering the reactivation of the herpes varicella-zoster infection. METHODS: Follow-up of patients under the care of the southern health district of Seville of the SAS (Andalusian Health Service) during the Spanish state of alarm over the COVID-19 pandemic. RESULTS: Two patients, a 79-year-old man and a 56-year-old woman, are reported who, after 4 and 16 days respectively of receiving the Pfizer-BNT162b2 vaccine against SARS-CoV-2, presented a state of reactivation of herpes varicella-zoster virus (VZV). DISCUSSION: The immunosenescence of the reported patients, together with the immunomodulation generated by administering the anti-SARS-CoV-2 vaccines, that depress certain cell subpopulations, could explain the awakening of VZV latency.

Serious complications of COVID-19 vaccines: A mini-review. Îthe most promising approach of fighting COVID-19 and restraining the course of this pandemic is indisputably the universal vaccination of the population with safe and effective vaccines. However, besides the common and usually mild side effects of the authorized vaccines, some rare, major adverse reactions are increasingly being reported worldwide during the post marketing surveillance phase of vaccines' circulation, such as anaphylaxis, vaccine-induced thrombotic thrombocytopenia, myopericarditis and Guillain-BarrÃ© syndrome. Despite rare cases with complications from COVID-19 vaccines, the net benefit-risk ratio shows a clearly favorable balance towards COVID-19 vaccination for all age and sex

groups. Vaccine adverse events should be identified early and monitored closely. As many aspects of these adverse effects remain still obscure for the medical community and the relevant stakeholders, it is also highly important to be promptly reported. Nonetheless, these complications should not constitute a reason to change the vaccine policy and further studies are needed to alleviate concerns and reluctance to COVID-19 vaccinations.

Concurrent Antiglomerular Basement Membrane Nephritis and Antineutrophil Cytoplasmic Autoantibody-Mediated Glomerulonephritis After Second Dose of SARS-CoV-2 mRNA Vaccination.

European stroke organization interim expert opinion on cerebral venous thrombosis occurring after SARS-CoV-2 vaccination. Severe cases of cerebral venous thrombosis (CVT) with thrombocytopenia and anti-platelet factor 4 (PF4) antibodies occurring after adenoviral vector anti-SARS-CoV-2 vaccines have been recently reported. We aim to present a guidance document on the diagnosis and treatment of patients presenting with CVT after vaccination against SARS-CoV-2 infection. We reviewed the available evidence which consists on case reports, small case series, expert opinion and analogy with heparin-induced thrombocytopenia (HIT) management. Because of the low level of evidence, this is an interim document, based only on expert opinion consensus. In patients presenting with CVT after being vaccinated against SARS-CoV-2 infection, if there is thrombocytopenia a reliable HIT PF4 Antibody ELISA test should be performed, to confirm vaccine-induced immune thrombotic thrombocytopenia (VITT). In patients with CVT and thrombocytopenia, in whom VITT is suspected or confirmed, heparin (unfractionated or low molecular weight) should be avoided and non-heparin anticoagulants are preferred. If possible, platelet transfusions should be avoided. If the diagnosis of VITT is confirmed or suspected, early intravenous immunoglobulins are indicated. This expert opinion is supported by low quality evidence. It should be periodically updated, or changed to a formal guideline, as new and higher quality evidence is eventually produced. Because of their potential unfavourable clinical course, patients developing symptoms and signs suggestive of CVT after being vaccinated against SARS-CoV-2 virus should undergo urgent clinical and neuroimaging evaluation. In cases of suspected or confirmed VITT, non-heparin anticoagulants should be used, platelet transfusions avoided and intravenous immunoglobulin started early.

Possible HSP reactivation post-COVID-19 vaccination and booster. A 45-year-old woman with a history of Henoch-SchÃ¶nlein (HSP) purpura received COVID-19 vaccination. The patient showed HSP reactivation after COVID-19 vaccination and booster. In HSP, autoimmune memory of vasculitis persists and might be reactivated with COVID-19 vaccination.

Vaccine-Associated Disease Enhancement (VADE): Considerations in Postvaccination COVID-19. INTRODUCTION: The COVID-19 pandemic has entered a new phase with the roll-out of several vaccines worldwide at an accelerated phase. The occurrence of a more severe presentation of COVID-19 after vaccination may affect policymakers' decision-making and vaccine uptake by the public. Vaccine-associated disease enhancement (VADE) is the modified presentation of infections in individuals after having received a prior vaccination. Currently, little is known about the potential of vaccine-associated disease enhancement (VADE) following COVID-19 immunization. Case Illustration. We herewith report two patients admitted with confirmed COVID-19 pneumonia with a history of CoronaVac vaccination. The first patient with a relatively milder course of the disease had received two doses of CoronaVac, whereas the second patient with a more progressive course of the disease received only one dose before developing symptoms and being admitted to the hospital. Our observations suggest that vaccination could act in boosting the inflammatory process and reveal the previously asymptomatic COVID-19 illness. Theoretically, vaccines could induce VADE, where only suboptimal, nonprotective titers of neutralizing antibodies were produced or proinflammatory T-helper type 2 response was induced. Secondly, enhanced respiratory disease (ERD) could manifest, where pulmonary symptoms are more severe due to peribronchial monocytic and eosinophilic

infiltration. Understanding VADE is important for the decision-making by the public, clinicians, and policymakers and is warranted for successful vaccination uptake. CONCLUSION: We report two cases of patients developing COVID-19 shortly after CoronaVac vaccination in which VADE is likely. We recommend that current vaccination strategies consider the measurement of neutralizing antibody titer as a guide in ensuring the safest strategy for mass immunization. Studies are needed to investigate the true incidence of VADE on vaccinated individuals as well as on how to differentiate between VADE and severe manifestations of COVID-19 that are unrelated to vaccination.

Complex Pathophysiological Mechanisms and the Propose of the Three-Dimensional Schedule For Future COVID-19 Treatment. At present, the global COVID-19 epidemic is still in a state of anxiety, and increasing the cure rate of critically ill patients is an important means to defeat the virus. From an immune perspective, ARDS driven by an inflammatory storm is still the direct cause of death in severe COVID-19 patients. Although some experience has been gained in the treatment of COVID-19, and intensive COVID-19 vaccination has been carried out recently, it is still effective to save lives to develop more effective programs to alleviate the inflammatory storm and ARDS in patients with SARS-CoV-2 or emerging variants of SARS-CoV-2. In reorganizing the ARDS-related inflammatory storm formation program in COVID-19 patients, we highlighted the importance of the vicious circle of inflammatory cytokines and inflammatory cell death, which is aggravated by blood circulation to form multi-system inflammation. Summarizes the interlocking and crisscrossing of inflammatory response and inflammatory cell death mechanisms including NETs, pyrolysis, apoptosis and PANoptosis in severe COVID-19. More importantly, in response to the inflammatory storm formation program we described, and on the premise of following ethical and clinical experimental norms, we propose a three-dimensional integrated program for future research based on boosting antiviral immune response at the initial stage, inhibiting inflammatory cytokine signaling at the exacerbation stage and inhibiting cell death before it's worse to prevent and alleviate ARDS.

Case Report: Multiple Sclerosis Relapses After Vaccination Against SARS-CoV2: A Series of Clinical Cases. Objective: To describe a temporal association between COVID-19 vaccine administration and multiple sclerosis (MS) relapses. Methods: This case series study was collected in four MS Centres in Central Italy, using data from 16 MS patients who received COVID-19 vaccination and presented both clinically and radiologically confirmed relapses between March and June 2021. We collected patients' relevant medical history, including demographics, MS clinical course, disease-modifying treatment (DMT) received (if applicable), and data from MRI scans obtained after the COVID-19 vaccination. Results: Three out of 16 patients received a diagnosis of MS with a first episode occurring after COVID-19 vaccination; 13 had already a diagnosis of MS and, among them, 9 were on treatment with DMTs. Ten patients received BNT162b2/Pfizer-BioNTech, 2 patients mRNA-1273/Moderna, and 4 patients ChAdOx1 nCoV-19/AstraZeneca. All MS relapses occurred from 3 days to 3 weeks after receiving the first dose of the COVID-19 vaccination or the booster. All patients had evidence of radiological activity on MRI. Discussion: Clinical and radiological findings in these cohort of MS patients confirmed disease re/activation and suggested a temporal association between disease activity and COVID-19 vaccination. The nature of this temporal association, whether causative or incidental, remains to be established.

Young Male With Myocarditis Following mRNA-1273 Vaccination Against Coronavirus Disease-2019 (COVID-19).

A neurologist's rhombencephalitis after comirnaty vaccination. A change of perspective. Rhombencephalitis is an orphan disease of multiple causes that may manifest with facial palsy, limb ataxia and reduced consciousness. Up to now it is described after COVID-19 infection and in this (personal) case was found up to 8Â weeks after Comirnaty vaccination. So far, we do not fully understand the pathophysiological characteristics of encephalitis associated with SARS-CoV-2. In rare

cases, vaccination may cause an immunological reaction and delayed inflammation, the consequences of which we have not yet deciphered. Rhombencephalitis should be considered as a rare potential mRNA-associated vaccination side effect.

Acute Corneal Epithelial Rejection of LR-CLAL After SARS-CoV-2 Vaccination. PURPOSE: The purpose of this study was to report a case of acute corneal epithelial rejection of living-related conjunctival limbal allograft (LR-CLAL) after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. OBSERVATIONS: A 27-year-old woman developed acute epithelial rejection of LR-CLAL 2 weeks after receiving the SARS-CoV-2 vaccine. She received the LR-CLAL transplant 4 years and 7 months previously and had a stable clinical course with no history of rejection. She had an ABO blood group and human leukocyte antigen compatible donor, no systemic comorbidities, and no rejection risk factors. CONCLUSIONS: The novel SARS-CoV-2 vaccine upregulates the immune system to produce an adaptive immune response. The SARS-CoV-2 vaccine may potentially be associated with increased risk of rejection in those with ocular surface transplants.

Predictors of poor seroconversion and adverse events to SARS-CoV-2 mRNA BNT162b2 vaccine in cancer patients on active treatment. PURPOSE: Initial findings in patients with cancer suggest a lower seroconversion to SARS-CoV-2 vaccination possibly related to myelo-immunosuppressive therapies. We conducted a prospective study to assess factors predicting poor seroconversion and adverse events following immunisation (AEFI) to the BNT162b2 vaccine in patients on active treatment. PATIENTS AND METHODS: Cancer patients, candidates to two doses of BNT162b2 SARS-CoV-2 vaccination, were enrolled. Patients on active surveillance served as controls. The primary endpoint was poor seroconversion (anti S1/S2 IgGÂ <Â 25Â AU/mL) after 21 days from the second dose. RESULTS: Between March and July 2021, 320 subjects were recruited, and 291 were assessable. The lack of seroconversion at 21 days from the second dose was 1.6% (95% CI, 0.4-8.7) on active surveillance, 13.9% (8.2-21.6) on chemotherapy, 11.4% (5.1-21.3) on hormone therapy, 21.7% (7.5-43.7) on targeted therapy and 4.8% (0.12-23.8) on immune-checkpoint-inhibitors (ICI). Compared to controls, the risk of no IgG response was greater for chemotherapy (pÂ =Â 0.033), targeted therapy (0.005) and hormonotherapy (pÂ =Â 0.051). Lymphocyte countÂ <Â 1Â Ã—Â 10(9)/L (pÂ =Â 0.04) and older age (pÂ =Â 0.03) also significantly predicted poor seroconversion. Overall, 43 patients (14.8%) complained of AEFI, mostly of mild grade. Risk of AEFI was greater in females (pÂ =Â 0.001) and younger patients (pÂ =Â 0.009). CONCLUSION: Chemotherapy, targeted therapy, hormone therapy, lymphocyte countÂ <Â 1Â Ã—Â 10(9)/L, and increasing age predict poor seroconversion after two doses of BNT162b2 in up to 20% of patients, indicating the need for a third dose and long-term serological testing in non-responders. AEFI occur much more frequently in women and younger subjects who may benefit from preventive medications. CLINICALTRIALS. GOV IDENTIFIER: NCT04932863.

Recurrence of alopecia areata after covid-19 vaccination: A report of three cases in Italy. BACKGROUND: Common COVID-19 vaccines side effects are pain at the injection site, muscle pain, fever, headaches, fatigue. Possible immune-related side effects in predisposed individuals have not been established so far. MATERIALS AND METHODS: We report three cases of recurrence of alopecia areata (AA) occurred after the first dose of COVID-19 vaccine. RESULTS: All patients had previous episodes of AA with total hair regrowth and stable remission during the months preceding the vaccination. Rapid hair loss occurred 2-3 weeks after BNT162b2 mRNA (patient 1) and AZD1222/ChAdOx1 vaccine (patient 2 and 3), with widespread hair loss in two cases and a single patch of the vertex in one case, with typical trichoscopic features of AA. DISCUSSION: Both BNT162b2 mRNA and AZD1222/ChAdOx1 vaccines share the same goal of inducing the immune system, with antibodies production and Th1 cells activation with release of pro-inflammatory cytokines. Thus, in patients with pre-existing inflammatory dysregulated pathways, the interaction between the immune

system and vaccines may enhance other autoimmune mechanisms. In our cases, we speculate that vaccine may have induced the hair loss focusing on components having a key role in both COVID-19 vaccination and AA pathogenesis. CONCLUSION: This report may help to collect new data concerning possible immune-related effects of vaccines. Certainly, only three cases are not sufficient to draw conclusion, thus a large-scale study is necessary. Immune-mediated side effects remain a rare event, thus the benefits of COVID-19 vaccines outweigh the risk of disease flares and we strongly recommend it in all eligible patients with AA.

Immune mediated events timely associated with COVID-19 vaccine. A comment on article by Badier, et al.: "IgA vasculitis in adult patients following vaccination by ChadOx1 nCoV-19".

Acute Myocarditis after COVID-19 vaccination: A case report. INTRODUCTION: The etiology of myocarditis often remains undetermined. A large variety of infectious agents, systemic diseases, drugs, and toxins can cause the disease. We report the case of a 19-year-old man who developed myocarditis three days after Pfizer-BioNTech COVID-19 booster vaccination. CASE REPORT: A 19-year-old man, presenting with troponin-positive acute chest pain, was referred to our department. He had received the Pfizer-BioNTech COVID-19 vaccine three days prior to his admission. The diagnosis of acute myocarditis was confirmed by cardiovascular magnetic resonance imaging. Patient hemodynamic status remained stable during hospitalization. The left ventricular ejection fraction was preserved during hospital stay and at one-month follow-up. We found no evidence for another infectious or autoimmune etiology. CONCLUSION: Although imputability of the vaccine cannot be formally established on the basis of this case report, the findings raise the possibility of an association between mRNA COVID-19 vaccination and acute myocarditis.

Brain venography performance following the pause of Ad.26.COV2.S COVID-19 vaccine administration. Cases of cerebral venous thrombosis (CVT) associated with vaccine induced thrombotic thrombocytopenia (VITT) were reported following administration of the adenoviral vector COVID-19 vaccines, resulting in a pause in Ad.26.COV2.S vaccine administration in the United States, beginning on April 14, 2021. We aimed to quantify and characterize an anticipated increase in brain venograms performed in response to this pause. Brain venogram cases were retrospectively identified during the three-week period following the vaccine pause and during the same calendar period in 2019. For venograms performed in 2021, we compared COVID vaccinated to unvaccinated patients. There was a 262% increase in venograms performed between 2019 (nâ€‰=â€‰26) and 2021 (nâ€‰=â€‰94), compared to only a 19% increase in all radiologic studies. Fifty-seven percent of patients in 2021 had a history of COVID-19 vaccination, with the majority being Ad.26.COV2.S. All patients diagnosed with CVT were unvaccinated. COVID vaccinated patients lacked platelet or D-dimer measurements consistent with VITT. Significantly more vaccinated versus unvaccinated patients had a headache (94% vs 70%, pâ€‰=â€‰0.0014), but otherwise lacked compelling CVT presentations, such as decreased/altered consciousness (7% vs 23%, pâ€‰=â€‰0.036), neurologic deficit (28% vs 48%, pâ€‰=â€‰0.049), and current/recent pregnancy (2% vs 28%, pâ€‰=â€‰0.0003). We found a dramatic increase in brain venograms performed following publicity of rare COVID-19 vaccine associated CVT cases, with no CVTs identified in vaccinated patients. Clinicians should carefully consider if brain venogram performance is indicated in COVID-19 vaccinated patients lacking thrombocytopenia and D-dimer elevation, especially without other compelling CVT risk factors or symptoms.

Safety surveillance after BNT162b2 mRNA COVID-19 vaccination: results from a cross-sectional survey among staff of a large Italian teaching hospital. BACKGROUND AND AIM: ComirnatyÂ® was the first COVID-19 vaccine available for the vaccination campaign of healthcare workers in Italy. With the aim of assessing vaccine safety, we conducted a cross-sectional survey administrating a voluntary-based questionnaire on adverse events following immunisation (AEFIs) in San Raffaele Hospital,

Milano, Italy. METHODS: From 4th January 2021 to 27th April 2021, we collected 2,659 questionnaires (response rate: 24,5%). We analyzed data, reporting AEFIs by gender, age, self-reported severity, type, time of insurgence and duration, and estimating relative-risk ratios (RRR) and corresponding 95% confidence intervals (CI). RESULTS: The most reported symptoms were injection site pain, fatigue, headache, myalgia, chills, fever, and arthralgia. Severe systemic reactions were more frequent after receiving the second dose (RRR 6.25, 95% CI 4.57-8.55), in women (RRR 3.33, 95% CI 2.30-4.82), and less frequent in individuals aged 60 or more (RRR 0.26, 95% CI 0.14-0.49). In addition, we noted a wide range of adverse events of special interest (AESIs). CONCLUSIONS: Consistently with clinical trials and pharmacovigilance surveillance, AEFIs were frequent, but severe ones were uncommon, supporting the massive implementation of the COVID-19 vaccination campaign and providing valuable data for a risk profiling of vaccinees. (www.actabiomedica.it).

Immediate adverse events following COVID-19 immunization. A cross-sectional study of 314,664 Italian subjects. BACKGROUND AND AIM: The urgency of having rapidly safe and efficient COVID-19 vaccines called for the need to shorten trial phases, reduce sample sizes, and speed-up the approval process by the regulatory Agencies. In light of this, monitoring adverse effects (AEFI) (both immediate and at medium-long term) become of great importance. Aim of this cross-sectional study was to explore the associations between several factors and risk of immediate AEFI. METHODS: Data come from the electronic dataset developed ad hoc to record demographic data, anamnesis and data related to immunization, set-up in the mass vaccination site in Novegro (Milan). Novegro mass vaccination site was one of the mass vaccinations sites with the highest flow in Lombardy Region, with a maximum capacity of 5,000 vaccinations/day. The center opened in April 2021 and closed the 1st of August 2021. A multivariable logistic regression model was used. Odds ratios adjusted (aOR) for age and sex are presented. Statistical significance was set at $p<0.05$. Analyses were conducting using STATA. RESULTS: Among the total of 314,671 subjects vaccinated, 0.5% developed an immediate AEFI, on average 17.0 Â± 0.43 minutes after the administration. The three most frequent AEFI recorded were vagal response (30%), anxiety reaction (24%) and dizziness (21%). AEFI were more frequently observed among women [aOR= 2.24 (95%CI= 2.00 - 2.50)], and those with at least one previous disease [aOR= 1.47 (95%CI= 1.22-1.76)]. CONCLUSIONS: In conclusion, AEFI were less likely to occur for increasing age and after the second dose. Results from this large, complete and representative sample population regarding enrich the interesting scientific debate on potential adverse events following COVID-19 immunization.

Radiation Recall Pneumonitis on FDG PET/CT Triggered by COVID-19 Vaccination. A 67-year-old man with metastatic lung adenocarcinoma was initially treated with whole-brain radiotherapy for intracranial metastases, followed by chemotherapy and pembrolizumab. After completing 2 years of systemic therapy, the primary right lung lesion was biopsy-proven to have residual adenocarcinoma, which was then treated with radiation (6000 cGy in 15 fractions). Follow-up serial FDG PET/CT showed radiation fibrosis. Eighteen months after radiotherapy, the patient received 2 doses of an mRNA COVID-19 vaccine. FDG PET/CT performed 4 days following his second vaccine dose showed FDG-avid multistation lymphadenopathy and radiation recall pneumonitis, likely vaccination-induced and mimicking recurrent disease. This resolved spontaneously without therapy.

Severe Acute Respiratory Syndrome Coronavirus 2 Infection Induces Greater T-Cell Responses Compared to Vaccination in Solid Organ Transplant Recipients. T-cell immunity associated with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection or vaccination in solid organ transplant recipients (SOTRs) is poorly understood. To address this, we measured T-cell responses in 50 SOTRs with prior SARS-CoV-2 infection. The majority of patients mounted SARS-CoV-2-specific CD4+ T-cell responses against spike (S), nucleocapsid, and membrane proteins; CD8+ T-cell responses were generated to a lesser extent. CD4+ T-cell responses correlated with antibody levels. Severity of

disease and mycophenolate dose were moderately associated with lower proportions of antigen-specific T cells. Relative to nontransplant controls, SOTRs had perturbations in both total and antigen-specific T cells, including higher frequencies of total PD-1+â€‰CD4+ T cells. Vaccinated SOTRs (nâ€…=â€…55) mounted significantly lower proportions of S-specific polyfunctional CD4+ T cells after 2 doses, relative to unvaccinated SOTRs with prior coronavirus disease 2019. Together, these results suggest that SOTRs generate robust T-cell responses following natural infection that correlate with disease severity but generate comparatively lower T-cell responses following mRNA vaccination.

Pediatric COVID-19 Vaccines: What Parents, Practitioners, and Policy Makers Need to Know.

A snapshot global survey on side effects of COVID-19 vaccines among healthcare professionals and armed forces with a focus on headache. BACKGROUND: New messenger RNA (mRNA) and adenovirus-based vaccines (AdV) against Coronavirus disease 2019 (COVID-19) have entered large scale clinical trials. Since healthcare professionals (HCPs) and armed forces personnel (AFP) represent a high-risk category, they act as a suitable target population to investigate vaccine-related side effects, including headache, which has emerged as a common complaint. METHODS: We investigated the side-effects of COVID-19 vaccines among HCPs and AFP through a 38 closed-question international survey. The electronic link was distributed via e-mail or via Whatsapp to more than 500 contacts. Responses to the survey questions were analyzed with bivariate tests. RESULTS: A total of 375 complete surveys have been analyzed. More than 88% received an mRNA vaccine and 11% received AdV first dose. A second dose of mRNA vaccine was administered in 76% of individuals. No severe adverse effects were reported, whereas moderate reactions and those lasting more than 1 day were more common with AdV (P=0.002 and P=0.024 respectively). Headache was commonly reported regardless of the vaccine type, but less frequently, with shorter duration and lower severity that usually experienced by participants, without significant difference irrespective of vaccine type. CONCLUSIONS: Both mRNA and AdV COVID-19 vaccines were safe and well tolerated in a real-life subset of HCPs and AFP subjects.

Evaluating the relationship between myocarditis and mRNA vaccination. INTRODUCTION: Inflammatory conditions affecting the heart and surrounding tissues have been recently reported following mRNA vaccination. Evaluating trends in the epidemiology of these events and possible mechanisms related to vaccination will enhance vaccine safety surveillance and inform best practices for future vaccine campaigns. AREAS COVERED: Epidemiology of the burden of vaccine-associated myocarditis are reviewed. Key summaries of available data from public health advisory bodies and vaccine safety surveillance databases are critically reviewed. The possible biological pathways for vaccine-associated heart inflammations are introduced. A critical synthesis of available information to inform vaccine recommendations and best practices is provided. The citations were selected by the authors based on PubMed searches of the literature, national vaccine safety surveillance databases and summaries from national public health bodies. EXPERT OPINION: Myocarditis may be associated with vaccination, through several biological mechanisms. Studies have shown that live viral vaccinations can act as a trigger for hypersensitivity inflammatory reactions, but further work is required to examine how the mRNA formulation may induce these autoimmune responses. Given that the risk of these adverse events is low, and the benefit of protection against disease is so great, the receipt of mRNA vaccines is recommended.

Erratum: Hepatitis C Virus Reactivation Following COVID-19 Vaccination - A Case Report [Corrigendum]. [This corrects the article DOI: 10.2147/IMCRJ.S328482.].

Psychosocial Factors Predict COVID-19 Vaccine Side Effects.

Acute disseminated encephalomyelitis (ADEM) following recent Oxford/AstraZeneca COVID-19 vaccination. This report describes the clinical context and autopsy findings in the first reported fatal case of acute disseminated encephalomyelitis (ADEM), developed after being vaccinated

usingÂ the Oxford/AstraZeneca COVID-19 vaccine. ADEM is a rare autoimmune disease, causing demyelination in the brain and spinal cord. A wide variety of precipitating factors can trigger ADEM, and it has long been known to be a rare adverse event following some types of vaccinations. Recently, ADEM has also been associated withÂ COVID-19 infection and (very rarely) with COVID-19 vaccination. The reports of the latter however all pertain to living patients. Our case demonstrates that ADEM should be considered in patients developing neurological symptoms post COVID-19 vaccination, although that this adverse reaction is likely to remain extremely rare. Our report further emphasizes the added value of comprehensive post mortem investigation to confirm ante mortem diagnosis and to determine vaccination safety.
The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines - United States, 2021. Three COVID-19 vaccines are currently approved under a Biologics License Application (BLA) or authorized under an Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) and recommended for primary vaccination by the Advisory Committee on Immunization Practices (ACIP) in the United States: the 2-dose mRNA-based Pfizer-BioNTech/Comirnaty and Moderna COVID-19 vaccines and the single-dose adenovirus vector-based Janssen (Johnson & Johnson) COVID-19 vaccine (1,2) (Box 1). In August 2021, FDA amended the EUAs for the two mRNA COVID-19 vaccines to allow for an additional primary dose in certain immunocompromised recipients of an initial mRNA COVID-19 vaccination series (1). During September-October 2021, FDA amended the EUAs to allow for a COVID-19 vaccine booster dose following a primary mRNA COVID-19 vaccination series in certain recipients aged â‰¥18 years who are at increased risk for serious complications of COVID-19 or exposure to SARS-CoV-2 (the virus that causes COVID-19), as well as in recipients aged â‰¥18 years of Janssen COVID-19 vaccine (1) (Table). For the purposes of these recommendations, an additional primary (hereafter additional) dose refers to a dose of vaccine administered to persons who likely did not mount a protective immune response after initial vaccination. A booster dose refers to a dose of vaccine administered to enhance or restore protection by the primary vaccination, which might have waned over time. Health care professionals play a critical role in COVID-19 vaccination efforts, including for primary, additional, and booster vaccination, particularly to protect patients who are at increased risk for severe illness and death.
Evolving Bilateral Hypermetabolic Axillary Lymphadenopathy on FDG PET/CT Following 2-Dose COVID-19 Vaccination. A 50-year-old woman with stage IV sigmoid adenocarcinoma presented for restaging FDG PET/CT status post neoadjuvant chemotherapy/immunotherapy and diverting sigmoid colostomy. FDG PET/CT demonstrated FDG uptake in the known sigmoid mass and in abdominopelvic lymph node metastases. Bilateral, asymmetric, hypermetabolic axillary lymphadenopathy was also observed, an atypical pattern of spread for colon cancer. Further investigation revealed the patient had received both doses of COVID-19 vaccine in the 2 months prior to presentation. The authors discuss immunogenic nodal hypermetabolism following vaccination against COVID-19 and incorporating vaccination history to aid in PET/CT interpretation, especially in malignancies involving the axillae.
A Seizure After COVID-19 Vaccination in a Patient on Clozapine.
Understanding Breakthrough Infections Following mRNA SARS-CoV-2 Vaccination.
Association Between mRNA Vaccination and COVID-19 Hospitalization and Disease Severity. IMPORTANCE: A comprehensive understanding of the benefits of COVID-19 vaccination requires consideration of disease attenuation, determined as whether people who develop COVID-19 despite vaccination have lower disease severity than unvaccinated people. OBJECTIVE: To evaluate the association between vaccination with mRNA COVID-19 vaccines-mRNA-1273 (Moderna) and BNT162b2 (Pfizer-BioNTech)-and COVID-19 hospitalization, and, among patients hospitalized with

COVID-19, the association with progression to critical disease. DESIGN, SETTING, AND PARTICIPANTS: A US 21-site case-control analysis of 4513 adults hospitalized between March 11 and August 15, 2021, with 28-day outcome data on death and mechanical ventilation available for patients enrolled through July 14, 2021. Date of final follow-up was August 8, 2021. EXPOSURES: COVID-19 vaccination. MAIN OUTCOMES AND MEASURES: Associations were evaluated between prior vaccination and (1) hospitalization for COVID-19, in which case patients were those hospitalized for COVID-19 and control patients were those hospitalized for an alternative diagnosis; and (2) disease progression among patients hospitalized for COVID-19, in which cases and controls were COVID-19 patients with and without progression to death or mechanical ventilation, respectively. Associations were measured with multivariable logistic regression. RESULTS: Among 4513 patients (median age, 59 years [IQR, 45-69]; 2202 [48.8%] women; 23.0% non-Hispanic Black individuals, 15.9% Hispanic individuals, and 20.1% with an immunocompromising condition), 1983 were case patients with COVID-19 and 2530 were controls without COVID-19. Unvaccinated patients accounted for 84.2% (1669/1983) of COVID-19 hospitalizations. Hospitalization for COVID-19 was significantly associated with decreased likelihood of vaccination (cases, 15.8%; controls, 54.8%; adjusted OR, 0.15; 95% CI, 0.13-0.18), including for sequenced SARS-CoV-2 Alpha (8.7% vs 51.7%; aOR, 0.10; 95% CI, 0.06-0.16) and Delta variants (21.9% vs 61.8%; aOR, 0.14; 95% CI, 0.10-0.21). This association was stronger for immunocompetent patients (11.2% vs 53.5%; aOR, 0.10; 95% CI, 0.09-0.13) than immunocompromised patients (40.1% vs 58.8%; aOR, 0.49; 95% CI, 0.35-0.69) (Pâ€‰<â€‰.001) and weaker at more than 120 days since vaccination with BNT162b2 (5.8% vs 11.5%; aOR, 0.36; 95% CI, 0.27-0.49) than with mRNA-1273 (1.9% vs 8.3%; aOR, 0.15; 95% CI, 0.09-0.23) (Pâ€‰<â€‰.001). Among 1197 patients hospitalized with COVID-19, death or invasive mechanical ventilation by day 28 was associated with decreased likelihood of vaccination (12.0% vs 24.7%; aOR, 0.33; 95% CI, 0.19-0.58). CONCLUSIONS AND RELEVANCE: Vaccination with an mRNA COVID-19 vaccine was significantly less likely among patients with COVID-19 hospitalization and disease progression to death or mechanical ventilation. These findings are consistent with risk reduction among vaccine breakthrough infections compared with absence of vaccination.

Acute myocarditis after coronavirus disease 2019 vaccination.

Pure sensitive chronic inflammatory axonal polyneuropathy following Pfizer COVID-19 vaccine. BACKGROUND: During the worldwide mass vaccination campaign against SARS-CoV-2, multiple side effects have been observed. We described the case of a patient who developed pure sensitive chronic inflammatory axonal polyneuropathy (CIAP) in a close temporal relationship with the administration of the BNT162b2 (PfizerÂ®) vaccine. CASE REPORT: An 82-year-old woman developed lower limb sensory loss and "pricking" associated with marked gait imbalance after she had received her second dose of Pfizer-BioNTech COVID-19 vaccine. At the electroneurographic examination, the motor nerves conduction study was normal. Median, ulnar, and sural nerves sensory compound nerve action potential (CNAP) were bilaterally absent. Somatosensory evoked potentials (SSEPs) were not recordable. Spine MRI demonstrated roots enhancement from C3 to Th2 and diffuse enhancement of cauda equina nerve roots. She was treated with IV methylprednisolone whit benefit. A follow-up visit was made 4Â months after the disease onset; a diagnosis of pure sensitive CIAP has been made. DISCUSSION: To the best of our knowledge, this is the first description of CIAP occurring in a close temporal relationship with the administration of Pfizer-BioNTech COVID-19 vaccine.

Anaphylaxis after Moderna COVID-19 vaccine. The authors of this article report on a case of a patient who presented to the emergency department (ED) in anaphylaxis after receiving the ModernaÂ® COVID-19 vaccine. The patient was hypoxic, with diffuse wheezing bilaterally to auscultation, flush skin, swollen face, and the feeling of her throat closing. Anaphylaxis can have wide

range of presentation, the key is recognizing the symptoms and treating early. The incidence of anaphylaxis from COVID-19 vaccine is not well documented to date.
Possible Risk of Thrombotic Events following Oxford-AstraZeneca COVID-19 Vaccination in Women Receiving Estrogen. People who receive the ChAdOx1 nCoV-19 vaccine, particularly perimenopausal women who are on birth control or postmenopausal women who take estrogen supplements, may experience thrombosis and thrombocytopenia. Estrogen and the ChAdOx1 nCoV-19 vaccine both have the potential to cause thrombus in different ways. Some postmenopausal women who are also taking estrogens may develop thrombosis and thrombocytopenia after receiving the ChAdOx1 nCoV-19 vaccine. Therefore, women are encouraged to stop taking drugs containing estrogen before receiving this vaccine. Furthermore, consuming fish oil can help reduce the risk of developing blood clots among women who are in the luteal phase and, thus, have high estrogen levels. In addition, ChAdOx1 nCoV-19's side effects in young women could be mitigated by administering it during the follicular phase.
Herpes Zoster Following COVID-19 Vaccination in Long-Term Breast Cancer Survivors. Mortality from coronavirus disease 2019 (COVID-19) is higher among patients with cancer. Vaccination represents a cornerstone in overcoming the disease, and vaccine safety needs to be closely assessed. This article discusses two cases of herpes zoster (HZ) following the administration of the BNT162b2 mRNA vaccine in patients who are long-term survivors of breast disease. HZ developed 24 days and two days after the second dose of the vaccine in women aged 81 and 61, respectively. These two patients were breast cancer operated respectively nine and 16 years before; interestingly HZ developed in the same site of previous surgical resection. The patients did not show lymphocytopenia or other signs of immunosuppression and were treated with acyclovir, resulting in the complete resolution of HZ. To our knowledge, these two patients are the first described cases of HZ reactivation following COVID-19 vaccination in cancer survivors.
The role and impact of polyethylene glycol on anaphylactic reactions to COVID-19 nano-vaccines.
[Development of thrombocytopenic purpura following BNT162b2 mRNA COVID-19 vaccination]. Because the coronavirus disease 2019 (COVID-19) pandemic is still rampant, vaccination is being promoted worldwide. However, the safety of various COVID-19 vaccines remains poorly understood. We herein report the case of a 37-year-old woman who experienced thrombocytopenia following BNT162b2 mRNA COVID-19 vaccination. The patient presented with purpura on the extremities 10 days after the first vaccination. She had marked thrombocytopenia and no thrombosis. Thrombocytopenia resolved spontaneously. Given the possibility of occurrence of post-vaccination thrombocytopenia, vaccinated persons should be instructed to consult a medical institution if they experience bleeding symptoms.
[Development of autoimmune hemolytic anemia after BNT162b2 mRNA COVID-19 vaccination]. A 75-year-old woman with a history of postoperative chemotherapy for lung adenocarcinoma and a history of Helicobacter pylori eradication for idiopathic thrombocytopenic purpura (ITP) was admitted to the department of hematology and oncology for the treatment of anemia 2 weeks after BNT162b2 mRNA COVID-19 vaccination. Her blood examination revealed direct and indirect Coombs test-positive hemolytic anemia and elevation of serum LDH and indirect bilirubin levels. No obvious trigger other than BNT162b2 mRNA COVID-19 vaccination was found. She was diagnosed with autoimmune hemolytic anemia (AIHA), and oral prednisolone therapy was administered. The anemia improved soon after the administration of prednisolone. Although vaccination is considered to be very important for suppressing the spread of COVID-19, there have been reports of increasing risk of ITP development and deterioration caused by BNT162b2 mRNA COVID-19 vaccination. Because the number of vaccinated people is increasing rapidly, hematologists must be vigilant to the development

of AIHA after BNT162b2 mRNA COVID-19 vaccination although case reports of this phenomenon have been very rare thus far.

Should children be vaccinated against COVID-19? Whether all children under 12 years of age should be vaccinated against COVID-19 remains an ongoing debate. The relatively low risk posed by acute COVID-19 in children, and uncertainty about the relative harms from vaccination and disease mean that the balance of risk and benefit of vaccination in this age group is more complex. One of the key arguments for vaccinating healthy children is to protect them from long-term consequences. Other considerations include population-level factors, such as reducing community transmission, vaccine supply, cost, and the avoidance of quarantine, school closures and other lockdown measures. The emergence of new variants of concern necessitates continual re-evaluation of the risks and benefits. In this review, we do not argue for or against vaccinating children against COVID-19 but rather outline the points to consider and highlight the complexity of policy decisions on COVID-19 vaccination in this age group.

Myocarditis Following mRNA COVID-19 Vaccine. A growing number of adolescents are being diagnosed with acute myocarditis following mRNA COVID-19 vaccinations. This case describes an adolescent who presented to the emergency department with chest pain and tachycardia following the Pfizer-BioNTech COVID-19 vaccination. Point-of-care ultrasound was performed prior to the return of laboratory studies and revealed depressed left ventricular systolic function. Point-of-care ultrasound may be a tool used to rapidly diagnose or risk stratify patients with potential post-COVID-19 vaccine myocarditis.

Regional lymphadenopathy following COVID-19 vaccination: Literature review and considerations for patient management in breast cancer care. PURPOSE: Over 1 billion doses of COVID-19 vaccines have been already administered across the United States, the United Kingdom and the European Union at the time of writing. Furthermore, 1.82 million booster doses have been administered in the US since 13th August, and similar booster programmes are currently planned or under consideration in the UK and the EU beginning in the autumn of 2021. Early reports showed an association between vaccine administration and the development of ipsilateral axillary and supraclavicular lymphadenopathy, which could interfere with the diagnosis, treatment and follow-up of breast cancer patients. In this paper, we review the available evidence on vaccine-related lymphadenopathy, and we discuss the clinical implications of the same on breast cancer diagnosis and management. METHODS: A literature search was performed - PubMed, Ovid Medline, Scopus, CINHAL, Springer Nature, ScienceDirect, Academic Search PremierÂ and the Directory of Open Access Journals were searched for articles reporting on regional palpable or image-detected lymphadenopathy following COVID-19 vaccination. Separately, we compiled a series of case studies from the University Hospitals of Derby and Burton, United Kingdom and the Mayo Clinic in Minnesota, United States of America, to illustrate the impact that regional lymphadenopathy post-COVID-19 vaccination can have on the diagnosis and management of patients being seen in diagnostic and therapeutic breast clinics. RESULTS: From the literature search, 15 studies met the inclusion criteria (nÂ =Â 2057 patients, 737 with lymphadenopathy). The incidence of lymphadenopathy ranged between 14.5% and 53% and persisted for >6 weeks in 29% of patients. CONCLUSIONS: Clinicians managing breast cancer patients should be aware that the COVID-19 vaccination may result in regional lymphadenopathy in a significant number of patients, which can result in unnecessary investigations, treatment and increased patient anxiety. An accurate COVID-19 vaccination history should be collected from all patients where regional lymphadenopathy is a clinical and/or an imaging finding and then combined with clinical judgement when managing individual cases.

SARS-CoV-2 infection long time after full vaccination is related to a lack of neutralizing antibodies. SARS-CoV-2 infections after COVID-19 vaccination are not unexpected, but those occurring more than

14 days after second vaccine dose need to be investigated. We describe a well-characterized infection which occurred almost 2 months after full vaccination, and provide the evidence of a link with a lack of anti-SARS-CoV-2 neutralizing antibodies.
Erythema annulare centrifugum induced by COVID-19 vaccination. With the expansion of the COVID-19 vaccination drive, an increasing number of adverse effects are surfacing. A 74-year-old woman presented with multiple erythematous and itchy patches on several sites. She had no relevant medical history, apart from the first AZD1222 vaccination 1 month previously. Microscopically, epidermal changes, including mild spongiosis and parakeratosis, were observed. Tight perivascular lymphocytic infiltration (coat-sleeve pattern) was also observed in the dermis. The final diagnosis was erythema annulare centrifugum (EAC) induced by SARS-CoV-2 vaccination. Based on this report, dermatologists should be aware of the possibility of EAC from the AZD1222 vaccination.
Takotsubo cardiomyopathy after vaccination for coronavirus disease 2019 in a patient on maintenance hemodialysis. Coronavirus disease-2019 (COVID-19) has affected more than 220 million individuals since the global pandemic began. There is an urgent need for safe and effective vaccines, and vaccinations, such as mRNA vaccines, have been initiated worldwide. However, the adverse effects of these vaccines remain unclear. We herein present a case of an 80-year-old female on maintenance hemodialysis who developed takotsubo cardiomyopathy 4Â days after receiving the first dose of the Pfizer-BioNTech COVID-19 vaccine. There was no obvious trigger for the onset of takotsubo cardiomyopathy other than the COVID-19 vaccination, which was the most significant event preceding her presentation. Echocardiograms obtained during her admission allowed us to monitor and show the recovery of left ventricular wall motion. We confirmed the diagnosis of takotsubo cardiomyopathy based on the findings, including transient left ventricular dysfunction, electrocardiographic abnormalities, an elevated troponin level, and the absence of occlusive coronary artery disease. In the present case, the vaccination may have triggered emotional or physical stress. Although difficulties are associated with proving the causal relationship in the present case, the temporal relationship between the vaccination and the onset of takotsubo cardiomyopathy is highly suggestive. The adverse effects associated with the vaccine are typical of COVID-19 vaccines administered to date, most of which are acceptable. Therefore, despite our experience of the present case, we still recommend the vaccination for COVID-19 because takotsubo cardiomyopathy induced by the COVID-19 vaccine is extremely rare and the prognosis of the patient was good. We herein present the first case of a patient on hemodialysis who developed takotsubo cardiomyopathy after receiving COVID-19 vaccination.
A case of myocarditis in a 60-year-old man 48 h after mRNA vaccination against SARS-CoV2.
Acute tubulointerstitial nephritis after COVID-19 m-RNA BNT162b2 vaccine.
Adverse events of active and placebo groups in SARS-CoV-2 vaccine randomized trials: A systematic review. BACKGROUND: For safety assessment in clinical trials, adverse events (AEs) are reported for the drug under evaluation and compared with AEs in the placebo group. Little is known about the nature of the AEs associated with clinical trials of SARS-CoV-2 vaccines and the extent to which these can be traced to nocebo effects, where negative treatment-related expectations favor their occurrence. METHODS: In our systematic review, we compared the rates of solicited AEs in the active and placebo groups of SARS-CoV-2 vaccines approved by the Western pharmaceutical regulatory agencies.We implemented a search strategy to identify trial-III studies of SARS-CoV-2 vaccines through the PubMed database. We adopted the PRISMA Statement to perform the study selection and the data collection and identified three trial: two mRNA-based (38403 participants) and one adenovirus type (6736 participants). FINDINGS: Relative risks showed that the occurrence of AEs reported in the vaccine groups was higher compared with the placebo groups. The most frequently AEs in both groups were fatigue, headache, local pain, as injection site reactions, and myalgia. In

particular, for first doses in placebo recipients, fatigue was reported in 29% and 27% in BNT162b2 and mRNA-1273 groups, respectively, and in 21% of Ad26.COV2.S participants. Headache was reported in 27% in both mRNA groups and in 24% of Ad26.COV2.S recipients. Myalgia was reported in 10% and 14% in mRNA groups (BNT162b2 and mRNA-1273, respectively) and in 13% of Ad26.COV2.S participants. Local pain was reported in 12% and 17% in mRNA groups (BNT162b2 and mRNA-1273, respectively), and in 17% of Ad26.COV2.S recipients. These AEs are more common in the younger population and in the first dose of placebo recipients of the mRNA vaccines. INTERPRETATION: Our results are in agreement with the expectancy theory of nocebo effects and suggest that the AEs associated with COVID-19 vaccines may be related to the nocebo effect. FUNDING: Fondazione CRT - Cassa di Risparmio di Torino, IT (grant number 66346, "GAIA-MENTE" 2019).

Lobar bleeding with ventricular rupture shortly after first dosage of an mRNA-based SARS-CoV-2 vaccine. Vaccination against SARS-CoV-2 is beneficial but may be rarely accompanied by side effects. We report a 67yo female who developed visual impairment, dysarthria, confusion, and fatigue a few hours after a first dosage with an mRNA-based SARS-CoV-2 vaccine (Pfizer). Her previous history listed diabetes, arterial hypertension, arterial occlusive disease, a single renal cyst on the left side, smoking, and ischemic stroke 20y earlier. Stroke was complicated by normal pressure hydrocephalus requiring placement of a ventriculo-atrial (VA)-shunt. Cerebral imaging revealed a right-sided intracerebral bleeding with ventricular rupture and correct placement of the VA-shunt. Neurosurgeons decided against surgical treatment. The further course was dominated by prolonged confusion, visual impairment, and disorientation but ultimately only minor deficits. In conclusion, a single patient experienced intracerebral bleeding with ventricular rupture shortly after application of the first jab of an mRNA-based SARS-CoV-2 vaccine. Whether bleeding was causally related to the vaccination or occurred coincidentally, remains speculative.

Viral loads of Delta-variant SARS-CoV-2 breakthrough infections after vaccination and booster with BNT162b2. The effectiveness of the coronavirus disease 2019 (COVID-19) BNT162b2 vaccine in preventing disease and reducing viral loads of breakthrough infections (BTIs) has been decreasing, concomitantly with the rise of the Delta variant of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, it is unclear whether the observed decreased effectiveness of the vaccine in reducing viral loads is inherent to the Delta variant or is dependent on time from immunization. By analyzing viral loads of over 16,000 infections during the current, Delta-variant-dominated pandemic wave in Israel, we found that BTIs in recently fully vaccinated individuals have lower viral loads than infections in unvaccinated individuals. However, this effect starts to decline 2 months after vaccination and ultimately vanishes 6 months or longer after vaccination. Notably, we found that the effect of BNT162b2 on reducing BTI viral loads is restored after a booster dose. These results suggest that BNT162b2 might decrease the infectiousness of BTIs even with the Delta variant, and that, although this protective effect declines with time, it can be restored, at least temporarily, with a third, booster, vaccine dose.

Side effects and Immunogenicity following administration of the Sputnik V COVID-19 vaccine in health care workers in Iran. The Sputnik V is a COVID- 19 vaccine developed by the Gamalia institute of epidemiology and microbiology and released on August 11, 2020. We provided independent evidence on side effects and immunogenicity following the administration of the Sputnik V COVID-19 in Iran. In this observational study, the healthcare workers who were vaccinated with the Sputnik V COVID-19 vaccine within February and April 2021 were evaluated. Among a total of 13,435 vaccinated healthcare workers, we received 3236 self-declaration reports of Sputnik V associated adverse events with the mean age 39.32â€‰Â±â€‰10.19Â years old which 38.8% were men and 61.2% were women. Totally 68.8% of females versus 66.2% of males reported side effects after receiving the first dose and 31.2% of females versus 33.8% of males reported side effects after the second dose of

vaccine. The most common side effect was a pain in the injection site (56.9%), fatigue (50.9%), body pain (43.9%), headache (35.7%), fever (32.9%), joint pain (30.3%), chilling (29.8%) and drowsiness (20.3%). Side effects of the vaccine were significantly more frequent in females and younger individuals. Among a total of 238 participants, more than 90% after the first and second dose of vaccine had a detectable level of SARS-CoV-2 RBD antibody and SARS-CoV-2 neutralizing antibody. Although the overall rate of adverse effects was higher than the interim results from randomized controlled trials, our findings support the manufacturer's reports about the high humoral immunogenicity of vaccine against COVID-19.
Serological response following vaccination with BNT162b2 mRNA in patients with chronic lymphocytic leukemia.
Occurrence and response to treatment of Graves' disease after COVID vaccination in two male patients.
COVID-19 vaccines and skin manifestations. Linked Article:Â CatalÃ etÂ al. Br J Dermatol 2022; 186:142â€“152.
Bilateral giant cell arteritis with skin necrosis following SARS-CoV-2 vaccination. [Image: see text]
Risk factors of impaired humoral response to COVID-19 vaccination in rituximab-treated patients. OBJECTIVE: To identify which factors influence humoral response to coronavirus disease 2019 (COVID-19) vaccination in rituximab (RTX)-treated patients. METHODS: This was an observational, prospective, usual care study including consecutive patients with inflammatory rheumatic diseases in maintenance therapy with RTX. All patients received a two-dose regimen COVID-19 vaccination. Serum IgG antibody levels against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike proteins were measured at the time of the new RTX infusion. RESULTS: From the recruited patients, 16/45 (36%) produced antibodies reaching the assay cut-off value of 15â€‰AU/ml and 29/45 (64%) had a negative serology. Within RTX-treated patients, 25 (56%) had undetectable B cells. Negative serology was associated with undetectable B cells (24/25 vs 5/20, Pâ€‰<â€‰0.001). Moreover, SARS-CoV-2 spike antibodies correlated with CD19 counts (râ€‰=â€‰0.86, Pâ€‰<â€‰0.001). The effect of RTX and MTX was additive in terms of seroconversion rates (23% vs 50% in patients receiving RTX in monotherapy, Pâ€‰=â€‰0.12) and SARS-CoV-2 spike antibody levels [3.80 (95% CI 3.80, 7.50) vs 75 (95% CI 3.8, 353)â€‰AU/ml in patients receiving RTX in monotherapy; Pâ€‰=â€‰0.025]. Multivariate analyses including demographics, disease characteristics, gammaglobulin levels, RTX and other therapies used, CD19 counts, and the time between the last RTX infusion and vaccination identified detectable B cells as the only variable independently associated with seropositivity [odds ratio 35.2 (95% CI 3.59, 344.20)]. CONCLUSIONS: B cell depletion is the main independent contributing factor of antibody response to SARS-CoV-2 vaccination in RTX-treated patients. Monitoring CD19 may be of interest to identify the most appropriate period to perform vaccination.
BNT162b2 vaccination induces durable SARS-CoV-2-specific T cells with a stem cell memory phenotype. Vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is effective in preventing hospitalization from severe COVID-19. However, multiple reports of breakthrough infections and of waning antibody titers have raised concerns on the durability of the vaccine, and current vaccination strategies now propose administration of a third dose. Here, we monitored T cell responses to the Spike protein of SARS-CoV-2 in 71 healthy donors vaccinated with two doses of the Pfizer-BioNTech mRNA vaccine (BNT162b2) for up to 6 months after vaccination. We found that vaccination induced the development of a sustained anti-viral CD4(+) and CD8(+) T cell response. These cells appeared before the development of high antibody titers, displayed markers of immunological maturity and stem cell memory, survived the physiological contraction of the immune response, and persisted for at least 6 months. Collectively, these data show that vaccination with

BNT162b2 elicits an immunologically competent and long-lived SARS-CoV-2â€“specific T cell population.
Cutaneous Lymphocytic Vasculitis After Administration of the Second Dose of AZD1222 (Oxford-AstraZeneca) Severe Acute Respiratory Syndrome Coronavirus 2 Vaccination: Casuality or Causality?
Humoral immune response following prime and boost BNT162b2 vaccination in people living with HIV on antiretroviral therapy. OBJECTIVES: People living with HIV (PLWH) with low CD4 T-cell counts may be at a higher risk for severe coronavirus disease 2019 (COVID-19) outcomes and in need of efficient vaccination. The World Health Organization (WHO) now recommends prioritizing PLHIV for COVID-19 vaccination. Data on immune responses after messenger RNA (mRNA) vaccination in PLHIV in relation to CD4 counts are scarce. We aimed at assessing the humoral immune response in PLHIV after mRNA vaccination against COVID-19. METHODS: We examined a cohort of PLHIV after prime (nÂ =Â 88) and boost (nÂ =Â 52) vaccination with BNT162b2. We assessed levels of anti-severe acute respiratory syndromeÂ coronavirus 2Â (SARS-CoV-2) spike (S) protein-specific immunoglobulin G (IgG)/IgA and circulating neutralizing antibodies in plasma and correlated results to the cellular immune status. BNT162b2-vaccinated health care workers served as controls. RESULTS: All PLWH had a viral load of â‰¤Â 200 HIV-1 RNA copies/mL and 96.5% had a viral load of <Â 50 copies/mL. Anti-S IgG and neutralizing antibody responses after BNT162b2 priming were significantly lower in PLHIV having a CD4:CD8 T-cell ratio of <Â 0.5. However, we observed robust humoral immunity in the majority of PLWH receiving antiretroviral therapy (ART) irrespective of CD4 T-cell nadir, current CD4 count or CD4:CD8 ratio after full BNT162b2 vaccination. Nevertheless, HIV-negative controls produced significantly higher mean anti-S IgG concentrations with less variability. CONCLUSIONS: The majority of PLWH mounted robust responses after complete BNT162b2 vaccination but overall amounts of antibodies directed against the SARS-CoV-2 receptor-binding domain were variable. The impact on clinical efficacy remains unclear.
Multiple cranial nerve palsies following COVID-19 vaccination-Case report. BACKGROUND: The novel COVID-19 vaccines have side effects that require efficient and close monitoring. AIMS OF THE STUDY: To examine whether the Pfizer-BioNTech vaccine is associated with multiple cranial neuropathy. METHODS: We report the case of a 29-year-old male patient with no notable history who presented with left oculomotor, abducens, trigeminal and facial palsies 6Â days after receiving the first dose of the Pfizer-BioNTech COVID-19 vaccine. RESULTS: Gadolinium-enhanced MRI of the brain revealed enhancement in the left facial, trigeminal and oculomotor nerves, which persisted upon repeated examination. The cerebrospinal fluid analysis showed no sign of inflammation, both initially and after 1Â month from the start of the patient's symptoms. Other causes were excluded by laboratory tests. The patient received high doses of corticosteroids, with improvement of symptoms. CONCLUSIONS: In our case, the most probable etiology of the patient's multiple cranial neuropathy is the Pfizer-BioNTech vaccine, which highlights the need for prolonged surveillance of COVID-19 vaccine neurological complications.
Antibody kinetics in patients with rheumatic diseases after SARS-CoV-2 mRNA vaccination.
[Not Available].
SARS-CoV-2 spike-dependent platelet activation in COVID-19 vaccine-induced thrombocytopenia.
Atypical Hemolytic Uremic Syndrome after ChAdOx1 nCoV-19 Vaccination in a Patient with Homozygous CFHR3/CFHR1 Gene Deletion. Hemolytic uremic syndrome (HUS) is a thrombotic microangiopathy (TMA) affecting the kidneys. Compared with typical HUS due to an infection from shiga toxin-producing Escherichia coli, atypical HUS involves a genetic or acquired dysregulation of the complement alternative pathway. In the presence of a mutation in a complement gene, a second trigger is often necessary for the development of the disease. We report a case of a 54-year-old female, with a past medical history of pulmonary tuberculosis, who was admitted to the emergency

service with general malaise and reduction in urine output, 5 days after vaccination with ChAdOx1 nCoV-19. Laboratory results revealed microangiopathic hemolytic anemia, thrombocytopenia, and acute kidney injury. Given the clinical picture of TMA, plasma exchange (PEX) was immediately started, along with hemodialysis. Complementary laboratory workup for TMA excluded thrombotic thrombocytopenic purpura and secondary causes. Complement study revealed normal levels of factors H, B, and I, normal activity of the alternate pathway, and absence of anti-factor H antibodies. Genetic study of complement did not show pathogenic variants in the 12 genes analyzed, but revealed a deletion in gene CFHR3/CFHR1 in homozygosity. Our patient completed 10 sessions of PEX, followed by eculizumab, with both clinical and laboratorial improvement. Actually, given the short time lapse between vaccination with ChAdOx1 nCoV-19 and the clinical manifestations, we believe that vaccine was the trigger for the presentation of aHUS in this particular case.

VaricellaÂ zoster virus-induced neurological disease after COVID-19 vaccination: a retrospective monocentric study. The description of every possible adverse effect or event related to vaccines is mandatory during the ongoing worldwide COVID-19 vaccination program. Although cases of cutaneous varicellaÂ zoster virus (VZV) reactivation after COVID-19 vaccination have been increasingly reported in literature and database sets, a description of VZV-induced neurological disease (VZV-ND) is still lacking. In the present study, we retrospectively evaluated patients admitted to our clinic and diagnosed with VZV-ND during the COVID-19 vaccination campaign (January-April 2021) and in the same months in the previous twoÂ years. We identified three patients with VZV-ND after COVID-19 vaccination and 19 unvaccinated VZV-ND cases as controls. In the case-control analysis, the two groups showed no difference in clinical features, results of diagnostic investigations, and outcome. Thus, VZVÂ reactivation with neurological involvement might be a possible event triggered by COVID-19 vaccination, but the benefit following COVID-19 vaccination overcomes significantly the potential risk associated with a VZVÂ reactivation.

Recommendations were made for diagnosis and management of allergic reactions to COVID-19 vaccines. Greenhawt M, Abrams EM, Shaker M, et al. The risk of allergic reaction to SARS-CoV-2 vaccines and recommended evaluation and management: a systematic review, meta-analysis, GRADE assessment, and international consensus approach. J Allergy Clin Immunol Pract. 2021;9:3546-67. 34153517.

A typical autoimmune hepatitis (AIH) case following Covid-19 mRNA vaccination. More than a coincidence?

Age- and Sex-Specific Incidence of Cerebral Venous Sinus Thrombosis Associated With Ad26.COV2.S COVID-19 Vaccination. This cohort study compares the sex- and age-adjusted incidence of cerebral venous sinus thrombosis before the COVID-19 pandemic with that during the first 92 days after Ad26.COV2.S vaccination.

Association of Prior SARS-CoV-2 Infection With Risk of Breakthrough Infection Following mRNA Vaccination in Qatar. IMPORTANCE: The effect of prior SARS-CoV-2 infection on vaccine protection remains poorly understood. OBJECTIVE: To assess protection from SARS-CoV-2 breakthrough infection after mRNA vaccination among persons with vs without prior SARS-CoV-2 infection. DESIGN, SETTING, AND PARTICIPANTS: Matched-cohort studies in Qatar for the BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) vaccines. A total of 1 531 736 individuals vaccinated with either vaccine between December 21, 2020, and September 19, 2021, were followed up beginning 14 days after receiving the second dose until September 19, 2021. EXPOSURES: Prior SARS-CoV-2 infection and COVID-19 vaccination. MAIN OUTCOMES AND MEASURES: Incident SARS-CoV-2 infection, defined as a polymerase chain reaction (PCR)-positive nasopharyngeal swab regardless of reason for PCR testing or presence of symptoms. Cumulative incidence was calculated using the Kaplan-Meier estimator method. RESULTS: The BNT162b2-vaccinated cohort comprised 99 226

individuals with and 290 432 matched individuals without prior PCR-confirmed infection (median age, 37 years; 68% male). The mRNA-1273-vaccinated cohort comprised 58 096 individuals with and 169 514 matched individuals without prior PCR-confirmed infection (median age, 36 years; 73% male). Among BNT162b2-vaccinated persons, 159 reinfections occurred in those with and 2509 in those without prior infection 14 days or more after dose 2. Among mRNA-1273-vaccinated persons, 43 reinfections occurred in those with and 368 infections in those without prior infection. Cumulative infection incidence among BNT162b2-vaccinated individuals was an estimated 0.15% (95% CI, 0.12%-0.18%) in those with and 0.83% (95% CI, 0.79%-0.87%) in those without prior infection at 120 days of follow-up (adjusted hazard ratio for breakthrough infection with prior infection, 0.18 [95% CI, 0.15-0.21]; Pâ€‰<â€‰.001). Cumulative infection incidence among mRNA-1273-vaccinated individuals was an estimated 0.11% (95% CI, 0.08%-0.15%) in those with and 0.35% (95% CI, 0.32%-0.40%) in those without prior infection at 120 days of follow-up (adjusted hazard ratio, 0.35 [95% CI, 0.25-0.48]; Pâ€‰<â€‰.001). Vaccinated individuals with prior infection 6 months or more before dose 1 had statistically significantly lower risk for breakthrough infection than those vaccinated less than 6 months before dose 1 (adjusted hazard ratio, 0.62 [95% CI, 0.42-0.92]; Pâ€‰=â€‰.02 for BNT162b2 and 0.40 [95% CI, 0.18-0.91]; Pâ€‰=â€‰.03 for mRNA-1273 vaccination). CONCLUSIONS AND RELEVANCE: Prior SARS-CoV-2 infection was associated with a statistically significantly lower risk for breakthrough infection among individuals receiving the BNT162b2 or mRNA-1273 vaccines in Qatar between December 21, 2020, and September 19, 2021. The observational study design precludes direct comparisons of infection risk between the 2 vaccines.
Vaccinating adolescents against SARS-CoV-2 in England: a risk-benefit analysis. OBJECTIVE: To offer a quantitative risk-benefit analysis of two doses of SARS-CoV-2 vaccination among adolescents in England. SETTING: England. DESIGN: Following the risk-benefit analysis methodology carried out by the US Centers for Disease Control, we calculated historical rates of hospital admission, Intensive Care Unit admission and death for ascertained SARS-CoV-2 cases in children aged 12-17 in England. We then used these rates alongside a range of estimates for incidence of long COVID, vaccine efficacy and vaccine-induced myocarditis, to estimate hospital and Intensive Care Unit admissions, deaths and cases of long COVID over a period of 16 weeks under assumptions of high and low case incidence. PARTICIPANTS: All 12-17 year olds with a record of confirmed SARS-CoV-2 infection in England between 1 July 2020 and 31 March 2021 using national linked electronic health records, accessed through the British Heart Foundation Data Science Centre. MAIN OUTCOME MEASURES: Hospitalisations, Intensive Care Unit admissions, deaths and cases of long COVID averted by vaccinating all 12-17 year olds in England over a 16-week period under different estimates of future case incidence. RESULTS: At high future case incidence of 1000/100,000 population/week over 16 weeks, vaccination could avert 4430 hospital admissions and 36 deaths over 16 weeks. At the low incidence of 50/100,000/week, vaccination could avert 70 hospital admissions and two deaths over 16 weeks. The benefit of vaccination in terms of hospitalisations in adolescents outweighs risks unless case rates are sustainably very low (below 30/100,000 teenagers/week). Benefit of vaccination exists at any case rate for the outcomes of death and long COVID, since neither have been associated with vaccination to date. CONCLUSIONS: Given the current (as at 15 September 2021) high case rates (680/100,000 population/week in 10-19 year olds) in England, our findings support vaccination of adolescents against SARS-CoV2.
Systemic drug-related intertriginous and flexural exanthema induced by the Pfizer-BioNTech COVID-19 vaccine: A report of 2 cases.
Cutaneous reaction reported after third Moderna COVID-19 vaccine.
Axonal-Variant Guillian-Barre Syndrome Temporally Associated With mRNA-Based Moderna SARS-CoV-2 Vaccine. We present a case of an 86-year-old woman who presented with a progressive

quadriparesis two days after her second dose of Moderna SARS-CoV-2 vaccine, with cerebrospinal fluid (CSF) evidence of cytoalbuminocytological dissociation and electromyogram/nerve conduction studies (EMG/NCS) findings suggestive of acute axonal motor neuropathy. Her clinical symptoms did not improve with plasmapheresis. There appears to be a potential temporal association between the inoculation of mRNA-based SARS-CoV-2 vaccines and the development of Guillain-Barre Syndrome (GBS). Despite this possible association, infection prevention using highly effective mRNA-based vaccines remains highly recommended. Large epidemiological studies of SARS-CoV-2 vaccine-related adverse events are needed. Physicians should be aware of this possible temporal association since the prompt diagnosis and treatment of GBS can drastically improve outcomes. The aim is to report a case of axonal-variant GBS that was temporally associated with an mRNA-based SARS-CoV-2 vaccine.

The evaluation of factors affecting antibody response after administration of the BNT162b2 vaccine: a prospective study in Japan. The aim of this study was to evaluate the antibody reaction after administration of the BNT162b2 vaccine, and to reveal the factors that affect antibody production. This prospective study was carried out in the Association of EISEIKAI Medical and Healthcare Corporation Minamitama Hospital, in Tokyo, Japan, from April 15, 2021 to June 09, 2021. All our hospital's workers who were administered the BNT162b2 vaccine as part of a routine program were included in this study. We calculated the anti-SARS-CoV-2 spike-specific antibody titter (1) before vaccination, (2) 7 to 20 days after the first vaccination, and (3) A total of 7 to 20 days after the second vaccination. The low-antibody titer group (LABG) was defined as the group having less than 25 percentiles of antibody titer. Univariate and Multivariate logistic regression analysis were performed to ascertain the effects of factors on the likelihood of LABG. A total of 374 participants were eventually included in our study, and they were divided into 94 LABG and 280 non-LABG. All samples showed significant antibody elevation in the second antibody test, with a mean value of 3,476 U/mL. When comparing the LABG and non-LABG groups, the median age, blood sugar, and HbA1c were significantly higher in the LABG group. The rates of participants with low BMI (<18.5) and high BMI (>30) were significantly higher in the LABG group. The proportion of chronic lung disease, hypertension, diabetes, dyslipidemia, autoimmune disease, and cancer were significantly higher in the LABG group. Although there was no significant difference confirmed with respect to the exercise hours per day, the proportion of participants that did not perform outdoor exercises was significantly higher in the LABG group. The time interval between the second vaccination and the second antibody test, and between the first and the second vaccination was significantly longer in the non-LABG group. In the multivariate logistic regression analysis, older than 60 years, the past history of hypertension, HbA1c higher than 6.5%, and lack of outdoor exercises were significant suppressors of antibody responses, whereas the length of days from the first to the second vaccination longer than 25 days promoted a significant antibody response. Again, our single-center study demonstrates that older than 60 years, hypertension, HbA1c higher than 6.5%, and lack of outdoor exercises were significant suppressors of antibody responses, whereas the length of days from the first to the second vaccination longer than 25 days promoted a significant antibody response. Evidence from multi-center studies is needed to develop further vaccination strategies.

Minimal change nephrotic syndrome four days after the administration of Pfizer-BioNTech COVID-19 vaccine-a new side effect or coincidence? The association between the COVID vaccine and MCD is temporal and by exclusion, and it is not fully established, but it should be considered in postvvaccine MCD.

Prime-Boost Vaccination With Covaxin/BBV152 Induces Heightened Systemic Cytokine and Chemokine Responses. Covaxin/BBV152 is a whole virion inactivated SARS-CoV-2 vaccine. The effect of prime-boost vaccination with Covaxin on systemic immune responses is not known. We investigated the effect of Covaxin on the plasma levels of a wide panel of cytokines and chemokines

at baseline (M0) and at months 1 (M1), 2 (M2) and 3 (M3) following prime-boost vaccination in healthy volunteers. Our results demonstrate that Covaxin induces enhanced plasma levels of Type 1 cytokines (IFNÎ³, IL-2, TNFÎ±), Type 2/regulatory cytokines (IL-4, IL-5, IL-10 and IL-13), Type 17 cytokine (IL-17A), other pro-inflammatory cytokines (IL-6, IL-12, IL-1Î±, IL-1Î²) and other cytokines (IL-3 and IL-7) but diminished plasma levels of IL-25, IL-33, GM-CSF and Type 1 IFNs. Covaxin also induced enhanced plasma levels of CC chemokine (CCL4) and CXC chemokines (CXCL1, CXCL2 and CX3CL1) but diminished levels of CXCL10. Covaxin vaccination induces enhanced cytokine and chemokine responses as early as month 1, following prime-boost vaccination, indicating robust activation of innate and adaptive immune responses in vaccine recipients.

Raynaud's Phenomenon after COVID-19 Vaccination: Causative Association, Temporal Connection, or Mere Bystander? Herein, we report a case of a new-onset Raynaud's phenomenon (RP), which occurred in an otherwise healthy 31-year-old Caucasian woman, who lacked any known risk factors and associations with possible causes for secondary RP. However, 2 weeks prior to the development of RP, the patient had received her first injection of the COVID-19 vaccine containing ChAdOx1-SARS-COV-2. The patient presented with well-demarcated, white-pale, cold areas involving the middle fingers of both hands and the ring finger of the right hand, which were triggered by exposure to cold environment and accompanied by a sensation of numbness. Infrared thermography revealed notable temperature differences of up to 10.9Â°C between affected and nonaffected fingers. Coagulation and immunological parameters, including cryoglobulins and pathological autoantibodies, were within the normal range and antibodies to the heparin/platelet factor 4 complex not detectable. It remains unclear if the development of RP in our patient is causally related to antecedent COVID-19 vaccination; however, the temporal connection to the vaccination, the complete absence of RP in her past medical history, and the lack of any risk factors and triggers raise the suspicion of a yet unknown association with the vaccine. Whether a clear association between the development of RP and COVID-19 vaccination exists or whether RP represents a bystander effect needs to be awaited in case observational reports on RP accumulate. Given the steadily rising numbers of people receiving COVID-19 vaccinations, physicians may remain alert to still unrecognized side effects.

Images in Vascular Medicine: Leukocytoclastic vasculitis after COVID-19 vaccine booster.

Spectrum of neurological complications following COVID-19 vaccination. COVID-19 vaccines have brought us a ray of hope to effectively fight against deadly pandemic of COVID-19 and hope to save lives. Many vaccines have been granted emergency use authorizations by many countries. Post-authorization, a wide spectrum of neurological complications is continuously being reported following COVID-19 vaccination. Neurological adverse events following vaccination are generally mild and transient, like fever and chills, headache, fatigue, myalgia and arthralgia, or local injection site effects like swelling, redness, or pain. The most devastating neurological post-vaccination complication is cerebral venous sinus thrombosis. Cerebral venous sinus is frequently reported in females of childbearing age, generally following adenovector-based vaccination. Another major neurological complication of concern is Bell's palsy that was reported dominantly following mRNA vaccine administration. Acute transverse myelitis, acute disseminated encephalomyelitis, and acute demyelinating polyneuropathy are other unexpected neurological adverse events that occur as result of phenomenon of molecular mimicry. Reactivation of herpes zoster in many persons, following administration of mRNA vaccines, has been also recorded. Considering the enormity of recent COVID-19-vaccinated population, the number of serious neurological events is miniscule. Large collaborative prospective studies are needed to prove or disprove causal association between vaccine and neurological adverse events occurring vaccination.

Editorial: What Can be Learned from National and International Vaccine Adverse Event Reporting Systems During the COVID-19 Pandemic? Healthcare professionals have an ethical, medico-legal,

and professional responsibility to report all suspected adverse events following immunization to relevant national reporting agencies as part of the process of post-marketing drug safety monitoring. In the US, the Vaccine Adverse Event Reporting System (VAERS) is co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). Data from VAERS and other national and global reporting systems show very low rates of adverse events related to currently approved SARS-CoV-2 vaccines. Populations studies have supported the findings from adverse event reporting systems. The presentation, monitoring, and reporting of adverse events related to SARS-CoV-2 vaccines may have future applications in vaccine monitoring for several other potential pandemic zoonotic infections. This editorial aims to summarize the current understanding of adverse events from current COVID-19 vaccines from global adverse event reporting systems, rather than individual case reports or anecdotal reporting in the media.

Isolation of SARS-CoV-2 from COVID-19 Patients and an Asymptomatic Individual. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged in Wuhan, China, in December 2019. Despite the recent introduction of vaccines against SARS-CoV-2, more effective vaccines and antiviral drugs must be developed. Here, we isolated five SARS-CoV-2 strains from four patients with coronavirus disease (COVID-19) and an asymptomatic individual using pharyngeal swabs, nasopharyngeal swabs, and sputum samples. Cytopathic effects in inoculated Vero cells were observed between days 3 and 7. SARS-CoV-2 infection was confirmed by quantitative reverse-transcription polymerase chain reaction (RT-qPCR) and next-generation sequencing. Phylogenetic analyses of the whole genome sequences showed that the virus isolates from the clinical samples belonged to the Wuhan and European lineages. These findings and the isolated viruses may contribute to the development of diagnostic tools, vaccines, and antiviral drugs for COVID-19.

[Possible mechanisms of impaired post-vaccination immune response in obesity]. Obese people are at high risk of developing infections, including COVID-19, and are prone to a more severe course and a poorer prognosis of diseases. The review summarizes information on the post-vaccination immune response in obesity in children and adults with infections. The SARS-COV-2 pandemic further exacerbates this problem of the adequacy of the immune response to vaccination of obese people. The purpose of this review is to present and summarize information on the changes in various links of cellular and humoral immunity in the experiment and in the clinic during the immune response to vaccination in obesity. Results. The mechanisms of action of obesity and associated chronic inflammation and metabolic dysregulation on the post-vaccination immune response in various infections are discussed. The systemic inflammatory response that occurs in obesity represents a barrier to the induction of a sustained immune response. In obese individuals, innate and adaptive immune responses are slowed down and diminished, contributing to the spread of infections. Conclusion. In obesity, the differentiation and proliferation of cells of the immune system is impaired, and the immune response to vaccination changes. Further research is needed to study post-vaccination immunity in obesity, taking into account the effect on the vaccination of the microbiota of a particular person, the presence of possible comorbid conditions.

Coordinated cellular and humoral immune responses after two-dose SARS-CoV2 mRNA vaccination in liver transplant recipients. Limited data are available on risks and benefits of anti-SARS-CoV2 vaccination in solid organ transplant recipients, and weaker responses have been described. At the Italian National Institute for Infectious Diseases, 61 liver transplant recipients underwent testing to describe the dynamics of humoral and cell-mediated immune response after two doses of anti-SARS-CoV2 mRNA vaccines and compared with 51 healthy controls. Humoral response was measured by quantifying both anti-spike and neutralizing antibodies; cell-mediated response was measured by PBMC proliferation assay with IFN-Î³ and IL-2 production. Liver transplant recipients showed lower response rates compared with controls in both humoral and cellular arms; shorter time since

transplantation and multi-drug immunosuppressive regimen containing mycophenolate mofetil were predictive of reduced response to vaccination. Specific antibody and cytokine production, though reduced, were highly correlated in transplant recipients.
Can SARS-CoV-2 vaccine increase the risk of reactivation of Varicella zoster? A systematic review. INTRODUCTION: Although the COVID-19 vaccination is deemed safe, exact incidence and nature if adverse effects, particularly dermatological ones, are still unknown. OBJECTIVE: To describe the demographic, clinical, morphological characteristics, outcomes, and timing of development of herpes zoster to the various COVID-19 vaccines. And to identify on whether COVID-19 vaccine has temporal relationship between development of herpes zoster (HZ). METHODS: We have performed a systemic review of articles from PubMed and Embase using MeSH and keywords likeÂ "Shingles," "Herpes zoster," "Varicella zoster," "COVID-19," "Vaccine," "SARS-CoV-2." No filters including country of publication, language, type of articles were applied. Individual case report references were filtered for any pertinent cases. RESULTS: A total of 54 cases consisting of 27Â male and 27 female patients have been reported. There were cases with known risk factors for herpes zoster, which included age more than 50Â years (nÂ =Â 36), immunological disorders (nÂ =Â 10), chronic disease (nÂ =Â 25), metabolic disorder (nÂ =Â 13), malignancy (nÂ =Â 4), and psychiatric disorder (nÂ =Â 2). The mean (SD) period between development of herpes zoster and COVID-19 vaccination was 7.64 (6.92) days. Majority of the cases were from the high-income and/or middle-income countries. 86.27% of the cases of HZ were reported due to mRNA vaccine. Thirty-six patients 36/45 (80%) developed herpes zoster following the priming dose of COVID-19 vaccine among those who received mRNA vaccine. CONCLUSION: We could not establish definite link but there may be possible association between COVID-19 vaccine and shingles. Large-scale studies may help to understand the cause-effect relationship.
Immunogenicity and Safety of COVID-19 mRNA Vaccine in STAT1 GOF Patients.
Eosinophilic granulomatosis with polyangiitis after COVID-19 vaccination.
Cellular and Humoral Response, Six Months After Two Doses of BNT162b2 Messenger Ribonucleic Acid Coronavirus Disease 2019 Vaccination, in Residents and Staff of Nursing Homes for the Elderly.
Safety of COVID-19 Vaccination in Inflammatory Bowel Disease Patients on Biologic Therapy.
The COVID-19 pandemic and ANCA-associated vasculitis - reports from the EUVAS meeting and EUVAS education forum. The Coronavirus Disease 2019 (COVID-19) pandemic influenced the management of patients with anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis. A paucity of data exists on outcome of patients with vasculitis following COVID-19, but mortality is higher than in the general population and comparable to patients undergoing haemodialysis or kidney transplant recipients (reported mortality rates of 20-25%). Delays in diagnosis have been reported, which are associated with sequelae such as dialysis-dependency. Management of ANCA-associated vasculitis has not changed with the aim to suppress disease activity and reduce burden of disease. The use of rituximab, an important and widely used agent, is associated with a more severe hospital course of COVID-19 and absence of antibodies following severe acute respiratory syndrome (SARS)-CoV-2 infections, which prone patients to re-infection. Reports on vaccine antibody response are scarce at the moment, but preliminary findings point towards an impaired immune response, especially when patients receive rituximab as part of their treatment. Seropositivity was reported in less than 20% of patients when rituximab was administered within the prior six months, and the antibody response correlated with CD19(+) B-cell repopulation. A delay in maintenance doses, if disease activity allows, has been suggested using a CD19(+) B-cell guided strategy. Other immunosuppressive measures, which are used in ANCA-associated vasculitis, also impair humoral and cellular vaccine responses. Regular measurements of vaccine response or a healthcare-policy time-based strategy are indicated to provide additional doses ("booster") of COVID-19 vaccines. This

review summarizes a recent educational forum and a recent virtual meeting of the European Vasculitis Society (EUVAS) focusing on COVID-19.
Seroconversion rate after vaccination against COVID-19 in patients with cancer-a systematic review. BACKGROUND: Coronavirus disease 2019 (COVID-19) has affected >210 million people worldwide. An optimal therapeutic approach for COVID-19 remains uncertain, to date. Since the history of cancer was linked to higher mortality rates due to COVID-19, the establishment of a safe and effective vaccine coverage is crucial in these patients. However, patients with cancer (PsC) were mostly excluded from vaccine candidates' clinical trials. This systematic review aims to investigate the current available evidence about the immunogenicity of COVID-19 vaccines in PsC. PATIENTS AND METHODS: All prospective studies that evaluated the safety and efficacy of vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) were included, with immunogenicity after the first and the second dose as the primary endpoint, when available. RESULTS: Vaccination against COVID-19 for PsC seems overall safe and immunogenic after well-conducted vaccination schedules. Yet the seroconversion rate remains lower, lagged or both compared to the general population. Patients with hematologic malignancies, especially those receiving B-cell-depleting agents in the past 12 months, are the most at risk of poor seroconversion. CONCLUSION: A tailored approach to vaccination may be proposed to PsC, especially on the basis of the type of malignancy and of the specific oncologic treatments received.
Vulvar Aphthous Ulcer Following Pfizer-BioNTech COVID-19 Vaccine - A Case Report. BACKGROUND: In this case report, we describe a potential association between the Pfizer-BioNTech COVID-19 vaccine and development of a vulvar aphthous ulcer in a virginal 14-year-old girl. CASE: A 14-year-old patient reported vulvar pain and visible lesion. Exam findings were consistent with vulvar aphthous ulcers. Two days prior to the onset of her symptoms she received her second Pfizer-BioNTech COVID-19 vaccine. The evening of vaccine administration, she experienced several hours duration of fatigue, muscle aching and insomnia but had otherwise been recently healthy and testing for common viral associations of vulvar ulcers was negative. SUMMARY AND CONCLUSION: Vaccination, in general, has been associated with mucosal side-effects and oral ulceration has been reported in subjects who received Pfizer-BioNTech COVID-19 vaccine. It is reasonable to hypothesize that vulvar ulceration may be caused by a similar mechanism and should be considered a rare side effect of this vaccine.
Side effects of messenger RNA vaccines and prior history of COVID-19, a cross-sectional study. BACKGROUND: There are concerns regarding immunogenicity with coronavirus disease 2019 (COVID-19) mRNA vaccines among persons with prior history of COVID-19 (PHC). This study was to analyze the short-term side effects of mRNA vaccines among health care workers (HCWs) with and without PHC. METHODS: A cross-sectional study was performed using an independent online survey questionnaire that gathered responses from HCWs. RESULTS: Among 1,475 HCWs, 1268 (85.97%) completed the survey, 102/1268 (44/447 in Moderna group and 58/821 in Pfizer-BioNTech group) reported PHC during pre-vaccination period. Symptoms of flushing/PÂ =Â .05, brain fogging/P= .005, vertigo/P= .041, numbness/P= .023, diarrhea/P= .047, hives/P= .028, itching/P= .028, swelling of lips/mouth/P= .001, shortness of breath/P= .022, and anxiety/P= .048 have greater occurrence among Pfizer-BioNtech group with PHC when compared to Pfizer-BioNtech group with no PHC. Symptoms of chills/P= .027, flushing/P= .045, tremor/P= .05, muscle spasm/P= .039, vomiting/P= .031, diarrhea/P= .015, and cough/P= .011 have higher occurrence among Moderna group with PHC when compared to Moderna group with no PHC. CONCLUSIONS: Few short-term side effects among mRNA vaccine recipients with PHC may have necessitated transient time-off from work. The PHC can be considered as a predictor for severity of side effects. While the vaccination program continues in

the United States, a future COVID legislation that mandates vaccination among employees along with paid time off provision may help with higher compliance and acceptance.
Increasing COVID-19 vaccine uptake in Black Americans.
Adverse event reporting and Bell's palsy risk after COVID-19 vaccination - Authors' reply.
Adverse event reporting and Bell's palsy risk after COVID-19 vaccination.
Distinct patterns of whole blood transcriptional responses are induced in mice following immunisation with adenoviral and poxviral vector vaccines encoding the same antigen. BACKGROUND: Viral vectors, including adenovirus (Ad) and modified vaccinia Ankara (MVA), have gained increasing attention as vaccine platforms in recent years due to their capacity to express antigens from a wide array of pathogens, their rapid induction of humoral and cellular protective immune responses, and their relatively low production costs. In particular, the chimpanzee Ad vector, ChAdOx1, has taken centre stage as a leading COVID-19 vaccine candidate. However, despite mounting data, both clinical and pre-clinical, demonstrating effective induction of adaptive immune responses, the innate immune signals that precede the protective responses that make these vectors attractive vaccine platforms remain poorly understood. RESULTS: In this study, a mouse immunisation model was used to evaluate whole blood gene expression changes 24â€‰h after either a single dose or heterologous prime-boost regimen of an Ad and/or MVA vaccine. We demonstrate through comparative analysis of Ad vectors encoding different antigens that a transgene product-specific gene signature can be discerned from the vector-induced transcriptional response. Expression of genes involved in TLR2 stimulation and Î³Î´ T cell and natural killer cell activation were induced after a single dose of Ad, while MVA led to greater expression of type I interferon genes. The order of prime-boost combinations was found to influence the magnitude of the gene expression changes, with MVA/Ad eliciting greater transcriptional perturbation than Ad/MVA. Contrasting the two regimens revealed significant enrichment of epigenetic regulation pathways and augmented expression of MHC class I and II molecules associated with MVA/Ad. CONCLUSION: These data demonstrate that the order in which vaccines from heterologous prime-boost regimens are administered leads to distinct transcriptional responses and may shape the immune response induced by such combinations. The characterisation of early vaccine-induce responses strengthens our understanding of viral vector vaccine mechanisms of action ahead of their characterisation in human clinical trials and are a valuable resource to inform the pre-clinical design of appropriate vaccine constructs for emerging infectious diseases.
Guillain-BarrÃ© Syndrome After COVID-19 Vaccination in an Adolescent.
Autoimmune hepatitis after COVID-19 vaccine - more than a coincidence. The COVID-19 pandemic is still raging across the world and vaccination is expected to lead us out of this pandemic. Although the efficacy of the vaccines is beyond doubt, safety still remains a concern. We report a case of a 65-year-old woman who experienced acute severe autoimmune hepatitis two weeks after receiving the first dose of Moderna-COVID-19 vaccine. Serum immunoglobulin G was elevated and antinuclear antibody was positive (1:100, speckled pattern). Liver histology showed a marked expansion of the portal tracts, severe interface hepatitis and multiple confluent foci of lobular necrosis. She started treatment with prednisolone, with a favorable clinical and analytical evolution. Some recent reports have been suggested that COVID-19 vaccination can lead to the development of autoimmune diseases. It is speculated that the vaccine can disturb self-tolerance and trigger autoimmune responses through cross-reactivity with host cells. Therefore, healthcare providers must remain vigilant during mass COVID-19 vaccination.
Reasons and consequences of COVID-19 vaccine failure in patients with chronic lymphocytic leukemia. People with hematologic malignancies are at a high risk of morbidity and mortality from COVID-19. The response to vaccination is highly limited in patients with chronic lymphocytic

leukemia. Less than half of the patients develop antibody response, suggesting that they remain at risk of SARS-CoV-2 infection even after the vaccination. Reasons for inadequate response to COVID-19 vaccination in chronic lymphocytic leukemia are multifactorial and attributed to disease-related immune dysregulation and patient- and therapy-related factors. The negative predictors of response to vaccination include hypogammaglobulinemia, advanced age, current active treatment, and past treatment anti-CD20Â monoclonal antibodies. Despite using booster doses and heterologous immunization to improve humoral and cellular immunity, some patients with chronic lymphocytic leukemia will fail to respond. Active treatment at the time of vaccination and a recent history of anti-CD20Â monoclonal antibodies use are the strongest predictors of the non-response. Current data support informing patients with chronic lymphocytic leukemia and other hematologic malignancies about the risk of infection regardless of vaccination. These individuals and members of their households should continue extreme preventive actions despite relaxed local regulations. Other emerging non-vaccine preventive strategies include passive and post-exposure prevention with monoclonal antibodies.
Acute immune thrombocytopenia following SARS-CoV-2 vaccination in chronic ITP patients and a healthy individual.
Adverse events and disease flares after SARS-CoV-2 vaccination in patients with systemic lupus erythematosus.
Impaired Humoral but Substantial Cellular Immune Response to Variants of Concern B1.1.7 and B.1.351 in Hemodialysis Patients after Vaccination with BNT162b2.
Humoral serological response to the BNT162b2 vaccine after allogeneic haematopoietic cell transplantation. OBJECTIVES: To assess the humoral immune response to the BNT162b2 vaccine after allogeneic haematopoietic cell transplantation (HCT). METHODS: This is a prospective cohort study. The SARS-CoV-2 IgGII Quant (AbbottÂ©) assay was performed 4-6Â weeks after the second BNT162b2 vaccine for quantitative measurement of anti-spike antibodies. RESULTS: The cohort included 106 adult patients. Median time from HCT to vaccination was 42 (range 4-439) months. Overall, 15/106 (14%, 95% confidence interval (CI) 7-21%) were seronegative despite vaccination, 14/52 patients on immunosuppression (27%, 95%CI 19-35%) compared to only 1/54 patients off immunosuppression (1.8%, 95%CI 1-4%) (p 0.0002). The proportion of seronegative patients declined with time; it was 46% (6/13) during the first year, 12.5% (3/24) during the second year and 9% (6/69) beyond 2Â years from transplant. Patients with acute graft-versus-host disease (GVHD) (odds ratio (OR) 3.3, 95%CI 0.97-11.1, p 0.06) and moderate to severe chronic GVHD (OR 5.9, 95%CI 1.2-29, p 0.03) were more likely to remain seronegative. Vaccination was well tolerated by most patients. However, 7% (7/106) reported that GVHD-related symptoms worsened within days following vaccination. CONCLUSION: A significant proportion of allogeneic HCT recipients receiving immunosuppression demonstrated an inadequate humoral response to the BNT162b2 vaccine. These patients should be recognized and instructed to take appropriate precautions. Recipients who were off immunosuppression had a humoral response that was comparable to that of the general population.
Dynamic SARS-CoV-2-specific B-cell and T-cell responses following immunization with an inactivated COVID-19 vaccine. OBJECTIVE: The dynamic adaptive immune responses elicited by the inactivated virus vaccine CoronaVac remain elusive. METHODS: In a prospective cohort of 100 healthcare professionals naÃ¯ve for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) who received two doses of CoronaVac, we analysed SARS-CoV-2-specific humoral and cellular responses at four different timepoints, including before vaccination (T1), 2Â weeks after the first dose (T2), 2Â weeks after the booster dose (T3), and 8-10Â weeks after the booster dose (T4). SARS-CoV-2-specific antibodies, serum neutralizing activities, peripheral B cells, CD4(+) and CD8(+) T cells and

their memory subsets were simultaneously measured in this cohort. RESULTS: SARS-CoV-2 spike-specific IgG responses reached a peak (geometric mean titre (GMT) 54827, 30969-97065) after two doses and rapidly declined (GMT 502, 212-1190) at T4, whereas suboptimal IgA responses were detected (GMT 5, 2-9). Spike-specific circulating B cells (0.60%, 0.46-0.73% of total B cells) and memory B cells (1.18%, 0.92-1.44% of total memory B cells) were effectively induced at T3 and sustained over time (0.33%, 0.23-0.43%; 0.87%, 0.05-1.67%, respectively). SARS-CoV-2-specific circulating CD4(+) T cells (0.57%, 0.47-0.66%) and CD8(+) T cells (1.29%, 1.04-1.54%) were detected at T3. At T4, 0.78% (0.43-1.20%) of memory CD4+ T cells and 0.68% (0.29-1.30%) of memory CD8+ T cells were identified as SARS-CoV-2-specific, while 0.62% (0.51-0.75%) of CD4(+) T cells and 0.47% (0.38-0.58%) of CD8(+) T cells were SARS-CoV-2-specific terminally differentiated effector memory cells. Furthermore, age and interval between doses affected the magnitude of CoronaVac-induced immune responses. SARS-CoV-2 memory CD4(+) T cells were strongly associated with both receptor binding domain (RBD)-specific memory B cells (r 0.87, p <0.0001) and SARS-CoV-2-specific memory CD8(+) T cells (r 0.48, p <0.0001). CONCLUSIONS: CoronaVac induced robust circulating and memory B cell and T cell responses. Our study offers new insight into the underlying immunobiology of inactivated virus vaccines in humans and may have implications for vaccine strategies in the future.

The willingness of Chinese adults to receive the COVID-19 vaccine and its associated factors at the early stage of the vaccination programme: a network analysis. BACKGROUND: The coronavirus disease (COVID-19) pandemic has been a continuous global threat since the first identification of the disease in December 2019. COVID-19 vaccination is a crucial preventive approach that can halt this pandemic. However, many factors affect the willingness of the public to be vaccinated against COVID-19 at the early stage of the vaccination programme. We used network analysis to investigate the interrelation of vaccination willingness and its associated factors. METHODS: A population-representative sample of 539 Chinese adults completed a battery of online self-assessments, including those on vaccination willingness, health status, attitude towards vaccines, COVID-19-related psychological elements and other variables. Network analysis was performed using the R qgraph package. RESULTS: In total, 445 (82.6%) participants scored high on their willingness to vaccinate. Attitude towards vaccines, the influence of people around an individual and health status were directly significantly related to vaccination willingness. The betweenness of age was the highest and, the emotional states had the strongest centrality. LIMITATIONS: Network analysis is not sufficient to determine the causal relationships of the links between nodes. In addition, there are other latent essential elements that were not evaluated. Finally, the sample size was relatively small. CONCLUSION: Network analysis showed that attitude toward vaccines and emotional states are the most critical factors affecting vaccination willingness, which indicates that we should pay attention to the impact of the dissemination of Internet information on vaccination willingness and public emotional states during a pandemic which is very important for promoting vaccination programs.

Review and evolution of guidelines for diagnosis of COVID-19 vaccine induced thrombotic thrombocytopenia (VITT). Coronavirus disease 2019 (COVID-19) is a life-threatening infectious disease caused by Severe acute respiratory syndrome Coronavirus-2 (SARS-CoV-2). In response to the still ongoing pandemic outbreak, a number of COVID-19 vaccines have been quickly developed and deployed. Although minor adverse events, either local (e.g., soreness, itch, redness) or systematic (fever, malaise, headache, etc.), are not uncommon following any COVID-19 vaccination, one rare vaccine-associated event can cause fatal consequences due to development of antibodies against platelet factor 4 (PF4), which trigger platelet activation, aggregation, and possible resultant thrombosis, often at unusual vascular sites. Termed thrombosis with thrombocytopenia syndrome (TTS) by reporting government agencies, the term vaccine-induced (immune) thrombotic thrombocytopenia (VITT) is more widely adopted by workers in the field. In response to increasing

reports of VITT, several expert groups have formulated guidelines for diagnosis and/or management of VITT. Herein, we review some key guidelines related to diagnosis of VITT, and also provide some commentary on their development and evolution.

Acute CNS demyelination in a subject with cerebellar ataxia following the first dose of COVID-19 vaccine; a case report. Vaccination-induced demyelination is a rare, unusual side effect of certain vaccines which can cause significant damage to patient's sensory-motor abilities within days. Although COVID-19 vaccines go through rigorous clinical trials before they are injected to the general population, certain unexpected side effects remain inevitable. We herein describe a case of a 42-year-old woman who experienced acute demyelination 10Â days after the Oxford-AstraZeneca vaccination. To the best of our knowledge, this is the first case of such nature and severity described regarding COVID-19 vaccines' side effects.

Reporting of recombinant adenovirus-based COVID-19 vaccine adverse events in online versions of three highly circulated US newspapers. Newspapers' reporting of adverse vaccine events may influence their readers vaccination behaviors. The purpose of this study was to examine the nature and extent of coverage of Johnson and Johnson (J & J) vaccine's adverse events reported in the online versions of the three most widely circulated US daily newspapers from April 13-25, 2021. Articles were identified in published online versions of the three most widely cited newspapers in the United States, using several databases. Dedoose software was used to apply a mixed methods approach to the 110 articles identified. The seven overarching themes were as follows: (1) J & J vaccine characteristics (nÂ =Â 78); (2) Description of the adverse events (nÂ =Â 183); (3) Emphasis that it is a rare event and vaccine is still safe (nÂ =Â 89); (4) Health authorities' investigation (nÂ =Â 55); (5) Pause in administering J & J vaccine (nÂ =Â 83); (6) Vaccine fear and anxiety and increased hesitancy (nÂ =Â 58); (7) J & J role and impact (nÂ =Â 108). Each theme included a series of subthemes. Overall, the newspaper coverage was aligned with handling of the pause from authoritative health agencies in the US. The findings of this study help to better understand how the US media covered adverse events related to the J & J vaccine, and provides insight for public health professionals regarding acceptance COVID-19 vaccines. Monitoring media coverage related to vaccine adverse events may help public health officials to develop new approaches to adequately inform the public, prevent misinformation, and maintain the optimal vaccination uptake.

Breastfeeding Mother and Child Clinical Outcomes After COVID-19 Vaccination. BACKGROUND: Pre-approval clinical trials of the Pfizer/BioNTech messenger RNA COVID-19 vaccine, BNT162b2 did not include participants who were breastfeeding. Therefore, there is limited evidence about outcomes of breastfeeding mother-child dyads and effects on breastfeeding after vaccination. RESEARCH AIMS: To determine: (1) solicited adverse effects (e.g., axillary lymphadenopathy, mastitis, and breast engorgement), which are unique to lactating individuals; and (2) systemic and local adverse effects of COVID-19 mRNA vaccine on mothers and potential effects on their breastfed infants. METHOD: This was a prospective cohort study of lactating healthcare workers (N = 88) in Singapore who received two doses of BNT162b2 vaccination (Pfizer/BioNTech). The outcomes of mother-child dyads within 28 days after the second vaccine dose were determined through a participant-completed questionnaire. RESULTS: Minimal effects related to breastfeeding were reported by this cohort; three of 88 (3.4%) participants had mastitis, one (1.1%) participant experienced breast engorgement, five of 88 (5.7%) participants reported cervical or axillary lymphadenopathy. There was no change in human milk supply after vaccination. The most common side effect was pain/redness/swelling at the injection site, which was experienced by 57 (64.8%) participants. There were no serious adverse events of anaphylaxis or hospital admissions. There were no short-term adverse effects reported in the infants of 67 lactating participants who breastfed within 72 hr after BNT162b2 vaccination. CONCLUSIONS: BNT162b2 vaccination was well tolerated in

lactating participants and was not associated with short-term adverse effects in their breastfed infants. STUDY PROTOCOL REGISTRATION: The study protocol was registered at clinicaltrials.gov (NCT04802278).
Leukocytoclastic vasculitis after coronavirus disease 2019 vaccination.
De novo guttate psoriasis following coronavirus disease 2019 vaccination.
Immunogenicity and safety of the BNT162b2 mRNA COVID-19 vaccine in haematopoietic stem cell transplantation recipients. The immunogenicity and safety of Pfizer-BioNTech BNT162b2 mRNA vaccine in allogeneic haematopoietic stem cell transplantation (HSCT) recipients are unknown. We prospectively followed 152 HSCT recipients who were at least six months following transplantation and with no active acute graft-versus-host disease (GVHD). Blood samples were taken 2-4â€‰weeks after the second vaccination and analyzed for receptor-binding domain (RBD) antibodies and neutralizing antibodies (NA). 272 immunocompetent healthcare workers served as controls. At a median of 28â€‰days after the second vaccination, 118 patients (77Â·6%) developed RBD immunoglobulin G (IgG) with a geometric mean titre (GMT) of 2Â·61 [95% CI (confidence interval), 2Â·16-3Â·16]. In the control group 269/272 (98Â·9%) developed RBD IgG, with a GMT of 5Â·98 (95% CI 5Â·70-6Â·28), Pâ€‰<â€‰0Â·0001. The GMT of NA in HSCT recipients and controls was 116Â·0 (95% CI 76Â·5-175Â·9), and 427Â·9 (95% CI 354Â·3-516Â·7) respectively (Pâ€‰<â€‰0001). Multivariate logistic regression analysis revealed that HSCT recipients with no chronic GVHD and no immunosuppressive therapy at the time of vaccination had significantly higher levels of NA following the second vaccination. Adverse events were minimal and were less common than in healthy controls. In conclusion; the BNT162b2 mRNA vaccination is safe and effective in HSCT recipients, especially those who are immunosuppression-free. A significant fraction developed protecting NA.
Case Report: Probable Myocarditis After Covid-19 mRNA Vaccine in a Patient With Arrhythmogenic Left Ventricular Cardiomyopathy. Arrhythmogenic left ventricular cardiomyopathy (ALVC) is a rare heritable heart-muscle disorder characterized by a progressive loss of left ventricular myocardium and its replacement by fibrofatty tissue. Myocarditis is an inflammatory disease of the heart that may occur secondary to infections, immune system activation or exposure to drugs. Hot phases of ALVC present with chest pain and troponin rise, mimicking acute viral myocarditis and indicate a progression of the disease. Recently, myocarditis has also been described as an infrequent complication of coronavirus disease 2019 (Covid-19) mRNA vaccines. We herein report for the first time a case of probable myocarditis induced by Covid-19 vaccine in a patient with previous medical history of ALVC. We aim to highlight the common characteristics of ALVC and Covid-19 vaccine myocarditis and work through the differential diagnosis of these two entities.
Aseptic Meningitis Following the Second Dose of Comirnaty Vaccination in an Adolescent Patient: A Case Report. Vaccination is currently the best strategy to control the coronavirus disease 2019 epidemic. This report describes a case of aseptic meningitis 3 weeks after administration of the second dose of Comirnaty. The patient recovered with conservative and symptomatic care after 5 days of admission. Surveillance of rare adverse events, including aseptic meningitis, and their management should be prompt and appropriate.
Herpes simplex, herpes zoster and periorbital erythema flares after SARS-CoV-2 vaccination: 4 cases.
Vaccine-Induced Thrombotic Thrombocytopenia: Insights from Blood Smear.
Anaphylactic reactions to polyethylene glycol-containing bowel cleansing preparations after Moderna COVID-19 vaccination.
Cardiovascular, neurological, and pulmonary events following vaccination with the BNT162b2, ChAdOx1 nCoV-19, and Ad26.COV2.S vaccines: An analysis of European data. The ChAdOx1 nCoV-19 (ChA) (AstraZeneca) and Ad26.COV2.S (AD26) (Janssen) vaccines are virus-based coronavirus disease 2019 (COVID-19) vaccines used worldwide. In spring 2021, venous blood clots and

thrombocytopenia were described in some vaccine recipients. We evaluated the frequency of severe adverse events (SAEs) documented in the EudraVigilance European database in young adult (18-64 years old) and older (â‰¥65 years old) vaccine recipients up to 23 June 2021 and related them to coagulation disorders and arterial, cardiac, and nervous system events. Comparison between the frequency of SAEs and SAE-related deaths in ChA and AD26 vs. BNT162b2 COVID-19 (BNT) (Pfizer/BioNTech) vaccine recipients demonstrated: 1) ChA and AD26 recipients than BNT recipients had higher frequencies of not only SAEs caused by venous blood clots and hemorrhage, but also thromboembolic disease and arterial events, including myocardial infarction and stroke; 2) a corresponding higher frequency of SAE-related deaths. The frequency was higher in both young adults and older adults. Comparison between the frequency of SAEs and SAE-related deaths in AD26 vs. ChA recipients demonstrated in AD26 recipients: 1) lower frequency of thrombocytopenia; 2) lower frequency of SAEs in young adult recipients; 3) higher frequency of SAEs in older recipients. Interestingly, most of the venous thrombotic SAEs associated with ChA and AD26 vaccines were not associated with thrombocytopenia, suggesting that TTS (thrombosis with thrombocytopenia syndrome) is not the only type of thrombosis observed following virus-based vaccines. In conclusion, both virus-based COVID-19 vaccines show more SAEs than BNT, but the frequency of the SAE type in the different age groups differs, suggesting that the mechanisms responsible of SAEs overlap only partly.

Comparative safety of mRNA COVID-19 vaccines to influenza vaccines: A pharmacovigilance analysis using WHO international database. Two messenger RNA (mRNA) vaccines developed by Pfizer-BioNTech and Moderna are being rolled out. Despite the high volume of emerging evidence regarding adverse events (AEs) associated with the COVID-19 mRNA vaccines, previous studies have thus far been largely based on the comparison between vaccinated and unvaccinated control, possibly highlightingÂ the AE risks with COVID-19 mRNA vaccination. Comparing the safety profile of mRNA vaccinated individuals with otherwise vaccinated individuals would enable a more relevant assessment for the safety of mRNA vaccination. We designed a comparative safety study between 18â€‰755 and 27â€‰895 individuals who reported to VigiBase for adverse events following immunization (AEFI) with mRNA COVID-19 and influenza vaccines, respectively, from January 1, 2020, to January 17, 2021. We employed disproportionality analysis to rapidly detect relevant safety signals and compared comparative risks of a diverse span of AEFIs for the vaccines. The safety profile of novel mRNA vaccines was divergent from that of influenza vaccines. The overall pattern suggested that systematic reactions like chill, myalgia, fatigue were more noticeable with the mRNA COVID-19 vaccine, while injection site reactogenicity events were more prevalent with the influenza vaccine. Compared to the influenza vaccine, mRNA COVID-19 vaccines demonstrated a significantly higher risk for a few manageable cardiovascular complications, such as hypertensive crisis (adjusted reporting odds ratio [ROR], 12.72; 95% confidence interval [CI], 2.47-65.54), and supraventricular tachycardia (adjusted ROR, 7.94; 95% CI, 2.62-24.00), but lower risk of neurological complications such as syncope, neuralgia, loss of consciousness, Guillain-Barre syndrome, gait disturbance, visual impairment, and dyskinesia. This study has not identified significant safety concerns regarding mRNA vaccination in real-world settings. The overall safety profile patterned a lower risk of serious AEFI following mRNA vaccines compared to influenza vaccines.

[Myocarditis and pericarditis following mRNA COVID-19 vaccination. Expert opinion of the Italian Society of Cardiology]. The coronavirus disease (COVID-19) pandemic has caused 2.69 million deaths and 122 million infections. Great efforts have been made worldwide to promptly develop effective vaccines and reduce morbidity and mortality rates from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Available vaccines have proven highly effective at preventing symptomatic disease in clinical trials and real-world reports and are playing an essential role in

flattening the epidemiology curve and, mostly, in reducing COVID-19 hospitalizations. Some concerns have been raised after very rare cases of myocarditis and pericarditis recently reported by the Centers for Disease Control and Prevention (CDC) as potentially associated with COVID-19 mRNA vaccinations, namely the Pfizer-BioNTech mRNA vaccine (BNT162b2) and the Moderna mRNA vaccine (mRNA-1273). Therefore, the aim of this document is to explore the possible link between COVID-19 mRNA vaccination and the development of myocarditis and/or pericarditis by performing a critical analysis of available data and to provide indications for specific subgroups of individuals.
[Acute myocarditis in a young adult two days after Pfizer vaccination]. We report the case of a 20-year-old healthy male who developed acute myopericarditis 2 days after receiving the second dose of the mRNA Pfizer-BioNTech COVID-19 vaccine. The course of the disease was mild and the patient was discharged after a few days of hospitalization.Recently, several case reports involving myopericarditis in patients who received an mRNA vaccine against SARS-CoV-2 have been published and the U.S. Centers for Disease Control and Prevention and the European Medicines Agency pharmacovigilance risk assessment committee are currently investigating an overall increased number of cases. They are also assessing whether there is a higher incidence than expected in vaccinated young adults and teenagers, especially males. Although a clear causal link has not been proven at this time, physicians should be aware of such potential adverse event, taking into account the increasing number of young people that will receive mRNA vaccination over the next few months.
A Case of COVID-19 Vaccine Associated New Diagnosis Myasthenia Gravis. An 82-year-old man presented with intermittent episodes of slurred speech during his evening meals after receiving the BNT162b2 COVID-19 vaccine. Thorough evaluation was conducted including lab work and EMG confirming a new diagnosis of late-onset myasthenia gravis. Despite treatment, the patient progressed rapidly to severe exacerbation requiring intubation and placement of a PEG tube. Infections provoking new diagnosis and exacerbations of myasthenia gravis have been reported. New diagnosis of myasthenia gravis associated with the COVID-19 vaccine is rarely reported. This case highlights the need for clinicians to be aware of the uncommon presenting symptoms in late-onset myasthenia gravis and the possibility of vaccine provoked diagnoses of immune mediated diseases.
A case of acquired haemophilia A in a 70-year-old post COVID-19 vaccine.
Acute Generalized Exanthematous Pustulosis in Close Temporal Association with mRNA-1273 Vaccine.
Johnson and Johnson COVID-19 Vaccination Triggering Pheochromocytoma Multisystem Crisis. Pheochromocytomas are rare tumors that may have variable presentations. The presentation may dependÂ on the type of catecholamine secreted, whether there is a paraneoplastic syndrome or not, or some other factor which may not be well understood. One rare presentation is a pheochromocytoma multisystem crisis. Many of these tumors are asymptomatic and found incidentally, butÂ some can be triggered after being previously dormant.Â In this case report, we describe the first case of pheochromocytoma multisystem crisis triggered by the Johnson and Johnson (J&J) coronavirus disease 2019 (COVID-19) vaccine. We describe a case of aÂ 63-year-old Caucasian male who presented with intractable nausea, vomiting, dyspnea, watery diarrhea, chills, sweats, and heavy chest pain starting one day status post J&J COVID-19 vaccination. He had no symptoms prior to this and no significant past medical history besides daily marijuana use. During his hospital stay, he had persistent high fevers, respiratory failure, cardiogenic shock, cardiomyopathy, and labile blood pressure measurements. After a retroperitoneal ultrasound, he was found to have a 7 cm mass in the right adrenal gland with elevated chromogranin A, urine vanillylmandelic acid (VMA), and urinary 24-hour metanephrines to confirm the diagnosis of a pheochromocytoma.
Rare cutaneous manifestation of COVID-19 infection and Pfizer-BioNTech COVID-19 vaccine with a unique pattern similarity. In December 2019, a new emerging virus causing mild-to-severe

pneumonia was detected in China. The virus was described as a variant of SARS-CoV and was called SARS-CoV-2, then declared a pandemic by theÂ WHOÂ on 11 March 2020. Millions of people contracted the virus and presented with a symptomatology of variable severity, including upper respiratory tract symptoms, systemic symptoms and diarrhea. We herein report a rare skin presentation in a 33-year-old female that occurred both during COVID-19 infection and after receiving the first dose of COVID-19 vaccine.

SARS-CoV-2 variants in severely symptomatic and deceased persons who had been vaccinated against COVID-19 in SÃ£o Paulo, Brazil. COVID-19 vaccination began in SÃ£o Paulo, Brazil in January 2021, first targeting healthcare workers (HCWs) and the elderly, using the CoronaVac vaccine (Sinovac/Butantan) and subsequently the Oxford/AstraZeneca (ChAdOx1) vaccine (AstraZeneca/FIOCRUZ-RJ). Studies on such vaccines have shown efficacy in preventing severe cases and deaths, but there is a lack of information regarding their effectiveness. This manuscript presents data from the Instituto Adolfo Lutz (IAL), a public health laboratory located in SÃ£o Paulo City that receives samples from 17 Regional Health Departments under the Secretary of Health of SÃ£o Paulo, for SARS-CoV-2 genomic surveillance. Through May 15, 2021 IAL received 20 samples for analysis from COVID-19 vaccinated individuals who needed hospitalization and/or died from COVID-19. Next-generation sequencing was performed on an Ion Torrent S5 platform using the AmpliSeqâ„¢ SARS-CoV-2 kit. Almost all cases were vaccinated with CoronaVac and presented the gamma variant of concern (VOC). Cases of death were observed mostly in the elderly in nursing homes, and severe cases in younger frontline HCWs. This data confirmed that the SARS-CoV-2 gamma variant is highly transmissible, severe, and lethal for COVID-19 in these groups of individuals, thereby highlighting the importance of continuous vaccination and non-pharmacological prevention measures to avoid virus dissemination and the emergence of new VOCs.

Efficacy, Immunogenicity and Safety of COVID-19 Vaccines: A Systematic Review and Meta-Analysis. There is a significant research gap in meta-analysis on the efficacy and safety of coronavirus disease 2019 (COVID-19) vaccines. This study analyzed the efficacy of COVID-19 vaccines. Published phase I, phase II, and phase III trials analyzing safety and immunogenicity and phase III randomized clinical trials evaluating the efficacy of COVID-19 vaccines were included. We searched MEDLINE, Scopus, and The Lancet for published articles evaluating the relative reduction in COVID-19 risk after vaccination. Selected literatures were published between December 15, 2019 and May 15, 2021 on the safety, efficacy, and immunogenicity of COVID-19 vaccines. This meta-analysis included studies that confirmed cases of COVID-19 using reverse transcriptase polymerase chain reaction. This study detected 8,926 eligible research articles published on COVID-19 vaccines. Of these, 25 studies fulfilled the inclusion criteria. Among the selected articles, 19 randomized clinical trials, 2 non-randomized clinical trials, and 3 observational studies were analyzed. Seven (28%) studies were included in the meta-analysis. The efficacy of the adenovirus vector vaccine was 73% (95% CI = 69-77) and that of the messenger RNA (mRNA) vaccine was 85% (95% CI = 82-88) in participants aged â‰¥18 years. There are no reports of clinical trials in participants aged under 16 years. The production of neutralizing antibodies against receptor-binding domains (RBDs) of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in >90% of the vaccinated samples was reported within 0-30 days of the first or the second dose of the vaccine. Pain at the injection site was the most common local symptom in people receiving mRNA vaccines (29%-85% of participants). Fever (0.2%-95%) was the most prevalent in people receiving adenovirus vector vaccines, and fatigue (8.4%-55%) was the most common side effect in people receiving the mRNA vaccines. Studies suggest that mRNA vaccines and adenovirus vector vaccines can provide moderate to high protection against COVID-19 infection in people over 18 years. Evidence of the long-term protection of the vaccines in people aged under 16

years against the multiple variants of COVID-19 are limited. This study will provide an integrated evaluation on the efficacy, safety, and immunogenicity of the COVID-19 vaccines.
Does immunosuppressive property of non-steroidal anti-inflammatory drugs (NSAIDs) reduce COVID-19 vaccine-induced systemic side effects? To help stop the coronavirus disease 2019 (COVID-19) pandemic, vaccines are currently the most critical tool. However, the COVID-19 mRNA vaccines frequently cause systemic side effects shortly after the injection, such as fever, headache and generalized fatigue. In our survey, after receiving the second dose of the COVID-19 vaccine, 80% developed fever, 62% headache and 69% generalized fatigue. Among people who required antipyretics, the average durations of fever and headache were significantly shorter in those who took non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin, loxoprofen and ibuprofen, than those who took acetaminophen. In our patch-clamp studies, NSAIDs effectively suppressed the delayed rectifier K(+)-channel (Kv1.3) currents in T-lymphocytes and thus exerted immunosuppressive effects. Because of this pharmacological property, the use of NSAIDs should be more effective in reducing the vaccine-induced systemic side effects that are caused primarily by the enhanced cellular immunity.
COVID-19 mRNA Vaccine-induced Pneumonitis. A 65-year-old man experienced cough and shortness of breath 3 days after receiving the first dose of the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine. Chest X-ray revealed bilateral infiltrates, and the desaturation deteriorated rapidly. The symptoms and radiographic abnormalities rapidly improved after the initiation of corticosteroid therapy. Intradermal testing of the Pfizer-BioNTech COVID-19 vaccine showed a delayed positive reaction. Based on these findings, the patient was diagnosed with COVID-19 vaccine-induced pneumonitis. The timing of the onset of pneumonitis after vaccination and the results of intradermal testing suggest that Type IV hypersensitivity against COVID-19 vaccine may have been responsible for this clinical condition.
Cerebral venous sinus thrombosis after ChAdOx1 vaccination: the first case of definite thrombosis with thrombocytopenia syndrome from India. Cerebral venous sinus thrombosis (CVST) following novel coronavirus-2019 (nCoV-19) vaccination is a rare adverse effect. We report the first case of CVST associated with ChAdOx1 vaccination, with positive anti-platelet factor 4 (PF4) antibodies, from India. A 44-year-old woman developed a thunderclap headache 4â€‰days after the first dose of the adenoviral vector vaccine ChAdOx1 (Covishield). Physical examination was unremarkable barring mild neck stiffness with no focal neurological deficits. MRI identified right transverse sinus thrombosis. Laboratory tests revealed raised D-dimer and thrombocytopenia; anti-PF4 antibodies were subsequently identified, consistent with thrombosis with thrombocytopenia syndrome (TTS). She was treated with non-heparin anticoagulation and intravenous immunoglobulin and made an uneventful recovery. Early recognition of adenoviral vector vaccine-related TTS, which resembles heparin-induced thrombocytopenia syndrome, is important as heparin and heparin analogues are best avoided in the treatment.
Covid-19: Just a third of blood cancer patients had antibodies against delta variant after two vaccine doses, study finds.
Vulvar Aphthous Ulcer in an Adolescent After Pfizer-BioNTech (BNT162b2) COVID-19 Vaccination. BACKGROUND: Vulvar aphthous ulcers are a rare type of genital lesion most common in non-sexually active adolescents. Vulvar aphthous ulcers are typically associated with viral infections. To date, there have been several cases reported in patients infected with COVID-19. Vulvar aphthous ulcers following vaccination have not been previously reported in the literature. CASE: We present the case of a 16-year-old adolescent who developed vulvar aphthous ulceration following Pfizer-BioNTech (BNT162b2) vaccination. SUMMARY AND CONCLUSION: Through an extensive literature search, we found no previous reports of vulvar aphthous ulcer following vaccination. Our case highlights a

potential novel side effect of Pfizer-BioNTech COVID-19 vaccination and a new etiology for vulvar aphthous ulcers. This case suggests that vulvar aphthous ulcers might be associated with COVID-19 vaccination through a yet undetermined mechanism that requires further investigation.
Audio Interview: A New Monoclonal Antibody for Covid-19 and Potential Vaccination for Children.
Rare Skin Reactions after mRNA Vaccination, Similar to Jones-Mote Basophil Responses.
Waning Immunity after the BNT162b2 Vaccine in Israel. BACKGROUND: In December 2020, Israel began a mass vaccination campaign against coronavirus disease 2019 (Covid-19) by administering the BNT162b2 vaccine, which led to a sharp curtailing of the outbreak. After a period with almost no cases of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, a resurgent Covid-19 outbreak began in mid-June 2021. Possible reasons for the resurgence were reduced vaccine effectiveness against the delta (B.1.617.2) variant and waning immunity. The extent of waning immunity of the vaccine against the delta variant in Israel is unclear. METHODS: We used data on confirmed infection and severe disease collected from an Israeli national database for the period of July 11 to 31, 2021, for all Israeli residents who had been fully vaccinated before June 2021. We used a Poisson regression model to compare rates of confirmed SARS-CoV-2 infection and severe Covid-19 among persons vaccinated during different time periods, with stratification according to age group and with adjustment for possible confounding factors. RESULTS: Among persons 60 years of age or older, the rate of infection in the July 11-31 period was higher among persons who became fully vaccinated in January 2021 (when they were first eligible) than among those fully vaccinated 2 months later, in March (rate ratio, 1.6; 95% confidence interval [CI], 1.3 to 2.0). Among persons 40 to 59 years of age, the rate ratio for infection among those fully vaccinated in February (when they were first eligible), as compared with 2 months later, in April, was 1.7 (95% CI, 1.4 to 2.1). Among persons 16 to 39 years of age, the rate ratio for infection among those fully vaccinated in March (when they were first eligible), as compared with 2 months later, in May, was 1.6 (95% CI, 1.3 to 2.0). The rate ratio for severe disease among persons fully vaccinated in the month when they were first eligible, as compared with those fully vaccinated in March, was 1.8 (95% CI, 1.1 to 2.9) among persons 60 years of age or older and 2.2 (95% CI, 0.6 to 7.7) among those 40 to 59 years of age; owing to small numbers, the rate ratio could not be calculated among persons 16 to 39 years of age. CONCLUSIONS: These findings indicate that immunity against the delta variant of SARS-CoV-2 waned in all age groups a few months after receipt of the second dose of vaccine.
Adverse Effects after BNT162b2 Vaccine and SARS-CoV-2 Infection, According to Age and Sex.
Reaction to dermal filler following COVID-19 vaccination.
Adverse events following immunization against SARS-CoV-2 (covid-19) in the state of Minas Gerais. OBJECTIVE: To analyze adverse events following immunization (AEFI) against SARS-CoV-2 (covid-19) in the state of Minas Gerais (MG), Brazil. METHODS: Epidemiological, descriptive study, with data from e-SUS Notifica (e-SUS Notification) in the state of Minas Gerais from January 20 to March 5, 2021. All suspected cases of AEFI of the covid-19 vaccine in the state were analyzed, totaling 7,305 cases. In this study, we verified the possible correlation between AEFI and the possible immunobiological administered causalities. The variables analyzed for AEFI cases were the immunobiological agent administered (AstraZeneca or Coronavac), the type of event, the evolution of the case, and the time in days since the administration of the immunobiological agent and the onset of symptoms and causality. The incidence rate (IT) was calculated for 100,000 doses applied. RESULTS: The occurrence of AEFI as a result of the covid-19 vaccine was frequent (TI: 777.12) in the state. However, only 3% were classified as a severe AEFI, with a 20.85 IT, and 4.71% of them evolved to deaths (8.19 deaths per 100,000 doses applied). Among the deaths analyzed, 84.4% were classified as preexisting conditions caused by factors other than vaccines. Regarding non-serious AEFI, 1.11% occurred by immunization errors (TI: 8.62 EI for every 100 thousand doses applied). CONCLUSION: This work

encourages the discussion about the importance of recording AEFI related to covid-19 vaccines, demonstrating its safety for the population.

Adverse events report of inactivated COVID-19 vaccine from 4040 healthcare workers. OBJECTIVES: Numerous vaccination studies are conducted to protect against COVID-19 infection, and preclinical and clinical studies are still ongoing worldwide. During this extraordinary period, the necessity to perform COVID-19 vaccine studies and immunization programs together has emerged. Vaccine Adverse Effects (VAEs) need to be documented quickly. We aimed to determine the VAEs and to compare the frequency of VAEs between groups according to sociodemographic characteristics after the inactivated vaccine (CoronaVac) was administered to healthcare workers (HCWs) in Turkey. METHODS: An online questionnaire was delivered to 4040 volunteer HCWs across the whole country who were vaccinated with CoronaVac. Sociodemographic characteristics, medical history, history of COVID-19 infection, and VAEs occurring after the first and second doses of the inactivated vaccine were evaluated. RESULTS: The most common local and systemic VAEs after first and second doses of the COVID-19 vaccine were reported as, pain at the injection site (37.9%; 37.6%), headache (21.5%; 16.8%), fatigue (18%; 15%), drowsiness (9.6%; 8.2%), back pain (8.8%; 8.2%), nausea (6.3%; 4.8%), and joint pain (4.7%; 4.7%). Individuals with a history of allergies (generalized or vaccine-related) and females had a higher rate of VAE. Participants aged 60 and over reported less frequent VAEs. CONCLUSION: It is extremely important to identify and document the VAEs occurring in the early postvaccination period in different groups of the community. These initial findings may provide reassurance to healthcare providers and vaccine recipients and promote confidence in the safety of this inactive COVID-19 vaccine, however longitudinal follow-up studies are recommended.

[Rare encephalitis after vaccination against SARS-CoV-2].

[Not Available].

Cardiac MRI Findings of Myocarditis After COVID-19 mRNA Vaccination in Adolescents. BACKGROUND. A possible association has been reported between COVID-19 messenger RNA (mRNA) vaccination and myocarditis. OBJECTIVE. The purpose of our study was to describe cardiac MRI findings in patients with myocarditis after COVID-19 mRNA vaccination. METHODS. This retrospective study included patients without known prior SARS-CoV-2 infection who underwent cardiac MRI between May 14, 2021, and June 14, 2021, for suspected myocarditis within 2 weeks of COVID-19 mRNA vaccination. Information regarding clinical presentation, hospital course, and events after hospital discharge were recorded. A cardiothoracic imaging fellow and cardiothoracic radiologist reviewed cardiac MRI examinations in consensus. Data were summarized descriptively. RESULTS. Of 52 patients without known prior SARS-CoV-2 infection who underwent cardiac MRI during the study period, five underwent MRI for suspected myocarditis after recent COVID-19 mRNA vaccination. All five patients were male patients ranging in age from 16 to 19 years (mean, 17.2 Â± 1.0 [SD] years) who presented within 4 days of receiving the second dose of a COVID-19 mRNA vaccine. Troponin levels were elevated in all patients (mean peak troponin I value, 6.82 Â± 4.13 ng/mL). Alternate possible causes of myocarditis were deemed clinically unlikely on the basis of medical history, physical examination findings, myocarditis viral panel, and toxicology screening. Cardiac MRI findings were consistent with myocarditis in all five patients on the basis of the Lake Louise criteria, including early gadolinium enhancement and late gadolinium enhancement (LGE) in all patients and corresponding myocardial edema in four patients. All five patients had a favorable hospital course and were discharged from the hospital in stable condition with improved or resolved symptoms after hospitalization (mean length of hospital stay, 4.8 days). Two patients underwent repeat cardiac MRI that showed persistent, although decreased, LGE. Three patients reported mild intermittent self-resolving chest pain after hospital discharge, and two patients had no recurrent symptoms after discharge. CONCLUSION. In this small case series, all patients with myocarditis after COVID-19

vaccination were male adolescents and had a favorable initial clinical course. All patients showed cardiac MRI findings typical of myocarditis from other causes. LGE persisted in two patients who underwent repeat MRI. These observations do not establish causality. CLINICAL IMPACT. Radiologists should be aware of a possible association of COVID-19 mRNA vaccination and myocarditis and recognize the role of cardiac MRI in the assessment of suspected myocarditis after COVID-19 vaccination.

New-onset and relapsing glomerular diseases related to COVID-19 vaccination. COVID-19 vaccine, as one of the critical measures to control the pandemic, has been administered in nearly all countries. However, the new-onset and relapsing glomerular diseases associated with COVID-19 vaccination have become a new concern. Both mRNA vaccine and inactivated vaccine may cause new-onset and relapsing glomerular diseases; these diseases would occur after the first dose vaccination or the second dose. New-onset glomerular disease is mainly minimal change glomerulopathy, which is mostly sensitive to steroid, while relapsing cases have good prognosis, and some cases can be spontaneously remitted. The pathogenesis of these vaccine-associated diseases is possibly due to the humoral and cellular immune responses. In this article, we provide a general review of the new-onset and relapsing glomerular diseases related to COVID-19 vaccination, and make suggestions for patients with kidney diseases to receive COVID-19 vaccination.

 COVID-19 vaccine, as one of the critical measures to control the pandemic, has been administered in nearly all countries. However, the new-onset and relapsing glomerular diseases associated with COVID-19 vaccination have become a new concern. Both mRNA vaccine and inactivated vaccine may cause new-onset and relapsing glomerular diseases; these diseases would occur after the first dose vaccination or the second dose. New-onset glomerular disease is mainly minimal change glomerulopathy, which is mostly sensitive to steroid, while relapsing cases have good prognosis, and some cases can be spontaneously remitted. The pathogenesis of these vaccine-associated diseases is possibly due to the humoral and cellular immune responses. In this article, we provide a general review of the new-onset and relapsing glomerular diseases related to COVID-19 vaccination, and make suggestions for patients with kidney diseases to receive COVID-19 vaccination.

Immune Responses in Fully Vaccinated Individuals Following Breakthrough Infection with the SARS-CoV-2 Delta Variant in Provincetown, Massachusetts. BACKGROUND: A cluster of over a thousand infections with the SARS-CoV-2 delta variant was identified in a predominantly fully vaccinated population in Provincetown, Massachusetts in July 2021. Immune responses in breakthrough infections with the SARS-CoV-2 delta variant remain to be defined. METHODS: Humoral and cellular immune responses were assessed in 35 vaccinated individuals who were tested for SARS-CoV-2 in the Massachusetts Department of Public Health outbreak investigation. RESULTS: Vaccinated individuals who tested positive for SARS-CoV-2 demonstrated substantially higher antibody responses than vaccinated individuals who tested negative for SARS-CoV-2, including 28-fold higher binding antibody titers and 34-fold higher neutralizing antibody titers against the SARS-CoV-2 delta variant. Vaccinated individuals who tested positive also showed 4.4-fold higher Spike-specific CD8+ T cell responses against the SARS-CoV-2 delta variant than vaccinated individuals who tested negative. CONCLUSIONS: Fully vaccinated individuals developed robust anamnestic antibody and T cell responses following infection with the SARS-CoV-2 delta variant. These data suggest important immunologic benefits of vaccination in the context of breakthrough infections.

SARS-CoV-2 variants associated with vaccine breakthrough in the Delaware Valley through summer 2021. The severe acute respiratory coronavirus-2 (SARS-CoV-2) is the cause of the global outbreak of COVID-19. Evidence suggests that the virus is evolving to allow efficient spread through the human population, including vaccinated individuals. Here we report a study of viral variants from surveillance of the Delaware Valley, including the city of Philadelphia, and variants infecting

vaccinated subjects. We sequenced and analyzed complete viral genomes from 2621 surveillance samples from March 2020 to September 2021 and compared them to genome sequences from 159 vaccine breakthroughs. In the early spring of 2020, all detected variants were of the B.1 and closely related lineages. A mixture of lineages followed, notably including B.1.243 followed by B.1.1.7 (alpha), with other lineages present at lower levels. Later isolations were dominated by B.1.617.2 (delta) and other delta lineages; delta was the exclusive variant present by the last time sampled. To investigate whether any variants appeared preferentially in vaccine breakthroughs, we devised a model based on Bayesian autoregressive moving average logistic multinomial regression to allow rigorous comparison. This revealed that B.1.617.2 (delta) showed three-fold enrichment in vaccine breakthrough cases (odds ratio of 3; 95% credible interval 0.89-11). Viral point substitutions could also be associated with vaccine breakthroughs, notably the N501Y substitution found in the alpha, beta and gamma variants (odds ratio 2.04; 95% credible interval of 1.25-3.18). This study thus provides a detailed picture of viral evolution in the Delaware Valley and a geographically matched analysis of vaccine breakthroughs; it also introduces a rigorous statistical approach to interrogating enrichment of viral variants.

Observations of a Potential Immune Response to Breast Implants After Immunization With COVID-19 Vaccines.

Acute urticarial rash after COVID-19 vaccination containing Polysorbate 80. We present the case of a 48-year-old Caucasian woman, who developed an acute urticarial rash after the second dose of coronavirus disease 2019 (COVID-19) vaccination with Oxford-AstraZeneca. Though the most common cutaneous adverse reactions to vaccines are non-allergic, we believe the rash may represent an immediate hypersensitivity type I reaction against the vaccine excipient Polysorbate 80 (Pol80), configuring an acute allergic urticaria. Skin prick test with Pol80, were performed and resulted positive, confirming the role of Pol80 in eliciting immediate hypersensitivity in our patient. Of note, sensitizing excipients contained in COVID-19 vaccines are commonly used in everyday products and preexisting sensitizations may cause allergic reactions to vaccines, highlighting the need to undergo allergy consultation upon vaccine administration.

A case of acute encephalopathy and non-ST segment elevation myocardial infarction following mRNA-1273 vaccination: possible adverse effect? A 77-year-old man with a past medical history of type 2 diabetes mellitus, peripheral neuropathy, and chronic obstructive pulmonary disease was admitted to the intensive care unit of Bangladesh Medical College Hospital with acute encephalopathy and non-ST segment elevation myocardial infarction (NSTEMI). The patient was on antidiabetic medicine along with H(2) blocker and multivitamins for his existing diseases. The patient's attendant reported that the patient had received his first dose of the Moderna coronavirus disease 2019 (COVID-19) vaccine just 2 days ago. Physical examination revealed that he had a Glasgow Coma Scale of 8/15; a pulse of 106 beats/min; a respiratory rate of 30 breaths/min; oxygen saturation of 80% on room air, which became with 10 L of oxygen and blood pressure of 90/60 mm Hg at the time of admission. During the hospital stay, the patient was treated conservatively with intravenous antibiotics and other necessary medication. Although we have observed the onset of encephalopathy and NSTEMI following COVID vaccination for this patient, we, as healthcare professionals, cannot directly attribute the cause of the complications to the Moderna vaccine without further epidemiological studies with large samples.

Reactogenicity after the first and second doses of BNT162b2 mRNA coronavirus disease vaccine: a single-center study. PURPOSE: This study was conducted to determine differences in adverse events associated with the first and second doses of the BNT162b2 coronavirus disease 2019 vaccine based on the age and sex of recipients. MATERIALS AND METHODS: An online survey on the post-vaccination adverse events of healthcare workers was conducted from March 2021 to April 2021. The

differences in the types of adverse events, including severity, onset time, and duration of symptoms, and how the adverse events were dealt with by the patient were analyzed based on the age and sex. The profiles of adverse events were compared after the first and second vaccination doses. RESULTS: Among the 131 participants who participated in the online survey out of 208 vaccine recipients, 43 and 80 recipients of the BNT162b2 vaccine experienced adverse events after the first and second dose, respectively. No sex-related differences were observed in the profiles of adverse events in vaccinated recipients. The overall frequency of adverse events did not differ based on age after the first dose. After the second dose, the frequency of adverse events, including both local and systemic reactions was significantly higher in the younger age group than in the older age group. CONCLUSION: The BNT162b2 vaccine resulted in a higher frequency of adverse events after the second dose than after the first dose especially in the younger age group; however, no sex-related differences associated with these adverse events were observed.

Post-vaccination COVID-19 deaths: a review of available evidence and recommendations for the global population. Coronavirus disease 2019 (COVID-19) vaccines undergo rigorous testing in clinical trials to meet high safety standards before rollout to the general population. While over 200 million vaccines are administered in more than 50 countries, coincidental adverse events including deaths and related fatalities are temporally associated with the vaccination campaign. Scientific evidence supports the safety of the vaccines and there are studies proving vaccination outweighs any risk or concerns except in rare cases. Reports of these post-vaccination deaths and misleading claims have fueled hesitancy among individuals that need to be addressed. In this review, we summarize epidemiological data related to COVID-19 vaccine deaths, including instances where scientific evidence exists to justify misinterpretation of surveillance data. Rare cases where vaccination-related deaths or serious side effects exist were described. Available evidence does not support making assumptions and conclusions that the vaccines are necessarily responsible for these deaths or adverse events. In addition, we share lessons from these experiences and recommendations to guide the mass population.

A Rare Variant of Guillain-Barre Syndrome Following Ad26.COV2.S Vaccination. Efforts to combat the global pandemic caused by severe acute respiratory syndromeÂ coronavirus 2 (SARS-CoV-2) range from adequate diagnostic testing and contract tracing to vaccination for the prevention of coronavirus disease 2019 (COVID-19). In the United States alone, three vaccinations have been authorized for emergency use (EUA) or approved to prevent COVID-19. The Ad26.COV2.S vaccine by Johnson and Johnson (New Brunswick, New Jersey) is the only adenovirus-based vaccine and deemed relatively effective and safe by the US Food and Drug Administration (FDA) following its clinical trial.Â Since its introduction, the US FDA has placed a warning on the vaccine adverse event reporting system (VAERS) after more than 100 cases of Guillain-Barre Syndrome (GBS) were reported. Herein, we outline the hospital course of a generally healthy 49-year-old female who experienced an axonal form of GBS nine days after receiving the Ad26.COV2.S vaccine.

Acute Myocardial Infarction Within 24Â Hours After COVID-19 Vaccination: Is Kounis Syndrome the Culprit?

Acute HIV infection syndrome mimicking COVID-19 vaccination side effects: a case report. BACKGROUND: Symptoms of primary HIV infection, including fever, rash, and headache, are nonspecific and are often described as flu-like. COVID-19 vaccination side effects, such as fever, which occur in up to 10% of people following COVID-19 vaccination, can make the diagnosis of acute HIV infection even more challenging. CASE PRESENTATION: A 26-year-old man presented with fever and headache following COVID-19 vaccination. The symptoms were initially thought to be vaccine side effects. A diagnostic workup was conducted due to persisting fever and headache >â€‰72Â h following vaccination, and he was diagnosed with Fiebig stage II acute HIV infection, 3Â weeks after

having unprotected anal intercourse with another man. CONCLUSION: Thorough anamnesis is key to estimating the individual risk of primary HIV infection, in patients presenting with flu-like symptoms. Early diagnosis and initiation of antiretroviral therapy is associated with better prognosis and limits transmission of the disease.
Initial clinical manifestation of multiple sclerosis after immunization with the Pfizer-BioNTech COVID-19 vaccine. Vaccine administration may be involved in the development of some central nervous system demyelinating diseases. The COVID-19 vaccine is being administered to the entire population, but to date, little association between vaccination and the risk of developing multiple sclerosis (MS) has been suggested, and only a few case reports have been published. Here, we present a 40-year-old woman who developed cervical myelitis after receiving the COVID-19 vaccine. Myelitis was considered the initial clinical manifestation of MS. Our case suggests a possible link between the vaccination and the clinical MS attack.
Delayed angioedema after administration of the severe acute respiratory syndrome coronavirus 2 messenger RNA vaccine.
Allergic reactions to coronavirus disease 2019 vaccines and addressing vaccine hesitancy: Northwell Health experience. BACKGROUND: Allergic and nonallergic adverse reactions have been reported with global coronavirus disease 2019 (COVID-19) vaccination. It was previously hypothesized that polyethylene glycol (PEG) may be responsible for anaphylactic reactions to messenger RNA (mRNA) COVID-19 vaccines. OBJECTIVE: To report the workflow established at our institution, types, and frequency of adverse reactions to mRNA COVID-19 vaccines in patients presenting for allergy evaluation. METHODS: A COVID-19 vaccine adverse reaction registry was established. We used PEG prick skin testing, followed by PEG challenges in selected cases, to ensure PEG tolerance and encourage completion of COVID-19 vaccination series. RESULTS: A total of 113 patients were included. Most vaccine reactions (86.7%) occurred in women. Anaphylaxis occurred only in women, all of which had a history of allergic disease and two-thirds had asthma. Anaphylaxis rate was 40.6 cases per million. None of the anaphylactic cases developed hypotension, required intubation, or required hospital admission. Systemic allergic symptoms, not fulfilling anaphylaxis criteria, were significantly more common in Pfizer-BioNTech than Moderna-vaccinated patients (PÂ =Â .02). We observed a higher incidence of dermatologic nonurticarial reactions in men (PÂ =Â .004). Among first-dose reactors, 86.7% received and tolerated the second dose. We observed a high rate of false-positive intradermal skin test results and frequent subjective symptoms with oral PEG challenge. CONCLUSION: Intradermal PEG testing has limited utility in evaluating anaphylaxis to mRNA vaccines. Most severe postvaccination allergic symptoms are not caused by hypersensitivity to PEG. Most people with reaction to the initial mRNA vaccine can be safely revaccinated. Patients with anaphylaxis to COVID-19 vaccines benefit from physician-observed vaccination.
Regarding: COVID-19 vaccination during pregnancy: coverage and safety.
Letter to the editor regarding the article ''Patil S, Patil A. Systemic lupus erythematosus after COVID-19 vaccination: A case report. J Cosmet Dermatol. 2021 Aug 21. 10.1111/jocd.14386".
Safety and potency of BIV1-CovIran inactivated vaccine candidate for SARS-CoV-2: A preclinical study. The development of effective and safe COVID-19 vaccines is a major move forward in our global effort to control the SARS-CoV-2 pandemic. The aims of this study were (1) to develop an inactivated whole-virus SARS-CoV-2 candidate vaccine named BIV1-CovIran and (2) to determine the safety and potency of BIV1-CovIran inactivated vaccine candidate against SARS-CoV-2. Infectious virus was isolated from nasopharyngeal swab specimen and propagated in Vero cells with clear cytopathic effects in a biosafety level-3 facility using the World Health Organization's laboratory biosafety guidance related to COVID-19. After characterisation of viral seed stocks, the virus working seed was scaled-up in Vero cells. After chemical inactivation and purification, it was formulated with alum

adjuvant. Finally, different animal species were used to determine the toxicity and immunogenicity of the vaccine candidate. The study showed the safety profile in studied animals including guinea pig, rabbit, mice and monkeys. Immunisation at two different doses (3 or 5Â Î¼g per dose) elicited a high level of SARS-CoV-2 specific and neutralising antibodies in mice, rabbits and nonhuman primates. Rhesus macaques were immunised with the two-dose schedule of 5 or 3Â Î¼g of the BIV1-CovIran vaccine and showed highly efficient protection against 10(4) TCID50 of SARS-CoV-2 intratracheal challenge compared with the control group. These results highlight the BIV1-CovIran vaccine as a potential candidate to induce a strong and potent immune response that may be a promising and feasible vaccine to protect against SARS-CoV-2 infection.

Safety of SARS-CoV-2 vaccines in psoriatic patients treated with biologics: A real life experience. Vaccination is the most effective method to prevent and control the SARS-CoV-2 infection and biologics are not considered a contraindication for vaccination. The burning question is that safety data are lacking since patients taking drugs affecting the immune system were excluded from clinical trials leading to vaccine approbation. Moreover, it seems that vaccination could worsen psoriasis. We conducted a survey to investigate the safety of SARS-CoV-2 vaccines in psoriatic patients treated with biologics. A total of 150 patients with stable plaque psoriasis treated with biologics for at least 2Â months were evaluated in a 3â€‰months period. Fifty patients (22 F/28 M; age: 33-83â€‰years) only underwent the first and second doses of SARS-CoV-2 vaccines. All patients discontinued their biological agents 10â€‰days before and 10â€‰days after each dose of vaccine. Of these, 24 patients were treated with anti-TNF, 14 with anti-IL17, 7 with anti-IL12-23, and 5 with anti-IL23. After the vaccines, all patients were evaluated at day 2, 7, and 14 for local and/or systemic side effects and/or adverse drug reactions to SARS-CoV-2 vaccines. None of the patients experienced any side effects or a psoriatic flare. Only one patient treated with infliximab biosimilar referred an exacerbation of psoriasis after vaccine. The remaining 100 patients reported that they did not get the vaccine yet. Our preliminary data confirm that SARS-CoV-2 mRNA vaccines are safe for patients with chronic plaque psoriasis treated with biologics and did not trigger psoriasis, although these data should be validated in a larger population. We encourage an early SARS-CoV-2 vaccines administration in all psoriatic patients on immunosuppressant drugs.

Association of Self-reported High-Risk Allergy History With Allergy Symptoms After COVID-19 Vaccination. IMPORTANCE: Allergic history in individuals with confirmed anaphylaxis to a messenger RNA (mRNA) COVID-19 vaccine is common. However, the risk factors for allergy symptoms after receiving the vaccine are unknown. OBJECTIVE: To assess the association between self-reported history of high-risk allergy and self-reported allergic reactions after mRNA COVID-19 vaccination of health care employees. DESIGN, SETTING, AND PARTICIPANTS: This cohort study obtained demographic, medical, and vaccine administration data of employees of Mass General Brigham from the institutional electronic health record. Employees who received at least 1 dose of an mRNA COVID-19 vaccine between December 14, 2020, and February 1, 2021, and who completed at least 1 postvaccination symptom survey in the 3 days after vaccination were included. EXPOSURES: Self-reported history of high-risk allergy, defined as a previous severe allergic reaction to a vaccine, an injectable medication, or other allergen. MAIN OUTCOMES AND MEASURES: The primary outcome was 1 or more self-reported allergic reactions in the first 3 days after dose 1 or dose 2 of an mRNA COVID-19 vaccine. Multivariable log binomial regression was used to assess the association between allergic reactions and high-risk allergy status. RESULTS: A total of 52â€¯998 health care employees (mean [SD] age, 42 [14] years; 38â€¯167 women [72.0%]) were included in the cohort, of whom 51â€¯706 (97.6%) received 2 doses of an mRNA COVID-19 vaccine and 474 (0.9%) reported a history of high-risk allergy. Individuals with vs without a history of high-risk allergy reported more allergic reactions after receiving dose 1 or 2 of the vaccine (11.6% [nâ€‰=â€‰55] vs 4.7%

[nâ€‰=â€‰2461]). In the adjusted model, a history of high-risk allergy was associated with an increased risk of allergic reactions (adjusted relative risk [aRR], 2.46; 95% CI, 1.92-3.16), with risk being highest for hives (aRR, 3.81; 95% CI, 2.33-6.22) and angioedema (aRR, 4.36; 95% CI, 2.52-7.54). CONCLUSIONS AND RELEVANCE: This cohort study found that self-reported history of high-risk allergy was associated with an increased risk of self-reported allergic reactions within 3 days of mRNA COVID-19 vaccination. However, reported allergy symptoms did not impede the completion of the 2-dose vaccine protocol among a cohort of eligible health care employees, supporting the overall safety of mRNA COVID-19 vaccine.

COVID-19 Vaccine-Associated Thrombosis With Thrombocytopenia Syndrome (TTS): A Systematic Review and Post Hoc Analysis. BACKGROUND: A new clinical syndrome has been recognized following the COVID-19 vaccine, termed thrombosis with thrombocytopenia syndrome (TTS). The following systematic review focuses on extrapolating thrombotic risk factors, clinical manifestations, and outcomes of patients diagnosed with TTS following the COVID-19 vaccine. METHODS: We utilized the World Health Organization's criteria for a confirmed and probable case of TTS following COVID-19 vaccination and conducted a systematic review and posthoc analysis using the PRISMA 2020 statement. Data analysis was conducted using SPSS V25 for factors associated with mortality, including age, gender, anti-PF4/heparin antibodies, platelet nadir, D-dimer peak, time to event diagnosis, arterial or venous thrombi. RESULTS: Of the 175 studies identified, a total of 25 studies with 69 patients were included in this systematic review and post hoc analysis. Platelet nadir (Pâ€‰<â€‰.001), arterial or venous thrombi (Ï‡2â€‰=â€‰41.911, Pâ€‰=â€‰.05), and chronic medical conditions (Ï‡2â€‰=â€‰25.507, Pâ€‰=â€‰.041) were statistically associated with death. The ROC curve analysis yielded D-dimer (AUCâ€‰=â€‰.646) and platelet nadir (AUCâ€‰=â€‰.604) as excellent models for death prediction. CONCLUSION: Adenoviral COVID-19 vaccines have been shown to trigger TTS, however, reports of patients having received mRNA COVID-19 vaccines are also present. Healthcare providers are recommended to maintain a high degree of suspicion among individuals who have received the COVID-19 vaccine within the last 4 weeks.

Clinical Outcomes of Adult Patients Hospitalized with COVID-19 after Vaccination. Vaccination remains the most effective way to prevent COVID-19. The aim of the present study was to assess the incidence of COVID-19 hospitalizations after vaccination, as well as the effect of prior vaccination on hospitalization outcomes among patients with COVID-19. We analyzed and compared all consecutive patients, with or without prior vaccination, who were admitted to our hospital network due to COVID-19 from January to April 2021. Our primary outcome was to identify and describe cases of COVID-19 hospitalized after vaccination. We also utilized a multivariate logistic regression model to investigate the association of previous vaccination with hospitalization outcomes. We identified 915 consecutive patients hospitalized due to COVID-19 with 91/915 (10%) previously vaccinated with at least one dose of a COVID-19 vaccine. Utilizing our multivariate logistic regression model, we found that prior vaccination, regardless of the number of doses or days since vaccination, was associated with decreased mortality (aOR 0.44, 95% CI: 0.20-0.98) when compared to unvaccinated individuals. Our study showed that COVID-19 related hospitalization after vaccination may occur to a small percentage of patients, mainly those who are partially vaccinated. However, our findings underline that prior vaccination, even when partial, is associated with a decreased risk of death. Ongoing vaccination efforts should remain an absolute priority.

Side Effects Following Administration of the First Dose of Oxford-AstraZeneca's Covishield Vaccine in Bangladesh: A Cross-Sectional Study. In response to the raging COVID-19 pandemic, Bangladesh started its vaccine administration in early 2021; however, due to the rapid development and launch of the vaccines in the market, many people had concerns regarding the safety of these vaccines. The purpose of this study was to evaluate the side effects that were experienced by the Bangladeshi

residents after receiving the first dose of the Oxford-AstraZeneca's Covishield vaccine (ChAdOx1nCoV-19). The study was conducted using both online and printed questionnaires and the data were analysed using SPSS. The results included the responses of 474 vaccine recipients from March-April 2021. Pain at the site of injection, fever, myalgia, fatigue and headache were the most commonly reported symptoms, and the overall side effects were found to be significantly more prevalent in the younger population (p â‰¤ 0.05). These findings were consistent with the results indicated by the clinical trial of ChAdOx1nCoV-19. Logistic regression analysis further revealed that compared to people aged 70 years or above, the incidence of reported side effects was significantly higher in people aged 18-30 years (odds ratio (OR) = 8.56), 31-40 years, (OR = 5.05), 41-50 years (OR = 4.08), 51-60 years (OR = 3.77) and 61-70 years (OR = 3.67). In addition, a significantly higher percentage of female participants suffered from post-vaccination side effects compared to males (OR = 1.51). It was concluded that the Covishield vaccine was well-tolerated among people of different age groups. Nevertheless, further long-term follow-up study with a larger sample size is warranted to establish the long-term safety of the COVID-19 vaccine.
Single-Center Clinico-Pathological Case Study of 19 Patients with Cutaneous Adverse Reactions Following COVID-19 Vaccines. (1) Background: Coronavirus disease 2019 (COVID-19) vaccines are currently employed on a population-wide scale in most countries worldwide. Data about unusual cutaneous adverse drug reactions (ADR) are scant, though. (2) Methods: We retrospectively analyzed moderate to severe vaccine-related ADR in the Department of Dermatology and Allergy of the University Hospital Bonn between May to June 2021 and analyzed related skin biopsies. (3) Results: As a specialized dermatological academic center, we encountered a total of n = 19 clinically and pathologically heterogeneous cutaneous ADR with a female predominance. Delayed cutaneous ADR occurred as late as 30 days after vaccination. The majority of ADR were mild, though a few patients required systemic treatment (antihistamines, glucocorticosteroids). (4) Conclusions: The clinico-pathological spectrum of cutaneous side effects with COVID-19 vaccines is wide; however, the benefits outweigh the risks by far. More dermatopathological studies on cutaneous ADR not limited to COVID-19 vaccines are desirable to enable a better understanding of underlying pathophysiological mechanisms.
Surviving COVID after vaccination.
Acral haemorrhage after the second dose administration of SARS-CoV-2 vaccine. A post-vaccinal reaction?
Neurological complications after first dose of COVID-19 vaccines and SARS-CoV-2 infection. Emerging reports of rare neurological complications associated with COVID-19 infection and vaccinations are leading to regulatory, clinical and public health concerns. We undertook a self-controlled case series study to investigate hospital admissions from neurological complications in the 28â€‰days after a first dose of ChAdOx1nCoV-19 (nâ€‰=â€‰20,417,752) or BNT162b2 (nâ€‰=â€‰12,134,782), and after a SARS-CoV-2-positive test (nâ€‰=â€‰2,005,280). There was an increased risk of Guillain-BarrÃ© syndrome (incidence rate ratio (IRR), 2.90; 95% confidence interval (CI): 2.15-3.92 at 15-21â€‰days after vaccination) and Bell's palsy (IRR, 1.29; 95% CI: 1.08-1.56 at 15-21â€‰days) with ChAdOx1nCoV-19. There was an increased risk of hemorrhagic stroke (IRR, 1.38; 95% CI: 1.12-1.71 at 15-21â€‰days) with BNT162b2. An independent Scottish cohort provided further support for the association between ChAdOx1nCoV and Guillain-BarrÃ© syndrome (IRR, 2.32; 95% CI: 1.08-5.02 at 1-28â€‰days). There was a substantially higher risk of all neurological outcomes in the 28â€‰days after a positive SARS-CoV-2 test including Guillain-BarrÃ© syndrome (IRR, 5.25; 95% CI: 3.00-9.18). Overall, we estimated 38 excess cases of Guillain-BarrÃ© syndrome per 10â€‰million people receiving ChAdOx1nCoV-19 and 145 excess cases per 10â€‰million people after a positive SARS-CoV-2 test. In summary, although we find an increased risk of neurological

complications in those who received COVID-19 vaccines, the risk of these complications is greater following a positive SARS-CoV-2 test.
Comprehensive investigations revealed consistent pathophysiological alterations after vaccination with COVID-19 vaccines. Large-scale COVID-19 vaccinations are currently underway in many countries in response to the COVID-19 pandemic. Here, we report, besides generation of neutralizing antibodies, consistent alterations in hemoglobin A1c, serum sodium and potassium levels, coagulation profiles, and renal functions in healthy volunteers after vaccination with an inactivated SARS-CoV-2 vaccine. Similar changes had also been reported in COVID-19 patients, suggesting that vaccination mimicked an infection. Single-cell mRNA sequencing (scRNA-seq) of peripheral blood mononuclear cells (PBMCs) before and 28 days after the first inoculation also revealed consistent alterations in gene expression of many different immune cell types. Reduction of CD8(+) T cells and increase in classic monocyte contents were exemplary. Moreover, scRNA-seq revealed increased NF-ÎºB signaling and reduced type I interferon responses, which were confirmed by biological assays and also had been reported to occur after SARS-CoV-2 infection with aggravating symptoms. Altogether, our study recommends additional caution when vaccinating people with pre-existing clinical conditions, including diabetes, electrolyte imbalances, renal dysfunction, and coagulation disorders.
SARS-CoV-2 Spike Impairs DNA Damage Repair and Inhibits V(D)J Recombination In Vitro. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has led to the coronavirus disease 2019 (COVID-19) pandemic, severely affecting public health and the global economy. Adaptive immunity plays a crucial role in fighting against SARS-CoV-2 infection and directly influences the clinical outcomes of patients. Clinical studies have indicated that patients with severe COVID-19 exhibit delayed and weak adaptive immune responses; however, the mechanism by which SARS-CoV-2 impedes adaptive immunity remains unclear. Here, by using an in vitro cell line, we report that the SARS-CoV-2 spike protein significantly inhibits DNA damage repair, which is required for effective V(D)J recombination in adaptive immunity. Mechanistically, we found that the spike protein localizes in the nucleus and inhibits DNA damage repair by impeding key DNA repair protein BRCA1 and 53BP1 recruitment to the damage site. Our findings reveal a potential molecular mechanism by which the spike protein might impede adaptive immunity and underscore the potential side effects of full-length spike-based vaccines.
The COVID-19 mRNA BNT163b2 Vaccine Was Well Tolerated and Highly Immunogenic in Young Adults in Long Follow-Up after Haematopoietic Stem Cell Transplantation. Sixty five patients (18-31 years) who had received allogeneic haematopoietic stem cell transplantation (3-27 years from HSCT) were evaluated for the tolerance and immunogenicity of the COVID-19 mRNA BNT163b2 vaccine. Methods: Patients were vaccinated with two doses at 5 weeks interval. After each dose, patients completed a survey concerning adverse events (AE) and anti-SARS-CoV-2 IgG antibodies were measured before the first vaccine dose (1stVD) and 14-21 days after the second dose (2ndVD). AE reported after 1stVD and 2ndVD, respectively were: fever 0%, 1.7%; fatigue 15.4%, 25.8%; headache 15.4%, 24.1%; chills 6.1%, 12.0%; muscle pain 15.4%, 24.1%; joint pain 3.0%, 6.9%; nausea 6.1%, 6.9%; pain at injection site 30.7%, 34.4%; swelling 3.0%, 10.3%; redness 0, 3.4%; pruritus 0, 5.2%; and axillary lymphadenopathy 3.0%, 1.7%. After 2ndVD, 96.5% patients were positive for anti-SARS-CoV-2 (GMC 3290.94 BAU/mL). No correlation presented between the antibody titer and symptoms of chronic Graft-versus-Host disease, total IgG, lymphocyte CD4+, or AE. Significantly higher titers were observed in COVID-19 convalescents, and inverse correlation ($R(2) = -0.0925$, $p = 0.02$) between the time from HSCT and titers after 2ndVD was present. Conclusions: The young adults after HSCT tolerate the COVID-19 mRNA vaccine well and show immunologic response.
Associations between Allelic Variants of the Human IgH 3' Regulatory Region 1 and the Immune Response to BNT162b2 mRNA Vaccine. The escalation of Coronavirus disease 2019 (COVID-19)

has required the development of safe and effective vaccines against the severe acute respiratory syndrome coronavirus 2-associated (SARS-CoV-2), which is the causative agent of the disease. Here, we determined the levels of antibodies, antigen-specific B cells, against a recombinant GFP-tagged SARS-CoV-2 spike (S) protein and total T and NK cell subsets in subjects up to 20 days after the injection of the BNT162b2 (Pfizer-BioNTech) vaccine using a combined approach of serological and flow cytometry analyses. In former COVID-19 patients and highly responsive individuals, a significant increase of antibody production was detected, simultaneous with an expansion of antigen-specific B cell response and the total number of NK-T cells. Additionally, through a genetic screening of a specific polymorphic region internal to the 3' regulatory region 1 (3'RR1) of human immunoglobulin constant-gene (IgH) locus, we identified different single-nucleotide polymorphic (SNP) variants associated with either highly or lowly responsive subjects. Taken together, these results suggest that favorable genetic backgrounds and immune profiles support the progression of an effective response to BNT162b2 vaccination.

Differences in Sources of Information, Risk Perception, and Cognitive Appraisals between People with Various Latent Classes of Motivation to Get Vaccinated against COVID-19 and Previous Seasonal Influenza Vaccination: Facebook Survey Study with Latent Profile Analysis in Taiwan. The present study aimed (1) to identify distinct latent classes of motivation to get vaccinated against coronavirus disease 2019 (COVID-19) and previous seasonal influenza vaccination among people in Taiwan and (2) to examine the roles of sources of information, risk perception, and cognitive appraisals of vaccination against COVID-19 in these classes. We recruited 1047 participants through a Facebook advertisement. The participants' motivation to get vaccinated against COVID-19, previous seasonal influenza vaccination, sources of information about COVID-19 vaccination, risk perception of COVID-19, and cognitive appraisals of vaccination against COVID-19 were determined. We examined the participants' motivation for COVID-19 vaccination and previous seasonal influenza vaccination through latent profile analysis. Four latent classes of motivation were identified: participants with high motivation for COVID-19 vaccination and high seasonal influenza vaccination, those with high motivation for COVID-19 vaccination but low seasonal influenza vaccination, those with low motivation for COVID-19 vaccination but high seasonal influenza vaccination, and those with low motivation for COVID-19 vaccination and low seasonal influenza vaccination. Compared with participants in the latent class of high motivation for COVID-19 vaccination and high seasonal influenza vaccination, those in the other three latent classes had lower levels of positive appraisals of COVID-19 vaccination; participants in the latent class of low motivation for COVID-19 vaccination and low seasonal influenza vaccination had lower risk perception of COVID-19 and were also less likely to obtain information about COVID-19 vaccination from the internet, friends, and family members. The various motivations and behaviors for vaccination, sources of information, risk perception, and cognitive appraisals of vaccination against COVID-19 should be considered in intervention programs aiming to increase people's motivation to get vaccinated against COVID-19.

Fear of Influenza Resurgence amid COVID-19 Pandemic: Need for Effective Flu Vaccine Still Exists. As influenza season was approaching in 2020, public health officials feared that influenza would worsen the COVID-19 situation [...].

Shedding the Light on Post-Vaccine Myocarditis and Pericarditis in COVID-19 and Non-COVID-19 Vaccine Recipients. Myocarditis and pericarditis have been linked recently to COVID-19 vaccines without exploring the underlying mechanisms, or compared to cardiac adverse events post-non-COVID-19 vaccines. We introduce an informatics approach to study post-vaccine adverse events on the systems biology level to aid the prioritization of effective preventive measures and mechanism-based pharmacotherapy by integrating the analysis of adverse event reports from the Vaccine Adverse Event Reporting System (VAERS) with systems biology methods. Our results indicated that

post-vaccine myocarditis and pericarditis were associated most frequently with mRNA COVID-19 vaccines followed by live or live-attenuated non-COVID-19 vaccines such as smallpox and anthrax vaccines. The frequencies of cardiac adverse events were affected by vaccine, vaccine type, vaccine dose, sex, and age of the vaccinated individuals. Systems biology results suggested a central role of interferon-gamma (INF-gamma) in the biological processes leading to cardiac adverse events, by impacting MAPK and JAK-STAT signaling pathways. We suggest that increasing the time interval between vaccine doses minimizes the risks of developing inflammatory adverse reactions. We also propose glucocorticoids as preferred treatments based on system biology evidence. Our informatics workflow provides an invaluable tool to study post-vaccine adverse events on the systems biology level to suggest effective mechanism-based pharmacotherapy and/or suitable preventive measures.

Course and Lethality of SARS-CoV-2 Epidemic in Nursing Homes after Vaccination in Florence, Italy. Evidence on the effectiveness of SARS-CoV-2 vaccines in nursing home (NHs) residents is limited. We examined the impact of the BNT162b2 mRNA SARS-CoV-2 vaccine on the course of the epidemic in NHs in the Florence Health District, Italy, before and after vaccination. Moreover, we assessed survival and hospitalization by vaccination status in SARS-CoV-2-positive cases occurring during the post-vaccination period. We calculated the weekly infection rates during the pre-vaccination (1 October-26 December 2020) and post-vaccination period (27 December 2020-31 March 2021). Cox analysis was used to analyze survival by vaccination status. The study involved 3730 residents (mean age 84, 69% female). Weekly infection rates fluctuated during the pre-vaccination period (1.8%-6.5%) and dropped to zero during the post-vaccination period. Nine unvaccinated (UN), 56 partially vaccinated (PV) and 35 fully vaccinated (FV) residents tested SARS-CoV-2+ during the post-vaccination period. FV showed significantly lower hospitalization and mortality rates than PV and UV (hospitalization: FV 3%, PV 14%, UV 33%; mortality: FV 6%, PV 18%, UV 56%). The death risk was 84% and 96% lower in PV (HR 0.157, 95%CI 0.049-0.491) and FV (HR 0.037, 95%CI 0.006-0.223) versus UV. SARS-CoV-2 vaccination was followed by a marked decline in infection rates and was associated with lower morbidity and mortality among infected NH residents.

Association between Immunoglobulin G Levels and Adverse Effects Following Vaccination with the BNT162b2 Vaccine among Japanese Healthcare Workers. The purpose of the study was to assess the association between the amount of immunoglobulin G (IgG) and the duration of adverse effects of COVID-19 vaccinations in the Japanese population. This cross-sectional study was conducted from April 2020 to August 2021 among workers at a community hospital. All participants received two doses of the BNT162b2 vaccine (Pfizer-BioNTech) in March and April 2021. Vaccine side effects were measured using a self-administered questionnaire. Serum anti-SARS-CoV-2 IgG was measured 3 months after vaccination. There was a total of 338 participants (mean age: 44.7 years). The incidence of adverse reactions after vaccination was higher in women. Adverse reactions associated with higher IgG levels included: erythema at the injection site after the first dose; induration and inflammation at the injection site; and systemic symptoms, e.g., fever and headache after the second dose. IgG levels were higher in younger participants. These findings could mitigate fears regarding the mild adverse effects of the COVID-19 vaccine and encourage uptake of the BNT162b2 vaccine.

Rapidly Declining SARS-CoV-2 Antibody Titers within 4 Months after BNT162b2 Vaccination. The efficacy and safety of the BNT162b2 vaccine are known, but antibodies are expected to decrease over time after vaccination. We collected blood samples from 104 fully vaccinated health care workers at 3 and 5 weeks after first vaccination and 4 months after second vaccination. Antibody titers and neutralizing antibodies were measured. In our study, both antibody titers and neutralizing antibodies increased significantly at 5 weeks after first vaccination but decreased rapidly at 4 months after second vaccination. Additionally, the results showed a significant decrease regardless of gender or age. Further studies are needed to help determine the interval of SARS-CoV-2 vaccinations.

SARS-CoV-2 Neutralizing Antibody Levels Post COVID-19 Vaccination Based on ELISA Method-A Small Real-World Sample Exploration. This study investigated the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) neutralizing antibodies following inoculation with the coronavirus disease (COVID-19) vaccine. From June to July 2021, 127 participants who had completed COVID-19 vaccination (inactivated SARS-CoV-2 vaccine, 64; CoronaVac, 61; CanSino, 2) were recruited and tested using SARS-CoV-2 neutralizing antibody kits. The positive detection rate (inhibition of neutralizing antibodies â‰¥ 30%) was calculated and stratified according to population characteristics and inoculation time. The positive rate of neutralizing antibody was 47.22% (17/36) in men and 53.85% (49/91) in women, and 54.55% (24/44) in BMI â‰¥ 24 and 50.60% (42/83) in BMI < 24. Age was stratified as 20-29, 30-39, 40-49, and â‰¥50; positive detection rates of SARS-CoV-2 neutralizing antibodies were observed in 60.00% (24/40), 50.00% (21/42), 48.39% (15/31), and 42.86% (6/14), respectively, but with no significant difference (x(2) = 1.724, p = 0.632). Among 127 vaccinated participants, 66 (51.97%) were positive. The positive detection rate was 63.93% (39/61) with CoronaVac and 42.19% (27/64) with the inactivated SARS-CoV-2 vaccine (significance x(2) = 5.927, p = 0.015). Multivariate analysis revealed a significant difference in vaccination times, with average vaccination weeks in the positive and negative groups of 11.57 Â± 6.48 and 17.87 Â± 9.17, respectively (t= -4.501, p < 0.001). The positive neutralizing antibody rate was 100.00%, 60.00%, 58.33%, 55.56%, 43.14%, 28.57%, and 0.00% at 2-4, 5-8, 9-12, 13-16,17-20, 21-24, and >24 weeks, respectively (x(2) = 18.030, p = 0.006). Neutralizing antibodies were detected after COVID-19 inoculation, with differences relating to inoculation timing. This study provides a reference for vaccine evaluation and follow-up immunization strengthening.

Reported COVID-19 Vaccination Coverage and Associated Factors among Members of Athens Medical Association: Results from a Cross-Sectional Study. There are limited data on the prevalence and determinants of COVID-19 vaccination coverage among physicians. A cross-sectional, questionnaire-based, online study was conducted among the members of the Athens Medical Association (I.S.A.) over the period 25 February to 13 March 2021. All members of I.S.A. were invited to participate in the anonymous online survey. A structured, anonymous questionnaire was used. Overall, 1993 physicians participated in the survey. The reported vaccination coverage was 85.3%. The main reasons of no vaccination were pending vaccination appointment followed by safety concerns. Participants being informed about the COVID-19 vaccines by social media resulted in lower COVID-19 vaccination coverage than health workers being informed by other sources. Logistic regression analysis demonstrated that no fear over COVID-19 vaccination-related side effects, history of influenza vaccination for flu season 2020-2021, and the perception that the information on COVID-19 vaccination from the national public health authorities is reliable, were independent factors of reported COVID-19 vaccination coverage. Our results demonstrate a considerable improvement of the COVID-19 vaccination uptake among Greek physicians. The finding that participants reported high reliability of the information related to COVID-19 vaccination provided by the Greek public health authorities is an opportunity which should be broadly exploited by policymakers in order to combat vaccination hesitancy, and further improve COVID-19 vaccination uptake and coverage among physicians/HCWs, and the general population.

Longitudinal Humoral Responses after COVID-19 Vaccination in Peritoneal and Hemodialysis Patients over Twelve Weeks. It has been demonstrated that patients on hemo- or peritoneal dialysis are particularly susceptible to SARS-CoV-2 infection and impaired seroconversion compared to healthy controls. Follow-up data on vaccination response in dialysis patients is limited but is greatly needed to individualize and guide (booster) vaccination strategies. In this prospective, multicenter study we measured anti-spike S1 and neutralizing antibodies in 124 hemodialysis patients, 41 peritoneal dialysis patients, and 20 age- and sex-matched healthy controls over 12 weeks after homologous

BNT162b2 vaccination. Compared to healthy controls, both hemodialysis and peritoneal dialysis patients had lower anti-S1 IgG antibodies (median (IQR) 7.0 (2.8-24.3) and 21.8 (5.8-103.9) versus 134.9 (23.8-283.6), respectively; $p < 0.001$ and $p < 0.05$) and a reduced SARS-CoV-2 spike protein-ACE2 binding inhibition caused by vaccine-induced antibodies (median (IQR) 56% (40-81) and 77% (52-89) versus 96% (90-98), respectively; $p < 0.001$ and $p < 0.01$) three weeks after the second vaccination. Twelve weeks after the second vaccination, the spike protein-ACE2 binding inhibition significantly decreased to a median (IQR) of 45% (31-60) in hemodialysis patients and 55% (36-78) in peritoneal dialysis patients, respectively ($p < 0.001$ and $p < 0.05$). Peritoneal dialysis patients mounted higher antibody levels compared with hemodialysis patients at all time points during the 12-week follow-up. Individual booster vaccinations in high-risk individuals without seroconversion or rapidly waning neutralizing antibody levels are required and further data on the neutralization of emerging variants of concern in these patients are urgently needed.

Antibody Persistence 6 Months Post-Vaccination with BNT162b2 among Health Care Workers. BACKGROUND: We present immunogenicity data 6 months after the first dose of BNT162b2 in correlation with age, gender, BMI, comorbidities and previous SARS-CoV-2 infection. METHODS: An immunogenicity evaluation was carried out among health care workers (HCW) vaccinated at the Istituti Fisioterapici Ospitalieri (IFO). All HCW were asked to be vaccine by the national vaccine campaign at the beginning of 2021. Serum samples were collected on day 1 just prior to the first dose of the vaccine and on day 21 just prior to the second vaccination dose. Thereafter sera samples were collected 28, 49, 84 and 168 days after the first dose of BNT162b2. Quantitative measurement of IgG antibodies against S1/S2 antigens of SARS-CoV-2 was performed with a commercial chemiluminescent immunoassay. RESULTS: Two hundred seventy-four HWCs were analyzed, 175 women (63.9%) and 99 men (36.1%). The maximum antibody geometric mean concentration (AbGMC) was reached at T2 (299.89 AU/mL; 95% CI: 263.53-339.52) with a significant increase compared to baseline ($p < 0.0001$). Thereafter, a progressive decrease was observed. At T5, a median decrease of 59.6% in COVID-19 negative, and of 67.8% in COVID-19 positive individuals were identified with respect to the highest antibody response. At T1, age and previous COVID-19 were associated with differences in antibody response, while at T2 and T3 differences in immune response were associated with age, gender and previous COVID-19. At T4 and T5, only COVID-19 positive participants demonstrated a greater antibody response, whereas no other variables seemed to influence antibody levels. CONCLUSIONS: Overall our study clearly shows antibody persistence at 6 months, albeit with a certain decline. Thus, the use of this vaccine in addressing the COVID-19 pandemic is supported by our results that in turn open debate about the need for further boosts.

Weak Cross-Lineage Neutralization by Anti SARS-CoV-2 Spike Antibodies after Natural Infection or Vaccination Is Rescued by Repeated Immunological Stimulation. After over one year of evolution, through billions of infections in humans, SARS-CoV-2 has evolved into a score of slightly divergent lineages. A few different amino acids in the spike proteins of these lineages can hamper both natural immunity against reinfection, and vaccine efficacy. In this study, the in vitro neutralizing potency of sera from convalescent COVID-19 patients and vaccinated subjects was analyzed against six different SARS-CoV-2 lineages, including the latest B.1.617.2 (or Delta variant), in order to assess the cross-neutralization by anti-spike antibodies. After both single dose vaccination, or natural infection, the neutralizing activity was low and fully effective only against the original lineage, while a double dose or a single dose of vaccine, even one year after natural infection, boosted the cross-neutralizing activity against different lineages. Neither binding, nor the neutralizing activity of sera after vaccination, could predict vaccine failure, underlining the need for additional immunological markers. This study points at the importance of the anamnestic response and repeated vaccine stimulations to elicit a reasonable cross-lineage neutralizing antibody response.

COVID-19 Vaccination in Patients with Myasthenia Gravis: A Single-Center Case Series. In this study, we report the safety of coronavirus disease 2019 (COVID-19) vaccine in patients with myasthenia gravis (MG). Patients who were vaccinated against COVID-19 were included. Demographics, clinical characteristics, medications, and vaccination information were collected. The main observation outcome is the worsening of MG symptoms within 4 weeks following COVID-19 vaccination. A total of 22 patients with MG vaccinated for COVID-19 were included. Ten (45.5%) patients had ocular MG (OMG), and 12 (55.5%) patients had generalized MG (GMG). Six (27.3%) patients were female, and the mean (SD) onset age was 45.4 (11.8) years. Nineteen (86.4%) patients were seropositive for acetylcholine receptors (AChR) antibody. Seven (31.8%) patients underwent thymectomy, and four of them confirmed thymoma pathologically. Twenty-one patients were administrated with inactivated vaccines, and the remaining one was administrated with recombinant subunit vaccine. Twenty (90.9%) patients did not present MG symptom worsening within 4 weeks of COVID-19 vaccination, and two (9.1%) patients reported slight symptom worsening but resolved quickly within a few days. Our findings suggest inactivated COVID-19 vaccines might be safe in MG patients with Myasthenia Gravis Foundation of America (MGFA) classification I to II, supporting the recommendation to promote vaccination for MG patients during the still expanding COVID-19 pandemic.

A Single Dose of a Hybrid hAdV5-Based Anti-COVID-19 Vaccine Induces a Long-Lasting Immune Response and Broad Coverage against VOC. Most approved vaccines against COVID-19 have to be administered in a prime/boost regimen. We engineered a novel vaccine based on a chimeric human adenovirus 5 (hAdV5) vector. The vaccine (named CoroVaxG.3) is based on three pillars: (i) high expression of Spike to enhance its immunodominance by using a potent promoter and an mRNA stabilizer; (ii) enhanced infection of muscle and dendritic cells by replacing the fiber knob domain of hAdV5 by hAdV3; (iii) use of Spike stabilized in a prefusion conformation. The transduction with CoroVaxG.3-expressing Spike (D614G) dramatically enhanced the Spike expression in human muscle cells, monocytes and dendritic cells compared to CoroVaxG.5 that expressed the native fiber knob domain. A single dose of CoroVaxG.3 induced a potent humoral immunity with a balanced Th1/Th2 ratio and potent T-cell immunity, both lasting for at least 5 months. Sera from CoroVaxG.3-vaccinated mice was able to neutralize pseudoviruses expressing B.1 (wild type D614G), B.1.117 (alpha), P.1 (gamma) and B.1.617.2 (delta) Spikes, as well as an authentic P.1 SARS-CoV-2 isolate. Neutralizing antibodies did not wane even after 5 months, making this kind of vaccine a likely candidate to enter clinical trials.

A Case of Exacerbation of Subclinical Hyperthyroidism after First Administration of BNT162b2 mRNA COVID-19 Vaccine. COVID-19 vaccines are the most critical measure for controlling the COVID-19 pandemic; however, we have little information on their complications. We experienced a case of a patient who developed hyperthyroidism complicated with atrial fibrillation and heart failure on the sixth day after the first dose of COVID-19 vaccination. This case report shows the importance of considering hyperthyroidism as a possible complication after COVID-19 vaccination.

Adverse Events Following Immunization Associated with the First and Second Doses of the ChAdOx1 nCoV-19 Vaccine among Healthcare Workers in Korea. As worldwide large-scale inoculation of novel vaccines is on the way, the importance of real-world data on safety cannot be overemphasized. We aimed to investigate the adverse events following immunization (AEFIs) associated with the ChAdOx1 nCoV-19 vaccine among healthcare workers (HCWs). We investigated the systemic and local adverse events reported within seven days following the first and second doses of vaccination, using the mobile vaccine adverse events reporting system (MVAERS) developed by our hospital. The response rates were 71.8% (994/1384) and 52.9% (727/1375) after the first and second doses, respectively. The most commonly reported AEFIs were tenderness and pain at the injection site and

fatigue after the first and second doses. In comparison to the first dose, the incidence and severity of AEFIs were lower following the second dose. Since the Korean government does not recommend the ChAdOx1 nCoV-19 vaccination for those under 30 years of age, with greater risk than benefit, we additionally compared the AEFIs of age groups under and above 30 years of age. The overall incidence of AEFIs was similar in both the under and over 30 age groups. In conclusion, AEFIs associated with the ChAdOx1 nCoV-19 vaccine were found to be tolerable, and AEFIs associated with the second dose were less common and severe compared to the first dose. Further safety surveillance studies on COVID-19 vaccines are required to validate our findings.

A Retrospective Cross-Sectional Study Assessing Self-Reported Adverse Events following Immunization (AEFI) of the COVID-19 Vaccine in Bangladesh. BACKGROUND: The Oxford-AstraZeneca vaccine (Covishield) was the first to be introduced in Bangladesh to fight the ongoing global COVID-19 pandemic. As this vaccine had shown some side-effects in its clinical trial, we aimed to conduct a study assessing short-term adverse events following immunization (AEFIs) in Bangladesh. METHOD: A cross-sectional study was conducted on social and electronic media platforms by delivering an online questionnaire among people who had taken at least one dose of the COVID-19 vaccine. The collected data were then analysed to evaluate various parameters related to the AEFIs of the respondents. RESULTS: A total of 626 responses were collected. Of these, 623 were selected based on complete answers and used for the analysis. Most of the respondents were between 30-60 years of age, and 40.4% were female. We found that a total of 8.5% of the total respondents had been infected with the SARS-CoV-2 virus. Our survey revealed that out of 623 volunteers, 317 reported various side-effects after taking the vaccine, which is about 50.88% of the total participants. The majority of participants (37.07%, 231/623) reported swelling and pain at the injection site and fever (25.84%, 162/623); these were some of the common localized and generalized symptoms after the COVID-19 vaccine administration. CONCLUSION: The side-effects reported after receiving the Oxford-AstraZeneca vaccine (Covishield) are similar to those reported in clinical trials, demonstrating that the vaccines have a safe therapeutic window. Moreover, further research is needed to determine the efficacy of existing vaccines in preventing SARS-CoV-2 infections or after-infection hospitalization.

Henoch-SchÃ¶nlein Purpura Following the First Dose of COVID-19 Viral Vector Vaccine: A Case Report. A 76 year-old female came to our observation one week after the vaccination with ChAdOx1 nCoV-19 AZD1222 for the onset of purpuric rash on her gluteal and legs regions associated with coxalgia and episodes of macrohaematuria. Henoch-SchÃ¶nlein purpura (HSP) was diagnosed on the basis of the revised criteria developed by the European League Against Rheumatism, the Paediatric Rheumatology International Trials Organization, and the Paediatric Rheumatology European Society (EULAR/PRINTO/PRES). HSP is a common IgA-mediated small vessel vasculitis, typical of childhood, that affects several systems and is characterized by a tetrad of dermatological, abdominal, joint, and renal manifestations. The Etiology of HSP is not completely understood, but it was observed following upper respiratory tract infections, medications, vaccinations, and malignancies. HSP has previously been reported following immunization with various vaccines, mostly within 12 weeks post, suggesting a possible correlation. To our knowledge, this is the first report of the possible association between COVID-19 ChAdOx1 nCoV-19 AZD1222 and the onset of HSP in a previously healthy woman. No similar cases were reported amongst 23.848 participants in the ChAdOx1 nCoV-19 AZD1222 trial.

Antibody Responses after a Third Dose of COVID-19 Vaccine in Kidney Transplant Recipients and Patients Treated for Chronic Lymphocytic Leukemia. The impact of a third dose of COVID-19 vaccine on antibody responses is unclear in immunocompromised patients. The objective of this retrospective study was to characterize antibody responses induced by a third dose of mRNA COVID-

19 vaccine in 160 kidney transplant recipients and 20 patients treated for chronic lymphocytic leukemia (CLL). Prevalence of anti-spike IgG â‰¥ 7.1 and â‰¥ 30 BAU/mL after the third dose were 47% (75/160) and 39% (63/160) in kidney transplant recipients, and 57% (29/51) and 50% (10/20) in patients treated for CLL. Longitudinal follow-up identified a moderate increase in SARS-CoV-2 anti-spike IgG levels after a third dose of vaccine in kidney transplant recipients (0.19 vs. 5.28 BAU/mL, p = 0.03) and in patients treated for CLL (0.63 vs. 10.7 BAU/mL, p = 0.0002). This increase in IgG levels had a limited impact on prevalence of anti-spike IgG â‰¥ 30 BAU/mL in kidney transplant recipients (17%, 2/12 vs. 33%, 4/12, p = 0.64) and in patients treated for CLL (5%, 1/20 vs. 45%, 9/20, p = 0.008). These results highlight the need for vaccination of the general population and the importance of non-medical preventive measures to protect immunocompromised patients.

Cerebral Venous Thrombosis Developing after COVID-19 Vaccination: VITT, VATT, TTS, and More. Despite the huge efforts globally underway for preventing or limiting the spread of severe acute respiratory coronavirus disease 2 (SARS-CoV-2), the coronavirus disease 2019 (COVID-19) pandemic outbreak appears still virtually unstoppable. As for many other infectious diseases, COVID-19 vaccination has now become crucial for limiting viral spread, especially for averting hospitalizations, need for intensive care, and fatal outcome. Nonetheless, as for other vaccines, COVID-19 vaccination is not completely free from side effects. Among the adverse events that have been reported after receiving COVID-19 vaccination, special emphasis has been given to an unexpected number of thrombocytopenic episodes with or without thrombotic complications, especially in recipients of adenovirus-based COVID-19 vaccines. Along with a specific clinical presentation, encompassing "atypical" thrombosis (especially cerebral venous [sinus] thrombosis, CVT) more prevalent in young female subjects, this new syndrome called vaccine-induced thrombocytopenia and thrombosis (VITT) is characterized by, and thereby diagnosed for, the presence of three paradigmatic laboratory abnormalities, i.e., low platelet count (<150â€‰Ã—â€‰10(9)/L), elevated plasma D-dimer levels (>0.5â€‰mg/L), accompanied by a positive test for anti-PF4 (platelet factor 4) antibodies assayed with ELISA (enzyme-linked immunosorbent assay) techniques. Timely identification of these important abnormalities by both clinicians and laboratory professional is essential for early diagnosis and management of VITT, since the outcome of this condition may be fatal in half or even more of effected patients with severe disease. Therefore, this narrative review aims to review here the epidemiology, pathogenesis, clinical, and laboratory characteristics of VITT and other COVID-19 vaccine-associated thrombocytopenias.

SARS-CoV-2-reactive antibody detection after SARS-CoV-2 vaccination in hematopoietic stem cell transplant recipients: Prospective survey from the Spanish Hematopoietic Stem Cell Transplantation and Cell Therapy Group. This is a multicenter prospective observational study that included a large cohort (nÂ =Â 397) of allogeneic (allo-HSCT; (nÂ =Â 311) and autologous (ASCT) hematopoietic stem cell transplant (nÂ =Â 86) recipients who were monitored for antibody detection within 3-6â€‰weeks after complete severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination from February 1, 2021, to July 20, 2021. Most patients (nÂ =Â 387, 97.4%) received mRNA-based vaccines. Most of the recipients (93%) were vaccinated more than 1Â year after transplant. Detectable SARS-CoV-2-reactive antibodies were observed in 242 (78%) of allo-HSCT and in 73 (85%) of ASCT recipients. Multivariate analysis in allo-HSCT recipients identified lymphopenia < 1â€‰Ã—â€‰10(9) /ml (odds ratio [OR] 0.33, 95% confidence interval [95% CI] 0.16-0.69, pÂ =Â .003), active graft versus host disease (GvHD; OR 0.51, 95% CI 0.27-0.98, pÂ =Â .04) and vaccination within the first year of transplant (OR 0.3, 95% CI 0.15-0.9, pÂ =Â .04) associated with lower antibody detection whereas. In ASCT, non-Hodgkin's lymphoma (NHL; OR 0.09, 95% CI 0.02-0.44, pÂ =Â .003) and active corticosteroid therapy (OR 0.2, 95% CI 0.02-0.87, pÂ =Â .03) were associated with lower detection rate. We report an encouraging rate of SARS-CoV-2-reactive

antibodies detection in these severe immunocompromised patients. Lymphopenia, GvHD, the timing of vaccine, and NHL and corticosteroids therapy should be considered in allo-HSCT and ASCT, respectively, to identify candidates for SARS-CoV-2 antibodies monitoring.
Imaging and Hematologic Findings in Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 (AstraZeneca) Vaccination.
A case series of vaccine-induced thrombotic thrombocytopenia in a London teaching hospital. The ChAdOx1 nCoV-19 vaccine has been associated with increased risk of thrombosis. Understanding of the management of these rare events is evolving, and currently recommended treatments include human normal immunoglobulin and nonheparin anticoagulation such as direct oral anticoagulants. Our report describes three consecutive patients presenting to a London teaching hospital with vaccine-induced thrombotic thrombocytopenia (VITT), also referred to as vaccine-induced prothrombotic immune thrombocytopenia. The patients ranged in age from 40 to 54â€‰years and two had no known previous medical comorbidities. Two patients had cerebral venous sinus thrombosis and one had a deep vein thrombosis. Two were treated with anticoagulation, one with oral rivaroxaban and the other with an intravenous argotraban infusion that was later converted to oral apixaban. One patient received three doses of human normal immunoglobulin and 5Â days of therapeutic plasma exchange. This case series may be used to improve understanding of the clinical course and management of VITT.
Deep axillary lymphadenopathy after coronavirus disease 2019 vaccination: a case report.
Vaccine-induced immune thrombotic thrombocytopenia (VITT): Update on diagnosis and management considering different resources. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare but severe immunological reaction to the non-replicable adenoviral vector-based COVID-19 vaccines. Extreme activation of platelets and the coagulation system leads to a high risk of death from venous or arterial thrombosis or secondary hemorrhage. Public and clinician awareness has reduced mortality of VITT by nearly 90%. The World Health Organization provided a guideline in July 2021 on diagnosis and management of VITT (also called thrombosis with thrombocytopenia syndrome, or TTS). Since July 2021, new, clinically relevant information has become available. This update has been summarized by the authors in an informal process with recommendations for low resource environments. We provide new available evidence on VITT to empower clinicians to recognize VITT early, then effectively diagnose and treat the disorder to reduce morbidity and mortality. We strongly encourage production of clear management pathways for primary care settings and hospital settings.
Characteristics and outcomes of adverse events after COVID-19 vaccination. OBJECTIVES: BNT-162b2, mRNA-1273, and Ad26.COV2.S vaccines data regarding adverse events (AEs) are scarce. In this report, we aimed to describe fatal and non-fatal possible AEs after COVID-19 vaccine administration. METHODS: An observational multicenter study investigating the causes of emergency department visits and hospital admissions within 10 days of COVID-19 vaccination. Patients who received first or second doses of COVID-19 vaccines and presented to the emergency department (ED), as well as those admitted to the hospitals or intensive care units (ICUs) were included. Causes of ED, hospital, and ICU admissions and discharges were collected based on the International Classification of Diseases, Tenth Revision (ICD-10) coding system. RESULTS: Between December 2020 and March 2021, 1842 patients visited the ED within 10 days of COVID-19 vaccine administration. The mean age was 70.3 years. Overall, 1221 patients presented after the first dose of the vaccine and 653 after the second dose. Trauma (14.9%), hypertensive emergency/urgency (7.8%), generalized pain and arthralgia (5.7%), and chest pain (4.4%) were the most common causes of presentation to the ED. Of all ED presentations, mortality rate was at 2.2% (41 patients) with a median follow-up time of 68.0 days, versus 2.6% in unvaccinated ED patients. Postvaccination acute hypoxemic respiratory failure

(46.3%), septic shock (24.4%), and cardiogenic shock (12.2%) were the most common causes of death. CONCLUSION: Although reported AEs are not necessarily caused by the vaccination, this study provides further information about possible AEs after COVID-19 immunization, especially those requiring hospital admission. This study also supports prior data that serious AEs post vaccination are much lower than primary COVID-19 infections. Further studies are needed to investigate causalities between vaccines and reported AEs across all age groups.

Thyroiditis following vaccination against COVID-19: Report of two cases and review of the literature. INTRODUCTION: Immune response following viral infections has been suggested as a probable mechanism leading to subacute thyroiditis (SAT). A few cases of SAT following SARS-CoV-2 infection have been described since the outbreak of the pandemic in 2019. Cases of SAT after vaccination against influenza have also been reported. We describe two female patients with thyroiditis after vaccination against SARS-CoV-2. PRESENTATION OF CASES: The first patient presented with fever and pain in the thyroid area typical of SAT two weeks after vaccination with the BNT162B2 mRNA (Pfizer-BioNTech) COVID-19 vaccine. The second patient presented with biochemical and imaging features consistent with silent thyroiditis three weeks after vaccination with the ChAdOx1-S (AstraZeneca) vaccine. Both patients were asymptomatic prior to vaccination and PCR of nasopharyngeal swab for SARS-CoV-2 and other respiratory viruses associated with SAT was negative. Serology testing for measles, mumps, rubella, CMV and EBV viruses was suggestive of immunity. Antibody titre against spike S protein of SARS-CoV-2 was measured for both patients and was indicative of adequate post vaccination antibody response. Two months after initial assessment, both patients were euthyroid and asymptomatic. CONCLUSIONS: Subacute as well as silent thyroiditis may rarely occur after vaccination against COVID-19. Further research is needed to investigate the prevalence and pathogenesis of thyroid dysfunction following vaccination against COVID-19.

A case report: symptomatic pericarditis post-COVID-19 vaccination. BACKGROUND: The Coronavirus disease 2019 (COVID-19) pandemic has led to the rapid development of COVID-19 vaccine. The Centers for Disease Control and Prevention (CDC) has recently reported increase in myopericarditis incidence post-COVID-19 vaccination. Post-vaccination myopericarditis as side effect has been reported, however, is infrequent. We described a case of pericarditis post-first dose of Pfizer-BioNTech vaccine. CASE SUMMARY: A patient presented with typical symptoms of pericarditis and related electrocardiogram and echocardiogram changes, 7 days post receiving the first dose of COVID-19 vaccine. No other causes were identified from series of investigations. Patient had good symptomatic relief with non-steroidal anti-inflammatory medication. DISCUSSION: The incidence of pericarditis post-vaccination is rare, with limited reporting in previous literatures. No causal relationship has yet to be established due to small number of cases. The benefits of COVID-19 vaccination currently outweigh the side effect profile and are recommended as the first-line approach to control the current pandemic.

BNT162b2 and ChAdOx1 SARS-CoV-2 Post-vaccination Side-Effects Among Saudi Vaccinees. Background: Vaccination against SARS-CoV-2 is important for reducing hospitalization and mortalities. Both Pfizer-BioNTech (BNT162b2) and the Oxford-AstraZeneca (ChAdOx1 nCoV-19) vaccines are used in Saudi Arabia and in many parts of the world. Post-vaccinal side effects were recorded, so we aimed to screen different complaints after vaccination among vaccinees in Saudi Arabia. Methods: An online questionnaire was designed to screen the local, systemic, and allergic post vaccination reactions for vaccinees who received either one or two doses of the BNT162b2 vaccine or one dose of the ChAdOx1 vaccine. The number and percentage were recorded for each response and analyzed using cross-tab and Chi square tests. The degree of the severity of post vaccination reactions were analyzed using Roc curve. The cofactors that may affect the severity of post-vaccinal reactions including previous COVID-19 infection, age, sex, body mass index, and comorbidities were investigated. Results:

During our study, 4,170 individuals reported their responses: 2,601 received one dose of BNT162b2, of whom 456 completed the second dose, and 1,569 received a single dose of ChAdOx1. The side effects were reported in 85.6% of BNT162b2 vaccinees and 96.05% of ChAdOx1 vaccinees who voluntarily responded to a survey about post-vaccination side effects. The side effects were more severe in BNT162b2 than ChAdOx1. ChAdOx1 vaccinees reported mild, moderate, severe and critical side effects in 30.13, 28.62, 29.73, and 1.53%, respectively. In contrast, mild side effects were recorded among the majority of BNT162b2 vaccinees (63.92%) while moderate, severe, and critical side effects were 27.67, 7.68, and 0.72%, respectively. Both local and systemic side effects were recorded more frequently in ChAdOx1 in comparison to BNT162b2 vaccinees. Palpitation was among the new systemic side effects reported in the current study in high frequency. Abnormal menstrual cycle (delaying/increase hemorrhages or pain) was also reported in 0.98% (18/1846) of Pfizer-BioNTech and 0.68% (7/1028) of ChAdOx1 vaccinees, while deep vein thrombosis was only reported in a single case vaccinated with BNT162b2 vaccine. Conclusion: Both vaccines induced post-vaccinal side effects; however, ChAdOx1 induces a higher frequency of post-vaccinal systemic side effects than BNT162b2.

Chronic Spontaneous Urticaria After COVID-19 Vaccine. Public health efforts over the past few months have been aimed at vaccinating young adults. Moderna and Pfizer COVID-19 vaccines are widely available options. Cutaneous reactions to these vaccines have been described as self-limiting and relatively immediate after vaccine administration. In this case report, we present a young adult who received the Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine and developed chronic, spontaneous urticaria.

Diphtheria And Tetanus Vaccination History Is Associated With Lower Odds of COVID-19 Hospitalization. BACKGROUND: COVID-19 is characterized by strikingly large, mostly unexplained, interindividual variation in symptom severity: while some individuals remain nearly asymptomatic, others suffer from severe respiratory failure. Previous vaccinations for other pathogens, in particular tetanus, may partly explain this variation, possibly by readying the immune system. METHODS: We made use of data on COVID-19 testing from 103,049 participants of the UK Biobank (mean age 71.5 years, 54.2% female), coupled to immunization records of the last ten years. Using logistic regression, covarying for age, sex, respiratory disease diagnosis, and socioeconomic status, we tested whether individuals vaccinated for tetanus, diphtheria or pertussis, differed from individuals that had only received other vaccinations on 1) undergoing a COVID-19 test, 2) being diagnosed with COVID-19, and 3) whether they developed severe COVID-19 symptoms. RESULTS: We found that individuals with registered diphtheria or tetanus vaccinations are less likely to develop severe COVID-19 than people who had only received other vaccinations (diphtheria odds ratio (OR)=0.47, p-value=5.3*10(-5); tetanus OR=0.52, p-value=1.2*10(-4)). DISCUSSION: These results indicate that a history of diphtheria or tetanus vaccinations is associated with less severe manifestations of COVID-19. These vaccinations may protect against severe COVID-19 symptoms by stimulating the immune system. We note the correlational nature of these results, yet the possibility that these vaccinations may influence the severity of COVID-19 warrants follow-up investigations.

Vaccine Development Against Tuberculosis Over the Last 140 Years: Failure as Part of Success. The year 2020 was shaped by the COVID-19 pandemic which killed more people than any other infectious disease in this particular year. At the same time, the development of highly efficacious COVID-19 vaccines within less than a year raises hope that this threat can be tamed in the near future. For the last 200 years, the agent of tuberculosis (TB) has been the worst killer amongst all pathogens. Although a vaccine has been available for 100 years, TB remains a substantial threat. The TB vaccine, Bacille Calmette-GuÃ©rin (BCG), has saved tens of millions of lives since its deployment. It was the best and only choice available amongst many attempts to develop efficacious vaccines and

all competitors, be they subunit vaccines, viable vaccines or killed whole cell vaccines have failed. Yet, BCG is insufficient. The last decades have witnessed a reawakening of novel vaccine approaches based on deeper insights into immunity underlying TB and BCG immunization. In addition, technical advances in molecular genetics and the design of viral vectors and adjuvants have facilitated TB vaccine development. This treatise discusses firstly early TB vaccine developments leading to BCG as the sole preventive measure which stood the test of time, but failed to significantly contribute to TB control and secondly more recent attempts to develop novel vaccines are described that focus on the genetically modified BCG-based vaccine VPM1002, which has become the frontrunner amongst viable TB vaccine candidates. It is hoped that highly efficacious vaccines against TB will become available even though it remains unclear whether and when this ambition can be accomplished. None the less it is clear that the goal of reducing TB morbidity and mortality by 90% or 95%, respectively, by 2030 as proposed by the World Health Organization depends significantly on better vaccines.

[Humoral immunity against SARS-CoV-2 in workers of social health care centers of Castilla y LeÃ³n after vaccination with the BNT162b2 mRNA vaccine from Pfizer/Biontech.]. OBJECTIVE: Workers and residents of care facilities for elder people/people with disabilities were particularly hit by the COVID-19 pandemic. Workers from these centres were included as a priority group for vaccination against SARS-CoV-2. The Family Ministry of Castilla y LeÃ³n realized a seroprevalence survey measuring the humoral immunity of its workers after the vaccination against SARS-CoV-2. METHODS: In February and March 2021, IgM/IgG antibodies were measured in 7 social health care centers in a total of 1,085 workers at least 15 days after completing the vaccination with the BNT162b2 vaccine from Pfizer/BioNtech. Using the ELISA technique for anti-nucleocapsid (N) IgM and CLIA S-RBD SARS-CoV-2 for anti-spicule (S) IgG, titers were compared between vaccinated with cero, one or two doses, and differentiating in these subgroups between having passed or not COVID-19. Means and percentages were compared using Student's t and Chi2 (EPIDAT 3.1). RESULTS: Among the 1,085 workers studied, there were 54 workers with a single dose of vaccine, of which 51 (94%) had a positive IgG (average titers of 459 AU/mL), 951 workers with 2 doses, of which 949 (99.8%) showed positive IgG (mean titers of 677 AU/mL), and 80 unvaccinated workers, of which 51 (64%) had positve IgG (mean titers of 49 AU/mL). 7 cases of COVID-19 were notified at least 15 days after full vaccination. The titers were significantly higher if COVID-19 had been passed in the group vaccinated with 1 and 2 doses (259 vs 894 and 601 vs 1,085 AU/mL respectively, $p<0.05$), but not in the unvaccinated group (53 vs 34 AU/mL, $p<0.05$). CONCLUSIONS: 99.8% of social health workers who received 2 doses of the BNT162b2 vaccine from Pfizer/BioNtech, and 94% of those who received 1 single dose, presented humoral immunity with high IgG titers, with high clinical effectiveness expressed in the absence of cases. 64% of unvaccinated workers presented humoral immunity. The history of having passed COVID-19 produces an important booster effect both after one and after two doses of vaccine. Measurement of humoral immunity against SARS-CoV-2 could be considered as a parameter for sufficient immunity.

Acute Corneal Transplant Rejection After Severe Acute Respiratory Syndrome Coronavirus 2 mRNA-1273 Vaccination. PURPOSE: The purpose of this article was to report a case of full-thickness corneal transplant rejection 3 days after immunization with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Moderna mRNA-1273 vaccine. METHODS: Case Report. RESULTS: A 51-year-old man with a history of keratoconus and penetrating keratoplasty underwent repeat penetrating keratoplasty for graft failure. The patient had an uncomplicated intraoperative and postoperative course with improved vision and a healthy graft. The patient received the SARS-CoV-2 Moderna vaccine on postoperative week 3, and within 3 days, the patient began developing eye pain, photophobia, and blurred vision. The patient was found to have graft rejection with corneal edema and endothelial keratic precipitates. The rejection did not improve despite a trial of increased topical

steroids and ultimately evolved into graft failure. CONCLUSIONS: To the best of our knowledge, this case of full-thickness graft rejection after the Moderna SARS-CoV-2 mRNA vaccination is the first to be reported worldwide. The temporal relationship between vaccination and subsequent rejection is highly suggestive of causation due to the short interval (3 days) between vaccination and rejection and the lack of other inciting factors in an otherwise healthy graft. Patients with corneal transplants who plan to take the COVID-19 vaccinations should be counseled on symptoms and closely monitored, and an individualized plan should be made in discussion with the ophthalmologist.

Herpes Zoster Ophthalmicus After COVID-19 Vaccination: Chance Occurrence or More? As the understanding of COVID-19 infection becomes better, it is being recognized as a complex multisystem pathology rather than just affecting the lungs. Several ocular findings have been documented by researchers in individuals infected with COVID-19, and ocular symptoms may even be the first presenting feature of COVID-19 infection in 2.26% individuals. Several countries have started vaccination with inactivated or live vaccines to combat this pandemic, and varied side effects have been reported after vaccination. Few cases of herpes zoster have previously been reported in elderly patients with comorbidities after receiving COVID-19 vaccines. In this article, the authors described 2 interesting cases of herpes zoster ophthalmicus (HZO) after receiving a live COVID-19 vaccine. The first case was a 35-year-old immunocompetent man who developed HZO 3 days postvaccine. The second case was a 40-year-old immunocompetent man who developed HZO 28 days postvaccine. To the best of our knowledge, no literature to date has described HZO after live vaccine.

COVID-19 vaccination and a severe pain in the neck.

Bilateral Retinal Detachments in a Healthy 22-year-old Woman After Moderna SARS-COV-2 Vaccination. BACKGROUND: Although uncommon, retinal detachments are medically urgent and can result in permanent vision loss if untreated. Bilateral retinal detachments in healthy individuals are even more rare. In addition, there are no cases to date of retinal detachment associated with either coronavirus disease 2019 (COVID-19) or after receiving the Moderna (mRNA-1273) severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) vaccine. CASE REPORT: A 22-year-old woman with myopia but no ocular trauma or other major medical history presented to the emergency department with 5 days of progressive, painless vision loss in her right eye. On examination, her visual acuity with corrective lenses was 20/70 in the right eye, 20/20 in the left eye, and 20/25 with both eyes open. Point-of-care ultrasound of the eye showed a retinal detachment in the right eye. She was subsequently seen by ophthalmology and diagnosed with bilateral retinal detachments (macula off in the right, macula on in the left), despite being asymptomatic in her left eye. She underwent bilateral vitrectomies for simultaneous rhegmatogenous retinal detachments. Although the patient denied any preceding trauma, she did note having received her second dose of the COVID-19 vaccine 10 days before the onset of symptoms.Why Should an Emergency Physician Be Aware of This? We present a rare and unusual case of simultaneous bilateral retinal detachments in a healthy, young woman with no major medical history or medications. She received the COVID-19 vaccine a few days prior. Our case outlines a possible association with the vaccine and emphasizes the importance of ultrasonography in diagnosing time-sensitive medical conditions.

Combined Vaccination Approaches for COVID-19. Will These Improve the Efficacy Spectrum?

Heart failure secondary to myocarditis after SARS-CoV-2 reinfection: a case report. INTRODUCTION: Cardiac involvement in COVID-19 can range from mild damage to severe myocarditis. The precise mechanism by which COVID-19 causes myocardial injury is still unknown. Myocarditis following administration of COVID-19 vaccines, especially those based on mRNA, has also been described. However, no reports of heart failure following reinfection with SARS-CoV-2 in patients immunized with an inactivated vaccine have been identified. CASE DESCRIPTION: The patient was a 47-year-old male construction worker of African descent, with type II diabetes and a history of

infection by SARS-CoV-2 in December 2020 and May 2021, confirmed by RT-PCR. He received two doses of an inactivated vaccine against COVID-19. Between the two COVID-19 episodes with positive RT-PCR, he had two episodes of bacterial lung infection. After the second episode of SARS-CoV-2 infection, he was diagnosed with severe heart failure as a sequela of myocarditis. CONCLUSION: It is essential to perform a thorough follow-up after infection with SARS-CoV-2 since, even with proper immunization, it is possible that the patient was reinfected and suffered severe cardiac sequelae as a consequence. The hypothesis of an etiology associated with the use of an inactivated vaccine against COVID-19, with a potential immune enhancement mechanism following reinfection with SARS-CoV-2, cannot be rejected.

Immunogenicity and safety of AZD1222 (ChAdOx1 nCoV-19) against SARS-CoV-2 in Japan: a double-blind, randomized controlled phase 1/2 trial. BACKGROUND: Immunogenicity and safety of the AZD1222 (ChAdOx1 nCoV-19) vaccine was evaluated in Japanese adults in an ongoing phase 1/2, randomized, double-blind, parallel-group, placebo-controlled, multi-centre trial (NCT04568031). METHODS: Adults (n=256, age â‰¥18 years) seronegative for severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) were stratified by age into 18-55- (n=128), 56-69- (n=86) and â‰¥70-year-old cohorts (n=42), and randomized 3:1 to receive AZD1222 or placebo (two intramuscular injections 4 weeks apart). Immunogenicity and safety were coprimary endpoints. Data collected up to Day 57 are reported. RESULTS: Positive seroresponses to SARS-CoV-2 spike and receptor-binding domain antigens were seen in all 174 participants who received two doses of AZD1222. Neutralizing antibody seroresponses were seen in 67.5%, 60.3% and 50.0% of participants receiving AZD1222 aged 18-55, 56-69 and â‰¥70 years, respectively. Solicited adverse events (AEs) were typically mild/moderate in severity and included pain and tenderness at the injection site, malaise, fatigue, muscle pain and headache. Common unsolicited AEs included pain and tenderness at the injection site, fatigue and elevated body temperature. No vaccine-related serious AEs or deaths were reported. CONCLUSIONS: AZD1222 elicited a strong humoral immune response against SARS-CoV-2, and was well tolerated in Japanese participants, including elderly participants.

Fertility rates and birth outcomes after ChAdOx1 nCoV-19 (AZD1222) vaccination.

SARS-COV-2 vaccine: first-month results of a six-month follow-up study. BACKGROUND: Various COVID-19 vaccines are being developed around the world. Important questions to be answered regarding vaccines are efficacy, safety, and whether antibodies are protective when used in different communities. This study aimed to determine seroconversion rates of the inactivated SARS-CoV-2 vaccine in healthcare workers in a hospital and short-term adverse events due to the vaccine. METHODS: The study carried out in Ã‡ukurova University, Turkey, comprised of 282 healthcare workers who received two doses of the inactivated SARS-CoV-2 vaccine administered in two 3 Âµg doses, 28 days apart. On day 28, after the second dose, antiS-RBD IgG and total anti-spike and anti-nucleocapsid IgM and IgG antibodies against SARS-CoV-2 were detected by using in vitro chemiluminescence immunoassay method. RESULTS: The mean age of participants was 39.06Â±10.65 (min=21, max=65) with 43.6% males and 56.4% females. On day 28, after the second dose, the seroconversion rates were found to be 92.9% for total anti-spike and anti-nucleocapsid IgG and 15.2% for IgM and 98.2% for anti-S-RBD IgG antibodies and having natural COVID-19 prior to vaccination, age and comorbidity were found to be significant factors for immunogenicity. The incidence of at least one adverse event was found as 29.8% after the first dose and 24.1% after the second dose, with the most common adverse events of having pain at the injection site, weakness, fatigue, and headache.

Hospital-based observational study of neurological disorders in patients recently vaccinated with COVID-19 mRNA vaccines. PURPOSE: We describe the spectrum of acute neurological disorders among hospitalized patients who recently had COVID-19 mRNA vaccination. METHOD: We performed

a prospective study at 7 acute hospitals in Singapore. Hospitalized patients who were referred for neurological complaints and had COVID-19 mRNA vaccines, BNT162b2 and mRNA-1273, in the last 6Â weeks were classified into central nervous system (CNS) syndromes, cerebrovascular disorders, peripheral nervous system (PNS) disorders, autonomic nervous system (ANS) disorders and immunization stress-related responses (ISRR). RESULTS: From 30 December 2020 to 20 April 2021, 1,398,074 persons (median age 59Â years, 54.5% males) received COVID-19 mRNA vaccine (86.7% BNT162b2, 13.3% mRNA-1273); 915,344(65.5%) completed 2 doses. Four hundred and fifty-seven(0.03%) patients were referred for neurological complaints [median age 67(20-97) years, 281(61.5%) males; 95.8% received BNT162b2 and 4.2% mRNA-1273], classified into 73(16.0%) CNS syndromes, 286(62.6%) cerebrovascular disorders, 59(12.9%) PNS disorders, 0 ANS disorders and 39(8.5%) ISRRs. Eleven of 27 patients with cranial mononeuropathy had Bell's palsy. Of 33 patients with seizures, only 4 were unprovoked and occurred within 2Â weeks of vaccination. All strokes occurred among individuals with pre-existing cardiovascular risk factors. We recorded 2 cases of cerebral venous thrombosis; none were vaccine-induced thrombotic thrombocytopenia. Five had mild flares of immune-mediated diseases. CONCLUSION: Our observational study does not establish causality of the described disorders to vaccines. Though limited by the lack of baseline incidence data of several conditions, we observed no obvious signal of serious neurological morbidity associated with mRNA vaccination. The benefits of COVID-19 vaccination outweigh concerns over neurological adverse events.

SARS-CoV-2 vaccine uptake, perspectives, and adverse reactions following vaccination in patients with cancer undergoing treatment.

Symptomology following mRNA vaccination against SARS-CoV-2. Despite demonstrated efficacy of vaccines against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the causative agent of coronavirus disease-2019 (COVID-19), widespread hesitancy to vaccination persists. Improved knowledge regarding frequency, severity, and duration of vaccine-associated symptoms may help reduce hesitancy. In this prospective observational study, we studied 1032 healthcare workers who received both doses of the Pfizer-BioNTech SARS-CoV-2 mRNA vaccine and completed post-vaccine symptom surveys both after dose 1 and after dose 2. We defined appreciable post-vaccine symptoms as those of at least moderate severity and lasting at least 2Â days. We found that symptoms were more frequent following the second vaccine dose than the first (74% vs. 60%, PÂ <Â 0.001), with >80% of all symptoms resolving within 2Â days. The most common symptom was injection site pain, followed by fatigue and malaise. Overall, 20% of participants experienced appreciable symptoms after dose 1 and 30% after dose 2. In multivariable analyses, female sex was associated with greater odds of appreciable symptoms after both dose 1 (OR, 95% CI 1.73, 1.19-2.51) and dose 2 (1.76, 1.28-2.42). Prior COVID-19 was also associated with appreciable symptoms following dose 1, while younger age and history of hypertension were associated with appreciable symptoms after dose 2. We conclude that most post-vaccine symptoms are reportedly mild and last <2Â days. Appreciable post-vaccine symptoms are associated with female sex, prior COVID-19, younger age, and hypertension. This information can aid clinicians in advising patients on the safety and expected symptomatology associated with vaccination.

New-onset Evans syndrome associated with systemic lupus erythematosus after BNT162b2 mRNA COVID-19 vaccination. Evans syndrome presents as concurrent autoimmune hemolytic anemia (AIHA) and immune thrombocytopenia (ITP). Systemic lupus erythematosus (SLE) is the most frequent autoimmune disorder associated with Evans syndrome. We herein report a case of new-onset Evans syndrome associated with SLE after BNT162b2 mRNA coronavirus disease 2019 (COVID-19) vaccination in a 53-year-old woman. Blood examination at diagnosis showed hemolytic anemia with a positive Coombs test and thrombocytopenia. Hypocomplementemia and the presence of lupus

anticoagulant indicated a strong association with SLE. Prednisolone administration rapidly restored hemoglobin level and platelet count. This case suggests that mRNA COVID-19 vaccination may cause an autoimmune disorder. Physicians should be aware of this adverse reaction by mRNA COVID-19 vaccination and should consider the benefits and risks of vaccination for each recipient.
Subacute thyroiditis after SARS-CoV-2 vaccination: a report of two sisters and summary of the literature.
T cells step up after SARS-CoV-2 vaccination with B cell depletion. Detailed immunological analysis in a new study provides insight into the mechanisms of immune responses after SARS-CoV-2 vaccination in people who are receiving B cell-depleting therapy for multiple sclerosis. The findings have implications for clinical practice, but more questions about SARS-CoV-2 vaccination and immunosuppression remain.
Two-dose COVID-19 vaccination and possible arthritis flare among patients with rheumatoid arthritis in Hong Kong. OBJECTIVES: To investigate the relationship between COVID-19 full vaccination (two completed doses) and possible arthritis flare. METHODS: Patients with rheumatoid arthritis (RA) were identified from population-based electronic medical records with vaccination linkage and categorised into BNT162b2 (mRNA vaccine), CoronaVac (inactive virus vaccine) and non-vaccinated groups. The risk of possible arthritis flare after vaccination was compared using a propensity-weighted cohort study design. We defined possible arthritis flare as hospitalisation and outpatient consultation related to RA or reactive arthritis, based on diagnosis records during the episode. Weekly prescriptions of rheumatic drugs since the launch of COVID-19 vaccination programme were compared to complement the findings from a diagnosis-based analysis. RESULTS: Among 5493 patients with RA (BNT162b2: 653; CoronaVac: 671; non-vaccinated: 4169), propensity-scored weighted Poisson regression showed no significant association between arthritis flare and COVID-19 vaccination ((BNT162b2: adjusted incidence rate ratio 0.86, 95% Confidence Interval 0.73 to 1.01); CoronaVac: 0.87 (0.74 to 1.02)). The distribution of weekly rheumatic drug prescriptions showed no significant differences among the three groups since the launch of the mass vaccination programme (all p values >0.1 from Kruskal-Wallis test). CONCLUSIONS: Current evidence does not support that full vaccination of mRNA or inactivated virus COVID-19 vaccines is associated with possible arthritis flare.
Severe Covid-19 Vaccine Side-Effects are Rare in Older Adults yet are Linked With Depressive Symptoms.
Bullous pemphigoid induced by the AstraZeneca COVID-19 vaccine.
Shedding Light on the Possible Link between ADAMTS13 and Vaccine-Induced Thrombotic Thrombocytopenia. Several recent reports have highlighted the onset of vaccine-induced thrombotic thrombocytopaenia (VITT) in some recipients (approximately 1 case out of 100k exposures) of the ChAdOx1 nCoV-19 vaccine (AstraZeneca). Although the underlying events leading to this blood-clotting phenomenon has yet to be elucidated, several critical observations present a compelling potential mechanism. Thrombus formation requires the von Willebrand (VWF) protein to be in ultra-large multimeric state. The conservation of this state is controlled by the ADAMTS13 enzyme, whose proteolytic activity reduces the size of VWF multimers, keeping blood clotting at bay. However, ADAMTS13 cannot act on VWF that is bound to platelet factor 4 (PF4). As such, it is of particular interest to note that a common feature between subjects presenting with VITT is high titres of antibodies against PF4. This raises the possibility that these antibodies preserve the stability of ultra-large VWF complexes, leading to the formation of endothelium-anchored VWF strings, which are capable of recruiting circulating platelets and causing uncontrolled thrombosis in terminal capillaries. Here, we share our viewpoint about the current understanding of the VITT pathogenesis

involving the prevention of ADAMTS13's activity on VWF by PF4 antibody-mediated stabilisation/ protection of the PF4-VWF complex.
Highly Specific Memory B Cells Generation after the 2nd Dose of BNT162b2 Vaccine Compensate for the Decline of Serum Antibodies and Absence of Mucosal IgA. Specific memory B cells and antibodies are a reliable read-out of vaccine efficacy. We analysed these biomarkers after one and two doses of BNT162b2 vaccine. The second dose significantly increases the level of highly specific memory B cells and antibodies. Two months after the second dose, specific antibody levels decline, but highly specific memory B cells continue to increase, thus predicting a sustained protection from COVID-19. We show that although mucosal IgA is not induced by the vaccination, memory B cells migrate in response to inflammation and secrete IgA at mucosal sites. We show that the first vaccine dose may lead to an insufficient number of highly specific memory B cells and low concentration of serum antibodies, thus leaving vaccinees without the immune robustness needed to ensure viral elimination and herd immunity. We also clarify that the reduction of serum antibodies does not diminish the force and duration of the immune protection induced by vaccination. The vaccine does not induce sterilizing immunity. Infection after vaccination may be caused by the lack of local preventive immunity because of the absence of mucosal IgA.
Acute Transverse Myelitis after COVID-19 Vaccination. The adverse effects of the COVID-19 vaccine have been discovered as the rapid application of the vaccines continues. Neurological complications such as transverse myelitis raise concerns as cases were observed in clinical trials. Transverse myelitis is a rare immune-mediated disease with spinal cord neural injury, resulting in neurological deficits in the motor, sensory, and autonomic system. Vaccine-related transverse myelitis is even rarer. We present a case of acute transverse myelitis after vaccination against COVID-19 with the ChAdOx1 nCOV-19 vaccine (AZD1222), which was the first case reported in Taiwan. Although it rarely occurs, post-vaccination neurological complications should not be ignored. As the pandemic of SARS-CoV-2 continues to spread and concern about vaccination efficacy and safety rises, heterologous vaccination were implemented in health public policy in several countries. A literature review of several clinical trials shows promising effects of mix-and-match vaccination. Further study on different combinations of vaccines can be expected.
Side Effects of mRNA-Based COVID-19 Vaccines among Young Adults (18-30 Years Old): An Independent Post-Marketing Study. Young adults had been widely perceived as a low-risk group for COVID-19 severity; therefore, they were deprioritised within the mass vaccination strategies as their prognosis of COVID-19 infection is relatively more favourable than older age groups. On the other hand, vaccination of this demographic group is indispensable to achieve herd immunity. A cross-sectional survey-based study was used to evaluate the side effects of mRNA-based COVID-19 vaccines among university students in the Czech Republic. The validated questionnaire was delivered in a digital form, and it consisted of demographic data; COVID-19 vaccine-related anamnesis; and local, systemic, orofacial, and skin-related side effects' prevalence, onset, and duration. Out of the 539 included participants, 70.1% were females and 45.8% were <23 years old. The vast majority (95.2%) reported at least one side effect. The most common side effect was injection site pain (91.8%), followed by fatigue (62.5%), headache (36.4%), and muscle pain (34.9%). The majority of local side effects occurred after both doses (74.4%), while most systemic side effects occurred after the second dose only (56.2%). Most local (94.2%) and systemic (93.3%) side effects resolved within three days after vaccination. Females participants' adjusted odds ratio (AOR) showed they were 2.566 (CI 95%: 1.103-5.970) times more likely to experience post-vaccination side effects, and the participants who received two doses reported an increased AOR of 1.896 (0.708-5.077) for experiencing side effects. The results of this study imply that mRNA-based COVID-19 vaccines are

highly probably safe for young adults, and further studies are required to investigate the role of medical anamnesis, prior COVID-19 infection, and gender in side effects incidence.
The Slower Antibody Response in Myelofibrosis Patients after Two Doses of mRNA SARS-CoV-2 Vaccine Calls for a Third Dose. Immunization with mRNA SARS-CoV-2 vaccines has been highly recommended and prioritized in fragile subjects, including patients with myelofibrosis (MF). Available data on the vaccine immune response developed by MF patients and the impact of ruxolitinib treatment are still too fragmented to support an informed decision on a third dose for this category of subjects. Here, we show that 76% of MF patients develop spike-specific IgG after the second mRNA SARS-CoV-2 vaccine dose, but the response has a slower kinetics compared to healthy subjects, suggesting a reduced capability of their immune system to promptly react to vaccination. A reduced ACE2/RBD binding inhibition activity of spike-specific antibodies was also observed, especially in ruxolitinib-treated patients. Our results, showing slow kinetics of antibody responses in MF patients following vaccination with mRNA SARS-CoV-2 vaccines, support the need for a third vaccine dose.
Case Report of COVID-19 after Full Vaccination: Viral Loads and Anti-SARS-CoV-2 Antibodies. The introduction of effective vaccines against SARS-CoV-2 is expected to prevent COVID-19. However, sporadic cases of infection in vaccinated persons have been reported. We describe a case of a double-dose vaccinated woman with COVID-19. All stages of infection were observed, from no identification of virus, then the start of the infection, a high viral load, coming out of viraemia, and finally no detection of the virus. Despite the high viral load, the woman demonstrated mild COVID-19 symptoms, manifested only by a sore throat. The antibody results showed that she produced both post-infectious and post-vaccination immune responses. Phylogenetic analysis of the obtained viral genome sequence indicated that the virus belonged to the UK SARS-CoV-2 lineage B.1.1.7 (GR 501Y.V1; 20I/S:501Y.V1; Alpha variant).
Thrombotic thrombocytopenia following ChAdOx1 nCov-19 vaccination. Serious thromboembolic events with concurrent thrombocytopenia, sometimes accompanied by bleeding, have occurred very rarely following administration of the ChAdOx1 nCoV-19 vaccine. We report the case of a 59-year-old male with an unremarkable medical history who presented to the emergency department with increasing breathlessness five days after receiving the first dose of ChAdOx1 nCov-19. The patient's blood results showed mild thrombocytopenia and a very high D-dimer, and a pulmonary embolism was confirmed through a CT pulmonary angiogram, which led to a provisional diagnosis of vaccine-induced immune thrombotic thrombocytopenia. The condition was then treated with immunoglobulin and intravenous argatroban in line with the guidance from the Expert Haematology Panel focussed on Vaccine-induced Thrombosis and Thrombocytopenia before conversion to apixaban.
SARS-CoV-2 vaccine breakthrough infection following a previous infection in a healthcare worker.
COVID-19 coagulopathies: Human blood proteins mimic SARS-CoV-2 virus, vaccine proteins and bacterial co-infections inducing autoimmunity: Combinations of bacteria and SARS-CoV-2 synergize to induce autoantibodies targeting cardiolipin, cardiolipin-binding proteins, platelet factor 4, prothrombin, and coagulation factors. Severe COVID-19 is often accompanied by coagulopathies such as thrombocytopenia and abnormal clotting. Rarely, such complications follow SARS-CoV-2 vaccination. The cause of these coagulopathies is unknown. It is hypothesized that coagulopathies accompanying SARS-CoV-2 infections and vaccinations result from bacterial co-infections that synergize with virus-induced autoimmunity due to antigenic mimicry of blood proteins by both bacterial and viral antigens. Coagulopathies occur mainly in severe COVID-19 characterized by bacterial co-infections with Streptococci, Staphylococci, Klebsiella, Escherichia coli, and Acinetobacter baumannii. These bacteria express unusually large numbers of antigens mimicking human blood antigens, as do both SARS-CoV-2 and adenoviruses. Bacteria mimic cardiolipin, prothrombin, albumin,

and platelet factor 4 (PF4). SARS-CoV-2 mimics complement factors, Rh antigens, platelet phosphodiesterases, Factors IX and X, von Willebrand Factor (VWF), and VWF protease ADAMTS13. Adenoviruses mimic prothrombin and platelet factor 4. Bacterial prophylaxis, avoidance of vaccinating bacterially infected individuals, and antigen deletion for vaccines may reduce coagulopathy risk. Also see the video abstract here: https://youtu.be/zWDOsghrPg8.
Acute asthma exacerbation after SARS-CoV-2 vaccine (SinovacÂ®): a case report. A 76-year-old female received a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine (CoronaVac, Sinovac(Â®), Beijing, China) and subsequently experienced chest discomfort. A computed tomography performed 1 day after vaccination showed multiple infiltrations in both lungs and ground-glass shadows in both lung fields. Her fingertip oxygen saturation was 81% and there was widespread wheezing on physical examination. Based on these findings, the patient was hospitalized with a preliminary diagnosis of drug-induced pneumonitis and acute asthma exacerbation due to a SARS-CoV-2 vaccine. During her hospitalization, 40 mg/d systemic steroid, 4 times a day salbutamol nebulized, 2 L/min inhaled oxygen therapy and 400 mg/d moxifloxacin intravenous were administered for 5 days. One month later, the thorax computed tomography scan revealed that the previous findings were almost completely regressed.
Generalized dermal hypersensitivity reaction following Moderna COVID-19 vaccination.
[Erythema multiforme following COVID-19 vaccination (BNT162b2)]. We report aÂ case of aÂ patient with erythema multiforme major following COVID-19 (coronavirus disease 2019) vaccination. Lesions on skin and mucous membranes developed 48â€¯h after the second dose of the mRNA-vaccine BNT162b2 (Tozinameran, ComirnatyÂ®). Under the application of external glucocorticoids complete resolution was achieved within 3Â weeks.
CoronaVac COVID-19 Vaccine-Induced Anaphylaxis: Clinical Characteristics and Revaccination Outcomes. Anaphylaxis to CoronaVac, an inactivated vaccine against COVID-19, is extremely rare. We report 12 cases of anaphylaxis after CoronaVac administration, focusing on clinical characteristics and management outcomes. Skin test and graded vaccine challenge were successfully performed in our cases and might be considered if an inactivated vaccine is the only remaining option.
COVID-19 interventions in children: a balancing act.
Impaired memory B-cell response to the Pfizer-BioNTech COVID-19 vaccine in patients with common variable immunodeficiency.
Models for SARS-CoV-2 associated thrombocytopenia associated with hemophagocytic histiocytes. A subset of COVID-19 patients is experiencing secondary immune thrombocytopenia, also called immune thrombocytopenic purpura (ITP) or secondary hemophagocytic lymphohistiocytosis (HLH). The pathogenesis of SARS-CoV-2 associated thrombocytopenia is unknown. Very rare cases of vaccine induced prothrombotic immune thrombocytopenia (VIPIT) are occurring associated with COVID-19 vaccines. COVID-19 VIPIT is associated with autoantibodies targeting platelet factor 4 (PF4) for COVID-19 adenovirus vaccines. Herein, four models for hemophagocytic histocytes contributions to the etiology of thrombocytopenia associated with SARS-CoV-2 are proposed. One of the models proposes potential involvement of hemophagocytic histocytes targeting platelets bound by autoantibodies consistent with observed PF4 autoantibodies in COVID-19 VIPIT.
GFHT proposals on the practical use of argatroban - With specifics regarding vaccine-induced immune thrombotic thrombocytopaenia (VITT). Argatroban is a direct anti-IIa (thrombin) anticoagulant, administered as a continuous intravenous infusion; it has been approved in many countries for the anticoagulant management of heparin-induced thrombocytopaenia (HIT). Argatroban was recently proposed as the non-heparin anticoagulant of choice for the management of patients diagnosed with Vaccine-induced Immune Thrombotic Thrombocytopaenia (VITT). Immunoglobulins are also promptly intravenously administered in order to rapidly improve platelet count; concomitant therapy with

steroids is also often considered. An ad hoc committee of the French Working Group on Haemostasis and Thrombosis members has worked on updated and detailed proposals regarding the management of anticoagulation with argatroban, based on previously released guidance for HIT, and adapted for VITT. In case of VITT, the initial dose to be preferred is 1.0â€‰Âµgâ€‰Ã—â€‰kg(-1)â€‰Ã—â€‰min(-1), with further dose-adjustments based on iterative and frequent clinical and laboratory assessments. It is strongly advised to involve a health practitioner experienced in the management of difficult cases in haemostasis. The first laboratory assessment should be performed 4â€‰h after the initiation of argatroban infusion, with further controls at 2-4-h intervals until steady state, and at least once daily thereafter. Importantly, full anticoagulation should be rapidly achieved in case of widespread thrombosis. Cerebral vein thrombosis (which is typical of VITT) should not call for an overly cautious anticoagulation scheme. Argatroban administration requires baseline laboratory assessment and should rely on an anti-IIa assay to derive argatroban plasma levels using a dedicated calibration, with a target range between 0.5 and 1.5â€‰Âµg/mL. Target argatroban plasma levels can be refined based on meticulous appraisal of risk factors for bleeding and thrombosis, on frequent reassessments of clinical status with appropriate vascular imaging, and on the changes in daily platelet counts. Regarding the use of aPTT, baseline value and possible causes for alterations of the clotting time must be taken into account. Specifically, in case of VITT, an aPTT ratio (patient's/mean normal clotting time) between 1.5 and 2.5 is suggested, to be refined according to the sensitivity of the reagent to the effect of a direct thrombin inhibitor. The sole use of aPTT is discouraged: one has to resort to a periodical check with an anti-IIa assay at least, with the help of a specialised laboratory if necessary. Dose modifications should proceed in a stepwise manner with 0.1 to 0.2â€‰Âµgâ€‰Ã—â€‰kg(-1)â€‰Ã—â€‰min(-1) up- or downward changes, taking into account the initial dose, laboratory results, and the whole individual setting. Nomograms are available to adjust the infusion rate. Haemoglobin level, platelet count, fibrinogen plasma level and liver tests should be periodically checked, depending on the clinical status, the more so when unstable.

Arthritis following COVID-19 vaccination: report of two cases. While most patients with coronavirus disease 2019 (COVID-19) present with mild or moderate symptoms, 15% may develop severe pneumonia, 5% develop acute respiratory distress syndrome (ARDS), septic shock, and multiple organ failure. Some patients may also experience arthralgia or arthritis. Cases of reactive arthritis have been reported during or after COVID-19. With the approval of the use of COVID-19 vaccines, the vaccination program was started in our country and is still continuing.Here we present two patients who developed arthritis after COVID-19 vaccination.

Caution in underrepresentation of older adults in clinical trials on COVID-19 vaccines. We read with great interest the article "Underrepresentation of older adults in clinical trials on COVID-19 vaccines: A systematic review" written by Nicola Veronese et al. This important work demonstrated that medications and vaccines commonly used in older adults have not been adequately evaluated. Concerning this systematic review, we shall like to mention some certain points deserved to be attended by the authors.

Refractory vaccine-induced immune thrombotic thrombocytopenia (VITT) managed with delayed therapeutic plasma exchange (TPE). Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a newly described hematologic disorder, which presents as acute thrombocytopenia and thrombosis after administration of the ChAdOx1 nCov-19 (AstraZeneca) and Ad26.COV2.S (Johnson & Johnson) adenovirus-based vaccines against COVID-19. Due to positive assays for antibodies against platelet factor 4 (PF4), VITT is managed similarly to autoimmune heparin-induced thrombocytopenia (HIT) with intravenous immunoglobulin (IVIG) and non-heparin anticoagulation. We describe a case of VITT in a 50-year-old man with antecedent alcoholic cirrhosis who presented with platelets of 7â€‰Ã—â€‰10(3) /Î¼L and portal vein thrombosis 21â€‰days following administration of the

Ad26.COV2.S COVID-19 vaccine. The patient developed progressive thrombosis and persistent severe thrombocytopenia despite IVIG, rituximab and high-dose steroids and had persistent anti-PF4 antibodies over 30â€‰days after his initial presentation. As such, delayed therapeutic plasma exchange (TPE) was pursued on day 32 of admission as salvage therapy, with a sustained improvement in his platelet count. Our case serves as proof-of-concept of the efficacy of TPE in VITT.

Interest of a third dose of BNT162b2 anti-SARS-CoV-2 messenger RNA vaccine after allotransplant.

Recurrence of Graves' Disease (a Th1-type Cytokine Disease) Following SARS-CoV-2 mRNA Vaccine Administration: A Simple Coincidence? Graves' disease is the most frequent cause of hyperthyroidism in young women. This auto-immune disease is due to the production of class 1 IgG stimulating the TSH receptor. These antibodies are produced secondary to a Th1 immune response in which interferon gamma plays a key role. Vaccination is ongoing worldwide against SARS-CoV-2 and some of the vaccines include mRNA which seems to stimulate the Th1 immune response. Here, we report a case of recurrence of hyperthyroidism due to Graves' disease following mRNA vaccination and discuss the possible implicated mechanism. This observation argues for a systematic study of a population of patients with previous Graves' disease in order to assess the risk of recurrence following vaccination. LEARNING POINTS: Graves' disease is a Th1-mediated immune disease in which interferon gamma plays a key role.The recurrence of hyperthyroidism due to Grave's disease should be monitored in patients exposed to risk factors.

A Rare Case of Guillain-BarrÃ© Syndrome following COVID-19 Vaccination. Various vaccines against COVID-19 have been developed since SARS-CoV-2 emerged at the end of 2019. Their emergency administration in healthcare settings has been accompanied by numerous adverse effects. A case of Guillain-BarrÃ© syndrome following vaccination with Covishield is presented here to highlight this possible adverse condition. LEARNING POINTS: Guillain-BarrÃ© Syndrome (GBS) is a very rare complication after vaccination against SARS-CoV-2.The key concepts related to the understanding, management and outcomes of patients with GBS are discussed.

Humoral and Cellular Response Following Vaccination With the BNT162b2 mRNA COVID-19 Vaccine in Patients Affected by Primary Immunodeficiencies. Mass SARS-Cov-2 vaccination campaign represents the only strategy to defeat the global pandemic we are facing. Immunocompromised patients represent a vulnerable population at high risk of developing severe COVID-19 and thus should be prioritized in the vaccination programs and in the study of the vaccine efficacy. Nevertheless, most data on efficacy and safety of the available vaccines derive from trials conducted on healthy individuals; hence, studies on immunogenicity of SARS-CoV2 vaccines in such populations are deeply needed. Here, we perform an observational longitudinal study analyzing the humoral and cellular response following the BNT162b2 mRNA COVID-19 vaccine in a cohort of patients affected by inborn errors of immunity (IEI) compared to healthy controls (HC). We show that both IEI and HC groups experienced a significant increase in anti-SARS-CoV-2 Abs 1 week after the second scheduled dose as well as an overall statistically significant expansion of the Ag-specific CD4+CD40L+ T cells in both HC and IEI. Five IEI patients did not develop any specific CD4+CD40L+ T cellular response, with one of these patients unable to also mount any humoral response. These data raise immunologic concerns about using Ab response as a sole metric of protective immunity following vaccination for SARS-CoV-2. Taken together, these findings suggest that evaluation of vaccine-induced immunity in this subpopulation should also include quantification of Ag-specific T cells.

Induction of High Levels of Specific Humoral and Cellular Responses to SARS-CoV-2 After the Administration of Covid-19 mRNA Vaccines Requires Several Days. OBJECTIVES: In the context of the Covid-19 pandemic, the fast development of vaccines with efficacy of around 95% preventing Covid-19 illness provides a unique opportunity to reduce the mortality associated with the pandemic. However, in the absence of efficacious prophylactic medications and few treatments for this

infection, the induction of a fast and robust protective immunity is required for effective disease control, not only to prevent the disease but also the infection and shedding/transmission. The objective of our study was to analyze the level of specific humoral and cellular T-cell responses against the spike protein of SARS-CoV-2 induced by two mRNA-based vaccines (BNT162b2 and mRNA-1273), but also how long it takes after vaccination to induce these protective humoral and cellular immune responses. METHODS: We studied in 40 healthy (not previously infected) volunteers vaccinated with BNT162b2 or mRNA-1273 vaccines the presence of spike-specific IgG antibodies and SARS-CoV-2-specific T cells at 3, 7 and 14 days after receiving the second dose of the vaccine. The specific T-cell response was analyzed stimulating fresh whole blood from vaccinated volunteers with SARS-CoV-2 peptides and measuring the release of cytokines secreted by T cells in response to SARS-CoV-2 stimulation. RESULTS: Our results indicate that the immunization capacity of both vaccines is comparable. However, although both BNT162b2 and mRNA-1273 vaccines can induce early B-cell and T-cell responses, these vaccine-mediated immune responses do not reach their maximum values until 14 days after completing the vaccination schedule. CONCLUSION: This refractory period in the induction of specific immunity observed after completing the vaccination could constitute a window of higher infection risk, which could explain some emerging cases of SARS-CoV-2 infection in vaccinated people.
Thrombosis and Thrombocytopenia Syndrome Causing Isolated Symptomatic Carotid Occlusion after Covid-19 Vaccine.
Sudden sensorineural hearing loss after COVID-19 vaccination. Coronavirus disease 2019 (COVID-19) spread rapidly and was declared a pandemic. In this situation, vaccination for COVID-19 is important and has been prompted in many countries. Rare serious adverse events including Guillain-BarrÃ© syndrome, thrombosis with thrombocytopenia syndrome, and myocarditis after COVID-19 vaccinations have been reported. Otolaryngologic adverse events after COVID-19 vaccination were reported, including several cases of sudden sensorineural hearing loss (SSNHL). We report three patients with SSNHL within three days after COVID-19 vaccination and consider an association between them. Although there is no evidence of an association between vaccination and SSNHL, the adverse event of SSNHL after COVID-19 vaccination should be kept in mind because viral infection could be the etiology of SSNHL, which is an otologic emergency that requires prompt treatment with steroids.
Covid-19 Vaccination during Pregnancy and First-Trimester Miscarriage.
Audio Interview: A New Look at Covid-19 Vaccine Boosters.
Second dose of COVID-19 vaccination in immediate reactions to the first BNT162b2.
SARS-CoV-2 Vaccine Induced Atypical Immune Responses in Antibody Defects: Everybody Does their Best. BACKGROUND: Data on immune responses to SARS-CoV-2 in patients with Primary Antibody Deficiencies (PAD) are limited to infected patients and to heterogeneous cohorts after immunization. METHODS: Forty-one patients with Common Variable Immune Deficiencies (CVID), six patients with X-linked Agammaglobulinemia (XLA), and 28 healthy age-matched controls (HD) were analyzed for anti-Spike and anti-receptor binding domain (RBD) antibody production, generation of Spike-specific memory B-cells, and Spike-specific T-cells before vaccination and one week after the second dose of BNT162b2 vaccine. RESULTS: The vaccine induced Spike-specific IgG and IgA antibody responses in all HD and in 20% of SARS-CoV-2 naive CVID patients. Anti-Spike IgG were detectable before vaccination in 4 out 7 CVID previously infected with SARS-CoV-2 and were boosted in six out of seven patients by the subsequent immunization raising higher levels than patients naÃ¯ve to infection. While HD generated Spike-specific memory B-cells, and RBD-specific B-cells, CVID generated Spike-specific atypical B-cells, while RBD-specific B-cells were undetectable in all patients, indicating the incapability to generate this new specificity. Specific T-cell responses were evident in all

HD and defective in 30% of CVID. All but one patient with XLA responded by specific T-cell only. CONCLUSION: In PAD patients, early atypical immune responses after BNT162b2 immunization occurred, possibly by extra-follicular or incomplete germinal center reactions. If these responses to vaccination might result in a partial protection from infection or reinfection is now unknown. Our data suggests that SARS-CoV-2 infection more effectively primes the immune response than the immunization alone, possibly suggesting the need for a third vaccine dose for patients not previously infected.

The very low risk of myocarditis and pericarditis after mRNA COVID-19 vaccination should not discourage vaccination. The benefits of vaccination - regarding COVID-19 infection and transmission, as well as COVID-associated complications - clearly outweigh the potential risk of vaccine-associated inflammation of the heart and other adverse events. Given the current state of knowledge, the outcome of myocarditis and pericarditis following vaccination is generally good. This review aims to guide physicians in the early diagnosis and management of suspected myocarditis following mRNA COVID vaccination. The initial work-up should include detailed history, a 12-lead electrocardiogram and serological biomarkers (high-sensitivity cardiac troponin T/I, natriuretic peptides and markers of inflammation) in accordance with the assessments recommended in current clinical practice guidelines for patients presenting with acute chest pain. In patients with suspected myocarditis, further assessment with transthoracic echocardiography and cardiovascular magnetic resonance imaging should be undertaken to confirm peri-/myocarditis and to distinguish the findings from other diseases with similar presentation. Patients with mRNA vaccine-associated myocarditis should be followed-up at least once to exclude chronic myocardial inflammation and deterioration of left ventricular ejection fraction. Consultation with an expert such as an immunologist with experience in vaccination regarding further mRNA vaccinations is advised in all patients with mRNA vaccine-associated perimyocarditis. Reporting of mRNA vaccine-associated myocarditis to Swissmedic is mandatory. Cohort studies prospectively follow-up on young adult and paediatric populations following immunisation with an mRNA COVID vaccine to monitor cardiac and immune parameters would generate valuable knowledge to better understand pathogenesis and risk factors for vaccine-associated perimyocarditis.

Neurological autoimmune diseases following vaccinations against SARS-CoV-2: a case series. BACKGROUND AND PURPOSE: Population-based studies suggest that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines may trigger immune-mediated thrombotic thrombocytopenia (VITT) raising concerns for other autoimmune responses. The aim was to characterize neurological autoimmunity after SARS-CoV-2 vaccinations. METHODS: In this single-centre prospective case study patients with neurological autoimmunity in temporal association (â‰¤6Â weeks) with SARS-CoV-2 vaccinations and without other triggers are reported. Clinical, laboratory and imaging data were collected with a median follow-up of 49Â days. RESULTS: In the study period 232,603 inhabitants from the main catchment area of our hospital (Rhein-Neckar-Kreis, county) received SARS-CoV-2 vaccinations. Twenty-one cases (new onset nÂ =Â 17, flares nÂ =Â 4) diagnosed a median of 11Â days (range 3-23) following SARS-CoV-2 vaccinations (BNT162b2 nÂ =Â 12, ChAdOx1 nÂ =Â 8, mRNA-1273 nÂ =Â 1) were identified. Cases included VITT with cerebral venous sinus thrombosis (nÂ =Â 3), central nervous system demyelinating diseases (nÂ =Â 8), inflammatory peripheral neuropathies (nÂ =Â 4), myositis (nÂ =Â 3), myasthenia (nÂ =Â 1), limbic encephalitis (nÂ =Â 1) and giant cell arteritis (nÂ =Â 1). Patients were predominantly female (ratio 3.2:1) and the median age at diagnosis was 50Â years (range 22-86). Therapy included administration of steroids (nÂ =Â 15), intravenous immunoglobulins in patients with Guillain-BarrÃ© syndrome or VITT (nÂ =Â 4), plasma exchange in cases unresponsive to steroids (nÂ =Â 3) and anticoagulation in VITT. Outcomes were favourable with partial and complete remissions achieved in 71% and 24%,

respectively. Two patients received their second vaccination without further aggravation of autoimmune symptoms under low-dose immunosuppressants. CONCLUSIONS: In this study various neurological autoimmune disorders encountered following SARS-CoV-2 vaccinations are characterized. Given the assumed low incidence and mostly favourable outcome of autoimmune responses, the benefits of vaccinations outweigh the comparatively small risks.

Prevalence of anti-platelet factor 4/polyanionic antibodies after COVID-19 vaccination with ChAdOx1 nCoV-19 and CoronaVac in Thais. INTRODUCTION: Vaccine-induced thrombotic thrombocytopenia (VITT) has been reported after vaccination with the adenoviral vector coronavirus disease 2019 (COVID-19) vaccine ChAdOx1 nCoV-19 in European countries. To date, two cases of VITT have been reported in Thais after COVID-19 vaccination. We determined the frequency of anti-platelet factor 4 (PF4)/polyanionic antibodies in the Thai population receiving the COVID-19 vaccines. METHODS: We conducted a cross-sectional study to evaluate the prevalence of anti-PF4/polyanionic antibodies in health care workers who received COVID-19 vaccination with ChAdOx1 nCoV-19 or CoronaVac within 7 to 35Â days. A control population who had not been vaccinated was also included. Anti-PF4/polyanionic antibodies were detected using ELISA. Functional assay with platelet aggregation was performed for all positive anti-PF4/polyanionic antibody ELISA tests. RESULTS: A total of 646 participants were included in the study; 221 received ChAdOx1 nCoV-19, 232 received CoronaVac, and 193 participants were in the control group. The prevalence of anti-PF4 antibodies was 2.3% (95% confidence interval [CI], 0.7-5.2), 1.7% (95% CI, 0.5-4.4) in the ChAdOx1 nCoV-19 and CoronaVac groups, respectively. There was no positive test in the control group. None of the PF4/polyanionic positive sera induced platelet aggregation. CONCLUSION: We found a low prevalence of anti-PF4 antibodies in Thais after vaccination with ChAdOx1 nCoV-19 and CoronaVac. None of the antibodies were functional and lacked an association with VITT.

Erythema Multiforme Major following SARS-CoV-2 vaccine. Erythema multiforme major, an immune-mediated skin reaction to infections or medications with oral involvement, should be taken into account as a potential side effect of several vaccines, including SARS-CoV-2. Correct patient history collection allows prompt recognition and subsequent successful medical management with oral corticosteroids.

COVID-19 BBIBP-CorV vaccine and transient heart block - A phenomenon by chance or a possible correlation - A case report. IMPORTANCE: Bradyarrhythmia during COVID19 illness carries prognostic significance. Electrophysiological side effects of COVID19 vaccine remain largely unknown. It is imperative to report nature of cardiovascular side effects of the vaccine. CASE PRESENTATION: An 80 years-old-man presented with complains of dizziness, trepidation and shortness of breath following his first shot of COVID-19 BBIBP-CorV (Sino-pharm). ECG on arrival showed 2:1 atrioventricular block with an underlying old left bundle branch block. The AV block changed into Mobitz type-I over the course of next 2 days and into a sinus 1:1 conduction on fourth day of presentation. However, our patient underwent permanent pacemaker implantation due to the underlying conduction tissue disease and intermittent 2:1 AV block during the hospital stay. CLINICAL DISCUSSION: It is likely that patients with an already diseased conduction system are at an increased risk of worsening of AV block following inoculation of the vaccine. Vaccine associated AV blocks are likely to be reversible. Presence of prior coronary artery disease and electrical abnormalities are important considerations. CONCLUSION: COVID-19 vaccine may have added side effects in subjects with known heart disease. Humoral response towards the vaccine might interfere with the conduction system of the heart and more so in patients with diseased and scarred myocardium.

Rare case of contralateral supraclavicular lymphadenopathy after COVID-19 vaccination: Computed tomography and ultrasonography findings. We present the computed tomography, ultrasonographic findings of a case of contralateral supraclavicular lymphadenopathy that occurred

after AstraZeneca COVID-19 vaccination. Contralateral supraclavicular lymphadenopathy is very rare, but may be expected as an adverse reaction after COVID-19 vaccination. Radiologists as well as referring clinicians should be aware of this self-limiting process and its imaging features.

B and T Cell Responses after a Third Dose of SARS-CoV-2 Vaccine in Kidney Transplant Recipients. BACKGROUND: Accumulating evidence sugges ts solid organ transplant recipients, as opposed to the general population, show strongly impaired responsiveness toward standard SARS-CoV-2 mRNA-based vaccination, demanding alternative strategies for protectio n o f this vulnerable group. METHODS: In line with recent recommendations, a third dose of either heterologous ChAdOx1 (AstraZeneca) or homologous BNT162b2 (BioNTech) was administered to 25 kidney transplant recipients (KTR) without humoral response after two doses of BNT162b2, followed by analysis of serological responses and vaccine-specific B- and T-cell immunity. RESULTS: Nine out of 25 (36%) KTR under standard immunosuppressive treatment seroconverted until day 27 after the third vaccination, whereas one patient developed severe COVID-19 infection immediately after vaccination. Cellular analysis 7 days after the third dose showed significantly elevated frequencies of viral spike-protein receptor-binding domain-specific B cells in humor al responders as compared with nonresponders. Likewise, portions of spike-reactive CD4 + T helper cells were significantly elevated in patients who were seroconverting. Furthermore, overall frequencies of IL-2 + , IL-4 + , and polyfunctional CD4 + T cells significantly increased after the third dose, whereas memory/effector differentiation remained unaffected. CONCLUSIONS: Our data suggest a fraction of transplant recipients benefit from triple vaccination, where seroconversion is associated with quantitative and qualitative changes of cellular immunity. At the same time, the study highlights that modified vaccination approaches for immunosuppressed patients remain an urgent medical need. PODCAST: This article contains a podcast at https://www.asn-online.org/media/podcast/JASN/2021_11_23_briggsgriffin112321.mp3.

[Factors Affecting Side Effects, Seroconversion Rates and Antibody Response After Inactivated SARS-CoV-2 Vaccination in Healthcare Workers]. In this study, it was aimed to prospectively evaluate the efficacy, side effects and seroconversion data of inactive severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), CoronaVacÂ® (Sinovac, China) vaccine in healthcare workers. A total of 1053 healthcare workers who were initially seronegative (COV2TÂ® SARS-CoV-2 Total Siemens, USA) and vaccinated with inactivated SARS-CoV-2 were included in the study. Quantitative IgG antibodies (ADVIA CentaurÂ® SARS-CoV-2 IgG, Siemens, USA) were investigated 28 days after the first vaccine (n= 939) and the second vaccine (n= 771). In addition, neutralizing antibodies were evaluated via "enzyme linked immunosorbent assay (ELISA)" test (ACE2-RBD Neutralization Assay, Dia-Pro, Italy) 28 days after the first vaccine. Antibody response of the vaccine was evaluated statistically by univariate (Chi-square, Fisher's exact test, Student's t test, Mann-Whitney U, one-way ANOVA and Kruskall Wallis ANOVA tests) analysis and linear regression models. The consistency between quantitative IgG test and neutralizing antibody test was also evaluated in blood samples taken 28 days after second vaccination. Statistical analysis was determined in logarithmically transformed data with statistical analysis with SPSS 23.0 and Stata, and type 1 error level was accepted as 0.05. At least one side effect was reported by 31.3% and 26.8% of the participants after the first and second vaccine, respectively. The most frequent side effect was pain at the injection site with a frequency of 20.4% vs 21.7%. The frequency of applying to a health center due to side effects was 1.0% after the first vaccine and 0.8% after the second vaccine. The percentage of those who produced sufficient quantitative IgG was found as 25.3% (95% CI= 22.5-28.1) 28 days after the first vaccine and 97.9% (95% CI= 96.91- 98.93) after the second vaccine. Neutralizing test antibody positivity was found as 97.7% 28 days after the second vaccine. In univariate analysis, the characteristics that significantly increased the quantitative IgG response against inactivated SARS-CoV-2 vaccine were young age ($p<0.01$), female gender ($p<0.01$), being a non smoker ($p<0.001$), not having a chronic disease ($p= 0.019$), having had the flu

vaccine this year (p= 0.012), not being overweight or obese (p= 0.020), and having a SARS-CoV2 infection prior to vaccination (p<0.001). In addition, allied health personnel showed significantly lower antibody responses than the other workers (p<0.001). Multiple linear regression models revealed that, female gender, younger age, smoking and previous COVID-19 polymerase chain reaction test positivity significantly affected the quantitative IgG response after vaccination. A 99% agreement was found between the ELISA-based neutralizing antibody test and the quantitative IgG test (Kappa p= 0.783) performed on the 28th day after the second vaccination. CoronaVacÂ® provides adequate antibody response in 25% of healthcare workers aged 18-64, after 28 days from a single vaccine, and 97% after 28 days from the second vaccine. Antibody response was significantly higher in younger ages, women, non-smokers, and those who had previously encountered SARS-CoV-2. Phase 3 and phase 4 results are needed to Show effectiveness of this vaccine in real life.

The nano-based theranostics for respiratory complications of COVID-19. High morbidity and mortality caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has made coronavirus disease 2019 (COVID-19) the leading challenge for health experts all over the world. Currently, there is no specific treatment for COVID-19; however, thanks to worldwide intense attempts, novel vaccines such as mRNA-1273 (Moderna TX, Inc.) and BNT162b2 (Biontech/Pfizer) were developed very fast and FDA approved them for emergency use. Nanomedicine-based drug delivery can be an advanced therapeutic strategy to deal with clinical complications of COVID-19. Given the fact that SARS-CoV-2 typically affects the respiratory tract, application of inhalable nanoparticles (NPs) for targeted drug delivery to the alveolar space appears to be an effective and promising therapeutic strategy. Loading the medicinal components into NPs enhances the stability, bioavailability, solubility and sustained release of them. This approach can circumvent major challenges in efficient drug delivery such as solubility and any adverse impact of medicinal components due to off-targeted delivery and resulting systemic complications. Inhalable NPs could be delivered through nasal sprays, inhalers, and nebulizers. NPs also could interfere in virus attachment to host cells and prevent infection. Moreover, nanomedicine-based technologies can facilitate accurate and rapid detection of virus compared to the conventional methods. In this review, the nano-based theranostics modalities for the management of respiratory complications of COVID-19 were discussed.

Transient increase in plasma HIV RNA after COVID-19 vaccination with mRNA-1272.

Airway antibodies emerge according to COVID-19 severity and wane rapidly but reappear after SARS-CoV-2 vaccination. Understanding the presence and durability of antibodies against SARS-CoV-2 in the airways is required to provide insights into the ability of individuals to neutralize the virus locally and prevent viral spread. Here, we longitudinally assessed both systemic and airway immune responses upon SARS-CoV-2 infection in a clinically well-characterized cohort of 147 infected individuals representing the full spectrum of COVID-19 severity, from asymptomatic infection to fatal disease. In addition, we evaluated how SARS-CoV-2 vaccination influenced the antibody responses in a subset of these individuals during convalescence as compared with naive individuals. Not only systemic but also airway antibody responses correlated with the degree of COVID-19 disease severity. However, although systemic IgG levels were durable for up to 8 months, airway IgG and IgA declined significantly within 3 months. After vaccination, there was an increase in both systemic and airway antibodies, in particular IgG, often exceeding the levels found during acute disease. In contrast, naive individuals showed low airway antibodies after vaccination. In the former COVID-19 patients, airway antibody levels were significantly elevated after the boost vaccination, highlighting the importance of prime and boost vaccinations for previously infected individuals to obtain optimal mucosal protection.

Cerebral venous sinus thrombosis associated with COVID-19 vaccine-induced thrombocytopenia: Improvement in mortality rate over time.
Letter to the Editor: Ischemic Stroke of the Corpus Callosum after SARS-CoV-2 Vaccination.
Myocarditis-induced Sudden Death after BNT162b2 mRNA COVID-19 Vaccination in Korea: Case Report Focusing on Histopathological Findings. We present autopsy findings of a 22-year-old man who developed chest pain 5 days after the first dose of the BNT162b2 mRNA vaccine and died 7 hours later. Histological examination of the heart revealed isolated atrial myocarditis, with neutrophil and histiocyte predominance. Immunohistochemical C4d staining revealed scattered single-cell necrosis of myocytes which was not accompanied by inflammatory infiltrates. Extensive contraction band necrosis was observed in the atria and ventricles. There was no evidence of microthrombosis or infection in the heart and other organs. The primary cause of death was determined to be myocarditis, causally-associated with the BNT162b2 vaccine.
Experience of Covid 19 vaccination in patients with bleeding disorders.
Vaccine-induced immune thrombosis and thrombocytopenia syndrome following adenovirus-vectored severe acute respiratory syndrome coronavirus 2 vaccination: a novel hypothesis regarding mechanisms and implications for future vaccine development. We hypothesize that thrombosis with thrombocytopenia syndrome recently described after administration of adenovirus-vectored vaccines for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) occurs as a result of the unique properties of the adenovirus vectors, which can have widespread biodistribution throughout the body. The antigen is delivered to megakaryocyte cells, which act as part of the primary immune system and distribute the antigen within progeny platelets, also a key component of the immune system. The interaction of the antigen induces preformed antiplatelet factor 4 (PF4) antibodies to bind to PF4-heparan sulfate complexes in the absence of exogenous heparin, at sites where the heparan sulfate concentration in the vascular glycocalyx is optimal for complex formation, causing thrombosis and thrombocytopenia as observed clinically. This hypothesis is testable in cell culture and animal models, and potentially inâ€‰vivo, and if proven correct has significant implications for vaccine development and our understanding of the links between the coagulation and immune systems.
Serological response following BNT162b2 anti-SARS-CoV-2 mRNA vaccination in haematopoietic stem cell transplantation patients.
Lessons from vaccine-induced immune thrombotic thrombocytopenia. Adenoviral vector vaccines are effective against SARS-CoV-2 but have been associated with a rare side effect termed vaccine-induced immune thrombotic thrombocytopenia (VITT). Here, we discuss our understanding of how vaccine-induced antibodies to platelet factor 4 (PF4) form immune complexes that activate platelets and trigger the thrombotic events seen in VITT.   Here, John Kelton and colleagues provide an overview of vaccine-induced immune thrombotic thrombocytopenia (VITT), a very rare complication that has been observed following vaccination with adenoviral vector-based COVID-19 vaccines.
[Not Available].
Erythema nodosum following the first dose of ChAdOx1-S nCoV-19 vaccine.
Mild Adverse Events of Sputnik V Vaccine in Russia: Social Media Content Analysis of Telegram via Deep Learning. BACKGROUND: There is a limited amount of data on the safety profile of the COVID-19 vector vaccine Gam-COVID-Vac (Sputnik V). Previous infodemiology studies showed that social media discourse could be analyzed to assess the most concerning adverse events (AE) caused by drugs. OBJECTIVE: We aimed to investigate mild AEs of Sputnik V based on a participatory trial conducted on Telegram in the Russian language. We compared AEs extracted from Telegram with other limited databases on Sputnik V and other COVID-19 vaccines. We explored symptom co-

occurrence patterns and determined how counts of administered doses, age, gender, and sequence of shots could confound the reporting of AEs. METHODS: We collected a unique dataset consisting of 11,515 self-reported Sputnik V vaccine AEs posted on the Telegram group, and we utilized natural language processing methods to extract AEs. Specifically, we performed multilabel classifications using the deep neural language model Bidirectional Encoder Representations from Transformers (BERT) "DeepPavlov," which was pretrained on a Russian language corpus and applied to the Telegram messages. The resulting area under the curve score was 0.991. We chose symptom classes that represented the following AEs: fever, pain, chills, fatigue, nausea/vomiting, headache, insomnia, lymph node enlargement, erythema, pruritus, swelling, and diarrhea. RESULTS: Telegram users complained mostly about pain (5461/11,515, 47.43%), fever (5363/11,515, 46.57%), fatigue (3862/11,515, 33.54%), and headache (2855/11,515, 24.79%). Women reported more AEs than men (1.2-fold, P<.001). In addition, there were more AEs from the first dose than from the second dose (1.1-fold, P<.001), and the number of AEs decreased with age (Î²=.05 per year, P<.001). The results also showed that Sputnik V AEs were more similar to other vector vaccines (132 units) than with messenger RNA vaccines (241 units) according to the average Euclidean distance between the vectors of AE frequencies. Elderly Telegram users reported significantly more (5.6-fold on average) systemic AEs than their peers, according to the results of the phase 3 clinical trials published in The Lancet. However, the AEs reported in Telegram posts were consistent (Pearson correlation r=0.94, P=.02) with those reported in the Argentinian postmarketing AE registry. CONCLUSIONS: After the Sputnik V vaccination, Russian Telegram users reported mostly pain, fever, and fatigue. The Sputnik V AE profile was comparable with other vector COVID-19 vaccines. Discussion on social media could provide meaningful information about the AE profile of novel vaccines.
Presumed Recurrent MEWDS following Covid-19 Vaccination. PURPOSE: To present an unusual case of recurrent multiple evanescent white dot syndrome (MEWDS) following the coronavirus 2019 (Covid-19) vaccination. METHODS: Review of the clinical, laboratory, photographic, and angiographic records of a patient with MEWDS. RESULTS: A 49-year-old female who had MEWDS nine years ago presented to our clinic with blurred vision in her left eye. These symptoms occurred 2Â days following Covid-19 vaccination. Fundus examinations and diagnostic testing were consistent with recurrent MEWDS. CONCLUSION: While rare, MEWDS can reoccur following Covid-19 vaccination.
Asymptomatic SARS-CoV-2 Vaccine Breakthrough Infections in Health Care Workers Identified Through Routine Universal Surveillance Testing.
Generalized erythema multiforme-like skin rash following the first dose of COVID-19 vaccine (Pfizer-BioNTech).
Cutaneous adverse reactions from 35,229 doses of Sinovac and AstraZeneca COVID-19 vaccination: a prospective cohort study in healthcare workers.
Cutaneous findings following COVID-19 vaccination: review of world literature and own experience. There is growing evidence that not only the novel coronavirus disease (COVID-19) but also the COVID-19 vaccines can cause a variety of skin reactions. In this review article, we provide a brief overview on cutaneous findings that have been observed since the emerging mass COVID-19 vaccination campaigns all over the world. Unspecific injection-site reactions very early occurring after the vaccination are most frequent. Type I hypersensitivity reactions (e.g. urticaria, angio-oedema and anaphylaxis) likely due to allergy to ingredients may rarely occur but can be severe. Type IV hypersensitivity reactions may be observed, including delayed large local skin lesions ("COVID arm"), inflammatory reactions in dermal filler or previous radiation sites or even old BCG scars, and more commonly morbilliform and erythema multiforme-like rashes. Autoimmune-mediated skin findings after COVID-19 vaccination include leucocytoclastic vasculitis, lupus erythematosus and immune thrombocytopenia. Functional angiopathies (chilblain-like lesions, erythromelalgia) may also be

observed. Pityriasis rosea-like rashes and reactivation of herpes zoster have also been reported after COVID-19 vaccination. In conclusion, there are numerous cutaneous reaction patterns that may occur following COVID-19 vaccination, whereby many of these skin findings are of immunological/autoimmunological nature. Importantly, molecular mimicry exists between SARS-CoV-2 (e.g. the spike-protein sequences used to design the vaccines) and human components and may thus explain some COVID-19 pathologies as well as adverse skin reactions to COVID-19 vaccinations.

Subdiaphragmatic Lymph Nodes Uptake on 18F-FDG PET/CT After COVID-19 Vaccination in the Thigh. Since worldwide COVID-19 vaccination, 18F-FDG uptake in reactive axillary lymph nodes has been frequently observed in PET/CT studies. We describe a patient with breast cancer who underwent 18F-FDG PET/CT 7 days after receiving COVID-19 vaccination in the right thigh. 18F-FDG uptake was observed in nonenlarged right-sided inguinal, iliac, and para-aortic lymph nodes. As the thigh can be used as an alternate site for COVID-19 vaccine injection in case of lymphedema in both arms or for adequate axillary staging in patients with breast cancer, physicians should be aware of such 18F-FDG uptake pattern.

Side effects of the BNT162b2 vaccine in the personnel of the Military Central Hospital. OBJECTIVE: The pandemic disease by SARS-CoV-2 infection does not have an effective treatment. To prevent the disease, scientists developed vaccines that the clinicians use as an emergency licensed vaccine. The objective of this study was to determine the side effects in personnel vaccinated at the Military Central Hospital of Mexico with the BNT162b2 vaccine. PATIENTS AND METHODS: This study included the subjects who had received both doses of the BNT162b2 vaccine between December 2020 and February 2021. We asked about the side effects after the first and the second vaccine doses. One group had no history of COVID-19, and the second had a history of COVID-19. ANTI-SARS-CoV-2 antibodies were measured by the immunodetection technique in the second group only. RESULTS: We included 946 participants, 62% were women, and 80% were without comorbidities; 680 were included in the first group, and only 266 were in the second group. After the first dose, 77% of the first group and 86% of the second group presented some side effects. After the second dose, 84% of the first group and 89% of the second group showed some side effects. The main side effect was mild pain. All participants (126) were IgG positive, and only 26.9% were IgM positive at 17.5 days (12.8 days, 20.3 days) after the second dose. CONCLUSIONS: There is a positive correlation between side effects after the first dose in patients with a history of previous SARS-CoV-2 infection compared to those who did not. Nevertheless, this correlation is not present after the second dose. The low percentage of IgM could be related to the time interval between vaccination and sample measure.

Sinovac COVID-19 vaccine-induced cutaneous leukocytoclastic vasculitis.

Potential Triggers for Thrombocytopenia and/or Hemorrhage by the BNT162b2 Vaccine, Pfizer-BioNTech. Immune thrombocytopenia is an autoimmune disease that can cause bleeding in severe cases. Although available published data do not associate the BNT162b2 vaccine (Pfizer-BioNTech) with the risk of developing thrombocytopenia, the ChAdOx1 nCov-19 vaccine has raised concerns about its potential link with thrombosis and thrombocytopenia. We would like to clarify whether the BNT162b2 vaccine administration may interfere with pre-existing conditions and whether it may cause a risk of thrombocytopenia. Herein, we report three cases of post-vaccine thrombocytopenia among patients with rheumatoid arthritis (RA); one case in which a causal relationship cannot be ruled out with the BNT162b2 vaccine was officially announced. Furthermore, we reviewed reports of adverse events and death cases with a focus on thrombocytopenia and hemorrhages, following vaccination with BNT162b2 in Japan between February 17, 2021 and July 16, 2021, as reported by the Ministry of Health, Labour, and Welfare within the general population. The three cases in this report share the common features of old age, RA, chronic renal failure or hypertension, and pre-existing mild thrombocytopenia at baseline. A total of 746 death cases were

reported during this time period, with death by bleeding accounting for 8.8% of the total deaths, of which 84.8% were cranial and statistically higher in young women than among elderly women. The risk-benefit ratio of the vaccine needs to be reconsidered based on high- and low-risk population types and ethnicity. To do so, the expansion of the pharmacovigilance system for BNT162b2 vaccination is urgently required worldwide.

Risk Factors for Grade 3 to Grade 4 Adverse Reactions to the ChAdOx1 nCoV-19 Vaccine (AZD1222) Against SARS-CoV-2. Objective: Limited data are available regarding the rates and risk factors of severe to serious adverse reactions (ARs) to the ChAdOx1 nCoV-19 vaccine. Methods: Eligible participants were healthcare workers who received their first dose of the ChAdOx1 nCoV-19 vaccine in either of two university hospitals in Seoul, Korea. We evaluated the type and severity of ARs 7 days after the first dose of the ChAdOx1 nCoV-19 vaccine using a questionnaire survey delivered via a smartphone application link. Results: Among the 1,603 participants who completed the survey, 684 (42.7%) participants experienced any kind of grade 3 to grade 4 AR. Being young (adjusted odds ratio [OR] for age 21-30 years = 2.49, 95% confidence interval [CI] = 1.75-3.56; adjusted OR for 31-40 years = 1.78, 95% CI = 1.22-2.62; adjusted OR for 41-50 years = 1.47, 95% CI = 1.03-2.11), being female (adjusted OR = 2.16. 95% CI = 1.62-2.89), and being underweight (adjusted OR = 1.61, 95% CI = 1.02-2.55) were identified as risk factors for grade 3 to grade 4 ARs. Among comorbidities, only diabetes mellitus (adjusted OR = 2.36, 95% CI = 1.03-5.53) was identified as a risk factor. When stratified by the type of AR, being young and being female were risk factors for both local and systemic grade 3 to grade 4 ARs. Conclusions: Being young, female, or underweight and having diabetes mellitus were associated with an increased risk of developing grade 3 to grade 4 ARs after receiving the first dose of the ChAdOx1 nCoV-19 vaccine.

Neuromyelitis Optica in a Healthy Female After Severe Acute Respiratory Syndrome Coronavirus 2 mRNA-1273 Vaccine. Neuromyelitis optica spectrum disorder is an autoimmuneÂ demyelinating disease with high relative prevalence in the East Asian population. Clinical manifestations include optic neuritis, longitudinally extensive transverse myelitis, area postrema syndrome, brainstem syndromes, and diencephalic syndromes. In this case report, we present a case of neuromyelitis optica spectrum disorder that developed 10 days after the first dose of the severe acute respiratory syndrome coronavirus 2 mRNA-1273 vaccine. The patient was a previously healthy White female, completely independent and functional at baseline. She presented with bilateral lower-extremity numbness/tingling, weakness, and urinary retention. Although her neuromyelitis optica IgG was negative, the MRI was consistent with neuromyelitis optica involving and spanning longitudinally the C6-T2 vertebrae. She was treated with IV steroids and her symptoms improved. Given the novelty of the COVID-19 vaccines and the paucity of literature regarding their adverse effects, case reports such as ours provide unique information that aids healthcare providers in accurately diagnosing and treating patients, ultimately minimizing long-term neurologic deficits.

Immune Thrombocytopenia Exacerbation After COVID-19 Vaccination in a Young Woman. The coronavirus disease 2019 (COVID-19) pandemic is one of the greatest healthÂ concerns worldwide. Safe and effective COVID-19 vaccines are urgently needed and have been rapidly approved. COVID-19 vaccine-induced thrombocytopenia was reported as a rare adverse effect in the Vaccine Adverse Events Reporting System. A 25-year-old woman, who was previously diagnosed with immune thrombocytopenia (ITP, stage I), had exacerbated severe thrombocytopenia (platelet count of 6,000/Î¼L) with a headache, joint pain, general fatigue, and bleeding tendency three days after receiving her second dose of the Pfizer BioNTech COVID-19 vaccine. Pulsed high-dose dexamethasone therapy rapidly ameliorated the ITP. Although it is difficult to confirm a causal association between Pfizer BioNTech COVID-19 vaccination and ITP exacerbation, abrupt onset of ITP exacerbation after vaccination suggests that the ITP may be vaccination-induced thrombocytopenia exacerbation. Rare

but severe adverse events such as ITP may be observed, depending on increased numbers of individuals who receive COVID-19 vaccines worldwide. Further investigation is needed to clarify the mechanisms of COVID-19 vaccine-induced ITP.

A Late Presentation of COVID-19 Vaccine-Induced Myocarditis. With the introduction of the coronavirus diseaseÂ 2019 (COVID-19) mRNA vaccines, the incidence of severe infection has significantly decreased. While the vaccines have been shown to be effective and safe, there have been few case reports of acute myocarditis within 3-5 days following the second dose of the vaccine.Â We reportÂ a case of an elderly man who presented with acute-onset chest pain after three months of receiving the second dose of the mRNA vaccine. He was found to have acute myocarditis on cardiac magnetic resonance imaging (CMRI), which was attributed to exposure to the COVID-19 vaccine in the absence of any other risk factors. Our patient demonstrated quick resolution of symptoms and was discharged within 72 hours. We review the literature and summarize published case reports on COVID-19 vaccine-associated myocarditis. The present case report provides new evidence regarding the possibleÂ subacute presentation of myocarditis post-COVID-19 vaccine, and further highlights the favorable outcome in this newly described clinical entity.

Nonarteritic Anterior Ischemic Optic Neuropathy following COVID-19 Vaccination: Consequence or Coincidence. To report a patient with nonarteritic anterior ischemic optic neuropathy (NA-AION) occurring soon after the COVID-19 vaccination. A 55-year-old woman presented with a 4-day history of inferior visual field disturbance in the right eye 7 days after receiving the first dose of Pfizer-BioNTech COVID-19 vaccine. Examination revealed a best-corrected visual acuity of 20/20 in both eyes. A relative afferent pupillary defect was observed in the right eye. Fundoscopy revealed diffuse optic disc swelling in the right eye, which was prominent above the optic disc. Goldmann visual field testing identified an inferior altitudinal visual field defect with I/2 isopter in the right eye. Although typical complete inferior visual field defect was not detected, a diagnosis of NA-AION was made. The patient was followed without any treatment. During the 2-month follow-up period, the optic disc swelling was gradually improved, and visual acuity was maintained 20/20; however, the optic disc looked diffusely pale in the right eye. Although it is uncertain whether the development of NA-AION after COVID-19 vaccination was consequential or coincidental, we speculate that the close temporal relationship with COVID-19 vaccination suggests the possibility of vasculopathy on the microvascular network of optic nerve head as background of inflammatory or immune-mediated element to the timing of the onset of NA-AION. The aim of this case report is to present this biological plausibility and to elucidate potential ophthalmological complications.

Deep Venous Thrombosis after Ad26.COV2.S Vaccination in Adult Male. With extensive loss of life and well-being seen since the beginning of the SARS-CoV-2 pandemic, the initiation of vaccinations has come with enormous hope towards the end of this pandemic. Detailed discussions regarding the safety and efficacy of these vaccines led to their approval. With such success, there have also been reports of vaccine-associated adverse events-allergic reactions, anaphylaxis, immune thrombocytopenia, and thrombosis. We discuss and report the first case of a healthy young adult male developing extensive thrombosis, after receiving the Ad26.COV2.S (Johnson & Johnson/Janssen) vaccine.

Post COVID-19 vaccination neuromyelitis optica spectrum disorder: Case report & MRI findings. There are rising concerns among the medical community and the public regarding the side effects of different vaccines developed throughout the world and their short and long-term effects, particularly COVID19 vaccines. Most notably, post-vaccination demyelinating diseases such as acute disseminated encephalomyelitis, transverse myelitis, and multiple sclerosis relapses have been reported. We present a case of a 32-year-old male who presented with a 2 weeks history of acute confusional state and imbalance 1 week after receiving the second dose of COVID19 vaccination. MRI findings showed

typical distribution of neuromyelitis optica spectrum disorder and the patient was positive for AQP4 IgG. The pathogenesis behind developing neuromyelitis optica and vaccines is still unknown. Few case reports have been reported of post-vaccination neuromyelitis optica spectrum disorder but to our knowledge, this would be the first case published of neuromyelitis optica following exposure to COVID19 vaccine.

Case Report: ANCA-Associated Vasculitis Presenting With Rhabdomyolysis and Pauci-Immune Crescentic Glomerulonephritis After Pfizer-BioNTech COVID-19 mRNA Vaccination. As the coronavirus disease 2019 (COVID-19) pandemic is ongoing and new variants of severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) are emerging, there is an urgent need for COVID-19 vaccines to control disease outbreaks by herd immunity. Surveillance of rare safety issues related to these vaccines is progressing, since more granular data emerge with regard to adverse events of COVID-19 vaccines during post-marketing surveillance. Interestingly, four cases of anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) presenting with pauci-immune crescentic glomerulonephritis (GN) after COVID-19 mRNA vaccination have already been reported. We here expand our current knowledge of this rare but important association and report a case of AAV presenting with massive rhabdomyolysis and pauci-immune crescentic GN after Pfizer-BioNTech COVID-19 mRNA vaccination. As huge vaccination programs are ongoing worldwide, post-marketing surveillance systems must continue to assess vaccine safety important for the detection of any events associated with COVID-19 vaccination. This is especially relevant in complex diseases where diagnosis is often challenging, as in our patient with AAV presenting with massive rhabdomyolysis and pauci-immune crescentic GN.

Immune Profile and Clinical Outcome of Breakthrough Cases After Vaccination With an Inactivated SARS-CoV-2 Vaccine. Constant efforts to prevent infections by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are actively carried out around the world. Several vaccines are currently approved for emergency use in the population, while ongoing studies continue to provide information on their safety and effectiveness. CoronaVac is an inactivated SARS-CoV-2 vaccine with a good safety and immunogenicity profile as seen in phase 1, 2, and 3 clinical trials around the world, with an effectiveness of 65.9% for symptomatic cases. Although vaccination reduces the risk of disease, infections can still occur during or after completion of the vaccination schedule (breakthrough cases). This report describes the clinical and immunological profile of vaccine breakthrough cases reported in a clinical trial in progress in Chile that is evaluating the safety, immunogenicity, and efficacy of two vaccination schedules of CoronaVac (clinicaltrials.gov NCT04651790). Out of the 2,263 fully vaccinated subjects, at end of June 2021, 45 have reported symptomatic SARS-CoV-2 infection 14 or more days after the second dose (1.99% of fully vaccinated subjects). Of the 45 breakthrough cases, 96% developed mild disease; one case developed a moderate disease; and one developed a severe disease and required mechanical ventilation. Both cases that developed moderate and severe disease were adults over 60 years old and presented comorbidities. The immune response before and after SARS-CoV-2 infection was analyzed in nine vaccine breakthrough cases, revealing that six of them exhibited circulating anti-S1-RBD IgG antibodies with neutralizing capacities after immunization, which showed a significant increase 2 and 4 weeks after symptoms onset. Two cases exhibited low circulating anti-S1-RBD IgG and almost non-existing neutralizing capacity after either vaccination or infection, although they developed a mild disease. An increase in the number of interferon-Î³-secreting T cells specific for SARS-CoV-2 was detected 2 weeks after the second dose in seven cases and after symptoms onset. In conclusion, breakthrough cases were mostly mild and did not necessarily correlate with a lack of vaccine-induced immunity, suggesting that other factors, to be defined in future studies, could lead to symptomatic infection after vaccination with CoronaVac.

SARS-CoV-2-specific humoral and cell-mediated immune responses after immunization with inactivated COVID-19 vaccine in kidney transplant recipients (CVIM 1 study). Immunogenicity following inactivated SARS-CoV-2 vaccination among solid organ transplant recipients has not been assessed. Seventy-five patients (37 kidney transplant [KT] recipients and 38 healthy controls) received two doses, at 4-week intervals, of an inactivated whole-virus SARS-CoV-2 vaccine. SARS-CoV-2-specific humoral (HMI) and cell-mediated immunity (CMI) were measured before, 4Â weeks post-first dose, and 2Â weeks post-second dose. The median (IQR) age of KT recipients was 50 (42-54) years and 89% were receiving calcineurin inhibitors/mycophenolate/corticosteroid regimens. The median (IQR) time since transplant was 4.5 (2-9.5) years. Among 35 KT patients, the median (IQR) of anti-RBD IgG level measured by CLIA after vaccination was not different from baseline, but was significantly lower than in controls (2.4 [1.1-3.7] vs. 1742.0 [747.7-3783.0] AU/ml, pÂ <Â .01) as well as percentages of neutralizing antibody inhibition measured by surrogate viral neutralization test (0 [0-0] vs. 71.2 [56.8-92.2]%, pÂ <Â .01). However, the median (IQR) of SARS-CoV-2 mixed peptides-specific T cell responses measured by ELISpot was significantly increased compared with baseline (30 [4-120] vs. 12 [0-56] T cells/10(6) Â PBMCs, pÂ =Â .02) and not different from the controls. Our findings revealed weak HMI but comparable CMI responses in fully vaccinated KT recipients receiving inactivated SARS-CoV-2 vaccination compared to immunocompetent individuals (Thai Clinical Trials Registry, TCTR20210226002).

Approximation and evaluation of the spontaneous abortion rate following COVID-19 vaccination in pregnancy.

Adjustment of the spontaneous abortion rate following COVID-19 vaccination.

Waning humoral response 6 months after SARS-CoV-2 vaccination with the mRNA-BNT162b2 vaccine in hemodialysis patients: time for a boost.

Erythema nodosum, after Medigen vaccination against COVID-19?

Anaphylactic and nonanaphylactic reactions to SARS-CoV-2 vaccines: a systematic review and meta-analysis. BACKGROUND: Currently there is no systematic review and meta-analysis of the global incidence rates of anaphylactic and nonanaphylactic reactions to SARS-CoV-2 vaccines in the general adult population. OBJECTIVES: To estimate the incidence rates of anaphylactic and nonanaphylactic reactions after COVID-19 vaccines and describe the demographic and clinical characteristics, triggers, presenting signs and symptoms, treatment and clinical course of confirmed cases. DESIGN: A systematic review and meta-analysis. Preferred Reporting Items for Systematic Reviews and Meta-Analyses [PRISMA] statement was followed. METHODS: Electronic databases (Proquest, Medline, Embase, Pubmed, CINAHL, Wiley online library, and Nature) were searched from 1 December 2020 to 31 May 2021 in the English language using the following keywords alone or in combination: anaphylaxis, non-anaphylaxis, anaphylactic reaction, nonanaphylactic reaction, anaphylactic/anaphylactoid shock, hypersensitivity, allergy reaction, allergic reaction, immunology reaction, immunologic reaction, angioedema, loss of consciousness, generalized erythema, urticaria, urticarial rash, cyanosis, grunting, stridor, tachypnoea, wheezing, tachycardia, abdominal pain, diarrhea, nausea, vomiting and tryptase. We included studies in adults of all ages in all healthcare settings. Effect sizes of prevalence were pooled with 95% confidence intervals (CIs). To minimize heterogeneity, we performed sub-group analyses. RESULTS: Of the 1,734 papers that were identified, 26 articles were included in the systematic review (8 case report, 5 cohort, 4 case series, 2 randomized controlled trial and 1 randomized cross-sectional studies) and 14 articles (1 cohort, 2 case series, 1 randomized controlled trial and 1 randomized cross-sectional studies) were included in meta-analysis. Studies involving 26,337,421 vaccine recipients [Pfizer-BioNTech (nâ€‰=â€‰14,505,399) and Moderna (nâ€‰=â€‰11,831,488)] were analyzed. The overall pooled prevalence estimate of anaphylaxis to both vaccines was 5.0 (95% CI 2.9 to 7.2, I(2)â€‰=â€‰81%,

pâ€‰=â€‰â€‰<â€‰0.0001), while the overall pooled prevalence estimate of nonanaphylactic reactions to both vaccines was 53.9 (95% CI 0.0 to 116.1, I(2)â€‰=â€‰99%, pâ€‰=â€‰â€‰<â€‰0.0001). Vaccination with Pfizer-BioNTech resulted in higher anaphylactic reactions compared to Moderna (8.0, 95% CI 0.0 to 11.3, I(2)â€‰=â€‰85% versus 2.8, 95% CI 0.0 to 5.7, I(2)â€‰=â€‰59%). However, lower incidence of nonanaphylactic reactions was associated with Pfizer-BioNTech compared to Moderna (43.9, 95% CI 0.0 to 131.9, I(2)â€‰=â€‰99% versus 63.8, 95% CI 0.0 to 151.8, I(2)â€‰=â€‰98%). The funnel plots for possible publication bias for the pooled effect sizes to determine the incidence of anaphylaxis and nonanaphylactic reactions associated with mRNA COVID-19 immunization based on mRNA vaccine type appeared asymmetrical on visual inspection, and Egger's tests confirmed asymmetry by producing p valuesâ€‰<â€‰0.05. Across the included studies, the most commonly identified risk factors for anaphylactic and nonanaphylactic reactions to SARS-CoV-2 vaccines were female sex and personal history of atopy. The key triggers to anaphylactic and nonanaphylactic reactions identified in these studies included foods, medications, stinging insects or jellyfish, contrast media, cosmetics and detergents, household products, and latex. Previous history of anaphylaxis; and comorbidities such as asthma, allergic rhinitis, atopic and contact eczema/dermatitis and psoriasis and cholinergic urticaria were also found to be important. CONCLUSION: The prevalence of COVID-19 mRNA vaccine-associated anaphylaxis is very low; and nonanaphylactic reactions occur at higher rate, however, cutaneous reactions are largely self-limited. Both anaphylactic and nonanaphylactic reactions should not discourage vaccination.

Humoral immune response in multiple sclerosis patients following PfizerBNT162b2 COVID19 vaccination: Up to 6Â months cross-sectional study. Appropriate immune response following COVID-19 vaccination is important in the context of disease-modifying treatments (DMTs). In a prospective cross-sectional study, we determined SARS-COV-2 IgG response up to 6Â months following PfizerBNT162b2 vaccination in 414 multiple sclerosis (MS) patients and 89 healthy subjects. Protective response was demonstrated in untreated MS patients (NÂ =Â 76, 100%), treated with Cladribine (NÂ =Â 48, 100%), Dimethyl fumarate (NÂ =Â 35, 100%), Natalizumab (NÂ =Â 32, 100%), and Teriflunomide (NÂ =Â 39, 100%), similarly to healthy subjects (NÂ =Â 89, 97.8%). Response was decreased in Fingolimod (NÂ =Â 42, 9.5%), Ocrelizumab (NÂ =Â 114, 22.8%) and Alemtuzumab (NÂ =Â 22, 86.4%) treated patients. IgG response can help tailor adequate vaccine guidelines for MS patients under various DMTs.

Sociodemographic, clinical, and immunological factors associated with SARS-CoV-2 diagnosis and severe COVID-19 outcomes in people living with HIV: a retrospective cohort study. BACKGROUND: Factors affecting outcomes of SARS-CoV-2 infection in people living with HIV are unclear. We assessed the factors associated with SARS-CoV-2 diagnosis and severe outcomes among people living with HIV. METHODS: We did a retrospective cohort study using data from the PISCIS cohort of people with HIV in Catalonia (Spain) between March 1 and Dec 15, 2020. We linked PISCIS data with integrated health-care, clinical, and surveillance registries through the Public Data Analysis for Health Research and Innovation Program of Catalonia (PADRIS) to obtain data on SARS-CoV-2 diagnosis, chronic comorbidities, as well as clinical and mortality outcomes. Participants were aged at least 16 years in care at 16 hospitals in Catalonia. Factors associated with SARS-CoV-2 diagnoses and severe outcomes were assessed using univariable and multivariable Cox regression models. We estimated the effect of immunosuppression on severe outcomes (hospital admission for >24 h with dyspnoea, tachypnoea, hypoxaemia, asphyxia, or hyperventilation; or death) using Kaplan-Meier survival analysis. FINDINGS: We linked 20â€‰847 (72Â·8%) of 28â€‰666 participants in the PISCIS cohort with PADRIS data; 13â€‰142 people had HIV. 749 (5Â·7%) people with HIV were diagnosed with SARS-CoV-2: their median age was 43Â·5 years (IQR 37Â·0-52Â·7), 131 (17Â·5%) were female, and 618 (82Â·5%) were male. 103 people with HIV (13Â·8%) were hospitalised, seven (0Â·9%)

admitted to intensive care, and 13 (1Â·7%) died. SARS-CoV-2 diagnosis was more common among migrants (adjusted hazard ratio 1Â·55, 95% CI 1Â·31-1Â·83), men who have sex with men (1Â·42, 1Â·09-1Â·86), and those with four or more chronic comorbidities (1Â·46, 1Â·09-1Â·97). Age at least 75 years (5Â·2, 1Â·8-15Â·3), non-Spanish origin (2Â·1, 1Â·3-3Â·4), and neuropsychiatric (1Â·69, 1Â·07-2Â·69), autoimmune disease (1Â·92, 1Â·14-3Â·23), respiratory disease (1Â·84, 1Â·09-3Â·09), and metabolic disease (2Â·59, 1Â·59-4Â·23) chronic comorbidities were associated with increased risk of severe outcomes. A Kaplan-Meier estimator showed differences in the risk of severe outcomes according to CD4 cell count in patients with detectable HIV RNA (p=0Â·039) but no differences were observed in patients with undetectable HIV RNA (p=0Â·15). INTERPRETATION: People living with HIV with detectable HIV viraemia, chronic comorbidities, and some subpopulations could be at increased risk of severe outcomes from COVID-19. These groups should be prioritised in clinical management and SARS-CoV-2 vaccination programmes. FUNDING: FundaciÃ³ "la Caixa". TRANSLATIONS: For the Catalan, Spanish and Russian translations of the Summary see Supplementary Materials section.

Unilateral axillary adenopathy induced by COVID-19 vaccine: US follow-up evaluation. OBJECTIVES: This study was conducted in order to investigate COVID-19 vaccine influence on unilateral axillary lymph nodes, comparing nodal basal features with their characteristics after the first and second vaccination dose. METHODS: Ninety-one volunteer employees from our center who participated in the BNT162b2 (Pfizer-BioNTech) vaccination campaign were prospectively recruited. A total of three axillary ultrasound evaluations of the ipsilateral vaccinated arm were performed: before vaccination, the week after the first dose and the week after the second dose. The following findings were recorded: the total number of visible nodes, the maximum measurements of the diameter and cortex, Bedi's classification, and color Doppler evaluation. The collected data were compared using paired-sample Student's t-test for quantitative continuous variables and Wilcoxon rank-sum test for ordinal variables. Additional analyses were performed after classifying patients according to the previous history of COVID-19 disease. Differences among both groups were evaluated with the Mann-Whitney U test. Variables with a p valueâ€‰<â€‰0.05 were considered statistically significant. RESULTS: Comparative analyses between the three US examinations showed a statistically significant augmentation of total visible nodes, maximum diameter, cortical thickness, grade of Bedi's classification, and Doppler signal (pâ€‰<â€‰0.001). Analyses between patients with and without previous COVID-19 infection showed a higher lymph node response in naÃ¯ve patients compared to those who were previously infected. CONCLUSIONS: According to our results, both doses of COVID-19 vaccine induced an increase of all axillary lymph node parameters with statistically significant differences, especially in coronavirus-naÃ¯ve patients. KEY POINTS: â€¢ Pfizer COVID-19 vaccine induces a high incidence of ipsilateral axillary lymphadenopathy. â€¢ US scan identified an increase of all lymph nodes parameters, especially in coronavirus-naÃ¯ve patients.

SARS-CoV-2 vaccine breakthrough infections with the alpha variant are asymptomatic or mildly symptomatic among health care workers. Vaccine breakthrough SARS-CoV-2 infection has been monitored in 3720 healthcare workers receiving 2 doses of BNT162b2. SARS-CoV-2 infection is detected in 33 subjects, with a 100-day cumulative incidence of 0.93%. Vaccine protection against acquisition of SARS-CoV-2 infection is 83% (95%CI: 58-93%) in the overall population and 93% (95%CI: 69-99%) in SARS-CoV-2-experienced subjects, when compared with a non-vaccinated control group from the same Institution, in which SARS-CoV-2 infection occurs in 20/346 subjects (100-day cumulative incidence: 5.78%). The infection is symptomatic in 16 (48%) vaccinated subjects vs 17 (85%) controls (pâ€‰=â€‰0.01). All analyzed patients, in whom the amount of viral RNA was sufficient for genome sequencing, results infected by the alpha variant. Antibody and T-cell responses are not reduced in subjects with breakthrough infection. Evidence of virus transmission, determined by contact tracing, is observed in two (6.1%) cases. This real-world data support the protective effect

of BNT162b2 vaccine. A triple antigenic exposure, such as two-dose vaccine schedule in experienced subjects, may confer a higher protection.

Cutting Edge: Circulating Exosomes with COVID Spike Protein Are Induced by BNT162b2 (Pfizer-BioNTech) Vaccination prior to Development of Antibodies: A Novel Mechanism for Immune Activation by mRNA Vaccines. Severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) causes severe acute respiratory syndrome. mRNA vaccines directed at the SARS-CoV-2 spike protein resulted in development of Abs and protective immunity. To determine the mechanism, we analyzed the kinetics of induction of circulating exosomes with SARS-CoV-2 spike protein and Ab following vaccination of healthy individuals. Results demonstrated induction of circulating exosomes expressing spike protein on day 14 after vaccination followed by Abs 14 d after the second dose. Exosomes with spike protein, Abs to SARS-CoV-2 spike, and T cells secreting IFN-Î³ and TNF-Î± increased following the booster dose. Transmission electron microscopy of exosomes also demonstrated spike protein Ags on their surface. Exosomes with spike protein and Abs decreased in parallel after four months. These results demonstrate an important role of circulating exosomes with spike protein for effective immunization following mRNA-based vaccination. This is further documented by induction of humoral and cellular immune responses in mice immunized with exosomes carrying spike protein.

Severe immune thrombocytopenia after COVID-19 vaccination: Report of four cases and review of the literature.

A case of Graves' disease and type 1 diabetes mellitus following SARS-CoV-2 vaccination. Autoimmune diseases, including autoimmune endocrine diseases (AIED), are thought to develop following environmental exposure in patients with genetic predisposition. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and vaccines against it could represent new environmental triggers for AIED. We report a patient, with history of vitiligo vulgaris and 8 years of type 2 diabetes, who came to our institution because of fever, weight loss, asthenia and thyrotoxicosis occurred 4 weeks later the administration of BNT162B2 (Pfizer-BioNTech) SARS-CoV-2 vaccine. Clinical, biochemical and instrumental work-up demonstrated Graves' disease and autoimmune diabetes mellitus. The occurrence of these disorders could be explained through different mechanism such as autoimmune/inflammatory syndrome induced by adjuvants (ASIA syndrome), mRNA "self-adjuvant" effect, molecular mimicry between human and viral proteins and immune disruption from external stimuli. However further studies are needed to better understand the underlying pathogenesis of AIED following SARS-CoV-2 vaccine.

The role of COVID-19 survivor status and gender towards neutralizing antibody titers 1, 2, 3 months after Sinovac vaccine administration on clinical-year medical students in Indonesia. BACKGROUND: Sinovac was the first vaccine used in Indonesia against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, data regarding the effects of certain variables such as clinical demographics on antibody levels in individuals vaccinated with Sinovac are scarce. This study aimed to investigate the impact of gender and previous SARS-CoV-2 infection status on neutralizing antibody titers 1, 2, and 3 months after administration of the Sinovac vaccine. METHOD: A cross-sectional study was conducted from February to May 2021. Data on neutralizing antibody levels, previous SARS-CoV-2 infection status, and gender were retrieved from the monthly quantitative serology evaluation database of Siloam Hospitals Lippo Village, Tangerang, Indonesia. The role of each variable was analyzed using the t-test or Mann-Whitney U test, depending on data distribution. RESULT: Data from 350 participants were collected for the study. Participants with a history of a positive SARS-CoV-2 RT-PCR test had significantly higher neutralizing antibody titers in the first (144 U/mL, pÂ =Â 0.036) and second months (144 U/mL, pÂ =Â 0.005) after vaccination compared with those without a history of positive RT-PCR test. Female participants also had significantly higher neutralizing antibody titers in the first, second, and third months (43Â U/mL, 42

U/mL, and 39 U/mL, respectively; pÂ =Â 0.001, pÂ =Â 0.002, and pÂ =Â 0.003, respectively) after vaccination compared to males. CONCLUSION: COVID-19 survivor status and the female gender were associated with higher neutralizing antibody titers after Sinovac vaccine administration.

COVID-19 and novel mRNA vaccines in pregnancy: an updated literature review. The novel coronavirus, SARS-CoV-2, or COVID-19, has affected the world on a pandemic scale resulting in catastrophic outcomes and deaths. Currently, there is limited safety data specific to mRNA vaccine use in pregnant or lactating individuals and the potential risks to a pregnant individual and the fetus are unknown. We report an updated literature review of current information and evidence available to aid in the decision whether to vaccinate against COVID-19 currently being made by pregnant individuals and their healthcare providers so that they are able to make a well-informed recommendation and decision.

A sigh of relief: vaccine-associated hypermetabolic lymphadenopathy following the third COVID-19 vaccine dose is short in duration and uncommonly interferes with the interpretation of [(18)F]FDG PET-CT studies performed in oncologic patients. PURPOSE: The incidence of COVID-19 vaccine-associated hypermetabolic lymphadenopathy (VAHL) is high following the administration of the first and second BNT162b2 vaccine doses. The impact of this finding on [(18)F]FDG PET-CT interpretation and its correlation with the induced humoral immunity have been reported. Assuming the amnestic immune response is different following the third vaccine dose, we aimed to explore the incidence of VAHL over time after the third BNT162b2 dose administration, and its relevance to [(18)F]FDG PET-CT interpretation in oncologic patients. METHODS: A total of 179 consecutive oncologic patients that underwent [(18)F]FDG PET-CT after a third BNT162b2 vaccine dose were included. The presence of VAHL was assessed. On VAHL-positive scans, the SUVmax, number, location, and size of the "hot" nodes were recorded. The median time interval between vaccination and imaging was 8 (IQR, 5-14) days. RESULTS: The incidences of all-grade VAHL and grade 3-4 VAHL were 47.5% and 8.9%, respectively. VAHL was identified on 82.5% of studies performed within the first 5Â days from vaccination. Grade 3-4 VAHL was observed on 28.1% of studies performed within the first 5Â days from vaccination, but was not detected on studies performed more than 5Â days from vaccination. Separation between VAHL and malignant lymphadenopathy was not possible in only 2 of the 179 study patients. On a multivariable logistic regression, independent predictors of grade 3-4 VAHL were short time interval between vaccination and imaging (Pvâ€‰<â€‰0.01), younger age (Pvâ€‰<â€‰0.01), and lower BMI (Pvâ€‰=â€‰0.03). CONCLUSION: VAHL is commonly identified on [(18)F]FDG PET-CT performed within the first 5Â days from the third BNT162b2 vaccine dose administration. High-grade VAHL is unlikely to be observed on a scan performed 6Â days or longer from vaccination, and is even less likely in older and obese patients.

Delayed Injection Site Reaction After mRNA-1273 Vaccination in Japan: A Retrospective, Cross-Sectional Study. The incidence of delayed injection site reaction after the first dose of mRNA-1273 vaccine was 12.5% among females and 1.5% among males in a cohort of primarily elderly Japanese. After the second dose, 48.4% of those who could be contacted reported recurrence. The reaction may be relatively common among Asian females.

Myocardial Infarction and Azygos Vein Thrombosis After ChAdOx1 nCoV-19 Vaccination in a Hemodialysis Patient. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare complication after vaccination of Oxford-AstraZeneca coronavirus disease 2019 (COVID-19) vaccine (AZD1222) or Janssen COVID-19 vaccine. It makes a rare complication of thrombosis at common and/or uncommon organs with thrombocytopenia after COVID-19 vaccination four to 28 days later and most patients were younger than 60 years of age. We reported the case of a 75-year-old female with end-stage renal disease who received regular hemodialysis. She received Oxford-AstraZeneca COVID-19 vaccination eight days ago and then she suffered from intermittent chest tightness and

epigastric pain with tarry stool passage for two days. Severe thrombocytopenia with elevated D-dimer value was noted and computed tomography of the chest showed azygos veinÂ thrombosis. Elevated cardiac enzyme with ST-T change in 12-lead electrocardiogram was also noted. For positive anti-platelet factor 4 antibodies, VITT with myocardial infarction and azygos vein thrombosis was diagnosed.

Evidence of SARS-CoV-2-Specific Memory B Cells Six Months After Vaccination With the BNT162b2 mRNA Vaccine. SARS-CoV-2 mRNA vaccines have demonstrated high efficacy and immunogenicity, but limited information is currently available on memory B cell generation and long-term persistence. Here, we investigated spike-specific memory B cells and humoral responses in 145 subjects, up to 6 months after the BNT162b2 vaccine (Comirnaty) administration. Spike-specific antibodies peaked 7 days after the second dose and significant antibody titers and ACE2/RBD binding inhibiting activity were still observed after 6 months, despite a progressive decline over time. Concomitant to antibody reduction, spike-specific memory B cells, mostly IgG class-switched, increased in the blood of vaccinees and persisted 6 months after vaccination. Following the in vitro restimulation, circulating memory B cells reactivated and produced spike-specific antibodies. A high frequency of spike-specific IgG(+) plasmablasts, identified by computational analysis 7 days after boost, positively correlated with the generation of IgG(+) memory B cells at 6 months. These data demonstrate that mRNA BNT162b2 vaccine elicits strong B cell immunity with spike-specific memory B cells that still persist 6 months after vaccination, playing a crucial role for a rapid response to SARS-CoV-2 virus encounter.

Thrombosis in pre- and post-vaccination phase of COVID-19. Acute infections may be complicated by thrombosis occurring in the venous and arterial circulation. This may be observed in patients with community-acquired pneumonia (CAP) and also in patients with coronavirus 2019 (COVID-19), that is a pandemic characterized by severe acute respiratory syndrome (SARS-CoV-2) needing mechanical ventilation and intensive care unit treatment. However, the type and rate of thrombosis can vary according to the cause of pneumonia as is more frequently complicated by arterial thrombosis in CAP, while an equal incidence of venous and arterial thrombosis occurs in SARS-CoV-2. The mechanisms of disease are overall platelet-related in CAP while activation of both platelets and clotting system is implicated in the pathogenesis of thrombosis in SARS-CoV-2; this finding could imply a different therapeutic approach of the two settings. Thrombosis may also occur in subjects vaccinated against SARS-CoV-2 even if its incidence is not so high (1/100Â 000); this rare effect occurs more prevalently in young women, is independent from known risk factors of thrombosis, is caused by antibodies against platelet PF4 and is counteracted by treatment with immunoglobulin and glucocorticoids.

INO-4800 DNA vaccine induces neutralizing antibodies and T cell activity against global SARS-CoV-2 variants. Global surveillance has identified emerging SARS-CoV-2 variants of concern (VOC) associated with broadened host specificity, pathogenicity, and immune evasion to vaccine-induced immunity. Here we compared humoral and cellular responses against SARS-CoV-2 VOC in subjects immunized with the DNA vaccine, INO-4800. INO-4800 vaccination induced neutralizing antibodies against all variants tested, with reduced levels detected against B.1.351. IFNÎ³ T cell responses were fully maintained against all variants tested.

Guillain-BarrÃ© syndrome presenting with facial diplegia following COVID-19 vaccination in two patients. In March 2020, the WHO declared COVID-19 to be a global pandemic and since December 2020, millions of vaccines have been administered. To date, cases of Guillain-BarrÃ© syndrome (GBS) following a COVID vaccine (Pfizer, Johnson & Johnson, Janssen, AstraZeneca) have been reported. A 61-year-old woman developed bilateral asymmetrical lower motor neuron (LMN) facial weakness followed by limb symptoms, 10 days after receiving the first dose of AstraZeneca

COVID vaccine. The second patient was a 56-year-old man who, 9 days after receiving first dose of AstraZeneca COVID vaccine, developed bilateral asymmetrical LMN facial weakness with limb symptoms. Intravenous immunoglobulin was administered with rapid recovery. These cases of GBS following the AstraZeneca COVID vaccine add to cohort of patients reported. We flag up to raise awareness of this condition post-COVID-19 vaccine and highlight the prominent bifacial involvement. Early diagnosis and prompt treatment with intravenous immunoglobulin led to rapid recovery.
T-cell immune response after mRNA SARS-CoV-2 vaccines is frequently detected also in the absence of seroconversion in patients with lymphoid malignancies. Patients affected by lymphoid malignancies (LM) are frequently immune-compromised, suffering increased mortality from COVID-19. This prospective study evaluated serological and T-cell responses after complete mRNA vaccination in 263 patients affected by chronic lymphocytic leukaemia, B- and T-cell lymphomas and multiple myeloma. Results were compared with those of 167 healthy subjects matched for age and sex. Overall, patient seroconversion rate was 64Â·6%: serological response was lower in those receiving anti-cancer treatments in the 12Â months before vaccination: 55% vs 81Â·9% (PÂ <Â 0Â·001). Anti-CD20 antibody plus chemotherapy treatment was associated with the lowest seroconversion rate: 17Â·6% vs. 71Â·2% (PÂ <Â 0Â·001). In the multivariate analysis conducted in the subgroup of patients on active treatment, independent predictors for seroconversion were: anti-CD20 treatment (PÂ <Â 0Â·001), aggressive B-cell lymphoma diagnosis (PÂ =Â 0Â·002), and immunoglobulin M levels <40Â mg/dl (PÂ =Â 0Â·030). The T-cell response was evaluated in 99 patients and detected in 85 of them (86%). Of note, 74% of seronegative patients had a T-cell response, but both cellular and humoral responses were absent in 13Â·1% of cases. Our findings raise some concerns about the protection that patients with LM, particularly those receiving anti-CD20 antibodies, may gain from vaccination. These patients should strictly maintain all the protective measures.
Thrombosis in peripheral artery disease and thrombotic thrombocytopenia after adenoviral COVID-19 vaccination.
Vaccine-induced immune thrombotic thrombocytopenia after the BNT162b2 mRNA Covid-19 vaccine: A case study.
Polyethylene glycol and polysorbate testing in 12 patients before or after coronavirus disease 2019 vaccine administration.
Guillain-â€‹BarrÃ© Syndrome Associated with COVID-19 Vaccination. We conducted a multi-institutional study in Taiwan and a systematic review of the literature for reports of Guillain-â€‹BarrÃ© syndrome after coronavirus disease vaccination. This condition, mostly the classic form and the acute inflammatory demyelinating polyneuropathy subtype, has been reported in 39 cases and has occurred within 2 weeks of vaccine administration.
mRNA vaccines induce durable immune memory to SARS-CoV-2 and variants of concern. The durability of immune memory after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) messenger RNA (mRNA) vaccination remains unclear. In this study, we longitudinally profiled vaccine responses in SARS-CoV-2â€“naÃ¯ve and â€“recovered individuals for 6 months after vaccination. Antibodies declined from peak levels but remained detectable in most subjects at 6 months. By contrast, mRNA vaccines generated functional memory B cells that increased from 3 to 6 months postvaccination, with the majority of these cells cross-binding the Alpha, Beta, and Delta variants. mRNA vaccination further induced antigen-specific CD4(+) and CD8(+) T cells, and early CD4(+) T cell responses correlated with long-term humoral immunity. Recall responses to vaccination in individuals with preexisting immunity primarily increased antibody levels without substantially altering antibody decay rates. Together, these findings demonstrate robust cellular immune memory to SARS-CoV-2 and its variants for at least 6 months after mRNA vaccination.

Graves' disease following SARS-CoV-2 vaccination.
Trying to Block SARS-CoV-2 Transmission With Intranasal Vaccines.
Inhibition of receptor-binding domain-ACE2 interaction after two doses of Sinovac's CoronaVac or AstraZeneca/Oxford's AZD1222 SARS-CoV-2 vaccines. Practical laboratory proxies that correlate to vaccine efficacy may facilitate trials, identify nonresponders, and inform about boosting strategies. Among clinical and laboratory markers, assays that evaluate antibodies that inhibit receptor-binding domain (RBD) ligation to angiotensin-converting enzyme-2 receptor (receptor-binding inhibition [RBI]) may provide a surrogate for viral neutralization assays. We evaluated RBI before and after a median of 34 days (interquartile range [IQR]: 33-40) of the second dose of severe acute respiratory syndromeÂ coronavirus 2 (SARS-CoV-2) Sinovac's CoronaVac (CN) or AstraZeneca/Oxford's AZD1222 (AZ) vaccines in 166 individuals. Both vaccines elicited high inhibitory titers in most subjects, 95% (158/166), with signal inhibition above 30% and 89% (127/143) with more than fourfold increase from prevaccination titers, but titers tend to decrease over time. Both postvaccination inhibitory titers (95%, IQR 85%-97% for AZ vs. 79%, IQR 60%-96% for CN, pâ€‰=â€‰0.004) and pre/post-titer increase (AZ 76%, IQR 51%-86% for AZ vs. 47%, IQR 24%-67% for CN, pâ€‰<â€‰0.0001) were higher among AZ vaccinees. Previous serological reactivity due to natural infection was associated with high prevaccination signal inhibition titers. The study documents a robust antibody response capable of interfering with RBD-angiotensin-converting enzyme binding. Evaluation of SARS-CoV-2 infection incidence in these populations is necessary to assess its association to protection and its duration.
Intracerebral Hemorrhage and Thrombocytopenia After AstraZeneca COVID-19 Vaccine: Clinical and Diagnostic Challenges of Vaccine-Induced Thrombotic Thrombocytopenia. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a prothrombotic disorder, which has been described as a rare adverse effect of the adenoviral-vectored coronavirus disease 2019 (COVID-19) vaccines. The diagnosis is confirmed by the detection of anti-platelet factor 4 (PF4) antibodies by enzyme-linked immunosorbent assay (ELISA) or functional assay in individuals with the appropriate clinical history. Here, we report a case of a patient who presented with a severe intracerebral hemorrhage and thrombocytopenia 14 days after receiving the first dose of the Oxford-AstraZeneca COVID-19 vaccine, with negative PF4/heparin antibodies tested with ELISA, but positive heparin-induced platelet activation assay (HIPAA).
VITT, COVID-19 and the Expert Haematology Panel: The story of how the UK responded to emerging cases of vaccine-induced immune thrombocytopenia and thrombosis during the vaccination programme. The COVID-19 pandemic has resulted in the development of highly effective vaccines that provide hope to the global community for reducing the spread of SARS-CoV-2 and limiting the mortality and morbidity caused by the disease. These vaccines have been produced using differing technologies, taken through clinical trials, and rolled out across the UK at unprecedented speed. However, the recent emergence of rare cases of life-threatening thrombosis in association with thrombocytopenia has threatened to derail one particular vaccine, the Oxford AstraZeneca ChAdOx1 vaccine, upon which many countries are dependent for their vaccination programmes. The story of how this situation has been managed in the UK at the height of the vaccine roll-out represents a remarkable collective endeavour on the part of the haematology community, working closely with other acute medical and surgical professionals within the NHS and the UK health regulatory bodies, to provide rapid expert guidance that has saved lives and helped keep the national vaccination programme on track.
Response to COVID-19 mRNA vaccination in multiple myeloma is conserved but impaired compared to controls. Patients with multiple myeloma are at high risk of severe forms of COVID-19. Despite data showing diminished response to vaccine, the era of highly efficient mRNA vaccine might be a gamechanger. We sought to examine response to mRNA vaccine between healthy controls

(nâ€‰=â€‰28) and multiple myeloma (MM) patients (nâ€‰=â€‰27). Response was analyzed 1Â month after the second dose of anti-SARS-CoV-2 BNT162b2 vaccine. Multiple myeloma patients showed diminished levels of Anti-Spike IgG levels compared to controls, but with a high proportion of patients achieving a humoral response (89% vs. 97% in controls). Neutralizing antibodies were present in 74% of patients versus 96% of controls. Patients under current daratumumab treatment had neutralizing activity of anti-SARS-CoV-2 antibodies. Multiple myeloma patients show diminished response to SARS-COV-2 vaccine but with still high response rate. The main potential risk factor of non-response to COVID-19 vaccine was uncontrolled disease under treatment.

Post SARS-CoV-2 vaccination Guillain-Barre syndrome in 19 patients. SARS-CoV-2 vaccinations are not free from side effects. Usually, they are mild or moderate but occasionally severe. One of these severe side effects is Guillain-BarrÃ© syndrome (GBS). This review summarizes and discusses GBS as a side effect of SARS-CoV-2 vaccinations (SCoVaG) based on recent research reports. Altogether, nine articles reporting 18 patients with SCoVaG were identified and one more report on another patient is under review. The age for the studies ranged between 20-86y. Nine patients were male, and ten were female. In all 19 patients, SCoVaG developed after the first dose of the vaccine. The Astra Zeneca vaccine was used in fourteen patients, the Pfizer vaccine in four patients, and the Johnson & Johnson vaccine was applied in one patient. The latency between vaccination and onset of GBS ranged from 3h to 39d. The treatment of SCoVaG included IVIGs (n=13), steroids (n=3), or no therapy (n=3). Six patients required mechanical ventilation. Only a single patient recovered completely and partial recovery was achieved in nine patients. In conclusion, GBS may develop time-linked to the first dose of a SARS-CoV-2 vaccination. Though a causal relationship between SARS-CoV-2 vaccinations and SCoVaG remains speculative, more evidence is in favour than against it.

Multiple Sites of Arterial Thrombosis in A 35-Year Old Patient after ChAdOx1 (AstraZeneca) Vaccination, Requiring Emergent Femoral and Carotid Surgical Thrombectomy. BACKGROUND: Vaccine Induced Thrombotic Thrombocytopenia (VITT) is a rare complication following ChAdOx1 (AstraZeneca) vaccination. Venous thrombosis in unusual sites such as splachnic or intracranial thrombosis, is the commonest manifestation. CASE REPORT: We report a 35-year-old male patient who presented with acute left leg ischemia and thrombocytopenia 11-days after vaccination requiring emergent thrombectomy. During work-up, a localized thrombus was detected in the left carotid bifurcation mandating carotid thrombectomy. Localized right iliac thrombus causing a non-limiting flow stenosis was treated conservatively. The platelet aggregating capacity of patient's plasma was confirmed in a functional assay, thereby establishing VITT. CONCLUSION: To the best of our knowledge this is the first case presenting multiple arterial thromboses requiring surgical treatment after ChAdOx1 vaccination.

Audio Interview: Reporting on Covid-19.

Maternal Outcomes After Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection in Vaccinated Compared With Unvaccinated Pregnant Patients.

Humoral response after SARS-CoV-2 vaccination in patients undergoing maintenance haemodialysis: loss of immunity, third dose and non-responders.

Comprehensive characterization of the antibody responses to SARS-CoV-2 Spike protein after infection and/or vaccination. BACKGROUND: Control of the COVID-19 pandemic will rely on SARS-CoV-2 vaccine-elicited antibodies to protect against emerging and future variants; an understanding of the unique features of the humoral responses to infection and vaccination, including different vaccine platforms, is needed to achieve this goal. METHODS: The epitopes and pathways of escape for Spike-specific antibodies in individuals with diverse infection and vaccination history were profiled using Phage-DMS. Principal component analysis was performed to identify regions of antibody binding along the Spike protein that differentiate the samples from one another.

Within these epitope regions we determined potential escape mutations by comparing antibody binding of peptides containing wildtype residues versus peptides containing a mutant residue. RESULTS: Individuals with mild infection had antibodies that bound to epitopes in the S2 subunit within the fusion peptide and heptad-repeat regions, whereas vaccinated individuals had antibodies that additionally bound to epitopes in the N- and C-terminal domains of the S1 subunit, a pattern that was also observed in individuals with severe disease due to infection. Epitope binding appeared to change over time after vaccination, but other covariates such as mRNA vaccine dose, mRNA vaccine type, and age did not affect antibody binding to these epitopes. Vaccination induced a relatively uniform escape profile across individuals for some epitopes, whereas there was much more variation in escape pathways in in mildly infected individuals. In the case of antibodies targeting the fusion peptide region, which was a common response to both infection and vaccination, the escape profile after infection was not altered by subsequent vaccination. CONCLUSIONS: The finding that SARS-CoV-2 mRNA vaccination resulted in binding to additional epitopes beyond what was seen after infection suggests protection could vary depending on the route of exposure to Spike antigen. The relatively conserved escape pathways to vaccine-induced antibodies relative to infection-induced antibodies suggests that if escape variants emerge, they may be readily selected for across vaccinated individuals. Given that the majority of people will be first exposed to Spike via vaccination and not infection, this work has implications for predicting the selection of immune escape variants at a population level. FUNDING: This work was supported by NIH grants AI138709 (PI Overbaugh) and AI146028 (PI Matsen). Julie Overbaugh received support as the Endowed Chair for Graduate Education (FHCRC). The research of Frederick Matsen was supported in part by a Faculty Scholar grant from the Howard Hughes Medical Institute and the Simons Foundation. Scientific Computing Infrastructure at Fred Hutch was funded by ORIP grant S10OD028685.

Prime-Boost Vaccination With BNT162b2 Induces High Neutralizing Activity Against SARS-CoV-2 Variants in NaÃ¯ve and COVID-19-Convalescent Individuals. BACKGROUND: The objective of this study was to investigate the neutralizing response against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants of concern (VoC) during coronavirus disease 2019 (COVID-19) convalescence and after vaccination. METHODS: COVID-19-convalescent and -naÃ¯ve individuals were tested for neutralizing activity against SARS-CoV-2 VoC Alpha, Beta, Gamma, and Delta at 1 and 7 months postinfection and 4-6 weeks after BNT162b2 vaccination. RESULTS: Vaccination induced a high neutralizing response in naÃ¯ve individuals. Interestingly, vaccination of convalescent patients induced a boosted response that was able to neutralize all VoC at high titers. CONCLUSIONS: Vaccination with BNT162b2 induced high levels of neutralization against SARS-CoV-2 VoC in most patients; this is especially beneficial in COVID-19-convalescent individuals.

COVID-19 Vaccines Programs: adverse events following immunization (AEFI) among medical Clerkship Student in Jember, Indonesia. INTRODUCTION: Coronavirus Disease (COVID-19) caused by Novel Coronavirus named as Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) was declared Pandemic by The World Health Organization (WHO) and a Public Health Emergency of International Concern (PHEIC) on January 30, 2020. Many COVID-19 vaccines have been developed, including CoronaVac vaccines by Sinovac. Health care workers, along with medical clerkship students are the priority to receive the vaccine. However, the Adverse Events Following Immunization (AEFI) of the CoronaVac remains unclear. This study aims to describe and analyze the adverse events following immunization (AEFI) of COVID-19 vaccination in medical students in clerkship programs. METHOD: We conducted a cross-sectional study using a questionnaire to assess AEFI after CoronaVac vaccination among medical clerkship students. A Chi-Square test with 95â€‰% of CI was used to determine whether gender correlated with symptoms of AEFI. RESULT: We identified 144 medical clerkship students. The most common AEFI of SARS-CoV-2 vaccinations was localized pain in the

injection site during the first dose with 25 (45â€‰%) reports and the booster dose with 34 (67â€‰%) reports. Then followed by malaise, the first dose with 20 (36â€‰%) reports and the booster dose with 21 (41â€‰%) reports. Other symptoms like headache, fever, shivering, sleepiness, nausea, dysphagia, and cold were also reported. CONCLUSIONS: CoronaVac SARS-COV-2 vaccine has several mild symptoms of AEFI and not correlated with gender. Nevertheless, follow-up after vaccination is needed to prevent immunologic responses that may occur in some patients.

Longitudinal extensive transverse myelitis following ChAdOx1 nCOV-19 vaccine: a case report. BACKGROUND: Transverse myelitis (TM) is a relatively uncommon condition, and vaccine-associated myelitis is even rarer. Concern regarding neurological complications following vaccination escalated following the report of TM during the safety and efficacy trials of the COVID-19 vaccine. CASE PRESENTATION: We report the first case of Longitudinal Extensive Transverse Myelitis (LETM) in Malaysia following administration of the chimpanzee adenovirus-vectored (ChAdOx1 nCoV-19) vaccine. A 25-year-old female presented with bilateral lower limb weakness and inability to walk with a sensory level up to T8 with absent visual symptoms. Urgent gadolinium-enhanced magnetic resonance imaging (MRI) of the spine showed long segment TM over the thoracic region. Cerebrospinal fluid autoantibodies for anti-aquaporin-4 and anti-myelin-oligodendrocyte were negative. A diagnosis of LETM following vaccination was made, and the patient was started on a high dose of intravenous methylprednisolone. The patient eventually made a recovery following treatment. CONCLUSION: LETM is a rare but serious adverse reaction following vaccination. Previously reported cases showed an onset of symptoms between 10 to 14â€‰days post-vaccination, suggesting a delayed immunogenic reaction. However, the incidence of myelitis in COVID-19 is much more common, far greater than the risk associated with vaccination.

Subacute thyroiditis after vaccination against SARS-CoV-2. BACKGROUND: Subacute thyroiditis is a clinical condition usually seen 1-2 weeks after a viral infection in the upper respiratory tract, and has also been reported following infection with COVID-19. Cases of subacute thyroiditis following a seasonal influenza vaccination have been described, and recent case reports have reported clinical symptoms and signs typical of subacute thyroiditis following vaccination with mRNA SARS-CoV-2Â vaccine. CASE PRESENTATION: A young, healthy female underwent surgery with left-side lobectomy for papillary thyroid carcinoma. Hashimoto's thyroiditis was revealed as an additional histological finding. Six days prior to complementary thyroidectomy of the right lobe the patient received mRNA SARS-CoV-2Â vaccine. The histological slides showed features consistent with extensive subacute thyroiditis throughout the entire lobe. INTERPRETATION: As no other aetiology could account for the subacute thyroiditis, the vaccination against COVID-19Â is seen as a plausible source.

Understanding the Patterns of Serological Testing for COVID-19 Pre- and Post-Vaccination Rollout in Michigan. Testing for SARS-CoV-2 antibodies is commonly used to determine prior COVID-19 infections and to gauge levels of infection- or vaccine-induced immunity. Michigan Medicine, a primary regional health center, provided an ideal setting to understand serologic testing patterns over time. Between 27 April 2020 and 3 May 2021, characteristics for 10,416 individuals presenting for SARS-CoV-2 antibody tests (10,932 tests in total) were collected. Relative to the COVID-19 vaccine roll-out date, 14 December 2020, the data were split into a pre- (8026 individuals) and post-vaccine launch (2587 individuals) period and contrasted with untested individuals to identify factors associated with tested individuals and seropositivity. Exploratory analysis of vaccine-mediated seropositivity was performed in 347 fully vaccinated individuals. Predictors of tested individuals included age, sex, smoking, neighborhood variables, and pre-existing conditions. Seropositivity in the pre-vaccine launch period was 9.2% and increased to 46.7% in the post-vaccine launch period. In the pre-vaccine launch period, seropositivity was significantly associated with age (10 year; OR = 0.80

(0.73, 0.89)), ever-smoker status (0.49 (0.35, 0.67)), respiratory disease (4.38 (3.13, 6.12)), circulatory disease (2.09 (1.48, 2.96)), liver disease (2.06 (1.11, 3.84)), non-Hispanic Black race/ethnicity (2.18 (1.33, 3.58)), and population density (1.10 (1.03, 1.18)). Except for the latter two, these associations remained statistically significant in the post-vaccine launch period. The positivity rate of fully vaccinated individual was 296/347(85.3% (81.0%, 88.8%)).

Vaccination for Respiratory Infections in Patients with Heart Failure. Bronchopulmonary infections are a major trigger of cardiac decompensation and are frequently associated with hospitalizations in patients with heart failure (HF). Adverse cardiac effects associated with respiratory infections, more specifically Streptococcus pneumoniae and influenza infections, are the consequence of inflammatory processes and thrombotic events. For both influenza and pneumococcal vaccinations, large multicenter randomized clinical trials are needed to evaluate their efficacy in preventing cardiovascular events, especially in HF patients. No study to date has evaluated the protective effect of the COVID-19 vaccine in patients with HF. Different guidelines recommend annual influenza vaccination for patients with established cardiovascular disease and also recommend pneumococcal vaccination in patients with HF. The Heart Failure group of the French Society of Cardiology recently strongly recommended vaccination against COVID-19 in HF patients. Nevertheless, the implementation of vaccination recommendations against respiratory infections in HF patients remains suboptimal. This suggests that a national health policy is needed to improve vaccination coverage, involving not only the general practitioner, but also other health providers, such as cardiologists, nurses, and pharmacists. This review first summarizes the pathophysiology of the interrelationships between inflammation, infection, and HF. Then, we describe the current clinical knowledge concerning the protective effect of vaccines against respiratory diseases (influenza, pneumococcal infection, and COVID-19) in patients with HF and finally we propose how vaccination coverage could be improved in these patients.

Factors Associated with Healthcare Workers' (HCWs) Acceptance of COVID-19 Vaccinations and Indications of a Role Model towards Population Vaccinations from a Cross-Sectional Survey in Greece, May 2021. A Knowledge, Attitudes and Practices (KAP) study was conducted at the end of May 2021 engaging 1456 healthcare workers (HCWs) from 20 hospitals throughout Greece. Acceptance of vaccination against coronavirus disease 2019 (COVID-19) was estimated at 77.7%, with lower vaccine acceptance identified in nurses compared to physicians. Fears related to vaccine safety, lack of information and general knowledge about vaccinations, influenza vaccine acceptance, education level and years of practice were among the factors independently associated with vaccine acceptance. A strong association was identified between vaccination of HCWs in each health region and the population coverage, indicating that HCWs may be role models for the general population. Information campaigns should continue despite decisions taken regarding mandatory vaccinations.

Coagulopathies after Vaccination against SARS-CoV-2 May Be Derived from a Combined Effect of SARS-CoV-2 Spike Protein and Adenovirus Vector-Triggered Signaling Pathways. Novel coronavirus SARS-CoV-2 has resulted in a global pandemic with worldwide 6-digit infection rates and thousands of death tolls daily. Enormous efforts are undertaken to achieve high coverage of immunization to reach herd immunity in order to stop the spread of SARS-CoV-2 infection. Several SARS-CoV-2 vaccines based on mRNA, viral vectors, or inactivated SARS-CoV-2 virus have been approved and are being applied worldwide. However, the recent increased numbers of normally very rare types of thromboses associated with thrombocytopenia have been reported, particularly in the context of the adenoviral vector vaccine ChAdOx1 nCoV-19 from Astra Zeneca. The statistical prevalence of these side effects seems to correlate with this particular vaccine type, i.e., adenoviral vector-based vaccines, but the exact molecular mechanisms are still not clear. The present review summarizes current data and hypotheses for molecular and cellular mechanisms into one integrated

hypothesis indicating that coagulopathies, including thromboses, thrombocytopenia, and other related side effects, are correlated to an interplay of the two components in the vaccine, i.e., the spike antigen and the adenoviral vector, with the innate and immune systems, which under certain circumstances can imitate the picture of a limited COVID-19 pathological picture.
Herpes Simplex Virus Keratitis Reactivation after SARS-CoV-2 BNT162b2 mRNA Vaccination: A Report of Two Cases. PURPOSE: To report two cases of herpes simplex virus keratitis reactivation following Pfizer-BioNTech COVID-19 (BNT162b2) mRNA vaccination. METHODS: Two patients (one male, age 42Â years, and one female, age 29Â years) who are known to have herpetic keratitis presented to our emergency room in a time frame between 4Â days and 4Â weeks of receiving the vaccine. One patient presented with necrotizing stromal keratitis; the other presented with endotheliitis and epithelial keratitis. PCR for herpes simplex virus (HSV) was obtained from the two patients, and all cases received systemic acyclovir. RESULTS: PCR for HSV came positive in both cases. Patients responded well to the provided treatment. CONCLUSION: Ocular herpetic infection may be activated by COVID-19 (BNT162b2) mRNA vaccine. Treating physician should be alert to such associations, and patients should be followed closely. No direct causality has been proven, but further reporting and investigating similar conditions is recommended.
Response to BNT162b2 mRNA COVID-19 vaccine among healthcare workers in Italy: a 3-month follow-up. This study investigated the response to BNT162b2 mRNA COVID-19 vaccine among healthcare workers (HCWs) in an Italian teaching hospital. 444 participants were surveyed with either multiple RT-PCR assays for detection of SARS-CoV-2 nucleic acid in nasopharyngeal swabs or serology testing for the research of virus-specific immunoglobulins. Adverse events following immunization (AEFI) were reported. Two weeks after the first dose anti-SARS-CoV-2 antibodies exceeded reactivity cut-off in 82.5% the participants. Four HCWs tested positive at nasopharyngeal swab after 3Â months. More than three-quarters reported AEFIs. Our findings offer an insight regarding the vaccine response after 3Â months from its administration, with a special focus on effectiveness data, as well as the type and number of AEFIs complained by HCW recipients. The presented study may serve as reference for future research which will be necessary to explore the long-term safety of this vaccine, especially in population at high risk for infection, such as HCWs.
COVID-19 vaccines and thrombosis.
Thyrotoxicosis after COVID-19 vaccination: seven case reports and a literature review.
Moderna's mRNA Vaccine for Seasonal Flu Enters Clinical Trials.
Vaccine-Induced SARS-CoV-2 Antibodies in Inflammatory Diseases.
mRNA vaccine-induced T cells respond identically to SARS-CoV-2 variants of concern but differ in longevity and homing properties depending on prior infection status. While mRNA vaccines are proving highly efficacious against SARS-CoV-2, it is important to determine how booster doses and prior infection influence the immune defense they elicit, and whether they protect against variants. Focusing on the T cell response, we conducted a longitudinal study of infection-naÃ¯ve and COVID-19 convalescent donors before vaccination and after their first and second vaccine doses, using a high-parameter CyTOF analysis to phenotype their SARS-CoV-2-specific T cells. Vaccine-elicited spike-specific T cells responded similarly to stimulation by spike epitopes from the ancestral, B.1.1.7 and B.1.351 variant strains, both in terms of cell numbers and phenotypes. In infection-naÃ¯ve individuals, the second dose boosted the quantity and altered the phenotypic properties of SARS-CoV-2-specific T cells, while in convalescents the second dose changed neither. Spike-specific T cells from convalescent vaccinees differed strikingly from those of infection-naÃ¯ve vaccinees, with phenotypic features suggesting superior long-term persistence and ability to home to the respiratory tract including the nasopharynx. These results provide reassurance that vaccine-elicited T cells respond robustly to emerging viral variants, confirm that convalescents may not need a second

vaccine dose, and suggest that vaccinated convalescents may have more persistent nasopharynx-homing SARS-CoV-2-specific T cells compared to their infection-naÃ¯ve counterparts.

 Vaccination is one of the best ways to prevent severe COVID-19. Two doses of mRNA vaccine protect against serious illness caused by the coronavirus SARS-CoV-2. They do this, in part, by encouraging the immune system to make specialised proteins known as antibodies that recognise the virus. Most of the vaccine research so far has focussed on these antibodies, but they are only one part of the immune response. Vaccines also activate immune cells called T cells. These cells have two main roles, coordinating the immune response and killing cells infected with viruses. It is likely that they play a key role in preventing severe COVID-19. There are many kinds of T cells, each with a different role. Currently, the identity and characteristics of the T cells that protect against COVID-19 is unclear. Different types of T cells have unique proteins on their surface. Examining these proteins can reveal details about how the T cells work, which part of the virus they recognise, and which part of the body they protect. A tool called cytometry by time of flight allows researchers to measure these proteins, one cell at a time. Using this technique, Neidleman, Luo et al. investigated T cells from 11 people before vaccination and after their first and second doses. Five people had never had COVID-19 before, and six had already recovered from COVID-19. Neidleman, Luo et al. found that the T cells recognizing SARS-CoV-2 in the two groups differed. In people who had never had COVID-19 before, the second dose of vaccine improved the quality and quantity of the T cells. The same was not true for people who had already recovered from COVID-19. However, although their T cells did not improve further after a second vaccine dose, they did show signs that they might offer more protection overall. The proteins on the cells suggest that they might last longer, and that they might specifically protect the nose, throat and lungs. Neidleman, Luo et al. also found that, for both groups, T cells activated by vaccination responded in the same way to different variants of the virus. This work highlights the importance of getting both vaccine doses for people who have never had COVID-19. It also suggests that vaccination in people who have had COVID-19 may generate better T cells. Larger studies could show whether these patterns remain true across the wider population. If so, it is possible that delivering vaccines to the nose or throat could boost immunity by mimicking natural infection. This might encourage T cells to make the surface proteins that allow them to home to these areas.

A Case Report for Myopericarditis after BNT162b2 COVID-19 mRNA Vaccination in a Korean Young Male. Mass vaccination with the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine (BNT162b2) in Korea has resulted in many reported adverse effects. These side effects are the object of much scrutiny in the medical community. We report the case of a 29-year-old male who was diagnosed with myopericarditis after his second dose of Pfizer-BioNTech COVID-19 vaccine. This patient is the second recognized case of Pfizer-BioNTech COVID-19 vaccine induced myopericarditis in Korea and the first to have recovered from it. He originally presented with chest discomfort and exertional chest pain. Lab tests revealed elevated cardiac marker levels and echocardiographic findings displayed minimal pericardial effusion, prompting diagnosis as myopericarditis. We decided on two weeks of outpatient treatment with non-steroidal anti-inflammatory drugs (NSAIDs) due to the patient's mild symptoms and his occupation in the military. When this proved insufficient, we shifted to combination therapy with low dose corticosteroids and NSAIDs. After two weeks of treatment, the patient's symptoms and pericardial effusion had improved, and he was recovered completely 37 days after the onset.

Reply to: Before attributing encephalomyelitis to SARS-CoV-2 vaccinations exclude differentials.

Immunosuppression reduction when administering a booster dose of the BNT162b2 mRNA SARS-CoV-2 vaccine in kidney transplant recipients without adequate humoral response following two vaccine doses: protocol for a randomised controlled trial (BECAME study). INTRODUCTION: Inadequate

antibody response to mRNA SARS-CoV-2 vaccination has been described among kidney transplant recipients. Immunosuppression level and specifically, use of antimetabolite in the maintenance immunosuppressive regimen, are associated with inadequate response. In light of the severe consequences of COVID-19 in solid organ transplant recipients, we believe it is justified to examine new vaccination strategies in these patients. METHODS AND ANALYSIS: BECAME is a single-centre, open-label, investigator-initiated randomised controlled, superiority trial, aiming to compare immunosuppression reduction combined with a third BNT162b2 vaccine dose versus third dose alone. The primary outcome will be seropositivity rate against SARS-CoV-2. A sample size of 154 patients was calculated for the seropositivity endpoint assuming 25% seropositivity in the control group and 50% in the intervention group. A sample of participants per arm will be also tested for T-cell response. We also plan to perform a prospective observational study, evaluating seropositivity among ~350 kidney transplant recipients consenting to receive a third vaccine dose, who are not eligible for the randomised controlled trial. ETHICS AND DISSEMINATION: The trial is approved by local ethics committee of Rabin Medical Center (RMC-0192-21). All participants will be required to provide written informed consent. Results of this trial will be published; trial data will be available. Protocol amendments will be submitted to the local ethics committee. TRAIL REGISTRATION NUMBER: NCT04961229.

A case series of acute pericarditis following COVID-19 vaccination in the context of recent reports from Europe and the United States. BACKGROUND: COVID-19 vaccines were efficacious and safe in clinical trials. We report nine events of acute pericarditis (AP) in eight patients following COVID-19 vaccination with BNT162b2 (6/9), AZD1222 (2/9) and mRNA-1273 (1/9). METHODS: All patients were referred for AP temporally linked with COVID-19 vaccination. Chest pain was the most common clinical manifestation. Alternative etiologies were excluded upon thorough diagnostic work up. AP diagnosis was established according to ESC guidelines. FINDINGS: Five events occurred after the first vaccine dose and four after the second. The mean age in this cohort was 65.8Â Â±Â 10.2Â years and the men/women ratio 3/5. All events resolved without sequelae; two events were complicated by cardiac tamponade requiring emergent pericardial decompression. Hospitalization was required in four cases. INTERPRETATION: Although causality cannot be firmly established, AP has emerged as a possible complication following COVID-19 vaccination. Further investigation is indispensable to fully characterize this new entity.

Two-Component Nanoparticle Vaccine Displaying Glycosylated Spike S1 Domain Induces Neutralizing Antibody Response against SARS-CoV-2 Variants. Vaccines pave the way out of the SARS-CoV-2 pandemic. Besides mRNA and adenoviral vector vaccines, effective protein-based vaccines are needed for immunization against current and emerging variants. We have developed a virus-like particle (VLP)-based vaccine using the baculovirus-insect cell expression system, a robust production platform known for its scalability, low cost, and safety. Baculoviruses were constructed encoding SARS-CoV-2 spike proteins: full-length S, stabilized secreted S, or the S1 domain. Since subunit S only partially protected mice from SARS-CoV-2 challenge, we produced S1 for conjugation to bacteriophage AP205 VLP nanoparticles using tag/catcher technology. The S1 yield in an insect-cell bioreactor was âˆ¼11â€‰mg/liter, and authentic protein folding, efficient glycosylation, partial trimerization, and ACE2 receptor binding was confirmed. Prime-boost immunization of mice with 0.5â€‰Îźg S1-VLPs showed potent neutralizing antibody responses against Wuhan and UK/B.1.1.7 SARS-CoV-2 variants. This two-component nanoparticle vaccine can now be further developed to help alleviate the burden of COVID-19. IMPORTANCE Vaccination is essential to reduce disease severity and limit the transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Protein-based vaccines are useful to vaccinate the world population and to boost immunity against emerging variants. Their safety profiles, production costs, and vaccine storage temperatures are advantageous

compared to mRNA and adenovirus vector vaccines. Here, we use the versatile and scalable baculovirus expression vector system to generate a two-component nanoparticle vaccine to induce potent neutralizing antibody responses against SARS-CoV-2 variants. These nanoparticle vaccines can be quickly adapted as boosters by simply updating the antigen component.

Time-dependent evolution of IgG antibody levels after first and second dose of mRNA-based SARS-CoV-2 vaccination in haemodialysis patients: a multicentre study. BACKGROUND: Vaccination programs are essential for the containment of the coronavirus disease 2019 pandemic, which has hit haemodialysis populations especially hard. Early reports suggest a reduced immunologic response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines in dialysis patients, in spite of a high degree of seroconversion. We aimed to identify risk factors for a reduced efficacy of an mRNA vaccine in a cohort of haemodialysis patients. METHOD: In a multicentre study, including 294 Portuguese haemodialysis patients who had received two doses of BNT162b2 with a 3-week interval, immunoglobulin G-class antibodies against the SARS-CoV-2 spike protein were determined 3 weeks after the first dose (M1) and 6 weeks after the second dose (M2). The threshold for seroconversion was 10 UR/mL. Demographic and clinical data were retrieved from a quality registry. Adverse events were registered using a questionnaire. RESULTS: At M2, seroconversion was 93.1% with a median antibody level of 197.5 U/mLÂ (1.2-3237.0)Â andÂ a median increase of 180.0 U/mLÂ (-82.9 to 2244.6)Â fromÂ M1. Age [beta -8.9; 95% confidence interval (95% CI) -12.88 to -4.91; PÂ <Â 0.0001], ferritinÂ >600 ng/mLÂ (betaÂ 183.93; 95% CI 74.75-293.10; PÂ =Â 0.001) and physical activity (beta 265.79; 95% CI 30.7-500.88; PÂ =Â 0.03) were independent predictors of SARS-CoV-2 antibody levels after two vaccine doses. Plasma albuminÂ >3.5 g/dLÂ independentlyÂ predictedÂ theÂ increase of antibody levels between both doses (odds ratio 14.72; 95% CI 1.38 to 157.45; PÂ =Â 0.03). Only mild adverse reactions were observed in 10.9% of patients. CONCLUSIONS: The SARS-CoV-2 vaccine BNT162b2 is safe and effective in haemodialysis patients. Besides age, iron status and nutrition are possible modifiable modulators of the immunologic response to SARS-CoV-2 mRNA vaccines. These data suggest the need for an early identification of populations at higher risk for diminished antibody production and the potential advantage of the implementation of oriented strategies to maximize the immune response to vaccination in these patients.

Antibody Responses After SARS-CoV-2 mRNA Vaccination in Adults With Inflammatory Bowel Disease.

Serological response to the BNT162b2 mRNA or ChAdOx1 nCoV-19 COVID-19 vaccine after first and second doses in patients with plasma cell disorders: influence of host and disease factors.

A novel adverse effect of the BNT162b2 mRNA vaccine: First episode of acute mania with psychotic features.

Unmet needs on the management of COVID-19 vaccination in patients with neuromuscular disorders. COVID-19 outbreak has quickly reached alarming morbidity and mortality with vaccines being the only weapon to fight. Although the critical situation, no international guidelines on the vaccination management of patients with neuromuscular disorders (NMDs) has still been issued. We aimed to address some unmet needs about the management of COVID-19 vaccination in patients with NMDs.

Lichenoid cutaneous skin eruption and associated systemic inflammatory response following Pfizer-BioNTech mRNA COVID-19 vaccine administration. The global effects of coronavirus disease 2019 (COVID-19) have driven unprecedented rapid development and mass deployment of vaccinations against the novel coronavirus. However, the short- and long-term adverse reactions following COVID-19 vaccinations are still under investigation as insufficient time has passed to fully explore these. The Pfizer-BioNTech COVID-19 mRNA vaccine has thus far shown a favourable safety profile in phase I-III studies. Although infrequent cases of generalized cutaneous reactions and systemic inflammatory response have been reported following other mRNA vaccines, these have not been reported following the Pfizer-BioNTech vaccine. We report a case of generalized lichenoid skin eruptions and

systemic inflammatory response occurring together following the first dose of the Pfizer-BioNTech vaccine. Our case report adds to an accumulating body of literature connecting autoimmunity with the pathophysiology of the novel coronavirus disease.

Herpes-like skin lesion after AstraZeneca vaccination for COVID-19: A case report. Recurrent herpes simplex virus or varicella zoster virus infection should be considered as one of the rare complications after AstraZeneca vaccination for COVID-19.

Subacute thyroiditis following COVID-19 vaccination. Physicians should be alert about the possibility of subacute thyroiditis (SAT) being induced by COVID-19 vaccination. SAT may present with anterior neck pain, extended fever or palpitation in recently vaccinated patients, which should not be easily dismissed as expected post-vaccination flu-like symptoms, thereby, facilitating in time diagnosis and treatment.

One year after first case of COVID-19 in Ghana: epidemiology, challenges and accomplishments. Coronavirus disease 2019 (COVID-19) caused by the novel coronavirus, has affected many lives, health systems and economies across the globe. Countries in both resource-rich and poor have equally been affected. In Ghana, COVID-19 has caused morbidity and mortality among the populace. The first two cases of COVID-19 were reported in Ghana in March 2020. At the onset of the pandemic in Ghana, there were challenges in securing isolation centers and quarantine facilities. Nonetheless, the government of Ghana put in place a number of measures in line with World Health Organization (WHO) guidelines, to halt the spread of the virus. Some measures taken by the government included partial lockdown of areas deemed hotspots for the spread of the virus. In April 2020, Ghana was ranked number one among African countries in administering tests per million people, because of the effective "trace and test" approach. The government of Ghana also encouraged local manufacturing of personal protective equipment, antivirals and hand sanitizers to help meet the demand of the nation. There were also restrictions on public gathering within the early parts of 2020, and these were eased with time. In February 2021, Ghana became the first country to receive vaccines through the COVAX initiative with a delivery of 600,000 doses of Oxford-AstraZeneca vaccines. The efforts by Ghana to deal with the COVID-19 pandemic have been commendable. Not withstanding, the adverse impact of the COVID-19 on public health in Ghana has been significant, and there is still a lot to learn from other countries in the sub-region, and the world as whole.

Peptides Derived From S and N Proteins of Severe Acute Respiratory Syndrome Coronavirus 2 Induce T Cell Responses: A Proof of Concept for T Cell Vaccines. The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants that escape vaccine-induced neutralizing antibodies has indicated the importance of T cell responses against this virus. In this study, we highlight the SARS-CoV-2 epitopes that induce potent T cell responses and discuss whether T cell responses alone are adequate to confer protection against SARS-CoV-2 and describe the administration of 20 peptides with an RNA adjuvant in mice. The peptides have been synthesized based on SARS-CoV-2 spike and nucleocapsid protein sequences. Our study demonstrates that immunization with these peptides significantly increases the proportion of effector memory T cell population and interferon-Î³ (IFN-Î³)-, interleukin-4 (IL-4)-, tumor necrosis factor-Î± (TNF-Î±)-, and granzyme B-producing T cells. Of these 20 peptides, four induce the generation of IFN-Î³-producing T cells, elicit CD8(+) T cell (CTL) responses in a dose-dependent manner, and induce cytotoxic T lymphocytes that eliminate peptide-pulsed target cells in vivo. Although it is not statistically significant, these peptide vaccines reduce viral titers in infected hamsters and alleviate pulmonary pathology in SARS-CoV-2-infected human ACE2 transgenic mice. These findings may aid the design of effective SARS-CoV-2 peptide vaccines, while providing insights into the role of T cells in SARS-CoV-2 infection.

Cerebral Venous Sinus Thrombosis, Pulmonary Embolism, and Thrombocytopenia After COVID-19 Vaccination in a Taiwanese Man: A Case Report and Literature Review. Objective: Coronavirus disease (COVID-19) vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare but fatal complication observed within 2 weeks of adenovirus-vectored vaccination. Case Report: A 52-year-old male patient, with a family history of autoimmune diseases, presented with a new onset of worsening headache with nausea and vomiting post-vaccination. The patient was diagnosed with VITT based on laboratory findings demonstrating thrombocytopenia, elevated D-dimer, and dural sinus thrombosis identified on neuroimaging. The patient was successfully treated with high-dose immunoglobulin, steroids, and non-heparin anticoagulants, without any neurologic sequelae. Finally, a confirmatory test with anti-platelet factor 4 antibody was strongly positive. Conclusion: Physicians should be vigilant when treating patients presenting with new-onset thunderclap headache, progressive worsening headache, and awakening headache accompanied by nausea or vomiting after vaccination, even if no definite clinical neurological deficits are identified. Emergency laboratory test results for demonstrating elevated D-dimer levels, decreased platelet count, and neuroimaging correlation are integral for diagnosis and must be the standard protocol. Treatment with non-heparin anticoagulants, high-dose intravenous immunoglobulin, and steroids that halt or slow the immune-mediated prothrombotic process should be initiated immediately. Considering the high mortality rate of VITT, treatment should be initiated prior to confirmatory test results.
Thrombosis formation after COVID-19 vaccination Immunological Aspects: Review article. COVID-19 deteriorates type II pneumocytes and damages the alveolar immunologic balancing process through the inadvertent activation of a sequence of localized and general inflammatory responses. Due to an aggregation of uncleaved angiotensin II, the stimulated inflammatory cells cause cytokines synthesis and secretion (cytokine storming). The cytokines cause the systemic inflammatory response syndrome (SIRS), leading to widespread tissue injuries. Consequently, pro-coagulant factors are activated which increases the microthrombi in different tissues, resulting in ischemia, multiple organ dysfunction syndrome, acute respiratory distress syndrome, and increased mortality. Vaccines recipients (via virus vector technology) have reported the incidence of thrombocytopenia and peculiar thrombotic events. After vaccination, using sera from patients who experienced thrombocytopenia and thrombosis showed increased reactivity in anti-PF4/heparin enzyme immunoassays and substantial platelet-activating antibodies (positive). In some sera of individuals suffering from heparin-induced thrombocytopenia (HIT), it has been observed that platelet-activating antibodies resulting from vaccination tend to bind to non-complexed PF4 alone.
Recurrence of cutaneous T-cell lymphoma post viral vector COVID-19 vaccination.
Active Surveillance of Adverse Events in Healthcare Workers Recipients After Vaccination with COVID-19 BNT162b2 Vaccine (Pfizer-BioNTech, Comirnaty): A Cross-Sectional Study. In this cross-sectional study, adverse events after the first and second dose of BNT162b2 mRNA (Pfizer-BioNTech, Comirnaty) vaccine against coronavirus disease 2019 were investigated among employees of clinics in central Italy. A 42-items questionnaire was administrated to vaccine recipients. Adverse events were classified based on severity and occurrence as reported in the literature. A descriptive/univariate analysis using Chi-square or Fisher's Exact tests was performed. Odds ratio (OR) and 95% confidence intervals were calculated to assess risk factors. 340 individuals (61.5% females; median age 49Â years) participated. Adverse events were reported by 279 (82%) and 281 (82.6%) individuals as induced by the first and second dose, respectively. Mild reactions were mainly reported (80.9% and 80.3%), followed by moderate (11.8% and 37.1%) and severe (3.8% and 4.7%). Adverse events were identical to those already described as very common (81.8% and 80.6%), although vaccine-coincidental events not cited in the literature were reported by 6% and 15.6% following each dose. Ageâ€‰â‰¤â€‰55Â years was a risk factor for any adverse event after each injection (ORs: 2.942

and 2.818), as well as female sex for those mild (ORs: 1.856 and 2.818) and common (ORs: 3.452 and 2.145). Findings were consistent with national reports as most of the adverse events were mild and associated with female sex and young age, while investigations are needed for reactions not described elsewhere. Data are useful to support the vaccine safety profile, also because largely targeted healthcare personnel more skilled than general population in self-diagnosis of health-related issues.

Treatment with abiraterone or enzalutamide does not impair immunological response to COVID-19 vaccination in prostate cancer patients. Data regarding the safety and efficacy of COVID-10 vaccines among cancer patients are lacking. Factors such as age, underlying disease and antineoplastic treatment confer negatively to the immune response due to vaccination. The degree of immunosuppression though may be lessen by targeted treatments like the androgen receptor-targeted agents (ARTA) that are commonly used in patients with metastatic prostate cancer. Herein, we report our data on 25 patients with prostate cancer under treatment with ARTA who were vaccinated for COVID-19. Our data suggest that these patients develop neutralizing antibodies against SARS-CoV-2 similarly to healthy volunteers. No safety issues were noted.

Cerebral Venous Sinus Thrombosis is not Significantly Linked to COVID-19 Vaccines or Non-COVID Vaccines in a Large Multi-State Health System. OBJECTIVE: To assess the association of COVID-19 vaccines and non-COVID-19 vaccines with cerebral venous sinus thrombosis (CVST). MATERIALS AND METHOD: We retrospectively analyzed a cohort of 771,805 vaccination events across 266,094 patients in the Mayo Clinic Health System between 01/01/2017 and 03/15/2021. The primary outcome was a positive diagnosis of CVST, identified either by the presence of a corresponding ICD code or by an NLP algorithm which detected positive diagnosis of CVST within free-text clinical notes. For each vaccine we calculated the relative risk by dividing the incidence of CVST in the 30 days following vaccination to that in the 30 days preceding vaccination. RESULTS: We identified vaccination events for all FDA-approved COVID-19 vaccines including Pfizer-BioNTech (nÂ =Â 94,818 doses), Moderna (nÂ =Â 36,350 doses) and Johnson & Johnson - J&J (nÂ =Â 1,745 doses). We also identified vaccinations events for 10 common FDA-approved non-COVID-19 vaccines (nÂ =Â 771,805 doses). There was no statistically significant difference in the incidence rate of CVST in 30-days before and after vaccination for any vaccine in this population. We further found the baseline CVST incidence in the study population between 2017 and 2021 to be 45 to 98 per million patient years. CONCLUSIONS: This real-world evidence-based study finds that CVST is rare and is not significantly associated with COVID-19 vaccination in our patient cohort. Limitations include the rarity of CVST in our dataset, a relatively small number of J&J COVID-19 vaccination events, and the use of a population drawn from recipients of a SARS-CoV-2 PCR test in a single health system.

COVID-19 mRNA Vaccine Short-Term Safety in Patients With Inflammatory Bowel Disease.

Fatal vaccine-induced immune thrombotic thrombocytopenia (VITT) post Ad26.COV2.S: first documented case outside US. PURPOSE: We reported the first described post Ad26.COV2.S (Janssen, Johnson & Johnson) vaccine-induced immune thrombocytopenia (VITT) case outside US.Â CASE DESCRIPTION: CA young woman without any medical history presented association of deep vein thrombosis and thrombocytopenia at day 10 after vaccine injection. The patient was treated with low-molecular weight heparin at a first medical institution. Twelve days post Ad26.COV2.S vaccination, the patient was admitted at our hospital for neurological deterioration and right hemiplegia. Medical imaging using MRI showed thrombosis of the major anterior part of the sagittal superior sinus with bilateral intraparenchymal hemorrhagic complications. Screening tests for antibodies against platelet factor 4 (PF4)-heparin by rapid lateral flow immunoassay and chemiluminescence techniques were negative. Platelet activation test using heparin-induced multiple electrode aggregometry confirmed the initial clinical hypothesis. Despite immediate treatment with

intravenous immunoglobulin, dexamethasone, danaparoid and attempted neurosurgery the patient evolved toward brain death. CONCLUSION: Even though it is an extremely rare complication of vaccinationÂ physicians should maintain a high index of suspicion of VITT in patients who received an adenovirus-vector-based SARS-CoV-2 vaccine within the last 30Â days with persistent complains compatible with VITT or thromboembolic event associated with thrombocytopenia.Â The diagnosis should not be excluded if the rapid anti-PF4 immunological nor chemiluminescence techniques yield negative results. An adapted functional assay should be performed to confirm the diagnosis.Â Early treatment with intravenous immunoglobulin and non-heparin anticoagulantsÂ is essential as delayed diagnosis and administration of appropriate treatment is associated with poor prognosis.
Risk of giant cell arteritis and polymyalgia rheumatica following COVID-19 vaccination: a global pharmacovigilance study.
Takotsubo (stress) cardiomyopathy after ChAdOx1 nCoV-19 vaccination. The global COVID-19 pandemic remains challenging with efforts for community vaccination the primary strategy to control transmission and disease sequalae in the mid to long term. While several candidate vaccines have been approved for use, there is an ongoing discussion regarding potential vaccine-related adverse events. Notably, thrombotic thrombocytopaenia has been reported following ChAdOx1 nCov-19 (AstraZeneca) vaccination. We report the first known case of takotsubo (stress) cardiomyopathy 4â€‰days after administration of the ChAdOx1 nCoV-19 vaccine in a 72-year-old man. While this condition remains one primarily seen in females, our case represents a new trigger that warrants careful consideration when assessing patients presenting with acute coronary syndromes following ChAdOx1 nCoV-19 vaccination.
Thrombotic thrombocytopenic purpura after ChAdOx1 nCoV-19 vaccine. A 50-year-old Indian woman presented with acute dysphasia, left upper limb numbness and thrombocytopenia 12 days after receiving the ChAdOx1 nCoV-19 vaccine (AstraZeneca/Vaxzevria). MRI of the brain was unremarkable. Microangiopathic haemolytic anaemia with thrombocytopenia was noted on her peripheral blood film. A diagnosis of thrombotic thrombocytopenic purpura (TTP) was confirmed through the findings of absent ADAMTS13 (a disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13) activity and markedly raised titre of ADAMTS13 autoantibodies. Prompt treatment with plasma exchange, adjunctive steroids and rituximab was commenced. A remission of TTP was achieved and she was discharged 3â€‰weeks after admission. While other immune-mediated conditions have been documented after receipt of the vaccine, this report highlights the first case of immune-mediated TTP diagnosed after administration of the ChAdOx1 nCoV-19 vaccine.
Long-term follow-up after successful treatment of vaccine-induced prothrombotic immune thrombocytopenia. BACKGROUND: Cases of ChAdOx1 nCoV-19 (AstraZeneca) vaccinated patients with thrombocytopenia, elevated D-dimer, and elevated platelet factor 4 (PF4) antibody levels with- and without thrombosis have been reported. No recommendations regarding the duration of anticoagulation have been made, because data on the long-term course beyond the first weeks is lacking. OBJECTIVE: To report on the treatment, medical course, and longitudinal follow-up of laboratory parameters in patients with vaccine-induced prothrombotic immune thrombocytopenia (VIPIT). PATIENTS: We followed VIPIT patients with- (nÂ =Â 3) and without (nÂ =Â 3) venous thromboembolism fulfilling the aforementioned laboratory criteria. RESULTS: Elevated D-dimer (median: 35.10Â Î¼g/ml, range: 17.80-52.70), thrombocytopenia (42Â G/l, 20-101), and strong positivity in the platelet factor 4 (PF4)/heparin-enzyme-immunoassay (2.42 optical density [OD], 2.06-3.13; reference rangeÂ <Â 0.50) were present in all patients after vaccination (10Â days, 7-17). Routine laboratory parameters rapidly improved upon initiation of treatment (comprising therapeutic non-heparin anticoagulation in all patients and high dose immunoglobulinsÂ Â±Â corticosteroids in 5

patients). PF4 antibody levels slowly decreased over several weeks. Patients were discharged in good physical health (8Â days, 5-13). VIPIT did not recur during follow-up (12Â weeks, 8-17). Five of 6 patients fully recovered (in 2 patients thrombosis had resolved, in 1 patient exertional dyspnea persisted). CONCLUSIONS: Remissions without sequelae can be achieved upon rapid initiation of treatment in patients with VIPIT. Platelet factor 4 antibody levels slowly decreased over several weeks but VIPIT did not recur in any of our patients. Continuation of anticoagulation in VIPIT patients at least until PF4 antibody negativity is reached seems reasonable.

The Ethics of Human Challenge Trials Using Emerging Severe Acute Respiratory Syndrome 2 Variants. The world's first coronavirus disease 2019 human challenge trial using the D614G strain of severe acute respiratory syndrome 2 (SARS-CoV-2) is underway in the United Kingdom. The Wellcome Trust is funding challenge stock preparation of the Beta and Delta variant for a follow-up human challenge trial, and researchers at hVIVO are considering conducting these trials. However, little has been written thus far about the ethical justifiability of human challenge trials with SARS-CoV-2 variants of concern. We explore 2 specific characteristics of some variants that may initially be thought to make such trials unethical and conclude that SARS-CoV-2 variant challenge trials can remain ethical.

Nocebo responses in randomized controlled trials of COVID-19 vaccines. OBJECTIVE: The aim of this study was to evaluate the frequency and magnitude of nocebo responses in -COVID-19 vaccine trials. MATERIALS AND METHODS: We performed a meta-analysis of adverse effects (AEs), severe adverse effects (SAEs), withdrawal due to AEs, death, and immune-mediated SAEs observed in randomized controlled trials (RCTs) of COVID-19 vaccines. RESULTS: Four RCTs with a total of 119,110 participants (65,254 from the vaccine group and 53,856 from the placebo group) were considered. The pooled estimate of AEs in the placebo and vaccine groups was 16.4% (95% confidence interval (CI), 9.1Â -Â 27.7%) and 25.3% (95% CI, 22.7Â -Â 28.1%), respectively. The pooled SAE rate in the placebo and vaccine groups was 0.7% (95% CI, 0.5Â -Â 1.0%) and 0.6% (95% CI, 0.4Â -Â 0.9%), respectively. The pooled estimate of participants who withdrew from treatment due to AEs in the placebo and vaccine groups was 0.3% (95% CI, 0.1Â -Â 1.0%) and 0.2% (95% CI, 0.1Â -Â 0.5%), respectively. The pooled death rate in the placebo and vaccine groups was 0.02% (95% CI, 0.01Â -Â 0.04%) and 0.01% (95% CI, 0.01Â -Â 0.03%), respectively. The pooled estimate of immune-mediated SAEs in the placebo and vaccine groups was 0.01% (95% CI, 0.01Â -Â 0.04%) and 0.02% (95% CI, 0.01Â -Â 0.05%), respectively. There were no differences observed in the pooled risk of AEs, SAEs, withdrawal due to AEs, death, and immune-mediated SAEs between placebo and vaccine groups. CONCLUSION: The frequency and magnitude of nocebo responses were 16.4% and 0.3%, respectively. Therefore, the incidence of nocebo responses was high, but their magnitude was low in COVID-19 vaccine trials.

Flare-up of adult-onset Still's disease after receiving a second dose of BNT162b2 COVID-19 mRNA vaccine.

Cutaneous adverse reactions after COVID-19 vaccines in a cohort of 2740 Italian subjects: An observational study. An in-depth characterization of the incidence, morphology, and onset of COVID-19-vaccines cutaneous adverse reactions is currently lacking. The existing literature on COVID-19 vaccination-related cutaneous adverse reactions largely focused on messenger RNA vaccines and mainly included type 1 hypersensitivity reactions, such as urticaria and angioedema. Other cutaneous manifestations are still poorly characterized and have been classified as delayed hypersensitivity rash. Our prospective observational study on a sample of 2740 subjects who underwent the COVID-19 vaccination aimed at defining the prevalence of cutaneous adverse reactions and at identifying their timing of onset and their correlation with the administered dose. Vaccine-related cutaneous adverse reactions occurred in 50 subjects. Patients were asked to complete a questionnaire on the type of COVID-19 vaccine received, the time of onset of cutaneous reactions, and the dates of administration.

Out of 2740 individuals who received the COVID-19 vaccination, 50 were diagnosed with cutaneous adverse reactions to vaccine, after the first dose in 28 patients, after the second in 20, and after both in two. We reported localized injection site erythema in 12 patients and generalized cutaneous reactions in 38 patients. Our study shows that cutaneous adverse reactions to COVID-19 vaccination are not common and most often occur after the first dose, recurring infrequently after the second dose. These reactions are usually easily manageable and, even in severe generalized cases, oral antihistamines and corticosteroids were sufficient for resolution. Therefore, except for immediate hypersensitivity reactions, cutaneous adverse reactions do not represent a contraindication to the completion of the vaccination cycle.

Attenuated humoral immune response following anti-SARS-CoV-2 vaccine in heavily pretreated patients with multiple myeloma and AL amyloidosis.

Adverse events of six COVID-19 vaccines in patients with autoimmune rheumatic diseases: a cross-sectional study. Data regarding COVID-19 vaccine efficacy and adverse eventsÂ (AE) in patients with autoimmune and inflammatory rheumatic diseases (AIIRD) have been published recently although these mostly include the mRNA vaccines (Pfizer-BioNTech and Moderna) and the ChAdOx1 nCoV-19/AZD1222 (Oxford-AstraZeneca). This research aimed to study the prevalence of AE presented with six different SARS-CoV-2 vaccines {ChadOX1 nCoV-19 (AZD1222), Ad5-nCoV2, Ad26.COV2.S, mRNA-1273, BNT162b2, and CoronaVac} in Mexican patients with AIIRD. We performed a cross-sectional study about vaccine history. Two hundred and twenty five consecutive patients were recruited, mean age was 50.7Â years and the majority (nâ€‰=â€‰213; 94.6%) were females. One hundred and seven (47.5%) received BNT162b2 mRNA, 34 (15.1%) Ad5-nCoV, 29 (12.8%) mRNA-1273, 28 (12.4%) ChAdOX1 nCoV-19 (AZD1222), 22 (9.7%) CoronaVac and 5 (2.2%) Ad26.COV2.S. The vaccines that had the most AE proportionally to the number of patients vaccinated were Janssen (5; 100%) followed by Pfizer-BioNTEch (86; 80%) and CanSinoBIO (27; 79.4%). Localized pain was the most frequent (158; 70.2%) AE. Fatigue (78; 34.7%), headache (69; 30.6%) and muscle ache (66; 29.3%) were the most common systemic symptoms. No serious AE that required medical attention or hospitalizationÂ were reported. The current results support the safety of different COVID-19 vaccines in patients with AIIRD. This information can help fight vaccine hesitancy in this population.

Bell's palsy after inactivated COVID-19 vaccination in a patient with history of recurrent Bell's palsy: A case report. BACKGROUND: With rapid and extensive administration of inactivated coronavirus disease 2019 (COVID-19) vaccine to the general population in China, it is crucial for clinicians to recognize neurological complications or other side effects associated with COVID-19 vaccination. CASE SUMMARY: Here we report the first case of Bell's palsy after the first dose of inactivated COVID-19 vaccine in China. The patient was a 36-year-old woman with a past history of Bell's palsy. Two days after receiving the first dose of the Sinovac Life Sciences inactivated COVID-19 vaccine, the patient developed right-side Bell's palsy and binoculus keratoconjunctivitis. Prednisone, artificial tears and fluorometholone eye drops were applied. The patient's symptoms began to improve by day 7 and resolved by day 54. CONCLUSION: As mRNA COVID-19 vaccine trials reported cases of Bell's palsy as adverse events, we should pay attention to the occurrence of Bell's palsy after inactivated COVID-19 vaccination. A history of Bell's palsy, rapid increase of immunoglobulin M and immunoglobin G-specific antibodies to severe acute respiratory syndrome coronavirus 2 may be risk factors for Bell's palsy after COVID-19 vaccination.

Acute Corneal Transplant Rejection After COVID-19 Vaccination. PURPOSE: The purpose of this report was to describe 4 cases of acute corneal transplant rejection occurring in association with coronavirus disease 2019 (COVID-19) mRNA vaccination. METHODS: Four patients with prior keratoplasty developed presumed immunologic rejection after the mRNA-1273 vaccination for

coronavirus 2 (SARS-CoV-2). Case 1 had received Descemet membrane endothelial keratoplasty 6 months ago and presented with endothelial graft rejection 3 weeks after the first vaccine dose. Case 2 had undergone penetrating keratoplasty 3 years previously and presented with acute endothelial rejection 9 days after the second vaccine dose. Case 3 had prior Descemet stripping automated endothelial keratoplasty (DSAEK) and began experiencing symptoms of endothelial graft rejection 2 weeks after the second vaccine dose. Case 4 presented with endothelial rejection of the penetrating keratoplasty graft 2 weeks after the second vaccine dose. RESULTS: Frequent topical corticosteroids alone were initiated in all 4 cases. In case 1, the endothelial rejection line appeared fainter with improvement in visual acuity and corneal edema 5 weeks after diagnosis. Case 2 experienced complete resolution of corneal stromal edema and rejection line 6 weeks after diagnosis. Cases 3 and 4 have both experienced initial improvement with steroid treatment as well. CONCLUSIONS: These cases suggest acute corneal endothelial rejection may occur soon after either dose of the COVID-19 mRNA vaccine. Prompt initiation of aggressive topical steroid therapy may result in complete resolution of clinical signs and symptoms. Further studies are needed to elucidate the causal mechanism of corneal graft rejection after COVID-19 vaccination.

Haematuria, a widespread petechial rash, and headaches following the Oxford AstraZeneca ChAdOx1 nCoV-19 Vaccination. With increasing presentations of headaches following COVID-19 vaccination, we present one of the UK's earliest proven cases of vaccine-induced thrombotic thrombocytopaenia (VITT), with the aim of giving colleagues a case to compare other patients against. Our patient was a 48-year-old man who presented with frank haematuria, a widespread petechial rash, and headaches, 2 weeks after receiving the first dose of the Oxford AstraZeneca ChAdOx1 nCoV-19 vaccine. He had a platelet count of 14Ã—10(9)/L and an extensive cerebral venous sinus thrombosis (CVST) with subarachnoid haemorrhage on imaging. He developed localising neurological signs and experienced a cardiopulmonary arrest. He was successfully resuscitated and transferred to a tertiary care centre for urgent thrombectomy. This case illustrates how the diagnosis of VITT should be based on the platelet count and imaging-and how patients with VITT should be cared for in centres with urgent neurosurgical and interventional radiology services.

Platelet trends after Covid-19 vaccination in patients with chronic or persistent immune thrombocytopenia.

Anti-SARS-CoV-2 receptor-binding domain antibody evolution after mRNA vaccination. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection produces B cell responses that continue to evolve for at least a year. During that time, memory B cells express increasingly broad and potent antibodies that are resistant to mutations found in variants of concern(1). As a result, vaccination of coronavirus disease 2019 (COVID-19) convalescent individuals with currently available mRNA vaccines produces high levels of plasma neutralizing activity against all variants tested(1,2). Here we examine memory B cell evolution five months after vaccination with either Moderna (mRNA-1273) or Pfizer-BioNTech (BNT162b2) mRNA vaccine in a cohort of SARS-CoV-2-naive individuals. Between prime and boost, memory B cells produce antibodies that evolve increased neutralizing activity, but there is no further increase in potency or breadth thereafter. Instead, memory B cells that emerge five months after vaccination of naive individuals express antibodies that are similar to those that dominate the initial response. While individual memory antibodies selected over time by natural infection have greater potency and breadth than antibodies elicited by vaccination, the overall neutralizing potency of plasma is greater following vaccination. These results suggest that boosting vaccinated individuals with currently available mRNA vaccines will increase plasma neutralizing activity but may not produce antibodies with equivalent breadth to those obtained by vaccinating convalescent individuals.

111In-Pentetreotide Uptake Due to COVID-19 Vaccination. A 72-year-old woman was referred for whole-body 111In-pentetreotide scintigraphy with SPECT/CT. There was increased uptake of lymphadenopathy in the left axilla and left deltoid muscle. The patient's history revealed that the patient received the first dose of the COVID-19 vaccine 3 days before the 111In-pentetreotide scintigraphy with SPECT/CT. This case demonstrates that the COVID-19 vaccine can cause 111In-pentetreotide uptake in the lymph nodes and the deltoid muscle.

Symptomatic post-vaccination SARS-CoV-2 infections in healthcare workers- A multicenter cohort study. BACKGROUND AND AIMS: During the COVID-19 vaccination program in India, the healthcare workers were given the first priority. There are concerns regarding the occurrence of breakthrough infections after vaccination. We aimed to investigate the effictiveness of COVID-19 vaccines in preventing and reducing the severity of post-vaccination infections. METHODS: This retrospective test-negative case-control study examined 28342 vaccinated healthcare workers for symptomatic SARS-CoV-2 infections between January 16 to June 15, 2021. They worked at 43 Apollo Group hospitals in 24 Indian cities. These cohorts received either ChAdOx nCOV-19 (Recombinant) or the whole virion inactivated Vero cell vaccines. Various demographic, vaccination related and clinical parameters were evaluated. RESULTS: Symptomatic symptomatic post-vaccination infections occurred in a small number of vaccinated cohorts (5.07%, pÂ <Â 0.001), and these were predominantly mild and did not result in hospitalization (pÂ <Â 0.0001), or death. Both vaccines provided similar protection, with symptomatic infections in 5.11% and 4.58%, following ChAdOx nCOV-19 (Recombinant) and the whole virion inactivated Vero cell vaccines, respectively (pÂ <Â 0.001). Nursing and Clinical staff and cohorts >50 years contracted more infections (pÂ <Â 0.001). Two-dose vaccination has significantly lower odds of developing symptomatic infection (0.83, 95%CI - 0.72 to 0.97). Maximum infections occurred during the peak of the second COVID-19 wave from mid-April to May 2021 (pÂ <Â 0.001). No significant difference existed in the infection between sex, vaccine type, and the number of vaccine doses received (pÂ â‰¥Â 0.05). CONCLUSION: Symptomatic infections occurred in a small percentage of healthcare workers after COVID vaccination. Vaccination protected them from not only infection but also severe disease.

Immunological response against SARS-CoV-2 following full-dose administration of ComirnatyÂ® COVID-19 vaccine in nursing home residents. OBJECTIVES: The current study was aimed at examining SARS-CoV-2 immune responses following two doses of ComirnatyÂ® COVID-19 vaccine among elderly people in nursing homes. METHODS: A prospective cohort study in a representative sample from nursing homes in Valencia (nÂ =Â 881; males: 271, females 610; median age, 86 years) recruited residents using a random one-stage cluster sampling approach. A lateral flow immunochromatography device (LFIC) (OnSite COVID-19 IgG/IgM Rapid Test; CTK BIOTECH, Poway, CA, USA) was used as the front-line test for detecting SARS-CoV-2-Spike (S)-specific antibodies in whole blood obtained using a fingerstick. Residents returning negative LFIC results underwent venipuncture and testing for presence of SARS-CoV-2-S-reactive antibodies and T cells using the Roche ElecsysÂ® Anti-SARS-CoV-2 S (Roche Diagnostics, Pleasanton, CA, USA), the LIAISONÂ® SARS-CoV-2 TrimericS IgG assay (Diasorin S.p.A, Saluggia, Italy) and by flow cytometry, respectively. RESULTS: The SARS-CoV-2-S antibody detection rate in nursing home residents was 99.6% (283/284) and 98.3% (587/597) for SARS-CoV-2 recovered and naÃ¯ve residents, respectively, within a median of 99Â days (range 17-125Â days) after full vaccination. Three out of five residents lacking SARS-CoV-2-S antibodies had detectable S-reactive CD8(+) and/or CD4(+) T cells. In addition, 50/50 and 40/50 participants with detectable SARS-CoV-2 antibodies also had SARS-CoV-2-S-reactive interferon-Î³-producing CD4(+) and CD8(+) T cells, respectively. DISCUSSION: The ComirnatyÂ® COVID-19 vaccine is highly immunogenic in nursing home residents.

Immune-mediated hepatitis with the Moderna vaccine, no longer a coincidence but confirmed.

Seroconversion After Coronavirus Disease 2019 Vaccination.
SARS-CoV-2 vaccine effectiveness in preventing confirmed infection in pregnant women. BackgroundSARS-CoV-2 infection in pregnancy is associated with a higher risk of pregnancy-related complications and neonatal respiratory distress and hospitalization. Effectiveness of SARS-CoV-2 vaccines in pregnant women is not known.MethodsAll women with confirmed pregnancy who presented to the national referral hospital in Qatar between December 20, 2020, and May 30, 2021, with at least 1 SARS-CoV-2 test and not testing prior to pregnancy were included. We determined the vaccine effectiveness of mRNA vaccines in preventing confirmed SARS-CoV-2 infection during pregnancy using both cohort and test-negative case-control designs. Analyses were adjusted for age group, nationality, and gestational age.ResultsAmong 4534 pregnant women, there were 407 vaccinated and 407 unvaccinated women in the matched cohort analysis. Vaccine effectiveness was 87.6% (95%CI 44.1%-97.2%) at least 14 days after the second dose. There were 386 test-positive and 834 matched women in the test-negative case control analysis. Vaccine effectiveness was 86.8% (95%CI 47.5%-98.5%) at least 14 days after the second dose. Adjustment for age, nationality, and gestational age yielded similar results for both designs. In the test-negative analysis, vaccine effectiveness at least 14 days after the first dose but before the second dose was 40.8% (95% CI 0.0%-80.4%). Of the 386 test-positive pregnant women, 74 cases were Alpha variant, 163 cases were Beta variant, and 156 cases were variants of unknown status. There were 9 severe or critical disease cases and no deaths in the test-positive pregnant women, all of whom were unvaccinated.ConclusionThe mRNA vaccines provide a high level of protection against documented SARS-CoV-2 infection, which supports the inclusion of pregnant women in vaccination campaigns.FUNDINGHamad Medical Corporation, Weill Cornell Medicine Qatar, and the Ministry of Public Health Qatar.
The landscape of COVID-19 vaccination among healthcare workers at the first round of COVID-19 vaccination in China: willingness, acceptance and self-reported adverse effects. The COVID-19 vaccines have been developed in a wide range of countries. This study aimed to examine factors that related to vaccination rates and willingness to be vaccinated against COVID-19 among Chinese healthcare workers (HCWs). From 3rd February to 18th February, 2021, an online cross-sectional survey was conducted among HCWs to investigate factors associated with the acceptance and willingness of COVID-19 vaccination. Sociodemographic characteristics and the acceptance of COVID-19 vaccination among Chinese HCWs were evaluated. A total of 2156 HCWs from 21 provinces in China responded to this survey (effective rate: 98.99%)), among whom 1433 (66.5%) were vaccinated with at least one dose. Higher vaccination rates were associated with older age, working as a clinician, having no personal religion, working in a fever clinic or higher hospital grade, and having received vaccine education, family history for influenza vaccination and strong familiarity with the vaccine. Willingness for vaccination was related to working in midwestern China, considerable knowledge of the vaccine, received vaccine education, and strong confidence in the vaccine. Results of this study can provide evidence for the government to improve vaccine coverage by addressing vaccine hesitancy in the COVID-19 pandemic and future public health emergencies.
A case of severe interstitial lung disease after COVID-19 vaccination.
BehÃ§et's-like adverse event or inaugural BehÃ§et's disease after SARS-CoV-2 mRNA-1273 vaccination?
Association of Receipt of the Ad26.COV2.S COVID-19 Vaccine With Presumptive Guillain-BarrÃ© Syndrome, February-July 2021. IMPORTANCE: As part of postauthorization safety surveillance, the US Food and Drug Administration (FDA) has identified a potential safety concern for Guillain-BarrÃ© syndrome (GBS) following receipt of the Ad26.COV2.S (Janssen/Johnson & Johnson) COVID-19 vaccine. OBJECTIVE: To assess reports of GBS received in the Vaccine Adverse Event Reporting System (VAERS) following Ad26.COV2.S vaccination. DESIGN, SETTING, AND PARTICIPANTS: Reports

of presumptive GBS were identified in a US passive reporting system (VAERS) February-July 2021 and characterized, including demographics, clinical characteristics, and relevant medical history. EXPOSURES: Receipt of the Ad26.COV2.S vaccine; the comparator was the background rate of GBS in the general (unvaccinated) population that had been estimated and published based on a standardized case definition. MAIN OUTCOMES AND MEASURES: Presumptive GBS; the reporting rate was analyzed, including calculation of the observed to expected ratio based on background rates and vaccine administration data. Because of limited availability of medical records, cases were not assessed according to the Brighton Collaboration criteria for GBS. RESULTS: As of July 24, 2021, 130 reports of presumptive GBS were identified in VAERS following Ad26.COV2.S vaccination (median age, 56 years; IQR, 45-62 years; 111 individuals [86.0%] were < 65 years; 77 men [59.7%]). The median time to onset of GBS following vaccination was 13 days (IQR, 10-18 days), with 105 cases (81.4%) beginning within 21 days and 123 (95.3%) within 42 days. One hundred twenty-one reports (93.1%) were serious, including 1 death. With approximately 13â€¯209â€¯858 doses of vaccine administered to adults in the US, the estimated crude reporting rate was 1 case of GBS per 100â€¯000 doses administered. The overall estimated observed to expected rate ratio was 4.18 (95% CI, 3.47-4.98) for the 42-day window, and in the worst-case scenario analysis for adults 18 years or older, corresponded to an estimated absolute rate increase of 6.36 per 100â€¯000 person-years (based on a rate of approximately 8.36 cases per 100â€¯000 person-years [123 cases per 1â€¯472â€¯162 person-years] compared with a background rate of approximately 2 cases per 100â€¯000 person-years). For both risk windows, the observed to expected rate ratio was elevated in all age groups except individuals aged 18 through 29 years. CONCLUSIONS AND RELEVANCE: These findings suggest a potential small but statistically significant safety concern for Guillain-BarrÃ© syndrome following receipt of the Ad26.COV2.S vaccine. However, the findings are subject to the limitations of passive reporting systems and presumptive case definition, and they must be considered preliminary pending analysis of medical records to establish a definitive diagnosis.

An ocular adverse event in temporal association with COVID-19 vaccination in a patient with systemic lupus erythematosus: a case report. After the COVID-19 pandemic, vaccines using inactivated viruses have attracted worldwide attention for the prevention of infectious diseases. Here, we report a patient who suffered from Systemic Lupus Erythematosus (SLE) for six years and developed ocular symptoms within 72Â hours after being vaccinated for COVID-19. The patient presented bilateral conjunctival congestion, eyelid edema with pruritus, and suffered from severe headaches. Recovery occurred within 10Â days after the onset of symptoms after treatment with anti-infection drugs. The early identification and extensive assessment of side effects help ensuring effective vaccine safety monitoring.

Abrupt onset of Sweet syndrome, pityriasis rubra pilaris, pityriasis lichenoides et varioliformis acuta and erythema multiforme: unravelling a possible common trigger, the COVID-19 vaccine.

Multisystem inflammatory syndrome in a male adolescent after his second Pfizer-BioNTech COVID-19 vaccine.

Comparison of five commercial anti-SARS-CoV-2 total antibodies and IgG immunoassays after vaccination with BNT162b2 mRNA. BACKGROUND: Since universal vaccinations represents the most effective strategy to mitigate coronavirus disease 2019 (COVID-19), baseline assessment and post-vaccine monitoring of anti-SARS-CoV-2 neutralizing antibodies are essential to vaccination programs. Therefore, this study aimed to compare data of five commercial anti-SARS-CoV2 immunoassays after administration of an mRNA vaccine. METHODS: Venous blood was collected from three healthcare workers, receiving a double (30 g) dose of BNT162b2 mRNA Covid-19 vaccine (Comirnaty, Pfizer), on the day of the first vaccine dose and then at fixed intervals for the following 2 months. Anti-SARS-CoV-2 neutralizing antibody response was assayed with Roche Total Ig anti-RBD

(receptor binding domain), DiaSorin TrimericS IgG (spike trimer), Beckman Coulter IgG anti-RBD, SNIBE IgG anti-RBD and Technogenetics IgG anti-N/S1. RESULTS: A total number of 45 samples were drawn at the end of the 2-month study period. The Spearman's correlations of absolute anti-SARS-CoV-2 antibodies were always excellent (all p<0.001), comprised between 0.967-0.994. Satisfactory results were also observed when absolute antiSARS-CoV-2 antibodies values of the five methods were compared with the mean consensus value, with correlations always higher than 0.979 (all p<0.001). The agreement of anti-SARS-CoV-2 antibodies positivity versus the consensus median positivity ranged between 0.764 and 1.000 (always p<0.001), but become always >0.900 after readjustment of one assay cutoff. CONCLUSIONS: All the immunoassays evaluated in this study appear suitable for monitoring anti-SARS-CoV-2 neutralizing antibodies response in subjects undergoing mRNA COVID-19 vaccination.

Anti-spike S1 IgA, anti-spike trimeric IgG, and anti-spike RBD IgG response after BNT162b2 COVID-19 mRNA vaccination in healthcare workers. BACKGROUND: Most studies on immune response after coronavirus disease 2019 (COVID-19) vaccination focused on serum IgG antibodies and cell-mediated immunity, discounting the role of anti-SARS-CoV-2 neutralizing IgA antibodies in preventing viral infection. This study was aimed to quantify serum IgG and IgA neutralizing antibodies after mRNA COVID-19 vaccination in baseline SARS-CoV-2 seronegative healthcare workers. METHODS: The study population consisted of 181 SARSCoV-2 seronegative healthcare workers (median age 42 years, 59.7% women), receiving two doses of Pfizer COVID-19 vaccine BNT162b2 (Comirnaty). Serum samples were collected before receiving the first vaccine dose, 21 days (before the second vaccine dose) and 50 days afterwards. We then measured anti-spike trimeric IgG (Liaison XL, DiaSorin), anti-spike receptor binding domain (RBD) IgG (Access 2, Beckman Coulter) and anti-spike S1 subunit IgA (ELISA, Euroimmun). Results were presented as median and interquartile range (IQR). RESULTS: Vaccine administration elicited all anti-SARS-CoV2 antibodies measured. Thirty days after the second vaccine dose, 100% positivization occurred for anti-spike trimeric IgG and anti-spike RBD IgG, whilst 1.7% subjects remained anti-spike S1 IgA negative. The overall increase of antibodies level ratio over baseline after the second vaccine dose was 576.1 (IQR, 360.7-867.8) for anti-spike trimeric IgG, 1426.0 (IQR, 742.0-2698.6) for anti-spike RBD IgG, and 20.2 (IQR, 12.5-32.1) for anti-spike S1 IgA. Significant inverse association was found between age and overall increase of anti-spike trimeric IgG (r=-0.24; p=0.001) and anti-spike S1 IgA (r=-0.16; p=0.028), but not with anti-spike RBD IgG (r=-0.05; p=0.497). CONCLUSIONS: mRNA COVID-19 vaccination elicits sustained serum levels of anti-spike trimeric IgG and anti-spike RBD IgG, while also modestly but significantly increasing those of anti-spike S1 IgA.

Fever-Related Ventricular Fibrillationã€€- Potential Adverse Effect of SARS-CoV-2 Vaccination in Patients With Brugada Syndrome.

Diffuse prothrombotic syndrome after ChAdOx1 nCoV-19 vaccine administration: a case report. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia is emerging as one of the most relevant side effects of adenoviral-based vaccines against coronavirus disease 2019. Given the novelty of this disease, the medical community is seeking new evidence and clinical experiences on the management of these patients. CASE PRESENTATION: In this article, we describe the case of a 73-year-old Caucasian woman who presented with diffuse prothrombotic syndrome, both in the arterial and venous districts, following the first dose administration of ChAdOx1 CoV-19 vaccine. The main thrombotic sites included the brain, with both a cortical ischemic lesion and thromboses of the left transverse and sigmoid sinuses and the lower limbs, with deep venous thrombosis accompanied by subsegmental pulmonary thromboembolism. The deep venous thrombosis progressively evolved into acute limb ischemia, requiring surgical intervention with thromboendoarterectomy. Anticoagulation was maintained throughout the whole hospitalization period and continued in the outpatient setting

using vitamin K antagonists for a recommended period of 6Â months. CONCLUSIONS: This case describes the management of vaccine-induced immune thrombotic thrombocytopenia in a complicated clinical scenario, including multisite arterial and venous thromboses. Given the complexity of the patient presentation, this case may implement the comprehension of the mechanisms and clinical features of this disease; it also provides a picture of the challenges related to the management, often requiring a multidisciplinary approach.
Signal transduction pathway involved in platelet activation in immune thrombotic thrombocytopenia after COVID-19 vaccination.
Six-month antibody persistence after BNT162b2 mRNA COVID-19 vaccination in patients with chronic lymphocytic leukemia.
Successful Treatment of Vaccine-Induced Immune Thrombotic Thrombocytopenia in a 26-Year-Old Female Patient. Vaccine-induced immune thrombotic thrombocytopenia (VITT) has already been described after vaccination with ChAdOx2 nCov-19 (AstraZeneca) and Ad26.COV2.S (Johnson & Johnson/Janssen). However, less knowledge so far has been gained about optimal therapeutic regimens in VITT-suspected patients. Here, we report the case of a 26-year-old female patient, who developed bilateral deep vein thrombosis in the lower legs and severe thrombocytopenia after ChAdOx2 nCov-19 vaccination. After initial anticoagulation therapy regimens including fondaparinux, apixaban, and danaparoid failed, the patient was successfully treated with high-dose intravenous immunoglobulins in combination with parental anticoagulation therapy with argatroban. As vaccination against severe acute respiratory syndrome coronavirus 2 affects billions of people worldwide, medical facilities and hospitals have to be prepared and provide effective treatment options in VITT-suspected patients, including rapid application of high-dose intravenous immunoglobulins, to improve patient outcomes.
B.1.617.2 enters and fuses lung cells with increased efficiency and evades antibodies induced by infection and vaccination. The Delta variant of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), B.1.617.2, emerged in India and has spread to over 80 countries. B.1.617.2 replaced B.1.1.7 as the dominant virus in the United Kingdom, resulting in a steep increase in new infections, and a similar development is expected for other countries. Effective countermeasures require information on susceptibility of B.1.617.2 to control by antibodies elicited by vaccines and used for coronavirus disease 2019 (COVID-19) therapy. We show, using pseudotyping, that B.1.617.2 evades control by antibodies induced upon infection and BNT162b2 vaccination, although to a lesser extent as compared to B.1.351. We find that B.1.617.2 is resistant against bamlanivimab, a monoclonal antibody with emergency use authorization for COVID-19 therapy. Finally, we show increased Calu-3 lung cell entry and enhanced cell-to-cell fusion of B.1.617.2, which may contribute to augmented transmissibility and pathogenicity of this variant. These results identify B.1.617.2 as an immune evasion variant with increased capacity to enter and fuse lung cells.
Audio Interview: Are Covid-19 Vaccine Boosters Necessary?
Myocarditis after Covid-19 Vaccination in a Large Health Care Organization. BACKGROUND: Reports have suggested an association between the development of myocarditis and the receipt of messenger RNA (mRNA) vaccines against coronavirus disease 2019 (Covid-19), but the frequency and severity of myocarditis after vaccination have not been extensively explored. METHODS: We searched the database of Clalit Health Services, the largest health care organization (HCO) in Israel, for diagnoses of myocarditis in patients who had received at least one dose of the BNT162b2 mRNA vaccine (Pfizer-BioNTech). The diagnosis of myocarditis was adjudicated by cardiologists using the case definition used by the Centers for Disease Control and Prevention. We abstracted the presentation, clinical course, and outcome from the patient's electronic health record. We performed a Kaplan-Meier analysis of the incidence of myocarditis up to 42 days after the first vaccine dose.

RESULTS: Among more than 2.5 million vaccinated HCO members who were 16 years of age or older, 54 cases met the criteria for myocarditis. The estimated incidence per 100,000 persons who had received at least one dose of vaccine was 2.13 cases (95% confidence interval [CI], 1.56 to 2.70). The highest incidence of myocarditis (10.69 cases per 100,000 persons; 95% CI, 6.93 to 14.46) was reported in male patients between the ages of 16 and 29 years. A total of 76% of cases of myocarditis were described as mild and 22% as intermediate; 1 case was associated with cardiogenic shock. After a median follow-up of 83 days after the onset of myocarditis, 1 patient had been readmitted to the hospital, and 1 had died of an unknown cause after discharge. Of 14 patients who had left ventricular dysfunction on echocardiography during admission, 10 still had such dysfunction at the time of hospital discharge. Of these patients, 5 underwent subsequent testing that revealed normal heart function. CONCLUSIONS: Among patients in a large Israeli health care system who had received at least one dose of the BNT162b2 mRNA vaccine, the estimated incidence of myocarditis was 2.13 cases per 100,000 persons; the highest incidence was among male patients between the ages of 16 and 29 years. Most cases of myocarditis were mild or moderate in severity. (Funded by the Ivan and Francesca Berkowitz Family Living Laboratory Collaboration at Harvard Medical School and Clalit Research Institute.).

Myocarditis after BNT162b2 mRNA Vaccine against Covid-19 in Israel. BACKGROUND: Approximately 5.1 million Israelis had been fully immunized against coronavirus disease 2019 (Covid-19) after receiving two doses of the BNT162b2 messenger RNA vaccine (Pfizer-BioNTech) by May 31, 2021. After early reports of myocarditis during adverse events monitoring, the Israeli Ministry of Health initiated active surveillance. METHODS: We retrospectively reviewed data obtained from December 20, 2020, to May 31, 2021, regarding all cases of myocarditis and categorized the information using the Brighton Collaboration definition. We analyzed the occurrence of myocarditis by computing the risk difference for the comparison of the incidence after the first and second vaccine doses (21 days apart); by calculating the standardized incidence ratio of the observed-to-expected incidence within 21 days after the first dose and 30 days after the second dose, independent of certainty of diagnosis; and by calculating the rate ratio 30 days after the second dose as compared with unvaccinated persons. RESULTS: Among 304 persons with symptoms of myocarditis, 21 had received an alternative diagnosis. Of the remaining 283 cases, 142 occurred after receipt of the BNT162b2 vaccine; of these cases, 136 diagnoses were definitive or probable. The clinical presentation was judged to be mild in 129 recipients (95%); one fulminant case was fatal. The overall risk difference between the first and second doses was 1.76 per 100,000 persons (95% confidence interval [CI], 1.33 to 2.19), with the largest difference among male recipients between the ages of 16 and 19 years (difference, 13.73 per 100,000 persons; 95% CI, 8.11 to 19.46). As compared with the expected incidence based on historical data, the standardized incidence ratio was 5.34 (95% CI, 4.48 to 6.40) and was highest after the second dose in male recipients between the ages of 16 and 19 years (13.60; 95% CI, 9.30 to 19.20). The rate ratio 30 days after the second vaccine dose in fully vaccinated recipients, as compared with unvaccinated persons, was 2.35 (95% CI, 1.10 to 5.02); the rate ratio was again highest in male recipients between the ages of 16 and 19 years (8.96; 95% CI, 4.50 to 17.83), with a ratio of 1 in 6637. CONCLUSIONS: The incidence of myocarditis, although low, increased after the receipt of the BNT162b2 vaccine, particularly after the second dose among young male recipients. The clinical presentation of myocarditis after vaccination was usually mild.

Providing children with COVID-19 vaccinations is challenging due to lack of data and wide-ranging parental acceptance. AIM: Vaccines are vital to ending the COVID-19 pandemic and we reviewed the data on vaccinating children, and including them in clinical trials, as most of the activity has focused on adults. METHODS: English and Chinese databases, including PubMed, Elsevier Scopus, Web of Science, CNKI and CQVIP were searched, along with websites such as the World Health

Organization and the University of Oxford. RESULTS: We identified 44 papers and 16 news items about vaccinating children against the virus, published from 10 February 2020 to 14Â July 2021. Child vaccination has been slow and only a few countries have included children in Phase II or III clinical trials. The data on children were much more limited than on adults, but most children were asymptomatic or had mild symptoms and some deaths had been recorded. More clinical trials are needed to assess the safety and efficacy of vaccinating children, as higher vaccination levels can help to build up herd immunity. The percentage of parents willing to vaccinate their children against the virus ranged from 48.2% to 72.6%, with much lower rates for letting them participate in clinical trials. CONCLUSION: Vaccines should be offered to children as soon as their safety and efficacy are established.

Comparison of the Results of Five SARS-CoV-2 Antibody Assays before and after the First and Second ChAdOx1 nCoV-19 Vaccinations among Health Care Workers: a Prospective Multicenter Study. Reliable results for serological positivity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody after the second dose of AstraZeneca (AZ) vaccination are important to estimate the real efficacy of vaccination. We evaluated positivity rates and changes in semiquantitative antibody titers before and after the first and second ChAdOx1 nCoV-19 vaccinations using five SARS-CoV-2 antibody assays, including two surrogate virus neutralization tests. A total of 674 serum samples were obtained from 228 participants during three blood sampling periods. A questionnaire on symptoms, severity, and adverse reaction duration was completed by participants after the second vaccination. The overall positive rates for all assays were 0.0 to 0.9% before vaccination, 66.2 to 92.5% after the first vaccination, and 98.2 to 100.0% after the second vaccination. Median antibody titers in five assays after the second dose of vaccination were increased compared to those after the first dose (106.4-fold increase for Roche total antibody, 3.6-fold for Abbott IgG, 3.6-fold for Siemens, 1.2-fold for SD Biosensor V1 neutralizing antibody, and 2.2-fold for GenScript neutralizing antibody). Adverse reactions were reduced after the second dose in 89.9% of participants compared to after the first dose. Overall, the second vaccination led to almost 100% positivity rates based on these SARS-CoV-2 antibody assays. The results should be interpreted with caution, considering the characteristics of the applied assays. Our findings could inform decisions regarding vaccination and the use of immunoassays, thus contributing to SARS-CoV-2 pandemic control.

COVID-19 vaccination in patients with heart failure: a position paper of the Heart Failure Association of the European Society of Cardiology. Patients with heart failure (HF) who contract SARS-CoV-2 infection are at a higher risk of cardiovascular and non-cardiovascular morbidity and mortality. Regardless of therapeutic attempts in COVID-19, vaccination remains the most promising global approach at present for controlling this disease. There are several concerns and misconceptions regarding the clinical indications, optimal mode of delivery, safety and efficacy of COVID-19 vaccines for patients with HF. This document provides guidance to all healthcare professionals regarding the implementation of a COVID-19 vaccination scheme in patients with HF. COVID-19 vaccination is indicated in all patients with HF, including those who are immunocompromised (e.g. after heart transplantation receiving immunosuppressive therapy) and with frailty syndrome. It is preferable to vaccinate against COVID-19 patients with HF in an optimal clinical state, which would include clinical stability, adequate hydration and nutrition, optimized treatment of HF and other comorbidities (including iron deficiency), but corrective measures should not be allowed to delay vaccination. Patients with HF who have been vaccinated against COVID-19 need to continue precautionary measures, including the use of facemasks, hand hygiene and social distancing. Knowledge on strategies preventing SARS-CoV-2 infection (including the COVID-19 vaccination) should be included in the comprehensive educational programmes delivered to patients with HF.

Increased risk for COVID-19 breakthrough infection in fully vaccinated patients with substance use disorders in the United States between December 2020 and August 2021. Individuals with substance use disorders (SUDs) are at increased risk for COVID-19 infection and for adverse outcomes of the infection. Though vaccines are highly effective against COVID-19, their effectiveness in individuals with SUDs might be curtailed by compromised immune status and a greater likelihood of exposures, added to the waning vaccine immunity and the new SARS-CoV-2 variants. In a population-based cohort study, we assessed the risk, time trends, outcomes and disparities of COVID-19 breakthrough infection in fully vaccinated SUD patients starting 14 days after completion of vaccination. The study included 579,372 individuals (30,183 with a diagnosis of SUD and 549,189 without such a diagnosis) who were fully vaccinated between December 2020 and August 2021, and had not contracted COVID-19 infection prior to vaccination. We used the TriNetX Analytics network platform to access de-identified electronic health records from 63 health care organizations in the US. Among SUD patients, the risk for breakthrough infection ranged from 6.8% for tobacco use disorder to 7.8% for cannabis use disorder, all significantly higher than the 3.6% in non-SUD population ($p<0.001$). Breakthrough infection risk remained significantly higher after controlling for demographics (age, gender, ethnicity) and vaccine types for all SUD subtypes, except for tobacco use disorder, and was highest for cocaine and cannabis use disorders (hazard ratio, HR=2.06, 95% CI: 1.30-3.25 for cocaine; HR=1.92, 95% CI: 1.39-2.66 for cannabis). When we matched SUD and non-SUD individuals for lifetime comorbidities and adverse socioeconomic determinants of health, the risk for breakthrough infection no longer differed between these populations, except for patients with cannabis use disorder, who remained at increased risk (HR=1.55, 95% CI: 1.22-1.99). The risk for breakthrough infection was higher in SUD patients who received the Pfizer than the Moderna vaccine (HR=1.49, 95% CI: 1.31-1.69). In the vaccinated SUD population, the risk for hospitalization was 22.5% for the breakthrough cohort and 1.6% for the non-breakthrough cohort (risk ratio, RR=14.4, 95% CI: 10.19-20.42), while the risk for death was 1.7% and 0.5% respectively (RR=3.5, 95% CI: 1.74-7.05). No significant age, gender and ethnic disparities for breakthrough infection were observed in vaccinated SUD patients. These data suggest that fully vaccinated SUD individuals are at higher risk for breakthrough COVID-19 infection, and this is largely due to their higher prevalence of comorbidities and adverse socioeconomic determinants of health compared with non-SUD individuals. The high frequency of comorbidities in SUD patients is also likely to contribute to their high rates of hospitalization and death following breakthrough infection.

Lung squamous cell carcinoma with hemoptysis after vaccination with tozinameran (BNT162b2, Pfizer-BioNTech). A 66-year-old man with squamous cell carcinoma had been receiving chemoradiation therapy after stereotactic radiotherapy for brain metastases. Atezolizumab was initiated as second-line therapy, after which the patient became progression- and recurrence-free. Four days after his second dose of tozinameran (BNT162b2, Pfizer-BioNTech), the patient developed persistent hemoptysis. The patient had no thrombocytopenia or coagulation abnormalities. Bronchoscopy revealed active bleeding from the left lingual tracheal branch. The patient was intubated and admitted to the intensive care unit because of increased bleeding. Subsequently, left bronchial artery embolization was performed using a Serescue. Hemostasis was achieved after the procedure, and the patient was discharged 7â€‰days after the onset of hemoptysis. Vaccination against coronavirus disease has been reported to be associated with thrombosis and cerebral hemorrhage, and the hemoptysis in this case was suspected to be induced by vaccination. In summary, the benefits of vaccination exceeded the risks of adverse events in a patient with cancer. However, in conditions such as after chemoradiation, especially in patients with radiation pneumonitis wherein the vasculature is vulnerable, patients should be carefully monitored for hemorrhagic events after vaccination.

Shoulder injury related to vaccine administration (SIRVA) following mRNA COVID-19 vaccination: Report of 2 cases of subacromial-subdeltoid bursitis. Shoulder pain has been reported as a common side-effect after COVID-19 vaccination particularly after administration of mRNA vaccines. Although it is usually mild and self-limiting, occasionally it can become more extensive causing severe pain and marked limited range of motion. Shoulder injury related to vaccine administration has been reported following injection of other routine vaccines. In this case report, we describe 2 cases of shoulder injury related to vaccine administration due to subacromial-subdeltoid bursitis after administration of mRNA COVID-19 vaccines.

COVID Arm After Moderna Booster in Healthcare Worker: A Case Report. SARS CoV-2 virus has infected more than 200 million people worldwide and more than 4.4 million in Indonesia. The vaccination program has become one of the solutions launched by many countries globally, including Indonesia, to reduce the transmission rate of COVID-19. Various vaccination platforms are produced, such as inactivated, viral vector, mRNA, and protein subunit. The vaccination booster program with mRNA platform (Moderna) was launched by the Indonesian government to give better protection for health care workers, particularly from delta variant. In this case report, we discuss one of the typical side effects of Moderna vaccine, which is referred to as the COVID arm.

Ischemic stroke after AstraZeneca (Covid-19) vaccination. Vaccination against SARS-COV-2 is considered an effective preventive strategy to halt COVID-19 pandemic. Reports of thromboembolic events in vaccine recipients has jolted some of the European countries to pause the vaccination process temporarily. It is still unclear whether the events are actually due to the vaccines or it is just a coincidence. The gravity of events particularly in young and previously normal patients merits further research to reach some conclusion. Here we present a similar case who sustained ischemic stroke shortly after receiving the first dose of his vaccine.

Cerebral Venous Sinus Thrombosis and Thrombotic Events After Vector-Based COVID-19 Vaccines: A Systematic Review and Meta-analysis. BACKGROUND AND OBJECTIVES: There is accumulating evidence supporting an association between the thrombosis and thrombocytopenia syndrome (TTS) and adenovirus vector-based vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Yet TTS and TTS-associated cerebral venous sinus thrombosis (CVST) remain poorly characterized. We aim to systematically evaluate the proportion of CVST among TTS cases and assess its characteristics and outcomes. METHODS: We performed a systematic review and meta-analysis of clinical trials, cohorts, case series, and registry-based studies with the aim to assess (1) the pooled mortality rate of CVST, TTS-associated CVST, and TTS and (2) the pooled proportion of patients with CVST among patients with any thrombotic event and TTS. Secondary outcomes comprised clinical characteristics of patients with postvaccination thrombotic event. This meta-analysis is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines and was written according to the Meta-analysis of Observational Studies in Epidemiology proposal. RESULTS: Sixty-nine studies were included in the qualitative analysis comprising 370 patients with CVST out of 4,182 patients with any thrombotic event associated with SARS-CoV-2 vector-based vaccine administration. Twenty-three studies were included further in quantitative meta-analysis. Among TTS cases, the pooled proportion of CVST was 51% (95% confidence interval [CI] 36%-66%; I (2) = 61%). TTS was independently associated with a higher likelihood of CVST when compared to patients without TTS with thrombotic events after vaccination (odds ratio 13.8; 95% CI 2.0-97.3; I (2) = 78%). The pooled mortality rates of TTS and TTS-associated CVST were 28% (95% CI 21%-36%) and 38% (95% CI 27%-49%), respectively. Thrombotic complications developed within 2 weeks of exposure to vector-based SARS-CoV-2 vaccines (mean interval 10 days; 95% CI 8-12) and affected predominantly women (69%; 95% CI 60%-77%) under age 45, even in the absence of prothrombotic risk factors. DISCUSSION: Approximately half of patients with TTS present with CVST; almost one-third

of patients with TTS do not survive. Further research is required to identify independent predictors of TTS following adenovirus vector-based vaccination. REGISTRATION INFORMATION: The prespecified study protocol has been registered in the International Prospective Register of Ongoing Systematic Reviews PROSPERO (CRD42021250709).

High-affinity memory B cells induced by SARS-CoV-2 infection produce more plasmablasts and atypical memory B cells than those primed by mRNA vaccines. Although both infections and vaccines induce memory B cell (MBC) populations that participate in secondary immune responses, the MBCs generated in each case can differ. Here, we compare SARS-CoV-2 spike receptor binding domain (S1-RBD)-specific primary MBCs that form in response to infection or a single mRNA vaccination. Both primary MBC populations have similar frequencies in the blood and respond to aÂ second S1-RBD exposure by rapidly producing plasmablasts with an abundant immunoglobulin (Ig)A(+) subset and secondary MBCs that are mostly IgG(+) and cross-react with the B.1.351 variant. However, infection-induced primary MBCs have better antigen-binding capacity and generate more plasmablasts and secondary MBCs of the classical and atypical subsets than do vaccine-induced primary MBCs. Our results suggest that infection-induced primary MBCs have undergone more affinity maturation than vaccine-induced primary MBCs and produce more robust secondary responses.

Humoral response after SARS-CoV-2 mRNA vaccines in dialysis patients: Integrating anti-SARS-CoV-2 Spike-Protein-RBD antibody monitoring to manage dialysis centers in pandemic times. Dialysis patients are both the most likely to benefit from vaccine protection against SARS-CoV-2 and at the highest risk of not developing an immune response. Data from the medical field are thus mandatory. We report our experience with a BNT162b2-mRNA vaccine in a retrospective analysis of 241 dialysis patients including 193 who underwent anti-Spike-Protein-Receptor-Binding-Domain (RBD) IgG analysis. We show that a pro-active vaccine campaign is effective in convincing most patients to be vaccinated (95%) and frequently elicits a specific antibody response (94.3% after two doses and 98.4% after three doses). Only immunocompromised Status is associated with lack of seroconversion (OR 7.6 [1.5-38.2], p = 0.02). We also identify factors associated with low response (last quartile; IgG<500AU/mL): immunocompromised status, age, absence of RAAS inhibitors, low lymphocytes count, high C Reactive Protein; and with high response (high quartile; IgG>7000AU/mL): age; previous SARS-CoV-2 infection and active Cancer. From this experience, we propose a strategy integrating anti-spike IgG monitoring to guide revaccination and dialysis center management in pandemic times.

Acute urticaria alone after CoronaVac COVID-19 vaccination should not be a contraindication for revaccination. Patients who develop an immediate allergic reaction within the first 4â€‰h of COVID-19 vaccine injection are recommended not to receive the same vaccine again. This recommendation mainly focuses on the mRNA and adenoviral vector COVID-19 vaccines, but data for whole virus vaccines are unknown. We report seven patients who developed an immediate reaction within 4â€‰h (six had generalized urticaria, one had localized urticaria) after the first vaccination with CoronaVac, the inactivated SARS-CoV-2 vaccine. The results of skin tests and basophil activation tests suggested that spike peptides play a role in exacerbating urticaria in some patients. However, all subjects who developed urticaria within 4â€‰h after CoronaVac vaccination were successfully revaccinated without graded challenge, although recurrent urticaria was common. This preliminary result indicates that acute urticaria alone should not be a contraindication for the second dose of CoronaVac if the supply of alternative vaccines is limited.

Adequate immune response after SARS-CoV-2 infection and single dose vaccination despite rapid heart transplantation. Adequate immune response to vaccination remains a challenge in patients after solid organ transplantation. We report a case of a 61-year-old male patient who received a left ventricular assist device as a bridge to transplant therapy. Three months before transplantation, he

suffered mild SARS-CoV-2 infection and was successfully discharged thereafter. Eight days before his successful heart transplantation, he received mRNA BNT 162b2 vaccination. Immediately after transplantation, we detected sufficient rise of nucleocapsid and spike antibodies despite immune suppression therapy. We suspect potential booster effects of the previous SARS-CoV-2 infection giving rise to adequate immune response following single vaccination.
Depression following ChAdOx1-S/nCoV-19 vaccine.
ACUTE MACULAR NEURORETINOPATHY AFTER SARS-COV-2 VACCINATION. PURPOSE: To present the rare case of a patient who developed acute macular neuroretinopathy (AMN) after administration of a single-dose adenovector coronavirus vaccine. METHODS: Retrospective chart review. RESULTS: A 26-year-old woman presented with paracentral scotomas in both eyes that acutely developed 2 days after administration of a single-dose adenovector SARS-CoV-2 vaccine (Johnson & Johnson, New Brunswick, NJ). She had previously received the seasonal influenza immunization without any symptoms and denied having any recent history of viral illnesses. On examination, optical coherence tomography showed parafoveal hyperreflective bands in the outer retina of both eyes without retinal thickening and near-infrared reflectance showed wedge-shaped parafoveal lesions pointing to the fovea, both classic findings in acute macular neuroretinopathy. DISCUSSION: This report highlights the development of acute macular neuroretinopathy after a SARS-CoV-2 vaccination in an otherwise healthy female patient. A single case cannot establish cause and effect, and millions of COVID-19 vaccines have been administered safely at the time of writing. However, this may be a rare association, and clinicians can consider inquiring about recent vaccination history in patients presenting with acute macular neuroretinopathy.
ACUTE MACULAR NEURORETINOPATHY AFTER COVID-19 VACCINATION. PURPOSE: To report a case of acute macular neuroretinopathy after the vaccination for coronavirus disease 2019. METHODS: A 22-year-old White woman presented with symptoms of paracentral scotomas within a week of receiving coronavirus disease 2019 vaccination. Complete evaluation was performing using multimodal imaging techniques. RESULTS: Spectral domain optical coherence tomography and near-infrared imaging showed characteristic features of acute macular neuroretinopathy. CONCLUSION/DISCUSSION: To the best of our knowledge this is the first reported case of acute macular neuroretinopathy after coronavirus disease 2019 vaccination. Optical coherence tomography angiography did not reveal any signal attenuation, and multifocal electroretinogram and central visual fields were normal indicating that near-infrared imaging and spectral domain optical coherence tomography remain the gold standard in diagnosing this condition especially in smaller lesions.
Acute-onset chronic inflammatory demyelinating polyneuropathy after COVID-19 infection and subsequent ChAdOx1 nCoV-19 vaccination. SARS-COV-2 predominantly results in a respiratory illness. However, it has also been associated with a wide range of neurological disorders including a broad range of immune neuropathies. These immune neuropathies associated with SARS-COV2 infection include Guillain-BarrÃ© syndrome (GBS), recurrent GBS and exacerbation of pre-existing chronic inflammatory demyelinating polyneuropathy (CIDP). We describe a case with acute-onset CIDP presenting with three relapses of demyelinating polyradiculoneuropathy, the third relapse occurring in the 8â€‰week of illness following a previous COVID-19 infection and a recent COVID-19 vaccination with ChAdOx1 nCoV-19 and high COVID-19 antibody level. In our knowledge, this is the ever reported case of acute-onset CIDP associated with COVID-19 vaccine and high COVID-19 antibody level.
BNT162b2 vaccine-induced humoral and cellular responses against SARS-CoV-2 variants in systemic lupus erythematosus. OBJECTIVES: Our aim was to evaluate systemic lupus erythematosus (SLE) disease activity and SARS-CoV-2-specific immune responses after BNT162b2 vaccination. METHODS: In this prospective study, disease activity and clinical assessments were recorded from the first dose

of vaccine until day 15 after the second dose in 126 patients with SLE. SARS-CoV-2 antibody responses were measured against wild-type spike antigen, while serum-neutralising activity was assessed against the SARS-CoV-2 historical strain and variants of concerns (VOCs). Vaccine-specific T cell responses were quantified by interferon-Î³ release assay after the second dose. RESULTS: BNT162b2 was well tolerated and no statistically significant variations of BILAG (British Isles Lupus Assessment Group) and SLEDAI (SLE Disease Activity Index) scores were observed throughout the study in patients with SLE with active and inactive disease at baseline. Mycophenolate mofetil (MMF) and methotrexate (MTX) treatments were associated with drastically reduced BNT162b2 antibody response (Î²=-78, p=0.007; Î²=-122, p<0.001, respectively). Anti-spike antibody response was positively associated with baseline total immunoglobulin G serum levels, naÃ¯ve B cell frequencies (Î²=2, p=0.018; Î²=2.5, p=0.003) and SARS-CoV-2-specific T cell response (r=0.462, p=0.003). In responders, serum neutralisation activity decreased against VOCs bearing the E484K mutation but remained detectable in a majority of patients. CONCLUSION: MMF, MTX and poor baseline humoral immune status, particularly low naÃ¯ve B cell frequencies, are independently associated with impaired BNT162b2 mRNA antibody response, delineating patients with SLE who might need adapted vaccine regimens and follow-up.

Factors influencing adverse events following immunization with AZD1222 in Vietnamese adults during first half of 2021. BACKGROUND: COVID-19 vaccines have been speedily developed and deployed. The more vaccine doses are delivered to users, the more common adverse events following immunization (AEFI) are reported. This study aimed to identify factors affecting AEFI in Vietnamese people receiving the COVID-19 vaccine AZD1222 developed by AstraZeneca and Oxford University. METHODS: In July 2021, an online cross-sectional survey was conducted among Vietnamese who have been vaccinated with COVID-19 vaccines. The questionnaire collected demographic characteristics, medical history, types of injected vaccines, common AEFI, and post-vaccination activities from respondents. The effects of host-related factors on AEFI including 24 specific symptoms were also explored. RESULTS: After screening, 1028 participants who were Vietnamese, over 18Â years old and received at least one dose of AZD1222, were included in the study. Only 40/1028 (3.9%) participants reported not having any AEFI, whereas 25/1028 (2.4%) reported to have severe symptoms. The most common AEFI were moderate fever (69.4%), muscle aches (68.6%), followed by fatigue/ sleepiness (62.5%), body aches (59.4%), headache (58.5%), pain at injection site (58.3%) and chills (45.7%). Data analysis showed that females complained about AEFI particularly gastrointestinal symptoms more frequently than males. Age of participants and number of doses were also important factors affecting AEFI as the increase of age or number of vaccine doses was associated with the decrease of self-reported AEFI frequency. CONCLUSIONS: This study provides a detailed assessment of risk factors associated with AEFI in Vietnamese people vaccinated with AZD1222. It seems that gender, age and vaccine doses are important factors affecting AEFI.

Outcomes associated with different vaccines in individuals with bipolar disorder and impact on the current COVID-19 pandemic- a systematic review. Bipolar disorder (BD) might be associated with higher infection rates of coronavirus disease (COVID-19) which in turn could result in worsening the clinical course and outcome. This may be due to a high prevalence of somatic comorbidities and an increased risk of delays in and poorer treatment of somatic disease in patients with severe mental illness in general. Vaccination is the most important public health intervention to tackle the ongoing pandemic. We undertook a systematic review regarding the data on vaccinations in individuals with BD. Proportion of prevalence rates, efficacy and specific side effects of vaccinations and in individuals with BD were searched. Results show that only five studies have investigated vaccinations in individuals with BD, which substantially limits the interpretation of overall findings. Studies on

antibody production after vaccinations in BD are very limited and results are inconsistent. Also, the evidence-based science on side effects of vaccinations in individuals with BD so far is poor.
Development of oral lichen planus after COVID-19 vaccination - a rare case report.
Eruptive angiomatosis after SARS-CoV-2 vaccine (Comirnaty, Pfizer).
Herpes zoster viral infection after AZD1222 and BNT162b2 coronavirus disease 2019 mRNA vaccines: a case series.
Antibody response to two doses of inactivated SARS-CoV-2 vaccine (CoronaVac) in kidney transplant recipients. BACKGROUND: Coronavirus Disease-19 (COVID-19) has high mortality in kidney transplant recipients (KTR), and vaccination against severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) is vital for this population. Although the humoral response to messenger RNA vaccines was shown to be impaired in KTR, there is a lack of data regarding the antibody response to inactivated vaccines. We investigated the antibody response to two consequent doses of the inactivated SARS-CoV-2 vaccine (CoronaVac; Sinovac Biotech, China). METHODS: A total of 118 patients from two centers were included. The levels of anti-SARS-CoV-2 immunoglobulin-G antibodies against the nucleocapsid and spike antigens were determined with enzyme immunoassay (DIA.PRO; Milano, Italy) before the vaccine and one month after the second dose of the vaccine. Thirty-three patients were excluded due to antibody positivity in the serum samples obtained before vaccination. RESULTS: Eighty-five patients, 47 of whom were female, with a mean age of 46 Â± 12, were included in the statistical analysis. The maintenance immunosuppressive therapy comprised tacrolimus (88.2%), mycophenolate (63.6%), and low-dose steroids (95.3%) in the majority of the patients. After a median of 31 days following the second dose of the vaccine, only 16 (18.8%) patients developed an antibody response. The median (IQR) antibody level was 52.5 IU/ml (21.5-96). Age (48Â vs. 38, pÂ =Â .005) and serum creatinine levels (1.14Â vs. 0.91, pÂ =Â .04) were higher in non-responders and were also found to be independently associated with the antibody response (odds ratio (OR): 0.93, pÂ =Â 0.012 and 0.15, pÂ =Â 0.045, respectively) in multivariate analysis. CONCLUSION: In this study, we found the antibody response to the inactivated vaccine to be considerably low (18.8%) in KTR. Increased age and impaired renal function were associated with worse antibody response. Based on the knowledge that mRNA vaccines yield better humoral responses, this special population might be considered for additional doses of mRNA vaccination.
Biphasic bullous pemphigoid starting after first dose and boosted by second dose of mRNA-1273 vaccine in an 84-year-old female with polymorbidity and polypharmacy.
Acute Myocarditis Following COVID-19 mRNA Vaccination in Adults Aged 18 Years or Older. This cohort study examines the incidence and clinical outcomes of acute myocarditis among adults following mRNA vaccination in an integrated health care system in the US.
COVID-19 Messenger RNA Vaccination and Myocarditis-A Rare and Mostly Mild Adverse Effect.
Variants of SARS-CoV-2, their effects on infection, transmission and neutralization by vaccine-induced antibodies. OBJECTIVE: The current study reviewed Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) variants for their effects on infection, transmission and neutralization by vaccine-induced antibodies. MATERIALS AND METHODS: The research articles for the current study were searched over PubMed, Google Scholar, EMBASE and Web of Science online databases. The keywords used were: (("SARS-CoV-2" OR "COVID-19") AND ("mutation" OR "variant") AND ("death" OR "hospitalization" OR "infection" OR "transmission") AND ("antibody" OR "neutralize" OR "vaccine")). A total of 333 research articles were retrieved through online-database search. These articles were further scrutinized for their relevancy. Additionally, searches were performed to find the latest relevant information over Google search engine and relevant news browsers. Finally, around 35 germane articles were considered for scripting the current report. RESULTS: The mutations have changed amino acids at key positions in spike protein viz. S477N, E484K, Q677H, E484Q, L452R,

K417T, K417N and N501Y. These mutations are relevant for different characteristics and are present in newly evolved strains of SARS-CoV-2 like E484K in B.1.526, B.1.525, P.2, B.1.1.7, P.1 and B.1.351. Mutations have increased the immune escape potential leading to 3.5-6.5-folds decrease in neutralization of antibodies (Pfizer and Moderna vaccines). The variant, B.1.617 circulating in India and many other countries (double variant) having E484Q and L452R mutations, has raised the infection rate and decreased the neutralization capacity of the vaccine-induced antibodies. Deadly K417N+E484K+N501Y triplet mutations found in B.1.351 and P.1 have increased the transmission ability of these strains by 50% leading to greater COVID-19 hospitalization, ICU admissions and deaths. CONCLUSIONS: The new SARS-CoV-2 variants have compromised the neutralization potential of the currently used vaccines, but still, they have considerable efficacy to reduce infection and mortality. GRAPHICAL ABSTRACT: https://www.europeanreview.org/wp/wp-content/uploads/Graphical_Abstract.jpg.

Intradermal-delivered DNA vaccine induces durable immunity mediating a reduction in viral load in a rhesus macaque SARS-CoV-2 challenge model. Coronavirus disease 2019 (COVID-19), caused by the SARS-CoV-2 virus, has had a dramatic global impact on public health and social and economic infrastructures. Here, we assess the immunogenicity and anamnestic protective efficacy in rhesus macaques of an intradermal (i.d.)-delivered SARS-CoV-2 spike DNA vaccine, INO-4800, currently being evaluated in clinical trials. Vaccination with INO-4800 induced TÂ cell responses and induced spike antigen and RBD binding antibodies with ADCP and ADCD activity. Sera from the animals neutralized both the D614 and G614 SARS-CoV-2 pseudotype viruses. Several months after vaccination, animals were challenged with SARS-CoV-2 resulting in rapid recall of anti-SARS-CoV-2 spike protein TÂ cell and neutralizing antibody responses. These responses were associated with lower viral loads in the lung. These studies support the immune impact of INO-4800 for inducing both humoral and cellular arms of the adaptive immune system, which are likely important for providing durable protection against COVID-19 disease.

Hyperglycemic Emergencies Associated With COVID-19 Vaccination: A Case Series and Discussion. CONTEXT: Hyperglycemic emergencies such as diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic syndrome (HHS) and new-onset diabetes mellitus (DM) have been reported in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections. Hyperglycemia is a predictor of poor prognosis in COVID-19 disease. OBJECTIVES: The objective of this work is to describe a case series of HHS and/or DKA likely triggered by the COVID-19 vaccine. The aim is to alert physicians of the potential hyperglycemic complications from the COVID-19 vaccination and to provide further insight into the underlying mechanism of the bidirectional relationship between SARS-CoV-2 and DM. CASE DESCRIPTIONS: All 3 patients developed HHS and/or DKA within 2 to 10 days of the COVID-19 vaccination. PCR testing for SARS-CoV-2 was negative and other clinical precipitating factors were excluded. Two patients had a history of type 2 DM (T2DM) with pre-admission HbA1c levels of 7.0% to 7.5% while 1 patient was newly diagnosed with T2DM during the hospitalization. They were each treated with insulin infusion and were discharged on subcutaneous insulin therapy. Due to the rapid resolution of the hyperglycemia, insulin was discontinued in all patients within 8 weeks and they remain well-controlled on oral DM medications. CONCLUSION: Severe hyperglycemia including HHS and DKA may be triggered by COVID-19 vaccination. Early evaluation and screening of patients with hyperglycemic symptoms after COVID-19 vaccination is recommended. The vaccine-induced hyperglycemia may provide further insight into the underlying pathogenesis caused by the SARS-CoV-2 infection itself. The underlying robust inflammatory response and "cytokine storm" may be the primary precipitant.

Influenza vaccination coverage and obstacles in healthcare workers (HCWs) and the follow up of side effects: a multicenter investigation in Iran. INTRODUCTION: Seasonal influenza is an annual

common occurrence in cold seasons; but the COVID-19 pandemic is also currently ongoing. These two diseases can't be distinguished from their symptoms alone; therefore, the importance of preventing influenza by vaccination is more than ever. Due to the high exposure of hospital personnel, widespread influenza vaccination of these high-risk groups seems to be a necessity. This Study conducted to determine vaccination coverage in the personnel of four tertiary referral collegiate hospitals in 2019 and to further investigate individual obstacles for Influenza vaccination. METHODS: In this cross-sectional descriptive study, 637 personnel were selected randomly from distinctive hospitals in a list-wised. Ones vaccinated filled the side effects questionnaire and who not vaccinated filled the vaccination obstacles questionnaire. The study was approved by the ethics committee of Tehran University of Medical Sciences with this reference number: IR.TUMS.IKHC.REC.1398.218. RESULTS: The mean vaccination coverage was 29.4% and the coverage difference among centers was not statistically significant ($p = 0.192$). The following items had the most impact on personnel decision: confidence about one's immune system ($p < 0.05$), the experience of side effects from previous vaccinations ($p = 0.011$), attitude about vaccination in colleagues ($p = 0.021$) and work experience ($p < 0.05$). About 23% of vaccinated individuals reported side effects following vaccination and the most common side effect was mild cold symptoms with 12.3% prevalence. CONCLUSION: The results of the current study revealed that influenza vaccination coverage among HCWs is not satisfactory in Iran. Hospital authorities and infection control units should plan to remove the obstacles of influenza vaccination.
New-onset vitiligo following mRNA-1273 (Moderna) COVID-19 vaccination. The COVID-19 mRNA vaccines not only provide remarkable protection but also have been characterized by an overall safe and well-tolerated side effect profile. Herein, we discuss a rare but manageable cutaneous reaction to COVID vaccination in order to further characterize dermatologic reactions and stress the continued vaccination of eligible patients.
Humoral response after BNT162b2 mRNA COVID-19 vaccination in patients on haemodialysis depends on immune status.
To Be or Not To Be Vaccinated: That Is a Question in Myasthenia Gravis. Myasthenia gravis (MG) is an autoimmune disease characterized by muscle weakness and abnormal fatigability due to the antibodies against postsynaptic receptors. Despite the individual discrepancy, patients with MG share common muscle weakness, autoimmune dysfunction, and immunosuppressive treatment, which predispose them to infections that can trigger or exacerbate MG. Vaccination, as a mainstay of prophylaxis, is a major management strategy. However, the past years have seen growth in vaccine hesitancy, owing to safety and efficacy concerns. Ironically, vaccines, serving as an essential and effective means of defense, may induce similar immune cross-reactivity to what they are meant to prevent. Herein, we outline the progress in vaccination, review the current status, and postulate the clinical association among MG, vaccination, and immunosuppression. We also address safety and efficacy concerns of vaccination in MG, in relation to COVID-19. Since only a handful of studies have reported vaccination in individuals with MG, we further review the current clinical studies and guidelines in rheumatic diseases. Overall, our reviews offer a reference to guide future vaccine clinical decision-making and improve the management of MG patients.
Successful treatment of thromboses of major arteries after ChAdOx1 nCov-19 vaccination. The ChAdOx1 nCoV-19 adenoviral vector vaccine to prevent contracting Covid-19 caused by infection with SARS-CoV-2 has been associated with vaccine-induced immune thrombotic thrombocytopenia (VITT) primarily leading to venous thromboses. Here, we report two cases of major arterial occlusions after ChAdOx1 nCov-19 vaccination, comprising a 42-year-old woman with thrombotic occlusion of the left carotid artery, and a 62-year-old man with occlusion of distal aorta and iliac arteries. Both were

successfully treated with intravenous immunoglobulins and non-heparin anticoagulant agents leading to a beneficial short-term outcome of 6Â weeks in case 1 and four months in case 2.

Massive Cervical Lymphadenopathy Post-COVID-19 Vaccination. The coronavirus disease 2019 (COVID-19) is a global pandemic caused by severe acute respiratory syndrome coronavirus 2. Rapid spread with rampant growth of cases and deaths brought forth an urgent need for novel therapies including vaccinations. The mRNA vaccines for COVID-19 disease have been implemented at an unprecedented scale in an effort to combat the unrelenting pandemic. Such a massive scale vaccination program is bound to coincide with adverse events related to treatment. We present a case of massive cervical lymphadenopathy in a 58-year-old male patient post-Moderna COVID-19 vaccination. Additional investigations did not identify malignancy and he was diagnosed with vaccine-related lymphadenopathy. Patient significantly improved with corticosteroid treatment within 2Â days of admission. Lymphadenopathy is reported as the second most common local reaction to the Moderna vaccine. Promoting knowledge of this side effect, particularly in the setting widespread vaccination efforts, would allow for better management of cases, especially in relation to oncologic patients.

Biventricular systolic dysfunction in acute myocarditis after SARS-CoV-2 mRNA-1273 vaccination.

Adverse effects on female fertility from vaccination against COVID-19 unlikely. This opinion paper briefly presents arguments that support the unlikelihood of an impact on female fertility from current covid-19 vaccines.

Low SARS-CoV-2 infection rates and high vaccine-induced immunity among German healthcare workers at the end of the third wave of the COVID-19 pandemic. In this longitudinal cohort study, we assessed the severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) seroconversion rates and analyzed the coronavirus disease 2019 (COVID-19) vaccine-induced immunity of 872 hospital workers at the University Medical Center Hamburg-Eppendorf between May 11 and May 31, 2021. The overall seroprevalence of anti-NC-SARS-CoV-2 antibodies was 4.7% (nÂ =Â 41), indicating low SARS-CoV-2 infection rates and persistent effectiveness of hospital-wide infection control interventions during the second and third wave of the pandemic. In total, 92.7% (nÂ =Â 808) out of the entire study cohort, 98.2% (nÂ =Â 325) of those who had been vaccinated once and all 393 individuals who had been vaccinated twice had detectable anti-S1-RBD-SARS-CoV-2 antibody titers and no significant differences in vaccine-induced immune response were detected between male and female individuals and between different age groups. Vaccinated study participants with detectable anti-NC-SARS-CoV-2 antibody titers (nÂ =Â 30) developed generally higher anti-S1-RBD-SARS-CoV-2 antibody titers compared to anti-NC-SARS-CoV-2 negative individuals (nÂ =Â 694) (median titer: 7812 vs. 345 BAU/ml, pÂ <Â 0.0001). Furthermore, study participants who received heterologous vaccination with AZD1222 followed by an mRNA vaccine showed markedly higher anti-S1-RBD-SARS-CoV-2 antibody titers than individuals who received two doses of an mRNA vaccine or two doses of AZD1222 (median titer: AZD1222/AZD1222: 1069 BAU/ml, mRNA/mRNA: 1388 BAU/ml, AZD1222/mRNA: 9450 BAU/ml; pÂ <Â 0.0001). Our results indicate that infection control interventions were generally effective in preventing nosocomial transmission of SARS-CoV-2 and that COVID-19 vaccines can elicit strong humoral responses in the majority of a real-world cohort of hospital workers.

Bilateral uveitis after inoculation with COVID-19 vaccine: A case report. BACKGROUND: Coronavirus disease 2019 (COVID-19) is a highly infectious and pathogenic respiratory disease. To date, there is no effective treatment, and there is an urgent need to develop vaccines against the virus. Five coronavirus COVID-19 vaccines have been approved for inoculation in China, with good safety and few adverse reactions. CASE PRESENTATION: A 50-year-old woman complained of bilateral blurred vision and visual distortion 5 days after vaccination with the inactivated COVID-19 vaccine.

Physical and auxiliary examination showed that she developed bilateral posterior uveitis. The patient was administered local and systemic steroids, and the symptoms were appreciably improved 5 weeks later. CONCLUSIONS: A case of bilateral uveitis after COVID-19 vaccination was reported and indicated that uveitis after vaccination appears transient and responds well to steroids.

Answer to Cadiou et al. "SARS-CoV-2, polymyalgia rheumatica and giant cell arteritis: COVID-19 vaccine shot as a trigger?". Joint Bone Spine 2021;88:105282.

Evaluation of anaphylaxis risk by skin testing with coronavirus disease 2019 messenger RNA vaccines on patients with anaphylaxis.

Antibody response after first and second-dose of ChAdOx1-nCOV (Covishield(TM)Â®) and BBV-152 (Covaxin(TM)Â®) among health care workers in India: The final results of cross-sectional coronavirus vaccine-induced antibody titre (COVAT) study. BACKGROUND: We assessed the humoral immune response of both ChAdOx1-nCOV (Covishield(TM)) and BBV-152 (Covaxin(TM)) vaccines in Indian health care workers (HCW). METHODS: A Pan-India, Cross-sectional, Coronavirus Vaccine-induced Antibody Titre (COVAT) study was conducted that measured SARS-CoV-2 anti-spike binding antibody quantitatively, 21Â days or more after the first and second dose of two vaccines in both severe acute respiratory syndrome (SARS-CoV-2) naÃ¨ve and recovered HCW. Primary aim was to analyze antibody response (seropositivity rate, Geometric Mean Titre [GMT] and 95% Confidence Interval [CI]) following each dose of both vaccines and its correlation to age, sex, blood group, body mass index (BMI) and comorbidities. Here we report the results of anti-spike antibody response after first and two completed doses. RESULTS: Among the 515 HCW (305 Male, 210 Female) who took two doses of both vaccines, 95.0% showed seropositivity to anti-spike antibody. However, both seropositivity rate and GMT (95% CI) of anti-spike antibody was significantly higher in Covishield vs. Covaxin recipients (98.1 vs. 80.0%; 129.3 vs. 48.3 AU/mL; both pÂ <Â 0.001). This difference persisted in 457 SARS-CoV-2 naÃ¨ve and propensity-matched (age, sex and BMI) analysis of 116 participants. AgeÂ >Â 60-years, males, people with any comorbidities, and history of hypertension (HTN) had a significantly less anti-spike antibody GMT compared to ageÂ â‰¤Â 60Â years, females, no comorbidities and no HTN respectively, after the completion of two doses of either vaccine. Gender, presence of comorbidities, and vaccine type were independent predictors of antibody seropositivity rate and anti-spike antibody titre levels in multiple logistic and log transformed linear regression analysis. Both vaccine recipients had similar solicited mild to moderate adverse events and none had severe or unsolicited side effects. CONCLUSIONS: Both vaccines elicited good immune response after two doses, although seropositivity rates and GMT of anti-spike antibody titre was significantly higher in Covishield compared to Covaxin recipients.

SARS-CoV-2, polymyalgia rheumatica and giant cell arteritis: COVID-19 vaccine shot as a trigger? Comment on: "Can SARS-CoV-2 trigger relapse of polymyalgia rheumatica?" by Manzo et al. Joint Bone Spine 2021;88:105150.

COVID-19 hospital admissions and deaths after BNT162b2 and ChAdOx1 nCoV-19 vaccinations in 2Â·57 million people in Scotland (EAVE II): a prospective cohort study. BACKGROUND: The UK COVID-19 vaccination programme has prioritised vaccination of those at the highest risk of COVID-19 mortality and hospitalisation. The programme was rolled out in Scotland during winter 2020-21, when SARS-CoV-2 infection rates were at their highest since the pandemic started, despite social distancing measures being in place. We aimed to estimate the frequency of COVID-19 hospitalisation or death in people who received at least one vaccine dose and characterise these individuals. METHODS: We conducted a prospective cohort study using the Early Pandemic Evaluation and Enhanced Surveillance of COVID-19 (EAVE II) national surveillance platform, which contained linked vaccination, primary care, RT-PCR testing, hospitalisation, and mortality records for 5Â·4 million people (around 99% of the population) in Scotland. Individuals were followed up from receiving their

first dose of the BNT162b2 (Pfizer-BioNTech) or ChAdOx1 nCoV-19 (Oxford-AstraZeneca) COVID-19 vaccines until admission to hospital for COVID-19, death, or the end of the study period on April 18, 2021. We used a time-dependent Poisson regression model to estimate rate ratios (RRs) for demographic and clinical factors associated with COVID-19 hospitalisation or death 14 days or more after the first vaccine dose, stratified by vaccine type. FINDINGS: Between Dec 8, 2020, and April 18, 2021, 2â€‰572â€‰008 individuals received their first dose of vaccine-841â€‰090 (32Â·7%) received BNT162b2 and 1â€‰730â€‰918 (67Â·3%) received ChAdOx1. 1196 (<0Â·1%) individuals were admitted to hospital or died due to COVID-19 illness (883 hospitalised, of whom 228 died, and 313 who died due to COVID-19 without hospitalisation) 14 days or more after their first vaccine dose. These severe COVID-19 outcomes were associated with older age (â‰¥80 years vs 18-64 years adjusted RR 4Â·75, 95% CI 3Â·85-5Â·87), comorbidities (five or more risk groups vs less than five risk groups 4Â·24, 3Â·34-5Â·39), hospitalisation in the previous 4 weeks (3Â·00, 2Â·47-3Â·65), high-risk occupations (ten or more previous COVID-19 tests vs less than ten previous COVID-19 tests 2Â·14, 1Â·62-2Â·81), care home residence (1Â·63, 1Â·32-2Â·02), socioeconomic deprivation (most deprived quintile vs least deprived quintile 1Â·57, 1Â·30-1Â·90), being male (1Â·27, 1Â·13-1Â·43), and being an ex-smoker (ex-smoker vs non-smoker 1Â·18, 1Â·01-1Â·38). A history of COVID-19 before vaccination was protective (0Â·40, 0Â·29-0Â·54). INTERPRETATION: COVID-19 hospitalisations and deaths were uncommon 14 days or more after the first vaccine dose in this national analysis in the context of a high background incidence of SARS-CoV-2 infection and with extensive social distancing measures in place. Sociodemographic and clinical features known to increase the risk of severe disease in unvaccinated populations were also associated with severe outcomes in people receiving their first dose of vaccine and could help inform case management and future vaccine policy formulation. FUNDING: UK Research and Innovation (Medical Research Council), Research and Innovation Industrial Strategy Challenge Fund, Scottish Government, and Health Data Research UK.

Importance of the sick day rule: a case of prerenal acute kidney injury after COVID-19 vaccination in a patient with chronic kidney disease.

Emergence of de novo cutaneous vasculitis post coronavirus disease (COVID-19) vaccination.

Cardiac Manifestations of Multisystem Inflammatory Syndrome in Children (MIS-C) Following COVID-19. PURPOSE OF REVIEW: To review the spectrum of cardiac manifestations and treatments of multisystem inflammatory syndrome in children (MIS-C) associated with coronavirus disease 2019 (COVID-19). RECENT FINDINGS: Studies demonstrate that up to 80% of children with MIS-C may have cardiac involvement on a spectrum of severity. Cardiac manifestations include myocarditis, coronary artery aneurysms, conduction abnormalities, and arrhythmias. Current treatments, including inotropic support, immunomodulatory therapy, and anti-coagulation, have been effective at resolving these cardiac findings in the majority of patients. COVID-19 can also cause myocarditis in the acute stage of illness and recent descriptions of COVID-19 vaccine myocarditis have occurred. Cardiac manifestations are common in MIS-C and should be assessed for at presentation and during the clinical course as indicated.

The associations between air pollutant exposure and neutralizing antibody titers of an inactivated SARS-CoV-2 vaccine. Air pollution is a critical risk factor for the prevalence of COVID-19. However, few studies have focused on whether air pollution affects the efficacy of the SARS-CoV-2 vaccine. To better guide the knowledge surrounding this vaccination, we conducted a cross-section study to identify the relationships between air pollutant exposure and plasma neutralizing antibody (NAb) titers of an inactivated SARS-CoV-2 vaccine (Vero cell, CoronaVac, SINOVÎ›C, China). We recruited 239 healthcare workers aged 21-50 years who worked at Suining Central Hospital. Of these, 207 were included in this study, depending on vaccination date. The data regarding air pollutants were collected to calculate individual daily exposure dose (DED). The geometric mean of all six

pollutant DEDs was applied to estimate the combined toxic effects (DED(complex)). Then, the participants were divided into two groups based on the mean value of DED(complex). The median plasma NAb titer was 12.81 AU/mL, with 85.99% vaccine efficacy in healthcare workers against SARS-CoV-2. In exposure group, observations included lower plasma NAb titers (median: 11.13 AU/mL vs. 14.56 AU/mL), more peripheral counts of white blood cells and monocytes (mean: 6.71 Ã— 10(9)/L vs. 6.29 Ã— 10(9)/L and 0.49 Ã— 10(9)/L vs. 0.40 Ã— 10(9)/L, respectively), and a higher peripheral monocyte ratio (7.38% vs. 6.50%) as compared to the reference group. In addition, elevated air pollutant DEDs were associated with decreased plasma NAb titers. To our knowledge, this study is the first to report the relationship between air pollutant exposure and plasma NAb titers of the SARS-CoV-2 vaccine. This suggests that long-term exposure to air pollutants may inhibit plasma NAb expression by inducing chronic inflammation. Therefore, to achieve early herd immunity and hopefully curb the COVID-19 epidemic, vaccinations should be administered promptly to those eligible, and environmental factors should be considered as well.
Vincristine therapy for severe and refractory immune thrombocytopenia following COVID-19 vaccination.
Coronavirus Disease 2019 Vaccine in Children.
Case of Giant Cell Arteritis After SARS-CoV-2 Vaccination: A Particular Phenotype?
Subacute thyroiditis after inactive SARS-CoV-2 vaccine. Viral infections have often been associated with subacute (De Quervain) thyroiditis. Rare cases of subacute thyroiditis have been reported after vaccines. Various vaccines have been developed with different techniques against SARS-CoV-2. This case report presents a rare case of subacute thyroiditis after the inactive SARS-CoV-2 virus vaccine, CoronaVac.
Vaccine induced immune thrombocytopenia and thrombosis: summary of NICE guidance.
VACOVEASÂ study, an observationalÂ survey onÂ the adverse events associated withÂ COVID-19 vaccines inÂ patients with systemic autoimmuneÂ diseases.
Portal Vein Thrombosis due to Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) after Covid Vaccination with ChAdOx1 nCoV-19.
Attitudes Toward COVID-19 Illness and COVID-19 Vaccination among Pregnant Women: A Cross-Sectional Multicenter Study during August-December 2020. OBJECTIVE: The aim of the study was to evaluate pregnant women's attitudes toward COVID-19 illness and vaccination and identify factors associated with vaccine acceptability. STUDY DESIGN: This was a cross-sectional survey among pregnant women enrolled in a prospective COVID-19 cohort study in Salt Lake City, UT, Birmingham, AL, and New York, NY, from August 9 to December 10, 2020. Women were eligible if they were 18 to 50 years old and <28 weeks of gestation. Upon enrollment, women completed surveys regarding concerns about COVID-19 illness and likelihood of getting COVID-19 vaccine if one were available during pregnancy. Vaccine acceptability was defined as a response of "very likely" or "somewhat likely" on a 4-point Likert scale. Factors associated with vaccine acceptability were assessed with multivariable logistic regression. RESULTS: Of 939 pregnant women eligible for the main cohort study, 915 (97%) consented to participate. Among these 915 women, 39% self-identified as White, 23% Black, 33% Hispanic, and 4% Other. Sixty-two percent received an influenza vaccine last season. Seventy-two percent worried about getting sick with COVID-19. If they were to get sick, 92% worried about harm to their pregnancy and 80% about harm to themselves. Only 41% reported they would get a vaccine. Of women who were unlikely to get vaccinated, the most frequently cited concern was vaccine safety for their pregnancy (82%). Non-Hispanic Black and Hispanic women had lower odds of accepting a vaccine compared with non-Hispanic White women (adjusted odds ratios [aOR] 0.4, 95% CI 0.2-0.6 for both). Receipt of influenza vaccine during the previous season was associated with higher odds of vaccine acceptability (aOR 2.1, 95% CI 1.5-3.0). CONCLUSION: Although most pregnant

women worried about COVID-19 illness, <50% were willing to get vaccinated during pregnancy. Racial and ethnic disparities in plans to accept COVID-19 vaccine highlight the need to prioritize strategies to address perceived barriers among groups at high risk for COVID-19. KEY POINTS: Â· Less than half of pregnant patients stated they would get a COVID-19 vaccine.. Â· Protecting their baby was the most common reason for acceptance and refusal of the COVID-19 vaccine.. Â· Patients of minority race/ethnicity and those without prior influenza vaccination were less likely to accept the COVID-19 vaccine..

Reduced humoral immune response after BNT162b2 coronavirus disease 2019 messenger RNA vaccination in cancer patients under antineoplastic treatment. BACKGROUND: Cancer patients are at a higher risk of developing severe coronavirus disease 2019 (COVID-19). However, the safety and efficacy of COVID-19 vaccination in cancer patients undergoing treatment remain unclear. PATIENTS AND METHODS: In this interventional prospective multicohort study, priming and booster doses of the BNT162b2 COVID-19 vaccine were administered 21 days apart to solid tumor patients receiving chemotherapy, immunotherapy, targeted or hormonal therapy, and patients with a hematologic malignancy receiving rituximab or after allogeneic hematopoietic stem cell transplantation. Vaccine safety and efficacy (until 3 months post-booster) were assessed. Anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) receptor-binding domain (RBD) antibody levels were followed over time (until 28 days after the booster) and inÂ vitro SARS-CoV-2 50% neutralization titers (NT50) toward the wild-type Wuhan strain were analyzed 28 days after the booster. RESULTS: Local and systemic adverse events (AEs) were mostly mild to moderate (only 1%-3% of patients experienced severe AEs). Local, but not systemic, AEs occurred more frequently after the booster dose. Twenty-eight days after the booster vaccination of 197 cancer patients, RBD-binding antibody titers and NT50 were lower in the chemotherapy group {234.05 IU/ml [95% confidence interval (CI) 122.10-448.66] and 24.54 (95% CI 14.50-41.52), respectively} compared with healthy individuals [1844.93 IU/ml (95% CI 1383.57-2460.14) and 122.63 (95% CI 76.85-195.67), respectively], irrespective of timing of vaccination during chemotherapy cycles. Extremely low antibody responses were seen in hematology patients receiving rituximab; only two patients had RBD-binding antibody titers necessary for 50% protection against symptomatic SARS-CoV-2 infection (<200 IU/ml) and only one had NT50 above the limit of detection. During the study period, five cancer patients tested positive for SARS-CoV-2 infection, including a case of severe COVID-19 in a patient receiving rituximab, resulting in a 2-week hospital admission. CONCLUSION: The BNT162b2 vaccine is well-tolerated in cancer patients under active treatment. However, the antibody response of immunized cancer patients was delayed and diminished, mainly in patients receiving chemotherapy or rituximab, resulting in breakthrough infections.

Hypersensitivity reaction to hyaluronic acid dermal filler after the Pfizer vaccination against SARS-CoV-2. The ongoing vaccination program in the control of novel coronavirus (COVID-19)is providing an opportunity to public health authorities to emerge from the current pandemic crisis.Covid vaccination which protects from getting CovidÂ may have some minor side effects and in rare cases was accompanied by severe or immediate reactions. The development of hyaluronic acid soft tissue filler delayed inflammatory reactions following COVID-19 vaccination was reported. Â Treatments based on hyaluronic acid represent one of the most largely used practice of aesthetic medicine. In this we present a case of a 38-year-old female patient with a confirmed hypersensitivity reaction after having the BNT162b2 vaccine (Pfizer, USA). This case indicates that an adequate patient knowledge prior to hyaluronic acid injections to avoid adverse effect of a delayed-type hypersensitivity response after COVID-19 vaccination is desirable.

Effect of a hospital-wide campaign on COVID-19 vaccination uptake among healthcare workers in the context of raised concerns for life-threatening side effects. BACKGROUND: All healthcare workers

(HCWs) in Yongin Severance Hospital were allocated to receive the ChAdOx1 nCov-19 vaccine according to national policy. A report of thrombosis and thrombocytopenia syndrome (TTS) associated with ChAdOx1 nCoV-19 led to hesitancy about receiving the second dose among HCWs who had received the first dose. METHODS: From 7 to 14 May, 2021, we performed a survey to identify the factors associated with hesitancy about receiving the second vaccine dose among HCWs at the hospital who had received the first dose of the vaccine. Based on survey results, a hospital-wide campaign was implemented on 18 May 2021 to improve vaccine coverage. HCWs who completed the second dose completed a self-administered questionnaire to evaluate the effect of the campaign. FINDINGS: Of 1,171 HCWs who had received the first dose of the vaccine, 71.5% completed the online survey, of whom 3.7% refused to take the second dose and 22.3% showed hesitancy. Hesitancy to receive a second dose was significantly associated with age under 30 years and concerns about TTS, and was less common among those who trusted effectiveness and safety of the vaccine. Among HCWs who received the first dose, 96.2% completed vaccination with the second dose between 27 May and 4 June, 2021. Of those who answered the questionnaire asked about the timing of their decision to receive the second dose, 57.1% reported that they were motivated by the hospital-wide campaign. CONCLUSION: A tailored intervention strategy based on a survey can improve COVID-19 vaccination uptake among HCWs.

Vaccine Videos and Information Sharing: The Effects of Framing, Evidence Type, and Speaker Expertise. YouTube videos have been used to inform and misinform the public about the safety of vaccines related to health threats such as measles and COVID-19. Understanding how such videos can promote the sharing of accurate vaccine safety information is of the utmost importance if health researchers are to combat the spread of misinformation and encourage widespread uptake of vaccines. Through the lens of prospect theory, this study conducted a 2 (framing: loss v. gain) x 2 (evidence type: episodic v. thematic) x 2 (speaker expertise: expert v. non-expert) between-subject factorial experiment in which a sample of N =Â 400 US adults over the age of 18 recruited through MTurk were asked their intention to share vaccine safety information with others after watching a manipulated YouTube video. The results showed that loss framing was associated with perceived MMR severity which was, in turn, associated with the likelihood that participants would share MMR vaccine information with others, via any means. However, this process varied depending on the type of evidence delivered, and the expertise of the speaker. Results and limitations are discussed in the context of vaccine communication and social media.

A Neonate With Vertical Transmission of COVID-19 and Acute Respiratory Failure: A Case Report. BACKGROUND: This case describes a case of vertical transmission of COVID-19 from a mother to her neonate. The neonate subsequently developed acute respiratory failure consistent with adult symptoms of COVID-19. CLINICAL FINDINGS: This preterm neonate was born at 33 4/7 weeks' gestational age to a COVID-19-positive mother and admitted to the neonatal intensive care unit (NICU) for prematurity and respiratory distress. The neonate developed acute respiratory failure with severe persistent pulmonary hypertension of newborn (PPHN) and required intubation and maximum respiratory and cardiovascular support. The neonate subsequently tested positive for COVID-19 at 24 hours of life. PRIMARY DIAGNOSIS: Acute respiratory failure related to COVID-19 infection. INTERVENTIONS: The neonate was admitted to the NICU on CPAP. At 11 hours of life, the neonate began to exhibit signs of worsening respiratory distress requiring intubation, mechanical, and high frequency ventilation. An echocardiogram revealed severe PPHN. The neonate required dopamine to manage hypotension and was treated with steroids to decrease inflammation associated with airway edema noted during intubation. Pharmaceutically induced paralysis, analgesia, and sedation was used to manage persistent hypoxia. OUTCOMES: The neonate fully recovered from acute respiratory failure and was discharged home with the mother. PRACTICE RECOMMENDATIONS: Newborns born

to mothers who are positive for COVID-19 are at risk for vertical transmission of COVID-19 and should be monitored closely for acute respiratory failure. Respiratory medical management should include supportive care. Staff should also encourage parents to consider receiving the COVID-19 vaccine to protect their newborn from the possibility of developing acute respiratory failure.
Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021. A nosocomial outbreak of SARS-CoV-2 Delta variant infected 42 patients, staff and family members; 39 were fully vaccinated. The attack rate was 10.6% (16/151) among exposed staff and reached 23.7% (23/97) among exposed patients in a highly vaccinated population, 16-26 weeks after vaccination (median: 25 weeks). All cases were linked and traced to one patient. Several transmissions occurred between individuals wearing face masks. Fourteen of 23 patients became severely sick or died, raising a question about possible waning immunity.
Diminished seroconversion following a single SARS-COV-2 vaccine in ocrelizumab-treated relapsing-remitting multiple sclerosis patients. BACKGROUND: Despite impressive efficacy in immunocompetent individuals, the immunogenicity of a single dose of COVID-19 vaccine in B-cell-deplete patients remains unknown. OBJECTIVES: We aimed to quantify real-world vaccine immunogenicity in ocrelizumab recipients. METHODS: We measured post-vaccination SARS-COV-2 immunoglobulin G (IgG) in ocrelizumab recipients using a highly sensitive Luminex assay. RESULTS: 44.1% of patients had detectable SARS-COV-2-IgG 21+ days after one vaccine dose, regardless of vaccine type (AZD1222 vs BNT162b2, odds ratio (OR) = 0.62, 95% confidence interval (CI) = 0.157-2.32, p = 0.72). B-cell count strongly predicted seroconversion (Î²1 = 12.38, 95% CI = 4.59-20.16, p = 0.0029), but undetectable B-cells did not preclude it. The second vaccine seroconverted 53% of the patients who had not already responded to dose 1. CONCLUSION: Humoral response after one COVID-19 vaccine dose is lower than expected in CD20-deplete patients.
Cerebral Venous Sinus Thrombosis After Pfizer-BioNTech COVID-19 (BNT162b2) Vaccination.
Darier's Disease Flare following COVID-19 Vaccine. Darier's disease is a rare genodermatosis characterized clinically by dyskeratotic papules in the seborrheic and intertriginous areas and nail abnormalities. Dyskeratosis and acantholysis are typical histological findings. Darier's disease is not known to be inflammatory by nature as inflammation occurs primarily due to local infections, and it may therefore differ from inflammatory dermatoses such as psoriasis and cutaneous lupus in response to antigen stimulation. Known triggers of Darier's disease primarily include exogenous factors such as sun exposure, friction, or infection. We present a case of a 47-year-old white female with a flare of Darier's disease 2 days following her first vaccination with COVID-19 vaccine (ChAdOx1-s [recombinant]) (Vaxzevria(Â®) [previously known as COVID-19 vaccine AstraZeneca]). In this case report, we discuss possible mechanisms linking the vaccination and the flare of Darier's disease. We consider inflammatory mechanisms as well as a random co-occurrence. Due to the close time-related association between the disease flare and the COVID-19 vaccination, we find an urge to make other clinicians aware of a possible association.
Fatal Case of Rhabdomyolysis Post-COVID-19 Vaccine. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or COVID-19 pandemic has taken away the lives of many people (>4 million per WHO) around the world as of July 2021. With the advancement of the vaccine against COVID-19, in less than a year since the start of the pandemic, the infection rate has come under control in certain regions but is still rising in many more. However, with time, we are also learning a lot more about the adverse events related to the vaccine. This report documents the first fatal case of rhabdomyolysis potentially associated with the COVID-19 vaccine and supports the possibility that autoimmunity is a major risk factor for covid vaccine-related rhabdomyolysis.
COVID-19, Guillain-BarrÃ© syndrome, and the vaccine. A dangerous combination.

Acquired Autoimmune Hemophilia Following SARS-CoV-2 Vaccines: Dual-Drug Effects on Blood Coagulation and the Scylla and Charybdis Phenomenon.

Consumption of complement in a 26-year-old woman with severe thrombotic thrombocytopenia after ChAdOx1 nCov-19 vaccination. Extremely rare reactions characterized by thrombosis and thrombocytopenia have been described in subjects that received ChAdOx1 nCoV-19 vaccination 5-16 days earlier. Although patients with vaccine-induced thrombotic thrombocytopenia (VITT) have high levels of antibodies to platelet factor 4 (PF4)-polyanion complexes, the exact mechanism of the development of thrombosis is still unknown. Here we reported serum studies as well as proteomics and genomics analyses demonstrating a massive complement activation potentially linked to the presence of anti-PF4 antibodies in a patient with severe VITT. At admission, complement activity of the classical and lectin pathways were absent (0% for both) with normal levels of the alternative pathway (73%) in association with elevated levels of the complement activation marker sC5b-9 (630Â ng/mL [n.v. 139-462Â ng/mL]) and anti-PF4 IgG (1.918 OD [n.v. 0.136-0.300 OD]). The immunoblotting analysis of C2 showed the complete disappearance of its normal band at 110Â kDa. Intravenous immunoglobulin treatment allowed to recover complement activity of the classical pathway (91%) and lectin pathway (115%), to reduce levels of sC5b-9 (135Â ng/mL) and anti-PF4 IgG (0.681 OD) and to normalize the C2 pattern at immunoblotting. Proteomics and genomics analyses in addition to serum studies showed that the absence of complement activity during VITT was not linked to alterations of the C2 gene but rather to a strong complement activation leading to C2 consumption. Our data in a single patient suggest monitoring complement parameters in other VITT patients considering also the possibility to target complement activation with specific drugs.

Real-world safety data for the Pfizer BNT162b2 SARS-CoV-2 vaccine: historical cohort study. OBJECTIVE: The Pfizer BNT162b2 vaccine showed a reassuring safety profile in clinical trials, but real-world data are scarce. Bell's palsy, herpes zoster, Guillain-BarrÃ© syndrome (GBS) and other neurological complaints in proximity to vaccination have received special public attention. We compared their rates among vaccinated and unvaccinated individuals. METHODS: Individuals â‰¥16Â years vaccinated with at least one dose of BNT162b2 were eligible for this historical cohort study in a health maintenance organization insuring 1.2 million citizens. Each vaccinee was matched to a non-vaccinated control by sex, age, population sector (general Jewish, Arab, ultra-orthodox Jewish) and comorbidities. Diagnosis of Covid-19 before or after vaccination was an exclusion criterion. The outcome was a diagnosis of Bell's palsy, GBS, herpes zoster or symptoms of numbness or tingling, coded in the visit diagnosis field using ICD-9 codes. Diagnoses of Bell's palsy and GBS were verified by individual file review. RESULTS: Of 406Â 148 individuals vaccinated during the study period, 394Â 609 (97.2%) were eligible (11Â 539 excluded). A total of 233Â 159 (59.1%) were matched with unvaccinated controls. Mean follow was 43Â Â±Â 15.14Â days. In vaccinated and unvaccinated individuals there were 23 versus 24 cases of Bell's palsy (RR 0.96, CI 0.54-1.70), one versus zero cases of GBS, 151 versus 141 cases of herpes zoster (RR 1.07, CI 0.85-1.35) and 605 versus 497 cases of numbness or tingling (RR 1.22, CI 1.08-1.37), respectively. DISCUSSION: No association was found between vaccination, Bell's palsy, herpes zoster or GBS. Symptoms of numbness or tingling were more common among vaccinees. This study adds reassuring data regarding the safety of the BNT162b2 vaccine.

Comparison of constitutional and dermatologic side effects between COVID-19 and non-COVID-19 vaccines: Review of a publicly available database of vaccine side effects.

Relapse of immune thrombocytopenia after COVID-19 vaccination.

Safety Monitoring of an Additional Dose of COVID-19 Vaccine - United States, August 12-September 19, 2021. On August 12, 2021, the Food and Drug Administration (FDA) amended Emergency Use Authorizations (EUAs) for the Pfizer-BioNTech and Moderna COVID-19 vaccines to authorize

administration of an additional dose after completion of a primary vaccination series to eligible persons with moderate to severe immunocompromising conditions (1,2). On September 22, 2021, FDA authorized an additional dose of Pfizer-BioNTech vaccine â‰¥6 months after completion of the primary series among persons aged â‰¥65 years, at high risk for severe COVID-19, or whose occupational or institutional exposure puts them at high risk for COVID-19 (1). Results from a phase 3 clinical trial conducted by Pfizer-BioNTech that included 306 persons aged 18-55 years showed that adverse reactions after receipt of a third dose administered 5-8 months after completion of a 2-dose primary mRNA vaccination series were similar to those reported after receipt of dose 2; these adverse reactions included mild to moderate injection site and systemic reactions (3). CDC developed v-safe, a voluntary, smartphone-based safety surveillance system, to provide information on adverse reactions after COVID-19 vaccination. Coincident with authorization of an additional dose for persons with immunocompromising conditions, the v-safe platform was updated to allow registrants to enter information about additional doses of COVID-19 vaccine received. During August 12-September 19, 2021, a total of 22,191 v-safe registrants reported receipt of an additional dose of COVID-19 vaccine. Most (97.6%) reported a primary 2-dose mRNA vaccination series followed by a third dose of the same vaccine. Among those who completed a health check-in survey for all 3 doses (12,591; 58.1%), 79.4% and 74.1% reported local or systemic reactions, respectively, after dose 3, compared with 77.6% and 76.5% who reported local or systemic reactions, respectively, after dose 2. These initial findings indicate no unexpected patterns of adverse reactions after an additional dose of COVID-19 vaccine; most of these adverse reactions were mild or moderate. CDC will continue to monitor vaccine safety, including the safety of additional doses of COVID-19 vaccine, and provide data to guide vaccine recommendations and protect public health.
AZD1222/ChAdOx1 nCoV-19 vaccination induces a polyfunctional spike protein-specific T(H)1 response with a diverse TCR repertoire. AZD1222 (ChAdOx1 nCoV-19), a replication-deficient simian adenovirusâ€“vectored vaccine, has demonstrated safety, efficacy, and immunogenicity against coronavirus disease 2019 in clinical trials and real-world studies. We characterized CD4(+) and CD8(+) T cell responses induced by AZD1222 vaccination in peripheral blood mononuclear cells from 296 unique vaccine recipients aged 18 to 85 years who enrolled in the phase 2/3 COV002 trial. Total spike proteinâ€“specific CD4(+) T cell helper type 1 (T(H)1) and CD8(+) T cell responses were increased in AZD1222-vaccinated adults of all ages after two doses of AZD1222. CD4(+) T(H)2 responses after AZD1222 vaccination were not detected. Furthermore, AZD1222-specific T(H)1 and CD8(+) T cells both displayed a high degree of polyfunctionality in all adult age groups. T cell receptor Î² (TCRÎ²) sequences from vaccinated participants mapped against TCR sequences known to react to SARS-CoV-2 revealed substantial breadth and depth across the SARS-CoV-2 spike protein for both AZD1222-induced CD4(+) and CD8(+) T cell responses. Overall, AZD1222 vaccination induced a polyfunctional T(H)1-dominated T cell response, with broad CD4(+) and CD8(+) T cell coverage across the SARS-CoV-2 spike protein.
The COVID antivaccination dilemma.
Postmortem investigation of fatalities following vaccination with COVID-19 vaccines. Thorough postmortem investigations of fatalities following vaccination with coronavirus disease 2019 (COVID-19) vaccines are of great social significance. From 11.03.2021 to 09.06.2021, postmortem investigations of 18 deceased persons who recently received a vaccination against COVID-19 were performed. Vaxzevria was vaccinated in nine, Comirnaty in five, Spikevax in three, and Janssen in one person. In all cases, full autopsies, histopathological examinations, and virological analyses for the severe acute respiratory syndrome coronavirus 2 were carried out. Depending on the case, additional laboratory tests (anaphylaxis diagnostics, VITT [vaccine-induced immune thrombotic thrombocytopenia] diagnostics, glucose metabolism diagnostics) and neuropathological examinations

were conducted. In 13 deceased, the cause of death was attributed to preexisting diseases while postmortem investigations did not indicate a causal relationship to the vaccination. In one case after vaccination with Comirnaty, myocarditis was found to be the cause of death. A causal relationship to vaccination was considered possible, but could not be proven beyond doubt. VITT was found in three deceased persons following vaccination with Vaxzevria and one deceased following vaccination with Janssen. Of those four cases with VITT, only one was diagnosed before death. The synopsis of the anamnestic data, the autopsy results, laboratory diagnostic examinations, and histopathological and neuropathological examinations revealed that VITT was the very likely cause of death in only two of the four cases. In the other two cases, no neuropathological correlate of VITT explaining death was found, while possible causes of death emerged that were not necessarily attributable to VITT. The results of our study demonstrate the necessity of postmortem investigations on all fatalities following vaccination with COVID-19 vaccines. In order to identify a possible causal relationship between vaccination and death, in most cases an autopsy and histopathological examinations have to be combined with additional investigations, such as laboratory tests and neuropathological examinations.
ADEM after ChAdOx1 nCoV-19 vaccine: A case report. Acute disseminated encephalomyelitis (ADEM) is an inflammatory demyelinating disease of the central nervous system (CNS), clinically defined by an acute polyfocal neurological syndrome usually with monophasic course. ADEM often occurs after infections, but 5%-10% of cases are preceded by vaccinations. Several cases of ADEM have been described after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, whereas no case has been reported after adenovirus-vectored or mRNA COVID-19 vaccine administration. Here we describe a case of ADEM presenting 2 weeks after receiving the first dose of ChAdOx1 nCoV-19 vaccine. Patient clinical/magnetic resonance imaging (MRI) status spontaneously improved and rapidly resolved with corticosteroids. A 4-month follow-up showed complete recovery and no relapses.
Demyelinating disorders following COVID-19 vaccination.
Dengue After COVID-19 Vaccination: Possible and Might be Missed.
Sweet syndrome after Oxford-AstraZeneca COVID-19 vaccine (AZD1222) in an elderly female. Vaccination for COVID19 infection is in full swing all around the world and while the vaccines are considered overall safe, many cutaneous and extracutaneous adverse effects have been reported after their use. Local injection-site reactions are the commonest adverse effect described with the use of these vaccines. We describe a case of Sweet syndrome in an elderly female after the first dose of Oxford-AstraZeneca COVID-19 vaccine (AZD1222).
Sudden Sensorineural Hearing Loss Following the Second Dose of COVID-19 Vaccine. Sudden sensorineural hearing loss (SSHL) is a common otolaryngology emergency that significantly affects the patient's quality of life. Although in most cases its etiology remains unknown (idiopathic SSHL), viral infections and vascular compromise constitute the most widely accepted etiopathogenic mechanisms. Specifically, occlusion of the internal auditory artery has been reported in cases of sudden deafness. Thrombotic events following the Oxford-AstraZeneca COVID-19 vaccine are rare. There have been reports of SSHL following immunization with Pfizer and Moderna COVID-19 vaccine; however, no etiologic relationship has been established between the two entities yet. We present a unique case of SSHL following the second dose of the Oxford-AstraZeneca COVID-19 vaccine. A 61-year-old female was referred to our department with a four-day history of the right-sided sense of fulness combined with almost complete hearing loss that had started two days after the second dose of Oxford-AstraZeneca COVID-19 vaccine. Pure tone audiometry showed profound right-sided sensorineural hearing loss. Magnetic resonance imaging of the brain and internal auditory canal and magnetic resonance angiography were both normal. The combination of glucocorticoids and

acetylsalicylic acid leads to almost full recovery 15 days after deafness. The COVID-19 era is full of new challenges and clinical dilemmas. In our case, the addition of acetylosalicid acid to the patient's initial treatment may have contributed to the hearing restoration; however, this fact will remain a hypothesis.
Acute Myopericarditis after COVID-19 Vaccine in Teenagers. BACKGROUND: There have been an increasing number of reports of myocarditis and pericarditis in adolescents and young adults after coronavirus disease 19 vaccinations. The pathophysiology of myocarditis after this vaccination is indeterminate currently. The problem is a relatively new phenomenon, and so there are no current guidelines on how to manage these cases of myopericarditis. We intend to describe our management in these two cases so that it can help guide pediatricians, intensivists, and cardiologists taking care of similar cases. Case Summaries. The first case is a young adolescent who presented with chest pain after receiving his second dose of coronavirus disease 19 vaccination with no other symptoms. His troponin was found to be 40â€‰ng/mL. He had a normal echocardiogram and chest CT angiogram. His troponins trended down with symptomatic pain management after 3 days. The second case is another adolescent who presented with fever, fatigue, headache, and chest pain 3 days after receiving his second dose of coronavirus vaccine. His troponin was elevated to 5â€‰ng/mL, electrocardiogram with ST segment elevations, and mildly decreased systolic function on echocardiogram. His troponins and electrocardiogram were normalized in 3 days at the time of his discharge. CONCLUSION: The clinical course of vaccine-associated myocarditis appears favorable as both our patients have responded well to medications and rest with prompt improvement in symptoms with full recovery. The experience remains limited at this time regarding the investigations, management, and follow-up of this novel clinical entity. It is vital for all the health care providers taking care of adolescents to have knowledge about this phenomenon and make correct diagnosis in those presenting with chest pain after COVID-19 vaccine and in preventing unnecessary invasive procedures such as coronary angiogram to rule out acute coronary syndromes.
Myopericarditis After COVID-19 mRNA Vaccination.
Clinical and biological features of cerebral venous sinus thrombosis following ChAdOx1 nCov-19 vaccination.
Viral-like Reaction or Hypersensitivity? Erythema Multiforme Minor Reaction and Moderate Eosinophilia After the Pfizer-BioNTech BNT162b2 (mRNA-Based) SARS-CoV-2 Vaccine.
Incidence of Audiological Adverse Effects Induced by COVID-19 Vaccines: A Preliminary Study.
Adverse events occurring post-covid-19 vaccination among healthcare professionals - A mixed method study. BACKGROUND: Healthcare professionals (HCPs) are at the front line of the nation's fight against COVID-19 and are always at a greater risk of contracting contagious disease. But amidst the crisis, the vaccines were not accepted by all the HCPs due to adverse events occurring post-COVID-19 vaccination. Hence, the present study was designed to assess adverse events occurring among HCPs post-COVID-19 vaccination both quantitatively and qualitatively. METHOD: Sequential mixed-method approach was employed. A cross-sectional E-survey was conducted among the healthcare professionals of a North Indian (*Statistically significant ($p < 0.05$)) college and hospital. The second phase included a semi-structured qualitative interview of the participants who were willing to participate. RESULTS: Among all the HCPs with age groups ranging from 20 to 70Â years, majority of them experienced pain at the site of injection (88.8-100%) followed by tiredness (87.7-60%) and body ache (86.6-40%) post-vaccination. There is an increased frequency of adverse events in females as compared to males. Qualitative findings are summarised in three major domains i.e vaccine adverse effects, fear and hesitancy for vaccines and vaccine acceptance. CONCLUSION: Short term adverse events of COVISHIELD vaccine were very few and were mild in severity yet interviews showed hesitancy of study participants for vaccination.

A case of varicella zoster virus meningitis following BNT162b2 mRNA COVID-19 vaccination in an immunocompetent patient. We report a case of varicella zoster virus (VZV) meningitis following BNT162b2 mRNA COVID-19 vaccination in an immunocompetent patient. A final diagnosis was made based on identification of VZV via positive polymerase chain reaction of cerebrospinal fluid along with characteristic symptoms such as fever, headache, and stiff neck. This phenomenon has been reported elsewhere; this is the 13th such case reported worldwide and the 7th case in immunocompetent patients, indicating the need for careful monitoring after COVID-19 vaccines.

Audio Interview: Covid-19 and the Media.

Phase 3 Safety and Efficacy of AZD1222 (ChAdOx1 nCoV-19) Covid-19 Vaccine. BACKGROUND: The safety and efficacy of the AZD1222 (ChAdOx1 nCoV-19) vaccine in a large, diverse population at increased risk for severe acute respiratory syndrome coronavirus 2Â (SARS-CoV-2) infection in the United States, Chile, and Peru has not been known. METHODS: In this ongoing, double-blind, randomized, placebo-controlled, phase 3 clinical trial, we investigated the safety, vaccine efficacy, and immunogenicity of two doses of AZD1222 as compared with placebo in preventing the onset of symptomatic and severe coronavirus disease 2019 (Covid-19) 15 days or more after the second dose in adults, including older adults, in the United States, Chile, and Peru. RESULTS: A total of 32,451 participants underwent randomization, in a 2:1 ratio, to receive AZD1222 (21,635 participants) or placebo (10,816 participants). AZD1222 was safe, with low incidences of serious and medically attended adverse events and adverse events of special interest; the incidences were similar to those observed in the placebo group. Solicited local and systemic reactions were generally mild or moderate in both groups. Overall estimated vaccine efficacy was 74.0% (95% confidence interval [CI], 65.3 to 80.5; P<0.001) and estimated vaccine efficacy was 83.5% (95% CI, 54.2 to 94.1) in participants 65 years of age or older. High vaccine efficacy was consistent across a range of demographic subgroups. In the fully vaccinated analysis subgroup, no severe or critical symptomatic Covid-19 cases were observed among the 17,662 participants in the AZD1222 group; 8 cases were noted among the 8550 participants in the placebo group (<0.1%). The estimated vaccine efficacy for preventing SARS-CoV-2 infection (nucleocapsid antibody seroconversion) was 64.3% (95% CI, 56.1 to 71.0; P<0.001). SARS-CoV-2 spike protein binding and neutralizing antibodies increased after the first dose and increased further when measured 28 days after the second dose. CONCLUSIONS: AZD1222 was safe and efficacious in preventing symptomatic and severe Covid-19 across diverse populations that included older adults. (Funded by AstraZeneca and others; ClinicalTrials.gov number, NCT04516746.).

VITT following Ad26.COV2.S vaccination presenting without radiographically demonstrable thrombosis. We report a case of vaccine-induced immune thrombotic thrombocytopenia (VITT) in a young man diagnosed 13 days after Ad26.COV2.S COVID-19 (Johnson & Johnson/Janssen) vaccination. He presented to us with 5 days of progressive left leg pain, thrombocytopenia, hypofibrinogenemia, and markedly elevated d-dimers, but without radiographically demonstrable thrombosis. Despite negative imaging, we initiated treatment of presumptive VITT given the striking clinical picture that included the timing of his recent adenovirus-based COVID-19 vaccine, leg symptoms, marked thrombocytopenia, and consumptive coagulopathy. He received intravenous immune globulin, prednisone, and argatroban and was discharged 7 days later much improved. His positive platelet factor 4 enzyme-linked immunosorbent assay antibody test returned after treatment was initiated. To our knowledge, this is the first reported case of VITT following Ad26.COV2.S vaccination presenting without radiographically demonstrable thrombosis. Our patient highlights the importance of knowing vaccine status and initiating treatment as soon as possible in the right clinical setting, even in the absence of radiographic evidence of thrombus. Early VITT recognition and treatment provide an opportunity to prevent serious thrombotic complications.

SARS-CoV-2 vaccination and ITP in patients with de novo or preexisting ITP. Cases of de novo immune thrombocytopenia (ITP), including a fatality, following SARS-CoV-2 vaccination in previously healthy recipients led to studying its impact in preexisting ITP. In this study, 4 data sources were analyzed: the Vaccine Adverse Events Reporting System (VAERS) for cases of de novo ITP; a 10-center retrospective study of adults with preexisting ITP receiving SARS-CoV-2 vaccination; and surveys distributed by the Platelet Disorder Support Association (PDSA) and the United Kingdom (UK) ITP Support Association. Seventy-seven de novo ITP cases were identified in VAERS, presenting with median platelet count of 3 [1-9] Ã—109/L approximately 1 week postvaccination. Of 28 patients with available data, 26 responded to treatment with corticosteroids and/or intravenous immunoglobulin (IVIG), and/or platelet transfusions. Among 117 patients with preexisting ITP who received a SARS-CoV-2 vaccine, 19 experienced an ITP exacerbation (any of: â‰¥50% decline in platelet count, nadir platelet count <30 Ã— 109/L with >20% decrease from baseline, and/or use of rescue therapy) following the first dose and 14 of 70 after a second dose. Splenectomized persons and those who received 5 or more prior lines of therapy were at highest risk of ITP exacerbation. Fifteen patients received and responded to rescue treatment. In surveys of both 57 PDSA and 43 UK patients with ITP, prior splenectomy was associated with worsened thrombocytopenia. ITP may worsen in preexisting ITP or be identified de novo post-SARS-CoV2 vaccination; both situations responded well to treatment. Proactive monitoring of patients with known ITP, especially those postsplenectomy and with more refractory disease, is indicated.

Insights in ChAdOx1 nCoV-19 vaccine-induced immune thrombotic thrombocytopenia. SARS-CoV-2 vaccine ChAdOx1 nCoV-19 (AstraZeneca) causes a thromboembolic complication termed vaccine-induced immune thrombotic thrombocytopenia (VITT). Using biophysical techniques, mouse models, and analysis of VITT patient samples, we identified determinants of this vaccine-induced adverse reaction. Super-resolution microscopy visualized vaccine components forming antigenic complexes with platelet factor 4 (PF4) on platelet surfaces to which anti-PF4 antibodies obtained from VITT patients bound. PF4/vaccine complex formation was charge-driven and increased by addition of DNA. Proteomics identified substantial amounts of virus production-derived T-REx HEK293 proteins in the ethylenediaminetetraacetic acid (EDTA)-containing vaccine. Injected vaccine increased vascular leakage in mice, leading to systemic dissemination of vaccine components known to stimulate immune responses. Together, PF4/vaccine complex formation and the vaccine-stimulated proinflammatory milieu trigger a pronounced B-cell response that results in the formation of high-avidity anti-PF4 antibodies in VITT patients. The resulting high-titer anti-PF4 antibodies potently activated platelets in the presence of PF4 or DNA and polyphosphate polyanions. Anti-PF4 VITT patient antibodies also stimulated neutrophils to release neutrophil extracellular traps (NETs) in a platelet PF4-dependent manner. Biomarkers of procoagulant NETs were elevated in VITT patient serum, and NETs were visualized in abundance by immunohistochemistry in cerebral vein thrombi obtained from VITT patients. Together, vaccine-induced PF4/adenovirus aggregates and proinflammatory reactions stimulate pathologic anti-PF4 antibody production that drives thrombosis in VITT. The data support a 2-step mechanism underlying VITT that resembles the pathogenesis of (autoimmune) heparin-induced thrombocytopenia.

mRNA vaccination in people over 80 years of age induces strong humoral immune responses against SARS-CoV-2 with cross neutralization of P.1 Brazilian variant. Age is the major risk factor for mortality after SARS-CoV-2 infection and older people have received priority consideration for COVID-19 vaccination. However, vaccine responses are often suboptimal in this age group and few people over the age of 80 years were included in vaccine registration trials. We determined the serological and cellular response to spike protein in 100 people aged 80-96 years at 2 weeks after the second vaccination with the Pfizer BNT162b2 mRNA vaccine. Antibody responses were seen in every donor

with high titers in 98%. Spike-specific cellular immune responses were detectable in only 63% and correlated with humoral response. Previous SARS-CoV-2 infection substantially increased antibody responses after one vaccine and antibody and cellular responses remained 28-fold and 3-fold higher, respectively, after dual vaccination. Post-vaccine sera mediated strong neutralization of live Victoria infection and although neutralization titers were reduced 14-fold against the P.1 variant first discovered in Brazil they remained largely effective. These data demonstrate that the mRNA vaccine platform delivers strong humoral immunity in people up to 96 years of age and retains broad efficacy against the P.1 variant of concern.
Fatal Multisystem Inflammatory Syndrome in Adult after SARS-CoV-2 Natural Infection and COVID-19 Vaccination. We describe a fatal case of multisystem inflammatory syndrome in an adult with onset 22 days after a second dose of mRNA coronavirus disease vaccine. Serologic and clinical findings indicated severe acute respiratory syndrome coronavirus 2 infection occurred before vaccination. The immunopathology of this syndrome, regardless of vaccination status, remains poorly understood.
Seropositive rheumatoid arthritis after vaccination against SARS-CoV-2 infection.
Herpes zoster ophthalmicus in two women after Pfizer-BioNTech (BNT162b2) vaccine.
Atypical pityriasis rosea associated with mRNA COVID-19 vaccine.
A case of COVID-19 vaccination-associated forme fruste purpura fulminans. We report the case of a female, 77 year old patient with multi-localized skin infarctions following vaccination with mRNA-1273 (Moderna). This phenomenon is to our knowledge otherwise only seen in infection-associated purpura fulminans - which was thoroughly ruled out in our patient. This report demonstrates that we need to be vigilant of a wider array of vascular phenomena related to Covid vaccinations.
Post-COVID-vaccine autoimmune/inflammatory syndrome in response to adjuvants (ASIA syndrome) manifesting as subacute thyroiditis.
Inflammatory myositis after ChAdOx1 vaccination.
Immunogenicity and Safety of COVID-19 Vaccine BNT162b2 for Patients with Solid Cancer: A Large Cohort Prospective Study from a Single Institution. PURPOSE: We assessed the immunogenicity and safety of the BNT162b2 vaccine in a large cohort of patients with cancer (CP). EXPERIMENTAL DESIGN: From March 1, 2021 to March 20, 2021, this prospective cohort study included 816 CP afferent to our institution and eligible for the vaccination. A cohort of 274 health care workers (HCW) was used as age- and sex-matched control group. BNT162b2 was administered as a two-dose regimen given 21 days apart. Blood samples to analyze anti-Spike (S) IgG antibodies (Ab) were collected prevaccination [timepoint (TP) 0], and at 3 weeks (TP1) and 7 weeks (TP2) after the first dose. RESULTS: Patients characteristics: median age 62 (range, 21-97); breast/lung cancer/others (31/21/48%); active treatment/follow-up (90/10%). In the whole CP cohort, the serologic response rate (RR) and the titre of anti-S IgG significantly increased across the TPs; at TP2, the responders (IgG >15 AU/mL) were 94.2%. Active chemotherapy and chronic use of steroids were independent predictors of lower RR. Adverse events (AE) after the booster predicted higher likelihood of response (OR, 4.04; 95% confidence interval, 1.63-9.99; P = 0.003). Comparing the matched cohorts, the responders were significantly lower in CP than in HCW at TP1 (61.2% vs. 93.2%) and TP2 (93.3% vs. 100%), while the geometric mean concentration of IgG did not significantly differ at TP2 being significantly lower in CP (23.3) than in HCW (52.1) at TP1. BNT162b2 was well tolerated in CP; severe-grade AEs were 3.5% and 1.3% after the first and second doses, respectively. CONCLUSIONS: BNT162b2 assures serologic immunization without clinically significant toxicity in CP. The second dose is needed to reach a satisfactory humoral response.
Influenza vaccination adherence after liver transplantation: A collateral benefit of the COVID-19 pandemic (results of a patients' survey).

Thrombocytopenia After Coronavirus Disease 2019 Vaccination: Remember to Put the Blame on Others Too.
Large-vessel giant cell arteritis after COVID-19 vaccine.
Characteristics and Outcomes of Patients With Cerebral Venous Sinus Thrombosis in SARS-CoV-2 Vaccine-Induced Immune Thrombotic Thrombocytopenia. IMPORTANCE: Thrombosis with thrombocytopenia syndrome (TTS) has been reported after vaccination with the SARS-CoV-2 vaccines ChAdOx1 nCov-19 (Oxford-AstraZeneca) and Ad26.COV2.S (Janssen/Johnson & Johnson). OBJECTIVE: To describe the clinical characteristics and outcome of patients with cerebral venous sinus thrombosis (CVST) after SARS-CoV-2 vaccination with and without TTS. DESIGN, SETTING, AND PARTICIPANTS: This cohort study used data from an international registry of consecutive patients with CVST within 28 days of SARS-CoV-2 vaccination included between March 29 and June 18, 2021, from 81 hospitals in 19 countries. For reference, data from patients with CVST between 2015 and 2018 were derived from an existing international registry. Clinical characteristics and mortality rate were described for adults with (1) CVST in the setting of SARS-CoV-2 vaccine-induced immune thrombotic thrombocytopenia, (2) CVST after SARS-CoV-2 vaccination not fulling criteria for TTS, and (3) CVST unrelated to SARS-CoV-2 vaccination. EXPOSURES: Patients were classified as having TTS if they had new-onset thrombocytopenia without recent exposure to heparin, in accordance with the Brighton Collaboration interim criteria. MAIN OUTCOMES AND MEASURES: Clinical characteristics and mortality rate. RESULTS: Of 116 patients with postvaccination CVST, 78 (67.2%) had TTS, of whom 76 had been vaccinated with ChAdOx1 nCov-19; 38 (32.8%) had no indication of TTS. The control group included 207 patients with CVST before the COVID-19 pandemic. A total of 63 of 78 (81%), 30 of 38 (79%), and 145 of 207 (70.0%) patients, respectively, were female, and the mean (SD) age was 45 (14), 55 (20), and 42 (16) years, respectively. Concomitant thromboembolism occurred in 25 of 70 patients (36%) in the TTS group, 2 of 35 (6%) in the no TTS group, and 10 of 206 (4.9%) in the control group, and in-hospital mortality rates were 47% (36 of 76; 95% CI, 37-58), 5% (2 of 37; 95% CI, 1-18), and 3.9% (8 of 207; 95% CI, 2.0-7.4), respectively. The mortality rate was 61% (14 of 23) among patients in the TTS group diagnosed before the condition garnered attention in the scientific community and 42% (22 of 53) among patients diagnosed later. CONCLUSIONS AND RELEVANCE: In this cohort study of patients with CVST, a distinct clinical profile and high mortality rate was observed in patients meeting criteria for TTS after SARS-CoV-2 vaccination.
Acute Hemichorea-Hemiballismus Following COVID-19 (AZD1222) Vaccination.
How the Global COVID-19 Pandemic Brought Drug and Vaccine Development into the Public Mainstream. Pharmaceutical development was at the forefront of efforts to prevent infection with the SARS-CoV-2 virus as well as to treat its often-devastating effects. Drug development, and its multifaceted and multi-disciplined activity toward effective vaccines and drugs, became part of everyday news. I review several key areas of vaccine and drug development that were brought into the public mainstream over the evolution of the pandemic. These include the unprecedented speed of vaccine discovery and development, issues uncovered from early clinical studies, and regulatory concepts that were highlighted throughout the development process. Among these was the importance of pharmacovigilance as each new agent was rapidly deployed to a mostly eager public. Critical challenges around production, packaging, and procurement of product for patient use were often centre stage. Finally, the ever-important need to transition not only from scientific concept to vaccine and drug, but from their authorized and approved use to their implementation in health systems to insure the intended effects both in individuals and populations.
Impact of multiple sclerosis disease-modifying therapies on SARS-CoV-2 vaccine-induced antibody and T cell immunity. Vaccine-elicited adaptive immunity is an essential prerequisite for effective prevention and control of coronavirus 19 (COVID-19). Treatment of multiple sclerosis (MS) involves a

diverse array of disease-modifying therapies (DMTs) that target antibody and cell-mediated immunity, yet a comprehensive understanding of how MS DMTs impact SARS-CoV-2 vaccine responses is lacking. We completed a detailed analysis of SARS-CoV-2 vaccine-elicited spike antigen-specific IgG and T cell responses in a cohort of healthy controls and MS participants in six different treatment categories. Two specific DMT types, sphingosine-1-phosphate (S1P) receptor modulators and anti-CD20 monoclonal antibodies (mAb), resulted in significantly reduced spike-specific IgG responses. Longer duration of anti-CD20 mAb treatment prior to SARS-CoV-2 vaccination were associated with absent antibody responses. Except for reduced CD4+ T cell responses in S1P-treated patients, spike-specific CD4+ and CD8+ T cell reactivity remained robust across all MS treatment types. These findings have important implications for clinical practice guidelines and vaccination recommendations in MS patients and other immunosuppressed populations.

Transient visual field loss after COVID-19 vaccination: Experienced by ophthalmologist, case report. PURPOSE: The first reported case of bilateral transient visual field defect, experienced by an ophthalmologist, which developed shortly after COVID-19 vaccination (CoronaVac, Sinovac Biotech Ltd., Beijing, China) and confirmed by computerized automated perimetry. OBSERVATION: The patient is a 42-year-old Thai ophthalmologist. He developed blurred vision within an hour after the second dose of COVID-19 vaccination. We described his self-observed of sequential symptoms, chronologic events, and management steps. The visual field of left congruous hemianopia with respect to vertical midline was detected with computerized automated perimetry. The possible mechanism could be related to an acute vasospasm of the artery in the postchiasmatic visual pathway, triggered by COVID-19 vaccine, Corona Vac. CONCLUSION AND IMPORTANCE: With increasing use of the COVID-19 vaccine in the near future, it would be prudent for medical staff and ophthalmologists to be considered and aware of this associated condition.

Acute macular neuroretinopathy (AMN) following COVID-19 vaccination. PURPOSE: To describe a case of acute macular neuroretinopathy (AMN) in a 23-year-old Caucasian female after a COVID-19 vaccination (Vaxzevira). OBSERVATIONS: Our patient perceived visual symptoms in both eyes one day after COVID-19 vaccination. Hyporeflective petalloid shaped perifoveal lesions appeared in infrared reflectance (IR) imaging, and Spectral domain-optical coherence tomography (SD-OCT) revealed structural alterations of outer retinal layers that resulted in persistent disruption of the ellipsoid zone (EZ) and the interdigitation zone (IZ). CONCLUSIONS AND IMPORTANCE: We report a novel association between AMN and COVID-19 vaccination. In addition to a febrile infection and oral contraception, previous vaccination should also be considered a potential risk factor for AMN.

Acute ST-segment elevation myocardial infarction secondary to vaccine-induced immune thrombosis with thrombocytopaenia (VITT). A 40-year-old man with no cardiac history presented with central chest pain 8â€‰days after receiving the ChAdOx1 nCov-19 vaccine against COVID-19. Initial blood tests demonstrated a thrombocytopaenia (24Ã—10(9)â€‰Î¼g/L) and a raised d-dimer (>110â€‰000â€‰Î¼g/L), and he was urgently transferred to our tertiary referral central for suspected vaccine-induced immune thrombocytopaenia and thrombosis (VITT). He developed dynamic ischaemic electrocardiographic changes with ST elevation, a troponin of 3185â€‰ng/L, and regional wall motion abnormalities. An occlusion of his left anterior descending coronary artery was seen on CT coronary angiography. His platelet factor-4 (PF-4) antibody returned strongly positive. He was urgently treated for presumed VITT with intravenous immunoglobulin, methylprednisolone and plasma exchange, but remained thrombocytopaenic and was initiated on rituximab. Argatroban was used for anticoagulation for his myocardial infarction while he remained thrombocytopaenic. After 6â€‰days, his platelet count improved, and his PF-4 antibody level, troponin and d-dimer fell. He was successfully discharged after 14 days.

Altered mental status and pronounced febrile response after second mRNA-1273 (Moderna) COVID-19 vaccine administration in a patient with previously documented COVID-19 infection. A 54-year-old man who was previously found to be COVID-19 positive received two doses of mRNA-1273 (Moderna) vaccine 4 weeks apart, as recommended by the manufacturer. He was brought to the emergency department 1 day after second dose of the vaccine with altered mental status, headache and high fever. The patient was hospitalised for 2 days and managed with supportive care. He completely recovered with return of mental status to baseline and resolution of fever.

Reactogenicity following two doses of the BNT162b2 mRNA COVID-19 vaccine: Real-world evidence from healthcare workers in Japan. As the first authorized COVID-19 vaccine in Japan, the BNT162b2 mRNA COVID-19 vaccine is utilized for mass vaccination. Although efficacy has been proved, real-world evidence on reactogenicity in Japanese personnel is needed to prepare the public. Healthcare workers in a large academic hospital in Japan received two doses of the Pfizer-BioNTech vaccine from March 17 to May 19, 2021. Online questionnaires were distributed to registered recipients following each dose, from day 0 through day 8. Primary outcomes are the frequency of reactogenicity including local and systemic reactions. Length of absence from work was also analyzed. Most recipients self-reported reactogenicity after the first dose (97.3%; nÂ =Â 3254; mean age [36.4]) and after the second dose (97.2%; nÂ =Â 3165; mean age [36.5]). Systemic reactions following the second dose were substantially higher than the first dose, especially for fever (OR, 27.38; 95% CI, [22.00-34.06]; pÂ <Â 0.001), chills (OR, 16.49; 95% CI, [13.53-20.11]; pÂ <Â 0.001), joint pain (OR, 8.49; 95% CI, [7.21-9.99]; pÂ <Â 0.001), fatigue (OR, 7.18; 95% CI, [6.43-8.02]; pÂ <Â 0.001) and headache (OR, 5.43; 95% CI, [4.80-6.14]; pÂ <Â 0.001). Reactogenicity was more commonly seen in young, female groups. 19.3% of participants took days off from work after the second dose (2.2% after the first dose), with 4.7% absent for more than two days. Although most participants reported reactogenicity, severe cases were limited. This study provides real-world evidence for the general population and organizations to prepare for BNT162b2 mRNA COVID-19 vaccination in Japan and other countries in the region.

COVID-19 vaccine induced interstitial lung disease. A 60-year-old man presented with dyspnea four days after the second dose of the coronavirus disease (COVID-19) vaccine. Imaging revealed extensive ground-glass opacification. Blood tests were notable for elevated KL-6 levels. Bronchoalveolar lavage fluid analysis showed increased lymphocyte-dominant inflammatory cells and decreased CD4/CD8 ratio. These findings were consistent with the diagnosis of drug-induced interstitial lung disease (DIILD). To the best of our knowledge, this has never been reported in previous literature. Treatment with glucocorticoids relieved his symptoms. This paper highlights that although extremely rare, COVID-19 vaccine could cause DIILD, and early diagnosis and treatment are crucial to improve patient outcomes.

Adverse events reported by Iranian patients with multiple sclerosis after the first dose of Sinopharm BBIBP-CorV. MS patients were one of the first populations vaccinated in Iran. To date, the most used vaccine brand on Iranian MS patients is Sinopharm COVID-19 vaccine. Here is the first study on the adverse events after the first dose of Sinopharm vaccine on 583 Iranian MS patients. A Google form link was sent to MS patients through social networks, between May 1, 2021 and May 22, 2021. No serious adverse event was reported. At least one complaint (mostly transient) was reported by 350 (60%) of vaccine recipients. Constitutional symptoms (malaise, fatigue, fever, shivering, & generalized body pain) (51%) and headache (9%) were the most reported complaints. We found a relation between gender and prior infection with COVID-19 and reported symptoms (p valueÂ less thanÂ 0.05). Only five recipients (0.9%) reported MS relapse after vaccination. MS worsening was a minor incident related to fever.

Acute Ischaemic Stroke Incidence after Coronavirus Vaccine in Indonesia: Case Series. BACKGROUND: Coronavirus disease-19 (COVID-19) is an infectious disease with high morbidity and mortality rates. Indonesia had reported a 2.8% of mortality rate up to June 2021. CASE PRESENTATION: A strategy to control the virus spreading is by vaccination. The Indonesian Food and Drug Monitoring Agency had approved the use of CoronaVac, an inactivated virus vaccine developed by Sinovac. Most Adverse Events Following Immunization (AEFI) for Corona- Vac are mild, and the most common symptoms are injection-site pain, headache, and fatigue. Neurovascular adverse events, including thrombosis or ischaemic stroke after receiving CoronaVac have not previously been reported. CONCLUSION: Correspondingly, we reported three patients with an Acute Ischaemic Stroke (AIS) after the administration of CoronaVac in our hospital.

Age and Smoking Predict Antibody Titres at 3 Months after the Second Dose of the BNT162b2 COVID-19 Vaccine. OBJECTIVE: We aimed to determine antibody (Ab) titres 3 months after the second dose of the BNT162b2 coronavirus disease-2019 (COVID-19) vaccine and to explore clinical variables predicting these titres in Japan. METHODS: We enrolled 378 healthcare workers (255 women, 123 men) whose blood samples were collected 91 Â± 15 days after the second of two inoculations of the BNT162b2 COVID-19 mRNA vaccine (Pfizer/BioNTech) given 3 weeks apart. Medical histories and demographic characteristics were recorded using a structured self-reported questionnaire. The relationships between Ab titres and these factors were analysed. RESULTS: Median age (interquartile range (IQR)) of the participants was 44 (32-54) years. Median Ab titre (IQR) against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike antigen was 764 (423-1140) U/mL. Older participants had significantly lower Ab titres; median (IQR) Ab titres were 942 (675-1390) and 1095 (741-1613) U/mL in men and women in their 20s, respectively, but 490 (297-571) and 519 (285-761) U/mL in men and women in their 60-70s, respectively. In the age-adjusted analysis, the only risk factors for lower Ab titres were male sex and smoking. However, the sex difference may have arisen from the sex difference in smoking rate. Moreover, Ab titres were significantly lower in current smokers than in ex-smokers. CONCLUSIONS: The most important factors associated with low Ab titres were age and smoking habit. In particular, current smoking status caused lower Ab titres, and smoking cessation before vaccination may improve the individual efficacy of the BNT162b2 vaccine.

Varicella Zoster Virus Reactivation Following COVID-19 Vaccination: A Systematic Review of Case Reports. The newly developed COVID-19 vaccines have established a safe profile, yet some individuals experience a wide range of adverse events. Recently, reactivation of varicella zoster virus (VZV) has been observed after administration of different COVID-19 vaccines, although causality remains a matter of debate. The aim of this systematic review was to examine the available literature and provide an overview of reported cases of VZV reactivation following COVID-19 vaccination. We identified 12 eligible articles which included 91 patients with herpes zoster (HZ) following COVID-19 vaccination. Hypertension was the main comorbidity present in 18% of patients (16/91). Additionally, 13% of patients (12/91) had an autoimmune condition with rheumatoid arthritis being the most common (4/12). Moreover, 10% of patients (9/91) were receiving immunosuppressants. The dermatomal distribution of skin lesions varied among patients, with the mammary region being most affected. On average, symptoms developed 5.8 days post-vaccination irrespective of dose and treatment with oral valacyclovir as a monotherapy was employed in most patients (23/91). HZ is possibly a condition clinicians may expect to encounter in patients receiving COVID-19 vaccines. While causality has not yet been established increased awareness and early recognition of the disorder would be crucial for the optimal management of these patients.

Increased Risk of Urticaria/Angioedema after BNT162b2 mRNA COVID-19 Vaccine in Health Care Workers Taking ACE Inhibitors. Urticarial eruptions and angioedema are the most common cutaneous reactions in patients undergoing mRNA COVID-19 vaccinations. The vasoactive peptide

bradykinin has long been known to be involved in angioedema and recently also in urticaria. Bradykinin is mainly catabolized by angiotensin-converting enzyme (ACE), which is inhibited by ACE inhibitors, a commonly employed class of antihypertensive drugs. We evaluated the risk of developing urticaria/angioedema after inoculation with the BNT162b2 mRNA COVID-19 vaccine in a population of 3586 health care workers. The influences of ACE inhibitors and selected potential confounding variables (sex, age, previous SARS-CoV-2 infection, and allergy history) were evaluated by fitting univariate and multivariable Poisson regression models. The overall cumulative incidence of urticaria/angioedema was 1.8% (65 out of 3586; 95% CI: 1.4-2.3%). Symptoms were mild, and no subject consulted a physician. Subjects taking ACE inhibitors had an adjusted three-fold increased risk of urticaria/angioedema (RR 2.98, 95% CI: 1.12-7.96). When we restricted the analysis to those aged 50 years or more, the adjusted RR was 3.98 (95% CI: 1.44-11.0). In conclusion, our data indicate that subjects taking ACE inhibitors have an increased risk of urticaria/angioedema after vaccination with the BNT162b2 mRNA COVID-19 vaccine. Symptoms are mild and self-limited; however, they should be considered to adequately advise subjects undergoing vaccination.

Acute Transverse Myelitis Following COVID-19 Vaccination. An increasing number of people are undergoing vaccination for COVID-19 because of the ongoing pandemic. The newly developed, genetically engineered mRNA vaccines are critical for controlling the epidemic disease. However, major adverse effects, including neuroimmunological disorders, are being attributed to this vaccine. For instance, several cases of acute transverse myelitis (ATM) after COVID-19 vaccination have been reported in clinical trials. Here, we report an exceedingly rare case of longitudinally extensive transverse myelitis (LETM), a rare subtype of ATM involving three or more vertebral segments, that occurred shortly after vaccination with the Moderna COVID-19 (mRNA-1273) vaccine, with a comorbidity of vitamin B12 deficiency. The findings of subsequent investigations suggest the possibility that autoimmune responses are triggered by the reactions between anti-SARS-CoV-2 spike protein antibodies and tissue proteins, as well as the interaction between spike proteins and angiotensin-converting enzyme 2 receptors.

IgG Antibodies Generation and Side Effects Caused by Ad5-nCoV Vaccine (CanSino Biologics) and BNT162b2 Vaccine (Pfizer/BioNTech) among Mexican Population. SARS-CoV-2 has rapidly generated a pandemic. Vaccines are currently being rolled out to control the viral spread and prevent deaths. Emergency vaccines, using new platforms, have been approved. Their effectiveness, safety and immunogenicity in different populations are not fully known. This study aimed to discover the immunogenicity of the messenger ribonucleic acid (mRNA) BNT162b2 and adenovirus vector Ad5-nCoV vaccines through IgG antibody generation against subunit 1 of protein S (S1 IgG) and assess the side effects of the vaccines. A total of 115 vaccinated people were included, 61 of whom received the BNT162b2 vaccine, while 54 received Ad5-nCoV. Measurements of S1 IgG antibodies were carried out using the enzyme-linked immunosorbent assay (ELISA) technique. The BNT162b2 vaccine generated S1 IgG antibodies in 80.3% of the participants after the first dose. The number of seropositive participants increased to 98.36% with the administration of the second dose. The Ad5-nCoV vaccine generated S1 IgG antibodies in 88.89% of those vaccinated. Women generated more antibodies when administered either vaccine. There were no serious adverse effects from vaccination. In conclusion, not all participants had detectable S1 IgG antibodies. The Ad5-nCoV vaccine presented the most seronegative cases. The studied vaccines were shown to be safe.

Factors Related to Caregiver Intentions to Vaccinate Their Children with Attention-Deficit/Hyperactivity Disorder against COVID-19 in Taiwan. The aims of this study were to examine the proportion of caregivers who were hesitant to vaccinate their children with attention-deficit/hyperactivity disorder (ADHD) against coronavirus disease 2019 (COVID-19) and the factors related to caregiver intentions to vaccinate their children against COVID-19. In total, 161 caregivers of

children with ADHD were recruited in this study. The caregivers completed an online questionnaire to provide data regarding their intention to vaccinate their children against COVID-19, concerns about the effectiveness and safety of vaccines, unfavorable family attitudes toward vaccines, and children's medication use for ADHD and comorbid psychopathology. The factors related to caregiver intentions to vaccinate their child were examined using linear regression analysis. The results indicated that 25.5% of caregivers were hesitant to vaccinate their children with ADHD, and 11.8% refused to vaccinate their children against COVID-19. The caregivers' concerns about the safety of vaccines and children's regular use of medication for ADHD were negatively associated with caregiver intentions to vaccinate, whereas the children's comorbid conduct or oppositional defiant problems were positively associated with the caregiver intentions to vaccinate. An intervention that enhances caregiver intentions to vaccinate their children with ADHD against COVID-19 by addressing the related factors found in this study is warranted.

Pseudo-Anaphylactic Reactions to Pfizer BNT162b2 Vaccine: Report of 3 Cases of Anaphylaxis Post Pfizer BNT162b2 Vaccination. Anaphylactic reactions were observed after Singapore's national coronavirus disease 2019 (COVID-19) vaccination programme started in December 2020. We report the clinical and laboratory features of three patients in our institution who developed anaphylactic reactions after receiving the Pifzer BNT162b2 vaccine. IgM and IgG antibodies, but not IgE antibodies to the Pfizer BNT162b2 vaccine, were detected in all subjects. Similarly, mild to high elevated levels of anti-polyethylene glycol (PEG) IgG (1035-19709 U/mL, vs. vaccine-naive < 265 U/mL, vaccine-tolerant < 785 U/mL) and IgM (1682-5310 U/mL, vs. vaccine-naive < 1011 U/mL, vaccine-tolerant < 1007 U/mL) were detected in two out of three patients via commercial ELISA. High levels of serum anaphylatoxin C3a (79.0 Â± 6.3 Î¼g/mL, mean Â± SD, vs. normal < 10 Î¼g/mL) were observed in all three patients during the acute phase of the reaction, while tryptase levels, a marker of mast cell activation, were not elevated. Finally, one patient with the highest levels of anti-PEG IgG, IgM, and anti-Pfizer BNT162b2 IgG and IgM exhibited an enhanced Th2 cytokine serum profile during an acute reaction, with high levels of IL-4 (45.7 pg/mL, vs. vaccine-naive/tolerant < 2.30 pg/mL), IL-33 (86.4 pg/mL, vs. vaccine-naive/tolerant < 5.51 pg/mL) and IL-10 (22.9 pg/mL, vs. vaccine-naive/tolerant < 12.49 pg/mL) diminishing over time following corticosteroid treatment. Taken together, we propose these cases of anaphylaxis described are driven by a complement activation-related pseudoallergy (CAPRA), rather than classical IgE-mediated mechanisms.

Enhancement of the HIV-1-Specific Immune Response Induced by an mRNA Vaccine through Boosting with a Poxvirus MVA Vector Expressing the Same Antigen. Development of a vaccine against HIV remains a major target goal in the field. The recent success of mRNA vaccines against the coronavirus SARS-CoV-2 is pointing out a new era of vaccine designs against pathogens. Here, we have generated two types of mRNA vaccine candidates against HIV-1; one based on unmodified vectors and the other on 1-methyl-3'-pseudouridylyl modified vectors expressing a T cell multiepitopic construct including protective conserved epitopes from HIV-1 Gag, Pol and Nef proteins (referred to as RNA-TMEP and RNA-TMEPmod, respectively) and defined their biological and immunological properties in cultured cells and in mice. In cultured cells, both mRNA vectors expressed the corresponding protein, with higher levels observed in the unmodified mRNA, leading to activated macrophages with differential induction of innate immune molecules. In mice, intranodal administration of the mRNAs induced the activation of specific T cell (CD4 and CD8) responses, and the levels were markedly enhanced after a booster immunization with the poxvirus vector MVA-TMEP expressing the same antigen. This immune activation was maintained even three months later. These findings revealed a potent combined immunization regimen able to enhance the HIV-1-specific immune responses induced by an mRNA vaccine that might be applicable to human vaccination programs with mRNA and MVA vectors.

Rhabdomyolysis Following Ad26.COV2.S COVID-19 Vaccination. We report the case of a 19-year-old male who complained of myalgia, muscle weakness, and darkened urine two days after receiving his Ad26.COV2.S (Johnson & Johnson, New Brunswick, New Jersey, United States) COVID-19 vaccination. Blood examination revealed an increased creatine kinase (CK) level, and his urinary dipstick tested positive for blood, indicative of acute rhabdomyolysis. Serum creatinine levels were normal. Rhabdomyolysis due to strenuous physical activity was ruled out and further diagnostics excluded an autoimmune cause. Under repeated treatment with intravenous fluid resuscitation (outpatient treatment), his symptoms resolved and peak CK levels of 44,180 U/L returned to almost normal levels within two weeks. Rhabdomyolysis is a rare, potentially fatal vaccine-induced reaction. Further research is needed to better understand the underlying pathomechanism and to investigate whether subcutaneous injection of vaccines may be able to prevent rhabdomyolysis.

Cutaneous Adverse Reactions to COVID-19 Vaccines: Insights from an Immuno-Dermatological Perspective. (1) Background: Numerous vaccines are under preclinical and clinical development for prevention of severe course and lethal outcome of coronavirus disease 2019 (COVID-19). In light of high efficacy rates and satisfactory safety profiles, some agents have already reached approval and are now distributed worldwide, with varying availability. Real-world data on cutaneous adverse drug reactions (ADRs) remain limited. (2) Methods: We performed a literature research concerning cutaneous ADRs to different COVID-19 vaccines, and incorporated our own experiences. (3) Results: Injection site reactions are the most frequent side effects arising from all vaccine types. Moreover, delayed cutaneous ADRs may occur after several days, either as a primary manifestation or as a flare of a pre-existing inflammatory dermatosis. Cutaneous ADRs may be divided according to their cytokine profile, based on the preponderance of specific T-cell subsets (i.e., Th1, Th2, Th17/22, Tregs). Specific cutaneous ADRs mimic immunogenic reactions to the natural infection with SARS-CoV-2, which is associated with an abundance of type I interferons. (4) Conclusions: Further studies are required in order to determine the best suitable vaccine type for individual groups of patients, including patients suffering from chronic inflammatory dermatoses.

COVID-19 Pneumonia in Vaccinated Population: A Six Clinical and Radiological Case Series. Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) and its related disease (COVID-19) continue to represent a challenge for humans. To date, vaccination programs have represented an opportunity to navigate the pandemic. However, the advent of new genetic COVID-19 variants has increased more attention representing a worrying threat not only for not vaccinated but also for vaccinated people as virus infections have been shown also in the last ones. Herein, we report different clinical cases and radiological findings of COVID-19 pneumonia in six fully vaccinated patients. Two patients had a history of Rituximab therapy for follicular lymphoma and with persistent positivity for SARS-CoV-2 on nasopharyngeal/oropharyngeal (NP/OP) swabs and with moderate pneumonia on the chest computed tomography (CT). One patient who resulted to be positive to delta variant 8 days after the second vaccination dose, died shortly after. Two patients were hospitalized due to the worsening of fever and dyspnea in presence of mild pneumonia on CT. In one patient mild pneumonia was found on the chest-CT performed after a lipothymic episode associated with chest pain and positive NP/OP swab tested for SARS-CoV-2. These data suggested that in fully vaccinated people, caution should be preserved, and the use of masks and social distancing should be continued in all closed environments. However, further clinical trials should be done to better understand how various factors can influence vaccine immunogenicity as the presence of virus mutations, age factors, and the presence of an immunocompromised state.

Side Effects of mRNA-Based COVID-19 Vaccine: Nationwide Phase IV Study among Healthcare Workers in Slovakia. mRNA-based COVID-19 vaccines such as BNT162b2 have recently been a target of anti-vaccination campaigns due to their novelty in the healthcare industry; nevertheless,

these vaccines have exhibited excellent results in terms of efficacy and safety. As a consequence, they acquired the first approvals from drug regulators and were deployed at a large scale among priority groups, including healthcare workers. This phase IV study was designed as a nationwide cross-sectional survey to evaluate the post-vaccination side effects among healthcare workers in Slovakia. The study used a validated self-administered questionnaire that inquired about participants' demographic information, medical anamneses, COVID-19-related anamnesis, and local, systemic, oral, and skin-related side effects following receiving the BNT162b2 vaccine. A total of 522 participants were included in this study, of whom 77% were females, 55.7% were aged between 31 and 54 years, and 41.6% were from Banska Bystrica. Most of the participants (91.6%) reported at least one side effect. Injection site pain (85.2%) was the most common local side effect, while fatigue (54.2%), headache (34.3%), muscle pain (28.4%), and chills (26.4%) were the most common systemic side effects. The reported side effects were of a mild nature (99.6%) that did not require medical attention and a short duration, as most of them (90.4%) were resolved within three days. Females and young adults were more likely to report post-vaccination side effects; such a finding is also consistent with what was previously reported by other phase IV studies worldwide. The role of chronic illnesses and medical treatments in post-vaccination side effect incidence and intensity requires further robust investigation among large population groups.

Exploring Drugs and Vaccines Associated with Altered Risks and Severity of COVID-19: A UK Biobank Cohort Study of All ATC Level-4 Drug Categories Reveals Repositioning Opportunities. Effective therapies for COVID-19 are still lacking, and drug repositioning is a promising approach to address this problem. Here, we adopted a medical informatics approach to repositioning. We leveraged a large prospective cohort, the UK-Biobank (UKBB, N ~ 397,000), and studied associations of prior use of all level-4 ATC drug categories (N = 819, including vaccines) with COVID-19 diagnosis and severity. Effects of drugs on the risk of infection, disease severity, and mortality were investigated separately. Logistic regression was conducted, controlling for main confounders. We observed strong and highly consistent protective associations with statins. Many top-listed protective drugs were also cardiovascular medications, such as angiotensin-converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB), calcium channel blocker (CCB), and beta-blockers. Some other drugs showing protective associations included biguanides (metformin), estrogens, thyroid hormones, proton pump inhibitors, and testosterone-5-alpha reductase inhibitors, among others. We also observed protective associations by influenza, pneumococcal, and several other vaccines. Subgroup and interaction analyses were also conducted, which revealed differences in protective effects in various subgroups. For example, protective effects of flu/pneumococcal vaccines were weaker in obese individuals, while protection by statins was stronger in cardiovascular patients. To conclude, our analysis revealed many drug repositioning candidates, for example several cardiovascular medications. Further studies are required for validation.

Anti-COVID-19 Vaccination in Patients with Autoimmune-Autoinflammatory Disorders and Primary/Secondary Immunodeficiencies: The Position of the Task Force on Behalf of the Italian Immunological Societies. The Coronavirus disease 2019 (COVID-19) pandemic has represented an unprecedented challenge for humankind from health, economic, and social viewpoints. In February 2020, Italy was the first western country to be deeply hit by the pandemic and suffered the highest case/fatality rate among western countries. Brand new anti-COVID-19 vaccines have been developed and made available in <1-year from the viral sequence publication. Patients with compromised immune systems, such as autoimmune-autoinflammatory disorders (AIAIDs), primary (PIDs) and secondary (SIDs) immunodeficiencies, have received careful attention for a long time regarding their capacity to safely respond to traditional vaccines. The Italian Immunological Societies, therefore, have promptly faced the issues of safety, immunogenicity, and efficacy/effectiveness of the innovative

COVID-19 vaccines, as well as priority to vaccine access, in patients with AIADs, PIDs, and SIDs, by organizing an ad-hoc Task Force. Patients with AIADs, PIDs, and SIDs: (1) Do not present contraindications to COVID-19 vaccines if a mRNA vaccine is used and administered in a stabilized disease phase without active infection. (2) Should usually not discontinue immunosuppressive therapy, which may be modulated depending on the patient's clinical condition. (3) When eligible, should have a priority access to vaccination. In fact, immunizing these patients may have relevant social/health consequences, since these patients, if infected, may develop chronic infection, which prolongs viral spread and facilitates the emergence of viral variants.

Ophthalmic complications of COVID-19 vaccination.

Central retinal vein occlusion after mRNA SARS-CoV-2 vaccination: A case report. A central retinal vein occlusion (CRVO) case in a patient developed with sudden blurred vision in some hemifield areas of his left eye, maintaining 20/20 vision 15-days after the COVID-19 vaccination. Initial retinal findings were venous dilation and tortuosity with dispersing dot hemorrhages. Fluorescein angiography (FA) and optical coherence tomography (OCT) confirmed a non-ischemic CRVO diagnosis, and a complete blood panel was requested with average results. An intravitreal steroid dose was applied. A decrease in best-corrected visual acuity (BCVA) (20/30) with more intraretinal hemorrhages was documented. An intravitreal dose of bevacizumab and oral apixaban were added with a final BCVA of 20/20 with decreased hemorrhages. There is no specific causal relationship between COVID-19 vaccines and CRVO. Without previous risk factors and positive treatment response, this case may correlate the first COVID-19 vaccine dose and the event.

Bilateral paracentral acute middle maculopathy and acute macular neuroretinopathy following COVID-19 vaccination. A 35-year-old male patient presented with blurring and black spots in vision after 1 month of the second dose of Covishield vaccination. His visual acuity was 6/6; both eyes and anterior and posterior segment examinations were normal. The optical coherence tomography (OCT) showed multiple hyperreflective lesions involving the nerve fiber layer with back shadowing. In addition, there were hyperreflective spots in the ganglion cell layer and outer plexiform layer with focal loss of external limiting membrane and an intact inner segment/outer segment junction involving the posterior pole in both eyes. The patient was diagnosed with paracentral acute middle maculopathy (PAMM) and acute macular neuroretinopathy (AMN) and advised observation. PAMM and AMN are unreported manifestations following the COVID-19 vaccination.

Humoral immune response following SARS-CoV-2 mRNA vaccination concomitant to anti-CD20 therapy in multiple sclerosis. BACKGROUND: The immunogenicity of COVID-19 vaccine among patients receiving anti-CD20 monoclonal antibody (Ab) treatment has not been fully investigated. Detectable levels of SARS-CoV-2 immunoglobulin G (IgG) are believed to have a predictive value for immune protection against COVID-19 and is currently a surrogate indicator for vaccine efficacy. OBJECTIVE: To determine IgG Abs in anti-CD20 treated patients with multiple sclerosis (MS). METHOD: IgG Abs against SARS-CoV-2 spike receptor-binding domain were measured with the SARS-CoV-2 IgG II Quant assay (Abbott Laboratories) before and after vaccination (nÂ =Â 60). RESULTS: 36.7% of patients mounted a positive SARS-CoV-2 spike Ab response after the second dose of vaccine. Five patients (8.3%) developed Abs >264 BAU/mL, another 12 patients (20%) developed intermediate Abs between 54 BAU/mL and 264 BAU/mL and five patients (8.3%) had low levels <54 BAU/mL. Of all seropositive patients, 63.6% converted from seronegative to seropositive after the 2nd vaccine. CONCLUSION: Our study demonstrates decreased humoral response after BNT162b2 mRNA SARS-CoV-2 vaccine in MS patients receiving B-cell depleting therapy. Clinicians should advise patients treated with anti-CD20 to avoid exposure to SARS-CoV-2. Future studies should investigate the implications of a third booster vaccine in patients with low or absent Abs after vaccination.

Outcome After Organ Transplantation From Brain-dead Donors After a Cerebral Insult Following SARS-CoV-2 Vaccination Within the Eurotransplant Region.

Thyroid Eye Disease Following COVID-19 Vaccine in a Patient With a History Graves' Disease: A Case Report. A 50-year-old woman with a history of controlled Graves' disease without clinical ophthalmopathy presents with 2 months of left more than right periorbital swelling and proptosis. Her eye symptoms and signs began 3 days following her second vaccination against the COVID-19 virus. Orbital imaging, elevated thyroid stimulating immunoglobulin, and negative systemic work up for other diseases were consistent with a diagnosis of active thyroid eye disease. The temporal relationship to her vaccination was likely consistent with autoimmune/inflammatory syndrome associated with adjuvants. Clinicians should remind patients of the symptoms and signs of thyroid eye disease and to seek appropriate medical and ophthalmic advice if they occur after the COVID-19 vaccine.

An analysis of antibody responses and clinical sequalae of the Sinopharm HB02 COVID19 vaccine in dialysis patients in the United Arab Emirates. AIM: To establish the responses to the Sinopharm HB02 COVID-19 vaccination in the dialysis population, which are not well established. We examined the humoral responses to the Sinopharm COVID vaccine in haemodialysis patients. METHODS: Standard vaccinations (two doses at interval of ~21â€‰days) were given to all consenting haemodialysis patients on dialysis (nÂ =Â 1296). We measured the antibody responses at 14-21â€‰days after the second vaccine to define the development of anti-spike antibodies >15â€‰AU/ml after vaccination and observed the clinical effects of vaccination. RESULTS: Vaccination was very well tolerated with few side-effects. In those who consented to antibody measurements, (nÂ =Â 446) baseline sampling showed 77 had positive antibodies, yet received full vaccination without any apparent adverse events. Positive anti-spike antibodies developed in 50% of the 270 baseline negative patients who had full sampling, compared with 78.1% in the general population. COVID infection continues to occur in both vaccinated and unvaccinated individuals, but in the whole group vaccination appears to have been associated with a reduction in the case fatality rate. CONCLUSION: The humoral immune responses to standard HB02 vaccination schedules are attenuated in a haemodialysis cohort, but likely the vaccine saves lives. We suggest that an enhanced HB02 vaccination course or antibody checking may be prudent to protect this vulnerable group of patients. We suggest a booster dose of this vaccine at 3Â months should be given to all dialysis patients, on the grounds that it is well tolerated even in those with good antibody levels and there may be a survival advantage.

SARS-COV-2 vaccination with BNT162B2 in renal transplant patients: Risk factors for impaired response and immunological implications. Solid organ transplant patients are at a higher risk for poor CoronaVirus Disease-2019 (COVID-19)-related outcomes and have been included as a priority group in the vaccination strategy worldwide. We assessed the safety and efficacy of a two-dose vaccination cycle with mRNA-based COVID-19 vaccine (BNT162b2) among 82 kidney transplant outpatients followed in our center in Rome, Italy. After a median of 43 post-vaccine days, a SARS-CoV-2 anti-Spike seroprevalence of 52.4% (nÂ =Â 43/82) was observed. No impact of the vaccination on antibody-mediated rejection or graft function was observed, and no significant safety concerns were reported. Moreover, no de novo HLA-donor-specific antibodies (DSA) were detected during the follow-up period. Only one patient with pre-vaccination HLA-DSA did not experience an increased intensity of the existing HLA-DSA. During the follow-up, only one infection (mild COVID-19) was observed in a patient after receiving the first vaccine dose. According to the multivariable logistic regression analysis, lack of seroconversion after two-dose vaccination independently associated with patient age â‰¥60Â years (ORÂ =Â 4.50; PÂ =Â .02) and use of anti-metabolite as an immunosuppressant drug (ORÂ =Â 5.26; PÂ =Â .004). Among younger patients not taking anti-

metabolites, the seroconversion rate was high (92.9%). Further larger studies are needed to assess the best COVID-19 vaccination strategy in transplanted patients.
Prevalence of thrombocytopenia, anti-platelet factor 4 antibodies and D-dimer elevation in Thai people After ChAdOx1 nCoV-19 vaccination. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare distinctive syndrome characterized by unusual site thrombosis accompanied by thrombocytopenia after ChAdOx1 nCoV-19 vaccination. Platelet-activating anti-platelet factor 4-dependent antibodies (anti-PF4 Abs) were detected in most cases of VITT. To date, data from Asian countries are lacking. OBJECTIVES: To determine the prevalence of thrombocytopenia, anti-PF4 Abs, and D-dimer elevation in Thai people administered the ChAdOx1 vaccine. PATIENTS/METHODS: A total of 521 vaccinated and 146 nonvaccinated subjects were enrolled. Blood samples were collected to determine platelet counts, anti-PF4 Abs using ELISA and D-dimer levels 5 to 30Â days after the first vaccination. RESULTS: None of the participants developed thrombocytopenia or had significantly decreased platelet counts from baseline after ChAdOx1 vaccination. The frequencies of anti-PF4 Abs between vaccinated (16/521; 3.1%; 95% confidence interval [CI], 1.8-4.9) and nonvaccinated Thai people (6/146; 4.1%; 95% CI, 1.5-8.7) were similar. None of the detectable anti-PF4 Abs activated platelets in vitro. The average D-dimer levels between vaccinated and control groups were similar (282.2Â Â±Â 286.3 vs 267.8Â Â±Â 219.3Â ng/mL; PÂ =Â 0.58). Four vaccinated and one nonvaccinated participants had markedly elevated D-dimer levels >2000Â ng/mL without detectable anti-PF4 Abs. Imaging studies of these asymptomatic subjects revealed incidental pulmonary embolism in a vaccinated elderly woman. CONCLUSIONS: This study demonstrated a low prevalence of thrombocytopenia and pathogenic anti-PF4 Abs after ChAdOx1 vaccination. D-dimer testing revealed no significant coagulation activation. Routine tests for platelet counts, anti-PF4 Abs, and D-dimer levels are not recommended for VITT screening without clinical suspicion.
Disseminated varicella-zoster virus infections following messenger RNA-based COVID-19 vaccination.
Sex Differences in Adverse Reactions to an Inactivated SARS-CoV-2 Vaccine Among Medical Staff in China. Objective: We investigated whether there were sex differences in adverse reactions to an inactivated SARS-CoV-2 vaccine among medical staff in China. Methods: From 24 February to 7 March 2021 an online cross-sectional survey was conducted with a self-administered COVID-19 vaccine questionnaire among medical staff in Taizhou, China. In total, 1397 interviewees (1,107 women and 290 men) participated in the survey. Results: In our study, 178 (16.1%) women and 23 (7.9%) men reported adverse reactions following their first vaccination, and 169 (15.3%) women and 35 (12.1%) men reported adverse reactions following their second vaccination. After adjusting for confounding factors, adverse reactions to other vaccines, worry about adverse reactions, knowledge of the inactivated vaccine being used in the hospital, taking the vaccine for one's family proactively and receiving an influenza vaccination were significantly related to adverse reactions to both injections in women. In contrast, in men, concerns about adverse reactions independently increased the risk of adverse reactions following either vaccination, and a history of adverse reactions to other vaccines also increased the risk of adverse reactions to both injections. Conclusions: Sex differences in the frequency of reported adverse reactions to an inactivated SARS-CoV-2 vaccine and potential factors were demonstrated in a sample of medical staff.
A comprehensive insight on the COVID-19 vaccine candidates. The world is currently facing a pandemic triggered by the novel corona virus (SARS - CoV2), which causes a highly infectious infection that predominantly affects the lungs, resulting in a variety of clinical symptoms some cases may be asymptomatic while others may result in to severe respiratory disorder, if the infection is left unattended it may result in multi-organ failure and eventually death of the patient. The transmission of infection is by droplet and fomites of the infected person. The incubation period of virus is from 2

to 14 days. Most common symptoms resemble flu-like but later progress to pneumonia along with dyspnoea and worsening of oxygen saturation, thus requiring ventilator support. The diagnostic modalities include Reverse transcriptase real time PCR (Quantitative Reverse transcriptase polymerase chain reaction) which is recommended method used for diagnosis of the COVID-19 infection using oro-pharyngeal or nasopharyngeal swabs of the patients. Recently serological tests for antigen and antibody detection has been approved by ICMR. Till now, nine COVID-19 vaccines are granted emergency approval for prevention and for the management of infection symptomatic and supportive measures are being adopted. Globally major pharmaceutical firms are engrossed for development of a potent vaccine candidate. This review highlights on various vaccine candidates under clinical trials.

A case of Guillain-Barre syndrome following Pfizer COVID-19 vaccine. Since the first-reported case of Severe Acute Respiratory Distress Syndrome-Coronavirus 2 in December 2019, COVID-19 has caused a global pandemic associated with significant morbidity and mortality. After a year of advances in vaccine research and development, three vaccines for the prevention of COVID-19 (manufactured by Pfizer, Moderna and Johnson & Johnson's Janssen Biotech) are approved for use in the USA. We report the first case of Guillain-Barre Syndrome after receiving the second dose of the Pfizer COVID-19 vaccine, in a 42-year-old woman presenting with progressive ascending weakness and paresthesias. Diagnostic workup demonstrated cytoalbuminologic dissociation on cerebrospinal fluid analysis with confirmatory evidence of early demyelinating electrodiagnostic features on nerve conduction study and an extensive serological workup being negative for other viral or autoimmune disease triggers. Management included administration of intravenous immunoglobulin (total of 2Â gm/kg), with frequent monitoring of forced vital capacity and negative inspiratory force. A longitudinal risk profile of neurologic complications caused from COVID-19 vaccines remains limited, and prompt recognition of potential neurological complications from the COVID-19 vaccine is of interest to public health.

Factors influencing COVID-19 vaccination intention: The roles of vaccine knowledge, vaccine risk perception, and doctor-patient communication. OBJECTIVE: This study aims to investigate factors influencing COVID-19 vaccination intention in the United States. METHODS: A cross-sectional survey was conducted with 800 respondents recruited from an online panel managed by a survey company. Path analysis was employed to examine the relationships between the study variables. RESULTS: First, perceived susceptibility to COVID-19 vaccine side effects was negatively associated with vaccination intention whereas perceived severity did not show any significant impact. Second, vaccine-related knowledge was not directly related to vaccination intention, but it had an indirect and positive effect on vaccination intention via decreasing perceived susceptibility. Third, doctor-patient communication strengthened the negative effect of vaccine knowledge on perceived susceptibility and severity. CONCLUSION: The results of this study offer insights on how to increase people's vaccination intention and reduce their psychological concerns when making COVID-19 vaccine-related decisions. PRACTICE IMPLICATIONS: Government agencies should actively promote the effectiveness and importance of vaccination, while addressing concerns about vaccine safety in the public; Health initiatives also need to enhance the level of knowledge about COVID-19 vaccines through various media channels; Doctors can start the conversations about COVID-19 vaccination with their patients at the point of care and/or via online communication platforms.

Seroconversion After Coronavirus Disease 2019 Vaccination in Patients Awaiting Liver Transplantation: Fact or Fancy? Chronic liver disease increased the risk of severe coronavirus disease 2019 (COVID-19). Trials to assess efficacy/safety of COVID-19 vaccines in liver disease are underway. We evaluated the humoral immune response and safety of anti-COVID-19 vaccination among patients waiting liver transplantation (LT). We enrolled all pre-LT adults who completed anti-

COVID-19 vaccination between January 2021-August 2021 as study group. Patients with histories of COVID-19 received 1 vaccine dose, and all others received 2 doses. Patients were tested for COVID-19 immunoglobulin G (IgG) within 1 and 2 months after vaccination. Safety was evaluated with telephone interviews/outpatient visits. A control group of 30 healthcare workers who underwent vaccination in January 2021 and tested for IgG after 4 months was included. In the 89 pre-LT patients, at T1 (23 days after vaccination), seroconversion rate was 94.4%, and median IgG value was 1980 binding antibody units/mL (interquartile range 646-2080), and at T2 (68 days after vaccination) was 92.0%, with IgG value of 1450 (577-2080); (T1 versus T2, P = 0.38). In the 10/89 patients who received 1 vaccine dose, the median IgG value was 274 (68-548) before vaccine (T0), 2080 (1165-2080) at T1, and 2030 (964-2080) at T2 (T0 versus T1, P = 0.03; T1 versus T2, P = 0.99). All controls tested positive at 4 months after vaccination, with a median value of 847 (509-1165; P < 0.001 versus T1 and P = 0.04 versus T2 in the study group). No serious adverse event was reported in both groups. Our data from 89 pre-LT patients suggest a high rate of immunization (94.4%) after a median time of 23 days from safe COVID-19 vaccine. None of the patients developed COVID-19.
HLA and PF4 antibody production after adenoviral vector SARS-CoV-2 vaccination.
Skin Adverse Reactions to Novel Messenger RNA Coronavirus Vaccination: A Case Series. Vaccines are actually the most effective strategy to control the COVID-19 spread and reduce mortality, but adverse reactions can occur. Skin involvement with novel messenger RNA coronavirus vaccines seems frequent but is not completely characterized. A real-world experience in the recent vaccination campaign among health care workers in Sardinia (Italy) is reported. In over a total of 1577 persons vaccinated, 9 cases of skin adverse reactions were observed (0.5%). All reactions have been reported to the Italian Pharmacovigilance Authority. Eight occurred in women (mean age 46 years), and five were physicians and four nurses. All patients had a significant allergology history but not for the known vaccine excipients. After dose one, no injection site reactions were observed, but widespread pruritus (n = 3), mild facial erythema (n = 1), and maculopapular rash (n = 3) occurred in the following 24-48 h in three patients. These three patients were excluded from the second dose. Of the remaining six patients, one developed mild anaphylaxis within the observation period at the vaccination hub and five delayed facial erythematous edema and maculopapular lesions, requiring antihistamines and short-course corticosteroid treatment. Spontaneous reporting is paramount to adjourning vaccination guidance and preventive measures in order to contribute to the development of a safe vaccine strategy. Dermatologist' expertise might provide better characterization, treatment, and screening of individuals at high risk of skin adverse reactions.
A focused review on technologies, mechanisms, safety, and efficacy of available COVID-19 vaccines. >20Â months has been passed since the detection of the first cases of SARS-CoV-2 infection named COVID-19 from Wuhan city of China. This novel coronavirus spread rapidly around the world and became a pandemic. Although different therapeutic options have been considered and approved for the management of COVID-19 infection in different stages of the disease, challenges in pharmacotherapy especially in patients with moderate to severe COVID-19 and with underlying diseases have still remained. Prevention of infection through public vaccination would be the only efficient strategy to control the morbidity and mortality caused by COVID-19. To date, several COVID-19 vaccines using different platforms including nucleic acid-based vaccines, adenovirus-based vaccines, protein-based vaccines, and inactivated vaccines have been introduced among which many have received approval for prevention against COVID-19. In this comprehensive review, available COVID-19 vaccines have been discussed. The mechanisms, safety, efficacy, dosage, dosing intervals, possible adverse reactions, storage, and coverage of these four different vaccine platforms against SARS-CoV-2 variants have been discussed in detail and summarized in tabular format for ease of comparison and conclusion. Although each COVID-19 vaccine has various advantages and

disadvantages over the others, accessibility and affordability of approved vaccines by the official health organizations, especially in developing countries, would be essential to terminate this pandemic. The main limitation of this study was the lack of access to the clinical data on available COVID-19 vaccines developed in Eastern countries since the data on their efficacy, safety, and adverse reactions were limited.
Adverse Ocular Events following COVID-19 Vaccination.
The syndrome of inappropriate antidiuresis after vaccination against COVID-19: case report. BACKGROUND: The Syndrome of Inappropriate Antidiuresis (SIADH) has been described to be associated with a multitude of conditions and medications, including the severe acute respiratory syndrome coronavirus 2. We describe the case of a patient with newly diagnosed and symptomatic SIADH after receiving the second COVID-19 vaccination not explained otherwise. CASE PRESENTATION: A 79-year-old male person was admitted to the emergency department due to a worsening of his general health state expressed by weakness, fatigue and anorexia. Vital signs and clinical findings were normal, in particular the patient was considered to be euvolemic. Laboratory investigations revealed a serum sodium of 117Â mmol/L, a serum osmolality of 241 mosm/kg and a urea of 1.2Â mmol/L with creatinine within normal range. Urine chemistry showed a urine osmolality of 412 mosm/kg and urine sodium of 110Â mmol/L. TSH, C-reactive protein, and basal cortisol levels were normal. Under therapy with balanced crystalloid fluids, hyponatremia worsened and in absence of diuretic medications, diagnosis of SIADH was made. Since fluid restriction was not sufficiently effective, oral urea was administered. Under this therapy regimen hyponatremia resolved. CONCLUSIONS: Local as well as systemic reactions have been described for the new mRNA-based vaccines including pain and fever. Therefore, it is imaginable that the vaccine might trigger SIADH in some patients.
AstraZeneca COVID-19 vaccine and Guillain- BarrÃ© Syndrome in Tasmania: A causal link? The emergence of the coronavirus 2019 (COVID-19) pandemic has presented an unprecedented global challenge. Vaccines against COVID have been developed to date. Covid-19 has been linked with the development of Guillain-Barre Syndrome (GBS), a rare immune-mediated demyelinating neuropathy. We report three cases of Guillain-Barre Syndrome and one case of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), presenting to a Tasmanian hospital, and review 15 other reported cases and discuss likely immunopathology. Nearly all reported cases of post-COVID-19 vacciation inflammatory demyelinating polyneuropathy are linked to AstraZeneca vaccination and a variant with bifacial weakness is the most reported form of GBS globally.
Severe COVID-19 vaccine associated myocarditis: Zebra or unicorn?
New-onset systemic lupus erythematosus beginning as class V lupus nephritis after COVID-19 vaccination.
Alopecia areata after ChAdOx1 nCoV-19 vaccine (Oxford/AstraZeneca): a potential triggering factor?
Parsonage-Turner Syndrome After SARS-CoV-2 BNT162b2 Vaccine: A Case Report. CASE: Parsonage-Turner syndrome, also known as brachial neuritis or neuralgic amyotrophy, is characterized by sudden-onset pain and subsequent weakness of the shoulder. Known precipitating factors include viral and bacterial infections and certain immunizations. Isolated cases after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection have been reported. We report the case of a 66-year-old woman with right shoulder dysfunction and medial scapular winging after immunization with the SARS-CoV-2 BNT162b2 vaccine (Pfizer). CONCLUSION: After physical therapy, the patient resumed her normal activities of daily living. Findings from this case represent the first known documentation of Parsonage-Turner syndrome after SARS-CoV-2 BNT162b2 vaccination.
Ocular Adverse Events After COVID-19 Vaccination. PURPOSE: The COVID-19 pandemic has galvanized the development of new vaccines at an unprecedented pace. Since the widespread

implementation of vaccination campaigns, reports of ocular adverse effects after COVID-19 vaccinations have emerged. This review summarizes ocular adverse effects possibly associated with COVID-19 vaccination, and discusses their clinical characteristics and management. METHODS: Narrative Literature Review. RESULTS: Ocular adverse effects of COVID-19 vaccinations include facial nerve palsy, abducens nerve palsy, acute macular neuroretinopathy, central serous retinopathy, thrombosis, uveitis, multiple evanescent white dot syndrome, Vogt-Koyanagi-Harada disease reactivation, and new-onset Graves' Disease. Studies in current literature are primarily retrospective case series or isolated case reports - these are inherently weak in establishing association or causality. Nevertheless, the described presentations resemble the reported ocular manifestations of the COVID-19 disease itself. Hence, we hypothesize that the human body's immune response to COVID-19 vaccinations may be involved in the pathogenesis of the ocular adverse effects post-COVID-19 vaccination. CONCLUSION: Ophthalmologists and generalists should be aware of the possible, albeit rare, ocular adverse effects after COVID-19 vaccination.
Herpes zoster after COVID-19 vaccination-Can the vaccine reactivate latent zoster virus?
Limited and Short-Lasting Virus Neutralizing Titers Induced by Inactivated SARS-CoV-2 Vaccine. In vitro determination of severe acute respiratory syndrome coronavirus 2 neutralizing antibodies induced in serum samples from recipients of the CoronaVac vaccine showed a short protection period against the original virus strain and limited protection against variants of concern. These data provide support for vaccine boosters, especially variants of concern circulate.
The clinical correlates of vaccine-induced immune thrombotic thrombocytopenia after immunisation with adenovirus vector-based SARS-CoV-2 vaccines. We are at a critical stage in the COVID-19 pandemic where vaccinations are being rolled out globally, in a race against time to get ahead of the SARS-CoV-2 coronavirus and the emergence of more highly transmissible variants. A range of vaccines have been created and received either emergency approval or full licensure. To attain the upper hand, maximum vaccine synthesis, deployment, and uptake as rapidly as possible is essential. However, vaccine uptake, particularly in younger adults is dropping, at least in part fuelled by reports of rare complications associated with specific vaccines. This review considers how vaccination with adenovirus vector-based vaccines against the SARS-CoV-2 coronavirus might cause rare cases of thrombosis and thrombocytopenia in some recipients. A thorough understanding of the underlying cellular and molecular mechanisms that mediate this syndrome may help to identify methods to prevent these very rare, but serious side effects. This will also help facilitate the identification of those at highest risk from these outcomes, so that we can work towards a stratified approach to vaccine deployment to mitigate these risks.
Cross-reactive Antibody Response to mRNA SARS-CoV-2 Vaccine After Recent COVID-19-Specific Monoclonal Antibody Therapy. The efficacy of coronavirus disease 2019 (COVID-19) vaccines administered after COVID-19-specific monoclonal antibody is unknown, and "antibody interference" might hinder immune responses leading to vaccine failure. In an institutional review board-approved prospective study, we found that an individual who received mRNA COVID-19 vaccination <40 days after COVID-19-specific monoclonal antibody therapy for symptomatic COVID-19 had similar postvaccine antibody responses to SARS-CoV-2 receptor binding domain (RBD) for 4 important SARS-CoV-2 variants (B.1, B.1.1.7, B.1.351, and P.1) as other participants who were also vaccinated following COVID-19. Vaccination against COVID-19 shortly after COVID-19-specific monoclonal antibody can boost and expand antibody protection, questioning the need to delay vaccination in this setting. TRIAL REGISTRATION: The St. Jude Tracking of Viral and Host Factors Associated with COVID-19 study; NCT04362995; https://clinicaltrials.gov/ct2/show/NCT04362995.
Case Report: Pityriasis Rosea-Like Eruption Following COVID-19 Vaccination. Vaccination is one of the cornerstones in the efforts towards ending the coronavirus disease 2019 (COVID-19) pandemic.

However, several adverse effects of COVID-19 vaccination have been identified. Pityriasis rosea (PR)-like eruption is a rare cutaneous complication of immunization. To the best of our knowledge, there have been no reports of PR-like eruptions following inoculation with Oxford/AstraZeneca ChAdOx1 nCoV-19 (AZD1222) vaccine. Here, we described a case of PR-like eruption that developed 14 days after Oxford/AstraZeneca vaccination in a 52-year-old Thai woman with glioblastoma. Treatment with topical 0.1% triamcinolone acetonide twice per day showed partial response after seven days. Despite this rare complication, our report highlights that the presence of PR-like eruption is not a contraindication for subsequent vaccinations.

COVID-19 Vaccine: Side Effects After the First Dose of the Oxford AstraZeneca Vaccine Among Health Professionals in Low-Income Country: Ethiopia. PURPOSE: The Oxford-AstraZeneca is one of COVID-19 vaccine which is expected to be mass-produced and plays a critical role in controlling the pandemic that the globe faced. Ethiopia launched the AstraZeneca vaccination and planned to vaccinate 20% of the population by the end of 2021. Health care professionals are one of the eligible groups of the community to receive the vaccine with priority. Although individuals are advised to take the vaccine to protect themselves and the people around them from COVID-19 infection, many are doubtful about the consequences of the vaccine. So, this study assessed the immediate symptoms associated with taking the Oxford-AstraZeneca COVID-19 vaccine. METHODS: This online study was conducted from April 15 to 30, 2021 at a national level across health care providers who took their first dose of Oxford-AstraZeneca vaccine in Ethiopia. RESULTS: There were 672 study participants engaged in this study and around 75.8% of health care providers who took the vaccine had injection site symptoms like pain (65.48%) and tenderness (57.89%). Most of them (60%) developed their injection site symptom within 12 hours after vaccination and the symptoms lasted for about 24-72 hours on most (63.53%) of the participants. Mild symptoms were identified among 70.98% of the study participants; tiredness and headache were the most reported symptoms with 52.08% and 50.15%, respectively. Only 6.1% of participants reported severe symptoms. CONCLUSION: As like that of other vaccines, the Oxford-AstraZeneca COVID-19 vaccine has some adverse effects and most side effects peaked within the first 24 hours following vaccination and usually lasted 1-3 days. Severe symptoms were uncommon, but they were found to be a major reason why vaccine recipients did not recommend it to others and did not plan to take their second dose. After receiving the COVID-19 vaccination, recipients should be advised about potential vaccine symptoms, how to handle them, and when and where to seek additional guidance if necessary.

Rare case of COVID-19 vaccine-associated intracranial haemorrhage with venous sinus thrombosis. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a relatively novel term which describes patients who have developed a low platelet count and prothrombotic tendencies secondary to receiving a vaccine. The concept has been derived from the well-established phenomenon of heparin-induced thrombocytopenia, and several cases of VITT have now been reported in patients who have received the AstraZeneca (ChAdOx1 nCov-19) vaccine. Unfortunately, some of these patients have gone on to develop intracranial venous sinus thrombosis. We present a case of VITT-associated sinus thrombosis secondary to the AstraZeneca (ChAdOx1 nCov-19) vaccine, which was complicated by a large intracerebral haemorrhage.

COVID-19 Vaccines and the Skin: The Landscape of Cutaneous Vaccine Reactions Worldwide. In 2021, we entered a new phase of the COVID-19 pandemic. As mass vaccinations are underway and more vaccines are approved, it is important to recognize cutaneous adverse events. We review the dermatologic manifestations of COVID-19 vaccines as reported in clinical trial data and summarize additional observational reports of skin reactions to COVID-19 vaccines. Early-onset local injection reactions were the most common cutaneous side effects observed in clinical trials; delayed injection reactions were the most common cutaneous side effect reported outside of clinical trials.

Understanding the landscape of cutaneous manifestations to COVID-19 vaccines is key to providing appropriate vaccine guidance.
Use of Pfizer-BioNTech COVID-19 Vaccine in Persons Aged â‰¥16 Years: Recommendations of the Advisory Committee on Immunization Practices - United States, September 2021. The Pfizer-BioNTech COVID-19 vaccine (BNT162b2) is a lipid nanoparticle-formulated, nucleoside mRNA vaccine encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. Vaccination with the Pfizer-BioNTech COVID-19 vaccine consists of 2 intramuscular doses (30 Î¼g, 0.3 mL each) administered 3 weeks apart. In December 2020, the vaccine was granted Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) as well as an interim recommendation for use among persons aged â‰¥16 years by the Advisory Committee on Immunization Practices (ACIP) (1). In May 2021, the EUA and interim ACIP recommendations for Pfizer-BioNTech COVID-19 vaccine were extended to adolescents aged 12-15 years (2). During December 14, 2020-September 1, 2021, approximately 211 million doses of Pfizer-BioNTech COVID-19 vaccine were administered in the United States.* On August 23, 2021, FDA approved a Biologics License Application for use of the Pfizer-BioNTech COVID-19 vaccine, Comirnaty (Pfizer, Inc.), in persons aged â‰¥16 years (3). The ACIP COVID-19 Vaccines Work Group's conclusions regarding the evidence for the Pfizer-BioNTech COVID-19 vaccine were presented to ACIP at a public meeting on August 30, 2021. To guide its deliberations regarding the Pfizer-BioNTech COVID-19 vaccine, ACIP used the Evidence to Recommendation (EtR) Framework,(â€) and incorporated a Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.(Â§) In addition to initial clinical trial data, ACIP considered new information gathered in the 8 months since issuance of the interim recommendation for Pfizer-BioNTech COVID-19 vaccine, including additional follow-up time in the clinical trial, real-world vaccine effectiveness studies, and postauthorization vaccine safety monitoring. The additional information increased certainty that benefits from prevention of asymptomatic infection, COVID-19, and associated hospitalization and death outweighs vaccine-associated risks. On August 30, 2021, ACIP issued a recommendation(Â¶) for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged â‰¥16 years for the prevention of COVID-19.
Covid-19 vaccination during the third trimester of pregnancy: rate of vaccination and maternal and neonatal outcomes, a multicentre retrospective cohort study. OBJECTIVE: To evaluate the impact of Covid-19 vaccination (Pfizer-BioNTech BNT162b2) during the third trimester of pregnancy on maternal and neonatal outcomes. DESIGN: A multicentre, retrospective computerised database. POPULATION: Women who gave birth at >24â€‰weeks of gestation in Israel, between January and April 2021, with full records of Covid-19 disease and vaccination status. METHODS: Women who received two doses of the vaccine were compared with unvaccinated women. Women who were recorded as having disease or a positive Covid-19 polymerase chain reaction (PCR) swab during pregnancy or delivery were excluded from both study groups. Univariate analysis was followed by multivariate logistic regression. MAIN OUTCOME MEASURES: Composite adverse maternal outcomes. Secondary outcomes were vaccination rate and composite adverse neonatal outcomes. RESULTS: The overall uptake of one or both vaccines was 40.2%; 712 women who received two doses of the Covid-19 vaccine were compared with 1063 unvaccinated women. Maternal composite outcomes were comparable between the groups; however, women who received the vaccine had higher rates of elective caesarean deliveries (CDs) and lower rates of vacuum deliveries. An adjusted multivariable logistic regression analysis demonstrated that Covid-19 vaccination was not associated with maternal composite adverse outcome (aORâ€‰0.8, 95%â€‰CI 0.61-1.03); a significant reduction in the risk for neonatal composite adverse outcomes was observed (aORâ€‰0.5, 95%â€‰CI 0.36-0.74). CONCLUSIONS: In a motivated population covered by a National Health Insurance Plan, we found a 40.2% rate of vaccination for the Covid-19 vaccine during the third trimester of pregnancy, which was

not associated with adverse maternal outcomes and, moreover, decreased the risk for neonatal adverse outcomes. TWEETABLE ABSTRACT: Covid-19 vaccine during pregnancy is safe for both mother and fetus.

A narrative review and clinical anatomy of herpes zoster infection following COVID-19 vaccination. INTRODUCTION: In this review, cases of herpes zoster (HZ) infection following receipt of COVID-19 vaccines will be analyzed. We also present two cases of oral HZ following the COVID-19 vaccine and discuss this clinical anatomy. MATERIALS AND METHODS: A database search using PubMed was conducted in August 2021 and 20 articles were found to be eligible for review. Patient data and vaccine information were analyzed. In addition, two cases of oral HZ infection following the receipt of COVID-19 vaccines are presented. RESULTS: A total of 399 cases were identified. The affected dermatomes mimicked the regular distribution of HZ. For the dermatomes of the face, the various reports used different ways to describe the areas involved; CNV, CNV1, CNV2, CNV3, lower jaw, forehead, and under the eyebrow (CNV, 2 cases; CNV1, 4 cases; CNV2, 3 cases; and CNV3, 3 cases). Some patients who had a history of varicella zoster virus vaccination had HZ following the COVID-19 vaccination. Two patients with oral HZ following vaccination were found to have involvement of the greater palatine nerve. CONCLUSIONS: Vaccine-related HZ cases have been reported worldwide. Although many studies with a larger number of cases are ongoing, detailed information can be obtained from case reviews as reported herein.

Comment on: Herpes zoster following BNT162b2 mRNA Covid-19 vaccination in patients with autoimmune inflammatory rheumatic diseases: a case series: reply.

Comment on: Herpes zoster following BNT162b2 mRNA Covid-19 vaccination in patients with autoimmune inflammatory rheumatic diseases: a case series.

Association of Disease-Modifying Treatment and Anti-CD20 Infusion Timing With Humoral Response to 2 SARS-CoV-2 Vaccines in Patients With Multiple Sclerosis. This cohort study investigates the humoral response to 2 SARS-CoV-2 messenger RNA vaccines in patients with multiple sclerosis treated with fingolimod and ocrelizumab.

A Case of Hypophysitis Following Immunization With the mRNA-1273 SARS-CoV-2 Vaccine. The emergence of a novel coronavirus and global pandemic raised the need for the rapid development of new vaccines to reduce the morbidity and mortality associated with Covid-19. Common side effects of these vaccines such as myalgia, arthralgia, nausea, fatigue, and injection site reaction are usually self-resolving. Recognition of other potential adverse effects of these novel vaccines is important due to their rapid and widespread distribution. We report a case of a 51-year-old man admitted to Parkland Memorial Hospital with headache, nausea, vomiting, malaise, and diffuse arthralgias 3 days after he received his second mRNA-1273 SARS-CoV-2 vaccination. He was found to have hyponatremia and a low serum cortisol level. Further workup revealed hypopituitarism with central hypothyroidism, hypogonadism, and a subnormal response to cosyntropin. Magnetic resonance imaging revealed a diffusely enlarged pituitary gland consistent with acute hypophysitis. The patient responded well to glucocorticoid and thyroid hormone supplementation and was discharged after 2 days in the hospital. This is the first reported case of hypopituitarism potentially associated with Covid-19 immunization.

Immunological Response Against SARS-COV-2 After BNT162b2 Vaccine Administration Is Impaired in Allogeneic but Not in Autologous Stem Cell Transplant Recipients. The efficacy of Covid-19 vaccine in hematopoietic stem cell transplantation (HSCT) recipients is still unknown. We planned a prospective study to evaluate the immune response after the administration of Covid-19 vaccine in HSCT recipients. Fifty patients previously submitted to HSCT (38 autologous and 12 allogeneic) received the mRNA-based SARS-CoV-2 vaccine BNT162b2 (Pfizer-BioNTech). Serum samples of all patients were tested for SARS-CoV-2 IgG against the Spike glycoprotein, 30 days after the second

dose of vaccine. Antibody response was compared to a control group of 45 healthy subjects. Of the 50 patients tested, 12 did not develop any antibody response, including 6 patients undergoing autologous (16%) and 6 allogeneic HSCT (50%). Cyclosporine administration in allogeneic recipients and prior administration of Rituximab in the autologous setting correlated with lower antibody titers ($p < 0.0003$ and $p=0.000$, respectively). Flow cytometry of peripheral blood samples, performed 30 days after the vaccination, showed a significant correlation between the antibody response to Sars-COV2 and an increased number in CD19+ B lymphocytes ($p = 0.0003$) and CD56+ natural killer (NK) cells ($p = 0.00$). In conclusion, prior Rituximab before autologous HSCT and cyclosporine administration after allogeneic HSCT negatively affected the antibody response to Sars-COV2 vaccine, possibly due to their immunosuppressive action on CD20 +B cells and T cells, respectively. The correlation between seroconversion to Sars-COV2 and higher number of CD19 + B cells and CD56+ NK cells, suggests a central role for B and NK cells in the development of COVID-19 immunity after vaccination with a mRNA-based platform.

Recurrence of Thrombotic Thrombocytopenic Purpura after mRNA-1273 COVID-19 Vaccine Administered Shortly after COVID-19. Thrombotic thrombocytopenic purpura (TTP) is a potentially life-threatening consumptive coagulopathy requiring emergent diagnosis and timely treatment. It is characterized by microangiopathic hemolytic anemia and thrombocytopenia with the development of microthrombi caused by inherited or acquired deficiency of the von Willebrand factor-cleaving protease ADAMTS13 and resulting end-organ damage. Most of the cases are the result of acquired deficiency of ADAMTS13, for which the exact etiology is unknown but reported to be related to various autoimmune disorders, infections, and medications. Our case report features of a patient with a history of idiopathic thrombocytopenic purpura and thrombotic thrombocytopenic purpura, who developed a recurrence of TTP 5â€‰days after his first dose of the mRNA Coronavirus disease 2019 (COVID-19) vaccine (mRNA-1273 vaccine) in the setting of recent COVID-19. The close temporal association between vaccine administration, recent COVID-19, and relapse of remitted TTP raises concern for an enhanced immune reaction to COVID-19 vaccine in the setting of recent COVID-19 and underlying autoimmune disease. The association is not absolute, but given the novelty of COVID-19 and the mRNA COVID-19 vaccine and the relapse timing, it leads us to pose this hypothesis. Vaccine distribution to a larger and more diverse population will allow for an increased rate of adverse event reporting. This case report exemplifies potential safety issues that may be encountered with new vaccine administration in patients with recent COVID-19 and underlying autoimmune disease. There are no specific recommendations for COVID-19 vaccine administration in such patients.

Trends, Uptake, and Predictors of Influenza Vaccination Among Healthcare Practitioners During the COVID-19 Pandemic Flu Season (2020) and the Following Season (2021) in Saudi Arabia. BACKGROUND: HealthcareÂ practitioners (HCPs) are at high risk of influenza. Seasonal influenza vaccines can reduce influenza-associated morbidity in healthcare settings, but despite mandatory influenza vaccination in the Kingdom of Saudi Arabia, the vaccination uptake rate among HCPs is below expectations. This study investigated vaccination trends from 2017 to 2020 to identify factors affecting vaccination among HCPs during the COVID-19 pandemic flu and subsequent seasons. METHODS: Cross-sectional study among HCPs was conducted in January 2021. A structured questionnaire was shared via social media. Vaccine uptake predictors were identified using descriptive statistics and logistic regression models (p-value 0.05). RESULTS: A total of 424 HCPs (118 physicians and 306 nurses) completed the questionnaire. Vaccine uptake increased from 2017 to 2019 (45% to 52% to 62%) but fell (to 59%) during the 2020 COVID-19 pandemic flu season. Multivariable analysis indicated participants >40 years old (AOR 3.09, 95% CI 1.64-5.83), female (AOR 1.74, 95% CI 1.13-2.67), non-Saudi (AOR 2.62, 95% CI 1.72-4.01), nurses (AOR 2.70, 95% CI 1.75-4.17),

and who possessed accurate knowledge of the flu vaccine efficacy duration (AOR 3.04, 95% CI 1.87-4.94) were more likely to have received the vaccine. However, 79% of HCPs declared their intention to be vaccinated in the 2021 flu season, with participants >40 years old, female (AOR 2.25, 95% CI 1.38-3.68), non-Saudi (AOR 3.79, 95% CI 2.34-6.16), or nurses (AOR 2.94, 95% CI 1.82-4.76) more likely to do so. CONCLUSION: Influenza vaccination uptake declined among HCPs during the 2020 flu season compared with the previous season but is expected to increase in the upcoming 2021 season. Nevertheless, the findings are encouraging and indicate increased willingness of HCPs to become vaccinated in the upcoming 2021 season, but coverage could be further increased by policymakers via a comprehensive plan focusing particularly on younger HCPs, Saudis, males, and physicians.

Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase. BACKGROUND: At interim analysis in a phase 3, observer-blinded, placebo-controlled clinical trial, the mRNA-1273 vaccine showed 94.1% efficacy in preventing coronavirus disease 2019 (Covid-19). After emergency use of the vaccine was authorized, the protocol was amended to include an open-label phase. Final analyses of efficacy and safety data from the blinded phase of the trial are reported. METHODS: We enrolled volunteers who were at high risk for Covid-19 or its complications; participants were randomly assigned in a 1:1 ratio to receive two intramuscular injections of mRNA-1273 (100 Î¼g) or placebo, 28 days apart, at 99 centers across the United States. The primary end point was prevention of Covid-19 illness with onset at least 14 days after the second injection in participants who had not previously been infected with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The data cutoff date was March 26, 2021. RESULTS: The trial enrolled 30,415 participants; 15,209 were assigned to receive the mRNA-1273 vaccine, and 15,206 to receive placebo. More than 96% of participants received both injections, 2.3% had evidence of SARS-CoV-2 infection at baseline, and the median follow-up was 5.3 months in the blinded phase. Vaccine efficacy in preventing Covid-19 illness was 93.2% (95% confidence interval [CI], 91.0 to 94.8), with 55 confirmed cases in the mRNA-1273 group (9.6 per 1000 person-years; 95% CI, 7.2 to 12.5) and 744 in the placebo group (136.6 per 1000 person-years; 95% CI, 127.0 to 146.8). The efficacy in preventing severe disease was 98.2% (95% CI, 92.8 to 99.6), with 2 cases in the mRNA-1273 group and 106 in the placebo group, and the efficacy in preventing asymptomatic infection starting 14 days after the second injection was 63.0% (95% CI, 56.6 to 68.5), with 214 cases in the mRNA-1273 group and 498 in the placebo group. Vaccine efficacy was consistent across ethnic and racial groups, age groups, and participants with coexisting conditions. No safety concerns were identified. CONCLUSIONS: The mRNA-1273 vaccine continued to be efficacious in preventing Covid-19 illness and severe disease at more than 5 months, with an acceptable safety profile, and protection against asymptomatic infection was observed. (Funded by the Biomedical Advanced Research and Development Authority and the National Institute of Allergy and Infectious Diseases; COVE ClinicalTrials.gov number, NCT04470427.).

Intensity of mycophenolate mofetil treatment is associated with an impaired immune response to SARS-CoV-2 vaccination in kidney transplant recipients. Kidney transplant recipients (KTRs) are extremely vulnerable to SARS-CoV-2 infection and show an impaired immune response to SARS-CoV-2 vaccination. We analyzed factors related to vaccination efficiency in KTRs. In a multicenter prospective observational study (NCT04743947), IgG antibodies levels against SARS-CoV-2Â spike S1Â subunit and their neutralization capacity after SARS-CoV-2 vaccination were analyzed in 225Â KTRs and compared to 176 controls. After the vaccination, 56 (24.9%) KTRs became seropositive of whom 68% had neutralizing antibodies. This immune response was significantly lower compared to controls (239 [78-519] BAU/ml versus 1826 [560-3180] BAU/ml for KTRs and controls, pÂ <Â .0001). The strongest predictor for an impaired response was mycophenolate mofetil (MMF) treatment. Multivariate regression analysis revealed that MMF-free regimen was highly associated with seroconversion (OR 13.25, 95% CI 3.22-54.6; pÂ <Â .001). In contrast, other immunosuppressive drugs

had no significant influence. 187 out of 225Â KTRs were treated with MMF of whom 26 (13.9%) developed antibodies. 23 of these seropositive KTRs had a daily MMF dose â‰¤1Â g. Furthermore, higher trough MMF concentrations correlated with lower antibody titers (R -0.354, pÂ <Â .001) supporting a dose-dependent unfavorable effect of MMF. Our data indicate that MMF dose modification could lead to an improved immune response.

In brief: Third dose of mRNA-based COVID-19 vaccines for immunocompromised persons.

In brief: Guillain-BarrÃ© syndrome with the Johnson and Johnson COVID-19 vaccine.

Severe autoimmune hemolytic anemia following receipt of SARS-CoV-2 mRNA vaccine. BACKGROUND: Large clinical trials have demonstrated the overall safety of vaccines for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, reports have emerged of autoimmune phenomena, including vaccine-associated myocarditis, immune thrombocytopenia, and immune thrombotic thrombocytopenia. CASE PRESENTATION: Here we present a novel case of a young woman who developed life-threatening autoimmune hemolytic anemia (AIHA) after her first dose of a SARS-CoV-2 mRNA vaccine. Notably, initial direct antiglobulin testing was negative using standard anti-IgG reagents, which are "blind" to certain immunoglobulin (IgG) isotypes. Further testing using an antiglobulin reagent that detects all IgG isotypes was strongly positive and confirmed the diagnosis of AIHA. The patient required transfusion with 13 units of red blood cells, as well as treatment with corticosteroids, rituximab, mycophenolate mofetil, and immune globulin. CONCLUSION: As efforts to administer SARS-CoV-2 vaccines continue globally, clinicians must be aware of potential autoimmune sequelae of these therapies.

Caution against injudicious vaccine allergy skin tests: Adverse reactions after intradermal COVID-19 vaccine testing.

Symptomatic peduncular, cavernous bleeding following SARS-CoV-2 vaccination induced immune thrombocytopenia. Therapy-responsive immune thrombocytopenia and anemia shortly after the second dose of an mRNA-based SARS-CoV-2 vaccine, which was complicated by symptomatic bleeding within a pre-existing brainstem cavernoma, has not been reported. The patient is a 68yo male who experienced gait disturbance and hypoesthesia of the left face and left upper extremity two days after the second dose of the mRNA-based SARS-CoV-2 vaccine BNT162b2 (Tozinameran). Clinical neurologic exam revealed hypoesthesia of the left face and the left upper extremity and ataxic gait. Blood tests revealed macrocytic anemia and marked thrombocytopenia, interpreted as vaccination induced immune thrombocytopenia (ITP). Cerebral MRI revealed subacute bleeding within a pre-existing solitary cavernoma located in the right cerebellar peduncle. With proceeding resorption of the bleeding, symptoms gradually regressed. This case shows that SARS-CoV-2 vaccinations may be followed by ITP and bleeding in pre-existing vascular malformations. In order to avoid cavernoma bleeding in patients with SARS-CoV-2 vaccination associated ITP and thrombocyte dysfunction, urgent treatment of ITP is warranted. In order to identify patients at risk for experiencing SARS-CoV-2 vaccination induced ITP, further studies are urgently warranted.

Guillain-BarrÃ© syndrome following ChAdOx1 nCoV-19 COVID-19 vaccination: A case series. ChAdOx1 nCoV-19 is an effective and well-tolerated coronavirus disease 2019 (COVID-19) vaccine. Rare cases of serious adverse events have been reported with this vaccine. We report three patients who developed Guillain-BarrÃ© syndrome following ChAdOx1 nCoV-19 vaccination, who did not have active or prior COVID-19 infection. The neurological illness in all patients had an onset of 11-13Â days after the first dose of vaccine. All were characterized by sensorimotor weakness of the upper and lower limbs, with facial diplegia in one and dysautonomia in the other. Nerve conduction studies were consistent with demyelination in two and axonopathy in one. Cerebrospinal fluid analysis showed albuminocytological dissociation in two patients. All patients had moderate-to-severe

disability. They were treated with intravenous immunoglobulin, with stabilization of the disease. Proper monitoring and prompt reporting of such cases is required to ensure safety of the vaccine.
COVID-19 vaccination among individuals with autism spectrum disorder: A population-based study. BACKGROUND: Individuals with autistic spectrum disorder (ASD) are more susceptible to COVID-19 morbidity and should therefore be prioritized for vaccination. Although individuals with neurodevelopmental disabilities are given some priority in Israel, it is unclear to what extent individuals with ASD are being vaccinated relative to that of the general population. This study was aimed to assess vaccination prevalence among individuals with ASD. METHOD: Individuals with ASD, and age- and sex-matched controls (total n = 11,080), were assessed for prevalence of COVID-19 vaccination by February 2021, approximately a month and a half after the national vaccination distribution plan was launched in Israel. Data were obtained from the database of Clalit Health Services (CHS), the largest healthcare organization in Israel. RESULTS: Individuals with ASD were more likely to be vaccinated for COVID-19 (OR = 2.55, 95 %CI 2.35-2.75, p < .001) across both sexes, but only in the 16-20 (OR = 2.04, 95 %CI 1.79-2.32, p < .001) and 21-40 (OR = 3.95, 95 %CI 3.52-4.43, p < .001) age groups. After adjusting for chronic illnesses, ASD remained significant in predicting the uptake of COVID-19 vaccination. CONCLUSIONS: Efforts to prioritize ASD patients may improve vaccination prevalence among individuals with ASD, especially among younger individuals. Healthcare providers worldwide should therefore consider prioritization policies so as to increase vaccination rates among this vulnerable population.
Ramsay Hunt syndrome following mRNA SARS-COV-2 vaccine.
Vaccine-Induced Immune Thrombotic Thrombocytopenia with Concurrent Arterial and Venous Thrombi Following Ad26.COV2.S Vaccination.
COVID vaccination and asthma exacerbation: might there be a link? INTRODUCTION: There is ongoing debate regarding the role of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection in asthma exacerbation, and its long-term impact on the lung function of individuals with asthma. In contrast, the potential impact of coronavirus disease 2019 (COVID-19) vaccination on asthma is entirely unexplored. CASE STUDY: This study examined a challenging case of severe asthma exacerbation in a 28-year-old female following two doses of the mRNA-based vaccine BNT162b2 (Pfizer-BioNTech) at IRCCS Policlinico San Matteo in Pavia, Italy. The patient, a fourth-year resident at the hospital, was vaccinated in early 2021. She was an occasional smoker with a 10-year history of asthma and seasonal allergic rhinitis. She tested negative for SARS-CoV-2 on several molecular swabs and serology tests. RESULTS: After receiving the second dose of vaccine, the patient started to experience worsening of respiratory symptoms. Following several episodes and a severe asthma attack, the patient required treatment with mepolizumab, a biologic drug (interleukin-5) antagonist monoclonal antibody. CONCLUSION: This single case study is insufficient to draw conclusions about the association between asthma exacerbation and the COVID-19 vaccine. While the cause-effect link between vaccination against SARS-CoV-2 and worsening of asthmatic disease might only be suggested at present, this case is a valuable prompt for further investigation. This is particularly true from the perspective of mass vaccination of adolescents and children currently underway across the globe.
Non-immunoglobulin E-mediated allergy associated with Pfizer-BioNTech coronavirus disease 2019 vaccine excipient polyethylene glycol.
Nevocentric erythema multiforme after SARS-COV-2 vaccine.
Eosinophilic cellulitis after BNT162b2 mRNA Covid-19 vaccine.
A case of bullous pemphigoid after the SARS-CoV-2 mRNA vaccine.
Erythema nodosum, zoster duplex and pityriasis rosea as possible cutaneous adverse effects of Oxford-AstraZeneca COVID-19 vaccine: report of three cases from India.

Pfizer-BioNTech SARS-CoV-2 mRNA vaccine-associated erythema multiforme.
Erythema multiforme after SARS-CoV-2 vaccine.
Non-life-threatening adverse reactions from COVID-19 vaccine; a cross-sectional study with self-reported symptoms among Ghanaian healthcare workers. Health-care professionals in Ghana were among the prioritized high-risk groups to be administered with the initial supply of Oxford/AstraZeneca vaccine procured by the Government of Ghana. This study sought to assess and identify the determinants of COVID-19 vaccine short-term side effects among health-care workers. A cross-sectional study was conducted on 654 Ghanaian healthcare workers between 16(th) March and 5(th) May 2021. The study included health-care workers in registered health settings, who had been vaccinated against COVID-19 and consented to participate in the survey. Descriptive statistics, binary and multivariable logistic regression analyses were executed using SPSS version 22 at p <Â .05. The findings revealed that, 528 (80.7%) of the participants experienced adverse reactions, which lasted between 0 and 2Â days among, 347 (53.1%) of the study participants. The most reported adverse reactions were general body weakness, 434 (32.0%), headache 371 (27.3%), and fever, 257 (19.1%). Health workers aged 35-39 and 40-44Â years had lower odds of adverse reactions compared with those aged 25-29Â years (aOR: 0.34, 95% C.I. 0.186,0.621, p <Â .001) and (aOR: 0.42, 95% C.I. 0.201,0.890, p =Â .023). Taking analgesics before vaccination decreased the likelihood of adverse reactions (aOR: 0.28, 95% C.I. 0.185,0.427, p <Â .001). High prevalence of adverse reactions was found among the healthcare workers, however short-lived. The most reported systemic adverse reactions were general body weakness, headache, and fever. We recommend intensification of campaigns on COVID-19 vaccines and their associated adverse effects to avoid the negative implication on uptake among the healthcare workers and the general population.
Leukocytoclastic vasculitis as a cutaneous manifestation of ChAdOx1 nCoV-19 corona virus vaccine (recombinant). With the present COVID-19 vaccination drive across the world, adverse skin reactions post COVID-19 vaccine is expected. Majority of these reactions seen were transient or local injection site reactions. However, as the larger population is being vaccinated, certain uncommon dermatological presentations including leukocytoclastic vasculitis, pityriasis rosea, and exacerbation of pre-existing autoimmune diseases are now being reported. Among all the COVID-19 vaccines, most of these reactions are seen with messenger ribonucleic acid-based Pfizer/BioNTech (BNT162b2) and Moderna (mRNA-1273) vaccine. We report two cases of leukocytoclastic vasculitis following ChAdOx1 nCoV-19 corona virus vaccine (recombinant) that bring out potential new dermatological manifestations of recombinant corona virus vaccine being administered across the European, South American, and Asian countries. It is important for all health care workers and patients to be aware of the corona virus vaccine associated adverse cutaneous reactions.
Non-episodic angioedema with eosinophilia after BNT162b2 mRNA COVID-19 vaccination.
Case of bullous pemphigoid following coronavirus disease 2019 vaccination.
Predictors of mortality in thrombotic thrombocytopenia after adenoviral COVID-19 vaccination: the FAPIC score. AIMS: The clinical manifestation and outcomes of thrombosis with thrombocytopenia syndrome (TTS) after adenoviral COVID-19 vaccine administration are largely unknown due to the rare nature of the disease. We aimed to analyse the clinical presentation, treatment modalities, outcomes, and prognostic factors of adenoviral TTS, as well as identify predictors for mortality. METHODS AND RESULTS: PubMed, Scopus, Embase, and Web of Science databases were searched and the resulting articles were reviewed. A total of 6 case series and 13 case reports (64 patients) of TTS after ChAdOx1 nCoV-19 vaccination were included. We performed a pooled analysis and developed a novel scoring system to predict mortality. The overall mortality of TTS after ChAdOx1 nCoV-19 vaccination was 35.9% (23/64). In our analysis, age â‰¤60â€‰years, platelet count <25â€‰Ã—â€‰10³/ÂµL, fibrinogen <150â€‰mg/dL, the presence of intracerebral

haemorrhage (ICH), and the presence of cerebral venous thrombosis (CVT) were significantly associated with death and were selected as predictors for mortality (1 point each). We named this novel scoring system FAPIC (fibrinogen, age, platelet count, ICH, and CVT), and the C-statistic for the FAPIC score was 0.837 (95% CI 0.732-0.942). Expected mortality increased with each point increase in the FAPIC score, at 2.08, 6.66, 19.31, 44.54, 72.94, and 90.05% with FAPIC scores 0, 1, 2, 3, 4, and 5, respectively. The FAPIC scoring model was internally validated through cross-validation and bootstrapping, then externally validated on a panel of TTS patients after Ad26.COV2.S administration. CONCLUSIONS: Fibrinogen levels, age, platelet count, and the presence of ICH and CVT were significantly associated with mortality in patients with TTS, and the FAPIC score comprising these risk factors could predict mortality. The FAPIC score could be used in the clinical setting to recognize TTS patients at high risk of adverse outcomes and provide early intensive interventions including intravenous immunoglobulins and non-heparin anticoagulants.

An immunologist's perspective on anti-COVID-19 vaccines. PURPOSE OF REVIEW: Antisevere acute respiratory syndrome-corona virus 2 (SARS-CoV-2) vaccines may provide prompt, effective, and safe solution for the COVID-19 pandemic. Several vaccine candidates have been evaluated in randomized clinical trials (RCTs). Furthermore, data from observational studies mimicking real-life practice and studies on specific groups, such as pregnant women or immunocompromised patients who were excluded from RCTs, are currently available. The main aim of the review is to summarize and provide an immunologist's view on mechanism of action, efficacy and safety, and future challenges in vaccination against SARS-CoV-2. RECENT FINDINGS: mRNA and recombinant viral vector-based vaccines have been approved for conditional use in Europe and the USA. They show robust humoral and cellular responses, high with efficacy in prevention of COVID-19 infection (66.9 95%) and favorable safety profile in RCTs. High efficacy of 80-92% was observed in real-life practice. A pilot study also confirmed good safety profile of the mRNA vaccines in pregnant women. Unlike in those with secondary immunodeficiencies where postvaccination responses did not occur, encouraging results were obtained in patients with inborn errors of immunity. SUMMARY: Although both RCTs and observational studies suggest good efficacy and safety profiles of the vaccines, their long-term efficacy and safety are still being discussed. Despite the promising results, clinical evidence for specific groups such as children, pregnant and breastfeeding women, and immunocompromised patients, and for novel virus variants are lacking. VIDEO ABSTRACT: http://links.lww.com/COAI/A21.

Risk prediction of covid-19 related death and hospital admission in adults after covid-19 vaccination: national prospective cohort study.

Correlation of healthcare worker vaccination with inpatient healthcare-associated coronavirus disease 2019 (COVID-19).

In brief: Myocarditis with the Pfizer/BioNTech and Moderna COVID-19 vaccines.

Adverse Events following AstraZeneca COVID-19 Vaccine in Saudi Arabia: A Cross-Sectional Study among Healthcare and Nonhealthcare Workers. INTRODUCTION: Many COVID-19 vaccines have been emerging with different efficacy and safety profiles. So far, very little attention has been paid to severity and reactogenicity of COVID-19 vaccine among healthcare workers. Thus, the aim of this study is to investigate the side effects associated with the first dose of AstraZeneca COVID-19 vaccine among healthcare workers (HCWs) and nonhealthcare workers (non-HCWs). METHOD: This is an observational cross-sectional study conducted at King Abdullah bin AbdulAziz University Hospital, Saudi Arabia, between February 28 and March 12, 2021. The major outcomes were the reported side effects of day 1, day 2, and day 3 after vaccination among HCWs and non-HCWs. Other outcomes included the onset and the duration of the reactions or the side effects that were reported. RESULTS: A total of 526 participants completed the survey with 173 (32.8%) HCWs and the remaining majority were non-HCWs. Some of the most frequently reported side effects among the participants on the

first day were muscle aches (49%), followed by fever (42%) and headache (40%). HCWs experienced more muscle aches, headache, sore throat, and abdominal pain, which were statically significant, compared to non-HCWs. The mean onset of symptoms was 16 (Â±15.3) h in the HCW arm compared with 12.2 (Â±10.2) h in non-HCWs (p = 0.0024). Furthermore, the mean duration of symptoms in the HCW group was 37 (Â±19) h compared with 32.3 (Â±13) h in the non-HCW group (p = 0.067). CONCLUSION: The reported side effects were common but not pressing in both groups. HCW respondents appeared to have more COVID-19 vaccine-associated symptoms.

Highly Potent SARS-CoV-2 Neutralization by Intravenous Immunoglobulins manufactured from Post-COVID-19 and COVID-19-Vaccinated Plasma Donations. From September 2020, some immunoglobulin lots from US plasma contained neutralizing antibodies against the newly emerged severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Paralleled by the increasing numbers of post-coronavirus disease 2019 (COVID-19) donors, immunoglobulin lot antibody positivity increased to 93% by January 2021, at a mean titer of approximately 30 IU/mL. The correlation predicted that anti-SARS-CoV-2 potency would reach 345 IU/mL by July 2021. In addition to post-COVID-19 donors, the rapidly increasing number of plasma donors vaccinated against COVID-19 resulted in a mean antibody titer of >600 IU/mL in July 2021 immunoglobulin lots, with SARS-CoV-2 antibody titers for several lots even higher than those of earlier produced hyperimmune globulin products.

Does reactogenicity after a second injection of the BNT162b2 vaccine predict spike IgG antibody levels in healthy Japanese subjects? BACKGROUND: Adverse reactions are more common after the second injection of messenger RNA vaccines such as Pfizer/BioNTech's BNT162b2. We hypothesized that the degree and severity of reactogenicity after the second injection reflects the magnitude of antibody production against the SARS CoV-2 virus spike protein (spike IgG). METHODS AND RESULTS: Blood samples were obtained from 67 Japanese healthcare workers three weeks after the first injection and two weeks after the second injection of the BNT162b2 vaccine to measure spike IgG levels. Using questionnaires, we calculated an adverse event (AE) score (0-11) for each participant. The geometric mean of spike IgG titers increased from 1,047 antibody units (AU/mL) (95% confidence interval (95% CI): 855-1282 AU/mL) after the first injection to 17,378 AU/mL (95% CI: 14,622-20,663 AU/mL) after the second injection. The median AE score increased from 2 to 5. Spike IgG levels after the second injection were negatively correlated with age and positively correlated with spike IgG after the first injection. AE scores after the second injection were not significantly associated with log-transformed spike IgG after the second injection, when adjusted for age, sex, AE score after the first injection, and log-transformed spike IgG after the first injection. CONCLUSIONS: Although the sample size was relatively small, reactogenicity after the second injection may not accurately reflect antibody production.

[Acute unilateral impaired vision after COVID vaccination].

Concern About the Adverse Effects of Thrombocytopenia and Thrombosis After Adenovirus-Vectored COVID-19 Vaccination. Since the outbreak of Covid-19 in December, 2019, scientists worldwide have been committed to developing COVID-19 vaccines. Only when most people have immunity to SARS-CoV-2, COVID-19 can reduce even wholly overcome. So far, nine kinds of COVID-19 vaccines have passed the phase III clinical trials and have approved for use. At the same time, adverse reactions after COVID-19 vaccination have also reported. This paper focuses on the adverse effects of thrombosis and thrombocytopenia caused by the COVID-19 vaccine, especially the adenovirus-vector vaccine from AstraZeneca and Pfizer, and discusses its mechanism and possible countermeasures.

Subcutaneous Uptake on [18F]Florbetaben PET/CT: a Case Report of Possible Amyloid-Beta Immune-Reactivity After COVID-19 Vaccination. INTRODUCTION: Large-scale worldwide COVID-19 vaccination programs are being rapidly deployed, and high-risk patients with comorbidity are now

receiving the first doses of the vaccine. Physicians should be, therefore, aware of new pitfalls associated with the current pandemic vaccination program, also in the case of [(18)F]Florbetaben PET/CT.Case PresentationWe described the first image of [(18)F]Florbetaben PET/CT in the evaluation of a 70-year-old male with suspicious Alzheimer disease and unclear history of heart disease. We detailed the diagnostic imaging PET/CT workup with different findings. CONCLUSION: In this case, [(18)F]Florbetaben PET/CT can demonstrate potential beta-amyloid immune-reactivity and deposition associated with the current COVID-19 pandemic vaccination programs.

Status epilepticus as a complication after COVID-19 mRNA-1273 vaccine: A case report. BACKGROUND: We present a rare case of status epilepticus in a 56-year-old man which arose as a complication after vaccination with the coronavirus disease 2019 (COVID-19) mRNA-1273 vaccine. The patient's history included well-compensated secondary epilepsy. The root cause of the situation was a fever which had developed as a side effect of the vaccination. CASE SUMMARY: A 56-year-old man received the first dose of mRNA-1273 vaccine against the severe acute respiratory syndrome-coronavirus-2. The vaccine was administered intramuscularly (100 mg, 0.5 mL). The next morning the man was found to be suffering from fever and headaches while at the same time experiencing general weakness. He lost consciousness suddenly and experienced generalized clonic seizures which turned into status epilepticus. When the Emergency Medical Service arrived the patient was unconscious with spontaneous breathing and generalized clonic seizures. It was necessary to administer diazepam repeatedly. It was also necessary to administer high doses of levetiracetam and temporary propofol. The status epilepticus was brought under control approximately 90 min after the patient's transport to the Emergency Department. A follow-up electroencephalogram no longer revealed abnormal indications of epileptic fit. The patient was temporarily hospitalized in the Intensive Care Unit and after seven days care was discharged without any further apparent effects. CONCLUSION: There is currently no specific treatment against COVID-19. Therefore, the benefits of COVID-19 vaccine protection outweigh the risks.

Toxic Epidermal Necrolysis Post COVID-19 Vaccination - First Reported Case. Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) is a spectrum of acute, delayed-type hypersensitivity reactions that affect the skin and the mucous membranes. Medications are the culprit cause of these disorders in addition to infections and in very rare instances vaccinations. We report a case of TEN in a 49-year-old woman with no previous medical history. The disorder developed one week after receiving the first dose of COVID-19 vaccine with no other identifiable causes. The patient received two doses of tumor necrosis factor-alpha inhibitor (etanercept) and she stopped developing new lesions after two days of the initial dose; complete healing was observed after 22 daysÂ and no side effects were observed in our patient. This case demonstrates an extremely rare complication to the COVID-19 vaccine. The benefits of receiving the COVID-19 outweigh the potential risk.

Takotsubo syndrome after receiving the COVID-19 vaccine. The coronavirus disease (COVID)-19 pandemic has affected millions worldwide with prevention efforts culminating in the development of a vaccine. An mRNA vaccine, developed by Moderna (Cambridge, MA, USA), mounts an immunologic response leading to antibody neutralization. Commonly reported vaccine side effects include myalgia, fever, and chills, with low reported rates of cardiovascular events. This case demonstrates the development of takotsubo syndrome (TTS) after administration of the COVID-19 vaccine. A 73-year-old woman with recently diagnosed myocardial infarction with no obstructive coronary atherosclerosis (MINOCA) presented with typical chest pain starting less than a day after receiving the Moderna vaccine. She had troponin elevations and new ST-segment abnormalities. Transthoracic echocardiogram (TTE) findings were consistent with mid-ventricular TTS. Treatment included diuretics, beta-blockers, and angiotensin receptor blockers. Prior to discharge, repeat imaging showed improvement in systolic function. This case presents a post-menopausal woman with a

recent diagnosis of MINOCA who developed TTS shortly after receiving the COVID-19 vaccine. Risk factors including sex, age, MINOCA, anxiety about the vaccine, and possibly the vaccine itself may have all contributed to the TTS presentation. TTS may occur after COVID-19 vaccination, and appreciation of this potential rare association is important for evaluating vaccine safety and optimizing patient outcomes. <Learning objective: Takotsubo syndrome (TTS) has been associated with multiple predisposing factors. We present a case of TTS which developed shortly after receipt of an mRNA COVID-19 vaccine. We discuss contributing factors, diagnosis, and treatment of TTS.>.

Guillain-BarrÃ© Syndrome Presenting as Facial Diplegia after COVID-19 Vaccination: A Case Report. BACKGROUND: Guillain-BarrÃ© Syndrome (GBS) is a rapidly progressive immune-mediated polyneuropathy often associated with an antecedent infectious illness or vaccination. The classic presentation of GBS is characterized by ascending limb weakness and numbness with loss of reflexes. However, atypical variants involving the face and arms or with purely sensory symptoms also exist. In up to 30% of cases, GBS progresses to respiratory failure, with patients requiring mechanical ventilation. CASE REPORT: We report a case of atypical GBS occurring after Coronavirus disease 2019 (COVID-19) vaccination in an otherwise healthy 38-year-old man. The patient's clinical presentation was characterized by bilateral hand and foot paresthesias, dysarthria, bilateral facial weakness, and an absence of classic ascending limb weakness. Albuminocytological dissociation within the cerebrospinal fluid was suggestive of GBS. The patient received intravenous immunoglobulin therapy, with modest improvement in his symptoms at the time of his discharge from the hospital. Why Should an Emergency PhysicianBe Aware of This? Patients with GBS are at risk for life-threatening complications, including respiratory failure requiring mechanical ventilation. It is critical for emergency physicians to be aware of the manifold presentations of GBS for early recognition and treatment. This may be of particular importance in the context of a worldwide vaccination campaign in response to the COVID-19 pandemic.

COVID-19 in Children: Clinical Manifestations and Pharmacologic Interventions Including Vaccine Trials. Children usually present with milder symptoms of COVID-19 as compared with adults. Supportive care alone is appropriate for most children with COVID-19. Antiviral therapy may be required for those with severe or critical diseases. Currently there has been a rapid development of vaccines globally to prevent COVID-19 and several vaccines are being evaluated in children and adolescents. Currently, only the Pfizer-BioNTech messenger RNA vaccine is approved for emergency authorization use in the pediatric population ages 16Â years and older.

Viewpoint of the European Pediatric Societies over Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccination in Children Younger Than Age 12Â Years Amid Return to School and the Surging Virus Variants.

Declining mortality of cerebral venous sinus thrombosis with thrombocytopenia after SARS-CoV-2 vaccination. BACKGROUND AND PURPOSE: High mortality rates have been reported in patients with cerebral venous sinus thrombosis (CVST) due to vaccine-induced immune thrombotic thrombocytopenia (VITT) after vaccination with adenoviral vector SARS-CoV-2 vaccines. The aim of this study was to evaluate whether the mortality of patients with CVST-VITT has decreased over time. METHODS: The EudraVigilance database of the European Medicines Agency was used to identify cases of CVST with concomitant thrombocytopenia occurring within 28Â days of SARS-CoV-2 vaccination. Vaccines were grouped based on vaccine type (adenoviral or mRNA). Cases with CVST onset until 28Â March were compared to cases after 28Â March 2021, which was the day when the first scientific paper on VITT was published. RESULTS: In total, 270 cases of CVST with thrombocytopenia were identified, of which 266 (99%) occurred after adenoviral vector SARS-CoV-2 vaccination (ChAdOx1 nCoV-19, nÂ =Â 243; Ad26.COV2.S, nÂ =Â 23). The reported mortality amongst adenoviral cases with onset up to 28Â March 2021 was 47/99 (47%, 95% confidence interval 37%-

58%) compared to 36/167 (22%, 95% confidence interval 16%-29%) in cases with onset after 28Â March (pÂ < 0.001). None of the four cases of CVST with thrombocytopenia occurring after mRNA vaccination died. CONCLUSION: The reported mortality of CVST with thrombocytopenia after vaccination with adenoviral vector-based SARS-CoV-2 vaccines has significantly decreased over time, which may indicate a beneficial effect of earlier recognition and/or improved treatment on outcome after VITT.

Acute myocarditis after COVID-19 vaccination with mRNA-1273 in a patient with former SARS-CoV-2 infection. We describe a case of a 20-year-old healthy man developing chest pain and classical symptoms of vaccine reactogenicity 12Â h after receiving the first dose of mRNA-1273 (Moderna). Cardiac troponin T was increased, and subepicardial inflammation and focal contractile dysfunction were detected by cardiac magnetic resonance imaging and echocardiography. We confirmed the diagnosis of acute myocarditis by endomyocardial biopsy demonstrating significant infiltration of monocytes and T lymphocytes. Although we detected IgG against nucleocapsid protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) indicating prior infection, the patient repeatedly tested negative for SARS-CoV-2 and had been asymptomatic for several months. Furthermore, viral genome analysis of endomyocardial biopsy samples was negative for SARS-CoV-2 and other potential cardiotropic viruses. These findings and the strong temporal relation between the vaccination and the symptom onset imply a potential side effect of mRNA-1273.

Case of immunoglobulin A vasculitis following coronavirus disease 2019 vaccination.

A rare case of COVID-19 vaccine-induced thrombotic thrombocytopaenia (VITT) involving the veno-splanchnic and pulmonary arterial circulation, from a UK district general hospital. A 47-year-old woman presented with a headache to the acute medical unit, 10 days after receiving AstraZeneca vaccination for COVID-19. Brain imaging was normal, but her blood tests showed a remarkably low platelet count, mildly deranged liver function tests and a high D-dimer. Further within her hospital admission, she developed right-sided abdominal pain and chest pain, and subsequent cross-sectional imaging confirmed a small segmental pulmonary embolism, and an acute portal vein thrombosis extending to the splenic and superior mesenteric veins. On the basis of her investigations, she was diagnosed as a case of vaccine-induced thrombotic thrombocytopenia and was treated with intravenous immunoglobulins. In a time where there is a strategic goal to vaccinate the global population from COVID-19 to inhibit the spread of infection and reduce hospitalisation, this particular clinical scenario emphasises the need of all clinicians to remain vigilant for rare complications of the COVID-19 vaccination.

Risk prediction of covid-19 related death and hospital admission in adults after covid-19 vaccination: national prospective cohort study. OBJECTIVES: To derive and validate risk prediction algorithms to estimate the risk of covid-19 related mortality and hospital admission in UK adults after one or two doses of covid-19 vaccination. DESIGN: Prospective, population based cohort study using the QResearch database linked to data on covid-19 vaccination, SARS-CoV-2 results, hospital admissions, systemic anticancer treatment, radiotherapy, and the national death and cancer registries. SETTINGS: Adults aged 19-100 years with one or two doses of covid-19 vaccination between 8 December 2020 and 15 June 2021. MAIN OUTCOME MEASURES: Primary outcome was covid-19 related death. Secondary outcome was covid-19 related hospital admission. Outcomes were assessed from 14 days after each vaccination dose. Models were fitted in the derivation cohort to derive risk equations using a range of predictor variables. Performance was evaluated in a separate validation cohort of general practices. RESULTS: Of 6â€‰952â€‰440 vaccinated patients in the derivation cohort, 5â€‰150â€‰310 (74.1%) had two vaccine doses. Of 2031 covid-19 deaths and 1929 covid-19 hospital admissions, 81 deaths (4.0%) and 71 admissions (3.7%) occurred 14 days or more after the second vaccine dose. The risk algorithms included age, sex, ethnic origin, deprivation, body mass

index, a range of comorbidities, and SARS-CoV-2 infection rate. Incidence of covid-19 mortality increased with age and deprivation, male sex, and Indian and Pakistani ethnic origin. Cause specific hazard ratios were highest for patients with Down's syndrome (12.7-fold increase), kidney transplantation (8.1-fold), sickle cell disease (7.7-fold), care home residency (4.1-fold), chemotherapy (4.3-fold), HIV/AIDS (3.3-fold), liver cirrhosis (3.0-fold), neurological conditions (2.6-fold), recent bone marrow transplantation or a solid organ transplantation ever (2.5-fold), dementia (2.2-fold), and Parkinson's disease (2.2-fold). Other conditions with increased risk (ranging from 1.2-fold to 2.0-fold increases) included chronic kidney disease, blood cancer, epilepsy, chronic obstructive pulmonary disease, coronary heart disease, stroke, atrial fibrillation, heart failure, thromboembolism, peripheral vascular disease, and type 2 diabetes. A similar pattern of associations was seen for covid-19 related hospital admissions. No evidence indicated that associations differed after the second dose, although absolute risks were reduced. The risk algorithm explained 74.1% (95% confidence interval 71.1% to 77.0%) of the variation in time to covid-19 death in the validation cohort. Discrimination was high, with a D statistic of 3.46 (95% confidence interval 3.19 to 3.73) and C statistic of 92.5. Performance was similar after each vaccine dose. In the top 5% of patients with the highest predicted covid-19 mortality risk, sensitivity for identifying covid-19 deaths within 70 days was 78.7%. CONCLUSION: This population based risk algorithm performed well showing high levels of discrimination for identifying those patients at highest risk of covid-19 related death and hospital admission after vaccination.

COVID-19 vaccine post-marketing surveillance: Cardiovascular doctors have a role to play!

Myocarditis following COVID-19 vaccination - A case series. There have been reports of myocarditis following COVID-19 vaccination. We surveyed all hospitalized military personnel in the Isareli Defense Forces during the period of the COVID-19 vaccination operation (12/28/2021-3/7/2021) for diagnosed myocarditis. We identified 7 cases of myocarditis with symptoms starting in the first week after the second dose of COVID-19 Pfizer-BioNTech vaccine. One case of myocarditis diagnosed 10Â days after the second dose of the vaccine was not included. These 8 cases comprise of all events of myocarditis diagnosed in military personnel during this time period. All patients were young and generally healthy. All had mild disease with no sequalae. The incidence of myocarditis in the week following a second dose of the vaccine was 5.07/100,000 people vaccinated. Due to the nature of this report no causality could be established. Clinicians should be aware of the possibility of myocarditis following Pfizer-BioNTech vaccination. True incidence rates should be further investigated.

Delayed headache after COVID-19 vaccination: a red flag for vaccine induced cerebral venous thrombosis. BACKGROUND: Headache is a frequent symptom following COVID-19 immunization with a typical onset within days post-vaccination. Cases of cerebral venous thrombosis (CVT) have been reported in adenovirus vector-based COVID-19 vaccine recipients. FINDINGS: We reviewed all vaccine related CVT published cases by April 30, 2021. We assessed demographic, clinical variables and the interval between the vaccination and onset of headache. We assessed whether the presence of headache was associated with higher probability of death or intracranial hemorrhage. We identified 77 cases of CVT after COVID-19 vaccination. Patients' age was below 60â€‰years in 74/77 (95.8%) cases and 61/68 (89.7%) were women. Headache was described in 38/77 (49.4%) cases, and in 35/38 (92.1%) was associated with other symptoms. Multiple organ thrombosis was reported in 19/77 (24.7%) cases, intracranial hemorrhage in 33/77 (42.9%) cases and 19/77 (24.7%) patients died. The median time between vaccination and CVT-related headache onset was 8 (interquartile range 7.0-9.7) days. The presence of headache was associated with a higher odd of intracranial hemorrhage (OR 7.4; 95% CI: 2.7-20.8, pÂ <â€‰0.001), but not with death (OR: 0.51, 95% CI: 0.18-1.47, pÂ =â€‰0.213). CONCLUSION: Delayed onset of headache following an adenovirus vector-based COVID-19 vaccine is associated with development of CVT. Patients with new-onset headache, 1 week

after vaccination with an adenovirus vector-based vaccine, should receive a thorough clinical evaluation and CVT must be ruled out.
Corrigendum to "COVID-19 vaccine-induced myocarditis case report with literature review" [Diabetes & Metabolic Syndrome: Clinical Research & Reviews Volume 15, Issue 5, September-October 2021, 102205].
SARS-CoV-2 vaccine-induced subacute thyroiditis.
COVID-19 vaccination followed by activation of glomerular diseases: does association equal causation?
Considerations in boosting COVID-19 vaccine immune responses.
Prevention of host-to-host transmission by SARS-CoV-2 vaccines. As the number of individuals vaccinated against SARS-CoV-2 rises worldwide, population-level data regarding the vaccines' ability to reduce infection are being generated. Randomised trials have shown that these vaccines dramatically reduce symptomatic COVID-19; however, less is known about their effects on transmission between individuals. The natural course of infection with SARS-CoV-2 involves infection of the respiratory epithelia and replication within the mucosa to sufficient viral titres for transmission via aerosol particles and droplets. Here we discuss the available data on the existing, approved SARS-CoV-2 vaccines' capacity to reduce transmissibility by reducing primary infection, viral replication, capacity for transmission, and symptomaticity. The potential for mucosal-targeted SARS-CoV-2 vaccine strategies to more effectively limit transmission than intramuscular vaccines is considered with regard to known immunological mechanisms. Finally, we enumerate the population-level effects of approved vaccines on transmission through observational studies following clinical trials and vaccine distribution in real-world settings.
Adverse Events Following One Dose of mRNA COVID-19 Vaccination Among US Nursing Home Residents With and Without a Previous SARS-CoV-2 Infection. OBJECTIVES: To compare rates of adverse events following Coronavirus Disease 2019 (COVID-19) vaccination among nursing home residents with and without previous severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. DESIGN: Prospective cohort. SETTING AND PARTICIPANTS: A total of 20,918 nursing home residents who received the first dose of messenger RNA COVID-19 vaccine from December 18, 2020, through February 14, 2021, in 284 facilities within Genesis Healthcare, a large nursing home provider spanning 24 US states. METHODS: We screened the electronic health record for adverse events, classified by the Brighton Collaboration, occurring within 15Â days of a resident's first COVID-19 vaccine dose. All events were confirmed by physician chart review. To obtain risk ratios, multilevel logistic regression model that accounted for clustering (variability) across nursing homes was implemented. To balance the probability of prior SARS-CoV-2 infection (previous positive test or diagnosis by the International Classification of Diseases, 10(th) Revision, Clinical Modification) more than 20Â days before vaccination, we used inverse probability weighting. To adjust for multiplicity of adverse events tested, we used a false discovery rate procedure. RESULTS: Statistically significant differences existed between those without (nÂ = 13,163) and with previous SARS-CoV-2 infection [symptomatic (nÂ = 5617) and asymptomatic (nÂ = 2138)] for all baseline characteristics assessed. Only 1 adverse event was reported among those with previous SARS-CoV-2 infection (asymptomatic), venous thromboembolism [46.8 per 100,000 residents 95% confidence interval (CI) 8.3-264.5], which was not significantly different from the rate reported for those without previous infection (30.4 per 100,000 95% CI 11.8-78.1). Several other adverse events were observed for those with no previous infection, but were not statistically significantly higher than those reported with previous infection after adjustments for multiple comparisons. CONCLUSIONS AND IMPLICATIONS: Although reactogenicity increases with preexisting immunity, we did not find that vaccination among those with previous SARS-CoV-2 infection resulted in higher rates of adverse events than those without

previous infection. This study stresses the importance of monitoring novel vaccines for adverse events in this vulnerable population.

Reply to "Psoriasis exacerbation after COVID-19 vaccination: report of 14 cases from a single centre" by Sotiriou E etÂ al.

Antibody maintenance 3 months after complete messenger RNA COVID-19 vaccination in haemodialysis patients.

Case study of hypertriglyceridemia from COVID-19 Pfizer-BioNTech vaccination in a patient with familial hypercholesteremia. The Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine is the first novel nucleoside-modified messenger ribonucleic acid (modRNA) vaccine to receive Emergency Use Authorization from the Food and Drug Administration in the United States. It is indicated to be used in patients â‰¥12 years-of-age as of May 25th, 2021, including populations with high atherosclerotic cardiovascular disease (ASCVD) burden. However, little is known about the potential impact this vaccine may have on serum lipoprotein levels in patients with familial hypercholesteremia (FH), who are predisposed to high ASCVD burden due to elevated low-density lipoprotein cholesterol (LDL-C). We present an interesting case where a patient with heterozygous FH (HeFH) and elevated triglycerides (TG)-controlled for years on medication and apheresis-experienced significantly elevated TG, one day after receiving his second Pfizer-BioNTech COVID-19 vaccine dose. It is not known whether this adverse event may be seen in other FH patients and may be worth assessing in such patients to determine the possibility of a rare adverse reaction from a COVID-19 vaccine.

Aggravation of hyperthyroidism after heterologous prime-boost immunization with inactivated and adenovirus-vectored SARS-CoV-2 vaccine in a patient with Graves' disease.

Assessment of Allergic and Anaphylactic Reactions to mRNA COVID-19 Vaccines With Confirmatory Testing in a US Regional Health System. IMPORTANCE: As of May 2021, more than 32 million cases of COVID-19 have been confirmed in the United States, resulting in more than 615â€¯000 deaths. Anaphylactic reactions associated with the Food and Drug Administration (FDA)-authorized mRNA COVID-19 vaccines have been reported. OBJECTIVE: To characterize the immunologic mechanisms underlying allergic reactions to these vaccines. DESIGN, SETTING, AND PARTICIPANTS: This case series included 22 patients with suspected allergic reactions to mRNA COVID-19 vaccines between December 18, 2020, and January 27, 2021, at a large regional health care network. Participants were individuals who received at least 1 of the following International Statistical Classification of Diseases and Related Health Problems, Tenth Revision anaphylaxis codes: T78.2XXA, T80.52XA, T78.2XXD, or E949.9, with documentation of COVID-19 vaccination. Suspected allergy cases were identified and invited for follow-up allergy testing. EXPOSURES: FDA-authorized mRNA COVID-19 vaccines. MAIN OUTCOMES AND MEASURES: Allergic reactions were graded using standard definitions, including Brighton criteria. Skin prick testing was conducted to polyethylene glycol (PEG) and polysorbate 80 (P80). Histamine (1 mg/mL) and filtered saline (negative control) were used for internal validation. Basophil activation testing after stimulation for 30 minutes at 37 Â°C was also conducted. Concentrations of immunoglobulin (Ig) G and IgE antibodies to PEG were obtained to determine possible mechanisms. RESULTS: Of 22 patients (20 [91%] women; mean [SD] age, 40.9 [10.3] years; 15 [68%] with clinical allergy history), 17 (77%) met Brighton anaphylaxis criteria. All reactions fully resolved. Of patients who underwent skin prick tests, 0 of 11 tested positive to PEG, 0 of 11 tested positive to P80, and 1 of 10 (10%) tested positive to the same brand of mRNA vaccine used to vaccinate that individual. Among these same participants, 10 of 11 (91%) had positive basophil activation test results to PEG and 11 of 11 (100%) had positive basophil activation test results to their administered mRNA vaccine. No PEG IgE was detected; instead, PEG IgG was found in tested individuals who had an allergy to the vaccine. CONCLUSIONS AND RELEVANCE: Based on this

case series, women and those with a history of allergic reactions appear at have an elevated risk of mRNA vaccine allergy. Immunological testing suggests non-IgE-mediated immune responses to PEG may be responsible in most individuals.
Pityriasis rosea-like cutaneous eruption as a possible dermatological manifestation after Oxford-AstraZeneca vaccine: Case report and brief literature review. Pityriasis rosea (PR) has been manifested in patients suffering from COVID-19 as well as after vaccine protocols against SARS-CoV-2. It has a possible association with the HHV-6B virus (roseola infantum) and can be controlled by antivirals such as acyclovir as well as by the amino acid l-Lysine that showed a positive result in reducing the number of lesions and healing time. The aim of this study was to report a case of PR after a second dose of Oxford-AstraZeneca, the adopted therapy and a brief literature review. A 53-year-old woman, phototype II, presented an erythematous lesion in the posterior right thigh 15â€‰days after the second dose of Oxford-AstraZeneca vaccine. Eight days after the initial injury, new injuries appeared in the calf, buttocks and thighs. The diagnosis was PR with a 5-week eruption cycle. The treatment consisted of the use of l-Lysine, 3 grams loading dose and 500â€‰mg for 30â€‰days and moisturizing/healing lotion, starting 14â€‰days after the herald patch. After the 5th week of the disease cycle, there were no new eruptions and the repair cycle continued for up to 8â€‰weeks leaving some residual skin spots. It is concluded that the patient may be a carrier a latent virus, HHV-6, and the vaccine administration with immune system stimulation, would have activated the possible virus causing PR. l-Lysine helped to control the manifestation by limiting the number of lesions and their location, which were restricted to the legs, thighs and buttocks.
Alcohol use disorder in the COVID-19 era: Position paper of the Italian Society on Alcohol (SIA). Coronavirus disease 2019 (COVID-19) first emerged in China in November 2019. Most governments have responded to the COVID-19 pandemic by imposing a lockdown. Some evidence suggests that a period of isolation might have led to a spike in alcohol misuse, and in the case of patients with alcohol use disorder (AUD), social isolation can favour lapse and relapse. The aim of our position paper is to provide specialists in the alcohol addiction field, in psychopharmacology, gastroenterology and in internal medicine, with appropriate tools to better manage patients with AUD and COVID-19,considering some important topics: (a) the susceptibility of AUD patients to infection; (b) the pharmacological interaction between medications used to treat AUD and to treat COVID-19; (c) the reorganization of the Centre for Alcohol Addiction Treatment for the management of AUD patients in the COVID-19 era (group activities, telemedicine, outpatients treatment, alcohol-related liver disease and liver transplantation, collecting samples); (d) AUD and SARS-CoV-2 vaccination. Telemedicine/telehealth will undoubtedly be useful/practical tools even though it remains at an elementary level; the contribution of the family and of caregivers in the management of AUD patients will play a significant role; the multidisciplinary intervention involving experts in the treatment of AUD with specialists in the treatment of COVID-19 disease will need implementation. Thus, the COVID-19 pandemic is rapidly leading addiction specialists towards a new governance scenario of AUD, which necessarily needs an in-depth reconsideration, focusing attention on a safe approach in combination with the efficacy of treatment.
Vaccine-induced immune thrombotic thrombocytopenia presenting with normal platelet count. Adenoviral-vector based vaccines for coronavirus disease 2019 (COVID-19) have been linked with a thrombotic syndrome, vaccine-induced thrombotic thrombocytopenia (VITT). A key clinical question is whether VITT can be reliably ruled out by the absence of thrombocytopenia. We report on three patients who presented to our institute with this syndrome. Noteworthy in our presentations are two patients who presented for medical assessment of thrombotic symptoms with a normal platelet count, one preceding and one following a period of thrombocytopenia. Prompt diagnosis of VITT is critical to prevent rapid patient decline. We provide herein a new diagnostic algorithm that we

believe will help optimally capture case presentations of VITT. These cases broaden and refine our understanding of the disease process and highlight to practitioners that VITT cannot be adequately ruled out by thrombocytopenia alone.
First description of immune complex vasculitis after COVID-19 vaccination with BNT162b2: a case report. BACKGROUND: Cases of immune complex vasculitis have been reported following COVID-19 infections; so far none in association with novel mRNA-based COVID-19 vaccination. This case report describes a cutaneous immune complex vasculitis after vaccination with BNT162b2. CASE PRESENTATION: A 76-year old male with liver cirrhosis developed an immune complex vasculitis 12 days after the second injection of BNT162b2. On physical examination, the patient presented with pruritic purpuric macules on hands and feet, flexor and extensor parts of both legs and thighs and lower abdomen, and bloody diarrhoea. Laboratory testing showed elevated inflammatory markers. After short treatment with oral steroids all clinical manifestations and laboratory findings resolved. CONCLUSIONS: An increasing number of clinical manifestations have been attributed to COVID-19 infection and vaccination. This is the first written report of immune complex vasculitis after vaccination with BNT162b2. We present our case report and a discussion in the light of type three hypersensitivity reaction.
India's COVID-19 vaccination drive: key challenges and resolutions.
Cutaneous small-vessel vasculitis following COVID-19 vaccine.
Poor neutralizing antibody responses in 106 patients with WM after vaccination against SARS-CoV-2: a prospective study. Immunocompromised patients with hematologic malignancies are more susceptible to COVID-19 and at higher risk of severe complications and worse outcomes compared with the general population. In this context, we evaluated the humoral response by determining the titers of neutralizing antibodies (NAbs) against SARS-CoV-2 in patients with WaldenstrÃ¶m macroglobulinemia (WM) after vaccination with the BNT162b2 or AZD1222 vaccine. A US Food and Drug Administration-approved enzyme-linked immunosorbent assay-based methodology was implemented to evaluate NAbs on the day of the first vaccine shot, as well as on days 22 and 50 afterward. A total of 106 patients with WM (43% men; median age, 73 years) and 212 healthy controls (46% men; median age, 66 years) who were vaccinated during the same period at the same center were enrolled in the study (which is registered at www.clinicaltrials.gov as #NCT04743388). Our data indicate that vaccination with either 2 doses of the BNT162b2 or 1 dose of the AZD1222 vaccine leads to lower production of NAbs against SARS-CoV-2 in patients with WM compared with controls on days 22 and 50 ($P < .001$ for all comparisons). Disease-related immune dysregulation and therapy-related immunosuppression are involved in the low humoral response. Importantly, active treatment with either rituximab or Bruton's tyrosine kinase inhibitors was proven as an independent prognostic factor for suboptimal antibody response after vaccination. In conclusion, patients with WM have low humoral response after COVID-19 vaccination, which underlines the need for timely vaccination ideally during a treatment-free period and for continuous vigilance on infection control measures.
Asymptomatic infection after BNT162b2 mRNA COVID-19 vaccination in multiple sclerosis patient.
Varicella-zoster virus reactivation causing herpes zoster ophthalmicus (HZO) after SARS-CoV-2 vaccination - report of three cases. PURPOSE: We are reporting 3 patients who presented acute zoster ophthalmicus (HZO), an activation of varicella-zoster virus, after mRNA anti-SARS-CoV-2 vaccination, seen directly or referred to our center. CASES: A 73-year-old woman with history of ocular sarcoidosis presented HZO in the right V1 dermatome 16â€‰days after a single booster dose of vaccination (Pfizer BioNTech). A 69-year-old woman presented HZO in her V1 left dermatome, occurring 10â€‰days after her first dose of Pfizer BioNTech vaccine. A 72-year-old woman with no history of autoimmune pathology, candidate for cataract surgery, presented 13â€‰days after the

first dose of a Moderna mRNA vaccine with an eruption in the left V1 dermatome. All patients presented the VZV infection after their first dose of a mRNA type of vaccine. Treatment with Valacyclovir 1000â€‰mgâ€‰Ã—â€‰3/ day for 7-14â€‰days was efficient in all cases. CONCLUSION: Vaccines have been reported in the past to trigger different types of side effects such as viral or flu-like symptoms. It is only logical to note many different side effects for SARS-CoV-2 vaccines as the population vaccinated is exceeding any other number in history. VZV is one of the more severe side effects that can, however, be treated. It is quite obvious that, as far as mRNA vaccines are concerned, and probably also other anti-SARS-CoV-2 vaccines, that the benefit of vaccination certainly outweighs the possible but very low risk of ocular side effects that can mostly be treated.

Anti-severe acute respiratory syndrome coronavirus-2 antibody responses following Pfizer-BioNTech vaccination in a patient with multiple sclerosis treated with ocrelizumab: a case report. Patients with multiple sclerosis (MS) repeatedly receive therapies that cause B-lymphocyte depletion. This may lead to abnormal immune responses following coronavirus disease 2019 (COVID-19) vaccination, as has been suggested previously. We therefore evaluated post-vaccination immune responses in a patient with MS treated with ocrelizumab. The intervals between ocrelizumab infusions and vaccination were as recommended by the Section of Multiple Sclerosis and Neuroimmunology of the Polish Neurological Society. A reactive immune response was observed in this patient following vaccination. This suggests that appropriate intervals between ocrelizumab infusions and COVID-19 vaccinations may permit the generation of efficacious immune responses in patients receiving B-lymphocyte depleting therapies.

Letter to the editor: Autoimmune hepatitis after COVID-19 vaccination: A rare adverse effect?

Rhabdomyolysis Following Administration of Comirnaty(Â®). INTRODUCTION: Vaccination against COVID-19 is essential to control the pandemic. The vaccines developed so far have good safety profiles but full knowledge of adverse effects will only be acquired with time and through case reports. CASE DESCRIPTION: We present the case of a man admitted with rhabdomyolysis 3 days after receiving his first dose of the Pfizer coronavirus vaccine Comirnaty(Â®) Other traumatic, infectious, endocrine, electrolyte disturbance and autoimmune causes of rhabdomyolysis were excluded. The temporal relationship between vaccine administration and disease onset indicated possible causality. The patient had a favourable evolution after receiving fluids and completely recovered. To our knowledge, there have been only 69 reports of rhabdomyolysis following Comirnaty(Â®) administration in Europe, as stated by the European Medicines Agency, and this is the first case report in Portugal. DISCUSSION: When a patient presents with rhabdomyolysis without an obvious traumatic or exertional cause, other aetiologies need to be excluded. Drug use is one of the most common causes of rhabdomyolysis in adults. CONCLUSION: We present a case compatible with an adverse effect of Comirnaty(Â®) in order to raise awareness of this condition in vaccinated patients. LEARNING POINTS: Rhabdomyolysis is frequently due to pharmacological causes.COVID-19 vaccines are safe but their adverse effects have not yet been fully elucidated and more case reporting would be beneficial.Rhabdomyolysis secondary to administration the Pfizer anti-COVID-19 vaccine ComirnatyÂ® can be a severe adverse effect and should be considered in the relevant clinical scenario.

Post-mRNA COVID-19 Vaccination Myocarditis. A new trend of myocarditis among young adults who received mRNA vaccines for COVID-19 is emerging. We present the case of a young adult who presented with chest pain 3 days after the second dose of Pfizer-BioNTech COVID-19 vaccine. He had elevated troponin I and C-reactive protein levels at the time of admission. Electrocardiogram (ECG) and echocardiogram findings were unremarkable. The patient improved with conservative management and was discharged home the next day. LEARNING POINTS: Myocarditis is rare but is

increasingly being reported in young adults post vaccination for COVID-19.Patients usually present with chest pain, elevated troponin and/or inflammatory markers.The condition carries a good prognosis and patients usually recover with supportive care.
COVID-19 Vaccine-Induced Thrombotic Thrombocytopenia: A Case Series. Vaccine-induced thrombotic thrombocytopenia is a life-threatening prothrombotic syndrome that has been associated with two adenoviral vector-based coronavirus disease 2019 (COVID-19) vaccines. Although it remains a rare disorder with relatively low incidence, awareness of this condition is crucial given the ongoing vaccination programs of millions around the world.Â In this case series, we report four cases of vaccine-induced thrombotic thrombocytopenia, diagnosed at Queen Alexandra Hospital, Portsmouth, United Kingdom. We also review the mechanism of this syndrome, its clinical presentation, diagnosis, and course of treatment with emphasis on the role of therapeutic plasma exchange.
Safety and immunogenicity of SARS-CoV-2 variant mRNA vaccine boosters in healthy adults: an interim analysis. The emergence of SARS-CoV-2 variants of concern (VOCs) and variants of interest (VOIs) with decreased susceptibility to neutralization has generated interest in assessments of booster doses and variant-specific vaccines. Clinical trial participants who received a two-dose primary series of the COVID-19 vaccine mRNA-1273 approximately 6 months earlier entered an open-label phase 2a study (NCT04405076) to evaluate the primary objectives of safety and immunogenicity of a single booster dose of mRNA-1273 or variant-modified mRNAs, including multivalent mRNA-1273.211. As the trial is currently ongoing, this exploratory interim analysis includes preliminary descriptive results only of four booster groups (nâ€‰=â€‰20 per group). Immediately before the booster dose, neutralizing antibodies against wild-type D614G virus had waned (Pâ€‰<â€‰0.0001) relative to peak titers against wild-type D614G measured 1 month after the primary series, and neutralization titers against B.1.351 (Beta), P.1 (Gamma) and B.1.617.2 (Delta) VOCs were either low or undetectable. Both the mRNA-1273 booster and variant-modified boosters were safe and well-tolerated. All boosters, including mRNA-1273, numerically increased neutralization titers against the wild-type D614G virus compared to peak titers against wild-type D614G measured 1 month after the primary series; significant increases were observed for mRNA-1273 and mRNA-1273.211 (Pâ€‰<â€‰0.0001). In addition, all boosters increased neutralization titers against key VOCs and VOIs, including B.1.351, P.1. and B.1.617.2, that were statistically equivalent to peak titers measured after the primary vaccine series against wild-type D614G virus, with superior titers against some VOIs. This trial is ongoing.
Menstrual changes after covid-19 vaccination.
Cervical lymphadenopathy following coronavirus disease 2019 vaccine: clinical characteristics and implications for head and neck cancer services. OBJECTIVE: Patients with coronavirus disease vaccine associated lymphadenopathy are increasingly being referred to healthcare services. This work is the first to report on the incidence, clinical course and imaging features of coronavirus disease vaccine associated cervical lymphadenopathy, with special emphasis on the implications for head and neck cancer services. METHODS: This was a retrospective cohort study of all patients referred to our head and neck cancer clinics between 16 December 2020 and 12 March 2021. The main outcomes measured were the proportion of patients with vaccine-associated cervical lymphadenopathy, and the clinical and imaging characteristics. RESULTS: The incidence of vaccine-associated cervical lymphadenopathy referrals was 14.8 per cent (n = 13). Five patients (38.5 per cent) had abnormal-looking enlarged and rounded nodes with increased vascularity. Only seven patients (53.9 per cent) reported full resolution within an average of 3.1 Â± 2.3 weeks. CONCLUSION: Coronavirus disease vaccine associated cervical lymphadenopathy can mimic malignant lymphadenopathy and therefore might prove challenging to diagnose and manage correctly. Healthcare services may encounter a significant increase in referrals.

Platelet factor 4 polyanion immune complexes: heparin induced thrombocytopenia and vaccine-induced immune thrombotic thrombocytopenia. BACKGROUND: This is a review article on heparin-induced thrombocytopenia, an adverse effect of heparin therapy, and vaccine-induced immune thrombotic thrombocytopenia, occurring in some patients administered certain coronavirus vaccines. MAIN BODY/TEXT: Immune-mediated thrombocytopenia occurs when specific antibodies bind to platelet factor 4 /heparin complexes. Platelet factor 4 is a naturally occurring chemokine, and under certain conditions, may complex with negatively charged molecules and polyanions, including heparin. The antibody-platelet factor 4/heparin complex may lead to platelet activation, accompanied by other cascading reactions, resulting in cerebral sinus thrombosis, deep vein thrombosis, lower limb arterial thrombosis, myocardial infarction, pulmonary embolism, skin necrosis, and thrombotic stroke. If untreated, heparin-induced thrombocytopenia can be life threatening. In parallel, rare incidents of spontaneous vaccine-induced immune thrombotic thrombocytopenia can also occur in some patients administered certain coronavirus vaccines. The role of platelet factor 4 in vaccine-induced thrombosis with thrombocytopenia syndrome further reinforces the importance the platelet factor 4/polyanion immune complexes and the complications that this might pose to susceptible individuals. These findings demonstrate, how auxiliary factors can complicate heparin therapy and drug development. An increasing interest in biomanufacturing heparins from non-animal sources has driven a growing interest in understanding the biology of immune-mediated heparin-induced thrombocytopenia, and therefore, the development of safe and effective biosynthetic heparins. SHORT CONCLUSION: In conclusion, these findings further reinforce the importance of the binding of platelet factor 4 with known and unknown polyanions, and the complications that these might pose to susceptible patients. In parallel, these findings also demonstrate how auxiliary factors can complicate the heparin drug development.

SARS-CoV-2 vaccinations may not only be complicated by GBS but also by distal small fibre neuropathy.

Audio Interview: New Evidence on SARS-CoV-2 Vaccine Boosters.

Vaccine-Induced Thrombocytopenia with Severe Headache.

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months. BACKGROUND: BNT162b2 is a lipid nanoparticle-formulated, nucleoside-modified RNA vaccine encoding a prefusion-stabilized, membrane-anchored severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) full-length spike protein. BNT162b2 is highly efficacious against coronavirus disease 2019 (Covid-19) and is currently approved, conditionally approved, or authorized for emergency use worldwide. At the time of initial authorization, data beyond 2 months after vaccination were unavailable. METHODS: In an ongoing, placebo-controlled, observer-blinded, multinational, pivotal efficacy trial, we randomly assigned 44,165 participants 16 years of age or older and 2264 participants 12 to 15 years of age to receive two 30-Î¼g doses, at 21 days apart, of BNT162b2 or placebo. The trial end points were vaccine efficacy against laboratory-confirmed Covid-19 and safety, which were both evaluated through 6 months after vaccination. RESULTS: BNT162b2 continued to be safe and have an acceptable adverse-event profile. Few participants had adverse events leading to withdrawal from the trial. Vaccine efficacy against Covid-19 was 91.3% (95% confidence interval [CI], 89.0 to 93.2) through 6 months of follow-up among the participants without evidence of previous SARS-CoV-2 infection who could be evaluated. There was a gradual decline in vaccine efficacy. Vaccine efficacy of 86 to 100% was seen across countries and in populations with diverse ages, sexes, race or ethnic groups, and risk factors for Covid-19 among participants without evidence of previous infection with SARS-CoV-2. Vaccine efficacy against severe disease was 96.7% (95% CI, 80.3 to 99.9). In South Africa, where the SARS-CoV-2 variant of concern B.1.351 (or beta) was predominant, a vaccine efficacy of 100% (95% CI, 53.5 to 100) was observed. CONCLUSIONS: Through 6 months of follow-up and despite a gradual decline in

vaccine efficacy, BNT162b2 had a favorable safety profile and was highly efficacious in preventing Covid-19. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.).

SARS-CoV-2 Neutralization with BNT162b2 Vaccine Dose 3.

Reply to a Letter to the Editor on a Published Manuscript: Bilateral Multifocal Choroiditis following COVID-19 Vaccination.

A case of anti-GBM nephritis following centipede bites and COVID-19 vaccination. A case of newly developed anti-glomerular basement membrane (GBM) glomerulonephritis (GN) following centipede bites and COVID-19 vaccination is presented. A 70-year-old woman presented for investigation of mild fever, generalized fatigue, and macroscopic hematuria with no past history of renal disease. One year earlier, she had been bitten by a centipede. Based on the governmental policy, she was given the first COVID-19 vaccination, and the second injection was planned 3Â weeks later. Accidentally, she was again bitten by a centipede, and the injured site had swollen severely. Based on a physician's judgment, the interval between vaccinations was extended to 8Â weeks. One week after the second vaccination, macroscopic hematuria occurred suddenly, coincident with mild fever. Her serum anti-GBM titer was above the upper limit. There was no pulmonary involvement. Renal pathology showed anti-GBM GN, and she was treated with corticosteroid pulse therapy followed by sequential plasmapheresis. She had advanced renal dysfunction, but was independent of dialysis therapy during the one month of the remission induction therapy phase, and she is being treated with immunosuppressant therapy. Both vaccination and animal bites skew towards Th1 immunity, a key mechanism involved in the development of necrotizing GN evoked by anti-GBM antibody. Though there is no direct evidence for causality linking centipede bites, vaccination, and anti-GBM GN, the risk of anti-GBM GN appears to be increased by excessively induced Th1 immunity.

Transient Eyelid Edema Following COVID-19 Vaccination.

Does COVID-19 vaccination cause excess deaths?

Detection of Unilateral Axillary Nodal Uptake Both at 68Ga-DOTATOC and 18F-FDG PET/CT After 1 Week From COVID-19 Vaccine. Recently, vaccination against COVID-19 has gained wide diffusion, especially among vulnerable individuals, such as cancer patients. At the same time, patients have been undergoing PET/CT examinations after vaccination in an increasing number, and cases of false-positive axillary nodal uptake have been described, mostly at 18F-FDG PET. Here, we describe the case of both 68Ga-DOTATOC and 18F-FDG axillary nodal uptake in a young woman affected by a metastatic retroperitoneal paraganglioma.

COVID-19 vaccination unveiling subclinical SjÃ¶gren's syndrome.

Acute generalized pustular psoriasis exacerbated by the COVID-19 vaccine.

Reporting at Least One Adverse Effect Post-COVID-19 Vaccination From Primary Health Care in Muscat. Introduction Vaccinations against COVID-19 were licensed with limited testing assurances to the public triggering a widespread hesitancy around expected adverse reactions. Limited data was reported from Arabian Gulf countries on vaccine adverse effects. Objectives This study looked at the rate of reporting at least one side effect post-COVID-19 vaccination and its associated factors (sociodemographic characteristics, clinical condition, and type of vaccines). Additionally, questions about safetyÂ and willingness to recommend them were included. Study design Phone interviews on post-COVID-19 vaccination adverse effects were utilized to record responses related to reporting at least one side effect post vaccinations across the studied variables. Data collection continued for two months (from 1(st) March to 30(th) April 2021). Methodology Participants were adults (Omani citizens and non-citizens) who received AstraZeneca (AZ) or Pfizer (PF) vaccines from primary care facilities in Muscat and were randomly selected from the health information system. Responses were saved in a bespoke Google form/questionnaire. Chi-squared tests were utilized to determine potential factors associated with the dependent variable. Results A

total of 753 participants completed the phone interviews. The mean age was 52 (3.5), males (54.1%), and 65.1% were Omanis. Hypertension (39.7%), diabetes (34.1%), and asthma (16.7%) were the commonest comorbidities. AZ and PF were administered to 78% and 22% of the participants. Of them, 49.8% reported at least one adverse effect post-COVID-19 vaccination. The proportion of participants with at least one adverse effect was significantly more in individuals who were younger, females, with more than secondary education, and employed (p value < 0.001, 0.01, <0.001, and <0.001, respectively). There was no severe reaction (anaphylactic shock) to the vaccines, and most adverse effects were mild-moderate. The proportion of individuals who reported adverse effects were higher with AZ vs PF (53% vs 38.6, p = 0.001). The most common reported localized adverse effects were pain and tenderness (28.3% and 12.1%). Fever and body aches were the commonly reported systemic adverse effects (33.5% and 29.2%). The safety of COVID-19 vaccines was well perceived, and most participants were willing to recommend them to others. Conclusions The current study confirms findings from existing literature on the mild to moderate adverse effects of AZ and PF vaccines. Despite the subjective nature of this study, it is reassuring that the studied COVID-19 vaccines can be administered safely. However, more longitudinal studies are needed to test their efficacy in disease prevention.

Comparison of Antibody and T Cell Responses Induced by Single Doses of ChAdOx1 nCoV-19 and BNT162b2 Vaccines. There are limited data directly comparing humoral and T cell responses to the ChAdOx1 nCoV-19 and BNT162b2 vaccines. We compared Ab and T cell responses after first doses of ChAdOx1 nCoV-19 vs. BNT162b2 vaccines. We enrolled healthcare workers who received ChAdOx1 nCoV-19 or BNT162b2 vaccine in Seoul, Korea. Anti-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) S1 protein-specific IgG Abs (S1-IgG), neutralizing Abs (NT Abs), and SARS-CoV-2-specific T cell response were evaluated before vaccination and at 1-wk intervals for 3 wks after vaccination. A total of 76 persons, comprising 40 injected with the ChAdOx1 vaccine and 36 injected with the BNT162b2 vaccine, participated in this study. At 3 wks after vaccination, the mean levels (Â±SD) of S1-IgG and NT Abs in the BNT162b2 participants were significantly higher than in the ChAdOx1 participants (S1-IgG, 14.03Â±7.20 vs. 6.28Â±8.87, p<0.0001; NT Ab, 183.1Â±155.6 vs. 116.6Â±116.2, p=0.035), respectively. However, the mean values of the T cell responses in the 2 groups were comparable after 2 wks. The humoral immune response after the 1st dose of BNT162b2 developed faster and was stronger than after the 1st dose of ChAdOx1. However, the T cell responses to BNT162b2 and ChAdOx1 were similar.

Evaluation of Post-Vaccination Symptoms of Two Common COVID-19 Vaccines Used in Abha, Aseer Region, Kingdom of Saudi Arabia. BACKGROUND: The Pfizer-BioNTech (BNT162b2) and the Oxford-AstraZeneca (ChAdOx1 nCoV-19) COVID-19 vaccines have shown promising safety and acceptability. However, COVID-19 vaccine side effects play an essential role in public vaccine confidence. We aimed to study the side effects of these COVID-19 vaccines. METHODS: A randomized, cross-sectional descriptive study was conducted between March and May of 2021. In total, 330 participants among the King Khalid University community in the Aseer region of the Kingdom of Saudi Arabia reported their side effects following the COVID-19 vaccine. A questionnaire was designed and validated to collect the participants' demographic data and COVID-19-related symptoms after COVID-19 vaccine injection. RESULTS: Symptoms associated with COVID-19 were reported by 226 participants (68.5%). The most common side effects reported by the participants were fever (n = 136, 41.2%), fatigue (n = 119, 36.1%), headache (n = 86, 24.2%), malaise (n = 121, 36.7%), myalgia (n = 121, 36.7%), and muscle and joint pain (n = 76, 23%). Of the participants, 5.1% became infected with COVID-19 after vaccination. Symptoms were significantly more common in males than in females (p = 0.006). CONCLUSION: The incidence of COVID-19 vaccination side effects in the Aseer region, Kingdom of Saudi Arabia, was consistent with the manufacturers' data. The most

common post-vaccination symptoms reported by the participants were fever, myalgia, malaise, fatigue, muscle and joint pain, and headache. The results of this study showed significant variation in adverse events between Pfizer-BioNTech and Oxford-AstraZeneca COVID-19 vaccines. Healthcare providers and recipients of vaccines can be more confident about the safety of Pfizer-BioNTech and Oxford-AstraZeneca COVID-19 vaccines.

Cellular and humoral immune responses following SARS-CoV-2 mRNA vaccination in patients with multiple sclerosis on anti-CD20 therapy. SARS-CoV-2 messenger RNA vaccination in healthy individuals generates immune protection against COVID-19. However, little is known about SARS-CoV-2 mRNA vaccine-induced responses in immunosuppressed patients. We investigated induction of antigen-specific antibody, B cell and T cell responses longitudinally in patients with multiple sclerosis (MS) on anti-CD20 antibody monotherapy (nâ€‰=â€‰20) compared with healthy controls (nâ€‰=â€‰10) after BNT162b2 or mRNA-1273 mRNA vaccination. Treatment with anti-CD20 monoclonal antibody (aCD20) significantly reduced spike-specific and receptor-binding domain (RBD)-specific antibody and memory B cell responses in most patients, an effect ameliorated with longer duration from last aCD20 treatment and extent of B cell reconstitution. By contrast, all patients with MS treated with aCD20 generated antigen-specific CD4 and CD8 T cell responses after vaccination. Treatment with aCD20 skewed responses, compromising circulating follicular helper T (T(FH)) cell responses and augmenting CD8 T cell induction, while preserving type 1 helper T (T(H)1) cell priming. Patients with MS treated with aCD20 lacking anti-RBD IgG had the most severe defect in circulating T(FH) responses and more robust CD8 T cell responses. These data define the nature of the SARS-CoV-2 vaccine-induced immune landscape in aCD20-treated patients and provide insights into coordinated mRNA vaccine-induced immune responses in humans. Our findings have implications for clinical decision-making and public health policy for immunosuppressed patients including those treated with aCD20.

The tangled history of mRNA vaccines.

Immune response variables and viral mutations impact on COVID-19 reinfection and relapse. The possibility of human reinfection with SARS-CoV-2, the coronavirus responsible for COVID-19, has not previously been thoroughly investigated. Although it is generally believed that virus-specific antibodies protect against COVID-19 pathogenesis, their duration of function and temporal activity remain unknown. Contrary to media reports that people retain protective antibody responses for a few months, science does not exclude reinfection and disease relapse shortly after initiating all immune responses during the primary onset of COVID-19. Despite production of antiviral antibodies, activated CD4+/CD8+ lymphocytes, and long-lived memory B cells, susceptibility to reinfection in humans for extended periods cannot be precluded due to repeated exposures to coronavirus or potential reactivation of the virus due to incomplete virus clearance. However, the mechanism of reinfection remains unknown. The biological characteristics of SARS-CoV-2, such as emergence of multiple mutations in the virus RNA molecules, transmissibility, rates of infection, reactivation and reinfection, can all affect the trajectory of the virus spread. Innate and adaptive immune response variables, differences in underlying diseases, and comorbidities, particularly in high risk individuals, can influence the dynamics of the virus infection. In this article, immune parameters and viral mutations pertaining to reinfection and disease relapse are reviewed and scientific gaps are discussed.

Seroprevalence and levels of IgG antibodies after COVID-19 infection or vaccination. BACKGROUND: In a country-wide seroprevalence study of COVID-19 in Estonia, we aimed to determine the seroprevalence and the dynamics of IgG against SARS-CoV-2 after vaccination or positive PCR-test. METHODS: Leftover blood samples were selected between 8 February and 25 March 2021, by SYNLAB Estonia from all counties and age groups (0-9, 10-19, 20-59, 60-69, 70-79 and

80-100â€‰years) proportionally to the whole Estonian population and tested for IgG against SARS-CoV-2 spike protein receptor-binding domain (anti-S-RBD IgG) using Abbott SARS-CoV-2 IgG II Quant assay. Antibody levels after positive PCR-test or vaccination were described by exponential increase-decrease models. RESULTS: According to total of 2517 samples, overall seroprevalence (95% confidence interval [CI]) was 20.1% (18.5-21.7%), similar in all age groups, but varied between counties. If individuals vaccinated with the first dose at least 14â€‰d before antibody measurement were assumed to be seronegative, the overall seroprevalence was 15.8% (14.4-17.3%), 4.0-fold larger than the proportion of PCR-confirmed COVID-19 cases. Of seropositive individuals (nâ€‰=â€‰506) 194 (38.3%; 33.8-43.1%) had not had positive PCR-test or been vaccinated. According to exponential increase-decrease model, the peak of anti-S-RBD IgG in a 52-year-old (median age of PCR-positive and/or vaccinated individuals) was significantly higher after vaccination compared with positive PCR-test (22,082 (12,897-26,875) vs. 6732 (2321-8243) AU/mL), but half-life was similar (26.5 (6.9-46.1) vs. 38.3 (8.2-68.5) d). CONCLUSIONS: One year after the start of COVID-19 pandemic the actual prevalence of infection is still underestimated compared with PCR-confirmed COVID-19 cases. Older compared with younger individuals have lower anti-S-RBD IgG level after vaccination, but similar decline rate.
Humoral Immunity After mRNA SARS-CoV-2 Vaccination in Allogeneic HCT Recipients-Room for Improvement and Much to Learn.
The real impact of COVID-19 on an East London Sickle cell population: results of a service-wide survey.
Lymphadenopathy with florid lymphoid and Langerhans cell hyperplasia and hemophagocytosis mimicking lymphoma after COVID-19 mRNA vaccination.
Hypermetabolic lymphadenopathy on positron emission tomography scan following COVID-19 vaccination: A mimicker of disease progression in Hodgkin lymphoma.
A Rare Case of Henoch-SchÃ¶nlein Purpura Following a COVID-19 Vaccine-Case Report. In the COVID-19 pandemic era, anti-SARS-CoV-2 vaccination is considered to be the most efficient way to overtake the COVID-19 scourge. Like all medicines, vaccines are not devoid of risks and can in rare cases cause some various side effects. The objective of this case report is to highlight this unusual presentation of Henoch-SchÃ¶nlein purpura following an anti-COVID-19 vaccination in a 62-year-old adult. The 62-year-old patient admitted to the emergency room for a petechial purpuric rash, sloping, occurring within hours, involving both legs and ascending. The clinical signs also included polyarthralgia and hematuria. Reported in the history the notion of an anti-COVID-19 vaccination 8 days prior to the onset of symptomatology. In the case of our patient, we retain the diagnosis of rheumatoid purpura based on the EULAR/PRINTO/PReS diagnostic criteria. Corticosteroid therapy (prednisone) was started, resulting to a rapid regression of clinical and laboratory symptoms, few days after the treatment. Patient was asymptomatic on subsequent visits. The low number of published cases of post-vaccine vasculitis does not question the safety of vaccines, but knowledge of such complications deserves to be known in order to avoid new immunizations that could have more serious consequences, and to avoid aggravating or reactivating a pre-existing vasculitis.
Polymyalgia rheumatica as uncommon adverse event following immunization with COVID-19 vaccine: A case report and review of literature. Polymyalgia rheumatica following immunization with Covid-19 mRNA vaccine: TRL-7 and TRL-9 as common link.
Cutaneous adverse effects of the available COVID-19 vaccines. Vaccination has played a crucial role in the improvement of global health. Some of the world's deadliest diseases, like smallpox and rinderpest, have been eradicated with the help of vaccines, and many others have been restrained. The appearance of the strain of coronavirus disease 2019 (COVID-19) severe acute respiratory syndrome coronavirus 2 and its impact on global health have made the development of effective and

safe vaccines crucial for this new lethal disease. So far, there are three main types of COVID-19 vaccines in use around the world: messenger RNA-based vaccines, adenoviral vector vaccines, and inactivated whole-virus vaccines. Some of them have passed through phase 3 of safety and efficacy trials and are widely used for prophylaxis of COVID-19 infection. A plethora of cutaneous adverse events have been reported, most of them mild or moderate injection-site reactions. Some rare delayed inflammatory reactions such as "COVID arm" have also been reported, posing questions on their pathophysiology and clinical importance. Some rare serious adverse events, such as vaccine-induced prothrombotic immune thrombocytopenia and anaphylaxis, have been described raising great concerns on the safety of some widely spread vaccines. More data need to be collected with further and more detailed analysis. The overall risk of such severe adverse reactions remains extremely low, and the benefits of the existing vaccines in combating the widespread threat of COVID-19 continue to outweigh the risk of their side effects.

Vaccine injury compensation: the Israeli case. BACKGROUND: Following other countries, Israel passed the Vaccine Injury Compensation Law in 1989, which provides for compensation to vaccine recipients who had suffered injuries without proving negligence. In 2021, after deliberations between the ministries of health and of finance Covid-19 vaccines (administered from the beginning of the campaign on December 20, 2020 and up to December 21, 2022) were included within the compensation law. The current study aims to examine the objectives of Israel's Vaccine Injury Compensation Law, at the time of its enactment, and to explore barriers to their fulfillment. These issues are especially relevant in light of the discussions held on the option for liability exemption which excludes the possibility of redress from the Covid-19 vaccine manufacturers in case of injury attributed to the vaccine, and considering the heavy burden of proof required in standard tort law. METHODS: The study employed a qualitative methodology which made use of both content analysis of relevant documents and in-depth interviews. RESULTS: In passing the Vaccine Injury Compensation Law, legislators sought to assist vaccine recipients who had suffered injuries by both lowering their burden of proof as well as establishing a short and efficient procedure for deliberating their claims. Furthermore, legislators believed that the assurance of compensation to vaccine recipients who had suffered injuries would help to encourage a high rate of vaccination compliance. An examination of the law's implementation over time revealed that the aforementioned goals were not attained. CONCLUSIONS: Implementation of the law since its enactment missed the opportunity to fulfill its original purposes to promote public health fundamental principles of fairness and solidarity. In addition, the adversarial proceedings as well as some of the law's provisions have the potential to undermine public trust in the State's willingness to grant compensation for injuries that are attributed to vaccines and thereby subvert the law's pivotal objective of promoting trust and vaccine compliance. We suggest that allowing circumstantial evidence as to an association between vaccine and an injury, transitioning to administrative deliberation, making available to the public details of cases where compensation was awarded, as well as other possible emendations would help it better reflect the values of fairness and solidarity that underlying the law's purpose. These would also promote the level of trust in healthcare authorities which is essential to preserving high vaccine coverage.

Clinical Characteristics and Outcomes of Adults With a History of Heart Failure Hospitalized for COVID-19. BACKGROUND: It is important to understand the risk for in-hospital mortality of adults hospitalized with acute coronavirus disease 2019 (COVID-19) infection with a history of heart failure (HF). METHODS: We examined patients hospitalized with COVID-19 infection from January 1, 2020 to July 22, 2020, from 88 centers across the US participating in the American Heart Association's COVID-19 Cardiovascular Disease registry. The primary exposure was history of HF and the primary outcome was in-hospital mortality. To examine the association between history of HF and in-hospital mortality,

we conducted multivariable modified Poisson regression models that included sociodemographics and comorbid conditions. We also examined HF subtypes based on left ventricular ejection fraction in the prior year, when available. RESULTS: Among 8920 patients hospitalized with COVID-19, mean age was 61.4Â±17.5 years and 55.5% were men. History of HF was present in 979 (11%) patients. In-hospital mortality occurred in 31.6% of patients with history of HF, and 16.9% in patients without a history of HF. In a fully adjusted model, history of HF was associated with increased risk for in-hospital mortality (relative risk: 1.16 [95% CI, 1.03-1.30]). Among 335 patients with left ventricular ejection fraction, heart failure with reduced ejection fraction was significantly associated with in-hospital mortality in a fully adjusted model (heart failure with reduced ejection fraction relative risk: 1.40 [95% CI, 1.10-1.79]; heart failure with mid-range ejection fraction relative risk: 1.06 [95% CI, 0.65-1.73]; heart failure with preserved ejection fraction relative risk, 1.06 [95% CI, 0.84-1.33]). CONCLUSIONS: Risk for in-hospital mortality was substantial among adults with history of HF, in large part due to age and comorbid conditions. History of heart failure with reduced ejection fraction may confer especially elevated risk. This population thus merits prioritization for the COVID-19 vaccine.

Clinical and pathologic correlation of cutaneous COVID-19 vaccine reactions including V-REPP: A registry-based study. BACKGROUND: Cutaneous reactions after COVID-19 vaccination have been commonly reported; however, histopathologic features and clinical correlations have not been well characterized. METHODS: We evaluated for a history of skin biopsy all reports of reactions associated with COVID-19 vaccination identified in an international registry. When histopathology reports were available, we categorized them by reaction patterns. RESULTS: Of 803 vaccine reactions reported, 58 (7%) cases had biopsy reports available for review. The most common histopathologic reaction pattern was spongiotic dermatitis, which clinically ranged from robust papules with overlying crust, to pityriasis rosea-like eruptions, to pink papules with fine scale. We propose the acronym "V-REPP" (vaccine-related eruption of papules and plaques) for this spectrum. Other clinical patterns included bullous pemphigoid-like (nÂ =Â 12), dermal hypersensitivity (nÂ =Â 4), herpes zoster (nÂ =Â 4), lichen planus-like (nÂ =Â 4), pernio (nÂ =Â 3), urticarial (nÂ =Â 2), neutrophilic dermatosis (nÂ =Â 2), leukocytoclastic vasculitis (nÂ =Â 2), morbilliform (nÂ =Â 2), delayed large local reactions (nÂ =Â 2), erythromelalgia (nÂ =Â 1), and other (nÂ =Â 5). LIMITATIONS: Cases in which histopathology was available represented a minority of registry entries. Analysis of registry data cannot measure incidence. CONCLUSION: Clinical and histopathologic correlation allowed for categorization of cutaneous reactions to the COVID-19 vaccine. We propose defining a subset of vaccine-related eruption of papules and plaques, as well as 12 other patterns, following COVID-19 vaccination.

Immunological and pathological outcomes of SARS-CoV-2 challenge following formalin-inactivated vaccine in ferrets and rhesus macaques. There is an urgent requirement for safe and effective vaccines to prevent COVID-19. A concern for the development of new viral vaccines is the potential to induce vaccine-enhanced disease (VED). This was reported in several preclinical studies with both SARS-CoV-1 and MERS vaccines but has not been reported with SARS-CoV-2 vaccines. We have used ferrets and rhesus macaques challenged with SARS-CoV-2 to assess the potential for VED in animals vaccinated with formaldehyde-inactivated SARS-CoV-2 (FIV) formulated with Alhydrogel, compared to a negative control vaccine. We showed no evidence of enhanced disease in ferrets or rhesus macaques given FIV except for mild transient enhanced disease seen 7 days after infection in ferrets. This increased lung pathology was observed at day 7 but was resolved by day 15. We also demonstrate that formaldehyde treatment of SARS-CoV-2 reduces exposure of the spike receptor binding domain providing a mechanistic explanation for suboptimal immunity.

Bilateral EK Rejection After COVID-19 Vaccine. Owing to its rapid development, short-term and long-term effects of the COVID-19 vaccine are still not well understood. This case report highlights bilateral corneal endothelial graft rejection after administration of the Pfizer COVID-19 vaccine. A 73-

year-old woman with bilateral Descemet stripping endothelial keratoplasty presented with bilateral decreased visual acuity, ocular pain, and photophobia after her second dose of the Pfizer-BioNTech COVID-19 vaccine. Two weeks after vaccine administration, the uncorrected visual acuity was 20/70 and 20/40. Central corneal thickness as measured by ultrasound was 809 and 825 Î¼m and by Scheimfplug imaging was 788 and 751 Î¼m at the pupil center. Slit-lamp biomicroscopy revealed quiet conjunctiva and sclera but was significant for thickened corneas with Descemet folds in both eyes. The patient was instructed to use prednisolone acetate 1% every 1 to 2 hours with Muro ointment at bedtime.

Transient Thrombocytopenia With Glycoprotein-Specific Platelet Autoantibodies After Ad26.COV2.S Vaccination: A Case Report.

Cancer or COVID-19? A Review of Recommendations for COVID-19 Vaccination in Cancer Patients. While emergency use is authorized for numerous COVID-19 vaccines and the high-risk population including cancer patients or those with immunosuppression due to disease or therapy is prioritized, data on this group's specific safety and efficacy of these vaccines remains limited. Safety data from clinical trials and population data may be extrapolated, and these vaccines may be used for cancer patients. However, concerns of efficacy due to the variable immune response in patients with active cancers undergoing active therapy and cancer survivors with chronic immunosuppression remain. The authors aim to discuss the current recommendations for use of COVID-19 vaccination in patients with cancer.

Immune response (IgG) following full inoculation with BNT162b2 COVIDâ€‘19 mRNA among healthcare professionals. Soon after the beginning of the severe acute respiratory syndrome coronavirusÂ 2 (SARSâ€‘CoVâ€‘2) pandemic in December, 2019, numerous research teams, assisted by vast capital investments, achieved vaccine development in a fraction of time. However, almost 8Â months following the initiation of the European vaccination programme, the need for prospective monitoring of the vaccineâ€‘induced immune response, its determinants and related sideâ€‘effects remains a priority. The present study aimed to quantify the immune response following full vaccination with the BNT162b2 coronavirus diseaseÂ 2019 (COVIDâ€‘19) mRNA vaccine by measuring the levels of immunoglobulinÂ G (IgG) titers in healthcare professionals. Moreover, common sideâ€‘effects and factors associated with IgG titers were identified. For this purpose, blood samples from 517Â individuals were obtained and analysed. Blood sampling was performed at a mean period of 69.0Â±23.5Â days following the second dose of the vaccine. SARSâ€‘CoVâ€‘2Â IgG titers had an overall mean value ofÂ 4.23Â±2.76. Females had higher titers than males (4.44Â±2.70 and 3.89 Â±2.84, respectively; P=0.007), while nonâ€‘smokers had higher titers than smokers (4.48Â±2.79 and 3.80Â±2.64, respectively; P=0.003). An older age was also associated with lower antibody titers (P<0.001). Moreover, the six most prevalent adverse effects were pain at the injection site (72.1%), generalized fatigue (40.5%), malaise (36.3%), myalgia (31,0%), headache (25.8%) and dizziness/weakness (21.6%). The present study demonstrated that the immune response after receiving the BNT162b2 COVIDâ€‘19 mRNA vaccine is dependent on various modifiable and nonâ€‘modifiable factors. Overall, the findings of the present study highlight two key aspects of the vaccination programs: First, the need for prospective immunosurveillance studies in order to estimate the duration of immunity, and second, the need to identify those individuals who are at a greater risk of developing low IgG titers in order to evaluate the need for a third dose of the vaccine.

Acute Perimyocarditis Following First Dose of mRNA Vaccine Against COVID-19.

Severe Diabetic Ketoacidosis After the Second Dose of mRNA-1273 COVID-19 Vaccine.

Effective viral vector response to SARS-CoV-2 booster vaccination in a patient with rheumatoid arthritis after initial ineffective response to messenger RNA vaccine.

Dynamics of the Cellular and Humoral Immune Response After BNT162b2 Messenger Ribonucleic Acid Coronavirus Disease 2019 (COVID-19) Vaccination in COVID-19-Naive Nursing Home Residents. Short-term humoral and cellular immune responses are diminished after BNT162b2 messenger ribonucleic acid coronavirus disease 2019 (COVID-19) vaccination in COVID-19-naive nursing home residents, a population particularly vulnerable to the disease. We found both responses to decline after 4 weeks and remain lower than those of healthcare workers after 24 weeks, with an estimated half-life of the antibody response of 47 days. At 4 weeks, older age was significantly associated with a decreased humoral response, and diabetes mellitus and active malignancy were associated with a decreased cellular response. Our results imply that COVID-19-naive nursing home residents are a target group for booster vaccination trials.

Dynamics of antibody response to BNT162b2 vaccine after six months: a longitudinal prospective study. BACKGROUND: SARS-CoV-2 mRNA vaccines have proven high efficacy, however, limited data exists on the duration of immune responses and their relation to age and side effects. METHODS: We studied the antibody and memory T cell responses after the two-dose BNT162b2 vaccine in 122 volunteers up to 6 months and correlated the findings with age and side effects. FINDINGS: We found a robust antibody response to Spike protein after the second dose. However, the antibody levels declined at 12 weeks and 6 months post-vaccination, indicating a waning of the immune response over time. At 6 months after the second dose, the Spike antibody levels were similar to the levels in persons vaccinated with one dose or in COVID-19 convalescent individuals. The antibodies efficiently blocked ACE2 receptor binding to SARS-CoV-2 Spike protein of five variants of concern at one week but this was decreased at three months. 87% of individuals developed Spike-specific memory T cell responses, which were lower in individuals with increased proportions of immunosenescent CD8(+) TEMRA cells. We found antibody response to correlate negatively with age and positively with the total score of vaccination side effects. INTERPRETATION: The mRNA vaccine induces a strong antibody response to SARS-CoV-2 and five VOCs at 1 week post-vaccination that decreases thereafter. T cell responses, although detectable in the majority, were lower in individuals with higher T cell immunosenescence. The deterioration of vaccine response suggests the need to monitor for the potential booster vaccination.

Erratum to: Clinical characteristics of headache after vaccination against COVID-19 (coronavirus SARS-CoV-2) with the BNT162b2 mRNA vaccine: a multicentre observational cohort study. [This corrects the article DOI: 10.1093/braincomms/fcab169.].

Case report: acute myocarditis following the second dose of mRNA-1273 SARS-CoV-2 vaccine. BACKGROUND: The SARS-CoV-2 pandemic has led to the development of the first mRNA vaccines used in humans. The vaccines are well tolerated, safe, and highly efficacious; however, post-marketing surveillance is revealing potential rare adverse effects. We report a case of symptomatic acute myocarditis following administration of the second dose of mRNA-1273 SARS-CoV-2 vaccine. CASE SUMMARY: A 44-year-old man presented with chest pain and ST-segment elevation 4 days after receiving the second dose of mRNA-1273 SARS-CoV-2 Vaccine. Emergent coronary angiogram showed minimal coronary artery disease. Cardiac magnetic resonance imaging confirmed acute myocarditis. Diagnosis of vaccine-associated myocarditis was made given the temporal relationship and supportive treatment initiated. Follow-up at 1 month confirmed complete symptomatic recovery and echocardiogram demonstrated normalization of cardiac function. DISCUSSION: Acute myocarditis should be considered in patients who present with chest pain or dyspnoea within days of receiving mRNA-1273 SARS-CoV-2 vaccination, especially after the second dose. This may be managed successfully with supportive therapies with complete recovery of cardiac function and symptoms. Further research is warranted to determine the mechanisms by which mRNA vaccines may cause myocarditis and for potential long-term cardiovascular injury.

Nanoparticles in the clinic: An update post COVID-19 vaccines. Nanoparticles are used in the clinic to treat cancer, resolve mineral deficiencies, image tissues, and facilitate vaccination. As a modular technology, nanoparticles combine diagnostic agents or therapeutics (e.g., elements, small molecules, biologics), synthetic materials (e.g., polymers), and biological molecules (e.g., antibodies, peptides, lipids). Leveraging these parameters, nanoparticles can be designed and tuned to navigate biological microenvironments, negotiate biological barriers, and deliver therapeutics or diagnostic agents to specific cells and tissues in the body. Recently, with the Emergency Use Authorization of the COVID-19 lipid nanoparticle vaccines, the advantages and potential of nanoparticles as a delivery vehicle have been displayed at the forefront of biotechnology. Here, we provide a 5-year status update on our original "Nanoparticles in the Clinic" review (also a 2-year update on our second "Nanoparticles in the Clinic" review) by discussing recent nanoparticle delivery system approvals, highlighting new clinical trials, and providing an update on the previously highlighted clinical trials.

Immune Thrombocytopenic Purpura Following Pfizer-BioNTech COVID-19 Vaccine in an Elderly Female. Mass vaccination campaigns are being run all over the globe to combat the ongoing COVID-19 pandemic. There have been several reports of immune thrombocytopenic purpura (ITP) occurrence following COVID-19 vaccination. However, ITP due to theÂ Pfizer-BioNTech vaccine has been rarely reported, and a causal link has not been identified. The pathophysiology behind immune thrombocytopenia is similar to heparin-inducedÂ thrombocytopenia. The management is also similar to other secondary immune thrombocytopenia. We present a case of a 67-year old female diagnosed with immune thrombocytopenia following Pfizer-BioNTech vaccination. The treatment was resistant to high-dose steroids, intravenous immunoglobulin (IVIG), and rituximab and eventually responded to a thrombopoietin-stimulating agent.

Petechiae and Desquamation of Fingers Following Immunization With BTN162b2 Messenger RNA (mRNA) COVID-19 Vaccine. Since late 2019, the coronavirus disease 2019 (COVID-19) pandemic, caused byÂ severe acute respiratory syndromeÂ coronavirus2Â (SARS-CoV-2), has killed over three million people. More than 600,000 of these deaths have occurred in the United States alone. While advances in the treatment of COVID-19 have been made, the advent of highly effective vaccines against this coronavirus variant has given hope that the end of the pandemic may be near. Unfortunately, resistance towards vaccination remains a barrier to virus eradication both in the United States and globally. The driving factor for much of this opposition is the concern over potential adverse reactions from the vaccines against SARS-CoV-2. In order to combat this, it is imperative that vaccine side effects and their corresponding clinical course are clearly described. This report details the case of a female patient who developed acral petechiae, desquamation of the fingers, and a facial rash that occurred shortly after receiving the second dose of the Pfizer-BioNTech COVID-19 vaccine.

Tolosa-Hunt Syndrome Presenting After COVID-19 Vaccination. Coronavirus disease 2019 (COVID-19) infection is associated with a plethora of neurological complications. Newly developed vaccinations targeting the severe acute respiratory syndromeÂ coronavirus 2Â (SARS-CoV-2) viral spike protein represent a great epidemiological promise with respect to the resolution of the pandemic. However, vaccinations are not without side effects and, in rare cases, have evenÂ been implicated in various autoimmune phenomena. In this report, we describe a case of Tolosa-Hunt syndrome (THS), a granulomatous inflammatory process of the cavernous sinus, occurring in a patient one week after getting COVID-19 vaccination. This rare diagnosis of exclusion must be considered in patients presenting with painful ophthalmoplegia.

A rare case of vaccine-induced immune thrombosis and thrombocytopenia and approach to management. BACKGROUND: The use of the COVID-19 vaccines Vaxzevria from AstraZeneca and Covishield from Janssen has been associated with sporadic reports of thrombosis with thrombocytopenia, a complication referred to as vaccine-induced immune thrombotic

thrombocytopenia (VITT) or vaccine-induced prothrombotic immune thrombocytopenia. It presents commonly as cerebral sinus venous thrombosis (CSVT), within 4-30 days of vaccination. Females under 55 years of age are considered to be especially at high risk. Mortality up to 50% has been reported in some countries. Identification of early warning signs and symptoms with prompt medical intervention is crucial. CASE DESCRIPTION: We report here a case of VITT in a young female who presented 11 days after receiving the first dose of the Covishield vaccine, with severe headache and hemiparesis. She was diagnosed with CSVT with a large intraparenchymal bleed, requiring decompressive craniectomy and extended period on mechanical ventilation. CONCLUSION: The patient was successfully treated with intravenous immunoglobulin and discharged after 19 days in ICU. Although she was left with long-term neurological deficits, an early presentation and a multidisciplinary approach to management contributed toward a relatively short stay in hospital and avoided mortality.

Combined subacromial-subdeltoid bursitis and supraspinatus tear following a COVID-19 vaccination: A case report. INTRODUCTION: After a vaccine administration, many people have localized symptoms such as pain, redness, warmth, swelling, itching and/or bruising, which usually improve in a few days. If the clinical symptoms do not improve in this period, a shoulder injury related to vaccine administration (SIRVA) should be ruled out. The most common cause of a SIRVA is an improper injection technique. Herein, we reported the first case of combined subacromial-subdeltoid bursitis and supraspinatus tendon tear which was apparently caused by an improper COVID-19 vaccination technique. CASE PRESENTATION: A 51-year-old Thai female began to experience severe right shoulder pain about 3 hours after receiving a COVID-19 vaccination. Ultrasonography showed combined subacromial-subdeltoid bursitis and supraspinatus tendon tear. Her clinical symptoms gradually improved after treatment with an oral non-steroidal anti-inflammatory drug. Our investigation found that an improper injection technique had been used, namely inserting the needle too deeply, and using an incorrect landmark. CONCLUSION: We report a case of combined subacromial-subdeltoid bursitis and supraspinatus tendon tear following a second dose of the Oxford-AstraZeneca COVID-19 vaccine. This is a rare condition which is usually related to an incorrect injection technique. To reduce the chance of SIRVA, the healthcare worker giving the injection should pay careful attention to find the appropriate landmark, and ensuring the correct needle length and direction of the injection.

Post-COVID-19 vaccine acute hyperactive encephalopathy with dramatic response to methylprednisolone: A case report. BACKGROUND: Since introducing the SARS-CoV-2 vaccination, different adverse effects and complications have been linked to the vaccine. Variable neurological complications have been reported after receiving the COVID-19 vaccine, such as acute encephalopathy. CASE PRESENTATION: In this report, we describe a 32-year-old previously healthy man who developed acute confusion, memory disturbances, and auditory hallucination within 24 hours from getting his first dose of the COVID-19 Moderna vaccine.EEG showed features of encephalopathy, CSF investigations were nonspecific, and MRI head did not depict any abnormality. He received five days of ceftriaxone and acyclovir without any benefit. DISCUSSION: Extensive workup for different causes of acute encephalopathy, including autoimmune encephalitis, was negative. Also, Our patient improved dramatically after receiving methylprednisolone, supporting an immune-mediated mechanism behind his acute presentation. Accordingly, we think the COVID-19 vaccine is the only possible cause of our patient presentation, giving the temporal relationship and the absence of other risk factors for encephalopathy. CONCLUSION: the clinician should be aware of the possible neurological complications of the different COVID-19 vaccines. Further research is needed to clarify the pathophysiology of such complications.

SARS-CoV-2 Antibody Isotypes in Systemic Lupus Erythematosus Patients Prior to Vaccination: Associations With Disease Activity, Antinuclear Antibodies, and Immunomodulatory Drugs During the

First Year of the Pandemic. OBJECTIVES: Impact of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic on individuals with arthritis has been highlighted whereas data on other rheumatic diseases, e.g., systemic lupus erythematosus (SLE), are scarce. Similarly to SLE, severe SARS-CoV-2 infection includes risks for thromboembolism, an unbalanced type I interferon response, and complement activation. Herein, SARS-CoV-2 antibodies in longitudinal samples collected prior to vaccination were analyzed and compared with SLE progression and antinuclear antibody (ANA) levels. METHODS: One hundred patients (83 women) with established SLE and a regular visit to the rheumatologist (March 2020 to January 2021) were included. All subjects donated blood and had done likewise prior to the pandemic. SARS-CoV-2 antibody isotypes (IgG, IgA, IgM) to the cell receptor-binding S1-spike outer envelope protein were detected by ELISA, and their neutralizing capacity was investigated. IgG-ANA were measured by multiplex technology. RESULTS: During the pandemic, 4% had PCR-confirmed infection but 36% showed SARS-CoV-2 antibodies of â‰¥1 isotype; IgA was the most common (30%), followed by IgM (9%) and IgG (8%). The antibodies had low neutralizing capacity and were detected also in prepandemic samples. Plasma albumin (p = 0.04) and anti-dsDNA (p = 0.003) levels were lower in patients with SARS-CoV-2 antibodies. Blood group, BMI, smoking habits, complement proteins, daily glucocorticoid dose, use of hydroxychloroquine, or self-reported coronavirus disease 2019 (COVID-19) symptoms (except fever, >38.5Â°C) did not associate with SARS-CoV-2 antibodies. CONCLUSION: Our data from early 2021 indicate that a large proportion of Swedish SLE patients had serological signs of exposure to SARS-CoV-2 but apparently with a minor impact on the SLE course. Use of steroids and hydroxychloroquine showed no distinct effects, and self-reported COVID-19-related symptoms correlated poorly with all antibody isotypes.

Tetravalent Influenza Vaccine Is Not Associated With Neuroaxonal Damage in Multiple Sclerosis Patients. BACKGROUND: Efficacy of vaccines and disease activity linked to immunization are major concerns among people with multiple sclerosis (pwMS). OBJECTIVE: To assess antibody responses to seasonal influenza antigens and vaccine-associated neuroaxonal damage utilizing serum neurofilament light chain (sNfL) in pwMS receiving dimethyl fumarate (DMF). METHODS: In this prospective study, the 2020/2021 seasonal tetravalent influenza vaccine was administered to 20 pwMS treated with DMF and 15 healthy controls (HCs). The primary endpoints were responder rate of strain-specific antibody production (seroconversion or significant (4-fold) increase in influenza-antibody titers for â‰¥2/4 strains) at 30 days post-vaccination and changes in sNfL levels. RESULTS: All patients treated with DMF fulfilled the responder criteria for immunization compared with 53% of the controls. However, higher proportions of HCs already had influenza-antibody titers â‰¥1:40 at baseline (53% vs. 41%, p = 0.174). sNfL levels were comparable among both groups at baseline and did not increase 34 days after vaccination. In addition, no clinical or radiological disease reactivation was found. CONCLUSION: DMF-treated patients mount an adequate humoral immune response to influenza vaccines. Within the limits of the small cohort investigated, our data suggest that influenza immunization is not associated with clinical or subclinical disease reactivation.

Hepatitis C Virus Reactivation Following COVID-19 Vaccination - A Case Report. PURPOSE: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection impacted morbidity and mortality during the pandemic of 2020-2021. A number of anti-COVID-19 vaccines have been developed with an unprecedented speed. While these vaccines have good efficacy and are safe, the experience with their use is limited and hence the knowledge of rare side effects. Identifying rare complications is important for future safe use of these vaccines. MATERIALS AND METHODS: Here, we report a case of a 82-year old patient with dementia who was admitted to a nursing home in the Netherlands. After vaccination with COVID-19 vaccination, physical examinations and lab tests were performed. RESULTS: She had a reactivation of hepatitis C infection after vaccination with the mRNA-based

Pfizer-BioNTech COVID-19 vaccine. This reactivation manifested with jaundice, loss of consciousness, hepatic coma and death. CONCLUSION: This reactivation of hepatitis C virus after vaccination with the Pfizer-BioNTech COVIDâ€‘19 vaccine suggests a need for critical consideration of individuals with prior HCV infection and considered for COVID-19 vaccination.

The characteristics of COVID-19 vaccine-related headache: Clues gathered from the healthcare personnel in the pandemic. INTRODUCTION: Headache is a frequent adverse event after viral vaccines. We aimed to investigate the frequency and clinical associations of COVID-19 vaccine-related headache. METHODS: The characteristics, associations of this headache, main comorbidities, headache history following the influenza vaccine and during COVID-19 were investigated using a web-based questionnaire. RESULTS: A total of 1819 healthcare personnel (mean age: 44.4â€‰Â±â€‰13.4 years, 1222 females), vaccinated with inactivated virus, contributed to the survey; 209 (11.4%) had been infected with COVID-19. A total of 556 participants (30.6%) reported headache with significant female dominance (36.1% vs. 19.3%), 1.8â€‰Â±â€‰3.5 (median: 1; IQR: 0-2) days following vaccination. One hundred and forty-four participants (25.9%) experienced headache lasting â‰¥3 days. Headache was mostly bilateral without accompanying phenomena, less severe, and shorter than COVID-19-related headache. The presence of primary headaches and migraine were significantly associated with COVID-19 vaccine-related headache (ORsâ€‰=â€‰2.16 [95% CI 1.74-2.68] and 1.65 [1.24-2.19], respectively). Headache during COVID-19 or following influenza vaccine also showed significant association with headache following COVID-19 vaccine (ORâ€‰=â€‰4.3 [95% CI 1.82-10.2] and ORâ€‰=â€‰4.84 [95% CI 2.84-8.23], respectively). Only thyroid diseases showed a significant association (ORâ€‰=â€‰1.54 [95% CI 1.15-2.08]) with vaccine-related headache among the common comorbidities. CONCLUSION: Headache is observed in 30.6% of the healthcare workers following COVID-19 vaccine and mostly experienced by females with pre-existing primary headaches, thyroid disorders, headache during COVID-19, or headache related to the influenza vaccine.

Substantial impact of post-vaccination contacts on cumulative infections during viral epidemics. Background: The start of 2021 was marked by the initiation of a global vaccination campaign against the novel coronavirus SARS-CoV-2. Formulating an optimal distribution strategy under social and economic constraints is challenging. Optimal distribution is additionally constrained by the potential emergence of vaccine resistance. Analogous to chronic low-dose antibiotic exposure, recently inoculated individuals who are not yet immune play an outsized role in the emergence of resistance. Classical epidemiological modelling is well suited to explore how the behavior of the inoculated population impacts the total number of infections over the entirety of an epidemic. Methods: A deterministic model of epidemic evolution is analyzed, with seven compartments defined by their relationship to the emergence of vaccine-resistant mutants and representing three susceptible populations, three infected populations, and one recovered population. This minimally computationally intensive design enables simulation of epidemics across a broad parameter space. The results are used to identify conditions minimizing the cumulative number of infections. Results: When an escape variant is only modestly less infectious than the originating strain within a naÃ¯ve population, the cumulative number of infections does not monotonically decrease with the rate of vaccine distribution. Analysis of the model also demonstrates that inoculated individuals play a major role in the mitigation or exacerbation of vaccine-resistant outbreaks. Modulating the rate of host-host contact for the inoculated population by less than an order of magnitude can alter the cumulative number of infections by more than 20%. Conclusions: Mathematical modeling shows that limiting post-vaccination contacts can perceptibly affect the course of an epidemic. The consideration of limitations on post-vaccination contacts remains relevant for the entire duration of any vaccination campaign including the current status of SARS-CoV-2 vaccination.

Recurrent herpes zoster after COVID-19 vaccination in patients with chronic urticaria being treated with cyclosporine-A report of 3 cases.

Humoral and cellular immune response to severe acute respiratory syndrome coronavirus-2 vaccination in haemodialysis and kidney transplant patients. End-stage renal disease (ESRD) patients are amongst the vulnerable groups and thus prioritized in the Coronavirus disease-2019 vaccination programmes. However, this cohort was excluded from vaccine-trials and yet shares the same vaccination scheme with the general population. Here, we explore trends of immune response-proportions amongst ESRD patients on renal replacement therapy for up to 4â€‰weeks post-vaccination completion with Pfizer/Moderna vaccines. From inception to 10 July 2021, we searched six online-databases for articles reporting humoral and cellular immune response proportions for up to 4â€‰weeks post booster-vaccination. We pooled the responders' proportions by meta-analysis and conducted a meta-regression stratifying outcomes by significant confounders. Twenty-seven eligible studies reported 2789 ESRD patients. 1337, 1452 and 477 were on haemodialysis, received kidney transplantation, and healthy controls, respectively. Haemodialysis patients' proportions of humoral and cellular immune responses varied from 87.29% (80.77-93.81)-88.78% (86.76-90.80) and 62.86% (56.56, 69.17)-85.78% (78.99, 92.57), respectively, between first- and fourth-weeks. Kidney transplant patients' proportions of humoral and cellular immune responses ranged from 2.6% (0.06-13.48)-29.87% (27.68, 32.07) and 5.13% (0.63-17.3)-59.84% (54.57-65.10), respectively, between first- and fourth-weeks. All healthy controls maintained â‰¥93% proportions of both responses throughout the follow-up. Study design and country of study influenced the pooled response proportions. Conclusively, haemodialysis and kidney transplant patients have lower proportions of humoral and cellular immune responses than healthy controls. However, haemodialysis patients' response proportions improve, reaching near healthy-control levels by the fourth week. Kidney transplant patients' lower responses' proportions also improve but remain significantly lower than healthy controls throughout four-weeks. The "one-size-fits-all" vaccination scheme might be inadequate for kidney transplant patients.

Vaccine-induced interstitial lung disease: a rare reaction to COVID-19 vaccination.

SARS-CoV2-specific Humoral and T-cell Immune Response After Second Vaccination in Liver Cirrhosis and Transplant Patients. BACKGROUND & AIMS: Detailed information on the immune response after second vaccination of cirrhotic patients and liver transplant (LT) recipients against severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) is largely missing. We aimed at comparing the vaccine-induced humoral and T-cell responses of these vulnerable patient groups. METHODS: In this prospective cohort study, anti-SARS-CoV-2 spike-protein titers were determined using the DiaSorin LIAISON (anti-S trimer) and Roche Elecsys (anti-S RBD) immunoassays in 194 patients (141 LT, 53 cirrhosis Child-Pugh A-C) and 56 healthy controls before and 10 to 84 days after second vaccination. The spike-specific T-cell response was assessed using an interferon-gamma release assay (EUROIMMUN). A logistic regression analysis was performed to identify predictors of low response. RESULTS: After the second vaccination, seroconversion was achieved in 63% of LT recipients and 100% of cirrhotic patients and controls using the anti-S trimer assay. Median anti-SARS-CoV-2 titers of responding LT recipients were lower compared with cirrhotic patients and controls ($P < .001$). Spike-specific T-cell response rates were 36.6%, 65.4%, and 100% in LT, cirrhosis, and controls, respectively. Altogether, 28% of LT recipients did neither develop a humoral nor a T-cell response after second vaccination. In LT recipients, significant predictors of absent or low humoral response were age >65 years (odds ratio [OR], 4.57; 95% confidence interval [CI], 1.48-14.05) and arterial hypertension (OR, 2.50; 95% CI, 1.10-5.68), whereas vaccination failure was less likely with calcineurin inhibitor monotherapy than with other immunosuppressive regimens (OR, 0.36; 95% CI, 0.13-0.99). CONCLUSION: Routine serological testing of the vaccination response and a third vaccination in

patients with low or absent response seem advisable. These vulnerable cohorts need further research on the effects of heterologous vaccination and intermittent reduction of immunosuppression before booster vaccinations.

Dynamic IgG seropositivity after rollout of CoronaVac and BNT162b2 COVID-19 vaccines in Chile: a sentinel surveillance study. BACKGROUND: By July 14, 2021, 81Â·3 % of adults (aged â‰¥18 years) in Chile had received a first SARS-CoV-2 vaccine and 72Â·3% had received a second SARS-CoV-2 vaccine, with the majority of people given Sinovac's inactivated CoronaVac vaccine (75Â·3% of vaccines dispensed) or Pfizer-BioNTech's mRNA BNT162b2 vaccine (20Â·9% of vaccines dispensed). Due to the absence of simultaneous real-world data for these vaccines, we aimed to compare SARS-CoV-2 IgG positivity between vaccines using a dynamic national monitoring strategy. METHODS: From March 12, 2021, 28 testing stations for SARS-CoV-2 IgG detection were installed in hotspots based on cellular-phone mobility tracking within the most populated cities in Chile. Individuals voluntarily approaching the testing stations were invited to do a lateral flow test by finger prick and respond to a questionnaire on sociodemographic characteristics, vaccination status (including type of vaccine if one was received), variables associated with SARS-CoV-2 exposure, and comorbidities. We compared the proportion of individuals testing positive for anti-SARS-CoV-2 IgG across sites by week since vaccination between recipients of CoronaVac and BNT162b2. Unvaccinated participants served as a control population and were matched to vaccinated individuals on the basis of date of presentation to the testing station, gender, and age group. Individuals were excluded from the analysis if they were younger than 18 years, had no declared gender, had an invalid IgG test result, had previously tested positive for SARS-CoV-2 infection on PCR, could not recall their vaccination status, or had been immunised against COVID-19 with vaccines other than CoronaVac or BNT162b2. Here, we report data collected up to July 2, 2021. FINDINGS: Of 64â€‰813 individuals enrolled, 56â€‰261 were included in the final analysis, of whom 33â€‰533 (59Â·6%) had received at least one dose of the CoronaVac vaccine, 8947 (15Â·9%) had received at least one dose of the BNT162b2 vaccine, and 13â€‰781 (24Â·5%) had not received a vaccine. SARS-CoV-2 IgG positivity during week 4 after the first dose of CoronaVac was 28Â·1% (95% CI 25Â·0-31Â·2; 220 of 783 individuals), reaching a peak of 77Â·4% (75Â·5-79Â·3; 1473 of 1902 individuals) during week 3 after the second dose. SARS-CoV-2 IgG positivity during week 4 after the first dose of the BNT162b2 vaccine was 79Â·4% (75Â·7-83Â·1; 367 of 462 individuals), increasing to 96Â·5% (94Â·9-98Â·1; 497 of 515 individuals) during week 3 after the second dose and remaining above 92% until the end of the study. For unvaccinated individuals, IgG seropositivity ranged from 6Â·0% (4Â·4-7Â·6; 49 of 810 individuals) to 18Â·7% (12Â·5-24Â·9; 28 of 150 individuals) during the 5 month period. Regression analyses showed that IgG seropositivity was significantly lower in men than women and in people with diabetes or chronic diseases for CoronaVac vaccine recipients (p<0Â·0001), and for individuals aged 60 years and older compared with people aged 18-39 years for both vaccines (p<0Â·0001), 3-16 weeks after the second dose. INTERPRETATION: IgG seropositivity was lower after CoronaVac than after BNT162b2 and declined over time since vaccination for CoronaVac recipients but not BNT162b2 recipients. Prolonged IgG monitoring will allow further evaluation of seropositivity overtime, providing data, in conjunction with effectiveness studies, for possible future re-assessment of vaccination strategies. FUNDING: Instituto Sistemas Complejos de IngenierÃ-a and Ministerio de Salud Chile. TRANSLATION: For the Spanish translation of the abstract see Supplementary Materials section.

Autoimmunity roots of the thrombotic events after COVID-19 vaccination. Although vaccination represents the most promising way to stop or contain the coronavirus disease 2019 (COVID-19) pandemic and safety and effectiveness of available vaccines were proven, a small number of individuals who received anti-SARS-CoV-2 vaccines developed a prothrombotic syndrome. Vaccine-induced immune thrombotic thrombocytopenia (VITT) can be triggered by the adenoviral vector-

based vaccine, whereas lipid nanoparticle-mRNA-based vaccines can induce rare cases of deep vein thrombosis (DVT). Although the main pathogenic mechanisms behind this rare phenomenon have not yet been identified, both host and vaccine factors might be involved, with pathology at least in part being related to the vaccine-triggered autoimmune reaction. In this review, we are considering some aspects related to pathogenesis, major risk factors, as well as peculiarities of diagnosis and treatment of this rare condition.

Decline of antibody titres 3Â months after two doses of BNT162b2 in non-immunocompromised adults. OBJECTIVE: To assess the antibody response in non-immunocompromised adults after two doses of BNT162b2. METHODS: Prospective, single-centre observational study in non-immunocompromised adults aged 18Â years or more who received two doses of BNT162b2. The study contemplates analyses of serum samples collected 1.5, 3, 6, 9 and 12Â months after the second dose of BNT162b2; results of the 1.5- and 3-month time-points are presented in this report. Antibodies against the receptor binding domain of the S1 subunit of the spike protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (anti-RBD antibodies) were measured using a commercial quantitative immunoassay. A threshold of 4160 AU/mL (corresponding to an ID(50) of 1:250) was used as surrogate marker for serum neutralizing activity. RESULTS: Of 273 hospital workers who received two doses of BNT162b2, 260 (95%) agreed to participate in the study; 2/260 (0.8%) were excluded because of immunocompromised conditions. At the time of this report, 230/258 (89%) participants (mean age 46.0Â years (SD 11.4Â years); 143/230 (62%) female; 87/230 (38%) male) had completed 3Â months of follow up after the second dose of BNT162b2. Thirty-six (16%) of the 230 had documented mild SARS-CoV-2 infection before receiving the first dose of BNT162b2. Median (interquartile range (IQR)) anti-RBD titres 1.5Â months after vaccination were 9356 (5844-16 876) AU/mL; 3Â months after vaccination, median anti-RBD titres had declined to 3952 (2190-8561) AU/mL (pÂ <Â 0.001). Of 199/230 (86.5%) participants who had anti-RBD titres above 4160 AU/mL 1.5Â months after the second dose of BNT162b2, only 95/230 (41%) maintained anti-RBD titres above this level 3Â months after vaccination (pÂ <Â 0.001). CONCLUSIONS: The decline of anti-RBD antibodies 3Â months after the second dose of BNT162b2 is of concern because it raises the possibility of a short-lived humoral immunity after vaccination. Booster doses of BNT162b2 might be required to maintain high titres of anti-RBD antibodies over time.

SARS-CoV-2 Antibody Response After a Third Dose of the BNT162b2 Vaccine in Patients Receiving Maintenance Hemodialysis or Peritoneal Dialysis. RATIONALE & OBJECTIVE: Recent studies showed that antibody titers after vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the dialysis population are diminished as compared with the general population, suggesting the possible value of a third booster dose. We characterized the humoral response after 3 doses of the BNT162b2 vaccine in patients treated with either maintenance hemodialysis (HD) or peritoneal dialysis (PD). STUDY DESIGN: Case series. SETTING & PARTICIPANTS: 69 French patients (38 HD and 31 PD) treated at a single center who received 3 doses of the BNT162b2 vaccine. FINDINGS: Humoral response was evaluated using plasma levels of anti-SARS-CoV-2 spike protein S1 immunoglobulin measured after the second dose and at least 3 weeks after the third dose of the BNT162b2 vaccine. Patients (median age 68 years [interquartile range (IQR), 53-76 years], 65% men) had a median anti-S1 antibody level of 284 [IQR, 83-1190] AU/mL after the second dose, and 7,554 [IQR, 2,268-11,736] AU/mL after the third dose. Three patients were nonresponders (anti-S1 antibody levelÂ < 0.8 AU/mL), and 12 were weak responders (anti-S1 antibody level 0.8-50 AU/mL) after the second vaccine dose. After the third dose, 1 of the 3 initial nonresponders produced anti-spike antibody, and all the 12 initial weak responders increased their antibody levels. Patients with a greater increase in anti-S1 antibody levels after a third dose had lower antibody levels after the second dose, and a longer time interval between the second and the third dose. Adverse events did

not seem to be more common or severe after a third vaccine dose. LIMITATIONS: Observational study, small sample size. Relationship between antibody levels and clinical outcomes is not well understood. CONCLUSIONS: A third dose of the BNT162b2 vaccine substantially increased antibody levels in patients receiving maintenance dialysis and appeared to be as well tolerated as a second dose.

Cardiovascular Complication following Covishield Vaccination in Nepal: A Case Report. Nepal started the COVID-19 vaccination on 27 January 2021 with AstraZeneca/Oxford Coronavirus Disease-19 AZD1222 (Covishield) vaccine to control the Coronavirus disease pandemic. The vaccine has a good safety profile, with cardiovascular complications being rare. Herein we report a rare case of cardiovascular complication following Covishield vaccination in a 33 years old female who had dizziness and elevated blood pressure immediately following vaccination and abnormal electrocardiogram showing T wave inversions followed by left bundle branch block. The patient was kept on observation, following which the blood pressure and electrocardiogram changes were normal by seven days. This cardiovascular complication following the vaccination demands further investigation into the adverse event of the vaccine. However, since the benefit of the vaccine outweighs the risk, World Health Organization has recommended the continuity of the vaccine as of now.

Side Effects after Second Dose of Covishield Vaccine among Health Care Workers: A Descriptive Cross Sectional Study. INTRODUCTION: COVID 19 vaccination will protect us from getting COVID-19. Some side effects are common which are signs that our body is building protection. This side effects will go away in a few days. The aim of this study is to find out side effects seen among health care workers after second dose of covishield vaccination. METHODS: This was a descriptive cross-sectional study conducted at Kathmandu medical college and Teaching Hospital from 22nd April 2021 till 30th April 2021. Ethical approval was revceived from Institutional Commitee of Instituite. Convienient sampling was done. The second dose of covishield vaccine was administered 12 weeks after its first dose. The vaccine was administered intramuscularly (IM) into deltoid muscle. Statistical Package for the Social Sciences were used for analysis. RESULTS: Out of 220 cases taken, 135 were male and 85 were female. In our study 178 (80.90%) complaint of pain at injection site after second dose of covishield vaccine followed by 97 (44.09%) complaint of fatigue, 43 (19.54%) complaint of headache, 18 (8.18%) complaint of chills, 11 (5.00%)complaint of fever, 6 (2.72%) complaint of dizziness and 5 (2.27%) complaint of nausea. CONCLUSIONS: Pain at injection site, fatigue and headache were common side effects seen after second dose of Covishield vaccination.

Continued need for non-pharmaceutical interventions after COVID-19 vaccination in long-term-care facilities. Long-term care facilities (LTCFs) bear disproportionate burden of COVID-19 and are prioritized for vaccine deployment. LTCF outbreaks could continue occurring during vaccine rollout due to incomplete population coverage, and the effect of vaccines on viral transmission are currently unknown. Declining adherence to non-pharmaceutical interventions (NPIs) against within-facility transmission could therefore limit the effectiveness of vaccination. We built a stochastic model to simulate outbreaks in LTCF populations with differing vaccination coverage and NPI adherence to evaluate their interacting effects. Vaccination combined with strong NPI adherence produced the least morbidity and mortality. Healthcare worker vaccination improved outcomes in unvaccinated LTCF residents but was less impactful with declining NPI adherence. To prevent further illness and deaths, there is a continued need for NPIs in LTCFs during vaccine rollout.

Lessons of the month 1: Longitudinal extensive transverse myelitis following AstraZeneca COVID-19 vaccination. Longitudinal extensive transverse myelitis (LETM) is a rare but recognised complication of vaccination. We report the case of a 58-year-old man admitted to hospital 10 days after his first AstraZeneca COVID-19 vaccination with progressive neurological symptoms and signs,

and investigations and imaging consistent with LETM.This case reviews the literature and the investigative process behind excluding other diagnoses given the patient's background of pulmonary sarcoidosis. It is unique in being the first UK report of a case of LETM with a strong temporal link to COVID-19 vaccination.

Supraclavicular and Axillary Lymphadenopathy Induced by COVID-19 Vaccination on 18F-Fluorthanatrace, 68Ga-DOTATATE, and 18F-Fluciclovine PET/CT. COVID-19 vaccination has started in most countries, and postvaccination imaging is inevitable in the oncologic population. The immune response to the vaccination in the form of reactive lymphadenopathy has been well documented on 18F-FDG PET/CT. We present the imaging findings of 3 patients who have undergone non-FDG PET/CT imaging including 18F-fluorthanatrace, 68Ga-DOTATATE, and 18F-fluciclovine PET/CT. It is crucial to recognize the timing and laterality of immunization to avoid false-positive findings.

Neurological symptoms and neuroimaging alterations related with COVID-19 vaccine: Cause or coincidence? Although vaccination against Coronavirus disease-2019 (COVID-19) is still occurring, several adverse effects temporally related to these vaccines are already being reported, even if through isolated case reports. In the present study, we describe the lesions seen on magnetic resonance imaging (MRI) of three patients who developed neurological symptoms after receiving the ChAdOX1 nCoV-19 vaccine (Oxford/AstraZeneca). The first patient presented with an ischemic stroke in the posterior limb of the left internal capsule, two days after vaccination. The second patient presented with a left facial nerve palsy, seven days after vaccination. The third patient presented with myelitis, eight days after receiving the vaccine. All patients presented the symptoms after the first dose of the vaccine and did not have a history of previous COVID-19. The real incidence of these types of complications is not known yet, but it is important to consider the possibility of COVID-19 vaccine complications, in patients with a recent history of vaccination and recent development of neurological symptoms, even though this association is only casual. Longitudinal studies are necessary to further analyze the incidence of the adverse effects of each vaccine against SARS-CoV-2.

Axillary Lymphadenopathy After Coronavirus Disease 2019 Vaccinations in Patients With Thoracic Malignancy: Incidence, Predisposing Factors, and Imaging Characteristics. OBJECTIVES: Axillary lymphadenopathy from coronavirus disease 2019 (COVID-19) vaccine is an emerging phenomenon during unprecedented mass vaccinations, which can be incidentally found on computed tomography (CT) scans. This study investigated the incidence, predisposing factors, and imaging characteristics of vaccine-related axillary lymphadenopathy in patients with thoracic malignancy who underwent CT scans before and after COVID-19 vaccinations. METHODS: The study included patients with thoracic malignancies who received two doses of mRNA-based COVID-19 vaccinations and had prevaccine and postvaccine chest CT scans. Postvaccine chest CT scan results were reviewed for increase in size of lymph nodes in the axilla and subpectoral areas, comparing with the prevaccine scan results. The cases with lymphadenopathy were further reviewed independently by two radiologists referring to clinical information to find whether lymphadenopathy was attributed to the vaccinations. RESULTS: Vaccine-related axillary lymphadenopathy was noted in 21 of 232 patients (9.0%). The median short-axis diameter of the largest node was 7 mm (range: 5-14 mm). The median number of increased nodes was 4 (range: 1-10). The median time to the postvaccine scan revealing lymphadenopathy was 1.7 weeks (range:Â -2.9 to 6.6) from the second dose. Vaccine-related lymphadenopathy was noted more often in women than in men (18 of 144, 12.5% versus 3 of 88, 3.4%, respectively; pÂ = 0.019) and with mRNA-1273 vaccines than BNT162b2 vaccines (6 of 28, 21% versus 15 of 204, 7.4%, respectively; pÂ = 0.026). CONCLUSIONS: The incidence of lymphadenopathy was 9%, with a median onset time of 1.7 weeks after the second vaccine dose. Female sex and vaccine type (mRNA-1273

vaccine) were associated with higher frequency of lymphadenopathy, providing initial observations to inform further investigations in larger cohorts.

Vogt-Koyanagi-Harada Disease Associated with COVID-19 mRNA Vaccine. A 54-year-old Chinese male with no previous ocular history presented to the ophthalmology department for the bilateral acute painless blurring of vision after receiving the 1st dose of COVID-19 mRNA vaccine (PFIZER-BioNTech/COMIRNATY). Clinical examination and imaging tests were consistent with Vogt-Koyanagi-Hara disease. The patient responded well with a high dose of intravenous methylprednisolone followed by a tapering dose of oral prednisolone.

Case Report: Two Cases of Subacute Thyroiditis Following SARS-CoV-2 Vaccination. Subacute thyroiditis is an inflammatory thyroid disorder associated with viral infections. Rare cases of subacute thyroiditis have also been described following vaccination. Recently, a few cases of subacute thyroiditis following SARS-CoV-2 vaccination have also been reported. Here, we present two cases of cytological proven subacute thyroiditis after receiving the first dose of a SARS-CoV-2 vaccination. We describe clinical, laboratory, imaging and cytological findings in two cases of subacute thyroiditis that presented in our department 2 weeks after SARS-CoV-2 vaccination with Spikevax (Moderna Biotech, Spain) and Vaxzevria (AstraZeneca; Sweden). Both cases did not have a previous history of thyroid disorders and presented with anterior and lateral neck pain. Clinical test results as well as cytological findings were consistent with subacute thyroiditis. Subacute thyroiditis may develop following a SARS-CoV-2 vaccination and should be considered as a possible side effect in cases that present with thyroid pain.

Poor Neutralizing Antibody Responses in 132 Patients with CLL, NHL and HL after Vaccination against SARS-CoV-2: A Prospective Study. Emerging data suggest suboptimal antibody responses to COVID-19 vaccination in patients with hematological malignancies. We evaluated the humoral response following the BNT162b2 vaccine in patients with chronic lymphocytic leukemia (CLL), non-Hodgkin's lymphoma (NHL), and Hodgkin's lymphoma (HL). An FDA-approved, ELISA-based methodology was implemented to evaluate the titers of neutralizing antibodies (NAbs) against SARS-CoV-2 on day 1 of the first vaccine, and afterwards on day 22 and 50. One hundred and thirty-two patients with CLL/lymphomas and 214 healthy matched controls vaccinated during the same period, at the same center were enrolled in the study (NCT04743388). Vaccination with two doses of the BNT162b2 vaccine led to lower production of NAbs against SARS-CoV-2 in patients with CLL/lymphomas compared with controls both on day 22 and on day 50 ($p < 0.001$ for all comparisons). Disease-related immune dysregulation and therapy-related immunosuppression are involved in the low humoral response. Importantly, active treatment with Rituximab, Bruton's tyrosine kinase inhibitors, or chemotherapy was an independent prognostic factor for suboptimal antibody response. Patients with HL showed superior humoral responses to the NHL/CLL subgroups. In conclusion, patients with CLL/lymphomas have low humoral response following COVID-19 vaccination, underlining the need for timely vaccination ideally during a treatment-free period and for continuous vigilance on infection control measures.

The Day after Mass COVID-19 Vaccination: Higher Hypermetabolic Lymphadenopathy Detection on PET/CT and Impact on Oncologic Patients Management. The widespread COVID-19 vaccination led to unexpected PET findings. Notably, axillary and interpectoral lymphadenopathies ipsilateral to the vaccine inoculation were observed. We aimed to assess the hypermetabolic lymphadenopathy (HLN) detection rate on PET/CT. Secondly, we investigated factors that might help in HLN differential diagnosis. A retrospective analysis on 1196 consecutive patients referred for a PET/CT was performed. All patients were asked about the date, type and site of vaccine injections. HLNs were recorded and categorized according to risk classes and SUVmax grades. A statistical analysis was performed to assess the correlation between HLN detection and different clinical/vaccine data. HLN

detection rate was 15% and 27% in the No Vac- and vac-groups ($p < 0.001$), respectively. In the Vac-group, age ($p < 0.001$) and time interval from vaccine-to-PET ($p = 0.010$) were inversely correlated with HLN detection. Furthermore, SUVmax significantly changed during time intervals, with lower values beyond 20 days ($p < 0.001$). In the era of mass COVID-19 vaccination, a higher axillary and interpectoral lymphadenopathies detection ipsilateral to vaccine injection was observed. These PET findings can be wrongly interpreted, complicating cancer patients' management. To minimize these pitfalls, a detailed vaccination anamnesis must be recorded and should take into account the appropriate PET schedule.

Healthcare Staff Perceptions Following Inoculation with the BNT162b2 mRNA COVID-19 Vaccine at University Hospitals Coventry & Warwickshire NHS Trust. Background: COVID-19 vaccination programmes offer hope for a potential end to the acute phase of the COVID-19 pandemic. We present perceptions following from a cohort of healthcare staff at the UK NHS hospital, which first initiated the BNT162b2 mRNA COVID-19 ("Pfizer") vaccination program. Methods: A paper-based survey regarding perceptions on the BNT162b2 mRNA COVID-19 vaccine was distributed to all healthcare workers at the University Hospitals Coventry & Warwickshire NHS Trust following receipt of the first vaccine dose. Results: 535 healthcare workers completed the survey, with a 40.9% response rate. Staff felt privileged to receive a COVID-19 vaccine. Staff reported that they had minimised contact with patients with confirmed or suspected COVID-19. Reported changes to activity following vaccination both at work and outside work were guarded. Statistically significant differences were noted between information sources used by staff groups and between groups of different ethnic backgrounds to inform decisions to receive vaccination. Conclusions: NHS staff felt privileged to receive the COVID-19 vaccine, and felt that their actions would promote uptake in the wider population. Concerns regarding risks and side effects existed, but were minimal. This research can be used to help inform strategies driving wider vaccine uptake amongst healthcare staff and the public.

SARS-CoV-2 infection shortly after BNT162b2 vaccination results in high anti-spike antibody levels in nursing home residents and staff. INTRODUCTION: One dose of a coronavirusÂ disease 2019 (COVID-19) vaccine can elicit high antibody titers in individuals who were previously infected by severe acute respiratory syndromeÂ coronavirus 2 (SARS-CoV-2). However, it is unclear how a SARS-CoV-2 infection shortly after a first COVID-19 vaccine dose affects antibody responses. METHODS: Here we investigate residents and staff of a nursing home, where a COVID-19 outbreak occurred shortly after the first BNT162b2 immunization. RESULTS AND CONCLUSIONS: Our data show that individuals who got infected as early as 10 days after their first immunization show antibody levels comparable to fully vaccinated individuals.

Hospitalizations Associated with COVID-19 Among Children and Adolescents - COVID-NET, 14 States, March 1, 2020-August 14, 2021. Although COVID-19-associated hospitalizations and deaths have occurred more frequently in adults,(â€) COVID-19 can also lead to severe outcomes in children and adolescents (1,2). Schools are opening for in-person learning, and many prekindergarten children are returning to early care and education programs during a time when the number of COVID-19 cases caused by the highly transmissible B.1.617.2 (Delta) variant of SARS-CoV-2, the virus that causes COVID-19, is increasing.(Â§) Therefore, it is important to monitor indicators of severe COVID-19 among children and adolescents. This analysis uses Coronavirus Disease 2019-Associated Hospitalization Surveillance Network (COVID-NET)(Â¶) data to describe COVID-19-associated hospitalizations among U.S. children and adolescents aged 0-17 years. During March 1, 2020-August 14, 2021, the cumulative incidence of COVID-19-associated hospitalizations was 49.7 per 100,000 children and adolescents. The weekly COVID-19-associated hospitalization rate per 100,000 children and adolescents during the week ending August 14, 2021 (1.4) was nearly five times the rate during

the week ending June 26, 2021 (0.3); among children aged 0-4 years, the weekly hospitalization rate during the week ending August 14, 2021, was nearly 10 times that during the week ending June 26, 2021.** During June 20-July 31, 2021, the hospitalization rate among unvaccinated adolescents (aged 12-17 years) was 10.1 times higher than that among fully vaccinated adolescents. Among all hospitalized children and adolescents with COVID-19, the proportions with indicators of severe disease (such as intensive care unit [ICU] admission) after the Delta variant became predominant (June 20-July 31, 2021) were similar to those earlier in the pandemic (March 1, 2020-June 19, 2021). Implementation of preventive measures to reduce transmission and severe outcomes in children is critical, including vaccination of eligible persons, universal mask wearing in schools, recommended mask wearing by persons aged â‰¥2 years in other indoor public spaces and child care centers,(â€ â€) and quarantining as recommended after exposure to persons with COVID-19.(Â§Â§).
False Coronavirus Disease 2019 Cases due to Contamination by Inactivated Virus Vaccine. A false-positive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reverse-transcription polymerase chain reaction result can lead to unnecessary public health measures. We report 2 individuals whose respiratory specimens were contaminated by an inactivated SARS-CoV-2 vaccine strain (CoronaVac), likely at vaccination premises. Incidentally, whole genome sequencing of CoronaVac showed adaptive deletions on the spike protein, which do not result in observable changes of antigenicity.
Gastrointestinal mucosal immunity and COVID-19. As the gastrointestinal tract may also be a crucial entry or interaction site of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the role of the gut mucosal immune system as a first-line physical and immunological defense is critical. Furthermore, gastrointestinal involvement and symptoms in coronavirus disease 2019 (COVID-19) patients have been linked to worse clinical outcomes. This review discusses recent data on the interactions between the virus and the immune cells and molecules in the mucosa during the infection. By carrying out appropriate investigations, the mucosal immune system role in SARS-CoV-2 infection in therapy and prevention can be established. In line with this, COVID-19 vaccines that stimulate mucosal immunity against the virus may have more advantages than the others.
Successful venous thromboprophylaxis in a patient with vaccine-induced immune thrombotic thrombocytopenia (VITT): a case report of the first reported case in Thailand. BACKGROUND: Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare but fatal complication of the Coronavirus Disease 2019 vaccine. The many reports of VITT have mostly been in the Caucasian population. Here, we present the first reported case in an Asian population. CASE PRESENTATION: A 26-year-old female had severe headache and severe thrombocytopenia 8â€‰days after administration of the ChAdOx1 nCoV-19 vaccine developed by AstraZeneca. Although no thrombosis was demonstrated by imaging studies, she had very highly elevated d-dimer levels during hospitalization. Serology for antibodies against platelet factor 4 was positive on several days with very high optical density readings. We found that the antibody could induce spontaneous platelet aggregation without the presence of heparin. We decided to treat her with intravenous immunoglobulin, high-dose dexamethasone, and a prophylactic dose of apixaban. She improved rapidly and was discharged from the hospital 6â€‰days after admission. Neither thrombocytopenia nor thrombosis was subsequently detected at the three-week follow-up. CONCLUSIONS: Despite the lower rate of thrombosis, VITT can occur in the Asian population. Early detection and prompt treatment of VITT can improve the patient's clinical outcome. Thromboprophylaxis with nonheparin anticoagulants also prevents clot formation.
Cardiovascular magnetic resonance findings in young adult patients with acute myocarditis following mRNA COVID-19 vaccination: a case series. BACKGROUND: Messenger RNA (mRNA) coronavirus disease of 2019 (COVID-19) vaccine are known to cause minor side effects at the injection site and

mild global systemic symptoms in first 24-48Â h. Recently published case series have reported a possible association between acute myocarditis and COVID-19 vaccination, predominantly in young males. METHODS: We report a case series of 5 young male patients with cardiovascular magnetic resonance (CMR)-confirmed acute myocarditis within 72Â h after receiving a dose of an mRNA-based COVID-19 vaccine. RESULTS: Our case series suggests that myocarditis in this setting is characterized by myocardial edema and late gadolinium enhancement in the lateral wall of the left ventricular (LV) myocardium, reduced global LV longitudinal strain, and preserved LV ejection fraction. All patients in our series remained clinically stable during a relatively short inpatient hospital stay. CONCLUSIONS: In conjunction with other recently published case series and national vaccine safety surveillance data, this case series suggests a possible association between acute myocarditis and COVID-19 vaccination in young males and highlights a potential pattern in accompanying CMR abnormalities.
Decline in Pathogenic Antibodies over Time in VITT.
Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion.
Vasculitis and bursitis on [(18)F]FDG-PET/CT following COVID-19 mRNA vaccine: post hoc ergo propter hoc?
Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy. This study presents findings from case-control surveillance of COVID-19 vaccination during pregnancy and spontaneous abortion.
Therapeutic approaches in COVID-19 followed before arrival of any vaccine. In present times covid-19 is spreading and is showing very destructive effects. It does not only affected the physical health but mental health as well as the economy of the major affected countries. Corona viruses are group of related RNA viruses. The first case of this virus was observed in China and then this virus got spread in the many countries and different strategies were made to stop the spread of this virus. Since no particular vaccine was available to cure this so different strategies were made. Due to the emergence of pandemic diseases, drug development and control strategies have been re-examined. One of the most important factors that scientists have to consider is the effectiveness of their drugs. This virus causes the respiratory tract infections which can range from mild to lethal. COVID-19 is a major cause of death in advanced countries. It is due to the absence of any particular vaccine that can effectively treat this condition. So in this review we will discuss about the therapeutic approaches followed to combat this deadly virus. Ayurveda, nitric oxide, nanoparticles and enzymes played a very important role in boosting the immunity and treatment of corona. Many herbs and some tips of using a combination of herbs proved to be very efficient while facing problems in breathing. Giving the dose of nitric oxide at some particular level and chloroquine the drug showed the antiviral activity against the virus. Developing methods to identify and contain COVID-19 is essential to successfully manage the virus. Various strains of the SARS-COV-2 were detected and were found more dangerous. The therapeutic approaches followed actually were efficient and can be used to combat the other variants also. This review focuses on the latest developments in the field of therapeutics and the strategies which were followed before any vaccine.
Effectiveness of the BNT162b2 mRNA COVID-19 vaccine in pregnancy. To evaluate the effectiveness of the BNT162b2 messenger RNA vaccine in pregnant women, we conducted an observational cohort study of pregnant women aged 16 years or older, with no history of SARS-CoV-2, who were vaccinated between 20 December 2020 and 3 June 2021. A total of 10,861 vaccinated pregnant women were matched to 10,861 unvaccinated pregnant controls using demographic and clinical characteristics. Study outcomes included documented infection with SARS-CoV-2, symptomatic COVID-19, COVID-19-related hospitalization, severe illness and death. Estimated vaccine effectiveness from 7 through to 56â€‰d after the second dose was 96% (95% confidence interval 89-100%) for any documented infection, 97% (91-100%) for infections with documented symptoms and

89% (43-100%) for COVID-19-related hospitalization. Only one event of severe illness was observed in the unvaccinated group and no deaths were observed in either group. In summary, the BNT162b2 mRNA vaccine was estimated to have high vaccine effectiveness in pregnant women, which is similar to the effectiveness estimated in the general population.

Reactivation of herpes simplex keratitis following vaccination for COVID-19. An 82-year-old man with a history of herpes simplex keratitis 40 years previously presented with recurrence, 1â€‰day following vaccination for novel COVID-19. His condition worsened despite topical treatment with ganciclovir gel. A diagnosis of herpetic stromal keratitis was made, requiring systemic aciclovir, topical prednisolone, moxifloxacin and atropine, and oral doxycycline. He improved clinically on treatment, with some residual corneal scarring. Visual acuity improved from 6/36 corrected at presentation, to 6/24 following treatment. Clearly, public and personal health benefits from vaccination are hugely important and we would not suggest avoiding vaccination in such patients. It is, however, important for ophthalmic providers to be aware of the rare potential for reactivation of herpetic eye disease following vaccination to enable prompt diagnosis and treatment.

Toxicity and Local Tolerance of COVID- eVax, a Plasmid DNA Vaccine for SARS-CoV-2, Delivered by Electroporation. COVID-19 is a rapidly spreading disease, posing a huge hazard to global health. The plasmid vaccine pTK1A-TPA-SpikeA (named COVID-eVax) encodes the severe acute respiratory syndrome coronavirus 2 S protein receptor-binding domain, developed for intramuscular injection followed by electroporation (EP). The aim of this study was to assess the systemic toxicity and local tolerance of COVID-eVax delivered intramuscularly followed by EP in Sprague Dawley (SD) rats. The animals were killed 2 days and 4 weeks after the last injection (30-day and 57-day, respectively). No mortality was observed, and no signs of toxicity were evident, including injection site reactions. A lasting and specific immune response was observed in all treated animals, confirming the relevance of the rat as a toxicological model for this vaccine. Histopathological evaluation revealed muscle fiber necrosis associated with subchronic inflammation at the injection sites (at the 30-day time point), with a clear trend for recovery at the 57-day time point, which is expected following EP, and considered a desirable effect to mount the immune response against the target antigen. In conclusion, the intramuscular EP-assisted DNA vaccine, COVID-eVax showed an excellent safety profile in SD rats under these experimental conditions and supports its further development for use in humans.

Facial nerve palsy following the administration of COVID-19 mRNA vaccines: analysis of a self-reporting database. OBJECTIVES: Facial nerve palsy (or Bell's palsy) has occasionally been reported following the administration of coronavirus disease 2019 (COVID-19) mRNA vaccines (BNT162b2 and mRNA-1273). Our study investigated such cases using a large self-reporting database from the USA (Vaccine Adverse Event Reporting System [VAERS]). METHODS: A disproportionality analysis, adjusted for age and sex, was conducted for VAERS reports from individuals who were vaccinated at the age of 18 years or over, between January 2010 and April 2021. RESULTS: The analysis revealed that the adverse events following immunization (AEFI) of facial nerve palsy, after administration of COVID-19 mRNA vaccines, was significantly highly reported, both for BNT162b2 (reporting odds ratio [ROR] 1.84; 95% confidence interval [CI] 1.65-2.06) and mRNA-1273 (ROR 1.54; 95% CI 1.39-1.70). These levels were comparable to that following influenza vaccination reported before the COVID-19 pandemic (ROR 2.04; 95% CI 1.76-2.36). CONCLUSIONS: Our pharmacovigilance study results suggest that the incidence of facial nerve palsy as a non-serious AEFI may be lower than, or equivalent to, that for influenza vaccines. This information might be of value in the context of promoting worldwide vaccination, but needs to be validated in future observational studies.

Maternal and Child Outcomes Reported by Breastfeeding Women Following Messenger RNA COVID-19 Vaccination. Background: In December 2020, two novel messenger RNA (mRNA) vaccines for

severe acute respiratory syndrome coronavirus-2 received emergency use authorization from the U.S. Food and Drug Administration; however, the early trials excluded lactating women. Methods: Breastfeeding women residing in the United States who received either of the two mRNA vaccines were enrolled into the Mommy's Milk Human Milk Research Biorepository at the University of California, San Diego. From December 14, 2020 to February 1, 2021, 180 women who received two doses of either mRNA vaccine were recruited into the study. Results: Similar proportions of women reported any one or more symptoms following vaccination with either mRNA vaccine. In addition, the frequency by specific type of symptom did not differ by brand. However, following the second dose of vaccine, women who received the Moderna brand were significantly more likely to report symptoms. A small proportion of women following the first dose of either vaccine brand reported a reduction in milk supply, and significantly, more women reported a reduction in milk supply following the second dose of Moderna. Few infant events were reported for either vaccine brand following either dose, and no serious adverse events were reported. Conclusions: These data are reassuring regarding the safety of vaccination in breastfeeding women and their breastfed children with either of the mRNA COVID-19 vaccines.
Safety and tolerability of the COVID-19 messenger RNA vaccine in adolescents with juvenile idiopathic arthritis treated with tumor necrosis factor inhibitors.
Two cases of pityriasis rosea after the injection of coronavirus disease 2019 vaccine.
[The precautionary principle and Covid-19: Passion or reason?].
SARS-CoV-2 Antibody Response to the BNT162b2 mRNA Vaccine in Persons with Past Natural Infection. There are still no agreed guidelines on the vaccination of coronavirus disease 2019 (COVID-19) for previously infected patients. Here, we present two seropositive healthcare workers (HCWs) working in an isolation ward who recovered from COVID-19 in April 2020 and got vaccinated with BNT162b2 vaccine in March 2021. We have assessed the clinical course, vaccine-related adverse events, and antibody response after natural infection and after first and second dose vaccination. One of the two HCWs was asymptomatic during quarantine, but the other had mild upper respiratory infection symptoms 1 day before admission, and the symptoms continued for 9 days. There was no pneumonic infiltration in chest X-ray in both patients, and no COVID-19 specific treatment was administered. Total immunoglobulin antibody and neutralizing antibody to anti-spike protein receptor-binding domain of severe acute respiratory syndrome coronavirus 2 were confirmed to be present in both HCWs in blood tests performed at 2 weeks and 4 weeks after discharge. Antibody response to mRNA vaccination showed marked elevation after the first vaccination, which was 30-40 times higher than that of antibody titer after natural infection in each patient (83.2 U/mL vs. > 2,500 U/mL in patient 1; 61.6 U/mL vs. > 2,500 U/mL in patient 2). Signal inhibition rate of neutralizing antibodies was also increased to over 97%. Due to this increased effect, there was little difference in antibody levels after the first and second dose. Both patients 1 and 2 suffered more from adverse vaccine reactions after the second vaccination than from COVID-19 symptoms.
Australian and New Zealand approach to diagnosis and management of vaccine-induced immune thrombosis and thrombocytopenia.
The 12-week kinetics of anti-SARS-CoV-2 antibodies in different haematological cancers after vaccination with BNT162b2.
Severe SARS-CoV-2 Breakthrough Reinfection With Delta Variant After Recovery From Breakthrough Infection by Alpha Variant in a Fully Vaccinated Health Worker. Background: Post infection immunity and post vaccination immunity both confer protection against COVID-19. However, there have been many whole genome sequencing proven reinfections and breakthrough infections. Both are most often mild and caused by Variants of Concern (VOC). Methods: The patient in our study underwent serial COVID-19 RT-PCR, blood tests for serology, acute phase reactants, and chest

imaging as part of clinical care. We interviewed the patient for clinical history and retrieved reports and case papers. We retrieved stored RT-PCR positive samples for whole genome sequencing (WGS) of SARS-CoV-2 from the patient's breakthrough infections and the presumed index case. Findings: The patient had three RT-PCR confirmed SARS-CoV-2 infections. Two breakthrough infections occurred in quick succession with the first over 3 weeks after complete vaccination with COVISHIELD and despite post-vaccination seroconversion. The first breakthrough infection was due to the Alpha variant and the second due to the Delta variant. The Delta variant infection resulted in hypoxia, hospitalization, and illness lasting seven weeks. Serial serology, acute phase reactants, and chest imaging supported WGS in establishing distinct episodes of infection. WGS established a fully vaccinated family member as the index case. Interpretation: The patient had an Alpha variant breakthrough infection despite past infection, complete vaccination, and seroconversion. Despite boosting after this infection, the patient subsequently had a severe Delta variant breakthrough infection. This was also a WGS proven reinfection and, therefore, a case of breakthrough reinfection. The patient acquired the infection from a fully vaccinated family member.
SARS-CoV-2 infection after vaccination in patients with inflammatory rheumatic and musculoskeletal diseases.
A 24-Year-Old Man With Hemoptysis Found to Have a Chest Mass and Contralateral Axillary Lymphadenopathy. A 24-year-old man, never smoker, with no medical or surgical history, not currently on medications, presented to the ED with a second episode of gross hemoptysis, 4Â months after an initial episode that had not previously been evaluated. He described the current episode of hemoptysis as "enough to fill the sink"; however, he did not further quantify. He has no history of recurrent epistaxis, hematemesis, or other evidence of clotting disorder. He denied any fevers, chills, night sweats, or recent travel. He denied any sick contacts and has no history of TB exposure or risk factors. The patient denied any shortness of breath, wheezing, or chest pain. He had no lower extremity pain or swelling. He routinely exercises and generally lives a healthy lifestyle. He is a health care worker who has not routinely worked with patients infected with SARS-CoV-2, although he received his second (of two) COVID-19 vaccines 4Â days before presentation.
A storm in a teacup: older adults' low prevalence of COVID-19 vaccine side-effects and their link with vaccination anxiety.
SARS-CoV-2 vaccination complicated by acute, disseminated encephalo-myelitis?
Coronavirus disease 2019 vaccine hypersensitivity evaluated with vaccine and excipient allergy skin testing.
Antibody response after third BNT162b2 dose in recipients of allogeneic HSCT.
Hyper-inflammation after COVID-19 mARN vaccination: at the crossroads of multisystem inflammatory disease and adult-onset Still's disease. Does terminology matter?
Varicella-zoster and herpes simplex virus reactivation post-COVID-19 vaccination: a review of 40 cases in an International Dermatology Registry.
Oxford-AstraZeneca COVID-19 vaccine-induced acute localized exanthematous pustulosis.
Psoriasis exacerbation after first dose of AstraZeneca coronavirus disease 2019 vaccine.
Should a third booster dose be scheduled after two doses of CoronaVac? A single-center experience. In the 10th month of the pandemic, coronavirusÂ disease 2019 (COVID-19) vaccination was given first to healthcare workers in Turkey after receiving emergency use approval from the Ministry of Health. This study, which was performed at the COVID-19 reference center in Ankara (the capital of Turkey) aimed to evaluate the seroconversion rate of the CoronaVac vaccine. The anti-spike immunoglobulin G response to the two-dose vaccination was retrospectively examined in healthcare workers who had no previous history of severe acute respiratory syndromeÂ coronavirus 2 (SARS-CoV-2) infection. The

postvaccine seroconversion rate was investigated by measuring the antibody levels of healthcare workers who had received CoronaVac. Vaccination was administered as 600â€‰SU in 28-day intervals. The healthcare workers' anti-SARS-CoV-2 immunoglobulin G levels were used to determine the seroconversion rate 2 months after the second dose of the vaccine.Â Of the healthcare workers, 22.9% (nâ€‰=â€‰155) were seronegative. The younger the age of the participant, the higher the level of anti-SARS-CoV-2 immunoglobulin G. Furthermore, anti-SARS-CoV-2 immunoglobulin G levels were much higher in women than men.
Biopsy-proven lymphocytic myocarditis following first mRNA COVID-19 vaccination in a 40-year-old male: case report.
Myopericarditis following SARS-CoV-2 mRNA vaccine: the role of cardiac biomarkers and multimodality imaging.
COVID-19 and immune-mediated inflammatory diseases: effect of disease and treatment on COVID-19 outcomes and vaccine responses. At the beginning of the COVID-19 pandemic, patients with immune-mediated inflammatory diseases were considered to be at high risk for SARS-CoV-2 infection and the development of severe COVID-19. Data collected over the past year, however, suggest that a diagnosis of inflammatory arthritis, psoriasis, or inflammatory bowel diseases does not increase risk for SARS-CoV-2 infection or severe COVID-19 compared with people without these diseases. Furthermore, substantial data suggest that certain medications frequently used in patients with immune-mediated inflammatory diseases, in particular cytokine inhibitors, might even lower the risk for severe COVID-19. Conversely, glucocorticoids and potentially B-cell-depleting treatments seem to worsen COVID-19 outcomes. Additionally, the first data on SARS-CoV-2 vaccination in patients with these diseases suggest that tolerability of vaccination in patients with immune-mediated inflammatory diseases is good, although the immune response to vaccination can be somewhat reduced in this patient group, particularly those taking methotrexate or CD20-targeted treatment.
Deterioration of vaccine-induced immune thrombotic thrombocytopenia treated by heparin and platelet transfusion: Insight from functional cytometry and serotonin release assay. We report a case of a 62-year-old man who developed cerebral venous sinus thrombosis with subarachnoid hemorrhage and concomitant thrombocytopenia, which occurred 13Â days after ChAdOx1 nCov-19 injection. The patient died in the intensive care unit after heparin infusion and platelet transfusion. The key clinical purpose of this case report is to better understand how to confirm vaccine-induced immune thrombotic thrombocytopenia (VITT). VITT diagnosis was made using (14)C-serotonin release and flow cytometry evaluating activation and platelet microvesicles on washed platelets. Four control patients were examined: a patient with heparin-induced thrombocytopenia (HIT), two patients with thrombotic events without thrombocytopenia after ChAdOx1 nCov-19 or BNT162b2, and a patient with suspected HIT and an excluded diagnosis. We evidenced in the VITT case a high level of IgG anti-platelet factor 4-heparin antibodies associated with a high level of platelet activation in the absence of heparin. Conversely, the functional assays were negative in the patients with thrombosis without thrombocytopenia.
Acute macular neuroretinopathy following Pfizer-BioNTech COVID-19 vaccination. PURPOSE: To describe a case of acute macular neuroretinopathy (AMN) in a patient immediately following administration of the Pfizer-BioNTech COVID-19 vaccine. OBSERVATIONS: The patient complained of paracentral scotoma supported by paracentral visual field loss on multiple Humphrey visual fields that corresponded to outer retinal pathology on optical coherence tomography. The patient's symptoms resolved without treatment. CONCLUSIONS AND IMPORTANCE: We conclude that the clinical testing demonstrated findings consistent with AMN. AMN may be an exceedingly rare adverse ocular effect of a novel vaccine and likely only in the setting of multiple other risk factors. Despite this, we strongly recommend vaccination against COVID-19.

Cutaneous hypersensitivity reaction with acute hepatitis following COVID-19 vaccine.
COVID-19 vaccine causing Guillain-Barre syndrome, a rare potential side effect. Patients with neurological symptoms should be enquired about recent vaccination history. It is important after the COVID-19 mRNA vaccine, which is newly introduced as it might link to the development of a wider variety of neurological diseases.
Pathogenic Mechanisms of Vaccine-Induced Immune Thrombotic Thrombocytopenia in People Receiving Anti-COVID-19 Adenoviral-Based Vaccines: A Proposal. VITT is a rare, life-threatening syndrome characterized by thrombotic symptoms in combination with thrombocytopenia, which may occur in individuals receiving the first administration of adenoviral non replicating vectors (AVV) anti Covid19 vaccines. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is characterized by high levels of serum IgG that bind PF4/polyanion complexes, thus triggering platelet activation. Therefore, identification of the fine pathophysiological mechanism by which vaccine components trigger platelet activation is mandatory. Herein, we propose a multistep mechanism involving both the AVV and the neo-synthetized Spike protein. The former can: i) spread rapidly into blood stream, ii), promote the early production of high levels of IL-6, iii) interact with erythrocytes, platelets, mast cells and endothelia, iv) favor the presence of extracellular DNA at the site of injection, v) activate platelets and mast cells to release PF4 and heparin. Moreover, AVV infection of mast cells may trigger aberrant inflammatory and immune responses in people affected by the mast cell activation syndrome (MCAS). The pre-existence of natural antibodies binding PF4/heparin complexes may amplify platelet activation and thrombotic events. Finally, neosynthesized Covid 19 Spike protein interacting with its ACE2 receptor on endothelia, platelets and leucocyte may trigger further thrombotic events unleashing the WITT syndrome.
Bilateral Immune-Mediated Keratolysis After Immunization With SARS-CoV-2 Recombinant Viral Vector Vaccine. PURPOSE: The purpose of this study was to report an unusual case of bilateral immune-mediated corneal melting and necrosis after ChAdOx1 nCoV-19 (Covishield) vaccination. METHODS: This is a case report and literature review. RESULTS: A 48-year-old man presented to the ophthalmic emergency department with progressive bilateral corneal melting 5 weeks after receiving the first dose of ChAdOx1 nCoV-19 (Covishield) vaccine. Systemic complaints of fever, diarrhea, and vomiting were noted in the first 2 weeks, which subsided before the onset of ocular symptoms at day 21 of vaccine administration. The patient could only perceive light bilaterally and demonstrated features of bilateral keratolysis with choroidal detachment on ultrasonography. The microbiological scraping specimen did not reveal growth of any microorganism. Tectonic penetrating keratoplasty was performed, and the host corneal tissue was sent for histopathology, bacterial culture, fungal culture, polymerase chain reaction for herpes simplex virus, varicella zoster virus, cytomegalovirus, adenovirus, and SARS-CoV-2. Microbial culture was sterile, and viral polymerase chain reaction reports were negative. Histopathological examination revealed dense inflammatory cell infiltration. Detailed systemic workup revealed no underlying systemic or autoimmune pathology. CONCLUSIONS: Immune-mediated keratolysis after ChAdOx1 nCoV-19 (Covishield) vaccination is a rare entity, and we believe that this is the first report of a temporal association between a serious ocular adverse event after a single dose of any SARS-CoV-19 vaccine. It may be included as a possible adverse event associated with this vaccine.
ChAdOx1 nCoV-19 vaccine-associated thrombocytopenia: three cases of immune thrombocytopenia after 107â€Š720 doses of ChAdOx1 vaccination in Thailand. We reported three cases of immune thrombocytopenia (ITP) that developed within 6 weeks after ChAdOx1 nCoV-19 vaccination. Antiplatelet factor 4 antibodies were undetectable in all three cases. Therefore, vaccine-induced immune thrombotic thrombocytopenia was very unlikely. Other potential causes of thrombocytopenia were excluded. Their clinical presentations, severity of thrombocytopenia and

outcomes were varied. Only one ITP case, an 80-year-old man, received ITP treatments and achieved complete response after 2 weeks of eltrombopag. An 84-year-old man had spontaneous complete remission, and a 55-year-old woman had partial platelet recovery without ITP treatments. Among 107â€Š720 Thais administered the ChAdOx1 vaccine between 16 March and 10 May 2021, these three ITP cases resulted in an estimated risk of ITP of at least one per 36â€Š000 doses, which was approximately similar to the risk of ITP after measles-mumps-rubella immunization. This raises the concern of an increased risk of ITP after ChAdOx1 vaccination.

Generalized bullous fixed drug eruption after Oxford-AstraZeneca (ChAdOx1 nCoV-19) vaccination.

Acute transverse myelitis following SARS-CoV-2 vaccination: a case report and review of literature. OBJECTIVE: To report a unique case and literature review of post COVID-19 vaccination associated transverse myelitis and with abnormal MRI findings. BACKGROUND: Coronavirus disease have been reported to be associated with several neurological manifestations such as stroke, Guillain-BarrÃ© syndrome, meningoencephalitis amongst others. There are only a few reported cases of transverse myelitis with the novel coronavirus (n-CoV-2). Here, we identify a post COVID-19 vaccination patient diagnosed with acute transverse myelitis. METHOD: A retrospective chart review of a patient diagnosed with post SARS-CoV-2 vaccination acute transverse myelitis, and a review of literature of all the reported cases of other post vaccination and transverse myelitis, from December 1st, 2010 till July 15th, 2021, was performed. CONCLUSION: To our knowledge, this is the one of early reported case of transverse myelitis and with post SARS-CoV-2 vaccination, who responded well to plasmapheresis. Further studies would be recommended to identify the underlying correlation between COVID-19 vaccination and transverse myelitis.

Faster decay of neutralizing antibodies in never infected than previously infected healthcare workers three months after the second BNT162b2 mRNA COVID-19 vaccine dose. OBJECTIVES: This study aimed to describe the longitudinal evolution of neutralizing antibody titres (NtAb) in three different cohorts of healthcare workers (HCWs), including vaccinated HCWs with and without a previous SARS-CoV-2 infection and previously infected unvaccinated HCWs. COVID-19 was mild or asymptomatic in those experiencing infection. METHODS: NtAb was tested before BNT162b2 mRNA COVID-19 vaccine (V0), 20Â±2 days after the first dose (V1_20), 20Â±3 days (V2_20) and 90Â±2 days (V2_90) after the second dose in vaccinated HCWs and after about 2 months (N_60), 10 months (N_300) and 13 months (N_390) from natural infection in unvaccinated HCWs. NtAb were measured by authentic virus neutralization with a SARS-CoV-2 B.1 isolate circulating in Italy at HCW enrolment. RESULTS: Sixty-two HCWs were enrolled. NtAb were comparable in infected HCWs with no or mild disease at all the study points. NtAb of uninfected HCWs were significantly lower with respect to those of previously infected HCWs at V1_20, V2_20 and V2_90. The median NtAb fold decrease from V2_20 to V2_90 was higher in the uninfected HCWs with respect to those with mild infection (6.26 vs 2.58, p=0.03) and to asymptomatic HCWs (6.26 vs 3.67, p=0.022). The median Nabt at N_390 was significantly lower than at N_60 (p=0.007). CONCLUSIONS: In uninfected HCWs completing the two-dose vaccine schedule, a third mRNA vaccine dose is a reasonable option to counteract the substantial NtAb decline occurring at a significantly higher rate compared with previously infected, vaccinated HCWs. Although low, Nabt were still at a detectable level after 13 months in two-thirds of previously infected and unvaccinated HCWs.

Oropharyngeal shedding of herpesviruses before and after BNT162b2 mRNA vaccination against COVID-19. INTRODUCTION: Concerns were raised over an increase in Bell's palsy, herpes simplex and herpes zoster after BNT162b2 vaccination, all are manifestations of herpesviruses reactivation. As herpesviruses commonly reactivate in the oropharynx, we have hypothesized that oropharyngeal shedding of herpesviruses will increase after vaccination. METHODS: Immune-competent Adults, excluding those using topical steroids or manifesting symptomatic herpesvirus infection, were

sampled before BNT162b2 vaccination and one week after. Herpesviruses 1-7 shedding was tested with a multiplexed PCR. RESULTS: In 103 paired samples the prevalence of herpesviruses was similar before and after vaccination: HSV1, 3.9% vs. 5.8% (pÂ =Â 0.75); HSV2, 0% vs. 1% (pÂ =Â not applicable, NA); VZV, 0% vs. 0% (pÂ =Â NA); EBV, 14.6% vs. 17.5% (pÂ =Â 0.63); CMV, 0% vs. 0% (pÂ =Â NA); HHV6, 4.9% vs. 7.8% (pÂ =Â 0.55); HHV7, 71.8% vs. 72.8% (pÂ =Â 1); any herpesvirus, 73.8% vs. 74.8% (pÂ =Â 1). DISCUSSION: We did not find evidence for increased oropharyngeal reactivation of herpesviruses one week after BNT162b2.

The race to make a COVID-19 vaccine.

SARS-CoV-2 neutralizing antibodies after first vaccination dose in breast cancer patients receiving CDK4/6 inhibitors. Undoubtedly, the development of COVID-19 vaccines displays a critical step towards ending this devastating pandemic, considering their protective benefits in the general population. Yet, data regarding their efficacy and safety in cancer patients are limited. Herein we provide the initial analysis of immune responses after the first dose of vaccination in 21 breast cancer patients receiving cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors. The levels of neutralizing antibodies post vaccination were similar to the matched healthy controls, whereas no safety issues have been raised. Further exploration is needed to reduce the uncertainty of SARS-CoV-2 immunity among cancer patients under treatment.

Risk factors and disease profile of post-vaccination SARS-CoV-2 infection in UK users of the COVID Symptom Study app: a prospective, community-based, nested, case-control study. BACKGROUND: COVID-19 vaccines show excellent efficacy in clinical trials and effectiveness in real-world data, but some people still become infected with SARS-CoV-2 after vaccination. This study aimed to identify risk factors for post-vaccination SARS-CoV-2 infection and describe the characteristics of post-vaccination illness. METHODS: This prospective, community-based, nested, case-control study used self-reported data (eg, on demographics, geographical location, health risk factors, and COVID-19 test results, symptoms, and vaccinations) from UK-based, adult (â‰¥18 years) users of the COVID Symptom Study mobile phone app. For the risk factor analysis, cases had received a first or second dose of a COVID-19 vaccine between Dec 8, 2020, and July 4, 2021; had either a positive COVID-19 test at least 14 days after their first vaccination (but before their second; cases 1) or a positive test at least 7 days after their second vaccination (cases 2); and had no positive test before vaccination. Two control groups were selected (who also had not tested positive for SARS-CoV-2 before vaccination): users reporting a negative test at least 14 days after their first vaccination but before their second (controls 1) and users reporting a negative test at least 7 days after their second vaccination (controls 2). Controls 1 and controls 2 were matched (1:1) with cases 1 and cases 2, respectively, by the date of the post-vaccination test, health-care worker status, and sex. In the disease profile analysis, we sub-selected participants from cases 1 and cases 2 who had used the app for at least 14 consecutive days after testing positive for SARS-CoV-2 (cases 3 and cases 4, respectively). Controls 3 and controls 4 were unvaccinated participants reporting a positive SARS-CoV-2 test who had used the app for at least 14 consecutive days after the test, and were matched (1:1) with cases 3 and 4, respectively, by the date of the positive test, health-care worker status, sex, body-mass index (BMI), and age. We used univariate logistic regression models (adjusted for age, BMI, and sex) to analyse the associations between risk factors and post-vaccination infection, and the associations of individual symptoms, overall disease duration, and disease severity with vaccination status. FINDINGS: Between Dec 8, 2020, and July 4, 2021, 1â€‰240â€‰009 COVID Symptom Study app users reported a first vaccine dose, of whom 6030 (0Â·5%) subsequently tested positive for SARS-CoV-2 (cases 1), and 971â€‰504 reported a second dose, of whom 2370 (0Â·2%) subsequently tested positive for SARS-CoV-2 (cases 2). In the risk factor analysis, frailty was associated with post-vaccination infection in older adults (â‰¥60 years) after their first vaccine dose (odds ratio [OR]

1Â·93, 95% CI 1Â·50-2Â·48; p<0Â·0001), and individuals living in highly deprived areas had increased odds of post-vaccination infection following their first vaccine dose (OR 1Â·11, 95% CI 1Â·01-1Â·23; p=0Â·039). Individuals without obesity (BMI <30 kg/m(2)) had lower odds of infection following their first vaccine dose (OR 0Â·84, 95% CI 0Â·75-0Â·94; p=0Â·0030). For the disease profile analysis, 3825 users from cases 1 were included in cases 3 and 906 users from cases 2 were included in cases 4. Vaccination (compared with no vaccination) was associated with reduced odds of hospitalisation or having more than five symptoms in the first week of illness following the first or second dose, and long-duration (â‰¥28 days) symptoms following the second dose. Almost all symptoms were reported less frequently in infected vaccinated individuals than in infected unvaccinated individuals, and vaccinated participants were more likely to be completely asymptomatic, especially if they were 60 years or older. INTERPRETATION: To minimise SARS-CoV-2 infection, at-risk populations must be targeted in efforts to boost vaccine effectiveness and infection control measures. Our findings might support caution around relaxing physical distancing and other personal protective measures in the post-vaccination era, particularly around frail older adults and individuals living in more deprived areas, even if these individuals are vaccinated, and might have implications for strategies such as booster vaccinations. FUNDING: ZOE, the UK Government Department of Health and Social Care, the Wellcome Trust, the UK Engineering and Physical Sciences Research Council, UK Research and Innovation London Medical Imaging and Artificial Intelligence Centre for Value Based Healthcare, the UK National Institute for Health Research, the UK Medical Research Council, the British Heart Foundation, and the Alzheimer's Society.

Spontaneous rare visceral pseudoaneurysm presenting with rupture after COVID-19 vaccination.

Persistence of the Immune Responses and Cross-Neutralizing Activity With Variants of Concern Following 2 Doses of Adjuvanted SCB-2019 Coronavirus Disease 2019 Vaccine. BACKGROUND: We have previously reported the safety and immunogenicity 4 weeks after 2 doses of the Clover coronavirus disease 2019 (COVID-19) vaccine candidate, SCB-2019, a stabilized prefusion form of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein (S-trimer). We now report persistence of antibodies up to 6 months after vaccination, and cross-neutralization titers against 3 variants of concern (VoCs). METHODS: In a phase 1 study, adult (18-54 years of age) and elderly (55-75 years of age) volunteers received 2 vaccinations 21 days apart with placebo or 3-, 9-, or 30-Âµg. We measured immunoglobulin G (IgG) antibodies against SCB-2019, angiotensin-converting enzyme 2 (ACE2) competitive binding antibodies, and neutralizing antibodies against wild-type SARS-CoV-2 (Wuhan-Hu-1) at days 101 and 184, and neutralizing antibodies against 3 VoCs, Alpha (B.1.1.7), Beta (B.1.351), and Gamma (P.1), in day 36 sera. RESULTS: Titers waned from their peak at days 36-50, but SCB-2019 IgG antibodies, ACE2 competitive binding antibodies, and neutralizing antibodies against wild-type SARS-CoV-2 persisted at 25%-35% of their observed peak levels at day 184. Day 36 sera also demonstrated dose-dependent increases in neutralizing titers against the 3 VoCs. CONCLUSIONS: SCB-2019 dose-dependently induced immune responses against wild-type SARS-CoV-2, which persisted up to day 184. Neutralizing antibodies were cross-reactive against 3 of the most prevalent VoCs.

Acute disseminated encephalomyelitis in a patient vaccinated against SARS-CoV-2. Acute disseminated encephalomyelitis (ADEM) is a demyelinating disease, and there are some data that link this event with various vaccinations. We report a young female admitted to the hospital with headache, fever, back pain, nausea, vomiting, and urinary retention. Two weeks prior, she received the first dose of SARS-CoV-2 mRNA vaccine. Brain and spinal cord magnetic resonance imaging (MRI) showed distinctive for ADEM widespread demyelinating lesions. The patient was successfully treated with methylprednisolone.

[SARS-CoV-2-update on skin manifestations, predictive markers and cutaneous reactions after vaccination].

Association between ChAdOx1 nCoV-19 vaccination and bleeding episodes: Large population-based cohort study. OBJECTIVE: To compare prevalence of skin, nose and gingival bleedings after receipt of adeno-vectored or mRNA-vaccines against COVID-19. The hypothesis is that milder symptoms indicating altered thrombocyte function may affect a larger proportion of vaccinated individuals than the recently reported severe cases with thrombosis and thrombocytopenia. METHODS: Using an ongoing large, population-based cohort study, more than 80000 cohort participants were asked through electronic questionnaires about COVID-19 vaccination and potential side effects during weeks 11-13, 2021. The response rate was 58% (81267/138924). Among the vaccinated, 83% were female, 85% health care workers and 80% were aged 40-55Â years. The prevalence of self-reported episodes of skin, nose and gingival bleedings were compared after mRNA and adenovirus-vectored vaccination. Estimates were adjusted for age, sex, occupation, previous COVID-19 infection and chronic disease. RESULTS: Four of the 3416 subjects (0.2%) who were vaccinated with a single dose of mRNA vaccine reported skin bleeding as a side effect, as opposed to 163 of 5132 subjects (3.2%) vaccinated with a single dose of the adenovirus-vectored vaccine, OR (odds ratio)Â =Â 16.0 (95% confidence interval (CI) 7.5-34.1). Corresponding ORs for nose and gingival bleeding were 8.0 (4.0-15.8) and 9.3 (4.3-20.0), respectively. CONCLUSIONS: These findings could potentially indicate that the adenovirus-vectored vaccine may lead to mild bleeding episodes in a larger proportion of vaccinated individuals, and not only in rare cases with documented thrombosis and thrombocytopenia. Studies are needed to understand the possible mechanisms behind these observations, and to establish or refute whether they share similarities with the severe thromboembolic bleeding complications.

Thrombosis post COVID-19 vaccinations: Potential link to ACE pathways.

Health care workers intention to accept COVID-19 vaccine and associated factors in southwestern Ethiopia, 2021. INTRODUCTION: Health care workers are the most affected part of the world population due to the COVID-19 pandemic. Countries prioritize vaccinating health workers against COVID-19 because of their susceptibility to the virus. However, the acceptability of the vaccine varies across populations. Thus, this study aimed to determine the health care worker's intentions to accept the COVID-19 vaccine and its associated factors in southwestern Ethiopia, 2021. METHODS: A facility-based cross-sectional study was conducted among health care workers in public hospitals in southwestern Ethiopia from March 15 to 28, 2021. A simple random sampling method was used to select 405 participants from each hospital. Data were collected using self-administered questionnaires. Descriptive statistics, such as frequency and percentage, were calculated. Multivariable logistic regression was also performed to identify factors associated with health care worker's intention to accept the COVID-19 vaccine. Statistically significant variables were selected based on p-values (<0.05) and the adjusted odds ratio was used to describe the strength of association with 95% confidence intervals. RESULT: Among the respondents, 48.4% [95% CI: 38.6, 58.2] of health care workers intended to accept COVID-19. Intention to accept COVID-19 vaccination was significantly associated with physicians (AOR = 9.27, 95% CI: 1.27-27.32), professionals with a history of chronic illness (AOR = 4.07, 95% CI: 2.02-8.21), perceived degree of risk of COVID-19 infection (AOR = 4.63, 95% CI: 1.26-16.98), positive attitude toward COVID-19 prevention (AOR = 6.08, 95% CI: 3.39-10.91) and good preventive practices (AOR = 2.83, 95% CI: 1.58-5.08). CONCLUSION: In this study, the intention of health care workers to accept the COVID-19 vaccine was low. Professional types, history of chronic illness, perceived degree of risk to COVID-19 infection, attitude toward COVID-19 and preventive practices were found to be factors for intention to accept COVID-19 vaccine in professionals. It is important to consider professional types, history of chronic

illness, perceived degree of risk to COVID-19, attitude of professionals and preventive behaviors to improve the intention of professionals' vaccine acceptance.
Central Venous Sinus Thrombosis with Subarachnoid Hemorrhage Following an mRNA COVID-19 Vaccination: Are These Reports Merely Co-Incidental? BACKGROUND Multiple vaccines have been developed against COVID-19 as a collaborative worldwide effort. On March 18, 2021 the European Medicines Agency reported a serious and rare adverse effect of thrombosis with thrombocytopenia syndrome (TTS) after receiving the ChAdOx1 nCoV-19 vaccine; most of these cases were associated with cerebral venous sinus thrombosis (CVST). To date, there are no cases of TTS-related CVST reported after receipt of either of the 2 mRNA COVID-19 vaccines authorized for use in the United States. We report a case of CVST with the Moderna mRNA vaccine. CASE REPORT A healthy 45-year-old male patient without any risk factors presented with new-onset seizures 8 days after the receipt of the 2nd dose of Moderna (mRNA-1273), with concomitant SAH as a complication. One day prior to admission, he noted headaches and neck pain unrelieved by over-the-counter analgesics. Computed tomography (CT) scan brain without contrast revealed a left frontal lobe intracerebral hemorrhage (ICH) along with subarachnoid hemorrhage (SAH). A subsequent contrast-enhanced magnetic resonance imaging (MRI) brain confirmed the CT findings as well as anterior superior sagittal sinus thrombosis. He had normal platelet count with a negative thrombophilia work-up and cancer screening. He was successfully anticoagulated with heparin and discharged on warfarin without neurological sequelae or further seizures. The case was reported to the US Vaccine Surveillance System. CONCLUSIONS mRNA vaccine-related CVST is an extremely rare phenomenon. More data are needed to establish causality and understand the role of vaccine-related immune response resulting in thrombotic events with or without TTS.
Cutaneous adverse effects and contraindications to COVID-19 vaccination; four cases and an illustrative review from an Asian country.
Surveillance for Adverse Events After COVID-19 mRNA Vaccination. IMPORTANCE: Safety surveillance of vaccines against COVID-19 is critical to ensure safety, maintain trust, and inform policy. OBJECTIVES: To monitor 23 serious outcomes weekly, using comprehensive health records on a diverse population. DESIGN, SETTING, AND PARTICIPANTS: This study represents an interim analysis of safety surveillance data from Vaccine Safety Datalink. The 10â€¯162â€¯227 vaccine-eligible members of 8 participating US health plans were monitored with administrative data updated weekly and supplemented with medical record review for selected outcomes from December 14, 2020, through June 26, 2021. EXPOSURES: Receipt of BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna) COVID-19 vaccination, with a risk interval of 21 days for individuals after vaccine dose 1 or 2 compared with an interval of 22 to 42 days for similar individuals after vaccine dose 1 or 2. MAIN OUTCOMES AND MEASURES: Incidence of serious outcomes, including acute myocardial infarction, Bell palsy, cerebral venous sinus thrombosis, Guillain-BarrÃ© syndrome, myocarditis/pericarditis, pulmonary embolism, stroke, and thrombosis with thrombocytopenia syndrome. Incidence of events that occurred among vaccine recipients 1 to 21 days after either dose 1 or 2 of a messenger RNA (mRNA) vaccine was compared with that of vaccinated concurrent comparators who, on the same calendar day, had received their most recent dose 22 to 42 days earlier. Rate ratios (RRs) were estimated by Poisson regression, adjusted for age, sex, race and ethnicity, health plan, and calendar day. For a signal, a 1-sided Pâ€‰<â€‰.0048 was required to keep type I error below .05 during 2 years of weekly analyses. For 4 additional outcomes, including anaphylaxis, only descriptive analyses were conducted. RESULTS: A total of 11â€¯845â€¯128 doses of mRNA vaccines (57% BNT162b2; 6â€¯175â€¯813 first doses and 5â€¯669â€¯315 second doses) were administered to 6.2 million individuals (mean age, 49 years; 54% female individuals). The incidence of events per 1â€¯000â€¯000 person-years during the risk vs comparison intervals for ischemic stroke was 1612 vs 1781 (RR, 0.97;

95% CI, 0.87-1.08); for appendicitis, 1179 vs 1345 (RR, 0.82; 95% CI, 0.73-0.93); and for acute myocardial infarction, 935 vs 1030 (RR, 1.02; 95% CI, 0.89-1.18). No vaccine-outcome association met the prespecified requirement for a signal. Incidence of confirmed anaphylaxis was 4.8 (95% CI, 3.2-6.9) per million doses of BNT162b2 and 5.1 (95% CI, 3.3-7.6) per million doses of mRNA-1273. CONCLUSIONS AND RELEVANCE: In interim analyses of surveillance of mRNA COVID-19 vaccines, incidence of selected serious outcomes was not significantly higher 1 to 21 days postvaccination compared with 22 to 42 days postvaccination. While CIs were wide for many outcomes, surveillance is ongoing.

Health Ministries Association Faith Community Nursing COVID-19 Vaccine Statement.

[Intracerebral haemorrhage twelve days after vaccination with ChAdOx1 nCoV-19]. The COVID-19-pandemic has had a huge impact on health and economics all over the world resulting in widespread vaccine development. Vaccine-induced immune thrombotic thrombocytropenia has been described, suggesting a link between the two adeno-vector vaccines ChAdOx1 nCoV-19 (Vaxzevria from AstraZeneca) and Ad26.COV2-S (Janssen from Johnson and Johnson). This rare clinical condition should be suspected in patients with headache, abdominal pain, suspected thrombosis or hemorrhage and thrombocytopenia within 3-30-day post vaccine. In this case report a previously healthy man had thrombocytopenia with fatal intracerebral haemorrhage which was suspected to be related to vaccine.

Safety and antibody response after one and/or two doses of BNT162b2 Anti-SARS-CoV-2 mRNA vaccine in patients treated by CAR T cells therapy.

Local and systemic reactogenicity of COVID-19 vaccine BNT162b2 in patients with systemic lupus erythematosus and rheumatoid arthritis. Vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) were launched in December 2020. Vaccination of patients with rheumatic diseases is recommended, as they are considered at higher risk of severe COVID-19 than the general population. Patients with rheumatic disease have largely been excluded from vaccine phase 3 trials. This study explores the safety and reactogenicity of BNT162b2 among patients with rheumatic diseases. Patients with systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA), median age 58.8Â years, 285 subjects in total, were vaccinated twice with the BNT162b2 (Pfizer/BioNTech). Questionnaires on reactogenicity matching the original phase 3 study were answered seven days after completed vaccination. The majority of SLE and RA patients experienced either local (78.0%) or systemic reactions (80.1%). Only 1.8% experienced a grade-4 reaction. Compared to the original study, we found more frequent fatigue [Odds ratio (OR) 2.2 (1.7-2.8)], headache [OR 1.7 (1.3-2.2)], muscle pain [OR 1.8 (1.4-2.3)], and joint pain [OR 2.3 (1.7-3.0)] in patients. In contrast, the use of antipyretics was less frequent [OR 0.5 (0.3-0.6)]. Patients with SLE and RA experience reactogenicity to the Pfizer-BioNTech BNT162b2 COVID-19 vaccine. Reactogenicity was more frequent in patients, however, not more severe compared with healthy controls.

Outcomes among patients with breakthrough SARS-CoV-2 infection after vaccination in a high-risk national population. BACKGROUND: Breakthrough infections after SARS-CoV-2 infection have been reported. Clinical outcomes among persons with breakthrough infection are not known. METHODS: We retrospectively identified all Veterans with a confirmed SARS-CoV-2 infection >14 days after the second dose of either Pfizer-BNT-162b2 or Moderna-mRNA-1273 vaccine between December 15, 2020 and March 30, 2021, and age, race, sex, body mass index, Charlson comorbidity index, geographical location, and date of positive test matched unvaccinated controls with SARS-CoV-2 infection. Our primary endpoint was the rate or severe disease defined as hospitalization, mechanical ventilation, or death in both groups. FINDINGS: Among 258,716 persons with both doses of vaccines and 756,150 without any vaccination, we identified 271 (0.1%) vaccinated persons with breakthrough infection and 48,114 (6.4%) unvaccinated matched controls with infection between

December 15, 2020 and March 30, 2021. Among 213 matched pairs, symptoms were present in 33.3% of those with breakthrough infection and 42.2% of the controls. A total of 79 persons met the definition of severe disease or death (42 in the breakthrough infection group and 37 in the control group). Rate of severe disease or death per 1,000 person-days (95% CI) was 4.08 (2.64,5.31) among those with breakthrough infection and 3.6 (2.53,4.73) among the controls (PÂ =Â 0.58). Rate was similar among both groups regardless of age-group, race, BMI or presence of comorbidities. Among persons with breakthrough infection and matched controls with infection, vaccination was not associated with a lower risk of severe disease or death in the main analyses but was associated with a lower risk when matching did not include geographic location (HR 0.62, 95% CI 0.43,0.91). INTERPRETATION: Demographic or clinical factors are not associated with a lower risk of severe disease or death in persons with breakthrough SARS-CoV-2 infection. FUNDING: None.

Six-Month Efficacy and Toxicity Profile of BNT162b2 Vaccine in Cancer Patients with Solid Tumors. We had previously reported short-term efficacy, immunogenicity, and safety of the BNT162b2 vaccine among cancer patients with solid tumors. We aimed to evaluate these outcomes at six months postvaccination. The study cohort comprised patients who were on treatment during vaccination and throughout six months postvaccination. Serologic tests were performed after second vaccination and six months afterward. An age-matched cohort of health care workers served as controls. Documentation of COVID-19 infection, blood tests, and imaging studies during the study period was reviewed. Participants included 154 patients and 135 controls. Six months postvaccination, 122 (79%) patients were seropositive compared with 114 (84%) controls (P = 0.32). Serology titer dramatically decreased in a similar manner in both cohorts. No COVID-19 cases were documented in controls, and one case occurred in patient cohort. All previously reported adverse effects resolved. Taken together, the pattern of immunogenicity, efficacy, and safety of BNT162b2 in patients with cancer with solid tumors at six months postvaccination resembles that of the general population. SIGNIFICANCE: Evidence regarding efficacy and safety of COVID-19 vaccines in patients with cancer indicate a favorable short-term profile. Immunomodulation due to anticancer treatments may affect immunity and immunogenicity of patients with cancer to the BNT162b2 vaccine over time. Our study sheds light on these long-term outcomes and portrays a trend that resembles the general population.This article is highlighted in the In This Issue feature, p. 2355.

Neurologic Safety Monitoring of COVID-19 Vaccines: Lessons From the Past to Inform the Present. The spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has triggered a global effort to rapidly develop and deploy effective and safe coronavirus disease 2019 (COVID-19) vaccinations. Vaccination has been one of the most effective medical interventions in human history, although potential safety risks of novel vaccines must be monitored, identified, and quantified. Adverse events must be carefully assessed to define whether they are causally associated with vaccination or coincidence. Neurologic adverse events following immunizations are overall rare but with significant morbidity and mortality when they occur. Here, we review neurologic conditions seen in the context of prior vaccinations and the current data to date on select COVID-19 vaccines including mRNA vaccines and the adenovirus-vector COVID-19 vaccines, ChAdOx1 nCOV-19 (AstraZeneca) and Ad26.COV2.S Johnson & Johnson (Janssen/J&J).

Covid-19: UK will offer third vaccine dose to severely immunosuppressed people.

Allergic reactions and adverse events associated with administration of mRNA-based vaccines. A health-care system experience. Background: Adverse reactions, including anaphylaxis, to messenger RNA coronavirus disease 2019 (COVID-19) vaccines rarely occur. Because of the need to administer a timely second dose in subjects who reported a reaction to their first dose, a panel of health-care professionals developed a safe triage of the employees and health care providers (EHCP) at a large health-care system to consider administration of future dosing. Methods: There were

28,544 EHCPs who received their first dose of COVID-19 vaccines between December 15, 2020, and March 8, 2021. The EHCPs self-reported adverse reactions to a centralized COVID-19 command center (CCC). The CCC screened and collected information on the quality of reaction, symptoms, and timing of the onset of the reaction. Results: Of 1253 calls to the CCC, 113 were identified as requiring consideration by a panel of three (American Board of Allergy and Immunology) ABAI-certified allergists for future dosing or formal in-person assessment. Of the 113 EHCPs, 94 (83.2%) were recommended to get their second dose. Eighty of 94 received their second planned dose without a severe or immediate reaction. Of the 14 of 113 identified as needing further evaluation, 6 were evaluated by a physician and subsequently received their second dose without a serious adverse reaction. Eight of 14 did not receive their second dose. Only 5 of the 113 EHCPs reported reactions (4.4%) were recommended to not take the second dose: 3 (2.6%) because of symptoms consistent with anaphylaxis, and 2 because of neurologic complications (seizure, stroke). Conclusion: The panel demonstrated that, by consideration of reaction history alone, the ECHPs could be appropriately triaged to receive scheduled second dosing of COVID-19 vaccines without delays for in-person evaluation and allergy testing.
Vaccine preventable diseases, vaccine hesitancy, and COVID-19: A role for the allergist/immunologist.
The future of tumor vaccines in the post-COVID-19 era-Current challenges.
Atypical erythema multiforme related to BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine.
Outbreak Associated with SARS-CoV-2 B.1.617.2 (Delta) Variant in an Elementary School - Marin County, California, May-June 2021. On May 25, 2021, the Marin County Department of Public Health (MCPH) was notified by an elementary school that on May 23, an unvaccinated teacher had reported receiving a positive test result for SARS-CoV-2, the virus that causes COVID-19. The teacher reported becoming symptomatic on May 19, but continued to work for 2 days before receiving a test on May 21. On occasion during this time, the teacher read aloud unmasked to the class despite school requirements to mask while indoors. Beginning May 23, additional cases of COVID-19 were reported among other staff members, students, parents, and siblings connected to the school. To characterize the outbreak, on May 26, MCPH initiated case investigation and contact tracing that included whole genome sequencing (WGS) of available specimens. A total of 27 cases were identified, including that of the teacher. During May 23-26, among the teacher's 24 students, 22 students, all ineligible for vaccination because of age, received testing for SARS-CoV-2; 12 received positive test results. The attack rate in the two rows seated closest to the teacher's desk was 80% (eight of 10) and was 28% (four of 14) in the three back rows (Fisher's exact test; p = 0.036). During May 24-June 1, six of 18 students in a separate grade at the school, all also too young for vaccination, received positive SARS-CoV-2 test results. Eight additional cases were also identified, all in parents and siblings of students in these two grades. Among these additional cases, three were in persons fully vaccinated in accordance with CDC recommendations (1). Among the 27 total cases, 22 (81%) persons reported symptoms; the most frequently reported symptoms were fever (41%), cough (33%), headache (26%), and sore throat (26%). WGS of all 18 available specimens identified the B.1.617.2 (Delta) variant. Vaccines are effective against the Delta variant (2), but risk of transmission remains elevated among unvaccinated persons in schools without strict adherence to prevention strategies. In addition to vaccination for eligible persons, strict adherence to nonpharmaceutical prevention strategies, including masking, routine testing, facility ventilation, and staying home when symptomatic, are important to ensure safe in-person learning in schools (3).
Association of E484K Spike Protein Mutation With Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection in Vaccinated Persons: Maryland, January-May 2021. Among 9048 people infected with SARS-CoV-2 between January and May 2021 in Maryland, in regression-adjusted analysis, SARS-CoV-2 viruses carrying the spike protein mutation E484K were disproportionately

prevalent among persons infected after full vaccination against COVID-19 compared with infected persons who were not fully vaccinated (aOR, 1.96; 95% CI: 1.36-2.83).

Association of Ocular Adverse Events With Inactivated COVID-19 Vaccination in Patients in Abu Dhabi. IMPORTANCE: As vaccinations against COVID-19 continue, potential ocular adverse events should be reported in detail to increase awareness among the medical community, although typically, a causal relationship cannot be established definitively. OBJECTIVE: To describe ocular adverse events that occur soon after receiving an inactivated COVID-19 vaccination (Sinopharm). DESIGN, SETTING, AND PARTICIPANTS: This case series took place from September 2020 to January 2021 at Cleveland Clinic Abu Dhabi, a tertiary referral center. Patients who reported ocular adverse events and presented within 15 days from the first of 2 doses of an inactivated COVID-19 vaccine were analyzed. MAIN OUTCOMES AND MEASURES: Each patient underwent Snellen best-corrected visual acuity that was then converted to logMAR, applanation tonometry, and biomicroscopic examination with indirect ophthalmoscopy. Color fundus photography was obtained with a conventional 9-field fundus photography camera or with a widefield fundus photography system. Optical coherence tomography and optical coherence tomographic angiography images were obtained. Sex, race, age, and clinical data were self-reported. RESULTS: Nine eyes of 7 patients (3 male individuals) presenting with ocular complaints following COVID-19 vaccine were included in the study. The mean (SD) age was 41.4 (9.3) years (range, 30-55 years); the mean best-corrected visual acuity was 0.23 logMAR (range, 0-1 logMAR; approximate Snellen equivalent, 20/32). The mean time of ocular adverse event manifestations was 5.2 days (range, 1-10 days). One patient was diagnosed with episcleritis, 2 with anterior scleritis, 2 with acute macular neuroretinopathy, 1 with paracentral acute middle maculopathy, and 1 with subretinal fluid. CONCLUSIONS AND RELEVANCE: In this case series study of 7 patients, the timing of transient and ocular complications 5.2 days after vaccination with an inactivated COVID-19 vaccine supported an association with the ocular findings, but a causal relationship cannot be established from this study design.

Estimated US Infection- and Vaccine-Induced SARS-CoV-2 Seroprevalence Based on Blood Donations, July 2020-May 2021. IMPORTANCE: People who have been infected with or vaccinated against SARS-CoV-2 have reduced risk of subsequent infection, but the proportion of people in the US with SARS-CoV-2 antibodies from infection or vaccination is uncertain. OBJECTIVE: To estimate trends in SARS-CoV-2 seroprevalence related to infection and vaccination in the US population. DESIGN, SETTING, AND PARTICIPANTS: In a repeated cross-sectional study conducted each month during July 2020 through May 2021, 17 blood collection organizations with blood donations from all 50 US states; Washington, DC; and Puerto Rico were organized into 66 study-specific regions, representing a catchment of 74% of the US population. For each study region, specimens from a median of approximately 2000 blood donors were selected and tested each month; a total of 1â€¯594â€¯363 specimens were initially selected and tested. The final date of blood donation collection was May 31, 2021. EXPOSURE: Calendar time. MAIN OUTCOMES AND MEASURES: Proportion of persons with detectable SARS-CoV-2 spike and nucleocapsid antibodies. Seroprevalence was weighted for demographic differences between the blood donor sample and general population. Infection-induced seroprevalence was defined as the prevalence of the population with both spike and nucleocapsid antibodies. Combined infection- and vaccination-induced seroprevalence was defined as the prevalence of the population with spike antibodies. The seroprevalence estimates were compared with cumulative COVID-19 case report incidence rates. RESULTS: Among 1â€¯443â€¯519 specimens included, 733â€¯052 (50.8%) were from women, 174â€¯842 (12.1%) were from persons aged 16 to 29 years, 292â€¯258 (20.2%) were from persons aged 65 years and older, 36â€¯654 (2.5%) were from non-Hispanic Black persons, and 88â€¯773 (6.1%) were from Hispanic persons. The overall infection-induced SARS-CoV-2 seroprevalence estimate increased from 3.5% (95% CI, 3.2%-3.8%) in July 2020

to 20.2% (95% CI, 19.9%-20.6%) in May 2021; the combined infection- and vaccination-induced seroprevalence estimate in May 2021 was 83.3% (95% CI, 82.9%-83.7%). By May 2021, 2.1 SARS-CoV-2 infections (95% CI, 2.0-2.1) per reported COVID-19 case were estimated to have occurred. CONCLUSIONS AND RELEVANCE: Based on a sample of blood donations in the US from July 2020 through May 2021, vaccine- and infection-induced SARS-CoV-2 seroprevalence increased over time and varied by age, race and ethnicity, and geographic region. Despite weighting to adjust for demographic differences, these findings from a national sample of blood donors may not be representative of the entire US population.
COVID-19, COVID-19 Vaccinations, and Subsequent Abnormalities in the Retina: Causation or Coincidence?
Incidence of Disease Flare After BNT162b2 Coronavirus Disease 2019 Vaccination in Patients With Rheumatoid Arthritis in Remission.
The known knowns and known unknowns of vaccine-induced thrombotic thrombocytopaenia.
Consider differentials of unilateral facial palsy as complications of SARS-CoV-2 vaccinations.
Ipsilateral Zoster Ophthalmicus Post COVID-19 Vaccine in Healthy Young Adults. Herpes zoster ophthalmicus (HZO), which is an ophthalmological emergency, accounts for 10%-20% of all Herpes zoster (HZ) cases. HZÂ infection in COVID-19 vaccinated individuals who are immunocompetent can be attributed to vaccine-induced immunomodulation allowing the varicella-zoster virus (VZV) to escape from the dorsal root ganglia. Another theory is similar to immune reconstitution syndrome (IRS). HZ infection in a young immunocompetent individual is a rare entity. As per our literature review, only four cases have been reported thus far. We are reporting two cases of two young individuals with no known risk factors who developed ipsilateral HZO after receiving the COVID-19 vaccination. The increasing incidence of HZ cases post COVID-19 vaccine indicates that this is not a mere coincidence. Awareness must be created among physicians, as well as the general population, for early recognition and early antiviral usage, which can halt the progression of the disease and thus prevent debilitating complications.
Vaccination of Pregnant Women Against COVID-19. Pregnant women are at increased risk for severe morbidity and mortality following infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), leading some countries to recommend vaccination of pregnant women against coronavirus disease 2019 (COVID-19). These recommendations are based on studies conducted early in the pandemic, and thus, the pregnant women in these studies most likely did not have pre-existing immunity to SARS-CoV-2 at the time of infection. The susceptibility of pregnant women and their infants to SARS-CoV-2 and the severity of infection may be attenuated as the pandemic progresses and an increasing number of women will have pre-existing immunity (following natural infection or vaccination prior to pregnancy) during pregnancy. The reactogenicity, immunogenicity and efficacy of COVID-19 vaccines administered in pregnancy may also be affected by the pre-existing immunity of pregnant women. Maternal vaccine trials should be evaluated in the context of their timing in the pandemic and interpreted based on the pre-existing immunity of pregnant women.
Immune-Mediated Thrombocytopenia Associated With Ad26.COV2.S (Janssen; Johnson & Johnson) Vaccine.
Rate of Recurrent Guillain-BarrÃ© Syndrome After mRNA COVID-19 Vaccine BNT162b2. This study establishes rates of Guillain-BarrÃ© syndrome relapse among Pfizer-BioNTech BNT162b2 vaccine receivers.
COVID-19: Post-vaccine Smell and Taste Disorders: Report of 6 Cases. Post-vaccine olfactory and gustatory disorders are very rare and were reported in patients who received influenza vaccines. In this article, we report 6 cases of post-coronavirus disease 2019 (COVID-19) vaccine olfactory and

gustatory disorders in patients with negative nasal swabs. Precisely, olfactory and gustatory dysfunctions were reported in 5 and 1 patients, respectively. Sense disorders occurred after the first injection of AstraZeneca (n = 4) or the second injection of Pfizer (n = 2) vaccines. In 4 cases, the olfactory or gustatory disorder was confirmed with psychophysical evaluations. The duration of chemosensory dysfunction ranged from 4 to 42 days. None of the patient reported mid- or long-term olfactory or gustatory disorder. The occurrence of olfactory and gustatory dysfunctions in adults benefiting from COVID-19 vaccines is still rare but has to be known by otolaryngologists.
Scientific premise for the involvement of neutrophil extracellular traps (NETs) in vaccine-induced thrombotic thrombocytopenia (VITT). Following on from the devastating spread of COVID-19, a major global priority has been the production, procurement, and distribution of effective vaccines to ensure that the global pandemic reaches an end. However, concerns were raised about worrying side effects, particularly the occurrence of thrombosis and thrombocytopenia after administration of the Oxford/AstraZeneca and Johnson & Johnson's Janssen COVID-19 vaccine, in a phenomenon being termed vaccine-induced thrombotic thrombocytopenia (VITT). Similar to heparin-induced thrombocytopenia (HIT), this condition has been associated with the development of anti-platelet factor 4 antibodies, purportedly leading to neutrophil-platelet aggregate formation. Although thrombosis has also been a common association with COVID-19, the precise molecular mechanisms governing its occurrence are yet to be established. Recently, increasing evidence highlights the NLRP3 (NOD-like, leucine-rich repeat domains, and pyrin domain-containing protein) inflammasome complex along with IL-1Î² and effete neutrophils producing neutrophil extracellular traps (NETs) through NETosis. Herein, we propose and discuss that perhaps the incidence of VITT may be due to inflammatory reactions mediated via IL-1Î²/NLRP3 inflammasome activation and consequent overproduction of NETs, where similar autoimmune mechanisms are observed in HIT. We also discuss avenues by which such modalities could be treated to prevent the occurrence of adverse events and ensure vaccine rollouts remain safe and on target to end the current pandemic.
Safety of anti-SARS-CoV-2 vaccination for patients with immune thrombocytopenia.
Vaccine-induced immune thrombotic thrombocytopenia following AstraZeneca (ChAdOx1 nCOV19) vaccine-A case report. Vaccination with ChAdOx1 nCov-19 can result in vaccine-induced immune thrombotic thrombocytopenia (VITT). This phenomenon mimics heparin-induced thrombocytopenia (HIT), yet it does not require heparin as a trigger. HIT screen/ELISA along with optical density and functional assay are useful in diagnosis. A 64-year-old man presented to the emergency department with intermittent fever and persistent, dull, nonspecific abdominal pain 7Â days after the first dose of ChAdOx1 nCov-19 vaccine. Laboratory results showed significantly reduced platelet count, acute kidney injury, and low basal cortisol. He underwent investigations including computed tomography angiography, which revealed multiple sites of arterial and venous thrombosis. We present the first reported case of VITT at our institution and in Oman. This case highlights the potentially life-threatening complication associated with ChAdOx1 nCov-19 vaccine, clinical presentation, diagnostic approach, and treatment.
Acute generalized exanthematous pustulosis induced by Moderna COVID-19 messenger RNA vaccine.
Isolated Tachycardia Presenting After Pfizer-BioNTech COVID-19 Vaccination. A 29-year-old woman presented to the emergency department with palpitations and a heart rate of over 140 beats per minute that started approximately six to eight hours after administration of her second COVID-19 vaccination. Many side effects have been associated with the administration of vaccines. We present the first documented case of tachycardia and palpitations, in the absence of other signs or symptoms, presenting within hours of receiving the Pfizer-BioNTech COVID-19 vaccination. Clinicians should be aware that this appears to be benign and resolved within 24 hoursÂ in our patient.

Immune thrombocytopenia in a 68-year-old woman after COVID-19 vaccination. This case discusses a patient who presented with immune thrombocytopenia purpura (ITP) one week after COVID-19 vaccination, introducing ITP as a consideration for a potential, but rare, adverse reaction to COVID-19 vaccination.

Allergic Reactions After COVID-19 Vaccination-Putting Risk Into Perspective.

Prevalence of Allergic Reactions After Pfizer-BioNTech COVID-19 Vaccination Among Adults With High Allergy Risk. IMPORTANCE: Allergic reactions among some individuals who received the Pfizer-BioNTech (BNT162b2) COVID-19 vaccine discourage patients with allergic conditions from receiving this vaccine and physicians from recommending the vaccine. OBJECTIVE: To describe the assessment and immunization of highly allergic individuals with the BNT162b2 vaccine. DESIGN, SETTING, AND PARTICIPANTS: In a prospective cohort study from December 27, 2020, to February 22, 2021, 8102 patients with allergies who applied to the COVID 19 vaccine referral center at the Sheba Medical Center underwent risk assessment using an algorithm that included a detailed questionnaire. High-risk patients (nâ€‰=â€‰429) were considered "highly allergic" and were immunized under medical supervision. EXPOSURES: Pfizer-BioNTech (BNT162b2) COVID-19 vaccine. MAIN OUTCOMES AND MEASURES: Allergic and anaphylactic reactions after the first and second doses of BNT162b2 vaccine among highly allergic patients. RESULTS: Of the 429 individuals who applied to the COVID-19 referral center and were defined as highly allergic, 304 (70.9%) were women and the mean (SD) age was 52 (16) years. This highly allergic group was referred to receive immunization under medical supervision. After the first dose of the BNT162b2 vaccine, 420 patients (97.9%) had no immediate allergic event, 6 (1.4%) developed minor allergic responses, and 3 (0.7%) had anaphylactic reactions. During the study period, 218 highly allergic patients (50.8%) received the second BNT162b2 vaccine dose, of which 214 (98.2%) had no allergic reactions and 4 patients (1.8%) had minor allergic reactions. Other immediate and late reactions were comparable with those seen in the general population, except for delayed itch and skin eruption, which were more common among allergic patients. CONCLUSIONS AND RELEVANCE: The rate of allergic reactions to BNT162b2 vaccine, is higher among patients with allergies, particularly among a subgroup with a history of high-risk allergies. This study suggests that most patients with a history of allergic diseases and, particularly, highly allergic patients can be safely immunized by using an algorithm that can be implemented in different medical facilities and includes a referral center, a risk assessment questionnaire, and a setting for immunization under medical supervision of highly allergic patients. Further studies are required to define more specific risk factors for allergic reactions to the BNT162b2 vaccine.

Comparison of Anti-SARS-CoV-2 S1 Receptor-Binding Domain Antibody Immunoassays in Health Care Workers Before and After the BNT162b2 mRNA Vaccine. OBJECTIVES: The Pfizer-BioNTech BNT162b2 vaccine against SARS-CoV-2 infection is now available. This vaccine induces antibody production against the receptor-binding domain (RBD) of the spike glycoprotein S1 (S1-RBD). This study evaluated the performance of new immunoassays to measure this type of antibody. METHODS: Blood samples were collected at t0 (prime dose), after 21 days (t1, booster dose), and then after another 15 days (t2) from 70 health care professionals who had tested negative for previous SARS-CoV-2 infection and underwent vaccination with BNT162b2. RESULTS: Antibodies against S1-RBD were measured using 4 commercial assays. At t0, t1, and t2, the median antibody concentrations (interquartile range) were, respectively, 0.2 (0.1-0.4), 49.5 (19.1-95.7), and 888.0 (603.6-1,345.8) U/mL by Maglumi SARS-CoV-2 S-RBD immunoglobulin G (IgG) (Shenzen New Industries Biomedical Engineering, Snibe Diagnostics); 0.0 (0.0-0.0), 7.9 (4.2-15.6), and 112.3 (76.4-205.6) U/mL by Atellica IM SARS-CoV-2 IgG assay (Siemens Healthineers); 0.0 (0.0-0.0), 59.9 (18.3-122.0), and 2,646.0 (1,351.2-4,124.0) U/mL by Elecsys Anti-SARS-CoV-2 S assay (Roche Diagnostics); and 1.8 (1.8-1.8), 184 (94-294), and 1,841.0 (1,080.0-2,900.0) AU/mL by LIAISON SARS-CoV-2 TrimericS IgG assay (DiaSorin).

The differences between medians at t0, t1, and t2 were all statistically significant (P < .001). CONCLUSIONS: Antibodies against nucleocapsid proteins (N) were also measured using Maglumi 2019-nCoV IgG assay, which showed all negative results. All the considered anti-RBD methods detected response to the vaccine, while the method directed against anti-N failed to show response.

Polyarthralgia and Myalgia Syndrome after ChAdOx1 nCOV-19 Vaccination. Since February 26, 2021, when vaccination against coronavirus disease 2019 (COVID-19) began in South Korea, patients who visited the Korea University Guro Hospital with suspected adverse events after COVID-19 vaccination were monitored actively with interest. We encountered five unusual cases of polyarthralgia and myalgia syndrome in patients who received the ChAdOx1 nCOV-19 (AstraZeneca) vaccine. The patients (median age 67 years) were not previously diagnosed with arthropathy and rheumatologic diseases. They developed fever, myalgia, joint pain, and swelling three to seven days after vaccination. The symptoms persisted for up to 47 days despite antipyretic treatment. Arthralgia occurred in multiple joints, including small and large joints. A whole-body Technetium-99m methylene diphosphonate bone scan revealed unusual uptakes in the affected joints. Non-steroidal anti-inflammatory drugs with or without prednisolone relieved the symptoms of all patients. Further monitoring is required to clarify the long-term prognosis of this syndrome.

The International Cerebral Venous Thrombosis Consortium report on cerebral venous thrombosis following vaccination against SARS-CoV-2.

Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection. BACKGROUND: Immune protection following either vaccination or infection with SARS-CoV-2 decreases over time. OBJECTIVE: To determine the kinetics of SARS-CoV-2 IgG antibodies following administration of two doses of BNT162b2 vaccine, or SARS-CoV-2 infection in unvaccinated individuals. METHODS: Antibody titers were measured between January 31, 2021, and July 31, 2021 in two mutually exclusive groups: i) vaccinated individuals who received two doses of BNT162b2 vaccine and had no history of previous infection with COVID-19 and ii) SARS-CoV-2 convalescents who had not received the vaccine. RESULTS: A total of 2,653 individuals fully vaccinated by two doses of vaccine during the study period and 4,361 convalescent patients were included. Higher SARS-CoV-2 IgG antibody titers were observed in vaccinated individuals (median 1581 AU/mL IQR [533.8-5644.6]) after the second vaccination, than in convalescent individuals (median 355.3 AU/mL IQR [141.2-998.7]; p<0.001). In vaccinated subjects, antibody titers decreased by up to 40% each subsequent month while in convalescents they decreased by less than 5% per month. Six months after BNT162b2 vaccination 16.1% subjects had antibody levels below the seropositivity threshold of <50 AU/mL, while only 10.8% of convalescent patients were below <50 AU/mL threshold after 9 months from SARS-CoV-2 infection. CONCLUSIONS: This study demonstrates individuals who received the Pfizer-BioNTech mRNA vaccine have different kinetics of antibody levels compared to patients who had been infected with the SARS-CoV-2 virus, with higher initial levels but a much faster exponential decrease in the first group. FUNDING: This research was internally funded by Leumit Health Services (LHS) and was supported in part by the Intramural Research Program, National Institutes of Health, National Cancer Institute, Center for Cancer Research.The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government. IMPACT STATEMENT: Large scale study display the kinetics of SARS-CoV-2 IgG antibodies present in individuals vaccinated with two doses of mRNA vaccine vs. unvaccinated patients who had recovered from the disease: initial levels of antibody are much higher in vaccinated patients, but decrease faster.

Infection with the SARS-CoV-2 Delta Variant is Associated with Higher Infectious Virus Loads Compared to the Alpha Variant in both Unvaccinated and Vaccinated Individuals. BACKGROUND:

The emerging SARS-CoV-2 variant of concern (VOC) B.1.6.17.2 (Delta) quickly displaced the B.1.1.7 (Alpha) and is associated with increases in COVID-19 cases nationally. The Delta variant has been associated with greater transmissibility and higher viral RNA loads in both unvaccinated and fully vaccinated individuals. Data is lacking regarding the infectious virus load in Delta infected individuals and how that compares to individuals infected with other SARS-CoV-2 lineages. METHODS: Whole genome sequencing of 2,785 clinical isolates was used to characterize the prevalence of SARS-CoV-2 lineages circulating in the National Capital Region between January and July 2021. Clinical chart reviews were performed for the Delta, Alpha, and B.1.2 (a control predominant lineage prior to both VOCs) variants to evaluate disease severity and outcome and Cycle threshold values (Cts) were compared. The presence of infectious virus was determined using Vero-TMPRSS2 cells and anti-SARS-CoV-2 IgG levels were determined from upper respiratory specimen. An analysis of infection in unvaccinated and fully vaccinated populations was performed. RESULTS: The Delta variant displaced the Alpha variant to constitute 88.2% of the circulating lineages in the National Capital Region by July, 2021. The Delta variant associated with increased breakthrough infections in fully vaccinated individuals that were mostly symptomatic when compared to the Alpha breakthrough infections, though it is important to note there was a significantly longer period of time between vaccination and infection with Delta infections. The recovery of infectious virus on cell culture was significantly higher with the Delta variant compared to Alpha in both vaccinated and unvaccinated groups. The impact of vaccination on reducing the recovery of infectious virus from clinical samples was only observed with Alpha variant infections but was strongly associated with low localized SARS-CoV-2 IgG for both variants. A comparison of Ct values showed a significant decrease in the Delta compared to Alpha with no significant differences between unvaccinated and vaccinated groups. CONCLUSIONS: Our data indicate that the Delta variant is associated with increased infectious virus loads when compared to the Alpha variant and decreased upper respiratory antiviral IgG levels. Measures to reduce transmission in addition to increasing vaccinations rates have to be implemented to reduce Delta variant spread. FUNDING: NIH/NIAID Center of Excellence in Influenza Research and Surveillance contract HHS N2772201400007C, Johns Hopkins University, Maryland department of health, Centers for Disease Control and Prevention contract 75D30121C11061.

mRNA Vaccination Induces Durable Immune Memory to SARS-CoV-2 with Continued Evolution to Variants of Concern. SARS-CoV-2 mRNA vaccines have shown remarkable efficacy, especially in preventing severe illness and hospitalization. However, the emergence of several variants of concern and reports of declining antibody levels have raised uncertainty about the durability of immune memory following vaccination. In this study, we longitudinally profiled both antibody and cellular immune responses in SARS-CoV-2 naÃ¯ve and recovered individuals from pre-vaccine baseline to 6 months post-mRNA vaccination. Antibody and neutralizing titers decayed from peak levels but remained detectable in all subjects at 6 months post-vaccination. Functional memory B cell responses, including those specific for the receptor binding domain (RBD) of the Alpha (B.1.1.7), Beta (B.1.351), and Delta (B.1.617.2) variants, were also efficiently generated by mRNA vaccination and continued to increase in frequency between 3 and 6 months post-vaccination. Notably, most memory B cells induced by mRNA vaccines were capable of cross-binding variants of concern, and B cell receptor sequencing revealed significantly more hypermutation in these RBD variant-binding clones compared to clones that exclusively bound wild-type RBD. Moreover, the percent of variant cross-binding memory B cells was higher in vaccinees than individuals who recovered from mild COVID-19. mRNA vaccination also generated antigen-specific CD8+ T cells and durable memory CD4+ T cells in most individuals, with early CD4+ T cell responses correlating with humoral immunity at later timepoints. These findings demonstrate robust, multi-component humoral and cellular immune memory to SARS-CoV-2 and current variants of concern for at least 6 months after mRNA vaccination.

Finally, we observed that boosting of pre-existing immunity with mRNA vaccination in SARS-CoV-2 recovered individuals primarily increased antibody responses in the short-term without significantly altering antibody decay rates or long-term B and T cell memory. Together, this study provides insights into the generation and evolution of vaccine-induced immunity to SARS-CoV-2, including variants of concern, and has implications for future booster strategies.

Thymic hyperplasia after mRNA based Covid-19 vaccination. Reactive lymphadenopathy with increased 18F-Fluordeoxyglucose uptake in positron emission tomography/computed tomography scans is known after mRNA vaccination (BNT162B2, mRNA-1273) against severe acute respiratory syndrome coronavirus type 2. Besides this, increased 18F-Fluordeoxyglucose uptake in the thymus might occur after mRNA vaccination as shown in our case of a young patient with mantle cell lymphoma. Especially in patients with lymphoma but also in other patients with cancer it is critical to distinguish between immune responses and involvement of the disease to avoid inadequate treatment decisions.

Balancing the reactogenicity of the ChAdOx1 nCov-19 vaccine against COVID-19 and the urgent need of a large immunization in healthcare workers.

Vogt-Koyanagi-Harada Syndrome following COVID-19 and ChAdOx1 nCoV-19 (AZD1222) vaccine. The challenge of COVID-19 has rapidly changed medical management worldwide. The relatively small time from pandemic to vaccines regulatory approval triggered a race toward vaccines development. However, important questions regarding SARS-CoV-2 vaccines remain. A case of complete Vogt-Koyanagi-Harada (VKH) Syndrome that occurred 4Â days following SARS-CoV-2 vaccination and another patient that developed VKH 14Â days post COVID-19 clinical onset are presented. A causal relationship between COVID-19 and uveitis may exist.

Treatment of ChAdOx1 nCoV-19 Vaccine-Induced Immune Thrombotic Thrombocytopenia Related Acute Ischemic Stroke. Recently cases of vaccine-induced immune thrombotic thrombocytopenia (VITT) and thrombosis following the adenoviral vector vaccine against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) were reported. A mechanism similar to heparin-induced thrombocytopenia was proposed with antibodies to platelet factor 4 (PF4). Vaccine related arterial thrombosis in the brain is rare but life-threatening and optimal treatment is not established. We report clinical, laboratory, imaging findings and treatment in a 51-year-old female presenting with acute left middle cerebral artery (MCA) occlusion 7 days after the first dose of ChAdOx1 nCoV-19 vaccine. Due to low platelet count and suspicion of VITT she was not eligible for intravenous thrombolysis (IVT) and proceeded to mechanical thrombectomy (MER) with successful recanalization four hours after onset of symptoms. Treatment with intravenous immunoglobulin (IVIG) and heparin pentasaccharide fondaparinux was initiated. Presence of anti-PF4 antibodies was confirmed. The patient improved clinically with normalization of platelet count. Clinicians should be alert of VITT in patients with acute ischemic stroke after ChAdOx1 nCov-19 vaccination and low platelet counts. MER showed to be feasible and effective. We propose considering MER in patients with VITT and large vessel occlusion despite thrombocytopenia. High-dose IVIG should be started immediately. Alternative anticoagulation to heparin should be started 24 hours after stroke onset unless significant hemorrhagic transformation occurred. Platelet transfusion is contraindicated and should be considered only in severe hemorrhagic complications. Restenosis or reocclusion of the revascularized artery is possible due to the hypercoagulable state in VITT and angiographic surveillance after the procedure is reasonable.

Neutralization of alpha, gamma, and D614G SARS-CoV-2 variants by CoronaVac vaccine-induced antibodies. Vaccination generates a neutralizing immune response against SARS-CoV-2. The genomic surveillance is showing the emergence of variants with mutations in spike, the main target of neutralizing antibodies. To understand the impact of these variants, we report the neutralization

potency against alpha, gamma, and D614G SARS-CoV-2 variants in 44 individuals that received two doses of CoronaVac vaccine, an inactivated SARS-CoV-2 vaccine. Plasma samples collected at 60 days after the second dose of CoronaVac were analyzed by the reduction of cytopathic effect in Vero E6 cells with the three infectious variants of SARS-CoV-2. Plasma showed lower neutralization with alpha (geometric mean titer [GMT]â€‰=â€‰18.5) and gamma (GMTâ€‰=â€‰10.0) variants than with D614G (GMTâ€‰=â€‰75.1) variant. Efficient neutralization against the alpha and gamma variants was not detected in 31.8% and 59.1% of plasma, respectively. These findings suggest the alpha and gamma variants could escape from neutralization by antibodies elicited by vaccination. Robust genomic and biological surveillance of viral variants could help to develop effective strategies for the control of SARS-CoV-2.

Fatal Systemic Capillary Leak Syndrome after SARS-CoV-2Vaccination in Patient with Multiple Myeloma. A young man with smoldering multiple myeloma died of hypotensive shock 2.5 days after severe acute respiratory syndrome coronavirus 2 vaccination. Clinical findings suggested systemic capillary leak syndrome (SCLS); the patient had experienced a previous suspected flare episode. History of SCLS may indicate higher risk for SCLS after receiving this vaccine.

Influenza Vaccination After Myocardial Infarction: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial. BACKGROUND: Observational and small, randomized studies suggest that influenza vaccine may reduce future cardiovascular events in patients with cardiovascular disease. METHODS: We conducted an investigator-initiated, randomized, double-blind trial to compare inactivated influenza vaccine with saline placebo administered shortly after myocardial infarction (MI; 99.7% of patients) or high-risk stable coronary heart disease (0.3%). The primary end point was the composite of all-cause death, MI, or stent thrombosis at 12 months. A hierarchical testing strategy was used for the key secondary end points: all-cause death, cardiovascular death, MI, and stent thrombosis. RESULTS: Because of the COVID-19 pandemic, the data safety and monitoring board recommended to halt the trial before attaining the prespecified sample size. Between October 1, 2016, and March 1, 2020, 2571 participants were randomized at 30 centers across 8 countries. Participants assigned to influenza vaccine totaled 1290 and individuals assigned to placebo equaled 1281; of these, 2532 received the study treatment (1272 influenza vaccine and 1260 placebo) and were included in the modified intention to treat analysis. Over the 12-month follow-up, the primary outcome occurred in 67 participants (5.3%) assigned influenza vaccine and 91 participants (7.2%) assigned placebo (hazard ratio, 0.72 [95% CI, 0.52-0.99]; P=0.040). Rates of all-cause death were 2.9% and 4.9% (hazard ratio, 0.59 [95% CI, 0.39-0.89]; P=0.010), rates of cardiovascular death were 2.7% and 4.5%, (hazard ratio, 0.59 [95% CI, 0.39-0.90]; P=0.014), and rates of MI were 2.0% and 2.4% (hazard ratio, 0.86 [95% CI, 0.50-1.46]; P=0.57) in the influenza vaccine and placebo groups, respectively. CONCLUSIONS: Influenza vaccination early after an MI or in high-risk coronary heart disease resulted in a lower risk of a composite of all-cause death, MI, or stent thrombosis, and a lower risk of all-cause death and cardiovascular death, as well, at 12 months compared with placebo. Registration: URL: https://www.clinicaltrials.gov; Unique identifier: NCT02831608.

Clinicopathological features of cutaneous reactions after mRNA-based COVID-19 vaccines. BACKGROUND: Cutaneous reactions, mostly on injection site after mRNA-based COVID-19 vaccines, have been reported but not with detailed histopathological characterization. OBJECTIVES: Characterization and classification of these reactions in a clinical and pathological point of view. METHODS: Monocentric case series of 11 patients with cutaneous manifestations, clinically and histologically characterized after COVID-19 vaccination. RESULTS: From January to June 2021, we recorded 11 cutaneous reactions to mRNA COVID-19 vaccines from BNT162b2 (nâ€‰=â€‰8) and mRNA-1273 (nâ€‰=â€‰3). Generalized reactions showing erythematous rash or purpura were the most common clinical presentation, and drug-reaction-like pattern was the most common histological

finding. CONCLUSIONS: A proper clinicopathological classification will be helpful in the early diagnosis and management of the cutaneous reactions to mRNA COVID-19 vaccines.

Five Japanese cases of delayed large local reactions to coronavirus disease 2019 vaccines.

SARS-CoV-2 Vaccination-Induced Transverse Myelitis. While mass immunization against coronavirus disease 2019 (COVID-19) rolls out around the globe, safety concerns and adverse events that need prompt evaluation are also emerging. We report a case of transverse myelitis and Bell's palsy after receiving Johnson and Johnson COVID-19 vaccination under the emergency use authorization in a healthy young woman with no past medical history. Other possible etiologies of her symptoms were ruled out, and she was treated successfully with steroids and plasma exchange.

[SARS-CoV-2 vaccines induced immune thrombotic thrombocytopenia].

Subacute cutaneous lupus erythematosus flare triggered by COVID-19 vaccine.

Evolution of antibody responses up to 13 months after SARS-CoV-2 infection and risk of reinfection. BACKGROUND: Assessment of the kinetics of SARS-CoV-2 antibodies is essential in predicting risk of reinfection and durability of vaccine protection. METHODS: This is a prospective, monocentric, longitudinal, cohort clinical study. Healthcare workers (HCW) from Strasbourg University Hospital were enrolled between April 6th and May 7th, 2020 and followed up to 422 days. Serial serum samples were tested for antibodies against the Receptor Binding Domain (RBD) of the spike protein and nucleocapsid protein (N) to characterize the kinetics of SARS-CoV-2 antibodies and the incidence of reinfection. Live-neutralization assays were performed for a subset of samples before and after vaccination to analyze sensitivity to SARS-CoV-2 variants. FINDINGS: A total of 4290 samples from 393 convalescent COVID-19 and 916 COVID-19 negative individuals were analyzed. In convalescent individuals, SARS-CoV-2 antibodies followed a triphasic kinetic model with half-lives at month (M) 11-13 of 283 days (95% CI 231-349) for anti-N and 725 days (95% CI 623-921) for anti-RBD IgG, which stabilized at a median of 1.54 log BAU/mL (95% CI 1.42-1.67). The incidence of SARS-CoV-2 infections was 12.22 and 0.40 per 100 person-years in COVID-19-negative and COVID-19-positive HCW, respectively, indicating a relative reduction in the incidence of SARS-CoV-2 reinfection of 96.7%. Live-virus neutralization assay revealed that after one year, variants D614G and B.1.1.7, but less so B.1.351, were sensitive to anti-RBD antibodies at 1.4 log BAU/mL, while IgG â‰¥ 2.0 log BAU/mL strongly neutralized all three variants. These latter anti-RBD IgG titers were reached by all vaccinated HCW regardless of pre-vaccination IgG levels and type of vaccine. INTERPRETATION: Our study demonstrates a long-term persistence of anti-RBD antibodies that may reduce risk of reinfection. By significantly increasing cross-neutralizing antibody titers, a single-dose vaccination strengthens protection against variants. FUN1DING: None.

The strength of association between pre-and post-booster BNT162b2 anti-SARS-CoV-2 antibodies levels depends on the immunoassay. OBJECTIVES: Reliable evidence suggests that anticipating the humoral response to coronavirus disease 2019 (COVID-19) vaccines is essential for predicting their clinical effectiveness. In this work, we sought to determine the extent to which the response of anti-SARS-CoV-2 antibodies BNT162b2 booster measured with four different commercial immunoassays could be predicted after initial homologous vaccination. METHODS: This observational study enrolled 181 SARS-CoV-2 baseline seronegative healthcare workers (mean age 42Â±13 years; 59.7% females), who received two doses of the BNT162b2 vaccine. Antibodies levels were assessed with Roche Elecsys Anti-SARS-CoV-2 S, ACCESS SARS-CoV-2 IgG II, Snibe S-RBD IgG, and LIAISON SARS-CoV-2 TrimericS IgG. The correlation of anti-SARS-CoV-2 serum antibodies 21 days after the first vaccine dose and 30 days after the second dose was assessed with Pearson's test. RESULTS: A significant correlation was found between serum anti-SARS-CoV-2 antibodies levels after the first (T1) and second (T2) BNT162b2 vaccine dose with all immunoassays, though the strength of such association depended on the immunoassay. Briefly, the highest correlation was found for LIAISON

SARS-CoV-2 TrimericS IgG (r=0.71), followed by ACCESS SARS-CoV-2 IgG II (r=0.65), Snibe S-RBD IgG (r=0.52), and then Roche Elecsys Anti-SARS-CoV-2 S (r=0.40). CONCLUSION: The value of predicting post-booster values of anti-SARS-CoV-2 antibodies levels from pre-booster levels significantly depends on the immunoassay used.

The roles of platelets in COVID-19-associated coagulopathy and vaccine-induced immune thrombotic thrombocytopenia. In coronavirus disease 2019 (COVID-19), multiple thromboinflammatory events contribute to the pathophysiology, including coagulation system activation, suppressed fibrinolysis, vascular endothelial cell injury, and prothrombotic alterations in immune cells such as macrophages and neutrophils. Although thrombocytopenia is not an initial presentation as an infectious coagulopathy, recent studies have demonstrated the vital role of platelets in COVID-19-associated coagulopathy SARS-CoV-2 and its spike protein have been known to directly or indirectly promote release of prothrombotic and inflammatory mediators that lead to COVID-19-associated coagulopathy. Although clinical features of vaccine-induced immune thrombotic thrombocytopenia include uncommon locations of thrombosis, including cerebral venous sinus, we speculate coronavirus spike-protein-initiated prothrombotic pathways are involved in the pathogenesis of vaccine-induced immune thrombotic thrombocytopenia, as current evidence suggests that the spike protein is the promotor and other cofactors such as perturbed immune response and inflammatory reaction enhance the production of anti-platelet factor 4 antibody.

Analysis of antibody responses after COVID-19 vaccination in liver transplant recipients and those with chronic liver diseases. BACKGROUND & AIMS: Liver transplant (LT) recipients or other immunocompromised patients were not included in the registration trials studying the efficacy of vaccines against SARS-CoV-2. Although the clinical efficacy of COVID-19 vaccines in immunocompromised patients is unknown, many societies have recommended vaccination of this highly vulnerable patient population. METHODS: In this prospective study, we determined antibody responses to spike protein, 4 weeks after the 2(nd) dose of mRNA vaccines or after the single dose of Johnson & Johnson vaccine, in LT recipients and those with chronic liver disease (CLD) with and without cirrhosis. RESULTS: Of the 233 patients enrolled so far, 62 were LT recipients, 79 had cirrhosis (10 decompensated) and 92 had CLD without cirrhosis. Antibody titers were defined as undetectable (<0.40 U/ml), suboptimal (0.40-250 U/ml) and adequate (>250 U/ml). Of the 62 patients who had LT, antibody levels were undetectable in 11 patients and suboptimal (median titer 17.6, range 0.47-212 U/ml) in 27 patients. Among 79 patients with cirrhosis, 3 had undetectable antibody levels and 15 had suboptimal (median titer 41.3, range 0.49-221 U/L) antibody responses. Of the 92 patients without cirrhosis, 4 had undetectable antibody levels and 19 had suboptimal (median titer 95.5, range 4.9-234 U/L) antibody responses. Liver transplantation, use of 2 or more immunosuppression medications and vaccination with a single dose of the Johnson & Johnson vaccine were associated with poor immune response on multivariable analysis. No patient had any serious adverse events. CONCLUSIONS: Poor antibody responses after SARS-CoV-2 vaccination were seen in 61% of LT recipients and 24% of those with CLD. LAY SUMMARY: The clinical efficacy of COVID-19 vaccines in immunocompromised patients is unknown. We performed a prospective study to evaluate immune responses to COVID-19 vaccines (Moderna, Pfizer or Johnson & Johnson) in 62 liver transplant recipients, 79 patients with cirrhosis and 92 with chronic liver diseases without cirrhosis. We found that 17.8% of liver transplant recipients, 3.8% of those with cirrhosis and 4.3% of those with chronic liver diseases without cirrhosis had undetectable antibody levels. In total, 61.3% of liver transplant recipients and 24% of those with chronic liver diseases (with or without cirrhosis) had poor antibody responses (undetectable or suboptimal). Liver transplantation, use of immunosuppressive medications and vaccination with a single dose of Johnson & Johnson vaccine were associated with poor antibody responses when adjusted for other factors.

Tocilizumab in SARS-COVID19 following postoperative laparoscopic transhiatal esophagectomy for the adenocarcinoma of esophagogastric tumor: A case report. INTRODUCTION AND IMPORTANCE: Esophagectomy for esophageal cancer is one of the most challenging surgical procedures, with high rates of morbidity, especially from respiratory complications. SARS-COVID19 represents a health threat nowadays. Peri-operative SARS-COVID19 infection after esophagectomy might negatively affect the postoperative outcomes. The use of tocilizumab as an alternative to reduce the inflammatory response in SARS-COVID19 is an option that has not been described in the literature after esophagectomy. CASE PRESENTATION: A SARS-COVID19-vaccinated (CORONAVAC) 73-year-old man with pulmonary emphysema, coronary artery disease, previous asymptomatic pulmonary embolism, and adenocarcinoma of the esophagogastric junction tumor was submitted to laparoscopic transhiatal esophagectomy (ypT2N0M0) after perioperative neoadjuvant chemotherapy. He was also infected with SARS-COVID19, confirmed by PCR test at the 14th postoperative day. During follow-up, mild hypoxemia persisted without evidence of infection except for SARS-COVID19, and a high-flow cannula was required to maintain oxygenation. Tocilizumab was administered following high parameters of a high-flow cannula, and invasive mechanical ventilation was avoided. DISCUSSION: Besides of the risk of secondary infection, after administration of tocilizumab, the parameters of oxygen supplementation were systematically reduced, and he stayed in the ICU for seven days. He was discharged from the ward six days later. He developed late cervical anastomotic leakage, which was treated with conservative therapy. CONCLUSION: Although the patient had high-risk comorbidities, esophagectomy, and SARS-COVID19 infection, the use of tocilizumab was safe and improved the pulmonary recovery.

Cellular immunity predominates over humoral immunity after homologous and heterologous mRNA and vector-based COVID-19 vaccine regimens in solid organ transplant recipients. Knowledge on the immunogenicity of vector-based and mRNA-vaccines in solid organ transplant recipients is limited. Therefore, SARS-CoV-2-specific T cells and antibodies were analyzed in 40 transplant recipients and 70 controls after homologous or heterologous vaccine-regimens. Plasmablasts and SARS-CoV-2-specific CD4 and CD8Â T cells were quantified using flow cytometry. Specific antibodies were analyzed by ELISA and neutralization assay. The two vaccine types differed after the first vaccination, as IgG and neutralizing activity were more pronounced after mRNA priming (pÂ =Â .0001 each), whereas CD4 and CD8Â T cell levels were higher after vector priming (pÂ =Â .009; pÂ =Â .0001). All regimens were well tolerated, and SARS-CoV-2-specific antibodies and/or T cells after second vaccination were induced in 100% of controls and 70.6% of transplant recipients. Although antibody and T cell levels were lower in patients, heterologous vaccination led to the most pronounced induction of antibodies and CD4Â T cells. Plasmablast numbers were significantly higher in controls and correlated with SARS-CoV-2-specific IgG- and T cell levels. While antibodies were only detected in 35.3% of patients, cellular immunity was more frequently found (64.7%) indicating that assessment of antibodies is insufficient to identify COVID-19-vaccine responders. In conclusion, heterologous vaccination seems promising in transplant recipients, and combined analysis of humoral and cellular immunity improves the identification of responders among immunocompromised individuals.

Cerebral venous thrombosis and myeloproliferative neoplasms: A three-center study of 74 consecutive cases. The recent association of cerebral venous thrombosis (CVT) with COVID-19 vaccinations prompted the current retrospective review of 74 cases of CVT (median ageÂ =Â 44â€‰years, range 15-85; 61% females) associated with myeloproliferative neoplasms (MPNs), seen at the Mayo Clinic, Catholic University of Rome, and University of Florence, between 1991 and 2021. Disease-specific frequencies were 1.3% (39/2893), 1.2% (21/1811) and 0.2% (3/1888) for essential thrombocythemia, polycythemia vera and primary myelofibrosis, respectively. Cerebral

venous thrombosis occurred either prior to (nÂ =Â 20, 27%), at (nÂ =Â 32, 44%) or after (nÂ =Â 22) MPN diagnosis. A total of 72% of patients presented with headaches. Transverse (51%), sagittal (43%) and sigmoid sinuses (35%) were involved with central nervous system hemorrhage noted in 10 (14%) patients. In all, 91% of tested patients harbored JAK2V617F. An underlying thrombophilic condition was identified in 19 (31%) cases and history of thrombosis in 10 (14%). Treatment for CVT included systemic anticoagulation alone (nÂ =Â 27) or in conjunction with aspirin (nÂ =Â 24), cytoreductive therapy (nÂ =Â 14), or both (nÂ =Â 9). At a median follow-up of 5.1â€‰years (range 0.1-28.6), recurrent CVT was documented in three (4%) patients while recurrent arterial and venous thromboses and major hemorrhage were recorded in 11%, 9% and 14%, respectively. Follow-up neurological assessment revealed headaches (nÂ =Â 9), vision loss (nÂ =Â 1) and cognitive impairment (nÂ =Â 1). The current study lends clarity to MPN-associated CVT and highlights its close association with JAK2V617F, younger age and female gender. Clinical features that distinguish COVID vaccine-related CVT from MPN-associated CVT include, in the latter, lower likelihood of concurrent venous thromboses and intracerebral hemorrhage; as a result, MPN-associated CVT was not fatal.

The Emergency Use Authorization of Pharmaceuticals: History and Utility During the COVID-19 Pandemic. The Emergency Use Authorization (EUA) originated in 2004 because of the need for emergency medical countermeasures (MCMs) against potential bioterrorist attacks. The EUA also proved useful in dealing with subsequent pandemics and has emerged as a critical regulatory pathway for therapeutics and vaccines throughout the Coronavirus Disease 2019 (COVID-19) pandemic. With the EUA process in the USA, we witnessed emergency authorizations, their expansions, as well as withdrawal of previously authorized products, which exemplifies the dynamic nature of scientific review of EUA products. EUAs proved vital for the first group of COVID-19 vaccines, including the temporary pause of one vaccine while emergency safety issues were evaluated. Although this review on the EUA is primarily focused on the USA, distinctions were made with other jurisdictions such as Europe and Canada with respect to the emergency authorizations of the vaccines. Finally, we discuss some important differences following EUA and formal new drug/vaccine application (NDA/BLA) approvals.

The impact of the COVID-19 pandemic on patients with primary SjÃ¶gren syndrome. The aim of this study was to investigate the perspective of Romanian patients with SjÃ¶gren syndrome (SS) on various aspects of the disease during the SARS-CoV-2 outbreak, including both the impact of COVID-19 on the disease itself as well as the effects of vaccination against SARS-CoV-2 in this group of patients. The study is an online questionnaire-based survey. We received responses from 137 SS patients. Regarding the general emotional status, 33 patients (24.0%) and 47 patients (34.3%) declared to have been sadder/depressive and more agitated/anxious during the SARS-CoV2 outbreak, respectively. During the lockdown, 49 (33.7%) patients strictly and 77 patients (56.2%) did their best to respect the home isolation measures. The income was unchanged for most of the patients (94 patients, 68.6%). Regarding access to healthcare providers, 27 patients (18.7%) postponed the consultation for fear of getting SARS-CoV2. In our study group, 31 patients (22.6%) responded that they have had COVID-19. Only one patient was completely asymptomatic, while the most frequently declared symptom was weakness (84.0%). In 17 patients among the respondents (68%) the symptoms lasted for at least 2Â weeks; the most frequent long-lasting symptoms were fatigue (40.0%) and weakness (36.0%). Out of all the respondents, 53 patients (41.4%) were vaccinated against SARS-CoV2 with at least one dose. After the first dose, the most prevalent side effect was pain at the site of injection (89.2%), followed by weakness (25.0%) and myalgias (21.4%). This information will be useful for developing special programs dedicated to SARS-CoV2 infection and vaccination in patients with SS and other autoimmune diseases.

Insights From a Murine Model of Coronavirus Disease 2019 (COVID-19) mRNA Vaccination-Induced Myopericarditis: Could Accidental Intravenous Vaccine Injection Induce Myopericarditis?

Nervous and Muscular Adverse Events after COVID-19 Vaccination: A Systematic Review and Meta-Analysis of Clinical Trials. Background: Nervous and muscular adverse events (NMAEs) have garnered considerable attention after the vaccination against coronavirus disease (COVID-19). However, the incidences of NMAEs remain unclear. We aimed to calculate the pooled event rate of NMAEs after COVID-19 vaccination. Methods: A systematic review and meta-analysis of clinical trials on the incidences of NMAEs after COVID-19 vaccination was conducted. The PubMed, Medline, Embase, Cochrane Library, and Chinese National Knowledge Infrastructure databases were searched from inception to 2 June 2021. Two independent reviewers selected the study and extracted the data. Categorical variables were analyzed using Pearson's chi-square test. The pooled odds ratio (OR) with the corresponding 95% confidence intervals (CIs) were estimated and generated with random or fixed effects models. The protocol of the present study was registered on PROSPERO (CRD42021240450). Results: In 15 phase 1/2 trials, NMAEs occurred in 29.2% vs. 21.6% ($p < 0.001$) vaccinated participants and controls. Headache and myalgia accounted for 98.2% and 97.7%, and their incidences were 16.4% vs. 13.9% (OR = 1.97, 95% CI = 1.28-3.06, $p = 0.002$) and 16.0% vs. 7.9% (OR = 3.31, 95% CI = 2.05-5.35, $p < 0.001$) in the vaccine and control groups, respectively. Headache and myalgia were more frequent in the newly licensed vaccines (OR = 1.97, 95% CI = 1.28-3.06, $p = 0.02$ and OR = 3.31, 95% CI = 2.05-5.35, $p < 0.001$) and younger adults (OR = 1.40, 95% CI = 1.12-1.75, $p = 0.003$ and OR = 1.54, 95% CI = 1.20-1.96, $p < 0.001$). In four open-label trials, the incidences of headache, myalgia, and unsolicited NMAEs were 38.7%, 27.4%, and 1.5%. Following vaccination in phase 3 trials, headache and myalgia were still common with a rate of 29.5% and 19.2%, although the unsolicited NMAEs with incidence rates of â‰¤ 0.7% were not different from the control group in each study. Conclusions: Following the vaccination, NMAEs are common of which headache and myalgia comprised a considerable measure, although life-threatening unsolicited events are rare. NMAEs should be continuously monitored during the ongoing global COVID-19 vaccination program.

Risk Factors Associated with the Clinical Outcomes of COVID-19 and Its Variants in the Context of Cytokine Storm and Therapeutics/Vaccine Development Challenges. The recent appearance of SARS-CoV-2 is responsible for the ongoing coronavirus disease 2019 (COVID-19) pandemic and has brought to light the importance of understanding this highly pathogenic agent to prevent future pandemics. This virus is from the same single-stranded positive-sense RNA family, Coronaviridae, as two other epidemic-causing viruses, SARS-CoV-1 and MERS-CoV. During this pandemic, one crucial focus highlighted by WHO has been to understand the risk factors that may contribute to disease severity and predict COVID-19 outcomes. In doing so, it is imperative to understand the virology of SARS-CoV-2 and the immunological response eliciting the clinical manifestation and progression of COVID-19. In this review, we provide clinical data-based analyses of how multiple risk factors (such as sex, race, HLA genotypes, blood groups, vitamin D deficiency, obesity, smoking, and asthma) contribute to the inflammatory overactivation and cytokine storm (frequently seen in COVID-19 patients) with a focus on the IL-6 pathway. We also draw comparisons to the virulence and pathophysiology of SARS and MERS to establish parallels in immune response and discuss the potential for therapeutic approaches that may limit disease progression in patients with higher risk profiles than others. Moreover, we cover the latest information on approved or upcoming COVID-19 vaccines. This paper also provides perspective on emerging variants and associated opportunistic infections such as black molds and fungus that have added to mortality in some parts of the world, such as India. This compilation of existing COVID-19 studies and data will provide an excellent referencing tool for the research, clinical, and public health communities.

A Modeling Study on Vaccination and Spread of SARS-CoV-2 Variants in Italy. From the end of 2020, different vaccines against COVID-19 have been approved, offering a glimmer of hope and relief worldwide. However, in late 2020, new cases of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) started to re-surge, worsened by the emergence of highly infectious variants. To study this scenario, we extend the Susceptible-Exposed-Infectious-Removed model with lockdown measures used in our previous work with the inclusion of new lineages and mass vaccination campaign. We estimate model parameters using the Bayesian method Conditional Robust Calibration in two case studies: Italy and the Umbria region, the Italian region being worse affected by the emergence of variants. We then use the model to explore the dynamics of COVID-19, given different vaccination paces and a policy of gradual reopening. Our findings confirm the higher reproduction number of Umbria and the increase of transmission parameters due to the presence of new variants. The results illustrate the importance of preserving population-wide interventions, especially during the beginning of vaccination. Finally, under the hypothesis of waning immunity, the predictions show that a seasonal vaccination with a constant rate would probably be necessary to control the epidemic.

Age- and Sex-Graded Data Evaluation of Vaccination Reactions after Initial Injection of the BNT162b2 mRNA Vaccine in a Local Vaccination Center in Germany. A high vaccination rate of older and particularly chronically ill people against coronavirus disease-2019 (COVID-19) is likely one of the most important factors in containing the pandemic. When Germany's vaccination campaign started on December 2020, vaccination prioritization was initially carried out starting with older population groups. Side effect rates in 1065 individuals who had received the first dose of the messenger ribonucleic acid (mRNA) vaccine BNT162b2 Tozinameran from BioNTech/Pfizer three weeks earlier were examined retrospectively. An age- and gender-graded data analysis showed clear age and gender differences with regard to vaccine-related adverse effects. In 77% of all individuals over 80 years of age, no local or systemic side effects were reported after the first vaccination, whereas in the age group up to 80 years, only 37% showed no side effects. In the whole study population, 64% of females and 73% of males reported no adverse effects. The initial vaccination with mRNA vaccine BNT162b2 shows an overall low profile of side effects. Particularly in those over 80 years, an extraordinarily good tolerance with equally good effectiveness is evident. The sex comparison showed that women suffer more often from adverse vaccination reactions. In order to achieve sufficient herd immunity, both age- and gender-dependent vaccination reactions and any difference in the maintenance of immunity should be considered in future vaccination strategies.

Antibody Responses to Natural SARS-CoV-2 Infection or after COVID-19 Vaccination. The novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is the causative agent of the ongoing pandemic of coronavirus disease 2019 (COVID-19). The clinical severity of COVID-19 ranges from asymptomatic to critical disease and, eventually, death in smaller subsets of patients. The first case of COVID-19 was declared at the end of 2019 and it has since spread worldwide and remained a challenge in 2021, with the emergence of variants of concern. In fact, new concerns were the still unclear situation of SARS-CoV-2 immunity during the ongoing pandemic and progress with vaccination. If maintained at sufficiently high levels, the immune response could effectively block reinfection, which might confer long-lived protection. Understanding the protective capacity and the duration of humoral immunity during SARS-CoV-2 infection or after vaccination is critical for managing the pandemic and would also provide more evidence about the efficacy of SARS-CoV-2 vaccines. However, the exact features of antibody responses that govern SARS-CoV-2 infection or after vaccination remain unclear. This review summarizes the main knowledge that we have about the humoral immune response during COVID-19 disease or after vaccination. Such knowledge should help to optimize vaccination strategies and public health decisions.

Efficient Maternal to Neonate Transfer of Neutralizing Antibodies after SARS-CoV-2 Vaccination with BNT162b2: A Case-Report and Discussion of the Literature. This case reports on the successful maternal to fetal transfer of neutralizing antibodies after vaccination with BNT162b2 in a pregnant woman at 25 weeks of gestation. The levels of neutralizing antibodies were approximately 5-fold higher in the umbilical cord than in the maternal blood while the level of total antibodies showed only a 2-fold increase. This suggest that the antibodies that crossed the syncytiotrophoblast cell barrier have specific characteristics that correlate to functional neutralizing capacity. Although pregnant and lactating women have been excluded from clinical trials for several reasons including ethical concerns about fetal exposure, accumulating evidence has now revealed that these vaccines are safe and efficient for both the fetus and the woman. Vaccination against COVID-19 in pregnancy is vital to control disease burden and to decrease morbidity in the ante-, peri- and post-natal periods. Inclusion of pregnant women in research programs for the development of SARS-CoV-2 vaccines should be mandatory to provide this population with the equitable benefits of vaccine research.

A Case of Acute Pulmonary Embolus after mRNA SARS-CoV-2 Immunization. Vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (COVID-19), is a critical strategy to overcome the COVID-19 pandemic. Multiple SARS-CoV-2 vaccines have been developed in a rapid timeframe to combat the pandemic. While generally safe and effective, rare cases of venous thromboembolism (VTE) have been reported after two adenovirus-based vaccines, the AstraZeneca ChAdOx1 nCoV-19 vaccine and the Janssen Ad.26.COV2.S vaccine, as well as after the Pfizer-BioNTech BNT162b2 mRNA vaccine. Here, we present the case of a patient who developed acute pulmonary emboli (PE) shortly after his second dose of the Moderna mRNA-1273 SARS-CoV-2 vaccine. We report the results of an extensive thrombophilia workup that was normal except for the identification of positive lupus anticoagulant (LA) signals. It is our goal to contribute to the body of knowledge regarding SARS-CoV-2 vaccines and encourage vaccine adverse event reporting so that clinicians can have a full appreciation and awareness of the possible adverse events related to these critical vaccines.

Impact of Low-Dose Methotrexate-Adalimumab Combination Therapy on the Antibody Response Induced by the mRNA-1273 SARS-CoV-2 Vaccine: Case of an Elderly Patient with Rheumatoid Arthritis. Patients with rheumatoid arthritis (RA) are treated with drugs that may impact their immune responses to SARS-CoV-2 vaccines. We describe here the anti-Spike (anti-S) IgG and neutralizing antibody responses induced by the mRNA-1273 SARS-CoV-2 vaccine in a 78-years-old patient with RA, who received a low-dose combination therapy of methotrexate and adalimumab, shortly before vaccine administration. Both near-normal and impaired immune responses to vaccines have been reported previously in patients treated with these drugs. Our case report shows that, even at low doses, combined methotrexate-adalimumab therapy can be associated with a weak immune response to the mRNA1273 vaccine in elderly patients.

Heterologous ChAdOx1 nCoV-19/BNT162b2 Prime-Boost Vaccination Induces Strong Humoral Responses among Health Care Workers. Despite limited data on safety and immunogenicity, heterologous prime-boost vaccination is currently recommended for individuals with ChAdOx1 nCoV-19 prime immunization in certain age groups. In this prospective, single-center study we included 166 health care workers from Heidelberg University Hospital who received either heterologous ChAdOx1 nCoV-19/BNT162b2, homologous BNT162b2 or homologous ChAdOx1 nCoV-19 vaccination between December 2020 and May 2021. We measured anti-S1 IgG, SARS-CoV-2 specific neutralizing antibodies, and antibodies against different SARS-CoV-2 fragments 0-3 days before and 19-21 days after boost vaccination. Before boost, 55/70 (79%) ChAdOx1 nCoV-19-primed compared with 44/45 (98%) BNT162b2-primed individuals showed positive anti-S1 IgG with a median (IQR) anti-S1 IgG index of 1.95 (1.05-2.99) compared to 9.38 (6.26-17.12). SARS-CoV-2 neutralizing antibodies

exceeded the threshold in 24/70 (34%) of ChAdOx1 nCoV-19-primed and 43/45 (96%) of BNT162b2-primed individuals. After boosting dose, median (IQR) anti-S1 IgG index in heterologous ChAdOx1 nCoV-19/BNT162b2 vaccinees was 116.2 (61.84-170), compared to 13.09 (7.03-29.02) in homologous ChAdOx1 nCoV-19 and 145.5 (100-291.1) in homologous BNT162b2 vaccinees. All boosted vaccinees exceeded the threshold for neutralization, irrespective of their vaccination scheme. Vaccination was well-tolerated overall. We show that heterologous ChAdOx1 nCoV-19/BNT162b2 vaccination is safe and induces a strong and broad humoral response in healthy individuals.

Propylthiouracil-Induced Antineutrophil Cytoplasmic Antibody-Associated Vasculitis after COVID-19 Vaccination. We report the case of a patient who developed antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) after receiving the coronavirus disease 2019 (COVID-19) vaccine BNT162b (Pfizer-BioNTech). A 37-year-old Japanese woman had been taking propylthiouracil for Graves' disease. She had erythema on her forearm on the 12th day after receiving the first dose of the vaccine, fever on the 13th day, and redness and swelling of her left auricle on the 25th day. Her serum myeloperoxidase-ANCA and proteinase 3-ANCA levels, which were negative before the Graves' disease treatment, were elevated. She had unilateral auricular symptoms but no other typical relapsing polychondritis findings. She was diagnosed with propylthiouracil-induced AAV. She was treated with oral glucocorticoids, and her symptoms improved. Propylthiouracil is considered to be the main cause of the onset of AAV in this case, but it cannot be ruled out that BNT162b may have had some effect on the onset of the disease. Although the development of propylthiouracil-induced AAV in this case may have been incidental and unrelated to the vaccination, this report provides important data for evaluating the safety of the vaccine.

Prevalence and Significance of Hypermetabolic Lymph Nodes Detected by 2-[(18)F]FDG PET/CT after COVID-19 Vaccination: A Systematic Review and a Meta-Analysis. Recently, several articles reported incidental findings at 2-[(18)F]FDG PET/CT in patients who have received COVID-19 vaccinations, including hypermetabolic axillary lymph nodes (HALNs) ipsilateral to the COVID-19 vaccine injection site which may cause diagnostic dilemmas. The aim of our work was to calculate the prevalence of this finding. A comprehensive computer literature search of PubMed/MEDLINE, Embase, and Cochrane library databases was performed to identify recently published articles that investigated the prevalence of HALNs detected by 2-[(18)F]FDG PET/CT after COVID-19 vaccination. Pooled prevalence of this finding was calculated through a meta-analytic approach. Nine recently published articles including 2354 patients undergoing 2-[(18)F]FDG PET/CT after recent COVID-19 vaccination have been included in the systematic review. Overall, HALNs ipsilateral to the vaccine injection site were frequent findings mainly due to vaccine-related immune response in most of the cases. The pooled prevalence of HALNs after COVID-19 vaccination was 37% (95% confidence interval: 27-47%) but with significant heterogeneity among the included studies. Physicians must be aware and recognize the significant frequency of HALNs at 2-[(18)F]FDG PET/CT related to immune response to vaccine injection. Larger studies are needed to confirm the findings of this systematic review and meta-analysis.

SARS-CoV-2 vaccination in solid-organ transplant recipients: What the clinician needs to know. In response to the COVID-19 pandemic, SARS-CoV-2 vaccines have been developed at an unparalleled speed, with 14 SARS-CoV-2 vaccines currently authorized. Solid-organ transplant (SOT) recipients are at risk for developing a higher rate of COVID-19-related complications and therefore they are at priority for immunization against SARS-CoV-2. Preliminary data suggest that although SARS-CoV-2 vaccines are safe in SOT recipients (with similar rate of adverse events than in the general population), the antibody responses are decreased in this population. Risk factors for poor vaccine immunogenicity include older age, shorter time from transplantation, use of mycophenolate and belatacept, and worse allograft function. SOT recipients should continue to be advised to maintain

hand hygiene, use of facemasks, and social distancing after SARS-CoV-2 vaccine. Vaccination of household contacts should be also prioritized. Although highly encouraged for research purposes, systematic assessment in clinical practice of humoral and cellular immune responses after SARS-CoV-2 vaccination is controversial, since correlation between immunological findings and clinical protection from severe COVID-19, and cutoffs for protection are currently unknown in SOT recipients. Alternative immunization schemes, including a booster dose, higher doses, and modulation of immunosuppression during vaccination, need to be assessed in the context of well-designed clinical trials.
The RECOVAC IR study: the immune response and safety of the mRNA-1273 COVID-19 vaccine in patients with chronic kidney disease, on dialysis or living with a kidney transplant.
The Emergence of new-onset SLE following SARS-CoV-2 vaccination.
New-onset autoimmune hepatitis following mRNA COVID-19 vaccination in a 36-year-old woman with primary sclerosing cholangitis - should we be more vigilant?
A Novel Case of Bifacial Diplegia Variant of Guillain-BarrÃ© Syndrome Following Janssen COVID-19 Vaccination. Guillain-BarrÃ© syndrome (GBS) is an immune-mediated demyelinating disorder which attacks the peripheral nervous system. Antecedent infection or vaccine administration are known to precipitate the onset of this disorder. Its typical presentation leads to a symmetric, rapidly progressive, ascending paresis with associated sensory deficits and impaired reflexes. We present a rare case of a bi-facial diplegia variant of GBS, within four weeks of the COVID-19 vaccination. Due to its chronology, clinical manifestations, and cerebrospinal fluid (CSF) findings, we propose this case to be a rare complication of the COVID-19 vaccination.
Attenuated activation of pulmonary immune cells in mRNA-1273-vaccinated hamsters after SARS-CoV-2 infection. The mRNA-1273 vaccine is effective against SARS-CoV-2 and was granted emergency use authorization by the FDA. Clinical studies, however, cannot provide the controlled response to infection and complex immunological insight that are only possible with preclinical studies. Hamsters are the only model that reliably exhibits severe SARS-CoV-2 disease similar to that in hospitalized patients, making them pertinent for vaccine evaluation. We demonstrate that prime or prime-boost administration of mRNA-1273 in hamsters elicited robust neutralizing antibodies, ameliorated weight loss, suppressed SARS-CoV-2 replication in the airways, and better protected against disease at the highest prime-boost dose. Unlike in mice and nonhuman primates, low-level virus replication in mRNA-1273-vaccinated hamsters coincided with an anamnestic response. Single-cell RNA sequencing of lung tissue permitted high-resolution analysis that is not possible in vaccinated humans. mRNA-1273 prevented inflammatory cell infiltration and the reduction of lymphocyte proportions, but enabled antiviral responses conducive to lung homeostasis. Surprisingly, infection triggered transcriptome programs in some types of immune cells from vaccinated hamsters that were shared, albeit attenuated, with mock-vaccinated hamsters. Our results support the use of mRNA-1273 in a 2-dose schedule and provide insight into the potential responses within the lungs of vaccinated humans who are exposed to SARS-CoV-2.
Making US poison centers a part of the solution to the COVID-19 pandemic. OBJECTIVES: Our six goals are: 1) describe the relationship between the National Strategy for the COVID-19 Response and Pandemic Preparedness and the 55â€‰US poison centers (PCs); 2) detail FDA emergency Use Authorization (EUA) COVID-19 vaccine-related regulatory procedures and associated acronyms; 3) list availability of specific vaccine clinical information to support PC staff COVID-19 vaccination and adverse event (AE) data collection; 4) describe required health care practitioner COVID-19 vaccine AE reporting to the Vaccine AE Reporting System (VAERS) and PC reporting options; 5) document public and health care professionals' use of PCs for COVID-19 vaccine information; and 6) propose strategy to maximize PCs contribution to the pandemic solution. METHODS: We reviewed 13-Feb-2020

through 15-Apr-2021 National Poison Data System (NPDS) COVID-19 records for changes over time. We examined NPDS cases and VAERS COVID-19 vaccine reports 1-Nov-2020 through 2-Apr-2021 for vaccine manufacturer, patient characteristics, state, and clinical effects. RESULTS: PCs reported 1,052,174 COVID-19 contacts; maximum (peak) contacts/day (12,163) on 16-Mar-2020. As of 5-Apr-2021 the US reported >167 million administrations of COVID-19 vaccines (Pfizer-BioNTech, Moderna or Janssen). US PCs reported 162,052 COVID-19 vaccine contacts. Most (61.1%) were medical information calls, 34.9% were drug information, and 2.58% were exposures. Over the same period VAERS reported 49,078 COVID-19 vaccine cases reporting 226,205 symptoms - headache most frequent, ranging from 20% to 40% across the 3 vaccines. CONCLUSIONS AND RECOMMENDATIONS: Although differences exist between the intent and content of the 2 data sets, NPDS volume is compelling. The PC nationwide 800 number facilitates data collection and suggests comingling the 2 data streams has merit. PC professionals received tens of thousands of calls and can: 1) support fact-based vaccine information; 2) contribute vaccine AE follow-up information: 3) advocate for best-case coding and reporting, especially for vaccine adverse experiences.

A real-world study of immune thrombocytopenia management during the COVID-19 pandemic in the UK. The COVID-19 pandemic has created many challenges in the management of immune thrombocytopenic purpura (ITP). The recommendation for avoidance of steroids by WHO led to the off-licence use, supported by NHS England, of thrombopoietin mimetics (TPO-RA) for newly diagnosed or relapsed ITP. This is a real-world prospective study which investigated the treatment patterns and outcomes in this setting. Twenty-four hospitals across the UK submitted 343 cases. Corticosteroids remain the mainstay of ITP treatment, but TPO-RAs were more effective. Incidental COVID-19 infection was identified in a significant number of patients (9Â·5%), while 14 cases were thought to be secondary to COVID-19 vaccination.

Thrombotic Thrombocytopenic Purpura Presentation in an Elderly Gentleman Following COVID Vaccine Circumstances. Thrombotic thrombocytopenic purpura (TTP) is a rare blood disorder that results in the formation of thrombi in the small blood vessels throughout the body. The two primary forms of TTP are acquired and familial forms. The acquired form usually presents in late childhood or adulthood. Almost 95% of the cases are due to an autoantibody directed against ADAMTS13, and the remaining 5% are due to drugs like ticlopidine, quinine, cyclosporine, gemcitabine, bevacizumab, and certain recreational drugs like ecstasy and cocaine. The familial forms present in infancy or early childhood, but sometimes they can present later in life. Management for acquired forms includes therapeutic plasma exchange and immunosuppressive agents. While for the hereditary forms, the mainstay of treatment is plasma infusion. We present a case of an 80-year-old male with a known medical history of hypertension, type II diabetes mellitus, hyperlipidemia, gout, iron deficiency anemia, andÂ Pfizer-BioNTech COVID-19 (coronavirus disease-19) vaccineÂ administered two weeks before presentation to the ER for evaluation of generalized weakness and malaise. Laboratory findings showed severe anemia with hemoglobin of 4.8 g/dl, platelet count of 48 x 10^3/mcL, elevated lactate dehydrogenase (LDH), decreased haptoglobin, and peripheral smear showing schistocytes. The serum creatinine, total bilirubin, and troponin were elevated. All these findings were raising concernÂ for presumptive diagnosis of TTP, which was confirmed with ADAMTS13 levelsÂ less than 10%. TTP was temporarily resolved in 10 days with plasma exchange therapy and high-dose corticosteroids. It is difficult at this time to differentiate vaccine-induced TTP from coincidental TTP presenting soon after vaccination. Further studies would be needed to understand better if this relationship between vaccination and TTP was coincidental or causal.

Facial Diplegia: A Rare, Atypical Variant of Guillain-BarrÃ© Syndrome and Ad26.COV2.S Vaccine. This potentially life-threatening disease poses an interesting perspective on adverse events that can occur or can be exacerbated following the Ad26.COV2.S (Johnson & Johnson) vaccine. The authors

report findings in a 65-year-old female patient who experienced facial diplegia, an atypical variant of Guillain-BarrÃ© syndrome, two weeks after receiving the Ad26.COV2.S vaccine against coronavirus disease 2019. Post-approval pharmacovigilance of each vaccine helps better understand the long-term outcomes, and reporting adverse events is crucial for advancements in medical knowledge.

Unusual Presentation of Acute Perimyocarditis Following SARS-COV-2 mRNA-1237 Moderna Vaccination. Since the start of the pandemic, to date, around 180 million cases have been diagnosed with COVID-19 worldwide with an estimated 3.9 million death toll. Mass vaccination has taken place to control spread of infection with the most commonly used vaccines being Pfizer-BioNTech and Moderna. However, the adverse events associated with vaccination have not been fully investigated. Of concern are some serious cardiovascular events such as myocarditis, pericarditis or perimyocarditis development post-vaccination. In this report, we presentÂ an unusual case of acute perimyocarditis and pericardial effusion 10 days following the second dose of Moderna COVID-19 vaccination in Qatar. At the time of presentation, the patient presented with non-specific symptoms of headache, diarrhea, vomiting, lethargy and dehydration. COVID-19 polymerase chain reaction (PCR) was negative. Once admitted to the emergency department, she started to deteriorate with very low blood pressure readings reaching 40/33 mmHg which was treated with aggressive fluid resuscitation. After 5.5 liters of intravenous fluids, echocardiography and electrocardiogram (ECG) were performed. Findings were consistent with pericardial effusion, signs of impending cardiac tamponade and acute perimyocarditis. Cardiac biomarkers including troponin T and pro-brain natriuretic peptide (BNP) were elevated. Hospital course was complicated with cardiac arrest, acute kidney injury, disseminated intravascular coagulation (DIC) and hemodynamic instability. Eventually, the patient recovered after a three-week hospital stay and was discharged on non-steroidal anti-inflammatory medication (NSAIDs). This case report highlights the hospital course and outcome linking the second dose of Moderna vaccination and the development of perimyocarditis.

SARS-CoV-2 Proteome Harbors Peptides Which Are Able to Trigger Autoimmunity Responses: Implications for Infection, Vaccination, and Population Coverage. Autoimmune diseases (ADs) could occur due to infectious diseases and vaccination programs. Since millions of people are expected to be infected with SARS-CoV-2 and vaccinated against it, autoimmune consequences seem inevitable. Therefore, we have investigated the whole proteome of the SARS-CoV-2 for its ability to trigger ADs. In this regard, the entire proteome of the SARS-CoV-2 was chopped into more than 48000 peptides. The produced peptides were searched against the entire human proteome to find shared peptides with similar experimentally confirmed T-cell and B-cell epitopes. The obtained peptides were checked for their ability to bind to HLA molecules. The possible population coverage was calculated for the most potent peptides. The obtained results indicated that the SARS-CoV-2 and human proteomes share 23 peptides originated from ORF1ab polyprotein, nonstructural protein NS7a, Surface glycoprotein, and Envelope protein of SARS-CoV-2. Among these peptides, 21 peptides had experimentally confirmed equivalent epitopes. Amongst, only nine peptides were predicted to bind to HLAs with known global allele frequency data, and three peptides were able to bind to experimentally confirmed HLAs of equivalent epitopes. Given the HLAs which have already been reported to be associated with ADs, the ESGLKTIL, RYPANSIV, NVAITRAK, and RRARSVAS were determined to be the most harmful peptides of the SARS-CoV-2 proteome. It would be expected that the COVID-19 pandemic and the vaccination against this pathogen could significantly increase the ADs incidences, especially in populations harboring HLA-B*08:01, HLA-A*024:02, HLA-A*11:01 and HLA-B*27:05. The Southeast Asia, East Asia, and Oceania are at higher risk of AD development.

COVID-19 Vaccination in Fragile Patients: Current Evidence and an Harmonized Transdisease Trial. Patients diagnosed with malignancy, neurological and immunological disorders, i.e., fragile patients, have been excluded from COVID-19 vaccine trials. However, this population may present immune

response abnormalities, and relative reduced vaccine responsiveness. Here we review the limited current evidence on the immune responses to vaccination of patients with different underlying diseases. To address open questions we present the VAX4FRAIL study aimed at assessing immune responses to vaccination in a large transdisease cohort of patients with cancer, neurological and rheumatological diseases.

Severe Multiple Sclerosis Relapse After COVID-19 Vaccination: A Case Report. We describe a case of acute relapse in a woman with Multiple Sclerosis (MS) shortly after the mRNA COVID-19 vaccination. The patient received a diagnosis of MS in November 2016 at the MS Centre of the A. Cardarelli Hospital (South of Italy). Since that moment, her clinical conditions and pharmacological therapies have been managed at this MS centre where, according to national recommendations, in April 2021, the patient received the BNT162b2 vaccine. Almost 48 h after receiving the vaccine, the patient developed paraesthesia and weakness in her left arm and limbs. The neurological examination revealed walking difficulties while the MRI showed three new voluminous enhancing lesions. After having received methylprednisolone iv for 5 days, the patient's neurological symptoms fully recovered. Along with the implementation of COVID-19 vaccination programmes among vulnerable population, further studies are needed in order to improve our knowledge on the benefit/risk ratio of COVID-19 vaccines.

Initial experience of the safety and tolerability of the BNT162b2 (Pfizer-Bio-N-Tech) vaccine in extremely vulnerable children aged 12-15 years.

Risk of thrombocytopenia and thromboembolism after covid-19 vaccination and SARS-CoV-2 positive testing: self-controlled case series study. OBJECTIVE: To assess the association between covid-19 vaccines and risk of thrombocytopenia and thromboembolic events in England among adults. DESIGN: Self-controlled case series study using national data on covid-19 vaccination and hospital admissions. SETTING: Patient level data were obtained for approximately 30 million people vaccinated in England between 1 December 2020 and 24 April 2021. Electronic health records were linked with death data from the Office for National Statistics, SARS-CoV-2 positive test data, and hospital admission data from the United Kingdom's health service (NHS). PARTICIPANTS: 29â€‰121â€‰633 people were vaccinated with first doses (19â€‰608â€‰008 with Oxford-AstraZeneca (ChAdOx1 nCoV-19) and 9â€‰513â€‰625 with Pfizer-BioNTech (BNT162b2 mRNA)) and 1â€‰758â€‰095 people had a positive SARS-CoV-2 test. People aged â‰¥16 years who had first doses of the ChAdOx1 nCoV-19 or BNT162b2 mRNA vaccines and any outcome of interest were included in the study. MAIN OUTCOME MEASURES: The primary outcomes were hospital admission or death associated with thrombocytopenia, venous thromboembolism, and arterial thromboembolism within 28 days of three exposures: first dose of the ChAdOx1 nCoV-19 vaccine; first dose of the BNT162b2 mRNA vaccine; and a SARS-CoV-2 positive test. Secondary outcomes were subsets of the primary outcomes: cerebral venous sinus thrombosis (CVST), ischaemic stroke, myocardial infarction, and other rare arterial thrombotic events. RESULTS: The study found increased risk of thrombocytopenia after ChAdOx1 nCoV-19 vaccination (incidence rate ratio 1.33, 95% confidence interval 1.19 to 1.47 at 8-14 days) and after a positive SARS-CoV-2 test (5.27, 4.34 to 6.40 at 8-14 days); increased risk of venous thromboembolism after ChAdOx1 nCoV-19 vaccination (1.10, 1.02 to 1.18 at 8-14 days) and after SARS-CoV-2 infection (13.86, 12.76 to 15.05 at 8-14 days); and increased risk of arterial thromboembolism after BNT162b2 mRNA vaccination (1.06, 1.01 to 1.10 at 15-21 days) and after SARS-CoV-2 infection (2.02, 1.82 to 2.24 at 15-21 days). Secondary analyses found increased risk of CVST after ChAdOx1 nCoV-19 vaccination (4.01, 2.08 to 7.71 at 8-14 days), after BNT162b2 mRNA vaccination (3.58, 1.39 to 9.27 at 15-21 days), and after a positive SARS-CoV-2 test; increased risk of ischaemic stroke after BNT162b2 mRNA vaccination (1.12, 1.04 to 1.20 at 15-21 days) and after a positive SARS-CoV-2 test; and increased risk of other rare arterial thrombotic events

after ChAdOx1 nCoV-19 vaccination (1.21, 1.02 to 1.43 at 8-14 days) and after a positive SARS-CoV-2 test. CONCLUSION: Increased risks of haematological and vascular events that led to hospital admission or death were observed for short time intervals after first doses of the ChAdOx1 nCoV-19 and BNT162b2 mRNA vaccines. The risks of most of these events were substantially higher and more prolonged after SARS-CoV-2 infection than after vaccination in the same population.

Melatonin as a Potential Adjuvant Treatment for COVID-19 beyond Sleep Disorders. Melatonin is registered to treat circadian rhythm sleep-wake disorders and insomnia in patients aged 55 years and over. The essential role of the circadian sleep rhythm in the deterioration of sleep quality during COVID-19 confinement and the lack of an adverse effect of melatonin on respiratory drive indicate that melatonin has the potential to be a recommended treatment for sleep disturbances related to COVID-19. This review article describes the effects of melatonin additional to its sleep-related effects, which make this drug an attractive therapeutic option for treating patients with COVID-19. The preclinical data suggest that melatonin may inhibit COVID-19 progression. It may lower the risk of the entrance of the SARS-CoV-2 virus into cells, reduce uncontrolled hyper-inflammation and the activation of immune cells, limit the damage of tissues and multiorgan failure due to the action of free radicals, and reduce ventilator-induced lung injury and the risk of disability resulting from fibrotic changes within the lungs. Melatonin may also increase the efficacy of COVID-19 vaccination. The high safety profile of melatonin and its potential anti-SARS-CoV-2 effects make this molecule a preferable drug for treating sleep disturbances in COVID-19 patients. However, randomized clinical trials are needed to verify the clinical usefulness of melatonin in the treatment of COVID-19.

Interactions of Spike-RBD of SARS-CoV-2 and Platelet Factor 4: New Insights in the Etiopathogenesis of Thrombosis. The rare but dangerous adverse events evidenced after massive vaccination against SARS-CoV-2 are represented by thrombosis and thrombocytopenia. The patients diagnosed with severe COVID-19 may develop a pro-thrombotic state with a much higher frequency, thus we decided to investigate the role of Spike protein (the only common product of the two conditions) or the anti-Spike antibodies in the etiopathogenesis of thrombosis. A pathogenic Platelet Factor 4 (PF4)-dependent syndrome, unrelated to the use of heparin therapy, has been reported after the administration of vaccines in the patients manifesting acute thrombocytopenia and thrombosis. Thus, we aimed at shedding light on the structural similarities of Spike of SARS-CoV-2 and PF4 on their eventual biochemical interactions and on the role of their specific antibodies. The similarities between PF4 and Spike-RBD proteins were evaluated by a comparison of the structures and by testing the cross-reactivity of their specific antibodies by ELISA assays. We found that the anti-Spike antibodies do not recognize PF4, on the contrary, the anti-PF4 antibodies show some cross-reactivity for Spike-RBD. More interestingly, we report for the first time that the PF4 and Spike-RBD proteins can bind each other. These data suggest that the interaction of the two proteins could be involved in the generation of anti-PF4 antibodies, their binding to Spike-RBD, which could lead to platelets aggregation due also to their high expression of ACE2.

COVID-19 Vaccines in Children with Cow's Milk and Food Allergies. The COVID-19 pandemic is the most challenging global health crisis of our times. Vaccination against COVID-19 plays a key role to control the current pandemic situation. The risk of allergic reactions to new COVID-19 vaccines is low. However, there is a debate on the safety in allergic patients following post marketing findings by different agencies. Our aim is to understand from current experiences whether children with cow's milk or food allergy are at higher risk than a general population for allergic reactions to COVID-19 vaccines. Current data indicate that patients with a history of allergy to cow's milk or other foods, even if severe, should receive COVID-19 vaccine in a setting with availability of treatments for anaphylactic reactions and under medical supervision. Recipients should be discharged after a protracted observation period of 30 min if no reaction developed.

An Update on COVID-19 Vaccine Induced Thrombotic Thrombocytopenia Syndrome and Some Management Recommendations. The thrombotic thrombocytopenia syndrome (TTS), a complication of COVID-19 vaccines, involves thrombosis (often cerebral venous sinus thrombosis) and thrombocytopenia with occasional pulmonary embolism and arterial ischemia. TTS appears to mostly affect females aged between 20 and 50 years old, with no predisposing risk factors conclusively identified so far. Cases are characterized by thrombocytopenia, higher levels of D-dimers than commonly observed in venous thromboembolic events, inexplicably low fibrinogen levels and worsening thrombosis. Hyper fibrinolysis associated with bleeding can also occur. Antibodies that bind platelet factor 4, similar to those associated with heparin-induced thrombocytopenia, have also been identified but in the absence of patient exposure to heparin treatment. A number of countries have now suspended the use of adenovirus-vectored vaccines for younger individuals. The prevailing opinion of most experts is that the risk of developing COVID-19 disease, including thrombosis, far exceeds the extremely low risk of TTS associated with highly efficacious vaccines. Mass vaccination should continue but with caution. Vaccines that are more likely to cause TTS (e.g., Vaxzevria manufactured by AstraZeneca) should be avoided in younger patients for whom an alternative vaccine is available.

Impact of Age and Sex on Antibody Response Following the Second Dose of COVID-19 BNT162b2 mRNA Vaccine in Greek Healthcare Workers. Anti-SARS-CoV-2 spike RBD (receptor-binding domain) IgG antibody levels were monitored in 1643 volunteer healthcare workers of Eginition, Evangelismos, and Konstantopoulio General Hospitals (Athens, Greece), who underwent vaccination with two doses of COVID-19 BNT162b2 mRNA vaccine (Pfizer) and had no history of SARS-CoV-2 infection. Venous blood was collected 20-30 days after the second vaccine dose and anti-RBD IgG levels were determined using CMIA SARS-CoV-2 IgG II Quant (Abbott) on ARCHITECT i System or ADVIA Centaur SARS-CoV-2 IgG (Siemens) on Centaur XP platform. From the total population of 1643 vaccinees (533 M/1110 F; median age = 49; interquartile range-IQR = 40-56), 1636 (99.6%) had anti-SARS-CoV-2 IgG titers above the positivity threshold of the assay used. One-Way ANOVA Kruskal-Wallis H test showed a statistically significant difference in the median of antibody titers between the different age groups ($p < 0.0001$). Consistently, Spearman's correlation coefficient (r) for IgGs and age as continuous variables was -0.2380 ($p = 1.98$ Ã— 10(-17)). Moreover, antibody titers were slightly higher by 1.2-mean fold ($p = 3$ Ã— 10(-6)) in the total female population of the three hospitals (median = 1594; IQR = 875-2584) as compared to males (median = 1292; IQR = 671.9-2188). The present study supports that BNT162b2 vaccine is particularly effective in producing high anti-SARS-CoV-2 IgG levels in healthy individuals, and this humoral response is age- and gender-dependent.

Differences in the Concentration of Anti-SARS-CoV-2 IgG Antibodies Post-COVID-19 Recovery or Post-Vaccination. At the end of 2020, population-based vaccination programs with new generation mRNA-based vaccines began almost all over the world. The aim of the study was to evaluate the titer of anti-SARS-CoV-2 IgG antibodies against the S1 subunit of the virus's spike protein as a marker of the humoral response in 477 patients and the concentration of interferon-gamma as an indicator of cellular response in 28 individuals. In our studies, we used serological enzyme-linked immunosorbent assays. IgG was measured in weeks 2 and 3 after the first dose and 1-5 weeks after the second dose of an mRNA vaccine in seropositive and seronegative individuals as well as in symptomatic and asymptomatic convalescents. High levels of antibodies were observed in 98% of our vaccinated cohort, and the presence of protective T cells was confirmed in the blood samples of all participants. The humoral immune response is diversified and is visible as early as 2-3 weeks after the first dose of the mRNA vaccine. The level of protection increased significantly after the second dose, with the increase being much greater in pre-vaccine healthy subjects and less in convalescents. In the second and third weeks after the second dose, the concentration of IgG antibodies was the highest, and in

the following weeks, it decreased gradually. Regular serological measurements on eight subjects show that antibody titers are lower four months after vaccination than before the second dose.

Picture of the Favourable Immune Profile Induced by Anti-SARS-CoV-2 Vaccination. COVID-19 pandemic has hit people's health, economy, and society worldwide. Great confidence in returning to normality has been placed in the vaccination campaign. The knowledge of individual immune profiles and the time required to achieve immunological protection is crucial to choose the best vaccination strategy. We compared anti-S1 antibody levels produced over time by BNT162b2 and AZD1222 vaccines and evaluated the induction of antigen-specific T-cells. A total of 2569 anti-SARS-CoV-2 IgG determination on dried blood spot samples were carried out, firstly in a cohort of 1181 individuals at random time-points, and subsequently, in an independent cohort of 88 vaccinated subjects, up to the seventeenth week from the first dose administration. Spike-specific T-cells were analysed in seronegative subjects between the two doses. AZD1222 induced lower anti-S1 IgG levels as compared to BNT162b2. Moreover, 40% of AZD1222 vaccinated subjects and 3% of BNT162b2 individuals resulted in seronegative during all the time-points, between the two doses. All these subjects developed antigen-specific T cells, already after the first dose. These results suggest that this test represents an excellent tool for a wide sero-surveillance. Both vaccines induce a favourable immune profile guaranteeing efficacy against severe adverse effects of SARS-CoV-2 infection, already after the first dose administration.

COVID-19 Disease, Women's Predominant Non-Heparin Vaccine-Induced Thrombotic Thrombocytopenia and Kounis Syndrome: A Passepartout Cytokine Storm Interplay. Coronavirus disease 2019 (COVID-19) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) constitute one of the deadliest pandemics in modern history demonstrating cardiovascular, gastrointestinal, hematologic, mucocutaneous, respiratory, neurological, renal and testicular manifestations and further complications. COVID-19-induced excessive immune response accompanied with uncontrolled release of cytokines culminating in cytokine storm seem to be the common pathogenetic mechanism of these complications. The aim of this narrative review is to elucidate the relation between anaphylaxis associated with profound hypotension or hypoxemia with pro-inflammatory cytokine release. COVID-19 relation with Kounis syndrome and post-COVID-19 vaccination correlation with heparin-induced thrombocytopenia with thrombosis (HITT), especially serious cerebral venous sinus thrombosis, were also reviewed. METHODS: A current literature search in PubMed, Embase and Google databases was performed to reveal the pathophysiology, prevalence, clinical manifestation, correlation and treatment of COVID-19, anaphylaxis with profuse hypotension, Kounis acute coronary syndrome and thrombotic events post vaccination. RESULTS: The same key immunological pathophysiology mechanisms and cells seem to underlie COVID-19 cardiovascular complications and the anaphylaxis-associated Kounis syndrome. The myocardial injury in patients with COVID-19 has been attributed to coronary spasm, plaque rupture and microthrombi formation, hypoxic injury or cytokine storm disposing the same pathophysiology with the three clinical variants of Kounis syndrome. COVID-19-interrelated vaccine excipients as polysorbate, polyethelene glycol (PEG) and trometamol constitute potential allergenic substances. CONCLUSION: Better acknowledgement of the pathophysiological mechanisms, clinical similarities, multiorgan complications of COVID-19 or other viral infections as dengue and human immunodeficiency viruses along with the action of inflammatory cells inducing the Kounis syndrome could identify better immunological approaches for prevention, treatment of the COVID-19 pandemic as well as post-COVID-19 vaccine adverse reactions.

Side Effects of mRNA-Based and Viral Vector-Based COVID-19 Vaccines among German Healthcare Workers. the increasing number of COVID-19 vaccines available to the public may trigger hesitancy or selectivity towards vaccination. This study aimed to evaluate the post-vaccination side

effects of the different vaccines approved in Germany; Methods: a cross-sectional survey-based study was carried out using an online questionnaire validated and tested for a priori reliability. The questionnaire inquired about demographic data, medical and COVID-19-related anamneses, and local, systemic, oral, and skin-related side effects following COVID-19 vaccination; Results: out of the 599 participating healthcare workers, 72.3% were females, and 79.1% received mRNA-based vaccines, while 20.9% received a viral vector-based vaccine. 88.1% of the participants reported at least one side effect. Injection site pain (75.6%) was the most common local side effect, and headache/fatigue (53.6%), muscle pain (33.2%), malaise (25%), chills (23%), and joint pain (21.2%) were the most common systemic side effects. The vast majority (84.9%) of side effects resolved within 1-3 days post-vaccination; Conclusions: the mRNA-based vaccines were associated with a higher prevalence of local side effects (78.3% vs. 70.4%; Sig. = 0.064), while the viral vector-based vaccine was associated with a higher prevalence of systemic side effects (87.2% vs. 61%; Sig. < 0.001). Females and the younger age group were associated with an increased risk of side effects either after mRNA-based or viral vector-based vaccines. The gender- and age-based differences warrant further rigorous investigation and standardized methodology.
Dermatology patients on biologics and certain other systemic therapies should receive a "booster" messenger RNA COVID-19 vaccine dose: A critical appraisal of recent Food and Drug Administration and Advisory Committee on Immunization Practices recommendations.
Audio Interview: Assessing Vaccine Safety.
Monitoring Vaccine Adverse Event Reporting System (VAERS) Reports Related to COVID-19 Vaccination Efforts in Rhode Island.
Exacerbation of Hailey-Hailey Disease Following SARS-CoV-2 Vaccination. is missing (Short communication).
Pityriasis rosea after administration of Pfizer-BioNTech COVID-19 vaccine. Pityriasis rosea (PR) is an acute papulosquamous cutaneous disorder that classically presents with a herald patch rapidly followed by a widespread rash along skin cleavage lines. Although the exact pathogenesis of PR is unknown, current evidence suggests that an inflammatory reaction due to a viral trigger may lead to the cutaneous manifestations. COVID-19 has been reported as one such viral trigger for PR. Previously, PR has been reported in temporal association with various viral inoculations. This article presents a case of PR in a 66-year-old black male 1 week after administration of the Pfizer-BioNTech COVID-19 vaccine.
Immune thrombocytopenia following vaccination during the COVID-19 pandemic.
COVID-19 mRNA vaccine induced rhabdomyolysis and fasciitis.
Delayed skin reaction after mRNA-1273 vaccine against SARS-CoV-2: a rare clinical reaction. BACKGROUND: The coronavirus disease 2019 (COVID-19) is associated with a wide clinical spectrum of skin manifestations, including urticarial, vesicular, vasculitic and chilblain-like lesions. Recently, delayed skin reactions have been reported in 1% individuals following mRNA vaccination against SARS-CoV-2. The exact pathophysiology and the risk factors still remain unclear. PATIENTS AND METHODS: 6821 employees and patients were vaccinated at our institutions between February and June 2021. Every patient received two doses of the mRNA-1273 vaccine in our hospitals, and reported back in case of any side effects which were collected in our hospital managed database. RESULTS: Eleven of 6821 vaccinated patients (0.16%) developed delayed skin reactions after either the first or second dose of the mRNA-1273 vaccine against SARS-CoV-2. Eight of 11 patients (73%) developed a rash after the first dose, while in 3/11 (27%), the rash occurred after the second dose. More females (9/11) were affected. FourÂ ofÂ 11 patients required antihistamines, with two needing additional topical steroids. All the cutaneous manifestations resolved within 14Â days. None of the skin reactions after the first dose of the vaccine prevented the administration of the second dose. There

were no long-term cutaneous sequelae in any of the affected individuals. CONCLUSION: Our data suggests that skin reactions after the use of mRNA-1273 vaccine against SARS-CoV-2 are possible, but rare. Further studies need to be done to understand the pathophysiology of these lesions.

COVID-19 vaccination mimicking lymph-node progression in a patient with melanoma: a case report. COVID-19 vaccination has been rapidly implemented among patients with cancer. We present the case of a patient with high-risk resected cutaneous melanoma, who was a candidate for adjuvant treatment, with postsurgery 18-fluorodeoxyglucose (FDG) PET/computed tomography (CT) scan showing positive axillary lymph nodes after COVID-19 vaccination. This report presents a 50-year-old man with a history of stage IIA cutaneous melanoma. During follow-up, the patient experienced subcutaneous and lymph-node disease progression, documented with 18FDG PET/CT scan. The patient underwent laparoscopic left para-aortic lymphadenectomy and excision of subcutaneous lesion. Histologic examination showed presence of melanoma metastases in 2 lymph nodes out of total 17 excised and neoplastic emboli to the subcutaneous tissue. In view of starting adjuvant nivolumab, the patient underwent CT scan restaging, with evidence of suspect centimetric periaortic and paracaval lymph nodes, which were deemed worthy of 18FDG PET investigation. The 18FDG PET/CT was negative for abdominal hypercaptation, but showed left axillary pathologic lymph nodes. The medical history of the patient revealed that he had received intramuscular Moderna COVID-19 mRNA vaccine in the left deltoid, one week before 18FDG PET examination. Since the patient's clinical examination was negative and suspecting postvaccination false-positive adenopathy, bilateral axillary ultrasound was performed, excluding the presence of pathologic lymph nodes. The patient has started adjuvant treatment with nivolumab, which is currently ongoing. This case demonstrates unexpected findings in response to COVID-19 vaccination in a patient with melanoma. In this specific case, the detection of 18FDG PET hypercaptation could significantly change the patient's management. With growing evidence about the pattern and occurrence of adenopathies after mRNA COVID-19 vaccination, recommendations for scheduling and interpretation of 18FDG PET/CT scans among cancer patients will be implemented, in order to reduce equivocal findings and improve outcomes.

The impact of COVID-19 in pregnancy: Part II. Vaccination to pregnant women. Effective strategies are urgently needed to decrease the risk of untoward outcomes of pregnant women with severe acute respiratory syndrome coronavirus 2 (coronavirus disease 2019 [COVID-19]) infection. Pregnant women are a vulnerable population to infectious disease pandemics with dramatically increased infectious diseases-related serious complications, such as the need of hospitalizations, the need of admission to intensive care unit, and the final disease-related death compared with those nonpregnant counterparts or those pregnant women without infection. Several studies have shown that vaccinations in pregnancy are a safe and highly effective strategy, not only for pregnant women but also for fetus and/or newborn because of the passive transplacental transfer of antibodies to the offspring. Active and passive prevention of infectious diseases is approved as effective strategies for women who attempt to become pregnant or during pregnancy. Despite the large and proven scientific evidence, pregnant women still puzzle over whether they should get vaccinated. The question therefore arises: Why are pregnant women so reluctant to receive vaccination? The explanation is more likely in the way that the benefits of vaccination have been communicated "confusedly." In fact, like virtually all clinical trials, all the COVID-19 vaccine trials have excluded pregnant and lactating women from participating, contributing to uncertainty of safety and efficacy in COVID-19 vaccines that have been well prepared and available for the general adult population worldwide. Moreover, messenger RNA vaccine is a relatively brand-new vaccine, and experience with this type of vaccine is still scarce. It is hard to overcome this innovation deadlock. The knowledge and awareness of pregnant women who are at risk, and full information on the knowledge of vaccines and

related preventable diseases in pregnant women may avoid hesitancy and increase vaccine acceptance. The current review is a part two addressing the impact of COVID-19 on pregnant women. We focus on the up-to-date information about the application of vaccination on pregnant women, especially during this COVID-19 pandemic.

No Correlation between Anti-PF4 and Anti-SARS-CoV-2 Antibodies after ChAdOx1 nCoV-19 Vaccination.

Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting. BACKGROUND: Preapproval trials showed that messenger RNA (mRNA)-based vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) had a good safety profile, yet these trials were subject to size and patient-mix limitations. An evaluation of the safety of the BNT162b2 mRNA vaccine with respect to a broad range of potential adverse events is needed. METHODS: We used data from the largest health care organization in Israel to evaluate the safety of the BNT162b2 mRNA vaccine. For each potential adverse event, in a population of persons with no previous diagnosis of that event, we individually matched vaccinated persons to unvaccinated persons according to sociodemographic and clinical variables. Risk ratios and risk differences at 42 days after vaccination were derived with the use of the Kaplan-Meier estimator. To place these results in context, we performed a similar analysis involving SARS-CoV-2-infected persons matched to uninfected persons. The same adverse events were studied in the vaccination and SARS-CoV-2 infection analyses. RESULTS: In the vaccination analysis, the vaccinated and control groups each included a mean of 884,828 persons. Vaccination was most strongly associated with an elevated risk of myocarditis (risk ratio, 3.24; 95% confidence interval [CI], 1.55 to 12.44; risk difference, 2.7 events per 100,000 persons; 95% CI, 1.0 to 4.6), lymphadenopathy (risk ratio, 2.43; 95% CI, 2.05 to 2.78; risk difference, 78.4 events per 100,000 persons; 95% CI, 64.1 to 89.3), appendicitis (risk ratio, 1.40; 95% CI, 1.02 to 2.01; risk difference, 5.0 events per 100,000 persons; 95% CI, 0.3 to 9.9), and herpes zoster infection (risk ratio, 1.43; 95% CI, 1.20 to 1.73; risk difference, 15.8 events per 100,000 persons; 95% CI, 8.2 to 24.2). SARS-CoV-2 infection was associated with a substantially increased risk of myocarditis (risk ratio, 18.28; 95% CI, 3.95 to 25.12; risk difference, 11.0 events per 100,000 persons; 95% CI, 5.6 to 15.8) and of additional serious adverse events, including pericarditis, arrhythmia, deep-vein thrombosis, pulmonary embolism, myocardial infarction, intracranial hemorrhage, and thrombocytopenia. CONCLUSIONS: In this study in a nationwide mass vaccination setting, the BNT162b2 vaccine was not associated with an elevated risk of most of the adverse events examined. The vaccine was associated with an excess risk of myocarditis (1 to 5 events per 100,000 persons). The risk of this potentially serious adverse event and of many other serious adverse events was substantially increased after SARS-CoV-2 infection. (Funded by the Ivan and Francesca Berkowitz Family Living Laboratory Collaboration at Harvard Medical School and Clalit Research Institute.).

COVID-19 post-vaccination lymphadenopathy: Report of cytological findings from fine needle aspiration biopsy. The coronavirus COVID-19 pandemic has spurred the rapid development of vaccines, with vaccination programmes already underway in many countries. Regional lymphadenopathy is one of the documented side effects of vaccination. We document the fine needle aspiration cytological findings of an enlarged supraclavicular lymph node in a 34-year-old Asian female following the first dose of the Pfizer-BioNTech COVID-19 mRNA vaccine, which appears to be the first such report in a premorbidly well patient with no known history of malignancy. The cytological findings featured a reactive pattern in keeping with follicular hyperplasia, with prominent germinal centre elements including lymphohistiocytic aggregates and tingible-body macrophages. Despite an increased proportion of larger lymphocytes, the overall pattern was in keeping with a reactive pattern, bearing in mind the temporal and geographic relation to the vaccination injection. In instances of localised lymphadenopathy, particularly in supraclavicular or axillary locations,

pathologists should be cognizant of the possibility of post-vaccination reactive lymphadenopathy, and seek clinical and radiological hints favouring a benign process, whilst recognising potential morphological overlaps with lymphoproliferative disorders. Awareness of this diagnostic pitfall is especially important as COVID-19 vaccination coverage is ramped up worldwide, leading to an expected increase in incidence of post-vaccination reactive lymphadenopathy.
Myeloperoxidase anti-neutrophil cytoplasmic antibody positive optic perineuritis after mRNA coronavirus disease-19 vaccine.
COVID-19 vaccination and exanthema-like eruption.
Guillain-BarrÃ© Syndrome After COVID-19 mRNA Vaccination in a Liver Transplantation Recipient With Favorable Treatment Response.
Drug-Induced Liver Injury After COVID-19 Vaccine. The first case of coronavirus disease 2019 (COVID-19) was reported in December 2019 in China. World Health Organization declared it a pandemic on March 11, 2020. It has caused significant morbidity and mortality worldwide. Persistent symptoms and serious complications are being reported in patients who survived COVID-19 infection, but long-term sequelae are still unknown. Several vaccines against COVID-19 have been approved for emergency use around the globe. These vaccines have excellent safety profiles with few reported side effects. Drug-induced hepatotoxicity is mainly seen with different drugs or chemicals. There are only a few reported cases of hepatotoxicity with vaccines.Â We present a case of liver injury after administration of the vaccine against the COVID-19 infection.
Rituximab-induced acute lympholysis and pancytopenia after COVID-19 vaccination. Rituximab and COVID-19 vaccine can cause massive hyperacute depletion of B cells and plasma cells, as well as subsequent cytokine release syndrome, coagulopathy, and pancytopenia. These effects differ from the adverse effects that have been reported for rituximab, and new guidelines regarding the timing of rituximab infusion and vaccination are urgently needed.
Vaccination against COVID-19 in a haemodialysis centre: what is the risk of bleeding complications?
Myocarditis Associated With COVID-19 Vaccination: Echocardiography, Cardiac Tomography, and Magnetic Resonance Imaging Findings.
Severe acute respiratory syndrome coronavirus 2 vaccination and cancer therapy: A successful but mindful mix.
Herpes zoster after COVID vaccination. COVID-19 presents in various ways, but mainly as a pulmonary disease (Marzano, 2020). Skin manifestations have been reported, including reactivation of the varicella-zoster virus (Marzano, 2020). Our case report describes two adults developing herpes zoster after vaccination with tozinameran (the Pfizer-BioNTech COVID-19 mRNA vaccine). A possible cause for this reaction is a transient lymphocytopenia that occurs after the vaccination - similar to that in COVID-19 disease (Mulligan, 2020; Wang, 2020; Qin, 2020; Brabilla, 2020; Wang, 2020; Wei, 2017). In the context of vaccinating older and/or immunocompromised adults, our observations can be the starting point for further evaluation of a possible relationship between COVID-19, COVID vaccines, and herpes zoster.
Seroconversion Following SARS-CoV-2 Infection or Vaccination in Pediatric IBD Patients.
Facial nerve palsy after COVID-19 vaccination - A rare association or a coincidence.
Long-term humoral immunogenicity, safety and protective efficacy of inactivated vaccine against COVID-19 (CoviVac) in preclinical studies. The unprecedented in recent history global COVID-19 pandemic urged the implementation of all existing vaccine platforms to ensure the availability of the vaccines against COVID-19 to every country in the world. Despite the multitude of high-quality papers describing clinical trials of different vaccine products, basic detailed data on general toxicity, reproductive toxicity, immunogenicity, protective efficacy and durability of immune response in

animal models are scarce. Here, we developed a Î²-propiolactone-inactivated whole virion vaccine CoviVac and assessed its safety, protective efficacy, immunogenicity and stability of the immune response in rodents and non-human primates. The vaccine showed no signs of acute/chronic, reproductive, embryo- and fetotoxicity, or teratogenic effects, as well as no allergenic properties in studied animal species. The vaccine induced stable and robust humoral immune response both in form of specific anti-SARS-CoV-2 IgG and NAbs in mice, Syrian hamsters, and common marmosets. The NAb levels did not decrease significantly over the course of one year. The course of two immunizations protected Syrian hamsters from severe pneumonia upon intranasal challenge with the live virus. Robustness of the vaccine manufacturing process was demonstrated as well. These data encouraged further evaluation of CoviVac in clinical trials.
Corneal graft rejection following COVID-19 vaccine.
Eyelid erythema after coronavirus vaccination.
Deaths associated with newly launched SARS-CoV-2 vaccination.
Pregnancy and birth outcomes after SARS-CoV-2 vaccination in pregnancy. BACKGROUND: SARS-CoV-2 infection during pregnancy is associated with significant maternal morbidity and increased rates of preterm birth. For this reason, COVID-19 vaccination in pregnancy has been endorsed by multiple professional societies, including the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine, despite the exclusion of pregnant women from initial clinical trials of vaccine safety and efficacy. However, to date, little data exist regarding the outcomes of pregnant patients after COVID-19 vaccination. OBJECTIVE: To assess the safety and efficacy of COVID-19 vaccines in pregnant patients. STUDY DESIGN: A comprehensive vaccine registry was combined with a delivery database for an integrated healthcare system to create a delivery cohort that included vaccinated patients. Maternal sociodemographic data were examined to identify factors associated with COVID-19 vaccination. Pregnancy and birth outcomes were analyzed, including a composite measure of maternal and neonatal pregnancy complications, the Adverse Outcome Index. RESULTS: Of 2002 patients in the delivery cohort, 140 (7.0%) received a COVID-19 vaccine during pregnancy, and 212 (10.6%) experienced a COVID-19 infection during pregnancy. The median gestational age at first vaccination was 32 weeks (range, 13 6/7-40 4/7 weeks), and patients vaccinated during pregnancy were less likely than unvaccinated patients to experience COVID-19 infection before delivery (2/140 [1.4%] vs 210/1862 [11.3%]; P<.001). No maternal COVID-19 infection occurred after the vaccination of pregnant patients. Factors significantly associated with increased likelihood of vaccination in a multivariable logistic regression model included older age, higher level of maternal education, being a nonsmoker, use of infertility treatment for the current pregnancy, and lower gravidity. Compared with unvaccinated patients, no significant difference in the composite adverse outcome (7/140 [5.0%] vs 91/1862 [4.9%]; P=.95) or other maternal or neonatal complications, including thromboembolic events and preterm birth, was observed in vaccinated patients. CONCLUSION: In this birth cohort, vaccinated pregnant women were less likely than unvaccinated pregnant patients to experience COVID-19 infection, and COVID-19 vaccination during pregnancy was not associated with increased pregnancy or delivery complications. The cohort was skewed toward late pregnancy vaccination, and thus, findings may not be generalizable to vaccination during early pregnancy.
Acute myocarditis associated with the Pfizer/BioNTech vaccine.
Cutaneous and hypersensitivity reactions associated with COVID-19 vaccination-aÂ narrative review. Vaccination against severe acute respiratory syndrome coronavirus typeÂ 2 (SARS-CoVâ€‘2) has become aÂ major tool in the battle against the coronavirus disease 2019 (COVID-19) pandemic. Numerous products have been developed and more are to come. Vaccination success varies greatly between different countries. There are aÂ number of different vaccine types, such as mRNA, DNA

vaccines, adenovirus vector vaccines, and full-length spike protein nanoparticles with aÂ special matrix. The different types may also cause aÂ different spectrum of adverse events. With mass vaccination, post-marketing surveillance for product safety becomes increasingly important. In this review, we discuss possible hypersensitivity and cutaneous adverse events related to SARS-CoVâ€‘2 vaccination-from local reactions like COVID arm to systemic and severe reactions like anaphylaxis. Vaccination may also induce or exacerbate preexisting disorders such as herpes zoster infection. This review should provide information to tailor, whenever possible, vaccination to patients' needs. It is aÂ contribution to patient safety as well. There is general consensus that the benefits of SARS-CoVâ€‘2 vaccination currently outweigh the risks of possible adverse events.
COVID-19 in Canada: Experience and Response to Waves 2 and 3.
A case of acute necrotising pancreatitis following the second dose of Pfizer-BioNTech COVID-19 mRNA vaccine.
Antineutrophil Cytoplasmic Autoantibody-Associated Glomerulonephritis Following the Pfizer-BioNTech COVID-19 Vaccine.
Moderna COVID-19 vaccine induced skin rash.
A case series of cutaneous COVID-19 vaccine reactions at Loma Linda University Department of Dermatology.
Lichen striatus post-COVID-19 vaccination.
Attitudes toward COVID-19 vaccination and willingness to pay: comparison of people with and without mental disorders in China. BACKGROUND: Acceptance and willingness to pay for the COVID-19 vaccine are unknown. AIMS: We compared attitudes toward COVID-19 vaccination in people suffering from depression or anxiety disorder and people without mental disorders, and their willingness to pay for it. METHOD: Adults with depression or anxiety disorder (n = 79) and healthy controls (n = 134) living in Chongqing, China, completed a cross-sectional study between 13 and 26 January 2021. We used a validated survey to assess eight aspects related to attitudes toward the COVID-19 vaccines. Psychiatric symptoms were assessed by the 21-item Depression, Anxiety and Stress Scale. RESULTS: Seventy-six people with depression or anxiety disorder (96.2%) and 134 healthy controls (100%) reported willingness to receive the COVID-19 vaccine. A significantly higher proportion of people with depression or anxiety disorder (64.5%) were more willing to pay for the COVID-19 vaccine than healthy controls (38.1%) (P â‰¤ 0.001). After multivariate adjustment, severity of depression and anxiety was significantly associated with willingness to pay for COVID-19 vaccination among psychiatric patients (P = 0.048). Non-healthcare workers (P = 0.039), health insurance (P = 0.003), living with children (P = 0.006) and internalised stigma (P = 0.002) were significant factors associated with willingness to pay for COVID-19 vaccine in healthy controls. CONCLUSIONS: To conclude, psychiatric patients in Chongqing, China, showed high acceptance and willingness to pay for the COVID-19 vaccine. Factors associated with willingness to pay for the COVID-19 vaccine differed between psychiatric patients and healthy controls.
COVID-19: the implications and consequences of prolonged lockdown and COVID-19 vaccine cost in a low-middle income country. Lockdowns and just recently, the COVID-19 vaccines, are amongst the disease containment measures instituted globally to check the spread of COVID-19. Prolonged lockdowns are however, not sustainable in low resource economies like Nigeria, where up to 70% of her population live on less than a dollar a day, with the majority, either unemployed, or working in the private/informal sector and depending on daily earnings for survival. If the lockdown remains sustained, it would not be long before the largely poor citizens starve to death. Also, spending over US $3.9 billion on COVID-19 vaccines for more than 200 million Nigerians, as intended by the Nigerian government, is not plausible, given that neglected tropical diseases (NTDs) like Lassa fever, and other more common causes of morbidity and mortality, continue to kill more Nigerians than COVID-19.

Public enlightenment of the populace on the need to strictly adhere to non-pharmacologic preventive measures, including social distancing, use of face masks, good personal hygiene, covering of the mouth and nose when coughing and sneezing, frequent hand washing and sanitizing with alcohol-based hand-sanitizers and disinfection of surfaces, is what is sustainable, feasible and compatible with the economic reality in our setting. As Sir Robert Hutchison, the highly revered doyen of medicine, wrote in his petition over 85 years ago, "And from making the cure of the disease more grievous than the endurance of the same, Good Lord, deliver us", we must be careful not to make the cure of COVID-19 worse than COVID-19 itself.

BCG Vaccine Derived Peptides Induce SARS-CoV-2 T Cell Cross-Reactivity. Epidemiological studies and clinical trials suggest Bacillus Calmette-GuÃ©rin (BCG) vaccine has protective effects against coronavirus disease 2019 (COVID-19). There are now over 30 clinical trials evaluating if BCG vaccination can prevent or reduce the severity of COVID-19. However, the mechanism by which BCG vaccination can induce severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-specific T cell responses is unknown. Here, we identify 8 novel BCG-derived peptides with significant sequence homology to either SARS-CoV-2 NSP3 or NSP13-derived peptides. Using an in vitro co-culture system, we show that human CD4+ and CD8+ T cells primed with a BCG-derived peptide developed enhanced reactivity to its corresponding homologous SARS-CoV-2-derived peptide. As expected, HLA differences between individuals meant that not all persons developed immunogenic responses to all 8 BCG-derived peptides. Nevertheless, all of the 20 individuals that were primed with BCG-derived peptides developed enhanced T cell reactivity to at least 7 of 8 SARS-CoV-2-derived peptides. These findings provide an in vitro mechanism that may account, in part, for the epidemiologic observation that BCG vaccination confers some protection from COVID-19.

An old entity, a new trigger: Post COVID-19 vaccine pityriasis rubra pilaris. BACKGROUND: Pityriasis rubra pilaris (PRP) is a rare, acquired, chronic papulosquamous dermatosis which can occur in all ages. PRP can be associated with infection, autoimmunity, drugs and malignancies, and can be idiopathic. OBJECTIVE: PRP following vaccination has been rarely described in the literature. To the best of our knowledge, we report the first case of PRP two weeks following COVID-19 vaccination (Covishield). CASE REPORT: A 72-year-old male presented to the outpatient dermatology department at All India Institute of Medical Sciences - Bhopal with minimally pruritic superficial plaques since one week. The patient was vaccinated against COVID-19 with Covishield two weeks earlier. The lesions developed as erythematous scaly follicular papules and plaques over axilla that rapidly spread to the trunk in the following weeks and involved palms and soles as well as thickening and fissuring. The clinical features suggested PRP. The histopathology showed epidermal acanthosis with hypergranulosis alternating with parakeratosis and orthokeratosis with broad rete ridges with follicular plugging. The patient had started taking topical corticosteroids and emollients, which proved effective. There was no recurrence after receiving a second dose on follow-up. CONCLUSION: In patients presenting with new onset PRP in this COVID-19 era, the possibility of vaccine as a trigger should be taken into consideration, and further dosing should be carefully monitored in view of possible recurrence.

Temporal Association Between the COVID-19 Ad26.COV2.S Vaccine and Acute Myocarditis: A Case Report and Literature Review. With the recent approval and widespread administration of the Pfizer-BioNTech, Moderna, and Janssen vaccines worldwide, incidence of severe Coronavirus Disease 2019 (COVID-19) infection has significantly decreased. In spite of their undisputed role in reducing the severity of the disease and reduction of the disease burden in the community, there have been case reports of serious side effects with these vaccines. We aim to describe a case report of myocarditis following administration of the Janssen vaccine in a healthy, young male and review the available literature on COVID-19 vaccine related myocarditis and its possible pathogenesis. This case and

literature review notes a temporal association between COVID-19 vaccination and myocarditis. Despite these observations, the benefits of the vaccines far outweigh the risks of possible myocarditis.
Newly diagnosed immune thrombocytopenia in a pregnant patient after coronavirus disease 2019 vaccination. Over 26 million cases of coronavirus disease 2019 (COVID-19) have been reported in the United States with over 440â€‰000 deaths. Despite COVID-19 vaccine approval, pregnant women were excluded from clinical trials. We report a case of immune thrombocytopenia in the first trimester, which occurred 13â€‰days after initiating the COVID-19 vaccination series. Thorough evaluation, including hematology consultation, established the diagnosis. High-dose oral corticosteroids were started, and she was discharged home with significant improvement in platelet count on her fourth day of hospitalization with no subsequent complications. We advocate that the benefits of COVID-19 vaccination outweigh the risk of infection in pregnancy and that pregnant women should be included in clinical trials. Closer post-vaccination surveillance may be warranted in the pregnant population pending further data.
Immunological changes after COVID-19 vaccination in an HIV-positive patient. Vaccination is an essential measure to stop the coronavirus disease 2019 (COVID-19) pandemic. We report a case of viral activation and CD4+ TÂ cell loss in a treatment-naÃ¯ve HIV-positive patient after receiving inactivated COVID-19 vaccine (Sinopharm). The vaccine should probably be given only to people living with HIV receiving antiretroviral therapy.
Membranous nephropathy following anti-COVID-19 mRNA vaccination.
Anti-SARS-CoV-2 spike protein S1 receptor-binding domain antibody after vaccination with inactivated whole-virus SARS-CoV-2 in end-stage kidney disease patients: an initial report.
Guillain-BarrÃ©Â syndrome after AstraZeneca COVID-19-vaccination: A causal or casual association? We report a case of Guillain-BarrÃ©Â syndrome (GBS) following the first dose of Oxford/AstraZeneca COVID-19 vaccine with papilledema as atypical onset. As the COVID-19 vaccination campaign progresses worldwide, GBSs vaccine-related have been increasingly reported. After reviewing the available literature, considering the annual incidence of GBS, in this historical moment, the public health systems cannot afford an unjustified distrust in vaccines, caused by misinterpretation of epidemiological data. Nonetheless, it is important for clinicians to promptly recognize neurological complications potentially associated with COVID-19 vaccinations and report them to pharmacovigilance agencies.
Systemic lupus erythematosus after COVID-19 vaccination: A case report.
Assessment of humoral and cellular immunity induced by the BNT162b2 SARS-CoV-2 vaccine in healthcare workers, elderly people, and immunosuppressed patients with autoimmune disease. The development of vaccines to prevent SARS-CoV-2 infection has mainly relied on the induction of neutralizing antibodies (nAbs) to the Spike protein of SARS-CoV-2, but there is growing evidence that T cell immune response can contribute to protection as well. In this study, an anti-receptor binding domain (RBD) antibody assay and an INFÎ³-release assay (IGRA) were used to detect humoral and cellular responses to the Pfizer-BioNTech BNT162b2 vaccine in three separate cohorts of COVID-19-naÃ¯ve patients: 108 healthcare workers (HCWs), 15 elderly people, and 5 autoimmune patients treated with immunosuppressive agents. After the second dose of vaccine, the mean values of anti-RBD antibodies (Abs) and INFÎ³ were 123.33 U/mL (range 27.55-464) and 1513 mIU/mL (range 145-2500) in HCWs and 210.7 U/mL (range 3-500) and 1167 mIU/mL (range 83-2500) in elderly people. No correlations between age and immune status were observed. On the contrary, a weak but significant positive correlation was found between INFÎ³ and anti-RBD Abs values (rhoâ€‰=â€‰0.354, pâ€‰=â€‰0.003). As to the autoimmune cohort, anti-RBD Abs were not detected in the two patients with absent peripheral CD19(+)B cells, despite high INFÎ³ levels being observed in all 5

patients after vaccination. Even though the clinical relevance of T cell response has not yet been established as a correlate of vaccine-induced protection, IGRA testing has showed optimal sensitivity and specificity to define vaccine responders, even in patients lacking a cognate antibody response to the vaccine.

COVID's Double Whammy: Drug Discontinuation Flares the Disease While Vaccination Takes the Blame.

[Friend or Foe? Evaluation of BCG Vaccine and Latent Tuberculosis Infection Effect in Patients Diagnosed with COVID-19 Infection]. While severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) continues to spread rapidly worldwide, some issues such as the uncertainty of the disease progress, whether intensive care will be needed, and risk classification are still important for clinicians. It is notable that in countries where latent tuberculosis infection (LTBI) is common and participating in the national Bacillus Calmette-Guerin (BCG) vaccination program, the case-fatality rates are relatively low throughout the world. In this study, it was aimed to evaluate the effects of the BCG vaccine and LTBI status on the course of the disease in patients diagnosed with coronavirus-19 (COVID-19) infection and to compare the LTBI rate with people with and without COVID-19 infection. The patients diagnosed with COVID-19 infection who were hospitalized during a period of seven months between May 1st to December 1st, 2020 were investigated by the QuantiFERON-TB Gold Plus (QFT-Plus) test in the blood samples for the presence of LTBI. For the comparison of the patients diagnosed with COVID-19 and people without COVID-19 infections in terms of LTBI rate retrospectively; all consecutive patients who were sent blood samples to the mycobacteriology laboratory for the QFT-Plus test between January 2016 and December 2019 were included in the study. Demographic, clinical, radiological, laboratory, and follow-up data of the patients were obtained from the electronic patient file. A total of 170 patients (n= 9 8 male [57.6%], n= 72 female [42.3%], mean age= 53.5 Â± 15.8 years) were enrolled. Twenty-five patients' (25/170 [14.7%]) QFT-plus tests were positive. When the cases with positive QFT-Plus test (n= 25) and the cases with negative QFT-Plus test (n = 145) were compared in terms of disease severity respectively; it was determined that mild/moderate patients were 18/25 (72%) and 108/145 (74.5%), severe patients were 7/25 (28%) and 37/145 (25.5%) (p= 0.988). When these two groups were compared in terms of the clinical course respectively; the need for intensive care was 6/25 (24%) and 34/145 (23.4%) (p= 1.00), oxygen therapy requirement was 13/25 (52%) and 49/145 (33.8%) (p= 0.128), and death was 5/25 (20%) and 18/145 (12.4%) (p= 0.341). QFT-Plus positivity was 25/170 (14.7%) in patients diagnosed with COVID-19, while in control group it was 198/496 (39.9%) (OR= 0.259, 95% CI [0.164-0.411], p<0.001). When the values were evaluated quantitatively, in the COVID-19 patient group, QFT-Plus T1/T2 (IU/ml) interferon (IFN)-É£ was 0.87 Â± 1.52/0.62 Â± 1.53, while in the control group it was 1.52 Â± 3.69/1.50 Â± 3.33 (p= 0.032, p= 0.04). There was no significant difference in the parameters investigated between 82 (48.2%) patients with BCG vaccine and those 88 (51.8%) without BCG vaccine. Although it was not statistically significant in our study, increased oxygen therapy requirement and higher mortality rates in the QFT-Plus positive group were remarkable. The detection of statistically significantly lower LTBI rates and T1-T2/IFN-É£ values in the COVID-19 group supported that SARS-CoV-2 infection may suppress lymphocyte functions in patients and IFN-É£ response. We believe that the results of our study are remarkably valuable, but more clinical studies are needed to elucidate the relationship between BCG vaccine, LTBI, and COVID-19 infection.

Sensory Guillain-Barre syndrome following the ChAdOx1 nCov-19 vaccine: Report of two cases and review of literature. Massive vaccination against COVID-19 has become a global priority. Simultaneously, concerns regarding the safety of vaccines are growing. We describe two patients who developed sensory Guillain-Barre syndrome (GBS) shortly after the first dose of the ChAdOx1 vaccine. We also summarize 12 published cases of GBS after ChAdOx1 vaccination, highlighting their unique

clinical and paraclinical features. We propose a possible association between the risk of GBS and the ChAdOx1 vaccine and recommend surveillance for GBS following vaccination. Population-based studies are needed to determine causality and whether specific subpopulations are susceptible.

Fulminant myocarditis and systemic hyperinflammation temporally associated with BNT162b2 mRNA COVID-19 vaccination in two patients. Immune-mediated myocardial injury following Severe Acute Respiratory Syndrome Coronavirys-2 (SARS-CoV2) infection has been described in adults and children. Cases of myocarditis following immunization for SARS-CoV2 have recently been documented, mostly associated with mild severity and spontaneous recovery. We herein report two cases of fulminant myocarditis following BNT162b2 mRNA Covid-19 vaccination associated with systemic hyperinflammatory syndrome and refractory shock requiring support with veno-arterial extracorporeal membrane oxygenation.

Safety and immunogenicity of the ChAdOx1 nCoV-19 (AZD1222) vaccine against SARS-CoV-2 in people living with and without HIV in South Africa: an interim analysis of a randomised, double-blind, placebo-controlled, phase 1B/2A trial. BACKGROUND: People living with HIV are at an increased risk of fatal outcome when admitted to hospital for severe COVID-19 compared with HIV-negative individuals. We aimed to assess safety and immunogenicity of the ChAdOx1 nCoV-19 (AZD1222) vaccine in people with HIV and HIV-negative individuals in South Africa. METHODS: In this ongoing, double-blind, placebo-controlled, phase 1B/2A trial (COV005), people with HIV and HIV-negative participants aged 18-65 years were enrolled at seven South African locations and were randomly allocated (1:1) with full allocation concealment to receive a prime-boost regimen of ChAdOx1 nCoV-19, with two doses given 28 days apart. Eligibility criteria for people with HIV included being on antiretroviral therapy for at least 3 months, with a plasma HIV viral load of less than 1000 copies per mL. In this interim analysis, safety and reactogenicity was assessed in all individuals who received at least one dose of ChAdOx1 nCov 19 between enrolment and Jan 15, 2021. Primary immunogenicity analyses included participants who received two doses of trial intervention and were SARS-CoV-2 seronegative at baseline. This trial is registered with ClinicalTrials.gov, NCT04444674, and the Pan African Clinicals Trials Registry, PACTR202006922165132. FINDINGS: Between June 24 and Nov 12, 2020, 104 people with HIV and 70 HIV-negative individuals were enrolled. 102 people with HIV (52 vaccine; 50 placebo) and 56 HIV-negative participants (28 vaccine; 28 placebo) received the priming dose, 100 people with HIV (51 vaccine; 49 placebo) and 46 HIV-negative participants (24 vaccine; 22 placebo) received two doses (priming and booster). In participants seronegative for SARS-CoV-2 at baseline, there were 164 adverse events in those with HIV (86 vaccine; 78 placebo) and 237 in HIV-negative participants (95 vaccine; 142 placebo). Of seven serious adverse events, one severe fever in a HIV-negative participant was definitely related to trial intervention and one severely elevated alanine aminotranferase in a participant with HIV was unlikely related; five others were deemed unrelated. One person with HIV died (unlikely related). People with HIV and HIV-negative participants showed vaccine-induced serum IgG responses against wild-type Wuhan-1 Asp614Gly (also known as D614G). For participants seronegative for SARS-CoV-2 antigens at baseline, full-length spike geometric mean concentration (GMC) at day 28 was 163Â·7 binding antibody units (BAU)/mL (95% CI 89Â·9-298Â·1) for people with HIV (n=36) and 112Â·3 BAU/mL (61Â·7-204Â·4) for HIV-negative participants (n=23), with a rising day 42 GMC booster response in both groups. Baseline SARS-CoV-2 seropositive people with HIV demonstrated higher antibody responses after each vaccine dose than did people with HIV who were seronegative at baseline. High-level binding antibody cross-reactivity for the full-length spike and receptor-binding domain of the beta variant (B.1.351) was seen regardless of HIV status. In people with HIV who developed high titre responses, predominantly those who were receptor-binding domain seropositive at enrolment, neutralising activity against beta was retained. INTERPRETATION: ChAdOx1 nCoV-19 was well tolerated, showing favourable safety and

immunogenicity in people with HIV, including heightened immunogenicity in SARS-CoV-2 baseline-seropositive participants. People with HIV showed cross-reactive binding antibodies to the beta variant and Asp614Gly wild-type, and high responders retained neutralisation against beta. FUNDING: The Bill & Melinda Gates Foundation, South African Medical Research Council, UK Research and Innovation, UK National Institute for Health Research, and the South African Medical Research Council.
A case of ANCA-associated vasculitis after AZD1222 (Oxford-AstraZeneca) SARS-CoV-2 vaccination: casualty or causality?
A Bullous Eruption following the Pfizer-BioNTech COVID-19 vaccination.
'COVID vaccine arm' may present after both mRNA vaccines vaccination.
Flagellate purpura associated with COVID-19 vaccination.
Two cases of papulo-pustular rosacea-like eruptions following COVID-19 vaccinations.
Peoples' understanding, acceptance, and perceived challenges of vaccination against COVID-19: A cross-sectional study in Bangladesh. In order to eliminate COVID-19, many countries provided vaccinations. However, success depends on peoples' knowledge levels and rates of acceptance. But, previous research on this topic is currently lacking in Bangladesh. This cross-sectional study aimed at to investigate Bangladeshi peoples' knowledge, acceptance, and perception of challenges regarding COVID-19 vaccines. Quantitative data were collected using an online survey (n = 1975) and face-to-face interviews (n = 2200) with a pre-tested structured questionnaire. In addition, seven open-ended interviews were conducted with health experts regarding challenges of vaccination. Binary logistic regression analyses were conducted to assess the association between explanatory and dependent variables. Effect size was estimated to understand the magnitude of relationship between two variables. Of 4175 respondents, 92.6% knew about COVID-19 vaccines, while only 37.4% believed vaccines to be effective in controlling COVID-19. Nearly 46% of respondents believed that COVID-19 vaccines have side-effects, and 16.4% of respondents believed that side-effects could be life-threatening. Only 60.5% of respondents indicated that they would receive the COVID-19 vaccine. Out of 1650 respondents (39.5%) who did not intend to receive the vaccine, 948 (57.4%) believed that they would be naturally protected. Regressions results indicated that men had higher rates of knowledge regarding the vaccine. In addition, rural respondents demonstrated lower knowledge regarding the vaccine. Furthermore, education had a significant association with knowledge of COVID-19 vaccines. Respondents with university education had more knowledge regarding the vaccine (Odds ratio, OR = 29.99; 95% confidence interval, CI 11.40-78.90, effect size 1.88; p = 0.01) and correct dosage (OR 27.34; 95% CI 15.25-49.00, effect size 1.83; p = 0.01). However, women (OR 1.16; 95% CI 0.96-1.40, effect size 0.08) and rural (OR 1.24; 95% CI 1.07-1.44, effect size 0.12; p = 0.01) respondents were more enthusiastic regarding receiving the COVID-19 vaccine. Higher educated respondents showed higher probability of receiving the vaccine. Those who believed in the effectiveness of the COVID-19 vaccine were 11.57 times more interested (OR 11.57; 95% CI 8.92-15.01, effect size 1.35; p = 0.01) in receiving the vaccine. Open-ended interviews identified several challenges toward successful COVID-19 vaccination. Mass awareness creation, uninterrupted supply, equitable distribution, and sectoral coordination were suggested to achieve at least 70% immunization across the country.
Allergic and cutaneous reactions following inactivated SARS-CoV-2 vaccine (CoronaVac(Â®)) in healthcare workers.
IgA nephropathy flare-up following SARS-CoV-2 vaccination.
Supraclavicular lymphadenopathy secondary to COVID-19 BNT162b2 vaccine.

Reports of anaphylaxis after coronavirus disease 2019 vaccination, South Korea, 26 February to 30 April 2021. The South Korea mass vaccination programme administered 3.8 million doses of COVID-19 vaccinations between 26 February and 30 April 2021. After 173 suspected anaphylaxis reports to the nationwide monitoring system for adverse events following immunisation, 44 anaphylaxis cases were confirmed using Brighton Collaboration case definitions. The rates per million doses were 18.2 cases and 6.2 cases for Vaxzevria and Comirnaty, respectively. Median time of onset was 14 min after vaccination and most cases had recovered at the time of review.

Cutaneous skin manifestation following messenger RNA Moderna SARS-CoV-2 vaccine with dermal hypersensitivity reaction histopathology.

Poliovirus Vaccination Induces a Humoral Immune Response That Cross Reacts With SARS-CoV-2. Background: Millions have been exposed to SARS-CoV-2, but the severity of resultant infections has varied among adults and children, with adults presenting more serious symptomatic cases. Children may possess an immunity that adults lack, possibly from childhood vaccinations. This retrospective study suggests immunization against the poliovirus may provide an immunity to SARS-CoV-2. Methods: Publicly available data were analyzed for possible correlations between national median ages and epidemiological outbreak patterns across 100 countries. Sera from 204 adults and children, who were immunized with the poliovirus vaccine, were analyzed using an enzyme-linked immunosorbent assay. The effects of polio-immune serum on SARS-CoV-2-induced cytopathology in cell culture were then evaluated. Results: Analyses of median population age demonstrated a positive correlation between median age and SARS-CoV-2 prevalence and death rates. Countries with effective poliovirus immunization protocols and younger populations have fewer and less pathogenic cases of COVID-19. Antibodies to poliovirus and SARS-CoV-2 were found in pediatric sera and in sera from adults recently immunized with polio. Sera from polio-immunized individuals inhibited SARS-CoV-2 infection of Vero cell cultures. These results suggest the anti-D3-pol-antibody, induced by poliovirus vaccination, may provide a similar degree of protection from SARS-CoV-2 to adults as to children. Conclusions: Poliovirus vaccination induces an adaptive humoral immune response. Antibodies created by poliovirus vaccination bind the RNA-dependent RNA polymerase (RdRp) protein of both poliovirus and SARS-CoV-2, thereby preventing SARS-CoV-2 infection. These findings suggest proteins other than "spike" proteins may be suitable targets for immunity and vaccine development.

Antibody response after COVID-19 vaccine BNT162b2 on health care workers in Japan. BACKGROUND: Vaccination is one of the most important tools to control the COVID-19 pandemic. However, there is little information on the antibody response in humans after the COVID-19 vaccination. METHODS: This single-center, prospective study was conducted in Yokohama, Japan. We included health care workers who had received two doses of COVID-19 vaccination (BNT162b2) 21 days apart. We measured serum immunoglobulin G (IgG) to nucleoprotein and spike protein of SARS-CoV-2 with commercially available kits before and 7, 14, and 35 days after the first dose of vaccination. RESULTS: A total of 104 workers participated in this study. Of these, 7 participants were seropositive with antibodies to spike protein at baseline and 4 of the 7 seropositive participants had COVID-19 history. The mean level of IgG to spike protein (QT) was 45.2, 1219, 2845, and 23489 AU/mL at baseline, on days 7, 14, and 35, respectively, although the values for nucleoprotein (NG) were 0.2, 0.21, 0.22, and 0.19Â S/C, respectively. On day 7, QT in seropositive participants at baseline was elevated, whereas it was not elevated in seronegative participants at baseline until day 14. CONCLUSIONS: QT was elevated over the cutoff in all the participants at day 35, but NG did not change between baseline and day 35.

FDG uptake in axillary lymph nodes after COVID-19 vaccination - a pitfall in a case of highly suspicious lymph node metastases of malignant melanoma.

[Not Available].

The association between COVID-19 vaccination and Bell's palsy.

Bell's palsy following vaccination with mRNA (BNT162b2) and inactivated (CoronaVac) SARS-CoV-2 vaccines: a case series and nested case-control study. BACKGROUND: Bell's palsy is a rare adverse event reported in clinical trials of COVID-19 vaccines. However, to our knowledge no population-based study has assessed the association between the inactivated SARS-CoV-2 vaccines and Bell's palsy. The aim of this study was to evaluate the risk of Bell's palsy after BNT162b2 and CoronaVac vaccination. METHODS: In this case series and nested case-control study done in Hong Kong, we assessed the risk of Bell's palsy within 42 days following vaccination with BNT162b2 (Fosun-BioNTech [equivalent to Pfizer-BioNTech]) or CoronaVac (from Sinovac Biotech, Hong Kong) using data from voluntary surveillance reporting with the Hospital Authority, the COVID-19 Vaccine Adverse Event Online Reporting system for all health-care professionals, and the Hospital Authority's territory-wide electronic health records from the Clinical Data Analysis and Reporting System. We described reported cases of Bell's palsy among vaccine recipients (aged 18-110 years for CoronaVac and aged 16-110 years for BNT162b2). We compared the estimated age-standardised incidence of clinically confirmed cases among individuals who had received the CoronaVac or BNT162b2 vaccination (up to 42 days before presentation) with the background incidence in the population. A nested case-control study was also done using conditional logistic regression to estimate the odds ratio (OR) for risk of Bell's palsy and vaccination. Cases and controls were matched (1:4) by age, sex, admission setting, and admission date. FINDINGS: Between February 23 and May 4, 2021, 451â€‰939 individuals received the first dose of CoronaVac and 537â€‰205 individuals received the first dose of BNT162b2. 28 clinically confirmed cases of Bell's palsy were reported following CoronaVac and 16 cases were reported following BNT162b2. The age-standardised incidence of clinically confirmed Bell's palsy was 66Â·9 cases per 100â€‰000 person-years (95% CI 37Â·2 to 96Â·6) following CoronaVac vaccination and 42Â·8 per 100â€‰000 person-years (19Â·4 to 66Â·1) for BNT162b2 vaccination. The age-standardised difference for the incidence compared with the background population was 41Â·5 (95% CI 11Â·7 to 71Â·4) for CoronaVac and 17Â·0 (-6Â·6 to 40Â·6) for BNT162b2, equivalent to an additional 4Â·8 cases per 100â€‰000 people vaccinated for CoronaVac and 2Â·0 cases per 100â€‰000 people vaccinated for BNT162b2. In the nested case-control analysis, 298 cases were matched to 1181 controls, and the adjusted ORs were 2Â·385 (95% CI 1Â·415 to 4Â·022) for CoronaVac and 1Â·755 (0Â·886 to 3Â·477) for BNT162b2. INTERPRETATION: Our findings suggest an overall increased risk of Bell's palsy after CoronaVac vaccination. However, the beneficial and protective effects of the inactivated COVID-19 vaccine far outweigh the risk of this generally self-limiting adverse event. Additional studies are needed in other regions to confirm our findings. FUNDING: The Food and Health Bureau of the Government of the Hong Kong Special Administrative Region, China. TRANSLATION: For the Chinese translation of the abstract see Supplementary Materials section.

Comment on: Thrombocytopenia in a teen with sickle cell disease following COVID-19 vaccination.

Epidemiologic characteristics of cases with reinfection, recurrence, and hospital readmission due to COVID-19: A systematic review and meta-analysis. Recent studies reported that some recovered COVID-19 patients have tested positive for virus nucleic acid again. A systematic search was performed in Web of Science, PubMed, Scopus, and Google Scholar up to March 6, 2021. The pooled estimation of reinfection, recurrence, and hospital readmission among recovered COVID-19 patients was 3, 133, and 75 per 1000 patients, respectively. The overall estimation of reinfection among males compared to females was greater. The prevalence of recurrence in females compared to males was more common. Also, hospital readmission between sex groups was the same. There is uncertainty about long-term immunity after SARS-Cov-2 infection. Thus, the possibility of reinfection and

recurrence after recovery is not unexpected. In addition, there is a probability of hospital readmission due to adverse events of COVID-19 after discharge. However, with mass vaccination of people and using the principles of prevention and appropriate management of the disease, frequent occurrence of the disease can be controlled.

A COVID-Positive 52-Year-Old Man Presented With Venous Thromboembolism and Disseminated Intravascular Coagulation Following Johnson & Johnson Vaccination: A Case-Study. The coronavirus disease 2019 (COVID-19) is caused by the severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2). Infection by the SARS-CoV-2 increases the risk for systematic multi-organ complications and venous, arterial thromboembolism. The need for an effective vaccine to combat the pandemic prompted the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) to approve a nationwide distribution of the Ad26.COV2.S vaccine manufactured by Johnson & Johnson (J&J). The use of the vaccine was halted after reported cases of cerebral venous sinus thrombosis (CVST) and thrombocytopenia among recipients. Researchers have postulated these rare occurrences as potentially immune-triggered responses associated with complement-mediated thrombotic microangiopathy (TMA). Thrombotic complications and thrombocytopenia increase the risk for blood clot growth due to the inflammation of immune complexes by pro-thrombotic activation of anti-platelet antibodies. A 52-year-old man presented to the intensive care unit (ICU) with severe dyspnea. He required bilevel positive airway pressure (BiPAP)Â for supplemental oxygen therapy. Endotracheal intubation was performed due to his worsened respiratory deterioration. Lab results suggestedÂ respiratory failure due to decreased partial pressure of oxygen (pO(2)) and increased partial pressure of carbon dioxide (pCO(2)). Findings of elevated D-dimer levels with decreased fibrinogenÂ and thrombocytopenia with prolonged prothrombin clotting time were consistent for disseminated intravascular coagulation (DIC). Chest radiography displayed moderate to heavy bilateral airspace consolidations, consistent with multifocal pneumonia suspicious for COVID-19. A computed tomography angiogram (CTA) revealed a mildly enlarged right ventricle and interventricular septum consistent for right heart strain due to a saddle pulmonary embolism (PE) that extended into the main pulmonary lobar segmental arteries bilaterally.Â The patient was transferred to a higher-level (tertiary) care for radiology intervention to remove the pulmonary embolism found on his lungs. This patient presented with severe dyspnea secondary to massive PEÂ and deep venous thrombosis (DVT) due to SARS-CoV2 infection following the administration of the J&J vaccine. Bilateral thrombus opacities and pulmonary emboli are consistent among COVID-19 patients by intravascular coagulation with increased prothrombin time and D-dimer concentration with a low platelet count. Adverse emboliÂ growths with increased D-dimer and thrombocytopenia strikes a similarity in recipients of the AstraZeneca vaccine due to vaccine-induced immune thrombotic thrombocytopenia (VITT). Administrative use of the J&J vaccine resumed in May 2021. The FDA's reassurance stemmed from their conclusive findings that the vaccine's benefits far outweigh these rare developments, which account for less than 0.01% of the total recipient population.Â Nevertheless, a further detailedÂ analysis must be conducted on the adverse thrombotic manifestations following adenoviral-based COVID-19 vaccinesÂ (J&J, AstraZeneca) compared to mRNA-based vaccines (Moderna, Pfizer) to assess causality with higher specificity.

Rapid whole-blood assay to detect SARS-CoV-2-specific memory T-cell immunity following a single dose of AstraZeneca ChAdOx1-S COVID-19 vaccine. OBJECTIVES: With the ongoing emergence of SARS-CoV-2 variants and potential to evade vaccine-induced neutralisation, understanding the magnitude and breadth of vaccine-induced T-cell immunity will be critical for the ongoing optimisation of vaccine approaches. Strategies that provide a rapid and easily translatable means of assessing virus-specific T-cell responses provide an opportunity to monitor the impact of vaccine

rollouts in the community. In this study, we assessed whether our recently developed SARS-CoV-2 whole-blood assay could be used effectively to analyse T-cell responses following vaccination. METHODS: Following a median of 15Â days after the first dose of the ChAdOx1-S (AstraZeneca(Â®)) vaccine, peripheral blood was isolated from 58 participants. Blood was incubated overnight with an overlapping set of spike protein peptides and assessed for cytokine production using a cytometric bead array. RESULTS: The majority of vaccine recipients (51/58) generated a T helper 1 response (IFN-Î³ and/or IL-2) following a single dose of ChAdOx1-S. The magnitude of the IFN-Î³ and IL-2 response strongly correlated in vaccine recipients. While the production of other cytokines was evident in individuals who did not generate IFN-Î³ and IL-2, they showed no correlation in magnitude, nor did we see a correlation between sex or age and the magnitude of the response. CONCLUSIONS: The whole-blood cytokine assay provides a rapid approach to assessing T-cell immunity against SARS-CoV-2 in vaccine recipients. While the majority of participants generated a robust SARS-CoV-2-specific T-cell response following their first dose, some did not, demonstrating the likely importance of the booster dose in improving T-cell immunity.

SARS-CoV-2 Antibodies in Breast Milk After Vaccination. BACKGROUND AND OBJECTIVES: Passive and active immunity transfer through human milk (HM) constitutes a key element in the infant's developing immunity. Certain infectious diseases and vaccines have been described to induce changes in the immune components of HM. METHODS: We conducted a prospective cohort single-institution study from February 2 to April 4, 2021. Women who reported to be breastfeeding at the time of their coronavirus disease 2019 (COVID-19) vaccination were invited to participate. Blood and milk samples were collected on day 14 after their second dose of the vaccine. Immunoglobulin G (IgG) antibodies against nucleocapsid protein as well as IgG, immunoglobulin M and immunoglobulin A (IgA) antibodies against the spike 1 protein receptor-binding domain against severe acute respiratory syndrome coronavirus 2 (anti-SARS-CoV-2 RBD-S1) were analyzed in both serum and HM samples. RESULTS: Most of the participants (ie, 94%) received the BNT162b2 messenger RNA COVID-19 vaccine. The mean serum concentration of anti-SARS-CoV-2 RBD-S-IgG antibodies in vaccinated individuals was 3379.6 Â± 1639.5 binding antibody units per mL. All vaccinated study participants had anti-SARS-CoV-2 RBD-S1-IgG, and 89% of them had anti-SARS-CoV-2 RBD-S-IgA in their milk. The antibody concentrations in the milk of mothers who were breastfeeding 24 months were significantly higher than in mothers with breastfeeding periods <24 months ($P < .001$). CONCLUSIONS: We found a clear association between COVID-19 vaccination and specific immunoglobulin concentrations in HM. This effect was more pronounced when lactation periods exceeded 23 months. The influence of the lactation period on immunoglobulins was specific and independent of other variables.

Functional disorders after COVID-19 vaccine fuel vaccination hesitancy.

mRNA COVID-19 vaccines do not increase the short-term risk of clinical relapses in multiple sclerosis.

Associations of BNT162b2 vaccination with SARS-CoV-2 infection and hospital admission and death with covid-19 in nursing homes and healthcare workers in Catalonia: prospective cohort study. OBJECTIVE: To determine associations of BNT162b2 vaccination with SARS-CoV-2 infection and hospital admission and death with covid-19 among nursing home residents, nursing home staff, and healthcare workers. DESIGN: Prospective cohort study. SETTING: Nursing homes and linked electronic medical record, test, and mortality data in Catalonia on 27 December 2020. PARTICIPANTS: 28â€‰456 nursing home residents, 26â€‰170 nursing home staff, and 61â€‰791 healthcare workers. MAIN OUTCOME MEASURES: Participants were followed until the earliest outcome (confirmed SARS-CoV-2 infection, hospital admission or death with covid-19) or 26 May 2021. Vaccination status was introduced as a time varying exposure, with a 14 day run-in after the first dose. Mixed effects Cox models were fitted to estimate hazard ratios with index month as a fixed effect and adjusted for confounders including sociodemographics, comorbidity, and previous

medicine use. RESULTS: Among the nursing home residents, SARS-CoV-2 infection was found in 2482, 411 were admitted to hospital with covid-19, and 450 died with covid-19 during the study period. In parallel, 1828 nursing home staff and 2968 healthcare workers were found to have SARS-CoV-2 infection, but fewer than five were admitted or died with covid-19. The adjusted hazard ratio for SARS-CoV-2 infection after two doses of vaccine was 0.09 (95% confidence interval 0.08 to 0.11) for nursing home residents, 0.20 (0.17 to 0.24) for nursing home staff, and 0.13 (0.11 to 0.16) for healthcare workers. Adjusted hazard ratios for hospital admission and mortality after two doses of vaccine were 0.05 (0.04 to 0.07) and 0.03 (0.02 to 0.04), respectively, for nursing home residents. Nursing home staff and healthcare workers recorded insufficient events for mortality analysis. CONCLUSIONS: Vaccination was associated with 80-91% reduction in SARS-CoV-2 infection in all three cohorts and greater reductions in hospital admissions and mortality among nursing home residents for up to five months. More data are needed on longer term effects of covid-19 vaccines.

Anti-Coronavirus Disease 2019 Vaccines: Need for Informed Consent. Vaccines are among some of the most efficacious medical and public health methods ever employed to contain a pandemic, in addition to providing protective and preventive measures. Evaluation of vaccineassociated adverse events through experimentation and empirical evidence is an integral part ofthoroughly assessing the safety of vaccines before authorization of their widespread use. History has highlighted the importance of continuous search for possible vaccine-related adverse effects and vaccine-induced immunogenicity long afterlicensure, suggesting that a primary concern with new vaccines is not only efficacy but also safety, particularly overthe long term. Many of the various anti-COVID-19 vaccines have used different types of technology, with some being introduced for the first time or rushed shortly into testing, bypassing animal experimentations. They have been adopted for use through emergency use authorizations, leading to a less than optimal collection of broad data on safety, immunogenicity, effectiveness, and time span of protection, as well as short follow-up of few months, despite many infectious disease experts arguing thatit takes 10 years to develop a vaccine. Given the valid concerns on well-recognized short-term and long-term safety issues, such as antibody-dependent enhancement and other processes like molecular mimicry and potential genomic transformation, the experimental nature of the vaccination process, the limited shortterm follow-up in the main trials, and the dismissal by law of pharma companies and health care providers from any medico-legal responsibilities, the application of an informed consent should become not only a necessity but also mandatory by law in accordance with all declarations on human rights. Such information should be provided to every potential recipient in the form of an official written digital consent prior to the registration for or the receipt of the vaccine.

Incidence of headache after COVID-19 vaccination in patients with history of headache: A cross-sectional study. BACKGROUND: Headache is an adverse event of coronavirus 2019 (COVID-19) vaccination. Whether patients with history of headache suffer more from vaccination-induced headaches is unknown. We aimed to uncover if headache patients develop more headaches after COVID-19 mRNA vaccination than healthy controls. METHODS: We performed a questionnaire survey for nursing staff in our hospital from April to May 2021. Based on baseline characteristics, we divided the participants into migraine, non-migrainous headache, and healthy control, and examined the occurrence and features of headache after COVID-19 vaccinations. RESULTS: We included 171 participants (15.2% migraine and 24.6% non-migrainous headache). Headache incidence after vaccinations was significantly higher in the migraine (69.2%) and non-migrainous headache (71.4%) groups than in the healthy control (37.9%) group. The incidence of headaches was significantly higher after the second dose compared to the first (45.6% vs. 20.5%). CONCLUSION: Migraineurs and non-migrainous headache participants developed more headaches compared to the healthy controls after COVID-19 vaccination.

Interactions of adenoviruses with platelets and coagulation and the vaccine-induced immune thrombotic thrombocytopenia syndrome. The COVID-19 pandemic has had a heavy impact on global health and economy and vaccination remains the primary way of controlling the infection. During the ongoing vaccination campaign some unexpected thrombotic events have emerged in subjects who had recently received the AstraZeneca (Vaxzevria) vaccine or the Johnson and Johnson (Janssen) vaccine, two adenovirus vector-based vaccines. Epidemiological studies confirm that the observed/expected ratio of these unusual thromboses is abnormally increased, especially in women in fertile age. The characteristics of this complication, with venous thromboses at unusual sites, most frequently in the cerebral vein sinuses but also in splanchnic vessels, often with multiple associated thromboses, thrombocytopenia, and sometimes disseminated intravascular coagulation, are unique and the time course and tumultuous evolution are suggestive of an acute immunological reaction. Indeed, plateletactivating anti-PF4 antibodies have been detected in a large proportion of the affected patients. Several data suggest that adenoviruses may interact with platelets, the endothelium and the blood coagulation system. Here we review interactions between adenoviral vectors and the hemostatic system that are of possible relevance in vaccine-associated thrombotic thrombocytopenia syndrome. We systematically analyze the clinical data on the reported thrombotic complications of adenovirus-based therapeutics and discuss all the current hypotheses on the mechanisms triggering this novel syndrome. Although, considering current evidence, the benefit of vaccination clearly outweighs the potential risks, it is of paramount importance to fully unravel the mechanisms leading to vaccineassociated thrombotic thrombocytopenia syndrome and to identify prognostic factors through further research.

Hemophagocytic lymphohistiocytosis following ChAdOx1 nCov-19 vaccination.

Intravenous Injection of Coronavirus Disease 2019 (COVID-19) mRNA Vaccine Can Induce Acute Myopericarditis in Mouse Model. BACKGROUND: Post-vaccination myopericarditis is reported after immunization with coronavirus disease 2019 (COVID-19) messenger RNA (mRNA) vaccines. The effect of inadvertent intravenous injection of this vaccine on the heart is unknown. METHODS: We compared the clinical manifestations, histopathological changes, tissue mRNA expression, and serum levels of cytokine/chemokine and troponin in Balb/c mice at different time points after intravenous (IV) or intramuscular (IM) vaccine injection with normal saline (NS) control. RESULTS: Although significant weight loss and higher serum cytokine/chemokine levels were found in IM group at 1-2 days post-injection (dpi), only IV group developed histopathological changes of myopericarditis as evidenced by cardiomyocyte degeneration, apoptosis, and necrosis with adjacent inflammatory cell infiltration and calcific deposits on visceral pericardium, although evidence of coronary artery or other cardiac pathologies was absent. Serum troponin level was significantly higher in IV group. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike antigen expression by immunostaining was occasionally found in infiltrating immune cells of the heart or injection site, in cardiomyocytes and intracardiac vascular endothelial cells, but not skeletal myocytes. The histological changes of myopericarditis after the first IV-priming dose persisted for 2 weeks and were markedly aggravated by a second IM- or IV-booster dose. Cardiac tissue mRNA expression of interleukin (IL)-1Î², interferon (IFN)-Î², IL-6, and tumor necrosis factor (TNF)-Î± increased significantly from 1 dpi to 2 dpi in the IV group but not the IM group, compatible with presence of myopericarditis in the IV group. Ballooning degeneration of hepatocytes was consistently found in the IV group. All other organs appeared normal. CONCLUSIONS: This study provided in vivo evidence that inadvertent intravenous injection of COVID-19 mRNA vaccines may induce myopericarditis. Brief withdrawal of syringe plunger to exclude blood aspiration may be one possible way to reduce such risk.

Post COVID-19 vaccine adenopathy: first Brazilian report.

Breast implant seroma: A SARS-CoV-2 mRNA vaccine side effect. Fluid collection surrounding breast implants, called seroma, is a frequent issue that has diverse etiologies. We describe a 48-year-old woman with an acute onset of bilateral breast swelling occurring 5â€‰years after aesthetic surgery and 10â€‰days after a second SARS-CoV-2 mRNA vaccine dose. At breast ultrasound, we found an abundant bilateral peri-implant seroma. Our patient noticed symptom improvement 48â€‰h after nonsteroidal anti-inflammatory drug treatment, complete disappearance of symptoms after 10â€‰days with seroma disappearance documented by ultrasound. We hypothesized a breast implant seroma as post-SARS-CoV-2 mRNA vaccine side effect, as different other diagnosis had been excluded.
Immune complexes, innate immunity, and NETosis in ChAdOx1 vaccine-induced thrombocytopenia. AIMS: We recently reported five cases of vaccine-induced immune thrombotic thrombocytopenia (VITT) 7-10â€‰days after receiving the first dose of the ChAdOx1 nCoV-19 adenoviral vector vaccine against corona virus disease 2019 (COVID-19). We aimed to investigate the pathogenic immunological responses operating in these patients. METHODS AND RESULTS: We assessed circulating inflammatory markers by immune assays and immune cell phenotyping by flow cytometry analyses and performed immunoprecipitation with anti-platelet factor (PF)4 antibody in plasma samples followed by mass spectrometry from all five patients. A thrombus was retrieved from the sinus sagittal superior of one patient and analysed by immunohistochemistry and flow cytometry. Precipitated immune complexes revealed multiple innate immune pathway triggers for platelet and leucocyte activation. Plasma contained increased levels of innate immune response cytokines and markers of systemic inflammation, extensive degranulation of neutrophils, and tissue and endothelial damage. Blood analyses showed activation of neutrophils and increased levels of circulating H3Cit, dsDNA, and myeloperoxidase-DNA complex. The thrombus had extensive infiltration of neutrophils, formation of neutrophil extracellular traps (NETs), and IgG deposits. CONCLUSIONS: The results show that anti-PF4/polyanion IgG-mediated thrombus formation in VITT patients is accompanied by a massive innate immune activation and particularly the fulminant activation of neutrophils including NETosis. These results provide novel data on the immune response in this rare adenoviral vector-induced VITT.
Survey of Adverse Events After The First Dose of The ChAdOx1 nCoV-19 Vaccine: A Single-Center Experience in Korea. Vaccination is an important strategy for controlling the coronavirus disease 2019 (COVID-19) pandemic. We conducted a web-based cross-sectional survey based on Google Forms to collect data on adverse events (AEs) after the first dose of the ChAdOx1 nCoV-19 vaccine for healthcare workers (HCWs). Among the 1,676 vaccinated HCWs, 59.5% (998/1,676) responded to the survey. In total, 809 (81.1%) respondents reported experiencing AEs. There were no serious AEs, such as anaphylaxis. The most common AE was pain at the injection site (76.2%), followed by fatigue (75.9%), myalgia (74.9%), and fever (58.4%). HCWs in the younger age group experienced significantly more AEs than in the older age group.
Thrombotic thrombocytopenic purpura temporally associated with BNT162b2 vaccination in an adolescent successfully treated with caplacizumab.
Inconsistent Safety Outcome Reporting in Randomized Clinical Trials of COVID-19 Vaccines Complicates Informed Medical Decisions.
Clinical characteristics of headache after vaccination against COVID-19 (coronavirus SARS-CoV-2) with the BNT162b2 mRNA vaccine: a multicentre observational cohort study. The novel coronavirus SARS-CoV-2 causes the infectious disease COVID-19. Newly developed mRNA vaccines can prevent the spread of the virus. Headache is the most common neurological symptom in over 50% of those vaccinated. Detailed information about the clinical characteristics of this form of headache has not yet been described. The aim of the study is to examine in detail the clinical characteristics of

headaches occurring after vaccination against COVID-19 with the BNT162b2 mRNA COVID-19 vaccine for the first time. In a multicentre observational cohort study, data on the clinical features and corresponding variables were recorded using a standardized online questionnaire. The questionnaire was circulated to 12â€‰000 residential care homes of the elderly as well as tertiary university hospitals in Germany and the United Arab Emirates. The primary outcomes of this study are the clinical features of headache after vaccination. Comorbidities, treatment with medication and sociodemographic variables are also analysed. A total of 2349 participants reported headaches after vaccination with the BNT162b2 mRNA COVID-19 vaccine. Headaches occur an average of 18.0â€‰Â±â€‰27.0â€‰h after vaccination and last an average duration of 14.2â€‰Â±â€‰21.3â€‰h. Only 9.7% of those affected also report headaches resulting from previous vaccinations. In 66.6% of the participants, headache occurs as a single episode. A bilateral location is indicated by 73.1% of the participants. This is most often found on the forehead (38.0%) and temples (32.1%). A pressing pain character is indicated by 49.2% and 40.7% report a dull pain character. The pain intensity is most often moderate (46.2%), severe (32.1%) or very severe (8.2%). The most common accompanying symptoms are fatigue (38.8%), exhaustion (25.7%) and muscle pain (23.4%). Headaches after COVID-19 vaccination show an extensive complex of symptoms. The constellation of accompanying symptoms together with the temporal and spatial headache characteristics delimit a distinctive headache phenotype.
Breakthrough cases of COVID-19 in vaccinated United States Veterans with spinal cord injuries and disorders.
The associations of geographic location and perceived risk of infection with the intentions to get vaccinated against COVID-19 in China. BACKGROUND: Vaccines are a critical tool against coronavirus disease 2019 (COVID-19) pandemic, yet little is known regarding the associations of geographic location and perceived risk with the intentions to get vaccinated against COVID-19 in China. METHODS: An on-site survey of adults aged 18 or older (n = 7261) was conducted from November to December, 2020 in China, and this survey selected six provinces based on the geographic location. RESULTS: In the total sample, 82.5% reported that they would intend to get vaccinated against COVID-19. Compared with Hubei province, respondents' intentions to get vaccinated decreased by 70% in Zhejiang, 61% in Guangdong, 87% in Gansu, and 71% in Jilin, respectively. However, within Hubei province, compared with Wuhan city, respondents' intentions to get vaccinated in other cities were not significantly different. Respondents with higher perceived risk of infection were associated with increased odds of intentions to get vaccinated against COVID-19. CONCLUSION: Our study identified priority geographic regions that need to pay attention on the vaccination campaign and help design effective immunization strategies to increase the vaccine uptake against COVID-19. More attention should be paid to adults residing farther from the epicenter of the outbreak and having lower perceived risk of infection.
Buyer beware: The risks of donor-derived vaccine-induced thrombosis and thrombocytopenia. The authors discuss two Letters to the Editor describing outcomes of transplantation using organs from donors who died with COVID-19 vaccine-induced thrombosis and thrombocytopenia and outline an evaluation algorithm for such donors and a management algorithm for recipients. See Greenhall et al. (page 4095) and Loupy et al. (page 4098).
Point-of-Care Ultrasound Is a Valuable Modality During Mass COVID-19 Vaccination Campaigns. Coronavirus disease 2019 has become a widespread public health crisis across the globe, requiring multiple approaches to containment, treatment, and prevention. Vaccines are an important tool to prevent morbidity and mortality from this devastating virus. Ensuring direct administration of vaccines into target tissue helps provide an optimal immune response while decreasing unintended adverse effects. Point-of-care ultrasound can better assist clinicians to determine appropriate needle

length and penetration level especially in special populations. Examples include patients who are obese, pregnant, or with refractory lymphedema, and those living in areas where needle supply is unstable or insufficient.
Acute Thyroiditis and Bilateral Optic Neuritis following SARS-CoV-2 Vaccination with CoronaVac: A Case Report. PURPOSE: To describe a case of acute thyroiditis and bilateral optic neuritis associated with SARS-CoV-2 vaccination. METHODS: A single case report from a tertiary referral center. RESULTS: The patient described in the following case report developed acute thyroiditis and bilateral optic neuritis following SARS-CoV-2 vaccination. The patient underwent pulse therapy followed by oral tapering corticosteroid therapy with an improvement of the bilateral disc swelling and the visual field, and recovery of thyroid-stimulating hormone to the normal limits. CONCLUSION: Although the association between immunization and the onset of demyelinating manifestations of the central nervous system is well documented, this is the first reported case of bilateral optic neuritis and acute thyroiditis and subsequent to administration of vaccination against SARS-CoV-2.
Parsonage-Turner Syndrome Following COVID-19 Vaccination: MR Neurography. Vaccination is one of the several known triggers of Parsonage-Turner syndrome (PTS). This case series describes two individuals with clinical presentations of PTS whose symptoms began 13 hours and 18 days following receipt of the Pfizer-BioNTech BNT162b2 and Moderna mRNA-1273 COVID-19 vaccine, respectively. The diagnosis of PTS was confirmed by using both electrodiagnostic testing and 3.0-T MR neurography. Although research is needed to understand the association between PTS and COVID-19 vaccination, MR neurography may be used to help confirm suspected cases of PTS as COVID-19 vaccines continue to be distributed worldwide.
Imaging and Hematologic Findings in Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 (AstraZeneca) Vaccination. This case series reports six patients (four men and two women; median age, 38 years; interquartile range, 26-48 years) who presented with vaccine-induced thrombocytopenia and thrombosis beginning 3-26 days after receiving the first dose of the ChAdOx1 nCoV-19 (AstraZeneca) vaccine for COVID-19. The patients were admitted to a general hospital between 9 and 31 days after the first dose. All patients had strongly detected antiplatelet factor 4 antibodies and severe thrombosis. Laboratory features included thrombocytopenia and elevated d-dimer levels. Thrombotic events were predominantly venous; two patients had arterial or mixed arterial and venous thrombosis. All patients recovered after receiving intravenous immunoglobulin and nonheparin-based anticoagulation. Â© RSNA, 2021 An earlier incorrect version appeared online. This article was corrected on August 18, 2021.
Cytotoxic Lesion of the Corpus Callosum (CLOCCs) after SARS-CoV-2 mRNA Vaccination.
Intracerebral Hemorrhage due to Thrombosis with Thrombocytopenia Syndrome after Vaccination against COVID-19: the First Fatal Case in Korea. Vaccination with an adenoviral vector vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) can result in the rare development of thrombosis with thrombocytopenia mediated by platelet-activating antibodies against platelet factor 4 (PF4). This is a life-threating condition that may be accompanied by bleeding due to thrombocytopenia with thrombosis of the cerebral venous sinus or splanchnic vein. Herein, we describe the first fatal case of thrombosis with thrombocytopenia syndrome in Korea, presenting with intracranial hemorrhage caused by cerebral venous sinus thrombosis. A 33-year-old Korean man received the first dose of the ChAdOx1 nCoV-19 vaccination. He developed severe headache with vomiting 9 days after the vaccination. Twelve days after vaccination, he was admitted to the hospital with neurological symptoms and was diagnosed with cerebral venous sinus thrombosis, which was accompanied by intracranial hemorrhage. Thrombocytopenia and D-dimer elevation were observed, and the result of the PF4 enzyme-linked immunosorbent assay antibody test was reported to be strongly positive. Despite intensive treatment, including intravenous immunoglobulin injection and

endovascular mechanical thrombectomy, the patient died 19 days after vaccination. Physicians need to be aware of thrombosis with thrombocytopenia syndrome (TTS) in adenoviral vector-vaccinated patients. Endovascular mechanical thrombectomy might be a useful therapeutic option for the treatment of TTS with cerebral venous sinus thrombosis.
Epidemiology and Clinical Features of Myocarditis/Pericarditis before the Introduction of mRNA COVID-19 Vaccine in Korean Children: a Multicenter Study. BACKGROUND: Korean health authority plans to vaccinate adolescents against coronavirus disease 2019 (COVID-19) starting high school seniors during the summer vacation of 2021. However, the myocarditis/pericarditis following COVID-19 vaccine has been reported recently in adolescents and young adults. This study was performed to answer the urgent questions about the basic epidemiology and clinical course of myocarditis/pericarditis in hospitalized patients prior to the introduction of COVID-19 vaccines in pediatric population. METHODS: A retrospective medical record analysis including frequency, clinical characteristics, etiology and outcome of myocarditis/pericarditis was conducted in 17 years and younger patients who were hospitalized in two referral hospitals in Korea between 2010 and 2019. RESULTS: Total 142 patients with myocarditis (n = 119) and/or pericarditis (n = 23) were identified. Median age was 5.4 years (interquartile range, 0.6-12.9 years; range, 11 days-17.8 years), and male was 61%. In adolescents aged 12-17 years, the male to female ratio was 3.2. Myocarditis/pericarditis occurred 0.70 per 1,000 in-patients during the study period: 0.96 (< 1 year), 0.50 (1-5 years), 0.67 (6-11 years) and 1.22 (12-17 years) per 1,000 in-patients, respectively. There was an increasing tendency for the annual frequency from 0.34 in 2010 to 1.25 per 1,000 in-patients in 2019 (P = 0.021). Among the 56 (40%) proven pathogens at admission, Mycoplasma pneumoniae (n = 11, 8%) and enterovirus (n = 10, 7%) were most common. Of the 142 patients, 99 (70%) required pediatric intensive care unit care and 10 (7%) received heart transplantation. In addition, 61 patients (61/131, 47%) without heart medication at admission needed heart medication when they were discharged. Eleven (7.7%) patients died, of which five patients were previously healthy. The median age of deceased patients was lower than the survival group (0.8 vs. 6.3 years, P = 0.014). CONCLUSION: The frequency of myocarditis/pericarditis was highest among male adolescent in-patients; however, the outcome was favorable in this group without any mortality.
Cardiac Imaging of Acute Myocarditis Following COVID-19 mRNA Vaccination. Increasing rates of coronavirus disease 2019 (COVID-19) vaccination coverage will result in more vaccine-related side effects, including acute myocarditis. In Korea, we present a 24-year-old male with acute myocarditis following COVID-19 vaccination (BNT162b2). His chest pain developed the day after vaccination and cardiac biomarkers were elevated. Echocardiography showed minimal pericardial effusion but normal myocardial contractility. Electrocardiography revealed diffuse ST elevation in lead II, and V2-5. Cardiac magnetic resonance images showed the high signal intensity of T2- short tau inversion recovery image, the high value of T2 mapping sequence, and late gadolinium enhancement in basal inferior and inferolateral wall. It was presumed that COVID-19 mRNA vaccination was probably responsible for acute myocarditis. Clinical course of the patient was favorable and he was discharged without any adverse event.
Two cases of mild systemic adverse skin eruption after coronavirus disease 2019 vaccination.
Activation of circulating platelets in vaccine-induced thrombotic thrombocytopenia and its reversal by intravenous immunoglobulin.
Safety and humoral responses to BNT162b2 mRNA vaccination of SARS-CoV-2 previously infected and naive populations. Since COVID-19 risk of reinfection is of great concern, the safety and efficacy of the mRNA-based vaccines in previously infected populations should be assessed. We studied 78 individuals previously infected with SARS-CoV-19, who received a single dose of BNT162b2 mRNA COVID-19 vaccine, and 1:2 ratio matched infection-naÃ¯ve cohort who received two injections. The

evaluation procedure included symptom monitoring, and serological tests. Among the post-infected population, the median IgG-S response after the first vaccine dose was 3.35 AU, compared to 2.38 AU after the second vaccine injection in the infection naive group. A strong correlation was demonstrated between IgG-S level before vaccination, and the corresponding responses after a single vaccine dose (râ€‰=â€‰0.8, pâ€‰<â€‰0.001) in the post infected population. Short-term severe symptoms that required medical attention were found in 6.8% among the post-infected individuals, while none were found in the infection naÃ¯ve population. Our data suggest that a single vaccine dose is sufficient to induce an intense immune response in post-infected population regardless of seropositivity. Although some short-term safety issues were observed compared to the infection naÃ¯ve population, a single dose regimen can be considered safe in post-infected populations.
Extensive thrombosis after COVID-19 vaccine: cause or coincidence? A 62-year-old Caucasian female patient presented with abdominal pain, vomiting and fever 1â€‰day after administration of COVID-19 vaccine. Bloodwork revealed anaemia and thrombocytosis. Abdominal CT angiography showed a mural thrombus at the emergence of the coeliac trunk, hepatic and splenic arteries, and extensive thrombosis of the superior and inferior mesenteric veins, splenic and portal veins, and the inferior vena cava, extending to the left common iliac vein. The spleen displayed extensive areas of infarction. Aetiological investigation included assessment of congenital coagulation disorders and acquired causes with no relevant findings. Administration of COVID-19 vaccine was considered a possible cause of the extensive multifocal thrombosis. After reviewing relevant literature, it was considered that other causes of this event should be further investigated. Thrombosis associated with COVID-19 vaccine is rare and an aetiological relationship should only be considered in the appropriate context and after investigation of other, more frequent, causes.
Managing the Risk of Delayed Breast Cancer Screening Versus COVID-19 Vaccination Associated Axillary Lymphadenopathy.
COVID-19 mRNA vaccines and immune-related adverse events in cancer patients treated with immune checkpoint inhibitors.
Acute myocarditis after SARS-CoV-2 vaccination in a 24-year-old man.
Association of total and neutralizing SARS-CoV-2 spike -receptor binding domain antibodies with epidemiological and clinical characteristics after immunization with the 1(st) and 2(nd) doses of the BNT162b2 vaccine. BACKGROUND: Data regarding the association of antibody levels elicited after immunization with the BNT162b2 mRNA COVID-19 vaccine with epidemiological and clinical parameters are limited. METHODS: We prospectively measured the total (TAbs-RBD) and the neutralizing antibodies (NAbs-RBD) against the receptor binding domain (RBD) of SARS-CoV-2 spike protein in a cohort of 268 Healthcare workers before immunization, 20â€¯days after the 1(st) dose and 30â€¯days after the 2(nd) dose of the BNT162b2 vaccine. A statistical analysis for possible association of antibodies' levels with epidemiological and clinical parameters was performed. RESULTS: The mean age (Â±SD) of the participants was 45.45â€¯years (Â±11.93) (range: 24-70â€¯years) and 211 (79.9%) were females. Statistically significant differences were detected regarding both TAbs-RBD and NAbs-RBD between the first and second doses of the vaccine (Pâ€¯<â€¯0.001). The median (IQR) percentage (%) of NAbs-RBD after the 1(st) dose was 51.07% (31.60%) and after the 2(nd) dose 95.31% (3.70%) (Pâ€¯<â€¯0.001). The correlation between the TAbs-RBD and NAbs-RBD was after the 1(st) dose, Spearman's, rho: 0.861 (Pâ€¯<â€¯0.001) and after the 2(nd) dose rho: 0.989 (Pâ€¯<â€¯0.001). Twenty days after the 1(st) dose, 56/264 (21.2%) of the participants had low levels of NAbs-RBD, while one month after the 2(nd) dose all of them had protective levels of NAbs-RBD. After the 2(nd) vaccine dose, a statistically significant negative association of TAbs-RBD was detected for age (Pâ€¯<â€¯0.001), smoking (Pâ€¯=â€¯0.011), and immunosuppressive medications (Pâ€¯<â€¯0.001), while a positive association was detected for BMI

(P =â€¯0.004) and systemic adverse events after immunization (Pâ€¯=â€¯0.001). CONCLUSION: A significant correlation of TAbs-RBD and NAbs-RBD was detected after both vaccine doses. Older age, smoking, and immunosuppressive medications negatively affected the final antibody level after SARS-CoV-2 immunization. Our findings emphasize the significance of the 2(nd) vaccine dose especially in the older age groups.

COVID-19 Vaccination for Endocrine Patients: A Position Statement from the Korean Endocrine Society. Since the first outbreak of coronavirus disease 2019 (COVID-19), ongoing efforts have been made to discover an efficacious vaccine against COVID-19 to combat the pandemic. In most countries, both mRNA and DNA vaccines have been administered, and their side effects have also been reported. The clinical course of COVID-19 and the effects of vaccination against COVID-19 are both influenced by patients' health status and involve a systemic physiological response. In view of the systemic function of endocrine hormones, endocrine disorders themselves and the therapeutics used to treat them can influence the outcomes of vaccination for COVID-19. However, there are very limited data to support the development of clinical guidelines for patients with specific medical backgrounds based on large clinical trials. In the current severe circumstances of the COVID-19 pandemic, position statements made by clinical specialists are essential to provide appropriate recommendations based on both medical evidence and clinical experiences. As endocrinologists, we would like to present the medical background of COVID-19 vaccination, as well as precautions to prevent the side effects of COVID-19 vaccination in patients with specific endocrine disorders, including adrenal insufficiency, diabetes mellitus, osteoporosis, autoimmune thyroid disease, hypogonadism, and pituitary disorders.

Controversy surrounding the Sputnik V vaccine. The Sputnik V COVID-19 vaccine is a member of the so-called vector vaccines and uses two different vectors (Ad26 priming and Ad5 boost) to reduce the risk of a reduction in the effectiveness of the vaccination. Real life data indicate an efficacy of the vaccine above 97%. Low cost and no need for ultra-cold storage temperature temperatures are other pluses of the Sputnik V vaccine. However, there are also several important shortcomings that must be considered such as the possible reduction of its immunogenicity in the presence of very high Ad5 neutralizing antibody titres and the decrease with age of the antibody titres neutralizing the virus. Furthermore, there is emerging documentation that Sputnik V has a reduced neutralizing capacity against the Beta variant and all variants with the spike protein carrying the E484K substitution. Nevertheless, due to its characteristics, Sputnik V could be another useful means of satisfying the need for mass vaccination. However, it is imperative to document the efficacy and safety of the Sputnik V vaccine in individuals with high pre-existing anti-Ad26 and Ad5-neutralizing antibody titres and in those under the age of 18 or older than 60 years and be certain that Sputnik V does not cause the rare development of immune thrombotic thrombocytopenia. It is hoped that the now widespread use of this vaccine will generate a large pragmatic real-world study with data accessible to anyone interested in verifying them.

Vaccinating children: fairness and childism.

Symmetrical drug-related intertriginous and flexural exanthema like eruption associated with COVID-19 vaccination. This is a case of symmetrical drug-related intertriginous and flexural exanthema-like eruption following ChAdOx1 nCoV-19 (AstraZeneca-Oxford) vaccination. Investigations, including repeated skin swabs, ruled out an infectious cause. He was subsequently treated with oral prednisolone, which led to a resolution of his symptoms.

De novo generalized pustular psoriasis following Oxford-AstraZeneca COVID-19 vaccine. We present an interesting and novel case of a de novo generalized pustular psoriasis following administration of first dose of Oxford-AstraZeneca COVID-19 vaccine in a patient with no pre-existing psoriasis or any previous dermatological issue.

Safety of administration of BNT162b2 mRNA (Pfizer-BioNTech) COVID-19 vaccine in youths and young adults with a history of acute lymphoblastic leukemia and allergy to PEG-asparaginase. Vaccinationis a critical tool in the prevention of COVID-19 infection for individuals and for communities. The mRNA vaccines contain polyethylene glycol (PEG) as a stabilizer. Currently, in North America, only the BNT162b2 (Pfizer-BioNTech) mRNA vaccine is approved for individuals aged 12-17. Most patients treated with contemporary regimens for acute lymphoblastic leukemia receive PEG-asparaginase (PEG-ASNase) and 10%-30% will develop allergic reactions. Optimizing access and safety for vaccine administration for these patients is critical. This report describes a process developed to support COVID vaccination in a cohort of adolescents and young adults with a history of PEG-ASNase allergy.

Pandemic COVID-19 caused by SARS-CoV-2: genetic structure, vaccination, and therapeutic approaches. We give a summary of SARS-genetic CoV-2's structure and evolution, as well as current attempts to develop efficient vaccine and treatment methods for SARS-CoV-2 infection, in this article. Most therapeutic strategies are based on repurposing of existing therapeutic agents used against various virus infections and focused mainly on inhibition of the virus replication cycle, enhancement of innate immunity, and alleviation of CRS caused by COVID-19. Currently, more than 100 clinical trials on COVID-19 aim to provide robust evidence on the efficacy of the currently available anti-SARS-CoV-2 antiviral substances, such as the nucleotide analogue remdesivir, the antimalarial drug chloroquine, and drugs directed against docking of SARS-CoV-2 to the membrane-associated angiotensin-converting enzyme 2 (ACE2) such as transmembrane protease serine 2 (TMPRSS2). The current vaccination campaign is ongoing worldwide using different types of vaccines such as Pfizer-BioNTech and Moderna, Johnson & Johnson, Oxford-AstraZeneca, Novavax, and others with efficacy ranging from 72-95%. In March 2021 Germany limited the use of the Oxford-AstraZeneca COVID-19 vaccine to people 60 years of age and older due to concerns that it may be causing blood clots. Further study and more data are needed to confirm the safety of different available vaccines.

Interpretation of vaccine associated neurological adverse events: a methodological and historical review. As a result of significant recent scientific investment, the range of vaccines available for COVID-19 prevention continues to expand and uptake is increasing globally. Although initial trial safety data have been generally reassuring, a number of adverse events, including vaccine induced thrombosis and thrombocytopenia (VITT), have come to light which have the potential to undermine the success of the vaccination program. However, it can be difficult to interpret available data and put these into context and to communicate this effectively. In this review, we discuss contemporary methodologies employed to investigate possible associations between vaccination and adverse neurological outcomes and why determining causality can be challenging. We demonstrate these issues by discussing relevant historical exemplars and explore the relevance for the current pandemic and vaccination program. We also discuss challenges in understanding and communicating such risks to clinicians and the general population within the context of the 'infodemic' facilitated by the Internet and other media.

Caution in Interpreting Facial Paralysis Data to Understand COVID-19 Vaccination Risks.

Caution in Interpreting Facial Paralysis Data to Understand COVID-19 Vaccination Risks-Reply.

Subcutaneous injection of mRNA vaccines against severe acute respiratory syndrome coronavirus 2: an option for severe bleeding disorders or anticoagulated patients?

Herpes Zoster Following COVID-19 Vaccination. Vaccination is an important intervention in preventing the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Messenger RNA (mRNA) vaccines from Pfizer™ and Moderna™ are the first to market in the United States, and while cutaneous adverse events have been reported in clinical trials for both of these

vaccines, they have not been well characterized. Here we report a case of a patient who developed herpes zoster after receiving the Moderna™ COVID-19 vaccine. Dermatologists should familiarize themselves with this and other potential cutaneous adverse events associated with COVID-19 vaccination. J Drugs Dermatol. 2021;20(8):898-900. doi:10.36849/JDD.6146.

Analysis of COVID-19 vaccines: Types, thoughts, and application. OBJECTIVE: To deal with COVID-19, various countries have made many efforts, including the research and development of vaccines. The purpose of this manuscript was to summarize the development, application, and problems of COVID-19 vaccines. METHODS: This article reviewed the existing literature to see the development of the COVID-19 vaccine. RESULTS: We found that different types of vaccines had their own advantages and disadvantages. At the same time, the side effects of the vaccine, the dose of vaccination, the evaluation of the efficacy, and the application of the vaccine were all things worth studying. CONCLUSION: The successful development of the COVID-19 vaccine concerns almost all countries and people in the world. We must do an excellent job of researching the immunogenicity and immune reactivity of the vaccines. We hope this review can help colleagues at home and abroad.

Type I Interferon Signature in Chilblains Following SARS-CoV-2 mRNA Vaccine: A Case Report.

Myocarditis following mRNA vaccination against SARS-CoV-2, a case series. INTRODUCTION: mRNA COVID-19 vaccines have emerged as a new form of vaccination that has proven to be highly safe and effective against COVID-19 vaccination. Rare adverse events including myocarditis have been reported in the literature. METHODS: Data were gathered from the electronic medical record of four patients personally treated by the authors. RESULTS: Four patients, ages 20 to 30, presented with myocarditis characterized by chest pain, elevations in troponin-I and C-reactive protein, and negative viral serologies two to four days following mRNA vaccine administration. One had a cardiac MRI showing delayed gadolinium enhancement in a subpericardial pattern. All experienced symptom resolution by the following day, and the two who have returned for follow-up had normal troponin-I and CRP values. DISCUSSION: Along with previously reported instances, these cases raise suspicion for a possible link between mRNA vaccines and myocarditis.

Antibody development after COVID-19 vaccination in patients with autoimmune diseases in the Netherlands: a substudy of data from two prospective cohort studies. BACKGROUND: Data are scarce on immunogenicity of COVID-19 vaccines in patients with autoimmune diseases, who are often treated with immunosuppressive drugs. We aimed to investigate the effect of different immunosuppressive drugs on antibody development after COVID-19 vaccination in patients with autoimmune diseases. METHODS: In this study, we used serum samples collected from patients with autoimmune diseases and healthy controls who were included in two ongoing prospective cohort studies in the Netherlands. Participants were eligible for inclusion in this substudy if they had been vaccinated with any COVID-19 vaccine via the Dutch national vaccine programme, which at the time was prioritising vaccination of older individuals. Samples were collected after the first or second COVID-19 vaccination. No serial samples were collected. Seroconversion rates and IgG antibody titres against the receptor-binding domain of the SARS-CoV-2 spike protein were measured. Logistic and linear regression analyses were used to investigate the association between medication use at the time of vaccination and at least until sampling, seroconversion rates, and IgG antibody titres. The studies from which data were collected are registered on the Netherlands Trial Register, Trial ID NL8513, and ClinicalTrials.org, NCT04498286. FINDINGS: Between April 26, 2020, and March 1, 2021, 3682 patients with rheumatic diseases, 546 patients with multiple sclerosis, and 1147 healthy controls were recruited to participate in the two prospective cohort studies. Samples were collected from patients with autoimmune diseases (n=632) and healthy controls (n=289) after their first (507 patients and 239 controls) or second (125 patients and 50 controls) COVID-19 vaccination. The mean age of both patients and controls was 63 years (SD 11), and 423 (67%) of 632 patients with

autoimmune diseases and 195 (67%) of 289 controls were female. Among participants without previous SARS-CoV-2 infection, seroconversion after first vaccination were significantly lower in patients than in controls (210 [49%] of 432 patients vs 154 [73%] of 210 controls; adjusted odds ratio 0Â·33 [95% CI 0Â·23-0Â·48]; p<0Â·0001), mainly due to lower seroconversion in patients treated with methotrexate or anti-CD20 therapies. After the second vaccination, seroconversion exceeded 80% in all patient treatment subgroups, except among those treated with anti-CD20 therapies (three [43%] of seven patients). We observed no difference in seroconversion and IgG antibody titres between patients with a previous SARS-CoV-2 infection who had received a single vaccine dose (72 [96%] of 75 patients, median IgG titre 127 AU/mL [IQR 27-300]) and patients without a previous SARS-CoV-2 infection who had received two vaccine doses (97 [92%] of 106 patients, median IgG titre 49 AU/mL [17-134]). INTERPRETATION: Our data suggest that seroconversion after a first COVID-19 vaccination is delayed in older patients on specific immunosuppressive drugs, but that second or repeated exposure to SARS-CoV-2, either via infection or vaccination, improves humoral immunity in patients treated with immunosuppressive drugs. Therefore, delayed second dosing of COVID-19 vaccines should be avoided in patients receiving immunosuppressive drugs. Future studies that include younger patients need to be done to confirm the generalisability of our results. FUNDING: ZonMw, Reade Foundation, and MS Center Amsterdam.

Personal and vaccination history as factors associated with SARS-CoV-2 infection. BACKGROUND AND OBJECTIVE: SARS-CoV-2 has been and is a major global Public Health challenge. Since the beginning of the pandemic, different comorbidities have been postulated and associated with spectra of increased severity and mortality. The objectives of this research are: 1) to analyse the factors associated with SARS-CoV-2 infection (COVID-19) in a health area in northern Spain; 2) to understand the possible role of influenza vaccination and pneumococcal vaccination in the development of COVID-19. MATERIALS AND METHOD: A test-negative case-control study was conducted. Variables related to personal and vaccination history were considered. Although the epidemiological definition of the case varied over time, the reference definition was that corresponding to 31/01/2020 in Spain. A bivariate and multivariate analysis was performed. RESULTS: The sample included 188 patients, of which 63 were cases and 125 controls. The results show that obesity increases the risk 2.4-fold of suffering this infection (IC 95% 1,301-4,521) and ARA-2 increases it 2.2-fold (95% CI 1,256-6,982). On the other hand, anti-pneumococcal vaccination of 13 serotypes showed results close to statistical significance (ORÂ =Â 0.4; 95% CI 0.170-1,006). CONCLUSION: Obesity and the use of ARA-2 increases the risk of COVID-19. Scientific knowledge about factors associated with COVID-19 should be expanded. The authors consider that the present research raises the need further investigate the role of vaccines in this infection and their possible heterologous properties.

Discordant Virus-Specific Antibody Levels, Antibody Neutralization Capacity, and T-cell Responses Following 3 Doses of SARS-CoV-2 Vaccination in a Patient With Connective Tissue Disease. We report a patient with connective tissue disease who developed modest severe acute respiratory syndrome coronavirus 2 receptor binding domain-specific antibody levels and a lack of neutralization capacity, despite having received 3 mRNA coronavirus disease 2019 vaccines and holding anti-B-cell therapy forâ€…>7 months before vaccination. The patient developed virus-specific T-cell responses.

Kikuchi-Fujimoto disease following SARS CoV2 vaccination: Case report. Kikuchi's disease (KD) also known as Kikuchi-Fujimoto disease (KFD), or histiocytic necrotizing lymphadenitis was first described in 1972 independently by Kikuchi and Fujimoto et al. It is a benign self-limited condition of unknown etiology which usually presents with cervical lymphadenopathy or fever of unknown origin. The diagnosis of KFD is based on histopathologic examination of the involved lymph node, showing the presence of well-defined necrosis without granulocytic cells. There is no special treatment for KFD. However non-steroidal anti-inflammatory drugs or corticosteroids are required occasionally to

control the associated systemic manifestations. The outcome of the disease is usually favorable with resolution of symptoms in most cases within one to four months. We report a case of Kikuchi-Fujimoto disease that occurred in a young Qatari male patient 10 days following receiving the first dose of BNT162b2 vaccine. Diagnosis was established by lymph node biopsy and recovery was complete after 10 days.

Myocardial infarction post COVID-19 vaccine - coincidence, Kounis syndrome or other explanation - time will tell. A case of ST elevation myocardial infarction reported post Coronavirus disease 2019 (COVID-19) vaccine. Probably premature to draw a link between COVID-19 vaccine and myocardial infarction.

COVID-19 Recombinant mRNA Vaccines and Serious Ocular Inflammatory Side Effects: Real or Coincidence? PURPOSE: To report two cases; bilateral arteritic anterior ischemic optic neuropathy (AAION) and bilateral acute zonal occult outer retinopathy (AZOOR) after COVID-19 mRNA vaccination. CASE REPORT: The first patient was a 79-year-old female was presented to us 35 days after a sudden bilateral loss of vision, which occurred two days after receiving the second recombinant mRNA vaccine (Pfizer) injection. Temporal artery biopsy was compatible with AAION. At presentation, the best-corrected visual acuity was 20/1250 and 20/40 in the right and left eyes on the Snellen acuity chart, respectively. There was 3+ afferent pupillary defect in the right eye. The anterior segment and posterior segment exams were normal except for pallor of the optic nerve head in both eyes. Intraocular pressure was normal in both eyes. She was diagnosed with bilateral AAION and Subcutaneous tocilizumab 162 mg weekly was recommended with monitoring her ESR, CRP, and IL-6.The second patient was a 33-year-old healthy female who was referred to us for a progressive nasal field defect in her left eye, and for flashes in both eyes. Her symptoms started 10 days after receiving the second recombinant mRNA vaccine (Moderna) injection. Complete bloodwork performed by a uveitis specialist demonstrated high ESR (25) and CRP (19) levels. As a result, she was diagnosed with unilateral AZOOR in her left eye and was subsequently treated with an intravitreal dexamethasone implant in the same eye. At presentation, vision was20/20 in both eyes. The anterior segment and posterior segment exams were completely normal except for the presence of abnormal white reflex in the temporal macula of her left eye. We diagnosed her with bilateral AZOOR. Since she was nursing, intravitreal dexamethasone implant was recommended for the right eye. CONCLUSION: There may be a correlation between ocular inflammatory diseases with autoimmune mechanism and the mRNA COVID-19 vaccination.

Vaccine Induced Immune Thrombotic Thrombocytopenia Causing a Severe Form of Cerebral Venous Thrombosis With High Fatality Rate: A Case Series. During a 2-week period, we have encountered five cases presenting with the combination of cerebral venous thrombosis (CVT), intracerebral hemorrhage and thrombocytopenia. A clinical hallmark was the rapid and severe progression of disease in spite of maximum treatment efforts, resulting in fatal outcome in for 4 out of 5 patients. All cases had received ChAdOx1 nCov-19 vaccine 1-2 weeks earlier and developed a characteristic syndrome thereafter. The rapid progressive clinical course and high fatality rate of CVT in combination with thrombocytopenia in such a cluster and in otherwise healthy adults is a recent phenomenon. Cerebral autopsy findings were those of venous hemorrhagic infarctions and thrombi in dural venous sinuses, including thrombus material apparently rich in thrombocytes, leukocytes and fibrin. Vessel walls were free of inflammation. Extra-cerebral manifestations included leech-like thrombi in large veins, fibrin clots in small venules and scattered hemorrhages on skin and membranes. CVT with thrombocytopenia after adenovirus vectored COVID-19 vaccination is a new clinical syndrome that needs to be recognized by clinicians, is challenging to treat and seems associated with a high mortality rate.

PEG/Polysorbate Skin Testing Has No Utility in the Assessment of Suspected Allergic Reactions to SARS-CoV-2 Vaccines.

Acute Myocardial Injury Following COVID-19 Vaccination.

Acute myelitis and ChAdOx1 nCoV-19 vaccine: Casual or causal association? A 44-year-old previously healthy woman developed acute myelitis in close temporal relationship with ChAdOx1 nCoV-19 vaccine first-dose administration. The neurological involvement was mainly sensory with neuroimaging showing two mono-metameric lesions involving the posterior and lateral cord at dorsal level. Significant improvement was promptly recorded with high-dose intravenous steroids, with complete recovery within one month. The strict temporal relationship between vaccination and myelitis, together with the absence of clues pointing to alternative diagnoses, might suggest a conceivable role for anti-SARS-CoV-2 vaccine as immunological trigger, although a causal relationship has yet to be established and our preliminary observation suggests caution.

Precautions after vaccinating immunosuppressed patients with mRNA-based vaccines against SARS-CoV-2: does one size fit all?

Palms and soles itchiness as a side effect of COVID-19 vaccination. BACKGROUND: COVID-19 is a pandemic disease that has no definite treatment or preventive medication until late 2020 when vaccines were developed. Vaccines are a very useful new tool against COVID-19 that stimulate the immune system after recognition of viruses or their parts. Complications post vaccination could happen and they depend on the types, vaccine mechanism of action as well as some other patients' factors. CASE REPORT: We are reporting a 39 years old lady who is known as allergic to a strawberry and kiwi, otherwise medically free. She presented to the outpatient unit with a ten-days history of palms of the hands and soles of the feet itchiness that is associated with occasional redness after receiving the first dose of COVID-19 vaccination. There were no skin rashes or pruritis at any other sites. The patient was treated conservatively by antihistamine and the symptoms gradually resolved within five days. CONCLUSION: Allergic reaction is one of the expected complications post any COVID-19 or non-COVID-19 vaccination. Although the type, distributions and severity of allergic reactions are variable from person to another, yet isolated itching to palms and soles could be a rare side effect post first dose of COVID-19 vaccination (Pfizer-BioNTech) which is worth reporting. This presentation could be a type of allergic reaction which may require holding further doses, debate is there for further case reporting, research or evaluation. Learning points.

Neutralising antibodies after COVID-19 vaccination in UK haemodialysis patients.

Antibody responses after a single dose of ChAdOx1 nCoV-19 vaccine in healthcare workers previously infected with SARS-CoV-2. BACKGROUND: Recent reports demonstrate robust serological responses to a single dose of messenger RNA (mRNA) vaccines in individuals previously infected with SARS-CoV-2. Data on immune responses following a single-dose adenovirus-vectored vaccine expressing the SARS-CoV-2 spike protein (ChAdOx1 nCoV-19) in individuals with previous SARS-CoV-2 infection are however limited, and current guidelines recommend a two-dose regimen regardless of preexisting immunity. METHODS: We compared RBD-specific IgG and RBD-ACE2 blocking antibodies against SARS-CoV-2 wild type and variants of concern following two doses of the mRNA vaccine BNT162b2 in SARS-CoV-2 naÃ¯ve healthcare workers (n=65) and a single dose of the adenovector vaccine ChAdOx1 nCoV-19 in 82 healthcare workers more than (n=45) and less than (n=37) 11 months post mild SARS-CoV-2 infection at time of vaccination. FINDINGS: The post-vaccine levels of RBD-specific IgG and neutralizing antibodies against the SARS-CoV-2 wild type and variants of concern including Delta lineage 1.617.2 were similar or higher in participants receiving a single dose of ChAdOx1 nCoV-19 vaccine post SARS-CoV-2 infection (both more than and less than 11 months post infection) compared to SARS-CoV-2 naÃ¯ve participants who received two doses of BNT162b2 vaccine. INTERPRETATION: Our data support that a single dose ChAdOx1 nCoV-19 vaccine that is

administered up to at least 11 months post SARS-CoV-2 infection serves as an effective immune booster. This provides a possible rationale for a single-dose vaccine regimen. FUNDING: A full list of funding bodies that contributed to this study can be found in the Acknowledgements section.
A case of reactivation of varicella-zoster virus after BNT162b2 vaccine second dose? We report a case of itchy papulovesicular rash consistent with varicella-zoster virus reactivation after Pfizer-BioNTech vaccine second dose administration. While there have been cases of varicella-zoster virus reactivation due to COVID-19 or COVID-19 vaccine inoculation in older individuals with pre-existing conditions, this case report describes the first case of varicella-zoster virus reactivation on a healthy, young male in the absence of pre-existing conditions.Â The mechanisms underlying varicella-zoster virus reactivation in patients with COVID-19 are unknown and should be further characterized.
COVID-19 Vaccination-Associated Myocarditis in Adolescents. OBJECTIVES: In this study, we aimed to characterize the clinical presentation, short-term prognosis, and myocardial tissue changes as noted on cardiovascular magnetic resonance (CMR) or cardiac MRI in pediatric patients with coronavirus disease 2019 vaccination-associated myocarditis (C-VAM). METHODS: In this retrospective multicenter study across 16 US hospitals, patients <21 years of age with a diagnosis of C-VAM were included and compared with a cohort with multisystem inflammatory syndrome in children. Younger children with C-VAM were compared with older adolescents. RESULTS: Sixty-three patients with a mean age of 15.6 years were included; 92% were male. All had received a messenger RNA vaccine and, except for one, presented after the second dose. Four patients had significant dysrhythmia; 14% had mild left ventricular dysfunction on echocardiography, which resolved on discharge; 88% met the diagnostic CMR Lake Louise criteria for myocarditis. Myocardial injury as evidenced by late gadolinium enhancement on CMR was more prevalent in comparison with multisystem inflammatory syndrome in children. None of the patients required inotropic, mechanical, or circulatory support. There were no deaths. Follow-up data obtained in 86% of patients at a mean of 35 days revealed resolution of symptoms, arrhythmias, and ventricular dysfunction. CONCLUSIONS: Clinical characteristics and early outcomes are similar between the different pediatric age groups in C-VAM. The hospital course is mild, with quick clinical recovery and excellent short-term outcomes. Myocardial injury and edema are noted on CMR. Close follow-up and further studies are needed to understand the long-term implications and mechanism of these myocardial tissue changes.
Acute tolerance of Moderna mRNA-1273 vaccine against COVID-19 in patients with cancer treated with radiotherapy.
Durability of mRNA-1273 vaccine-induced antibodies against SARS-CoV-2 variants. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mutations may diminish vaccine-induced protective immune responses, particularly as antibody titers wane over time. Here, we assess the effect of SARS-CoV-2 variants B.1.1.7 (Alpha), B.1.351 (Beta), P.1 (Gamma), B.1.429 (Epsilon), B.1.526 (Iota), and B.1.617.2 (Delta) on binding, neutralizing, and angiotensin-converting enzyme 2 (ACE2)â€“competing antibodies elicited by the messenger RNA (mRNA) vaccine mRNA-1273 over 7 months. Cross-reactive neutralizing responses were rare after a single dose. At the peak of response to the second vaccine dose, all individuals had responses to all variants. Binding and functional antibodies against variants persisted in most subjects, albeit at low levels, for 6 months after the primary series of the mRNA-1273 vaccine. Across all assays, B.1.351 had the lowest antibody recognition. These data complement ongoing studies to inform the potential need for additional boost vaccinations.
COVID-19 vaccination in Israel.
Autoimmune hepatitis developing after coronavirus disease 2019 (COVID-19) vaccine: One or even several swallows do not make a summer.

Stevens-Johnson syndrome post second dose of Pfizer COVID-19 vaccine: a case report. Coronavirus disease 2019 (COVID-19) began in December 2019 and has affected millions of people all over the world. Respiratory illness in the form of severe pneumonia, in addition to multiorgan failure and death, is the clinical spectrum of COVID-19. Although there are no specific therapeutic agents for COVID-19 infection, the COVID-19 vaccine reduces morbidity and mortality associated with COVID-19 infection and is generally well tolerated. We report one potential complication of the Pfizer COVID-19 vaccine: a known case of Stevens-Johnson syndrome (SJS) that occurred after the second dose of the Pfizer COVID-19 vaccine alone without exposure to any other drug. Despite the initial severe adverse reaction, the patient showed a full recovery. Although SJS can be associated with COVID-19 vaccination, it is rare, and the benefits of receiving the vaccination outweigh the potential harms.

Acute prolonged motor aura resembling ischemic stroke after COVID -â€‰19 vaccination (CoronaVac): the first case report. BACKGROUND: We report the first case of a patient who suffered transient focal neurological deficit mimicking stroke following CoronaVac vaccination. However, instead of an ischemic stroke, motor aura was suspected. CASE PRESENTATIONS: A 24 year-old Thai female presented with left hemiparesis fifteen minutes after receiving CoronaVac. She also had numbness of her left arm and legs, flashing lights, and headaches. On physical examination, her BMI was 32.8. Her vital signs were normal. She had moderate left hemiparesis (MRC grade III), numbness on her left face, arms, and legs. Her weakness continued for 5 days. A brain CT scan was done showing no evidence of acute infarction. Acute treatment with aspirin was given. MRI in conjunction with MRA was performed in which no restricted diffusion was seen. A SPECT was performed to evaluate the function of the brain showing significant hypoperfusion of the right hemisphere. The patient gradually improved and was discharged. DISCUSSIONS: In this study, we present the first case of stroke mimic after CoronaVac vaccination. After negative imaging studies had been performed repeatedly, we reach a conclusion that stroke is unlikely to be the cause. Presumably, this phenomenon could possibly have abnormal functional imaging study. Therefore, we believed that it might be due to cortical spreading depression, like migraine aura, which we had conducted a literature review.

Venous Thromboembolism and Mild Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination.

Use of COVID-19 Vaccines After Reports of Adverse Events Among Adult Recipients of Janssen (Johnson & Johnson) and mRNA COVID-19 Vaccines (Pfizer-BioNTech and Moderna): Update from the Advisory Committee on Immunization Practices - United States, July 2021. In December 2020, the Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUAs) for Pfizer-BioNTech and Moderna COVID-19 vaccines, and in February 2021, FDA issued an EUA for the Janssen (Johnson & Johnson) COVID-19 vaccine. After each EUA, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for vaccine use; currently Pfizer-BioNTech is authorized and recommended for persons aged â‰¥12 years and Moderna and Janssen for persons aged â‰¥18 years (1-3). Both Pfizer-BioNTech and Moderna vaccines, administered as 2-dose series, are mRNA-based COVID-19 vaccines, whereas the Janssen COVID-19 vaccine, administered as a single dose, is a recombinant replication-incompetent adenovirus-vector vaccine. As of July 22, 2021, 187 million persons in the United States had received at least 1 dose of COVID-19 vaccine (4); close monitoring of safety surveillance has demonstrated that serious adverse events after COVID-19 vaccination are rare (5,6). Three medical conditions have been reported in temporal association with receipt of COVID-19 vaccines. Two of these (thrombosis with thrombocytopenia syndrome [TTS], a rare syndrome characterized by venous or arterial thrombosis and thrombocytopenia, and Guillain-BarrÃ© syndrome [GBS], a rare autoimmune neurologic disorder characterized by ascending weakness and paralysis) have been reported after Janssen COVID-19 vaccination. One (myocarditis, cardiac inflammation) has been reported after Pfizer-BioNTech COVID-19 vaccination or Moderna COVID-19

vaccination, particularly after the second dose; these were reviewed together and will hereafter be referred to as mRNA COVID-19 vaccination. ACIP has met three times to review the data associated with these reports of serious adverse events and has comprehensively assessed the benefits and risks associated with receipt of these vaccines. During the most recent meeting in July 2021, ACIP determined that, overall, the benefits of COVID-19 vaccination in preventing COVID-19 morbidity and mortality outweigh the risks for these rare serious adverse events in adults aged â‰¥18 years; this balance of benefits and risks varied by age and sex. ACIP continues to recommend COVID-19 vaccination in all persons aged â‰¥12 years. CDC and FDA continue to closely monitor reports of serious adverse events and will present any additional data to ACIP for consideration. Information regarding risks and how they vary by age and sex and type of vaccine should be disseminated to providers, vaccine recipients, and the public.

Considerations for COVID-19 vaccination in pregnancy. Pregnant women are at greater risk of severe COVID-19 than non-pregnant women. Despite limited safety data on use of COVID-19 vaccines in pregnancy, many international societies have recommended their use when pregnant women are at particularly high risk of acquiring COVID-19, or have suggested that vaccines should not be withheld from pregnant women where no other contraindications to COVID-19 vaccination exist. A number of vaccines, including those against influenza, tetanus and pertussis, have been shown to reduce both maternal and infant morbidity and mortality when used antenatally. We explore the role of COVID-19 vaccination in the setting of pregnancy, discuss the limited data available, and summarise current international guidelines.

Recommendations for the diagnosis and management of vaccine-induced immune thrombotic thrombocytopenia. There have recently been safety concerns regarding an increased risk of vaccine-induced immune thrombotic thrombocytopenia (VITT) following administration of SARS-CoV-2 adenoviral vector vaccines. The Southern African Society of Thrombosis and Haemostasis reviewed the emerging literature on this idiosyncratic complication. A draft document was produced and revised by consensus agreement by a panel of professionals from various specialties. The recommendations were adjudicated by independent international experts to avoid local bias. We present concise, practical guidelines for the clinical management of VITT.

The J&J COVID-19 vaccine: Fit for purpose in our setting.

Immune-mediated thrombotic thrombocytopenic purpura following administration of Pfizer-BioNTech COVID-19 vaccine.

Immune thrombocytopenia associated with Pfizer-BioNTech's BNT162b2 mRNA COVID-19 vaccine. The recent global pandemic of coronavirus disease 2019 (COVID-19) has led to vaccination in many parts of the world for herd immunity, and as vaccination has progressed, several rare adverse events have been reported. Immune thrombocytopenia (ITP) has been reported to be one of the rare adverse events caused by vaccination with MMR (measles-mumps-rubella) vaccine and influenza vaccine. In addition, ITP has been reported to occur in a small number of cases associated with the COVID-19 messenger ribonucleic acid (mRNA) vaccine. However, there are few reports on the details of the treatment and clinical course; optimal treatment has not yet been established. We report the case of a 20-year-old woman who developed ITP after receiving Pfizer-BioNTech's BNT162b2 vaccine. She had generalized subcutaneous hemorrhage, 14 days after vaccination. At the time of our visit, she had marked thrombocytopenia and intraoral bleeding; she was diagnosed with ITP. Treatment with oral steroids was started and the platelet count promptly improved after 4 days of treatment. Since the response to treatment was very good, we tapered off the steroids. As these vaccines will be increasingly used in the future, it is important to recognize ITP as a possible adverse event.

Evaluation of mRNA-1273 SARS-CoV-2 Vaccine in Adolescents. BACKGROUND: The incidence of coronavirus disease 2019 (Covid-19) among adolescents between 12 and 17 years of age was

approximately 900 per 100,000 population from April 1 through June 11, 2021. The safety, immunogenicity, and efficacy of the mRNA-1273 vaccine in adolescents are unknown. METHODS: In this ongoing phase 2-3, placebo-controlled trial, we randomly assigned healthy adolescents (12 to 17 years of age) in a 2:1 ratio to receive two injections of the mRNA-1273 vaccine (100 Î¼g in each) or placebo, administered 28 days apart. The primary objectives were evaluation of the safety of mRNA-1273 in adolescents and the noninferiority of the immune response in adolescents as compared with that in young adults (18 to 25 years of age) in a phase 3 trial. Secondary objectives included the efficacy of mRNA-1273 in preventing Covid-19 or asymptomatic severe acute respiratory syndrome coronavirus 2 infection. RESULTS: A total of 3732 participants were randomly assigned to receive mRNA-1273 (2489 participants) or placebo (1243 participants). In the mRNA-1273 group, the most common solicited adverse reactions after the first or second injections were injection-site pain (in 93.1% and 92.4%, respectively), headache (in 44.6% and 70.2%, respectively), and fatigue (in 47.9% and 67.8%, respectively); in the placebo group, the most common solicited adverse reactions after the first or second injections were injection-site pain (in 34.8% or 30.3%, respectively), headache (in 38.5% and 30.2%, respectively), and fatigue (in 36.6% and 28.9%, respectively). No serious adverse events related to mRNA-1273 or placebo were noted. The geometric mean titer ratio of pseudovirus neutralizing antibody titers in adolescents relative to young adults was 1.08 (95% confidence interval [CI], 0.94 to 1.24), and the absolute difference in serologic response was 0.2 percentage points (95% CI, -1.8 to 2.4), which met the noninferiority criterion. No cases of Covid-19 with an onset of 14 days after the second injection were reported in the mRNA-1273 group, and four cases occurred in the placebo group. CONCLUSIONS: The mRNA-1273 vaccine had an acceptable safety profile in adolescents. The immune response was similar to that in young adults, and the vaccine was efficacious in preventing Covid-19. (Funded by Moderna and the Biomedical Advanced Research and Development Authority; Teen COVE ClinicalTrials.gov number, NCT04649151.).

Clinical Features of Vaccine-Induced Immune Thrombocytopenia and Thrombosis.
BACKGROUND: Vaccine-induced immune thrombocytopenia and thrombosis (VITT) is a new syndrome associated with the ChAdOx1 nCoV-19 adenoviral vector vaccine against severe acute respiratory syndrome coronavirus 2. Data are lacking on the clinical features of and the prognostic criteria for this disorder. METHODS: We conducted a prospective cohort study involving patients with suspected VITT who presented to hospitals in the United Kingdom between March 22 and June 6, 2021. Data were collected with the use of an anonymized electronic form, and cases were identified as definite or probable VITT according to prespecified criteria. Baseline characteristics and clinicopathological features of the patients, risk factors, treatment, and markers of poor prognosis were determined. RESULTS: Among 294 patients who were evaluated, we identified 170 definite and 50 probable cases of VITT. All the patients had received the first dose of ChAdOx1 nCoV-19 vaccine and presented 5 to 48 days (median, 14) after vaccination. The age range was 18 to 79 years (median, 48), with no sex preponderance and no identifiable medical risk factors. Overall mortality was 22%. The odds of death increased by a factor of 2.7 (95% confidence interval [CI], 1.4 to 5.2) among patients with cerebral venous sinus thrombosis, by a factor of 1.7 (95% CI, 1.3 to 2.3) for every 50% decrease in the baseline platelet count, by a factor of 1.2 (95% CI, 1.0 to 1.3) for every increase of 10,000 fibrinogen-equivalent units in the baseline d-dimer level, and by a factor of 1.7 (95% CI, 1.1 to 2.5) for every 50% decrease in the baseline fibrinogen level. Multivariate analysis identified the baseline platelet count and the presence of intracranial hemorrhage as being independently associated with death; the observed mortality was 73% among patients with platelet counts below 30,000 per cubic millimeter and intracranial hemorrhage. CONCLUSIONS: The high mortality associated with VITT was highest among patients with a low platelet count and intracranial

hemorrhage. Treatment remains uncertain, but identification of prognostic markers may help guide effective management. (Funded by the Oxford University Hospitals NHS Foundation Trust.).
Pityriasis rubra pilaris-like eruption following administration of the BNT163b2 (Pfizer-BioNTech) mRNA COVID-19 vaccine. We describe a case of a pityriasis rubra pilaris (PRP)-like eruption occurring following administration of the Pfizer-Biontech mRNA COVID-19 vaccine, with worsening of the condition following the second dose. To our knowledge, this is the first reported case of a PRP-like eruption as a cutaneous adverse event of the Pfizer-Biontech mRNA COVID-19 vaccine.
T Cell Response After SARS-CoV-2 Vaccination in Immunocompromised Patients with Inflammatory Bowel Disease. BACKGROUND: Vaccination is a promising strategy to protect vulnerable groups like immunocompromised inflammatory bowel disease [IBD] patients from an infection with SARS-CoV-2. These patients may have lower immune responses. Little is known about the cellular and humoral immune response after a SARS-CoV-2 vaccination in IBD patients. METHODS: Totals of 28 patients with IBD and 27 age- and sex-matched healthy controls were recruited at Jena University Hospital. Blood samples were taken before, after the first, and in a subgroup of 11 patients after second dose of a SARS-CoV-2 vaccination. Cellular immune response, including IFN-Î³ and TNF-Î± response and antibody titres, were analysed. RESULTS: Overall, 71.4% of the IBD patients and 85.2% of the controls showed levels of anti-SARS-CoV-2 antibodies above the cutoff of 33.8 BAU/ml [p = 0.329] after the first dose. Even in the absence of SARS-CoV-2 antibodies, IBD patients showed significant T cell responses after first SARS-CoV-2 vaccination compared with healthy controls, which was not influenced by different immunosuppressive regimens. Associated with the vaccination, we could also detect a slight increase of the TNF production among SARS-CoV-2-reactive TH cells in healthy donorsn [HD] and IBD patients. After the second dose of vaccination, in IBD patients a further increase of humoral immune response in all but one patient was observed. CONCLUSIONS: Already after the first dose of a SARS-CoV-2 vaccination, cellular immune response in IBD patients is comparable to controls, indicating a similar efficacy. However, close monitoring of long-term immunity in these patients should be considered.
Acute Uveitis following COVID-19 Vaccination. PURPOSE: To describe a case of juvenile idiopathic arthritis (JIA)-associated anterior uveitis after receiving the Sinopharm COVID-19 vaccine. METHODS: A retrospective case report. RESULTS: An 18-year-old girl, with a history of antinuclear antibody positive oligoarticular JIA, presented with bilateral anterior uveitis 5 days after the second dose of the Sinopharm COVID-19 vaccine. Ocular examination revealed anterior uveitis with reduced visual acuity in both eyes. Anterior segment optical coherence tomography showed hyperreflective dots in the anterior chamber (AC) and fine endothelial granularities representing the circulating cells in the AC. Uveitis in both eyes resolved gradually after topical steroid treatment without recurrence. CONCLUSION: This report demonstrates a potential causal association of COVID-19 vaccine with anterior uveitis.
Aseptic meningitis after vaccination of the BNT162b2 mRNA COVID-19 vaccine.
Commentary on: A Case Report of Capsular Contracture Immediately Following COVID-19 Vaccination.
Secondary Immune Thrombocytopenia (ITP) Associated with ChAdOx1 Covid-19 Vaccination - A Case Report. Novel mRNA and vector-based covid-19 vaccinations have shown high efficacy in preventing symptomatic COVID-19 infections. Compared with the number of performed vaccinations, rates of severe side effects seem low. Rare prothrombotic coagulation disorders with suspected association to ChAdOx1 nCoV-19 (AstraZeneca) have been reported. These cases have gathered considerable media attention and caused a temporary pause of usage of the AstraZeneca vaccine in Europe and several other countries and are currently discussed as vaccine-induced immune thrombotic thrombocytopenia (VITT). However, hemorrhagic complications from ChAdOx1 nCoV-19

vaccination have also been reported but, so far, received less public attention despite considerable potential for life-threatening complications. Here we present a case of severe immune thrombocytopenia after ChAdOx1 covid-19 vaccination and its successful primary management.

Absence of Antibody Reponses and Severe COVID-19 in Patients on Hemodialysis Following mRNA Vaccination. Inpatient dialysis patients cannot isolate, resulting in a higher rate of coronavirus disease 2019 (COVID-19) infections, with increased severity and higher mortality rate [1]. We present 2 African American dialysis patients who developed severe COVID-19 infections after vaccination. Both patients had not mounted antibody response to the COVID-19 vaccine or to hepatitis B vaccination.

Antibody persistence 100 days following the second dose of BNT162b mRNA Covid19 vaccine in patients with chronic lymphocytic leukemia.

From program suspension to the pandemic: A qualitative examination of Australia's vaccine pharmacovigilance system over 10Â years. BACKGROUND: In 2010, the Australian seasonal influenza vaccination program for children under 5Â years of age was suspended due to an unexpected increase in fever and febrile convulsions causally associated with one particular influenza vaccine brand. A subsequent national review made seven recommendations to improve vaccine pharmacovigilance. Ten years on, in advance of implementing the COVID-19 immunisation program, we evaluated views on the capacity of Australia's vaccine pharmacovigilance system to promptly detect, examine and communicate a signal. METHODS: Semi-structured interviews were conducted between July and October 2020 with individuals with expertise in vaccine safety in Australia using an interview guide informed by key Australian and international frameworks. Interviews were digitally recorded and transcribed verbatim. Thematic analysis was used to code data using a deductive approach. RESULTS: Interviews with seventeen participants enabled six themes to be identified. Participants described improvement and significant innovation within Australia's vaccine pharmacovigilance system over the decade since 2010, particularly through establishment of a new active, cohort event monitoring system using short message service surveys. Participants thought Australia had a good foundation for COVID-19 vaccine safety surveillance; implementation of the COVID-19 immunisation program was seen as a potential driver for ongoing enhancement through: a) improved integration of the active surveillance and spontaneous reporting systems, and; b) development of population-level active surveillance, including through data linkage. Transparent communication was considered essential to address the unprecedented challenges of COVID-19 and broader vaccine safety concerns. CONCLUSIONS: Vaccine safety experts in Australia convey confidence in the innovative pharmacovigilance systems implemented over the past 10Â years. While Australia has a multifaceted system incorporating both active surveillance and spontaneous reporting systems, COVID-19 vaccine implementation represents an opportunity to enhance current systems and to develop new, systematic approaches to vaccine pharmacovigilance that should make both a local and global contribution.

Double high-dose immunoglobulin for ChAdOx1 nCov-19 vaccine-induced immune thrombotic thrombocytopenia.

Outcomes Among Patients with Breakthrough SARS-CoV-2 Infection After Vaccination. BACKGROUND: Breakthrough infections after SARS-CoV-2 vaccination have been reported. Clinical outcomes in these persons are not widely known. METHODS: We evaluated all vaccinated persons with breakthrough infection â‰¥14 days after the second vaccine dose and unvaccinated controls matched on age, sex, nationality, and reason for testing between December 23, 2020 and March 28, 2021 in Qatar. Our primary outcome was severe disease defined as hospitalization, mechanical ventilation, or death. RESULTS: Among 456 persons cases of breakthrough infection and 456 unvaccinated matched controls with confirmed infection, median age was 45 years, 60.7% were

males, and â‰¥1 comorbid condition was present in 61.2% of the vaccinated and 47.8% of the unvaccinated persons (P=0.009). Severe disease was recorded in 48 (10.5%) of the vaccinated and 121 (26.5%) of the unvaccinated group (P<0.001). Factors associated with severe disease included increasing age (HR vs. <40 years old: >40-60 years, HR 2.32; >60-70 years, HR 4.34; >70 years, HR 5.43); presence of symptoms at baseline (HR 2.42, 95%CI 1.44-4.07); and being unvaccinated (HR 2.84, 95%CI 1.80-4.47). CONCLUSIONS: In persons with breakthrough SARS-CoV-2 infection, increasing age is associated with a higher risk of severe disease or death, while vaccination is associated with a lower risk. Presence of comorbidities was not associated with severe disease or death among persons with breakthrough infection.

Myocarditis and Pericarditis After COVID-19 mRNA Vaccination: Practical Considerations for Care Providers. The mRNA vaccines against COVID-19 infection have been effective in reducing the number of symptomatic cases worldwide. With widespread uptake, case series of vaccine-related myocarditis/pericarditis have been reported, particularly in adolescents and young adults. Men tend to be affected with greater frequency, and symptom onset is usually within 1 week after vaccination. Clinical course appears to be mild in most cases. On the basis of the available evidence, we highlight a clinical framework to guide providers on how to assess, investigate, diagnose, and report suspected and confirmed cases. In any patient with highly suggestive symptoms temporally related to COVID-19 mRNA vaccination, standardized workup includes serum troponin measurement and polymerase chain reaction testing for COVID-19 infection, routine additional lab work, and a 12-lead electrocardiogram. Echocardiography is recommended as the imaging modality of choice for patients with unexplained troponin elevation and/or pathologic electrocardiogram changes. Cardiovascular specialist consultation and hospitalization should be considered on the basis of the results of standard investigations. Treatment is largely supportive, and myocarditis/pericarditis that is diagnosed according to defined clinical criteria should be reported to public health authorities in every jurisdiction. Finally, we recommend COVID-19 vaccination in all individuals in accordance with the Health Canada and National Advisory Committee on Immunization guidelines. In patients with suspected myocarditis/pericarditis after the first dose of an mRNA vaccine, deferral of a second dose is recommended until additional reports become available.

Comparison of adverse drug reactions among four COVID-19 vaccines in Europe using the EudraVigilance database: Thrombosis at unusual sites. BACKGROUND: Real-world experience with adenoviral vector vaccines against COVID-19 raised some safety concerns. Cases of cerebral vein thrombosis (CVT) associated with thrombocytopenia have been observed after the first dose of the adenoviral vector vaccines CHADOX1Â NCOV-19 and AD26.COV2.S. OBJECTIVES: To assess the reporting rate of CVT as adverse drug reaction (ADR) for the COVID-19 vaccines authorized in Europe. PATIENTS AND METHODS: This observational study assessed the CVT reporting rate attributed to four COVID-19 vaccines authorized in Europe, namely Tozinameran (Pfizer-Biontech), CX-024414 (Moderna), CHADOX1Â NCOV-19 (AstraZeneca), and AD26.COV2.S (Janssen). Data on thrombotic ADRs reported on EudraVigilance database between January 1, 2021 and July 30, 2021, were collected. ADRs referring to CVT were identified. The reporting rate of CVT was expressed as 1Â million individual vaccinated-days with 95% confidence interval. Finally, an observed-to-expected (OE) analysis was performed. RESULTS: The reporting rate of CVT per 1Â million person vaccinated-days was 1.92 (95% confidence interval [CI], 1.71-2.12) for Tozinameran, 5.63 (95% CI, 4.74-6.64) for CX-024414, 21.60 (95% CI, 20.16-23.11) for CHADOX1Â NCOV-19, and 11.48 (95% CI, 9.57-13.67) for AD26.COV2.S. CVT occurred alongside thrombocytopenia for the four vaccines. The OE ratio was greater than one for all four vaccines, both with the lowest and the highest CVT background incidence. CONCLUSIONS: This report on EudraVigilance data strengthens anecdotal findings on CVT following COVID-19 vaccinations. Although the European Medicines Agency released an alert only for

CHADOX1Â NCOV-19 and AD26.COV2.S, Tozinameran and CX-024414 also are complicated by CVT, albeit to lesser extent.
Analysis of continuous glucose tracking data in people with type 1 diabetes after COVID-19 vaccination reveals unexpected link between immune and metabolic response, augmented by adjunctive oral medication. INTRODUCTION: The COVID-19 vaccination programme is under way worldwide. Anecdotal evidence is increasing that some people with type 1 diabetes mellitus (T1DM) experience temporary instability of blood glucose (BG) levels post-vaccination which normally settles within 2-3Â days. We report an analysis of BG profiles of 20 individuals before/after vaccination. METHODS: We examined the BG profile of 20 consecutive adults (18Â years of age or more) with T1DM using the FreeStyle Libre flash glucose monitor in the period immediately before and after COVID-19 vaccination. The primary outcome measure was percentage (%) BG readings in the designated target range 3.9-10 mmmol/L as reported on the LibreView portal for 7Â days prior to the vaccination (week -1) and the 7Â days after the vaccination (week +1). RESULTS: There was a significant decrease in the %BG on target following the COVID-vaccination for the 7Â days following vaccination (mean 45.2%Â Â±Â SE 4.2%) vs pre-COVID-19 vaccination (mean 52.6%Â Â±Â SE 4.5%). This was mirrored by an increase in the proportion of readings in other BG categories 10.1%-13.9%/â‰¥14%. There was no significant change in BG variability in the 7days post-COVID-19 vaccination. This change in BG proportion on target in the week following vaccination was most pronounced for people taking Metformin/Dapagliflozin+basal-bolus insulin (-23%) vs no oral hypoglycaemic agents (-4%), and median age <53 vs â‰¥53Â years (greater reduction in %BG in target for older individuals (-18% vs -9%)). CONCLUSION: In T1DM, we have shown that COVID-19 vaccination can cause temporary perturbation of BG, with this effect more pronounced in patients talking oral hypoglycaemic medication plus insulin, and in older individuals. This may also have consequences for patients with T2DM who are currently not supported by flash glucose monitoring.
Antiplatelet drugs block platelet activation by VITT patient serum.
Dominance of Alpha and Iota variants in SARS-CoV-2 vaccine breakthrough infections in New York City. The efficacy of COVID-19 mRNA vaccines is high, but breakthrough infections still occur. We compared the SARS-CoV-2 genomes of 76 breakthrough cases after full vaccination with BNT162b2 (Pfizer/BioNTech), mRNA-1273 (Moderna), or JNJ-78436735 (Janssen) to unvaccinated controls (February-April 2021) in metropolitan New York, including their phylogenetic relationship, distribution of variants, and full spike mutation profiles. The median age of patients in the study was 48 years; 7 required hospitalization and 1 died. Most breakthrough infections (57/76) occurred with B.1.1.7 (Alpha) or B.1.526 (Iota). Among the 7 hospitalized cases, 4 were infected with B.1.1.7, including 1 death. Both unmatched and matched statistical analyses considering age, sex, vaccine type, and study month as covariates supported the null hypothesis of equal variant distributions between vaccinated and unvaccinated in Ï‡2 and McNemar tests (P > 0.1), highlighting a high vaccine efficacy against B.1.1.7 and B.1.526. There was no clear association among breakthroughs between type of vaccine received and variant. In the vaccinated group, spike mutations in the N-terminal domain and receptor-binding domain that have been associated with immune evasion were overrepresented. The evolving dynamic of SARS-CoV-2 variants requires broad genomic analyses of breakthrough infections to provide real-life information on immune escape mediated by circulating variants and their spike mutations.
COVID-19 Vaccine-Associated Takotsubo Cardiomyopathy.
Vaccine-induced pseudothrombocytopenia after Ad26.COV2.S vaccination.
Association of Myocarditis With BNT162b2 Messenger RNA COVID-19 Vaccine in a Case Series of Children. IMPORTANCE: The BNT162b2 (Pfizer-BioNTech) messenger RNA COVID-19 vaccine was authorized on May 10, 2021, for emergency use in children aged 12 years and older. Initial reports

showed that the vaccine was well tolerated without serious adverse events; however, cases of myocarditis have been reported since approval. OBJECTIVE: To review results of comprehensive cardiac imaging in children with myocarditis after COVID-19 vaccine. DESIGN, SETTING, AND PARTICIPANTS: This study was a case series of children younger than 19 years hospitalized with myocarditis within 30 days of BNT162b2 messenger RNA COVID-19 vaccine. The setting was a single-center pediatric referral facility, and admissions occurred between May 1 and July 15, 2021. MAIN OUTCOMES AND MEASURES: All patients underwent cardiac evaluation including an electrocardiogram, echocardiogram, and cardiac magnetic resonance imaging. RESULTS: Fifteen patients (14 male patients [93%]; median age, 15 years [range, 12-18 years]) were hospitalized for management of myocarditis after receiving the BNT162b2 (Pfizer) vaccine. Symptoms started 1 to 6 days after receipt of the vaccine and included chest pain in 15 patients (100%), fever in 10 patients (67%), myalgia in 8 patients (53%), and headache in 6 patients (40%). Troponin levels were elevated in all patients at admission (median, 0.25 ng/mL [range, 0.08-3.15 ng/mL]) and peaked 0.1 to 2.3 days after admission. By echocardiographic examination, decreased left ventricular (LV) ejection fraction (EF) was present in 3 patients (20%), and abnormal global longitudinal or circumferential strain was present in 5 patients (33%). No patient had a pericardial effusion. Cardiac magnetic resonance imaging findings were consistent with myocarditis in 13 patients (87%) including late gadolinium enhancement in 12 patients (80%), regional hyperintensity on T2-weighted imaging in 2 patients (13%), elevated extracellular volume fraction in 3 patients (20%), and elevated LV global native T1 in 2 patients (20%). No patient required intensive care unit admission, and median hospital length of stay was 2 days (range 1-5). At follow-up 1 to 13 days after hospital discharge, 11 patients (73%) had resolution of symptoms. One patient (7%) had persistent borderline low LV systolic function on echocardiogram (EF 54%). Troponin levels remained mildly elevated in 3 patients (20%). One patient (7%) had nonsustained ventricular tachycardia on ambulatory monitor. CONCLUSIONS AND RELEVANCE: In this small case series study, myocarditis was diagnosed in children after COVID-19 vaccination, most commonly in boys after the second dose. In this case series, in short-term follow-up, patients were mildly affected. The long-term risks associated with postvaccination myocarditis remain unknown. Larger studies with longer follow-up are needed to inform recommendations for COVID-19 vaccination in this population.

Clinical Characteristics and Pharmacological Management of COVID-19 Vaccine-Induced Immune Thrombotic Thrombocytopenia With Cerebral Venous Sinus Thrombosis: A Review.

IMPORTANCE: The COVID-19 pandemic saw one of the fastest developments of vaccines in an effort to combat an out-of-control pandemic. The 2 most common COVID-19 vaccine platforms currently in use, messenger RNA (mRNA) and adenovirus vector, were developed on the basis of previous research in use of this technology. Postauthorization surveillance of COVID-19 vaccines has identified safety signals, including unusual cases of thrombocytopenia with thrombosis reported in recipients of adenoviral vector vaccines. One of the devastating manifestations of this syndrome, termed vaccine-induced immune thrombotic thrombocytopenia (VITT), is cerebral venous sinus thrombosis (CVST). This review summarizes the current evidence and indications regarding biology, clinical characteristics, and pharmacological management of VITT with CVST. OBSERVATIONS: VITT appears to be similar to heparin-induced thrombocytopenia (HIT), with both disorders associated with thrombocytopenia, thrombosis, and presence of autoantibodies to platelet factor 4 (PF4). Unlike VITT, HIT is triggered by recent exposure to heparin. Owing to similarities between these 2 conditions and lack of high-quality evidence, interim recommendations suggest avoiding heparin and heparin analogues in patients with VITT. Based on initial reports, female sex and age younger than 60 years were identified as possible risk factors for VITT. Treatment consists of therapeutic anticoagulation with nonheparin anticoagulants and prevention of formation of autoantibody-PF4 complexes, the

latter being achieved by administration of high-dose intravenous immunoglobin (IVIG). Steroids, which can theoretically inhibit the production of new antibodies, have been used in combination with IVIG. In severe cases, plasma exchange should be used for clearing autoantibodies. Monoclonal antibodies, such as rituximab and eculizumab, can be considered when other therapies fail. Routine platelet transfusions, aspirin, and warfarin should be avoided because of the possibility of worsening thrombosis and magnifying bleeding risk. CONCLUSIONS AND RELEVANCE: Adverse events like VITT, while uncommon, have been described despite vaccination remaining the most essential component in the fight against the COVID-19 pandemic. While it seems logical to consider the use of types of vaccines (eg, mRNA-based administration) in individuals at high risk, treatment should consist of therapeutic anticoagulation mostly with nonheparin products and IVIG.

Pityriasis Rosea as a Possible Complication of Vaccination Against COVID-19.

Correlates of Neutralizing/SARS-CoV-2-S1-binding Antibody Response with Adverse Effects and Immune Kinetics in BNT162b2-Vaccinated Individuals. BACKGROUND: While mRNA vaccines against SARS-CoV-2 have been exceedingly effective in preventing symptomatic viral infection, the features of immune response remain to be clarified. METHODS: In the present prospective observational study, 225 healthy individuals in Kumamoto General Hospital, Japan, who received two BNT162b2 doses in February 2021, were enrolled. Correlates of BNT162b2-elicited SARS-CoV-2-neutralizing activity (50% neutralization titer: NT (50) ; assessed using infectious virions and live target cells) with SARS-CoV-2-S1-binding-IgG and -IgM levels, adverse effects (AEs), ages, and genders were examined. The average half-life of neutralizing activity and the average time length for the loss of detectable neutralizing activity were determined and the potency of serums against variants of concerns was also determined. FINDINGS: Significant rise in NT (50) s was seen in serums on day 28 post-1st dose. A moderate inverse correlation was seen between NT (50) s and ages, but no correlation was seen between NT (50) s and AEs. NT (50) s and IgG levels on day 28 post-1st dose and pain scores following the 2nd shot were greater in women than in men. The average half-life of neutralizing activity in the vaccinees was approximately 67.8 days and the average time length for their serums to lose the detectable neutralizing activity was 198.3 days. While serums from elite-responders (NT (50) s>1,500-fold: the top 4% among all participants' NT (50) s) potently to moderately blocked the infectivity of variants of concerns, some serums with moderate NT (50) s failed to block the infectivity of a beta strain. INTERPRETATION: BNT162b2-elicited immune response has no significant association with AEs. BNT162b2-efficacy is likely diminished to under detection limit by 6-7 months post-1st shot. High-level neutralizing antibody-containing serums potently to moderately block the infection of SARS-CoV-2 variants; however, a few moderate-level neutralizing antibody-containing serums failed to do so. If BNT162b2-elicited immunity memory is short, an additional vaccine or other protective measures would be needed. RESEARCH IN CONTEXT: Evidence before this study: While mRNA vaccines against SARS-CoV-2 have been exceedingly effective in preventing symptomatic viral infection, the salient features of immune response including the persistence of protection remain to be clarified. There is a report that anti-SARS-CoV-2 antibodies persist through 6 months after the second dose of mRNA-1273 vaccine (Doria-Rose et al. N Engl J Med . 2021;384:2259-2261); however, more definite immune kinetics following mRNA-vaccine-elicited protection have to be clarified. The mRNA-vaccine-elicited protection against SARS-CoV-2 variants are also to be determined. Added value of this study: In the present prospective study, 225 twice-BNT162b2-dose-receiving individuals in Japan were enrolled. No significant correlation was seen between 50% neutralizing titers (NT (50) s), determined by using infectious SARS-CoV-2 virions and live target cells, and adverse effects. Largely, NT (50) s and IgG levels were greater in women than in men. Following 28 days post-2 (nd) shot, significant reduction was seen in NT (50) s, IgG, and IgM levels. The average half-life of NT (50) s was âˆ¼68 days and the average time-length for participants'

serums to lose the detectable activity was âˆ¼198 days. Although serums from elite-responders potently to moderately blocked the infectivity of variants of concerns, some serums with moderate NT (50) s failed to block the infectivity of a beta strain. Implications of all the available evidence: BNT162b2 efficacy is likely to be diminished to under detection limit by 6-7 months post-1 (st) shot on average. Individuals with moderate NT (50) s may fail to block beta variants. If BNT162b2-elicited immune memory is lost soon, additional vaccine(s) or other protective means would be needed.

A Case Report of Capsular Contracture Immediately Following COVID-19 Vaccination. Capsular contracture is fundamentally an immunological/inflammatory response to the implant, treating it as a foreign body in need of exclusion from the immune system. The capsule surrounding the implant is populated by a rich variety of immunologically active cells such as macrophages, T lymphocytes, and myofibroblasts. Vaccination in general and the COVID-19 vaccine in particular result in specific and nonspecific activation of the immune system, including those immune cells in proximity to the implant. This phenomenon has been previously demonstrated in delayed inflammatory reactions to previously implanted hyaluronic acid fillers following COVID-19 vaccination. This report is what is believed to be the first case of the rapid development of severe ipsilateral capsular contracture in the immediate aftermath of the second dose of the BNT162b2 (Pfizer) vaccine.

Decline in SARS-CoV-2 Infections Among Health Care Workers at 2 Hospitals Following Rollout and Administration of mRNA Vaccines.

Progress of the COVID-19 vaccine effort: viruses, vaccines and variants versus efficacy, effectiveness and escape. Where 2020 saw the development and testing of vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) at an unprecedented pace, the first half of 2021 has seen vaccine rollout in many countries. In this Progress article, we provide a snapshot of ongoing vaccine efficacy studies, as well as real-world data on vaccine effectiveness and the impact of virus variants of concern. Where they have been deployed in a high proportion of the adult population, the currently approved vaccines have been extremely effective in preventing COVID-19, particularly severe disease. Nonetheless, there are still significant challenges in ensuring equitable vaccine access around the globe and lessons that can be learned for controlling this pandemic and for the next pandemic.

[Cerebral vein/venous sinus thrombosis with thrombocytopenia syndrome after COVID-19 vaccination]. Vaccines are important in managing the COVID-19 pandemic caused by SARS-CoV-2. Despite the very low incidence, severe cases of thrombosis with thrombocytopenia after COVID-19 vaccination termed as Thrombosis with Thrombocytopenia Syndrome (TTS) have been reported. TTS clinically resembles autoimmune heparin-induced thrombocytopenia. TTS can cause disability and even death. It usually presents 4-28 days after vaccination characterized by thrombocytopenia and progressive thrombosis, often causing cerebral vein/venous thrombosis (CVT) and splanchnic venous thrombosis. We should avoid all forms of heparin and platelet transfusion. While awaiting further information on the pathophysiological mechanism and treatment of TTS, clinicians should be aware of TTS with CVT in patients receiving COVID-19 vaccinations. This new syndrome of TTS is an active area of investigation globally. Here, we review the available literature.

Factors associated with high compliance behaviour against COVID-19 in the early phase of pandemic: a cross-sectional study in 12 Asian countries. INTRODUCTION: Regardless of having effective vaccines against COVID-19, containment measures such as enhanced physical distancing and good practice of personal hygiene remain the mainstay of controlling the COVID-19 pandemic. Countries across Asia have imposed these containment measures to varying extents. However, residents in different countries would have a differing degree of compliance to these containment measures potentially due to differences in the level of awareness and motivation in the early phase of pandemic. OBJECTIVES: In our study, we aimed to describe and correlate the level of knowledge and

attitude with the level of compliance with personal hygiene and physical distancing practices among Asian countries in the early phase of pandemic. METHODS: A multinational cross-sectional study was carried out using electronic surveys between May and June 2020 across 14 geographical areas. Subjects aged 21 years and above were invited to participate through social media, word of mouth and electronic mail. RESULTS: Among the 2574 responses obtained, 762 (29.6%) participants were from East Asia and 1812 (70.4%) were from Southeast Asia (SEA). A greater proportion of participants from SEA will practise physical distancing as long as it takes (72.8% vs 60.6%). Having safe distancing practices such as standing more than 1 or 2â€‰m apart (AdjOR 5.09 95%â€‰CI (1.08 to 24.01)) or more than 3 or 4â€‰m apart (AdjOR 7.05 95%â€‰CI (1.32 to 37.67)), wearing a mask when they had influenza-like symptoms before the COVID-19 pandemic, preferring online news channels such as online news websites/applications (AdjOR 1.73 95%â€‰CI (1.21 to 2.49)) and social media (AdjOR 1.68 95%â€‰CI (1.13 to 2.50) as sources of obtaining information about COVID-19 and high psychological well-being (AdjOR 1.39 95%â€‰CI (1.04 to 1.87)) were independent factors associated with high compliance. CONCLUSIONS: We found factors associated with high compliance behaviour against COVID-19 in the early phase of pandemic and it will be useful to consider them in risk assessment, communication and pandemic preparedness.

Background rates of all-cause mortality, hospitalizations, and emergency department visits among nursing home residents in Ontario, Canada to inform COVID-19 vaccine safety assessments. BACKGROUND: Nursing home (NH) residents are prioritized for COVID-19 vaccination. We report monthly mortality, hospitalizations, and emergency department (ED) visit incidence rates (IRs) during 2010-2020 to provide context for COVID-19 vaccine safety assessments. METHODS: We observed outcomes among all NH residents in Ontario using administrative databases. IRs were calculated by month, sex, and age group. Comparisons between months were assessed using one-sample t-tests; comparisons by age and sex were assessed using chi-squared tests. RESULTS: From 2010 to 2019, there were 83,453 (SD: 652.4) NH residents per month, with an average of 2.3 (SD: 0.28) deaths, 3.1 (SD: 0.16) hospitalizations, and 3.6 (SD: 0.17) ED visits per 100 residents per month. From March to December 2020, mortality IRs were increased, but hospitalization and ED visit IRs were reduced (pÂ <Â 0.05). CONCLUSION: We identified consistent monthly mortality, hospitalization, and ED visit IRs during 2010-2019. Marked differences in these rates were observed during 2020, coinciding with the COVID-19 pandemic.

COVID-19 vaccines and vaccine hesitancy: Role of the allergist/immunologist in promotion of vaccine acceptance. Background: Vaccine hesitancy has been defined as a delay in acceptance or refusal of vaccines, despite the availability of vaccine services. In the past, despite an impressive record of vaccine effectiveness in the United States, several factors have contributed to a decreased acceptance of vaccines that has resulted in outbreaks of infectious diseases, e.g., measles. More recently, vaccine hesitancy has spread to coronavirus disease 2019 (COVID-19) vaccines. There are many causes of vaccine hesitancy, such as misinformation, fallacies, and myths, that have contributed to vaccine hesitancy. Objective: The purpose of the present report is to address the many causes of vaccine hesitancy and to suggest ways that the allergist/immunologist can be involved in the promotion of vaccine acceptance. Methods: The current COVID-19 vaccines were reviewed, together with their mechanisms(s) of action and adverse reactions to them. Results: The many causes of vaccine hesitancy include many doubts and concerns related to COVID-19 vaccines as well as a diminished level of confidence and trust by segments of the public in the nation's leaders in government, medical, and business communities, that those groups once enjoyed. Conclusion: Vaccination with COVID-19 vaccines is the only way that COVID-19 will be eliminated or at least controlled today, and vaccine hesitancy is the potential nemesis. The present report describes how the allergist/immunologist not only plays a major role in the delivery of specialized therapy of COVID-

19 but also in educating the public with regard to the importance of COVID-19 vaccines, in dispelling misinformation, and in promoting trust for vaccine acceptance but must be informed with the most accurate and current information to do so.

Cerebral venous thrombosis after vaccination against COVID-19 in the UK: a multicentre cohort study. BACKGROUND: A new syndrome of vaccine-induced immune thrombotic thrombocytopenia (VITT) has emerged as a rare side-effect of vaccination against COVID-19. Cerebral venous thrombosis is the most common manifestation of this syndrome but, to our knowledge, has not previously been described in detail. We aimed to document the features of post-vaccination cerebral venous thrombosis with and without VITT and to assess whether VITT is associated with poorer outcomes. METHODS: For this multicentre cohort study, clinicians were asked to submit all cases in which COVID-19 vaccination preceded the onset of cerebral venous thrombosis, regardless of the type of vaccine, interval between vaccine and onset of cerebral venous thrombosis symptoms, or blood test results. We collected clinical characteristics, laboratory results (including the results of tests for anti-platelet factor 4 antibodies where available), and radiological features at hospital admission of patients with cerebral venous thrombosis after vaccination against COVID-19, with no exclusion criteria. We defined cerebral venous thrombosis cases as VITT-associated if the lowest platelet count recorded during admission was below 150â€ˆÃ—â€ˆ10(9) per L and, if the D-dimer was measured, the highest value recorded was greater than 2000 Î¼g/L. We compared the VITT and non-VITT groups for the proportion of patients who had died or were dependent on others to help them with their activities of daily living (modified Rankin score 3-6) at the end of hospital admission (the primary outcome of the study). The VITT group were also compared with a large cohort of patients with cerebral venous thrombosis described in the International Study on Cerebral Vein and Dural Sinus Thrombosis. FINDINGS: Between April 1 and May 20, 2021, we received data on 99 patients from collaborators in 43 hospitals across the UK. Four patients were excluded because they did not have definitive evidence of cerebral venous thrombosis on imaging. Of the remaining 95 patients, 70 had VITT and 25 did not. The median age of the VITT group (47 years, IQR 32-55) was lower than in the non-VITT group (57 years; 41-62; p=0Â·0045). Patients with VITT-associated cerebral venous thrombosis had more intracranial veins thrombosed (median three, IQR 2-4) than non-VITT patients (two, 2-3; p=0Â·041) and more frequently had extracranial thrombosis (31 [44%] of 70 patients) compared with non-VITT patients (one [4%] of 25 patients; p=0Â·0003). The primary outcome of death or dependency occurred more frequently in patients with VITT-associated cerebral venous thrombosis (33 [47%] of 70 patients) compared with the non-VITT control group (four [16%] of 25 patients; p=0Â·0061). This adverse outcome was less frequent in patients with VITT who received non-heparin anticoagulants (18 [36%] of 50 patients) compared with those who did not (15 [75%] of 20 patients; p=0Â·0031), and in those who received intravenous immunoglobulin (22 [40%] of 55 patients) compared with those who did not (11 [73%] of 15 patients; p=0Â·022). INTERPRETATION: Cerebral venous thrombosis is more severe in the context of VITT. Non-heparin anticoagulants and immunoglobulin treatment might improve outcomes of VITT-associated cerebral venous thrombosis. Since existing criteria excluded some patients with otherwise typical VITT-associated cerebral venous thrombosis, we propose new diagnostic criteria that are more appropriate. FUNDING: None.

Safety and immunogenicity of heterologous versus homologous prime-boost schedules with an adenoviral vectored and mRNA COVID-19 vaccine (Com-COV): a single-blind, randomised, non-inferiority trial. BACKGROUND: Use of heterologous prime-boost COVID-19 vaccine schedules could facilitate mass COVID-19 immunisation. However, we have previously reported that heterologous schedules incorporating an adenoviral vectored vaccine (ChAdOx1 nCoV-19, AstraZeneca; hereafter referred to as ChAd) and an mRNA vaccine (BNT162b2, Pfizer-BioNTech; hereafter referred to as BNT) at a 4-week interval are more reactogenic than homologous schedules.

Here, we report the safety and immunogenicity of heterologous schedules with the ChAd and BNT vaccines. METHODS: Com-COV is a participant-blinded, randomised, non-inferiority trial evaluating vaccine safety, reactogenicity, and immunogenicity. Adults aged 50 years and older with no or well controlled comorbidities and no previous SARS-CoV-2 infection by laboratory confirmation were eligible and were recruited at eight sites across the UK. The majority of eligible participants were enrolled into the general cohort (28-day or 84-day prime-boost intervals), who were randomly assigned (1:1:1:1:1:1:1:1) to receive ChAd/ChAd, ChAd/BNT, BNT/BNT, or BNT/ChAd, administered at either 28-day or 84-day prime-boost intervals. A small subset of eligible participants (n=100) were enrolled into an immunology cohort, who had additional blood tests to evaluate immune responses; these participants were randomly assigned (1:1:1:1) to the four schedules (28-day interval only). Participants were masked to the vaccine received but not to the prime-boost interval. The primary endpoint was the geometric mean ratio (GMR) of serum SARS-CoV-2 anti-spike IgG concentration (measured by ELISA) at 28 days after boost, when comparing ChAd/BNT with ChAd/ChAd, and BNT/ChAd with BNT/BNT. The heterologous schedules were considered non-inferior to the approved homologous schedules if the lower limit of the one-sided 97Â·5% CI of the GMR of these comparisons was greater than 0Â·63. The primary analysis was done in the per-protocol population, who were seronegative at baseline. Safety analyses were done among participants receiving at least one dose of a study vaccine. The trial is registered with ISRCTN, 69254139. FINDINGS: Between Feb 11 and Feb 26, 2021, 830 participants were enrolled and randomised, including 463 participants with a 28-day prime-boost interval, for whom results are reported here. The mean age of participants was 57Â·8 years (SD 4Â·7), with 212 (46%) female participants and 117 (25%) from ethnic minorities. At day 28 post boost, the geometric mean concentration of SARS-CoV-2 anti-spike IgG in ChAd/BNT recipients (12â€ˆ906 ELU/mL) was non-inferior to that in ChAd/ChAd recipients (1392 ELU/mL), with a GMR of 9Â·2 (one-sided 97Â·5% CI 7Â·5 to â^ž). In participants primed with BNT, we did not show non-inferiority of the heterologous schedule (BNT/ChAd, 7133 ELU/mL) against the homologous schedule (BNT/BNT, 14â€ˆ080 ELU/mL), with a GMR of 0Â·51 (one-sided 97Â·5% CI 0Â·43 to â^ž). Four serious adverse events occurred across all groups, none of which were considered to be related to immunisation. INTERPRETATION: Despite the BNT/ChAd regimen not meeting non-inferiority criteria, the SARS-CoV-2 anti-spike IgG concentrations of both heterologous schedules were higher than that of a licensed vaccine schedule (ChAd/ChAd) with proven efficacy against COVID-19 disease and hospitalisation. Along with the higher immunogenicity of ChAd/BNT compared with ChAD/ChAd, these data support flexibility in the use of heterologous prime-boost vaccination using ChAd and BNT COVID-19 vaccines. FUNDING: UK Vaccine Task Force and National Institute for Health Research.

Acute transverse myelitis after inactivated COVID-19 vaccine. Vaccines against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been rapidly developed to prevent coronavirus disease 2019 (COVID-19) pandemic. There is increasing safety concerns regarding COVID-19 vaccines. We report a 78-year old woman who was presented with tetraparesis, paresthesias of bilateral upper extremities, and urinary retention of one-day duration. Three weeks before these symptoms, she was vaccinated with CoronaVAC vaccine (Sinovac Life Sciences, China). Spine magnetic resonance imaging showed longitudinally extensive transverse myelitis (TM) from the C1 to the T3 spinal cord segment. An extensive diagnostic workup was performed to exclude other possible causes of TM. We suggest that longitudinally extensive TM may be associated with COVID-19 vaccination in this case. To the best of our knowledge, this is the first report of longitudinally extensive TM developing after CoronaVac vaccination. Clinicians should be aware of neurological symptoms after vaccination of COVID-19.

A variant of Guillain-Barre syndrome after SARS-CoV-2 vaccination: AMSAN. Introduction - Coronavirus disease 2019 (COVID-19) is a respiratory infection that has rapidly become a global

pandemic and vaccines against SARS-CoV-2 have been developed with great success. In this article, we would like to present a patient who developed Guillain-BarrÃ© syndrome (GBS), which is a serious complication after receiving the inactive SARS-CoV-2 vaccine (CoronaVac). Case report - A 76-year-old male patient presented to the emergency department with nine days of progressive limb weakness. Two weeks prior to admission, he received the second dose of CoronaVac vaccine. Motor examination revealed decreased extremity strength with 3/5 in the lower extremities versus 4/5 in the upper extremities. Deep tendon reflexes were absent in all four extremities. Nerve conduction studies showed predominantly reduced amplitude in both motor and sensory nerves, consistent with AMSAN (acute motor and sensory axonal neuropathy). Conclusion - Clinicians should be aware of the neuro-logical complications or other side effects associated with COVID-19 vaccination so that early treatment can be an option.

Cutaneous reactions following CoronaVac COVID-19 vaccination: a case series of six healthcare workers from a single centre.

UVEITIS AFTER THE BNT162b2 mRNA VACCINATION AGAINST SARS-CoV-2 INFECTION: A Possible Association. PURPOSE: To describe uveitis cases after the BNT162b2 mRNA SARS-CoV-2 vaccination. METHODS: This is a multicenter, retrospective study. Vaccine-related uveitis diagnosis was supported by the classification of the World Health Organization Adverse Drug Terminology and the Naranjo criteria. RESULTS: Twenty-one patients (23 eyes) with a mean age of 51.3 years (23-78 years) were included. Eight of the 21 patients had a known history of uveitis. The median time from previous to current attack was 1 year (0.5-15 years). There were 21 anterior uveitis cases, two with bilateral inflammation. Eight cases occurred after the first vaccination and 13 after the second vaccination. All but three presented as mild to moderate disease. Two patients developed multiple evanescent white dot syndrome after the second vaccination. The mean time from vaccination to uveitis onset was 7.5 Â± 7.3 days (1-30 days). At final follow-up, complete resolution was achieved in all but two eyes, which showed significant improvement. One case of severe anterior uveitis developed vitritis and macular edema after the second vaccination, which completely resolved after an intravitreal dexamethasone injection. CONCLUSION: Uveitis may develop after the administration of the BNT162b2 mRNA vaccine. The most common complication was mild to moderate anterior uveitis, while multiple evanescent white dot syndrome can also occur less frequently.

Severe Dyskinesia After Administration of SARS-CoV2 mRNA Vaccine in Parkinson's Disease.

Adverse Events Following COVISHIELD Vaccination Among Adult Population in Bangladesh. The study aimed to determine how frequently the adverse events of the COVISHIELD vaccine occur among the Bangladeshi population. This cross-sectional study was conducted at Sheikh Russel Gastroliver Institute and Hospital, Mohakhali, Dhaka, Bangladesh, in May 2021. The inclusion criteria were the adult populations who received the 2nd dose of the COVISHELD vaccine and had passed 28 days following the completion of the 2nd dose. Three hundred and five persons fulfilling the inclusion criteria were asked over the telephone-based on a predesigned questionnaire. The rates of adverse events were 54.1% and 41.3% after the 1st and 2nd dose of vaccine, respectively, and the difference was statistically significant ($p < 0.001$). Pain at the injection site was the most common adverse event (32.5% following the 1st dose and 27.9% following the 2nd dose). All of the symptoms were mild and lasted for about 2 days. Age and comorbidities were significantly associated with the adverse events ($p < 0.001$). Neither doses had any vaccine-related life-threatening adverse event nor had any symptoms related to vaccine-related blood clotting. Nineteen persons (6.2%) had been diagnosed with COVID-19 after the 1st dose of vaccination, and three (1%) persons had been diagnosed with COVID-19 after the 2nd dose of vaccination. As no significant life-threatening adverse event was observed, this study might help reduce the hesitancy for vaccination among the population and thus help reduce transmission of this highly contagious virus.

Case Report: Infection With SARS-CoV-2 in the Presence of High Levels of Vaccine-Induced Neutralizing Antibody Responses. We present a case of SARS-CoV-2 B.1. 525 infection in a healthcare worker despite the presence of highly neutralizing, multivariant-specific antibodies 7 weeks after full vaccination with the mRNA vaccine BNT162b2. We show that the virus replicated to high levels in the upper respiratory tract over the course of several days in the presence of strong antibody responses. The virus was readily propagatable in vitro, demonstrating the potential to transmit to others, bolstered by the fact that several household members were equally infected. This highlights the importance of protective measures even in vaccinated individuals.

Two Cases of Post-Moderna COVID-19 Vaccine Encephalopathy Associated With Nonconvulsive Status Epilepticus. Coronavirus disease 2019 (COVID-19) infections can cause many complications, including central nervous system (CNS) complications. One of the most common COVID-19 CNS complications is COVID-19 encephalopathy, a disorder characterized by cognitive impairment, altered consciousness, and even seizures. The Moderna COVID-19Â vaccine is a recently approved mRNA-based vaccine aimed at preventing COVID-19 infections and their complications.Â Here,Â we describe two patients withÂ no known neurological or psychiatric history who presented with encephalopathy and seizures that began after part one of their Moderna COVID-19 vaccine series.Â To our knowledge, there are no other reports of post-Moderna COVID-19 vaccine encephalopathy in the literature.Â We suggest a mechanism for this complication and thoroughly discuss why the Moderna vaccine is possibly responsible, by addressing confounders in our patients.

Acute myocarditis following Comirnaty vaccination in a healthy man with previous SARS-CoV-2 infection. Myopericarditis following mRNA Covid-19 vaccination has recently been reported to health authorities in a lot of countries. They can occur in very rare cases after either the Moderna (mRNA-1273 - Spikevax) or Pfizer-BioNTech (BNT162b2 - Comirnaty) vaccination. Cases predominately occur in younger adult men within 14 days following the second dose. In this article, we present a 56 year-old man with no prior medical history, whit the exception of a mild Covid-19 infection 4 months earlier, who experienced an episode of acute epigastric pain, profuse sweating, tachycardia, hypotension 4 days after the first dose of BNT162b2 vaccine. Troponin I level was elevated. Chest X-ray, electrocardiogram, echocardiogram, coronary angiography didn't show significant abnormalities. Cardiac Magnetic Resonance showed a pattern of acute myocarditis. The condition appeared to be self-limited and the patient recovered without specific therapy. No report of acute myocarditis was observed in the BNT162b2 and mRNA-1273 trials and very rare cases, in comparison to given doses, have been reported to pharmacovigilance systems worldwide. Further surveillance and evaluation of this side effect are warranted to establish the correct balance of benefits and risks of Covid-19 mRNA vaccines, above all in children and younger people (categories with the higher reactogenicity and the lower risk of Covid-19 complications). At the present time the benefits of Covid-19 vaccination significantly exceed possible risks.

Adverse events related to COVID-19 vaccines: the need to strengthen pharmacovigilance monitoring systems. Coronavirus disease 2019 (COVID-19) is an infectious disease caused by a new species of Î²-coronavirus genus named severe acute respiratory syndrome coronavirus 2. The COVID-19 pandemic, which started in late 2019 and continues as at mid-2021, has caused enormous damage to health and lives globally. The urgent public health need has led to the development of vaccines against COVID-19 in record-breaking time. The COVID-19 vaccines have been widely rolled out for the masses by many countries following approval for emergency use by the World Health Organization and regulatory agencies in many countries. In addition, several COVID-19 vaccine candidates are undergoing clinical trials. However, myths, fears, rumors, and misconceptions persist, particularly in regard to adverse events. In this commentary, we describe the adverse events associated with

COVID-19 vaccines and discuss why it is essential to have a functional adverse event monitoring system in this context.

Concerning the unexpected prothrombotic state following some coronavirus disease 2019 vaccines. Currently, the world is coping with the COVID-19 pandemic with a few vaccines. So far, the European Medicine Agency has approved four of them. However, following widespread vaccination with the recombinant adenoviral vector-based Oxford-AstraZeneca vaccine, available only in the United Kingdom and Europe, many concerns have emerged, especially the report of several cases of the otherwise rare cerebral sinus vein thrombosis and splanchnic vein thrombosis. The onset of thrombosis particularly at these unusual sites, about 5--14â€Šdays after vaccination, along with thrombocytopenia and other specific blood test abnormalities, are the main features of the vaccine side effects. The acronym vaccine-induced prothrombotic immune thrombocytopenia (VIPIT) has been coined to name this new condition, with the aim of highlighting the difference from the classic heparin-induced thrombocytopenia (HIT). VIPIT seems to primarily affect young to middle-aged women. For this reason, the vaccine administration has been stopped or limited in a few European countries. Coagulopathy induced by the Oxford-AstraZeneca vaccine (and probably by Janssen/Johnson & Johnson vaccine as well in the USA) is likely related to the use of recombinant vector DNA adenovirus, as experimentally proven in animal models. Conversely, Pfizer and Moderna vaccines use mRNA vectors. All vaccine-induced thrombotic events should be treated with a nonheparin anticoagulant. As the condition has some similarities with HIT, patients should not receive any heparin or platelet transfusion, as these treatments may potentially worsen the clinical course. Aspirin has limited rational use in this setting and is not currently recommended. Intravenous immunoglobulins may represent another potential treatment, but, most importantly, clinicians need to be aware of this new unusual postvaccination syndrome.

Live attenuated coronavirus vaccines deficient in N7-Methyltransferase activity induce both humoral and cellular immune responses in mice. Coronaviruses (CoVs) can infect a variety of hosts, including humans, livestock and companion animals, and pose a serious threat to human health and the economy. The current COVID-19 pandemic, which is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has killed millions of people. Unfortunately, effective treatments for CoVs infection are still lacking, suggesting the importance of coronavirus vaccines. Our previous work showed that CoV nonstuctural protein 14 (nsp14) functions as (guanine-N7)-methyltransferase (N7-MTase), which is involved in RNA cap formation. Moreover, we found that N7-MTase is well conserved among different CoVs and is a universal target for developing antivirals against CoVs. Here, we show that N7-MTase of CoVs can be an ideal target for designing live attenuated vaccines. Using murine hepatitis virus strain A59 (MHV-A59), a representative and well-studied model of coronaviruses, we constructed N7-MTase-deficient recombinant MHV D330A and Y414A. These two mutants are highly attenuated in mice and exhibit similar replication efficiency to the wild-type (WT) virus in the cell culture. Furthermore, a single dose immunization of D330A or Y414A can induce long-term humoral immune responses and robust CD4(+) and CD8(+) T cell responses, which can provide full protection against the challenge of a lethal-dose of MHV-A59. Collectively, this study provides an ideal strategy to design live attenuated vaccines for coronavirus by abolishing viral RNA N7-MTase activity. This approach may apply to other RNA viruses that encode their own conservative viral N7-methyltransferase.

Vaccine-induced immune thrombotic thrombocytopenia and cerebral venous sinus thrombosis post COVID-19 vaccination; a systematic review. INTRODUCTION: The common reported adverse effects of COVID-19 vaccination consist of the injection site's local reaction followed by several non-specific flu-like symptoms. However, rare cases of vaccine-induced immune thrombotic thrombocytopenia (VITT) and cerebral venous sinus thrombosis (CVST) after viral vector vaccines

(ChAdOx1 nCoV-19 vaccine, Ad26.COV2 vaccine) have been reported. Herein we systemically reviewed the reported cases of CVST and VITT following the COVID-19 vaccination. METHODS: This systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. We searched PubMed until May 19, 2021, and the following Keywords were used: COVID Vaccine & Neurology, AstraZeneca COVID vaccine, ChAdOx1 nCoV-19 COVID vaccine, AZD1222 COVID vaccine, Janssen COVID vaccine, Johnson & Johnson COVID vaccine, Ad26.COV2 COVID vaccine. The authors evaluated the abstracts and titles of each article for screening and inclusion. English reports about post-vaccine CVST and VITT in humans were collected. RESULTS: Until May 19, we found 877 articles with the searched terms. We found 12 articles, which overall present clinical features of 36 patients with CVST and VITT after the ChAdOx1 nCoV-19 vaccine. Moreover, two articles were noted, which present 13 patients with CVST and VITT after Ad26.COV2 vaccine. The majority of the patients were females. Symptom onset occurred within one week after the first dose of vaccination (Range 4-19Â days). Headache was the most common presenting symptom. Intracerebral hemorrhage (ICH) and/or Subarachnoid hemorrhage (SAH) were reported in 49% of the patients. The platelet count of the patients was between 5 and 127 cellsÃ—10(9)/l, PF4 IgG Assay and d-Dimer were positive in the majority of the reported cases. Among 49 patients with CVST, at least 19 patients died (39%) due to complications of CVST and VITT. CONCLUSION: Health care providers should be familiar with the clinical presentations, pathophysiology, diagnostic criteria, and management consideration of this rare but severe and potentially fatal complication of the COVID-19 vaccination. Early diagnosis and quick initiation of the treatment may help to provide patients with a more favorable neurological outcome.

A comprehensive analysis of the efficacy and safety of COVID-19 vaccines. The numbers of cases and deaths from coronavirus disease 2019 (COVID-19) are continuously increasing. Many people are concerned about the efficacy and safety of the COVID-19 vaccines. We performed a comprehensive analysis of the published trials of COVID-19 vaccines and the real-world data from the Vaccine Adverse Event Reporting System. Globally, our research found that the efficacy of all vaccines exceeded 70%, and RNA-based vaccines had the highest efficacy of 94.29%; moreover, Black or African American people, young people, and males may experience greater vaccine efficacy. The spectrum of vaccine-related adverse drug reactions (ADRs) is extremely broad, and the most frequent ADRs are pain, fatigue, and headache. Most ADRs are tolerable and are mainly grade 1 or 2 in severity. Some severe ADRs have been identified (thromboembolic events, 21-75 cases per million doses; myocarditis/pericarditis, 2-3 cases per million doses). In summary, vaccines are a powerful tool that can be used to control the COVID-19 pandemic, with high efficacy and tolerable ADRs. In addition, the spectrum of ADRs associated with the vaccines is broad, and most of the reactions appear within a week, although some may be delayed. Therefore, ADRs after vaccination need to be identified and addressed in a timely manner.

Acute Myocardial Infarction Within 24 Hours After COVID-19 Vaccination. COVID-19 vaccination was launched in the United States in mid-December 2020. There are limited data on the risk of thrombotic events related to COVID-19 vaccines. In conclusion, we report 2 cases of acute myocardial infarction with onset <24 hours after the first dose of a COVID-19 vaccine in patients presenting with shoulder pain.

COVID-19 hospitalisation, mortality, vaccination, and postvaccination trends among people with schizophrenia in Israel: a longitudinal cohort study. BACKGROUND: Individuals with schizophrenia have an increased risk of severe COVID-19 outcomes, nonetheless, no previous study has provided a year-long account of this risk, or assessed postvaccination trends in this population. This study assessed temporal trends in COVID-19 hospitalisation and mortality among people with schizophrenia during the first year of the pandemic, the predictors for COVID-19 vaccination, postvaccination

infection, admission to hospital, and mortality. METHODS: In this longitudinal cohort study, people with schizophrenia (n=25â€‰539) and controls (n=25â€‰539) were assessed for COVID-19 outcomes before and after vaccination, up to April 30, 2021. Cox proportional hazard regression models and Kaplan-Meier analyses were done to assess longitudinal trends. The study used the databases of Clalit Health Services, the largest health-care organisation in Israel. FINDINGS: The sample included 51â€‰078 participants, of which 31â€‰141 (61Â·0%) male and 19â€‰937 (39Â·0%) female participants, with a mean age of 51Â·94 years (SD 15Â·62). Most of the sample was from the general Jewish population (75Â·9%), followed by the Arab (19Â·1%) and Jewish Ultraorthodox population (5Â·1%). Overall of 51â€‰078 individuals, 356 (0Â·7%) people had been hospitalised, 133 (0Â·3%) had died, and a total of 27â€‰400 (53Â·6%) had been vaccinated. People with schizophrenia showed a higher risk for COVID-19 hospitalisation (HR 4Â·81, 95% CI 3Â·57-6Â·48, p<0Â·0001) and mortality (HR 2Â·52, 95% CI 1Â·64-3Â·85, p<0Â·0001), and showed a sharper decline in survival as time progressed. The control group showed a sharper incline in probability to vaccinate (log-rank=309Â·88, p<0Â·0001). Medical comorbidity of diabetes, hypertension, obesity, or ischaemic heart disease played a significant role in predicting vaccination rates in the schizophrenia group (all p<0Â·0001), but not in the control group. Hospitalisation and mortality disparities remained higher among people with schizophrenia who had not been vaccinated in comparison to controls (incidence rate difference of 6Â·2 and 3Â·2, respectively) but substantially declined in fully vaccinated groups (incidence rate difference of 1Â·1 and -0Â·9, respectively). INTERPRETATION: People with schizophrenia have higher hospitalisation and mortality risk, yet have lower rates of vaccination than in the general population. Disparities in COVID-19 severe outcomes can be substantially reduced by national vaccination plans aimed at actively reaching out to people with schizophrenia. FUNDING: No funding.
COVID-19 vaccine safety and efficacy in patients with immune-mediated inflammatory disease: Review of available evidence. Dermatologists diagnose and treat many immune-mediated inflammatory diseases (IMID). Understanding the inherent immune dysregulation of these diseases as well as the additional disruption that comes as a result of IMID treatments has been important during the COVID-19 pandemic. With vaccines becoming widely available, dermatologists need to be familiar with the risks and benefits of vaccination in these patients, particularly those taking biologics, in order to have informed discussions with their patients. In this review, we present the current evidence related to COVID-19 vaccine safety and efficacy in patients with IMID and review existing recommendations for vaccination against SARS-CoV-2. Given the current evidence, there is minimal concern that these patients are at any greater risk of harm from COVID-19 vaccination compared to healthy controls. For most, the benefit of avoiding severe COVID-19 through vaccination will outweigh the theoretical risk of these vaccines. A question that is still outstanding is whether patients on biologics will generate a sufficient immune response to the vaccine, which may be dependent on the specific biologic therapy and indication being treated. This underscores the importance of following patients with IMID after vaccination to determine the safety, efficacy, and duration of the vaccine in this population.
Herpes zoster after ChAdOx1 nCoV-19 vaccine: a case series.
Cutaneous reactions to inactivated SARS-CoV-2 vaccine and ChAdOx1-S (recombinant) vaccine against SARS-CoV-2: a case series from the Philippines.
Psoriasis exacerbation after COVID-19 vaccination: a report of 14 cases from a single centre.
Rare cutaneous adverse effects of COVID-19 vaccines: a case series and review of the literature.
Hypertension and Covid-19 vaccines: are there any differences between the different vaccines? A safety signal.

Determining the Incidence of Asymptomatic SARS-CoV-2 Among Early Recipients of COVID-19 Vaccines (DISCOVER-COVID-19): A Prospective Cohort Study of Healthcare Workers Before, During and After Vaccination. The impact of coronavirus disease 2019 vaccination on viral characteristics of breakthrough infections is unknown. In this prospective cohort study, incidence of severe acute respiratory syndrome coronavirus 2 infection decreased following vaccination. Although asymptomatic positive tests were observed following vaccination, the higher cycle thresholds, repeat negative tests, and inability to culture virus raise questions about their clinical significance.
Arthritis of the left elbow joint after vaccination against SARS-CoV-2 infection.
Three cases of vesiculobullous non-IgE-mediated cutaneous reactions to tozinameran (Pfizer-BioNTech COVID-19 vaccine).
Herpes zoster after inactivated SARS-CoV-2 vaccine in two healthy young adults.
68Ga-DOTATOC-avid lymphadenopathies induced from COVID-19 mRNA vaccination.
Considerations for causality assessment of neurological and neuropsychiatric complications of SARS-CoV-2 vaccines: from cerebral venous sinus thrombosis to functional neurological disorder.
Systemic capillary leak syndrome after ChAdOx1 nCOV-19 (Oxford-AstraZeneca) vaccination.
Post-Vaccination Anti-SARS-CoV-2-Antibody Response in Patients with Multiple Myeloma Correlates with Low CD19+ B-Lymphocyte Count and Anti-CD38 Treatment. Few data are available regarding the efficacy of anti-SARS-CoV-2 vaccines in patients with hematological malignancies, and particular, plasma cell neoplasia. This ongoing single-center study aimed to describe the level of post-vaccination anti-SARS-CoV-2-antibodies depending on B lymphocyte count, current therapy, and remission status of patients with multiple myeloma and related plasma cell dyscrasia, after the first dose of anti-SARS-CoV-2 vaccination. The 82 patients included in this study received SARS-CoV-2 vaccines (including mRNA- and vector-based vaccines) as a routine measure. After the first vaccination, a positive SARS-CoV-2 spike protein antibody titer (SP-AbT) was detected in 23% of assessable patients. SARS-CoV-2 SP-AbT was significantly higher in patients with higher CD19+ B lymphocyte counts. A cut-off value of â‰¥30 CD19+ B cells/ÂµL was significantly positive correlating with higher SARS-CoV-2 SP-AbT. In contrast, current treatment with anti-CD38-antibodies has led to significantly reduced SP-AbT titers. Furthermore, in multivariable linear regression, higher age and insufficiently controlled disease significantly correlated negatively with SARS-CoV-2 SP-AbT. Conversely, treatment with immunomodulatory drugs did not harm the development of antibody titers. Based on our results, the majority of myeloma patients respond poorly after receiving the first dose of any anti-SARS-CoV-2 vaccination and need booster vaccination.
Guillain-BarrÃ© syndrome is infrequent among recipients of the BNT162b2 mRNA COVID-19 vaccine. Vaccines are the most effective strategy to mitigate the global impact of COVID-19. However, vaccine hesitancy is common, particularly among minorities. Guillain-BarrÃ© syndrome (GBS) is the most common autoimmune illness of the peripheral nervous system, occurring at an incidence of 1.1/100,000 worldwide. A causal link between mRNA vaccines and GBS has not been previously evaluated. We analyzed a cohort of 3,890,250 Hispanic/Latinx recipients of the BNT162b2 mRNA vaccine (613,780 of whom had already received both doses) for incident GBS occurring within 30Â days from vaccine administration. Seven cases of GBS were detected among first-dose recipients, for an observed incidence of 0.18/100,000 administered doses during the prespecified timeframe of 30Â days. No cases were reported after second-dose administration. Our data suggest that, among recipients of the BNT162b2 mRNA vaccine, GBS may occur at the expected community-based rate; however, this should be taken with caution as the current incidence of GBS among the unvaccinated population against COVID-19 is still undetermined. We hope that this preliminary data will increase the public perception of safety toward mRNA-based vaccines and reduce vaccine hesitancy.

Multiple Sclerosis, Disease-Modifying Therapies and COVID-19: A Systematic Review on Immune Response and Vaccination Recommendations. Understanding the risks of COVID-19 in patients with Multiple Sclerosis (MS) receiving disease-modifying therapies (DMTs) and their immune reactions is vital to analyze vaccine response dynamics. A systematic review on COVID-19 course and outcomes in patients receiving different DMTs was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement. Emerging data on SARS-CoV-2 vaccines was used to elaborate recommendations. Data from 4417 patients suggest that MS per se do not portend a higher risk of severe COVID-19. As for the general population, advanced age, comorbidities, and higher disability significantly impact COVID-19 outcomes. Most DMTs have a negligible influence on COVID-19 incidence and outcome, while for those causing severe lymphopenia and hypogammaglobulinemia, such as anti-CD20 therapies, there might be a tendency of increased hospitalization, worse outcomes and a higher risk of re-infection. Blunted immune responses have been reported for many DMTs, with vaccination implications. Clinical evidence does not support an increased risk of MS relapse or vaccination failure, but vaccination timing needs to be individually tailored. For cladribine and alemtuzumab, it is recommended to wait 3-6 months after the last cycle until vaccination. For the general anti-CD20 therapies, vaccination must be deferred toward the end of the cycle and the next dose administered at least 4-6 weeks after completing vaccination. Serological status after vaccination is highly encouraged. Growing clinical evidence and continuous surveillance are extremely important to continue guiding future treatment strategies and vaccination protocols.

Neutralizing Antibodies Titers and Side Effects in Response to BNT162b2 Vaccine in Healthcare Workers with and without Prior SARS-CoV-2 Infection. The main expected result of a vaccine against viruses is the ability to produce neutralizing antibodies. Currently, several vaccines against SARS-CoV-2 are being applied to prevent mortal complications, being Pfizer-BioNTech (BNT162b2) one of the first to be authorized in the USA and Mexico (11 December 2020). This study evaluated the efficacy of this vaccine on antibody production with neutralizing capacity and its side effects in healthcare workers with and without prior SARS-CoV-2 infection and in a group of unvaccinated individuals with prior COVID-19. The main findings are the production of 100% neutralizing antibodies in both groups after the second dose, well-tolerated adverse effects, the possible presence of immunosenescence, and finally, we support that a single dose of this vaccine in individuals with prior COVID-19 would be sufficient to achieve an immunization comparable to people without prior COVID-19 with a complete vaccination program (2 doses).

Association of Influenza Vaccination and Prognosis in Patients Testing Positive to SARS-CoV-2 Swab Test: A Large-Scale Italian Multi-Database Cohort Study. To investigate the association of the 2019-2020 influenza vaccine with prognosis of patients positive for SARS-CoV-2A, a large multi-database cohort study was conducted in four Italian regions (i.e., Lazio, Lombardy, Veneto, and Tuscany) and the Reggio Emilia province (Emilia-Romagna). More than 21 million adults were residing in the study area (42% of the population). We included 115,945 COVID-19 cases diagnosed during the first wave of the pandemic (February-May, 2020); 34.6% of these had been vaccinated against influenza. Three outcomes were considered: hospitalization, death, and intensive care unit (ICU) admission/death. The adjusted relative risk (RR) of being hospitalized in the vaccinated group when compared with the non-vaccinated group was 0.87 (95% CI: 0.86-0.88). This reduction in risk was not confirmed for death (RR = 1.04; 95% CI: 1.01-1.06), or for the combined outcome of ICU admission or death. In conclusion, our study, conducted on the vast majority of the population during the first wave of the pandemic in Italy, showed a 13% statistically significant reduction in the risk of hospitalization in some geographical areas and in the younger population. No impact of seasonal

influenza vaccination on COVID-19 prognosis in terms of death and death or ICU admission was estimated.
Nationwide Seroprevalence of SARS-CoV-2 IgG Antibodies among Four Groups of Primary Health-Care Workers and Their Household Contacts 6 Months after the Initiation of the COVID-19 Vaccination Campaign in France: SeroPRIM Study Protocol. BACKGROUND: The protocol study will focus on the seroprevalence of IgG antibodies to SARS-CoV-2 achieved by vaccination and/or natural protection as well as the history, symptoms, and risk factors for SARS-CoV-2 in four primary health-care workers (PHCWs) and their household contacts in metropolitan France. METHODS: Here, we propose a protocol for a nationwide survey to determine the seroprevalence of IgG antibodies to SARS-CoV-2 achieved by vaccination and/or natural protection in four PHCW populations (general practitioners, pediatricians, pharmacists and assistants, and dentists and assistants) and their household contacts. Participants will be included from June to July 2021 (Phase 1) among PHCW populations located throughout metropolitan France. They will be asked to provide a range of demographic and behavioral information since the first SARS-CoV-2 wave and a self-sampled dried blood spot. Phase 1 will involve also a questionnaire and serological study of PHCWs' household contacts. Seroprevalence will be estimated using two ELISAs designed to detect specific IgG antibodies to SARS-CoV-2 in humoral fluid, and these results will be confirmed using a virus neutralization test. This study will be repeated from November to December 2021 (Phase 2) to evaluate the evolution of immune status achieved by vaccination and/or natural protection of PHCWs and to describe the history of exposure to SARS-CoV-2.
COVID-19 Vaccines and Thrombosis-Roadblock or Dead-End Street? Two adenovirus-based vaccines, ChAdOx1 nCoV-19 and Ad26.COV2.S, and two mRNA-based vaccines, BNT162b2 and mRNA.1273, have been approved by the European Medicines Agency (EMA), and are invaluable in preventing and reducing the incidence of coronavirus disease-2019 (COVID-19). Recent reports have pointed to thrombosis with associated thrombocytopenia as an adverse effect occurring at a low frequency in some individuals after vaccination. The causes of such events may be related to SARS-CoV-2 spike protein interactions with different C-type lectin receptors, heparan sulfate proteoglycans (HSPGs) and the CD147 receptor, or to different soluble splice variants of the spike protein, adenovirus vector interactions with the CD46 receptor or platelet factor 4 antibodies. Similar findings have been reported for several viral diseases after vaccine administration. In addition, immunological mechanisms elicited by viral vectors related to cellular delivery could play a relevant role in individuals with certain genetic backgrounds. Although rare, the potential COVID-19 vaccine-induced immune thrombotic thrombocytopenia (VITT) requires immediate validation, especially in risk groups, such as the elderly, chronic smokers, and individuals with pre-existing incidences of thrombocytopenia; and if necessary, a reformulation of existing vaccines.
Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination: What Do We Know So Far? This is a cross-sectional study of 29 published cases of acute myopericarditis following COVID-19 mRNA vaccination. The most common presentation was chest pain within 1-5 days after the second dose of mRNA COVID-19 vaccination. All patients had an elevated troponin. Cardiac magnetic resonance imaging revealed late gadolinium enhancement consistent with myocarditis in 69% of cases. All patients recovered clinically rapidly within 1-3 weeks. Most patients were treated with non-steroidal anti-inflammatory drugs for symptomatic relief, and 4 received intravenous immune globulin and corticosteroids. We speculate a possible causal relationship between vaccine administration and myocarditis. The data from our analysis confirms that all myocarditis and pericarditis cases are mild and resolve within a few days to few weeks. The bottom line is that the risk of cardiac complications among children and adults due to severe acute respiratory syndrome

coronavirus 2 (SARS-CoV-2) infection far exceeds the minimal and rare risks of vaccination-related transient myocardial or pericardial inflammation.

Lymphadenopathy after the Anti-COVID-19 Vaccine: Multiparametric Ultrasound Findings. Background: Post-anti-COVID-19 vaccine lymphadenopathy has recently been described in the literature. In this study, we investigated the multiparametric US findings of patients with post-vaccine lymphadenopathy and compared these findings among different anti-COVID-19 vaccines. Methods: We retrospectively evaluated 24 patients who underwent US between January and May 2021 due to post-anti-COVID-19 lymphadenopathy. The presence, size, location, number, morphology, cortex-hilum, superb microvascular imaging (SMI) and elastosonography of lymph nodes were assessed. Descriptive statistics were calculated and differences among anti-COVID-19 vaccines were analyzed using the Kruskal-Wallis test. A p-value â‰¤ 0.05 was considered statistically significant. Results: Sixty-six nodes were assessed. They were axillary (mean 1.6 cm Â± 0.16) in 11 patients (45.8%) and supraclavicular (mean 0.9 cm Â± 0.19) in 13 patients (54.2%). In 20 patients (83.3%), the number of nodes was â‰¤3. Prevalent US features included oval morphology (18, 75%), asymmetric cortex with hilum evidence (9, 37.5%), central and peripheral vascular signals (12, 50%) at SMI and elastosonography patterns similar to the surrounding tissue (15, 71.4%). No significant differences among the three anti-COVID-19 vaccines were observed ($p > 0.05$). Conclusions: Anti-COVID-19 vaccines may present lymphadenopathy with "worrisome" US features regarding size, shape, morphology, cortex-hilum, SMI and elastosonography. An awareness of the patient's history and US findings may help in the early recognition of this clinical scenario and in the appropriate selection of patients for a short-term US follow-up.

[SARS-CoV-2 vaccine-induced immune thrombosis and thrombocytopenia]. Vaccine-induced immune thrombosis and thrombocytopenia (VITT) is a new syndrome, which has emerged after introduction of the adenovirus vector-based COVID-19 vaccines ChAdOx1 nCoV-19 og Ad26.COV2-SVITT is characterised by venous thrombosis at unusual, and often multiple localisations, especially including cerebral venous sinus thrombosis. Besides, bleeding manifestations often occur. Biochemically, VITT is characterised by thrombocytopaenia and elevated fibrin d-dimer. VITT is a rapidly progressing and potentially life-threatening syndrome where rapid diagnosis and treatment are essential as argued in this review.

Vaccine-induced severe thrombotic thrombocytopenia following COVID-19 vaccination: a report of an autoptic case and review of the literature. OBJECTIVE: Vaccine-induced immune thrombocytopenia (VITT) is a new syndrome occurring primarily in healthy young adults, with a female predominance, after receiving the first dose of ChAdOx1 nCoV-19 vaccine. We describe VITT syndrome characterized by severe thrombosis and thrombocytopenia found in our patient, with fatal outcome. CASE REPORT: A 58-year-old man, after 13 days from the first administration of ChAdOx1 nCoV-19 vaccine (AstraZeneca), presented with abdominal pain, diarrhea and vomitus. Laboratory tests revealed a severe thrombocytopenia, low fibrinogen serum levels and marked increase of D-dimer serum levels. The patient quickly developed a multiple organ failure, till death, three days after the hospital admission. RESULTS: At histology, in the lungs, interalveolar septa appeared thickened with microthrombi in the capillaries and veins. Interalveolar septa appeared thickened and showed vascular proliferation. Thrombi were detected in the capillaries of glomerular tufts. In the hearth, thrombi were observed in veins and capillaries. In the liver, voluminous fibrin thrombi were diffusely observed in the branches of the portal vein. Microthrombi were also found in the vasa vasorum of the wall of abdominal aorta. In the brain, microthrombi were observed in the capillaries of the choroid plexuses. Diffuse hemorrhagic necrosis was observed in the intestinal wall with marked congestion of the venous vessels. CONCLUSIONS: In our patient, the majority of data necessary for a VITT final diagnosis were present: thrombocytopenia and thrombosis in pulmonary, portal, hepatic, renal and

mesenteric veins, associated with a marked increase of D-dimer serum levels. The finding of cerebral thrombosis in choroid plexuses, is a new finding in VITT. These features are suggestive for a very aggressive form of VITT.
2021 Clinical Practice Guidelines for Diabetes Mellitus of the Korean Diabetes Association. The Committee of Clinical Practice Guidelines of the Korean Diabetes Association (KDA) updated the previous clinical practice guidelines for Korean adults with diabetes and prediabetes and published the seventh edition in May 2021. We performed a comprehensive systematic review of recent clinical trials and evidence that could be applicable in real-world practice and suitable for the Korean population. The guideline is provided for all healthcare providers including physicians, diabetes experts, and certified diabetes educators across the country who manage patients with diabetes or the individuals at the risk of developing diabetes mellitus. The recommendations for screening diabetes and glucose-lowering agents have been revised and updated. New sections for continuous glucose monitoring, insulin pump use, and non-alcoholic fatty liver disease in patients with diabetes mellitus have been added. The KDA recommends active vaccination for coronavirus disease 2019 in patients with diabetes during the pandemic. An abridgement that contains practical information for patient education and systematic management in the clinic was published separately.
Autoimmunity after Coronavirus Disease 2019 (COVID-19) Vaccine: A Case of Acquired Hemophilia A.
Three cases of acute venous thromboembolism in females after vaccination for coronavirus disease 2019. Since December 2020, four vaccines for SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) have been developed, and three have been approved for immediate use in the United States. Two are mRNA vaccines, and one uses a viral vector mechanism. Thrombotic complications have been reported after vaccine administration, which were primarily cerebral sinus thromboses after administration of the viral vector vaccines. To the best of our knowledge, we are the first to report venous thrombotic complications within days of administration of the mRNA-1273 (Moderna) vaccine. We present a series of three women who developed venous thromboembolism after RNA-1273 vaccination at a single healthcare system.
Detection of neutralizing anti-severe acute respiratory syndrome coronavirus 2 antibodies in patients with common variable immunodeficiency after immunization with messenger RNA vaccines.
Relapse of class V lupus nephritis after vaccination with COVID-19 mRNA vaccine.
Acute kidney injury with gross hematuria and IgA nephropathy after COVID-19 vaccination.
Systemic IL-15, IFN-Î³, and IP-10/CXCL10 signature associated with effective immune response to SARS-CoV-2 in BNT162b2 mRNA vaccine recipients. Early responses to vaccination are important for shaping both humoral and cellular protective immunity. Dissecting innate vaccine signatures may predict immunogenicity to help optimize the efficacy of mRNA and other vaccine strategies. Here, we characterize the cytokine and chemokine responses to the 1(st) and 2(nd) dose of the BNT162b2 mRNA (Pfizer/BioNtech) vaccine in antigen-naive and in previously coronavirus disease 2019 (COVID-19)-infected individuals (NCT04743388). Transient increases in interleukin-15 (IL-15) and interferon gamma (IFN-Î³) levels early after boost correlate with Spike antibody levels, supporting their use as biomarkers of effective humoral immunity development in response to vaccination. We identify a systemic signature including increases in IL-15, IFN-Î³, and IP-10/CXCL10 after the 1(st) vaccination, which were enriched by tumor necrosis factor alpha (TNF-Î±) and IL-6 after the 2(nd) vaccination. In previously COVID-19-infected individuals, a single vaccination results in both strong cytokine induction and antibody titers similar to the ones observed upon booster vaccination in antigen-naive individuals, a result with potential implication for future public health recommendations.
Immunity to SARS-CoV-2 induced by infection or vaccination. Adaptive immune responses play critical roles in viral clearance and protection against re-infection, and SARS-CoV-2 is no exception. What is exceptional is the rapid characterization of the immune response to the virus performed by

researchers during the first 20 months of the pandemic. This has given us a more detailed understanding of SARS-CoV-2 compared to many viruses that have been with us for a long time. Furthermore, effective COVID-19 vaccines were developed in record time, and their rollout worldwide is already making a significant difference, although major challenges remain in terms of equal access. The pandemic has engaged scientists and the public alike, and terms such as seroprevalence, neutralizing antibodies, antibody escape and vaccine certificates have become familiar to a broad community. Here, we review key findings concerning B cell and antibody (Ab) responses to SARS-CoV-2, focusing on non-severe cases and anti-spike (S) Ab responses in particular, the latter being central to protective immunity induced by infection or vaccination. The emergence of viral variants that have acquired mutations in S acutely highlights the need for continued characterization of both emerging variants and Ab responses against these during the evolving pathogen-immune system arms race.

Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings - Barnstable County, Massachusetts, July 2021. During July 2021, 469 cases of COVID-19 associated with multiple summer events and large public gatherings in a town in Barnstable County, Massachusetts, were identified among Massachusetts residents; vaccination coverage among eligible Massachusetts residents was 69%. Approximately three quarters (346; 74%) of cases occurred in fully vaccinated persons (those who had completed a 2-dose course of mRNA vaccine [Pfizer-BioNTech or Moderna] or had received a single dose of Janssen [Johnson & Johnson] vaccine â‰¥14 days before exposure). Genomic sequencing of specimens from 133 patients identified the B.1.617.2 (Delta) variant of SARS-CoV-2, the virus that causes COVID-19, in 119 (89%) and the Delta AY.3 sublineage in one (1%). Overall, 274 (79%) vaccinated patients with breakthrough infection were symptomatic. Among five COVID-19 patients who were hospitalized, four were fully vaccinated; no deaths were reported. Real-time reverse transcription-polymerase chain reaction (RT-PCR) cycle threshold (Ct) values in specimens from 127 vaccinated persons with breakthrough cases were similar to those from 84 persons who were unvaccinated, not fully vaccinated, or whose vaccination status was unknown (medianÂ =Â 22.77 and 21.54, respectively). The Delta variant of SARS-CoV-2 is highly transmissible (1); vaccination is the most important strategy to prevent severe illness and death. On July 27, CDC recommended that all persons, including those who are fully vaccinated, should wear masks in indoor public settings in areas where COVID-19 transmission is high or substantial.* Findings from this investigation suggest that even jurisdictions without substantial or high COVID-19 transmission might consider expanding prevention strategies, including masking in indoor public settings regardless of vaccination status, given the potential risk of infection during attendance at large public gatherings that include travelers from many areas with differing levels of transmission.

COVID-19 Vaccine Safety in Adolescents Aged 12-17 Years - United States, December 14, 2020-July 16, 2021. As of July 30, 2021, among the three COVID-19 vaccines authorized for use in the United States, only the Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine is authorized for adolescents aged 12-17 years. The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Pfizer-BioNTech vaccine for use in persons aged â‰¥16 years on December 11, 2020 (1); the EUA was expanded to include adolescents aged 12-15 years on May 10, 2021 (2), based on results from a Phase 3 clinical trial (3). Beginning in June 2021, cases of myocarditis and myopericarditis (hereafter, myocarditis) after receipt of Pfizer-BioNTech vaccine began to be reported, primarily among young males after receipt of the second dose (4,5). On June 23, 2021, CDC's Advisory Committee on Immunization Practices (ACIP) reviewed available data and concluded that the benefits of COVID-19 vaccination to individual persons and the population outweigh the risks for myocarditis and recommended continued use of the vaccine in persons aged â‰¥12 years (6). To

further characterize safety of the vaccine, adverse events after receipt of Pfizer-BioNTech vaccine reported to the Vaccine Adverse Event Reporting System (VAERS) and adverse events and health impact assessments reported in v-safe (a smartphone-based safety surveillance system) were reviewed for U.S. adolescents aged 12-17 years during December 14, 2020-July 16, 2021. As of July 16, 2021, approximately 8.9 million U.S. adolescents aged 12-17 years had received Pfizer-BioNTech vaccine.* VAERS received 9,246 reports after Pfizer-BioNTech vaccination in this age group; 90.7% of these were for nonserious adverse events and 9.3% were for serious adverse events, including myocarditis (4.3%). Approximately 129,000 U.S. adolescents aged 12-17 years enrolled in v-safe after Pfizer-BioNTech vaccination; they reported local (63.4%) and systemic (48.9%) reactions with a frequency similar to that reported in preauthorization clinical trials. Systemic reactions were more common after dose 2. CDC and FDA continue to monitor vaccine safety and provide data to ACIP to guide COVID-19 vaccine recommendations.
Delayed Cutaneous Hypersensitivity Reaction to Vaxzevria (ChAdOx1-S) Vaccine against SARS-CoV-2. Recently, an increasing number of cases with delayed cutaneous reaction after immunization with mRNA-based vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been reported. This adverse reaction, which is considered a delayed-type or T cell-mediated hypersensitivity reaction, has been described for the Moderna (mRNA-1273) and Comirnaty (Pfizer/BioNTech, BNT162b2) vaccines. We describe a delayed large local cutaneous reaction in a patient who received the viral vector vaccine Vaxzevria (ChAdOx1-S, AstraZeneca). The time course and clinical symptoms of delayed skin reaction after mRNA vaccines have a similar pattern that we recognized in our patient after Vaxzevria vaccination. This phenomenon has not been described in the Vaxzevria clinical trials and is to our knowledge the first report of this adverse reaction to a vector-based SARS-CoV-2 vaccine. With this, we hope to raise awareness about delayed injection site reactions that also occur after viral vector vaccines and to encourage additional reporting and patient education regarding the cutaneous reactions after coronavirus disease 2019 (COVID-19) vaccination.
To clot or not to clot? Ad is the question-Insights on mechanisms related to vaccine-induced thrombotic thrombocytopenia. Vaccine-induced immune thrombotic thrombocytopenia (VITT) has caused global concern. VITT is characterized by thrombosis and thrombocytopenia following COVID-19 vaccinations with the AstraZeneca ChAdOx1 nCov-19 and the Janssen Ad26.COV2.S vaccines. Patients present with thrombosis, severe thrombocytopenia developing 5-24Â days following first dose of vaccine, with elevated D-dimer, and PF4 antibodies, signifying platelet activation. As of June 1, 2021, more than 1.93Â billion COVID-19 vaccine doses had been administered worldwide. Currently, 467 VITT cases (0.000024%) have been reported across the UK, Europe, Canada, and Australia. Guidance on diagnosis and management of VITT has been reported but the pathogenic mechanism is yet to be fully elucidated. Here, we propose and discuss potential mechanisms in relation to adenovirus induction of VITT. We provide insights and clues into areas warranting investigation into the mechanistic basis of VITT, highlighting the unanswered questions. Further research is required to help solidify a pathogenic model for this condition.
A vaccination update for rheumatologists-SARS-CoV-2, influenza and herpes zoster.
Age and Gender Disparities in Adverse Events Following COVID-19 Vaccination: Real-World Evidence Based on Big Data for Risk Management. Background: Two coronavirus disease 2019 (COVID-19) vaccines have received emergency use authorizations in the U.S. However, the safety of these vaccines in the real-world remains unknown. Methods: We reviewed adverse events (AEs) following COVID-19 vaccination among adults in the Vaccine Adverse Event Reporting System (VAERS) from December 14, 2020, through January 22, 2021. We compared the top 10 AEs, serious AEs, along with office and emergency room (ER) visits by age (18-64 years, â‰¥65 years) and gender (female, male). Results: There were age and gender disparities among adults with AEs following COVID-19

vaccination. Compared to younger adults aged between 18 and 64 years, older adults were more likely to report serious AEs, death, permanent disability, and hospitalization. Males were more likely to report serious AEs, death, and hospitalization compared to females. Conclusions: COVID-19 vaccines are generally safe but possible age and gender disparities in reported AEs may exist.

Cardiovascular Adverse Events Reported from COVID-19 Vaccines: A Study Based on WHO Database. BACKGROUND: Thirteen COVID-19 vaccines are granted emergency approval. It is crucial to monitor their adverse events post vaccination. The present study focuses on cardiovascular adverse events post-COVID-19 vaccination and aims to determine adverse events with the administered vaccine. METHODOLOGY: The cardiovascular (CVS) adverse events were extracted for three broad headings (SOCs) - cardiac disorders, vascular disorders, and investigations. Descriptive statistics were reported in the form of percentage and frequency, and the disproportionality analysis was conducted. RESULTS: For the cardiovascular system, 4863 adverse events (AEs) were reported from BNT162b2 Pfizer, 1222 AstraZeneca, Moderna, and other COVID-19 vaccines. Common adverse events observed with vaccines under study were tachycardia (16.41%), flushing (12.17%), hypertension (5.82%), hypotension (3.60%) and peripheral coldness (2.41%). Based on disproportionality analysis (IC(025) values), acute myocardial infarction, cardiac arrest, and circulatory collapse were linked to the vaccines in the age group >75 years. Hypertension, severe hypertension, supraventricular tachycardia, sinus tachycardia, and palpitations were associated across all age groups and either gender. Amongst the investigations, abnormal ECG findings raised C-reactive protein, elevated D dimer, and troponin were reported in specific age groups or gender or all subjects. CONCLUSION: Although cardiovascular events have been reported with the COVID-19 vaccines, the causality is yet to be established because such CVS AEs are also usually associated with the general public even without intervention. Hence, people should be administered these vaccines, and sustained monitoring of these AEs should be done.

A Postoperative Man with Marfan Syndrome with Palpitations and Chest Pain After Receiving the SARS-CoV-2 Vaccine. At the moment, the SARS-CoV-19 pandemic is still attacking the health of humanity, and vaccines are the primary health strategy to eradicate this global challenge. So, with the exception of the SARS-CoV-2 vaccine, no vaccine for any disease has been brought to clinical use so quickly. Therefore, even with strict management, it can still bring some special adverse effects. One of the most notable is the adverse cardiovascular reactions to SARS-CoV-2 vaccines. No case reports of individuals with irreversible arrhythmia complications following the SARS-CoV-2 vaccine have been found in the available literature. We report the first case of a postoperative man with Marfan syndrome with atrial fibrillation after receiving the SARS-CoV-2 vaccine.

Remitting seronegative symmetrical synovitis with pitting oedema following BNT162b2 mRNA COVID-19 vaccination. Remitting seronegative symmetrical synovitis with pitting oedema (RS3PE) is a rare inflammatory condition that occurs in older adults. Here, we report a case of an 80-year-old man with no history of rheumatic disease who presented with acute onset of bilateral hand pain, pitting oedema and synovitis after the second dose of the BNT162b2 mRNA C0VID-19 vaccine. Laboratory workup revealed elevated inflammatory markers and negative autoantibodies. Significant improvement was noted with prednisolone. This is the first reported case of RS3PE in an elderly patient with no previous rheumatic disease following mRNA COVID-19 vaccination.

Analysis of intracranial haemorrhage following tozinameran (BNT162b2, Pfizer-BioNTech).

Perimyocarditis following first dose of the mRNA-1273 SARS-CoV-2 (Moderna) vaccine in a healthy young male: a case report. BACKGROUND: Half of U.S. adults have received at least one dose of the COVID-19 vaccines produced by either Pfizer, Moderna, or Johnson and Johnson, which represents a major milestone in the ongoing pandemic. Given the emergency use authorizations for these vaccines, their side effects and safety were assessed over a compressed time period. Hence,

ongoing monitoring for vaccine-related adverse events is imperative for a full understanding and delineation of their safety profile. CASE PRESENTATION: An 22-year-old Caucasian male presented to our hospital center complaining of pleuritic chest pain. Six months prior he had a mild case of COVID-19, but was otherwise healthy. He had received his first dose of the Moderna vaccine three days prior to developing symptoms. Laboratory analysis revealed a markedly elevated troponin and multiple imaging modalities during his hospitalization found evidence of wall motion abnormalities consistent with a diagnosis of perimyocarditis. He was started on aspirin and colchicine with marked improvement of his symptoms prior to discharge. CONCLUSIONS: We present a case of perimyocarditis that was temporally related to COVID-19 mRNA vaccination in an young male with prior COVID-19 infection but otherwise healthy. Our case report highlights an albeit rare but important adverse event for clinicians to be aware of. It also suggests a possible mechanism for the development of myocardial injury in our patient.

Antibody and TÂ cell immune responses following mRNA COVID-19 vaccination in patients with cancer.

Accelerated COVID-19 vaccine development: milestones, lessons, and prospects. The development of effective vaccines to combat infectious diseases is a complex multi-year and multi-stakeholder process. To accelerate the development of vaccines for coronavirus disease 2019 (COVID-19), a novel pathogen emerging in late 2019 and spreading globally by early 2020, the United States government (USG) mounted an operation bridging public and private sector expertise and infrastructure. The success of the endeavor can be seen in the rapid advanced development of multiple vaccine candidates, with several demonstrating efficacy and now being administered around the globe. Here, we review the milestones enabling the USG-led effort, the methods utilized, and ensuing outcomes. We discuss the current status of COVID-19 vaccine development and provide a perspective for how partnership and preparedness can be better utilized in response to future public-health pandemic emergencies.

Evaluation of Immune Response and Disease Status in Systemic Lupus Erythematosus Patients Following SARS-CoV-2 Vaccination. OBJECTIVE: To evaluate seroreactivity and disease flares after COVID-19 vaccination in a multiethnic/multiracial cohort of patients with systemic lupus erythematosus (SLE). METHODS: Ninety SLE patients and 20 healthy controls receiving a complete COVID-19 vaccine regimen were included. IgG seroreactivity to the SARS-CoV-2 spike receptor-binding domain (RBD) and SARS-CoV-2 microneutralization were used to evaluate B cell responses; interferon-Î³ (IFNÎ³) production was measured by enzyme-linked immunospot (ELISpot) assay in order to assess T cell responses. Disease activity was measured by the hybrid SLE Disease Activity Index (SLEDAI), and flares were identified according to the Safety of Estrogens in Lupus Erythematosus National Assessment-SLEDAI flare index. RESULTS: Overall, fully vaccinated SLE patients produced significantly lower IgG antibodies against SARS-CoV-2 spike RBD compared to fully vaccinated controls. Twenty-six SLE patients (28.8%) generated an IgG response below that of the lowest control (<100 units/ml). In logistic regression analyses, the use of any immunosuppressant or prednisone and a normal anti-double-stranded DNA antibody level prior to vaccination were associated with decreased vaccine responses. IgG seroreactivity to the SARS-CoV-2 spike RBD strongly correlated with the SARS-CoV-2 microneutralization titers and correlated with antigen-specific IFNÎ³ production determined by ELISpot. In a subset of patients with poor antibody responses, IFNÎ³ production was similarly diminished. Pre- and postvaccination SLEDAI scores were similar in both groups. Postvaccination flares occurred in 11.4% of patients; 1.3% of these were severe. CONCLUSION: In a multiethnic/multiracial study of SLE patients, 29% had a low response to the COVID-19 vaccine which was associated with receiving immunosuppressive therapy. Reassuringly, severe disease flares were

rare. While minimal protective levels remain unknown, these data suggest that protocol development is needed to assess the efficacy of booster vaccination.
Electromyoneurography and laboratory findings in a case of Guillain-BarrÃ© syndrome after second dose of Pfizer COVID-19 vaccine. Guillain-Barre syndrome (GBS) is an acute immune-mediated disease of the peripheral nerves and nerve roots (polyradiculoneuropathy) that is usually elicited by various infections. We present a case of GBS after receiving the second dose of Pfizer-COVID 19 vaccine. Diagnosis was made after performing an accurate clinical examination, electromyoneurography and laboratory tests. In particular, anti-ganglioside antibodies have tested positive. During this pandemic with ongoing worldwide mass vaccination campaign, it is critically important for clinicians to rapidly recognize neurological complications or other side effects associated with COVID-19 vaccination.
Cumulative Adverse Event Reporting of Anaphylaxis After mRNA COVID-19 Vaccine (Pfizer-BioNTech) Injections in Japan: The First-Month Report. INTRODUCTION: In mid-February, the nationwide immunization plan for the prevention of coronavirus disease 2019 (COVID-19) started in Japan (at first primarily focused on health professionals) using an mRNA-based vaccine (Pfizer/BioNTech). During the phase-in period from February to March, attention was focused on post-vaccination anaphylaxis and anaphylactoid symptoms from the viewpoint of ensuring the safety of the vaccination program. OBJECTIVE: The aim of this report was to provide an update on the status of anaphylaxis and anaphylactoid symptoms occurring after vaccination for COVID-19, as reported under the Adverse Event Following Immunization (AEFI) reporting system in Japan. METHODS: The Pharmaceutical and Medical Devices Agency (PMDA) received AEFI reports from health professionals and manufacturers under the reporting system for AEFI after vaccination for COVID-19, which has been in operation since mid-February 2021. Reported AEFIs of anaphylaxis and anaphylactoid symptoms were assessed using the Brighton Collaboration Criteria to assess diagnostic certainty. RESULTS: 1-month since Japan started the vaccination program for COVID-19 in February 2021, 578,835 doses have been administered to health professionals, with the PMDA receiving 181 suspected event reports of anaphylaxis and anaphylactoid symptoms. In 171 of these 181 cases, women developed these symptoms. Among 181 cases evaluated according to the Brighton Collaboration Criteria, 47 cases (26%) were classified as level 1-3 (reporting rate: 8.1/100,000 doses). CONCLUSION: The results appear similar to reported AEFIs in foreign studies of coronavirus vaccine administration to health professionals, although the reporting rate was higher. Further work is needed to examine the causal relationship of anaphylaxis reactions to coronavirus vaccine administration. Issues of multiple reporting and possible sex/age bias also remain to be analyzed.
Neuralgic amyotrophy following COVID-19 mRNA vaccination.
Myocarditis and Pericarditis After Vaccination for COVID-19. This study investigates the incidence of myocarditis and pericarditis emergency department or inpatient hospital encounters before COVID-19 vaccine availability (January 2019â€“January 2021) and during a COVID-19 vaccination period (February-May 2021) in a large US health care system.
[Confusion and abdominal pain after COVID-19 vaccination]. BACKGROUND: Vaccine-induced immune thrombotic trombocytopenia (VITT) is a rare phenomenon, that may present with diffuse and atypical symptoms. CASE DESCRIPTION: We present a case of 63 years old female patient with abdominal pain, confusion and tromboctytopenia. CT scan shows sinustrombosis and trombosis of the vena renalis. The diagnosis VITT was confirmed by a positive HIT test. After initiating treatment with immunoglobulines and a non-heparinoid anticoagulans, symptoms improved and platelet count increased. CONCLUSION: This case illustrates that awareness in case of atypical symptoms and a history of vaccination is important to recognize this phenomenon.

[Vaccine-induced immune thrombotic thrombocytopenia; extremely rare adverse event with major potential consequences]. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is diagnosed if there is venous or arterial thrombosis with thrombocytopenia caused by antibodies against platelet factor 4 (PF4) that activate thrombocytes and is confirmed by a heparin-induced platelet activation (HIPA) test, occurring 4 to 28 days after vaccination against COVID19. This extremely rare syndrome has been recognized after Astra Zeneca (reporting incidence 0.91 per 100.000) and Janssen vaccins (0.22 per 100.000). Causality with the vaccine is difficult to ascertain if the HIPA test is negative, or if there is severe thrombosis (such as cerebral sinus or splanchnic thrombosis) without thrombocytopenia. Symptoms compatible with thrombosis or bleeding occurring in a specific time window after vaccination should prompt urgent assessment of the thrombocyte count and appropriate diagnostic tests. Heparin-like anticoagulants should be avoided and central laboratory assessment is essential. Early recognition likely improves prognosis of this extremely rare but severe complication of vaccination against COVID-19.

Disease Flare and Reactogenicity in Patients With Rheumatic and Musculoskeletal Diseases Following Two-Dose SARS-CoV-2 Messenger RNA Vaccination. OBJECTIVE: To evaluate disease flare and postvaccination reactions (reactogenicity) in patients with rheumatic and musculoskeletal diseases (RMDs) following 2-dose SARS-CoV-2 messenger RNA (mRNA) vaccination. METHODS: RMD patients (nÂ =Â 1,377) who received 2-dose SARS-CoV-2 mRNA vaccination between December 16, 2020 and April 15, 2021 completed questionnaires detailing local and systemic reactions experienced within 7â€‰days of each vaccine dose (dose 1 and dose 2), and 1 month after dose 2, detailing any flares of RMD. Associations between demographic/clinical characteristics and flares requiring treatment were evaluated using modified Poisson regression. RESULTS: Among the patients, 11% reported flares requiring treatment; there were no reports of severe flares. Flares were associated with prior SARS-CoV-2 infection (incidence rate ratio [IRR] 2.09, PÂ =Â 0.02), flares in the 6 months preceding vaccination (IRR 2.36, Pâ€‰<â€‰0.001), and the use of combination immunomodulatory therapy (IRR 1.95, Pâ€‰<â€‰0.001). The most frequently reported local and systemic reactions included injection site pain (87% after dose 1, 86% after dose 2) and fatigue (60% after dose 1, 80% after dose 2). Reactogenicity increased after dose 2, particularly for systemic reactions. No allergic reactions or SARS-CoV-2 diagnoses were reported. CONCLUSION: Flares of underlying RMD following SARS-CoV-2 vaccination were uncommon. There were no reports of severe flares. Local and systemic reactions typically did not interfere with daily activity. These early safety data can help address vaccine hesitancy in RMD patients.

Serological SARS-CoV-2 antibody response, potential predictive markers and safety of BNT162b2 mRNA COVID-19 vaccine in haematological and oncological patients. Haemato-oncological patients are at risk in case of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection. Currently, vaccination is the best-evaluated preventive strategy. In the present study, we aimed to assess serological response, predictive markers, and safety of BNT162b2 in haemato-oncological patients. A total of 259 haemato-oncological patients were vaccinated with two 30â€‰Âµg doses of BNT162b2 administered 21â€‰days apart. Serological response was assessed by ELECSYS(Â®) Anti-SARS-CoV-2-S immunoassay before vaccination, and at 3 and 7â€‰weeks after the first dose (T1, T2). Safety assessment was performed. At T2 spike protein receptor binding domain (S/RBD) antibodies were detected in 71Â·4% of haematological and in 94Â·5% of oncological patients (Pâ€‰<â€‰0Â·001). Haematological patients receiving systemic treatment had a 14Â·2-fold increased risk of non-responding (95% confidence interval 3Â·2-63Â·3, Pâ€‰=â€‰0Â·001). Subgroups of patients with lymphoma or chronic lymphocytic leukaemia were at highest risk of serological non-response. Low immunoglobulin G (IgG) level, lymphocyte- and natural killer (NK)-cell counts were significantly associated with poor serological response (Pâ€‰<â€‰0Â·05). Vaccination

was well tolerated with only 2Â·7% of patients reporting severe side-effects. Patients with side-effects developed a higher S/RBD-antibody titre compared to patients without side-effects (Pâ€‰=â€‰0Â·038). Haematological patients under treatment were at highest risk of serological non-response. Low lymphocytes, NK cells and IgG levels were found to be associated with serological non-response. Serological response in oncological patients was encouraging. The use of BNT162b2 is safe in haemato-oncological patients.

Guillain-BarrÃ© syndrome following BNT162b2 COVID-19 vaccine.

Thromboembolism after COVID-19 vaccine in patients with preexisting thrombocytopenia. While vaccination is the single most effective intervention to drastically reduce severe disease and death following SARS-CoV-2 infection, as shown in UK and Israel, some serious concerns have been raised for an unusual adverse drug reaction (ADR), including vaccine-induced immune thrombotic thrombocytopenia (VITT) with concurrent low platelets as well as capillary leak syndrome. In fact, the overall safety of the vaccine is highlighted by the low frequency of ADR considering that in UK, by the early June, 40 million first doses and 29 million second doses have been injected; nonetheless, 390 thrombotic events, including 71 fatal events have been reported. Interestingly, the cases reported low platelet counts with the presence of anti-platelet factor-4 (PF4) antibodies, indicating an abnormal clotting reaction. Here, out of three referred cases, we report a post-vaccine clinical case of fatal thrombosis with postmortem examination and whole exome sequencing (WES) analysis, whose pathogenesis appeared associated to a preexisting condition of thrombocytopenia due to myelodysplasia.

Parents' Intentions and Perceptions About COVID-19 Vaccination for Theirâ€‰Children: Results From a National Survey. OBJECTIVES: Assess the degree to which US parents are likely to have their children get coronavirus disease 2019 (COVID-19) vaccines and identify parental concerns about the vaccines. METHODS: In February 2021 to March 2021, we surveyed parent members of a nationally representative probability-based Internet panel of âˆ¼9000 adults regarding their intent to have their children receive a COVID-19 vaccination, perceptions of COVID-19 vaccines for children, and trust in sources of information about COVID-19 vaccines for children. We used descriptive and multivariate analyses to evaluate parent-stated likelihood of having their children get a COVID-19 vaccine and to assess the association between likelihood of child COVID-19 vaccination and child age, parent demographics, and parental perceptions about COVID-19 vaccines. RESULTS: Altogether, 1745 parents responded (87% of eligible parents, 3759 children). Likelihood of child COVID-19 vaccination was as follows: very likely (28%), somewhat likely (18%), somewhat unlikely (9%), very unlikely (33%), and unsure (12%). The stated likelihood of child vaccination was greater among parents of older children (P < .001) as well as among parents who had a bachelor's degree or higher education (P < .001), had already received or were likely to receive a COVID-19 vaccine (P < .001), or had Democratic affiliation (P < .001); variations existed by race and ethnicity (P = .04). Parental concerns centered around vaccine safety and side effects. A key trusted source of information about COVID-19 vaccines for children was the child's doctor. CONCLUSIONS: Less than one-half of US participants report that they are likely to have their child receive a COVID-19 vaccine. Pediatric health care providers have a major role in promoting and giving COVID-19 vaccination for children.

Bacillus Calmette-GuÃ©rin scar flare after an mRNA SARS-CoV-2 vaccine.

Bilateral Multifocal Choroiditis following COVID-19 Vaccination. Purpose: To report a case of bilateral choroiditis following COVID-19 vaccination.Study Design: Case report.Results: A 34-year old male presented with visual loss one week after the second dose of COVID-19 vaccine. Examination showed large serous detachment of the macula in the right eye and severe choroidal thickening noted on ultrasonography in both eyes. The patient's condition improved rapidly with oral corticosteroids with significant resolution of the serous detachments within two weeks of initiating

treatment and complete visual recovery subsequently.Conclusions: The onset of ocular symptoms starting within one week following vaccination suggests an inflammatory or autoimmune response to the vaccine. Ophthalmologists should consider the option of autoimmune and other inflammatory ocular problems, which may manifest as uveitis, following COVID-19 vaccination. Timely diagnosis and treatment with corticosteroids can result in good visual and structural outcome.
Longitudinal observation of antibody responses for 14Â months after SARS-CoV-2 infection. Better understanding of antibody responses against SARS-CoV-2 after natural infection might provide valuable insights into the future implementation of vaccination policies. Longitudinal analysis of IgG antibody titers was carried out in 32 recovered COVID-19 patients based in the Umbria region of Italy for 14Â months after Mild and Moderately-Severe infection.Two FDA-approved immunoassays against SARS-CoV-2 Nucleocapsid protein (NCP) and anti-spike-receptor binding domain (S-RBD) were used for sequential serological tests at different time points. The demographics,clinical history and symptom profile associated with the magnitude and longevity of antibody responses were also analyzed. Anti-S-RBD IgG persisted in 96.8% (31 of 32) subjects at 14Â months. Patients reporting loss of smell and taste during the clinical course of the disease developed significantly higher antibody titers. Anti-NCP IgG seronegative patients(n=7) at 10Â months, tested positive for anti-S-RBD IgG at 12,13 and 14Â months emphasizing on a higher false-negative rate for NCP protein-based antibody assays. This study also highlights the importance of adopting specific immunoassays for routine estimation of antibody titers and the decreased rate of re-infections in recovered patients.
Biphasic anaphylaxis after first dose of messenger RNA coronavirus disease 2019 vaccine with positive polysorbate 80 skin testing result.
Two further cases of Graves' disease following SARS-Cov-2 vaccination.
Immunogenicity and safety of the CoronaVac vaccine in patients with cancer receiving active systemic therapy. Aim: To evaluate the immunogenicity and safety of the CoronaVac vaccine in patients with cancer receiving active systemic therapy. Methods: This multicenter, prospective, observational study was conducted with 47 patients receiving active systemic therapy for cancer. CoronaVac was administered as two doses (3Â Î¼g/day) on days 0 and 28. Antibody level higher than 1Â IU/ml was defined as 'immunogenicity.' Results: The immunogenicity rate was 63.8% (30/47) in the entire patient group, 59.5% (25/42) in those receiving at least one cytotoxic drug and 100% (five of five) in those receiving monoclonal antibody or immunotherapy alone. Age was an independent predictive factor for immunogenicity (odds ratio: 0.830; pÂ =Â 0.043). Conclusion: More than half of cancer patients receiving active systemic therapy developed immunogenicity.
Evaluation of Three Anti-SARS-CoV-2 Serologic Immunoassays for Post-Vaccine Response. BACKGROUND: In North America, both messenger RNA (mRNA) vaccines, Pfizer-BioNTech BNT162b2, and Moderna mRNA-1273, each utilizing a 2-dose regimen, have started to be administered to individuals. METHODS: We evaluated the quantitative serologic antibody response following administration of either a single dose or both doses of an mRNA severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine in a cohort of 98 participants (88 healthcare workers [HCW] and 10 solid organ transplant [SOT] recipients). Antibody levels were compared across 3 immunoassays: Elecsys Anti-SARS-CoV-2 S (Roche Diagnostics), SARS-CoV-2 TrimericS IgG (DiaSorin), and SARS-CoV-2 IgG II Quant (Abbott). RESULTS: Among HCW, sensitivity ranged from 100% (Roche), 99% (Abbott) and 98% (DiaSorin). The SARS-CoV-2 IgG II Quant and SARS-CoV-2 TrimericS IgG assays showed good agreement with a Pearson correlation coefficient of Râ€‰=â€‰0.95. Pearson correlation coefficients of Râ€‰=â€‰0.82 and 0.83 were obtained for Elecsys Anti-SARS-CoV-2 S vs SARS-CoV-2 TrimericS IgG and SARS-CoV-2 IgG II Quant vs Elecsys Anti-SARS-CoV-2 S, respectively. Significant differences in antibody levels between HCW and SOT recipients were observed. A decrease in antibody levels from time of vaccine administration to blood draw was evident. Among those with a

second dose, an increase in antibody levels with increased time between administration of the first and second dose was observed. CONCLUSIONS: The absolute values generated from each of the assay platforms are not interchangeable. Antibody levels differed with increased time between vaccine administration and with increased time between administration of the first and second dose. Further, significant differences in antibody levels between HCW and SOT recipients were observed.

New-onset Nephrotic Syndrome after Janssen COVID-19 Vaccination: a Case Report and Literature Review. Various coronavirus disease 2019 (COVID-19) vaccines are being developed, which show practical preventive effects. Here, we report a 51-year-old healthy man with nephrotic syndrome secondary to minimal change disease (MCD) after Ad26.COV.2 (Janssen) vaccination. He had no comorbid disease and received Ad26.COV.2 on April 13, 2021. Seven days after vaccination, he developed edema and foamy urine. Edema rapidly aggravated with decreased urine volume. He was admitted to the hospital 28 days after vaccination, and his body weight increased by 21 kg after vaccination. His serum creatinine level was 1.54 mg/dL, and 24-h urinary protein excretion was 8.6 g/day. Kidney biopsy revealed no abnormality in the glomeruli and interstitium of the cortex and medulla under the light microscope. Electron microscopy revealed diffuse effacement of the podocyte foot processes, thus, he was diagnosed with MCD. High-dose steroid therapy was applied, and his kidney function improved three days after steroid therapy. Three weeks after steroid use, his serum creatinine decreased to 0.95 mg/dL, and spot urine protein-to-creatine decreased to 0.2 g/g. This case highlights the risk of new-onset nephrotic syndrome secondary to MCD after vectored COVID-19 vaccination. Although the pathogenesis is uncertain, clinicians need to be careful about adverse renal effects of COVID-19 vaccines.

Herd immunity induced by COVID-19 vaccination programs and suppression of epidemics caused by the SARS-CoV-2 Delta variant in China. BACKGROUND: To allow a return to a pre-COVID-19 lifestyle, virtually every country has initiated a vaccination program to mitigate severe disease burden and control transmission. However, it remains to be seen whether herd immunity will be within reach of these programs. METHODS: We developed a data-driven model of SARS-CoV-2 transmission for China, a population with low prior immunity from natural infection. The model is calibrated considering COVID-19 natural history and the estimated transmissibility of the Delta variant. Three vaccination programs are tested, including the one currently enacted in China and model-based estimates of the herd immunity level are provided. RESULTS: We found that it is unlike to reach herd immunity for the Delta variant given the relatively low efficacy of the vaccines used in China throughout 2021, the exclusion of underage individuals from the targeted population, and the lack of prior natural immunity. We estimate that, assuming a vaccine efficacy of 90% against the infection, vaccine-induced herd immunity would require a coverage of 93% or higher of the Chinese population. However, even when vaccine-induced herd immunity is not reached, we estimated that vaccination programs can reduce SARS-CoV-2 infections by 53-58% in case of an epidemic starts to unfold in the fall of 2021. CONCLUSIONS: Efforts should be taken to increase population's confidence and willingness to be vaccinated and to guarantee highly efficacious vaccines for a wider age range.

An mRNA SARS-CoV-2 Vaccine Employing Charge-Altering Releasable Transporters with a TLR-9 Agonist Induces Neutralizing Antibodies and T Cell Memory. The SARS-CoV-2 pandemic has necessitated the rapid development of prophylactic vaccines. Two mRNA vaccines have been approved for emergency use by the FDA and have demonstrated extraordinary effectiveness. The success of these mRNA vaccines establishes the speed of development and therapeutic potential of mRNA. These authorized vaccines encode full-length versions of the SARS-CoV-2 spike protein. They are formulated with lipid nanoparticle (LNP) delivery vehicles that have inherent immunostimulatory properties. Different vaccination strategies and alternative mRNA delivery vehicles would be desirable to ensure flexibility of future generations of SARS-CoV-2 vaccines and the development of

mRNA vaccines in general. Here, we report on the development of an alternative mRNA vaccine approach using a delivery vehicle called charge-altering releasable transporters (CARTs). Using these inherently nonimmunogenic vehicles, we can tailor the vaccine immunogenicity by inclusion of coformulated adjuvants such as oligodeoxynucleotides with CpG motifs (CpG-ODN). Mice vaccinated with the mRNA-CART vaccine developed therapeutically relevant levels of receptor binding domain (RBD)-specific neutralizing antibodies in both the circulation and in the lung bronchial fluids. In addition, vaccination elicited strong and long-lasting RBD-specific T(H)1 T cell responses including CD4(+) and CD8(+) T cell memory.

Seroconversion after COVID-19 vaccine in a dialysis patient on immunosuppressants.

Malignant cerebral infarction after ChAdOx1 nCov-19 vaccination: a catastrophic variant of vaccine-induced immune thrombotic thrombocytopenia. Vaccine-induced thrombotic thrombocytopenia with cerebral venous thrombosis is a syndrome recently described in young adults within two weeks from the first dose of the ChAdOx1 nCoV-19 vaccine. Here we report two cases of malignant middle cerebral artery (MCA) infarct and thrombocytopenia 9-10 days following ChAdOx1 nCoV-19 vaccination. The two cases arrived in our facility around the same time but from different geographical areas, potentially excluding epidemiological links; meanwhile, no abnormality was found in the respective vaccine batches. Patient 1 was a 57-year-old woman who underwent decompressive craniectomy despite two prior, successful mechanical thrombectomies. Patient 2 was a 55-year-old woman who developed a fatal bilateral malignant MCA infarct. Both patients manifested pulmonary and portal vein thrombosis and high level of antibodies to platelet factor 4-polyanion complexes. None of the patients had ever received heparin in the past before stroke onset. Our observations of rare arterial thrombosis may contribute to assessment of possible adverse effects associated with COVID-19 vaccination.

The neutralizing antibody response post COVID-19 vaccination in patients with myeloma is highly dependent on the type of anti-myeloma treatment. Recent data suggest a suboptimal antibody response to COVID-19 vaccination in patients with hematological malignancies. Neutralizing antibodies (NAbs) against SARS-CoV-2 were evaluated in 276 patients with plasma cell neoplasms after vaccination with either the BNT162b2 or the AZD1222 vaccine, on days 1 (before the first vaccine shot), 22, and 50. Patients with MM (nâ€‰=â€‰213), SMM (nâ€‰=â€‰38), and MGUS (nâ€‰=â€‰25) and 226 healthy controls were enrolled in the study (NCT04743388). Vaccination with either two doses of the BNT162b2 or one dose of the AZD1222 vaccine leads to lower production of NAbs in patients with MM compared with controls both on day 22 and on day 50 (pâ€‰<â€‰0.001 for all comparisons). Furthermore, MM patients showed an inferior NAb response compared with MGUS on day 22 (pâ€‰=â€‰0.009) and on day 50 (pâ€‰=â€‰0.003). Importantly, active treatment with either anti-CD38 monoclonal antibodies (Mabs) or belantamab mafodotin and lymphopenia at the time of vaccination were independent prognostic factors for suboptimal antibody response following vaccination. In conclusion, MM patients have low humoral response following SARS-CoV-2 vaccination, especially under treatment with anti-CD38 or belamaf. This underlines the need for timely vaccination, possibly during a treatment-free period, and for continuous vigilance on infection control measures in non-responders.

SARS-CoV-2 infection after COVID-19 immunization in healthcare workers: A retrospective, pilot study. BACKGROUND & OBJECTIVES: COVID-19 pandemic has taken a significant toll on the health of the people across the globe, including India, and is still continuing with its rapidly evolving second wave. Although the COVID-19 vaccines effectively prevent infection, yet some cases of infections have been reported post-vaccination, raising concerns about their efficacy and safety. This study was aimed to investigate the occurrence of SARS-CoV-2 infection among the symptomatic-vaccinated healthcare workers (HCWs) and to analyze the severity of their disease. METHODS: This

retrospective study was done at a single multispecialty hospital, on the HCWs who have had COVID-19 vaccination, during the initial period of the vaccination drive (January 16 to April 24, 2021). The symptomatic post-vaccination infections in these HCWs were evaluated. RESULTS: Eighty five of 3235 (2.63%) vaccinated HCWs acquired the SARS-CoV-2 infection after vaccination, during the study period. Of these, 65 (76.5%) were fully vaccinated (FV), and 20 (23.5%) were partially vaccinated (PV) and the protection rate of vaccination was 97.4 per cent [95 % confidence interval (CI)=96.8-97.9]. The odds ratio of acquiring infection among females was higher at 1.84 (95% CI=1.17-2.88; P=0.008) mainly because of their greater involvement in the patient care as nursing personnel. The chances of infections were the highest in the medical and nursing personnel, as compared to paramedical, administrative and supporting staff (P<0.001). Among the HCWs studied, only two required hospitalization (0.06%), none needed an intensive care unit (ICU) admission and there were no deaths. INTERPRETATION & CONCLUSIONS: The COVID-19 infection after vaccination occurred in a smaller subset (2.63%) of HCWs, in both PV and the FV groups. These infections were primarily minor and did not lead to severe disease. Overall, the vaccination with ChAdOx1 nCoV-19 vaccine (recombinant) prevented SARS-CoV-2 severe infection in the HCWs, leading to ICU admission and deaths.

Correspondence on "SARS-CoV-2 vaccination in rituximab-treated patients: evidence for impaired humoral but inducible cellular immune response"by Bonelli et al.

Myocarditis, Pericarditis and Cardiomyopathy After COVID-19 Vaccination.

Mammographic and sonographic findings in the breast and axillary tail following a COVID-19 vaccine. Axillary lymphadenopathy on breast imaging after recent coronavirus disease 2019 (COVID-19) vaccination has been reported in the literature as immunization has become more widespread. While muscle edema at the injection site has been observed on MRI secondary to an immune response, ipsilateral breast imaging observations of edema have not been reported to be seen with the COVID-19 vaccinations to date. Mammographic findings such as trabecular and skin thickening, along with increased echogenicity on ultrasound, can be seen with edema secondary to capillary leak or poor lymphatic drainage, and should be considered as a possible etiology for the observed breast edema following a recent COVID-19 vaccine. Inflammatory changes observed in the breast and axillary tail post vaccination described in this case series are transient, but clinically relevant for patients who experience swelling following injection. Similar to evaluations for suspected mastitis, a short interval imaging follow up to confirm resolution may be appropriate for patients with ipsilateral vaccination histories, and could potentially reduce the number of false positive examinations in this clinical scenario. However, inflammatory breast cancer can mimic inflammation and infection, therefore close follow up to resolution is critical as to not miss cancer.

Liver injury following SARS-CoV-2 vaccination: A multicenter case series.

Scleroderma renal crisis following mRNA vaccination against SARS-CoV-2.

Myopericarditis after messenger RNA Coronavirus Disease 2019 Vaccination in Adolescents 12 to 18Â Years of Age. OBJECTIVES: To characterize the clinical course and outcomes of children 12-18Â years of age who developed probable myopericarditis after vaccination with the Pfizer-BioNTech (BNT162b2) coronavirus disease 2019 (COVID-19) messenger RNA (mRNA) vaccine. STUDY DESIGN: A cross-sectional study of 25 children, aged 12-18Â years, diagnosed with probable myopericarditis after COVID-19 mRNA vaccination as per the Centers for Disease Control and Prevention criteria for myopericarditis at 8 US centers between May 10, 2021, and June 20, 2021. We retrospectively collected the following data: demographics,Â severe acute respiratory syndrome coronavirus 2 virus detection or serologic testing, clinical manifestations,Â laboratory test results, imaging study results, treatment, and time to resolutions of symptoms. RESULTS: Most (88%) cases followed the second dose of vaccine, and chest pain (100%) was the most common presenting symptom. Patients came to

medical attention a median of 2Â days (range, <1-20Â days) after receipt of Pfizer mRNA COVID-19 vaccination. All adolescents had an elevated plasma troponin concentration. Echocardiographic abnormalities were infrequent, and 92% showed normal cardiac function at presentation. However, cardiac magnetic resonance imaging, obtained in 16 patients (64%), revealed that 15 (94%) had late gadolinium enhancement consistent with myopericarditis. Most were treated with ibuprofen or an equivalent nonsteroidal anti-inflammatory drug for symptomatic relief. One patient was given a corticosteroid orally after the initial administration of ibuprofen or an nonsteroidal anti-inflammatory drug; 2 patients also received intravenous immune globulin. Symptom resolution was observed within 7Â days in all patients. CONCLUSIONS: Our data suggest that symptoms owing to myopericarditis after the mRNA COVID-19 vaccination tend to be mild and transient. Approximately two-thirds of patients underwent cardiac magnetic resonance imaging, which revealed evidence of myocardial inflammation despite a lack of echocardiographic abnormalities.
Unusual Fever, Headache, and Abdominal Pain in a Healthy Woman.
Response to SARS-CoV-2 vaccination in patients after hematopoietic cell transplantation and CAR T-cell therapy.
COVID-19 vaccines approved in the European Union: current evidence and perspectives.
Serum antibody response to BNT162b2 after natural SARS-CoV-2 infection. BACKGROUND: There is preliminary evidence that individuals with previous SARS-CoV-2 infections exhibit a more pronounced antibody response. However, these assumptions have not yet been supported by data obtained through various CE-marked tests. This study aimed to close this gap. METHODS: Sixty-nine seronegatives and 12 individuals post-SARS-CoV-2 infection (tested by CE-labelled Roche NC immunoassay or PCR-confirmed assay) were included 21Â Â±Â 1Â days after receiving the first dose of the Pfizer/BioNTech BNT162b2 vaccine. Antibody response to viral spike protein (S) was assessed by CE-labelled Roche S and DiaSorin S1/S2 assays and by a surrogate virus neutralization test (sVNT). RESULTS: After a single dose of BNT162b2, individuals after natural SARS-CoV-2 infection presented with markedly higher anti-S levels than naÃ¯ve individuals (Roche S: 9078.5Â BAU/mL [5267.0-24Â 298.5] vs 79.6 [24.7-142.3]; and DiaSorin S1/S2: 1465.0Â AU/mL [631.0-5365.0] vs 63.7 [47.8-87.5]) and showed all the maximum observed inhibition activity in the sVNT (98%), without overlaps between groups. There was a trend for higher responses in those with a more distant infection, although not statistically significant. The relative antibody increase after dose 2 was significantly higher among naÃ¯ve individuals (25-fold), but antibody levels remained below that of seropositives. CONCLUSIONS: Compared with naÃ¯ve individuals, seropositives after natural SARS-CoV-2 infection presented with a substantially higher antibody response already after dose 1 of BNT162b2, as measured by two CE-marked in vitro diagnostic tests and a sVNT. These results should stimulate discussion and research on whether individuals after previous SARS-CoV-2 infection would benefit from a two-part vaccination schedule or whether these currently much-needed second doses could be saved.
Myocarditis and pericarditis after vaccination for COVID-19. Two previously healthy males presented to the emergency symptoms with signs of pericarditis/myocarditis after being vaccinated with an mRNA vaccine for COVID-19.
Report of Three Cases of Minimal Change Disease Following the Second Dose of mRNA SARS-CoV-2 COVID-19 Vaccine.
Cutaneous small vessel vasculitis following single-dose Janssen Ad26.COV2.S vaccination.
Bell's Palsy After 24 Hours of mRNA-1273 SARS-CoV-2 Vaccine. Coronavirus disease 2019 (COVID-19) has become the fastest-spreading pandemic of the 21st century. Various vaccines have been made available via emergency use authorization. Currently, two mRNA vaccines are being offered internationally, BNT162b2Â and mRNA-1273. In randomized trials of these vaccines, the incidence of

Bell's palsy in the vaccinated group does not statistically exceed the placebo group. The FDA recommends increased surveillance for Bell's palsy as a potential side effect with the administration of the vaccines among larger populations globally. There have been a few case reports of Bell's palsy associated with mRNA vaccines. Type I interferons have been proposed as the potential mechanism linking mRNA COVID-19 vaccines to Bell's palsy. Here, we report the case of a 36-year-old previously healthy patient who developed symptoms of Bell's palsy along with left-arm numbness, tingling, and subjective weakness masquerading as a subacute stroke after receiving the second dose of the mRNA-1273 vaccine. CT and MRI of the brain were unremarkable. He was discharged home with a diagnosis of Bell's palsy and improved on follow-up. mRNA COVID-19 vaccines may be consideredÂ a risk factor for Bell's palsy.

Anaphylaxis and Coronavirus Disease 2019 vaccine: a danger relationship? PURPOSE OF REVIEW: Anaphylactic reactions reported after Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) RNA vaccines were expected to be more frequent in atopic subjects and attributed to its polyethylene glycol component. RECENT FINDINGS: Anaphylaxis to SARS-CoV2 RNA vaccines is no more frequent than in any vaccine and direct proofs for the role of its polyethylene glycol component are lacking. SUMMARY: Vaccines against coronavirus disease 2019 (COVID-19) are an essential global intervention to control the current pandemic situation. Anaphylactic reactions have rapidly been reported after SARS-CoV2 RNA vaccines. This risk is now measured at 2.5-11/1 000 000 in the context of vaccine safety surveillance programs and only one case was documented to be due to polyethylene glycol. Suggestions for its role are indirect. The COVID-19 vaccination is rolling out vastly and surveillance programs are key to monitor severe adverse reactions, such as anaphylaxis. Anaphylaxis due to vaccine is extremely rare and specific cases should receive individualized investigation and care, highlighting the key role of allergists in the vaccination programmes.

Cerebral venous sinus thrombosis associated with vaccine-induced thrombotic thrombocytopenia. Thrombosis-thrombocytopenia syndrome and cerebral venous sinus thrombosis have been rarely reported in patients who have received severe acute respiratory syndrome coronavirus 2 adenoviral vector vaccines. Awareness of this potential adverse effect, recognizing early clinical symptoms and subtle signs of cerebral venous sinus thrombosis on head computed tomography and brain magnetic resonance imaging, appropriate vascular imaging, and unique treatment for this condition is critical. This is a report of a case of vaccine-induced thrombotic thrombocytopenia and associated cerebral venous sinus thrombosis with emphasis on imaging and clinical course.

Allergic reactions against CovÄ±d-19 vaccines. Coronavirus Disease 2019 (COVID-19) affected the whole world in a short time. One of the most influential public health initiatives modern medicine has to offer, the vaccine has become even more important as the COVID-19 pandemic continues to worsen worldwide. Many vaccine trials were launched during the COVID-19 pandemic, and these vaccines were widely used around the world, offering realistic hope for ending the pandemic. Allergic reactions to vaccines were reported shortly after their approval. These reactions, in general, are rare, but, in some circumstances, they can be serious. Allergy to vaccines can occur because of either the active vaccine component or vaccine ingredients. The spectrum of the reactions may be just a local hypersensitiviy reaction or may be as severe as an anaphylaxis, which is an acute severe, life-threatening systemic hypersensitive reaction, and it requires quick intervention. If an allergy is suspected, a correct examination followed by algorithms is important for true diagnosis, treatment, and decision regarding revaccination. Patients who experience an allergic reaction with the first dose of covid 19 vaccine should be directed to the allergy-immunologist, and the evaluation of at-risk patients should be individualized. Finally, we should point out that the benefits of current COVID-19 vaccines go far beyond the side effects, and that the vaccine is the most important way to recover from the pandemic.

Occurrence of acute infarct-like myocarditis following COVID-19 vaccination: just an accidental co-incidence or rather vaccination-associated autoimmune myocarditis?
Reduced SARS-CoV-2 infection and death after two doses of COVID-19 vaccines in a series of 1503 cancer patients.
Important Insights into Myopericarditis after the Pfizer mRNA COVID-19 Vaccination in Adolescents.
Autoimmune hepatitis triggered by SARS-CoV-2 vaccination. The development of autoimmune diseases has been reported after SARS-CoV-2 infection. Vaccination against SARS-CoV-2 could also trigger auto-immunity, as it has been described with other vaccines. An aberrant immune response induced by molecular mimicry and bystander activation, especially in predisposed individuals, is a potential mechanism. We report the case of a 76-year-old woman with Hashimoto thyroiditis and prior COVID-19 infection who developed severe autoimmune hepatitis (with typical features including strongly positive anti-smooth muscle antibody and markedly elevated immunoglobulins G, as well as typical histological findings) following SARS-CoV-2 vaccination (mRNA-1273 SARS-CoV-2 vaccine, ModernaÂ®). The link between SARS-CoV-2 vaccination and the development of autoimmune diseases needs to be further investigated. Although a causality relationship cannot be proven, caution may be warranted when vaccinating individuals with known autoimmune diseases.
Thrombocytopenia after COVID-19 vaccination.
COVID-19 after two doses of mRNA vaccines in kidney transplant recipients.
Patients with suspected allergic reactions to COVID-19 vaccines can be safely revaccinated after diagnostic work-up. BACKGROUND: When initiating the Danish vaccination program against COVID-19, the incidence of anaphylaxis was estimated to be 10 times higher compared to other virus-based vaccines. In this study, we present data on patients referred with suspected allergic reactions to COVID-19 vaccines. The main purpose of the study is to investigate the incidence and severity of the allergic reactions, and to evaluate the safety of revaccination. METHODS: All patients in the region of Southern Denmark with case histories of allergic reactions to COVID-19 vaccines in a defined period are included in this study. Diagnostic work up consisted of a detailed case history, evaluation of Brighton level of diagnostic certainty and World Allergy Organization grade of anaphylaxis and skin prick testing- and basophil histamine release testing with COVID-19 vaccines and relevant drug excipients. Patients were revaccinated at the Allergy Center when possible. RESULTS: Sixty-one patients are included in this study. In 199,377 doses administered, nine patients fulfilled the criteria of anaphylaxis when using the Brighton Criteria (incidence being 45 per million). Of 55 patients with reactions to the first dose, 52 patients were revaccinated without adverse reactions. We found no proven cases of immediate anaphylaxis due to COVID-19 vaccines. By skin prick test, we diagnosed three patients with drug excipient allergy and further a patient with mastocytosis was found. CONCLUSIONS: Anaphylactic reactions to COVID-19 vaccines are rare and the incidence is similar to what is seen with other virus-based vaccines. Revaccination is safe in the majority of patients; however, allergological evaluation is important since some prove to have drug excipient allergy.
Thrombocytopenia in a teen with sickle cell disease following COVID-19 vaccination.
Reply to the letter entitled "Suggested treatment of serious complications to Covid-19 vaccination with IdeS, a bacterial antibody-cleaving enzyme".
Every rose has its thorns - acute myocarditis following COVID-19 vaccination.
Immunogenicity and safety of the CoronaVac inactivated vaccine in patients with autoimmune rheumatic diseases: a phase 4 trial. CoronaVac, an inactivated SARS-CoV-2 vaccine, has been approved for emergency use in several countries. However, its immunogenicity in immunocompromised individuals has not been well established. We initiated a prospective phaseâ€‰4 controlled trial (no. NCT04754698, CoronavRheum) in 910â€‰adults with autoimmune

rheumatic diseases (ARD) and 182â€‰age- and sex-frequency-matched healthy adults (control group, CG), who received two doses of CoronaVac. The primary outcomes were reduction of â‰¥15% in both anti-SARS-CoV-2 IgG seroconversion (SC) and neutralizing antibody (NAb) positivity 6â€‰weeks (day 69 (D69)) after the second dose in the ARD group compared with that in the CG. Secondary outcomes were IgG SC and NAb positivity at D28, IgG titers and neutralizing activity at D28 and D69 and vaccine safety. Prespecified endpoints were met, with lower anti-SARS-Cov-2 IgG SC (70.4 versus 95.5%, Pâ€‰<â€‰0.001) and NAb positivity (56.3 versus 79.3%, Pâ€‰<â€‰0.001) at D69 in the ARD group than in the CG. Moreover, IgG titers (12.1 versus 29.7, Pâ€‰<â€‰0.001) and median neutralization activity (58.7 versus 64.5%, Pâ€‰=â€‰0.013) were also lower at D69 in patients with ARD. At D28, patients with ARD presented with lower IgG frequency (18.7 versus 34.6%, Pâ€‰<â€‰0.001) and NAb positivity (20.6 versus 36.3%, Pâ€‰<â€‰0.001) than that of the CG. There were no moderate/severe adverse events. These data support the use of CoronaVac in patients with ARD, suggesting reduced but acceptable short-term immunogenicity. The trial is still ongoing to evaluate the long-term effectiveness/immunogenicity.

A single dose of ChAdOx1 Chik vaccine induces neutralizing antibodies against four chikungunya virus lineages in a phase 1 clinical trial. Chikungunya virus (CHIKV) is a reemerging mosquito-borne virus that causes swift outbreaks. Major concerns are the persistent and disabling polyarthralgia in infected individuals. Here we present the results from a first-in-human trial of the candidate simian adenovirus vectored vaccine ChAdOx1 Chik, expressing the CHIKV full-length structural polyprotein (Capsid, E3, E2, 6k and E1). 24 adult healthy volunteers aged 18-50 years, were recruited in a dose escalation, open-label, nonrandomized and uncontrolled phase 1 trial (registry NCT03590392). Participants received a single intramuscular injection of ChAdOx1 Chik at one of the three preestablished dosages and were followed-up for 6 months. The primary objective was to assess safety and tolerability of ChAdOx1 Chik. The secondary objective was to assess the humoral and cellular immunogenicity. ChAdOx1 Chik was safe at all doses tested with no serious adverse reactions reported. The vast majority of solicited adverse events were mild or moderate, and self-limiting in nature. A single dose induced IgG and T-cell responses against the CHIKV structural antigens. Broadly neutralizing antibodies against the four CHIKV lineages were found in all participants and as early as 2 weeks after vaccination. In summary, ChAdOx1 Chik showed excellent safety, tolerability and 100% PRNT(50) seroconversion after a single dose.

Antibody responses after first and second Covid-19 vaccination in patients with chronic lymphocytic leukaemia. B-cell chronic lymphocytic leukaemia (CLL) is associated with immunosuppression and patients are at increased clinical risk following SARS-CoV-2 infection. Covid-19 vaccines offer the potential for protection against severe infection but relatively little is known regarding the profile of the antibody response following first or second vaccination. We studied spike-specific antibody responses following first and/or second Covid-19 vaccination in 299 patients with CLL compared with healthy donors. 286 patients underwent extended interval (10-12 week) vaccination. 154 patients received the BNT162b2 mRNA vaccine and 145 patients received ChAdOx1. Blood samples were taken either by venepuncture or as dried blood spots on filter paper. Spike-specific antibody responses were detectable in 34% of patients with CLL after one vaccine (nâ€‰=â€‰267) compared to 94% in healthy donors with antibody titres 104-fold lower in the patient group. Antibody responses increased to 75% after second vaccine (nâ€‰=â€‰55), compared to 100% in healthy donors, although titres remained lower. Multivariate analysis showed that current treatment with BTK inhibitors or IgA deficiency were independently associated with failure to generate an antibody response after the second vaccine. This work supports the need for optimisation of vaccination strategy in patients with CLL including the potential utility of booster vaccines.

Guillain-BarrÃ© syndrome after COVID-19 vaccination. We report a case of Guillain-BarrÃ© syndrome (GBS) occurring soon after the first dose of Vaxzevria (previously known as COVID-19 vaccine AstraZeneca). Thus far, there has been no evidence of an increased risk of GBS resulting from either COVID-19 infection nor from COVID-19 vaccines; however, individual cases and population cohorts should be scrutinised, in order to ensure the constant evaluation of such risks. It is as yet not possible to draw conclusions about any significant association between COVID-19 vaccination and GBS. A temporal correlation does not imply, and should not be deemed to signify, causality. However, it is important to remain vigilant, so that any potential increased risk is properly evaluated. The specific presentation of bifacial weakness as the initial symptom may be a characteristic feature of GBS in the context of recent COVID-19 vaccination.

Immune thrombocytopenic purpura and acute liver injury after COVID-19 vaccine. A 26-year-old woman was sent to the emergency room by her primary care physician for a new petechial rash and thrombocytopenia 2â€‰weeks after receiving the Moderna mRNA-1273 SARS-CoV-2 vaccine. Her hospital course was complicated by transaminitis. Her platelet count improved to normal on hospital day 5 after receiving intravenous steroids and intravenous immunoglobulin to treat her suspected diagnosis of immune thrombocytopenic purpura. Extensive workup for her thrombocytopenia and transaminitis was unremarkable including ruling out infectious, autoimmune and toxic causes. A liver biopsy was unrevealing and her transaminitis was improved on discharge. Although not proven, the temporal relationship of her vaccination with thrombocytopenia and abnormal liver enzymes points towards the Moderna mRNA-1273 SARS-CoV-2 vaccine as the most likely inciting factor.

Bell's palsy following COVID-19 vaccination: a case report.

Takotsubo Cardiomyopathy After mRNA COVID-19 Vaccination.

Antibody response induced by the BNT162b2 mRNA COVID-19 vaccine in a cohort of health-care workers, with or without prior SARS-CoV-2 infection: a prospective study. OBJECTIVES: To assess the antibody response to BNT162b2 mRNA COVID-19 vaccine in a cohort of health-care workers (HCW), comparing individuals with previous severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and SARS-CoV-2-naive individuals. METHODS: HCW were tested at T0 (day of first dose), T1 (day of second dose) and T2 (2-3Â weeks after second dose) for IgG anti-nucleocapsid protein, IgM anti-spike protein and IgG anti-receptor binding domain (IgG-RBD-S). The antibody response was compared between four main groups: group A, individuals with previous infection and positive antibodies at baseline; group B, individuals with the same history but negative antibodies; group C, individuals with no infection history but positive antibodies; group D, naive individuals. Repeated measures analysis was used to compare results over time-points. RESULTS: A total of 1935 HCW were included. Median IgG-RBD-S titre was significantly higher for group A (232 individuals) than for group B (56 individuals) both at T1 (A: 22Â 763 AU/mL, interquartile range (IQR) 14Â 222-37 204 AU/mL; B: 1373 AU/mL, IQR 783-3078 AU/mL, p 0.0003) and T2 (A: 30Â 765 AU/mL, IQR 19Â 841-42 813 AU/mL; B: 13Â 171 AU/mL, IQR 2324-22 688 AU/mL, p 0.0038) and for group D (1563 individuals; 796 AU/mL, IQR 379-1510 AU/mL at T1; 15Â 494 AU/mL, IQR 9122-23 916 AU/mL at T2, pÂ <Â 0.0001 for both time-points). T1 values of group A were also significantly higher than T2 values of group D (pÂ <Â 0.0001). Presence of symptoms, younger age and being female were associated with stronger antibody response. HCW infected in March showed a significantly stronger response (T1: 35Â 324 AU/mL, IQR 22Â 003-44 531 AU/mL; T2: 37Â 648 AU/mL, IQR 27Â 088-50 451 AU/mL) than those infected in November (T1: 18Â 499 AU/mL, IQR 11Â 492-27 283 AU/mL; T2: 23Â 210 AU/mL, IQR 18Â 074-36 086 AU/mL, pÂ <Â 0.0001 for both time-points. CONCLUSIONS: Individuals with past SARS-CoV-2 infection had a strong antibody response after one single vaccine shot. A single dose might be sufficient for this group, regardless of the time elapsed since infection; however, the clinical correlation with antibody response needs to be studied.

Very rare thrombosis with thrombocytopenia after second AZD1222 dose: a global safety database analysis.
Septic Arthritis of the Shoulder After SARS-CoV-2 Pfizer Vaccination: A Case Report. CASE: We report a case of a 68-year-old woman who developed left shoulder glenohumeral joint septic arthritis within 1 week of receiving the COVID-19 Pfizer-BioNTech vaccine. CONCLUSION: Common vaccine complications include injection site pain, fever, chills, arthralgia, and hypersensitivity reactions. A less common and more serious complication of septic arthritis has been reported and requires invasive treatment of surgical irrigation and debridement, and culture-specific parenteral antibiotic therapy. The current report highlights the clinical presentation and significant potential for serious complication with the improper technique. We urge vaccine administrators to practice caution and aseptic technique when vaccinating patients to reduce the risk of complication and morbidity.
An outbreak caused by the SARS-CoV-2 Delta variant (B.1.617.2) in a secondary care hospital in Finland, May 2021. An outbreak caused by the SARS-CoV-2 Delta variant (B.1.617.2) spread from one inpatient in a secondary care hospital to three primary care facilities, resulting in 58 infections including 18 deaths in patients and 45 infections in healthcare workers (HCW). Only one of the deceased cases was fully vaccinated. Transmission occurred despite the use of personal protective equipment by the HCW, as advised in national guidelines, and a high two-dose COVID-19 vaccination coverage among permanent staff members in the COVID-19 cohort ward.
Cutaneous lymphocytic vasculitis after administration of COVID-19 mRNA vaccine.
[Cerebral venous sinus thrombosis after COVID-19 vaccination : Neurological and radiological management]. BACKGROUND: Vaccine-induced cerebral venous and sinus thrombosis (VI-CVST) is aÂ rare complication in recipients of the adenovirus-vectored coronavirus disease 2019 (COVID-19) vaccine ChAdOx1 nCov-19 (VaxzevriaÂ®; AstraZeneca). OBJECTIVES: Development of aÂ diagnostic and therapeutic standard. MATERIALS AND METHODS: Analysis of clinical and basic research findings, expert opinions, and experience with our own cases. RESULTS: VI-CVST usually manifests on day 4-24 after vaccination, mostly in individuals aged <â€¯60Â years, and women. In the majority there is an immune pathogenesis caused by antibodies against platelet factor 4/polyanion complexes, leading to thrombotic thrombocytopenia which can result in severe, sometimes fatal, course. The cardinal symptom is headache worsening within days which, however, also can be of variable intensity. Other possible symptoms are seizures, visual disturbance, focal neurological deficits and signs of increased intracranial pressure. If VI-CVST is suspected, the determination of plasma Dâ€‘dimer level, platelet count, and screening for heparin-induced thrombocytopenia (HIT-2) are essential for treatment decision-making. Magnetic resonance imaging (MRI) with venous MR-angiography is the neuroimaging modality of choice to confirm or exclude VI-CVST. On T2* susceptibility-weighted MRI, the clot in the sinuses or veins produces marked susceptibility artifacts ("blooming"), which also enables the detection of isolated cortical venous thromboses. MRI/MR-angiography or computed tomography (CT)/CT-angiography usually allow-in combination with clinical and laboratory findings-reliable diagnosis of VI-CVST. CONCLUSIONS: The clinical suspicion of VI-CVST calls for urgent laboratory and neuroimaging workup. In the presence of thrombocytopenia and/or pathogenic antibodies, specific medications for anticoagulation and immunomodulation are recommended.
COVID-19 vaccinations are associated with reduced fatality rates: Evidence from cross-country quasi-experiments. BACKGROUND: Scientists have demonstrated the efficacy of vaccines against severe acute respiratory syndrome coronavirus 2 in randomized controlled trials. However, the extent to which reductions in COVID-19 case fatality ratio (CFR) are attributable to mass vaccination in the real world remains unclear. This study evaluated the association of COVID-19 vaccine coverage with CFR on a global scale. METHODS: The sample was a longitudinal data set of 90 countries over 25 weeks, from the first week of November 2020 to the third week of April 2021. CFR was measured in

deaths per 100 COVID-19 confirmed cases; vaccine coverage was defined as the number of people who received at least one vaccine dose per 10 people in the total population. Data were retrieved from open-access databases, including Our World in Data and the Oxford COVID-19 Government Response Tracker. A country-level random effects model was used; a comprehensive set of variables for country characteristics and nonpharmaceutical interventions were included. RESULTS: A 10% increase in vaccine coverage was associated with a 7.6% reduction in the CFR (95% confidence interval (CIâ€‰=â€‰-12.6 to -2.7%, Pâ€‰=â€‰0.002). This association was stronger in countries with more effective governments (-8.3%; 95% CIâ€‰=â€‰-13.6 to -3.1%, Pâ€‰=â€‰0.002) and higher transport infrastructure quality (-8.1%; 95% CIâ€‰=â€‰-13.3 to -2.9%, Pâ€‰=â€‰0.002). Moreover, the vaccine coverage was associated with a reduced CFR in a dose-dependent manner. When vaccine coverage achieved 0.8 to 1.6, 1.6 to 3.2 and â‰¥3.2 per 10 people, the CFR reduced by 12.7% (95 CIâ€‰=â€‰-21.8 to -3.6%, Pâ€‰=â€‰0.006), 21.2% (95 CIâ€‰=â€‰-33.9 to -8.5%, Pâ€‰=â€‰0.001) and 31.3% (95 CIâ€‰=â€‰-51.5 to -11.0%, Pâ€‰=â€‰0.002), respectively as compared with no vaccination. CONCLUSIONS: Our results provide supporting evidence that vaccination is critical to preventing deaths among infected people. Vaccination programmes have yielded significant health benefits in certain countries. However, globally, a large gap remains between observed and achievable fatality reductions. Continuous improvement in vaccine coverage will be critical to transforming efficacious vaccines into desired health outcomes.

'Erring on the side of rare events'? A behavioural explanation for COVID-19 vaccine regulatory misalignment.

Multisystem inflammatory syndrome in an adult following the SARS-CoV-2 vaccine (MIS-V). SARS-CoV-2 vaccine roll-out has been successful in the UK and other parts of the world; however, there are increasing concerns about adverse events. A 44-year-old woman presented to a UK hospital with left upper arm pain at the vaccine site a couple of days after receiving the Pfizer-BioNTech mRNA vaccine, which progressed to fever, diarrhoea and abdominal pain over the next few days. She had an erythematous rash on the chest with subcutaneous oedema. Her C reactive protein was 539â€‰mg/L, white cell count of 17Ã—10(9)/L (1.8-7.5), troponin-T of 1013â€‰ng/L and creatine kinase of 572â€‰u/L. She developed an unprovoked pulmonary embolism with acute kidney injury. After administration of intravenous methylprednisolone, the muscle oedema, skin rashes and acute kidney injury resolved. Although multisystem inflammatory syndrome (MIS) is described in children (MIS-C) and adults (MIS-A) following SARS-CoV-2 infection, we highlight the first reported MIS-V case after the SARS-CoV-2 vaccine.

Cord blood antibody following maternal SARS-CoV-2 inactive vaccine (CoronaVac) administration during the pregnancy. Maternal vaccination with SARS-CoV-2 vaccines has not been well studied yet in terms of safety and efficacy for protecting the newborn by the placental passage of antibodies. We reported 34Â years of old health care worker (HCW) without any known SARS-CoV-2 infection. She had the first dose of SARS-CoV-2 inactivated virus vaccine (CoronaVac, Sinovac Life Science Co, Ltd, Beijing, China) at a gestational age of 28Â weeks. The second dose of vaccine was given four weeks later at a gestational age of 32Â weeks. HCW did not report any vaccine-related adverse events after either the first or second dose of the vaccine. Three weeks after the second dose of the vaccine, her anti-receptor-binding domain (RBD) of SARS-CoV-2 spike protein antibody was 779 arbitrary units (AU) per ml. She gave a birth of 38Â weeks three days gestation age of healthy, full-term girl with a birth weight of 2770Â gr. The mother's anti-RBD antibody was 734Â AU/ml, the infant's cord blood anti-RBD antibody level was 764Â AU/ml, respectively, cord sera/maternal sera transfer ratio was 1,04. This infant is the first identified case of SARS-CoV-2 IgG antibodies detectable in cord blood after maternal vaccination with CoronaVac.

Acute disseminated encephalomyelitis after SARS-CoV-2 vaccination. Several central and peripheral nervous system complications associated with the severe acute respiratory syndrome coronavirus (SARS-CoV-2) infection have been recently described. An effective mass vaccination program is necessary to effectively reduce infection spread and, consequently, limit long-term sequelae, including those affecting the nervous system. Nevertheless, as more patients gain access to coronavirus disease 2019 (COVID-19) vaccines, it is important to report potential adverse events. Herein, we report a patient with previous history of post-infectious rhombencephalitis who developed an acute disseminated encephalomyelitis (ADEM) two weeks after being vaccinated for COVID-19.

Developmental and reproductive safety of AZD1222 (ChAdOx1 nCoV-19) in mice. AZD1222 (ChAdOx1 nCoV-19) is a COVID-19 vaccine that is not yet licensed for use during pregnancy. To support the inclusion of pregnant and breastfeeding people in AZD1222 clinical studies, a non-clinical developmental and reproductive toxicity study was performed to evaluate its effects on fertility and reproductive processes of female CD-1 mice during the embryofetal development phase, and postnatal outcomes during the littering phase. Immunogenicity assessments were also made in dams, fetuses, and pups. There were no vaccine-related unscheduled deaths throughout the study. Furthermore, there were no vaccine-related effects on female reproduction, fetal or pup survival, fetal external, visceral, or skeletal findings, pup physical development, and no abnormal gross pathology findings in pups or dams. Antibody responses raised in dams were maintained throughout gestation and postnatal periods, and seroconversion in fetuses and pups indicate placental and lactational transfer of immunoglobulins. Together with clinical data from non-pregnant people, these results support the inclusion of pregnant and breastfeeding people in AZD1222 clinical studies.

Safety, tolerability, and immunogenicity of an aerosolised adenovirus type-5 vector-based COVID-19 vaccine (Ad5-nCoV) in adults: preliminary report of an open-label and randomised phase 1 clinical trial. BACKGROUND: SARS-CoV-2 has caused millions of deaths, and, since Aug 11, 2020, 20 intramuscular COVID-19 vaccines have been approved for use. We aimed to evaluate the safety and immunogenicity of an aerosolised adenovirus type-5 vector-based COVID-19 vaccine (Ad5-nCoV) in adults without COVID-19 from China. METHOD: This was a randomised, single-centre, open-label, phase 1 trial done in Zhongnan Hospital (Wuhan, China), to evaluate the safety and immunogenicity of the Ad5-nCoV vaccine by aerosol inhalation in adults (â‰¥18 years) seronegative for SARS-CoV-2. Breastfeeding or pregnant women and people with major chronic illnesses or history of allergies were excluded. Participants were enrolled and randomly assigned (1:1:1:1:1) into five groups to be vaccinated via intramuscular injection, aerosol inhalation, or both. Randomisation was stratified by sex and age (18-55 years or â‰¥56 years) using computer-generated randomisation sequences (block sizes of five). Only laboratory staff were masked to group assignment. The participants in the two aerosol groups received an initial high dose (2â€ˆÃ—â€ˆ10(10) viral particles; HDmu group) or low dose (1â€ˆÃ—â€ˆ10(10) viral particles; LDmu group) of Ad5-nCoV vaccine on day 0, followed by a booster on day 28. The mixed vaccination group received an initial intramuscular (5â€ˆÃ—â€ˆ10(10) viral particles) vaccine on day 0, followed by an aerosolised booster (2â€ˆÃ—â€ˆ10(10) viral particles) vaccine on day 28 (MIX group). The intramuscular groups received one dose (5â€ˆÃ—â€ˆ10(10) viral particles; 1Dim group) or two doses (10â€ˆÃ—â€ˆ10(10) viral particles; 2Dim group) of Ad5-nCoV on day 0. The primary safety outcome was adverse events 7 days after each vaccination, and the primary immunogenicity outcome was anti-SARS-CoV-2 spike receptor IgG antibody and SARS-CoV-2 neutralising antibody geometric mean titres at day 28 after last vaccination. This trial is registered with ClinicalTrials.gov, number NCT04552366. FINDINGS: Between Sept 28, 2020, and Sept 30, 2020, 230 individuals were screened for inclusion, of whom 130 (56%) participants were enrolled into the trial and randomly assigned into one of the five groups (26 participants per group). Within 7 days

after vaccination, adverse events occurred in 18 (69%) in the HDmu group, 19 (73%) in the LDmu group, 19 (73%) in the MIX group, 19 (73%) in the 1Dim group, and 15 (58%) in the 2Dim group. The most common adverse events reported 7 days after the first or booster vaccine were fever (62 [48%] of 130 participants), fatigue (40 [31%] participants), and headache (46 [35%] participants). More adverse events were reported in participants who received intramuscular vaccination, including participants in the MIX group (49 [63%] of 78 participants), than those who received aerosol vaccine (13 [25%] of 52 participants) after the first vaccine vaccination. No serious adverse events were noted within 56 days after the first vaccine. At days 28 after last vaccination, geometric mean titres of SARS-CoV-2 neutralising antibody was 107 (95% CI 47-245) in the HDmu group, 105 (47-232) in the LDmu group, 396 (207-758) in the MIX group, 95 (61-147) in the 1Dim group, and 180 (113-288) in the 2Dim group. The geometric mean concentrations of receptor binding domain-binding IgG was 261 EU/mL (95% CI 121-563) in the HDmu group, 289 EU/mL (138-606) in the LDmu group, 2013 EU/mL (1180-3435) in the MIX group, 915 EU/mL (588-1423) in the 1Dim group, and 1190 EU/mL (776-1824) in the 2Dim group. INTERPRETATION: Aerosolised Ad5-nCoV is well tolerated, and two doses of aerosolised Ad5-nCoV elicited neutralising antibody responses, similar to one dose of intramuscular injection. An aerosolised booster vaccination at 28 days after first intramuscular injection induced strong IgG and neutralising antibody responses. The efficacy and cost-effectiveness of aerosol vaccination should be evaluated in future studies. FUNDING: National Key Research and Development Programme of China and National Science and Technology Major Project. TRANSLATION: For the Chinese translation of the Summary see Supplementary Material.

SARS-CoV-2 Infection in Public School District Employees Following a District-Wide Vaccination Program - Philadelphia County, Pennsylvania, March 21-April 23, 2021. The School District of Philadelphia reopened for in-school instruction the week of March 21, 2021, and required weekly testing for SARS-CoV-2, the virus that causes COVID-19, for all employees returning to in-school responsibilities. The resumption of in-school instruction followed a mass vaccination program using the Pfizer-BioNTech 2-dose vaccine offered under a partnership between the Philadelphia Department of Public Health and Children's Hospital of Philadelphia to all 22,808 School District of Philadelphia employees during February 23-April 3, 2021.* The subsequent mandatory testing program provided an opportunity to assess the percentage of positive BinaxNow point-of-care antigen tests (Abbott Laboratories) identified among school staff members based on their self-reported vaccination status (i.e., received zero, 1, or 2 vaccine doses) at the time of testing. During the initial 5 weeks after schools reopened, 34,048 screening tests were performed. Overall, 0.70% of tests returned a positive result. The percentage of positive test results was lower among persons who reported receipt of 2 vaccine doses (0.09%) compared with those who reported receipt of 1 dose (1.21%) or zero doses (1.76%) ($p<0.001$) representing a 95% reduction in percentage of positive SARS-CoV-2 test results among persons reporting receipt of 2 compared with zero doses of Pfizer-BioNTech vaccine. Vaccination of school staff members has been highlighted as an important strategy to maximize the safety of in-person education of K-12 students this fall (1). These findings reinforce the importance of promoting COVID-19 vaccination among school staff members before commencement of the 2021-22 school year.

Postvaccinal Encephalitis after ChAdOx1 nCov-19. The global SARS-CoV-2 pandemic has contributed to more than 163 million confirmed infections and 3.3 million deaths worldwide. The severity of the pandemic has led to an unprecedented effort to develop multiple effective vaccines. Due to excellent safety and efficacy data from clinical trials, several vaccines were approved. We report a case series of postvaccinal encephalitis in temporal correlation to vaccination with ChAdOx1 nCov-19. The diagnostic criteria for possible autoimmune encephalitis were fulfilled. Our patients responded well to immunosuppressive therapy with corticosteroids. The incidence has been

estimated to be approximately 8 per 10 million vaccine doses. Complication of postvaccinal encephalitis after ChAdOx1 nCoV-19 vaccination still appear to be very rare, but need to be diagnosed and treated adequately. Large pooled data from observational epidemiologic studies are necessary to verify causality. ANN NEUROL 2021;90:506-511.
Presence of specific T cell response after SARS-CoV-2 vaccination in rheumatoid arthritis patients receiving rituximab.
Functional neurological disorder after COVID-19 vaccination.
The effect of a single dose of BNT162b2 vaccine on the incidence of severe COVID-19 infection in patients on chronic hemodialysis: a single-centre study. INTRODUCTION: In this single-centre retrospective observational study, the 8-week safety and the efficiency of a single dose of BNT162b2 vaccine was studied in 83 HD patients. METHODS: All clinically stable adult ESRD patients on chronic HD for at least 4Â weeks were screened for participation in the study. Exclusion criteria for enrollment in the study included a medical history of COVID-19 infection within the last 12Â weeks or delivery of both vaccine doses less than 8Â weeks apart from each other. The same patients during the 8-week period that preceded the vaccination served as controls of themselves. The vaccine was administered intramuscularly in the deltoid muscle, on a dialysis day, at least 30Â min either pre- or post-dialysis. The primary end-point of the study was severe COVID-19 infection, and/or death due to COVID-19 pneumonitis. Furthermore, all vaccinated patients were scrutinized for any local or systemic reactions within the first 7Â days post-vaccination. RESULTS: Amongst 113 adult HD patients in our Unit, in total 83 patients had the first 30Â Î¼g dose of the BNT162b2 vaccine and were considered eligible to be included in the study. The 8-week survival rate was 91% for the controls and 100% for the vaccine group. No life-threatening allergic reaction or other side-effect was observed post-vaccination. CONCLUSION: The BNT162b2 vaccine can be safely used in HD patients and seems to offer significant protection against the infection even after the first vaccine dose.
Vaccine-induced immune thrombotic thrombocytopenia: what we know and do not know. The development of vaccines to fight COVID-19 has been a remarkable medical achievement. However, this global immunization effort has been complicated by a rare vaccine-related outcome characterized by thrombocytopenia and thrombosis in association with platelet-activating anti-platelet factor 4 antibodies. In this Spotlight, we will discuss the recently described complication of vaccine-induced immune thrombotic thrombocytopenia (VITT) occurring in response to certain COVID-19 vaccines. Although information about this clinical condition is rapidly evolving, we will summarize our current understanding of VITT.
Prothrombotic immune thrombocytopenia after COVID-19 vaccination. We report 5 cases of prothrombotic immune thrombocytopenia after exposure to the ChAdOx1 vaccine (AZD1222, Vaxzevria) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Patients presented 5 to 11 days after first vaccination. The spectrum of clinical manifestations included cerebral venous sinus thrombosis, splanchnic vein thrombosis, arterial cerebral thromboembolism, and thrombotic microangiopathy. All patients had thrombocytopenia and markedly elevated D-dimer. Autoantibodies against platelet factor 4 (PF4) were detected in all patients, although they had never been exposed to heparin. Immunoglobulin from patient sera bound to healthy donor platelets in an AZD1222-dependent manner, suppressed by heparin. Aggregation of healthy donor platelets by patient sera was demonstrated in the presence of buffer or AZD1222 and was also suppressed by heparin. Anticoagulation alone or in combination with eculizumab or intravenous immunoglobulin (IVIG) resolved the pathology in 3 patients. Two patients had thromboembolic events despite anticoagulation at a time when platelets were increasing after IVIG. In summary, an unexpected autoimmune prothrombotic disorder is described after vaccination with AZD1222. It is characterized

by thrombocytopenia and anti-PF4 antibodies binding to platelets in AZD1222-dependent manner. Initial clinical experience suggests a risk of unusual and severe thromboembolic events.
Development of antibody response to SARS-CoV-2 following asymptomatic infection in patients with plasma cell disorders on immunomodulatory therapy.
Analysis of Continuous Blood Glucose Data in People with Type 1 Diabetes (T1DM) After COVID-19 Vaccination Indicates a Possible Link Between the Immune and the Metabolic Response.
Bell's palsy following COVID-19 vaccination with high CSF antibody response.
Humoral serological response to the BNT162b2 vaccine is abrogated in lymphoma patients within the first 12 months following treatment with anti-CD2O antibodies. Patients with lymphoma, especially those treated with anti-CD20 monoclonal antibodies, suffer high COVID-19-associated morbidity and mortality. The goal of this study was to assess the ability of lymphoma patients to generate a sufficient humoral response after two injections of BNT162b2 Pfizer vaccine and to identify factors influencing the response. Antibody titers were measured with the SARS-CoV-2 IgG II Quant (Abbottâ€,) assay in blood samples drawn from lymphoma patients 4â€,2 weeks after the second dose of vaccine. The cutoff for a positive response was set at 50 AU/mL. Positive serological responses were observed in 51% of the 162 patients enrolled in this cross-sectional study. In a multivariate analysis, an interval of <12 months between the last anti-CD20 monoclonal antibody dose and the second vaccine dose (odds ratio=31.3 [95% confidence interval: 8.4-116.9], P<0.001) and presence of active lymphoma (odds ratio=4.2 (95% confidence interval: 2.1- 8.2), P=0.006) were identified as negative response predictors. The rate of seropositivity increased from 3% in patients vaccinated within 45 days after the last monoclonal antibody administration to 80% in patients vaccinated >1 year after this therapy. The latter percentage was equal to that of patients never exposed to monoclonal antibodies. In conclusion, lymphoma patients, especially those recently treated with anti- CD20 monoclonal antibodies, fail to develop sufficient humoral response to BNT162b2 vaccine. While a serological response is not the only predictor of immunity, its low level could make this population more vulnerable to COVID-19, which implies the need for a different vaccination schedule for such patients.
Safety and efficacy of the BNT162b mRNA COVID-19 vaccine in patients with chronic lymphocytic leukemia. Patients with chronic lymphocytic leukemia (CLL) have a suboptimal humoral response to vaccination. Recently, BNT162b2, an mRNA COVID-19 vaccine with a high efficacy of 95% in immunocompetent individuals, was introduced. We investigated the safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine in patients with CLL from nine medical centers in Israel, Overall 400 patients were included, of whom 373 were found to be eligible for the analysis of antibody response. The vaccine appeared to be safe and only grade 1-2 adverse events were seen in 50% of the patients. Following the second dose, an antibody response was detected in 43% of the cohort. Among these CLL patients, 61% of the treatment-naâ€,ve patients responded to the vaccine, while responses developed in only 18% of those with ongoing disease, 37% of those previously treated with a BTK inhibitor and 5% of those recently given an anti-CD20 antibody. Among patients treated with BCL2 as monotherapy or in combination with anti-CD20, 62% and 14%, respectively, developed an immune response. There was a high concordance between neutralizing antibodies and positive serological response to spike protein. Based on our findings we developed a simple seven-factor score including timing of any treatment with anti-CD20, age, treatment status, and IgG, IgA, IgM and hemoglobin levels. The sum of all the above parameters can serve as a possible estimate to predict whether a given CLL patient will develop sufficient antibodies. In conclusion, the BNT162b2 mRNA COVID-19 vaccine was found to be safe in patients with CLL, but its efficacy is limited, particularly in treated patients.

Addressing structural discrimination: prioritising people with mental health and addiction issues during the COVID-19 pandemic. Structural discrimination worsens physical health inequities and significantly reduces life expectancy for people with mental health and addiction issues. Aotearoa has recently made some notable changes in health policy by formally recognising the physical health needs of people with mental health and addiction issues. The COVID-19 vaccination sequencing framework provides an important opportunity to protect and promote the health of people with addiction and mental health issues. An expert advisory group, convened as part of the Aotearoa Equally Well collaborative, considered findings of a literature review on the vulnerability of people with mental health and addiction issues of contracting and dying from COVID-19. Evidence indicates an association between mental health and addiction issues and infection risk and worse outcomes. The group concluded mental health and addiction issues should be recognised as underlying health conditions that increase COVID-19 vulnerability, and that people with these issues should be prioritised for vaccination. For too long the health system has failed to address the life expectancy gap of people with addiction and mental health issues. Now is an opportunity to change the kÅ•rero. People with mental health and addiction issues experience significant physical health inequities. Addressing these inequities must be integral in modern health policy-including our COVID-19 pandemic response.
Breakthrough COVID-19 Infections After mRNA Vaccination in Solid Organ Transplant Recipients in Miami, Florida.
Association of Facial Pustular Neutrophilic Eruption With Messenger RNA-1273 SARS-CoV-2 Vaccine.
Adult-onset Still's disease following COVID-19 vaccination.
Varicella zoster virus reactivation and mRNA vaccines as a trigger.
Herpes zoster reactivation after mRNA-1273 (Moderna) SARS-CoV-2 vaccination.
Intranasal ChAdOx1 nCoV-19/AZD1222 vaccination reduces viral shedding after SARS-CoV-2 D614G challenge in preclinical models. ChAdOx1 nCoV-19/AZD1222 is an approved adenovirus-based vaccine for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) currently being deployed globally. Previous studies in rhesus macaques revealed that intramuscular vaccination with ChAdOx1 nCoV-19/AZD1222 provided protection against pneumonia but did not reduce shedding of SARS-CoV-2 from the upper respiratory tract. Here, we investigated whether intranasally administered ChAdOx1 nCoV-19 reduces detection of virus in nasal swabs after challenging vaccinated macaques and hamsters with SARS-CoV-2 carrying a D614G mutation in the spike protein. Viral loads in swabs obtained from intranasally vaccinated hamsters were decreased compared to control hamsters, and no viral RNA or infectious virus was found in lung tissue after a direct challenge or after direct contact with infected hamsters. Intranasal vaccination of rhesus macaques resulted in reduced virus concentrations in nasal swabs and a reduction in viral loads in bronchoalveolar lavage and lower respiratory tract tissue. Intranasal vaccination with ChAdOx1 nCoV-19/AZD1222 reduced virus concentrations in nasal swabs in two different SARS-CoV-2 animal models, warranting further investigation as a potential vaccination route for COVID-19 vaccines.
Continuing to Challenge the Paradigm of What Is Possible in Pharmacy Education and Practice Post-COVID-19. The COVID-19 pandemic has caused boundless disruptions to every element of life. It has also brought with it lessons from the past that will likely extend into the future as humans continue to interface with the ever-increasing threats of zoonotic diseases. The pandemic has challenged the profession and the Academy to adjust, modify, and adapt. It has also stretched the bounds of what had previously been thought possible within the realms of medicine. As the Academy begins to reach and crest the apex of the epidemic it should be reminded of the many lessons associated with the pandemic and of the constant need to challenge the paradigm of what is possible.

Evaluation of the safety profile of COVID-19 vaccines: a rapid review. BACKGROUND: The rapid process of research and development and lack of follow-up time post-vaccination aroused great public concern about the safety profile of COVID-19 vaccine candidates. To provide comprehensive overview of the safety profile of COVID-19 vaccines by using meta-analysis technique. METHODS: English-language articles and results posted on PubMed, Embase, Web of Science, PMC, official regulatory websites, and post-authorization safety surveillance data were searched through June 12, 2021. Publications disclosing safety data of COVID-19 candidate vaccines in humans were included. A meta-analysis of proportions was performed to estimate the pooled incidence and the pooled rate ratio (RR) of safety outcomes of COVID-19 vaccines using different platforms. RESULTS: A total of 87 publications with safety data from clinical trials and post-authorization studies of 19 COVID-19 vaccines on 6 different platforms were included. The pooled rates of local and systemic reactions were significantly lower among inactivated vaccines (23.7%, 21.0%), protein subunit vaccines (33.0%, 22.3%), and DNA vaccines (39.5%, 29.3%), compared to RNA vaccines (89.4%, 83.3%), non-replicating vector vaccines (55.9%, 66.3%), and virus-like particle vaccines (100.0%, 78.9%). Solicited injection-site pain was the most common local reactions, and fatigue and headache were the most common systemic reactions. The frequency of vaccine-related serious adverse events was low (< 0.1%) and balanced between treatment groups. Vaccine platforms and age groups of vaccine recipients accounted for much of the heterogeneity in safety profiles between COVID-19 vaccines. Reporting rates of adverse events from post-authorization observational studies were similar to results from clinical trials. Crude reporting rates of adverse events from post-authorization safety monitoring (passive surveillance) were lower than in clinical trials and varied between countries. CONCLUSIONS: Available evidence indicates that eligible COVID-19 vaccines have an acceptable short-term safety profile. Additional studies and long-term population-level surveillance are strongly encouraged to further define the safety profile of COVID-19 vaccines.
Secondary thrombocytopenia after SARS-CoV-2 vaccine: Report of a case of hemorrhage and hematoma after minor oral surgery. The authors present the case of a patient who underwent the removal of a small bluish lesion of the cheek. After discharge, the patient presented with profuse bleeding and hematoma of the cheek. Blood tests revealed severe secondary immune thrombocytopenia (SITP). SITP was probably triggered by the anti-SARS-CoV-2 Pfizer vaccine, which was inoculated to the patient 3 days before the lesion appeared and 12 days before surgery. The authors' aim is to inform colleagues about this possible, rare, adverse effect of the vaccine. In all patients who have recently undergone the COVID-19 vaccine and who present lesions suspected to be due to blood extravasation of the oral mucosa or unjustified gingival bleeding it is advisable to request a blood count before surgery.
Maternal COVID-19, vaccination safety in pregnancy, and evidence of protective immunity.
COVID-19 Vaccine Reactions in Dermatology: "Filling" in the Gaps.
Haemophagocytosis and atypical vacuolated lymphocytes in bone marrow and blood films after SARS-CoV-2 vaccination.
Adenovirus-Vectored COVID-19 Vaccine-Induced Immune Thrombosis of Carotid Artery: A Case Report. OBJECTIVES: Venous thrombosis and thrombocytopenia after vaccination with the adenovirus-vectored COVID-19 vaccine ChAdOx1 nCov-19 (AstraZeneca) have been linked to serum antibodies against platelet factor 4 (PF4)-polyanion complexes. We here report vaccine-induced isolated carotid arterial thrombosis. METHODS: Imaging and laboratory findings, treatment decisions, and outcome of this case are presented. RESULTS: Eight days after having received the first dose of ChAdOx1 nCov-19 vaccine, a 31-year-old man was admitted to our stroke unit with acute headache, aphasia, and hemiparesis. D-dimers were slightly elevated, but platelet count and fibrinogen level were normal. MRI-confirmed mainstem occlusion of middle cerebral artery resolved within 1 hour

after the start of IV thrombolysis. A wall-adherent, nonoccluding thrombus in the ipsilateral carotid bulb was identified as the source of embolism. Cardiac or paradoxical (venous) embolism was excluded. Screening for the presence of heparin-induced thrombocytopenia-related antibodies was positive, and highly elevated serum IgG antibodies against PF4-polyanion complexes were subsequently proven. Treatment with aspirin and subcutaneous danaparoid, followed by phenprocoumon, led to thrombus shrinkage and dissolution within 19 days and favorable clinical outcome. DISCUSSION: Vaccine history is important in patients not only with venous but also with arterial thromboembolic events. Vaccine-induced immune thrombosis of brain-supplying arteries may well be handled.
Humoral Response to mRNA versus an Adenovirus Vector-Based SARS-CoV-2 Vaccine in Dialysis Patients.
Acute encephalitis, myoclonus and Sweet syndrome after mRNA-1273 vaccine. A patient presented with fever, generalised rash, confusion, orofacial movements and myoclonus after receiving the first dose of mRNA-1273 vaccine from Moderna. MRI was unremarkable while cerebrospinal fluid showed leucocytosis with lymphocyte predominance and hyperproteinorrachia. The skin evidenced red, non-scaly, oedematous papules coalescing into plaques with scattered non-follicular pustules. Skin biopsy was consistent with a neutrophilic dermatosis. The patient fulfilled the criteria for Sweet syndrome. A thorough evaluation ruled out alternative infectious, autoimmune or malignant aetiologies, and all manifestations resolved with glucocorticoids. While we cannot prove causality, there was a temporal correlation between the vaccination and the clinical findings.
Correction to: The Canadian Society of Breast Imaging/Canadian Association of Radiologists' Recommendations for the Management of Axillary Adenopathy in Patients With Recent COVID-19 Vaccination.
Herpes Zoster following SARS-CoV-2 vaccination - a series of four cases.
Two Doses of SARS-CoV-2 Vaccines Reduce Risk of Death Due to COVID-19 in Solid Organ Transplant Recipients: Preliminary Outcomes From a UK Registry Linkage Analysis.
New onset of mainly guttate psoriasis after COVID-19 vaccination: a case report.
Acquired thrombotic thrombocytopenic purpura after first vaccination dose of BNT162b2 mRNA COVID-19 vaccine.
Impact of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Variant-Associated Receptor Binding Domain (RBD) Mutations on the Susceptibility to Serum Antibodies Elicited by Coronavirus Disease 2019 (COVID-19) Infection or Vaccination. BACKGROUND: Several severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) lineages with mutations at the spike protein receptor binding domain (RBD) have reduced susceptibility to antibody neutralization, and have been classified as variants of concern (VOCs) or variants of interest (VOIs). Here we systematically compared the neutralization susceptibility and RBD binding of different VOCs/VOIs, including B.1.617.1 (kappa variant) and P.3 (theta variant), which were first detected in India and the Philippines, respectively. METHODS: The neutralization susceptibility of the VOCs/VOIs (B.1.351, B.1.617.1, and P.3) and a non-VOC/VOI without RBD mutations (B.1.36.27) to convalescent sera from coronavirus disease 2019 (COVID-19) patients or BNT162b2 vaccinees was determined using a live virus microneutralization (MN) assay. Serum immunoglobulin G (IgG) binding to wild-type and mutant RBDs were determined using an enzyme immunoassay. RESULTS: The geometric mean neutralization titers (GMT) of B.1.351, P.3, and B.1.617.1 were significantly lower than that of B.1.36.27 for COVID-19 patients infected with non-VOCs/VOIs (3.4- to 5.7-fold lower) or individuals who have received 2 doses of BNT162b2 vaccine (4.4- to 7.3-fold lower). The GMT of B.1.351 or P.3 were lower than that of B.1.617.1. For the 4 patients infected with B.1.351 or B.1.617.1, the MN titer was highest for their respective lineage. RBD with E484K or E484Q mutation, either alone or in combination with other

mutations, showed greatest reduction in serum IgG binding. CONCLUSIONS: P.3 and B.1.617.1 escape serum neutralization induced by natural infection or vaccine. Infection with 1 variant does not confer cross-protection for heterologous lineages. Immunogenicity testing for second generation COVID-19 vaccines should include multiple variant and "nonvariant" strains.
Safety Evaluation of the Second Dose of Messenger RNA COVID-19 Vaccines in Patients With Immediate Reactions to the First Dose. This case series study examines the safety of second doses of messenger RNA COVID-19 vaccines after first-dose allergic reactions.
Polyethylene Glycol Allergy and Immediate-Type Hypersensitivity Reaction to COVID-19 Vaccination: Case Report.
Low rate of seroconversion after mRNA anti-SARS-CoV-2 vaccination in patients with hematological malignancies.
Case report of lymph node activation mimicking cancer progression: A false positive F(18) FDG PET CT after COVID-19 vaccination. This case illustrates a false positive F(18) FDG PET CT in the left axilla of a woman being treated for metastatic breast cancer after COVID-19 vaccination. Follow-up ultrasound of the axilla indicated no metastasis, indicating that the lymphadenopathy was likely due to an immune response following vaccination. This case report, in conjunction with prior studies of other vaccines with similar findings suggest that providers should be aware of potential false positive imaging following COVID-19 vaccination. In light of these findings, clinicians and imaging providers should record the date and side of the vaccination and inform patient of potential false positive results to reduce patient anxiety and unnecessary tests as COVID-19 vaccines become widely available.
Acute Myocarditis Following mRNA-1273 SARS-CoV-2 Vaccination. Myocarditis has been described previously as a rare side effect of both influenza and smallpox vaccines. In this report, we present a case of acute perimyocarditis in a young, healthy man after vaccination with the mRNA-1273 severe acute respiratory syndrome coronavirus -2 (SARS-CoV-2; Moderna) vaccine. He presented with chest pain and decompensated heart failure 3 days after administration of his second dose, and his symptoms resolved by 9 days post-inoculation. This case highlights a rare but potentially serious side effect of this mRNA vaccine that primary care physicians and cardiologists should be aware of in order to identify and appropriately manage these patients.
Acute Immune Thrombocytopenia (ITP) Following COVID-19 Vaccination in a Patient With Previously Stable ITP. Immune thrombocytopenia (ITP) is an autoimmune condition associated with multiple risk factors including viral infections (hepatitis B virus/hepatitis C virus/cytomegalovirus, HIV, and recently severe acute respiratory syndrome coronavirus 2) and vaccines. Though immune mechanisms have been proposed to explain the pathogenesis of acute ITP, autoimmunity with the coronavirus disease 2019 (COVID-19) vaccine is still unclear and needs further research. We report a case of acute ITP after administration of the Pfizer-BioNTech mRNA COVID-19 vaccine in a patient with previously stable ITP.
SARS-CoV-2 vaccinations are unsafe for those experiencing post-vaccination Guillain-Barre syndrome.
Quadrilateral space region inflammation and other incidental findings on shoulder MRI following recent COVID-19 vaccination: Three case reports. We present 3 cases reporting the normal appearance of the post COVID-19 vaccination on shoulder MRI exams. All 3 patients were imaged 1 to 5 days post-vaccination for unrelated MSK shoulder symptoms, and none reported any symptoms besides mild shoulder discomfort for a day or 2 following vaccine administration. All 3 patients demonstrated characteristic deltoid edema, quadrilateral space region edema and axillary nodal prominence. Vessel prominence with t2 and t1 increased signal draining to the approximate location of the quadrilateral space and axilla was an associated feature. The normal appearance of the covid-19 vaccine on shoulder MRI has not been previously described, and recognition by the radiologist will

prevent erroneous differential diagnosis, unnecessary medical workups, and detract from the clinically relevant pathological imaging findings in patients with shoulder pain.
Cerebral Vein Thrombosis With Vaccine-Induced Immune Thrombotic Thrombocytopenia. In the spring of 2021, reports of rare and unusual venous thrombosis in association with the ChAdOx1 and Ad26.COV2.S adenovirus-based coronavirus vaccines led to a brief suspension of their use by several countries. Thromboses in the cerebral and splanchnic veins among patients vaccinated in the preceding 4 weeks were described in 17 patients out of 7.98 million recipients of the Ad26.COV2.S vaccine (with 3 fatalities related to cerebral vein thrombosis) and 169 cases of cerebral vein thrombosis among 35 million ChAdOx1 recipients. Events were associated with thrombocytopenia and anti-PF4 (antibodies directed against platelet factor 4), leading to the designation vaccine-induced immune thrombotic thrombocytopenia. Unlike the related heparin-induced thrombotic thrombocytopenia, with an estimated incidence of <1:1000 patients treated with heparin, and a mortality rate of 25%, vaccine-induced immune thrombotic thrombocytopenia has been reported in 1:150â€‰000 ChAdOx1 recipients and 1:470â€‰000 Ad26.COV.2 recipients, with a reported mortality rate of 20% to 30%. Early recognition of this complication should prompt testing for anti-PF4 antibodies and acute treatment targeting the autoimmune and prothrombotic processes. Intravenous immunoglobulin (1 g/kg for 2 days), consideration of plasma exchange, and nonheparin anticoagulation (argatroban, fondaparinux) are recommended. In cases of cerebral vein thrombosis, one should monitor for and treat the known complications of venous congestion as they would in patients without vaccine-induced immune thrombotic thrombocytopenia. Now that the Ad26.COV2.S has been reapproved for use in several countries, it remains a critical component of our pharmacological armamentarium in stopping the spread of the human coronavirus and should be strongly recommended to patients. At this time, the patient and community-level benefits of these two adenoviral vaccines vastly outweigh the rare but serious risks of vaccination. Due to the relatively low risk of severe coronavirus disease 2019 (COVID-19) in young women (<50 years), it is reasonable to recommend an alternative vaccine if one is available. Ongoing postmarketing observational studies are important for tracking new vaccine-induced immune thrombotic thrombocytopenia cases and other rare side effects of these emergent interventions.
Misinterpretation of glioblastoma as ADEM: potentially harmful consequences of over-diagnosis of COVID-19 vaccine-associated adverse events.
Axillary adenopathy following COVID-19 vaccination: A single institution case series. Axillary adenopathy is a potential side effect following COVID-19 vaccination. We report four cases of axillary adenopathy in the setting of recent COVID-19 vaccination (Moderna and Pfizer-BioNTech) at our institution. Our cases show unilateral axillary adenopathy, as well as adenopathy persisting for two to three weeks following vaccination. The Society of Breast Imaging (SBI) and Harvard University have each released guidelines for management of axillary adenopathy following COVID-19 vaccination. While SBI recommends short term imaging 4-12Â weeks following the second dose, a group of physicians from Harvard suggest clinical follow-up with sonographic imaging if clinical concern persists beyond six weeks. As a larger percentage of the general population becomes vaccinated, it is important for radiologists to be aware of potential vaccine-induced ipsilateral axillary adenopathy on screening and diagnostic breast imaging to reduce the number of unnecessary biopsies performed in this patient population.
Active Covid-19 infection and transmission after the first dose of the BNT162b2 mRNA vaccination in Saudi Arabia: A case report. A 47-year-old non-smoker male who has received the first dose of the BNT162b2 mRNA Covid-19 vaccine in Saudi Arabia. At day 3 post-vaccination, he tested negative for Covid-19 and travelled to Egypt. On day 12 he developed runny nose, body ache and fever, and he reportedly tested (PCR) negative for Covid-19 Upon his return to Saudi on day 15, his symptoms have

worsened and he presented to the Emergency Department, at which he tested positive for Covid-19. The patient was overweight (BMI = 29), was not suffering from any comorbidities and was not taking any medication. Upon examination, he was vitally stable and his laboratory investigation only revealed a slightly increased Creatinine. His chest X-ray was unremarkable. His condition did not require hospital admission, so he was discharged and advised to home-isolate himself. Four days after his discharge, his entire household came to the hospital and tested positive for Covid-19. This is the first case report, in Saudi Arabia, of a person receiving the first dose of the BNT162b2 vaccine and got infected with Covid-19 afterwards. The report highlights the significance of receiving the second dose of the vaccine to be effective. It also demonstrates that those with a single dose mRNA vaccine, could get infected and transmit the infection.

BCG vaccination induces enhanced frequencies of dendritic cells and altered plasma levels of type I and type III interferons in elderly individuals. OBJECTIVE: BCG can improve the response to vaccines directed against viral infections, and also, BCG vaccination reduces all-cause mortality, most likely by protecting against unrelated infections. However, the effect of BCG vaccination on dendritic cell (DC) subsets is not well characterized. METHODS: We investigated the impact of BCG vaccination on the frequencies of DC subsets and type I and III interferons (IFNs) using whole blood and plasma samples in a group of elderly individuals (age 60-80 years) at one-month post-vaccination as part of our clinical study to examine the effect of BCG on COVID-19. RESULTS: Our results demonstrate that BCG vaccination induced enhanced frequencies of plasmacytoid DC (pDC) and myeloid DC (mDC). BCG vaccination also induced diminished plasma levels of type I IFNs, IFNÎ±Â and IFNÎ² but increased levels of type III IFNs, IL-28A and IL-29. CONCLUSIONS: Thus, BCG vaccination was associated with enhanced DC subsets and IL-28A/IL-29 in elderly individuals, suggesting its ability to induce non-specific innate immune responses.

Neutralizing Antibodies Against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Variants Induced by Natural Infection or Vaccination: A Systematic Review and Pooled Analysis. Recently emerged severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants may pose a threat to immunity. A systematic landscape of neutralizing antibodies against emerging variants is needed. We systematically searched for studies that evaluated neutralizing antibody titers induced by previous infection or vaccination against SARS-CoV-2 variants and collected individual data. We identified 106 studies meeting the eligibility criteria. Lineage B.1.351 (beta), P.1 (gamma) and B.1.617.2 (delta) significantly escaped natural infection-mediated neutralization, with an average of 4.1-fold (95% confidence interval [CI]: 3.6-4.7-fold), 1.8-fold (1.4-2.4-fold), and 3.2-fold (2.4-4.1-fold) reduction in live virus neutralization assay, while neutralizing titers against B.1.1.7 (alpha) decreased slightly (1.4-fold [95% CI: 1.2-1.6-fold]). Serum from vaccinees also led to significant reductions in neutralization of B.1.351 across different platforms, with an average of 7.1-fold (95% CI: 5.5-9.0-fold) for nonreplicating vector platform, 4.1-fold (3.7-4.4-fold) for messenger RNA platform, and 2.5-fold (1.7-2.9-fold) for protein subunit platform. Neutralizing antibody levels induced by messenger RNA vaccines against SARS-CoV-2 variants were similar to, or higher, than that derived from naturally infected individuals.

Haemophagocytic lymphohistiocytosis after ChAdOx1 nCoV-19 vaccination.

Lessons Learned from Post-COVID-19 Vaccination PET/CT Studies. Vaccination against coronavirus 2019 (COVID-19) has created new challenges. Lymphadenopathy with increased uptake in patients undergoing PET/CT may mislead to unnecessary further evaluation. We have analyzed routinely performed PET/CT studies after Pfizer-BioNTech vaccination to familiarize ourselves with the PET/CT appearance of various PET tracers and to prevent the consequences of misinterpretation. Methods: We analyzed 1,018 PET/CT studies performed between January 1, 2021, and February 15, 2021. Information about the dates and sites of vaccination was collected. Visual and semiquantitative

analysis of axillary-neck lymphadenopathy and arm uptake was correlated with immunization data. Results: Increased uptake in axillary lymphadenopathy was observed unilaterally in 66% of vaccinated patients, in 55% of patients vaccinated once, and in 69% of those vaccinated twice. The intensity of uptake decreased over time. Fifty-four of 274 patients (20%) had simultaneous increased activity in the posterior arm and ipsilateral axillary lymphadenopathy (double sign [DS]). The sensitivity, specificity, positive predictive value, and negative predictive value were 55.4%, 83.6%, 86.7%, 49.2%, respectively, for axillary lymphadenopathy and 38.6%, 100%, 100%, and 66.1%, respectively, for DS. No DS was observed later than 10 and 21â€‰d after the first and the second vaccinations, respectively. None of the nonvaccinated patients had arm uptake or DS. Conclusion: Vaccination against COVID-19 frequently causes nonspecific axillary lymphadenopathy with increased PET tracer activity. In one fifth of our study population, this lymphadenopathy was associated with increased uptake at the vaccination site, DS. DS was 100% specific, with a 100% positive predictive value for postvaccination lymphadenopathy, hence enabling avoidance of misinterpretation of PET/CT studies and further unnecessary evaluation.

Operational challenges in the COVID-19 era: Asymptomatic infections and vaccination timing.
The coronavirus disease 2019 (COVID-19) pandemic has created unprecedented challenges for solid organ transplant programs. While transplant activity has largely recovered, appropriate management of deceased donor candidates who are asymptomatic but have positive nucleic acid testing (NAT) for SARS-CoV-2 is unclear, as this result may reflect active infection or prolonged viral shedding. Furthermore, candidates who are unvaccinated or partially vaccinated continue to receive donor offers. In the absence of robust outcomes data, transplant professionals at US adult kidney transplant centers were surveyed (February 13, 2021 to April 29, 2021) to determine community practice (N: 92 centers, capturing 41% of centers and 57% of transplants performed). The majority (97%) of responding centers declined organs for asymptomatic NAT+ patients without documented prior infection. However, 32% of centers proceed with kidney transplant in NAT+ patients who were at least 30 days from initial diagnosis with negative chest imaging. Less than 7% of programs reported inactivating patients who were unvaccinated or partially vaccinated. In conclusion, despite national recommendations to wait for negative testing, many centers are proceeding with kidney transplant in patients with positive SARS-CoV-2 NAT results due to presumed viral shedding. Furthermore, few centers are requiring COVID-19 vaccination prior to transplantation at this time.

Immune thrombocytopenic purpura after vaccination with COVID-19 vaccine (ChAdOx1 nCov-19).

SARS-CoV-2 Antibodies Detected in Mother's Milk Post-Vaccination. BACKGROUND: The Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) pandemic has infected over 127 million people worldwide, with almost 2.8 million deaths at the time of writing. Since no lactating individuals were included in initial trials of vaccine safety and efficacy, research on SARS-CoV-2 vaccination in lactating women and the potential transmission of passive immunity to the infant through mother's milk is needed to guide patients, clinicians, and policy makers on whether to recommend immunization during the worldwide effort to curb the spread of this virus. RESEARCH AIMS: (1) To determine whether SARS-CoV-2 specific immunoglobins are found in human milk after vaccination, and (2) to characterize the time course and types of immunoglobulins present. METHODS: A longitudinal cohort study of lactating women (N = 7) who planned to receive both doses of the Pfizer-BioNTech or Moderna SARS-CoV-2 vaccine between December 2020 and January 2021 provided milk samples. These were collected pre-vaccination and at 11 additional timepoints, with the last sample at 14 days after the second dose of vaccine. Samples were analyzed for levels of SARS-CoV-2 specific immunoglobulins A and G (IgA and IgG). RESULTS: We observed significantly elevated levels of SARS-CoV-2 specific IgG and IgA antibodies in human milk beginning approximately 7 days after the initial

vaccine dose, with an IgG-dominant response. CONCLUSIONS: Maternal vaccination results in SARS-CoV-2 specific immunoglobulins in human milk that may be protective for infants.

Breakthrough COVID-19 infections among health care workers after two doses of ChAdOx1 nCoV-19 vaccine.

The reversible tinnitus and cochleopathy followed first-dose AstraZeneca COVID-19 vaccination. The current case was the first report demonstrating a single case presenting with sudden-onset tinnitus and cochleopathy after his first dosage of the AstraZeneca COVID-19 vaccine. Audiometry revealed an abnormally high short increment sensitivity index. His tinnitus/cochleopathy was reversible and recoverable under conservative steroid management. The abnormality of the high short increment sensitivity index returned to the normal range after steroid management. This case report aimed to increase the cautionary awareness of clinicians concerning the potential adverse events of the AstraZeneca COVID-19 vaccine and the new onset of tinnitus/cochleopathy. In addition, immediate treatment is recommended for managing these patients after the onset of tinnitus/cochleopathy. Furthermore, due to the fact that the adverse event of new-onset tinnitus was reversible and recoverable, we still strongly recommend the continuation of the administration of the AstraZeneca COVID-19 vaccine, based on its merits and demerits.

Response to: Breakthrough COVID-19 infections among health care workers after two doses of ChAdOx1 nCoV-19 vaccine.

Bullous drug eruption after second dose of mRNA-1273 (Moderna) COVID-19 vaccine: Case report. BACKGROUND: In December 2020, Moderna released the mRNA-1273 vaccine. The most common side effects are headache, muscle pain, redness, swelling, and tenderness at the injection site. In addition, there have been dermatological adverse events, such as hypersensitivity reactions. Although rare, various bullous eruptions have been described following vaccination. Bullous pemphigoid has been reported to occur most often after receipt of influenza and the diphtheria-tetanus-pertussis vaccine. To the best of our knowledge, there have been no reports of bullous drug eruptions resulting from mRNA vaccines. CASE SUMMARY: A 66-years-old obese Guyanese male presented with a bullous rash following receipt of a commercial COVID-19 mRNA vaccine. He received the first dose uneventfully. However, within 24 h of receiving the second dose, he developed fever, myalgias, and malaise accompanied by a painful blistering rash of his torso, arms, and legs. His fever and myalgias improved after 24 h, but his painful rash did not, and five days after the initial symptoms, he presented to the hospital. There were many violaceous, poorly demarcated patches on his trunk, arms, and thighs on examination, many of which had large flaccid bullae within, and a few areas on his buttocks, posterior shoulder, and scrotum were eroded. The exam was also significant for lower extremity muscle tenderness, stiffness with preserved strength. A skin biopsy showed epidermal necrosis and sparse perivascular dermatitis concerning Stevens-Johnson syndrome or erythema multiforme. However, in the absence of mucous membrane involvement or targetoid lesions, the diagnosis of an extensive bullous fixed drug eruption was made. CONCLUSION: This case illustrates that the bullae eruption occurred as a result of receiving the Moderna vaccination.

Acute autoimmune-like hepatitis with atypical anti-mitochondrial antibody after mRNA COVID-19 vaccination: A novel clinical entity? Autoimmune phenomena and clinically apparent autoimmune diseases, including autoimmune hepatitis, are increasingly been reported not only after natural infection with the SARS-CoV-2 virus, but also after vaccination against it. We report the case of a 63-year old man without a history of autoimmunity or SARS-CoV-2 natural infection who experienced acute severe autoimmune-like hepatitis seven days after the first dose of the mRNA-1273 SARS-CoV-2 vaccine. Liver histology showed inflammatory portal infiltrate with interface hepatitis, lobular and centrilobular inflammation with centrilobular necrosis, in absence of fibrosis and steatosis. Serum immunoglobulin G was slightly elevated. Autoimmune liver serology showed an

indirect immunofluorescence pattern on triple rodent tissue compatible with anti-mitochondrial antibody (AMA), but, unexpectedly, this pattern was not mirrored by positivity for primary biliary cholangitis (PBC)-specific molecular tests, indicating that this antibody is different from classical AMA. Anti-nuclear antibody (ANA) was also positive with a rim-like indirect immunofluorescence pattern on liver and HEp2 cell substrates, similar to PBC-specific ANA; however, anti-gp210 and a large panel of molecular-based assays for nuclear antigens were negative, suggesting a unique ANA in our patient. He carries the HLA DRB1*11:01 allele, which is protective against PBC. Response to prednisone treatment was satisfactory. The clinical significance of these novel specificities needs to be further evaluated in this emerging condition.
COVID-19 vaccine-induced myocarditis: Case report with literature review.
Serologic Responses following a Single Dose of SARS-Cov-2 Vaccination in Allogeneic Stem Cell Transplantation Recipients. Immunocompromised individuals were not included in formal trials of SARS-CoV-2 mRNA vaccines. Subsequent studies in patients with hematologic malignancies and solid organ transplantation recipients suggest inferior responses to vaccination. We determined antibody responses to a single dose of vaccines in one of the most vulnerable patient groups, allogeneic hematopoietic cell transplantation (allo-HCT) recipients. Pfizer-BioNTech (PB) or AstraZeneca (AZ) SARS-CoV-2 vaccines were administered at least 3 months post-transplantation to 55 adult allo-HCT recipients. We found that older age and concurrent use of immunosuppressive medications were significantly associated with lack of antibody response to vaccination. Only 21% of patients on systemic immunosuppression mounted a response, compared with 58% of patients not on immunosuppression (PÂ =Â .006). We also show that responses to the AZ vaccine may be superior to responses to the PB vaccine in this cohort. These findings highlight the need for novel immunogenic vaccine formulations and schedules in these highest-risk patients, as well as continued public healthy safety measures to protect the most vulnerable members of our society.
Delayed cutaneous reactions after the administration of mRNA vaccines against COVID-19.
Post-SARS-CoV-2-vaccination cerebral venous sinus thrombosis: an analysis of cases notified to the European Medicines Agency. BACKGROUND AND PURPOSE: Cerebral venous sinus thrombosis (CVST) has been described after vaccination against SARS-CoV-2. The clinical characteristics of 213 post-vaccination CVST cases notified to the European Medicines Agency are reported. METHODS: Data on adverse drug reactions after SARS-CoV-2 vaccination notified until 8 April 2021 under the Medical Dictionary for Regulatory Activities Term 'Central nervous system vascular disorders' were obtained from the EudraVigilance database. Post-vaccination CVST was compared with 100 European patients with CVST from before the COVID-19 pandemic derived from the International CVST Consortium. RESULTS: In all, 213 CVST cases were identified: 187 after AstraZeneca/Oxford (ChAdOx1 nCov-19) vaccination and 26 after a messenger RNA (mRNA) vaccination (25 with Pfizer/BioNTech, BNT162b2, and one with Moderna, mRNA-1273). Thrombocytopenia was reported in 107/187 CVST cases (57%, 95% confidence interval [CI] 50%-64%) in the ChAdOx1 nCov-19Â group, in none in the mRNA vaccine group (0%, 95% CI 0%-13%) and in 7/100 (7%, 95% CI 3%-14%) in the pre-COVID-19 group. In the ChAdOx1 nCov-19 group, 39 (21%) reported COVID-19 polymerase chain reaction tests were performed within 30Â days of CVST symptom onset, and all were negative. Of the 117 patients with a reported outcome in the ChAdOx1 nCov-19 group, 44 (38%, 95% CI 29%-47%) had died, compared to 2/10 (20%, 95% CI 6%-51%) in the mRNA vaccine group and 3/100 (3%, 95% CI 1%-8%) in the pre-COVID-19 group. Mortality amongst patients with thrombocytopenia in the ChAdOx1 nCov-19 group was 49% (95% CI 39%-60%). CONCLUSIONS: Cerebral venous sinus thrombosis occurring after ChAdOx1 nCov-19 vaccination has a clinical profile distinct from CVST unrelated to vaccination. Only CVST after ChAdOx1 nCov-19 vaccination was associated with thrombocytopenia.
Herpes zoster following COVID-19 vaccine: a report of three cases.

Clinical and histopathological spectrum of delayed adverse cutaneous reactions following COVID-19 vaccination. BACKGROUND: As more people become vaccinated against the SARS-CoV-2 virus, reports of delayed cutaneous hypersensitivity reactions are beginning to emerge. METHODS: In this IRB-approved retrospective case series, biopsy specimens of potential cutaneous adverse reactions from the Pfizer-BioNTech or Moderna mRNA vaccine were identified and reviewed. Clinical information was obtained through the requisition form, referring clinician, or medical chart review. RESULTS: Twelve cases were included. Histopathological features from two injection-site reactions showed a mixed-cell infiltrate with eosinophils and a spongiotic dermatitis with eosinophils. Three biopsy specimens came from generalized eruptions that showed interface changes consistent with an exanthematous drug reaction. Three biopsy specimens revealed a predominantly spongiotic pattern, consistent with eczematous dermatitis. Small-vessel vascular injury was seen in two specimens, which were diagnosed as urticarial vasculitis and leukocytoclastic vasculitis, respectively. There were two cases of new-onset bullous pemphigoid supported by histopathological examination and direct immunofluorescence studies. Eosinophils were seen in 10 cases. CONCLUSIONS: Dermatopathologists should be aware of potential cutaneous adverse reactions to mRNA-based COVID-19 vaccines. Histopathological patterns include mixed-cell infiltrates, epidermal spongiosis, and interface changes. Eosinophils are a common finding but are not always present. Direct immunofluorescence studies may be helpful for immune-mediated cutaneous presentations such as vasculitis or bullous pemphigoid.

Incidence of Axillary Adenopathy in Breast Imaging After COVID-19 Vaccination. This case series examines the incidence, timing, and characteristics of mammographic axillary adenopathy following COVID-19 vaccination.

Intention to get vaccinated against COVID-19 among the general population in France: Associated factors and gender disparities. As the coronavirus disease 2019 (COVID-19) spreads across the world, the rapid distribution of an effective vaccine and its acceptability among the population constitute priorities for health authorities. This study aimed to document attitudes of the general population toward a future vaccine against COVID-19. We used the national COCONEL surveys conducted during the lockdown to identify factors associated with vaccine refusal, in the whole population, and separately among men and women. We investigate the role of socioeconomic and demographic factors as well as exposure to COVID-19. Among the 5,018 participants, 24.0% reported their intention to refuse the vaccine. Thinking this vaccine would not be safe, being against vaccination in general, and perceiving COVID-19 to be harmless were the three main reasons given to explain vaccine refusal. Women were more likely to refuse the vaccine, especially due to a reluctance toward vaccination in general or the perception that a COVID-19 vaccine would not be safe. Some factors associated with the intention to refuse the vaccine were the same among men and women such as a lack of prior vaccination against influenza, and concern over being infected with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), while others differed slightly according to gender such as age, and high prevalence of COVID-19 in their region of residence. Authorities should therefore guarantee that all the necessary precautions are taken before marketing the vaccine and communicate transparently on the process of its development, and on the coverage rate required to reach herd immunity.Abbreviation: EHI: Equivalized Household Income per month; SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2.

Unique Case of Urticarial Skin Eruptions After COVID-19 Vaccination.

Cellular and humoral immune response after mRNA-1273 SARS-CoV-2 vaccine in liver and heart transplant recipients. Recently published studies have found an impaired immune response after SARS-CoV-2 vaccination in solid organ recipients. However, most of these studies have not assessed immune cellular responses in liver and heart transplant recipients. We prospectively studied heart

and liver transplant recipients eligible for SARS-CoV-2 vaccination. Patients with past history of SARS-CoV-2 infection or SARS-CoV-2 detectable antibodies (IgM or IgG) were excluded. We assessed IgM/IgG antibodies and ELISpot against the S protein 4Â weeks after receiving the second dose of the mRNA-1273 (Moderna) vaccine. Side effects, troponin I, liver tests and anti-HLA donor-specific antibodies (DSA) were also assessed. A total of 58Â liver and 46Â heart recipients received two doses of mRNA-1273 vaccine. Median time from transplantation to vaccination was 5.4Â years (IQR 0.3-27). Sixty-four percent of the patients developed SARS-CoV-2 IgM/IgG antibodies and 79% S-ELISpot positivity. Ninety percent of recipients developed either humoral or cellular response (87% in heart recipients and 93% in liver recipients). Factors associated with vaccine unresponsiveness were hypogammaglobulinemia and vaccination during the first year after transplantation. Local and systemic side effects were mild or moderate, and none presented DSA or graft dysfunction after vaccination. Ninety percent of our patients did develop humoral or cellular responses to mRNA-1273 vaccine. Factors associated with vaccine unresponsiveness were hypogammaglobulinemia and vaccination during the first year after transplantation, highlighting the need to further protect these patients.

Induction and exacerbation of subacute cutaneous lupus erythematosus following mRNA-based or adenoviral vector-based SARS-CoV-2 vaccination. Evidence is accumulating that COVID-19 vaccines might induce or exacerbate autoimmune rheumatic diseases. The currently available COVID-19 vaccines include mRNA and recombinant adenoviral vector vaccines, both encoding SARS-CoV-2 spike protein production as the primary target for neutralizing antibodies. We report a case of subacute cutaneous lupus erythematosus (SCLE) following mRNA vaccination with the Pfizer mRNA vaccine BNT162b2, and summarize the current literature on CLE occurring after COVID-19 vaccination.

Delayed Hypersensitivity Reactions Following First Dose of the SARS-CoV2 mRNA Vaccines.

Guillain-Barre syndrome 15 days after COVID-19 despite SARS-CoV-2 vaccination. Guillain-Barre syndrome (GBS) following a SARS-CoV-2 vaccination has been repeatedly observed but GBS following a SARS-CoV-2 infection in a vaccinated patient has not been reported. A 69yo female developed paresthesias of both lower and upper limbs which were followed by progressive muscle weakness. The history was positive for a mild SARS-CoV-2 infection 15 days earlier. COVID-19 occurred despite a first dose of a vector-based SARS-CoV-2 vaccine, 40 days prior to onset of GBS. Since CSF investigations and nerve conduction studies were indicative of GBS, subtype acute, inflammatory, demyelinating polyneuropathy (AIDP), immunoglobulins (30 g/d) were started. After two weeks complete recovery was achieved. In conclusion, SARS-CoV-2 infections may develop despite full vaccination and may be complicated by GBS. Since no other trigger of GBS could be identified, a causal relation between the SARS-CoV-2 infection and GBS was suspected.

Anterior uveitis onset after bnt162b2 vaccination: is this just a coincidence? BACKGROUND: Uveitis is a vision-threatening inflammation and is considered an ophthalmic emergency. It generally arises as a result of autoimmune conditions, infections, or ocular trauma, but it may also occur as an isolated disorder. Over the past decades, several cases of vaccine-associated uveitis have been described, with the hepatitis B virus vaccine being the leading cause. CLINICAL CASE: A case of anterior uveitis in a 23-year-old male, with onset 14 days after the second dose of BNT162b2 COVID-19 vaccine, is reported here. Initial symptoms were pain, photophobia, and red eye. Ocular examination showed pericheratic and conjunctival hyperaemia, posterior synechiae, and anterior chamber cells Â± keratic precipitates in the lower quadrants. The posterior segment did not show any alteration, and optical coherence tomography ruled out the presence of cystoid macular oedema. After a 10-day treatment course of topical steroids and cycloplegic eye drops, the ocular inflammatory signs disappeared and visual acuity was completely restored. Even if causality remains

presumed, a warning should be given to physicians about the possibility of eye inflammation following SARS-CoV-2 vaccination.
Delayed localized hypersensitivity reactions to COVID-19 mRNA vaccines: a 6-month retrospective study. Several individuals have developed delayed localized cutaneous vaccine reactions to the two novel mRNA Covid-19 vaccines. Clinical and histopathologic results of this case series study confirm that the localized injection-site reactions to the mRNA COVID-19 vaccines are delayed hypersensitivity reactions that, unlike immediate hypersensitivity reactions, are not a contraindication to vaccination.
COVID-19 Vaccine-Associated Cerebral Venous Thrombosis in Germany. OBJECTIVE: We aimed to estimate the incidence of cerebral sinus and venous thrombosis (CVT) within 1 month from first dose administration and the frequency of vaccine-induced immune thrombotic thrombocytopenia (VITT) as the underlying mechanism after vaccination with BNT162b2, ChAdOx1, and mRNA-1273, in Germany. METHODS: A web-based questionnaire was e-mailed to all departments of neurology. We requested a report of cases of CVT occurring within 1 month of a COVID-19 vaccination. Other cerebral events could also be reported. Incidence rates of CVT were calculated by using official statistics of 9 German states. RESULTS: A total of 45 CVT cases were reported. In addition, 9 primary ischemic strokes, 4 primary intracerebral hemorrhages, and 4 other neurological events were recorded. Of the CVT patients, 35 (77.8%) were female, and 36 (80.0%) were younger than 60â€‰years. Fifty-three events were observed after vaccination with ChAdOx1 (85.5%), 9 after BNT162b2 (14.5%) vaccination, and none after mRNA-1273 vaccination. After 7,126,434 first vaccine doses, the incidence rate of CVT within 1 month from first dose administration was 0.55 (95% confidence interval [CI] =â€‰0.38-0.78) per 100,000 person-months (which corresponds to a risk of CVT within the first 31â€‰days of 0.55 per 100,000 individuals) for all vaccines and 1.52 (95% CIÂ =Â 1.00-2.21) for ChAdOx1 (after 2,320,535 ChAdOx1 first doses). The adjusted incidence rate ratio was 9.68 (95% CIÂ =Â 3.46-34.98) for ChAdOx1 compared to mRNA-based vaccines and 3.14 (95% CIÂ =Â 1.22-10.65) for females compared to non-females. In 26 of 45 patients with CVT (57.8%), VITT was graded highly probable. INTERPRETATION: Given an incidence of 0.02 to 0.15 per 100,000 person-months for CVT in the general population, these findings point toward a higher risk for CVT after ChAdOx1 vaccination, especially for women. ANN NEUROL 2021;90:627-639.
Bilateral Acute Macular Neuroretinopathy After Vaccination Against SARS-CoV-2.
Potency of BNT162b2 and mRNA-1273 vaccine-induced neutralizing antibodies against severe acute respiratory syndrome-CoV-2 variants of concern: A systematic review of in vitro studies. BNT162b2 and mRNA-1273 are two types of mRNA-based vaccine platforms that have received emergency use authorization. The emergence of novel severe acute respiratory syndrome (SARS-CoV-2) variants has raised concerns of reduced sensitivity to neutralization by their elicited antibodies. We aimed to systematically review the most recent in vitro studies evaluating the effectiveness of BNT162b2 and mRNA-1273 induced neutralizing antibodies against SARS-CoV-2 variants of concern. We searched PubMed, Scopus, and Web of Science in addition to bioRxiv and medRxiv with terms including 'SARS-CoV-2', 'BNT162b2', 'mRNA-1273', and 'neutralizing antibody' up to June 29, 2021. A modified version of the Consolidated Standards of Reporting Trials (CONSORT) checklist was used for assessing included study quality. A total 36 in vitro studies meeting the eligibility criteria were included in this systematic review. B.1.1.7 (Alpha), B.1.351 (Beta), P.1 (Gamma), and B.1.617.2 (Delta) are four SARS-CoV-2 variants that have recently been identified as variants of concern. Included studies implemented different methods regarding pseudovirus or live virus neutralization assays for measuring neutralization titres against utilized viruses. After two dose vaccination by BNT162b2 or mRNA-1273, the B.1.351 variant had the least sensitivity to neutralizing antibodies, while B.1.1.7 variant had the most sensitivity; that is, it was better neutralized relative to the comparator strain.

P.1 and B.1.617.2 variants had an intermediate level of impaired naturalization activity of antibodies elicited by prior vaccination. Our review suggests that immune sera derived from vaccinated individuals might show reduced protection of individuals immunized with mRNA vaccines against more recent SARS-CoV-2 variants of concern.

Antibody response after one and two jabs of the BNT162b2 vaccine in nursing home residents: The CONsort-19 study. BACKGROUND: The humoral immune response following COVID-19 vaccination in nursing home residents is poorly known. A longitudinal study compared levels of IgG antibodies against the spike protein (S-RBD IgG) (S-RDB protein IgG) after one and two BNT162b2/Pfizer jabs in residents with and without prior COVID-19. METHODS: In 22 French nursing homes, COVID-19 was diagnosed with real-time reverse-transcriptase polymerase chain reaction (RT-PCR) for SARS-CoV-2. Blood S-RDB-protein IgG and nucleocapsid (N) IgG protein (N-protein IgG) were measured 21-24Â days after the first jab (1,004 residents) and 6Â weeks after the second (820 residents). RESULTS: In 735 residents without prior COVID-19, 41.7% remained seronegative for S-RDB-protein IgG after the first jab vs. 2.1% of the 270 RT-PCR-positive residents (pÂ <Â 0.001). After the second jab, 3% of the 586 residents without prior COVID-19 remained seronegative. However, 26.5% had low S-RDB-protein IgG levels (50-1050Â UA/ml) vs. 6.4% of the 222 residents with prior COVID-19. Residents with an older infection (first wave), or with N-protein IgG at the time of vaccination, had the highest S-RDB-protein IgG levels. Residents with a prior COVID-19 infection had higher S-RDB-protein IgG levels after one jab than those without after two jabs. INTERPRETATION: A single vaccine jab is sufficient to reach a high humoral immune response in residents with prior COVID-19. Most residents without prior COVID-19 are seropositive for S-RDB-protein IgG after the second jab, but around 30% have low levels. Whether residents with no or low post-vaccine S-RDB protein IgG are at higher risk of symptomatic COVID-19 requires further analysis.

Fine needle aspiration in COVID-19 vaccine-associated lymphadenopathy. AIMS: With ongoing intensive vaccination programme against COVID-19, numerous cases of adverse reactions occur, some of which represent rare events. Enlargement of the injection site’s draining lymph nodes is increasingly reported, but is not yet widely recognised as being possibly associated with recent vaccination. As patients at risk of a severe course of COVID-19, indicated by their medical history such as a previous diagnosis of malignancy, receive priority vaccination, newly palpable lymph nodes raise concerns of disease progression. In this case series, we report on five patients who presented with enlarged lymph nodes after COVID-19 vaccination. METHODS: Sonography guided fine needle aspiration (FNA) was performed in five patients presenting with PET-positive and/or enlarged lymph nodes after COVID-19 vaccination with either the Pfizer-BioNTech or Moderna vaccine. RESULTS: COVID-19 vaccination had been carried out in all cases, with an interval of between 3 and 33 days prior to FNA. Three of five patients had a history of neoplasms. The vaccine was administered into the deltoid muscle, with subsequent enlargement of either the cervical, supra-, infra- or retroclavicular, or axillary lymph nodes, in four out of five cases ipsilaterally. In all cases, cytology and additional analyses showed a reactive lymphadenopathy without any sign of malignancy. CONCLUSIONS: Evidence of newly enlarged lymph nodes after recent COVID-19 vaccination should be considered reactive in the first instance, occurring owing to stimulation of the immune system. A clinical follow-up according to the patient’s risk profile without further diagnostic measures is justified. In the case of preexisting unilateral cancer, vaccination should be given contralaterally whenever possible. Persistently enlarged lymph nodes should be re-evaluated (2 to) 6 weeks after the second dose, with additional diagnostic tests tailored to the clinical context. Fine needle aspiration is a well established, safe, rapid and cost-effective method to investigate an underlying malignancy, especially metastasis. Recording vaccination history, including date of injection, site and vaccine type, as well as

communicating this information to treating physicians of different specialties is paramount for properly handling COVID-19 vaccine-associated lymphadenopathy.
Cerebral venous thrombosis after COVID-19 vaccination: is the risk of thrombosis increased by intravascular application of the vaccine?
Should children get COVID vaccines? What the science says.
A Case of Immune Thrombocytopenia After BNT162b2 mRNA COVID-19 Vaccination. BACKGROUND Immune thrombocytopenic purpura (ITP) is an immune response that destroys platelets and increases the risk of bleeding, which can range from bruising to intracranial hemorrhage. ITP is a known complication of coronavirus disease 2019 (COVID-19). In the first studies of the BNT162b2 messenger RNA (mRNA) COVID-19 vaccine, there were no reports of ITP and the incidence of serious adverse events (AEs) was low overall. Here, we present a case of ITP as a complication of the BNT162b2 mRNA COVID-19 vaccine. CASE REPORT Three days after receiving a second dose of the BNT162b2 mRNA COVID-19 vaccine, a 39-year-old woman presented with a petechial rash on her trunk, legs, and arms, and fatigue and muscle aches. At the time of her hospital admission, her platelet count was 1000/ÂµL. A peripheral smear showed profound thrombocytopenia. During the course of the patient's hospitalization, she was treated with 2 units of platelets, 2 infusions of i.v. immunoglobulin, and i.v. methylprednisolone. Her platelet count increased to 92 000/ÂµL on the day of discharge and she was prescribed a tapered dose of oral prednisone. One day later, her rash had resolved and her platelet count was 243 000/ÂµL. The patient recovered completely with no complications. CONCLUSIONS ITP should be considered a severe AE of the BNT162b2 mRNA COVID-19 vaccine. Knowing the early signs and symptoms of ITP will become increasingly important as more of the population receives this vaccine. Quick diagnosis and management are essential to avoid life-threatening bleeding.
Hyperacute reversible encephalopathy related to cytokine storm following COVID-19 vaccine. We describe the first case of hyperacute reversible encephalopathy following COVID-19 vaccination. A patient presented with acute onset encephalopathy, mainly characterized by agitation and confusion, rapidly responsive to high dosage steroid therapy and complete remission within 3Â days from onset. The clinical manifestation was related with systemic and CSF cytokine hyperproduction, responsive to steroid therapy. Although the occurrence of encephalopathy after vaccination may be just a casual temporal association, we speculate that the cytokine-storm could be the result of an excessive innate immune response against the vaccine, in a predisposed patient susceptible to autoimmunity.
Elucidating causes of COVID-19 infection and related deaths after vaccination. BACKGROUND AND AIMS: Symptomatic or asymptomatic COVID-19 infection has been reported in vaccination. In the current article, we try to elucidate various causes behind COVID-19 infection and mortality following COVID-19 vaccination and suggest possible strategies to counteract this threat. METHODS: We carried out a comprehensive review of the literature using suitable keywords such as 'COVID-19', 'Pandemics', 'Vaccines', 'Mortality', 'deaths', 'infections', and 'India' on the search engines of PubMed, SCOPUS, Google Scholar, and ResearchGate in from January to May 2021. Epidemiology, risk factors, Adverse Events Following Immunization (AEFI) and mortality after COVID-19 vaccination were assessed. RESULTS: A number of factors have been associated with symptomatic or asymptomatic COVID-19 infection reported after vaccination. A high viral load, comorbidities, mutant strains, Variants of Concern (VOC) leading to Vaccine escape and casual attitude towards COVID Appropriate Behaviors appear to be the most important factors for infection and deaths after COVID-19 vaccination. CONCLUSIONS: COVID-19 Infection and mortality after COVID-19 vaccination are of great concern. Application of COVID Appropriate Behaviour (CAB) before and after vaccination is essential for the population. Effective Vaccines against mutant strains and enhanced vaccination drive are key

strategies to avoid this quintessential threat. Early medical intervention in high-risk groups can prevent overall mortality.

The ROMANOV study found impaired humoral and cellular immune responses to SARS-CoV-2 mRNA vaccine in virus-unexposed patients receiving maintenance hemodialysis. Patients on maintenance hemodialysis (MHD), which are at high risk of infection by SARS-CoV-2 virus and death due to COVID-19, have been prioritized for vaccination. However, because they were excluded from pivotal studies and have weakened immune responses, it is not known whether these patients are protected after the "standard" two doses of mRNA vaccines. To answer this, anti-spike receptor binding domain (RBD) IgG and interferon gamma-producing CD4(+) and CD8(+) specific-T cells were measured in the circulation 10-14 days after the second injection of BNT162b2 vaccine in 106 patients receiving MHD (14 with history of COVID-19) and compared to 30 healthy volunteers (four with history of COVID-19). After vaccination, most (72/80, 90%) patients receiving MHD naÃ¯ve for the virus generated at least one type of immune effector, but their response was weaker and less complete than that of healthy volunteers. In multivariate analysis, hemodialysis and immunosuppressive therapy were significantly associated with absence of both anti-RBD IgGs and anti-spike CD8(+) T cells. In contrast, previous history of COVID-19 in patients receiving MHD correlated with the generation of both types of immune effectors anti-RBD IgG and anti-spike CD8(+) T cells at levels similar to healthy volunteers. Patients receiving MHD naÃ¯ve for SARS-Cov-2 generate mitigated immune responses after two doses of mRNA vaccine. Thus, the good response to vaccine of patients receiving MHD with a history of COVID-19 suggest that these patients may benefit from a third vaccine injection.

Low neutralizing antibody responses in WM, CLL and NHL patients after the first dose of the BNT162b2 and AZD1222 vaccine. Vaccination against SARS-CoV-2 is considered as the most important preventive strategy against COVID-19, but its efficacy in patients with hematological malignancies is largely unknown. We investigated the development of neutralizing antibodies (NAbs) against SARS-CoV-2 in patients with Waldenstrom Macroglobulinemia (WM), Chronic Lymphocytic Leukemia (CLL) and Non-Hodgkin Lymphoma (NHL). After the first dose of the vaccine, on D22, WM/CLL/NHL patients had lower NAb titers compared to controls: the median NAb inhibition titer was 17% (range 0-91%, IQR 8-27%) for WM/CLL/NHL patients versus 32% (range 2-98%, IQR 19-48%) for controls (PÂ <Â 0.001). Only 8 (14%) patients versus 114 (54%) controls developed NAb titers â‰¥Â 30% on D22 (pÂ <Â 0.001). Our data indicate that the first dose of both BNT162b2 and AZD1222 leads to lower production of NAbs against SARS-CoV-2 in patients with WM/CLL/NHL compared to controls of similar age and gender and without malignant disease. Even though the response rates were not optimal, vaccination is still considered essential and if possible should be performed before treatment initiation. These patients with suboptimal responses should be considered to be prioritized for booster doses.

Myocarditis Associated with mRNA COVID-19 Vaccination.

COVID-19 Vaccination Imperatives in People on Maintenance Dialysis: An International Perspective.

Sequential contralateral facial nerve palsies following COVID-19 vaccination first and second doses. A 61-year-old man presented to the ENT emergency clinic with a history of unilateral facial nerve palsy occurring shortly after each dose of the Pfizer-BioNTech COVID-19 vaccine. The first episode developed 5 hours after administration of the first dose and the second 2 days after administration of the second dose. Investigations at initial presentation to the emergency department were unremarkable, and the patient was diagnosed with Bell's palsy on both occasions. We describe the first case of Bell's palsy occurring after each dose of any UK-approved COVID-19 vaccine. Single episodes of unilateral facial nerve palsies have been reported in clinical trials and in subsequent case reports. There has been no evidence, however, of an episode after each dose. We also describe the

earliest onset of symptoms from timing of administration of the vaccine, further suggesting the Bell's palsy was associated with the vaccine.
Acute corneal endothelial graft rejection following COVID-19 vaccination.
Myocarditis With COVID-19 mRNA Vaccines. Myocarditis has been recognized as a rare complication of coronavirus disease 2019 (COVID-19) mRNA vaccinations, especially in young adult and adolescent males. According to the US Centers for Disease Control and Prevention, myocarditis/pericarditis rates are â‰ˆ12.6 cases per million doses of second-dose mRNA vaccine among individuals 12 to 39 years of age. In reported cases, patients with myocarditis invariably presented with chest pain, usually 2 to 3 days after a second dose of mRNA vaccination, and had elevated cardiac troponin levels. ECG was abnormal with ST elevations in most, and cardiac MRI was suggestive of myocarditis in all tested patients. There was no evidence of acute COVID-19 or other viral infections. In 1 case, a cardiomyopathy gene panel was negative, but autoantibody levels against certain self-antigens and frequency of natural killer cells were increased. Although the mechanisms for development of myocarditis are not clear, molecular mimicry between the spike protein of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) and self-antigens, trigger of preexisting dysregulated immune pathways in certain individuals, immune response to mRNA, and activation of immunologic pathways, and dysregulated cytokine expression have been proposed. The reasons for male predominance in myocarditis cases are unknown, but possible explanations relate to sex hormone differences in immune response and myocarditis, and also underdiagnosis of cardiac disease in women. Almost all patients had resolution of symptoms and signs and improvement in diagnostic markers and imaging with or without treatment. Despite rare cases of myocarditis, the benefit-risk assessment for COVID-19 vaccination shows a favorable balance for all age and sex groups; therefore, COVID-19 vaccination is recommended for everyone â‰¥12 years of age.
Coronavirus disease 2019 vaccine mimics lymph node metastases in patients undergoing skin cancer follow-up: A monocentre study. INTRODUCTION: The coronavirus disease 2019 (COVID-19) pandemic has changed the lives of people around the world. Fortunately, sufficient vaccines are now available. Local reactions with ipsilateral lymphadenopathy are among the most common side effects. We investigated the impact of lymphadenopathy after COVID-19 vaccination on the value of ultrasound in tumour patients. PATIENTS AND METHODS: Patients with melanoma or Merkel cell carcinoma were included who underwent lymph node excision and received COVID-19 vaccination within 6 weeks before surgery. The consistency of the preoperative ultrasound findings with the histopathologic findings was investigated. RESULTS: Eight patients were included (two Merkel cell carcinoma and six melanoma patients) who underwent lymph node excision between 16th April 2021Â and 19th May 2021Â and had previously received COVID-19 vaccination. In three of the eight patients (one Merkel cell carcinoma and two melanoma patients), lymph node metastases were erroneously diagnosed preoperatively during tumour follow-up with physical examination, ultrasound, and or fluorodeoxyglucose (FDG)-positron emission tomography (PET)/computed tomography (CT). In these three patients, the suspected lymph node metastases were located in the left axilla after COVID-19 vaccination in the left upper arm, which resulted in selective lymph node removal in two patients and complete lymphadenectomy in one patient. CONCLUSION: COVID-19 vaccine-associated lymphadenopathy is expected to be observed much more frequently in the near future because of increasing vaccination rates. This cause of lymphadenopathy, which may in ultrasound as well as in FDG PET/CT resemble lymph node metastases, must be considered, especially in oncologic patients undergoing tumour follow-up. In addition, COVID-19 vaccination should be given as far away as possible from an underlying primary on the contralateral side to avoid oncologic misdiagnosis followed by malpractice.

Autoimmune phenomena following SARS-CoV-2 vaccination. Vaccines represent an attractive possible solution to the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) pandemic. Widespread vaccine distribution has yet to occur in most countries, partially due to public concerns regarding possible side effects. While studies indicate the vaccine is exceptionally safe, rare systemic side effects remain possible. In Israel, where a large percentage of the population has been rapidly vaccinated, such adverse events may be more apparent. We report a series of patients presenting with de-novo or flares of existing autoimmune conditions associated with the Pfizer BNT162b2 mRNA SARS-CoV-2 vaccine. All patients were assessed in our tertiary care center in Israel and had no history of previous SARS-COV-2 infection. We observed that while immune phenomena may occur following vaccination, they usually follow a mild course and require modest therapy. We briefly expound on the theoretical background of vaccine related autoimmunity and explore future research prospects.

Potential adverse effects of COVID19 vaccines among Iraqi population; a comparison between the three available vaccines in Iraq; a retrospective cross-sectional study. AIMS: the objectives of this study are to reveal the potential side effects after taking the covid19 vaccines, associated risk factors with severe side effects, and to compare the three COVID-19 vaccines available in Iraq (Sinopharm, AstraZeneca-Oxford and Pfizer- BioNTech). METHODS: a randomized cross-sectional study was conducted in April 2021. A standardized questionnaire platform was utilized to collect information about the Iraqi population. RESULTS: 1012 were enrolled in the study, 60.2% were male and 39.8% were female. 84% were symptomatic post vaccination. Young aged participants, females, participants with history of COVID19 infection, those with comorbid diseases and AstraZeneca vaccine receivers were statistically significant risk factors for having adverse reactions post vaccination, P value (0.03, 0.028, 0.007, 0.019 and 0.0001) respectively. Regarding severity of symptoms, most symptoms were mild and moderate. Residency in Kurdistan Region of Iraq and AstraZeneca vaccine were the statistically significant risk factors for getting severe symptoms P valueÂ <Â 0.0001 of both. Females were an associated risk factor for D-dimer elevation P valueÂ =Â 0.05. CONCLUSION: fatigue, injection site reactions, fever, myalgia, headache and chills were the most reported side effects. Most symptoms were mild to moderate in term of severity.

ANCA-Associated Vasculitis Following Pfizer-BioNTech COVID-19 Vaccine. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) continues to spread around the world. As of the end of June 2021, there were approximately 181 million confirmed cases and more than 3.9 million deaths across the globe. The colossal impact of coronavirus disease 2019 (COVID-19) is driving the biggest vaccination campaign in human history. All 3 vaccines authorized for emergency use by the US Food and Drug Administration (Pfizer-BioNTech, Moderna, and Janssen/Johnson & Johnson) have been thoroughly studied and found to be safe and effective in preventing severe COVID-19 cases. While short-term side effects of COVID-19 vaccine resemble those of other vaccines, long-term side effects remain unknown. Rare side effects continue to surface as millions of people receive COVID-19 vaccines around the world, as compared with the thousands enrolled in the clinical trials. We report a case of new-onset renal-limited ANCA-associated vasculitis (AAV) in a 78-year-old woman with previously normal kidney function after receiving the Pfizer-BioNTech COVID-19 vaccine. The patient developed acute kidney injury with proteinuria and microscopic hematuria with many dysmorphic red blood cells in the urine. Anti-myeloperoxidase antibody titer was elevated. Kidney biopsy showed pauci-immune crescentic necrotizing glomerulonephritis. Kidney function improved after treatment with steroids and rituximab. Our patient had normal routine laboratory testing before the vaccination. Although this case cannot demonstrate a causal relationship between COVID-19 vaccination and AAV, ongoing surveillance for similar complications would be prudent as worldwide vaccination efforts continue.

Anti-platelet factor 4 antibodies causing VITT do not cross-react with SARS-CoV-2 spike protein. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a severe adverse effect of ChAdOx1 nCoV-19 COVID-19 vaccine (Vaxzevria) and Janssen Ad26.COV2.S COVID-19 vaccine, and it is associated with unusual thrombosis. VITT is caused by anti-platelet factor 4 (PF4) antibodies activating platelets through their FcÎ³RIIa receptors. Antibodies that activate platelets through FcÎ³RIIa receptors have also been identified in patients with COVID-19. These findings raise concern that vaccination-induced antibodies against anti-SARS-CoV-2 spike protein cause thrombosis by cross-reacting with PF4. Immunogenic epitopes of PF4 and SARS-CoV-2 spike protein were compared using in silico prediction tools and 3D modeling. The SARS-CoV-2 spike protein and PF4 share at least 1 similar epitope. Reactivity of purified anti-PF4 antibodies from patients with VITT was tested against recombinant SARS-CoV-2 spike protein. However, none of the affinity-purified anti-PF4 antibodies from 14 patients with VITT cross-reacted with SARS-CoV-2 spike protein. Sera from 222 polymerase chain reaction-confirmed patients with COVID-19 from 5 European centers were tested by PF4-heparin enzyme-linked immunosorbent assays and PF4-dependent platelet activation assays. We found anti-PF4 antibodies in sera from 19 (8.6%) of 222 patients with COVID-19. However, only 4 showed weak to moderate platelet activation in the presence of PF4, and none of those patients developed thrombotic complications. Among 10 (4.5%) of 222 patients who had COVID-19 with thrombosis, none showed PF4-dependent platelet-activating antibodies. In conclusion, antibodies against PF4 induced by vaccination do not cross-react with the SARS-CoV-2 spike protein, indicating that the intended vaccine-induced immune response against SARS-CoV-2 spike protein is not the trigger of VITT. PF4-reactive antibodies found in patients with COVID-19 in this study were not associated with thrombotic complications.

IgA Nephropathy After SARS-CoV-2 Vaccination. Here we present the first case of newly diagnosed IgA nephropathy (IgAN) after a SARS-CoV-2 vaccination. A 30-year-old man with no known past medical history presented with gross hematuria and subnephrotic proteinuria 24 hours after the second dose of the mRNA-1273 SARS-CoV-2 vaccine. A kidney biopsy showed IgAN. He was started on an angiotensin receptor blocker, resulting in proteinuria reduction. Similar to natural infection of SARS-CoV-2, persons who receive 2 mRNA-based vaccines demonstrate robust antibodies against the receptor-binding domain (RBD) of the S1 protein. Given the uniqueness of glycosylation of RBD and potent stimulation of immune response from mRNA-based vaccine compared to other vaccines, we hypothesize that our patient developed de novo antibodies, leading to IgA-containing immune-complex deposits. This case highlights the urgency of understanding the immunological responses to novel mRNA-based SARS-CoV-2 vaccines in more diverse populations. Despite the lack of clear causality, nephrologists should be alerted if any new-onset hematuria or proteinuria is observed.

Comparison of IgG and neutralizing antibody responses after one or two doses of COVID-19 mRNA vaccine in previously infected and uninfected individuals. BACKGROUND: Recent reports have suggested that among individuals previously infected with SARS-CoV-2, a single mRNA vaccine dose is sufficient to elicit high levels of immunity. METHODS: We compared anti-SARS-CoV-2 spike receptor binding domain (RBD) IgG antibody concentrations and antibody-mediated neutralization of spike-angiotensin-converting enzyme (ACE2) receptor binding in vitro following vaccination of non-hospitalized participants by sero-status and acute virus diagnosis history. Participants were analysed before and after mRNA vaccination (BNT162b2/Pfizer or mRNA-1273/Moderna) in a community-based, home-collected, longitudinal serosurvey in the Chicago area (USA); none reported hospitalization for COVID-19. Samples were collected in January and February 2021. Before vaccination, some reported prior positive acute viral diagnostic testing and were seropositive (COVID-19+); the others who did not report acute viral diagnostic testing were categorized as seropositive or seronegative based on anti-spike RBD IgG test results. FINDINGS: Of 307 unique vaccine recipients, 46

reported a prior COVID-19 diagnosis and were seropositive (COVID-19 +). Of the 261 with no history of acute viral diagnostic testing, 117 were seropositive and 144 seronegative before vaccination. The median age was 38 years (range 21-83) with 67 female and 33% male; 40% were non-White. Responses were evaluated after one (nÂ =Â 142) or two (nÂ =Â 191) doses of BNT162b2 or mRNA-1273 vaccine. After one dose, median post-vaccine IgG concentration and percent surrogate neutralization were each significantly higher among the COVID-19+ (median 48Â·2Â Âµg/ml, IgG; >Â 99.9% neutralization) compared to the seropositives (3Â·6Â Âµg /ml IgG; 56.5% neutralization) and seronegatives (2Â·6Â Âµg /ml IgG; 38Â·3% neutralization). The latter two groups reached >Â 95% neutralization after the second vaccine dose. INTERPRETATION: After one dose of mRNA vaccine, individuals previously diagnosed with COVID-19 responded with high levels of anti-RBD IgG and surrogate neutralization of spike-ACE2 interaction. One dose of mRNA vaccine was not sufficient to generate comparably high responses among most persons previously infected with SARS-CoV-2 without a clinical COVID-19 diagnosis, nor among seronegative persons. FUNDING: National Science Foundation 2035114, NIH 3UL1TR001422-06S4, and Northwestern University Office of Research.

Antibody Response After Initial Vaccination for SARS-CoV-2 in Patients With Amyloidosis.

New-Onset Neurologic Symptoms and Related Neuro-Oncologic Lesions Discovered After COVID-19 Vaccination: Two Neurosurgical Cases and Review of Post-Vaccine Inflammatory Responses. A global effort is underway to distribute coronavirus disease 2019 (COVID-19) vaccines to limit the crisis. Although adverse events related to vaccination are rare, there have been cases of new-onset neurologic symptoms following vaccination. We present two cases of new-onset neurologic symptoms post-vaccination that, upon further workup, revealed two different neuro-oncologic processes requiring neurosurgical intervention and further treatment. We hypothesize that despite these processes being unrelated to vaccination, the COVID-19 vaccines may induce an inflammatory cascade with the ability to uncover underlying sinister pathology. Our report therefore emphasizes the need for careful evaluation in the setting ofÂ new-onset neurologic symptoms after COVID-19 vaccination.

Myocarditis and Other Cardiovascular Complications of the mRNA-Based COVID-19 Vaccines. Cardiovascular complications following the receipt of mRNA-based (Pfizer-BioNTech and Moderna) coronavirus disease 2019 (COVID-19) vaccines have not yet been described. In this case series, we describe two patients with clinically suspected myocarditis, one patient with stress cardiomyopathy, and two patients with pericarditis after receiving an mRNA-based COVID-19 vaccine. The two patients with clinically suspected myocarditis were otherwise healthy young men who presented with acute substernal chest pressure and/or dyspnea after receiving the second dose of the vaccine and were found to have diffuse ST elevations on electrocardiogram (ECG), elevated cardiac biomarkers and inflammatory markers, and mildly reduced left ventricular (LV) function on echocardiography. Both patients met the modified Lake Louise Criteria for acute myocarditis by cardiac magnetic resonance imaging. We subsequently discuss a case of a 60-year-old woman with known coronary artery disease (CAD) and previously normal LV function, who presented with new exertional symptoms, ECG changes, and apical akinesis following the second dose of the vaccine, and was diagnosed with a stress cardiomyopathy. Finally, we describe two patients with pericarditis who presented with chest pain, elevated inflammatory markers, and pericardial effusions after receiving the vaccine. Overall, this case series describes the first reported cases of myocarditis, stress cardiomyopathy, and pericarditis after receiving an mRNA-based COVID-19 vaccine.

[Erratum : MANAGEMENT, DIAGNOSIS, AND TREATMENT OF SEVERE ALLERGIC REACTIONS INCLUDING ANAPHYLAXIS TO COVID-19 VACCINE Vol.70 (2021) No.3 p.215-223]].

Frequent Premature Ventricular Contraction and Non-Sustained Ventricular Tachycardia After the SARS-CoV-2 Vaccination in Patient With Implantable Cardioverter Defibrillator Due to Acquired Long-QT Syndrome.

Inadequate deltoid muscle penetration and concerns of improper COVID mRNA vaccine administration can be avoided by injection technique modification. BACKGROUND: Recent phase-3 clinical trials have demonstrated very encouraging results for mRNA based vaccines against COVID-19. Current FDA and manufacturer guidelines mandate intramuscular administration of these vaccines, as other administration routes may not provide the same levels of effectiveness and safety. Observing the vast amount of published media images of persons receiving their vaccines, the authors noted in many cases the injection technique involved skin bunching, raising concerns of inadequate deltoid muscle penetration and consequent lowered vaccine efficacy. Our study hypothesis was that skin bunching will increase the skin-to-muscle distance over 20Â mm, the maximal distance allowing the required 5Â mm muscle penetration with a 25Â mm needle. MATERIALS AND METHODS: 60 adult volunteers from our hospital staff were recruited, and using ultrasound, the skin-to-muscle distance measured in three positions: flat, skin bunching and muscle bunching. The skin-to-muscle distance difference and correlation with gender and BMI were calculated. RESULTS: Skin bunching significantly increased the skin-to-muscle distance in all subjects. In 6 (10%) subjects, this increase exceeded the 20Â mm limit. Having a skin-to-deltoid distance of 20Â mm or more strongly correlated with a BMI of 30 or more. CONCLUSIONS: Skin bunching will prevent adequate intramuscular injection of vaccines in a small percentage of persons, but as hundreds of millions are expected to receive mRNA vaccines in the coming months, the multiplied result can have significant personal and societal consequences for millions of people globally, especially in obese populations, and therefore this practice should be strictly discouraged.

Subepidermal blistering eruptions, including bullous pemphigoid, following COVID-19 vaccination.

Commentary: The spectrum of neurological manifestations related to COVID-19 and vaccinations.

Middle-age Asian male with cerebral venous thrombosis after COVID-19 AstraZeneca vaccination. Vaccine-associated cerebral venous thrombosis has become an issue following the extensive vaccination program of the Coronavirus Disease of 2019 (COVID-19) Vaccine AstraZeneca (ChAdOx1 vaccine). The importance of early diagnosis should be emphasized due to the high mortality rate without appropriate treatment. Young female populations in western countries have been reported to be at a greater risk of this vaccine related thrombotic event, but cases in East Asia are lacking. Herein, we present the first case of cerebral venous sinus thrombosis 10 days after ChAdOx1 vaccination in a middle-age Asian male in Taiwan.

Intention to COVID-19 vaccination and associated factors among health care workers: A systematic review and meta-analysis of cross-sectional studies. OBJECTIVES: To gain insight into willingness and its influencing factors to vaccinate against COVID-19 among health care workers (HCWs), and provide a scientific basis for more reasonable epidemic prevention and control strategies. METHODS: A comprehensive literature search was conducted in 4 English databases (PubMed, EMBASE, Web of Science and the Cochrane Library) and 4 Chinese databases (Chinese National Knowledge Infrastructure (CNKI), the Chongqing VIP Chinese Science (VIP), Wanfang Database and China Biomedical Literature Database (CBM)) to collect the related studies. Quality evaluation was carried out for papers meeting the inclusion criteria using 6 items from the Downs and Black assessment checklist. The STATA statistical software version 15.1 was hired to perform meta-analysis. RESULTS: Nine records with a total of 24,952 subjects were included in this meta-analysis. The results of this meta-analysis revealed that the pooled effect value of COVID-19 vaccination willingness among HCWs using a random-effects model was 51% (95% confidence interval (CI) 0.41-0.62). Male, aged 30 years or older, having a history of prior influenza vaccination were facilitators for HCWs' intention to

vaccinate against COVID-19 (odds ratio (OR) 1.82, 95% CI 1.37-2.41, PÂ =Â .000, I(2)Â =Â 59.4%; OR 1.32, 95% CI 1.16-1.51, PÂ =Â .000, I(2)Â =Â 31.7%; OR 2.97, 95% CI 1.82-4.84, PÂ =Â .000, I(2)Â =Â 88.1%). The impact of occupation on HCWs' intention to get vaccinated could not yet be definitively confirmed (OR 0.85, 95% CI 0.69-1.06, PÂ =Â .160, I(2)Â =Â 85.5%). CONCLUSION: COVID-19 vaccination acceptance of HCWs was at moderate level. Strengthening awareness of COVID-19 vaccine among HCWs, particularly female HCWs under 30 years who have no history of prior influenza vaccination, is crucial to eliminate concerns about vaccination and promote the application of COVID-19 vaccine in this population.

Estimating global and regional disruptions to routine childhood vaccine coverage during the COVID-19 pandemic in 2020: a modelling study. BACKGROUND: The COVID-19 pandemic and efforts to reduce SARS-CoV-2 transmission substantially affected health services worldwide. To better understand the impact of the pandemic on childhood routine immunisation, we estimated disruptions in vaccine coverage associated with the pandemic in 2020, globally and by Global Burden of Disease (GBD) super-region. METHODS: For this analysis we used a two-step hierarchical random spline modelling approach to estimate global and regional disruptions to routine immunisation using administrative data and reports from electronic immunisation systems, with mobility data as a model input. Paired with estimates of vaccine coverage expected in the absence of COVID-19, which were derived from vaccine coverage models from GBD 2020, Release 1 (GBD 2020 R1), we estimated the number of children who missed routinely delivered doses of the third-dose diphtheria-tetanus-pertussis (DTP3) vaccine and first-dose measles-containing vaccine (MCV1) in 2020. FINDINGS: Globally, in 2020, estimated vaccine coverage was 76Â·7% (95% uncertainty interval 74Â·3-78Â·6) for DTP3 and 78Â·9% (74Â·8-81Â·9) for MCV1, representing relative reductions of 7Â·7% (6Â·0-10Â·1) for DTP3 and 7Â·9% (5Â·2-11Â·7) for MCV1, compared to expected doses delivered in the absence of the COVID-19 pandemic. From January to December, 2020, we estimated that 30Â·0 million (27Â·6-33Â·1) children missed doses of DTP3 and 27Â·2 million (23Â·4-32Â·5) children missed MCV1 doses. Compared to expected gaps in coverage for eligible children in 2020, these estimates represented an additional 8Â·5 million (6Â·5-11Â·6) children not routinely vaccinated with DTP3 and an additional 8Â·9 million (5Â·7-13Â·7) children not routinely vaccinated with MCV1 attributable to the COVID-19 pandemic. Globally, monthly disruptions were highest in April, 2020, across all GBD super-regions, with 4Â·6 million (4Â·0-5Â·4) children missing doses of DTP3 and 4Â·4 million (3Â·7-5Â·2) children missing doses of MCV1. Every GBD super-region saw reductions in vaccine coverage in March and April, with the most severe annual impacts in north Africa and the Middle East, south Asia, and Latin America and the Caribbean. We estimated the lowest annual reductions in vaccine delivery in sub-Saharan Africa, where disruptions remained minimal throughout the year. For some super-regions, including southeast Asia, east Asia, and Oceania for both DTP3 and MCV1, the high-income super-region for DTP3, and south Asia for MCV1, estimates suggest that monthly doses were delivered at or above expected levels during the second half of 2020. INTERPRETATION: Routine immunisation services faced stark challenges in 2020, with the COVID-19 pandemic causing the most widespread and largest global disruption in recent history. Although the latest coverage trajectories point towards recovery in some regions, a combination of lagging catch-up immunisation services, continued SARS-CoV-2 transmission, and persistent gaps in vaccine coverage before the pandemic still left millions of children under-vaccinated or unvaccinated against preventable diseases at the end of 2020, and these gaps are likely to extend throughout 2021. Strengthening routine immunisation data systems and efforts to target resources and outreach will be essential to minimise the risk of vaccine-preventable disease outbreaks, reach children who missed routine vaccine doses during the pandemic, and accelerate progress towards higher and more equitable vaccination coverage over the next decade. FUNDING: Bill & Melinda Gates Foundation.

Impaired Antibody Response to the BNT162b2 Messenger RNA Coronavirus Disease 2019 Vaccine in Patients With Systemic Lupus Erythematosus and Rheumatoid Arthritis. OBJECTIVE: With a vaccine effectiveness of 95% for preventing coronavirus disease 2019 (COVID-19), Pfizer-BioNTech BNT162b2 (BNT162b2) was the first vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to be approved. However, immunosuppressive therapy was an exclusion criterion in the phase 3 trial that led to approval. Thus, extrapolation of the trial results to patients with rheumatic diseases treated with immunosuppressive drugs warrants caution. METHODS: Patients with systemic lupus erythematosus (SLE; n = 61) and rheumatoid arthritis (RA; n = 73) were included from the COPANARD (Corona Pandemic Autoimmune Rheumatic Disease) cohort, followed since the beginning of the COVID-19 pandemic. Patients received the BNT162b2 vaccine between December 2020 and April 2021. All patients had total antibodies against SARS-CoV-2 measured before vaccination and 1 week after the second vaccination (VITROS Immunodiagnostic Products). RESULTS: Of 134 patients (median age, 70 years), 77% were able to mount a detectable serological response to the vaccine. Among patients treated with rituximab, only 24% had detectable anti-SARS-CoV-2 antibodies in their serum after vaccination. The time since the last rituximab treatment did not seem to influence the vaccine response. No significant difference was observed between patients with RA or SLE when adjusting for treatment, and no correlation between antibody levels and age was detected (r = -0.12; P = 0.18). CONCLUSION: Antibody measurements against SARS-CoV-2 in patients with RA and SLE after two doses of the BNT162b2 vaccine demonstrated that 23% of patients could not mount a detectable serological response to the vaccine. B cell-depleting therapy (BCDT) is of specific concern, and our findings call for particular attention to the patients receiving BCDT.

Large hemorrhagic stroke after ChAdOx1 nCoV-19 vaccination: A case report. BACKGROUND: The anti-COVID-19 vaccines are new, and we should be alert of potential adverse effects of them. AIMS OF THE STUDY: To report a case of a large hemorrhagic stroke 5Â days after ChAdOx1 nCoV-19 vaccination. METHODS: Clinical, imaging, and laboratory data of a patient with stroke admitted to our emergency department. RESULTS: A woman, 57Â years old, took the first dose of the ChAdOx1 nCoV-19 vaccine and shortly thereafter presented mild systemic symptoms and started on aspirin. On day 5, she had a sudden onset of sweating and paleness, which has followed by left hemiparesis, vomiting, and somnolence. Computed tomography showed a large right deep frontal lobe parenchymal hematoma with the inundation of the entire ventricular system. Platelets count, fibrinogen, prothrombin time, and D-dimer were normal. Digital subtraction angiography did not show any signs of thrombosis or aneurysms in brain circulation. CONCLUSIONS: Clinicians should be aware of cerebrovascular adverse effects of ChAdOx1 nCoV-19, including out-of-context of vaccine-induced immune thrombotic thrombocytopenia.

Coincidence of fever following COVID-19 vaccine and endemic tropical diseases: a challenge to clinicians during the global rollout of COVID-19 vaccination. Coincidence of fever following COVID-19 vaccine and endemic tropical diseases may occur during the global rollout of COVID-19 vaccination. Clinicians should aware of this scenario when dealing with fever post-vaccination to prevent delayed diagnosis.

A case of acute demyelinating polyradiculoneuropathy with bilateral facial palsy after ChAdOx1 nCoV-19 vaccine. BACKGROUND: The coronavirus disease 2019 (COVID-19) global pandemic, caused by severe acute respiratoryÂ syndrome coronavirus 2 (SARS-CoV-2), began in late 2019. Researchers around the world areÂ aggressively working to develop a vaccine. One of the vaccines approved against COVID-19 is Oxford-AstraZeneca chimpanzee adenovirus vectored vaccine ChAdOx1 nCoV-19. CASE REPORT: We described a patient who developed four limb distal paraesthesia, postural instability, and facialÂ diplegia, ten days after vaccination with ChAdOx1 nCoV-19 (ABW1277). The electrophysiologicalÂ findings were compatible with acute demyelinating motor polyneuropathy

(Guillain-BarrÃ¨ syndrome). DISCUSSION: We therefore want to describe a temporal correlation between administration of ChAdOx1 nCoV-19Â (ABW1277) vaccine and GBS without evidence of other predisposing infectious or autoimmune factors.Â This paper aims to highlight the importance of pharmacovigilance and subsequent reports will be neededÂ to evaluate the possible correlation between these two events.

Important Considerations for COVID-19 Vaccination of Children With Developmental Disabilities.

Thrombosis with Thrombocytopenia Syndrome (TTS) following AstraZeneca ChAdOx1 nCoV-19 (AZD1222) COVID-19 vaccination - A risk-benefit analysis for peopleÂ <Â 60Â years in Australia. The AstraZeneca ChAdOx1 nCoV-19 (AZD1222) vaccine is associated with Thrombosis with Thrombocytopenia Syndrome (TTS) in 3/100,000 vaccinations with high fatality rates reported in many countries. We conducted a risk-benefit analysis for Australians aged 18-59Â years, comparing the risk of vaccination versus infection, and rate of TTS to other vaccines which prompted policy change following rare adverse events - rotavirus, smallpox and oral polio vaccines. COVID-19 deaths over 12Â months range from 0 to 417 in current and future worst case scenarios. In the past 15Â months 20 COVID-19 deaths occurred in peopleÂ <Â 60Â years compared to 890 deaths over 60Â years. The estimated possible number of TTS cases is 347, with vaccine-related deaths ranging from 17 to 153if 80% of adults 18-59Â years are vaccinated. The reported rate of TTS is in the same range as rare but serious adverse events associated with other vaccines that have been subject to policy change. In Australia, the potential risks of the AZD1222 vaccine in younger adults, who are at low risk of dying from COVID-19, may outweigh the benefits.

[Eczematiform eruption after Pfizer-BioNTech COVID-19Â vaccine].

Reduction in COVID-19 prevalence in healthcare workers in a university hospital in southern Brazil after the start of vaccination. INTRODUCTION: The quick spread of SARS-CoV-2 led to the development of vaccines that are capable of reducing infection and the number of more severe COVID-19 cases. AIM: To assess COVID-19 prevalence among healthcare workers (HCWs) after vaccination against SARS-CoV-2. METHODS: This was a cross-sectional study on the prevalence of COVID-19 diagnosis among 7523 HCWs vaccinated against SARS-CoV-2 with CoronaVac and ChAdOx1 nCoV-19 in a university hospital, in southern Brazil, between January 18 and March 18, 2021.The variables evaluated were: sex, age, work area, role, source of infection, previous diagnosis of COVID-19, date of vaccine administration, type of vaccine, and need for hospitalization. The statistical analysis used Poisson regression and Fisher's exact test with SPSS software version 25, and a level of significance set at 5%. RESULTS: 813 vaccinated HCWs showed symptoms suggestive of COVID-19, of whom 35.4% (288) had a detectable result after undergoing RT-PCR for SARS-CoV-2. There was a reduction of 62% in new cases of COVID-19 among HCWs in the institution 7 weeks after the start of vaccine rollout. CONCLUSION: Our data suggest that the vaccines used by the institution reduced the number of COVID-19 cases among healthcare workers, demonstrating the effectiveness of the vaccines.

Antibody response after second BNT162b2 dose in allogeneic HSCT recipients.

SARS-CoV-2 variant B.1.617 is resistant to bamlanivimab and evades antibodies induced by infection and vaccination. The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants threatens efforts to contain the coronavirus disease 2019 (COVID-19) pandemic. The number of COVID-19 cases and deaths in India has risen steeply, and a SARS-CoV-2 variant, B.1.617, is believed to be responsible for many of these cases. The spike protein of B.1.617 harbors two mutations in the receptor binding domain, which interacts with the angiotensin converting enzyme 2 (ACE2) receptor and constitutes the main target of neutralizing antibodies. Therefore, we analyze whether B.1.617 is more adept in entering cells and/or evades antibody responses. B.1.617 enters two of eight cell lines tested with roughly 50% increased efficiency and is equally inhibited by two

entry inhibitors. In contrast, B.1.617 is resistant against bamlanivimab, an antibody used for COVID-19 treatment. B.1.617 evades antibodies induced by infection or vaccination, although less so than the B.1.351 variant. Collectively, our study reveals that antibody evasion of B.1.617 may contribute to the rapid spread of this variant.

Safety of COVID-19 vaccines. This study is aimed to identify the adverse effects associated with three types of coronavirus disease 2019 vaccines. Approximately 1736 individuals agreed to participate in this study. The participants involved in the study were individuals who had received the first dose or full course (two doses) of the vaccine at least 30 days before the survey. A direct and interactive web-based system interview with a paper and electronic version of the questionnaire was used for all participants. A total of 1736 randomized individuals were identified. The reactogenicity of the vaccines including pain, redness, urticaria, and swelling at the site of the injection was reported in 34.56% of the participants. Local site reaction was reported in more individuals who had Pfizer and AstraZeneca vaccines than those who received the Sinopharm vaccine. The systemic events were more common with AstraZeneca and Pfizer vaccines, symptoms reported were fatigue, body pain, headache, muscle pain, fever, and gastrointestinal side effects. There were no correlations between age or gender, and the duration of the adverse effects for the three vaccines. Swelling and severe allergic reaction of the eyelids, severe hypotension, generalized body aches, shortness of breath, weakness and numbness on the injected arm, acute hyperglycemia, severe chest pain, and fever more than 39Â°C were among the unusual signs and symptoms reported by the participants. Pfizer, AstraZeneca, and Sinopharm vaccines were found to be safe and Sinopharm vaccine showed a lower prevalence of adverse effects compared with the other vaccines. The duration and severity of adverse effects were not affected by age or gender. Unusual side effects should be closely monitored to establish determine they are linked to the immunization.

Immunization practices and risk of anaphylaxis: a current update, comprehensive of COVID-19 vaccination data. PURPOSE OF REVIEW: This review aims to provide an updated report in regards to the correlation between vaccines and anaphylaxis and the related risk in the population. RECENT FINDINGS: Initial reports showed higher incidence of anaphylaxis following messenger RNA COVID-19 vaccines compared with 'routine' vaccinations, likely influenced by the great attention paid to these 'new' vaccines. However, anaphylaxis has still to be considered quite rare and its incidence will be systematically reconsidered in the light of additional data collected. SUMMARY: Adverse reactions to vaccines are commonly reported but most of them are nonspecific mild events, whereas vaccine-related anaphylaxis is considered a rare event, with an incidence rate equal to 1.3 cases per million vaccine doses administered. As anaphylaxis reports usually start to be reported to passive pharmacovigilance during postmarketing surveillance, the first data are used to be influenced by under- and over-reporting and lack of denominators and following studies are needed to confirm the causal relationship. This might create an initial overcautiously approach to new immunization practices but, being anaphylaxis a potential life-threatening event, every suspected contraindication has to be deepened to maximize effectiveness and safety profile and constantly redefined not to exclude an overestimated population group who could receive the vaccine uneventfully.

DOTATATE Uptake in an Axillary Lymph Node After COVID-19 Vaccination. A 58-year-old man underwent DOTATATE PET/CT scan for follow-up of pulmonary neuroendocrine tumor after resection and adjuvant chemotherapy. On screening paperwork, the patient indicated having received the Johnson & Johnson/Janssen COVID-19 vaccine (Janssen Biotech, Inc) 1 day previously, administered in the right deltoid muscle. Reactive changes in regional lymph nodes is a known response for all 3 currently Food and Drug Administration-approved COVID-19 vaccines. Recent published data have demonstrated FDG PET-avid axillary lymphadenopathy subsequent to COVID-19 vaccination, and

included here is a report of DOTATATE PET-avid axillary lymph node after injection of the Johnson & Johnson COVID-19 vaccine.
COVID-19 infection, progression, and vaccination: Focus on obesity and related metabolic disturbances. Coronaviruses are constantly circulating in humans, causing common colds and mild respiratory infections. In contrast, infection with the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), responsible for coronavirus disease-2019 (COVID-19), can cause additional severe complications, particularly in patients with obesity and associated metabolic disturbances. Obesity is a principal causative factor in the development of the metabolic syndrome; a series of physiological, biochemical, clinical, and metabolic factors that increase the risk of obesity-associated diseases. "Metabolically unhealthy" obesity is, in addition to metabolic disturbances, also associated with immunological disturbances. As such, patients with obesity are more prone to develop serious complications from infections, including those from SARS-CoV-2. In this review, we first describe how obesity and related metabolic disturbances increase the risk of SARS-CoV-2 infection. Then, mechanisms contributing to COVID-19 complications and poor prognosis in these patients are discussed. Finally, we discuss how obesity potentially reduces long-term COVID-19 vaccination efficacy. Despite encouraging COVID-19 vaccination results in patients with obesity and related metabolic disturbances in the short-term, it is becoming increasingly evident that long-term COVID-19 vaccination efficacy should be closely monitored in this vulnerable group.
Real-world data shows increased reactogenicity in adults after heterologous compared to homologous prime-boost COVID-19 vaccination, March-June 2021, England. Adults receiving heterologous COVID-19 immunisation with mRNA (Comirnaty) or adenoviral-vector (Vaxzevria) vaccines had higher reactogenicity rates and sought medical attention more often after two doses than homologous schedules. Reactogenicity was higher amongâ€‰â‰¤â€‰50 thanâ€‰>â€‰50 year-olds, women and those with prior symptomatic/confirmed COVID-19. Adults receiving heterologous schedules on clinical advice after severe first-dose reactions had lower reactogenicity after dose 2 following Vaxzevria/Comirnaty (93.4%; 95% confidence interval: 90.5-98.1 vs 48% (41.0-57.7) but not Comirnaty/Vaxzevria (91.7%; (77.5-98.2 vs 75.0% (57.8-87.9).
Background rates of hospital transfer and death in Australian aged care facilities: estimates to assist interpretation of rates after COVID-19 vaccination.
SARS-CoV-2 Infections in mRNA Vaccinated Individuals are Biased for Viruses Encoding Spike E484K and Associated with Reduced Infectious Virus Loads that Correlate with Respiratory Antiviral IgG levels. INTRODUCTION: COVID-19 large scale immunization in the US has been associated with infrequent breakthrough positive molecular testing. Whether a positive test is associated with a high viral RNA load, specific viral variant, recovery of infectious virus, or symptomatic infection is largely not known. METHODS: In this study, we identified 133 SARS-CoV-2 positive patients who had received two doses of either Pfizer-BioNTech (BNT162b2) or Moderna (mRNA-1273) vaccines, the 2nd of which was received between January and April of 2021. The positive samples were collected between January and May of 2021 with a time that extended from 2 to 100 days after the second dose. Samples were sequenced to characterize the whole genome and Spike protein changes and cycle thresholds that reflect viral loads were determined using a single molecular assay. Local SARS-CoV-2 IgG antibodies were examined using ELISA and specimens were grown on cell culture to assess the recovery of infectious virus as compared to a control unvaccinated cohort from a matched time frame. RESULTS: Of 133 specimens, 24 failed sequencing and yielded a negative or very low viral load on the repeat PCR. Of 109 specimens that were used for further genome analysis, 68 (62.4%) were from symptomatic infections, 11 (10.1%) were admitted for COVID-19, and 2 (1.8%) required ICU admission with no associated mortality. The predominant virus variant was the alpha (B.1.1.7), however a significant association between lineage B.1.526 and amino acid change S: E484K with

positives after vaccination was noted when genomes were compared to a large control cohort from a matched time frame. A significant reduction of the recovery of infectious virus on cell culture as well as delayed time to the first appearance of cytopathic effect was accompanied by an increase in local IgG levels in respiratory samples of vaccinated individuals but upper respiratory tract IgG levels were not different between symptomatic or asymptomatic infections. CONCLUSIONS: Vaccination reduces the recovery of infectious virus in breakthrough infections accompanied by an increase in upper respiratory tract local immune responses. FUNDING: National Institute of Health (The Johns Hopkins Center of Excellence in Influenza Research and Surveillance, HHSN272201400007C), Johns Hopkins University, Maryland Department of Health, Centers for Disease Control and Prevention.

Renal Vein Thrombosis and Pulmonary Embolism Secondary to Vaccine-induced Thrombotic Thrombocytopenia (VITT). The Medicines and Healthcare products Regulatory Agency (MHRA) of the UK has approved the use of three vaccines to combat COVID-19 (SARS-CoV-2). There have been rare reports of thrombosis after vaccination with the AstraZeneca vaccine. We present three cases of vaccine-induced thrombotic thrombocytopenia (VITT) in one UK district general hospital following administration of this vaccine. Two of the patients had asymptomatic pulmonary emboli, while the other is the first known case of both renal vein thrombosis and pulmonary embolism. LEARNING POINTS: Vaccine-induced thrombotic thrombocytopenia (VITT) can be associated with unusual and multiple sites of thrombosis.Clinicians should have a low threshold for requesting anti-PF4 antibody tests and imaging (especially pulmonary imaging) in thrombocytopenic patients after administration of the AstraZeneca vaccine.We describe a localised cluster of VITT despite its rarity according to current statistics, highlighting the need for an efficient data collection system to ensure the incidence of VITT is accurately reported.

The Meaning of SARS-CoV-2 Antibodies in a Patient with a Systemic Reaction to the mRNA-1273 SARS-CoV-2 Vaccine after Previous Natural Immunization. OBJECTIVES: There is limited experience regarding the meaning of SARS-CoV-2 antibodies after vaccination in patients with naturally acquired immunity. METHODS: We describe the case of a patient who received the first dose of the mRNA-1273 SARS-CoV-2 vaccine 6 months after his recovery from moderately severe COVID-19. RESULTS: Our patient had a positive nucleocapsid SARS-CoV-2 IgG/IgM titre with 78.7 multiple of cut-off indicating persistent humoral immune response 6 months after infection. After vaccination, he developed prolonged systemic symptoms (fever, fatigue, nausea, diarrhoea and myalgia) for a duration of 6 days. CONCLUSION: SARS-CoV-2 nucleocapsid antibodies provide information about naturally acquired immunity. For the assessment of immune response to vaccination, measurement of the SARS-CoV-2 spike antibody titre before and after vaccination is essential. Patients with naturally acquired immunity might develop a prolonged systemic reaction to the first dose of the mRNA-1273 SARS-CoV-2 vaccine. LEARNING POINTS: Patients with naturally acquired immunity might develop a prolonged systemic reaction after receiving an mRNA SARS-CoV-2 vaccine.Depending on the clinical situation of SARS-CoV-2 infection and/or vaccination, different antibody titres should be determined.The SARS-CoV-2 nucleocapsid antibodies provide information on whether or not natural immunization has taken place. To quantify the immune response induced by vaccination, the SARS-CoV-2 spike antibody titre before and after vaccination has to be measured.

COVID-19 Vaccination-Induced Rash: Does the Choice of Vaccine Matter? With the introduction of large-scale vaccination programmes against the coronavirus disease 2019 (COVID-19), the world has now begun to visualise a possible end to the ongoing pandemic. As with any vaccination programme, reports of side effects have begun to emerge in the wake of vaccinations. Initial reports were about mild side effects, such as local inflammation, pain, and fever. However, as a significant number of the population began to receiveÂ various COVID-19 vaccines, reports of various other moderate to severe side effects have now started to emerge. Although these side effects seem to be

rare, the symptoms can be severe, andÂ information and guidelines on how to manage them are scarce. In this case series, we discuss the incidence of widespread rashes that develop in some individuals after receiving COVID-19 vaccinesÂ by both AstraZeneca (AstraZeneca plc, Cambridge, UK) and Pfizer-BioNTech (Pfizer Inc., Brooklyn, NY; BioNTech SE, Mainz, Germany). The systemic skin reaction varied from maculopapular rashes to papules and patches that were widespread and not simply localised to the vaccine injection site. Further clinical information, awareness, and guidelines for practicing clinicians need to be exigently provided as vaccination programmes approach completion and the incidences of moderate to severe side effects of COVID-19 vaccination are becoming more apparent and pervasive.

Otologic Manifestations After COVID-19 Vaccination: The House Ear Clinic Experience. OBJECTIVE: With the increasing numbers of COVID-19 vaccinations available there are some reports of new onset of otologic symptoms. We present our experience in recently vaccinated patients over a 30-day time frame. STUDY DESIGN: Retrospective chart review. SETTING: Tertiary otology ambulatory practice. PATIENTS: All patients with available diagnostic codes, COVID-19 questionnaires and clinical notes. INTERVENTIONS: Observational recordings. MAIN OUTCOME MEASURES: Within the same 30-day time period in 2019, 2020, and 2021, 1.6, 2.4, and 3.8% respectively, of all office visits were for patients with the diagnosis of new onset idiopathic sensorineural hearing loss (SNHL) without other underlying otologic diagnoses. In this time frame in 2021, 30 patients out of the 1,325 clinical visits had new or significantly exacerbated otologic symptoms that began shortly after COVID-19 vaccination. Specifically, 18 patients received Moderna and 12 patients received Pfizer vaccine. Their mean age was 60.9Â±13.8â€Šyears old; 11 were women and 19 men. The mean onset of symptoms was 10.18â€ŠÂ±â€Š9â€Šdays post-vaccination. Symptoms included 25 patients (83.3%) with hearing loss, 15 (50%) with tinnitus, eight (26.7%) with dizziness, and five (16.7%) with vertigo. Eleven patients had previous otologic diagnoses, including six patients with MeniÃ¨re's disease, two with autoimmune inner ear disease (AIED), and three having both. CONCLUSIONS: There are no definite correlations to the COVID-19 pandemic or vaccination and new or worsened otologic symptoms. Vaccinated patients with new or exacerbated otologic symptoms should be promptly referred for evaluation. Suspected cases of post-vaccination otologic symptoms should be reported to the Center for Disease Control (CDC) vaccine adverse event reporting system (VAERS).

[Kidney damage in COVID-19]. COVID-19 is a disease caused by the RNA virus SARS-CoV-2. It is characterised by an attack mainly affecting the respiratory system. There is renal involvement which is characterised by three main types of damage, acute tubular necrosis occurring in the most severe cases, proximal tubulopathy which is a prognostic marker of the disease and segmental and focal hyalinosis occurring in a genetically predisposed terrain. The pathophysiology of SARS-CoV-2 renal involvement is not yet defined. The direct role of the virus is debated, whereas the cytokine storm and the hypoxic and thrombotic complications seem more important. The long-term outcome of the renal damage appears to be quite good. Long-term follow-up will allow us to say whether the renal damage is part of the long COVID.

COVID-19 vaccination associated severe immune thrombocytopenia. BACKGROUND: Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 has emerged as a deadliest global pandemic after its identification in December 2019 in Wuhan, China resulting in more than three million deaths worldwide. Recently FDA issued emergency authorization for three vaccines for prevention of COVID-19. Here in, we report three cases of severe immune thrombocytopenia (ITP) following COVID-19 vaccination and their clinical course. CASE PRESENTATIONS: Case #1: 53Â year old male with past medical history of Crohn's disease was admitted for myalgias and diffuse petechial rash 8Â days after receiving second dose of Pfizer-BioNTech COVID-19 vaccine. A complete blood test showed a platelet count of 2â€‰Ã—â€‰10(9)/L.

Patient did not have a prior history of thrombocytopenia and other causes of thrombocytopenia were ruled out by history and pertinent lab data. He received two doses of intravenous immunoglobulin and oral dexamethasone for 4Â days resulting in normalization of platelet counts. Case #2: 67Â year male with past medical history of chronic ITP in remission was admitted for melena 2Â days after receiving his first dose of Pfizer-BioNTech COVID-19 vaccine. A complete blood test showed a platelet count of 2â€‰Ã—â€‰10(9)/L. Physical exam showed generalized petechiae. There was no history of recent flares of ITP and patient had normal platelet counts following his splenectomy 4Â years ago. He received two doses of IVIG and oral dexamethasone for 4Â days with gradual improvement in platelet counts. Case #3: 59Â year old female with past medical history of chronic ITP secondary to SLE was admitted for bloody diarrhea 2Â days after receiving her first dose of Johnson and Johnson COVID-19 vaccine. Physical exam was unremarkable. A complete blood test showed platelet count of 64â€‰Ã—â€‰10(9)/L which dropped to 27â€‰Ã—â€‰10(9)/L during hospital course. She received oral dexamethasone for 4Â days with improvement in platelet counts. CONCLUSION: COVID-19 vaccination induced ITP has been recently acknowledged. However, given very few cases and limited data, currently there are no guidelines for management of ITP caused by COVID-19 vaccine as well as vaccination of people with predisposing conditions.

Lack of vaccination and associated comorbidities predispose to the need for intensive care in individuals infected with the delta variant - A case cohort study from a tertiary care hospital in New Delhi, India.

Neutralizing antibody response against variants of concern after vaccination of dialysis patients with BNT162b2.

Acceptability of Adolescent COVID-19 Vaccination Among Adolescents and Parents of Adolescents - United States, April 15-23, 2021. On May 10, 2021, the Food and Drug Administration (FDA) expanded its Emergency Use Authorization for the Pfizer-BioNTech COVID-19 vaccine to include adolescents aged 12-15 years; this authorization was followed by interim recommendations from the Advisory Committee on Immunization Practices (ACIP) for the vaccine among this age group (1). Using data from nonprobability-based Internet panel surveys administered by the Healthcare and Public Perceptions of Immunizations (HaPPI) Survey Collaborative, the acceptability of adolescent COVID-19 vaccination and self-reported factors increasing vaccination intent were assessed among independently recruited samples of 985 adolescents aged 13-17 years and 1,022 parents and guardians (parents) of adolescents aged 12-17 years during April 15-April 23, 2021, prior to vaccine authorization for this age group. Approximately one quarter (27.6%) of parents whose adolescents were already vaccine-eligible (i.e., aged 16-17 years) reported their adolescent had received â‰¥1 COVID-19 vaccine dose, similar to the proportion reported by vaccine-eligible adolescents aged 16-17 years (26.1%). However, vaccine receipt reported by parents of adolescents differed across demographic groups; parents identifying as female or Hispanic, or who had an education lower than a bachelor's degree reported the lowest adolescent COVID-19 vaccination receipt. Among parents of unvaccinated adolescents aged 12-17 years, 55.5% reported they would "definitely" or "probably" have their adolescent receive a COVID-19 vaccination. Among unvaccinated adolescents aged 13-17 years, 51.7% reported they would "definitely" or "probably" receive a COVID-19 vaccination. Obtaining more information about adolescent COVID-19 vaccine safety and efficacy, as well as school COVID-19 vaccination requirements, were the most commonly reported factors that would increase vaccination intentions among both parents and adolescents. Federal, state, and local health officials and primary care professionals were the most trusted sources of COVID-19 vaccine information among both groups. Efforts focusing on clearly communicating to the public the benefits and safety of COVID-19 vaccination for adolescents, particularly by health care professionals, could help increase confidence in adolescent COVID-19 vaccine and vaccination coverage.

Safety and effectiveness of SARS-CoV-2 vaccines: A systematic review and meta-analysis. OBJECTIVE: To systematically evaluate the effectiveness and safety of the SARS-CoV-2 vaccines currently undergoing clinical trials. METHODS: PubMed, EMBASE,Â and Cochrane Library databasesÂ were searched to collect open human COVID-19 vaccines randomized controlled trials, without limiting the search time and language. The research papers collected in the above-mentioned databasesÂ were initially screened according to the title and abstract content and merged, and the repeated onesÂ were removed. After reading the full text of the remaining research, the studies that did not meet the inclusion criteria were excluded, and finally, nine studies were obtained. After extracting the statistical data of adverse events in the study, load them into Review Manager for heterogeneity analysis. RESULTS: The incidence of adverse reactions of inactivated virus vaccines, RNA vaccines, and adenovirus vector vaccines was higher than that of placebo. Common adverse reactions included pain, swelling, and fever at the injection site. CONCLUSION: From the perspective of effectiveness, RNA vaccineâ€‰>â€‰adenovirus vector vaccineâ€‰>â€‰inactivated virus vaccine.Â From the perspective of safety, the incidence of adverse reactions of the three vaccines is higher than that of a placebo, and the incidence of adverse reactions of the adenovirus vector vaccine is higher.

Thrombotic thrombocytopenic purpura: a new menace after COVID bnt162b2 vaccine. Thrombotic thrombocytopenic purpura (TTP) is a known menace in hematology and is quite rare in practice with known triggers. Lately, in the COVID-19 pandemic, hematology has seen a new pathology amongst which TTP associated with COVID-19 messenger RNA (mRNA) vaccine is unique. We report a case of a 69-year-old male with multiple comorbidities who presented to the hospital with severe fatigue and shortness of breath. Labs were significant for thrombocytopenia, anemia, and hemolysis with schistocytes consistent with TTP with a second dose of BNT162b2 mRNA vaccine as a likely culprit been documented.

Thromboembolic events in younger women exposed to Pfizer-BioNTech or Moderna COVID-19 vaccines. Introduction: Concerns about the increased risk of blood clots associated with the VAXZEVRIA (previously named Oxford-AstraZeneca COVID-19 vaccine) and Johnson & Johnson (Janssen) COVID-19 vaccines raises the question of the thrombotic safety of other COVID-19 vaccines such as Pfizer-BioNTech or Moderna, especially in younger women, who at the early stage of the pandemic was a priority group for vaccination. Methods: Using the US-based Vaccine Adverse Event Reporting System (VAERS) and the FDA Event Reporting System (FAERS), we retrieved cases of thrombosis following vaccinations or hormonal contraceptive use in women aged â‰¤ 50Â years. We used the reporting odds ratio (ROR) as a disproportionality measure. Results: On 19 March 2021, out of 13.6 million women aged â‰¤ 50 exposed to at least one dose of Pfizer-BioNTech or Moderna COVID-19 vaccines in the US, only 61 cases were reported with a total of 68 thromboembolic events (1 case per 222,951 vaccinated). None of the thromboembolic events included in our analysis were disproportionally reported for the two COVID-19 vaccines. Conclusion: Our results do support that, when compared to hormonal contraceptive use, the mRNA vaccines do not show disproportional reporting of thromboembolic events in younger women.

Autoimmune Hematologic Disorders in Two Patients After mRNA COVID-19 Vaccine.

Immune responses against SARS-CoV-2 variants after heterologous and homologous ChAdOx1 nCoV-19/BNT162b2 vaccination. Currently approved viral vector-based and mRNA-based vaccine approaches against coronavirus disease 2019 (COVID-19) consider only homologous prime-boost vaccination. After reports of thromboembolic events, several European governments recommended using AstraZeneca's ChAdOx1-nCov-19 (ChAd) only in individuals older than 60 years, leaving millions of already ChAd-primed individuals with the decision to receive either a second shot of ChAd or a heterologous boost with mRNA-based vaccines. However, such combinations have not been tested so

far. We used Hannover Medical School's COVID-19 Contact Study cohort of healthcare professionals to monitor ChAd-primed immune responses before and 3 weeks after booster with ChAd (nâ€‰=â€‰32) or BioNTech/Pfizer's BNT162b2 (nâ€‰=â€‰55). Although both vaccines boosted prime-induced immunity, BNT162b2 induced significantly higher frequencies of spike-specific CD4(+) and CD8(+) T cells and, in particular, high titers of neutralizing antibodies against the B.1.1.7, B.1.351 and P.1 variants of concern of severe acute respiratory syndrome coronavirus 2.

Bilateral facial weakness with paraesthesia variant of Guillain-BarrÃ© syndrome following Vaxzevria COVID-19 vaccine.

Pulmonary embolism, transient ischaemic attack and thrombocytopenia after the Johnson & Johnson COVID-19 vaccine. As with past illnesses, an approach has been taken to vaccinate the population and halt the spread of COVID-19. On 13 April 2021, the US Food and Drug Administration called for a halt in the administration of the Johnson & Johnson (J&J) COVID-19 vaccine due to reports of thrombosis and thrombocytopenia being associated with vaccination. We present the case of a 43-year-old woman with a history of dyslipidaemia, depression, gastro-oesophageal reflux disease and obesity presenting with dyspnoea, headache and light headedness of 3â€‰days' duration. Ten days prior, she had received the J&J COVID-19 vaccine. She was found to have thrombocytopenia, elevated D-dimers, pulmonary emboli and presented 1â€‰day after discharge with an arterial clot despite being on apixaban. Six other US-based cases of venous thrombotic events are being reviewed at present. Patients should be informed of the possibility of such events to provide informed consent.

Coeliac artery and splenic artery thrombosis complicated with splenic infarction 7 days following the first dose of Oxford vaccination, causal relationship or coincidence? The novel coronavirus SARS-CoV-2 became a global pandemic in late 2019, and is still ongoing in 2021 causing significant morbidity and mortality. The advent of vaccinations heralded the turning of the tide. The Oxford jab, a vector-based vaccine was favoured due to its low cost and ease of storage. However, its potential association with thromboembolic adverse events resulted in controversy and disrupted its roll-out and use. The aetiopathogenesis of these thromboembolic events and its association with the Oxford vaccine are still speculative and uncertain, more so in the background of SARS-CoV-2 infection being highly thrombogenic in its own right. This paper presents a case of an otherwise healthy 50-year-old Caucasian man who developed acute abdominal pain 7â€‰days following the first dose of Oxford vaccine and was found to have coeliac and splenic artery thrombosis complicated with splenic infarction.

Functional Neurological Disorder After SARS-CoV-2 Vaccines: Two Case Reports and Discussion of Potential Public Health Implications.

Intracerebral hemorrhage associated with vaccine-induced thrombotic thrombocytopenia following ChAdOx1 nCOVID-19 vaccine in a pregnant woman.

Heterologous ChAdOx1 nCoV-19 and mRNA-1273 Vaccination.

Audio Interview: Monoclonal Antibodies and Vaccine Boosts.

Severe cutaneous adverse reaction following COVID-19 vaccination and immunotherapy: a second hit?

Recognizing Vaccine-Induced Immune Thrombotic Thrombocytopenia. OBJECTIVES: Vaccine-induced immune thrombotic thrombocytopenia is an unexpected consequence of the coronavirus disease 2019 pandemic era. We reviewed the pathogenesis, clinical presentation, diagnosis, and treatment of this rare side effect. DATA SOURCES: Online search of published medical literature through PubMed, Scopus, Web of Science, and Google Scholar using the terms "COVID-19," "vaccine," "thrombosis" was performed. STUDY SELECTION: Articles were chosen for inclusion based on their relevance to coronavirus disease 2019, vaccine, and thrombosis. DATA SYNTHESIS: Vaccine-induced immune thrombotic thrombocytopenia manifests most often as unusual thromboses (cerebral

venous sinus thrombosis, splanchnic vein thrombosis) but sometimes also "usual" thromboses (arterial stroke, pulmonary embolism, deep-vein thrombosis), with oftentimes severe thrombocytopenia, that becomes clinically evident 5-30 days after adenovirus-vectored coronavirus disease 2019 vaccine administration. Most patients have disseminated intravascular coagulation. These features are the result of vaccine-triggered formation of anti-platelet factor 4 immunoglobulin G that activate platelets, clinically mimicking autoimmune heparin-induced thrombocytopenia. Early recognition based on thrombosis (sometimes, hemorrhage), thrombocytopenia, and d-dimer elevation within the day 5-30 postvaccine "window" is important given treatment with high-dose IV immunoglobulin plus nonheparin anticoagulation. CONCLUSIONS: Vaccine-induced immune thrombotic thrombocytopenia is a serious complication of vaccination that is not feasible to anticipate or prevent. When the patient presents with sustained headache, neurologic symptoms/signs, abdominal pain, dyspnea, or limb pain/swelling beginning 5-30 days post vaccination, platelet count and d-dimer must be measured, and imaging for thrombosis performed. Confirmation of vaccine-induced immune thrombotic thrombocytopenia diagnosis should be ordered (platelet factor 4/polyanion enzyme-linked immunosorbent assay; platelet factor 4-enhanced platelet activation testing) as treatment is initiated (nonheparin anticoagulation, IV immunoglobulin).
FDG-Avid Ipsilateral Iliac and Inguinal Lymphadenopathy After COVID-19 Vaccination With Thigh Injection.
A case of severe autoimmune hemolytic anemia after a receipt of a first dose of SARS-CoV-2 vaccine.
Impact of Previous Coronavirus Disease 2019 on Immune Response After a Single Dose of BNT162b2 Severe Acute Respiratory Syndrome Coronavirus 2 Vaccine. Immune response after a single dose of BNT162b2 vaccine was markedly increased in subjects with previous severe acute respiratory syndrome coronavirus 2 infection, reaching similar immunoglobulin titers to those elicited by the full 2 doses in naive cases, and increased modestly after the second dose. These data may inform the priority of the boosting dose.
Addressing Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) Following COVID-19 Vaccination: A Mini-Review of Practical Strategies. In response to the COVID-19 pandemic, several vaccines were developed and rolled out at unprecedented speed, and notwithstanding this rapid pace of development, the results from initial clinical trials involving tens of thousands of adult subjects generally indicated that most vaccines were remarkably effective and safe, with no major safety warnings noted. However, with more than 2 billion vaccination doses administered to date, reports of rare adverse events following immunization (AEFI) are beginning to emerge. In late February 2021, atypical thrombotic events following immunization with the adenoviral vector-based ChAdOx1 nCov-19 vaccine were first reported, and similar events have also been observed in recipients of the adenoviral vector-based Ad26.COV2.S vaccine and the mRNA-based BNT162b2 and mRNA-1273 vaccines. These manifestations of atypical thrombosis and thrombocytopenia following COVID-19 vaccine immunization are now collectively referred to as vaccine-induced immune thrombotic thrombocytopenia (VITT). Although the reported incidence remains very low and does not affect the overall benefit of immunization, it is also true that if left untreated, VITT can be debilitating or even fatal. Therefore, this review seeks to provide a comprehensive overview regarding the incidence, pathogenesis, presentation, diagnosis, and treatment of VITT, as well as considerations for special populations, based on the currently available evidence in the literature. It is hoped that this will enhance awareness of this vaccine side effect, so that cases of VITT may be identified and treated in a timely and appropriate manner.
Thrombosis and thrombocytopaenia after ChAdOx1 nCoV-19 vaccination: a single UK centre experience. We report clinical findings of three patients presenting with thrombosis and thrombocytopaenia 10-16â€‰days following the first dose of the ChAdOx1 nCoV-19 vaccine against

SARS-CoV-2. All patients presented to a major university teaching hospital in the UK over a 5-day period and were found to have high-titre antibodies against platelet factor 4 (PF4) without previous exposure to heparin. All three patients presented with extensive venous thrombosis, significant thrombocytopaenia, elevated D-dimer and borderline low fibrinogen. Two had fatal intracerebral haemorrhage secondary to cavernous venous sinus thrombosis and one had PE. Reference laboratory testing of serum demonstrated anti-PF4 antibodies in all three patients. The clinical and laboratory findings confirmed vaccine-induced thrombotic thrombocytopaenia (VITT) which was poorly described at the time of presentation. We were able to manage successfully one patient with PE with intravenous immunoglobulin and corticosteroids.

COVID-19 Vaccination Induced Lymphadenopathy in a Specialized Breast Imaging Clinic in Israel: Analysis of 163 cases. INTRODUCTION: Following vaccination of Israeli population with Pfizer-BioNTech COVID-19 Vaccine, an unusual increase in axillary-lymphadenopathy was noted. This study assesses the rate and magnitude of this trend from breast-imaging standpoint. MATERIALS AND METHODS: Participants undergoing breast-imaging, in whom isolated axillary-lymphadenopathy was detected were questioned regarding SARS-CoV-2 vaccine to the ipsilateral arm. Patients' and imaging characteristics were statistically compared. In order to perform a very short-term follow-up, twelve healthy vaccinated medical staff-members, underwent axillary-ultrasound shortly after the second dose, and follow-up. RESULTS: Axillary-lymphadenopathy attributed to vaccination was found in 163 women undergoing breast-imaging, including BRCA-carriers. During the study, number of detected lymphadenopathies increased by 394% (pÂ =Â 0.00001) in comparison with previous 2 consecutive years. Mean cortical-thickness of abnormal lymph-nodes after second dose vaccination was 5 Â± 2 mm. Longer lymph-node diameter after second vaccination was noted (from 15 Â± 5 mm, to 18 Â± 6 mm, pÂ =Â 0.005). In the subgroup of medical staff members, following trends were observed: in patients with positive antibodies, lymph-node cortical-thickness was larger than patients with negative serology (pÂ =Â 0.03); lymph-node cortical-thickness decreased in 4-5 weeks follow-up (pÂ =Â 0.007). Lymphadenopathy was evident on mammography in only 49% of cases. DISCUSSION: Vaccine-associated lymphadenopathy is an important phenomenon with great impact on breast-imaging clinic workload. Results suggest the appearance of cortical thickening shortly after both doses. Positive serology is associated with increased lymph-node cortical-thickness. In asymptomatic vaccinated women with ipsilateral axillary-lymphadenopathy as the only abnormal finding, radiological follow-up is probably not indicated. BRCA-carriers, although at higher risk for breast-cancer, should probably receive the same management as average-risk patients.

Primary adrenal insufficiency associated with Oxford-AstraZeneca ChAdOx1 nCoV-19 vaccine-induced immune thrombotic thrombocytopenia (VITT).

An unusual case of acute cholestatic hepatitis after m-RNABNT162b2 (Comirnaty) SARS-CoV-2 vaccine: Coincidence, autoimmunity or drug-related liver injury.

Autoimmune- and complement-mediated hematologic condition recrudescence following SARS-CoV-2 vaccination. A variety of autoimmune disorders have been reported after viral illnesses and specific vaccinations. Cases of de novo immune thrombocytopenia (ITP) have been reported after SARS-CoV-2 vaccination, although its effect on preexisting ITP has not been well characterized. In addition, although COVID-19 has been associated with complement dysregulation, the effect of SARS-CoV-2 vaccination on preexisting complementopathies is poorly understood. We sought to better understand SARS-CoV-2 vaccine-induced recurrence of autoimmune- and complement-mediated hematologic conditions. Three illustrative cases were identified at the University of Washington Medical Center and the Seattle Cancer Care Alliance from January through March 2021. We describe the recrudescence of 2 autoimmune conditions (ITP and acquired von Willebrand Disease [AvWD]/acquired hemophilia A) and 1 complementopathy (paroxysmal nocturnal hemoglobinuria

[PNH]). We report the first known case of AvWD/acquired hemophilia A, and describe the first PNH exacerbation in the absence of complement inhibition after SARS-CoV-2 vaccination. Although SARS-CoV-2 vaccine-induced ITP is a known concern, our case clearly depicts how thrombocytopenia in the setting of preexisting ITP can sequentially worsen with each vaccine dose. Based on our experiences and these examples, we provide considerations for how to monitor and assess risk in patients with underlying autoimmune- and complement-mediated hematologic conditions.

Association of BNT162b2 mRNA and mRNA-1273 Vaccines With COVID-19 Infection and Hospitalization Among Patients With Cirrhosis. IMPORTANCE: Two mRNA-based vaccines against coronavirus disease 2019 (COVID-19) were found to be highly efficacious in phase 3 clinical trials in the US. However, patients with chronic illnesses, including cirrhosis, were excluded from clinical trials. Patients with cirrhosis have immune dysregulation that is associated with vaccine hyporesponsiveness. OBJECTIVE: To study the association of receipt of the Pfizer BNT162b2 mRNA or the Moderna mRNA-1273 vaccines in patients with cirrhosis compared with a propensity-matched control group of patients at similar risk of infection and severe disease from COVID-19. DESIGN, SETTING, AND PARTICIPANTS: We performed a retrospective cohort study of patients with cirrhosis who received at least 1 dose of a COVID-19 mRNA vaccine at the Veterans Health Administration. Patients who received at least 1 dose of the vaccine (nâ€‰=â€‰20â€¯037) were propensity matched with 20â€¯037 controls to assess the associations of vaccination with new COVID-19 infection and COVID-19 hospitalization and death. EXPOSURES: Receipt of at least 1 dose of the BNT162b2 mRNA or the mRNA-1273 vaccines between December 18, 2020, and March 17, 2021. MAIN OUTCOMES AND MEASURES: COVID-19 infection as documented by a positive result for COVID-19 by polymerase chain reaction, hospitalization, and death due to COVID-19 infection. RESULTS: The median (interquartile range) age of the vaccinated individuals in the study cohort was 69.1 (8.4) years and 19â€¯465 (97.2%) of the participants in each of the vaccinated and unvaccinated groups were male, consistent with a US veteran population. The mRNA-1273 vaccine was administered in 10â€¯236 (51%) and the BNT162b2 mRNA in 9801 (49%) patients. Approximately 99.7% of patients who received the first dose of either vaccine with a follow-up of 42 days or more received a second dose. The number of COVID-19 infections in the vaccine recipients was similar to the control group in days 0 to 7, 7 to 14, 14 to 21, and 21 to 28 after the first dose. After 28 days, receipt of 1 dose of an mRNA vaccine was associated with a 64.8% reduction in COVID-19 infections and 100% protection against hospitalization or death due to COVID-19 infection. The association of reduced COVID-19 infections after the first dose was lower among patients with decompensated (50.3%) compared with compensated cirrhosis (66.8%). Receipt of a second dose was associated with a 78.6% reduction in COVID-19 infections and 100% reduction in COVID-19-related hospitalization or death after 7 days. CONCLUSIONS AND RELEVANCE: This cohort study of US veterans found that mRNA vaccine administration was associated with a delayed but modest reduction in COVID-19 infection but an excellent reduction in COVID-19-related hospitalization or death in patients with cirrhosis.

Predicted and Observed Incidence of Thromboembolic Events among Koreans Vaccinated with ChAdOx1 nCoV-19 Vaccine. We used the nationwide claims database to calculate the incidence of thrombotic events and predict their overall 2-week incidence. From 2006 to 2020, the incidence of deep vein thrombosis (DVT), pulmonary embolism (PE), and disseminated intravascular coagulation (DIC) tended to increase. Unlike intracranial venous thrombosis (ICVT) and intracranial thrombophlebitis (ICTP), which showed no age difference, other venous embolism, and thrombosis (OVET), DIC, DVT, and PE were significantly more common in over 65 years. The overall 2-week incidence of ICVT was 0.21/1,000,000 (95% confidence interval [CI], 0.11-0.32). ICTP, OVET, DIC, DVT and PE were expected to occur in 0.08 (95% CI, 0.02-0.14), 7.66 (95% CI, 6.08-9.23), 5.95 (95% CI, 4.88-7.03), 13.28 (95% CI, 11.92-14.64), 14.09 (95% CI, 12.80-15.37) per 1,000,000, respectively. To

date, of 8,548,231 patients vaccinated with ChAdOx1 nCoV-19 in Korea, two had confirmed thrombosis with thrombocytopenia syndrome within 2 weeks. The observed incidence of ICVT after vaccination was 0.23/1,000,000.
Emergency Department Utilization by In-hospital Healthcare Workers after COVID-19 Vaccination. BACKGROUND: This is an observational study to analyze an emergency department (ED) utilization pattern of coronavirus disease 2019 (COVID-19) vaccinated in-hospital healthcare workers (HCWs). METHODS: We included 4,703 HCWs who were administered the first dose of the COVID-19 vaccine between March 4 and April 2, 2021, in a tertiary hospital in Korea where fast-track and post-vaccination cohort zone (PVCZ) were introduced in ED. We analyzed data of participants' age, sex, occupation, date and type of vaccination, and their clinical information using SPSS v25.0. RESULTS: The sample comprised HCWs, who received either the ChAdOx1 (n = 4,458) or the BNT162B2 (n = 245) vaccines; most participants were female (73.5%), and 81.1% were under 50 years old. Further, 153 (3.3%) visited the ED and reported experiencing fever (66.9%) and myalgia (56.1%). Additionally, 91 (59.5%) of them were in their 20s, and 106 (67.5%) were assigned to the PVCZ. Lastly, 107 (68.2%) of the patients received parenteral management. No patient required hospitalization. CONCLUSION: In conclusion, vaccinated HCWs who visited the ED with adverse events had a high incidence of fever and a low likelihood of developing serious illnesses. As the COVID-19 vaccination program for Korean citizens continues to expand, strategies to minimize unnecessary ED overcrowding should be put into effect.
Cutaneous reactions after SARS-CoV-2 vaccination: a cross-sectional Spanish nationwide study of 405 cases. BACKGROUND: Cutaneous reactions after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines are poorly characterized. OBJECTIVE: To describe and classify cutaneous reactions after SARS-CoV-2 vaccination. METHODS: A nationwide Spanish cross-sectional study was conducted. We included patients with cutaneous reactions within 21â€‰days of any dose of the approved vaccines at the time of the study. After a face-to-face visit with a dermatologist, information on cutaneous reactions was collected via an online professional survey and clinical photographs were sent by email. Investigators searched for consensus on clinical patterns and classification. RESULTS: From 16 February to 15 May 2021, we collected 405 reactions after vaccination with the BNT162b2 (Pfizer-BioNTech; 40Â·2%), mRNA-1273 (Moderna; 36Â·3%) and AZD1222 (AstraZeneca; 23Â·5%) vaccines. Mean patient age was 50Â·7â€‰years and 80Â·2% were female. Cutaneous reactions were classified as injection site ('COVID arm', 32Â·1%), urticaria (14Â·6%), morbilliform (8Â·9%), papulovesicular (6Â·4%), pityriasis rosea-like (4Â·9%) and purpuric (4%) reactions. Varicella zoster and herpes simplex virus reactivations accounted for 13Â·8% of reactions. The COVID arm was almost exclusive to women (95Â·4%). The most reported reactions in each vaccine group were COVID arm (mRNA-1273, Moderna, 61Â·9%), varicella zoster virus reactivation (BNT162b2, Pfizer-BioNTech, 17Â·2%) and urticaria (AZD1222, AstraZeneca, 21Â·1%). Most reactions to the mRNA-1273 (Moderna) vaccine were described in women (90Â·5%). Eighty reactions (21%) were classified as severe/very severe and 81% required treatment. CONCLUSIONS: Cutaneous reactions after SARS-CoV-2 vaccination are heterogeneous. Most are mild-to-moderate and self-limiting, although severe/very severe reactions are reported. Knowledge of these reactions during mass vaccination may help healthcare professionals and reassure patients.
COVID-19 vaccination for children: may be necessary for the full eradication of the disease.
New infections by SARS-CoV-2 variants of concern after natural infections and post-vaccination in Rio de Janeiro, Brazil. After a one-year rollout of the pandemic caused by SARS-CoV-2, the continuous dissemination of the virus has generated a number of variants with increased transmissibility and infectivity, called variants of concern (VOC), which now predominate worldwide. Concerns about the susceptibility of humans that have already been infected before or those already

vaccinated to infection by VOC rise among scientists and clinicians. Herein, we assessed the prevalence of different VOC among recent infections at the Brazilian National Cancer Institute (Rio de Janeiro, Brazil). By using a Sanger-based sequencing approach targeting the viral S gene to identify VOC, we have analyzed 72 recent infections. The overall prevalence of VOC was 97%. Among the subjects analyzed, six had been vaccinated with the ChAdOx1-S/nCoV-19 (nÂ =Â 4; one with two doses and three with one dose) or the CoronaVac (nÂ =Â 2; both with 2 doses) vaccine, while five subjects represented reinfection cases, being two of them also part of the vaccinated group (each one with one vaccine type). All vaccinated and re-infected subjects carried VOC irrespective of the vaccine type taken, the number of doses taken, IgG titers or being previously infected during the first wave of the Brazilian pandemic. Importantly, all six vaccinees only had mild symptoms. We present here several examples of how natural infections or vaccination may not be fully capable of conferring sterilizing immunity against VOC.

Adverse rare events to vaccines for COVID-19: From hypersensitivity reactions to thrombosis and thrombocytopenia. Vaccines for the prevention of coronavirus disease 2019 (COVID-19) started to be developed since the initiation of the COVID-19 pandemic. Up to now, four vaccines have been authorized by international agencies such as European Medicines Agency (EMA). Two are DNA vaccines (ChAdOx1 nCov-19 and Ad26.COV2.S) and two mRNA vaccines (BNT162b2 and mRNA-1273). The administration of the vaccines has been associated with a strong decrease in the infections by SARS-CoV-2 and deaths associated with it. However, in parallel to these results, some rare adverse events have also been described. In that sense, events of thrombosis, thrombocytopenia, and hemorrhage have been described in close temporal proximity to the administration of the DNA vaccines ChAdOx1 nCov-19 and Ad26.COV2.S, but also mRNA vaccines. Recent scientific reports have been released with updated information on the possible association of thrombotic thrombocytopenia and COVID-19 vaccines. On the other hand, since the initiation of the vaccination campaigns, adverse hypersensitivity reactions have been described after mRNA and DNA vaccines administration for COVID-19. Although globally these adverse events are rare, a high proportion of the world population will be exposed to these vaccines. For that reason, their safety and tolerance should be carefully considered. In this review, we provide an updated review of the last scientific findings that can explain the rare side effects that the vaccines for COVID-19 can produce.

The Case for Mandating COVID-19 Vaccines for Health Care Workers. Not all health care workers have been vaccinated against COVID-19, and their reasons are multiple and varied. Some additional health care workers might decide to be vaccinated if the argument for vaccination were sufficiently clear. This article attempts to provide that clarity.

Relapse of microscopic polyangiitis after vaccination against COVID-19: A case report.

Association Between BNT162b2 Vaccination and Incidence of SARS-CoV-2 Infection in Pregnant Women. IMPORTANCE: Data on BNT162b2 messenger RNA (mRNA) vaccine (Pfizer-BioNTech) effectiveness and safety in pregnancy are currently lacking because pregnant women were excluded from the phase 3 trial. OBJECTIVE: To assess the association between receipt of BNT162b2 mRNA vaccine and risk of SARS-CoV-2 infection among pregnant women. DESIGN, SETTING, AND PARTICIPANTS: This was a retrospective cohort study within the pregnancy registry of a large state-mandated health care organization in Israel. Pregnant women vaccinated with a first dose from December 19, 2020, through February 28, 2021, were 1:1 matched to unvaccinated women by age, gestational age, residential area, population subgroup, parity, and influenza immunization status. Follow-up ended on April 11, 2021. EXPOSURES: Exposure was defined by receipt of the BNT162b2 mRNA vaccine. To maintain comparability, nonexposed women who were subsequently vaccinated were censored 10 days after their exposure, along with their matched pair. MAIN OUTCOMES AND MEASURES: The primary outcome was polymerase chain reaction-validated SARS-CoV-2 infection at

28 days or more after the first vaccine dose. RESULTS: The cohort included 7530 vaccinated and 7530 matched unvaccinated women, 46% and 33% in the second and third trimester, respectively, with a mean age of 31.1 years (SD, 4.9 years). The median follow-up for the primary outcome was 37 days (interquartile range, 21-54 days; range, 0-70). There were 118 SARS-CoV-2 infections in the vaccinated group and 202 in the unvaccinated group. Among infected women, 88 of 105 (83.8%) were symptomatic in the vaccinated group vs 149 of 179 (83.2%) in the unvaccinated group (Pâ€‰â‰¥â€‰.99). During 28 to 70 days of follow-up, there were 10 infections in the vaccinated group and 46 in the unvaccinated group. The hazards of infection were 0.33% vs 1.64% in the vaccinated and unvaccinated groups, respectively, representing an absolute difference of 1.31% (95% CI, 0.89%-1.74%), with an adjusted hazard ratio of 0.22 (95% CI, 0.11-0.43). Vaccine-related adverse events were reported by 68 patients; none was severe. The most commonly reported symptoms were headache (nâ€‰=â€‰10, 0.1%), general weakness (nâ€‰=â€‰8, 0.1%), nonspecified pain (nâ€‰=â€‰6, <0.1%), and stomachache (nâ€‰=â€‰5, <0.1%). CONCLUSIONS AND RELEVANCE: In this retrospective cohort study of pregnant women, BNT162b2 mRNA vaccination compared with no vaccination was associated with a significantly lower risk of SARS-CoV-2 infection. Interpretation of study findings is limited by the observational design.

COVID-19 vaccination: possible short-term exacerbations of oral mucosal diseases.

Erythema migrans-like rash after Moderna vaccine: An uncommon type of "COVID arm".

Decreased infectivity following BNT162b2 vaccination: A prospective cohort study in Israel. BACKGROUND: BNT162b2 was shown to be 92% effective in preventing COVID-19. Prioritizing vaccine rollout, and achievement of herd immunity depend on SARS-CoV-2 transmission reduction. The vaccine's effect on infectivity is thus a critical priority. METHODS: Among all 9650 HCW of a large tertiary medical center in Israel, we calculated the prevalence of positive SARS-CoV-2 qRT-PCR cases with asymptomatic presentation, tested following known or presumed exposure and the infectious subset (N-gene-Ct-value<30) of these. Additionally, infection incidence rates were calculated for symptomatic cases and infectious (Ct<30) cases. Vaccine effectiveness within three months of vaccine rollout was measured as one minus the relative risk or rate ratio, respectively. To further assess infectiousness, we compared the mean Ct-value and the proportion of infections with a positive SARS-CoV-2 antigen test of vaccinated vs. unvaccinated. The correlation between IgG levels within the week before detection and Ct level was assessed. FINDINGS: Reduced prevalence among fully vaccinated HCW was observed for (i) infections detected due to exposure, with asymptomatic presentation (VE(i)=65.1%, 95%CI 45-79%), (ii) the presumed infectious (Ct<30) subset of these (VE(ii)=69.6%, 95%CI 43-84%) (iii) never-symptomatic infections (VE(iii)=72.3%, 95%CI 48-86%), and (iv) the presumed infectious (Ct<30) subset (VE(iv)=83.0%, 95%CI 51-94%).Incidence of (v) symptomatic and (vi) symptomatic-infectious cases was significantly lower among fully vaccinated vs. unvaccinated individuals (VE(v)= 89.7%, 95%CI 84-94%, VE(vi)=88.1%, 95%CI 80-95%).The mean Ct-value was significantly higher in vaccinated vs. unvaccinated (27.3Â±1.2 vs. 22.2Â±1.0, p<0.001) and the proportion of positive SARS-CoV-2 antigen tests was also significantly lower among vaccinated vs. unvaccinated PCR-positive HCW (80% vs. 31%, p<0.001). Lower infectivity was correlated with higher IgG concentrations (R=0.36, p=0.01). INTERPRETATION: These results suggest that BNT162b2 is moderately to highly effective in reducing infectivity, via preventing infection and through reducing viral shedding. FUNDING: Sheba Medical Center, Israel.

Two Cases of Well Controlled Chronic Spontaneous Urticaria Triggered by the Moderna COVID-19 Vaccine. Chronic spontaneous urticaria (CSU, chronic idiopathic urticaria) is a clinical diagnosis characterized by recurrent urticaria of unknown origin, with or without angioedema, that occurs for six weeks or longer. Management of CSU includes a second-generation H1 antihistamine and/or elimination of exacerbating factors. If initial treatment is unsuccessful, trials of first generation H1

antihistamine, H2 blocking antihistamine, leukotriene-receptor antagonist, anti-inflammatory or immunosuppressive agents may be administered. Exacerbating factors include stress, environmental conditions, medications, physical stimuli, and infections. We report the first two cases of a COVID-19 vaccine triggered relapse of CSU that was previously well controlled on therapy.

Post-COVID-19 vaccine Guillain-BarrÃ© syndrome; first reported case from Qatar. INTRODUCTION: Guillain-BarrÃ© syndrome (GBS) is an immune-mediated peripheral neuropathy that was reported following meningococcus, polio, influenza and rabies vaccines. However, an association with the COVID-19 vaccine is yet to be established. PRESENTATION OF CASE: We present the case of an elderly gentleman with no history of SARS-CoV-2 infection or any recent viral or bacterial illnesses who presented with GBS 20 days after the second dose of COVID-19 vaccination. The diagnosis was established based on physical examination, magnetic resonance imaging (MRI) of the spine, cerebrospinal fluid (CSF) analysis and electromyography (EMG). DISCUSSION: Due to the occurrence of GBS after certain types of infections, molecular mimicry has become widely acceptable as the underlying pathophysiology. The reported cases of GBS following vaccination further supported this theory, however proving a causal relationship between vaccines and GBS on the molecular level remains a challenge. CONCLUSIONS: To the best of our knowledge this is the first reported case in the state of Qatar. It is important to mention that more research is needed to establish an association between COVID-19 vaccine and GBS. In our opinion, the benefits of COIVID-19 vaccine largely outweigh its risks.

Live Virus Neutralisation of the 501Y.V1 and 501Y.V2 SARS-CoV-2 Variants following INO-4800 Vaccination of Ferrets. The ongoing COVID-19 pandemic has resulted in significant global morbidity and mortality on a scale similar to the influenza pandemic of 1918. Over the course of the last few months, a number of SARS-CoV-2 variants have been identified against which vaccine-induced immune responses may be less effective. These "variants-of-concern" have garnered significant attention in the media, with discussion around their impact on the future of the pandemic and the ability of leading COVID-19 vaccines to protect against them effectively. To address concerns about emerging SARS-CoV-2 variants affecting vaccine-induced immunity, we investigated the neutralisation of representative 'G614', '501Y.V1' and '501Y.V2' virus isolates using sera from ferrets that had received prime-boost doses of the DNA vaccine, INO-4800. Neutralisation titres against G614 and 501Y.V1 were comparable, but titres against the 501Y.V2 variant were approximately 4-fold lower, similar to results reported with other nucleic acid vaccines and supported by in silico biomolecular modelling. The results confirm that the vaccine-induced neutralising antibodies generated by INO-4800 remain effective against current variants-of-concern, albeit with lower neutralisation titres against 501Y.V2 similar to other leading nucleic acid-based vaccines.

Maintenance of Muscle Mass and Cardiorespiratory Fitness to Cancer Patients During COVID-19 Era and After SARS-CoV-2 Vaccine. There is emerging evidence that decreased muscle mass and cardiorespiratory fitness (CRF) are associated with increased risk of cancer-related mortality. This paper aimed to present recommendations to prescribe effective and safe exercise protocols to minimize losses, maintain or even improve muscle mass, strength, and CRF of the cancer patients who are undergoing or beyond treatment during the COVID-19 era. Overall, we recommend performing exercises with bodyweight, elastic bands, or suspension bands to voluntary interruption (i.e., interrupt the exercise set voluntarily, according to their perception of fatigue, before concentric muscular failure) to maintain or increase muscle strength and mass and CRF during COVID-19 physical distancing. Additionally, rest intervals between sets and exercises (i.e., long or short) should favor maintaining exercise intensities between 50 and 80% of maxHR and/or RPE of 12. In an exercise program with these characteristics, the progression of the stimulus must be carried out by increasing exercise complexity, number of sets, and weekly frequency. With feasible exercises attainable

anywhere, modulating only the work-to-rest ratio and using voluntary interruption, it is possible to prescribe exercise for a wide range of patients with cancer as well as training goals. Exercise must be encouraged; however, exercise professionals must be aware of the patient's health condition even at a physical distance to provide a safe and efficient exercise program. Exercise professionals should adjust the exercise prescription throughout home confinement whenever necessary, keeping in mind that minimal exercise stimuli are beneficial to patients in poor physical condition.
Antibodies against Receptor Binding Domain of SARS-CoV-2 spike protein induced by BNT162b2 vaccine: results from a pragmatic, real-life study. BACKGROUND: As part of the fight against SARS CoV2 infection, vaccination program for health workers at Giannina Gaslini pediatric hospital (IGG) in Genoa, Italy, started on December 2020. We evaluated the anti-Spike protein response in healthcare workers after a complete vaccination scheme of 2 doses spaced by 3 weeks. METHODS: Immunoglobulin class G (IgG) against SARS-CoV-2 spike RBD were detected by means of a chemiluminescence immunoassay for quantitative IgG antibodies using Maglumi SARS-CoV-2-S-RBD IgG kit during the 3rd week after vaccination completion. RESULTS: IgG anti SARS-CoV-2 spike protein were detected in 99.88% of 1765 healthcare workers 3 weeks after 2nd dose of BNT162b2. Higher median IgG values were observed in younger subjects (807 UA/mL in under 30 vs 429 UA/mL in over 60; $p < 0.001$) and those with previous COVID-19 (1284 vs 574 UA/mL; $p < 0.001$). CONCLUSION: BNT162b2 is effective in inducing anti SARS-CoV-2 antibodies even in real-life setting. The higher antibody title observed in workers with a previous documented SARS CoV2 infection confirms the possibility to carry out only one dose of BNT162b2 in a context of vaccines shortage.
Henoch-SchÃ¶nlein purpura presenting post COVID-19 vaccination.
COVID-19 vaccine-associated acute cerebral venous thrombosis and pulmonary artery embolism.
Exploration of potential risk factors for COVID-19 severity in patients participating in oncology clinical trials.
Possible Association Between COVID-19Â Vaccine and Myocarditis: Clinical and CMR Findings.
A Series of Patients With Myocarditis Following SARS-CoV-2 Vaccination With mRNA-1279 and BNT162b2.
Absence of hypercoagulability after nCoV-19 vaccination: An observational pilot study. BACKGROUND: It is still unknown whether COVID-19 vaccines induce a prothrombotic state or increase the hypercoagulable condition in subjects with a predisposition to thrombosis. OBJECTIVES: We evaluated the coagulation profile in a series of healthy subjects who received the first dose of the BNT162b2 or the ChAdOx1 vaccines and assessed whether hypercoagulability developed. PATIENTS/METHODS: Volunteers among the staff of the University of Padua or health care professionals in the Padua University Hospital who had received either the ChAdOx1 or BNT162b2 vaccine in the previous 10Â Â±Â 2Â days were eligible. A cohort of unvaccinated volunteers among family members of the University staff acted as control group. Global coagulation monitoring was assessed by whole blood rotational thromboelastometry, whole blood impedance aggregometry and thrombin generation. Platelet count was also obtained. RESULTS: One hundred and ninety subjects were enrolled: 101 (53.2%) received the ChAdOx1 vaccine and 89 (46.8%) the BNT162b2 vaccine. Twenty-eight non-vaccinated subjects acted as controls. Thromboelastometry parameters were all comparable among groups. Thrombin receptor activating peptide (TRAP)-, ADP- and ASPI-induced platelet aggregation were similar among groups, as well as platelet count. Endogenous thrombin potential (ETP) was comparable among groups. The results were confirmed after controlling for age, gender and hormonal. Considering women taking combined oral contraceptives or thrombophilia carriers, no differences were detected in thromboelastometry or thrombin generation parameters between subjects who received ChAdOx1 vs. BNT162b2 vaccines. CONCLUSIONS: No significant

activation of fibrinogen-driven coagulation, plasma thrombin generation or clinically meaningful platelet aggregation after ChAdOx1 or BNT162b2 vaccination was observed.
The mRNA COVID-19 vaccine - A rare trigger of autoimmune hepatitis?
Delirium in a patient with Alzheimer's dementia following COVID-19 vaccination.
Nephrotic syndrome and vasculitis following SARS-CoV-2 vaccine: true association or circumstantial?
Rheumatology university faculty opinion on coronavirus disease-19 (COVID-19) vaccines: the vaXurvey study from Egypt. OBJECTIVES: The aim of the present work was to explore the perspectives of Egyptian Rheumatology staff members as regards the coronavirus disease-19 (COVID-19) vaccine. METHODS: The survey is composed of 25 questions. Some questions were adapted from the global rheumatology alliance COVID-19 survey for patients. RESULTS: 187 rheumatology staff members across Egypt from 18 universities and authorizations actively participated with a valid response. The mean time needed to complete the survey was 17.7â€‰Â±â€‰13Â min. Participants were 159 (85%) females (F:M 5.7:1). One-third agreed that they will be vaccinated once available, 24.6% have already received at least one dose, 29.4% are unsure while 16% will not take it. Furthermore, 70.1% agreed that they will recommend it to the rheumatic diseases (RD) patients once available, 24.1% are not sure while 5.9% will not recommend it. RD priority to be vaccinated against COVID-19 in descending order include SLE (82.9%), RA (55.1%), vasculitis (51.3%), systemic sclerosis (39.6%), MCTD (31.6%), Behcet's disease (28.3%). The most common drugs to be avoided before vaccination included biologics (71.7%), DMARDs (44.4%), biosimilars (26.7%), IVIg (17.1%) and NSAIDs (9.1%). CONCLUSIONS: The results of the study and specifically the low rate of acceptability are alarming to Egyptian health authorities and should stir further interventions to reduce the levels of vaccine hesitancy. As rheumatic disease patients in Egypt were not systematically provided with the vaccine till present, making the vaccine available could as well enhance vaccine acceptance. Further studies to investigate any possible side effects, on a large scale of RD patients are warranted.
Successful management of vaccine-induced immune thrombotic thrombocytopenia-related cerebral sinus venous thrombosis after ChAdOx1 nCov-19 vaccination.
Cerebral venous sinus thrombosis after ChAdOx1 nCov-19 vaccination with a misleading first cerebral MRI scan. Vaccine-induced immune thrombotic thrombocytopenia (VITT) and cerebral venous sinus thrombosis (CVST) have been recently described as rare complications following vaccination against SARS-CoV-2 with vector vaccines. We report a case of a young woman who presented with VITT and cerebral CVST 7â€‰days following vaccination with ChAdOx1 nCov-19 (AstraZeneca). While the initial MRI was considered void of pathological findings, MRI 3â€‰days later revealed extensive CVST of the transversal and sigmoidal sinus with intracerebral haemorrhage. Diagnostic tests including a platelet-factor-4-induced platelet activation assay confirmed the diagnosis of VITT. Treatment with intravenous immunoglobulins and argatroban resulted in a normalisation of platelet counts and remission of CVST.
COVID-19 vaccination among Spanish nephrologists: Acceptance and side effects. INTRODUCTION: Four vaccines against Covid-19 have been approved to date. Their acceptance and safety have not been addressed on healthcare workers. The aim of the present study is to evaluate vaccination rates and side effects among Spanish nephrologists. METHODS: All the Spanish nephrologists were invited to participate in this survey. Data on demographics, Covid-19 infection status, received vaccine doses and side effects were collected. Acceptance and side effects were analyzed for Covid-19 vaccination. Factors associated to vaccination were assessed and a multivariate adjusted model was constructed to determine independent predictors for Covid-19 vaccine side effects. RESULTS: A total of 708 nephrologists answered the survey (460 [65%] women, mean age 44Â±11 years). Six-hundred and eight (86%) had received the first dose and 513 (72%) were fully vaccinated. Most of the subjects (565, 93%) received BNT162b2 (Pfizer-BioNTechÂ®) vaccine. Among

vaccinated nephrologists, 453 (75%) presented any side effect; the most frequent was local reaction (68%), followed by myalgia (44%), tiredness (39%) and headache (34%). Age (OR 0.97, 95%CI [0.95-0.99], p<0.0001) and prior Covid-19 infection (OR 2.37, 95%CI [1.27-4.42], p=0.007) were independent predictors for developing side effects with Covid-19 vaccine. Overall side effects were similar with both vaccines, being myalgia (p=0.006) and tiredness (p=0.032) more frequent with the Pfizer-BioNTechÂ® one. CONCLUSION: Age and prior Covid-19 infection were predictors of vaccination side effects among Spanish nephrologists.

Vaccine-induced thrombotic thrombocytopenia, a rare but severe case of friendly fire in the battle against COVID-19 pandemic: What pathogenesis?

Transition of cutaneous into systemic lupus erythematosus following adenoviral vector-based SARS-CoV-2 vaccination.

[Subjective well-being and ability to work of hospital staff after SARS-CoV2 immunization with the mRNA vaccine BNT162b2]. BACKGROUND: â€,Since December 27, 2020, employees of the health system in Germany have been vaccinated against the SARS coronavirus-2 with the vaccine BNT162B2. Initial observations show that especially among younger vaccinated people side effects are common. In this study, using the example of clinic employees, the self-perceived well-being after the first and second dose of the vaccine was examined. METHODS: â€,Anonymized online questionnaire to be filled out once by all employees after the second dose of BNT162B2 was offered. The severity of side effects was queried using an ordinal numerical rating scale with values between 0 and 10. Other key data points were age, gender, and occupational group.â€ŠThe ability to work in the days following the injections was recorded by self-reporting. RESULTS: â€,Data from 555 respondents were evaluated. The mean age was 40.25 years (standard deviation 12.35). 56â€Š% of the respondents were female, 44.3â€Š% belonged to the medical service, 42.9â€Š% to the nursing service and 12.8â€Š% were assigned to other professional groups with COVID-19 patient contact. Around 2â€Š% of all employees did not experience any side effects at all. The most common side effect was pain at the injection site. Fatigue, headaches and myalgia followed with decreasing frequency. After the first dose, Â¾ of the respondents said they had tolerated the vaccination well overall, after the second dose it was only half. After the first dose, over 90â€Š% of the respondents felt that they were able to work again on the following day, after the second dose one third stated that they were only able to work again on the second day. 2.2â€Š% of all employees had to report that they were unable to work for at least one day after the first dose and 19.5â€Š% after the second dose. CONCLUSIONS: â€,Vaccination with BNT162B2 frequently leads to side effects, especially after the second dose. Perception of side effects resulted in 19â€Š% of those questioned being sick after the second dose. Nevertheless, 95â€Š% of all respondents would choose a coronavirus vaccination again.

Current perspectives for SARS-CoV-2 vaccination efficacy improvement in patients with active treatment against cancer. A higher risk of death from coronavirus disease 19Â has been shown for patients with solid cancersÂ or haematological malignancies (HM). Thanks to the accelerated development of anti-SARS-SoV-2 vaccines in less than a year since the start of the global pandemic, patients with cancer were quickly prioritised in early 2021 for vaccination, however dependent on the very unequal availability at the global level. Impaired immunogenicity of SARS-CoV-2 mRNA vaccines in immunocompromised patients was rapidly reported as early as April 2021, although the vaccination fortunately appears to be generally effective without increasing the spacing. Worryingly, the humoral response of the SARS-CoV-2 vaccination is, however, considered insufficient in patients followed for HM, in particular when they are on anti-CD20 treatment. Thus, improving vaccination coverage by strengthening immune stimulation should be evaluated in patients under active treatment against cancer. Here, we discuss three different approaches: a third dose of early vaccine (repeated immune stimulation), heterologous prime-boost vaccination (multimodal immune

stimulation) and a double-dose strategy (maximisation of immune response). Dedicated therapeutic trials, currently almost non-existent, seem rapidly necessary.

Minimal Change Disease With Severe Acute Kidney Injury Following the Oxford-AstraZeneca COVID-19 Vaccine: A Case Report. We report a case of minimal change disease (MCD) with severe acute kidney injury (AKI) following the first injection of the ChAdOx1 nCoV-19 (AZD1222) vaccine from Oxford-AstraZeneca against coronavirus disease 2019 (COVID-19). A 71-year-old man with a history of dyslipidemia and a baseline serum creatinine of 0.7mg/dL presented with nephrotic syndrome, AKI, and severe hypertension 13 days after receiving the Oxford-AstraZeneca vaccine. Refractory hyperkalemia and hypervolemia with oligoanuria prompted initiation of hemodialysis. His serum albumin was 2.6g/dL and his urinary protein-creatinine ratio was 2,321mg/mmol. Given a high suspicion for rapidly progressive glomerulonephritis, empirical glucocorticoid treatment was initiated (3 methylprednisolone pulses followed by high-dose prednisone). A kidney biopsy showed MCD and acute tubular injury. Kidney function and proteinuria subsequently improved, and hemodialysis was discontinued 38 days after the start of therapy. This case describes de novo MCD after the Oxford-AstraZeneca vaccine. It adds to the few published case reports of MCD after the Pfizer-BioNTech COVID-19 vaccine. Further reports and studies will be needed to elucidate whether MCD is truly associated with COVID-19 vaccination.

'COVID arm' - histological features of a delayed-type hypersensitivity reaction to Moderna mRNA-1273 SARS-CoV2 vaccine.

Positive flow cytometry crossmatch with discrepant antibody testing results following COVID-19 vaccination. The impact of COVID-19 vaccination on the alloimmunity of transplant candidates is unknown. We report a case of positive B cell flow cytometry crossmatch in a patient waiting for second kidney transplantation, 37Â days after receiving the COVID-19 vaccine. The preliminary crossmatch, using sample collected before COVID-19 vaccination, was negative. The antibodies to mismatched donor HLA-DR7 were detected only with multi-antigen beads but not with single-antigen beads, excluding possible prozone effects in solid-phase antibody assays. The crossmatches were positive with HLA-DR7-positive surrogates (nÂ =Â 2) while negative with HLA-DR7-negative surrogates (nÂ =Â 3), which confirms the HLA-DR7 alloreactivity. The antigen configurations on B lymphocytes are similar to that on the multi-antigen beads while distinct from the single-antigen beads. HLA-DR7 was the repeating mismatched antigen with the failing first kidney allograft. The newly emerged antibody to HLA-DR7 probably is the consequence of bystander activation of memory response by the COVID-19 vaccination. This case highlights the importance of verifying allo-sensitization history and utilizing multiple assays, including cell-based crossmatch and solid-phase assays with multi-antigens. COVID-19 immunization may deserve special attention when assessing the immunological risk before and after organ transplantation.

Poor humoral and T-cell response to two-dose SARS-CoV-2 messenger RNA vaccine BNT162b2 in cardiothoracic transplant recipients. AIMS: Immunocompromised patients have been excluded from studies of SARS-CoV-2 messenger RNA vaccines. The immune response to vaccines against other infectious agents has been shown to be blunted in such patients. We aimed to analyse the humoral and cellular response to prime-boost vaccination with the BNT162b2 vaccine (Pfizer-BioNTech) in cardiothoracic transplant recipients. METHODS AND RESULTS: A total of 50 transplant patients [1-3Â years post heart (42), lung (7), or heart-lung (1) transplant, mean age 55â€‰Â±â€‰10Â years] and a control group of 50 healthy staff members were included. Blood samples were analysed 21Â days after the prime and the boosting dose, respectively, to quantify anti-SARS-CoV-2 spike protein (S) immunoglobulin titres (tested by Abbott, Euroimmun and RocheElecsys Immunoassays, each) and the functional inhibitory capacity of neutralizing antibodies (Genscript). To test for a specific T-cell response, heparinized whole blood was stimulated with SARS-CoV-2 specific peptides,

covering domains of the viral spike, nucleocapsid and membrane protein, and the interferon-Î³ release was measured (QuantiFERON Monitor ELISA, Qiagen). The vast majority of transplant patients (90%) showed neither a detectable humoral nor a T-cell response three weeks after the completed two-dose BNT162b2 vaccination; these results are in sharp contrast to the robust immunogenicity seen in the control group: 98% exhibited seroconversion after the prime dose already, with a further significant increase of IgG titres after the booster dose (average >â€‰tenfold increase), a more than 90% inhibition capability of neutralizing antibodies as well as evidence of a T-cell responsiveness. CONCLUSIONS: The findings of poor immune responses to a two-dose BNT162b2 vaccination in cardiothoracic transplant patients have a significant impact for organ transplant recipients specifically and possibly for immunocompromised patients in general. It urges for a review of future vaccine strategies in these patients.

An outbreak caused by the SARS-CoV-2 Delta (B.1.617.2) variant in a care home after partial vaccination with a single dose of the COVID-19 vaccine Vaxzevria, London, England, April 2021. We investigated a COVID-19 outbreak of the SARS-CoV-2 Delta variant of concern in a London care home, where 8/21 residents and 14/21 staff had received a single dose of Vaxzevria (ChAdOx1-S; AstraZeneca) vaccine. We identified 24 SARS-CoV-2 infections (16 residents, 8 staff) among 40 individuals (19 residents, 21 staff); four (3 residents, 1 staff) were hospitalised, and none died. The attack rate after one vaccine dose was 35.7% (5/14) for staff and 81.3% (13/16) for residents.

Coronavirus Disease 2019 (COVID-19) Outbreak Associated With Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) P.1 Lineage in a Long-Term Care Home After Implementation of a Vaccination Program-Ontario, Canada, April-May 2021. In a P.1 coronavirus disease 2019 (COVID-19) outbreak in a long-term care home, vaccine effectiveness against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection was 52.5% (95% confidence interval: 26.9%-69.1%) in residents and 66.2% (2.3%-88.3%) in staff. Vaccine effectiveness against severe illness was 78.6% (47.9%-91.2%) in residents. Two of 19 vaccinated resident case patients died. Outbreak management required both vaccination and infection control measures.

Deep sequence modelling for predicting COVID-19 mRNA vaccine degradation. The worldwide coronavirus (COVID-19) pandemic made dramatic and rapid progress in the year 2020 and requires urgent global effort to accelerate the development of a vaccine to stop the daily infections and deaths. Several types of vaccine have been designed to teach the immune system how to fight off certain kinds of pathogens. mRNA vaccines are the most important candidate vaccines because of their capacity for rapid development, high potency, safe administration and potential for low-cost manufacture. mRNA vaccine acts by training the body to recognize and response to the proteins produced by disease-causing organisms such as viruses or bacteria. This type of vaccine is the fastest candidate to treat COVID-19 but it currently facing several limitations. In particular, it is a challenge to design stable mRNA molecules because of the inefficient in vivo delivery of mRNA, its tendency for spontaneous degradation and low protein expression levels. This work designed and implemented a sequence deep model based on bidirectional GRU and LSTM models applied on the Stanford COVID-19 mRNA vaccine dataset to predict the mRNA sequences responsible for degradation by predicting five reactivity values for every position in the sequence. Four of these values determine the likelihood of degradation with/without magnesium at high pH (pH 10) and high temperature (50 degrees Celsius) and the fifth reactivity value is used to determine the likely secondary structure of the RNA sample. The model relies on two types of features, namely numerical and categorical features, where the categorical features are extracted from the mRNA sequences, structure and predicted loop. These features are represented and encoded by numbers, and then, the features are extracted using embedding layer learning. There are five numerical features depending on the likelihood for each pair of nucleotides in the RNA. The model gives promising results because it predicts the five reactivity

values with a validation mean columnwise root mean square error (MCRMSE) of 0.125 using LSTM model with augmentation and the codon encoding method. Codon encoding outperforms Base encoding in MCRMSE validation error using the LSTM model meanwhile Base encoding outperforms codon encoding due to less over-fitting and the difference between the training and validation loss error is 0.008.

Blood donor deferral periods after COVID-19 vaccination.

After the pandemic: perspectives on the future trajectory of COVID-19. There is a realistic expectation that the global effort in vaccination will bring the pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) under control. Nonetheless, uncertainties remain about the type of long-term association that the virus will establish with the human population and, in particular, whether coronavirus disease 2019 (COVID-19) will become an endemic disease. Although the trajectory is difficult to predict, the conditions, concepts and variables that influence this transition can be anticipated. Persistence of SARS-CoV-2 as an endemic virus, perhaps with seasonal epidemic peaks, may be fuelled by pockets of susceptible individuals and waning immunity after infection or vaccination, changes in the virus through antigenic drift that diminish protection and re-entries from zoonotic reservoirs. Here we review relevant observations from previous epidemics and discuss the potential evolution of SARS-CoV-2 as it adapts during persistent transmission in the presence of a level of population immunity. Lack of effective surveillance or adequate response could enable the emergence of new epidemic or pandemic patterns from an endemic infection of SARS-CoV-2. There are key pieces of data that are urgently needed in order to make good decisions; we outline these and propose a way forward.

IgA nephropathy presenting as macroscopic hematuria in 2 pediatric patients after receiving the Pfizer COVID-19 vaccine.

Granulomatous vasculitis after the AstraZeneca anti-SARS-CoV-2 vaccine.

Thrombosis and severe acute respiratory syndrome coronavirus 2 vaccines: vaccine-induced immune thrombotic thrombocytopenia. The development of vaccines against severe acute respiratory syndrome coronavirus 2, which features high mortality and morbidity rates, has progressed at an unprecedented rate, and vaccines are currently in use worldwide. Thrombotic events after vaccination are accompanied by thrombocytopenia, and this issue was recently termed vaccine-induced immune thrombotic thrombocytopenia. This manuscript describes recently published guidelines and other related issues and demonstrates characteristic cases.

Pityriasis rosea developing after COVID-19 vaccination.

Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices - United States, June 2021. In December 2020, the Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUAs) for the Pfizer-BioNTech COVID-19 (BNT162b2) vaccine and the Moderna COVID-19 (mRNA-1273) vaccine,(â€) and the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for their use in persons aged â‰¥16 years and â‰¥18 years, respectively.(Â§) In May 2021, FDA expanded the EUA for the Pfizer-BioNTech COVID-19 vaccine to include adolescents aged 12-15 years; ACIP recommends that all persons aged â‰¥12 years receive a COVID-19 vaccine. Both Pfizer-BioNTech and Moderna vaccines are mRNA vaccines encoding the stabilized prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. Both mRNA vaccines were authorized and recommended as a 2-dose schedule, with second doses administered 21 days (Pfizer-BioNTech) or 28 days (Moderna) after the first dose. After reports of myocarditis and pericarditis in mRNA vaccine recipients,(Â¶) which predominantly occurred in young males after the second dose, an ACIP meeting was rapidly convened to review reported cases of myocarditis and pericarditis and discuss the benefits and risks of mRNA COVID-19 vaccination in the United States. Myocarditis is an

inflammation of the heart muscle; if it is accompanied by pericarditis, an inflammation of the thin tissue surrounding the heart (the pericardium), it is referred to as myopericarditis. Hereafter, myocarditis is used to refer to myocarditis, pericarditis, or myopericarditis. On June 23, 2021, after reviewing available evidence including that for risks of myocarditis, ACIP determined that the benefits of using mRNA COVID-19 vaccines under the FDA's EUA clearly outweigh the risks in all populations, including adolescents and young adults. The EUA has been modified to include information on myocarditis after receipt of mRNA COVID-19 vaccines. The EUA fact sheets should be provided before vaccination; in addition, CDC has developed patient and provider education materials about the possibility of myocarditis and symptoms of concern, to ensure prompt recognition and management of myocarditis.
Generalized eczematous reactions to the Pfizer-BioNTech COVID-19 vaccine.
Erythema multiforme after CoronaVac vaccination.
New-onset cutaneous lichen planus triggered by COVID-19 vaccination.
Widespread purpura annularis telangiectodes following mRNA SARS-CoV-2 vaccine.
Vitiligo in a COVID-19-vaccinated patient with ulcerative colitis: coincidence?
Vesiculobullous skin reactions induced by COVID-19 mRNA vaccine: report of four cases and review of the literature.
Asymptomatic and Symptomatic COVID-19 Infections Among Health Care Personnel Before and After Vaccination. This cohort study investigates asymptomatic and symptomatic COVID-19 case rates before and after the initial vaccine rollout among health care personnel in Orange County, California.
Serologic Status and Toxic Effects of the SARS-CoV-2 BNT162b2 Vaccine in Patients Undergoing Treatment for Cancer. IMPORTANCE: The efficacy and safety profile of SARS-CoV-2 vaccines have been acquired from phase 3 studies; however, patients with cancer were not represented in these trials. Owing to the recommendation to prioritize high-risk populations for vaccination, further data are warranted. OBJECTIVE: To evaluate the use and safety of the BNT162b2 vaccine in patients undergoing treatment for cancer. DESIGN, SETTING, AND PARTICIPANTS: In January 2021, mass SARS-CoV-2 vaccination of high-risk populations, including patients with cancer, was initiated in Israel. This cohort study prospectively enrolled and followed up patients with cancer and healthy participants between January 15 and March 14, 2021. The study was conducted at the Division of Oncology of Rambam Health Care Campus, the major tertiary (referral) medical center of northern Israel. Participants included 232 patients with cancer who were receiving active treatment after the first and second doses of the BNT162b2 vaccine and 261 healthy, age-matched health care workers who served as controls. EXPOSURES: Serum samples were collected after each vaccine dose and in cases of seronegativity. Questionnaires regarding sociodemographic characteristics and adverse reactions were administered at serum collection. A regulatory agencies-approved assay was used to assess IgG at all time points. Patients' electronic medical records were reviewed for documentation of COVID-19 infection and results of blood cell counts, liver enzyme levels, and imaging studies. MAIN OUTCOMES AND MEASURES: Seroconversion rate after the first and second doses of the BNT162b2 vaccine and documented COVID-19 infection. RESULTS: Of the 232 patients undergoing treatment for cancer, 132 were men (57%); mean (SD) age was 66 (12.09) years. After the first dose of BNT162b2 vaccine, 29% (nâ€‰=â€‰25) patients were seropositive compared with 84% (nâ€‰=â€‰220) of the controls (Pâ€‰<â€‰.001). After the second dose, the seropositive rate reached 86% (nâ€‰=â€‰187) in the patients. Testing rate ratios per 1000 person-days after the first dose were 12.5 (95% CI, 3.4-45.7) for the patients and 48.5 (95% CI, 37.2-63.2) for the controls. Patients undergoing chemotherapy showed reduced immunogenicity (odds ratio, 0.41; 95% CI, 0.17-0.98). In seronegative patients, the rate of documented absolute leukopenia reached 39%. No COVID-19 cases were documented throughout the study period; however, 2 cases in the patient cohort were noted immediately after the first dose.

Reported adverse events were similar to data in former trials comprising mostly healthy individuals. CONCLUSIONS AND RELEVANCE: In this cohort study, the SARS-CoV-2 BNT162b2 vaccine appeared to be safe and achieve satisfactory serologic status in patients with cancer. There was a pronounced lag in antibody production compared with the rate in noncancer controls; however, seroconversion occurred in most patients after the second dose. Future real-world data are warranted to determine the long-term efficacy of the vaccine with regard to type of anticancer treatment.

Thrombosis with thrombocytopenia syndrome after COVID-19 vaccination.

Acute myocarditis after the second dose of SARS-CoV-2 vaccine: Serendipity or atypical causal relationship?

Subacute Thyroiditis After Receiving the Adenovirus-Vectored Vaccine for Coronavirus Disease (COVID-19). Since the emergence of the coronavirus disease pandemic, several effective vaccines have been introduced. These vaccines work through several different immunogenic pathways to produce effective immunity. There have been a number of reports of patients developing subacute thyroiditis and thyroid dysfunction after receiving the coronavirus (COVID-19) vaccine. This paper presents a case of a female patient who developed subacute thyroiditis soon after receiving the adenovirus-vectored COVID-19 vaccine. The patient presented with severe neck pain and her blood results demonstrated an initial thyrotoxic phase followed by a hypothyroid phase. She had no past history of thyroiditis or thyroid dysfunction. Subacute thyroiditis occurring after COVID-19 vaccination is rare but also probably underreported. We hope that this case report not only contributes to the literature but also raises awareness of subacute thyroiditis occurring after receiving the COVID-19 vaccine.

Antibody epitopes in vaccine-induced immune thrombotic thrombocytopaenia. Vaccine-induced immune thrombotic thrombocytopaenia (VITT) is a rare adverse effect of COVID-19 adenoviral vector vaccines(1-3). VITT resembles heparin-induced thrombocytopaenia (HIT) in that it is associated with platelet-activating antibodies against platelet factorÂ 4 (PF4)(4); however, patients with VITT develop thrombocytopaenia and thrombosis without exposure to heparin. Here we sought to determine the binding site on PF4 of antibodies from patients with VITT. Using alanine-scanning mutagenesis(5), we found that the binding of anti-PF4 antibodies from patients with VITT (nÂ =Â 5) was restricted to eight surface amino acids on PF4, all of which were located within the heparin-binding site, and that the binding was inhibited by heparin. By contrast, antibodies from patients with HIT (nÂ =Â 10) bound to amino acids that corresponded to two different sites on PF4. Biolayer interferometry experiments also revealed that VITT anti-PF4 antibodies had a stronger binding response to PF4 and PF4-heparin complexes than did HIT anti-PF4 antibodies, albeit with similar dissociation rates. Our data indicate that VITT antibodies can mimic the effect of heparin by binding to a similar site on PF4; this allows PF4 tetramers to cluster and form immune complexes, which in turn causes FcÎ³ receptorÂ IIa (FcÎ³RIIa; also known as CD32a)-dependent platelet activation. These results provide an explanation for VITT-antibody-induced platelet activation that could contribute to thrombosis.

The BNT162b2 mRNA COVID-19 vaccine in adolescents and young adults with cancer: A monocentric experience. BACKGROUND AND AIMS: COVID-19 infection in paediatric patients with cancer is severe or critical in 20% of the patients. It can therefore directly affect paediatric patients with cancer and/or their care. We aimed at evaluating the safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine in adolescents and young adults (AYA) with solid tumour. METHODS: This study includes a retrospective analysis of safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine administered to patients, â‰¥16 years old, under treatment for a solid tumour or within 6 monthsÂ after treatment from 15th February 2021 to 15th April 2021. Two administrations of the vaccine 3 weeks apart were given. Sera were tested for anti-SARS-Cov-2 immunoglobulin G (IgG) antibodies directed against the S1 domain of the spike protein. In case of positive serology, neutralisation of SARS-Cov-2

was tested. RESULTS: Twenty-three patients with solid tumours were identified and proposed to get vaccinated. Nine patients refused, and 1 previously developed COVID-19 infection with positive serology. At the time of writing, 13 patients (10Â M/2Â F; median age: 17) started vaccination. All patients received 2 injections except 2 patients who stopped vaccination because of tumour progression. Ten patients were under treatment (alone or in combination: chemotherapy: 7 patients [pts], immunotherapy: 2 pts, targeted therapy: 3 pts, follow-up: 3 patients). Overall, vaccines were well tolerated. Five patients did not report any side-effects after the first injection and 4 after the second injection. The main local reactivity symptom was mild pain at the site of injection (6 and 2Â pts). Fatigue (2Â pts and 5Â pts) was the most frequent systemic symptom. One patient refused serology testing. All patients but 1 had pre-vaccination negative serology; 7 of 10 patients tested had positive serology before second vaccine injection, and 9 of 10 patients had positive serology one month after the second injection. All patients with seroconversion had positive COVID-19 neutralisation test. No patient developed COVID infections. CONCLUSIONS: We report the good safety profile and good efficacy of the BNT162B2 vaccine in AYA with solid tumours. Larger series and monitoring of the kinetics of anti-Sars-Cov-2 IgG antibodies for several months are mandatory to confirm these preliminary results and to determine long-term vaccination.
Breakthrough SARS-CoV-2 Infections in Prison after Vaccination.
Therapeutic Plasma Exchange in Vaccine-Induced Immune Thrombotic Thrombocytopenia.
COVID-19 vaccines: What dermatologists should know? As COVID-19 vaccination has started worldwide to control this pandemic, dermatologists may face various challenges with these new vaccines. In this manuscript, we review different types of available COVID-19 vaccines and their various production platforms. Vaccination considerations in patients with skin diseases, especially those using immunomodulatory drugs will be presented. Finally, adverse cutaneous reactions of COVID-19 vaccines will be reviewed.
SARS-CoV-2 vaccine-induced prothrombotic immune thrombocytopenia: Promoting awareness to improve patient-doctor trust.
Antibody titres decline 3-month post-vaccination with BNT162b2. Several studies reported on the humoral response in subjects having received the BNT162b2 mRNA COVID-19 vaccine. However, data on the kinetics of antibodies 3 months post-vaccination are currently lacking and are important to drive the future vaccination strategy. The CRO-VAX HCP study is an ongoing multicentre, prospective and interventional study designed to assess the antibody response in a population of healthcare professionals who had received two doses of the BNT162b2 mRNA COVID-19 vaccine. Two hundred individuals underwent a blood drawn within 2 days before the first vaccine dose. One-hundred and forty-two persons (71%) were categorized as seronegative at baseline while 58 (29%) were seropositive. Samples were then collected after 14, 28, 42, 56, and 90 days. Antibodies against the SARS-CoV-2 nucleocapsid and the receptor binding domain of the S1 subunit of the spike protein were measured in all individuals at different time points. Using a one-compartment kinetics model, the time to maximum concentration was estimated at 36â€‰Â±â€‰3 days after the first dose and the estimated half-life of antibodies was 55 days (95% CI: 37-107 days) in seronegative participants. In seropositive participants, the time to maximum concentration was estimated at 24â€‰Â±â€‰4 days and the estimated half-life was 80 days (95% CI: 46-303 days). The antibody response was higher in seropositive compared to seronegative participants. In both seropositive and seronegative subjects, a significant antibody decline was observed at 3 months compared to the peak response. Nevertheless, the humoral response remained robust in all participants.
Influenza vaccination coverage in elderly and high-risk adults: characterization of associated factors. OBJECTIVE: To evaluate the prevalence and factors associated with non-vaccination against influenza in the risk group. METHODS: A cross-sectional, population-based study, carried out in the city of Rio

Grande (RS). The outcome was defined as belonging to risk groups and not having been vaccinated in the last 12 months. Demographic, socioeconomic, behavioral variables, and access for health services were analyzed. RESULTS: In this study, 680 individuals participated. The prevalence was 46.0% (95%CI: 41.8-50.3), ranging from 27.9% (elderly) to 81.8% (pregnant women). Young adults, single, intermediate socioeconomic bracket, smoker, with depressive symptoms, who did not perform physical activity and did not consult a physician in the last year, had a higher prevalence of non-vaccination. CONCLUSION: Half of the sample was not vaccinated in the period. Due to the similarity of influenza-like illness and the coronavirus 2019 disease (COVID-19), increasing vaccination would minimize mortality and use of hospital beds due to influenza, optimizing the response of hospital capacity.

Management of patients at risk of anaphylaxis after COVID 19 vaccination. The success of a vaccination campaign depends on the possibility of guaranteeing not only a wide distribution of effective vaccines, but also on their safety and acceptance by the population. Vaccine safety questions should be answered by correct, unbiased and evidence-based reports, and by addressing all possible problems including allergic reactions. Despite the fact that many COVID-19 vaccines are free from the majority of potentially sensitizing components, an allergic reaction can occur even in the form of a severe, life-threatening anaphylaxis. The frequency of allergic reactions against COVID vaccine is greater than that observed for other vaccinations. National and international allergology societies have proposed specific guidelines for individuals at risk of anaphylaxis by vaccine. Vaccines, like all the pharmaceutical preparations, are submitted to great safety and efficacy valuations, however, even the greatest pre-licensure experimentations are insufficient to evaluate the vaccine's potential to provoke anaphylaxis. Therefore, post-market surveillance is essential to analyze, record and characterize all adverse events. To this purpose, specific algorithms should be used as a monitoring strategy of adverse events in patients undergoing vaccination against COVID 19.

Exacerbation of psoriasis following COVID-19 vaccination in a patient previously treated with PD-1 inhibitor.

Adverse effects and antibody titers in response to the BNT162b2 mRNA COVID-19 vaccine in a prospective study of healthcare workers. BACKGROUND: mRNA COVID-19 vaccines are playing a key role in controlling the COVID-19 pandemic. The relationship between post-vaccination symptoms and strength of antibody responses is unclear. OBJECTIVE: To determine whether adverse effects caused by vaccination with the Pfizer/BioNTech BNT162b2 vaccine are associated with the magnitude of vaccine-induced antibody levels. DESIGN: Single center, prospective, observational cohort study. SETTING: Participants worked at Walter Reed National Military Medical Center and were seen monthly at the Naval Medical Research Center Clinical Trials Center. PARTICIPANTS: Generally healthy adults that were not severely immunocompromised, had no history of COVID-19, and were seronegative for SARS-CoV-2 spike protein prior to vaccination. MEASURES: Severity of vaccine-associated symptoms was obtained through participant completed questionnaires. Testing for IgG antibodies against SARS-CoV-2 spike protein and receptor binding domain was conducted using microsphere-based multiplex immunoassays. RESULTS: 206 participants were evaluated (69.4% female, median age 41.5 years old). We found no correlation between vaccine-associated symptom severity scores and vaccine-induced antibody titers one month after vaccination. We also observed that 1) post-vaccination symptoms were inversely correlated with age and weight and more common in women, 2) systemic symptoms were more frequent after the second vaccination, 3) high symptom scores after first vaccination were predictive of high symptom scores after second vaccination, and 4) older age was associated with lower titers. LIMITATIONS: Study only observes antibody responses and consists of healthy participants. CONCLUSIONS: Lack of post-vaccination symptoms following receipt of the BNT162b2 vaccine does not equate to lack of vaccine-induced antibodies one month after

vaccination. This study also suggests that it may be possible to design future mRNA vaccines that confer robust antibody responses with lower frequencies of vaccine-associated symptoms. FUNDING: This study was executed by the Infectious Disease Clinical Research Program (IDCRP), a Department of Defense (DoD) program executed by the Uniformed Services University of the Health Sciences (USUHS) through a cooperative agreement by the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF). This project has been funded by the Defense Health Program, U.S. DoD, under award HU00012120067. Project funding for JHP was in whole or in part with federal funds from the National Cancer Institute, National Institutes of Health, under Contract No. HHSN261200800001E. The funding bodies have had no role in the study design or the decision to submit the manuscript for publication.

Real-time analysis of a mass vaccination effort confirms the safety of FDA-authorized mRNA COVID-19 vaccines. BACKGROUND: As the coronavirus disease 2019 (COVID-19) vaccination campaign unfolds, it is important to continuously assess the real-world safety of Food and Drug Administration (FDA)-authorized vaccines. Curation of large-scale electronic health records (EHRs) enables near-real-time safety evaluations that were not previously possible. METHODS: In this retrospective study, we deployed deep neural networks over a large EHR system to automatically curate the adverse effects mentioned by physicians in over 1.2 million clinical notes between December 1, 2020 and April 20, 2021. We compared notes from 68,266 individuals who received at least one dose of BNT162b2 (nÂ = 51,795) or mRNA-1273 (nÂ = 16,471) to notes from 68,266 unvaccinated individuals who were matched by demographic, geographic, and clinical features. FINDINGS: Individuals vaccinated with BNT162b2 or mRNA-1273 had a higher rate of return to the clinic, but not the emergency department, after both doses compared to unvaccinated controls. The most frequently documented adverse effects within 7Â days of each vaccine dose included myalgia, headache, and fatigue, but the rates of EHR documentation for each side effect were remarkably low compared to those derived from active solicitation during clinical trials. Severe events, including anaphylaxis, facial paralysis, and cerebral venous sinus thrombosis, were rare and occurred at similar frequencies in vaccinated and unvaccinated individuals. CONCLUSIONS: This analysis of vaccine-related adverse effects from over 1.2 million EHR notes of more than 130,000 individuals reaffirms the safety and tolerability of the FDA-authorized mRNA COVID-19 vaccines in practice. FUNDING: This study was funded by nference.

Mounting evidence suggests Sputnik COVID vaccine is safe and effective.

Myocarditis after BNT162b2 vaccination in a healthy male. Myocarditis following mRNA COVID-19 vaccination has recently been reported to health authorities in the United States and other countries. Cases predominately occur in young adult males within four days following the second dose of either the Moderna (mRNA-1273) or Pfizer-BioNTech (BNT162b2) vaccines. Although the number of cases reported have been small in comparison with the large number of people vaccinated, myocarditis may be a rare adverse reaction to the COVID-19 vaccination that is now only becoming apparent due to the widespread use of the vaccine. In this article, we present a case of a 20-year-old male with no prior medical history who presented to the emergency department (ED) with chest pain. He had received the BNT162b2 vaccine two days prior to his presentation to the ED. The patient had an elevated troponin at 89 ng/L which increased on repeat examination. His electrocardiogram showed diffuse concave ST segment elevations and a later MRI confirmed the diagnosis of myocarditis. Based on these findings, the patient was diagnosed with myocarditis. The patient had a previous infection with SARS-CoV-2 approximately two months prior to the onset of his symptoms, but since he had fully recovered before the time of his presentation to the ED, it is unlikely that the infection caused the myocarditis. To our knowledge, this is the first published case of myocarditis following BNT162b3 vaccination.

Unusual lymphadenopathies secondary to the BNT162b2 mRNA Covid-19 vaccine.

Delayed Cutaneous Reactivity Associated With COVID-19 Vaccines Is Rare.
SARS-CoV-2 vaccination induced cerebral venous sinus thrombosis: Do megakaryocytes, platelets and lipid mediators make up the orchestra? The COVID-19 vaccines comprised of adenoviral vectors encoding the Spike (S) glycoprotein of SARS-CoV-2 are highly effective but associated with rare thrombotic complications. The adenovirus vector infects epithelial cells expressing the coxsackievirus and adenovirus receptor (CAR). The S glycoprotein expressed locally stimulates neutralizing antibody and cellular immune responses. These vaccines have been associated with thromboembolic events including cerebral venous sinus thrombosis (CVST). S glycoprotein stimulates the expression of cyclooxygenase-2 (COX-2) and leads to massive generation of thromboxane A(2) in COVID-19. Megakaryocytes express CAR and we postulate that S glycoprotein stimulated generation of thromboxane A(2) leads to megakaryocyte activation, biogenesis of activated platelets and thereby increased thrombogenicity. Cerebral vein sinuses express podoplanin, a natural ligand for CLEC2 receptors on platelets. Platelets traversing through the cerebral vein sinuses could be further activated by thromboxane A(2)-dependent podoplanin-CLEC2 signaling, leading to CVST. A prothrombotic hormonal milieu, and increased generation of thromboxane A(2) and platelet activation in healthy females compared to males is consistent with increased risk for CVST observed in women. We propose that antiplatelet agents targeting thromboxane A(2) receptor signaling such as low-dose aspirin merit consideration for chemoprophylaxis when administering the adenovirus based COVID-19 vaccines to young adults at risk of thrombosis provided there are no contraindications.
Myopericarditis After the Pfizer Messenger Ribonucleic Acid Coronavirus Disease Vaccine in Adolescents. Reports have emerged of myocarditis and pericarditis predominantly after the second dose of the coronavirus disease messenger ribonucleic acid vaccine. We describe 13 patients aged 12-17Â years who presented with chest pain within 1Â week after their second dose of the Pfizer vaccine and were found to have elevated serum troponin levels and evidence of myopericarditis.
Primary cutaneous anaplastic large-cell lymphoma with marked spontaneous regression of organ manifestation after SARS-CoV-2 vaccination.
Postinfectious Immunity After COVID-19 and Vaccination Against SARS-CoV-2. Early results suggest that SARS-CoV-2 vaccines are highly effective for the prevention of COVID-19. Unfortunately, until we can safely, rapidly, and affordably vaccinate enough people to achieve collective immunity, we cannot afford to disregard the benefits of naturally acquired immunity in those, whose prior documented infections have already run their course. As long as the vaccine manufacturing, supply, or administration are limited in capacity, vaccination of individuals with naturally acquired immunity at the expense of others without any immune protection is inherently inequitable, and violates the principle of justice in biomedical ethics. Any preventable disease acquired during the period of such unnecessary delay in vaccination should not be overlooked, as it may and will result in some additional morbidity, mortality, related hospitalizations, and expense. Low vaccine production capacity complicated by inefficiencies in vaccine administration suggests, that vaccinating preferentially those without any prior protection will result in fewer natural infections more rapidly.
Anti-PF4 testing for vaccine-induced immune thrombocytopenia and thrombosis and heparin induced thrombocytopenia: Results from a UK National External Quality Assessment Scheme exercise April 2021. BACKGROUND: Vaccine-induced immune thrombocytopenia and thrombosis (VITT) following the administration of the AstraZeneca (AZ) ChAdOx1 nCOV-19 vaccine has recently been reported. The associated clinical and laboratory features have included thrombosis at unusual sites, thrombocytopenia, and raised D-dimers with positivity for IgG anti-platelet factor 4 (PF4) antibodies. OBJECTIVES: A UK National External Quality Control Assessment Scheme external quality control

exercise was carried out by distributing liquid and lyophilized samples from a subject with VITT, a pool of samples from subjects with classical heparin-induced thrombocytopenia (HIT), and a non-VITT/non-HIT case to 85 centers performing HIT testing. METHODS: Participating centers employed their locally validated testing methods for HIT assays. RESULTS: The lyophilized and liquid samples were found to be commutable for the ELISA assays used in the detection of anti-PF4 antibodies. The Aeskulisa, Stago, Hyphen, and LIFECODES anti-PF4 ELISA assays successfully detected the VITT antibody, whereas the Acustar HIT, Werfen LIA, and the Stago STIC assays did not. CONCLUSION: It is important that clinical and laboratory teams are aware of the limitations of some anti-PF4 assays when using them to aid diagnosis of VITT syndrome.

Side effects after COVID-19 vaccinations among residents of Poland. OBJECTIVE: Side effects of vaccines are common, but people react differently to different vaccines. Manufacturers provide lists of the side effects of their products. Adverse reactions are proof of the effectiveness of vaccines and that the immune system is responding. In this study, we compare the side effects of the AstraZeneca and Pfizer vaccines. Our survey results show that the side effects of the first dose of the AstraZeneca vaccine are more common than after the first and second doses of the Pfizer vaccine. Most respondents in our survey reported at least one side-effect after the AstraZeneca and Pfizer vaccine, but these reactions were less common after the Pfizer preparation. PATIENTS AND METHODS: A survey was distributed via the internet. It was conducted among people vaccinated with Pfizer or AstraZeneca. The respondents were asked about the side effects after the first and second doses of the vaccines, such as injection site pain, arm pain, muscle pain, headache, fever, chills, and fatigue. RESULTS: The questionnaire was completed by 705 people. 196 of them had been vaccinated with Pfizer and 509 with AstraZeneca. Among those vaccinated with the first dose of the AstraZeneca vaccine, 96.5% reported at least one post-vaccination reaction. 17.1% of respondents reported all the side effects listed in the survey. Among those vaccinated with the first Pfizer dose, vaccine reactions were reported by 93.9% of respondents; 2% of respondents experienced all the side effects mentioned in the survey. The second dose of the Pfizer vaccine caused post-vaccinal reactions in most of the subjects: 54.8% of respondents had more adverse reactions, and 15.8% had fewer adverse reactions than after the first dose of this vaccine; 29.4% experienced the same side effects after the first and second doses of the Pfizer vaccine. CONCLUSIONS: Side effects as a result of vaccination are not rare and are proof that the immune system is responding. However, severe adverse reactions to vaccines can be dangerous, and they engender fear. Concerns about the side effects and complications of COVID-19 vaccines may eclipse opinions regarding their benefits. This study shows that the first dose of the AstraZeneca vaccine causes side effects more often than either dose of the Pfizer vaccine.

Acquired thrombotic thrombocytopenic purpura with possible association with AstraZeneca-Oxford COVID-19 vaccine. Acquired thrombotic thrombocytopenic purpura is characterized by the microvascular aggregation of platelets and microangiopathic hemolytic anemia causing ischemia of multiple organs including the brain mainly and less likely the kidney and the heart. The disease is caused by severe reduction in the activity of ADAMTS 13 due to presence of inhibitory antibodies.

A bivalent recombinant vaccine targeting the S1 protein induces neutralizing antibodies against both SARS-CoV-2 variants and wild-type of the virus. The emerging variants of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) in pandemic call for the urgent development of universal corona virus disease 2019 (COVID-19) vaccines which could be effective for both wild-type SARS-CoV-2 and mutant strains. In the current study, we formulated protein subunit vaccines with AS03 adjuvant and recombinant proteins of S1 subunit of SARS-CoV-2 (S1-WT) and S1 variant (K417N, E484K, N501Y, and D614G) subunit (S1-Mut), and immunized transgenic mice that express human angiotensin-converting enzyme 2 (hACE2). The S1 protein-specific antibody production and the

neutralization capability for SARS-CoV-2 and B.1.351 variant were measured after immunization in mice. The results revealed that the S1-Mut antigens were more effective in inhibiting the receptor-binding domain and ACE2 binding in B.1.351 variant than in wild-type SARS-CoV-2. Furthermore, the development of a bivalent vaccine exhibited the ideal neutralization properties against wild-type and B.1.351 variant, as well as other variants. Our findings may provide a rationale for the development of a bivalent recombinant vaccine targeting the S1 protein that can induce the neutralizing antibodies against both SARS-CoV-2 variants and wild-type of the virus and may be of importance to explore the potential clinical use of bivalent recombinant vaccine in the future.
Changes in influenza vaccination coverage associated during the COVID-19 pandemic in Japan. Changes in influenza vaccination coverage during the COVID-19 pandemic in Japan were limited. Not only changes in individual behavior and the threat of disease, but also vaccine dissemination policy based on system-based interventions, including behavioral economic approaches, is desirable.
Early Outcomes of Bivalirudin Therapy for Thrombotic Thrombocytopenia and Cerebral Venous Sinus Thrombosis After Ad26.COV2.S Vaccination. Vaccine-induced thrombotic thrombocytopenia is a newly described disease process in the setting of expanding access to COVID-19 vaccination. The United States Centers for Disease Control and Prevention recommends treatment with an alternative to heparin in patients suspected of having vaccine-induced thrombotic thrombocytopenia. At this time there have been no reported outcomes from the treatment of vaccine-induced thrombotic thrombocytopenia with bivalirudin as a heparin alternative. We describe the early outcomes from the treatment of vaccine-induced thrombotic thrombocytopenia with bivalirudin as a heparin alternative. A 40-year-old Caucasian woman was found to have thrombocytopenia, cerebral venous sinus thrombosis, and pulmonary embolism following vaccination for COVID-19 with Ad26.COV2.S. She exhibited aÂ steady rise in platelet count: 20Ã—10(9)/L at hospital day 0, 115Ã—10(9)/L at discharge on hospital day 6, and 182Ã—10(9)/L on outpatient follow-up on day 9. While the patient exhibited a transient drop in hemoglobin, there was no clinical evidence of bleeding. This patient did not demonstrate any clinical sequelae of thrombosis, and she reported resolution of her headache. Vaccination withÂ Ad26.COV2.S appears to be associated with a small but significant risk for thrombotic thrombocytopenia within 13 days of receipt. The Centers for Disease Control and Prevention guidance to consider an alternative to heparin was not accompanied by specifically recommended alternatives. A single patient treated with bivalirudin for suspected vaccine-induced thrombotic thrombocytopenia subsequently experienced symptom improvement and a rise in platelet count and did not demonstrate any immediate negative outcomes. A provider may consider bivalirudin as an alternative to heparin in patients with suspected vaccine-induced thrombotic thrombocytopenia following Ad26.COV2.S vaccination, pending more definitive research.
Safety of SARS-CoV-2 vaccines: a systematic review and meta-analysis of randomized controlled trials. BACKGROUND: Various modalities of vaccines against coronavirus disease 2019 (COVID-19), based on different platforms and immunization procedures, have been successively approved for marketing worldwide. A comprehensive review for clinical trials assessing the safety of COVID-19 vaccines is urgently needed to make an accurate judgment for mass vaccination. MAIN TEXT: A systematic review and meta-analysis wasÂ conducted to determine the safety of COVID-19 vaccine candidates in randomized controlled trials (RCTs). Data search was performed in PubMed, Embase, Cochrane library, Scopus, Web of Science, and MedRxiv. Included articles were limited to RCTs on COVID-19 vaccines. A total of 73,633 subjects from 14 articles were included to compare the risks of adverse events following immunization (AEFI) after vaccinating different COVID-19 vaccines. Pooled risk ratios (RR) of total AEFI for inactivated vaccine, viral-vectored vaccine, and mRNA vaccine were 1.34 [95% confidence interval (CI) 1.11-1.61, Pâ€‰<â€‰0.001], 1.65 (95% CI 1.31-2.07, Pâ€‰<â€‰0.001), and 2.01 (95% CI 1.78-2.26, Pâ€‰<â€‰0.001), respectively. No significant differences on local and

systemic AEFI were found between the first dose and second dose. In addition, people aged â‰¤â€‰55Â years were at significantly higher risk of AEFI than people aged â‰¥â€‰56Â years, with a pooled RR of 1.25 (95% CI 1.15-1.35, Pâ€‰<â€‰0.001). CONCLUSIONS: The safety and tolerance of current COVID-19 vaccine candidates are acceptable for mass vaccination, with inactivated COVID-19 vaccines candidates having the lowest reported AEFI. Long-term surveillance of vaccine safety is required, especially among elderly people with underlying medical conditions.

Auto-immune hepatitis following COVID vaccination. Unprecedented loss of life due to the COVID pandemic has necessitated the development of several vaccines in record time. Most of these vaccines have received approval without being extensively whetted for their adverse effect and efficacy profiles. Most adverse effects have been mild, nonetheless, more serious thromboembolic events have also been reported. Autoimmune hepatitis (AIH) can occur in predisposed individuals where an immune mediated reaction against hepatocytes is triggered by environmental factors. Vaccines are a very rare cause of AIH. We report two such cases of AIH triggered by COVID (Covishield) vaccination. While one patient made an uneventful recovery, another succumbed to the liver disease. Ours is the first report of Covishield vaccination related AIH and second ever after any form of COVID vaccination. We hope that our report does not deter COVID vaccination drives. However, we also hope to raise awareness of its potential side effects and the increased role of pharmacovigilance in guiding treatment.

Blunted humoral response after mRNA vaccine in patients with haematological malignancies.

Reactivation of Vogt-Koyanagi-Harada disease under control for more than 6â€‰years, following anti-SARS-CoV-2 vaccination. BACKGROUND/PURPOSE: Vogt-Koyanagi-Harada (VKH) disease is a primary stromal choroiditis with bilateral granulomatous panuveitis. If initial-onset VKH is treated early and relentlessly the disease can be controlled and even "cured" in a substantial number of cases. We are reporting on a patient treated early and in a sustained fashion who was inflammation free for seven years but who presented a reactivation 6â€‰weeks after the second dose of anti-SARS-CoV-2 vaccination. CASE REPORT: A 43-year-old woman presented with severe initial-onset VKH disease which was brought under control using steroidal and non-steroidal Immunosuppression (mycophenolic acid and cyclosporine) with additional infliximab infusions because of the persistence of subclinical choroiditis identified on ICGA. Under infliximab alone disease had been inflammation free with no subclinical disease and absence of sunset glow fundus for 6â€‰years. However, following anti-SARS-CoV-2 vaccination, severe resurgence of the disease occurred with exudative retinal detachments. Disease was rapidly brought again under control with oral prednisone (1â€‰mg/kg) therapy and a new loading scheme of infliximab therapy. CONCLUSION: VKH disease results from an autoimmune process directed against melanocyte associated antigens which can be controlled when early and sustained immunosuppressive treatment is introduced. It seems that anti-SARS-CoV-2 vaccination can be at the origin of reactivation of long-time controlled disease.

A colloidal gold-based immunochromatographic strip for rapid detection of SARS-CoV-2 antibodies after vaccination. Vaccination interventions is consideredan important preventive measure to block the transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and protect the organism from pathogen infection effectively. However, a quick and accurate technique to evaluate the immune efficacy of the SARS-CoV-2 inactivated vaccine remains scarce. In this paper, an IgM-IgG antibody combined detection colloidal gold immunochromatography assay kit was optimized and developed, which can assess the efficacy of the inactivated SARS-CoV-2 vaccine. We collected fingertip blood samples from 3 vaccinees and 1 unvaccinated sample. The results showed that the proportion of antibody was high after the second shots immunization. The colloidal gold-based immunochromatographic strip is rapid, convenient and easy to operate. It can be used as an auxiliary

method for preliminary evaluation of the antibody effect of vaccine recipients, and provide a reference index for the potential clinical application value of the vaccine.
Cutaneous mucormycosis following COVID-19 vaccination in a patient with bullous pemphigoid.
Attitude and associated factors of COVID-19 vaccine acceptance among health professionals in Debre Tabor Comprehensive Specialized Hospital, North Central Ethiopia; 2021: cross-sectional study. Control of coronavirus disease through vaccination is not merely dependent on vaccine efficacy and safety. Professional and general public acceptance is vital for the successful control of the virus. This study aimed (1) to assess health professionals' attitude towards COVID-19 vaccine acceptance; (2) to identify factors associated with health professional's attitude towards COVID-19 vaccine acceptance. An Institutional based cross-sectional study was conducted on health professionals working at Debre Tabor Comprehensive Specialized Hospital. A structured questionnaire containing 16 items was used to assess the attitude of health professionals on vaccine acceptance. Bivariable and multivariable logistic analysis was done to identify factors associated with the attitude of health professionals. In this study, 42.3% [95% CI (36.7-47.6)] participants had positive attitude to COVID-19 vaccine acceptance. Age 30-39Â years [AOR 2.23; (CI 1.23-4.04)] andâ€‰â‰¥â€‰40Â years [AOR 5.51; (CI 2.47-12.30)] of respondents have positive attitude than their counterparts. Also physicians [AOR 3.67; (CI 1.90-7.09)], pharmacists [AOR 4.27; (CI 1.39-13.09)] and laboratory professionals [AOR 4.56; (CI 1.34-15.39)] have higher attitude to COVID vaccine acceptance than nurses. In conclusion, the attitude level of health professionals on COVID-19 vaccine acceptance was poor. Age and profession were factors significantly associated with the attitude level of health professionals for COVID-19 vaccine acceptance.
A rare case of shingles after COVID-19 vaccine: is it a possible adverse effect? Coronavirus disease 2019 (COVID-19) exhibit mild to moderate symptoms, whereas 15% of COVID-19 cases progress to pneumonia, some associated cutaneous findings are also reported as maculopapular eruptions, morbilliform rashes, urticaria, chickenpox-like lesions, and livedo reticularis. The inactivated COVID-19 vaccines are authorized for use in some countries including Turkey. Here, we report an unusual case of varicella-zoster virus (VZV) reactivation in a 68-year-old male patient who was vaccinated against COVID-19. The patient presented to family medicine clinic with a stinging sensation and pain radiating from the right side of his chest to his back. Physical examination revealed multiple pinheaded vesicular lesions upon an erythematous base occupying an area on his right mammary region and back corresponding to T3-T5 dermatomes. He reported that he got his second dose of COVID-19 vaccine 5 days ago. As COVID 19 decreases the cell-mediated immunity, it could also increase the risk of herpes zoster (HZ). Although the exact reason remains unsolved, vaccine-induced immunomodulation caused by live attenuated vaccines and attenuated alloreactivity caused by inactivated vaccines may be responsible mechanisms for the reactivation of HZ. Epidemiological studies are needed to clarify the possible connection between vaccination and reactivation of herpesvirus infections.
Acute myocarditis associated with anti-COVID-19 vaccination. Novel anti-coronavirus disease 2019 mRNA vaccines are rapidly implemented worldwide. Therefore, attention should be given to potentially life-threatening adverse reactions. We report on three young male patients, who developed acute myocarditis 2 days after receiving the second dose of the BNT162b2 vaccine. Primary acute myocarditis was not previously reported in association with vaccines that do not include adjuvants. A high index of suspicion should be maintained in order to diagnose and treat patients who develop auto-inflammatory vaccine-related complications in a timely manner. Further research is required in order to explore the significance of this phenomenon and its underlying molecular mechanism.

The Safety and Immunogenicity of the mRNA-BNT162b2 SARS-CoV-2 Vaccine in Hemodialysis Patients. BACKGROUND: Hemodialysis patients are at high risk for severe COVID-19. SARS-CoV-2 vaccination related safety and immunogenicity data in these patients are rare. METHODS: In this observational study SARS-CoV-2-seronegative hemodialysis patients were vaccinated with two doses of the Pfizer/BioNTech mRNA-BNT162b2 vaccine (COMIRNATY(Â®) 30 Âµg) and followed for 90 days. Local and systemic side effects were assessed at every dialysis session during the first post-vaccination week after the first and second vaccine dose. Immunogenicity was determined four weeks after vaccination by quantifying anti-SARS-CoV-2 spike protein IgG antibodies (LIAISON(Â®) SARS-CoV-2-TrimericS IgG chemiluminescent immunoassay) expressed in binding activity units per milliliter (BAU/mL) adapted to the WHO International standard. RESULTS: Fifty patients (32% women, 68% men) with a mean (SD) age of 67.6 (14.8) years were included. Mild local reactions occurred in 38% after the first injection, and in 29.2% with mild, in 2.1% with moderate and in 2.1% with severe degree after the second injection. Systemic reactive events occurred less often, with diarrhea (4% mild, 4% moderate) and fatigue (8% mild) being the most frequent ones. After the first injection 42% of the patients developed a positive response using the assay specific cut-off value of 33.8 binding activity units per milliliter (BAU/mL) with a median (Q1, Q3) anti-SARS-CoV-2 spike IgG concentration of 20.0 (11.7, 51.0) BAU/mL. After the second injection the percentage of seropositive patients increased to 97.9% with an anti-SARS-CoV-2 spike IgG concentration of 1075 (290.8, 1735) BAU/mL. Higher age and immunosuppression were associated with lower, calcitriol treatment and prior seroconversion to hepatitis B vaccination with significantly higher antibody concentration. CONCLUSIONS: The mRNA-BNT162b2 SARS-CoV-2 vaccine appears to be safe and well-tolerated and shows a high immunogenicity in hemodialysis patients.

Demonstrating the capacity of the National Advisory Committee on Immunization for timely responses to post-market vaccine monitoring signals: Canada's experience with the live-attenuated influenza vaccine. Over the last several years, the recommended use of the live-attenuated influenza vaccine (LAIV) for children has evolved in the United States (US) in response to evidence of a potential decrease in LAIV effectiveness based on post-market monitoring. These issues were not observed in Canada or elsewhere; consequently, recommendations from Canada's National Advisory Committee on Immunization (NACI) and the US Advisory Committee on Immunization Practices (ACIP) on whether to use LAIV differed for two influenza seasons (2016-2017 and 2017-2018). This retrospective describes how NACI arrived at its recommendations in response to post-market signals of reduced LAIV performance from the US in 2013-2014 and again in 2015-2016. NACI's experience with LAIV marks the first time in Canada where a preferential recommendation on the use of an influenza vaccine in a routine immunization program was reversed. This experience highlights the importance of ongoing post-market monitoring of vaccines, international collaboration and careful consideration of local context to inform vaccine recommendations. NACI's capacity for timely responses to post-market vaccine performance signals will facilitate responsiveness to similar post-market monitoring signals from the coronavirus disease 2019 (COVID-19) vaccines.

Determining the frequency of serious adverse reactions of inactive SARS-COV-2 vaccine. BACKGROUND: Vaccines are a new combat strategy against COVID-19. The success of a large number of vaccines and the continued development of vaccines will change the course of the current pandemic. OBJECTIVE: The aim of the study was to determine the frequency of serious adverse reactions caused by the administration of inactive vaccine administration on healthcare workers during the COVID-19 pandemic. METHODS: The prospective study was conducted among healthcare professionals working in city a Training and Research Hospital and applied to have the second dose of CoronaVac vaccine. The number of personnel included in the study were 329. The data were recorded in the SPSS 23 program and the chi-square test was used for statistical analysis. RESULTS:

The average age of the participants in the study was 35.77Â±9.07. Of the participants, 28.1%were physicians. The frequency ratio of those who stated that they had serious adverse reactions after vaccination was 33.2%. Three most common systemic serious adverse reactions were headache, state of sleep/fatigue, and nausea and vomiting respectively. Serious adverse reactions occurred within 1.14Â±04 days after vaccine administration. The average duration of serious adverse reactions was determined as 1.68Â±0.77 days. 62.2%of the participants with serious side effects were women (pâ€Š<â€Š0.001). Of the participants who had serious adverse reactions, 77.5%were health care professionals (pâ€Š<â€Š0.01). CONCLUSION: No life-threatening serious adverse reaction was determined regarding the CoronaVac vaccine administered in this study. However, local serious adverse reactions, nausea/vomiting, fever and sleepiness/fatigue occurred frequently. Further studies are required on the newly introduced vaccine.
Acute Myocardial Injury Following COVID-19 Vaccination: A Case Report and Review of Current Evidence from Vaccine Adverse Events Reporting System Database. COVID-19 vaccination related adverse events is an evolving field. Here we present a case of acute myocardial injury that developed as a result of an acute immune response following the second dose of COVID-19 vaccination (Moderna) in a 67-year-old man who presented in acute congestive heart failure. His clinical course improved over 3â€‰days. Review of the Vaccine Adverse Events Reporting System (VAERS) in the Centers for Disease Control and Prevention websites identified 37 vaccine recipients who developed myocarditis as an adverse event following COVID-19 vaccination. With the mass expansion of COVID-19 vaccine administration, physicians need to be vigilant about the possibility of new adverse events.
Vaccination Safety: Don't Toss the Champagne With the Cork.
High levels of anti-SARS-CoV-2 IgG antibodies in previously infected patients with cancer after a single dose of BNT 162b2 vaccine.
Specialist confirmed allergic reactions to COVID-19 mRNA vaccines at a mass vaccination site. Healthcare providers can play a key role in reaching the target for vaccine uptake through educating the public on the risk may be of severe allergic reactions to COVID-19 vaccines. Thus, it is important to resolve reports in the literature which present conflicting data on vaccine safety. We performed a prospective study of Pfizer-BioNTech vaccinations administered at the Albany Community Vaccination Center. All potential vaccinees to the site were screened for allergic history prior to triage by a board-certified allergist. In the first 14Â days of operation, our site vaccinated 14,655 individuals, 3.9% of which had a personal history of anaphylaxis. While some vaccine recipients had non-allergic complications, none of the visitors suffered any objective, immediate allergic symptoms. Our findings indicate that specialist-confirmed rates of immediate allergic reaction to mRNA SARS-CoV-2 vaccination are far lower than self-reported rates defined by subjective, unconfirmed symptoms.
Guillain-BarrÃ© syndrome following first injection of ChAdOx1 nCoV-19 vaccine: First report.
Humoral response after 3 doses of the BNT162b2 mRNA COVID-19 vaccine in patients on hemodialysis.
Moderate acceptance of COVID-19 vaccination in patients pre- and post-heart transplantation: Experiences from a German Transplant Centre. INTRODUCTION AND OBJECTIVES: Patients awaiting heart transplantation (HTx) are at increased risk developing severe coronavirus disease 2019 (COVID-19). Patients supported by a left ventricular assist device (LVAD) face additional risks due to coagulopathies during COVID-19. Following HTx, elevated risk factors for severe COVID-19 persist due to chronic immunosuppression and frequent comorbidities. Taken together, COVID-19 vaccination is of critical importance in all three patient cohorts. Here, we report our experience to deliver COVID-19 vaccination in a German transplant center. METHODS AND RESULTS: We screened 211 patients for contraindications and offered the remaining 186 eligible patients COVID-19 vaccination. Of those, 133 patients (71%) accepted the offer and were vaccinated. Acceptance of vaccination differed between

HTx recipients (84 of 113, 74%), patients on the waiting list (34 of 47, 72%), and patients with LVAD support (28 of 50, 56%). The LVAD cohort demonstrated lower acceptance levels for vaccination compared to HTx recipients and patients awaiting HTx (74%Â vs. 56%; pÂ =Â 0.028). CONCLUSION: We demonstrate for the first time only moderate acceptance levels of COVID-19 vaccination in HTx recipients and candidates on the waiting list compared to general population, despite perceived high-risk for severe disease. Additionally, those supported by LVAD have even lower adherence. Efforts may need to be made to increase acceptance in this vulnerable as well as cost-intensive patient cohort.

Relationship between pre-existing allergies and anaphylactic reactions post mRNA COVID-19 vaccine administration. Two mRNA vaccines for COVID-19, Pfizer-BioNTech and Moderna, are approved for emergency use in the United States. After their approval and dosing in millions of recipients, reports of anaphylaxis began to appear in the Vaccine Adverse Reporting System (VAERS). Here we provide an analysis of the relationship between prior history of allergy and/or anaphylaxis and anaphylaxis rates following the administration of mRNA COVID-19 vaccines. Overall reported incidence of anaphylaxis was estimated to be rare at 4.2 cases per million doses. It appeared that the relative incidence of anaphylaxis following administration of these COVID-19 vaccines was two and seven times higher for recipients with a prior history of allergies and/or anaphylaxis, respectively. This report provides valuable metrics to make evidence-based decisions for subjects with pre-existing allergic conditions receiving a COVID-19 mRNA vaccine.

AstraZeneca (AZD1222) COVID-19 vaccine-associated adverse drug event: A case report.

Panuveitis following Vaccination for COVID-19. Background: COVID-19 vaccination has been accompanied by reports of inflammatory events. This report details a case of panuveitis following vaccination for COVID-19 Case.Description: A 43 year old female developed panuveitis with decreased vision three days after her second dose of Pfizer-Biontech mRNA vaccine. The choroid was significantly thickened and there was anterior chamber and vitreous inflammation. Shortly after onset of ocular symptoms she was also found have an asymptomatic COVID-19 infection. Treatment with oral and topical corticosteroids resulted in improvement in the panuveitis, with a mild recurrence after the initial attempt to taper these drugs.Conclusion: This report demonstrates a likely occurrence of vaccine-related panuveitis secondary to the Pfizer-Biotech mRNA vaccine for COVID-19.

COVID-19 vaccine hesitancy in patients with systemic autoimmune rheumatic disease: an interview-based survey. Patients with a systemic autoimmune rheumatic disease (AIRD) are vulnerable to SARS Cov-2 infection. Vaccination against this infection can prevent the patients from developing severe disease. But vaccine hesitancy in this group can emerge as a hurdle. So there is a need to understand the perception regarding vaccination in AIRD patients. The study is an interview-based survey done in AIRD patients and a control group from the general population. The questionnaire included the subject's demographic details, duration, diagnosis, the activity of AIRD, and questions regarding the perception of the vaccination. The survey included 280 patients with AIRD and 102 control subjects. 54% (152/280) of the patients and 67% (68/102) of the controls were willing to get vaccinated (pâ€‰=â€‰0.03). Patientsâ€‰>â€‰45-years of age were more willing to vaccinate than those with ageâ€‰â‰¤â€‰45-years (61.9% vs. 44.8%; pâ€‰=â€‰0.001). Patients with lower education had more vaccine hesitancy than those with graduation and above (38% vs. 69%; pâ€‰<â€‰0.001). The common reason for vaccine hesitancy was not-yet-decided, fear related to vaccine side-effects, and disease worsening. 29% (82/280) patients were already vaccinated, out of which 35% (35/82) had mild events (fever/myalgia/headache). AIRD patients had fewer side effects than controls, and disease flare was seen in only one patient. Thus, educating AIRD patients regarding the pros and cons of vaccination, particularly concerning immunological disease, can help us

overcome vaccine hesitancy. The message should clearly penetrate that there is a negligible risk of AIRD-flares with the COVID-19 immunization and the side effects are mild and manageable.
Frequency of Thrombocytopenia and Platelet Factor 4/Heparin Antibodies in Patients With Cerebral Venous Sinus Thrombosis Prior to the COVID-19 Pandemic. IMPORTANCE: Cases of cerebral venous sinus thrombosis in combination with thrombocytopenia have recently been reported within 4 to 28 days of vaccination with the ChAdOx1 nCov-19 (AstraZeneca/Oxford) and Ad.26.COV2.S (Janssen/Johnson & Johnson) COVID-19 vaccines. An immune-mediated response associated with platelet factor 4/heparin antibodies has been proposed as the underlying pathomechanism. OBJECTIVE: To determine the frequencies of admission thrombocytopenia, heparin-induced thrombocytopenia, and presence of platelet factor 4/heparin antibodies in patients diagnosed with cerebral venous sinus thrombosis prior to the COVID-19 pandemic. DESIGN, SETTING, AND PARTICIPANTS: This was a descriptive analysis of a retrospective sample of consecutive patients diagnosed with cerebral venous sinus thrombosis between January 1987 and March 2018 from 7 hospitals participating in the International Cerebral Venous Sinus Thrombosis Consortium from Finland, the Netherlands, Switzerland, Sweden, Mexico, Iran, and Costa Rica. Of 952 patients, 865 with available baseline platelet count were included. In a subset of 93 patients, frozen plasma samples collected during a previous study between September 2009 and February 2016 were analyzed for the presence of platelet factor 4/heparin antibodies. EXPOSURES: Diagnosis of cerebral venous sinus thrombosis. MAIN OUTCOMES AND MEASURES: Frequencies of admission thrombocytopenia (platelet count <150â€‰Ã—103/Î¼L), heparin-induced thrombocytopenia (as diagnosed by the treating physician), and platelet factor 4/heparin IgG antibodies (optical density >0.4, in a subset of patients with previously collected plasma samples). RESULTS: Of 865 patients (median age, 40 years [interquartile range, 29-53 years], 70% women), 73 (8.4%; 95% CI, 6.8%-10.5%) had thrombocytopenia, which was mild (100-149â€‰Ã—103/Î¼L) in 52 (6.0%), moderate (50-99â€‰Ã—103/Î¼L) in 17 (2.0%), and severe (<50â€‰Ã—103/Î¼L) in 4 (0.5%). Heparin-induced thrombocytopenia with platelet factor 4/heparin antibodies was diagnosed in a single patient (0.1%; 95% CI, <0.1%-0.7%). Of the convenience sample of 93 patients with cerebral venous sinus thrombosis included in the laboratory analysis, 8 (9%) had thrombocytopenia, and none (95% CI, 0%-4%) had platelet factor 4/heparin antibodies. CONCLUSIONS AND RELEVANCE: In patients with cerebral venous sinus thrombosis prior to the COVID-19 pandemic, baseline thrombocytopenia was uncommon, and heparin-induced thrombocytopenia and platelet factor 4/heparin antibodies were rare. These findings may inform investigations of the possible association between the ChAdOx1 nCoV-19 and Ad26.COV2.S COVID-19 vaccines and cerebral venous sinus thrombosis with thrombocytopenia.
Benefits and risks associated with different uses of the COVID-19 vaccine Vaxzevria: a modelling study, France, May to September 2021. Thrombosis with thrombocytopenia (TTS) has been identified as a rare adverse event following COVID-19 vaccination with Vaxzevria. We modelled the benefits and risks of Vaxzevria distribution from May to September 2021 in metropolitan France where other vaccines are available, considering French hospitalisation data and European data on TTS. Across different scenarios, benefits of Vaxzevria distribution in people 55 years and older exceeded the risk of death from COVID-19. In young adults, risks were at least of similar magnitude as benefits.
Misrepresentation about vaccines that are scaring women. The coronavirus disease 2019 (COVID-19) pandemic has contributed greatly to morbidity and mortality worldwide. The production of COVID-19 vaccines has been tested for efficacy and safety via clinical trials. However, false information on the side effects of the vaccine has been spread via social media, creating fear of vaccination. Currently, the vaccine has been falsely reported to cause infertility in women of

reproductive age and miscarriages in pregnant women. There is no evidence to support this information as the COVID-19 vaccines have been clinically approved for safety. Furthermore, pregnant and lactating women were not included in the clinical trials. Therefore, the objective of this report is to raise awareness that the rumours on the vaccine are false and to encourage every individual to accept the vaccination for their safety and the safety of their loved ones.
COVID-19 Vaccine-associated Anaphylaxis and Allergic Reactions: Consensus Statements of the KAAACI Urticaria/Angioedema/Anaphylaxis Working Group. In the era of novel coronavirus epidemics, vaccines against coronavirus disease 2019 (COVID-19) have been recognized as the most effective public health interventions to control the pandemic. An adverse event following immunization (AEFI) is defined as any untoward occurrence following immunization, and the majority of AEFIs are caused by protective immune responses stimulated by vaccines. Most of the reported AEFIs are not serious, and many are not immunologically mediated or even reproducible on re-exposure. However, uncommon severe allergic adverse reactions, such as anaphylaxis or other allergic reactions, can occur after vaccinations. Confirmed allergic reactions to vaccines may be caused by residual non-human protein, preservatives, or stabilizers in the vaccine formulation (also known as excipients). There are 2 main potential allergenic/immunogenic excipients in COVID-19 vaccines, polyethylene glycol (PEG) and polysorbate 80. PEG, also known as macrogol, is an ingredient in various laxatives and injectable formulations, such as depot steroids. Polysorbate 80 is present in various medical products, creams, ointments, lotions, and medication tablets. Contraindications to the administration of COVID-19 vaccines include a previous history of severe allergic reactions to the first dose of COVID-19 vaccine or proven hypersensitivity to a vaccine component, such as PEG or polysorbate 80. Anaphylaxis or other allergic reactions following immunization can cause fear and loss of confidence in the safety of vaccines among the public. A better understanding of these events is thought to help alleviate concerns about the current COVID-19 vaccines and provide reassurance to the general population by analyzing the exact incidence of anaphylaxis and potential risk factors. COVID-19 vaccine-associated anaphylaxis could be prevented and managed by risk stratification based on our local and global experience.
Mix-and-match COVID vaccines: the case is growing, but questions remain.
A Case of Chilblains-like Lesions Post SARS-CoV-2 Vaccine?
Side effects and antibody titer transition of the BNT162b2 messenger ribonucleic acid coronavirus disease 2019 vaccine in Japan. BACKGROUND: The coronavirus disease (COVID-19) has afflicted large populations worldwide. Although vaccines aroused great expectations, their side effects on Japanese people and the antibody titer transition after vaccination are unclear. METHODS: The side effects of the BNT162b2 mRNA COVID-19 vaccine in participants who received vaccination at our center were investigated. Some participants were also surveyed for the antibody titer transition. RESULTS: In this study, 983 and 798 Japanese participants responded to the first and second doses, respectively. Side effects occurred in 757 (77.0%) and 715 participants (90.0%) after the first and second doses, respectively. No Grade 4 side effects occurred. The second dose had significantly more side effects than the first dose (pÂ <Â 0.001). Side effects occurred after the second dose in 571 female (92.1%) and 178 male participants (80.1%). Female participants had a higher incidence of side effects than the male participants (pÂ <Â 0.001). A comparison among the age groups showed significant differences (pÂ =Â 0.018), and the frequency of side effects decreased with age. Twenty-three individuals participated in the survey of antibody titer transition. After the second vaccine dose, the median antibody titers for IgG and IgM were 3.76 and 0.07 AU/mL, respectively. Both IgG and IgM titers showed a significant increase over the study period (pÂ <Â 0.001). CONCLUSIONS: The BNT162b2 mRNA COVID-19 vaccine might be safe for Japanese people, and the antibody titer

increased with two doses of vaccination. Larger nationwide studies are warranted to verify these findings.

ISIDOG Consensus Guidelines on COVID-19 Vaccination for Women before, during and after Pregnancy. INTRODUCTION: Sars-CoV-2 infection poses particular problems in pregnancy, as the infection more frequently causes severe complications than in unaffected pregnant women or nonpregnant women with SARS-CoV-2 infection. Now that vaccination is available and rapidly being implemented worldwide, the question arises whether pregnant women should be vaccinated, and if so, whether they should receive priority. METHODS: Available scientific data and available guidelines about vaccination against SARS-CoV-2 were collected by the Guideline Committee of the International Society of Infectious Diseases in Obstetrics and Gynecology (ISIDOG) and were analyzed, discussed and summarized as guidelines for healthcare workers caring for pregnant women. Concluding statements were graded according to the Oxford evidence-based medicine grading system. RESULTS: There is evidence to consider pregnancy as a risk factor for serious complications of COVID-19 infection, even in the absence of additional risk factors, such as hypertension, diabetes and obesity which increase these risks even more in pregnancy. Currently available data slightly favor mRNA-based vaccines above vector-based vaccines during pregnancy and breastfeeding, until more safety data become available. CONCLUSION: ISIDOG advises policy makers and societies to prioritize pregnant women to receive vaccination against SARS-CoV-2 and favor the mRNA vaccines until further safety information becomes available.

Serological Response in Lung Transplant Recipients after Two Doses of SARS-CoV-2 mRNA Vaccines. BACKGROUND: Lung-transplant (LT) recipients are at high risk for COVID-19 due to immunosuppression and respiratory tropism of SARS-CoV-2. The information on the effect of COVID-19 mRNA vaccines to elicit immunogenic responses after a two-dose (2D) regimen in LT recipients is sparse. Thus, we assessed the effect of Pfizer-BioNTech and Moderna mRNA vaccines' 2D regimen on anti-spike responses in immunocompromised LT recipients. METHODS: We utilized serum samples from LT recipients vaccinated for SARS-CoV-2 with 2D of either the Pfizer-BioNTech or Moderna vaccines and 2D-vaccinated naÃ¯ve (non-transplanted and non-exposed to COVID-19) group. Antibody responses were assessed using the FDA-approved SARS-CoV-2 anti-nucleocapsid protein IgG assay (IgG(NC)), the SARS-CoV-2 anti-spike protein IgM assay (IgM(SP)), and the SARS-CoV-2 anti-spike protein IgG II assay (IgG(SP)). CD4+ T-cell activity was assessed as a marker of immune competence using the ImmuKnow(Â®) assay. RESULTS: About 25% (18/73) of SARS-CoV-2 uninfected-LT patients generated a positive spike-IgG response following 2D of vaccines, with 36% (9/25) in the Moderna cohort and only 19% (9/48) in the Pfizer cohort. 2D in LT patients elicited a significantly lesser median IgG(SP) response (1.7 AU/mL, 95% CI: 0.6-7.5 AU/mL) compared to non-transplanted, uninfected naÃ¯ve subjects (14,209 AU/mL, 95% CI: 11,261-18,836 AU/mL; $p < 0.0001$). In LT patients, the Moderna-evoked seropositivity trend was higher than Pfizer. CONCLUSION: 2D COVID-19 vaccination elicits a dampened serological response in LT patients. Whether assessing other arms of host immunity combined with a higher vaccine dose can better capture and elicit improved immunogenicity in this immunocompromised population warrants investigation.

Evaluation of Side Effects Associated with COVID-19 Vaccines in Saudi Arabia. BACKGROUND: Pfizer-BioNTech and Oxford-AstraZeneca are recently introduced vaccines to combat COVID-19 pandemic. During clinical trials, mild to moderate side effects have been associated with these vaccines. Thus, we aimed to evaluate short-term post-vaccination side effects. METHODS: Cross-sectional, retrospective study using an online questionnaire was conducted among COVID-19 vaccines recipients in Saudi Arabia. General and demographic data were collected, and vaccine-associated side effects after receiving at least one dose of each vaccine were evaluated. RESULTS: Our final sample consisted of 515 participants with a median age of 26 years. Most of the study participants were

female (57%). Nearly 13% of the study subjects have reported previous infections with SARS-CoV-2. Oxford-AstraZeneca and Pfizer-BioNTech vaccines have been received by 75% and 25% of the study participants, respectively. Side effects associated with COVID-19 vaccines have been reported by 60% of the study subjects, and most of them reported fatigue (90%), pain at the site of the injections (85%). CONCLUSION: Side effects that are reported post Oxford-AstraZeneca and Pfizer-BioNTech vaccines among our study participants are not different from those that were reported in the clinical trials, indicating safe profiles for both vaccines. Further studies are needed to evaluate the effectiveness of the current vaccines in protection against SARS-CoV-2 reinfections.

Case Study of Two Post Vaccination SARS-CoV-2 Infections with P1 Variants in CoronaVac Vaccinees in Brazil. The rapid development of efficacious and safe vaccines against coronavirus disease 2019 (COVID-19) has been instrumental in mitigating the transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Moreover, the emergence of SARS-CoV-2 variants raised concerns on the efficacy of these vaccines. Herein, we report two cases of breakthrough infections with the P1 variant in patients vaccinated with CoronaVac, which is one of the two vaccines authorized for emergency use in the Brazilian immunization program. Our observations suggest that the vaccine reduced the severity of the disease and highlight the potential risk of illness following vaccination and subsequent infection with the P1 variant as well as for continued efforts to prevent and diagnose infection in vaccinated persons.

Evaluation of Anti-SARS-Cov-2 S-RBD IgG Antibodies after COVID-19 mRNA BNT162b2 Vaccine. (1) Background: The evaluation of anti-spike protein receptor-binding domain (S-RBD) antibodies represents a useful tool to estimate the individual protection against Severe Acute Respiratory Syndrome CoronaVirus 2 (SARS-CoV-2) infection; (2) Methods: We evaluated anti S-RBD IgG levels by indirect chemiluminescence immunoassay on Maglumi 800 (SNIBE, California) in 2248 vaccinated subjects without previous SARS-CoV-2 infection, 91 vaccinated individuals recovered from COVID-19, and 268 individuals recovered from COVID-19 who had not been vaccinated. Among those who were healthy and vaccinated, 352 subjects performed a re-dosing after about 72 days from the first measurement. (3) Results: Anti S-RBD IgG levels were lower in subjects with previous infection than vaccinated subjects, with or without previous infection ($p < 0.001$). No difference was observed between vaccinated subjects, with and without previous SARS-CoV-2 infection. Overall, anti-RBD IgG levels were higher in females than males (2110 vs. 1341 BAU/mL; $p < 0.001$) as well as in subjects with symptoms after vaccination than asymptomatic ones (2085 vs. 1332 BAU/mL; $p = 0.001$) and lower in older than younger subjects. Finally, a significant decrease in anti-RBD IgG levels was observed within a short period from a complete two-dose cycle vaccination. (4) Conclusions: Our results show an efficacy antibody response after vaccination with age-, time- and sex-related differences.

DIC-Like Syndrome Following Administration of ChAdOx1 nCov-19 Vaccination. In recent weeks, adverse reactions have been reported after administration of Oxford-AstraZeneca chimpanzee adenovirus vectored vaccine ChAdOx1 nCoV-19 (AZD1222), in particular thrombus formation, which has led several European Countries to discontinue administration of this vaccine. On March 8, 2021, the European Medicines Agency Safety Committee did not confirm this probable association. We report the case of a patient who developed disseminated intravascular coagulation after the first dose of Oxford-Astra Zeneca vaccine, which resolved in a few days with the administration of dexamethasone and enoxaparin. This work demonstrates the safety of the Oxford-Astra Zeneca vaccine and that any development of side effects can be easily managed with a prompt diagnosis and in a short time with a few commonly used drugs.

Side Effects Reported by Jordanian Healthcare Workers Who Received COVID-19 Vaccines. Background Distribution of COVID-19 vaccines has been surrounded by suspicions and rumors making

it necessary to provide the public with accurate reports from trustworthy experts such as healthcare professionals. Methods We distributed a questionnaire in Jordan among physicians, dentists and nurses who received a COVID-19 vaccine to explore the side effects (SE) they encountered after the first or the second dose of one of three vaccines namely: AstraZeneca Vaxzevria (AZ), Pfizer-BioNTeck (PB), and SinoPharm (SP) vaccines. Results A total of 409 professionals participated. Approximately 18% and 31% of participants reported no SE after the first dose and second dose, respectively. The remainder had mostly local side effects related to injection site (74%). Systemic side effects in the form of fatigue (52%), myalgia (44%), headache (42%), and fever (35%) prevailed mainly after the first dose. These were significantly associated with AZ vaccine, and age â‰¤ 45 years (p = 0.000 and 0.01, respectively). No serious SE were reported. Conclusions We can conclude that SE of COVID-19 vaccines distributed in Jordan are within the common range known so far for these vaccines. Further studies are needed to include larger sample size and longer follow-up period to monitor possible serious and long-term SE of the vaccines.

Pancreatic Injury after COVID-19 Vaccine-A Case Report. The COVID-19 pandemic has caused more than 3 million deaths worldwide. Recently developed genetically engineered vaccines are the most critical solution for controlling the pandemic. Clinical trials on a large number of participants confirmed their safety and efficacy. However, with the growing number of vaccinated people, new infrequent adverse effects have been reported, not described in the medicinal product characteristics. We would like to report a case of acute pancreatic injury that occurred shortly after administering Pfizer BioNTech COVID-19 mRNA vaccine (Comirnaty). The report points out the potential need for close monitoring of patients reporting abdominal pain after vaccination (unresponsive to standard oral painkillers) because such symptom can be associated with acute pancreatitis.

The Beauty of Simplicity: Delayed-Type Hypersensitivity Reaction to Measure Cellular Immune Responses in RNA-SARS-Cov-2 Vaccinated Individuals. BACKGROUND: Monitoring cellular immune responses elicited in vaccinated individuals is highly complicated. METHODS: 28 individuals participated during the vaccination process with 12 BNT162b2 mRNA (Pfizer) vaccine. Specific anti-RBD IgG using a classic ELISA was performed in days 10 and 20 (after one dose of the vaccine) and on day 35 (after two vaccine doses) in serum samples of all participants. In parallel, DTH (delayed-type hypersensitivity) Skin Test using S protein was performed before (11/28) and after two doses (28/28) of the vaccine. RESULTS: 6/28 individuals were considered positive for the specific anti-RBD IgG positive at day 10, whereas all 28 individuals were positive at day 20. Moreover, 28/28 individuals increased the OD ratios at day 36 (2 doses). DTH cutaneous test was performed on 11/28 participants at day 20 (1 dose) showing 8/11 a positive reaction at 12 h. DTH of all participants was performed on day 36 (2 doses), showing 28/28 positive reactions at 12 h. CONCLUSION: This report describes the first publication of the results obtained using an in vivo method, the classical DTH response to the Spike protein to assess T-cell immune responses in vaccinated individuals. This affordable and simple test would help to answer basic immunogenicity questions on large-scale population vaccine studies.

Reactivation of Varicella Zoster Virus after Vaccination for SARS-CoV-2. Seven immunocompetent patients aged > 50 years old presented with herpes zoster (HZ) infection in a median of 9 days (range 7-20) after vaccination against SARS-CoV-2. The occurrence of HZ within the time window 1-21 days after vaccination defined for increased risk and the reported T cell-mediated immunity involvement suggest that COVID-19 vaccination is a probable cause of HZ. These cases support the importance of continuing assessment of vaccine safety during the ongoing massive vaccination for the COVID-19 pandemic and encourage reporting and communication of any vaccination-associated adverse event.

Confounding Factors Influencing the Kinetics and Magnitude of Serological Response Following Administration of BNT162b2. BACKGROUND: Little is known about potential confounding factors

influencing the humoral response in individuals having received the BNT162b2 vaccine. METHODS: Blood samples from 231 subjects were collected before and 14, 28, and 42 days following coronavirus disease 2019 (COVID-19) vaccination with BNT162b2. Anti-spike receptor-binding-domain protein (anti-Spike/RBD) immunoglobulin G (IgG) antibodies were measured at each time-point. Impact of age, sex, childbearing age status, hormonal therapy, blood group, body mass index and past-history of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection were assessed by multivariable analyses. RESULTS AND CONCLUSIONS: In naÃ¯ve subjects, the level of anti-Spike/RBD antibodies gradually increased following administration of the first dose to reach the maximal response at day 28 and then plateauing at day 42. In vaccinated subjects with previous SARS-CoV-2 infection, the plateau was reached sooner (i.e., at day 14). In the naÃ¯ve population, age had a significant negative impact on anti-Spike/RBD titers at days 14 and 28 while lower levels were observed for males at day 42, when corrected for other confounding factors. Body mass index (BMI) as well as B and AB blood groups had a significant impact in various subgroups on the early response at day 14 but no longer after. No significant confounding factors were highlighted in the previously infected group.

Evaluation of SARS-CoV-2 Spike Protein Antibody Titers in Cord Blood after COVID-19 Vaccination during Pregnancy in Polish Healthcare Workers: Preliminary Results. BACKGROUND: The coronavirus disease 2019 (COVID-19) pandemic has given rise to the need to develop a vaccine as quickly as possible. As pregnant women are at increased risk of contracting severe COVID-19, with higher mortality, it is essential to assess the safety of the vaccines administered during pregnancy. METHODS: The aim of this study was to determine the titer of specific maternal and cord antibodies against severe acute respiratory syndrome coronavirus 2 S protein after antenatal vaccination. The secondary objective was to evaluate the ratio of the umbilical cord to the maternal antibody titers. Patients included in the study were enrolled after undergoing voluntary vaccination against COVID-19 during pregnancy at different weeks of gestation. All patients analyzed in our initial study were vaccinated with the BNT162b2 mRNA COVID-19 vaccine. RESULTS: The results of the current study document high anti-S total IgG antibody titers in cord serum at birth in all mother-infant pairs analyzed. The mean umbilical cord blood sample IgG antibody titer anti-S protein was 1026.51 U/mL (Â±SD 769.25). The mean cord-to-maternal anti-S IgG antibody ratio was 1.28 (Â±SD 0.798). A significant positive correlation was observed between the week of gestation at which the first dose was administered and the week of gestation at which the second dose was administered, and the respective cord-to-maternal ratio ($r = 0.48$; $p = 0.0029$) for the first dose and ($r = 0.39$; $p = 0.0102$) for the second dose. CONCLUSIONS: To date, despite the prevalence of COVID-19 vaccination, there is a lack of conclusive evidence supporting the safety and efficacy of vaccination of pregnant women. Therefore, the results we present are complementary. Our study suggests that maternal immunization may provide neonatal protection through the transplacental transfer of antibodies. Of particular importance is the demonstration that antibody transfer is correlated with the time from vaccination to delivery, which may allow future determination of the optimal timing of COVID-19 vaccination in pregnant women.

A Pilot Study on Covid and Autism: Prevalence, Clinical Presentation and Vaccine Side Effects. Background: Several neurobiological mechanisms have been proposed to support the hypothesis of a higher COVID-19 risk in individuals with autism spectrum disorder (ASD). However, no real-world data are available on this population. Methods: We compared the period prevalence (March-May 2020) and symptom presentation of COVID-19 infections between a sample of individuals with severe ASD ($n = 36$) and the staff personnel ($n = 35$) of two specialized centers. Anti-SARS-Cov-2 antibody positivity was used as a proxy of infection. Additionally, we evaluated vaccine side effects in the same groups. Results: No significant difference was found between the prevalence of COVID-19 positivity

between autistic participants and staff personnel. Levels of antibodies against the spike protein and the receptor binding domain were not significantly different between autistic and staff participants. The level of antibodies against the N-terminal domain were higher in autistic individuals. There was a significant difference between the prevalence of symptomatic COVID-19 in autistic participants (9.1%) compared to staff personnel (92.3%). The most frequent side effect among autistic participants was light fever. Conclusions: The present study provides preliminary data on COVID-19 transmission and presentation in ASD. Our data do not support the hypothesis of a higher susceptibility and severity of COVID-19 in people with ASD.

Emerging Advances of Nanotechnology in Drug and Vaccine Delivery against Viral Associated Respiratory Infectious Diseases (VARID). Viral-associated respiratory infectious diseases are one of the most prominent subsets of respiratory failures, known as viral respiratory infections (VRI). VRIs are proceeded by an infection caused by viruses infecting the respiratory system. For the past 100 years, viral associated respiratory epidemics have been the most common cause of infectious disease worldwide. Due to several drawbacks of the current anti-viral treatments, such as drug resistance generation and non-targeting of viral proteins, the development of novel nanotherapeutic or nano-vaccine strategies can be considered essential. Due to their specific physical and biological properties, nanoparticles hold promising opportunities for both anti-viral treatments and vaccines against viral infections. Besides the specific physiological properties of the respiratory system, there is a significant demand for utilizing nano-designs in the production of vaccines or antiviral agents for airway-localized administration. SARS-CoV-2, as an immediate example of respiratory viruses, is an enveloped, positive-sense, single-stranded RNA virus belonging to the coronaviridae family. COVID-19 can lead to acute respiratory distress syndrome, similarly to other members of the coronaviridae. Hence, reviewing the current and past emerging nanotechnology-based medications on similar respiratory viral diseases can identify pathways towards generating novel SARS-CoV-2 nanotherapeutics and/or nano-vaccines.

Neurosurgical Considerations Regarding Decompressive Craniectomy for Intracerebral Hemorrhage after SARS-CoV-2-Vaccination in Vaccine Induced Thrombotic Thrombocytopenia-VITT. Given the ongoing global SARS-CoV-2-vaccination efforts, clinical awareness needs to be raised regarding the possibility of an increased incidence of SARS-CoV-2-vaccine-related immune-mediated thrombocytopenia in patients with intracerebral hemorrhage (ICH) secondary to cerebral sinus and vein thrombosis (CVT) requiring (emergency) neurosurgical treatment in the context of vaccine-induced immune thrombotic thrombocytopenia (VITT). Only recently, an association of vaccinations and cerebral sinus and vein thrombosis has been described. In a number of cases, neurosurgical treatment is warranted for these patients and special considerations are warranted when addressing the perioperative coagulation. We, herein, describe the past management of patients with VITT and established a literature-guided algorithm for the treatment of patients when addressing the impaired coagulation in these patients. Increasing insights addressing the pathophysiology of SARS-CoV-2-vaccine-related immune-mediated thrombocytopenia guide physicians in developing an interdisciplinary algorithm taking into account the special considerations of this disease.

Understanding Post Entry Sorting of Adenovirus Capsids; A Chance to Change Vaccine Vector Properties. Adenovirus vector-based genetic vaccines have emerged as a powerful strategy against the SARS-CoV-2 health crisis. This success is not unexpected because adenoviruses combine many desirable features of a genetic vaccine. They are highly immunogenic and have a low and well characterized pathogenic profile paired with technological approachability. Ongoing efforts to improve adenovirus-vaccine vectors include the use of rare serotypes and non-human adenoviruses. In this review, we focus on the viral capsid and how the choice of genotypes influences the uptake and subsequent subcellular sorting. We describe how understanding capsid properties, such as

stability during the entry process, can change the fate of the entering particles and how this translates into differences in immunity outcomes. We discuss in detail how mutating the membrane lytic capsid protein VI affects species C viruses' post-entry sorting and briefly discuss if such approaches could have a wider implication in vaccine and/or vector development.

Development of SARS-CoV-2 Specific IgG and Virus-Neutralizing Antibodies after Infection with Variants of Concern or Vaccination. The humoral immunity after SARS-CoV-2 infection or vaccination was examined. Convalescent sera after infection with variants of concern (VOCs: B.1.1.7, n = 10; B.1.351, n = 1) and sera from 100 vaccinees (Pfizer/BioNTech, BNT162b2, n = 33; Moderna, mRNA-1273, n = 11; AstraZeneca, ChAdOx1 nCoV-19/AZD1222, n = 56) were tested for the presence of immunoglobulin G (IgG) directed against the viral spike (S)-protein, its receptor-binding domain (RBD), the nucleoprotein (N) and for virus-neutralizing antibodies (VNA). For the latter, surrogate assays (sVNT) and a Vero-cell based neutralization test (cVNT) were used. Maturity of IgG was determined by measuring the avidity in an immunoblot (IB). Past VOC infection resulted in a broad reactivity of anti-S IgG (100%), anti-RBD IgG (100%), and anti-N IgG (91%), while latter were absent in 99% of vaccinees. Starting approximately two weeks after the first vaccine dose, anti-S IgG (75-100%) and particularly anti-RBD IgG (98-100%) were detectable. After the second dose, their titers increased and were higher than in the convalescents. The sVNT showed evidence of VNA in 91% of convalescents and in 80-100%/100% after first/second vaccine dose, respectively. After the second dose, an increase in VNA titer and IgGs of high avidity were demonstrated by cVNT and IB, respectively. Re-vaccination contributes to a more robust immune response.

Subjective Feelings of Polish Doctors after Receiving the COVID-19 Vaccine. The COVID-19 pandemic has caused enormous confusion around the world in our daily existence. The security measures taken, such as physical distance, wearing a mask, quarantine or closing shopping malls, and even isolating large groups of the population, did not contribute to the complete overcoming of the problem. Information on the positive results of research into the COVID-19 vaccine and, finally, its administration offered hope that the pandemic would be overcome. The undertaken problem of research concerning the subjective analysis of the feelings of doctors in Poland after receiving the COVID-19 vaccine shows an important area of the medical world, which is directly responsible for their own health and the patients entrusted to them. In addition, 149 people participated in the study (8-13 February 2021), including 57% of women and 43% of men. The minimum and maximum age of the respondents are 26 and 69 years old. Furthermore, 85% of respondents took two doses of the vaccine and 15% took one. The authorial questionnaire was completed by the participants in the study online in February 2021. The results obtained indicate that the COVID-19 vaccine generates hope for stopping the pandemic. In addition, 96% of research participants think so. Doctors in middle and mature age are the most optimistic, while the youngest ones are less optimistic. In addition, 57% of respondents do not worry about side effects after taking the vaccine. Fear at the time of vaccination was experienced by over 9% of doctors. The most frequently reported post-vaccination reactions are injection site pain, fatigue and headache. Increased temperature occurred in older female respondents. From a psychosocial perspective, men are more likely to fear being infected personally with the virus, and women are more likely to be infected with their loved ones. The presented subjective assessment presents the physicians' view captured at the moment in terms of existential and emotional. The presented feelings of the research participants reflect their personal satisfaction, responsibility for their own health, care for their relatives and patients.

Comparison and Analysis of Neutralizing Antibody Levels in Serum after Inoculating with SARS-CoV-2, MERS-CoV, or SARS-CoV Vaccines in Humans. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), Middle East respiratory syndrome coronavirus (MERS-CoV), and severe acute respiratory syndrome coronavirus (SARS-CoV) pose a great threat to humanity. Every pandemic

involving these coronaviruses has seriously affected human health and economic development. Currently, there are no approved therapeutic drugs against their infections. Therefore, the development of vaccines is particularly important to combat these coronaviruses. In this review, we summarized and analyzed the progress of vaccines against SARS-CoV, MERS-CoV, and SARS-CoV-2, including inactivated vaccines, live attenuated vaccines, subunit vaccines, nucleic acid vaccines, and viral vector vaccines. In addition, we compared the levels of neutralizing antibodies in the serum of patients with these three kinds of coronaviruses at different stages, and their ability and effects against SARS-CoV-2, MERS-CoV, and SARS-CoV. This review provides useful information for vaccine evaluation and analysis.

Titers, Prevalence, and Duration of SARS-CoV-2 Antibodies in a Local COVID-19 Outbreak and Following Vaccination. Information concerning the development of neutralizing antibodies and their duration will be critical to establishing herd immunity for COVID-19. We sought to evaluate SARS-CoV-2 spike protein receptor-binding domain (RBD)-specific antibodies, their duration, and capacity for SARS-CoV-2 neutralization in volunteers while the pandemic spread within our community starting in March 2020. Those participants with the highest starting titers had the longest-lasting response, up to 12 months post-diagnosis. SARS-CoV-2 neutralization capacity was correlated with anti-RBD antibody levels. The majority of our participants with confirmed COVID-19 diagnosis had very mild or asymptomatic infections. We also detected low and largely non-neutralizing anti-RBD IgG titers in a few participants with no known COVID-19 diagnosis. Finally, we found that antibody responses induced by vaccination were significantly higher than those induced by natural infection. Thus, our study suggests that vaccination is still critical even for those naturally infected or diagnosed with COVID-19.

Systemic Adverse Events and Use of Antipyretics Predict the Neutralizing Antibody Positivity Early after the First Dose of ChAdOx1 Coronavirus Disease Vaccine. Vaccination is considered crucial for the eradication of the coronavirus disease (COVID-19). In our medical center in Korea, most health care workers (HCWs) were vaccinated with the ChAdOx1 COVID-19 vaccine. After vaccination, many HCWs complained of adverse events (AEs). However, it remains unclear whether the production of neutralizing antibodies (NAb) was affected. Therefore, here, we aimed to evaluate AEs and early NAb production in relatively healthy Asians who received the ChAdOx1 vaccine and determine the effect of AEs and antipyretics on early NAb production against COVID-19. Of the 182 Korean HCWs who received the first dose of ChAdOx1 vaccine, 172 (94.5%) experienced â‰¥1 adverse events and 148 (81.3%) tested positive for NAb 33-40 days after the vaccination. NAb-positive vaccine recipients reported systemic AEs and consumed acetaminophen more frequently than NAb-negative recipients. We identified an association between antibody response and COVID-19 vaccine-related AEs. In conclusion, most ChAdOx1 vaccine recipients reported AEs in our medical center.

Short-term outcome of pregnant women vaccinated with BNT162b2 mRNA COVID-19 vaccine. OBJECTIVES: To determine the immunogenicity and reactogenicity of the Pfizer/BioNTech BNT162b2 mRNA coronavirus disease 2019 (COVID-19) vaccine among pregnant women compared with non-pregnant women, and to evaluate obstetric outcome following vaccination. METHODS: This was an observational case-control study of pregnant women who were vaccinated with a two-dose regimen of the BNT162b2 vaccine during gestation between January and February 2021 (study group) and age-matched non-pregnant women who received the vaccine during the same time period (control group). Participants received a digital questionnaire 1-4â€‰weeks after the second dose and were asked to provide information regarding demographics, medication, medical history, history of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, timing of COVID-19 vaccine doses and side effects after each vaccine dose. A second digital questionnaire, regarding current pregnancy and delivery outcomes, was sent to patients in the study group after the calculated due date. All

recruited women were offered a serology blood test for SARS-CoV-2 immunoglobulin G (IgG) following the second vaccination dose and SARS-CoV-2 IgG levels were compared between the two groups. RESULTS: Of 539 pregnant women who were recruited after completion of the two-dose regimen of the vaccine, 390 returned the digital questionnaire and were included in the study group and compared to 260 age-matched non-pregnant vaccinated women. The rates of rash, fever and severe fatigue following vaccination among pregnant women were comparable to those in non-pregnant women. Myalgia, arthralgia and headache were significantly less common among pregnant women after each dose, local pain or swelling and axillary lymphadenopathy were significantly less common among pregnant women after the first and second doses, respectively, while paresthesia was significantly more common among the pregnant population after the second dose. Among pregnant women, there were no significant differences in the rates of side effects according to whether the vaccine was administered during the first, second or third trimester of pregnancy, except for local pain/swelling, which was significantly less common after the first dose when administered during the third trimester, and uterine contractions, which were significantly more common after the second dose when administered during the third trimester. The rates of obstetric complications, including uterine contractions (1.3% after the first dose and 6.4% after the second dose), vaginal bleeding (0.3% after the first dose and 1.5% after the second dose) and prelabor rupture of membranes (0% after the first dose and 0.8% after the second dose), were very low following vaccination. All serum samples in both groups were positive for SARS-CoV-2 IgG. However, pregnant women had significantly lower serum SARS-CoV-2 IgG levels compared to non-pregnant women (signal-to-cut-off ratio, 27.03 vs 34.35, respectively; Pâ€‰<â€‰0.001). Among the 57 pregnant women who delivered during the study period and who completed the second questionnaire, median gestational age at delivery was 39.5 (interquartile range, 38.7-40.0) weeks, with no cases of preterm birth <â€‰37â€‰weeks, no cases of fetal or neonatal death and two (3.5%) cases of admission to the neonatal intensive care unit for respiratory support. CONCLUSIONS: The adverse-effect profile and short-term obstetric and neonatal outcomes among pregnant women who were vaccinated with the BNT162b2 vaccine at any stage of pregnancy do not indicate any safety concerns. The vaccine is effective in generating a humoral immune response in pregnant women, although SARS-CoV-2 IgG levels were lower than those observed in non-pregnant vaccinated women. Â© 2021 International Society of Ultrasound in Obstetrics and Gynecology.

SARS-CoV-2 new infections among health-care workers after the first dose of the BNT162b2 mRNA COVID-19 vaccine. A hospital-wide cohort study. OBJECTIVES: To evaluate the effect of mRNA severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination on the incidence of new SARS-CoV-2 infections in health-care workers (HCW). METHODS: The evolution of the incident rate of microbiologically confirmed SARS-CoV-2 infection in a cohort of 2590 HCW after BNT162b2 mRNA SARS-CoV-2 vaccination, compared with the rate in the community (nÂ =Â 170Â 513) was evaluated by mixed Poisson regression models. RESULTS: A total of 1820 HCW (70.3% of total) received the first dose of the BNT162b2 mRNA vaccine between 10 January and 16 January 2021, and 296 (11.4%) received it the following week. All of them completed vaccination 3Â weeks later. Incidence rates of SARS-CoV-2 infection after the first dose of mRNA SARS-CoV-2 vaccine declined by 71% (Incidence Rate Ratio (IRR) 0.286, 95% CI 0.174-0.468; pÂ <Â 0.001) and by 97% (IRR 0.03, 95% CI 0.013-0.068; pÂ <Â 0.001) after the second dose, compared with the perivaccine time. SARS-CoV-2 incidence rates in the community (with a negligible vaccination rate) had a much lower decline: 2% (IRR 0.984, 95% CI 0.943-1.028; p 0.47) and 61% (IRR 0.390, 95% CI 0.375-0.406; pÂ <Â 0.001) for equivalent periods. Adjusting for the decline in the community, the reduction in the incident rates among HCW were 73% (IRR 0.272, 95% CI 0.164-0.451 pÂ <Â 0.001) after the first dose of the vaccine and 92% (IRR 0.176, 95% CI 0.033-0.174; pÂ <Â 0.001) after the second dose. CONCLUSIONS: mRNA SARS-CoV-2

vaccination is associated with a dramatic decline in new SARS-CoV-2 infection among HCW, even before the administration of the second dose of the vaccine.

Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine (CoronaVac) in healthy children and adolescents: a double-blind, randomised, controlled, phase 1/2 clinical trial. BACKGROUND: A vaccine against SARS-CoV-2 for children and adolescents will play an important role in curbing the COVID-19 pandemic. Here we aimed to assess the safety, tolerability, and immunogenicity of a candidate COVID-19 vaccine, CoronaVac, containing inactivated SARS-CoV-2, in children and adolescents aged 3-17 years. METHODS: We did a double-blind, randomised, controlled, phase 1/2 clinical trial of CoronaVac in healthy children and adolescents aged 3-17 years old at Hebei Provincial Center for Disease Control and Prevention in Zanhuang (Hebei, China). Individuals with SARS-CoV-2 exposure or infection history were excluded. Vaccine (in 0Â·5 mL aluminum hydroxide adjuvant) or aluminum hydroxide only (alum only, control) was given by intramuscular injection in two doses (day 0 and day 28). We did a phase 1 trial in 72 participants with an age de-escalation in three groups and dose-escalation in two blocks (1Â·5â€‰Î¼g or 3Â·0â€‰Î¼g per injection). Within each block, participants were randomly assigned (3:1) by means of block randomisation to receive CoronaVac or alum only. In phase 2, participants were randomly assigned (2:2:1) by means of block randomisation to receive either CoronaVac at 1Â·5â€‰Î¼g or 3Â·0â€‰Î¼g per dose, or alum only. All participants, investigators, and laboratory staff were masked to group allocation. The primary safety endpoint was adverse reactions within 28 days after each injection in all participants who received at least one dose. The primary immunogenicity endpoint assessed in the per-protocol population was seroconversion rate of neutralising antibody to live SARS-CoV-2 at 28 days after the second injection. This study is ongoing and is registered with ClinicalTrials.gov, NCT04551547. FINDINGS: Between Oct 31, 2020, and Dec 2, 2020, 72 participants were enrolled in phase 1, and between Dec 12, 2020, and Dec 30, 2020, 480 participants were enrolled in phase 2. 550 participants received at least one dose of vaccine or alum only (n=71 for phase 1 and n=479 for phase 2; safety population). In the combined safety profile of phase 1 and phase 2, any adverse reactions within 28 days after injection occurred in 56 (26%) of 219 participants in the 1Â·5â€‰Î¼g group, 63 (29%) of 217 in the 3Â·0â€‰Î¼g group, and 27 (24%) of 114 in the alum-only group, without significant difference (p=0Â·55). Most adverse reactions were mild and moderate in severity. Injection site pain was the most frequently reported event (73 [13%] of 550 participants), occurring in 36 (16%) of 219 participants in the 1Â·5â€‰Î¼g group, 35 (16%) of 217 in the 3Â·0â€‰Î¼g group, and two (2%) in the alum-only group. As of June 12, 2021, only one serious adverse event of pneumonia has been reported in the alum-only group, which was considered unrelated to vaccination. In phase 1, seroconversion of neutralising antibody after the second dose was observed in 27 of 27 participants (100Â·0% [95% CI 87Â·2-100Â·0]) in the 1Â·5â€‰Î¼g group and 26 of 26 participants (100Â·0% [86Â·8-100Â·0]) in the 3Â·0â€‰Î¼g group, with the geometric mean titres of 55Â·0 (95% CI 38Â·9-77Â·9) and 117Â·4 (87Â·8-157Â·0). In phase 2, seroconversion was seen in 180 of 186 participants (96Â·8% [93Â·1-98Â·8]) in the 1Â·5â€‰Î¼g group and 180 of 180 participants (100Â·0% [98Â·0-100Â·0]) in the 3Â·0â€‰Î¼g group, with the geometric mean titres of 86Â·4 (73Â·9-101Â·0) and 142Â·2 (124Â·7-162Â·1). There were no detectable antibody responses in the alum-only groups. INTERPRETATION: CoronaVac was well tolerated and safe and induced humoral responses in children and adolescents aged 3-17 years. Neutralising antibody titres induced by the 3Â·0â€‰Î¼g dose were higher than those of the 1Â·5â€‰Î¼g dose. The results support the use of 3Â·0â€‰Î¼g dose with a two-immunisation schedule for further studies in children and adolescents. FUNDING: The Chinese National Key Research and Development Program and the Beijing Science and Technology Program.

Vaccine-induced immune thrombotic thrombocytopenia after vaccination against Covid-19: A clinical dilemma for clinicians and patients. The coronavirus disease 2019 (Covid-19) pandemic has had

devastating effects on public health worldwide, but the deployment of vaccines for Covid-19 protection has helped control the spread of SARS Coronavirus 2 (SARS-CoV-2) infection where they are available. The common side effects reported following Covid-19 vaccination were mostly self-restricted local reactions that resolved quickly. Nevertheless, rare vaccine-induced immune thrombotic thrombocytopenia (VITT) cases have been reported in some people being vaccinated against Covid-19. This review summarizes the thromboembolic events after Covid-19 vaccination and discusses its molecular mechanism, incidence rate, clinical manifestations and differential diagnosis. Then, a step-by-step algorithm for diagnosing such events, along with a management plan, are presented. In conclusion, considering the likeliness of acquiring severe SARS-CoV-2 infection and its subsequent morbidity and mortality, the benefits of vaccination outweigh its risks. Hence, if not already initiated, all governments should begin an effective and fast public vaccination plan to overcome this pandemic.
Safety and immunogenicity of a recombinant interferon-armed RBD dimer vaccine (V-01) for COVID-19 in healthy adults: a randomized, double-blind, placebo-controlled, Phase I trial. Safe and effective vaccines are still urgently needed to cope with the ongoing COVID-19 pandemic. Recently, we developed a recombinant COVID-19 vaccine (V-01) containing fusion protein (IFN-PADRE-RBD-Fc dimer) as antigen verified to induce protective immunity against SARS-CoV-2 challenge in pre-clinical study, which supported progression to Phase I clinical trials in humans. A Randomized, double-blind, placebo-controlled Phase I clinical trial was initiated at the Guangdong Provincial Center for Disease Control and Prevention (Gaozhou, China) in February 2021. Healthy adults aged between 18 and 59 years and over 60 years were sequentially enrolled and randomly allocated into three subgroups (1:1:1) either to receive the vaccine (10, 25, and 50 Î¼g) or placebo (V-01: Placebo = 4:1) intramuscularly with a 21-day interval by a sentinel and dose escalation design. The data showed a promising safety profile with approximately 25% vaccine-related overall adverse events (AEs) within 30 days and no grade 3 or worse AEs. Besides, V-01 provoked rapid and strong immune responses, elicited substantially high-titre neutralizing antibodies and anti-RBD IgG peaked at day 35 or 49 after first dose, presented with encouraging immunogenicity at low dose (10 Î¼g) subgroup and elderly participants, which showed great promise to be used as all-aged (18 and above) vaccine against COVID-19. Taken together, our preliminary findings indicate that V-01 is safe and well tolerated, capable of inducing rapid and strong immune responses, and warrants further testing in Phase II/III clinical trials.
Subacute thyroiditis following COVID-19 vaccination in a 67-year-old male patient: a case report. Subacute thyroiditis is the most common cause of painful thyroid gland diseases. It is characterized by inflammation of the thyroid gland and usually occurs after viral upper respiratory tract infections. Coronavirus disease 2019 (COVID-19) can lead to subacute thyroiditis. There are also vaccine-related subacute thyroiditis cases in the literature. Here, we describe a 67-year-old male patient developing subacute thyroiditis following COVID-19 vaccination.
Leukocytoclastic Vasculitis After Vaccination With a SARS-CoV-2 Vaccine.
Humoral response rate and predictors of response to BNT162b2 mRNA COVID19 vaccine in patients with multiple myeloma. Multiple myeloma (MM) patients are at excess risk for clinically significant COVID19 infection. BNT162b2 mRNA COVID19 (BNT162b2) vaccine provides effective protection against COVID19 for the general population, yet its effect in MM patients may be compromised due to disease and therapy-related factors and was not yet evaluated. This single-centre prospective study included MM patients tested for serological response 14-21Â days post second vaccine. Vaccinated healthy volunteers served as controls. In all, 171 MM patients, median age 70 (38-94) were included; 159 active MM and 12 smouldering myeloma (SMM). Seropositive response rate (median titer) was 76% (91Â U/ml) in active MM patients vs 98% (992Â U/ml) in the 64

controls (PÂ <Â 0Â·0001), and 100% (822Â U/ml) in SMM patients. Multivariate analysis revealed older age (PÂ =Â 0Â·009), exposure to â‰¥4 novel anti-myeloma drugs (PÂ =Â 0Â·02) and hypogammaglobulinaemia (PÂ =Â 0Â·002) were associated with lower response rates. None of the novel agents significantly decreased response rate, whereas daratumumab trended towards reduced response (PÂ =Â 0Â·08). Adverse events occurred in 53% and 55% of the MM patients and controls, respectively, all transient grade 1-2. In conclusion, BNT162b2 vaccine was safe and provided a high seropositivity rate in MM patients, independent of treatment type. Older, hypogammaglobulinaemic and heavily pretreated patients had lower response rates.

A generalized pustular psoriasis flare after CoronaVac COVID-19 vaccination: Case report. CoronoVac is a non-viable vaccine for severe acute respiratory syndrome coronavirus 2 (SARSCoV-2). Nowadays, there has been vaccination program for at-risk groups and older adults in Turkey. We here present 72-year-old male psoriasis patient who developed generalized pustular psoriasis flare after administration of CoronoVac. The COVID-PCR test was negative and investigations for flare etiology were all normal. He was first (to the best of our knowledge) psoriasis patient who developed an erythrodermic flare after the first dose of CoronaVac vaccine.

COVID-19 Vaccination Acceptance and Its Associated Factors in Sodo Town, Wolaita Zone, Southern Ethiopia: Cross-Sectional Study. BACKGROUND: Coronavirus disease (COVID-19) pandemic has still affected many countries around the world. The COVID-19 vaccine has been presented as the perfect solution for solving the current pandemic. Understanding the willingness of the community to receive the COVID-19 vaccine will help in the development and implementation of effective COVID-19 vaccination promotion programs. The aim of this study was to assess the COVID-19 vaccination acceptance and its associated factors in Sodo town, Wolaita zone, Southern Ethiopia. METHODS: A community-based cross-sectional study was conducted among 415 participants in Wolaita Sodo, from April 1 to 30, 2021. To collect data, structured interviewer administered questionnaire was used. A p-value â‰¤0.05 in a multivariable logistic regression model was considered statistically significant. RESULTS: Of 415 participants, 189 (45.5%) of them accepted of COVID-19 vaccines if available. Sex (AOR=2.15, 95% CI: 1.29, 3.56), educational status (AOR=3.09, 95% CI: 1.50, 6.37), mass media (AOR=1.97, 95% CI: 1.06, 3.63), received any vaccination during childhood (AOR=5.16, 95% CI: 2.44, 10.92), family members have been diagnosed with COVID-19 (AOR=4.40, 95% CI: 2.1, 9.25), friends have been diagnosed with COVID-19 (AOR=3.91, 95% CI: 1.52, 10.04), and respondents have tested for COVID-19 (AOR=4.40, 95% CI: 1.70, 11.36) were significantly associated with acceptance of COVID-19 vaccine. CONCLUSION: The prevalence of COVID-19 vaccination acceptance was law. To enhance the acceptance of COVID-19 vaccine, the government with different stakeholders should strengthen public education using mass media about the advantage of getting COVID-19 vaccination.

We Cannot Win the Access to Medicines Struggle Using the Same Thinking That Causes the Chronic Access Crisis. The inequity in access to COVID-19 vaccines that we are witnessing today is yet another symptom of a pharmaceutical economy that is not fit for purpose. That it was possible to develop multiple COVID-19 vaccines in less than a year, while at the same time fostering extreme inequities, calls for transformative change in the health innovation and access ecosystem. Brought into the spotlight through the AIDS drugs access crisis, challenges in accessing lifesaving medicines and vaccines-because they are either not available or inaccessible due to excessive pricing-are being faced by people all over the world. To appreciate the underlying framing of current access discussions, it is important to understand past trends in global health policies and the thinking behind the institutions and mechanisms that were designed to solve access problems. Contrary to what might be expected, certain types of solutions intrinsically carry the conditions that enable scarcity, rationing, and inequity, and lead us away from ensuring the right to health. Analyzing the root causes of access problems and the political economy that allows them to persist and even become

exacerbated is necessary to fix access inequities today and to design better solutions to ensure equitable access to health technologies in the future.

COVID-19: SARS-CoV-2 Vaccine-Induced Immune Thrombotic Thrombocytopenia.

Cerebral Venous Thrombosis.

Safety and Efficacy of NVX-CoV2373 Covid-19 Vaccine. BACKGROUND: Early clinical data from studies of the NVX-CoV2373 vaccine (Novavax), a recombinant nanoparticle vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that contains the full-length spike glycoprotein of the prototype strain plus Matrix-M adjuvant, showed that the vaccine was safe and associated with a robust immune response in healthy adult participants. Additional data were needed regarding the efficacy, immunogenicity, and safety of this vaccine in a larger population. METHODS: In this phase 3, randomized, observer-blinded, placebo-controlled trial conducted at 33 sites in the United Kingdom, we assigned adults between the ages of 18 and 84 years in a 1:1 ratio to receive two intramuscular 5-Î¼g doses of NVX-CoV2373 or placebo administered 21 days apart. The primary efficacy end point was virologically confirmed mild, moderate, or severe SARS-CoV-2 infection with an onset at least 7 days after the second injection in participants who were serologically negative at baseline. RESULTS: A total of 15,187 participants underwent randomization, and 14,039 were included in the per-protocol efficacy population. Of the participants, 27.9% were 65 years of age or older, and 44.6% had coexisting illnesses. Infections were reported in 10 participants in the vaccine group and in 96 in the placebo group, with a symptom onset of at least 7 days after the second injection, for a vaccine efficacy of 89.7% (95% confidence interval [CI], 80.2 to 94.6). No hospitalizations or deaths were reported among the 10 cases in the vaccine group. Five cases of severe infection were reported, all of which were in the placebo group. A post hoc analysis showed an efficacy of 86.3% (95% CI, 71.3 to 93.5) against the B.1.1.7 (or alpha) variant and 96.4% (95% CI, 73.8 to 99.5) against non-B.1.1.7 variants. Reactogenicity was generally mild and transient. The incidence of serious adverse events was low and similar in the two groups. CONCLUSIONS: A two-dose regimen of the NVX-CoV2373 vaccine administered to adult participants conferred 89.7% protection against SARS-CoV-2 infection and showed high efficacy against the B.1.1.7 variant. (Funded by Novavax; EudraCT number, 2020-004123-16.).

Aphasia seven days after second dose of an mRNA-based SARS-CoV-2 vaccine. OBJECTIVES: Though rare, neurological side effects of SARS-CoV-2 vaccinations are increasingly reported. Even if the first dosage goes uncomplicated, the second dose may be complicated by severe adverse reactions as in the following case. CASE REPORT: A 52yo male developed sudden-onset reading difficulty and aphasia 7d after the second dose of an mRNA-based SARS-CoV-2 vaccine. He had a previous history of myocardial infarction, arterial hypertension, hyperlipidemia, and nephrolithiasis. Blood pressure was slightly elevated on admission. Blood tests revealed mildly elevated D-dimer, pre-diabetes and hyperuricemia. Cerebral magnetic resonance imaging revealed an intracerebral bleeding (ICB) in the left temporal lobe. Aphasia resolved almost completely within a few days. Blood pressure values were normal throughout hospitalisation. Whether there was a causal relation between the ICB and the vaccination remains speculative but cannot be definitively excluded. CONCLUSIONS: A second dose of a SARS-CoV-2 vaccination may be followed by ICB. Though the pathophysiology of ICB remains unexplained a causal relation between ICB and the vaccination cannot be excluded. Risk factors for ICB should be carefully monitored in patients undergoing SARS-CoV-2 vaccination.

Comparing Results of Five SARS-CoV-2 Antibody Assays Before and After the First Dose of ChAdOx1 nCoV-19 Vaccine among Health Care Workers. Reliable results regarding serologic positivity for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody before and after AstraZeneca (AZ) vaccination are essential for estimating the efficacy of vaccination. We assessed positivity rates and associated factors using five SARS-CoV-2 antibody assays. A total of 228 paired

serum samples (456 samples) were obtained from 228 participants. After baseline sampling, the second sampling was conducted between 11 and 28â€‰days after the first dose of the AZ vaccine. Sera were tested using five SARS-CoV-2 antibody assays, including two surrogate virus neutralization tests. A questionnaire on the symptoms, severity, and duration of adverse reactions was completed by all participants. The overall positivity rates for SARS-CoV-2 antibody were 84.6% for the Roche assay, 92.5% for the Abbott assay, 75.4% for the Siemens assay, 90.7% for the SD Biosensor assay, and 66.2% for the GenScript assay after the first dose of the AZ vaccine. The positivity rates and antibody titers of sera obtained between 21 and 28â€‰days were significantly higher than those obtained between 11 and 20â€‰days in all five assays. More-severe adverse reactions and longer durations of adverse reactions were related to higher SARS-CoV-2 antibody levels. The agreements and correlations among the assays applied were substantial (Đº, 0.73 to 0.95) and strong (Ï•, 0.83 to 0.91). A single dose of the AZ vaccine led to high positivity rates based on the five assays. Days after vaccination and adverse reactions could help estimate serologic conversion rates. The results should be interpreted cautiously considering the assays and cutoffs applied. Our findings could inform decisions regarding vaccination and laboratory settings and could thus contribute to the control of the spread of SARS-CoV-2 infection.

Vaccine-induced thrombotic thrombocytopenia: the elusive link between thrombosis and adenovirus-based SARS-CoV-2 vaccines. The amazing effort of vaccination against COVID-19, with more than 2 billion vaccine doses administered all around the world as of 16 June 2021, has changed the history of this pandemic, drastically reducing the number of severe cases or deaths in countries were mass vaccination campaign have been carried out. However, the people's rising enthusiasm has been blunted in late February 2021 by the report of several cases of unusual thrombotic events in combination with thrombocytopenia after vaccination with ChAdOx1 nCov-19 (Vaxzevria), and a few months later also after Ad26.COV2. S vaccines. Of note, both products used an Adenovirus-based (AdV) platform to deliver the mRNA molecule - coding for the spike protein of SARS-CoV-2. A clinical entity characterized by cerebral and/or splanchnic vein thrombosis, often associated with multiple thromboses, with thrombocytopenia and bleeding, and sometimes disseminated intravascular coagulation (DIC), was soon recognized as a new syndrome, named vaccine-induced immune thrombotic thrombocytopenia (VITT) or thrombosis with thrombocytopenia syndrome (TTS). VITT was mainly observed in females under 55 years of age, between 4 and 16 days after receiving only Adenovirus-based vaccine and displayed a seriously high fatality rate. This prompted the Medicine Regulatory Agencies of various countries to enforce the pharmacovigilance programs, and to provide some advices to restrict the use of AdV-based vaccines to some age groups. This point-of view is aimed at providing a comprehensive review of epidemiological issues, pathogenetic hypothesis and treatment strategies of this rare but compelling syndrome, thus helping physicians to offer an up-to dated and evidence-based counseling to their often alarmed patients.

A spectrum of cardiac manifestations post Pfizer-BioNTech COVID-19 vaccination.

Indications for and contraindications of immune checkpoint inhibitors in cancer patients with COVID-19 vaccination. The COVID-19 pandemic has lasted over 1 year and will not disappear in a short time. There is no specific remedy against the virusÂ as yet. Vaccination is thus far one of the most important strategies for preventing COVID-19. Cancer patients with COVID-19 have a higher mortality because of immunosuppression. Immune checkpoint inhibitors (ICIs) are a novel anticancer strategy for blocking inhibitory pathways, which are related to the immune response. There is a question regarding whether COVID-19 vaccination and ICI treatment impact each other in cancer patients. This review explores both sides of the relationship between ICI treatment and COVID-19 vaccination and suggests good efficacy and safety of ICI treatment after COVID-19 vaccination as well as little impact on the virus protection and toxicity associated with COVID-19 vaccination during ICI treatment.

   Lay abstract The COVID-19 pandemic has lasted over 1 year. Vaccination is a promising strategy for preventing COVID-19. Cancer patients are prone to infection with COVID-19, and these patients have high mortality. Immune checkpoint inhibitors (ICIs) are a novel anticancer strategy. Whether COVID-19 vaccination and ICI treatment impact each other in cancer patients remains unknown. This review explores both sides of the relationship between ICI treatment and COVID-19 vaccination and suggests good efficacy and safety of ICI treatment after COVID-19 vaccination as well as little impact on the virus protection and toxicity associated with COVID-19 vaccination during ICI treatment.
Cutaneous thrombosis associated with skin necrosis following Oxford-AstraZeneca COVID-19 vaccination.
Watch out for neuromyelitis optica spectrum disorder after inactivated virus vaccination for COVID-19. With recent availability of COVID-19 vaccine, post-vaccination neurological complications had been occasionally reported. Here, we reported for the first time a case of neuromyelitis optica spectrum disorder (NMOSD) that developed after the first dose of inactivated virus vaccine for COVID-19. The patient developed mild fever, vomiting, diarrhea, and cough after receiving the first dose of inactivated virus vaccine. Two months later, she experienced dizziness and unsteady walking. MRI scanning of the brain revealed lesions in area postrema and bilateral hypothalamus, typical for NMOSD. Serum antibodies for AQP4, ANA, SSA, SSB, Ro-52, and p-ANCA were positive. The patient was diagnosed as AQP4-positive NMOSD with coexisting systemic autoimmunity. After treatment with methylprednisolone (500Â mg for 5Â days), symptoms were greatly relieved. As NMOSD is seriously harmful and curative, it is important to be aware of the NMOSD symptoms after vaccination. Cautions should be given for those with preexisting systemic autoimmune abnormalities in vaccination for COVID-19.
T-cell mediated immunity after AZD1222 vaccination: A polyfunctional spike-specific Th1 response with a diverse TCR repertoire. AZD1222 (ChAdOx1 nCoV-19), a replication-deficient simian adenovirus-vectored vaccine, has demonstrated safety, efficacy, and immunogenicity against coronavirus disease 2019 (COVID-19) in clinical trials and real-world studies. We characterized CD4+ and CD8+ T-cell responses induced by AZD1222 vaccination in peripheral blood mononuclear cells (PBMCs) from 280 unique vaccine recipients aged 18-85 years who enrolled in the phase 2/3 COV002 trial. Total spike-specific CD4+ T cell helper type 1 (Th1) and CD8+ T-cell responses were significantly increased in AZD1222-vaccinated adults of all ages following two doses of AZD1222. CD4+ Th2 responses following AZD1222 vaccination were not detected. Furthermore, AZD1222-specific Th1 and CD8+ T cells both displayed a high degree of polyfunctionality in all adult age groups. T-cell receptor (TCR) Î² sequences from vaccinated participants mapped against TCR sequences known to react to SARS-CoV-2 revealed substantial breadth and depth across the SARS-CoV-2 spike protein for the AZD1222-induced CD4+ and CD8+ T-cell responses. Overall, AZD1222 vaccination induced a robust, polyfunctional Th1-dominated T-cell response, with broad CD4+ and CD8+ T-cell coverage across the SARS-CoV-2 spike protein. ONE SENTENCE SUMMARY: Polyfunctional CD4+ and CD8+ T-cell responses are elicited against the SARS-CoV-2 spike protein following vaccination with AZD1222.
Acute myocarditis following administration of BNT162b2 vaccine. The wide use of vaccines was linked with rare but serious complications in adults, causing a global concern. Here, we describe a young male patient, who presented with acute myocarditis, three days after the second dose of BNT162b2 vaccine.
Gastroparesis After Pfizer-BioNTech COVID-19 Vaccination.
Case of Guillain-BarrÃ© syndrome following COVID-19 vaccine. Guillain-BarrÃ© syndrome (GBS) is a rare immune-mediated disorder of the peripheral nerves. Although its cause is not fully understood, the syndrome often follows infection with a virus or bacteria, although in rare occasions,

vaccination may precede GBS. We describe a case of a 62-year-old woman who presented with paraesthesia and progressive weakness of both lower limbs over 3â€‰days. Clinical examination and investigation findings including lumbar puncture and nerve conduction studies were consistent with the diagnosis of GBS. She had no history of either diarrhoea or respiratory tract infections preceding her presentation. However, she had her first intramuscular dose of the Oxford/AstraZeneca COVID-19 vaccine 11 days prior to her presentation. Although no direct link could be ascertained, the purpose of this report is to highlight the incidence and consider this issue while evaluating any case of GBS in the light of the current pandemic and vaccination programme.
Acute Macular Neuroretinopathy following Coronavirus Disease 2019 Vaccination. Purpose: To report acute macular neuroretinopathy (AMN) in two young women two days after receiving Vaxzevria Coronavirus disease (COVID-19) vaccination.Methods: Observational case reports.Observation: The first patient was an Italian 22-year-old female with acute onset of paracentral scotoma two days post vaccination. The second patient was an Austrian 28-year-old female who presented with sudden onset paracentral scotoma two days after vaccination. Multimodal retinal imaging was consistent with AMN in both cases. Both patients were on long-term oral contraceptives, had no history of COVID-19 and experienced one-day duration fever the day after the vaccination.Conclusions: Vaccination may represent a possible risk factor for AMN onset in women on oral contraceptives. We encourage ophthalmologists to investigate recent vaccination status when dealing with new onset AMN. Further studies are needed to assess the link between vaccinations and AMN.
Anti-PF4 antibody negative cerebral venous sinus thrombosis without thrombocytopenia following immunization with COVID-19 vaccine in an elderly non-comorbid Indian male, managed with conventional heparin-warfarin based anticoagulation.
Indian citizen's perspective about side effects of COVID-19 vaccine - A machine learning study. BACKGROUND AND AIMS: Ever since the vaccination drive for COVID-19 has started in India, the citizens have been sharing their views on social media about it. The present study examines the attitude of Indian citizens towards the side effects of the COVID-19 vaccine. METHODS: Social media posts were used for this research. Using Python, we have collected social media posts of Indians focusing on side effects of COVID -19 vaccines. In study one, sentimental analysis was done to find overall attitude of Indian citizens towards the side effects of COVID-19 vaccine and in study two, topic modeling done to analyze the major side effects voiced out by the citizens after taking COVID-19 vaccine. RESULTS: The studies conducted have revealed that nearly 78.5% of tweets posted by Indian citizens about the side effects of the COVID-19 vaccine were either in neutral or positive sentiments. Our topic modeling studies have found that fear of efficiency in the workplace and the fear of death as the prime two issues that contributes Indian citizens to have negative sentiment about the side effects of the COVID-19 vaccine. CONCLUSION: While it is important for the Indian government to actively encourage its citizens to have vaccine, it is also important to help the citizens understand the important of the vaccination program. The best way to educate citizens regarding the positive aspect of the vaccination program is by addressing the fears, Indian citizens have voiced in their social media post about the COVID-19 vaccines.
COVID-19 vaccine induced rhabdomyolysis: Case report with literature review.
Exacerbation of hyperglycemia in patients with type 2 diabetes after vaccination for COVID19: Report of three cases.
Innate immunity, inflammation activation and heat-shock protein in COVID-19 pathogenesis. SARS-CoV-2-induced COVID-19 is a serious pandemic of the 21st century, which has caused a devastating loss of lives and a global economic catastrophe. A successful vaccine against SARS-CoV-2 has suffered a delay due to lack of substantial knowledge about its mechanisms of action.

Understanding the innate immune system against SARS-CoV-2 and the role of heat shock proteins' (HSP) inhibiting and resolution of inflammatory pathways may provide information to the low SARS-CoV-2 mortality rates in Africa. In addition, bats being a host to different viruses, including SARS-CoV-2 possess a well specialized IFN-innate antiviral inflammatory response, showing no signs of disease or pro-inflammatory cytokine storm. We discuss the molecular pathways in COVID-19 with a focus on innate immunity, inflammation, HSP responses, and suggest appropriate candidates for therapeutic targets and The contribution of the innate immune system to the efficacy of mRNA or vector based Corona immunizations.
Acute hyperglycaemic crisis after vaccination against COVID-19: A case series.
Patients With Acute Myocarditis Following mRNA COVID-19 Vaccination. IMPORTANCE: Vaccine-associated myocarditis is an unusual entity that has been described for the smallpox vaccine, but only anecdotal case reports have been described for other vaccines. Whether COVID-19 vaccination may be linked to the occurrence of myocarditis is unknown. OBJECTIVE: To describe a group of 7 patients with acute myocarditis over 3 months, 4 of whom had recent messenger RNA (mRNA) COVID-19 vaccination. DESIGN, SETTING, AND PARTICIPANTS: All patients referred for cardiovascular magnetic resonance imaging at Duke University Medical Center were asked to participate in a prospective outcomes registry. Two searches of the registry database were performed: first, to identify patients with acute myocarditis for the 3-month period between February 1 and April 30 for 2017 through 2021, and second, to identify all patients with possible vaccine-associated myocarditis for the past 20 years. Once patients with possible vaccine-associated myocarditis were identified, data available in the registry were supplemented by additional data collection from the electronic health record and a telephone interview. EXPOSURES: mRNA COVID-19 vaccine. MAIN OUTCOMES AND MEASURES: Occurrence of acute myocarditis by cardiovascular magnetic resonance imaging. RESULTS: In the 3-month period between February 1 and April 30, 2021, 7 patients with acute myocarditis were identified, of which 4 occurred within 5 days of COVID-19 vaccination. Three were younger male individuals (age, 23-36 years) and 1 was a 70-year-old female individual. All 4 had received the second dose of an mRNA vaccine (2 received mRNA-1273 [Moderna], and 2 received BNT162b2 [Pfizer]). All presented with severe chest pain, had biomarker evidence of myocardial injury, and were hospitalized. Coincident testing for COVID-19 and respiratory viruses provided no alternative explanation. Cardiac magnetic resonance imaging findings were typical for myocarditis, including regional dysfunction, late gadolinium enhancement, and elevated native T1 and T2. CONCLUSIONS AND RELEVANCE: In this study, magnetic resonance imaging findings were found to be consistent with acute myocarditis in 7 patients; 4 of whom had preceding COVID-19 vaccination. Further investigation is needed to determine associations of COVID-19 vaccination and myocarditis.
Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military. IMPORTANCE: Myocarditis has been reported with COVID-19 but is not clearly recognized as a possible adverse event following COVID-19 vaccination. OBJECTIVE: To describe myocarditis presenting after COVID-19 vaccination within the Military Health System. DESIGN, SETTING, AND PARTICIPANTS: This retrospective case series studied patients within the US Military Health System who experienced myocarditis after COVID-19 vaccination between January and April 2021. Patients who sought care for chest pain following COVID-19 vaccination and were subsequently diagnosed with clinical myocarditis were included. EXPOSURE: Receipt of a messenger RNA (mRNA) COVID-19 vaccine between January 1 and April 30, 2021. MAIN OUTCOMES AND MEASURES: Clinical diagnosis of myocarditis after COVID-19 vaccination in the absence of other identified causes. RESULTS: A total of 23 male patients (22 currently serving in the military and 1 retiree; median [range] age, 25 [20-51] years) presented with acute onset of marked chest pain within 4 days after receipt of an mRNA COVID-19 vaccine. All military members were previously healthy with a high level of fitness. Seven

received the BNT162b2-mRNA vaccine and 16 received the mRNA-1273 vaccine. A total of 20 patients had symptom onset following the second dose of an appropriately spaced 2-dose series. All patients had significantly elevated cardiac troponin levels. Among 8 patients who underwent cardiac magnetic resonance imaging within the acute phase of illness, all had findings consistent with the clinical diagnosis of myocarditis. Additional testing did not identify other etiologies for myocarditis, including acute COVID-19 and other infections, ischemic injury, or underlying autoimmune conditions. All patients received brief supportive care and were recovered or recovering at the time of this report. The military administered more than 2.8 million doses of mRNA COVID-19 vaccine in this period. While the observed number of myocarditis cases was small, the number was higher than expected among male military members after a second vaccine dose. CONCLUSIONS AND RELEVANCE: In this case series, myocarditis occurred in previously healthy military patients with similar clinical presentations following receipt of an mRNA COVID-19 vaccine. Further surveillance and evaluation of this adverse event following immunization is warranted. Potential for rare vaccine-related adverse events must be considered in the context of the well-established risk of morbidity, including cardiac injury, following COVID-19 infection.
Facial paralysis and vaccinations: a vaccine adverse event reporting system review. BACKGROUND: Vaccinations are a cornerstone of preventative medicine in the USA. However, growing concerns regarding facial nerve palsy following vaccination exist. OBJECTIVE: This study aims to assess the occurrence of facial palsy as reported by the Vaccine Adverse Event Reporting System (VAERS) database. METHODS: A retrospective analysis of the VAERS database was performed for cases of 'Facial Palsy', 'Bell's Palsy', 'Facial Paralysis' and 'Ramsay Hunt Syndrome' between 2009 and 2018. Subgroup analysis was performed to determine gender, age, history of facial palsy, type of vaccine used, number of days until onset of symptoms and overall facial palsy rate. RESULTS: Nine hundred and forty-four entries met our inclusion criteria with 961 vaccine administrations resulting in facial paralysis. Facial palsy following vaccinations was evenly distributed across all age cohorts with two peaks between 60 and 74 years old and between 0 and 14 years old. Most patients were female (N = 526, 55.7%) without a reported history of facial palsy (N = 923, 97.8%). In 2009, reported incidence rate was 0.53%, as compared with 0.23% in 2018. The influenza vaccine had the greatest number of cases (N = 166, 17.3%), followed by the varicella (N = 87, 9.1%) and human papillomavirus vaccines (N = 47, 4.9%). CONCLUSIONS: With the SARS-CoV-2 pandemic and recent approvals of the vaccinations, there is growing concern of facial palsy following vaccination. Although it is a known adverse event following vaccination, the likelihood of facial palsy following vaccination is low, with only 0.26% of overall reported cases over a 10-year span.
18F-Fluciclovine-Avid Reactive Axillary Lymph Nodes After COVID-19 Vaccination. A 74-year-old man presenting with biochemical recurrent prostate cancer 9 months after robotic-assisted radical prostatectomy and pelvic lymphadenectomy underwent 18F-fluciclovine PET/CT for restaging to determine subsequent treatment strategy. Serum prostate-specific antigen was 0.7 ng/mL at the time of imaging. Images demonstrated foci of abnormal increased 18F-fluciclovine uptake corresponding to prominent round lymph nodes in the left axilla, some of which with fatty hila. Due to recent mRNA COVID-19 vaccination in the ipsilateral arm and the low likelihood of nodal metastases to the axilla from prostate cancer in this patient, the lymph nodes were considered to be benign, reactive to the vaccine.
Persistence and baseline determinants of seropositivity and reinfection rates in health care workers up to 12.5 months after COVID-19. We assessed the duration and baseline determinants of antibody responses to SARS-CoV-2 spike antigens and the occurrence of reinfections in a prospective cohort of 173 Spanish primary health care worker patients followed initially for 9 months and subsequently up to 12.5 months after COVID-19 symptoms onset. Seropositivity to SARS-CoV-2 spike

and receptor-binding domain antigens up to 149-270 days was 92.49% (90.17% IgG, 76.3% IgA, 60.69% IgM). In a subset of 64 health care workers who had not yet been vaccinated by April 2021, seropositivity was 96.88% (95.31% IgG, 82.81% IgA) up to 322-379 days post symptoms onset. Four suspected reinfections were detected by passive case detection, two among seronegative individuals (5 and 7 months after the first episode), and one low antibody responder. Antibody levels significantly correlated with fever, hospitalization, anosmia/hypogeusia, allergies, smoking, and occupation. Stable sustainment of IgG responses raises hope for long-lasting COVID-19 vaccine immunity.

SARS-CoV-2 mRNA vaccines induce persistent human germinal centre responses. SARS-CoV-2 mRNA-based vaccines are about 95% effective in preventing COVID-19(1-5). The dynamics of antibody-secreting plasmablasts and germinal centre BÂ cells induced by these vaccines in humans remain unclear. Here we examined antigen-specific BÂ cell responses in peripheral blood (nÂ =Â 41) and draining lymph nodes in 14Â individuals who had received 2Â doses of BNT162b2, an mRNA-based vaccine that encodes the full-length SARS-CoV-2 spike (S) gene(1). Circulating IgG- and IgA-secreting plasmablasts that target the S protein peaked one week after the second immunization and then declined, becoming undetectable three weeks later. These plasmablast responses preceded maximal levels of serum anti-S binding and neutralizing antibodies to an early circulating SARS-CoV-2 strain as well as emerging variants, especially in individuals who had previously been infected with SARS-CoV-2 (who produced the most robust serological responses). By examining fine needle aspirates of draining axillary lymph nodes, we identified germinal centre B cells that bound S protein in all participants who were sampled after primary immunization. High frequencies of S-binding germinal centre BÂ cells and plasmablasts were sustained in these draining lymph nodes for at least 12Â weeks after the booster immunization. S-binding monoclonal antibodies derived from germinal centre BÂ cells predominantly targeted the receptor-binding domain of the S protein, and fewer clones bound to the N-terminal domain or to epitopes shared with the S proteins of the human betacoronaviruses OC43 and HKU1. These latter cross-reactive B cell clones had higher levels of somatic hypermutation as compared to those that recognized only the SARS-CoV-2 S protein, which suggests a memory BÂ cell origin. Our studies demonstrate that SARS-CoV-2 mRNA-based vaccination of humans induces a persistent germinal centre BÂ cell response, which enables the generation of robust humoral immunity.

A case of longitudinally extensive transverse myelitis following vaccination against Covid-19. BACKGROUND: Longitudinally extensive transverse myelitis (LETM) is a rare subtype of transverse myelitis (TM) that potentially results in relevant disability. Apart from association to neuromyelitis optica and other chronic demyelinating diseases of the central nervous system, many other aetiologies are known. Particularly systemic infections and vaccination are considered potential triggers for immune mediated inflammation of the spinal cord. In the course of the current Covid-19 pandemic several cases of TM following Covid-19 infection have been described. Here we present a case of LETM following vaccination against Covid-19 with AZD1222, AstraZeneca. An extensive diagnostic work up was performed to rule out alternative causes, including prior and current Covid-19 infection. CONCLUSION: To our knowledge this is first case of LETM possibly related to Covid-19 vaccination that is published after marketing authorisation of various vaccine candidates.

Common Variable Immunodeficiency Disorders, T-Cell Responses to SARS-CoV-2 Vaccines, and the Risk of Chronic COVID-19. COVID-19 has had a calamitous effect on the global community. Despite intense study, the immunologic response to the infection is only partially understood. In addition to older age and ethnicity, patients with comorbidities including obesity, diabetes, hypertension, coronary artery disease, malignancy, renal, and pulmonary disease may experience severe outcomes. Some patients with primary immunodeficiency (PID) and secondary

immunodeficiency also appear to be at increased risk from COVID-19. In addition to vulnerability to SARS-CoV-2, patients with PIDs often have chronic pulmonary disease and may not respond to vaccines, which exacerbates their long-term risk. Patients with common variable immunodeficiency disorders, the most frequent symptomatic PID in adults and children, have a spectrum of B- and T-cell defects. It may be possible to stratify their risk for severe COVID-19 based on age, ethnicity, the severity of the T-cell defect, and the presence of other comorbidities. Patients with common variable immunodeficiency disorders and other immunodeficiencies are at risk for Chronic COVID-19, a dangerous stalemate between a suboptimal immune response and SARS-CoV-2. Intra-host viral evolution could result in the rapid emergence of vaccine-resistant mutants and variants of high consequence; it is a public health emergency. Vaccination and prevention of Chronic COVID-19 in immunodeficient patients is therefore of the utmost priority. Having a reliable diagnostic assay for T-cell immunity to SARS-CoV-2 is critical for evaluating responses to vaccines in these patients. New treatments for SARS-CoV-2 such as NZACE2-PÄ•tari are likely to be particularly beneficial for immunodeficient patients, especially those who fail to mount a robust T-cell response to COVID-19 vaccines.
De Novo and Relapsing Glomerular Diseases After COVID-19 Vaccination: What Do We Know So Far?
Thrombosis With Thrombocytopenia After the Messenger RNA-1273 Vaccine.
Thrombosis After Vaccination With Messenger RNA-1273: Is This Vaccine-Induced Thrombosis and Thrombocytopenia or Thrombosis With Thrombocytopenia Syndrome? In their article, Sangli and colleagues described catastrophic thrombosis after the second dose of the SARS-CoV-2 messenger RNAâ€“1273 vaccine from Moderna. The editorialists discuss vaccine-induced thrombosis and thrombocytopenia and thrombosis with thrombocytopenia syndrome and why this case cannot be definitively attributed to the vaccine. They also note that the remarkable speed with which clinicians and scientists have recognized this rare entity and developed evidence-based diagnosis and treatment guidelines should bolster public confidence in postlicensure vaccine safety monitoring.
Relapse of minimal change disease after inactivated SARS-CoV-2 vaccination: case report.
Intolerance Reaction After Vaccination Against SARS-CoV-2.
Self-limited myocarditis presenting with chest pain and ST segment elevation in adolescents after vaccination with the BNT162b2 mRNA vaccine. Two adolescent males presented within 3 days after the first and second dose of the BNT162b2 vaccine with chest pain. Elevated troponin levels, ST segment elevation, and enhancement of the myocardium in cardiac MRI suggested myocarditis. Left ventricular function remained normal, symptoms resolved, and patients were discharged in 4 days. BNT162b2 vaccine may be associated with self-limited myocarditis in youth.
COVID-19 vaccines: concerns beyond protective efficacy and safety. INTRODUCTION: Several vaccine candidates have been developed using different platforms, including nucleic acids (DNA and RNA), viral vectors (replicating and non-replicating), virus-like particles, peptide-based, recombinant proteins, live attenuated, and inactivated virus modalities. Although many of these vaccines are undergoing pre-clinical trials, several large clinical trials investigating the clinical efficacy and safety of coronavirus disease 2019 (COVID-19) vaccines have produced promising findings. AREAS COVERED: In this review, we provide a status update on COVID-19 vaccines currently undergoing clinical trials and discuss issues of concern beyond vaccine efficacy and safety, including dosing regimens, the mixed vaccine strategy, prior severe acute respiratory syndrome coronavirus-2 infection, antibody levels, cellular immunity and protection, variants of concern, COVID-19 vaccine distribution, vaccination willingness, herd immunity, immunity passports, and vaccine indications. EXPERT OPINION: Four vaccines have obtained emergency use authorization, 87 are at the clinical development stage, and 186 are in pre-clinical development. While the knowledge and development of COVID-19 vaccines is rapidly expanding, the benefits of COVID-19 vaccines must outweigh the potential risks of adverse

events. To combat the COVID-19 pandemic, clinicians should consistently update COVID-19-associated information, and healthcare authorities and manufacturers should work together to provide adequate and appropriate vaccinations for the prevention of COVID-19. PLAIN LANGUAGE SUMMARY: What is the context?Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) caused a global pandemic: the coronavirus disease 2019 (COVID-19) outbreak. The development and implementation of the COVID-19 vaccine could be an important measure to control the COVID-19 pandemic.What is new?Several phase 3 clinical trials have demonstrated the effectiveness and safety of COVID-19 vaccines for the prevention of SARS-CoV-2 infections. Several COVID-19 vaccines have obtained emergency use authorization and been implemented in many countries. Although concerns regarding unusual blood clots and low platelet counts have been raised, the benefits of COVID-19 vaccines outweigh the potential risks of adverse events.What is the impact?Except for children, the COVID-19 vaccine is recommended for all people, including those pregnant or immunocompromised. Healthcare authorities should advise people receiving the vaccine that they must seek medical attention if they have associated thromboembolism and thrombocytopenia symptoms. More studies are necessary to determine the appropriate vaccine dose and regimen strategy, as well as the effectiveness of COVID-19 vaccines against variants of concerns. A global effort must be made to achieve widespread vaccination and herd immunity.

Adverse events after first COVID-19 vaccination in patients with autoimmune diseases.

Vaccine induced thrombotic thrombocytopenia: The shady chapter of a success story. The recognition of the rare but serious and potentially lethal complication of vaccine induced thrombotic thrombocytopenia (VITT) raised concerns regarding the safety of COVID-19 vaccines and led to the reconsideration of vaccination strategies in many countries. Following the description of VITT among recipients of adenoviral vector ChAdOx1 vaccine, a review of similar cases after Ad26.COV2Â·S vaccination gave rise to the question whether this entity may constitute a potential class effect of all adenoviral vector vaccines. Most cases are females, typically younger than 60 years who present shortly (range: 5-30 days) following vaccination with thrombocytopenia and thrombotic manifestations, occasionally in multiple sites. Following initial incertitude, concrete recommendations to guide the diagnosis (clinical suspicion, initial laboratory screening, PF4-polyanion-antibody ELISA) and management of VITT (non-heparin anticoagulants, corticosteroids, intravenous immunoglobulin) have been issued. The mechanisms behind this rare syndrome are currently a subject of active research and include the following: 1) production of PF4-polyanion autoantibodies; 2) adenoviral vector entry in megacaryocytes and subsequent expression of spike protein on platelet surface; 3) direct platelet and endothelial cell binding and activation by the adenoviral vector; 4) activation of endothelial and inflammatory cells by the PF4-polyanion autoantibodies; 5) the presence of an inflammatory co-signal; and 6) the abundance of circulating soluble spike protein variants following vaccination. Apart from the analysis of potential underlying mechanisms, this review aims to synopsize the clinical and epidemiologic features of VITT, to present the current evidence-based recommendations on diagnostic and therapeutic work-up of VITT and to discuss new dilemmas and perspectives that emerged after the description of this entity.

Letter regarding: "A Case of Gross Hematuria and IgA Nephropathy Flare-Up Following SARS-CoV-2 Vaccination".

COVID-19 vaccines and thrombosis with thrombocytopenia syndrome. INTRODUCTION: To combat COVID-19, scientists all over the world have expedited the process of vaccine development. Although interim analyses of clinical trials have demonstrated the efficacy and safety of COVID-19 vaccines, a serious but rare adverse event, thrombosis with thrombocytopenia syndrome (TTS), has been reported following COVID-19 vaccination. AREAS COVERED: This review, using data from both peer-reviewed and non-peer-reviewed studies, aimed to provide updated information about the

critical issue of COVID-19 vaccine-related TTS. EXPERT OPINION: : The exact epidemiological characteristics and possible pathogenesis of this adverse event remain unclear. Most cases of TTS developed in women within 2Â weeks of the first dose of vaccine on the receipt of the ChAdOx1 nCoV-19 and Ad26.COV2.S vaccines. In countries with mass vaccination against COVID-19, clinicians should be aware of the relevant clinical features of this rare adverse event and perform related laboratory and imaging studies for early diagnosis. Non-heparin anticoagulants, such as fondaparinux, argatroban, or a direct oral anticoagulant (e.g. apixaban or rivaroxaban) and intravenous immunoglobulins are recommended for the treatment of TTS. However, further studies are required to explore the underlying mechanisms of this rare clinical entity. PLAIN LANGUAGE SUMMARY: What is the context?Thrombosis with thrombocytopenia syndrome (TTS) usually develops within 2Â weeks of the first doses of the ChAdOx1 nCoV-19 and Ad26.COV2.S COVID-19 vaccines.TTS mainly occurs in patients aged < 55Â years and is associated with high morbidity and mortality.What is new?TTS mimics autoimmune heparin-induced thrombocytopenia and can be mediated by platelet-activating antibodies against platelet factor 4. Non-heparin anticoagulants, such as fondaparinux, argatroban, or a direct oral anticoagulant (e.g. apixaban or rivaroxaban) should be considered as the treatment of choice if the platelet count is > 50Â Ã—Â 10(9)/L and there is no serious bleeding. Intravenous immunoglobulins and glucocorticoids may help increase the platelet count within days and reduce the risk of hemorrhagic transformation when anticoagulation is initiated.What is the impact?TTS should be a serious concern during the implementation of mass COVID-19 vaccination, and patients should be educated about this complication along with its symptoms such as severe headache, blurred vision, seizure, severe and persistent abdominal pain, painful swelling of the lower leg, and chest pain or dyspnea. The incidence of TTS is low; therefore, maintenance of high vaccination coverage against COVID-19 should be continued.

The Levels of SARS-CoV-2 Specific Antibodies in Human Milk Following Vaccination. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines are being administered around the world; however, lactating women were excluded from SARS-CoV-2 vaccine trials. Therefore, knowledge about the effect of vaccination in this specific group is limited. This information is essential to empower lactating women to make a well-informed decision on their choice for vaccination. After natural infection, SARS-CoV-2 specific antibodies are present in human milk, which might offer protection for her newborn. The dynamics of these antibodies in human milk following vaccination remain to be elucidated. RESEARCH AIM: To determine the effect of vaccination with BNT162b2 on the levels of SARS-CoV-2 specific IgA in human milk. METHODS: In this prospective longitudinal study, we included lactating women who received the BNT162b2 vaccine. Human milk samples were collected prior to vaccination and 3, 5, 7, 9, 11, 13, and 15 days after both vaccine doses. Samples were analyzed using enzyme-linked immunosorbent assay against the spike protein of SARS-CoV-2. RESULTS: In total, 366 human milk samples from 26 lactating women were analyzed. A biphasic response was observed, with SARS-CoV-2 specific immunoglobulin A (IgA) starting to increase between day 5 and 7 after the first dose of the vaccine. After the second dose, an accelerated IgA antibody response was observed. CONCLUSION: After vaccination with the mRNA-based BNT162b2 vaccine, a SARS-CoV-2 specific antibody response was observed in human milk. The presence of SARS-CoV-2 specific IgA after vaccination is important as antibodies are transferred via human milk, and thereby might provide protection to infants against COVID-19.

Cold agglutinin disease after COVID-19 vaccine.

Acute Ischemic Stroke Revealing ChAdOx1 nCov-19 Vaccine-Induced Immune Thrombotic Thrombocytopenia: Impact on Recanalization Strategy. Vaccine-induced immune thrombotic thrombocytopenia is a rare syndrome following the ChAdOx1 nCov-19 or Ad26.COV2.S vaccine. Reported patients developed mainly venous thrombosis. We describe a case of a young healthy

women suffering from acute ischemic stroke due to large vessel occlusion without cerebral venous thrombosis 8 days after vaccination and its consequences on recanalization strategy. Considering the thrombocytopenia, intravenous thrombolysis was contraindicated. She underwent mechanical thrombectomy with complete recanalization and dramatically improved clinically. Positive detection of anti-PF4-heparin-antibodies confirmed vaccine-induced immune thrombotic thrombocytopenia diagnosis. In case of acute ischemic stroke after recent ChAdOx1 nCov-19 or Ad26.COV2.S vaccine, platelet count should be systematically checked before giving thrombolysis, and direct mechanical thrombectomy should be proposed in patients with large vessel occlusion.

A patient presenting with ARDS after COVID-19 vaccination: A COVID-19 case report. COVID-19 is a disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). The introduction of vaccines against COVID-19 caused great enthusiasm around the world as immunization might end the pandemic. However, it was previously stated that COVID-19 cases would rarely continue to occur despite immunization. Fourteen days after the second dose of the vaccine, a 66-year-old male patient with a negative COVID-19 PCR test result and high levels of IgG and low levels of IgM-A against SARS-CoV-2 was admitted to our intensive care unit (ICU) due to the clinical picture of Acute Respiratory Distress Syndrome (ARDS). We aimed to stress the need for continuing preventive measures in vaccinated individuals, too, by presenting the clinical findings of the patient, who was considered to have developed ARDS due to COVID-19, as high levels of IgG and IgM-A against SARS-CoV-2 were detected on day 8 during ICU admission.

Potential immune response to breast implants after immunization with COVID-19 vaccines. Besides reports of alarming potential side effects after COVID-19 vaccinations there have been rare observations of rather benign reactions to foreign materials such as cosmetic hyaluronic acid filler injections after a COVID-19 immunization. Likewise to dermal fillers any foreign material may cause a reaction when the immune system is triggered. In the recent weeks we observed four noteworthy potential reactions in association with breast implants between one and three days after COVID-19 vaccinations. We release these information at the earliest to educate colleagues and draw attention to possible reactions between the COVID-19 vaccines and foreign bodies such as breast implants.

Blood clots and bleeding events following BNT162b2 and ChAdOx1 nCoV-19 vaccine: An analysis of European data. The involvement of viruses and SARS-CoV-2 in autoimmune diseases is well known. The recent demonstration that ChAdOx1 nCoV-19 Covid-19 (AstraZeneca) vaccine (ChA) favors the production of anti-platelet factor 4 (anti-PF4) antibodies, blood clots, and thrombocytopenia raises the question of whether other anti-CoViD-19 vaccines favor the same patterns of events. We assessed the frequency of severe adverse events (SAEs) documented in the EudraVigilance European database up to April 16, 2021 related to thrombocytopenia, bleeding, and blood clots in recipients of ChA compared to that of recipients of the BNT162b2 Covid-19 (Pfizer/BioNTech) vaccine (BNT). ChA administration was associated with a much higher frequency of SAEs in each AE Reaction Group as compared with that elicited by BNT. When considering AEs caused by thrombocytopenia, bleeding and blood clots, we observed 33 and 151 SAEs/1 million doses in BNT and ChA recipients, respectively. When considering patients with AEs related to cerebral/splanchnic venous thrombosis, and/or thrombocytopenia, we documented 4 and 30 SAEs and 0.4 and 4.8 deaths/1 million doses for BNT and ChA recipients, respectively. The highest risk following ChA vaccination is in young people and, likely, women of reproductive age, as suggested by hypothesized scenarios. In conclusion, the immune reaction promoted by ChA vaccine may lead to not only thrombocytopenia and cerebral/splanchnic venous thrombosis but also other thrombotic and thromboembolic SAEs. These events are not favored by BNT vaccine. Our study may help in the evaluation of the benefit/risk profile of the ChA vaccine considering the epidemic curve present in a country.

Humoral and Cellular Responses to mRNA-1273 and BNT162b2 SARS-CoV-2 Vaccines Administered to Hemodialysis Patients. RATIONALE & OBJECTIVE: Patients with kidney failure who are receiving maintenance dialysis have a higher risk of infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and worse clinical outcomes after coronavirus disease 2019 (COVID-19) than the general population. Therefore, immunization against SARS-CoV-2 with effective vaccines is an important component of health-maintenance strategies for these patients. This study evaluated the humoral and cellular responses to messenger RNA (mRNA) SARS-CoV-2 vaccines in this population. STUDY DESIGN: Observational prospective multicenter cohort study. SETTING & PARTICIPANTS: 205 patients treated at 3 dialysis units at the Hospital ClÃ-nic of Barcelona (Spain) were vaccinated from February 3 to April 4, 2021, and followed until April 23,Â 2021. EXPOSURE: Immunization with either the mRNA-1273 (Moderna) or BNT162b2 (Pfizer-BioNTech) SARS-CoV-2 mRNA vaccine. OUTCOME: Seroconversion, defined as the detection of IgG antibodies to the receptor-binding domain of the S1 spike antigen of SARS-CoV-2 (anti-S1-RBD IgG), and the identification of activated CD4(+)T cells 3 weeks after completing vaccination. Anti-S1-RBD IgG levels were also analyzed as a secondary outcome. ANALYTICAL APPROACH: Univariate and multivariable logistic and multiple linear regression models were used to evaluate the associations between vaccination and study outcomes. RESULTS: We found that 97.7% of 175 vaccinated patients who were seronegative at baseline developed a response (humoral, cellular, or both); 95.4% of these patients seroconverted, while 62% of those tested for cellular immunity had a positive response. Greater age and immunosuppressive treatment were associated with lower antibody levels. LIMITATIONS: Mandatory vaccine administration by health authorities. Anti-S1-RBD IgG levels were reported up to 150U/mL and cellular immune responses were characterized qualitatively. Antibody assay and cellular response assessment may not be comparable with previously published laboratory approaches. CONCLUSIONS: Immunization with mRNA vaccines generated a humoral and cellular immune response in a high proportion of patients with kidney failure receiving maintenance dialysis. These findings as well as the high risk of infection and poor clinical outcomes among these patients make their vaccination a health priority.

Hyaluronic acid soft tissue filler delayed inflammatory reaction following COVID-19 vaccination - A case report. BACKGROUND: The use of hyaluronic acid soft tissue fillers in aesthetic medicine exploded in recent years for many reasons, including being relatively safe. Incidence of delayed inflammatory reactions (DIRs) to hyaluronic acid soft tissue fillers range between 0.3% and 4.25%. These reactions are mediated by T-lymphocytes and can be triggered by flu-like illnesses, including SARS-CoV-2 infection. Vaccination may also induce hypersensitivity. AIM: In this case report, we present two cases of delayed reaction after hyaluronic acid soft tissue filler treatment of the tear trough area and following mRNA vaccination against SARS-Cov-2, also known as COVID-19, months later. PATIENTS: A 39-year old female who previously had her tear trough area treated with hyaluronic acid soft tissue filler developed swelling days after getting the mRNA Pfizer-BioNTech COVID-19 vaccine. Another patient, a 61-year-olf female, developed intermittent facial swelling in areas previously treated with hyaluronic acid soft tissue fillers days after receiving her first dose of the mRNA Pfizer-BioNTech COVID-19 vaccine. RESULTS: As demonstrated in our case report, vaccination against COVID-19 may induce DIRs in patients who previously had hyaluronic soft tissue fillers. CONCLUSION: Delayed inflammatory reactions to hyaluronic acid soft tissue fillers are uncommon and usually self-limited, with frequent spontaneous resolution. However, considering the ongoing pandemic and the worldwide demand for vaccines against COVID-19, the aesthetic providers should be conscious of the risks posed by the interaction of such vaccines in patients who previously had or seeking hyaluronic acid soft tissue filler injections.

Covid and Cardiovascular Diseases: Direct and Indirect Damages and Future Perspective. SARS-CoV-2 infection determines a disease that predominantly affects lungs. However the cytokines storms, determined by the huge immune response to the infection, could affect also other organs and apparatus such as heart and vessels. Beyond the acute inflammation itself also hypercoagulative status has been linked to SARSCoV-2 infection and this surely relates to the increase seen in prevalence of pulmonary embolism and myocardial infarction. A number of cardiac abnormalities and pathologies have been observed, with special attention to cardiac arrhythmias and myocardial involvement. Furthermore, indirect damages determined by the reduction in acute and chronic cardiovascular care, results in a strong mortality and morbidity outcomes in cardiological patients. In this review we will summarise current knowledge on both direct and indirect cardiovascular damages determined by the SARS-CoV-2 pandemia.
Observing willingness of obtaining the influenza vaccine during and after COVID-19.
Orofacial adverse effects of COVID-19 vaccines exist but are rare. Data sources The US Food and Drug Administration (FDA), Health Canada, European Medicines Agency (EMA)/European Commission and UK's Medicines and Healthcare products Regulatory Agency (MHRA).Study selection Product monographs, product information and consumer medicine information for the BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) vaccines.Data extraction and synthesis Reported side/adverse/undesirable effects concerning the orofacial region were extracted and tabulated.Results There were rare reports of adverse events affecting the orofacial region for both vaccines in their pertaining documents, including acute peripheral facial paralysis (Bell's palsy), facial swelling and swelling of the lips, face or tongue associated with anaphylaxis. There was heterogeneity in the acknowledgement of vaccine-related adverse events in North America compared with Europe.Conclusions There are rare reports of orofacial adverse effects of two mRNA-based COVID-19 vaccines in their documents; however, there are inconsistencies in the description of these adverse effects in different countries.
Successful Liver Transplantation From a Deceased Donor With Vaccine-Induced Thrombotic Thrombocytopenia Causing Cerebral Venous Sinus and Hepatic Veins Thrombosis After ChAdOx1 nCov-19 Vaccination.
Impact of disease-modifying treatments on humoral response after COVID-19 vaccination: A mirror of the response after SARS-CoV-2 infection. OBJECTIVE: To analyze the humoral response after COVID-19 vaccination in patients with multiple sclerosis (MS) according to disease-modifying treatments (DMTs) and in comparison with the humoral response after SARS-CoV-2 infection. METHODS: We included 28 MS patients with serological results after COVID-19 vaccination (Pfizer-BioNTech or Moderna ARNm) and 61 MS patients with serological results after COVID-19 (COVID-19 group) among patients followed up at the MS Center of Strasbourg, France, between January and April 2021. The primary endpoint was the IgG index according to DMTs (anti-CD20 mAb, sphingosine 1-phosphate receptor [S1PR] modulator and other treatments) and COVID-19 vaccine or COVID-19 groups. RESULTS: In the vaccinated MS patients, the median IgG index was lower in patients treated with anti-CD20 mAb and in patients treated with S1PR modulator compared to patients receiving other or no DMTs (4.80 [1.58-28.6], 16.5 [16.3-48.5], 1116 [434-1747] and 1272 [658-1886], respectively, P<0.001). Similar results were found for MS patients after COVID-19. CONCLUSIONS: Patients with MS and treated with S1PR modulators or anti-CD20 mAb had a reduced humoral response after COVID-19 vaccine.
Maternal and Child Symptoms Following COVID-19 Vaccination Among Breastfeeding Mothers. Background: The impact of COVID-19 vaccination on breastfeeding is unknown. The primary aim of this study was to determine whether vaccine-related side effects following COVID-19 vaccination were associated with an adverse impact on breastfeeding. Secondarily, we sought to determine

perceived symptoms in breastfed children and maternal opinion about COVID-19 vaccination. Materials and Methods: We conducted a cross-sectional survey of breastfeeding mothers who underwent COVID-19 vaccination >2 days before the survey. Subjects were recruited through social media and websites. Data included sociodemographic information, vaccine history, maternal and child symptoms, and impact on lactation/breastfeeding. Bivariate statistics (chi-square, Wilcoxon rank sum, and t tests) and multivariable logistic regression models examined the association of vaccine side effects with lactation, symptoms in breastfed children, and maternal opinion on vaccination. Results: Analysis included 4,455 breastfeeding mothers. Maternal postvaccination symptoms were more common after the second dose (pâ€‰<â€‰0.001). Overall, 77 (1.7%) respondents reported a negative impact on breastfeeding postvaccination, and these mothers were more likely to have experienced fatigue, headache, muscle pain, injection site pain, chills, fever, or allergic reactions. After adjusting for confounding variables, higher odds of an adverse impact on lactation were associated with lower breastfeeding intensity, dose of vaccine, and child symptoms. Even among mothers who reported an adverse impact on breastfeeding, maternal opinion about vaccination and confidence in their decision to receive the COVID-19 vaccine were high. Conclusions: COVID-19 vaccination among breastfeeding mothers resulted in minimal disruption of lactation or adverse impact on the breastfed child. These findings may be considered in vaccination decision-making.

Cardiac arrest secondary to Covid19 pneumonia post full vaccination.

Vaccine-Induced Immune Thrombotic Thrombocytopenia with Disseminated Intravascular Coagulation and Death following the ChAdOx1 nCoV-19 Vaccine. Coronavirus is a novel human pathogen causing fulminant respiratory syndrome (COVID-19). Although COVID-19 is primarily a disease of the lungs with florid respiratory manifestations, there are increasing reports of cardiovascular, musculoskeletal, gastrointestinal, and thromboembolic complications. Developing an effective and reliable vaccine was emergently pursued to control the catastrophic spread of the global pandemic. We report a fatal case of vaccine-induced immune thrombotic thrombocytopenia (VITT) after receiving the first dose of the ChAdOx1 nCoV-19 vaccine. We attribute this fatal thrombotic condition to the vaccine due to the remarkable temporal relationship. The proposed mechanism of VITT is production of rogue antibodies against platelet factor-4 resulting in massive platelet aggregation. Healthcare providers should be aware of the possibility of such fatal complication, and the vaccine recipients should be warned about the symptoms of VITT.

Factors associated with reported likelihood to get vaccinated for COVID-19 in a nationally representative US survey. OBJECTIVES: Although general principles related to vaccination hesitancy have been well researched, reports on reluctance to be vaccinated for coronavirus disease 2019 (COVID-19) in the United States are somewhat surprising, given the disease's substantive disruption of everyday life. However, the landscape in which people are making COVID-19 vaccination decisions has recently evolved with releases of encouraging vaccine-related data and changes to official messaging about the virus. Therefore, this study sought to identify factors associated with reported likelihood to get vaccinated for COVID-19 among US adults in late January 2021. STUDY DESIGN: We used the Prolific online research panel to survey a nationally representative sample of 1017 US adults. METHODS: Respondents were asked about their behavioral intentions toward COVID-19 vaccination, trust in science, perceptions related to COVID-19, and selected sociodemographic factors. We computed associations between those 11 independent variables and likelihood to get vaccinated for COVID-19 using multiple linear regression. RESULTS: Around 73.9% of respondents indicated at least some likelihood to get vaccinated for COVID-19. Trust in science and perceived seriousness of COVID-19 were positively associated with intention to get vaccinated, and identifying as Black or African American was negatively associated with intention to get vaccinated. Other factors were moderately, weakly, or not at all associated with intention. CONCLUSIONS: Building trust in

science and truthfully emphasizing the seriousness of catching COVID-19 should be further researched for their potential to support campaigns to encourage COVID-19 vaccination. Data continue to suggest the importance of dialogue with Black communities about COVID-19 vaccination.
High seroconversion rate but low antibody titers after two injections of BNT162b2 (Pfizer-BioNTech) vaccine in patients treated with chemotherapy for solid cancers.
Autoimmune hepatitis developing after the ChAdOx1 nCoV-19 (Oxford-AstraZeneca) vaccine.
Management of patients with Intestinal Bowel Disease and COVID-19: A review of current evidence and future perspectives. The COVID-19 pandemic has been a challenge for countries and health professionals worldwide. Viral entry by ACE-2 receptor and an excessive activation of the immune system are key to understand both incidence and severity of disease. Inflammatory Bowel Disease (IBD) represents a special condition associated with an inordinate response of the immune system to external agents. IBD treatments have been associated to an increased risk of bacterial and viral infections. This has raised the question of possible higher incidence and severity of COVID-19 infection in IBD patients. Several papers have been published during this year of pandemic to answer that question. Moreover, COVID-19 vaccination offers great promise in controlling infection in patients with IBD. Based on current evidence, patients with IBD do not have a higher incidence of COVID-19 than the general population, and they do not have worse disease evolution. Advanced age and presence of a greater number of comorbidities have been associated with worse outcomes, similar to the general population. Corticosteroids are associated to an increased risk of COVID-19 infection, higher hospitalization rate and higher risk of severe COVID-19. 5-ASA/Sulfasalazine and Thiopurines have a possible increased risk of severe COVID-19, although studies are lacking. On the other hand, Anti-TNF may have a possible protective effect. It is recommended to maintain the treatment. Anti-IL-12/23, anti-integrins and tofacitinib have results comparable to anti-TNF. Based on the efficacy, expert recommendations, and the absence of other evidence, it is recommended that patients with IBD be vaccinated.
Vaccines for COVID-19 in patients with atopic dermatitis: three things every dermatologist should know. Almost 13 months have passed since the World Health Organization (WHO) declared the coronavirus disease 19 (COVID-19) pandemic, caused by the SARS-CoV-2, on March 11th, 2020. During this period, we have realized that the most effective weapon we have to prevent SARS-CoV-2 infection, or to make it less aggressive, is vaccines. Currently, according to the WHO document "Draft landscape of COVID-19 candidate vaccines," there are 275 vaccines in development against the virus, although at the moment there are four preparations in distribution in the United States and in Europe. The characteristics of these vaccines are quite different from each other and may even be unfamiliar in the medical field. In particular, among dermatologists, knowledge of vaccines is of fundamental importance, especially in atopic dermatitis. Atopic patients are aware of having a predisposition to develop allergies, and so they are asking dermatologists about the safety of the vaccines currently available against the SARS-CoV-2. This article provides an up-to-date overview of this topic by reviewing current literature and sharing our personal experience.
Risk of symptomatic severe acute respiratory syndrome coronavirus 2 infection not associated with influenza vaccination in the 2019-2020 season. The association of influenza vaccine and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection was assessed by test-negative design using data collected for a study of outpatient COVID-19-like illness with onset dates from June to September 2020. Multivariable logistic regression models examined the association between receipt of 2019-2020 influenza vaccine and PCR-confirmed SARS-CoV-2 with adjustment for potential confounders. Receipt of influenza vaccine during the 2019-2020 influenza season was not associated with increased odds of SARS-CoV-2 infection in adults (aOR 0.83, 95% CI 0.63 to 1.10) or children (aOR 0.92, 95% CI 0.47 to 1.80).

The first dose of COVID-19 vaccine may trigger pemphigus and bullous pemphigoid flares: is the second dose therefore contraindicated?

The COVID-19 Pandemic and the Need for an Integrated and Equitable Approach: An International Expert Consensus Paper. BACKGROUND: One year after the declaration of the coronavirus disease 2019 (COVID-19) pandemic by the World Health Organization (WHO) and despite the implementation of mandatory physical barriers and social distancing, humanity remains challenged by a long-lasting and devastating public health crisis. MANAGEMENT: Non-pharmacological interventions (NPIs) are efficient mitigation strategies. The success of these NPIs is dependent on the approval and commitment of the population. The launch of a mass vaccination program in many countries in late December 2020 with mRNA vaccines, adenovirus-based vaccines, and inactivated virus vaccines has generated hope for the end of the pandemic. CURRENT ISSUES: The continuous appearance of new pathogenic viral strains and the ability of vaccines to prevent infection and transmission raise important concerns as we try to achieve community immunity against severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) and its variants. The need of a second and even third generation of vaccines has already been acknowledged by the WHO and governments. PERSPECTIVES: There is a critical and urgent need for a balanced and integrated strategy for the management of the COVID-19 outbreaks organized on three axes: (1) Prevention of the SARS-CoV-2 infection, (2) Detection and early diagnosis of patients at risk of disease worsening, and (3) Anticipation of medical care (PDA). CONCLUSION: The "PDA strategy" integrated into state policy for the support and expansion of health systems and introduction of digital organizations (i.e., telemedicine, e-Health, artificial intelligence, and machine-learning technology) is of major importance for the preservation of citizens' health and life world-wide.

PF4-Dependent Immunoassays in Patients with Vaccine-Induced Immune Thrombotic Thrombocytopenia: Results of an Interlaboratory Comparison. BACKGROUND: Coronavirus disease 2019 vaccine ChAdOx1 nCov-19 may rarely lead to vaccine-induced thrombotic thrombocytopenia (VITT). Antibody-mediated, platelet factor 4 (PF4)-dependent platelet activation appears to resemble a key mechanism in VITT, partially comparable to heparin-induced thrombocytopenia. The use of PF4/heparin immunoassays has been proposed as part of a diagnostic approach, but their sensitivity has not been established. METHODS: Sera from 12 well-defined VITT patients were first studied by two different laboratories in functional assays. Sera where then used for an interlaboratory comparison, in which five different PF4/heparin immunoassays were used by four laboratories. RESULTS: Results for functional testing were highly concordant. VITT antibodies were also reliably detected by PF4/heparin enzyme-linked immunosorbent assays (ELISAs) (92-100%). In contrast, only 25% of VITT antibodies were reactive in a particle gel immunoassay (PaGIA), and 8% in a lateral flow assay (LFA). An automated chemiluminescence immunoassay (CLIA) was negative for all sera tested (0%). CONCLUSION: It seems feasible to establish functional antibody testing for the confirmation of VITT. For the initial screening of suspected VITT cases, PaGIA, LFA, and CLIA are useless when applied as single tests. Only ELISA-based PF4/heparin immunoassays are sensitive enough to be incorporated in the diagnostic workup. However, a combination of a positive ELISA and a negative CLIA may be useful to identify VITT antibodies in the absence of confirmatory functional assays.

Effect of epitope variant co-delivery on the depth of CD8 TÂ cell responses induced by HIV-1 conserved mosaic vaccines. To stop the HIV-1 pandemic, vaccines must induce responses capable of controlling vast HIV-1 variants circulating in the population as well as those evolved in each individual following transmission. Numerous strategies have been proposed, of which the most promising include focusing responses on the vulnerable sites of HIV-1 displaying the least entropy among global isolates and using algorithms that maximize vaccine match to circulating HIV-1 variants

by vaccine cocktails of optimized complementing sequences. In this study, we investigated CD8 TÂ cell responses induced by a bi-valent mosaic of highly conserved HIVconsvX regions delivered by a combination of simian adenovirus ChAdOx1 and poxvirus MVA. We compared partially and fully mono- and bi-valent prime-boost regimens and their ability to elicit TÂ cells recognizing natural epitope variants using an interferon-Î³ enzyme-linked immunospot (ELISPOT) assay. We used 11 well-defined CD8 TÂ cell epitopes in two mouse haplotypes and, for each epitope, assessed recognition of the two vaccine forms together with the other most frequent epitope variants in the HIV-1 database. We conclude that for the magnitude and depth of epitope recognition, CD8 TÂ cell responses benefitted in most comparisons from the combined bi-valent mosaic and envisage the main advantage of the bi-valent vaccine during its deployment to diverse populations.
Clinical and histopathological views of morbilliform rash after COVID-19 mRNA vaccination mimic those in SARS-CoV-2 virus infection-associated cutaneous manifestations.
Acute myocarditis after a second dose of the mRNA COVID-19 vaccine: a report of two cases. We report two cases of myocarditis, in two young and previously healthy individuals, temporally related to the second dose of the mRNA-COVID-19 vaccine. Both patients developed acute chest pain, changes on electrocardiogram (ECG), and elevated serum troponin within two days of receiving their second dose. Cardiac magnetic resonance (CMR) findings were consistent with acute myocarditis.
First-Dose mRNA COVID-19 Vaccine Allergic Reactions: Limited Role for Excipient Skin Testing. BACKGROUND: The Centers for Disease Control and Prevention state that a severe or immediate allergic reaction to the first dose of an mRNA COVID-19 vaccine is a contraindication for the second dose. OBJECTIVE: To assess outcomes associated with excipient skin testing after a reported allergic reaction to the first dose of mRNA COVID-19 vaccine. METHODS: We identified a consecutive sample of patients withÂ reported allergic reactions after the first dose of mRNA COVID-19 vaccine who underwent allergy assessment with skin testing to polyethylene glycol (PEG) and, when appropriate, polysorbate 80. Skin testing results in conjunction with clinical phenotyping of the first-dose mRNA COVID-19 vaccine reaction guided second-dose vaccination recommendation. Second-dose mRNA COVID-19 vaccine reactions were assessed. RESULTS: Eighty patients with reported first-dose mRNA COVID-19 vaccine allergic reactions (nÂ = 65; 81% immediate onset) underwent excipient skin testing. Of those, 14 (18%) had positive skin tests to PEG (nÂ = 5) and/or polysorbate 80 (nÂ =Â 12). Skin testing result did not affect tolerance of the second dose in patients with immediate or delayed reactions. Of the 70 patients who received the second mRNA COVID-19 vaccine dose (88%), 62 had either no reaction or a mild reaction managed with antihistamines (89%), but 2 patients required epinephrine treatment. Three patients with positive PEG-3350 intradermal (methylprednisolone) testing tolerated second-dose mRNA COVID-19 vaccination. Refresh Tears caused nonspecific skin irritation. CONCLUSIONS: Most individuals with a reported allergic reaction to the first dose of mRNA COVID-19 vaccines, regardless of skin test result, received the second dose safely. More data are needed on the value of skin prick testing to PEG (MiraLAX) in evaluating patients with mRNA COVID-19 vaccine anaphylaxis. Refresh Tears should not be used for skin testing.
Recurrence of Acute Myocarditis Temporally Associated with Receipt of the mRNA Coronavirus Disease 2019 (COVID-19) Vaccine in a Male Adolescent.
Delayed cutaneous reaction to ChAdOx1 nCoV-19 vaccine: Is it an 'AstraZeneca arm'?
The use of IV immunoglobulin in the treatment of vaccine-induced immune thrombotic thrombocytopenia.
Poor Antibody Response After Two Doses of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine in Transplant Recipients. A low anti-spike antibody response of 28.6% was observed 28 days after BNT162b2 vaccine second dose among 133 solid organ transplant recipients without previous coronavirus disease 2019 (COVID-19). No serious adverse events were recorded.

Four severe COVID-19 cases were reported between or after the 2 doses. Our data suggest to change the vaccine strategy.
Association of COVID-19 Vaccination and Facial Nerve Palsy: A Case-Control Study. IMPORTANCE: Peripheral facial nerve (Bell) palsy has been reported and widely suggested as a possible adverse effect of the BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine. Israel is currently the leading country in vaccination rates per capita, exclusively using the BNT162b2 vaccine, and all residents of Israel are obligatory members of a national digital health registry system. These factors enable early analysis of adverse events. OBJECTIVE: To examine whether the BNT162b2 vaccine is associated with an increased risk of acute-onset peripheral facial nerve palsy. DESIGN, SETTING, AND PARTICIPANTS: This case-control study was performed from January 1 to February 28, 2021, at the emergency department of a tertiary referral center in central Israel. Patients admitted for facial nerve palsy were matched by age, sex, and date of admission with control patients admitted for other reasons. EXPOSURES: Recent vaccination with the BNT162b2 vaccine. MAIN OUTCOMES AND MEASURES: Adjusted odds ratio for recent exposure to the BNT162b2 vaccine among patients with acute-onset peripheral facial nerve palsy. The proportion of patients with Bell palsy exposed to the BNT162b2 vaccine was compared between groups, and raw and adjusted odds ratios for exposure to the vaccine were calculated. A secondary comparison with the overall number of patients with facial nerve palsy in preceding years was performed. RESULTS: Thirty-seven patients were admitted for facial nerve palsy during the study period, 22 (59.5%) of whom were male, and their mean (SD) age was 50.9â€‰(20.2) years. Among recently vaccinated patients (21 [56.7%]), the mean (SD) time from vaccination to occurrence of palsy was 9.3â€‰(4.2 [range, 3-14]) days from the first dose and 14.0â€‰(12.6 [range, 1-23]) days from the second dose. Among 74 matched controls (2:1 ratio) with identical age, sex, and admittance date, a similar proportion were vaccinated recently (44 [59.5%]). The adjusted odds ratio for exposure was 0.84 (95% CI, 0.37-1.90; Pâ€‰=â€‰.67). Furthermore, analysis of the number of admissions for facial nerve palsy during the same period in preceding years (2015-2020) revealed a relatively stable trend (mean [SD], 26.8â€‰[5.8]; median, 27.5 [range, 17-35]). CONCLUSIONS AND RELEVANCE: In this case-control analysis, no association was found between recent vaccination with the BNT162b2 vaccine and risk of facial nerve palsy.
Suggested treatment of serious complications to COVID-19 vaccination with IdeS, a bacterial antibody-cleaving enzyme.
Post Covid-19 vaccination papulovesicular pityriasis rosea-like eruption in a young male.
Impact of COVID-19-related disruptions to measles, meningococcal A, and yellow fever vaccination in 10 countries. BACKGROUND: Childhood immunisation services have been disrupted by the COVID-19 pandemic. WHO recommends considering outbreak risk using epidemiological criteria when deciding whether to conduct preventive vaccination campaigns during the pandemic. METHODS: We used two to three models per infection to estimate the health impact of 50% reduced routine vaccination coverage in 2020 and delay of campaign vaccination from 2020 to 2021 for measles vaccination in Bangladesh, Chad, Ethiopia, Kenya, Nigeria, and South Sudan, for meningococcal A vaccination in Burkina Faso, Chad, Niger, and Nigeria, and for yellow fever vaccination in the Democratic Republic of Congo, Ghana, and Nigeria. Our counterfactual comparative scenario was sustaining immunisation services at coverage projections made prior to COVID-19 (i.e. without any disruption). RESULTS: Reduced routine vaccination coverage in 2020 without catch-up vaccination may lead to an increase in measles and yellow fever disease burden in the modelled countries. Delaying planned campaigns in Ethiopia and Nigeria by a year may significantly increase the risk of measles outbreaks (both countries did complete their supplementary immunisation activities (SIAs) planned for 2020). For yellow fever vaccination, delay in campaigns leads to a potential disease burden rise of >1 death per 100,000 people per year until the campaigns

are implemented. For meningococcal A vaccination, short-term disruptions in 2020 are unlikely to have a significant impact due to the persistence of direct and indirect benefits from past introductory campaigns of the 1- to 29-year-old population, bolstered by inclusion of the vaccine into the routine immunisation schedule accompanied by further catch-up campaigns. CONCLUSIONS: The impact of COVID-19-related disruption to vaccination programs varies between infections and countries. Planning and implementation of campaigns should consider country and infection-specific epidemiological factors and local immunity gaps worsened by the COVID-19 pandemic when prioritising vaccines and strategies for catch-up vaccination. FUNDING: Bill and Melinda Gates Foundation and Gavi, the Vaccine Alliance.

Awareness and Attitude Towards COVID-19 Vaccination and Associated Factors in Ethiopia: Cross-Sectional Study. BACKGROUND: Coronavirus disease (COVID-19) is a deadly virus that continues to afflict many countries worldwide. The development of a COVID-19 vaccine to combat the disease's spread and devastating effects is still ongoing, and as the pandemic progresses, new, more effective vaccines are likely to be created. The aim of this study was to assess awareness and attitude towards COVID-19 vaccination in Ethiopia. METHODS: A population-based cross-sectional e-survey was conducted among 425 participants from March 13, 2021 to April 10, 2021. The survey was conducted using a structured and self-reported questionnaire containing informed consent along with three sections (socio-demographic, awareness, and attitude); a multivariable logistic regression model was performed to determine the variables predicting awareness towards COVID-19 vaccinations. RESULTS: The mean score of awareness was 4.3 (SD=1.1) out of 7, with the overall awareness of 40.8%, and the mean score of attitudes was 4.09 (SD=2.16) out of 9, with an overall "positive attitude" score of 24.2%. College and above educational level (AOR=2.21, 95% CI=1.32, 4.62), had access to mass media (AOR=4.75, 95% CI =2.74, 8.24), and urban residency (AOR=2.83, 95% C.I = 1.57, 5.09) were significantly associated with awareness towards COVID-19 vaccination. CONCLUSION: In Ethiopia, there is a poor knowledge toward COVID-19 vaccines, according to the current report. The findings indicate that authorities should implement an urgent health education program and disseminate more reliable information. Using the media, policymakers should take measures to ensure adequate awareness of COVID-19 vaccinations with various stakeholders.

An update review of globally reported SARS-CoV-2 vaccines in preclinical and clinical stages. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the causative agent of the rapidly spreading pandemic COVID-19 in the world. As an effective therapeutic strategy is not introduced yet and the rapid genetic variations in the virus, there is an emerging necessity to design, evaluate and apply effective new vaccines. An acceptable vaccine must elicit both humoral and cellular immune responses, must have the least side effects and the storage and transport systems should be available and affordable for all countries. These vaccines can be classified into different types: inactivated vaccines, live-attenuated virus vaccines, subunit vaccines, virus-like particles (VLPs), nucleic acid-based vaccines (DNA and RNA) and recombinant vector-based vaccines (replicating and non-replicating viral vector). According to the latest update of the WHO report on April 2nd, 2021, at least 85 vaccine candidates were being studied in clinical trial phases and 184 candidate vaccines were being evaluated in pre-clinical stages. In addition, studies have shown that other vaccines, including the Bacillus Calmette-GuÃ©rin (BCG) vaccine and the Plant-derived vaccine, may play a role in controlling pandemic COVID-19. Herein, we reviewed the different types of COVID-19 candidate vaccines that are currently being evaluated in preclinical and clinical trial phases along with advantages, disadvantages or adverse reactions, if any.

Incidence of Cutaneous Reactions After Messenger RNA COVID-19 Vaccines. This cohort study examines cutaneous reactions in hospital employees who received messenger RNA COVID-19 vaccination.

Vaccine-induced immune thrombotic thrombocytopenia (VITT) - a novel clinico-pathological entity with heterogeneous clinical presentations. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a novel entity that emerged in March 2021 following reports of unusual thrombosis after ChAdOx1 nCoV-19, (AstraZeneca) vaccination. Following the recognition of this syndrome, multiple consensus guidelines have been released to risk stratify patients presenting with possible symptoms after ChAdOx1 nCoV-19 vaccination. All guidelines rapidly identify VITT in patients with the complete triad of thrombocytopenia, thrombosis and elevated D-dimers after ChAdOx1 nCoV-19 vaccination. However, with earlier recognition of the associated symptoms, the clinical manifestations are likely to be more heterogeneous and represent an evolving spectrum of disease. In this setting, current guidelines may lack the sensitivity to detect early cases of VITT and risk missed or delayed diagnoses. The broad clinical phenotype and challenges associated with diagnosis of VITT are highlighted in our present case series of four patients with confirmed VITT. Dependent on the guidance used, each patient could have been classified as a low probability of VITT at presentation. The present study highlights the issues associated with the recognition of VITT, the limitations of current guidance and the need for heightened clinical vigilance as our understanding of the pathophysiology of this novel condition evolves.
Antibody Responses to SARS-CoV-2 after Infection or Vaccination in Children and Young Adults with Inflammatory Bowel Disease. BACKGROUND: Characterization of neutralization antibodies to SARS-CoV-2 infection or vaccination in children and young adults with inflammatory bowel disease (IBD) receiving biologic therapies is crucial. METHODS: W e performed a prospective longitudinal cohort study evaluating SARS-CoV-2 Spike protein receptor binding domain (S-RBD) IgG positivity along with consistent clinical symptoms in patients with IBD receiving infliximab or vedolizumab. Serum was also obtained following immunization with approved vaccines. IgG antibody to the spike protein binding domain of SARS-CoV-2 was assayed with a fluorescent bead-based immunoassay that takes advantage of the high dynamic range of fluorescent molecules using flow cytometry. A sensitive and high-throughput neutralization assay that incorporates SARS-CoV-2 Spike protein onto a lentivirus and measures pseudoviral entry into ACE2 expressing HEK-293 cells was used. RESULTS: 436 patients were enrolled (mean age 17 years, range 2-26 years, 58% male, 71% CrohnÃ¢â‚¬â„¢s disease, 29% ulcerative colitis, IBD-unspecified). 44 (10%) of enrolled subjects had SARS-CoV-2 S-RBD IgG antibodies. Compared to non-IBD adults (ambulatory) and hospitalized pediatric patients with PCR documented SARS-CoV-2 infection, S-RBD IgG antibody levels were significantly lower in the IBD cohort and by 6 months post infection most patients lacked neutralizing antibody. Following vaccination (n=33) patients had a 15-fold higher S-RBD antibody response in comparison to natural infection, and all developed neutralizing antibodies to both wild type and variant SARS-CoV-2. CONCLUSIONS AND RELEVANCE: The lower and less durable SARS-CoV-2 S-RBD IgG response to natural infection in IBD patients receiving biologics puts them at risk of reinfection. The robust response to immunization is likely protective. SUMMARY: Our study showed a low and poorly durable SARS-CoV-2 S-RBD neutralizing IgG response to natural infection in IBD patients receiving biologics potentially putting them at risk of reinfection. However, they also had a robust response to immunization that is likely protective.
COVID-19 vaccine side effects: The positives about feeling bad. The side effects of SARS-CoV-2 vaccines are often troubling but may merely reflect transient production of type I interferons, a normal physiological response to contact with invading microorganisms.
Systemic rheumatic disease flares after SARS-CoV-2 vaccination among rheumatology outpatients in New York City.
Blood pressure increase after Pfizer/BioNTech SARS-CoV-2 vaccine.

Type I Hypersensitivity in Ferrets Following Exposure to SARS-CoV-2 Inoculum: Lessons Learned. This case report discusses Type I hypersensitivity in ferrets following exposure to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) inoculum, observed during a study investigating the efficacy of candidate COVID-19 vaccines. Following a comprehensive internal root-cause investigation, it was hypothesized that prior prime-boost immunization of ferrets with a commercial canine C3 vaccine to protect against the canine distemper virus had resulted in primary immune response to fetal bovine serum (FBS) in the C3 preparation. Upon intranasal exposure to SARS-CoV-2 virus cultured in medium containing FBS, an allergic airway response occurred in 6 out of 56 of the ferrets. The 6 impacted ferrets were randomly dispersed across study groups, including different COVID-19 vaccine candidates, routes of vaccine candidate administration, and controls (placebo). The root-cause investigation and subsequent analysis determined that the allergic reaction was unrelated to the COVID-19 vaccine candidates under evaluation. Histological assessment suggested that the allergic response was characterized by eosinophilic airway disease; increased serum immunoglobulin levels reactive to FBS further suggested this response was caused by immune priming to FBS present in the C3 vaccine. This was further supported by in vivo studies demonstrating ferrets administered diluted FBS also presented clinical signs consistent with a hyperallergic response, while clinical signs were absent in ferrets that received a serum-free SARS-CoV-2 inoculum. It is therefore recommended that vaccine studies in higher order animals should consider the impact of welfare vaccination and use serum-free inoculum whenever possible.

COVID-19 vaccination and breast cancer surgery timing. There have been recent reports in the breast imaging literature of unilateral axillary lymphadenopathy following COVID-19 vaccination. It is unclear whether the reactive lymphadenopathy may impact the sentinel lymph node biopsy procedure. In this article, we provide guidelines regarding the timing of the COVID-19 vaccine and breast cancer surgery which were formulated after a review of the available literature and in consultation with infectious disease specialists.

[(18)F]FDG uptake of axillary lymph nodes after COVID-19 vaccination in oncological PET/CT: frequency, intensity, and potential clinical impact. OBJECTIVES: To assess the frequency, intensity, and clinical impact of [(18)F]FDG-avidity of axillary lymph nodes after vaccination with COVID-19 vaccines BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) in patients referred for oncological FDG PET/CT. METHODS: One hundred forty patients referred for FDG PET/CT during February and March 2021 after first or second vaccination with Pfizer-BioNTech or Moderna were retrospectively included. FDG-avidity of ipsilateral axillary lymph nodes was measured and compared. Assuming no knowledge of prior vaccination, metastatic risk was analyzed by two readers and the clinical impact was evaluated. RESULTS: FDG PET/CT showed FDG-avid lymph nodes ipsilateral to the vaccine injection in 75/140 (54%) patients with a mean SUV(max) of 5.1 (range 2.0 - 17.3). FDG-avid lymph nodes were more frequent in patients vaccinated with Moderna than Pfizer-BioNTech (36/50 [72%] vs. 39/90 [43%] cases, $p < 0.001$). Metastatic risk of unilateral FDG-avid axillary lymph nodes was rated unlikely in 52/140 (37%), potential in 15/140 (11%), and likely in 8/140 (6%) cases. Clinical management was affected in 17/140 (12%) cases. CONCLUSIONS: FDG-avid axillary lymph nodes are common after COVID-19 vaccination. The avidity of lymph nodes is more frequent in Moderna compared to that in Pfizer-BioNTech vaccines. To avoid relatively frequent clinical dilemmas, we recommend carefully taking the history for prior vaccination in patients undergoing FDG PET/CT and administering the vaccine contralateral to primary cancer. KEY POINTS: â€¢ PET/CT showed FDG-avid axillary lymph nodes ipsilateral to the vaccine injection site in 54% of 140 oncological patients after COVID-19 vaccination. â€¢ FDG-avid lymphadenopathy was observed significantly more frequently in Moderna compared to patients receiving Pfizer-BioNTech-vaccines. â€¢ Patients should be screened

for prior COVID-19 vaccination before undergoing PET/CT to enable individually tailored recommendations for clinical management.
Immune Thrombocytopenic Purpura (ITP) Triggered by COVID-19 Infection and Vaccination.
Immune Thrombocytopenia Following the Pfizer-BioNTech BNT162b2 mRNA COVID-19 Vaccine.
Trigeminal and cervical radiculitis after tozinameran vaccination against COVID-19. In this report, we describe a patient who developed an acute trigeminal neuritis and cervical radiculitis after receiving a Pfizer-BioNtech vaccination (tozinameran) against SARS-CoV-2.
New-onset refractory status epilepticus following the ChAdOx1 nCoV-19 vaccine. Coronavirus is a novel human pathogen causing fulminant respiratory syndrome (COVID-19). Developing an effective and reliable vaccine was emergently pursued to control the dramatic spread of the global pandemic. The standard stages for vaccine development were unprecedentedly accelerated over a few months. We report a case of new-onset refractory status epilepticus (NORSE) after receiving the first dose of the ChAdOx1 nCoV-19 vaccine. We attribute the occurrence of NORSE to the vaccine due to the temporal relationship and the lack of risk factors for epilepsy in the patient. This report adds to the literature a possible rare side effect of a COVID-19 vaccine and contributes to the extremely limited literature on potential neurological side effects of viral vector vaccines. Healthcare providers should be aware of the possibility of post-vaccination epilepsy. The patient had recurrent seizures that were refractory to conventional antiepileptic drug therapy with a dramatic response to immunotherapy with pulse steroids and plasmapheresis. This likely reflects an underlying autoimmune mechanism in the genesis of post-vaccination generalized seizures without fever. Further research is needed to probe and study the exact mechanism at a more molecular level.
The Risk of Allergic Reaction to SARS-CoV-2 Vaccines and Recommended Evaluation and Management: A Systematic Review, Meta-Analysis, GRADE Assessment, and International Consensus Approach. Concerns for anaphylaxis may hamper severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) immunization efforts. We convened a multidisciplinary group of international experts in anaphylaxis composed of allergy, infectious disease, emergency medicine, and front-line clinicians to systematically develop recommendations regarding SARS-CoV-2 vaccine immediate allergic reactions. Medline, EMBASE, Web of Science, the World Health Organizstion (WHO) global coronavirus database, and the gray literature (inception, March 19, 2021) were systematically searched. Paired reviewers independently selected studies addressing anaphylaxis after SARS-CoV-2 vaccination, polyethylene glycol (PEG) and polysorbate allergy, and accuracy of allergy testing for SARS-CoV-2 vaccine allergy. Random effects models synthesized the data to inform recommendations based on the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) approach, agreed upon using a modified Delphi panel. The incidence of SARS-CoV-2 vaccine anaphylaxis is 7.91 cases per million (nÂ = 41,000,000 vaccinations; 95% confidence interval [95% CI] 4.02-15.59; 26 studies, moderate certainty), the incidence of 0.15 cases per million patient-years (95% CI 0.11-0.2), and the sensitivity for PEG skin testing is poor, although specificity is high (15 studies, very low certainty). We recommend vaccination over either no vaccination or performing SARS-CoV-2 vaccine/excipient screening allergy testing for individuals without history of a severe allergic reaction to the SARS-CoV-2 vaccine/excipient, and a shared decision-making paradigm in consultation with an allergy specialist for individuals with a history of a severe allergic reaction to the SARS-CoV-2 vaccine/excipient. We recommend further research to clarify SARS-CoV-2 vaccine/vaccine excipient testing utility in individuals potentially allergic to SARS-CoV2 vaccines or their excipients.
Autoimmune hepatitis following COVID-19 vaccination: True causality or mere association?
Radiation Recall Phenomenon Following COVID-19 Vaccination.

Safety and immunogenicity of the ChAdOx1 nCoV-19 (AZD1222) vaccine against SARS-CoV-2 in HIV infection: a single-arm substudy of a phase 2/3 clinical trial. BACKGROUND: Data on vaccine immunogenicity against SARS-CoV-2 are needed for the 40 million people globally living with HIV who might have less functional immunity and more associated comorbidities than the general population. We aimed to explore safety and immunogenicity of the ChAdOx1 nCoV-19 (AZD1222) vaccine in people with HIV. METHODS: In this single-arm open-label vaccination substudy within the protocol of the larger phase 2/3 trial COV002, adults aged 18-55 years with HIV were enrolled at two HIV clinics in London, UK. Eligible participants were required to be on antiretroviral therapy (ART), with undetectable plasma HIV viral loads (<50 copies per mL), and CD4 counts of more than 350 cells per Î¼L. A prime-boost regimen of ChAdOx1 nCoV-19, with two doses was given 4-6 weeks apart. The primary outcomes for this substudy were safety and reactogenicity of the vaccine, as determined by serious adverse events and solicited local and systemic reactions. Humoral responses were measured by anti-spike IgG ELISA and antibody-mediated live virus neutralisation. Cell-mediated immune responses were measured by ex-vivo IFN-Î³ enzyme-linked immunospot assay (ELISpot) and T-cell proliferation. All outcomes were compared with an HIV-uninfected group from the main COV002 study within the same age group and dosing strategy and are reported until day 56 after prime vaccination. Outcomes were analysed in all participants who received both doses and with available samples. The COV002 study is registered with ClinicalTrials.gov, NCT04400838, and is ongoing. FINDINGS: Between Nov 5 and Nov 24, 2020, 54 participants with HIV (all male, median age 42Â·5 years [IQR 37Â·2-49Â·8]) were enrolled and received two doses of ChAdOx1 nCoV-19. Median CD4 count at enrolment was 694Â·0 cells per Î¼L (IQR 573Â·5-859Â·5). No serious adverse events occurred. Local and systemic reactions occurring during the first 7 days after prime vaccination included pain at the injection site (26 [49%] of 53 participants with available data), fatigue (25 [47%]), headache (25 [47%]), malaise (18 [34%]), chills (12 [23%]), muscle ache (19 [36%]), joint pain (five [9%]), and nausea (four [8%]), the frequencies of which were similar to the HIV-negative participants. Anti-spike IgG responses by ELISA peaked at day 42 (median 1440 ELISA units [EUs; IQR 704-2728]; n=50) and were sustained until day 56 (median 941 EUs [531-1445]; n=49). We found no correlation between the magnitude of the anti-spike IgG response at day 56 and CD4 cell count (p=0Â·93) or age (p=0Â·48). ELISpot and T-cell proliferative responses peaked at day 14 and 28 after prime dose and were sustained to day 56. Compared with participants without HIV, we found no difference in magnitude or persistence of SARS-CoV-2 spike-specific humoral or cellular responses (p>0Â·05 for all analyses). INTERPRETATION: In this study of people with HIV, ChAdOx1 nCoV-19 was safe and immunogenic, supporting vaccination for those well controlled on ART. FUNDING: UK Research and Innovation, National Institutes for Health Research (NIHR), Coalition for Epidemic Preparedness Innovations, NIHR Oxford Biomedical Research Centre, Thames Valley and South Midland's NIHR Clinical Research Network, and AstraZeneca.

[Flickering scotoma after COVID vaccination : A further possible side effect of vaccination?].

[Erythema chronicum migrans-like appearance as sequel to COVID vaccination].

Vaccine response following anti-CD20 therapy: a systematic review and meta-analysis of 905 patients. The objective of this study was to perform a systematic review of the literature on vaccine responsiveness in patients who have received anti-CD20 therapy. PubMed and EMBASE were searched up to 4 January 2021 to identify studies of vaccine immunogenicity in patients treated with anti-CD20 therapy, including patients with hematologic malignancy or autoimmune disease. The primary outcomes were seroprotection (SP), seroconversion (SC), and/or seroresponse rates for each type of vaccine reported. As the pandemic influenza vaccine (2009 H1N1) has standardized definitions for SP and SC, and represented a novel primary antigen similar to the COVID-19 vaccine, meta-analysis was conducted for SC of studies of this vaccine. Pooled estimates, relative benefit

ratios (RBs), and 95% confidence intervals (CIs) were calculated using a random-effects model. Thirty-eight studies (905 patients treated with anti-CD20 therapy) were included (19 studies of patients with hematologic malignancies). Patients on active (<3 months since last dose) anti-CD20 therapy had poor responses to all types of vaccines. The pooled estimate for SC after 1 pandemic influenza vaccine dose in these patients was 3% (95% CI, 0% to 9%), with an RB of 0.05 (95% CI, 0-0.73) compared with healthy controls and 0.22 (95% CI, 0.09-0.56) compared with disease controls. SC compared with controls seems abrogated for at least 6 months following treatment (3-6 months post anti-CD20 therapy with an RB of 0.50 [95% CI, 0.24-1.06] compared with healthy and of 0.44 [95% CI, 0.23-0.84] compared with disease controls). For all vaccine types, response to vaccination improves incrementally over time, but may not reach the level of healthy controls even 12 months after therapy.

Acute-onset central serous retinopathy after immunization with COVID-19 mRNA vaccine. PURPOSE: We report the case of a 33-year-old male who presented with unilateral central serous retinopathy three days after the injection of a COVID-19 vaccine. OBSERVATIONS: A 33-year-old healthy Hispanic male referred to the ophthalmology service due to blurry vision and metamorphopsia in the right eye without any flashes, floaters, eye redness or pain. The patient reported that 69 hours prior to presentation he received the first dose of the Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine. He denied any past ocular history or pertinent medical history. He does not take any medicines and denies stressful factors in his life. The clinical examination and imaging tests were consistent with central serous retinopathy that resolved in three months. CONCLUSIONS AND IMPORTANCE: This is the first report of an ocular complication potentially associated with a COVID-19 vaccination. Our case contributes information of a side effect potentially related to this new vaccine.

A Case of Autoimmune Hemolytic Anemia Following COVID-19 Messenger Ribonucleic Acid Vaccination. Autoimmune hemolytic anemia (AIHA) is a condition characterized by the increased destruction of red blood cells (RBCs) mediated by anti-erythrocyte autoantibodies with or without complement activation. Its clinical presentation is heterogeneous, ranging from asymptomatic to severe forms with fatal outcomes, and it can be either idiopathic or secondary to a coexisting disorder. In this report, we present a case of a patient who suffered from acute and severe AIHA after receiving the second dose of the coronavirus disease 2019 (COVID-19) messenger ribonucleic acidÂ (mRNA) vaccine.

Axillary lymphadenopathy in a renal cell carcinoma patient after COVID-19 Vaccination. The distribution of the novel Covid-19 vaccines has been on a scale as unprecedented as the pandemic itself. While the vaccines promise to greatly reduce the spread and impact of the disease, encountering side-effects in clinical practice may pose diagnostic dilemmas. In this case report, we describe a patient with known metastatic renal cell carcinoma who presents with axillary lymphadenopathy found on PET/CT imaging after receiving a Covid-19 vaccine, which was subsequently confirmed to be reactive lymphadenopathy following biopsy.

Inaction, under-reaction action and incapacity: communication breakdown in Italy's vaccination governance. This article explores why governments do not respond to public compliance problems in a timely manner with appropriate instruments, and the consequences of their failure to do so. Utilising a case study of Italian vaccination policy, the article considers counterfactuals and the challenges of governing health policy in an age of disinformation. It counterposes two methods of governing vaccination compliance: discipline, which uses public institutions to inculcate the population with favourable attitudes and practices, and modulation, which uses access to public institutions as a form of control. The Italian government ineffectively employed discipline for a number of years. Epistemological and organisational constraints stymied its efforts to tackle a

significant childhood vaccination compliance problem. With a loss of control over the information environment, vaccinations were not served well by exogenous crises, the sensationalism of the news cycle and online misinformation. Hampered by austerity, lack of capacity and epistemic shortcomings, the Italian government did not protect the public legitimacy of the vaccination programme. Instead of employing communications to reassure a hesitant population, they focused on systemic and delivery issues, until it was too late to do anything except make vaccinations mandatory (using modulation). The apparent short-term success of this measure in generating population compliance does not foreclose the need for ongoing governance of vaccine confidence through effective discipline. This is evident for the COVID-19 vaccination campaign, with many Italians still indicating that they would not accept a vaccine despite the devastation that the disease has wrought throughout their country.
Type 1 Kounis Syndrome Induced by Inactivated SARS-COV-2 Vaccine. Background Vaccination is the most important way out of the novel coronavirus disease 2019 (COVID-19) pandemic. Vaccination practices have started in different countries for community immunity. In this process, health authorities in different countries have preferred different type of COVID-19 vaccines. Inactivated COVID-19 vaccine is one of these options and has been administered to more than 7 million people in Turkey. Inactivated vaccines are generally considered safe. Kounis syndrome (KS) is a rare clinical condition defined as the co-existence of acute coronary syndromes and allergic reactions. Case Report We present the case of a 41-year-old woman with no cardiovascular risk factors who was admitted at our emergency department with flushing, palpitation, dyspnea, and chest pain 15 min after the first dose of inactivated CoronaVac (Sinovac Life Sciences, Beijing, China). Electrocardiogram (ECG) showed V4-6 T wave inversion, and echocardiography revealed left ventricular wall motion abnormalities. Troponin-I level on arrival was elevated. Coronary angiography showed no sign of coronary atherosclerosis. She was diagnosed with type 1 KS. The patient's symptoms resolved and she was discharged from hospital in a good condition. Why Should an Emergency Physician Be Aware of This? To the best of our knowledge, this is the first case of allergic myocardial infarction secondary to inactivated coronavirus vaccine. This case demonstrates that KS can occur after inactivated virus vaccine against COVID-19. Although the risk of severe allergic reaction after administration of CoronaVac seems to be very low, people who developed chest pain after vaccine administration should be followed by ECG and troponin measurements.
Should women undergoing inÂ vitro fertilization treatment or who are in the first trimester of pregnancy be vaccinated immediately against COVID-19.
Coronavirus disease 2019 vaccination in women seeking pregnancy or in early pregnancy: What is there to debate?
Neurologic adverse events among 704,003 first-dose recipients of the BNT162b2 mRNA COVID-19 vaccine in Mexico: A nationwide descriptive study. mRNA vaccines against SARS-CoV-2 are remarkably effective. Limited information exists about the incidence of adverse events following immunization (AEFI) with their use. We conducted a prospective observational study including data from 704,003 first-doses recipients; 6536 AEFI were reported, of whom 65.1% had at least one neurologic AEFI (non-serious 99.6%). Thirty-three serious events were reported; 17 (51.5%) were neurologic (observed frequency, 2.4/100,000 doses). At the time of writing this report, 16/17 cases had been discharged without deaths. Our data suggest that the BNT162b2 mRNA COVID-19 vaccine is safe; its individual and societal benefits outweigh the low percentage of serious neurologic AEFI. This information should help to dissipate hesitancy towards this new vaccine platform.
[Guidelines on: COVID-19 Vaccine Induced Thrombosis, Bleeding, and Thrombocytopenia]. After widespread vaccination with COVID-19 vaccines, there have been worldwide reports on thrombosis, bleeding, and thrombocytopenia. Recently, a rare syndrome with a high mortality rate consisting of an unusual combination of thrombocytopenia and thrombosis, in particular cerebral venous sinus

thrombosis, which clinically resembles heparin-induced thrombocytopenia, was reported following vaccination. Different statements and recommendations were developed regarding the definition, diagnosis, and treatment of these rare complications. We present here a protocol with recommendations, based on current evidence.
Liver injury after mRNA-based SARS-CoV-2 vaccination in a liver transplant recipient.
Answer to Cabona et al Â«Â Isolated musculocutaneous nerve involvement in COVID-19 related Neuralgic amyotrophyÂ» Joint Bone Spine 2021;88:105238 and to Finsterer and Scorza Â«Â SARS-CoV-2 or SARS-CoV-2 vaccination associated Parsonage-Turner syndromeÂ». Joint Bone Spine 2021;88:105239.
Reply to: "Comment on "Autoimmune hepatitis developing after coronavirus disease 2019 (COVID-19) vaccine: Causality or casualty?"".
Histologic correlates of gross hematuria following Moderna COVID-19 vaccine in patients with IgA nephropathy.
Skin rashes after SARS-CoV-2 vaccine: which relationship, if any? â€‰   [Image: see text]
Prostate cancer and the human papilloma virus: causative association, role of vaccines, and the impact of the COVID-19 pandemic. Prostate cancer affects a significant proportion of men worldwide. Evidence from genetic and clinical studies suggests that there may be a causal association between prostate cancer and the human papilloma virus (HPV). As HPV is a vaccine-preventable pathogen, the possibility of a role in prostate cancer causation may reinforce the importance of effective HPV vaccination campaigns. This is of particular relevance in light of the COVID-19 pandemic, which may have considerable effects on HPV vaccine uptake and distribution.
CureVac COVID vaccine let-down spotlights mRNA design challenges.
Disease activity and humoral response in patients with inflammatory rheumatic diseases after two doses of the Pfizer mRNA vaccine against SARS-CoV-2. BACKGROUND: The registration trials of messenger RNA (mRNA) vaccines against SARS-CoV-2 did not address patients with inflammatory rheumatic diseases (IRD). OBJECTIVE: To assess the humoral response after two doses of mRNA vaccine against SARS-CoV-2, in patients with IRD treated with immunomodulating drugs and the impact on IRD activity. METHODS: Consecutive patients treated at the rheumatology institute, who received their first SARS-CoV-2 (Pfizer) vaccine, were recruited to the study, at their routine visit. They were reassessed 4-6 weeks after receiving the second dose of vaccine, and blood samples were obtained for serology. IRD activity assessment and the vaccine side effects were documented during both visits. IgG antibodies (Abs) against SARS-CoV-2 were detected using the SARS-CoV-2 IgG II Quant (Abbott) assay. RESULTS: Two hundred and sixty-four patients with stable disease, (mean(SD) age 57.6 (13.18) years, disease duration 11.06 (7.42) years), were recruited. The immunomodulatory therapy was not modified before or after the vaccination. After the second vaccination, 227 patients (86%) mounted IgG Ab against SARS-CoV-2 (mean (SD) 5830.8 (8937) AU/mL) and 37 patients (14%) did not, 22/37 were treated with B cell-depleting agents. The reported side effects of the vaccine were minor. The rheumatic disease remained stable in all patients. CONCLUSIONS: The vast majority of patients with IRD developed a significant humoral response following the administration of the second dose of the Pfizer mRNA vaccine against SARS-CoV-2 virus. Only minor side effects were reported and no apparent impact on IRD activity was noted.
Global covid-19 vaccine rollout and safety surveillance-how to keep pace.
Spontaneous HIT syndrome: Knee replacement, infection, and parallels with vaccine-induced immune thrombotic thrombocytopenia. Heparin-induced thrombocytopenia (HIT) is characterized clinically by thrombocytopenia, hypercoagulability, and increased thrombosis risk, and serologically

by platelet-activating anti-platelet factor 4 (PF4)/heparin antibodies. Heparin-"induced" acknowledges that HIT is usually triggered by a proximate immunizing exposure to heparin. However, certain non-heparin medications (pentosan polysulfate, hypersulfated chondroitin sulfate, fondaparinux) can trigger "HIT". Further, naturally-occurring polyanions (bacterial lipopolysaccharide, DNA/RNA) can interact with PF4 to recapitulate HIT antigens. Indeed, immunologic presensitization to naturally-occurring polyanions could explain why HIT more closely resembles a secondary, rather than a primary, immune response. In 2008 it was first reported that a HIT-mimicking disorder can occur without any preceding exposure to heparin or polyanionic medications. Termed "spontaneous HIT syndrome", two subtypes are recognized: (a) surgical (post-orthopedic, especially post-total knee arthroplasty, and (b) medical (usually post-infectious). Recently, COVID-19 adenoviral vector vaccination has been associated with a thrombotic thrombocytopenic disorder associated with positive PF4-dependent enzyme-immunoassays and serum-induced platelet activation that is maximal when PF4 is added. Vaccine-induced immune thrombotic thrombocytopenia (VITT) features unusual thromboses (cerebral venous thrombosis, splanchnic vein thrombosis) similar to those seen in spontaneous HIT syndrome. The emerging concept is that classic HIT reflects platelet-activating anti-PF4/heparin antibodies whereas spontaneous HIT syndrome and other atypical "autoimmune HIT" presentations (delayed-onset HIT, persisting HIT, heparin "flush" HIT) reflect heparin-independent platelet-activating anti-PF4 antibodies-although the precise relationships between PF4 epitope targets and the clinical syndromes remain to be determined. Treatment of spontaneous HIT syndrome includes non-heparin anticoagulation (direct oral Xa inhibitors favored over direct thrombin inhibitors) and high-dose immunoglobulin.
COVID-19 Vaccination Is Safe and Effective in Patients WithÂ Inflammatory Bowel Disease: Analysis of a Large Multi-institutional Research Network in the United States.
Interpreting and addressing suboptimal immune responses after COVID-19 vaccination in solid-organ transplant recipients. Transplant recipients were excluded from the initial clinical trials determining safety and efficacy of the landmark COVID-19 vaccines. Further, there is increasing evidence that immunosuppressed transplant recipients have a blunted antibody response to COVID-19 vaccination. In a concerning report by Sattler et al. in this issue of the JCI, kidney transplant recipients not only lacked a humoral response following two doses of Pfizer BNT162b2, but also displayed substantial impairment of the cellular response to SARS-CoV-2 antigens. This Commentary addresses potential strategies for transplant providers to evaluate and augment vaccine immunogenicity given the likelihood that COVID-19 will remain a world-wide threat to the health of transplant recipients.
Sweet syndrome induced by SARS-CoV-2 Pfizer-BioNTech mRNA vaccine.
Minimal change disease following vaccination for SARS-CoV-2.
Headache after COVID-19 vaccination: updated report from the Italian Medicines Agency database.
Thrombosis following COVID-19 vaccination: a possible role of alcohol consumption? A Suggestion from the Italian Society on Alcohol.
Expected Viscosity After COVID-19 Vaccination, Hyperviscosity and Previous COVID-19.
Safety of the ChAdOx1 nCoV-19 and the BBV152 vaccines in 724 patients with rheumatic diseases: a post-vaccination cross-sectional survey. Patients with rheumatic and musculoskeletal (RMD) diseases may be at higher risks for COVID-19 infection. Data on the safety of the adenoviral vector-borne ChAdOx1 nCoV-19 and the heat-inactivated BBV152 Vaccines in this group are limited. 724 patients with RMD who had received at least one dose of either the ChAdOx1 or the BBV152 were audited to find out post-vaccination adverse effect (AE) or disease flares. The AE rates in patients with autoimmune rheumatic disease (AIRD) were compared with those with non-AIRD RMDs. The mean age of the cohort was 59.9 (Â±â€‰10.43) years with a female (nâ€‰=â€‰581; 80.24%) majority.

523 (70.8%) had AIRD. The ChAdOx1 and the BBV152 vaccines were received by 624 (86.18%) and 77 (10.63%), respectively. 23 (3.17%) were unaware of which vaccine they had received. 238 (32.87%) of patients had at least one comorbidity. 436 (60.22%) participants [306 (59.64%) of those with AIRD and 130 (61.61%) with other RMDs] had at least one adverse effect (AE). Four patients reported flare of arthritis that resolved within 5Â days. No patient had any severe AE or required hospitalization. All AEs were self-limiting. Both the ChAdOx1 and the BBV152 vaccines appear safe in RMDs. AEs do not differ between patients with AIRD or non-AIRD. This information can help negate vaccine hesitancy amongst all stakeholders.

COVID-19 vaccination and dialysis patients: why the variable response. Uremia affects all parts of the immune system. Since hemodialysis patients travel to the dialysis center three times per week and are surrounded by many other patients and staffs, these could predispose them to a greater risk of coronavirus disease of 2019 (COVID-19) infection. Mortality associated with COVID-19 infection is high in patients receiving dialysis. Currently, the World Health Organization has approved six types of vaccines (ChAdOx1-S, Ad26.COV2.S, BNT162b2, mRNA-1273, BBIBP-CorV and CoronaVac) for COVID-19. Literature data regarding the response rate toward COVID-19 vaccination in dialysis patients is inconclusive. The published response rates varied from 29.6% to 96.4%. The variable response rates across these clinical trials may be explained by different vaccine types, vaccine doses, criteria for positive immune response, timings of antibody detection, races and ethnicities. Side effects of COVID-19 vaccination comprise of pain at injection site, fatigue, myalgia, headache, low fever, syncope, pericarditis, etc. Clinical predictors of positive response toward COVID-19 vaccination include age, previous infection, immunosuppressive therapy, body mass index and serum albumin level. No one is safe until everyone is safe. Therefore, vaccination against COVID-19 infection in dialysis patients is an urgent issue of worldwide concern.

A Case of Cervical Lymphadenopathy After Vaccination Against COVID-19. The coronavirus disease 2019 (COVID-19) pandemic has caused a major global healthcare crisis, and the fields of science and medicine have been engaged in a massive effortÂ to control and prevent the resultant deaths and morbidity. Researchers and pharmaceutical companies have developed in record time vaccines against COVID-19 that are intended to be safe and effective; however, the short validation time has been a challenge for doctors and epidemiologists, especially in light of the increase in reports emerging from various parts of the world about the adverse effects of the new vaccines. Portugal's national regulatory authority, the National Authority of Medicines and Health Products (INFARMED), has recently granted approval for Pfizer-BioNTech (Pfizer Inc., New York, NY;Â BioNTech SE,Â Mainz, Germany) and Moderna (Moderna, Inc,Â Cambridge, MA) COVID-19 vaccines, and they are being rolled out to be administered among the general population. In light of this, it is important for breast surgeons, family doctors, hematologists, and radiologists to consider the effects of recent COVID-19 vaccination historyÂ as a possible cause in the differential diagnosis for patients with unilateral cervical adenopathy. The objective of this report is to present a case that involves an adverse reaction involving acute-onset cervical lymphadenopathy in a female patient that coincided with her vaccination against COVID-19, even thoughÂ cervical lymphadenopathy had not been previously reported as a potential side effect of theÂ COVID-19 vaccination. We discuss the case of a Portuguese physician with a family history of breast cancer, who developed right cervical lymphadenopathy after receiving the first dose of the COVID-19 vaccine. Lymph node growth and ultrasound changes observed in the patient over the weeks, and a lack of information on the COVID-19 vaccine's adverse effects, promptedÂ an in-depth study to understand its etiology.

Comparison of vaccine-induced thrombotic events between ChAdOx1 nCoV-19 and Ad26.COV.2.S vaccines. Cerebral venous thrombosis (CVT) events have been reported after vaccination with adenoviral COVID-19 vector vaccines. This study aimed to compare the clinical presentations and

courses of vaccine-induced thrombotic thrombocytopenia (VITT) between the two adenoviral vector vaccines, Ad26.COV.2.S (Janssen/Johnson & Johnson) and ChAdOx1 nCoV-19 (Astra-Zeneca). We found that CVT after Ad26.COV.2.S vaccination presents later with similar symptoms compared to CVT after administration of ChAdOx1 nCoV-19, albeit with more thrombosis and intracerebral hemorrhage, lower D-dimer and aPTT levels but similar mortality. These findings could help guide clinical assessment and management of CVT after COVID-19 vaccination.

SARS-CoV-2 or SARS-CoV-2 vaccination associated Parsonage-Turner syndrome. Comment on: "Neuralgic amyotrophy and COVID-19 infection: 2 cases of spinal accessory nerve palsy" by Coll et al. Joint Bone Spine 2021;88:105196.

Laboratory testing for suspected COVID-19 vaccine-induced (immune) thrombotic thrombocytopenia. COVID-19 (coronavirus disease 2019) represents a pandemic, and several vaccines have been produced to prevent infection and/or severe sequelae associated with SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) infection. There have been several reports of infrequent post vaccine associated thrombotic events, in particular for adenovirus-based vaccines. These have variously been termed VIPIT (vaccine-induced prothrombotic immune thrombocytopenia), VITT (vaccine-induced [immune] thrombotic thrombocytopenia), VATT (vaccine-associated [immune] thrombotic thrombocytopenia), and TTS (thrombosis with thrombocytopenia syndrome). In this report, the laboratory test processes, as utilised to assess suspected VITT, are reviewed. In published reports to date, there are notable similarities and divergences in testing approaches, potentially leading to identification of slightly disparate patient cohorts. The key to appropriate identification/exclusion of VITT, and potential differentiation from heparin-induced thrombocytopenia with thrombosis (HITT), is identification of potentially differential test patterns. In summary, testing typically comprises platelet counts, D-dimer, fibrinogen, and various immunological and functional assays for platelet factor 4 (PF4) antibodies. In suspected VITT, there is a generally highly elevated level of D-dimer, thrombocytopenia, and PF4 antibodies can be identified by ELISA-based assays, but not by other immunological assays typically positive in HITT. In addition, in some functional platelet activation assays, standard doses of heparin have been identified to inhibit activation in suspected VITT, but they tend to augment activation in HITT. Conversely, it is also important to not over-diagnose VITT, given that not all cases of thrombosis post vaccination will have an immune basis and not all PF4-ELISA positive patients will be VITT.

Systemic drug-related intertriginous and flexural exanthema like eruption after CoronaVac vaccine.

Post-Vaccination Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infections and Incidence of the Presumptive B.1.427/B.1.429 Variant Among Healthcare Personnel at a Northern California Academic Medical Center. BACKGROUND: Although mRNA-based severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines report >90% efficacy, breakthrough infections occur. Little is known about their effectiveness against SARS-CoV-2 variants, including the highly prevalent B.1.427/B.1.429 variant. METHODS: In this quality improvement project, we collected demographic and clinical information from post-vaccine SARS-CoV-2 cases (PVSCs), defined as healthcare personnel (HCP) with positive SARS-CoV-2 nucleic acid amplification test after receiving â‰¥1 vaccine dose. Available specimens were tested for L452R, N501Y, and E484K mutations using reverse-transcription polymerase chain reaction. Mutation prevalence was compared among unvaccinated, early post-vaccinated (â‰¤14 days after dose 1), partially vaccinated (positive test >14 days after dose 1 and <14 days after dose 2), and fully vaccinated (>14 days after dose 2) PVSCs. RESULTS: From December 2020 to April 2021, â‰¥23â€‰090 HCP received â‰¥1 dose of an mRNA-based SARS-CoV-2 vaccine, and 660 HCP cases of SARS-CoV-2 occurred, of which 189 were PVSCs. Among the PVSCs, 114 (60.3%), 49 (25.9%), and 26 (13.8%) were early post-vaccination, partially vaccinated, and fully vaccinated, respectively. Of 261 available samples from vaccinated and

unvaccinated HCP, 103 (39.5%), including 42 PVSCs (36.5%), had the L452R mutation presumptive of B.1.427/B.1.429. When adjusted for community prevalence of B.1.427/B.1.429, PVSCs did not have significantly elevated risk of B.1.427/B.1.429 compared with unvaccinated HCP. CONCLUSIONS: Most PVSCs occurred prior to expected onset of full, vaccine-derived immunity. Presumptive B.1.427/B.1.429 was not more prevalent in post-vaccine cases than in unvaccinated SARS-CoV-2 HCP. Continued infection control measures, particularly <14 days post-vaccination, and continued variant surveillance in PVSCs are imperative to control future SARS-CoV-2 surges.

A case of thrombocytopenia and multiple thromboses after vaccination with ChAdOx1 nCoV-19 against SARS-CoV-2. Recently, reports of severe thromboses, thrombocytopenia, and hemorrhage in persons vaccinated with the chimpanzee adenovirus-vectored vaccine (ChAdOx1 nCoV-19, AZD1222, Vaxzevria; Oxford/AstraZeneca) against severe acute respiratory syndrome coronavirus 2 have emerged. We describe an otherwise healthy 30-year-old woman who developed thrombocytopenia, ecchymosis, portal vein thrombosis, and cerebral venous sinus thrombosis the second week after she received the ChAdOx1 nCoV-19 vaccine. Extensive diagnostic workup for thrombosis predispositions showed heterozygosity for the prothrombin mutation, but no evidence of myeloproliferative neoplasia or infectious or autoimmune diseases. Her only temporary risk factor was long-term use of oral contraceptive pills (OCPs). Although both the prothrombin mutation and use of OCPs predispose to portal and cerebral vein thrombosis, the occurrence of multiple thromboses within a short time and the associated pattern of thrombocytopenia and consumption coagulopathy are highly unusual. A maximum 4T heparin-induced thrombocytopenia (HIT) score and a positive immunoassay for anti-platelet factor 4/heparin antibodies identified autoimmune HIT as a potential pathogenic mechanism. Although causality has not been established, our case emphasizes the importance of clinical awareness. Further studies of this potentially new clinical entity have suggested that it should be regarded as a vaccine-induced immune thrombotic thrombocytopenia.

Sperm Parameters Before and After COVID-19 mRNA Vaccination. To address vaccine hesitancy based on concerns about fertility, this study assesses sperm parameters before and after mRNA vaccine administration.

Bioinformatic HLA Studies in the Context of SARS-CoV-2 Pandemic and Review on Association of HLA Alleles with Preexisting Medical Conditions. After the announcement of a new coronavirus in China in December 2019, which was then called SARS-CoV-2, this virus changed to a global concern and it was then declared as a pandemic by WHO. Human leukocyte antigen (HLA) alleles, which are one of the most polymorphic genes, play a pivotal role in both resistance and vulnerability of the body against viruses and other infections as well as chronic diseases. The association between HLA alleles and preexisting medical conditions such as cardiovascular diseases and diabetes mellitus is reported in various studies. In this review, we focused on the bioinformatic HLA studies to summarize the HLA alleles which responded to SARS-CoV-2 peptides and have been used to design vaccines. We also reviewed HLA alleles that are associated with comorbidities and might be related to the high mortality rate among COVID-19 patients. Since both genes and patients' medical conditions play a key role in both severity of the disease and the mortality rate in COVID-19 patients, a better understanding of the connection between HLA alleles and SARS-CoV-2 can provide a wider perspective on the behavior of the virus. Such understanding can help scientists, especially in terms of protecting healthcare workers and designing effective vaccines.

Full Vaccination Coverage and Associated Factors Among 12-to-23-Month Children at Assosa Town, Western Ethiopia, 2020. INTRODUCTION: Vaccination means the injection of a killed microbe to stimulate the immune system against the microbe, which prevents communicable diseases. It's the most important and cost-effective public health intervention to reduce child mortality and morbidity. Ethiopian national full vaccination coverage is 43%. This research aimed to assess full vaccination

coverage and associated factors among 12-to-23-month children at Assosa Town. METHODS: A community-based cross-sectional study was conducted among children aged of 12 to 23 months from November to December 2020. Assosa town has two woredas. Each woreda has five kebeles. By using lottery method, five kebeles were selected from two woredas. Systematic sampling technique was used for sampling. The total sample size was 372. It was calculated by the proportionate allocation method. Questioners were used to collect data by the observation of vaccination caring and mother interviewing. Data were entered into SPSS and analyzed. Multivariance analysis was used by considering a 95% confidence interval. Variables whose p-value less than 0.05 were identified as significant. RESULTS: The respondent rate of this study was 372 (100%). Of the total respondents, 338 (90.8%) were females and 34 (9.1%) of them were males. The coverage of full, partial, and non-vaccination is 71.77%, 16.67%, and 11.56%, respectively. Based on multivariate logistic regression analysis, child age [AOR=2.7, 95% CI: (1.36, 5.4)], no antenatal care visit [AOR=0.41, 95% CI: (0.24, 0.71)] and fear of covid 19 at health institutions [AOR=3.5, 95% CI: (2, 6)] were identified as significant variables. There are major identified factors for partial and non-vaccination. CONCLUSION: Coverage of full, partial, and non-vaccination was 71.77%, 16.67%, and 11.56%, respectively. Child age, no antenatal care visit, and fear of covid 19 at health institutions were significant variables. Fear of covid-19 is the commonest factor for partial and non-vaccination.

COVID-19 Vaccine Acceptance and Its Associated Factors Among Pregnant Women Attending Antenatal Care Clinic in Southwest Ethiopia: Institutional-Based Cross-Sectional Study. BACKGROUND: COVID-19 vaccination is a safe and effective approach to control the pandemic and to prevent its associated morbidity and mortality. To our knowledge, there is no study conducted to assess the prevalence of COVID-19 vaccine acceptance among pregnant women in Ethiopia. Therefore, the main objective of this study was to assess the prevalence of COVID-19 vaccine acceptance and its associated factors among pregnant women attending antenatal care clinic in Southwest Ethiopia. METHODS: An institution-based cross-sectional study was employed from January 1 up to 30, 2021. A systematic random sampling technique was used to select 396 study participants. A structured and face-to-face interview was used to collect data. Data were entered into Epi-data version 4.2.0 and exported to SPSS version 23 for analysis. Bivariate and multivariate analyses were used to identify factors associated with COVID-19 vaccine acceptance. P values <0.05 result were considered as a statistically significant association. RESULTS: The COVID-19 vaccine acceptance was found to be 70.7% (95% CI, 66.7%-74.7%). Maternal age (34-41) years [AOR=1.464, (95% CI; 1.218-5.129)], primary maternal educational status [AOR=3.476, (95% CI; 1.520-7.947), good knowledge [AOR=5.946, (95% CI; 3.147-7.065)], and good practice [AOR =9.15, (95% CI; 8.734-12.189)] of pregnant women towards COVID-19 and its preventive measures were factors associated with COVID-19 vaccine acceptance. CONCLUSION: COVID-19 vaccine acceptance was found to be 70.9%. Maternal age (34-41) years, primary maternal educational status, good knowledge, and good practice of pregnant women towards COVID-19 and its preventive measures were factors associated with COVID-19 vaccine acceptance. Health care workers should provide health education to pregnant women to increase their knowledge about the diseases and disseminate leaflets regarding COVID-19 preventive measures. Moreover, before initiation of COVID-19 vaccine administration to pregnant women they must promote the safety and effectiveness of COVID-19 vaccine.

COVID-19 vaccination and the power of rumors: Why we must "Tune in". Rumors have significantly affected immunization campaigns in the past. The ongoing COVID-19 vaccination program in India needs to frame public communication messages both to promote vaccine demand and update as well as counter COVID-related rumors. COVID-related rumors have had wide-ranging effects in the country, from stigmatization of health workers to a crash of prices in the poultry sector. Appropriate communication strategies are critical for tracking, negotiating, and shaping perceptions

around the vaccines and the program. Issues that will shape perceptions around the vaccines include product development, prioritization strategies, program rollout activities, and adverse effects following immunization and adverse effects of special interest.

Humoral Response after SARS-CoV-2 mRNA Vaccination in a Cohort of Hemodialysis Patients and Kidney Transplant Recipients. BACKGROUND: Kidney transplant recipients and patients receiving hemodialysis are immunocompromised populations that are prioritized for COVID-19 vaccination but were excluded from clinical trials of SARS-CoV-2 mRNA vaccines. Antibody titers and rates of seroconversion after vaccination are lower among patients with CKD and those taking immunosuppressants compared with controls. Data are lacking regarding their humoral response to vaccination to prevent COVID-19. METHODS: This investigation of early serological response after COVID-19 vaccination with the Pfizer/BioNTech (BNT162b2) mRNA vaccine included 78 patients undergoing hemodialysis, 74 kidney transplant recipients, and seven healthy controls. We recorded data from the medical file for various clinical parameters, including response to hepatitis B vaccination, and measured antibody titers against SARS-CoV-2 at 0, 14, 28, 36, and 58 days after the first injection. RESULTS: In controls, we detected antibodies at a positive level (>13 arbitrary units per ml; AU/ml) at day 14 postinjection, which increased progressively to peak at day 36 (1082 AU/ml; interquartile range [IQR], 735.0-1662.0). Patients undergoing hemodialysis had lower titers that peaked at day 58 (276 AU/ml; IQR, 83.4-526.0). We detected a positive antibody level in only three transplant recipients at day 36. In patients on hemodialysis, those aged <75 years had a higher antibody response versus those aged >75 years, and serum albumin and Kt/V were positively correlated with serological response ($P<0.04$ and $P<0.0$, respectively); nonresponders to HBV vaccine had the lowest anti-SARS-CoV-2 antibody titers. CONCLUSIONS: Our results suggest that the postvaccination humoral response is strongly inhibited by immunosuppressant therapy in kidney transplant recipients, and is reduced by the uremic condition in patients undergoing hemodialysis.

ChAdOx1 nCOV-19 vaccine-induced immune thrombotic thrombocytopenia and cerebral venous sinus thrombosis (CVST). A 27-year-old fit and well man presented with intermittent headaches associated with eye floaters and vomiting. His symptoms started 48 hours after having the first dose of ChADOx1 nCOV-19 vaccine (Vaxzevria, previously AstraZeneca COVID-19 vaccine; AstraZeneca) and bloods showed raised D-dimer, low platelets and fibrinogen. CT venogram demonstrated significant cerebral venous sinus thrombosis. He was immediately started on intravenous immunoglobulins and dabigatran after liasing with haematologist. The next day, he complained of worsening headache and new homonymous hemianopia. Repeat CT of the head showed an acute parenchymal bleed with subdural extension and was given idarucizumab and high-dose steroids. He had an emergency decompressive craniotomy and external ventricular drain as his intracranial pressures were difficult to control. Despite full medical and surgical management, his intracranial pressures continued to rise and his brain injury was felt to be too devastating and was deemed unsurvivable.

Lupus, vaccinations and COVID-19: What we know now. Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the virus causing Coronavirus disease 2019 (COVID-19), has had a huge impact on health services, with a high mortality associated with complications including pneumonia and acute respiratory distress syndrome. Patients with systemic lupus erythematosus (SLE) are at increased risk of viral infections, and recent data suggests they may be at an increased risk of poor outcomes with COVID-19. This may be particularly true for those on rituximab or high dose steroids. A huge international effort from the scientific community has so far resulted in the temporary authorisation of three vaccines which offer protection against SARS-CoV-2, with over 30 other vaccines being evaluated in ongoing trials. Although there has historically been concern that vaccines may trigger disease flares of SLE, there is little convincing evidence to show this. In general lupus patients appear to gain good protection from vaccination, although there may be reduced efficacy in

those with high disease activity or those on immunosuppressive therapies, such as rituximab or high dose steroids. Recent concerns have been raised regarding rare clotting events with the AstraZeneca/Oxford vaccine and it is currently unknown whether this risk is higher for those patients with secondary antiphospholipid syndrome. With the possibility of annual COVID vaccination programmes in the future, prospective data collection and registries looking at the effect of vaccination on SLE disease control, the incidence of COVID-19 in SLE patients and severity of COVID-19 disease course would all be useful. As mass vaccination programmes begin to roll out across the world, we assess the evidence of the use of vaccines in SLE patients and in particular vaccines targeting SARS-CoV-2.

Humoral and Cellular Immune Responses Against Severe Acute Respiratory Syndrome Coronavirus 2 Variants and Human Coronaviruses After Single BNT162b2 Vaccination. BACKGROUND: Vaccine-induced neutralizing antibodies are key in combating the coronavirus disease 2019 (COVID-19) pandemic. However, delays of boost immunization due to limited availability of vaccines may leave individuals vulnerable to infection and prolonged or severe disease courses. The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants of concern (VOC)-B.1.1.7 (United Kingdom), B.1.351 (South Africa), and P.1 (Brazil)-may exacerbate this issue, as the latter two are able to evade control by antibodies. METHODS: We assessed humoral and T-cell responses against SARS-CoV-2 wild-type (WT), VOC, and endemic human coronaviruses (hCoVs) that were induced after single and double vaccination with BNT162b2. RESULTS: Despite readily detectable immunoglobulin G (IgG) against the receptor-binding domain of the SARS-CoV-2 S protein at day 14 after a single vaccination, inhibition of SARS-CoV-2 S-driven host cell entry was weak and particularly low for the B.1.351 variant. Frequencies of SARS-CoV-2 WT and VOC-specific T cells were low in many vaccinees after application of a single dose and influenced by immunity against endemic hCoV. The second vaccination significantly boosted T-cell frequencies reactive for WT and B.1.1.7 and B.1.351 variants. CONCLUSIONS: These results call into question whether neutralizing antibodies significantly contribute to protection against COVID-19 upon single vaccination and suggest that cellular immunity is central for the early defenses against COVID-19.

Clinical review of cerebral venous thrombosis in the context of COVID-19 vaccinations: Evaluation, management, and scientific questions. BACKGROUND: Vaccine induced immune mediated thrombocytopenia or VITT, is a recent and rare phenomenon of thrombosis with thrombocytopenia, frequently including cerebral venous thromboses (CVT), that has been described following vaccination with adenovirus vaccines ChAdOx1 nCOV-19 (AstraZeneca) and Ad26.COV2Â·S Johnson and Johnson (Janssen/J&J). The evaluation and management of suspected cases of CVT post COVID-19 vaccination are critical skills for a broad range of healthcare providers. METHODS: A collaborative comprehensive review of literature was conducted among a global group of expert neurologists and hematologists. FINDINGS: Strategies for rapid evaluation and treatment of the CVT in the context of possible VITT exist, including inflammatory marker measurements, PF4 assays, and non-heparin anticoagulation.

Seroconversion rates following COVID-19 vaccination among patients with cancer. As COVID-19 adversely affects patients with cancer, prophylactic strategies are critically needed. Using a validated antibody assay against SARS-CoV-2 spike protein, we determined a high seroconversion rate (94%) in 200 patients with cancer in New York City that had received full dosing with one of the FDA-approved COVID-19 vaccines. On comparison with solid tumors (98%), a significantly lower rate of seroconversion was observed in patients with hematologic malignancies (85%), particularly recipients following highly immunosuppressive therapies such as anti-CD20 therapies (70%) and stem cell transplantation (73%). Patients receiving immune checkpoint inhibitor therapy (97%) or hormonal therapies (100%) demonstrated high seroconversion post vaccination. Patients with prior COVID-19

infection demonstrated higher anti-spike IgG titers post vaccination. Relatively lower IgG titers were observed following vaccination with the adenoviral than with mRNA-based vaccines. These data demonstrate generally high immunogenicity of COVID-19 vaccination in oncology patients and identify immunosuppressed cohorts that need novel vaccination or passive immunization strategies.
Myocarditis Temporally Associated With COVID-19 Vaccination. Supplemental Digital Content is available in the text.
Myocarditis After BNT162b2 and mRNA-1273 Vaccination. Supplemental Digital Content is available in the text.
In-Depth Evaluation of a Case of Presumed Myocarditis After the Second Dose of COVID-19 mRNA Vaccine. Supplemental Digital Content is available in the text.
Thrombotic Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination. Reply.
Myopericarditis in a previously healthy adolescent male following COVID-19 vaccination: A case report. We report the case of a previously healthy 16-year-old male who developed myopericarditis following the second dose of his Pfizer-BioNTech COVID-19 vaccine, with no other identified triggers. Adolescents and young adults experiencing chest pain after COVD-19 vaccination should seek emergent medical care, and emergency providers should have a low threshold to consider and evaluate for myopericarditis. More data are needed to better understand the potential association between COVID-19 vaccines and myopericarditis. If a true causal link is identified, the risk must also be viewed in context with the millions of patients who have been safely vaccinated and the known morbidity and mortality from COVID-19 infection. As we see widespread vaccine rollout, it is important that all potential adverse reactions are reported as we continue to monitor for more rare but potentially serious side effects not identified in vaccination trials.
Cerebral venous thrombosis post BNT162b2 mRNA SARS-CoV-2 vaccination: A black swan event.
Thromboaspiration and fibrinolysis infusion for portomesenteric thrombosis after AstraZeneca COVID-19 vaccine administration.
Immediate-Type Hypersensitivity to Polyethylene Glycol (PEG) and a PEG-Containing COVID-19 Vaccine Revealed by Intradermal Testing.
Impaired antibody response to COVID-19 vaccination in patients with chronic myeloid neoplasms.
COVIDâ€‘19 vaccination and IgG and IgA antibody dynamics in healthcare workers. Given the current outbreak of coronavirus diseaseÂ 2019 (COVIDâ€‘19) and the development and implementation of mass vaccination, data are being obtained by analyzing vaccination campaigns. In the present study, 69Â healthcare workers who were exposed to patients with severe acute respiratory syndrome coronavirusâ€‘2 were monitored for specific immunoglobulin (Ig)G and IgA levels at different time periods. Prior to vaccination, after the first round of vaccination at 21Â days (when the second dose of vaccine was administrated) and 24Â days after the second round of vaccination, with an mRNAâ€‘based vaccine. The basal IgG and IgA levels in previously infected subjects and nonâ€‘infected subjects notably differed. Vaccination increased the IgG and IgA levels after the first dose in most subjects from both groups, the levels of which further increased following the second round of vaccination. The associations between IgG and IgA levels following the first and second rounds of vaccination demonstrated that in the entire vaccination group, regardless of prior exposure to the infectious agent, the increment and levels of IgG and IgA were similar. Thus, the levels upon vaccination were statistically similar irrespective of the starting base line prior to vaccination. In the present study, seroconversion was achieved in all subjects following the second round of vaccination, with similar antibodies levels.
Chilblain-like lesions after BNT162b2 mRNA COVID-19 vaccine: a case report suggesting that 'COVID toes' are due to the immune reaction to SARS-CoV-2.

Acute bilateral optic/chiasm neuritis with longitudinal extensive transverse myelitis in longstanding stable multiple sclerosis following vector-based vaccination against the SARS-CoV-2.

Impaired humoral immunity to SARS-CoV-2 BNT162b2 vaccine in kidney transplant recipients and dialysis patients. Patients with kidney failure are at increased risk for SARS-CoV-2 infection making effective vaccinations a critical need. It is not known how well mRNA vaccines induce B and plasma cell responses in dialysis patients (DP) or kidney transplant recipients (KTR) compared to healthy controls (HC). We studied humoral and B cell responses of 35 HC, 44 DP and 40 KTR. Markedly impaired anti-BNT162b2 responses were identified among KTR and DP compared to HC. In DP, the response was delayed (3-4 weeks after boost) and reduced with anti-S1 IgG and IgA positivity in 70.5% and 68.2%, respectively. In contrast, KTR did not develop IgG responses except one patient who had a prior unrecognized infection and developed anti-S1 IgG. The majority of antigen-specific B cells (RBD+) were identified in the plasmablast or post-switch memory B cell compartments in HC, whereas RBD+ B cells were enriched among pre-switch and naÃ¯ve B cells from DP and KTR. The frequency and absolute number of antigen-specific circulating plasmablasts in the cohort correlated with the Ig response, a characteristic not reported for other vaccinations. In conclusion, these data indicated that immunosuppression resulted in impaired protective immunity after mRNA vaccination, including Ig induction with corresponding generation of plasmablasts and memory B cells. Thus, there is an urgent need to improve vaccination protocols in patients after kidney transplantation or on chronic dialysis.

COVID-19 vaccine-induced acute generalized exanthematous pustulosis.

Reconstituted mRNA COVID-19 vaccines may maintain stability after continuous movement. OBJECTIVES: There is an urgent need to ameliorate the possibilities of transporting reconstituted mRNA vaccines from the centralized preparation centres to the vaccination sites to improve the efficiency of the vaccination campaign against coronavirus disease 2019 (COVID-19). We have analysed the integrity of the Pfizer-BioNTech and Moderna vaccines under different movement conditions to provide information that may improve the distribution of vaccines to the target population. METHODS: Syringes of reconstituted Pfizer-BioNTech or Moderna COVID-19 vaccines were prepared in a laminar flow chamber to be subjected to a stability analysis in order to evaluate the impact of movement on mRNA integrity. RNA integrity was checked by the lack of RNA peaks under the original mRNA peak in the electropherogram resulting from potential fragments from RNA degradation. Samples were then exposed for 180Â min at room temperature (21Â Â±Â 1Â°C, 55Â Â±Â 10% humidity) under different movement conditions. RESULTS: We report that the integrity of the mRNA in the reconstituted COVID-19 vaccines after continuous moderate movement at room temperature is maintained for at least 3Â hours, with values of fluorescence units (FU) under the original mRNA peak of 0.38Â Â±Â 0.06 in the Pfizer-BioNTech vaccine and 0.96Â Â±Â 1.18 FU in the Moderna vaccine, equal to the values obtained without movement (0.36Â Â±Â 0.08 FU in the Pfizer-BioNTech and 1.12Â Â±Â 0.19 FU in the Moderna). In contrast, the integrity of these vaccines exposed to repeated Vortex shaking was significantly impaired (pÂ <Â 0.001) with values under the original mRNA peak of 1.34Â Â±Â 0.31 FU for the Pfizer-BioNTech and 5.03Â Â±Â 1.16 FU for the Moderna samples. CONCLUSIONS: The stability of these reconstituted vaccines reported here may improve the efficiency of the ground transportation and distribution of the vaccines, which may lead to shorter and more homogeneous vaccinations in cities and rural areas.

Another case of autoimmune hepatitis after SARS-CoV-2 vaccination - still casualty?

Antibody Responses After mRNA-Based COVID-19 Vaccination in Residential Older Adults: Implications for Reopening. OBJECTIVE: COVID-19 disproportionately impacts residents in long-term care facilities. Our objective was to quantify the presence and magnitude of antibody response in vaccinated, older adult residents at assisted living, personal care, and independent living

communities. DESIGN: A cross-sectional quality improvement study was conducted March 15 - April 1, 2021 in the greater Pittsburgh region. SETTING AND POPULATION: Participants were older adult residents at assisted living, personal care, and independent living communities, who received mRNA-based COVID-19 vaccine. Conditions that impair immune responses were exclusionary criteria. METHODS: Sera were collected to measure IgG anti-SARS-CoV-2 antibody level with reflex to total anti-SARS-CoV-2 immunoglobulin levels, and blinded evaluation of SARS-CoV-2 pseudovirus neutralization titers. Descriptive statistics, Pearson correlation coefficients, and multiple linear regression analysis evaluated relationships between factors potentially associated with antibody levels. Spearman correlations were calculated between antibody levels and neutralization titers. RESULTS: All participants (NÂ = 70) had received two rounds of vaccination and were found to have antibodies with wide variation in relative levels. Antibody levels trended lower in males, advanced age, current use of steroids, and longer length of time from vaccination. Pseudovirus neutralization titer levels were strongly correlated (P < .001) with Beckman Coulter antibody levels [D614Â G NT50, r(s)Â = 0.91; B.1.1.7 (UK) NT50, r(s)Â = 0.91]. CONCLUSIONS AND IMPLICATIONS: Higher functioning, healthier, residential older adults mounted detectable antibody responses when vaccinated with mRNA-based COVID-19 vaccines. Data suggests some degree of immunity is present during the immediate period following vaccination. However, protective effects remain to be determined in larger studies as clinical protection is afforded by ongoing adaptive immunity, which is known to be decreased in older adults. This study provides important preliminary results on level of population risk in older adult residents at assisted living, personal care, and independent living communities to inform reopening strategies, but are not likely to be translatable for residents in nursing homes.
Localized cutaneous reaction to an mRNA COVID-19 vaccine.
Delayed local reactions after the first administration of the ChAdOx1 nCoV-19 vaccine.
Procoagulant microparticles: a possible link between vaccine-induced immune thrombocytopenia (VITT) and cerebral sinus venous thrombosis.
COVID-19 vaccines and the role of other potential allergenic components different from PEG. A reply to: "Other excipients than PEG might cause serious hypersensitivity reactions in COVID-19 vaccines".
Other excipients than PEG might cause serious hypersensitivity reactions in COVID-19 vaccines.
Immunogenicity and safety of the BNT162b2 mRNA COVID-19 vaccine in adult patients with autoimmune inflammatory rheumatic diseases and in the general population: a multicentre study. INTRODUCTION: Vaccination represents a cornerstone in mastering the COVID-19 pandemic. Data on immunogenicity and safety of messenger RNA (mRNA) vaccines in patients with autoimmune inflammatory rheumatic diseases (AIIRD) are limited. METHODS: A multicentre observational study evaluated the immunogenicity and safety of the two-dose regimen BNT162b2 mRNA vaccine in adult patients with AIIRD (n=686) compared with the general population (n=121). Serum IgG antibody levels against SARS-CoV-2 spike S1/S2 proteins were measured 2-6 weeks after the second vaccine dose. Seropositivity was defined as IgG â‰¥15 binding antibody units (BAU)/mL. Vaccination efficacy, safety, and disease activity were assessed within 6 weeks after the second vaccine dose. RESULTS: Following vaccination, the seropositivity rate and S1/S2 IgG levels were significantly lower among patients with AIIRD versus controls (86% (n=590) vs 100%, p<0.0001â€‰and 132.9Â±91.7 vs 218.6Â±82.06 BAU/mL, p<0.0001, respectively). Risk factors for reduced immunogenicity included older age and treatment with glucocorticoids, rituximab, mycophenolate mofetil (MMF), and abatacept. Rituximab was the main cause of a seronegative response (39% seropositivity). There were no postvaccination symptomatic cases of COVID-19 among patients with AIIRD and one mild case in the control group. Major adverse events in patients with AIIRD included death (n=2) several weeks after the second vaccine dose, non-disseminated herpes zoster (n=6), uveitis (n=2), and pericarditis (n=1). Postvaccination disease activity remained stable in the majority of patients. CONCLUSION:

mRNA BNTb262 vaccine was immunogenic in the majority of patients with AIIRD, with an acceptable safety profile. Treatment with glucocorticoids, rituximab, MMF, and abatacept was associated with a significantly reduced BNT162b2-induced immunogenicity.
Allergic symptoms after mRNA COVID-19 vaccination and risk of incomplete vaccination.
SARS-CoV-2 vaccine-induced immune thrombotic thrombocytopenia treated with immunoglobulin and argatroban.
Severe Exacerbations of Systemic Capillary Leak Syndrome After COVID-19 Vaccination: A Case Series.
Safety and Immunogenicity of a Third Dose of SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients: A Case Series.
Outbreak of infections with the COVID-19 virus mutation B.1.351 about four weeks after the second successful vaccination with BNT162b2.
Symptoms, antibody levels and vaccination attitude after asymptomatic to moderate COVID-19 infection in 200 healthcare workers. Aim: In Germany, the willingness to be vaccinated against COVID-19 is rather low among medical staff. We collected data on symptoms, antibody titers and vaccination readiness from clinic employees at a municipal clinic who had already been through a COVID-19 infection (asymptomatic to moderate). We also examined the antibody titers for their possible importance as an individual decision-making aid with regard to vaccination. Method: 200 employees of our municipal clinics were included in the study. COVID-19 antibody determination was performed using an ELISA (EUROIMMUNâ„¢, PerkinElmer, Inc. Company). The participants were given an anonymous questionnaire containing anthropometrical issues, symptoms of the infection and questions concerning the vaccination decision. Finally, the antibody levels were reported to the participants and the attitude towards a vaccination was reevaluated. Results: In all 200 participants who had already gone through a COVID-19 infection, 75 employees were in favor of a vaccination (37.5%), 96 were opposed to vaccination (48%), and 29 were undecided (14.5%). In the different occupational groups, the positive trend in terms of willingness to be vaccinated was highest among physicians and is least among nurses. The antibody results showed considerable variation in titer levels and therefore did not correlate with disease severity in asymptomatic to moderately ill persons. We also observed a pro-vaccination trend with increasing age of the participants. The specifically-asked symptom of cutaneous hyperesthesia during COVID-19 infection occurred in 5% of the participants. Conclusion: In medical personnel who had already suffered from a COVID-19 infection, the willingness to receive a vaccination tends to be highest among physicians, and lowest in nurses, and increases with age. For the vast majority of those affected, knowledge of the antibody titers only reinforces the vaccination decision made beforehand and thus does not contribute to a change in vaccination decision. The specifically-requested symptom of cutaneous hyperesthesia during COVID-19 infection was unexpectedly frequent.
Hypersensitivity to Covid-19 Vaccine Confirmed by a Positive Skin Test Result: A Case Report.
Tinnitus following COVID-19 vaccination: report of three cases. OBJECTIVE: To ensure the safety and quality of vaccines, especially the newest RNA-vaccines against COVID-19, is one of the World Health Organization's current highest priorities. DESIGN: Case description. STUDY SAMPLE: We report three cases of sudden unilateral tinnitus following BNT162b2 mRNA-vaccine injection, which rapidly resolved in 2 out of 3 cases. RESULTS: The mechanism responsible for its development remains unclear. A hypersensitivity reaction with an abnormal autoimmune response or a vasculitic event may be implicated. CONCLUSIONS: Large-scale and well-designed studies are needed to improve surveillance of the COVID-19 vaccine and better define possible adverse reactions involving the cochleo-vestibular system and/or immunisation anxiety-related reactions.
COVID-19 vaccine-induced immune thrombotic thrombocytopenia: A review of the potential mechanisms and proposed management. With over 600â€‰million coronavirus (COVID-19)

vaccine doses administered globally, adverse events are constantly monitored. Recently however, reports of thrombosis and thrombocytopenia following vaccination with the ChAdOx1 nCoV-19 vaccine have emerged. This paper aims to review the available literature and guidelines pertaining to vaccine-induced immune thrombotic thrombocytopenia (VITT) and the proposed guidelines, while offering a potential approach that unifies the available evidence. While the risk of VITT remains extremely low and the benefits outweigh the risks, experimental studies are needed to clarify the pathophysiology behind VITT and possibly decrease the risk of thrombosis and other adverse events occurring. However, treatment should not be delayed in suspected cases, and IV immunoglobulin and non-heparin anticoagulation should be initiated.

COVID Arm: Delayed Hypersensitivity Reactions to SARS-CoV-2 Vaccines Misdiagnosed as Cellulitis. The term "COVID arm" has been coined to describe a harmless delayed hypersensitivity reaction occurring approximately a week after administration of the novel SARS-CoV-2 mRNA vaccine. It appears as a red, warm, pruritic, indurated, or swollen area in the vicinity of the vaccine site. These reactions, especially if accompanied by systemic symptoms, have been mistaken for cellulitis. We report 3 cases of COVID arm, 2 of which were mistaken for cellulitis. Distinguishing features of COVID arm from cellulitis include pruritus as a common finding, occurrence approximately a week after vaccination, a lack of progression of symptoms, rapid response to topical steroids, and/or spontaneous resolution usually over 4 to 5â€‰days.Practice Points:â€¢â€ƒPatients receiving SARS-CoV-2 vaccines may experience delayed hypersensitivity reactions characterized by erythema, swelling, and itching occurring near the vaccination site (COVID arm), approximately a week after vaccination.â€¢â€ƒClinicians can distinguish SARS-CoV-2 vaccine reactions from cellulitis by the time of onset (approximately a week vs 5â€‰days), by the lack of progression of symptoms, and resolution over 4 to 5â€‰days.â€¢â€ƒSevere cases of COVID arm may be treated with topical steroids.

Diabetes and COVID-19: The past, the present, and the future. Diabetes, one of the most prevalent chronic diseases in the world, is strongly associated with a poor prognosis in COVID-19. Scrupulous blood sugar management is crucial, since the worse outcomes are closely associated with higher blood sugar levels in COVID-19 infection. Although recent observational studies showed that insulin was associated with mortality, it should not deter insulin use in hospitalized patients requiring tight glucose control. Back and forth dilemma in the past with regards to continue/discontinue certain medications used in diabetes have been mostly resolved. The initial fears of consequences related to continuing certain medications have been largely dispelled. COVID-19 also necessitates the transformation in diabetes care through the integration of technologies. Recent advances in health-related technologies, notably telemedicine and remote continuous glucose monitoring, have become essential in the management of diabetes during the pandemic. Today, these technologies have changed the landscape of medicine and become more important than ever. Being a high-risk population, patients with type 1 or type 2 diabetes, should be prioritized for vaccination. In the future, as the pandemic fades, the prevalence of non-communicable diseases is expected to rise due to lifestyle changes and medical issues/dilemma encountered during the pandemic.

Relapse of minimal change disease following the AstraZeneca COVID-19 vaccine.

Evaluation of Covid-19 vaccines: Pharmacoepidemiological aspects. The marketing authorization granted to SARS-Cov-2 vaccines was accompanied by reinforced safety monitoring plans. These plans' implementation was part of the usual logic of post-marketing surveillance of new and innovative health products. It was especially adapted to the context of post-marketing monitoring of drugs developed according to the usual scientific quality standards but in an accelerated schedule. In Europe, the reinforced surveillance system relies on the complementary strengths of pharmacovigilance and pharmacoepidemiology. If the performances of pharmacovigilance monitoring

are incomparable for the detection of safety signals relating to rare events of atypical presentation, it needs to be completed with pharmacoepidemiology activities for more common events, either multifactorial or frequently classified as idiopathic. The pharmacoepidemiological monitoring developed in Europe was elaborated before the first SARS-Cov-2 vaccines where marketed, taking into account the lessons learned from the vaccination campaign against 2009 A (H1N1) influenza. It includes numerous academic studies as well as studies performed within vaccines risk management plans. In terms of safety, those defined a priori mostly concerns a list of pre-established health events of specific interest. Aside of these planned activities, ad-hoc studies will be latter developed on purpose to investigate safety signals or potential signals that could be identified as the result of pharmacovigilance activities. Aside of these regulated activities, as for today, very few studies have been published regarding SARS-Cov-2 vaccines; most of the existing consist in preprints that should be considered with caution. Pharmacoepidemiology of vaccines is thought to allow near-real time monitoring that needs sufficient time to provide with valid results. In the constant urge for information that accompanies COVID-related science, it is important not to make haste the enemy of speed and to let pharmacoepidemiology provides with what it is expected to do: rock-solid scientific information contributing to evidence-based decision-making.
Myocarditis After SARS-CoV-2 Vaccination: A Vaccine-Induced Reaction? Vaccination plays an important role in the fight against SARS-CoV-2 to minimie the spread of coronavirus disease 2019 (COVID-19) and its life-threatening complications. Myocarditis has been reported as a possible and rare adverse consequence of different vaccines, and its clinical presentation can range from influenza-like symptoms to acute heart failure. We report a case of a 30-year-old man who presented progressive dyspnea and constrictive retrosternal pain after receiving SARS-CoV-2 vaccine. Cardiac magnetic resonance and laboratory data revealed typical findings of acute myopericarditis.
Adverse effects of COVID-19 messenger RNA vaccines among pregnant women: a cross-sectional study on healthcare workers with detailed self-reported symptoms.
The first known case of vaccine-induced thrombotic thrombocytopenia in Australia.
A 59-Year-Old Woman with Extensive Deep Vein Thrombosis and Pulmonary Thromboembolism 7 Days Following a First Dose of the Pfizer-BioNTech BNT162b2 mRNA COVID-19 Vaccine. BACKGROUND The COVID-19 pandemic is an ongoing cause of the current global healthcare crisis. Several vaccines were approved for use by emergency vaccination campaigns worldwide. At present, there are very few reports of COVID-19 vaccine-induced immune-thrombotic thrombocytopenia, a variant of heparin-induced thrombocytopenia (HIT), in comparison to the massive number of vaccinated people worldwide. CASE REPORT A 59-year-old woman presented to the Emergency Department with a 3-day history of sudden-onset left leg pain 7 days after receiving her first dose of BNT162b2 mRNA COVID-19 (Pfizer-BioNTech). She was diagnosed with deep vein thrombosis (DVT) and pulmonary embolism (PE) and found to have a positive HIT screen with optical density (OD) of 0.6 via ELISA test. She was hospitalized for 4 days and discharged home with an oral anticoagulant (rivaroxaban). CONCLUSIONS This case report describes a possible link between BNT162b2 mRNA COVID-19 (Pfizer-BioNTech) vaccination and thromboembolism. However, further data are needed to support such an association.
Implications of mRNA-based SARS-CoV-2 vaccination for cancer patients. SARS-CoV-2 infection and the resulting COVID-19 have afflicted millions of people in an ongoing worldwide pandemic. Safe and effective vaccination is needed urgently to protect not only the general population but also vulnerable subjects such as patients with cancer. Currently approved mRNA-based SARS-CoV-2 vaccines seem suitable for patients with cancer based on their mode of action, efficacy, and favorable safety profile reported in the general population. Here, we provide an overview of mRNA-based vaccines including their safety and efficacy. Extrapolating from insights gained from a different

preventable viral infection, we review existing data on immunity against influenza A and B vaccines in patients with cancer. Finally, we discuss COVID-19 vaccination in light of the challenges specific to patients with cancer, such as factors that may hinder protective SARS-CoV-2 immune responses in the context of compromised immunity and the use of immune-suppressive or immune-modulating drugs.
Vaccines and Disease Relapses in Children with Nephrotic Syndrome.
COVID-19 vaccine: the gender disparity.
Supraclavicular lymphadenopathy after COVID-19 vaccination in Korea: serial follow-up using ultrasonography. We present serial sonographic findings of a case of supraclavicular lymphadenopathy that occurred after COVID-19 vaccination. Ipsilateral lymphadenopathy near the vaccine injection site following COVID-19 vaccination is a rather uncommon but expected adverse reaction. While axillary lymphadenopathy is more common, cases of supraclavicular lymphadenopathy in the setting of recent vaccination against COVID-19 are also being reported. Radiologists as well as referring physicians should be aware of this self-limiting process along with its ultrasonographic features and manage patients conservatively rather than performing an unnecessary immediate biopsy.
Cerebral Venous Sinus Thrombosis in the U.S. Population, After Adenovirus-Based SARS-CoV-2 Vaccination, and After COVID-19.
Relapse of IgG4-related nephritis following mRNA COVID-19 vaccine.
Autoimmune hepatitis following SARS-CoV-2 vaccine: May not be a casuality.
Portal vein thrombosis associated with ChAdOx1 nCov-19 vaccination.
Asymmetrical cutaneous vasculitis following COVID-19 vaccination with unusual eosinophil preponderance.
COVID-19 Vaccination-Associated Lymphadenopathy on FDG PET/CT: Distinctive Features in Adenovirus-Vectored Vaccine. PURPOSE: This study investigated 18F-FDG PET/CT features of adenovirus-vectored vaccination against COVID-19 in healthy subjects. PATIENTS AND METHODS: Thirty-one health care workers had been vaccinated Vaxzevria and underwent FDG PET/CT as an optional test for a cancer screening program. Size and FDG uptake of the hypermetabolic lymph nodes were measured. Uptake value of spleen was also measured with liver for comparison. RESULTS: All examinees who underwent FDG PET/CT within 14 days' interval showed hypermetabolic lymphadenopathies ipsilateral to vaccine injection. All examinees with hypermetabolic lymphadenopathy had simultaneous muscular uptakes until 23 days' interval. Among 12 examinees who underwent FDG PET/CT more than 15 days after vaccination, only 3 male examinees did not show hypermetabolism in the axillary lymph nodes. There was no female examinee with negative hypermetabolic lymphadenopathy until 29 days after vaccination. CONCLUSIONS: Hypermetabolic reactive lymphadenopathy in the ipsilateral axillary area with or without supraclavicular area is most likely to occur in a healthy person with recent adenovirus-vectored COVID-19 vaccination on FDG PET/CT.
Transplantation Outcome in Recipients Engrafted With Organs Recovered From the First French Deceased Donor With a SARS-COV-2 Vaccine-induced Thrombotic Thrombocytopenia.
COVID-19 Vaccine-Related Discussion on Twitter: Topic Modeling and Sentiment Analysis. BACKGROUND: Vaccination is a cornerstone of the prevention of communicable infectious diseases; however, vaccines have traditionally met with public fear and hesitancy, and COVID-19 vaccines are no exception. Social media use has been demonstrated to play a role in the low acceptance of vaccines. OBJECTIVE: The aim of this study is to identify the topics and sentiments in the public COVID-19 vaccine-related discussion on social media and discern the salient changes in topics and sentiments over time to better understand the public perceptions, concerns, and emotions that may

influence the achievement of herd immunity goals. METHODS: Tweets were downloaded from a large-scale COVID-19 Twitter chatter data set from March 11, 2020, the day the World Health Organization declared COVID-19 a pandemic, to January 31, 2021. We used R software to clean the tweets and retain tweets that contained the keywords vaccination, vaccinations, vaccine, vaccines, immunization, vaccinate, and vaccinated. The final data set included in the analysis consisted of 1,499,421 unique tweets from 583,499 different users. We used R to perform latent Dirichlet allocation for topic modeling as well as sentiment and emotion analysis using the National Research Council of Canada Emotion Lexicon. RESULTS: Topic modeling of tweets related to COVID-19 vaccines yielded 16 topics, which were grouped into 5 overarching themes. Opinions about vaccination (227,840/1,499,421 tweets, 15.2%) was the most tweeted topic and remained a highly discussed topic during the majority of the period of our examination. Vaccine progress around the world became the most discussed topic around August 11, 2020, when Russia approved the world's first COVID-19 vaccine. With the advancement of vaccine administration, the topic of instruction on getting vaccines gradually became more salient and became the most discussed topic after the first week of January 2021. Weekly mean sentiment scores showed that despite fluctuations, the sentiment was increasingly positive in general. Emotion analysis further showed that trust was the most predominant emotion, followed by anticipation, fear, sadness, etc. The trust emotion reached its peak on November 9, 2020, when Pfizer announced that its vaccine is 90% effective. CONCLUSIONS: Public COVID-19 vaccine-related discussion on Twitter was largely driven by major events about COVID-19 vaccines and mirrored the active news topics in mainstream media. The discussion also demonstrated a global perspective. The increasingly positive sentiment around COVID-19 vaccines and the dominant emotion of trust shown in the social media discussion may imply higher acceptance of COVID-19 vaccines compared with previous vaccines.

Guillain-BarrÃ© Syndrome Variant Occurring after SARS-CoV-2 Vaccination. Although SARS-CoV-2 vaccines are very safe, we report 4 cases of the bifacial weakness with paresthesias variant of Guillain-BarrÃ© syndrome (GBS) occurring within 3â€‰weeks of vaccination with the Oxford-AstraZeneca SARS-CoV-2 vaccine. This rare neurological syndrome has previously been reported in association with SARS-CoV-2 infection itself. Our cases were given either intravenous immunoglobulin, oral steroids, or no treatment. We suggest vigilance for cases of bifacial weakness with paresthesias variant GBS following vaccination for SARS-CoV-2 and that postvaccination surveillance programs ensure robust data capture of this outcome, to assess for causality. ANN NEUROL 2021;90:315-318.

No, it's not 1976 all over again.

Guillain-BarrÃ© Syndrome following ChAdOx1-S/nCoV-19 Vaccine. As of April 22, 2021, around 1.5 million individuals in three districts of Kerala, India had been vaccinated with COVID-19 vaccines. Over 80% of these individuals (1.2 million) received the ChAdOx1-S/nCoV-19 vaccine. In this population, during this period of 4â€‰weeks (mid-March to mid-April 2021), we observed seven cases of Guillain-Barre syndrome (GBS) that occurred within 2â€‰weeks of the first dose of vaccination. All seven patients developed severe GBS. The frequency of GBS was 1.4- to 10-fold higher than that expected in this period for a population of this magnitude. In addition, the frequency of bilateral facial weakness, which typically occurs in <20% of GBS cases, suggests a pattern associated with the vaccination. While the benefits of vaccination substantially outweigh the risk of this relatively rare outcome (5.8 per million), clinicians should be alert to this possible adverse event, as six out of seven patients progressed to areflexic quadriplegia and required mechanical ventilatory support. ANN NEUROL 2021;90:312-314.

Transient akathisia after the SARS-Cov-2 vaccine. We describe a case of transient akathisia after the second dose of the Pfizer COVID-19 vaccine. Movement disorder symptoms such as parkinsonism

have been described after other vaccinations and acute COVID-19 infection. This suggests a potential vulnerability of the extrapyramidal system to the immune response against even a component of the virus.
Newly Diagnosed Idiopathic Thrombocytopenia Post COVID-19 Vaccine Administration. A few individuals are believed to have developed immune thrombocytopenia (ITP) following the administration of the coronavirus disease 2019 (COVID-19) vaccine. This phenomenon has been reported in a few case reports and also in some recent news articles. In this report, we discuss a case of a 54-year-old Caucasian female who presented to the emergency room withÂ life-threatening thrombocytopenia in the setting of de novo ITP following COVID-19 vaccine administration. Due to the relapsing nature of ITP, it is unclear if the patient has achieved complete remission of the disease.
Mixing vaccines may boost immune responses.
Diagnostic and treatment recommendations from the FACME ad-hoc expert working group on the management of cerebral venous sinus thrombosis associated with COVID-19 vaccination. INTRODUCTION: Cases of cerebral venous sinus thrombosis have been reported in individuals vaccinated against COVID-19 with non-replicating adenoviral vector vaccines. We issue our recommendations on the diagnosis and management of patients presenting this complication. METHODS: The multidisciplinary working group, led by the Spanish Federation of Medical and Scientific Associations (FACME) and including representatives of several scientific societies, reviewed the available evidence from the literature and reports of the European Medicines Agency. We establish a definition for suspected cases and issue diagnostic and treatment recommendations regarding vaccine-induced immune thrombotic thrombocytopaenia. RESULTS: We define suspected cases as those cases of cerebral venous sinus thrombosis occurring between 3 and 21 days after the administration of non-replicating adenoviral vector vaccines, in patients with a platelet count below 150â€‰000/Î¼L or presenting a decrease of 50% with respect to the previous value. Findings suggestive of vaccine-induced immune thrombotic thrombocytopaenia include the presence of antibodies to platelet factor 4, D-dimer levels 4 times greater than the upper limit of normal, and unexplained thrombosis. The recommended treatment includes intravenous administration of non-specific human immunoglobulin or alternatively plasmapheresis, avoiding the use of heparin, instead employing argatroban, bivalirudin, fondaparinux, rivaroxaban, or apixaban for anticoagulation, and avoiding platelet transfusion. CONCLUSIONS: Non-replicating adenoviral vector vaccines may be associated with cerebral venous sinus thrombosis with thrombocytopaenia; it is important to treat the dysimmune phenomenon and the cerebral venous sinus thrombosis.
July 2021: Lisinopril for delayed inflammatory responses to hyaluronic acid fillers after COVID-19 vaccinations.
Cerebral Venous Thrombosis after BNT162b2 mRNA SARS-CoV-2 vaccine. The development of SARS-CoV-2 vaccines has raised several concerns regarding venous thromboembolism, namely cerebral venous thrombosis. Although cerebral venous thrombosis has been reported after administration of a viral vector vaccine, due to a possible auto-immune mechanism inducing thrombocytopenia, the same has not happened in mRNA vaccines. We report two cases of cerebral venous thrombosis, shortly after administration of mRNA vaccine. In both patients, there was no evidence of thrombocytopenia or antiplatelet antibodies, and alternative causes for cerebral venous thrombosis were found. As such, despite the temporal relation of both cases to vaccine administration, these types of cerebral venous thrombosis do not seem to be pathophysiological different from cerebral venous thrombosis not associated to SARS-CoV-2 vaccination. Continuous pharmacovigilance is necessary to monitor possible new events and clarify this association.
Successful treatment of acute spleno-porto-mesenteric vein thrombosis after ChAdOx1 nCoV-19 vaccine. A case report. Several cases of deep venous thrombosis in people who had recently

received Vaxzevria (previously known as COVID-19 Vaccine AstraZeneca) have recently been reported, mainly presenting as cerebral vein/cerebral venous sinus thrombosis. This syndrome has been termed "vaccine-induced immune thrombotic thrombocytopenia (VITT)". Acute spleno-porto-mesenteric vein thrombosis is an uncommon but serious condition with potential sequelae, such as small-bowel gangrene and end-stage liver failure. We describe a case of concomitant thrombosis of portal, superior mesenteric and splenic veins in a young female patient with no other risk factors who received Vaxzevria (previously ChAdOx1 nCoV-19 vaccine, AstraZeneca) 17 days before. The diagnostic workup and the successful endovascular treatment and systemic anticoagulation management is reported.
Decreases in COVID-19 Cases, Emergency Department Visits, Hospital Admissions, and Deaths Among Older Adults Following the Introduction of COVID-19 Vaccine - United States, September 6, 2020-May 1, 2021. Throughout the COVID-19 pandemic, older U.S. adults have been at increased risk for severe COVID-19-associated illness and death (1). On December 14, 2020, the United States began a nationwide vaccination campaign after the Food and Drug Administration's Emergency Use Authorization of Pfizer-BioNTech COVID-19 vaccine. The Advisory Committee on Immunization Practices (ACIP) recommended prioritizing health care personnel and residents of long-term care facilities, followed by essential workers and persons at risk for severe illness, including adults aged â‰¥65 years, in the early phases of the vaccination program (2). By May 1, 2021, 82%, 63%, and 42% of persons aged â‰¥65, 50-64, and 18-49 years, respectively, had received â‰¥1 COVID-19 vaccine dose. CDC calculated the rates of COVID-19 cases, emergency department (ED) visits, hospital admissions, and deaths by age group during November 29-December 12, 2020 (prevaccine) and April 18-May 1, 2021. The rate ratios comparing the oldest age groups (â‰¥70 years for hospital admissions; â‰¥65 years for other measures) with adults aged 18-49 years were 40%, 59%, 65%, and 66% lower, respectively, in the latter period. These differential declines are likely due, in part, to higher COVID-19 vaccination coverage among older adults, highlighting the potential benefits of rapidly increasing vaccination coverage.
Symptomatic SARS-CoV-2 infections after full schedule BNT162b2 vaccination in seropositive healthcare workers: a case series from a single institution. We report 11 cases of SARS-CoV-2 infection in healthcare workers (HCW) naÃ¯ve for COVID-19 and seropositive after the second dose of the BNT162b2 mRNA vaccine. Based on voluntary-based surveillance, they tested positive for different strains of SARS-CoV-2, as Spike gene sequencing showed. Five of them reported mild symptoms. Given the risk for SARS-CoV-2 introduction from asymptomatic vaccinees, this case series suggests the need to continue nasopharyngeal screening programmes.
Association of COVID-19 mRNA Vaccine With Ipsilateral Axillary Lymph Node Reactivity on Imaging. This cohort study examines ipsilateral axillary nodal reactivity seen on positron emission tomographic and computed tomographic imaging after intramuscular administration of the coronavirus 2019 mRNA vaccines.
Pityriasis rosea after mRNA COVID-19 vaccination.
Myositis ossificans following COVID-19 vaccination.
Willingness to receive future COVID-19 vaccines following the COVID-19 epidemic in Shanghai, China. BACKGROUND: There are no pharmacological interventions currently available to prevent the transmission of SARS-CoV-2 or to treat COVID-19. The development of vaccines against COVID-19 is essential to contain the pandemic. we conducted a cross-sectional survey of Shanghai residents to understand residents' willingness to be vaccinated with any future COVID-19 vaccines and take measures to further improve vaccination coverage. METHODS: We conducted a cross-sectional survey using self-administered anonymous questionnaires from 1 July to 8 September 2020. The main outcome was willingness of participants, and any children or older individuals living with them, to

receive future COVID-19 vaccines. Logistic regression analyses were used to explore potential factors associated with vaccination willingness. RESULTS: A total of 1071 participants were asked about their willingness to receive future COVID-19 vaccines, for themselves and at least 747 children and 375 older individuals (â‰¥60â€‰years old) living with them. The highest proportion of expected willingness to vaccinate was among participants (88.6%), followed by children (85.3%) and older individuals (84.0%). The main reasons for reluctance to vaccinate among 119 participants were doubts regarding vaccine safety (60.0%) and efficacy (28.8%). Participants with a self-reported history of influenza vaccination were more likely to accept COVID-19 vaccines for themselves [adjusted odds ratio (OR)â€‰=â€‰1.83; 95% confidence interval (CI): 1.19-2.82], their children (adjusted ORâ€‰=â€‰2.08; 95%CI: 1.30-3.33), and older individuals in their household (adjusted ORâ€‰=â€‰2.12; 95%CI: 1.14-3.99). Participants with older individuals in their families were less willing to vaccinate themselves (adjusted ORâ€‰=â€‰0.59; 95%CI: 0.40-0.87) and their children (adjusted ORâ€‰=â€‰0.58; 95%CI: 0.38-0.89). CONCLUSIONS: Participants were more reluctant to accept COVID-19 vaccines for older individuals living with them. The presence of older individuals in the home also affected willingness of participants and their children to be vaccinated.

Adjunct Immune Globulin for Vaccine-Induced Immune Thrombotic Thrombocytopenia. The use of high-dose intravenous immune globulin (IVIG) plus anticoagulation is recommended for the treatment of vaccine-induced immune thrombotic thrombocytopenia (VITT), a rare side effect of adenoviral vector vaccines against coronavirus disease 2019 (Covid-19). We describe the response to IVIG therapy in three of the first patients in whom VITT was identified in Canada after the receipt of the ChAdOx1 nCoV-19 vaccine. The patients were between the ages of 63 and 72 years; one was female. At the time of this report, Canada had restricted the use of the ChAdOx1 nCoV-19 vaccine to persons who were 55 years of age or older on the basis of reports that VITT had occurred primarily in younger persons. Two of the patients in our study presented with limb-artery thrombosis; the third had cerebral venous and arterial thrombosis. Variable patterns of serum-induced platelet activation were observed in response to heparin and platelet factor 4 (PF4), indicating the heterogeneity of the manifestations of VITT in serum. After the initiation of IVIG, reduced antibody-induced platelet activation in serum was seen in all three patients. (Funded by the Canadian Institutes of Health Research.).

Audio Interview: Treating Complications of Covid Vaccination.

Vaccinations in Patients Receiving Systemic Drugs for Skin Disorders: What Can We Learn for SARS-Cov-2 Vaccination Strategies? Large-scale vaccination strategies are currently being deployed against severe acute respiratory syndrome coronavirus-2 (SARS-Cov-2). Whether systemic medication for skin diseases affects the efficacy of vaccination and whether temporary interruption or extension of the dosing interval is necessary is under debate. Most immunomodulating/immunosuppressive drugs only affect vaccine-induced immune responses to a limited or moderate extent, preserving sufficient immunity in most patients. Mycophenolate mofetil, Janus kinase inhibitors, and rituximab require a more cautious approach, and judicious timing of vaccination might be appropriate in patients receiving these treatments. It should be noted that, for most drugs except methotrexate, data on the length of the interruption period to restore vaccine-induced immune responses to normal levels are either very limited or absent. In these cases, only the drug half-life can be used as a practical guideline. In most patients, systemic medication can be continued through the vaccination process, although case-by-case decisions can be considered.

Anaphylaxis is a rare reaction in COVID-19 vaccination. Anaphylaxis is a severe multisystem reaction that occurs rapidly after the introduction of an antigen that would otherwise be a harmless substance. It is characterized by airway and respiratory problems, cardiovascular collapse, mucosal inflammation, and other complications, all severe symptoms that can cause death. IgE-dependent

anaphylaxis involves mast cells (MCs) which are the main sources of biologically active mediators that contribute to the pathological and lethal phenomena that can occur in anaphylaxis. Antibody-mediated anaphylaxis can follow multiple pathways such as that mediated by MCs carrying the FcÎµRI receptor, which can be activated by very small amounts of antigen including a vaccine antigen and trigger an anaphylactic reaction. In addition, anaphylaxis can also be provoked by high concentrations of IgG antibodies that bind to the FcÎ³R receptor present on basophils, neutrophils, macrophages and MCs. For this reason, the IgG concentration should be kept under control in vaccinations. Activation of MCs is a major cause of anaphylaxis, which requires immediate treatment with epinephrine to arrest severe lethal symptoms. MCs are activated through the antigen binding and cross-linking of IgE with release of mediators such as histamine, proteases, prostaglandins, leukotrienes and inflammatory cytokines. The release of these compounds causes nausea, vomiting, hives, wheezing, flushing, tachycardia, hypotension, laryngeal edema, and cardiovascular collapse. mRNA and viral vector vaccines have been cleared by the United States, Food and Drug Administration (FDA), generating hope of prevention and cure for COVID-19 around the world. Scientists advise against giving the vaccine to individuals who have had a previous history of anaphylaxis. The US Centers for Disease Control and Prevention (CDC) advises people with a previous history of any immediate allergic reaction to remain under observation for approximately 30 minutes after COVID-19 vaccination. To date, vaccines that prevent SARS-CoV-2 infection have not raised major concerns of severe allergic reactions, although, in some cases, pain and redness at the injection site and fever have occurred after administration of the vaccine. These reactions occur in the first 24-48 hours after vaccination. It has been reported that probable forms of anaphylaxis could also occur, especially in women approximately 40 years of age. But after tens of millions of vaccinations, only a few patients had this severe reaction with a low incidence. Anaphylactic and severe allergic reactions can also occur to any component of the vaccine including polysorbates and polyethylene glycol. To date, there is no precise information on allergic reactions to COVID-19 vaccines. Individuals with MCs and complement with higher activation than others may be at greater allergic risk. Moreover, the reactions called anaphylactoids, are those not mediated by IgE because they do not involve this antibody and can also occur in COVID-19 vaccination. These not-IgE-mediated reactions occur through direct activation of MCs and complement with tryptase production, but to a lesser extent than IgE-mediated anaphylaxis. However, at the moment it is not known exactly which component of the vaccine causes the allergic reaction and which vaccine causes the most side effects, including anaphylaxis. Thus, individuals who have a known allergy to any component of the vaccine should not be vaccinated. However, should an anaphylactic reaction occur, this requires immediate treatment with epinephrine to arrest severe lethal symptoms. In conclusion, the purpose of this editorial is to encourage the population to be vaccinated in order to extinguish this global pandemic that is afflicting the world population, and to reassure individuals that anaphylactic reactions do not occur with a higher incidence than other vaccinations.

Acquired thrombotic thrombocytopenic purpura: A rare disease associated with BNT162b2 vaccine. BACKGROUND: In December 2020 the Israeli Health Ministry began a mass vaccination campaign with the BNT162b2 vaccine. This was an important step in overcoming the severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) pandemic. Autoimmune phenomenon have been described after receiving vaccinations. PATIENTS/METHODS: Here we describe a case series of patients who developed acquired Thrombotic Thrombocytopenic Purpura, a rare autoimmune disease, within several days of receiving the BNT162b2 vaccine. CONCLUSIONS: A disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13 (ADAMTS13) activity should be evaluated in patients with history of aTTP before and after any vaccination, especially the SARS-CoV-2 vaccination, and immunosuppression treatment should be considered before vaccination in cases of low

ADAMTS13 activity. Patients should be closely monitored after the vaccine for clinical situation and laboratory data. Post vaccination thrombocytopenia assessment should include immune thrombocytopenic purpura, vaccine-induced immune thrombotic thrombocytopenia and acquired thrombotic thrombocytopenic purpura.
First report of a de novo iTTP episode associated with an mRNA-based anti-COVID-19 vaccination. Thrombotic thrombocytopenic purpura (TTP) is a rare but potentially life-threatening thrombotic microangiopathy, characterized by disseminated thrombus formation in the microvasculature, causing severe organ failure. Immune-mediated TTP (iTTP) is occasionally described after vaccination, especially against viral agents. We report a case of a 38-year-old woman with a de novo iTTP after exposure to the mRNA-based anti-coronavirus disease 2019 (COVID-19) vaccine produced by Pfizer-BioNTech. She presented with increased bruising and petechiae starting 2Â weeks after receiving the first dose of the anti-COVID-19 vaccine. Laboratory data revealed a severe ADAMTS13-deficiency in combination with a very high autoantibody titer against ADAMTS13. She was successfully treated with plasma exchange, corticosteroids, rituximab, and caplacizumab. To our knowledge, this is the first case report of iTTP after mRNA-based COVID-19 vaccination in a previously TTP-naÃ¯ve patient.
Delayed large local reaction to the adenovirus-vectored (ChAdOx1) vaccine.
Outbreak of SARS-CoV-2 B.1.1.7 Lineage after Vaccination in Long-Term Care Facility, Germany, February-March 2021. One week after second vaccinations were administered, an outbreak of B.1.1.7 lineage severe acute respiratory syndrome coronavirus 2 infections occurred in a long-term care facility in Berlin, Germany, affecting 16/20 vaccinated and 4/4 unvaccinated residents. Despite considerable viral loads, vaccinated residents experienced mild symptoms and faster time to negative test results.
The statistical risk of diagnosing coincidental acquired hemophilia A following anti-SARS-CoV-2 vaccination.
Impaired humoral and cellular immunity after SARS-CoV-2 BNT162b2 (tozinameran) prime-boost vaccination in kidney transplant recipients. Novel mRNA-based vaccines have been proven to be powerful tools in combating the global pandemic caused by SARS-CoV-2, with BNT162b2 (trade name: Comirnaty) efficiently protecting individuals from COVID-19 across a broad age range. Still, it remains largely unknown how renal insufficiency and immunosuppressive medication affect development of vaccine-induced immunity. We therefore comprehensively analyzed humoral and cellular responses in kidney transplant recipients after the standard second vaccination dose. As opposed to all healthy vaccinees and the majority of hemodialysis patients, only 4 of 39 and 1 of 39 transplanted individuals showed IgA and IgG seroconversion at day 8 Â± 1 after booster immunization, with minor changes until day 23 Â± 5, respectively. Although most transplanted patients mounted spike-specific T helper cell responses, frequencies were significantly reduced compared with those in controls and dialysis patients and this was accompanied by a broad impairment in effector cytokine production, memory differentiation, and activation-related signatures. Spike-specific CD8+ T cell responses were less abundant than their CD4+ counterparts in healthy controls and hemodialysis patients and almost undetectable in transplant patients. Promotion of anti-HLA antibodies or acute rejection was not detected after vaccination. In summary, our data strongly suggest revised vaccination approaches in immunosuppressed patients, including individual immune monitoring for protection of this vulnerable group at risk of developing severe COVID-19.
Cerebral venous sinus thrombosis 2Â weeks after the first dose of mRNA SARS-CoV-2 vaccine. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), also known as coronavirus disease 2019 (COVID-19) is a highly transmissible virus and has become pandemic. Part of the prevention of disease spread by the Malaysian government is by getting COVID-19 vaccine. Using the

mRNA technology, the Pfizer/BioNTech vaccine is one of the vaccines been approved by the Drug Control Authority in Malaysia. Herein, we report an immediate complication of cerebral VST after the first dose of the Pfizer/BioNTech vaccine.

Use of COVID-19 vaccines in patients with liver disease and post-liver transplantation: Position statement of the Saudi association for the study of liver diseases and transplantation. Patients with chronic liver disease (CLD) and liver transplant recipients are at increased risk of morbidity and mortality from coronavirus disease 2019 (COVID-19). Although several studies demonstrated the safety and efficacy of COVID-19 vaccines in the general population, data in CLD patients and liver transplant recipients are lacking. Two COVID-19 vaccines were approved by the Saudi Food and Drug Authority and rolled out to several million recipients in Saudi Arabia. These vaccines are mRNA-based vaccine BNT162b2 from Pfizer/BioNTech and adenovirus-based AZD1222 from Oxford/AstraZeneca from three manufacturing sites (EU Nodes, Serum Institute of India, and South Korea Bio). The Saudi Association for the Study of Liver diseases and Transplantation (SASLT) has reviewed the available evidence and issued interim recommendations for COVID-19 vaccination in CLD and liver transplant recipients. Since there is no evidence contradicting the safety and immunogenicity of the currently approved COVID-19 vaccines in patients with CLD and hepatobiliary cancer and liver transplant recipients, the SASLT recommends vaccination in those patient populations. CLD and hepatobiliary cancer patients and liver transplant recipients should be prioritized depending on the risk factors for severe COVID-19. In transplant recipients, the optimal timing of vaccination remains unknown; however, immunization is recommended after the initial immunosuppression phase. Patients with CLD and liver transplant candidates or recipients should be closely monitored after COVID-19 vaccination. These patient populations should be included in future clinical trials to provide further evidence on the efficacy and safety of COVID-19 vaccines.

Late-onset cutaneous reaction to BNT162b2 mRNA COVID-19 vaccine in an immunocompromised patient.

Tozinameran (BNT162b2) Vaccine: The Journey from Preclinical Research to Clinical Trials and Authorization. Vaccination development and production was an essential question for the prevention and global control of COVID-19. The strong support from governing authorities such as Operation Warp Speed and robust funding has led to the development and authorization of the tozinameran (BNT162b2) vaccine. The BNT162b2 vaccine is a lipid nanoparticle-encapsulated mRNA that encodes for SARS-CoV-2 spike protein, the main site for neutralizing antibodies. Once it binds with the host cells, the lipid nanoparticles enable the transfer of the RNA, causing S antigens' expression of the SARS-CoV-2, conferring immunity. The vaccine is administered as a 2-dose regime 21 days apart for individuals 16 years and older. Pfizer-BioNTech's BNT162b2 vaccine was the first candidate to receive FDA-Emergency Use Authorization (EUA) on December 11, 2020. During phase 2/3 clinical trials, 95% efficacy was reported among 37,706 participants over the age of 16 who received the BNT162b2 vaccination; additionally, 52% efficacy was noted 12 days following the administration of the first dose of BNT162b2, reflecting early protection of COVID-19. The BNT162b2 vaccine has exhibited 100% efficacy in clinical trials of adolescents between the ages of 12 and 15. Clinical trials in pregnant women and children under the age of 12 are expected to also exhibit promising results. This review article encompasses tozinameran (BNT162b2) vaccine journey, summarizing the BNT162b1 and BNT162b2 vaccines from preclinical studies, clinical trial phases, dosages, immune response, adverse effects, and FDA-EUA.

Impaired Humoral Immunity to SARS-CoV-2 Vaccination in Non-Hodgkin Lymphoma and CLL Patients. Patients with hematologic malignancies are a high priority for SARS-CoV-2 vaccination, yet the benefit they will derive is uncertain. We investigated the humoral response to vaccination in 53 non-Hodgkin lymphoma (NHL), Hodgkin lymphoma (HL), or CLL patients. Peripheral blood was obtained 2 weeks

after first vaccination and 6 weeks after second vaccination for antibody profiling using the multiplex bead-binding assay. Serum IgG, IgA, and IgM antibody levels to the spike specific receptor binding domain (RBD) were evaluated as a measure of response. Subsequently, antibody-positive serum were assayed for neutralization capacity against authentic SARS-CoV-2. Histology was 68% lymphoma and 32% CLL; groups were: patients receiving anti-CD20-based therapy (45%), monitored with disease (28%), receiving BTK inhibitors (19%), or chemotherapy (all HL) (8%). SARS-CoV-2 specific RBD IgG antibody response was decreased across all NHL and CLL groups: 25%, 73%, and 40%, respectively. Antibody IgG titers were significantly reduced ($p < 0.001$) for CD20 treated and targeted therapy patients, and ($p = 0.003$) for monitored patients. In 94% of patients evaluated after first and second vaccination, antibody titers did not significantly boost after second vaccination. Only 13% of CD20 treated and 13% of monitored patients generated neutralizing antibodies to SARS-CoV-2 with ICD50s 135 to 1767, and 445 and > 10240. This data has profound implications given the current guidance relaxing masking restrictions and for timing of vaccinations. Unless immunity is confirmed with laboratory testing, these patients should continue to mask, socially distance, and to avoid close contact with non-vaccinated individuals. STATEMENT OF TRANSLATIONAL RELEVANCE: Non Hodgkin lymphoma (NHL) and Chronic Lymphocytic leukemia (CLL) patients who are treated with anti-CD20 antibody therapy, BTK inhibitor therapy, or who are monitored with active disease, have decreased antibody response to SARS-CoV-2 vaccination and decreased antibody titers compared to healthy controls. Antibody titers do not boost following second vaccination, and very few patients generate neutralizing antibodies against SARS-CoV-2. This data is of particular importance, given the recent guidance from the CDC that vaccinated patients no longer need to be masked indoors as well as outdoors. Patients with NHL or CLL who fall into these categories should not consider their immunity from vaccination to be assured. If infected with SARS-CoV-2, they should be a high priority for monoclonal antibody directed therapy. Unless immune response to vaccination is confirmed with laboratory testing, they should continue to mask, socially distance, and to avoid close contact with non-vaccinated individuals.
Therapeutic vaccine for chronic diseases after the COVID-19 Era. There is currently a respiratory disease outbreak caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). After rapid development, RNA vaccines and adenoviral vector vaccines were approved within a year, which has demonstrated the strong impact of preventing infectious diseases using gene therapy technology. Furthermore, intensive immunological analysis has been performed to evaluate the efficiency and safety of these vaccines, potentially allowing for rapid progress in vaccine technology. After the coronavirus disease 2019 (COVID-19) era, the novel vaccine technology developed will expand to other vaccines. We have been developing vaccines for chronic diseases, such as hypertension, for >10 years. Regarding the development of vaccines against self-antigens (i.e., angiotensin II), the vaccine should efficiently induce a blocking antibody response against the self-antigen without activating cytotoxic T cells. Therefore, the epitope vaccine approach has been proposed to induce antibody production in response to a combination of a B cell epitope and exogenous T cell epitopes through major histocompatibility complex molecules. When these vaccines are established as therapeutic options for hypertension, their administration regimen, which might be a few times per year, will replace daily medication use. Thus, therapeutic vaccines for hypertension may be a novel option to control the progression of cerebrovascular diseases. Hopefully, the accumulation of immunological findings and vaccine technology advances due to COVID-19 will provide a novel concept for vaccines for chronic diseases.
Coronavirus disease vaccination in heart failure: No time to waste.
Breakthrough COVID-19 case after full-dose administration of CoronaVac vaccine.

Management of a patient with a rare congenital limb malformation syndrome after SARS-CoV-2 vaccine-induced thrombosis and thrombocytopenia (VITT).
Unique Imaging Findings of Neurologic Phantosmia Following Pfizer-BioNtech COVID-19 Vaccination: A Case Report. Olfactory dysfunction related to SARS-CoV-2 infection and COVID-19 disease is now well established in the literature. In December 2020, the FDA approved the Pfizer-BioNTech and Moderna vaccines for use in preventing COVID-19 in the United States. To the best of our knowledge, this is the first report of a phantosmia post-Pfizer COVID-19 vaccination, with positive magnetic resonance imaging radiographic findings in a patient with documented absence of infection by SARS-CoV-2 virus or concomitant sinonasal disease.
Vaccine-induced thrombotic thrombocytopenia following Ad26.COV2.S vaccine in a man presenting as acute venous thromboembolism.
COVID-19 mRNA Vaccines Are Generally Safe in the Short Term: A Vaccine Vigilance Real-World Study Says. BACKGROUND: The prophylactic vaccination of COVID-19 mRNA vaccines is the first large-scale application of this kind in the human world. Over 1.8 million doses of the COVID-19 vaccine had been administered in the US until December 2020, and around 0.2% submitted AE reports to the Vaccine Adverse Event Reporting System (VAERS). This study aimed to evaluate the AEs following immunization (AEFIs) and analyze the potential associations based on the information from the VAERS database. METHODS: We searched the VAERS database recorded AEFIs after COVID-19 vaccines in December 2020. After data mapping, we summarized demographic and clinical features of reported cases. Fisher exact test was used to comparing the clinical characteristics among AE groups with an anaphylactic response, concerning neurological disorders andÂ death. RESULTS: VAERS reported 3,908 AEFIs of COVID-19 vaccines in December 2020. Most (79.68%) were reported after the first dose of the vaccine. Among the reported cases, we found that general disorders (48.80%), nervous system disorders (46.39%), and gastrointestinal disorders (25.54%) were the most common AEFIs. The allergy history was more frequent in vaccine recipients with anaphylactic reactions than those without (64.91% vs. 49.62%, OR = 1.88, P <0.017). History of anxiety or depression was more common in subjects reporting severe neurological AEFIs than those reporting other AEFIs (18.37% vs. 7.85%, OR = 2.64, P <0.017). Cases reporting death were significantly older (79.36 Â± 10.41-year-old vs. 42.64 Â± 12.55-year-old, P <0.01, 95% CI 29.30-44.15) and more likely experienced hypertension (50.00% vs. 11.42%, OR = 7.76, P <0.01) and neurological disorders (50.00% vs. 5.36%, OR = 17.65, P <0.01) than other vaccine recipients. The outpatient and emergency room visit rates were 11.92 and 22.42% for AEFIs, and 2.53% of cases needed hospitalization. CONCLUSION: AEFIs of COVID-19 mRNA vaccines were generally non-severe local or systemic reactions. A prior allergy history is the risk factor for anaphylaxis, while a history of anxiety may link with severe neurological AEs. Such vaccine recipients need further evaluation and monitor.
Thrombosis with Thrombocytopenia Syndrome associated with viral vector COVID-19 vaccines.
Adverse events following mRNA SARS-CoV-2 vaccination among U.S. nursing home residents. BACKGROUND: The devastating impact of the SARS-CoV-2 pandemic prompted the development and emergency use authorization of two mRNA vaccines in early 2020. Vaccine trials excluded nursing home (NH) residents, limiting adverse event data that directly apply to this population. METHODS: To prospectively monitor for potential adverse events associated with vaccination, we used Electronic Health Record (EHR) data from Genesis HealthCare, the largest NH provider in the United States. EHR data on vaccinations and pre-specified adverse events were updated daily and monitored for signal detection among residents of 147 facilities who received the first dose of vaccine between December 18, 2020 and January 3, 2021. For comparison, unvaccinated residents during the same time period were included from 137 facilities that started vaccinating at least 15Â days after the vaccinating-facilities. RESULTS: As of January 3, 2021, 8553 NH residents had received one dose of SARS-CoV-2

vaccine and by February 20, 2021, 8371 residents had received their second dose of vaccine; 11,072 were included in the unvaccinated comparator group. No significant associations were noted for neurologic outcomes, anaphylaxis, or cardiac events. CONCLUSIONS: No major safety problems were detected following the first or second dose of the vaccine to prevent COVID-19 in the study cohort from December 18, 2020 through March 7, 2021.

Myocarditis following COVID-19 mRNA vaccination. BACKGROUND: Clinical trials of the BNT162b2 vaccine, revealed efficacy and safety. We report six cases of myocarditis, which occurred shortly after BNT162b2 vaccination. METHODS: Patients were identified upon presentation to the emergency department with symptoms of chest pain/discomfort. In all study patients, we excluded past and current COVID-19. Routine clinical and laboratory investigations for common etiologies of myocarditis were performed. Laboratory tests also included troponin and C-reactive protein levels. The diagnosis of myocarditis was established after cardiac MRI. FINDINGS: Five patients presented after the second and one after the first dose of the vaccine. All patients were males with a median age of 23Â years. Myocarditis was diagnosed in all patients, there was no evidence of COVID-19 infection. Laboratory assays excluded concomitant infection; autoimmune disorder was considered unlikely. All patients responded to the BNT162b2 vaccine. The clinical course was mild in all six patients. INTERPRETATION: Our report of myocarditis after BNT162b2 vaccination may be possibly considered as an adverse reaction following immunization. We believe our information should be interpreted with caution and further surveillance is warranted.

Reported adverse effects following COVID-19 vaccination at a tertiary care hospital, focus on cerebral venous sinus thrombosis (CVST). Objectives: Several cases of unusual thrombotic events with thrombocytopenia were reported in several countries, in association with AstraZeneca's COVID-19 vaccine. The European medicines agency conducted a detailed review and concluded that there was no evidence to suggest an association of thrombotic events with the use of COVID-19 vaccine AstraZeneca.Methods: King Abdulaziz Medical City is a 1500 bed tertiary care hospital in Riyadh, Saudi Arabia; this study describes spontaneously reported vaccine adverse effects received through the hospital's internal electronic safety reporting system from December 2020 to 13 April 2021.We assessed each report for causality association utilizing the world health organization's (WHO) causality assessment of an adverse event following immunization (AEFI) classification 2nd Edition 2019.Results: The majority of the reported events were mild to moderate, there were five serious events, one reported cardiac arrest, two cerebral venous sinus thrombosis, and two pulmonary embolism. Clinical and laboratory summary of the five patients are presented in detail.Conclusions: Efforts of pharmacovigilance in mediating the rare risk of thrombosis associated with COVID-19 vaccine are crucial in providing awareness on the possible risk factors and signs/symptoms that should raise red flags.

Adverse Outcomes Associated With Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Variant B.1.351 Infection in Vaccinated Residents of a Long-Term Care Home, Ontario, Canada.

Vaccine allergy: evidence to consider for COVID-19 vaccines. PURPOSE OF REVIEW: Whereas the COVID-19 pandemic has changed our lives worldwide, we hope that vaccination can combat the disease. We propose how to evaluate suspected severe allergic reactions to the vaccines so that as many as possible may be safely vaccinated. RECENT FINDINGS: Rare cases of severe allergic reactions after COVID-19 vaccination have been observed, seemingly at a higher frequency than for other vaccines. Few excipients are likely to have caused these reactions. IgE-mediated reactions to polyethylene glycol (PEG) and its derivatives are the most suspected, albeit hitherto unproven, causes. We suggest to make a diagnosis based on skin tests with PEG and PEG derivatives and that these be considered in relation to the decisions required before the first and the second vaccine dose. A vaccine without these excipients is available, but published data about its side effects are

limited. SUMMARY: The underlying immunological mechanisms of the rare severe allergic reactions to the COVID-19 vaccines are poorly understood and need to be clarified. Identifying those who have an undiagnosed allergy to PEG and PEG derivatives is crucial before vaccination, and these substances are found in laxatives, cosmetics and in 30% of all our medications today.

Antiphospholipid antibodies and risk of post-COVID-19 vaccination thrombophilia: The straw that breaks the camel's back? Antiphospholipid antibodies (aPLs), present in 1-5 % of healthy individuals, are associated with the risk of antiphospholipid syndrome (APS), which is the most common form of acquired thrombophilia. APLs may appear following infections or vaccinations and have been reported in patients with COronaVIrus Disease-2019 (COVID-19). However, their association with COVID-19 vaccination is unclear. Notably, a few cases of thrombocytopenia and thrombotic events resembling APS have been reported to develop in recipients of either adenoviral vector- or mRNA-based COVID-19 vaccines. The aim of this review is therefore to speculate on the plausible role of aPLs in the pathogenesis of these rare adverse events. Adenoviral vector-based vaccines can bind platelets and induce their destruction in the reticuloendothelial organs. Liposomal mRNA-based vaccines may instead favour activation of coagulation factors and confer a pro-thrombotic phenotype to endothelial cells and platelets. Furthermore, both formulations may trigger a type I interferon response associated with the generation of aPLs. In turn, aPLs may lead to aberrant activation of the immune response with participation of innate immune cells, cytokines and the complement cascade. NETosis, monocyte recruitment and cytokine release may further support endothelial dysfunction and promote platelet aggregation. These considerations suggest that aPLs may represent a risk factor for thrombotic events following COVID-19 vaccination, and deserve further investigations.

SARS-CoV-2 vaccine-induced cerebral venous thrombosis. The nosological entity of the cerebral venous thrombosis caused by the SARS-CoV-2 vaccination differs from the common cerebral venous thrombosis in that it is due to immune thrombocytopenia triggered by vaccination. Cerebral venous thrombosis is one of several manifestations of this type of immune thrombocytopenia. Albeit many general aspects of management of cerebral venous thrombosis are similar, immune thrombocytopenia requires a specific therapeutic approach, which is not normally adopted for cerebral venous thrombosis due to other causes, therefore its early recognition is essential.

Effective DNA damage response after acute but not chronic immune challenge: SARS-CoV-2 vaccine versus Systemic Lupus Erythematosus. Whether and how an acute immune challenge may affect DNA Damage Response (DDR) is unknown. By studying vaccinations against Influenza and SARS-CoV-2 (mRNA-based) we found acute increases of type-I interferon-inducible gene expression, oxidative stress and DNA damage accumulation in blood mononuclear cells of 9 healthy controls, coupled with effective anti-SARS-CoV-2 neutralizing antibody production in all. Increased DNA damage after SARS-CoV-2 vaccine, partly due to increased oxidative stress, was transient, whereas the inherent DNA repair capacity was found intact. In contrast, in 26 patients with Systemic Lupus Erythematosus, who served as controls in the context of chronic immune activation, we validated increased DNA damage accumulation, increased type-I interferon-inducible gene expression and induction of oxidative stress, however aberrant DDR was associated with deficiencies in nucleotide excision repair pathways. These results indicate that acute immune challenge can indeed activate DDR pathways, whereas, contrary to chronic immune challenge, successful repair of DNA lesions occurs.

A Review on SARS-CoV-2-Induced Neuroinflammation, Neurodevelopmental Complications, and Recent Updates on the Vaccine Development. Coronavirus disease 2019 (COVID-19) is a devastating viral infection caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The incidence and mortality of COVID-19 patients have been increasing at an alarming rate. The mortality is much higher in older individuals, especially the ones suffering from respiratory distress,

cardiac abnormalities, renal diseases, diabetes, and hypertension. Existing evidence demonstrated that SARS-CoV-2 makes its entry into human cells through angiotensin-converting enzyme 2 (ACE-2) followed by the uptake of virions through cathepsin L or transmembrane protease serine 2 (TMPRSS2). SARS-CoV-2-mediated abnormalities in particular cardiovascular and neurological ones and the damaged coagulation systems require extensive research to develop better therapeutic modalities. As SARS-CoV-2 uses its S-protein to enter into the host cells of several organs, the S-protein of the virus is considered as the ideal target to develop a potential vaccine. In this review, we have attempted to highlight the landmark discoveries that lead to the development of various vaccines that are currently under different stages of clinical progression. Besides, a brief account of various drug candidates that are being tested to mitigate the burden of COVID-19 was also covered. Further, in a dedicated section, the impact of SARS-CoV-2 infection on neuronal inflammation and neuronal disorders was discussed. In summary, it is expected that the content covered in this article help to understand the pathophysiology of COVID-19 and the impact on neuronal complications induced by SARS-CoV-2 infection while providing an update on the vaccine development.
Six months of COVID vaccines: what 1.7 billion doses have taught scientists.
Symptomatic Acute Myocarditis in 7 Adolescents After Pfizer-BioNTech COVID-19 Vaccination. Trials of coronavirus disease 2019 (COVID-19) vaccination included limited numbers of children, so they may not have detected rare but important adverse events in this population. We report 7 cases of acute myocarditis or myopericarditis in healthy male adolescents who presented with chest pain all within 4 days after the second dose of Pfizer-BioNTech COVID-19 vaccination. Five patients had fever around the time of presentation. Acute COVID-19 was ruled out in all 7 cases on the basis of negative severe acute respiratory syndrome coronavirus 2 real-time reverse transcription polymerase chain reaction test results of specimens obtained by using nasopharyngeal swabs. None of the patients met criteria for multisystem inflammatory syndrome in children. Six of the 7 patients had negative severe acute respiratory syndrome coronavirus 2 nucleocapsid antibody assay results, suggesting no previous infection. All patients had an elevated troponin. Cardiac MRI revealed late gadolinium enhancement characteristic of myocarditis. All 7 patients resolved their symptoms rapidly. Three patients were treated with nonsteroidal antiinflammatory drugs only, and 4 received intravenous immunoglobulin and corticosteroids. In this report, we provide a summary of each adolescent's clinical course and evaluation. No causal relationship between vaccine administration and myocarditis has been established. Continued monitoring and reporting to the US Food and Drug Administration Vaccine Adverse Event Reporting System is strongly recommended.
Myocarditis After SARS-CoV-2 Vaccination: True, True, andâ€¦ Related?
Therapeutic plasma exchange (TPE) as a plausible rescue therapy in severe vaccine-induced immune thrombotic thrombocytopenia. Vaccine-induced immune thrombotic thrombocytopenia (VITT) is associated with high titers of immunoglobulin G class antibodies directed against the cationic platelet chemokine platelet factor 4 (PF4). These antibodies activate platelets via FcÎ³IIa receptors. VITT closely resembles heparin-induced thrombocytopenia. Inflammation and tissue trauma substantially increase the risk for forming pathogenic PF4 antibodies. We therefore propose the use of therapeutic plasma exchange as rescue therapy in VITT to deplete antibodies plus factors promoting inflammation such as excess cytokines in the circulation as well as extracellular vesicles derived from activated platelets.
Hemophagocytic lymphohistiocytosis after COVID-19 vaccination. Cases of thrombotic thrombocytopenia induced by coronavirus disease 2019 (COVID-19) vaccines have been reported recently. Herein, we describe the first case of another critical disorder, hemophagocytic lymphohistiocytosis (HLH), in a healthy individual after COVID-19 vaccination. A 43-year-old Chinese farmer developed malaise, vomiting, and persistent high fever (up to 39.7Â Â°C) shortly after

receiving the first dose of the inactivated SARS-CoV-2 vaccine. The initial evaluation showed pancytopenia (neutrophil count, 0.70â€‰Ã—â€‰10(9)/L; hemoglobin, 113Â g/L; platelet, 27â€‰Ã—â€‰10(9)/L), elevated triglyceride (2.43Â mmol/L), and decreased fibrinogen (1.41Â g/L). Further tests showed high serum ferritin levels (8140.4Â Î¼g/L), low NK cell cytotoxicity (50.13%-60.83%), and positive tests for Epstein-Barr virus (EBV) DNA. Hemophagocytosis was observed in the bone marrow. Therefore, HLH was confirmed, and dexamethasone acetate (10Â mg/day) was immediately prescribed without etoposide. Signs and abnormal laboratory results resolved gradually, and the patient was discharged. HLH is a life-threatening hyperinflammatory syndrome caused by aberrantly activated macrophages and cytotoxic T cells, which may rapidly progress to terminal multiple organ failure. In this case, HLH was induced by the COVID-19 vaccination immuno-stimulation on a chronic EBV infection background. This report indicates that it is crucial to exclude the presence of active EBV infection or other common viruses before COVID-19 vaccination.
Gross hematuria following SARS-CoV-2 vaccination in patients with IgA nephropathy.
De novo vasculitis after mRNA-1273 (Moderna) vaccination.
COVID-19 mRNA vaccine-related adenopathy mimicking metastatic melanoma.
Divergent vaccination policies could fuel mistrust and hesitancy.
Failure to seroconvert after two doses of BNT162b2 SARS-CoV-2 vaccine in a patient with uncontrolled HIV.
Incidence and Characteristics of Delayed Injection Site Reaction to the mRNA-1273 Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine (Moderna) in a Cohort of Hospital Employees. BACKGROUND: mRNA SARS-CoV-2 vaccines are administered to 2 million individuals per day in the United States under US Food and Drug Administration emergency use authorization. METHODS: Observational cohort study of hospital employees who received their first SARS-CoV-2 mRNA vaccination between 14 December 2020 and 8 January 2021, including employees who reported onset of an injection site reaction â‰¥48 hours after administration of their first or second dose to an employee hotline. RESULTS: Thirteen female employees who received the mRNA-1273 vaccine (Moderna) during the first 3 weeks of the SARS-CoV-2 vaccine rollout at San Francisco General Hospital reported a pruritic rash at the injection site appearing 3 -9 days after receipt of their initial dose. Five had milder or similar reactions with earlier onset after the second dose. One additional female employee reported this delayed reaction only after the second dose. None reported serious adverse events or had symptoms severe enough to seek medical attention. These cases represented 1.1% of the 1275 female employees who received their first mRNA-1273 dose and 2.0% of the 557 who were aged 31 -45 years during this initial vaccine rollout. None of 675 males who initiated mRNA-1273 or 3612 employees of any sex who initiated BNT162b (Pfizer) vaccination during this period reported delayed-onset reactions. CONCLUSIONS: These results suggest that delayed-onset, injection site pruritic rashes after mRNA-1273 SARS-CoV-2 vaccine administration, lasting up to 1 week, occur commonly in females, do not lead to serious sequela, and should not deter receipt of the second vaccine dose.
Hesitancy Toward a COVID-19 Vaccine. The scientific community has come together in a mass mobilization to combat the public health risks of COVID-19, including efforts to develop a vaccine. However, the success of any vaccine depends on the share of the population that gets vaccinated. We designed a survey experiment in which a nationally representative sample of 3,133 adults in the USA stated their intentions to vaccinate themselves and their children for COVID-19. The factors that we varied across treatments were: the stated severity and infectiousness of COVID-19 and the stated source of the risk information (White House or the Centers for Disease Control). We find that 20% of people in the USA intend to decline the vaccine. We find no statistically significant effect on vaccine intentions from the severity of COVID-19. In contrast, we find that the degree of infectiousness of the

coronavirus influences vaccine intentions and that inconsistent risk messages from public health experts and elected officials may reduce vaccine uptake. However, the most important determinants of COVID-19 vaccine hesitancy seem to be distrust of the vaccine safety (including uncertainty due to vaccine novelty), as well as general vaccine avoidance, as implied by not having had a flu shot in the last two years.
Acute reduction of visual acuity and visual field after Pfizer-BioNTech COVID-19 vaccine 2nd dose: a case report. Long-term and rare adverse effects of COVID-19 vaccines are unknown. Hence, it is important to report them to improve the safety profile of the vaccines and enhance their use worldwide. Here, weÂ describe a case of acute visual impairment after Pfizer-BioNTech vaccine second dose.
Fractional Dosing of the Comirnaty Vaccine in 2Â Patients With Immediate Acute Urticaria After theÂ First Dose.
Single dose of BNT162b2 mRNA vaccine against severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) induces neutralising antibody and polyfunctional T-cell responses in patients with chronic myeloid leukaemia. Patients receiving targeted cancer treatments such as tyrosine kinase inhibitors (TKIs) have been classified in the clinically extremely vulnerable group to develop severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), including patients with chronic myeloid leukaemia (CML) taking TKIs. In addition, concerns that immunocompromised individuals with solid and haematological malignancies may not mount an adequate immune response to a single dose of SARS-CoV-2 BNT162b2 (Pfizer-BioNTech) vaccine have been raised. In the present study, we evaluated humoral and cellular immune responses after a first injection of BNT162b2 vaccine in 16 patients with CML. Seroconversion and cellular immune response before and after vaccination were assessed. By day 21 after vaccination, anti-Spike immunoglobulin G was detected in 14/16 (87Â·5%) of the patients with CML and all developed a neutralising antibody response [serum dilution that inhibits 50% infection (ID(50)) >50], including medium (ID(50) of 200-500) or high (ID(50) of 501-2000) neutralising antibodies titres in nine of the 16 (56Â·25%) patients. T-cell response was seen in 14/15 (93Â·3%) evaluable patients, with polyfunctional responses seen in 12/15 (80%) patients (polyfunctional CD4(+) response nine of 15, polyfunctional CD8(+) T-cell response nine of 15). These data demonstrate the immunogenicity of a single dose of SARS-CoV-2 BNT162b2 vaccine in most patients with CML, with both neutralising antibodies and polyfunctional T-cell responses seen in contrast to patients with solid tumour or lymphoid haematological malignancies.
Acute Pancreatitis: A Possible Side Effect of COVID-19 Vaccine. For the first time, the mRNA technology was utilized to produce a vaccine against COVID-19 after the unprecedented pandemic equally affected every part of the world. Pfizer-BioNTech (BNT162b2) mRNA vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was granted emergency use authorization (EUA) by Food and Drug Administration (FDA) in December 2020. EUA has been widely discussed in the medical literature and the general public. The safety of the BNT162b2 vaccine has been investigated in short-term trials with data available for three months. We present a case of a 96-year-old female with a past surgical history of cholecystectomy who presented with acute onset severe abdominal pain a few days after getting the first dose of Pfizer-BioNTech COVID-19 vaccine. She was diagnosed with acute pancreatitis with a lipase level of 4036 U/L. Extensive history and investigations were unable to find any etiology. The patient was conservatively managed and discharged home without any complications. There has been some data available in medical literature showing an association between acute pancreatitis and COVID-19 infection. Trial data of Pfizer COVID-19 also shows one case of acute pancreatitis in the treatment group. There have also been individual cases of unexplained acute pancreatitis shared by medical professionals on online forums. Our main goal to

write this case is to make medical literature aware of possible emerging side effects of the COVID-19 vaccine, one of such side effects being self-resolving uncomplicated acute pancreatitis.

Dynamics of the COVID-19 epidemic in the post-vaccination period in Korea: a rapid assessment. OBJECTIVES: Coronavirus disease 2019 (COVID-19) has had a tremendous impact on public health and socioeconomic conditions globally. Although non-pharmaceutical interventions (NPIs) such as social distancing effectively reduced the incidence of COVID-19, especially in Korea, demand for vaccination has increased to minimize the social costs of NPIs. This study estimated the potential benefits of COVID-19 vaccination in Korea. METHODS: A mathematical model with vaccinated-susceptible-latent-infectious-recovered compartments was used to simulate the COVID-19 epidemic. The compartments were stratified into age groups of 0-19 years, 20-59 years, and 60 years or older. Based on the Korea Disease Control and Prevention Agency national vaccination plan for the second quarter of 2021, announced on March 15, we developed vaccination scenarios (with 150,000 dose/d and 100% compliance as the main scenario). Comparing scenarios without vaccination or with higher/lower vaccination rates and compliance, we estimated the numbers of COVID-19 cases that will be prevented by vaccination. RESULTS: The results projected 203,135 cases within a year after April 2021 without vaccination, which would be reduced to 71,248 (64.9% decrease) by vaccination. Supposing a vaccination rate of 150,000 dose/d and 100% compliance, social distancing interventions for those aged 20 or more can be retracted after January 1, 2022. CONCLUSIONS: We expect COVID-19 vaccination to be effective in Korea. Health authorities should minimize delays in vaccination and vaccine avoidance to maximize the effectiveness of vaccination and end social distancing early.

ANCA glomerulonephritis after the Moderna COVID-19 vaccination.

Reduced humoral response to mRNA SARS-CoV-2 BNT162b2 vaccine in kidney transplant recipients without prior exposure to the virus: Not alarming, but should be taken gravely.

Radiation recall dermatitis triggered by inactivated COVID-19 vaccine.

Causes of anxiety among teachers giving face-to-face lessons after the reopening of schools during the COVID-19 pandemic: a cross-sectional study. BACKGROUND: Coronavirus infections are spreading rapidly worldwide, and primary and middle schools are closed in many countries. After the state of emergency was lifted in Japan, schools have reopened, and teachers are conducting face-to-face classes while maintaining safety precautions. This study aimed to assess the factors contributing to infection-related anxiety and educational anxiety among teachers conducting face-to-face classes during the COVID-19 pandemic after schools reopened. METHODS: This questionnaire-based cross-sectional study was conducted with 263 primary and middle school teachers in the Shinagawa area of Tokyo (October 10-30, 2020). The questionnaire assessed the type of school (primary or middle school), sex, age, and factors contributing to infection-related anxiety and educational anxiety that arose from the pandemic. The levels of anxiety and the factors contributing to anxiety were assessed using a 5-point Likert scale ranging from 1 (not at all) to 5 (very anxious). RESULTS: In an analysis of the data of 237 participants excluding the missing data, many teachers reported feeling infection- and education-related anxiety. A majority of the participants were women (nâ€‰=â€‰152, 64.1%), and the mean age of the participants was 39.8â€‰Â±â€‰11.3â€‰years. A stepwise multiple regression analysis identified six factors for infection-related anxiety as significant (R(2)â€‰=â€‰0.61, pâ€‰<â€‰0.001). Among these variables, the largest partial regression coefficient value was reported for the following reason: "I feel anxious because we cannot ensure the safety of teachers themselves or of their families" (Î²â€‰=â€‰0.37, pâ€‰<â€‰0.001). For educational anxiety, four of six reasons were identified as significant (R(2)â€‰=â€‰0.64, pâ€‰<â€‰0.001). Among these, "anxiety about the students' home situations" (Î²â€‰=â€‰0.41, pâ€‰<â€‰0.001) and "delay in education (students' side)" (Î²â€‰=â€‰0.27, pâ€‰<Â 0.001) had stronger associations with anxiety compared to the others. CONCLUSION: In-person education during the COVID-19 pandemic has

caused teachers to experience anxiety. This report provides useful information by highlighting the reasons for infection-related anxiety and educational anxiety that teachers experience in face-to-face classes during a pandemic. Even if the coverage of a COVID-19 vaccine becomes widespread worldwide, we will still be combating COVID-19 infections for at least a few years. Given concerns regarding such infections, to ensure students' right to education, it is essential to understand why teachers feel anxious and to determine appropriate measures to decrease such anxiety.
COVID-19 vaccine hesitancy: the five Cs to tackle behavioural and sociodemographic factors.
Audio Interview: Vaccinating Children.
Thromboembolic Events in the South African Ad26.COV2.S Vaccine Study.
Herpes zoster after inactivated COVID-19 vaccine: A cutaneous adverse effect of the vaccine.
Exacerbation of subacute cutaneous lupus erythematosus following vaccination with BNT162b2 mRNA vaccine.
Exacerbation of immune thrombocytopenia following COVID-19 vaccination. There is concern that COVID-19 vaccination may adversely affect immune thrombocytopenia (ITP) patients. Fifty-two consecutive chronic ITP patients were prospectively followed after COVID-19 vaccination. Fifteen percent had no worsening of clinical symptoms but no post-vaccination platelet count; 73% had no new symptoms and no significant platelet count decline. However, 12% had a median platelet count drop of 96% within 2-5â€‰days post vaccination with new bleeding symptoms; after rescue therapy with corticosteroids +/- intravenous immunoglobulin (IVIG), platelets recovered to >30â€‰Ã—â€‰10(9) /l a median three days later. ITP exacerbation occurred independently of remission status, concurrent ITP treatment, or vaccine type. Safety of a second vaccine dose needs careful assessment.
Coronavirus disease 2019 vaccination in transplant recipients. PURPOSE OF REVIEW: Coronavirus disease 2019 (COVID-19) vaccination is considered one of the most promising and socioeconomically sustainable strategy to help control the pandemic and several vaccines are currently being distributed in nationwide mass immunization campaigns. Very limited data are available on benefits and risks of COVID-19 vaccination in immunocompromised patients and in particular in solid organ or hematopoietic stem cell transplant recipients as they were excluded from phase III trials. This review summarizes current knowledge, international guidelines and controversies regarding COVID-19 vaccination in these vulnerable populations. RECENT FINDINGS: Various COVID-19 vaccine platforms showed good efficacy in phase III trials in the immunocompetent and there are data arising on the safety and immunogenicity of these vaccines in the immunocompromised population. SUMMARY: Transplant recipients could benefit significantly from COVID-19 vaccination, both through active immunization provided they elicit protective vaccine responses, and probably through cocooning by immunization of caregivers and healthcare personnel and thus reducing the risk of SARS-coronavirus-2 exposure. Although awaiting more data on the safety and efficacy of COVID-19 vaccines to inform potential adaptations of vaccine regimens, we strongly recommend prioritizing COVID-19 vaccination of solid and hematopoietic stem cell transplant recipients to decrease COVID-19-related morbidity and mortality.
Ethical Considerations in Chemotherapy and Vaccines in Cancer Patients in Times of the COVID-19 Pandemic. The COVID-19 situation is a worldwide health emergency with strong implications in clinical oncology. In this viewpoint, we address two crucial dilemmas from the ethical dimension: (1) Is it ethical to postpone or suspend cancer treatments which offer a statistically significant benefit in quality of life and survival in cancer patients during this time of pandemic?; (2) Should we vaccinate cancer patients against COVID-19 if scientific studies have not included this subgroup of patients? Regarding the first question, the best available evidence applied to the ethical principles of Beauchamp and Childress shows that treatments (such as chemotherapy) with clinical benefit are fair and beneficial. Indeed, the suspension or delay of such treatments should be considered malefic.

Regarding the second question, applying the doctrine of double-effect, we show that the potential beneficial effect of vaccines in the population with cancer (or those one that has had cancer) is much higher than the potential adverse effects of these vaccines. In addition, there is no better and less harmful known solution.

Thromboembolic Complications of SARS-CoV-2 and Metabolic Derangements: Suggestions from Clinical Practice Evidence to Causative Agents. Severe Acute Respiratory Syndrome (SARS) Coronavirus (CoV)-2 is a recently identified positive sense single-strand RNA (ssRNA) Î²-coronavirus. The viral spike proteins infect human hosts by binding to the cellular receptor angiotensin-converting enzyme 2 (ACE2). The infection causes a systemic illness involving cell metabolism. This widespread involvement is implicated in the pathophysiology of the illness which ranges from mild to severe, requiring multi organ support, ranging from oxygen supplementation to full cardiovascular and respiratory support. Patients with multiple co-existing comorbidities are also at a higher risk. The aim of this review is to explore the exact mechanisms by which COVID-19 affects patients systemically with a primary focus on the bleeding and thrombotic complications linked with the disease. Issues surrounding the thrombotic complications following administration of the ChAdOx1 nCoV-19 (Astra-Zeneca-Oxford) vaccine have also been illustrated. Risk stratification and treatment options in these patients should be tailored according to clinical severity with input from a multidisciplinary team.

Pfizer-BioNTech COVID-19 Vaccine Tolerance in Allergic versus Non-Allergic Individuals. Individuals with a history of allergy are potentially at risk of suffering from adverse effects after COVID-19 vaccination. We sought to assess the tolerance towards the Pfizer-BioNTech vaccine in allergic patients. To address this issue, we used a questionnaire conducted on-line in a group of medical professionals who were vaccinated with the Pfizer-BioNTech vaccine. A total of 1808 respondents, out of whom 1707 received two doses of the vaccine, returned the questionnaire. Local reactions after injection were more frequent in allergic individuals after both doses (swelling $p = 0.0003$). Systemic adverse events (AE-SYS) occurred more often after the second than the first dose in both groups (allergic persons: 77.29% vs. 41.06%); vomiting and arthralgia occurred more often in allergic subjects ($p = 0.0009$). AE-SYS in allergic individuals lasted longer than in non-allergic ones after the first ($p = 0.01$) and the second dose ($p = 0.0009$). Allergic reactions after vaccination were reported more frequently in allergic subjects: after the first dose ($p = 0.00001$) and after the second dose ($p = 0.001$). Rhinitis was the most frequent symptom observed more often in allergic patients. No severe allergic reactions occurred during the full cycle of vaccination. Although the Pfizer-BioNTech vaccine is tolerated worse by allergic than non-allergic individuals, the occurring adverse symptoms are mild and do not preclude a successful completion of the vaccination cycle. The presence of symptoms suggestive of allergy does not constitute a condition of increased risk of developing clinically significant adverse events following Pfizer COVID-19 vaccination.

Attitudes toward Vaccination against COVID-19 in Poland. A Longitudinal Study Performed before and Two Months after the Commencement of the Population Vaccination Programme in Poland. Despite the fact that more than a year has passed since the WHO declared the pandemic, there is still no effectivetreatment of COVID-19. According to current knowledge, the only method to stop the virus from spreading is prophylactic vaccination of the population. However, to achieve herd immunity, 60-72% of the population needs to be vaccinated, which is a significant challenge for current healthcare systems. As it has already been proven, having an effective vaccine is not the same as using it. Public acceptance is essential here. The study aimed to assess the changes in the attitudes of online respondents toward vaccination against COVID-19 over time. In the research, a questionnaire designed by the author of the study was used and it was distributed via the Internet in two stages. The questionnaire included a section assessing a sociodemographic status as well as the questions, designed by the author, evaluating the willingness of the respondents to get vaccinated

and their main concerns associated with it. The first stage covered the period before the commencement of the population vaccination programme in Poland, i.e., 14-27 December 2020. Then, the survey was redistributed 2 months after the vaccination programme was started, i.e., 1-19 March 2021. Participation in the study was fully anonymous, voluntary and there was a possibility to opt out at any stage of the research. A total of 2048 respondents were surveyed and 26 persons refused to be involved in the research. A total number of 2022 responses were analysed. Stage I of the research involved 22.9% of the respondents (463 persons). The questions were answered by 1559 persons (72.9%) after the survey was redistributed. Among the participants of stage II of the study, 422 (27.1%) persons have already been vaccinated against COVID-19. A comparison of the responses that were collected from both stages of the study showed a slight increase in the willingness to get vaccinated against COVID-19 over time. It turned out that women, residents of large cities, people with a higher level of education and healthcare workers showed a more favourable attitude toward vaccination. According to the results of the survey, chronic diseases do not have a significant impact on the attitude toward vaccinations ($p = 0.155$). As the social vaccination promotion campaign continued, a slight increase in the willingness to get vaccinated was observed. According to the survey, women, residents of large cities and those with higher education demonstrated more favourable attitudes toward getting vaccinated against COVID-19. It should be stressed that despite the passage of time and the increasing experience with the new types of vaccines against COVID-19, the percentage of people who are afraid of the complications after the vaccination has not decreased significantly and the concern related to the ineffectiveness of vaccination has dramatically increased. This demonstrates the limited effectiveness of the current information system regarding passing the knowledge on of the safety and efficiency of vaccination and it indicates a necessity to modernise it as soon as possible.

The Incidence and Severity of Post-Vaccination Reactions after Vaccination against COVID-19. The pandemic of COVID-19 might be limited by vaccination. Society should be vaccinated to prevent the spread of coronavirus disease 2019 (COVID-19) and to protect persons who are at high risk for complications. In Poland, the National Vaccination Program has been introduced, which is a strategy for planning activities to ensure safe and effective vaccinations among Polish citizens. It includes not only the purchase of an appropriate number of vaccines, their distribution but also monitoring of the course and effectiveness of vaccination and the safety of Poles. The national COVID-19 immunization program has been divided into four stages. Stage 0 covers the healthcare workers to be vaccinated first, as they are most at risk of being infected with the coronavirus. The study aims to prove the thesis that GIS statistical data on the incidence of COVID-19 post-vaccination reactions should be verified, as patients do not report their occurrence through the procedure indicated by GIS. In March 2021, an anonymous questionnaire survey was conducted using an electronic questionnaire among persons belonging to group zero of the National Vaccination Program. The survey consisted of 19 short questions concerning, inter alia, getting COVID-19, post-vaccination reactions after receiving the first and second doses of the COVID-19 vaccine, and motivation to proceed with vaccination. A total of 1678 complete responses were received. It has been shown that only a small number of post-vaccination reactions are reported to the Sanitary Inspection, which makes GIS statistics on the incidence of post-vaccination reactions in COVID-19 unreliable. In addition, having earlier suffered from COVID-19 had an impact on the occurrence of more severe side effects after the first dose of the COVID-19 vaccine.

Facial and Oral Manifestations Following COVID-19 Vaccination: A Survey-Based Study and a First Perspective. (1) Background: Severe acute respiratory syndrome Coronavirus-2 (SARS-CoV-2) emerged in Wuhan, China, in late 2019. The development of effective and safe vaccines against SARS-CoV-2 has been extremely fast. The list of orofacial adverse effects of BNT162b2 and mRNA-1273

vaccines based on the clinical trials are reported to be rare. The aim of this study was to investigate the facial and oral manifestations of COVID-19 vaccination using a survey-based study. (2) Methods: The questionnaire was developed using Google Forms and sent anonymously to a total of 700 subjects (medical personnel) in Poland, Italy, and other EU countries. (3) Results: 223 people answered the questionnaire, mainly vaccinated with BNT162b2. Only 3.1% and 5.4% experienced oral and facial symptoms, respectively. General diseases presence and age have significant influence on the probability of oral symptoms occurrence after the second dose. Facial symptoms are correlated with general disease; autoimmune pathologies and age, at first and second dose, respectively. Gender, smoking and regular medication intake have significant influence on the probability of taking an absence day. Gender, age, and smoking have a significant influence on the duration of symptoms after second dose. (4) Conclusions: Based on the results of this preliminary survey, there is no observed significant correlation between vaccine administration for COVID-19 and facial and oral manifestations.

The Association between Influenza Vaccination and COVID-19 and Its Outcomes: A Systematic Review and Meta-Analysis of Observational Studies. Influenza could circulate in parallel with COVID-19. In the context of COVID-19, some studies observed inverse associations between influenza vaccination and SARS-CoV-2 infection and clinical outcomes, while others did not. We conducted a meta-analysis to assess the association between influenza vaccination and SARS-CoV-2 infection and clinical outcomes, aiming to provide evidence for COVID-19 prevention and vaccination promotion. We searched four databases from inception to 10 March, 2021. Random effects and fixed effects models were used to pool odds ratios (ORs) and adjusted estimates with 95% confidence intervals (CIs). We used funnel plots to evaluate the publication bias, I2 statistics to evaluate the heterogeneity, and conducted subgroup analyses. Sixteen observational studies involving 290,327 participants were included. Influenza vaccination was associated with a lower risk of SARS-CoV-2 infection (pooled adjusted OR: 0.86, 95%CI: 0.81-0.91), while not significantly associated with adverse outcomes (intensive care: adjusted OR 0.63, 95%CI: 0.22-1.81; hospitalization: adjusted OR 0.74, 95%CI: 0.51-1.06; mortality: adjusted OR 0.89, 95%CI: 0.73-1.09). Our findings suggest that influenza vaccination is associated with a lower risk of SARS-CoV-2 infection. It is crucial for policy makers to implement strategies on influenza vaccination, for it may also have benefits for COVID-19 prevention.

Thrombosis with thrombocytopenia syndrome associated with COVID-19 vaccines. BACKGROUND: Current vaccines for the Coronavirus Disease of 2019 (COVID-19) have demonstrated efficacy with low risk of adverse events. However, recent reports of thrombosis with thrombocytopenia syndrome (TTS) associated with adenovirus vector vaccines have raised concern. OBJECTIVE: This narrative review summarizes the current background, evaluation, and management of TTS for emergency clinicians. DISCUSSION: TTS, also known as vaccine-induced immune thrombotic thrombocytopenia, is a reaction associated with exposure to the ChAdOx1 nCoV-19 (Oxford-AstraZeneca) and AD26.COV2Â·S (Johnson & Johnson) vaccine, which may result in thrombocytopenia and thrombotic events. There are several case series of patients diagnosed with TTS, but the overall incidence is rare. TTS is characterized by exposure to one of the aforementioned vaccines 4-30 days prior to presentation, followed by thrombosis, mild-to-severe thrombocytopenia, and a positive platelet factor-4 (PF4)-heparin enzyme-linked immunosorbent assay (ELISA). Thrombosis typically involves atypical locations, including cerebral venous thrombosis and splanchnic vein thrombosis. Evaluation should include complete blood count, peripheral smear, D-dimer, fibrinogen, coagulation panel, renal and liver function, and electrolytes, as well as PF4-heparin ELISA if available. Consultation with hematology is recommended if suspected or confirmed. Treatment may include intravenous immunoglobulin and anticoagulation, while avoiding heparin-based agents and platelet transfusion.

CONCLUSIONS: With increasing vaccine distribution, it is essential for emergency clinicians to be aware of the evaluation and management of this condition.

Africa's need for more COVID-19 clinical trials.

Chemical system biology approach to identify multi-targeting FDA inhibitors for treating COVID-19 and associated health complications. In view of many European countries and the USA leading to the second wave of COVID-19 pandemic, winter season, the evolution of new mutations in the spike protein, and no registered drugs and vaccines for COVID-19 treatment, the discovery of effective and novel therapeutic agents is urgently required. The degrees and frequencies of COVID-19 clinical complications are related to uncontrolled immune responses, secondary bacterial infections, diabetes, cardiovascular disease, hypertension, and chronic pulmonary diseases. It is essential to recognize that the drug repurposing strategy so far remains the only means to manage the disease burden of COVID-19. Despite some success of using single-target drugs in treating the disease, it is beyond suspicion that the virus will acquire drug resistance by acquiring mutations in the drug target. The possible synergistic inhibition of drug efficacy due to drug-drug interaction cannot be avoided while treating COVID-19 and allied clinical complications. Hence, to avoid the unintended development drug resistance and loss of efficacy due to drug-drug interaction, multi-target drugs can be promising tools for the most challenging disease. In the present work, we have carried out molecular docking studies of compounds from the FDA approved drug library, and the FDA approved and passed phase -1 drug libraries with ten therapeutic targets of COVID-19. Results showed that known drugs, including nine anti-inflammatory compounds, four antibiotics, six antidiabetic compounds, and one cardioprotective compound, could effectively inhibit multiple therapeutic targets of COVID-19. Further in-vitro, in vivo, and clinical studies will guide these drugs' proper allocation to treat COVID-19.Communicated by Ramaswamy H. Sarma.

Association of Simulated COVID-19 Vaccination and Nonpharmaceutical Interventions With Infections, Hospitalizations, and Mortality. IMPORTANCE: Vaccination against SARS-CoV-2 has the potential to significantly reduce transmission and COVID-19 morbidity and mortality. The relative importance of vaccination strategies and nonpharmaceutical interventions (NPIs) is not well understood. OBJECTIVE: To assess the association of simulated COVID-19 vaccine efficacy and coverage scenarios with and without NPIs with infections, hospitalizations, and deaths. DESIGN, SETTING, AND PARTICIPANTS: An established agent-based decision analytical model was used to simulate COVID-19 transmission and progression from March 24, 2020, to September 23, 2021. The model simulated COVID-19 spread in North Carolina, a US state of 10.5 million people. A network of 1â€¯017â€¯720 agents was constructed from US Census data to represent the statewide population. EXPOSURES: Scenarios of vaccine efficacy (50% and 90%), vaccine coverage (25%, 50%, and 75% at the end of a 6-month distribution period), and NPIs (reduced mobility, school closings, and use of face masks) maintained and removed during vaccine distribution. MAIN OUTCOMES AND MEASURES: Risks of infection from the start of vaccine distribution and risk differences comparing scenarios. Outcome means and SDs were calculated across replications. RESULTS: In the worst-case vaccination scenario (50% efficacy, 25% coverage), a mean (SD) of 2â€¯231â€¯134 (117â€¯867) new infections occurred after vaccination began with NPIs removed, and a mean (SD) of 799â€¯949 (60â€¯279) new infections occurred with NPIs maintained during 11 months. In contrast, in the best-case scenario (90% efficacy, 75% coverage), a mean (SD) of 527â€¯409 (40â€¯637) new infections occurred with NPIs removed and a mean (SD) of 450â€¯575 (32â€¯716) new infections occurred with NPIs maintained. With NPIs removed, lower efficacy (50%) and higher coverage (75%) reduced infection risk by a greater magnitude than higher efficacy (90%) and lower coverage (25%) compared with the worst-case scenario (mean [SD] absolute risk reduction, 13% [1%] and 8% [1%], respectively). CONCLUSIONS AND RELEVANCE: Simulation outcomes suggest that removing NPIs while vaccines are

distributed may result in substantial increases in infections, hospitalizations, and deaths. Furthermore, as NPIs are removed, higher vaccination coverage with less efficacious vaccines can contribute to a larger reduction in risk of SARS-CoV-2 infection compared with more efficacious vaccines at lower coverage. These findings highlight the need for well-resourced and coordinated efforts to achieve high vaccine coverage and continued adherence to NPIs before many prepandemic activities can be resumed.
Case Report: Thrombotic Thrombocytopenia after COVID-19 Janssen Vaccination.
An Update on the Pathogenesis of COVID-19 and the Reportedly Rare Thrombotic Events Following Vaccination. Today the coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), has become a global health problem. After more than a year with the pandemic, although our knowledge has progressed on COVID-19, there are still many unknowns in virological, pathophysiological and immunological aspects. It is obvious that the most efficient solution to end this pandemic are safe and efficient vaccines. This manuscript summarizes the pathophysiological and thrombotic features of COVID-19 and the safety and efficacy of currently approved COVID-19 vaccines with an aim to clarify the recent concerns of thromboembolic events after COVID-19 vaccination. The influx of newer information is rapid, requiring periodic updates and objective assessment of the data on the pathogenesis of COVID-19 variants and the safety and efficacy of currently available vaccines.
Positivity of SARS-CoV-2 Antibodies among Korean Healthy Healthcare Workers 1 and 2 Weeks after Second Dose of Pfizer-BioNTech Vaccination. The antibody titer of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was observed in 289 healthy healthcare workers who had completed the second dose of the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine. Antibody tests were performed using both the automated electrochemiluminescence immunoassay (ECLIA) and the chromatographic lateral flow immunoassay (LFIA). All subjects had antibodies against the receptor binding domain of the spike protein of SARS-CoV-2 only one week after completing the vaccination, and the antibody titer became significantly higher after another week ($P < 0.001$). Since there was a large amount of antibody formation within two weeks after completion of vaccination, the less sensitive method, LFIA, also showed high sensitivity. There was no significant difference between whole blood and serum in detecting SARS-CoV-2 antibodies after vaccination. This is an early study of vaccinations among Koreans and is expected to contribute to the establishment of national guidelines on COVID-19 vaccination.
Adverse Reactions of the Second Dose of the BNT162b2 mRNA COVID-19 Vaccine in Healthcare Workers in Korea. We conducted a prospective, mobile-based survey on the self-reported adverse reactions in healthcare workers (HCWs) who received both doses of the BNT162b2 mRNA vaccine. Of the 342 HCWs who completed the two-dose vaccination, 265 (77.5%) responded to the survey at least once. Overall, the rates of adverse reactions were higher after the second dose compared with the first dose (89.1% vs. 80.1%, $P = 0.006$). The most common systemic reactions were muscle ache (69.1%), fatigue (65.7%), headache (48.7%), chills (44.2%), and fever (32.1%), and were notably more common after the second dose vaccine as well. We also noted a sex difference in which the frequency of adverse reactions after the second dose of the vaccine was significantly higher in females, which was not observed after the first dose. The rates of adverse reactions were lower in older age groups, and the rates and severities of the adverse reactions decreased during the 3-day period following vaccination.
After COVID-19 successes, researchers push to develop mRNA vaccines for other diseases.
Secondary immune thrombocytopenia supposedly attributable to COVID-19 vaccination. Immune thrombocytopenia (ITP) has been widely reported as a complication of SARS-CoV-2 infection, but to our knowledge, there have been no reports on the association of the COVID-19 vaccine with

thrombocytopenia. Here, we report a case of secondary ITP in a patient who was recently immunised with the messenger RNA COVID-19 vaccine BNT162b2 (Pfizer-BioNTech).
Extending the clinical spectrum of thrombotic thrombocytopenic syndrome attributable to adenovirus-based vaccines for Covid-19.
French organization for the pharmacovigilance of COVID-19 vaccines: A major challenge. In this special issue, we present the main highlights of the first weeks of pharmacovigilance monitoring of coronavirus disease 2019 (COVID-19) vaccines in this unprecedented situation in France: the deployment of a vaccination during an epidemic period with the aim of vaccinating the entire population and the intense pharmacovigilance and surveillance of these vaccines still under conditional marketing authorizations. In this unprecedented situation, the cross approach and interaction between the French pharmacovigilance network and French National Agency for the Safety of Medicines and Health Products (ANSM) has been optimized to provide a real-time safety related to COVID-19 vaccines. Every week, pair of regional pharmacovigilance centers gathered safety data from the French pharmacovigilance network, to acutely expertise all the adverse drug reactions (ADRs) reported with each COVID-19 vaccine within a direct circuit with ANSM. Results of this expertise are presented and discussed with ANSM in order to raise safety signals and take appropriate measures if necessary. These reports are then published online. At the 25th of March 2021, more than 9 815Â 000 doses were injected and 20,265 ADRs were reported, mostly non-serious (76%). Several potential or confirmed signals were raised at the european level for those vaccines and others ADRs are under special attentions. This underlines the adaptiveness of the French pharmacovigilance system to both the identification of new patient profiles experiencing ADRs and the evolution of the vaccine strategy. Such an efficiency is necessary to manage a careful and acute surveillance of these new COVID-19 vaccines for and to face the pandemic at the same time.
PotentialÂ adverse events in Japanese women who received tozinameran (BNT162b2, Pfizer-BioNTech). Reports of cerebral venous sinus thrombosis and intracranial hemorrhage (ICH) following the administration of coronavirus vaccines have raised concerns regarding their safety. Although no regulatory authority has recognized ICH as an adverse event associated with tozinameran (BNT162b2, Pfizer-BioNTech), fatal and non-fatal cases have been reported. In Japan, 10 fatal cases (five men and women) have been reported to date. Four of the five women died of ICH and the other died of aspiration pneumonia, whereas all five men died of causes other than stroke. This imbalance is incompatible with the mortality data on cardiovascular diseases in the National Statistics, which show no apparent disparity between sexes or between hemorrhagic and ischemic stroke. Cumulatively, our analysis reveals a disproportionately high incidence of death by ICH in Japanese women who received tozinameran, suggesting a potential association of ICH with the vaccine. Although we understand that the benefits of tozinameran still outweigh the risks, we believe that a causal link with the vaccine is not proven but possible and warrants further analysis.
Low titers of SARS-CoV-2 neutralizing antibodies after first vaccination dose in cancer patients receiving checkpoint inhibitors. Vaccination for SARS-CoV-2 provides significant protection against the infection in the general population. However, only limited data exist for patients with cancer under systemic therapy. Based on this, our site has initiated a study evaluating safety and efficacy of SARS-CoV-2 vaccination in patients with solid and hematological malignancies under several systemic therapies. The initial results of the cohort of 59 patients receiving Immune Checkpoint Inhibitors are presented here. Despite no new safety issues have been noticed, the levels of SARS-CoV-2 neutralizing antibodies are significantly lower in comparison to matched healthy volunteers up to day 22 post the first dose. These results should be taken into consideration for the patients under treatment.

Lack of effects on female fertility and prenatal and postnatal offspring development in rats with BNT162b2, a mRNA-based COVID-19 vaccine. BNT162b2 is a vaccine developed to prevent coronavirus disease 2019 (COVID-19). BNT162b2 is a lipid nanoparticle formulated nucleoside-modified messenger RNA (mRNA) encoding the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein locked in its prefusion conformation. A developmental and reproductive toxicity study was conducted in rats according to international regulatory guidelines. The full human BNT162b2 dose of 30 Î¼g mRNA/dose (>300 times the human dose on a mg/kg basis) was administered intramuscularly to 44 female rats 21 and 14 days prior to mating and on gestation days 9 and 20. Half of the rats were subject to cesarean section and full fetal examination at the end of gestation, and the other half were allowed to deliver and were monitored to the end of lactation. A robust neutralizing antibody response was confirmed prior to mating and at the end of gestation and lactation. The presence of neutralizing antibodies was also confirmed in fetuses and offspring. Nonadverse effects, related to the local injection site reaction, were noted in dams as expected from other animal studies and consistent with observations in humans. There were no effects of BNT162b2 on female mating performance, fertility, or any ovarian or uterine parameters nor on embryo-fetal or postnatal survival, growth, physical development or neurofunctional development in the offspring through the end of lactation. Together with the safety profile in nonpregnant people, this ICH-compliant nonclinical safety data supports study of BNT162b2 in women of childbearing potential and pregnant and lactating women.
Impaired anti-SARS-CoV-2 humoral and cellular immune response induced by Pfizer-BioNTech BNT162b2 mRNA vaccine in solid organ transplanted patients.
Ipsilateral herpes zoster after the first dose of BNT162b2 mRNA COVID-19 vaccine.
SARS-CoV-2 vaccination induces breakthrough hemolysis in paroxysmal nocturnal hemoglobinuria on complement inhibitor.
Thrombocytopenia and splanchnic thrombosis after Ad26.COV2.S vaccination successfully treated with transjugular intrahepatic portosystemic shunting and thrombectomy.
A case of severe cutaneous adverse reaction following administration of the Janssen Ad26.COV2.S COVID-19 vaccine.
Mortality Rate and Characteristics of Deaths Following COVID-19 Vaccination. Background: The emergency use authorization for coronavirus disease 2019 (COVID-19) vaccines brought both hopes and concerns to the Americans and others. We aimed to estimate the mortality rate of COVID-19 vaccination and presented characteristics of deaths following COVID-19 vaccination. Methods: Data on deaths following COVID-19 vaccination were obtained from the Vaccine Adverse Event Reporting System (VAERS) from December 11, 2020 through January 8, 2021. The Centers for Disease Control and Prevention (CDC) COVID Data Tracker was used to identify the total number of people receiving COVID-19 vaccines during the same period to estimate the mortality rate. Stratified analysis was conducted by the location of vaccination. Results: As of January 8, 2021, 55 deaths were reported, and the mortality rate of COVID-19 vaccination was 8.2 per million population. A total of 37 deaths were reported among long-term care facility residents, and the mortality rate was 53.4 per million population. Top reported comorbidities associated with deaths included hypertension, dementia, chronic obstructive pulmonary disease (COPD), diabetes, and heart failure. In addition, dementia was more likely to be associated with deaths vaccinated at long-term care facilities than at other locations. Conclusion: The benefits of COVID-19 vaccines outweigh the potential risks in older frail populations, and our findings do not support actions to exclude older adults from being vaccinated. However, continued monitoring of COVID-19 vaccination is still warranted.
Exacerbating Guillain-BarrÃ© Syndrome Eight Days after Vector-Based COVID-19 Vaccination. Since the introduction of mRNA technology-based and vector-based COVID-19 vaccines, adverse

reactions to these agents have been occasionally reported. Exacerbation of Guillain-BarrÃ© syndrome (GBS) shortly after COVID-19 vaccination has not been communicated. The patient is a 32-year-old male who developed progressive sensory disturbances and muscle weakness 8 days after the first dosage of a vector-based vaccine. Cerebrospinal fluid investigations revealed a dissociation cyto-albuminque, and nerve conduction studies revealed demyelination. Intravenous immunoglobulin (IVIG) exhibited only a marginal effect for both sensory and motor deficits. The patient's history was moreover positive for previous GBS with marked motor deficits 14 years earlier, which responded favourably to IVIG leading to almost complete recovery within 9 months of rehabilitation. Although apparently extremely rare, neurologists should remain vigilant for a potential recurrence of GBS after vaccination with a vector-based COVID-19 vaccine.

Unilateral axillary adenopathy following COVID-19 vaccination: a multimodality pictorial illustration and review of current guidelines. We present a multimodality pictorial review of axillary lymphadenopathy in patients recently vaccinated against COVID-19. As the mass vaccination programme continues to be rolled out worldwide in an effort to combat the pandemic, it is important that radiologists consider recent COVID-19 vaccination in the differential diagnosis of unilateral axillary lymphadenopathy and are aware of typical appearances across all imaging methods. We review current guidelines on the management of unilateral axillary lymphadenopathy in the context of recent COVID-19 vaccination.

2019 Novel Coronavirus Vaccination among Post-graduate Residents and Fellows. BACKGROUND: Coronavirus-2 (COVID-19) has caused a worldwide pandemic since December 2019. Since then, clinical trials with vaccines have been started and completed, and at present, 3 COVID-19 vaccines have been approved for use in the United States. Healthcare providers were among the first to get vaccinated, but the precise attitudes of healthcare workers toward vaccination are uncertain. OBJECTIVE: To understand residents and fellows' attitudes toward vaccination and record any side effects after vaccination. METHODS: We conducted an anonymous survey that was open from 3-1-2021 to 3-12-2021 using distribution lists from the Graduate Medical Education office on the Lubbock campus of the Texas Tech University Health Sciences Center after getting approval from the Institutional Review Board (L21-088). RESULTS: Eighty-one residents and fellows (26.6% out of 304) responded to our survey. Among those who responded, 63 (77.8 %) were between 25 and 35â€‰years old, and 41 (50.6%) were males. Seventy-seven (95.1%) received the vaccine (Pfizer-BioNTech), 78 (96.3%) reported that they supported vaccination, and 3 (3.7%) reported that they did not want vaccination. Eight members (9.8%) had tested positive for COVID-19 infection before vaccination, but only 1 (1.23%) had tested positive for COVID-19 antibodies. All residents and fellows reported side effects after the vaccination, including pain at the injection site (77; 100%), local redness (9; 11.6%), local swelling (13; 16.8%), fever (25; 32.5%), fatigue (25; 32.5%), chills (34; 44.1 %), headache (38; 49.4%). CONCLUSIONS: Most medical trainees have a high interest in COVID-19 vaccination; however, a few reported that they did not want vaccination.

Optimizing investigation of suspected allergy to polyethylene glycols. BACKGROUND: Polyethylene glycols (PEGs) are polymers of varying molecular weight (MW) used widely as excipients in drugs and other products, including the mRNA vaccines against coronavirus disease 2019. Allergy to PEGs is rare. Skin testing and graded challenge carries a high risk of inducing systemic reactions. OBJECTIVE: We evaluated skin prick test (SPT) results and inÂ vitro reactivity over time to different MW PEGs and assessed cross-sensitization patterns in PEG allergy. METHODS: Ten patients with previously diagnosed PEG allergy underwent SPT twice with PEGs 26 months apart. Lower MW (PEG 300, 3000, 6000) were tested, followed by PEG 20,000, in stepwise, increasing concentrations. Cross-sensitization to polysorbate 80 and poloxamer 407 was assessed. SPT was performed in 16 healthy controls. InÂ vitro basophil histamine release (HR) test and passive sensitization HR test were

performed in patients and controls. RESULTS: Patients previously testing positive on SPT to PEG 3000 and/or 6000 also tested positive to PEG 20,000. Patients with a longer interval since diagnosis tested negative to lower MW PEGs and positive mainly to higher concentrations of PEG 20,000. Three patients developed systemic urticaria during SPT. Eight patients showed cross-sensitization to poloxamer 407 and 3 to polysorbate 80. All controls tested negative. InÂ vitro tests showed limited usefulness. CONCLUSIONS: Skin test reactivity to PEG can decrease over time, but titrated SPT with increasing concentrations of PEG 20,000 can be diagnostic when lower MW PEGs test negative. To avoid systemic reactions, stepwise SPT is mandatory.
Rate and risk factors for breakthrough SARS-CoV-2 infection after vaccination.
Letter regarding "Minimal change disease relapse following SARS-CoV-2 mRNA vaccine".
Mechanisms of Immunothrombosis in Vaccine-Induced Thrombotic Thrombocytopenia (VITT) Compared to Natural SARS-CoV-2 Infection. Herein, we consider venous immunothrombotic mechanisms in SARS-CoV-2 infection and anti-SARS-CoV-2 DNA vaccination. Primary SARS-CoV-2 infection with systemic viral RNA release (RNAaemia) contributes to innate immune coagulation cascade activation, with both pulmonary and systemic immunothrombosis - including venous territory strokes. However, anti-SARS-CoV-2 adenoviral-vectored-DNA vaccines -initially shown for the ChAdOx1 vaccine-may rarely exhibit autoimmunity with autoantibodies to Platelet Factor-4 (PF4) that is termed Vaccine-Induced Thrombotic Thrombocytopenia (VITT), an entity pathophysiologically similar to Heparin-Induced Thrombocytopenia (HIT). The PF4 autoantigen is a polyanion molecule capable of independent interactions with negatively charged bacterial cellular wall, heparin and DNA molecules, thus linking intravascular innate immunity to both bacterial cell walls and pathogen-derived DNA. Crucially, negatively charged extracellular DNA is a powerful adjuvant that can break tolerance to positively charged nuclear histone proteins in many experimental autoimmunity settings, including SLE and scleroderma. Analogous to DNA-histone interactons, positively charged PF4-DNA complexes stimulate strong interferon responses via Toll-Like Receptor (TLR) 9 engagement. A chain of events following intramuscular adenoviral-vectored-DNA vaccine inoculation including microvascular damage; microbleeding and platelet activation with PF4 release, adenovirus cargo dispersement with DNA-PF4 engagement may rarely break immune tolerance, leading to rare PF4-directed autoimmunity. The VITT cavernous sinus cerebral and intestinal venous territory immunothrombosis proclivity may pertain to venous drainage of shared microbiotal-rich areas of the nose and in intestines that initiates local endovascular venous immunity by PF4/microbiotal engagement with PF4 autoantibody driven immunothrombosis reminiscent of HIT. According to the proposed model, any adenovirus-vectored-DNA vaccine could drive autoimmune VITT in susceptible individuals and alternative mechanism based on molecular mimicry, vaccine protein contaminants, adenovirus vector proteins, EDTA buffers or immunity against the viral spike protein are secondary factors. Hence, electrochemical DNA-PF4 interactions and PF4-heparin interactions, but at different locations, represent the common denominator in HIT and VITT related autoimmune-mediated thrombosis.
Biphasic anaphylaxis after exposure to the first dose of Pfizer-BioNTech COVID-19 mRNA vaccine. In the setting of a coronavirus disease 2019 (COVID-19) global pandemic and increased disease burden, vaccination has become one of the major solutions. With the increase in vaccination numbers worldwide, it is important to stay vigilant to the potential side effects and life-threatening complications of such vaccines. We report the case of a 30-year-old male with a biphasic allergic reaction post messenger (mRNA) Pfizer-BioNTech COVID-19 vaccination. Several reports of allergic reactions have been cited in the literature after the administration of the mRNA Pfizer-BioNTech COVID-19 vaccine. It is important to keep a high index of suspicion in severe anaphylactic cases as some patients may have a recurrence of symptoms after discharge. It is crucial to acknowledge the

potential risk of anaphylaxis in select individuals and have the appropriate measures in place to deal with adverse events. In case of severe symptoms, the administration of epinephrine is advised to prevent the development of a delayed biphasic anaphylactic reaction.
Development of COVID-19 Infection in Transplant Recipients After SARS-CoV-2 Vaccination.
Using Nonheparin Anticoagulant to Treat a Near-Fatal Case With Multiple Venous Thrombotic Lesions During ChAdOx1 nCoV-19 Vaccination-Related Vaccine-Induced Immune Thrombotic Thrombocytopenia. OBJECTIVES: To describe the successful recovery from multiple and life-threatening venous thrombosis after ChAdOx1 nCoV-19 vaccination. DESIGN: Case report. SETTING: University Hospital. PATIENT: Few days after the first dose of the ChAdOx1 nCoV-19 vaccine, a 21-year-old woman experienced massive thrombosis in the deep and superficial cerebral veins together with seizures, neurologic focal deficit, and thrombocytopenia. In the neurointensive care unit, her condition worsened despite early decompressive craniectomy. She developed bilateral segmental pulmonary embolism, left hepatic, and left external iliac venous thrombosis. INTERVENTION: Argatroban (0.5-2.2 Âµg/kg/min) and high-dose IV immunoglobulin (1 g/kg/d for 2 consecutive days) were initiated on day 6 after admission. With these therapies, there was a gradual resolution of multiple sites of venous thrombosis, and platelet count returned to normal. The patient left the ICU with full consciousness, expressive aphasia, and right hemiparesis. CONCLUSIONS: This case of vaccine-induced immune thrombotic thrombocytopenia shows that a good outcome can be obtained even with multiple and life-threatening venous thrombotic lesions. Argatroban and high-dose IV immunoglobulin along with management of severe cerebral venous thrombosis played a major role in this epilogue.
SARS-CoV-2 vaccines - the biggest medical research project of the 21st century. SARS-CoV-2 has been detected in more than 141 million people and caused more than 3 million deaths worldwide. To reduce the additional loss of millions of lives until natural immunity is reached, researchers have focused on the only known method to stop the COVID-19 pandemic: vaccines. The pandemic has propelled high-speed vaccine development, some based on novel technology previously not utilized in the vaccine field. The new technology opens new possibilities and comes with challenges because the long-term performance of the new platforms is unknown. Here we review the current leading vaccine candidates against COVID-19 and outline the advantages and disadvantages as well as the unknowns of each candidate.
Minimal change disease following the Moderna mRNA-1273 SARS-CoV-2 vaccine.
Effectiveness of SARS-CoV-2 Vaccination in a Veterans Affairs Cohort of Patients With Inflammatory Bowel Disease With Diverse Exposure to Immunosuppressive Medications. BACKGROUND & AIMS: Vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has rapidly expanded; however, clinical trials excluded patients taking immunosuppressive medications such as those with inflammatory bowel disease (IBD). Therefore, we explored real-world effectiveness of coronavirus disease 2019 (COVID-19) vaccination on subsequent infection in patients with IBD with diverse exposure to immunosuppressive medications. METHODS: This was a retrospective cohort study of patients in the Veterans Health Administration with IBD diagnosed before December 18, 2020, the start date of the Veterans Health Administration patient vaccination program. IBD medication exposures included mesalamine, thiopurines, anti-tumor necrosis factor biologic agents, vedolizumab, ustekinumab, tofacitinib, methotrexate, and corticosteroid use. We used inverse probability weighting and Cox's regression with vaccination status as a time-updating exposure and computed vaccine effectiveness from incidence rates. RESULTS: The cohort comprised 14,697 patients, 7321 of whom received at least 1 vaccine dose (45.2% Pfizer, 54.8% Moderna). The cohort had median age 68 years, 92.2% were men, 80.4% were White, and 61.8% had ulcerative colitis. In follow-up data through April 20, 2021, unvaccinated individuals had the highest raw proportion of

SARS-CoV-2 infection (197 [1.34%] vs 7 [0.11%] fully vaccinated). Full vaccination status, but not partial vaccination status, was associated with a 69% reduced hazard of infection relative to an unvaccinated status (hazard ratio, 0.31, 95% confidence interval, 0.17-0.56; P < .001), corresponding to an 80.4% effectiveness. CONCLUSIONS: Full vaccination (> 7 days after the second dose) against SARS-CoV-2 infection has an âˆ¼80.4% effectiveness in a broad IBD cohort with diverse exposure to immunosuppressive medications. These results may serve to increase patient and provider willingness to pursue vaccination in these settings.

Purpuric lesions on the eyelids developed after BNT162b2 mRNA COVID-19 vaccine: another piece of SARS-CoV-2 skin puzzle?

Evaluation of Seropositivity Following BNT162b2 Messenger RNA Vaccination for SARS-CoV-2 in Patients Undergoing Treatment for Cancer. IMPORTANCE: Patients with cancer undergoing treatment are at high risk of COVID-19 following SARS-CoV-2 infection; however, their ability to produce an adequate antibody response to messenger RNA SARS-CoV-2 vaccines is unclear. OBJECTIVE: To evaluate rates of antispike (anti-S) antibody response to a BNT162b2 vaccine in patients with cancer who are undergoing systemic treatment vs healthy controls. DESIGN, SETTING, AND PARTICIPANTS: This prospective cohort study included 102 adult patients with solid tumors undergoing active intravenous anticancer treatment and 78 controls who received the second dose of the BNT162b2 vaccine at least 12 days before enrollment. The controls were taken from a convenience sample of the patients' family/caregivers who accompanied them to treatment. The study was conducted between February 22, 2021, and March 15, 2021 at Davidoff Cancer Center at Beilinson Hospital (Petah Tikva, Israel). INTERVENTIONS: Blood samples were drawn from the study participants. Serum samples were analyzed and the titers of the IgG antibodies against SARS-CoV-2 spike receptor-binding domain were determined using a commercially available immunoassay. Seropositivity was defined as 50 or greater AU/mL. MAIN OUTCOMES AND MEASURES: The primary outcome was the rate of seropositivity. Secondary outcomes included comparisons of IgG titers and identifying factors that were associated with seropositivity using univariate/multivariable analyses. RESULTS: The analysis included 180 participants, which comprised 102 patients with cancer (median [interquartile range (IQR)] age, 66 [56-72] years; 58 men [57%]) and 78 healthy controls (median [IQR] age, 62 [49-70] years; 25 men [32%]). The most common tumor type was gastrointestinal (29 [28%]). In the patient group, 92 (90%) were seropositive for SARS-CoV 2 antispike IgG antibodies after the second vaccine dose, whereas in the control group, all were seropositive. The median IgG titer in the patients with cancer was significantly lower than that in the controls (1931 [IQR, 509-4386] AU/mL vs 7160 [IQR, 3129-11â€¯241] AU/mL; Pâ€‰<â€‰.001). In a multivariable analysis, the only variable that was significantly associated with lower IgG titers was treatment with chemotherapy plus immunotherapy (Î², -3.5; 95% CI, -5.6 to -1.5). CONCLUSIONS AND RELEVANCE: In this cohort study of patients with cancer who were receiving active systemic therapy, 90% of patients exhibited adequate antibody response to the BNT162b2 vaccine, although their antibody titers were significantly lower than those of healthy controls. Further research into the clinical relevance of lower titers and their durability is required. Nonetheless, the data support vaccinating patients with cancer as a high priority, even during therapy.

Olfactory dysfunction after coronavirus disease 2019 (COVID-19) vaccination.

Adverse Events After SARS-CoV-2 mRNA Vaccination Among Patients With Inflammatory Bowel Disease. INTRODUCTION: Patients with immune-mediated inflammatory diseases such as inflammatory bowel disease (IBD) on immunosuppressive and biologic therapies were largely excluded from severe acute respiratory syndrome coronavirus-2 messenger RNA vaccine trials. METHODS: We evaluated adverse events (AE) after messenger RNA vaccination in 246 adults with IBD participating in a longitudinal vaccine registry. RESULTS: In general, AE frequency was similar to that

reported in the general population. AEs were more common among younger patients and those with previous COVID-19. AEs were less common in individuals receiving advanced therapies with biologics or small-molecule inhibitors. DISCUSSION: Those with IBD and other immune-mediated inflammatory diseases can be reassured that the AE risk is likely not increased, and may be reduced, while on advanced therapies.
mRNA COVID-19 Vaccine for People with Kidney Failure: Hope but Prudence Warranted.
Cerebral Venous Thrombosis following COVID-19 Vaccination.
BNT162b2 vaccine induces neutralizing antibodies and poly-specific T cells in humans. BNT162b2, a nucleoside-modified mRNA formulated in lipid nanoparticles that encodes the SARS-CoV-2 spike glycoprotein (S) stabilized in its prefusion conformation, has demonstrated 95% efficacy in preventing COVID-19(1). Here we extend a previous phase-I/II trial report(2) by presenting data on the immune response induced by BNT162b2 prime-boost vaccination from an additional phase-I/II trial in healthy adults (18-55Â years old). BNT162b2 elicited strong antibody responses: at one week after the boost, SARS-CoV-2 serum geometric mean 50% neutralizing titres were up to 3.3-fold above those observed in samples from individuals who had recovered from COVID-19. Sera elicited by BNT162b2 neutralized 22Â pseudoviruses bearing the S of different SARS-CoV-2 variants. Most participants had a strong response of IFNÎ³(+) or IL-2(+) CD8(+) and CD4(+) T helper typeÂ 1 cells, which was detectable throughout the full observation period of nine weeks following the boost. Using peptide-MHC multimer technology, we identified several BNT162b2-induced epitopes that were presented by frequent MHC alleles and conserved in mutant strains. One week after the boost, epitope-specific CD8(+) T cells of the early-differentiated effector-memory phenotype comprised 0.02-2.92% of total circulating CD8(+) T cells and were detectable (0.01-0.28%) eight weeks later. In summary, BNT162b2 elicits an adaptive humoral and poly-specific cellular immune response against epitopes that are conserved in a broad range of variants, at well-tolerated doses.
Acute abducens nerve palsy following COVID-19 vaccination. We report the case of a healthy 59-year-old woman who presented with an acute abducens nerve palsy 2Â days after receiving the Pfizer-BioNTech COVID-19 vaccine. In adults, such palsies are typically caused by microvascular disease or compressive tumors, although they have also been described after routine vaccinations. Given the temporal relationship between vaccination and the onset of symptoms, the lack of preexisting medical conditions, and unremarkable magnetic resonance imaging, the patient's abducens nerve palsy was felt to be related to her vaccination. This case highlights the importance of recognizing the potential of a COVID-19 vaccine to have neurologic sequelae similar to those that as have been reported with the virus itself as well as with other vaccines.
Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. BACKGROUND: Until very recently, vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) had not been authorized for emergency use in persons younger than 16 years of age. Safe, effective vaccines are needed to protect this population, facilitate in-person learning and socialization, and contribute to herd immunity. METHODS: In this ongoing multinational, placebo-controlled, observer-blinded trial, we randomly assigned participants in a 1:1 ratio to receive two injections, 21 days apart, of 30 Î¼g of BNT162b2 or placebo. Noninferiority of the immune response to BNT162b2 in 12-to-15-year-old participants as compared with that in 16-to-25-year-old participants was an immunogenicity objective. Safety (reactogenicity and adverse events) and efficacy against confirmed coronavirus disease 2019 (Covid-19; onset, â‰¥7 days after dose 2) in the 12-to-15-year-old cohort were assessed. RESULTS: Overall, 2260 adolescents 12 to 15 years of age received injections; 1131 received BNT162b2, and 1129 received placebo. As has been found in other age groups, BNT162b2 had a favorable safety and side-effect profile, with mainly transient mild-to-moderate reactogenicity (predominantly injection-site pain [in 79 to 86% of participants], fatigue [in

60 to 66%], and headache [in 55 to 65%]); there were no vaccine-related serious adverse events and few overall severe adverse events. The geometric mean ratio of SARS-CoV-2 50% neutralizing titers after dose 2 in 12-to-15-year-old participants relative to 16-to-25-year-old participants was 1.76 (95% confidence interval [CI], 1.47 to 2.10), which met the noninferiority criterion of a lower boundary of the two-sided 95% confidence interval greater than 0.67 and indicated a greater response in the 12-to-15-year-old cohort. Among participants without evidence of previous SARS-CoV-2 infection, no Covid-19 cases with an onset of 7 or more days after dose 2 were noted among BNT162b2 recipients, and 16 cases occurred among placebo recipients. The observed vaccine efficacy was 100% (95% CI, 75.3 to 100). CONCLUSIONS: The BNT162b2 vaccine in 12-to-15-year-old recipients had a favorable safety profile, produced a greater immune response than in young adults, and was highly effective against Covid-19. (Funded by BioNTech and Pfizer; C4591001 ClinicalTrials.gov number, NCT04368728.).

Three Cases of Subacute Thyroiditis Following SARS-CoV-2 Vaccine: Postvaccination ASIA Syndrome. CONTEXT: Autoimmune/inflammatory syndrome induced by adjuvants (ASIA syndrome) can be seen as a postvaccination phenomenon that occurs after exposure to adjuvants in vaccines that increase the immune responses. There are very limited data regarding ASIA syndrome following severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines. OBJECTIVES: This work aims to report cases of subacute thyroiditis related to the SARS-CoV-2 vaccine. METHODS: We describe the clinical, laboratory, and imaging features of 3 cases of subacute thyroiditis after inactivated SARS-CoV-2 vaccine (CoronaVacÂ®). Three female healthcare workers have applied to our clinic with anterior neck pain and fatigue 4 to 7 days after SARS-CoV-2 vaccination. Two of them were in the breastfeeding period. They were negative for thyroid antibodies, and there was no previous history of thyroid disease, upper respiratory tract infection, or COVID-19. Laboratory test results and imaging findings were consistent with subacute thyroiditis. RESULTS: SARS-CoV-2 vaccination can lead to subacute thyroiditis as a phenomenon of ASIA syndrome. Subacute thyroiditis may develop within a few days after the SARS-CoV-2 vaccination. Being in the postpartum period may be a facilitating factor for the development of ASIA syndrome after the SARS-CoV-2 vaccination. CONCLUSIONS: This is the first report of subacute thyroiditis as a phenomenon of ASIA syndrome after inactivated COVID-19 vaccination. Clinicians should be aware that subacute thyroiditis may develop as a manifestation of ASIA syndrome after the inactive SARS-CoV-2 vaccine.

Cytokine release syndrome in a patient with colorectal cancer after vaccination with BNT162b2. Patients with cancer are currently prioritized in coronavirus disease 2019 (COVID-19) vaccination programs globally, which includes administration of mRNA vaccines. Cytokine release syndrome (CRS) has not been reported with mRNA vaccines and is an extremely rare immune-related adverse event of immune checkpoint inhibitors. We present a case of CRS that occurred 5 d after vaccination with BTN162b2 (tozinameran)-the Pfizer-BioNTech mRNA COVID-19 vaccine-in a patient with colorectal cancer on long-standing anti-PD-1 monotherapy. The CRS was evidenced by raised inflammatory markers, thrombocytopenia, elevated cytokine levels (IFN-Î³/IL-2R/IL-18/IL-16/IL-10) and steroid responsiveness. The close temporal association of vaccination and diagnosis of CRS in this case suggests that CRS was a vaccine-related adverse event; with anti-PD1 blockade as a potential contributor. Overall, further prospective pharmacovigillence data are needed in patients with cancer, but the benefit-risk profile remains strongly in favor of COVID-19 vaccination in this population.

The COVID vaccine pioneer behind southeast Asia's first mRNA shot.

COVID-19 vaccination in pregnant and lactating diabetic women. AIM: To discuss available information on the opportunity for pregnant women affected by diabetes/obesity to receive COVID-19 vaccine. DATA SYNTHESIS: Pregnant women with SARS-CoV-2 (COVID-19) infection are at high risk for severe acute respiratory syndrome and adverse outcomes. Pregnant women with severe COVID-

19 present increased rates of preterm delivery (<37 gestational weeks), cesarean delivery and neonatal admissions to the intensive care unit. Comorbidity such as diabetes (pregestational or gestational) or obesity further increased maternal and fetal complications. It is known that diabetic or obese patients with COVID-19 present an unfavorable course and a worse prognosis, with a direct association between worse outcome and suboptimal glycol-metabolic control or body mass index (BMI) levels. Critical COVID-19 infection prevention is important for both mother and fetus. Vaccination during pregnancy is a common practice. Vaccines against COVID-19 are distributed across the world with some population considered to have a priority. Since pregnant women are excluded from clinical trials very little information are available on safety and efficacy of COVD-19 vaccines during pregnancy. However, it is well known the concept of passive immunization of the newborn obtained with transplacental passage of protective antibodies into the fetal/neonatal circulation after maternal infection or vaccination. Moreover, it has been reported that COVID-19 vaccine-induced IgG pass to the neonates through breastmilk. Therefore, maternal vaccination can protect mother, fetus and baby. CONCLUSIONS: After an individual risk/benefit evaluation pregnant and lactating women should be counselled to receive COVID-19 vaccines.

Vaccine hesitancy due to vaccine country of origin, vaccine technology, and certification. Vaccine hesitancy is a global health threat which may hinder the widespread acceptance of several COVID-19 vaccines. Following the collection of 2470 responses from an anonymous questionnaire distributed between October and November 2020 across Israel, we analyzed the responses of physicians, life science graduates (biology, virology, chemistry, etc.), and the general public to whether they would obtain a COVID-19 vaccine with particular vaccine characteristics such as vaccine country of origin, technology, side effect profile, efficacy, and other attributes. Physicians and life science graduates were least likely to accept a vaccine based on mRNA technology (30%) while the general population seemed to adopt any vaccine technology if the declared efficacy is above 90% and the country of manufacturing is the USA/UK rather than China or Russia. However, current inoculation rates in Israel far outpace our predicted rate. Our results highlight the importance of tailored vaccine educational campaigns based on population demographic details and specific vaccine concerns.

Effect of 2 Inactivated SARS-CoV-2 Vaccines on Symptomatic COVID-19 Infection in Adults: A Randomized Clinical Trial. IMPORTANCE: Although effective vaccines against COVID-19 have been developed, additional vaccines are still needed. OBJECTIVE: To evaluate the efficacy and adverse events of 2 inactivated COVID-19 vaccines. DESIGN, SETTING, AND PARTICIPANTS: Prespecified interim analysis of an ongoing randomized, double-blind, phase 3 trial in the United Arab Emirates and Bahrain among adults 18 years and older without known history of COVID-19. Study enrollment began on July 16, 2020. Data sets used for the interim analysis of efficacy and adverse events were locked on December 20, 2020, and December 31, 2020, respectively. INTERVENTIONS: Participants were randomized to receive 1 of 2 inactivated vaccines developed from SARS-CoV-2 WIV04 (5 Âµg/dose; nâ€‰=â€‰13 459) and HB02 (4 Âµg/dose; nâ€‰=â€‰13 465) strains or an aluminum hydroxide (alum)-only control (nâ€‰=â€‰13 458); they received 2 intramuscular injections 21 days apart. MAIN OUTCOMES AND MEASURES: The primary outcome was efficacy against laboratory-confirmed symptomatic COVID-19 14 days following a second vaccine dose among participants who had no virologic evidence of SARS-CoV-2 infection at randomization. The secondary outcome was efficacy against severe COVID-19. Incidence of adverse events and reactions was collected among participants who received at least 1 dose. RESULTS: Among 40 382 participants randomized to receive at least 1 dose of the 2 vaccines or alum-only control (mean age, 36.1 years; 32 261 [84.4%] men), 38 206 (94.6%) who received 2 doses, contributed at least 1 follow-up measure after day 14 following the second dose, and had negative reverse transcriptase-polymerase chain reaction test results at enrollment were included in the primary efficacy analysis. During a median (range) follow-up duration

of 77 (1-121) days, symptomatic COVID-19 was identified in 26 participants in the WIV04 group (12.1 [95% CI, 8.3-17.8] per 1000 person-years), 21 in the HB02 group (9.8 [95% CI, 6.4-15.0] per 1000 person-years), and 95 in the alum-only group (44.7 [95% CI, 36.6-54.6] per 1000 person-years), resulting in a vaccine efficacy, compared with alum-only, of 72.8% (95% CI, 58.1%-82.4%) for WIV04 and 78.1% (95% CI, 64.8%-86.3%) for HB02 (Pâ€‰<â€‰.001 for both). Two severe cases of COVID-19 occurred in the alum-only group and none occurred in the vaccine groups. Adverse reactions 7 days after each injection occurred in 41.7% to 46.5% of participants in the 3 groups; serious adverse events were rare and similar in the 3 groups (WIV04: 64 [0.5%]; HB02: 59 [0.4%]; alum-only: 78 [0.6%]). CONCLUSIONS AND RELEVANCE: In this prespecified interim analysis of a randomized clinical trial, treatment of adults with either of 2 inactivated SARS-CoV-2 vaccines significantly reduced the risk of symptomatic COVID-19, and serious adverse events were rare. Data collection for final analysis is pending. TRIAL REGISTRATION: ClinicalTrials.gov Identifier: NCT04510207; Chinese Clinical Trial Registry: ChiCTR2000034780.

[Thrombosis and COVID-19 vaccine: much ado about nothing?]. Several cases of thrombosis in unusual sites associated with thrombocytopenia have been described after vaccination with the recombinant adenoviral vector encoding the spike protein antigen of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), ChAdOx1 nCov-19 (AstraZeneca) and Ad26.COV.2 (Johnson & Johnson/Janssen). This new clinical entity has many analogies with heparin-induced thrombocytopenia, and recent studies suggest that an immunologic mechanism may be implicated in the pathogenesis of this unusual thrombotic disorder. However, more data are needed to identify subjects at risk for this rare clotting disease.

Cellular and humoral response after MRNA-1273 SARS-CoV-2 vaccine in kidney transplant recipients. According to preliminary data, seroconversion after mRNA SARS-CoV-2 vaccination might be unsatisfactory in Kidney Transplant Recipients (KTRs). However, it is unknown if seronegative patients develop at least a cellular response that could offer a certain grade of protection against SARS-CoV-2. To answer this question, we prospectively studied 148 recipients of either kidney (133) or kidney-pancreas (15) grafts with assessment of IgM/IgG spike (S) antibodies and ELISpot against the nucleocapside (N) and the S protein at baseline and 2Â weeks after receiving the second dose of the mRNA-1273 (Moderna) vaccine. At baseline, 31 patients (20.9%) had either IgM/IgG or ELISpot positivity and were considered to be SARS-CoV-2-pre-immunized, while 117 (79.1%) patients had no signs of either cellular or humoral response and were considered SARS-CoV-2-naÃ¯ve. After vaccination, naÃ¯ve patients who developed either humoral or cellular response were finally 65.0%, of which 29.9% developed either IgG or IgM and 35.0% S-ELISpot positivity. Factors associated with vaccine unresponsiveness were diabetes and treatment with antithymocytes globulins during the last year. Side effects were consistent with that of the pivotal trial and no DSAs developed after vaccination. In conclusion, mRNA-1273 SARS-CoV-2 vaccine elicits either cellular or humoral response in almost two thirds of KTRs.

SARS-CoV-2 mRNA vaccine-associated fixed drug eruption.

AZD1222 vaccine-related coagulopathy and thrombocytopenia without thrombosis in a young female.

Confronting Covid-19 by exploring the possibility of vaccinating with live SARS-CoV-2 virus itself, via a route that would reduce the incidence of pulmonary complications. This article proposes that one should explore whether the pulmonary complications of Covid-19 can be reduced or avoided by bypassing the airway entry of the SARS-CoV-2 virus. This could possibly be achieved by injecting live SARS-CoV-2 virus intradermal (ID), subcutaneous, intra-muscular (IM) or intra-peritoneal (IP), or by targeting the virus to the digestive tract.Â The effectiveness and innocuity of using those various routes could be tested very rapidly in animal models, such as Macaques, Hamsters, Ferrets or Cats. The hope is that these experiments will reveal a route of inoculation that can reliably lead to bona-

fide infections, resulting in strong immune responses, with both cellular and serological components, but with much less viral replication in the lungs. This would not only hopefully reduce the incidence of pulmonary complications in the infected subjects, but would also probably reduce the amount of virus released by them via aerosols, and thus reduce the vector of contagiosity that is hardest to control, and that probably leads most effectively to viral replication in the lungs. If those experiments in animal models reveal that one or several routes can be used effectively to reduce pulmonary pathology, a clinical trial could be conducted in human volunteers with very low risk profiles. The ID route should probably be considered as a priority, since it could double-up as a skin test to reveal the immune status of the recipients towards the SARS-CoV-2 virus. The course of action proposed here may possibly provide a way of taking a step ahead of the virus, and if it works as hoped, could help to end the need for confinement within a matter of months, if not weeks.
Ischaemic stroke as a presenting feature of ChAdOx1 nCoV-19 vaccine-induced immune thrombotic thrombocytopenia.
Streptococcus gordonii septic arthritis of the glenohumeral joint following deltoid intramuscular vaccination. A 68-year-old woman presented for left shoulder pain, decreased range of motion (ROM) and fever 7â€‰days following COVID-19 vaccination. Investigations showed a tender left deltoid mass, decreased shoulder ROM and elevated inflammatory markers. MRI demonstrated a large glenohumeral effusion with synovitis, and arthrocentesis confirmed septic arthritis (SA). She required subtotal bursectomy. Intraoperative joint cultures grew Streptococcus gordonii She completed 6â€‰weeks of antibiotics and is undergoing physical therapy for post-infectious adhesive capsulitis. SA is most commonly due to Staphylococcus aureus and Î²-haemolytic streptococci, and rarely due to viridans group streptococci including S.â€¯gordonii To avoid inadvertent injection into the glenohumeral joint, vaccination should be performed posteriorly and inferiorly into the deltoid musculature. Progressive pain, fever or decreased passive ROM following vaccination should raise concern for SA. Given its rarity, however, concern for secondary SA should not affect the general population's consideration for vaccination.
Patient information on covid-19 vaccines-a vaccine centre lottery.
BNT162b2 vaccination in heart transplant recipients: Clinical experience and antibody response. BACKGROUND: Data on the safety and efficacy of SARS-CoV-2 vaccines in immunocompromised populations are sparse. METHODS: We conducted a prospective study of 77 heart transplant (HT) recipients vaccinated with two doses of BNT162b2 vaccine and monitored for adverse events following both doses, the receptor-binding domain (RBD) IgG response, and neutralizing antibodies. RESULTS: BNT162b2 vaccination was associated with a low rate of adverse events, characterized mostly by pain at the injection site. By a mean 41 days post second dose there were no clinical episodes of rejection, as suggested by a troponin leak or allograft dysfunction. At a mean 21 days following the second dose, IgG anti-RBD antibodies were detectable in 14 (18%) HT recipients. Immune sera neutralized SARS-CoV-2 pseudo-virus in 8 (57%) of those with IgG anti-RBD antibodies. Immunosuppressive regimen containing mycophenolic acid was associated with lower odds of an antibody response (ORâ€¯=â€¯0.12, pâ€¯=â€¯0.042). CONCLUSIONS: Whether a longer time-frame for observation of an antibody response is required after vaccination in immunosuppressed individuals remains unknown.
Multisystem Inflammatory Syndrome after SARS-CoV-2 Infection and COVID-19 Vaccination. We report 3 patients in California, USA, who experienced multisystem inflammatory syndrome (MIS) after immunization and severe acute respiratory syndrome coronavirus 2 infection. During the same period, 3 adults who were not vaccinated had MIS develop at a time when â‰ˆ7% of the adult patient population had received >1 vaccine.

Oxford-AstraZeneca COVID-19 vaccine-induced cerebral venous thrombosis and thrombocytopaenia: A missed opportunity for a rapid return of experience.
Is COVID-19 vaccination unmasking glomerulonephritis?
Reactive arthritis after COVID-19 vaccination. The severe acute respiratory syndrome coronavirus 2-induced coronavirus disease 2019 (COVID-19) has had a global spread. Vaccines play an essential role in preventing the spread. However, almost all types of vaccines have been reported to be associated with adverse events. Reactive arthritis (ReA) after vaccination has been reported; however, ReA after COVID-19 vaccination has not been reported. We reported a 23-year-old woman who suffered from an acute ReA on her left knee joint after COVID-19 vaccination and discussed the etiology and preventive strategy. She presented with swollen, painful left knee joint for 18Â d. She had been inoculated 0.5Â ml CoronaVac vaccine on 0Â d and the 14th day with deltoid intramuscular injection. Finally, she was diagnosed as ReA after CoronaVac vaccination and was administered a single intra-articular injection of 1Â ml compound betamethasone. The swelling and pain nearly disappeared after 2Â d. On 1month follow-up, her condition was normal. ReA after COVID-19 vaccination is rare. The benefits of vaccination far outweigh its potential risks and vaccination should be administered according to the current recommendations. Further attentions should be put to determine which individual is at higher risk for developing autoimmune diseases after COVID-19 vaccination. More versatile and safer vaccines should be explored.
Guillain-Barre syndrome should be monitored upon mass vaccination against SARS-CoV-2. In response to the recent pandemic, vaccines have been developed for large-scale immunization. Despite safety and efficacy verified by health authorities, Guillain-Barre syndrome (GBS) remains a risk of unexpected adverse reactions. Since COVID-19-related GBS cases have largely been reported in Europe, vaccines involving viral genetic materials can potentially trigger GBS, as demonstrated in clinical trials in the Americas. Therefore, medical professionals should be aware of GBS as a potential adverse reaction in SARS-CoV-2 vaccination. Consultation with a neurologist may be needed. Nevertheless, this is not to say that the use of vaccines against SARS-CoV-2 should be suspended and that the association between GBS and the vaccine is confirmed or excluded. The benefits of vaccine still outweigh potential adverse effects.
Early Humoral Responses of Hemodialysis Patients after COVID-19 Vaccination with BNT162b2. BACKGROUND AND OBJECTIVES: Patients receiving hemodialysis are at high risk for both severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and severe coronavirus disease 2019. A lifesaving vaccine is available, but sensitivity to vaccines is generally lower in patients on dialysis. Little is yet known about antibody responses after coronavirus disease 2019 (COVID-19) vaccination in this vulnerable group. DESIGN, SETTING, PARTICIPANTS, AND MEASUREMENTS: In this prospective single-center study, we included 22 patients on dialysis and 46 healthy controls from Heidelberg University Hospital between December 2020 and February 2021. We measured anti-S1 IgG with a threshold index for detection greater than one, neutralizing antibodies with a threshold for viral neutralization of â‰¥30%, and antibodies against different SARS-CoV2 fragments 17-22 days after the first dose and 18-22 days after the second dose of the mRNA vaccine BNT162b2. RESULTS: After the first vaccine dose, four of 22 (18%) patients on dialysis compared with 43 of 46 (93%) healthy controls developed positive anti-S1 IgG, with a median anti-S1 IgG index of 0.2 (interquartile range, 0.1-0.7) compared with nine (interquartile range, 4-16), respectively. SARS-CoV2 neutralizing antibodies exceeded the threshold for neutralization in four of 22 (18%) patients on dialysis compared with 43 of 46 (93%) healthy controls, with a median percent inhibition of 11 (interquartile range, 3-24) compared with 65 (interquartile range, 49-75), respectively. After the second dose, 14 of 17 (82%) patients on dialysis developed neutralizing antibodies exceeding the threshold for viral neutralization and antibodies against the receptor binding S1 domain of the spike protein, compared

with 46 of 46 (100%) healthy controls, respectively. The median percent inhibition was 51 (interquartile range, 32-86) compared with 98 (interquartile range, 97-98) in healthy controls. CONCLUSIONS: Patients receiving long-term hemodialysis show a reduced antibody response to the first and second doses of the mRNA vaccine BNT162b2. The majority (82%) develop neutralizing antibodies after the second dose but at lower levels than healthy controls.

Idiopathic Thrombocytopenic Purpura and the Moderna Covid-19 Vaccine.

Letter to the Editor: Thyroiditis and Thyrotoxicosis After the SARS-CoV-2 mRNA Vaccine.

Coordination and optimization of FDG PET/CT and COVID-19 vaccination; Lessons learned in the early stages of mass vaccination. As the world embarks on mass vaccination for COVID-19, we are beginning to encounter unintended dilemmas in imaging oncology patients; particularly with regards to FDG PET/CT. In some cases, vaccine-related lymphadenopathy and FDG uptake on PET/CT can mimic cancer and lead to confounding imaging results. These cases where findings overlap with cancer pose a significant dilemma for diagnostic purposes, follow-up, and management leading to possible treatment delays, unnecessary repeat imaging and sampling, and patient anxiety. These cases can largely be avoided by optimal coordination between vaccination and planned imaging as well as preemptive selection of vaccine administration site. This coordination hinges on patient, oncologist, and radiologists' awareness of this issue and collaboration. Through close communication and patient education, we believe this will eliminate significant challenges for our oncology patients as we strive to end this pandemic.

Hypotheses behind the very rare cases of thrombosis with thrombocytopenia syndrome after SARS-CoV-2 vaccination. As of 4 April 2021, a total of 169 cases of cerebral venous sinus thrombosis (CVST) and 53 cases of splanchnic vein thrombosis were reported to EudraVigilance among around 34 million people vaccinated in the European Economic Area and United Kingdom with COVID-19 Vaccine AstraZeneca, a chimpanzee adenoviral vector (ChAdOx1) encoding the spike protein antigen of the SARS-CoV-2 virus. The first report of the European Medicines Agency gathering data on 20 million people vaccinated with VaxzevriaÂ® in the UK and the EEA concluded that the number of post-vaccination cases with thromboembolic events as a whole reported to EudraVigilance in relation to the number of people vaccinated was lower than the estimated rate of such events in the general population. However, the EMA's Pharmacovigilance Risk Assessment Committee concluded that unusual thromboses with low blood platelets should be listed as very rare side effects of VaxzevriaÂ®, pointing to a possible link. The same issue was identified with the COVID-19 Vaccine Janssen (Ad26.COV2.S). Currently, there is still a sharp contrast between the clinical or experimental data reported in the literature on COVID-19 and the scarcity of data on the unusual thrombotic events observed after the vaccination with these vaccines. Different hypotheses might support these observations and should trigger further in vitro and ex vivo investigations. Specialized studies were needed to fully understand the potential relationship between vaccination and possible risk factors in order to implement risk minimization strategies.

AGA Rapid Review and Guideline for SARS-CoV2 Testing and Endoscopy Post-Vaccination: 2021 Update. This guideline provides updated recommendations on the role of preprocedure testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) in individuals undergoing endoscopy in the post-vaccination period and replaces the prior guideline from the American Gastroenterological Association (AGA) (released July 29, 2020). Since the start of the pandemic, our increased understanding of transmission has facilitated the implementation of practices to promote patient and health care worker (HCW) safety. Simultaneously, there has been increasing recognition of the potential harm associated with delays in patient care, as well as inefficiency of endoscopy units. With widespread vaccination of HCWs and the general population, a re-evaluation of AGA's prior recommendations was warranted. In order to update the role of preprocedure testing for SARS-

CoV2, the AGA guideline panel reviewed the evidence on prevalence of asymptomatic SARS-CoV2 infections in individuals undergoing endoscopy; patient and HCW risk of infections that may be acquired immediately before, during, or after endoscopy; effectiveness of COVID-19 vaccine in reducing risk of infections and transmission; patient and HCW anxiety; patient delays in care and potential impact on cancer burden; and endoscopy volumes. The panel considered the certainty of the evidence, weighed the benefits and harms of routine preprocedure testing, and considered burden, equity, and cost using the Grading of Recommendations Assessment, Development and Evaluation framework. Based on very low certainty evidence, the panel made a conditional recommendation against routine preprocedure testing for SARS-CoV2 in patients scheduled to undergo endoscopy. The panel placed a high value on minimizing additional delays in patient care, acknowledging the reduced endoscopy volumes, downstream impact on delayed cancer diagnoses, and burden of testing on patients.
Absence of Humoral Response After Two-Dose SARS-CoV-2 Messenger RNA Vaccination in Patients With Rheumatic and Musculoskeletal Diseases: A Case Series.
Safety and Immunogenicity of Anti-SARS-CoV-2 Messenger RNA Vaccines in Recipients of Solid Organ Transplants.
Symptoms After COVID-19 Vaccination in Patients With Persistent Symptoms After Acute Infection: A Case Series.
Thrombotic thrombocytopenia associated with COVID-19 infection or vaccination: Possible paths to platelet factor 4 autoimmunity. Michel Goldman and CÃ©dric Hermans discuss thrombotic mechanisms in COVID-19 and rare adverse reactions to SARS-CoV-2 vaccinations.
Keratoplasty Rejection After the BNT162b2 messenger RNA Vaccine. PURPOSE: The aim of this report was to report 2 patients who presented with acute corneal graft rejection 2 weeks after receiving the BNT162b2 messenger RNA (mRNA) vaccine for severe acute respiratory syndrome coronavirus 2. METHODS: Case report. RESULTS: Two men, aged 73 and 56 years, with a history of penetrating keratoplasty due to keratoconus were noted to have acute corneal graft rejection 2 weeks after receiving a first dose of the BNT162b2 mRNA vaccine. Both patients were treated with hourly dexamethasone 0.1% and oral prednisone 60 mg per day with prompt resolution of keratoplasty rejection. CONCLUSIONS: The BNT162b2 mRNA vaccine may be have been associated with a low-risk corneal graft rejection that responded well to topical and systemic steroids. Treating physicians should be aware of this potential complication and patients should be advised to report any visual changes after vaccination.
Can integrated post-exposure vaccination against SARS-COV2 mitigate severe disease?
Myocarditis following COVID-19 vaccination. The coronavirus disease 2019 (COVID-19) vaccination frequently leads to minor side-effects, that may be more intense after the second dose, but more serious side effects have been reported. We report a case of a 24-year-old man who presented to the hospital with acute substernal chest pain, 4 days after his second COVID-19 Moderna vaccination. Laboratory studies revealed elevated troponins and negative viral serologies. Cardiac magnetic resonance imaging (cMRI) demonstrated edema and delayed gadolinium enhancement of the left ventricle in a midmyocardial and epicardial distribution. The patient was diagnosed with myocarditis following Moderna vaccination. Our case report raises concern that myocarditis is a rare side effect of COVID-19 vaccine. Despite our report, it appears that there is a significantly higher risk of cardiac involvement from COVID-19 infection compared to COVID-19 vaccination.
Immediate high-dose intravenous immunoglobulins followed by direct thrombin-inhibitor treatment is crucial for survival in Sars-Covid-19-adenoviral vector vaccine-induced immune thrombotic thrombocytopenia VITT with cerebral sinus venous and portal vein thrombosis.

Relapse of Minimal Change Disease Following the Pfizer-BioNTech COVID-19 Vaccine.
Seroconversion after coronavirus disease 2019 vaccination in patients with immune deficiency.
Are the Allergic Reactions of COVID-19 Vaccines Caused by mRNA Constructs or Nanocarriers? Immunological Insights. The Food and Drug Administration (FDA) has recently authorized the two messenger RNA (mRNA) vaccines BNT162b2 and mRNA-1273 for emergency use against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causing the COVID-19 coronavirus disease. BNT162b2 and mRNA-1273 vaccines were developed by Pfizer-BioNTech and Moderna, respectively, in 2020. The United Kingdom, Bahrain, Canada, Mexico, United States, Singapore, Oman, Saudi Arabia, Kuwait, and European Union began their vaccination programs with the BNT162b2 vaccine, while the United States and Canada also started the mRNA-1273 vaccination program in mid December 2020. On 28th December 2020, studies reported severe allergic reactions in people who received the BNT162b2, and few people who received the mRNA-1273 vaccine. Authors of the letter thus attempt to explore possible causes of anaphylaxis following COVID-19 vaccination.
Cutaneous adverse reactions after m-RNA COVID-19 vaccine: early reports from Northeast Italy.
SARS-CoV-2 vaccination intentions among mothers of children aged 9 to 12 years: a survey of the All Our Families cohort. BACKGROUND: Acceptance of a vaccine against SARS-CoV-2 is critical to achieving high levels of immunization. The objectives of this study were to understand mothers' SARS-CoV-2 vaccine intentions to explore reasons for and against SARS-CoV-2 vaccination. METHODS: Participants from the All Our Families pregnancy longitudinal cohort whose children had reached ages 9-12 years were invited in May-June 2020 to complete a survey on the impact of COVID-19. The survey covered topics about the impact of the pandemic and included 2 specific questions on mothers' intentions to vaccinate their child against SARS-CoV-2. Current responses were linked to previously collected data, including infant vaccine uptake. Multinomial regression models were run to estimate associations between demographic factors, past vaccination status and vaccination intention. Qualitative responses regarding factors affecting decision-making were analyzed thematically. RESULTS: The response rate was 53.8% (1321/2455). A minority of children of participants had partial or no vaccinations at age 2 (n = 200, 15.1%). A total of 60.4% of mothers (n = 798) intended to vaccinate their children with the SARS-CoV-2 vaccine, 8.6% (n = 113) did not intend to vaccinate and 31.0% (n = 410) were unsure. Lower education, lower income and incomplete vaccination history were inversely associated with intention to vaccinate. Thematic analysis of qualitative responses showed 10 themes, including safety and efficacy, long-term effects and a rushed process. INTERPRETATION: Within a cohort with historically high infant vaccination, a third of mothers remained unsure about vaccinating their children against SARS-CoV-2. Given the many uncertainties about future SARS-CoV-2 vaccines, clear communication regarding safety will be critical to ensuring vaccine uptake.
Influenza and pneumococcal vaccinations are not associated to COVID-19 outcomes among patients admitted to a university hospital. In order to reduce the burden on healthcare systems and to support differential diagnosis with COVID-19, influenza and pneumococcal vaccinations were strongly recommended during the COVID-19 pandemic, especially in vulnerable groups. However, no univocal and conclusive evidence on the relationship between influenza and pneumococcal vaccinations and COVID-19 outcomes exists. We evaluated the association between such vaccinations, COVID-19 hospitalization, intensive care unit admissions and deaths in a cohort (NÂ =Â 741) of COVID-19 patients who had access to the emergency room of a large Italian University hospital between March 1, 2020 and June 1, 2020. Results show that influenza and pneumococcal vaccinations did not affect hospitalization, intensive care unit admission and deaths in COVID-19 patients in the overall sample and in those â‰¥65Â years. The same pattern of results was confirmed considering timing of influenza vaccine administration, vaccination type, and number of uptakes in the last five vaccination

campaigns. In conclusion, our study does not support an impact of influenza and pneumococcal vaccinations on COVID-19 outcomes.

Perspectives on vaccine induced thrombotic thrombocytopenia. As the novel SARS-CoV-2 continues to infect numerous individuals worldwide, one of the leading approaches in dealing with the global health crisis is vaccination against the COVID-19. Due to recent reports, vaccination with ChAdOx1 nCov-19 (developed by Oxford and AstraZeneca) may result in a vaccine-induced catastrophic thrombotic thrombocytopenia disorder. Thus, as of March 16 of 2021, vaccination programs in 18 countries had been suspended until further examination, including Sweden, Germany and France. This disorder presents as extensive thrombosis in atypical sites, primarily in the cerebral venous, alongside thrombocytopenia and the production of autoantibody against platelet-factor 4 (PF4). PF4 autoantibody has the ability to binds the human FcRÎ³IIA receptor of platelets and contribute to their aggregation. This rare adverse effect extremely resembles the clinical presentation of the classical immune-mediated HIT disorder, which occurs following exposure to heparin. Surprisingly, none of these patients had been pre-exposed to heparin before disease onset, leading to the hypothesis that a viral antigen from the vaccine had triggered the response. Importantly, COVID-19 had been associated with numerous autoimmune manifestations, including the production of pathogenic autoantibodies, new onset of autoimmune diseases and disorders. As the ChAdOx1 nCov-19 vaccination leads to the synthesis of specific SARS-CoV-2-proteins, they may trigger a production of PF4 autoantibody though molecular mimicry phenomena, while vaccination compounds lead to a rigorous bystander activation of immune cells. If existing, removing such homological sequences from the vaccine may eliminate this phenomenon. In contrast, it needs to be emphasized that the ChAdOx1 nCoV-19 vaccine was found to be safe and efficacious against symptomatic COVID-19 in randomized controlled trials, which included 23,848 participants from the UK, Brazil and South Africa.

Quantitation of antibodies against SARS-CoV-2 spike protein after two doses of CoronaVac in healthcare workers. Quantitation of antibodies to the spike protein of severe acute respiratory syndrome coronavirus 2Â (SARS-CoV-2) was performed for the detection of adaptive immune response in healthcare workers (HCWs) vaccinated with CorovaVac. We prospectively recruited HCWs from a university hospital in Turkey. Serum samples from 1072 HCWs were obtained following 28 days of the first, and 21 days of the second dose. Detection and quantitation of SARS-CoV-2 antispike antibodies were performed by the chemiluminescent microparticle immunoassay (SARS-CoV-2 IgG II Quant; Abbott). Results greater than or equal to the cutoff value 50.0â€‰AU/ml were reported as positive. After the first dose, antispike antibodies were detected in 834 of 1072 (77.8%) HCWs. Seropositivity was higher among females (84.6%) than males (70.6%) (pâ€‰<â€‰0.001) and was found to be highest in both women and men between the ages of 18-34. After the second dose, antibodies were detected in 1008 of 1012 (99.6%) HCWs. Antibody titers were significantly higher in those who had coronavirus disease-2019 before vaccination than those who did not (pâ€‰<â€‰0.001). Antibody positivity and median antibody titers were significantly less in HCWs with chronic diseases compared to those without (pâ€‰<â€‰0.05 and pâ€‰<â€‰0.001, respectively). In conclusion, our findings indicated that a relatively high frequency (99.6%) of humoral immunity was produced in HCWs aged 18-59 after two doses of CoronaVac. Quantitation of antibodies may help facilitate longitudinal monitoring of the antibody response, which will be especially useful in deciding the dose of the vaccine in vulnerable groups such as those over 60 years of age and those with chronic diseases.

Determining the Cutoff Points of the 5C Scale for Assessment of COVID-19 Vaccines Psychological Antecedents among the Arab Population: A Multinational Study. BACKGROUND: One of the newly faced challenges during the COVID-19 is vaccine hesitancy (VH). The validated 5C scale, that assesses 5 psychological antecedents of vaccination, could be effective in exploring COVID-19 VH. This

study aimed to determine a statistically valid cutoff points for the 5C sub-scales among the Arab population. METHODS: A cross-sectional study was conducted among 446 subjects from 3 Arab countries (Egypt, United Arab Emirates (UAE), and Jordan). Information regarding sociodemographics, clinical history, COVID-19 infection and vaccination history, and 5C scale were collected online. The 5C scores were analyzed to define the cutoff points using the receiver operating characteristic curve (ROC) and to verify the capability of the questionnaire to differentiate whether responders are hesitant or non-hesitant to accept vaccination. ROC curve analysis was conducted for previous vaccine administration as a response, with the predictors being the main 5 domains of the 5C questionnaire. The mean score of each sub-scale was compared with COVID-19 vaccine intake. RESULTS: The mean age of the studied population was 37â€‰Â±â€‰11, 42.9% were males, 44.8% from Egypt, 21.1% from Jordan, and 33.6% from the UAE. Statistically significant differences between vaccinated and unvaccinated participants, respectively, were detected in the median score of confidence [6.0(1.3) versus 4.7(2.0)], complacency [(2.7(2.0) versus 3.0(2.0)], constraints [1.7(1.7) versus 3.7(2.3)], and collective responsibility [6.7(1.7) versus 5.7(1.7)]. The area under the curve of the 5 scales was 0.72, 0.60, 0.76, 0.66, 0.66 for confidence, complacency, constraints, calculation, and collective responsibility at cutoff values of 5.7, 4.7, 6.0, 6.3, and 6.2, respectively. CONCLUSION: The Arabic validated version of the 5C scale has a good discriminatory power to predict COVID-19 vaccines antecedent.
A Possible Case of Hypertensive Crisis With Intracranial Haemorrhage After an mRNA Anti-COVID-19 Vaccine.
Nursing home deaths after COVID-19 vaccination. BACKGROUND: In the period 27 December 2020 to 15 February 2021, about 29Â 400 of Norway's roughly 35Â 000 nursing home patients were vaccinated with the mRNA vaccine BNT162b2. During the same period, the Norwegian Medicines Agency received 100 reports of suspected fatal adverse reactions to the vaccine. An expert group has examined the reports and assessed the extent of a causal link between vaccination and death. MATERIAL AND METHOD: The expert group worked in two pairs, each of which examined 50 anonymised reports. Each member first examined the reports alone and classified the causality as unlikely, possible, probable, certain or unclassifiable. Each pair then discussed their results until they reached a consensus. All four experts assessed a random sample of 20 reports. The degree of agreement was assessed using weighted kappa and McNemar's test of symmetry. RESULTS: The mean age of the patients was 87.7 years (range 61-103 years). Among 100 reported deaths, a causal link to the vaccine was considered probable in 10 cases, possible in 26 and unlikely in 59. Five were unclassifiable. Weighted kappa was 0.40 and 0.38 in the two expert pairs, respectively. INTERPRETATION: Most nursing home patients have a short remaining life expectancy, but vaccination may, in a few cases, have accelerated a process of dying that had already begun. Nursing home patients should still be given priority for vaccination, but the benefits versus risk must be carefully weighed up for the frailest patients.
Acute disseminated encephalomyelitis-like presentation after an inactivated coronavirus vaccine.
Role of Psychiatric Hospitals in the Equitable Distribution of COVID-19 Vaccines. OBJECTIVE: This study examined the feasibility of offering COVID-19 vaccinations to patients in inpatient psychiatric facilities (IPFs). METHODS: Descriptive analyses were conducted to examine relationships among measures of influenza immunization, transmission of transition records, and attainment of follow-up care with data from 1,602 IPFs in 2018 and the COVID-19 Community Vulnerability Index. RESULTS: One-quarter of IPFs were in counties with high or very high COVID-19 vulnerability. On average, 84% of patients at IPFs were screened for influenza immunization status and were offered an immunization if indicated. Only 57% of patients had their records transmitted to another provider within 24 hours of discharge, and 50% had a follow-up visit with a mental health provider within 30

days. Scores on attainment of follow-up care were worse in counties with higher COVID-19 vulnerability. CONCLUSIONS: IPFs may be well positioned to offer COVID-19 vaccinations but will need new processes and improved rates of follow-up care to ensure that patients receive the second dose.

Acute relapse and poor immunization following COVID-19 vaccination in a rituximab-treated multiple sclerosis patient. With the progress of COVID-19 vaccination programs worldwide, some new adverse events associated with the available vaccines may unfold, especially in subpopulations, representatives of whom were not included in phase I, II, and III clinical trials of these vaccines, such as patients with autoimmune diseases, including multiple sclerosis (MS). A 34-year-old woman presented with severe right hemiplegia and ataxia. She was diagnosed with relapsing-remitting MS (RRMS) 13Â years ago and treated with rituximab (an anti-CD20 monoclonal antibody) during the last 15Â months. She had received her first dose of adenovirus-vectored COVID-19 vaccine Gam-COVID-Vac (Sputnik V) three months after her last infusion of rituximab and three days before experiencing her latest MS relapse episode, preceded by mild symptoms (fatigue, myalgia, generalized weakness, etc.). Magnetic resonance imaging revealed several new periventricular, juxtacortical, brainstem, and cerebellar peduncle lesions. She received corticosteroid therapy for five consecutive days, and her neurological deficits slightly improved. Twenty-one days after receiving the first dose of the vaccine, her anti-SARS-CoV-2 antibodies were below the lower detection limit. However, a decision was made to adhere to the vaccination schedule and not risk the patient's safety against an unfortunate COVID-19 contraction, and thus, she was advised to receive the second Gam-COVID-Vac dose after discontinuation of oral steroid taper. The safety of adenovirus-based vaccines in patients with autoimmune diseases requires further investigation. Meanwhile, clinicians should raise awareness among their patients regarding the potentially limited efficacy of COVID-19 vaccination in those treated with anti-CD20 treatments. After careful, individualized risk-benefit assessments, planning a delay/pause in such treatments to create a time window for patients to receive the vaccine and develop anti-SARS-CoV-2 immunity may be recommended.

Preliminary Analysis of Association Between COVID-19 Vaccination and Sudden Hearing Loss Using US Centers for Disease Control and Prevention Vaccine Adverse Events Reporting System Data. This cross-sectional study examines the national incidence of sudden sensorineural hearing loss after COVID-19 vaccination using data from the CDC Vaccine Adverse Events Reporting System.

Infection and vaccine-induced neutralizing antibody responses to the SARS-CoV-2 B.1.617.1 variant. SARS-CoV-2 has caused a devastating global pandemic. The recent emergence of SARS-CoV-2 variants that are less sensitive to neutralization by convalescent sera or vaccine-induced neutralizing antibody responses has raised concerns. A second wave of SARS-CoV-2 infections in India is leading to the expansion of SARS-CoV-2 variants. The B.1.617.1 variant has rapidly spread throughout India and to several countries throughout the world. In this study, using a live virus assay, we describe the neutralizing antibody response to the B.1.617.1 variant in serum from infected and vaccinated individuals. We found that the B.1.617.1 variant is 6.8-fold more resistant to neutralization by sera from COVID-19 convalescent and Moderna and Pfizer vaccinated individuals. Despite this, a majority of the sera from convalescent individuals and all sera from vaccinated individuals were still able to neutralize the B.1.617.1 variant. This suggests that protective immunity by the mRNA vaccines tested here are likely retained against the B.1.617.1 variant. As the B.1.617.1 variant continues to evolve, it will be important to monitor how additional mutations within the spike impact antibody resistance, viral transmission and vaccine efficacy.

Antibody-mediated procoagulant platelets in SARS-CoV-2-vaccination associated immune thrombotic thrombocytopenia. The COVID-19 pandemic has resulted in significant morbidity and mortality worldwide. To prevent severe infection, mass COVID-19 vaccination campaigns with several vaccine

types are currently underway. We report pathological and immunological findings in 8 patients who developed vaccine-induced immune thrombotic thrombocytopenia (VITT) after administration of SARS-CoV-2 vaccine ChAdOx1 nCoV-19. We analyzed patient material using enzyme immune assays, flow cytometry and heparin-induced platelet aggregation assay and performed autopsies on two fatal cases. Eight patients (5 female, 3 male) with a median age of 41.5 years (range, 24 to 53) were referred to us with suspected thrombotic complications 6 to 20 days after ChAdOx1 nCoV-19 vaccination. All patients had thrombocytopenia at admission. Patients had a median platelet count of 46.5 x109/L (range, 8 to 92). Three had a fatal outcome and 5 were successfully treated. Autopsies showed arterial and venous thromboses in various organs and the occlusion of glomerular capillaries by hyaline thrombi. Sera from VITT patients contain high titer antibodies against platelet factor 4 (PF4) (OD 2.59Â±0.64). PF4 antibodies in VITT patients induced significant increase in procoagulant markers (P-selectin and phosphatidylserine externalization) compared to healthy volunteers and healthy vaccinated volunteers. The generation of procoagulant platelets was PF4 and heparin dependent. We demonstrate the contribution of antibody-mediated platelet activation in the pathogenesis of VITT.

Safety of mRNA-Based Vaccines for SARS CoV-2. SARS-CoV-2 has infected more than 100 million people, causing 2 million deaths globally. Studies on the development of a vaccine ended up with different formulations. We herein discuss the safety record of the two approved vaccines.

Frequency and Characteristics of Nodal and Deltoid FDG and (11)C-Choline Uptake on PET Performed After COVID-19 Vaccination. BACKGROUND. COVID-19 vaccination may trigger reactive lymphadenopathy, confounding imaging interpretation. There has been limited systematic analysis of PET findings after COVID-19 vaccination. OBJECTIVE. The purpose of this study was to evaluate the frequency and characteristics of abnormal FDG and (11)C-choline uptake on PET performed after COVID-19 vaccination. METHODS. This retrospective study included 67 patients (43 men and 24 women; mean [Â± SD] age, 75.6 Â± 9.2 years) who underwent PET examination between December 14, 2020, and March 10, 2021, after COVID-19 vaccination and who had undergone prevaccination PET examination without visible axillary node uptake. A total of 52 patients received the BNT162b2 mRNA COVID-19 vaccine (Pfizer-BioNTech; hereafter referred to as the Pfizer-BioNTech vaccine), and 15 received the SARS-CoV-2 mRNA-1273 vaccine (Moderna; hereafter referred to as the Moderna vaccine). Sixty-six of the patients underwent PET/CT, and one underwent PET/MRI. Fifty-four PET examinations used FDG, and 13 used (11)C-choline. PET was performed a median of 13 and 10 days after vaccination for patients who had received one (n = 44) and two (n = 23) vaccine doses, respectively. Two nuclear medicine physicians independently reviewed images and were blinded to injection laterality and the number of days since vaccination. Lymph node or deltoid SUV(max) greater than the blood pool SUV(max) was considered positive. Interreader agreement was assessed, and the measurements made by the more experienced physician were used for subsequent analysis. RESULTS. Positive axillary lymph node uptake was observed in 10.4% (7/67) of patients (7.4% [4/54] of FDG examinations and 23.1% [3/13] of (11)C-choline examinations); of the patients with positive axillary lymph nodes, four had received the Pfizer vaccine, and three had received the Moderna vaccine. Injection laterality was documented for five of seven patients with positive axillary lymph nodes and was ipsilateral to the positive node in all five patients. PET was performed within 24 days of vaccination for all patients with a positive node. One patient showed extraaxillary lymph node uptake (ipsilateral supraclavicular uptake on FDG PET). Ipsilateral deltoid uptake was present in 14.5% (8/55) of patients with documented injection laterality, including 42.9% (3/7) of patients with positive axillary lymph nodes. Interreader agreement for SUV measurements (expressed as intraclass correlation coefficients) ranged from 0.600 to 0.988. CONCLUSION. Increased axillary lymph node or ipsilateral deltoid uptake is occasionally observed on FDG or (11)C-choline PET performed after

COVID-19 vaccination with the Pfizer-BioNTech or Moderna vaccine. CLINICAL IMPACT. Interpreting physicians should recognize characteristics of abnormal uptake on PET after COVID-19 vaccination to guide optimal follow-up management and reduce unnecessary biopsies.

Data and Safety Monitoring of COVID-19 Vaccine Clinical Trials. To speed the development of vaccines against SARS-CoV-2, the United States Federal Government has funded multiple phase 3 trials of candidate vaccines. A single 11-member data and safety monitoring board (DSMB) monitors all government-funded trials to ensure coordinated oversight, promote harmonized designs, and allow shared insights related to safety across trials. DSMB reviews encompass 3 domains: (1) the conduct of trials, including overall and subgroup accrual and data quality and completeness; (2) safety, including individual events of concern and comparisons by randomized group; and (3) interim analyses of efficacy when event-driven milestones are met. Challenges have included the scale and pace of the trials, the frequency of safety events related to the combined enrollment of over 100 000 participants, many of whom are older adults or have comorbid conditions that place them at independent risk of serious health events, and the politicized environment in which the trials have taken place.

Phase 1 randomized trial of a plant-derived virus-like particle vaccine for COVID-19. Several severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines are being deployed, but the global need greatly exceeds the supply, and different formulations might be required for specific populations. Here we report Day 42 interim safety and immunogenicity data from an observer-blinded, dose escalation, randomized controlled study of a virus-like particle vaccine candidate produced in plants that displays the SARS-CoV-2 spike glycoprotein (CoVLP: NCT04450004). The co-primary outcomes were the short-term tolerability/safety and immunogenicity of CoVLP formulations assessed by neutralizing antibody (NAb) and cellular responses. Secondary outcomes in this ongoing study include safety and immunogenicity assessments up to 12 months after vaccination. Adults (18-55 years, nâ€‰=â€‰180) were randomized at two sites in Quebec, Canada, to receive two intramuscular doses of CoVLP (3.75â€‰Î¼g, 7.5â€‰Î¼g, and 15â€‰Î¼g) 21 d apart, alone or adjuvanted with AS03 or CpG1018. All formulations were well tolerated, and adverse events after vaccination were generally mild to moderate, transient and highest in the adjuvanted groups. There was no CoVLP dose effect on serum NAbs, but titers increased significantly with both adjuvants. After the second dose, NAbs in the CoVLP + AS03 groups were more than tenfold higher than titers in Coronavirus 2019 convalescent sera. Both spike protein-specific interferon-Î³ and interleukin-4 cellular responses were also induced. This pre-specified interim analysis supports further evaluation of the CoVLP vaccine candidate.

COVID-19 reinfection: a rapid systematic review of case reports and case series. The COVID-19 pandemic has infected millions of people worldwide and many countries have been suffering from a large number of deaths. Acknowledging the ability of SARS-CoV-2 to mutate into distinct strains as an RNA virus and investigating its potential to cause reinfection is important for future health policy guidelines. It was thought that individuals who recovered from COVID-19 generate a robust immune response and develop protective immunity; however, since the first case of documented reinfection of COVID-19 in August 2020, there have been a number of cases with reinfection. Many cases are lacking genomic data of the two infections, and it remains unclear whether they were caused by different strains. In the present study, we undertook a rapid systematic review to identify cases infected with different genetic strains of SARS-CoV-2 confirmed by PCR and viral genome sequencing. A total of 17 cases of genetically confirmed COVID-19 reinfection were found. One immunocompromised patient had mild symptoms with the first infection but developed severe symptoms resulting in death with the second infection. Overall, 68.8% (11/16) had similar severity; 18.8% (3/16) had worse symptoms; and 12.5% (2/16) had milder symptoms with the second episode.

Our case series shows that reinfection with different strains is possible, and some cases may experience more severe infections with the second episode. The findings also suggest that COVID-19 may continue to circulate even after achieving herd immunity through natural infection or vaccination, suggesting the need for longer-term transmission mitigation efforts.

Thrombocytopenia including immune thrombocytopenia after receipt of mRNA COVID-19 vaccines reported to the Vaccine Adverse Event Reporting System (VAERS). BACKGROUND: The objective of this study is to assess cases of thrombocytopenia, including immune thrombocytopenia (ITP), reported to the Vaccine Adverse Event Reporting System (VAERS) following vaccination with mRNA COVID-19 vaccines. METHODS: This case-series study analyzed VAERS reports of thrombocytopenia after vaccination with Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine. RESULTS: Fifteen cases of thrombocytopenia were identified among 18,841,309 doses of Pfizer-BioNTech COVID-19 Vaccine and 13 cases among 16,260,102 doses of Moderna COVID-19 Vaccine. The reporting rate of thrombocytopenia was 0.80 per million doses for both vaccines. Based on an annual incidence rate of 3.3 ITP cases per 100,000 adults, the observed number of all thrombocytopenia cases, which includes ITP, following administration of mRNA COVID-19 vaccines is not greater than the number of ITP cases expected. CONCLUSIONS: The number of thrombocytopenia cases reported to VAERS does not suggest a safety concern attributable to mRNA COVID-19 vaccines at this time.

Vaccine-escape and fast-growing mutations in the United Kingdom, the United States, Singapore, Spain, India, and other COVID-19-devastated countries. Recently, the SARS-CoV-2 variants from the United Kingdom (UK), South Africa, and Brazil have received much attention for their increased infectivity, potentially high virulence, and possible threats to existing vaccines and antibody therapies. The question remains if there are other more infectious variants transmitted around the world. We carry out a large-scale study of 506,768 SARS-CoV-2 genome isolates from patients to identify many other rapidly growing mutations on the spike (S) protein receptor-binding domain (RBD). We reveal that essentially all 100 most observed mutations strengthen the binding between the RBD and the host angiotensin-converting enzyme 2 (ACE2), indicating the virus evolves toward more infectious variants. In particular, we discover new fast-growing RBD mutations N439K, S477N, S477R, and N501T that also enhance the RBD and ACE2 binding. We further unveil that mutation N501Y involved in United Kingdom (UK), South Africa, and Brazil variants may moderately weaken the binding between the RBD and many known antibodies, while mutations E484K and K417N found in South Africa and Brazilian variants, L452R and E484Q found in India variants, can potentially disrupt the binding between the RBD and many known antibodies. Among these RBD mutations, L452R is also now known as part of the California variant B.1.427. Finally, we hypothesize that RBD mutations that can simultaneously make SARS-CoV-2 more infectious and disrupt the existing antibodies, called vaccine escape mutations, will pose an imminent threat to the current crop of vaccines. A list of most likely vaccine escape mutations is given, including S494P, Q493L, K417N, F490S, F486L, R403K, E484K, L452R, K417T, F490L, E484Q, and A475S. Mutation T478K appears to make the Mexico variant B.1.1.222 the most infectious one. Our comprehensive genetic analysis and protein-protein binding study show that the genetic evolution of SARS-CoV-2 on the RBD, which may be regulated by host gene editing, viral proofreading, random genetic drift, and natural selection, gives rise to more infectious variants that will potentially compromise existing vaccines and antibody therapies.

Primary care provider-reported prevalence of vaccine and polyethylene glycol allergy in Canada. BACKGROUND: The coronavirus disease 2019 pandemic has highlighted the importance of accurate capture of vaccine, and vaccine component, allergy. There remains a gap in the prevalence literature from the perspective of direct primary care provider (PCP) reporting at a population level. OBJECTIVE: To determine the prevalence of PCP-documented vaccine and polyethylene glycol (PEG) allergy using electronic medical record data from the Canadian Primary Care Sentinel Surveillance Network.

METHODS: Retrospective cohort study using the Canadian Primary Care Sentinel Surveillance Network repository. Machine learning algorithms were applied to evaluate for vaccine allergy documentation, and Anatomic Therapeutic Chemical codes were used for PEG allergy or allergy to common injectable medications containing PEG (CIMCP). RESULTS: The prevalence of PCP-documented vaccine allergy in Canada was 0.037% (395/1,055,677) and of PEG allergy was 0.0009% (10/1,055,677). In total, 0.01% of patients had a documented allergy to either PEG or CIMCP (135/1,055,677). None of the patients with PEG allergy had a documented allergy to a CIMCP. Patients with vaccine allergy and PEG allergy were significantly more likely to have other atopic comorbidities, including asthma (P < .001 for both), eczema (P < .001 and PÂ =Â .001, respectively), rhinitis (PÂ =Â .002 and P < .001, respectively), and food allergy (P < .001 for both). Significantly higher rates of depression (P < .001 and P < .001, respectively) and anxiety (PÂ =Â .003 and P < .001, respectively) were found in those with vaccine allergy, or PEG allergy, than those without vaccine allergy or PEG allergy. CONCLUSION: This is the first study to estimate the prevalence of vaccine and PEG allergy in a national cohort that uses PCP documentation, revealing a low reported rate of vaccine allergy and PEG allergy.

Neurological side effects of COVID-19 vaccines are rare.

The importance of recognizing cerebral venous thrombosis following anti-COVID-19 vaccination.

Fifth-week immunogenicity and safety of anti-SARS-CoV-2 BNT162b2 vaccine in patients with multiple myeloma and myeloproliferative malignancies on active treatment: preliminary data from a single institution. BACKGROUND: Safety and immunogenicity of BNT162b2 mRNA vaccine are unknown in hematological patients; both were evaluated prospectively in 42 patients with multiple myeloma (MM) and 50 with myeloproliferative malignancies (MPM) (20 chronic myeloid leukemias and 30 myeloproliferative neoplasms), all of them on active anti-cancer treatment, in comparison with 36 elderly controls not suffering from cancer. Subjects serologically and/or molecularly (by nasal/throat swab) positives at basal for SARS-CoV-2 were excluded. Primary endpoint was to compare titers of neutralizing anti-SARS-CoV-2 IgG and seroprotection rates among the cohorts at 3 and 5Â weeks from first dose. METHODS: Titration was done using LIAISONÂ® SARS-CoV-2 S1/S2 IgG test, a quantitative chemiluminescent immunoassay approved by FDA on the basis of robust evidences of concordance (94.4%) between the test at cutoff of 15Â AU/mL and the Plaque Reduction Neutralization Test 90% at 1:40 ratio. Cutoff of 15Â AU/mL was assumed to discriminate responders to vaccination with a protective titer. Cohorts were compared using Fisher' exact test and the Mann-Whitney test as appropriated. Geometric mean concentrations (GMCs), geometric mean ratios and response rates after 1st and 2nd dose were compared in each cohort by Wilcoxon and McNemar tests, respectively. RESULTS: At 5Â weeks, GMC of IgG in elderly controls was 353.3Â AU/mL versus 106.7 in MM (pâ€‰=â€‰0.003) and 172.9 in MPM patients (pâ€‰=â€‰0.049). Seroprotection rate at cutoff of 15Â AU/mL was 100% in controls compared to 78.6% in MM (pâ€‰=â€‰0.003) and 88% in MPM patients (pâ€‰=â€‰0.038). In terms of logarithm of IgG titer, in a generalized multivariate linear model, no gender effect was observed (pâ€‰=â€‰0.913), while there was a significant trend toward lower titers by increasing age (pâ€‰<â€‰0.001) and in disease cohorts with respect to controls (MM: pâ€‰<â€‰0.001 and MPM: pâ€‰<â€‰0.001). An ongoing treatment without daratumumab was associated with higher likelihood of response in MM patients (pâ€‰=â€‰0.003). No swabs resulted positive on each time point. No safety concerns were observed. CONCLUSIONS: BNT162b2 has demonstrated to be immunogenic at different extent among the cohorts. Response was 88% and robust in MPM patients. MM patients responded significantly less, particularly those on anti-CD38-based treatment. These latter patients should be advised to maintain masks and social distancing regardless of vaccination status, and their cohabiting family members need to be vaccinated in order to reduce the risk of contagion from the family. Additional boosters and titer monitoring could be

considered. Trial registration Study was formally approved by the IRCCS Central Ethical Committee of Regione Lazio in January 2021 (Prot. N-1463/21).
Focal onset non-motor seizure following COVID-19 vaccination: A mere coincidence?
Minimal change disease and acute kidney injury following the Pfizer-BioNTech COVID-19 vaccine.
COVID-19 Vaccination in Patients With Inflammatory Bowel Disease and History of Reaction to Injectable Therapies.
Haemodialysis patients show a highly diminished antibody response after COVID-19 mRNA vaccination compared with healthy controls. BACKGROUND: Haemodialysis (HD) patients are exposed to a high risk due to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. They are prone to acquiring the infection and are threatened by high mortality rates in case of infection. However, HD patients were not included in the efficacy trials of the SARS-CoV-2 vaccines. Such efficacy data would have been critical because HD patients show decreased responses against various other vaccines and this could translate to the SARS-CoV-2 vaccines as well. METHODS: We conducted a prospective cohort study that contained a group of 81 HD patients and 80 healthy controls. All of them had been vaccinated with the BioNTech/Pfizer mRNA vaccine (two doses, as per the manufacturer's recommendation). The anti-SARS-CoV-2 spike (S) antibody response was measured for all participants 21â€‰days after the second dose. The groups were compared using univariate quantile regressions and a multivariate analysis. The adverse events (AEs) of the vaccination were assessed via a questionnaire. Finally, a correlation between the HBs-antibody response and the SARS-CoV-2 antibody response in the HD patients was established. RESULTS: The HD patients had significantly lower anti-SARS-CoV-2 S antibody titres than the control patients 21â€‰days after vaccination (median was 171â€‰U/mL for dialysis patients and 2500â€‰U/mL for the controls). Further, the HD group presented fewer AEs than the control group. No correlation was found between the antibody response to previous Hepatitis B vaccination and that of the SARS-CoV-2 vaccine. CONCLUSIONS: HD patients present highly diminished SARS-CoV-2 S antibody titres compared with a cohort of controls. Therefore, they could be much less protected by SARS-CoV-2 mRNA vaccinations than expected. Further studies to test alternative vaccination schemes should be considered.
COVID-19 vector-based vaccine causing thrombosis. The number of people affected by COVID-19 is staggering and countries are rushing and competing to vaccinate their populations. However, there has been a concern about the association between COVID-19 vector-based vaccines and thrombosis. The proposed mechanism by which a COVID-19 vector-based vaccine can cause thrombosis is called vaccine-induced immune thrombotic thrombocytopenia (VITT). This commentary will provide an easy sketch of VITT as well as presentation of thrombosis after COVID-19 vaccines and proposed treatment.Communicated by Ramaswamy H. Sarma.
Widespread annular eruption after Ad26.COV2.S COVID-19 vaccine.
BCG Scar Local Skin Inflammation as a Novel Reaction Following mRNA COVID-19 Vaccines in Two International Healthcare Workers. Bacillus Calmette-GuÃ©rin (BCG) local scar inflammatory reactions have been mostly associated with Kawasaki disease in childrenÂ and less commonly with other viral infections (i.e., measles). BCG scar inflammation associated with or following vaccine administration has only been reported with the influenza vaccine. We describe the first reports in the literature of local BCG inflammation following two different available messenger ribonucleic acid (mRNA) anti-severe acute respiratory syndrome coronavirus 2 (anti-SARS-CoV-2) vaccines (mRNA-1273, and BNT162b2)Â in two young healthy physicians, one from Costa Rica, and another from the United States of America, with normal cell blood counts, flow cytometries, and negative forÂ human immunodeficiency virus (HIV). In both cases, BCG scar inflammation appeared after 24 hours of vaccination of the second dose, without signs of reaction on the injection site, and resolved within

four days. Dermoscopic findings in one case showed arborizing and comma-shaped vessels. Pharmacovigilance surveillance of BCG scar reactions following coronavirus disease 2019 (COVID-19) vaccines should be considered particularly in countries where BCG is part of their national immunization programs.

COVID-19 vaccine adverse reactions bring patients to emergency departments.

Prime-boost vaccination of mice and rhesus macaques with two novel adenovirus vectored COVID-19 vaccine candidates. ABSTRACTCOVID-19 vaccines are being developed urgently worldwide. Here, we constructed two adenovirus vectored COVID-19 vaccine candidates of Sad23L-nCoV-S and Ad49L-nCoV-S carrying the full-length gene of SARS-CoV-2 spike protein. The immunogenicity of two vaccines was individually evaluated in mice. Specific immune responses were observed by priming in a dose-dependent manner, and stronger responses were obtained by boosting. Furthermore, five rhesus macaques were primed with 5 Ã— 10(9) PFU Sad23L-nCoV-S, followed by boosting with 5 Ã— 10(9) PFU Ad49L-nCoV-S at 4-week interval. Both mice and macaques well tolerated the vaccine inoculations without detectable clinical or pathologic changes. In macaques, prime-boost regimen induced high titers of 10(3.16) anti-S, 10(2.75) anti-RBD binding antibody and 10(2.38) pseudovirus neutralizing antibody (pNAb) at 2 months, while pNAb decreased gradually to 10(1.45) at 7 months post-priming. Robust T-cell response of IFN-Î³ (712.6 SFCs/10(6) cells), IL-2 (334 SFCs/10(6) cells) and intracellular IFN-Î³ in CD4(+)/CD8(+) T cell (0.39%/0.55%) to S peptides were detected in vaccinated macaques. It was concluded that prime-boost immunization with Sad23L-nCoV-S and Ad49L-nCoV-S can safely elicit strong immunity in animals in preparation of clinical phase 1/2 trials.

Steroid-Resistant Acute Cellular Rejection of the Liver After Severe Acute Respiratory Syndrome Coronavirus 2 mRNA Vaccination.

Canadian Rheumatology Association Recommendation for the Use of COVID-19 Vaccination for Patients With Autoimmune Rheumatic Diseases. OBJECTIVE: To develop guidance on the use of coronavirus disease 2019 (COVID-19) vaccines in patients with autoimmune rheumatic diseases (ARD). METHODS: The Canadian Rheumatology Association (CRA) formed a multidisciplinary panel including rheumatologists, researchers, methodologists, vaccine experts, and patients. The panel used the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach. Outcomes were prioritized according to their importance for patients and clinicians. Evidence from the COVID-19 clinical trials was summarized. Indirect evidence for non-COVID-19 vaccines in ARD was also considered. The GRADE evidence-to-decision (EtD) framework was used to develop a recommendation for the use of the 4 COVID-19 vaccines approved in Canada as of March 25, 2021 (BNT162b2, mRNA-1273, ChAdOx1, and Ad26.COV2.S), over 4 virtual panel meetings. RESULTS: The CRA guideline panel suggests using COVID-19 vaccination in persons with ARD. The panel unanimously agreed that for the majority of patients, the potential health benefits of vaccination outweigh the potential harms in people with ARDs. The recommendation was graded as conditional because of low or very low certainty of the evidence on the effects in the population of interest, primarily due to indirectness and imprecise effect estimates. The panel felt strongly that persons with autoimmune rheumatic diseases who meet local eligibility should not be required to take additional steps compared to people without ARDs to obtain their vaccination. Guidance on medications, implementation, monitoring of vaccine uptake, and research priorities are also provided. CONCLUSION: This recommendation will be updated over time as new evidence emerges, with the latest recommendation, evidence summaries, and EtD available on the CRA website.

Post-vaccination cases of COVID-19 among healthcare workers at Siloam Teaching Hospital, Indonesia. BACKGROUND: Healthcare workers (HCWs) are at increased risk of exposure to severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the cause of coronavirus disease 2019 (COVID-19), compared with the general population. Therefore, they are given priority for the COVID-

19 vaccine in the national COVID-19 vaccination campaign in Indonesia. However, while the daily number of new COVID-19 cases remains high, and data regarding the efficacy of the vaccine in healthcare settings remain unavailable, vaccinated HCWs remain at risk of COVID-19 infection and further transmission. OBJECTIVE: To identify cases of COVID-19 among vaccinated HCWs at Siloam Teaching Hospital, Indonesia via active and passive surveillance conducted by the hospital's COVID-19 infection prevention and control unit. RESULTS: Of 1040 HCWs who had received two doses of the COVID-19 vaccine, 13 (1.25%) tested positive for SARS-CoV-2 RNA on reverse transcriptase polymerase chain reaction between 2 and 11 days (median 5 days) after the second vaccination. CONCLUSION: Laboratory-confirmed COVID-19 among vaccinated HCWs soon after the second vaccination indicates that HCWs remain at risk of COVID-19. Therefore, the presence of symptoms soon after full vaccination cannot be considered as vaccine-related symptoms, and regular COVID-19 testing should be conducted among HCWs.
An Additional Case of Minimal Change Disease Following the Pfizer-BioNTech COVID-19 Vaccine.
Relapse of primary membranous nephropathy after inactivated SARS-CoV-2 virus vaccination.
Breakthrough COVID19 infections after vaccinations in healthcare and other workers in a chronic care medical facility in New Delhi, India. BACKGROUND AND AIMS: Vaccinations for COVID19 are now open to all adults in India. However, spread of COVID19 infection continues unabated. We aimed to ascertain number of breakthrough COVID19 infections after vaccinations in a chronic care, diabetes-centric healthcare facility. METHODS: We reviewed rigorously maintained data of vaccinations, health status, symptoms of COVID19 & RT-PCR testing of all staff (doctors, nurses, paramedical workers, and other staff) in our health care facility from January 16, 2021 till date. RESULTS: Out of 123 employees, 113 were vaccinated (Covaxin, 28, Covishield, 85). Second dose was completed in 107 (94.7%) and first dose in 6 persons (5.3%). Symptomatic COVD19 infections occurred in 19 persons (16.9%) post any dose of vaccine. Symptomatic breakthrough infections > 14 days after second dose occurred in 15 persons (13.3%). Except one (required hospitalization), all 14 had mild COVID19 disease. CONCLUSIONS: We report mild symptomatic breakthrough infections as seen in our health care facility. Research in breakthrough infections in India should be extended to other institutions and community to obtain larger data.
Heterologous prime-boost COVID-19 vaccination: initial reactogenicity data.
20 Post-COVID-19 vaccine-related shingles cases seen at the Las Vegas Dermatology clinic and sent to us via social media.
Limb ischemia and pulmonary artery thrombosis after the ChAdOx1 nCoV-19 (Oxford-AstraZeneca) vaccine: a case of vaccine-induced immune thrombotic thrombocytopenia.
Successful treatment of thrombotic thrombocytopenia with cerebral sinus venous thrombosis following Ad26.COV2.S vaccination.
Frequency of positive anti-PF4/polyanion antibody tests after COVID-19 vaccination with ChAdOx1 nCoV-19 and BNT162b2. Vaccination using the adenoviral vector COVID-19 vaccine ChAdOx1 nCoV-19 (AstraZeneca) has been associated with rare vaccine-induced immune thrombotic thrombocytopenia (VITT). Affected patients test strongly positive in platelet factor 4 (PF4)/polyanion enzyme immunoassays (EIAs), and serum-induced platelet activation is maximal in the presence of PF4. We determined the frequency of anti-PF4/polyanion antibodies in healthy vaccinees and assessed whether PF4/polyanion EIA+ sera exhibit platelet-activating properties after vaccination with ChAdOx1 nCoV-19 (n = 138) or BNT162b2 (BioNTech/Pfizer; n = 143). In total, 19 of 281 participants tested positive for anti-PF4/polyanion antibodies postvaccination (All: 6.8% [95% confidence interval (CI), 4.4-10.3]; BNT162b2: 5.6% [95% CI, 2.9-10.7]; ChAdOx1 nCoV-19: 8.0% [95% CI, 4.5% to 13.7%]). Optical densities were mostly low (between 0.5 and 1.0 units; reference range, <0.50), and none of the PF4/polyanion EIA+ samples induced platelet activation in the presence of

PF4. We conclude that positive PF4/polyanion EIAs can occur after severe acute respiratory syndrome coronavirus 2 vaccination with both messenger RNA- and adenoviral vector-based vaccines, but many of these antibodies likely have minor (if any) clinical relevance. Accordingly, low-titer positive PF4/polyanion EIA results should be interpreted with caution when screening asymptomatic individuals after vaccination against COVID-19. Pathogenic platelet-activating antibodies that cause VITT do not occur commonly following vaccination.

COVID-19 vaccine-associated immune thrombosis and thrombocytopenia (VITT): Diagnostic and therapeutic recommendations for a new syndrome. Very rare cases of thrombosis associated with thrombocytopenia have occurred following the vaccination with AstraZeneca COVID-19 vaccine. The aim of this concise review is to summarize the current knowledge on the epidemiologic and pathogenic mechanisms of this syndrome named vaccine-associated immune thrombosis and thrombocytopenia (VITT). A practical patient management section will also be dealt with using information available from national and international scientific societies as well as expert panels. A literature search on the VITT syndrome was carried out in PubMed using appropriate MeSH headings. Overall, 40 VITT cases have been reported. Continuous pharmacovigilance monitoring is needed to collect more data on the real incidence and the pathogenesis of VITT syndrome. Such information will also help us to optimize the management this rare but often clinically severe thrombotic condition associated with COVID-19 vaccination.

Lymphadenopathy Following COVID-19 Vaccination: Imaging Findings Review. RATIONALE AND OBJECTIVES: Despite all the benefits and effectiveness of the coronavirus disease 2019 (COVID-19) vaccines mentioned in recent clinical trials, some post-vaccination side effects such as lymphadenopathy (LAP) were observed. The present study reviewed all studies with imaging findings presentation of LAP after COVID-19 vaccination. MATERIALS AND METHODS: We conducted a literature search in online databases, including Scopus, Medline (PubMed), Web of Science, Embase (Elsevier), Cochrane library, and Google Scholar. RESULTS: A total of 19 studies (68 cases), including 60 (88.2%) females and eight (11.8%) males with a presentation of LAP after COVID-19 vaccination, were reviewed. LAP was identified after first or second dosages of three types of COVID-19 vaccines, including Pfizer-BioNTech (nâ€¯=â€¯30, 44.1%), Moderna (nâ€¯=â€¯17, 25%), and Oxford-AstraZeneca (nâ€¯=â€¯1, 1.5%). In 20 (29.4%) cases, vaccine type was not reported or only reported as mRNA COVID-19 vaccine. The median days of LAP presentation after the first and second dosages of COVID-19 vaccination, were 12 and 5 days, respectively. Most of the LAP imaging findings related to COVID-19 vaccination (nâ€¯=â€¯66, 97%) were seen from first day to 4 weeks after vaccination. However, LAP remained after 5 and 6 weeks of the first and second dosages of COVID-19 vaccination with decreased lymph nodes' size and residual cortical thickening in two cases. CONCLUSION: This review study of cases with LAP-associated COVID-19 vaccination guides radiologists and physicians to rely on patient's clinical context and updated resources to prevent potential disease upstaging and change in therapy.

Childhood Bacille Calmette-Guerin Vaccination and Its Association With Less Severe COVID-19 Pneumonia. INTRODUCTION: The potential for Bacille Calmette-Guerin vaccination to mitigate COVID-19 severity and perhaps infection susceptibility has been hypothesized, attracting global attention given its off-target benefits shown in several respiratory viral infections. METHODS: In this retrospective study, patients with laboratory-confirmed COVID-19 from Wuhan Pulmonary Hospital, China were categorized into Bacille Calmette-Guerinâ€'vaccinated and nonvaccinated groups. Clinical records, demography, laboratory results, and chest computed tomography scans were extracted from electronic medical records and compared between the 2 groups. RESULTS: No adverse events were observed, except for an increased frequency of chills in the Bacille Calmette-Guerinâ€'vaccinated group compared with that in the unvaccinated group (p=0.014). There were no significant differences

in oxygen demand for breathing, computed tomography scans, treatments, or outcomes between the 2 groups. However, Bacille Calmette-Guerinâ€'vaccinated group had significantly less severe pneumonia (p=0.028) and milder deficiency in liver function, consistent with a lower death rate than in the unvaccinated group. CONCLUSIONS: Bacille Calmette-Guerin vaccination received in childhood is associated with less severe COVID-19 pneumonia and milder liver function deficiency in addition to a lower death rate in Bacille Calmette-Guerinâ€'vaccinated patients than in nonvaccinated individuals.
Does mRNA SARS-CoV-2 vaccine influence patients' performance during IVF-ET cycle? OBJECTIVE: No information exists in the literature regarding the effect of mRNA SARS-CoV-2 vaccine on subsequent IVF cycle attempt. We therefore aim to assess the influence of mRNA SARS-CoV-2 vaccine on IVF treatments. DESIGN: An observational study. SETTING: A tertiary, university-affiliated medical center. PATIENTS AND METHODS: All couples undergoing consecutive ovarian stimulation cycles for IVF before and after receiving mRNA SARS-CoV-2 vaccine, and reached the ovum pick-up (OPU) stage. The stimulation characteristics and embryological variables of couples undergoing IVF treatments after receiving mRNA SARS-CoV-2 vaccine were assessed and compared to their IVF cycles prior to vaccination. MAIN OUTCOME MEASURES: Stimulation characteristics and embryological variables. RESULTS: Thirty-six couples resumed IVF treatment 7-85 days after receiving mRNA SARS-CoV-2 vaccine. No in-between cycles differences were observed in ovarian stimulation and embryological variables before and after receiving mRNA SARS-CoV-2 vaccination. CONCLUSIONS: mRNA SARS-CoV-2 vaccine did not affect patients' performance or ovarian reserve in their immediate subsequent IVF cycle. Future larger studies with longer follow-up will be needed to validate our observations.
Fatal cerebral venous sinus thrombosis after COVID-19 vaccination.
Pityriasis rosea-like eruptions following vaccination with BNT162b2 mRNA COVID-19 Vaccine.
Problems associated with antiviral drugs and vaccines development for COVID-19: approach to intervention using expression vectors via GPI anchor. The outbreak of a novel coronavirus responsible for the severe acquired respiratory syndrome: SARS-CoV-2, also known as coronavirus disease 2019: COVID-19, represents a pandemic threat that has been declared a public health emergency of international concern. The CoV spike (S) glycoprotein is a key target for diagnostic, development of antibodies, entry inhibitors, and vaccines. COVID-19 also recognizes angiotensin-converting enzyme 2 (ACE2) as its host receptor binding to viral S protein. Several antiviral drugs and vaccines have been evaluated for the treatment and prevention of the infection by the virus. To facilitate medical countermeasure development, the problems associated with antiviral drugs and vaccines development for containing the spread of COVID-19 are discussed. There is an urgent need to study deeply on the structure, mutations, and function of COVID-19 as well as its pathophysiology from a large population. Construction of expression vectors for any protein targeting to the cell plasma membrane via the glycosyl-phosphatidylinositol, GPI, anchor for studying intermolecular interactions, as described in Ref. # 62 (Nguyen, K. V., Naviaux, R. K., Nyhan, W. L. Lesch-Nyhan disease: I. Construction of expression vectors for hypoxanthine-guanine phosphoribosyltransferase (HGprt) enzyme and amyloid precursor protein (APP). Nucleosides Nucleotides Nucleic Acids 2020, 39, 905-922), between the S protein of COVID-19 as well as its variants and ACE2 could be useful in antiviral drugs and vaccines development.
Acute Transverse Myelitis (ATM):Clinical Review of 43 Patients With COVID-19-Associated ATM and 3 Post-Vaccination ATM Serious Adverse Events With the ChAdOx1 nCoV-19 Vaccine (AZD1222). INTRODUCTION: Although acute transverse myelitis (ATM) is a rare neurological condition (1.34-4.6 cases per million/year) COVID-19-associated ATM cases have occurred during the pandemic. CASE-FINDING METHODS: We report a patient from Panama with SARS-CoV-2 infection complicated by ATM and present a comprehensive clinical review of 43 patients with COVID-19-associated ATM from

21 countries published from March 2020 to January 2021. In addition, 3 cases of ATM were reported as serious adverse events during the clinical trials of the COVID-19 vaccine ChAdOx1 nCoV-19 (AZD1222). RESULTS: All patients had typical features of ATM with acute onset of paralysis, sensory level and sphincter deficits due to spinal cord lesions demonstrated by imaging. There were 23 males (53%) and 20 females (47%) ranging from ages 21- to 73- years-old (mean age, 49 years), with two peaks at 29 and 58 years, excluding 3 pediatric cases. The main clinical manifestations were quadriplegia (58%) and paraplegia (42%). MRI reports were available in 40 patients; localized ATM lesions affected â‰¤3 cord segments (12 cases, 30%) at cervical (5 cases) and thoracic cord levels (7 cases); 28 cases (70%) had longitudinally-extensive ATM (LEATM) involving â‰¥4 spinal cord segments (cervicothoracic in 18 cases and thoracolumbar-sacral in 10 patients). Acute disseminated encephalomyelitis (ADEM) occurred in 8 patients, mainly women (67%) ranging from 27- to 64-years-old. Three ATM patients also had blindness from myeloneuritis optica (MNO) and two more also had acute motor axonal neuropathy (AMAN). CONCLUSIONS: We found ATM to be an unexpectedly frequent neurological complication of COVID-19. Most cases (68%) had a latency of 10 days to 6 weeks that may indicate post-infectious neurological complications mediated by the host's response to the virus. In 32% a brief latency (15 hours to 5 days) suggested a direct neurotropic effect of SARS-CoV-2. The occurrence of 3 reported ATM adverse effects among 11,636 participants in the AZD1222 vaccine trials is extremely high considering a worldwide incidence of 0.5/million COVID-19-associated ATM cases found in this report. The pathogenesis of ATM remains unknown, but it is conceivable that SARS-CoV-2 antigens -perhaps also present in the AZD1222 COVID-19 vaccine or its chimpanzee adenovirus adjuvant- may induce immune mechanisms leading to the myelitis.

Short-term antibody response after 1 dose of BNT162b2 vaccine in patients receiving hemodialysis. BACKGROUND: Patients receiving in-centre hemodialysis are at high risk of exposure to SARS-CoV-2 and death if infected. One dose of the BNT162b2 SARS-CoV-2 vaccine is efficacious in the general population, but responses in patients receiving hemodialysis are uncertain. METHODS: We obtained serial plasma from patients receiving hemodialysis and health care worker controls before and after vaccination with 1 dose of the BNT162b2 mRNA vaccine, as well as convalescent plasma from patients receiving hemodialysis who survived COVID-19. We measured anti-receptor binding domain (RBD) immunoglobulin G (IgG) levels and stratified groups by evidence of previous SARS-CoV-2 infection. RESULTS: Our study included 154 patients receiving hemodialysis (135 without and 19 with previous SARS-CoV-2 infection), 40 controls (20 without and 20 with previous SARS-CoV-2 infection) and convalescent plasma from 16 patients. Among those without previous SARS-CoV-2 infection, anti-RBD IgG was undetectable at 4 weeks in 75 of 131 (57%, 95% confidence interval [CI] 47% to 65%) patients receiving hemodialysis, compared with 1 of 20 (5%, 95% CI 1% to 23%) controls ($p < 0.001$). No patient with nondetectable levels at 4 weeks developed anti-RBD IgG by 8 weeks. Results were similar in non-immunosuppressed and younger individuals. Three patients receiving hemodialysis developed severe COVID-19 after vaccination. Among those with previous SARS-CoV-2 infection, median anti-RBD IgG levels at 8 weeks in patients receiving hemodialysis were similar to controls at 3 weeks ($p = 0.3$) and to convalescent plasma ($p = 0.8$). INTERPRETATION: A single dose of BNT162b2 vaccine failed to elicit a humoral immune response in most patients receiving hemodialysis without previous SARS-CoV-2 infection, even after prolonged observation. In those with previous SARS-CoV-2 infection, the antibody response was delayed. We advise that patients receiving hemodialysis be prioritized for a second BNT162b2 dose at the recommended 3-week interval.

Thrombotic Thrombocytopenic Purpura after Ad26.COV2-S Vaccination. The U.S. Food and Drug Administration (FDA) recently issued an Emergency Use Authorization (EUA) for two highly effective Sars-CoV-2 (COVID-19) vaccines from Pfizer-BioNTech and Moderna. More recently, EUA was granted for the Johnson and Johnson COVID-19 vaccine which uses traditional virus-based technology. In this

vaccine, researchers added the gene for the coronavirus spike protein to modified Adenovirus 26 and named it Ad26.COV2-S. Nearly 7 million doses of the Ad26.COV2-S have been administered as of mid-April 2021. Recently the Federal Drug Administration and Center for Disease Control and Prevention reviewed data involving six reported cases in the United States of cerebral venous sinus thrombosis in combination with thrombocytopenia in people who received the vaccination. All cases were in women between 18 and 48, with symptoms developing six to 13 days after vaccination. A recent study in the United Kingdom reported similar events in 23 patients age 21 to 77, 61% of which were female, with cases of presumed vaccine induced thrombosis and thrombocytopenia occurring six to 24 days after vaccination. We report a 62-year-old female who presented to the emergency department (ED) with acute onset of altered mental status. She had received the Ad26.COV2-S vaccine 37 days prior to ED presentation. She developed thrombotic thrombocytopenic purpura (TTP) and no other cause was found. To our knowledge this is the first case in the United States of thrombotic thrombocytopenic purpura after receiving the Ad26.COV2-S COVID-19 vaccine.
Delayed Localized Hypersensitivity Reactions to the Moderna COVID-19 Vaccine: A Case Series. IMPORTANCE: In response to the coronavirus disease 2019 (COVID-19) pandemic, 2 mRNA vaccines (Pfizer-BioNTech and Moderna) received emergency use authorization from the US Food and Drug Administration in December 2020. Some patients in the US have developed delayed localized cutaneous vaccine reactions that have been dubbed "COVID arm." OBJECTIVE: To describe the course of localized cutaneous injection-site reactions to the Moderna COVID-19 vaccine, subsequent reactions to the second vaccine dose, and to characterize the findings of histopathologic examination of the reaction. DESIGN, SETTING, AND PARTICIPANTS: This retrospective case series study was performed at Yale New Haven Hospital, a tertiary medical center in New Haven, Connecticut, with 16 patients referred with localized cutaneous injection-site reactions from January 20 through February 12, 2021. MAIN OUTCOMES AND MEASURES: We collected each patient's demographic information, a brief relevant medical history, clinical course, and treatment (if any); and considered the findings of a histopathologic examination of 1 skin biopsy specimen. RESULTS: Of 16 patients (median [range] age, 38 [25-89] years; 13 [81%] women), 14 patients self-identified as White and 2 as Asian. The delayed localized cutaneous reactions developed in a median (range) of 7 (2-12) days after receiving the Moderna COVID-19 vaccine. These reactions occurred at or near the injection site and were described as pruritic, painful, and edematous pink plaques. None of the participants had received the Pfizer-BioNTech vaccine. Results of a skin biopsy specimen demonstrated a mild predominantly perivascular mixed infiltrate with lymphocytes and eosinophils, consistent with a dermal hypersensitivity reaction. Of participants who had a reaction to first vaccine dose (15 of 16 patients), most (11 patients) developed a similar localized injection-site reaction to the second vaccine dose; most (10 patients) also developed the second reaction sooner as compared with the first-dose reaction. CONCLUSIONS AND RELEVANCE: Clinical and histopathologic findings of this case series study indicate that the localized injection-site reactions to the Moderna COVID-19 vaccine are a delayed hypersensitivity reaction. These reactions may occur sooner after the second dose, but they are self-limited and not associated with serious vaccine adverse effects. In contrast to immediate hypersensitivity reactions (eg, anaphylaxis, urticaria), these delayed reactions (dubbed "COVID arm") are not a contraindication to subsequent vaccination.
In brief: Johnson & Johnson COVID-19 vaccine suspended.
In brief: Suspension of Johnson & Johnson COVID-19 vaccine lifted.
FDA authorizes Johnson & Johnson COVID-19 vaccine.
Rituximab, but not other antirheumatic therapies, is associated with impaired serological response to SARS- CoV-2 vaccination in patients with rheumatic diseases.

Will Mutations in the Spike Protein of SARS-CoV-2 Lead to the Failure of COVID-19 Vaccines? Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) is the causative agent of coronavirus disease 2019 (COVID-19), which has spread worldwide since it was first identified in Wuhan, China, at the end of 2019. With the global transmission of the virus, a large number of SARS-CoV-2 variants have also appeared, especially, emerging strains that have recently been discovered in the United Kingdom (variant 20I/501Y.V1, lineage B.1.1.7), South Africa (variant 20H/501Y.V2, lineage B.1.351), and Brazil (variant 20 J/501Y.V3, and lineage P.1). The common feature of these variants is that they share the N501Y mutation involving the SARS-CoV-2 spike (S) protein, which is precisely the target of most COVID-19 vaccines. Furthermore, mutations such as N501Y, E484K, and K417N in the S protein may affect viral fitness and transmissibility. However, current research on the impact of these variants on COVID-19 vaccines is still lacking. Herein, we briefly explain why most COVID-19 vaccines target the S protein, update the progress of research regarding S protein-related COVID-19 vaccines, review the latest studies concerning the effects of S protein variants on COVID-19 vaccines, and finally, propose certain strategies to deal with SARS-CoV-2 variants.

[Acute facial paresis as a possible complication of vaccination against SARS-CoV-2]. Although acute facial nerve palsy (Bell's palsy) is explicitly mentioned in the information sheets for vaccines as a possible complication of vaccination against SARS-CoV-2, from our point of view the benefits of the vaccination clearly outweigh the possible risks. At most, if at all, a slightly increased risk can be derived from the previous case reports. In general, the risk of acute facial palsy is described in association with many vaccinations. The risk, if any, does not appear to be a specific risk of SARS-CoV-2 vaccines. On the other hand, cases of acute facial palsy as symptom of a COVID-19 disease have also been described, so that the theoretical question arises as to the extent to which the vaccination may prevent rather than promote the occurrence of facial palsy. Ultimately, if acted quickly, acute facial paralysis can be treated well and its severity and sequelae cannot be compared with the severity of a COVID-19 disease and its possible long-COVID sequelae.

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccination in Pregnancy: Measures of Immunity and Placental Histopathology. Receipt of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination was not associated with placental histopathologic lesions.

Early antibody response in health-care professionals after two doses of SARS-CoV-2 mRNA vaccine (BNT162b2). OBJECTIVES: Data on the immune response after two doses of BNT162b2 are so far limited. Previously infected individuals were excluded from pivotal clinical trials and the optimum dose regimen in this population has not been clearly studied. The CRO-VAX HCP study aims to investigate the early antibody response in a population of health-care professionals having received two doses of the BNT162b2 mRNA coronavirus disease 2019 (COVID-19) vaccine. METHODS: The CRO-VAX HCP study is a multicentre, prospective, interventional study conducted in several sites in Belgium. The study included 231 health-care professional volunteers who received the two-dose regimen of the BNT162b2 mRNA COVID-19 vaccine. Of these, 73 were previously infected by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and 158 were uninfected and seronegative. In the first group, blood samples were collected at baseline and after 2, 4, 7, 10, 14, 21 and 28Â days. In the second group, samples were obtained at baseline and after 14 and 28Â days. Antibodies against the SARS-CoV-2 nucleocapsid and the receptor binding domain of the S1 subunit of the spike protein were measured in all individuals at different time-points. RESULTS: In uninfected individuals, 95.5% (95% CI 91.0%-98.2%) developed anti-spike antibodies after 14Â days and a 24.9-fold rise (95% CI 21.4%-28.9%) in antibody titre was observed after the second dose. In previously infected individuals, peak antibody response was reached after 7Â days (i.e. 6347 U/mL) and the second dose did not lead to significantly higher antibody titres (i.e. 8856-11 911 U/mL). Antibody titres were

higher in previously infected individuals. CONCLUSIONS: This study supports the concept that a single dose of BNT162b2 would be sufficient in previously infected individuals.

Recurrence of primary cutaneous CD30-positive lymphoproliferative disorder following COVID-19 vaccination.

Evaluation of laboratory assays for anti-platelet factor 4 antibodies after ChAdOx1 nCOV-19 vaccination. INTRODUCTION: Vaccine-induced immune thrombocytopenia and thrombosis (VITT) following ChAdOx1 nCOV-19 vaccine has been described, associated with unusual site thrombosis, thrombocytopenia, raised D-dimer, and high-titer immunoglobulin-G (IgG) class anti-platelet factor 4 (PF4) antibodies. Enzyme-linked immunosorbent assays (ELISA) have been shown to detect anti-PF4 in patients with VITT, but chemiluminescence assays do not reliably detect them. ELISA assays are not widely available in diagnostic laboratories, and, globally, very few laboratories perform platelet activation assays. METHODS: Assays that are commercially available in the United Kingdom were evaluated for their ability to identify anti-PF4 antibodies in samples from patients with suspected VITT. Four IgG-specific ELISAs, two polyspecific ELISAs, and four rapid assays were performed on samples from 43 patients with suspected VITT from across the United Kingdom. Cases were identified after referral to the UK Expert Haematology Panel multidisciplinary team and categorized into unlikely, possible, or probable VITT. RESULTS AND DISCUSSION: We demonstrated that the HemosIL AcuStar HIT-IgG, HemosIL HIT-Ab, Diamed PaGIA gel, and STic Expert assays have poor sensitivity for VITT in comparison to ELISA. Where these assays are used for heparin-induced thrombocytopenia (HIT) diagnosis, laboratories should ensure that requests for suspected VITT are clearly identified so that an ELISA is performed. No superiority of IgG-ELISAs over polyspecific ELISAs in sensitivity to VITT could be demonstrated. No single ELISA method detected all possible/probable VITT cases; if a single ELISA test is negative, a second ELISA or a platelet activation assay should be considered where there is strong clinical suspicion.

SARS -CoV-2 T-cell immunity to variants of concern following vaccination. Recently, two mRNA vaccines to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have become available, but there is also an emergence of SARS-CoV-2 variants with increased transmissibility and virulence(1-6). A major concern is whether the available vaccines will be equally effective against these variants. The vaccines are designed to induce an immune response against the SARS-CoV-2 spike protein(7,8), which is required for viral entry to host cells(9). Immunity to SARS-CoV-2 is often evaluated by antibody production, while less is known about the T-cell response. Here we developed, characterized, and implemented two standardized, functional assays to measure T-cell immunity to SARS-CoV-2 in uninfected, convalescent, and vaccinated individuals. We found that vaccinated individuals had robust T-cell responses to the wild type spike and nucleocapsid proteins, even more so than convalescent patients. We also found detectable but diminished T-cell responses to spike variants (B.1.1.7, B.1.351, and B.1.1.248) among vaccinated but otherwise healthy donors. Since decreases in antibody neutralization have also been observed with some variants(10-12), investigation into the T-cell response to these variants as an alternative means of viral control is imperative. Standardized measurements of T-cell responses to SARS-CoV-2 are feasible and can be easily adjusted to determine changes in response to variants.

COVID arm and PET/FDG imaging.

What we have learned from the COVID-19 pandemic: Time to think outside the box, maybe far outside. The coronavirus disease 2019 pandemic has had a profound effect on our lives and careers; this presentation explores some of the lessons we have learned from it and others that it may yet teach us. Socioeconomic effects have been profound, not all of them favorable. Travel and meeting activities, as well as many other activities, have been severely restricted. Social unrest has

become intense, and it may have questionable political consequences, as the United States is undergoing a contested election result.

COVID-19 vaccines do not trigger psoriasis flares in patients with psoriasis treated with apremilast.

Survey data of COVID-19 vaccine side effects among hospital staff in a national referral hospital in Indonesia. In response to the current global challenge due to COVID-19, a dataset in this paper presented survey data of COVID-19 vaccine side effects among hospital staff in a national referral hospital in Indonesia. This survey data included the hospital staff of Dr. M. Djamil Hospital Padang, a national referral hospital in Indonesia, through a survey distributed via an online questionnaire, assessing COVID-19 vaccine side effects from 9th February to 13th February 2021. The items of the side effects included swelling, redness, itching, fever, headache, muscle pain, fatigue, coughing, diarrhea, nausea and vomiting, breathlessness, joint pain, fainted, anaphylactic reaction, itch, and swollen lymph nodes. In this survey data, we collected a total of 840 responses. The survey data were analyzed using univariate and bivariate analysis. Data analysis was performed using IBM version 25.0.

Guillain-BarrÃ© syndrome following the first dose of SARS-CoV-2 vaccine: A temporal occurrence, not a causal association. Safety monitoring is of paramount importance for vaccines authorized for emergent use (EUA) by the US Food and Drug Administration (FDA) against SARS-CoV-2. Mass immunization is an essential tool to end the current pandemic, but vaccine surveillance is necessary to identify any potentially associated harms. At the same time, probability of temporal bias should be borne in mind before making conclusions about causality between the vaccine and an attributable undesired effect. We report a case of Guillain-BarrÃ© syndrome after the first dose of SARS-CoV-2 vaccine and believe this is a temporal, rather than causal association.

Rapid Development of Clinically Symptomatic Radiation Recall Pneumonitis Immediately Following COVID-19 Vaccination. In this report, we present the case of a 66-year-old man whoÂ received local consolidation radiotherapy to the right lung and mediastinum forÂ oligometastaticÂ non-small cell lung cancerÂ (NSCLC)Â following partial response toÂ upfrontÂ chemoimmunotherapy. He continuedÂ with maintenance immunotherapy and was asymptomatic for eight monthsÂ afterÂ completing radiation therapy. HeÂ thenÂ developed symptoms consistent with pneumonitisÂ within three to five days of his firstÂ administration ofÂ the coronavirus disease 2019 (COVID-19) vaccineÂ injection.Â He reported that these symptoms significantly intensified within three to five days of receiving his second dose of the vaccine.Â The clinical time frameÂ and radiographic evidenceÂ raised suspicion for radiation recall pneumonitis (RRP).Â Patients undergoing maintenance immunotherapy after prior irradiationÂ may be at increased risk of this phenomenon that may beÂ triggeredÂ by the administration of theÂ COVID-19 vaccine.

COVID-19 vaccine induced Axillary and Pectoral Lymphadenopathy on PET scan. Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has caused the ongoing global pandemic. It can manifest a wide range of complications depending upon the severity of infection and comorbidities of the patient. Vaccines are very important measure to provide protection against COVID-19. We report a case of 72-year-old female with past medical history of hypertension and diabetes mellitus who underwent imaging with positron emission tomography (PET) scan imaging for staging of her small cell urinary bladder cancer and was found to have hypermetabolic uptake in the deltoid muscle of the left shoulder and hypermetabolic left axillary and pectoral lymph nodes due to mRNA BNT-162b2 (Pfizer-BioNTech COVID-19 vaccine) vaccine administrated 3 days ago prior to PET scan.

Severe acute respiratory coronavirus virus 2 (SARS-CoV-2) infection in asymptomatic vaccinated healthcare workers.

Correlation between BNT162b2 mRNA Covid-19 vaccine-associated hypermetabolic lymphadenopathy and humoral immunity in patients with hematologic malignancy. PURPOSE:

Vaccine-associated hypermetabolic lymphadenopathy (VAHL) is frequently observed on [(18)F]FDG PET-CT following BNT162b2 administration. Recent data suggest a prominent B cell germinal-center (GC) response elicited by mRNA vaccines in draining lymph nodes. Thus, in this study we aimed to explore the correlation between VAHL and humoral immunity as reflected by post-vaccination serologic testing and by comparing the incidence of VAHL between lymphoma patients treated recently with B cell depleting therapy and those that were not. METHODS: A total of 137 patients with hematologic malignancy that had post-vaccination [(18)F]FDG PET-CT were included (All-PET group), 86 received both vaccine doses before imaging (PET-2 group). Their VAHL status and grade on imaging were recorded. Among 102 lymphoma patients, 34 (33.3%) were treated during the year prior vaccination with anti-CD20 antibody containing therapy. A subgroup of 54 patients also underwent serologic testing 2-3Â weeks after the booster dose, and their anti-spike titers were recorded and graded as well. RESULTS: The overall incidence of VAHL in patients with hematologic malignancy was 31.4%. The 34 lymphoma patients treated during the year prior vaccination with anti-CD20 antibody containing therapy had significantly lower rates of VAHL comparted with all other lymphoma patients (8.8 versus 41.2% in all-PET patients, Pvâ€‰<â€‰0.01). VAHL rates were 10% in patients with negative serology, 31.3% in patients with low anti-spike titers, and 72.2% in patients with high anti-spike titers. The positive predictive values of VAHL were 90 and 93.3% in all-PET and PET-2 patients, respectively. A positive statistically significant correlation was found between VAHL and serology ranks in All-PET patients (r(s)â€‰=â€‰0.530, Pvâ€‰<â€‰0.001), and stronger correlation was found in PET-2 patients (r(s)â€‰=â€‰0.642, Pvâ€‰<â€‰0.001). CONCLUSION: VAHL on [(18)F]FDG PET-CT of patients with hematologic malignancy may reflect GC B cell proliferation and an effective humoral response elicited by BNT162b2 vaccine.

Comment on "Autoimmune hepatitis developing after coronavirus disease 2019 (COVID-19) vaccine: Causality or casualty?".

Minimal change disease relapse following SARS-CoV-2 mRNA vaccine.

Imaging of Oxford/AstraZenecaÂ® COVID-19 vaccine-induced immune thrombotic thrombocytopenia.

Allergy to COVID-19 vaccines: A current update. Adverse allergic reactions due to the administration of the vaccines developed for the protection of coronavirus disease 2019 (COVID-19) have been reported since the initiation of the vaccination campaigns. Current analyses provided by the Center for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) in the United States have estimated the rates of anaphylactic reactions in 2.5 and 11.1 per million of mRNA-1273 and BNT162b2 vaccines administered, respectively. Although rather low, such rates could have importance due to the uncommon fact that a large majority of the world population will be subjected to vaccination with the aforementioned vaccines in the following months and vaccination will most likely be necessary every season as for influenza vaccines. Health regulators have advised that any subject with a previous history of allergy to drugs or any component of the vaccines should not be vaccinated, however, certain misunderstanding exists since allergy to specific excipients in drugs and vaccines are in occasions misdiagnosed due to an absence of suspicion to specific excipients as allergenic triggers or due to inaccurate labeling or nomenclature. In this review, we provide an updated revision of the most current data regarding the anaphylactic reactions described for BNT162b2 vaccine, mRNA-1273 vaccine, and AZD1222 vaccine. We extensively describe the different excipients in the vaccines with the potential to elicit systemic allergic reactions such as polyethylene glycol (PEG), polysorbates, tromethamine/trometamol, and others and the possible immunological mechanisms involved.

Risk of allergic reaction in patients with atopic disease and recent coronavirus disease 2019 vaccination.

Adverse cutaneous and mucous reactions from anti SARS-CoV-2 vaccines: recommendations from the Italian Society of Dermatology (SIDeMaST).
How many COVID deaths are acceptable in a post-pandemic world?
Acute Coronary Tree Thrombosis After Vaccination for COVID-19.
Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine - United States, March-April 2021. On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Janssen (Ad.26.COV2.S) COVID-19 vaccine (Janssen Biotech, Inc., a Janssen Pharmaceutical company, Johnson & Johnson) (1). The Janssen COVID-19 vaccine, the third COVID-19 vaccine authorized for use in the United States, uses a replication-incompetent human adenoviral type 26 vector platform* (2) and is administered as a single intramuscular dose, whereas the first two authorized vaccines use an mRNA platform and require 2 doses. On February 28, 2021, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for use of Janssen COVID-19 vaccine among persons aged â‰¥18 years (3). During April 13-23, CDC and FDA recommended a pause in use of Janssen vaccine after reports of six cases of cerebral venous sinus thrombosis (CVST) with thrombocytopenia (platelet count <150,000/Î¼L of blood) among Janssen vaccine recipients (4). Similar thrombotic events, primarily among women aged <60 years, have been described in Europe after receipt of the AstraZeneca COVID-19 vaccine, which uses a replication-incompetent chimpanzee adenoviral vector (5-7). The U.S. CVST cases that prompted the pause in Janssen vaccination, as well as subsequently detected CVST cases, are described elsewhere (8). This report summarizes adverse events among Janssen vaccine recipients, including non-CVST cases of thrombosis with thrombocytopenia syndrome (TTS), reported to the Vaccine Adverse Events Reporting System (VAERS), a passive surveillance system, and through v-safe, an active monitoring system. As of April 21, 2021, 7.98 million doses of the Janssen COVID-19 vaccine had been administered. Among 13,725 VAERS reports reviewed, 97% were classified as nonserious and 3% as serious,(â€) including three reports among women of cases of thrombosis in large arteries or veins accompanied by thrombocytopenia during the second week after vaccination. These three cases and the previously detected CVST cases are consistent with 17 cases of TTS,(Â§) a newly defined condition. Approximately 338,700 Janssen COVID-19 vaccine recipients completed at least one v-safe survey during the week after vaccination; 76% reported a systemic reaction, 61% reported a local reaction, and 34% reported a health impact.(Â¶) Fatigue and pain were commonly reported symptoms in both VAERS and v-safe. The overall safety profile is consistent with preauthorization clinical trials data. Prompt review of U.S. vaccine safety data detected three additional cases of non-CVST TTS, in addition to the previously recognized CVST cases that initiated the pause in use of the Janssen COVID-19 vaccine. Ongoing monitoring of adverse events after COVID-19 vaccination, including vaccination with the Janssen single-dose vaccine, is essential for evaluating the risks and benefits of each vaccine.
Anxiety-Related Adverse Event Clusters After Janssen COVID-19 Vaccination - Five U.S. Mass Vaccination Sites, April 2021. On April 7, 2021, after 5 weeks' use of the Janssen COVID-19 vaccine under the Food and Drug Administration (FDA) Emergency Use Authorization (EUA), CDC received reports of clusters of anxiety-related events after administration of Janssen COVID-19 vaccine from five mass vaccination sites, all in different states. To further investigate these cases, CDC interviewed vaccination site staff members to gather additional information about the reported events and vaccination site practices. Four of the five sites temporarily closed while an investigation took place. Overall, 64 anxiety-related events, including 17 reports of syncope (fainting), an anxiety-related event, among 8,624 Janssen COVID-19 vaccine recipients, were reported from these sites for vaccines administered during April 7-9. As a follow-up to these interviews, CDC analyzed reports of syncope shortly after receipt of Janssen COVID-19 vaccine to the Vaccine Adverse Event Reporting

System (VAERS), the vaccine safety monitoring program managed by CDC and FDA. To compare the occurrence of these events with those reported after receipt of other vaccines, reports of syncopal events after influenza vaccine administered in the 2019-20 influenza season were also reviewed. Syncope after Janssen COVID-19 vaccination was reported to VAERS (8.2 episodes per 100,000 doses). By comparison, after influenza vaccination, the reporting rate of syncope was 0.05 episodes per 100,000 doses. Anxiety-related events can occur after any vaccination. It is important that vaccination providers are aware that anxiety-related adverse events might be reported more frequently after receipt of the Janssen COVID-19 vaccine than after influenza vaccination and observe all COVID-19 vaccine recipients for any adverse reactions for at least 15 minutes after vaccine administration.

Asymptomatic and Symptomatic SARS-CoV-2 Infections After BNT162b2 Vaccination in a Routinely Screened Workforce. This study aims to describe an association between the Pfizer-BioNTech (BNT162b2) vaccine and decreased risk of symptomatic and asymptomatic infections with SARS-CoV-2 in hospital employees.

Association Between Vaccination With BNT162b2 and Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infections Among Health Care Workers. IMPORTANCE: Randomized clinical trials have provided estimates of the effectiveness of the BNT162b2 vaccine against symptomatic SARS-CoV-2 infection, but its effect on asymptomatic infections remains unclear. OBJECTIVE: To estimate the association of vaccination with the Pfizer-BioNTech BNT162b2 vaccine with symptomatic and asymptomatic SARS-CoV-2 infections among health care workers. DESIGN, SETTING, AND PARTICIPANTS: This was a single-center, retrospective cohort study conducted at a tertiary medical center in Tel Aviv, Israel. Data were collected on symptomatic and asymptomatic SARS-CoV-2 infections confirmed via polymerase chain reaction (PCR) tests in health care workers undergoing regular screening with nasopharyngeal swabs between December 20, 2020, and February 25, 2021. Logistic regression was used to calculate incidence rate ratios (IRRs) comparing the incidence of infection between fully vaccinated and unvaccinated participants, controlling for demographics and the number of PCR tests performed. EXPOSURES: Vaccination with the BNT162b2 vaccine vs unvaccinated status was ascertained from the employee health database. Full vaccination was defined as more than 7 days after receipt of the second vaccine dose. MAIN OUTCOMES AND MEASURES: The primary outcome was the regression-adjusted IRR for symptomatic and asymptomatic SARS-CoV-2 infection of fully vaccinated vs unvaccinated health care workers. The secondary outcomes included IRRs for partially vaccinated health care workers (days 7-28 after first dose) and for those considered as late fully vaccinated (>21 days after second dose). RESULTS: A total of 6710 health care workers (mean [SD] age, 44.3 [12.5] years; 4465 [66.5%] women) were followed up for a median period of 63 days; 5953 health care workers (88.7%) received at least 1 dose of the BNT162b2 vaccine, 5517 (82.2%) received 2 doses, and 757 (11.3%) were not vaccinated. Vaccination was associated with older age compared with those who were not vaccinated (mean age, 44.8 vs 40.7 years, respectively) and male sex (31.4% vs 17.7%). Symptomatic SARS-CoV-2 infection occurred in 8 fully vaccinated health care workers and 38 unvaccinated health care workers (incidence rate, 4.7 vs 149.8 per 100â€¯000 person-days, respectively, adjusted IRR, 0.03 [95% CI, 0.01-0.06]). Asymptomatic SARS-CoV-2 infection occurred in 19 fully vaccinated health care workers and 17 unvaccinated health care workers (incidence rate, 11.3 vs 67.0 per 100â€¯000 person-days, respectively, adjusted IRR, 0.14 [95% CI, 0.07-0.31]). The results were qualitatively unchanged by the propensity score sensitivity analysis. CONCLUSIONS AND RELEVANCE: Among health care workers at a single center in Tel Aviv, Israel, receipt of the BNT162b2 vaccine compared with no vaccine was associated with a significantly lower incidence of symptomatic and asymptomatic SARS-CoV-2 infection more than 7 days after the second dose. Findings are limited by the observational design.

Central obesity, smoking habit, and hypertension are associated with lower antibody titres in response to COVID-19 mRNA vaccine. AIMS: To explore variables associated with the serological response following COVID-19 mRNA vaccine. METHODS: Eighty-six healthcare workers adhering to the vaccination campaign against COVID-19 were enrolled in January-February 2021. All subjects underwent two COVID-19 mRNA vaccine inoculations (Pfizer/BioNTech) separated by 3 weeks. Blood samples were collected before the 1st and 1-4 weeks after the second inoculation. Clinical history, demographics, and vaccine side effects were recorded. Baseline anthropometric parameters were measured, and body composition was performed through dual-energy-X-ray absorptiometry. RESULTS: Higher waist circumference was associated with lower antibody (Ab) titres (RÂ =Â -0.324, pÂ =Â 0.004); smokers had lower levels compared to non-smokers [1099 (1350) vs. 1921 (1375), pÂ =Â 0.007], as well as hypertensive versus normotensive [650Â Â±Â 1192 vs. 1911 (1364), pÂ =Â 0.001] and dyslipideamic compared to those with normal serum lipids [534 (972) vs 1872 (1406), pÂ =Â 0.005]. Multivariate analysis showed that higher waist circumference, smoking, hypertension, and longer time elapsed since second vaccine inoculation were associated with lower Ab titres, independent of BMI, age. and gender. CONCLUSIONS: Central obesity, hypertension, and smoking are associated with lower Ab titres following COVID-19 vaccination. Although it is currently impossible to determine whether lower SARS-CoV-2 Abs lead to higher likelihood of developing COVID-19, it is well-established that neutralizing antibodies correlate with protection against several viruses including SARS-CoV-2. Our findings, therefore, call for a vigilant approach, as subjects with central obesity, hypertension, and smoking could benefit from earlier vaccine boosters or different vaccine schedules.

The BNT162b2 vaccine is associated with lower new COVID-19 cases in nursing home residents and staff. BACKGROUND/OBJECTIVES: The effectiveness of the BNT162b2 vaccine on preventing the spread of COVID-19 and deaths in nursing homes (NH) is unknown. DESIGN: We used zero-inflated negative binomial mixed effects regressions to model the associations of time since the vaccine clinic ending the week of December 27, 2020 (cohort 1), January 3, 2021 (cohort 2), or January 10, 2021 (cohort 3) controlling for county rate of COVID-19, bed size, urban location, racial and ethnic census, and level of registered nurses with resident cases and deaths of COVID-19 and staff cases of COVID-19. SETTING AND PARTICIPANTS: All 2501 NHs who held a vaccine clinic from the first 17 states to initiate clinics as part of the Pharmacy Partnership for Long-Term Care Program. MAIN OUTCOME(S) AND MEASURE(S): Adjusted Incidence Rate Ratio (IRR) for time in 3, 4, 5, and 6â€‰weeks after the first vaccine clinic for resident cases and deaths of COVID-19 and staff cases of COVID-19. RESULTS: Resident and staff cases trended downward in all three cohorts following the vaccine clinics. Time following the first clinic at 5 and 6â€‰weeks was consistently associated with fewer resident cases (IRR: 0.68 [95% CI: 0.54-0.84], IRR: 0.64 [95% CI: 0.48-0.86], respectively); resident deaths (IRR: 0.59 [95% CI: 0.45-0.77], IRR: 0.45 [95% CI: 0.31-0.65], respectively); and staff cases (IRR: 0.64 [95% CI: 0.56-0.73], IRR: 0.51 [95% CI: 0.42-0.62], respectively). Other factors associated with fewer resident and staff cases included facilities with less than 50 certified beds and high nurse staffing per resident day (>0.987). Contrary to prior research, higher Hispanic non-white resident census was associated with fewer resident cases (IRR: 0.42, 95% CI: 0.31-0.56) and deaths (IRR: 0.18, 95% CI: 0.12-0.27). CONCLUSIONS: The BNT162b2 vaccine is associated with decreased spread of SARS-CoV-2 in both residents and staff as well as decreased deaths among residents.

Avoiding a "Twindemic": Sociodemographic Factors Associated With the Influenza Vaccination During the COVID-19 Pandemic.

Delayed production of neutralizing antibodies correlates with fatal COVID-19. Recent studies have provided insights into innate and adaptive immune dynamics in coronavirus disease 2019 (COVID-19). However, the exact features of antibody responses that govern COVID-19 disease

outcomes remain unclear. In this study, we analyzed humoral immune responses in 229 patients with asymptomatic, mild, moderate and severe COVID-19 over time to probe the nature of antibody responses in disease severity and mortality. We observed a correlation between anti-spike (S) immunoglobulin G (IgG) levels, length of hospitalization and clinical parameters associated with worse clinical progression. Although high anti-S IgG levels correlated with worse disease severity, such correlation was time dependent. Deceased patients did not have higher overall humoral response than discharged patients. However, they mounted a robust, yet delayed, response, measured by anti-S, anti-receptor-binding domain IgG and neutralizing antibody (NAb) levels compared to survivors. Delayed seroconversion kinetics correlated with impaired viral control in deceased patients. Finally, although sera from 85% of patients displayed some neutralization capacity during their disease course, NAb generation before 14 d of disease onset emerged as a key factor for recovery. These data indicate that COVID-19 mortality does not correlate with the cross-sectional antiviral antibody levels per se but, rather, with the delayed kinetics of NAb production.

CCR2 Regulates Vaccine-Induced Mucosal T-Cell Memory to Influenza A Virus. Elicitation of lung tissue-resident memory CD8 T cells (T(RM)s) is a goal of T cell-based vaccines against respiratory viral pathogens, such as influenza A virus (IAV). C-C chemokine receptor type 2 (CCR2)-dependent monocyte trafficking plays an essential role in the establishment of CD8 T(RM)s in lungs of IAV-infected mice. Here, we used a combination adjuvant-based subunit vaccine strategy that evokes multifaceted (T(C)1/T(C)17/T(H)1/T(H)17) IAV nucleoprotein-specific lung T(RM)s to determine whether CCR2 and monocyte infiltration are essential for vaccine-induced T(RM) development and protective immunity to IAV in lungs. Following intranasal vaccination, neutrophils, monocytes, conventional dendritic cells (DCs), and monocyte-derived dendritic cells internalized and processed vaccine antigen in lungs. We found that basic leucine zipper ATF-like transcription factor 3 (BATF3)-dependent DCs were essential for eliciting T cell responses, but CCR2 deficiency enhanced the differentiation of CD127(hi), KLRG-1(lo), OX40(+ve) CD62L(+ve), and mucosally imprinted CD69(+ve) CD103(+ve) effector and memory CD8 T cells in lungs and airways of vaccinated mice. Mechanistically, increased development of lung T(RM)s induced by CCR2 deficiency was linked to dampened expression of T-bet but not altered TCF-1 levels or T cell receptor signaling in CD8 T cells. T1/T17 functional programming, parenchymal localization of CD8/CD4 effector and memory T cells, recall T cell responses, and protective immunity to a lethal IAV infection were unaffected in CCR2-deficient mice. Taken together, we identified a negative regulatory role for CCR2 and monocyte trafficking in mucosal imprinting and differentiation of vaccine-induced T(RM)s. Mechanistic insights from this study may aid the development of T-cell-based vaccines against respiratory viral pathogens, including IAV and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). IMPORTANCE While antibody-based immunity to influenza A virus (IAV) is type and subtype specific, lung- and airway-resident memory T cells that recognize conserved epitopes in the internal viral proteins are known to provide heterosubtypic immunity. Hence, broadly protective IAV vaccines need to elicit robust T cell memory in the respiratory tract. We have developed a combination adjuvant-based IAV nucleoprotein vaccine that elicits strong CD4 and CD8 T cell memory in lungs and protects against H1N1 and H5N1 strains of IAV. In this study, we examined the mechanisms that control vaccine-induced protective memory T cells in the respiratory tract. We found that trafficking of monocytes into lungs might limit the development of antiviral lung-resident memory T cells following intranasal vaccination. These findings suggest that strategies that limit monocyte infiltration can potentiate vaccine-induced frontline T-cell immunity to respiratory viruses, such as IAV and SARS-CoV-2.

Arterial events, venous thromboembolism, thrombocytopenia, and bleeding after vaccination with Oxford-AstraZeneca ChAdOx1-S in Denmark and Norway: population based cohort study. OBJECTIVE: To assess rates of cardiovascular and haemostatic events in the first 28 days after

vaccination with the Oxford-AstraZeneca vaccine ChAdOx1-S in Denmark and Norway and to compare them with rates observed in the general populations. DESIGN: Population based cohort study. SETTING: Nationwide healthcare registers in Denmark and Norway. PARTICIPANTS: All people aged 18-65 years who received a first vaccination with ChAdOx1-S from 9 February 2021 to 11 March 2021. The general populations of Denmark (2016-18) and Norway (2018-19) served as comparator cohorts. MAIN OUTCOME MEASURES: Observed 28 day rates of hospital contacts for incident arterial events, venous thromboembolism, thrombocytopenia/coagulation disorders, and bleeding among vaccinated people compared with expected rates, based on national age and sex specific background rates from the general populations of the two countries. RESULTS: The vaccinated cohorts comprised 148â€‰792 people in Denmark (median age 45 years, 80% women) and 132â€‰472 in Norway (median age 44 years, 78% women), who received their first dose of ChAdOx1-S. Among 281â€‰264 people who received ChAdOx1-S, the standardised morbidity ratio for arterial events was 0.97 (95% confidence interval 0.77 to 1.20). 59 venous thromboembolic events were observed in the vaccinated cohort compared with 30 expected based on the incidence rates in the general population, corresponding to a standardised morbidity ratio of 1.97 (1.50 to 2.54) and 11 (5.6 to 17.0) excess events per 100â€‰000 vaccinations. A higher than expected rate of cerebral venous thrombosis was observed: standardised morbidity ratio 20.25 (8.14 to 41.73); an excess of 2.5 (0.9 to 5.2) events per 100â€‰000 vaccinations. The standardised morbidity ratio for any thrombocytopenia/coagulation disorders was 1.52 (0.97 to 2.25) and for any bleeding was 1.23 (0.97 to 1.55). 15 deaths were observed in the vaccine cohort compared with 44 expected. CONCLUSIONS: Among recipients of ChAdOx1-S, increased rates of venous thromboembolic events, including cerebral venous thrombosis, were observed. For the remaining safety outcomes, results were largely reassuring, with slightly higher rates of thrombocytopenia/coagulation disorders and bleeding, which could be influenced by increased surveillance of vaccine recipients. The absolute risks of venous thromboembolic events were, however, small, and the findings should be interpreted in the light of the proven beneficial effects of the vaccine, the context of the given country, and the limitations to the generalisability of the study findings.

Immune response induced by oral administration with a Saccharomyces cerevisiae-based SARS-CoV-2 vaccine in mice. BACKGROUND: The global pandemic of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) highlights the need to develop safe and effective vaccines with a top priority. Multiple vaccine candidates are under development, and several vaccines are currently available. Efforts need to be undertaken to counter the threat of the global COVID-19 pandemic. RESULTS: We generated a Saccharomyces cerevisiae (S. cerevisiae)-based SARS-CoV-2 vaccine, EBY100/pYD1-RBD, in which the full-length receptor binding domain (RBD) of the spike protein of SARS-CoV-2 was expressed on the surface of yeast. Mice vaccinated orally with unadjuvanted EBY100/pYD1-RBD could produce significant humoral and mucosal responses as well as robust cellular immune responses. Notably, EBY100/pYD1-RBD elicited a mixed Th1/Th2-type cellular immune response with a Th1-biased immune response in a mouse model. CONCLUSIONS: Our findings highlight the importance of the RBD as a key target to design and develop vaccines against SARS-CoV-2 and provide evidence of oral administration of a S. cerevisiae-based SARS-CoV-2 vaccine eliciting significant immune responses. Most importantly, the S. cerevisiae surface display system can serve as a universal technology platform and be applied to develop other oral viral or bacterial vaccines.

Efficacy of NVX-CoV2373 Covid-19 Vaccine against the B.1.351 Variant. BACKGROUND: The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants threatens progress toward control of the coronavirus disease 2019 (Covid-19) pandemic. In a phase 1-2 trial involving healthy adults, the NVX-CoV2373 nanoparticle vaccine had an acceptable safety profile and

was associated with strong neutralizing-antibody and antigen-specific polyfunctional CD4+ T-cell responses. Evaluation of vaccine efficacy was needed in a setting of ongoing SARS-CoV-2 transmission. METHODS: In this phase 2a-b trial in South Africa, we randomly assigned human immunodeficiency virus (HIV)-negative adults between the ages of 18 and 84 years or medically stable HIV-positive participants between the ages of 18 and 64 years in a 1:1 ratio to receive two doses of either the NVX-CoV2373 vaccine (5 Î¼g of recombinant spike protein with 50 Î¼g of Matrix-M1 adjuvant) or placebo. The primary end points were safety and vaccine efficacy against laboratory-confirmed symptomatic Covid-19 at 7 days or more after the second dose among participants without previous SARS-CoV-2 infection. RESULTS: Of 6324 participants who underwent screening, 4387 received at least one injection of vaccine or placebo. Approximately 30% of the participants were seropositive for SARS-CoV-2 at baseline. Among 2684 baseline seronegative participants (94% HIV-negative and 6% HIV-positive), predominantly mild-to-moderate Covid-19 developed in 15 participants in the vaccine group and in 29 in the placebo group (vaccine efficacy, 49.4%; 95% confidence interval [CI], 6.1 to 72.8). Vaccine efficacy among HIV-negative participants was 60.1% (95% CI, 19.9 to 80.1). Of 41 sequenced isolates, 38 (92.7%) were the B.1.351 variant. Post hoc vaccine efficacy against B.1.351 was 51.0% (95% CI, -0.6 to 76.2) among the HIV-negative participants. Preliminary local and systemic reactogenicity events were more common in the vaccine group; serious adverse events were rare in both groups. CONCLUSIONS: The NVX-CoV2373 vaccine was efficacious in preventing Covid-19, with higher vaccine efficacy observed among HIV-negative participants. Most infections were caused by the B.1.351 variant. (Funded by Novavax and the Bill and Melinda Gates Foundation; ClinicalTrials.gov number, NCT04533399.).

COVID-19 vaccination and low cervical lymphadenopathy in the two week neck lump clinic - a follow up audit. The UK COVID vaccination programme has progressed at an astonishing rate since the first patients received their doses in December 2020. It is well known that other vaccines including influenza and human papilloma virus (HPV) can result in reactive lymphadenopathy in the axilla and/or neck. Patients are now presenting via the two week wait neck lump clinic with supraclavicular fossa and low neck lymphadenopathy related to COVID vaccination, and to similar one stop breast clinics with axillary lymph nodes. In an audit of 80 patients seen over a period of one month, we found COVID vaccine-related low neck lymphadenopathy in four cases (5%), with an additional rectal cancer patient thought to have metastatic disease who presented with a Virchow type node. COVID vaccine-related lymphadenopathy should be considered in the differential diagnosis of low-neck nodes if they occurred shortly after vaccination, but it is important to exclude sinister disease using ultrasound and other investigations as necessary.

Immune-Mediated Disease Flares or New-Onset Disease in 27 Subjects Following mRNA/DNA SARS-CoV-2 Vaccination. BACKGROUND: Infectious diseases and vaccines can occasionally cause new-onset or flare of immune-mediated diseases (IMDs). The adjuvanticity of the available SARS-CoV-2 vaccines is based on either TLR-7/8 or TLR-9 agonism, which is distinct from previous vaccines and is a common pathogenic mechanism in IMDs. METHODS: We evaluated IMD flares or new disease onset within 28-days of SARS-CoV-2 vaccination at five large tertiary centres in countries with early vaccination adoption, three in Israel, one in UK, and one in USA. We assessed the pattern of disease expression in terms of autoimmune, autoinflammatory, or mixed disease phenotype and organ system affected. We also evaluated outcomes. FINDINGS: 27 cases included 17 flares and 10 new onset IMDs. 23/27 received the BNT - 162b2 vaccine, 2/27 the mRNA-1273 and 2/27 the ChAdOx1 vaccines. The mean age was 54.4 Â± 19.2 years and 55% of cases were female. Among the 27 cases, 21 (78%) had at least one underlying autoimmune/rheumatic disease prior the vaccination. Among those patients with a flare or activation, four episodes occurred after receiving the second-dose and in one patient they occurred both after the first and the second-dose. In those patients with a new

onset disease, two occurred after the second-dose and in one patient occurred both after the first (new onset) and second-dose (flare). For either dose, IMDs occurred on average 4 days later. Of the cases, 20/27 (75%) were mild to moderate in severity. Over 80% of cases had excellent resolution of inflammatory features, mostly with the use of corticosteroid therapy. Other immune-mediated conditions included idiopathic pericarditis (n = 2), neurosarcoidosis with small fiber neuropathy (n = 1), demyelination (n = 1), and myasthenia gravis (n = 2). In 22 cases (81.5%), the insurgence of Adverse event following immunization (AEFI)/IMD could not be explained based on the drug received by the patient. In 23 cases (85.2%), AEFI development could not be explained based on the underlying disease/co-morbidities. Only in one case (3.7%), the timing window of the insurgence of the side effect was considered not compatible with the time from vaccine to flare. INTERPRETATION: Despite the high population exposure in the regions served by these centers, IMDs flares or onset temporally-associated with SARS-CoV-2 vaccination appear rare. Most are moderate in severity and responsive to therapy although some severe flares occurred. FUNDING: none.

SARS-CoV-2 Vaccine and Thrombosis: An Expert Consensus on Vaccine-Induced Immune Thrombotic Thrombocytopenia. Historically, the vaccination strategies developed in the second half of the 20th century have facilitated the eradication of infectious diseases. From the onset of COVID-19 pandemic to the end of April 2021, more than 150 million cases and 3 million deaths were documented worldwide with disruption of the economic and social activity, and with devastating material, physical, and psychological consequences. Reports of unusual and severe thrombotic events, including cerebral and splanchnic venous thrombosis and other autoimmune adverse reactions, such as immune thrombocytopenia or thrombotic microangiopathies in connection with some of the SARS-CoV-2 vaccines, have caused a great deal of concern within the population and the medical community. This report is intended to provide practical answers following an overview of our knowledge on these thrombotic events that are extremely rare but have serious consequences. Vaccine hesitancy threatens to reverse the progress made in controlling vaccine-preventable diseases. These adverse events must be put into perspective with an objective analysis of the facts and the issues of the vaccination strategy during this SARS-CoV-2 pandemic. Health care professionals remain the most pertinent advisors and influencers regarding vaccination decisions; they have to be supported to provide reliable and credible information on vaccines. We need to inform, reassure, and support our patients when the prescription is made. Facing these challenges and observations, a panel of experts express their insights and propose a tracking algorithm for vaccinated patients based on a 10-point guideline for decision-making on what to do and not to do.

COVID-19 vaccines induce severe hemolysis in paroxysmal nocturnal hemoglobinuria.

A flow cytometric assay to detect platelet-activating antibodies in VITT after ChAdOx1 nCov-19 vaccination. Vaccination is crucial in combatting the severe acute respiratory syndrome coronavirus 2 pandemic. The rare complication of thrombocytopenia and thrombotic complications at unusual sites after ChAdOx1 nCov-19 vaccination is caused by platelet-activating antibodies directed against platelet factor 4 (PF4). We present a widely applicable whole-blood standard flow cytometric assay to identify the pathogenic antibodies associated with vaccine-induced immune-mediated thrombotic thrombocytopenia (VITT) after ChAdOx1 nCov-19 vaccination. This assay will enable rapid diagnosis by many laboratories. This trial was registered at www.clinicaltrials.gov as #NCT04370119.

Is complement the culprit behind COVID-19 vaccine-related adverse reactions?

Subacromial-subdeltoid bursitis following COVID-19 vaccination: a case of shoulder injury related to vaccine administration (SIRVA). Vaccination injection site adverse reactions are usually mild and transient, and post-vaccination musculoskeletal symptoms, such as myalgia and arthralgia, are very common. Shoulder injury related to vaccine administration (SIRVA), defined as shoulder pain and

limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm, is a well-established condition in the medical literature, yet underreported. In such cases, subacromial-subdeltoid bursitis may occur, leading to shoulder dysfunction and ongoing pain. Millions of doses of vaccines for the prevention of COVID-19 have been administered to adults worldwide during the pandemic. We report a case of subacromial-subdeltoid bursitis after COVID-19 vaccination, related to the unintentional injection of vaccine solution into the bursa resulting in a robust immune-mediated inflammatory reaction.

COVID-19 and ANCA-associated vasculitis: recommendations for vaccine preparedness and the use of rituximab.

COVID-19 vaccination: Recommendations for management of patients with allergy or immune-based diseases. As South Africa continues to battle the second wave of SARS-CoV-2 infections, the imminent arrival of vaccines against COVID-19 offers hope. Vaccine roll-out has been accompanied by heightened media coverage that has created both excitement and anxiety, reporting on the shortened timeline of vaccine trials and approvals, as well as the recent series of anaphylaxis cases associated with the two approved mRNA COVID-19 vaccines. Patients with allergic and other immune-based diseases are subgroups especially concerned about vaccine safety and efficacy. This practice guideline offers broad recommendations for COVID-19 vaccination in various subgroups of allergic and immunebased disease, highlighting risk/benefit evaluation, and where and how routine vaccination should be altered.

Adverse Reactions Following the First Dose of ChAdOx1 nCoV-19 Vaccine and BNT162b2 Vaccine for Healthcare Workers in South Korea. BACKGROUND: We performed a prospective survey on the adverse reactions following the first dose of two types of vaccines against coronavirus disease 2019 (COVID-19) in healthcare workers (HCWs) in South Korea. METHODS: HCWs at a tertiary referral hospital in Seoul, South Korea, received a chimpanzee adenovirus-vectored vaccine (ChAdOx1 nCoV-19) or an mRNA-based vaccine (BNT162b2) between March 5 and March 26, 2021. The HCWs were asked to report adverse reactions through a mobile self-report questionnaire for three days after vaccination. RESULTS: A total of 7,625 HCWs received the first dose of ChAdOx1 or BNT162b2 vaccine during the study period. Of them, 5,866 (76.9%) HCWs (ChAdOx1, n = 5,589 [95.3%]; BNT162b2, n = 277 [4.7%]) participated at least once in the survey, of whom 77% were female and 86% were younger than 50 years. The overall adverse reaction rate was 93% in the ChAdOx1 group and 80% in the BNT162b2 group ($P < 0.001$). Both local and systemic reactions were more commonly reported in the ChAdOx1 group, and the difference was larger in systemic reactions such as fever and fatigue. In the ChAdOx1 group, the incidence of adverse reactions was significantly higher in females and those in the younger age groups, while the BNT162b2 group showed such difference according to age. CONCLUSION: In our prospective survey, vaccine-associated adverse reactions were more commonly reported in the ChAdOx1 group than in the BNT162b2 group. Females and younger age groups experienced vaccine-associated adverse reactions more frequently.

Adverse Events Following Immunization Associated with Coronavirus Disease 2019 Vaccination Reported in the Mobile Vaccine Adverse Events Reporting System. BACKGROUND: Vaccination against coronavirus disease 2019 (COVID-19) is underway globally to prevent the infection caused by the severe acute respiratory syndrome coronavirus 2. We aimed to investigate the adverse events following immunization (AEFIs) for COVID-19 among healthcare workers (HCWs). METHODS: This was a retrospective study of the AEFIs associated with the first dose of the ChAdOx1 nCoV-19 vaccine at the Kosin University Gospel Hospital from March 3 to March 22, 2021. We investigated the systemic and local adverse events during the 7 days following the vaccination using the Mobile Vaccine Adverse Events Reporting System (MVAERS) developed by our hospital. RESULTS: A total of 1,503 HCWs were vaccinated, and the data of 994 HCWs were reported in the MVAERS. The most

commonly reported AEFIs were tenderness at the injection site (94.5%), fatigue (92.9%), pain at the injection site (88.0%), and malaise (83.8%). The severity of most AEFIs was mild-to-moderate, and the severity and number of AEFIs were less in the older age group. There were no serious events requiring hospitalization, and most AEFIs improved within a few days. CONCLUSION: The AEFIs associated with the ChAdOx1 nCoV-19 vaccine were tolerable, and the use of the MVAERS was helpful in monitoring the AEFIs. The use of MVAERS will help in sharing accurate and ample information about vaccination against COVID-19.
Italian association for the study of the liver position statement on SARS-CoV2 vaccination. The vaccination campaign against Sars-CoV-2 commenced in Italy at the end of December 2020. The first ones to receive the immunization against the virus were the health workers and the residents of nursing homes, following which the vaccine would be available for the entire population, beginning with the most vulnerable individuals. SARS-CoV2 vaccines have been demonstrated to be safe for the general population, although no data for patients with liver diseases or those having undergone liver transplantation are available so far. The present position statement AISF is an attempt to suggest, based on the published data on the impact of Sars-Cov-2 infection in patients with chronic liver disease, a possible priority for vaccination for this category of patients.
COVID-19 vaccine-induced immune thrombotic thrombocytopenia: An emerging cause of splanchnic vein thrombosis.
Hemolytic crisis due to Covid-19 vaccination in a woman with cold agglutinin disease.
Factors associated with behavioral intention of free and self-paid severe acute respiratory coronavirus virus 2 (SARS-CoV-2) vaccination based on the social cognitive theory among nurses and doctors in China. OBJECTIVE: To examine the associations between factors based on the social cognitive theory (SCT) and behavioral intention among doctors and nurses in China toward free and self-paid (600 RMB or US$91) severe acute respiratory coronavirus virus 2 (SARS-CoV-2) vaccination given 80% effectiveness and rare mild side effects. DESIGN: Cross-sectional study. SETTING: Public hospitals. PARTICIPANTS: The study included 362 doctors and 1,702 nurses in major departments of 5 hospitals of 3 Chinese provinces. METHODS: An anonymous online survey was conducted from October to November 2020, facilitated by hospital administrators through online WeChat/QQ working groups. Data on outcome expectations, self-efficacy, norms, and COVID-19-related work experiences were collected. Multivariate logistic regression models were used for data analyses. RESULTS: The logistic regression analysis showed that physical (eg, protective effect of vaccination) and self-evaluative outcome expectations (eg, anticipated regret), self-efficacy, norms (eg, descriptive norm, subjective norm, professional norm, and moral norm), and job satisfaction were significantly and positively associated with the free and self-paid SARS-CoV-2 vaccination intention outcomes among doctors and nurses, adjusted for background variables. Doctors who had engaged in COVID-19-related work reported higher self-paid vaccination intention. CONCLUSIONS: Health promotion is needed to improve the uptake of SARS-CoV-2 vaccination among healthcare workers. Such interventions may consider modifying the identified factors of vaccination intention, including strengthening perceived efficacy, positive feelings about vaccination, the need to avoid future regret, self-efficacy, and social norms. Future studies should examine the actual behavior patterns of SARS-CoV-2 vaccination, and the efficacy of promotion intervention should be tested in randomized controlled studies.
The Associations Between Sociodemographic Characteristics and Trust in Physician With Immunization Service Use in U.S. Chinese Older Adults. This study investigated sociodemographic factors for immunization care use and the relationship between trust in physician (TIP) and immunization service use in older Chinese Americans. Data were collected through the Population Study of Chinese Elderly, including survey information of 3,157 older adults in the Greater Chicago

area. Regression results showed that the odds of getting vaccinated were higher for those who were older, female, and had higher education and income. After adjusting for the covariates, higher TIP was associated with greater immunization service use. The highest tertile of TIP was associated with higher odds of using immunization service (OR 2.19, 95% CI [1.76, 2.72]), especially for flu and pneumonia vaccines. Findings suggests that immunization service use may be increased by improving TIP and promoting targeted health care management plans for racial/ethnic minorities, which is highly relevant to increase the vaccination rate and contain the pandemic as the COVID-19 vaccine is available.

Accelerated vaccine rollout is imperative to mitigate highly transmissible COVID-19 variants. BACKGROUND: More contagious variants of SARS-CoV-2 have emerged around the world, sparking concerns about impending surge in cases and severe outcomes. Despite the development of effective vaccines, rollout has been slow. We evaluated the impact of accelerated vaccine distribution on curbing the disease burden of novel SARS-CoV-2 variants. METHODS: We used an agent-based model of SARS-CoV-2 transmission and vaccination to simulate the spread of novel variants with S-Gene Target Failure (SGTF) in addition to the original strain. We incorporated age-specific risk and contact patterns and implemented a two-dose vaccination campaign in accord with CDC-recommended prioritization. As a base case, we projected hospitalizations and deaths at a daily vaccination rate of 1 million doses in the United States (US) and compared with accelerated campaigns in which daily doses were expanded to 1.5, 2, 2.5, or 3 million. FINDINGS: We found that at a vaccination rate of 1 million doses per day, an emergent SGTF variant that is 20-70% more transmissible than the original variant would become dominant within 2 to 9 weeks, accounting for as much as 99% of cases at the outbreak peak. Our results show that accelerating vaccine delivery would substantially reduce severe health outcomes. For a SGTF with 30% higher transmissibility, increasing vaccine doses from 1 to 3 million per day would avert 152,048 (95% CrI: 134,772-168,696) hospitalizations and 48,448 (95% CrI: 42,042-54,285) deaths over 300 days. Accelerated vaccination would also prevent additional COVID-19 waves that would otherwise be fuelled by waning adherence to non-pharmaceutical interventions (NPIs). INTERPRETATION: We found that the current pace of vaccine rollout is insufficient to prevent the exacerbation of the pandemic that will be attributable to the novel, more contagious SARS-CoV-2 variants. Accelerating the vaccination rate should be a public health priority for averting the expected surge in COVID-19 hospitalizations and deaths that would be associated with widespread dissemination of the SGTF variants. Our results underscore the need to bolster the production and distribution of COVID-19 vaccines, to rapidly expand vaccination priority groups and distribution sites.

Varicella-zoster virus reactivation after SARS-CoV-2 BNT162b2 mRNA vaccination: Report of 5 cases.

Immune thrombocytopenic purpura after SARS-CoV-2 vaccine.

Anaphylaxis associated with the mRNA COVID-19 vaccines: Approach to allergy investigation. Reports about cases of anaphylaxis to mRNA vaccines have created anxiety in the community and could increase vaccine hesitancy in the population. There are no standardized protocols for allergy testing to mRNA vaccines. PEG is currently the only excipient in both vaccines with recognized allergenic potential. Allergy to PEG has been reported with increasing frequency over recent years, often in patients who had repeated systemic allergic reactions/anaphylaxis to several classes of drugs before diagnosis. Proposed protocols are based on current knowledge about potential mechanisms of anaphylaxis associated with the mRNA vaccines, and the assumption that polyethylene glycol (PEG) is the most likely culprit. Allergy testing to PEGs and mRNA vaccines is complex and carries the risk of anaphylaxis and should be conducted in a specialist drug allergy center. Appropriate PEG-free emergency medical treatment and supervision should be readily available.

Acute rejection after anti-SARS-CoV-2 mRNA vaccination in a patient who underwent a kidney transplant.

A case of gross hematuria and IgA nephropathy flare-up following SARS-CoV-2 vaccination.

Immune response to SARS-CoV-2 infection and vaccination in patients receiving kidney replacement therapy. In this issue of Kidney International, the initial experience regarding the immunogenicity of prior coronavirus disease 2019 (COVID-19) infection and the response to the COVID-19 vaccines among patients on maintenance dialysis and kidney transplant recipients is summarized. Preliminary data suggest that there is durability of immune response after COVID-19 infection. Although immune response to the first dose of vaccine is less in infection-naÃ¯ve patients than healthy individuals in both groups, after the second vaccine dose a significant portion of patients receiving maintenance dialysis develop robust antibody titers, whereas kidney transplant recipients show a less-strong immune response.

The incremental burden of invasive pneumococcal disease associated with a decline in childhood vaccination using a dynamic transmission model in Japan: A secondary impact of COVID-19. The coronavirus disease 2019 (COVID-19) pandemic has disrupted childhood vaccinations, including pneumococcal conjugate vaccine (PCV). Evaluating the possible impact on the invasive pneumococcal disease (IPD) incidence associated with a decline in childhood pneumococcal vaccination is important to advocate the PCV programs. Using a deterministic, dynamic transmission model, the differential incidence and burden of IPD in children younger than 5 years in Japan were estimated between the rapid vaccination recovery (January 2021) and the delayed vaccination recovery (April 2022) scenarios for the next 10 years. In our model, the IPD incidence was reduced from 11.9/100,000 in 2019 to 6.3/100,000 in 2020, caused by a reduced transmission rate due to the COVID-19 mitigation measures. Assuming a recovery in the transmission rate in 2022 April, the incidence of IPD was estimated to increase with maximal incidence of 12.1 and 13.1/100,000 children under 5 years in the rapid and the delayed vaccination recovery scenarios. The difference in the total IPD incidence between these two scenarios was primarily driven by vaccine serotypes IPD incidence. The difference of incidence was not observed between the two scenarios after 2025. The persistent decline in childhood pneumococcal vaccination rates due to the impact of COVID-19 might lead to an increased IPD incidence and an incremental disease burden.

Cancer and COVID-19 vaccines: a complex global picture.

Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: a prospective observational study. BACKGROUND: The Pfizer-BioNTech (BNT162b2) and the Oxford-AstraZeneca (ChAdOx1 nCoV-19) COVID-19 vaccines have shown excellent safety and efficacy in phase 3 trials. We aimed to investigate the safety and effectiveness of these vaccines in a UK community setting. METHODS: In this prospective observational study, we examined the proportion and probability of self-reported systemic and local side-effects within 8 days of vaccination in individuals using the COVID Symptom Study app who received one or two doses of the BNT162b2 vaccine or one dose of the ChAdOx1 nCoV-19 vaccine. We also compared infection rates in a subset of vaccinated individuals subsequently tested for SARS-CoV-2 with PCR or lateral flow tests with infection rates in unvaccinated controls. All analyses were adjusted by age (â‰¤55 years vs >55 years), sex, health-care worker status (binary variable), obesity (BMI <30 kg/m(2)vs â‰¥30 kg/m(2)), and comorbidities (binary variable, with or without comorbidities). FINDINGS: Between Dec 8, and March 10, 2021, 627â€‰383 individuals reported being vaccinated with 655â€‰590 doses: 282â€‰103 received one dose of BNT162b2, of whom 28â€‰207 received a second dose, and 345â€‰280 received one dose of ChAdOx1 nCoV-19. Systemic side-effects were reported by 13Â·5% (38â€‰155 of 282â€‰103) of individuals after the first dose of BNT162b2, by 22Â·0% (6216 of 28â€‰207) after the second dose of BNT162b2, and by 33Â·7% (116â€‰473 of 345â€‰280) after the first dose of ChAdOx1 nCoV-19. Local side-effects were reported by 71Â·9% (150â€‰023 of 208â€‰767) of individuals after the first dose of BNT162b2, by 68Â·5% (9025 of

13â€‰179) after the second dose of BNT162b2, and by 58Â·7% (104â€‰282 of 177â€‰655) after the first dose of ChAdOx1 nCoV-19. Systemic side-effects were more common (1Â·6 times after the first dose of ChAdOx1 nCoV-19 and 2Â·9 times after the first dose of BNT162b2) among individuals with previous SARS-CoV-2 infection than among those without known past infection. Local effects were similarly higher in individuals previously infected than in those without known past infection (1Â·4 times after the first dose of ChAdOx1 nCoV-19 and 1Â·2 times after the first dose of BNT162b2). 3106 of 103â€‰622 vaccinated individuals and 50â€‰340 of 464â€‰356 unvaccinated controls tested positive for SARS-CoV-2 infection. Significant reductions in infection risk were seen starting at 12 days after the first dose, reaching 60% (95% CI 49-68) for ChAdOx1 nCoV-19 and 69% (66-72) for BNT162b2 at 21-44 days and 72% (63-79) for BNT162b2 after 45-59 days. INTERPRETATION: Systemic and local side-effects after BNT162b2 and ChAdOx1 nCoV-19 vaccination occur at frequencies lower than reported in phase 3 trials. Both vaccines decrease the risk of SARS-CoV-2 infection after 12 days. FUNDING: ZOE Global, National Institute for Health Research, Chronic Disease Research Foundation, National Institutes of Health, UK Medical Research Council, Wellcome Trust, UK Research and Innovation, American Gastroenterological Association.

Incidence of cerebral venous thrombosis and COVID-19 vaccination: possible causal effect or just chance?

Safety of an inactivated SARS-CoV-2 vaccine among healthcare workers in China. Background: Although the inactivated SARS-CoV-2 vaccine (CoronaVac) has undergone preclinical tests and clinical trials evaluating its efficacy and safety, few data have been reported in the post-licensure real-world setting. We aimed to assess the safety of the vaccine among healthcare workers.Methods: A self-administered online survey on monitoring adverse reactions post vaccination was conducted among the staff who worked at and were vaccinated in a tertiary hospital in Taizhou, China, from February 24 to 7 March 2021. A total of 1526 subjects responded to the questionnaire when they received an e-mail or an e-poster on WeChat.Results: The incidences of overall adverse reactions after the first and second injections were 15.6% (238/1526) and 14.6% (204/1397), respectively. The most common adverse reaction was localized pain at the injection site, with an incidence of 9.6% and 10.7% after each dose, accounting for 61.8% and 73.0% of adverse reactions, respectively. Fatigue, muscle pain, and headache were the most common systemic adverse reactions.Conclusions: These findings implied that the inactivated CoronaVac vaccine has an acceptable safety profile among healthcare workers due to the low incidence of self-reported adverse reactions. This may boost public confidence in nationwide mass vaccination campaigns.

US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021. IMPORTANCE: Cerebral venous sinus thrombosis (CVST) with thrombocytopenia, a rare and serious condition, has been described in Europe following receipt of the ChAdOx1 nCoV-19 vaccine (Oxford/AstraZeneca), which uses a chimpanzee adenoviral vector. A mechanism similar to autoimmune heparin-induced thrombocytopenia (HIT) has been proposed. In the US, the Ad26.COV2.S COVID-19 vaccine (Janssen/Johnson & Johnson), which uses a human adenoviral vector, received Emergency Use Authorization (EUA) on February 27, 2021. By April 12, 2021, approximately 7 million Ad26.COV2.S vaccine doses had been given in the US, and 6 cases of CVST with thrombocytopenia had been identified among the recipients, resulting in a temporary national pause in vaccination with this product on April 13, 2021. OBJECTIVE: To describe reports of CVST with thrombocytopenia following Ad26.COV2.S vaccine receipt. DESIGN, SETTING, AND PARTICIPANTS: Case series of 12 US patients with CVST and thrombocytopenia following use of Ad26.COV2.S vaccine under EUA reported to the Vaccine Adverse Event Reporting System (VAERS) from March 2 to April 21, 2021 (with follow-up reported through April 21, 2021). EXPOSURES: Receipt of Ad26.COV2.S vaccine. MAIN OUTCOMES AND MEASURES: Clinical course, imaging, laboratory

tests, and outcomes after CVST diagnosis obtained from VAERS reports, medical record review, and discussion with clinicians. RESULTS: Patients' ages ranged from 18 to younger than 60 years; all were White women, reported from 11 states. Seven patients had at least 1 CVST risk factor, including obesity (nâ€‰=â€‰6), hypothyroidism (nâ€‰=â€‰1), and oral contraceptive use (nâ€‰=â€‰1); none had documented prior heparin exposure. Time from Ad26.COV2.S vaccination to symptom onset ranged from 6 to 15 days. Eleven patients initially presented with headache; 1 patient initially presented with back pain and later developed headache. Of the 12 patients with CVST, 7 also had intracerebral hemorrhage; 8 had non-CVST thromboses. After diagnosis of CVST, 6 patients initially received heparin treatment. Platelet nadir ranged from 9â€‰Ã—103/ÂµL to 127â€‰Ã—103/ÂµL. All 11 patients tested for the heparin-platelet factor 4 HIT antibody by enzyme-linked immunosorbent assay (ELISA) screening had positive results. All patients were hospitalized (10 in an intensive care unit [ICU]). As of April 21, 2021, outcomes were death (nâ€‰=â€‰3), continued ICU care (nâ€‰=â€‰3), continued non-ICU hospitalization (nâ€‰=â€‰2), and discharged home (nâ€‰=â€‰4). CONCLUSIONS AND RELEVANCE: The initial 12 US cases of CVST with thrombocytopenia after Ad26.COV2.S vaccination represent serious events. This case series may inform clinical guidance as Ad26.COV2.S vaccination resumes in the US as well as investigations into the potential relationship between Ad26.COV2.S vaccine and CVST with thrombocytopenia.

Deep vein thrombosis more than two weeks after vaccination against COVID-19. Two young, healthy doctors were diagnosed with deep vein thrombosis 27 and 29 days, respectively, after receiving the AstraZeneca ChAdOx1 nCoV-19 vaccine. Both had a negative D-dimer test and a low Wells score.

Fatal cerebral haemorrhage after COVID-19 vaccine. BACKGROUND: New vaccines against COVID-19 are being rolled out globally. AstraZeneca's vaccine ChAdOx1 nCoV-19 was not known to cause vaccine-induced immune thrombotic thrombocytopenia (VITT) at the time of this case. CASE PRESENTATION: The patient was a previously healthy woman in her thirties with headaches that developed one week after vaccination with ChAdOx1 nCoV-19. Three days later, her condition deteriorated rapidly, and she presented to the emergency department with slurred speech, uncoordinated movements and reduced consciousness. Symptoms progressed to left-sided hemiparesis and her level of consciousness deteriorated. Computed tomography (CT) of the head showed a large right-sided haemorrhage and incipient herniation. She was found to have severe thrombocytopenia 37Â xÂ 109/l, (ref 145Â -Â 390Â xÂ 109/l). In spite of efforts to reduce intracranial pressure, the patient died the following day. Post mortem examination revealed antibodies to PF4, and fresh small thrombi were found in the transverse sinus, frontal lobe and pulmonary artery. INTERPRETATION: Severe thrombocytopenia and antibodies to PF4Â make a diagnosis of vaccine-induced immune thrombotic thrombocytopenia (VITT) likely.

COVID-19: vaccination problems. This minireview addresses problems of financing the vaccine development, regulatory questions, the ethics and efficacy of vaccine prioritization strategies and the coverage of variant viruses by current vaccines. Serious adverse effects observed with adenovirus vectored vaccines and mRNA vaccines in mass vaccination campaigns are reported. The ethical problems of continuing with placebo controlled vaccine trials and alternative clinical trial protocols are discussed as well as concrete vaccination issues such as the splitting of doses, the delaying of the second dose, the immunization with two different vaccine types and the need of vaccinating seropositive subjects. Strategies to increase vaccine acceptance in the population are shortly mentioned.

Assessing vaccine durability in randomized trials following placebo crossover. Randomized vaccine trials are used to assess vaccine efficacy (VE) and to characterize the durability of vaccine-induced protection. If efficacy is demonstrated, the treatment of placebo volunteers becomes an

issue. For COVID-19 vaccine trials, there is broad consensus that placebo volunteers should be offered a vaccine once efficacy has been established. This will likely lead to most placebo volunteers crossing over to the vaccine arm, thus complicating the assessment of long term durability. We show how to analyze durability following placebo crossover and demonstrate that the VE profile that would be observed in a placebo controlled trial is recoverable in a trial with placebo crossover. This result holds no matter when the crossover occurs and with no assumptions about the form of the efficacy profile. We only require that the VE profile applies to the newly vaccinated irrespective of the timing of vaccination. We develop different methods to estimate efficacy within the context of a proportional hazards regression model and explore via simulation the implications of placebo crossover for estimation of VE under different efficacy dynamics and study designs. We apply our methods to simulated COVID-19 vaccine trials with durable and waning VE and a total follow-up of 2 years.
Leukocytoclastic vasculitis flare following the COVID-19 vaccine.
Coronavirus disease 2019 (COVID-19) vaccination in systemic lupus erythematosus and anti-neutrophil cytoplasmic antibody-associated vasculitis.
Analysis of Thrombotic Adverse Reactions of COVID-19 AstraZeneca Vaccine Reported to EudraVigilance Database. The development of safe, effective, affordable vaccines against COVID-19 remains the cornerstone to mitigating this pandemic. Early in December 2020, multiple research groups had designed potential vaccines. From 11 March 2021, several European countries temporarily suspended the use of the Oxford-AstraZeneca vaccine amid reports of blood clot events and the death of a vaccinated person, despite the European Medicines Agency (EMA) and the World Health Organization's assurance that there was no indication that vaccination was linked. This study aimed to identify and analyse the thrombotic adverse reactions associated with the Oxford-AstraZeneca vaccine. This was a retrospective descriptive study using spontaneous reports submitted to the EudraVigilance database in the period from 17 February to 12 March 2021. There were 54,571 adverse reaction reports, of which 28 were associated with thrombotic adverse reactions. Three fatalities were related to pulmonary embolism; one fatality to thrombosis. With 17 million people having had the AstraZeneca vaccine, these are extremely rare events The EMA's Pharmacovigilance Risk Assessment Committee (18 March 2021) concluded that the vaccine was safe, effective and the benefits outweighed the risks. Conducting further analyses based on more detailed thrombotic adverse event reports, including patients' characteristics and comorbidities, may enable assessment of the causality with higher specificity.
Impaired Humoral Response in Renal Transplant Recipients to SARS-CoV-2 Vaccination with BNT162b2 (Pfizer-BioNTech). The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) has a major impact on transplant recipients, with mortality rates up to 20%. Therefore, the effect of established messenger RNA (mRNA)-based SARS-CoV-2 vaccines have to be evaluated for solid organ transplant patients (SOT) since they are known to have poor responses after vaccination. We investigated the SARS-CoV-2 immune response via SARS-CoV-2 IgG detection in 23 renal transplant recipients after two doses of the mRNA-based SARS-CoV-2 vaccine BNT162b2 following the standard protocol. The antibody response was evaluated once with an anti-SARS-CoV-2 IgG CLIA 15.8 +/- 3.0 days after the second dose. As a control, SARS-CoV-2 IgG was determined in 23 healthcare workers (HCW) and compared to the patient cohort. Only 5 of 23 (22%) renal transplant recipients were tested positive for SARS-CoV-2 IgG antibodies after the second dose of vaccine. In contrast, all 23 (100%) HCWs were tested positive for antibodies after the second dose. Thus, the humoral response of renal transplant recipients after two doses of the mRNA-based vaccine BNT162b2 (Pfizer-BioNTech, Kronach, Germany) is impaired and significantly lower compared to healthy controls (22% vs. 100%; p = 0.0001). Individual vaccination strategies might be beneficial in these vulnerable patients.

Association between Influenza Vaccination and Positive SARS-CoV-2 IgG and IgM Tests in the General Population of Katowice Region, Poland. The explanation of the potential interaction between the influenza vaccine and SARS-CoV-2 infection is urgently needed in the public health. The objective of the study is to compare the occurrence of positive SARS-CoV-2 IgG and IgM tests in subjects with and without recent (last year) seasonal influenza vaccinations. In a cross-sectional study located in three large towns of Silesian Voivodeship (Poland), we studied 5479 subjects in which 1253 (22.9%) had a positive anti-SARS-CoV-2 IgG test and 400 (7.3%) had a positive anti-SARS-CoV-2 IgM test. Seasonal influenza vaccination remains an independent factor protecting against positive IgG tests (OR = 0.68; 0.55-0.83). The effect is not apparent with IgM antibodies. The obtained results confirmed that the serological status of SARS-CoV-2 infection depends on vaccination against seasonal influenza.

Thrombocytopenia and Intracranial Venous Sinus Thrombosis after "COVID-19 Vaccine AstraZeneca" Exposure. BACKGROUND: As of 8 April 2021, a total of 2.9 million people have died with or from the coronavirus infection causing COVID-19 (Corona Virus Disease 2019). On 29 January 2021, the European Medicines Agency (EMA) approved a COVID-19 vaccine developed by Oxford University and AstraZeneca (AZD1222, ChAdOx1 nCoV-19, COVID-19 vaccine AstraZeneca, Vaxzevria, Covishield). While the vaccine prevents severe course of and death from COVID-19, the observation of pulmonary, abdominal, and intracranial venous thromboembolic events has raised concerns. OBJECTIVE: To describe the clinical manifestations and the concerning management of patients with cranial venous sinus thrombosis following first exposure to the "COVID-19 vaccine AstraZeneca". METHODS: Patient files, laboratory findings, and diagnostic imaging results, and endovascular interventions of three concerning patients were evaluated in retrospect. RESULTS: Three women with intracranial venous sinus thrombosis after their first vaccination with "COVID-19 vaccine AstraZeneca" were encountered. Patient #1 was 22 years old and developed headaches four days after the vaccination. On day 7, she experienced a generalized epileptic seizure. Patient #2 was 46 years old. She presented with severe headaches, hemianopia to the right, and mild aphasia 13 days after the vaccination. MRI showed a left occipital intracerebral hemorrhage. Patient #3 was 36 years old and presented 17 days after the vaccination with acute somnolence and right-hand hemiparesis. The three patients were diagnosed with extensive venous sinus thrombosis. They were managed by heparinization and endovascular recanalization of their venous sinuses. They shared similar findings: elevated levels of D-dimers, platelet factor 4 antiplatelet antibodies, corona spike protein antibodies, combined with thrombocytopenia. Under treatment with low-molecular-weight heparin, platelet counts normalized within several days. CONCLUSION: Early observations insinuate that the exposure to the "COVID-19 vaccine AstraZeneca" might trigger the expression of antiplatelet antibodies, resulting in a condition with thrombocytopenia and venous thrombotic events (e.g., intracranial venous sinus thrombosis). These patients' treatment should address the thrombo-embolic manifestations, the coagulation disorder, and the underlying immunological phenomena.

Strategies for Immunomonitoring after Vaccination and during Infection. Immunomonitoring is the study of an individual's immune responses over the course of vaccination or infection. In the infectious context, exploring the innate and adaptive immune responses will help to investigate their contribution to viral control or toxicity. After vaccination, immunomonitoring of the correlate(s) and surrogate(s) of protection is a major asset for measuring vaccine immune efficacy. Conventional immunomonitoring methods include antibody-based technologies that are easy to use. However, promising sensitive high-throughput technologies allowed the emergence of holistic approaches. This raises the question of data integration methods and tools. These approaches allow us to increase our knowledge on immune mechanisms as well as the identification of key effectors of the immune response. However, the depiction of relevant findings requires a well-rounded consideration beforehand about the hypotheses, conception, organization and objectives of the

immunomonitoring. Therefore, well-standardized and comprehensive studies fuel insight to design more efficient, rationale-based vaccines and therapeutics to fight against infectious diseases. Hence, we will illustrate this review with examples of the immunomonitoring approaches used during vaccination and the COVID-19 pandemic.
Immune Response Visualized In Vivo by [18F]-FDG PET/CT after COVID-19 Vaccine. Worldwide deployment of COVID-19 vaccines is in progress. Recent immune activation following vaccination can sometimes be seen in fluorine-18-fluorodeoxyglucose positron emission tomography/computed tomography ([18F]-FDG PET/CT). As previously evidenced, FDG-avid axillary lymph node(s) are common in patients receiving vaccines against SARS-CoV-2, influenza virus, or human papillomavirus, and reflect a regional immune response. In addition, these findings may also be accompanied by an increased spleen glucose metabolism after the COVID-19 vaccine, which captures a systemic immune response. Hence, we provide here a clinical example demonstrating that immune response could be associated with increased glucose metabolism in lymphoid organs such as lymph nodes and the spleen, which are critical modulators of T cell immunity. We believe that it is of paramount importance that nuclear physicians should be able to recognize clinical and imaging features of such immune responses upon vaccination for COVID-19 and beyond.
A Rare Case of Cerebral Venous Thrombosis and Disseminated Intravascular Coagulation Temporally Associated to the COVID-19 Vaccine Administration. Globally, at the time of writing (20 March 2021), 121.759.109 confirmed COVID-19 cases have been reported to the WHO, including 2.690.731 deaths. Globally, on 18 March 2021, a total of 364.184.603 vaccine doses have been administered. In Italy, 3.306.711 confirmed COVID-19 cases with 103.855 deaths have been reported to WHO. In Italy, on 9 March 2021, a total of 6.634.450 vaccine doses have been administered. On 15 March 2021, Italian Medicines Agency (AIFA) decided to temporarily suspend the use of the AstraZeneca COVID-19 vaccine throughout the country as a precaution, pending the rulings of the European Medicines Agency (EMA). This decision was taken in line with similar measures adopted by other European countries due to the death of vaccinated people. On 18 March 2021, EMA's safety committee concluded its preliminary review about thromboembolic events in people vaccinated with COVID-19 Vaccine AstraZeneca at its extraordinary meeting, confirming the benefits of the vaccine continue to outweigh the risk of side effects, however, the vaccine may be associated with very rare cases of blood clots associated with thrombocytopenia, i.e., low levels of blood platelets with or without bleeding, including rare cases of cerebral venous thrombosis (CVT). We report the case of a 54-year-old woman who developed disseminated intravascular coagulation (DIC) with multi-district thrombosis 12 days after the AstraZeneca COVID-19 vaccine administration. A brain computed tomography (CT) scan showed multiple subacute intra-axial hemorrhages in atypical locations, including the right frontal and the temporal lobes. A plain old balloon angioplasty (POBA) of the right coronary artery was performed, without stent implantation, with restoration of distal flow, but with persistence of extensive thrombosis of the vessel. A successive thorax angio-CT added the findings of multiple contrast filling defects with multi-vessel involvement: at the level of the left upper lobe segmental branches, of left interlobar artery, of the right middle lobe segmental branches and of the right interlobar artery. A brain magnetic resonance imaging (MRI) in the same day showed the presence of an acute basilar thrombosis associated with the superior sagittal sinus thrombosis. An abdomen angio-CT showed filling defects at the level of left portal branch and at the level of right suprahepatic vein. Bilaterally, it was adrenal hemorrhage and blood in the pelvis. An evaluation of coagulation factors did not show genetic alterations so as the nasopharyngeal swab ruled out a COVID-19 infection. The patient died after 5 days of hospitalization in intensive care.
Current Immunological and Clinical Perspective on Vaccinations in Multiple Sclerosis Patients: Are They Safe after All? Vaccines work by stimulating the immune system, and their immunogenicity

is key in achieving protection against specific pathogens. Questions have been raised whether in Multiple Sclerosis (MS) patients they could induce disease exacerbation and whether vaccines could possibly act as a trigger in the onset of MS in susceptible populations. So far, no correlation has been found between the vaccinations against influenza, hepatitis B, tetanus, human papillomavirus, measles, mumps, rubella, varicella zoster, tuberculosis, yellow fever, or typhoid fever and the risk of MS. Further research is needed for the potential protective implications of the tetanus and Bacillus Calmette-Guerin vaccines in MS patients. Nowadays with the emerging coronavirus disease 2019 (COVID-19) and recent vaccinations approval and arrival, the risk-benefit in MS patients with regards to safety and efficacy of COVID-19 vaccination in those treated with immunosuppressive therapies is of paramount importance. In this manuscript, we demonstrate how different vaccine types could be related to the immunopathogenesis of MS and discuss the risks and benefits of different vaccinations in MS patients.
Prevalence of COVID-19 Vaccine Side Effects among Healthcare Workers in the Czech Republic. BACKGROUND: COVID-19 vaccine side effects have a fundamental role in public confidence in the vaccine and its uptake process. Thus far, the evidence on vaccine safety has exclusively been obtained from the manufacturer-sponsored studies; therefore, this study was designed to provide independent evidence on Pfizer-BioNTech COVID-19 vaccine side effects. METHODS: A cross-sectional survey-based study was carried out between January and February 2021 to collect data on the side effects following the COVID-19 vaccine among healthcare workers in the Czech Republic. The study used a validated questionnaire with twenty-eight multiple-choice items covering the participants' demographic data, medical anamneses, COVID-19-related anamneses, general, oral, and skin-related side effects. RESULTS: Injection site pain (89.8%), fatigue (62.2%), headache (45.6%), muscle pain (37.1%), and chills (33.9%) were the most commonly reported side effects. All the general side effects were more prevalent among the â‰¤43-year-old group, and their duration was mainly one day (45.1%) or three days (35.8%) following the vaccine. Antihistamines were the most common drugs associated with side effects, thus requiring further investigation. The people with two doses were generally associated with a higher frequency of side effects. CONCLUSIONS: The distribution of side effects among Czech healthcare workers was highly consistent with the manufacturer's data, especially in terms of their association with the younger age group and the second dose. The overall prevalence of some local and systemic side effects was higher than the manufacturer's report. Further independent studies on vaccine safety are strongly required to strengthen public confidence in the vaccine.
BNT162b2 mRNA COVID-19 vaccine-induced chilblain-like lesions reinforces the hypothesis of their relationship with SARS-CoV-2.
A flare of pre-existing erythema multiforme following BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine.
Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients - United States, April 2021. On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Janssen COVID-19 (Ad.26.COV2.S) vaccine (Janssen Biotech, Inc., a Janssen Pharmaceutical company, Johnson & Johnson; New Brunswick, New Jersey), and on February 28, 2021, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for its use in persons aged â‰¥18 years (1,2). On April 13, 2021, CDC and FDA recommended a pause in the use of the Janssen COVID-19 vaccine after reports of six U.S. cases of cerebral venous sinus thrombosis (CVST) with thrombocytopenia, a rare thromboembolic syndrome, among Janssen COVID-19 vaccine recipients (3). Two emergency ACIP meetings were rapidly convened to review reported cases of thrombosis with thrombocytopenia syndrome (TTS) and to consider updated recommendations for use of the

Janssen COVID-19 vaccine in the United States. On April 23, 2021, after a discussion of the benefits and risks of resuming vaccination, ACIP reaffirmed its interim recommendation for use of the Janssen COVID-19 vaccine in all persons aged â‰¥18 years under the FDA's EUA, which now includes a warning that rare clotting events might occur after vaccination, primarily among women aged 18-49 years. Patient and provider education about the risk for TTS with the Janssen COVID-19 vaccine, especially among women aged <50 years, as well as the availability of alternative COVID-19 vaccines, is required to guide vaccine decision-making and ensure early recognition and clinical management of TTS.

COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program - Kentucky, March 2021. Although COVID-19 mRNA vaccines demonstrated high efficacy in clinical trials (1), they were not 100% efficacious. Thus, some infections postvaccination are expected. Limited data are available on effectiveness in skilled nursing facilities (SNFs) and against emerging variants. The Kentucky Department for Public Health (KDPH) and a local health department investigated a COVID-19 outbreak in a SNF that occurred after all residents and health care personnel (HCP) had been offered vaccination. Among 83 residents and 116 HCP, 75 (90.4%) and 61 (52.6%), respectively, received 2 vaccine doses. Twenty-six residents and 20 HCP received positive test results for SARS-CoV-2, the virus that causes COVID-19, including 18 residents and four HCP who had received their second vaccine dose >14 days before the outbreak began. An R.1 lineage variant was detected with whole genome sequencing (WGS). Although the R.1 variant has multiple spike protein mutations, vaccinated residents and HCP were 87% less likely to have symptomatic COVID-19 compared with those who were unvaccinated. Vaccination of SNF populations, including HCP, is critical to reduce the risk for SARS-CoV-2 introduction, transmission, and severe outcomes in SNFs. An ongoing focus on infection prevention and control practices is also essential.

Diagnosis and Management of Cerebral Venous Sinus Thrombosis With Vaccine-Induced Immune Thrombotic Thrombocytopenia.

[Temporary suspension of AstraZeneca's vaccine; a reconstruction]. In the middle of the worldwide COVID-19 crisis, the whole of Europe was alarmed about a possible side effect of the AstraZeneca vaccine against COVID-19. Consequently, the use of this AstraZeneca vaccine was temporarily suspended in many European nations including the Netherlands. In this article, we chronologically describe the decisions that were made about the use of this vaccine in the Netherlands and we discuss the risk-benefit ratios of these actions as well as possible non-medical reasons that may explain why these actions were taken.

Lack of immune response after mRNA vaccination to SARS-CoV-2 in a solid organ transplant patient. The recent approval and distribution of vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been a major development in the fight against the current coronavirus disease 2019 (COVID-19) pandemic. The first two vaccines approved in the United States, mRNA-1273, and BNT162b2, are both messenger RNA (mRNA) based and highly effective in immunocompetent persons, but efficacy in patients on immunosuppressants has not been established. Additionally, data suggests these patients are less likely than immunocompetent people to develop neutralizing antibodies after COVID-19 infection. Given the high risk of poor outcomes in organ transplant and immunosuppressed patients, effective vaccination is paramount in this group. We present the first reported case of a solid organ transplant patient who failed to achieve seroconversion after two doses of mRNA vaccine. This case has significant implications about how immunosuppressed patients should be counseled about SARS-CoV-2 vaccination and the protection provided. Physicians should remain clinically suspicious for infection with SARS-CoV-2 despite vaccination status in solid organ transplant patients.

Herpes zoster emergence following mRNA COVID-19 vaccine.
Potential culprits for immediate hypersensitivity reactions to BNT162b2 mRNA COVID-19 vaccine: not just PEG.
COVID-19 Vaccines: Current Understanding on Immunogenicity, Safety, and Further Considerations. The world has entered the second wave of the COVID-19 pandemic, and its intensity is significantly higher than that of the first wave of early 2020. Many countries or regions have been forced to start the second round of lockdowns. To respond rapidly to this global pandemic, dozens of COVID-19 vaccine candidates have been developed and many are undergoing clinical testing. Evaluating and defining effective vaccine candidates for human use is crucial for prioritizing vaccination programs against COVID-19. In this review, we have summarized and analyzed the efficacy, immunogenicity and safety data from clinical reports on different COVID-19 vaccines. We discuss the various guidelines laid out for the development of vaccines and the importance of biological standards for comparing the performance of vaccines. Lastly, we highlight the key remaining challenges, possible strategies for addressing them and the expected improvements in the next generation of COVID-19 vaccines.
Characteristics of endothelial corneal transplant rejection following immunisation with SARS-CoV-2 messenger RNA vaccine. AIM: We report two cases of endothelial corneal allograft rejection following immunisation with SARS-CoV-2 messenger RNA (mRNA) vaccine BNT162b2 and describe the implications for management of transplant recipients postvaccination for COVID-19. METHODS: A 66-year-old woman with Fuchs endothelial corneal dystrophy (FECD) and a unilateral Descemet's membrane endothelial keratoplasty (DMEK) transplant received COVID-19 mRNA vaccine BNT162b2 14 days post-transplant. Seven days later, she presented with symptoms and signs of endothelial graft rejection. An 83-year-old woman with bilateral DMEK transplants for FECD 3 and 6â€‰years earlier developed simultaneous acute endothelial rejection in both eyes, 3â€‰weeks post second dose of COVID-19 mRNA vaccine BNT162b2. Rejection in both cases was treated successfully with topical corticosteroids. CONCLUSIONS: We believe this is the first report of temporal association between corneal transplant rejection following immunisation against COVID-19 and the first report of DMEK rejection following any immunisation. We hypothesise that the allogeneic response may have been initiated by the host antibody response following vaccination. Clinicians and patients should be aware of the potential of corneal graft rejection associated with vaccine administration and may wish to consider vaccination in advance of planned non-urgent keratoplasties. Patients should be counselled on the symptoms and signs that require urgent review to allow early treatment of any confirmed rejection episode.
An observational study to identify the prevalence of thrombocytopenia and anti-PF4/polyanion antibodies in Norwegian health care workers after COVID-19 vaccination. BACKGROUND: The COVID-19 vaccine from AstraZeneca (AZD1222) is one of several vaccines introduced to provide immunity against SARS-CoV-2. Recently, more than 50 cases have been reported presenting a combination of thrombosis, thrombocytopenia, and remarkably high levels of anti-platelet factor 4 (PF4)/polyanion antibodies post-AZD1222 vaccination. Now linked to the vaccine, the condition is referred to as vaccine-induced immune thrombotic thrombocytopenia. The European Medicines Agency still recommends vaccination with AZD1222, but several European countries have temporally paused and/or restricted its use because of the perceived risk of this severe side effect. Because there is no description of PF4/polyanion antibody testing in the clinical trials, knowledge about the prevalence of such antibodies in a vaccinated cohort is needed. OBJECTIVES: To investigate prevalence of thrombocytopenia and anti-PF4/polyanion antibodies in a population recently vaccinated with AZD1222. PATIENTS/METHODS: Four hundred and ninety-two health care workers recently vaccinated with the first dose of AZD1222 were recruited from two hospitals in Norway. Study individuals were screened for thrombocytopenia and the presence of anti-PF4/polyanion

antibodies with a PF4/PVS immunoassay. Side effects after vaccination were registered. RESULTS: The majority of study participants had normal platelet counts and negative immunoassay. Anti-PF4/polyanion antibodies without platelet activating properties were only detected in six individuals (optical density â‰¥0.4, range 0.58-1.16), all with normal platelet counts. No subjects had severe thrombocytopenia. CONCLUSIONS: We found low prevalence of both thrombocytopenia and antibodies to PF4/polyanion-complexes among Norwegian health care workers after vaccination with AZD1222.

Post-vaccination SARS-CoV-2 infections and incidence of the B.1.427/B.1.429 variant among healthcare personnel at a northern California academic medical center. BACKGROUND: Distribution of mRNA-based SARS-CoV-2 vaccines to healthcare personnel (HCP) in the United States began in December 2020, with efficacy â‰¥ 90%. However, breakthrough infections in fully vaccinated individuals have been reported. Meanwhile, multiple SARS-CoV-2 variants of concern have emerged worldwide, including the B.1.427/B.1.429 variant first described in California. Little is known about the real-world effectiveness of the mRNA-based SARS-CoV-2 vaccines against novel variants including B.1.427/B.1.429. METHODS: In this quality improvement project, post-vaccine SARS-CoV-2 cases (PVSCs) were defined as individuals with positive SARS-CoV-2 nucleic acid amplification test (NAAT) after receiving at least one dose of a SARS-CoV-2 vaccine. Chart extraction of demographic and clinical information was performed, and available specimens meeting cycle threshold value criteria were tested for L452R, N501Y and E484K mutations by RT-PCR. RESULTS: From December 2020 to March 2021, 189 PVSCs were identified out of 22,729 healthcare personnel who received at least one dose of an mRNA-based SARS-CoV-2 vaccine. Of these, 114 (60.3%) occurred within 14 days of first vaccine dose (early post-vaccination), 49 (25.9%) within 14 days of the second vaccine dose (partially vaccinated), and 26 (13.8%) â‰¥14 days after the second dose (fully vaccinated). Of 115 samples available for mutation testing, 42 were positive for L452R alone, presumptive of B.1.427/B.1.429; three had N501Y mutation alone and none were found with E484K mutation. Though on univariate analysis partially- and fully-vaccinated PVSCs were more likely than early post-vaccination PVSCs to be infected with presumptive B.1.427/B.1.429, when adjusted for community prevalence of B.1.427/B.1.429 at the time of infection, partially- and fully-vaccinated PVSC did not have statistically significantly elevated risk ratios for infection with this variant (RR 1.40, 95% CI 0.81-2.43 and RR 1.13, 95% CI 0.59-2.16, respectively). CONCLUSIONS: The great majority of PVSCs occurred prior to the expected onset of full, vaccine-derived immunity. Although the B.1.427/B.1.429 variant did not represent a significantly higher proportion of PVSCs than expected, numbers were small and there was a trend towards higher representation in the partially- and fully-vaccinated subset. Continued infection control measures in the workplace and in the community including social distancing and masking, particularly in the early days post-vaccination, as well as continued variant surveillance in PVSCs, is imperative in order to anticipate and control future surges of infection.

Is the heparin-induced thrombocytopenia-like syndrome associated with ChAdOx vaccine related to the vaccine itself or to an autoimmune reaction to severe acute respiratory syndrome 2 coronavirus: insights and implications from previous reports in infected cases? Prothrombotic states, similar to heparin-induced thrombocytopenia (HIT) in recipients of the ChAdOx vaccine, sounded alarm bells internationally. Equivalent episodes of HIT were detailed in several case reports of coronavirus disease 2019. This suggests a common pathogenesis and warrants a shift in the management of implicated cases.

Minor to Moderate Side Effects of Pfizer-BioNTech COVID-19 Vaccine Among Saudi Residents: A Retrospective Cross-Sectional Study. BACKGROUND: The Pfizer-BioNTech COVID-19 vaccine has recently received emergency approval from the US FDA. The mRNA technology was used to manufacture the Pfizer vaccine; however, as a pioneering technology that has never been used in the

manufacture of vaccines, many people have concerns about the vaccine's side effects. Thus, the current study aimed to track the short-term side effects of the vaccine. METHODS: The information in this study was gathered by a Google Form-questionnaire (online survey). The results included the responses of 455 individuals, all of whom are Saudi Arabia inhabitants. Adverse effects of the vaccine were reported after the first and the second doses. RESULTS: The most common symptoms were injection site pain, headaches, flu-like symptoms, fever, and tiredness. Less common side effects were a fast heartbeat, whole body aches, difficulty breathing, joint pain, chills, and drowsiness. Rare side effects include Bell's palsy and lymph nodes swelling and tenderness. Flu-like symptoms were more common among those under 60 years of age, while injection site pain was more frequent among recipients who were 60 years and older. The study revealed a significant increase in the number of females who suffered from the vaccine side effects compared to males. Difficulty of breathing was more reported among recipients who had been previously infected with the coronavirus compared to those who had not been previously infected. CONCLUSION: Most of the side effects reported in this study were consistent with Pfizer's fact sheet for recipients and caregivers. Further studies are required to determine the long-term side effects.
Safety and immunogenicity of COVID-19 vaccination in patients with non-alcoholic fatty liver disease (CHESS2101): A multicenter study. BACKGROUND & AIMS: The development of COVID-19 vaccines has progressed with encouraging safety and efficacy data. Concerns have been raised about SARS-CoV-2 vaccine responses in the large population of patients with non-alcoholic fatty liver disease (NAFLD). The study aimed to explore the safety and immunogenicity of COVID-19 vaccination in NAFLD. METHODS: This multicenter study included patients with NAFLD without a history of SARS-CoV-2 infection. All patients were vaccinated with 2 doses of inactivated vaccine against SARS-CoV-2. The primary safety outcome was the incidence of adverse reactions within 7 days after each injection and overall incidence of adverse reactions within 28 days, and the primary immunogenicity outcome was neutralizing antibody response at least 14 days after the whole-course vaccination. RESULTS: A total of 381 patients with pre-existing NAFLD were included from 11 designated centers in China. The median age was 39.0 years (IQR 33.0-48.0 years) and 179 (47.0%) were male. The median BMI was 26.1Â kg/m(2) (IQR 23.8-28.1Â kg/m(2)). The number of adverse reactions within 7 days after each injection and adverse reactions within 28 days totaled 95 (24.9%) and 112 (29.4%), respectively. The most common adverse reactions were injection site pain in 70 (18.4%), followed by muscle pain in 21 (5.5%), and headache in 20 (5.2%). All adverse reactions were mild and self-limiting, and no grade 3 adverse reactions were recorded. Notably, neutralizing antibodies against SARS-CoV-2 were detected in 364 (95.5%) patients with NAFLD. The median neutralizing antibody titer was 32 (IQR 8-64), and the neutralizing antibody titers were maintained. CONCLUSIONS: The inactivated COVID-19 vaccine appears to be safe with good immunogenicity in patients with NAFLD. LAY SUMMARY: The development of vaccines against coronavirus disease 2019 (COVID-19) has progressed rapidly, with encouraging safety and efficacy data. This study now shows that the inactivated COVID-19 vaccine appears to be safe with good immunogenicity in the large population of patients with non-alcoholic fatty liver disease.
Association of Facial Paralysis With mRNA COVID-19 Vaccines: A Disproportionality Analysis Using the World Health Organization Pharmacovigilance Database. This disproportionality analysis uses the World Health Organization pharmacovigilance database to explore the potential safety signal of facial paralysis after COVID-19 vaccination.
Prevalence of Increased FDG PET/CT Axillary Lymph Node Uptake Beyond 6 Weeks after mRNA COVID-19 Vaccination. Ipsilateral avid axillary lymph node uptake at FDG PET/CT persists in 29% (49 of 169) of patients between 7 to 10 weeks after the second dose of the mRNA-based BNT162b2 COVID-19 vaccination.

Post-adenoviral-based COVID-19 vaccines thrombosis: A proposed mechanism.
Chilblain lesions after COVID-19 mRNA vaccine.
Pityriasis rosea-like eruption after Pfizer-BioNTech COVID-19 vaccination.
[COVID-19 vaccines and cancer patients: State of the art and guidelines summary].
[Vaccination against COVID-19 in patients with solid cancer: Review and point of view from a French oncology inter-group (CGO, TNCD, UNICANCER)]. The COVID-19Â pandemic has a major impact at all stages of cancer treatment. Risk of death from COVID-19Â in patients treated for a cancer is high. COVID-19Â vaccines represent a major issue to decrease the rate of severe forms of the COVID-19Â cases and to maintain a normal cancer care. It is difficult to define the target population for vaccination due to the limited data available and the lack of vaccine doses available. It appears theoretically important to vaccinate patients with active cancer treatment or treated since less than three years, as well as their family circle. In France, patients actually defined at "high risk" for priority access to vaccination are those with a cancer treated by chemotherapy. A panel of experts recently defined another "very high-priority" population, which includes patients with curative or palliative first or second-line chemotherapy, as well as patients requiring surgery or radiotherapy involving a large lung volume, lymph nodes and/or of hematopoietic tissue. Ideally, it is best to vaccinate before cancer treatment. Despite the lack of published data, COVID-19Â vaccines can also be performed during chemotherapy by avoiding periods of bone marrow aplasia and if possible, to do it in cancer care centers. It is necessary to implement cohorts with immunological and clinical monitoring of vaccinated cancer patients. To conclude, considering the current state of knowledge, the benefit-risk ratio strongly favours COVID-19Â vaccination of all cancer patients.
SARS-CoV-2 inactivated vaccine (Vero cells) shows good safety in repeated administration toxicity test of Sprague Dawley rats. The outbreak of COVID-19 has posed a serious threat to global public health. Vaccination may be the most effective way to prevent and control the spread of the virus. The safety of vaccines is the focus of preclinical research, and the repeated dose toxicity test is the key safety test to evaluate the vaccine before clinical trials. The purpose of this study was (i) to observe the toxicity and severity of an inactivated SARS-CoV-2 vaccine (Vero cells) in rodent Sprague Dawley rats after multiple intramuscular injections under the premise of Good Laboratory Practice principles and (ii) to provide a basis for the formulation of a clinical trial scheme. The results showed that all animals in the experimental group were in good condition, no regular changes related to the vaccine were found in the detection of various toxicological indexes, and no noticeable stimulating reaction related to the vaccine was found in the injected local tissues. The neutralizing antibodies in the low- and high-dose vaccine groups began to appear 14 days after the last administration. In the negative control group, no neutralizing antibodies were observed from the administration period to the recovery period. Therefore, the repeated administration toxicity test of the inactivated SARS-CoV-2 vaccine (Vero cells) in Sprague Dawley rats showed no obvious toxic reaction. It was preliminarily confirmed that the vaccine can stimulate production of neutralizing antibodies and is safe in Sprague Dawley rats.
Acral chilblain-like lesions following inactivated SARS-CoV-2 vaccination.
Editorial: SARS-CoV-2 mRNA Vaccines and the Possible Mechanism of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). During 2020 and 2021, the global pandemic of coronavirus disease 2019 (COVID-19) due to severe acute respi- ratory syndrome coronavirus 2 (SARS-CoV-2) has resulted in high death rates and acute and chronic morbidity in all countries. The rapid development of new mRNA vaccines to SARS-CoV-2 brings hope that the spread of this virus can be controlled. The ChAdOx1 nCoV-19 vaccine developed by a collaboration between the University of Oxford and AstraZeneca showed efficacy in clinical trials, with a good safety profile. However, there have been recent reports of the rare development of thrombotic events in young women following vaccination

with ChAdOx1 nCoV-19, particularly of the rare condition of cavernous sinus thrombosis. Studies have begun to in- vestigate whether antibodies to the SARS-CoV-2 spike cross-react with platelet factor 4 (PF4/CXLC4) and mim- ic autoimmune heparin-induced thrombocytopenia. This Medical Science Monitor Editorial aims to briefly update the current status of studies on a possible rare complication of using new mRNA vaccines to prevent COVID-19.

New-onset chilblains in close temporal association to mRNA-1273 vaccination.

Practical handling of allergic reactions to COVID-19 vaccines: AÂ position paper from German and Austrian Allergy Societies AeDA, DGAKI, GPA and Ã–GAI. BACKGROUND: For the preventive treatment of the 2019 coronavirus disease (COVID-19) an unprecedented global research effort studied the safety and efficacy of new vaccine platforms that have not been previously used in humans. Less than one year after the discovery of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral sequence, these vaccines were approved for use in the European Union (EU) as well as in numerous other countries and mass vaccination efforts began. The so far in the EU approved mRNA vaccines BNT162b2 and mRNA-1273 are based on similar lipid-based nanoparticle carrier technologies; however, the lipid components differ. Severe allergic reactions and anaphylaxis after COVID-19 vaccination are very rare adverse events but have drawn attention due to potentially lethal outcomes and have triggered aÂ high degree of uncertainty. METHODS: Current knowledge on anaphylactic reactions to vaccines and specifically the new mRNA COVID-19 vaccines was compiled using aÂ literature search in Medline, PubMed, as well as the national and international study and guideline registries, the Cochrane Library, and the Internet, with special reference to official websites of the World Health Organization (WHO), US Centers for Disease Control and Prevention (CDC), Robert Koch Institute (RKI), and Paul Ehrlich Institute (PEI). RESULTS: Based on the international literature and previous experience, recommendations for prophylaxis, diagnosis and therapy of these allergic reactions are given by aÂ panel of experts. CONCLUSION: Allergy testing is not necessary for the vast majority of allergic patients prior to COVID-19 vaccination with currently licensed vaccines. In case of allergic/anaphylactic reactions after vaccination, allergy workup is recommended, as it is for aÂ small potential risk population prior to the first vaccination. Evaluation and approval of diagnostic tests should be done for this purpose.

Interim statement of the COVID-19 subcommittee of the WHO Global Advisory Committee on vaccine safety on AstraZeneca COVID-19 vaccine.

Deaths associated with newly launched SARS-CoV-2 vaccination (ComirnatyÂ®). Since 27th December 2020, a mRNA vaccine from BioNTech / Pfizer (ComirnatyÂ®) has been used across Germany. As of 12th March 2021, 286 fatalities of vaccinated German individuals were registered at the Paul-Ehrlich-Institute with time intervals after vaccination between one hour to 40Â days. From our catchment area in northern Germany, we have so far become aware of 22 deaths in connection with vaccination in a 5Â week period (range: 0-28Â days after vaccination). Three death cases after vaccination with ComirnatyÂ®, which were autopsied at the Institute of Legal Medicine Hamburg, are presented in more detail. All three deceased had severe cardiovascular diseases, among other comorbidities, and died in the context of these pre-existing conditions, while one case developed a COVID-19 pneumonia as cause of death. Taking into account the results of the postmortem examination a causal relation between the vaccination and the death was not established in any case. If there are indications of an allergic reaction, histological and postmortem laboratory examinations should be performed subsequent to the autopsy (tryptase, total IgE, CRP, interleukin-6, complement activity C3/C5).

Potential SARS-CoV-2 vaccines: Concept, progress, and challenges. Since September 2020, the world has had more than 28 million cases of coronavirus disease 2019 (COVID-19). Many countries are facing a second wave of the COVID-19 outbreak. A pressing need is evident for the development

of a potent vaccine to control the SARS-CoV-2. Institutions and companies in many countries have announced their vaccine research programs and progress against the COVID-19. While most vaccines go through the designation and preparation stages, some of them are under evaluation for efficacy among animal models and clinical trials, and three approved vaccine candidates have been introduced for limited exploitation in Russia and China. An effective vaccine must induce a protective response of both cell-mediated and humoral immunity and should meet the safety and efficacy criteria. Although the emergence of new technologies has accelerated the development of vaccines, there are several challenges on the way, such as limited knowledge about the pathophysiology of the virus, inducing humoral or cellular immunity, immune enhancement with animal coronavirus vaccines, and lack of an appropriate animal model. In this review, we firstly discuss the immune responses against SARS-CoV-2 disease, subsequently, give an overview of several vaccine platforms for SARS-CoV-2 under clinical trials and challenges in vaccine development against this virus.
COVID-19 vaccines surveillance in France: a global response to a major national challenge.
Costs associated with COVID-19 in healthcare personnel in Greece: a cost-of-illness analysis. BACKGROUND: Healthcare personnel (HCP) are at increased risk of infection with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the aetiological agent of coronavirus disease 2019 (COVID-19). AIM: To estimate the costs related to SARS-CoV-2 exposure and infection among HCP in Greece. METHODS: Data were retrieved from the national database of SARS-CoV-2 infections and from the database of HCP exposed to patients with COVID-19. A cost-of-illness analysis was performed to estimate total, direct and indirect costs. RESULTS: In total, 254 HCP with COVID-19 and 3332 HCP exposed to patients with COVID-19 during the first epidemic wave were studied. Of the 254 HCP with COVID-19, 49 (19.3%) were hospitalized (mean length of hospitalization 11.6 days) and four were admitted to intensive care units (mean duration 10.8 days). Overall, 1332 (40%) exposed HCP had a mean duration of absenteeism of 7.5 days, and 252 (99.2%) HCP with COVID-19 had a mean duration of absenteeism of 25.8 days. The total costs for the management of the two groups were estimated at â,¬1,735,830 (â,¬772,890 Euros for HCP with COVID-19 and â,¬962,940 for exposed HCP). Absenteeism accounted for a large proportion of the total costs (80.4% of all expenditures), followed by costs for reverse transcriptase polymerase chain reaction and hospitalization (10.2% and 6.5% of all expenditures, respectively). CONCLUSION: COVID-19 is associated with increased rates and duration of absenteeism among HCP. Indirect costs, particularly absenteeism, are the major driver of total costs among exposed HCP and HCP with COVID-19. The estimated total costs are conservative. Studies are needed to explore the impact of COVID-19 vaccination of HCP on absenteeism and COVID-19-associated costs.
COVID-19 vaccines: building and maintaining confidence.
Care without a compass: Including patients with cancer in COVID-19 studies.
First Dose of BNT162b2 mRNA Vaccine in a Healthcare Worker Cohort Is Associated With Reduced Symptomatic and Asymptomatic Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection. Over the first 2 months of 2021, vaccination coverage of staff at Hull Teaching Hospitals with BNT162b2 increased from 8.3% to 82.5% and was associated with a significant reduction in symptomatic and asymptomatic severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) cases. The proportion of positive lateral flow tests from asymptomatic screening was maintained over this period.
COVID-19 mRNA Vaccination: Age and Immune Status and Its Association with Axillary Lymph Node PET/CT Uptake. With hundreds of millions of coronavirus disease 2019 (COVID-19) messenger RNA (mRNA)-based vaccine doses planned to be delivered worldwide in the upcoming months, it is important to recognize PET/CT findings in recently vaccinated immunocompetent or immunocompromised patients. We aimed to assess PET/CT uptake in the deltoid muscle and axillary

lymph nodes of patients who received a COVID-19 mRNA-based vaccine and to evaluate its association with patient age and immune status. Methods: All consecutive adults who underwent PET/CT scans with any radiotracer at our center during the first month of a national COVID-19 vaccination rollout (between December 23, 2020, and January 27, 2021) and had received the vaccination were included. Data on clinical status, laterality, and time from vaccination were prospectively collected, retrospectively analyzed, and correlated with deltoid muscle and axillary lymph node uptake. Results: Of 426 eligible subjects (median age, 67â€‰Â±â€‰12 y; 49% female), 377 (88%) underwent PET/CT with (18)F-FDG, and positive axillary lymph node uptake was seen in 45% of them. Multivariate logistic regression analysis revealed a strong inverse association between positive (18)F-FDG uptake in ipsilateral lymph nodes and patient age (odds ratio [OR], 0.57; 95% CI, 0.45-0.72; Pâ€‰<â€‰0.001), immunosuppressive treatment (OR, 0.37; 95% CI, 0.20-0.64; Pâ€‰=â€‰0.003), and presence of hematologic disease (OR, 0.44; 95% CI, 0.24-0.8; Pâ€‰=â€‰0.021). No such association was found for deltoid muscle uptake. The number of days from the last vaccination and the number of vaccine doses were also significantly associated with increased odds of positive lymph node uptake. Conclusion: After mRNA-based COVID-19 vaccination, a high proportion of patients showed ipsilateral lymph node axillary uptake, which was more common in immunocompetent patients. This information will help with the recognition of PET/CT pitfalls and may hint about the patient's immune response to the vaccine.

Covid-19: Infections fell by 65% after first dose of AstraZeneca or Pfizer vaccine, data show.

Low immunogenicity to SARS-CoV-2 vaccination among liver transplant recipients. BACKGROUND & AIMS: Two SARS-CoV-2 mRNA vaccines were approved to prevent COVID-19 infection, with reported vaccine efficacy of 95%. Liver transplant (LT) recipients are at risk of lower vaccine immunogenicity and were not included in the registration trials. We assessed vaccine immunogenicity and safety in this special population. METHODS: LT recipients followed at the Tel-Aviv Sourasky Medical Center and healthy volunteers were tested for SARS-CoV-2 IgG antibodies directed against the Spike-protein (S) and Nucleocapsid-protein (N) 10-20 days after receiving the second Pfizer-BioNTech BNT162b2 SARS-CoV-2 vaccine dose. Information regarding vaccine side effects and clinical data was collected from patients and medical records. RESULTS: Eighty LT recipients were enrolled. Mean age was 60 years and 30% were female. Twenty-five healthy volunteer controls were younger (mean age 52.7 years, pÂ = 0.013) and mostly female (68%, pÂ = 0.002). All participants were negative for IgG N-protein serology, indicating immunity did not result from prior COVID-19 infection. All controls were positive for IgG S-protein serology. Immunogenicity among LT recipients was significantly lower with positive serology in only 47.5% (p <0.001). Antibody titer was also significantly lower in this group (mean 95.41 AU/ml vs. 200.5 AU/ml in controls, p <0.001). Predictors for negative response among LT recipients were older age, lower estimated glomerular filtration rate, and treatment with high dose steroids and mycophenolate mofetil. No serious adverse events were reported in either group. CONCLUSION: LT recipients developed substantially lower immunological response to the Pfizer-BioNTech SARS-CoV-2 mRNA-based vaccine. Factors influencing serological antibody responses include age, renal function and immunosuppressive medications. The findings require re-evaluation of vaccine regimens in this population. LAY SUMMARY: The Pfizer-BioNTech BNT162b2 SARS-CoV-2 vaccine elicited substantially inferior immunity in liver transplant recipients. Less than half of the patients developed sufficient levels of antibodies against the virus, and in those who were positive, average antibody levels were 2x less compared to healthy controls. Factors predicting non-response were older age, renal function and immunosuppressive medications.

Association between Influenza Vaccination and severe COVID-19 outcomes at a designated COVID-only hospital in Brooklyn. Maintaining influenza vaccination at high coverage has the potential to prevent a proportion of COVID-19 morbidity and mortality. We examined whether flu-vaccination is

associated with severe corona virus disease 2019 (COVID-19) disease, as measured by intensive care unit (ICU)-admission, ventilator-use, and mortality. Other outcome measures included hospital length of stay and total ICU days. Our findings showed that flu-vaccination was associated with a significantly reduced likelihood of an ICU admission especially among aged <65 and non-obese patients. Public health promotion of flu-vaccination may help mitigate the overwhelming demand for critical COVID-19 care pending the large-scale availability of COVID-19 vaccines.
Parsonage Turner syndrome after COVID-19 vaccination.
COVID-19 infection in solid organ transplant recipients after SARS-CoV-2 vaccination.
Safety and immunogenicity of the SARS-CoV-2 BNT162b1 mRNA vaccine in younger and older Chinese adults: a randomized, placebo-controlled, double-blind phase 1 study. An effective vaccine is needed to end the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. Here, we assess the preliminary safety, tolerability and immunogenicity data from an ongoing single-center (in Jiangsu province, China), parallel-group, double-blind phase 1 trial of the vaccine candidate BNT162b1 in 144 healthy SARS-CoV-2-naive Chinese participants. These participants are randomized 1:1:1 to receive prime and boost vaccinations of 10â€‰Âµg or 30â€‰Âµg BNT162b1 or placebo, given 21â€‰d apart, with equal allocation of younger (aged 18-55â€‰years) and older adults (aged 65-85â€‰years) to each treatment group (ChiCTR2000034825). BNT162b1 encodes the SARS-CoV-2 spike glycoprotein receptor-binding domain (RBD) and is one of several messenger RNA-based vaccine candidates under clinical investigation. Local reactions and systemic events were generally dose dependent, transient and mild to moderate. Fever was the only grade 3 adverse event. BNT162b1 induced robust interferon-Î³ Tâ€‰cell responses to a peptide pool including the RBD in both younger and older Chinese adults, and geometric mean neutralizing titers reached 2.1-fold (for younger participants) and 1.3-fold (for the older participants) that of a panel of COVID-19 convalescent human sera obtained at least 14â€‰d after positive SARS-CoV-2 polymerase chain reaction test. In summary, BNT162b1 has an acceptable safety profile and produces high levels of humoral and Tâ€‰cell responses in an Asian population.
Thrombotic complications of vaccination against SARS-CoV-2: what pharmacovigilance reports tell us - and what they don't. Thrombotic complications of COVID-19 vaccination are very rare, but awareness is needed https://bit.ly/3n4vaXe   In the present issue of the European Respiratory Journal, Smadja et al. [1] present an analysis of global pharmacovigilance reports of thrombotic events following severe acute respiratory distress syndrome coronavirus 2 (SARS-CoV-2) vaccination. More specifically, the authors analysed the data entered into the World Health Organization (WHO) Global Database for Individual Case Safety Reports (VigiBase) between 13 December, 2020 and 16 March, 2021, covering, at that time, a population of almost 362 million vaccinated individuals across the world. The study focuses on three of the coronavirus disease 2019 (COVID-19) vaccines available to date, namely Pfizer-BioNtech (BNT162b2), Moderna (mRNA-1273) and OxfordAstraZeneca (ChAdOx1 nCov-19). The study by Smadja et al. [1] confirms the rarity of possible thrombotic complications in association with COVID-19 vaccination, reporting only 0.21 (95% CI 0.19â€“0.22) cases of thrombotic events per million person vaccinated-days. However, there were also some unexpected observations which deserve closer attention and cautious interpretation.
Guillain-Barre syndrome following the first dose of the chimpanzee adenovirus-vectored COVID-19 vaccine, ChAdOx1. Prevention strategies for COVID-19 transmission are at the forefront of healthcare paradigms worldwide, the main emphasis of which is vaccination. We present an interesting case of a 37-year-old man who, 3â€‰weeks following his first dose of the chimpanzee adenovirus-vectored COVID-19 vaccine, ChAdOx1, presented to hospital with a rapidly progressive ascending muscle weakness and back pain in the absence of any other triggers. He also had a negative COVID-19 swab during admission. A diagnosis of Guillain-Barre syndrome was confirmed by

correlating the clinical features with cerebrospinal fluid analysis, nerve conduction studies and MRI of the brain and whole spine. The patient received treatment with 5â€‰days of intravenous immunoglobulin and did not require any respiratory support. He was also regularly reviewed by a multidisciplinary team consisting of neurologists, speech and language therapists, and physiotherapists and is on the course to a recovery.
Myocardial infarction after COVID-19 vaccination-casual or causal?
Relapse of thrombotic thrombocytopenic purpura after COVID-19 vaccine.
Neutralizing SARS-CoV-2 antibody response in dialysis patients after the first dose of the BNT162b2 mRNA COVID-19 vaccine: the war is far from being won.
Seroprevalence of antibody to S1 spike protein following vaccination against COVID-19 in patients receiving hemodialysis: a call to arms.
Response to first vaccination against SARS-CoV-2 in patients with multiple myeloma.
COVID vaccines and kids: five questions as trials begin.
Covid-19: Unusual blood clots are "very rare side effect" of Janssen vaccine, says EMA.
Adult multisystem inflammatory syndrome in a patient who recovered from COVID-19 postvaccination. Multisystem inflammatory syndrome in children has become a recognised syndrome, whereas a parallel syndrome in adults, multisystem inflammatory syndrome in adults (MIS-A), has not been well defined. Most cases occur several weeks following confirmed or suspected SARS-CoV-2 infection, but none have been reported in association with SARS-CoV-2 vaccines. Here we describe the case of a 22-year-old man, who received the inactivated SARS-CoV-2 vaccine 6 weeks following a mild COVID-19 infection. He presented after his second dose of the vaccine with a clinical picture of a multisystem inflammatory syndrome-like illness. Additionally, there was laboratory evidence of acute inflammation. The patient's condition markedly improved after initiation of steroids. Whether the vaccine augmented an already-primed immunity from the infection and contributed to the occurrence of MIS-A is difficult to prove. Understanding the pathogenesis of this condition will shed light on this question and entail major implications on treatment and prevention.
Delayed Large Local Reactions to mRNA Vaccines.
Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19. BACKGROUND: The Ad26.COV2.S vaccine is a recombinant, replication-incompetent human adenovirus type 26 vector encoding full-length severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein in a prefusion-stabilized conformation. METHODS: In an international, randomized, double-blind, placebo-controlled, phase 3 trial, we randomly assigned adult participants in a 1:1 ratio to receive a single dose of Ad26.COV2.S (5Ã—10(10) viral particles) or placebo. The primary end points were vaccine efficacy against moderate to severe-critical coronavirus disease 2019 (Covid-19) with an onset at least 14 days and at least 28 days after administration among participants in the per-protocol population who had tested negative for SARS-CoV-2. Safety was also assessed. RESULTS: The per-protocol population included 19,630 SARS-CoV-2-negative participants who received Ad26.COV2.S and 19,691 who received placebo. Ad26.COV2.S protected against moderate to severe-critical Covid-19 with onset at least 14 days after administration (116 cases in the vaccine group vs. 348 in the placebo group; efficacy, 66.9%; adjusted 95% confidence interval [CI], 59.0 to 73.4) and at least 28 days after administration (66 vs. 193 cases; efficacy, 66.1%; adjusted 95% CI, 55.0 to 74.8). Vaccine efficacy was higher against severe-critical Covid-19 (76.7% [adjusted 95% CI, 54.6 to 89.1] for onset at â‰¥14 days and 85.4% [adjusted 95% CI, 54.2 to 96.9] for onset at â‰¥28 days). Despite 86 of 91 cases (94.5%) in South Africa with sequenced virus having the 20H/501Y.V2 variant, vaccine efficacy was 52.0% and 64.0% against moderate to severe-critical Covid-19 with onset at least 14 days and at least 28 days after administration, respectively, and efficacy against severe-critical Covid-19 was 73.1% and 81.7%,

respectively. Reactogenicity was higher with Ad26.COV2.S than with placebo but was generally mild to moderate and transient. The incidence of serious adverse events was balanced between the two groups. Three deaths occurred in the vaccine group (none were Covid-19-related), and 16 in the placebo group (5 were Covid-19-related). CONCLUSIONS: A single dose of Ad26.COV2.S protected against symptomatic Covid-19 and asymptomatic SARS-CoV-2 infection and was effective against severe-critical disease, including hospitalization and death. Safety appeared to be similar to that in other phase 3 trials of Covid-19 vaccines. (Funded by Janssen Research and Development and others; ENSEMBLE ClinicalTrials.gov number, NCT04505722.).

Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. BACKGROUND: Many pregnant persons in the United States are receiving messenger RNA (mRNA) coronavirus disease 2019 (Covid-19) vaccines, but data are limited on their safety in pregnancy. METHODS: From December 14, 2020, to February 28, 2021, we used data from the "v-safe after vaccination health checker" surveillance system, the v-safe pregnancy registry, and the Vaccine Adverse Event Reporting System (VAERS) to characterize the initial safety of mRNA Covid-19 vaccines in pregnant persons. RESULTS: A total of 35,691 v-safe participants 16 to 54 years of age identified as pregnant. Injection-site pain was reported more frequently among pregnant persons than among nonpregnant women, whereas headache, myalgia, chills, and fever were reported less frequently. Among 3958 participants enrolled in the v-safe pregnancy registry, 827 had a completed pregnancy, of which 115 (13.9%) resulted in a pregnancy loss and 712 (86.1%) resulted in a live birth (mostly among participants with vaccination in the third trimester). Adverse neonatal outcomes included preterm birth (in 9.4%) and small size for gestational age (in 3.2%); no neonatal deaths were reported. Although not directly comparable, calculated proportions of adverse pregnancy and neonatal outcomes in persons vaccinated against Covid-19 who had a completed pregnancy were similar to incidences reported in studies involving pregnant women that were conducted before the Covid-19 pandemic. Among 221 pregnancy-related adverse events reported to the VAERS, the most frequently reported event was spontaneous abortion (46 cases). CONCLUSIONS: Preliminary findings did not show obvious safety signals among pregnant persons who received mRNA Covid-19 vaccines. However, more longitudinal follow-up, including follow-up of large numbers of women vaccinated earlier in pregnancy, is necessary to inform maternal, pregnancy, and infant outcomes.

Audio Interview: Covid-19 Vaccines and Pregnancy - A Conversation with CDC Director Rochelle Walensky.

Cerebral venous thrombosis and thrombocytopenia post-COVID-19 vaccination.

COVID-19 Vaccine Perceptions Among Patients With Chronic Disease in a Large Gastroenterology and Hepatology Practice. INTRODUCTION: To assess beliefs about safety, effectiveness, and delivery of the coronavirus disease 2019 (COVID-19) vaccine among chronic Gastroenterology and Hepatology patients at an academic health system. METHODS: We asked about vaccine beliefs, vaccine concerns, and preferred location to receive the COVID-19 vaccine. RESULTS: A total of 1,215 patients responded (response rate: 37%). Most patients believed that vaccines are safe, effective, and that they would take the COVID-19 vaccine at a medical office or pharmacy. However, we identified important sociodemographic factors associated with vaccine hesitancy. DISCUSSION: Patients have high level of trust in the COVID-19 vaccine and are likely to follow their specialist physician recommendations.

Prevalence and associated factors of intention of COVID-19 vaccination among healthcare workers in China: application of the Health Belief Model. Healthcare workers (HCWs) are at an increased risk of coronavirus disease 2019 (COVID-19) and warrant COVID-19 vaccination to reduce nosocomial infections. This study investigated: (1) the prevalence of behavioral intention of COVID-19 vaccination (BICV) under eight scenarios combining vaccines' effectiveness/safety/cost, plus two general scenarios of free/self-paid vaccination given governmental/hospital recommendations, (2)

perceptions involving preferred timing of COVID-19 vaccination and impacts of various attributes on BICV, and (3) factors of BICV based on the Health Belief Model. An anonymous online cross-sectional survey was conducted among 2,254 full-time doctors/nurses in three Chinese provinces during 10/2020-11/2020. The prevalence of BICV was 75.1%/68.0% among nurses/doctors under the most optimum scenario of this study (free/80% effectiveness/rare mild side effects); it dropped to 64.6%/56.5% if it costed 600 Yuan (USD90). Similar prevalence was obtained (72.7%/71.2%) if the vaccination was recommended by the government/hospitals but dropped to <50% if effectiveness was 50% or mild side effects were common; 13.0% preferred to take up COVID-19 vaccination at the soonest (81.8% would wait and see). Scientific proof (completion of phase III clinical trials and approval from health authorities) was rated the highest in its impacts on vaccination decision, followed by vaccines' performance, and then logistics. Multivariable logistic regression analyses showed that perceived severity, perceived barriers, cues to action, and self-efficacy (but neither perceived susceptibility nor perceived barriers) were significantly associated with the two BICV outcomes. The coverage of COVID-19 vaccination would be high only if the vaccines perform well. Health promotion may take the findings into account.

Successful treatment of vaccine-induced prothrombotic immune thrombocytopenia (VIPIT).
Cases of unusual thrombosis and thrombocytopenia after administration of the ChAdOx1 nCoV-19 vaccine (AstraZeneca) have been reported. The term vaccine-induced prothrombotic immune thrombocytopenia (VIPIT) was coined to reflect this new phenomenon. In vitro experiments with VIPIT patient sera indicated that high-dose intravenous immunoglobulins (IVIG) competitively inhibit the platelet-activating properties of ChAdOx1 nCoV-19 vaccine induced antibodies. Here, we report a case of a 62-year-old woman who had received this vaccine and developed VIPIT. She visited the emergency ward because of petechiae and hematomas. In the laboratory work-up, thrombocytopenia, low fibrinogen, elevated D-dimer, and positivity in the platelet factor 4/heparin-enzyme-immunoassay were present. Signs and symptoms of thrombosis were absent. Upon immediate therapy with non-heparin anticoagulation, high-dose IVIG, and prednisolone, laboratory parameters steadily improved and the patient was discharged from hospital without thrombotic complications. We conclude that early initiation of VIPIT treatment results in a swift response without thrombotic complications.

COVID-19 Vaccine Concerns: Fact or Fiction? One year has elapsed since a team of Chinese scientists reported the first case of COVID-19 in Wuhan, China on January 8, 2020, after sequencing the first viral genetic material. Since then, many vaccines were rushed into testing, bypassing animal experimentations, with more than 200 pharma companies in different countries declaring the development of different vaccines, each with their own strategy for generating immunity, despite the arguments of many infectious disease experts that 18 months for a first vaccine is an incredibly aggressive schedule because it takes an average of 10 years to develop a vaccine. Ten vaccine candidates have already entered phase 3 clinical trials in humans. These vaccines rely on different types of technology, the most innovative of which use the genetic material messenger RNA. Many provocative questions and genuine concerns have been raised, such as short durations of efficacy and safety follow-ups, lack of identified correlates of protection, morbidity and mortality cases reported shortly after vaccination, uncertainties regarding the risk of enhanced disease on exposure to the virus in the long-term, the possibility of viral transmission after vaccination, the reported reduced efficacies of these vaccines against new variants, the efficacy and safety of these vaccines in the previously excluded subgroups (such as children, pregnant women, the frail elderly high-risk population, and immunocompromised individuals), the unknown risk of immunogenicity-induced autoimmune diseases, cancer and chronic inflammation, the risk of genome transformation (mainly in the presence of reverse transcriptase), and finally the potential coercion that may be imposed by

either public or private sectors on citizens to receive the vaccine. Many plausible questions are apparent, with no clear and convincing answers.
Early Safety Monitoring of COVID-19 Vaccines in Healthcare Workers. Hospital-based surveillance for adverse events was conducted on healthcare workers after they received the first dose of coronavirus disease 2019 (COVID-19) vaccine. Among the two new platform vaccines (messenger RNA- and adenoviral vector-based vaccines), the rates of systemic adverse events were significantly higher among adenovirus-vectored vaccine recipients. Fatigue (87.6% vs. 53.8%), myalgia (80.8% vs. 50.0%), headache (72.0% vs. 28.8%), and fever (â‰¥ 38.0Â°C, 38.7% vs. 0%) were the most common adverse events among adenovirus-vectored vaccine recipients, but most symptoms resolved within 2 days. Both types of COVID-19 vaccines were generally safe, and serious adverse events rarely occurred.
COVID-19 dynamics after a national immunization program in Israel. Studies on the real-life effect of the BNT162b2 vaccine for Coronavirus Disease 2019 (COVID-19) prevention are urgently needed. In this study, we conducted a retrospective analysis of data from the Israeli Ministry of Health collected between 28 August 2020 and 24 February 2021. We studied the temporal dynamics of the number of new COVID-19 cases and hospitalizations after the vaccination campaign, which was initiated on 20 December 2020. To distinguish the possible effects of the vaccination on cases and hospitalizations from other factors, including a third lockdown implemented on 8 January 2021, we performed several comparisons: (1) individuals aged 60 years and older prioritized to receive the vaccine first versus younger age groups; (2) the January lockdown versus the September lockdown; and (3) early-vaccinated versus late-vaccinated cities. A larger and earlier decrease in COVID-19 cases and hospitalization was observed in individuals older than 60 years, followed by younger age groups, by the order of vaccination prioritization. This pattern was not observed in the previous lockdown and was more pronounced in early-vaccinated cities. Our analysis demonstrates the real-life effect of a national vaccination campaign on the pandemic dynamics.
Impact of reduced human papillomavirus vaccination coverage rates due to COVID-19 in the United States: A model based analysis. The coronavirus disease 2019 (COVID-19) pandemic has significantly affected utilization of preventative health care, including vaccines. We aimed to assess HPV vaccination rates during the pandemic, and conduct a simulation model-based analysis to estimate the impact of current coverage and future pandemic recovery scenarios on disease outcomes. The model population included females and males of all ages in the US. The model compares pre-COVID vaccine uptake to 3 reduced coverage scenarios with varying recovery speed. Vaccine coverage was obtained from Truven Marketscanâ„¢. Substantially reduced coverage between March-August 2020 was observed compared to 2018-2019. The model predicted that 130,853 to 213,926 additional cases of genital warts; 22,503 to 48,157 cases of CIN1; 48,682 to 110,192 cases of CIN2/3; and 2,882 to 6,487 cases of cervical cancer will occur over the next 100Â years, compared to status quo. Providers should plan efforts to recover HPV vaccination and minimize potential long-term consequences.
COVID-19 Vaccination-Related Lymphadenopathy: What To Be Aware Of.
People's Willingness to Vaccinate Against COVID-19 Despite Their Safety Concerns: Twitter Poll Analysis. BACKGROUND: On January 30, 2020, the World Health Organization's Emergency Committee declared the rapid, worldwide spread of COVID-19 a global health emergency. Since then, tireless efforts have been made to mitigate the spread of the disease and its impact, and these efforts have mostly relied on nonpharmaceutical interventions. By December 2020, the safety and efficacy of the first COVID-19 vaccines were demonstrated. The large social media platform Twitter has been used by medical researchers for the analysis of important public health topics, such as the public's perception on antibiotic use and misuse and human papillomavirus vaccination. The analysis of

Twitter-generated data can be further facilitated by using Twitter's built-in, anonymous polling tool to gain insight into public health issues and obtain rapid feedback on an international scale. During the fast-paced course of the COVID-19 pandemic, the Twitter polling system has provided a viable method for gaining rapid, large-scale, international public health insights on highly relevant and timely SARS-CoV-2-related topics. OBJECTIVE: The purpose of this study was to understand the public's perception on the safety and acceptance of COVID-19 vaccines in real time by using Twitter polls. METHODS: We developed 2 Twitter polls to explore the public's views on available COVID-19 vaccines. The surveys were pinned to the Digital Health and Patient Safety Platform Twitter timeline for 1 week in mid-February 2021, and Twitter users and influencers were asked to participate in and retweet the polls to reach the largest possible audience. RESULTS: The adequacy of COVID-19 vaccine safety (ie, the safety of currently available vaccines; poll 1) was agreed upon by 1579 out of 3439 (45.9%) Twitter users. In contrast, almost as many Twitter users (1434/3439, 41.7%) were unsure about the safety of COVID-19 vaccines. Only 5.2% (179/3439) of Twitter users rated the available COVID-19 vaccines as generally unsafe. Poll 2, which addressed the question of whether users would undergo vaccination, was answered affirmatively by 82.8% (2862/3457) of Twitter users, and only 8% (277/3457) categorically rejected vaccination at the time of polling. CONCLUSIONS: In contrast to the perceived high level of uncertainty about the safety of the available COVID-19 vaccines, we observed an elevated willingness to undergo vaccination among our study sample. Since people's perceptions and views are strongly influenced by social media, the snapshots provided by these media platforms represent a static image of a moving target. Thus, the results of this study need to be followed up by long-term surveys to maintain their validity. This is especially relevant due to the circumstances of the fast-paced pandemic and the need to not miss sudden rises in the incidence of vaccine hesitancy, which may have detrimental effects on the pandemic's course.

Carnitine palmitoyltransferase II deficiency and post-COVID vaccination rhabdomyolysis.
Carnitine palmitoyltransferase II (CPT II) deficiency is a disorder affecting fatty acid oxidation. The myopathic form of the condition is the most common among adults and manifests itself with a high serum creatine kinase (CK) concentration. Triggers of very high CK concentrations include periods of fasting, infection, exercise, stress, and exposure to extreme temperatures. A 27-year-old man known to have CPT II deficiency presented feeling generally unwell after his COVID-19 vaccine. His CK concentration of 105,000â€‰U/L and deranged liver function tests (ALT 300â€‰U/L and AST 1496â€‰U/L) were in keeping with rhabdomyolysis. His biochemical parameters and myopathy resolved with continuous intravenous dextrose 10% and a high carbohydrate diet. Caution should be exercised when administering vaccinations (including the COVID-19 vaccination) to this population. Clinicians should be wary for signs and symptoms of CPT II deficiency exacerbations and be vigilant in monitoring serum CK.

Management of cerebral and splanchnic vein thrombosis associated with thrombocytopenia in subjects previously vaccinated with Vaxzevria (AstraZeneca): a position statement from the Italian Society for the Study of Haemostasis and Thrombosis (SISET).

Sustained COVID-19 vaccine willingness after safety concerns over the Oxford-AstraZeneca vaccine. INTRODUCTION Prompted by reports of thromboembolic events - some with fatal outcomes - among people who had received the ChAdOx1 nCoV-19 (AZD1222) vaccine from Oxford-AstraZeneca against COVID-19, a number of European countries paused vaccination with this vaccine in early and mid-March 2021. Prior studies have suggested that vaccine willingness is highly dependent on public trust in the safety of vaccines. We therefore investigated whether vaccine willingness dropped in the wake of the reported cases of thromboembolic events in relation to the Oxford-AstraZeneca COVID-19 vaccine. METHODS Using longitudinal survey data from Denmark, we compared vaccine willingness shortly before and after the reported cases of thromboembolic events, as well as the perceived safety

of the two most widely used COVID-19 vaccines in Denmark - those from Pfizer-BioNTech and Oxford-AstraZeneca - in the wake of these events. RESULTS We found sustained vaccine willingness after the reported cases of thromboembolic events (89% both before and after). However, the safety of the Oxford-AstraZeneca COVID-19 vaccine was perceived to be significantly and substantially lower than the safety of the vaccine from Pfizer-BioNTech, and this difference was particularly pronounced among those who were vaccine-hesitant. CONCLUSIONS The vaccine willingness of Danes does not seem to have been affected by the reports of thromboembolic events in relation to the Oxford-AstraZeneca COVID-19 vaccine. FUNDING The study was funded by a grant from the Novo Nordisk Foundation (grant number: NNF20SA0062874). TRIAL REGISTRATION not relevant.

Unilateral axillary lymphadenopathy following COVID-19 vaccination: A case report and imaging findings. As more people receive coronavirus disease 2019 (COVID-19) vaccinations, the side effects of the vaccines will become more apparent. One reported side effect that has come to light is unilateral axillary lymphadenopathy ipsilateral to the vaccination site. In general, unilateral axillary lymphadenopathy has a broad differential including malignancy, infection, autoimmune disorder, and iatrogenic etiologies. We present a case of a previously healthy 38-year-old woman who received her first dose of Pfizer COVID-19 vaccination 3 days prior to presenting to the emergency department complaining of 2 weeks of abdominal pain and 20-pound unintentional weight loss. Unilateral axillary lymphadenopathy, ipsilateral to the vaccination site, was found on a contrast-enhanced computed tomography examination of the chest, abdomen, and pelvis. Subsequent diagnostic mammograms did not demonstrate evidence of malignancy; however, axillary ultrasound again revealed nonspecific lymphadenopathy. A short-term follow-up axillary ultrasound was recommended, rather than a lymph node biopsy, given the history of recent vaccination. At clinical follow-up, the patient's abdominal pain resolved and no further weight loss was noted. This case report discusses the key components and workup recommendation of unilateral axillary lymphadenopathy in the setting of COVID-19 vaccination.

State estimation-based control of COVID-19 epidemic before and after vaccine development. In this study, a nonlinear robust control policy is designed together with a state observer in order to manage the novel coronavirus disease (COVID-19) outbreak having an uncertain epidemiological model with unmeasurable variables. This nonlinear model for the COVID-19 epidemic includes eight state variables (susceptible, exposed, infected, quarantined, hospitalized, recovered, deceased, and insusceptible populations). Two plausible scenarios are put forward in this article to control this epidemic before and after its vaccine invention. In the first scenario, the social distancing and hospitalization rates are employed as two applicable control inputs to diminish the exposed and infected groups. However, in the second scenario after the vaccine development, the vaccination rate is taken into account as the third control input to reduce the susceptible populations, in addition to the two objectives of the first scenario. The proposed feedback control measures are defined in terms of the hospitalized and deceased populations due to the available statistical data, while other unmeasurable compartmental variables are estimated by an extended Kalman filter (EKF). In other words, the susceptible, exposed, infected, quarantined, recovered, and insusceptible individuals cannot be identified precisely because of the asymptomatic infection of COVID-19 in some cases, its incubation period, and the lack of an adequate community screening. Utilizing the Lyapunov theorem, the stability and bounded tracking convergence of the closed-loop epidemiological system are investigated in the presence of modeling uncertainties. Finally, a comprehensive simulation study is conducted based on Canada's reported cases for two defined timing plans (with different treatment rates). Obtained results demonstrate that the developed EKF-based control scheme can achieve desired epidemic goals (exponential decrease of infected, exposed, and susceptible people).

COVID-19 Vaccination in Patients with Reported Allergic Reactions: Updated Evidence and Suggested Approach.
Side effects of BNT162b2 mRNA COVID-19 vaccine: A randomized, cross-sectional study with detailed self-reported symptoms from healthcare workers. INTRODUCTION: Concerns are prevailing about the safety and side effects of the BNT162b2 mRNA vaccine for coronavirus disease 2019 (COVID-19). METHODS: A randomized, cross-sectional study was performed to investigate the side effects of the BNT162b2 vaccine using an independent online questionnaire gathering responses from healthcare workers (HCWs) with detailed review of organ systems. RESULTS: Of all HCWs, 87.98% (1245/1415) completed the survey. Of them, 64.5% (803/1245) received the BNT162b2 mRNA vaccine and reported at least one or more symptoms (classified based on organ systems and occurrence rate) post vaccination. Of these, 640/803 (79.7%) were able to continue activities of daily living (ADL), 103/803 (12.83%) had trouble temporarily to perform ADL, 99/803 (12.33%) took time off work temporarily, 20/803 (2.49%) required help from an outpatient provider, 5/803 (0.62%) required help from an emergency department and 2/803 (0.25%) required hospitalization. Despite this, 97.61% intended to have the second dose and 92.9% had already received it. CONCLUSIONS: Commonly reported symptoms (occurrence in descending order) were soreness, fatigue, myalgia, headache, chills, fever, joint pain, nausea, muscle spasm, sweating, dizziness, flushing, feelings of relief, brain fogging, anorexia, localized swelling, decreased sleep quality, itching, tingling, diarrhoea, nasal stuffiness and palpitations. Despite this, remarkable acceptance for the second dose of the BNT162b2 vaccine was found among HCWs.
"COVID Arm": Very delayed large injection site reactions to mRNA COVID-19 vaccines.
Low Rates of Urologic Side Effects Following Coronavirus Disease Vaccination: An Analysis of the Food and Drug Administration Vaccine Adverse Event Reporting System. OBJECTIVE: To quantify and describe urologic adverse events and symptoms after vaccination with the Pfizer-BioNTech and Moderna COVID-19 vaccines. METHODS AND MATERIALS: We queried the FDA Vaccine Adverse Event Reporting System (VAERS) for all reported symptoms following the Pfizer-BioNTech and Moderna vaccines as of February 12th, 2021. All urologic symptoms were isolated and the reported adverse events associated with each symptom were reviewed. RESULTS: Out of 15,785 adverse event reports, only 0.7% (113) described urologic symptoms. A total of 156 urologic symptoms were described amongst the 113 adverse event reports. The Pfizer-BioNTech vaccine was responsible for 61% of these reports and the Moderna vaccine was responsible for 39%. These symptoms were grouped into five different categories: Lower Urinary Tract Symptoms (nÂ =Â 34, 22%), Hematuria (nÂ =Â 22, 14%), Urinary Infection (nÂ =Â 41, 26%), Skin and/or Soft Tissue (nÂ =Â 16, 10%), and Other (nÂ =Â 43, 28%). The median age of the patients reporting urologic symptoms was 63 years (IQR 44-79, Range: 19-96) and 54% of the patients were female. CONCLUSION: Urologic symptoms reported after COVID-19 vaccination are extremely rare. Given the common prevalence of many of these reported symptoms in the general population, there does not appear to be a correlation between vaccination and urologic symptoms, but as the vaccination criteria expands, further monitoring of the Vaccine Adverse Event Reporting System is needed.
Bilateral superior ophthalmic vein thrombosis, ischaemic stroke, and immune thrombocytopenia after ChAdOx1 nCoV-19 vaccination.
Pulmonary embolism and thrombocytopenia following ChAdOx1 vaccination.
COVID vaccines and blood clots: five key questions.
Perioperative risk evaluation in patients scheduled for elective surgery in close relation to their SARS-CoV-2 vaccination.
Autoimmune hepatitis developing after coronavirus disease 2019 (COVID-19) vaccine: Causality or casualty?

Pathologic Antibodies to Platelet Factor 4 after ChAdOx1 nCoV-19 Vaccination. BACKGROUND: The mainstay of control of the coronavirus disease 2019 (Covid-19) pandemic is vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Within a year, several vaccines have been developed and millions of doses delivered. Reporting of adverse events is a critical postmarketing activity. METHODS: We report findings in 23 patients who presented with thrombosis and thrombocytopenia 6 to 24 days after receiving the first dose of the ChAdOx1 nCoV-19 vaccine (AstraZeneca). On the basis of their clinical and laboratory features, we identify a novel underlying mechanism and address the therapeutic implications. RESULTS: In the absence of previous prothrombotic medical conditions, 22 patients presented with acute thrombocytopenia and thrombosis, primarily cerebral venous thrombosis, and 1 patient presented with isolated thrombocytopenia and a hemorrhagic phenotype. All the patients had low or normal fibrinogen levels and elevated d-dimer levels at presentation. No evidence of thrombophilia or causative precipitants was identified. Testing for antibodies to platelet factor 4 (PF4) was positive in 22 patients (with 1 equivocal result) and negative in 1 patient. On the basis of the pathophysiological features observed in these patients, we recommend that treatment with platelet transfusions be avoided because of the risk of progression in thrombotic symptoms and that the administration of a nonheparin anticoagulant agent and intravenous immune globulin be considered for the first occurrence of these symptoms. CONCLUSIONS: Vaccination against SARS-CoV-2 remains critical for control of the Covid-19 pandemic. A pathogenic PF4-dependent syndrome, unrelated to the use of heparin therapy, can occur after the administration of the ChAdOx1 nCoV-19 vaccine. Rapid identification of this rare syndrome is important because of the therapeutic implications.

Consensus Recommendations for Intramuscular COVID-19 Vaccination in Patients with Hemophilia. BACKGROUND: â€ƒCurrently available coronavirus disease 2019 (COVID-19) vaccines are approved for intramuscular injection and efficacy may not be ensured when given subcutaneously. For years, subcutaneous vaccination was recommended in patients with hemophilia to avoid intramuscular bleeds. Therefore, recommendations for the application of COVID-19 vaccines are needed. METHODS: â€ƒThe Delphi methodology was used to develop consensus recommendations. An initial list of recommendations was prepared by a steering committee and evaluated by 39 hemophilia experts. Consensus was defined as â‰¥75% agreement and strong consensus as â‰¥95% agreement, and agreement as a score â‰¥7 on a scale of 1 to 9. After four rounds, a final list of statements was compiled. RECOMMENDATIONS: â€ƒConsensus was achieved that COVID-19 vaccines licensed only for intramuscular injection should be administered intramuscularly in hemophilia patients. Prophylactic factor replacement, given on the day of vaccination with a maximum interval between prophylaxis and vaccination of 24â€‰hours (factor VIII and conventional factor IX concentrates) or 48â€‰hours (half-life extended factor IX), should be provided in patients with moderate or severe hemophilia. Strong consensus was achieved that patients with mild hemophilia and residual factor activity greater than 10% with mild bleeding phenotype or patients on emicizumab usually do not need factor replacement before vaccination. Swelling, erythema, and hyperthermia after vaccination are not always signs of bleeding but should prompt consultation of a hemophilia care center. In case of injection-site hematoma, patients should receive replacement therapy until symptoms disappear. CONCLUSIONS: â€ƒConsensus was achieved on recommendations for intramuscular COVID-19 vaccination after replacement therapy for hemophilia patients depending on disease severity.

Association between COVID-19 morbidity and mortality rates and BCG vaccination policies in OECD countries. We compared whether the national BCG vaccination (BCGV) policy influenced coronavirus disease 2019 (COVID-19) in Organisation for Economic Co-operation and Development (OECD) countries. Those currently implementing BCGV have a reduced number of COVID-19

morbidity and mortality cases, compared to those who have never implemented a BCGV policy, suggesting the potential protective effect of BCGV against COVID-19.
Safety and Reactogenicity of 2 Doses of SARS-CoV-2 Vaccination in Solid Organ Transplant Recipients. BACKGROUND: We studied the safety and reactogenicity SARS-CoV-2 mRNA vaccines in transplant recipients because immunosuppressed patients were excluded from vaccine trials. METHODS: US transplant recipients were recruited into this prospective cohort study through social media; those who completed the full vaccine series between December 9, 2020 and March 1, 2021 were included. We collected demographics, medical history, and safety information within 7 d after doses 1 and 2 (D1, D2). Associations between characteristics and reactions were evaluated using modified Poisson regression. RESULTS: We studied 741 transplant recipients who underwent BNT162b2 (54%) or mRNA-1273 (46%) vaccination. Median (interquartile range) age was 60 (44-69) y, 57% were female, and 10% were non-White. Although local site reactions decreased after D2 (85% D1 versus 78% D2, Pâ€‰<â€‰0.001), systemic reactions increased (49% D1 versus 69% D2, Pâ€‰<â€‰0.001). Younger participants were more likely to develop systemic symptoms after D1 (adjusted incidence rate ratio [aIRR] per 10 yâ€‰=â€‰0.850.900.94, Pâ€‰<â€‰0.001) and D2 (aIRR per 10 yâ€‰=â€‰0.910.930.96, Pâ€‰<â€‰0.001). Participants who experienced pain (aIRRâ€‰=â€‰1.111.662.47, Pâ€‰=â€‰0.01) or redness (aIRRâ€‰=â€‰1.833.928.41, Pâ€‰<â€‰0.01) were more likely to develop an antibody response to D1 of mRNA vaccines. No anaphylaxis, neurologic diagnoses, or SARS-CoV-2 diagnoses were reported. Infections were minimal (3% after D1, <0.01% after D2). One patient reported incident acute rejection post-D2. CONCLUSIONS: In solid organ transplant recipients undergoing mRNA vaccination, reactogenicity was similar to that reported in the original trials. Severe reactions were rare. These early safety data may help address vaccine hesitancy in transplant recipients.
Vaccine link to serious clotting disorder firms up.
Pediatric Vaccination During the COVID-19 Pandemic. OBJECTIVES: The impact of the coronavirus disease 2019 pandemic on vaccination coverage, critical to preventing vaccine-preventable diseases, has not been assessed during the reopening period. METHODS: Vaccine uptake and vaccination coverage for recommended vaccines and for measles-containing vaccines at milestone ages were assessed in a large cohort of children aged 0 to 18 years in Southern California during January to August 2020 and were compared with those in the same period in 2019. Differences in vaccine uptake and vaccination coverage (recommended vaccines and measles-containing vaccines) in prepandemic (January to March), stay-at-home (April to May), and reopening (June to August) periods in 2020 and 2019 were compared. RESULTS: Total and measles-containing vaccine uptake declined markedly in all children during the pandemic period in 2020 compared with 2019, but recovered in children aged 0 to 23 months. Among children aged 2 to 18 years, measles-containing vaccine uptake recovered, but total vaccine uptake remained lower. Vaccination coverage (recommended and measles-containing vaccines) declined and remained reduced among most milestone age cohorts â‰¤24 months during the pandemic period, whereas recommended vaccination coverage in older children decreased during the reopening period in 2020 compared with 2019. CONCLUSIONS: Pediatric vaccine uptake decreased dramatically during the pandemic, resulting in decreased vaccination coverage that persisted or worsened among several age cohorts during the reopening period. Additional strategies, including immunization tracking, reminders, and recall for needed vaccinations, particularly during virtual visits, will be required to increase vaccine uptake and vaccination coverage and reduce the risk of outbreaks of vaccine-preventable diseases.
Type I interferons as the potential mechanism linking mRNA COVID-19 vaccines to Bell's palsy.
Two Cases of Graves' Disease Following SARS-CoV-2 Vaccination: An Autoimmune/Inflammatory Syndrome Induced by Adjuvants. Background: The autoimmune/inflammatory syndrome induced

by adjuvants (ASIA) comprises four entities, including the postvaccination phenomenon, which appears after being exposed to adjuvants in vaccines that increase the immune response. There is limited information about autoimmune endocrine diseases and ASIA after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination. Patient's Findings: Two female health care workers received a SARS-CoV-2 vaccine, and three days later developed clinical manifestations of thyroid hyperactivity, with increased thyroid hormone levels on thyroid function tests, suppressed thyroid-stimulating hormone, and elevated antithyroid antibodies. Summary: Vaccines have been shown to trigger an immune response that leads to a broad spectrum of autoimmune diseases, including autoimmune thyroid disease. Our patients met the diagnostic criteria for ASIA; they were exposed to an adjuvant (vaccine), and they developed clinical manifestations of thyroid hyperfunction within a few days, with the appearance of antithyroid antibodies, despite being healthy before vaccination. Conclusion: Graves' disease can occur after SARS-CoV-2 vaccination.

Cerebral venous sinus thrombosis and thrombocytopenia after COVID-19 vaccination - A report of two UK cases. Recent reports have highlighted rare, and sometimes fatal, cases of cerebral venous sinus thrombosis (CVST) and thrombocytopenia following the Vaxzevria vaccine. An underlying immunological mechanism similar to that of spontaneous heparin-induced thrombocytopenia (HIT) is suspected, with the identification of antibodies to platelet factor-4 (PF4), but without previous heparin exposure. This unusual mechanism has significant implications for the management approach used, which differs from usual treatment of CVST. We describe the cases of two young males, who developed severe thrombocytopenia and fatal CVST following the first dose of Vaxzevria. Both presented with a headache, with subsequent rapid neurological deterioration. One patient underwent PF4 antibody testing, which was positive. A rapid vaccination programme is essential in helping to control the COVID-19 pandemic. Hence, it is vital that such COVID-19 vaccine-associated events, which at this stage appear to be very rare, are viewed through this lens. However, some cases have proved fatal. It is critical that clinicians are alerted to the emergence of such events to facilitate appropriate management. Patients presenting with CVST features and thrombocytopenia post-vaccination should undergo PF4 antibody testing and be managed in a similar fashion to HIT, in particular avoiding heparin and platelet transfusions.

Potential mechanisms of anaphylaxis to COVID-19 mRNA vaccines. Anaphylaxis to vaccines is historically a rare event. The coronavirus disease 2019 pandemic drove the need for rapid vaccine production applying a novel antigen delivery system: messenger RNA vaccines packaged in lipid nanoparticles. Unexpectedly, public vaccine administration led to a small number of severe allergic reactions, with resultant substantial public concern, especially within atopic individuals. We reviewed the constituents of the messenger RNA lipid nanoparticle vaccine and considered several contributors to these reactions: (1) contact system activation by nucleic acid, (2) complement recognition of the vaccine-activating allergic effector cells, (3) preexisting antibody recognition of polyethylene glycol, a lipid nanoparticle surface hydrophilic polymer, and (4) direct mast cell activation, coupled with potential genetic or environmental predispositions to hypersensitivity. Unfortunately, measurement of anti-polyethylene glycol antibodies inÂ vitro is not clinically available, and the predictive value of skin testing to polyethylene glycol components as a coronavirus disease 2019 messenger RNA vaccine-specific anaphylaxis marker is unknown. Even less is known regarding the applicability of vaccine use for testing (inÂ vitro/vivo) to ascertain pathogenesis or predict reactivity risk. Expedient and thorough research-based evaluation of patients who have suffered anaphylactic vaccine reactions and prospective clinical trials in putative at-risk individuals are needed to address these concerns during a public health crisis.

Countries with high deaths due to flu and tuberculosis demonstrate lower COVID-19 mortality: roles of vaccinations. Deaths due to the ongoing COVID-19 pandemic vary (3-1681 deaths/million and

mortality rates 0.71-14.54%) and are far greater in some countries compared to others. This observation led us to perform epidemiological analysis, using data in the public domain, to study the correlation of COVID-19 with the prevalence and vaccination strategies for two respiratory pathogens: flu and tuberculosis (TB). Countries showing more than 1000 COVID-19 deaths were selected at three time points during the ongoing pandemic: 17 May, 1 October and 31 December 2020. The major findings of this study that are broadly consistent at all three time points are: First, countries with high flu deaths negatively correlate with COVID-19 deaths/million. Second, TB incidences and deaths negatively correlate with COVID-19 deaths/million. Countries displaying high TB and flu deaths (Nigeria, Ethiopia, Myanmar, Indonesia, India) display lower COVID-19 deaths/million compared to countries with low TB and flu deaths (Italy, Spain, USA, France). Third, countries with greater flu vaccination display lower flu incidences but higher COVID-19 deaths/million and mortality rates. On the other hand, Bacillus Calmette Guerin (BCG) vaccination negatively correlates with Covid-19 deaths/million. Fourth, countries with only BCG, but no flu, vaccination show delayed and lower number of COVID-19 deaths/million compared to countries with flu, but no BCG, vaccination. Fifth, countries with high BCG vaccination coverage as well as high TB deaths display the lowest COVID-19 deaths/million. The implications of this global study are discussed with respect to the roles of respiratory infections and vaccinations in lowering COVID-19 deaths.

COVID-19 vaccination in patients with multiple sclerosis: What we have learnt by February 2021. BACKGROUND: Since vaccination against coronavirus disease 2019 (COVID-19) became available, risks related to vaccinating patients with multiple sclerosis (MS) need to be carefully assessed. OBJECTIVE: Characterize safety and occurrence of immediate relapses following COVID-19 vaccination in a large cohort of MS patients. METHODS: We assessed the safety of BNT162b2 COVID-19 vaccination in adult MS patients. RESULTS: Between 20 December 2020 and 25 January 2021, 555 MS patients received the first dose of BNT162b2 vaccine and 435 received the second dose. There were three cases of COVID-19 infection encountered after the first dose. Safety profile of COVID-19 vaccine was characterized by pain at the injection site, fatigue, and headache. No increased risk of relapse activity was noted over a median follow-up of 20 and 38â€‰days after first and second vaccine doses, respectively. The rate of patients with acute relapse was 2.1% and 1.6% following the first and second doses, respectively, similar to the rate in non-vaccinating patients during the corresponding period. Mild increase in the rate of adverse events was noted in younger patients (18-55â€‰years), among patients with lower disability (Expanded Disability Status Scale (EDSS) â©½3.0), and in patients treated with immunomodulatory drugs. CONCLUSION: COVID-19 BNT162b2 vaccine proved safe for MS patients. No increased risk of relapse activity was noted.

Cutaneous reaction to BNT162b2 mRNA COVID-19 vaccine.

Severe, Refractory Immune Thrombocytopenia Occurring After SARS-CoV-2 Vaccine. The rollout of the SARS-CoV-2 vaccine is underway, and millions have already been vaccinated. At least 25 reports of "immune thrombocytopenia" (ITP) or "thrombocytopenia" following the Moderna or Pfizer vaccine have been added to the Vaccine Adverse Event Reporting System (VAERS) in the US. ITP is a rare but known complication of several vaccinations. SARS-CoV-2 vaccine is new, with a novel mechanism of action, and understanding the epidemiology, clinical manifestations, treatment success and natural history of post-vaccination thrombocytopenia is evolving. We report a 74-year-old man who developed refractory thrombocytopenia within one day of receiving the Moderna SARS-CoV-2 vaccine. Several hours after vaccination, he developed significant epistaxis and cutaneous purpura. Severe thrombocytopenia was documented the following day, and he developed extremity weakness and encephalopathy with facial muscle weakness. Over a 14-day period, thrombocytopenia was treated first with high dose dexamethasone, intravenous immunoglobulin, platelet transfusions, rituximab, plasma exchange (for presumed acute inflammatory demyelinating polyneuropathy

(AIDP)), and four daily doses of the thrombopoietin receptor agonist (TPO-RA) eltrombopag (Promactaâ„¢), without a platelet response. Three days later, he received the TPO-RA romiplostim (Nplateâ„¢). Five days later, his platelet count began to rise and by post-vaccination day 25, his platelet count was in the normal range. Thrombocytopenia was refractory to frontline and second-line treatment. The eventual rise in his platelet count suggests that one or both TPO-RAs may have impacted platelet recovery. Possibly, but less likely given the temporality, the drug-induced thrombocytopenia was subsiding. The aggressive use of immunosuppressive treatment may jeopardize the intended purpose of the SARS-CoV-2 vaccine, and earlier use of non-immunosuppressive second-line treatment for vaccine-related severe thrombocytopenia, such as with TPO-RAs, should be considered. While it is imperative to continue the global vaccination program, vigilance to the occurrence of post-vaccination severe thrombocytopenia is warranted.
Promoting COVID-19 Vaccination on Social Media.
Thrombotic Thrombocytopenia after Ad26.COV2.S Vaccination.
Audio Interview: Vaccine Successes and Vaccine Adverse Events.
SARS-CoV-2 Vaccination in the Context of Ongoing HIV Cure-Related Research Studies.
Global Recommendations on COVID-19 Vaccines and Soft Tissue Filler Reactions: A Survey-Based Investigation in Cooperation With the International Society for Dermatologic and Aesthetic Surgery (ISDS). BACKGROUND: Recent reports have surfaced from the United States Food and Drug Administration hearings in December 2020 regarding the COVID-19 vaccines and study participants who developed facial and/or lip swelling after receiving the newly developed drug. Despite an incidence rate of 0.02% in the vaccine arm of the Moderna mRNA-1273 trial, concerns have been expressed about the association of adverse reactions following soft tissue filler injections and the COVID-19 vaccines. The International Society for Dermatologic and Aesthetic Surgery (ISDS) understands these concerns and has designed the following study. METHODS: A global survey was designed to capture the incidence of adverse events related to: (1) previous soft tissue filler injections, (2) soft tissue filler injections during positive testing for COVID-19, and (3) soft tissue filler injections during and after receiving any of the COVID-19 vaccines globally available. RESULTS: The information of 106 survey participants from 18 different countries was analyzed. 80.2% (n=85) never experienced any adverse reaction following their soft tissue filler injection whereas 15.1% (n=16) experienced swelling and 4.7% (n=5) experienced pain that lasted longer than two days. Of those who received at least one dose of the COVID-19 vaccine (n=78), 94.9% reported not to have experienced any adverse reaction related to their previous soft tissue filler injection, whereas 5.1% (n=4) reported to have perceived pain that lasted longer than two days. CONCLUSION: The data collected does not support the concern for an increased risk of developing adverse reactions following soft tissue filler injections associated with the COVID-19 vaccines compared to that risk associated with other previously described triggers or the default risk following soft tissue filler injections. J Drugs Dermatol. 20(4):374-378. doi:10.36849/JDD.2021.6041.
Severe Acute Respiratory Syndrome Coronavirus 2 Vaccines and Cutaneous Adverse Reactions: A Review. We are entering a new stage of the severe acute respiratory syndrome coronavirus 2 pandemic with the initiation of large-scale vaccination programs globally. In these circumstances, even rare adverse effects of vaccines may be encountered more often, if millions of people are to be vaccinated in a short period. Vaccination has the potential for causing cutaneous adverse effects. Thus, it is paramount that dermatologists worldwide are acquainted with the possible skin reaction patterns to the coming vaccines. Herein, we conduct a review to discuss the most frequent cutaneous adverse effects of vaccines and their management, with a particular focus on the expected adverse reactions for the coming severe acute respiratory syndrome coronavirus 2 vaccines, such as local reactions, as well as immediate- and delayed-type hypersensitivity reactions, including erythema

multiforme, Stevens-Johnson syndrome, toxic epidermal necrosis, serum sickness-like reactions, and vasculitides. We also discuss the yet unanswered questions on vaccines for which we may soon be asked to provide an expert opinion.

Post COVID-19 vaccine small fiber neuropathy.

Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT): Targeting Pathomechanisms with Bruton Tyrosine Kinase Inhibitors. A series of cases with rare thromboembolic incidents including cerebral sinus vein thrombosis (some of them fatal) and concomitant thrombocytopenia occurring shortly after vaccination with the coronavirus disease 2019 (COVID-19) vaccine AZD1222 (Vaxzevria) have caused significant concern and led to its temporary suspension in many countries. Immediate laboratory efforts in four of these patients have identified a tentative pathomechanism underlying this syndrome termed initially vaccine-induced prothrombotic immune thrombocytopenia (VIPIT) and renamed recently vaccine-induced immune thrombotic thrombocytopenia (VITT). It encompasses the presence of platelet-activating antibodies to platelet factor-4/heparin complexes, possibly emulated by polyanionic constituents of AZD1222, and thus resembles heparin-induced thrombocytopenia (HIT). Because these immune complexes bind and activate platelets via Fcî³ receptor IIA (Fcî³RIIA), high-dose intravenous immunoglobulin G has been suggested for treatment of VITT in addition to non-heparin anticoagulants. Here we propose inhibitors of Bruton tyrosine kinase (Btk) approved for B cell malignancies (e.g., ibrutinib) as another therapeutic option in VITT, as they are expected to pleiotropically target multiple pathways downstream of Fcî³RIIA-mediated Btk activation, for example, as demonstrated for the effective inhibition of platelet aggregation, dense granule secretion, P-selectin expression and platelet-neutrophil aggregate formation stimulated by Fcî³RIIA cross-linking. Moreover, C-type lectin-like receptor CLEC-2- and GPIb-mediated platelet activation, the interactions and activation of monocytes and the release of neutrophil extracellular traps, as encountered in HIT, could be attenuated by Btk inhibitors. As a paradigm for emergency repurposing of approved drugs in COVID-19, off-label use of Btk inhibitors in a low-dose range not affecting haemostatic functions could thus be considered a sufficiently safe option to treat VITT.

Covid-19: EU investigates four reports of blood clots after Janssen vaccine.

A randomized, double-blind, placebo-controlled phase III clinical trial to evaluate the efficacy and safety of SARS-CoV-2 vaccine (inactivated, Vero cell): a structured summary of a study protocol for a randomised controlled trial. OBJECTIVES: The primary objective is to evaluate the efficacy of an inactivated and aluminium hydroxide adsorbed SARS-CoV-2 vaccine (Sinovac, China) in voluntary participants after 14 days of the second dose against RT-PCR confirmed symptomatic COVID-19 cases. The secondary objectives include evaluating the efficacy after at least one dose of the vaccine against RT-PCR confirmed symptomatic COVID-19 cases; the efficacy of two doses of the vaccine on the rates of hospitalization and death; the safety of the vaccine including adverse reactions up to one year after the 2(nd) dose of vaccination; and the immunogenicity of the vaccine and its duration up to 120 days. TRIAL DESIGN: This is a phase III, randomized, double-blind, placebo-controlled case driven clinical trial to assess the efficacy and safety of the vaccine. The study is planned to be carried out within two separate cohorts in voluntary participants aged between 18-59 years old. The first cohort includes healthcare professionals actively working in healthcare units, who are assumed to have higher risk of acquiring COVID-19, and the second cohort includes other immunocompetent subjects in the same age group, who are at a regular risk for COVID-19 disease. In Cohort 1, healthcare professionals will be randomized to receive two intramuscular doses of investigational product or the placebo in a 1:1 ratio and they will be monitored for 12 months by active surveillance of COVID-19. In Cohort 2, immunocompetent subjects will be randomized to receive vaccine or the placebo in a 2:1 ratio. PARTICIPANTS: Healthcare professionals of both genders, including medical doctors, nurses, cleaners, hospital technicians, and administrative personnel who work in any department of a

healthcare unit and immunocompetent individuals of both genders are included. Pregnant (confirmed by positive beta-hCG test) and breastfeeding women as well as those intending to become pregnant within three months after vaccination are excluded. Other exclusion criteria include history of COVID-19 test positivity (PCR or immunoglobulin test results), any form of immunosuppressive therapy including corticosteroids within 6 months, history of bleeding disorders, asplenia, and administration of any form of immunoglobulins or blood products within 3 months. Exclusion criteria for the second dose include any serious adverse events related with the vaccine, anaphylaxis or hypersensitivity after vaccination, or any confirmed or suspected autoimmune or immunosuppressive disease (including HIV infection). Participants are only included after signing the voluntary informed consent form, ensuring cooperation in visits, undergoing screening for evaluation, and conforming to all the inclusion and exclusion criteria. All clinical sites are located in Turkey. INTERVENTION AND COMPARATOR: The vaccine was manufactured by Sinovac Research & Development Co., Ltd. It is a preparation made from a novel coronavirus (strain CZ02) grown in the kidney cell cultures (Vero Cell) of the African green monkey and contains inactivated SARS-CoV-2 virus, aluminium hydroxide, disodium hydrogen phosphate, sodium dihydrogen phosphate, and sodium chloride. A dose of 0.5 mL contains 600 SU of SARS-CoV-2 virus antigen. The placebo contains aluminium hydroxide, disodium hydrogen phosphate, sodium dihydrogen phosphate, and sodium chloride (0.5mL/dose). Scheduled visits and additional unscheduled weekly visits will be performed for the first 13 weeks and neutralizing antibody test, IgG test, T-Cell activation test, pregnancy test, and RT-PCR tests along with total antibody test will be performed. Adverse events and serious adverse events during the follow-up will be recorded on diary cards. Diary cards will collect information on the timing and severity of COVID-19 symptoms and solicited adverse events recorded by the subjects during one-year follow-up period. All serious adverse events will be managed and necessary treatment will be ensured according to the local regulations. All serious adverse events following vaccination will be reported to the ethics committee, the Ministry of Health, and the study sponsor within 24 hours of detection. MAIN OUTCOMES: The primary efficacy endpoint is the incidence of symptomatic cases of COVID-19 disease confirmed by RT-PCR two weeks after the second dose of vaccination. Secondary efficacy endpoints are the incidence of hospitalization/mortality rates among one or two dose regimens, duration of immunogenicity rates up to 120 days, the seroconversion rate, the seropositivity rate, neutralizing antibody titer, and IgG levels 14 days after each dose of vaccination. The primary safety endpoint is the severity and frequency of local and systemic adverse reactions during the period of one week after vaccination. The study would be terminated if more than 15% of the subjects have grade â‰¥3 adverse events related to vaccination including local reactions. RANDOMISATION: Eligible subjects will be randomized at their Study Day 0 to two study groups using an Interactive Web Response System (IWRS; developed by Omega CRO, Ankara, Turkey) in both risk groups. The IWRS system customizes the randomization algorithm. After enrolment in the study, each participant will be randomly assigned to either of the two treatment arms at a ratio of 1:1 in the high-risk group and at a ratio of 2:1 in the normal risk group. Each enrolled participant will be assigned to a code and will receive the treatment labelled with the code. BLINDING (MASKING): The trial is a double-blind study to avoid introducing bias. The blinding may be broken by the investigator in the event of a medical emergency in which knowledge of the identity of the study vaccine is critical for management of the subject's immediate treatment. The Data and Safety Monitoring Board is to be contacted in case of breaking the blinding for a study object. The blood samples will be taken from both placebo and vaccinated groups, in order not to break the blinding. NUMBERS TO BE RANDOMISED (SAMPLE SIZE): The study is planned to be carried out with two separate cohorts. The Cohort 1 includes healthcare professionals working in healthcare units and the Cohort 2 consists of immunocompetent subjects having normal risk for COVID-19 disease. The Cohort 2 will be initiated after the evaluation of the interim safety report of the Cohort 1 by the Data and Safety Monitoring Board. Both cohorts will be

followed-up via RT-PCR to confirm symptomatic COVID-19 cases. If the clinical efficacy of the vaccine is shown in the Cohort 1 or 2, the subjects randomized into the placebo arm will also be vaccinated. In the Cohort 1, 588 subjects should be included in both arms with the assumption that the risk of infection with COVID-19 will be 5% for the placebo arm and 2% for the vaccine arm in the high-risk group. Considering 10% of drop-out rate and 5% of seropositivity or PCR positivity at baseline, 680 subjects should be screened at both arms of the Cohort 1. Group sample sizes of 7545 SARS-CoV-2 vaccine and 3773 placebo suits at a two-sided 95% confidence interval for the difference in population proportions with a width equal to 1.0%, when the estimated incidence rate for vaccinated group is 1.0% and the estimated incidence rate for placebo group is 2.0%. Drop-out rate is assumed to be 10% and seropositivity or PCR positivity at baseline is assumed to be 5%; accordingly, 13000 participants are needed to be enrolled totally in both cohorts. The remaining 11640 subjects will be screened in the Cohort 2 and eligible subjects will be randomized at a ratio of 2:1. TRIAL STATUS: Protocol version 6.0 - 15 October 2020. Recruitment started on 15.09.2020 and is expected to end on February 2022. TRIAL REGISTRATION: ClinicalTrials.gov, NCT04582344 . Registered 8 October 2020 FULL PROTOCOL: The full protocol of the trial is attached as an additional file, accessible from the Trials website (Additional file 1). In the interest in expediting dissemination of this material, the familiar formatting has been eliminated; this Letter serves as a summary of the key elements of the full protocol.

Willingness to get a COVID-19 vaccine among critical care non-medical healthcare workers and impact of a vaccine information session.

Herpes zoster following BNT162b2 mRNA COVID-19 vaccination in patients with autoimmune inflammatory rheumatic diseases: a case series. OBJECTIVES: As global vaccination campaigns against COVID-19 disease commence, vaccine safety needs to be closely assessed. The safety profile of mRNA-based vaccines in patients with autoimmune inflammatory rheumatic diseases (AIIRD) is unknown. The objective of this report is to raise awareness of reactivation of herpes zoster (HZ) following the BNT162b2 mRNA vaccination in patients with AIIRD. METHODS: The safety of the BNT162b2 mRNA vaccination was assessed in an observational study monitoring post-vaccination adverse effects in patients with AIIRD (nâ€‰=â€‰491) and controls (nâ€‰=â€‰99), conducted in two rheumatology departments in Israel. RESULTS: The prevalence of HZ was 1.2% (nâ€‰=â€‰6) in patients with AIIRD compared with none in controls. Six female patients aged 49â€‰Â±â€‰11â€‰years with stable AIIRD: RA (nâ€‰=â€‰4), Sjogren's syndrome (nâ€‰=â€‰1), and undifferentiated connective disease (nâ€‰=â€‰1), developed the first in a lifetime event of HZ within a short time after the first vaccine dose in five cases and after the second vaccine dose in one case. In the majority of cases, HZ infection was mild, except a case of HZ ophthalmicus, without corneal involvement, in an RA patient treated with tofacitinib. There were no cases of disseminated HZ disease or postherpetic neuralgia. All but one patient received antiviral treatment with a resolution of HZ-related symptoms up to 6â€‰weeks. Five patients completed the second vaccine dose without other adverse effects. CONCLUSION: Epidemiologic studies on the safety of the mRNA-based COVID-19 vaccines in patients with AIIRD are needed to clarify the association between the BNT162b2 mRNA vaccination and reactivation of zoster.

[Newly discovered catastrophic antibody formation after the AstraZeneca vaccine].

Adverse Events in Healthcare Workers after the First Dose of ChAdOx1 nCoV-19 or BNT162b2 mRNA COVID-19 Vaccination: a Single Center Experience. Coronavirus disease 2019 vaccinations for healthcare workers (HCWs) have begun in South Korea. To investigate adverse events (AEs) of the first dose of each vaccine, any symptom was collected daily for seven days after vaccination in a tertiary hospital. We found that 1,301 of 1,403 ChAdOx1 nCoV-19 recipients and 38 of 80 BNT162b2 recipients reported AEs respectively (90.9% vs. 52.5%): injection-site pain (77.7% vs. 51.2%), myalgia

(60.5% vs. 11.2%), fatigue (50.7% vs. 7.5%), headache (47.4% vs. 7.5%), and fever (36.1% vs. 5%; P < 0.001 for all). Young HCWs reported more AEs with ChAdOx1 nCoV-19 than with BNT162b2. No incidences of anaphylaxis were observed. Only one serious AE required hospitalization for serious vomiting, and completely recovered. In conclusion, reported AEs were more common in recipients with ChAdOx1 nCoV-19 than in those with BNT162b2. However, most of the reported AEs were mild to moderate in severity. Sufficient explanation and preparation for expected AEs required to promote widespread vaccination.
Covid-19: Rare immune response may cause clots after AstraZeneca vaccine, say researchers.
Reporting of AstraZeneca studies may have caused vaccine reservations.
Anaphylactic reactions to mRNA COVID-19 vaccines: A call for further study.
Cerebral venous sinus thrombosis associated with thrombocytopenia post-vaccination for COVID-19.
Factors affecting nurses' intention to accept the COVID-19 vaccine: A cross-sectional study. OBJECTIVE: To measure COVID-19 vaccine acceptance and related factors to undercover nurses' concerns and fears. DESIGN: A cross-sectional study. SAMPLE: The study included 639 nurses; 83% were women and 80% under 50Â years. MEASUREMENT: A self-administered questionnaire was used. It included demographic characteristics, COVID-19-related fears and concerns, COVID-19 vaccine perceived benefits, and intention toward getting the vaccine. RESULTS: Forty percent of the nurses planned to get the vaccine when available, 41% would take it later when adequate protection and safety were presented, and 18% would never take it. Significant factors associated with vaccination intention were as follows: age (adjusted OR 1.42, 95% CI: 1.02-1.99); lack of knowledge about the vaccine (adjusted OR 2.6, 95% CI 1.81-3.8); concern about long-term side effects (adjusted OR 2.0, 95% CI 1.4-2.9); fear of injection (adjusted OR 1.5, 95% CI 1.04-2.13); natural immunity preference (adjusted OR 5.8, 95% CI 4.5-8.3); media misrepresentation (adjusted OR 1.7, 95% CI 1.2-2.4); and getting COVID-19 from the vaccine (adjusted OR 1.5, 95% CI 1.1-2.1). CONCLUSION: COVID-19 vaccine safety and side-effects concerns impact nurses' intentions to accept the vaccine and may result in low acceptance rates. Urgent action is needed to address these fears and raise confidence, as nurses' vaccine-related decisions can affect the public's vaccine acceptance.
AI Aided Design of Epitope-Based Vaccine for the Induction of Cellular Immune Responses Against SARS-CoV-2. The heavy burden imposed by the COVID-19 pandemic on our society triggered the race toward the development of therapies or preventive strategies. Among these, antibodies and vaccines are particularly attractive because of their high specificity, low probability of drug-drug interaction, and potentially long-standing protective effects. While the threat at hand justifies the pace of research, the implementation of therapeutic strategies cannot be exempted from safety considerations. There are several potential adverse events reported after the vaccination or antibody therapy, but two are of utmost importance: antibody-dependent enhancement (ADE) and cytokine storm syndrome (CSS). On the other hand, the depletion or exhaustion of T-cells has been reported to be associated with worse prognosis in COVID-19 patients. This observation suggests a potential role of vaccines eliciting cellular immunity, which might simultaneously limit the risk of ADE and CSS. Such risk was proposed to be associated with FcR-induced activation of proinflammatory macrophages (M1) by Fu et al. (2020) and Iwasaki and Yang (2020). All aspects of the newly developed vaccine (including the route of administration, delivery system, and adjuvant selection) may affect its effectiveness and safety. In this work we use a novel in silico approach (based on AI and bioinformatics methods) developed to support the design of epitope-based vaccines. We evaluated the capabilities of our method for predicting the immunogenicity of epitopes. Next, the results of our approach were compared with other vaccine-design strategies reported in the literature. The risk of immuno-toxicity was also assessed. The analysis of epitope conservation among other Coronaviridae was carried out in order to facilitate the selection of peptides shared across different SARS-CoV-2

strains and which might be conserved in emerging zootic coronavirus strains. Finally, the potential applicability of the selected epitopes for the development of a vaccine eliciting cellular immunity for COVID-19 was discussed, highlighting the benefits and challenges of such an approach.
Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Based Novel Epitopes Induce Potent Immune Responses in vivo and Inhibit Viral Replication in vitro. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) initiates infection by attachment of the surface-exposed spike glycoprotein to the host cell receptors. The spike glycoprotein (S) is a promising target for inducing immune responses and providing protection; thus the ongoing efforts for the SARS-CoV-2 vaccine and therapeutic developments are mostly spiraling around S glycoprotein. The matured functional spike glycoprotein is presented on the virion surface as trimers, which contain two subunits, such as S1 (virus attachment) and S2 (virus fusion). The S1 subunit harbors the N-terminal domain (NTD) and the receptor-binding domain (RBD). The RBD is responsible for binding to host-cellular receptor angiotensin-converting enzyme 2 (ACE2). The NTD and RBD of S1, and the S2 of S glycoprotein are the major structural moieties to design and develop spike-based vaccine candidates and therapeutics. Here, we have identified three novel epitopes (20-amino acid peptides) in the regions NTD, RBD, and S2 domains, respectively, by structural and immunoinformatic analysis. We have shown as a proof of principle in the murine model, the potential role of these novel epitopes in-inducing humoral and cellular immune responses. Further analysis has shown that RBD and S2 directed epitopes were able to efficiently inhibit the replication of SARS-CoV-2 wild-type virus in vitro suggesting their role as virus entry inhibitors. Structural analysis revealed that S2-epitope is a part of the heptad repeat 2 (HR2) domain which might have plausible inhibitory effects on virus fusion. Taken together, this study discovered novel epitopes that might have important implications in the development of potential SARS-CoV-2 spike-based vaccine and therapeutics.
Minimal Change Disease Following the Pfizer-BioNTech COVID-19 Vaccine. We report on the development of minimal change disease (MCD) with nephrotic syndrome and acute kidney injury (AKI), shortly after first injection of the BNT162b2 COVID-19 vaccine (Pfizer-BioNTech). A 50-year-old previously healthy man was admitted to our hospital following the appearance of peripheral edema. Ten days earlier, he had received the first injection of the vaccine. Four days after injection, he developed lower leg edema, which rapidly progressed to anasarca. On admission, serum creatinine was 2.31 mg/dL and 24-hour urinary protein excretion was 6.9 grams. As kidney function continued to decline over the next days, empirical treatment was initiated with prednisone 80 mg/d. A kidney biopsy was performed and the findings were consistent with MCD. Ten days later, kidney function began to improve, gradually returning to normal. The clinical triad of MCD, nephrotic syndrome, and AKI has been previously described under a variety of circumstances, but not following the Pfizer-BioNTech COVID-19 vaccine. The association between the vaccination and MCD is at this time temporal and by exclusion, and by no means firmly established. We await further reports of similar cases to evaluate the true incidence of this possible vaccine side effect.
Disproportionality analysis of anaphylactic reactions after vaccination with messenger RNA coronavirus disease 2019 vaccines in the United States.
Cutaneous reactions reported after Moderna and Pfizer COVID-19 vaccination: A registry-based study of 414 cases. BACKGROUND: Cutaneous reactions after messenger RNA (mRNA)-based COVID-19 vaccines have been reported but are not well characterized. OBJECTIVE: To evaluate the morphology and timing of cutaneous reactions after mRNA COVID-19 vaccines. METHODS: A provider-facing registry-based study collected cases of cutaneous manifestations after COVID-19 vaccination. RESULTS: From December 2020 to February 2021, we recorded 414 cutaneous reactions to mRNA COVID-19 vaccines from Moderna (83%) and Pfizer (17%). Delayed large local reactions were most common, followed by local injection site reactions, urticarial eruptions, and morbilliform eruptions.

Forty-three percent of patients with first-dose reactions experienced second-dose recurrence. Additional less common reactions included pernio/chilblains, cosmetic filler reactions, zoster, herpes simplex flares, and pityriasis rosea-like reactions. LIMITATIONS: Registry analysis does not measure incidence. Morphologic misclassification is possible. CONCLUSIONS: We report a spectrum of cutaneous reactions after mRNA COVID-19 vaccines. We observed some dermatologic reactions to Moderna and Pfizer vaccines that mimicked SARS-CoV-2 infection itself, such as pernio/chilblains. Most patients with first-dose reactions did not have a second-dose reaction and serious adverse events did not develop in any of the patients in the registry after the first or second dose. Our data support that cutaneous reactions to COVID-19 vaccination are generally minor and self-limited, and should not discourage vaccination.

Comprehensive assessment of humoral response after Pfizer BNT162b2 mRNA Covid-19 vaccination: a three-case series. OBJECTIVES: Since universal vaccination is a pillar against coronavirus disease 2019 (COVID-19), monitoring anti-SARS-CoV-2 neutralizing antibodies is essential for deciphering post-vaccination immune response. METHODS: Three healthcare workers received 30Â Î¼g BNT162b2 mRNA Covid-19 Pfizer Vaccine, followed by a second identical dose, 21Â days afterwards. Venous blood was drawn at baseline and at serial intervals, up to 63Â days afterwards, for assessing total immunoglobulins (Ig) anti-RBD (receptor binding domain), anti-S1/S2 and anti-RBD IgG, anti-RBD and anti-N/S1 IgM, and anti-S1 IgA. RESULTS: All subjects were SARS-CoV-2 seronegative at baseline. Total Ig anti-RBD, anti-S1/S2 and anti-RBD IgG levels increased between 91 and 368 folds until 21Â days after the first vaccine dose, then reached a plateau. The levels raised further after the second dose (by âˆ¼30-, âˆ¼8- and âˆ¼8-fold, respectively), peaking at day 35, but then slightly declining and stabilizing âˆ¼50Â days after the first vaccine dose. Anti-S1 IgA levels increased between 7 and 11Â days after the first dose, slightly declined before the second dose, after which levels augmented by âˆ¼24-fold from baseline. The anti-RBD and anti-N/S1 IgM kinetics were similar to that of anti-S1 IgA, though displaying substantially weaker increases and modest peaks, only 4- to 7-fold higher than baseline. Highly significant inter-correlation was noted between total Ig anti-RBD, anti-S1/S2 and anti-RBD IgG (all r=0.99), whilst other anti-SARS-CoV-2 antibodies displayed lower, though still significant, correlations. Serum spike protein concentration was undetectable at all-time points. CONCLUSIONS: BNT162b2 mRNA vaccination generates a robust humoral immune response, especially involving anti-SARS-Cov-2 IgG and IgA, magnified by the second vaccine dose.

United States internet searches for "infertility" following COVID-19 vaccine misinformation. CONTEXT: On December 1, 2020, Drs. Wolfgang Wodarg and Micheal Yeadon petitioned to withhold emergency use authorization of the BNT162b2 messenger ribonucleic acid vaccine for coronavirus disease 2019 (COVID-19) manufactured by BioNTech and Pfizer, raising concern for female infertility risks but acknowledging the lack of evidence. The European Medicines Agency and the US Food and Drug Administration ultimately issued emergency useÂ authorizations, but misinformation claiming that COVID-19 vaccines cause female infertility began circulating on social media, potentially influencing public perception and medical decision making among pregnant patients or those seeking to become pregnant. OBJECTIVES: To determine the potential influence misinformation may have had on public interest in infertility related topics, as analyzed through internet search statistics in the US. METHODS: The Google Trends tool was used to analyze results for the search terms "infertility," "infertility AND vaccine," and "infertility AND COVID vaccine" in the US from February 4, 2020 to February 3, 2021. We applied autoregressive integrated moving average models to forecast expected values, comparing them with actual observed values. RESULTS: At peak interest (100), the forecasted relative search volumes interest for the search terms "infertility," "infertility AND vaccine," and "infertility AND COVID vaccine" were 45.47 (95% CI, 33.27-57.66; p<0.001), 0.88 (95% CI, 2.87-4.63; p<0.001), and 0.29 (95% CI,Â -2.25-2.82; p<0.001). The actual relative search volumes at peak

searching represented 119.9, 11,251, and 34,900% increases, respectively, when compared with forecasted values. CONCLUSIONS: COVID-19 vaccine misinformation corresponded with increased internet searches for topics related to infertility in the US. Dispelling misinformation and informing patients about the risks and benefits of COVID-19 vaccination may prevent unnecessary vaccine hesitancy or refusal, contributing to successful vaccination efforts.
Thrombotic Thrombocytopenia after ChAdOx1 nCov-19 Vaccination. BACKGROUND: Several cases of unusual thrombotic events and thrombocytopenia have developed after vaccination with the recombinant adenoviral vector encoding the spike protein antigen of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (ChAdOx1 nCov-19, AstraZeneca). More data were needed on the pathogenesis of this unusual clotting disorder. METHODS: We assessed the clinical and laboratory features of 11 patients in Germany and Austria in whom thrombosis or thrombocytopenia had developed after vaccination with ChAdOx1 nCov-19. We used a standard enzyme-linked immunosorbent assay to detect platelet factor 4 (PF4)-heparin antibodies and a modified (PF4-enhanced) platelet-activation test to detect platelet-activating antibodies under various reaction conditions. Included in this testing were samples from patients who had blood samples referred for investigation of vaccine-associated thrombotic events, with 28 testing positive on a screening PF4-heparin immunoassay. RESULTS: Of the 11 original patients, 9 were women, with a median age of 36 years (range, 22 to 49). Beginning 5 to 16 days after vaccination, the patients presented with one or more thrombotic events, with the exception of 1 patient, who presented with fatal intracranial hemorrhage. Of the patients with one or more thrombotic events, 9 had cerebral venous thrombosis, 3 had splanchnic-vein thrombosis, 3 had pulmonary embolism, and 4 had other thromboses; of these patients, 6 died. Five patients had disseminated intravascular coagulation. None of the patients had received heparin before symptom onset. All 28 patients who tested positive for antibodies against PF4-heparin tested positive on the platelet-activation assay in the presence of PF4 independent of heparin. Platelet activation was inhibited by high levels of heparin, Fc receptor-blocking monoclonal antibody, and immune globulin (10 mg per milliliter). Additional studies with PF4 or PF4-heparin affinity purified antibodies in 2 patients confirmed PF4-dependent platelet activation. CONCLUSIONS: Vaccination with ChAdOx1 nCov-19 can result in the rare development of immune thrombotic thrombocytopenia mediated by platelet-activating antibodies against PF4, which clinically mimics autoimmune heparin-induced thrombocytopenia. (Funded by the German Research Foundation.).
Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination. We report findings in five patients who presented with venous thrombosis and thrombocytopenia 7 to 10 days after receiving the first dose of the ChAdOx1 nCoV-19 adenoviral vector vaccine against coronavirus disease 2019 (Covid-19). The patients were health care workers who were 32 to 54 years of age. All the patients had high levels of antibodies to platelet factor 4-polyanion complexes; however, they had had no previous exposure to heparin. Because the five cases occurred in a population of more than 130,000 vaccinated persons, we propose that they represent a rare vaccine-related variant of spontaneous heparin-induced thrombocytopenia that we refer to as vaccine-induced immune thrombotic thrombocytopenia.
Ribonucleic acid COVID-19 vaccine-associated cutaneous adverse drug events: a case series of two patients.
Helping the Public Understand Adverse Events Associated With COVID-19 Vaccinations: Lessons Learned From Functional Neurological Disorder.
Transient cutaneous manifestations after administration of Pfizer-BioNTech COVID-19 Vaccine: an Italian single-centre case series.
Delirium triggered by COVID-19 vaccine in an elderly patient.

SARS-CoV-2 infection and H1N1 vaccination: does a relationship between the two factors really exist? A retrospective analysis of a territorial cohort in Ferrara, Italy. OBJECTIVE: SARS-CoV-2 has been compared with other strains of coronaviruses, SARS-CoV and MERS-CoV, and with the flu viruses: all of them manifest themselves with respiratory symptoms and, although their genetic patterns are similar, the spread of SARS-CoV-2 infection has quickly reached global dimensions, demonstrating that SARS-CoV-2 is a virus with greater spreading capacity, albeit less lethal. Compared with influenza viruses, coronaviruses have a longer incubation period and the patients with coronaviruses' syndromes develop more severe diseases requiring frequent hospitalizations and intensive care admissions. The aim was to explore the relationships between seasonal influenza vaccination and coronavirus infection and to understand whether this hypothetic role by the flu vaccines modifies SARS-CoV-2 infection's outcomes. PATIENTS AND METHODS: In this retrospective, multicenter study, we enrolled 952 patients diagnosed with SARS-CoV-2 infection; 448 were admitted to our two main hospitals in Ferrara territory, while the remaining 504 were isolated at home. We compared the group of patients who had been vaccinated for influenza in the previous 12 months to that of unvaccinated patients. RESULTS: Significant differences were found for both the need for hospitalization and 30-day mortality between vaccinated and unvaccinated patients. We found age to be the only independent risk factor for a worse 30-day prognosis, while gender, influenza vaccinations and age itself were independent risk factors for undergoing hospitalization. CONCLUSIONS: In our groups of patients, we found a relationship between seasonal influenza vaccinations and SARS-CoV-2 infection. Age seems to be the main risk factor for short-term mortality in COVID-19 inpatients, while the influenza vaccination is, together with gender and age itself, a determining factor in predicting the need for hospitalization.

Correction: Association between influenza vaccination and hospitalisation or all-cause mortality in people with COVID-19: a retrospective cohort study.

Hospitalist perspectives on barriers to recommend and potential benefit of the COVID-19 vaccine. Background: Hospitalists, comprised of nurse practitioners and physician assistants (collectively, advanced practice providers [APPs]) and physicians, have opportunities to counsel patients and reduce SARS-CoV-2 related coronavirus disease 2019 (COVID-19) vaccine hesitancy. However, hospitalist perspectives on the COVID-19 vaccine and potential differences between APPs and physicians are unknown. Understanding hospitalist perspectives could help to address vaccine hesitancy among patients.Methods: We conducted an online survey of hospitalists at Mayo Clinic sites in Arizona, Florida, Minnesota, and Wisconsin from 14 December 2020 through 4 January 2021. We collected demographic information and assessed perspectives on the COVID-19 vaccine and, for comparison, on the influenza vaccine. Descriptive statistics were used to compare responses between APPs and physicians.Results: The overall response rate was 42.7% (nÂ =Â 128/300) and comprised of 53.9% women (nÂ =Â 69/128) and 41.4% APPs (nÂ =Â 53/128). Most hospitalists reported receiving or planning to receive vaccination against COVID-19 (93.7%; n =Â 119/128) and influenza (97.7%; n =Â 125/128). Most hospitalists reported they would advise 100% of patients to receive the COVID-19 vaccine (66% for APPs; 74.7% for physicians) and influenza vaccine (83% for APPs; 80% for physicians). Barriers to recommending the COVID-19 vaccine included patient health status and vaccine safety profile. Hospitalists reported that patients and coworkers receiving the COVID-19 vaccine would reduce their anxiety (~80% of hospitalists), social isolation (~64% of hospitalists), and improve their emotional support (~40% of hospitalists). APP and physician responses were similar. The possible reduction in social isolation was associated with higher odds of hospitalists advising all patients to receive the COVID-19 vaccine (adjusted odds ratio 2.95 [95% confidence interval, 1.32-6.59]; P<Â .008), whereas hospitalist age, gender, and profession showed no association.Conclusion: Most hospitalists would reportedly advise patients to receive the COVID-19 vaccine. Barriers to this

recommendation included patient health status and vaccine safety. Hospitalists are an important resource to provide patient education and reduce COVID-19 vaccine hesitancy.
Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Outbreak in a Long-term Care Facility After Vaccination With BNT162b2.
Polyethylene glycol (PEG) is a cause of anaphylaxis to the Pfizer/BioNTech mRNA COVID-19 vaccine.
Untimely Myocardial Infarction or COVID-19 Vaccine Side Effect. We present the case of a 96-year-old female, with no known cardiac history, who suffered a myocardial infarction (MI) one hour after her first Moderna coronavirus disease 2019 (COVID-19) vaccination. The patient was medically managed and discharged three days later. We are unable to attribute the cause of the patient's MI to the Moderna vaccine unless further data are published. As healthcare providers, we need to be aware of attempts to correlate bad outcomes with the vaccine without substantiated data, and anticipate patient questions that may arise from these reports. Any research on the topic should be written carefully and avoid overstating the findings. If more reports of serious side effects in older adults are published, providers should consider additional screenings prior to COVID-19 vaccination.
Guillain-BarrÃ© Syndrome in the Placebo and Active Arms of a COVID-19 Vaccine Clinical Trial: Temporal Associations Do Not Imply Causality.
Covid-19 vaccine and autoimmunity: Awakening the sleeping dragon.
Non-life-threatening adverse effects with COVID-19 mRNA-1273 vaccine: A randomized, cross-sectional study on healthcare workers with detailed self-reported symptoms. There are concerns regarding the side effects of the new coronavirus disease 2019 (COVID-19) mRNA-1273 vaccine among healthcare workers (HCWs) in the United States. The objective of the study was to investigate the side effects of the mRNA-1273 vaccine with detailed review of organ systems. A randomized, cross-sectional study using an independent online survey questionnaire was conducted to collect responses from HCWs. Of all participants, 87.8% (1116/1271) provided complete responses. Of them, 38.7% (432/1116) received the mRNA-1273 vaccine, among which, 89.35% were females; 425 of these 432 mRNA-1273 vaccine recipients (98.34%) reported at least one or more symptoms. The results were classified based on the frequency of symptoms reported postvaccination. Of these, 254/432 (58.8%) were able to continue their daily routine activities. 108/432 (25%) temporarily had trouble to perform daily activities, 120/432 (27.78%) required transient time off from work, 17/432 (3.94%) required help from an outpatient provider, 1/432 (0.23%) required help from emergency department, and none of them were hospitalized. Despite the wide array of self-reported symptoms, 97.02% of the HCWs did not intend to skip the second dose of vaccine. Among all the symptoms reported, localized pain, generalized weakness, headache, myalgia, chills, fever, nausea, joint pains, sweating, localized swelling at the injection site, dizziness, itching, rash, decreased appetite, muscle spasm, decreased sleep quality, and brain fogging were the most commonly reported symptoms (in descending order of occurrence). Most of the symptoms reported were nonlife threatening. Despite the wide array of self-reported symptoms, there appears to be a higher acceptance for this vaccine.
Diagnosis and Management of Vaccine-Related Thrombosis following AstraZeneca COVID-19 Vaccination: Guidance Statement from the GTH. The COVID-19 pandemic is an ongoing global healthcare crisis. Based on reports of atypically located thromboses following vaccination with the AstraZeneca COVID-19 vaccine, the Society of Thrombosis and Haemostasis Research (GTH) has issued guidance statements on the recognition, diagnosis, and treatment of this rare complication. It shares pathophysiological features with heparin-induced thrombocytopenia (HIT) and is referred to as vaccine-induced prothrombotic immune thrombocytopenia (VIPIT).
Efficient Maternofetal Transplacental Transfer of Anti- Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Spike Antibodies After Antenatal SARS-CoV-2 BNT162b2 Messenger RNA Vaccination. Maternal and cord blood sera were collected from 20 parturients who received the

BNT162b2 vaccine. All women and infants were positive for anti S- and anti-receptor binding domain antibody-specific immunoglobulin G. Cord blood antibody concentrations were correlated to maternal levels and to time since vaccination. Antenatal severe acute respiratory syndrome coronavirus 2 vaccination may provide maternal and neonatal protection.

Adverse Events Following SARS-CoV-2 mRNA Vaccination Among Patients with Inflammatory Bowel Disease. Patients with immune-mediated inflammatory diseases (IMID) such as inflammatory bowel disease (IBD) on immunosuppressive and biologic therapies were largely excluded from SARS-CoV-2 mRNA vaccine trials. We thus evaluated post-mRNA vaccination adverse events (AE) in 246 vaccinated adults with IBD participating in a longitudinal vaccine registry. In general, AE frequency was similar to that reported in the general population. As in the general population, AE were more common among younger patients, and those with prior COVID-19. We additionally found that AE were less common in individuals receiving biologic therapy. Those with IBD and other IMID on these commonly prescribed therapies can be reassured that the AE risk is likely not increased, and may be reduced, while on biologics.

COVID-19 vaccine impact on rates of SARS-CoV-2 cases and post vaccination strain sequences among healthcare workers at an urban academic medical center: a prospective cohort study. BACKGROUND: COVID-19 vaccine trials and post-implementation data suggest vaccination decreases SARS-CoV-2 infections. We examine COVID-19 vaccination's impact on SARS-CoV-2 case rates and viral diversity among healthcare workers (HCW) during a high community prevalence period. METHODS: A prospective cohort study from Boston Medical Center (BMC)'s HCW vaccination program, where staff received two doses of BNT162b2 or mRNA-1273. We included PCR-confirmed SARS-CoV-2 cases among HCWs from December 09, 2020 to February 23, 2021. Weekly SARS-CoV-2 rates per 100,000 person-day overall and by time from first injection (1-14 and >14 days) were compared with surrounding community rates. Viral genomes were sequenced from SARS CoV-2 positive samples. RESULTS: SARS-CoV-2 cases occurred in 1.4% (96/7109) of HCWs given at least a first dose and 0.3% (17/5913) of HCWs given both vaccine doses. Adjusted SARS-CoV-2 infection rate ratios were 0.73 (95% CI 0.53-1.00) 1-14 days and 0.18 (0.10-0.32) >14 days from first dose. HCW SARS-CoV-2 cases >14 days from initial dose compared to within 14 days were more often older (46 versus 38 years, p=0.007), Latinx (10% versus 8%, p=0.03), and asymptomatic (48% versus 11%, p=0.0002). SARS-CoV-2 rates among HCWs fell below those of the surrounding community, with a 18% versus 11% weekly decrease respectively (p=0.14). Comparison of 48 SARS-CoV-2 genomes sequenced from post-first dose cases did not indicate selection pressure towards known spike-antibody escape mutations. CONCLUSIONS: Our results indicate a positive impact of COVID-19 vaccines on SARS-CoV-2 case rates. Post-vaccination isolates did not show unusual genetic diversity or selection for mutations of concern. MAIN POINT: Cases of SARS-CoV-2 among health care workers dropped rapidly with COVID-19 vaccination. Sequencing 48 breakthrough infections (overwhelmingly in 14 days after 1st dose) showed no clear sign of any differences in spike protein compared with time-matched, unvaccinated control sequences.

Administration of a Second Dose of the Moderna COVID-19 Vaccine After an Immediate Hypersensitivity Reaction With the First Dose: Two Case Reports.

Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines.

COVID-19 Vaccine for Elderly: Should We Be Reactive or Proactive? It has been a year since the Indonesian government announced its first COVID-19 identified in Jakarta. Since then, there have been more than 900,000 cases in Indonesia with case fatality rate (CFR) of 2.9%. The number of new cases per day is now ranging from 9,000 cases to almost 13,000 cases. Not only in Indonesia, but the number of new cases along with the mortality rate in other countries, such as Malaysia, Japan, United States, and Europe region also increased dramatically. COVID-19 vaccines are being investigated and

the world hopes that vaccines will be the answer to tackle this pandemic. Is it really so? Immunization is an effort to induce immunity in individuals to prevent a disease or the complication related to the diseases that may be catastrophic. Immunization can be divided into passive, which is by giving certain type of antibody and active, which means that either we get the disease, or we get the antigen injected into our body.Having prior vaccination or past COVID-19 does not mean that someone is totally immune to COVID-19 as a recent study suggested that the antibody related to COVID-19 past infection is significantly decreasing after 3 months post-infection. Compliance to implementation of health protocol remained the most crucial strategy during this pandemic.
The precautionary principle, the AstraZeneca COVID-19 vaccine and mixed messaging.
Flare of rheumatoid arthritis after COVID-19 vaccination.
Adverse Events Reported From Â COVID-19 Vaccine Trials: A Systematic Review. COVID-19 infection originated in Wuhan, China in December 2019 and crippled human health globally in no time. The public health emergency required urgent efforts to develop and test the efficacy and safety of vaccines to combat the COVID-19 pandemic. The emergency use approval has been granted to COVID-19 vaccines before the completion of conventional phases of clinical trials. However, there is no comprehensive review of safety data reported from the vaccine trials, which is critical information to inform the policies in order to improve uptake of COVID-19 vaccines and mitigate the risk aversion perceived due to the COVID-vaccine side effects. This study aims to systematically review and synthesize the evidence on the safety data from the published COVID-19 vaccine trials. This study followed PRISMA guidelines. We searched three major electronic databases (PubMed, Embase, and Google Scholar) for published studies between Dec 2019 and 2020. Eligible study designs were randomized trials and pre-and post-intervention evaluations. Descriptive findings of included studies were reported stratified by target population, setting, outcomes, and overall results. From PubMed, Embase, WHO database, and Google Scholar screened titles and abstracts, 11 studies were identified in this review. Most of the reactions reported were mild to moderate whereas a few with severe intensity. All reactions resolved within 3-4Â days. The commonly reported local adverse events were pain at the site of injection, swelling, and redness. The systemic reactions included fever, fatigue, myalgia, and headache. Some trials also reported laboratory derangements Â like decreased hemoglobin, increased bilirubin, altered SGOT and SGPT. None of these alterations were clinically manifested and were self-limiting. Few clinical trials reported serious adverse events, but they were unrelated to vaccination. This systematic review indicates that COVID-19 vaccines can be safe with no serious adverse events. However, long-term post-marketing surveillance data, particularly in high-risk vulnerable populations (elderly and those with co-morbidities, pregnant women, and children) is warranted to ensure the safety of COVID-19 vaccines.
Can technology increase COVID-19 vaccination rates?
Adverse reactions to COVID-19 vaccines: A practical approach. COVID-19-related mortality in high-risk individuals is substantial and current treatment options are limited. There is convincing evidence that the COVID-19 vaccines reduce the severity of infection and prevent deaths. Three COVID-19 vaccines are approved in the United Kingdom with many more in development. There are limited data on the triggers and mechanisms of anaphylaxis to these vaccines. We review the potential allergenic compounds in the COVID-19 vaccines and describe an innovative allergy support model for the vaccination hubs that allows most patients with severe allergy be immunized. Finally, we propose a practical algorithm for the investigations of anaphylaxis to these vaccines.
What Indians Think of the COVID-19 vaccine: A qualitative study comprising focus group discussions and thematic analysis. BACKGROUND AND AIMS: The study aims to interpret current knowledge, attitude, perceptions and concerns regarding COVID-19 vaccine in the Indian population. METHODS: Eight focus group discussions were conducted. Participants were recruited via purposive sampling.

Discussions were recorded and transcribed verbatim. Key themes were extracted using thematic analysis method. RESULTS: There were 19 males and 24 females, with a mean age of 36Â Â±Â 11 years. Sub-themes identified were knowledge, attitude, perception and concerns regarding COVID-19 vaccine, leading to the main theme, i.e., views about the COVID-19 vaccine. CONCLUSION: People have mixed perceptions regarding COVID-19 vaccine. Channelling correct messages may improve people's willingness to get vaccinated.
Cord blood antibodies following maternal coronavirus disease 2019 vaccination during pregnancy.
Short-term safety of the BNT162b2 mRNA COVID-19 vaccine in patients with cancer treated with immune checkpoint inhibitors.
COVID-19 vaccines for patients with haematological conditions.
Vaccines and allergic reactions: The past, the current COVID-19 pandemic, and future perspectives. Vaccines are essential public health tools with a favorable safety profile and prophylactic effectiveness that have historically played significant roles in reducing infectious disease burden in populations, when the majority of individuals are vaccinated. The COVID-19 vaccines are expected to have similar positive impacts on health across the globe. While serious allergic reactions to vaccines are rare, their underlying mechanisms and implications for clinical management should be considered to provide individuals with the safest care possible. In this review, we provide an overview of different types of allergic adverse reactions that can potentially occur after vaccination and individual vaccine components capable of causing the allergic adverse reactions. We present the incidence of allergic adverse reactions during clinical studies and through post-authorization and post-marketing surveillance and provide plausible causes of these reactions based on potential allergenic components present in several common vaccines. Additionally, we review implications for individual diagnosis and management and vaccine manufacturing overall. Finally, we suggest areas for future research.
Management of anaphylaxis due to COVID-19 vaccines in the elderly. Older adults, especially men and/or those with diabetes, hypertension, and/or obesity, are prone to severe COVID-19. In some countries, older adults, particularly those residing in nursing homes, have been prioritized to receive COVID-19 vaccines due to high risk of death. In very rare instances, the COVID-19 vaccines can induce anaphylaxis, and the management of anaphylaxis in older people should be considered carefully. An ARIA-EAACI-EuGMS (Allergic Rhinitis and its Impact on Asthma, European Academy of Allergy and Clinical Immunology, and European Geriatric Medicine Society) Working Group has proposed some recommendations for older adults receiving the COVID-19 vaccines. Anaphylaxis to COVID-19 vaccines is extremely rare (from 1 per 100,000 to 5 per million injections). Symptoms are similar in younger and older adults but they tend to be more severe in the older patients. Adrenaline is the mainstay treatment and should be readily available. A flowchart is proposed to manage anaphylaxis in the older patients.
Allergic Reactions to Current Available COVID-19 Vaccinations: Pathophysiology, Causality, and Therapeutic Considerations. Vaccines constitute the most effective medications in public health as they control and prevent the spread of infectious diseases and reduce mortality. Similar to other medications, allergic reactions can occur during vaccination. While most reactions are neither frequent nor serious, anaphylactic reactions are potentially life-threatening allergic reactions that are encountered rarely, but can cause serious complications. The allergic responses caused by vaccines can stem from activation of mast cells via FcÎµ receptor-1 type I reaction, mediated by the interaction between immunoglobulin E (IgE) antibodies against a particular vaccine, and occur within minutes or up to four hours. The type IV allergic reactions initiate 48 h after vaccination and demonstrate their peak between 72 and 96 h. Non-IgE-mediated mast cell degranulation via activation of the complement system and via activation of the Mas-related G protein-coupled receptor X2 can also

induce allergic reactions. Reactions are more often caused by inert substances, called excipients, which are added to vaccines to improve stability and absorption, increase solubility, influence palatability, or create a distinctive appearance, and not by the active vaccine itself. Polyethylene glycol, also known as macrogol, in the currently available Pfizer-BioNTech and Moderna COVID-19 mRNA vaccines, and polysorbate 80, also known as Tween 80, in AstraZeneca and Johnson & Johnson COVID-19 vaccines, are excipients mostly incriminated for allergic reactions. This review will summarize the current state of knowledge of immediate and delayed allergic reactions in the currently available vaccines against COVID-19, together with the general and specific therapeutic considerations. These considerations include: The incidence of allergic reactions and deaths under investigation with the available vaccines, application of vaccination in patients with mast cell disease, patients who developed an allergy during the first dose, vasovagal symptoms masquerading as allergic reactions, the COVID-19 vaccination in pregnancy, deaths associated with COVID-19 vaccination, and questions arising in managing of this current ordeal. Careful vaccine-safety surveillance over time, in conjunction with the elucidation of mechanisms of adverse events across different COVID-19 vaccine platforms, will contribute to the development of a safe vaccine strategy. Allergists' expertise in proper diagnosis and treatment of allergic reactions is vital for the screening of high-risk individuals.

COVID-19 Vaccine Failure in a Patient with Multiple Sclerosis on Ocrelizumab. Vaccines will play a key role in ending the COVID-19 pandemic. Vaccination against infections remains an important part of the management of patients with multiple sclerosis. However, there are limited data about the safety and efficacy of the currently available COVID-19 mRNA vaccines in patients with multiple sclerosis receiving concurrent immunosuppressive therapies. Patients on B cell depleting therapy such as ocrelizumab have an attenuated vaccine response. We report the first case of COVID-19 vaccine failure in a patient with relapsing-remitting multiple sclerosis on B cell depleting therapy, ocrelizumab. We offer suggestions to improve vaccine efficacy in these patients.

COVID-19 Vaccine Acceptance among an Online Sample of Sexual and Gender Minority Men and Transgender Women. Sexual and gender minority (SGM) populations are particularly vulnerable to poor COVID-19 outcomes and are more likely to experience stigma and medical mistrust that may impact COVID-19 vaccine acceptance. This study examined the prevalence of COVID testing and diagnosis and assessed COVID-19 vaccine acceptance among a large sample of SGM. Participants were recruited as part of an online cross-sectional study focused on an HIV biomedical prevention technology willingness in the United States at increased risk for HIV sero-conversion. Multivariate linear analysis was conducted to examine COVID-19 vaccine acceptance. The study sample included 1350 predominately gay (61.6%), Black (57.9%), cis-gender (95.7%) males with a mean age of 32.9 years. Medical mistrust and social concern regarding COVID-19 vaccine stigma were significantly associated with decreased COVID-19 vaccine acceptance, and altruism was significantly associated with increased vaccine acceptance. Black participants were significantly less likely to accept a COVID-19 vaccine, and Asian participants were significantly more likely to accept a vaccine, compared to White peers. As the planning of COVID-19 vaccine rollout efforts is conceptualized and designed, these data may inform equitable implementation strategies and prevent worsening health inequities among SGM populations.

Comparative Assessment of Sera from Individuals after S-Gene RNA-Based SARS-CoV-2 Vaccination with Spike-Protein-Based and Nucleocapsid-Based Serological Assays. Due to the beginning of vaccination against COVID-19, serological discrimination between vaccine-associated humoral response and serology-based surveillance of natural SARS-CoV-2 infections as well as breakthrough infections becomes an issue of relevance. Here, we assessed the differentiated effects of the application of an RNA vaccine using SARS-CoV-2 spike protein epitopes on the results of both anti-

spike protein-based serology (EUROIMMUN) and anti-nucleocapsid-based serology (VIROTECH). A total of 80 serum samples from vaccinees acquired at different time points after vaccination was assessed. While positive or borderline serological response in the anti-spike protein assay was observed for all samples (90% both IgG and IgA, 6.3% IgA only, 3.8% borderline IgG only), only a single case of a falsely positive IgM was observed for the anti-nucleocapsid assay as expected due to this assay's specificity. Positive anti-spike protein antibodies were already detectable in the second week after the first dose of vaccination, with higher titers after the second dose of the vaccine. In conclusion, the combined application of anti-spike protein-based serology and anti-nucleocapsid-based serology will provide a useful option for the discrimination of vaccination response and natural infection.

Lymphadenopathy after BNT162b2 Covid-19 Vaccine: Preliminary Ultrasound Findings. During a spontaneous and autonomous study, we assessed the ultrasound finding of lymphadenopathy after BNT162b2 Pfizer vaccine. We enrolled 18 patients with 58 lymphadenopathies: in 10 patients, they were in the laterocervical side, while in 8 patients in the axillar site. The largest diameter was 16 mm with a range from 7 to 16 mm (median value = 10 mm). In the same patient, we found different ultrasound nodal findings. A total of 25 nodes showed eccentric cortical thickening with wide echogenic hilum and oval shape. In total, 19 nodes showed asymmetric eccentric cortical thickening with wide echogenic hilum and oval shape. Overall, 10 nodes showed concentric cortical thickening with reduction in the width of the echogenic hilum and oval shape. A total of four nodes showed huge reduction and displacement of the echogenic hilum and round or oval shape. No anomaly was found at the Doppler echocolor study. In conclusion, eccentric cortical thickening with wide echogenic hilum and oval shape, asymmetric eccentric cortical thickening with wide echogenic hilum and oval shape, concentric cortical thickening with reduction in the width of the echogenic hilum and oval shape, and a huge reduction and displacement of the echogenic hilum and round shape are the features that we found in post BNT162b2 Covid-19 Vaccine lymphadenopathies.

Efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine against SARS-CoV-2 variant of concern 202012/01 (B.1.1.7): an exploratory analysis of a randomised controlled trial. BACKGROUND: A new variant of SARS-CoV-2, B.1.1.7, emerged as the dominant cause of COVID-19 disease in the UK from November, 2020. We report a post-hoc analysis of the efficacy of the adenoviral vector vaccine, ChAdOx1 nCoV-19 (AZD1222), against this variant. METHODS: Volunteers (aged â‰¥18 years) who were enrolled in phase 2/3 vaccine efficacy studies in the UK, and who were randomly assigned (1:1) to receive ChAdOx1 nCoV-19 or a meningococcal conjugate control (MenACWY) vaccine, provided upper airway swabs on a weekly basis and also if they developed symptoms of COVID-19 disease (a cough, a fever of 37Â·8Â°C or higher, shortness of breath, anosmia, or ageusia). Swabs were tested by nucleic acid amplification test (NAAT) for SARS-CoV-2 and positive samples were sequenced through the COVID-19 Genomics UK consortium. Neutralising antibody responses were measured using a live-virus microneutralisation assay against the B.1.1.7 lineage and a canonical non-B.1.1.7 lineage (Victoria). The efficacy analysis included symptomatic COVID-19 in seronegative participants with a NAAT positive swab more than 14 days after a second dose of vaccine. Participants were analysed according to vaccine received. Vaccine efficacy was calculated as 1â€‰-â€‰relative risk (ChAdOx1 nCoV-19 vs MenACWY groups) derived from a robust Poisson regression model. This study is continuing and is registered with ClinicalTrials.gov, NCT04400838, and ISRCTN, 15281137. FINDINGS: Participants in efficacy cohorts were recruited between May 31 and Nov 13, 2020, and received booster doses between Aug 3 and Dec 30, 2020. Of 8534 participants in the primary efficacy cohort, 6636 (78%) were aged 18-55 years and 5065 (59%) were female. Between Oct 1, 2020, and Jan 14, 2021, 520 participants developed SARS-CoV-2 infection. 1466 NAAT positive nose and throat swabs were collected from these participants during the trial. Of these, 401 swabs from 311 participants

were successfully sequenced. Laboratory virus neutralisation activity by vaccine-induced antibodies was lower against the B.1.1.7 variant than against the Victoria lineage (geometric mean ratio 8Â·9, 95% CI 7Â·2-11Â·0). Clinical vaccine efficacy against symptomatic NAAT positive infection was 70Â·4% (95% CI 43Â·6-84Â·5) for B.1.1.7 and 81Â·5% (67Â·9-89Â·4) for non-B.1.1.7 lineages. INTERPRETATION: ChAdOx1 nCoV-19 showed reduced neutralisation activity against the B.1.1.7 variant compared with a non-B.1.1.7 variant in vitro, but the vaccine showed efficacy against the B.1.1.7 variant of SARS-CoV-2. FUNDING: UK Research and Innovation, National Institute for Health Research (NIHR), Coalition for Epidemic Preparedness Innovations, NIHR Oxford Biomedical Research Centre, Thames Valley and South Midlands NIHR Clinical Research Network, and AstraZeneca.

Anti-severe acute respiratory syndrome coronavirus 2 antibodies induced in breast milk after Pfizer-BioNTech/BNT162b2 vaccination.

A COVID-19-ready public health surveillance system: The Food and Drug Administration's Sentinel System. The US Food and Drug Administration's Sentinel System was established in 2009 to use routinely collected electronic health data for improving the national capability to assess post-market medical product safety. Over more than a decade, Sentinel has become an integral part of FDA's surveillance capabilities and has been used to conduct analyses that have contributed to regulatory decisions. FDA's role in the COVID-19 pandemic response has necessitated an expansion and enhancement of Sentinel. Here we describe how the Sentinel System has supported FDA's response to the COVID-19 pandemic. We highlight new capabilities developed, key data generated to date, and lessons learned, particularly with respect to working with inpatient electronic health record data. Early in the pandemic, Sentinel developed a multi-pronged approach to support FDA's anticipated data and analytic needs. It incorporated new data sources, created a rapidly refreshed database, developed protocols to assess the natural history of COVID-19, validated a diagnosis-code based algorithm for identifying patients with COVID-19 in administrative claims data, and coordinated with other national and international initiatives. Sentinel is poised to answer important questions about the natural history of COVID-19 and is positioned to use this information to study the use, safety, and potentially the effectiveness of medical products used for COVID-19 prevention and treatment.

Antibody responses to the BNT162b2 mRNA vaccine in individuals previously infected with SARS-CoV-2. In a cohort of BNT162b2 (Pfizer-BioNTech) mRNA vaccine recipients (nâ€‰=â€‰1,090), we observed that spike-specific IgG antibody levels and ACE2 antibody binding inhibition responses elicited by a single vaccine dose in individuals with prior SARS-CoV-2 infection (nâ€‰=â€‰35) were similar to those seen after two doses of vaccine in individuals without prior infection (nâ€‰=â€‰228). Post-vaccine symptoms were more prominent for those with prior infection after the first dose, but symptomology was similar between groups after the second dose.

Why is it so hard to investigate the rare side effects of COVID vaccines?

DOTATATE -Avid Bilateral Axilla and Subpectoral Lymphadenopathy Induced From COVID-19 mRNA Vaccination Visualized on PET/CT. A 64-year-old woman with malignant carcinoid tumor of the ileum received right ileocolectomy 9 years ago. Series follow-up imaging studies including most recent 68Ga-DOTATATE PET/CT scan in June 2020 have been negative for disease. Current 68Ga-DOTATATE PET/CT scan showed new cluster of bilateral axillary and subpectoral lymphadenopathy with normal CT morphology, but with avid DOTATATE uptake. There was no other abnormal DOTATATE-avid lesion or suspicious CT image findings. The medical history revealed that the patient received 2 doses of COVID-19 (coronavirus disease 2019) mRNA vaccine at bilateral upper arm deltoid muscles at 21 and 42 days prior to the PET/CT examination, respectively.

Covid-19 vaccination during Ramadan.

Fear of COVID-19 infection among surgeons and hesitancy for vaccination. Who is the culprit to blame?

Allergic reactions to COVID-19 vaccines: statement of the Belgian Society for Allergy and Clinical Immunology (BelSACI). Vaccination against COVID-19 constitutes a huge hope and a major challenge. For the first time in modern history, a global vaccination campaign has started worldwide in a short period of time and with products that were recently developed. Consequently, legitimate concerns regarding the safety and tolerability of COVID-19 vaccines arise.In line with international allergy societies, the Belgian Society for Allergy and Clinical Immunology (BelSACI) provides this statement to guide health care providers (general practitioners, specialists including allergists) and stakeholders.In this statement, we first review current evidence on allergic reactions to vaccines and the potential risk factors that have been identified.Second, we provide a risk stratification method that may be used as a worksheet during the vaccination campaign.Finally, we discuss the management of suspected or confirmed allergic reactions following vaccination.

Characterizing the incidence of adverse events of special interest for COVID-19 vaccines across eight countries: a multinational network cohort study. BACKGROUND: As large-scale immunization programs against COVID-19 proceed around the world, safety signals will emerge that need rapid evaluation. We report population-based, age- and sex-specific background incidence rates of potential adverse events of special interest (AESI) in eight countries using thirteen databases. METHODS: This multi-national network cohort study included eight electronic medical record and five administrative claims databases from Australia, France, Germany, Japan, Netherlands, Spain, the United Kingdom, and the United States, mapped to a common data model. People observed for at least 365 days before 1 January 2017, 2018, or 2019 were included. We based study outcomes on lists published by regulators: acute myocardial infarction, anaphylaxis, appendicitis, Bell's palsy, deep vein thrombosis, disseminated intravascular coagulation, encephalomyelitis, Guillain-Barre syndrome, hemorrhagic and non-hemorrhagic stroke, immune thrombocytopenia, myocarditis/pericarditis, narcolepsy, pulmonary embolism, and transverse myelitis. We calculated incidence rates stratified by age, sex, and database. We pooled rates across databases using random effects meta-analyses. We classified meta-analytic estimates into Council of International Organizations of Medical Sciences categories: very common, common, uncommon, rare, or very rare. FINDINGS: We analysed 126,661,070 people. Rates varied greatly between databases and by age and sex. Some AESI (e.g., myocardial infarction, Guillain-Barre syndrome) increased with age, while others (e.g., anaphylaxis, appendicitis) were more common in young people. As a result, AESI were classified differently according to age. For example, myocardial infarction was very rare in children, rare in women aged 35-54 years, uncommon in men and women aged 55-84 years, and common in those aged â‰¥85 years. INTERPRETATION: We report robust baseline rates of prioritised AESI across 13 databases. Age, sex, and variation between databases should be considered if background AESI rates are compared to event rates observed with COVID-19 vaccines.

Audio Interview: Delivering Covid-19 Vaccines to Minority Communities.

Antibody response to SARS-CoV-2 vaccination is extremely vivacious in subjects with previous SARS-CoV-2 infection. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic calls for rapid actions, now principally oriented to a world-wide vaccination campaign. In this study we verified if, in individuals with a previous SARS-CoV-2 infection, a single dose of messenger RNA (mRNA) vaccine would be immunologically equivalent to a full vaccine schedule in naÃ¯ve individuals. Health care workers (184) with a previous SARS-CoV-2 infection were sampled soon before the second dose of vaccine and between 7 and 10 days after the second dose, the last sampling time was applied to SARS-CoV-2 naÃ¯ve individuals, too. Antibodies against SARS-CoV-2 were measured using Elecsys Anti-SARS-CoV-2 S immunoassay. The study was powered for non-inferiority. We used non parametric tests and Pearson correlation test to perform inferential analysis. After a single vaccine injection, the median titer of specific antibodies in individuals with previous coronavirus disease 2019

was 30.527 U/ml (interquartile range [IQR]: 19.992-39.288) and in subjects with previous SARS-CoV-2 asymptomatic infection was 19.367.5 U/ml (IQR: 14.688-31.353) (pâ€‰=â€‰.032). Both results were far above the median titer in naÃ¯ve individuals after a full vaccination schedule: 1974.5 U/ml (IQR: 895-3455) (pâ€‰<â€‰.0001). Adverse events after vaccine injection were more frequent after the second dose of vaccine (mean: 0.95; 95% confidence interval [CI]: 0.75-1.14 vs. mean: 1.91; 95% CI: 1.63-2.19) (pâ€‰<â€‰.0001) and in exposed compared to naÃ¯ve (mean: 1.63; 95% CI: 1.28-1.98 vs. mean: 2.35; 95% CI: 1.87-2.82) (pâ€‰=â€‰.015). In SARS-CoV-2 naturally infected individuals a single mRNA vaccine dose seems sufficient to reach immunity. Modifying current dosing schedules would speed-up vaccination campaigns.

Vigilance regarding immune thrombocytopenic purpura after COVID-19 vaccine. INTRODUCTION: Based on the severity of thrombocytopenia, patients with immune thrombocytopenic purpura (ITP) are at an increased risk of mucocutaneous or major bleeding. DISCUSSION: There has been an increased risk of ITP after administration of various vaccines like influenza, measles-mumps-rubella, hepatitis B, and diphtheria-tetanus-pertussis. The pathogenesis of vaccine-related thrombocytopenia is not completely clear and is probably caused by molecular mimicry. Till date, there have been few reported cases of thrombocytopenia in the pharmacovigilance databases after patients received the Pfizer and Moderna coronavirus disease-19 (COVID-19) vaccines. CONCLUSION: Emergency physicians should be aware of the occurrence of vaccine-induced ITP in patients who present with bleeding manifestations, especially after the current boost in COVID-19 vaccination drive worldwide.

COVID-19 vaccination-associated myelitis.

Is SARS-CoV-2 vaccination safe and effective for elderly individuals with neurodegenerative diseases? INTRODUCTION: Coronavirus Disease 2019 (COVID-19) poses a substantial threat to the lives of the elderly, especially those with neurodegenerative diseases, and vaccination against viral infections is recognized as an effective measure to reduce mortality. However, elderly patients with neurodegenerative diseases often suffer from abnormal immune function and take multiple medications, which may complicate the role of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines. Currently, there is no expert consensus on whether SARS-CoV-2 vaccines are suitable for patients with neurodegenerative diseases. AREAS COVERED: We searched Pubmed to conduct a systematic review of published studies, case reports, reviews, meta-analyses, and expert guidelines on the impact of SARS-CoV-2 on neurodegenerative diseases and the latest developments in COVID-19 vaccines. We also summarized the interaction between vaccines and age-related neurodegenerative diseases. The compatibility of future SARS-CoV-2 vaccines with neurodegenerative diseases is discussed. EXPERT OPINION: Vaccines enable the body to produce immunity by activating the body's immune response. The pathogenesis and treatment of neurodegenerative diseases is complex, and these diseases often involve abnormal immune function, which can substantially affect the safety and effectiveness of vaccines. In short, this article provides recommendations for the use of vaccine candidates in patients with neurodegenerative diseases.

Reply to "Unilateral Axillary Lymphadenopathy After Coronavirus Disease (COVID-19) Vaccination".

SARS-CoV-2 (COVID-19) vaccination in dermatology patients on immunomodulatory and biologic agents: Recommendations from the Australasian Medical Dermatology Group. As the phase III COVID-19 vaccine trials excluded patients on immunosuppressive treatments, or patients with significant autoimmunity, the Australasian Medical Dermatology Group make the following preliminary recommendations around COVID-19 vaccination in dermatology patients on immunomodulatory and/or biologic agents. Vaccination against COVID-19 is strongly encouraged for all patients on immunomodulatory drugs and/or biologic agents. There are currently insufficient data to recommend one COVID-19 vaccine or vaccine type (mRNA, recombinant, inactivated virus) over another. No specific additional risk in patients on immunomodulatory or biologic therapies has so far

been identified. Data on vaccine efficacy in patients on immunomodulatory or biologic therapies are missing, so standard vaccination protocols are recommended until otherwise advised.
Purpuric Rash and Thrombocytopenia After the mRNA-1273 (Moderna) COVID-19 Vaccine. The mRNA-1273 vaccine, popularly called the "Moderna vaccine" is being widely administered in the United States for the prevention of COVID-19 infection since December 2020. Mild to moderate intensity side effects like low-grade fever, myalgia, chills and malaise were reported in the trials related to the vaccine.Â With this case report, we report a case of purpuric rash and thrombocytopenia after receiving the first dose of the m-RNA-1273 vaccine. The patient, in this case, is a 60-year-old male patient who received the first vaccine dose and within two days, he developed diffuse papular rash associated with some thrombocytopenia. He had a history of tobacco use, Hepatitis C liver cirrhosis, chronic kidney disease stage 4, untreated hypertension and systolic congestive heart failure at the baseline.Â With review of the limited literature related to the vaccine and its side effect profile and with no other etiology explaining the sudden onset of rash, we attribute this thrombocytopenia and purpuric rash as the side effects of the mRNA-1273 vaccine.
Lymphadenopathy Associated With the COVID-19 Vaccine. The coronavirus disease 2019 (COVID-19) pandemic has dominated nearly everyone's life since its initial outbreak in the Hubei province of China in December 2019. The disease had spread quickly throughout the world causing extensive, widespread morbidity, over two million deaths, and economical and social devastation over the entire world. Researchers and pharmaceutical companies around the globe have been racing to develop potent and safe vaccines for the disease. Pfizer-BioNTech COVID-19 vaccine followed by Moderna COVID-19 mRNA-1273 vaccine were the first to receive FDA approval. These vaccines are based on messenger RNA novel technology and considered efficient in preventing contagion ensuring safety. Known side effects for this vaccine have been reported as very similar to those known for other vaccines. Specifically, lymphadenopathy has not been considered a common manifestation of COVID-19 vaccination. Israel has been cited as leading in the introduction of these vaccines, which are available for every citizen older than 16 years. Here, we present the cases of three patients who developed lymphadenopathy after the first dose of Pfizer-BioNTech COVID-19 vaccine. Time elapsed from the injection until the appearance of the enlarged nodes, clinical symptoms, and sonographic features differed between the patients, but in all cases gradual regression was noted in the enlarged nodes until complete resolution. Accordingly, to our knowledge, this is the first report describing post-COVID-19 vaccine lymphadenopathy detailing the clinical aspects, sonographic features, and outcomes.
A case report of acquired hemophilia following COVID-19 vaccine. Acquires hemophilia A (AHA) is rare bleeding condition commonly associated with malignancy, autoimmune disease, or pregnancy. We report a case of a 69-year-old gentleman who developed bleeding symptoms after receiving COVID-19 vaccine. Laboratory testing showed isolated prolongation of the activated partial thromboplastin time, and normal von Willebrand factor. Further testing confirmed the presence of factor VIII inhibitor. To date, no cases of AHA have been reported after exposure to COVID-19 vaccine. There have been two cases of AHA following seasonal flu and H1N1 vaccination, as well as two cases of AHA following COVID-19 infection. We present a summary of these cases and review of literature of autoimmune reactions following vaccination.
Skin manifestations of the BNT162b2 mRNA COVID-19 vaccine in healthcare workers. 'COVID-arm': a clinical and histological characterization.
United States COVID-19 Vaccination Preferences (CVP): 2020 Hindsight. BACKGROUND: Shortly after the 2020 US election, initial evidence on first-generation COVID-19 vaccines showed 70-95% efficacy and minimal risks. Yet, many US adults expressed reluctance. AIMS: The aim of this study was to compare persons willing and unwilling to be vaccinated against COVID-19 and to estimate the

effects of vaccination attributes on uptake: proof of vaccination, vaccination setting, effectiveness, duration of immunity, and risk of severe side effects. METHOD: Between 9 and 11 November 2020, 1153 US adults completed a discrete choice experiment (DCE) on Phase 2 of the CDC Vaccination Program (August 2021). Each of its eight choice tasks had three vaccination alternatives and "no vaccination for 6Â months." An opt-out inflated logit model was estimated to test for respondent differences and attribute effects. RESULTS: Respondent demographics were unrelated to one's willingness to be vaccinated (p value 0.533), but those with less education were more likely to be unwilling (pâ€‰<â€‰0.001). Among those willing, uptake ranged from 61.70 to 97.75%, depending on the vaccination attributes. Effectiveness and safety had the largest effects. Offering proof of vaccination and a choice of setting increased uptake as much as increasing immunity from 3 to 6Â months. CONCLUSIONS: To maximize uptake, the CDC Program should standardize proof of vaccination and offer a choice of setting, instead of a one-size-fits-all approach. If the first-generation vaccines are efficacious, widely available, and free, overall predicted uptake is 68.81% by the end of Phase 2 (August 2021), which is well below the 75-90% needed for herd immunity. Further health preference research is necessary to uncover and address unwillingness and reluctance to vaccinate against COVID-19.

Initial report of decreased SARS-CoV-2 viral load after inoculation with the BNT162b2 vaccine. Beyond their substantial protection of individual vaccinees, coronavirus disease 2019 (COVID-19) vaccines might reduce viral load in breakthrough infection and thereby further suppress onward transmission. In this analysis of a real-world dataset of positive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) test results after inoculation with the BNT162b2 messenger RNA vaccine, we found that the viral load was substantially reduced for infections occurring 12-37â€‰d after the first dose of vaccine. These reduced viral loads hint at a potentially lower infectiousness, further contributing to vaccine effect on virus spread.

18F-FDG-Avid Lymph Nodes After COVID-19 Vaccination on 18F-FDG PET/CT. A 68-year-old man with right cheek melanoma after resection underwent 18F-FDG PET/CT, which was unremarkable except for multiple FDG-avid subcentimeter but rounded lymph nodes in the left axilla. The patient had undergone a COVID-19 vaccination in the left arm 3 weeks prior. As under vaccinations have been documented to cause reactive FDG-avid lymph nodes, the nodes in our patient were considered benign, reactive to the COVID-19 vaccination. Although FDG-avid benign, reactive nodes have been an uncommon finding in the past, the upcoming surge in COVID-19 vaccinations makes this an important finding for the interpreting physician to consider and recognize.

Axillary Lymph Nodes Hypermetabolism After BNT162b2 mRNA COVID-19 Vaccination in Cancer Patients Undergoing 18F-FDG PET/CT: A Cohort Study. PURPOSE: Recognition of the pattern of FDG uptake in hypermetabolic axillary lymph nodes (HALs) and association with recent messenger RNA (mRNA) vaccination are important to prevent patient anxiety and further needless examinations or costly biopsies in cancer patients. MATERIALS AND METHODS: This study was a retrospective cohort study in a single tertiary care institution. We investigate the occurrence and pattern of HAL on FDG PET/CT scans from 650 consecutive cancer patients with recent BNT162b2 mRNA COVID-19 vaccination. RESULTS: Between December 20, 2020, and February 8, 2021, 650 patients (351 female patients [54%]; mean age, 68.9 years) had recent mRNA COVID-19 vaccination and an FDG PET/CT scan. HALs were found in 57 (14.5%) of 394 patients (95% confidence interval [CI], 10.9%-18.7%) 12.3 Â± 5.9 (1-22) days after dose 1 and in 111 (43.3%) of 256 patients (95% CI, 35.3%-52.2%; P < 0.0001) after 7.5 Â± 5.4 (1-22) days after dose 2. There was no difference between dose 1 and dose 2 concerning SUVmax (3.7 Â± 1.8 [1.3-11.3] and 4.5 Â± 3.9 [1.4-26.3], P = 0.13, respectively), SUVmean (2.1 Â± 1.0 [0.7-6.5] and 2.7 Â± 2.4 [0.8-17], P = 0.08, respectively), and reactogenicity volume (2.7 Â± 2.3 [0.2-11.6] cm3 and 2.7 Â± 2.4 [0.2-15.5] cm3, P = 0.98, respectively). There was no difference in

number and in size of positive lymph nodes between dose 1 and dose 2: 3.2 Â± 2.2 (1-10) and 3.7 Â± 2.4 (1-12) (P = 0.18), and 1.4 Â± 0.4 cm (0.7-2.5 cm) and 1.5 Â± 0.4 cm (0.6-3.2 cm) (P = 0.75), respectively. CONCLUSIONS: A cluster pattern of hypermetabolic ipsilateral small axillary lymph nodes is common after mRNA COVID-19 vaccination, mainly after the second injection.
Misdiagnosis of systemic allergic reactions to mRNA COVID-19 vaccines.
[SARS-CoV-2 vaccines - what the nephrologist should know]. Only fifteen months after the beginning of the COVID-19 pandemic, several vaccines are already available for clinical use. While the spike protein of SARS-CoV-2 constitutes the main target of all predominant SARS-CoV-2 vaccines, they work by different mechanisms (mRNA-based vaccines vs. vector-based vaccines vs. protein-based vaccines).Though there are slight differences regarding the level of protection against mild COVID-19, all five vaccines that have been through phase 3 trials were nearly 100â€Š% effective in preventing severe or fatal cases of COVID-19. The side effects were of short duration.Patients with chronic kidney disease (or other significant comorbidities) were largely excluded from Phase 3 trials, which makes definite recommendations concerning their vaccination difficult. The vaccine's effectiveness may be reduced in that population due to a uremic immune defect and/or immunosuppressive medication. However, these patients have an increased risk for severe or fatal COVID-19, so that they may particularly benefit from the vaccine.
The potential neurological effect of the COVID-19 vaccines: A review. The coronavirus disease 2019 caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has become a pandemic with people infected in almost all countries. The most efficient solution to end this pandemic is a safe and efficient vaccine. Classic platforms are used to develop vaccines including live-attenuated vaccine, inactivated vaccine, protein subunit vaccine, and viral vector. Nucleic acid vaccine uses next-generation platforms for their development. Vaccines are now rushing to the market. Eleven candidates are in advance development. These comprise inactivated vaccines, viral vector vaccine, nucleic acid vaccine, and the protein subunit vaccine platform, which are now quite advanced in trials in various geographic and ethnic populations. The reported severe adverse effects raised the worries about their safety. It becomes critical to know whether these vaccines will cause neurologic disorders like previously recognized vaccine-related demyelinating diseases, fever-induced seizure, and other possible deficits. We reviewed the most promising COVID-2 vaccines with a particular interest in mechanism(s) and adverse effect(s). We exemplify potential neurological problems these vaccines could cause by looking at previous studies. The current evidence indicated a minor risk of the acute neurological disorders after the application. The observation of the long-time effect is still needed.
Axillary Lymphadenopathy After mRNA COVID-19 Vaccination.
Controlled Human Infection to Speed Up SARS-CoV-2 Vaccine Development.
Mini Review Immunological Consequences of Immunization With COVID-19 mRNA Vaccines: Preliminary Results. Background: BNT162b2 and mRNA-1273 are the two recently approved mRNA-based vaccines against COVID-19 which has shown excellent safety and efficacy. Preliminary data about specific and neutralizing antibodies is available covering the first 100 days after vaccination. Methods: We reviewed all the publications regarding the immunologic consequences of BNT162b2 and mRNA-1273 vaccination. A summary of specific antibodies concentration and neutralizing antibodies titers elicited by each vaccine is provided. Results: BNT162b2 and mRNA-1273 displayed a reassuring safety and efficacy profile, with the latter above 94%. They can elicit specific antibodies titers and neutralizing antibodies concentrations that are far superior from those observed among COVID-19 human convalescent serum, across a wide span of age, for at least 100 days after vaccination. Moreover, the vaccine-induced T cellular response is oriented toward a T(H)1 response and no evidence of vaccine-enhanced disease have been reported. Discussion: BNT162b2 and mRNA-

1273 can elicit specific antibodies titers and neutralizing antibodies concentrations above those observed among COVID-19 human convalescent serum in the first 100 days after vaccination. Data about vaccine efficacy in those with previous COVID-19 or immunocompromised is still limited.

Polyethylene glycol and polysorbate skin testing in the evaluation of coronavirus disease 2019 vaccine reactions: Early report.

Hypermetabolic lymphadenopathy following administration of BNT162b2 mRNA Covid-19 vaccine: incidence assessed by [(18)F]FDG PET-CT and relevance to study interpretation. PURPOSE: Nationwide mass vaccination against Covid-19 started in Israel in late 2020. Soon we identified on [(18)F]FDG PET-CT studies vaccine-associated hypermetabolic lymphadenopathy (VAHL) in axillary or supraclavicular lymph nodes (ASLN) ipsilateral to the vaccination site. Sometimes, differentiation between the malignant and benign nature of the hypermetabolic lymphadenopathy (HLN) could not be made, and equivocal HLN (EqHL) was reported. The purpose of the study was to determine the overall incidence of VAHL after BNT162b2 vaccination and also its relevance to PET-CT interpretation in oncologic patients. METHODS: A total of 951 consecutive patients that underwent [(18)F]FDG PET-CT studies in our department were interviewed regarding the sites and dates of the vaccine doses. A total of 728 vaccinated patients (All-Vac group) were included: 346 received the first dose only (Vac-1 group) and 382 received the booster dose as well (Vac-2 group). Studies were categorized as no HLN, malignant-HLN (MHL), VAHL, or EqHL. In studies with VAHL, location, [(18)F]FDG-intensity uptake and nodes size were recorded. RESULTS: The incidences of HLN were 45.6%, 36.4%, and 53.9% in All-Vac, Vac-1, and Vac-2 groups, respectively. VAHL was reported in 80.1% of vaccinated patients with HLN. Lower incidences of VAHL were found during the first 5Â days or in the third week after the first vaccine and beyond 20Â days after the booster dose. In 49 of 332 (14.8%) vaccinated patients, we could not determine whether HLN was MHL or VAHL. Breast cancer and lymphoma were the leading diseases with EqHL. CONCLUSION: VAHL is frequently observed after BNT162b2 administration, more commonly and with higher intensity following the booster dose. To minimize false and equivocal reports in oncological patients, timing of [(18)F]FDG PET-CT should be based on the time intervals found to have a lower incidence of VAHL, and choice of vaccine injection site should be advised, mainly in patients where ASLN are a relevant site of tumor involvement.

Rapid decrease of SARS-CoV-2 circulation in a large Italian hospital six weeks after the start of the immunization program.

Safety and immunogenicity of a recombinant tandem-repeat dimeric RBD-based protein subunit vaccine (ZF2001) against COVID-19 in adults: two randomised, double-blind, placebo-controlled, phase 1 and 2 trials. BACKGROUND: Although several COVID-19 vaccines have been developed so far, they will not be sufficient to meet the global demand. Development of a wider range of vaccines, with different mechanisms of action, could help control the spread of SARS-CoV-2 globally. We developed a protein subunit vaccine against COVID-19 using a dimeric form of the receptor-binding domain (RBD) of the SARS-CoV-2 spike protein as the antigen. We aimed to assess the safety and immunogenicity of this vaccine, ZF2001, and determine the appropriate dose and schedule for an efficacy study. METHODS: We did two randomised, double-blind, placebo-controlled, phase 1 and phase 2 trials. Phase 1 was done at two university hospitals in Chongqing and Beijing, China, and phase 2 was done at the Hunan Provincial Center for Disease Control and Prevention in Xiangtan, China. Healthy adults aged 18-59 years, without a history of SARS-CoV or SARS-CoV-2 infection, an RT-PCR-positive test result for SARS-CoV-2, a history of contact with confirmed or suspected COVID-19 cases, and severe allergies to any component of the vaccine were eligible for enrolment. In phase 1, participants were randomly assigned (2:2:1) to receive three doses of the vaccine (25 Î¼g or 50 Î¼g) or placebo intramuscularly, 30 days apart. In phase 2, participants were randomly assigned (1:1:1:1:1:1) to receive the vaccine (25 Î¼g or 50 Î¼g) or placebo intramuscularly, 30 days apart, in

either a two-dose schedule or a three-dose schedule. Investigators, participants, and the laboratory team were masked to group allocation. For phase 1, the primary outcome was safety, measured by the occurrence of adverse events and serious adverse events. For phase 2, the primary outcome was safety and immunogenicity (the seroconversion rate and the magnitude, in geometric mean titres [GMTs], of SARS-CoV-2-neutralising antibodies). Analyses were done on an intention-to-treat and per-protocol basis. These trials are registered with ClinicalTrials.gov (NCT04445194 and NCT04466085) and participant follow-up is ongoing. FINDINGS: Between June 22 and July 3, 2020, 50 participants were enrolled into the phase 1 trial and randomly assigned to receive three doses of placebo (n=10), the 25 Î¼g vaccine (n=20), or the 50 Î¼g vaccine (n=20). The mean age of participants was 32Â·6 (SD 9Â·4) years. Between July 12 and July 17, 2020, 900 participants were enrolled into the phase 2 trial and randomly assigned to receive two doses of placebo (n=150), 25 Î¼g vaccine (n=150), or 50 Î¼g vaccine (n=150), or three doses of placebo (n=150), 25 Î¼g vaccine (n=150), or 50 Î¼g vaccine (n=150). The mean age of participants was 43Â·5 (SD 9Â·2) years. In both phase 1 and phase 2, adverse events reported within 30 days after vaccination were mild or moderate (grade 1 or 2) in most cases (phase 1: six [60%] of ten participants in the placebo group, 14 [70%] of 20 in the 25 Î¼g group, and 18 [90%] of 20 in the 50 Î¼g group; phase 2: 37 [25%] of 150 in the two-dose placebo group, 43 [29%] of 150 in the two-dose 25 Î¼g group, 50 [33%] of 150 in the two-dose 50 Î¼g group, 47 [31%] of 150 in the three-dose placebo group, 72 [48%] of 150 in the three-dose 25 Î¼g group, and 65 [43%] of 150 in the three-dose 50 Î¼g group). In phase 1, two (10%) grade 3 or worse adverse events were reported in the 50 Î¼g group. In phase 2, grade 3 or worse adverse events were reported by 18 participants (four [3%] in the two-dose 25 Î¼g vaccine group, two [1%] in the two-dose 50 Î¼g vaccine group, two [1%] in the three-dose placebo group, four [3%] in the three-dose 25 Î¼g vaccine group, and six [4%] in the three-dose 50 Î¼g vaccine group), and 11 were considered vaccine related (two [1%] in the two-dose 25 Î¼g vaccine group, one [1%] in the two-dose 50 Î¼g vaccine group, one [1%] in the three-dose placebo group, two [1%] in the three-dose 25 Î¼g vaccine group, and five [3%] in the three-dose 50 Î¼g vaccine group); seven participants reported serious adverse events (one [1%] in the two-dose 25 Î¼g vaccine group, one [1%] in the two-dose 50 Î¼g vaccine group, two [1%] in the three-dose placebo group, one [1%] in the three-dose 25 Î¼g vaccine group, and two [1%] in the three-dose 50 Î¼g vaccine group), but none was considered vaccine related. In phase 2, on the two-dose schedule, seroconversion rates of neutralising antibodies 14 days after the second dose were 76% (114 of 150 participants) in the 25 Î¼g group and 72% (108 of 150) in the 50 Î¼g group; on the three-dose schedule, seroconversion rates of neutralising antibodies 14 days after the third dose were 97% (143 of 148 participants) in the 25 Î¼g group and 93% (138 of 148) in the 50 Î¼g group. In the two-dose groups in phase 2, the SARS-CoV-2-neutralising GMTs 14 days after the second dose were 17Â·7 (95% CI 13Â·6-23Â·1) in the 25 Î¼g group and 14Â·1 (10Â·8-18Â·3) in the 50 Î¼g group. In the three-dose groups in phase 2, the SARS-CoV-2-neutralising GMTs 14 days after the third dose were 102Â·5 (95% CI 81Â·8-128Â·5) in the 25 Î¼g group and 69Â·1 (53Â·0-90Â·0) in the 50 Î¼g group. INTERPRETATION: The protein subunit vaccine ZF2001 appears to be well tolerated and immunogenic. The safety and immunogenicity data from the phase 1 and 2 trials support the use of the 25 Î¼g dose in a three-dose schedule in an ongoing phase 3 trial for large-scale evaluation of ZF2001's safety and efficacy. FUNDING: National Program on Key Research Project of China, National Science and Technology Major Projects of Drug Discovery, Strategic Priority Research Program of the Chinese Academy of Sciences, and Anhui Zhifei Longcom Biopharmaceutical. TRANSLATION: For the Chinese translation of the abstract see Supplementary Materials section.

Gross hematuria following vaccination for severe acute respiratory syndrome coronavirus 2 in 2 patients with IgA nephropathy.

COVID-19 vaccination: intramuscular injection technique.

Dispelling anti-vaxxer misinformation about COVID-19 vaccination. University of Southampton, discusses strategies to enhance vaccination uptake among certain groups in society who are influenced by anti-vaxxers.
Factors associated with intention to uptake pneumococcal vaccines among Chinese elderly aged 60 years and older during the early stage of COVID-19 pandemic. Innoculation of pneumococcal vaccines among the elderly is an effective public health policy to prevent pneumococcal diseases and it is widely promoted by many developed countries. The pneumococcal vaccination rate among the elderly in China was only 3.7% in 2019, it grew rapidly during the early stage of the COVID-19 pandemic. The purpose of this cross-sectional study was to investigate the psychological and demographic-economic factors related to the uptake behavior of pneumococcal vaccination among the Chinese elderly by using an integrated model based on the unified theory of acceptance and use of technology (UTAUT), and knowledge, attitudes and practices (KAP). The theoretical model was tested via structural equation modeling (SEM) with data collected from 516 Chinese older adults aged 60Â years and older. Our results suggested that knowledge, performance expectancy, effort expectancy, attitude, and trust had a significant correlation with behavioral intention; behavioral intention and trust had a positive correlation with the uptake behavior, gender, and and education level and chronic obstructive pulmonary disease exerted significant moderating effects. To increase the coverage of pneumococcal vaccination among the elderly, it is necessary to provide effective health education by authoritative experts, thereby enhancing their knowledge and positive attitude towardthe vaccination.
Single Dose of an mRNA Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-Cov-2) Vaccine Is Associated With Lower Nasopharyngeal Viral Load Among Nursing Home Residents With Asymptomatic Coronavirus Disease 2019 (COVID-19). In nursing home residents with asymptomatic COVID-19 diagnosed through twice-weekly surveillance testing, single-dose BNT162b2 vaccination (Pfizer-BioNTech) was associated with -2.4 mean log10 lower nasopharyngeal viral load than detected in absence of vaccination (Pâ€…=â€….004). Since viral load is linked to transmission, single-dose mRNA SARS-CoV-2 vaccination may help control outbreaks.
Editorial: Immune Responses to Persistent or Recurrent Antigens: Implications for Immunological Memory and Immunotherapy.
New problems erode confidence in AstraZeneca's vaccine.
Volatility of vaccine confidence.
From influenza to COVID-19 vaccinations: Counselling anxious parents about deaths following influenza immunizations in Korea.
Decreasing transmission and initiation of countrywide vaccination: Key challenges for future management of COVID-19 pandemic in Bangladesh. With a fragile healthcare system, Bangladesh, much like other countries in South East Asia, struggled during the early days of COVID-19 pandemic. In following months several encouraging initiatives were undertaken including nationwide lockdown, maintaining social distancing and setting up COVID-19 dedicated laboratories and hospitals. Despite fear of an escalation in COVID-19 transmission during the winter months like their European counterparts, fortunately infection rates subsided and Bangladesh came out largely unharmed. But the next phase of COVID-19 pandemic management that includes viral transmission suppression and conduction of nationwide immunization program require several urgent steps from government of Bangladesh (GoB) and relevant stakeholders. This qualitative research piece discussed about issues including an urgent need to enhance critical care facilities around the country, especially in peripheral districts; ramping up COVID-19 testing at existing laboratories in view of diagnosing each case, and ensuring vaccines for the vulnerable populations in the country. Furthermore, the researchers shed light on other issues including a need to reinforce a struggling healthcare workforce,

encouraging people to take vaccine, proper maintenance of social distancing regulations, routine epidemiological surveillance, management of environment and biomedical waste and undertaking a holistic approach to combat the pandemic and its environmental and financial consequences.

[Vaccination against SARS-CoV-2 in patients with multiple sclerosis]. INTRODUCTION: The recent availability of SARS-CoV-2 vaccines has raised concerns in certain patient groups, such as those with multiple sclerosis. However, there are currently few publications that provide information on this issue. We pooled the information available on the safety and efficacy of vaccination against SARS-CoV-2 in patients with multiple sclerosis, with and without disease-modifying therapy. DEVELOPMENT: The study consisted in a literature search focused on the types of SARS-CoV-2 vaccines, the current status of their approval, and the data available on the safety and efficacy of vaccines in patients with multiple sclerosis, including the new COVID-19 vaccines. Based on this search, the document has been designed taking into account current evidence and expert recommendations. There are no data on the safety and efficacy of SARS-CoV-2 vaccines in patients with multiple sclerosis. However, evidence does exist to suggest that messenger RNA (mRNA) vaccines against SARS-CoV-2 are as safe in these patients as in other individuals. Some therapies with immunosuppressants might reduce the effectiveness of these vaccines and require the scheduling of their administration, preferably before the start of treatment if possible. CONCLUSION: The data available make it possible to recommend mRNA vaccines against SARS-CoV-2 in patients with multiple sclerosis. In patients on fingolimod, cladribine, alemtuzumab, ocrelizumab and rituximab, vaccination prior to the initiation of medication administration would be recommendable whenever possible.

Stage III Hypertension in Patients After mRNA-Based SARS-CoV-2 Vaccination.

What scientists do and don't know about the Oxford-AstraZeneca COVID vaccine.

SARS-CoV-2 Vaccines in Kidney Transplant Recipients: Will They Be Safe and Effective and How Will We Know?

Factors associated with the willingness and acceptance of SARS-CoV-2 vaccine from adult subjects in China. Aim: We aimed to investigate factors affecting the willingness and acceptance of the SARS-CoV-2 vaccination among adults in China and sources of knowledge about the vaccine.Methods: A cross-sectional, web-based survey was conducted from September 8th to 15th, 2020, comprising of 23 questions. Binary logistic regression analysis was performed to examine factors associated with vaccination willingness and acceptance.Results: A total of 983 questionnaires were included and 81.3% of the participants were willing to receive the SARS-CoV-2 vaccine. With a "bachelor degree or above" (OR = 0.56, p = 0.020) and believing that the vaccine would not cause SARS-CoV-2 infection (OR = 0.50, p = 0.003) were associated with an increased willingness. Aged :30 years (OR = 0.38, p = 0.001), and believing that the vaccine would not cause SARS-CoV-2 infection (OR = 0.52, p = 0.004) were associated with higher acceptance; while from Henan province (OR = 2.49, p < 0.001), not willing to vaccinate (OR = 3.86, p < 0.001), not suffering from chronic diseases (OR = 2.25, p = 0.013), and thinking it was not safe and effective in preventing COVID-19 (OR = 1.94, p = 0.001) were correlated with a lower acceptance.Conclusions: In conclusion, age, education, and vaccine perception might be key factors affecting the vaccine willingness and acceptance. Triggering positive perception of vaccine, especially by targeting those aged <30 years, or those with below bachelor degree, or without chronic diseases might be key approaches for improving the willingness and acceptance of vaccine in China.

Neurological Complications of COVID-19: Guillain-Barre Syndrome Following Pfizer COVID-19 Vaccine. Since the first case of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was reported in Wuhan, China, in December 2019, Coronavirus - 19 (COVID-19) has become a global pandemic with multiple neurological complications. In December 2020, two vaccines have been approved in the

United States for the prevention of COVID-19. We report a case of Guillain-Barre Syndrome (GBS) after receiving the first dose of Pfizer - COVID-19 vaccine.
Politicians must dial down the rhetoric over COVID vaccines.
Safety monitoring of COVID-19 vaccines - Lessons learned from the 1976 national influenza immunization program about detecting rare vaccine-related severe adverse events in emergency mass-vaccination programs.
[Anaphylactic reactions to vaccine shall be reported as an adverse effect].
Can mRNA Vaccines Turn the Tables During the COVID-19 Pandemic? Current Status and Challenges. The COVID-19 pandemic continues to affect millions of people across the world. The current global statistics for the disease are 111 million cases and 2.45 million deaths, with new cases emerging each day. Although several drugs including remdesivir have been approved for emergency use, they remain ineffective in bringing the infection under control. Therefore, there is a need for highly effective and safe vaccines against COVID-19. The recent advancements in mRNA vaccines have catapulted them to be forefront in the race to develop vaccines for COVID-19. Two mRNA vaccines, BNT162b2 and mRNA-1273, developed by Pfizer-BioNTech and Moderna Therapeutics, respectively, have been granted authorization for emergency use by the US Food and Drug Administration. Interim analysis of the clinical trials for BNT162b2 and mRNA-1273 vaccines reported an efficacy of 95% and 94.1%, respectively, after the second dose. The adverse events for both the vaccines have been found to be mild to moderate, with mostly injection-site reactions and fatigue. No serious adverse events have been reported. Moreover, Pfizer-BioNTech and Moderna Therapeutics have announced that their vaccines are effective even against the new strains (B.1.17 and B.1.351) of the virus. Both companies are now scaling up the production of the vaccines to meet the global demand. Although the long-term efficacy, safety, and immunogenicity of these vaccines is uncertain, there is hope that they can turn the tables against COVID-19 in this current pandemic situation.
Newborn antibodies to SARS-CoV-2 detected in cord blood after maternal vaccination - a case report. BACKGROUND: Maternal vaccination for Influenza and Tetanus, Diphtheria, acellular Pertussis (TDaP) have been well studied in terms of safety and efficacy for protection of the newborn by placental passage of antibodies. Similar newborn protection would be expected after maternal vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus responsible for coronavirus disease 2019 (COVID-19). There is a significant and urgent need for research regarding safety and efficacy of vaccination against SARS-CoV-2 during pregnancy. CASE PRESENTATION: A vigorous, healthy, full-term female was born to a COVID-19 naÃ¯ve mother who had received a single dose of messenger RNA (mRNA) vaccine for SARS-CoV-2 3 weeks prior to delivery. IgG cord blood antibodies were detected to SARS-CoV-2 at the time of birth. CONCLUSION: Here, we report the first known case of an infant with SARS-CoV-2 IgG antibodies detectable in cord blood after maternal vaccination.
Risk of severe allergic reactions to COVID-19 vaccines among patients with allergic skin diseases - practical recommendations. A position statement of ETFAD with external experts.
Human Papillomavirus Vaccination After COVID-19. The current global novel coronavirus disease 2019 (COVID-19) pandemic threatens to derail the uptake of human papillomavirus (HPV) vaccination in low- and lower-middle income countries with major disruptions to routine immunization and the introduction of new vaccines delayed. This has a major impact on the World Health Organization cervical cancer elimination strategy, where it is dependent on HPV vaccination as well as cervical cancer screening and treatment. We discuss current opportunities and barriers to achieve high uptake of HPV vaccination in low- and lower-middle income countries as well as the impact of COVID-19. Implementation of 4 key recommendations for HPV vaccination in low- and lower-middle income countries is needed: increased global financial investment; improved vaccine supply and accelerated

use of a single-dose schedule; education and social marketing; and adoption of universal school-based delivery. With the commitment of the global health community, the adoption of these strategies would underpin the effective elimination of cervical cancer.
"COVID arm": A reaction to the Moderna vaccine.
COVID-19 vaccine research focusses on safety, efficacy, immunoinformatics, and vaccine production and delivery: a bibliometric analysis based on VOSviewer. Coronavirus Disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), has affected tens of millions of people globally since it was declared a pandemic by the World Health Organization (WHO) on March 11, 2020. There is an urgent need for safe and effective preventive vaccines to curb this pandemic. A growing amount of related research has been published. This study aimed to provide the current status of COVID-19 vaccine using bibliometric analysis. We searched Embase.com and MEDLINE comprehensively and included articles, articles in press, reviews, short surveys, conference abstracts and conference papers about COVID-19 vaccine. VOSviewer1.6.11 (Leiden University, Leiden, Netherlands) was applied to perform the bibliometric analysis of these papers. A total of 1,312 papers were finally included. The BMJ has been the most popular journal in this field. The United States maintained a top position worldwide and has provided a pivotal influence, followed by China, India and United Kingdom. Among all the institutions, Harvard University was regarded as a leader for research collaboration. We analyzed the keywords and identified seven COVID-19 vaccine research hotspot clusters. COVID-19 vaccine research hotspots focus on clinical trials on vaccine safety and efficacy, research on vaccine immunology and immunoinformatics, and vaccine hesitancy. Our analysis results demonstrated that cooperation between countries, institutions, and authors were insufficient. The results suggested that clinical trials on vaccine safety, efficacy, immunology, immunoinformatics, production and delivery are research hotspots. Furthermore, we can predict that there will be a lot of research focusing on vaccine adverse reactions.
Vaccines for COVID-19: learning from ten phase II trials to inform clinical and public health vaccination programmes. Public health professionals and clinicians, in many countries, are immersed in the ongoing and upcoming vaccination programmes for COVID-19. Published information from vaccine trials is complex. There are important and helpful insights about the nature of the available and forthcoming vaccines, immune responses and side-effects from phase II trials. We have systematically summarised information from 10 such trials on the nature of the vaccines, exclusions from the trials, immunological effects and side-effects. Some important information within these trial reports is not available in the phase III trial articles, so a complete picture requires examination of phase II and phase III trials for each vaccine. We recommend our systematic approach for the examination of other upcoming COVID-19 vaccine phase II and III trials.
(18)F-FDG-Avid Axillary Lymph Nodes After COVID-19 Vaccination.
Safety ofâ€¯theâ€¯firstâ€¯dose ofâ€¯mRNA SARS-CoV-2â€¯vaccines inâ€¯patients with rheumatic and musculoskeletal diseases.
Debunking mRNA Vaccine Misconceptions-An Overview for Medical Professionals.
Peripheral Facial Nerve Palsy Following BNT162b2 (COVID-19) Vaccination.
[SARS-CoV-2 vaccines]. Control of the ongoing coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) will require one or more vaccines. Currently, numerous SARS-CoV-2 vaccines are in either pre-clinical or clinical development. Twenty are in fase III development. In this review we summarise available safety and efficacy data of two RNA based vaccines, two non-replication competent vector-based vaccine, one inactivated whole-virus vaccine, and one subunit. All being either approved or nearing approval.
Profile of respiratory syncytial virus prefusogenic fusion protein nanoparticle vaccine. INTRODUCTION: Respiratory Syncytial Virus (RSV) is a leading cause of acute lower respiratory

infections worldwide. The RSV fusion (F) glycoprotein is a major focus of vaccine development. Despite over 60Â years of research, there is no licensed vaccine for RSV. AREAS COVERED: The primary focus of this review is a novel RSV-F recombinant nanoparticle vaccine from Novavax utilizing the F protein, a conserved and immunodominant surface glycoprotein. This RSV F recombinant nanoparticle vaccine adsorbed to 0.4 mg of aluminum phosphate was ultimately administered by a single intramuscular injection during the third trimester of pregnancy in an effort to induce passive immunity in newborns. Its mechanism, performance in clinical trials, and place in RSV vaccine history are discussed. EXPERT OPINION: The vaccine was safe and well tolerated in pregnant women and the results suggest potential benefits with respect to other medically relevant end-point events involving RSV-associated respiratory and all-cause disease in infants. However, the RSV-F recombinant nanoparticle vaccine did not meet the pre-specified primary success criteria for efficacy against RSV-associated, medically significant lower respiratory tract infection in infants up to 90Â days of life. The potential benefits to infants from maternal immunization and excellent safety profile warrant further confirmatory studies.
[Research study on nucleic acid testing of hemostatic stickers used and the surface of the recipients' hands after the inoculation of inactivated SARS-CoV-2 vaccine]. Among the staff of Beijing Chao-Yang Hospital, Capital Medical University, who received the inactivated SARS-CoV-2 vaccine on January 30 in 2021, 28 recipients were selected for this research. Samples for nucleic acid tests were collected from the surface of the recipients' both hands before and after vaccination. The hemostatic stickers used after the inoculation were also collected for nucleic acid tests. The nucleic acid tests of the samples collected from the surface of both hands of the 28 recipients before vaccination were all negative. After vaccination, the nucleic acid tests of the samples collected from the surface of both hands of recipients were positive in 3 cases, and suspicious in 8 cases, with a positive rate of 10.7%. A total of 25 hemostatic stickers used were collected, 24 of them had positive nucleic acid tests, and the rest one had suspicious nucleic acid test result, with a positive rate of 96%. The hemostatic stickers used after the inoculation have the risk of nucleic acid contamination.
Evidence of escape of SARS-CoV-2 variant B.1.351 from natural and vaccine-induced sera. The race to produce vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) began when the first sequence was published, and this forms the basis for vaccines currently deployed globally. Independent lineages of SARS-CoV-2 have recently been reported: UK, B.1.1.7; South Africa, B.1.351; and Brazil, P.1. These variants have multiple changes in the immunodominant spike protein that facilitates viral cell entry via the angiotensin-converting enzyme-2 (ACE2) receptor. Mutations in the receptor recognition site on the spike are of great concern for their potential for immune escape. Here, we describe a structure-function analysis of B.1.351 using a large cohort of convalescent and vaccinee serum samples. The receptor-binding domain mutations provide tighter ACE2 binding and widespread escape from monoclonal antibody neutralization largely driven by E484K, although K417N and N501Y act together against some important antibody classes. In a number of cases, it would appear that convalescent and some vaccine serum offers limited protection against this variant.
Vaccine Liability in COVID-19.
COVID-19 vaccine fast facts.
Efficacy of the ChAdOx1 nCoV-19 Covid-19 Vaccine against the B.1.351 Variant. BACKGROUND: Assessment of the safety and efficacy of vaccines against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in different populations is essential, as is investigation of the efficacy of the vaccines against emerging SARS-CoV-2 variants of concern, including the B.1.351 (501Y.V2) variant first identified in South Africa. METHODS: We conducted a multicenter, double-blind, randomized, controlled trial to assess the safety and efficacy of the ChAdOx1 nCoV-19 vaccine

(AZD1222) in people not infected with the human immunodeficiency virus (HIV) in South Africa. Participants 18 to less than 65 years of age were assigned in a 1:1 ratio to receive two doses of vaccine containing 5Ã—10(10) viral particles or placebo (0.9% sodium chloride solution) 21 to 35 days apart. Serum samples obtained from 25 participants after the second dose were tested by pseudovirus and live-virus neutralization assays against the original D614G virus and the B.1.351 variant. The primary end points were safety and efficacy of the vaccine against laboratory-confirmed symptomatic coronavirus 2019 illness (Covid-19) more than 14 days after the second dose. RESULTS: Between June 24 and November 9, 2020, we enrolled 2026 HIV-negative adults (median age, 30 years); 1010 and 1011 participants received at least one dose of placebo or vaccine, respectively. Both the pseudovirus and the live-virus neutralization assays showed greater resistance to the B.1.351 variant in serum samples obtained from vaccine recipients than in samples from placebo recipients. In the primary end-point analysis, mild-to-moderate Covid-19 developed in 23 of 717 placebo recipients (3.2%) and in 19 of 750 vaccine recipients (2.5%), for an efficacy of 21.9% (95% confidence interval [CI], -49.9 to 59.8). Among the 42 participants with Covid-19, 39 cases (95.1% of 41 with sequencing data) were caused by the B.1.351 variant; vaccine efficacy against this variant, analyzed as a secondary end point, was 10.4% (95% CI, -76.8 to 54.8). The incidence of serious adverse events was balanced between the vaccine and placebo groups. CONCLUSIONS: A two-dose regimen of the ChAdOx1 nCoV-19 vaccine did not show protection against mild-to-moderate Covid-19 due to the B.1.351 variant. (Funded by the Bill and Melinda Gates Foundation and others; ClinicalTrials.gov number, NCT04444674; Pan African Clinical Trials Registry number, PACTR202006922165132).

Prompt onset of Rowell's syndrome following the first BNT162b2 SARS-CoV-2 vaccination.

Lichen planus arising after COVID-19 vaccination.

SARS-CoV-2 Vaccination and Solid Organ Transplant Patients: Data Needed to Inform Safety and Efficacy.

Association between live childhood vaccines and COVID-19 outcomes: a national-level analysis. We investigated whether countries with higher coverage of childhood live vaccines [BCG or measles-containing-vaccine (MCV)] have reduced risk of coronavirus disease 2019 (COVID-19)-related mortality, while accounting for known systems differences between countries. In this ecological study of 140 countries using publicly available national-level data, higher vaccine coverage, representing estimated proportion of people vaccinated during the last 14 years, was associated with lower COVID-19 deaths. The associations attenuated for both vaccine variables, and MCV coverage became no longer significant once adjusted for published estimates of the Healthcare access and quality index (HAQI), a validated summary score of healthcare quality indicators. The magnitude of association between BCG coverage and COVID-19 death rate varied according to HAQI, and MCV coverage had little effect on the association between BCG and COVID-19 deaths. While there are associations between live vaccine coverage and COVID-19 outcomes, the vaccine coverage variables themselves were strongly correlated with COVID-19 testing rate, HAQI and life expectancy. This suggests that the population-level associations may be further confounded by differences in structural health systems and policies. Cluster randomised studies of booster vaccines would be ideal to evaluate the efficacy of trained immunity in preventing COVID-19 infections and mortality in vaccinated populations and on community transmission.

SARS-CoV-2 vaccine ChAdOx1 nCoV-19 infection of human cell lines reveals low levels of viral backbone gene transcription alongside very high levels of SARS-CoV-2 S glycoprotein gene transcription. BACKGROUND: ChAdOx1 nCoV-19 is a recombinant adenovirus vaccine against SARS-CoV-2 that has passed phase III clinical trials and is now in use across the globe. Although replication-defective in normal cells, 28Â kbp of adenovirus genes is delivered to the cell nucleus

alongside the SARS-CoV-2 S glycoprotein gene. METHODS: We used direct RNA sequencing to analyse transcript expression from the ChAdOx1 nCoV-19 genome in human MRC-5 and A549 cell lines that are non-permissive for vector replication alongside the replication permissive cell line, HEK293. In addition, we used quantitative proteomics to study over time the proteome and phosphoproteome of A549 and MRC5 cells infected with the ChAdOx1 nCoV-19 vaccine. RESULTS: The expected SARS-CoV-2 S coding transcript dominated in all cell lines. We also detected rare S transcripts with aberrant splice patterns or polyadenylation site usage. Adenovirus vector transcripts were almost absent in MRC-5 cells, but in A549 cells, there was a broader repertoire of adenoviral gene expression at very low levels. Proteomically, in addition to S glycoprotein, we detected multiple adenovirus proteins in A549 cells compared to just one in MRC5 cells. CONCLUSIONS: Overall, the ChAdOx1 nCoV-19 vaccine's transcriptomic and proteomic repertoire in cell culture is as expected. The combined transcriptomic and proteomics approaches provide a detailed insight into the behaviour of this important class of vaccine using state-of-the-art techniques and illustrate the potential of this technique to inform future viral vaccine vector design.

Hesitant or Not? The Association of Age, Gender, and Education with Potential Acceptance of a COVID-19 Vaccine: A Country-level Analysis. In December 2020, the first COVID-19 vaccines were approved. Despite more than 85 million reported cases and 1.8 million known deaths, millions worldwide say they may not accept it. This study assesses the associations of age, gender, and level of education with vaccine acceptance, from a random sample of 13,426 participants selected from 19 high-COVID-19 burden countries in June 2020. Based on univariable and multivariable logistic regression, several noteworthy trends emerged: women in France, Germany, Russia, and Sweden were significantly more likely to accept a vaccine than men in these countries. Older (â‰¥50) people in Canada, Poland, France, Germany, Sweden, and the UK were significantly more favorably disposed to vaccination than younger respondents, but the reverse trend held in China. Highly educated individuals in Ecuador, France, Germany, India, and the US reported that they will accept a vaccine, but higher education levels were associated with lower vaccination acceptance in Canada, Spain, and the UK. Heterogeneity by demographic factors in the respondents' willingness to accept a vaccine if recommended by employers were substantial when comparing responses from Brazil, Ecuador, France, India, Italy, Mexico, Poland, Russia, South Africa, South Korea, Sweden, and the US. This information should help public health authorities target vaccine promotion messages more effectively.

Guidance for design and analysis of observational studies of fetal and newborn outcomes following COVID-19 vaccination during pregnancy. COVID-19 vaccines are now being deployed as essential tools in the public health response to the global SARS-CoV-2 pandemic. Pregnant individuals are a unique subgroup of the population with distinctive considerations regarding risk and benefit that extend beyond themselves to their fetus/newborn. As a complement to traditional pharmacovigilance and clinical studies, evidence to comprehensively assess COVID-19 vaccine safety in pregnancy will need to be generated through observational epidemiologic studies in large populations. However, there are several unique methodological challenges that face observational assessments of vaccination during pregnancy, some of which may be more pronounced for COVID-19 studies. In this contribution, we discuss the most critical study design, data collection, and analytical issues likely to arise. We offer brief guidance to optimize the quality of such studies to ensure their maximum value for informing public health decision-making.

Unilateral Lymphadenopathy After COVID-19 Vaccination: A Practical Management Plan for Radiologists Across Specialties. Reports are rising of patients with unilateral axillary lymphadenopathy, visible on diverse imaging examinations, after recent coronavirus disease 2019 vaccination. With less than 10% of the US population fully vaccinated, we can prepare now for

informed care of patients imaged after recent vaccination. The authors recommend documenting vaccination information (date[s] of vaccination[s], injection site [left or right, arm or thigh], type of vaccine) on intake forms and having this information available to the radiologist at the time of examination interpretation. These recommendations are based on three key factors: the timing and location of the vaccine injection, clinical context, and imaging findings. The authors report isolated unilateral axillary lymphadenopathy (i.e., no imaging findings outside of visible lymphadenopathy), which is ipsilateral to recent (prior 6 weeks) vaccination, as benign with no further imaging indicated. Clinical management is recommended, with ultrasound if clinical concern persists 6 weeks after the final vaccination dose. In the clinical setting to stage a recent cancer diagnosis or assess response to therapy, the authors encourage prompt recommended imaging and vaccination (possibly in the thigh or contralateral arm according to the location of the known cancer). Management in this clinical context of a current cancer diagnosis is tailored to the specific case, ideally with consultation between the oncology treatment team and the radiologist. The aim of these recommendations is to (1) reduce patient anxiety, provider burden, and costs of unnecessary evaluation of enlarged nodes in the setting of recent vaccination and (2) avoid further delays in vaccinations and recommended imaging for best patient care during the pandemic.
ANA Investigates: Neurological Complications of COVID-19 Vaccines.
Vaccinations in multiple sclerosis patients receiving disease-modifying drugs. PURPOSE OF REVIEW: This review focuses on new evidence supporting the global immunization strategy for multiple sclerosis (MS) patients receiving disease-modifying drugs (DMDs), including the recently available vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. RECENT FINDINGS: New data strengthen the evidence against a causal link between MS and vaccination. Recent consensus statements agree on the need to start vaccination early. Timings for vaccine administration should be adjusted to ensure safety and optimize vaccine responses, given the potential interference of DMDs. Patients treated with Ocrelizumab (and potentially other B-cell depleting therapies) are at risk of diminished immunogenicity to vaccines. This has relevant implications for the upcoming vaccination against SARS-CoV-2. SUMMARY: An early assessment and immunization of MS patients allows optimizing vaccine responses and avoiding potential interference with treatment plans. Vaccinations are safe and effective but some specific considerations should be followed when vaccinating before, during, and after receiving immunotherapy. A time-window for vaccination taking into account the kinetics of B cell repopulation could potentially improve vaccine responses. Further understanding of SARS-CoV-2 vaccine response dynamics in MS patients under specific therapies will be key for defining the best vaccination strategy.
Preclinical efficacy and safety analysis of gamma-irradiated inactivated SARS-CoV-2 vaccine candidates. COVID-19 outbreak caused by SARS-CoV-2 created an unprecedented health crisis since there is no vaccine for this novel virus. Therefore, SARS-CoV-2 vaccines have become crucial for reducing morbidity and mortality. In this study, in vitro and in vivo safety and efficacy analyzes of lyophilized vaccine candidates inactivated by gamma-irradiation were performed. The candidate vaccines in this study were OZG-3861 version 1 (V1), an inactivated SARS-CoV-2 virus vaccine, and SK-01 version 1 (V1), a GM-CSF adjuvant added vaccine. The candidate vaccines were applied intradermally to BALB/c mice to assess toxicity and immunogenicity. Preliminary results in vaccinated mice are reported in this study. Especially, the vaccine models containing GM-CSF caused significant antibody production with neutralization capacity in absence of the antibody-dependent enhancement feature, when considered in terms of T and B cell responses. Another important finding was that the presence of adjuvant was more important in T cell in comparison with B cell response. Vaccinated mice showed T cell response upon restimulation with whole inactivated SARS-CoV-2 or peptide pool. This study shows that the vaccines are effective and leads us to start the challenge test

to investigate the gamma-irradiated inactivated vaccine candidates for infective SARS-CoV-2 virus in humanized ACE2â€‰+â€‰mice.

Covid-19: European countries suspend use of Oxford-AstraZeneca vaccine after reports of blood clots.

Acute onset supraclavicular lymphadenopathy coinciding with intramuscular mRNA vaccination against COVID-19 may be related to vaccine injection technique, Spain, January and February 2021. Monitoring adverse reactions following immunisation is essential, particularly for new vaccines such as those against COVID-19. We describe 20 cases of acute onset of a single supraclavicular lymphadenopathy manifesting between 24 h and 9 days after ipsilateral intramuscular administration of an mRNA-based COVID-19 vaccine, referred to our WHO Collaborating Centre for Vaccine Safety. Our results indicate that the swelling of supraclavicular lymph nodes following immunisation may constitute a benign and self-limited condition, related to a higher than recommended injection site.

Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBV152: interim results from a double-blind, randomised, multicentre, phase 2 trial, and 3-month follow-up of a double-blind, randomised phase 1 trial. BACKGROUND: BBV152 is a whole-virion inactivated SARS-CoV-2 vaccine (3 Î¼g or 6 Î¼g) formulated with a toll-like receptor 7/8 agonist molecule (IMDG) adsorbed to alum (Algel). We previously reported findings from a double-blind, multicentre, randomised, controlled phase 1 trial on the safety and immunogenicity of three different formulations of BBV152 (3 Î¼g with Algel-IMDG, 6 Î¼g with Algel-IMDG, or 6 Î¼g with Algel) and one Algel-only control (no antigen), with the first dose administered on day 0 and the second dose on day 14. The 3 Î¼g and 6 Î¼g with Algel-IMDG formulations were selected for this phase 2 study. Herein, we report interim findings of the phase 2 trial on the immunogenicity and safety of BBV152, with the first dose administered on day 0 and the second dose on day 28. METHODS: We did a double-blind, randomised, multicentre, phase 2 clinical trial to evaluate the immunogenicity and safety of BBV152 in healthy adults and adolescents (aged 12-65 years) at nine hospitals in India. Participants with positive SARS-CoV-2 nucleic acid and serology tests were excluded. Participants were randomly assigned (1:1) to receive either 3 Î¼g with Algel-IMDG or 6 Î¼g with Algel-IMDG. Block randomisation was done by use of an interactive web response system. Participants, investigators, study coordinators, study-related personnel, and the sponsor were masked to treatment group allocation. Two intramuscular doses of vaccine were administered on day 0 and day 28. The primary outcome was SARS-CoV-2 wild-type neutralising antibody titres and seroconversion rates (defined as a post-vaccination titre that was at least four-fold higher than the baseline titre) at 4 weeks after the second dose (day 56), measured by use of the plaque-reduction neutralisation test (PRNT(50)) and the microneutralisation test (MNT(50)). The primary outcome was assessed in all participants who had received both doses of the vaccine. Cell-mediated responses were a secondary outcome and were assessed by T-helper-1 (Th1)/Th2 profiling at 2 weeks after the second dose (day 42). Safety was assessed in all participants who received at least one dose of the vaccine. In addition, we report immunogenicity results from a follow-up blood draw collected from phase 1 trial participants at 3 months after they received the second dose (day 104). This trial is registered at ClinicalTrials.gov, NCT04471519. FINDINGS: Between Sept 5 and 12, 2020, 921 participants were screened, of whom 380 were enrolled and randomly assigned to the 3 Î¼g with Algel-IMDG group (n=190) or 6 Î¼g with Algel-IMDG group (n=190). Geometric mean titres (GMTs; PRNT(50)) at day 56 were significantly higher in the 6 Î¼g with Algel-IMDG group (197Â·0 [95% CI 155Â·6-249Â·4]) than the 3 Î¼g with Algel-IMDG group (100Â·9 [74Â·1-137Â·4]; p=0Â·0041). Seroconversion based on PRNT(50) at day 56 was reported in 171 (92Â·9% [95% CI 88Â·2-96Â·2] of 184 participants in the 3 Î¼g with Algel-IMDG group and 174 (98Â·3% [95Â·1-99Â·6]) of 177 participants in the 6 Î¼g with Algel-IMDG group. GMTs (MNT(50)) at day 56 were 92Â·5 (95% CI 77Â·7-110Â·2) in the 3 Î¼g with Algel-IMDG group and 160Â·1 (135Â·8-188Â·8) in the 6 Î¼g with Algel-IMDG group. Seroconversion based on MNT(50) at day

56 was reported in 162 (88Â·0% [95% CI 82Â·4-92Â·3]) of 184 participants in the 3 Î¼g with Algel-IMDG group and 171 (96Â·6% [92Â·8-98Â·8]) of 177 participants in the 6 Î¼g with Algel-IMDG group. The 3 Î¼g with Algel-IMDG and 6 Î¼g with Algel-IMDG formulations elicited T-cell responses that were biased to a Th1 phenotype at day 42. No significant difference in the proportion of participants who had a solicited local or systemic adverse reaction in the 3 Î¼g with Algel-IMDG group (38 [20Â·0%; 95% CI 14Â·7-26Â·5] of 190) and the 6 Î¼g with Algel-IMDG group (40 [21Â·1%; 15Â·5-27Â·5] of 190) was observed on days 0-7 and days 28-35; no serious adverse events were reported in the study. From the phase 1 trial, 3-month post-second-dose GMTs (MNT(50)) were 39Â·9 (95% CI 32Â·0-49Â·9) in the 3Î¼g with Algel-IMDG group, 69Â·5 (53Â·7-89Â·9) in the 6 Î¼g with Algel-IMDG group, 53Â·3 (40Â·1-71Â·0) in the 6 Î¼g with Algel group, and 20Â·7 (14Â·5-29Â·5) in the Algel alone group. INTERPRETATION: In the phase 1 trial, BBV152 induced high neutralising antibody responses that remained elevated in all participants at 3 months after the second vaccination. In the phase 2 trial, BBV152 showed better reactogenicity and safety outcomes, and enhanced humoral and cell-mediated immune responses compared with the phase 1 trial. The 6 Î¼g with Algel-IMDG formulation has been selected for the phase 3 efficacy trial. FUNDING: Bharat Biotech International. TRANSLATION: For the Hindi translation of the abstract see Supplementary Materials section.

(18)F-fluorodeoxyglucose PET/CT findings in a systemic inflammatory response syndrome after COVID-19 vaccine.

Impact of the Coronavirus Disease 2019 (COVID-19) Vaccine on Asymptomatic Infection Among Patients Undergoing Preprocedural COVID-19 Molecular Screening. BACKGROUND: Several vaccines are now available under emergency use authorization in the United States and have demonstrated efficacy against symptomatic COVID-19. Vaccine impact on asymptomatic severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection is largely unknown. METHODS: We conducted a retrospective cohort study of consecutive, asymptomatic adult patients (nâ€…=â€…39 156) within a large US healthcare system who underwent 48 333 preprocedural SARS-CoV-2 molecular screening tests between 17 December 2020 and 8 February 2021. The primary exposure of interest was vaccination with â‰¥1 dose of an mRNA COVID-19 vaccine. The primary outcome was relative risk (RR) of a positive SARS-CoV-2 molecular test among those asymptomatic persons who had received â‰¥1 dose of vaccine compared with persons who had not received vaccine during the same time period. RR was adjusted for age, sex, race/ethnicity, patient residence relative to the hospital (local vs nonlocal), healthcare system regions, and repeated screenings among patients using mixed-effects log-binomial regression. RESULTS: Positive molecular tests in asymptomatic individuals were reported in 42 (1.4%) of 3006 tests and 1436 (3.2%) of 45 327 tests performed on vaccinated and unvaccinated patients, respectively (RR, .44; 95% CI, .33-.60; Pâ€…<â€….0001). Compared with unvaccinated patients, risk of asymptomatic SARS-CoV-2 infection was lower among those >10 days after the first dose (RR, .21; 95% CI, .12-.37; Pâ€…<â€….0001) and >0 days after the second dose (RR, .20; 95% CI, .09-.44; Pâ€…<â€….0001) in the adjusted analysis. CONCLUSIONS: COVID-19 vaccination with an mRNA-based vaccine showed a significant association with reduced risk of asymptomatic SARS-CoV-2 infection as measured during preprocedural molecular screening. Results of this study demonstrate the impact of the vaccines on reduction in asymptomatic infections supplementing the randomized trial results on symptomatic patients.

Impressive Boosting of Anti-S1/S2 Immunoglobulin G Production in Coronavirus Disease 2019 (COVID-19)-experienced Patients After the First Shot of the BNT162b2 Messenger RNA COVID-19 Vaccine.

Are Some COVID-19 Vaccines Better Than Others? Interpreting and Comparing Estimates of Efficacy in Vaccine Trials. Coronavirus disease 2019 (COVID-19) vaccine trials provide valuable insight into the safety and efficacy of vaccines, with individually randomized, placebo-controlled trials being the gold standard in trial design. However, a myriad of variables must be considered as clinical trial data

are interpreted and used to guide policy decisions. These variables include factors such as the characteristics of the study population and circulating severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) strains, the force of infection, the definition and ascertainment of endpoints, the timing of vaccine efficacy assessment, and the potential for performance bias. In this Viewpoints article, we discuss critical variables to consider when comparing efficacy measurements across current and future COVID-19 vaccine trials.

Heterologous prime-boost: breaking the protective immune response bottleneck of COVID-19 vaccine candidates. COVID-19 vaccines emerging from different platforms differ in efficacy, duration of protection, and side effects. To maximize the benefits of vaccination, we explored the utility of employing a heterologous prime-boost strategy in which different combinations of the four types of leading COVID-19 vaccine candidates that are undergoing clinical trials in China were tested in a mouse model. Our results showed that sequential immunization with adenovirus vectored vaccine followed by inactivated/recombinant subunit/mRNA vaccine administration specifically increased levels of neutralizing antibodies and promoted the modulation of antibody responses to predominantly neutralizing antibodies. Moreover, a heterologous prime-boost regimen with an adenovirus vector vaccine also improved Th1-biased T cell responses. Our results provide new ideas for the development and application of COVID-19 vaccines to control the SARS-CoV-2 pandemic.

Broad-Spectrum Anti-coronavirus Vaccines and Therapeutics to Combat the Current COVID-19 Pandemic and Future Coronavirus Disease Outbreaks. While the COVID-19 pandemic caused by SARS-CoV-2 is continuing, it may become worse in the coming winter months with a high potential for the emergence and spread of escape variants of SARS-CoV-2. SARS-related CoVs (SARSr-CoVs) from bats may also cause outbreaks of emerging coronavirus diseases in the future. These predictions call for the development of broad-spectrum anti-coronavirus vaccines and therapeutics to combat the current COVID-19 pandemic and future emerging coronavirus disease epidemics. In this review, we describe advances and challenges in the development of broad-spectrum vaccines and neutralizing antibodies against lineage B betacoronaviruses (Î²-CoV-Bs), including SARS-CoV-2, SARS-CoV, and SARSr-CoVs, as well as peptide-based pan-CoV fusion inhibitors and their potential in the prevention and treatment of COVID-19 and other human coronavirus infections.

Antibody Responses in Seropositive Persons after a Single Dose of SARS-CoV-2 mRNA Vaccine.

Feasibility of the vaccine development for SARS-CoV-2 and other viruses using the shell disorder analysis. Several related viral shell disorder (disorder of shell proteins of viruses) models were built using a disorder predictor via AI. The parent model detected the presence of high levels of disorder at the outer shell in viruses, for which vaccines are not available. Another model found correlations between inner shell disorder and viral virulence. A third model was able to positively correlate the levels of respiratory transmission of coronaviruses (CoVs). These models are linked together by the fact that they have uncovered two novel immune evading strategies employed by the various viruses. The first involve the use of highly disordered "shape-shifting" outer shell to prevent antibodies from binding tightly to the virus thus leading to vaccine failure. The second usually involves a more disordered inner shell that provides for more efficient binding in the rapid replication of viral particles before any host immune response. This "Trojan horse" immune evasion often backfires on the virus, when the viral load becomes too great at a vital organ, which leads to death of the host. Just as such virulence entails the viral load to exceed at a vital organ, a minimal viral load in the saliva/mucus is necessary for respiratory transmission to be feasible. As for the SARS-CoV-2, no high levels of disorder can be detected at the outer shell membrane (M) protein, but some evidence of correlation between virulence and inner shell (nucleocapsid, N) disorder has been observed. This suggests that not only the development of vaccine for SARS-CoV-2, unlike HIV, HSV and HCV, is

feasible but its attenuated vaccine strain can either be found in nature or generated by genetically modifying N.
Obesity is associated with an altered baseline and post-vaccination influenza antibody repertoire. As highlighted by the ongoing COVID-19 pandemic, vaccination is critical for infectious disease prevention and control. Obesity is associated with increased morbidity and mortality from respiratory virus infections. While obese individuals respond to influenza vaccination, what is considered a seroprotective response may not fully protect the global obese population. In a cohort vaccinated with the 2010-2011 trivalent inactivated influenza vaccine, baseline immune history and vaccination responses were found to significantly differ in obese individuals compared to healthy controls, especially towards the 2009 pandemic strain of A/H1N1 influenza virus. Young, obese individuals displayed responses skewed towards linear peptides versus conformational antigens, suggesting aberrant obese immune response. Overall, these data have vital implications for the next generation of influenza vaccines, and towards the current SARS-CoV-2 vaccination campaign.
Deep vein thrombosis (DVT) occurring shortly after the second dose of mRNA SARS-CoV-2 vaccine.
[Scientific research in times of pandemics.]. When a pandemic occurs, scientific research moves fast in order to achieve readily results, such as effective therapies to fight the SARS-CoV-2 and vaccines. But this high-speed science, engaged by the emergency and characterized by the explosion of online publications in preprint form not subject to scrutiny by peer reviewers, carries some risks. And it represents a challenge to maintain research integrity and to comply with those globally recognized standard principles of fairness. Competition and the pressure to publish immediately - a way of encouraging rapid data sharing - can favor the dissemination of incomplete if not erroneous results obtained from partial studies, which feed false news, such as the benefits of a drug, and illusory hopes. It is commonly through press releases that "speed science" disseminates information to an audience that wants to be informed and reassured. Financial and political interests often mix with the urgency to find solutions. Covid-19 has highlighted in particular the risk of a politicization of science at the expense of transparency.
SARS-CoV-2 vaccines in patients with SLE. As the Moderna (mRNA-1273) and Pfizer/BioNTech (BNT162b2) vaccines become available to patients with autoimmune diseases and SLE, practitioners will have to inform them about the safety and efficacy of these vaccines. Here we discuss the challenges of applying vaccine data to patients with autoimmune diseases and the evidence available in the literature that may help in the decision process.
Supraclavicular lymphadenopathy following COVID-19 vaccination: an increasing presentation to the two-week wait neck lump clinic? The first COVID-19 vaccination was given in December 2020 and there is an effort to vaccinate the international population on a massive scale. Common side effects from the vaccine include headache and tiredness. Regional lymphadenopathy has been described in relation to other vaccines. We describe two cases of supraclavicular reactive lymphadenopathy presenting in patients who had the COVID vaccination in the ipsilateral arm. Awareness of this diagnosis is important for patients presenting to the neck lump clinic.
[COVID-19 vaccines increase the risk of anaphylaxis].
Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antibodies in Neonatal Cord Blood After Vaccination in Pregnancy. BACKGROUND: Studies evaluating the safety and efficacy of currently available vaccines for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) do not include pregnant participants. No data are available to counsel on vaccine safety and potential for neonatal passive immunity. CASE: A 34-year-old multigravid patient working in health care received the Pfizer-BioNTech (BNT162b2) mRNA vaccine for SARS-CoV-2 in the third trimester of pregnancy. Uncomplicated spontaneous vaginal delivery of a female neonate with Apgar scores of 9 and 9 occurred at term. The patient's blood as well as neonatal cord blood were evaluated for SARS-CoV-2-

specific antibodies. Both the patient and the neonate were positive for antibodies at a titer of 1:25,600. CONCLUSION: In this case, passage of transplacental antibodies for SARS-CoV-2 was shown after vaccination in the third trimester of pregnancy.
Acute Allergic Reactions to mRNA COVID-19 Vaccines. This study examines the incidence of acute allergic reactions to mRNA COVID-19 vaccine administrations in health care employees in Massachusetts.
Coronavirus Vaccination Adverse Reactions and the Role of the Dermatologist.
How do nocebo effects in placebo groups of randomized controlled trials provide a possible explicative framework for the COVID-19 pandemic? Introduction: Randomized clinical trials (RCTs) are useful to study the role of individual and contextual factors in which therapies vs placebos are administered and to provide an important perspective for understanding the phenomenon of nocebo-related risks.Areas covered: The results of nocebo effects in RCT placebo groups, measured in terms of adverse events (AEs) and dropouts, will be presented as an explicative framework for the COVID-19 pandemic. Currently, SARS-CoV-2 vaccines are the only RCTs routinely conducted during the pandemic. Information about efficacy and safety of different vaccines represents a fertile ground for nocebo phenomena. Individual and contextual factors will be emphasized in order to understand the presence of a refusal of immunization associated with a specific vaccine considered less effective and safe. Critical aspects and some guidelines will be presented in order to counteract the nocebo effects and to improve adherence to drug treatments and the vaccination campaign.Expert opinion: The nocebo effect could explain the presence of strong resistance in European countries to immunization with a vaccine perceived as less effective, compared to others. Increased awareness of the nocebo effect would be relevant as it could lead to a greater participation in the vaccination campaign and in protecting individuals against SARS-CoV-2 infection.
Oral angiotensin-converting enzyme inhibitors for treatment of delayed inflammatory reaction to dermal hyaluronic acid fillers following COVID-19 vaccination-a model for inhibition of angiotensin II-induced cutaneous inflammation.
COVID-19 Vaccine-Induced Radiation Recall Phenomenon. Radiation recall phenomenon (RRP) is an uncommon, late occurring, acute inflammatory skin reaction that emerges in localized areas coincident with previously irradiated radiation therapy (RT) treatment fields. RRP has been known to be triggered by a number of chemotherapy agents. To the best of our knowledge, this report is the first description of RRP after administration of the Pfizer-BioNTech vaccine for COVID-19, or any other currently available vaccine against COVID-19. Acute skin reactions were observed in 2 RT patients with differing timelines of RT and vaccinations. In both cases however, the RRP presented within days of the patient receiving the second dose of vaccine. For each RT course, the treatment planning dosimetry of the radiation fields was compared with the area of the observable RRP. RRP developed within the borders of treatment fields where prescription dose constraints were prioritized over skin sparing. Our observation is currently limited to 2 patients. The actual incidence of RRP in conjunction with Pfizer-BioNTech vaccine or any other vaccine against COVID-19 is unknown. For patients with cancer being treated with radiation with significant dose to skin, consideration should be given to the probability of RRP side effects from vaccinations against COVID-19.
Ophthalmological Considerations for COVID-19 Vaccination in Patients with Inflammatory Eye Diseases and Autoimmune Disorders. The global impact imposed by the coronavirus disease 2019 (COVID-19) pandemic may be soon alleviated by the introduction and worldwide dissemination of safe and effective vaccines. This expedited timetable for development and approval of COVID-19 vaccines is an unprecedented extraordinary, concerted achievement by the scientific community. With the pending global rollout of vaccines, each with different mechanisms of action, physicians of various specialties will need to identify vulnerable patient groups for special considerations or advice.

In this commentary, we analyse the important considerations for COVID-19 vaccines in patients with inflammatory eye diseases. Scrutiny of immunogenicity and adverse effects, particularly antibody-dependent enhancement, would better help in counselling these patients undergoing vaccination. More research on pharmacovigilance would allow for tailored guidelines and personalised management strategies.
Nucleoside-modified messenger RNA COVID-19 vaccine platform. On March 11, 2020, the World Health Organization declared coronavirus disease 2019 (COVID-19) a pandemic; from that date, the vaccine race has begun, and many technology platforms to develop a specific and effective COVID-19 vaccine have been launched in several clinical trials (protein subunit, RNA-based, DNA-based, replicating viral vector, nonreplicating viral vector, inactivated virus, live attenuated virus, and virus-like particle). Among the next-generation strategies, nucleoside-modified messenger RNA vaccines appear the most attractive, not only to counteract emerging pathogens but also for the possible applications in regenerative medicine and cancer therapy. However, exactly as all innovative drugs, they deserve careful pharmacovigilance in the short and long term.
Willingness to Receive SARS-CoV-2 Vaccination and Associated Factors among Chinese Adults: A Cross Sectional Survey. Vaccination is a key strategy to prevent the pandemic caused by the coronavirus disease 2019 (COVID-19). This study aims to investigate the willingness of Chinese adults to be vaccinated against COVID-19 and further explore the factors that may affect their willingness. We used a self-design anonymous questionnaire to conduct an online survey via the Sojump. A total of 1009 valid questionnaires were analyzed. The age of the participants ranged from 18 to 74. Among them, 609 (60.4%, 95%CI: 57.4-63.4%) were willing to receive the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. Logistic regression analysis results showed that the age of 30-49 (OR = 2.042, 95%CI: 1.098-3.799), universities and colleges education (OR = 1.873, 95% CI = 1.016-3.451), master degree or above education (OR = 1.885, 95%CI = 1.367-2.599), previous influenza vaccination history (OR = 2.176, 95%CI: 1.474-3.211), trust in the effectiveness of the vaccine (OR = 6.419, 95%CI: 3.717-11.086), and close attention to the latest news of the vaccine (OR = 1.601, 95%CI: 1.046-2.449) were facilitative factors that affected their willingness to be vaccinated. More than half of the adults in China would be willing to receive a SARS-CoV-2 vaccine. Middle-aged people with higher education, those who had been vaccinated against influenza, and those who believed that COVID-19 vaccine was effective and paid close attention to it were more willing to be vaccinated. Our findings can provide reference for the implementation of vaccination and the prevention of COVID-19 in China. More studies are needed after the vaccine is launched.
Elevated clozapine levels and toxic effects after SARS-CoV-2 vaccination.
COVID-19 vaccination and patients with psoriasis under biologics: real-life evidence on safety and effectiveness from Italian vaccinated healthcare workers.
Vaccination hesitancy and the "myth" on mRNA-based vaccines in Italy in the COVID-19 era: Does urgency meet major safety criteria? Coronavirus disease 2019 (COVID-19) vaccination campaign in Italy has started with a huge perplexity about vaccine efficacy, vaccine-borne adverse effects and vaccine clinical trial studies. In this commentary I tried to elucidate these issues, which represent a fundamental topic to be thoroughly addressed in COVID-19 pandemic.
Lessons learned 1 year after SARS-CoV-2 emergence leading to COVID-19 pandemic. Without modern medical management and vaccines, the severity of the Coronavirus Disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome (SARS) coronavirus 2 (SARS-CoV-2) might approach the magnitude of 1894-plague (12 million deaths) and 1918-A(H1N1) influenza (50 million deaths) pandemics. The COVID-19 pandemic was heralded by the 2003 SARS epidemic which led to the discovery of human and civet SARS-CoV-1, bat SARS-related-CoVs, Middle East respiratory syndrome (MERS)-related bat CoV HKU4 and HKU5, and other novel animal coronaviruses. The

suspected animal-to-human jumping of 4 betacoronaviruses including the human coronaviruses OC43(1890), SARS-CoV-1(2003), MERS-CoV(2012), and SARS-CoV-2(2019) indicates their significant pandemic potential. The presence of a large reservoir of coronaviruses in bats and other wild mammals, culture of mixing and selling them in urban markets with suboptimal hygiene, habit of eating exotic mammals in highly populated areas, and the rapid and frequent air travels from these areas are perfect ingredients for brewing rapidly exploding epidemics. The possibility of emergence of a hypothetical SARS-CoV-3 or other novel viruses from animals or laboratories, and therefore needs for global preparedness should not be ignored. We reviewed representative publications on the epidemiology, virology, clinical manifestations, pathology, laboratory diagnostics, treatment, vaccination, and infection control of COVID-19 as of 20 January 2021, which is 1 year after person-to-person transmission of SARS-CoV-2 was announced. The difficulties of mass testing, labour-intensive contact tracing, importance of compliance to universal masking, low efficacy of antiviral treatment for severe disease, possibilities of vaccine or antiviral-resistant virus variants and SARS-CoV-2 becoming another common cold coronavirus are discussed.

COVID-19 pandemic: from origins to outcomes. A comprehensive review of viral pathogenesis, clinical manifestations, diagnostic evaluation, and management. Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), the causative pathogen for the COVID-19, first emerged in Wuhan, China, in December 2019 and by March 2020, it was declared a pandemic. COVID-19 pandemic has overburdened healthcare systems in most countries and has led to massive economic losses. SARS-CoV-2 transmission typically occurs by respiratory droplets. The average incubation period is 6.4 days and presenting symptoms typically include fever, cough, dyspnea, myalgia or fatigue. While the majority of patients tend to have a mild illness, a minority of patients develop severe hypoxia requiring hospitalization and mechanical ventilation. Management is mostly supportive. However, several direct anti-viral agents, and immunomodulatory therapy with steroids and various cytokine blockers seem promising in early results. However, an effective vaccine has been established, which will help curb the pandemic.

Association between influenza vaccination and hospitalisation or all-cause mortality in people with COVID-19: a retrospective cohort study. INTRODUCTION: Recent evidence suggests that influenza vaccination may offer protection against COVID-19 severity. Our aim was to quantify the association between influenza vaccination status and risk of hospitalisation or all-cause mortality in people diagnosed with COVID-19. METHODS: A retrospective cohort study using routinely collected health records from patients registered to a General Practitioner (GP) practice in South West England within the Electronic Care and Health Information Analytics database. The cohort included 6921 people with COVID-19 during the first wave of the pandemic (1 January-31 July 2020). Data on influenza vaccination, hospitalisation and all-cause mortality were ascertained through linked clinical and demographic records. We applied propensity score methods (stabilised inverse probability of treatment weight) to quantify the association between influenza vaccination status and COVID-19 outcomes (hospitalisation or all-cause mortality). RESULTS: 2613 (38%) participants received an influenza vaccination between 1 January 2019 and COVID-19 diagnosis. Receipt of influenza vaccination was associated with a significantly lower odds of hospitalisation or all-cause mortality (adjusted OR: 0.85, 95% CI 0.75 to 0.97, p=0.02), and 24% reduced odds of all-cause mortality (adjusted OR: 0.76, 95% CI 0.64 to 0.90). DISCUSSION: Influenza vaccination was associated with a 15%-24% lower odds of severe COVID-19 outcomes. The current UK influenza vaccination programme needs urgent expansion as an integral component of the ongoing response plans to the COVID-19 pandemic.

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine - United States, February 2021.

COVID-19 Vaccine-Related Local FDG Uptake. We present a case of increased FDG uptake in the lymph nodes after COVID-19 vaccine administration. Restaging PET/CT scan of a 70-year-old woman with a history of multiple relapsed Hodgkin lymphoma showed muscle activity in the left upper arm laterally, which is in the deep musculature of the left deltoid muscle. There was also increased activity in several normal-sized left axillary nodes as well. On further review of the patient's history, she had received her second shot of the Pfizer-BioNTech COVID-19 vaccine approximately 2 days before the restaging PET/CT scan.

COVID-19 Vaccination Manifesting as Incidental Lymph Nodal Uptake on 18F-FDG PET/CT. Benign uptake on 18F-FDG PET can be seen with inflammatory conditions. We report a case of an 86-year-old woman with successfully treated nasal melanoma who underwent routine follow-up 18F-FDG PET, day 6 after the second dose of Pfizer-BioNTech COVID-19 vaccine inoculated in the left deltoid muscle. 18F-FDG PET showed increase tracer uptake in the left deltoid muscle and in 2 normal-sized left subpectoral nodes. These findings were considered secondary to vaccination. With the current drive of global COVID-19 immunization, this case highlights the importance of documenting vaccination history at the time of scanning to avoid false-positive results.

FDG PET Findings Post-COVID Vaccinations: Signs of the Times? Vaccinations can cause hypermetabolic axillary lymphadenopathy on FDG PET. We present the case of a 71-year-old man who underwent FDG PET/CT for melanoma staging 6 days following a COVID (coronavirus disease) vaccination. Imaging showed a prominent intramuscular mass at the vaccination site, in addition to extensive axillary lymphadenopathy. The mass was compatible with a hematoma at the vaccination site, and the lymphadenopathy was most likely reactive. This case demonstrates unconventional findings in response to a routine vaccination event-findings that, in light of current world events, are likely to be routinely encountered on PET imaging and that should be recognized reactive rather malignant.

Informing patients that they are at high risk for serious complications of viral infection increases vaccination rates. For many vaccine-preventable diseases like influenza, vaccination rates are lower than optimal to achieve community protection. Those at high risk for infection and serious complications are especially advised to be vaccinated to protect themselves. Using influenza as a model, we studied one method of increasing vaccine uptake: informing high-risk patients, identified by a machine learning model, about their risk status. Patients (N=39,717) were evenly randomized to (1) a control condition (exposure only to standard direct mail or patient portal vaccine promotion efforts) or to be told via direct mail, patient portal, and/or SMS that they were (2) at high risk for influenza and its complications if not vaccinated; (3) at high risk according to a review of their medical records; or (4) at high risk according to a computer algorithm analysis of their medical records. Patients in the three treatment conditions were 5.7% more likely to get vaccinated during the 112 days post-intervention ($p < .001$), and did so 1.4 days earlier ($p < .001$), on average, than those in the control group. There were no significant differences among risk messages, suggesting that patients are neither especially averse to nor uniquely appreciative of learning their records had been reviewed or that computer algorithms were involved. Similar approaches should be considered for COVID-19 vaccination campaigns.

Reduced binding and neutralization of infection- and vaccine-induced antibodies to the B.1.351 (South African) SARS-CoV-2 variant. The emergence of SARS-CoV-2 variants with mutations in the spike protein is raising concerns about the efficacy of infection- or vaccine-induced antibodies to neutralize these variants. We compared antibody binding and live virus neutralization of sera from naturally infected and spike mRNA vaccinated individuals against a circulating SARS-CoV-2 B.1 variant and the emerging B.1.351 variant. In acutely-infected (5-19 days post-symptom onset), convalescent COVID-19 individuals (through 8 months post-symptom onset) and mRNA-1273 vaccinated individuals

(day 14 post-second dose), we observed an average 4.3-fold reduction in antibody titers to the B.1.351-derived receptor binding domain of the spike protein and an average 3.5-fold reduction in neutralizing antibody titers to the SARS-CoV-2 B.1.351 variant as compared to the B.1 variant (spike D614G). However, most acute and convalescent sera from infected and all vaccinated individuals neutralize the SARS-CoV-2 B.1.351 variant, suggesting that protective immunity is retained against COVID-19.
Communicating COVID-19 vaccines: lessons from the dengue vaccine controversy in the Philippines.
Vaccination against COVID-19: Rationale, modalities and precautions for patients with haemophilia and other inherited bleeding disorders.
[Allergic reactions to COVID-19 vaccines]. In 2021 many people in the Netherlands will be vaccinated against COVID-19. The mass vaccination and the new types of vaccines trigger questions about the safety of these vaccines. In this paper we discuss: (1) what reactions are expected from COVID-19 vaccines, (2) what precautions are needed when vaccinating people, and (3) how to act when allergic reactions occur. The COVID-19 vaccines include the first vaccines produced with the mRNA platform. The most frequent adverse reactions are comparable with other vaccines. Allergic reactions to COVID-19 vaccines are rare but can occur. These reactions may be related to excipients in the vaccines, like polyethylene glycol. In case of a possible allergic reaction, a doctor, in consultation with an allergist, can investigate whether vaccination is safe in the future and whether precautions are necessary. Allergic reactions to vaccine components must be recorded completely and unambiguously in the patient file.
Safety of New mRNA Vaccines Against COVID-19 in Severely Allergic Patients.
FDA authorizes Pfizer-BioNTech COVID-19 vaccine.
COVID-19 Vaccination-Related Uptake on FDG PET/CT: An Emerging Dilemma and Suggestions for Management. As mass COVID-19 vaccination is underway, radiologists are encountering transient FDG uptake in normal or enlarged axillary, supraclavicular, and cervical lymph nodes after ipsilateral deltoid vaccination. This phenomenon may confound interpretation in patients with cancer undergoing FDG PET/CT. In this article, we present our institutional approach for management of COVID-19 vaccine-related lymphadenopathy on FDG PET/CT according to early experience. We suggest performing PET/CT at least 2 weeks after vaccination in patients with a cancer for which interpretation is anticipated to be potentially impacted by the vaccination but optimally 4-6 weeks after vaccination given increased immunogenicity of mRNA vaccines and potentially longer time for resolution than lymphadenopathy after other vaccines. PET/CT should not be delayed when clinically indicated to be performed sooner. Details regarding vaccination should be collected at the time of PET/CT to facilitate interpretation. Follow-up recommendations for postvaccination lymphadenopathy are provided, considering the lymph node's morphology and likely clinical relevance. Consideration should be given to administering the vaccine in the arm contralateral to a unilateral cancer to avoid confounding FDG uptake on the side of cancer. Our preliminary experience and suggested institutional approach should guide radiologists in management of patients with cancer undergoing PET/CT after COVID-19 vaccination.
The Johnson & Johnson Vaccine for COVID-19.
COVID-19 Vaccination in Patients With Inflammatory Bowel Disease: CommuniquÃ© From the Canadian Association of Gastroenterology.
COVID-19 Vaccination Acceptance and Its Associated Factors Among a Middle Eastern Population. Background: The Coronavirus disease 2019 (COVID-19) pandemic is a major threat to public health and has had a significant impact on all aspects of life. An effective vaccine is the most anticipated resolution. This study aims to evaluate Jordanian intent to be vaccinated. Methods: This is a cross-sectional web-based study. Sample characteristics were gathered, and the participants were classified

according to the degree of COVID-19 risk based on the categories of the Centers for Disease Control and Prevention (CDC). Participants' KAP toward COVID-19 were assessed, and two scores were calculated: knowledge score and practice score. The association between different sample characteristics and these scores was identified using binary logistical regressions. The participants' vaccination intention was evaluated and multinomial logistic regression was applied to identify the predictors of vaccination intention. Finally, the reasons behind the participants' vaccination refusal/hesitation were determined and categorized into different groups. Results: 1,144 participants were enrolled in the study (females = 66.5%). 30.4% of the participants were at high risk of COVID-19 complications, and 27.5% were at medium risk. Overall, participants' knowledge of COVID-19 symptoms, transmission methods, protective measures, and availability of cure were high (median of knowledge score = 17 out of 21). High protective practices were followed by many participants (median of practice score = 7 out of 10). 3.7% of participants were infected, and 6.4% suspected they were infected with the COVID-19 virus. 36.8% of the participants answered "No" when asked if they would take the vaccine once it becomes available, and 26.4% answered, "Not sure." The main reasons for the participants' vaccination refusal or hesitancy were concerns regarding the use of vaccines and a lack of trust in them. Conclusion: Participants reported high refusal/hesitancy. Several barriers were identified, and efforts should be intensified to overcome these barriers.
Severe allergic reactions after COVID-19 vaccination with the Pfizer/BioNTech vaccine in Great Britain and USA: Position statement of the German Allergy Societies: Medical Association of German Allergologists (AeDA), German Society for Allergology and Clinical Immunology (DGAKI) and Society for Pediatric Allergology and Environmental Medicine (GPA). Two employees of the National Health Service (NHS) in England developed severe allergic reactions following administration of BNT162b2 vaccine against COVID-19 (coronavirus disease 2019). The British SmPC for the BNT162b2 vaccine already includes reference to aÂ contraindication for use in individuals who have had an allergic reaction to the vaccine or any of its components. As aÂ precautionary measure, the Medicines and Healthcare products Regulatory Agency (MHRA) has issued interim guidance to the NHS not to vaccinate in principle in "patients with severe allergies". Allergic reactions to vaccines are very rare, but vaccine components are known to cause allergic reactions. BNT162b2 is aÂ vaccine based on an mRNA embedded in lipid nanoparticles and blended with other substances to enable its transport into the cells. In the pivotal phase III clinical trial, the BNT162b2 vaccine was generally well tolerated, but this large clinical trial, used to support vaccine approval by the MHRA and US Food and Drug Administration, excluded individuals with aÂ "history of aÂ severe adverse reaction related to the vaccine and/or aÂ severe allergic reaction (e.g., anaphylaxis) to aÂ component of the study medication". Vaccines are recognized as one of the most effective public health interventions. This repeated administration of aÂ foreign protein (antigen) necessitates aÂ careful allergological history before each application and diagnostic clarification and aÂ risk-benefit assessment before each injection. Severe allergic reactions to vaccines are rare but can be life-threatening, and it is prudent to raise awareness of this hazard among vaccination teams and to take adequate precautions while more experience is gained with this new vaccine.
Neuroleptic malignant syndrome following COVID-19 vaccination.
Allergic reactions including anaphylaxis after receipt of the first dose of Moderna COVID-19 vaccine - United States, December 21, 2020-January 10, 2021.
Allergic reactions including anaphylaxis after receipt of the first dose of Pfizer-BioNTech COVID-19 vaccine - United States, December 14-23, 2020.
Talk to Patients About: Vaccine Testing. The COVID-19 vaccines currently under production are expected to reach the public faster than any previous vaccine. But no matter how quickly a vaccine is

produced, it still must pass a series of rigorous scientific tests before the U.S. Food and Drug Administration (FDA) will license it for public use.

Our Best Shot: Texas Physicians Help Find Safe, Effective COVID-19 Vaccines. Vaccine scientists normally toil in anonymity, spending years nursing their creation through a series of regulatory and financial hurdles before finally earning a license from the Food and Drug Administration (FDA). But not in 2020. Creating a vaccine for COVID-19 has become the world's top priority, so vaccine development is suddenly moving very fast in a high-profile way.

Biosecurity risks associated with vaccine platform technologies. Vaccine platforms have been critical for accelerating the timeline of COVID-19 vaccine development. Faster vaccine timelines demand further development of these technologies. Currently investigated platform approaches include virally vectored and RNA-based vaccines, as well as DNA vaccines and recombinant protein expression system platforms, each featuring different advantages and challenges. Viral vector-based and DNA vaccines in particular have received a large share of research funding to date. Platform vaccine technologies may feature dual-use potential through informing or enabling pathogen engineering, which may raise the risk for the occurrence of deliberate, anthropogenic biological events. Research on virally vectored vaccines exhibits relatively high dual-use potential for two reasons. First, development of virally vectored vaccines may generate insights of particular dual-use concern such as techniques for circumventing pre-existing anti-vector immunity. Second, while the amount of work on viral vectors for gene therapy exceeds that for vaccine research, work on virally vectored vaccines may increase the number of individuals capable of engineering viruses of particular concern, such as ones closely related to smallpox. Other platform vaccine approaches, such as RNA vaccines, feature relatively little dual-use potential. The biosecurity risk associated with platform advancement may be minimised by focusing preferentially on circumventing anti-vector immunity with non-genetic rather than genetic modifications, using vectors that are not based on viruses pathogenic to humans, or preferential investment into promising RNA-based vaccine approaches. To reduce the risk of anthropogenic pandemics, structures for the governance of biotechnology and life science research with dual-use potential need to be reworked. Scientists outside of the pathogen research community, for instance those who work on viral vectors or oncolytic viruses, need to become more aware of the dual-use risks associated with their research. Both public and private research-funding bodies need to prioritise the evaluation and reduction of biosecurity risks.

COVID-19 vaccines for patients with cancer: benefits likely outweigh risks. Less than a year since the start of the COVID-19 pandemic, ten vaccines against SARS-CoV-2 have been approved for at least limited use, with over sixty others in clinical trials. This swift achievement has generated excitement and arrives at a time of great need, as the number of COVID-19 cases worldwide continues to rapidly increase. Two vaccines are currently approved for full use, both built on mRNA and lipid nanotechnology platforms, a success story of mRNA technology 20Â years in the making. For patients with cancer, questions arise around the safety and efficacy of these vaccines in the setting of immune alterations engendered by their malignancy and/or therapies. We summarize the current data on leading COVID-19 vaccine candidates and vaccination of patients undergoing immunomodulatory cancer treatments. Most current cancer therapeutics should not prevent the generation of protective immunity. We call for more research in this area and recommend that the majority of patients with cancer receive COVID vaccinations when possible.

How to Test Severe Acute Respiratory Syndrome Coronavirus 2 Vaccines Ethically Even After One Is Available. Although vaccines against severe acute respiratory syndrome coronavirus 2 have now been found safe and efficacious, there remains an urgent global health need to test both these vaccines and additional vaccines against the same virus. Under variable conditions, either standard or

unusual designs would for both familiar and often-missed reasons make continued testing possible and ethical.
Bell's palsy and SARS-CoV-2 vaccines.
Herpes zoster following inactivated COVID-19 vaccine: A coexistence or coincidence?
COVID-19 vaccination induced axillary nodal uptake on [18F]FDG PET/CT.
Suitability of databases in the Asia-Pacific for collaborative monitoring of vaccine safety. INTRODUCTION: Information regarding availability of electronic healthcare databases in the Asia-Pacific region is critical for planning vaccine safety assessments particularly, as COVID-19 vaccines are introduced. This study aimed to identify data sources in the region, potentially suitable for vaccine safety surveillance. This manuscript is endorsed by the International Society for Pharmacoepidemiology (ISPE). METHODS: Nineteen countries targeted for database reporting were identified using published country lists and review articles. Surveillance capacity was assessed using two surveys: a 9-item introductory survey and a 51-item full survey. Survey questions related to database characteristics, covariate and health outcome variables, vaccine exposure characteristics, access and governance, and dataset linkage capability. Other questions collated research/regulatory applications of the data and local publications detailing database use for research. RESULTS: Eleven databases containing vaccine-specific information were identified across 8 countries. Databases were largely national in coverage (8/11, 73%), encompassed all ages (9/11, 82%) with population size from 1.4 to 52 million persons. Vaccine exposure information varied particularly for standardized vaccine codes (5/11, 46%), brand (7/11, 64%) and manufacturer (5/11, 46%). Outcome data were integrated with vaccine data in 6 (55%) databases and available via linkage in 5 (46%) databases. Data approval processes varied, impacting on timeliness of data access. CONCLUSIONS: Variation in vaccine data availability, complexities in data access including, governance and data release approval procedures, together with requirement for data linkage for outcome information, all contribute to the challenges in building a distributed network for vaccine safety assessment in the Asia-Pacific and globally. Common data models (CDMs) may help expedite vaccine safety research across the region.
Association between vaccinations and clinical manifestations in children with COVID-19. BACKGROUND: The infection rate of Coronavirus Disease 2019 (COVID-19) in children was less than that in adults. However, the underlining reason is not well known. METHODS: Children with COVID-19 were recruited from two Children's Hospitals in Wuhan and Shanghai in this case-control study. The associations of initial symptoms with age, vaccinations of Bacillus Calmette Guerin (BCG), and influenza and pathogens were determined by Chi-square t-test. RESULTS: We evaluated 248 confirmed cases, and 56 suspected cases with COVID-19. The median age was 6.82 years old, and 118 cases (38.82%) were girls. Furthermore, 30.26% of all patients were asymptomatic cases. The percentage of asymptomatic cases vaccinated with BCG was not significantly higher than that without BCG vaccination [86/280 (30.71%) vs. 6/13 (46.15%), P=0.203], and initial symptoms were not related with immunized influenza vaccine (P=0.267). Compared to parameters in pediatric patients with normal body temperatures, patients with fever had higher C reactive protein (CRP) (P<0.001). CONCLUSIONS: Pediatric COVID-19 patients with BCG vaccinations exhibit similar clinical manifestations compared to those without BCG vaccinations, and the severity of symptoms in pediatric patients may be related to the maturity of immune function.
Traditional Chinese medicine auricular point acupressure for the relief of pain, fatigue, and gastrointestinal adverse reactions after the injection of novel coronavirus-19 vaccines: a structured summary of a study protocol for a multicentre, three-arm, single-blind, prospective randomized controlled trial. OBJECTIVES: To investigate if traditional Chinese medicine (TCM) auricular point acupressure (APA) can alleviate and (or) reduce the pain (including injection site pain, headache, other muscle and joint pain), fatigue, and gastrointestinal adverse reactions (including nausea,

vomiting, diarrhea), after the injection of novel coronavirus-19 vaccines (NCVs). TRIAL DESIGN: The study is designed as a multicentre, parallel-group, three-arm, single-blind, prospective, randomized (1:1:1 ratio) study. PARTICIPANTS: More than 360 participants will be recruited from healthy people who vaccinate NCVs in 5 community healthcare centres in the Sichuan province of China and 1 university hospital (Hospital of Chengdu University of Traditional Chinese Medicine). INCLUSION CRITERIA: â‘ Vaccinators meets the conditions of NCVs injection and have no contraindications to it. The details shall be subject to the instructions of the NCVs used and the statement of medical institutions. The first dose of NCVs injection shall be completed within 24 hours from the time of injection to the time of enrolment; â‘¡No redness, swelling, injury or infection of the skin or soft tissue of both ears, which is not suitable for APA; â‘¢No history of alcohol and adhesive tape contact allergy; â‘£18-59 years old, regardless of gender; â‘¤Those who were able to complete the questionnaire independently at the time of the first and second dose of NCVs and on the 3rd, 7th and 15th day after the first and second dose of NCVs respectively; â‘¥Those who agree to participate in the trial and sign the informed consent, and can seriously abide by the precautions after the injection of NCVs and the requirements of traditional Chinese medicine auricular point plasters sticking and acupressure. EXCLUSION CRITERIA: â‘ Those who are not suitable to be vaccinated because they belong to the contraindication or cautious population; â‘¡Those who have participated in other clinical trials within 4 weeks before the start of this study; â‘¢No chronic/habitual/persistent headache, Muscle or joint pain, fatigue, diarrhea, nausea, retching or vomiting before the injection of NCVs, and no related diseases present (details of this item is listed in full protocol); â‘£Those who are in use or have received TCMAPA within 2 weeks before the trial; â‘¤Pregnant or lactating women; â‘¥Participants with other serious primary diseases and psychosis. INTERVENTION AND COMPARATOR: â‘ Auricular point acupressure group: participants receive bilateral, symptom-specific TCMAPA in 5 auricular points (per side, 10 points bilateral) for 5 days, 3-4 times (about 1 min each time) of self-acupressure per day, after each NCVs injection (10 days in total). â‘¡Sham auricular point acupressure group: participants receive bilateral, none symptom-specific, sham APA in 5 auricular points (per side, 10 points bilateral) for 5 days, 3-4 times (about 1 min each time) of self-acupressure per day, after each NCVs injection (10 days in total). â‘¢Blank control group: Non-intervention blank control. The Hebei medical device Co. Ltd, Hebei, China manufactured the auricular point sticking plasters. MAIN OUTCOMES: Primary outcomes are all scores of visual analogue scale (VAS) based on subjective judgment of the participants included, including VAS score of pain at injection site, headache, muscle and joint pain, fatigue, nausea, retching, vomiting and diarrhea. Time points for outcomes above are the same: â‘ Immediately after first and second injection of the vaccine (Baseline assessment); â‘¡Three days after first and second injection of the vaccine; â‘¢Seven days after first and second injection of the vaccine; â‘£Fifteen days after first and second injection of the vaccine. RANDOMISATION: Participants will be randomized in 1:1:1 ratio to each group by computerized random number generator, and independently in each sub-centre. BLINDING (MASKING): Participants, information collectors and statistical evaluators will be blinded between APA group and sham APA group. No blinding in the control group. NUMBERS TO BE RANDOMISED (SAMPLE SIZE): No less than 360 participants will be randomized in 1:1:1 ratio to each group. TRIAL STATUS: Protocol version 2.0 of February 3rd, 2021. Recruitment is expected to start on February 18th, 2021, and to finish on March 12th, 2021. TRIAL REGISTRATION: This trial was registered in the China Clinical Trial Registry (ChiCTR) (ChiCTR2100043210) on 8th February, 2021. FULL PROTOCOL: The full protocol is attached as an additional file, accessible from the Trials website (Additional file 1). In the interest in expediting dissemination of this material, the familiar formatting has been eliminated; this Letter serves as a summary of the key elements of the full protocol.

[Disseminated infection caused by the bacillus Calmette-GuÃ©rin vaccine and SARS-CoV-2 coinfection in a patient with IL-12 receptor Î²1 subunit deficiency]. BACKGROUND: Inborn errors of immunity manifest with a greater susceptibility to infections, autoimmunity, autoinflammatory diseases, allergies, or malignancies. One of these is the mendelian susceptibility to mycobacterial disease. The most frequent etiology is the complete autosomal recessive deficiency of the Î²1 subunit of the interleukin 12 receptor. CASE REPORT: A female patient who, by the age of six months, started with a nodular lesion in the right shoulder and ipsilateral axillary adenitis after the bacillus Calmette-GuÃ©rin vaccine was applied. Later, she developed a cutaneous fistula in the anterior thorax, the inframammary region, and chronic recidivant suppurative lymphadenitis. A disseminated infection caused by Mycobacterium bovis was diagnosed, therefore, individualized pharmacological treatment was required due to failure with the primary treatment. The patient was diagnosed with deficiency in the Î²1 subunit of the interleukin 12 receptor at age six. During her last hospitalization, she presented fever, cough, and tachypnea, and SARS-CoV-2 was detected by quantitative polymerase chain reaction. The patient has had a favorable evolution. CONCLUSION: In patients with disseminated infections caused by bacillus Calmette-GuÃ©rin vaccination or by environmental mycobacteria, there should be suspicion of an inborn error of immunity and the patient should be referred to a third level hospital for an early immunological assessment.

First Month of COVID-19 Vaccine Safety Monitoring - United States, December 14, 2020-January 13, 2021. Two coronavirus disease 2019 (COVID-19) vaccines are currently authorized for use in the United States. The Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine on December 11, 2020, and for the Moderna COVID-19 vaccine on December 18, 2020; each is administered as a 2-dose series. The Advisory Committee on Immunization Practices issued interim recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines on December 12, 2020 (1), and December 19, 2020 (2), respectively; initial doses were recommended for health care personnel and long-term care facility (LTCF) residents (3). Safety monitoring for these vaccines has been the most intense and comprehensive in U.S. history, using the Vaccine Adverse Event Reporting System (VAERS), a spontaneous reporting system, and v-safe,* an active surveillance system, during the initial implementation phases of the COVID-19 national vaccination program (4). CDC conducted descriptive analyses of safety data from the first month of vaccination (December 14, 2020-January 13, 2021). During this period, 13,794,904 vaccine doses were administered, and VAERS received and processed(â€) 6,994 reports of adverse events after vaccination, including 6,354 (90.8%) that were classified as nonserious and 640 (9.2%) as serious.(Â§) The symptoms most frequently reported to VAERS were headache (22.4%), fatigue (16.5%), and dizziness (16.5%). A total of 113 deaths were reported to VAERS, including 78 (65%) among LTCF residents; available information from death certificates, autopsy reports, medical records, and clinical descriptions from VAERS reports and health care providers did not suggest any causal relationship between COVID-19 vaccination and death. Rare cases of anaphylaxis after receipt of both vaccines were reported (4.5 reported cases per million doses administered). Among persons who received Pfizer-BioNTech vaccine, reactions reported to the v-safe system were more frequent after receipt of the second dose than after the first. The initial postauthorization safety profiles of the two COVID-19 vaccines in current use did not indicate evidence of unexpected serious adverse events. These data provide reassurance and helpful information regarding what health care providers and vaccine recipients might expect after vaccination.

COVID-19 - pathogenesis and immunological findings across the clinical manifestation spectrum. PURPOSE OF REVIEW: The wide spectrum of COVID-19 clinical manifestations demonstrates the determinant role played by the individual immune response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the course of the disease. Thanks to the large number of published

data, we are beginning to understand the logic of the human response to a virus adapted to bat immunity. RECENT FINDINGS: Impairment of types I and III interferon responses may facilitate the occurrence of severe COVID-19 with reduced antiviral activity associated to potent inflammation. The human T and B-cell germline repertoire contain the specificities able to react against SARS-CoV-2 antigens. Although inflammation disrupts the structure of germinal centers, memory T and B cells can be found in the blood of patients after mild and severe COVID 19. SUMMARY: Further studies are indispensable to better understand the human immune response to SARS-CoV-2. The diversity of the individual reaction may contribute to explain the clinical manifestation spectrum. Immunological memory can be demonstrated in patients, convalescent from mild, moderate, or severe COVID-19, but we do not know whether asymptomatic individuals have memory of the virus. Tailored vaccination protocols may be needed for individuals with previous SAS-CoV-2 infection.

COVID-19 vaccines: comparison of biological, pharmacological characteristics and adverse effects of Pfizer/BioNTech and Moderna Vaccines. OBJECTIVE: The "Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)" disease has caused a worldwide challenging and threatening pandemic (COVID-19), with huge health and economic losses. The US Food and Drug Administration, (FDA) has granted emergency use authorization for treatment with the Pfizer/BioNTechÂ and ModernaÂ COVID-19Â vaccines.Â Many people have a history of a significant allergic reaction to a specific food, medicine, or vaccine; hence, people all over the world have great concerns about these two authorized vaccines. This article compares the pharmacology, indications, contraindications, and adverse effects of the Pfizer/BioNTech and Moderna vaccines. MATERIALS AND METHODS: The required documents and information were collected from the relevant databases, including Web of Science (Clarivate Analytics), PubMed, EMBASE, World Health Organization (WHO), Food and Drug Authorities (FDA) USA, Local Ministries, Health Institutes, and Google Scholar. The key terms used were: Coronavirus, SARS-COV-2, COVID-19 pandemic, vaccines, Pfizer/BioNTech vaccine, Moderna vaccine, pharmacology, benefits, allergic responses, indications, contraindications, and adverse effects. The descriptive information was recorded, and we eventually included 12 documents including research articles, clinical trials, and websites to record the required information. RESULTS: Based on the currently available literature, both vaccines are beneficial to provide immunity against SARS-CoV-2 infection. Pfizer/BioNTech Vaccine has been recommended to people 16 years of age and older, with a dose of 30 Î¼g (0.3 m) at a cost of $19.50. It provides immunogenicity for at least 119 days after the first vaccination and is 95% effective in preventing the SARS-COV-2 infection. However, Moderna Vaccine has been recommended to people 18 years of age and older, with a dose of 50 Î¼g (0.5 mL) at a cost of $32-37. It provides immunogenicity for at least 119 days after the first vaccination and is 94.5% effective in preventing the SARS-CoV-2 infection. However, some associated allergic symptoms have been reported for both vaccines. The COVID-19Â vaccines can cause mild adverse effects after the first or second doses, including pain, redness or swelling at the site of vaccine shot, fever, fatigue, headache, muscle pain, nausea, vomiting, itching, chills, and joint pain, and can also rarely cause anaphylactic shock. The occurrence of adverse effects is reported to be lower in the Pfizer/BioNTech vaccine compared to the Moderna vaccine; however, the Moderna vaccine compared to the Pfizer vaccine is easier to transport and store because it is less temperature sensitive. CONCLUSIONS: The FDA has granted emergency use authorization for the Pfizer/BioNTech and Moderna COVID-19 vaccines. These vaccines can protect recipients from a SARS-CoV- 2 infection by formation of antibodies and provide immunity against a SARS-CoV-2 infection. Both vaccines can cause various adverse effects, but these reactions are reported to be less frequent in the Pfizer/BioNTech vaccine compared to the Moderna COVID-19 vaccine; however, the Moderna vaccine compared to the Pfizer vaccine is easier to transport and store because it is less temperature sensitive.

SARS-CoV-2 vaccine testing and trials in the pediatric population: biologic, ethical, research, and implementation challenges. As the nation implements SARS-CoV-2 vaccination in adults at an unprecedented scale, it is now essential to focus on the prospect of SARS-CoV-2 vaccinations in pediatric populations. To date, no children younger than 12 years have been enrolled in clinical trials. Key challenges and knowledge gaps that must be addressed include (1) rationale for vaccines in children, (2) possible effects of immune maturation during childhood, (3) ethical concerns, (4) unique needs of children with developmental disorders and chronic conditions, (5) health inequities, and (6) vaccine hesitancy. Because COVID-19 is minimally symptomatic in the vast majority of children, a higher acceptable risk threshold is required when evaluating pediatric clinical trials. Profound differences in innate and adaptive immunity during childhood and adolescence are known to affect vaccine responsiveness for a variety of childhood diseases. COVID-19 and the accompanying social disruption, such as the school shutdowns, has been disproportionately damaging to minority and low-income children. In this commentary, we briefly address each of these key issues, specify research gaps, and suggest a broader learning health system approach to accelerate testing and clinical trial development for an ethical and effective strategy to implement a pediatric SARS-CoV-2 vaccine as rapidly and safely as possible. IMPACT: As the US begins an unprecedented implementation of SARS-CoV-2 vaccination, substantial knowledge gaps have yet to be addressed regarding vaccinations in the pediatric population. Maturational changes in the immune system during childhood have influenced the effectiveness of pediatric vaccines for other diseases and conditions, and could affect SARS-CoV-2 vaccine responsiveness in children. Given that COVID-19 disease is far milder in the majority of children than in adults, the risk-benefit of a pediatric SARS-CoV-2 vaccine must be carefully weighed. The needs of children with developmental disabilities and with chronic disease must be addressed. Minority and low-income children have been disproportionately adversely affected by the COVID-19 pandemic; care must be taken to address issues of health equity regarding pediatric SARS-CoV-2 vaccine trials and allocation. Research and strategies to address general vaccine hesitancy in communities must be addressed in the context of pediatric SARS-CoV-2 vaccines.

Point of view on the vaccination against COVID-19 in patients with autoimmune inflammatory rheumatic diseases. In view of the COVID-19 pandemic, there is an unmet clinical need for the guidelines on vaccination of patients with autoimmune inflammatory rheumatic diseases (AIIRD). This position paper summarises the current data on COVID-19 infection in patients with AIIRD and development of vaccines against COVID-19, discusses the aspects of efficacy and safety of vaccination, and proposes preliminary considerations on vaccination against COVID-19 in patients with AIIRD, mainly based on the expert opinion and knowledge on the use of other vaccines in this population of patients.

Vaccination of patients with inflammatory rheumatic diseases against SARS-CoV-2: considerations before widespread availability of the vaccines. Vaccination against SARS-CoV-2 has become available and will hopefully end the current pandemic. Understandably, patients with inflammatory rheumatic diseases (iRMDs) and their physicians are feverishly preoccupied with questions about vaccination and the vaccines against SARS-CoV-2. However, as it will take months before all patients with iRMDs will have access to the vaccines, measures that are taken now in order to increase potential safety and efficacy of the vaccines may impose a risk for the patients with regard to reactivation of their underlying iRMD. The ad hoc commission 'Covid-19' and the board of directors of the German Society for Rheumatology have addressed this topic and have developed considerations, which are intended to answer urgent questions, to take away concerns and fears and to make initial recommendations for patients with iRMDs.

Evolution of Lymphadenopathy at PET/MRI after COVID-19 Vaccination.

Lymphadenopathy in COVID-19 Vaccine Recipients: Diagnostic Dilemma in Oncologic Patients. Five cases of axillary lymphadenopathy are presented, which occurred after COVID-19 vaccination and mimicked metastasis in a vulnerable oncologic patient group. Initial radiologic diagnosis raised concerns for metastasis. However, further investigation revealed that patients received COVID-19 vaccinations in the ipsilateral arm prior to imaging. In two cases, lymph node biopsy results confirmed vaccination-related reactive lymphadenopathy. Ipsilateral axillary swelling or lymphadenopathy was reported based on symptoms and physical examination in COVID-19 vaccine trials. Knowledge of the potential for COVID-19 vaccine-related ipsilateral adenopathy is necessary to avoid unnecessary biopsy and change in therapy. Â© RSNA, 2021.
Adenopathy Following COVID-19 Vaccination.
Multidisciplinary Recommendations Regarding Post-Vaccine Adenopathy and Radiologic Imaging: Radiology Scientific Expert Panel. Vaccination-associated adenopathy is a frequent imaging finding after administration of COVID-19 vaccines that may lead to a diagnostic conundrum in patients with manifest or suspected cancer, in whom it may be indistinguishable from malignant nodal involvement. To help the medical community address this concern in the absence of studies and evidence-based guidelines, this special report offers recommendations developed by a multidisciplinary panel of experts from three of the leading tertiary care cancer centers in the United States. According to these recommendations, some routine imaging examinations, such as those for screening, should be scheduled before or at least 6 weeks after the final vaccination dose to allow for any reactive adenopathy to resolve. However, there should be no delay of other clinically indicated imaging (eg, for acute symptoms, short-interval treatment monitoring, urgent treatment planning or complications) due to prior vaccination. The vaccine should be administered on the side contralateral to the primary or suspected cancer, and both doses should be administered in the same arm. Vaccination information-date(s) administered, injection site(s), laterality, and type of vaccine-should be included in every preimaging patient questionnaire, and this information should be made readily available to interpreting radiologists. Clear and effective communication between patients, radiologists, referring physician teams, and the general public should be considered of the highest priority when managing adenopathy in the setting of COVID-19 vaccination.
COVID-19 Vaccination-Associated Axillary Adenopathy: Imaging Findings and Follow-Up Recommendations in 23 Women. The purpose of this article is to report on 23 women with evidence of axillary adenopathy at breast imaging after recent COVID-19 vaccination. A total of 13% of patients had symptoms (axillary lump), 43% were undergoing screening, and 43% were undergoing diagnostic imaging for other reasons. BI-RADS category 2 was assigned in one case, BI-RADS 3 in 21 (ultrasound in 4-24 weeks), and BI-RADS 4 in one. Radiologist familiarity and evidence-based guidelines are needed to avoid follow-up imaging and biopsies for reactive adenopathy after COVID-19 vaccination.
Idiopathic Ipsilateral External Jugular Vein Thrombophlebitis After Coronavirus Disease (COVID-19) Vaccination.
The Canadian Society of Breast Imaging Recommendations for the Management of Axillary Adenopathy in Patients with Recent COVID-19 Vaccination - Update.
Acute and chronic inflammatory neuropathies and COVID-19 vaccines: Practical recommendations from the task force of the Italian Peripheral Nervous System Association (ASNP). BACKGROUND AND AIMS: To develop recommendations for vaccination for coronavirus-19 (COVID-19) in patients with inflammatory neuropathies. METHODS: Key questions were formulated in order to perform a literature review on the safety and efficacy of vaccines in patients with inflammatory neuropathies. Based on the best evidence and expert opinion, a list of recommendations was formulated to inform decision on vaccination for COVID-19 in patients with inflammatory neuropathies and increase

adherence to vaccination programmes. RESULTS: Recommendations addressing safety and efficacy of vaccination in patients with inflammatory neuropathies were formulated. No data are currently available on the safety and efficacy of COVID-19 vaccines in patients with inflammatory neuropathies or other immune-mediated conditions. There is only sparse data on the safety of previous available vaccines in patients with inflammatory neuropathies, but studies on other autoimmune disorders indicate that these are safe and mostly efficacious. Patients with inflammatory neuropathies might be at increased risk for severe illness from COVID-19. INTERPRETATION: Patients with inflammatory neuropathies should be encouraged to adhere to the vaccination campaign for COVID-19. These recommendations provide guidance on the management of vaccinations for COVID-19 in patients with inflammatory neuropathies. More research is needed regarding the safety and efficacy of vaccination in patients with inflammatory neuropathies and other immune conditions.

'Blue toes' following vaccination with the BNT162b2 mRNA COVID-19 vaccine. Highlights: COVID toes can be encountered in young individuals during acute COVID-19 infection while it results from the direct action of Spike protein on vessels. We report the case of COVID toes during the French campaign of vaccination that occurred 4Â days after the vaccination with the Pfizer-BioNTech mRNA vaccine against COVID-19.

SARS-CoV-2 vaccination induces neutralizing antibodies against pandemic and pre-emergent SARS-related coronaviruses in monkeys. Betacoronaviruses (betaCoVs) caused the severe acute respiratory syndrome (SARS) and Middle East Respiratory Syndrome (MERS) outbreaks, and now the SARS-CoV-2 pandemic. Vaccines that elicit protective immune responses against SARS-CoV-2 and betaCoVs circulating in animals have the potential to prevent future betaCoV pandemics. Here, we show that immunization of macaques with a multimeric SARS-CoV-2 receptor binding domain (RBD) nanoparticle adjuvanted with 3M-052-Alum elicited cross-neutralizing antibody responses against SARS-CoV-1, SARS-CoV-2, batCoVs and the UK B.1.1.7 SARS-CoV-2 mutant virus. Nanoparticle vaccination resulted in a SARS-CoV-2 reciprocal geometric mean neutralization titer of 47,216, and robust protection against SARS-CoV-2 in macaque upper and lower respiratory tracts. Importantly, nucleoside-modified mRNA encoding a stabilized transmembrane spike or monomeric RBD protein also induced SARS-CoV-1 and batCoV cross-neutralizing antibodies, albeit at lower titers. These results demonstrate current mRNA vaccines may provide some protection from future zoonotic betaCoV outbreaks, and provide a platform for further development of pan-betaCoV nanoparticle vaccines.

Influence of a COVID-19 vaccine's effectiveness and safety profile on vaccination acceptance. Although a safe and effective vaccine holds the greatest promise for resolving the COVID-19 pandemic, hesitancy to accept vaccines remains common. To explore vaccine acceptance decisions, we conducted a national survey of 1,000 people from all US states in August of 2020 and a replication in December of 2020. Using a 3 Ã— 3 Ã— 3 factorial experimental design, we estimated the impact of three factors: probability of 1) protection against COVID-19, 2) minor side effects, and 3) a serious adverse reactions. The outcome was respondents' reported likelihood of receiving a vaccine for the coronavirus. Probability of vaccine efficacy (50%, 70%, or 90%) had the largest effect among the three factors. The probability of minor side effects (50%, 75%, 90%) including fever and sore arm, did not significantly influence likelihood of receiving the vaccine. The chances of a serious adverse reaction, such as temporary or permanent paralysis, had a small but significant effect. A serious adverse reaction rate of 1/100,000 was more likely to discourage vaccine use in comparison to rates of 1/million or 1/100 million. All interactions between the factors were nonsignificant. A replication following the announcement that vaccines were 95% effective showed small, but significant increases in the likelihood of taking a vaccine. The main effects and interactions in the model remained unchanged. Expected benefit was more influential in respondents' decision making than expected

side effects. The absence of interaction effects suggests that respondents consider the side effects and benefits independently.

COVID-19 and cardiovascular complications: an update from the underlying mechanism to consequences and possible clinical intervention. Introduction: The novel coronavirus has caused significant mortality worldwide and is primarily associated with severe acute respiratory distress syndrome (ARDS). Apart from ARDS, clinical reports have shown noticeable cardiovascular complications among the patients of COVID-19. Infection from virus, stimulation of cytokine storm, altered immune response, and damage to myocardial tissue are some of the proposed mechanisms of cardiovascular complications in COVID-19.Areas covered: Based on the clinical reports of CVDs among COVID-19 patients, we have discussed the molecular mechanisms involved in cardiovascular pathogenesis, its prevalence, and association with COVID-19, and various available therapeutic modality for the treatment.Expert opinion: Seeing the cardiovascular complications in COVID-19 patients and its association with the existing drug, risk-benefit ratio of treatment paradigm, as well as the level of cardiac injury biomarkers must be monitored regularly. Additionally, a well-designed clinical trial should be conducted where head to head comparison can be made with anti-COVID-19 drugs and cardioprotective anti-inflammatory drugs. Nevertheless, vaccines are the best-suited approach, but until then, sanitization, social distancing, and active lifestyle are the best ways to beat this global pandemic situation.

Single-dose administration and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine: a pooled analysis of four randomised trials. BACKGROUND: The ChAdOx1 nCoV-19 (AZD1222) vaccine has been approved for emergency use by the UK regulatory authority, Medicines and Healthcare products Regulatory Agency, with a regimen of two standard doses given with an interval of 4-12 weeks. The planned roll-out in the UK will involve vaccinating people in high-risk categories with their first dose immediately, and delivering the second dose 12 weeks later. Here, we provide both a further prespecified pooled analysis of trials of ChAdOx1 nCoV-19 and exploratory analyses of the impact on immunogenicity and efficacy of extending the interval between priming and booster doses. In addition, we show the immunogenicity and protection afforded by the first dose, before a booster dose has been offered. METHODS: We present data from three single-blind randomised controlled trials-one phase 1/2 study in the UK (COV001), one phase 2/3 study in the UK (COV002), and a phase 3 study in Brazil (COV003)-and one double-blind phase 1/2 study in South Africa (COV005). As previously described, individuals 18 years and older were randomly assigned 1:1 to receive two standard doses of ChAdOx1 nCoV-19 (5â€ˆÃ—â€ˆ10(10) viral particles) or a control vaccine or saline placebo. In the UK trial, a subset of participants received a lower dose (2Â·2â€ˆÃ—â€ˆ10(10) viral particles) of the ChAdOx1 nCoV-19 for the first dose. The primary outcome was virologically confirmed symptomatic COVID-19 disease, defined as a nucleic acid amplification test (NAAT)-positive swab combined with at least one qualifying symptom (fever â‰¥37Â·8Â°C, cough, shortness of breath, or anosmia or ageusia) more than 14 days after the second dose. Secondary efficacy analyses included cases occuring at least 22 days after the first dose. Antibody responses measured by immunoassay and by pseudovirus neutralisation were exploratory outcomes. All cases of COVID-19 with a NAAT-positive swab were adjudicated for inclusion in the analysis by a masked independent endpoint review committee. The primary analysis included all participants who were SARS-CoV-2 N protein seronegative at baseline, had had at least 14 days of follow-up after the second dose, and had no evidence of previous SARS-CoV-2 infection from NAAT swabs. Safety was assessed in all participants who received at least one dose. The four trials are registered at ISRCTN89951424 (COV003) and ClinicalTrials.gov, NCT04324606 (COV001), NCT04400838 (COV002), and NCT04444674 (COV005). FINDINGS: Between April 23 and Dec 6, 2020, 24â€ˆ422 participants were recruited and vaccinated across the four studies, of whom 17â€ˆ178

were included in the primary analysis (8597 receiving ChAdOx1 nCoV-19 and 8581 receiving control vaccine). The data cutoff for these analyses was Dec 7, 2020. 332 NAAT-positive infections met the primary endpoint of symptomatic infection more than 14 days after the second dose. Overall vaccine efficacy more than 14 days after the second dose was 66Â·7% (95% CI 57Â·4-74Â·0), with 84 (1Â·0%) cases in the 8597 participants in the ChAdOx1 nCoV-19 group and 248 (2Â·9%) in the 8581 participants in the control group. There were no hospital admissions for COVID-19 in the ChAdOx1 nCoV-19 group after the initial 21-day exclusion period, and 15 in the control group. 108 (0Â·9%) of 12â€ˆ282 participants in the ChAdOx1 nCoV-19 group and 127 (1Â·1%) of 11â€ˆ962 participants in the control group had serious adverse events. There were seven deaths considered unrelated to vaccination (two in the ChAdOx1 nCov-19 group and five in the control group), including one COVID-19-related death in one participant in the control group. Exploratory analyses showed that vaccine efficacy after a single standard dose of vaccine from day 22 to day 90 after vaccination was 76Â·0% (59Â·3-85Â·9). Our modelling analysis indicated that protection did not wane during this initial 3-month period. Similarly, antibody levels were maintained during this period with minimal waning by day 90 (geometric mean ratio [GMR] 0Â·66 [95% CI 0Â·59-0Â·74]). In the participants who received two standard doses, after the second dose, efficacy was higher in those with a longer prime-boost interval (vaccine efficacy 81Â·3% [95% CI 60Â·3-91Â·2] at â‰¥12 weeks) than in those with a short interval (vaccine efficacy 55Â·1% [33Â·0-69Â·9] at <6 weeks). These observations are supported by immunogenicity data that showed binding antibody responses more than two-fold higher after an interval of 12 or more weeks compared with an interval of less than 6 weeks in those who were aged 18-55 years (GMR 2Â·32 [2Â·01-2Â·68]). INTERPRETATION: The results of this primary analysis of two doses of ChAdOx1 nCoV-19 were consistent with those seen in the interim analysis of the trials and confirm that the vaccine is efficacious, with results varying by dose interval in exploratory analyses. A 3-month dose interval might have advantages over a programme with a short dose interval for roll-out of a pandemic vaccine to protect the largest number of individuals in the population as early as possible when supplies are scarce, while also improving protection after receiving a second dose. FUNDING: UK Research and Innovation, National Institutes of Health Research (NIHR), The Coalition for Epidemic Preparedness Innovations, the Bill & Melinda Gates Foundation, the Lemann Foundation, Rede D'Or, the Brava and Telles Foundation, NIHR Oxford Biomedical Research Centre, Thames Valley and South Midland's NIHR Clinical Research Network, and AstraZeneca.

Unilateral Axillary Lymphadenopathy After Coronavirus Disease (COVID-19) Vaccination.

Mitigating the Impact of Coronavirus Disease (COVID-19) Vaccinations on Patients Undergoing Breast Imaging Examinations: A Pragmatic Approach. Reports of patients with axillary adenopathy identified on breast imaging after coronavirus disease (COVID-19) vaccination are rising. We propose a pragmatic management approach based on clinical presentation, vaccination delivery, and imaging findings. In the settings of screening mammography, screening MRI, and diagnostic imaging workup of breast symptoms, with no imaging findings beyond unilateral axillary adenopathy ipsilateral to recent (within the past 6 weeks) vaccination, we report the adenopathy as benign with no further imaging indicated if no nodes are palpable 6 weeks after the last dose. For patients with palpable axillary adenopathy in the setting of ipsilateral recent vaccination, clinical follow-up of the axilla is recommended. In all these scenarios, axillary ultrasound is recommended if clinical concern persists 6 weeks after vaccination. In patients with a recent breast cancer diagnosis in the pre- or peritreatment setting, prompt recommended imaging is encouraged as well as vaccination (in the thigh or contralateral arm). Our recommendations align with the ACR BI-RADS Atlas and aim to reduce patient anxiety, provider burden, and costs of unnecessary evaluation of enlarged nodes in the setting of recent vaccinations and, also, to avoid further delays in vaccinations and breast cancer screening during the pandemic.

Do recipients of the first dose of the Pfizer/BioNTech vaccine in December have a legal case against the UK government's decision to postpone their second dose? The Covid-19 pandemic in the UK has been greatly worsened by the mutation of the virus, which began in the South East and was rapidly spreading and in danger of overwhelming the NHS as hospital admissions and deaths continued to rise. In consequence, the Chief Medical Officers of all four nations supported the UK government's sudden decision to delay the second dose of the Pfizer/BioNtech and Oxford/AstraZeneka vaccines for 12â€‰weeks (instead of 3) so that more people in the most vulnerable population groups would receive a first dose and some immunity sooner. The expectation is that this strategy would reduce hospital admissions and deaths. This article considers key medical and legal issues arising from this decision and discusses inter alia rationing of scarce resources, fairness, whether it is for the greater good, consent, individual human rights, negligence and claims for potential or actual injury.
Is there a link between pre-existing antibodies acquired due to childhood vaccinations or past infections and COVID-19? A case control study. BACKGROUND: There is growing evidence indicating that children are less affected from COVID-19. Some authors speculate that childhood vaccinations may provide some cross-protection against COVID-19. In this study, our aim was to compare the circulating antibody titers for multiple childhood vaccine antigens, as an indicator of the state of immune memory between patients with COVID-19 and healthy controls, with a specific aim to identify the association between disease severity and antibody titrations which may indicate a protective function related to vaccine or disease induced memory. METHODS: This study is a case-control study including 53 patients with COVID-19 and 40 healthy volunteers. COVID-19 severity was divided into three groups: asymptomatic, mild and severe. We measured the same set of antibody titers for vaccine antigens, and a set of biochemical and infection markers, in both the case and control groups. RESULTS: Rubella ($p = 0.003$), pneumococcus ($p = 0.002$), and Bordetella pertussis ($p < 0.0001$) titers were found to be significantly lower in the case group than the control group. There was a significant decline in pneumococcus titers with severity of disease ($p = 0.021$) and a significant association with disease severity for Bordetella pertussis titers ($p = 0.014$) among COVID patients. Levels of AST, procalcitonin, ferritin and D-dimer significantly increased with the disease severity. DISCUSSION: Our study supports the hypothesis that pre-existing immune memory, as monitored using circulating antibodies, acquired from childhood vaccinations, or past infections confer some protection against COVID-19. Randomized controlled studies are needed to support a definitive conclusion.
[In subjects 16 years of age and older, is messenger RNA vaccine BNT162b2 against COVID-19 effective and safe?].
Bell's palsy following COVID-19 vaccination.
The SARS-CoV-2 as an instrumental trigger of autoimmunity. Autoimmunity may be generated by a variety of factors by creating a hyper-stimulated state of the immune system. It had been established long ago that viruses are a substantial component of environmental factors that contribute to the production of autoimmune antibodies, as well as autoimmune diseases. Epstein-Barr virus (EBV), cytomegalovirus (CMV) and human immunodeficiency virus (HIV) are viruses that withhold these autoimmune abilities. In a similar manner, SARS-CoV-2 may be counted to similar manifestations, as numerous records demonstrating the likelihood of COVID-19 patients to develop multiple types of autoantibodies and autoimmune diseases. In this review, we focused on the association between COVID-19 and the immune system concerning the tendency of patients to develop over 15 separate types of autoantibodies and above 10 distinct autoimmune diseases. An additional autoimmunity manifestation may be one of the common initial symptoms in COVID-19 patients, anosmia, the complete loss of the ability to sense smell, and other olfactory alterations. We

summarize current knowledge on principal mechanisms that may contribute to the development of autoimmunity in the disease: the ability of SARS-CoV-2 to hyper-stimulate the immune system, induce excessive neutrophil extracellular traps formation with neutrophil-associated cytokine responses and the molecular resemblance between self-components of the host and the virus. Additionally, we will examine COVID-19 potential risk on the new-onsets of autoimmune diseases, such as antiphospholipid syndrome, Guillain-BarrÃ© syndrome, Kawasaki disease and numerous others. It is of great importance to recognize those autoimmune manifestations of COVID-19 in order to properly cope with their outcomes in the ongoing pandemic and the long-term post-pandemic period. Lastly, an effective vaccine against SARS-CoV-2 may be the best solution in dealing with the ongoing pandemic. We will discuss the new messenger RNA vaccination strategy with an emphasis on autoimmunity implications.
Immunotherapy for COVID-19: Evolving treatment of viral infection and associated adverse immunological reactions. This review on COVID-19 immunotherapy enables a comparative analysis of the short-list of currently approved major vaccines. These include the Pfizer and Moderna first mRNA vaccines under FDA purview and the Oxford/AstraZeneca simian adenovirus-vectored vaccine (under UK-MHPRA guidance), all produced in record time, being safe and effective. The Pfizer and Moderna double dose vaccines have the clear edge in treatment efficacy, being in the 90% range compared to AstraZeneca in the average 70%. However, the AZ double dose vaccine has significant advantages with respect to lower cost and stability in storage. We enumerate several potential advances in the technology of the manufacturers: (1) combination vaccines such as testing AstraZeneca's product with a component of the Russian's Sputnik V to achieve durable immunity; (2) the potential for single dose vaccines coming on-line, and with Johnson & Johnson/Janssen; and (3) the need for refined thermotolerant formulations obviating the need for cold storage. As an adjunct to vaccinotherapy, affinity adsorption column technology is another facet recruited in the processing of corona convalescent plasma/cryosupernatant to concentrate neutralizing antibodies against the virus. Clinical trials, to date, of infected patients have been indeterminate as to whether plasmapheresis-based products are effective or not. This is due to the failure to standardize the composition of the plasma derived component, ambiguous clinical indications for use in human subjects, and inconsistent timing of administration in the course of the infection. Known T-cell lymphopenia, which is attendant to progressive viral infection and immune driven inflammation, may be a quantitative surrogate biological marker as to when to start treatment. This is not only for initiating plasmapheresis-based therapeutics but also the judicious selection of ancillary pharmaceuticals, ie. monoclonal antibodies, recombinant proteins and anti-viral drugs.
Thrombocytopenia following Pfizer and Moderna SARS-CoV-2 vaccination.
Coronavirus Vaccine Considerations for the Aesthetic Patient.
COVID vaccines and safety: what the research says.
The Era of the Coronavirus Disease 2019 Pandemic: A Review on Dynamics, Clinical Symptoms and Complications, Diagnosis, and Treatment. Coronavirus disease 2019 (COVID-19) displays a broad spectrum of clinical presentations ranging from lack of symptoms to severe multiorgan system complications and death. Various laboratory assays have been employed in the diagnosis of COVID-19, including: nucleic acid-based tests; antigen tests; and serum testing for anti-severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) antibodies. The disease can also be diagnosed based on suggestive clinical features and radiological findings. Until now, remdesivir is the only medication approved for the treatment of COVID-19 by the U.S. Food and Drug Administration (FDA); however, it is anticipated that several anti-SARS-CoV-2 monoclonal antibodies will gain soon approval. Other methods of treatment include supportive care directed toward treating the symptoms. Nevertheless, many studies have recently emerged, showing controversial preliminary

results with the off-label medication hydroxychloroquine. Given that all results are still preliminary, including those seen by remdesivir, additional evidence and research are required to identify effective medications that are broadly effective and well tolerated. Importantly, two RNA-based vaccines have recently gained approval from Pfizer and Moderna, with many others still in clinical trials. This article reviews various aspects of COVID-19, including its epidemiology; its evolution and mutational spectrum; and its clinical dynamics, symptoms and complications, diagnosis, and treatment.
The disproportionate excess mortality risk of COVID-19 in younger people with diabetes warrants vaccination prioritisation.
Bell's Palsy after second dose of Pfizer COVID-19 vaccination in a patient with history of recurrent Bell's palsy. OBJECTIVE: To report a patient with history of recurrent Bell's Palsy who developed Bell's Palsy 36Â â€‹h after the administration of the second dose of the Pfizer-BioNTech COVID-19 vaccine. CASE: The patient is a 57-year-old female with past medical history of 3 episodes of Bell's Palsy. She responded to prednisone treatment and returned to her baseline after each occurrence. Less than 36Â â€‹h following the second dose of the vaccine, the patient developed a left Bell's Palsy. The facial droop progressed in severity over the next 72Â â€‹h. CONCLUSION: Given the expedited production of the vaccine and the novelty associated with its production, there may be information pertaining to side effects and individual response that remain to be discovered. Since both the Moderna and Pfizer Vaccine trials reported Bell's Palsy as medically attended adverse events, the association between vaccine administration and onset of symptomatic Bell's Palsy may warrant further investigation.
[The lack of confidence to vaccination as information planting]. The key requirements to vaccine are its safety and efficiency. Nowadays, when issue of vaccination is extremely acute, certain citizens began voluntarily to refuse important procedure, not becoming thoughtful that they endanger both themselves and other people. The purpose of the study is to specify the arguments and methods of circulation of anti-vaccination propaganda and to find out scientific counterarguments. Actually, there is sufficient data concerning lack of confidence to vaccination and vaccine prevention of infectious diseases. The systematic qualitative review of publications on issues of interest was carried out. It is established that lack of confidence to vaccination is maintained artificially and can be characterized as an information virus. The information throw-ins of fake-news about danger of vaccine and harm of vaccination undermine population trust to health care and vaccine prevention. The problem continues to be actual and controversial. So, every individual is independently to determine one's attitude to vaccination and to take charge of one's own health. Also, a number of facts is presented refuting convictions of anti-vaccinators.
[The organizational aspects of security support of participants of clinical testing of vaccine "Gam-COVID-Vac"]. The COVID-19 pandemic resulted in many aftermaths, economic crisis and extra charging of health care. The development of vaccine against SARS-nCoV-2 agent turned out as the priority task of world and Russian medicine and pharmaceutics. The investigation of efficiency and safety of vaccines can be prolonged for many years that can aggravate the observed crisis. Having regard to the global scope and speed of pandemic spreading, the vaccine "Gam-COVID-Vac" was registered with special procedure by the Decree of the Government of the Russian Federation No. 441 of 03.04.2020 for accelerated access to civic turn-over. To monitor safety of vaccine on the basis of international experience, the decision was made to organize the independent Committee of monitoring data concerning efficacy and safety of vaccines applied to prevent COVID-19. The article presents rationale for necessity to create independent committee and to implement such a practice.
COVID-19 mRNA Vaccination-Induced Lymphadenopathy Mimics Lymphoma Progression on FDG PET/CT. We present here a 72-year-old man with mantle cell lymphoma who has completed

chemotherapy and achieved complete metabolic response to the therapy 10 months ago. Series follow-up FDG PET/CT scans have been negative for lymphoma. Current FDG PET/CT scan showed a new cluster of subcentimeter left axillary lymphadenopathy with avid FDG uptake. There was also focal FDG uptake in the left upper arm deltoid muscle and adjacent subcutaneous soft tissue, with no other abnormal FDG-avid lesion or suspicious CT image findings. The medical history revealed that the patient received COVID-19 mRNA vaccine 2 days before the FDG PET/CT examination.

MAIT cells boost adenovirus-induced CD8(+) T cells. MAIT cells found to have central role in the induction of CD8(+) T cell immunity in response to vaccination with ChAdOx1 adenoviral vectors.

Exploration of Association Between Respiratory Vaccinations With Infection and Mortality Rates of COVID-19. OBJECTIVE: Respiratory disease vaccines may affect coronavirus disease 2019 (COVID-19) - associated infection and mortality rates due to vaccine nonspecific effects against viral infections. We compared the infection and mortality rates in relation to COVID-19 between countries with and without universal respiratory disease vaccine policies. METHODS: In this ecological study, 186 countries with COVID-19 statistics from the World Health Organization (WHO) were included. RESULTS: The study found that countries with universal BCG (bacillus Calmette GuÃ©rin) vaccine had significantly lower total infection and mortality rates, 0.2979 and 0.0077 versus 3.7445, and 0.0957/1000 people and confirmed cases ($P < 0.001$). The countries with universal pneumococcal vaccine (PCV), including PCV1, PCV2, and PCV3 vaccines, had significantly higher total mortality, 0.0111 versus 0.0080, respectively ($P = 0.032$). Higher income was associated with increasing total infection and mortality rates. Whereas, BCG vaccination was associated with a lower total mortality rate only ($P = 0.030$). The high-income countries were more likely to not receive universal BCG and receive second dose of meningococcal conjugate vaccine (MCV2) and third dose of PCV3 vaccination coverage. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection rates increased with increasing years of the second dose of measles-containing vaccine ($P = 0.026$) and pneumococcal conjugate third dose (PCV3). CONCLUSIONS: This study suggests that BCG vaccination could reduce the infection caused by COVID-19, and MCV2 vaccine years increases the total infection rate. This study identified high economic characteristics and not having universal BCG coverage as the independent risk factors of mortality by multivariate analysis.

Tanzania refuses COVID-19 vaccines.

Familial thrombocytopenia flare-up following the first dose of mRNA-1273 Covid-19 vaccine.

[Allergic reactions to COVID-19 vaccines: evidence and practice-oriented approach]. Less than a year after the first detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), vaccines have been approved for routine use in numerous countries and have already been used in mass vaccination programs. Vaccines include the mRNA BNT162b2 and mRNA 1273. Allergic reactions and anaphylaxis account for a substantial proportion of the adverse reactions to these vaccines observed to date, but overall they are rare. The incidence of anaphylaxis in the context of SARS-CoVâ€‘2 vaccination with the mRNA vaccines appears to be approximately 10-fold higher than with previous vaccines, at approximately 1 per 100,000 vaccine injections. One focus of the present article is a systematic review of the components of mRNA vaccines against "â€‰coronavirus disease 2019â€‰" (COVID-19). Differences from established vaccines are addressed and the allergic potential of liposomes, polyethylene glycol, tromethamine/trometamol, and mRNA are discussed. Another focus is on the clinical presentation and course of allergic reactions to the COVID-19 vaccines. This is followed by a discussion of the therapeutic approach to anaphylactic reactions, as well as the drugs and medical supplies required to treat them. It is important to note that any vaccinee may be affected by anaphylaxis, regardless of whether or not allergic diseases are already known. Therefore, every vaccination site and every vaccinator must be prepared to recognize and treat severe allergic reactions.

Postvaccination anaphylaxis and mRNA-based SARS-CoV-2 vaccines-Much ado about nothing?
AZD1222 (Covishield) vaccination for COVID-19: Experiences, challenges, and solutions in Nepal.
Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US-December 14, 2020-January 18, 2021.
This COVID-vaccine designer is tackling vaccine hesitancy - in churches and on Twitter.
Delving Into COVID-19 Vaccination-Induced Anaphylaxis: Are mRNA Vaccines Safe in Mast Cell Disorders?
Synthetic Messenger RNA-Based Vaccines: from Scorn to Hype. In the race for a vaccine against SARS-CoV-2, the synthetic mRNA format has been shown to be the fastest one and proved to be safe and highly efficient, even at the very low dose of a few Âµg per injection. The mRNA vaccines are not new: vaccines that are based on attenuated mRNA viruses, such as Mumps, Measles, and Rubella, immunize by delivering their mRNAs into the cells of the vaccinated individual, who produces the viral proteins that then prime the immune response. Synthetic mRNA in liposomes can be seen as a modern, more refined, and thereby a safer version of those live attenuated RNA viruses. The anti-COVID-19 mRNA vaccine (coding the SARS-CoV-2 spike protein) is the third synthetic RNA therapeutic being approved. It follows the aptamer Macugen(Â®) (which neutralizes VEGF) and the siRNA Onpattro(Â®) (which destroys the transthyretin-coding mRNA). Remarkably, the 30 Âµg of mRNA that are contained in the first approved anti-COVID-19 vaccine are sufficient for generating high levels of neutralizing antibodies against the virus in all injected volunteers (including participants over 65 years old). The efficacy and safety data are stunning. The distribution of these vaccines throughout the world will bring a halt to the coronavirus pandemic.
Allergic Reactions and Anaphylaxis to LNP-Based COVID-19 Vaccines.
Glucocorticoid use in patients with adrenal insufficiency following administration of the COVID-19 vaccine: a pituitary society statement. PURPOSE: Side effects of the coronavirus disease 2019 (COVID-19) vaccines include pain at the injection site, fatigue, headache, myalgias, arthralgias, chills, and fever, all of which can be early indicators of an increased need for glucocorticoid replacement in patients with adrenal insufficiency. The Pituitary Society surveyed its membership to understand planned approaches to glucocorticoid management in patients with adrenal insufficiency who will receive a COVID-19 vaccine. METHODS: Members were asked to complete up to 3 questions regarding their planned approach for use of glucocorticoid replacement in patients with proven adrenal insufficiency. RESULTS: Surveys were sent to 273 members and 103 responded. Thirty-six percent plan to recommend that patients automatically increase glucocorticoid dosage with administration of the first vaccine injection. Of these, 84% plan to increase glucocorticoid dose on the day of vaccination, and 49% plan to increase glucocorticoid dose prior to vaccination. Of the 64% who do not plan to recommend automatic glucocorticoid dose increase with vaccine administration, 88% plan to increase the dose if the patient develops a fever, and 47% plan to increase the dose if myalgias and arthralgias occur. CONCLUSIONS: Most clinicians plan to maintain the current glucocorticoid dose with vaccine administration. The vast majority plan and to increase glucocorticoid dose in case of fever, and just under half in case of arthralgias and myalgias. These survey results offer suggested management guidance for glucocorticoid management in patients with adrenal insufficiency.
With Great Hopes Come Great Expectations: Access and Adoption Issues Associated With COVID-19 Vaccines. Although COVID-19 vaccines are becoming increasingly available, their ability to effectively control and contain the spread of the COVID-19 pandemic is highly contingent on an array of factors. This paper discusses how limitations to vaccine accessibility, issues associated with vaccine side effects, concerns regarding vaccine efficacy, along with the persistent prevalence of vaccine hesitancy among the public, including health care professionals, might impact the potential of COVID-

19 vaccines to curb the pandemic. We draw insights from the literature to identify practical solutions that could boost people's adoption of COVID-19 vaccines and their accessibility. We conclude with a discussion on health experts' and government officials' moral and ethical responsibilities to the public, even in light of the urgency to adopt and endorse "the greatest amount of good for the greatest number" utilitarian philosophy in controlling and managing the spread of COVID-19.

Morbilliform rash after administration of Pfizer-BioNTech COVID-19 mRNA vaccine.

Safety of the First Dose of SARS-CoV-2 Vaccination in Solid Organ Transplant Recipients.

Pharmacological treatment during CoViD-19 and mental health issues. Infection outbreak has been prevalent since previous decades. The impact of infection outbreak not merely limited to physical suffering but grounded for massive mental health issues. The fear of getting contagion and persistent exposure to diverse medication and vaccination contribute enormously to develop mental health issues among people. During previous infection treatment with diverse vaccination and antiviral agent, the common mental health issues found to be a mood disorder, delirium, schizophrenia, and psychotic symptoms. Cumbersomely, it is almost impossible to treat mental health issues during the pandemic with the help of only pharmacological availability. Hence psychological intervention is also important to ameliorate better consequences. The current study highlights the impact of CoViD-19 related diverse medication and vaccination on the mental health of the people.

"COVID-19/SARS-CoV-2 virus spike protein-related delayed inflammatory reaction to hyaluronic acid dermal fillers: a challenging clinical conundrum in diagnosis and treatment". We present the first reported cases of delayed inflammatory reactions (DIR) to hyaluronic acid (HA) dermal fillers after exposure to the COVID-19 spike protein. DIR to HA is reported to occur in the different scenarios including: secondary to poor injection technique, following dental cleaning procedures, following bacterial/viral illness, and after vaccination. In this report of 4 cases with distinct clinical histories and presentations: one case occured following a community acquired COVID-19 infection, one case occured in a study subject in the mRNA-1273 clinical phase III trial, one case occurred following the first dose of publically available mRNA-1273 vaccine (Moderna, Cambridge MA), and the last case occurred after the second dose of BNT162b2 vaccine (Pfizer, New York, NY). Injectable HA dermal fillers are prevalent in aesthetic medicine for facial rejuvenation. Structural modifications in the crosslinking of HA fillers have enhanced the products' resistance to enzymatic breakdown and thus increased injected product longevity, however, have also led to a rise in DIR. Previous, DIR to HA dermal fillers can present clinically as edema with symptomatic and inflammatory erythematous papules and nodules. The mechanism of action for the delayed reaction to HA fillers is unknown and is likely to be multifactorial in nature. A potential mechanism of DIR to HA fillers in COVID-19 related cases is binding and blockade of angiotensin 2 converting enzyme receptors (ACE2), which are targeted by the SARS-CoV-2 virus spike protein to gain entry into the cell. Spike protein interaction with dermal ACE2 receptors favors a pro-inflammatory, loco-regional TH1 cascade, promoting a CD8+T cell mediated reaction to incipient granulomas, which previously formed around residual HA particles. Management to suppress the inflammatory response in the native COVID-19 case required high-dose corticosteroids (CS) to suppress inflammatory pathways, with concurrent ACE2 upregulation, along with high-dose intralesional hyaluronidase to dissolve the inciting HA filler. With regards to the two vaccine related cases; in the mRNA-1273 case, a low dose angiotensin converting enzyme inhibitor (ACE-I) was utilized for treatment, to reduce pro-inflammatory Angiotensin II. Whereas, in the BNT162b2 case the filler reaction was suppressed with oral corticosteroids. Regarding final disposition of the cases; the vaccine-related cases returned to baseline appearance within 3Â days, whereas the native COVID-19 case continued to have migratory, evanescent, periorbital edema for weeks which ultimately subsided.

What We Do Know and Do Not Yet Know about COVID-19 Vaccines as of the Beginning of the Year 2021. Coronavirus disease 2019 (COVID-19), which started at the end of 2019 and has spread worldwide, has remained unabated in 2021. Since non-pharmaceutical interventions including social distancing are facing limitations in controlling COVID-19, additional absolute means to change the trend are necessary. To this end, coronavirus-specific antiviral drugs and vaccines are urgently needed, but for now, the priority is to promote herd immunity through extensive nationwide vaccination campaign. In addition to the vaccines based on the conventional technology such inactivated or killed virus or protein subunit vaccines, several vaccines on the new technological platforms, for example, nucleic acids-based vaccines delivered by viral carriers, nanoparticles, or plasmids as a medium were introduced in this pandemic. In addition to achieving sufficient herd immunity with vaccination, the development of antiviral treatments that work specifically against COVID-19 will also be necessary to terminate the epidemic completely.

COVID-19 vaccine-associated anaphylaxis: A statement of the World Allergy Organization Anaphylaxis Committee. Vaccines against COVID-19 (and its emerging variants) are an essential global intervention to control the current pandemic situation. Vaccines often cause adverse events; however, the vast majority of adverse events following immunization (AEFI) are a consequence of the vaccine stimulating a protective immune response, and not allergic in etiology. Anaphylaxis as an AEFI is uncommon, occurring at a rate of less than 1 per million doses for most vaccines. However, within the first days of initiating mass vaccination with the Pfizer-BioNTech COVID-19 vaccine BNT162b2, there were reports of anaphylaxis from the United Kingdom and United States. More recent data imply an incidence of anaphylaxis closer to 1:200,000 doses with respect to the Pfizer-BioNTech vaccine. In this position paper, we discuss the background to reactions to the current COVID-19 vaccines and relevant steps to mitigate against the risk of anaphylaxis as an AEFI. We propose a global surveillance strategy led by allergists in order to understand the potential risk and generate data to inform evidence-based guidance, and thus provide reassurance to public health bodies and members of the public.

General determination of causation between Covid-19 vaccines and possible adverse events.

COVID-19 vaccination in athletes: ready, set, goâ€¦.

Vaccination against SARS-CoV-2 in patients with rheumatic diseases: doubts and perspectives. Since January 2020, the whole world has been facing the worst epidemic for a century. SARS-CoV- 2 infection has so far caused more than one million deaths, with the only measures capable of containing the spread of the virus being social distancing, frequent hand washing, and the wearing of masks. Vaccine development was urgently needed and there are now more than 90 candidate vaccines being developed using different technologies. The European Medicines Agency has recently approved a second mRNA-based vaccine, but the introduction of vaccines has raised some doubts about patients with rheumatic disease, who are at high risk of infection because of disease activity and the therapies used to treat it. The aim of this study was to investigate how vaccines may interact with the immune system and treatment of such patients, and how to monitor the post-vaccine antibody titres and T cell responses in order to assess their efficacy and safety.

Should Antipyretics Be Used to Relieve Acute Adverse Events Related to COVID-19 Vaccines?

In favour of a bespoke COVID-19 vaccines compensation scheme.

Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine (CoronaVac) in healthy adults aged 60 years and older: a randomised, double-blind, placebo-controlled, phase 1/2 clinical trial. BACKGROUND: A vaccine against COVID-19 is urgently needed for older adults, in whom morbidity and mortality due to the disease are increased. We aimed to assess the safety, tolerability, and immunogenicity of a candidate COVID-19 vaccine, CoronaVac, containing inactivated SARS-CoV-2, in adults aged 60 years and older. METHODS: We did a randomised, double-blind, placebo-controlled,

phase 1/2 clinical trial of CoronaVac in healthy adults aged 60 years and older in Renqiu (Hebei, China). Vaccine or placebo was given by intramuscular injection in two doses (days 0 and 28). Phase 1 comprised a dose-escalation study, in which participants were allocated to two blocks: block 1 (3 Î¼g inactivated virus in 0Â·5 mL of aluminium hydroxide solution per injection) and block 2 (6 Î¼g per injection). Within each block, participants were randomly assigned (2:1) using block randomisation to receive CoronaVac or placebo (aluminium hydroxide solution only). In phase 2, participants were randomly assigned (2:2:2:1) using block randomisation to receive either CoronaVac at 1Â·5 Î¼g, 3 Î¼g, or 6 Î¼g per dose, or placebo. All participants, investigators, and laboratory staff were masked to treatment allocation. The primary safety endpoint was adverse reactions within 28 days after each injection in all participants who received at least one dose. The primary immunogenicity endpoint was seroconversion rate at 28 days after the second injection (which was assessed in all participants who had received the two doses of vaccine according to their random assignment, had antibody results available, and did not violate the trial protocol). Seroconversion was defined as a change from seronegative at baseline to seropositive for neutralising antibodies to live SARS-CoV-2 (positive cutoff titre 1/8), or a four-fold titre increase if the participant was seropositive at baseline. This study is ongoing and is registered with ClinicalTrials.gov (NCT04383574). FINDINGS: Between May 22 and June 1, 2020, 72 participants (24 in each intervention group and 24 in the placebo group; mean age 65Â·8 years [SD 4Â·8]) were enrolled in phase 1, and between June 12 and June 15, 2020, 350 participants were enrolled in phase 2 (100 in each intervention group and 50 in the placebo group; mean age 66Â·6 years [SD 4Â·7] in 349 participants). In the safety populations from both phases, any adverse reaction within 28 days after injection occurred in 20 (20%) of 100 participants in the 1Â·5 Î¼g group, 25 (20%) of 125 in the 3 Î¼g group, 27 (22%) of 123 in the 6 Î¼g group, and 15 (21%) of 73 in the placebo group. All adverse reactions were mild or moderate in severity and injection site pain (39 [9%] of 421 participants) was the most frequently reported event. As of Aug 28, 2020, eight serious adverse events, considered unrelated to vaccination, have been reported by seven (2%) participants. In phase 1, seroconversion after the second dose was observed in 24 of 24 participants (100Â·0% [95% CI 85Â·8-100Â·0]) in the 3 Î¼g group and 22 of 23 (95Â·7% [78Â·1-99Â·9]) in the 6 Î¼g group. In phase 2, seroconversion was seen in 88 of 97 participants in the 1Â·5 Î¼g group (90Â·7% [83Â·1-95Â·7]), 96 of 98 in the 3 Î¼g group (98Â·0% [92Â·8-99Â·8]), and 97 of 98 (99Â·0% [94Â·5-100Â·0]) in the 6 Î¼g group. There were no detectable antibody responses in the placebo groups. INTERPRETATION: CoronaVac is safe and well tolerated in older adults. Neutralising antibody titres induced by the 3 Î¼g dose were similar to those of the 6 Î¼g dose, and higher than those of the 1Â·5 Î¼g dose, supporting the use of the 3 Î¼g dose CoronaVac in phase 3 trials to assess protection against COVID-19. FUNDING: Chinese National Key Research and Development Program and Beijing Science and Technology Program.

COVID-19 vaccination for people with severe mental illness: why, what, and how? Psychiatric disorders, and especially severe mental illness, are associated with an increased risk of severe acute respiratory syndrome coronavirus 2 infection and COVID-19-related morbidity and mortality. People with severe mental illness should therefore be prioritised in vaccine allocation strategies. Here, we discuss the risk for worse COVID-19 outcomes in this vulnerable group, the effect of severe mental illness and psychotropic medications on vaccination response, the attitudes of people with severe mental illness towards vaccination, and, the potential barriers to, and possible solutions for, an efficient vaccination programme in this population.

Allergic Reactions to COVID-19 Vaccines: An Allergist's Perspective.

An in silico deep learning approach to multi-epitope vaccine design: a SARS-CoV-2 case study.
The rampant spread of COVID-19, an infectious disease caused by SARS-CoV-2, all over the world has led to over millions of deaths, and devastated the social, financial and political entities around the

world. Without an existing effective medical therapy, vaccines are urgently needed to avoid the spread of this disease. In this study, we propose an in silico deep learning approach for prediction and design of a multi-epitope vaccine (DeepVacPred). By combining the in silico immunoinformatics and deep neural network strategies, the DeepVacPred computational framework directly predicts 26 potential vaccine subunits from the available SARS-CoV-2 spike protein sequence. We further use in silico methods to investigate the linear B-cell epitopes, Cytotoxic T Lymphocytes (CTL) epitopes, Helper T Lymphocytes (HTL) epitopes in the 26 subunit candidates and identify the best 11 of them to construct a multi-epitope vaccine for SARS-CoV-2 virus. The human population coverage, antigenicity, allergenicity, toxicity, physicochemical properties and secondary structure of the designed vaccine are evaluated via state-of-the-art bioinformatic approaches, showing good quality of the designed vaccine. The 3D structure of the designed vaccine is predicted, refined and validated by in silico tools. Finally, we optimize and insert the codon sequence into a plasmid to ensure the cloning and expression efficiency. In conclusion, this proposed artificial intelligence (AI) based vaccine discovery framework accelerates the vaccine design process and constructs a 694aa multi-epitope vaccine containing 16 B-cell epitopes, 82 CTL epitopes and 89 HTL epitopes, which is promising to fight the SARS-CoV-2 viral infection and can be further evaluated in clinical studies. Moreover, we trace the RNA mutations of the SARS-CoV-2 and ensure that the designed vaccine can tackle the recent RNA mutations of the virus.

A lymph node-targeted Amphiphile vaccine induces potent cellular and humoral immunity to SARS-CoV-2. The profound consequences of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mandate urgent development of effective vaccines. Here, we evaluated an Amphiphile (AMP) vaccine adjuvant, AMP-CpG, composed of diacyl lipid-modified CpG, admixed with the SARS-CoV-2 Spike-2 receptor binding domain protein as a candidate vaccine (ELI-005) in mice. AMP modification efficiently delivers CpG to lymph nodes, where innate and adaptive immune responses are generated. Compared to alum, immunization with AMP-CpG induced >25-fold higher antigen-specific T cells that produced multiple T helper 1 (T(H)1) cytokines and trafficked into lung parenchyma. Antibody responses favored T(H)1 isotypes (IgG2c and IgG3) and potently neutralized Spike-2-ACE2 receptor binding, with titers 265-fold higher than natural convalescent patient COVID-19 responses; T cell and antibody responses were maintained despite 10-fold dose reduction in Spike antigen. Both cellular and humoral immune responses were preserved in aged mice. These advantages merit clinical translation to SARS-CoV-2 and other protein subunit vaccines.

Safety and efficacy of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine: an interim analysis of a randomised controlled phase 3 trial in Russia. BACKGROUND: A heterologous recombinant adenovirus (rAd)-based vaccine, Gam-COVID-Vac (Sputnik V), showed a good safety profile and induced strong humoral and cellular immune responses in participants in phase 1/2 clinical trials. Here, we report preliminary results on the efficacy and safety of Gam-COVID-Vac from the interim analysis of this phase 3 trial. METHODS: We did a randomised, double-blind, placebo-controlled, phase 3 trial at 25 hospitals and polyclinics in Moscow, Russia. We included participants aged at least 18 years, with negative SARS-CoV-2 PCR and IgG and IgM tests, no infectious diseases in the 14 days before enrolment, and no other vaccinations in the 30 days before enrolment. Participants were randomly assigned (3:1) to receive vaccine or placebo, with stratification by age group. Investigators, participants, and all study staff were masked to group assignment. The vaccine was administered (0Â·5 mL/dose) intramuscularly in a prime-boost regimen: a 21-day interval between the first dose (rAd26) and the second dose (rAd5), both vectors carrying the gene for the full-length SARS-CoV-2 glycoprotein S. The primary outcome was the proportion of participants with PCR-confirmed COVID-19 from day 21 after receiving the first dose. All analyses excluded participants with protocol violations: the primary outcome was assessed in participants who

had received two doses of vaccine or placebo, serious adverse events were assessed in all participants who had received at least one dose at the time of database lock, and rare adverse events were assessed in all participants who had received two doses and for whom all available data were verified in the case report form at the time of database lock. The trial is registered at ClinicalTrials.gov (NCT04530396). FINDINGS: Between Sept 7 and Nov 24, 2020, 21â€ˆ977 adults were randomly assigned to the vaccine group (n=16â€ˆ501) or the placebo group (n=5476). 19â€ˆ866 received two doses of vaccine or placebo and were included in the primary outcome analysis. From 21 days after the first dose of vaccine (the day of dose 2), 16 (0Â·1%) of 14â€ˆ964 participants in the vaccine group and 62 (1Â·3%) of 4902 in the placebo group were confirmed to have COVID-19; vaccine efficacy was 91Â·6% (95% CI 85Â·6-95Â·2). Most reported adverse events were grade 1 (7485 [94Â·0%] of 7966 total events). 45 (0Â·3%) of 16â€ˆ427 participants in the vaccine group and 23 (0Â·4%) of 5435 participants in the placebo group had serious adverse events; none were considered associated with vaccination, with confirmation from the independent data monitoring committee. Four deaths were reported during the study (three [<0Â·1%] of 16 427 participants in the vaccine group and one [<0Â·1%] of 5435 participants in the placebo group), none of which were considered related to the vaccine. INTERPRETATION: This interim analysis of the phase 3 trial of Gam-COVID-Vac showed 91Â·6% efficacy against COVID-19 and was well tolerated in a large cohort. FUNDING: Moscow City Health Department, Russian Direct Investment Fund, and Sberbank.

Auto-antibodies to type I IFNs can underlie adverse reactions to yellow fever live attenuated vaccine. Yellow fever virus (YFV) live attenuated vaccine can, in rare cases, cause life-threatening disease, typically in patients with no previous history of severe viral illness. Autosomal recessive (AR) complete IFNAR1 deficiency was reported in one 12-yr-old patient. Here, we studied seven other previously healthy patients aged 13 to 80 yr with unexplained life-threatening YFV vaccine-associated disease. One 13-yr-old patient had AR complete IFNAR2 deficiency. Three other patients vaccinated at the ages of 47, 57, and 64 yr had high titers of circulating auto-Abs against at least 14 of the 17 individual type I IFNs. These antibodies were recently shown to underlie at least 10% of cases of life-threatening COVID-19 pneumonia. The auto-Abs were neutralizing in vitro, blocking the protective effect of IFN-Î±2 against YFV vaccine strains. AR IFNAR1 or IFNAR2 deficiency and neutralizing auto-Abs against type I IFNs thus accounted for more than half the cases of life-threatening YFV vaccine-associated disease studied here. Previously healthy subjects could be tested for both predispositions before anti-YFV vaccination.

A Viral Pandemic, Vaccine Safety, and Compensation for Adverse Events.

Anticipated reduction in COVID-19 mortality due to population-wide BCG vaccination: evidence from Germany. Bacillus Calmette-GuÃ©rin (BCG) vaccine is known to have "bystander benefits" in protecting against heterologous infections; interim analysis of the "ACTIVATE" trial shows protection against respiratory infections in the elderly population. Epidemiologic studies suggest a potential benefit of BCG vaccination on COVID-19 outcomes. Differential past BCG vaccination policies between the former East and West German states provides a unique natural experiment to assess the potential effect of prior BCG vaccination on COVID-19. We estimated a 5% heterologous vaccine efficacy in the highly vaccinated former East Germany using the COVID-19 International Modeling (CoMo) Consortium model. A comparable BCG vaccination campaign undertaken prior to the pandemic in former West Germany, instituted along with known country-wide transmission reduction measures, is associated with a 37% decrease in projected mortality by mid-summer, 2020. These findings support a combined heterologous vaccine and non-pharmaceutical interventions (HVI+NPI) approach to mitigate the SARS-CoV-2 pandemic until SARS-CoV-2 specific vaccines are widely distributed.

Management of Unilateral Axillary Lymphadenopathy Detected on Breast MRI in the Era of COVID-19 Vaccination. Early clinical experience with COVID-19 vaccination suggests that approved COVID-19 vaccines cause a notably higher incidence of axillary lymphadenopathy on breast MRI compared with other vaccines. Guidelines are needed to appropriately manage unilateral axillary lymphadenopathy detected by MRI in the era of COVID-19 vaccination and to avoid biopsies of benign reactive nodes. This article examines the available data on vaccine-related lymphadenopathy and offers a basic strategy for assessing axillary lymphadenopathy on MRI and guiding management. At our institution, we are adding questions regarding the date(s) and laterality of administration of COVID-19 vaccination to the intake form given to patients before all breast imaging examinations. We consider MRI-detected isolated unilateral axillary lymphadenopathy ipsilateral to the vaccination arm to most likely be related to the COVID-19 vaccine if it develops within 4 weeks of administration of either dose. In these cases, we assess the lymphadenopathy as BI-RADS 3 and recommend that follow-up ultrasound be performed within 6-8 weeks after administration of the second dose. These guidelines may be refined as we acquire further data on the expected time course of axillary lymphadenopathy after COVID-19 vaccination. Until that time, this management pathway will help avoid unnecessary biopsies of benign vaccine-related reactive lymphadenopathy.

DNA-launched RNA replicon vaccines induce potent anti-SARS-CoV-2 immune responses in mice. The outbreak of the SARS-CoV-2 virus and its rapid spread into a global pandemic made the urgent development of scalable vaccines to prevent coronavirus disease (COVID-19) a global health and economic imperative. Here, we characterized and compared the immunogenicity of two alphavirus-based DNA-launched self-replicating (DREP) vaccine candidates encoding either SARS-CoV-2 spike glycoprotein (DREP-S) or a spike ectodomain trimer stabilized in prefusion conformation (DREP-S(ecto)). We observed that the two DREP constructs were immunogenic in mice inducing both binding and neutralizing antibodies as well as T cell responses. Interestingly, the DREP coding for the unmodified spike turned out to be more potent vaccine candidate, eliciting high titers of SARS-CoV-2 specific IgG antibodies that were able to efficiently neutralize pseudotyped virus after a single immunization. In addition, both DREP constructs were able to efficiently prime responses that could be boosted with a heterologous spike protein immunization. These data provide important novel insights into SARS-CoV-2 vaccine design using a rapid response DNA vaccine platform. Moreover, they encourage the use of mixed vaccine modalities as a strategy to combat SARS-CoV-2.

Covid-19: Israel sees new infections plummet following vaccinations.

Balancing risks: making decisions for maternal treatment without data on fetal safety. Challenges arise when treatment to improve maternal health brings the possibility of risk to fetal health. The coronavirus disease 2019 (COVID-19) vaccine is the most recent, but hardly the only, example. Because pregnant patients are often specifically excluded from trials of new therapies, this is often the dilemma that patients and providers face when considering new treatments. In this study, we used the COVID-19 vaccine as an exemplar to question the broader issue of how society, in general, and obstetricians, in particular, should balance obligations to pregnant women's right of access to new therapeutic agents with the physician's desire to protect the fetus from potential risks. We will argue that in almost all circumstances (with few exceptions, as will also be discussed), maternal benefit and respect for autonomy create the uncertainty that absent safety data bring. Consequently, if pregnant women choose to try new interventions and treatments, such as the COVID-19 vaccination, they should be offered those new regimens and their decision supported. In addition, we will argue that the right solution to avoid the dilemma of absent data is to include pregnant individuals in clinical trials studying new treatments, drugs, and other therapies. We will also discuss the basis for our opinion, which are mainstream obstetrical ethics, precedents in law (supreme court ruling that forbids companies to exclude women from jobs that might pose a risk to the fetus), and

historic events (thalidomide). The ethical framework includes the supposition that sacrifice to improve fetal outcome is a virtue and not a mandate. Denying a pregnant patient treatment because of threats to their life can create absurd and paradoxical consequences. Either requiring abortion or premature delivery before proceeding with treatments to optimize maternal health, or risking a patient's own life and ability to parent a child by delaying treatment brings clear and significant risks to fetal and/or neonatal outcomes. With rare exceptions, properly and ethically balancing such consequential actions cannot be undertaken without considering the values and goals of the pregnant patient. Therefore, active participation of both the pregnant patient and their physician in shared decision making is needed.

Development and deployment of COVID-19 vaccines for those most vulnerable. Development of safe and effective COVID-19 vaccines is a global priority and the best hope for ending the COVID-19 pandemic. Remarkably, in less than 1 year, vaccines have been developed and shown to be efficacious and are already being deployed worldwide. Yet, many challenges remain. Immune senescence and comorbidities in aging populations and immune dysregulation in populations living in low-resource settings may impede vaccine effectiveness. Distribution of vaccines among these populations where vaccine access is historically low remains challenging. In this Review, we address these challenges and provide strategies for ensuring that vaccines are developed and deployed for those most vulnerable.

Vaccines, masks, distancing and credibility: An urgent warning for pandemic management.

COVID-19 vaccine trials: The use of active controls and non-inferiority studies. BACKGROUND: Recently emerging results from a few placebo-controlled randomized trials of COVID-19 vaccines revealed estimates of 62%-95% relative reductions in risk of virologically confirmed symptomatic COVID-19 disease, over approximately 2-month average follow-up period. Additional safe and effective COVID-19 vaccines are needed in a timely manner to adequately address the pandemic on an international scale. Such safe and effective vaccines would be especially appealing for international deployment if they also have favorable stability, supply, and potential for implementation in mass vaccination campaigns. Randomized trials provide particularly reliable insights about vaccine efficacy and safety. While enhanced efficiency and interpretability can be obtained from placebo-controlled trials, in settings where their conduct is no longer possible, randomized non-inferiority trials may enable obtaining reliable evaluations of experimental vaccines through direct comparison with active comparator vaccines established to have worthwhile efficacy. METHODS: The usual objective of non-inferiority trials is to reliably assess whether the efficacy of an experimental vaccine is not unacceptably worse than that of an active control vaccine previously established to be effective, likely in a placebo-controlled trial. This is formally achieved by ruling out a non-inferiority margin identified to be the minimum threshold for what would constitute an unacceptable loss of efficacy. This article not only investigates non-inferiority margins, denoted by Î′, that address the usual objective of determining whether the experimental vaccine is "at least similarly effective to" the active comparator vaccine in the non-inferiority trial, but also develops non-inferiority margins, denoted by Î′(o), intended to address the worldwide need for multiple safe and effective vaccines by satisfying the less stringent requirement that the experimental vaccine be "at least similarly effective to" an active comparator vaccine having efficacy that satisfies the widely accepted World Health Organization-Food and Drug Administration criteria for "worthwhile" vaccine efficacy. RESULTS: Using the margin Î′ enables non-inferiority trials to reliably evaluate experimental vaccines that truly are similarly effective to an active comparator vaccine having any level of "worthwhile" efficacy. When active comparator vaccines have efficacy in the range of 50%-70%, non-inferiority trials designed to use the margin Î′(o) have appealing properties, especially for experimental vaccines having true efficacy of approximately 60%. CONCLUSION: Non-inferiority trials

using the proposed margins may enable reliable randomized evaluations of efficacy and safety of experimental COVID-19 vaccines. Such trials often require approximately two- to three-fold the person-years follow-up than a placebo-controlled trial. This could be achieved, without substantive increases in sample size, by increasing the average duration of follow-up from 2â€‰months to approximately 4-6â€‰months, assuming efficacy of the active comparator vaccine has been reliably evaluated over that longer duration.

Challenges and Opportunities for COVID-19 Vaccines in Patients with Cancer. Given the rapidly expanding global spread of the SARS-Co-V-2 virus and the expanding number of individuals with the serious and potentially fatal illness, COVID-19, there is an urgent need for safe and effective vaccines. Based on compelling evidence that patients with cancer are at increased risk for greater morbidity and mortality with COVID-19, several professional organizations have provided early guidance on the role of COVID-19 vaccines in patients with malignant disease. In this commentary we review the available data on the efficacy and safety of the approved and forthcoming vaccines in patients with cancer. Based on a review of the totality of available evidence, we recommend that most patients with cancer should receive the recommended dose and schedule of one of the COVID-19 vaccines when available. We encourage industry, regulators and professional research organizations to carefully track the efficacy and safety of COVID-19 vaccination in patients with cancer in the real world setting and routinely report unanticipated adverse events and signs of loss of efficacy. Particular attention is needed for patients on active cancer therapy to carefully evaluate efficacy and safety in relationship to the timing of vaccination relative to that of active cancer treatment and immunosuppression.

The E484K mutation in the SARS-CoV-2 spike protein reduces but does not abolish neutralizing activity of human convalescent and post-vaccination sera. One year in the coronavirus disease 2019 (COVID-19) pandemic, the first vaccines are being rolled out under emergency use authorizations. It is of great concern that newly emerging variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) can escape antibody-mediated protection induced by previous infection or vaccination through mutations in the spike protein. The glutamate (E) to Lysine (K) substitution at position 484 (E484K) in the receptor binding domain (RBD) of the spike protein is present in the rapidly spreading variants of concern belonging to the B.1.351 and P.1 lineages. We performed in vitro microneutralization assays with both the USA-WA1/2020 virus and a recombinant (r)SARS-CoV-2 virus that is identical to USA-WA1/2020 except for the E484K mutation introduced in the spike RBD. We selected 34 sera from study participants based on their SARS-CoV-2 spike ELISA antibody titer (negative [N=4] versus weak [N=8], moderate [N=11] or strong positive [N=11]). In addition, we included sera from five individuals who received two doses of the Pfizer SARS-CoV-2 vaccine BNT162b2. Serum neutralization efficiency was lower against the E484K rSARS-CoV-2 (vaccination samples: 3.4 fold; convalescent low IgG: 2.4 fold, moderate IgG: 4.2 fold and high IgG: 2.6 fold) compared to USA-WA1/2020. For some of the convalescent donor sera with low or moderate IgG against the SARS-CoV-2 spike, the drop in neutralization efficiency resulted in neutralization ID50 values similar to negative control samples, with low or even absence of neutralization of the E484K rSARS-CoV-2. However, human sera with high neutralization titers against the USA-WA1/2020 strain were still able to neutralize the E484K rSARS-CoV-2. Therefore, it is important to aim for the highest titers possible induced by vaccination to enhance protection against newly emerging SARS-CoV-2 variants. Two vaccine doses may be needed for induction of high antibody titers against SARS-CoV-2. Postponing the second vaccination is suggested by some public health authorities in order to provide more individuals with a primer vaccination. Our data suggests that this may leave vaccinees less protected against newly emerging variants.

The coronavirus disease 2019 vaccine in pregnancy: risks, benefits, and recommendations. The coronavirus disease 2019 has caused over 2 million deaths worldwide, with over 412,000 deaths reported in Unites States. To date, at least 57,786 pregnant women in the United States have been infected, and 71 pregnant women have died. Although pregnant women are at higher risk of severe coronavirus disease 2019-related illness, clinical trials for the available vaccines excluded pregnant and lactating women. The safety and efficacy of the vaccines for pregnant women, the fetus, and the newborn remain unknown. A review of maternal and neonatal coronavirus disease 2019 morbidity and mortality data along with perinatal vaccine safety considerations are presented to assist providers with shared decision-making regarding vaccine administration for this group, including the healthcare worker who is pregnant, lactating, or considering pregnancy. The coronavirus disease 2019 vaccine should be offered to pregnant women after discussing the lack of safety data, with preferential administration for those at highest risk of severe infection, until safety and efficacy of these novel vaccines are validated.

Reported orofacial adverse effects of COVID-19 vaccines: The knowns and the unknowns. INTRODUCTION: Adverse events associated with vaccine administration can manifest in the oral cavity and orofacial region. Hence, the aim of this study was to compare the orofacial adverse effects of two recently authorised COVID-19 vaccines, namely BNT162b2 and mRNA-1273. METHODS: Publicly available data on BNT162b2 and mRNA-1273 vaccines were accessed from the relevant regulatory authorities in the United States, Canada, European Union and United Kingdom. Both patient/recipient information and healthcare professional fact sheets for each of these drugs were manually searched to find their orofacial adverse effects. RESULTS: Adverse events affecting the orofacial region were reported for both vaccines. These were rare and included acute peripheral facial paralysis (Bell's palsy), facial swelling, and swelling of the lips, face or tongue associated with anaphylaxis. There was heterogeneity in the acknowledgement of vaccine-related adverse events in North America compared with Europe. CONCLUSION: Globally, there are inconsistencies in the description of adverse effects presenting in the orofacial region of the COVID-19 vaccines BNT162b2 and mRNA-1273. We believe that awareness of these orofacial manifestations will improve recognition, management and reporting of vaccine-related adverse effects.

Reply to: Epidemiological evidence for an association between higher influenza vaccine uptake in the elderly and lower COVID-19 deaths in Italy.

Acute disseminated encephalomyelitis after severe acute respiratory syndrome coronavirus 2 vaccination: a case report.

Safety and immunogenicity of S-Trimer (SCB-2019), a protein subunit vaccine candidate for COVID-19 in healthy adults: a phase 1, randomised, double-blind, placebo-controlled trial. BACKGROUND: As part of the accelerated development of vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), we report a dose-finding and adjuvant justification study of SCB-2019, a protein subunit vaccine candidate containing a stabilised trimeric form of the spike (S)-protein (S-Trimer) combined with two different adjuvants. METHODS: Our study is a phase 1, randomised, double-blind placebo-controlled trial at a specialised clinical trials centre in Australia. We enrolled healthy adult volunteers in two age groups: younger adults (aged 18-54 years) and older adults (aged 55-75 years). Participants were randomly allocated either vaccine or placebo using a list prepared by the study funder. Participants were to receive two doses of SCB-2019 (either 3 Î¼g, 9 Î¼g, or 30 Î¼g) or a placebo (0Â·9% NaCl) 21 days apart. SCB-2019 either had no adjuvant (S-Trimer protein alone) or was adjuvanted with AS03 or CpG/Alum. The assigned treatment was administered in opaque syringes to maintain masking of assignments. Reactogenicity was assessed for 7 days after each vaccination. Humoral responses were measured as SCB-2019 binding IgG antibodies and ACE2-competitive blocking IgG antibodies by ELISA and as neutralising antibodies by wild-type SARS-CoV-2

microneutralisation assay. Cellular responses to pooled S-protein peptides were measured by flow-cytometric intracellular cytokine staining. This trial is registered with ClinicalTrials.gov, NCT04405908; this is an interim analysis and the study is continuing. FINDINGS: Between June 19 and Sept 23, 2020, 151 volunteers were enrolled; three people withdrew, two for personal reasons and one with an unrelated serious adverse event (pituitary adenoma). 148 participants had at least 4 weeks of follow-up after dose two and were included in this analysis (database lock, Oct 23, 2020). Vaccination was well tolerated, with two grade 3 solicited adverse events (pain in 9 Î¼g AS03-adjuvanted and 9 Î¼g CpG/Alum-adjuvanted groups). Most local adverse events were mild injection-site pain, and local events were more frequent with SCB-2019 formulations containing AS03 adjuvant (44-69%) than with those containing CpG/Alum adjuvant (6-44%) or no adjuvant (3-13%). Systemic adverse events were more frequent in younger adults (38%) than in older adults (17%) after the first dose but increased to similar levels in both age groups after the second dose (30% in older and 34% in younger adults). SCB-2019 with no adjuvant elicited minimal immune responses (three seroconversions by day 50), but SCB-2019 with fixed doses of either AS03 or CpG/Alum adjuvants induced high titres and seroconversion rates of binding and neutralising antibodies in both younger and older adults (anti-SCB-2019 IgG antibody geometric mean titres at day 36 were 1567-4452 with AS03 and 174-2440 with CpG/Alum). Titres in all AS03 dose groups and the CpG/Alum 30 Î¼g group were higher than were those recorded in a panel of convalescent serum samples from patients with COVID-19. Both adjuvanted SCB-2019 formulations elicited T-helper-1-biased CD4(+) T-cell responses. INTERPRETATION: The SCB-2019 vaccine, comprising S-Trimer protein formulated with either AS03 or CpG/Alum adjuvants, elicited robust humoral and cellular immune responses against SARS-CoV-2, with high viral neutralising activity. Both adjuvanted vaccine formulations were well tolerated and are suitable for further clinical development. FUNDING: Clover Biopharmaceuticals and the Coalition for Epidemic Preparedness Innovations.

Postvaccination COVID-19 among Healthcare Workers, Israel. Coronavirus disease (COVID-19) symptoms can be mistaken for vaccine-related side effects during initial days after immunization. Among 4,081 vaccinated healthcare workers in Israel, 22 (0.54%) developed COVID-19 from 1-10 days (median 3.5 days) after immunization. Clinicians should not dismiss postvaccination symptoms as vaccine-related and should promptly test for COVID-19.

Practical recommendations for the allergological risk assessment of the COVID-19 vaccination - a harmonized statement of allergy centers in Germany. Severe allergic reactions to vaccines are very rare. Single severe reactions have occurred worldwide after vaccination with the new mRNA-based COVID-19 vaccines. PEG2000 is discussed as a possible trigger. We provide guidance on risk assessment regarding COVID-19 vaccination in patients with allergic diseases and suggest a standardized, resource-oriented diagnostic and therapeutic procedure. Reports of severe allergic reactions in the context of COVID-19 vaccination can be made via www.anaphylaxie.net using an online questionnaire.

Recombinant SARS-CoV-2 RBD with a built in T helper epitope induces strong neutralization antibody response. Without approved vaccines and specific treatments, COVID-19 is spreading around the world with above 26 million cases and approximately 864 thousand deaths until now. An efficacious and affordable vaccine is urgently needed. The Val308 - Gly548 of spike protein of SARS-CoV-2 linked with Gln830 - Glu843 of Tetanus toxoid (TT peptide) (designated as S1-4) and without TT peptide (designated as S1-5) were expressed and renatured. The antigenicity and immunogenicity of S1-4 were evaluated by Western Blotting (WB) in vitro and immune responses in mice, respectively. The protective efficiency was measured preliminarily by microneutralization assay (MN50). The soluble S1-4 and S1-5 protein was prepared to high homogeneity and purity. Adjuvanted with Alum, S1-4 protein stimulated a strong antibody response in immunized mice and caused a major Th2-type

cellular immunity supplemented with Th1-type immunity. Furthermore, the immunized sera could protect the Vero E6 cells from SARS-CoV-2 infection with neutralizing antibody titer 256. Recombinant SARS-CoV-2 RBD with a built in T helper epitope could stimulate both strong humoral immunity supplemented with cellular immunity in mice, demonstrating that it could be a promising subunit vaccine candidate.
SARS-CoV-2 vaccines and autoimmune diseases amidst the COVID-19 crisis. Coronavirus disease 2019 (COVID-19) pandemic has become challenging even for the most durable healthcare systems. It seems that vaccination, one of the most effective public-health interventions, presents a ray of hope to end the pandemic by achieving herd immunity. In this review, we aimed to cover aspects of the current knowledge of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines and vaccine candidates in the light of autoimmune inflammatory diseases (AIIDs) and to analyze their potential in terms of safety and effectiveness in patients with AIIDs. Therefore, a focused narrative review was carried out to predict the possible implications of different types of SARS-CoV-2 vaccines which confer distinct immune mechanisms to establish immune response and protection against COVID-19: whole virus (inactivated or weakened), viral vector (replicating and non-replicating), nucleic acid (RNA, DNA), and protein-based (protein subunit, virus-like particle). Still, there is uncertainty among patients with AIIDs and clinicians about the effectiveness and safety of the new vaccines. There are a variety of approaches towards building a protective immunity against SARS-CoV-2. Only high-quality clinical trials would clarify the underlying immunological mechanisms of the newly implemented vaccines/adjuvants in patients living with AIIDs.
How to redesign COVID vaccines so they protect against variants.
FDA authorizes Moderna COVID-19 vaccine.
Novavax offers first evidence that COVID vaccines protect people against variants.
The need for a global COVID-19 maternal immunisation research plan.
Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. As of January 20, 2021, a total of 24,135,690 cases of coronavirus disease 2019 (COVID-19) and 400,306 associated deaths had been reported in the United States (https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days). On December 18, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Moderna COVID-19 vaccine administered as 2 doses, 1 month apart to prevent COVID-19. On December 19, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of Moderna COVID-19 vaccine (1). As of January 10, 2021, a reported 4,041,396 first doses of Moderna COVID-19 vaccine had been administered in the United States, and reports of 1,266 (0.03%) adverse events after receipt of Moderna COVID-19 vaccine were submitted to the Vaccine Adverse Event Reporting System (VAERS). Among these, 108 case reports were identified for further review as possible cases of severe allergic reaction, including anaphylaxis. Anaphylaxis is a life-threatening allergic reaction that occurs rarely after vaccination, with onset typically within minutes to hours (2). Among these case reports, 10 cases were determined to be anaphylaxis (a rate of 2.5 anaphylaxis cases per million Moderna COVID-19 vaccine doses administered), including nine in persons with a documented history of allergies or allergic reactions, five of whom had a previous history of anaphylaxis. The median interval from vaccine receipt to symptom onset was 7.5 minutes (rangeÂ =Â 1-45 minutes). Among eight persons with follow-up information available, all had recovered or been discharged home. Among the remaining case reports that were determined not to be anaphylaxis, 47 were assessed to be nonanaphylaxis allergic reactions, and 47 were considered nonallergic adverse events. For four case reports, investigators have been unable to obtain sufficient information to assess the likelihood of anaphylaxis. This report summarizes the clinical and epidemiologic characteristics of case reports of

allergic reactions, including anaphylaxis and nonanaphylaxis allergic reactions, after receipt of the first dose of Moderna COVID-19 vaccine during December 21, 2020-January 10, 2021, in the United States. CDC has issued updated interim clinical considerations for use of mRNA COVID-19 vaccines currently authorized in the United States (3) and interim considerations for preparing for the potential management of anaphylaxis (4).

Pregnancy, breastfeeding and the SARS-CoV-2 vaccine: an ethics-based framework for shared decision-making.

The N501Y mutation in SARS-CoV-2 spike leads to morbidity in obese and aged mice and is neutralized by convalescent and post-vaccination human sera. The current COVID-19 (coronavirus disease 19) pandemic, caused by SARS-CoV-2, disproportionally affects the elderly and people with comorbidities like obesity and associated type 2 diabetes mellitus. Small animal models are crucial for the successful development and validation of antiviral vaccines, therapies and to study the role that comorbidities have on the outcome of viral infections. The initially available SARS-CoV-2 isolates require adaptation in order to use the mouse angiotensin converting enzyme 2 (mACE-2) entry receptor and to productively infect the cells of the murine respiratory tract. We have "mouse-adapted" SARS-CoV-2 by serial passaging a clinical virus isolate in the lungs of mice. We then used low doses of this virus in mouse models for advanced age, diabetes and obesity. Similar to SARS-CoV-2 infection in humans, the outcome of infection with mouse-adapted SARS-CoV-2 resulted in enhanced morbidity in aged and diabetic obese mice. Mutations associated with mouse adaptation occurred in the S, M, N and ORF8 genes. Interestingly, one mutation in the receptor binding domain of the S protein results in the change of an asparagine to tyrosine residue at position 501 (N501Y). This mutation is also present in the newly emerging SARS-CoV-2 variant viruses reported in the U.K. (20B/501Y.V1, B1.1.7 lineage) that is epidemiologically associated with high human to human transmission. We show that human convalescent and post vaccination sera can neutralize the newly emerging N501Y virus variant with similar efficiency as that of the reference USA-WA1/2020 virus, suggesting that current SARS-CoV-2 vaccines will protect against the 20B/501Y.V1 strain.

mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants. Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) is the causative infection of a global pandemic that has led to more than 2 million deaths worldwide. The Moderna mRNA-1273 vaccine has demonstrated ~94% efficacy in a Phase 3 study and has been approved under Emergency Use Authorization. The emergence of SARS-CoV-2 variants with mutations in the spike protein, most recently circulating isolates from the United Kingdom (B.1.1.7) and Republic of South Africa (B.1.351), has led to lower neutralization from convalescent serum by pseudovirus neutralization (PsVN) assays and resistance to certain monoclonal antibodies. Here, using two orthogonal VSV and lentivirus PsVN assays expressing spike variants of 20E (EU1), 20A.EU2, D614G-N439, mink cluster 5, B.1.1.7, and B.1.351 variants, we assessed the neutralizing capacity of sera from human subjects or non-human primates (NHPs) that received mRNA-1273. No significant impact on neutralization against the B.1.1.7 variant was detected in either case, however reduced neutralization was measured against the mutations present in B.1.351. Geometric mean titer (GMT) of human sera from clinical trial participants in VSV PsVN assay using D614G spike was 1/1852. VSV pseudoviruses with spike containing K417N-E484K-N501Y-D614G and full B.1.351 mutations resulted in 2.7 and 6.4-fold GMT reduction, respectively, when compared to the D614G VSV pseudovirus. Importantly, the VSV PsVN GMT of these human sera to the full B.1.351 spike variant was still 1/290, with all evaluated sera able to fully neutralize. Similarly, sera from NHPs immunized with 30 or 100Î¼g of mRNA-1273 had VSV PsVN GMTs of ~ 1/323 or 1/404, respectively, against the full B.1.351 spike variant with a ~ 5 to 10-fold reduction compared to D614G. Individual mutations that are characteristic of the B.1.1.7 and B.1.351 variants had a similar impact on neutralization when tested in VSV or in lentivirus PsVN

assays. Despite the observed decreases, the GMT of VSV PsVN titers in human vaccinee sera against the B.1.351 variant remained at ~1/300. Taken together these data demonstrate reduced but still significant neutralization against the full B.1.351 variant following mRNA-1273 vaccination.

Audio Interview: Covid-19 in South Africa and a New SARS-CoV-2 Variant.

Immunosuppressants, immunomodulators and COVID-19 vaccines: anticipating patient concerns.

Insights from American College of Allergy, Asthma, and Immunology COVID-19 Vaccine Task Force: Allergic Reactions to mRNA SARS-CoV-2 Vaccines.

[A summary of characteristics of the first wave of new type coronavirus epidemic and potential association with tuberculosis vaccination]. Ã–sszefoglalÃ³. BevezetÃ©s: A COVID-19-jÃ¡rvÃ¡ny az egÃ©sz vilÃ¡gon elterjedt. A jÃ¡rvÃ¡ny EurÃ³pÃ¡ban valÃ³ elsÅ‘ megjelenÃ©se sorÃ¡n megfigyelhetÅ‘ volt, hogy a terjedÃ©s mÃ©rtÃ©ke kisebb azokban az orszÃ¡gokban, ahol a tuberkulÃ³zis elleni vÃ©dekezÃ©sÃ¼l kiterjedt BCG-vakcinÃ¡ciÃ³t vÃ©geznek. CÃ©lkitÅ±zÃ©s: A jelen munkÃ¡ban olyan Ã¶sszefÃ¼ggÃ©seket igyekeztÃ¼nk feltÃ¡rni, amelyek befolyÃ¡soltÃ¡k a jÃ¡rvÃ¡nyterjedÃ©s paramÃ©tereit, kÃ¼lÃ¶nÃ¶s figyelemmel a BCG-vakcinÃ¡ciÃ³s gyakorlatra. MÃ³dszerek: A vilÃ¡g Ã¶sszes olyan orszÃ¡gÃ¡ra vonatkozÃ³an, ahol megfelelÅ‘ minÅ‘sÃ©gÅ± statisztikai adatok Ã¡lltak rendelkezÃ©sÃ¼nkre, vizsgÃ¡ltuk a jÃ¡rvÃ¡ny terjedÃ©sÃ©nek elsÅ‘ hullÃ¡mÃ¡t. A mozgÃ³Ã¡tlagolt jÃ¡rvÃ¡nygÃ¶rbÃ©ken elemeztÃ¼k a jÃ¡rvÃ¡ny idÅ‘tartamÃ¡t, a tetÅ‘zÃ©s mÃ©rtÃ©kÃ©t, a fertÅ‘zÃ¶ttek Ã©s a halÃ¡lesetek egymilliÃ³ lakosra vetÃtett szÃ¡mÃ¡t. Figyelembe vettÃ¼k az orszÃ¡gok gazdasÃ¡gi mutatÃ³it (GDP, lÃ©gi forgalom, a tengeri hajÃ³zÃ¡s mÃ©rtÃ©ke). Statisztikai analÃzis: A vizsgÃ¡lt paramÃ©terek nem mutattak normÃ¡lis eloszlÃ¡st, Ã-gy nemparamÃ©teres prÃ³bÃ¡kkal (rangkorrelÃ¡ciÃ³, Kruskal-Wallis ANOVA) statisztikai kapcsolatot kerestÃ¼nk a jÃ¡rvÃ¡nyterjedÃ©s mÃ©rtÃ©ke, a BCG-vakcinÃ¡ciÃ³ Ã©s mÃ¡s paramÃ©terek kÃ¶zÃ¶tt. EredmÃ©nyek: A jÃ¡rvÃ¡ny gyorsan elterjedt a vilÃ¡gon, de mÃ©gis, februÃ¡r elsÅ‘ hÃ¡rom hetÃ©ben a terjedÃ©sben egy szÃ¼net volt megfigyelhetÅ‘. A jÃ¡rvÃ¡nyhullÃ¡m EurÃ³pÃ¡ban nagyjÃ¡bÃ³l egyszerre Ã©rt vÃ©get. A jÃ¡rvÃ¡ny Ã¡ltal leginkÃ¡bb azok az orszÃ¡gok Ã©rintettek, ahol nem alkalmaztak rendszeres BCG-vakcinÃ¡ciÃ³t, bÃ¡r a kÃ©pet bonyolÃtja, hogy ezek az orszÃ¡gok gazdasÃ¡gilag tÃ¶bbnyire fejlettek. A halÃ¡lozÃ¡si rÃ¡tÃ¡ban nem mutatkozott ilyen kÃ¼lÃ¶nbsÃ©g. KÃ¶vetkeztetÃ©s: Statisztikailag igazolhatÃ³ tÃ©ny, hogy a vakcinÃ¡ciÃ³t vÃ©gzÅ‘ orszÃ¡gokbÃ³l az elsÅ‘ hullÃ¡m alatt kevesebb fertÅ‘zÃ¶ttet jelentettek; az ok-okozati Ã¶sszefÃ¼ggÃ©s bizonytalan, hiszen az orszÃ¡gok mÃºltja, szokÃ¡sai, tÃ¡rsadalmi berendezkedÃ©se, gazdasÃ¡gi fejlettsÃ©ge nem azonos. EredmÃ©nyeink alÃ¡tÃ¡masztjÃ¡k az Ã¶sszehasonlÃtÃ³ kontaktkutatÃ¡s fontossÃ¡gÃ¡t annak tisztÃ¡zÃ¡sÃ¡ra, hogy a BCG-oltÃ¡s hogyan befolyÃ¡solja az emberek vÃ-russal szembeni Ã©rzÃ©kenysÃ©gÃ©t, valamint a vÃ-rus terjesztÃ©sÃ©nek, tovÃ¡bbadÃ¡sÃ¡nak kÃ©pessÃ©gÃ©t. Orv Hetil. 2021; 162(4): 123-134. INTRODUCTION: The new type of coronavirus (SARS-CoV-2) epidemic is widespread throughout the world. During the outbreak of the pandemic in Europe it was revealed that the rate of spread was lower in countries where extensive BCG vaccination is used to protect against tuberculosis. OBJECTIVE: In the present work, we sought to explore relationships that influenced epidemic spreading parameters, with particular reference to BCG vaccination practice. METHODS: We examined the first wave of the spread of the epidemic for all countries in the world where adequate quality statistics were available. We analyzed the duration of the epidemic, the extent of the peak, the number of infected people, and the number of deaths per million inhabitants with the moving average of epidemic curves. We took into account the economic indicators of the countries (GDP, air traffic and extent of maritime shipping). STATISTICAL ANALYSIS: The examined parameters did not show a normal distribution, so we looked for a statistical relationship with non-parametric tests (rank correlation, Kruskal-Wallis ANOVA) between the extents of epidemic spread, BCG vaccination and other parameters. RESULTS: The epidemic spread rapidly around the world, but still, in the first three weeks of February, there was a

pause in the spread. The first wave of epidemics ended roughly at the same time in Europe. Those countries are the most affected by the epidemic where regular BCG vaccination has not been used, although the picture is complicated by the fact that these countries are mostly economically developed. There was no such difference observable in the mortality rate. CONCLUSION: Although this work clearly demonstrates that during the first wave of the pandemic, fewer infections were reported worldwide in countries where BCG vaccination is obligatory, however, the causal relationship is uncertain, as the countries' past, customs, social organization and economic development are different. Our results support the necessity of comparative contact tracing to clarify how BCG vaccination affects people's susceptibility to this new type of coronavirus as well as their ability to spread and transmit the virus. Orv Hetil. 2021; 162(4): 123-134.

mRNA COVID-19 vaccine is well tolerated in patients with cutaneous and systemic mastocytosis with mast cell activation symptoms and anaphylaxis.

Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBV152: a double-blind, randomised, phase 1 trial. BACKGROUND: To mitigate the effects of COVID-19, a vaccine is urgently needed. BBV152 is a whole-virion inactivated SARS-CoV-2 vaccine formulated with a toll-like receptor 7/8 agonist molecule adsorbed to alum (Algel-IMDG) or alum (Algel). METHODS: We did a double-blind, multicentre, randomised, controlled phase 1 trial to assess the safety and immunogenicity of BBV152 at 11 hospitals across India. Healthy adults aged 18-55 years who were deemed healthy by the investigator were eligible. Individuals with positive SARS-CoV-2 nucleic acid and/or serology tests were excluded. Participants were randomly assigned to receive either one of three vaccine formulations (3 Î¼g with Algel-IMDG, 6 Î¼g with Algel-IMDG, or 6 Î¼g with Algel) or an Algel only control vaccine group. Block randomisation was done with a web response platform. Participants and investigators were masked to treatment group allocation. Two intramuscular doses of vaccines were administered on day 0 (the day of randomisation) and day 14. Primary outcomes were solicited local and systemic reactogenicity events at 2 h and 7 days after vaccination and throughout the full study duration, including serious adverse events. Secondary outcome was seroconversion (at least four-fold increase from baseline) based on wild-type virus neutralisation. Cell-mediated responses were evaluated by intracellular staining and ELISpot. The trial is registered at ClinicalTrials.gov (NCT04471519). FINDINGS: Between July 13 and 30, 2020, 827 participants were screened, of whom 375 were enrolled. Among the enrolled participants, 100 each were randomly assigned to the three vaccine groups, and 75 were randomly assigned to the control group (Algel only). After both doses, solicited local and systemic adverse reactions were reported by 17 (17%; 95% CI 10Â·5-26Â·1) participants in the 3 Î¼g with Algel-IMDG group, 21 (21%; 13Â·8-30Â·5) in the 6 Î¼g with Algel-IMDG group, 14 (14%; 8Â·1-22Â·7) in the 6 Î¼g with Algel group, and ten (10%; 6Â·9-23Â·6) in the Algel-only group. The most common solicited adverse events were injection site pain (17 [5%] of 375 participants), headache (13 [3%]), fatigue (11 [3%]), fever (nine [2%]), and nausea or vomiting (seven [2%]). All solicited adverse events were mild (43 [69%] of 62) or moderate (19 [31%]) and were more frequent after the first dose. One serious adverse event of viral pneumonitis was reported in the 6 Î¼g with Algel group, unrelated to the vaccine. Seroconversion rates (%) were 87Â·9, 91Â·9, and 82Â·8 in the 3 Î¼g with Algel-IMDG, 6 Î¼g with Algel-IMDG, and 6 Î¼g with Algel groups, respectively. CD4(+) and CD8(+) T-cell responses were detected in a subset of 16 participants from both Algel-IMDG groups. INTERPRETATION: BBV152 led to tolerable safety outcomes and enhanced immune responses. Both Algel-IMDG formulations were selected for phase 2 immunogenicity trials. Further efficacy trials are warranted. FUNDING: Bharat Biotech International.

India begins COVID-19 vaccination amid trial allegations.

An evidence-based guide to SARS-CoV-2 vaccination of patients on immunotherapies in dermatology. Immune-mediated diseases and immunotherapeutics can negatively affect normal immune

functioning and, consequently, vaccine safety and response. The COVID-19 pandemic has incited research aimed at developing a novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. As SARS-CoV-2 vaccines are developed and made available, the assessment of anticipated safety and efficacy in patients with immune-mediated dermatologic diseases and requiring immunosuppressive and/or immunomodulatory therapy is particularly important. A review of the literature was conducted by a multidisciplinary committee to provide guidance on the safety and efficacy of SARS-CoV-2 vaccination for dermatologists and other clinicians when prescribing immunotherapeutics. The vaccine platforms being used to develop SARS-CoV-2 vaccines are expected to be safe and potentially effective for dermatology patients on immunotherapeutics. Current guidelines for the vaccination of an immunocompromised host remain appropriate when considering future administration of SARS-CoV-2 vaccines.
Absence of association between 2019-20 influenza vaccination and COVID-19: Results of the European I-MOVE-COVID-19 primary care project, March-August 2020. BACKGROUND: Claims of influenza vaccination increasing COVID-19 risk are circulating. Within the I-MOVE-COVID-19 primary care multicentre study, we measured the association between 2019-20 influenza vaccination and COVID-19. METHODS: We conducted a multicentre test-negative case-control study at primary care level, in study sites in five European countries, from March to August 2020. Patients presenting with acute respiratory infection were swabbed, with demographic, 2019-20 influenza vaccination and clinical information documented. Using logistic regression, we measured the adjusted odds ratio (aOR), adjusting for study site and age, sex, calendar time, presence of chronic conditions. The main analysis included patients swabbed â‰¤7Â days after onset from the three countries with <15% of missing influenza vaccination. In secondary analyses, we included five countries, using multiple imputation with chained equations to account for missing data. RESULTS: We included 257 COVID-19 cases and 1631 controls in the main analysis (three countries). The overall aOR between influenza vaccination and COVID-19 was 0.93 (95% CI: 0.66-1.32). The aOR was 0.92 (95% CI: 0.58-1.46) and 0.92 (95% CI: 0.51-1.67) among those aged 20-59 and â‰¥60Â years, respectively. In secondary analyses, we included 6457 cases and 69Â 272 controls. The imputed aOR was 0.87 (95% CI: 0.79-0.95) among all ages and any delay between swab and symptom onset. CONCLUSIONS: There was no evidence that COVID-19 cases were more likely to be vaccinated against influenza than controls. Influenza vaccination should be encouraged among target groups for vaccination. I-MOVE-COVID-19 will continue documenting influenza vaccination status in 2020-21, in order to learn about effects of recent influenza vaccination.
Immunoinformatics prediction of overlapping CD8(+) T-cell, IFN-Î³ and IL-4 inducer CD4(+) T-cell and linear B-cell epitopes based vaccines against COVID-19 (SARS-CoV-2). At the beginning of the year 2020, the world was struck with a global pandemic virus referred to as SARS-CoV-2 (COVID-19) which has left hundreds of thousands of people dead. To control this virus, vaccine design becomes imperative. In this study, potential epitopes-based vaccine candidates were explored. Six hundred (600) genomes of SARS-CoV-2 were retrieved from the viPR database to generate CD8(+) T-cell, CD4+ T-cell and linear B-cell epitopes which were screened for antigenicity, immunogenicity and non-allergenicity. The results of this study provide 19 promising candidate CD8(+) T-cell epitopes that strongly overlap with 8 promising B-cells epitopes. Another 19 CD4(+) T-cell epitopes were also identified that can induce IFN-Î³ and IL-4 cytokines. The most conserved MHC-I and MHC-II for both CD8(+)Â and CD4(+) T-cell epitopes are HLA-A*02:06 and HLA-DRB1*01:01 respectively. These epitopes also bound to Toll-like receptor 3 (TLR3). The population coverage of the conserved Major Histocompatibility Complex Human Leukocyte Antigen (HLA) for both CD8(+) T-cell and CD4(+) T-cell ranged from 65.6% to 100%. The detailed analysis of the potential epitope-based vaccine and their mapping to the complete COVID-19 genome reveals that they are predominantly found in the

location of the surface (S) and membrane (M) glycoproteins suggesting the potential involvement of these structural proteins in the immunogenic response and antigenicity of the virus. Since the majority of the potential epitopes are located on M protein, the design of multi-epitope vaccine with the structural protein is highly promising though the whole M protein could also serve as a viable epitope for the development of an attenuated vaccine. Our findings provide a baseline for the experimental design of a suitable vaccine against SARS-CoV-2.

Immune Responses Induced by mRNA Vaccination in Mice, Monkeys and Humans. In this concise review, we summarize the concepts behind mRNA vaccination. We discuss the innate and adaptive immune response generated by mRNA vaccines in different animal models and in humans. We give examples of viral infections where mRNA vaccines have shown to induce potent responses and we discuss in more detail the recent SARS-CoV-2 mRNA vaccine trials in humans.

Immune thrombocytopenia in a 22-year-old post Covid-19 vaccine.

The Costs of Contradictory Messages About Live Vaccines in Pregnancy. The increased risk of harm from COVID-19 infection in pregnancy highlights the importance of including pregnant people in COVID-19 vaccine development and deployment. Promising vaccines being developed include replication-competent platforms, which are typically contraindicated during pregnancy because of theoretical risk. However, replicating vaccines are administered in and around pregnancy, either inadvertently because of unknown pregnancy status or when recommended.The historical cases of Ebola virus, yellow fever, and rubella demonstrate that contradictory messages around the safety of live vaccines in pregnancy have critical public health costs. First, restricting study or use of replicating vaccines in pregnancy may delay or deny access to the only available protection against deadly diseases. Additionally, not vaccinating pregnant people may slow epidemic control. Finally, uncertainty and worry around the safety of live vaccines may lead to terminations of otherwise desired pregnancies after inadvertent vaccination in pregnancy.If one of the vaccines deployed to combat the current global COVID-19 pandemic is replication competent, historical cases offer important lessons for ethical and effective protection for pregnant populations.

Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine.

Covid-19 Vaccine Injuries - Preventing Inequities in Compensation.

Important Management Considerations In Patients With Pituitary Disorders During The Time Of The Covid-19 Pandemic. OBJECTIVE: In December 2019, a novel coronavirus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) caused an outbreak of coronavirus disease 2019 (COVID-19) that resulted in a global pandemic with substantial morbidity and mortality. Currently, there is no specific treatment or approved vaccine against COVID-19. The underlying associated comorbidity and diminished immune function of some pituitary patients (whether caused by the disease and its sequelae or treatment with excess glucocorticoids) increases their risk of contracting and developing complications from COVID-19 infection. METHODS: A review of studies in PubMed and Google Scholar published between January 2020 to the time of writing (May 1, 2020) was conducted using the search terms 'pituitary,' 'coronavirus,' 'COVID-19', '2019-nCoV', 'diabetes mellitus', 'obesity', 'adrenal,' and 'endocrine.' RESULTS: Older age and pre-existing obesity, hypertension, cardiovascular disease, and diabetes mellitus increase the risk of hospitalization and death in COVID-19 patients. Men tend to be more severely affected than women; fortunately, most men, particularly of younger age, survive the infection. In addition to general comorbidities that may apply to many pituitary patients, they are also susceptible due to the following pituitary disorder-specific features: hypercortisolemia and adrenal suppression with Cushing disease, adrenal insufficiency and diabetes insipidus with hypopituitarism, and sleep-apnea syndrome and chest wall deformity with acromegaly. CONCLUSION: This review aims to focus on the impact of COVID-19 in

patients with pituitary disorders. As most countries are implementing mobility restrictions, we also discuss how this pandemic has affected patient attitudes and impacted our decision-making on management recommendations for these patients. ABBREVIATIONS: ACE = angiotensin-converting enzyme; AI = adrenal insufficiency; ARB = angiotensin receptor blocker; ARDS = acute respiratory disease syndrome; COVID-19 = coronavirus disease 2019; CPAP = continuous positive airway pressure; DI = diabetes insipidus; DM = diabetes mellitus; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Doctor-Should I get the COVID-19 vaccine? Infection and immunization in individuals with neuromuscular disorders. The clinical course of neuromuscular disorders (NMDs) can be affected by infections, both in immunocompetent individuals, and in those with reduced immunocompetence due to immunosuppressive/immunomodulating therapies. Infections and immunizations may also trigger NMDs. There is a potential for reduced efficacy of immunizations in patients with reduced immunocompetence. The recent vaccination program for coronavirus disease-2019 (COVID-19) raises several questions regarding the safety and efficacy of this vaccine in individuals with NMDs. In this Practice Topic article, we address the role of vaccine-preventable infections in NMDs and the safety and efficacy of immunization in individuals with NMDs, with emphasis on vaccination against COVID-19.

COVID-19 vaccines: the importance of transparency and fact-based education.

[Covid-19 vaccination and risk of anaphylaxis - Recommendations for practical management].

Equity in coronavirus disease 2019 vaccine development and deployment. The coronavirus disease 2019 pandemic exposed weaknesses in multiple domains and widened gender-based inequalities across the world. It also stimulated extraordinary scientific achievement by bringing vaccines to the public in less than a year. In this article, we discuss the implications of current vaccination guidance for pregnant and lactating women, if their exclusion from the first wave of vaccine trials was justified, and if a change in the current vaccine development pathway is necessary. Pregnant and lactating women were not included in the initial severe acute respiratory syndrome coronavirus 2 vaccine trials. Therefore, perhaps unsurprisingly, the first vaccine regulatory approvals have been accompanied by inconsistent advice from public health, governmental, and professional authorities around the world. Denying vaccination to women who, although pregnant or breastfeeding, are fully capable of autonomous decision making is a throwback to a paternalistic era. Conversely, lack of evidence generated in a timely manner, upon which to make an informed decision, shifts responsibility from research sponsors and regulators and places the burden of decision making upon the woman and her healthcare advisor. The World Health Organization, the Task Force on Research Specific to Pregnant Women and Lactating Women, and others have highlighted the long-standing disadvantage experienced by women in relation to the development of vaccines and medicines. It is uncertain whether there was sufficient justification for excluding pregnant and lactating women from the initial severe acute respiratory syndrome coronavirus 2 vaccine trials. In future, we recommend that regulators mandate plans that describe the development pathway for new vaccines and medicines that address the needs of women who are pregnant or lactating. These should incorporate, at the outset, a careful consideration of the balance of the risks of exclusion from or inclusion in initial studies, patient and public perspectives, details of "developmental and reproductive toxicity" studies, and approaches to collect data systematically from participants who are unknowingly pregnant at the time of exposure. This requires careful consideration of any previous knowledge about the mode of action of the vaccine and the likelihood of toxicity or teratogenicity. We also support the view that the default position should be a "presumption of inclusion," with exclusion of women who are pregnant or lactating only if justified on

specific, not generic, grounds. Finally, we recommend closer coordination across countries with the aim of issuing consistent public health advice.

At the Crossroads: COVID-19 and Immune-Checkpoint Blockade for Cancer. The immunomodulatory effects of immune-checkpoint blockade (ICB) therapy for cancer may act at the crossroads between the need to increase antiviral immune responses to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and to decrease the inflammatory responses in severe cases of coronavirus disease 2019 (COVID-19). There is evidence from preclinical models that blocking programmed death receptor 1 (PD1) protects against RNA virus infections, which suggests that patients with cancer receiving ICB may have lower rates of viral infection. However, given the heterogeneity of patient characteristics, this would be difficult to demonstrate using population-based registries or in clinical trials. Most studies of the impact of ICB therapy on the course of COVID-19 have centered on studying its potential detrimental impact on the course of the COVID-19 infection, in particular on the development of the most severe inflammatory complications. This is a logical concern as it is becoming clear that complications of COVID-19 such as severe respiratory distress syndrome are related to interferon signaling, which is the pathway that leads to expression of the PD1 ligand PD-L1. Therefore, PD1/PD-L1 ICB could potentially increase inflammatory processes, worsening the disease course for patients. However, review of the current evidence does not support the notion that ICB therapy worsens complications from COVID-19, and we conclude that it supports the continued use of ICB therapy during the COVID-19 pandemic provided that we now collect data on the effects of such therapy on COVID-19 vaccination.

Covid-19: Norway investigates 23 deaths in frail elderly patients after vaccination.

Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. As of January 3, 2021, a total of 20,346,372 cases of coronavirus disease 2019 (COVID-19) and 349,246 associated deaths have been reported in the United States. Long-term sequalae of COVID-19 over the course of a lifetime currently are unknown; however, persistent symptoms and serious complications are being reported among COVID-19 survivors, including persons who initially experience a mild acute illness.* On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 vaccine to prevent COVID-19, administered as 2 doses separated by 21 days. On December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of Pfizer-BioNTech COVID-19 vaccine (1); initial doses were recommended for health care personnel and long-term care facility residents (2). As of December 23, 2020, a reported 1,893,360 first doses of Pfizer-BioNTech COVID-19 vaccine had been administered in the United States, and reports of 4,393 (0.2%) adverse events after receipt of Pfizer BioNTech COVID-19 vaccine had been submitted to the Vaccine Adverse Event Reporting System (VAERS). Among these, 175 case reports were identified for further review as possible cases of severe allergic reaction, including anaphylaxis. Anaphylaxis is a life-threatening allergic reaction that does occur rarely after vaccination, with onset typically within minutes to hours (3). Twenty-one cases were determined to be anaphylaxis (a rate of 11.1 per million doses administered), including 17 in persons with a documented history of allergies or allergic reactions, seven of whom had a history of anaphylaxis. The median interval from vaccine receipt to symptom onset was 13 minutes (rangeÂ =Â 2-150 minutes). Among 20 persons with follow-up information available, all had recovered or been discharged home. Of the remaining case reports that were determined not to be anaphylaxis, 86 were judged to be nonanaphylaxis allergic reactions, and 61 were considered nonallergic adverse events. Seven case reports were still under investigation. This report summarizes the clinical and epidemiologic characteristics of case reports of allergic reactions, including anaphylaxis and nonanaphylaxis allergic reactions, after receipt of the first dose of Pfizer-BioNTech COVID-19 vaccine during December 14-23,

2020, in the United States. CDC has issued updated interim clinical considerations for use of mRNA COVID-19 vaccines currently authorized in the United States (4) and interim considerations for preparing for the potential management of anaphylaxis (5). In addition to screening for contraindications and precautions before administering COVID-19 vaccines, vaccine locations should have the necessary supplies available to manage anaphylaxis, should implement postvaccination observation periods, and should immediately treat persons experiencing anaphylaxis signs and symptoms with intramuscular injection of epinephrine (4,5).
Anaphylactic reactions to novel mRNA SARS-CoV-2/COVID-19 vaccines.
Who Is Really at Risk for Anaphylaxis Due to COVID-19 Vaccine? The vaccination campaign against the Severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) started on 8 December 2020 in UK, after the approval of BNT162b2 by the Healthcare products Regulatory Agency (MHRA) [...].
Interim Results of a Phase 1-2a Trial of Ad26.COV2.S Covid-19 Vaccine. BACKGROUND: Efficacious vaccines are urgently needed to contain the ongoing coronavirus disease 2019 (Covid-19) pandemic of infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). A candidate vaccine, Ad26.COV2.S, is a recombinant, replication-incompetent adenovirus serotype 26 (Ad26) vector encoding a full-length and stabilized SARS-CoV-2 spike protein. METHODS: In this multicenter, placebo-controlled, phase 1-2a trial, we randomly assigned healthy adults between the ages of 18 and 55 years (cohort 1) and those 65 years of age or older (cohort 3) to receive the Ad26.COV2.S vaccine at a dose of 5Ã—10(10) viral particles (low dose) or 1Ã—10(11) viral particles (high dose) per milliliter or placebo in a single-dose or two-dose schedule. Longer-term data comparing a single-dose regimen with a two-dose regimen are being collected in cohort 2; those results are not reported here. The primary end points were the safety and reactogenicity of each dose schedule. RESULTS: After the administration of the first vaccine dose in 805 participants in cohorts 1 and 3 and after the second dose in cohort 1, the most frequent solicited adverse events were fatigue, headache, myalgia, and injection-site pain. The most frequent systemic adverse event was fever. Systemic adverse events were less common in cohort 3 than in cohort 1 and in those who received the low vaccine dose than in those who received the high dose. Reactogenicity was lower after the second dose. Neutralizing-antibody titers against wild-type virus were detected in 90% or more of all participants on day 29 after the first vaccine dose (geometric mean titer [GMT], 212 to 354), regardless of vaccine dose or age group, and reached 96% by day 57 with a further increase in titers (GMT, 288 to 488) in cohort 1a. Titers remained stable until at least day 71. A second dose provided an increase in the titer by a factor of 2.6 to 2.9 (GMT, 827 to 1266). Spike-binding antibody responses were similar to neutralizing-antibody responses. On day 15, CD4+ T-cell responses were detected in 76 to 83% of the participants in cohort 1 and in 60 to 67% of those in cohort 3, with a clear skewing toward type 1 helper T cells. CD8+ T-cell responses were robust overall but lower in cohort 3. CONCLUSIONS: The safety and immunogenicity profiles of Ad26.COV2.S support further development of this vaccine candidate. (Funded by Johnson & Johnson and the Biomedical Advanced Research and Development Authority of the Department of Health and Human Services; COV1001 ClinicalTrials.gov number, NCT04436276.).
How COVID unlocked the power of RNA vaccines.
Excipients as Potential Agents of Anaphylaxis in Vaccines: Analyzing the Formulations of Currently Authorized COVID-19 Vaccines.
Allergic reactions to COVID-19 vaccinations-unveiling the secret(s).
Vaccinology in the post-COVID-19 era. The COVID-19 pandemic is a shocking reminder of how our world would look in the absence of vaccination. Fortunately, new technologies, the pace of understanding new and existing pathogens, and the increased knowledge of the immune system

allow us today to develop vaccines at an unprecedented speed. Some of the vaccine technologies that are fast-tracked by the urgency of COVID-19 may also be the answer for other health priorities, such as antimicrobial resistance, chronic infections, and cancer, that the post-COVID-19 world will urgently need to face. This perspective analyzes the way COVID-19 is transforming vaccinology and the opportunities for vaccines to have an increasingly important role in health and well-being.

Severe allergic reactions to the COVID-19 vaccine - statement and practical consequences. No abstract available.

Testing SARS-CoV-2 vaccine efficacy through deliberate natural viral exposure. BACKGROUND: A vaccine trial with a conventional challenge design can be very fast once it starts, but it requires a long prior process, in part to grow and standardize challenge virus in the laboratory. This detracts somewhat from its overall promise for accelerated efficacy testing of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine candidates, and from the ability of developing countries and small companies to conduct it. AIMS: We set out to identify a challenge design that avoids this part of the long prior process. SOURCES: Literature in trial design (including a proof of concept flu challenge trial by B. Killingley etÂ al.), vaccinology, medical ethics, and various aspects of COVID response. CONTENT: A challenge design with deliberate natural viral exposure avoids the need to grow culture. This new design is described and compared both to a conventional challenge design and to a conventional phase III field trial. In comparison, the proposed design has ethical, scientific, and feasibility strengths. IMPLICATIONS: The proposed new design should be considered for future vaccine trials.

Evaluation of COVID-19 Vaccine Refusal in Parents. OBJECTIVE: The frequency of vaccine refusal, which is associated with many factors, is increasing worldwide. The aim of this study was to predict the frequency of vaccine refusal against domestic and foreign COVID-19 vaccines and identify the factors underlying refusal. METHODS: A survey consisting of 16 questions about COVID-19 vaccination was conducted either face-to-face or online with 428 parents who agreed to participate in the study. The parents had children who were inpatients or outpatients in the Children's Hospital of Ankara City Hospital. In the survey, parents were asked about family sociodemographic characteristics, opinions on domestic and foreign COVID-19 vaccines, and reasons for vaccine refusal. RESULTS: While 66.1% of parents were reluctant to receive foreign COVID-19 vaccines, only 37.4% were reluctant to receive domestic COVID-19 vaccines. The participants' preference for the domestic vaccine was significantly higher for themselves and their children (Pâ€‰<â€‰0.05). Women were less likely to be willing to receive foreign vaccines than men (Pâ€‰<â€‰0.05). As the education level increased, fewer parents preferred the domestic vaccine for themselves (Pâ€‰=â€‰0.046) and their children (Pâ€‰=â€‰0.005). Both domestic and foreign vaccine acceptability for parents and their children was higher among parents with high anxiety levels regarding COVID-19 infection (Pâ€‰<â€‰0.05). The most common reasons for refusal were anxiety about vaccine side effects, lack of knowledge about the effectiveness of vaccines, and distrust of vaccines originating from abroad. CONCLUSION: Most of the participants were hesitant about COVID-19 vaccines. This study demonstrates that vaccine uptake can be increased by considering the higher preference for domestic vaccines.

Influenza Vaccination and Myo-Pericarditis in Patients Receiving Immune Checkpoint Inhibitors: Investigating the Likelihood of Interaction through the Vaccine Adverse Event Reporting System and VigiBase. BACKGROUND: Evidence on whether the influenza vaccine could exacerbate immune-related adverse events, including myopericarditis (MP), in patients treated with immune checkpoint inhibitors (ICIs), is still conflicting. We explored this issue through a global real-world approach. METHODS: We queried the Vaccine Adverse Event Reporting System (VAERS) and VigiBase to retrieve cases of MP in which the influenza vaccine and ICIs were recorded as suspect and were concomitantly reported. For the included cases, causality assessment and Drug Interaction Probability Scale (DIPS)

algorithms were applied. RESULTS: There were 191 and 399 reports of MP with the influenza vaccine that were retrieved (VAERS and VigiBase, respectively). No case of MP reporting the concomitant use of ICIs and the influenza vaccine was found in VAERS, while three cases of myocarditis were retrieved in VigiBase. All of the cases were unclassifiable for a causality assessment because of the lack of data concerning latency. According to the DIPS, one report was categorized as possible and two as doubtful. CONCLUSION: The paucity of cases coupled with the doubtful causality assessment make the potential interaction between influenza vaccines and ICIs in cancer patients negligible from clinical and epidemiological standpoints. These findings support the cardiovascular safety of the influenza vaccination, which remains strongly recommended in cancer patients, especially in the current COVID-19 era.

Should children be vaccinated against COVID-19 now?

Recent Developments on Therapeutic and Diagnostic Approaches for COVID-19. The ongoing pandemic of coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has made a serious public health threat worldwide with millions of people at risk in a growing number of countries. Though there are no clinically approved antiviral drugs and vaccines for COVID-19, attempts are ongoing for clinical trials of several known antiviral drugs, their combination, as well as development of vaccines in patients with confirmed COVID-19. This review focuses on the latest approaches to diagnostics and therapy of COVID-19. We have summarized recent progress on the conventional therapeutics such as antiviral drugs, vaccines, anti-SARS-CoV-2 antibody treatments, and convalescent plasma therapy which are currently under extensive research and clinical trials for the treatment of COVID-19. The developments of nanoparticle-based therapeutic and diagnostic approaches have been also discussed for COVID-19. We have assessed recent literature data on this topic and made a summary of current development and future perspectives.

Substantial Impact of Post Vaccination Contacts on Cumulative Infections during Viral Epidemics. BACKGROUND: The start of 2021 will be marked by a global vaccination campaign against the novel coronavirus SARS-CoV-2. Formulating an optimal distribution strategy under social and economic constraints is challenging. Optimal distribution is additionally constrained by the potential emergence of vaccine resistance. Analogous to chronic low-dose antibiotic exposure, recently inoculated individuals who are not yet immune play an outsized role in the emergence of resistance. Classical epidemiological modelling is well suited to explore how the behavior of the inoculated population impacts the total number of infections over the entirety of an epidemic. METHODS: A deterministic model of epidemic evolution is analyzed, with 7 compartments defined by their relationship to the emergence of vaccine-resistant mutants and representing three susceptible populations, three infected populations, and one recovered population. This minimally computationally intensive design enables simulation of epidemics across a broad parameter space. The results are used to identify conditions minimizing the cumulative number of infections. RESULTS: When an escape variant is only modestly less infectious than the originating strain within a naÃ¯ve population, there exists an optimal rate of vaccine distribution. Exceeding this rate increases the cumulative number of infections due to vaccine escape. Analysis of the model also demonstrates that inoculated individuals play a major role in the mitigation or exacerbation of vaccine-resistant outbreaks. Modulating the rate of host-host contact for the inoculated population by less than an order of magnitude can alter the cumulative number of infections by more than 20%. CONCLUSIONS: Mathematical modeling shows that optimization of the vaccination rate and limiting post-vaccination contacts can affect the course of an epidemic. Given the relatively short window between inoculation and the acquisition of immunity, these results might merit consideration for an immediate, practical public health response.

Lead SARS-CoV-2 Candidate Vaccines: Expectations from Phase III Trials and Recommendations Post-Vaccine Approval. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is transmitted primarily through respiratory droplets/aerosols and it causes COVID-19. The virus infects epithelial cells by using the spike protein on its surface to bind to angiotensin-converting enzyme 2 receptor on the cells. Thus, candidate vaccines targeting the spike protein are currently being developed to prevent against infections. Approximately 44 SARS-CoV-2 candidate vaccines are in clinical trials (phase I-III) and an additional 164 candidates are in preclinical stages. The efficacy data from phase I/II trials of lead candidate vaccines look very promising with virus-neutralizing geometric mean antibody titers in the range of 16.6-3906. Most recently, two SARS-CoV-2 candidate vaccines, BNT162b2 and mRNA-1273, have been granted the first emergency use authorization (EUA) in the U.S.; BNT162b2 has also been granted an EUA in the United Kingdom, Canada, and in the European Union. This review assesses whether SARS-CoV-2 candidate vaccines (with approved EUA or in phase III trials) meet the criteria for an ideal SARS-CoV-2 vaccine. The review concludes with expectations from phase III trials and recommendations for phase IV studies (post-vaccine approval).

When Epidemics Collide: Why People With Human Immunodeficiency Virus May Have Worse Coronavirus Disease 2019 Outcomes and Implications for Vaccination.

Clinical manifestations and impact on daily life of allergy to polyethylene glycol (PEG) in ten patients. BACKGROUND: Polyethylene glycols (PEGs) are widely used as excipients in drugs, cosmetics and household products. Immediate-type allergy to PEGs including anaphylaxis is rare. The recent introduction of the mRNA-based COVID-19 vaccines has led to an increased focus on PEG as a possible culprit of allergic reactions to the vaccines. A low awareness of the allergenic potential of PEG among consumers, manufacturers and doctors leads to under-diagnosis and under-reporting of allergy to PEGs, putting patients at risk of repeated severe reactions. OBJECTIVES: To investigate clinical manifestations, time to diagnosis and impact of a PEG allergy diagnosis on the daily life of patients diagnosed with allergy to PEG from 2010 to 2019. METHOD: Ten patients diagnosed with allergy to PEG were included. Detailed clinical history was obtained, and allergy investigations had been performed at the time of diagnosis. All patients were contacted and asked to retrospectively complete a questionnaire about causes and impact on daily life of an allergy to PEG, scored on a likert scale (0-10) before and after diagnosis. RESULTS: Eight patients had experienced at least one anaphylactic reaction requiring adrenaline treatment. Anaphylaxis was primarily caused by antibiotic/analgesic tablets, depot-steroids, antacids and laxatives. Seven patients reported repeated reactions before diagnosis (median 3, range 2-6). Median time from first reaction to diagnosis was 20Â months (range 2-120). None of the patients experienced severe allergic reactions after the diagnosis. Median likert score of the impact on daily life before diagnosis was 7 compared with 4 after diagnosis. CONCLUSION AND CLINICAL RELEVANCE: The clinical manifestations of PEG allergy are often dramatic. Improved awareness about the clinical presentation and common culprits, clear product labelling and a standardized nomenclature is needed to ensure the timely diagnosis of PEG allergy to prevent repeated anaphylactic reactions with severe impact on patients' lives.

The Century of mRNA Vaccines: COVID-19 Vaccines and Allergy.

Current advances in the development of SARS-CoV-2 vaccines. Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is now a global pandemic that has wreaked havoc globally, which has put a heavy toll on public health, lives, and the world economy. Vaccination is considered as one of the greatest successes in medical history. Based on prior experience with the development of SARS-CoV vaccines, all COVID-19 vaccines must be subjected to the tests for protective effects and harmful risks derived from antibody-dependent enhancement that may contribute to augmented infectivity and/or eosinophilic infiltration. The SARS-CoV-2 vaccine is now being developed urgently in several different ways. China is regarded as one of

the world's leading countries in SARS-CoV-2 vaccine development, up to date the last inactivated vaccine international clinical (Phase III) trial was launched in the United Arab Emirates by Sinopharm China National Biotec Group (CNBG). In this review, we outline the current status of vaccine development against clinically relevant SARS-CoV-2 strains, anticipating that such attempts would help create efficacious and sage SARS-CoV-2 vaccines.
mRNA Vaccines to Prevent COVID-19 Disease and Reported Allergic Reactions: Current Evidence and Suggested Approach. The U.S. Food and Drug Administration (FDA) has recently issued an Emergency Use Authorization (EUA) for 2 highly effective coronavirus disease 2019 (COVID-19) vaccines from Pfizer-BioNTech and Moderna. This has brought hope to millions of Americans in the midst of an ongoing global pandemic. The FDA EUA guidance for both vaccines is to not administer the vaccine to individuals with a known history of a severe allergic reaction (eg, anaphylaxis) to any component of the COVID-19 vaccine. The Centers for Disease Control and Prevention (CDC) additionally advises individuals with a history of an immediate allergic reaction to a vaccine or injectable or any history of anaphylaxis be observed for 30 minutes after COVID-19 vaccination. All other individuals should be observed for 15 minutes after COVID-19 vaccination. Staff at vaccine clinics must be able to identify and manage anaphylaxis. Post-FDA EUA, despite very strong safety signals in both phase 3 trials, reports of possible allergic reactions have raised public concern. To provide reassurance and support during widespread global vaccination, allergists must offer clear guidance to individuals based on the best information available, but also in accordance with the broader recommendations of regulatory agencies. This review summarizes vaccine allergy epidemiology and proposes drug and vaccine allergy expert opinion informed risk stratification for Allergy specialist use in conjunction with guidance of public health and regulatory authorities. The risk stratification schema guide care for (1) individuals with different allergy histories to safely receive their first mRNA COVID-19 vaccine and (2) individuals who develop a reaction to their first dose of mRNA COVID-19 vaccine.
HPV vaccination introduction worldwide and WHO and UNICEF estimates of national HPV immunization coverage 2010-2019. WHO/UNICEF estimates for HPV vaccination coverage from 2010 to 2019 are analyzed against the backdrop of the 90% coverage target for HPV vaccination by 2030 set in the recently approved global strategy for cervical cancer elimination as a public health problem. As of June 2020, 107 (55%) of the 194 WHO Member States have introduced HPV vaccination. The Americas and Europe are by far the WHO regions with the most introductions, 85% and 77% of their countries having already introduced respectively. A record number of introductions was observed in 2019, most of which in low- and middle- income countries (LMIC) where access has been limited. Programs had an average performance coverage of around 67% for the first dose and 53% for the final dose of HPV. LMICs performed on average better than high- income countries for the first dose, but worse for the last dose due to higher dropout. Only 5 (6%) countries achieved coverages with the final dose of more than 90%, 22 countries (21%) achieved coverages of 75% or higher while 35 (40%) had a final dose coverage of 50% or less. When expressed as world population coverage (i.e., weighted by population size), global coverage of the final HPV dose for 2019 is estimated at 15%. There is a long way to go to meet the 2030 elimination target of 90%. In the post-COVID era attention should be paid to maintain the pace of introductions, specially ensuring the most populous countries introduce, and further improving program performance globally.
Anaphylaxis to the first COVID-19 vaccine: is polyethylene glycol (PEG) the culprit?
A Call to Arms: The War of the COVID.
Pfizer's vaccine raises allergy concerns.
Uncommon thrombotic complications after SARS-CoV-2 vaccination. Shortly after the worldwide initiation of vaccination against SARS-CoV-2, concerns emerged about a possible link between

vaccination, severe thrombocytopenia, and the development of atypical venous thrombosis. Concerns were primarily about AstraZeneca (ChAdOx1 nCov-19), later Johnson & Johnson (Ad26.COV2.S), but cases of acute immune thrombocytopenic purpura (ITP) and bleeding without thrombosis and also atypical venous thrombosis after exposure to the messenger RNA-based vaccines produced by Pfizer-BioNTech and Moderna have been reported. Examination of the circumstances of these complications revealed that this is a similar mechanism to heparin-induced thrombocytopenia (HIT), a prothrombotic thrombocytopenic hypercoagulable disorder with venous and arterial thrombosis. HIT is caused by platelet-activating IgG antibodies directed against an antigen that is a macromolecular complex consisting of platelet factor 4 (PF4) and heparin. Naming this new entity vaccine-induced immune thrombotic thrombocytopenia (VITT) was suggested to avoid confusion with HIT. Patients had high levels of antibodies to the immune complex formed by PF 4 and the polyanionic component of the vaccine (double-stranded DNA). In patients with thrombosis at any vascular site after vaccination, accompanied by absolute or relative thrombocytopenia and systemic manifestations, HIT Ig ELISA assay to detect antibodies against PF4 and platelet-activating functional tests may be used for VITT recognition and differentiation from venous thromboembolic disease. Immune globulin impedes antibody-mediated platelet clearance and down-regulate platelet activation by immune complexes, as in HIT. It is prudent to choose from among the nonheparin antithrombotic agents - direct oral F.Xa inhibitors, direct thrombin inhibitors and indirect F.Xa inhibitors for the treatment of thrombosis.

SARS-CoV-2 vaccine induced Sweet syndrome : a case report. Sweet syndrome (SS), also known as acute febrile neutrophilic dermatosis is a rare cutaneous disorder characterized by specific clinical, biological and microscopic findings. Although the exact cause of SS is still unknown, it may be triggered by infections, malignancies and drugs but also occurring after vaccinations such as bacille calmette guerin vaccination and influenza vaccine. While the recently discovered SARS COV2 vaccines are almost safe, many cutaneous and extracutaneous minor adverse effects are reported. We herein describe the fourth case of Sweet Syndrome induced by SARS-COV2 vaccine.

 Sweet syndrome (SS), also known as acute febrile neutrophilic dermatosis is a rare cutaneous disorder characterized by specific clinical, biological and microscopic findings. Although the exact cause of SS is still unknown, it may be triggered by infections, malignancies and drugs but also occurring after vaccinations such as bacille calmette guerin vaccination and influenza vaccine. While the recently discovered SARS COV2 vaccines are almost safe, many cutaneous and extracutaneous minor adverse effects are reported. We herein describe the fourth case of Sweet Syndrome induced by SARS-COV2 vaccine.

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine - United States, December 2020. On December 18, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Moderna COVID-19 (mRNA-1273) vaccine (ModernaTX, Inc; Cambridge, Massachusetts), a lipid nanoparticle-encapsulated, nucleoside-modified mRNA vaccine encoding the stabilized prefusion spike glycoprotein of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19) (1). This vaccine is the second COVID-19 vaccine authorized under an EUA for the prevention of COVID-19 in the United States (2). Vaccination with the Moderna COVID-19 vaccine consists of 2 doses (100 Î¼g, 0.5 mL each) administered intramuscularly, 1 month (4 weeks) apart. On December 19, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation* for use of the Moderna COVID-19 vaccine in persons aged â‰¥18 years for the prevention of COVID-19. To guide its deliberations regarding the vaccine, ACIP employed the Evidence to Recommendation (EtR) Framework,(â€) using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.(Â§) Use of all COVID-19 vaccines authorized under an EUA, including the Moderna

COVID-19 vaccine, should be implemented in conjunction with ACIP's interim recommendations for allocating initial supplies of COVID-19 vaccines (3). The ACIP recommendation for the use of the Moderna COVID-19 vaccine under EUA is interim and will be updated as additional information becomes available.

ARIA-EAACI statement on severe allergic reactions to COVID-19 vaccines - An EAACI-ARIA Position Paper. Further to the approval of the Coronavirus disease 2019 (COVID-19) vaccine BNT162b2, several severe anaphylaxis cases occured within the first few days of public vaccination. An investigation is taking place to understand the cases and their triggers. The vaccine will be administered to a large number of individuals worldwide and there are raising concerns that severe adverse events might occur. With the current information, the European Academy of Allergy and Clinical Immunology (EAACI) states its position for the following preliminary recommendations that are to be revised as soon as more data emerge. To minimize the risk of severe allergic reactions in vaccinated individuals, it is urgently required to understand the specific nature of the reported severe allergic reactions, including the background medical history of the individuals affected and the mechanisms involved. To achieve this goal, all clinical and laboratory information should be collected and reported. Mild and moderate allergic patients should not be excluded from the vaccine as this could have a significant impact on reaching the goal of population immunity. Healthcare practitioners vaccinating against COVID-19 are required to be sufficiently prepared to recognize and treat anaphylaxis properly with the ability to administer adrenaline. Further to vaccine administration, a mandatory observation period of at least 15 minutes should be followed for all individuals. The current data have not shown any higher risk for patients suffering from allergic rhinitis or asthma, and this message should be clearly stated by physicians to enable our patients to trust the vaccine. More than 30% of the population suffers from allergic diseases and the benefit of the vaccination clearly outweighs the risk of severe COVID-19 development.

Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. BACKGROUND: Vaccines are needed to prevent coronavirus disease 2019 (Covid-19) and to protect persons who are at high risk for complications. The mRNA-1273 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine that encodes the prefusion stabilized full-length spike protein of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes Covid-19. METHODS: This phase 3 randomized, observer-blinded, placebo-controlled trial was conducted at 99 centers across the United States. Persons at high risk for SARS-CoV-2 infection or its complications were randomly assigned in a 1:1 ratio to receive two intramuscular injections of mRNA-1273 (100 Î¼g) or placebo 28 days apart. The primary end point was prevention of Covid-19 illness with onset at least 14 days after the second injection in participants who had not previously been infected with SARS-CoV-2. RESULTS: The trial enrolled 30,420 volunteers who were randomly assigned in a 1:1 ratio to receive either vaccine or placebo (15,210 participants in each group). More than 96% of participants received both injections, and 2.2% had evidence (serologic, virologic, or both) of SARS-CoV-2 infection at baseline. Symptomatic Covid-19 illness was confirmed in 185 participants in the placebo group (56.5 per 1000 person-years; 95% confidence interval [CI], 48.7 to 65.3) and in 11 participants in the mRNA-1273 group (3.3 per 1000 person-years; 95% CI, 1.7 to 6.0); vaccine efficacy was 94.1% (95% CI, 89.3 to 96.8%; P<0.001). Efficacy was similar across key secondary analyses, including assessment 14 days after the first dose, analyses that included participants who had evidence of SARS-CoV-2 infection at baseline, and analyses in participants 65 years of age or older. Severe Covid-19 occurred in 30 participants, with one fatality; all 30 were in the placebo group. Moderate, transient reactogenicity after vaccination occurred more frequently in the mRNA-1273 group. Serious adverse events were rare, and the incidence was similar in the two groups. CONCLUSIONS: The mRNA-1273 vaccine showed 94.1% efficacy at preventing Covid-19 illness, including severe disease. Aside from transient

local and systemic reactions, no safety concerns were identified. (Funded by the Biomedical Advanced Research and Development Authority and the National Institute of Allergy and Infectious Diseases; COVE ClinicalTrials.gov number, NCT04470427.).

Maintaining Safety with SARS-CoV-2 Vaccines.

The association of previous influenza vaccination and coronavirus disease-2019. Studies have shown similarities in the structure of influenza and coronaviruses, in their binding receptors and in patterns of immune responses; and that influenza vaccine can induce cross-immunity. We examined the association of previous influenza vaccination and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, resulting in coronavirus disease-2019 (COVID-19), among 715,164 members of a health maintenance organization. In a multivariate regression model, the odds ratios for SARS-CoV-2 infection among individuals vaccinated for influenza in 2018-2019, 2019-2020, and in both seasons, compared to non-vaccinated individuals, were 0.82 (95% CI 0.68-0.99, p =Â .048), 0.79 (95% CI 0.67-0.98, p =Â .005), and 0.76 (95% CI 0.61-0.97, p =Â .004), respectively. Based on our findings, administration of influenza vaccine before the influenza season is highly recommended to reduce the burden of influenza, which is critical in scenarios of outbreaks of both influenza and SARS-CoV-2 infections, and also regarding its association with reduced rate of COVID-19.

Messengers of hope. Emergency Use Authorizations for two mRNA COVID-19 vaccines represent a turning point in the pandemic. They also herald a new era for vaccinology.

Fighting Strategies Against the Novel Coronavirus Pandemic: Impact on Global Economy. Sudden outbreak of a new pathogen in numbers of pneumonic patients in Wuhan province during December 2019 has threatened the world population within a short period of its occurrence. This respiratory tract-isolated pathogen was initially named as novel coronavirus 2019 (nCoV-2019), but later termed as SARS-CoV-2. The rapid spreading of this infectious disease received the label of pandemic by the World Health Organization within 4 months of its occurrence, which still seeks continuous attention of the researchers to prevent the spread and for cure of the infected patients. The propagation of the disease has been recorded in 215 countries, with more than 25.5 million cases and a death toll of more than 0.85 million. Several measures are taken to control the disease transmission, and researchers are actively engaged in finding suitable therapeutics to effectively control the disease to minimize the mortality and morbidity rates. Several existing potential candidates were explored in the prevention and treatment of worsening condition of COVID-19 patients; however, none of the formulation has been approved for the treatment but used under medical supervision. In this article, a focus has been made to highlight on current epidemiology on the COVID-19 infection, clinical features, diagnosis, and transmission, with special emphasis on treatment measures of the disease at different stages of clinical research and the global economic influence due to this pandemic situation. Progress in the development on vaccine against COVID-19 has also been explored as important measures to immunize people. Moreover, this article is expected to provide information to the researchers, who are constantly combating in the management against this outbreak.

The lightning-fast quest for COVID vaccines - and what it means for other diseases.

T cell and antibody responses induced by a single dose of ChAdOx1 nCoV-19 (AZD1222) vaccine in a phase 1/2 clinical trial. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of Coronavirus Disease 2019 (COVID-19), has caused a global pandemic, and safe, effective vaccines are urgently needed(1). Strong, Th1-skewed T cell responses can drive protective humoral and cell-mediated immune responses(2) and might reduce the potential for disease enhancement(3). Cytotoxic T cells clear virus-infected host cells and contribute to control of infection(4). Studies of patients infected with SARS-CoV-2 have suggested a protective role for both humoral and cell-mediated immune responses in recovery from COVID-19 (refs. (5,6)). ChAdOx1 nCoV-19 (AZD1222) is a candidate SARS-CoV-2 vaccine comprising a replication-deficient simian

adenovirus expressing full-length SARS-CoV-2 spike protein. We recently reported preliminary safety and immunogenicity data from a phase 1/2 trial of the ChAdOx1 nCoV-19 vaccine (NCT04400838)(7) given as either a one- or two-dose regimen. The vaccine was tolerated, with induction of neutralizing antibodies and antigen-specific T cells against the SARS-CoV-2 spike protein. Here we describe, in detail, exploratory analyses of the immune responses in adults, aged 18-55 years, up to 8 weeks after vaccination with a single dose of ChAdOx1 nCoV-19 in this trial, demonstrating an induction of a Th1-biased response characterized by interferon-Î³ and tumor necrosis factor-Î± cytokine secretion by CD4(+) T cells and antibody production predominantly of IgG1 and IgG3 subclasses. CD8(+) T cells, of monofunctional, polyfunctional and cytotoxic phenotypes, were also induced. Taken together, these results suggest a favorable immune profile induced by ChAdOx1 nCoV-19 vaccine, supporting the progression of this vaccine candidate to ongoing phase 2/3 trials to assess vaccine efficacy.

Phase 1/2 trial of SARS-CoV-2 vaccine ChAdOx1 nCoV-19 with a booster dose induces multifunctional antibody responses. More than 190 vaccines are currently in development to prevent infection by the novel severe acute respiratory syndrome coronavirus 2. Animal studies suggest that while neutralizing antibodies against the viral spike protein may correlate with protection, additional antibody functions may also be important in preventing infection. Previously, we reported early immunogenicity and safety outcomes of a viral vector coronavirus vaccine, ChAdOx1 nCoV-19 (AZD1222), in a single-blinded phase 1/2 randomized controlled trial of healthy adults aged 18-55 years (NCT04324606). Now we describe safety and exploratory humoral and cellular immunogenicity of the vaccine, from subgroups of volunteers in that trial, who were subsequently allocated to receive a homologous full-dose (SD/SD D56; nâ€‰=â€‰20) or half-dose (SD/LD D56; nâ€‰=â€‰32) ChAdOx1 booster vaccine 56â€‰d following prime vaccination. Previously reported immunogenicity data from the open-label 28-d interval prime-boost group (SD/SD D28; nâ€‰=â€‰10) are also presented to facilitate comparison. Additionally, we describe volunteers boosted with the comparator vaccine (MenACWY; nâ€‰=â€‰10). In this interim report, we demonstrate that a booster dose of ChAdOx1 nCoV-19 is safe and better tolerated than priming doses. Using a systems serology approach we also demonstrate that anti-spike neutralizing antibody titers, as well as Fc-mediated functional antibody responses, including antibody-dependent neutrophil/monocyte phagocytosis, complement activation and natural killer cell activation, are substantially enhanced by a booster dose of vaccine. A booster dose of vaccine induced stronger antibody responses than a dose-sparing half-dose boost, although the magnitude of T cell responses did not increase with either boost dose. These data support the two-dose vaccine regime that is now being evaluated in phase 3 clinical trials.

Enrolling Minors in COVID-19 Vaccine Trials. It is widely agreed that an effective response to the coronavirus disease 2019 pandemic needs to include a vaccine that is safe and effective for minors. However, many current vaccine trials have no plans for when to enroll minors. Others have recently proposed enrolling minors as young as 12 years old. This lack of a systematic approach raises 2 concerns. Waiting too long to enroll minors could unjustly deny minors and their families the benefits of a vaccine and has the potential to delay an effective response to the pandemic by a year or longer. At the same time, enrolling minors too soon runs the risk of exposing them to excessive risks. With these concerns in mind, in the present article, we propose recommendations for when and how to enroll minors in vaccine trials for the coronavirus disease 2019.

An ecological study to evaluate the association of Bacillus Calmette-Guerin (BCG) vaccination on cases of SARS-CoV2 infection and mortality from COVID-19. As the SARS-CoV2 pandemic has progressed, there have been marked geographical differences in the pace and extent of its spread. We evaluated the association of BCG vaccination on morbidity and mortality of SARS-CoV2, adjusted for country-specific responses to the epidemic, demographics and health. SARS-CoV2 cases and

deaths as reported by 31 May 2020 in the World Health Organization situation reports were used. Countries with at least 28 days following the first 100 cases, and available information on BCG were included. We used log-linear regression models to explore associations of cases and deaths with the BCG vaccination policy in each country, adjusted for population size, gross domestic product, proportion aged over 65 years, stringency level measures, testing levels, smoking proportion, and the time difference from date of reporting the 100th case to 31 May 2020. We further looked at the association that might have been found if the analyses were done at earlier time points. The study included 97 countries with 73 having a policy of current BCG vaccination, 13 having previously had BCG vaccination, and 11 having never had BCG vaccination. In a log-linear regression model there was no effect of country-level BCG status on SARS-CoV2 cases or deaths. Univariable log-linear regression models showed a trend towards a weakening of the association over time. We found no statistical evidence for an association between BCG vaccination policy and either SARS-CoV2 morbidity or mortality. We urge countries to rather consider alternative tools with evidence supporting their effectiveness for controlling SARS-CoV2 morbidity and mortality.
The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine - United States, December 2020. On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 (BNT162b2) vaccine (Pfizer, Inc; Philadelphia, Pennsylvania), a lipid nanoparticle-formulated, nucleoside-modified mRNA vaccine encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19) (1). Vaccination with the Pfizer-BioNTech COVID-19 vaccine consists of 2 doses (30 Î¼g, 0.3 mL each) administered intramuscularly, 3 weeks apart. On December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation* for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged â‰¥16 years for the prevention of COVID-19. To guide its deliberations regarding the vaccine, ACIP employed the Evidence to Recommendation (EtR) Framework,(â€) using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.(Â§) The recommendation for the Pfizer-BioNTech COVID-19 vaccine should be implemented in conjunction with ACIP's interim recommendation for allocating initial supplies of COVID-19 vaccines (2). The ACIP recommendation for the use of the Pfizer-BioNTech COVID-19 vaccine under EUA is interim and will be updated as additional information becomes available.
Psoriasis flare after influenza vaccination in Covid-19 era: A report of four cases from a single center.
Is a COVID-19 Vaccine Likely to Make Things Worse? In order to limit the disease burden and economic costs associated with the COVID-19 pandemic, it is important to understand how effective and widely distributed a vaccine must be in order to have a beneficial impact on public health. To evaluate the potential effect of a vaccine, we developed risk equations for the daily risk of COVID-19 infection both currently and after a vaccine becomes available. Our risk equations account for the basic transmission probability of COVID-19 ($Î^2$) and the lowered risk due to various protection options: physical distancing; face coverings such as masks, goggles, face shields or other medical equipment; handwashing; and vaccination. We found that the outcome depends significantly on the degree of vaccine uptake: if uptake is higher than 80%, then the daily risk can be cut by 50% or more. However, if less than 40% of people get vaccinated and other protection options are abandoned-as may well happen in the wake of a COVID-19 vaccine-then introducing even an excellent vaccine will produce a worse outcome than our current situation. It is thus critical that effective education strategies are employed in tandem with vaccine rollout.
Audio Interview: Covid-19 Vaccine Fundamentals.
Allergic reactions to the first COVID-19 vaccine: A potential role of polyethylene glycol?

Efficacy and safety of COVID-19 vaccines in older people. Several vaccines against coronavirus disease 2019 (COVID-19) are on the cusp of regulatory approval. Their safety and efficacy in older people is critical to their success. Even though care home residents and older people are likely to be amongst the first to be vaccinated, these patient groups are usually excluded from clinical trials. Data from several Phase II trials have given cause for optimism, with strong antibody responses and reassuring safety profiles but, with the exception of AstraZeneca's vaccine, recruited few older people. Overall, the sparse data from Phase II trials suggest a reduction in both antibody responses and mild to moderate adverse events in well older people compared to younger participants. Many of the Phase III trials have made a conscious effort to recruit older people, and interim analyses of the Pfizer and Moderna vaccine have led to press releases announcing high degrees of efficacy. However, older people with co-morbidities and frailty have once again been largely excluded and there are no published data on safety and efficacy in this group. Although the speed and impact of the pandemic on older people with frailty justify an approach where they are offered vaccination first, patients and their carers and supervising health care professionals alike will need to make a decision on accepting vaccination based on limited evidence. Here we review the main candidate vaccines that may become available, with a focus on the evidence of safety and efficacy in older people.

Therapeutic and Vaccine Options for COVID-19: Status after Six Months of the Disease Outbreak. An outbreak of the coronavirus disease 2019 (COVID-19) caused by an infection of the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) occurred in Wuhan, China, in December 2019. This new virus belongs to the group of enveloped RNA beta-coronaviruses. Symptoms may differ in various infected persons, but major presentations include dry cough, nasal congestion, shortness of breath, fever, and general malaise. The disease appears to be more severe in patients above the age of 60 years and those with underlying conditions such as diabetes, cancer, cardiovascular diseases, chronic respiratory disease, and hypertension. There is still no approved vaccine against COVID-19, but more than a hundred are at different stages of development. It is known that the development of new drugs takes a relatively long time, so several known and already-approved drugs are being repurposed for the treatment of this disease. In this review, we explore the therapeutic and vaccine options that are available for COVID-19 6 months after its outbreak. Most noteworthy among the therapeutic options are dexamethasone, remdesivir, Avigan (favipiravir) and convalescent plasma.

Arab nations first to approve Chinese COVID vaccine - despite lack of public data.

Inactivated trivalent influenza vaccination is associated with lower mortality among patients with COVID-19 in Brazil. OBJECTIVE: To estimate associations between trivalent influenza vaccination and COVID-19 mortality as well as severe clinical outcomes among hospitalised patients. DESIGN: Retrospective observational study. SETTING: This study was conducted among hospitalised patients with COVID-19 in Brazil. PARTICIPANTS: We analysed all hospitalised patients with COVID-19 with available vaccination information captured in Brazil's national electronic respiratory infection data system between 1 January 2020 and 23 June 2020. MAIN OUTCOME MEASURES: The primary outcomes were age-specific mortality rates of hospitalised patients with COVID-19 with and without recent inactivated trivalent influenza vaccination. RESULTS: A total of 53â€‰752 clinically confirmed COVID-19 cases were analysed. Controlling for health facility of treatment, comorbidities as well as an extensive range of sociodemographic factors, patients who received a recent influenza vaccine experienced on average 7% lower odds of needing intensive care treatment (95% CI 0.87 to 0.98), 17% lower odds of requiring invasive respiratory support (95% CI 0.77 to 0.88) and 16% lower odds of death (95% CI 0.78 to 0.90). Protective effects were larger when the vaccine was administered after onset of symptoms as well as among younger patients. CONCLUSION: Patients with COVID-19 with recent inactivated influenza vaccination experience significantly better health outcomes than non-

vaccinated patients in Brazil. Beneficial off-target effects of influenza vaccination through trained innate immune responses seem plausible and need to be further explored. Large-scale promotion of influenza vaccines seems advisable, especially in populations at high risk for severe COVID-19 disease progression.

Androgenetic alopecia may be associated with weaker COVID-19Â T-cell immune response: An insight into a potential COVID-19 vaccine booster.

Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. BACKGROUND: A safe and efficacious vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), if deployed with high coverage, could contribute to the control of the COVID-19 pandemic. We evaluated the safety and efficacy of the ChAdOx1 nCoV-19 vaccine in a pooled interim analysis of four trials. METHODS: This analysis includes data from four ongoing blinded, randomised, controlled trials done across the UK, Brazil, and South Africa. Participants aged 18 years and older were randomly assigned (1:1) to ChAdOx1 nCoV-19 vaccine or control (meningococcal group A, C, W, and Y conjugate vaccine or saline). Participants in the ChAdOx1 nCoV-19 group received two doses containing 5â€ˆÃ—â€ˆ10(10) viral particles (standard dose; SD/SD cohort); a subset in the UK trial received a half dose as their first dose (low dose) and a standard dose as their second dose (LD/SD cohort). The primary efficacy analysis included symptomatic COVID-19 in seronegative participants with a nucleic acid amplification test-positive swab more than 14 days after a second dose of vaccine. Participants were analysed according to treatment received, with data cutoff on Nov 4, 2020. Vaccine efficacy was calculated as 1â€ˆ-â€ˆrelative risk derived from a robust Poisson regression model adjusted for age. Studies are registered at ISRCTN89951424 and ClinicalTrials.gov, NCT04324606, NCT04400838, and NCT04444674. FINDINGS: Between April 23 and Nov 4, 2020, 23â€ˆ848 participants were enrolled and 11â€ˆ636 participants (7548 in the UK, 4088 in Brazil) were included in the interim primary efficacy analysis. In participants who received two standard doses, vaccine efficacy was 62Â·1% (95% CI 41Â·0-75Â·7; 27 [0Â·6%] of 4440 in the ChAdOx1 nCoV-19 group vs71 [1Â·6%] of 4455 in the control group) and in participants who received a low dose followed by a standard dose, efficacy was 90Â·0% (67Â·4-97Â·0; three [0Â·2%] of 1367 vs 30 [2Â·2%] of 1374; p(interaction)=0Â·010). Overall vaccine efficacy across both groups was 70Â·4% (95Â·8% CI 54Â·8-80Â·6; 30 [0Â·5%] of 5807 vs 101 [1Â·7%] of 5829). From 21 days after the first dose, there were ten cases hospitalised for COVID-19, all in the control arm; two were classified as severe COVID-19, including one death. There were 74â€ˆ341 person-months of safety follow-up (median 3Â·4 months, IQR 1Â·3-4Â·8): 175 severe adverse events occurred in 168 participants, 84 events in the ChAdOx1 nCoV-19 group and 91 in the control group. Three events were classified as possibly related to a vaccine: one in the ChAdOx1 nCoV-19 group, one in the control group, and one in a participant who remains masked to group allocation. INTERPRETATION: ChAdOx1 nCoV-19 has an acceptable safety profile and has been found to be efficacious against symptomatic COVID-19 in this interim analysis of ongoing clinical trials. FUNDING: UK Research and Innovation, National Institutes for Health Research (NIHR), Coalition for Epidemic Preparedness Innovations, Bill & Melinda Gates Foundation, Lemann Foundation, Rede D'Or, Brava and Telles Foundation, NIHR Oxford Biomedical Research Centre, Thames Valley and South Midland's NIHR Clinical Research Network, and AstraZeneca.

Covid-19: People with history of significant allergic reactions should not receive Pfizer vaccine, says regulator.

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and the resulting coronavirus disease 2019 (Covid-19) have afflicted tens of millions of people in a worldwide pandemic. Safe and effective vaccines are needed urgently. METHODS: In an ongoing multinational, placebo-controlled, observer-

blinded, pivotal efficacy trial, we randomly assigned persons 16 years of age or older in a 1:1 ratio to receive two doses, 21 days apart, of either placebo or the BNT162b2 vaccine candidate (30 Î¼g per dose). BNT162b2 is a lipid nanoparticle-formulated, nucleoside-modified RNA vaccine that encodes a prefusion stabilized, membrane-anchored SARS-CoV-2 full-length spike protein. The primary end points were efficacy of the vaccine against laboratory-confirmed Covid-19 and safety. RESULTS: A total of 43,548 participants underwent randomization, of whom 43,448 received injections: 21,720 with BNT162b2 and 21,728 with placebo. There were 8 cases of Covid-19 with onset at least 7 days after the second dose among participants assigned to receive BNT162b2 and 162 cases among those assigned to placebo; BNT162b2 was 95% effective in preventing Covid-19 (95% credible interval, 90.3 to 97.6). Similar vaccine efficacy (generally 90 to 100%) was observed across subgroups defined by age, sex, race, ethnicity, baseline body-mass index, and the presence of coexisting conditions. Among 10 cases of severe Covid-19 with onset after the first dose, 9 occurred in placebo recipients and 1 in a BNT162b2 recipient. The safety profile of BNT162b2 was characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of serious adverse events was low and was similar in the vaccine and placebo groups. CONCLUSIONS: A two-dose regimen of BNT162b2 conferred 95% protection against Covid-19 in persons 16 years of age or older. Safety over a median of 2 months was similar to that of other viral vaccines. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.).

Association between seasonal flu vaccination and COVID-19 among healthcare workers. BACKGROUND: In next fall and winter, SARS-CoV-2 could circulate in parallel with seasonal influenza. The dual epidemics will result in considerable morbidity and mortality; therefore, influenza vaccination may be essential. Recent studies found increased risk of coronavirus in individuals receiving influenza vaccination. AIMS: Our aim is to analyse the association between influenza vaccination and COVID-19 in a population of healthcare workers (HCWs). METHODS: IgG antibodies against SARS-CoV-2 were detected in 3520 HCWs at a large hospital in Northern Italy. For each participant, we collected data on flu immunization status for the last five flu seasons. Logistic regression was used to test associations between seasonal flu vaccination status and a positive serology tests for COVID-19. RESULTS: During the last five flu seasons, 2492 vaccinations were administered. Serology tests were negative for 3196 (91%) HCWs and residents and only 21 (1%) people had an equivocal test (12.0-15.0 AU/mL). Only 128 (4%) people received a diagnosis of COVID-19, with a positive swab test. No flu vaccinations for the last five flu seasons were specifically associated with diagnosis of COVID-19 or with positive results of serology tests. CONCLUSIONS: Flu vaccinations did not appear to be associated with SARS-CoV-2 infection. Influenza vaccination should continue to be recommended for HCWs and for individuals at increased risk for severe illness from respiratory infection.

Covid-19: Oxford vaccine could be 59% effective against asymptomatic infections, analysis shows.

SARS-CoV-2 mRNA Vaccines Foster Potent Antigen-Specific Germinal Center Responses Associated with Neutralizing Antibody Generation. The deployment of effective vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is critical to eradicate the coronavirus disease 2019 (COVID-19) pandemic. Many licensed vaccines confer protection by inducing long-lived plasma cells (LLPCs) and memory B cells (MBCs), cell types canonically generated during germinal center (GC) reactions. Here, we directly compared two vaccine platforms-mRNA vaccines and a recombinant protein formulated with an MF59-like adjuvant-looking for their abilities to quantitatively and qualitatively shape SARS-CoV-2-specific primary GC responses over time. We demonstrated that a single immunization with SARS-CoV-2 mRNA, but not with the recombinant protein vaccine, elicited potent SARS-CoV-2-specific GC B and T follicular helper (Tfh) cell responses as well as LLPCs and MBCs. Importantly, GC responses strongly correlated with neutralizing antibody production. mRNA

vaccines more efficiently induced key regulators of the Tfh cell program and influenced the functional properties of Tfh cells. Overall, this study identifies SARS-CoV-2 mRNA vaccines as strong candidates for promoting robust GC-derived immune responses.
The UK has approved a COVID vaccine - here's what scientists now want to know.
COVID-19 vaccine race: watch your step for cancer patients. Patients with cancer should benefit from COVID-19 vaccination. Some of the most advanced vaccine candidates are mRNAs encapsulated into lipid carriers, and small liposomes are expected to accumulate in tumour tissues through the enhanced and permeation retention effect. However, to what extent solid tumours could take up a significant part of the vaccine dose as well remains unknown. This calls for a careful evaluation of the efficacy of these promising mRNA COVID-19 vaccines administered as lipid carriers for patients with solid tumours, including a possible re-appraisal of the dosing for optimal protection of this specific and frail population.
Definitions for coronavirus disease 2019 reinfection, relapse and PCR re-positivity.
Number of Childhood and Adolescent Vaccinations Administered Before and After the COVID-19 Outbreak in Colorado. This study assesses the association of social distancing due to coronavirus disease 2019 (COVID-19) with immunizations administered by age category (0-2 years, 3-9 years, and 10-17 years) in Colorado.
A Nursing Researcher's Experience in a COVID-19 Vaccine Trial.
A model for the incremental burden of invasive Haemophilus influenzae type b due to a decline of childhood vaccination during the COVID-19 outbreak: A dynamic transmission model in Japan. BACKGROUND: The current coronavirus disease 2019 (COVID-19) outbreak has caused a persistent decline in childhood vaccination coverage, including Haemophilus influenzae type b (Hib) vaccine, in some countries. Our objective was to evaluate the impact of decreased Hib vaccination due to COVID-19 on invasive Hib disease burden in Japan. METHODS: Using a deterministic dynamic transmission model (susceptible-carriage-infection-recovery model), the incidence rates of invasive Hib disease in under 5Â year olds in rapid vaccination recovery and persistent vaccination declined scenarios were compared for the next 10Â years after 2020. The national Hib vaccination rate after the impact of COVID-19 reduced to 87% and 73% in 2020 from approximately 97% each in 2013-2019 for primary and booster doses. RESULTS: While the persistent decline scenarios revealed an increase in invasive Hib disease incidence to 0.50/100,000 children under 5Â years old, the incidence of the rapid recovery scenario slightly increased with a consistent decline of incidence after 2021. The shorter the duration of the decline in vaccination rate was, the smaller the incremental disease burden observed in the model. Compared to the rapid recovery scenario, the permanent decline scenario showed a 296.87 cumulative incremental quality-adjusted life years (QALY) loss for the next 10Â years. CONCLUSIONS: The persistent decline of Hib vaccination rate due to COVID-19 causes an incremental disease burden irrespective of the possible decline of Hib transmission rate by COVID-19 mitigation measures. A rapid recovery of vaccination coverage rate can prevent this possible incremental disease burden.
COVID-19 vaccine trial ethics once we have efficacious vaccines.
Vaccine safety - is the SARS-CoV-2 vaccine any different? Vaccines have changed modern medicine, and are a mainstay in reducing morbidity and mortality from infections. Our research group recently published a study in which we found that vaccines approved by the US Food and Drugs Administration were safe with few clinically important post-approval adverse effects. The current COVID-19 pandemic presents regulators with the unprecedented challenge of balancing a public demand for the rapid development and approval of a safe and effective SARS-CoV-2 vaccine without compromising the strict pre-marketing requirements used for previous vaccines. Here, we review the

approval process and safety profiles of FDA approved vaccines and discuss some of the challenges currently facing the FDA regarding the SARS-CoV-2 vaccine approval.
Inside China's response to COVID.
Frontrunners in the race to develop a SARS-CoV-2 vaccine. Numerous studies continue to be published on the COVID-19 pandemic that is being caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Given the rapidly evolving global response to SARS-CoV-2, here we primarily review the leading COVID-19 vaccine strategies that are currently in PhaseÂ III clinical trials. Nonreplicating viral vector strategies, inactivated virus, recombinant protein subunit vaccines, and nucleic acid vaccine platforms are all being pursued in an effort to combat the infection. Preclinical and clinal trial results of these efforts are examined as well as the characteristics of each vaccine strategy from the humoral and cellular immune responses they stimulate, effects of any adjuvants used, and the potential risks associated with immunization such as antibody-dependent enhancement. A number of promising advancements have been made toward the development of multiple vaccine candidates. Preliminary data now emerging from phaseÂ III clinical trials show encouraging results for the protective efficacy and safety of at least 3 frontrunning candidates. There is hope that one or more will emerge as potent weapons to protect against SARS-CoV-2.
A single-dose live-attenuated YF17D-vectored SARS-CoV-2 vaccine candidate. The expanding pandemic of coronavirus diseaseÂ 2019 (COVID-19) requires the development of safe, efficacious and fast-acting vaccines. Several vaccine platforms are being leveraged for a rapid emergency response(1). Here we describe the development of a candidate vaccine (YF-S0) for severe acute respiratory syndrome coronavirusÂ 2 (SARS-CoV-2) that uses live-attenuated yellow fever 17D (YF17D) vaccine as a vector to express a noncleavable prefusion form of the SARS-CoV-2 spike antigen. We assess vaccine safety, immunogenicity and efficacy in several animal models. YF-S0 has an excellent safety profile and induces high levels of SARS-CoV-2 neutralizing antibodies in hamsters (Mesocricetus auratus), mice (Mus musculus) and cynomolgus macaques (Macaca fascicularis), and-concomitantly-protective immunity against yellow fever virus. Humoral immunity is complemented by a cellular immune response with favourable TÂ helperÂ 1 polarization, as profiled in mice. In a hamster model(2) and in macaques, YF-S0 prevents infection with SARS-CoV-2. Moreover, a single dose conferred protection from lung disease in most of the vaccinated hamsters within as little as 10Â days. Taken together, the quality of the immune responses triggered and the rapid kinetics by which protective immunity can be attained after a single dose warrant further development of this potent SARS-CoV-2 vaccine candidate.
COVID-19 vaccine development: What lessons can we learn from TB? At the time of writing, the SARS-CoV-2 virus has infected more than 49 million people causing more than 1.2 million deaths worldwide since its emergence from Wuhan, China in December 2019. Vaccine development against SARS-CoV-2 has drawn the global attention in order to stop the spread of the virus, with more than 10 vaccines being tested in phase III clinical trials, as of November 2020. However, critical to vaccine development is consideration of the immunological response elicited as well as biological features of the vaccine and both need to be evaluated thoroughly. Tuberculosis is also a major infectious respiratory disease of worldwide prevalence and the vaccine development for tuberculosis has been ongoing for decades. In this review, we highlight some of the common features, challenges and complications in tuberculosis vaccine development, which may also be relevant for, and inform, COVID-19 vaccine development.
Heme oxygenase-1 (HO-1) cytoprotective pathway: A potential treatment strategy against coronavirus disease 2019 (COVID-19)-induced cytokine storm syndrome. The outbreak of coronavirus disease 2019 (COVID-19) requires urgent need for effective treatment. Severe COVID-19 is characterized by a cytokine storm syndrome with subsequent multiple organ failure (MOF) and

acute respiratory distress syndrome (ARDS), which may lead to intensive care unit and increased risk of death. While awaiting a vaccine, targeting COVID-19-induced cytokine storm syndrome appears currently as the efficient strategy to reduce the mortality of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The stress-responsive enzyme, heme oxygenase-1 (HO-1) is largely known to protect against inflammatory response in animal models. HO-1 is induced by hemin, a well-tolerated molecule, used for decades in the treatment of acute intermittent porphyria. Experimental studies showed that hemin-induced HO-1 mitigates cytokine storm and lung injury in mouse models of sepsis and renal ischemia-reperfusion injury. Furthermore, HO-1 may also control numerous viral infections by inhibiting virus replication. In this context, we suggest the hypothesis that HO-1 cytoprotective pathway might be a promising target to control SARS-CoV-2 infection and mitigate COVID-19-induced cytokine storm and subsequent ARDS.
[Lightning fast development of pandemic vaccines in 2020].
Why METH users are at high risk of fatality due to COVID-19 infection?
RBD-Fc-based COVID-19 vaccine candidate induces highly potent SARS-CoV-2 neutralizing antibody response. The pandemic of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has posed serious threats to global health and economy, thus calling for the development of safe and effective vaccines. The receptor-binding domain (RBD) in the spike protein of SARS-CoV-2 is responsible for its binding to angiotensin-converting enzyme 2 (ACE2) receptor. It contains multiple dominant neutralizing epitopes and serves as an important antigen for the development of COVID-19 vaccines. Here, we showed that immunization of mice with a candidate subunit vaccine consisting of SARS-CoV-2 RBD and Fc fragment of human IgG, as an immunopotentiator, elicited high titer of RBD-specific antibodies with robust neutralizing activity against both pseudotyped and live SARS-CoV-2 infections. The mouse antisera could also effectively neutralize infection by pseudotyped SARS-CoV-2 with several natural mutations in RBD and the IgG extracted from the mouse antisera could also show neutralization against pseudotyped SARS-CoV and SARS-related coronavirus (SARSr-CoV). Vaccination of human ACE2 transgenic mice with RBD-Fc could effectively protect mice from the SARS-CoV-2 challenge. These results suggest that SARS-CoV-2 RBD-Fc has good potential to be further developed as an effective and broad-spectrum vaccine to prevent infection of the current SARS-CoV-2 and its mutants, as well as future emerging SARSr-CoVs and re-emerging SARS-CoV.
A Case-Control Study of the 2019 Influenza Vaccine and Incidence of COVID-19 Among Healthcare Workers. PURPOSE: The influenza vaccine is essential in reducing the influenza burden, especially among healthcare workers (HCW). Experimental studies suggest both coronaviruses and influenza viruses engage with the angiotensin-converting enzyme 2 (ACE 2) and tetraspanin antibodies, and that ACE 2 tetraspanin antibodies in turn may inhibit both coronavirus and low-pathogenicity influenza A viruses (LP IAV) infections. This study aims to investigate the potential clinical association between receiving the 2019 influenza vaccine and the incidence of COVID-19 among HCW. METHODS: We designed a case-control study within a hospital setting in Iran when it became a center for treating COVID-19 patients. We collected data and calculated relevant incidence and associative measures among HCW who had received the 2019 influenza vaccine as compared to HCW who had not received the vaccine. RESULTS: Our total sample size was 261 HCW. Of 80 COVID-19 incident cases, three cases had received the influenza vaccine, while 87 of 181 controls had received the vaccine. The odds ratio (OR) and confidence interval (CI) of being vaccinated were 0.04 (95% CI: 0.01 to 0.14) among COVID-19 cases as compared to controls. CONCLUSIONS: Significant findings suggest that the 2019 influenza vaccine may have a protective association against COVID-19 among HCW.
Public needs to prep for vaccine side effects.

Low toxicity and high immunogenicity of an inactivated vaccine candidate against COVID-19 in different animal models. The ongoing COVID-19 pandemic is causing huge impact on health, life, and global economy, which is characterized by rapid spreading of SARS-CoV-2, high number of confirmed cases and a fatality/case rate worldwide reported by WHO. The most effective intervention measure will be to develop safe and effective vaccines to protect the population from the disease and limit the spread of the virus. An inactivated, whole virus vaccine candidate of SARS-CoV-2 has been developed by Wuhan Institute of Biological Products and Wuhan Institute of Virology. The low toxicity, immunogenicity, and immune persistence were investigated in preclinical studies using seven different species of animals. The results showed that the vaccine candidate was well tolerated and stimulated high levels of specific IgG and neutralizing antibodies. Low or no toxicity in three species of animals was also demonstrated in preclinical study of the vaccine candidate. Biochemical analysis of structural proteins and purity analysis were performed. The inactivated, whole virion vaccine was characterized with safe double-inactivation, no use of DNases and high purity. Dosages, boosting times, adjuvants, and immunization schedules were shown to be important for stimulating a strong humoral immune response in animals tested. Preliminary observation in ongoing phase I and II clinical trials of the vaccine candidate in Wuzhi County, Henan Province, showed that the vaccine is well tolerant. The results were characterized by very low proportion and low degree of side effects, high levels of neutralizing antibodies, and seroconversion. These results consistent with the results obtained from preclinical data on the safety.

Challenge Trials: What Are the Ethical Problems? If, as is alleged, challenge trials of vaccines against COVID-19 are likely to save thousands of lives and vastly diminish the economic and social harms of the pandemic while subjecting volunteers to risks that are comparable to kidney donation, then it would seem that the only sensible objection to such trials would be to deny that they have low risks or can be expected to have immense benefits. This essay searches for a philosophical rationale for rejecting challenge trials while supposing that they have huge benefits and relatively low risks. Although it finds some force in objections to challenge trials grounded in the obligations of researchers to limit the harms imposed on some individuals for the benefit of others, it argues that there is no compelling objection to challenge trials of vaccines for COVID-19-if they have the benefits and risks that have been claimed.

Virology, epidemiology, immunology and vaccine development of SARS-CoV-2, update after nine months of pandemic. This International Alliance for Biological Standardization COVID-19 webinar was organized to provide an update on the virology, epidemiology and immunology of, and the vaccine development for SARS-CoV-2, none months after COVID-19 was declared a public health emergency of international concern. It brought together a broad range of international stakeholders, including academia, regulators, funders and industry, with a considerable delegation from low- and middle-income countries.

Indirect benefits are a crucial consideration when evaluating SARS-CoV-2 vaccine candidates.

Factors associated with parents' willingness to enroll their children in trials for COVID-19 vaccination. The coronavirus disease 2019 (COVID-19) pandemic has taken an unprecedented global toll and vaccination is needed to restore healthy living. Timely inclusion of children in vaccination trials is critical. We surveyed caregivers of children seeking care in 17 Emergency Departments (ED) across 6 countries during the peak of the pandemic to identify factors associated with intent to participate in COVID-19 vaccine trials. Questions about child and parent characteristics, COVID-19 expressed concerns and parental attitudes toward participation in a trial were asked.Of 2768 completed surveys, 18.4% parents stated they would enroll their child in a clinical trial for a COVID-19 vaccine and 14.4% would agree to a randomized placebo-controlled study. Factors associated with willingness to participate were parents agreeing to enroll in a COVID-19 vaccine trial themselves (Odds Ratio (OR)

32.9, 95% Confidence Interval (CI) (21.9-51.2)) having an older child (OR 1.0 (1.0-1.01)), having children who received all vaccinations based on their country schedule (OR 2.67 (1.35-5.71)) and parents with high school education or lower (OR 1.79 (1.18-2.74)). Mothers were less likely to enroll their child in a trial (OR 0.68 (0.47-0.97)). Only one fifth of families surveyed will consider enrolling their child in a vaccine trial. Parental interest in participation, history of vaccinating their child, and the child being older all are associated with parents allowing their child to participate in a COVID vaccine trial. This information may help decision-makers and researchers shape their strategies for trial design and participation engagement in upcoming COVID19 vaccination trials.

The legacy of MeNZB and possible implications for COVID-19 vaccination. It is now over a decade since the meningococcal B vaccine, MeNZB, was in routine use in New Zealand. From July 2004 until June 2008 it was administered in a three-dose schedule to over a million individuals, aged six weeks to 20 years, to provide protection against the epidemic strain of group B Meningococci. The cost of the campaign, including the development of the vaccine was substantial, in excess of $200M, but it contributed to a reduced incidence of meningococcal infections along with a reduction in morbidity and mortality. The campaign led to the development of a national immunisation register (NIR), which is still in existence today. As well as considering the legacies of the MeNZB vaccination programme, this paper examines whether there are any lessons to be learned, specifically concerning active vaccine safety monitoring, which may be important if, and when, a COVID-19 vaccine is developed and a national immunisation campaign instituted.

Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. BACKGROUND: Older adults (aged â‰¥70 years) are at increased risk of severe disease and death if they develop COVID-19 and are therefore a priority for immunisation should an efficacious vaccine be developed. Immunogenicity of vaccines is often worse in older adults as a result of immunosenescence. We have reported the immunogenicity of a novel chimpanzee adenovirus-vectored vaccine, ChAdOx1 nCoV-19 (AZD1222), in young adults, and now describe the safety and immunogenicity of this vaccine in a wider range of participants, including adults aged 70 years and older. METHODS: In this report of the phase 2 component of a single-blind, randomised, controlled, phase 2/3 trial (COV002), healthy adults aged 18 years and older were enrolled at two UK clinical research facilities, in an age-escalation manner, into 18-55 years, 56-69 years, and 70 years and older immunogenicity subgroups. Participants were eligible if they did not have severe or uncontrolled medical comorbidities or a high frailty score (if aged â‰¥65 years). First, participants were recruited to a low-dose cohort, and within each age group, participants were randomly assigned to receive either intramuscular ChAdOx1 nCoV-19 (2Â·2â€‾Ã—â€‾10(10) virus particles) or a control vaccine, MenACWY, using block randomisation and stratified by age and dose group and study site, using the following ratios: in the 18-55 years group, 1:1 to either two doses of ChAdOx1 nCoV-19 or two doses of MenACWY; in the 56-69 years group, 3:1:3:1 to one dose of ChAdOx1 nCoV-19, one dose of MenACWY, two doses of ChAdOx1 nCoV-19, or two doses of MenACWY; and in the 70 years and older, 5:1:5:1 to one dose of ChAdOx1 nCoV-19, one dose of MenACWY, two doses of ChAdOx1 nCoV-19, or two doses of MenACWY. Prime-booster regimens were given 28 days apart. Participants were then recruited to the standard-dose cohort (3Â·5-6Â·5â€‾Ã—â€‾10(10) virus particles of ChAdOx1 nCoV-19) and the same randomisation procedures were followed, except the 18-55 years group was assigned in a 5:1 ratio to two doses of ChAdOx1 nCoV-19 or two doses of MenACWY. Participants and investigators, but not staff administering the vaccine, were masked to vaccine allocation. The specific objectives of this report were to assess the safety and humoral and cellular immunogenicity of a single-dose and two-dose schedule in adults older than 55 years. Humoral responses at baseline and after each vaccination until 1 year after the booster were assessed using an in-house standardised

ELISA, a multiplex immunoassay, and a live severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) microneutralisation assay (MNA(80)). Cellular responses were assessed using an ex-vivo IFN-Î³ enzyme-linked immunospot assay. The coprimary outcomes of the trial were efficacy, as measured by the number of cases of symptomatic, virologically confirmed COVID-19, and safety, as measured by the occurrence of serious adverse events. Analyses were by group allocation in participants who received the vaccine. Here, we report the preliminary findings on safety, reactogenicity, and cellular and humoral immune responses. This study is ongoing and is registered with ClinicalTrials.gov, NCT04400838, and ISRCTN, 15281137. FINDINGS: Between May 30 and Aug 8, 2020, 560 participants were enrolled: 160 aged 18-55 years (100 assigned to ChAdOx1 nCoV-19, 60 assigned to MenACWY), 160 aged 56-69 years (120 assigned to ChAdOx1 nCoV-19: 40 assigned to MenACWY), and 240 aged 70 years and older (200 assigned to ChAdOx1 nCoV-19: 40 assigned to MenACWY). Seven participants did not receive the boost dose of their assigned two-dose regimen, one participant received the incorrect vaccine, and three were excluded from immunogenicity analyses due to incorrectly labelled samples. 280 (50%) of 552 analysable participants were female. Local and systemic reactions were more common in participants given ChAdOx1 nCoV-19 than in those given the control vaccine, and similar in nature to those previously reported (injection-site pain, feeling feverish, muscle ache, headache), but were less common in older adults (aged â‰¥56 years) than younger adults. In those receiving two standard doses of ChAdOx1 nCoV-19, after the prime vaccination local reactions were reported in 43 (88%) of 49 participants in the 18-55 years group, 22 (73%) of 30 in the 56-69 years group, and 30 (61%) of 49 in the 70 years and older group, and systemic reactions in 42 (86%) participants in the 18-55 years group, 23 (77%) in the 56-69 years group, and 32 (65%) in the 70 years and older group. As of Oct 26, 2020, 13 serious adverse events occurred during the study period, none of which were considered to be related to either study vaccine. In participants who received two doses of vaccine, median anti-spike SARS-CoV-2 IgG responses 28 days after the boost dose were similar across the three age cohorts (standard-dose groups: 18-55 years, 20â€ˆ713 arbitrary units [AU]/mL [IQR 13â€ˆ898-33â€ˆ550], n=39; 56-69 years, 16â€ˆ170 AU/mL [10â€ˆ233-40â€ˆ353], n=26; and â‰¥70 years 17â€ˆ561 AU/mL [9705-37â€ˆ796], n=47; p=0Â·68). Neutralising antibody titres after a boost dose were similar across all age groups (median MNA(80) at day 42 in the standard-dose groups: 18-55 years, 193 [IQR 113-238], n=39; 56-69 years, 144 [119-347], n=20; and â‰¥70 years, 161 [73-323], n=47; p=0Â·40). By 14 days after the boost dose, 208 (>99%) of 209 boosted participants had neutralising antibody responses. T-cell responses peaked at day 14 after a single standard dose of ChAdOx1 nCoV-19 (18-55 years: median 1187 spot-forming cells [SFCs] per million peripheral blood mononuclear cells [IQR 841-2428], n=24; 56-69 years: 797 SFCs [383-1817], n=29; and â‰¥70 years: 977 SFCs [458-1914], n=48). INTERPRETATION: ChAdOx1 nCoV-19 appears to be better tolerated in older adults than in younger adults and has similar immunogenicity across all age groups after a boost dose. Further assessment of the efficacy of this vaccine is warranted in all age groups and individuals with comorbidities. FUNDING: UK Research and Innovation, National Institutes for Health Research (NIHR), Coalition for Epidemic Preparedness Innovations, NIHR Oxford Biomedical Research Centre, Thames Valley and South Midlands NIHR Clinical Research Network, and AstraZeneca.

How to Investigate a Serious Adverse Event Reported During a Clinical Trial for a COVID-19 Vaccine.

A review of vaccine effects on women in light of the COVID-19 pandemic. The pandemic situation triggered by the spread of COVID-19 has caused great harm worldwide. More than six million people have been infected, and more than 360,000 of them have died. This is the worst catastrophe suffered by mankind in recent history. In the face of this severe disaster, people all over the world are frightened of the prospect of facing an outbreak or an annual recurrence. However, the development of a vaccine will help control the impact of COVID-19. Women in particular have been more seriously

affected by the pandemic. Since the pressure and physical load they suffer are often greater than what men endure, women are more threatened by COVID-19. Though women have a poorer quality of life and work and face worse economic conditions, they also tend to have better physiological immunity than men, which can ease the effect of COVID-19. The early development of a vaccine against COVID-19 is an important issue that must take into consideration women's better immune response to the virus along with the technique of hormone regulation. Relevant research has been conducted on female-specific vaccines in the past, and women's issues were considered during those clinical trials to ensure that complications and antibody responses were positive and effective in women. National policies should also propose good strategies for women to be vaccinated. This could improve consciousness, give women a better vaccination experience, enhance their willingness to vaccinate, and protect them from COVID-19 infection.

Vaccines to prevent COVID-19: a protocol for a living systematic review with network meta-analysis including individual patient data (The LIVING VACCINE Project). BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causes coronavirus disease 2019 (COVID-19) which has rapidly spread worldwide. Several human randomized clinical trials assessing potential vaccines are currently underway. There is an urgent need for a living systematic review that continuously assesses the beneficial and harmful effects of all available vaccines for COVID-19. METHODS/DESIGN: We will conduct a living systematic review based on searches of major medical databases (e.g., MEDLINE, EMBASE, CENTRAL) and clinical trial registries from their inception onwards to identify relevant randomized clinical trials. We will update the literature search once a week to continuously assess if new evidence is available. Two review authors will independently extract data and conduct risk of bias assessments. We will include randomized clinical trials comparing any vaccine aiming to prevent COVID-19 (including but not limited to messenger RNA; DNA; non-replicating viral vector; replicating viral vector; inactivated virus; protein subunit; dendritic cell; other vaccines) with any comparator (placebo; "active placebo;" no intervention; standard care; an "active" intervention; another vaccine for COVID-19) for participants in all age groups. Primary outcomes will be all-cause mortality; a diagnosis of COVID-19; and serious adverse events. Secondary outcomes will be quality of life and non-serious adverse events. The living systematic review will include aggregate data meta-analyses, trial sequential analyses, network meta-analyses, and individual patient data meta-analyses. Within-study bias will be assessed using Cochrane risk of bias tool. The Grading of Recommendations, Assessment, Development and Evaluations (GRADE) and Confidence in Network Meta-Analysis (CINeMA) approaches will be used to assess certainty of evidence. Observational studies describing harms identified during the search for trials will also be included and described and analyzed separately. DISCUSSION: COVID-19 has become a pandemic with substantial mortality. A living systematic review assessing the beneficial and harmful effects of different vaccines is urgently needed. This living systematic review will regularly inform best practice in vaccine prevention and clinical research of this highly prevalent disease. SYSTEMATIC REVIEW REGISTRATION: PROSPERO CRD42020196492.

Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine in healthy adults aged 18-59 years: a randomised, double-blind, placebo-controlled, phase 1/2 clinical trial. BACKGROUND: With the unprecedented morbidity and mortality associated with the COVID-19 pandemic, a vaccine against COVID-19 is urgently needed. We investigated CoronaVac (Sinovac Life Sciences, Beijing, China), an inactivated vaccine candidate against COVID-19, containing inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), for its safety, tolerability and immunogenicity. METHODS: In this randomised, double-blind, placebo-controlled, phase 1/2 clinical trial, healthy adults aged 18-59 years were recruited from the community in Suining County of Jiangsu province, China. Adults with SARS-CoV-2 exposure or infection history, with axillary temperature

above 37Â·0Â°C, or an allergic reaction to any vaccine component were excluded. The experimental vaccine for the phase 1 trial was manufactured using a cell factory process (CellSTACK Cell Culture Chamber 10, Corning, Wujiang, China), whereas those for the phase 2 trial were produced through a bioreactor process (ReadyToProcess WAVE 25, GE, Umea, Sweden). The phase 1 trial was done in a dose-escalating manner. At screening, participants were initially separated (1:1), with no specific randomisation, into two vaccination schedule cohorts, the days 0 and 14 vaccination cohort and the days 0 and 28 vaccination cohort, and within each cohort the first 36 participants were assigned to block 1 (low dose CoronaVac [3 Î¼g per 0Â·5 mL of aluminium hydroxide diluent per dose) then another 36 were assigned to block 2 (high-dose Coronavc [6 Î¼g per 0Â·5 mL of aluminium hydroxide diluent per dse]). Within each block, participants were randomly assigned (2:1), using block randomisation with a block size of six, to either two doses of CoronaVac or two doses of placebo. In the phase 2 trial, at screening, participants were initially separated (1:1), with no specific randomisation, into the days 0 and 14 vaccination cohort and the days 0 and 28 vaccination cohort, and participants were randomly assigned (2:2:1), using block randomisation with a block size of five, to receive two doses of either low-dose CoronaVac, high-dose CoronaVac, or placebo. Participants, investigators, and laboratory staff were masked to treatment allocation. The primary safety endpoint was adverse reactions within 28 days after injection in all participants who were given at least one dose of study drug (safety population). The primary immunogenic outcome was seroconversion rates of neutralising antibodies to live SARS-CoV-2 at day 14 after the last dose in the days 0 and 14 cohort, and at day 28 after the last dose in the days 0 and 28 cohort in participants who completed their allocated two-dose vaccination schedule (per-protocol population). This trial is registered with ClinicalTrials.gov, NCT04352608, and is closed to accrual. FINDINGS: Between April 16 and April 25, 2020, 144 participants were enrolled in the phase 1 trial, and between May 3 and May 5, 2020, 600 participants were enrolled in the phase 2 trial. 743 participants received at least one dose of investigational product (n=143 for phase 1 and n=600 for phase 2; safety population). In the phase 1 trial, the incidence of adverse reactions for the days 0 and 14 cohort was seven (29%) of 24 participants in the 3 ug group, nine (38%) of 24 in the 6 Î¼g group, and two (8%) of 24 in the placebo group, and for the days 0 and 28 cohort was three (13%) of 24 in the 3 Î¼g group, four (17%) of 24 in the 6 Î¼g group, and three (13%) of 23 in the placebo group. The seroconversion of neutralising antibodies on day 14 after the days 0 and 14 vaccination schedule was seen in 11 (46%) of 24 participants in the 3 Î¼g group, 12 (50%) of 24 in the 6 Î¼g group, and none (0%) of 24 in the placebo group; whereas at day 28 after the days 0 and 28 vaccination schedule, seroconversion was seen in 20 (83%) of 24 in the 3 Î¼g group, 19 (79%) of 24 in the 6 Î¼g group, and one (4%) of 24 in the placebo group. In the phase 2 trial, the incidence of adverse reactions for the days 0 and 14 cohort was 40 (33%) of 120 participants in the 3 Î¼g group, 42 (35%) of 120 in the 6 Î¼g group, and 13 (22%) of 60 in the placebo group, and for the days 0 and 28 cohort was 23 (19%) of 120 in the 3 Î¼g group, 23 (19%) of 120 in the 6 Î¼g group, and 11 (18%) of 60 for the placebo group. Seroconversion of neutralising antibodies was seen for 109 (92%) of 118 participants in the 3 Î¼g group, 117 (98%) of 119 in the 6 Î¼g group, and two (3%) of 60 in the placebo group at day 14 after the days 0 and 14 schedule; whereas at day 28 after the days 0 and 28 schedule, seroconversion was seen in 114 (97%) of 117 in the 3 Î¼g group, 118 (100%) of 118 in the 6 Î¼g group, and none (0%) of 59 in the placebo group. INTERPRETATION: Taking safety, immunogenicity, and production capacity into account, the 3 Î¼g dose of CoronaVac is the suggested dose for efficacy assessment in future phase 3 trials. FUNDING: Chinese National Key Research and Development Program and Beijing Science and Technology Program.

Implementation of a Pooled Surveillance Testing Program for Asymptomatic SARS-CoV-2 Infections on a College Campus - Duke University, Durham, North Carolina, August 2-October 11, 2020. On

university campuses and in similar congregate environments, surveillance testing of asymptomatic persons is a critical strategy (1,2) for preventing transmission of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19). All students at Duke University, a private research university in Durham, North Carolina, signed the Duke Compact (3), agreeing to observe mandatory masking, social distancing, and participation in entry and surveillance testing. The university implemented a five-to-one pooled testing program for SARS-CoV-2 using a quantitative, in-house, laboratory-developed, real-time reverse transcription-polymerase chain reaction (RT-PCR) test (4,5). Pooling of specimens to enable large-scale testing while minimizing use of reagents was pioneered during the human immunodeficiency virus pandemic (6). A similar methodology was adapted for Duke University's asymptomatic testing program. The baseline SARS-CoV-2 testing plan was to distribute tests geospatially and temporally across on- and off-campus student populations. By September 20, 2020, asymptomatic testing was scaled up to testing targets, which include testing for residential undergraduates twice weekly, off-campus undergraduates one to two times per week, and graduate students approximately once weekly. In addition, in response to newly identified positive test results, testing was focused in locations or within cohorts where data suggested an increased risk for transmission. Scale-up over 4 weeks entailed redeploying staff members to prepare 15 campus testing sites for specimen collection, developing information management tools, and repurposing laboratory automation to establish an asymptomatic surveillance system. During August 2-October 11, 68,913 specimens from 10,265 graduate and undergraduate students were tested. Eighty-four specimens were positive for SARS-CoV-2, and 51% were among persons with no symptoms. Testing as a result of contact tracing identified 27.4% of infections. A combination of risk-reduction strategies and frequent surveillance testing likely contributed to a prolonged period of low transmission on campus. These findings highlight the importance of combined testing and contact tracing strategies beyond symptomatic testing, in association with other preventive measures. Pooled testing balances resource availability with supply-chain disruptions, high throughput with high sensitivity, and rapid turnaround with an acceptable workload.

Development of CpG-adjuvanted stable prefusion SARS-CoV-2 spike antigen as a subunit vaccine against COVID-19. The COVID-19 pandemic is a worldwide health emergency which calls for an unprecedented race for vaccines and treatment. In developing a COVID-19 vaccine, we applied technology previously used for MERS-CoV to produce a prefusion-stabilized SARS-CoV-2 spike protein, S-2P. To enhance immunogenicity and mitigate the potential vaccine-induced immunopathology, CpG 1018, a Th1-biasing synthetic toll-like receptor 9 (TLR9) agonist was selected as an adjuvant candidate. S-2P in combination with CpG 1018 and aluminum hydroxide (alum) was found to be the most potent immunogen and induced high titer of neutralizing antibodies in sera of immunized mice against pseudotyped lentivirus reporter or live wild-type SARS-CoV-2. In addition, the antibodies elicited were able to cross-neutralize pseudovirus containing the spike protein of the D614G variant, indicating the potential for broad spectrum protection. A marked Th1 dominant response was noted from cytokines secreted by splenocytes of mice immunized with CpG 1018 and alum. No vaccine-related serious adverse effects were found in the dose-ranging study in rats administered single- or two-dose regimens of S-2P combined with CpG 1018 alone or CpG 1018 with alum. These data support continued development of CHO-derived S-2P formulated with CpG 1018 and alum as a candidate vaccine to prevent COVID-19 disease.

Audio Interview: Covid-19 in Europe and New Information on Vaccines.

Ensuring vaccine safety.

50 policies, 1 pandemic, 500,000 deaths: Associations between state-level COVID-19 testing recommendations, tests per capita, undercounted deaths, vaccination policies, and doses per capita in the United States. BACKGROUND: State health departments have been responsible for

prioritizing and allocating SARS-CoV-2 tests and vaccines. Testing and vaccination recommendations in the United States varied by state and over time, as did vaccine rollouts, COVID-19 cases, and estimates of excess mortality. METHODS: We compiled data about COVID-19 testing, cases, and deaths, and excess pneumonia + influenza + COVID-19 deaths to assess relationships between testing recommendations, per capita tests performed, epidemic intensity, and excess mortality during the early months of the COVID-19 pandemic in the United States. We compiled further data about state-level SARS-CoV-2 vaccination policies and doses administered during the early months of the vaccine rollout. RESULTS: As of July 2020, 16 states recommended testing asymptomatic members of the general public. The rate of COVID-19 tests reported in each state correlated with more inclusive testing recommendations and with higher epidemic intensity. Higher per capita testing was associated with more complete reporting of COVID-19 deaths, which is a fundamental requirement for analyzing the pandemic. Testing per capita during the first three months was associated with vaccination per capita in the first three months of rollout. Per capita vaccine doses in each state were not associated with adherence to national guidelines. CONCLUSIONS: Reported deaths due to COVID-19 likely represent an undercount of the true burden of the pandemic. States that struggled with testing rollout have also frequently struggled with vaccine rollout. Coordinated, consistent guidelines for COVID-19 testing and vaccine administration should be a high priority for state and national health systems.

Immunotherapeutics for Covid-19 and post vaccination surveillance. Severe acute respiratory syndrome coronavirus (SARS-CoV-2) has emerged as a pandemic and named as novel coronavirus disease (nCOVID-19). SARS-CoV-2 is different from other known viruses due to multiple mutations on the sites of nonstructural proteins (NSP) 2 and 3, and the varying nature of virulence between different persons. Immunotherapies such as vaccines and monoclonal antibodies have a protective effect on the patients bringing them to the front of the line of potential treatments. The present review intends to cover the development of 20 different vaccine candidates categorized under live attenuated vaccines, inactivated vaccines, subunit vaccines, viral vector-based vaccines, and nucleic acid vaccines. Formulation of these vaccine candidates by various companies in collaboration with global organizations and their status of clinical trials were addressed. On the other hand, various approaches for post-vaccination surveillance using nucleic acid and protein biomarkers imbued on suitable platforms were also highlighted to sum up the immune therapeutics for Covid-19.

COVID vaccine excitement builds as Moderna reports third positive result.

Association between Exposure to Influenza Vaccination and COVID-19 Diagnosis and Outcomes. We explored whether influenza vaccination (IV) affects susceptibility to SARS-CoV-2 infection and clinical outcomes in COVID-19 patients in 17,608 residents of the Italian province of Reggio Emilia undergoing a SARS-CoV-2 test. Exposure to IV was ascertained and the strength of the association with SARS-CoV-2 positivity expressed with odds ratios (OR). Rates of hospitalisations and death in those found positive were assessed and hazard ratios (HR) were estimated. The prevalence of IV was 34.3% in the 4885 SARS-CoV-2 positive and 29.5% in the 12,723 negative subjects, but the adjusted OR indicated that vaccinated individuals had a lower probability of testing positive (OR = 0.89; 95% CI 0.80-0.99). Among the 4885 positive individuals, 1676 had received IV. After adjusting for confounding factors, there was no association between IV and hospitalisation (1.00; 95% CI 0.84-1.29) or death (HR = 1.14; 95% CI 0.95-1.37). However, for patients age â‰¥65 vaccinated close to the SARS-CoV-2 outbreak, HRs were 0.66 (95% CI: 0.44-0.98) and 0.70 (95% CI 0.50-1.00), for hospitalisation and death, respectively. In this study, IV was associated with a lower probability of COVID-19 diagnosis. In COVID-19 patients, overall, IV did not affect outcomes, although a protective effect was observed for the elderly receiving IV almost in parallel with the SARS-CoV-2 outbreak.

These findings provide reassurance in planning IV campaigns and underscore the need for exploring further their impact on COVID-19.
T cell immunity to SARS-CoV-2 following natural infection and vaccination. SARS-CoV-2 first emerged in the human population in late 2019 in Wuhan, China, and in a matter of months, spread across the globe resulting in the Coronavirus Disease 19 (COVID-19) pandemic and substantial economic fallout. SARS-CoV-2 is transmitted between humans via respiratory particles, with infection presenting a spectrum of clinical manifestations ranging from asymptomatic to respiratory failure with multiorgan dysfunction and death in severe cases. Prior experiences with human pathogenic coronaviruses and respiratory virus diseases in general have revealed an important role for cellular immunity in limiting disease severity. Here, we review some of the key mechanisms underlying cell-mediated immunity to respiratory viruses and summarize our current understanding of the functional capacity and role of SARS-CoV-2-specific T cells following natural infection and vaccination.
SARS-CoV-2 infection in patients with a normal or abnormal liver. Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), a novel coronavirus causing coronavirus disease 19 (COVID-19), with an estimated 22 million people infected worldwide so far although involving primarily the respiratory tract, has a remarkable tropism for the liver and the biliary tract. Patients with SARS-CoV-2 infection and no antecedent liver disease may display evidence of cytolytic liver damage, proportional to the severity of COVID-19 but rarely of clinical significance. The mechanism of hepatocellular injury is unclear and possibly multifactorial. The clinical impact of SARS-CoV-2 infection in patients with underlying chronic liver disease, a cohort whose global size is difficult to estimate, has been assessed appropriately only recently and data are still evolving. Patients with cirrhosis are at higher risk of developing severe COVID-19 and worse liver-related outcomes as compared to those with non-cirrhotic liver disease. OLT patients have an intermediate risk. Specific interventions in order to reduce the risk of transmission of infection among this high-risk population have been outlined by international societies, together with recommendations for modified treatment and follow-up regimens during the COVID-19 pandemic. When a vaccine against SARS-CoV-2 becomes available, patients with fibrotic liver disease and those with OLT should be considered as prime targets for prophylaxis of COVID-19, as all other highly susceptible subjects.
Digging the rabbit hole, COVID-19 edition: anti-vaccine themes and the discourse around COVID-19. This article draws on a broadcast popular among the anti-vaccine community to map out six themes used by the broadcast to mislead viewers about COVID-19. The themes are the claim that "they" - government and pharma - are lying to you, claims that COVID-19 is an excuse to remove civil liberties, viewing everyone as an expert, claiming that science cannot save us, skewing the science, and a claim that "they" are out to harm the viewers. The article points out that similar themes are used to mislead followers with anti-vaccine information. It highlights the concern that these themes will not only mislead people who are already anti-vaccine about the pandemic, but may draw in people who are not anti-vaccine but are seeking information about COVID-19, and suggests some options for dealing with the misinformation. Scientists benefit from understanding these claims, as we are often tasked with providing rebuttals to this misinformation.
COVID vaccination logistics: five steps to take now.
The issues of individualized medicine and pharmacovigilance: A consideration of COVID-19 and vaccination.
A Review of the Progress and Challenges of Developing a Vaccine for COVID-19. A novel coronavirus, which has been designated as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was first detected in December 2019 in Wuhan China and causes the highly infectious disease referred to as COVID-19. COVID-19 has now spread worldwide to become a global pandemic affecting over 24 million people as of August 26th, 2020 and claimed the life of more than 800,000 people

worldwide. COVID-19 is asymptomatic for some individuals and for others it can cause symptoms ranging from flu-like to acute respiratory distress syndrome (ARDS), pneumonia and death. Although it is anticipated that an effective vaccine will be available to protect against COVID-19, at present the world is relying on social distancing and hygiene measures and repurposed drugs. There is a worldwide effort to develop an effective vaccine against SARS-CoV-2 and, as of late August 2020, there are 30 vaccines in clinical trials with over 200 in various stages of development. This review will focus on the eight vaccine candidates that entered Phase 1 clinical trials in mid-May, including AstraZeneca/Oxford's AZD1222, Moderna's mRNA-1273 and Sinovac's CoronaVac vaccines, which are currently in advanced stages of vaccine development. In addition to reviewing the different stages of vaccine development, vaccine platforms and vaccine candidates, this review also discusses the biological and immunological basis required of a SARS-CoV-2 vaccine, the importance of a collaborative international effort, the ethical implications of vaccine development, the efficacy needed for an immunogenic vaccine, vaccine coverage, the potential limitations and challenges of vaccine development. Although the demand for a vaccine far surpasses the production capacity, it will be beneficial to have a limited number of vaccines available for the more vulnerable population by the end of 2020 and for the rest of the global population by the end of 2021.

Shelter from the cytokine storm: pitfalls and prospects in the development of SARS-CoV-2 vaccines for an elderly population. The SARS-CoV-2 pandemic urgently calls for the development of effective preventive tools. COVID-19 hits greatly the elder and more fragile fraction of the population boosting the evergreen issue of the vaccination of older people. The development of a vaccine against SARS-CoV-2 tailored for the elderly population faces the challenge of the poor immune responsiveness of the older population due to immunosenescence, comorbidities, and pharmacological treatments. Moreover, it is likely that the inflammaging phenotype associated with age could both influence vaccination efficacy and exacerbate the risk of COVID-19-related "cytokine storm syndrome" with an overlap between the factors which impact vaccination effectiveness and those that boost virulence and worsen the prognosis of SARS-CoV-2 infection. The complex and still unclear immunopathological mechanisms of SARS-CoV-2 infection, together with the progressive age-related decline of immune responses, and the lack of clear correlates of protection, make the design of vaccination strategies for older people extremely challenging. In the ongoing effort in vaccine development, different SARS-CoV-2 vaccine candidates have been developed, tested in pre-clinical and clinical studies and are undergoing clinical testing, but only a small fraction of these are currently being tested in the older fraction of the population. Recent advances in systems biology integrating clinical, immunologic, and omics data can help to identify stable and robust markers of vaccine response and move towards a better understanding of SARS-CoV-2 vaccine responses in the elderly.

COVID-19 Vaccines Currently under Preclinical and Clinical Studies, and Associated Antiviral Immune Response. With a death toll of over one million worldwide, the COVID-19 pandemic caused by SARS-CoV-2 has become the most devastating humanitarian catastrophe in recent decades. The fear of acquiring infection and spreading to vulnerable people has severely impacted society's socio-economic status. To put an end to this growing number of infections and deaths as well as to switch from restricted to everyday living, an effective vaccine is desperately needed. As a result, enormous efforts have been made globally to develop numerous vaccine candidates in a matter of months. Currently, over 30 vaccine candidates are under assessment in clinical trials, with several undergoing preclinical studies. Here, we reviewed the major vaccine candidates based on the specific vaccine platform utilized to develop them. We also discussed the immune responses generated by these candidates in humans and preclinical models to determine vaccine safety, immunogenicity, and efficacy. Finally, immune responses induced in recovered COVID-19 patients and their possible vaccine development implications were also briefly reviewed.

[COVID-19 and vaccination: a global disruption]. Coronavirus disease (COVID)-19 is an emerging pandemic infection whose significant ability to spread in a naÃ¯ve population is well established. The first response of states to the COVID-19 outbreak was to impose lock-down and social barrier measures, such as wearing a surgical mask or social distancing. One of the consequences of this pandemic in terms of public health was the suspension or slowdown of infant vaccination campaigns, in almost all countries. The indirect effects of COVID-19 may therefore weigh on mortality from measles and polio in developing countries. In this pandemic chaos, the only hope lies in the rapid development of an effective vaccine against severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2). However, acceptance of this vaccine has not yet been won, as beyond the many unknowns that will inevitably weigh around such rapid development, skepticism among vaccine hesitants is growing.

Opinion: For now, it's unethical to use human challenge studies for SARS-CoV-2 vaccine development.

The estimated impact of decreased childhood vaccination due to COVID-19 using a dynamic transmission model of mumps in Japan. The exact impact of the decline in childhood vaccination coverage during COVID-19 outbreak has not been estimated for any vaccine-preventable diseases. Our objective was to evaluate the impact of decreased mumps vaccination due to COVID-19 on the disease burden of mumps in Japan. Using a previously validated dynamic transmission model of mumps infection in Japan, the incidence rate of mumps over the next 30Â y since July 2020 was estimated. The estimated average incidences were 269.1, 302.0, and 455.4/100,000 person-years in rapid recovery, slow recovery, and permanent decline scenarios. Compared with the rapid recovery scenario, the incremental number of mumps cases, total costs, and QALYs loss over the next 30Â y were 6.53 million cases, 2.63 billion USD, and 49,246 for the permanent decline scenario, respectively. In conclusion, the persistent decline of mumps vaccination rate as an impact of COVID-19 causes a significant incremental disease burden of mumps, which is consistent irrespective of the possible decline of transmission rate of mumps infection, unless the rapid recovery of coverage rate is achieved. The immediate measures to advocate the vaccination program is essential to mitigate the incremental disease burden in the COVID-19 period.

The Association between Influenza Vaccination and the Risk of SARS-CoV-2 Infection, Severe Illness, and Death: A Systematic Review of the Literature. We reviewed the association between seasonal influenza vaccination and the risk of SARS-CoV-2 infection or complicated illness or poor outcome (e.g., severe disease, need for hospitalization or ventilatory support, or death) among COVID-19 patients. None of the studies that were reviewed (n = 12) found a significant increase in the risk of infection or in the illness severity or lethality, and some reported significantly inverse associations. Our findings support measures aimed at raising influenza vaccination coverage in the coming months.

No-Fault Compensation for Vaccine Injury - The Other Side of Equitable Access to Covid-19 Vaccines.

Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease. AIMS OF THE STUDY: Patient comprehension is a critical part of meeting medical ethics standards of informed consent in study designs. The aim of the study was to determine if sufficient literature exists to require clinicians to disclose the specific risk that COVID-19 vaccines could worsen disease upon exposure to challenge or circulating virus. METHODS USED TO CONDUCT THE STUDY: Published literature was reviewed to identify preclinical and clinical evidence that COVID-19 vaccines could worsen disease upon exposure to challenge or circulating virus. Clinical trial protocols for COVID-19 vaccines were reviewed to determine if risks were properly disclosed. RESULTS OF THE STUDY: COVID-19 vaccines designed to elicit neutralising antibodies may sensitise vaccine recipients to more severe disease than if they were not vaccinated. Vaccines for SARS, MERS and RSV have never been approved, and the data generated in the development and testing of these vaccines

suggest a serious mechanistic concern: that vaccines designed empirically using the traditional approach (consisting of the unmodified or minimally modified coronavirus viral spike to elicit neutralising antibodies), be they composed of protein, viral vector, DNA or RNA and irrespective of delivery method, may worsen COVID-19 disease via antibody-dependent enhancement (ADE). This risk is sufficiently obscured in clinical trial protocols and consent forms for ongoing COVID-19 vaccine trials that adequate patient comprehension of this risk is unlikely to occur, obviating truly informed consent by subjects in these trials. CONCLUSIONS DRAWN FROM THE STUDY AND CLINICAL IMPLICATIONS: The specific and significant COVID-19 risk of ADE should have been and should be prominently and independently disclosed to research subjects currently in vaccine trials, as well as those being recruited for the trials and future patients after vaccine approval, in order to meet the medical ethics standard of patient comprehension for informed consent.
Is there a role for childhood vaccination against COVID-19? Tremendous efforts are undertaken to quickly develop COVID-19 vaccines that protect vulnerable individuals from severe disease and thereby limit the health and socioeconomic impacts of the pandemic. Potential candidates are tested in adult populations, and questions arise of whether COVID-19 vaccination should be implemented in children. Compared to adults, the incidence and disease severity of COVID-19 are low in children, and despite their infectiveness, their role in disease propagation is limited. Therefore, COVID-19 vaccines will need to have fully demonstrated safety and efficacy in preventing not only complications but transmission to justify childhood vaccination. This work summarizes currently tested vaccine platforms and debates practical and ethical considerations for their potential use in children. It also discusses the already deleterious effect of the pandemic on routine childhood vaccine coverage, calling for action to limit the risks for a rise in vaccine-preventable diseases.
Epidemiologic Evaluation and Risk Communication Regarding the Recent Reports of Sudden Death after Influenza Vaccination in the COVID-19 Pandemic.
The Interaction of Natural and Vaccine-Induced Immunity with Social Distancing Predicts the Evolution of the COVID-19 Pandemic. The existence and nature of immunity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are currently unknown; however, neutralizing antibodies are thought to play the major role and data from studying other coronaviruses suggest that partial clinical immunity lasting up to 1 year will occur postinfection. We show how immunity, depending on its durability, may work with current social practices to limit the spread of the virus. We further show that a vaccine that is 50% effective and taken by 50% of the population will prevent further loss of life, providing that social distancing is still practiced and that immunity does not wane quickly.IMPORTANCE The ability of our society to function effectively moving forward will depend on how the spread of the SARS-CoV-2 virus is contained. Immunity to the virus will be critical to this equation.
Clinical Endpoints for Evaluating Efficacy in COVID-19 Vaccine Trials. Several vaccine candidates to protect against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection or coronavirus disease 2019 (COVID-19) have entered or will soon enter large-scale, phase 3, placebo-controlled randomized clinical trials. To facilitate harmonized evaluation and comparison of the efficacy of these vaccines, a general set of clinical endpoints is proposed, along with considerations to guide the selection of the primary endpoints on the basis of clinical and statistical reasoning. The plausibility that vaccine protection against symptomatic COVID-19 could be accompanied by a shift toward more SARS-CoV-2 infections that are asymptomatic is highlighted, as well as the potential implications of such a shift.
Rabies virus-based COVID-19 vaccine CORAVAXâ„¢ induces high levels of neutralizing antibodies against SARS-CoV-2. The recently emerged coronavirus SARS-CoV-2, the causative agent of COVID-19, is rapidly spreading in the world. The exponentially expanding threat of SARS-CoV-2 to

global health highlights the urgent need for a vaccine. Herein we show the rapid development of a novel, highly efficient, and safe COVID-19 vaccine using a rabies virus-based vector that has proven to be an efficient vaccine against several emerging infectious diseases. This study reports that both a live and an inactivated rabies virus containing the SARS-CoV-2 spike S1 protein induces potent virus-neutralizing antibodies at much higher levels than seen in the sera of convalescent patients. In summary, the results provided here warrant further development of this safe and established vaccine platform against COVID-19.

A global survey of potential acceptance of a COVID-19 vaccine. Several coronavirus disease 2019 (COVID-19) vaccines are currently in human trials. In June 2020, we surveyed 13,426 people in 19 countries to determine potential acceptance rates and factors influencing acceptance of a COVID-19 vaccine. Of these, 71.5% of participants reported that they would be very or somewhat likely to take a COVID-19 vaccine, and 48.1% reported that they would accept their employer's recommendation to do so. Differences in acceptance rates ranged from almost 90% (in China) to less than 55% (in Russia). Respondents reporting higher levels of trust in information from government sources were more likely to accept a vaccine and take their employer's advice to do so.

The Missing Link in the Covid-19 Vaccine Race. Operation Warp Speed and global vaccine research efforts have succeeded in rapidly launching three vaccine candidates for coronavirus disease 2019 (COVID-19) into Phase III clinical trials. A recent letter from Centers for Disease Control and Prevention (CDC) Director Redfield underscored the possibility of "large-scale" distribution of a coronavirus vaccine as early as November 1, 2020. However, recent polling reveals that the majority of Americans remain skeptical of both the safety and efficacy of a potential Covid-19 vaccine. Even more troublesome is the fact that a comprehensive, collaborative vaccine marketing campaign has not been initiated to educate the U.S. public on and encourage widespread Covid-19 vaccination. Accordingly, this article lays out a plan of action, utilizing proven immunization marketing strategies and novel approaches, that could be used to combat vaccine hesitancy toward Covid-19. A vaccine may indeed be our ticket out of this pandemic, but targeted marketing is needed to increase public optimism toward that fact.

All eyes on a hurdle race for a SARS-CoV-2 vaccine.

After the honeymoon, the divorce: Unexpected outcomes of disease control measures against endemic infections. The lack of effective vaccines for many endemic diseases often forces policymakers to rely on non-immunizing control measures, such as vector control, to reduce the massive burden of these diseases. Controls can have well-known counterintuitive effects on endemic infections, including the honeymoon effect, in which partially effective controls cause not only a greater initial reduction in infection than expected, but also large outbreaks during control resulting from accumulation of susceptibles. Unfortunately, many control measures cannot be maintained indefinitely, and the results of cessation are poorly understood. Here, we examine the results of stopped or failed non-immunizing control measures in endemic settings. By using a mathematical model to compare the cumulative number of cases expected with and without control, we show that deployment of control can lead to a larger total number of infections, counting from the time that control started, than without any control-the divorce effect. This result is directly related to the population-level loss of immunity resulting from non-immunizing controls and is seen in a variety of models when non-immunizing controls are used against an infection that confers immunity. Finally, we examine three control plans for minimizing the magnitude of the divorce effect in seasonal infections and show that they are incapable of eliminating the divorce effect. While we do not suggest stopping control programs that rely on non-immunizing controls, our results strongly argue that the accumulation of susceptibility should be considered before deploying such controls against endemic infections when indefinite use of the control is unlikely. We highlight that our results are

particularly germane to endemic mosquito-borne infections, such as dengue virus, both for routine management involving vector control and for field trials of novel control approaches, and in the context of non-pharmaceutical interventions aimed at COVID-19.

Brighton Collaboration Viral Vector Vaccines Safety Working Group (V3SWG) standardized template for collection of key information for benefit-risk assessment of live-attenuated viral vaccines. Several live-attenuated viral vaccine candidates are among the COVID-19 vaccines in development. The Brighton Collaboration Viral Vector Vaccines Safety Working Group (V3SWG) has prepared a standardized template to describe the key considerations for the benefit-risk assessment of live-attenuated viral vaccines. This will help key stakeholders assess potential safety issues and understand the benefit-risk of such vaccines. The standardized and structured assessment provided by the template would also help to contribute to improved communication and support public acceptance of licensed live-attenuated viral vaccines.

A promising inactivated whole-virion SARS-CoV-2 vaccine.

Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBIBP-CorV: a randomised, double-blind, placebo-controlled, phase 1/2 trial. BACKGROUND: The ongoing COVID-19 pandemic warrants accelerated efforts to test vaccine candidates. We aimed to assess the safety and immunogenicity of an inactivated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine candidate, BBIBP-CorV, in humans. METHODS: We did a randomised, double-blind, placebo-controlled, phase 1/2 trial at Shangqiu City Liangyuan District Center for Disease Control and Prevention in Henan Province, China. In phase 1, healthy people aged 18-80 years, who were negative for serum-specific IgM/IgG antibodies against SARS-CoV-2 at the time of screening, were separated into two age groups (18-59 years and â‰¥60 years) and randomly assigned to receive vaccine or placebo in a two-dose schedule of 2 Î¼g, 4 Î¼g, or 8 Î¼g on days 0 and 28. In phase 2, healthy adults (aged 18-59 years) were randomly assigned (1:1:1:1) to receive vaccine or placebo on a single-dose schedule of 8 Î¼g on day 0 or on a two-dose schedule of 4 Î¼g on days 0 and 14, 0 and 21, or 0 and 28. Participants within each cohort were randomly assigned by stratified block randomisation (block size eight) and allocated (3:1) to receive vaccine or placebo. Group allocation was concealed from participants, investigators, and outcome assessors. The primary outcomes were safety and tolerability. The secondary outcome was immunogenicity, assessed as the neutralising antibody responses against infectious SARS-CoV-2. This study is registered with www.chictr.org.cn, ChiCTR2000032459. FINDINGS: In phase 1, 192 participants were enrolled (mean age 53Â·7 years [SD 15Â·6]) and were randomly assigned to receive vaccine (2 Î¼g [n=24], 4 Î¼g [n=24], or 8 Î¼g [n=24] for both age groups [18-59 years and â‰¥60 years]) or placebo (n=24). At least one adverse reaction was reported within the first 7 days of inoculation in 42 (29%) of 144 vaccine recipients. The most common systematic adverse reaction was fever (18-59 years, one [4%] in the 2 Î¼g group, one [4%] in the 4 Î¼g group, and two [8%] in the 8 Î¼g group; â‰¥60 years, one [4%] in the 8 Î¼g group). All adverse reactions were mild or moderate in severity. No serious adverse event was reported within 28 days post vaccination. Neutralising antibody geometric mean titres were higher at day 42 in the group aged 18-59 years (87Â·7 [95% CI 64Â·9-118Â·6], 2 Î¼g group; 211Â·2 [158Â·9-280Â·6], 4 Î¼g group; and 228Â·7 [186Â·1-281Â·1], 8 Î¼g group) and the group aged 60 years and older (80Â·7 [65Â·4-99Â·6], 2 Î¼g group; 131Â·5 [108Â·2-159Â·7], 4 Î¼g group; and 170Â·87 [133Â·0-219Â·5], 8 Î¼g group) compared with the placebo group (2Â·0 [2Â·0-2Â·0]). In phase 2, 448 participants were enrolled (mean age 41Â·7 years [SD 9Â·9]) and were randomly assigned to receive the vaccine (8 Î¼g on day 0 [n=84] or 4 Î¼g on days 0 and 14 [n=84], days 0 and 21 [n=84], or days 0 and 28 [n=84]) or placebo on the same schedules (n=112). At least one adverse reaction within the first 7 days was reported in 76 (23%) of 336 vaccine recipients (33 [39%], 8 Î¼g day 0; 18 [21%], 4 Î¼g days 0 and 14; 15 [18%], 4 Î¼g days 0 and 21; and ten [12%], 4 Î¼g days 0 and 28). One placebo recipient in the 4 Î¼g

days 0 and 21 group reported grade 3 fever, but was self-limited and recovered. All other adverse reactions were mild or moderate in severity. The most common systematic adverse reaction was fever (one [1%], 8 Î¼g day 0; one [1%], 4 Î¼g days 0 and 14; three [4%], 4 Î¼g days 0 and 21; two [2%], 4 Î¼g days 0 and 28). The vaccine-elicited neutralising antibody titres on day 28 were significantly greater in the 4 Î¼g days 0 and 14 (169Â·5, 95% CI 132Â·2-217Â·1), days 0 and 21 (282Â·7, 221Â·2-361Â·4), and days 0 and 28 (218Â·0, 181Â·8-261Â·3) schedules than the 8 Î¼g day 0 schedule (14Â·7, 11Â·6-18Â·8; all p<0Â·001). INTERPRETATION: The inactivated SARS-CoV-2 vaccine, BBIBP-CorV, is safe and well tolerated at all tested doses in two age groups. Humoral responses against SARS-CoV-2 were induced in all vaccine recipients on day 42. Two-dose immunisation with 4 Î¼g vaccine on days 0 and 21 or days 0 and 28 achieved higher neutralising antibody titres than the single 8 Î¼g dose or 4 Î¼g dose on days 0 and 14. FUNDING: National Program on Key Research Project of China, National Mega projects of China for Major Infectious Diseases, National Mega Projects of China for New Drug Creation, and Beijing Science and Technology Plan.

Learning from the past: development of safe and effective COVID-19 vaccines. The rapid spread of severe acute respiratory syndrome coronavirusÂ 2 (SARS-CoV-2) has elicited an equally rapid response aiming to develop a COVID-19 vaccine. These efforts are encouraging; however, comprehensive efficacy and safety evaluations are essential in the development of a vaccine, and we can learn from previous vaccine development campaigns. In this Perspective, we summarize examples of vaccine-associated disease enhancement in the history of developing vaccines against respiratory syncytial virus, dengue virus, SARS-CoV and Middle East respiratory syndrome coronavirus, which highlight the importance of a robust safety and efficacy profile, and present recommendations for preclinical and clinical evaluation of COVID-19 vaccine candidates as well as for vaccine design and optimization.

A Possible Path towards Rapid Development of Live-Attenuated SARS-CoV-2 Vaccines: Plunging into the Natural Pool. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is the causative agent of the coronavirus disease 2019 (COVID-19) pandemic spreading around the world, causing massive distress to the world's economy and affecting healthcare systems worldwide. Although some exposed individuals have no symptoms and most symptomatic infections are not severe, COVID-19 cases span a wide spectrum, ranging from mild to critical and sometimes resulting in life-threatening complications, such as pneumonia, severe respiratory distress and cardiac problems. Currently, there is no curative drug for COVID-19 and vaccines are still under development. We are presenting here a strategy for the fast development of natural live-attenuated SARS-CoV-2 vaccines. Our proposed approach is based on screening for, identifying, analyzing and selecting naturally attenuated yet highly immunogenic SARS-CoV-2 strains, which may lead to a shorter cycle of vaccine development, as well as higher vaccine effectiveness.

Winter Is Coming! Clinical, Immunologic, and Practical Considerations for Vaccinating Patients With Inflammatory Bowel Disease During the Coronavirus Disease-2019 Pandemic.

Pros and Cons of Adenovirus-Based SARS-CoV-2 Vaccines.

Evidence and speculations: vaccines and therapeutic options for COVID-19 pandemic. A novel coronavirus (2019-nCov) emerged in China, at the end of December 2019 which posed an International Public Health Emergency, and later declared as a global pandemic by the World Health Organization (WHO). The International Committee on Taxonomy of Viruses (ICTV) named it SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus-2), while the disease was named COVID-19 (Coronavirus Disease- 2019). Many questions related to the exact mode of transmission, animal origins, and antiviral therapeutics are not clear yet. Nevertheless, it is required to urgently launch a new protocol to evaluate the side effects of unapproved vaccines and antiviral therapeutics to accelerate the clinical application of new drugs. In this review, we highlight the most salient

characteristics and recent findings of COVID-19 disease, molecular virology, interspecies mechanisms, and health consequences related to this disease.

Emergency Use Authorization of Covid Vaccines - Safety and Efficacy Follow-up Considerations.

Postapproval Vaccine Safety Surveillance for COVID-19 Vaccines in the US.

Answering Key Questions About COVID-19 Vaccines.

Post lockdown COVID-19 seroprevalence and circulation at the time of delivery, France. BACKGROUND: To fight the COVID-19 pandemic, lockdown has been decreed in many countries worldwide. The impact of pregnancy as a severity risk factor is still debated, but strict lockdown measures have been recommended for pregnant women. OBJECTIVES: To evaluate the impact of the COVID-19 pandemic and lockdown on the seroprevalence and circulation of SARS-CoV-2 in a maternity ward in an area that has been significantly affected by the virus. STUDY DESIGN: Prospective study at the Antoine BÃ©clÃ¨re Hospital maternity ward (Paris area, France) from May 4 (one week before the end of lockdown) to May 31, 2020 (three weeks after the end of lockdown). All patients admitted to the delivery room during this period were offered a SARS-CoV-2 serology test as well concomitant SARS-CoV-2 RT-PCR on one nasopharyngeal sample. RESULTS: A total of 249 women were included. Seroprevalence of SARS-CoV-2 was 8%. The RT-PCR positive rate was 0.5%. 47.4% of the SARS-CoV-2-IgG-positive pregnant women never experienced any symptoms. A history of symptoms during the epidemic, such as fever (15.8%), myalgia (36.8%) and anosmia (31.6%), was suggestive of previous infection. CONCLUSIONS: Three weeks after the end of French lockdown, SARS-CoV-2 infections were scarce in our region. A very high proportion of SARS-CoV-2-IgG-negative pregnant women, which is comparable to that of the general population, must be taken into consideration in the event of a resurgence of the pandemic. The traces of a past active circulation of the virus in this fragile population during the spring wave should encourage public health authorities to take specific measures for this independent at-risk group, in order to reduce viral circulation in pregnant patients.

Audio Interview: Vaccinology and Covid-19.

Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates. BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections and the resulting disease, coronavirus disease 2019 (Covid-19), have spread to millions of persons worldwide. Multiple vaccine candidates are under development, but no vaccine is currently available. Interim safety and immunogenicity data about the vaccine candidate BNT162b1 in younger adults have been reported previously from trials in Germany and the United States. METHODS: In an ongoing, placebo-controlled, observer-blinded, dose-escalation, phase 1 trial conducted in the United States, we randomly assigned healthy adults 18 to 55 years of age and those 65 to 85 years of age to receive either placebo or one of two lipid nanoparticle-formulated, nucleoside-modified RNA vaccine candidates: BNT162b1, which encodes a secreted trimerized SARS-CoV-2 receptor-binding domain; or BNT162b2, which encodes a membrane-anchored SARS-CoV-2 full-length spike, stabilized in the prefusion conformation. The primary outcome was safety (e.g., local and systemic reactions and adverse events); immunogenicity was a secondary outcome. Trial groups were defined according to vaccine candidate, age of the participants, and vaccine dose level (10 Î¼g, 20 Î¼g, 30 Î¼g, and 100 Î¼g). In all groups but one, participants received two doses, with a 21-day interval between doses; in one group (100 Î¼g of BNT162b1), participants received one dose. RESULTS: A total of 195 participants underwent randomization. In each of 13 groups of 15 participants, 12 participants received vaccine and 3 received placebo. BNT162b2 was associated with a lower incidence and severity of systemic reactions than BNT162b1, particularly in older adults. In both younger and older adults, the two vaccine candidates elicited similar dose-dependent SARS-CoV-2-neutralizing geometric mean titers, which were similar to or higher than the geometric mean titer of a panel of

SARS-CoV-2 convalescent serum samples. CONCLUSIONS: The safety and immunogenicity data from this U.S. phase 1 trial of two vaccine candidates in younger and older adults, added to earlier interim safety and immunogenicity data regarding BNT162b1 in younger adults from trials in Germany and the United States, support the selection of BNT162b2 for advancement to a pivotal phase 2-3 safety and efficacy evaluation. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.).

Australia needs a vaccine injury compensation scheme: Upcoming COVID-19 vaccines make its introduction urgent. There is a strong public health ethical justification to introduce a vaccine injury compensation scheme in Australia, and it needs to be in place before widespread use of COVID-19 vaccines.

COVID-19 Vaccine Frontrunners and Their Nanotechnology Design. Humanity is experiencing a catastrophic pandemic. SARS-CoV-2 has spread globally to cause significant morbidity and mortality, and there still remain unknowns about the biology and pathology of the virus. Even with testing, tracing, and social distancing, many countries are struggling to contain SARS-CoV-2. COVID-19 will only be suppressible when herd immunity develops, either because of an effective vaccine or if the population has been infected and is resistant to reinfection. There is virtually no chance of a return to pre-COVID-19 societal behavior until there is an effective vaccine. Concerted efforts by physicians, academic laboratories, and companies around the world have improved detection and treatment and made promising early steps, developing many vaccine candidates at a pace that has been unmatched for prior diseases. As of August 11, 2020, 28 of these companies have advanced into clinical trials with Moderna, CanSino, the University of Oxford, BioNTech, Sinovac, Sinopharm, Anhui Zhifei Longcom, Inovio, Novavax, Vaxine, Zydus Cadila, Institute of Medical Biology, and the Gamaleya Research Institute having moved beyond their initial safety and immunogenicity studies. This review analyzes these frontrunners in the vaccine development space and delves into their posted results while highlighting the role of the nanotechnologies applied by all the vaccine developers.

What China's speedy COVID vaccine deployment means for the pandemic.

A call to test new vaccines head to head, in monkeys.

Rapid Serological Assays and SARS-CoV-2 Real-Time Polymerase Chain Reaction Assays for the Detection of SARS-CoV-2: Comparative Study. BACKGROUND: Real-time polymerase chain reaction (RT-PCR) testing for the identification of viral nucleic acid is the current standard for the diagnosis of SARS-CoV-2 infection, but technical issues limit its utilization for large-scale screening. Serological immunoglobulin M (IgM)/IgG testing has been proposed as a useful tool for detecting SARS-CoV-2 exposure. OBJECTIVE: The objective of our study was to compare the results of the rapid serological VivaDiag test for SARS-CoV-2-related IgM/IgG detection with those of the standard RT-PCR laboratory test for identifying SARS-CoV-2 nucleic acid. METHODS: We simultaneously performed both serological and molecular tests with a consecutive series of 191 symptomatic patients. The results provided by a new rapid serological colorimetric test for analyzing IgM/IgG expression were compared with those of RT-PCR testing for SARS-CoV-2 detection. RESULTS: Of the 191 subjects, 70 (36.6%) tested positive for SARS-CoV-2 based on RT-PCR results, while 34 (17.3%) tested positive based on serological IgM/IgG expression. Additionally, 13 (6.8%) subjects tested positive based on serological test results, but also tested negative based on RT-PCR results. The rapid serological test had a sensitivity of 30% and a specificity of 89% compared to the standard RT-PCR assay. Interestingly, the performance of both assays improved 8 days after symptom appearance. After 10 days had passed since symptom appearance, the predictive value of the rapid serological test was higher than that of the standard molecular assay (proportion of positive results: 40% vs 20%). Multivariate analysis showed that age >58 years (P<.01) and period of >15 days after symptom onset (P<.02) were significant and independent factors associated with serological test positivity. CONCLUSIONS: The rapid serological test analyzed in this study seems limited in terms of usefulness

when diagnosing SARS-CoV-2 infection. However, it may be useful for providing relevant information on people's immunoreaction to COVID-19 exposure.
[Not Available].
Plan now to speed vaccine supply for future pandemics.
COVID-19 vaccines: how to ensure Africa has access.
Mitigating Coronavirus Induced Dysfunctional Immunity for At-Risk Populations in COVID-19: Trained Immunity, BCG and "New Old Friends". The novel, highly contagious coronavirus SARS-CoV-2 spreads rapidly throughout the world, leading to a deadly pandemic of a predominantly respiratory illness called COVID-19. Safe and effective anti-SARS-CoV-2 vaccines are urgently needed. However, emerging immunological observations show hallmarks of significant immunopathological characteristics and dysfunctional immune responses in patients with COVID-19. Combined with existing knowledge about immune responses to other closely related and highly pathogenic coronaviruses, this could forebode significant challenges for vaccine development, including the risk of vaccine failure. Animal data from earlier coronavirus vaccine efforts indicate that elderly people, most at risk from severe COVID-19 disease, could be especially at risk from immunopathologic responses to novel coronavirus vaccines. Bacterial "new old friends" such as Bacille Calmette-GuÃ©rin (BCG) or Mycobacterium obuense have the ability to elevate basal systemic levels of type 1 cytokines and immune cells, correlating with increased protection against diverse and unrelated infectious agents, called "trained immunity." Here we describe dysfunctional immune responses induced by coronaviruses, representing potentially difficult to overcome obstacles to safe, effective vaccine development for COVID-19, and outline how trained immunity could help protect high risk populations through immunomodulation with BCG and other "new old friends."
A Novel Strategy for the Development of Vaccines for SARS-CoV-2 (COVID-19) and Other Viruses Using AI and Viral Shell Disorder. A model that predicts levels of coronavirus (CoV) respiratory and fecal-oral transmission potentials based on the shell disorder has been built using neural network (artificial intelligence, AI) analysis of the percentage of disorder (PID) in the nucleocapsid, N, and membrane, M, proteins of the inner and outer viral shells, respectively. Using primarily the PID of N, SARS-CoV-2 is grouped as having intermediate levels of both respiratory and fecal-oral transmission potentials. Related studies, using similar methodologies, have found strong positive correlations between virulence and inner shell disorder among numerous viruses, including Nipah, Ebola, and Dengue viruses. There is some evidence that this is also true for SARS-CoV-2 and SARS-CoV, which have N PIDs of 48% and 50%, and case-fatality rates of 0.5-5% and 10.9%, respectively. The underlying relationship between virulence and respiratory potentials has to do with the viral loads of vital organs and body fluids, respectively. Viruses can spread by respiratory means only if the viral loads in saliva and mucus exceed certain minima. Similarly, a patient is likelier to die when the viral load overwhelms vital organs. Greater disorder in inner shell proteins has been known to play important roles in the rapid replication of viruses by enhancing the efficiency pertaining to protein-protein/DNA/RNA/lipid bindings. This paper suggests a novel strategy in attenuating viruses involving comparison of disorder patterns of inner shells (N) of related viruses to identify residues and regions that could be ideal for mutation. The M protein of SARS-CoV-2 has one of the lowest M PID values (6%) in its family, and therefore, this virus has one of the hardest outer shells, which makes it resistant to antimicrobial enzymes in body fluid. While this is likely responsible for its greater contagiousness, the risks of creating an attenuated virus with a more disordered M are discussed.
Engineering Antiviral Vaccines. Despite the vital role of vaccines in fighting viral pathogens, effective vaccines are still unavailable for many infectious diseases. The importance of vaccines cannot be overstated during the outbreak of a pandemic, such as the coronavirus disease 2019 (COVID-19) pandemic. The understanding of genomics, structural biology, and innate/adaptive

immunity have expanded the toolkits available for current vaccine development. However, sudden outbreaks and the requirement of population-level immunization still pose great challenges in today's vaccine designs. Well-established vaccine development protocols from previous experiences are in place to guide the pipelines of vaccine development for emerging viral diseases. Nevertheless, vaccine development may follow different paradigms during a pandemic. For example, multiple vaccine candidates must be pushed into clinical trials simultaneously, and manufacturing capability must be scaled up in early stages. Factors from essential features of safety, efficacy, manufacturing, and distributions to administration approaches are taken into consideration based on advances in materials science and engineering technologies. In this review, we present recent advances in vaccine development by focusing on vaccine discovery, formulation, and delivery devices enabled by alternative administration approaches. We hope to shed light on developing better solutions for faster and better vaccine development strategies through the use of biomaterials, biomolecular engineering, nanotechnology, and microfabrication techniques.
[Comment] COVIDâ€'19 vaccine safety. In response to the SARSâ€'CoVâ€'2 outbreak, and the resulting COVIDâ€'19 pandemic, a global competition to develop an antiâ€'COVIDâ€'19 vaccine has ensued. The targeted time frame for initial vaccine deployment is late 2020. The present article examines whether shortâ€'term, midâ€'term, and longâ€'term vaccine safety can be achieved under such an accelerated schedule, given the myriad vaccineâ€'induced mechanisms that have demonstrated adverse effects based on previous clinical trials and laboratory research. It presents scientific evidence of potential pitfalls associated with eliminating critical phaseÂ IIÂ andÂ III clinical trials, and concludes that there is no substitute currently available for longâ€'term human clinical trials to ensure longâ€'term human safety.
COVID-19 vaccine BNT162b1 elicits human antibody and T(H)1 T cell responses. An effective vaccine is needed to halt the spread of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) pandemic. Recently, we reported safety, tolerability and antibody response data from an ongoing placebo-controlled, observer-blinded phase I/II coronavirus disease 2019 (COVID-19) vaccine trial with BNT162b1, a lipid nanoparticle-formulated nucleoside-modified mRNA that encodes the receptor binding domain (RBD) of the SARS-CoV-2 spike protein(1). Here we present antibody and T cell responses after vaccination with BNT162b1 from a second, non-randomized open-label phase I/II trial in healthy adults, 18-55 years of age. Two doses of 1-50Â Î¼g of BNT162b1 elicited robust CD4(+) and CD8(+) T cell responses and strong antibody responses, with RBD-binding IgG concentrations clearly above those seen in serum from a cohort of individuals who had recovered from COVID-19. Geometric mean titres of SARS-CoV-2 serum-neutralizing antibodies on day 43 were 0.7-fold (1-Î¼g dose) to 3.5-fold (50-Î¼g dose) those of the recovered individuals. Immune sera broadly neutralized pseudoviruses with diverse SARS-CoV-2 spike variants. Most participants had T helper type 1 (T(H)1)-skewed T cell immune responses with RBD-specific CD8(+) and CD4(+) T cell expansion. Interferon-Î³ was produced by a large fraction of RBD-specific CD8(+) and CD4(+) T cells. The robust RBD-specific antibody, T cell and favourable cytokine responses induced by the BNT162b1 mRNA vaccine suggest that it has the potential to protect against COVID-19 through multiple beneficial mechanisms.
Assessing the Safety of COVID-19 Vaccines: A Primer. Vaccines against COVID-19 are being developed at speeds not previously achieved. With this unprecedented effort comes challenges for post-marketing safety monitoring and challenges for vaccine safety communication. To deploy these new vaccines fast across diverse populations, it is vital that robust pharmacovigilance and active surveillance systems are in place. Not all countries have the capability or resources to undertake adequate surveillance and will rely on data from those who can. The tools exist to assess COVID-19 vaccines as they are deployed such as surveillance systems, administrative data and case definitions for adverse events of special interest. However, stitching these all together and using them effectively

requires investment and collaboration. This paper provides a high-level overview of some of the facets of modern vaccine safety assessment and how they are, or can be, applied to COVID-19 vaccines.
COVID vaccine confidence requires radical transparency.
COVID-19 vaccine development during pandemic: gap analysis, opportunities, and impact on future emerging infectious disease development strategies. The world remains cautiously optimistic about a COVID-19 vaccine that is relatively safe and efficacious and that offers sufficient long-lasting protection/immunity by neutralizing the virus infectivity. However, key technical hurdles pertaining to antigen-adjuvant formulation, delivery, and manufacturing challenges of lipid nanoparticles (LNPs) for mRNA vaccines and stability of formulations need to be addressed for successful product development and stockpiling. In addition, the dosage form, the dosage level and regimen for eliciting a protective immune response remain to be established. The high dependence of global supply chains and demand-supply to sourcing quality raw materials, glassware and other supplies, along with the stress on existing production capacities and platform-specific manufacturing challenges could impede vaccine development and access. This article provides critical analysis of vaccine development processes and unit operations that can derail the pandemic response, and also extends to other emerging infectious disease development efforts - issues that take on added significance given the global mandate for an accelerated and at-risk development path to tackle the COVID-19 pandemic.
Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults. BACKGROUND: Testing of vaccine candidates to prevent infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in an older population is important, since increased incidences of illness and death from coronavirus disease 2019 (Covid-19) have been associated with an older age. METHODS: We conducted a phase 1, dose-escalation, open-label trial of a messenger RNA vaccine, mRNA-1273, which encodes the stabilized prefusion SARS-CoV-2 spike protein (S-2P) in healthy adults. The trial was expanded to include 40 older adults, who were stratified according to age (56 to 70 years or â‰¥71 years). All the participants were assigned sequentially to receive two doses of either 25 Î¼g or 100 Î¼g of vaccine administered 28 days apart. RESULTS: Solicited adverse events were predominantly mild or moderate in severity and most frequently included fatigue, chills, headache, myalgia, and pain at the injection site. Such adverse events were dose-dependent and were more common after the second immunization. Binding-antibody responses increased rapidly after the first immunization. By day 57, among the participants who received the 25-Î¼g dose, the anti-S-2P geometric mean titer (GMT) was 323,945 among those between the ages of 56 and 70 years and 1,128,391 among those who were 71 years of age or older; among the participants who received the 100-Î¼g dose, the GMT in the two age subgroups was 1,183,066 and 3,638,522, respectively. After the second immunization, serum neutralizing activity was detected in all the participants by multiple methods. Binding- and neutralizing-antibody responses appeared to be similar to those previously reported among vaccine recipients between the ages of 18 and 55 years and were above the median of a panel of controls who had donated convalescent serum. The vaccine elicited a strong CD4 cytokine response involving type 1 helper T cells. CONCLUSIONS: In this small study involving older adults, adverse events associated with the mRNA-1273 vaccine were mainly mild or moderate. The 100-Î¼g dose induced higher binding- and neutralizing-antibody titers than the 25-Î¼g dose, which supports the use of the 100-Î¼g dose in a phase 3 vaccine trial. (Funded by the National Institute of Allergy and Infectious Diseases and others; mRNA-1273 Study ClinicalTrials.gov number, NCT04283461.).
Willingness-to-pay for a COVID-19 vaccine and its associated determinants in Indonesia. How countries, particularly low- and middle-income economies, should pay the coronavirus disease 2019 (COVID-19) vaccine is an important and understudied issue. We undertook an online survey to

measure the willingness-to-pay (WTP) for a COVID-19 vaccine and its determinants in Indonesia. The WTP was assessed using a simple dichotomous contingent valuation approach and a linear regression model was used to assess its associated determinants. There were 1,359 respondents who completed the survey. In total, 78.3% (1,065) were willing to pay for the COVID-19 vaccine with a mean and median WTP of US$ 57.20 (95%CI: US$ 54.56, US$ 59.85) and US$ 30.94 (95%CI: US$ 30.94, US$ 30.94), respectively. Being a health-care worker, having a high income, and having high perceived risk were associated with higher WTP. These findings suggest that the WTP for a COVID-19 vaccine is relatively high in Indonesia. This WTP information can be used to construct a payment model for a COVID-19 vaccine in the country. Nevertheless, to attain higher vaccine coverage, it may be necessary to partially subsidize the vaccine for those who are less wealthy and to design health promotion materials to increase the perceived risk for COVID-19 in the country.
What Would Jenner and Pasteur Have Done About COVID-19 Coronavirus? The Urges of a Vaccinologist.
Impact of catch-up vaccination on aluminum exposure due to new laws and post social distancing. BACKGROUND: The COVID-19 pandemic has placed significant stressors on the medical community and on the general public. Part of this includes patients skipping well-child visits to reduce risk of exposure to SARS-CoV-2 virus. Published estimates of the duration of whole-body aluminum (Al) toxicity from vaccines in infants from birth to six months indicate that CDC's recommended vaccination schedule leads to unacceptably long periods of time in which infants are in aluminum toxicity (as measured by %AlumTox). METHODS: We utilize these established clearance and accumulation models to calculate expected per-body-weight whole-body toxicity of aluminum from vaccines considering for children of all ages under CDC's Catch-Up schedule from birth to ten years, assuming social distancing for 6 months. Our updated Pediatric Dose Limit (PDL) model assumes a linear improvement in renal function from birth to two years. RESULTS: Our results indicate that due diligence in considering alternative spacing and use of non-aluminum containing vaccines when possible will reduce whole body toxicity and may reduce risk of morbidity associated with exposure to aluminum. CONCLUSIONS: While reduction or elimination of aluminum exposure from all sources is always a good idea, our results indicate that careful consideration of expected aluminum exposures during regular and Catch-Up vaccination is found to be especially important for infants and children below 2 years of age. We urge caution in the mass re-starting of vaccination under CDC's Catch-Up schedule for children under 12 months and offer alternative strategies to minimize per-day/week/month exposure to aluminum hydroxide following the COVID-19 period of isolation.
Preparing for COVID-19 vaccine safety surveillance: A United States perspective.
COVID-vaccine results are on the way - and scientists' concerns are growing.
Risk factors associated with adverse fetal outcomes in pregnancies affected by Coronavirus disease 2019 (COVID-19): a secondary analysis of the WAPM study on COVID-19. Objectives To evaluate the strength of association between maternal and pregnancy characteristics and the risk of adverse perinatal outcomes in pregnancies with laboratory confirmed COVID-19. Methods Secondary analysis of a multinational, cohort study on all consecutive pregnant women with laboratory-confirmed COVID-19 from February 1, 2020 to April 30, 2020 from 73 centers from 22 different countries. A confirmed case of COVID-19 was defined as a positive resultÂ on real-time reverse-transcriptase-polymerase-chain-reactionÂ (RT-PCR) assay of nasal and pharyngeal swab specimens.Â The primary outcome was a composite adverse fetal outcome, defined as the presence of either abortion (pregnancy loss before 22Â weeks of gestations), stillbirth (intrauterine fetal death after 22Â weeks of gestation), neonatal death (death of a live-born infant within the first 28Â days of life), and perinatal death (either stillbirth or neonatal death). Logistic regression analysis was performed to evaluate parameters independently associated with the primary outcome. Logistic regression was reported as

odds ratio (OR) with 95% confidence interval (CI). Results Mean gestational age at diagnosis was 30.6Â±9.5Â weeks, with 8.0% of women being diagnosed in the first, 22.2% in the second and 69.8% in the third trimester of pregnancy. There were six miscarriage (2.3%), six intrauterine device (IUD) (2.3) and 5 (2.0%) neonatal deaths, with an overall rate of perinatal death of 4.2% (11/265), thus resulting into 17 cases experiencing and 226 not experiencing composite adverse fetal outcome. Neither stillbirths nor neonatal deaths had congenital anomalies found at antenatal or postnatal evaluation. Furthermore, none of the cases experiencing IUD had signs of impending demise at arterial or venous Doppler. Neonatal deaths were all considered as prematurity-related adverse events. Of the 250 live-born neonates, one (0.4%) was found positive at RT-PCR pharyngeal swabs performed after delivery. The mother was tested positive during the third trimester of pregnancy. The newborn was asymptomatic and had negative RT-PCR test after 14Â days of life. At logistic regression analysis, gestational age at diagnosis (OR: 0.85, 95% CI 0.8-0.9 per week increase; p<0.001), birthweight (OR: 1.17, 95% CI 1.09-1.12.7 per 100Â g decrease; p=0.012) and maternal ventilatory support, including either need for oxygen or CPAP (OR: 4.12, 95% CI 2.3-7.9; p=0.001) were independently associated with composite adverse fetal outcome. Conclusions Early gestational age at infection, maternal ventilatory supports and low birthweight are the main determinants of adverse perinatal outcomes in fetuses with maternal COVID-19 infection. Conversely, the risk of vertical transmission seems negligible.

The 2020 Pandemic: Current SARS-CoV-2 Vaccine Development. Coronaviruses are enveloped viruses with a positive-sense single-stranded RNA genome infecting animals and humans. Coronaviruses have been described more than 70 years ago and contain many species. Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) are lethal species caused by human coronaviruses (HCoVs). Currently, a novel strain of HCoVs, named Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) causes coronavirus disease 2019 (Covid-19). SARS-CoV-2 was first identified in December 2019 in Wuhan, the capital city of the Hubei province of China, and has since spread worldwide causing an outbreak in more than 200 countries. The SARS-CoV-2 outbreak was declared a pandemic on March 11th, 2020 and a public health emergency of international concern (PHEIC) in late January 2020 by the World Health Organization (WHO). SARS-CoV-2 infects the respiratory tract causing flu-like symptoms and, in some, may cause severe illness like pneumonia and multi-organ failure leading to death. Today, Covid-19 cases almost reaching 9 million, with more than 450 thousand deaths. There is an urgent demand for developing a vaccine since no effective therapies or vaccines have been approved to this day to prevent or minimize the spread of the infection. In this review, we summarized the furthest vaccines in the clinical pipeline.

SARS-CoV-2 vaccines in development. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first reported in late 2019 in China and is the causative agent of the coronavirus disease 2019 (COVID-19) pandemic. To mitigate the effects of the virus on public health, the economy and society, a vaccine is urgently needed. Here I review the development of vaccines against SARS-CoV-2. Development was initiated when the genetic sequence of the virus became available in early January 2020, and has moved at an unprecedented speed: a phase I trial started in March 2020 and there are currently more than 180 vaccines at various stages of development. Data from phase I and phase II trials are already available for several vaccine candidates, and many have moved into phase III trials. The data available so far suggest that effective and safe vaccines might become available within months, rather than years.

Impact of COVID-19 on vaccination programs: adverse or positive? The COVID-19 pandemic has posed multiple substantial challenges, affecting not only public health but also economic systems, socio-cultural patterns, and political institutions. Studies have focused on the relationships between complex emergencies and natural disasters with outbreaks of infectious diseases. However, there is a

dearth of relevant literature on the impact of a global pandemic on vaccination programs - an important topic because delays or stops in such programs are likely to result in outbreaks and epidemics of other infectious diseases. Thus, this article discusses the negative and positive impacts that the COVID-19 pandemic may exert on vaccination for vaccine-preventable diseases (VPDs). Negative impacts include the increased risk of VPD outbreaks in low-resource countries where vaccination programs must be temporarily halted to prevent the spread of infection. Positive effects include the strong possibility that the universally-recognized need for a coronavirus vaccine may increase people's appreciation for vaccines in general, resulting in improved vaccination uptake once the pandemic passes. Concerned stakeholders, such as governments and the World Health Organization (WHO), should seize this moment to effectively build on these positive impacts by planning renewed and revitalized post-COVID vaccination programs.

Activate: Randomized Clinical Trial of BCG Vaccination against Infection in the Elderly. BCG vaccination in children protects against heterologous infections and improves survival independently of tuberculosis prevention. The phase III ACTIVATE trial assessed whether BCG has similar effects in the elderly. In this double-blind, randomized trial, elderly patients (nÂ = 198) received BCG or placebo vaccine at hospital discharge and were followed for 12Â months for new infections. At interim analysis, BCG vaccination significantly increased the time to first infection (median 16Â weeks compared to 11Â weeks after placebo). The incidence of new infections was 42.3% (95% CIs 31.9%-53.4%) after placebo vaccination and 25.0% (95% CIs 16.4%-36.1%) after BCG vaccination; most of the protection was against respiratory tract infections of probable viral origin (hazard ratio 0.21, pÂ = 0.013). No difference in the frequency of adverse effects was found. Data show that BCG vaccination is safe and can protect the elderly against infections. Larger studies are needed to assess protection against respiratory infections, including COVID-19 (ClinicalTrials.gov NCT03296423).

T-cell responses and therapies against SARS-CoV-2 infection. Coronavirus disease 2019 (COVID-19) is caused by SARS-CoV-2, a novel coronavirus strain. Some studies suggest that COVID-19 could be an immune-related disease, and failure of effective immune responses in initial stages of viral infection could contribute to systemic inflammation and tissue damage, leading to worse disease outcomes. T cells can act as a double-edge sword with both pro- and anti-roles in the progression of COVID-19. Thus, better understanding of their roles in immune responses to SARS-CoV-2 infection is crucial. T cells primarily react to the spike protein on the coronavirus to initiate antiviral immunity; however, T-cell responses can be suboptimal, impaired or excessive in severe COVID-19 patients. This review focuses on the multifaceted roles of T cells in COVID-19 pathogenesis and rationalizes their significance in eliciting appropriate antiviral immune responses in COVID-19 patients and unexposed individuals. In addition, we summarize the potential therapeutic approaches related to T cells to treat COVID-19 patients. These include adoptive T-cell therapies, vaccines activating T-cell responses, recombinant cytokines, Th1 activators and Th17 blockers, and potential utilization of immune checkpoint inhibitors alone or in combination with anti-inflammatory drugs to improve antiviral T-cell responses against SARS-CoV-2.

Scientists relieved as coronavirus vaccine trial restarts - but question lack of transparency.

Review of Current Vaccine Development Strategies to Prevent Coronavirus Disease 2019 (COVID-19). The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) outbreak that started in Wuhan, China, in 2019 resulted in a pandemic not seen for a century, and there is an urgent need to develop safe and efficacious vaccines. The scientific community has made tremendous efforts to understand the disease, and unparalleled efforts are ongoing to develop vaccines and treatments. Toxicologists and pathologists are involved in these efforts to test the efficacy and safety of vaccine candidates. Presently, there are several SARS-CoV-2 vaccines in clinical trials, and the pace of vaccine development has been highly accelerated to meet the urgent need. By 2021, efficacy and safety data

from clinical trials are expected, and potentially a vaccine will be available for those most at risk. This review focuses on the ongoing SARS-CoV-2 vaccine development efforts with emphasis on the nonclinical safety assessment and discusses emerging preliminary data from nonclinical and clinical studies. It also provides a brief overview on vaccines for other coronaviruses, since experience gained from these can be useful in the development of SARS-CoV-2 vaccines. This review will also explain why, despite this unprecedented pace of vaccine development, rigorous standards are in place to ensure nonclinical and clinical safety and efficacy. [Box: see text].

Antibody-dependent enhancement and SARS-CoV-2 vaccines and therapies. Antibody-based drugs and vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are being expedited through preclinical and clinical development. Data from the study of SARS-CoV and other respiratory viruses suggest that anti-SARS-CoV-2 antibodies could exacerbate COVID-19 through antibody-dependent enhancement (ADE). Previous respiratory syncytial virus and dengue virus vaccine studies revealed human clinical safety risks related to ADE, resulting in failed vaccine trials. Here, we describe key ADE mechanisms and discuss mitigation strategies for SARS-CoV-2 vaccines and therapies in development. We also outline recently published data to evaluate the risks and opportunities for antibody-based protection against SARS-CoV-2.

The Brighton Collaboration standardized template for collection of key information for benefit-risk assessment of viral vector vaccines. Many of the vaccines under development for COVID-19 involve the use of viral vectors. The Brighton Collaboration Benefit-Risk Assessment of Vaccines by Technology (BRAVATO, formerly the Viral Vector Vaccine Safety Working Group, V3SWG) working group has prepared a standardized template to describe the key considerations for the benefit-risk assessment of viral vector vaccines. This will facilitate key stakeholders to anticipate potential safety issues and interpret or assess safety data. This would also help improve communication and public acceptance of licensed viral vector vaccines.

Current state of vaccine development and targeted therapies for COVID-19: impact of basic science discoveries. Coronavirus disease-19 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). SARS-CoV-2 is closely related to two other coronaviruses that caused disease epidemic breakouts in humans in the last 2 decades, namely, severe acute respiratory distress syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV). The similarities have enabled the scientists to apply the basic scientific discoveries garnered from studying the structure and modus operandi of SARS-CoV and MERS-CoV to develop therapies that specifically target SARS-CoV-2 and to develop vaccines to prevent COVID-19. Targeted therapies including the use of antibodies to prevent virus entry, nucleotide analogues to prevent viral replication, and inhibitors of proteases to prevent virion formation, among others, are being tested for their clinical efficacy. Likewise, complete sequencing of the SARS-CoV-2 and identification of its structural and nonstructural proteins have enabled development of RNA-, DNA-, and peptide-based vaccines as well attenuated viral vaccines to instigate the host-immune responses. The clinical impacts of the basic science discoveries are amply evident on the rapid pace of progress in developing specific antiviral therapies and vaccines against SARS-CoV-2. The progress emphasizes the merit of discovering the fundamental scientific elements, regardless of whether or not they have apparent or immediate clinical applications.

Broad and strong memory CD4(+) and CD8(+) T cells induced by SARS-CoV-2 in UK convalescent individuals following COVID-19. The development of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines and therapeutics will depend on understanding viral immunity. We studied T cell memory in 42 patients following recovery from COVID-19 (28 with mild disease and 14 with severe disease) and 16 unexposed donors, using interferon-Î³-based assays with peptides spanning SARS-CoV-2 except ORF1. The breadth and magnitude of T cell responses were significantly

higher in severe as compared with mild cases. Total and spike-specific T cell responses correlated with spike-specific antibody responses. We identified 41 peptides containing CD4(+) and/or CD8(+) epitopes, including six immunodominant regions. Six optimized CD8(+) epitopes were defined, with peptide-MHC pentamer-positive cells displaying the central and effector memory phenotype. In mild cases, higher proportions of SARS-CoV-2-specific CD8(+) T cells were observed. The identification of T cell responses associated with milder disease will support an understanding of protective immunity and highlights the potential of including non-spike proteins within future COVID-19 vaccine design.

Phase 1-2 Trial of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine. BACKGROUND: NVX-CoV2373 is a recombinant severe acute respiratory syndrome coronavirus 2 (rSARS-CoV-2) nanoparticle vaccine composed of trimeric full-length SARS-CoV-2 spike glycoproteins and Matrix-M1 adjuvant. METHODS: We initiated a randomized, placebo-controlled, phase 1-2 trial to evaluate the safety and immunogenicity of the rSARS-CoV-2 vaccine (in 5-Î¼g and 25-Î¼g doses, with or without Matrix-M1 adjuvant, and with observers unaware of trial-group assignments) in 131 healthy adults. In phase 1, vaccination comprised two intramuscular injections, 21 days apart. The primary outcomes were reactogenicity; laboratory values (serum chemistry and hematology), according to Food and Drug Administration toxicity scoring, to assess safety; and IgG anti-spike protein response (in enzyme-linked immunosorbent assay [ELISA] units). Secondary outcomes included unsolicited adverse events, wild-type virus neutralization (microneutralization assay), and T-cell responses (cytokine staining). IgG and microneutralization assay results were compared with 32 (IgG) and 29 (neutralization) convalescent serum samples from patients with Covid-19, most of whom were symptomatic. We performed a primary analysis at day 35. RESULTS: After randomization, 83 participants were assigned to receive the vaccine with adjuvant and 25 without adjuvant, and 23 participants were assigned to receive placebo. No serious adverse events were noted. Reactogenicity was absent or mild in the majority of participants, more common with adjuvant, and of short duration (mean, â‰¤2 days). One participant had mild fever that lasted 1 day. Unsolicited adverse events were mild in most participants; there were no severe adverse events. The addition of adjuvant resulted in enhanced immune responses, was antigen dose-sparing, and induced a T helper 1 (Th1) response. The two-dose 5-Î¼g adjuvanted regimen induced geometric mean anti-spike IgG (63,160 ELISA units) and neutralization (3906) responses that exceeded geometric mean responses in convalescent serum from mostly symptomatic Covid-19 patients (8344 and 983, respectively). CONCLUSIONS: At 35 days, NVX-CoV2373 appeared to be safe, and it elicited immune responses that exceeded levels in Covid-19 convalescent serum. The Matrix-M1 adjuvant induced CD4+ T-cell responses that were biased toward a Th1 phenotype. (Funded by the Coalition for Epidemic Preparedness Innovations; ClinicalTrials.gov number, NCT04368988).

Implications for SARS-CoV-2 Vaccine Design: Fusion of Spike Glycoprotein Transmembrane Domain to Receptor-Binding Domain Induces Trimerization. The ongoing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic presents an urgent need for an effective vaccine. Molecular characterization of SARS-CoV-2 is critical to the development of effective vaccine and therapeutic strategies. In the present study, we show that the fusion of the SARS-CoV-2 spike protein receptor-binding domain to its transmembrane domain is sufficient to mediate trimerization. Our findings may have implications for vaccine development and therapeutic drug design strategies targeting spike trimerization. As global efforts for developing SARS-CoV-2 vaccines are rapidly underway, we believe this observation is an important consideration for identifying crucial epitopes of SARS-CoV-2.

We Need a Vaccine.

Current national policies for infant universal bacille Calmette-GuÃ©rin vaccination were associated with lower mortality from coronavirus disease 2019. An exciting debate has emerged whether bacille Calmette-GuÃ©rin (BCG) vaccination is effective for the coronavirus disease 2019 (COVID-19)

pandemic. Some advocated that BCG-vaccinated people are less suffered from the virus because BCG vaccination is recommendedin COVID-19 high burden countries. However, the others objected because this seemingly attractive relationship is explainable with confounding factors. In a multiple regression with 171 countries adjusting socioeconomical and climatic covariates, countries with current universal pediatric BCG policy were associated with 30-fold (95% confidence interval, 17-52) decrease of COVID-19 mortality per population compared to countries without the policy.

Overview of the current promising approaches for the development of an effective severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. Coronavirus disease 2019 (COVID-19) is a pandemic infectious disease caused by the novel coronavirus called SARS-CoV-2. There is a gap in our understanding regarding the immunopathogenesis of COVID-19. However, many clinical trials are underway across the world for screening effective drugs against COVID-19. Nevertheless, currently, no proven effective therapies for this virus exists. The vaccines are deemed as a significant part of disease prevention for emerging viral diseases, since, in several cases, other therapeutic choices are limited or non-existent, or that diseases result in such an accelerated clinical worsening that the efficacy of treatments is restricted. Therefore, effective vaccines against COVID-19 are urgently required to overcome the tremendous burden of mortality and morbidity correlated with SARS-CoV-2. In this review, we will describe the latest evidence regarding outstanding vaccine approaches and the challenges for vaccine production.

The danger of DIY vaccines.

COVID-19 vaccines: ethical framework concerning human challenge studies. BACKGROUND: The pandemic associated with the new SARS-CoV-2 coronavirus continues to spread worldwide. The most favorable epidemic control scenario, which provides long-term protection against COVID-19 outbreak, is the development and distribution of an effective and safe vaccine. The need to develop a new COVID-19 vaccine is pressing; however, it is likely to take a long time, possibly several years. This is due to the time required to demonstrate the safety and efficacy of the proposed vaccine. and the time required to manufacture and distribute millions of doses. OBJECTIVES: To accelerate this development and associated safety testing, the deliberate infection of healthy volunteers has been suggested. The purpose of this short communication is to describe the ethical aspects of this type of testing, RESULTS: Deliberate infection of volunteers with a dangerous virus such as SARS-CoV-2 was initially considered unethical by researchers; but the current pandemic is so different from previous ones that these studies are considered ethical if certain criteria are met. Participants in human challenge studies must be relatively young, in good health and must receive the highest quality medical care, with frequent monitoring. Tests should also be performed with great caution and specialized medical supervision. Besides, the fact that obtaining vaccines faster through deliberate infection studies of healthy people has greater benefits than risks, has been demonstrated by obtaining other vaccines in other historical pandemics such as: smallpox, influenza, malaria, typhoid fever, Dengue fever and Zika. CONCLUSIONS: One possibility to shorten the time required for the development of COVID-19 vaccines is to reduce clinical phases II and III by using human challenge studies through eliberate infection of healthy volunteers with SARS-CoV-2 after administration of the candidate vaccine. Accelerating the development of a COVID-19 vaccine even for a few weeks or months would have a great beneficial impact on public health by saving many lives.

Reverse-transcriptase polymerase chain reaction versus chest computed tomography for detecting early symptoms of COVID-19. A diagnostic accuracy systematic review and meta-analysis. BACKGROUND: A positive real-time reverse-transcriptase polymerase chain reaction (RT-PCR) for SARS CoV-2, from nasopharyngeal swabs, is the current gold standard diagnostic test for this virus and has sensitivity of 60-70%. Some studies have demonstrated a significant number of false-negative RT-PCR tests while displaying significant tomographic findings, in the early days of symptoms of

COVID-19. OBJECTIVE: To compare accuracy between RT-PCR and computed tomography (CT) for detecting COVID-19 in the first week of its symptoms during the pandemic. DESIGN AND SETTING: Systematic review of comparative studies of diagnostic accuracy within the Evidence-based Health Program of a federal university in SÃ£o Paulo (SP), Brazil. METHODS: A systematic search of the relevant literature was conducted in the PubMed, EMBASE, Cochrane Library, CINAHL and LILACS databases, for articles published up to June 6, 2020, relating to studies evaluating the diagnostic accuracy of RT-PCR and chest CT for COVID-19 diagnoses. The QUADAS 2 tool was used for methodological quality evaluation. RESULTS: In total, 1204 patients with COVID-19 were evaluated; 1045 had tomographic findings while 755 showed positive RT-PCR for COVID-19. RT-PCR demonstrated 81.4% sensitivity, 100% specificity and 92.3% accuracy. Chest CT demonstrated 95.3% sensitivity, 43.8% specificity and 63.3% accuracy. CONCLUSION: The high sensitivity and detection rates shown by CT demonstrate that this technique has a high degree of importance in the early stages of the disease. During an outbreak, the higher prevalence of the condition increases the positive predictive value of CT. REGISTRATION NUMBER: DOI: 10.17605/OSF.IO/UNGHA in the Open Science Framework.

The Association between Influenza and Pneumococcal Vaccinations and SARS-Cov-2 Infection: Data from the EPICOVID19 Web-Based Survey. The present study aims to evaluate whether influenza and pneumococcal vaccinations are associated with positive nasopharyngeal swab (NPS) testing to detect SARS-CoV-2. Data from the Italian cross-sectional web-based survey (EPICOVID19), based on a self-selection sample of individuals aged â‰¥18, were considered. The probability of a positive SARS-CoV-2 NPS test result as a function of influenza or anti-pneumococcal vaccination was evaluated using multivariable logistic regression, stratifying analysis by age (<65 years, â‰¥65 years). From April 2020, 170,731 individuals aged <65 years and 28,097 â‰¥65 years filled out the EPICOVID19 questionnaire. Influenza and anti-pneumococcal vaccinations were received, respectively, by 16% and 2% of those <65 years, and by 53% and 13% of those â‰¥65 years. SARS-CoV-2 NPS testing was reported by 6680 participants. Anti-pneumococcal and influenza vaccinations were associated with a decreased probability of a SARS-CoV-2 NPS positive test in the younger participants (OR = 0.61, 95% CI 0.41-0.91; OR = 0.85, 95%CI 0.74-0.98; respectively). A significantly lower probability of a positive test result was detected in the individuals â‰¥65 years who received anti-pneumococcal vaccination (OR = 0.56, 95%CI 0.33-0.95). These results need to be confirmed by further investigations, but they are relevant given the probable coexistence of influenza, bacterial infections, and COVID-19 over the coming autumn-winter season.

Vaccination against SARS-CoV-2 and disease enhancement - knowns and unknowns. INTRODUCTION: The world is currently fighting a COVID-19 pandemic, perhaps the most disruptive infectious disease outbreak since the 1918 Spanish influenza. Governments have taken drastic measures to curb the spread of SARS-CoV-2, and the development of safe and efficacious vaccine candidates is being accelerated. The possibility of vaccine-mediated disease enhancement with coronavirus vaccines has been flagged as a potential safety concern, and, despite the urgent need, should be thoroughly assessed as vaccines against SARS-CoV-2 are being tested. AREA COVERED: We review the in vivo evidence suggesting a theoretical risk of disease enhancement after vaccination with SARS-CoV and MERS-CoV vaccine candidates. We also identify knowledge gaps that need to be filled to maximize the chance of developing a safe vaccine and minimize the risk of encountering disease enhancement in vaccinated individuals after exposure to SARS-CoV-2. EXPERT OPINION: We compile and propose avenues to investigate the risk of vaccine-mediated disease enhancement both during pre-clinical and early clinical development. While the pressing need for a vaccine against COVID-19 (and future epidemic coronaviruses) cannot be ignored, we advocate to keep safety at the

center of the debate. Protecting individuals with effective and safe vaccines should be a priority, even during extraordinary times like the COVID-19 pandemic.

[Recovering lost vaccine coverage due to COVID-19 pandemic]. The 2019 coronavirus disease pandemic can have an alarming impact on vaccination coverage. WHO, UNICEF and Gavi warn that at least 80Â million children under the age ofÂ 1 are at risk of contracting diseases such as diphtheria, measles and polio due to the interruption of routine immunization and the temporary suspension of 93 campaigns of large-scale vaccination.In Spain, a new healthcare scenario, which prioritizes telematics over in person, fear of contagion by going to health centers, and recommendations for physical distance and restricted mobility, reduce attendance at primary care centers. Despite recommendations established by the health authorities, vaccination coverage has decreased in all Autonomous Communities between 5% and 60%, depending on the age and type of vaccine. School vaccinations have been suspended and only vaccination of pregnant women against tetanus, diphtheria and pertussis has been maintained. The decrease has been more evident for non gratuity vaccines: the first dose of meningococcal vaccineÂ B has decreased by 68.4% in the Valencian Community, and Andalusia has observed a 39% decrease in the total doses of this vaccine and of 18% for that of rotavirus.The recovering of vaccinations should be planned, organized and carried out in the shortest possible time.This article discusses some aspects of the recovery of vaccination coverage for different groups: children, adolescents and adults, and patients at risk and in special situations.

Development of potential COVID-19 vaccines continues to accelerate.

Emergence, Transmission, and Potential Therapeutic Targets for the COVID-19 Pandemic Associated with the SARS-CoV-2. The pandemic of the severe acute respiratory syndrome coronavirus (SARS-CoV)-2 at the end of 2019 marked the third outbreak of a highly pathogenic coronavirus affecting the human population in the past twenty years. Cross-species zoonotic transmission of SARS-CoV-2 has caused severe pathogenicity and led to more than 655,000 fatalities worldwide until July 28, 2020. Outbursts of this virus underlined the importance of controlling infectious pathogens across international frontiers. Unfortunately, there is currently no clinically approved antiviral drug or vaccine against SARS-CoV-2, although several broad-spectrum antiviral drugs targeting multiple RNA viruses have shown a positive response and improved recovery in patients. In this review, we compile our current knowledge of the emergence, transmission, and pathogenesis of SARS-CoV-2 and explore several features of SARS-CoV-2. We emphasize the current therapeutic approaches used to treat infected patients. We also highlight the results of in vitro and in vivo data from several studies, which have broadened our knowledge of potential drug candidates for the successful treatment of patients infected with and discuss possible virus and host-based treatment options against SARS-CoV-2.

Changes in lung ultrasound of symptomatic healthcare professionals with COVID-19 pneumonia and their association with clinical findings. PURPOSE: To evaluate ultrasound signs of coronavirus disease-19 (COVID-19) pneumonia in symptomatic healthcare professionals and to correlate those changes with clinical findings. METHODS: All patients underwent real-time polymerase chain reaction (RT-PCR), lung ultrasound (LUS) and clinical evaluation on the same day. In each of the 12 areas evaluated in the LUS, the LUS signs were scored to generate the aeration score. RESULTS: A total of 409 participants had positive PCR, with a median age of 41 (35-51) years. All participants had clinical symptoms, with cough in 84.1%, fever in 69.7%, and dyspnea in 36.2% of cases. In the LUS, 72.6% of participants had B-lines >2, 36.2% had coalescent B-lines, and 8.06% had subpleural consolidations. The median aeration score was 3 (2-7). The aeration score differed significantly regarding the presence of cough (P =â€‰.002), fever (P =â€‰.001), and dyspnea (P <â€‰.0001). The finding of subpleural consolidations in the LUS showed significant differences between participants with or without dyspnea (P <â€‰.0001). CONCLUSIONS: In healthcare professionals with COVID-19, LUS

plays a key role in the characterization of lung involvement. Although B-lines are the most common ultrasound sign, subpleural consolidations are those that most impact the respiratory condition.

COVID-19: Underpinning Research for Detection, Therapeutics, and Vaccines Development. BACKGROUND: The newly emerged coronavirus SARS-CoV-2, first reported in December 2019, has infected about five and a half million people globally and resulted in nearly 9063264 deaths until the 24th of June 2020. Nevertheless, the highly contagious virus has instigated an unimaginably rapid response from scientific and medical communities. OBJECTIVES: Pioneering research on molecular mechanisms underlying the viral transmission, molecular pathogenicity, and potential treatments will be highlighted in this review. The development of antiviral drugs specific to SARS-CoV-2 is a complicated and tedious process. To accelerate scientific discoveries and advancement, researchers are consolidating available data from associated coronaviruses into a single pipeline, which can be readily made available to vaccine developers. METHODS: In order to find studies evaluating the COVID-19 virus epidemiology, repurposed drugs and potential vaccines, web searches and bibliographical bases have been used with keywords that matches the content of this review. RESULTS: The published results of SARS-CoV-2 structures and interactomics have been used to identify potential therapeutic candidates. We illustrate recent publications on SARS-CoV-2, concerning its molecular, epidemiological, and clinical characteristics, and focus on innovative diagnostics technologies in the production pipeline. This objective of this review is to enhance the comprehension of the unique characteristics of SARS-CoV-2 and strengthen future control measures. LAY SUMMARY: An innovative analysis is evaluating the nature of the COVID-19 pandemic. The aim is to increase knowledge of possible viral detection methods, which highlights several new technology limitations and advantages. We have assessed some drugs currently for patients (Lopinavir, Ritonavir, Anakinra and Interferon beta 1a), as the feasibility of COVID-19 specific antivirals is not presently known. The study explores the race toward vaccine development and highlights some significant trials and candidates in various clinical phases. This research addresses critical knowledge gaps by identifying repurposed drugs currently under clinical trials. Findings will be fed back rapidly to the researchers interested in COVID 19 and support the evidence and potential of possible therapeutics and small molecules with their mode of action.

COVID-19 Vaccines: Should We Fear ADE? Might COVID-19 vaccines sensitize humans to antibody-dependent enhanced (ADE) breakthrough infections? This is unlikely because coronavirus diseases in humans lack the clinical, epidemiological, biological, or pathological attributes of ADE disease exemplified by dengue viruses (DENV). In contrast to DENV, SARS and MERS CoVs predominantly infect respiratory epithelium, not macrophages. Severe disease centers on older persons with preexisting conditions and not infants or individuals with previous coronavirus infections. Live virus challenge of animals given SARS or MERS vaccines resulted in vaccine hypersensitivity reactions (VAH), similar to those in humans given inactivated measles or respiratory syncytial virus vaccines. Safe and effective COVID-19 vaccines must avoid VAH.

Preliminary concerns with vaccine vectors.

PhaseÂ I/II study of COVID-19 RNA vaccine BNT162b1 in adults. In March 2020, the World Health Organization (WHO) declared coronavirus disease 2019 (COVID-19), which is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)(1), a pandemic. With rapidly accumulating numbers of cases and deaths reported globally(2), a vaccine is urgently needed. Here we report the available safety, tolerability and immunogenicity data from an ongoing placebo-controlled, observer-blinded dose-escalation study (ClinicalTrials.gov identifier NCT04368728) among 45Â healthy adults (18-55Â years of age), who were randomized to receive 2 doses-separated by 21 days-of 10Â Î¼g, 30Â Î¼g or 100Â Î¼g of BNT162b1. BNT162b1 is a lipid-nanoparticle-formulated, nucleoside-modified mRNA vaccine that encodes the trimerized receptor-binding domain (RBD) of the spike glycoprotein of SARS-

CoV-2. Local reactions and systemic events were dose-dependent, generally mild to moderate, and transient. A second vaccination with 100Â Î¼g was not administered because of the increased reactogenicity and a lack of meaningfully increased immunogenicity after a single dose compared with the 30-Î¼g dose. RBD-binding IgG concentrations and SARS-CoV-2 neutralizing titres in sera increased with dose level and after a second dose. Geometric mean neutralizing titres reached 1.9-4.6-fold that of a panel of COVID-19 convalescent human sera, which were obtained at least 14Â days after a positive SARS-CoV-2 PCR. These results support further evaluation of this mRNA vaccine candidate.

Influenza Vaccination: An Ally to Mitigate Influenza-associated Risks During the Coronavirus Disease 2019 (COVID-19) Pandemic.

A Family Cluster of Coronavirus Disease (COVID-19) Infection with Different Clinical Manifestations. Coronavirus disease 2019 (COVID-19) caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) had been declared as a global pandemic by WHO. During the pandemic, a suspicion of COVID-19 infection could be found on patients presented with clinical symptoms of COVID-19. However, several new clinical symptoms of COVID-19 had also been reported recently. This caused difficulties to identify COVID-19 based on the clinical symptoms only. Real-Time Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) was absolutely needed to determine the correct diagnosis. We report a family cluster of COVID-19 with different clinical manifestations to show a potential COVID-19 transmission in person who has no symptoms initially but may develop symptoms later as the incubation period varies from 5-14 days. This asymptomatic person remains potential to transmit the virus. This report describes the epidemiological, clinical, radiological, laboratory findings, and different clinical manifestation of a family cluster of COVID-19 case in Indonesia. COVID-19 was transmitted from asymptomatic person in the incubation period.

The rate of SARS-CoV-2 positivity in asymptomatic pregnant women admitted to hospital for delivery: Experience of a pandemic center in Turkey. OBJECTIVE: To investigate the rate of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) positivity in asymptomatic pregnant women admitted to hospital for delivery in a Turkish pandemic center. STUDY DESIGN: This prospective cohort study was conducted in Ankara City Hospital between April, 15, 2020 and June, 5, 2020. A total of 206 asymptomatic pregnant women (103 low-risk pregnant women without any defined risk factor and 103 high-risk pregnant women) were screened for SARS-CoV-2 positivity upon admission to hospital for delivery. Detection of SARS-CoV2 in nasopharyngeal and oropharyngeal samples was performed by Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) method targeting RdRp (RNA dependent RNA polymerase) gene. Two groups were compared in terms of demographic features, clinical characteristics and SARS-CoV-2 positivity. RESULTS: Three of the 206 pregnant women participating in the study had positive RT-PCR tests (1.4 %) and all positive cases were in the high-risk pregnancy group. Although, one case in the high-risk pregnancy group had developed symptoms highly suspicious for COVID-19, two repeated RT-PCR tests were negative. SARS-CoV-2 RT-PCR positivity rate was significantly higher in the high-risk pregnancy group (2.9 % vs 0%, p = 0.04). CONCLUSION: Healthcare professionals should be cautious in the labor and delivery of high-risk pregnant women during the pandemic period and universal testing for COVID-19 may be considered in selected populations.

Fast-and-fit vaccines.

Avoiding COVID-19 complications with diabetic patients could be achieved by multi-dose Bacillus Calmette-GuÃ©rin vaccine: a case study of beta cells regeneration. Diabetes mellitus (DM) is one of the major risk factors for COVID-19 complications as it is one of the chronic immune-compromising conditions especially if patients have uncontrolled diabetes, poor HbA(1c) and/or irregular blood glucose levels. Diabetic patients' mortality rates with COVID-19 are higher than those of

cardiovascular or cancer patients. Recently, Bacillus Calmette-GuÃ©rin (BCG) vaccine has shown successful results in reversing diabetes in both rats and clinical trials based on different mechanisms from aerobic glycolysis to beta cells regeneration. BCG is a multi-face vaccine that has been used extensively in protection from tuberculosis (TB) and leprosy and has been repositioned for treatment of bladder cancer, diabetes and multiple sclerosis. Recently, COVID-19 epidemiological studies confirmed that universal BCG vaccination reduced morbidity and mortality in certain geographical areas. Countries without universal policies of BCG vaccination (Italy, Nederland, USA) have been more severely affected compared to countries with universal and long-standing BCG policies that have shown low numbers of reported COVID-19 cases. Some countries have started clinical trials that included a single dose BCG vaccine as prophylaxis from COVID-19 or an attempt to minimize its side effects. This proposed research aims to use BCG vaccine as a double-edged weapon countering both COVID-19 and diabetes, not only as protection but also as therapeutic vaccination. The work includes a case study of regenerated pancreatic beta cells based on improved C-peptide and PCPRI laboratory findings after BCG vaccination for a 9 year old patient. The patient was re-vaccinated based on a negative tuberculin test and no scar at the site of injection of the 1(st) BCG vaccination at birth. The authors suggest and invite the scientific community to take into consideration the concept of direct BCG re-vaccination (after 4 weeks) because of the reported gene expressions and exaggerated innate immunity consequently. As the diabetic MODY-5 patient (mutation of HNF1B, Val2Leu) was on low dose Riomet(Â®) while eliminating insulin gradually, a simple analytical method for metformin assay was recommended to ensure its concentration before use as it is not approved yet by the Egyptian QC labs.
[A race against the clock: creation of SARS-Cov-2 in the laboratory, a month after its emergence!]. SARS-CoV-2 (severe acute respiratory syndrome-coronavirus-2, which emerged in China at the end of 2019, is responsible for a global health crisis resulting in the confinement of more than 3 billion people worldwide and the sharp decline of the world economy. In this context, a race against the clock is launched in order to develop a treatment to stop the pandemic as soon as possible. A study published in Nature by the Volker Thiel team reports the development of reverse genetics for SARS-CoV-2 allowing them to recreate the virus in just a few weeks. The perspectives of this work are very interesting since it will allow the genetic manipulation of the virus and thus the development of precious tools which will be useful to fight the infection. Even though this approach represents a technological leap that will improve our knowledge of the virus, it also carries the germ of possible misuse and the creation of the virus for malicious purposes. The advantages and disadvantages of recreating SARS-CoV-2 in this pandemic period are discussed in this mini-synthesis.
The Development of COVID-19 Vaccines: Safeguards Needed.
China's coronavirus vaccines are leaping ahead - but face challenges as virus wanes.
Working Hypothesis for Glucose Metabolism and SARS-CoV-2 Replication: Interplay Between the Hexosamine Pathway and Interferon RF5 Triggering Hyperinflammation. Role of BCG Vaccine?
Developing a low-cost and accessible COVID-19 vaccine for global health.
Opinion: It's ethical to test promising coronavirus vaccines against less-promising ones.
An Alphavirus-derived replicon RNA vaccine induces SARS-CoV-2 neutralizing antibody and T cell responses in mice and nonhuman primates. The coronavirus disease 2019 (COVID-19) pandemic, caused by infection with the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), is having a deleterious impact on health services and the global economy, highlighting the urgent need for an effective vaccine. Such a vaccine would need to rapidly confer protection after one or two doses and would need to be manufactured using components suitable for scale up. Here, we developed an Alphavirus-derived replicon RNA vaccine candidate, repRNA-CoV2S, encoding the SARS-CoV-2 spike (S) protein. The RNA replicons were formulated with lipid inorganic nanoparticles (LIONs) that were

designed to enhance vaccine stability, delivery, and immunogenicity. We show that a single intramuscular injection of the LION/repRNA-CoV2S vaccine in mice elicited robust production of anti-SARS-CoV-2 S protein IgG antibody isotypes indicative of a type 1 T helper cell response. A prime/boost regimen induced potent T cell responses in mice including antigen-specific responses in the lung and spleen. Prime-only immunization of aged (17 months old) mice induced smaller immune responses compared to young mice, but this difference was abrogated by booster immunization. In nonhuman primates, prime-only immunization in one intramuscular injection site or prime/boost immunizations in five intramuscular injection sites elicited modest T cell responses and robust antibody responses. The antibody responses persisted for at least 70 days and neutralized SARS-CoV-2 at titers comparable to those in human serum samples collected from individuals convalescing from COVID-19. These data support further development of LION/repRNA-CoV2S as a vaccine candidate for prophylactic protection against SARS-CoV-2 infection.

Potential role of Bacillus Calmette-GuÃ©rin (BCG) vaccination in COVID-19 pandemic mortality: Epidemiological and Immunological aspects. SARS-CoV-2 had already killed more than 400,000 patients around the world according to data on 7 June 2020. Bacillus Calmette-GuÃ©rin (BCG) vaccine is developed from live-attenuated Mycobacterium bovis, which is a microorganism found in a cow. Discovered by Dr. Albert Calmette and Camille GuÃ©rin since 1921, the BCG has served as a protection against tuberculosis and its complications. It is noticeable that countries which use mandatory BCG vaccination approach had lower COVID-19 infection and death rate. Current review aims to clarify this issue through epidemiological illustration of correlation between national BCG immunization and COVID-19 mortality, in addition to biological background of BCG-induced immunity Epidemiological data shows that universal BCG policy countries have lower median mortality rate compare to countries with past universal BCG policy and non-mass immunization BCG. (18 May 2020). Still, the links between BCG vaccination and better COVID-19 situation in certain countries are unclear, and more data on actual infection rate using SAR-CoV-2 antibody testing in large population sample is crucial for disease spreading comparison. Two immunological mechanisms, heterologous effects of adaptive immunity and trained innate immunity which induced by BCG vaccination, may explain host tolerance against COVID-19 infection, however, there is no direct evidence to support this biological background. Clinical trials related to BCG vaccination against COVID-19 are under investigation. Without a strong evidence, BCG must not be recommended for COVID-19 prevention, although, this should not be absolute contraindication. Risk of local and systemic complications from the vaccine should be informed to individual, who request BCG immunization.

SARS-CoV-2 replicating in nonprimate mammalian cells probably have critical advantages for COVID-19 vaccines due to anti-Gal antibodies: A minireview and proposals. Glycoproteins of enveloped viruses replicating in nonprimate mammalian cells carry Î±-1,3-galactose (Î±-Gal) glycans, and can bind to anti-Gal antibodies which are abundant in humans. The antibodies have protected humans and their ancestors for millions of years, because they inhibit replication of many kinds of microbes carrying Î±Gal glycans and aid complements and macrophages to destroy them. Therefore, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) replicating in nonprimate mammalian cells (eg, PK-15 cells) carry Î±Gal glycans and could be employed as a live vaccine for corona virus 2019 (COVID-19). The live vaccine safety could be further enhanced through intramuscular inoculation to bypass the fragile lungs, like the live unattenuated adenovirus vaccine safely used in US recruits for decades. Moreover, the immune complexes of SARS-CoV-2 and anti-Gal antibodies could enhance the efficacy of COVID-19 vaccines, live or inactivated, carrying Î±-Gal glycans. Experiments are imperatively desired to examine these novel vaccine strategies which probably have the critical advantages for defeating the pandemic of COVID-19 and preventing other viral infectious diseases.

Risk Factors Associated With Mortality Among Patients With COVID-19 in Intensive Care Units in Lombardy, Italy. IMPORTANCE: Many patients with coronavirus disease 2019 (COVID-19) are critically ill and require care in the intensive care unit (ICU). OBJECTIVE: To evaluate the independent risk factors associated with mortality of patients with COVID-19 requiring treatment in ICUs in the Lombardy region of Italy. DESIGN, SETTING, AND PARTICIPANTS: This retrospective, observational cohort study included 3988 consecutive critically ill patients with laboratory-confirmed COVID-19 referred for ICU admission to the coordinating center (Fondazione IRCCS [Istituto di Ricovero e Cura a Carattere Scientifico] Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy) of the COVID-19 Lombardy ICU Network from February 20 to April 22, 2020. Infection with severe acute respiratory syndrome coronavirus 2 was confirmed by real-time reverse transcriptase-polymerase chain reaction assay of nasopharyngeal swabs. Follow-up was completed on May 30, 2020. EXPOSURES: Baseline characteristics, comorbidities, long-term medications, and ventilatory support at ICU admission. MAIN OUTCOMES AND MEASURES: Time to death in days from ICU admission to hospital discharge. The independent risk factors associated with mortality were evaluated with a multivariable Cox proportional hazards regression. RESULTS: Of the 3988 patients included in this cohort study, the median age was 63 (interquartile range [IQR] 56-69) years; 3188 (79.9%; 95% CI, 78.7%-81.1%) were men, and 1998 of 3300 (60.5%; 95% CI, 58.9%-62.2%) had at least 1 comorbidity. At ICU admission, 2929 patients (87.3%; 95% CI, 86.1%-88.4%) required invasive mechanical ventilation (IMV). The median follow-up was 44 (95% CI, 40-47; IQR, 11-69; range,â€‰0-100) days; median time from symptoms onset to ICU admission was 10 (95% CI, 9-10; IQR, 6-14) days; median length of ICU stay was 12 (95% CI, 12-13; IQR, 6-21) days; and median length of IMV was 10 (95% CI, 10-11; IQR, 6-17) days. Cumulative observation time was 164â€¯305 patient-days. Hospital and ICU mortality rates were 12 (95% CI, 11-12) and 27 (95% CI, 26-29) per 1000 patients-days, respectively. In the subgroup of the first 1715 patients, as of May 30, 2020, 865 (50.4%) had been discharged from the ICU, 836 (48.7%) had died in the ICU, and 14 (0.8%) were still in the ICU; overall, 915 patients (53.4%) died in the hospital. Independent risk factors associated with mortality included older age (hazard ratio [HR], 1.75; 95% CI, 1.60-1.92), male sex (HR, 1.57; 95% CI, 1.31-1.88), high fraction of inspired oxygen (Fio2) (HR, 1.14; 95% CI, 1.10-1.19), high positive end-expiratory pressure (HR, 1.04; 95% CI, 1.01-1.06) or low Pao2:Fio2 ratio (HR, 0.80; 95% CI, 0.74-0.87) on ICU admission, and history of chronic obstructive pulmonary disease (HR, 1.68; 95% CI, 1.28-2.19), hypercholesterolemia (HR, 1.25; 95% CI, 1.02-1.52), and type 2 diabetes (HR, 1.18; 95% CI, 1.01-1.39). No medication was independently associated with mortality (angiotensin-converting enzyme inhibitors HR, 1.17; 95% CI, 0.97-1.42; angiotensin receptor blockers HR, 1.05; 95% CI, 0.85-1.29). CONCLUSIONS AND RELEVANCE: In this retrospective cohort study of critically ill patients admitted to ICUs in Lombardy, Italy, with laboratory-confirmed COVID-19, most patients required IMV. The mortality rate and absolute mortality were high.

An mRNA Vaccine against SARS-CoV-2 - Preliminary Report. BACKGROUND: The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged in late 2019 and spread globally, prompting an international effort to accelerate development of a vaccine. The candidate vaccine mRNA-1273 encodes the stabilized prefusion SARS-CoV-2 spike protein. METHODS: We conducted a phase 1, dose-escalation, open-label trial including 45 healthy adults, 18 to 55 years of age, who received two vaccinations, 28 days apart, with mRNA-1273 in a dose of 25 Î¼g, 100 Î¼g, or 250 Î¼g. There were 15 participants in each dose group. RESULTS: After the first vaccination, antibody responses were higher with higher dose (day 29 enzyme-linked immunosorbent assay anti-S-2P antibody geometric mean titer [GMT], 40,227 in the 25-Î¼g group, 109,209 in the 100-Î¼g group, and 213,526 in the 250-Î¼g group). After the second vaccination, the titers increased (day 57 GMT, 299,751, 782,719, and 1,192,154, respectively). After the second vaccination, serum-neutralizing activity was detected by two methods in all participants evaluated, with values generally similar to

those in the upper half of the distribution of a panel of control convalescent serum specimens. Solicited adverse events that occurred in more than half the participants included fatigue, chills, headache, myalgia, and pain at the injection site. Systemic adverse events were more common after the second vaccination, particularly with the highest dose, and three participants (21%) in the 250-Î¼g dose group reported one or more severe adverse events. CONCLUSIONS: The mRNA-1273 vaccine induced anti-SARS-CoV-2 immune responses in all participants, and no trial-limiting safety concerns were identified. These findings support further development of this vaccine. (Funded by the National Institute of Allergy and Infectious Diseases and others; mRNA-1273 ClinicalTrials.gov number, NCT04283461).

Why continuing uncertainties are no reason to postpone challenge trials for coronavirus vaccines. To counter the pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), some have proposed accelerating SARS-CoV-2 vaccine development through controlled human infection (or 'challenge') trials. These trials would involve the deliberate exposure of relatively few young, healthy volunteers to SARS-CoV-2. We defend this proposal against the charge that there is still too much uncertainty surrounding the risks of COVID-19 to responsibly run such a trial.

Virus shedding dynamics in asymptomatic and mildly symptomatic patients infected with SARS-CoV-2. OBJECTIVES: Asymptomatic patients, together with those with mild symptoms of coronavirus disease 2019 (COVID-19), may play an important role in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission. However, the dynamics of virus shedding during the various phases of the clinical course of COVID-19 remains unclear at this stage. METHODS: A total of 18 patients found to be positive for SARS-CoV-2 infection by real-time reverse transcription PCR (RT-PCR) assay and admitted to Chongqing University Central Hospital between 29 January and 5 February 2020 were enrolled into this study. Medical data, pulmonary computed tomographic (CT) scan images and RT-PCR results were periodically collected during the patients' hospital stay. All participants were actively followed up for 2Â weeks after discharge. RESULTS: A total of nine (50%) asymptomatic patients and nine (50%) patients with mild symptoms of COVID-19 were identified at admission. Six patients (66.7%) who were asymptomatic at admission developed subjective symptoms during hospitalization and were recategorized as being presymptomatic. The median duration of virus shedding was 11.5, 28 and 31Â days for presymptomatic, asymptomatic and mildly symptomatic patients, separately. Seven patients (38.9%) continued to shed virus after hospital discharge. During the convalescent phase, detectable antibodies to SARS-CoV-2 and RNA were simultaneously observed in five patients (27.8%). CONCLUSIONS: Long-term virus shedding was documented in patients with mild symptoms and in asymptomatic patients. Specific antibody production to SARS-CoV-2 may not guarantee virus clearance after discharge. These observations should be considered when making decisions regarding clinical and public health, and when considering strategies for the prevention and control of SARS-CoV-2 infection.

The Brighton Collaboration standardized template for collection of key information for benefit-risk assessment of protein vaccines. Several protein vaccine candidates are among the COVID-19 vaccines in development. The Brighton Collaboration Viral Vector Vaccines Safety Working Group (V3SWG) has prepared a standardized template to describe the key considerations for the benefit-risk assessment of protein vaccines. This will help key stakeholders to assess potential safety issues and understand the benefit-risk of such a vaccine platform. The structured and standardized assessment provided by the template would also help contribute to improved public acceptance and communication of licensed protein vaccines.

Recombinant SARS-CoV-2 spike S1-Fc fusion protein induced high levels of neutralizing responses in nonhuman primates. The COVID-19 outbreak has become a global pandemic responsible for over 2,000,000 confirmed cases and over 126,000 deaths worldwide. In this study, we examined the

immunogenicity of CHO-expressed recombinant SARS-CoV-2 S1-Fc fusion protein in mice, rabbits, and monkeys as a potential candidate for a COVID-19 vaccine. We demonstrate that the S1-Fc fusion protein is extremely immunogenic, as evidenced by strong antibody titers observed by day 7. Strong virus neutralizing activity was observed on day 14 in rabbits immunized with the S1-Fc fusion protein using a pseudovirus neutralization assay. Most importantly, in <20Â days and three injections of the S1-Fc fusion protein, two monkeys developed higher virus neutralizing titers than a recovered COVID-19 patient in a live SARS-CoV-2 infection assay. Our data strongly suggests that the CHO-expressed SARS-CoV-2 S1-Fc recombinant protein could be a strong candidate for vaccine development against COVID-19.

Laboratory Tests for COVID-19: A Review of Peer-Reviewed Publications and Implications for Clinical Use. Diagnostic tests for the coronavirus infection 2019 (COVID-19) are critical for prompt diagnosis, treatment and isolation to break the cycle of transmission. A positive real-time reverse-transcriptase polymerase chain reaction (RT-PCR), in conjunction with clinical and epidemiologic data, is the current standard for diagnosis, but several challenges still exist. Serological assays help to understand epidemiology better and to evaluate vaccine responses but they are unreliable for diagnosis in the acute phase of illness or assuming protective immunity. Serology is gaining attention, mainly because of convalescent plasma gaining importance as treatment for clinically worsening COVID-19 patients. We provide a narrative review of peer-reviewed research studies on RT-PCR, serology and antigen immune-assays for COVID-19, briefly describe their lab methods and discuss their limitations for clinical practice.

Epitope-based peptide vaccines predicted against novel coronavirus disease caused by SARS-CoV-2. The outbreak of the 2019 novel coronavirus (SARS-CoV-2) has infected millions of people with a large number of deaths across the globe. The existing therapies are limited in dealing with SARS-CoV-2 due to the sudden appearance of the virus. Therefore, vaccines and antiviral medicines are in desperate need. We took immune-informatics approaches to identify B- and T-cell epitopes for surface glycoprotein (S), membrane glycoprotein (M) and nucleocapsid protein (N) of SARS-CoV-2, followed by estimating their antigenicity and interactions with the human leukocyte antigen (HLA) alleles. Allergenicity, toxicity, physiochemical properties analysis and stability were examined to confirm the specificity and selectivity of the epitope candidates. We identified a total of five B cell epitopes in RBD of S protein, seven MHC class-I, and 18 MHC class-II binding T-cell epitopes from S, M and N protein which showed non-allergenic, non-toxic and highly antigenic features and non-mutated in 55,179 SARS-CoV-2 virus strains until June 25, 2020. The epitopes identified here can be a potentially good candidate repertoire for vaccine development.

Virolactia in an Asymptomatic Mother with COVID-19. Background: Limited data are available on the perinatal and postnatal transmission of novel coronavirus disease 2019 (COVID-19). The Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) recommended breastfeeding with necessary precautions to mothers with COVID-19. Case Presentation: A 20-year-old pregnant woman with no symptoms of COVID-19 presented to the hospital for delivery at 39 weeks of gestation. She was tested for severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) by reverse transcriptase polymerase chain reaction (RT-PCR) because her father had been diagnosed with COVID-19. A nasopharyngeal swab RT-PCR test was positive for SARS-CoV-2. Therefore, the baby and the mother were cared for separately after delivery. Breast milk obtained after first lactation was tested by real-time RT-PCR and was positive for SARS-CoV-2. Conclusions: In this article, we aimed to report the presence of SARS-CoV-2 in breast milk. Although further studies are needed, this situation may have an impact on breastfeeding recommendations.

Active surveillance of acute paediatric hospitalisations demonstrates the impact of vaccination programmes and informs vaccine policy in Canada and Australia. Sentinel surveillance of acute

hospitalisations in response to infectious disease emergencies such as the 2009 influenza A(H1N1)pdm09 pandemic is well described, but recognition of its potential to supplement routine public health surveillance and provide scalability for emergency responses has been limited. We summarise the achievements of two national paediatric hospital surveillance networks relevant to vaccine programmes and emerging infectious diseases in Canada (Canadian Immunization Monitoring Program Active; IMPACT from 1991) and Australia (Paediatric Active Enhanced Disease Surveillance; PAEDS from 2007) and discuss opportunities and challenges in applying their model to other contexts. Both networks were established to enhance capacity to measure vaccine preventable disease burden, vaccine programme impact, and safety, with their scope occasionally being increased with emerging infectious diseases' surveillance. Their active surveillance has increased data accuracy and utility for syndromic conditions (e.g. encephalitis), pathogen-specific diseases (e.g. pertussis, rotavirus, influenza), and adverse events following immunisation (e.g. febrile seizure), enabled correlation of biological specimens with clinical context and supported responses to emerging infections (e.g. pandemic influenza, parechovirus, COVID-19). The demonstrated long-term value of continuous, rather than incident-related, operation of these networks in strengthening routine surveillance, bridging research gaps, and providing scalable public health response, supports their applicability to other countries.

Influenza vaccination in the COVID-19 era. Influenza spreads globally annually with significant paediatric and adult attack rates and considerable morbidity, mortality and the exacerbation of extant chronic disease. In the northern and southern hemispheres, outbreaks occur mainly in the respective winter seasons. Influenza vaccination is available but only partially effective. In the absence of a vaccine, in winter, novel coronavirus COVID-19 will also circulate in parallel with seasonal influenza. Thus far it appears that with the current strains of these two viruses, the clinical outcome of co-infection is not significantly worse than infection with COVID-19 alone. However, several strains of influenza circulate, including strains still to come. Similarly, COVID-19 has several strains, with probably more to come. This paper discusses these issues and estimates ideal minimum influenza vaccination coverage based on an estimated influenza Basic Reproduction Number (R0) of 0.9-2.1 so as to obtain herd immunity or approach it. There is a strong argument for attempting near universal population coverage with the annual influenza vaccine leading up to next winter.

Coronavirus vaccine-associated lung immunopathology-what is the significance?

COVID-19 Vaccines: "Warp Speed" Needs Mind Melds, Not Warped Minds. In this review, we address issues that relate to the rapid "Warp Speed" development of vaccines to counter the COVID-19 pandemic. We review the antibody response that is triggered by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection of humans and how it may inform vaccine research. The isolation and properties of neutralizing monoclonal antibodies from COVID-19 patients provide additional information on what vaccines should try to elicit. The nature and longevity of the antibody response to coronaviruses are relevant to the potency and duration of vaccine-induced immunity. We summarize the immunogenicity of leading vaccine candidates tested to date in animals and humans and discuss the outcome and interpretation of virus challenge experiments in animals. By far the most immunogenic vaccine candidates for antibody responses are recombinant proteins, which were not included in the initial wave of Warp Speed immunogens. A substantial concern for SARS-CoV-2 vaccines is adverse events, which we review by considering what was seen in studies of SARS-CoV-1 and Middle East respiratory syndrome coronavirus (MERS-CoV) vaccines. We conclude by outlining the possible outcomes of the Warp Speed vaccine program, which range from the hoped-for rapid success to a catastrophic adverse influence on vaccine uptake generally.

Evaluation of Chilblains as a Manifestation of the COVID-19 Pandemic. IMPORTANCE: During the coronavirus disease 2019 (COVID-19) pandemic, several cases of chilblains have been reported.

OBJECTIVE: To determine if chilblains are associated with COVID-19. DESIGN, SETTING, AND PARTICIPANTS: This monocentric case series was conducted at the Department of Dermatology at Cliniques universitaires Saint-Luc, a tertiary care hospital in Brussels, Belgium, between April 10 and April 17, 2020. We evaluated a total of 31 referred patients who had recently developed chilblains. MAIN OUTCOMES AND MEASURES: Real-time reverse transcriptase-polymerase chain reaction (RT-PCR) was used to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA on nasopharyngeal swabs for all patients and in skin biopsy specimens for 22 patients. Blood samples from all patients were tested for specific anti-SARS-CoV-2 immunoglobulin (Ig) M and IgG antibodies. All patients had extended blood analyses. Histologic (22 patients) and immunofluorescence examinations (15 patients) were performed on the skin biopsy specimens. RESULTS: The 31 patients were generally in good health; most were teenagers or young adults, and 19 were women. Histopathologic analysis of skin biopsy specimens (22 patients) confirmed the diagnosis of chilblains and showed occasional lymphocytic or microthrombotic phenomena. Immunofluorescence analyses showed vasculitis of small-diameter vessels in 7 patients. In all patients, SARS-CoV-2 RNA remained undetected by RT-PCR on nasopharyngeal swabs and in biopsy samples of the skin lesions. The IgM and IgG antibody titers were negative for SARS-CoV-2 in all patients (<1.0 arbitrary unit/mL). No significant abnormalities in blood test results were suggestive of systemic disease. Antinuclear antibody titers were low in 7 patients and higher in 1 patient. CONCLUSIONS AND RELEVANCE: Chilblains appeared not to be directly associated with COVID-19 in this case series. Lifestyle changes associated with community containment and lockdown measures are a possible explanation for these lesions.

The Brighton Collaboration standardized template for collection of key information for benefit-risk assessment of nucleic acid (RNA and DNA) vaccines. Nucleic acid (DNA and RNA) vaccines are among the most advanced vaccines for COVID-19 under development. The Brighton Collaboration Viral Vector Vaccines Safety Working Group (V3SWG) has prepared a standardized template to describe the key considerations for the benefit-risk assessment of nucleic acid vaccines. This will facilitate the assessment by key stakeholders of potential safety issues and understanding of overall benefit-risk. The structured assessment provided by the template can also help improve communication and public acceptance of licensed nucleic acid vaccines.

Nanotechnology for COVID-19: Therapeutics and Vaccine Research. The current global health threat by the novel coronavirus disease 2019 (COVID-19) requires an urgent deployment of advanced therapeutic options available. The role of nanotechnology is highly relevant to counter this "virus" nano enemy. Nano intervention is discussed in terms of designing effective nanocarriers to counter the conventional limitations of antiviral and biological therapeutics. This strategy directs the safe and effective delivery of available therapeutic options using engineered nanocarriers, blocking the initial interactions of viral spike glycoprotein with host cell surface receptors, and disruption of virion construction. Controlling and eliminating the spread and reoccurrence of this pandemic demands a safe and effective vaccine strategy. Nanocarriers have potential to design risk-free and effective immunization strategies for severe acute respiratory syndrome coronavirus 2 vaccine candidates such as protein constructs and nucleic acids. We discuss recent as well as ongoing nanotechnology-based therapeutic and prophylactic strategies to fight against this pandemic, outlining the key areas for nanoscientists to step in.

Are Genetic Vaccines the Right Weapon against COVID-19?

Could sudden sensorineural hearing loss be the sole manifestation of COVID-19? An investigation into SARS-COV-2 in the etiology of sudden sensorineural hearing loss. OBJECTIVE: This study aimed to investigate the presence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in patients presenting with only sudden sensorineural hearing loss (SSHNL) during the COVID-19 pandemic.

METHODS: The study included five male patients who presented with the sole complaint of unilateral SSNHL to the otolaryngology outpatient clinic between 03-12 April 2020. The patients were referred to the infectious diseases clinic to be evaluated for SARS-CoV-2 by real time polymerase chain reaction (RT-PCR) testing. RESULTS: RT-PCR testing for SARS-CoV-2 was positive in one of the patients and negative in the other four patients. A positive response to COVID-19-specific treatment in the SARS-CoV-2 positive SSNHL patient was noted. CONCLUSION: It should be remembered that non-specific symptoms such as SSNHL could be the only sign with which to recognize a COVID-19 case. Awareness of such a non-specific presentation of COVID-19 patients is crucial during this pandemic period for preventing infectious spread through isolation and early initiation of COVID-19 targeted treatment.

First Detection of SARS-CoV-2 by Real-Time Reverse Transcriptase-Polymerase Chain Reaction Assay in Pleural Fluid. Coronavirus disease 2019 (COVID-19) is a pandemic infection due to the spread of a novel coronavirus (severe acute respiratory syndrome coronavirus 2), resulting in a wide range of clinical features, from asymptomatic carriers to ARDS. The gold standard for diagnosis is nucleic acid detection by real-time reverse transcriptase-polymerase chain reaction in nasopharyngeal swabs. However, due to limitations in this technique's sensitivity, thoracic imaging plays a crucial, complementary role in diagnostic evaluation and also allows for detection of atypical findings and potential alternative targets for sampling (eg, pleural effusion). Although less common, pleural involvement has been described in a minority of patients. This report describes the first case of reverse transcriptase-polymerase chain reaction detection of severe acute respiratory syndrome coronavirus 2 in pleural fluid obtained by means of ultrasound-guided thoracentesis, and its main characteristics are detailed. Pleural effusion is not a common finding in COVID-19 infection, but a prompt recognition of this potential localization may be useful to optimize diagnostic evaluation as well as the management of these patients.

Current and emerging therapeutics for neuromyelitis optica spectrum disorder: Relevance to the COVID-19 pandemic. Neuromyelitis optica spectrum disorder (NMOSD) can lead to immobility and bulbar weakness. This, in addition to the older age of onset and the higher rate of hospitalization compared to multiple sclerosis, makes this patient group a potential target for complicated COVID-19 infection. Moreover, many of the commonly used preventive therapies for NMOSD are cell-depleting immunouppsressants with increased risk of viral and bacterial infections. The emergence of several new NMOSD therapeutics, including immune-modulating agents, concurrently with the worldwide spread of the COVID-19 global pandemic call for careful therapeutic planning and add to the complexity of NMOSD management. Altering the common therapeutic approach to NMOSD during the pandemic may be necessary to balance both efficacy and safety of treatment. Selection of preventive therapy should take in consideration the viral exposure risk related to the route and frequency of administration and, most importantly, the immunological properties of each therapeutic agent and its potential impact on the risk of SARS-CoV-2 susceptibility and severity of infection. The impact of the therapeutic agent on the immune response against the future SARS-CoV-2 vaccine should also be considered in the clinical decision-making. In this review, we will discuss the immune response against SARS-CoV-2 and evaluate the potential impact of the current and emerging NMOSD therapeutics on infection risk, infection severity, and future SARS-CoV-2 vaccination. We propose a therapeutic approach to NMOSD during the COVID-19 pandemic based on analysis of the mechanism of action, route of administration, and side effect profile of each therapeutic agent.

Factors associated with the duration of hospitalisation among COVID-19 patients in Vietnam: A survival analysis. BACKGROUND: The median duration of hospital stays due to COVID-19 has been reported in several studies on China as 10-13 days. Global studies have indicated that the length of hospitalisation depends on different factors, such as the time elapsed from exposure to symptom

onset, and from symptom onset to hospital admission, as well as specificities of the country under study. The goal of this paper is to identify factors associated with the median duration of hospital stays of COVID-19 patients during the second COVID-19 wave that hit Vietnam from 5 March to 8 April 2020. METHOD: We used retrospective data on 133 hospitalised patients with COVID-19 recorded over at least two weeks during the study period. The Cox proportional-hazards regression model was applied to determine the potential risk factors associated with length of hospital stay. RESULTS: There were 65 (48.9%) females, 98 (73.7%) patients 48 years old or younger, 15 (11.3%) persons with comorbidities, 21 (16.0%) severely ill patients and 5 (3.8%) individuals with life-threatening conditions. Eighty-two (61.7%) patients were discharged after testing negative for the SARS-CoV-2 virus, 51 were still in the hospital at the end of the study period and none died. The median duration of stay in a hospital was 21 (IQR: 16-34) days. The multivariable Cox regression model showed that age, residence and sources of contamination were significantly associated with longer duration of hospitalisation. CONCLUSION: A close look at how long COVID-19 patients stayed in the hospital could provide an overview of their treatment process in Vietnam, and support the country's National Steering Committee on COVID-19 Prevention and Control in the efficient allocation of resources over the next stages of the COVID-19 prevention period.

Universal Testing for COVID-19 in Essential Orthopaedic Surgery Reveals a High Percentage of Asymptomatic Infections. BACKGROUND: The long incubation period and asymptomatic spread of COVID-19 present considerable challenges for health-care institutions. The identification of infected individuals is vital to prevent the spread of illness to staff and other patients as well as to identify those who may be at risk for disease-related complications. This is particularly relevant with the resumption of elective orthopaedic surgery around the world. We report the results of a universal testing protocol for COVID-19 in patients undergoing orthopaedic surgery during the coronavirus pandemic and to describe the postoperative course of asymptomatic patients who were positive for COVID-19. METHODS: A retrospective review of adult operative cases between March 25, 2020, and April 24, 2020, at an orthopaedic specialty hospital in New York City was performed. Initially, a screening questionnaire consisting of relevant signs and symptoms (e.g., fever, cough, shortness of breath) or exposure dictated the need for nasopharyngeal swab real-time quantitative polymerase chain reaction (RT-PCR) testing for all admitted patients. An institutional policy change occurred on April 5, 2020, that indicated nasopharyngeal swab RT-PCR testing for all orthopaedic admissions. Screening and testing data for COVID-19 as well as relevant imaging, laboratory values, and postoperative complications were reviewed for all patients. RESULTS: From April 5, 2020, to April 24, 2020, 99 patients underwent routine nasopharyngeal swab testing for COVID-19 prior to their planned orthopaedic surgical procedure. Of the 12.1% of patients who tested positive for COVID-19, 58.3% were asymptomatic. Three asymptomatic patients developed postoperative hypoxia, with 2 requiring intubation. The negative predictive value of using the signs and symptoms of disease to predict a negative test result was 91.4% (95% confidence interval [CI], 81.0% to 97.1%). Including a positive chest radiographic finding as a screening criterion did not improve the negative predictive value of screening (92.5% [95% CI, 81.8% to 97.9%]). CONCLUSIONS: A protocol for universal testing of all orthopaedic surgery admissions at 1 hospital in New York City during a 3-week period revealed a high rate of COVID-19 infections. Importantly, the majority of these patients were asymptomatic. Using chest radiography did not significantly improve the negative predictive value of screening. These results have important implications as hospitals anticipate the resumption of elective surgical procedures. LEVEL OF EVIDENCE: Diagnostic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Neutralizing antibodies mediate virus-immune pathology of COVID-19. SARS-CoV-2 is a novel beta-coronavirus causing over 200.000 lethal cases within six months of first infecting humans. SARS-

CoV-2 causes COVID-19, a form of severe acute respiratory syndrome (SARS). COVID-19 is characterized by two phases: the first resembles the flu with pneumonia, but after about seven or eight days the disease suddenly worsens to a sepsis-like syndrome. It is difficult to explain this virus-immune-pathology sequence from virology or immunology only. This paper hypothesizes that host-produced anti-spike protein antibodies are responsible for immune-induced viral dissemination. Subsequently, systemic distribution of virus-antibodies complexes activates the immune pathology observed in severe COVID-19. This hypothesis may be counterintuitive to immunologist that consider many anti-spike antibodies to be virus-neutralizing antibodies. Although anti-spike antibodies may hinder infection of epithelial cells, antibody binding to the spike protein may facilitate virus infection of myeloid leukocytes. If myeloid leukocytes reenter the circulation, they could spread the virus from a locoregional infection to a systemic disease. Disseminated virus in combination with antibodies results in dispersed virus-antibody complexes that overstimulate the immune system. The hypothesis aligns with the sequences of virus, immune and pathological events in COVID-19. The delay in onset from both syndromes results from an immune system still naÃ¯ve to the non-cross-reactive spike protein. Details of this hypothesis are in concordance with many clinical characteristics of COVID-19, including its predominant lethality for the elderly, and the mostly asymptomatic course of disease in children. It predicts putative detrimental effects of vaccines that induce virus-neutralizing antibodies against the spike protein, as has been shown for other coronaviruses. This hypothesis has consequences for treatment of patients, evaluation of personal and herd immunity and vaccine development. In patients, cellular immunity should be stimulated. Neutralizing antibodies might not be indicative for immunity. Vaccines should aim to stimulate cellular immunity COVID-19 and/or stimulate humoral immunity against viral proteins except for the immunodominant spike protein.

Consensus summary report for CEPI/BC March 12-13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines. A novel coronavirus (CoV), Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), emerged in late 2019 in Wuhan, China and has since spread as a global pandemic. Safe and effective vaccines are thus urgently needed to reduce the significant morbidity and mortality of Coronavirus Disease 2019 (COVID-19) disease and ease the major economic impact. There has been an unprecedented rapid response by vaccine developers with now over one hundred vaccine candidates in development and at least six having reached clinical trials. However, a major challenge during rapid development is to avoid safety issues both by thoughtful vaccine design and by thorough evaluation in a timely manner. A syndrome of "disease enhancement" has been reported in the past for a few viral vaccines where those immunized suffered increased severity or death when they later encountered the virus or were found to have an increased frequency of infection. Animal models allowed scientists to determine the underlying mechanism for the former in the case of Respiratory syncytial virus (RSV) vaccine and have been utilized to design and screen new RSV vaccine candidates. Because some Middle East respiratory syndrome (MERS) and SARS-CoV-1 vaccines have shown evidence of disease enhancement in some animal models, this is a particular concern for SARS-CoV-2 vaccines. To address this challenge, the Coalition for Epidemic Preparedness Innovations (CEPI) and the Brighton Collaboration (BC) Safety Platform for Emergency vACcines (SPEAC) convened a scientific working meeting on March 12 and 13, 2020 of experts in the field of vaccine immunology and coronaviruses to consider what vaccine designs could reduce safety concerns and how animal models and immunological assessments in early clinical trials can help to assess the risk. This report summarizes the evidence presented and provides considerations for safety assessment of COVID-19 vaccine candidates in accelerated vaccine development.

Changes in breast cancer management during the Corona Virus Disease 19 pandemic: An international survey of the European Breast Cancer Research Association of Surgical Trialists

(EUBREAST). BACKGROUND: Corona Virus Disease 19 (COVID-19) had a worldwide negative impact on healthcare systems, which were not used to coping with such pandemic. Adaptation strategies prioritizing COVID-19 patients included triage of patients and reduction or re-allocation of other services. The aim of our survey was to provide a real time international snapshot of modifications of breast cancer management during the COVID-19 pandemic. METHODS: A survey was developed by a multidisciplinary group on behalf of European Breast Cancer Research Association of Surgical Trialists and distributed via breast cancer societies. One reply per breast unit was requested. RESULTS: In ten days, 377 breast centres from 41 countries completed the questionnaire. RT-PCR testing for SARS-CoV-2 prior to treatment was reported by 44.8% of the institutions. The estimated time interval between diagnosis and treatment initiation increased for about 20% of institutions. Indications for primary systemic therapy were modified in 56% (211/377), with upfront surgery increasing from 39.8% to 50.7% (pÂ <Â 0.002) and from 33.7% to 42.2% (pÂ <Â 0.016) in T1cN0 triple-negative and ER-negative/HER2-positive cases, respectively. Sixty-seven percent considered that chemotherapy increases risks for developing COVID-19 complications. Fifty-one percent of the responders reported modifications in chemotherapy protocols. Gene-expression profile used to evaluate the need for adjuvant chemotherapy increased in 18.8%. In luminal-A tumours, a large majority (68%) recommended endocrine treatment to postpone surgery. Postoperative radiation therapy was postponed in 20% of the cases. CONCLUSIONS: Breast cancer management was considerably modified during the COVID-19 pandemic. Our data provide a base to investigate whether these changes impact oncologic outcomes.
Epidemiological evidence for association between higher influenza vaccine uptake in the elderly and lower COVID-19 deaths in Italy.
SARS-CoV-2 SPIKE PROTEIN: an optimal immunological target for vaccines. COVID-19 has rapidly spread all over the world, progressing into a pandemic. This situation has urgently impelled many companies and public research institutes to concentrate their efforts on research for effective therapeutics. Here, we outline the strategies and targets currently adopted in developing a vaccine against SARS-CoV-2. Based on previous evidence and experience with SARS and MERS, the primary focus has been the Spike protein, considered as the ideal target for COVID-19 immunotherapies.
European Federation for Colposcopy (EFC) and European Society of Gynaecological Oncology (ESGO) joint considerations about human papillomavirus (HPV) vaccination, screening programs, colposcopy, and surgery during and after the COVID-19 pandemic.
What We Need to Consider During and After the SARS-CoV-2 Pandemic. Even though extreme containment and mitigation strategies were implemented by numerous governments around the world to slow down the spread of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the number of critically ill patients and fatalities keeps rising. This crisis has highlighted the socioeconomic disparities of health care systems within and among countries. As new CoVID policies and responses are implemented to lessen the impact of the virus, it is imperative (1) to consider additional mitigation strategies critical for the development of effective countermeasures, (2) to promote long-term policies and strict regulations of the trade of wildlife and live animal markets, and (3) to advocate for necessary funding and investments in global health, specifically for the prevention of and response to natural and manmade pandemics. This document considers some of these challenges.
A Guide to COVID-19: a global pandemic caused by the novel coronavirus SARS-CoV-2. The emergence of the SARS-CoV-2 strain of the human coronavirus has thrown the world into the midst of a new pandemic. In the human body, the virus causes COVID-19, a disease characterized by shortness of breath, fever, and pneumonia, which can be fatal in vulnerable individuals. SARS-CoV-2 has characteristics of past human coronaviruses, with close genomic similarities to SARS-CoV, the

virus that causes the disease SARS. Like these related coronaviruses, SARS-CoV-2 is transmitted through the inhalation of droplets and interaction with contaminated surfaces. Across the world, laboratories are developing candidate vaccines for the virus - with vaccine trials underway in the United States and the United Kingdom - and considering various drugs for possible treatments and prophylaxis. Here, we provide an overview of SARS-CoV-2 by analyzing its virology, epidemiology, and modes of transmission while examining the current progress of testing procedures and possible treatments through drugs and vaccines.

COVID19 meets the antivaccine movement.

Prioritizing infants in a time of Bacille Calmette-GuÃ©rin vaccine shortage caused by premature expectations against COVID-19.

Why Challenge Trials of SARS-CoV-2 Vaccines Could Be Ethical Despite Risk of Severe Adverse Events. Human challenge trials to test the efficacy of vaccine candidates against SARS-CoV-2, the novel coronavirus behind Covid-19, could save considerable time and many lives. But they may initially seem unethical because they expose healthy volunteers to a live virus that is killing many people and for which no cure exists. This article argues that this is not the correct test of their ethics. The correct test is comparative. And in the special circumstances of the Covid-19 pandemic, human challenge trials meet the correct test better than standard efficacy testing would.

Positive RT-PCR in urine from an asymptomatic patient with novel coronavirus 2019 infection: a case report. Introduction: With the emergence of novel coronavirus disease 2019 (COVID-19) in many countries, medical resources currently focus on the treatment of confirmed patients and screening of suspected cases. Asymptomatic patients may be contagious, which makes epidemic control difficult. We describe an asymptomatic patient with a positive real-time polymerase chain reaction (RT-PCR) test in urine.Case report: An asymptomatic girl was identified during the epidemiological investigation of a confirmed COVID-19 patient. When admitted to the hospital on 24 February 2020, she had no clinical manifestations. A throat swab was negative for RT-PCR, but urine was positive. She was given antiviral and symptomatic supportive treatment. On 26 February, a throat swab RT-PCR was positive. RT-PCR in throat swabs and urine were negative on 3 and 5 March, and on 9 and 12 March, throat swabs were still negative. At follow-up on 26 March, she felt well, throat swab RT-PCR was negative, and isolation was lifted.Conclusion: The urine of asymptomatic patients may be contagious. RT-PCR in urine might be a useful supplement in screening when the RT-PCR is negative in throat swabs.

Screening of healthcare workers for SARS-CoV-2 highlights the role of asymptomatic carriage in COVID-19 transmission. Significant differences exist in the availability of healthcare worker (HCW) SARS-CoV-2 testing between countries, and existing programmes focus on screening symptomatic rather than asymptomatic staff. Over a 3 week period (April 2020), 1032 asymptomatic HCWs were screened for SARS-CoV-2 in a large UK teaching hospital. Symptomatic staff and symptomatic household contacts were additionally tested. Real-time RT-PCR was used to detect viral RNA from a throat+nose self-swab. 3% of HCWs in the asymptomatic screening group tested positive for SARS-CoV-2. 17/30 (57%) were truly asymptomatic/pauci-symptomatic. 12/30 (40%) had experienced symptoms compatible with coronavirus disease 2019 (COVID-19)>7 days prior to testing, most self-isolating, returning well. Clusters of HCW infection were discovered on two independent wards. Viral genome sequencing showed that the majority of HCWs had the dominant lineage Bâˆ™1. Our data demonstrates the utility of comprehensive screening of HCWs with minimal or no symptoms. This approach will be critical for protecting patients and hospital staff.

 Patients admitted to NHS hospitals are now routinely screened for SARS-CoV-2 (the virus that causes COVID-19), and isolated from other patients if necessary. Yet healthcare workers, including frontline patient-facing staff such as doctors, nurses and physiotherapists, are only tested and excluded from work if they develop symptoms of the illness. However, there is emerging evidence that many people

infected with SARS-CoV-2 never develop significant symptoms: these people will therefore be missed by â€˜symptomatic-onlyâ€™ testing. There is also important data showing that around half of all transmissions of SARS-CoV-2 happen before the infected individual even develops symptoms. This means that much broader testing programs are required to spot people when they are most infectious. Rivett, Sridhar, Sparkes, Routledge et al. set out to determine what proportion of healthcare workers was infected with SARS-CoV-2 while also feeling generally healthy at the time of testing. Over 1,000 staff members at a large UK hospital who felt they were well enough to work, and did not fit the government criteria for COVID-19 infection, were tested. Amongst these, 3% were positive for SARS-CoV-2. On closer questioning, around one in five reported no symptoms, two in five very mild symptoms that they had dismissed as inconsequential, and a further two in five reported COVID-19 symptoms that had stopped more than a week previously. In parallel, healthcare workers with symptoms of COVID-19 (and their household contacts) who were self-isolating were also tested, in order to allow those without the virus to quickly return to work and bolster a stretched workforce. Finally, the rates of infection were examined to probe how the virus could have spread through the hospital and among staff â€“ and in particular, to understand whether rates of infection were greater among staff working in areas devoted to COVID-19 patients. Despite wearing appropriate personal protective equipment, healthcare workers in these areas were almost three times more likely to test positive than those working in areas without COVID-19 patients. However, it is not clear whether this genuinely reflects greater rates of patients passing the infection to staff. Staff may give the virus to each other, or even acquire it at home. Overall, this work implies that hospitals need to be vigilant and introduce broad screening programmes across their workforces. It will be vital to establish such approaches before â€˜lockdownâ€™ is fully lifted, so healthcare institutions are prepared for any second peak of infections.
Rapid COVID-19 vaccine development.
Towards effective COVIDâ€‘19 vaccines: Updates, perspectives and challenges (Review). In the current context of the pandemic triggered by SARS-COV-2, the immunization of the population through vaccination is recognized as a public health priority. In the case of SARSâ€‘COVâ€‘2, the genetic sequencing was done quickly, in one month. Since then, worldwide research has focused on obtaining a vaccine. This has a major economic impact because new technological platforms and advanced genetic engineering procedures are required to obtain a COVIDâ€‘19 vaccine. The most difficult scientific challenge for this future vaccine obtained in the laboratory is the proof of clinical safety and efficacy. The biggest challenge of manufacturing is the construction and validation of production platforms capable of making the vaccine on a large scale.
Development of an inactivated vaccine candidate for SARS-CoV-2. The coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has resulted in an unprecedented public health crisis. Because of the novelty of the virus, there are currently no SARS-CoV-2-specific treatments or vaccines available. Therefore, rapid development of effective vaccines against SARS-CoV-2 are urgently needed. Here, we developed a pilot-scale production of PiCoVacc, a purified inactivated SARS-CoV-2 virus vaccine candidate, which induced SARS-CoV-2-specific neutralizing antibodies in mice, rats, and nonhuman primates. These antibodies neutralized 10 representative SARS-CoV-2 strains, suggesting a possible broader neutralizing ability against other strains. Three immunizations using two different doses, 3 or 6 micrograms per dose, provided partial or complete protection in macaques against SARS-CoV-2 challenge, respectively, without observable antibody-dependent enhancement of infection. These data support the clinical development and testing of PiCoVacc for use in humans.
Coronavirus Pandemic-Therapy and Vaccines. The current coronavirus COVID-19 pandemic, which originated in Wuhan, China, has raised significant social, psychological and economic concerns

in addition to direct medical issues. The rapid spread of severe acute respiratory syndrome-coronavirus (SARS-CoV)-2 to almost every country on the globe and the failure to contain the infections have contributed to fear and panic worldwide. The lack of available and efficient antiviral drugs or vaccines has further worsened the situation. For these reasons, it cannot be overstated that an accelerated effort for the development of novel drugs and vaccines is needed. In this context, novel approaches in both gene therapy and vaccine development are essential. Previous experience from SARS- and MERS-coronavirus vaccine and drug development projects have targeted glycoprotein epitopes, monoclonal antibodies, angiotensin receptor blockers and gene silencing technologies, which may be useful for COVID-19 too. Moreover, existing antivirals used for other types of viral infections have been considered as urgent action is necessary. This review aims at providing a background of coronavirus genetics and biology, examples of therapeutic and vaccine strategies taken and potential innovative novel approaches in progress.
Balancing Expediency and Scientific Rigor in Severe Acute Respiratory Syndrome Coronavirus 2 Vaccine Development.
SARS-CoV-2 causing pneumonia-associated respiratory disorder (COVID-19): diagnostic and proposed therapeutic options. SARS-CoV-2 is responsible for the outbreak of severe respiratory illness (COVID-19) in Wuhan City, China and is now spreading rapidly throughout the world. The prompt outbreak of COVID-19 and its quick spread without any controllable measure defines the severity of the situation. In this crisis, a collective pool of knowledge about the advancement of clinical diagnostic and management for COVID-19 is a prerequisite. Here, we summarize all the available updates on the multidisciplinary approaches for the advancement of diagnosis and proposed therapeutic strategies for COVID-19. Moreover, the review discusses different aspects of the COVID-19, including its epidemiology; incubation period; the general clinical features of patients; the clinical features of intensive care unit (ICU) patients; SARS-CoV-2 infection in the presence of co-morbid diseases and the clinical features of pediatric patients infected with the SARS-CoV-2. Advances in various diagnostic approaches, such as the use of real-time polymerase chain reaction (RT-PCR), chest radiography, and computed tomography (CT) imaging; and other modern diagnostic methods, for this infection have been highlighted. However, due to the unavailability of adequate evidence, presently there are no officially approved drugs or vaccines available against SARS-CoV-2. Additionally, we have discussed various therapeutic strategies for COVID-19 under different categories, like the possible treatment plans with drug (antiviral drugs and anti-cytokines) therapy for disease prevention. Lastly, potentials candidates for the vaccines against SARS-CoV-2 infection have been described. Collectively, the review provides an overview of the SARS-CoV-2 infection outbreak along with the recent advancements and strategies for diagnosis and therapy of COVID-19.
The post-lockdown period should be used to acquire effective therapies for future resurgence in SARS-Cov-2 infections. COVID-19 will be with us through the remainder of 2020 and almost certainly beyond. New Zealand needs a viable strategy to protect its populace until a vaccine is developed and in wide use. Until that time, it makes sense to protect the population by putting in place treatments that will be safe and effective, such as the use of convalescent sera and the use of direct-acting anti-virals. These treatments should be sourced externally or made locally, but steps in this direction must now begin as the lockdown ends. New Zealand has the scientists, the facilities and the will to make this happen, but the support of the government and the population will be needed if this plan is to succeed.
The potential role of Th17 immune responses in coronavirus immunopathology and vaccine-induced immune enhancement. Increasing evidence points to host Th17 inflammatory responses as contributing to the severe lung pathology and mortality of lower respiratory tract infections from coronaviruses. This includes host inflammatory and cytokine responses to COVID-19 caused by the

SARS-2 coronavirus (SARS CoV2). From studies conducted in laboratory animals, there are additional concerns about immune enhancement and the role of potential host immunopathology resulting from experimental human COVID-19 vaccines. Here we summarize evidence suggesting there may be partial overlap between the underlying immunopathologic processes linked to both coronavirus infection and vaccination, and a role for Th17 in immune enhancement and eosinophilic pulmonary immunopathology. Such findings help explain the link between viral-vectored coronavirus vaccines and immune enhancement and its reduction through alum adjuvants. Additional research may also clarify links between COVID-19 pulmonary immunopathology and heart disease.
Progress and Concept for COVID-19 Vaccine Development.
COVID-19 and neuromuscular disorders. The coronavirus 2019 (COVID-19) pandemic has potential to disproportionately and severely affect patients with neuromuscular disorders. In a short period of time, it has already caused reorganization of neuromuscular clinical care delivery and education, which will likely have lasting effects on the field. This article reviews (1) potential neuromuscular complications of COVID-19, (2) assessment and mitigation of COVID-19-related risk for patients with preexisting neuromuscular disease, (3) guidance for management of immunosuppressive and immunomodulatory therapies, (4) practical guidance regarding neuromuscular care delivery, telemedicine, and education, and (5) effect on neuromuscular research. We outline key unanswered clinical questions and highlight the need for team-based and interspecialty collaboration. Primary goals of clinical research during this time are to develop evidence-based best practices and to minimize morbidity and mortality related to COVID-19 for patients with neuromuscular disorders.
If a coronavirus vaccine arrives, can the world make enough?
Corona (COVID-19) time musings: Our involvement in COVID-19 pathogenesis, diagnosis, treatment and vaccine planning.
Case Report: Walking Pneumonia in Novel Coronavirus Disease (COVID-19): Mild Symptoms with Marked Abnormalities on Chest Imaging. This case report underlines the appearance of a "walking pneumonia" in a novel coronavirus disease (COVID-19) patient, with evidence of progressive lung involvement on chest imaging studies. The patient traveled from Wuhan, Hubei, China, to Thailand in January 2020. One of her family members was diagnosed with COVID-19. She presented to the hospital because of her concern, but she was without fever or any respiratory symptoms. Three days earlier, her nasopharyngeal and throat swabs revealed a negative severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) test by real-time reverse transcriptase polymerase chain reaction (RT-PCR). Her initial chest radiography was abnormal, and her first sputum SARS-CoV-2 test yielded inconclusive results. A subsequent sputum test was positive for SARS-CoV-2. Diagnosis in this patient was facilitated by chest imaging and repeat viral testing. Thus, chest imaging studies might enhance capabilities for early diagnosis of COVID-19 pneumonia.
News Feature: Avoiding pitfalls in the pursuit of a COVID-19 vaccine.
Coronavirus vaccines: five key questions as trials begin.
Could enhanced influenza and pneumococcal vaccination programs help limit the potential damage from SARS-CoV-2 to fragile health systems of southern hemisphere countries this winter?
Chest CT manifestations of new coronavirus disease 2019 (COVID-19): a pictorial review. Coronavirus disease 2019 (COVID-19) outbreak, first reported in Wuhan, China, has rapidly swept around the world just within a month, causing global public health emergency. In diagnosis, chest computed tomography (CT) manifestations can supplement parts of limitations of real-time reverse transcription polymerase chain reaction (RT-PCR) assay. Based on a comprehensive literature review and the experience in the frontline, we aim to review the typical and relatively atypical CT manifestations with representative COVID-19 cases at our hospital, and hope to strengthen the

recognition of these features with radiologists and help them make a quick and accurate diagnosis.Key Pointsâ€¢ Ground glass opacities, consolidation, reticular pattern, and crazy paving pattern are typical CT manifestations of COVID-19.â€¢ Emerging atypical CT manifestations, including airway changes, pleural changes, fibrosis, nodules, etc., were demonstrated in COVID-19 patients.â€¢ CT manifestations may associate with the progression and prognosis of COVID-19.

False-Negative Results of Real-Time Reverse-Transcriptase Polymerase Chain Reaction for Severe Acute Respiratory Syndrome Coronavirus 2: Role of Deep-Learning-Based CT Diagnosis and Insights from Two Cases. The epidemic of 2019 novel coronavirus, later named as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is still gradually spreading worldwide. The nucleic acid test or genetic sequencing serves as the gold standard method for confirmation of infection, yet several recent studies have reported false-negative results of real-time reverse-transcriptase polymerase chain reaction (rRT-PCR). Here, we report two representative false-negative cases and discuss the supplementary role of clinical data with rRT-PCR, including laboratory examination results and computed tomography features. Coinfection with SARS-COV-2 and other viruses has been discussed as well.

The First Disease X is Caused by a Highly Transmissible Acute Respiratory Syndrome Coronavirus. Based on the announcement of the World Health Organization (WHO) in 2018, the Wuhan pneumonia caused by an unknown etiology should be recognized as the first Disease X. Later, the pathogen was identified to be a novel coronavirus denoted 2019-nCoV, which has 79.5% and 96% whole genome sequence identify to SARS-CoV and bat SARS-related coronavirus (SARSr-CoV-RaTG13), respectively, suggesting its potential bat origin. With high human-to-human transmission rate (R0), 2019-nCoV has quickly spread in China and other countries, resulting in 34,953 confirmed cases and 725 deaths as of 8 February 2020, thus calling for urgent development of therapeutics and prophylactics. Here we suggest renaming 2019-nCoV as "transmissible acute respiratory syndrome coronavirus (TARS-CoV)" and briefly review the advancement of research and development of neutralizing antibodies and vaccines targeting the receptor-binding domain (RBD) and viral fusion inhibitors targeting the heptad repeat 1 (HR1) domain in spike protein of 2019-nCoV.

Case of the Index Patient Who Caused Tertiary Transmission of COVID-19 Infection in Korea: the Application of Lopinavir/Ritonavir for the Treatment of COVID-19 Infected Pneumonia Monitored by Quantitative RT-PCR. Since mid-December of 2019, coronavirus disease 2019 (COVID-19) infection has been spreading from Wuhan, China. The confirmed COVID-19 patients in South Korea are those who came from or visited China. As secondary transmissions have occurred and the speed of transmission is accelerating, there are rising concerns about community infections. The 54-year old male is the third patient diagnosed with COVID-19 infection in Korea. He is a worker for a clothing business and had mild respiratory symptoms and intermittent fever in the beginning of hospitalization, and pneumonia symptoms on chest computerized tomography scan on day 6 of admission. This patient caused one case of secondary transmission and three cases of tertiary transmission. Hereby, we report the clinical findings of the index patient who was the first to cause tertiary transmission outside China. Interestingly, after lopinavir/ritonavir (Kaletra, AbbVie) was administered, Î²-coronavirus viral loads significantly decreased and no or little coronavirus titers were observed.

Correction: COVID-19 Vaccine-Induced Myocarditis and Pericarditis: Towards Identification of Risk Factors. [This corrects the article DOI: 10.5334/gh.1252.].

HLA-DQ diversity is associated with humoral response to vaccines in patients awaiting or after liver transplantation.

Comment on published article "Exacerbation of psoriasis after post-COVID-19 vaccine reported in a young female".

The increased odds ratio for Bell's palsy following COVID-19 infection or vaccination.

Systems biology analysis reveals distinct molecular signatures associated with immune responsiveness to the BNT162b COVID-19 vaccine. BACKGROUND: Human immune responses to COVID-19 vaccines display a large heterogeneity of induced immunity and the underlying immune mechanisms for this remain largely unknown. METHODS: Using a systems biology approach, we longitudinally profiled a unique cohort of female high and low responders to the BNT162b vaccine, who were known from previous COVID-19 vaccinations to develop maximum and minimum immune responses to the vaccine. We utilized high dimensional flow cytometry, bulk and single cell mRNA sequencing and 48-plex serum cytokine analyses. FINDINGS: We revealed early, transient immunological and molecular signatures that distinguished high from low responders and correlated with B and T cell responses measured 14 days later. High responders featured a distinct transcriptional activity of interferon-driven genes and genes connected to enhanced antigen presentation. This was accompanied by a robust cytokine response related to Th1 differentiation. Both transcriptome and serum cytokine signatures were confirmed in two independent confirmatory cohorts. INTERPRETATION: Collectively, our data contribute to a better understanding of the immunogenicity of mRNA-based COVID-19 vaccines, which might lead to the optimization of vaccine designs for individuals with poor vaccine responses. FUNDING: German Center for Infection Research, German Center for Lung Research, German Research Foundation, Excellence Strategy EXC 2155 "RESIST" and European Regional Development Fund.

Impact of SARS-CoV-2 vaccine rollout on Hispanic and non-Hispanic admission and mortality trends: an interrupted time series analysis. BACKGROUND: Challenges with SARS-CoV-2 vaccine prioritization, access, hesitancy influenced vaccination uptake RESEARCH QUESTION: Was the impact of SARS-CoV-2 vaccine rollout on COVID-19 monthly admission and mortality trends different between Hispanic and non-Hispanic populations? STUDY DESIGN AND METHODS: We used Interrupted Time Series analysis to conduct an ancillary study of the VIRUS (Viral Infection and Respiratory illness Universal Study) registry supplemented by electronic health record data from 5 participating Mayo Clinic sites in Florida, Arizona, Minnesota Wisconsin states. We included hospitalized patients with COVID-19 admitted between April 2020 and December 2021. Our primary outcome was the impact of vaccine rollout on admission trends. Our secondary outcome was the impact of vaccine rollout on mortality trends. RESULTS: This interrupted time series analysis includes 6442 patients. Vaccine rollout was associated with improved monthly hospital admission trends among both Hispanic and non-Hispanic patients. Among Hispanic patients, pre-vaccine rollout, monthly admissions were increasing by 12.9%, [95% CI 8.1,17.9%]. Immediately following vaccine rollout, patient admissions declined by -66.3%, [95% CI -75.6, -53.9]. Post vaccine rollout, monthly admissions were increasing by 3.7%, [95% CI 0.2,7.3%]. Among non-Hispanic patients, pre-vaccine rollout, monthly admissions were increasing by 35.8% [95% CI 33.4,38.1%]. Immediately following vaccine rollout, patient admissions declined by -75.2% [95% CI -77.6, -72.7%]. Post-vaccine rollout, monthly admissions were increasing by 5.6%, [95% CI 4.5-6.7%]. These pre-vaccine rollout admission trends were significantly different ($p<0.001$) and post-vaccine rollout the change in admission trend was significantly different ($p<0.001$). The associated beneficial impact from vaccine rollout on monthly hospital admission trends among Hispanic patients was significantly lower. The trend in monthly mortality rate was four-fold greater (worse) 8.3% [95% CI 3.6,13.4%] among Hispanic patients versus 2.2% [95% CI 0.6,3.8%] among non-Hispanic patients but this was not related to vaccine rollout. INTERPRETATION: SARS-CoV-2 vaccine rollout was associated with improved COVID-19 admission trends among non-Hispanic versus Hispanic patients. Vaccine rollout did not influence mortality trends in either group, which were four times higher among Hispanic patients. Improved

vaccine rollout may have reduced disparities in admission trends for Hispanic patients, but other factors influenced their mortality trends.

Intranasal murine pneumonia virus-vectored SARS-CoV-2 vaccine induces mucosal and serum antibodies in macaques. Next-generation SARS-CoV-2 vaccines are needed that induce systemic and mucosal immunity. Murine pneumonia virus (MPV), a murine homolog of respiratory syncytial virus, is attenuated by host-range restriction in nonhuman primates and has a tropism for the respiratory tract. We generated MPV vectors expressing the wild-type SARS-CoV-2 spike protein (MPV/S) or its prefusion-stabilized form (MPV/S-2P). Both vectors replicated similarly in cell culture and stably expressed S. However, only S-2P was associated with MPV particles. After intranasal/intratracheal immunization of rhesus macaques, MPV/S and MPV/S-2P replicated to low levels in the airways. Despite its low-level replication, MPV/S-2P induced high levels of mucosal and serum IgG and IgA to SARS-CoV-2Â S or its receptor-binding domain. Serum antibodies from MPV/S-2P-immunized animals efficiently inhibited ACE2 receptor binding to S proteins of variants of concern. Based on its attenuation and immunogenicity in macaques, MPV/S-2P will be further evaluated as a live-attenuated vaccine for intranasal immunization against SARS-CoV-2.

Generalized pustulosis following Covid 19 vaccination in a patient in treatment with adalimumab.

Correction: Shen et al. Platelet Activation and Cytokine Release of Interleukin-8 and Interferon-Gamma-Induced Protein 10 after ChAdOx1 nCoV-19 Coronavirus Vaccine Injection. Vaccines 2023, 11, 456. The authors wish to make the following corrections to this published paper [...].

Analysis of the Economic Burden of COVID-19 on the Workers of a Teaching Hospital in the Centre of Italy: Changes in Productivity Loss and Healthcare Costs Pre and Post Vaccination Campaign. Introduction: Following the concerning levels of spread and severity of the infection, on 11 March 2020, the World Health Organisation declared the COVID-19 outbreak a pandemic. In response to the pandemic, governments adopted several mitigation strategies. The pandemic posed a great threat to the Italian healthcare workforce (HW), with Italy being one of the hardest-hit countries. The aim of this study is to estimate the economic burden of COVID-19 on the workforce of a teaching hospital in Central Italy. Two periods are compared: 1 March 2020-9 February 2021 vs. 10 February 2021-31 March 2022. Methods: This study is conducted from a societal perspective. The database (n = 3298) of COVID-19-confirmed cases among the HW was obtained from the occupational health office of the hospital. The first entry on the database refers to 1 March 2020. Cost data were used to assess the economic burden of COVID-19 on the hospital workforce. They include two main groups: hourly salaries and medical expenses. The cost of productivity loss, hospital admission, at-home treatments, and contact tracing and screening tests were computed for the first and second periods of the analysis. Results: The total economic burden during the first period is estimated to be around EUR 3.8 million and in the second period EUR 4 million. However, the average cost per person is smaller in the second period (EUR 1561.78) compared to the first one (EUR 5906). In both periods, the cost of productivity loss is the largest component of the economic burden (55% and 57%). The cost of hospital admission decreased by more than 60% in the second period. Conclusion: Outcomes of the analysis suggest that the economic burden of COVID-19 on the HW is higher in the first period of analysis compared to the second period. The main reason could be identified in the shift from more severe and critical confirmed cases to more asymptomatic, mild, and moderate cases. The causes of this shift are not easily detectable. Vaccination, variants of the virus, and an individual's determinants of health could all be causes of the decrease in the economic burden of COVID-19 on the HW. COVID-19 can generate a high economic burden on healthcare workers and, more generally, on HWs. However, a comprehensive estimate of the economic burden of the pandemic needs to integrate the mental health repercussions and the long-term COVID-19 that will become evident in the coming years.

Determinants of durable humoral and T cell immunity in myeloma patients following COVID-19 vaccination. OBJECTIVE: To describe determinants of persisting humoral and cellular immune response to the second COVID-19 vaccination among patients with myeloma. METHODS: This is a prospective, observational study utilising the RUDYstudy.org platform. Participants reported their second and third COVID-19 vaccination dates. Myeloma patients had an Anti-S antibody level sample taken at least 21â€‰days after their second vaccination and a repeat sample before their third vaccination. RESULTS: 60 patients provided samples at least 3â€‰weeks (median 57.5â€‰days) after their second vaccination and before their third vaccination (median 176.0â€‰days after second vaccine dose). Low Anti-S antibody levels (<50â€‰IU/mL) doubled during this interval (pâ€‰=â€‰.023) and, in the 47 participants with T-spot data, there was a 25% increase negative T-spot tests (pâ€‰=â€‰.008). Low anti-S antibody levels prior to the third vaccination were predicted by lower Anti-S antibody level and negative T-spot status after the second vaccine. Independent determinants of a negative T-spot included increasing age, previous COVID infection, high CD4 count and lower percentage change in Anti-S antibody levels. CONCLUSIONS: Negative T-spot results predict low Anti-S antibody levels (<50â€‰IU/mL) following a second COVID-19 vaccination and a number of biomarkers predict T cell responses in myeloma patients.

SARS-CoV-2 anti-spike IgG antibodies are present in all liver transplant recipients after fifth vaccine dose.

First case of Lucio's phenomenon in a lepromatous leprosy patient following COVID-19 viral vector vaccine.

Serum levels of prostate specific antigen (PSA) after primary vaccination with BNT162b2.

SARS-CoV-2 mucosal neutralising immunity after vaccination.

Lichen planus after COVID-19 infection and vaccination. BACKGROUND: Lichen planus is one of the common adverse reactions after COVID-19 infection and vaccination. Despite it being reported in several case reports, the literature including a large sample of the studied population is lacking. The current study was performed to assess the risk of LP after COVID-19 infection as well as COVID-19 vaccination. METHODS: The current study was designed as a retrospective cross-sectional hospital-based study of registered patients at the University of Florida (UF) health centers. The diagnoses of LP, COVID-19 infection, and COVID-19 vaccines were detected. The logistic regression model was used to assess the risk of developing LP after COVID-19 infection and vaccination. RESULTS: A total hospital patient of 684,110 attended UF Health centers were included in this study. 181 patients reported LP after COVID-19 vaccination and 24 patients developed LP after COVID-19 infection. The risk of developing LP after COVID-19 vaccination was 1.573 while the risk of developing LP after COVID-19 infection was 1.143. CONCLUSION: The odds of getting LP after COVID-19 vaccination are significantly developed. The current study showed that COVID-19 infection and vaccination are associated with LP. So, healthcare practitioners should be aware of this reaction for rapid recognition and treatment.

Does COVID-19 vaccination affect post-traumatic stress symptoms via risk perception? A large cross-sectional study among the Chinese population. OBJECTIVES: Although infection rates may increase after relaxation of the zero COVID strategy, the extensive vaccination campaign in China could potentially curb the spread of COVID-19, which may be associated with a low level of risk perception and post-traumatic stress symptoms (PTSS). However, the relationship between vaccination, risk perception and PTSS has not been studied extensively. This study aims to examine the associations between the number of COVID-19 vaccine doses, consistency in the type of each dose and time since vaccination with PTSS, and the mediating role of risk perception on such relationships in China. STUDY DESIGN: Cross-sectional sampling with a self-report questionnaire was used to measure vaccination, PTSS and risk perception. METHODS: The survey was conducted in

Beijing, China, from 13 January to 9 February 2023. Linear regression analyses were conducted to test the relationship between vaccination, risk perception and PTSS. RESULTS: The analysis included 55,803 individuals. In total, 72.86Â % of participants received two doses of the COVID-19 vaccine. Regression results indicated that people with two doses of the COVID-19 vaccine had a lower level of PTSS (Î²Â =Â -1.232, 95Â % confidence interval [CI]:Â -1.930,Â -0.534) than those who had not received any doses of the COVID-19 vaccine. Only the negative relationship between two-dose vaccination and PTSS was mediated by risk perception, while the negative relationship between the time since vaccination and PTSS was suppressed by risk perception. CONCLUSIONS: This study showed that receiving the COVID-19 vaccine reduced PTSS by decreasing perceived risk. Vaccination time was negatively associated with PTSS, but this relationship was suppressed by risk perception.

SARS-CoV-2 monoclonal antibody treatment followed by vaccination shifts human memory B cell epitope recognition suggesting antibody feedback. Therapeutic anti-SARS-CoV-2 monoclonal antibodies (mAbs) have been extensively studied in humans, but the impact on immune memory of mAb treatment during an ongoing immune response has remained unclear. Here, we evaluated the effect of infusion of the anti-SARS-CoV-2 spike receptor binding domain (RBD) mAb bamlanivimab on memory B cells (MBCs) in SARS-CoV-2-infected individuals. Bamlanivimab treatment skewed the repertoire of memory B cells targeting Spike towards non-RBD epitopes. Furthermore, the relative affinity of RBD memory B cells was weaker in mAb-treated individuals compared to placebo-treated individuals over time. Subsequently, after mRNA COVID-19 vaccination, memory B cell differences persisted and mapped to a specific defect in recognition of the class II RBD site, the same RBD epitope recognized by bamlanivimab. These findings indicate a substantial role of antibody feedback in regulating human memory B cell responses, both to infection and vaccination. These data indicate that mAb administration can promote alterations in the epitopes recognized by the B cell repertoire, and the single administration of mAb can continue to determine the fate of B cells in response to additional antigen exposures months later.

Adverse events following immunization (AEFI): COVID-19 vaccine dose and characteristics in Central Java, Indonesia. INTRODUCTION: Vaccination is an effort to control the COVID-19 pandemic. Although vaccines can be effective prevention, they can have potential side effects, or adverse events following immunization (AEFI). CoronaVac, BBIBP-CorV, BNTb262-BioNTech, mRNA-1273, and ChAdOx1NCoV-19 were vaccines used in Indonesia when this study was conducted. This study aimed to analyze the factors associated with AEFI for the COVID-19 vaccines for each dose in the community. METHODS: This study used a cross-sectional design. The study was conducted in Central Java Province, Indonesia from August to October 2021. The variables included respondent characteristics, COVID-19 infection history, COVID-19 vaccine AEFI, dose, and type. Data collection was performed through questionnaires and data was analyzed by a logistic regression test. RESULTS: The percentage of AEFI was 21.1% after the first dose, 14.1% after the second dose, and 83.9% after the third dose of the vaccine. The factors associated with higher odds of COVID-19 vaccine AEFI were different for each dose, as follows: for the first dose: age group >45 years (p=0.009; OR=2.837; 95%CI: 1.301-6.187) and overweight (p=0.007; OR=3.323; 95%CI: 1.242-8.689); for the second dose: overweight (p=0.007; OR=9.118; 95%CI: 1.827-45.5), female sex (p=0.011; OR=2.885; 95%CI: 1.274-6.531), age group >45 years (p=0.017; OR=3.257; 95%CI: 1.24-8.555) and prior episode of COVID-19 (p=0.044; OR=2.459; 95%CI: 1.026-5.893); and for the third dose: female sex (p=0.040; OR=3.650; 95%CI: 1.062-12.550). CONCLUSIONS: The factors that were associated with AEFI of COVID-19 vaccine were sex, age, nutritional status and prior history of COVID-19.

Systematical assessment of the impact of single spike mutations of SARS-CoV-2 Omicron sub-variants on the neutralization capacity of post-vaccination sera. INTRODUCTION: The evolution of novel SARS-CoV-2 variants significantly affects vaccine effectiveness. While these effects can only be

studied retrospectively, neutralizing antibody titers are most used as correlates of protection. However, studies assessing neutralizing antibody titers often show heterogeneous data. METHODS: To address this, we investigated assay variance and identified virus infection time and dose as factors affecting assay robustness. We next measured neutralization against Omicron sub-variants in cohorts with hybrid or vaccine induced immunity, identifying a gradient of immune escape potential. To evaluate the effect of individual mutations on this immune escape potential of Omicron variants, we systematically assessed the effect of each individual mutation specific to Omicron BA.1, BA.2, BA.2.12.1, and BA.4/5. RESULTS: We cloned a library of pseudo-viruses expressing spikes with single point mutations, and subjected it to pooled sera from vaccinated hosts, thereby identifying multiple mutations that independently affect neutralization potency. DISCUSSION: These data might help to predict antigenic features of novel viral variants carrying these mutations and support the development of broad monoclonal antibodies.

COVID-19 vaccine-related myocarditis: Could antipyretic drugs be a trigger?

Association of Maternal Inactivated COVID-19 Vaccination within 3 Months before Conception with Neonatal Outcomes. There is limited available data addressing whether inactivated COVID-19 vaccination before conception is associated with adverse neonatal outcomes. This cohort study included all singleton live births at our center from March 1 to June 30, 2022. According to whether a maternal inactivated COVID-19 vaccination had been administered within 3 months before conception or not, neonates were identified as being in the vaccinated or unvaccinated group. Vaccination information and clinical characteristics were extracted for analysis. Furthermore, neonatal outcomes were analyzed and compared between these two groups in the present study. The cohort included 856 eligible newborns, of whom 369 were exposed to maternal vaccination before conception and 487 were unexposed newborns. No differences were observed in rates of preterm birth, newborns being small for gestational age, or neonatal intensive care unit admission between exposed and unexposed newborns. Furthermore, even after adjusting for social-economic status and maternal characteristics, there remained no significant differences in these neonatal outcomes. Our study revealed no statistically significant differences between newborns born to women who received inactivated vaccines prior to conception compared with those who did not receive any vaccinations. In addition, our study also highlights the importance of considering COVID-19 vaccination before conception.

Cultural tightness-looseness and normative social influence in eight Asian countries: Associations of individual and collective norms with vaccination intentions. RATIONALE: Countries worldwide faced the same public health crisis that required promoting the same health behavior-vaccinations-during the COVID-19 pandemic. Thus, scholars have a unique opportunity to test behavioral change theories across countries with different cultural backgrounds. OBJECTIVE: Employing the extended theory of social normative behavior, this study examines the influence of individual and collective norms on COVID-19 vaccination intention across eight Asian countries. We examine how cultural tightness-looseness, defined as the degree of a culture's emphasis on norms and tolerance of deviant behavior, shapes normative social influence on COVID-19 vaccination intention. METHODS: We conducted a multicountry online survey (NÂ =Â 2676) of unvaccinated individuals in China, Indonesia, Japan, Malaysia, Singapore, South Korea, Thailand, and Vietnam in May and June 2021, when COVID-19 vaccination mandates had not yet been implemented in those countries. We conducted hierarchical regression analyses with interaction terms for the total sample and then re-categorizied the eight countries as either "tight" (nÂ =Â 1102) or "loose" (nÂ =Â 1574) to examine three-way interactions between individual norms, collective norms, and cultural tightness-looseness. RESULTS: Perceived injunctive norms exerted the strongest impact of all normative factors on vaccination intention. Collective injunctive norms' influence depended on both perceived injunctive and

descriptive norms, which was larger when norms were lower (vs. higher). The interactive pattern between perceived and collective norms was more pronounced in countries with greater cultural tightness. CONCLUSION: Our findings reveal nuanced patterns of how individual and collective social norms influence health behavioral decisions, depending on the degree of cultural tightness-looseness.

Vitiligo Repigmentation After SARS-CoV-2 Vaccine.

Response to: Comment on: Retinal venous occlusion in a child following Corbevax COVID-19 vaccination.

Clinical considerations and practical issues of kidney complications in children after COVID-19 infection or vaccination.

Polymyalgia rheumatica and polymyalgia-like syndromes as adverse events following immunisation with COVID-19 vaccines: a 15 months update.

Impact of nutritional status on antibody titer after booster mRNA COVID-19 vaccine among elderly adults in Japan. BACKGROUND: Published studies about mRNA COVID-19 vaccine effects focus on younger individuals comprising the majority of workforce. However, studies about elderly adults are sparse. METHODS: 107 subjects (median 78 (IQR 58.5-90.5, range 35-105) yo) were recruited, and factors associated with antibody titer after the third mRNA COVID-19 vaccine were analyzed between 49 elderly (age â‰¥80, median 94 (IQR 86-97, range 80-105) yo) and 58 younger (â‰¤79, median 61 (IQR 46-71, range 35-79) yo) adults. RESULTS: Among BMI categories, the underweight group in elderly adults had a lower antibody titer compared to the normal weight group (pâ€‰<â€‰0.01 after one, three and five months). Elderly adults were less likely to maintain effective antibody titer (â‰¥4,160â€…AU/ml) compared to younger adults; 76% vs 98%, pâ€‰<â€‰0.001 after one month, and 45% vs 78%, pâ€‰<â€‰0.001 after three months. Elderly adults who maintained effective antibody titer for five months had a higher BMI (22.9â€…kg/m2 vs 20.1â€…kg/m2, pâ€‰=â€‰0.02), and were less likely to have underweight BMI (0% vs 31%, pâ€‰=â€‰0.02) compared to the subjects who failed its maintenance. CONCLUSIONS: These highlight the impact of nutritional status, and the deleterious effect of underweight BMI on antibody titer and its maintenance among elderly adults following booster mRNA COVID-19 vaccine.

"Be honest and gain trust": a population health study to understand the factors associated with building trust in local government related to COVID-19 and vaccination in three historically disinvested neighborhoods in New York City. BACKGROUND: Distrust in government among people of color is a response to generations of systemic racism that have produced preventable health inequities. Higher levels of trust in government are associated with better adherence to government guidelines and policies during emergencies, but factors associated with trust and potential actions to increase trust in local government are not well understood. METHODS: The COVID-19 Community Recovery study sampled participants from the New York City (NYC) Department of Health and Mental Hygiene's NYC Health Panel, a probability-based survey panel who complete health surveys periodically. Participants who lived in one of three historically disinvested communities in NYC where the NYC Department of Health and Mental Hygiene has dedicated resources to reduce health inequities were included. The cross-sectional survey was fielded from September 30 to November 4, 2021 and could be self-administered online or conducted via CATI (Computer Assisted Telephone Interviewing) in English, Spanish, and Simplified Chinese (Mandarin and Cantonese by phone). Demographic data were summarized by descriptive statistics. Crude and adjusted logistic regression analyses were used to assess factors predictive of trust in local government as a source of information about COVID-19 vaccines. Open-ended responses about strengthening residents' trust in local government were coded using an iteratively generated codebook. RESULTS: In total, 46% of respondents indicated NYC local government was a trusted

source of information about COVID-19 vaccines, relatively high compared to other sources. In bivariate analyses, race/ethnicity, age group, educational attainment, length of time living in NYC, and household income were significantly associated with identifying NYC government as a trusted source of information about COVID-19 vaccines. In multivariable logistic regression, no variables remained significant predictors of selecting local government as a trusted source of information. Key recommendations for local government agencies to build residents' trust include communicating clearly and honestly, addressing socioeconomic challenges, and enhancing public COVID-19 protection measures. CONCLUSION: Study findings demonstrate that nearly half of residents in three historically divested NYC communities consider local government to be a trusted source of information about COVID-19 vaccines. Strategies to increase trust in local government can help reduce community transmission of COVID-19 and protect public health.
The risk of miscarriage after COVID-19 vaccination before and during pregnancy. PURPOSE: Pregnant women are at higher risk of severe illness and adverse pregnancy outcomes due to a SARS-CoV-2 infection, which can be prevented by vaccination. Observational studies are needed to ascertain the safety of COVID-19 vaccination during pregnancy. We aimed to determine whether COVID-19 vaccination before and during pregnancy is associated with the risk of miscarriage. METHODS: In this cohort study, we included 4640 pregnant women (mean age: 32.8â€‰Â±â€‰3.7â€‰years) from the Dutch Pregnancy Drug Register between February 2021 and August 2022. Information on COVID-19 vaccinations, miscarriage, and confounders was self-reported, using web-based questionnaires. The hazard ratio (HR) of miscarriage (in gestational weeks 6-20) after a COVID-19 vaccination, was estimated using the survival analyses. A COVID-19 vaccination during pregnancy (â‰¥1 COVID-19 vaccination between week 2 and 20 of pregnancy) was included as a time-dependent exposure and vaccination prior to pregnancy was included as a binary exposure. RESULTS: A total of 3202 pregnant women (69%) received â‰¥1 COVID-19 vaccine in gestational week 2-20. We observed no association of vaccination during pregnancy with the risk of miscarriage (adjusted HR = 1.29, 95% CIâ€‰=â€‰0.93-1.74). Vaccination prior to pregnancy, however, was associated with a decreased risk of miscarriage (adjusted HRâ€‰=â€‰0.69, 95% CIâ€‰=â€‰0.48-0.99). CONCLUSIONS: We demonstrated that COVID-19 vaccination during pregnancy is not associated with an increased risk of miscarriage in gestational weeks 6-20. This study adds to the growing body of evidence demonstrating the safety of COVID-19 vaccination during pregnancy.
In Response to Otolaryngologic Side Effects After COVID-19 Vaccination.
In Reference to Otolaryngologic Side Effects After COVID-19 Vaccination.
COVID, the end of pandemic and vaccine-induced Uveitis: is this the showdown?
National governance and excess mortality due to COVID-19 in 213 countries: a retrospective analysis and perspectives on future pandemics. BACKGROUND: National governance may have influenced the response of institutions to the Covid-19 pandemic, being a key factor in preparing for the next pandemics. The objective was to analyze the association between excess mortality due to COVID-19 (daily and cumulative per 100 thousand people) and national governance indicators in 213 countries. METHOD: Multiple linear regression models using secondary data from large international datasets that are in the public domain were performed. Governance indicators corresponded to six dimensions: (i) Voice and Accountability; (ii) Political Stability and Absence of Violence/Terrorism; (iii) Government Effectiveness; (iv) Regulatory Quality; (v) Rule of Law and (vi) Control of Corruption. The statistical analysis consisted of adjusting a multiple linear regression model. Excess mortality due to COVID-19 was adjusted for potential confounding factors (demographic, environmental, health, economic, and ethnic variables). RESULTS: The indicators Control of Corruption, Government Effectiveness, Regulatory Quality and Rule of Law had a significant inverse association (pâ€‰<â€‰0.0001) with the estimated excess mortality in 2020, 2021 and 2022. Furthermore, the

governance indicators had a direct significant association (pâ€‰<â€‰0.0001) with the vaccination variables (People_fully_vaccinated; Delivered population; The total number of vaccination doses administered per 100 people at the country level), except for the variables Vaccination policies and Administration of first dose, which were inversely associated. In countries with better governance, COVID-19 vaccination was initiated earlier. CONCLUSION: Better national governance indicators were associated with lower excess mortality due to COVID-19 and faster administration of the first dose of the COVID-19 vaccine.

Behavioral Changes Associated With COVID-19 Vaccination: Cross-National Online Survey. BACKGROUND: During the initial phases of the vaccination campaign worldwide, nonpharmaceutical interventions (NPIs) remained pivotal in the fight against the COVID-19 pandemic. In this context, it is important to understand how the arrival of vaccines affected the adoption of NPIs. Indeed, some individuals might have seen the start of mass vaccination campaigns as the end of the emergency and, as a result, relaxed their COVID-safe behaviors, facilitating the spread of the virus in a delicate epidemic phase such as the initial rollout. OBJECTIVE: The aim of this study was to collect information about the possible relaxation of protective behaviors following key events of the vaccination campaign in four countries and to analyze possible associations of these behavioral tendencies with the sociodemographic characteristics of participants. METHODS: We developed an online survey named "COVID-19 Prevention and Behavior Survey" that was conducted between November 26 and December 22, 2021. Participants were recruited using targeted ads on Facebook in four different countries: Brazil, Italy, South Africa, and the United Kingdom. We measured the onset of relaxation of protective measures in response to key events of the vaccination campaign, namely personal vaccination and vaccination of the most vulnerable population. Through calculation of odds ratios (ORs) and regression analysis, we assessed the strength of association between compliance with NPIs and sociodemographic characteristics of participants. RESULTS: We received 2263 questionnaires from the four countries. Participants reported the most significant changes in social activities such as going to a restaurant or the cinema and visiting relatives and friends. This is in good agreement with validated psychological models of health-related behavioral change such as the Health Belief Model, according to which activities with higher costs and perceived barriers (eg, social activities) are more prone to early relaxation. Multivariate analysis using a generalized linear model showed that the two main determinants of the drop of social NPIs were (1) having previously tested positive for COVID-19 (after the second vaccine dose: OR 2.46, 95% CI 1.73-3.49) and (2) living with people at risk (after the second vaccine dose: OR 1.57, 95% CI 1.22-2.03). CONCLUSIONS: This work shows that particular caution has to be taken during vaccination campaigns. Indeed, people might relax their safe behaviors regardless of the dynamics of the epidemic. For this reason, it is crucial to maintain high compliance with NPIs to avoid hindering the beneficial effects of the vaccine.

Correction: Mahasing et al. Myocarditis and Pericarditis following COVID-19 Vaccination in Thailand. Vaccines 2023, 11, 749. The authors wish to make the following corrections to this published paper [...].

Comparison of Post-Vaccination Response between mRNA and Vector Vaccines against SARS-CoV-2 in Terms of Humoral Response after Six Months of Observation. BACKGROUND: The emergence of the SARS-CoV-2 (COVID-19) pandemic has accelerated work on the creation of effective vaccines, both in terms of previously known vector vaccines and new-generation (mRNA) vaccines. The scientific research on vaccination against COVID-19 infection is limited; therefore, understanding how the immune system responds to vaccines is critical. In our study, we conducted a long-term analysis of the presence and persistence of the immune response via chemiluminescence, analyzing the level of IgG antibodies and neutralizing antibodies in subjects vaccinated with two types of mRNA (Comirnaty) and vector (Vaxzevria) vaccines. MATERIALS AND METHODS: Healthcare workers and a

group of teachers were recruited for this study according to the 2021 government-launched vaccination calendar. They received two doses of the Comirnaty or Vaxzevria vaccine. SRBD (spike-receptor binding domain) IgG antibody levels were measured monthly for 6 consecutive months with a chemiluminescent assay (CLIA) and neutralizing antibodies for two periods-1 and 5 months from the completion of the vaccination course. RESULTS: 168 people were recruited for this study: 135 people for the mRNA vaccine group and 33 people for the vector vaccine group. Comparing the serum IgG levels between the two types of vaccines, a significant difference in median values can be noted at all time points. In consecutive months, the mRNA-vaccinated group exhibited significantly higher SRBD levels compared to the vector group, with peak concentrations at one month after the complete vaccination cycle (745 AU/mL vs. 15.44 AU/mL; $p < 0.001$). Peak antibody concentration for the vector vaccine was observed one month later, at the third follow-up visit; however, the median IgG concentration was almost 7.7 times higher for the Comirnaty group. Both products were effective in stimulating neutralizing antibody production after vaccination. Higher median values were observed for the mRNA vaccines in both evaluations. At first evaluation, the median value for NA concentration in the Comirnaty group was 6 times higher than in the Vaxzevria group (median value 12.23 [IQR 27.3] vs. 1.7 [IQR 3.3]; $p < 0.001$. CONCLUSIONS: People vaccinated with the mRNA vaccine (Comirnaty) showed a stronger immune response to the vaccination than the group of people administered the vector vaccine (Vaxzevria). The Comirnaty group showed higher levels of IgG, including neutralizing antibodies, at all time points during the follow-up period, and this was independent of having had a SARS-CoV-2 infection. A natural decrease in antibody levels was seen within 6 months. A booster vaccination may be required. No serious side effects were observed in either group.

Respiratory mucosal immune memory to SARS-CoV-2 after infection and vaccination. Respiratory mucosal immunity induced by vaccination is vital for protection from coronavirus infection in animal models. In humans, the capacity of peripheral vaccination to generate sustained immunity in the lung mucosa, and how this is influenced by prior SARS-CoV-2 infection, is unknown. Here we show using bronchoalveolar lavage samples that donors with history of both infection and vaccination have more airway mucosal SARS-CoV-2 antibodies and memory B cells than those only vaccinated. Infection also induces populations of airway spike-specific memory CD4+ and CD8+ T cells that are not expanded by vaccination alone. Airway mucosal T cells induced by infection have a distinct hierarchy of antigen specificity compared to the periphery. Spike-specific T cells persist in the lung mucosa for 7 months after the last immunising event. Thus, peripheral vaccination alone does not appear to induce durable lung mucosal immunity against SARS-CoV-2, supporting an argument for the need for vaccines targeting the airways.

Factors associated with COVID-19 vaccination among pregnant women in Rio De Janeiro City, Brazil. COVID-19 vaccination during pregnancy is safe and effective in reducing the risk of complications. However, the uptake is still below targets worldwide. This study aimed to explore the factors associated with COVID-19 vaccination uptake among pregnant women since data on this topic is scarce in low-to-middle-income countries. A retrospective cohort study included linked data on COVID-19 vaccination and pregnant women who delivered a singleton live birth from August 1, 2021, to July 31, 2022, in Rio de Janeiro City, Brazil. Multiple logistic regression was performed to identify factors associated with vaccination during pregnancy, applying a hierarchical model and describing odds ratio with 95% confidence intervals. Of 65,304 pregnant women included in the study, 53.0% (95% CI, 52-53%) received at least one dose of COVID-19 vaccine during pregnancy. Higher uptake was observed among women aged older than 34 (aOR 1.21, 95%CI 1.15-1.28), black (aOR 1.10, 1.04-1.16), or parda/brown skin colour (aOR 1.05, 1.01-1.09), with less than eight years of education (aOR 1.09, 1.02-1.17), living without a partner (aOR 2.24, 2.16-2.34), more than six antenatal care

appointments (aOR 1.92, 1.75-2.09), and having a previous child loss (OR 1.06, 1.02-1.11). These results highlight the need for targeted educational campaigns, trustful communication, and accessibility strategies for specific populations to improve vaccination uptake during pregnancy.

"I am Young, Why Should I Vaccinate?" How empathetic and aggressive communication on social media impact young adults' attitudes toward COVID-19 vaccination. INTRODUCTION: To combat the current COVID-19 pandemic, high vaccination rates are of crucial value. However, young people in particular tend to be hesitant toward vaccination. On social media, young adults are often called to vaccinate in an aggressive tone, arguing that there is no choice than to vaccinate and that all else is wrong. METHODS: In an experimental study (N = 410), we investigated the effects of (a) empathetic vs. aggressive communication styles in social media postings and (b) the origin of the communicator on young adults' supportive attitudes toward COVID-19 vaccinations. We treated the gender of the communicator as a moderator, and expectancy violation, psychological distance as well as the perceived credibility of the communicator as mediators. RESULTS: Findings showed that an aggressive communication style generally had a negative impact on young adults' COVID-19 vaccination attitudes, fully mediated by expectancy violation and perceived credibility of the communicator. Gender and the origin of the communicator did not moderate this mediation processes. DISCUSSION: Further implications for online health communication strategies are discussed.

Corrigendum to "Recombinant measles virus encoding the spike protein of SARS-CoV-2 efficiently induces Th1 responses and neutralizing antibodies that block SARS-CoV-2 variants" [Vaccine 41(11) (2023) 1892-1901].

Multiple evanescent white dot syndrome relapse following BNT162b2 mRNA COVID-19 vaccination.

Stevens-Johnson Syndrome Following ChAdOx1 nCoV-19 Vaccination (AstraZeneca).

Activation and induction of antigen-specific T follicular helper cells play a critical role in recombinant SARS-CoV-2 RBD vaccine-induced humoral responses. The role of follicular T helper (Tfh) cells in humoral response has been considered essential in recent years. Understanding how Tfh cells control complex humoral immunity is critical to developing strategies to improve the efficacy of vaccines against SARS-CoV-2 and other emerging pathogens. However, the immunologic mechanism of Tfh cells in SARS-CoV-2 receptor binding domain (RBD) vaccine strategy is limited. In this study, we expressed and purified recombinant SARS-CoV-2 RBD protein in Drosophila S2 cells for the first time and explored the mechanism of Tfh cells induced by RBD vaccine in humoral immune response. We mapped the dynamic of Tfh cell in lymph node and spleen following RBD vaccination and revealed the relationship between Tfh cells and humoral immune response induced by SARS-CoV-2 RBD vaccine through correlation analysis, blocking of IL-21 signaling pathway, and co-culture of Tfh with memory B cells. Recombinant RBD protein elicited a predominant Tfh1 and Tfh1-17 subset response and strong GC responses in spleen and lymph nodes, especially to enhanced vaccination. IL-21 secreted by Tfh cells affected the development and differentiation of B cells and played a key role in the humoral immune response. These observations will help us further understand the mechanism of protective immune response induced by COVID-19 vaccine and has guiding significance for the development of vaccines against newly emerging mutants.

Social media trust predicts lower COVID-19 vaccination rates and higher excess mortality over 2 years. Trust plays a crucial role in implementing public health interventions against the COVID-19 pandemic. We examined the prospective associations of interpersonal, institutional, and media trust with vaccination rates and excess mortality over time in two multinational studies. In study 1, we investigated the country-level relationships between interpersonal trust, vaccination rates, and excess mortality across 54 countries. Interpersonal trust at the country level was calculated by aggregating data of 80,317 participants from the World Values Survey in 2017-20. Data on vaccination rates and excess mortality were obtained from the World Health Organization. Our

findings indicated that higher levels of interpersonal trust were linked to higher vaccination rates and lower excess mortality rates in both 2020 and 2021. In study 2, we collected data from 18,171 adults in 35 countries/societies, stratified by age, gender, and region of residence. At the country/society level, interpersonal trust and trust in local healthcare facilities, local healthcare services, and healthcare professionals were associated with higher vaccination rates and lower excess mortality, whereas social media trust was associated with lower vaccination rates and higher excess mortality across three time points over 2 years. Our findings are robust when controlling for country-level covariates of the government stringency index, population density, and medical resources (i.e. critical care beds) in both studies.
Optic Neuritis After COVID-19 Vaccination: Response.
Optic Neuritis After COVID-19 Vaccination: Comment.
Divergence of variant binding/neutralizing antibodies following SARS-CoV-2 booster vaccines in myeloma: Impact of hybrid immunity. We characterized virus-neutralization and spike-binding antibody profiles in myeloma patients following monovalent or bivalent-SARS-CoV-2 booster vaccination. Vaccination improves the breadth of binding antibodies but not neutralization activity against current variants. Hybrid immunity and immune imprinting impact vaccine-elicited immunity.
Post-vaccination SARS-Cov-2 T-cell receptor repertoires and multiple sclerosis and related disorders: Correspondence.
Noninfectious Uveitis Risk After COVID-19 Vaccination: A Nationwide Retrospective Cohort Study. PURPOSE: To investigate the incidence and risk of noninfectious uveitis (NIU) following COVID-19 vaccination compared with an unvaccinated, uninfected control group. DESIGN: Retrospective population-based cohort study. METHODS: We included 5,185,153 individuals who received the first vaccine dose in the exposed group and 2,680,164 individuals in the unexposed, uninfected control group. The study observed for 180 days from their index date. Cumulative incidence and risk of NIU following COVID-19 vaccination, and attributable risk factors were assessed. RESULTS: Multivariable analysis showed elevated risk of nonanterior NIU within 60 days (hazard ratio [HR] 1.27 [95% confidence interval {CI} 1.03-1.55] and 61-180 days (HR 1.39 [95% CI 1.20-1.62]). Subgroup analysis highlighted an increased risk in females for early and delayed nonanterior uveitis (HR 1.44 [95% CI 1.08-1.92]; HR 1.78 [95% CI 1.43-2.20], respectively). Regardless of the location and onset timing of uveitis, a history of NIU was identified as the most significant risk factor, with a high hazard ratio ranging from 100 to 200. CONCLUSIONS: COVID-19 vaccination may modestly increase the risk of nonanterior uveitis especially in females. Despite adjustments, bias may persist in the exposed group, owing to significant differences between unexposed and exposed groups and low incidence of nonanterior uveitis in the unexposed group. Future research should aim to refine these findings by assessing uveitis risk in prior NIU patients and by enlarging the sample size or cohort matching.
An Enigma of Sudden-Onset Vitiligo after COVID-19 Vaccination: A Literature Review.
Myocardial injury after COVID-19 infection and vaccination. Two sides of the same coin or different?
Response to: myositis after SARS-CoV-2 vaccination occurs more frequently than assumed and is probably causally related. We thank Finsterer et al. for the attention paid to our publication; we recognize the validity of the points mentioned in their letter to the editor and will try to answer the observations made.
Alterations in the gut microbiome and its metabolites are associated with the immune response to mucosal immunization with Lactiplantibacillus plantarum-displaying recombinant SARS-CoV-2 spike epitopes in mice. Lactic acid bacteria (LAB) expressing foreign antigens have great potential as mucosal vaccines. Our previous study reported that recombinant Lactiplantibacillus plantarum SK156 displaying SARS-CoV-2 spike S1 epitopes elicited humoral and cell-mediated immune responses in mice. Here, we further examined the effect of the LAB-based mucosal vaccine on gut microbiome

composition and function, and gut microbiota-derived metabolites. Forty-nine (49) female BALB/c mice were orally administered L. plantarum SK156-displaying SARS-CoV-2 spike S1 epitopes thrice (at 14-day intervals). Mucosal immunization considerably altered the gut microbiome of mice by enriching the abundance of beneficial gut bacteria, such as Muribaculaceae, Mucispirillum, Ruminococcaceae, Alistipes, Roseburia, and Clostridia vadinBB60. Moreover, the predicted function of the gut microbiome showed increased metabolic pathways for amino acids, energy, carbohydrates, cofactors, and vitamins. The fecal concentration of short-chain fatty acids, especially butyrate, was also altered by mucosal immunization. Notably, alterations in gut microbiome composition, function, and butyrate levels were positively associated with the immune response to the vaccine. Our results suggest that the gut microbiome and its metabolites may have influenced the immunogenicity of the LAB-based SARS-CoV-2 vaccine.
Response to the Letter to the Editor on "Clinical characteristics of unvaccinated or incompletely vaccinated children with neurological manifestations due to SARS-CoV-2 Omicron infection".
Delta variant neutralizing antibody response following maternal COVID-19 vaccination. The Delta pandemic wave saw increased maternal morbidity and mortality compared to prior viral strains. COVID-19 vaccination in pregnancy elicits detectable levels of neutralizing antibodies to SARS-CoV-2 wild type and SARS-CoV-2 Delta variants in both maternal and neonatal samples at delivery. Our results demonstrate the effectiveness of vaccination which confers an immunological response against newer, and potentially more dangerous, viral variants.
Retinal vein occlusion following BNT162b2 (Pfizer-BioNTech) COVID-19 vaccination.
Evolution of anti-spike responses to SARS-CoV-2 vaccination within 6 months post-transplantation in patients previously vaccinated while on the transplant waiting list.
Lipschutz's vulvar ulcer in an adolescent after Pifzer COVID-19 vaccine.
First Onset of IgA Vasculitis and Nephritis Following COVID-19 Vaccination. The article presents a case of a 32-year-old male who developed IgA vasculitis (IgAV) and IgA vasculitis nephritis (IgAVN) after receiving the second dose of the AstraZeneca COVID-19 vaccine. IgAVN can be a rare side effect of COVID-19 vaccines. Healthcare providers should be aware of this potential adverse event, and promptly recognize and manage it. However, the benefits of vaccination in reducing the morbidity and mortality associated with COVID-19 far outweigh the risks of this rare adverse event.
Side Effects of COVID-19 Vaccines in Pregnant and Lactating Mexican Women and Breastfed Infants: A Survey-Based Study. COVID-19 vaccines' safety has been extensively studied; however, further analysis is required in pregnant women, nursing mothers, and breastfed infants. Our aim was to compare the extension and severity of self-reported COVID-19 vaccine side effects in pregnant and breastfeeding women, and breastfed infants. In this cross-sectional study, COVID-19-vaccinated subjects were enrolled using an online survey in Mexico. Women were classified by pregnancy and breastfeeding status at the time of vaccination (n = 3167). After the first or only dose, there was a trend toward fewer systemic effects in pregnant women (p = 0.06). BNT162b2 (Pfizer-BioNTech) had a higher frequency of local symptoms in pregnancy. Lactating women experienced fewer local symptoms after the first or single dose (p = 0.04) and the opposite occurred after the second dose (p = 0.001). ChAdOx1 (AstraZeneca) increased the chances of developing both local and systemic symptoms after the first dose but decreased them after the second dose. The severity was similar across groups, although the result of lack of association in pregnancy requires studies with a larger sample size. Irritability was the most reported symptom in breastfed infants. This study contributes to the knowledge about the side effects in pregnant and lactating women, and breastfed babies.
Ulcerating reaction in association with Pfizer-BioNTech COVID-19 vaccine in an 11-year-old boy.
A Case of Morphea After COVID-19 Vaccination.

Atypical B cells and impaired SARS-CoV-2 neutralization following heterologous vaccination in the elderly. Suboptimal responses to a primary vaccination course have been reported in the elderly, but there is little information regarding the impact of age on responses to booster third doses. Here, we show that individuals 70 years or older (median age 73, range 70-75) who received a primary two-dose schedule with AZD1222 and booster third dose with mRNA vaccine achieve significantly lower neutralizing antibody responses against SARS-CoV-2 spike pseudotyped virus compared with those younger than 70 (median age 66, range 54-69) at 1Â month post booster. Impaired neutralization potency and breadth post third dose in the elderly is associated with circulating "atypical" spike-specific B cells expressing CD11c and FCRL5. However, when considering individuals who received three doses of mRNA vaccine, we did not observe differences in neutralization or enrichment in atypical B cells. This work highlights the finding that AdV and mRNA COVID-19 vaccine formats differentially instruct the memory B cell response.

Intradermal administration of DNA vaccine targeting Omicron SARS-CoV-2 via pyro-drive jet injector provides the prolonged neutralizing antibody production via germinal center reaction. Emerging SARS-CoV-2 Omicron variants are highly contagious with enhanced immune escape mechanisms against the initially approved COVID-19 vaccines. Therefore, we require stable alternative-platform vaccines that confer protection against newer variants of SARS-CoV-2. We designed an Omicron B.1.1.529 specific DNA vaccine using our DNA vaccine platform and evaluated the humoral and cellular immune responses. SD rats intradermally administered with Omicron-specific DNA vaccine via pyro-drive jet injector (PJI) thrice at 2-week intervals elicited high antibody titers against the Omicron subvariants as well as the ancestral strain. Indeed, the Omicron B.1.1.529-specific antibody titer and neutralizing antibody were higher than that of other strains. Longitudinal monitoring indicated that anti-spike (ancestral and Omicron) antibody titers decreased toward 30Â weeks after the first vaccination dose. However, neutralization activity remained unaltered. Germinal center formation was histologically detected in lymph nodes in rats immunized with Omicron DNA vaccine. Ancestral spike-specific immune cell response was slightly weaker than Omicron spike-specific response in splenocytes with Omicron-adapted DNA vaccine, evaluated by ELISpot assay. Collectively, our findings suggest that Omicron targeting DNA vaccines via PJI can elicit robust durable antibody production mediated by germinal center reaction against this new variant as well as partially against the spike protein of other SARS-CoV-2 variants.

Saliva antiviral antibody levels are detectable but correlate poorly with serum antibody levels following SARS-CoV-2 infection and/or vaccination. The importance of salivary SARS-CoV-2 antibodies, following infection and vaccination, has not been fully established. 875 healthcare workers were sampled during the first wave in 2020 and 66 longitudinally in response to Pfizer BioNTech 162b2 vaccination. We measured SARS-CoV-2 total IgGAM and individual IgG, IgA and IgM antibodies. IgGAM seroprevalence was 39.9%; however, only 34.1% of seropositive individuals also had salivary antibodies. Infection generated serum IgG antibodies in 51.4% and IgA antibodies in 34.1% of individuals. In contrast, the salivary antibody responses were dominated by IgA (30.9% and 12% generating IgA and IgG antibodies, respectively). Post 2nd vaccination dose, in serum, 100% of infection naÃ¯ve individuals had IgG and 82.8% had IgA responses; in saliva, 65.5% exhibited IgG and 55.2% IgA antibodies. Prior infection enhanced the vaccine antibody response in serum but no such difference was observed in saliva. Strong neutralisation responses were seen for serum 6 months post 2nd-vaccination dose (median 87.1%) compared to low neutralisation responses in saliva (median 1%). Intramuscular vaccination induces significant serum antibodies and to a lesser extent, salivary antibodies; however, salivary antibodies are typically non-neutralising. This study provides further evidence for the need of mucosal vaccines to elicit nasopharyngeal/oral protection. Although

saliva is an attractive non-invasive sero-surveillance tool, due to distinct differences between systemic and oral antibody responses, it cannot be used as a proxy for serum antibody measurement.

Factors associated with COVID-19 vaccine uptake among foreign migrants in China. BACKGROUND/PURPOSE: The COVID-19 outbreak created unique policy challenges for vaccinating special groups like migrants. As part of sustainable development goals, the equitable distribution of the COVID-19 vaccine can contribute to ensuring health for all. This study examined COVID-19 vaccine uptake among foreign migrants in China based on sociodemographics, cultural beliefs, past vaccine behaviors, and psychosocial factors. DESIGN: An online cross-sectional survey was conducted among foreign migrants in mainland China via social media platforms from 21 November through 20 December 2021. Bivariate (unadjusted odd-ratio) and multivariate logistic regression analyses were performed to establish the correlates of COVID-19 vaccine uptake. RESULT: Surveyed foreign migrants that are culture neutral (AOR: 2.5, CI: 95%, 1.02-5.90, pÂ =Â 0.044), willing to pay for vaccination (AOR: 2.27, CI: 95%, 1.18-3.98, pÂ =Â 0.012), believe in vaccine efficacy (AOR: 3.00, CI: 95%, 1.75-5.16, pÂ <Â 0.000), have poor psychological health (AOR: 1.96, CI: 95%, 1.14-3.38, pÂ =Â 0 0.014), and have higher perceived seriousness of COVID-19 (AOR: 2.12, CI: 95%, 1.26-3.57, pÂ =Â 0.005) are more likely to receive COVID-19 vaccine. Those migrants with a history of declining vaccination (AOR: 0.34, CI: 95%, 0.18-0.65, pÂ =Â 0.000) and middle-income earners $1701-3500 (AOR: 0.43, CI: 95%, 0.23-0.82, pÂ =Â 0.010) are less likely to receive the COVID-19 vaccine. CONCLUSION: This study brings a unique perspective to understanding vaccine behavior among international migrants in China. There is an urgent call from the World Health Organization and countries for complete vaccination and efforts to improve vaccine coverage. However, fewer studies have been conducted globally on the vaccination of migrant populations. The current study provides empirical information to increase the knowledge of the correlates of vaccine behavior among immigrants in countries around the globe. Future studies should conduct cross-country comparisons to understand the factors associated with increasing vaccination rates among immigrant populations to formulate a strong policy to increase vaccine coverage among immigrant populations across countries.

Systematic review of the oral manifestations produced by the SARS-CoV-2 vaccine. BACKGROUND: To combat the coronavirus pandemic different vaccines have been developed. However, diverse adverse effects have been reported due to their use, including oral manifestations. Our objective is to review the existing bibliography to analyze what complications these vaccines have caused in the oral cavity. MATERIAL AND METHODS: A bibliographic search was conducted by two independent reviewers (TS and CL), in parallel in 6 electronic databases (PubMed, Scopus, Cochrane, Google Scholar, LILACS, BioMed Central). A total of 22 articles were analyzed. RESULTS: The most frequent adverse effect was oral lichen planus, with a higher prevalence in women and after the Pfizer mRNA BNT162b2 vaccine. CONCLUSIONS: These complications are minor and resolve with treatment, so the benefit of the use of vaccines outweigh the potential risks associated with these. Key words:Covid-19 vaccine, oral lesions, oral manifestations, SARS-CoV-2 vaccine, oral symptoms.

Comments on: Clinical characteristics of unvaccinated or incompletely vaccinated children with neurological manifestations due to SARS-CoV-2 Omicron infection.

Receptor-Binding-Domain-Specific B Cell Responses Induced by mRNA Immunization against SARS-CoV-2. mRNA vaccines have been instrumental in controlling the SARS-CoV-2 pandemic, but the short-lived protection mediated by Receptor Binding Domain (RBD)-specific antibodies necessitates frequent revaccinations to enhance vaccine-induced immunity. The development of RBD-specific B cell memory is critical for improving the qualitative and quantitative characteristics of the immune response. However, the effect of additional doses of mRNA vaccines on the composition of the RBD-specific B cell memory pool remains unclear. In this study, we found that dual BNT162b2 vaccination significantly increased both total RBD-specific and memory RBD-specific B cells and neutralizing

antibodies. Following the second BNT162b2 dose, we showed a trend for the enrichment of CD27+IgM- memory RBD-specific B cells, which are known to correlate with a strong humoral response upon re-challenge. Repeated Measures Correlation (rmcorr) analysis revealed a significant correlation between antibody titers and both total and memory RBD-specific B cells, demonstrating that B cell and antibody responses are generated in a coordinated manner following BNT162b2 mRNA immunization. Our findings indicate that additional doses of the BNT162b2 mRNA vaccine enhance the qualitative and quantitative enrichment of the memory B cell pool against the vaccine antigens and collectively demonstrate the induction of a coordinated immune response to mRNA vaccination.

A Randomized Controlled Trial of a Parent-Led Memory-Reframing Intervention to Reduce Distress and Pain Associated with Vaccine Injections in Young Children. Children remember their memories of pain long after the painful experience is over. Those memories predict higher levels of future pain intensity. Young children's memories can be reframed to be less distressing. Parents and the way they reminisce about past events with their children play a key role in the formation of pain memories. A novel parent-led memory-reframing intervention changed children's memories of post-surgical pain to be less distressing. The intervention efficacy in the context of vaccine injections is unclear. This registered randomized controlled trial (NCT05217563) aimed to fill this gap. Seventy-four children aged 4.49 years (SD = 1.05) and scheduled to obtain two COVID-19 vaccine injections and one of their parents were randomized to receive: (1) standard care; (2) standard care and memory-reframing information; and (3) standard care and memory-reframing information with verbal instructions. Children reported their pain after vaccine injections. One week after the first vaccination, children reported memory of pain. Parents reported their use of memory-reframing strategies and intervention feasibility and acceptability. The intervention did not result in significant differences in children's recalled or future pain. Parents rated the intervention as acceptable and feasible.

Humoral Response After 6 or More Successive Doses of SARS-CoV-2 mRNA Vaccines in Kidney Transplant Recipients-Should We Keep Vaccinating?

Delivery and Expression of mRNA in the Secondary Lymphoid Organs Drive Immune Responses to Lipid Nanoparticle-mRNA Vaccines after Intramuscular Injection. Lipid nanoparticles (LNPs) are the prime delivery vehicle for mRNA vaccines. Previous hypotheses suggested that LNPs contribute to innate reactogenicity and lead to the establishment of a vaccine adaptive response. It has not been clear whether LNP adjuvancy in the muscle is the prime driver of adaptive immune responses or whether delivery to secondary lymphatic organs is necessary to induce strong adaptive responses. To address this, we formulated reporter gene (NLuc) or OVA mRNA into LNP or coadministered the mRNA with empty LNP. After IM injection, we correlated the delivery with adaptive immune responses. Additionally, we investigated humoral responses to modified mRNA encoding the SARS-CoV-2 spike protein. Compared to unformulated mRNA encoding nanoluciferase, with or without co-administered empty LNPs, LNP-formulated mRNA resulted in high levels of nanoluciferase in the secondary lymphoid organs. Similarly, LNP-mRNA encoding ovalbumin led to a cellular immune response against OVA while free mRNA, with or without empty adjuvanted LNPs, caused little or no immune response. Finally, only mice injected with LNP-formulated mRNA encoding SARS-CoV-2 spike protein elicited robust cellular and humoral immune responses. Our results suggest that the mRNA delivery and transfection of secondary lymphatic organs, not LNP adjuvancy or RNA expression in muscle, are the main drivers for adaptive immune response in mice. This work informs the design of next-generation mRNA delivery systems where better delivery to secondary lymphatic organs should lead to a better vaccine response.

Comparison of vaccination and booster rates and their impact on excess mortality during the COVID-19 pandemic in European countries. AIM: To evaluate the effect of vaccination/booster

administration dynamics on the reduction of excess mortality during COVID-19 infection waves in European countries. METHODS: We selected twenty-nine countries from the OurWorldInData project database according to their population size of more than one million and the availability of information on dominant SARS-CoV-2 variants during COVID-19 infection waves. After selection, we categorized countries according to their "faster" or "slower" vaccination rates. The first category included countries that reached 60% of vaccinated residents by October 2021 and 70% by January 2022. The second or "slower" category included all other countries. In the first or "faster" category, two groups, "boosters faster'' and "boosters slower" were created. Pearson correlation analysis, linear regression, and chi-square test for categorical data were used to identify the association between vaccination rate and excess mortality. We chose time intervals corresponding to the dominance of viral variants: Wuhan, Alpha, Delta, and Omicron BA.1/2. RESULTS AND DISCUSSION: The "faster" countries, as opposed to the "slower" ones, did better in protecting their residents from mortality during all periods of the SARS-CoV-2 pandemic and even before vaccination. Perhaps higher GDP per capita contributed to their better performance throughout the pandemic. During mass vaccination, when the Delta variant prevailed, the contrast in mortality rates between the "faster" and "slower" categories was strongest. The average excess mortality in the "slower" countries was nearly 5 times higher than in the "faster" countries, and the odds ratio (OR) was 4.9 (95% CI 4.4 to 5.4). Slower booster rates were associated with significantly higher mortality during periods dominated by Omicron BA.1 and BA.2, with an OR of 2.6 (CI 95%. 2.1 to 3.3). Among the European countries we analyzed, Denmark, Norway, and Ireland did best, with a pandemic mortality rate of 0.1% of the population or less. By comparison, Bulgaria, Serbia, and Russia had a much higher mortality rate of up to 1% of the population. CONCLUSION: Thus, slow vaccination and booster administration was a major factor contributing to an order of magnitude higher excess mortality in "slower" European countries compared to more rapidly immunized countries.

Vestibular disorders following BNT162b2 mRNA COVID-19 vaccination: A retrospective case series. BACKGROUND: There are few publications regarding manifestations of vestibular disorders (VDs) following BNT162b2 mRNA COVID-19 vaccination. PURPOSE: We describe cases of VD potentially related to BNT162b2 vaccination and calculate its reporting rate, in order to enlarge knowledge about this adverse effect. METHODS: A retrospective analysis of cases of VD following BNT162b2 vaccination reported to the pharmacovigilance centre of Georges-Pompidou European Hospital (France), in 2021 was performed. In order to identify these cases from the pharmacovigilance database containing all our registered cases, we used the Standardised MedDRA Query (SMQ) 'vestibular disorders'. Then we analysed cases with vestibular symptoms, based on the association of typical manifestations. The reporting rate was calculated based on the number of VD cases and the number of vaccinated patients. RESULTS: Among 6608 cases reported to our centre related to COVID-19 vaccines during 2021, 34 VDs associated with BNT162b2 administration were included. They were mainly reported in females (79%), 62% occurred after the first dose and 32% were serious. Symptoms had completely resolved in 13 cases (38%). Vertigo was the most common symptom followed by balance disorders. Three patients received second dose without reappearance of VD. The final diagnosis was reported in 10 patients (six cases of vestibular neuritis, two cases of central VD, two cases of benign paroxysmal positional vertigo). The regional reporting rate was 26 [95% CI: 17-34] cases of VD per 1 million persons vaccinated. CONCLUSION: Although the relationship between vaccination and VD cannot be established, clinicians should be aware of this rare adverse effect.

Incidence Rates and Clinical Characteristics of Patients With Confirmed Myocarditis or Pericarditis Following COVID-19 mRNA Vaccination: Experience of the Veterans Health Administration Through 9 October 2022. BACKGROUND: Although the benefits outweigh the risks, COVID-19 vaccines have been associated with an increased risk of myocarditis and pericarditis. This report is based on a

national US veteran population with confirmed myocarditis/pericarditis following mRNA COVID-19 vaccines according to the near real-time active surveillance program of Veterans Affairs. METHODS: This study is based on a cohort evaluation of all adults administered â‰¥1 mRNA COVID-19 vaccine, including boosters, in the Veterans Health Administration between 14 December 2020 and 9 October 2022. ICD-10-CM diagnosis codes were used to identify potential safety signals in near real time through a database analysis. All potential cases of myocarditis/pericarditis identified in the database analysis underwent in-depth chart review and case validation by a team of pharmacists and expert clinicians. Our main outcome was the incidence rate of confirmed myocarditis/pericarditis among vaccine recipients (overall and those aged 18-39 years) within 21 days of a first, second, or booster dose of a mRNA COVID-19 vaccine. We calculated the ratio of observed events among COVID-19 vaccine recipients over expected events from historical vaccine recipient controls (2015-2020) in the Veterans Health Administration. We used confirmed cases to calculate incidence rates and 95% CIs. RESULTS: Through 9 October 2022, 3 877 453 doses of BNT162b2 (Pfizer-BioNTech) and 4 221 397 doses of mRNA-1273 (Moderna) were administered as first or second dose across Veterans Affairs, and 1 012 561 BNT162b2 and 1 156 160 mRNA-1273 booster doses were administered. Among all doses, the rapid cycle analysis identified 178 potential cases of myocarditis/pericarditis among vaccinees of any age and 22 potential cases among those aged 18-39 years. Of these, 33 cases, including 6 among those 18-39 years old, were confirmed after in-depth chart review and validation, corresponding with an overall incidence rate per million ranging from 0.46 (95% CI, .01-2.55) for Moderna dose 1 to 6.91 (95% CI, 2.78-14.24) for Pfizer booster. Among those aged 18-39, incidence rates ranged from 7.1 (95% CI, .18-39.56) for Moderna dose 2 to 19.76 (95% CI, 5.38-50.58) for Pfizer dose 2. Patients with confirmed cases were hospitalized for a mean 4.1 days (range, 1-15). The final disposition for 32 (97%) of 33 cases was discharge to home. CONCLUSIONS: This report is a real-world demonstration of the Veterans Affairs' active surveillance system for vaccines. Although the rapid cycle analysis initially identified 178 potential cases of myocarditis/pericarditis, only 1 of 5 cases was confirmed to be related to a COVID-19 vaccine after chart review. These findings highlight the paramount importance of active surveillance and chart validation for rare but serious adverse events related to COVID-19 vaccines.

Factors associated with long-term antibody response after COVID-19 vaccination in patients treated with systemic treatment for solid tumors.

Real-Time Quantitative Measurement of Tumor Cell Migration and Invasion Following Synthetic mRNA Transfection. Tumor cells are highly motile and invasive and display altered gene expression patterns. Knowledge of how changes in gene expression regulate tumor cell migration and invasion is essential for understanding the mechanisms of tumor cell infiltration into neighboring healthy tissues and metastasis. Previously, it was demonstrated that gene knockdown followed by the impedance-based real-time measurement of tumor cell migration and invasion enables the identification of the genes required for tumor cell migration and invasion. Recently, the mRNA vaccines against SARS-CoV-2 have increased interest in using synthetic mRNA for therapeutic purposes. Here, the method using synthetic mRNA was revised to study the effect of gene overexpression on tumor cell migration and invasion. This study demonstrates that elevated gene expression with synthetic mRNA transfection followed by impedance-based real-time measurement may help identify the genes that stimulate tumor cell migration and invasion. This method paper provides important details on the procedures for examining the effect of altered gene expression on tumor cell migration and invasion.

Infection and Vaccine Induced Spike Antibody Responses Against SARS-CoV-2 Variants of Concern in COVID-19-NaÃ¯ve Children and Adults. Although a more efficient adaptive humoral immune response has been proposed to underlie the usually favorable outcome of pediatric COVID-19, the

breadth of viral and vaccine cross-reactivity toward the ever-mutating Spike protein among variants of concern (VOCs) has not yet been compared between children and adults. We assessed antibodies to conformational Spike in COVID-19-naÃ¯ve children and adults vaccinated by BNT162b2 and ChAdOx1, and naturally infected with SARS-CoV-2 Early Clade, Delta, and Omicron. Sera were analyzed against Spike including naturally occurring VOCs Alpha, Beta, Gamma, Delta, and Omicron BA.1, BA.2, BA.5, BQ.1.1, BA2.75.2, and XBB.1, and variants of interest Epsilon, Kappa, Eta, D.2, and artificial mutant Spikes. There was no notable difference between breadth and longevity of antibody against VOCs in children and adults. Vaccinated individuals displayed similar immunoreactivity profiles across variants compared with naturally infected individuals. Delta-infected patients had an enhanced cross-reactivity toward Delta and earlier VOCs compared to patients infected by Early Clade SARS-CoV-2. Although Omicron BA.1, BA.2, BA.5, BQ.1.1, BA2.75.2, and XBB.1 antibody titers were generated after Omicron infection, cross-reactive binding against Omicron subvariants was reduced across all infection, immunization, and age groups. Some mutations, such as 498R and 501Y, epistatically combined to enhance cross-reactive binding, but could not fully compensate for antibody-evasive mutations within the Omicron subvariants tested. Our results reveal important molecular features central to the generation of high antibody titers and broad immunoreactivity that should be considered in future vaccine design and global serosurveillance in the context of limited vaccine boosters available to the pediatric population.
Phenotypic Changes in T and NK Cells Induced by Sputnik V Vaccination. A highly effective humoral immune response induced by the Sputnik V vaccine was demonstrated in independent studies, as well as in large-scale post-vaccination follow-up studies. However, the shifts in the cell-mediated immunity induced by Sputnik V vaccination are still under investigation. This study was aimed at estimating the impact of Sputnik V on activating and inhibitory receptors, activation and proliferative senescence markers in NK and T lymphocytes. The effects of Sputnik V were evaluated by the comparison of PBMC samples prior to vaccination, and then three days and three weeks following the second (boost) dose. The prime-boost format of Sputnik V vaccination induced a contraction in the T cell fraction of senescent CD57(+) cells and a decrease in HLA-DR-expressing T cells. The proportion of NKG2A(+) T cells was down-regulated after vaccination, whereas the PD-1 level was not affected significantly. A temporal increase in activation levels of NK cells and NKT-like cells was recorded, dependent on whether the individuals had COVID-19 prior to vaccination. A short-term elevation of the activating NKG2D and CD16 was observed in NK cells. Overall, the findings of the study are in favor of the Sputnik V vaccine not provoking a dramatic phenotypic rearrangement in T and NK cells, although it induces their slight temporal non-specific activation.
Rhabdomyolysis or Myositis following a SARS-CoV-2 Vaccination.
Myocarditis with ventricular tachycardia following bivalent COVID-19 mRNA vaccination.
Serum Neutralization of Omicron XBB.1.5 in Kidney Transplant Recipients After Bivalent mRNA Booster Vaccination.
Author Correction: Myocarditis after COVID-19 mRNA vaccination: clinical observations and potential mechanisms.
The anti-COVID-19 vaccine unveils latent systemic sclerosis.
IgA pemphigus following COVID-19 vaccination: A case report. A patient presented with pruritic lesions on their back and leg after COVID-19 vaccination. Biopsy and direct immunofluorescence were consistent with IgA pemphigus-likely caused by the COVID-19 vaccine.
Tubulointerstitial nephritis and uveitis syndrome (TINU) following COVID-19 vaccination.
Exacerbation of psoriasis after post-COVID-19 vaccine reported in a young female.

Incidence of myocarditis and pericarditis considered as separate clinical events over the years and post-SARS-CoV2 vaccination in adults and children.
Apparent Risks of Postural Orthostatic Tachycardia Syndrome Diagnoses After COVID-19 Vaccination and SARS-Cov-2 Infection. Postural orthostatic tachycardia syndrome (POTS) has been previously described after SARS-CoV-2 infection; however, limited data is available on the relation of POTS with COVID-19 vaccination. Here we show in a cohort of 284,592 COVID-19 vaccinated individuals using a sequence-symmetry analysis, that the odds of POTS are higher 90 days after vaccine exposure than 90 days prior to exposure, and that the odds for POTS are higher than referent conventional primary care diagnoses, but lower than the odds of new POTS diagnosis after SARS-CoV-2 infection. Our results identify a possible association between COVID-19 vaccination and incidence of POTS. Notwithstanding the probable low incidence of POTS after COVID-19 vaccination, particularly when compared to SARS-Cov-2 post-infection odds which were five times higher, our results suggest that further studies, are needed to investigate the incidence and etiology of POTS occurring after COVID-19 vaccination.
Systematic review and meta-analysis of myocarditis and pericarditis in adolescents following COVID-19 BNT162b2 vaccination. Myocarditis and pericarditis are frequent complications of COVID-19, but have also been reported following vaccination against COVID-19 in adolescents. To build vaccine confidence and inform policy, we characterized the incidence of myocarditis/pericarditis in adolescents following BNT162b2 vaccination and explored the association with dose and sex. We searched national and international databases for studies reporting the incidence of myocarditis/pericarditis following BNT162b2 vaccination as the primary endpoint. The intra-study risk of bias was appraised, and random-effects meta-analyses were performed to estimate the pooled incidence by dose stratified by sex. The pooled incidence of myocarditis/pericarditis was 4.5 (95%CI: 3.14-6.11) per 100,000 vaccinations across all doses. Compared to dose 1, the risk was significantly higher after dose 2 (RR: 8.62, 95%CI: 5.71-13.03). However, adolescents experienced a low risk after a booster dose than after dose 2 (RR: 0.06; 95%CI: 0.04-0.09). Males were approximately seven times (RR: 6.66, 95%CI: 4.77-4.29) more likely than females to present myocarditis/pericarditis. In conclusion, we found a low frequency of myocarditis/pericarditis after BNT162b2, which occurred predominantly after the second dose in male adolescents. The prognosis appears to be favorable, with full recovery in both males and females. National programs are recommended to adopt the causality framework to reduce overreporting, which undercuts the value of the COVID-19 vaccine on adolescent life, as well as to extend the inter-dose interval policy, which has been linked to a lower frequency of myocarditis/pericarditis.
Immune response enhancement with GLS-5310 DNA primary vaccine against SARS-CoV-2 followed by administration of an mRNA vaccine heterologous boost. Heterologous boost regimens are being increasingly considered against SARS-CoV-2. We report results for the 32 of 45 participants in the Phase 1 CoV2-001 clinical trial (Kim et al., Int J Iinfect Dis 2023, 128:112-120) who elected to receive an EUA-approved SARS-CoV-2 mRNA vaccine 6 to 8Â months following a two-dose primary vaccination with the GLS-5310 bi-cistronic DNA vaccine given intradermally and followed by application of suction using the GeneDerm device. Receipt of EUA-approved mRNA vaccines after GLS-5310 vaccination was well-tolerated, with no reported adverse events. Immune responses were enhanced such that binding antibody titers, neutralizing antibody titers, and T-cell responses increased 1,187-fold, 110-fold, and 2.9-fold, respectively. This paper is the first description of the immune responses following heterologous vaccination with a DNA primary series and mRNA boost.
Immune Thrombocytopenia Relapse in Patients Who Received mRNA COVID-19 Vaccines [Letter].
Ipsilateral Upper-Limb Lymphedema After COVID-19 Vaccine Booster: Reply.

Humoral and cellular responses after third dose of SARS-CoV-2 vaccine in myeloproliferative neoplasms patients on ruxolitinib therapy.
Neutralizing antibodies against SARS-CoV-2 virus after vaccination in patients with neurofibromatosis type 1.
Oral adverse events following immunization against SARS-CoV-2: A case series.
Results on SARS-CoV-2 mRNA Vaccine Booster from an Open-Label Multicenter Study in Ofatumumab-Treated Participants with Relapsing Multiple Sclerosis. BACKGROUND: Few data exist on how ofatumumab treatment impacts SARS-CoV-2 booster vaccination response. METHODS: KYRIOS is an ongoing prospective open-label multicenter study on the response to initial and booster SARS-CoV-2 mRNA vaccination before or during ofatumumab treatment in relapsing MS patients. The results on the initial vaccination cohort have been published previously. Here, we describe 23 patients who received their initial vaccination outside of the study but booster vaccination during the study. Additionally, we report the booster results of two patients in the initial vaccination cohort. The primary endpoint was SARS-CoV-2-specific T-cell response at month 1. Furthermore, serum total and neutralizing antibodies were measured. RESULTS: The primary endpoint was reached by 87.5% of patients with booster before (booster cohort 1, N = 8) and 46.7% of patients with booster during ofatumumab treatment (booster cohort 2, N = 15). Seroconversion rates for neutralizing antibodies increased from 87.5% at baseline to 100.0% at month 1 in booster cohort 1 and from 71.4% to 93.3% in booster cohort 2. Of note, 3 of 4 initially seronegative patients in booster cohort 2 and one seronegative patient in the initial vaccination cohort seroconverted after the booster during ofatumumab treatment. CONCLUSIONS: Booster vaccinations increase neutralizing antibody titers in ofatumumab-treated patients. A booster is recommended in ofatumumab-treated patients.
Long-Term Cross Immune Response in Mice following Heterologous Prime-Boost COVID-19 Vaccination with Full-Length Spike mRNA and Recombinant S1 Protein. (1) Background: As the COVID-19 pandemic enters its fourth year, it continues to cause significant morbidity and mortality worldwide. Although various vaccines have been approved and the use of homologous or heterologous boost doses is widely promoted, the impact of vaccine antigen basis, forms, dosages, and administration routes on the duration and spectrum of vaccine-induced immunity against variants remains incompletely understood. (2) Methods: In this study, we investigated the effects of combining a full-length spike mRNA vaccine with a recombinant S1 protein vaccine, using intradermal/intramuscular, homologous/heterologous, and high/low dosage immunization strategies. (3) Results: Over a period of seven months, vaccination with a mutant recombinant S1 protein vaccine based on the full-length spike mRNA vaccine maintained a broadly stable humoral immunity against the wild-type strain, a partially attenuated but broader-spectrum immunity against variant strains, and a comparable level of cellular immunity across all tested strains. Furthermore, intradermal vaccination enhanced the heterologous boosting of the protein vaccine based on the mRNA vaccine. (4) Conclusions: This study provides valuable insights into optimizing vaccination strategies to address the ongoing challenges posed by emerging SARS-CoV-2 variants.
Long COVID and Hybrid Immunity among Children and Adolescents Post-Delta Variant Infection in Thailand. This study aimed to assess long COVID, and describe immunogenicity against Omicron variants following BNT162b2 vaccination. A prospective cohort study was conducted among children (aged 5-11) and adolescents (aged 12-17) who had SARS-CoV-2 infection from July to December 2021 (Delta predominant period). Long COVID symptoms were assessed by questionnaires at 3 months after infection. Immunogenicity was evaluated by using a surrogate virus-neutralizing antibody test (sVNT) against the Omicron variant. We enrolled 97 children and 57 adolescents. At 3 months, 30 children (31%) and 34 adolescents (60%) reported at least one long COVID symptom, with respiratory symptoms prevailing (25% children and 32% adolescents). The median time from infection to

vaccination was 3 months in adolescents and 7 months in children. At 1 month following vaccination, in children who received one-dose and two-dose BNT162b2 vaccines, the median (IQR) sVNT against Omicron was 86.2% inhibition (71.1-91.8) and 79.2% inhibition (61.5-88.9), respectively (p = 0.26). Among adolescents who received one-dose and two-dose BNT162b2 vaccines, the median (IQR) sVNT against Omicron was 64.4% inhibition (46.8-88.8) and 68.8% inhibition (65.0-91.2) (p = 0.64). Adolescents had a higher prevalence of long COVID than children. Immunogenicity against the Omicron variant after vaccination was high and did not vary between one or two doses of the vaccine in either children or adolescents.

SARS-CoV-2 RBD and Its Variants Can Induce Platelet Activation and Clearance: Implications for Antibody Therapy and Vaccinations against COVID-19. The COVID-19 pandemic caused by SARS-CoV-2 virus is an ongoing global health burden. Severe cases of COVID-19 and the rare cases of COVID-19 vaccine-induced-thrombotic-thrombocytopenia (VITT) are both associated with thrombosis and thrombocytopenia; however, the underlying mechanisms remain inadequately understood. Both infection and vaccination utilize the spike protein receptor-binding domain (RBD) of SARS-CoV-2. We found that intravenous injection of recombinant RBD caused significant platelet clearance in mice. Further investigation revealed the RBD could bind platelets, cause platelet activation, and potentiate platelet aggregation, which was exacerbated in the Delta and Kappa variants. The RBD-platelet interaction was partially dependent on the Î²3 integrin as binding was significantly reduced in Î²3(-/-) mice. Furthermore, RBD binding to human and mouse platelets was significantly reduced with related Î±IIbÎ²3 antagonists and mutation of the RGD (arginine-glycine-aspartate) integrin binding motif to RGE (arginine-glycine-glutamate). We developed anti-RBD polyclonal and several monoclonal antibodies (mAbs) and identified 4F2 and 4H12 for their potent dual inhibition of RBD-induced platelet activation, aggregation, and clearance inÂ vivo, and SARS-CoV-2 infection and replication in Vero E6 cells. Our data show that the RBD can bind platelets partially though Î±IIbÎ²3 and induce platelet activation and clearance, which may contribute to thrombosis and thrombocytopenia observed in COVID-19 and VITT. Our newly developed mAbs 4F2 and 4H12 have potential not only for diagnosis of SARS-CoV-2 virus antigen but also importantly for therapy against COVID-19.

Association between COVID-19 vaccination and 28-day all-cause mortality in SARS-CoV-2-infected older people living in residential aged care facilities. This retrospective cross-sectional study reviewed the association between COVID-19 vaccination and the 28-day all-cause mortality amongst SARS-CoV-2-infected older people living in residential aged care facilities. A lower mortality rate was observed in fully vaccinated residents compared with not fully vaccinated residents. Further research is required to investigate the optimal timing of vaccination boosters and vaccine efficacy as variants evolve.

The person-time ratio distribution for the exact monitoring of adverse events: Historical vs surveillance Poisson data. In the postmarket drug and vaccine safety surveillance, when the number of adverse events follows a Poisson distribution, the ratio between the exposed and the unexposed person-time information is the random variable that governs the decision rule about the safety of the drug or vaccine. The probability distribution function of such a ratio is derived in this paper. Exact point and interval estimators for the relative risk are discussed as well as statistical hypothesis testing. To the best of our knowledge, this is the first paper that provides an unbiased estimator for the relative risk based on the person-time ratio. The applicability of this new distribution is illustrated through a real data analysis aimed to detect increased risk of occurrence of Myocarditis/Pericarditis following mRNA COVID-19 vaccination in Manitoba, Canada.

Assessing SARS-CoV-2-specific T-cell reactivity in late convalescents and vaccinees: Comparison and combination of QuantiFERON and activation-induced marker assays, and relation with antibody status. OBJECTIVES: Monitoring of SARS-CoV-2 spread and vaccination strategies have relied on

antibody (Ab) status as a correlate of protection. We used QuantiFERONâ„¢ (QFN) and Activation-Induced Marker (AIM) assays to measure memory T-cell reactivity in unvaccinated individuals with prior documented symptomatic infection (late convalescents) and fully vaccinated asymptomatic donors (vaccinees). METHODS: Twenty-two convalescents and 13 vaccinees were enrolled. Serum anti-SARS-CoV-2 S1 and N Abs were measured using chemiluminescent immunoassays. QFN was performed following instructions and interferon-gamma (IFN-Î³) measured by ELISA. AIM was performed on aliquots of antigen-stimulated samples from QFN tubes. SARS-CoV-2-specific memory CD4+CD25+CD134+, CD4+CD69+CD137+ and CD8+CD69+CD137+ T-cell frequencies were measured by flow cytometry. RESULTS: In convalescents, substantial agreement was observed between QFN and AIM assays. IFN-Î³ concentrations and AIM+ (CD69+CD137+) CD4+ T-cell frequencies correlated with each other, with Ab levels and AIM+ CD8+ T-cell frequencies, whereas AIM+ (CD25+CD134+) CD4+ T-cell frequencies correlated with age. AIM+ CD4+ T-cell frequencies increased with time since infection, whereas AIM+ CD8+ T-cell expansion was greater after recent reinfection. QFN-reactivity and anti-S1 titers were lower, whereas anti-N titers were higher, and no statistical difference in AIM-reactivity and Ab positivity emerged compared to vaccinees. CONCLUSIONS: Albeit on a limited sample size, we confirm that coordinated, cellular and humoral responses are detectable in convalescents up to 2 years after prior infection. Combining QFN with AIM may enhance detection of naturally acquired memory responses and help stratify virus-exposed individuals in T helper 1-type (TH1)-reactive (QFNpos AIMpos Abshigh), non-TH1-reactive (QFNneg AIMpos Abshigh/low), and pauci-reactive (QFNneg AIMneg Abslow).

Severe superior mesenteric vein thrombosis after COVID-19 mRNA vaccination. Venous thrombosis is a rare occurrence following the administration of the COVID-19 mRNA vaccine. The occurrence of superior mesenteric vein (SMV) is even more rare. SMV thrombosis should be considered as a differential diagnosis in patients who develop abdominal pain after COVID-19 mRNA vaccination.

Measles outbreak in American Samoa: Alarm to strengthen vaccination post COVID-19 pandemic.

Humoral response after a BNT162b2 heterologous third dose of COVID-19 vaccine following two doses of BBIBP-CorV among healthcare personnel in Peru. BACKGROUND: The inactivated virus vaccine, BBIBP-CorV, was principally distributed across low- and middle-income countries as primary vaccination strategy to prevent poor COVID-19 outcomes. Limited information is available regarding its effect on heterologous boosting. We aim to evaluate the immunogenicity and reactogenicity of a third booster dose of BNT162b2 following a double BBIBP-CorV regime. METHODS: We conducted a cross-sectional study among healthcare providers from several healthcare facilities of the Seguro Social de Salud del PerÃº - ESSALUD. We included participants two-dose BBIBP-CorV vaccinated who presented a three-dose vaccination card at least 21Â days passed since the vaccinees received their third dose and were willing to provide written informed consent. Antibodies were determined using LIAISONÂ® SARS-CoV-2 TrimericS IgG (DiaSorin Inc., Stillwater, USA). Factors potentially associated with immunogenicity, and adverse events, were considered. We used a multivariable fractional polynomial modeling approach to estimate the association between anti-SARS-CoV-2 IgG antibodies' geometric mean (GM) ratios and related predictors. RESULTS: We included 595 subjects receiving a third dose with a median (IQR) age of 46 [37], [54], from which 40% reported previous SARS-CoV-2 infection. The overall geometric mean (IQR) of anti-SARS-CoV-2 IgG antibodies was 8,410 (5,115 - 13,000) BAU/mL. Prior SARS-CoV-2 history and full/part-time in-person working modality were significantly associated with greater GM. Conversely, time from boosting to IgG measure was associated with lower GM levels. We found 81% of reactogenicity in the study population; younger age and being a nurse were associated with a lower incidence of adverse events. CONCLUSIONS: Among healthcare providers, a booster dose of BNT162b2 following a full BBIBP-CorV regime

provided high humoral immune protection. Thus, SARS-CoV-2 previous exposure and working in person displayed as determinants that increase anti-SARS-CoV-2 IgG antibodies.

Incidence of SARS-CoV-2 Infection and Factors Associated With Complete COVID-19 Vaccine Uptake Among Migrant Origin Persons in Finland. Objective: We examined incidence of SARS-CoV-2 infection, COVID-19 vaccine uptake and factors associated with complete COVID-19 vaccine uptake among persons of migrant origin in Finland. Methods: Data on laboratory-confirmed SARS-CoV-2 infection and COVID-19 vaccine doses between March 2020 and November 2021 were linked to FinMonik register sample (n = 13,223) and MigCOVID (n = 3,668) survey data using unique personal identifier. Logistic regression was the main method of analyses. Results: Among FinMonik sample, complete COVID-19 vaccine uptake was lower among persons of Russia/former Soviet Union, Estonia, and rest of Africa and higher among persons of Southeast Asia, rest of Asia, and the Middle East/North Africa than among persons originating from Europe/North America/Oceania. Male sex, younger age, migration age (<18Â years) and shorter length of residence were associated with lower vaccine uptake among FinMonik sample, whereas younger age, being economically inactive, poorer language skills, experiences of discrimination and psychological distress were associated with lower vaccine uptake among MigCOVID sub-sample. Conclusion: Our Findings point to a further need of tailored and targeted communication and community outreach strategies to increase vaccine uptake among persons of migrant origin.

Reply to the Letter to the Editor for "Parsonage-Turner syndrome after SARS-CoV-2 vaccination: A case report".

Ability of SpikoGenÂ®, an Advax-CpG adjuvanted recombinant spike protein vaccine, to induce cross-neutralising antibodies against SARS-CoV-2 variants. SpikoGenÂ® vaccine is a subunit COVID-19 vaccine expressed in insect cells comprising recombinant spike protein extracellular domain formulated with Advax-CpG55.2â„¢ adjuvant. A Phase 2 trial was conducted in 400 adult participants randomised 3:1 to receive two intramuscular doses of SpikoGenÂ® vaccine or saline placebo 3â€‰weeks apart. Some Phase 2 trial participants later enrolled in a separate booster study and received a third dose of SpikoGenÂ® vaccine. This stored serum was used to assess the ability of SpikoGenÂ® vaccine to induce cross-neutralising antibodies against SARS-CoV-2 variants of concern. Sera taken at baseline and 2â€‰weeks after the second vaccine dose from baseline seronegative Phase 2 subjects was evaluated using a panel of spike pseudotype lentivirus neutralisation assays for the ability to cross-neutralise a wide range of SARS-CoV-2 variants, including Omicron BA.1, BA.2 and BA.4/5. Stored samples of subjects who participated in both the 2-dose Phase 2 trial and a third dose booster trial 6â€‰months later were also analysed for changes in cross-neutralising antibodies over time and dose. Two weeks after the second dose, sera broadly cross-neutralised most variants of concern, albeit with titres against Omicron variants being ~10-fold lower. While Omicron titres fell to low levels 6â€‰months after the second vaccine dose in most subjects, they showed a ~20-fold rise after the third dose booster, after which there was only a ~2-3-fold difference in neutralisation of Omicron and the ancestral strains. Despite being based on the ancestral Wuhan sequence, after two doses, SpikoGenÂ® vaccine induced broadly cross-neutralising serum antibodies. Titres then reduced over time but were rapidly restored by a third dose booster. This resulted in high neutralisation including against the Omicron variants. This data supports ongoing use of SpikoGenÂ® vaccine for protection against recent SARS-CoV-2 Omicron variants.

The association of care burden with motivation of vaccine acceptance among caregivers of stroke patients during the COVID-19 pandemic: mediating roles of problematic social media use, worry, and fear. BACKGROUND: The aim of the present study was to investigate the relationship between care burden and motivation of COVID-19 vaccine acceptance among caregivers of patients who have experienced a stroke and to explore the mediating roles of social media use, fear of COVID-19, and

worries about infection in this relationship. METHODS: A cross-sectional survey study with 172 caregivers of patients who had experienced a stroke took part in a Taiwan community hospital. All participants completed the Zarit Burden Interview, Bergen Social Media Addiction Scale, Worry of Infection Scale, Fear of COVID-19 Scale, and Motors of COVID-19 Vaccine Acceptance Scale. Multiple linear regression model was applied to construct and explain the association among the variables. Hayes Process Macro (Models 4 and 6) was used to explain the mediation effects. RESULTS: The proposed model significantly explained the direct association of care burden with motivation of COVID-19 vaccine acceptance. Despite the increased care burden associated with decreased vaccine acceptance, problematic social media use positively mediated this association. Moreover, problematic social media use had sequential mediating effects together with worry of infection or fear of COVID-19 in the association between care burden and motivation of vaccine acceptance. Care burden was associated with motivation of vaccine acceptance through problematic social media use followed by worry of infection. CONCLUSIONS: Increased care burden among caregivers of patients who have experienced a stroke may lead to lower COVID-19 vaccines acceptance. Moreover, problematic social media use was positively associated with their motivation to get COVID-19 vaccinated. Therefore, health experts and practitioners should actively disseminate accurate and trustworthy factual information regarding COVID-19, while taking care of the psychological problems among caregivers of patients who have experienced a stroke.

Associated factors for mortality in a COVID-19 colombian cohort: is the third wave relevant when Mu variant was predominant epidemiologically? OBJECTIVES: To evaluate the association between Colombia's third wave when the Mu variant was predominant epidemiologically (until 75%) in Colombia and COVID-19 all-cause in-hospital mortality. METHODS: In this retrospective cohort, we included hospitalized patients â‰¥18 years with SARS-CoV-2 infection between March 2020 to September 2021 in ten hospitals from three cities in Colombia. Description analysis, survival, and multivariate Cox regression analyses were performed to evaluate the association between the third epidemic wave and in-hospital mortality. RESULTS: A total of 25,371 patients were included. The age-stratified time-to-mortality curves showed differences according to epidemic waves in patients â‰¥75 years (log-rank test pÂ =Â 0.012). In the multivariate Cox analysis, the third wave was not associated with increased mortality relative to the first wave (aHR 0.95; 95%CI 0.84-1.08), but there was an interaction between age â‰¥75 years and the third wave finding a lower HR for mortality (aHR 0.56, 95%CI 0.36-0.86). CONCLUSIONS: We did not find an increase in in-hospital mortality during the third epidemic wave in which the Mu variant was predominant in Colombia. The reduced hazard in mortality in patients â‰¥75 years hospitalized in the third wave could be explained by the high coverage of SARS-CoV-2 vaccination in this population and patients with underlying conditions.

Beyond mental stress-induced myocardial ischemia following the COVID-19 vaccine.

Metabolic Adaptations Correlated with Antibody Response after Immunization with Inactivated SARS-CoV-2 in Brazilian Subjects. The adsorbed vaccine SARS-CoV-2 (inactivated) produced by Sinovac (SV) was the first vaccine against COVID-19 to be used in Brazil. To understand the metabolic effects of SV in Brazilian subjects, NMR-based metabolomics was used, and the immune response was studied in Brazilian subjects. Forty adults without (group(-), n = 23) and with previous COVID-19 infection (group(+), n = 17) were followed-up for 90 days postcompletion of the vaccine regimen. After 90 days, our results showed that subjects had increased levels of lipoproteins, lipids, and N-acetylation of glycoproteins (NAG) as well as decreased levels of amino acids, lactate, citrate, and 3-hydroxypropionate. NAG and threonine were the highest correlated metabolites with N and S proteins, and neutralizing Ab levels. This study sheds light on the immunometabolism associated with the use of SV in Brazilian subjects from Rio de Janeiro and identifies potential metabolic markers associated with the immune status.

COVID-19 vaccination, incidence, and mortality rates among individuals with mental disorders in South Korea: A nationwide retrospective study. We examined COVID-19 vaccination, incidence, and mortality rates among patients with mental health disorders in South Korea from 1 January 2020 to 31 December 2021. The study found that individuals with mental disorders had higher COVID-19 incidence and mortality than those without. Patients with mood disorders had higher vaccination rates and COVID-19 incidence and mortality than those without mental disorders. In contrast, patients with schizophrenia had lower vaccination rates, slightly lower COVID-19 incidence, and higher COVID-19 mortality. Patients with mental health disorders have been vulnerable to COVID-19, and more attention should be paid to their vaccination and health needs.

Enantioselective Effect of Chiral Small Molecules in SARS-CoV-2 Vaccine-Induced Immune Response. Although numerous chiral small molecules have been discovered and synthesized, the investigation on their enantioselective immunological effects remains limited. In this study, we designed and synthesized a pair of small molecule enantiomers (R/S-ResP) by covalently bonding two immunostimulators (resiquimod/Res) onto a planar chiral framework (paracyclophane/P). Notably, we found that S-ResP exhibits a 4.05-fold higher affinity for toll-like receptor 7 (TLR7) than R-ResP, thereby more effectively enhancing the functions of dendritic cells and macrophages in cytokine secretion and antigen internalization. Furthermore, we observed that S-ResP significantly enhances RBD antigen-induced cross-neutralization against various SARS-CoV-2 strains compared to R-ResP. These findings demonstrate the enantioselective effects of small molecules on regulating vaccine-induced immune responses and emphasize the significance of chirality in designing small molecular adjuvants.

Comments on: "Spectrum of Neurological Complications Following COVID-19 Vaccination in India".

COVID-19 Anti-Vaccine Sentiments in Malaysia: Narratives of Comments from Facebook Post. The anti-vaccination movement was an ongoing issue in Malaysia, a Muslim-majority country, even before the COVID-19 pandemic. It is unclear whether the introduction of new COVID-19 vaccines would similarly provoke anti-vaccine sentiments. This study analyzed COVID-19 anti-vaccine sentiments in the Malaysian community. Anti-vaccine comments from Facebook page posts were extracted. The qualitative software QSR-NVivo 10 was used to manage, code and analyze the data. The fast-track COVID-19 vaccine evoked the fear of unknown long-term effects, safety, effectiveness and the duration of protection. The halal status of the COVID-19 vaccines is important. Although it is permissible to use vaccines that are not certified halal under the state of darurah (emergency), there was doubt that the current state has reached the stage of darurah that warrants the use of vaccines. COVID-19 vaccine microchip conspiracy theories were raised. COVID-19 is viewed as only severe for vulnerable populations, and hence vaccination is not needed for the healthy. There were opinions that coronavirus treatments would be more beneficial than vaccination. The anti-COVID-19 vaccine sentiments uncovered in this study provide important insights for the formulation of public health messages to instill confidence in new COVID-19 vaccines. Despite the pandemic being nearly over and many people worldwide having received COVID-19 vaccines, the findings provide important insight into potential issues regarding the introduction of new vaccines in the event of future pandemics.

Humoral and cellular response induced by a second booster of an inactivated SARS-CoV-2 vaccine in adults. BACKGROUND: The Omicron variant has challenged the control of the COVID-19 pandemic due to its immuno-evasive properties. The administration of a booster dose of a SARS-CoV-2 vaccine showed positive effects in the immunogenicity against SARS-CoV-2, effect that is even enhanced after the administration of a second booster. METHODS: During a phase-3 clinical trial, we evaluated the effect of a second booster of CoronaVacÂ®, an inactivated vaccine administered 6 months after the first booster, in the neutralization of SARS-CoV-2 (nÂ =Â 87). In parallel, cellular immunity (nÂ =Â 45) was analyzed in stimulated peripheral mononuclear cells by flow cytometry and

ELISPOT. FINDINGS: Although a 2.5-fold increase in neutralization of the ancestral SARS-CoV-2 was observed after the second booster when compared with prior its administration (Geometric mean units pÂ <Â 0.0001; Geometric mean titer pÂ =Â 0.0002), a poor neutralization against the Omicron variant was detected. Additionally, the activation of specific CD4(+) T lymphocytes remained stable after the second booster and, importantly, equivalent activation of CD4(+) TÂ lymphocytes against the Omicron variant and the ancestral SARS-CoV-2 were found. INTERPRETATION: Although the neutralizing response against the Omicron variant after the second booster of CoronaVacÂ® was slightly increased, these levels are far from those observed against the ancestral SARS-CoV-2 and could most likely fail to neutralize the virus. In contrast, a robust CD4(+)T cell response may confer protection against the Omicron variant. FUNDING: The Ministry of Health, Government of Chile, the Confederation of Production and Commerce, Chile and SINOVAC Biotech.NIHNIAID. The Millennium Institute on Immunology and Immunotherapy.

Stroke seven hours after SARS-CoV-2 vaccination.

Commentary on: "Autopsy-based histopathological characterization of myocarditis after anti-SARS-CoV-2-vaccination" by C. Schwab et al.

Letter to the Editors: "Autopsy-based histopathological characterization of myocarditis after anti-SARS-CoV-2-vaccination" by C. Schwab et al.

Persistent myopericarditis after heterologous SARS-CoV-2 mRNA vaccination.

Myocarditis/pericarditis following vaccination with BNT162b2, CoronaVac, and ChAdOx1 among adolescent and adult in Malaysia. This study evaluates 21-day risk of myocarditis/pericarditis following COVID-19 vaccination among those aged 12Â years and older in Malaysia. We used data from nationwide COVID-19 vaccine registry linked to hospital episode database to identify individuals vaccinated with BNT162b2, CoronaVac, or ChAdOx1 and hospitalised for myocarditis/pericarditis between 1 February 2021 and 28 February 2022. There were 87 myocarditis/pericarditis cases identified within 1-21Â days after vaccination. Most cases were reported following BNT16262 vaccination (77.0%) with absolute risk of 0.33 cases/100,000 vaccinated persons or 1.73 per million doses administered. Highest risk was observed following second dose and in younger, male individuals. The risk of myocarditis/pericarditis following CoronaVac and ChAdOx1 were much lower compared to BNT162b2. The findings on higher risk observed among younger following mRNA vaccine were consistent with literature and important for targeted surveillance.

Association between COVID-19 symptoms, COVID-19 vaccine, and somatization among a sample of the Lebanese adults. OBJECTIVES: Long COVID syndrome, the poorly defined illness, has been increasingly mentioned in recent studies yet is still poorly understood especially when it comes to precipitating and modulating factors, the high prevalence of mental health problems associated with the COVID-19 pandemic has brought to light the hypothesis of the existence of a psychological component associated with the persistence of symptoms and if vaccination may serve as a modulating factor. This study aims to examine the prevalence of somatization disorders and association between persistent COVID-19 symptoms and COVID-19 vaccine with somatization among a sample of the Lebanese general population. METHODS: A cross-sectional study was carried out between September and October 2021. The snowball sampling technique was picked to choose a sample that addressed all Lebanese Mohafazat. Patient Health Questionnaire-15 (PHQ-15) was used to assess somatization. RESULTS: A total of 403 participants was enrolled in this study, with a mean age of 32.76 Â± 13.24 years, 108 (26.8%) had medium somatization symptoms (PHQ-15 scores â‰¥10). Having persistent COVID symptoms (Î²=2.15) was significantly associated with more somatization, whereas the intake of COVID vaccine (Î²=-1.17) was significantly associated with less somatization. CONCLUSION: Long lasting COVID-19 symptoms were closely related to somatization, although the administration of the COVID-19 vaccine was associated with less somatization. However,

further studies are needed to provide a better understanding of the relationship between long COVID and somatization, on one hand, and the modulating factors on the other hand.

Mucosal immune responses following a fourth SARS-CoV-2 vaccine dose.

Post-vaccination Symptoms of Covishield Vaccine among Frontline Workers of a Tertiary Care Center in Pathanamthitta District. INTRODUCTION: The COVID-19 pandemic, which began in late 2019 and is still ongoing, has affected health and life across the world. Widespread vaccination with highly effective vaccines is an important tool in the efforts to control this pandemic. To determine post-vaccination symptoms after the first dose of Covishield vaccine among health care workers at a tertiary care centre in Pathanamthitta District. MATERIALS AND METHODS: A descriptive cross-sectional study in a tertiary care hospital in Pathanamthitta District. Data on adverse effects following vaccination with the first dose of Covishield vaccine were collected from health care workers through online surveys and interviews. Baseline characteristics were described with frequency, percentages, and mean. Associations between categorical variables were assessed using the Chi-square test. RESULTS: Of the 1,115 health care workers who participated in the study, the majority were medical students (28.3%), followed by nurses (24.8%), and doctors (19.1%). Post-vaccination symptoms were reported by the majority of the participants (95.1%). The most common symptoms were pain at the site of injection (79.8%), followed by myalgia (67.2%), and tiredness (64.6%). Hospitalization was required for six (0.5%) of the participants. CONCLUSION: The symptoms reported in the study were those already known to be the general side effects associated with vaccines. The information obtained from this study will aid in health promotion activities related to COVID-19 vaccination.

Reply to the Letter "Reversible Vasoconstriction Syndrome Is a Complication of SARS-CoV-2 Infection/Vaccination Rather than That of Leigh Syndrome".

Erratum: Immune-mediated thrombotic thrombocytopenic purpura following mRNA-based COVID-19 vaccine BNT162b2: Case report and mini-review of the literature. [This corrects the article DOI: 10.3389/fmed.2022.890661.].

Intention to take COVID-19 vaccine and associated factors among pregnant women attending antenatal care at public health facilities in Bahir Dar city, Northwest Ethiopia. BACKGROUND: Pregnant mothers are a risky population group for COVID-19 and pregnant mothers with COVID-19 are at increased risk of hospitalization, intensive-care unit admission, invasive ventilation support, and maternal mortality. Vaccination is an essential tool in stopping the effect of the pandemic on maternal and child health. However, there are only limited studies in Ethiopia on the intention to take the COVID-19 vaccine among pregnant women. Thus, this study aimed to assess intention to take the COVID-19 vaccine and associated factors among pregnant women in Bahir Dar city, Northwest Ethiopia. METHODS: Facility based cross-sectional study was conducted among 590 pregnant women from 23 May to 07 July 2022. The study participants were selected using a systematic sampling technique. Interviewer administrative questionnaire with epicollect5 application was used to collect the data. Both bi-variable and multivariable binary logistic regression analysis was performed. Statistical significance was defined at a 95% CI with a p-valueâ€‰<â€‰0.05. RESULT: Overall, 19.8% (95% CI: 16.60-23.06%) of pregnant women intend to take the COVID-19 vaccine. Being urban residence (AORâ€‰=â€‰3.40, 95% CI: 1.71-6.78), third trimester of gestational age (AORâ€‰=â€‰3.11, 95% CI: 1.61-6.03), multipara (AORâ€‰=â€‰2.30, 95% CI: 1.33-3.97), knowledge of COVID-19 vaccine (AORâ€‰=â€‰2.33, 95% CI: 1.44-3.77) and having good attitude towards COVID-19 vaccine (AORâ€‰=â€‰2.68, 95% CI: 1.65-4.33) were significantly associated with intention to take COVID-19 vaccine. CONCLUSION: In conclusion, the pregnant women's intention to take the COVID-19 vaccine in this study area was very low. It was significantly associated with residency, gestational age, parity, knowledge, and attitude toward the vaccine. Therefore, strengthening interventions that improve knowledge and attitude about the COVID-19 vaccine,

predominantly among those primipara mothers and mothers from rural residences, may raise the intention to take it.
Why a major study on myocarditis risk following COVID vaccination should not influence public-health policy.
Pityriasis rubra pilaris following COVID-19 vaccination successfully treated with ixekizumab.
Humoral and cellular immunity to SARS-CoV-2 Ancestral and Omicron BA.5 variants following vaccination in myelofibrosis patients.
A new set-up of vanishing antibodies: A biennial follow-up of five different clients' humoral responses against SARS-CoV-2 after systemic vaccination in an oncology hospital in Poland.
Optic neuritis following COVID-19 vaccination.
Influence of vaccination on adverse health outcomes after SARS-CoV-2 infection among individuals with alcohol use disorder: a population-based study. BACKGROUND AND AIMS: Alcohol use disorders (AUD) have not been included in the priority groups for early vaccine against SARS-CoV-2. We aimed to determine adverse outcomes after SARS-CoV-2 infection among individuals with AUD and how this is modified by vaccination. DESIGN, SETTING AND PARTICIPANTS: This was a registry-based cohort study carried out in Denmark, 27 February 2020 to 15 October 2021, comprising 2157 individuals with AUD and 237â€‰541 without AUD who had had a polymerase chain reaction (PCR)-confirmed SARS-CoV-2 infection during the study period. MEASUREMENTS: The association of AUD with the absolute and relative risk of hospitalization, intensive care and 60-day mortality after SARS-CoV-2 infection and of all-cause mortality throughout the follow-up period were measured. Potential interactions with SARS-CoV-2 vaccination, education and sex were explored in stratified analyses and tested by including interaction terms and using likelihood ratio tests. FINDINGS: Individuals with AUD had an increased absolute and relative risk of adverse outcomes, including hospitalization [incidence rate ratio (IRR)â€‰=â€‰1.72, 95% confidence interval (CI)â€‰=â€‰1.51-1.95], intensive care (IRRâ€‰=â€‰1.47, 95% CIâ€‰=â€‰1.07-2.02) and 60-day mortality [mortality rate ratio (MRR)â€‰=â€‰2.35, 95% CIâ€‰=â€‰1.94-2.85] compared with SARS-CoV-2-positive individuals without AUD. Irrespective of AUD, highest risks of these adverse health outcomes were observed for individuals not vaccinated against SARS-CoV-2 infection, for individuals of low educational level and in males. However, for all-cause mortality throughout the follow-up period, SARS-CoV-2 infection showed a lower relative mortality risk increase, whereas being unvaccinated showed a higher relative mortality risk increase, in individuals with AUD than in the reference population without AUD (P of interaction testsâ€‰<â€‰0.0001). CONCLUSIONS: Both alcohol use disorder and being unvaccinated for SARS-CoV-2 appear to be independent risk factors for adverse health outcomes following SARS-CoV-2 infection.
A Case of Papulovesicular Skin Rash Following Vaccination against SARS-CoV-2 in A Young Adult: Gianotti-Crosti Syndrome-Like Rash.
New-onset and flares of psoriasis after COVID-19 infection or vaccination successfully treated with biologics: a case series.
Stroke four days after vaccination with a vector-based SARS-CoV-2 vaccine.
Ex Vivo Immune Responsiveness to SARS-CoV-2 Omicron BA.5.1 Following Vaccination with Unmodified mRNA-Vaccine. (1) Background: The high incidence of SARS-CoV-2 infection in vaccinated persons underscores the importance of individualized re-vaccination. PanIg antibodies that act against the S1/-receptor binding domain quantified in serum by a routine diagnostic test (ECLIA, Roche) can be used to gauge the individual ex vivo capacity of SARS-CoV-2 neutralization. However, that test is not adapted to mutations in the S1/-receptor binding domain, having accumulated in SARS-CoV-2 variants. Therefore, it might be unsuited to determine immune-reactivity

against SARS-CoV-2 BA.5.1. (2) Method: To address this concern, we re-investigated sera obtained six months after second vaccinations with un-adapted mRNA vaccine Spikevax (Moderna). We related serum levels of panIg against the S1/-receptor binding domain quantified by the un-adapted ECLIA with full virus neutralization capacity against SARS-CoV-2 B.1 or SARS-CoV-2 BA5.1. (3) Results: 92% of the sera exhibited sufficient neutralization capacity against the B.1 strain. Only 20% of the sera sufficiently inhibited the BA5.1 strain. Sera inhibiting BA5.1 could not be distinguished from non-inhibiting sera by serum levels of panIg against the S1/-receptor binding domain quantified by the un-adapted ECLIA. (4) Conclusion: Quantitative serological tests for an antibody against the S1/-receptor binding domain are unsuited as vaccination companion diagnostics, unless they are regularly adapted to mutations that have accumulated in that domain.

Durability of Immune Response after Application of a Third Dose of SARS-CoV-2 Vaccination in Liver Transplant Recipients. Immunogenicity after SARS-CoV-2 vaccination is known to be impaired in liver transplant (LT) recipients, but the results after the application of a third dose show significant improvement in seroconversion rates. In the general population, the antibody response wanes over the course of time after two doses of the vaccination, but seems to be more robust after the application of three doses. Still, the durability of the antibody response in LT recipients who receive a third dose of SARS-CoV-2 vaccination has not been analyzed yet. We therefore assessed antibody responses in a total of 300 LT recipients and observed antibody titers for six months each after patients had received the second and the third doses of the vaccination, explicitly excluding all patients who had suffered from SARS-CoV-2 infection. The initial antibody response was compared to a control group of 122 healthcare workers. After the application of two doses of the vaccination, 74% of LT recipients (158 out of 213) developed antibodies against SARS-CoV-2; this result depended significantly on whether the patients were taking the medication mycophenolate mofetil, and on the age of the patients. Antibody titers declined significantly within six months from 407 BAU/mL (IQR: 0-1865) to 105 BAU/mL (IQR: 0-145) (p â‰¤ 0.001), but increased after the application of the third vaccine dose in 92% of patients (105 out of 114), showing an antibody response (p â‰¤ 0.001). After a further six-month period, despite showing a decline from 2055 BAU/mL (IQR: 500 to >2080) to 1805 BAU/mL (IQR: 517 to >2080), the waning of antibody titers was not significant (p = 0.706), and antibody durability appeared to be more robust than that after the second dose. In conclusion, our study confirms the high efficacy of the application of a third dose of SARS-CoV-2 vaccination in LT recipients, and a reasonably sustained humoral response with superior durability in comparison to antibody kinetics after the application of the second dose of the vaccination.

ZnO-Based Electrochemical Immunosensor to Assess Vaccine-Induced Antibody-Mediated Immunity against Wild-Type and Gamma SARS-CoV-2 Strains. The evaluation of serological responses to COVID-19 is crucial for population-level surveillance, developing new vaccines, and evaluating the efficacy of different immunization programs. Research and development of point-of-care test technologies remain essential to improving immunity assessment, especially for SARS-CoV-2 variants that partially evade vaccine-induced immune responses. In this work, an impedimetric biosensor based on the immobilization of the recombinant trimeric wild-type spike protein (S protein) on zinc oxide nanorods (ZnONRs) was employed for serological evaluation. We successfully assessed its applicability using serum samples from spike-based COVID-19 vaccines: ChAdOx1-S (Oxford-AstraZeneca) and BNT162b2 (Pfizer-BioNTech). Overall, the ZnONRs/ spike-modified electrode displayed accurate results for both vaccines, showing excellent potential as a tool for assessing and monitoring seroprevalence in the population. A refined outcome of this technology was achieved when the ZnO immunosensor was functionalized with the S protein from the P.1 linage (Gamma variant). Serological responses against samples from vaccinated individuals were acquired with excellent performance. Following studies based on traditional serological tests, the ZnONRs/spike

immunosensor data reveal that ChAdOx1-S vaccinated individuals present significantly less antibody-mediated immunity against the Gamma variant than the BNT162b2 vaccine, highlighting the great potential of this point-of-care technology for evaluating vaccine-induced humoral immunity against different SARS-CoV-2 strains.
Antibody Responses Against Emerging SARS-CoV-2 Omicron Lineages After the Fourth Dose of mRNA Vaccine in Kidney Transplant Recipients.
Associated factors of burnout among Chinese vaccination staff during COVID-19 epidemic: A cross-sectional study. OBJECTIVE: During the COVID-19 epidemic, vaccination staff had three main aspects of work: routine vaccination for children and adults, COVID-19 vaccination and COVID-19 prevention and control. All these works significantly increased the workload of vaccination staff. This study aimed to investigate the prevalence and influencing factors of burnout among vaccination staff in Hangzhou, China. METHODS: A total of 501 vaccination staff from 201 community/township healthcare centers in Hangzhou were recruited using a cross-sectional survey through WeChat social platform. The Maslach Burnout Inventory-General Scale (MBI-GS) was used to assess the level of burnout. Descriptive statistics were made on the characteristics of participants. Univariate analysis using the chi-square test and multivariable analysis using binary logistic regression were conducted to determine the relative predictors of burnout. Univariate analysis and multiple linear regression were used to determine the relative predictors of exhaustive emotion, cynicism, and personal accomplishment. RESULTS: During the COVID-19 pandemic, 20.8% of the vaccination staff experienced burnout. Educational level above undergraduate education level, medium professional title, and more working time in COVID-19 vaccination work reported a higher degree of job burnout. The vaccination staff was experiencing a high degree of exhaustive emotion, cynicism, and low personal accomplishment. Professional title, working place, and working time for COVID-19 vaccination were associated with exhaustive emotion and cynicism. Professional title and participation time for COVID-19 prevention and control were associated with personal accomplishment. CONCLUSIONS: Our findings suggest that the prevalence rate of burnout is high among vaccination staff during the COVID-19 pandemic, especially with a low level of personal accomplishment. Psychological intervention for vaccination staff is urgently needed.
Antigen presentation dynamics shape the antibody response to variants like SARS-CoV-2 Omicron after multiple vaccinations with the original strain. The Omicron variant of SARS-CoV-2 is not effectively neutralized by most antibodies elicited by two doses of mRNA vaccines, but a third dose increases anti-Omicron neutralizing antibodies. We reveal mechanisms underlying this observation by combining computational modeling with data from vaccinated humans. After the first dose, limited antigen availability in germinal centers (GCs) results in a response dominated by B cells that target immunodominant epitopes that are mutated in an Omicron-like variant. After the second dose, these memory cells expand and differentiate into plasma cells that secrete antibodies that are thus ineffective for such variants. However, these pre-existing antigen-specific antibodies transport antigen efficiently to secondary GCs. They also partially mask immunodominant epitopes. Enhanced antigen availability and epitope masking in secondary GCs together result in generation of memory B cells that target subdominant epitopes that are less mutated in Omicron. The third dose expands these cells and boosts anti-variant neutralizing antibodies.
Systemic reactogenicity following homologues and heterologous prime-boost AZD1222 and BNT162b2 COVID-19 vaccination of 2862 healthcare workers compared with an unvaccinated population. During spring 2021, AZD1222 and BNT162b2 were used as prime and BNT162b2 as booster COVID-19 vaccines in Denmark. We obtained self-reported information on systemic reactogenicity day-by-day during two weeks for 2862 healthcare workers vaccinated with heterologous AZD1222Â +Â BNT162b2 or homologous BNT162b2Â +Â BNT162b2 regimens and

compared prevalences of symptoms with unvaccinated healthcare workers. We found comparable systemic reactogenicity during the first week in the two vaccine regimens and no reactogenicity during the second week. Most of the symptoms returned to a level equal to the control population four days after booster vaccination.

Human memory T cell dynamics after aluminum-adjuvanted inactivated whole-virion SARS-CoV-2 vaccination. This study evaluates the functional capacity of CD4(+) and CD8(+) terminally-differentiated effector (T(EMRA)), central memory (T(CM)), and effector memory (T(EM)) cells obtained from the volunteers vaccinated with an aluminum-adjuvanted inactivated whole-virion SARS-CoV-2 vaccine (CoronaVac). The volunteers were followed for T cell immune responses following the termination of a randomized phase III clinical trial. Seven days and four months after the second dose of the vaccine, the memory T cell subsets were collected and stimulated by autologous monocyte-derived dendritic cells (mDCs) loaded with SARS-CoV-2 spike glycoprotein S1. Compared to the placebo group, memory T cells from the vaccinated individuals significantly proliferated in response to S1-loaded mDCs. CD4(+) and CD8(+) memory T cell proliferation was detected in 86% and 78% of the vaccinated individuals, respectively. More than 73% (after a short-term) and 62% (after an intermediate-term) of the vaccinated individuals harbored T(CM) and/or T(EM) cells that responded to S1-loaded mDCs by secreting IFN-Î³. The expression of CD25, CD38, 4-1BB, PD-1, and CD107a indicated a modulation in the memory T cell subsets. Especially on day 120, PD-1 was upregulated on CD4(+) T(EMRA) and T(CM), and on CD8(+) T(EM) and T(CM) cells; accordingly, proliferation and IFN-Î³ secretion capacities tended to decline after 4Â months. In conclusion, the combination of inactivated whole-virion particles with aluminum adjuvants possesses capacities to induce functional T cell responses.

Relapse of neuromyelitis optica spectrum disorder after BNT162b2 mRNA Covid-19 vaccination.

Identification of genes related to immune enhancement caused by heterologous ChAdOx1-BNT162b2 vaccines in lymphocytes at single-cell resolution with machine learning methods. The widely used ChAdOx1 nCoV-19 (ChAd) vector and BNT162b2 (BNT) mRNA vaccines have been shown to induce robust immune responses. Recent studies demonstrated that the immune responses of people who received one dose of ChAdOx1 and one dose of BNT were better than those of people who received vaccines with two homologous ChAdOx1 or two BNT doses. However, how heterologous vaccines function has not been extensively investigated. In this study, single-cell RNA sequencing data from three classes of samples: volunteers vaccinated with heterologous ChAdOx1-BNT and volunteers vaccinated with homologous ChAd-ChAd and BNT-BNT vaccinations after 7 days were divided into three types of immune cells (3654 B, 8212 CD4(+) T, and 5608 CD8(+) T cells). To identify differences in gene expression in various cell types induced by vaccines administered through different vaccination strategies, multiple advanced feature selection methods (max-relevance and min-redundancy, Monte Carlo feature selection, least absolute shrinkage and selection operator, light gradient boosting machine, and permutation feature importance) and classification algorithms (decision tree and random forest) were integrated into a computational framework. Feature selection methods were in charge of analyzing the importance of gene features, yielding multiple gene lists. These lists were fed into incremental feature selection, incorporating decision tree and random forest, to extract essential genes, classification rules and build efficient classifiers. Highly ranked genes include PLCG2, whose differential expression is important to the B cell immune pathway and is positively correlated with immune cells, such as CD8(+) T cells, and B2M, which is associated with thymic T cell differentiation. This study gave an important contribution to the mechanistic explanation of results showing the stronger immune response of a heterologous ChAdOx1-BNT vaccination schedule than two doses of either BNT or ChAdOx1, offering a theoretical foundation for vaccine modification.

Case report: SARS-CoV-2 specific T-cells are associated with myocarditis after COVID-19 vaccination with mRNA-1273. Vaccination of SARS-CoV-2 with BNT162b2 or mRNA-1273 both have a low incidence of induction of myocarditis. Here we report on utilizing adaptive immune receptor repertoire sequencing (AIRR-Seq) as a way to assess the specificity of tissue infiltrating immune cells.

Prior SARS-CoV-2 infection enhances and reshapes spike protein-specific memory induced by vaccination. The diversity of vaccination modalities and infection history are both variables that have an impact on the immune memory of individuals vaccinated against SARS-CoV-2. To gain more accurate knowledge of how these parameters imprint on immune memory, we conducted a long-term follow-up of SARS-CoV-2 spike protein-specific immune memory in unvaccinated and vaccinated COVID-19 convalescent individuals as well as in infection-naÃ¯ve vaccinated individuals. Here, we report that individuals from the convalescent vaccinated (hybrid immunity) group have the highest concentrations of spike protein-specific antibodies at 6 months after vaccination. As compared with infection-naÃ¯ve vaccinated individuals, they also display increased frequencies of an atypical mucosa-targeted memory B cell subset. These individuals also exhibited enhanced T(H)1 polarization of their SARS-CoV-2 spike protein-specific follicular T helper cell pool. Together, our data suggest that prior SARS-CoV-2 infection increases the titers of SARS-CoV-2 spike protein-specific antibody responses elicited by subsequent vaccination and induces modifications in the composition of the spike protein-specific memory B cell pool that are compatible with enhanced functional protection at mucosal sites.

Clinical characteristics of patients with pityriasis rubra pilaris following SARS-CoV-2 vaccination.

SARS-CoV-2 vaccination status and adverse events among patients with psoriasis-Data from the German Registries PsoBest and CoronaBest.

Shoulder injury following COVID-19 vaccine administration: a case series and proposed diagnostic algorithm. BACKGROUND: Shoulder Injury Related to Vaccine Administration (SIRVA) is a preventable adverse event following incorrect vaccine administration, which can result in significant long-term morbidity. There has been a notable surge in reported cases of SIRVA as a rapid national population-based COVID-19 immunization program has been rolled out across Australia. METHODS: Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) in Victoria identified 221 suspected cases of SIRVA following the commencement of the COVID-19 vaccination program, reported between February 2021 and February 2022. This review describes the clinical features and outcomes of SIRVA in this population. Additionally, a suggested diagnostic algorithm is proposed, in order to facilitate early recognition and management of SIRVA. RESULTS: 151 cases were confirmed as SIRVA, with 49.0% having received vaccines at state vaccination centers. 75.5% were suspected incorrect administration site, with most patients experiencing shoulder pain and restricted movement within 24Â hours of vaccination, lasting on average 3Â months. CONCLUSION: Improved awareness and education regarding SIRVA is imperative in a pandemic vaccine roll-out. The development of a structured framework for evaluating and managing suspected SIRVA will aid in timely diagnosis and treatment, essential to mitigate potential long-term complications.

Pre-existing immunity to SARS-CoV-2 associates with strong T cell responses induced by inactivated COVID-19 vaccines. Individuals with a recent common cold coronavirus infection, which leads to pre-existing immunity against SARS-CoV-2, displayed a less severe course of COVID-19. However, the relationship between pre-existing immunity against SARS-CoV-2 and the inactivated-vaccine-induced immune response is still unknown. Here, 31Â healthcare workers who received standard two doses of inactivated COVID-19 vaccines (Weeks 0 and 4, respectively) were enrolled, vaccine-induced neutralization and T cell responses were detected, and the correlation between the pre-existing SARS-CoV-2-specific immunity was analyzed. We found the SARS-CoV-2-specific antibodies, pseudovirus neutralization testÂ (pVNT) titers, and spike-specific interferon gamma (IFN-Î³)

production in CD4(+) and CD8(+) T cells were significantly elevated after two doses of inactivated vaccines. Interestingly, the pVNT titers after the second dose of vaccination displayed no significant correlation with the pre-existing SARS-CoV-2-specific antibodies or B cells, nor the pre-existing spike-specific CD4(+) T cells. Notably, the spike-specific T cell response after the second dose of vaccination was positively correlated with the pre-existing receptor binding domain (RBD)-specific B cells and CD4(+) T cells, which were documented by the frequencies of RBD-binding B cells, the breadth of RBD-specific B cell epitopes, and the frequency of IFN-Î³-expressing RBD-specific CD4(+) T cells. Overall, the inactivated-vaccine-induced T cell responses, not the inactivated-vaccine-induced neutralization, closely correlated with pre-existing immunity to SARS-CoV-2. Our results provide a better understanding of inactivated-vaccine-induced immunity and help predict the immunogenicity induced by inactivated vaccines in individuals.

Impact of COVID-19 pandemic on the availability of maternal and child health products and childhood vaccines. BACKGROUND: In many low- and middle-income countries, the 2019 novel coronavirus (COVID-19) has challenged efforts to ensure access to and availability of quality maternal, newborn, and child health (MCH) services and essential MCH commodities. OBJECTIVES: This study evaluated the impact of COVID-19 pandemic on the availability of maternal and child health products and childhood vaccines at selected health facilities in Ethiopia. METHODS: We have prospectively assessed 28 maternal-child health products and 14 childhood vaccines and accessories, which are listed in the Ethiopian national essential medicines list. Data were collected from 5 hospitals located in the Jimma zone of Oromia regional state in the southwestern part of Ethiopia. We extracted data on drug availability, and order fill rates for these pharmaceutical products between May 2019 and August 2020. RESULTS: The overall mean availability of selected maternal and child health products was 43.2%. It was 52.9% (range 21.0-63.6%) prior COVID-19 and 42.6% (range 19-56.4) during COVID-19 time. The average monthly orders fill rates of hospitals for the selected products ranged from 39 to 79%. Before COVID-19 the average order fill rate was near 70% of total orders placed by the hospitals. However, immediately after the COVID-19 case notification in Ethiopia, the percentage of order filled correctly in items and quantities began decreasing. CONCLUSION: This study illustrates that the availability of key essential medicines for maternal and child health in the study area was low. The overall stock-out situation of MCH products has worsened during COVID-19 compared to pre-COVID-19 pandemic. None of the surveyed MCH products met the ideal availability benchmark of 80% in the public hospitals. To allow governments to guarantee these products are constantly available and affordable, a variety of policy frameworks and choices addressing inevitable epidemics should exist.

Re: Ipsilateral Upper-Limb Lymphedema After COVID-19 Vaccine Booster.

Elective surgery after COVID19 infection: long exclusion times may not be justified in a highly vaccinated population and milder strains of the virus.

One-Year Post-Vaccination Longitudinal Follow-Up of Quantitative SARS-CoV-2 Anti-Spike Total Antibodies in Health Care Professionals and Evaluation of Correlation with Surrogate Neutralization Test. Numerous vaccines have been generated to decrease the morbidity and mortality of COVID-19. This study aims to evaluate the immunogenicity of the heterologous boosts by BioNTech against homologous boosts by CoronaVac at three-month intervals in two health care worker (HCW) cohorts, with or without prior COVID-19, for one year post-vaccination. This is a prospective cohort study in which the humoral responses of 386 HCWs were followed-up longitudinally in six main groups according to their previous COVID-19 exposure and vaccination status. Anti-SARS-CoV-2 spike-RBD total antibody levels were measured and SARS-CoV-2 neutralization antibody (NAbs) responses against the ancestral Wuhan and the Omicron variant were evaluated comparatively using international standard serum for Wuhan and Omicron, as well as with the aid of a conversion tool.

The anti-SARS-CoV-2 spike-RBD total Ab and Nab difference between with and without prior COVID-19, three months after two-dose primary vaccination with CoronaVac, was statistically significant (p = 0.001). In the subsequent follow-ups, this difference was not observed between the groups. Those previously infected (PI) and non-previously infected (NPI) groups receiving BioNTech as the third dose had higher anti-SARS-CoV-2 spike total Ab levels (14.2-fold and 17.4-fold, respectively, p = 0.001) and Nab responses (against Wuhan and Omicron) than those receiving CoronaVac. Ab responses after booster vaccination decreased significantly in all groups at the ninth-month follow-up (p < 0.05); however, Abs were still higher in all booster received groups than that in the primary vaccination. Abs were above the protective level at the twelfth-month measurement in the entire of the second BioNTech received group as the fourth dose of vaccination. In the one-year follow-up period, the increased incidence of COVID-19 in the groups vaccinated with two or three doses of CoronaVac compared with the groups vaccinated with BioNTech as a booster suggested that continuing the heterologous CoronaVac/BioNTech vaccination, revised according to current SARS-CoV-2 variants and with at least a six-month interval booster would be an effective and safe strategy for protection against COVID-19, particularly in health care workers.

Did the mental health and well-being of young people increase after the COVID-19 vaccination campaign period? A cross-sectional multicentre study in Austria and Turkey. In 2019, the global Coronavirus (COVID-19) pandemic and associated prevention measures affected the mental health and psychological well-being of young people with and without a migratory background. The present study aimed to compare the mental health and psychological well-being of migrant and non-migrant young people before and after the COVID-19 vaccination campaign period in two countries which had different policies to deal with the pandemic. The "Psychological General Well-being" of young people and their experiences during the pandemic were investigated using an anonymous online survey during two pandemic waves before the vaccination campaign and 6Â months after its start. A majority of the 6154 participants (aged between 15 and 25Â years in all study groups) reported a decrease of mental health from the time period before the vaccination (BV) to after the vaccination (AV) campaign (bâ€‰=â€‰0.27, pâ€‰<â€‰.001). This association was higher in females (bâ€‰=â€‰0.04, pâ€‰=â€‰0.008) and in youth with financial problems (bâ€‰=â€‰0.13, pâ€‰<â€‰.001). Furthermore, this decrease was more pronounced in people â‰¤17Â years old (40% to 62%) than in those >17Â years (59% to 67%). Contrary to expectation, vulnerable groups such as the economically disadvantaged, younger, and female participants did not experience a significant easing of the pandemic's psychological burden AV. Vaccination campaigns should continue emphasizing the beneficial effects of COVID-19 vaccination on general well-being, but with an acknowledgement that the road to recovery is still a long one. Concurrently, free access to psychological treatment and financial support should be offered, especially for vulnerable groups. SUPPLEMENTARY INFORMATION: The online version contains supplementary material available at 10.1007/s12144-023-04366-x.

Lichen Planus and Lichen Planus Pigmentosus Inversus Following COVID-19 Vaccine in Dark Phototype Patients.

Prevalence of COVID-19 in Kidney Transplant Patients in Relation to Their Immune Status after Repeated Anti-SARS-CoV-2 Vaccination. The prospective study was conducted to evaluate the prevalence of COVID-19 in kidney transplant patients in relation to their immune status after three doses of the BNT162b2 (Pfizer-BioNTech) vaccine during one post-pandemic year based on the experience of one center-Hospital of Lithuanian University of Health Sciences. Thirty-three patients were invited for a follow-up visit 3 to 6 weeks after anti-SARS-CoV-2 vaccination and were obliged to report having COVID-19 during the one-year post-pandemic period. Forty-two percent of patients developed antibody response against SARS-CoV-2 after the third dose of the vaccine. The number of

COVID-19 cases during the post-pandemic period did not differ significantly between seropositive and seronegative patients. However, only seronegative patients were hospitalized due to COVID-19. The anti-SARS-CoV-2 antibody titer in seropositive patients correlated with a relative number of CD3(+) cells (R = 0.685, p = 0.029). The CD8(+)/CD38(+) ratio in this group increased 2-fold after the anti-SARS-CoV-2 vaccination. Higher antibody response to the COVID-19 vaccine was associated with better kidney function. The anti-SARS-CoV-2 antibody titer relation with the components of cellular immunity (CD3(+) cells and CD8(+)/CD38(+) ratio) shows a role of both chains during the response to the anti-SARS-CoV-2 vaccine in kidney transplant patients.
Anti-COVID-19 Vaccination, COVID-19, and Female Contraception: The Exacerbated Risks (Thromboembolism) of the Estrogen-progestin Pill.
Lymphadenopathy following COVID-19 vaccination: a wake-up call from case reports.
Recurrence of Thrombotic Thrombocytopenic Purpura After COVID-19 Vaccination: Correspondence.
Refractory Seronegative Immune-Mediated Necrotizing Myopathy After Receiving mRNA-1273 SARS-CoV-2 Vaccine: A Case Report.
The COVID-19 vaccines and menstrual disorders. OBJECTIVE: The COVID-19 vaccinationÂ has been linked to numerous reports of menstrual disorders as potential side effects. However, menstrual cycle results after vaccination were not collected throughout clinical trials. According to other research, COVID-19 vaccination and menstrual disorders have no discernible connection, and menstrual disorders are temporary. SUBJECTS AND METHODS: We asked questions about menstruation disturbances following the first and second doses of the COVID-19 vaccine in a population-based cohort of adult Saudi women to determine whether the vaccination is linked to menstrual cycle irregularities. RESULTS: According to the results, 63.9% of women experienced variations in their menstrual cycle either after the first or second dose. Such results show that COVID-19 vaccination impacts women's menstrual cycles. However, there is no need for concern because the alterations are relatively minor, and the menstrual cycle usually returns to normal within two months. Additionally, there are no obvious distinctions between the various vaccine types or body mass. CONCLUSIONS: Our findings support and explain the self-reports of menstrual cycle variations. We have discussed reasons for these problems that describe the mechanism of the relationship between them and the immune response. Such reasons will help prevent hormonal imbalances and the influence of therapies and immunizations on the reproductive system.
Menstrual cycle changes after COVID-19 vaccination or infection: not two sides of the same coin.
Corrigendum to 'To be or not to be vaccinated: The risk of MS or NMOSD relapse after COVID-19 vaccination and infection'[Multiple sclerosis and related disorders vol. 65 (2022) 104014].
The risk of miscarriage following COVID-19 vaccination: a systematic review and meta-analysis. STUDY QUESTION: What is the risk of miscarriage among pregnant women who received any of the COVID-19 vaccines? SUMMARY ANSWER: There is no evidence that COVID-19 vaccines are associated with an increased risk of miscarriage. WHAT IS KNOWN ALREADY: In response to the COVID-19 pandemic, the mass roll-out of vaccines helped to boost herd immunity and reduced hospital admissions, morbidity, and mortality. Still, many were concerned about the safety of vaccines for pregnancy, which may have limited their uptake among pregnant women and those planning a pregnancy. STUDY DESIGN, SIZE, DURATION: For this systematic review and meta-analysis, we searched MEDLINE, EMBASE, and Cochrane CENTRAL from inception until June 2022 using a combination of keywords and MeSH terms. PARTICIPANTS/MATERIALS, SETTING, METHODS: We included observational and interventional studies that enrolled pregnant women and evaluated any of the available COVID-19 vaccines compared to placebo or no vaccination. We primarily reported on miscarriage in addition to ongoing pregnancy and/or live birth. MAIN RESULTS AND THE ROLE OF CHANCE: We included data from 21 studies (5 randomized trials and 16 observational studies)

reporting on 149â€Š685 women. The pooled rate of miscarriage among women who received a COVID-19 vaccine was 9% (nâ€‰=â€‰14â€Š749/123â€Š185, 95% CI 0.05-0.14). Compared to those who received a placebo or no vaccination, women who received a COVID-19 vaccine did not have a higher risk of miscarriage (risk ratio (RR) 1.07, 95% CI 0.89-1.28, I2 35.8%) and had comparable rates for ongoing pregnancy or live birth (RR 1.00, 95% CI 0.97-1.03, I2 10.72%). LIMITATIONS, REASONS FOR CAUTION: Our analysis was limited to observational evidence with varied reporting, high heterogeneity and risk of bias across included studies, which may limit the generalizability and confidence in our findings. WIDER IMPLICATIONS OF THE FINDINGS: COVID-19 vaccines are not associated with an increase in the risk of miscarriage or reduced rates of ongoing pregnancy or live birth among women of reproductive age. The current evidence remains limited and larger population studies are needed to further evaluate the effectiveness and safety of COVID-19 vaccination in pregnancy. STUDY FUNDING/COMPETING INTEREST(S): No direct funding was provided to support this work. M.P.R. was funded by the Medical Research Council Centre for Reproductive Health Grant No: MR/N022556/1. B.H.A.W. hold a personal development award from the National Institute of Health Research in the UK. All authors declare no conflict of interest. REGISTRATION NUMBER: CRD42021289098.

Uncommon Cause of Myocarditis After COVID-19 Protein Subunit Vaccine.

Profiling Humoral Immunity After Mixing and Matching COVID-19 Vaccines Using SARS-CoV-2 Variant Protein Microarrays. In November 2022, 68% of the population received at least one dose of COVID-19 vaccines. Owing to the ongoing mutations, especially for the variants of concern (VOCs), it is important to monitor the humoral immune responses after different vaccination strategies. In this study, we developed a SARS-CoV-2 variant protein microarray that contained the spike proteins from the VOCs, e.g., alpha, beta, gamma, delta, and omicron, to quantify the binding antibody and surrogate neutralizing antibody. Plasmas were collected after two doses of matching AZD1222 (AZx2), two doses of matching mRNA-1273 (Mx2), or mixing AZD1222 and mRNA-1273 (AZ+M). The results showed a significant decrease of surrogate neutralizing antibodies against the receptor-binding domain in all VOCs in AZx2 and Mx2 but not AZ+M. A similar but minor reduction pattern of surrogate neutralizing antibodies against the extracellular domain was observed. While Mx2 exhibited a higher surrogate neutralizing level against all VOCs compared with AZx2, AZ+M showed an even higher surrogate neutralizing level in gamma and omicron compared with Mx2. It is worth noting that the binding antibody displayed a low correlation to the surrogate neutralizing antibody (R-square 0.130-0.382). This study delivers insights into humoral immunities, SARS-CoV-2 mutations, and mixing and matching vaccine strategies, which may provide a more effective vaccine strategy especially in preventing omicron.

More on Myocarditis after BNT162b2 Vaccination in Israeli Adolescents. Reply.

[Myopericarditis in adolescents after COVID-19 mRNA vaccination-A current meta-analysis].

Stigma, Post-traumatic Stress, and COVID-19 Vaccination Intent in Mongolia, India, and the United States. Background: Stigma and discrimination during the coronavirus (COVID-19) pandemic have increased precipitously worldwide. This multinational study examines how stigma, blaming groups for virus spread, concern regarding contracting the virus, resource loss, life satisfaction, and protective behaviors that help control the spread of COVID-19 are associated with post-traumatic stress and vaccine intent in Mongolia, India, and the United States. Method: 1429 people in Mongolia, India, and the United States completed measures assessing stigma during the COVID-19 pandemic, post-traumatic stress, blame, protective behaviors, and vaccine intent. Results: Mean post-traumatic stress scores in all three countries exceeded the cut-off that is commonly used to determine probable post-traumatic stress. Post-traumatic stress was associated with COVID-19 stigma experience, personal behavior change due to COVID-19 stigma, blaming groups for the spread of COVID-19, fear of COVID-

19, and resource loss. In India and the United States, personal behavior change due to COVID-19 stigma, anger at individuals spreading COVID-19, and perceived susceptibility to illness were positively associated with vaccine intent. Conclusions: Stigma is a collateral stressor during the pandemic. The findings underscore the importance of prompt action to address stigma as a deleterious consequence of the pandemic. The findings illuminate potential barriers to receiving the vaccine and provide direction for future research to address barriers.

Uptake of HPV vaccination among boys after the introduction of gender-neutral HPV vaccination in Germany before and during the COVID-19 pandemic. BACKGROUND: HPV vaccination has been recommended and reimbursed for girls in Germany since 2007. In June 2018 the German Standing Committee on Vaccination (STIKO) recommended the gender-neutral vaccination of adolescents aged 9 to 14Â years with catch-up through age 17. Objectives of this study were to describe the uptake of vaccination in boys before and during the COVID-19 pandemic. METHODS: The study used data from a proprietary electronic medical record database and a database with information on nationally dispensed vaccine doses. The monthly number of first doses of HPV vaccinations in boys and girls aged 9-17Â years in the period from 01/2018 to 12/2021 was determined. In addition, for boys the cumulative vaccination rates were calculated for initiated and completed vaccination series. RESULTS: Four months after the introduction of mandatory reimbursement for boys, the monthly numbers of first doses were comparable to that of girls. Compared to the same month in 2019, the number of first doses declined by up to 49% (girls) in 2020 and 71% (boys) in 2021. At the end of 2021, the vaccination rate for 15-year-old boys (2006 birth cohort) reached 44.4% for initiated and 26.4% for completed series. CONCLUSION: After an initial dynamic increase in HPV vaccinations in boys, the impact of COVID-19 was particularly strong in the second year of the pandemic. At the end of 2021 vaccination rates were still low. Efforts are needed to catch-up on adolescents that missed doses during the pandemic and to increase uptake.

Morphea after SARS-CoV2 vaccine.

Neutralization against SARS-CoV-2 Delta/Omicron variants and B cell response after inactivated vaccination among COVID-19 convalescents. Emerging SARS-CoV-2 variants have made COVID-19 convalescents susceptible to re-infection and have raised concern about the efficacy of inactivated vaccination in neutralization against emerging variants and antigen-specific B cell response. To this end, a study on a long-term cohort of 208 participants who have recovered from COVID-19 was conducted, and the participants were followed up at 3.3 (Visit 1), 9.2 (Visit 2), and 18.5 (Visit 3) months after SARS-CoV-2 infection. They were classified into three groups (no-vaccination (n = 54), one-dose (n = 62), and two-dose (n = 92) groups) on the basis of the administration of inactivated vaccination. The neutralizing antibody (NAb) titers against the wild-type virus continued to decrease in the no-vaccination group, but they rose significantly in the one-dose and two-dose groups, with the highest NAb titers being observed in the two-dose group at Visit 3. The NAb titers against the Delta variant for the no-vaccination, one-dose, and two-dose groups decreased by 3.3, 1.9, and 2.3 folds relative to the wild-type virus, respectively, and those against the Omicron variant decreased by 7.0, 4.0, and 3.8 folds, respectively. Similarly, the responses of SARS-CoV-2 RBD-specific B cells and memory B cells were boosted by the second vaccine dose. Results showed that the convalescents benefited from the administration of the inactivated vaccine (one or two doses), which enhanced neutralization against highly mutated SARS-CoV-2 variants and memory B cell responses. Two doses of inactivated vaccine among COVID-19 convalescents are therefore recommended for the prevention of the COVID-19 pandemic, and vaccination guidelines and policies need to be updated.

Leber Hereditary Optic Neuropathy 3 Weeks After COVID-19 Vaccination.

The emergence of mumps after the COVID-19 pandemic in Pakistan: Time to consider MMR vaccination strategies.

Waning humoral and cellular immunity after COVID-19 vaccination in patients with psoriasis treated with methotrexate and biologics: a cohort study. BACKGROUND: mRNA-based COVID-19 vaccines have short- and long-term efficacy in healthy individuals, but their efficacy in patients with psoriasis receiving immunomodulatory therapy is less studied. OBJECTIVES: To investigate long-term immunity after COVID-19 vaccination in patients with psoriasis receiving immunomodulatory therapy. METHODS: A prospective cohort study including patients (n = 123) with psoriasis receiving methotrexate (MTX) or biologics and controls (n = 226). Only mRNA-based COVID-19 vaccines administered with standard intervals between doses were investigated. Markers of immunity included SARS-CoV-2 spike glycoprotein-specific IgG and IgA, neutralizing capacity, and interferon-Î³ release from T cells stimulated with peptides of the SARS-CoV-2 spike glycoprotein. RESULTS: The proportion of IgG responders was lower 6â€…months after vaccination in patients receiving anti-tumour necrosis factor (TNF) treatment compared with controls. Anti-TNF treatment was associated with lower IgG levels (Î² = -0.82, 95% confidence interval -1.38 to -0.25; P = 0.001). The median neutralizing index was lower in the anti-TNF group [50% inhibition (interquartile range [IQR] 37-89)] compared with controls [98% inhibition (IQR 96-99)]; P < 0.001. Cellular responses were numerically lowest in the anti-TNF group. CONCLUSIONS: Treatment with anti-TNF has an impact on the immunity elicited by mRNA-based COVID-19 vaccination in patients with psoriasis, resulting in a faster waning of humoral and cellular markers of immunity; however, the clinical implications are unknown.

Novavax NVX-COV2373 triggers neutralization of Omicron sub-lineages. The SARS-CoV-2 Omicron (B.1.1.529) Variant of Concern (VOC) and its sub-lineages (including BA.2, BA.4, BA.5, BA.2.12.1) contain spike mutations that confer high level resistance to neutralizing antibodies induced by vaccination with ancestral spike or infection with previously circulating variants. The NVX-CoV2373 vaccine, a protein nanoparticle vaccine containing the ancestral spike sequence, has value in countries with constrained cold-chain requirements. Here we report neutralizing titers following two or three doses of NVX-CoV2373. We show that after two doses, Omicron sub-lineages BA.1 and BA.4/BA.5 were resistant to neutralization by 72% (21/29) and 59% (17/29) of samplesÂ respectively. However, after a third dose of NVX-CoV2373, we observed high titers against Omicron BA.1 (GMT: 1,197) and BA.4/BA.5 (GMT: 582), with responses similar in magnitude to those triggered by three doses of an mRNA vaccine. These data are of particular relevance as BA.4/BA.5 is dominating in multiple locations, and highlight the potential utility of the NVX-CoV2373 vaccine as a booster in resource-limited environments.

Development of Vitiligo After COVID-19 Vaccination.

Durable immune responses after BNT162b2 vaccination in home-dwelling old adults. OBJECTIVES: Elderly are an understudied, high-risk group vulnerable to severe COVID-19. We comprehensively analyzed the durability of humoral and cellular immune responses after BNT162b2 vaccination and SARS-CoV-2 infection in elderly and younger adults. METHODS: Home-dwelling old (nÂ =Â 100, median 86Â years) and younger adults (nÂ =Â 449, median 38Â years) were vaccinated with two doses of BNT162b2 vaccine at 3-week intervals and followed for 9-months. Vaccine-induced responses were compared to home-isolated COVID-19 patients (nÂ =Â 183, median 47Â years). Our analysis included neutralizing antibodies, spike-specific IgG, memory B-cells, IFN-Î³ and IL-2 secreting T-cells and sequencing of the T-cell receptor (TCR) repertoire. RESULTS: Spike-specific breadth and depth of the CD4(+) and CD8(+) TCR repertoires were significantly lower in the elderly after one and two vaccinations. Both vaccinations boosted IFN-Î³ and IL-2 secreting spike-specific T-cells responses, with 96Â % of the elderly and 100Â % of the younger adults responding after the second dose, although responses were not maintained at 9-months. In contrast, T-cell responses persisted up to 12-months in infected patients. Spike-specific memory B-cells were induced after the first dose in 87Â % of the younger adults compared to 38Â % of the elderly, which increased to 83Â % after the

second dose. Memory B-cells were maintained at 9-months post-vaccination in both vaccination groups. Neutralizing antibody titers were estimated to last for 1-year in younger adults but only 6-months in the older vaccinees. Interestingly, infected older patients (nÂ =Â 15, median 75Â years) had more durable neutralizing titers estimated to last 14-months, 8-months longer than the older vaccinees. CONCLUSIONS: Vaccine-induced spike-specific IgG and neutralizing antibodies were consistently lower in the older than younger vaccinees. Overall, our data provide valuable insights into the kinetics of the humoral and cellular immune response in the elderly after SARS-CoV-2 vaccination or infection, highlighting the need for two doses, which can guide future vaccine design.Clinical trials.gov; NCT04706390.

RNAdegformer: accurate prediction of mRNA degradation at nucleotide resolution with deep learning. Messenger RNA-based therapeutics have shown tremendous potential, as demonstrated by the rapid development of messenger RNA based vaccines for COVID-19. Nevertheless, distribution of mRNA vaccines worldwide has been hampered by mRNA's inherent thermal instability due to in-line hydrolysis, a chemical degradation reaction. Therefore, predicting and understanding RNA degradation is a crucial and urgent task. Here we present RNAdegformer, an effective and interpretable model architecture that excels in predicting RNA degradation. RNAdegformer processes RNA sequences with self-attention and convolutions, two deep learning techniques that have proved dominant in the fields of computer vision and natural language processing, while utilizing biophysical features of RNA. We demonstrate that RNAdegformer outperforms previous best methods at predicting degradation properties at nucleotide resolution for COVID-19 mRNA vaccines. RNAdegformer predictions also exhibit improved correlation with RNA in vitro half-life compared with previous best methods. Additionally, we showcase how direct visualization of self-attention maps assists informed decision-making. Further, our model reveals important features in determining mRNA degradation rates via leave-one-feature-out analysis.

Mucosal immune response after the booster dose of the BNT162b2 COVID-19 vaccine. BACKGROUND: To date, only a few studies reported data regarding the development of mucosal immune response after the BNT162b2-booster vaccination. METHODS: Samples of both serum and saliva of 50 healthcare workers were collected at the day of the booster dose (T3) and after two weeks (T4). Anti-S1-protein IgG and IgA antibody titres and the neutralizing antibodies against the Wuhan wild-type Receptor-Binding Domain in both serum and saliva were measured by quantitative and competitive ELISA, respectively. Data were compared with those recorded after the primary vaccination cycle (T2). Neutralizing antibodies against the variants of concern were measured in those individuals with anti-Wuhan neutralizing antibodies in their saliva. FINDINGS: After eight months from the second dose, IgG decreased in both serum (T2(GMC): 23,838.5Â ng/ml; T3(GMC): 1473.8Â ng/ml) and saliva (T2(GMC): 12.9Â ng/ml; T3(GMC): 0.3Â ng/ml). Consistently, serum IgA decreased (T2(GMC): 48.6Â ng/ml; T3(GMC): 6.4Â ng/ml); however, salivary IgA showed a different behaviour and increased (T2(GMC): 0.06Â ng/ml; T3(GMC): 0.41Â ng/ml), indicating a delayed activation of mucosal immunity. The booster elicited higher titres of both IgG and IgA when compared with the primary cycle, in both serum (IgG T4(GMC): 98,493.9Â ng/ml; IgA T4(GMC): 187.5Â ng/ml) and saliva (IgG T4(GMC): 21.9Â ng/ml; IgA T4(GMC): 0.65Â ng/ml). Moreover, the booster re-established the neutralizing activity in the serum of all individuals, not only against the Wuhan wild-type antigen (NÂ =Â 50; INH: 91.6%) but also against the variants (Delta INH: 91.3%; Delta Plus INH: 89.8%; Omicron BA.1 INH: 85.1%). By contrast, the salivary neutralizing activity was high against the Wuhan antigen in 72% of individuals (NÂ =Â 36, INH: 62.2%), but decreased against the variants, especially against the Omicron BA.1 variant (Delta NÂ =Â 27, INH: 43.1%; Delta Plus NÂ =Â 24, INH: 35.2%; Omicron BA.1Â NÂ =Â 4; INH: 4.7%). This was suggestive for a different behaviour of systemic immunity observed in serum with respect to mucosal immunity described in saliva (Wald chi-square

test, 3 df of interaction between variants and sample typeÂ =Â 308.2, pÂ <Â 0.0001). INTERPRETATION: The BNT162b2-booster vaccination elicits a strong systemic immune response but fails in activating an effective mucosal immunity against the Omicron BA.1 variant. FUNDING: This work was funded by the Department of Medicine and Surgery, University of Insubria, and supported by Fondazione Umberto Veronesi (COVID-19 Insieme per la ricerca di tutti, 2020), Italy.

Long-term durability of antibody responses after SARS-CoV-2 vaccination and influencing factors.

Comment on "Tachycardia following Pfizer-BioNTech COVID-19 vaccine".

Tachycardia following Pfizer-BioNTech COVID-19 vaccine.

Neutralizing antibody titers to Omicron six months after vaccination with BNT162b2 in Colombia. The emergence of the Omicron variant has generated concerns about the efficacy of COVID-19 vaccines. We evaluated the serum neutralizing activity of antibodies against the Omicron (lineage BA.1.1) by plaque reduction neutralizing test, as well as its correlation with age and gender, in a Colombian cohort six months after being vaccinated with BNT162b2 (Pfizer/BioNTech). Compared to all other variants analyzed, a significantly lower neutralizing activity ($p<0.001$) was observed against Omicron. Interestingly, older individuals exhibited lower titers against Omicron than those younger than 40. No statistical differences in neutralizing activity were observed according to gender. Our results showed that two doses of BNT162b2 might not provide robust protection against the Omicron variant over time. It is necessary to consider including changes in the composition of the vaccines to protect against new emerging variants of SARS-CoV-2 and campaigns to implement additional booster vaccinations.

COVID-19 Vaccine-Induced Immune Response in Oral Fluids and Serum: Correspondence.

B cell analyses after SARS-CoV-2 mRNA third vaccination reveals a hybrid immunity like antibody response. The continuous evolution of SARS-CoV-2 generated highly mutated variants able to escape natural and vaccine-induced primary immunity. The administration of a third mRNA vaccine dose induces a secondary response with increased protection. Here we investigate the longitudinal evolution of the neutralizing antibody response in four donors after three mRNA doses at single-cell level. We sorted 4100 spike protein specific memory B cells identifying 350 neutralizing antibodies. The third dose increases the antibody neutralization potency and breadth against all SARS-CoV-2 variants as observed with hybrid immunity. However, the B cell repertoire generating this response is different. The increases of neutralizing antibody responses is largely due to the expansion of B cell germlines poorly represented after two doses, and the reduction of germlines predominant after primary immunization. Our data show that different immunization regimens induce specific molecular signatures which should be considered while designing new vaccines and immunization strategies.

The BNT162b2 vaccine induces humoral and cellular immune memory to SARS-CoV-2 Wuhan strain and the Omicron variant in children 5 to 11 years of age. SARS-CoV-2 mRNA vaccines prevent severe COVID-19 by generating immune memory, comprising specific antibodies and memory B and T cells. Although children are at low risk of severe COVID-19, the spreading of highly transmissible variants has led to increasing in COVID-19 cases and hospitalizations also in the youngest, but vaccine coverage remains low. Immunogenicity to mRNA vaccines has not been extensively studied in children 5 to 11 years old. In particular, cellular immunity to the wild-type strain (Wuhan) and the cross-reactive response to the Omicron variant of concern has not been investigated. We assessed the humoral and cellular immune response to the SARS-CoV-2 BNT162b2 vaccine in 27 healthy children. We demonstrated that vaccination induced a potent humoral and cellular immune response in all vaccinees. By using spike-specific memory B cells as a measurable imprint of a previous infection, we found that 50% of the children had signs of a past, undiagnosed infection before vaccination. Children with pre-existent immune memory generated significantly increased levels of

specific antibodies, and memory T and B cells, directed against not only the wild type virus but also the omicron variant.

Optic neuritis associated with COVID-19-related vaccines.

The frequency of defective genomes in Omicron differs from that of the Alpha, Beta and Delta variants. The SARS-CoV-2 Omicron variant emerged showing higher transmissibility and possibly higher resistance to current COVID-19 vaccines than other variants dominating the global pandemic. In March 2020 we performed a study in clinical samples, where we found that a portion of genomes in the SARS-CoV-2 viral population accumulated deletions immediately before the S1/S2 cleavage site (furin-like cleavage site, PRRAR/S) of the spike gene, generating a frameshift and appearance of a premature stop codon. The main aim of this study was to determine the frequency of defective deletions in prevalent variants from the first to sixth pandemic waves in our setting and discuss whether the differences observed might support epidemiological proposals. The complete SARS-CoV-2 spike gene was deeply studied by next-generation sequencing using the MiSeq platform. More than 90 million reads were obtained from respiratory swab specimens of 78 COVID-19 patients with mild infection caused by the predominant variants circulating in the Barcelona city area during the six pandemic waves: B.1.5, B.1.1, B.1.177, Alpha, Beta, Delta, and Omicron. The frequency of defective genomes found in variants dominating the first and second waves was similar to that seen in Omicron, but differed from the frequencies seen in the Alpha, Beta and Delta variants. The changing pattern of mutations seen in the various SARS-CoV-2 variants driving the pandemic waves over time can affect viral transmission and immune escape. Here we discuss the putative biological effects of defective deletions naturally occurring before the S1/S2 cleavage site during adaption of the virus to human infection.

Alarming antibody evasion properties of rising SARS-CoV-2 BQ and XBB subvariants. The BQ and XBB subvariants of SARS-CoV-2 Omicron are now rapidly expanding, possibly due to altered antibody evasion properties deriving from their additional spike mutations. Here, we report that neutralization of BQ.1, BQ.1.1, XBB, and XBB.1 by sera from vaccinees and infected persons was markedly impaired, including sera from individuals boosted with a WA1/BA.5 bivalent mRNA vaccine. Titers against BQ and XBB subvariants were lower by 13- to 81-fold and 66- to 155-fold, respectively, far beyond what had been observed to date. Monoclonal antibodies capable of neutralizing the original Omicron variant were largely inactive against these new subvariants, and the responsible individual spike mutations were identified. These subvariants were found to have similar ACE2-binding affinities as their predecessors. Together, our findings indicate that BQ and XBB subvariants present serious threats to current COVID-19 vaccines, render inactive all authorized antibodies, and may have gained dominance in the population because of their advantage in evading antibodies.

COVID-19 vaccine induced myocarditis in young males: AÂ systematic review. BACKGROUND: Myocarditis is a rare but significant adverse event associated with COVID-19 vaccination, especially for men under 40. If the risk of myocarditis is not stratified by pertinent risk factors, it may be diluted for high-risk and inflated for low-risk groups. We sought to assess how the risk of myocarditis is reported in the literature. METHODS: In accordance with PRISMA standards, we reviewed primary publications in PubMed, Embase, Google Scholar and MedRxiv (through 3/2022) and included studies that estimated the incidence of myocarditis/pericarditis after receiving either the BNT162b2 (Pfizer), mRNA-1273 (Moderna) or Ad26COVS1 (Janssen) vaccine. The main outcome was the percentage of studies using 4, 3, 2, 1 or 0 stratifiers (i.e. sex, age, dose number and manufacturer) when reporting the highest risk of myocarditis. Secondary outcomes included the incidence of myocarditis in males after dose 1 and 2 of the BNT162b2 (Pfizer) or mRNA-1273 (Moderna) vaccine. RESULTS: The 29 included studies originated in North America, Europe, Asia, or were Worldwide. Of them, 28% (8/29) used all four stratifiers, and 45% (13/29) used 1 or 0 stratifiers. The highest incidence of myocarditis

ranged from 8.1-39 cases per 100,000 persons (or doses) in studies using four stratifiers. Six studies reported an incidence greater than 15 cases per 100,000 persons (or doses) in males aged 12-24 after dose 2 of an mRNA-based vaccine. CONCLUSIONS: Only one in four articles reporting myocarditis used four stratifiers, and men younger than 40 receiving a second dose of an mRNA vaccine are at greatest risk.

Confidence in COVID-19 vaccines moderates the association between vaccination status and mental distress. Previous research has demonstrated that becoming vaccinated with the Coronavirus vaccine may lower mental distress. However, it remains uncertain whether this relationship holds amid concerns of vaccine side effects and doubts of the vaccine's protective capabilities. We presented three studies that showed how vaccine confidence negatively influences the relationship between vaccine uptake and mental distress. Using two-way fixed effects regression models, Study 1 analyzes longitudinal survey of respondents from Los Angeles County in the US, while Study 2 uses the same analytical strategy but generalises findings by analysing longitudinal data of participants across all 50 US states. Main results of both studies show that (i) vaccination uptake is linked with reduced mental distress among individuals with high vaccine confidence (ii) vaccine uptake has no effect on mental distress among individuals with low vaccine confidence. Lastly, Study 3 applies multilevel analysis to a large-scale pseudo-panel study of 15 developed countries. Results for the third study corroborate finding (i) but not (ii) in that the multinational study finds that vaccine uptake is actually associated with higher mental distress among individuals with low vaccine confidence. In sum, our paper shows that the palliative effect of vaccination on mental health only exists when vaccine confidence is high. Results are mixed on whether vaccination affects mental distress when individual vaccine confidence is low.

A flare of systemic sclerosis potentially triggered by anti-SARS-CoV-2 mRNA vaccination.

Myopericarditis following both BNT162b2 and NVX-CoV2373. BACKGROUND: Myopericarditis is a well reported complication associated with SARS-Cov-2 (COVID-19) infection and vaccinations; particularly with mRNA vaccines (BNT162b2 and mRNA-1273), and in the young male population. The risk-to-benefit ratio in sequential vaccination dosing in young males is further clouded in the era of the omicron variant with its reported enhanced immune escape. STUDY DESIGN: A case series of two cases of post vaccination myopericarditis following the NVX-CoV2373 after also developing myopericarditis with BNT162b2. CONCLUSION: To our knowledge, we are the first to describe post vaccination myopericarditis following NVX-CoV2373 after also developing myopericarditis with BNT162b2. The similarities in presentation between the reactions of both platforms would suggest a similar pathogenesis, although the exact mechanism remains unknown. Further studies are necessary to identify these mechanisms, as well as to identify biomarkers that may identify vulnerable populations. On-going vigilance is necessary to identify those who may be at an increased risk of post-COVID vaccine myopericarditis.

COVID-19 vaccine-related psychiatric adverse events: Correspondence.

Determinants of Anti-S Immune Response at 9 Months after COVID-19 Vaccination in a Multicentric European Cohort of Healthcare Workers-ORCHESTRA Project. Background: The persistence of antibody levels after COVID-19 vaccination has public health relevance. We analyzed the determinants of quantitative serology at 9 months after vaccination in a multicenter cohort. Methods: We analyzed data on anti-SARS-CoV-2 spike antibody levels at 9 months from the first dose of vaccinated HCW from eight centers in Italy, Germany, Spain, Romania and Slovakia. Serological levels were log-transformed to account for the skewness of the distribution and normalized by dividing them by center-specific standard errors. We fitted center-specific multivariate regression models to estimate the cohort-specific relative risks (RR) of an increase of one standard deviation of log antibody level and the corresponding 95% confidence interval (CI), and combined them in

random-effects meta-analyses. Finally, we conducted a trend analysis of 1 to 7 months' serology within one cohort. Results: We included 20,216 HCW with up to two vaccine doses and showed that high antibody levels were associated with female sex (p = 0.01), age (RR = 0.87, 95% CI = 0.86-0.88 per 10-year increase), 10-day increase in time since last vaccine (RR = 0.97, 95% CI 0.97-0.98), previous infection (3.03, 95% CI = 2.92-3.13), two vaccine doses (RR = 1.22, 95% CI = 1.09-1.36), use of Spikevax (OR = 1.51, 95% CI = 1.39-1.64), Vaxzevria (OR = 0.57, 95% CI = 0.44-0.73) or heterologous vaccination (OR = 1.33, 95% CI = 1.12-1.57), compared to Comirnaty. The trend in the Bologna cohort, based on 3979 measurements, showed a decrease in mean standardized antibody level from 8.17 to 7.06 (1-7 months, p for trend 0.005). Conclusions: Our findings corroborate current knowledge on the determinants of COVID-19 vaccine-induced immunity and declining trend with time.

Immune Response to SARS-CoV-2 mRNA Vaccines in an Open-Label Multicenter Study in Participants with Relapsing Multiple Sclerosis Treated with Ofatumumab. BACKGROUND: It is unclear whether multiple sclerosis (MS) patients receiving ofatumumab mount an immune response after SARS-CoV-2 mRNA vaccination. METHODS: KYRIOS is an ongoing, multicenter, open-label, prospective clinical study on immune responses in MS patients after initial or booster SARS-CoV-2 mRNA vaccination prior to (cohort 1) or during (cohort 2) ofatumumab treatment. We report one-week and one-month results of the initial vaccination. A comparison with patients vaccinated while receiving beta-interferon, glatiramer acetate, dimethyl fumarate, teriflunomide or no treatment was included (cohort 3). RESULTS: In total, 11 patients received their initial vaccination during the study. The primary endpoint of SARS-CoV-2-specific T-cells at month 1 was reached by 80.0% of patients in cohort 1 (N = 6) and 100.0% in cohort 2 (N = 5). T-cell reactivity peaked at week 1. All cohort 1 patients reached seroconversion for SARS-CoV-2 neutralizing antibodies at week 1 and month 1. In cohort 2, neutralizing antibodies increased in all patients and exceeded the cut-off for seropositivity in 40.0% of patients at week 1 and 25.0% at month 1. Immune responses in cohort 3 were comparable to cohort 1. CONCLUSION: Presence of T-cell response and increase in levels of neutralizing antibodies, although less pronounced compared to controls, suggest that MS patients receiving ofatumumab are able to mount an immune response to SARS-CoV-2 mRNA vaccination.

Association between Î³-Glutamyl Transpeptidase and SARS-CoV-2 Spike Antibody Titers among BNT162b2 Vaccine Recipients. BACKGROUND: Increased Î³-glutamyl transpeptidase (GGT) levels can deplete plasma glutathione, which in turn impairs immune regulation; however, evidence on GGT levels and post-vaccine immunogenicity is lacking. OBJECTIVE: To examine the association between GGT and SARS-CoV-2 spike IgG antibodies. METHODS: Participants were 1479 medical staff (aged 21 to 75 years) who received a SARS-CoV-2 antibody test after their second vaccine and whose GGT levels were measured before the vaccine rollout. Elevated and highly elevated GGT levels were defined as 51-80 and â‰¥81 U/L, respectively. Multivariable linear regression was used to calculate the means of SARS-CoV-2 spike IgG. RESULTS: In a basic model, both elevated and highly elevated GGT levels were associated with significantly lower antibody titers. The ratio of mean (95% CI) was 0.83 (0.72-0.97) and 0.69 (0.57-0.84) for elevated and highly elevated GGT levels, respectively. However, these associations were largely attenuated after additional adjustment for potential confounders. An inverse association between GGT levels and antibody titers was found in women [0.70 (0.51-0.97)], normal-weight adults [0.71 (0.51-0.98)], and non-drinkers [0.73 (0.46-1.14)] but not in men, overweight adults, and alcohol drinkers. CONCLUSIONS: Circulating GGT concentrations were associated with the humoral immune response after COVID-19 vaccination, but this relationship could be ascribed to confounders such as sex, BMI, and alcohol drinking rather than GGT per se.

Impact of anti-PEG antibodies induced by SARS-CoV-2 mRNA vaccines. The successful mRNA vaccines against COVID-19 contain polyethylene glycol (PEG) to stabilize the lipid nanoparticles. Recent data show that PEG-specific antibodies can be induced or boosted by mRNA vaccination.

Further research is needed to study theÂ potential links between PEG-specific antibodies, vaccine reactogenicity and enhanced clearance of other PEG-containing medicines.
Lymphadenopathy After COVID-19 Vaccine Mimicking Lymph-Node Progression in a Patient With Metastatic Melanoma.
Comparing hybrid and regular COVID-19 vaccine-induced immunity against the Omicron epidemic. Evidence on the effectiveness of COVID-19 vaccines among people who recovered from a previous SARS-CoV-2 infection is warranted to inform vaccination recommendations. Using the territory-wide public healthcare and vaccination records of over 2.5 million individuals in Hong Kong, we examined the potentially differential risk of SARS-CoV-2 infection, hospitalization, and mortality between those receiving two homologous doses of BNT162b2 or CoronaVac versus those with a previous infection receiving only one dose amid the Omicron epidemic. Results show a single dose after a SARS-CoV-2 infection is associated with a lower risk of infection (BNT162b2: adjusted incidence rate ratio [IRR]â€‰=â€‰0.475, 95% CI: 0.410-0.550; CoronaVac: adjusted IRRâ€‰=â€‰0.397, 95% CI: 0.309-0.511) and no significant difference was detected in the risk of COVID-19-related hospitalization or mortality compared with a two-dose vaccination regimen. Findings support clinical recommendations that those with a previous infection could receive a single dose to gain at least similar protection as those who received two doses without a previous infection.
Humoral Responses in the Omicron Era Following 3-Dose SARS-CoV-2 Vaccine Series in Kidney Transplant Recipients. Kidney transplant recipients (KTRs) have a diminished response to SARS-CoV-2 vaccination compared with immunocompetent individuals. Deeper understanding of antibody responses in KTRs following third-dose vaccination would enable identification of those who remain unprotected against Omicron. METHODS: We profiled antibody responses in KTRs pre- and at 1 and 3 mo post-third-dose SARS-CoV-2 mRNA-based vaccine. Binding antibody levels were determined by ELISA. Neutralization against wild type, Beta, Delta, and Omicron (BA.1) variants was determined using a SARS-CoV-2 spike-pseudotyped lentivirus assay. RESULTS: Forty-four KTRs were analyzed at 1 and 3 mo (nâ€‰=â€‰26) post-third dose. At 1 mo, the proportion of participants with a robust antibody response had increased significantly from baseline, but Omicron-specific neutralizing antibodies were detected in just 45% of KTRs. Median binding antibody levels declined at 3 mo, but the proportion of KTRs with a robust antibody response was unchanged; 38.5% KTRs maintained Omicron-specific neutralization at 3 mo. No clinical variables were significantly associated with Omicron-neutralizing antibodies, but antireceptor binding domain titers appeared to identify those with Omicron-specific neutralizing capacity. CONCLUSIONS: Over 50% of KTRs lack Omicron-specific neutralization capacity 1 mo post-third mRNA-vaccine dose. Antibody levels of responders were well preserved at 3 mo. Anti receptor binding domain antibody titers may identify patients with a detectable Omicron-neutralizing antibody response.
Menstrual disturbances in 12- to 15-year-old girls after one dose of COVID-19 Comirnaty vaccine: Population-based cohort study in Norway.
Oral mucous membrane pemphigoid after SARS-CoV-2 vaccination.
CD4 and IL-2 mediated NK cell responses after COVID-19 infection and mRNA vaccination in adults. A detailed understanding of protective immunity against SARS-CoV-2 is incredibly important in fighting the pandemic. Central to protective immunity is the ability of the immune system to recall previous exposures. Although antibody and T cell immunity have gained considerable attention, the contribution of the NK cell compartment to immune recall and protection from SARS-CoV-2 has not been explored. In this study, we investigate the NK cell responses to stimulation with SARS-CoV-2 in previously exposed and non-exposed individuals. We show that NK cells demonstrate an enhanced CD4+ T cell dependent response when re-exposed to SARS-CoV-2 antigen. The enhanced response is dependent on T cells and correlates with the number of SARS-CoV-2 specific CD4 T cells. We find that

IL-2 is a critical mediator of NK cell function. These findings suggest that NK cells contribute to the protective responses against SARS-CoV-2 through a cooperation with antigen-specific CD4 T cells and have significant implications on our understanding of protective immunity in SARS-CoV-2.

Myocarditis and pericarditis associated with SARS-CoV-2 vaccines: A population-based descriptive cohort and a nested self-controlled risk interval study using electronic health care data from four European countries. Background: Estimates of the association between COVID-19 vaccines and myo-/pericarditis risk vary widely across studies due to scarcity of events, especially in age- and sex-stratified analyses. Methods: Population-based cohort study with nested self-controlled risk interval (SCRI) using healthcare data from five European databases. Individuals were followed from 01/01/2020 until end of data availability (31/12/2021 latest). Outcome was first myo-/pericarditis diagnosis. Exposures were first and second dose of Pfizer, AstraZeneca, Moderna, and Janssen COVID-19 vaccines. Baseline incidence rates (IRs), and vaccine- and dose-specific IRs and rate differences were calculated from the cohort The SCRI calculated calendar time-adjusted IR ratios (IRR), using a 60-day pre-vaccination control period and dose-specific 28-day risk windows. IRRs were pooled using random effects meta-analysis. Findings: Over 35 million individuals (49Â·2% women, median age 39-49Â years) were included, of which 57Â·4% received at least one COVID-19 vaccine dose. Baseline incidence of myocarditis was low. Myocarditis IRRs were elevated after vaccination in those aged < 30Â years, after both Pfizer vaccine doses (IRR = 3Â·3, 95%CI 1Â·2-9.4; 7Â·8, 95%CI 2Â·6-23Â·5, respectively) and Moderna vaccine dose 2 (IRR = 6Â·1, 95%CI 1Â·1-33Â·5). An effect of AstraZeneca vaccine dose 2 could not be excluded (IRR = 2Â·42, 95%CI 0Â·96-6Â·07). Pericarditis was not associated with vaccination. Interpretation: mRNA-based COVID-19 vaccines and potentially AstraZeneca are associated with increased myocarditis risk in younger individuals, although absolute incidence remains low. More data on children (â‰¤ 11Â years) are needed.

Evaluation of antibody response to SARS-CoV-2 variants after 2 doses of mRNA COVID-19 vaccine in a correctional facility. The SARS-CoV-2 pandemic has posed a challenge for correctional facilities worldwide. People in such settings are more vulnerable to severe forms of infection and it is impossible to completely isolate inmates from the outside world. This study aimed to assess the antibody-mediated immune response in terms of neutralizing antibodies against Alpha, Beta, Gamma and Omicron (sub-lineage BA.1) variants of concern after two doses of mRNA vaccine in correctional officers and inmates from an Italian correctional facility. Most of the correctional officers (56.5%) and inmates (52.3% and 63.6%) retained their neutralizing activity toward the Alpha and Gamma variants, respectively. By contrast, the most striking reduction in comparison with the ancestral virus was found in the antibody response toward the Beta and Omicron variants, in both correctional officers (91.2% and 93.9%) and inmates (85.1% and 92.8%). In addition, subjects who had undergone primary vaccination and had previously been naturally infected had higher neutralizing antibody titers toward the 4 variants than negative subjects. Overall, our findings indicate that primary mRNA vaccination is able to induce neutralizing antibodies toward the ancestral virus, while titers toward variants may vary, depending on the mutations harboring by the variants. Although the correctional setting is often considered distinct or isolated from the wider society and sanitary system, the health of correctional workers and prisoners is inexorably linked to the public health of the country as a whole and it is of paramount importance to monitor the antibody response in these settings.

Association between COVID-19 Burden, Population Vaccination Status, and Urologic Oncology Surgery Volume: A National Multicenter Cross-Sectional Study. Initial deleterious effects of the COVID-19 pandemic on urologic oncology surgeries are well described, but the possible influence of vaccination efforts and those of pandemic conditions on surgical volumes is unclear. Our aim was to examine the association between changing vaccination status and COVID-19 burden throughout the pandemic and the volume of urologic oncology surgeries in Israel. This multi-center cross-sectional

study included data collected from five tertiary centers between January 2019 and December 2021. All 7327 urologic oncology surgeries were included. Epidemiological data were obtained from the Israeli Ministry of Health database. A rising trend in total urologic oncology surgery volumes was observed with ensuing COVID-19 wave peaks over time ($X2 = 13.184$, $df = 3$, $p = 0.004$). Total monthly surgical volumes correlated with total monthly hospitalizations due to COVID-19 ($R = -0.36$, $p = 0.015$), as well as with the monthly average Oxford Stringency Index ($R = -0.31$, $p = 0.035$). The cumulative percent of vaccinations and of new COVID-19 cases per month did not correlate with total monthly urologic surgery volumes. Our study demonstrates the gradual acclimation of the Israeli healthcare system to the COVID-19 pandemic. However, hospitalizations due to COVID-19, as well as restriction stringency, correlate with lower volumes of urologic oncological surgeries, regardless of the population's vaccination status.

Low Spike Antibody Levels and Impaired BA.4/5 Neutralization in Patients with Multiple Myeloma or Waldenstrom's Macroglobulinemia after BNT162b2 Booster Vaccination. Patients with symptomatic monoclonal gammopathies have impaired humoral responses to COVID-19 vaccination. Their ability to recognize SARS-CoV-2 Omicron variants is of concern. We compared the response to BNT162b2 mRNA vaccinations of patients with multiple myeloma (MM, n = 60) or Waldenstrom's macroglobulinemia (WM, n = 20) with healthy vaccine recipients (n = 37). Patient cohorts on active therapy affecting B cell development had impaired binding and neutralizing antibody (NAb) response rate and magnitude, including several patients lacking responses, even after a 3rd vaccine dose, whereas non-B cell depleting therapies had a lesser effect. In contrast, MM and WM cohorts off-therapy showed increased NAb with a broad response range. ELISA Spike-Receptor Binding Domain (RBD) Ab titers in healthy vaccine recipients and patient cohorts were good predictors of the ability to neutralize not only the original WA1 but also the most divergent Omicron variants BA.4/5. Compared to WA1, significantly lower NAb responses to BA.4/5 were found in all patient cohorts on-therapy. In contrast, the MM and WM cohorts off-therapy showed a higher probability to neutralize BA.4/5 after the 3rd vaccination. Overall, the boost in NAb after the 3rd dose suggests that repeat vaccination of MM and WM patients is beneficial even under active therapy.

Study of thyroid function among COVID-19-affected and non-affected people during pre and post-vaccination. The novel coronavirus COVID-19 has caused a global pandemic with many long-ranging effects on the physiological balance of the human body. The impact of COVID-19 on the thyroid axis remains uncertain. Our aim was to assess the long-term consequences of COVID-19 infection and its vaccination with thyroid hormones. Thirty laboratory-confirmed COVID-19-positive patients with no vaccination record, thirty COVID-19-negative patients with vaccination records, and ten healthy subjects were retrospectively, and cross-sectionally enrolled in this study. An ELISA assay was performed to evaluate thyroid function tests, including the total triiodothyronine (TT3), total thyroxine (TT4), and thyroid stimulating hormone (TSH). We found decreased levels of TT3, average or low plasma T4 levels, and standard or slightly decreased TSH levels in unvaccinated COVID-19-positive patients than in the healthy group, while the vaccinated COVID-19-negative group had normal thyroid hormone levels compared to controls. The correlation between TT3 and TSH levels gradually shifted from no association to a negative pattern in the unvaccinated COVID-19-positive group. Again, a highly significant negative correlation between TSH and TT3 was observed on days above 150, although a slight fluctuation was noted on day 90. This pilot study from Bangladesh shows that abnormalities in thyroid function can be observed during COVID-19 infection and after vaccination, which gradually recovers over time.

Delayed skin reactions and mRNA vaccines against SARS-CoV-2: correspondence.

The role of antigen availability during B cell induction and its effect on sustained memory and antibody production after infection and vaccination-lessons learned from the SARS-CoV-2 pandemic.

The importance of antibodies, particularly neutralizing antibodies, has been known for decades. When examining the immune responses against a pathogen after a vaccination or infection it is easier to measure the levels of antigen-specific antibodies than the T-cell response, but it does not give the whole picture. The levels of neutralizing antibodies are harder to determine but give a better indication of the quality of the antibody response. The induction of long-lived antibody-secreting plasma cells is crucial for a persistent humoral immune response, which has been shown for example after vaccination with the vaccinia vaccine, where antibody levels have been shown to persist for decades. With the SARS-CoV-2 pandemic ravaging the world for the past years and the monumental effort in designing and releasing novel vaccines against the virus, much effort has been put into analysing the quantity, quality, and persistence of antibody responses.

Antibody feedback regulates immune memory after SARS-CoV-2 mRNA vaccination. Feedback inhibition of humoral immunity by antibodies was first documented in 1909(1). Subsequent studies showed that, depending on the context, antibodies can enhance or inhibit immune responses(2,3). However, little is known about how pre-existing antibodies influence the development of memory B cells. Here we examined the memory B cell response in individuals who received two high-affinity anti-SARS-CoV-2 monoclonal antibodies and subsequently two doses of an mRNA vaccine(4-8). We found that the recipients of the monoclonal antibodies produced antigen-binding and neutralizing titres that were only fractionally lower compared than in control individuals. However, the memory B cells of the individuals who received the monoclonal antibodies differed from those of control individuals in that they predominantly expressed low-affinity IgM antibodies that carried small numbers of somatic mutations and showed altered receptor binding domain (RBD) target specificity, consistent with epitope masking. Moreover, only 1 out of 77 anti-RBD memory antibodies tested neutralized the virus. The mechanism underlying these findings was examined in experiments in mice that showed that germinal centres formed in the presence of the same antibodies were dominated by low-affinity B cells. Our results indicate that pre-existing high-affinity antibodies bias germinal centre and memory B cell selection through two distinct mechanisms: (1) by lowering the activation threshold for B cells, thereby permitting abundant lower-affinity clones to participate in the immune response; and (2) through direct masking of their cognate epitopes. This may in part explain the shifting target profile of memory antibodies elicited by booster vaccinations(9).

Coincidental or causal? A case report of acquired thrombotic thrombocytopenic purpura following mRNA-1273 Covid-19 vaccination.

Paxlovid Associated with Decreased Hospitalization Rate Among Adults with COVID-19 - United States, April-September 2022. Nirmatrelvir-ritonavir (Paxlovid), an oral antiviral treatment, is authorized for adults with mild-to-moderate COVID-19 who are at increased risk for progression to severe illness. However, real-world evidence on the benefit of Paxlovid, according to vaccination status, age group, and underlying health conditions, is limited. To examine the benefit of Paxlovid in adults aged â‰¥18 years in the United States, a large electronic health record (EHR) data set (Cosmos(â€)) was analyzed to assess the association between receiving a prescription for Paxlovid and hospitalization with a COVID-19 diagnosis in the ensuing 30 days. A Cox proportional hazards model was used to estimate this association, adjusted for demographic characteristics, geographic location, vaccination, previous infection, and number of underlying health conditions. Among 699,848 adults aged â‰¥18 years eligible for Paxlovid during April-August 2022, 28.4% received a Paxlovid prescription within 5 days of COVID-19 diagnosis. Being prescribed Paxlovid was associated with a lower hospitalization rate among the overall study population (adjusted hazard ratio [aHR]Â =Â 0.49), among those who had received â‰¥3 mRNA COVID-19 vaccines (aHRÂ =Â 0.50), and across age groups (18-49 years: aHRÂ =Â 0.59; 50-64 years: aHRÂ =Â 0.40; and â‰¥65 years: aHRÂ =Â 0.53).

Paxlovid should be prescribed to eligible adults to reduce the risk of COVID-19-associated hospitalization.
Waning of specific antibodies against Delta and Omicron variants five months after a third dose of BNT162b2 SARS-CoV-2 vaccine in elderly individuals. The emergence of new SARS-CoV-2 variants, such as the more transmissible Delta and Omicron variants, has raised concerns on efficacy of the COVID-19 vaccines. Here, we examined the waning of antibody responses against different variants following primary and booster vaccination. We found that antibody responses against variants were low following primary vaccination. The antibody response against Omicron was almost non-existent. Efficient boosting of antibody response against all variants, including Omicron, was observed following a third dose. The antibody response against the variants tested was significantly higher at one month following booster vaccination, compared with two months following primary vaccination, for all individuals, including the low antibody responders identified at two months following primary vaccination. The antibody response, for all variants tested, was significantly higher at four months post booster than at five months post primary vaccination, and the proportion of low responders remained low (6-11%). However, there was significant waning of antibody response in more than 95% of individuals at four months, compared to one month following booster. We also observed a robust memory B cell response following booster, which remained higher at four months post booster than prior to booster. However, the memory B cell responses were on the decline for 50% of individuals at four months following booster. Similarly, while the T cell response is sustained, at cohort level, at four months post booster, a substantial proportion of individuals (18.8 - 53.8%) exhibited T cell response at four months post booster that has waned to levels below their corresponding levels before booster. The findings show an efficient induction of immune response against SARS-CoV-2 variants following booster vaccination. However, the induced immunity by the third BNT162b2 vaccine dose was transient. The findings suggest that elderly individuals may require a fourth dose to provide protection against SARS-CoV-2.
Spirituality is associated with Covid-19 vaccination scepticism. Vaccine scepticism poses a significant global health risk, which has again become clear during the ongoing Covid-19 pandemic. Previous research has identified spirituality as an important contributor to general vaccine scepticism. In the present manuscript, we assessed whether self-identified spirituality similarly contributes to scepticism towards Covid-19 vaccines, vaccine uptake, and indecisiveness in intention to be vaccinated. We conducted three studies online in the UK in late 2020, early 2021, and the summer 2021. In Studies 1 and 2 (NÂ =Â 585), as expected, individuals who strongly identified as spiritual were more sceptical about Covid-19 vaccines. This association was explained by low faith in science, but not by conspiracy beliefs. Importantly, among the vaccinated participants, those who were more spiritual were more indecisive to get a Covid-19 vaccine. Using structural equation modelling (SEM), we further found that spirituality directly predicted lower likelihood of being vaccinated against Covid-19 (Study 3, NÂ =Â 456). We also identified low science literacy as an additional predictor of Covid-19 scepticism, but not self-reported vaccine uptake. To conclude, spiritual beliefs are an important factor to consider when aiming to increase understanding of vaccine-related science scepticism and vaccination rejection.
New-Onset Myasthenic Crisis with Prodromal Elevation of Troponin-T after AstraZeneca COVID-19 Vaccination.
SARS-CoV-2 vaccinations can trigger polyradiculitis.
6-month antibody kinetics and durability after four doses of a SARS-CoV-2 vaccine in solid organ transplant recipients.
Early CD4(+) T cell responses induced by the BNT162b2 SARS-CoV-2 mRNA vaccine predict immunological memory. Longitudinal studies have revealed large interindividual differences in

antibody responses induced by SARS-CoV-2 mRNA vaccines. Thus, we performed a comprehensive analysis of adaptive immune responses induced by three doses of the BNT162b2 SARS-CoV-2 mRNA vaccines. The responses of spike-specific CD4(+) T cells, CD8(+) T cells and serum IgG, and the serum neutralization capacities induced by the two vaccines declined 6Â months later. The 3(rd) dose increased serum spike IgG and neutralizing capacities against the wild-type and Omicron spikes to higher levels than the 2(nd) dose, and this was supported by memory B cell responses, which gradually increased after the 2(nd) dose and were further enhanced by the 3(rd) dose. The 3(rd) dose moderately increased the frequencies of spike-specific CD4(+) T cells, but the frequencies of spike-specific CD8(+) T cells remained unchanged. T cells reactive against the Omicron spike were 1.3-fold fewer than those against the wild-type spike. The early responsiveness of spike-specific CD4(+) T, circulating T follicular helper cells and circulating T peripheral helper cells correlated with memory B cell responses to the booster vaccination, and early spike-specific CD4(+) T cell responses were also associated with spike-specific CD8(+) T cell responses. These findings highlight the importance of evaluating cellular responses to optimize future vaccine strategies.

Delayed onset urticaria and symptomatic dermographism following COVID-19 booster vaccination: A case series.

Ophthalmologic compromise following SARS-CoV-2 vaccinations.

Saliva and Plasma Neutralizing Activity Induced by the Administration of a Third bnt162b2 Vaccine Dose. The BNT162b2 vaccine induces neutralizing activity (NA) in serum, but no data are available on whether a third-dose activates specific-immunity within the oral mucosa, representing the primary route of viral-entry. To carefully address this issue, we investigated if such immunity is boosted by SARS-CoV-2-infection; how long it is maintained over-time; and if it protects against the SARS-CoV-2 lineage B.1 (EU) and the emerging Delta and Omicron variants. NA was measured in plasma and saliva samples from: uninfected SARS-CoV-2-Vaccinated (SV), subjects infected prior to vaccination (SIV), and subjects who were infected after the second (SIV2) or the third (SIV3) vaccine dose. Samples were collected immediately before (T0), 15 days (T1), and 90 days (T2) post third-dose administration (SV and SIV), or 15 days post-infection (SIV2 and SIV3). In all the enrolled groups, NA in plasma and saliva: (i) was higher against EU compared to the other variants at all time-points (SV: T0 and T1, EU vs. both Delta and Omicron $p < 0.001$; T2 $p < 0.01$) (SIV: T0, EU vs. Delta $p < 0.05$; EU vs. Omi $p < 0.01$; T1 and T2 EU vs. Delta $p < 0.01$; EU vs. Omi $p < 0.001$); (ii) was boosted by the administration of the third dose; iii) declined over-time, albeit being detectable in almost all subjects at T2. The monitoring of NA over time will be important in clarifying if different NA levels may influence either acquisition or course of infection to properly plan the timing of a fourth vaccine dose administration.

Imaging characteristics of myocarditis after mRNA-based COVID-19 vaccination: a meta-analysis.

Titers and breadth of neutralizing antibodies against SARS-CoV-2 variants after heterologous booster vaccination in health care workers primed with two doses of ChAdOx1 nCov-19: A single-blinded, randomized clinical trial. OBJECTIVES: We conducted a single-blinded, randomized trial to evaluate the safety, reactogenicity, and immunogenicity of heterologous booster vaccination in health care workers (HCW) who had received two doses of ChAdOx1 nCov-19. METHODS: HCW who had at least 90 days after the second dose were enrolled to receive one of the four vaccines: BNT162b2 (30 Î¼g), half-dose mRNA-1273 (50 Î¼g), mRNA-1273 (100 Î¼g), and MVC-COV1901 (15 Î¼g). The primary outcomes were humoral and cellular immunogenicity and secondary outcomes assessed safety and reactogenicity at 28 days post-booster. RESULTS: MVC-COV1901 Three hundred and forty HCW were enrolled: 83 received BNT162b2 (2 excluded), 85 half-dose mRNA-1273, 85 mRNA-1273, and 85 MVC-COV1901. mRNA vaccines had more reactogenicity than protein vaccine. The fold-rise of anti-spike IgG geometric mean titer was 8.4 (95% CI 6.8-10.4) for MVC-COV1901, 32.2

(27.2-38.1) for BNT162b2, 47.6 (40.8-55.6) for half-dose mRNA-1273 and 63.2 (53.6-74.6) for mRNA-1273. The live virus microneutralization assays (LVMNA) against the wild type, alpha and delta variants were consistent with anti-spike IgG for all booster vaccines. The LVMNA in the four groups against omicron BA.1 variant were 6.4 to 13.5 times lower than those against the wild type. All booster vaccines induced a comparable T cell response. CONCLUSIONS: Third dose booster not only increases neutralizing antibody titer but also enhances antibody breadth against SARS-CoV-2 variants. mRNA vaccines are preferred booster vaccines for those who received primary series of ChAdOx1 nCov-19.

Vaccine-Induced Psychosis as an Etiology to Consider in the Age of COVID-19.

Psychiatric symptoms before and after COVID-19 vaccination: A cohort study of hospitalized schizophrenia patients. This study aimed to examine the impact of COVID-19 vaccination on the psychiatric symptoms of hospitalized schizophrenia patients and to evaluate the association between the severity of psychiatric symptoms and the COVID-19 vaccination decision. We assessed the psychiatric symptoms of 330 hospitalized schizophrenia patients who accepted the vaccine and 114 patients who declined the vaccine option with PANSS before and after vaccination. We showed that the unwillingness to receive the vaccine is correlated with a higher level of psychiatric symptoms. COVID-19 vaccination is associated with slight deterioration of the schizophrenia symptoms of elderly hospitalized patients.

Occupation, Worker Vulnerability, and COVID-19 Vaccination Uptake: Analysis of the Virus Watch prospective cohort study. BACKGROUND: Occupational disparities in COVID-19 vaccine uptake can impact the effectiveness of vaccination programmes and introduce particular risk for vulnerable workers and those with high workplace exposure. This study aimed to investigate COVID-19 vaccine uptake by occupation, including for vulnerable groups and by occupational exposure status. METHODS: We used data from employed or self-employed adults who provided occupational information as part of the Virus Watch prospective cohort study (nÂ =Â 19,595) and linked this to study-obtained information about vulnerability-relevant characteristics (age, medical conditions, obesity status) and work-related COVID-19 exposure based on the Job Exposure Matrix. Participant vaccination status for the first, second, and third dose of any COVID-19 vaccine was obtained based on linkage to national records and study records. We calculated proportions and Sison-Glaz multinomial 95% confidence intervals for vaccine uptake by occupation overall, by vulnerability-relevant characteristics, and by job exposure. FINDINGS: Vaccination uptake across occupations ranged from 89-96% for the first dose, 87-94% for the second dose, and 75-86% for the third dose, with transport, trade, service and sales workers persistently demonstrating the lowest uptake. Vulnerable workers tended to demonstrate fewer between-occupational differences in uptake than non-vulnerable workers, although clinically vulnerable transport workers (76%-89% across doses) had lower uptake than several other occupational groups (maximum across doses 86%-96%). Workers with low SARS-CoV-2 exposure risk had higher vaccine uptake (86%-96% across doses) than those with elevated or high risk (81-94% across doses). INTERPRETATION: Differential vaccination uptake by occupation, particularly amongst vulnerable and highly-exposed workers, is likely to worsen occupational and related socioeconomic inequalities in infection outcomes. Further investigation into occupational and non-occupational factors influencing differential uptake is required to inform relevant interventions for future COVID-19 booster rollouts and similar vaccination programmes.

Slower Waning of Anti-SARS-CoV-2 IgG Levels Six Months after the Booster Dose Compared to Primary Vaccination. Anti-SARS-CoV-2 IgG titer decreases rapidly after primovaccination, leading to a mandatory booster vaccination. We analysed anti-SARS-CoV-2 Spike RBD IgG levels (positive â‰¥ 50 AU/mL) in 405 healthcare workers (3010 sera) who received a booster dose (BD) 9 months after two-dose BNT162b2 primovaccination. Median antibody titer at the time of BD (582.6 AU/mL)

was 1.7-fold and 16.4-fold lower than the peak titer after the first (961.5 AU/mL) and the second vaccine dose (SVD) (10,232.6 AU/mL), respectively. One month after vaccination, IgG titer increased 40.6-fold after BD compared with a 10.8-fold increase after primovaccination. Three months after vaccination, post-booster antibodies decreased significantly slower (2.2-fold) than after primovaccination (3.3-fold). At six months, antibodies decreased slower after BD (4.5-fold; median 5556.0 AU/mL) than after primovaccination (9.6-fold; median 1038.5 AU/mL). Antibody titers before and one month after BD correlated weakly (r = 0.30) compared with a strong correlation (r = 0.65) between the corresponding post-primovaccination titers. Pre-vaccination COVID-19 had no effect on IgG levels after BD compared with a positive effect after primovaccination. Despite high post-booster IgG levels, 22.5% of participants contracted mild COVID-19. The trend of IgG decline indicates the need for further revaccination, but the vaccine type should be defined according to viral mutations.

Differential Kinetics of Effector and Memory Responses Induced by Three Doses of SARS-CoV-2 mRNA Vaccine in a Cohort of Healthcare Workers. We reported the long-term kinetics of immune response after vaccination and evaluated the immunogenicity after a third dose of mRNA vaccine in 86 healthcare workers. Humoral response was analyzed by measuring anti-spike IgG and SARS-CoV-2 NTAbs titer; cell-mediated response was measured as frequency of IFN-Î³ producing T-cells and cell proliferation. Memory B cells secreting SARS-CoV-2 RBD-IgG were measured by B-spot assay. At three weeks after the third dose (T4), the frequency of subjects showing NT-Abs titer at the upper detection limit (â‰¥640) was significantly higher than that observed at three weeks after the second dose (26/77; 33.7% vs. 9/77; 11.6%; p = 0.0018). Additionally, at T4, all the subjects reached positive levels of T-cell mediated response (median 110 SFU/10(6) PBMC, IQR 73-231). While the number of IFNÎ³-producing T-cells decreased between second and third dose administration, the T-cell proliferative response did not decrease but was sustained during the follow-up. Among T-cell subsets, a higher proliferative response was observed in CD4+ than in CD8+ population. Moreover, even if a decline in antibody response was observed between the second and third dose, a sustained persistence of memory B cells was observed. Subsequently, the third dose did not affect the frequency of memory B cells, while it restored or increased the peak antibody levels detected after the second dose.

Remarks on Myocarditis Associated with COVID-19 Infection and Myocarditis Following mRNA COVID-19 Vaccination. COVID-19 virus infection is responsible for one of the worst reported pandemics as of August 2022 [...].

Seroconversion after Inactive SARS-CoV-2 Vaccination and Obesity: Correspondence.

The vaccination rift effect provides evidence that source vaccination status determines the rejection of calls to get vaccinated. COVID vaccination protects individuals and helps end the pandemic, but a sizable minority in Western countries rejects the vaccine. Vaccination status should serve as a group membership, critical communication between groups undermines trust, and we accordingly suggest that calls to get vaccinated by vaccinated sources lead to defensive rejection instead of desired behavior change. We term this the vaccination rift effect. A unique collaboration with national print, online and TV news media yielded a large (Nâ€‰=â€‰1170), age-representative sample of Austrian citizens for our fully randomized experiment. Participants exhibited the vaccination rift: They ascribed less constructive motives, dâ€‰=â€‰0.28, 95% CI [0.17; 0.40], experienced more threat, dâ€‰=â€‰-Â 0.30, 95% CI [-Â 0.42; -Â 0.19], and ascribed worse personality characteristics to vaccinated (vs. unvaccinated) commenters, dâ€‰=â€‰0.17, 95% CI [0.06; 0.29]. Constructiveness consistently predicted behavioral measures of counterarguing and vaccination planning (indirect effects Bâ€‰=â€‰0.033, SEâ€‰=â€‰0.013 and Bâ€‰=â€‰-Â 0.056, SEâ€‰=â€‰0.014). The vaccination rift was substantially stronger among the critical group of unvaccinated participants, dsâ€‰=Â |0.39-0.52|, than among those fully vaccinated,

dsâ€‰=Â |0.08-0.17|. We discuss how to apply these psychological mechanics of the vaccination rift to public campaigns.

Viral load dynamics of SARS-CoV-2 Delta and Omicron variants following multiple vaccine doses and previous infection. An important aspect of vaccine effectiveness is its impact on pathogen transmissibility, harboring major implications for public health policies. As viral load is a prominent factor affecting infectivity, its laboratory surrogate, qRT-PCR cycle threshold (Ct), can be used to investigate the infectivity-related component of vaccine effectiveness. While vaccine waning has previously been observed for viral load during the Delta wave, less is known regarding how Omicron viral load is affected by vaccination status, and whether vaccine-derived and natural infection protection are sustained. By analyzing results of more than 460,000 individuals, we show that while recent vaccination reduces Omicron viral load, its effect wanes rapidly. In contrast, a significantly slower waning rate is demonstrated for recovered COVID-19 individuals. Thus, while the vaccine is effective in decreasing morbidity and mortality, its relatively small effect on transmissibility of Omicron (as measured here by Ct) and its rapid waning call for reassessment of future booster campaigns.

Humoral and cellular immune responses to CoronaVac up to one year after vaccination. Coronavac is a widely used SARS-CoV-2 inactivated vaccine, but its long-term immune response assessment is still lacking. We evaluated SARS-CoV-2-specific immune responses, including T cell activation markers, antigen-specific cytokine production and antibody response following vaccination in 53 adult and elderly individuals participating in a phase 3 clinical trial. Activated follicular helper T (Tfh), non-Tfh and memory CD4(+) T cells were detected in almost all subjects early after the first vaccine dose. Activated memory CD4(+) T cells were predominantly of central and effector memory T cell phenotypes and were sustained for at least 6 months. We also detected a balanced Th1-, Th2- and Th17/Th22-type cytokine production that was associated with response over time, together with particular cytokine profile linked to poor responses in older vaccinees. SARS-CoV-2-specific IgG levels peaked 14 days after the second dose and were mostly stable over one year. CoronaVac was able to induce a potent and durable antiviral antigen-specific cellular response and the cytokine profiles related to the response over time and impacted by the senescence were defined.

Extended SARS-CoV-2 RBD booster vaccination induces humoral and cellular immune tolerance in mice. The repetitive applications of vaccine boosters have been brought up in face of continuous emergence of SARS-CoV-2 variants with neutralization escape mutations, but their protective efficacy and potential adverse effects remain largely unknown. Here, we compared the humoral and cellular immune responses of an extended course of recombinant receptor binding domain (RBD) vaccine boosters with those from conventional immunization strategy in a Balb/c mice model. Multiple vaccine boosters after the conventional vaccination course significantly decreased RBD-specific antibody titers and serum neutralizing efficacy against the Delta and Omicron variants, and profoundly impaired CD4(+) and CD8(+)T cell activation and increased PD-1 and LAG-3 expressions in these TÂ cells. Mechanistically, we confirmed that extended vaccination with RBD boosters overturned the protective immune memories by promoting adaptive immune tolerance. Our findings demonstrate potential risks with the continuous use of SARS-CoV-2 vaccine boosters, providing immediate implications for the global COVID-19 vaccination enhancement strategies.

Intranasal COVID-19 vaccine fails to induce mucosal immunity.

The association between vaccination status identification and societal polarization. Public discord between those vaccinated and those unvaccinated for COVID-19 has intensified globally. Theories of intergroup relations propose that identifying with one's social group plays a key role in the perceptions and behaviours that fuel intergroup conflict. We test whether identification with one's vaccination status is associated with current societal polarization. The study draws on panel data

from samples of vaccinated (nâ€‰=â€‰3,267) and unvaccinated (nâ€‰=â€‰2,038) respondents in Germany and Austria that were collected in December 2021 and February, March and July 2022. The findings confirm that vaccination status identification (VSI) explains substantial variance in a range of polarizing attitudes and behaviours. VSI was also related to higher psychological reactance toward mandatory vaccination policies among the unvaccinated. Higher levels of VSI reduced the gap between intended and actual counterbehaviours over time by the unvaccinated. VSI appears to be an important measure for predicting behavioural responses to vaccination policies.

Pityriasis Rosea Following Covaxin (BBV152) Vaccination for COVID-19.

Menstrual changes after COVID-19 vaccination and/or SARS-CoV-2 infection and their demographic, mood, and lifestyle determinants in Arab women of childbearing age, 2021. BACKGROUND: By September 2, 2021, over 30,000 COVID-19-vaccinated females had reported menstrual changes to the MHRA's Yellow Card surveillance system. As a result, the National Institutes of Health (NIH) is urging researchers to investigate the COVID-19 vaccine's effects on menstruation. Therefore, this study was conducted to explore the menstrual changes after COVID-19 vaccination and/or SARS-CoV-2 infection and their interrelations with demographic, mood, and lifestyle factors in Arab women of childbearing age (CBA). METHODOLOGY: A cross-sectional study was conducted during October 2021 using an Arabic validated and self-administrated questionnaire. In total, 1,254 Women of CBA in the Arabic Population (15-50 y) with regular menstrual cycles were randomly selected from five countries (Saudi Arabia, Egypt, Syria, Libya, and Sudan). RESULTS: The mean (SD) age of the 1,254 studied females was 29.6 (8.5) years old. In total, 634 (50%) were married, 1,104 (88.0%) had a University education or above, 1,064 (84.4%) lived in urban areas, and 573 (45.7%) had normal body weight. Moreover, 524 (41.8%) were COVID-19 cases and 98 women (18.7%) reported menstrual changes (MCs). The 1,044 (83.5%) vaccinated females reported 418 (38.5%) MCs after being vaccinated, and these MCs resolved in 194 women (55.1%) after more than 9 months. Statistically significant relationships were observed between the reported MCs and the following variables: age, marital status, level of education, nationality, residence, and BMI. MCs were reported at 293(80.6) after the 2nd dose, and were mainly reported after 482 (46.1) Pfizer, 254 (24.3) Astrazenica, and 92 (8.8) Senopharm. CONCLUSION: MCs among women of CBA after COVID-19 infection and vaccination are prevalent and complex problems, and had many determinates.

Giant cell vasculitis post-COVID-19 mRNA vaccine and COVID-19 asymptomatic infection: Correspondence. The possible adverse effect of COVID-19 vaccine is interesting. This correspondence discussed on the case of Giant cell vasculitis post-COVID-19 mRNA vaccine. The possible effect of the COVID-19 asymptomatic infection is highlighted.

Systemic and Mucosal Humoral Immune Response Induced by Three Doses of the BNT162b2 SARS-CoV-2 mRNA Vaccines. BNT162b2 (BioNTech/Pfizer) was the first SARS-CoV-2 mRNA vaccine approved by the European Medicines Agency. We monitored the long-term humoral responses of healthcare workers (HCWs) who received three vaccine doses. A total of 59 healthcare workers were studied: 47 were never SARS-CoV-2-infected (naÃ¯ve-HCWs), and 12 (infected-HCWs) recovered from COVID-19 before the first vaccine. Serum and saliva were collected at baseline (before the first dose), just before the second dose, 1, 3, 6, and 9 months after the second dose, and 10 days after the third vaccine. SARS-CoV-2-specific IgG and IgA were evaluated in serum and saliva, respectively, and the presence of neutralizing antibodies (NAb) was analyzed in serum. SARS-CoV-2-specific IgG peaked one month after the second vaccine in naÃ¯ve-HCWs but right before this timepoint in infected-HCWs. IgG titers significantly decreased during follow-up and at month 9 were still detectable in 50% of naÃ¯ve-HCWs and 90% of infected-HCWs. NAb were significantly decreased 6 months after the second vaccine in naÃ¯ve-HCWs and 9 months after this dose in infected-HCWs. Salivary SARS-CoV-2-specific IgA titers were significantly higher in infected-HCWs and were undetectable 9 months after

the second vaccine in 43% of the naÃ¯ve-HCWs alone. The third vaccine greatly increased humoral IgG and mucosal IgA in both groups. Two BNT162b2 doses induced strong systemic and humoral immune responses; to note, these responses weakened over time, although they are more prolonged in individuals who had recovered from COVID-19. The third vaccine dose quickly boosts systemic and mucosal humoral responses.
Hospitalised Myocarditis and Pericarditis Cases in Germany Indicate a Higher Post-Vaccination Risk for Young People Mainly after COVID-19 Vaccination. It was recently described that the overall risk of myopericarditis after receiving a COVID-19 vaccine is low, except for younger males receiving mRNA vaccines [...].
Feelings of Polish and Palestinian Students after Receiving Vaccinations against COVID-19. The COVID-19 pandemic has limited human freedom in many areas. Developing a COVID-19 vaccine has been a key task to contain the spread of the virus. In many countries, there is increasing concern about anti-vaccines due to complications after receiving the vaccine. The research problem concerns the opinions of Polish and Palestinian students after receiving vaccinations against COVID-19. This study involved 657 respondents (332 from Poland and 325 from Palestine) who completed the original questionnaire online. The respondents present two different cultures, embedded in different existential conditions, also in terms of health care, and especially the availability of vaccines. The obtained data indicate that almost 50% of research participants from both countries believe that vaccines are an effective antidote to the pandemic situation. Respondents in both populations believed that it was their personal choice to undergo vaccinations. The social motivation for vaccination in both groups was the desire to participate in public life, and the possibility of free travel for Poles, and the fear of infecting other people for Palestinians. The most common side effect reported after vaccination was pain at the site of the infection. Medical assistance was more often sought by respondents from Palestine. From an existential, psychosocial and health perspective, vaccines contributed to strengthening the vital forces in a large part of the population, allowed rebuilding social interactions and gave a sense of security in the daily functioning of a person.
Assessing T-Cell Immunity in Kidney Transplant Recipients with Absent Antibody Production after a 3rd Dose of the mRNA-1273 Vaccine. The vulnerable population of kidney transplant recipients (KTRs) are low responders to COVID-19 vaccines, so specific immune surveillance is needed. The interferon-gamma (IFN-Î³) release assay (IGRA) is effective in assessing T cell-mediated immunity. We assessed SARS-CoV-2-directed T cell responses in KTRs with absent antibody production after a third dose of the mRNA-1273 vaccine, using two different IGRAs. A cohort of 57 KTRs, who were actively followed up, received a third dose of the mRNA-1273 vaccine. After the evaluation of humoral immunity to SARS-CoV-2, 14 seronegative patients were tested with two commercial IGRAs (SD Biosensor and Euroimmun). Out of 14 patients, one and three samples were positive by IGRAs with Euroimmun and SD Biosensor, respectively. The overall agreement between the two assays was 85.7% (Îº = 0.444). In addition, multivariate linear regression analysis showed no statistically significant association between the IFN-Î³ concentration, and the independent variables analyzed (age, gender, years since transplant, total lymphocytes cells/mcl, CD3+ cells/mcl, CD3+ CD4+ cells/mcl, CD3+ CD8+ cells/mcl, CD19+ cells/mcl, CD3-CD16+CD56+ cells/mcl) ($p > 0.01$). In a vulnerable setting, assessing cellular immune response to complement the humoral response may be advantageous. Since the two commercial IGRAs showed a good agreement on negative samples, the three discordant samples highlight the need for further investigations.
Myocardial microthrombi after COVID-19 mRNA vaccination.
Severe Myocarditis in a Female Following mRNA-1273 Vaccine: A Case Report and Review of the Literature. Myocarditis was recently described as one of the complications secondary to COVID-19 vaccination. We present a 38-year-old lady diagnosed with vaccine-related myocarditis a few days

after receiving the mRNA-1273 vaccine. We also summarize what is reported in the literature about the association between COVID-19 vaccination and myocarditis. In conclusion, COVID-19 immunization appears to be associated with significantly fewer adverse outcomes than COVID-19 infection among all age groups.

Trends and factors associated with change in COVID-19 vaccination intent among residents and staff in six Seattle homeless shelters, March 2020 to August 2021. INTRODUCTION: Achieving high COVID-19 vaccination coverage in homeless shelters is critical in preventing morbidity, mortality, and outbreaks, however, vaccination coverage remains lower among people experiencing homelessness (PEH) than the general population. METHODS: We conducted a cross-sectional study to retrospectively describe attitudes and identify factors associated with change in COVID-19 vaccination intent among shelter residents and staff during March 2020 - August 2021. To identify factors associated with change in COVID-19 vaccine intent becoming more positive overall compared to other attitudes, we utilized a Poisson model to calculate Risk Ratios with robust standard errors, adjusting for confounding by shelter site and demographic variables determined a priori. RESULTS: From July 12 - August 2, 2021, 97 residents and 20 staff participated in surveys across six shelters in Seattle King County, Washington. Intent to be vaccinated against COVID-19 increased from 45.3Â % (nÂ =Â 53) when recalling attitudes in March 2020 to 74.4Â % (nÂ =Â 87) as of August 2021, and was similar among residents and staff. Many participants (43.6Â %, nÂ =Â 51) indicated feeling increasingly accepting about receiving a COVID-19 vaccine since March 2020, while 13.7Â % (nÂ =Â 16) changed back and forth, 10.3Â % (nÂ =Â 12) became more hesitant, and 32.5Â % (nÂ =Â 38) had no change in intent. In the model examining the relationship between becoming more positive about receiving a COVID-19 vaccine compared to all other attitudes (nÂ =Â 116), we found a 57.2Â % increase in vaccine acceptability (RR 1.57; 95Â % CI: 1.01, 2.45) among those who reported worsening mental health since the start of the pandemic. CONCLUSIONS: Findings highlight opportunities to improve communication with residents and staff about COVID-19 vaccination and support a need for continued dialogue and a person-centered approach to understanding the sociocultural complexities and dynamism of vaccine attitudes at shelters.Clinical Trial Registry Number: NCT04141917.

Intramuscular injection of a mixture of COVID-19 peptide vaccine and tetanus vaccine in horse induced neutralizing antibodies against authentic virus of SARS-CoV-2 Delta variant. Peptide vaccine is not effective due to its low immunogenicity. To improve the efficacy of peptide vaccine against COVID-19, a novel method was developed by mixing a COVID-19 peptide vaccine with a tetanus vaccine. In this study, intramuscular injection of a mixture of COVID-19 peptide vaccine and tetanus vaccine twice, i.e., first dose on day 0 and second dose on day 21, induced neutralizing antibodies against authentic virus of SARS-CoV-2 Delta variant in a horse. Horse serum of day 35, i.e., two weeks after the second dose, neutralized authentic virus of SARS-CoV-2 Delta variant, equal to half effectiveness of human serum from vaccinees of Moderna COVID-19 vaccine. However, neither horse serum nor human serum neutralized Omicron variant authentic virus. No side effects were observed after each dose. This study indicates intramuscular injection of a mixture of COVID-19 peptide vaccine and tetanus vaccine may work in humans to improve peptide vaccine efficacy against SARS-CoV-2.

Evidence for the heterologous benefits of prior BCG vaccination on COVISHIELDâ„¢ vaccine-induced immune responses in SARS-CoV-2 seronegative young Indian adults. This proof-of-concept study tested if prior BCG revaccination can qualitatively and quantitively enhance antibody and T-cell responses induced by Oxford/AstraZeneca ChAdOx1nCoV-19 or COVISHIELDâ„¢, an efficacious and the most widely distributed vaccine in India. We compared COVISHIELDâ„¢ induced longitudinal immune responses in 21 BCG re-vaccinees (BCG-RV) and 13 BCG-non-revaccinees (BCG-NRV), all of

whom were BCG vaccinated at birth; latent tuberculosis negative and SARS-CoV-2 seronegative prior to COVISHIELDâ„¢ vaccination. Compared to BCG-NRV, BCG-RV displayed significantly higher and persistent spike-specific neutralizing (n) Ab titers and polyfunctional CD4+ and CD8+ T-cells for eight months post COVISHIELDâ„¢ booster, including distinct CD4+IFN-Î³+ and CD4+IFN-Î³- effector memory (EM) subsets co-expressing IL-2, TNF-Î± and activation induced markers (AIM) CD154/CD137 as well as CD8+IFN-Î³+ EM,TEMRA (T cell EM expressing RA) subset combinations co-expressing TNF-Î± and AIM CD137/CD69. Additionally, elevated nAb and T-cell responses to the Delta mutant in BCG-RV highlighted greater immune response breadth. Mechanistically, these BCG adjuvant effects were associated with elevated markers of trained immunity, including higher IL-1Î² and TNF-Î± expression in CD14+HLA-DR+monocytes and changes in chromatin accessibility highlighting BCG-induced epigenetic changes. This study provides first in-depth analysis of both antibody and memory T-cell responses induced by COVISHIELDâ„¢ in SARS-CoV-2 seronegative young adults in India with strong evidence of a BCG-induced booster effect and therefore a rational basis to validate BCG, a low-cost and globally available vaccine, as an adjuvant to enhance heterologous adaptive immune responses to current and emerging COVID-19 vaccines.
Evaluation of the systemic and mucosal immune response induced by COVID-19 and the BNT162b2 mRNA vaccine for SARS-CoV-2. BACKGROUND: The currently used SARS-CoV-2 mRNA vaccines have proven to induce a strong and protective immune response. However, functional relevance of vaccine-generated antibodies and their temporal progression are still poorly understood. Thus, the central aim of this study is to gain a better understanding of systemic and mucosal humoral immune response after mRNA vaccination with BNT162b2. METHODS: We compared antibody production against the S1 subunit and the RBD of the SARS-CoV-2 spike protein in sera of BNT162b2 vaccinees, heterologous ChAdOx1-S/BNT162b2 vaccinees and COVID-19 patients. We monitored the neutralizing humoral response against SARS-CoV-2 wildtype strain and three VOCs over a period of up to eight months after second and after a subsequent third vaccination. RESULTS: In comparison to COVID-19 patients, vaccinees showed higher or similar amounts of S1- and RBD-binding antibodies but similar or lower virus neutralizing titers. Antibodies peaked two weeks after the second dose, followed by a decrease three and eight months later. Neutralizing antibodies (nAbs) poorly correlated with S1-IgG levels but strongly with RBD-IgGAM titers. After second vaccination we observed a reduced vaccine-induced neutralizing capacity against VOCs, especially against the Omicron variant. Compared to the nAb levels after the second vaccination, the neutralizing capacity against wildtype strain and VOCs was significantly enhanced after third vaccination. In saliva samples, relevant levels of RBD antibodies were detected in convalescent samples but not in vaccinees. CONCLUSIONS: Our data demonstrate that BNT162b2 vaccinated individuals generate relevant nAbs titers, which begin to decrease within three months after immunization and show lower neutralizing potential against VOCs as compared to the wildtype strain. Large proportion of vaccine-induced S1-IgG might be non-neutralizing whereas RBD-IgGAM appears to be a good surrogate marker to estimate nAb levels. A third vaccination increases the nAb response. Furthermore, the systemic vaccine does not seem to elicit readily detectable mucosal immunity.
Spikevax booster and delayed urticaria: a Swiss signal with diagnostic uncertainties due to a high proportion of direct patient reports.
SARS-CoV-2 mRNA Vaccination Is Not Associated With the Risk of Allosensitization in Patients Awaiting Kidney Transplantation.
Impact of SARS-CoV-2-specific memory B cells on the immune response after mRNA-based Comirnaty vaccine in seronegative health care workers. PURPOSE: To analyze the impact of SARS-COV-2-specific memory B cells (MBC) on the immune response after two doses of mRNA-based Comirnaty COVID-19 vaccine in seronegative health care workers. This study is seeking a rationale for boosting

vaccines. METHODS: Longitudinal study including 31 seronegative health care workers with undetectable specific MBCs (IgG(-)MBC(-) group), 24 seronegative with detectable specific MBCs (IgG(-)MBC(+) group), and 24 seropositive with detectable specific MBCs (IgG(+)MBC(+) group). The level of antibodies that inhibit ACE2-RBD interaction, and anti-Spike IgG, IgA, and IgM antibodies was quantified by ELISA. In addition, specific memory B and T cells were quantified by flow cytometry. RESULTS: The level of specific MBCs, and isotypes, in the IgG(-)MBC(-) group was lower compared to that found in IgG(-)MBC(+) (pâ€‰=â€‰0.0001) and IgG(+)MBC(+) (pâ€‰<â€‰0.0001) groups, respectively. ACE2-RBD neutralizing antibodies and anti-S IgG antibodies were at lower levels in the IgG(-)MBC(-)group after the vaccine. Specific MBCs directly correlated with specific CD4(+) T cells (although not significant, pâ€‰=â€‰0.065), while no correlation was found with specific CD8(+) T cells (pâ€‰=â€‰0.156) after the vaccine. In parallel, ACE2-RBD neutralizing antibodies only positively correlated with specific CD4(+) T cells (pâ€‰=â€‰0.034). CONCLUSION: IgG(-)MBC(-) individuals showed the worst humoral and cellular responses, both in frequency and magnitude, after vaccination. Individuals whose antibodies wane and become undetectable after a given period of time post vaccination and show no specific MBCs are less protected and hence are good candidates for boosting vaccine. On the other hand, seronegative individuals with specific MBC showed faster and higher responses compared to the IgG(-)MBC(-) group.

Dynamics of humoral and cellular immune responses after homologous and heterologous SARS-CoV-2 vaccination with ChAdOx1 nCoV-19 and BNT162b2. BACKGROUND: Vaccines are an important means to overcome the SARS-CoV-2 pandemic. They induce specific antibody and T-cell responses but it remains open how well vaccine-induced immunity is preserved over time following homologous and heterologous immunization regimens. Here, we compared the dynamics of humoral and cellular immune responses up to 180 days after homologous or heterologous vaccination with either ChAdOx1-nCoV-19 (ChAd) or BNT162b2 (BNT) or both. METHODS: Various tests were used to determine the humoral and cellular immune response. To quantify the antibody levels, we used the surrogate neutralization (sVNT) assay from YHLO, which we augmented with pseudo- and real virus neutralization tests (pVNT and rVNT). Antibody avidity was measured by a modified ELISA. To determine cellular reactivity, we used an IFN-Î³ Elispot, IFN-Î³/IL Flurospot, and intracellular cytokine staining. FINDINGS: Antibody responses significantly waned after vaccination, irrespective of the regimen. The capacity to neutralize SARS-CoV-2 - including variants of concern such as Delta or Omicron - was superior after heterologous compared to homologous BNT vaccination, both of which resulted in longer-lasting humoral immunity than homologous ChAd immunization. All vaccination regimens induced stable, polyfunctional T-cell responses. INTERPRETATION: These findings demonstrate that heterologous vaccination with ChAd and BNT is a potent alternative to induce humoral and cellular immune protection in comparison to the homologous vaccination regimens. FUNDING: The study was funded by the German Centre for Infection Research (DZIF), the European Union's "Horizon 2020 Research and Innovation Programme" under grant agreement No. 101037867 (VACCELERATE), the "Bayerisches Staatsministerium fÃ¼r Wissenschaft und Kunst" for the CoVaKo-2021 and the For-COVID projects and the Helmholtz Association via the collaborative research program "CoViPa". Further support was obtained from the Federal Ministry of Education and Science (BMBF) through the "Netzwerk UniversitÃ¤tsmedizin", project "B-Fast" and "Cov-Immune". KS is supported by the German Federal Ministry of Education and Research (BMBF, 01KI2013) and the Else KrÃ¶ner-Stiftung (2020_EKEA.127).

Saliva is suitable for SARS-CoV-2 antibodies detection after vaccination: A rapid systematic review. Since the introduction of efficient vaccines anti-SARS-CoV-2, antibody quantification becomes increasingly useful for immunological monitoring and COVID-19 control. In several situations, saliva samples may be an alternative to the serological test. Thus, this rapid systematic review aimed to

evaluate if saliva is suitable for SARS-CoV-2 detection after vaccination. For this purpose, search strategies were applied at EMBASE, PubMed, and Web of Science. Studies were selected by two reviewers in a two-phase process. After selection, 15 studies were eligible and included in data synthesis. In total, salivary samples of approximately 1,080 vaccinated and/or convalescent individuals were analyzed. The applied vaccines were mostly mRNA-based (BioNTech 162b2 mRNA/Pfizer and Spikevax mRNA-1273/Moderna), but recombinant viral-vectored vaccines (Ad26. COV2. S Janssen - Johnson & Johnson and Vaxzevria/Oxford AstraZeneca) were also included. Different techniques were applied for saliva evaluation, such as ELISA assay, Multiplex immunoassay, flow cytometry, neutralizing and electrochemical assays. Although antibody titers are lower in saliva than in serum, the results showed that saliva is suitable for antibody detection. The mean of reported correlations for titers in saliva and serum/plasma were moderate for IgG (0.55, 95% CI 0.38-9.73), and weak for IgA (0.28, 95% CI 0.12-0.44). Additionally, six out of nine studies reported numerical titers for immunoglobulins detection, from which the level in saliva reached their reference value in four (66%). IgG but not IgA are frequently presented in saliva from vaccinated anti-COVID-19. Four studies reported lower IgA salivary titers in vaccinated compared to previously infected individuals, otherwise, two reported higher titers of IgA in vaccinated. Concerning IgG, two studies reported high antibody titers in the saliva of vaccinated individuals compared to those previously infected and one presented similar results for vaccinated and infected. The detection of antibodies anti-SARS-CoV-2 in the saliva is available, which suggests this type of sample is a suitable alternative for monitoring the population. Thus, the results also pointed out the possible lack of mucosal immunity induction after anti-SARS-CoV-2 vaccination. It highlights the importance of new vaccination strategies also focused on mucosal alternatives directly on primary routes of SARS-CoV-2 entrance. SYSTEMATIC REVIEW REGISTRATION: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022336968, identifier CRD42022336968.

Remission of extranodal NK/T-cell lymphoma, nasal type, after SARS-CoV-2 vaccination.

Pityriasis rubra pilaris (type I) following administration of the BNT162b2 mRNA COVID-19 vaccine: Successful treatment with ustekinumab and acitretin.

Enhanced immune responses following heterologous vaccination with self-amplifying RNA and mRNA COVID-19 vaccines. The optimal vaccination strategy to boost responses in the context of pre-existing immune memory to the SARS-CoV-2 spike (S) glycoprotein is an important question for global public health. To address this, we explored the SARS-CoV-2-specific humoral and cellular immune responses to a novel self-amplifying RNA (saRNA) vaccine followed by a UK authorised mRNA vaccine (BNT162b2) in individuals with and without previous COVID-19, and compared these responses with those who received an authorised vaccine alone. 35 subjects receiving saRNA (saRNA group) as part of the COVAC1 clinical trial and an additional 40 participants receiving an authorised SARS-CoV-2 vaccine only (non-saRNA group) were recruited. Antibody responses were measured by ELISA and a pseudoneutralisation assay for wildtype, Delta and Omicron variants. Cellular responses were measured by IFN-Æ´ ELISpot and an activation induced marker (AIM) assay. Approximately 50% in each group had previous COVID-19 prior to vaccination, confirmed by PCR or antibody positivity on ELISA. All of those who received saRNA subsequently received a full course of an authorised vaccine. The majority (83%) of those receiving saRNA who were COVID-19 naÃ¯ve at baseline seroconverted following the second dose, and those with previous COVID-19 had an increase in antibody titres two weeks following saRNA vaccination (median 27-fold), however titres were lower when compared to mRNA vaccination. Two weeks following the 2nd authorised mRNA vaccine dose, binding and neutralising antibody titres were significantly higher in the saRNA participants with previous COVID-19, compared to non-saRNA, or COVID-19 naive saRNA participants. Cellular responses were again highest in this group, with a higher proportion of spike specific CD8+ than CD4+ T cells when

compared to those receiving the mRNA vaccine only. These findings suggest an immunological benefit of increased antigen exposure, both from natural infection and vaccination, particularly evident in those receiving heterologous vaccination with saRNA and mRNA.
Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States.
Predicting the sentiment of South Korean Twitter users toward vaccination after the emergence of COVID-19 Omicron variant using deep learning-based natural language processing. Although the full vaccination rate of South Korea compared to other countries, concerns about the effectiveness of the vaccine are growing as new COVID variants such as Alpha, Beta, Gamma, Delta, and Omicron appear over time. In this study, we collected Twitter data in South Korea that contained keywords like vaccines after the outbreak of the Omicron variant from 27 November 2021 to 14 February 2022. First, we analyzed the relationship between potential keywords associated with vaccination after the appearance of the Omicron variant in Twitter using network analysis. Second, we developed an efficient model for predicting the emotion of speech regarding vaccination after the COVID-19 Omicron variant pandemic by using deep learning algorithms. We constructed sentiment analysis models regarding vaccination after the COVID-19 Omicron pandemic by using five algorithms [i.e., support vector machine (SVM), recurrent neural networks (RNNs), long short-term memory models (LSTMs), bidirectional encoder representations from transformers (BERT), and Korean BERT (KoBERT)]. The results confirmed that KoBERT showed the best performance (71%) in all predictive performance indicators (accuracy, precision, and F1 score). It is necessary to prepare measures to alleviate the negative factorss of the public about vaccination in the long-term pandemic situation and help the public recognize the efficacy and safety of vaccination by using big data based on the results of this study.
SARS-CoV-2 anti-spike antibodies after a fourth dose of COVID-19 vaccine in adult solid-organ transplant recipients. BACKGROUND: A fourth dose of SARS-CoV-2 vaccine is recommended in solid-organ transplant (SOT) recipients, but the immunogenicity is poorly known. METHODS: We conducted a retrospective, observational, monocentric study between the 1st January 2021 and 31st March 2022 of the anti-Spike antibody titers after one to four doses of vaccine in SOT. RESULTS: 825 SOT were included. Median age at first vaccine injection was 61.2 (IQR 50.9-69.3) years; 66.7â€¯% were male; 63.4â€¯% had received four vaccine doses. The proportion of participants with a strong humoral response (>260 BAU/mL) increased with the number of vaccine doses: 10.6â€¯% after the 1st dose (D1), 35.1â€¯% after the 2nd (D2), 48.5â€¯% after the 3rd (D3), and 65.1â€¯% after the 4th (D4) (pâ€¯<â€¯0.001). Among the tested patients, the proportion with a detectable humoral response was significantly higher after D4 than after D3 (47â€¯% vs 22â€¯%, pâ€¯=â€¯0.01). Liver transplant recipients had more frequently a strong humoral response after D2, D3 and D4 (ORâ€¯=â€¯5.3, 3.7 and 6.6 respectively when compared with other organ transplant recipients, pâ€¯<â€¯0.001). In kidney transplant recipients, belatacept-containing regimen was associated with a lower rate of detectable humoral (9â€¯% vs 40â€¯%, pâ€¯=â€¯0.025) after D3, but there was no statistical difference after D4. CONCLUSION: A fourth dose should be proposed to SOT recipients who did not developed an immune response after 3 doses. Kidney transplant recipients receiving belatacept have a poorer, although frequently detectable response.
Livedo Reticularis After COVID-19 Vaccination.
Thrombotic thrombocytopenic purpura after vaccination for COVID-19: lesson for the clinical nephrologist.
Myocarditis Following SARS-CoV2 mRNA Vaccination Against COVID-19: Facts and Open Questions.
Delayed skin reactions after the second dose of mRNA vaccines against SARS-CoV-2.

Neutralization of SARS-CoV-2 Omicron and Delta Variants in Relation to Vaccine-Induced Antibody Levels in Kidney Transplant Recipients and Healthy Controls.

Patients with B-cell malignancies experience reduced antibody responses with class switching defect following BNT162b2 SARS-CoV-2 vaccination. Vaccines having aided in escaping the majority of the population from immunological naÃ¯vety, our strategies are now shifting towards an increased focus on identifying and protecting the extremely vulnerable. We here describe the results of testing 12 patients, those with lymphoid malignancies having been targeted their B-cells for therapy with rituximab-containing regimens or a Bruton tyrosine kinase inhibitor, for anti-SARS-CoV-2 spike antibodies after receiving the BNT162b2 mRNA vaccine doses. The interval from last dosing of B-cell depletion therapy to SARS-CoV-2 vaccination was at median 5.3 (range 3.1-6.6) months. Using the 'seroprotection' threshold of 775 [BAU/mL] for the anti-spike antibody titer, our finding points out the crucial unresponsiveness of the targeted population with 0/12 (0%) achieving 'seroprotection'. Although IgG seroconversion was observed in 4/12 (33%), supporting the overall benefit of vaccination, the figures still point out a potential need for optimization of practice. IgA was further less responsive (unsuccessful 'seroconversion' in 11/12 (92%)), implicating an underlying class switch defect. Those with depletion on B-cells are caught at a dilemma between, being too early and too late on receiving SARS-CoV-2 vaccines. They wish to get over their immunological naÃ¯vety at the earliest, while, in order to assure quality immune memory, are also required to hold the patience for their B-cells to repopulate. Although it remains an issue whether intensified vaccine schedules and/or regimens will lead to stronger immunogenicity or more effective boosters for non-responders, we shall take advantage of every increasing evidence in order to optimize current options.

Recombinant COVID-19 vaccine based on recombinant RBD/Nucleoprotein and saponin adjuvant induces long-lasting neutralizing antibodies and cellular immunity. SARS-CoV-2 has caused a global pandemic, infecting millions of people. An effective preventiveÂ vaccineÂ against this virus is urgently needed. Here, we designed and developed a novel formulated recombinant receptor-binding domain (RBD) nucleocapsid (N) recombinantÂ vaccineÂ candidates. The RBD and N were separately expressed in E. coli and purified using column chromatography. The female Balb/c mice were immunized subcutaneously with the combination of purified RBD and N alone or formulated with saponin adjuvant in a two-week interval in three doses. Neutralization antibody (Nabs) titers against the SARS-CoV-2 were detected by a Surrogate Virus Neutralization (sVNT) Test. Also, total IgG and IgG1, and IgG2a isotypes and the balance of cytokines in the spleen (IFN-Î³, Granzyme B, IL-4, and IL-12) were measured by ELISA. The percentages of CD4+ and CD8+ T cells were quantified by flow cytometry. The lymphoproliferative activity of restimulated spleen cells was also determined. The findings showed that the combination of RBD and N proteins formulated with saponin significantly promoted specific total IgG and neutralization antibodies, elicited robust specific lymphoproliferative and T cell response responses. Moreover, markedÂ increase in CD4+ and CD8+ T cells were observed in the adjuvanted RBD and N vaccineÂ group compared with other groups. The results suggest that the formulations are able to elicit a specific long-lasting mixed Th1/Th2 balanced immune response. Our data indicate the significance of the saponin-adjuvanted RBD/N vaccine in the design of SARS-CoV-2 vaccines and provide a rationale for the development of a protective long-lasting and strong vaccine.

Improved Neutralisation of the SARS-CoV-2 Omicron Variant following a Booster Dose of Pfizer-BioNTech (BNT162b2) COVID-19 Vaccine. In late November 2021, the World Health Organization declared the SARS-CoV-2 lineage B.1.1.529 the fifth variant of concern, Omicron. This variant has acquired over 30 mutations in the spike protein (with 15 in the receptor-binding domain), raising concerns that Omicron could evade naturally acquired and vaccine-derived immunity. We utilized an authentic virus, multicycle neutralisation assay to demonstrate that sera collected one, three, and six

months post-two doses of Pfizer-BioNTech BNT162b2 had a limited ability to neutralise SARS-CoV-2. However, four weeks after a third dose, neutralising antibody titres were boosted. Despite this increase, neutralising antibody titres were reduced fourfold for Omicron compared to lineage A.2.2 SARS-CoV-2.
Vaccine-Induced T-Cell and Antibody Responses at 12 Months after Full Vaccination Differ with Respect to Omicron Recognition. More than a year after the first vaccines against the novel SARS-CoV-2 were approved, many questions still remain about the long-term protection conferred by each vaccine. How long the effect lasts, how effective it is against variants of concern and whether further vaccinations will confer additional benefits remain part of current and future research. For this purpose, we examined 182 health care employees-some of them with previous SARS-CoV-2 infection-12 months after different primary immunizations. To assess antibody responses, we performed an electrochemiluminescence assay (ECLIA) to determine anti-spike IgGs, followed by a surrogate virus neutralization assay against Wuhan-Hu-1 and B.1.1.529/BA.1 (Omicron). T cell response against wild-type and the Omicron variants of concern were assessed via interferon-gamma ELISpot assays and T-cell surface and intracellular cytokine staining. In summary, our results show that after the third vaccination with an mRNA vaccine, differences in antibody quantity and functionality observed after different primary immunizations were equalized. As for the T cell response, we were able to demonstrate a memory function for CD4+ and CD8+ T cells alike. Importantly, both T and antibody responses against wild-type and omicron differed significantly; however, antibody and T cell responses did not correlate with each other and, thus, may contribute differentially to immunity.
[Transmission characteristics and risk factors of household COVID-19 clusters caused by 2019-nCoV Omicron variant in Tianjin]. Objective: To understand the transmission characteristics and risk factors of household COVID-19 clusters caused by 2019-nCoV Omicron variant in Tianjin and provide evidence for COVID-19 prevention and control. Methods: Field epidemiological method was used to investigate the epidemiological characteristics of COVID-19 cases, and descriptive analysis was used to describe the epidemiological information. Results: A total of 430 cases were reported in this epidemic in Tianjin, in which 409 cases were included in this study. Among these cases, 70.90% (290/409) occurred in families. The family secondary attack rate was 33.64% The family secondary attack rate in age group 12-17 years (13.79%) was significantly lower than that in age group 18-49 years (36.48%), the OR was 0.378 (95%CI: 0.170-0.840). The logistic regression analysis showed that compared with centralized quarantine, the OR of the index cases found in closed-off/controlled areas and in home quarantine were 2.951 (95%CI:1.322-6.586) and 2.287 (95%CI:1.164-4.495), respectively, compared with the cases without sore throat, the OR of the index cases with sore throat was 3.003 (95%CI: 1.576-5.720), and compared with cases in families without completed COVID-19 vaccinations in all members, the OR of the cases in families with completed COVID-19 vaccinations in all members was 0.268 (95%CI: 0.132-0.552). Conclusions: The risk of household transmission of infection with Omicron variant was high. Detecting the index case in closed-off/controlled areas or in home quarantine and sore throat in index cases were the risk factors of the household transmission, completed COVID-19 vaccination was the protective factor.
Successful alternative vaccination with BNT162b2 mRNA COVID-19 vaccine for new-onset IgA vasculitis after receiving mRNA-1273-case report.
Recalling fake news during real news corrections can impair or enhance memory updating: the role of recollection-based retrieval. Fake news can impair memory leading to societal controversies such as COVID-19 vaccine efficacy. The pernicious influence of fake news is clear when ineffective corrections leave memories outdated. A key theoretical issue is whether people should recall fake news while reading corrections with contradictory details. The familiarity backfire view proposes that recalling fake news increases its familiarity, leading to interference. However, the integrative

encoding view proposes that recalling fake news promotes co-activation and binding of contradictory details, leading to facilitation. Two experiments examined if one theory better accounts for memory updating after participants recalled actual fake news details when reading headlines that corrected misinformation. In Phase 1, participants read real and fake news headlines of unclear veracity taken from various internet sources. In Phase 2, participants read real news headlines that reaffirmed real news and corrected fake news from Phase 1. When they detected that Phase 2 real news corrected fake news, they attempted to recall Phase 1 fake news. In Phase 3, participants first recalled real news details. When they remembered that those details were corrections from Phase 2, they attempted to recall fake news from Phase 1. Recalling fake news when noticing corrections in Phase 2 led to better memory for real news in Phase 3 when fake news was recalled again and worse memory for real news in Phase 3 when fake news was not recalled again. Both views explain part of the memory differences associated with recalling fake news during corrections, but only when considering whether people recollected that fake news had been corrected.

COVID-19 vaccine-associated myositis - a case report. Myositis is one of the uncommon adverse events following COVID-19 vaccination, and its mechanism is still unclear. A strong clinical suspicion and further evaluation are important not only for early diagnosis and management but also for better understanding of the unprecedented effects of this novel vaccine. We present a case of myositis following the first dose of the ChAdOx1 nCoV-19 Corona Virus Vaccine, evidenced by serology and MRI.

Increased CD8 T-cell immunity after COVID-19 vaccination in lymphoid malignancy patients lacking adequate humoral response: An immune compensation mechanism?

Preexisting antibodies targeting SARS-CoV-2 S2 cross-react with commensal gut bacteria and impact COVID-19 vaccine induced immunity. The origins of preexisting SARS-CoV-2 cross-reactive antibodies and their potential impacts on vaccine efficacy have not been fully clarified. In this study, we demonstrated that S2 was the prevailing target of the preexisting S protein cross-reactive antibodies in both healthy human and SPF mice. A dominant antibody epitope was identified on the connector domain of S2 (1147-SFKEELDKYFKNHT-1160, P144), which could be recognized by preexisting antibodies in both human and mouse. Through metagenomic sequencing and fecal bacteria transplant, we demonstrated that the generation of S2 cross-reactive antibodies was associated with commensal gut bacteria. Furthermore, six P144 reactive monoclonal antibodies were isolated from naÃ¨ve SPF mice and were proven to cross-react with commensal gut bacteria collected from both human and mouse. A variety of cross-reactive microbial proteins were identified using LC-MS, of which E. coli derived HSP60 and HSP70 proteins were confirmed to be able to bind to one of the isolated monoclonal antibodies. Mice with high levels of preexisting S2 cross-reactive antibodies mounted higher S protein specific binding antibodies, especially against S2, after being immunized with a SARS-CoV-2 S DNA vaccine. Similarly, we found that levels of preexisting S2 and P144-specific antibodies correlated positively with RBD binding antibody titers after two doses of inactivated SARS-CoV-2 vaccination in human. Collectively, our study revealed an alternative origin of preexisting S2-targeted antibodies and disclosed a previously neglected aspect of the impact of gut microbiota on host anti-SARS-CoV-2 immunity.

Corrigendum to 'Long follow-up of symptomatic Multiple Myeloma patients after Covid-19 vaccination (BNT162b2): A single-institution retrospective experience' Leukemia research reports 18C (100,342). [This corrects the article DOI: 10.1016/j.lrr.2022.100342.].

Re: Systemic Vasculitis Following SARS-CoV-2 mRNA Vaccination Demonstrated on FDG PET/CT.

Comparison of Semen Quality Before and After Inactivated SARS-CoV-2 Vaccination Among Men in China. This cohort study examines changes in semen qualityâ€”including semen volume, sperm

concentration, total sperm count, and total and progressive sperm motilityâ€”before and after inactivated SARS-CoV-2 vaccination among men in China.
Myocarditis After BNT162b2 COVID-19 Third Booster Vaccine in Israel.
45 and Up COVID Insights: a dynamic and collaborative approach to evidence-making during the COVID-19 pandemic. OBJECTIVES: In response to the coronavirus 2019 (COVID-19) pandemic, a research project was developed with a cohort of 45 and Up Study participants to generate timely, relevant evidence to guide policy, practice and planning. This paper describes the research model, the cohort establishment and characteristics, and some findings. METHODS: A subgroup of 45 and Up Study participants was invited to enrol in 45 and Up COVID Insights -a series of five online surveys conducted during 2020-22. The model involved a close collaborative partnership with the New South Wales Ministry of Health and a panel of scientific advisers, an agile data collection methodology and rapid dissemination of findings. Frequent, iterative engagement with stakeholders provided a framework for identifying survey themes and questions and ensured wide dissemination of findings. Themes included healthcare use, attitudes toward and uptake of COVID-19 prevention measures, and the impact of the pandemic on mental health, loneliness, and lifestyle behaviours. RESULTS: 45 and Up COVID Insights achieved strong stakeholder engagement through extensive consultation and rapid reporting of results. The project recruited a diverse cohort of 32 115 participants: median age 68 years (range: 56-100+); 8% from outer regional/remote areas; 12% from the most socioeconomically disadvantaged communities; and 9% from culturally and linguistically diverse backgrounds. The first four surveys found that the impact of the pandemic varied across populations and stages of the pandemic. Between February-April (survey 2) 2021, 10% reported missed healthcare in the past month because of the pandemic, rising to 26% by September-November 2021 (survey 4). Quality of life remained high (>90% good-excellent across the surveys). As the pandemic progressed, the proportion reporting worsened mental health as a result increased from 29% (July-December 2020, survey 1) to 46% (survey 4). In survey 2 (February-April 2021), 89% intended to get the COVID-19 vaccine, with 8% unsure. By late 2021, vaccination uptake was high, with 98% of respondents having received at least one vaccination. CONCLUSION: There is great value in harnessing a large longitudinal, well-described, and diverse cohort study to generate evidence in a changing context with evolving information needs. The collaborative model enhanced the value and relevance of the data to inform decisions.
Pros and cons factors influence population attitudes toward non-pharmaceutical interventions and vaccination during post-COVID-19. OBJECTIVES: Population compliance greatly influences the effectiveness of vaccination and non-pharmaceutical interventions (NPIs) for the curtaining of COVID-19 transmission. We aimed to determine the conceptual framework of potential factors that influence compliance. STUDY DESIGN: This was a cross-sectional study. METHODS: Questionnaires were used to survey population attitudes toward vaccination and NPIs in China. Confirmatory factor analysis of the survey data by structural equation model was used to define the pros and cons factors of attitudes. The strength and direction of each factor's effect on population attitudes were illustrated by Bayesian network analysis. RESULTS: A total of 1700 respondents aged 18-70 years were surveyed with a panel of 34 questionnaires. Of these questionnaires, the confirmatory factor and structural equation model analysis identified five categories contributing to positive attitudes, including response efficiency, willingness and behavior, trust, cues to action, and knowledge, as well as four categories contributing to negative attitudes, including autonomy, perceived barriers, threat, and mental status. Bayesian networks revealed that cues to action produced a driving force for positive attitudes, followed by willingness and behavior, trust, response efficiency, and knowledge, whereas perceived barriers produced a driving force for negative attitudes, followed by autonomy and threat. CONCLUSIONS: This study established a concise and representative list of questionnaires

that could be applied to investigate the conceptual framework of potential pros and cons factors of attitudes toward vaccination and NPIs for COVID-19 prevention. The factors with driving forces should be addressed with a priority to effectively improve population compliance.
Immune response to SARS-CoV-2 Omicron variant in patients and vaccinees following homologous and heterologous vaccinations. The SARS-CoV-2 Omicron variant has rapidly replaced the Delta variant of concern. This new variant harbors worrisome mutations on the spike protein, which are able to escape the immunity elicited by vaccination and/or natural infection. To evaluate the impact and susceptibility of different serum samples to the Omicron variant BA.1, samples from COVID-19 patients and vaccinated individuals were tested for their ability to bind and neutralize the original SARS-CoV-2 virus and the Omicron variant BA.1. COVID-19 patients show the most drastic reduction in Omicron-specific antibody response in comparison with the response to the wild-type virus. Antibodies elicited by a triple homologous/heterologous vaccination regimen or following natural SARS-CoV-2 infection combined with a two-dose vaccine course, result in highest neutralization capacity against the Omicron variant BA.1. Overall, these findings confirm that vaccination of COVID-19 survivors and booster dose to vaccinees with mRNA vaccines is the correct strategy to enhance the antibody cross-protection against Omicron variant BA.1.
Elevated serum IgA following vaccination against SARS-CoV-2 in a cohort of high-risk first responders. IgA plays an important early neutralizing role after SARS-CoV-2 infection. Systemically administered vaccines typically produce an IgM/IgG predominant response. We evaluated the serum anti-spike (anti-S) IgG, anti-nucleocapsid (anti-N) IgG and anti-S IgA response following vaccination against SARS-CoV-2 in a cohort of first-responders. Among the 378 completely vaccinated participants, 98% were positive for anti-S IgG and 96% were positive for anti-S IgA. Nine percent were positive for anti-N IgG suggesting prior exposure to SARS-CoV-2. No statistically significant difference was seen in IgA response based on prior evidence infection (pâ€‰=â€‰0.18). Ninety-eight of those receiving the Moderna vaccine (98%) were positive for anti-S IgA as compared to 91% of those who received the Pfizer vaccine (pâ€‰=â€‰0.0009). The high proportion of participants observed to have a positive anti-S IgA response after vaccination suggests that the vaccines elicit a systemic response characterized by elevated levels of both IgG and IgA.
Intranasal immunization with recombinant Vaccinia virus encoding trimeric SARS-CoV-2 spike receptor-binding domain induces neutralizing antibody. Respiratory transmission of SARS-CoV-2 is considered to be the major dissemination route for COVID-19, therefore, mucosal immune responses have great importance in preventing SARS-CoV-2 from infection. In this study, we constructed a recombinant Vaccinia virus (VV) harboring trimeric receptor-binding domain (RBD) of SARS-CoV-2 spike protein (VV(-tRBD)), and evaluated the immune responses towards RBD following intranasal immunization against mice and rabbits. In BALB/c mice, intranasal immunization with VV(-tRBD) elicited robust humoral and cellular immune responses, with high-level of both neutralizing IgG and IgA in sera against SARS-CoV-2 psudoviruses, and a number of RBD-specific IFN-Î³-secreting lymphocytes. Sera from immunized rabbits also exhibited neutralization effects. Notably, RBD-specific secretory IgA (sIgA) in both nasal washes and bronchoalveolar lavage fluids (BALs) were detectable and showed substantial neutralization activities. Collectively, a recombinant VV expressing trimeric RBD confers robust systemic immune response and mucosal neutralizing antibodies, thus warranting further exploration as a mucosal vaccine.
Erratum to: "Microvascular manifestations revealing vaccine-induced thrombotic thrombocytopenia after COVID-19 vaccination" [J. Med. Vasc. 47 (2022) 36-38].
To vaccinate or not to vaccinate - BNT162b2 seroconversion rate and side effects among Polish healthcare workers. OBJECTIVES: The study aimed to analyze the effect of BNT162b2 vaccination among Polish healthcare workers in terms of serologic response and adverse events. MATERIAL AND

METHODS: A questionnaire survey covered data in the period January 1-March 31, 2021 gathered in 2 hospitals in Wielkopolska, Poland. Additionally, serological analysis (SARS-CoV-2 anti-S protein IgG) was performed. RESULTS: A total of 617 medical workers were vaccinated with BNT162b2 (Comirnaty, Pfizer). Data from the questionnaires were received from all of the staff after the first and the second dose. No severe side effects were observed. The most common side effect following the first and second doses of vaccination was pain at the injection site. After the first dose, 3 (1.4 %) women aged 18-55 years, 5 women (3.9 %), and 3 men (8.3 %) aged >55 years had negative SARS-CoV-2 anti-S protein IgG result. After the second dose, all those who agreed to have antibodies tested responded to vaccination with positive SARS-CoV-2 anti-S protein IgG results. CONCLUSIONS: Vaccination tolerance was good in the studied population; no severe side effects were observed. After the second dose, all tested healthcare workers responded to vaccination with antibody production. Int J Occup Med Environ Health. 2022;35(6):761-66.

Vaccine-Induced Myocarditis: Correspondence.

Antigen presentation dynamics shape the response to emergent variants like SARS-CoV-2 Omicron strain after multiple vaccinations with wild type strain. The Omicron variant of SARS-CoV-2 evades neutralization by most serum antibodies elicited by two doses of mRNA vaccines, but a third dose of the same vaccine increases anti-Omicron neutralizing antibodies. By combining computational modeling with data from vaccinated humans we reveal mechanisms underlying this observation. After the first dose, limited antigen availability in germinal centers results in a response dominated by B cells with high germline affinities for immunodominant epitopes that are significantly mutated in an Omicron-like variant. After the second dose, expansion of these memory cells and differentiation into plasma cells shape antibody responses that are thus ineffective for such variants. However, in secondary germinal centers, pre-existing higher affinity antibodies mediate enhanced antigen presentation and they can also partially mask dominant epitopes. These effects generate memory B cells that target subdominant epitopes that are less mutated in Omicron. The third dose expands these cells and boosts anti-variant neutralizing antibodies.

Gaps between official and excess Covid-19 mortality measures: The effects of institutional quality and vaccinations. We evaluate quartile rankings of countries during the Covid-19 pandemic using both official (confirmed) and excess mortality data. By December 2021, the quartile rankings of three-fifths of the countries differ when ranked by excess vs. official mortality. Countries that are 'doing substantially better' in the excess mortality are characterized by higher urban population shares; higher GDP/Capita; and higher scores on institutional and policy variables. We perform two regressions in which the ratio of Cumulative Excess to Official Covid-19 mortalities (E/O ratio) is regressed on covariates. In a narrow study, controlling for GDP/Capita and vaccination rates, by December 2021 the E/O ratio was smaller in countries with higher vaccination rates. In a broad study, adding institutional and policy variables, the E/O ratio was smaller in countries with higher degree of voice and accountability. The arrival of vaccines in 2021 and voice and accountability had a discernible association on the E/O ratio.

De novo psoriasis induced by ChAdOx1-S COVID 19 vaccine.

Venous Thromboembolism following Two Doses of COVID-19 mRNA Vaccines in the US Population, 2020-2022. The COVID-19 mRNA vaccine is one of the most effective strategies used to fight against COVID-19. Recently, venous thromboembolism (VTE) events after COVID-19 mRNA vaccination have been reported in various research. Such a concern may hamper the ongoing COVID-19 vaccination campaign. Based on the US Vaccine Adverse Event Reporting System data, this modified self-controlled case series study investigated the association of COVID-19 mRNA vaccination with VTE events among US adults. We found the VTE incidence rate in the recommended dose interval does not change significantly after receiving COVID-19 mRNA vaccines. This conclusion still

holds if the analysis is stratified by age and gender. The VTE onset may not be significantly associated with COVID-19 mRNA vaccination.

Use of a Practitioner-Friendly Behavior Model to Identify Factors Associated with COVID-19 Vaccination and Other Behaviors. The lack of capacity for the design and implementation of behavioral interventions in low-and-middle income countries (LMICs) has been recognized by the World Health Organization (WHO) and other global health institutions. There is a need to task-shift, to translate social and behavioral science concepts into "practitioner-friendly" models-models which can be used by intervention designers, implementers, and evaluators with limited technical and financial resources. We illustrate the use of the Fogg Behavior Model (FBM), a model identified as being easy for practitioners to adopt in low-resource settings. The study uses data across four different behaviors in Nigeria, Pakistan, and India. The behaviors examined are COVID-19 vaccine uptake, condom use, iron folate use, and modern contraceptive use. The data are from surveys of healthcare workers (HCWs), married men, women of reproductive age, and adolescents, respectively. The FBM states that behavior happens when both motivation and ability are present, and a prompt occurs. In other words, persons with high motivation and high ability are the first to adopt a behavior. We created a categorical variable for motivation and ability and tested whether high motivation and high ability are associated with a greater likelihood of adopting a behavior. In Nigeria, HCWs with high motivation and high ability had 27 times higher odds of being vaccinated. In Pakistan, married men with high motivation and high ability had 35 times higher odds of condom use with their wives. In India, women with high motivation and high ability had 9 times higher odds of iron folate use. In Nigeria, adolescents and young women with high motivation and high ability had 8 times higher odds of contraceptive use. The study findings suggest that the FBM has the potential to be applied in low resource settings for the design, implementation, and evaluation of behavioral interventions. Rigorous testing of the FBM using data from experimental or quasi-experimental studies is recommended.

Correlation between Adverse Events and Antibody Titers among Healthcare Workers Vaccinated with BNT162b2 mRNA COVID-19 Vaccine. Objectives: The BNT162b2 mRNA COVID-19 vaccine has been found to be highly effective in preventing COVID-19 but is associated with increased reactogenicity. We aimed to examine the correlation between immunogenicity and reactogenicity of the BNT162b2 vaccine. Methods: Subjects without prior SARS-CoV-2 infection that participated in active surveillance after being vaccinated with the BNT162b2 vaccine were included. Study participants reported adverse drug reactions (ADRs) through questionnaires administered by text message after receiving each dose of the vaccine. A reactogenicity score was developed based on the type and duration of ADRs. In addition, anti-receptor binding domain (RBD) levels and neutralization assays were performed 7âˆ’21 and 7âˆ’38 days after the first and second vaccine doses, respectively. Associations between ADRs and antibody levels were assessed by Spearman correlations. Multivariable logistic regression analyses were used to identify factors associated with ADRs. Results: A total of 831 health care workers were included. The mean age was 46.5 years (SD = 11.8) and 75.5% were females. 83.4% and 83.3% had at least one local ADR after the first and second doses, respectively. 33% and 83.2% had at least one systemic ADR after the first and second doses, respectively. Multivariate logistic regression analysis found a significant correlation between ADR score and anti-RBD-IgG titers ($r = 0.366$; $p < 0.0001$) after adjustment for age, gender, and days after the second vaccination. High anti-RBD-IgG levels, being younger than 55 and being female, were all correlated with increased rates of ADRs. Conclusion: BNT162b2 mRNA COVID-19 vaccine reactogenicity appears to be correlated with higher post-vaccination antibody levels and is independently associated with younger age and female gender.

Distrustful, Dissatisfied, and Conspiratorial: A Latent Profile Analysis of COVID-19 Vaccination Rejection. Trust in science and scientists, satisfaction with the national government, and endorsement of conspiracy theories are important factors in the decision to be vaccinated. In this study, we investigated whether there are different profiles of individuals depending on the above factors and whether they differ in their sociodemographic composition. We used data from Round 10 of the European Social Survey for Slovenia, employing a nationally representative sample of 1252 participants. Based on latent profile analysis, three distinct profiles emerged: Profile 1 expressed moderate trust in science, satisfaction with government, and high endorsement of conspiracies; Profile 2 expressed low trust and satisfaction and moderate endorsement of conspiracies; Profile 3 expressed high trust and satisfaction and low beliefs in conspiracy theories. In addition, Profile 3 expressed the strongest support for vaccination and Profile 2 the lowest. Our results suggest that distrust, dissatisfaction, and the presence of conspiracy theories are the "perfect storm" for vaccination rejection. In contrast, despite conspiracy theories, a certain level of trust and satisfaction may reduce vaccination rejection.
Uncoupling of all-cause excess mortality from COVID-19 cases in a highly vaccinated state.
T-Cell Assay after COVID-19 Vaccination Could Be a Useful Tool? A Pilot Study on Interferon-Gamma Release Assay in Healthcare Workers. Background: SARS-CoV-2 T-cells are crucial for long-term protection against reinfection. The aim was to demonstrate the Interferon-gamma Release Assay (IGRA) test could be useful for vaccination monitoring. Methods: In a prospective cohort of 98 vaccinated healthcare workers for SARS-CoV-2, we selected 23 people in low-antibodies (Group 1, N = 8), high-antibodies (Group 2, N = 9), and negative control groups (Group 3, N = 6). SARS-CoV-2-specific humoral and cellular responses were analyzed at 8 months after two doses of Pfizer BioNTech, evaluating anti-RBD (Receptor Binding Domain) and RBD-ACE2 (Angiotensin Converting Enzyme-2) blocking antibodies in sera through a Chemiluminescence Immunoassay (CLIA) and T-cells through the IGRA test in heparinized plasma. Moreover, lymphocyte subtyping was executed by a flow cytometer. Statistical analysis was performed. Results: The data confirmed that RBD and RBD-ACE2 blocking ACE2 antibody levels of Group 1 were significantly lower than Group 2; $p < 0.001$. However, T-cells showed no significant difference between Group 1 and Group 2. Conclusions: This work suggests the need for new strategies for booster doses administration.
Very severe immune thrombocytopenia following SARS-CoV-2 vaccination requiring splenectomy: a case report. BACKGROUND: Some conventional vaccines have been recognized as a cause of secondary immune thrombocytopenia (ITP). According to recent publications, mRNA vaccines are probably associated with an increased risk of ITP. CASE PRESENTATION: Our patient developed severe ITP one week after the second dose of COVID-19 mRNA vaccine. Medical management was not effective, requiring splenectomy to obtain sustained remission. CONCLUSION: Considering the temporality and immunological hypothesis, we consider the vaccine to be the trigger of this ITP. To our knowledge, our case is, to date, the most severe case of ITP reported following SARS-CoV-2 vaccination and could help for the therapeutic management of similar patients.
Stevens-Johnson syndrome after ChAdOx1 nCoV-19 vaccine.
Comparative outcomes after early Sotrovimab administration in vaccinated and unvaccinated kidney transplant recipients with SARS-CoV-2 infection during the Delta and Omicron BA.1 surges.
Factors Associated With Reduced Anti-SARS-CoV-2 Antibody Responses After mRNA Vaccination in Kidney Transplant Recipients on Belatacept.
BNT162b2 booster after heterologous prime-boost vaccination induces potent neutralizing antibodies and T cell reactivity against SARS-CoV-2 Omicron BA.1 in young adults. In light of the decreasing immune protection against symptomatic SARS-CoV-2 infection after initial vaccinations and the now dominant immune-evasive Omicron variants, 'booster' vaccinations are regularly performed to

restore immune responses. Many individuals have received a primary heterologous prime-boost vaccination with long intervals between vaccinations, but the resulting long-term immunity and the effects of a subsequent 'booster', particularly against Omicron BA.1, have not been defined. We followed a cohort of 23 young adults, who received a primary heterologous ChAdOx1 nCoV-19 BNT162b2 prime-boost vaccination, over a 7-month period and analysed how they responded to a BNT162b2 'booster'. We show that already after the primary heterologous vaccination, neutralization titers against Omicron BA.1 are recognizable but that humoral and cellular immunity wanes over the course of half a year. Residual responsive memory T cells recognized spike epitopes of the early SARS-CoV-2 B.1 strain as well as the Delta and BA.1 variants of concern (VOCs). However, the remaining antibody titers hardly neutralized these VOCs. The 'booster' vaccination was well tolerated and elicited both high antibody titers and increased memory T cell responses against SARS-CoV-2 including BA.1. Strikingly, in this young heterologously vaccinated cohort the neutralizing activity after the 'booster' was almost as potent against BA.1 as against the early B.1 strain. Our results suggest that a 'booster' after heterologous vaccination results in effective immune maturation and potent protection against the Omicron BA.1 variant in young adults.
Differences in B-Cell Immunophenotypes and Neutralizing Antibodies Against SARS-CoV-2 After Administration of BNT162b2 (Pfizer-BioNTech) Vaccine in Individuals with and without Prior COVID-19 - A Prospective Cohort Study. PURPOSE: Understanding the humoral immune response dynamics carried out by B cells in COVID-19 vaccination is little explored; therefore, we analyze the changes induced in the different cellular subpopulations of B cells after vaccination with BNT162b2 (Pfizer-BioNTech). METHODS: This prospective cohort study evaluated thirty-nine immunized health workers (22 with prior COVID-19 and 17 without prior COVID-19) and ten subjects not vaccinated against SARS-CoV-2 (control group). B cell subpopulations (transitional, mature, naÃ¯ve, memory, plasmablasts, early plasmablast, and double-negative B cells) and neutralizing antibody levels were analyzed and quantified by flow cytometry and ELISA, respectively. RESULTS: The dynamics of the B cells subpopulations after vaccination showed the following pattern: the percentage of transitional B cells was higher in the prior COVID-19 group ($p < 0.05$), whereas virgin B cells were more prevalent in the group without prior COVID-19 ($p < 0.05$), mature B cells predominated in both vaccinated groups ($p < 0.01$), and memory B cells, plasmablasts, early plasmablasts, and double-negative B cells were higher in the not vaccinated group ($p < 0.05$). CONCLUSION: BNT162b2 vaccine induces changes in B cell subpopulations, especially generating plasma cells and producing neutralizing antibodies against SARS-CoV-2. However, the previous infection with SARS-CoV-2 does not significantly alter the dynamics of these subpopulations but induces more rapid and optimal antibody production.
An Unusual Side Effect of the COVID-19 Vaccine: A Possible Trigger of Polymyalgia Rheumatica. Polymyalgia rheumatica (PMR) is characterized by myalgia and severe stiffness with decreased range of motion in the shoulder and pelvic girdles. The efficacy of the BNT 162b2 Pfizer vaccine has been proven and has been well-tolerated by patients; however, some instances of PMR have been reported after the COVID-19 vaccine. We are writing a case of a new-onset PMR in a 72-year-old woman with typical findings after receiving a booster dose of the BNT 162b2 Pfizer vaccine. This case report highlights that PMR should be in the differential diagnosis of myalgias caused by the vaccine.
To Wait or Not to Wait?: COVID-19 Vaccination Mitigates Adverse Surgical Outcomes.
Lower vaccine-acquired immunity in the elderly population following two-dose BNT162b2 vaccination is alleviated by a third vaccine dose. Understanding the impact of age on vaccinations is essential for the design and delivery of vaccines against SARS-CoV-2. Here, we present findings from a comprehensive analysis of multiple compartments of the memory immune response in 312 individuals vaccinated with the BNT162b2 SARS-CoV-2 mRNA vaccine. Two vaccine doses induce high antibody and T cell responses in most individuals. However, antibody recognition of the Spike protein

of the Delta and Omicron variants is less efficient than that of the ancestral Wuhan strain. Age-stratified analyses identify a group of low antibody responders where individuals â‰¥60â€‰years are overrepresented. Waning of the antibody and cellular responses is observed in 30% of the vaccinees after 6â€‰months. However, age does not influence the waning of these responses. Taken together, while individuals â‰¥60â€‰years old take longer to acquire vaccine-induced immunity, they develop more sustained acquired immunity at 6â€‰months post-vaccination. A third dose strongly boosts the low antibody responses in the older individuals against the ancestral Wuhan strain, Delta and Omicron variants.
Myelin-Oligodendrocyte Glycoprotein Antibody-Positive Longitudinally Extensive Transverse Myelitis following ChAdOx1-S/nCoV-19 Vaccine.
SARS-CoV-2 Spike Protein Vaccine-Induced Immune Imprinting Reduces Nucleocapsid Protein Antibody Response in SARS-CoV-2 Infection. Immune imprinting or original antigenic sin (OAS) is the process by which the humoral memory response to an antigen can inhibit the response to new epitopes of that antigen originating from a second encounter with the pathogen. Given the situation of the COVID-19 pandemic, multiple vaccines have been developed against SARS-CoV-2 infection. These vaccines are directed to the spike protein (S protein) of the original variant of Wuhan D614G. Vaccine memory immune response against S protein in noninfected subjects could inhibit, through the OAS mechanism, the response to new epitopes of SARS-CoV-2 after infection. The present study analyzes whether the memory antibody B cell response generated by mRNA vaccines against S protein can inhibit the primary antibody immune response to other SARS-CoV-2 antigens, such as nucleocapsid protein (N protein). SARS-CoV-2 primary infection in vaccinated healthcare workers (HCWs) produced significantly lower titers of anti-N antibodies than that in nonvaccinated HCWs: 5.7 (IQR 2.3-15.2) versus 12.2 (IQR 4.2-32.0), respectively (p = 0.005). Therefore, spike protein vaccine-induced immune imprinting (original antigenic sin) reduces N protein antibody response.
Delayed kinetics of SARS-CoV-2 IgG antibody production in kidney transplant recipients following the third dose of COVID-19 vaccination.
Humoral and cellular response before and after the fourth BNT162b2 vaccine dose in patients with solid tumors on active treatment.
B-cell-guided strategy for SARS-CoV2 vaccination after autologous stem cell transplantation for B-cell lymphoma - a case report.
Portal vein thrombosis as a thrombotic complication of COVID-19 mRNA vaccine: A case report and literature review. Thrombosis following COVID-19 vaccination commonly occurs with vector-based vaccines. The proposed mechanism is vaccine-induced thrombotic thrombocytopenia (VITT), with thrombocytopenia as principal manifestation. We present a 51-year-old male who came with isolated portal vein thrombosis (PVT) one day after Moderna vaccination, without associated thrombocytopenia, challenging VITT as being the only patho-mechanism. Further exploration of these possible alternative mechanisms is needed for COVID-19 vaccine-related thrombotic complications.
Another Case of Bell's Palsy Recurrence After Pfizer-BioNTech COVID-19 Vaccination. Twenty-seven months into the current pandemic and 18 months after vaccinations were made available, there are still relatively limited data on the incidence of recurrent Bell's Palsy after the administration of mRNA-based vaccines. The authors continue to believe that it is through rigorous reporting that the true incidence can be tabulated eventually.
[Venous thrombosis after Covid-19 vaccination].
Reactogenicity of mRNA- and Non-mRNA-Based COVID-19 Vaccines among Lactating Mother and Child Dyads. The aims of the study are to: (a) Describe the reactogenicity of WHO-approved two mRNA (Pfizer-BioNTech, Moderna) and two non-RNA (Oxford-AstraZeneca, Sinovac) vaccines among lactating mother and child pairs, and (b) Compare and contrast the reactogenicity between mRNA

and non-mRNA vaccines. A cross-sectional, self-reported survey was conducted amongst 1784 lactating women who received COVID-19 vaccinations. The most common maternal adverse reaction was a local reaction at the injection site, and the largest minority of respondents, 49.6% (780/1571), reported experiencing worse symptoms when receiving the second dose compared to the first dose. Respondents reported no major adverse effects or behavioural changes in the breastfed children for the duration of the study period. Among respondents who received non-mRNA COVID-19 vaccines, a majority reported no change in lactation, but those who did more commonly reported changes in the quantity of milk supply and pain in the breast. The more commonly reported lactation changes (fluctuations in breast milk supply quantity and pain in the breast) for the non-mRNA vaccines were similar to those of respondents who received mRNA vaccines. Our study, with a large, racially diverse cohort, further augments earlier reported findings in that the COVID-19 vaccines tested in this study did not cause any serious adverse events in our population for the duration of our survey period, although long-term effects are yet to be studied.
Pityriasis lichenoides chronica induced by COVID-19 messenger RNA vaccination.
Rare Adverse Event after CoronaVac(Â®) Administration: Neutropenia in a Kidney Transplant Recipient.
Prospective, Case-Control Study of Serological Response after Two Doses of BNT162b2 anti-SARS-CoV-2 mRNA Vaccine in Transfusion-Dependent Thalassemic Patients.
Persistent Maintenance of Intermediate Memory B Cells Following SARS-CoV-2 Infection and Vaccination Recall Response. Robust population-wide immunity will help to curb the SARS-CoV-2 pandemics. To maintain the immunity at protective levels, the quality and persistence of the immune response elicited by infection or vaccination must be determined. We analyzed the dynamics of B cell response during 12â€‰months following SARS-CoV-2 infection on an individual level. In contrast to antibodies, memory B cells specific for the spike (S) protein persisted at high levels throughout the period. These cells efficiently secreted neutralizing antibodies and correlated with IFN-Î³-secreting CD4(+) T cells. Interestingly, the CD27(-)CD21(+) intermediate memory B cell phenotype was associated with high B cell receptor avidity and the production of neutralizing antibodies. Vaccination of previously infected individuals triggered a recall response enhancing neutralizing antibody and memory B cell levels. Collectively, our findings provide a detailed insight into the longevity of SARS-CoV-2-infection-induced B cell immunity and highlight the importance of vaccination among previously infected. IMPORTANCE To efficiently maintain immunity against SARS-CoV-2 infection, we must first determine the durability of the immune response following infection or vaccination. Here, we demonstrated that, unlike antibodies, virus-specific memory B cells persist at high levels for at least 12â€‰months postinfection and successfully respond to a secondary antigen challenge. Furthermore, we demonstrated that vaccination of previously infected individuals significantly boosters B cell immunity.
Vaccine-induced spike- and nucleocapsid-specific cellular responses maintain potent cross-reactivity to SARS-CoV-2 Delta and Omicron variants. Cell-mediated immunity may contribute to providing protection against SARS-CoV-2 and its variants of concern (VOC). We developed COH04S1, a synthetic multiantigen modified vaccinia Ankara (MVA)-based COVID-19 vaccine that stimulated potent spike (S)Â and nucleocapsid (N)Â antigen-specific humoral and cellular immunity in a phase 1 clinical trial in healthy adults. Here, we show that individuals vaccinated with COH04S1 or mRNA vaccine BNT162b2 maintain robust cross-reactive cellular immunity for six or more months post-vaccination. Although neutralizing antibodies induced in COH04S1- and BNT162b2-vaccinees showed reduced activity against Delta and Omicron variants compared to ancestral SARS-CoV-2, S-specific TÂ cells elicited in both COH04S1- and BNT162b2-vaccinees and N-specific TÂ cells elicited in COH04S1-vaccinees demonstrated potent and equivalent cross-reactivity against ancestral SARS-CoV-2 and the major

VOC. These results suggest that vaccine-induced TÂ cells to S and N antigens may constitute a critical second line of defense to provide long-term protection against SARS-CoV-2 VOC.

Association between IgG antibody levels and adverse events after first and second Bnt162b2 mRNA vaccine doses. OBJECTIVES: This study sought to correlate the SARS-CoV-2 IgG antibody response level to the BNT162b2 (Pfizer BioNTech) mRNA vaccine after the first and second doses with the reported adverse events. METHODS: This cohort study examined the adverse events profiles of people vaccinated with BNT162b2 in our institute between late 2020 and May 2021. Adverse events, age, and sex were reported using an electronic questionnaire, and their SARS-CoV-2 IgG antibody levels were retrieved from the hospital database. RESULTS: Between 20 December 2020 and 31 May 2021, the adverse events questionnaire was completed by 9700 individuals who received the first vaccine dose and 8321 who received the second dose. After the first and second doses, the average antibody levels were 62.34 AU/mL (mean 4-373) and 188.19 AU/mL (mean 20-392), respectively. All of the adverse events, except local pain, were more common after the second vaccine dose. Multivariate analysis showed that after the first vaccine dose, female sex and younger age (but not IgG titres) were associated with a higher probability of adverse events (OR 2.377, 95% CI, 1.607-3.515, pÂ =Â 0.000; OR 0.959, 95% CI, 0.944-0.977, p Â£0.000; OR 1.002, 95% CI, 0.995-1.008, p Â£0.601; respectively); however, all three parameters were associated with the incidence of adverse events after the second dose (OR 2.332, 95% CI, 1.636-3.322, pÂ =Â 0.000; OR 0.984, 95% CI, 0.970-0.999, p Â£0.039; OR 1.004, 95% CI, 1.001-1.007, p Â£0.022; respectively). DISCUSSION: Adverse events are significantly more common after the second BNT162b2 vaccine dose than after the first dose. We found an association between sex, age, and SARS-CoV-2 IgG antibody titre with the incidence of adverse events.

The generation of stem cell-like memory cells early after BNT162b2 vaccination is associated with durability of memory CD8(+) TÂ cell responses. COVID-19 vaccines elicit humoral and cellular immune responses. Durable maintenance of vaccine-induced immunity is required for long-term protection of the host. Here, we examine activation and differentiation of vaccine-induced CD8(+) TÂ cells using MHC class I (MHC-I) multimers and correlations between early differentiation and the durability of CD8(+) TÂ cell responses among healthcare workers immunized with two doses of BNT162b2. The frequency of MHC-I multimer(+) cells is robustly increased by BNT162b2 but decreases 6Â months post-second vaccination to 2.4%-65.6% (23.0% on average) of the peak. MHC-I multimer(+) cells dominantly exhibit phenotypes of activated effector cells 1-2Â weeks post-second vaccination and gradually acquire phenotypes of long-term memory cells, including stem cell-like memory T (T(SCM)) cells. Importantly, the frequency of T(SCM) cells 1-2Â weeks post-second vaccination significantly correlates with the 6-month durability of CD8(+) TÂ cells, indicating that early generation of T(SCM) cells determines the longevity of vaccine-induced memory CD8(+) TÂ cell responses.

Systemic Vasculitis Following SARS-CoV-2 mRNA Vaccination Demonstrated on FDG PET/CT: Reply.

Humoral and cellular immune responses to CoronaVac assessed up to one year after vaccination. BACKGROUND: The Sinovac SARS-CoV-2 inactivated vaccine (CoronaVac) has been demonstrated to be safe, well tolerated, and efficacious in preventing mild and severe Covid-19. Although different studies have demonstrated its short-term immunogenicity, long-term cellular and humoral response evaluations are still lacking. METHODS: Cellular and humoral responses were assessed after enrollment of volunteers in the PROFISCOV phase 3 double-blind, randomized, placebo-controlled clinical trial to evaluate CoronaVac. Assays were performed using flow cytometry to evaluate cellular immune response and an antigen binding electrochemiluminescence assay to detect antigen-specific antibodies to the virus. RESULTS: Fifty-three volunteers were selected for long term assessment of their SARS-CoV-2-specific immune responses. CD4 (+) T cell responses (including circulating follicular

helper (cTfh, CD45RA (-) CXCR5 (+)) expressing CD40L, as well as non-cTfh cells expressing CXCR3) were observed early upon the first vaccine dose, increased after the second dose, remaining stable for 6-months. Memory CD4 (+) T cells were detected in almost all vaccinees, the majority being central memory T cells. IgG levels against Wuhan/WH04/2020 N, S and receptor binding domain (RBD) antigens and the variants of concern (VOCs, including B.1.1.7/Alpha, B.1.351/Beta and P.1/Gamma) S and RBD antigens peaked 14 days after the second vaccine shot, and were mostly stable for a 1-year period. CONCLUSIONS: CoronaVac two-doses regimen is able to induce a potent and durable SARS-CoV-2 specific cellular response. The cellular reaction is part of a coordinated immune response that includes high levels of specific IgG levels against parental and SARS-CoV-2 VOC strains, still detected after one year. FUNDING: FundaÃ§Ã£o Butantan, Instituto Butantan and SÃ£o Paulo Research Foundation (FAPESP) (grants 2020/10127-1 and 2020/06409-1). This work has also been supported by NIH contract 75N93019C00065 (A.S, D.W). PATH facilitated reagent donations for this work with support by the Bill & Melinda Gates Foundation (INV-021239). Under the grant conditions of the foundation, a Creative Commons Attribution 4.0 generic License has already been assigned to the Author Accepted Manuscript version that might arise from this submission.

Letter to the editor: Six-month antibody kinetics and durability in liver transplant recipients after two doses of SARS-CoV-2 mRNA vaccination. [Image: see text]

Subacute thyroiditis after SARS-CoV2 vaccine: possible relapse after boosting.

Correction: Reports of myocarditis and pericarditis following mRNA COVID-19 vaccination: a systematic review of spontaneously reported data from the UK, Europe and the USA and of the scientific literature.

Changes in interferon-Î³ release assay readout after COVID-19 vaccination: A prospective cohort study. OBJECTIVES: Interferon-Î³ release assays (IGRAs) are widely used in public health practice to diagnose latent tuberculosis. During the COVID-19 pandemic and rollout of COVID-19 vaccination, it has remained unclear whether COVID-19 vaccines interfere with IGRA readouts. METHODS: We prospectively recruited healthcare workers during their annual occupational health examinations in 2021. Baseline IGRA readouts were compared with follow-up data after the participants had received two doses of COVID-19 vaccination. RESULTS: A total of 134 baseline IGRA-negative cases (92 with ChAdOx1 vaccine, 27 with mRNA-1273 vaccine, and 15 with heterologous vaccination) and seven baseline IGRA-positive cases were analyzed. Among the baseline IGRA-negative cases, there were decreased interferon-Î³ concentrations over the Nil (PÂ =Â 0.005) and increased Mitogen-Nil (P < 0.001) values after vaccination. For TB2-Nil value, a similar trend (PÂ =Â 0.057) of increase was observed. Compared with the 0.35 IU/ml threshold, the baseline and follow-up readout differences were less than |Â± 0.10| IU/ml over the TB1-Nil and TB2-Nil values in >90% baseline IGRA-negative cases. No significant readout difference was observed among baseline IGRA-positive cases. CONCLUSION: COVID-19 vaccination did not change IGRA interpretation in most cases. Cases showing conversion/borderline IGRA readouts should be given special consideration.

Neurological Side Effects of SARS-CoV-2 Vaccinations are Not Uncommon but Frequently Ignored [Letter].

Booster dose of BNT162b2 after two doses of CoronaVac improves neutralization of SARS-CoV-2 Omicron variant. BACKGROUND: The emergence of the new SARS-CoV-2 Omicron variant, which is known to have a large number of mutations when compared to other variants, brought to light the concern about vaccine escape, especially from the neutralization by antibodies induced by vaccination. METHODS: Based on viral microneutralization assays, we evaluated in 90 individuals the impact on antibody neutralization induction, against Omicron variant, by a booster dose of BNT162b2 mRNA vaccine after the CoronaVac primary vaccination scheme. RESULTS: Here we show that the percentage of seroconverted individuals 30 and 60 days after CoronaVac scheme was 16.6% and 10%,

respectively. After booster dose administration, the seroconvertion rate increased to 76.6%. The neutralization mean titer against Omicron in the CoronaVac protocol decreased over time, but after the booster dose, the mean titer increased 43.1 times. CONCLUSIONS: These results indicate a positive impact of this vaccine combination in the serological immune response against SARS-CoV-2 Omicron variant.

How Were Healthcare Workers after Anti-SARS-CoV-2 Vaccination? A Study of the Emotional Side Effects of Vaccination. Anti-SARS-CoV-2 vaccines appear to be the only escape from the COVID-19 pandemic. As healthcare workers were among the first in society to be vaccinated, understanding their emotional status post-vaccination is fundamental to the promotion of COVID-19 vaccines among the rest of society. The aims of this study were to investigate the predictors of positive and negative emotions experienced by healthcare workers after being vaccinated and to understand whether those emotions were related to the modalities of vaccine promotion within the community. A cohort of 5790 Italian healthcare workers completed an original online survey regarding their experience with anti-SARS-CoV-2 vaccines and reported on a series of personal and environmental factors. The data obtained show that increased risk perception of COVID-19, vaccine confidence and receipt of greater quantities of information regarding vaccines are predictors of a more positive emotional state post-vaccination. Predictors of a more negative emotional state are older age, lower education, lower confidence and receipt of smaller quantities of information, in addition to neurotic personality traits and high risk perception of COVID-19. Importantly, vaccination promotion may be favoured by a happy emotional status after vaccination. This study can serve as a source of guidelines for the promotion of COVID-19 vaccination among healthcare workers and laypeople.

NMOSD typical brain lesions after COVID-19 mRNA vaccination.

RelCoVaxÂ®, a two antigen subunit protein vaccine candidate against SARS-CoV-2 induces strong immune responses in mice. The COVID-19 pandemic has spurred an unprecedented movement to develop safe and effective vaccines against the SARS-CoV-2 virus to immunize the global population. The first set of vaccine candidates that received emergency use authorization targeted the spike (S) glycoprotein of the SARS-CoV-2 virus that enables virus entry into cells via the receptor binding domain (RBD). Recently, multiple variants of SARS-CoV-2 have emerged with mutations in S protein and the ability to evade neutralizing antibodies in vaccinated individuals. We have developed a dual RBD and nucleocapsid (N) subunit protein vaccine candidate named RelCoVaxÂ® through heterologous expression in mammalian cells (RBD) and E. coli (N). The RelCoVaxÂ® formulation containing a combination of aluminum hydroxide (alum) and a synthetic CpG oligonucleotide as adjuvants elicited high antibody titers against RBD and N proteins in mice after a prime and boost dose regimen administered 2Â weeks apart. The vaccine also stimulated cellular immune responses with a potential Th1 bias as evidenced by increased IFN-Î³ release by splenocytes from immunized mice upon antigen exposure particularly N protein. Finally, the serum of mice immunized with RelCoVaxÂ® demonstrated the ability to neutralize two different SARS-CoV-2 viral strains in vitro including the Delta strain that has become dominant in many regions of the world and can evade vaccine induced neutralizing antibodies. These results warrant further evaluation of RelCoVaxÂ® through advanced studies and contribute towards enhancing our understanding of multicomponent subunit vaccine candidates against SARS-CoV-2.

Differences in SARS-CoV-2-Specific Antibody Responses After the First, Second, and Third Doses of BNT162b2 in NaÃ¯ve and Previously Infected Individuals: A 1-Year Observational Study in Healthcare Professionals. BACKGROUND: Safe and effective vaccines against COVID-19 are critical for preventing the spread of SARS-CoV-2, but little is known about the humoral immune response more than 9 months after vaccination. We aimed to assess the humoral immune response after the first,

second, and third (booster) doses of BNT162b2 vaccine in SARS-CoV-2 naÃ¯ve and previously infected healthcare professionals (HCP) and the humoral immune response after infection in vaccinated HCP. METHODS: We measured anti-spike (anti-S) and anti-nucleocapsid antibodies at different time points up to 12 months in the sera of 300 HCP who had received two or three doses of BNT162b2 vaccine. Mixed-model analyses were used to assess anti-S antibody dynamics and to determine their predictors (age, sex, BMI, and previous infection). RESULTS: NaÃ¯ve individuals had statistically lower anti-S antibody concentrations after the first dose (median 253 BAU/ml) than previously infected individuals (median 3648 BAU/ml). After the second dose, anti-S antibody concentrations increased in naÃ¯ve individuals (median 3216 BAU/ml), whereas the second dose did not significantly increase concentrations in previously infected individuals (median 4503 BAU/ml). The third dose resulted in an additional increase in concentrations (median 4844 BAU/ml in naÃ¯ve and median 5845 BAU/ml in previously infected individuals). Anti-S antibody concentrations steadily decreased after the second dose and after the third dose in naÃ¯ve and previously infected individuals. In addition, we found that age had an effect on the humoral immune response. Younger individuals had higher anti-S antibody concentrations after the first and second doses. After infection with the new variant Omicron, a further increase in anti-S antibody concentrations to a median value of 4794 BAU/ml was observed in three times vaccinated HCP whose anti-S antibody concentrations were relatively high before infection (median 2141 BAU/ml). Our study also showed that individuals with systemic adverse events achieved higher anti-S antibody concentrations. CONCLUSION: In this study, significant differences in humoral immune responses to BNT162b2 vaccine were observed between naÃ¯ve and previously infected individuals, with age playing an important role, suggesting that a modified vaccination schedule should be practiced in previously infected individuals. In addition, we showed that the high anti-S antibodies were not protective against new variants of SARS-CoV-2.

CMV Infection Following mRNA SARS-CoV-2 Vaccination in Solid Organ Transplant Recipients.

Immunologic Responses After COVID-19 Vaccination in Patients With Membranous Nephropathy Receiving Anti-CD38 Felzartamab Therapy: Results From the Phase 1b/2a M-PLACE Study.

[Menstrual abnormalities after COVID-19 vaccination].

Immune thrombocytopenia following ChAdOx1 vaccine and positive rechallenge with BNT162b2 vaccine: A case report with pharmacovigilance analysis.

SARS-CoV-2 antibody response after BNT162b2 mRNA vaccine in healthcare workers: Nine-month of follow-up. We collected sequential serum samples (0, 4, 12Â weeks, 9Â months) for the determination of S-RDB IgG levels from 103 vaccinated healthy subjects (age 45Â Â±Â 13Â years; 60 women), in order to evaluate neutralizing antibody response against SARS-CoV-2 in healthy healthcare workers (HCWs) after the administration of two doses of BNT162b2 SARS-CoV-2 mRNA vaccine. Every subject received two doses of mRNA vaccine BNT162b2 (Pfizer-BioNTech), 21Â days apart (January-February 2021). Furthermore, antibody titer of 14 subjects who were hospitalized for symptomatic COVID-19 was evaluated. Antibody response was (median, interquartile range) 35 U/mL (10-104) at baseline, 1960 (1241-3221) at 4Â weeks, 791 (388-1179) at 12Â weeks and 524 (273-931) at 6Â months. Antibody response was inversely correlated with age at all timepoints (pÂ <Â 0.001) while gender and Body Mass Index had no significant effect. At multivariate analysis, post-baseline values were significantly higher than baseline (pÂ <Â 0.001) with a reduction at 12Â weeks and 9Â months (pÂ <Â 0.001). Antibody response of hospitalized subjects who did not receive vaccination, symptomatic for COVID 19 infection, was 103 (25-557) U/mL, significantly higher than baseline (pÂ =Â 0.007) of study population but lower than all post-baseline determinations (pÂ <Â 0.001). Younger subjects showed a stronger response and a lower decrease of antibody titers compared to the classes of older subjects. SARS-CoV2 infection was excluded by performing 1017 nasopharyngeal RT-PCR swabs on the study cohort. The second dose of mRNA vaccine resulted in an antibody

response effective in preventing infection in a population of healthcare professionals. The antibody level was stable through week 12, showing a reduction in the following six months.

Durable antibody responses elicited by 1 dose of Ad26.COV2.S and substantial increase after boosting: 2 randomized clinical trials. BACKGROUND: Ad26.COV2.S is a well-tolerated and effective vaccine against COVID-19. We evaluated durability of anti-SARS-CoV-2 antibodies elicited by single-dose Ad26.COV2.S and the impact of boosting. METHODS: In randomized, double-blind, placebo-controlled, phase 1/2a and phase 2 trials, participants received single-dose Ad26.COV2.S (5Â Ã—Â 10(10) viral particles [vp]) followed by booster doses of 5Â Ã—Â 10(10) vp or 1.25Â Ã—Â 10(10) vp. Neutralizing antibody levels were determined by a virus neutralization assay (VNA) approximately 8-9Â months after dose 1. Binding and neutralizing antibody levels were evaluated by an enzyme-linked immunosorbent assay and pseudotyped VNA 6Â months after dose 1 and 7 and 28Â days after boosting. RESULTS: Data were analyzed from phase 1/2a participants enrolled from 22 July-18 December 2020 (Cohort 1a, 18-55Â years [y], NÂ =Â 25; Cohort 2a, 18-55y, NÂ =Â 17; Cohort 3, â‰¥65y, NÂ =Â 22), and phase 2 participants from 14 to 22 September 2020 (18-55y andÂ â‰¥Â 65y, NÂ =Â 73). Single-dose Ad26.COV2.S elicited stable neutralizing antibodies for at least 8-9Â months and stable binding antibodies for at least 6Â months, irrespective of age. A 5Â Ã—Â 10(10) vp 2-month booster dose increased binding antibodies by 4.9- to 6.2-fold 14Â days post-boost versus 28Â days after initial immunization. A 6-month booster elicited a steep and robust 9-fold increase in binding antibody levels 7Â days post-boost. A 5.0-fold increase in neutralizing antibodies was observed by 28Â days post-boost for the Beta variant. A 1.25Â Ã—Â 10(10) vp 6-month booster elicited a 3.6-fold increase in binding antibody levels at 7Â days post-boost versus pre-boost, with a similar magnitude of post-boost responses in both age groups. CONCLUSIONS: Single-dose Ad26.COV2.S elicited durable antibody responses for at least 8Â months and elicited immune memory. Booster-elicited binding and neutralizing antibody responses were rapid and robust, even with a quarter vaccine dose, and stronger with a longer interval since primary vaccination. TRIAL REGISTRATION: ClinicalTrials.gov Identifier: NCT04436276, NCT04535453.

Longitudinal humoral response in MS patients treated with cladribine tablets after receiving the second and third doses of SARS-CoV-2 mRNA vaccine. BACKGROUND: Multiple sclerosis (MS) patients receive immunomodulatory treatments which can influence their ability to maintain vaccine specific serological response overtime. MS patients treated with cladribine tablets developed a positive serology response following two doses of mRNA COVID-19 vaccine. However, there is only limited data regarding the effect of cladribine tablets on long-term humoral response after the second and the third booster. METHODS: Serology response to SARS-CoV-2 was tested in healthy controls (HCs) and MS patients treated with cladribine tablets 6 and 9-12 months after the second dose, and 1 and 3-6 months following the third booster-dose of the BTN162b2 mRNA vaccine. RESULTS: Thirty-five out of 36 MS patients treated with cladribine tablets and 100% (46/46) of HCs had a positive serology response up to 10 months after the second vaccine dose. In addition, all cladribine tablets -treated MS patients (22/22) and HCs (24/24) had a positive robust serology response following the third vaccine with a positive humoral response sustain up to 6 months. One month after the third vaccine dose IgG levels were significantly lower in patients treated with cladribine tablets compared to HCs (15,598+11,313Â vs 26,394+11,335, p<0.01). Six-month post second vaccine and 3-6 months post third vaccine there was no difference in IgG levels between the groups (1088.0Â Â±Â 1072.0Â vs 1153.0Â Â±Â 997.1, pÂ =Â 0.79; 5234+4097Â vs 11,198+14,679, pÂ =Â 0.4). CONCLUSION AND RELEVANCE: MS patients treated with cladribine tablets have sustained positive vaccine specific serology response following the second and third SARS-CoV-2 vaccine dose.

Omicron BA.1 and BA.2 Neutralizing Activity Following Pre-Exposure Prophylaxis with Tixagevimab plus Cilgavimab in Vaccinated Solid Organ Transplant Recipients. Neutralizing antibody responses

are attenuated in many solid organ transplant recipients (SOTRs) despite SARS-CoV-2 vaccination. Pre-exposure prophylaxis (PrEP) with the monoclonal antibody combination Tixagevimab and Cilgavimab (T+C) might augment immunoprotection, yet activity against Omicron sublineages in vaccinated SOTRs is unknown. Vaccinated SOTRs who received 300+300mg T+C (either single dose or two 150+150mg doses) within a prospective observational cohort submitted pre- and post-injection samples between 1/10/2022-4/4/2022. Binding antibody (anti-receptor binding domain [RBD], Roche) and surrogate neutralization (%ACE2 inhibition; â‰¥20% connoting neutralizing inhibition, Meso Scale Discovery) were measured against variants including Omicron sublineages BA.1 and BA.2. Data were analyzed using the Wilcoxon matched-pairs signed-rank test and McNemar's test. Among 61 participants, median (IQR) anti-RBD increased from 424 (IQR <0.8-2322.5) to 3394.5 (IQR 1403.9-7002.5) U/ml post T+C (p<0.001). The proportion demonstrating vaccine strain neutralizing inhibition increased from 46% to 100% post-T+C (p<0.001). BA.1 neutralization was low and did not increase (8% to 16% of participants post-T+C, p=0.06). In contrast, BA.2 neutralization increased from 7% to 72% of participants post-T+C (p<0.001). T+C increased anti-RBD levels, yet BA.1 neutralizing activity was minimal. Encouragingly, BA.2 neutralization was augmented and in the current variant climate T+C PrEP may serve as a useful complement to vaccination in high-risk SOTRs.
More than myocarditis, a rare adverse effect after the ChAdOx1 vaccine.
Response to comment on: Stromal rejection in penetrating keratoplasty following COVID-19 vector vaccine (Covishield): A case report and review of literature.
Correction: The Impact of Vaccination on Incidence and Outcomes of SARS-CoV-2 Infection in Patients with Kidney Failure in Scotland.
Subacute thyroiditis after anti-SARS-CoV-2 (Ad5-nCoV) vaccine.
New-onset psoriasis after Comirnaty (BNT162b2, BioNTech/Pfizer) vaccine successfully treated with ixekizumab.
Coronavirus Vaccination and Mortality in the Omicron Outbreak in Iran: Mortality Reduction due to Attenuated Pathogenicity and Booster Vaccine Doses.
Early and Longitudinal Humoral Response to the SARS-CoV-2 mRNA BNT162b2 Vaccine in Healthcare Workers: Significance of BMI, Adipose Tissue and Muscle Mass on Long-Lasting Post-Vaccinal Immunity. BACKGROUND: This study aimed to investigate the early and longitudinal humoral response in Healthcare Workers (HCWs) after two doses of the BNT162b2 vaccine and to assess the association between metabolic and anthropometric parameters and the humoral response after vaccination. METHODS: The study included 243 fully vaccinated HCWs: 25.50% previously infected with SARS-CoV-2 (with prior history of COVID-19-PH) and 74.40%-uninfected, seronegative before the first vaccination (with no prior history of COVID-19-NPH). IgG antibodies were measured, and sera were collected: prior to the vaccination, 21 days after the first dose, and 14 days and 8 months after the second dose. RESULTS: 21 days after the first dose, 90.95% of individuals were seropositive; 14 days after the second dose, persistent immunity was observed in 99.18% HCWs, 8 months after complete vaccination-in 61.73%. Statistical analysis revealed that HCWs with PH had a greater chance of maintaining a humoral response beyond eight months after vaccination. Increased muscle mass, decreased fat mass, and younger age may positively affect long-term immunity. Smokers have a reduced chance of developing immunity compared to non-smokers. CONCLUSIONS: Fully vaccinated HCWs with PH are more likely to be seropositive than fully inoculated volunteers with NPH.
Risk of Myocarditis and Pericarditis among Young Adults following mRNA COVID-19 Vaccinations. There have been reports of cases of myocarditis and pericarditis as rare complications following mRNA COVID-19 vaccinations among young adults. While most reported cases are mild, this potential vaccine safety signal should be closely monitored. Using data from the CDC and the Vaccine Adverse Event Reporting System (VAERS), we calculated the combined reporting rate of myocarditis and

pericarditis stratified by age group, sex, vaccine dose, and manufacturer, and compared these rates to the crude background incidence rates. Compared to the general population prior to the administration of the first COVID-19 vaccines in December 2020, we identified a higher-than-expected reporting rate of myocarditis and pericarditis following mRNA vaccination; the risk was higher after a second vaccine dose, higher in males than in females, and decreased with age. The highest risk was seen in males 12-17 years of age with approximately 6 cases per 100,000 second doses. Our findings suggest an increased risk of myocarditis and pericarditis in young males following a second dose of an mRNA COVID-19 vaccine. Since these findings are based on safety signals derived from passive surveillance data, confirmatory epidemiological studies should be undertaken.

The Effect of Waning on Antibody Levels and Memory B Cell Recall following SARS-CoV-2 Infection or Vaccination. In order to longitudinally track SARS-CoV-2 antibody levels after vaccination or infection, we assessed anti-RBD antibody levels in over 1000 people and found no significant decrease in antibody levels during the first 14 months after infection in unvaccinated participants, however, a significant waning of antibody levels was observed following vaccination. Participants who were pre-immune to SARS-CoV-2 prior to vaccination seroconverted to higher antibody levels, which were maintained at higher levels than in previously infected, unvaccinated participants. Older participants exhibited lower level of antibodies after vaccination, but a higher level after infection than younger people. The rate of antibody waning was not affected by pre-immunity or age. Participants who received a third dose of an mRNA vaccine not only increased their antibody levels ~14-fold, but also had ~3 times more antibodies compared to when they received their primary vaccine series. PBMC-derived memory B cells from 13 participants who lost all circulating antibodies were differentiated into antibody secreting cells (ASCs). There was a significant recall of memory B cell ASCs in the absence of serum antibodies in 5-8 of the 10 vaccinated participants, but not in any of the 3 infected participants, suggesting a strong connection between antibody levels and the effectiveness of memory B cell recall.

Willingness to Receive a COVID-19 Vaccine and Associated Factors among Older Adults: A Cross-Sectional Survey in Shanghai, China. Background: Older individuals have a high risk of morbidity and mortality due to COVID-19, and one of the most effective ways to prevent COVID-19 is vaccination. Little is known about older peopleâ€™s willingness to receive a COVID-19 vaccine. Therefore, the objective of this study was to assess the acceptance of and factors influencing the intention to receive a COVID-19 vaccination among older adults in Shanghai, China. Methods: A cross-sectional study was conducted among older adults (â‰¥60 years old) in Shanghai. Face-to-face interviews with a questionnaire were conducted in community health service centers, recording several parameters: demographic information, health-related factors; perceived likelihood, severity, and burden of COVID-19; perceived safety, effectiveness, necessity, and benefit of the COVID-19 vaccine, as well as their trust in the vaccine delivery system and doctors; willingness to receive a COVID-19 vaccination. Bivariate analysis between several survey items and the willingness to receive a COVID-19 vaccination was conducted using a chi-square test. Logistic regression was used to assess to what degree each variable affected the willingness to receive a COVID-19 vaccination. Results: Of the 1067 participants, 90.91% (970/1067) confirmed that they were willing to receive a COVID-19 vaccination. The participants were more likely to be willing to be vaccinated if they were immigrants (OR = 1.988, 95%CI = 1.062â^'3.717), had an education level of junior high school (OR = 2.724, 95%CI = 1.000â^'7.423) or high school or above (OR = 3.993, 95%CI = 1.576â^'10.119), and had a monthly income of CNY 3000â^'5000 (OR = 32.770, 95%CI = 1.144â^'6.711) or CNY >5000 (OR = 2.309, 95%CI = 1.003â^'5.319). The participants were also more likely to be willing to be vaccinated if they had received a pneumonia vaccination previously (OR = 2.138, 95%CI = 1.016â^'4.500), perceived the safety of the COVID-19 vaccine (OR = 1.508, 95%CI = 1.073â^'2.119), perceived the necessity of the

COVID-19 vaccine (OR = 2.604, 95%CI = 1.946âˆ’3.484), or trusted the suggestions of doctors (OR = 1.706, 95%CI = 1.115âˆ’2.618). The participants were less likely to be willing to be vaccinated if they were aged â‰¥76 years (OR = 0.498, 95%CI = 0.264âˆ’0.939), reported a physical health condition of bad or below (OR = 0.229, 95% CI = 0.095âˆ’0.549), or were worried about the adverse effects of a COVID-19 vaccination (OR = 0.503, 95%CI = 0.364âˆ’0.695). Conclusions: Under the free vaccination policy for COVID-19, older adults have a high intention to be vaccinated to prevent COVID-19 in Shanghai, China. Widely publicizing the safety and necessity of COVID-19 vaccination is necessary.

Disentangling a Thorny Issue: Myocarditis and Pericarditis Post COVID-19 and Following mRNA COVID-19 Vaccines. Considering the clinical significance for myocarditis and pericarditis after immunization with mRNA COVID-19 vaccines, the present pharmacovigilance study aimed to describe these events reported with mRNA COVID-19 vaccines in the Vaccine Adverse Events Reporting System (VAERS). From 1990 to July 2021, the mRNA vaccines were the most common suspected vaccines related to suspected cases of myocarditis and/or pericarditis (myocarditis: N = 1,165; 64.0%; pericarditis: N = 743; 55.1%), followed by smallpox vaccines (myocarditis: N = 222; 12.2%; pericarditis: N = 200; 14.8%). We assessed all suspected cases through the case definition and classification of the Brighton Collaboration Group, and only definitive, probable, and possible cases were included in the analysis. Our findings suggested that myocarditis and pericarditis mostly involve young male, especially after the second dose with a brief time to onset. Nevertheless, this risk is lower (0.38/100,000 vaccinated people; 95% CI 0.36-0.40) than the risk of developing myocarditis after SARS-CoV-2 infection (1000-4000 per 100,000 people) and the risk of developing "common" viral myocarditis (1-10 per 100,000 people/year). Comparing with the smallpox vaccine, for which is already well known the association with myocarditis and pericarditis, our analysis showed a lower probability of reporting myocarditis (ROR 0.12, 95% CI 0.10-0.14) and pericarditis (ROR 0.06, 95% CI 0.05-0.08) following immunization with mRNA COVID-19 vaccines.

Functional Neurological Disorders and COVID-19 Vaccine: A Call for Action.

Ultrasensitive detection of salivary SARS-CoV-2 IgG antibodies in individuals with natural and COVID-19 vaccine-induced immunity. We assessed the feasibility of a highly sensitive immunoassay method based on single molecule array (Simoa) technology to detect IgG and IgA antibodies against SARS-CoV-2 spike protein receptor binding domain (RBD) in saliva from individuals with natural or vaccine-induced COVID-19 immunity. The performance of the method was compared to a laboratory-developed SARS-CoV-2 RBD total antibody enzyme-linked immunosorbent assay (ELISA). Paired serum and saliva specimens were collected from individuals (nâ€‰=â€‰40) prior to and 2Â weeks after receiving an initial prime COVID-19 vaccine dose (Pfizer/BioNTech BNT162b2 or Moderna mRNA-1273). Saliva was collected using a commercially available collection device (OraSure Inc.) and SARS-CoV-2 RBD IgG antibodies were measured by an indirect ELISA using concentrated saliva samples and a Simoa immunoassay using unconcentrated saliva samples. The IgG results were compared with paired serum specimens that were analyzed for total RBD antibodies using the ELISA method. The analytical sensitivity of the saliva-based Simoa immunoassay was five orders of magnitude higher than the ELISA assay: 0.24Â pg/mL compared to 15Â ng/mL. The diagnostic sensitivity of the saliva ELISA method was 90% (95% CI 76.3-97.2%) compared to 91.7% (95% CI 77.5-98.2%) for the Simoa immunoassay without total IgG-normalization and 100% (95% CI 90.3-100%) for the Simoa immunoassay after total IgG-normalization when compared to the serum ELISA assay. When analyzed using the SARS-CoV-2 RBD IgG antibody ELISA, the average relative increase in antibody index (AI) between the saliva of the post- and pre-vaccinated individuals was 8.7 (AI(post/pre)). An average relative increase of 431Â pg/mL was observed when the unconcentrated saliva specimens were analyzed using the Simoa immunoassay (SARS-CoV-2 RBD IgG(post/pre)). These findings support the suitability of concentrated saliva specimens for the measurement of SARS-

CoV-2 RBD IgG antibodies via ELISA, and unconcentrated saliva specimens for the measurement of SARS-CoV-2 RBD IgG and IgA using an ultrasensitive Simoa immunoassay.

Competent immune responses to SARS-CoV-2 variants in older adults following two doses of mRNA vaccination. Aging is associated with a reduced magnitude of primary immune responses to vaccination. mRNA-based SARS-CoV-2 vaccines have shown efficacy in older adults but virus variant escape is still unclear. Here we analyze humoral and cellular immunity against an early-pandemic viral isolate and compare that to the P.1 (Gamma) and B.1.617.2 (Delta) variants in two cohorts (<50 and >55 age) of mRNA vaccine recipients. We further measure neutralizing antibody titers for B.1.617.1 (Kappa) and B.1.595, with the latter SARS-CoV-2 isolate bearing the spike mutation E484Q. Robust humoral immunity is measured following second vaccination, and older vaccinees manifest cellular immunity comparable to the adult group against early-pandemic SARS-CoV-2 and more recent variants. More specifically, the older cohort has lower neutralizing capacity at 7-14 days following the second dose but equilibrates with the younger cohort after 2-3 months. While long-term vaccination responses remain to be determined, our results implicate vaccine-induced protection in older adults against SARS-CoV-2 variants and inform thinking about boost vaccination.

Vestibular Neuritis Following COVID-19 Vaccination: A Retrospective Study. Objective To determine if the COVID-19 vaccine can cause vestibular neuritis (VN). Design Retrospective study. Setting Vertigo outpatient clinic of the Department of Otolaryngology JR Tokyo General Hospital. Participants: 378 patients who presented at the Vertigo clinic between July 2018 and March 2022 Results 23 out of 378 cases were diagnosed with vestibular neuritis. There was a significant seasonal bias of the onset of VN in 2021-3Q compared to other seasons. All 7 patients diagnosed with VN whose onset was 2021-3Q and 2021-4Q had received the BNT162b2 (Pfizer-BioNTech) vaccine within the previous 3 months and one patient diagnosed with VN whose onset was 2022-1Q had a history of COVID-19 infection six months earlier. Conclusions VN should be recognized as one of the side-effects of the BNT162b2 COVID-19 vaccination.

Heterologous ChAdOx1 and Bnt162b2 vaccination induces strong neutralizing antibody responses against SARS-CoV-2 including delta variant with tolerable reactogenicity. OBJECTIVES: We assessed humoral responses and reactogenicity following the heterologous vaccination compared to the homologous vaccination groups. METHODS: We enrolled healthcare workers (HCWs) who were either vaccinated with ChAdOx1 followed by BNT162b2 (heterologous group) or 2 doses of ChAdOx1 (ChAdOx1 group) or BNT162b2 (BNT162b2 group). Immunogenicity was assessed by measuring antibody titers against receptor-binding domain (RBD) of SARS-CoV-2 spike protein in all participants and neutralizing antibody titer in 100 participants per group. Reactogenicity was evaluated by a questionnaire-based survey. RESULTS: We enrolled 499 HCWs (ChAdOx1, nÂ =Â 199; BNT162b2, nÂ =Â 200; heterologous ChAdOx1/BNT162b2, nÂ =Â 100). The geometric mean titer of anti-receptor-binding domain antibody at 14Â days after the booster dose was significantly higher in the heterologous group (11Â 780.55 binding antibody unit (BAU)/mL [95% CI, 10Â 891.52-12 742.14]) than in the ChAdOx1 (1561.51 [95% CI, 1415.03-1723.15]) or BNT162b2 (2895.90 [95% CI, 2664.01-3147.98]) groups (both pÂ <Â 0.001). The neutralizing antibody titer of the heterologous group (geometric mean ND(50), 2367.74 [95% CI, 1970.03-2845.74]) was comparable to that of the BNT162b2 group (2118.63 [95% CI, 1755.88-2556.32]; pÂ >Â 0.05) but higher than that of the ChAdOx1 group (391.77 [95% CI, 326.16-470.59]; pÂ <Â 0.001). Compared with those against wild-type SARS-CoV-2, the geometric mean neutralizing antibody titers against the Delta variant at 14Â days after the boosting were reduced by 3.0-fold in the heterologous group (geometric mean ND(50), 872.01 [95% CI, 685.33-1109.54]), 4.0-fold in the BNT162b2 group (337.93 [95% CI, 262.78-434.57]), and 3.2-fold in the ChAdOx1 group (206.61 [95% CI, 144.05-296.34]). The local or systemic reactogenicity after the booster dose in the heterologous group was higher than that of the ChAdOx1

group but comparable to that of the BNT162b2 group. DISCUSSION: Heterologous ChAdOx1 followed by BNT162b2 vaccination with a 12-week interval induced a robust humoral immune response against SARS-CoV-2, including the Delta variant, that was comparable to the homologous BNT162b2 vaccination and stronger than the homologous ChAdOx1 vaccination, with a tolerable reactogenicity profile.

Humoral Response to BNT162b2 Vaccine Against SARS-CoV-2 Variants Decays After Six Months. SARS-CoV-2 vaccines have shown very high effectiveness in real-world scenarios. However, there is compelling evidence for a fast-paced waning of immunity. The increasing number of new variants that could alter the severity, transmissibility, and potential to evade the immune response raised significant concern. Therefore, elucidating changes in the humoral immune response against viral variants induced by vaccines over time is crucial for improving immunization protocols. We carried out a 6-month longitudinal prospective study in which 60 individuals between 21 and 71 years of age who have received the complete scheme of the BNT162b2 vaccine were followed to determine titers of serum neutralizing activity. The neutralizing capacity was measured at one, three, and six-months post-vaccination by plaque reduction neutralization assay using SARS-CoV-2 B.1 (D614G) and the Gamma, Alpha, Delta, and Mu variants. Data were analyzed using GraphPad 5.0. Neutralizing activity against five different SARS-CoV-2 variants was detected in the serum samples of all vaccinated participants to a different extent after one month, with a progressive decrease according to age and gender. Overall, after one month of vaccination, the neutralizing titer was lower for all evaluated variants when compared to B.1, most remarkable against Delta and Mu, with a reduction of 83.1% and 92.3%, respectively. In addition, the Titer at 3- or 6-months follow-up decreased dramatically for all variants. Our results support the decaying of serum neutralizing activity, both over time and across SARS-CoV-2 variants, being more significant in older men. Since Delta and Mu appear to evade the neutralizing activity, these and further new variants of immune escape mutations should be considered for novel vaccine formulations.

Post-COVID-19 vaccine-associated menstrual cycle changes: A multifaceted problem for Pakistan.

COVID-19 Vaccines and Potential Implications for COVID-19-Specific Obsessive-Compulsive Disorder Presentations. Public health crises, including the ongoing COVID-19 pandemic, have wide reaching implications on mental health, and have resulted in unique OCD presentations specific to respective crises. The distribution of highly efficacious and effective vaccines for COVID-19 present a crossroads for the COVID-19-specific OCD presentation, including the potential for COVID-19 presentation perpetuation or remission in the face of vaccinations. Individual differences may play a unique role in who does and does not see a reduction of OCD symptoms specific to this virus as a function of vaccination status. Here, we discuss prior health crises that have resulted in unique OCD presentations, review relevant assessment and intervention guidelines, discuss potential implications that vaccines may have on this COVID-19-specifc presentation, and provide case presentations and future recommendations for treatment providers and researchers.

Mortality due to COVID-19 during the vaccination plan against the SARS-CoV-2 virus in Cali, Colombia.

Patients with plasma cell disorders undergoing autologous stem cell transplant retain their humoral response to COVID-19 vaccination but falling titers emphasize the importance of re-vaccination.

Serum levels of anti-PF4 IgG after AZD1222 (ChAdOx1 nCoV-19) vaccination. Rare cases of thrombosis with thrombocytopenia syndrome (TTS) have been reported after AZD1222. Anti-platelet factor-4 (PF4) antibodies were observed in patients following presentation of TTS, however it is unclear if AZD1222 wasÂ responsible for inducing production of anti-PF4. Paired samples (baseline and day-15) from a phase 3 trial of AZD1222 vs placebo were analyzed for anti-PF4 levels; 19/1727 (1.1%, AZD1222) vs 7/857 (0.8%, placebo) participants were anti-PF4-IgG-negative at baseline but had moderate Day-15 levels (Pâ€‰=â€‰0.676) and 0/35 and 1/20 (5.0%) had moderate levels at

baseline but high Day-15 levels. These data indicate that AZD1222 does not induce a clinically relevant general increase in anti-PF4 IgG.

Heterologous immunization with inactivated vaccine followed by mRNA-booster elicits strong immunity against SARS-CoV-2 Omicron variant. The recent emergence of the Omicron variant has raised concerns on vaccine efficacy and the urgent need to study more efficient vaccination strategies. Here we observed that an mRNA vaccine booster in individuals vaccinated with two doses of inactivated vaccine significantly increased the plasma level of specific antibodies that bind to the receptor-binding domain (RBD) or the spike (S) ectodomain (S1â€‰+â€‰S2) of both the G614 and the Omicron variants, compared to two doses of homologous inactivated vaccine. The level of RBD- and S-specific IgG antibodies and virus neutralization titers against variants of concern in the heterologous vaccination group were similar to that in individuals receiving three doses of homologous mRNA-vaccine or a boost of mRNA vaccine after infection, but markedly higher than that in individuals receiving three doses of a homologous inactivated vaccine. This heterologous vaccination regime furthermore significantly enhanced the RBD-specific memory B cell response and S1-specific T cell response, compared to two or three doses of homologous inactivated vaccine. Our study demonstrates that mRNA vaccine booster in individuals vaccinated with inactivated vaccines can be highly beneficial, as it markedly increases the humoral and cellular immune responses against the virus, including the Omicron variant.

Cutting Edge: T Cell Responses to B.1.1.529 (Omicron) SARS-CoV-2 Variant Induced by COVID-19 Infection and/or mRNA Vaccination Are Largely Preserved. Several studies have demonstrated that the SARS-CoV-2 variant-of-concern B.1.1.529 (Omicron) exhibits a high degree of escape from Ab neutralization. Therefore, it is critical to determine how well the second line of adaptive immunity, T cell memory, performs against Omicron. To this purpose, we analyzed a human cohort (n = 327 subjects) of two- or three-dose mRNA vaccine recipients and COVID-19 postinfection subjects. We report that T cell responses against Omicron were largely preserved. IFN-Î³-producing T cell responses remained equivalent to the response against the ancestral strain (WA1/2020), with some (âˆ¼20%) loss in IL-2 single or IL-2(+)IFN-Î³(+) polyfunctional responses. Three-dose vaccinated participants had similar responses to Omicron relative to post-COVID-19 participants and exhibited responses significantly higher than those receiving two mRNA vaccine doses. These results provide further evidence that a three-dose vaccine regimen benefits the induction of optimal functional T cell immune memory.

Willingness to receive the COVID-19 vaccine and associated factors among residents of Southwestern Ethiopia: A cross-sectional study. INTRODUCTION: The COVID-19 vaccine is a key intervention toward containing the pandemic. Vaccines are thought to be a form of defense. One of the major challenges to managing the COVID-19 pandemic is the uncertainty or willingness to accept vaccinations. Our study aimed willingness to get the COVID-19 vaccine and the factors that influence it in Mettu Woreda, Ilu Ababor Zone, Ethiopia. METHODOLOGY: Cross-sectional study design was conducted from August 1, 2021, to September 1, 2021, among rural residents of Mettu woreda's of Ilu Ababor Zone, Oromia, Ethiopia. The semi-structured data collection format was prepared to assess the magnitude of the communities' acceptance of the COVID-19 vaccine. A multivariable logistic regression analysis was used to determine the predictors of communities' acceptance of the COVID-19 vaccine at 95% CI. RESULTS: Of 350 participants from the study area, 59% of them were males and 41% females. Less than one-third (29.8%) of participants were willing to accept the COVID-19 vaccine. The results multivariable logistic regression revealed that the age group of â‰¥50 years (OR=0.29; 95% CI: -3.1-0.34) as compare with the 18-29 years, low monthly income (OR=0.85; 95% CI: -0.74-2.33), low perception level (OR=0.35; 95% CI: -2.03-0.24), government unemployed (OR=0.86; 95% CI: -0.72-0.1), low Level of acceptance (OR=0.72; 95% CI: -0.67, 0.08) and unwillingness to test COVID-19

(OR=0.13; 95% CI: -4.47, 0.58) were predictors of willingness to receive COVID-19 vaccine. CONCLUSION: Less than one-third of the study, participants were willing to accept the COVID-19 vaccine. The likelihood of Willingness to accept the COVID-19 vaccine was low in the study area. Overall; low education, low vaccination perception, low income, jobless occupation, older age, and unwillingness to test for COVID-19 were associated with greater willingness to take the COVID-19 vaccine and are significantly associated with willingness to get the COVID-19 immunization.

Fourth dose of the SARS-CoV-2 vaccine in kidney transplant recipients with previously impaired humoral antibody response.

Worsening of immune thrombocytopenic purpura in SARS-CoV-2 vaccinated patients.

Efficient recall of Omicron-reactive B cell memory after a third dose of SARS-CoV-2 mRNA vaccine. We examined antibody and memory B cell responses longitudinally for âˆ¼9-10Â months after primary 2-dose SARS-CoV-2 mRNA vaccination and 3Â months after a 3rd dose. Antibody decay stabilized between 6 and 9Â months, and antibody quality continued to improve for at least 9Â months after 2-dose vaccination. Spike- and RBD-specific memory B cells remained durable over time, and 40%-50% of RBD-specific memory B cells simultaneously bound the Alpha, Beta, Delta, and Omicron variants. Omicron-binding memory B cells were efficiently reactivated by a 3rd dose of wild-type vaccine and correlated with the corresponding increase in neutralizing antibody titers. In contrast, pre-3rd dose antibody titers inversely correlated with the fold-change of antibody boosting, suggesting that high levels of circulating antibodies may limit the added protection afforded by repeat short interval boosting. These data provide insight into the quantity and quality of mRNA-vaccine-induced immunity over time through 3 or more antigen exposures.

Response to "Lymphatic osteopathic manipulative treatment and soreness after receiving the COVID-19 vaccine".

Hyper inflammatory syndrome following COVID-19 mRNA vaccine in children: A national post-authorization pharmacovigilance study. BACKGROUND: Multisystem inflammatory syndrome in children (MIS-C) is the most severe clinical entity associated with pediatric SARS-CoV-2 infection with a putative role of the spike protein into the immune system activation. Whether COVID-19 mRNA vaccine can induce this complication in children is unknown. We aimed to assess the risk of hyper-inflammatory syndrome following COVID-19 mRNA vaccine in children. METHODS: We conducted a post-authorization national population-based surveillance using the French enhanced pharmacovigilance surveillance system for COVID-19 vaccines. All cases of suspected hyper-inflammatory syndrome following COVID-19 mRNA vaccine in 12-17-year-old children between June 15(th), 2021 and January 1(st), 2022, were reported. Cases were reviewed according to WHO criteria for MIS-C. The reporting rate of this syndrome was compared to the MIS-C rate per 1,000,000 12-17-year-old children infected by SARS-CoV-2. FINDINGS: Up to January 2022, 8,113,058 COVID-19 mRNA vaccine doses were administered to 4,079,234 12-17-year-old children. Among them, 12 presented a hyper-inflammatory syndrome with multisystemic involvement. Main clinical features included male predominance (10/12, 83%), cardiac involvement (10/12, 83%), digestive symptoms (10/12, 83%), coagulopathy (7/12, 58%), cytolytic hepatitis (6/12, 50%), and shock (5/12, 42%). 4/12 (33%) required intensive care unit transfer, and 3/12 (25%) hemodynamic support. All cases recovered. In eight cases, no evidence of previous SARS-CoV-2 infection was found. The reporting rate was 1.5 (95%CI [0.8; 2.6]) per 1,000,000 doses injected, i.e. 2.9 (95%CI [1.5; 5.1]) per 1,000,000 12-17-year-old vaccinated children. As a comparison, 113 MIS-C (95%CI [95; 135]) occurred per 1,000,000 12-17-year-old children infected by SARS-CoV-2. INTERPRETATION: Very few cases of hyper-inflammatory syndrome with multi-organ involvement occurred following COVID-19 mRNA vaccine in 12-17-year-old children. The low reporting rate of this syndrome, compared to the rate of post-SARS-CoV-2 MIS-C

in the same age-group, largely supports the vaccination in a context of an important circulation of SARS-CoV-2. FUNDING: ESPID Fellowship Award; Grandir-Fonds de SolidaritÃ© Pour L'enfance.

Correction to: COVID-19 Outcomes and Vaccination in People with Relapsing Multiple Sclerosis Treated with Ofatumumab.

Effect of mycophenolate mofetil dose on antibody response following initial SARS-CoV-2 vaccination in patients with systemic sclerosis.

Association Between SARS-CoV-2 Messenger RNA Vaccines and Lower Infection Rates in Kidney Transplant Recipients : A Registry-Based Report. BACKGROUND: The real-world protection provided by SARS-CoV-2 messenger RNA (mRNA) vaccines to kidney transplant recipients (KTRs) remains uncertain. OBJECTIVE: To study the association between mRNA vaccination and SARS-CoV-2 infection rate in KTRs. DESIGN: Retrospective observational cohort study. SETTING: The Czech Republic (17 February to 16 May 2021). PATIENTS: 2101 KTRs followed in the Department of Nephrology at the Institute for Clinical and Experimental Medicine. MEASUREMENTS: Positive result for SARS-CoV-2 on polymerase chain reaction test and vaccination status of KTRs. RESULTS: The incidence rate in the vaccinated group was 0.474 per 1000 person-days (33 cases in 69Â 672 days at risk). The incidence rate in the unvaccinated group was 1.370 per 1000 person-days (79 cases in 57Â 658 days at risk). The unadjusted incidence rate ratio (IRR; incidence rate of vaccinated/incidence rate of unvaccinated) for KTRs was 0.346 (95% CI, 0.227 to 0.514). The multivariable adjusted IRR for KTRs was 0.544 (CI, 0.324 to 0.876). LIMITATION: Retrospective observational design, uneven follow-up of patient groups, and different exposition to SARS-CoV-2 stemming from strong temporal trends and differences in clinical and probably behavioral characteristics. CONCLUSION: Vaccination of KTRs is associated with lower risk for SARS-CoV-2 infection. PRIMARY FUNDING SOURCE: The Ministry of Health of the Czech Republic.

Reply: Subacute thyroiditis after anti-SARS-CoV-2 (Ad5-nCoV) vaccine.

Status of Humoral and Cellular Immune Responses within 12 Months following CoronaVac Vaccination against COVID-19. Understanding immune memory to COVID-19 vaccines is critical for the design and optimal vaccination schedule for curbing the COVID-19 pandemic. Here, we assessed the status of humoral and cellular immune responses at 1, 3, 6, and 12â€‰months after two-dose CoronaVac vaccination. A total of 150 participants were enrolled, and 136 of them completed the study through the 12-month endpoint. Our results show that, at 1â€‰month after vaccination, both binding and neutralizing antibodies could be detected; the seropositive rate of binding antibodies and seroconversion rate of neutralizing antibodies were 99% and 50%, respectively. From 3 to 12â€‰months, the binding and neutralizing antibodies declined over time. At 12â€‰months, the binding and neutralizing antibodies were still detectable and significantly higher than the baseline. Gamma interferon (IFN-Î³) and interleukin 2 (IL-2) secretion specifically induced by the receptor-binding domain (RBD) persisted at high levels until 6â€‰months and could be observed at 12â€‰months, while the levels of IL-5 and granzyme B (GzmB) were hardly detected, demonstrating a Th1-biased response. In addition, specific CD4(+) T central memory (T(CM)), CD4(+) effector memory (T(EM)), CD8(+) T(EM), and CD8(+) terminal effector (T(E)) cells were all detectable and functional up to 12â€‰months after the second dose, as the cells produced IFN-Î³, IL-2, and GzmB in response to stimulation of SARS-CoV-2 RBD. Our work provides evidence that CoronaVac induced not only detectable binding and neutralizing antibody responses, but also functional SARS-CoV-2-specific CD4(+) and CD8(+) memory T cells for up to 12â€‰months. IMPORTANCE CoronaVac is an inactivated vaccine containing whole-virion SARS-CoV-2, which has been approved in 43 countries for emergency use as of 26 November 2021. However, the long-term immune persistence of the CoronaVac vaccine is still unknown. Here, we reported the status of the persistence of

antibodies and cellular responses within 12â€‰months after two doses of CoronaVac. Such data are crucial to inform ongoing and future vaccination strategies to combat COVID-19.
No evidence of increased rate of thrombotic recurrences in patients with history of venous thromboembolism after vaccination for COVID-19.
Simultaneous analysis of antigen-specific B and T cells after SARS-CoV-2 infection and vaccination. Conventional methods for quantifying and phenotyping antigen-specific lymphocytes can rapidly deplete irreplaceable specimens. This is due to the fact that antigen-specific T and B cells have historically been analyzed in independent assays each requiring millions of cells. A technique that facilitates the simultaneous detection of antigen-specific T and B cells would allow for more thorough immune profiling with significantly reduced sample requirements. To this end, we developed the B and T cell tandem lymphocyte evaluation (BATTLE) assay, which allows for the simultaneous identification of SARS-CoV-2 Spike reactive T and B cells using an activation induced marker (AIM) T cell assay and dual-color B cell antigen probes. Using this assay, we demonstrate that antigen-specific B and T cell subsets can be identified simultaneously using conventional flow cytometry platforms and provide insight into the differential effects of mRNA vaccination on B and T cell populations following natural SARS-CoV-2 infection.
Partial COVID-19 vaccination associated with reduction in postoperative mortality and SARS-CoV-2 infection. BACKGROUND: There are currently no data to guide decisions about delaying surgery to achieve full vaccination. METHODS: We analyzed data from patients undergoing surgery at any of the 1,283 VA medical facilities nationwide and compared postoperative complication rates by vaccination status. RESULTS: Of 87,073 surgical patients, 20% were fully vaccinated, 15% partially vaccinated, and 65% unvaccinated. Mortality was reduced in full vaccination vs. unvaccinated (Incidence Rate Ratio 0.77, 95% CI [0.62, 0.94]) and partially vaccinated vs. unvaccinated (0.75 [0.60, 0.94]). Postoperative COVID-19 infection was reduced in fully (0.18 [0.12, 0.26]) and partially vaccinated patients (0.34 [0.24, 0.48]). Fully vaccinated compared to partially vaccinated patients, had similar postoperative mortality (1.02, [0.78, 1.33]), but had decreased COVID-19 infection (0.53 [0.32, 0.87]), pneumonia (0.75 [0.62, 0.93]), and pulmonary failure (0.79 [0.68, 0.93]). CONCLUSIONS: Full and partial vaccination reduces postoperative complications indicating the importance of any degree of vaccination prior to surgery.
COVID Vaccine-Associated Myocarditis in Adolescent Siblings: Does It Run in the Family? The development of myocarditis after receiving messenger RNA vaccination against COVID-19 is well documented, particularly in adolescent and young adult males. We report a case of vaccine-associated myocarditis in adolescent brothers following their second dose of the BNT162b2 mRNA vaccine (Pfizer-BioNTech, Mainz, Germany). This report illustrates the need to better understand the mechanisms leading to myocarditis after mRNA vaccination.
Higher Antibody Concentrations in U.S. Health Care Workers Associated with Greater Reactogenicity Post-Vaccination. Multiple factors may be associated with immune responses to SARS-CoV-2 vaccines. Factors potentially related to magnitude and durability of response include age, time, and vaccine reactogenicity. This study analyzed SARS-CoV-2 IgG spike antibody responses following the second dose of vaccine in healthcare workers (HCWs). Data were collected from participants enrolled in a longitudinal SARS-CoV-2 serology study over a 12-month period. Participants completed a survey documenting symptoms post-vaccination. Serum specimens were tested for SARS-CoV-2 IgG antibodies using the Abbott Architect AdvisdeDx SARS-CoV-2 IgGII assay. Antibody levels were compared against time from second vaccine dose, and symptoms following vaccination. Altogether, 335 women (86.6%) and 52 men (13.4%) participated. Median age was 37 years (IQR 30-43). Overall median antibody level was 2150.80 [1246.12, 3556.98] AU/mL (IQR). Age was not associated with antibody concentration (p-value = 0.10). Higher antibody responses (2253 AU/mL vs. 1506 AU/mL; p =

0.008) were found in HCWs with one or more symptoms after the second dose of the vaccine (n = 311). Antibody responses persisted throughout the study period post-vaccination; statistically significant decreases in antibody responses were observed over time ($p < 0.001$). Higher antibody response was associated with reactogenicity post-vaccine. Age and sex were not associated with higher antibody responses.
Development of Flat Warts on the Cheeks after BioNTech-Pfizer BNT162b2 Vaccine: Is There a Correlation? The SARS-CoV-2 pandemic has affected health systems across the globe, making the use of vaccines more urgent and topical than ever. Since the first months after the introduction of vaccinations, several reactions, both local and systemic, have been reported although they were mostly very mild and only rarely harbingers of more serious complications. We present a case of multiple flat warts onset over the cheeks in a patient after the second dose of mRNA BioNTech-Pfizer BNT162b2 vaccine, and we discuss the possible temporal association between the two events, also considering the patient's antibody status.
Alterations in 18 F-FDG PET/MRI and 15 O-Water PET Brain Findings in Patients With Neurological Symptoms After COVID-19 Vaccination: A Pilot Study: Reply.
Myocarditis following COVID-19 mRNA (mRNA-1273) vaccination. In this case report, we presented a case of myocarditis as a rare complication that developed after Covid mRNA-1273 vaccine. Cases of post-vaccine myocarditis usually progress with mild symptoms. However, it should be a situation that healthcare workers should keep in mind, that myocarditis may develop after vaccination.
Morphea in two patients after being infected to and being vaccinated against SARS-CoV-2 infection. Although the presence of morphea following COVID-19Â has been rarely reported, the development of its generalized form following COVID-19 vaccination has not been reported yet. Here, we reported the first case of generalized morphea following COVID-19 vaccination and another similar case following SARS-Cov-2 infection. Other etiologic factors were also dealt with.
Somatostatin receptor positron emission tomography/computed tomography in myocarditis following mRNA COVID-19 vaccination.
Re: Alterations in 18 F-FDG PET/MRI and 15 O-Water PET Brain Findings in Patients With Neurological Symptoms After COVID-19 Vaccination: A Pilot Study.
Suboptimal antibody response against SARS-CoV-2 Omicron variant after third dose of mRNA vaccine in kidney transplant recipients.
Risk factors, contemporary challenges and psychological well-being of the Rohingya refugees in Bangladesh: Policy implications. Over the last few years, the number of Rohingya refugees in Bangladesh has increased exponentially. On arrival, they experience poor mental health and psychological well-being. This commentary explores the risk factors and contemporary challenges that deteriorate Rohingyas' psychological well-being in Bangladesh. The onslaught of Covid-19 compounds the pre-existing psychological health conditions of the Rohingyas living in cramped and flimsy camps. The recent relocation to Bhashan Char may likely trigger tensions and eventually exacerbates their existing psychological well-being. The relocation to Bhashan Char has presumably happened against their volition. Meanwhile, the Myanmar military's coup has added additional fear about their bleak future of a safe and dignified return from Bangladesh to Myanmar. All these have contributed to the worsening of their existing psychological well-being. In order to subside their psychological health challenges, this commentary suggests: (a) the immediate execution of 'National Deployment and Vaccination Plan for Covid-19 Vaccines and initiation of vaccine rollout among the refugees; and (b) involving Rohingyas in economic activities and making them a self-reliant and economically empowered community. We suggest that safe and dignified repatriation is the only

solution to the challenges they have been going through in Bangladesh and to preserve their psychological well-being.
Intranasal administration of a virus like particles-based vaccine induces neutralizing antibodies against SARS-CoV-2 and variants of concern. BACKGROUND: The highly contagious SARS-CoV-2 is mainly transmitted by respiratory droplets and aerosols. Consequently, people are required to wear masks and maintain a social distance to avoid spreading of the virus. Despite the success of the commercially available vaccines, the virus is still uncontained globally. Given the tropism of SARS-CoV-2, a mucosal immune reaction would help to reduce viral shedding and transmission locally. Only seven out of hundreds of ongoing clinical trials are testing the intranasal delivery of a vaccine against COVID-19. METHODS: In the current study, we evaluated the immunogenicity of a traditional vaccine platform based on virus-like particles (VLPs) displaying RBD of SARS-CoV-2 for intranasal administration in a murine model. The candidate vaccine platform, CuMV(TT) -RBD, has been optimized to incorporate a universal T helper cell epitope derived from tetanus-toxin and is self-adjuvanted with TLR7/8Â ligands. RESULTS: CuMV(TT) -RBD vaccine elicited a strong systemic RBD- and spike-IgG and IgA antibodies of high avidity. Local immune response was assessed, and our results demonstrate a strong mucosal antibody and plasma cell production in lung tissue. Furthermore, the induced systemic antibodies could efficiently recognize and neutralize different variants of concern (VOCs). CONCLUSION: Our data demonstrate that intranasal administration of CuMV(TT) -RBD induces a protective systemic and local specific antibody response against SARS-CoV-2 and its VOCs.
SARS-CoV-2 Spike S1-specific IgG kinetic profiles following mRNA or vector-based vaccination in the general Dutch population show distinct kinetics. mRNA- and vector-based vaccines are used at a large scale to prevent COVID-19. We compared Spike S1-specific (S1) IgG antibodies after vaccination with mRNA-based (Comirnaty, Spikevax) or vector-based (Janssen, Vaxzevria) vaccines, using samples from a Dutch nationwide cohort. In adults 18-64Â years old (nâ€‰=â€‰2412), the median vaccination interval between the two doses was 77Â days for Vaxzevria (interquartile range, IQR: 69-77), 35Â days (28-35) for Comirnaty and 33Â days (28-35) for Spikevax. mRNA vaccines induced faster inclines and higher S1 antibodies compared to vector-based vaccines. For all vaccines, one dose resulted in boosting of S1 antibodies in adults with a history of SARS-CoV-2 infection. For Comirnaty, two to four months following the second dose (nâ€‰=â€‰196), S1 antibodies in adults aged 18-64Â years old (436 BAU/mL, IQR: 328-891) were less variable and median concentrations higher compared to those in personsâ€‰â‰¥â€‰80Â years old (366, 177-743), but differences were not statistically significant (pâ€‰>â€‰0.100). Nearly all participants seroconverted following COVID-19 vaccination, including the aging population. These data confirm results from controlled vaccine trials in a general population, including vulnerable groups.
Enhanced SARS-CoV-2 Antibody Response After a Third Heterologous Vector Vaccine Ad26COVS1 Dose in mRNA Vaccine-Primed Kidney Transplant Recipients.
Augmentation of humoral and cellular immune responses after third-dose SARS-CoV-2 vaccination and viral neutralization in myeloma patients.
Pneumonitis and Myopericarditis After Booster COVID-19 mRNA Vaccination.
Vaccine and Psychological Booster: Factors Associated With Older Adults' Compliance to the Booster COVID-19 Vaccine in Israel. Israel became the first country to offer the booster COVID-19 vaccination. The study tested for the first time the role of sense of control (SOC) due to vaccinations, trust and vaccination hesitancy (VH), and their association with compliance to the booster COVID-19 vaccine among older adults, during the first 2Â weeks of the campaign. 400 Israeli citizens (â‰¥ 6Â years old), eligible for the booster vaccine, responded online. They completed demographics, self-reports, and booster vaccination status (already vaccinated, booked-a-slot, vaccination intent, and

vaccination opposers). Multinomial logistic regression was conducted with pseudo R(2) = .498. Higher SOC and lower VH were related to the difference between early and delayed vaccination (booked-a-slot, OR = 0.7 [0.49-0.99]; 2.2 [1.32-3.62], intent OR = 0.6 [0.42-0.98]; 2.7 [1.52-4.86]), as well as to rejection (OR = 0.3 [0.11-0.89]; 8.5 [3.39-21.16]). Increased trust was only related to the difference between early vaccinations and vaccine rejection (OR = 0.3 [0.11-0.89]). We suggest that SOC, as well as low VH, can be used as positive motivators, encouraging earlier vaccinations in older age.
What's Next after Lipid Nanoparticles? A Perspective on Enablers of Nucleic Acid Therapeutics. Recent success of mRNA-based COVID-19 vaccines have bolstered the strength of nucleic acids as a therapeutic platform. The number of new clinical trial candidates is skyrocketing with the potential to address many unmet clinical needs. Despite advancements in other aspects, the systemic delivery of nucleic acids to target sites remains a major challenge. Thus, nucleic acid based therapy has yet to reach its full potential. In this review, we shed light on a select few prospective technologies that exhibit substantial potential over traditional nanocarrier designs for nucleic acid delivery. We critically analyze these systems with specific attention to the possibilities for clinical translation.
Myopericarditis After COVID-19 Booster Dose Vaccination.
Correspondence on 'BNT162b2 vaccine-associated myo/pericarditis in adolescents'.
A call for vigilance: thrombotic thrombocytopenic syndrome caused by mRNA COVID-19 vaccine associated with muscle weakness.
Takotsubo syndrome after BNT162b2 mRNA Covid-19 vaccine: Emotional or causative relationship with vaccination?
COVID-19: Vaccination Side Effects and Sick Leave in Frontline Healthcare-Workers-A Web-Based Survey in Germany. (1) Background: The COVID-19 vaccination has caused uncertainty among employees and employers regarding vaccination reactions and incapacitation. At the time of our study, three vaccines are licensed in Germany to combat the COVID-19 pandemic (BioNTech/Pfizer (Comirnaty), AstraZeneca (Vaxzevria), and Moderna (Spikevax). We aim to assess how often and to what extent frontline healthcare workers had vaccination reactions after the first and second vaccination. The main focus is on the amount of sick leave after the vaccinations. (2) Methods: We create a web-based online questionnaire and deliver it to 270 medical directors in emergency medical services all over Germany. They are asked to make the questionnaire public to employees in their area of responsibility. To assess the association between independent variables and adverse effects of vaccination, we use log-binomial regression to estimate prevalence ratios (PR) with 95% confidence intervals (95%CI) for dichotomous outcomes (sick leave). (3) Results: A total of 3909 individuals participate in the survey for the first vaccination, of whom 3657 (94%) also provide data on the second vaccination. Compared to the first vaccination, mRNA-related vaccine reactions are more intense after the second vaccination, while vaccination reactions are less intense for vector vaccines. (4) Conclusion: Most vaccination reactions are physiological (local or systemic). Our results can help to anticipate the extent to which personnel will be unable to work after vaccination. Even among vaccinated HCWs, there seems to be some skepticism about future vaccinations. Therefore, continuous education and training should be provided to all professionals, especially regarding vaccination boosters. Our results contribute to a better understanding and can therefore support the control of the pandemic.
HLA Class II Polymorphism and Humoral Immunity Induced by the SARS-CoV-2 mRNA-1273 Vaccine. The vaccines designed against the SARS-CoV-2 coronavirus are based on the spike (S) protein. Processing of the S protein by antigen-presenting cells (APC) and its subsequent presentation to T cells is an essential part of the development of a humoral response. HLA-class II alleles are considered immune response genes because their codified molecules, expressed on the surface of APCs (macrophages, dendritic, and B cells) present antigenic peptides to T cell via their T cell receptor

(TCR). The HLA-class II genes are highly polymorphic, regulating what specific peptides induce follicular helper T cells (TFH) and promote B lymphocyte differentiation into plasma or memory B cells. This work hypothesizes that the presence of certain HLA-class II alleles could be associated with the intensity of the humoral response (amount, length) to the SARS-CoV2 mRNA 1273 vaccine. We have studied the relationship between the HLA-class II typing of 87 health workers and the level of antibodies produced 30 days after vaccination. We show a possible association between the HLA-DRB1* 07:01 allele and the HLA-DRB1*07:01~DQA1*02:01~DQB1*02:02 haplotype to a higher production of antibodies 30 days after the administration of the second dose of mRNA-1273.

Lymphatic osteopathic manipulative treatment and soreness after receiving the COVID-19 vaccine.

Impaired Neutralizing Antibody Activity against B.1.617.2 (Delta) after Anti-SARS-CoV-2 Vaccination in Patients Receiving Anti-CD20 Therapy. Background: To characterize humoral response after standard anti-SARS-CoV-2 vaccination in Rituximab-treated patients and to determine the optimal time point after last Rituximab treatment for appropriate immunization. Methods: Sixty-four patients who received Rituximab within the last seven years prior to the first anti-SARS-CoV-2 vaccination were recruited in a prospective observational study. Anti-S1 IgG, SARS-CoV-2 specific neutralization, and various SARS-CoV-2 target antibodies were determined. A live virus assay was used to assess neutralizing antibody activity against B.1.617.2 (delta). In Rituximab-treated patients, CD19+ peripheral B-cells were quantified using flow cytometry. Results: After second vaccination, all antibodies were significantly reduced compared to healthy controls. Neutralizing antibody activity against B.1.617.2 (delta) was detectable with a median (IQR) ID50 of 0 (0â^'1:20) compared to 1:320 (1:160â^'1:320) in healthy controls (for all p < 0.001). Longer time period since last Rituximab administration correlated with higher anti-SARS-CoV-2 antibody levels and a stronger neutralization of B.1.617.2 (delta). With one exception, only patients with a CD19+ cell proportion â‰¥ 1% had detectable neutralizing antibodies. Conclusion: Our data indicate that a reconstitution of the B-cell population to >1% seems crucial in developing neutralizing antibodies against SARS-CoV-2. We suggest that anti-SARS-CoV-2 vaccination should be administered at least 8â^'12 months after the last Rituximab treatment for sufficient humoral responses.

The Association Between Quarantine Duration and Psychological Outcomes, Social Distancing, and Vaccination Intention During the Second Outbreak of COVID-19 in China. Objectives: To examine the association between quarantine duration and psychological outcomes, social distancing, as well as vaccination intention during the second outbreak of COVID-19 in China. Methods: A cross-sectional online survey was conducted in January 2021. Participants were invited to complete the measurement of quarantine duration, social distancing, psychological distress, wellbeing (WHO-5), and vaccination intention. Multiple linear regression and logistic regression were performed to examine the relationship between quarantine duration and psychological distress, wellbeing, social distancing, and vaccination intention. Results: Of the 944 participants, 17.2% of the participants experienced quarantine. Quarantine for 1-7Â days increased the social distancing (Î² = 2.61 95% confidence interval (CI) 1.90-3.33) and vaccination intention (OR = 2.16 95% CI 1.22-3.82). Quarantine for >7Â days was associated with the increased social distancing (Î² = 3.00 95% CI 2.37-3.64) and psychological distress (Î² = 1.03 95% CI 0.22-1.86), and decreased wellbeing (Î² = 1.27 95% CI 0.29-2.26). Conclusion: Longer quarantine duration showed increased social distancing, increased psychological distress, and decreased wellbeing. Quarantine for 1-7Â days was associated with increased vaccination intention.

COVID-19 vaccine-induced recovery and the implications of vaccine apartheid on the global tourism industry. According to United Nations, World Tourism Organization COVID-19 has had the most devastating impact on the entire global tourism value chain, which resulted in a 74% decline in international passenger arrival, a US$1.3 trillion loss in international tourism receipts, over the US $

2trillion loss of global domestic product and placing between 100 and 120 million jobs at risk globally. While the initial impact of the pandemic was uniform across the world, the recovery was expected to be varied across the region due to inequitable access to the COVID-19 vaccine. This study seeks to examine the implications of vaccination inequity on tourism recovery in the global tourism market. The study uses secondary, archival data and harnesses the advantages of big data generated from online activities from tourists and tourism companies obtained from authoritative sources. The study found that inequitable access to vaccinations produced a skewed recovery favouring vaccinated regions concentrated in the developed world, leaving poor regions such as Africa behind. The robot system characterising the vaccine-induced recovery had also created a vaccine diplomatic nightmare that scuttled global tourism recovery efforts. To ensure sustainable recovery, there is a need to ensure global vaccination access by rechannelling some of the excess vaccines in developed countries to countries that needs them to ensure the opening up of the entire tourism global market and reduce vulnerabilities that are coming from COVID-19 variants, which poses a threat to the gains made from the current vaccination program. The study concludes that there will not be any meaningful economic recovery without a wholesale approach covering the entire global population.

The effect of waning on antibody levels and memory B cell recall following SARS-CoV-2 infection or vaccination. As of March 2022, there have been over 450 million reported SARS-CoV-2 cases worldwide, and more than 4 billion people have received their primary series of a COVID-19 vaccine. In order to longitudinally track SARS-CoV-2 antibody levels in people after vaccination or infection, a large-scale COVID-19 sero-surveillance progam entitled SPARTA (SeroPrevalence and Respiratory Tract Assessment) was established early in the pandemic. Anti-RBD antibody levels were tracked in more than 1,000 people. There was no significant decrease in antibody levels during the first 14 months after infection in unvaccinated participants, however, significant waning of antibody levels was observed following vaccination, regardless of previous infection status. Moreover, participants who were pre-immune to SARS-CoV-2 prior to vaccination seroconverted to significantly higher antibody levels, and antibodies were maintained at significantly higher levels than in previously infected, unvaccinated participants. This pattern was entirely due to differences in the magnitude of the initial seroconversion event, and the rate of antibody waning was not significantly different based on the pre-immune status. Participants who received a third (booster) dose of an mRNA vaccine not only increased their anti-RBD antibody levels âˆ¼14-fold, but they also had âˆ¼3 times more anti-RBD antibodies compared to the peak of their antibody levels after receiving their primary vaccine series. In order to ascertain whether the presence of serum antibodies is important for long-term seroprotection, PBMCs from 13 participants who lost all detectable circulating antibodies after vaccination or infection were differentiated into memory cells in vitro . There was a significant recall of memory B cells in the absence of serum antibodies in 70% of the vaccinated participants, but not in any of the infected participants. Therefore, there is a strong connection between anti-RBD antibody levels and the effectiveness of memory B cell recall.

The first case report of Pityriasis lichenoides chronica following COVID-19 mRNA vaccination.

Memory B Cells Induced by Sputnik V Vaccination Produce SARS-CoV-2 Neutralizing Antibodies Upon Ex Vivo Restimulation. The development of effective vaccines against SARS-CoV-2 remains a global health priority. Despite extensive use, the effects of Sputnik V on B cell immunity need to be explored in detail. We performed comprehensive profiling of humoral and B cell responses in a cohort of vaccinated subjects (n = 22), and demonstrate that Sputnik vaccination results in robust B cell immunity. We show that B memory cell (MBC) and antibody responses to Sputnik V were heavily dependent on whether the vaccinee had a history of SARS-CoV-2 infection or not. 85 days after the first dose of the vaccine, ex vivo stimulated MBCs from the vast majority of Sputnik V vaccinees produced antibodies that robustly neutralized the Wuhan Spike-pseudotyped lentivirus. MBC-derived

antibodies from all previously infected and some of the naÃ¯ve vaccine recipients could also cross-neutralize Beta (B.1.351) variant of SARS-CoV-2. Virus-neutralizing activity of MBC-derived antibodies correlated well with that of the serum antibodies, suggesting the interplay between the MBC and long-lived plasma cell responses. Thus, our in-depth analysis of MBC responses in Sputnik V vaccinees complements traditional serological approaches and may provide important outlook into future B cell responses upon re-encounter with the emerging variants of SARS-CoV-2.
Pityriasis rubra pilaris (type I) following ChAdOx1 COVID-19 vaccine: A report of two cases with successful treatment with oral isotretinoin.
Existence of immunological memory response in true sero-negative individuals post COVID-19 molecular diagnosis. Approximately 1-8% of individuals do not develop antibodies following SARS-CoV-2 infection (sero-negatives). One BNT162b2 dose resulted in potent humoral response in 14 sero-negatives and 15 sero-positives, significantly higher than the response of 15 naÃ¯ve-individuals, to two doses suggesting that COVID-19 provoked a memory response in individuals without detectable antibodies.
Pityriasis Rosea Induced by COVID-19 Vaccination. It is increasingly recognized that SARS-CoV-2 infection and COVID-19 vaccines have been associated with skin disorders, including pityriasis rosea. It has been reported that pityriasis rosea has been triggered by several vaccines, as a rare side-effect. We present two cases of COVID-19 vaccine-induced pityriasis rosea. Skin lesions appeared in a 49-year-old female 8 days after the first dose of the BNT162b2 mRNA vaccine and in a 53-year-old male 7 days after the second dose of the same vaccine. The exanthem was self-limited in both patients over a period of a month. LEARNING POINTS: Physicians should be aware that pityriasis rosea is a rare side-effect of COVID-19 vaccination.Pityriasis rosea is self-limiting and no medical treatment is usually required.
BCG revaccination qualitatively and quantitatively enhances SARS-CoV-2 spike-specific neutralizing antibody and T cell responses induced by the COVISHIELD(â„¢) vaccine in SARS-CoV-2 seronegative young Indian adults. This study tested if prior BCG revaccination can further boost immune responses subsequently induced by a widely distributed and otherwise efficacious Oxford/AstraZeneca ChAdOx1nCoV-19 vaccine, referred to as COVISHIELD(â„¢), in India. We compared COVISHIELD(â„¢) induced longitudinal immune responses in 21 BCG re-vaccinees (BCG-RV) and 13 BCG-non-revaccinees (BCG-NRV), all of whom were BCG vaccinated at birth and latent tuberculosis negative, after COVISHIELD(â„¢) prime and boost with baseline samples that were collected pre-pandemic and pre-BCG revaccination. Compared to BCG-NRV, BCG-RV displayed significantly higher magnitude of spike-specific Ab and T cell responses, including a greater proportion of high responders; better quality polyfunctional CD4 and CD8 T cells that persisted and a more robust Ab and T cell response to the Delta mutant of SARS-CoV-2 highlighting greater breadth. Mechanistically, BCG adjuvant effects on COVISHIELD(â„¢) induced adaptive responses was associated with more robust innate responses to pathogen-associated-molecular-patterns through TNF-Î± and IL-1Î² secretion. This study provides first in-depth analysis of immune responses induced by COVISHIELD(â„¢) in India and highlights the potential of using a cheap and globally available vaccine, BCG, as an adjuvant to enhance heterologous adaptive immune responses induced by COVIDSHIELD(â„¢) and other emerging vaccines.
B-cell responses to vaccination with BNT162b2 and mRNA-1273 6Â months after second dose. OBJECTIVES: To examine the state of B-cell immunity 6Â months after the second vaccination against SARS-CoV-2 in comparison to the state observed 2Â weeks after vaccination. METHODS: Sera of 439 participants, whose immune responses to two doses of an mRNA-based vaccine (BNT162b2 or mRNA-1273) were previously characterized, was examined for anti-S1 IgG and IgA, anti-NCP IgG and neutralizing antibodies (nAb), and antinuclear antibodies (ANA). RESULTS: Levels of all examined

markers decreased significantly from 2Â weeks to 6Â months after second vaccination (anti-S1 IgG: 3744Â Â±Â 2571.4 vs. 253Â Â±Â 144 binding antibody units (BAU)/mL; anti-S1 IgA: 12Â Â±Â 0 vs. 1.98Â Â±Â 1.75 optical density (OD) ratio; nAb: 100%Â Â±Â 0% vs. 82%Â Â±Â 19.3%), the vast majority of participants retaining reactive levels of anti-S1 IgG (436/439) and anti-S1 IgA (334/439) at 6Â months. Immune responses were stronger for mRNA-1273 compared with BNT162b2 (anti-S1 IgG: 429Â Â±Â 289 vs. 243Â Â±Â 143 BAU/mL; anti-S1 IgA: 5.38Â Â±Â 3.91 vs. 1.89Â Â±Â 1.53 OD ratio; nAb: 90.5%Â Â±Â 12.6% vs. 81%Â Â±Â 19.3%). There was no meaningful influence of sex and age on the examined markers. There was a strong correlation between anti-S1 IgG and the surrogate neutralization assay (rhoÂ =Â 0.91, p <0.0001), but not for for IgA and the surrogate neutralization assay (rhoÂ =Â 0.52, p <0.0001). There was a ceiling effect for the association between anti-S1 IgG titres and the inhibition of binding between S1 and ACE2. ANA prevalence was unchanged from 2 weeks to 6Â months after the second vaccination (87/498 vs. 77/435), as were the median ANA titres (1:160 vs. 1:160). DISCUSSION: Although the clinical consequences of decreasing anti-SARS-CoV-2 antibody titres cannot be estimated with certainty, a lowered degree of clinical protection against SARS-CoV-2 is possible. Persistently stronger responses to mRNA-1273 suggest that it might confer greater protection than BNT162b2, even 6Â months after the second vaccination. Neither examined vaccinations induced ANA within the examined time frame.

SARS-CoV-2 adaptive immunity in nursing home residents up to eight months after two doses of the ComirnatyÂ® COVID-19 vaccine. Burgos JS (General Directorate of Research and Healthcare Supervision, Department of Health, Valencia Government, Valencia, Spain); Meneu de Guillerna R (Vice-President Foundation Research Institute in Public Services, Valencia, Spain); Vanaclocha Luna H (General Directorate of Public Health, Department of Health, Valencia Government, Valencia, Spain); Burks DJ (The Prince Felipe Research Center-CIPF-, Valencia, Spain; Cervantes A (INCLIVA Health Research Institute, Valencia, Spain); Comas I (Biomedicine Institute of Valencia, Spanish Research Council (CSIC); DÃ-ez-Domingo J (Foundation for the promotion of health and biomedical research of the Valencian Community-FISABIO-, Valencia, Spain); Peiro S (Foundation for the promotion of health and biomedical research of the Valencian Community-FISABIO-, Valencia, Spain); GonzÃ¡lez-Candelas F (CIBER in Epidemiology and Public Health, Spain; Joint Research Unit "Infection and Public Health" FISABIO-University of Valencia, Valencia, Spain; Institute for Integrative Systems Biology (I2SysBio), CSIC-University of Valencia, Valencia, Spain); Ferrer Albiach C (FundaciÃ³n Hospital Provincial de CastellÃ³); HernÃ¡ndez-Aguado I (University Miguel HernÃ¡ndez, Alicante, Spain); Oliver RamÃ-rez N (DataPop Alliance); SÃ¡nchez-PayÃ¡ J (Preventive Medicine Service, Alicante General and University Hospital, Alicante, Spain; Alicante Institute of Health and Biomedical Research (ISABIAL), Alicante, Spain; Vento Torres M (Instituto de InvestigaciÃ³n Sanitaria La Fe); Zapater Latorre E (FundaciÃ³n Hospital General Universitario de ValÃ¨ncia); Navarro D (Microbiology Service, Clinic University Hospital, INCLIVA Health Research Institute, Valencia, Spain;Department of Microbiology, School of Medicine, University of Valencia, Valencia, Spain).

Generation of neutralizing antibodies against Omicron, Gamma and Delta SARS-CoV-2 variants following CoronaVac vaccination. Vaccination is a fundamental tool to prevent SARS-CoV-2 infection and to limit the COVID-19 pandemic. The emergence of SARS-CoV-2 variants with multiple mutations has raised serious concerns about the ability of neutralizing antibody responses elicited by prior vaccination to effectively combat these variants. The neutralizing capacity against the Gamma, Delta and Omicron variants of sera from individuals immunized with the CoronaVac vaccine remains incompletely determined. The present study evaluated 41 health care workers at the Faculdade de Medicina of the Universidade de Sao Paulo, in Sao Paulo, Brazil, naive to previous SARS- CoV-2 infection, who were vaccinated with two doses of the CoronaVac SARS-CoV-2 vaccine 28 days apart. Neutralizing antibody levels against the Gamma, Delta, and Omicron variants were measured at 32

and 186 days after the second vaccination. We also measured neutralizing antibodies against Omicron in 34 of these individuals following a subsequent booster immunization with the Pfizer vaccine. Quantification of neutralizing antibodies was performed using the Cytopathic Effect-based Virus Neutralization test. Neutralization antibody activity against the Gamma, Delta and Omicron variants was observed in 78.0%, 65.9% and 58.5% of serum samples, respectively, obtained at a mean of 32 days after the second immunization. This decreased to 17.1%, 24.4% and 2.4% of sera having activity against Delta, Gamma and Omicron, respectively, at 186 days post-vaccination. The median neutralizing antibody titers at 32 days were 1:40, 1:20 and 1:20 against Gamma, Delta and Omicron, respectively, and decreased to an undetectable median level against all variants at the later time. A booster immunization with the Pfizer vaccine elicited neutralizing antibodies against Omicron in 85% of subjects tested 60 days after vaccination. We conclude that two doses of the CoronaVac vaccine results in limited protection of short duration against the Gamma, Delta and Omicron SARS-CoV-2 variants. A booster dose with the Pfizer vaccine induced antibody neutralizing activity against Omicron in most patients which was measurable 60 days after the booster.

Sex-associated differences between BMI and SARS-CoV-2 antibody titers following the BNT162b2 vaccine. OBJECTIVE: This study investigated the sex-associated difference in the impact of obesity on antibody response to a COVID-19 vaccine. METHODS: This study included 2,435 health care workers who received two doses of the BioNTech, Pfizer (BNT162b2) vaccine and participated in a serological survey, during which they were tested for anti-SARS-CoV-2 spike immunoglobin G (IgG) antibodies and asked for information on height, weight, and vaccination history via a questionnaire. Multivariable linear regression analysis was used to estimate the geometric mean titers (GMT) of antibodies for each sex and BMI category. RESULTS: The relationship between BMI and anti-SARS-CoV-2 spike IgG titers markedly differed by sex (p value for interaction = 0.04). Spike IgG antibody titers tended to decrease with increasing BMI in men (p value for trend = 0.03); GMT (95% CI) were 6,093 (4,874-7,618) and 4,655 (3,795-5,708) for BMI < 18.5 and â‰¥30 kg/m(2) , respectively. In contrast, spike IgG antibody titers did not significantly differ across BMI categories in women (p value for for trend = 0.62); GMT (95% CI) were 6,171 (5,714-6,665) and 5,506 (4,404-6,883) for BMI <18.5 and â‰¥30, respectively. CONCLUSIONS: Higher BMI was associated with lower titers of SARS-CoV-2 spike antibodies in men, but not in women, suggesting the need for careful monitoring of vaccine efficacy in men with obesity, who are at high risk of severe COVID-19 outcomes.

Generalized pustular psoriasis flare in a patient affected by plaque psoriasis after BNT162b2 mRNA COVID-19 vaccine, successfully treated with risankizumab.

New-onset of vitiligo in a child following COVID-19 vaccination.

Cellular Responses to Membrane and Nucleocapsid Viral Proteins Are Also Boosted After SARS-CoV-2 Spike mRNA Vaccination in Individuals With Either Past Infection or Cross-Reactivity. SARS-CoV-2 spike mRNA vaccines have shown remarkable clinical efficacy in the general population, although the nature of T-cell priming is not fully understood. We performed longitudinal spike-, membrane-, and nucleocapsid-specific T-cell analysis in individuals with past infection and infection-naÃ¯ve individuals with cross-reactivity. We found an additional enhancement of T-cell response to the structural membrane (M) and nucleocapsid (N) SARS-CoV-2 proteins after mRNA vaccine in these individuals. Thus, despite the spike-specific response, we found that the first dose of the vaccine boosted a significant CD8 cell response to M and N proteins, whereas no cellular response to those proteins was found in infection-naÃ¯ve individuals without pre-existing cross-reactivity who were tested for eventual asymptomatic infection. These findings highlight the additional benefit of mRNA vaccines as broad boosters of cellular responses to different viral epitopes in these individuals and suggest extended protection to other viral variants.

Self-Assembled Particles Combining SARS-CoV-2 RBD Protein and RBD DNA Vaccine Induce Synergistic Enhancement of the Humoral Response in Mice. Despite the fact that a range of vaccines against COVID-19 have already been created and are used for mass vaccination, the development of effective, safe, technological, and affordable vaccines continues. We have designed a vaccine that combines the recombinant protein and DNA vaccine approaches in a self-assembled particle. The receptor-binding domain (RBD) of the spike protein of SARS-CoV-2 was conjugated to polyglucin:spermidine and mixed with DNA vaccine (pVAXrbd), which led to the formation of particles of combined coronavirus vaccine (CCV-RBD) that contain the DNA vaccine inside and RBD protein on the surface. CCV-RBD particles were characterized with gel filtration, electron microscopy, and biolayer interferometry. To investigate the immunogenicity of the combined vaccine and its components, mice were immunized with the DNA vaccine pVAXrbd or RBD protein as well as CCV-RBD particles. The highest antigen-specific IgG and neutralizing activity were induced by CCV-RBD, and the level of antibodies induced by DNA or RBD alone was significantly lower. The cellular immune response was detected only in the case of DNA or CCV-RBD vaccination. These results demonstrate that a combination of DNA vaccine and RBD protein in one construct synergistically increases the humoral response to RBD protein in mice.

Systemic COVID-19 Vaccination Enhances the Humoral Immune Response after SARS-CoV-2 Infection: A Population Study from a Hospital in Poland Criteria for COVID-19 Reimmunization Are Needed. Systemic vaccination with the BNT162b2 mRNA vaccine stimulates the humoral response. Our study aimed to compare the intensity of the humoral immune response, measured by SARS-CoV-2 IgG, SARS-CoV-2 IgM, and S-RBD-neutralizing IgG antibody levels after COVID-19 vaccination versus after SARS-CoV-2 infection. We analyzed 1060 people in the following groups: convalescents; healthy unvaccinated individuals; individuals vaccinated with Comirnaty, AstraZeneca, Moderna, or Johnson & Johnson; and vaccinated SARS-CoV-2 convalescents. The concentrations of SARS-CoV-2 IgG, SARS-CoV-2 IgM, and S-RBD-neutralizing antibodies were estimated in an oncology hospital laboratory by chemiluminescent immunoassay (CLIA; MAGLUMI). Results: (1) We observed a rise in antibody response in both the SARS-CoV-2 convalescent and COVID-19-vaccinated groups. (2) The levels of all antibody concentrations in vaccinated COVID-19 convalescents were significantly higher. (3) We differentiated asymptomatic SARS-CoV-2 convalescents from the control group. Our analysis suggests that monitoring SARS-CoV-2 IgG antibody concentrations is essential as an indicator of asymptomatic COVID-19 and as a measure of the effectiveness of the humoral response in convalescents and vaccinated people. Considering the time-limited effects of post-SARS-CoV-2 infection recovery or vaccination and the physiological half-life, among other factors, we suggest monitoring IgG antibody levels as a criterion for future vaccination.

Overview of Anti-SARS-CoV-2 Immune Response Six Months after BNT162b2 mRNA Vaccine. BACKGROUND: We have designed a prospective study aiming to monitor the immune response in 178 health care workers six months after BNT162b2 mRNA vaccination. METHODS: The humoral immune response of all subjects was evaluated by chemiluminescence (CMIA); in 60 serum samples, a live virus-based neutralization assay was also tested. Moreover, 6 months after vaccination, B- and T-cell subsets from 20 subjects were observed by FACS analysis after restimulation with the trimeric SARS-CoV-2 Spike protein as an antigen, thus mimicking reinfection in vitro. RESULTS: A significant decrease of circulating IgG levels and neutralizing antibodies over time were observed. Moreover, six months after vaccination, a variable T-cell immune response after in vitro antigen stimulation of PBMC was observed. On the contrary, the analysis of B-cell response showed a shift from unswitched to switched memory B-cells and an increase of Th17 cells. CONCLUSIONS: Although the variability of the CD4(+) and CD8(+) immune response and an antibody decline was observed among vaccinated

subjects, the increase of switched memory B-cells and Th17 cells, correlating with the presence of neutralizing antibodies, opened the debate on the correct timing of vaccination.
Sequentially immune-induced antibodies could cross-neutralize SARS-CoV-2 variants. BACKGROUND: The Omicron (B.1.1.529) SARS-COV-2 variant has raised serious concerns because of its unprecedented rapid rate of spreading and the fact that there are 36Â mutations in the spike protein. Since the vaccine-induced neutralizing antibody targets are the spike protein, this may lead to the possibility of vaccine-induced humoral immunity escape. METHODS: We measured the neutralizing activity in vitro for Omicron and compared this with wild type (WH-09) and Delta variants in human and monkey sera from different types of immunity. The monkey sera samples were collected at 1 and 3Â months post three-dose inactivated (PiCoVacc) and recombinant protein (ZF2001) vaccination. Human sera were collected from 1Â month post three-dose inactivated vaccination. RESULTS: In inactivated vaccine sera, at 1/3Â months post three-dose, geometric mean titers (GMTs) of neutralization antibody (NAb) against the Omicron variant were 4.9/5.2-fold lower than those of the wild type. In recombinant protein vaccine sera, GMTs of NAb against Omicron were 15.7/8.9-fold lower than those of the wild type. In human sera, at 1Â month post three-dose inactivated vaccination, GMTs of NAb against Omicron were 3.1-fold lower than those of the wild type. CONCLUSION: This study demonstrated that despite a reduction in neutralization titers, cross-neutralizing activity against Omicron and Delta variants was still observed after three doses of inactivated and recombinant protein vaccination.
Myocarditis Following COVID-19 BNT162b2 Vaccination Among Adolescents in Hong Kong. This cohort study assesses the association between the single-dose COVID-19 BNT162b2 vaccination regimen and myocarditis risk among vaccinated adolescents in Hong Kong before and after the single-dose policy.
Self-Assessment of Health Status and Willingness to Be Vaccinated in Adolescents from the Niigata Prefecture and the Khabarovsk Region during COVID-19. This study examined the self-assessment of Niigata's and Khabarovsk's adolescents' health status and their willingness to be vaccinated during the COVID-19 pandemic. A self-reported questionnaire was administered to 735 boys and girls (aged 15 years) from Niigata, Japan (n = 387), and Khabarovsk, Russia (n = 394), between May and July 2021. Specifically, this questionnaire focused on COVID-19, including a self-assessment of health status, adaptation to a new lifestyle, and impressions about the COVID-19 vaccination. The self-assessment was based on a 4-point scale: "Got very bad"; "Got a little bit bad"; "Did not change"; "Got better/I don't know". Additionally, binomial logistic regression was conducted to determine the association between the self-assessment of health status and the factors exacerbating their responses. Based on the findings, 25.7 and 29.9% of Niigata and Khabarovsk's adolescents, respectively, selected "Got very bad" and "Got a little bit bad" for their self-assessments, while the binomial logistic regression showed that the difficulty of adapting to a new lifestyle was a factor worsening the boys' subjective health. However, the items could not explain the deterioration of their subjective health in girls. Moreover, 76.9% of Niigata's adolescents were positive about the COVID-19 vaccination, compared to 35.5% of the adolescents in Khabarovsk.
Nintedanib-induced liver injury: Not every liver injury is virus or vaccine-induced in the era of COVID-19.
Meta-analysis of immunologic response after COVID-19 mRNA vaccination in solid organ transplant recipients.
Pityriasis lichenoides et varioliformis acuta after SARS-CoV-2 infection and relapse after vaccination.
Psychosis Associated With COVID-19 Vaccination.
Improved Antibody Response After a Fifth Dose of a SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients: A Case Series. [Image: see text]

Evaluation of the Immune Response Induced by CoronaVac 28-Day Schedule Vaccination in a Healthy Population Group. CoronaVac vaccine from Sinovac Life Science is currently being used in several countries. In Chile, the effectiveness of preventing hospitalization is higher than 80% with a vaccination schedule. However, to date, there are no data about immune response induction or specific memory. For this reason, we recruited 15 volunteers without previous suspected/diagnosed COVID-19 and with negative PCR over time to evaluate the immune response to CoronaVac 28 and 90 days after the second immunization (dpi). The CoronaVac administration induces total and neutralizing anti-spike antibodies in all vaccinated volunteers at 28 and 90 dpi. Furthermore, using ELISpot analysis to assay cellular immune responses against SARS-CoV-2 spike protein, we found an increase in IFN-gamma- and Granzyme B-producing cells in vaccinated volunteers at 28 and 90 dpi. Together, our results indicate that CoronaVac induces a robust humoral immune response and cellular immune memory of at least 90 dpi.

Deep Vein Thrombosis and Pulmonary Thrombosis After BNT162b2 mRNA SARS-CoV2 Vaccination.

Incidence of COVID-19 infection in hospital workers from March 1, 2020 to May 31, 2021 routinely tested, before and after vaccination with BNT162B2. To evaluate the incidence of COVID-19 infection in health care workers from the start of the COVID-19 pandemic in NE Italy, vaccination with BNT162b2. This was a retrospective cohort study. Healthcare workers were routinely tested for SARS-CoV-2 infection using real-time polymerase chain reaction tests in nasopharyngeal swabs. Logistic regression was used to calculate the incidence rate ratios (IRRs) of the factors associated with COVID-19. A total of 4251 workers were followed up, and the prevalence of COVID-19 was 13.6%. In March 2021 the incidence of infection was 4.88 and 103.55 cases for 100,000 person-days in vaccinated and non-vaccinated workers, respectively, with an adjusted IRRs of 0.05 (95% CI 0.02-0.08). Our study evaluated the monthly incidence in health care workers in Trieste hospitals before and after vaccination, finding an estimated vaccine effectiveness of 95% in health care workers routinely tested.

A Case of New-Onset Lichen Planus after COVID-19 Vaccination. The COVID 19 vaccination campaign has been underway for about a year now, and there are now many skin reactions associated with the administration of these vaccines in the literature. In view of the forthcoming third dose, we believe it is important to report our experience.

ICU-Associated Costs during the Fourth Wave of the COVID-19 Pandemic in a Tertiary Hospital in a Low-Vaccinated Eastern European Country. The COVID-19 pandemic has been associated with a tremendous financial and social impact. The pressure on healthcare systems worldwide has increased with each pandemic wave. The present study assesses the impact of the COVID-19 pandemic on healthcare-derived costs of critically ill patients during the fourth wave of the COVID-19 pandemic in a tertiary hospital in Romania. We prospectively included patients admitted to a single-centre intensive care unit (ICU) during the fourth wave of the COVID-19 pandemic. Median daily costs were calculated from financial records and divided in three groups: administrative costs, treatment costs and investigation costs. These were then compared to two retrospective cohorts of non-COVID-19 patients admitted to the same ICU during the same time interval in 2020 and 2019. Demographic data and the management of SARS-CoV-2 infection and of associated organ dysfunctions were recorded to identify risk factors for higher costs. Our results show that the COVID-19 pandemic has been associated with a 70.8% increase in total costs compared to previous years. This increase was mainly determined by an increase in medication and medical-device-related costs. We identified the following as risk factors for increased costs: higher degrees of lung involvement, severity of respiratory dysfunction, need for renal replacement therapy and the use of antiviral or immunomodulatory therapy. Costs were higher in patients who had a shorter duration of hospitalization. In conclusion, the COVID-19 pandemic is associated with increased costs for patients,

and rapid measures need to be taken to ensure adequate financial support during future pandemic waves, especially in developing countries.
Effect of cladribine on COVID-19 serology responses following two doses of the BNT162b2 mRNA vaccine in patients with multiple sclerosis. BACKGROUND: multiple sclerosis (MS) patients are treated with immunomodulatory treatments that can influence their ability to develop a protective antibody response to the SARS-CoV-2 vaccine. Vaccine efficacy is important for treatment decision and for patients' reassurance. The main objective is to assess antibody response to SARS-CoV-2 vaccine in MS patients treated with cladribine. METHODS: Serology response was tested in 97 participants, 67 MS patients and 30 healthy controls (HCs), using two independent methods, 2-3 weeks following the second dose of the BNT162b2 vaccine. RESULTS: HCs (nÂ =Â 30) and MS patients treated with cladribine (nÂ =Â 32) had 100% positive serology response against the SARS-CoV-2 spike protein following the second vaccine dose (mean S1/S2-IgG and RBD-IgG:284.5Â Â±Â 104.9, 13,041Â±9411 AU/mL and 226.3Â Â±Â 121.4, 10,554Â±11,405 AU/mL respectively). Comparable findings were observed for untreated MS patients, and interferon beta-1a-treated MS patients (mean S1/S2-IgG: 282.1Â Â±Â 100.1, 276.9Â Â±Â 94.31 AU/mL respectively). No correlation was found between lymphocyte counts, treatment duration, or time between cladribine dose and vaccination, and serology response or antibody titers. CONCLUSION AND RELEVANCE: Cladribine treated MS patients are able to produce antibodies to the SARS-CoV-2 mRNA vaccine. In the era of the COVID-19 pandemic, it is reassuring and important for both patients and physicians and will allow to develop consensus guidelines.
A Decrease of Neutrophils After COVID-19 Vaccination in a Treatment-Resistant Patient With Schizophrenia Taking Clozapine.
SARS-CoV-2 vaccination induces immunological T cell memory able to cross-recognize variants from Alpha to Omicron. We address whether TÂ cell responses induced by different vaccine platforms (mRNA-1273, BNT162b2, Ad26.COV2.S, and NVX-CoV2373) cross-recognize early SARS-CoV-2 variants. TÂ cell responses to early variants were preserved across vaccine platforms. By contrast, significant overall decreases were observed for memory B cells and neutralizing antibodies. In subjects âˆ¼6Â months post-vaccination, 90% (CD4(+)) and 87% (CD8(+)) of memory TÂ cell responses were preserved against variants on average by AIM assay, and 84% (CD4(+)) and 85% (CD8(+)) preserved against Omicron. Omicron RBD memory B cell recognition was substantially reduced to 42% compared with other variants. TÂ cell epitope repertoire analysis revealed a median of 11 and 10 spike epitopes recognized by CD4(+) and CD8(+) TÂ cells, with average preservation > 80% for Omicron. Functional preservation of the majority of TÂ cell responses may play an important role as a second-level defense against diverse variants.
Temporal Associations Between Immunization With the COVID-19 mRNA Vaccines and Myocarditis.
A case report of vaccine-induced immune thrombocytopenia and thrombosis syndrome after Ad26.COV2.S vaccine (Janssen/Johnson & Johnson).
Salivary antibodies are detected with a commercial anti-SARS-CoV-2 assay only after two doses of vaccine using serum thresholds. Salivary matrix is an appealing specimen type for SARS-CoV-2 serology because of ease of collection and potential for concurrent nucleic acid testing. We address the feasibility of salivary matrix to detect anti-SARS-CoV-2 antibodies using two commercially available anti-SARS-CoV-2 Total antibody assays including analytical validations. Matched serum and saliva samples were collected from 10 convalescent COVID-19 patients and tested using a quantitative anti-Spike Total antibody assay and a qualitative anti-Nucleocapsid Total antibody assay from Roche Diagnostics. Both assays were 100% sensitive for COVID-19 history in serum. However, saliva samples were below serum positivity thresholds. We then collected longitudinal salivary samples from a volunteer cohort receiving the Pfizer-BioNTech COVID-19 BNT162b2 vaccine. Saliva

was negative for anti-SARS-CoV-2 antibodies at 5 time points after a single dose of vaccine including day 56 when mean (min-max) serum levels of anti-Spike Total antibody were 79.0Â U/mL (46.6-110.1) (NÂ =Â 8). After a second vaccine dose serum-matched samples were beyond the analytical measuring range of the assay (>2500Â U/mL), and detection of salivary anti-Spike Total antibody was achieved in all volunteers (12.2Â U/mL [2.0-32.7]) (NÂ =Â 11) 30Â days after the second dose. Mean anti-Spike Total antibody levels in serum (1558Â U/mL (434->2500)) and saliva (2.6Â U/mL (<0.4-11.4)) declined 216-233Â days after the first dose of vaccine (PÂ <Â 0.05); and saliva was 75% sensitive for two doses of vaccination at this latter time point (NÂ =Â 25). These data suggest commercial assays are capable of detecting vaccine status after two doses of BNT162b2 vaccine up to 6Â months and could inform COVID-19 surveillance.

A Vector-Based Vaccine Dose After 3 Doses of mRNA-Based COVID-19 Vaccination Does Not Substantially Improve Humoral SARS-CoV-2 Immunity in Renal Transplant Recipients.

CD4+ T Cell Immune Specificity Changes After Vaccination in Healthy And COVID-19 Convalescent Subjects. The immune response promoted by SARS-CoV-2 vaccination is relevant to develop novel vaccines and optimized prevention strategies. We analyzed the adaptive immunity in healthy donors (HD) and convalescent individuals (CD), before and after administering BNT162b2 vaccine. Our results revealed specific changes in CD4+ T cell reactivity profile in vaccinated HD and CD, with an increase in S1 and S2 positive individuals, proportionally higher for S2. On the contrary, NCAP reactivity observed in HD and CD patients was no longer detectable after vaccination. Despite the substantial antibody response in CD, MPro-derived peptides did not elicit CD4+ lymphocyte activation in our assay in either condition. HD presented an increment in anti-S and anti-RBD IgG after first dose vaccination, which increased after the second vaccination. Conversely, anti-S and anti-RBD IgG and IgA titers increased in already positive CD after first dose administration, remaining stable after second dose inoculation. Interestingly, we found a strong significant correlation between S1-induced CD4+ response and anti-S IgA pre-vaccination, which was lost after vaccine administration.

Cutting Edge: Serum but Not Mucosal Antibody Responses Are Associated with Pre-Existing SARS-CoV-2 Spike Cross-Reactive CD4(+) T Cells following BNT162b2 Vaccination in the Elderly. Advanced age is a main risk factor for severe COVID-19. However, low vaccination efficacy and accelerated waning immunity have been reported in this age group. To elucidate age-related differences in immunogenicity, we analyzed human cellular, serological, and salivary SARS-CoV-2 spike glycoprotein-specific immune responses to the BNT162b2 COVID-19 vaccine in old (69-92 y) and middle-aged (24-57 y) vaccinees compared with natural infection (COVID-19 convalescents, 21-55 y of age). Serological humoral responses to vaccination excee-ded those of convalescents, but salivary anti-spike subunit 1 (S1) IgA and neutralizing capacity were less durable in vaccinees. In old vaccinees, we observed that pre-existing spike-specific CD4(+) T cells are associated with efficient induction of anti-S1 IgG and neutralizing capacity in serum but not saliva. Our results suggest pre-existing SARS-CoV-2 cross-reactive CD4(+) T cells as a predictor of an efficient COVID-19 vaccine-induced humoral immune response in old individuals.

Evaluation of circulating leucocyte populations both in subjects with previous SARS-COV-2 infection and in healthy subjects after vaccination. Innate immune mechanisms are central players in response to the binding of pathogens to pattern-recognition receptors providing a crucial initial block on viral replication. Moreover, innate immune response mobilizes cells of the cellular-mediated immune system, which develop into effector cells that promote viral clearance. Here, we observed circulating leukocyte T cell response in healthy subjects, COVID-19 infected, and in healthy vaccinated subjects. We found a significant CD8(+) T cells (pÂ <Â 0,05) decrease and an augmented CD4(+)/CD8(+) ratio (pÂ <Â 0,05) in COVID-19 infected group compared with vaccinated subjects. In addition, healthy vaccinated subjects have a significant increased expression of CD8(+) T cells, and a

reduction of CD4(+)/CD8(+) ratio with respect to subjects previously COVID-19 infected. Central Memory and Terminal Effector Memory cells (TEMRA) increased after vaccine but not among groups.
Immune responses following the first dose of the Sputnik V (Gam-COVID-Vac). As the first dose of Gam-COVID-Vac, is currently used as a single dose vaccine in some countries, we investigated the immunogenicity of this at 4Â weeks (327 naÃ¯ve individuals). 88.7% seroconverted, with significantly lower seroconversion rates in those over 60Â years (pâ€‰=â€‰0.004) and significantly lower than previously seen with AZD1222 (pâ€‰=â€‰0.018). 82.6% developed ACE2 receptor blocking antibodies, although levels were significantly lower than following natural infection (pâ€‰=â€‰0.0009) and a single dose of AZD1222 (pâ€‰<â€‰0.0001). Similar titres of antibodies were observed to the receptor binding domain of WT, B.1.1.7 and B.1.617.2 compared to AZD1222, while the levels for B.1.351 were significantly higher (pâ€‰=â€‰0.006) for Gam-COVID-Vac. 30% developed ex vivo IFNÎ³ ELISpot responses (significantly lower than AZD1222), and high frequency of CD107a expressing T cells along with memory B cell responses. Although single dose of Gam-COVID-Vac was highly immunogenic, administration of a second dose is likely to be beneficial.
[Pharmacovigilance - mRNA COVID-19 vaccines : current state of knowledge on their adverse effects]. The COVID-19 pandemic has stimulated the rapid development and large-scale use of technologically innovative vaccines, such as the mRNA vaccines Spikevax (Moderna) and Comirnaty (Pfizer-BioNTech). This unprecedented deployment has challenged pharmacovigilance, requiring combined skills in safety monitoring, prompt data analysis and continuous dissemination of knowledge. Main recognised adverse events of these vaccines are moderate and transient, linked to their significant reactogenicity. Active post-marketing surveillance has identified rare adverse events such as myopericarditis and a variety of skin reactions. A number of potential rare adverse events are being evaluated and could be retained at the individual level, but do not question the overall safety of these vaccines.
Myocarditis after BNT162b2 mRNA SARS-CoV-2 vaccine: low incidence and mild severity.
Ocular Surface Erosion after Suspected Exposure to Evaporated COVID-19 Vaccine. The purpose is to report ocular surface erosion of health personnel who were exposed to evaporated CoronaVac during a vaccination campaign. A campaign for CoronaVac vaccination was conducted in a closed space of 11.04 Ã— 5.96 m, partially divided into 6 rooms with interconnected area among the rooms. A total of 20 health personnel worked in the vaccination rooms. On the third day of campaign, a vial, containing a single dose of 0.5 mL, of the vaccine was dropped accidentally onto the floor and broken by an administering nurse. A total of 15 personnel had symptoms and signs of ocular surface erosion at the average time from the accident to the onset of 10.2 Â± 7.1 h; 4 personnel also had skin rash. These personnel included all 13 persons who already worked in the rooms when the accident occurred and continued for additional 4-6 h and 2 personnel who presented in the rooms 1-2 h after the accident and stayed for 2-3 h. Proximity and timing suggest CoronaVac correlation with the ocular and skin reactions. Cautions should be taken to avoid broken vials, spills, and aerosolization of CoronaVac during the vaccination.
Perniosis-like lesions after vaccination with mRNA against COVID-19.
COVID-19 infection and BNT162b2 vaccine triggering sarcoid-like lesions in the same patient. Response to: Sarcoid-like reaction in a patient recovering from COVID-19 pneumonia.
Oral subunit SARS-CoV-2 vaccine induces systemic neutralizing IgG, IgA and cellular immune responses and can boost neutralizing antibody responses primed by an injected vaccine. The rapid spread of the COVID-19 pandemic, with its devastating medical and economic impacts, triggered an unprecedented race toward development of effective vaccines. The commercialized vaccines are parenterally administered, which poses logistic challenges, while adequate protection at the mucosal sites of virus entry is questionable. Furthermore, essentially all vaccine candidates target

the viral spike (S) protein, a surface protein that undergoes significant antigenic drift. This work aimed to develop an oral multi-antigen SARS-CoV-2 vaccine comprised of the receptor binding domain (RBD) of the viral S protein, two domains of the viral nucleocapsid protein (N), and heat-labile enterotoxin B (LTB), a potent mucosal adjuvant. The humoral, mucosal and cell-mediated immune responses of both a three-dose vaccination schedule and a heterologous subcutaneous prime and oral booster regimen were assessed in mice and rats, respectively. Mice receiving the oral vaccine compared to control mice showed significantly enhanced post-dose-3 virus-neutralizing antibody, anti-S IgG and IgA production and N-protein-stimulated IFN-Î³ and IL-2 secretion by T cells. When administered as a booster to rats following parenteral priming with the viral S1 protein, the oral vaccine elicited markedly higher neutralizing antibody titres than did oral placebo booster. A single oral booster following two subcutaneous priming doses elicited serum IgG and mucosal IgA levels similar to those raised by three subcutaneous doses. In conclusion, the oral LTB-adjuvanted multi-epitope SARS-CoV-2 vaccine triggered versatile humoral, cellular and mucosal immune responses, which are likely to provide protection, while also minimizing technical hurdles presently limiting global vaccination, whether by priming or booster programs.

Response to "Varicella-zoster virus reactivation after SARS-CoV-2 BNT162b2 mRNA vaccination: Report of 5 cases".

Six-month Antibody Kinetics and Durability After 3 Doses of SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients: A Case Series.

Intention to vaccinate children for COVID-19: A segmentation analysis among Medicaid parents in Florida. COVID-19 vaccines have been granted emergency use authorization for children ages 5Â years and older. To understand how racially and ethnically diverse parents of young children enrolled in Medicaid feel about a prospective COVID-19 vaccine for their children, we administered an online survey that included both close-ended and open-ended items to a statewide sample in Florida (nÂ =Â 1951). We used quantitative responses to conduct a statistical audience segmentation analysis that identified five distinct sub-groups that varied widely in the likelihood that they would get a COVID-19 vaccine for their child. Qualitative responses were used to illustrate differences between the groups. The youngest Black and White mothers were least likely to vaccinate their child (24%), followed by Black and White mothers in their early 30s (36%), younger Hispanic and mixed-race or other race parents (45%), older mothers (48%) and older fathers (71%). Unique challenges to building vaccine confidence emerged for each group. The youngest Black and White mothers were more likely to report their lives being worse during the COVID-19 pandemic, were far more negative and less positive about a COVID-19 vaccine, and were more concerned about paying bills than preventing COVID-19. Younger Hispanic and mixed-race parents were less negative, but more likely to use emotional language (e.g., scared, nervous, worried) talking about a COVID-19 vaccine, and more likely to report that protecting their child's health was their top concern. Recommendations are made for applying the insights gained in outreach and education efforts.

Assessing SARS-CoV-2 Neutralizing Antibodies after BNT162b2 Vaccination and Their Correlation with SARS-CoV-2 IgG Anti-S1, Anti-RBD and Anti-S2 Serological Titers. The humoral response through neutralizing antibodies (NAbs) is a key component of the immune response to COVID-19. However, the plaque reduction neutralization test (PRNT), the gold standard for determining NAbs, is technically demanding, time-consuming and requires BSL-3 conditions. Correlating the NAbs and total antibodies levels, assessed by generalized and automated serological tests, is crucial. Through a commercial surrogate virus neutralization test (sVNT), we aimed to evaluate the production of SARS-CoV-2 NAbs in a set of vaccinated healthcare workers and to correlate these NAbs with the SARS-CoV-2 IgG anti-S1, anti-RBD and anti-S2 serological titers. We found that 6 months after vaccination, only 74% maintain NAbs for the Wuhan strain/UK variant (V1) and 47% maintain NAbs for the South

African and Brazil variants (V2). Through Spearman's correlation, we found the following correlations between the percentage of inhibition of NAbs and the SARS-CoV-2 IgG II Quant (Abbott Laboratories, Chicago, IL, USA) and BioPlex 2200 SARS-CoV-2 IgG Panel (Bio-Rad, Hercules, CA, USA) immunoassays: rho = 0.87 (V1) and rho = 0.73 (V2) for anti-S1 assessed by Abbott assay; rho = 0.77 (V1) and rho = 0.72 (V2) for anti-S1, rho = 0.88 (V1) and rho = 0.82 (V2) for anti-RBD, and rho = 0.68 (V1) and rho = 0.60 (V2) for anti-S2 assessed by BioPlex assay ($p < 0.001$ for all). In conclusion, we found a strong correlation between this fast, user-friendly, mobile and bio-safe sVNT and the serological immunoassays.

Neutralizing antibodies against the SARS-CoV-2 Delta and Omicron variants following heterologous CoronaVac plus BNT162b2 booster vaccination. The recent emergence of the SARS-CoV-2 Omicron variant is raising concerns because of its increased transmissibility and its numerous spike mutations, which have the potential to evade neutralizing antibodies elicited by COVID-19 vaccines. Here we evaluated the effects of a heterologous BNT162b2 mRNA vaccine booster on the humoral immunity of participants who had received a two-dose regimen of CoronaVac, an inactivated vaccine used globally. We found that a heterologous CoronaVac prime vaccination of two doses followed by a BNT162b2 booster induces elevated virus-specific antibody levels and potent neutralization activity against the ancestral virus and the Delta variant, resembling the titers obtained after two doses of mRNA vaccines. Although neutralization of Omicron was undetectable in participants who had received a two-dose regimen of CoronaVac, the BNT162b2 booster resulted in a 1.4-fold increase in neutralization activity against Omicron compared with the two-dose mRNA vaccine. Despite this increase, neutralizing antibody titers were reduced by 7.1-fold and 3.6-fold for Omicron compared with the ancestral strain and the Delta variant, respectively. These findings have immediate implications for multiple countries that previously used a CoronaVac regimen and reinforce the idea that the Omicron variant is associated with immune escape from vaccines or infection-induced immunity, highlighting the global need for vaccine boosters to combat the impact of emerging variants.

Neutralizing antibodies against the SARS-CoV-2 Omicron variant BA.1 following homologous and heterologous CoronaVac or BNT162b2 vaccination. The Omicron variant is rapidly becoming the dominant SARS-CoV-2 virus circulating globally. It is important to define reductions in virus neutralizing activity in the serum of convalescent or vaccinated individuals to understand potential loss of protection against infection by Omicron. We previously established that a 50% plaque reduction neutralization antibody titer (PRNT(50)) â‰¥25.6 in our live virus assay corresponded to the threshold for 50% protection from infection against wild-type (WT) SARS-CoV-2. Here we show markedly reduced serum antibody titers against the Omicron variant (geometric mean titer (GMT)â€‰<â€‰10) compared to WT virus 3-5 weeks after two doses of BNT162b2 (GMTâ€‰=â€‰218.8) or CoronaVac vaccine (GMTâ€‰=â€‰32.5). A BNT162b2 booster dose elicited Omicron PRNT(50) titers â‰¥25.6 in 88% of individuals (22 of 25) who previously received 2 doses of BNT162b2 and 80% of individuals (24 of 30) who previously received CoronaVac. However, few (3%) previously infected individuals (1 of 30) or those vaccinated with three doses of CoronaVac (1 of 30) met this threshold. Our findings suggest that countries primarily using CoronaVac vaccines should consider messenger RNA vaccine boosters in response to the spread of Omicron. Studies evaluating the effectiveness of different vaccines against the Omicron variant are urgently needed.

Platelet and immune signature associated with a rapid response to the BNT162b2 mRNA COVID-19 vaccine. BACKGROUND: A rapid immune response is critical to ensure effective protection against COVID-19. Platelets are first-line sentinels of the vascular system able to rapidly alert and stimulate the immune system. However, their role in the immune response to vaccines is not known. OBJECTIVE: To identify features of the platelet-immune crosstalk that would provide an early readout

of vaccine efficacy in adults who received the mRNA-based COVID-19 vaccine (BNT162b2). METHODS: We prospectively enrolled 11 young healthy volunteers (54% females, median age: 28Â years) who received two doses of BNT162b2, 21Â days apart, and we studied their platelet and immune response before and after each dose of the vaccine (3 and 10Â Â±Â 2Â days post-injection), in relation to the kinetics of the humoral response. RESULTS: Participants achieving an effective level of neutralizing antibodies before the second dose of the vaccine (fast responders) had a higher leukocyte count, mounted a rapid cytokine response that incremented further after the second dose, and an elevated platelet turnover that ensured platelet count stability. Their circulating platelets were not more reactive but expressed lower surface levels of the immunoreceptor tyrosine-based inhibitory motif (ITIM)-coupled receptor CD31 (PECAM-1) compared to slow responders, and formed specific platelet-leukocyte aggregates, with B cells, just 3Â days after the first dose, and with non-classical monocytes and eosinophils. CONCLUSION: We identified features of the platelet-immune crosstalk that are associated with the development of a rapid humoral response to an mRNA-based vaccine (BNT162b2) and that could be exploited as early biomarkers of vaccine efficacy.

Women's views on accepting COVID-19 vaccination during and after pregnancy, and for their babies: a multi-methods study in the UK. BACKGROUND: COVID-19 vaccines are advised for pregnant women in the United Kingdom (UK) however COVID-19 vaccine uptake among pregnant women is inadequate. METHODS: An online survey and semi-structured interviews were used to investigate pregnant women's views on COVID-19 vaccine acceptability for themselves when pregnant, not pregnant and for their babies. One thousand one hundred eighty-one women, aged over 16â€‰years, who had been pregnant since 23rd March 2020, were surveyed between 3rd August-11th October 2020. Ten women were interviewed. RESULTS: The majority of women surveyed (81.2%) reported that they would 'definitely' or were 'leaning towards' accepting a COVID-19 vaccine when not pregnant. COVID-19 vaccine acceptance was significantly lower during pregnancy (62.1%, pâ€‰<â€‰0.005) and for their babies (69.9%, pâ€‰<â€‰0.005). Ethnic minority women were twice as likely to reject a COVID-19 vaccine for themselves when not pregnant, pregnant and for their babies compared to women from White ethnic groups (pâ€‰<â€‰0.005). Women from lower-income households, aged under 25-years, and from some geographic regions were more likely to reject a COVID-19 vaccine when not pregnant, pregnant and for their babies. Multivariate analysis revealed that income and ethnicity were the main drivers of the observed age and regional differences. Women unvaccinated against pertussis in pregnancy were over four times more likely to reject COVID-19 vaccines when not pregnant, pregnant and for their babies. Thematic analysis of the survey freetext responses and interviews found safety concerns about COVID-19 vaccines were common though wider mistrust in vaccines was also expressed. Trust in vaccines and the health system were also reasons women gave for accepting COVID-19 vaccines. CONCLUSION: Safety information on COVID-19 vaccines must be clearly communicated to pregnant women to provide reassurance and facilitate informed pregnancy vaccine decisions. Targeted interventions to promote COVID-19 vaccine uptake among ethnic minority and lower-income women may be needed.

CD19-positive lymphocyte count is critical for acquisition of anti-SARS-CoV-2 IgG after vaccination in B-cell lymphoma.

MRI Negative Myelitis Induced by Pfizer-BioNTech COVID-19 Vaccine.

Varicella Zoster Virus Reactivation in Central and Peripheral Nervous Systems Following COVID-19 Vaccination in an Immunocompetent Patient.

COVID vaccine-induced reaction around molluscum contagiosum with secondary partial clearance of lesions.

Evaluation of Neutralizing Antibodies against SARS-CoV-2 Variants after Infection and Vaccination Using a Multiplexed Surrogate Virus Neutralization Test. BACKGROUND: The SARS-CoV-2 virus

has mutated and evolved since the inception of the COVID-19 pandemic bringing into question the future effectiveness of current vaccines and antibody therapeutics. With evolution of the virus updated methods for the evaluation of the immune response in infected and vaccinated individuals are required to determine the durability of the immune response to SARS-CoV-2 variants. METHODS: We developed a multiplexed surrogate virus neutralization test (plex-sVNT) that simultaneously measures the ability of antibodies in serum to inhibit binding between angiotensin converting enzyme-2 (ACE2) and 7 SARS-CoV-2 trimeric spike protein variants, including wild type, B.1.1.7(Î±), B.1.351(Î²), P.1(Î³), B.1.617.2(Î´), B.1.617.1(Îº), and B.1.429(Îµ). The assay was validated against a plaque reduction neutralization test (PRNT).We evaluated 170 samples from 97 COVID-19 patients and 281 samples from 188 individuals that received the Pfizer-BioNTech or Moderna mRNA vaccines. RESULTS: The plex-sVNT demonstrated >96% concordance with PRNT. Antibody neutralization activity was significantly reduced for all SARS-CoV-2 variants compared to wild type in both the infected and vaccinated cohorts. There was a decline in overall antibody neutralization activity, within both cohorts, out to 5 months post infection or vaccination, with the rate of decline being more significant for the vaccinated. CONCLUSIONS: The plex-sVNT provides a correlative measure to PRNT and a convenient approach for evaluating antibody neutralization against SARS-CoV-2 variants. Neutralization of SARS-CoV-2 variants is reduced compared to wild type and declines over the ensuing months after exposure or vaccination within each cohort, however it is still unknown what degree of neutralizing capacity is protective.

COVID-19 with a heavily mutated variant in a multiple myeloma after vaccination: Correspondence.

Pityriasis lichenoides et varioliformis acuta following COVID-19 mRNA vaccination.

Increased neutralization of SARS-CoV-2 Delta variant after heterologous ChAdOx1 nCoV-19/BNT162b2 versus homologous BNT162b2 vaccination. Heterologous SARS-CoV-2 vaccine approaches with a second mRNA-based vaccine have been favored in the recommendations of many countries over homologous vector-based ChAdOx1 nCoV-19 vaccination after reports of thromboembolic events and lower efficacy of this regimen. In the middle of 2021, the SARS-CoV-2 Delta variant of concern (VoC) has become predominant in many countries worldwide. Data addressing the neutralization capacity of a heterologous ChAdOx1 nCoV-19/mRNA-based vaccination approach against the Delta VoC in comparison to the widely used homologous mRNA-based vaccine regimen are limited. Here, we compare serological immune responses of a cohort of ChAdOx1 nCoV-19/BNT162b2-vaccinated participants with those of BNT162b2/BNT162b2 vaccinated ones and show that neutralization capacity against the Delta VoC is significantly increased in sera of ChAdOx1 nCoV-19/BNT162b2-vaccinated participants. This overall effect can be attributed to ChAdOx1 nCoV-19/BNT162b2-vaccinated women, especially those with more severe adverse effects leading to sick leave following second immunization.

Waning antibody response and cellular immunity 6 months after third dose SARS-Cov-2 mRNA BNT162b2 vaccine in kidney transplant recipients.

mRNA-based COVID-19 vaccine boosters induce neutralizing immunity against SARS-CoV-2 Omicron variant. Recent surveillance has revealed the emergence of the SARS-CoV-2 Omicron variant (BA.1/B.1.1.529) harboring up to 36 mutations in spike protein, the target of neutralizing antibodies. Given its potential to escape vaccine-induced humoral immunity, we measured the neutralization potency of sera from 88 mRNA-1273, 111 BNT162b, and 40 Ad26.COV2.S vaccine recipients against wild-type, Delta, and Omicron SARS-CoV-2 pseudoviruses. We included individuals that received their primary series recently (<3Â months), distantly (6-12Â months), or an additional "booster" dose, while accounting for prior SARS-CoV-2 infection. Remarkably, neutralization of Omicron was undetectable in most vaccinees. However, individuals boosted with mRNA vaccines exhibited potent neutralization of Omicron, only 4-6-fold lower than wild type, suggesting enhanced cross-reactivity of

neutralizing antibody responses. In addition, we find that Omicron pseudovirus infects more efficiently than other variants tested. Overall, this study highlights the importance of additional mRNA doses to broaden neutralizing antibody responses against highly divergent SARS-CoV-2 variants.
Comment on a case of pityriasis rosea shortly after Moderna COVID-19 vaccination.
Lichen planus after CoronaVac: a rare complication of vaccines.
Omicron's feeble attack on the lungs could make it less dangerous.
Limited increase in antibody titers following mRNA SARS-CoV-2 vaccination for more than 3 years after final dose of anti-CD20 antibody. We investigated the efficacy of BNT162b2 mRNA COVID-19 vaccine in patients with B-cell malignancies treated with anti-CD20 antibody. Although T-cell-mediated immune responses were detected even in patients receiving R-CHOP treatment, the S1 antibody titer following BNT162b2 vaccination remained only marginally increased for more than 3Â years after the final dose of anti-CD20 antibody. We found no relationship between the percent of B-cells and S1 antibody titer. The duration of this suppression was much longer than we anticipated. Further protection and treatment strategies against COVID-19 for these patients are warranted.
SARS-CoV-2 Omicron neutralization by therapeutic antibodies, convalescent sera, and post-mRNA vaccine booster. The rapid spread of the highly contagious Omicron variant of SARS-CoV-2 along with its high number of mutations in the spike gene has raised alarm about the effectiveness of current medical countermeasures. To address this concern, we measured neutralizing antibodies against Omicron in three important settings: (1) post-vaccination sera after two and three immunizations with the Pfizer/BNT162b2 vaccine, (2) convalescent sera from unvaccinated individuals infected by different variants, and (3) clinical-stage therapeutic antibodies. Using a pseudovirus neutralization assay, we found that titers against Omicron were low or undetectable after two immunizations and in most convalescent sera. A booster vaccination significantly increased titers against Omicron to levels comparable to those seen against the ancestral (D614G) variant after two immunizations. Neither age nor sex were associated with differences in post-vaccination antibody responses. Only three of 24 therapeutic antibodies tested retained their full potency against Omicron and high-level resistance was seen against fifteen. These findings underscore the potential benefit of booster mRNA vaccines for protection against Omicron and the need for additional therapeutic antibodies that are more robust to highly mutated variants. ONE SENTENCE SUMMARY: Third dose of Pfizer/BioNTech COVID-19 vaccine significantly boosts neutralizing antibodies to the Omicron variant compared to a second dose, while neutralization of Omicron by convalescent sera, two-dose vaccine-elicited sera, or therapeutic antibodies is variable and often low.
Recurring subacute thyroiditis after SARS-CoV-2 mRNA vaccine: A case report. SARS-CoV-2 vaccination is the most powerful and promising tool against the COVID-19 pandemic. Millions of people have been vaccinated worldwide. Recently, few cases of subacute thyroiditis following SARS-CoV-2 vaccination with various types of vaccine have been reported. We describe here a 36-year-old woman who presented with subacute thyroiditis 10Â days after she had received her first dose of the SARS-CoV-2 mRNA vaccine Comirnaty (Pfizer/BioNTech); the condition receded but then recurred 10Â days after she received her second dose. As vaccination programmes proceed, clinicians' attention and vigilance for such cases will be increased. Physicians need to know that subacute thyroiditis is a mild and self-limiting condition in the majority of cases. Last but not least, the benefits of vaccination against COVID-19 outweigh the side-effects reported so far.
Management of COVID-19 post-vaccine Bell's palsy in an outpatient.
Detection of persistent SARS-CoV-2 IgG antibodies in oral mucosal fluid and upper respiratory tract specimens following COVID-19 mRNA vaccination. COVID-19 mRNA vaccines are highly effective at preventing COVID-19. Prior studies have found detectable SARS-CoV-2 IgG antibodies in oral

mucosal specimens of participants with history of COVID-19. To assess the development of oral SARS-CoV-2 IgG antibodies among people who received either the Moderna or Pfizer/BioNTech COVID-19 vaccination series, we developed a novel SARS-CoV-2 IgG enzyme-linked immunosorbent assay (ELISA) to quantify the concentrations of oral and nasal mucosal SARS-CoV-2 IgG levels. We enrolled 52 participants who received the Moderna vaccine and 80 participants who received the Pfizer/BioNTech vaccine. Oral mucosal specimens were self-collected by participants prior to or on the day of vaccination, and on days 5, 10, 15, and 20 following each vaccination dose and 30, 60, and 90Â days following the second vaccination dose. A subset of the cohort provided additional nasal mucosal specimens at every time point. All participants developed detectable oral mucosal SARS-CoV-2 IgG antibodies by 15Â days after the first vaccination dose. There were no significant differences in oral mucosal antibody concentrations once participants were fully vaccinated in the Moderna and Pfizer/BioNTech vaccines. Oral or nasal mucosal antibody testing could be an inexpensive and less invasive alternative to serum antibody testing. Further research is needed to understand the duration of detectable oral or nasal mucosal antibodies and how antibody concentrations change with time.

Venous sinus thrombosis after the second dose of SARS-CoV-2 vaccine administration.

SARS-CoV-2 Antibodies Are Persisting in Saliva for More Than 15 Months After Infection and Become Strongly Boosted After Vaccination. SARS-CoV-2 antibodies in saliva serve as first line of defense against the virus. They are present in the mucosa, more precisely in saliva, after a recovered infection and also following vaccination. We report here the antibody persistence in plasma and in saliva up to 15 months after mild COVID-19. The IgG antibody response was measured every two months in 72 participants using an established and validated in-house ELISA assay. In addition, the virus inhibitory activity of plasma antibodies was assessed in a surrogate virus neutralization test before and after vaccination. SARS-CoV-2-specific antibody concentrations remained stable in plasma and saliva and the response was strongly boosted after one dose COVID-19 vaccination.

Impaired immune response to COVID-19 vaccination in patients with B-cell malignancies after CD19 CAR T-cell therapy.

Comment on: COVID-19 vaccine-associated reactivation of uveitis.

Parsonage-Turner Syndrome After COVID-19 Vaccination: A Case Report. CASE: A 43-year-old man developed Parsonage-Turner syndrome shortly after receiving a COVID-19 vaccine. The patient presented to the hospital 5 days after receiving a COVID-19 vaccine to the right shoulder complaining of severe right shoulder pain, right upper extremity swelling, and weakness. Clinical examination, physical examination, and magnetic resonance imaging findings were consistent with Parsonage-Turner syndrome. CONCLUSION: It is important that Parsonage-Turner syndrome remains in the differential diagnosis in a patient with severe shoulder pain and weakness after the administration of a COVID-19 vaccine.

Prevalence and factors associated with the intention to be vaccinated against COVID-19 in Peru. OBJECTIVES: To estimate the prevalence and factors associated with the intention to be vaccinated (ITV) against COVID-19 in Peru. MATERIALS AND METHODS: Analytical cross-sectional study using the survey conducted by the University of Maryland, USA, on Facebook. The dependent variable is the ITV. Crude and adjusted prevalence ratios (PR) were calculated, with their 95% confidence intervals (95% CI) using generalized linear models of the Poisson family, in order to evaluate the association of sociodemographic variables, compliance with community mitigation strategies, symptoms of COVID-19, mental health and acceptance of vaccination before the recommendation (AVR) by various actors and health authorities, with the ITV. RESULTS: Data from 17,162 adults were analyzed. The overall prevalence of the ITV was 74.9%. A lower prevalence of the ITV was associated with the female sex (PR=0.95; 95% CI: 0.94-0.97), living in a town (PR=0.95; 95% CI: 0.91-0.99) or village or other rural area (PR=0.90; 95% CI: 0.86-0.93) and the AVR of politicians (PR=0.89; 95% CI: 0.87-0.92). Conversely,

having COVID-19 symptoms (PR=1.06; 95% CI: 1.03-1.09), economic insecurity (PR=1.04; 95% CI: 1.01-1.06), fears of becoming seriously ill or that a family member becomes seriously ill from COVID-19 (PR=1.49; 95% CI: 1.36-1.64) and the AVR of family and friends (PR=1.10; 95% CI: 1.08-1.12), healthcare workers (PR=1.29; 95% CI: 1.26-1.32), World Health Organization (PR=1.34; 95% CI: 1.29-1.40) and government officials (PR=1.18; 95% CI: 1.15-1.22) was associated with a higher prevalence of the ITV. CONCLUSIONS: Three-quarters of the respondents had the ITV. There are potentially modifiable factors that could improve vaccine acceptance.
Renal Complications Following COVID-19 Vaccination. There is no abstract.
SARS-CoV-2 Vaccine Response in Patients With Antineutrophil Cytoplasmic Autoantibody-Associated Vasculitis.
Covid-19 vaccines and thromboembolic complications.
Significantly elevated antibody levels and neutralization titers in nursing home residents after SARS-CoV-2 BNT162b2 mRNA booster vaccination. Nursing home (NH) residents have experienced significant morbidity and mortality to SARS-CoV-2 throughout the pandemic. Vaccines initially curbed NH resident morbidity and mortality, but antibody levels and protection have declined with time since vaccination, prompting introduction of booster vaccination. This study assesses humoral immune response to booster vaccination in 85 NH residents and 44 health care workers (HCW) that we have followed longitudinally since initial SARS-CoV-2 BNT162b2 mRNA vaccination. The findings reveal that booster vaccination significantly increased anti-spike, anti-receptor binding domain, and neutralization titers above the pre-booster levels in almost all NH residents and HCW to significantly higher levels than shortly after the completion of the initial vaccine series. These data support the CDC recommendation to offer vaccine boosters to HCWs and NH residents on an immunological basis. Notably, even the older, more frail and more multi-morbid NH residents have sizable antibody increases with boosting.
Immune thrombocytopenia associated with COVID-19 mRNA vaccine tozinameran - a clinical case and global pharmacovigilance data. We report the occurrence of immune thrombocytopenia (ITP) in a 77-year-old man a few days after receiving the first dose of the COVID-19 mRNA vaccine tozinameran (ComirnatyÂ®). The patient was treated with systemic corticosteroids, intravenous immunoglobulins and eltrombopag. He elected to proceed with the second dose of tozinameran 14 weeks after the first and his platelet count remained stable under a tapered eltrombopag dose. To our knowledge, this is the first case in which a second tozinameran dose has been administered to a patient who developed presumed secondary ITP after the first vaccination. We also report global pharmacovigilance data for the occurrence of ITP after vaccination with tozinameran.
Anti-CD38 therapy impairs SARS-CoV-2 vaccine response against alpha and delta variants in patients with multiple myeloma.
COVID-19 Vaccine Uptake, Acceptance, and Hesitancy Among Persons With Mental Disorders During the Second Stage of China's Nationwide Vaccine Rollout. Persons with mental disorders (PwMDs) are a priority group for COVID-19 vaccination, but empirical data on PwMDs' vaccine uptake and attitudes toward COVID-19 vaccines are lacking. This study examined the uptake, acceptance, and hesitancy associated with COVID-19 vaccines among Chinese PwMDs during China's nationwide vaccine rollout. In total, 906 adult PwMDs were consecutively recruited from a large psychiatric hospital in Wuhan, China, and administered a self-report questionnaire, which comprised standardized questions regarding sociodemographics, COVID-19 vaccination status, attitudes toward COVID-19 vaccines, and psychopathology. Vaccine-recipients were additionally asked to report adverse events that occurred following vaccination. PwMDs had a much lower rate of vaccination than Wuhan residents (10.8 vs. 40.0%). The rates of vaccine acceptance and hesitancy were 58.1 and 31.1%, respectively. Factors associated with vaccine uptake included having other mental disorders

[odds ratio (OR) = 3.63], believing that â‰¥50% of vaccine-recipients would be immune to COVID-19 (OR = 3.27), being not worried about the side effects (OR = 2.59), and being an outpatient (OR = 2.24). Factors associated with vaccine acceptance included perceiving a good preventive effect of vaccines (OR = 12.92), believing that vaccines are safe (OR = 4.08), believing that â‰¥50% of vaccine-recipients would be immune to COVID-19 (OR = 2.20), and good insight into the mental illness (OR = 1.71). Adverse events occurred in 21.4% of vaccine-recipients and exacerbated pre-existing psychiatric symptoms in 2.0% of vaccine-recipients. Nevertheless, 95.2% of vaccine-recipients rated adverse events as acceptable. Compared to the 58.1% vaccine acceptance rate and the 40.0% vaccination rate in the general population, the 10.8% vaccine coverage rate suggested a large unmet need for COVID-19 vaccination in Chinese PwMDs. Strategies to increase vaccination coverage among PwMDs may include provision of reliable sources of information on vaccines, health education to foster positive attitudes toward vaccines, a practical guideline to facilitate clinical decision-making for vaccination, and the involvement of psychiatrists in vaccine consultation and post-vaccination follow-up services.
Optic neuritis after COVID-19 vaccine application. As the COVID-19 pandemic continues to rise, the development of effective vaccines is of crucial importance to prevent further morbidity and mortality. In parallel, some rare adverse events related to COVID-19 vaccines, have been reported, most of them mild. Here we report the case of a previously healthy 19-year-old woman who developed optic neuritis 1Â week after single dose of Ad26.COV2.S vaccine with marked improvement after management with steroids. Although causality cannot be confirmed due to lack of a biological marker, this case may help to guide further research for potential pathogenic mechanism.
Development of pemphigus vulgaris following mRNA SARS-CoV-19 BNT162b2 vaccination in an 89-year-old patient.
Post RNA-based COVID vaccines myocarditis: Proposed mechanisms.
Attenuated response to SARS-CoV-2 vaccine in patients with asymptomatic precursor stages of multiple myeloma and Waldenstrom macroglobulinemia.
Functional neurological disorder after vaccination: a balanced approach informed by history.
Beyond prioritization: Challenges to the COVID-19 vaccination of people with mental disorders in the Philippines.
Impaired Humoral Response to Third Dose of BNT162b2 mRNA COVID-19 Vaccine Despite Detectable Spike Protein-specific T cells in Lung Transplant Recipients.
Neutralizing Antibody Testing in Patients With Multiple Myeloma Following COVID-19 Vaccination.
Dissociated humoral and cellular immune responses after a three-dose schema of BNT162b2 vaccine in patients receiving anti-CD20 monoclonal antibody maintenance treatment for B-cell lymphomas.
The emergence of powerful oral anti-COVID-19 drugs in the post-vaccine era.
A case of generalized Sweet syndrome with vasculitis triggered by recent COVID-19 vaccination.
Publisher Correction: Neurological complications after first dose of COVID-19 vaccines and SARS-CoV-2 infection.
Leukocytoclastic vasculitis after exposure to COVID-19 vaccine.
Comments on "Initial clinical manifestation of multiple sclerosis after immunization with the Pfizer-BioNTech COVID-19 vaccine" by , J Neuroimmunol.
Antibody response to COVID-19 booster vaccine in rituximab-treated patients with anti-neutrophil cytoplasmic antibody-associated vasculitis.
Rapid relaxation of pandemic restrictions after vaccine rollout favors growth of SARS-CoV-2 variants: A model-based analysis. The development and deployment of several SARS-CoV-2 vaccines in a little over a year is an unprecedented achievement of modern medicine. The high levels of efficacy

against transmission for some of these vaccines makes it feasible to use them to suppress SARS-CoV-2 altogether in regions with high vaccine acceptance. However, viral variants with reduced susceptibility to vaccinal and natural immunity threaten the utility of vaccines, particularly in scenarios where a return to pre-pandemic conditions occurs before the suppression of SARS-CoV-2 transmission. In this work we model the situation in the United States in May-June 2021, to demonstrate how pre-existing variants of SARS-CoV-2 may cause a rebound wave of COVID-19 in a matter of months under a certain set of conditions. A high burden of morbidity (and likely mortality) remains possible, even if the vaccines are partially effective against new variants and widely accepted. Our modeling suggests that variants that are already present within the population may be capable of quickly defeating the vaccines as a public health intervention, a serious potential limitation for strategies that emphasize rapid reopening before achieving control of SARS-CoV-2.
Pityriasis rosea after Moderna mRNA-1273 vaccine: A case series.
Evidence of extensive cellular immune response after SARS-CoV-2 vaccination in ocrelizumab-treated patients with multiple sclerosis. BACKGROUND: Patients with multiple sclerosis receiving ocrelizumab-treatment are in desperate need of a protection against SARS-CoV-2 infection. METHODS: In this study, Euroimmun semi-quantitative Anti-SARS-CoV-2 IgG for detection of humoral response and ELISpot assays for detection of SARS-CoV-2-specific T-cell-response were used in 10 ocrelizumab-treated patients with multiple sclerosis twice vaccinated with ComirnatyÂ® mRNA vaccine. This data was compared with a control group of 20 age- and sex-matched healthy volunteers, who had all previously received a full SARS-CoV-2 mRNA vaccination with ComirnatyÂ® or SpikevaxÂ®. RESULTS: While all subjects in the control group had high humoral response to the vaccination, in B-cell-depleted individuals a significantly reduced antibody response to vaccination against SARS-CoV-2 was observed. SARS-CoV-2 specific T-cell-response, however, did not differ significantly between both cohorts. CONCLUSIONS: T-cell-mediated response to ComirnatyÂ® vaccination is observable despite attenuated humoral response in B-cell-depleted patients. This might enable partial protection against COVID-19. Trial registration Retrospectively registered.
Subclinical thrombotic thrombocytopenic purpura after vaccination with ChAdOx1 nCoV-19.
Isolation of 4000 SARS-CoV-2 shows that contagiousness is associated with viral load, not vaccine or symptomatic status. Culture inoculation of 6722 nasopharyngeal samples since February 2020 allowed isolation of 3637 SARS-CoV-2 and confirmed that isolation rate is correlated to viral load, regardless symptomatology or vaccination status. Moreover, the delta variant is associated with higher viral loads and therefore higher rates of viral isolation, explaining its greater contagiousness.
SARS Cov-2 vaccination induces de novo donor-specific HLA antibodies in a renal transplant patient on waiting list: A case report. The ability of COVID-19 vaccination to induce anti-HLA antibodies (Abs) formation in renal transplant candidates is not well studied. A 42-year-old man on a renal transplant waitlist, with no sensitization history, was tested for DSA before and after COVID-19 vaccination. Patient has consistently tested negative for COVID-19 virus. Eighteen days after receiving first dose of mRNA-based vaccine, flow cytometry crossmatch (FCXM) was strongly positive with de novo donor-specific Ab (dnDSA) against B57 and de novo non-DSA against B58. Before vaccination, preliminary FCXM was negative with no anti-HLA Abs. This event prompted the transplant team to cancel the surgery. COVID-19 vaccination could be associated with anti-HLA Abs formation in renal patients on waitlists that could affect future transplantability.
Lupus nephritis flare post Moderna mRNA-1273 coronavirus vaccine.
Web Exclusive. Annals for Hospitalists Inpatient Notes - Myocarditis After Vaccination for SARS-CoV-2.
The path of uncovering a prothrombotic thrombocytopenic syndrome after viral vector-based COVID-19 vaccination: Where there is much light, the shadow is deep.
Romiplostim for SARS-CoV-2 Vaccine Induced Immune Thrombocytopenia.

SARS-CoV-2 neutralizing antibodies after one or two doses of Comirnaty (BNT162b2, BioNTech/Pfizer): Kinetics and comparison with chemiluminescent assays. BACKGROUND: Studies evaluating neutralizing antibody (NAb) after BNT162b2 vaccine are scarce. We therefore compared NAb using the plaque reduction neutralization test (PRNT) in vaccinated subjects, with those from five chemiluminescent (CLIA) assays, two targeting ACE and S-RBD interaction. METHODS: Sera from 174 completely Comirnaty/BNT162b2 vaccinated healthcare workers (HCW) were evaluated at t(12) and t(28). NAb titers at low (PRNT(50)) or high (PRNT(90)) stringency were compared with: Liaison SARS-CoV-2 Trimeric-S IgG, Elecsys S-RBD Ab, Maglumi SARS-CoV-2 S-RBD IgG and SARS-CoV-2 Nab; iFlash 2019-nCoV NAb. RESULTS: Neither PRNT(50) nor PRNT(90) correlated with age (range, 24-65Â years); no significant differences were found for gender. PRNT(50) and PRNT(90) seropositive titers (â‰¥1:20) were 43 (24.7%) and 15 (8.6%) at t(12) and 167 (95.9%) and 149 (85.6%) at t(28). CLIA results at t(28) were uncorrelated with age, apart from Elecsys S-RBD Ab (rÂ =Â -0.164, pÂ =Â 0.046). Gender differences were found for Maglumi SARS-CoV-2 S-RBD IgG (pÂ =Â 0.037) and Maglumi NAb (pÂ =Â 0.046). Considering PRNT(50) at thresholds of 1:20 (or 1:40) and 1:160 (or 1:320), corresponding to different immune protective levels, CLIA cut-offs have been identified. CONCLUSIONS: Comirnaty/BNT162b2 elicits strong NAb production, especially 28Â days after first inoculum. Differences in correlation between Nab titers and circulating antibodies measured by 5 immunoassays have been found, being stronger the correlation for Maglumi Nab.

RT-qPCR assays for SARS-CoV-2 variants of concern in wastewater reveals compromised vaccination-induced immunity. SARS-CoV-2 variants of concern, demonstrating higher infection rate and lower vaccine effectiveness as compared with the original virus, are important factors propelling the ongoing COVID-19 global outbreak. Therefore, prompt identification of these variants in the environment is essential for pandemic assessment and containment efforts. One well established tool for such viral monitoring is the use of wastewater systems. Here, we describe continuous monitoring of traces of SARS-CoV-2 viruses in the municipal wastewater of a large city in Israel. By observing morbidity fluctuations (during three main COVID-19 surges) occurring in parallel with Pfizer-BioNTech COVID-19 vaccine vaccination rate, compromised immunity was revealed in the current morbidity peak. RT-qPCR assays for the Original (D614G), Alpha and Beta variants had been previously developed and are being employed for wastewater surveillance. In the present study we developed a sensitive RT-qPCR assay designed for the rapid, direct detection of Gamma and Delta variants of concern. Sensitive quantification and detection of the various variants showed the prevalence of the original variant during the first morbidity peak. The dominance of the Alpha variant over the original variant correlated with the second morbidity peak. These variants decreased concurrently with an increase in vaccinations (Feb-March 2021) and the observed decrease in morbidity. The appearance and subsequent rise of the Delta variant became evident and corresponded to the third morbidity peak (June-August 2021). These results suggest a high vaccine neutralization efficiency towards the Alpha variant compared to its neutralization efficiency towards the Delta variant. Moreover, the third vaccination dose (booster) seems to regain neutralization efficiency towards the Delta variant. The developed assays and wastewater-based epidemiology are important tools aiding in morbidity surveillance and disclosing vaccination efforts and immunity dynamics in the community.

Sudden onset of vitiligo after COVID-19 vaccine.

A localised vasculitic-like skin rash following the second dose of COVID-19 vaccine.

A case of myopericarditis with pleuritis following AstraZeneca Covid-19 vaccination.

Comparing neurological complications after COVID-19 vaccination and SARS-CoV-2 infection.

Serum antibody response in patients with philadelphia-chromosome positive or negative myeloproliferative neoplasms following vaccination with SARS-CoV-2 spike protein messenger RNA (mRNA) vaccines.

Pityriasis Rosea Shortly After mRNA-1273 COVID-19 Vaccination.
Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19-Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity - Nine States, January-September 2021. Previous infection with SARS-CoV-2 (the virus that causes COVID-19) or COVID-19 vaccination can provide immunity and protection from subsequent SARS-CoV-2 infection and illness. CDC used data from the VISION Network* to examine hospitalizations in adults with COVID-19-like illness and compared the odds of receiving a positive SARS-CoV-2 test result, and thus having laboratory-confirmed COVID-19, between unvaccinated patients with a previous SARS-CoV-2 infection occurring 90-179 days before COVID-19-like illness hospitalization, and patients who were fully vaccinated with an mRNA COVID-19 vaccine 90-179 days before hospitalization with no previous documented SARS-CoV-2 infection. Hospitalized adults aged â‰¥18 years with COVID-19-like illness were included if they had received testing at least twice: once associated with a COVID-19-like illness hospitalization during January-September 2021 and at least once earlier (since February 1, 2020, and â‰¥14 days before that hospitalization). Among COVID-19-like illness hospitalizations in persons whose previous infection or vaccination occurred 90-179 days earlier, the odds of laboratory-confirmed COVID-19 (adjusted for sociodemographic and health characteristics) among unvaccinated, previously infected adults were higher than the odds among fully vaccinated recipients of an mRNA COVID-19 vaccine with no previous documented infection (adjusted odds ratio [aOR]Â =Â 5.49; 95% confidence interval [CI]Â =Â 2.75-10.99). These findings suggest that among hospitalized adults with COVID-19-like illness whose previous infection or vaccination occurred 90-179 days earlier, vaccine-induced immunity was more protective than infection-induced immunity against laboratory-confirmed COVID-19. All eligible persons should be vaccinated against COVID-19 as soon as possible, including unvaccinated persons previously infected with SARS-CoV-2.
VITT after ChAdOx1 nCoV-19 Vaccination. Reply.
VITT after ChAdOx1 nCoV-19 Vaccination.
Potential role of macrophage activation in mediating thrombotic complications associated with the different vaccines against COVID-19.
Neuro-ophthalmic complications with ChAdOx1 nCoV-19 vaccine-induced thrombocytopenia and thrombosis.
BioNTech/Pfizer vaccine after Oxford/AZ vaccine increased immune response vs. no second vaccine. Borobia AM, Carcas AJ, Perez-Olmeda M, et al. Immunogenicity and reactogenicity of BNT162b2 booster in ChAdOx1-S-primed participants (CombiVacS): a multicentre, open-label, randomised, controlled, phase 2 trial. Lancet. 2021;398:121-30. 34181880.
Clinical Factors Associated With Lack of Serological Response to SARS-CoV-2 Messenger RNA Vaccine in Liver Transplantation Recipients.
Thyrotoxicosis after COVID-19 vaccination.
Possible case of mRNA COVID-19 vaccine-induced small-vessel vasculitis.
Evaluation of antibody response after COVID-19 vaccination of healthcare workers. The common goal of all vaccines developed against COVID-19, although they have been designed with different methods, is to develop an effective immunity and antibody response against SARS-CoV-2. However, the postvaccination immune response and antibody levels differ between individuals. This study examined the relationship between postvaccine seropositivity rates, age, gender, smoking, and body mass index (BMI), and antibody titers. A total ofÂ 314 healthcare workers (HCW) who were not previously infected with COVID-19 and who had received two doses of CoronaVac inactivated vaccine participated in the study. Seropositivity against the receptor-binding domain (RBD) of the SARS-CoV-2 spike protein was measured from the participants 4 weeks after the second dose of vaccine using the

electrochemiluminescence (ECLIA) method. In addition, the antibody developed against the nucleocapsid protein (NCP) was evaluated and compared using Elecsys Anti-SARS-CoV-2 kit. One hundred and eighty-oneÂ of the participants were female (57.6%) with a median age of 39 (interquartile range [IQR], 10) and 133 (42.4%) were male with a median age of 41 (IQR, 11). 99.6% of the volunteers developed seropositivity 4 weeks after the second dose of vaccine. It was also observed that the rate of RBDÂ proteinÂ antibody titer was >250â€‰U/ml in smokers, which is quite low compared to nonsmokers (pâ€‰=â€‰0.032), and that high RBD antibody titers were proportionally lower in obese participants, according to BMI values, compared to those with normal BMI (49.5% and 9.9%). It was observed that seropositivity developed in almost all participants after the CoronaVac vaccine. However, it was determined that the antibody titer measured varied depending on factors such as smoking, BMI, and duration.
COVID-19 Vaccination Attitudes, Perceptions, and Side Effect Experiences in Malaysia: Do Age, Gender, and Vaccine Type Matter? This study aimed to investigate the attitudes, perceptions, and experiences of side effects with the COVID-19 vaccines in Malaysia among participants in the National Vaccination Program. A cross-sectional survey was conducted among a sample of vaccine-eligible and vaccinated individuals in Malaysia between May and July 2021. A total of 428 respondents completed the survey. A vast majority (98.6%) of the respondents had registered to be vaccinated. Twenty participants (4.7%) expressed concerns about either registering or receiving the COVID-19 vaccination, mainly due to their uncertainty of vaccine safety. Approximately 77.5% received their vaccinations. Of them, 76.8% had experienced vaccine-related side effects. About 40% of the side effects occurred more with the second dose, particularly those who received the Pfizer-BioNTech vaccine ($p < 0.001$). Pain at the injection site (61.1%) and tiredness (48.8%) were the most reported side effects. Compared to those aged â‰¥60 years, all age groups were more likely to exhibit vaccine-related side effects; meanwhile, males (OR: 0.51, 95% CI: 0.27-0.93) were less likely to experience side effects than females. Those who received the Sinovac vaccine were at lower risk of experiencing side effects (OR: 0.08, 95% CI: 0.03-0.22) and were more likely to report fewer side effects than Pfizer-BioNTech ($p = 0.012$) and Oxford-AstraZeneca groups ($p= 0.001$). The overall attitudes toward the COVID-19 vaccination program were positive. Several differences in the experiences of vaccine-related side effects, in terms of prevalence and numbers, were attributed to age, gender, and received vaccine type.
Humoral Response Induced by Prime-Boost Vaccination with the ChAdOx1 nCoV-19 and mRNA BNT162b2 Vaccines in a Teriflunomide-Treated Multiple Sclerosis Patient. Patients with multiple sclerosis (MS) are treated with drugs that may impact immune responses to SARS-CoV-2 vaccination. Evaluation of "prime-boost" (heterologous) vaccination regimens including a first administration of a viral vector-based vaccine and a second one of an mRNA-based vaccine in such patients has not yet been completed. Here, we present the anti-spike protein S humoral response, including the neutralizing antibody response, in a 54-year-old MS patient who had been treated with teriflunomide for the past 2 years and who received a heterologous ChAdOx1 nCoV-19/ BNT162b2 vaccination regimen. The results showed a very strong anti-S IgG response and a good neutralizing antibody response. These results show that teriflunomide did not prevent the development of a satisfactory humoral response in this MS patient after vaccination with a ChAdOx1 nCoV-19/ BNT162b2 prime-boost protocol.
First report of COVID-19 vaccine induced flare of compensated congenital thrombotic thrombocytopenic purpura.
Pathophysiology of Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) and Vaccine-Induced Thrombocytopenic Thrombosis (VITT) and Their Diagnostic Approach in Emergency. SARS-CoV-2 induced a pandemic that is reported to have started in Asia and was then extended to

other countries in the world. Main clinical aspects of this viral infection have been lung injuries with severe pneumonia requiring prolonged hospitalization and associated morbidities such as venous thromboembolism and/or superinfection by bacteria, fungus or other pests. Immediately there was a need to develop a sustainable therapeutic strategy, such as vaccination. Vaccines against Covid-19, in fact, exert a protective action for common people and reduce viral diffusion. Yet, vaccination of a large number of people raises the question of a well-known complication of several types of vaccines; this complication is immune thrombocytopenia, which is sometimes associated with thrombosis as well. In this short review, we summarized mechanisms involved in the pathogenesis of vaccine-induced prothrombotic immune thrombocytopenia and vaccine-induced thrombocytopenic thrombosis.
Humoral and cellular responses after COVID-19 vaccination in anti-CD20-treated lymphoma patients.
Severe necrotizing myopathy after COVID-19 vaccine with BNT162b2 and regimen with ipilimumab plus nivolumab in a patient with advanced melanoma.
ChAdOx1 nCov-19 vaccine-induced thrombotic thrombocytopenic purpura successfully treated with plasmapheresis.
Abnormal Thyroid Function Following COVID-19 Vaccination.
Response to 'A skin reaction with rust-like discolouration to mRNA COVID-19 vaccine'.
Severe impairment of T-cell responses to BNT162b2 immunization in patients with multiple myeloma.
Does a lack of vaccine side effects correlate with reduced BNT162b2 mRNA vaccine response among healthcare workers and nursing home residents? BACKGROUND: The BNT162b2 SARS-CoV-2 mRNA vaccination has mitigated the burden of COVID-19 among residents of long-term care facilities considerably, despite being excluded from the vaccine trials. Data on reactogenicity (vaccine side effects) in this population are limited. AIMS: To assess reactogenicity among nursing home (NH) residents. To provide a plausible proxy for predicting vaccine response among this population. METHODS: We enrolled and sampled NH residents and community-dwelling healthcare workers who received the BNT162b2 mRNA vaccine, to assess local or systemic reactogenicity and antibody levels (immunogenicity). RESULTS: NH residents reported reactions at a much lower frequency and lesser severity than the community-dwelling healthcare workers. These reactions were mild and transient with all subjects experiencing more local than systemic reactions. Based on our reactogenicity and immunogenicity data, we developed a linear regression model predicting log-transformed anti-spike, anti-receptor-binding domain (RBD), and neutralizing titers, with a dichotomous variable indicating the presence or absence of reported reactions which revealed a statistically significant effect, with estimated shifts in log-transformed titers ranging from 0.32 to 0.37 (all pâ€‰<â€‰0.01) indicating greater immunogenicity in subjects with one or more reported reactions of varying severity. DISCUSSION: With a significantly lower incidence of post-vaccination reactions among NH residents as reported in this study, the BNT162b2 mRNA vaccine appears to be well-tolerated among this vulnerable population. If validated in larger populations, absence of reactogenicity could help guide clinicians in prioritizing vaccine boosters. CONCLUSIONS: Reactogenicity is significantly mild among nursing home residents and overall, subjects who reported post-vaccination reactions developed higher antibody titers.
Decreased vaccination coverage and recurrence risk of measles due to COVID-19 pandemic.
ACE polymorphism is a determinant for COVID-19 mortality in the post-vaccination era.
Immune Thrombocytopenic Purpura following Administration of mRNA-Based SARS-CoV-2 and MMR Vaccinations: A Cautionary Tale. We report a case of immune thrombocytopenic purpura (ITP) in an otherwise healthy 31-year-old man following coadministration of the live measles, mumps, and rubella (MMR) vaccine with the Pfizer-BioNTech mRNA SARS-CoV-2 vaccine. The patient was

hospitalized briefly and treated for ITP with glucocorticoids, IVIG, and platelet transfusion. Although our patient's clinical presentation and subsequent course are similar to those of other cases of ITP in association with SARS-CoV-2 vaccination, to our knowledge, this is the first reported case of ITP following MMR and mRNA SARS-CoV-2 vaccine coadministration. It would be impossible to conclusively prove that the patient's thrombocytopenia was secondary to the SARS-CoV-2 vaccine alone, the MMR vaccine, or an additive effect of both vaccines. However, with the CDC guidelines recommending the coadministration of the mRNA SARS-CoV-2 vaccine without regards to timing with other vaccines, we urge further caution as there is limited evidence to inform practice. This case highlights the need for further safety data regarding the coadministration and timing of the mRNA SARS-CoV-2 vaccine with other vaccines.
Impact of circulating SARS-CoV-2 variants on mRNA vaccine-induced immunity. The emergence of SARS-CoV-2 variants with mutations in major neutralizing antibody-binding sites can affect humoral immunity induced by infection or vaccination(1-6). Here we analysed the development of anti-SARS-CoV-2 antibody and T cell responses in individuals who were previously infected (recovered) or uninfected (naive) and received mRNA vaccines to SARS-CoV-2. While individuals who were previously infected sustained higher antibody titres than individuals who were uninfected post-vaccination, the latter reached comparable levels of neutralization responses to the ancestral strain after the second vaccine dose. T cell activation markers measured upon spike or nucleocapsid peptide in vitro stimulation showed a progressive increase after vaccination. Comprehensive analysis of plasma neutralization using 16 authentic isolates of distinct locally circulating SARS-CoV-2 variants revealed a range of reduction in the neutralization capacity associated with specific mutations in the spike gene: lineages with E484K and N501Y/T (for example, B.1.351 and P.1) had the greatest reduction, followed by lineages with L452R (for example, B.1.617.2). While both groups retained neutralization capacity against all variants, plasma from individuals who were previously infected and vaccinated displayed overall better neutralization capacity than plasma from individuals who were uninfected and also received two vaccine doses, pointing to vaccine boosters as a relevant future strategy to alleviate the effect of emerging variants on antibody neutralizing activity.
Covid-19 vaccination, adverse events, and detection of antibodies.
COVID-19 Vaccine-Induced Immune Thrombosis with Thrombocytopenia (VITT) and the Shades of Grey in Thrombus Formation.
The first presentation of COVID-19 two hours after vaccination in a patient with multiple sclerosis: Can COVID vaccine provoke cytokine storm in a patient with asymptomatic COVID-19?
Vaccination induced complacency in adherence to COVID-19 precautionary measures among oral health care professionals in India and the United States: a retrospective pretest-posttest design. In the context of the COVID-19 pandemic, vaccination-induced behavioral complacency in adherence to COVID-19 appropriate behavior emerged as a significant concern. This study was conducted among a convenience sample of 540 oral health care professionals in India and the United States. This was a retrospective pretest-post-test design, a choice to eliminate response-shift bias, where the participants responded online on their adherence or otherwise to COVID-19 precautionary measures before and after vaccination. The difference between post-test and retrospective pretest scores was used in assessing the magnitude of complacency demonstrated by the individual as a function of getting vaccinated, and the process was validated using exploratory factor analysis (EFA) with principal axis factoring and confirmatory factor analysis (CFA) on two randomly split subsets of the overall sample. It was observed that there had been a decline in the adherence to all the considered COVID-19 precautionary measures from the time before vaccination to the time of achievement of the fully vaccinated status. EFA performed on the randomly split sub sample of 240 subjects returned a two factor solution with five items in factor 1 and seven items in factor 2. Items in both the factors

demonstrated adequate internal consistency in reliability analysis (Cronbach's alpha 0.84 and 0.82, respectively). The two factor solution obtained in EFA demonstrated good model fit in CFA [RMSEA (90%CI) - 0.077 (0.063-0.092); TLI - 0.872; CFI - 0.897; SRMR - 0.056]. These results highlight the vaccination-induced complacency in observing COVID-19 appropriate behavior among oral health professionals in India and the United States.
A peptide-based subunit candidate vaccine against SARS-CoV-2 delivered by biodegradable mesoporous silica nanoparticles induced high humoral and cellular immunity in mice. Development of a rapidly scalable vaccine is still an urgent task to halt the spread of COVID-19. We have demonstrated biodegradable mesoporous silica nanoparticles (BMSNs) as a good drug delivery carrier for tumor therapy. In this study, seven linear B cell epitopes and three CD8(+) T cell epitopes were screened from the spike (S) glycoprotein of SARS-CoV-2 by computer-based immunoinformatic approaches for vaccine design. A nanoparticle-based candidate vaccine (B/T@BMSNs) against SARS-CoV-2 was rapidly prepared by encapsulating these ten epitope peptides within BMSNs, respectively. BMSNs with potential biodegradability, proved to possess excellent safety in vitro and in vivo, could efficiently deliver epitope peptides into the cytoplasm of RAW264.7 cells. Strong Th1-biased humoral and cellular immunity were induced by B/T@BMSNs in mice and all the 10 selected epitopes were identified as effective antigen epitopes, which could induce robust peptide-specific immune response. The elicited functional antibody could bind to the recombinant S protein and block the binding of the S protein to the ACE-2 receptor. These results demonstrate the potential of a nanoparticles vaccine platform based on BMSNs to rapidly develop peptide-based subunit vaccine candidates against SARS-CoV-2.
Case of de novo nail psoriasis triggered by the second dose of Pfizer-BioNTech BNT162b2 COVID-19 messenger RNA vaccine.
COVID-19 Vaccine-Induced Thrombosis and Thrombocytopenia: First Confirmed Case from India.
Response to case report on myocarditis and pericarditis after COVID-19 vaccination.
Factors associated with humoral response after BNT162b2 mRNA COVID-19 vaccination in kidney transplant patients.
WITHDRAWN: A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products. The Publisher regrets that this article has been temporarily removed. A replacement will appear as soon as possible in which the reason for the removal of the article will be specified, or the article will be reinstated.
Understanding risk of thrombosis with thrombocytopenia syndrome after Ad26.COV2.S vaccination.
Rapid Decline in Vaccine-induced Anti-SARS-CoV-2 Antibody Titers 3 Months After Kidney Transplantation: A Case Series From Belgium.
Immunological Analysis of People in Northeast China after SARS-CoV-2 Inactivated Vaccine Injection. Clarifying changes in the immune microenvironment caused by vaccination is crucial for the development and application of vaccines. In this study, we analyzed seroconversion of antibodies, 12 key cytokines, and 34 lymphocyte subsets at three time points (D-1, D14, and D42) around vaccination and differences between two inactivated vaccines (Sinopharm and Sinovas) to understand the immune response induced by inactivated vaccines in the real world. The results showed that 62.5% and 75% of the participants achieved neutralizing antibody seroconversion on D14 and D42, respectively. After vaccination, IL-5 and IL-6 increased, and INF-Î³ decreased. IL6, IL-1B, INF-Î³, IL-8, and IL-12p70 showed statistical significance in the comparison of different groups. In terms of lymphocyte subsets, CD3 +, CD56 +, CD3 + CD8 +, CD8 + CD71 +, and CD56 + CD71 + showed upward trend, while CD19 +, CD4 + CD8 +, CD8 + CD45RA +, CD4 + HLA-DR +, CD8 + HLA-DR +, and CD8 + CD38 + showed downward trend. Additionally, we found certain differences between the two vaccines in neutralizing antibodies, cytokines, and lymphocyte subsets. This research is a clinical

observation on the immune response after vaccination through detecting various immune indicators, which showed that the inactivated vaccines induced both humoral immunity by producing neutralizing antibodies and cellular immunity. The cellular immunity induced by these two vaccines was a Th2-biased response, and it may also lead to a mild Th1-type response.

Intradermal ChAdOx1 Vaccine Following Two CoronaVac Shots: A Case Report. Inactivated SARS-CoV-2 vaccines are used in many countries with uncertain immunogenicity. Intradermal ChAdOx1 has been proposed as a resource-efficient heterologous third booster shot. A 52-year-old healthy male healthcare professional had received two intramuscular CoronaVac shots on 21 April and 23 May 2021, and volunteered to take a 0.1 mL ChAdOx1 vaccine intradermally on 29 June 2021, with minimal local reactions. The declining IgG levels against spike protein from the two CoronaVac shots increased to higher than 10,000 AU/mL two weeks after the intradermal ChAdOx1. Moreover, the neutralizing antibody increased from 66.77% to almost 100%. A ratio of 6.6:9.7 of IgA:IgG was observed. The 50% pseudovirus neutralization titer (PVNT50) against lentiviral pseudovirus bearing a codon-optimized spike gene (wild type, alpha, beta, and delta) were 1812.42, 822.99, 1025.42, 1347.13, respectively. The SARS-CoV-2-specific T cells to spike protein-peptide pools (532-788 SFU/10(6) PBMCs) were detected. In conclusion, the antibody and cellular responses to the intradermal ChAdOx1, as a third booster dose in a healthy volunteer who received two intramuscular CoronaVac shots, revealed a dramatic increase in the total antibodies, including IgG, IgA, as well as T cell responses against spike protein. The immune response from intradermal ChAdOx1 should be further investigated in a larger population.

Qualitative Assessment of Early Adverse Effects of Pfizer-BioNTech and Sinopharm COVID-19 Vaccines by Telephone Interviews. Vaccines are considered the best approach for countering the COVID-19 pandemic. In this study, we compared early side effects associated with vaccination with the Sinopharm and Pfizer-BioNTech COVID-19 vaccines. Participants of this observational cohort were interviewed based on semi-structured telephone interviews, with enquiries about side effects that developed after vaccination with each dose of these vaccines. Overall, 1004 participants were enrolled, of which 51.1% received Sinopharm vaccine and 48.9% received the Pfizer-BioNTech vaccine. After the first dose, 46.3% of participants had an adverse reaction, with injection site pain most commonly being reported (33.2%). Participants who received the Pfizer-BioNTech vaccine had significantly higher frequencies of all types of adverse reactions ($p < 0.01$), with no significant differences in the duration of adverse reactions between the two vaccines. Regarding the second dose, 48.6% of participants had adverse reactions, with injection site pain being most commonly reported (29%). Those who received the Pfizer vaccine reported higher frequencies of all adverse reactions ($p < 0.01$). However, a longer duration of adverse reactions was seen among Sinopharm vaccine recipients as compared to Pfizer-BioNTech vaccine recipients ($p = 0.01$). In conclusion, early adverse effects are reported following all types of vaccines but these are more likely to be encountered following the administration of new-generation vaccines. These side effects are mostly mild and treatable.

COVID-19 vaccine-associated reactivation of uveitis.

Immunity after COVID-19 and vaccination: follow-up study over 1Â year among medical personnel. BACKGROUND: The long-term course of immunity among individuals with a history of COVID-19, in particular among those who received a booster vaccination, has not been well defined so far. METHODS: SARS-CoV-2-specific antibody levels were measured by ELISA over 1Â year among 136 health care workers infected during the first COVID-19 wave and in a subgroup after booster vaccination approximately 1Â year later. Furthermore, spike-protein-reactive memory T cells were quantified approximately 7Â months after the infection and after booster vaccination. Thirty healthy individuals without history of COVID-19 who were routinely vaccinated served as controls. RESULTS:

Levels of SARS-CoV-2-specific IgM- and IgA-antibodies showed a rapid decay over time, whereas IgG-antibody levels decreased more slowly. Among individuals with history of COVID-19, booster vaccination induced very high IgG- and to a lesser degree IgA-antibodies. Antibody levels were significantly higher after booster vaccination than after recovery from COVID-19. After vaccination with a two-dose schedule, healthy control subjects developed similar antibody levels as compared to individuals with history of COVID-19 and booster vaccination. SARS-CoV-2-specific memory T cell counts did not correlate with antibody levels. None of the study participants suffered from a reinfection. CONCLUSIONS: Booster vaccination induces high antibody levels in individuals with a history of COVID-19 that exceeds by far levels observed after recovery. SARS-CoV-2-specific antibody levels of similar magnitude were achieved in healthy, COVID-19-naÃ¯ve individuals after routine two-dose vaccination.
Comment on 'De novo generalized pustular psoriasis following Oxford-AstraZeneca COVID-19 vaccine': possible role for Type I interferons.
The SARS-CoV-2-neutralizing capacity of kidney transplant recipients 4 weeks after receiving a second dose of the BNT162b2 vaccine.
New-onset and exacerbations of psoriasis after mRNA COVID-19 vaccines: two sides of the same coin?
COVID vaccine-induced lichen planus on areas previously affected by vitiligo.
COVID-19 vaccination with BNT162b2 and ChAdOx1 vaccines has the potential to induce nasal neutralizing antibodies.
Early insight into antibody-dependent enhancement after SARS-CoV-2 mRNA vaccination. Current vaccines, which induce a B-cell-mediated antibody response against the spike protein of SARS-CoV-2, have markedly reduced infection rates. However, the emergence of new variants as a result of SARS-CoV-2 evolution requires the development of novel vaccines that are T-cell-based and that target mutant-specific spike proteins along with ORF1ab or nucleocapsid protein. This approach is more accommodative in inducing highly neutralizing antibodies,Â without the risk of antibody-dependent enhancement, as well as memory CD8(+)T-cell immunity.
COVID-19 Case Rates After Surveillance and Vaccinations in a Statewide Psychiatric Hospital System. Individuals with serious mental illness are particularly vulnerable to COVID-19. The New York State (NYS) Office of Mental Health implemented patient and staff rapid testing, quarantining, and vaccination to limit COVID-19 spread in 23 state-operated psychiatric hospitals between November 2020 and February 2021. COVID-19 infection rates in inpatients and staff decreased by 96% and 71%, respectively, and the NYS population case rate decreased by 6%. Repeated COVID-19 testing and vaccination should be priority interventions for state-operated psychiatric hospitals. (Am J Public Health. 2021;111(10):1780-1783. https://doi.org/10.2105/AJPH.2021.306444).
Risk of COVID-19 transmission in heterogeneous age groups and effective vaccination strategy in Korea: a mathematical modeling study. OBJECTIVES: This study aims to analyze the possibility and conditions of maintaining an effective reproductive number below 1 using a mathematical model. METHODS: The total population was divided into five age groups (0-17, 18-29, 30-59, 60-74, and â‰¥75 years). Maximum likelihood estimation (MLE) was used to estimate the transmission rate of each age group. Mathematical model simulation was conducted until December 31, 2021, by establishing various strategies for vaccination and social distancing without considering variants. RESULTS: MLE results revealed that the group aged 0-17 years had a lower risk of transmission than other age groups, and the older age group had relatively high risks of infection. If 70% of the population will be vaccinated by the end of 2021, then simulations showed that even if social distancing was eased, the effective reproductive number would remain below 1 near August if it was not at the level of the third re-spreading period. However, if social distancing was eased and it

reached the level of the re-spreading period, the effective reproductive number could be below 1 at the end of 2021. CONCLUSIONS: Considering both stable and worsened situations, simulation results emphasized that sufficient vaccine supply and control of the epidemic by maintaining social distancing to prevent an outbreak at the level of the re-spreading period are necessary to minimize mortality and maintain the effective reproductive number below 1.
T-cell response after first dose of BNT162b2 SARS-CoV-2 vaccine among healthcare workers with previous infection or cross-reactive immunity. OBJECTIVES: Antibody response to the first dose of BNT162b2 SARS-CoV-2 is greater in COVID-19-convalescent than in infection-naÃ¯ve individuals. However, there are no data about T-cell response in individuals with pre-existing cellular immunity. METHODS: We evaluated T-cell responses in parallel with SARS-CoV-2 antibody level after first dose of BNT162b2 vaccine in 23 infection-naÃ¯ve and 27 convalescent healthcare workers (HCWs) previously included in a study about humoral and T-cell immunity. RESULTS: Overall, the antibody response was lower in the infection-naÃ¯ve group than in convalescent individuals (18Â 895 vs 662.7Â AUÂ mL(-1), PÂ <Â 0.001), and intermediate but significantly lower in convalescent HCWs with previous negative serology (25Â 174 vs 1793Â AUÂ mL(-1); PÂ =Â 0.015). Indeed, anti-spike IgG titres after the first dose correlated with baseline anti-nucleocapsid IgG titres (rhoÂ =Â 0.689; PÂ <Â 0.001). Pre-existing T-cell immunity was observed in 78% of convalescent and 65% of the infection-naÃ¯ve HCWs. T-cell response after the first dose of the vaccine was observed in nearly all the cases with pre-existing T-cell immunity, reaching 94% in convalescent HCWs and 93% in those with cross-reactive T cells. It was lower in the infection-naÃ¯ve group (50%; PÂ =Â 0.087) and in convalescent HCWs with negative serology (56%; PÂ =Â 0.085). Notably, systemic reactogenicity after vaccination was mainly observed in those with pre-existing T-cell immunity (PÂ =Â 0.051). CONCLUSION: Here, we report that the first dose of BTN162b2 elicits a similar S-specific T-cell response in cases of either past infection or cross-reactive T cells, but lower in the rest of infection-naÃ¯ve individuals and in convalescent HCWs who have lost detectable specific antibodies during follow-up.
Covid-19: Boys are more at risk of myocarditis after vaccination than of hospital admission for covid.
Adolescent Myocarditis After COVID-19 Vaccination Is Rare.
Delayed Humoral Response After 2 Doses of the BNT162b2 Vaccine in a Belgian Kidney Transplant Cohort.
Lymphohistocytic myocarditis after Ad26.COV2.S viral vector COVID-19 vaccination.
IgA vasculitis in adult patient following vaccination by ChadOx1 nCoV-19.
Subtle immunological differences in mRNA-1273 and BNT162b2 COVID-19 vaccine induced Fc-functional profiles. The successful development of several COVID-19 vaccines has substantially reduced morbidity and mortality in regions of the world where the vaccines have been deployed. However, in the wake of the emergence of viral variants, able to evade vaccine induced neutralizing antibodies, real world vaccine efficacy has begun to show differences across the mRNA platforms, suggesting that subtle variation in immune responses induced by the BNT162b2 and mRNA1273 vaccines may provide differential protection. Given our emerging appreciation for the importance of additional antibody functions, beyond neutralization, here we profiled the postboost binding and functional capacity of the humoral response induced by the BNT162b2 and mRNA-1273 in a cohort of hospital staff. Both vaccines induced robust humoral immune responses to WT SARS-CoV-2 and VOCs. However, differences emerged across epitopespecific responses, with higher RBD- and NTD-specific IgA, as well as functional antibodies (ADNP and ADNK) in mRNA-1273 vaccine recipients. Additionally, RBD-specific antibody depletion highlighted the different roles of non-RBD-specific antibody effector function induced across the mRNA vaccines, providing novel insights into potential differences in protective immunity generated across these vaccines in the setting of newly emerging VOCs.
Risk factors associated with poor response to COVID-19 vaccination in kidney transplant recipients.

Multiple sclerosis relapses not associated with mRNA COVID-19 vaccine.
Platelet activation and modulation in thrombosis with thrombocytopenia syndrome associated with ChAdOÃ—1 nCov-19 vaccine.
Thrombosis of the palmar digital vein after Oxford-AstraZeneca COVID-19 vaccination.
Rapid induction of antigen-specific CD4(+) TÂ cells is associated with coordinated humoral and cellular immunity to SARS-CoV-2 mRNA vaccination. SARS-CoV-2 mRNA vaccines have shown remarkable clinical efficacy, but questions remain about the nature and kinetics of TÂ cell priming. We performed longitudinal antigen-specific TÂ cell analyses on healthy SARS-CoV-2-naive and recovered individuals prior to and following mRNA prime and boost vaccination. Vaccination induced rapid antigen-specific CD4(+) TÂ cell responses in naive subjects after the first dose, whereas CD8(+) TÂ cell responses developed gradually and were variable in magnitude. Vaccine-induced Th1 and Tfh cell responses following the first dose correlated with post-boost CD8(+) TÂ cells and neutralizing antibodies, respectively. Integrated analysis revealed coordinated immune responses with distinct trajectories in SARS-CoV-2-naive and recovered individuals. Last, whereas booster vaccination improved TÂ cell responses in SARS-CoV-2-naive subjects, the second dose had little effect in SARS-CoV-2-recovered individuals. These findings highlight the role of rapidly primed CD4(+) TÂ cells in coordinating responses to the second vaccine dose in SARS-CoV-2-naive individuals.
DNA Vaccine Administered by Cationic Lipoplexes or by In Vivo Electroporation Induces Comparable Antibody Responses against SARS-CoV-2 in Mice. In view of addressing the global necessity of an effective vaccine in the SARS-CoV-2 pandemic, a plasmid DNA vaccine, expressing for the spike (S) protein and formulated in lipoplexes, was manufactured and tested for in vitro transfection and in vivo immunogenicity. Blank cationic liposomes of 130.9 Â± 5.8 nm in size and with a zeta potential of +48 Â± 12 mV were formulated using the thin-film layer rehydration method. Liposomes were complexed with pCMVkan-S at different N/P ratios. Ratios of 0.25:1 and 1:1 were selected according to their complex stability and controlled size compared to other ratios and tested in vitro for transfection studies and in vivo for immunogenicity. Both selected formulations showed enhanced neutralizing antibody responses compared to pCMVkan-S injected alone, as well as an increased T cell response. The titers observed were similar to those of intramuscular electroporation (IM-EP), which was set as an efficacy goal.
Anti-SARS-CoV-2 Strategies and the Potential Role of miRNA in the Assessment of COVID-19 Morbidity, Recurrence, and Therapy. Recently, we have experienced a serious pandemic. Despite significant technological advances in molecular technologies, it is very challenging to slow down the infection spread. It appeared that due to globalization, SARS-CoV-2 spread easily and adapted to new environments or geographical or weather zones. Additionally, new variants are emerging that show different infection potential and clinical outcomes. On the other hand, we have some experience with other pandemics and some solutions in virus elimination that could be adapted. This is of high importance since, as the latest reports demonstrate, vaccine technology might not follow the new, mutated virus outbreaks. Thus, identification of novel strategies and markers or diagnostic methods is highly necessary. For this reason, we present some of the latest views on SARS-CoV-2/COVID-19 therapeutic strategies and raise a solution based on miRNA. We believe that in the face of the rapidly increasing global situation and based on analogical studies of other viruses, the possibility of using the biological potential of miRNA technology is very promising. It could be used as a promising diagnostic and prognostic factor, as well as a therapeutic target and tool.
ChAdOx1 COVID-19 vaccine-induced thrombocytopenia syndrome.
Exacerbation of plaque psoriasis after inactivated and BNT162b2 mRNA COVID-19 vaccines: A report of two cases.
Central retinal vein occlusion occurring immediately after 2nd dose of mRNA SARS-CoV-2 vaccine.

COVID-19 Vaccination Associated With Reduced Postoperative SARS-CoV-2 Infection and Morbidity. OBJECTIVE: The purpose of this study was to determine the effect of COVID-19 vaccination on postoperative mortality, pulmonary and thrombotic complications, readmissions and hospital lengths of stay among patients undergoing surgery in the United States. BACKGROUND: While vaccination prevents COVID-19, little is known about its impact on postoperative complications. METHODS: This is a nationwide observational cohort study of all 1,255 Veterans Affairs facilities nationwide. We compared patients undergoing surgery at least 2â€Šweeks after their second dose of the Pfizer BioNTech or Moderna vaccines, to contemporary propensity score matched controls. Primary endpoints were 30-day mortality and postoperative COVID-19 infection. Secondary endpoints were pulmonary or thrombotic complications, readmissions, and hospital lengths of stay. RESULTS: 30,681 patients met inclusion criteria. After matching, there were 3,104 in the vaccination group (1,903 received the Pfizer BioNTech, and 1,201 received the Moderna vaccine) and 7,438 controls. Full COVID-19 vaccination was associated with lower rates of postoperative 30-day COVID-19 infection (Incidence Rate Ratio and 95% confidence intervals, 0.09 [0.01,0.44]), pulmonary complications (0.54 [0.39, 0.72]), thrombotic complications (0.68 [0.46, 0.99]) and decreased hospital lengths of stay (0.78 [0.69, 0.89]). Complications were also low in vaccinated patients who tested COVID-19 positive before surgery but events were too few to detect a significant difference compared to controls. CONCLUSION: COVID-19 vaccination is associated with lower rates of postoperative morbidity. The benefit is most pronounced among individuals who have never had a COVID-19 infection before surgery.
COVID-19 vaccine uptake in patients with psychiatric disorders admitted to or residing in a university psychiatric hospital.
Seasonal Coronavirus Pneumonia After SARS-CoV-2 Infection and Vaccination: New Frenemies?
SARS-CoV-2 Infection After Full Vaccination in Kidney Transplant Recipients.
Mucosal immunity to SARS-CoV-2: a clinically relevant key to deciphering natural and vaccine-induced defences.
Can new onset psychosis occur after mRNA based COVID-19 vaccine administration? A case report.
Immune Response Post-SARS-CoV-2 mRNA Vaccination in Kidney Transplant Recipients Receiving Belatacept.
COVID-19 vaccine-induced urticarial vasculitis.
Pericarditis after administration of the BNT162b2 mRNA COVID-19 vaccine.
Pityriasis rosea following SARS-CoV-2 vaccination: A case series.
Poor Humoral Response in Solid Organ Transplant Recipients Following Complete mRNA SARS-CoV-2 Vaccination.
Accelerated Development of COVID-19 Vaccines: Technology Platforms, Benefits, and Associated Risks. Multiple preventive COVID-19 vaccines have been developed during the ongoing SARS coronavirus (CoV) 2 pandemic, utilizing a variety of technology platforms, which have different properties, advantages, and disadvantages. The acceleration in vaccine development required to combat the current pandemic is not at the expense of the necessary regulatory requirements, including robust and comprehensive data collection along with clinical product safety and efficacy evaluation. Due to the previous development of vaccine candidates against the related highly pathogenic coronaviruses SARS-CoV and MERS-CoV, the antigen that elicits immune protection is known: the surface spike protein of SARS-CoV-2 or specific domains encoded in that protein, e.g., the receptor binding domain. From a scientific point of view and in accordance with legal frameworks and regulatory practices, for the approval of a clinic trial, the Paul-Ehrlich-Institut requires preclinical testing of vaccine candidates, including general pharmacology and toxicology as well as

immunogenicity. For COVID-19 vaccine candidates, based on existing platform technologies with a sufficiently broad data base, pharmacological-toxicological testing in the case of repeated administration, quantifying systemic distribution, and proof of vaccination protection in animal models can be carried out in parallel to phase 1 or 1/2 clinical trials. To reduce the theoretical risk of an increased respiratory illness through infection-enhancing antibodies or as a result of Th2 polarization and altered cytokine profiles of the immune response following vaccination, which are of specific concern for COVID-19 vaccines, appropriate investigative testing is imperative. In general, phase 1 (vaccine safety) and 2 (dose finding, vaccination schedule) clinical trials can be combined, and combined phase 2/3 trials are recommended to determine safety and efficacy. By applying these fundamental requirements not only for the approval and analysis of clinical trials but also for the regulatory evaluation during the assessment of marketing authorization applications, several efficacious and safe COVID-19 vaccines have been licensed in the EU by unprecedentedly fast and flexible procedures. Procedural and regulatory-scientific aspects of the COVID-19 licensing processes are described in this review.
High Prevalence of Anti-PF4 Antibodies Following ChAdOx1 nCov-19 (AZD1222) Vaccination Even in the Absence of Thrombotic Events. It is unclear whether the ChAdOx1 nCov-19 vaccine can induce the development of anti-PF4 antibodies in vaccinated individuals who have not developed thrombosis. The aim of this prospective study was to evaluate the presence of antibodies against heparin/PF4 in adults who received a first dose of the ChAdOx1 nCov-19 vaccine, and correlate them with clinical data and antibody responses to the vaccine. We detected non-platelet activating anti-PF4 antibodies in 67% (29/43) of the vaccinated individuals on day 22 following the first dose of the ChAdOx1 nCov-19 vaccine, though these were detected in low titers. Furthermore, there was no correlation between the presence of anti-PF4 IgG antibodies and the baseline clinical characteristics of the patients. Our findings suggest that the ChAdOx1 nCov-19 vaccine can elicit anti-PF4 antibody production even in recipients without a clinical manifestation of thrombosis. The presence of anti-PF4 antibodies was not sufficient to provoke clinically evident thrombosis. Our results offer an important insight into the ongoing investigations regarding the underlying multifactorial pathophysiology of thrombotic events induced by the ChAdOx1 nCov-19 vaccine.
Onset/flare of psoriasis following the ChAdOx1 nCoV-19 Corona virus vaccine (Oxford-AstraZeneca/Covishield): Report of two cases.
Cellular and Humoral Immune Responses After 3 Doses of BNT162b2 mRNA SARS-CoV-2 Vaccine in Kidney Transplant. Supplemental Digital Content is available in the text.
Response to: Correspondence on "SARS-CoV-2 vaccination in rituximab-treated patients: evidence for impaired humoral but inducible cellular immune response" by Bonelli et al.
Adverse events following ChAdOx1 nCoV-19 Vaccine (COVISHIELD) amongst health care workers: A prospective observational study. BACKGROUND: During ongoing COVID-19 pandemic, researchers worked enormously to develop effective vaccines against COVID-19 infection. Two Indian-made vaccines [Covishield (ChAdOx1 nCoV-19) and Covaxin] were granted Emergency Use Authorization. India launched its COVID-19 vaccination drive starting with healthcare workers (HCW). Aim of the study was to evaluate adverse events following immunization (AEFI) amongst the HCW with two doses of Covishield vaccine. We also evaluated association of AEFI according to sex, profession and age groups. METHODS: A prospective observational study was conducted in a tertiary care COVID dedicated hospital of Southern India from 16 Jan - 15 Apr 2021. Nine hundred and eighty one HCW who received 2 doses (4 weeks apart) were enrolled. Active and passive surveillance was conducted after 48 hours, and at days 8,15, 22 and 28 for both doses. The rate of AEFI for each dose was determined. Incidence and association of AEFI with various demographic variables was determined. RESULTS: 1020 non-serious and two serious AEFI (altered sensorium) were reported

within 48 hours of first dose. Two hundred and twenty non-serious AEFI were reported within 48 hours of second dose. No AEFI was reported after 15 days for both the doses. We found no association of AEFI with sex and profession (p >0.5). Significant association of AEFI was found with age (p <0.01). CONCLUSION: Short-term AEFI were predominantly observed in first 48 hours. Incidence decreased in subsequent weeks with no occurrence after 15 days in both doses. Symptoms were mild in severity and short-lived. No serious AEFI attributable to vaccines were reported.
A case of membranous nephropathy following Pfizer-BioNTech mRNA vaccination against COVID-19.
Patients with history of covid-19 had more side effects after the first dose of covid-19 vaccine. INTRODUCTION: COVID-19 vaccination seems to be the most pertinent pharmacologic public health measure to control the pandemic. Reactogenicity symptoms were frequent in vaccine recipients mostly mild to moderate and commonly reported after the second dose. However, there is a lack of data in patients with a previous diagnosis of Covid-19. METHODS: We analysed side effects of 311 patients after the first dose of Pfizer-BioNTech COVID-19 vaccine, in a french university hospital. We compared patients with COVID-19 history to naive individuals. All the data collected are based on self-reported, including COVID-19 exposure status. RESULTS: Overall, 229 (74%) patients reported at least one side effect. Among participants with history of Covid-19, 95% reported at least one adverse event versus 70% in naive patients (pÂ <Â 0.01). However, symptom intensity was not different between the 2 groups. CONCLUSION: Vaccine recipients with prior COVID-19 reported more, but no more serious, side effects than naive participants.
Immune responses and reactogenicity after ChAdOx1 in individuals with past SARS-CoV-2 infection and those without.
Impaired response to first SARS-CoV-2 dose vaccination in myeloproliferative neoplasm patients receiving ruxolitinib.
Covid-19: NICE issues guidance on vaccine induced immune thrombocytopenia and thrombosis.
Perimyocarditis in Adolescents After Pfizer-BioNTech COVID-19 Vaccine. On May 10, 2021, the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) was expanded to include adolescents (May 10, 2021. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use). We describe clinical characteristics of 8 adolescents who presented over the course of 36 days to Nicklaus Children's Hospital with perimyocarditis within 4 days of receiving a dose of BNT162b2 vaccine.
Laboratory testing for post ChAdOx1 nCOV-19 vaccination VITT: A challenge. Comment on: Recommendations for the clinical and laboratory diagnosis of VITT against COVID-19: Communication from the ISTH SSC Subcommittee on Platelet Immunology.
Myopericarditis in young adults presenting to the emergency department after receiving a second COVID-19 mRNA vaccine.
Pityriasis rubra pilaris after VaxzevriaÂ® COVID-19 vaccine.
New-onset acral lesions on hands after administration of mRNA-1273 vaccine against SARS-CoV-2: clinical images and histopathological study of three cases.
Small-vessel vasculitis following Oxford-AstraZeneca vaccination against SARS-CoV-2.
Small vessel vasculitis related to varicella-zoster virus after Pfizer-BioNTech COVID-19 vaccine.
A skin reaction with rust-like discolouration to mRNA COVID-19 vaccine.
T-cell and Antibody Response After 2 Doses of the BNT162b2 Vaccine in a Belgian Cohort of Kidney Transplant Recipients.
Ruxolitinib does not impair humoral immune response to COVID-19 vaccination with BNT162b2 mRNA COVID-19 vaccine in patients with myelofibrosis.

Antibody Response After a Third Dose of the mRNA-1273 SARS-CoV-2 Vaccine in Kidney Transplant Recipients With Minimal Serologic Response to 2 Doses. This study examines the antibody responses to a third dose (100 Î¼g) of the mRNA-1273 SARS-CoV-2 vaccine among kidney transplant recipients in France who had not responded to 2 doses of the vaccine.
SARS-CoV-2 anti-spike antibody titres after vaccination with BNT162b2 in naÃ¯ve and previously infected individuals. Great expectations are placed in vaccines against COVID-19 to control the pandemic. We reviewed the antibody titres in a cohort of healthcare workers (HCWs) vaccinated with BNT162b2 to assess the influence of a previous infection on them. We stratified the results according to the individual history of nasopharyngeal swab (NPS) and symptoms. Among 3475 HCWs the highest titres were recorded among those infected more than 6 months before vaccination, independently of symptoms, followed by those infected less than 6 months before vaccination, especially in those with symptoms, and by uninfected HCWs. Vaccination with BNT162b2 can boost immunity acquired through infection, particularly in those infected more than 6 months before vaccination.
A Rare Case of Superior Ophthalmic Vein Thrombosis and Thrombocytopenia Following ChAdOx1 nCoV-19 Vaccine Against SARS-CoV-2.
Delayed Skin Rash After Receiving SARS-CoV-2 mRNA Moderna Vaccine.
Paucisymptomatic COVID-19 in lung transplant recipient following two doses of mRNA-1273 (Moderna) vaccine.
Patients with Solid Tumors Seroconvert after SARS-CoV-2 mRNA Vaccine. Patients with tumors had low seropositivity rates after one vaccine dose but high rates after both doses.
Thrombotic Thrombocytopenia and Central Venous Sinus Thrombosis Post - COVID-19 Vaccination and its Treatment with Heparin Alternatives.
Strong antibody response after a first dose of a SARS-CoV-2 mRNA-based vaccine in kidney transplant recipients with a previous history of COVID-19.
Reactivation of IgA vasculitis after COVID-19 vaccination.
Nephrotic Syndrome Following ChAdOx1 nCoV-19 Vaccine Against SARScoV-2.
The association between coronaphobia and attitude towards COVID-19 Vaccine: A sample in the east of Turkey. PURPOSE: This study was conducted to examine the association between coronaphobia and attitude towards COVID-19 vaccine in the society. METHODS: This cross-sectional descriptive study was conducted with snowball sampling method between December 30, 2020 and January 10, 2021. The survey form was sent online to individuals who were 18 years of age and older. 1252 individuals who responded to the surveys were included in the study. The data were collected by using "Descriptive Information Form", "Attitudes towards the Covid-19 vaccine scale" and "Coronavirus 19 Phobia Scale (CP19-S)". Descriptive statistics and Pearson Correlation analysis were used in the evaluation of data. RESULTS: In the study, it was found that the participants had a mean ATV-COVID-19 scale positive attitude sub-dimension score of 2.81Â±1.04, while they had a mean negative attitude sub-dimension score of 2.95Â±0.78 and a mean total score of 2.89Â±0.78. It was found that the participants had a mean C19P-S psychological sub-dimension score of 21.03Â±5.36, a mean psychosomatic sub-dimension score of 10.30Â±4.11, a mean social sub-dimension score of 15.04Â±4.71, a mean economic sub-dimension score of 8.89Â±3.46 and a mean total scale score of 55.28Â±15.00. It was found in the study that there was a positive association between the participants' C19P-S and social sub-dimension and ATV-COVID-19 and positive attitude sub-dimension, while there was a negative association between ATV-COVID-19 and negative attitude sub-dimension ($p<0.05$). CONCLUSIONS: It was found that the participants had a moderate level of

coronavirus phobia and positive attitudes towards the vaccine. It was found that positive attitudes towards COVID-19 vaccine increased as the coronavirus phobia increased.
Disappointing Immunization Rate After 2 Doses of the BNT162b2 Vaccine in a Belgian Cohort of Kidney Transplant Recipients. Supplemental Digital Content is available in the text.
New-onset leukocytoclastic vasculitis after COVID-19 vaccine.
Pernio-like skin lesions after the second dose of Pfizer-BioNTech COVID-19 vaccine.
New onset of remitting seronegative symmetrical synovitis with pitting oedema and palmoplantar psoriasis flare-up after Sars-Cov-2 vaccination.
N-terminal domain of SARS CoV-2 spike protein mutation associated reduction in effectivity of neutralizing antibody with vaccinated individuals.
Optimizing COVID-19 vaccine distribution across the United States using deterministic and stochastic recurrent neural networks. Optimizing COVID-19 vaccine distribution can help plan around the limited production and distribution of vaccination, particularly in early stages. One of the main criteria for equitable vaccine distribution is predicting the geographic distribution of active virus at the time of vaccination. This research developed sequence-learning models to predict the behavior of the COVID-19 pandemic across the US, based on previously reported information. For this objective, we used two time-series datasets of confirmed COVID-19 cases and COVID-19 effective reproduction numbers from January 22, 2020 to November 26, 2020 for all states in the US. The datasets have 310 time-steps (days) and 50 features (US states). To avoid training the models for all states, we categorized US states on the basis of their similarity to previously reported COVID-19 behavior. For this purpose, we used an unsupervised self-organizing map to categorize all states of the US into four groups on the basis of the similarity of their effective reproduction numbers. After selecting a leading state (the state with earliest outbreaks) in each group, we developed deterministic and stochastic Long Short Term Memory (LSTM) and Mixture Density Network (MDN) models. We trained the models with data from each leading state to make predictions, then compared the models with a baseline linear regression model. We also remove seasonality and trends from a dataset of non-stationary COVID-19 cases to determine the effects on prediction. We showed that the deterministic LSTM model trained on the COVID-19 effective reproduction numbers outperforms other prediction methods.
Laser-facilitated epicutaneous immunization of mice with SARS-CoV-2 spike protein induces antibodies inhibiting spike/ACE2 binding. The skin represents an attractive target tissue for vaccination against respiratory viruses such as SARS-CoV-2. Laser-facilitated epicutaneous immunization (EPI) has been established as a novel technology to overcome the skin barrier, which combines efficient delivery via micropores with an inherent adjuvant effect due to the release of danger-associated molecular patterns. Here we delivered the S1 subunit of the Spike protein of SARS-CoV-2 to the skin of BALB/c mice via laser-generated micropores with or without CpG-ODN1826 or the B subunit of heat-labile enterotoxin of E.coli (LT-B). EPI induced serum IgG titers of 1:3200 that could be boosted 5 to 10-fold by co-administration of LT-B and CpG, respectively. Sera were able to inhibit binding of the spike protein to its receptor ACE2. Our data indicate that delivery of recombinant spike protein via the skin may represent an alternative route for vaccines against Covid-19.
Antibody responses after SARS-CoV-2 vaccination in patients with lymphoma.
SARS-CoV-2 RBD-Tetanus Toxoid Conjugate Vaccine Induces a Strong Neutralizing Immunity in Preclinical Studies. Controlling the global COVID-19 pandemic depends, among other measures, on developing preventive vaccines at an unprecedented pace. Vaccines approved for use and those in development intend to elicit neutralizing antibodies to block viral sites binding to the host's cellular receptors. Virus infection is mediated by the spike glycoprotein trimer on the virion surface via its

receptor binding domain (RBD). Antibody response to this domain is an important outcome of immunization and correlates well with viral neutralization. Here, we show that macromolecular constructs with recombinant RBD conjugated to tetanus toxoid (TT) induce a potent immune response in laboratory animals. Some advantages of immunization with RBD-TT conjugates include a predominant IgG immune response due to affinity maturation and long-term specific B-memory cells. These result demonstrate the potential of the conjugate COVID-19 vaccine candidates and enable their advance to clinical evaluation under the name SOBERANA02, paving the way for other antiviral conjugate vaccines.

Implications of defective immune responses in SARS-CoV-2 vaccinated organ transplant recipients. Organ transplant patients have poor immune responses to COVID-19 vaccines; thus designing vaccine strategies to protect this vulnerable population from SARS-CoV-2 infection is crucial.

Early Onset of SARS-COV-2 Antibodies after First Dose of BNT162b2: Correlation with Age, Gender and BMI. BACKGROUND: The first goal of the study was to analyse the antibody titre 21 days after the first dose of the BNT162b2 vaccine in a group of 252 healthcare workers (HCW). The second goal was to analyse how the antibody titre changes in correlation with age, gender and body mass index (BMI). METHODS: Participants had a nasopharyngeal swab for SARS-CoV-2 and were assessed for the presence of SARS-CoV-2 antibodies at baseline and 21 days after the BNT162b2 priming dose. RESULTS: First dose of BNT162b2 activated immune responses in 98% of the participants. Five HWC had no increase in antibody titre 21 days after the first dose. Antibody titre was greater in young (<38 years) vs. older participants (<38 vs. 47-56 $p = 0.002$; <38 vs. >56 $p = 0.001$). Higher antibody levels were detected in underweight vs. pre-obesity group ($p = 0.026$) and in normal-weight vs. pre-obesity group ($p = 0.007$). This association was confirmed after adjusting for age ($p = 0.0001$) and gender ($p = 0.00001$). CONCLUSIONS: Our study demonstrates that a single dose of BNT162b2 activates the immune response, and being young and normal-weight correlate positively with this response. Larger specifically designed clinical trials are needed to validate these results.

SARS-CoV-2 mRNA vaccination induces functionally diverse antibodies to NTD, RBD, and S2. In this study we profiled vaccine-induced polyclonal antibodies as well as plasmablast-derived mAbs from individuals who received SARS-CoV-2 spike mRNA vaccine. Polyclonal antibody responses in vaccinees were robust and comparable to or exceeded those seen after natural infection. However, the ratio of binding to neutralizing antibodies after vaccination was greater than that after natural infection and, at the monoclonal level, we found that the majority of vaccine-induced antibodies did not have neutralizing activity. We also found a co-dominance of mAbs targeting the NTD and RBD of SARS-CoV-2 spike and an original antigenic-sin like backboost to spikes of seasonal human coronaviruses OC43 and HKU1. Neutralizing activity of NTD mAbs but not RBD mAbs against a clinical viral isolate carrying E484K as well as extensive changes in the NTD was abolished, suggesting that a proportion of vaccine-induced RBD binding antibodies may provide substantial protection against viral variants carrying single E484K RBD mutations.

COVID-19-related disruptions to routine vaccination services in India: a survey of paediatric providers. The COVID-19 pandemic has led to disruptions in essential health services globally. We surveyed Indian paediatric providers on their perceptions of the impact of the pandemic on routine vaccination. Among 424 (survey 1) and 141 (survey 2) respondents representing 26 of 36 Indian states and union territories, complete suspension of vaccination services was reported by 33.4% and 7.8%, respectively. In April-June 2020, 83.1% perceived that vaccination services dropped by half, followed by 32.6% in September 2020, indicating slow resumption of services. Concerns that vaccine coverage gaps can lead to mortality were expressed by 76.6%. Concerted multipronged efforts are needed to sustain gains in vaccination coverage.

Impaired humoral responses to COVID-19 vaccination in patients with lymphoma receiving B-cell-directed therapies.
Myocarditis Occurring After Immunization With mRNA-Based COVID-19 Vaccines.
[Rheumatic symptoms associated with a COVID-19-vaccination].
Asymptomatic SARS-CoV-2 infection following first dose mRNA-1273 COVID-19 vaccine in a veterans affairs long term care facility. An outbreak of SARS-CoV-2 involving four residents of a United States Veterans Affairs long term care facility occurred following administration of the first dose of the mRNA-1273 vaccine (Moderna) to thirty out of 33 residents. Three out of 4 positive cases were partially vaccinated and remained asymptomatic. One of 2 partially vaccinated patients who were tested for anti-spike protein antibodies had detectable levels at the time of diagnosis. The mortality rate was lower compared to a prior outbreak reported in this facility.
Response to correspondence in reference to the previously published Epub manuscript: immune thrombocytopenic purpura after SARS-CoV-2 vaccine.
Development of severe pemphigus vulgaris following SARS-CoV-2 vaccination with BNT162b2.
Covid-19: Should we be worried about reports of myocarditis and pericarditis after mRNA vaccines?
COVID-19 and vaccination rollout in Fiji: Challenges caused by digital platform. Since the beginning of the pandemic, a variety of interventions have reduced SARS-CoV-2 virus infection and mortality, including individual precautions such as wearing proper personal protective equipment (i.e., hand gloves, facemasks, and face shields), social distancing, handwashing, and limiting interpersonal interaction to outside situations. The most promising hope for ending the COVID-19 pandemic is the successful launch of COVID-19 vaccines. In response, this letter to editor will disclose the rollout of COVID-19 vaccination and challenges caused by digital platforms in Fiji.
Vaccine-induced Immune Thrombocytopenia and Thrombosis (VITT).
Thrombotic Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination.
Low Immunization Rate in Kidney Transplant Recipients Also After Dose 2 of the BNT162b2 Vaccine: Continue to Keep Your Guard up!
Psoriasis flare-up associated with second dose of Pfizer-BioNTech BNT16B2b2 COVID-19 mRNA vaccine.
Anti-GBM nephritis with mesangial IgA deposits after SARS-CoV-2 mRNA vaccination.
Reduced mortality rate after coronavac vaccine among healthcare workers.
Maternal and neonatal SARS-CoV-2 antibodies assessment after mRNA maternal vaccination in the third trimester of pregnancy. Vaccine immunization against SARSâ€•Covâ€•2 is transferred to the fetus; however, transplacental passage of antibodies after vaccination might be less efficient than in natural infection.
First manifestation of multiple sclerosis after immunization with the Pfizer-BioNTech COVID-19 vaccine.
Correspondence in reference to the previously published Epub manuscript: immune thrombocytopenic purpura after SARS-CoV-2 vaccine.
Negative SARS-CoV-2 antibodies, T-cell response and virus neutralization following full vaccination in a renal transplant recipient: a call for vigilance.
Immune thrombocytopenia following COVID-19 mRNA vaccine: casuality or causality?
Association between previous infection with SARS CoV-2 and the risk of self-reported symptoms after mRNA BNT162b2 vaccination: Data from 3,078 health care workers. BACKGROUND: Health care workers (HCWs) are at high risk of contracting an infection by SARS CoV-2 and thus they are a priority for vaccination. We hereby aim to investigate whether the risk of severe and moderate systemic

symptoms (MSS) after vaccination is higher in HCWs with a history of previous COVID-19. METHODS: An online questionnaire was offered to the cohort all HCWs undergoing anti-SARS CoV-2 mRNA BNT162b2 vaccination between January 4th and February 9th 2021 in two large tertiary hospitals (ASST Santi Paolo and Carlo) in Milan, Italy. Previous SARS-CoV-2 infection/COVID-19 was recorded. Local and systemic symptoms after each of the two doses were reported. MSS were those either interfering with daily activities or resulting in time off-work. Factors associated to MSS were identified by logistic regression. FINDINGS: 3,078 HCW were included. Previous SARS-CoV-2 infection/COVID-19 occurred in 396 subjects (12Â·9%). 59Â·6% suffered from â‰¥1 local or systemic symptom after the first and 73Â·4% after the second dose. MSS occurred in 6Â·3% of cases (14Â·4% with previous vs 5Â·1% with no COVID-19 p<0Â·001) and in 28Â·3% (24Â·5% in COVID-19Â vs 28Â·3% no COVID, pÂ =Â 0Â·074) after the first and second dose, respectively. Subjects already experiencing COVID-19 had an independent 3-fold higher risk of MSS after the first and a 30% lower risk after the second dose. No severe adverse events were reported. INTERPRETATION: Our data confirm in a real-world setting, the lack of severe adverse events and the short duration of reactogenicity in already infected HCWs. Possible differences in immune reactivity are drivers of MSS among this group of HCWs, as well as among females and younger individuals. FUNDING: None.
Atypical thrombosis associated with VaxZevriaÂ® (AstraZeneca) vaccine: Data from the French Network of Regional Pharmacovigilance Centres.
COVID-19 vaccine-induced Stevens-Johnson syndrome. Herein, we are reporting a case of Stevensâ€“Johnson syndrome due to COVIDâ€•19 vaccine, which has been proved by history taking, clinical examination and histopathology. To the best of our knowledge we are reporting the first case of COVIDâ€•19 vaccineâ€•induced Stevensâ€“Johnson syndrome.
Immune thrombocytopenic purpura associated with COVID-19 Pfizer-BioNTech BNT16B2b2 mRNA vaccine.
SARS-COV-2 vaccination after stem cell transplantation for scleroderma.
Implications of Global and Local Inequalities in COVID-19 Vaccine Distribution for People With Severe Mental Disorders in Latin America.
Regional lymphadenopathy following COVID-19 vaccination: considerations for primary care management.
Bell's palsy following a single dose of mRNA SARS-CoV-2 vaccine: a case report.
COVID-19 in a kidney transplant recipient after mRNA-based SARS-CoV-2 vaccination.
Durability of mRNA-1273-induced antibodies against SARS-CoV-2 variants. SARS-CoV-2 mutations may diminish vaccine-induced protective immune responses, and the durability of such responses has not been previously reported. Here, we present a comprehensive assessment of the impact of variants B.1.1.7, B.1.351, P.1, B.1.429, and B.1.526 on binding, neutralizing, and ACE2-blocking antibodies elicited by the vaccine mRNA-1273 over seven months. Cross-reactive neutralizing responses were rare after a single dose of mRNA-1273. At the peak of response to the second dose, all subjects had robust responses to all variants. Binding and functional antibodies against variants persisted in most subjects, albeit at low levels, for 6 months after the primary series of mRNA-1273. Across all assays, B.1.351 had the greatest impact on antibody recognition, and B.1.1.7 the least. These data complement ongoing studies of clinical protection to inform the potential need for additional boost vaccinations. ONE-SENTENCE SUMMARY: Most mRNA-1273 vaccinated individuals maintained binding and functional antibodies against SARS-CoV-2 variants for 6 months.
Single dose of BNT162b2 mRNA vaccine against SARS-CoV-2 induces high frequency of neutralising antibody and polyfunctional T-cell responses in patients with myeloproliferative neoplasms.
Clinically Significant COVID-19 Following SARS-CoV-2 Vaccination in Kidney Transplant Recipients.

Covid-19 vaccine- induced thrombosis and thrombocytopenia-a commentary on an important and practical clinical dilemma.
Bell's palsy following the Ad26.COV2.S COVID-19 vaccination.
mRNA vaccine-induced T cells respond identically to SARS-CoV-2 variants of concern but differ in longevity and homing properties depending on prior infection status. While mRNA vaccines are proving highly efficacious against SARS-CoV-2, it is important to determine how booster doses and prior infection influence the immune defense they elicit, and whether they protect against variants. Focusing on the T cell response, we conducted a longitudinal study of infection-naÃ¯ve and COVID-19 convalescent donors before vaccination and after their first and second vaccine doses, using a high-parameter CyTOF analysis to phenotype their SARS-CoV-2-specific T cells. Vaccine-elicited spike-specific T cells responded similarly to stimulation by spike epitopes from the ancestral, B.1.1.7 and B.1.351 variant strains, both in terms of cell numbers and phenotypes. In infection-naÃ¯ve individuals, the second dose boosted the quantity and altered the phenotypic properties of SARS-CoV-2-specific T cells, while in convalescents the second dose changed neither. Spike-specific T cells from convalescent vaccinees differed strikingly from those of infection-naÃ¯ve vaccinees, with phenotypic features suggesting superior long-term persistence and ability to home to the respiratory tract including the nasopharynx. These results provide reassurance that vaccine-elicited T cells respond robustly to emerging viral variants, confirm that convalescents may not need a second vaccine dose, and suggest that vaccinated convalescents may have more persistent nasopharynx-homing SARS-CoV-2-specific T cells compared to their infection-naÃ¯ve counterparts.
SARS-CoV-2 vaccines are not free of neurological side effects.
Recurrent varicella following SARS-CoV-2 vaccination with BNT162b2.
Very Low Immunization Rate in Kidney Transplant Recipients After One Dose of the BNT162b2 Vaccine: Beware not to Lower the Guard!
Demographic and Social Factors Associated with COVID-19 Vaccination Initiation Among Adults Aged â‰¥65 Years - United States, December 14, 2020-April 10, 2021. Compared with other age groups, older adults (defined here as persons aged â‰¥65 years) are at higher risk for COVID-19-associated morbidity and mortality and have therefore been prioritized for COVID-19 vaccination (1,2). Ensuring access to vaccines for older adults has been a focus of federal, state, and local response efforts, and CDC has been monitoring vaccination coverage to identify and address disparities among subpopulations of older adults (2). Vaccine administration data submitted to CDC were analyzed to determine the prevalence of COVID-19 vaccination initiation among adults aged â‰¥65 years by demographic characteristics and overall. Characteristics of counties with low vaccination initiation rates were quantified using indicators of social vulnerability data from the 2019 American Community Survey.* During December 14, 2020-April 10, 2021, nationwide, a total of 42,736,710 (79.1%) older adults had initiated vaccination. The initiation rate was higher among men than among women and varied by state. On average, counties with low vaccination initiation rates (<50% of older adults having received at least 1 vaccine dose), compared with those with high rates (â‰¥75%), had higher percentages of older adults without a computer, living in poverty, without Internet access, and living alone. CDC, state, and local jurisdictions in partnerships with communities should continue to identify and implement strategies to improve access to COVID-19 vaccination for older adults, such as assistance with scheduling vaccination appointments and transportation to vaccination sites, or vaccination at home if needed for persons who are homebound.(â€) Monitoring demographic and social factors affecting COVID-19 vaccine access for older adults and prioritizing efforts to ensure equitable access to COVID-19 vaccine are needed to ensure high coverage among this group.
Recurrent injection-site reactions after incorrect subcutaneous administration of a COVID-19 vaccine.

Erratum: Diagnosis and Management of Vaccine-Related Thrombosis following AstraZeneca COVID-19 Vaccination: Guidance Statement from the GTH.
Local skin reaction to the AZD1222 vaccine in a patient who survived COVID-19.
SARS-CoV-2 vaccine-related neurological complications need large collaborative studies, not single case reports or small descriptive series.
Anti-SARS-CoV-2 T-cell Responses After mRNA Vaccination in Belatacept-treated Renal Transplant Patients.
SARS-CoV-2 Spike Protein Stabilized in the Closed State Induces Potent Neutralizing Responses. The majority of SARS-CoV-2 vaccines in use or advanced development are based on the viral spike protein (S) as their immunogen. S is present on virions as prefusion trimers in which the receptor binding domain (RBD) is stochastically open or closed. Neutralizing antibodies have been described against both open and closed conformations. The long-term success of vaccination strategies depends upon inducing antibodies that provide long-lasting broad immunity against evolving SARS-CoV-2 strains. Here, we have assessed the results of immunization in a mouse model using an S protein trimer stabilized in the closed state to prevent full exposure of the receptor binding site and therefore interaction with the receptor. We compared this with other modified S protein constructs, including representatives used in current vaccines. We found that all trimeric S proteins induced a T cell response and long-lived, strongly neutralizing antibody responses against 2019 SARS-CoV-2 and variants of concern P.1 and B.1.351. Notably, the protein binding properties of sera induced by the closed spike differed from those induced by standard S protein constructs. Closed S proteins induced more potent neutralizing responses than expected based on the degree to which they inhibit interactions between the RBD and ACE2. These observations suggest that closed spikes recruit different, but equally potent, immune responses than open spikes and that this is likely to include neutralizing antibodies against conformational epitopes present in the closed conformation. We suggest that closed spikes, together with their improved stability and storage properties, may be a valuable component of refined, next-generation vaccines. IMPORTANCE Vaccines in use against SARS-CoV-2 induce immune responses against the spike protein. There is intense interest in whether the antibody response induced by vaccines will be robust against new variants, as well as in next-generation vaccines for use in previously infected or immunized individuals. We assessed the use as an immunogen of a spike protein engineered to be conformationally stabilized in the closed state where the receptor binding site is occluded. Despite occlusion of the receptor binding site, the spike induces potently neutralizing sera against multiple SARS-CoV-2 variants. Antibodies are raised against a different pattern of epitopes to those induced by other spike constructs, preferring conformational epitopes present in the closed conformation. Closed spikes, or mRNA vaccines based on their sequence, can be a valuable component of next-generation vaccines.
Thrombotic thrombocytopenia due to SARS-CoV-2 vaccination. Vaccine-induced thrombotic thrombocytopenia (VITT) has been reported after vaccination with the AztraZeneca ChAdOx1 nCoV-19 and the Johnson and Johnson Ad26. COV2.S vaccines. This manuscript provides a brief overview of reported cases, clinical and laboratory features, and current understanding of the pathogenesis of VITT. The author also poses unananswered questions and identifies directions for future study.
SARS-CoV-2 vaccination in rituximab-treated patients: evidence for impaired humoral but inducible cellular immune response.
COVID-19 vaccine induced prothrombotic immune thrombocytopenia.
Unilateral lymphadenopathy after COVID-19 vaccination.
First-dose mRNA vaccination is sufficient to reactivate immunological memory to SARS-CoV-2 in subjects who have recovered from COVID-19. The characterization of the adaptive immune response to COVID-19 vaccination in individuals who recovered from SARS-CoV-2 infection may

define current and future clinical practice. To determine the effect of the 2-dose BNT162b2 mRNA COVID-19 vaccination schedule in individuals who recovered from COVID-19 (COVID-19-recovered subjects) compared with naive subjects, we evaluated SARS-CoV-2 Spike-specific T and B cell responses, as well as specific IgA, IgG, IgM, and neutralizing antibodies titers in 22 individuals who received the BNT162b2 mRNA COVID-19 vaccine, 11 of whom had a previous history of SARS-CoV-2 infection. Evaluations were performed before vaccination and then weekly until 7 days after second injection. Data obtained clearly showed that one vaccine dose is sufficient to increase both cellular and humoral immune response in COVID-19-recovered subjects without any additional improvement after the second dose. On the contrary, the second dose proved mandatory in naive subjects to further enhance the immune response. These findings were further confirmed at the serological level in a larger cohort of naive (n = 68) and COVID-19-recovered (n = 29) subjects, tested up to 50 days after vaccination. These results question whether a second vaccine injection in COVID-19-recovered subjects is required, and indicate that millions of vaccine doses may be redirected to naive individuals, thus shortening the time to reach herd immunity.
Prior SARS-CoV-2 infection rescues B and T cell responses to variants after first vaccine dose. SARS-CoV-2 vaccine rollout has coincided with the spread of variants of concern. We investigated if single dose vaccination, with or without prior infection, confers cross protective immunity to variants. We analyzed T and B cell responses after first dose vaccination with the Pfizer/BioNTech mRNA vaccine BNT162b2 in healthcare workers (HCW) followed longitudinally, with or without prior Wuhan-Hu-1 SARS-CoV-2 infection. After one dose, individuals with prior infection showed enhanced T cell immunity, antibody secreting memory B cell response to spike and neutralizing antibodies effective against B.1.1.7 and B.1.351. By comparison, HCW receiving one vaccine dose without prior infection showed reduced immunity against variants. B.1.1.7 and B.1.351 spike mutations resulted in increased, abrogated or unchanged T cell responses depending on human leukocyte antigen (HLA) polymorphisms. Single dose vaccination with BNT162b2 in the context of prior infection with a heterologous variant substantially enhances neutralizing antibody responses against variants.
SARS-CoV-2 infection after two doses of mRNA vaccine in renal transplant recipients.
Pityriasis rosea following CoronaVac COVID-19 vaccination: a case report.
Thrombotic events after AstraZeneca vaccine: What if it was related to dysfunctional immune response?
Beyond Covid-19 vaccination-associated pitfalls on [(18)F]Fluorodeoxyglucose (FDG) PET: a case of a concomitant sarcoidosis.
Thrombotic Thrombocytopenia after Ad26.COV2.S Vaccination - Response from the Manufacturer.
Low neutralizing antibody responses against SARS-CoV-2 in older patients with myeloma after the first BNT162b2 vaccine dose.
Distinct antibody and memory B cell responses in SARS-CoV-2 naÃ¯ve and recovered individuals following mRNA vaccination. Novel mRNA vaccines for SARS-CoV-2 have been authorized for emergency use. Despite their efficacy in clinical trials, data on mRNA vaccine-induced immune responses are mostly limited to serological analyses. Here, we interrogated antibody and antigen-specific memory B cells over time in 33 SARS-CoV-2 naÃ¯ve and 11 SARS-CoV-2 recovered subjects. SARS-CoV-2 naÃ¯ve individuals required both vaccine doses for optimal increases in antibodies, particularly for neutralizing titers against the B.1.351 variant. Memory B cells specific for full-length spike protein and the spike receptor binding domain (RBD) were also efficiently primed by mRNA vaccination and detectable in all SARS-CoV-2 naive subjects after the second vaccine dose, though the memory B cell response declined slightly with age. In SARS-CoV-2 recovered individuals, antibody and memory B cell responses were significantly boosted after the first vaccine dose; however, there was no increase in circulating antibodies, neutralizing titers, or antigen-specific memory B cells after the

second dose. This robust boosting after the first vaccine dose strongly correlated with levels of pre-existing memory B cells in recovered individuals, identifying a key role for memory B cells in mounting recall responses to SARS-CoV-2 antigens. Together, our data demonstrated robust serological and cellular priming by mRNA vaccines and revealed distinct responses based on prior SARS-CoV-2 exposure, whereby COVID-19 recovered subjects may only require a single vaccine dose to achieve peak antibody and memory B cell responses. These findings also highlight the utility of defining cellular responses in addition to serologies and may inform SARS-CoV-2 vaccine distribution in a resource-limited setting.
An episode of oral mucositis after the first administration of the ChAdOx1 COVID-19 vaccine.
Poor Anti-SARS-CoV-2 Humoral and T-cell Responses After 2 Injections of mRNA Vaccine in Kidney Transplant Recipients Treated With Belatacept.
Exponential increase in neutralizing and spike specific antibodies following vaccination of COVID-19 convalescent plasma donors. BACKGROUND: With the recent approval of COVID-19 vaccines, recovered COVID-19 subjects who are vaccinated may be ideal candidates to donate COVID-19 convalescent plasma (CCP). CASE SERIES: Eleven recovered COVID-19 patients were screened to donate CCP. All had molecularly confirmed COVID-19, and all but one were antibody positive by chemiluminescence immunoassay (DiaSorin) prior to vaccination. All were tested again for antibodies 11-21â€‰days after they were vaccinated (Pfizer/Moderna). All showed dramatic increases (~50-fold) in spike-specific antibody levels and had at least a 20-fold increase in the IC50 neutralizing antibody titer based on plaque reduction neutralization testing (PRNT). The spike-specific antibody levels following vaccination were significantly higher than those seen in any non-vaccinated COVID-19 subjects tested to date at our facility. CONCLUSION: Spike-specific and neutralizing antibodies demonstrated dramatic increases following a single vaccination after COVID-19 infection, which significantly exceeded values seen with COVID-19 infection alone. Recovered COVID-19 subjects who are vaccinated may make ideal candidates for CCP donation.
SARS-CoV-2 mRNA vaccines induce broad CD4+ T cell responses that recognize SARS-CoV-2 variants and HCoV-NL63. Recent studies have shown T cell cross-recognition of SARS-CoV-2 and common cold coronavirus spike proteins. However, the effect of SARS-CoV-2 vaccines on T cell responses to common cold coronaviruses (CCCs) remains unknown. In this study, we analyzed CD4+ T cell responses to spike peptides from SARS-CoV-2 and 3 CCCs (HCoV-229E, HCoV-NL63, and HCoV-OC43) before and after study participants received Pfizer-BioNTech (BNT162b2) or Moderna (mRNA-1273) mRNA-based COVID-19 vaccines. Vaccine recipients showed broad T cell responses to the SARS-CoV-2 spike protein, and we identified 23 distinct targeted peptides in 9 participants, including 1 peptide that was targeted in 6 individuals. Only 4 of these 23 targeted peptides would potentially be affected by mutations in the UK (B.1.1.7) and South African (B.1.351) variants, and CD4+ T cells from vaccine recipients recognized the 2 variant spike proteins as effectively as they recognized the spike protein from the ancestral virus. Interestingly, we observed a 3-fold increase in the CD4+ T cell responses to HCoV-NL63 spike peptides after vaccination. Our results suggest that T cell responses elicited or enhanced by SARS-CoV-2 mRNA vaccines may be able to control SARS-CoV-2 variants and lead to cross-protection against some endemic coronaviruses.
Thromboembolism and the Oxford-AstraZeneca COVID-19 vaccine: side-effect or coincidence?
Infection- and vaccine-induced antibody binding and neutralization of the B.1.351 SARS-CoV-2 variant. The emergence of SARS-CoV-2 variants with mutations in the spike protein is raising concerns about the efficacy of infection- or vaccine-induced antibodies. We compared antibody binding and live virus neutralization of sera from naturally infected and Moderna-vaccinated individuals against two SARS-CoV-2 variants: B.1 containing the spike mutation D614G and the emerging B.1.351 variant containing additional spike mutations and deletions. Sera from acutely

infected and convalescent COVID-19 patients exhibited a 3-fold reduction in binding antibody titers to the B.1.351 variant receptor-binding domain of the spike protein and a 3.5-fold reduction in neutralizing antibody titers against SARS-CoV-2 B.1.351 variant compared to the B.1 variant. Similar results were seen with sera from Moderna-vaccinated individuals. Despite reduced antibody titers against the B.1.351 variant, sera from infected and vaccinated individuals containing polyclonal antibodies to the spike protein could still neutralize SARS-CoV-2 B.1.351, suggesting that protective humoral immunity may be retained against this variant.
SARS-CoV-2 spike variants exhibit differential infectivity and neutralization resistance to convalescent or post-vaccination sera. Toward eradicating the COVID-19 pandemic, vaccines that induce high humoral and cellular immune responses are essential. However, SARS-CoV-2 variants have begun to emerge and raise concerns, as they may potentially compromise vaccine efficiency. Here, we monitored neutralization potency of convalescent or Pfizer-BTN162b2 post-vaccination sera against pseudoviruses displaying spike proteins derived from wild-type SARS-CoV-2, or its UK-B.1.1.7 and SA-B.1.351 variants. Compared to convalescent sera, vaccination induces high titers of neutralizing antibodies, which exhibit efficient neutralization potential against pseudovirus carrying wild-type SARS-CoV-2. However, while wild-type and UK-N501Y pseudoviruses were similarly neutralized, those displaying SA-N501Y/K417N/E484K spike mutations moderately resist neutralization. Contribution of single or combined spike mutations to neutralization and infectivity were monitored, highlighting mechanisms by which viral infectivity and neutralization resistance are enhanced by N501Y or E484K/K417N mutations. Our study validates the importance of the Pfizer vaccine but raises concerns regarding its efficacy against specific SARS-CoV-2 circulating variants.
Persistent maculopapular rash after the first dose of Pfizer-BioNTech COVID-19 vaccine.
Weak anti-SARS-CoV-2 antibody response after the first injection of an mRNA COVID-19 vaccine in kidney transplant recipients.
May 2021: Heterogeneity in reported skin manifestations of COVID-19 and vaccines.
Multiple SARS-CoV-2 variants escape neutralization by vaccine-induced humoral immunity. Vaccination elicits immune responses capable of potently neutralizing SARS-CoV-2. However, ongoing surveillance has revealed the emergence of variants harboring mutations in spike, the main target of neutralizing antibodies. To understand the impact of these variants, we evaluated the neutralization potency of 99 individuals that received one or two doses of either BNT162b2 or mRNA-1273 vaccines against pseudoviruses representing 10 globally circulating strains of SARS-CoV-2. Five of the 10 pseudoviruses, harboring receptor-binding domain mutations, including K417N/T, E484K, and N501Y, were highly resistant to neutralization. Cross-neutralization of B.1.351 variants was comparable to SARS-CoV and bat-derived WIV1-CoV, suggesting that a relatively small number of mutations can mediate potent escape from vaccine responses. While the clinical impact of neutralization resistance remains uncertain, these results highlight the potential for variants to escape from neutralizing humoral immunity and emphasize the need to develop broadly protective interventions against the evolving pandemic.
Kidney Transplant Recipients Rarely Show an Early Antibody Response Following the First COVID-19 Vaccine Administration.
Longitudinal Analysis Reveals Distinct Antibody and Memory B Cell Responses in SARS-CoV2 NaÃ¯ve and Recovered Individuals Following mRNA Vaccination. Novel mRNA vaccines for SARS-CoV2 have been authorized for emergency use and are currently being administered to millions of individuals worldwide. Despite their efficacy in clinical trials, there is limited data on vaccine-induced immune responses in individuals with a prior SARS-CoV2 infection compared to SARS-CoV2 naÃ¯ve subjects. Moreover, how mRNA vaccines impact the development of antibodies as well as memory B cells in COVID-19 experienced versus COVID-19 naÃ¯ve subjects remains poorly understood. In this

study, we evaluated antibody responses and antigen-specific memory B cell responses over time in 33 SARS-CoV2 naÃ¯ve and 11 SARS-CoV2 recovered subjects. mRNA vaccination induced significant antibody and memory B cell responses against full-length SARS-CoV2 spike protein and the spike receptor binding domain (RBD). SARS-CoV2 naÃ¯ve individuals benefitted from both doses of mRNA vaccine with additional increases in antibodies and memory B cells following booster immunization. In contrast, SARS-CoV2 recovered individuals had a significant immune response after the first dose with no increase in circulating antibodies or antigen-specific memory B cells after the second dose. Moreover, the magnitude of the memory B cell response induced by vaccination was lower in older individuals, revealing an age-dependence to mRNA vaccine-induced B cell memory. Side effects also tended to associate with post-boost antibody levels, but not with post-boost memory B cells, suggesting that side effect severity may be a surrogate of short-term antibody responses. The frequency of pre-vaccine antigen-specific memory B cells in SARS-CoV2 recovered individuals strongly correlated with post-vaccine antibody levels, supporting a key role for memory B cells in humoral recall responses to SARS-CoV2. This observation may have relevance for future booster vaccines and for responses to viral variants that partially escape pre-existing antibodies and require new humoral responses to be generated from memory B cells. Finally, post-boost antibody levels were not correlated with post-boost memory responses in SARS-CoV2 naÃ¯ve individuals, indicating that short-term antibody levels and memory B cells are complementary immunological endpoints that should be examined in tandem when evaluating vaccine response. Together, our data provide evidence of both serological response and immunological memory following mRNA vaccination that is distinct based on prior SARS-CoV2 exposure. These findings may inform vaccine distribution in a resource-limited setting.

Recombinant protein subunit SARS-CoV-2 vaccines formulated with CoVaccine HT adjuvant induce broad, Th1 biased, humoral and cellular immune responses in mice. The speed at which several COVID-19 vaccines went from conception to receiving FDA and EMA approval for emergency use is an achievement unrivaled in the history of vaccine development. Mass vaccination efforts using the highly effective vaccines are currently underway to generate sufficient herd immunity and reduce transmission of the SARS-CoV-2 virus. Despite the most advanced vaccine technology, global recipient coverage, especially in resource-poor areas remains a challenge as genetic drift in naÃ¯ve population pockets threatens overall vaccine efficacy. In this study, we described the production of insect-cell expressed SARS-CoV-2 spike protein ectodomain and examined its immunogenicity in mice. We demonstrated that, when formulated with CoVaccine HTâ„¢adjuvant, an oil-in-water nanoemulsion compatible with lyophilization, our vaccine candidates elicit a broad-spectrum IgG response, high neutralizing antibody titers, and a robust, antigen-specific IFN-Î³ secreting response from immune splenocytes in outbred mice. Our findings lay the foundation for the development of a dry-thermostabilized vaccine that is deployable without refrigeration.

Delivering High-Quality, Equitable Care in India: An Ethically-Resilient Framework for Healthcare Innovation After COVID-19. Developing countries struggle to provide high-quality, equitable care to all. Challenges of resource allocation frequently lead to ethical concerns of healthcare inequity. To tackle this, such developing nations continually need to implement healthcare innovation, coupled with capacity building to ensure new strategies continue to be developed and executed. The COVID-19 pandemic has made significant demands of healthcare systems across the world-to provide equitable healthcare to all, to ensure public health principles are followed, to find novel solutions for previously unencountered healthcare challenges, and to rapidly develop new therapeutics and vaccines for COVID-19. Countries worldwide have struggled to accomplish these demands, especially the latter two, considering that few nations had long-standing systems in place to ensure processes for innovation were on-going before the pandemic struck. The crisis represents a critical juncture to

plan for a future. This future needs to incorporate a vision for the implementation of healthcare innovation, coupled with capacity building to ensure new strategies continue to be developed and executed. In this paper, the case of the massive Indian healthcare system is utilized to describe how it could implement this vision. An inclusive, ethically-resilient framework has been broadly laid out for healthcare innovation in the future, thereby ensuring success in both the short- and the long-term.
Oxford-AstraZeneca COVID-19 vaccination induced lymphadenopathy on [18F]Choline PET/CT-not only an FDG finding.
Ferritin nanoparticle-based SARS-CoV-2 RBD vaccine induces a persistent antibody response and long-term memory in mice.
Neurological complications of vaccines for COVIDâ€“19.
Oral side effects of COVID-19 vaccine.
Monte Carlo Simulation of SARS-CoV-2 Radiation-Induced Inactivation for Vaccine Development. Immunization with an inactivated virus is one of the strategies currently being tested towards developing a SARS-CoV-2 vaccine. One of the methods used to inactivate viruses is exposure to high doses of ionizing radiation to damage their nucleic acids. While gamma (Î³) rays effectively induce lesions in the RNA, envelope proteins are also highly damaged in the process. This in turn may alter their antigenic properties, affecting their capacity to induce an adaptive immune response able to confer effective protection. Here, we modeled the effect of sparsely and densely ionizing radiation on SARS-CoV-2 using the Monte Carlo toolkit Geant4-DNA. With a realistic 3D target virus model, we calculated the expected number of lesions in the spike and membrane proteins, as well as in the viral RNA. Our findings showed that Î³ rays produced significant spike protein damage, but densely ionizing charged particles induced less membrane damage for the same level of RNA lesions, because a single ion traversal through the nuclear envelope was sufficient to inactivate the virus. We propose that accelerated charged particles produce inactivated viruses with little structural damage to envelope proteins, thereby representing a new and effective tool for developing vaccines against SARS-CoV-2 and other enveloped viruses.
Bell's Palsy After Second Dose of Moderna COVID-19 Vaccine: Coincidence or Causation? US Food and Drug Administration (FDA) recommended enhanced safety surveillance to monitor for cases of Bell's palsy following Moderna vaccine administration in larger populations. The author reports a patient who developed right sided Bell's palsy 2 weeks after administration of the second dose of Moderna COVID-19 vaccine. Considering this development of symptoms 2 weeks after the second dose of Moderna vaccine administration, there remains a possibility of a causal association. As more people get vaccinated, more information may be available in the future to establish association. Physicians need to maintain enhanced safety surveillance to monitor for cases of Bell's palsy following mRNA vaccine administration.
Defusing SARS-CoV-2: Emergency Brakes in a Vaccine Failure Scenario. Deactivation of primed SARS-CoV-2 prior to cell entry constitutes an emergency brake in COVID-19 infection if vaccine-induced antibodies fail to block recognition of the human angiotensin-converting enzyme 2 (hACE2) receptor. The timing and locus for the therapeutic intervention are dictated by the cell entry mechanism and by the selective advantage of the dominant D614G mutation.
Biochemical and antigenic characterization of the structural proteins and their post-translational modifications in purified SARS-CoV-2 virions of an inactivated vaccine candidate. In the face of COVID-19 pandemic caused by the newly emerged SARS-CoV-2, an inactivated, Vero cell-based, whole virion vaccine candidate has been developed and entered into phase III clinical trials within six months. Biochemical and immunogenic characterization of structural proteins and their post-translational modifications in virions, the end-products of the vaccine candidate, would be essential for the quality control and process development of vaccine products and for studying the

immunogenicity and pathogenesis of SARS-CoV-2. By using a panel of rabbit antisera against virions and five structural proteins together with a convalescent serum, the spike (S) glycoprotein was shown to be N-linked glycosylated, PNGase F-sensitive, endoglycosidase H-resistant and cleaved by Furin-like proteases into S1 and S2 subunits. The full-length S and S1/S2 subunits could form homodimers/trimers. The membrane (M) protein was partially N-linked glycosylated; the accessory protein 3a existed in three different forms, indicative of cleavage and dimerization. Furthermore, analysis of the antigenicity of these proteins and their post-translationally modified forms demonstrated that S protein induced the strongest antibody response in both convalescent and immunized animal sera. Interestingly, immunization with the inactivated vaccine did not elicit antibody response against the S2 subunit, whereas strong antibody response against both S1 and S2 subunits was detected in the convalescent serum. Moreover, vaccination stimulated stronger antibody response against S multimers than did the natural infection. This study revealed that the native S glycoprotein stimulated neutralizing antibodies, while bacterially-expressed S fragments did not. The study on S modifications would facilitate design of S-based anti-SARS-CoV-2 vaccines.
COVID mink analysis shows mutations are not dangerous - yet.
Ad26 vector-based COVID-19 vaccine encoding a prefusion-stabilized SARS-CoV-2 Spike immunogen induces potent humoral and cellular immune responses. Development of effective preventative interventions against SARS-CoV-2, the etiologic agent of COVID-19 is urgently needed. The viral surface spike (S) protein of SARS-CoV-2 is a key target for prophylactic measures as it is critical for the viral replication cycle and the primary target of neutralizing antibodies. We evaluated design elements previously shown for other coronavirus S protein-based vaccines to be successful, e.g., prefusion-stabilizing substitutions and heterologous signal peptides, for selection of a S-based SARS-CoV-2 vaccine candidate. In vitro characterization demonstrated that the introduction of stabilizing substitutions (i.e., furin cleavage site mutations and two consecutive prolines in the hinge region of S2) increased the ratio of neutralizing versus non-neutralizing antibody binding, suggestive for a prefusion conformation of the S protein. Furthermore, the wild-type signal peptide was best suited for the correct cleavage needed for a natively folded protein. These observations translated into superior immunogenicity in mice where the Ad26 vector encoding for a membrane-bound stabilized S protein with a wild-type signal peptide elicited potent neutralizing humoral immunity and cellular immunity that was polarized towards Th1 IFN-Î³. This optimized Ad26 vector-based vaccine for SARS-CoV-2, termed Ad26.COV2.S, is currently being evaluated in a phase I clinical trial (ClinicalTrials.gov Identifier: NCT04436276).
Withdrawn: Theoretical novel COVID-19 vaccination risk of rare and severe adverse events versus COVID-19 mortality. This article has been withdrawn at the request of the author(s) and/or editor. The Publisher apologizes for any inconvenience this may cause. The full Elsevier Policy on Article Withdrawal can be found at https://www.elsevier.com/about/our-business/policies/article-withdrawal.
Identification of SARS-CoV-2 Vaccine Epitopes Predicted to Induce Long-Term Population-Scale Immunity. Here we propose a SARS-CoV-2 vaccine design concept based on identification of highly conserved regions of the viral genome and newly acquired adaptations, both predicted to generate epitopes presented on major histocompatibility complex (MHC) class I and II across the vast majority of the population. We further prioritize genomic regions that generate highly dissimilar peptides from the human proteome and are also predicted to produce B cell epitopes. We propose sixty-five 33-mer peptide sequences, a subset of which can be tested using DNA or mRNA delivery strategies. These include peptides that are contained within evolutionarily divergent regions of the spike protein reported to increase infectivity through increased binding to the ACE2 receptor and within a newly evolved furin cleavage site thought to increase membrane fusion. Validation and

implementation of this vaccine concept could specifically target specific vulnerabilities of SARS-CoV-2 and should engage a robust adaptive immune response in the vast majority of the population.

National policies for paediatric universal BCG vaccination were associated with decreased mortality due to COVID-19. See related Reply

Single-dose replicating RNA vaccine induces neutralizing antibodies against SARS-CoV-2 in nonhuman primates. The ongoing COVID-19 pandemic, caused by infection with SARS-CoV-2, is having a dramatic and deleterious impact on health services and the global economy. Grim public health statistics highlight the need for vaccines that can rapidly confer protection after a single dose and be manufactured using components suitable for scale-up and efficient distribution. In response, we have rapidly developed repRNA-CoV2S, a stable and highly immunogenic vaccine candidate comprised of an RNA replicon formulated with a novel Lipid InOrganic Nanoparticle (LION) designed to enhance vaccine stability, delivery and immunogenicity. We show that intramuscular injection of LION/repRNA-CoV2S elicits robust anti-SARS-CoV-2 spike protein IgG antibody isotypes indicative of a Type 1 T helper response as well as potent T cell responses in mice. Importantly, a single-dose administration in nonhuman primates elicited antibody responses that potently neutralized SARS-CoV-2. These data support further development of LION/repRNA-CoV2S as a vaccine candidate for prophylactic protection from SARS-CoV-2 infection.

Usefulness of bronchoalveolar lavage in the management of patients presenting with lung infiltrates and suspect COVID-19-associated pneumonia: A case report. OBJECTIVE: To report a clinical case of a patient with a compatible HRCT scan and two negative SARS-CoV-2 RNA upper respiratory tract specimens but with a confirmed viral infection by BAL (19 days after symptom onset). METHODS: Revision of a patient's clinical charts with COVID-19 admitted at INMI L. Spallanzani Hospital RESULTS: Two oropharyngeal swab tests of SARS-CoV-2 by qualitative real-time reverse-transcriptase-polymerase-chain-reaction (RT-PCR) assay were performed at admission (17 days from symptoms onset) and a day apart and were found negative. BAL fluid collected 19 days after symptoms onset was positive for SARS-CoV-2. CONCLUSION: This case highlights importance of clinical suspicion of SARS-CoV-2 infection in diagnosis and infectivity assessment. We suggest collection of BAL fluid when consecutive nasopharyngeal swabs are negative, to confirm or exclude the diagnosis of COVID-19-associated pneumonia. Healthcare workers should perform aerosol-generating procedures in an adequately ventilated room and should wear adequate PPE.

Emergence of genomic diversity and recurrent mutations in SARS-CoV-2. SARS-CoV-2 is a SARS-like coronavirus of likely zoonotic origin first identified in December 2019 in Wuhan, the capital of China's Hubei province. The virus has since spread globally, resulting in the currently ongoing COVID-19 pandemic. The first whole genome sequence was published on January 5 2020, and thousands of genomes have been sequenced since this date. This resource allows unprecedented insights into the past demography of SARS-CoV-2 but also monitoring of how the virus is adapting to its novel human host, providing information to direct drug and vaccine design. We curated a dataset of 7666 public genome assemblies and analysed the emergence of genomic diversity over time. Our results are in line with previous estimates and point to all sequences sharing a common ancestor towards the end of 2019, supporting this as the period when SARS-CoV-2 jumped into its human host. Due to extensive transmission, the genetic diversity of the virus in several countries recapitulates a large fraction of its worldwide genetic diversity. We identify regions of the SARS-CoV-2 genome that have remained largely invariant to date, and others that have already accumulated diversity. By focusing on mutations which have emerged independently multiple times (homoplasies), we identify 198 filtered recurrent mutations in the SARS-CoV-2 genome. Nearly 80% of the recurrent mutations produced non-synonymous changes at the protein level, suggesting possible ongoing adaptation of SARS-CoV-2. Three sites in Orf1ab in the regions encoding Nsp6, Nsp11, Nsp13, and one in the Spike

protein are characterised by a particularly large number of recurrent mutations (>15 events) which may signpost convergent evolution and are of particular interest in the context of adaptation of SARS-CoV-2 to the human host. We additionally provide an interactive user-friendly web-application to query the alignment of the 7666 SARS-CoV-2 genomes.

Neurologic manifestations in an infant with COVID-19.

A recombinant VSV-vectored MERS-CoV vaccine induces neutralizing antibody and T cell responses in rhesus monkeys after single dose immunization. Middle East respiratory syndrome coronavirus (MERS-CoV) has been a highly threatening zoonotic pathogen since its outbreak in 2012. Similar to SARS-CoV, MERS-CoV belongs to the coronavirus family and can induce severe respiratory symptoms in humans, with an average case fatality rate of 35% according to the World Health Organization. Spike (S) protein of MERS-CoV is immunogenic and can induce neutralizing antibodies, thus is a potential major target for vaccine development. Here we constructed a chimeric virus based on the vesicular stomatitis virus (VSV) in which the G gene was replaced by MERS-CoV S gene (VSVÎ”G-MERS). The S protein efficiently incorporated into the viral envelope and mediated cell entry through binding its receptor, human DPP4. Knockdown of clathrin expression by siRNA drastically abrogated the infection of VSVÎ”G-MERS in Vero cells. Furthermore, in animal studies, the recombinant virus induced neutralizing antibodies and T cell responses in rhesus monkeys after a single intramuscular or intranasal immunization dose. Our findings indicate the potential of the chimeric VSVÎ”G-MERS as a rapid response vaccine candidate against emerging MERS-CoV disease.

HIV-1-neutralizing antibody induced by simian adenovirus- and poxvirus MVA-vectored BG505 native-like envelope trimers. Rabbits and monkeys immunized with HIV type 1 (HIV-1) native-like BG505 SOSIP.664 (BG505s) glycoprotein trimers are known to induce antibodies that can neutralize the autologous tier-2 virus. Here, we assessed the induction of HIV-1 trimer binding and neutralizing antibody (nAb) titres when BG505s trimers were also delivered by non-replicating simian (chimpanzee) adenovirus and non-replicating poxvirus modified vaccinia virus Ankara (MVA) vaccine vectors. First, we showed that approximately two-thirds and one-third of the trimers secreted from the ChAdOx1.BG505s (C) and MVA.BG505s (M) vaccine-infected cells, respectively, were cleaved and in a native-like conformation. Rabbits were immunized intramuscularly with these vaccine vectors and in some cases boosted with ISCOMATRIXâ„¢-adjuvanted BG505s protein trimer (P), using CCC, MMM, PPP, CPP, MPP and CMP vaccine regimens. We found that the peak trimer-binding antibody and tier-1A and autologous tier-2 nAb responses induced by the CC, CM, PPP, CPP, MPP and CMP regimens were comparable, although only PPP induced autologous tier-2 nAbs in all the immunized animals. Three animals developed weak heterologous tier-2 nAbs. These results demonstrate that ChAdOx1 and MVA vectors are useful delivery modalities for not only T-cell, but also antibody vaccine development.

The relative magnitude of transgene-specific adaptive immune responses induced by human and chimpanzee adenovirus vectors differs between laboratory animals and a target species. Adenovirus vaccine vectors generated from new viral serotypes are routinely screened in pre-clinical laboratory animal models to identify the most immunogenic and efficacious candidates for further evaluation in clinical human and veterinary settings. Here, we show that studies in a laboratory species do not necessarily predict the hierarchy of vector performance in other mammals. In mice, after intramuscular immunization, HAdV-5 (Human adenovirus C) based vectors elicited cellular and humoral adaptive responses of higher magnitudes compared to the chimpanzee adenovirus vectors ChAdOx1 and AdC68 from species Human adenovirus E. After HAdV-5 vaccination, transgene specific IFN-Î³(+) CD8(+) T cell responses reached peak magnitude later than after ChAdOx1 and AdC68 vaccination, and exhibited a slower contraction to a memory phenotype. In cattle, cellular and humoral immune responses were at least equivalent, if not higher, in magnitude after ChAdOx1

vaccination compared to HAdV-5. Though we have not tested protective efficacy in a disease model, these findings have important implications for the selection of candidate vectors for further evaluation. We propose that vaccines based on ChAdOx1 or other Human adenovirus E serotypes could be at least as immunogenic as current licensed bovine vaccines based on HAdV-5.

Humoral and cellular immune responses induced by 3a DNA vaccines against severe acute respiratory syndrome (SARS) or SARS-like coronavirus in mice. Vaccine development for severe acute respiratory syndrome coronavirus (SARS-CoV) has mainly focused on the spike (S) protein. However, the variation of the S gene between viruses may affect the efficacy of a vaccine, particularly for cross-protection against SARS-like CoV (SL-CoV). Recently, a more conserved group-specific open reading frame (ORF), the 3a gene, was found in both SARS-CoV and SL-CoV. Here, we studied the immunogenicity of human SARS-CoV 3a and bat SL-CoV 3a DNA vaccines in mice through electroporation immunization followed by enzyme-linked immunosorbent, enzyme-linked immunospot, and flow cytometry assays. Our results showed that high levels of specific humoral responses were induced by SARS-CoV 3a and SL-CoV 3a DNA vaccines. Furthermore, a strong Th1-based cellular immune response was stimulated by both DNA vaccines. The vaccines stimulated gamma interferon production mainly by CD8(+) T cells and interleukin-2 (IL-2) mainly by CD4(+) T cells. Of interest, the frequency of IL-2-positive cells elicited by the SARS-CoV 3a DNA vaccine was significantly higher than that elicited by the SL-CoV 3a DNA vaccine. In summary, our study provides a reference for designing cross-protective DNA vaccines based on the group-specific ORFs of CoVs.

A SARS DNA vaccine induces neutralizing antibody and cellular immune responses in healthy adults in a Phase I clinical trial. BACKGROUND: The severe acute respiratory syndrome (SARS) virus is a member of the Coronaviridae (CoV) family that first appeared in the Guangdong Province of China in 2002 and was recognized as an emerging infectious disease in March 2003. Over 8000 cases and 900 deaths occurred during the epidemic. We report the safety and immunogenicity of a SARS DNA vaccine in a Phase I human study. METHODS: A single-plasmid DNA vaccine encoding the Spike (S) glycoprotein was evaluated in 10 healthy adults. Nine subjects completed the 3 dose vaccination schedule and were evaluated for vaccine safety and immune responses. Immune response was assessed by intracellular cytokine staining (ICS), ELISpot, ELISA, and neutralization assays. RESULTS: The vaccine was well tolerated. SARS-CoV-specific antibody was detected by ELISA in 8 of 10 subjects and neutralizing antibody was detected in all subjects who received 3 doses of vaccine. SARS-CoV-specific CD4+ T-cell responses were detected in all vaccinees, and CD8+ T-cell responses in approximately 20% of individuals. CONCLUSIONS: The VRC SARS DNA vaccine was well tolerated and produced cellular immune responses and neutralizing antibody in healthy adults.

A chimeric multi-epitope DNA vaccine elicited specific antibody response against severe acute respiratory syndrome-associated coronavirus which attenuated the virulence of SARS-CoV in vitro. Epitope-based vaccines designed to induce antibody responses specific for severe acute respiratory syndrome-associated coronavirus (SARS-CoV) are being developed as a means for increasing vaccine potency. In this study, we identified four B cell epitopes from the spike (S) and membrane (M) protein through bioinformatics analysis and constructed a multi-epitope DNA vaccine. Intramuscular immunization of mice with this vaccine was sufficient to induce specific prime as well as a long-term memory humoral immune response to at least two candidate epitopes, S(437-459) and M(1-20). A DNA prime-protein boost strategy greatly enhanced the antibody generation and the immune sera not only reacted with the lysates of SARS-CoV-infected Vero cells but also neutralized the cytopathic effect of SARS by 75% at 1:160 dilution. The novel immunogenic S protein peptide revealed in this study provides new target for SARS vaccine design; and our work indicated multi-epitope DNA vaccine as an effective means for eliciting polyvalent humoral immune response against SARS-CoV.

SARS vaccine based on a replication-defective recombinant vesicular stomatitis virus is more potent than one based on a replication-competent vector. A SARS vaccine based on a live-attenuated vesicular stomatitis virus (VSV) recombinant expressing the SARS-CoV S protein provides long-term protection of immunized mice from SARS-CoV infection (Kapadia, S.U., Rose, J. K., Lamirande, E., Vogel, L., Subbarao, K., Roberts, A., 2005. Long-term protection from SARS coronavirus infection conferred by a single immunization with an attenuated VSV-based vaccine. Virology 340(2), 174-82.). Because it is difficult to obtain regulatory approval of vaccine based on live viruses, we constructed a replication-defective single-cycle VSV vector in which we replaced the VSV glycoprotein (G) gene with the SARS-CoV S gene. The virus was only able to infect cells when pseudotyped with the VSV G protein. We measured the effectiveness of immunization with the single-cycle vaccine in mice. We found that the vaccine given intramuscularly induced a neutralizing antibody response to SARS-CoV that was approximately ten-fold greater than that required for the protection from SARS-CoV infection, and significantly greater than that generated by the replication-competent vector expressing SARS-CoV S protein given by the same route. Our results, along with earlier studies showing potent induction of T-cell responses by single-cycle vectors, indicate that these vectors are excellent alternatives to live-attenuated VSV.

Avian coronavirus infectious bronchitis attenuated live vaccines undergo selection of subpopulations and mutations following vaccination. In this study, we were interested in determining if high titered egg adapted modified live infectious bronchitis virus (IBV) vaccines contain spike gene related quasispecies that undergo selection in chickens, following vaccination. We sequenced the spike glycoprotein of 12 IBV vaccines (5 different serotypes from 3 different manufacturers) directly from the vaccine vial, then compared that sequence with reisolated viruses from vaccinated and contact-exposed birds over time. We found differences in the S1 sequence within the same vaccine serotype from different manufacturers, differences in S1 sequence between different vaccine serials from the same manufacturer, and intra-vaccine differences or quasispecies. Comparing the sequence data of the reisolated viruses with the original vaccine virus, we were able to identify in vivo selection of viral subpopulations as well as mutations. To our knowledge, this is the first report showing selection of a more fit virus subpopulation as well as mutations associated with replication of modified live IBV vaccine viruses in chickens. This information is important for our understanding of how attenuated virus vaccines, including potential vaccines against the SARS-CoV, can ensure long-term survival of the virus and can lead to changes in pathogenesis and emergence of new viral pathogens. This information is also valuable for the development of safer modified live coronavirus vaccines.

Type IVB pilus operon promoter controlling expression of the severe acute respiratory syndrome-associated coronavirus nucleocapsid gene in Salmonella enterica Serovar Typhi elicits full immune response by intranasal vaccination. Attenuated Salmonella enterica serovar Typhi strains have been considered to be attractive as potential live oral delivery vector vaccines because of their ability to elicit the full array of immune responses in humans. In this study, we constructed an attenuated S. enterica serovar Typhi strain stably expressing conserved nucleocapsid (N) protein of severe acute respiratory syndrome-associated coronavirus (SARS-CoV) by integrating the N gene into the pilV gene, which was under the control of the type IVB pilus operon promoter in S. enterica serovar Typhi. BALB/c mice were immunized with this recombinant strain through different routes: intranasally, orogastrically, intraperitoneally, and intravenously. Results showed that the intranasal route caused the highest production of specific immunoglobulin G (IgG), IgG2a, and secretory IgA, where IgG2a was imprinted as a Th1 cell bias. Moreover, this recombinant live vaccine induced significantly high levels of specific cytotoxic T-lymphocyte activities and increased gamma interferon-producing T cells compared with the parental strain. Our work provides insights into how the type IVB pilus operon promoter controlling SARS-CoV N gene expression in Salmonella might be attractive for a live-vector

vaccine against SRAS-CoV infection, for it could induce mucosal, humoral, and cellular immune responses. Our work also indicates that the type IVB pilus operon promoter controlling foreign gene expression in Salmonella can elicit full immune responses by intranasal vaccination.

Children's vaccines do not induce cross reactivity against SARS-CoV. In contrast with adults, children infected by severe acute respiratory syndrome-corona virus (SARS-CoV) develop milder clinical symptoms. Because of this, it is speculated that children vaccinated with various childhood vaccines might develop cross immunity against SARS-CoV. Antisera and T cells from mice immunised with various vaccines were used to determine whether they developed cross reactivity against SARS-CoV. The results showed no marked cross reactivity against SARS-CoV, which implies that the reduced symptoms among children infected by SARS-CoV may be caused by other factors.

Exosomal vaccines containing the S protein of the SARS coronavirus induce high levels of neutralizing antibodies. Infection with the SARS-associated coronavirus (SARS-CoV) induces an atypical pulmonary disease with a high lethality rate. Although the initial SARS epidemic was contained, sporadic outbreaks of the disease still occur, suggesting a continuous need for a vaccine against this virus. We therefore explored exosome-based vaccines containing the spike S proteins of SARS-CoV. S-containing exosomes were obtained by replacing the transmembrane and cytoplasmic domains of the S protein by those of VSV-G. The immunogenicity and efficacy of the S-containing exosomes were tested in mice and compared to an adenoviral vector vaccine expressing the S protein. Both, S-containing exosomes and the adenoviral vector vaccine induced neutralizing antibody titers. After priming with the SARS-S exosomal vaccine and boosting with the adenoviral vector the neutralizing antibody titers exceeded those observed in the convalescent serum of a SARS patient. Both approaches were effective in a SARS-S-expressing tumor challenge model and thus warrant further investigation.

SARS-CoV spike protein-expressing recombinant vaccinia virus efficiently induces neutralizing antibodies in rabbits pre-immunized with vaccinia virus. A vaccine for severe acute respiratory syndrome (SARS) is being intensively pursued against its re-emergence. We generated a SARS coronavirus (SARS-CoV) spike protein-expressing recombinant vaccinia virus (RVV-S) using highly attenuated strain LC16m8. Intradermal administration of RVV-S into rabbits induced neutralizing (NT) antibodies against SARS-CoV 1 week after administration and the NT titer reached 1:1000 after boost immunization with RVV-S. Significantly, NT antibodies against SARS-CoV were induced by administration of RVV-S to rabbits that had been pre-immunized with LC16m8. RVV-S can induce NT antibodies against SARS-CoV despite the presence of NT antibodies against VV. These results suggest that RVV-S may be a powerful SARS vaccine, including in patients previously immunized with the smallpox vaccine.

Enhanced induction of SARS-CoV nucleocapsid protein-specific immune response using DNA vaccination followed by adenovirus boosting in BALB/c mice. OBJECTIVE: To investigate immunogenicity in the induction of humoral and cellular immune responses to genetic vaccines of the recombinant severe acute respiratory syndrome-associated coronavirus (SARS-CoV)-N gene expressing the same protein plasmid, pcDNA3.1-N, and replication-defective adenoviral vector, rAd-N, in a pcDNA3.1-N prime-rAd-N boost regimen and the reverse sequence in a rAd-N prime-pcDNA3.1-N boost regimen. METHOD: After the mice had been immunized intramuscularly and/or intraperitoneally with pcDNA3.1-N and rAd-N in prime-triple boost immunization, humoral and cellular immune responses were detected. RESULTS: After detection, different levels of anti-N humoral and cellular responses are shown compared to controls. The humoral immune response was induced more effectively by the DNA priming and recombinant adenovirus boosting regimen and the reverse sequence of heterogeneous combinations. There is a significant difference between heterogeneous and homologous vaccinations. However, the cytotoxic T lymphocyte (CTL) response

was not significantly altered by the different prime-boost immunizations or the recombinant adenovirus of pcDNA3.1-N prime-rAd-N boost regimen alone, but lymphoproliferation and interferon-gamma (IFN-gamma) secretion were all enhanced by heterologous combination immunizations compared to homologous combinations. For the reverse sequence immunization regimen, lymphoproliferation, IFN-gamma and CTL responses were all significantly weaker compared with pcDNA3.1-N prime-rAd-N boost regimen. CONCLUSION: Taken together, of all the combinations, the prime-triple boost immunization of pcDNA3.1-N/pcDNA3.1-N/pcDNA3.1-N/rAd-N can effectively induce SARS-CoV-N-specific and strong humoral and cellular immune responses in mice. The present results suggest that DNA immunization followed by recombinant adenovirus boosting could be used as a potential SARS-CoV vaccine in the induction of an enhanced humoral and cellular immune response.

Recombinant adeno-associated virus expressing the receptor-binding domain of severe acute respiratory syndrome coronavirus S protein elicits neutralizing antibodies: Implication for developing SARS vaccines. Development of an effective vaccine for severe acute respiratory syndrome (SARS) remains to be a priority to prevent possible re-emergence of SARS coronavirus (SARS-CoV). We previously demonstrated that the receptor-binding domain (RBD) of SARS-CoV S protein is a major target of neutralizing antibodies. This suggests that the RBD may serve as an ideal vaccine candidate. Recombinant adeno-associated virus (rAAV) has been proven to be an effective system for gene delivery and vaccine development. In this study, a novel vaccine against SARS-CoV was developed based on the rAAV delivery system. The gene encoding RBD was cloned into a pAAV-IRES-hrGFP plasmid. The immunogenicity induced by the resulting recombinant RBD-rAAV was evaluated in BALB/c mice. The results demonstrated that (1) a single dose of RBD-rAAV vaccination could induce sufficient neutralizing antibody against SARS-CoV infection; (2) two more repeated doses of the vaccination boosted the neutralizing antibody to about 5 times of the level achieved by a single dose of the immunization and (3) the level of the antibody continued to increase for the entire duration of the experiment of 5.5 months. These results suggested that RBD-rAAV is a promising SARS candidate vaccine.

SARS coronavirus spike polypeptide DNA vaccine priming with recombinant spike polypeptide from Escherichia coli as booster induces high titer of neutralizing antibody against SARS coronavirus. Different forms of SARS coronavirus (SARS-CoV) spike protein-based vaccines for generation of neutralizing antibody response against SARS-CoV were compared using a mouse model. High IgG levels were detected in mice immunized with intraperitoneal (i.p.) recombinant spike polypeptide generated by Escherichia coli (S-peptide), mice primed with intramuscular (i.m.) tPA-optimize800 DNA vaccine (tPA-S-DNA) and boosted with i.p. S-peptide, mice primed with i.m. CTLA4HingeSARS800 DNA vaccine (CTLA4-S-DNA) and boosted with i.p. S-peptide, mice primed with oral live-attenuated Salmonella typhimurium (Salmonella-S-DNA-control) and boosted with i.p. S-peptide, mice primed with oral live-attenuated S. typhimurium that contained tPA-optimize800 DNA vaccine (Salmonella-tPA-S-DNA) and boosted with i.p. S-peptide, and mice primed with oral live-attenuated S. typhimurium that contained CTLA4HingeSARS800 DNA vaccine (Salmonella-tPA-S-DNA) and boosted with i.p. S-peptide. No statistical significant difference was observed among the Th1/Th2 index among these six groups of mice with high IgG levels. Sera of all six mice immunized with i.p. S-peptide, i.m. DNA vaccine control and oral Salmonella-S-DNA-control showed no neutralizing antibody against SARS-CoV. Sera of the mice immunized with i.m. tPA-S-DNA, i.m. CTLA4-S-DNA, oral Salmonella-S-DNA-control boosted with i.p. S-peptide, oral Salmonella-tPA-S-DNA, oral Salmonella-tPA-S-DNA boosted with i.p S-peptide, oral Salmonella-CTLA4-S-DNA and oral Salmonella-CTLA4-S-DNA boosted with i.p. S-peptide showed neutralizing antibody titers of <1:20-1:160. Sera of all the mice immunized with i.m. tPA-S-DNA boosted with i.p. S-peptide and i.m. CTLA4-S-DNA boosted with

i.p. S-peptide showed neutralizing antibody titers of >or=1:1280. The present observation may have major practical value, such as immunization of civet cats, since production of recombinant proteins from E. coli is far less expensive than production of recombinant proteins using eukaryotic systems.

Identification of a critical neutralization determinant of severe acute respiratory syndrome (SARS)-associated coronavirus: importance for designing SARS vaccines. The spike (S) protein of severe acute respiratory syndrome-associated coronavirus (SARS-CoV) is not only responsible for receptor binding, but also a major antigenic determinant capable of inducing protective immunity. In this study, we demonstrated that the receptor-binding domain (RBD) of S protein is an important immunogenic site in patients with SARS and rabbits immunized with inactivated SARS-CoV. Serum samples from convalescent SARS patients and immunized rabbits had potent neutralizing activities against infection by pseudovirus expressing SARS-CoV S protein. Depletion of RBD-specific antibodies from patient or rabbit immune sera by immunoadsorption significantly reduced serum-mediated neutralizing activity, while affinity-purified anti-RBD antibodies had relatively higher potency neutralizing infectivity of SARS pseudovirus, indicating that the RBD of S protein is a critical neutralization determinant of SARS-CoV during viral infection and immunization. Two monoclonal antibodies (1A5 and 2C5) targeting at the RBD of S protein were isolated from mice immunized with inactivated SARS-CoV. Both 1A5 and 2C5 possessed potent neutralizing activities, although they directed against distinct conformation-dependant epitopes as shown by ELISA and binding competition assay. We further demonstrated that 2C5, but not 1A5, was able to block binding of the RBD to angiotensin-converting enzyme 2 (ACE2), the functional receptor on targeted cells. These data provide important information for understanding the antigenicity and immunogenicity of SARS-CoV and for designing SARS vaccines.

Amino acids 1055 to 1192 in the S2 region of severe acute respiratory syndrome coronavirus S protein induce neutralizing antibodies: implications for the development of vaccines and antiviral agents. The spike (S) protein of the severe acute respiratory syndrome coronavirus (SARS-CoV) interacts with cellular receptors to mediate membrane fusion, allowing viral entry into host cells; hence it is recognized as the primary target of neutralizing antibodies, and therefore knowledge of antigenic determinants that can elicit neutralizing antibodies could be beneficial for the development of a protective vaccine. Here, we expressed five different fragments of S, covering the entire ectodomain (amino acids 48 to 1192), as glutathione S-transferase fusion proteins in Escherichia coli and used the purified proteins to raise antibodies in rabbits. By Western blot analysis and immunoprecipitation experiments, we showed that all the antibodies are specific and highly sensitive to both the native and denatured forms of the full-length S protein expressed in virus-infected cells and transfected cells, respectively. Indirect immunofluorescence performed on fixed but unpermeabilized cells showed that these antibodies can recognize the mature form of S on the cell surface. All the antibodies were also able to detect the maturation of the 200-kDa form of S to the 210-kDa form by pulse-chase experiments. When the antibodies were tested for their ability to inhibit SARS-CoV propagation in Vero E6 culture, it was found that the anti-SDelta10 antibody, which was targeted to amino acid residues 1029 to 1192 of S, which include heptad repeat 2, has strong neutralizing activities, suggesting that this region of S carries neutralizing epitopes and is very important for virus entry into cells.

Immune responses against SARS-coronavirus nucleocapsid protein induced by DNA vaccine. The nucleocapsid (N) protein of SARS-coronavirus (SARS-CoV) is the key protein for the formation of the helical nucleocapsid during virion assembly. This protein is believed to be more conserved than other proteins of the virus, such as spike and membrane glycoprotein. In this study, the N protein of SARS-CoV was expressed in Escherichia coli DH5alpha and identified with pooled sera from patients in the convalescence phase of SARS. A plasmid pCI-N, encoding the full-length N gene of SARS-CoV, was

constructed. Expression of the N protein was observed in COS1 cells following transfection with pCI-N. The immune responses induced by intramuscular immunization with pCI-N were evaluated in a murine model. Serum anti-N immunoglobulins and splenocytes proliferative responses against N protein were observed in immunized BALB/c mice. The major immunoglobulin G subclass recognizing N protein was immunoglobulin G2a, and stimulated splenocytes secreted high levels of gamma interferon and IL-2 in response to N protein. More importantly, the immunized mice produced strong delayed-type hypersensitivity (DTH) and CD8(+) CTL responses to N protein. The study shows that N protein of SARS-CoV not only is an important B cell immunogen, but also can elicit broad-based cellular immune responses. The results indicate that the N protein may be of potential value in vaccine development for specific prophylaxis and treatment against SARS.

Humoral immune responses in rabbits induced by an experimental inactivated severe acute respiratory syndrome coronavirus vaccine prepared from F69 strain. BACKGROUND: The etiologic agent of severe acute respiratory syndrome (SARS) has been confirmed to be a novel coronavirus (CoV), namely SARS-CoV. Developing safe and effective SARS-CoV vaccines is essential for us to prevent the possible reemergence of its epidemic. Previous experiences indicate that inactivated vaccine is conventional and more hopeful to be successfully developed. Immunogenicity evaluation of an experimental inactivated SARS-CoV vaccine in rabbits was conducted and reported in this paper. METHODS: The large-scale cultured SARS-CoV F69 strain was inactivated with 0.4% formaldehyde and purified, then used as the immunogen combined with Freund's adjuvant. Eight adult New Zealand rabbits were immunized four times with this experimental inactivated vaccine. Twelve sets of rabbit serum were sampled from the third day to the seventy-fourth day after the first vaccination. The titers of specific anti-SARS-CoV IgG antibody were determined by indirect enzyme-linked immunosorbent assay, and the neutralizing antibody titers were detected with micro-cytopathic effect neutralization test. RESULTS: Rapid and potent humoral immune responses were induced by the inactivated SARS-CoV vaccine in all the eight test rabbits. Titers of both specific IgG antibody and neutralizing antibody peaked at about six weeks after first vaccination, with the maximum value of 1:81 920 and 1:20 480, respectively. After that, serum antibody levels remained at a plateau or had a slight decrease, though two boosters were given in the succedent 4 to 5 weeks. Cross neutralization response existed between SARS-CoV F69 strain and Z2-Y3 strain. CONCLUSIONS: The inactivated SARS-CoV vaccine made from F69 strain owns strong immunogenicity, and the cross neutralization response between the two different SARS-CoV strains gives a hint of the similar neutralizing epitopes, which provide stable bases for the development of inactivated SARS-CoV vaccines.

Immunization with modified vaccinia virus Ankara-based recombinant vaccine against severe acute respiratory syndrome is associated with enhanced hepatitis in ferrets. Severe acute respiratory syndrome (SARS) caused by a newly identified coronavirus (SARS-CoV) is a serious emerging human infectious disease. In this report, we immunized ferrets (Mustela putorius furo) with recombinant modified vaccinia virus Ankara (rMVA) expressing the SARS-CoV spike (S) protein. Immunized ferrets developed a more rapid and vigorous neutralizing antibody response than control animals after challenge with SARS-CoV; however, they also exhibited strong inflammatory responses in liver tissue. Inflammation in control animals exposed to SARS-CoV was relatively mild. Thus, our data suggest that vaccination with rMVA expressing SARS-CoV S protein is associated with enhanced hepatitis.

Receptor-binding domain of SARS-CoV spike protein induces highly potent neutralizing antibodies: implication for developing subunit vaccine. The spike (S) protein of severe acute respiratory syndrome (SARS) coronavirus (CoV), a type I transmembrane envelope glycoprotein, consists of S1 and S2 domains responsible for virus binding and fusion, respectively. The S1 contains a receptor-binding domain (RBD) that can specifically bind to angiotensin-converting enzyme 2 (ACE2), the receptor on target cells. Here we show that a recombinant fusion protein (designated RBD-Fc)

containing 193-amino acid RBD (residues 318-510) and a human IgG1 Fc fragment can induce highly potent antibody responses in the immunized rabbits. The antibodies recognized RBD on S1 domain and completely inhibited SARS-CoV infection at a serum dilution of 1:10,240. Rabbit antisera effectively blocked binding of S1, which contains RBD, to ACE2. This suggests that RBD can induce highly potent neutralizing antibody responses and has potential to be developed as an effective and safe subunit vaccine for prevention of SARS.